

Note: Due to file size restrictions on the HMA – EMA Catalogues of Real-World Data Sources and Studies this report has been split into two parts.

The following is part 1.

NON-INTERVENTIONAL (NI)/LOW-INTERVENTIONAL STUDY TYPE 1 (LIS1)

FINAL STUDY REPORT

PASS information

Title	Post-Authorisation Active Surveillance Study of Myocarditis and Pericarditis Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine
Protocol number	C4591038
Version identifier of the final study report	1.0.
Date	11 June 2025
EU Post Authorization Study (PAS) register number	EUPAS47708
Active substance	BNT162b2
Medicinal product	COVID-19 messenger ribonucleic acid (mRNA) vaccine is a nucleoside-modified ribonucleic acid (modRNA) encoding the viral spike glycoprotein S of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
Product reference	EMA/H/C/005735
Procedure number	N/A
Marketing Authorization Holder (MAH)	BioNTech Manufacturing GmbH
Joint PASS	No

Research question and objectives	The research question addressed by this study is: what is the clinical course of myocarditis and pericarditis cases after being vaccinated with the Pfizer-BioNTech COVID-19 vaccine in European countries? Primary study objective: To describe the clinical course (treatment, survival, hospitalisations, long-term cardiac outcomes) of myocarditis and pericarditis among individuals diagnosed with myocarditis and/or pericarditis after receiving at least 1 dose of the Pfizer-BioNTech COVID-19 vaccine and among individuals diagnosed with myocarditis or pericarditis who had no prior COVID-19 vaccination, using a cohort study design. Secondary study objective: To examine and identify potential risk factors for myocarditis and pericarditis, such as age, sex, Pfizer-BioNTech COVID-19 vaccination status, vaccine doses received (e.g., first, second, third, and booster doses), and history of COVID-19, using a cohort study design.
Country(-ies) of study	Italy (IT), The Netherlands (NL), Norway (NO), Spain (ES), United Kingdom (UK)
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Marketing Authorization Holder(s)

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Annex 1. List of stand-alone documents

Appendix 1. SIGNATURES

Standalone document.

Appendix 2. PROTOCOL

Standalone document.

Appendix 3. INVESTIGATORS AND CORRESPONDING INDEPENDENT ETHICS COMMITTEES (IECs) OR INSTITUTIONAL REVIEW BOARDS (IRBs)

Appendix 3.1. List of Investigators by country

Standalone document.

Appendix 3.2. List of independent ethics committees (IECs) and corresponding protocol approval dates

Standalone document.

Appendix 4. STATISTICAL ANALYSIS PLAN

Standalone document.

Appendix 5. SAMPLE DATA COLLECTION TOOL (DCT)

Standalone document.

Appendix 6. SAMPLE STANDARD SUBJECT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT (ICD)

Not applicable.

Appendix 7. LIST OF SUBJECT DATA LISTINGS

Appendix 7.1 Withdrawn Subjects

Not applicable.

Appendix 7.2 Protocol Deviations

PENTA Deviation Report

Appendix 7.3 Subjects Excluded from the Analysis

Not applicable.

Appendix 7.4 Demographic Data

Not applicable.

Appendix 7.5 Medication/Treatment Data

Not applicable.

Appendix 7.6 Endpoint Data

Not applicable.

Appendix 7.7 Adverse Events

Not applicable.

Appendix 7.8 Laboratory listings

Not applicable.

Appendix 8. ADDITIONAL DOCUMENTS

Appendix 8.1 [Validation Plan](#)

Standalone document.

Appendix 8.2 [Code Lists](#)

Standalone document.

Annex 2. Additional information

[Appendix tables](#)

Standalone document.

1. ABSTRACT (STAND-ALONE DOCUMENT)

2. LIST OF ABBREVIATIONS

Abbreviation	Definition
ACCESS	vACCine covid-19 monitoring readinESS
ACE	angiotensin-converting enzyme
AE	adverse event
AEM	adverse event monitoring
AESI	adverse event of special interest
ARB	angiotensin-II receptor blocker
ATC	Anatomical Therapeutic Chemical
AV	atrioventricular
BDU	user database at EpiChron
BIFAP	Base de Datos para la Investigación Farmacoepidemiológica en Atención Primaria
CDC	Centers for Disease Control and Prevention
CDM	common data model
CHES	COVID-19 Hospitalisation in England Surveillance System
CI	confidence interval
CK	creatinine kinase
cMR	cardiac magnetic resonance
COVID-19	coronavirus disease 2019
CPRD Aurum	Clinical Practice Research Datalink General Practitioner Online Database
CRF	case report form
CT	computed tomography
DEAP	data expert access partner
DRE	Digital Research Environment
DSRU	Drug Safety Research Unit
DTP	diphtheria, tetanus, and pertussis
ECDC	European Centre for Disease Prevention and Control
ECMO	extracorporeal membrane oxygenation
EHR	electronic health record
EKG	electrocardiogram
EMA	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EpiChron	EpiChron Research Group on Chronic Diseases
ES	Spain
ETL	extraction, transformation, and loading
EU PAS	European Union Post-Authorisation Studies
EU	European Union
FAIR	findable, accessible, interoperable, and re-usable

Abbreviation	Definition
GI	gastrointestinal
GP	general practitioner
GPP	Good Pharmacoepidemiology Practices
GVP	Good Pharmacovigilance Practices
HepB	hepatitis B virus vaccine
HELFO	Norwegian Health Economics Administration
HES	Hospital Episode Statistics
HPV	human papillomavirus
HSD	Health Search Database
HZ	herpes zoster virus
ICD	International Classification of Diseases
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICD-10	International Classification of Diseases, Tenth Revision
ICNARC	Intensive Care National Audit and Research Centre
ICPC	International Classification of Primary Care
IEC	independent ethics committee
IVIG	intravenous immunoglobulin
IT	Italy
KM	Kaplan-Meier
KUHR	Norway Control and Payment of Health Reimbursement
MAH	marketing authorisation holder
MBRN	Medical Birth Registry of Norway
MMR	measles-mumps-rubella
MR	magnetic resonance
mRNA	messenger RNA
modRNA	modified ribonucleic acid
MSIS	Norwegian Surveillance System for Communicable Diseases
NHS	National Health Service
NIPH	Norwegian Institute of Public Health
NIS	non-interventional study
NL	Netherlands
NO	Norway
NorPD	Norwegian Prescription Database
NPR	National Patient Register
NSAID	non-steroidal anti-inflammatory drug
ONS	Office for National Statistics
PASS	post-authorisation safety study
PCR	polymerase chain reaction
PHARMO	PHARMO Institute for Drug Outcomes Research
PHE	Public Health England
PRAC	Pharmacovigilance Risk Assessment Committee

Abbreviation	Definition
QC	quality control
RTI-HS	Research Triangle Institute Health Solutions
SAP	statistical analysis plan
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SGSS	Second Generation Surveillance System
SIDIAP	Sistema d'Informació per el Desenvolupament de la Investigació en Atenció Primària [Information System for the Improvement of Research in Primary Care]
SQL	Structured Query Language
SSB	Statistics Norway
SYSVAK	Norwegian Immunisation Registry
TPV	poliovirus vaccine
UK	United Kingdom
UMCU	University Medical Center Utrecht
US	United States
VAC4EU	Vaccine monitoring Collaboration for Europe
VZV	varicella zoster virus
WHO	World Health Organization

3. INVESTIGATORS

Principal Investigator(s) of the Protocol

Name, degree(s)	Title	Affiliation
Cynthia de Luise, PhD, MPH	Senior Director, Safety Surveillance Research	Pfizer, Inc
Miriam Sturkenboom, PhD	Professor, Director, Data Science & Biostatistics Department	University Medical Center Utrecht
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Xabier Garcia de Albeniz, MD, PhD	Director, Epidemiology	RTI Health Solutions
Estel Plana, MSc	Director, Biostatistics	RTI Health Solutions
Rachel Weinrib, MPH	Research Epidemiologist	RTI Health Solutions
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Name, degree(s)	Title	Affiliation
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Antonio Gimeno-Miguel, MPH, PhD	Researcher	EpiChron Research Group. Instituto Aragonés de Ciencias de la Salud, Spain
Debabrata Roy, PhD	Head of Epidemiology and Research	Drug Safety Research Unit (DSRU, CPRD), United Kingdom

*Replaced Angela Lupattelli, PhD, deceased on 23 January 2025

4. OTHER RESPONSIBLE PARTIES

Responsible Party Name and Affiliation	Role in the study
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Oisin Ryan, PhD	Lead Statistician
Wijnand Laan, PhD	Data engineer
Emmy Manders, PhD	Data engineer
Jan Willem Maaskant, MD	Data engineer
Nicole Boekema	Data engineer
Vjola Hoxhaj, PharmD	Data quality checks
Judit Riera, MD	Data quality checks

5. MILESTONES

Milestone	Planned date	Actual date	Comments
Date of independent ethics committee (IEC) approval of protocol:	01 June 2022	02 June 2022	First approval
	31 October 2023		Last approval
Start of data collection	31 December 2022	10 February 2023	
End of data collection	31 March 2024	31 March 2025	
Registration in the HMA-EMA Catalogues of RWD Studies	Before start of data collection	22 August 2022	
Interim report	30 September 2023	29 September 2023	
Final report of study results	30 September 2024	11 June 2025	

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6. RATIONALE AND BACKGROUND

The novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the cause of coronavirus disease 2019 (COVID-19), resulted in a global pandemic. The Pfizer-BioNTech COVID-19 vaccine, Comirnaty® (tozinameran), a novel mRNA-based vaccine, was authorised for use for the prevention of COVID-19 in several countries, including those in the European Union (EU). Efficient and timely monitoring of the safety of the vaccine was warranted in European countries because of the relatively short prelicensure period and limited number of participants in clinical studies.

The safety of the Pfizer-BioNTech COVID-19 vaccine has been investigated in clinical studies that included over 43,000 individuals aged 16 years or older, conducted in the United States (US), Europe, Turkey, South Africa, and South America. The overall safety profile of the vaccine was found to be favourable in the clinical trial setting.¹ On 27 May 2021, the Centers for Disease Control and Prevention (CDC) in the US issued a statement indicating a possible link between myocarditis and vaccination with both the Pfizer-BioNTech COVID-19 vaccine and the mRNA-1273 COVID-19 vaccine produced by Moderna.²

Researchers in Israel reported a 3-fold increased risk of myocarditis within 42 days of receiving the Pfizer-BioNTech COVID-19 vaccine (hazard ratio, 3.24; 95% confidence interval [CI], 1.55 to 12.44), compared with unexposed individuals. Myocarditis events were mostly reported in young males.¹ Among individuals who had received at least 1 dose of the Pfizer-BioNTech COVID-19 vaccine, the estimated incidence of myocarditis within 42 days after receiving the first dose was 2.13 cases per 100,000 individuals; the highest incidence was among males between the ages of 16 and 29 years, and most cases of myocarditis were mild or moderate in severity.³ Another publication from Israel reported that the incidence of definite or probable cases of myocarditis (as defined by the Brighton Collaboration), although low, increased after vaccination with the Pfizer-BioNTech COVID-19 vaccine, also in young male recipients, particularly after the second dose. The clinical presentation of myocarditis after vaccination was usually mild.⁴

A publication reported the incidence of definite, probable or possible cases of myocarditis and pericarditis (as defined by the Brighton Collaboration), using data from Ontario, Canada.⁵ The crude incidence of myocarditis or pericarditis after one dose of Pfizer-BioNTech COVID-19 vaccine was 15.6 (95% CI: 10.4-22.4) per million doses, and was higher after the second dose, 29.0 (95% CI: 20.2-40.3) per million doses.

A study requested by the EMA assessed the rates of myocarditis and pericarditis and their association with COVID-19.⁶ Across the European data sources used, the background myocarditis incidence rates in 2020 in individuals without COVID-19 disease ranged from 0.5 to 2.9/100,000 person-years (PY) in children aged 5–11 years, 1.2 to 9.9 in individuals aged 12–17 years, 2.8 to 6.4 for individuals aged 18–

29 years, and 2.7 to 4.5 for individuals ≥ 30 year. For pericarditis, these values were 0.6 to 5.2, 2.8 to 12.6, 10.0 to 21.9, and 11.6 to 29.7, respectively. These cases were not validated.

EMA's safety committee (Pharmacovigilance Risk Assessment Committee [PRAC]) assessed data from two large European epidemiological studies in France and Norway, on the known risk of myocarditis and pericarditis following vaccination with the COVID-19 vaccines, Comirnaty and Spikevax, i.e., the Pfizer-BioNTech and Moderna COVID-19 vaccines, respectively. The outcome of their review confirmed the risk of myocarditis and pericarditis, which is already reflected in the product information for these two vaccines.⁷

Both the EMA and the United States Food and Drug Administration (FDA) have requested that Pfizer-BioNTech evaluate the clinical course and risk factors associated with myocarditis and pericarditis following vaccination with the Pfizer-BioNTech COVID-19 vaccine. To do so, this study utilised data from the Pfizer-BioNTech Study, C4591021 entitled Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine which estimated the risk of prespecified adverse events of special interest (AESIs), including myocarditis and pericarditis, among individuals who have received at least 1 dose of the Pfizer-BioNTech COVID 19 vaccine (exposed) and among individuals who have not received any COVID-19 vaccine (unexposed). This non-interventional study (NIS) was designated as a post-authorisation safety study (PASS) and is a commitment to the European Medicines Agency (EMA) and a post-marketing requirement to the U.S FDA.

7. RESEARCH QUESTION AND OBJECTIVES

The research question addressed by this study was, 'What is the clinical course of myocarditis and of pericarditis cases after being vaccinated with the Pfizer-BioNTech COVID-19 vaccine in European countries?'

7.1. Primary study objective

To describe the clinical course (treatment, survival, hospitalisations, long-term cardiac outcomes) of myocarditis or pericarditis among individuals diagnosed with myocarditis or pericarditis after receiving at least 1 dose of the Pfizer-BioNTech COVID-19 vaccine and among individuals diagnosed with myocarditis or pericarditis who had no prior COVID-19 vaccination, using a cohort study design.

7.2. Secondary study objective

To examine and identify potential risk factors for myocarditis and pericarditis, such as age, sex, Pfizer-BioNTech COVID-19 vaccination status, vaccine doses received (e.g., first, second, third, and subsequent doses), and history of COVID-19, using a cohort study design.



8. AMENDMENTS AND UPDATES

Table 1. Amendments to the protocol

Amendment number	Date	Substantial or administrative amendment	Protocol section(s) changed	Summary of amendment	Reason
4	11 Jun 2025		Throughout	DAP (data access provider) changed to DEAP (data expert and access partner)	To reflect the change in VAC4EU name for partners
4	11 Jun 2025		3. Responsible Parties	Additions and removals of staff members at participating institutions	Personnel changes
4	11 Jun 2025		3. Responsible Parties	ID/AP removed from list of country coordinating investigators	To have only one country coordinating investigator per country. EpiChron serves as the coordinating institution for the study in Spain
4	11 Jun 2025		4. Abstract 6. Milestones 9.2.3 Study Period	Updated milestones and study period dates	Revision of milestone dates to reflect delay of end of data collection date and final study report date
4	11 Jun 2025		9.3.3.1 Identification and validation of myocarditis and pericarditis, by data source	Additional details on the validation process added	To provide further clarity
3	08 Aug 2024		General	Presentation of data sources was switched to alphabetical order throughout the document Minor administrative, formatting, and typographical changes have been made.	Updated to provide clarity and be consistent with remainder of protocol and other studies (C4591021 and C4591052)
3	08 Aug 2024		2. LIST OF ABBREVIATIONS	Removed abbreviations that only appear once or not at all in the text and added new ones	To conform with Pfizer style guide
3	08 Aug 2024		3. RESPONSIBLE PARTIES	Updated PIs list Updated country teams Updated degree(s) and added Other Responsible Parties Contributing to the Protocol	To list current team members
3	08 Aug 2024		4. ABSTRACT 6. MILESTONES	Updated milestones and study period dates	Revision of milestone dates to reflect delay of Study Completion date and Final Study Report date



Table 1. Amendments to the protocol

Amendment number	Date	Substantial or administrative amendment	Protocol section(s) changed	Summary of amendment	Reason
3	08 Aug 2024		N/A	Justification for delay of final study report	The MAH requests an extension for delivery of the Final Study Report. The Final Study Report was initially planned for submission by 30 September 2024. This extension is needed to fully complete the validation of cases of myocarditis and pericarditis. Although the incidence of myocarditis and pericarditis continues to be extremely low, the size of the cohorts in the largest data sources (e.g. CPRD (UK), Norwegian health registers (NO), IDIAP (ES)) and the follow-up time of two years have yielded a large number of cases that require validation. Additional time is needed to complete this task. uSince only a limited number of data sources have fit-for-purpose data, COVID-19 vaccine studies with VAC4EU have been mostly conducted in the same data sources which has led to capacity issues and queuing for scripts for the different PASS. This unexpected situation could not have been controlled by the MAH and given the unprecedented worldwide pandemic, could not have been reasonably anticipated when the timelines and milestones were initially planned in 2021. The MAH estimates that delivery of the Final Study Report is feasible by 30 June 2025. Estimated Study Completion date (same as End of Data Collection) will now be 31 December 2024 instead of the original date of 31 March 2024. These dates have been revised in 6: MILESTONES

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CT24-WI-GL15-RF02 3.0 Non-Interventional/Low-Interventional Study Type 1 Study Report Template



Table 1. Amendments to the protocol

Amendment number	Date	Substantial or administrative amendment	Protocol section(s) changed	Summary of amendment	Reason
3	08 Aug 2024		9.2.3 Study period; Table 1	End of study period updated. Summary of vaccine launch and data availability dates added	The study period will end on 31 August 2023 (before 31 March 2023) to include the latest data availability from Pedianet and EpiChron. To further describe data availability dates in the various data sources
3	08 Aug 2024		9.3.4.1 Treatments for myocarditis	Replace aldosterone agonists by aldosterone antagonists	Correction of an error. Aldosterone agonists were erroneously mentioned as one of the myocarditis treatments.
3	08 Aug 2024		9.4. Data sources	Re-ordered and re-named data sources to be consistent with order in other studies (C4591021 and C4591052). ARS and HSD data sources removed	For consistency and to revise outdated information
			9.4.2 PHARMO (NL)	Update sources of data for PHARMO	Outpatient Pharmacy Database will not be used
			9.4.3 NHR (NO)	Updated number of active individuals	Outdated information
			9.4.5 SIDIAP (ES)	Updated number of active individuals	Outdated information
			9.4.6 CPRD (UK)	Updated sources of data for CPRD and numbers of active individuals. Disclaimer updated	Some COVID-19 specific databases linked to CPRD were identified as not being necessary in order to obtain study variables based on recent experience in the study
3	08 Aug 2024		9.6.1 Case report forms (CRFs)/Data collection tools (DCTs)/Electronic data record	Deleted sentence indicating that CRFs need to be signed	CRFs will not be collected and therefore it will not be possible to verify if they are signed as part of the QC process
3	08 Aug 2024		9.8 Quality control	Re-ordered and re-named data sources to be consistent with order in other studies (C4591021 and C4591052). ARS and HSD data sources removed	For consistency
3	08 Aug 2024		9.8.3 NHR (NO)	Added quality control information from NHR.	Previously missing
2	13 May 2022		4. ABSTRACT 6. MILESTONES	Added an interim report 9 months after the start of data collection	Request from EMA



Table 1. Amendments to the protocol

Amendment number	Date	Substantial or administrative amendment	Protocol section(s) changed	Summary of amendment	Reason
2	13 May 2022		4. ABSTRACT 9.3.3.1 Identification and validation of myocarditis and pericarditis, by data source, 9.7.1.2 Natural history of myocarditis and pericarditis	Added a sensitivity analysis considering only cases of myocarditis or pericarditis that meet the Brighton Collaboration “definitive” classification	Request from EMA
2	13 May 2022		4. ABSTRACT 9.5. Study size	Refined the study size description and added precision estimates	Request from EMA
1	05 April 2022		8. RESEARCH QUESTION AND OBJECTIVES	Added stratification by vaccine dose received (e.g., first, second, third, and booster doses) to the secondary study objective	Request from CBER
1	05 April 2022		9.2.2.2. Risk factors for myocarditis and pericarditis (secondary objective)	Removed the exclusion criterion, “Have had a medical visit or a hospital visit in the 7 days before matching time zero (as an indicator of a health event not related to subsequent vaccination that could reduce the probability of receiving the vaccine).”	To align with request from EMA for the parent study (i.e., study C4591021)
1	05 April 2022		9.3.1. Exposure to vaccines, 9.7.2.1. Identification of risk factors for myocarditis and for pericarditis	Specified risk windows of 1-14 days after each vaccine dose for the risk factors analysis and 1-7 days and 1-21 days for sensitivity analyses	Request from CBER



Table 1. Amendments to the protocol

Amendment number	Date	Substantial or administrative amendment	Protocol section(s) changed	Summary of amendment	Reason
1	05 April 2022		9.3.1. Exposure to vaccines, 9.7.1.1.Characterisation of myocarditis and pericarditis cases, 9.7.1.2 Natural history of myocarditis and pericarditis, 9.7.2.1. Identification of risk factors for myocarditis and for pericarditis	Added analysis stratified by vaccine dose received (e.g., first, second, third, and booster doses) to the natural history and risk factors analyses	Request from CBER
1	05 April 2022		9.3.2 COVID-19	Modified definition of history of COVID-19 to be more specific	Request from CBER
1	05 April 2022		9.3.4.3Outcomes for myocarditis or pericarditis	Added definition for recovery from myocarditis and pericarditis	Request from CBER
1	05 April 2022		9.3.5.1 Demographics	Modified age categories	To align with age groups as authorized and prioritized during vaccine rollout, and in anticipation of future indications of the vaccine in children younger than 16 years old
1	05 April 2022		General	Minor administrative, formatting, and typographical changes have been made	Updated to provide clarity and be consistent throughout protocol

9. RESEARCH METHODS

Full details of the research methods can be found in the final protocol (See [Appendix 2](#)).

9.1. Study design

This was a retrospective cohort study that used data from the study (C4591021, EUPAS41623), entitled Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine. The completed C4591021 study included individuals from five European countries who received at least one dose of the Pfizer-BioNTech COVID-19 vaccine, as well as individuals who did not receive a COVID-19 vaccine. The final report for C4591021 will also be available by 30 September 2025.

9.2. Setting

The setting for this study involves data from multiple electronic healthcare data sources in five European countries. For further information see [Section 9.6](#).

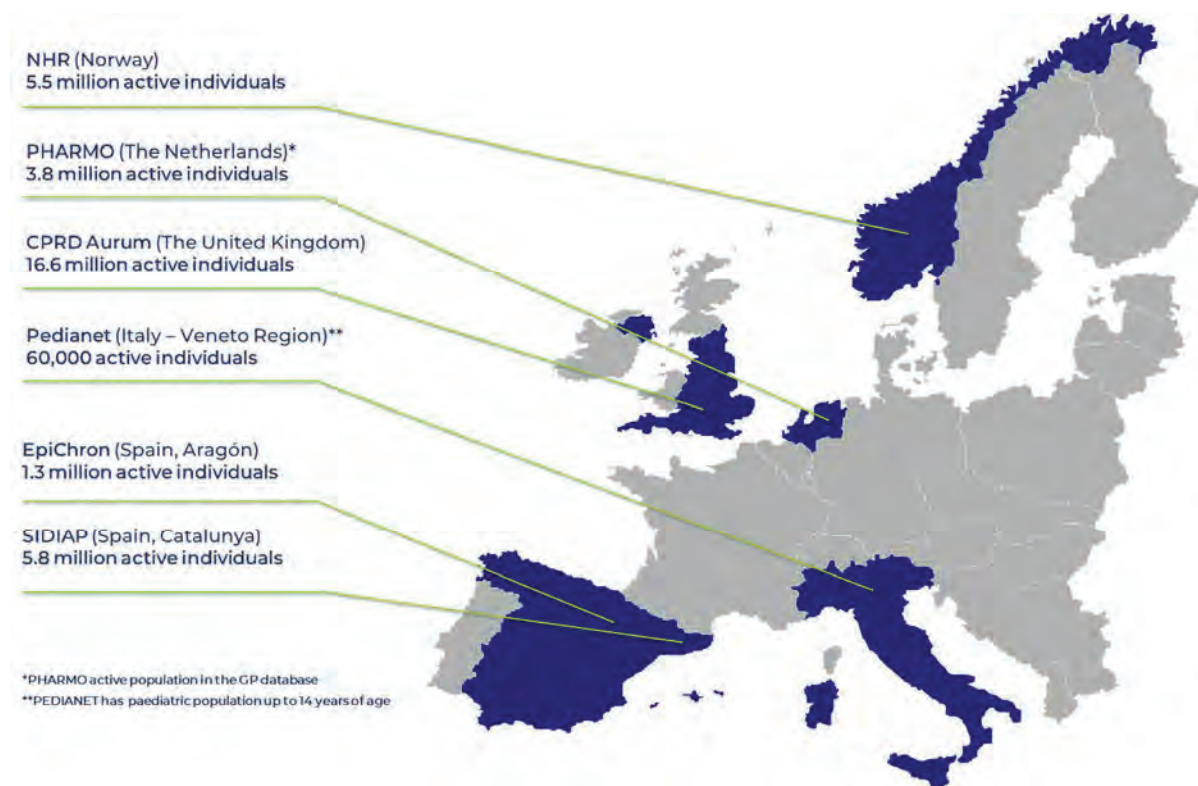
9.2.1. Data sources

The following European electronic healthcare data sources with their two-letter country codes contributed data to the study:

- ! Pédianet (IT)
- ! PHARMO (PHARMO Institute for Drug Outcomes Research) (NL)
- ! NHR (The Norwegian health registers) (NO)
- ! EpiChron (EpiChron Research Group on Chronic Diseases at the Aragon Health Sciences Institute) (ES)
- ! SIDIAP (Sistema d'Informació per el Desenvolupament de la Investigació en Atenció Primària) [Information System for the Improvement of Research in Primary Care] (ES)
- ! CPRD Aurum (Clinical Practice Research Datalink) (UK)

[Figure 1](#) below shows the location and number of active individuals in each data source.

Figure 1. Location and number of active individuals in each data source



9.2.2. Study period and follow-up

The study period for this final report started with the date of authorisation of the Pfizer-BioNTech COVID-19, which was 02 December 2020 in the UK and 21 December 2020 in the other countries. The dates for data collection for this final report are summarised in [Table 2](#). The data expert and access partners (DEAPs) recommended the end of the observation period for the analyses based on lag times for data availability in their data source. Actual end dates were: 31 December 2022 for Pedianet; 30 June 2023 for PHARMO; 14 January 2023 for NHR; 31 July 2023 for EpiChron; 30 June 2023 for SIDIAP; and 7 June 2023 for CPRD Aurum.

Table 2. Date of administration of first dose of Pfizer-BioNTech COVID-19 vaccine and dates of data collection for this report

Country (data source)	Date first dose administered	End of data collection	First and latest data availability
Italy (Pedianet)	26 February 2021	31 March 2025	26 February 2021 – 31 December 2022
The Netherlands (PHARMO)	08 January 2021 ⁸	31 March 2025	General practitioner data: 6 January 2021 – 30 June 2023 Hospital data: 6 January 2021 – 31 Dec 2022
Norway (NHR)	27 December 2020 ⁹	31 March 2025	1 January 2021 – 14 January 2023
Spain (EpiChron, SIDIAP)	27 December 2020 ¹⁰	31 March 2025	EpiChron: 27 December 2020 – 31 July 2023 SIDIAP: 01 January 2021 – 30 June 2023
UK (CPRD Aurum)	08 December 2020 ¹¹	31 March 2025	2 December 2020 – 7 June 2023

9.3. Study populations

9.3.1. Study population for the primary objective

For the primary objective (natural history), the study was conducted in a cohort of individuals with a diagnosis of myocarditis or pericarditis during the study period ([Section 9.2.2](#)) who satisfied the inclusion and exclusion criteria below. When possible, myocarditis and pericarditis cohorts were constructed separately. For more details see the protocol ([Appendix 2](#))

9.3.1.1. Inclusion criteria

Individuals had to meet the following inclusion criteria to be eligible for inclusion in the cohort for the primary objective:

- ! Have experienced an incident event of myocarditis or pericarditis within the study period. A sample of cases were further classified as definitive, probable, or possible according to the Brighton Collaboration case definitions, (see [Section 9.4.2](#)). All cases identified were selected for cohort entry at the time of diagnosis (time zero_{Dx})

- ! Have a minimum of 12 months active enrolment in one of the participating data sources at time zero_{Dx}, or from birth, if enrolled in the data source at birth (this criterion could be met after the start of the study)

9.3.1.2. Exclusion criteria

Individuals meeting any of the following criteria were not included in the cohort for the primary objective:

- ! History of vaccination with a non–Pfizer-BioNTech COVID-19 vaccine before time zero_{Dx}
- ! History of myocarditis or pericarditis in the 12 months before time zero_{Dx}

9.3.1.3. Follow-up

Individuals were followed from the date of diagnosis of myocarditis or pericarditis (time zero_{Dx}) until the earliest occurrence of the following:

- ! Death
- ! Disenrollment from the data source
- ! End of the study period
- ! 1 year after time zero_{Dx}

9.3.2. Study population for the secondary objective

The potential risk factors for myocarditis and pericarditis (secondary objective) were evaluated separately for each Pfizer-BioNTech COVID-19 vaccine dose in the matched population. Three dose-specific analysis populations were created:

- ! First dose cohort: Individuals who receive a first dose of the Pfizer-BioNTech COVID-19 vaccine matched to unvaccinated individuals.
- ! Second dose cohort: Individuals who receive a second dose of the Pfizer-BioNTech COVID-19 vaccine matched to unvaccinated individuals.
- ! Third dose cohort: Individuals who receive a third dose of the Pfizer-BioNTech COVID-19 vaccine matched to unvaccinated individuals.

The matching variables, vaccination status, and other baseline variables identified in a review of the medical literature, were considered potential risk factors for the development of myocarditis and of pericarditis. The potential risk factors for each outcome (myocarditis and pericarditis) were assessed separately for each Pfizer-BioNTech COVID-19 vaccine dose cohort and the corresponding matched unvaccinated individuals. These analyses were repeated for all cases with a level of

diagnostic certainty of definite, possible, or probable and a sensitivity analysis was performed for those with a definite level of diagnostic certainty only.

9.3.2.1. Inclusion criteria

Individuals had to meet the following inclusion criteria to be eligible for inclusion in each of the cohorts for the secondary objective:

- ! Have received a first, second, or third dose of the Pfizer-BioNTech COVID-19 vaccine, or were unvaccinated on the date of the matched dose (time zero: time zero_{Dose1}, time zero_{Dose2}, time zero_{Dose3})
- ! Have a minimum of 12 months active enrolment and history, or from birth, if enrolled at birth, in one of the data sources to ensure adequate characterisation of medical history before the cohort-specific time zero (time zero_{Dose1}, time zero_{Dose2}, time zero_{Dose3}).

9.3.2.2. Exclusion criteria

Individuals meeting any of the following criteria were not included in the dose-specific cohorts for the secondary objective: history of vaccination with a non–Pfizer-BioNTech COVID-19 vaccine before the cohort-specific time zero (time zero_{Dose1}, time zero_{Dose2}, time zero_{Dose3}), Individuals with history of myocarditis or pericarditis any time before the cohort-specific time zero (time zero_{Dose1}, time zero_{Dose2}, time zero_{Dose3}).

9.3.2.3. Follow-up

For each dose-specific cohort, individuals were followed from the cohort-specific time zero (time zero_{Dose1}, time zero_{Dose2}, time zero_{Dose3}) until the earliest occurrence of the following: diagnosis of myocarditis or pericarditis, death, administrative end of follow-up, receipt of the Pfizer-BioNTech COVID-19 vaccine by the unvaccinated individual in the pair¹, Receipt of a non–Pfizer-BioNTech COVID-19 vaccine by either the vaccinated or unvaccinated individual in the pair, end of the risk window (14 days after the cohort-specific time zero for the main analysis, 7 and 21 days for sensitivity analyses).

9.4. Variables

Below we only include core information. For further details on the variables refer to the protocol ([Appendix 2](#)).

¹ This individual was then eligible for inclusion in the vaccinated cohort at the date of vaccination.

9.4.1. Exposure to Pfizer BioNTech COVID-19 vaccine

Exposure was based on recorded prescription, dispensing, or administration of the Pfizer-BioNTech COVID-19 vaccine. Vaccine receipt and date of vaccination was obtained from all possible sources that captured COVID-19 vaccination, such as pharmacy dispensing records, general practice records, immunisation registers, vaccination records, medical records, or other secondary data sources. Details for the DEAPs are in the protocol ([Appendix 2](#)).

9.4.2. Myocarditis and pericarditis

Myocarditis and pericarditis were eligibility criteria for inclusion in each specific cohort for the primary objective to assess the clinical course of myocarditis and pericarditis and were study outcomes for the secondary objective of assessing risk factors for the occurrence of these conditions. Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the outer lining of the heart. In both cases, the body's immune system causes inflammation in response to an infection or some other trigger. These conditions can occur alone or simultaneously.

Standard code lists to identify potential cases of myocarditis and pericarditis, developed by VAC4EU, were used to identify cases.

For a sample of cases from the cohorts assembled for either the primary or secondary objective, the level of diagnostic certainty of myocarditis and pericarditis was assessed by medical doctors who were trained and certified using the VAC4EU validation workflow. These medical doctors were unaware of the individuals' COVID-19 vaccination status.

Modified Brighton Collaboration case definitions were used for the classification and validation of the cases.¹⁵ Criteria were modified by the VAC4EU task force, to create sublevels 2a/2b, 3a/3b and 4a/4b (see [Appendix 8.1](#)). Brighton Collaboration case definitions allow the classification of the certainty of a diagnosis based on objective evidence (imaging, symptoms, measurements). Level 4 is given when there is a diagnosis code, but no further information to confirm or reject a case.

The DEAPs extracted information from the source data they could access and completed a data collection form in the Research Electronic Data Capture (REDCap) software system. All data remained local. Logic to assign the level of certainty was developed by VAC4EU in collaboration with the REDCAP managing centre.

The validation of the myocarditis and pericarditis cases is fully described in the validation plan ([Appendix 8.1](#)). Briefly, each data source identified or validated myocarditis and pericarditis cases as follows:

Pedinet (IT): COVID-19 vaccination of children started later in 2021 than in adults, which is reflected by the later dates for the first doses of Pfizer-BioNTech COVID-19 vaccine. Myocarditis and pericarditis were based on diagnoses in the paediatricians'

records, which could include information from hospitalisation when it was reported back to them. However, this reporting may not be complete. The computerised medical record, available at SoSeTe with free text, was utilised to extract information.

PHARMO (NL): For this final study report, information on myocarditis and pericarditis was extracted from patient medical records by local medical professionals or PHARMO employees, following medical chart review approval by ethics committees and other local or national governing bodies. The computerised medical record from GPs, with anonymised additional GP EHR free text available from Stizon (journal entries, discharge letters), as well as available hospital diagnostic codes from in-patient and out-patient encounters, were utilised to validate cases.

NHR (NO): In Norway, the validation process for this final report involved a structured manual review of hospital charts for a subsample of individuals with myocarditis or pericarditis by physicians across multiple hospitals in Norway. The subsample of individuals diagnosed with myocarditis or pericarditis was selected from the Patient Registry of Norway (NPR). Physicians used a project-specific form to evaluate predefined criteria, such as cardiac symptoms, physical tests, and diagnostic results, to confirm the accuracy of NPR diagnoses. These physicians were blinded to COVID-19 vaccination status.

EpiChron (ES): The validation process for this final report involved review of the individual EHRs containing information from primary care reports, hospital discharge reports (including hospital emergency rooms), and results of diagnostic tests and laboratory tests by clinicians from the research team. The reviewers were blinded to COVID-19 vaccination status.

SIDIAP (ES): In the SIDIAP validation process, a systematic review of EHRs was conducted by five trained medical reviewers. The source data included both structured records and unstructured free text (clinical notes) from primary care. The Catalan Institute of Health, acting as a third party, extracted the free text data. Reviewers, who were blinded to the COVID-19 vaccination status (this information was extracted into a separate table), analysed these notes to validate cases, extract symptoms, and identify relevant clinical information. A consolidated table in Excel, combining structured and unstructured data, was prepared for review. Reviewed data were securely returned to SIDIAP in accordance with the data protection protocols.

CPRD Aurum (UK): Validation of myocarditis and pericarditis events for this final report was conducted by review of EHR information by Drug Safety Research Unit (DSRU) clinicians blinded to COVID-19 vaccination status. The computerised medical records from GPs available in CPRD Aurum, excluding free text, were transformed into individual patient profiles. These profiles contain detailed

information on primary care medical observations, prescriptions, and laboratory results. Additionally, patient profiles may have included data from hospital discharge notes, provided that the GP coded this information in the primary care record. These profiles were then used to validate cases.

9.4.3. Diagnostic tests performed for the diagnosis of myocarditis and pericarditis

The use of the diagnostic tests was identified for ± 30 days around the date of the myocarditis or pericarditis diagnosis and can be found in the protocol ([Appendix 2](#)). Information for all cases was obtained from computerised records using codes. For the sample of validated cases the information was also obtained from questionnaires after validation by medical assessors.

9.4.4. Treatments for myocarditis

Treatments were assessed from 15 days before the date of the myocarditis diagnosis up to 365 days after diagnosis in all identified cases and the list is available in the protocol ([Appendix 2](#)).

Information for all cases was obtained from computerised records using codes. For the sample of validated cases the information was also obtained from questionnaires after validation by medical assessors.

9.4.5. Treatments for pericarditis

Treatments were assessed in the period from 15 days before the date of the pericarditis diagnosis up to 90 days after diagnosis in all identified cases. List of treatments is available in the protocol ([Appendix 2](#)).

Information for all cases was obtained from computerised records using codes. For the sample of validated cases the information was also obtained from questionnaires after validation by medical assessors.

9.4.6. Outcomes for myocarditis or pericarditis

The occurrence of the following outcomes was assessed during the study follow-up, as described in [Section 9.2.2](#), for all cases identified using EHR data.

- ! Hospitalisation;
- ! Death;
- ! Recovery: Recovery from myocarditis and pericarditis was determined by a medically trained person following review of individuals' medical records. Factors that were considered included discharge from hospital with a recovery outcome indicated in the discharge notes, resolution of signs/symptoms, discontinuation of therapy with anti-inflammatory

- medications, and normalised test values. Tests that were evaluated by the clinical adjudicator included: troponin normalised; cardiac magnetic resonance imaging; computed tomography; echocardiogram; and electrocardiogram.
- ! Sudden cardiac death;
 - ! Heart failure;
 - ! Cardiogenic shock;
 - ! Fulminant myocarditis for individuals with myocarditis;
 - ! Chronic myocarditis for individuals with myocarditis;
 - ! Inflammatory cardiomyopathy;
 - ! Heart transplant;
 - ! Arrhythmia;
 - ! Chronic pericarditis for individuals with pericarditis;
 - ! Constrictive pericarditis for individuals with pericarditis;
 - ! Recurrent myocarditis (new diagnosis of myocarditis during follow-up) for individuals with myocarditis;
 - ! Recurrent pericarditis (new diagnosis of pericarditis during follow-up) for individuals with pericarditis.

9.4.7. Vaccination after myocarditis or pericarditis

Subsequent doses of the Pfizer-BioNTech COVID-19 vaccine as well as the administration of any non-Pfizer-BioNTech COVID-19 vaccine (mRNA vs non-mRNA) were described during the study follow-up for individuals who experienced a myocarditis or pericarditis event in all identified cases.

9.5. Covariates

For the primary objective, variables were assessed at the time of myocarditis or pericarditis diagnosis. In the primary objective analyses, baseline covariates were used to characterise the individuals with myocarditis or pericarditis, and to define subgroups of interest.

For the secondary objective, variables were assessed at the date of matching for each dose of the Pfizer-BioNTech COVID-19 vaccine. For the secondary objective

analyses, baseline covariates were treated as known or potential risk factors for myocarditis or pericarditis. For a detailed list of covariates, refer to the protocol ([Appendix 2](#)).

The code lists for the variables can be found in [Appendix 8.2](#).

9.6. Data sources and measurement

Full details of the participating data sources can be found in the statistical analysis plan (SAP) in [Appendix 4](#).

9.7. Bias

Details of potential biases can be found in the protocol ([Appendix 2](#)) and [Section 11.2](#).

9.8. Handling of missing values

It was assumed that the absence of information on clinical events means the absence of that event. Therefore, the exposure status or any of the outcome data are assumed not to be missing.

No method to deal with missing data was applied and missing values were described as a separate category for categorical variables or as the number of missing values for numerical variables. For the identification of risk factors, variables with a high amount of missing data (i.e., >30%) were excluded from the analyses, and variables with less than 30% of missing data were included in the identification of risk factors only for individuals who had complete information.

9.9. Data transformation

Detailed methodology for data transformations, particularly complex transformations, e.g., many raw variables used to derive an analytic variable, are documented in the SAP, which is dated, filed and maintained by the sponsor ([Appendix 4](#)).

9.10. Statistical methods

Full details of the statistical methods used can be found in the SAP ([Appendix 4](#)).

The analyses performed are summarised in [Table 3](#).

Table 3. Main summary measures for the primary and secondary objectives

Type of analysis	Objective(s)	Measure	Statistical methods
Descriptive	Primary, Secondary	Mean Standard deviation Median Quartiles Minimum Maximum Counts Proportions	Standard statistics
Time-to-event	Primary	1-Kaplan-Meier (KM) curves up to the longest available follow-up Risk at month t, where t was between 3 and 36 (or longest available follow-up), in increments of 3.	KM estimator The variance was estimated using the Greenwood formula and a log-log transformation
Identification of risk factors	Secondary	Regression coefficients and odds ratios with 95% CIs	Logistic regression model with selection method, if necessary
Prediction model assessment	Secondary	Regression coefficients and standard errors C-statistic Marginal R ²	Logistic regression model with final set of independent variables
External validation	Secondary	Calibration plot receiver operating characteristic (ROC) curve and c-statistic	Locally weighted least squares regression smoother (LOESS) algorithm Logistic regression model: sensitivity and specificity

9.10.1. Statistical analyses for the primary objective: natural history of myocarditis and pericarditis

The analyses for the primary objective included descriptive statistics for the diagnostic tests, treatments, outcomes for myocarditis and pericarditis and COVID-19 vaccination listed in [Sections 9.4.3 to 9.4.7](#) and the covariates listed in

[Section 9.5](#) at time zero_{Dx} separately for the myocarditis and pericarditis cohorts and by Pfizer-BioNTech COVID-19 vaccination status (vaccinated or unvaccinated). Categorical variables were summarised using frequencies and proportions, and continuous variables were summarised using mean, standard deviation, median, first quartile, third quartile, and minimum and maximum values.

The treatments received were described during a therapeutic window around the time of myocarditis or pericarditis diagnosis, as specified in [Section 9.4.4](#) and [Section 9.4.5](#).

Outcomes for myocarditis and pericarditis ([Section 9.4.6](#)) during follow-up were analysed as time-to-event data by Pfizer-BioNTech COVID-19 vaccination status at time zero_{Dx}. Cumulative incidence curves (1-Kaplan-Meier (KM) risk) with 95% CIs and the number of events and censored individuals were reported. Risk (1-KM estimator) at different timepoints during follow-up were reported in 3-month periods, starting at month 3 after time zero_{Dx}, up to month 36 or end of follow-up, whichever occurred first.

9.10.2. Statistical analyses for the secondary objective

In the matched cohorts, the risk factors were assessed separately for all cases of myocarditis and pericarditis and also by the number of Pfizer-BioNTech COVID-19 vaccine doses received by the vaccinated individual in the matched pair ([Section 9.3.2](#)). Each dose of the Pfizer-BioNTech COVID-19 vaccine (first, second, third) was evaluated as an independent risk factor by considering them as one of the potential risk factors used to feed the models described below in each dose-specific cohort ([Section 9.4.1](#)). Other variables that were analysed as potential risk factors are listed in [Section 9.5](#).

The algorithm to identify risk factors took into account the events per variable (i.e., ratios of the number of outcomes and the number of independent variables), subject specific knowledge about additional risk factors, and a selection algorithm, in a process that is described in the SAP ([Appendix 4](#)).³²

9.10.3. Sensitivity analyses

Sensitivity analyses to assess robustness were conducted by repeating the analyses described in [Section 9.10.2](#) using only data for cases of myocarditis or pericarditis that met the Brighton Collaboration classification of a definitive case (See [Appendix 8.1](#)).

9.10.4. Amendments to the statistical analysis plan

Following a request from EMA, the SAP was amended to include known risk factors for myocarditis and pericarditis identified in a literature review. Also, the process for selection of risk factors for the regression model was modified so that the known risk factors were forced into the model and an automated selection process was used for

the other covariates. In addition, the amendment included the estimation of individual logistic regression models for each of the known risk factors.

An updated SAP is provided with this final report to include non-major changes in the methodology made during the implementation of the study. The changes included as part of SAP amendments are summarised in [Table 4](#).

Also, a *post-hoc* analyses using a Cox proportional hazard regression model with sandwich estimator of variance were used to explore the risk of outcomes among vaccinated versus unvaccinated individuals in the myocarditis and pericarditis cohorts. These *post-hoc* analyses aimed to improve our understanding of the unadjusted results, which showed that vaccinated individuals had more comorbidities and a higher median age than unvaccinated individuals. To account for these differences, the analysis adjusted for linear and quadratic effect of (centered) age, sex, CDC comorbidity score, and Charlson comorbidity index. Reference categories were 'unvaccinated' (group), 'male' (sex), 'Group 0: no conditions' (CDC score), and 'Group 0: no comorbidities' (Charlson index). Robust standard errors (SEs) were used to calculate confidence intervals (CIs). Separate models were fitted for each cohort and each outcome. Hazard ratios (HRs) were reported for the vaccinated groups using zero for all covariates, e.g., average age, male, no comorbidities, for both unadjusted and adjusted models, with cells taking the value '-88' if the model failed, e.g., due to no events, no cases, or lack of convergence. These analyses were exploratory, intended to clarify observed associations without establishing causality, and were not quality controlled.

Additional *post-hoc* analyses were conducted for the 1-KM estimates for outcomes, excluding individuals with pre-existing arrhythmia or heart failure at baseline based on the outcome that was studied after the diagnosis.



Table 4. Amendments to the statistical analysis plan

Amendment number	Date	Section of SAP changed	Summary of amendment/update	Reason
3	11 Jun 2025	Throughout the document	Minor changes to wording and correction of typographical errors throughout the document	To improve clarity
3	11 Jun 2025	Section 3.1, Table 1	Updated final report data availability end date	To reflect delay of Study Completion Date and align dates with the end of validation activities
3	11 Jun 2025	Section 3.3.1	Added inclusion criterion	To specify that the population for objective 2 is those who had a 1st, 2nd, or 3rd vaccine dose. This was previously implied by the sentence, "three dose-specific analysis populations will be used" in section 3.3, but not made explicit in the inclusion criteria.
3	11 Jun 2025	Section 3 Section 4.1 Section 7.1.5 Section 7.3.2	Language improvement. Description of the populations used for the main and sensitivity analysis and the main and sensitivity analyses to be performed	Clarify the main and sensitivity analyses performed for Objective 1 and 2
3	11 Jun 2025	Section 5.3	Added information on natural history of myocarditis and pericarditis questionnaire	Include a general description of the natural history questionnaire
3	11 Jun 2025	Section 5.4 Outcomes for myocarditis or pericarditis	Delete Inflammatory cardiomyopathy	Not an outcome as it is a synonym of myocarditis.
3	11 Jun 2025	Section 7.3/ Table 6	Updated milestones	Revision of milestone dates to reflect delay of Study Completion Date and Final Study Report Date
2	15 Aug 2024	Throughout the document	Minor changes to wording and correction of typographical errors throughout the document	To improve clarity
2	15 Aug 2024	Section 3.1, Table 1	Updated and explained why ARS and HSD will not contribute to the study.	Dates updated to reflect changes in data delivery.



Table 4. Amendments to the statistical analysis plan

Amendment number	Date	Section of SAP changed	Summary of amendment/update	Reason
				Data from ARS will not be extracted for the study due to national and regional re-assessment of regulations affecting their ability to provide public data for PASS studies.
2	15 Aug 2024	Section 3.2.1	Updated	In the HSD data source (Italian GP databases) data on COVID-19 vaccination were missing for a high percentage of individuals and it was, therefore, not considered as fit for purpose and will not be extracted
2	15 Aug 2024	Section 3.2.3	Added end of follow-up criteria	To align with Protocol
2	15 Aug 2024	Section 3.4	ARS and HSD removed from the study	To reflect end of follow-up at 1 year after time zero
2	15 Aug 2024	Section 5.1	CPRD description updated	See above
2	15 Aug 2024	Section 5.1	ARS and HSD removed from the study	To reflect data that will be available from CPRD
2	15 Aug 2024	Section 5.3	Added sampling strategy for validation. In Pedianet, EpiChron and PHARMO all cases of myocarditis and pericarditis will be validated. In NHR, SIDIAP and CPRD the number of potential cases originally identified is large and there are insufficient resources (e.g. clinical reviewers) to validate all cases, therefore a sample of cases will be validated as follows: 1) All cases of myocarditis and pericarditis occurring within the first 21 days after T0 (for dose 1, dose 2, and dose 3) will be prioritised and selected for validation, 2) A random selection of additional cases of myocarditis and pericarditis events will be obtained and validated to reach a total of 300 cases for each diagnosis (myocarditis and pericarditis) in each of the three data sources, which includes the already validated cases described in 1) above.	See above
				To describe the sampling strategy for validation of cases of myocarditis and pericarditis.



Table 4. Amendments to the statistical analysis plan

Amendment number	Date	Section of SAP changed	Summary of amendment/update	Reason
2	15 Aug 2024	Section 5.3	ARS and HSD removed from the study	See above
2	15 Aug 2024	Section 5.3	Addition of table shell 36 for reporting PPV values	To complete table shells
2	15 Aug 2024	Section 5.4.4	Addition of lag time of 30 days for arrhythmia and recurrent myo/pericarditis	Clinical criteria of scientific advisory board applied
2	15 Aug 2024	Section 5.5.10 / Table 3	Charlson Comorbidity Index (CCI)	Update to reflect changes in the CCI that will be used
2	15 Aug 2024	Section 7.1.4	Subgroup analysis	Update to reflect changes in the age categories
2	15 Aug 2024	Section 7.2.3.	Identification of risk factors for myocarditis and pericarditis	Added more details that are necessary for the implementation and changed the order for clarity
2	15 Aug 2024	Section 7.3 / Table 6	Updated milestones.	Revision of milestone dates to reflect delay of Study Completion Date and Final Study Report Date
2	15 Aug 2024	N/A	Justification for delay of Final Study Report	The MAH requests an extension for delivery of the Final Study Report. The Final Study Report was initially planned for submission by 30 September 2024. This extension is needed to fully complete the validation of cases of myocarditis and pericarditis. Although the incidence of myocarditis and pericarditis continues to be extremely low, the size of the cohorts in the largest data sources (e.g. CPRD (UK), Norwegian health registers (NO), IDIAP (ES)) and the follow-up time of two years have yielded a large number of cases that require validation. Additional time is needed to complete the task of validating all cases. Since only a limited number of data sources have fit-for-purpose data, COVID-19 vaccine studies with VAC4EU have been mostly conducted in the same data sources which has led to capacity issues and queuing for scripts for the different PASS. This unexpected situation could not have been controlled by the MAH and given the unprecedented worldwide pandemic, could not have been anticipated when the timelines and milestones were initially planned in 2021. The MAH estimates that delivery of the Final Study Report is feasible by 30 June 2025, Estimated End of data collection date will now be 31 December 2024 instead of the original date of 31 March 2024. These dates have been revised in Section 7.3, Analysis Timelines.
2	15 Aug 2024	Section 7.3.2	Updated	Rewritten to align with other sections. In the final study report the natural history of myocarditis and pericarditis for all cases of



Table 4. Amendments to the statistical analysis plan

Amendment number	Date	Section of SAP changed	Summary of amendment/update	Reason
2	15 Aug 2024	Section 7.4	Changed the type of event from outcome to cohort inclusion criteria	myocarditis and pericarditis will be reported as a main analysis. A sensitivity analysis including the validated cases will be included,
2	15 Aug 2024	Section 7.4	ARS and HSD removed from the study	To correct an error
1	19 April 2023	Throughout the document	Minor changes to wording throughout the SAP	See above
1	19 April 2023	Table 1	ARS and HSD will not contribute to IR	Improved clarity following reviews by additional statisticians
1	19 April 2023	5.4.2 Treatments for myocarditis	Replace aldosterone agonists by aldosterone antagonists	Data from ARS will not be extracted for the interim report due to national and regional re-assessment of regulations affecting their ability to provide public data for PASS studies. This is expected to be resolved for the final report and analysis. Data on COVID-19 vaccination were missing for a high percentage of individuals in the HSD data source (Italian GP databases), and it was, therefore, not considered as fit for purpose. Since it is mandatory for Italian GPs to collect vaccine-related information for their own electronic dossiers, the accuracy of vaccine registration is expected to improve over time and the plan is to include HSD for the final report. We will monitor vaccine uptake data in HSD to assess whether data are fit for purpose. Correction of an error. Aldosterone agonists were erroneously mentioned as one of the myocarditis treatments, Aldosterone antagonists (spironolactone) are the drugs that improve cardiac structure, function and prognosis in individuals with heart failure and delay the progression of cardiac fibrosis. Aldosterone agonists are drugs with mineralo-corticoid like activity, which are frequently administered as replacement therapy whenever the natural production of mineralo-corticoids is impaired, such as chronic adrenocortical insufficiency (Addison disease), following adrenalectomy.
1	19 April 2023	5.6 Known risk factors	Added a detailed list of risk factors for myocarditis and pericarditis identified in published literature	Request from EMA
1	19 April 2023	Table 1	Data availability end dates for interim report 1 have been changed	End dates updated



Table 4. Amendments to the statistical analysis plan

Amendment number	Date	Section of SAP changed	Summary of amendment/update	Reason
1	19 April 2023	7.2	'Conditional logistic regression' changed to 'logistic regression'	This is typically used for case-control matched designs and there are some references that explain that for cohorts there is no need to do conditional regression. Sjölander A, Greenland S. Ignoring the matching variables in cohort studies – when is it valid and why? Stat Med. 2013 Nov 30;32(27):4696-708. Doi: 10.1002/sim.5879. Epub 2013 Jun 12. PMID: 23761197.
1	19 April 2023	7.2.3 Identification of risk factors for myocarditis and pericarditis	The process for selecting risk factors for the regression model has been modified. Now, a set of known risk factors identified from published literature will be forced in the model, and an automated selection process will be used for other covariates. In addition, individual logistic regression models will be calculated for each of the known risk factors.	Request from EMA
1	19 April 2023	7.2.3.1. Generation of an initial working set of variables ('global model')	Changes to section text	To improve clarity and flow and incorporate the EMA request to force known risk factors (section 5.6) in the models
1	19 April 2023	7.2.3.2 Decision about applying variable selection or not	Changes to text and added a less restrictive EPV criteria	To improve clarity and incorporate the EMA request to force known risk factors in the models. The EPV criteria was lowered (15 to 8). The initial proposed value would have resulted in very few variables included in the risk models as it is expected that myocarditis and pericarditis will be rare. Besides this, there are studies reporting that lower values of EPV can be used: Vittinghoff E, McCulloch CE. Relaxing the rule of ten events per variable in logistic and Cox regression. Am J Epidemiol. 2007;165(6):710-8. doi: 10.1093/aje/kwk052

9.11. Quality control

Rigorous quality control (QC) procedures were used, as described below for each data source. Data transformation into the common data model (CDM) was conducted by each DEAP in their associated database, following the processes described below. Standard operating procedures and internal process guidance were followed for the conduct of the study by each DEAP. These included rules for secure and confidential data storage, backup, and recovery; methods to maintain and archive project documents; QC procedures for programming; standards for writing analysis plans; and requirements for scientific review by senior staff.

At University Medical Center Utrecht (UMCU), the scientific coordinating centre responsible for central data management and analysis, all documents underwent QC, senior scientific and editorial reviews.

At RTI Health Solutions (RTI-HS), the project scientific co-leader, all versions of the protocol and SAP underwent QC, and senior scientific reviews. Senior reviewers with expertise in the appropriate subject matter area provided advice on the design of research study approaches and the conduct of the study and reviewed results, reports, and other key study documents.

9.11.1. Pédianet (IT)

Pédianet data processing included QC steps to verify the correspondence between a diagnostic code and its open-text descriptor, conducted through manual validation of clinical histories, in addition to standardised procedures in Structured Query Language (SQL) and Microsoft Access to extract data from the database. Quality control checks of patient general data were conducted through the detection of outlier values and validation rules; grouping of diseases; and regular monitoring of aggregate clinical and drug data. All transformations in the data were logged in R scripts. To ensure code reliability, double programming in R and Stata or Python was used for all scripts.

9.11.2. PHARMO (NL)

PHARMO adhered to high standards throughout the research process based on robust methodologies, transparency, and scientific independence, in accordance with the ENCePP *Guide on Methodological Standards in Pharmacoepidemiology*³³ and the *ENCEPP Code of Conduct*³⁴. PHARMO is ISO 9001:2015 certified. Standard operating procedures, work instructions, and checklists were used to guide the conduct of this study. These procedures and documents included internal quality audits, rules for secure and confidential data storage, methods to maintain and archive project documents, rules and procedures for execution and QC of SAS programming, standards for writing protocols and reports, and requirements for senior scientific review of key study documents.

9.11.3. NHR (NO)

The University of Oslo had centralised information security policies in place to preserve the confidentiality, integrity and availability of the organisation's systems and data. All data were stored and analysed within the TSD platform, a service for sensitive data at the University of Oslo

(<https://www.uio.no/english/services/it/research/sensitive-data/>). Only authorised researchers had access to the data within TSD via a two-step authentication process. The study was conducted according to the *Guidelines for Good Pharmacoepidemiology Practices (GPP)*³⁵ and the *ENCePP Code of Conduct*.³⁴

Data quality is a high priority at the Norwegian Health Registries; updated data are released regularly for research purposes after centralised quality control. The University of Oslo had rules for secure and confidential data storage and analysis, as well as rules for data cleaning, linkage, and programming.

9.11.4. EpiChron (ES)

The data QC process in Aragon was conducted in 3 steps (i.e., data collection, data request and extraction, and data processing). Common data collection software and procedures guaranteed standardised data input by all healthcare professionals. In the case of the hospital CMBD register and the drug dispensation database, their completion by health professionals was mandatory and conducted in compliance with instructions and guidelines set out in legal regulations that are applicable to all hospitals and community pharmacies in the region. Specific online training and chart documentation on the use of EHR software was regularly provided to physicians and nurses in Aragon. The data contained in each of the registers was routed to a specific service of the Department of Health, which performed a pseudonymisation of the data to encrypt individual-level identification codes, protecting individuals' privacy and complying with data protection laws. This new encrypted code was applied in all registers, enabling the linkage of data at the patient level. The resulting databases were stored on a central computer server, and access to the files was protected by a double-entry password restricted to only members of the research group. The research group was a multidisciplinary qualified team including public health specialists, epidemiologists, clinicians, pharmacists, statisticians, and data managers who were all trained in data management and patient data protection. Given that the original databases were in different formats (e.g., Microsoft Access, Microsoft Excel, plain text), the SQL programming language was used to extract the data. Stata statistical software (Release 12) was used for data processing, which included a number of systematic steps aimed at improving the quality, accuracy, and reliability of the data for research purposes e.g.,

- ! QC of diagnoses to verify the correspondence between a diagnostic code and its open-text descriptor through manual validation of clinical histories and use of specific algorithms to search for specific key words or roots of words in open-text fields;

- ! QC of general patient data through the detection of outlier values and validation rules, grouping of diseases, and regular monitoring of aggregate clinical and drug data;
- ! the original databases also had their own QC processes.
- ! all changes made to the data were logged in Stata scripts, which were continuously revised and updated due to the dynamic nature of the data processing.

9.11.5. SIDIAP (ES)

Data quality processes were implemented at each phase of the data flow cycle. QC checks were performed at the extraction and uploading steps. To assess data completeness, the presence of elements was described by geographical area, registering physician, time, and the distribution function of values. Correctness was assessed by validity checks on outliers, out-of-range values, formatting errors, and logical date incompatibilities. Completeness and correctness measures were used to inform decisions on the transformations required to improve data quality (e.g., harmonisation, normalisation, and clean-up) and the data fitness for the purpose of specific research projects.

9.11.6. CPRD Aurum (UK)

The DSRU had information security policies in place to preserve the confidentiality, integrity and availability of the organisation's systems and data. These included ensuring that the premises provide suitable physical and environmental security, all equipment was secure and protected against malicious software, the network was only accessed by authorised staff, telecommunication lines to the premises were protected from interception by being routed overhead or underground, and personnel received training regarding security awareness. The study was conducted according to the *Guidelines for Good Pharmacoepidemiology Practices (GPP)*³⁶ and according to the *ENCePP Code of Conduct*³⁴. Data quality is a high priority at the DSRU and was guaranteed through a number of methods based on staff training, validated systems, error prevention, data monitoring, data cleaning, and documentation and included the following:

- ! staff training on data processing standard operating procedures;
- ! data management plans for every research project, outlining the legal basis for data collection, data flows, data access rights, data retention periods, etc.;
- ! routine data cleaning to screen for errors, missing values, and extreme values and diagnose their cause;
- ! system process logs to document staff access, etc.

9.12. Protection of human subjects

9.12.1. Subject information and consent

Not Applicable.

9.12.2. Independent ethics committee

The final protocol and amendments were reviewed and approved by internal ethics committee for each DEAP.

9.12.3. Ethical conduct of the study

This post-authorisation study of vaccine safety is a non-interventional (observational) study as defined in the International Conference on Harmonisation tripartite guideline *Pharmacovigilance Planning E2E*³⁷ and in the EMA *Guideline on Good Pharmacovigilance Practices (GVP) Module VIII: Post-Authorisation Safety Studies*³⁸, and with the 2012 EU pharmacovigilance legislation, adopted 19 June 2012.³⁹

This study was conducted in accordance with legal and regulatory requirements, as well as with scientific purpose, value, and rigour, and followed the principles of generally accepted research practices described in the *Guidelines for Good Pharmacoepidemiology Practices (GPP)* issued by the International Society for Pharmacoepidemiology³⁶ and was designed in line with guidance from ENCePP, specifically, the *ENCEPP Guide on Methodological Standards in Pharmacoepidemiology*.³³ The *ENCEPP Checklist for Study Protocols*⁴⁰ was completed (see Annex 2 in the protocol).

The study was registered in the HMA-EMA Catalogues of RWD Studies⁴¹ before data collection started.⁴¹

The research team and study sponsor adhered to the general principles of transparency and independence in the *ENCEPP Code of Conduct*³⁴ and the *ADVANCE Code of Conduct*.³⁸ An independent scientific advisory committee, comprising experts in vaccine safety studies, was set up.

10. RESULTS

10.1. Data source participation

Data were included from six data sources: Pedianet, PHARMO, NHR, EpiChron, SIDIAP and CPRD Aurum, for both the primary and secondary objectives.

10.2. Study population and follow-up

10.2.1. Overall study population for natural history study

The source population of the study comprised 34,470,945 individuals. A total of 5,674 individuals with myocarditis and 10,655 individuals with pericarditis were identified but for both conditions, only around 55% were eligible for inclusion in the study, mostly because of receipt of non-Pfizer-BioNTech COVID-19 vaccine prior to disease onset. A total of 3,142 individuals were included in the myocarditis and 5,966 in the pericarditis cohort, respectively ([Table 5](#)).

10.2.2. Study populations for the primary objective (natural history)

Table 5 shows the number of individuals in the myocarditis and pericarditis cohorts and the attrition after inclusion/exclusion criteria are applied. Overall, 45% of cases were excluded due to receipt of a non-Pfizer-BioNTech COVID-19 vaccine prior to disease onset.

10.2.3. Follow-up for the primary objective (natural history)

The length of follow-up in the myocarditis and pericarditis cohorts in each data source and the reasons for censoring are summarised in [Table 6](#).

The median person-months of follow-up from diagnosis to censoring ranged from 13.2 months in NHR to 18.6 months in EpiChron for the myocarditis cohorts and from 12.5 months in Pedianet to 21.7 months in SIDIAP for the pericarditis cohorts. The most frequent reason for censoring was end of the study period, although in CPRD Aurum and PHARMO exit from data source was an important reason for censoring, which is based on the GP not having delivered data until the end of the study period. Death was also a frequent reason for censoring in EpiChron (12.9%) and SIDIAP (9.9%). The percentages were higher in the myocarditis cohorts than in the pericarditis cohorts in all data sources, except in PHARMO.



Table 5. Attrition table for the natural history of myocarditis and pericarditis cohorts by data source

	Pedinet	PHARMO ^e	NHR	EpiChron	SIDIAP	CPRD Aurum
All individuals registered in data source* N	46,392	4,095,291	5,635,615	1,420,230	6,399,492	16,873,925
Myocarditis cohort, n (%)						
Received a myocarditis ^a diagnosis during the study period	0 (0)	1,118 (0.03)	1,204 (0.02)	184 (0.01)	1,274 (0.02)	1,894 (0.01)
≥12 months active enrolment ^b at time zero ^{c,*}	0	1,112 (99.46)	1,200 (99.67)	182 (98.91)	1,234 (96.86)	1,594 (84.16)
No non-Pfizer-BioNTech COVID-19 vaccine before time zero ^{d,*}	0	698 (62.43)	906 (75.25)	125 (67.94)	742 (58.24)	1,173 (61.93)
No history of myocarditis or pericarditis in the 12 months before time zero ^{d,*}	0	1,090 (97.50)	1,098 (91.20)	177 (96.20)	1,229 (96.47)	1,720 (90.81)
Total myocarditis cohort ^{*d}	0	674 (60.29)	813 (67.53)	116 (63.04)	676 (53.06)	863 (45.56)
Pericarditis cohort, n (%)						
Received a pericarditis ^a diagnosis during the study period	3 (0.01)	191 (0.00)	2,832 (0.05)	669 (0.05)	2,880 (0.04)	4,080 (0.02)
≥12 months active enrolment ^b at time zero ^{d,c,**}	2 (66.67)	191 (100)	2,818 (99.51)	660 (98.66)	2,818 (97.85)	3,484 (85.39)
No non-Pfizer-BioNTech COVID-19 vaccine before time zero ^{d,c,**}	3 (100)	115 (60.21)	2,174 (76.77)	460 (68.76)	1,794 (62.29)	2,367 (58.02)
No history of myocarditis or pericarditis in the 12 months before time zero ^{d,c,**}	3 (100)	171 (89.53)	2,599 (91.77)	649 (97.01)	2,787 (96.77)	3,850 (94.36)
Total pericarditis cohort ^{d**}	2 (66.67)	102 (53.40)	1,941 (68.54)	435 (65.02)	1,664 (57.78)	1,822 (44.66)

*Eligible to receive Pfizer-BioNTech COVID-19 vaccine

^aThe first qualifying event will be reported (definite, probable, or possible case).

^bOr lifetime enrolment if age <12 months and enrolled at birth.

^cTime zero^{dx} is the date of diagnosis of the first qualifying myocarditis or pericarditis event during the study period.

^dIndividuals could have >1 attrition factor

*Denominator was the number of individuals who received a myocarditis diagnosis during the study period.

**Denominator was the number of individuals who received a pericarditis diagnosis during the study period.

Data collection start and end dates: Pedinet: 26 February 2021–31 December 2022; PHARMO GP: 06 January 2021–30 June 2023; PHARMO Hospital: 06 January 2021–31 December 2022; NHR 01 January 2020–14 January 2023; EpiChron: 27 December 2020–31 July 2023; SIDIAP: 01 January 2020–30 June 2023 CPRD: 1 December 2020–7 June 2023

^ePHARMO myocarditis cases may include pericarditis since they were retrieved by general ICD code that does not distinguish



Table 6. Cohort follow-up and reasons for censoring for the natural history of myocarditis and pericarditis cohorts by data source

	Pedinet	PHARMO	NHR	EpiChron	SIDIAP	CPRD Aurum
Myocarditis cohort						
Total	0	674	813	116	676	863
Person-months of follow-up		11,161.55	10,247.11	1,986.78	8,904.07	12,227.97
Median follow-up (Q1–Q3)		18.03 (9.75–23.44)	13.19 (6.21–18.64)	18.60 (9.39–24.98)	13.67 (5.98–19.74)	13.98 (6.15–21.62)
Min, Max		0, 30.45	0, 24.76	0, 31.07	0, 30.21	0, 30.25
Reasons for censoring, n %						
End of the study period	0	465 (68.99)	752 (92.5)	101 (87.07)	596 (88.17)	16 (1.85)
Exit from data source	0	179 (26.56)	3 (0.37)	0 (0)	13 (1.92)	830 (96.18)*
Death	0	30 (4.45)	58 (7.13)	15 (12.93)	67 (9.91)	17 (1.97)
Pericarditis cohort						
Total	2	102	1,941	435	1,664	1,822
Person-months of follow-up		1,694.28	25,336.26	7,232.86	31,717.55	27,336.43
Median follow-up (Q1 - Q3)	12.45 (9.02 - 15.87)	16.99 (10.74 - 23.01)	13.59 (6.91 - 19.07)	17.82 (8.43 - 24.89)	21.74 (12.58 - 26.28)	14.93 (6.74 - 23.17)
Min, Max	9.02, 16	0.1, 30	0, 25	0, 31	0, 30	0, 30
Reasons for censoring, n (%)						
End of the study period	1 (50)	59 (57.84)	1,848 (95.21)	398 (91.49)	1,486 (89.3)	26 (1.43)
Exit from data source	1 (50)	36 (35.29)	6 (0.31)	0 (0)	29 (1.74)	1,762 (96.71)*
Death	0 (0)	7 (6.86)	87 (4.48)	37 (8.51)	149 (8.95)	34 (1.87)

*this was due to GPs not updating data until end of study period.

10.2.4. Validation of sample of myocarditis and pericarditis cases

A subset of cases of myocarditis and pericarditis were validated, and levels of certainty were assigned based on modified Brighton Collaboration criteria (see [Appendix 8.1](#)). A subset of validated cases was taken from the data instance for the interim report and the study cohorts in objectives 1 and 2, which had different inclusion and exclusion criteria ([Appendix 2 \(protocol\)](#) and [Appendix 8.1 Validation plan](#)). [Table 7](#) shows the number of cases that were validated which varied across data sources. Also, the source data for validation varied across the data sources; some had access to in-hospital data, others to GP data with clinical notes, whereas CPRD Aurum could only validate based on information in the computerised medical records, without clinical notes.

A total of approximately (considering masking) 990 myocarditis cases, and 1250 pericarditis cases were validated across all sites, 19% of myocarditis cases were classified as Level 1 (definite) cases and this was much higher in data sources with access to in-hospital records, such as NHR (51% Level 1) and EpiChron (56% Level 1). For pericarditis 20% were classified as Level 1, but rates varied across data sources, highest were EpiChron and SIDIAP.

In contrast, data sources without access to hospital data showed lower rates of definite (Level 1) cases due to lack of access to verifiable evidence required to meet that level. They more frequently had higher percentages of level 4 (not enough information to classify).

As a result of this, the positive predictive values (PPVs) for myocarditis based on confirmed cases (Levels 1–3, definite, probable, possible) were low in data sources without access to in-hospital data, but the PPV increased substantially when including cases with just a diagnosis code (level 4, reported event but insufficient data to meet levels 1–3). Sources with access to hospital information showed much higher PPVs for levels 1–3. For pericarditis, PPVs were generally higher than for myocarditis across all sources, particularly when level 4 cases were included.

The percentage of cases classified as non-cases (false positives) varied; in PHARMO, EpiChron, SIDIAP this was between 20% and 25%, compared with 0% in NHR and CPRD.

Validated cases (Level 1, or Levels 1–3) were used for sensitivity analyses for the primary objective (natural history) and secondary objective (risk factors).



Table 7. Validation results for myocarditis (Myo) and pericarditis (Peri) cases, based on individuals sampled from cohorts in Objective 1 and Objective 2 by data source

Brighton classification, n (%)	Pedianet		PHARMO		NHR		EpiChron		SIDIAP		CPRD	
	Myo	Peri	Myo	Peri	Myo	Peri	Myo	Peri	Myo	Peri	Myo	Peri
Loc 1: Certain/definite	0 (0)	<5	5 (8)	12 (13)	123 (51)	12 (5)	44 (56)	133 (45)	15 (5)	79 (27)	<5	16 (5)
Loc2a: Probable	0 (0)	0 (0)	9 (14)	<5 (1)	53 (22)	55 (22)	15 (19)	71 (24)	51 (17)	<5	14 (5)	0 (0)
Loc2b: Probable	0 (0)	0 (0)	0 (0)	<5 (1)	0 (0)	0 (0)	0 (0)	<5 (1)	<5	<5	0 (0)	0 (0)
Loc3a: Possible	0 (0)	0 (0)	0 (0)	0 (0)	<5	87 (35)	0 (0)	0 (0)	18 (6)	<5	<5	0 (0)
Loc3b: Possible	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Loc4a: Specialist diagnosis code, no further information	0 (0)	0 (0)	30 (40)	63 (66)	14 (6)	<5 (<0.1)	<5	30 (10)	54 (18)	59 (20)	136 (45)	130 (43)
Loc4b: GP diagnosis no further information	<5	0 (0)	<5	<5	50 (21)	97 (38)	<5	36 (12)	89 (30)	71 (24)	149 (49)	156 (52)
Loc5: Not a case	<5	<5	15 (24)	17 (18)	0 (0)	0 (0)	18 (23)	26 (9)	69 (23)	80 (27)	0 (0)	0 (0)
Total	<5	5	63	95	242	252	79	298	300	298	304	302
PPV (1-3), total, %, (95% CI)	0.0 (0-77.6)	80.0 (33.4-99.0)	22.2 (13.2-32.7)	14.7 (8.6-33.0)	73.6 (67.7-78.8)	61.1 (57.4-69.5)	74.7 (64.2-83.3)	69.1 (63.7-74.2)	29.3 (24.4-34.7)	29.5 (24.5-34.9)	6.3 (3.9-9.4)	5.3 (3.2-8.3)
PPV (1-4), total, %, (95% CI)	50.0 (2.2-98.7)	80.0 (33.4-99.0)	76.2 (64.5-85.5)	82.1 (73.4-88.9)	100 (98.8-100)	100 (98.8-100)	77.2 (67.0-85.5)	91.3 (87.7-94.1)	77.0 (71.9-81.5)	73.2 (67.9-80.0)	100.0 (99.0-100)	100 (99.0-100)

10.3. Outcome data for the primary objective (natural history)

The key baseline characteristics for the two pericarditis cases identified in Pedianet for the objective on natural history are described here and have not been included in the tables. The individuals in Pedianet with pericarditis were 12 and 13 years of age. One was vaccinated with Pfizer-BioNTech COVID-19 vaccine in the year prior to diagnosis and the other was not. The vaccinated individual had chronic respiratory disease, and both had had a respiratory infection in the year prior to diagnosis. The unvaccinated individual had a positive COVID-19 test in the year prior to diagnosis.

10.3.1. Vaccinations with Pfizer-BioNTech COVID-19 vaccine prior to diagnosis

10.3.1.1. Myocarditis

Table 8 summarises the timing and number of Pfizer-BioNTech COVID-19 vaccine doses received prior to and at the date of diagnosis of myocarditis and pericarditis. Patterns differed slightly between the myocarditis and pericarditis cohorts. The numbers of individuals with myocarditis who were vaccinated prior to diagnosis by data source were: PHARMO, 304 of 674 cases (45.1%); NHR, 543 of 813 cases (66.8%); EpiChron, 75 of 116 cases (64.7%); SIDIAP, 386 of 676 cases (57.1%) and CPRD Aurum, 513 of 863 cases (59.4%).

Across all data sources, more than 90% of the vaccinated individuals with myocarditis had received their last dose more than 15 days prior to the date of diagnosis, and the majority had received two doses. The percentage of individuals with at least one dose was highest in PHARMO (32.9%), compared with less than 20% in the other data sources. In PHARMO 15% had three or four doses prior to diagnosis, in NHR 40%, in EpiChron 31%, in SIDIAP 24% and in CPRD Aurum 37%.

10.3.1.2. Pericarditis

Across all data sources, variable numbers of individuals with pericarditis had received the Pfizer-BioNTech COVID-19 vaccine before diagnosis. In most cases (>90%), the last vaccine dose was administered more than 15 days before diagnosis, and the majority had received two doses. The percentage of individuals with three or more doses varied between data sources (Table 8).



Table 8. Timing and number of doses received at first diagnosis of myocarditis or pericarditis in individuals who had been vaccinated with Pfizer-BioNTech COVID-19 vaccine by data source

Vaccination variables, n (%)	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
Total, N	Myo	Peri	Myo	Peri	Myo	Peri	Myo	Peri	Myo	Peri
Time since last dose										
Received last dose <14 days ago	27 (8.88)	<5	49 (9.02)	132 (9.45)	6 (8.00)	20 (6.62)	21 (5.44)	82 (9.17)	48 (9.36)	60 (5.60)
Received last dose ≥15 days ago	275 (90.46)	32 (88.89)	494 (90.98)	1265 (90.55)	69 (92.00)	281 (93.05)	365 (94.56)	810 (90.6)	464 (90.45)	1011 (94.31)
Number of doses received										
1	100 (32.89)	13 (36.11)	85 (15.65)	183 (13.1)	14 (18.67)	29 (9.6)	56 (14.51)	111 (12.42)	100 (19.49)	208 (19.40)
2	158 (51.97)	17 (47.22)	242 (44.57)	592 (42.38)	38 (50.67)	184 (60.93)	238 (61.66)	571 (63.87)	223 (43.47)	441 (41.14)
3	40 (13.16)	6 (16.67)	186 (34.25)	536 (38.37)	23 (30.67)	77 (25.5)	67 (17.36)	148 (16.55)	179 (34.89)	393 (36.66)
4+	6 (1.97)	0 (0)	30 (5.52)	86 (6.16)	0 (0)	12 (3.97)	25 (6.48)	64 (7.16)	11 (2.14)	30 (2.80)
Vaccination status										
Received 1 dose <14 days ago	12 (3.95)	<5	18 (3.31)	49 (3.51)	<5	9 (2.98)	8 (2.07)	41 (4.59)	17 (3.31)	26 (2.43)
Received 1 dose ≥15 days ago	88 (28.95)	11 (30.56)	67 (12.34)	134 (9.59)	12 (16.00)	20 (6.62)	48 (12.44)	70 (7.83)	83 (16.18)	182 (16.98)
Received 2 doses, last dose <14 days ago	13 (4.28)	<5	12 (2.21)	59 (4.22)	<5	8 (2.65)	13 (3.37)	35 (3.91)	24 (4.68)	25 (2.33)
Received 2 doses, last dose ≥15 days ago	145 (47.70)	16 (44.44)	230 (42.36)	533 (38.15)	35 (46.67)	175 (57.95)	225 (58.29)	535 (59.84)	198 (38.6)	415 (38.71)
Received 3 doses, last dose <14 days ago	<5	<5	13 (2.39)	24 (1.72)	<5	<5 (0.99)	0 (0)	6 (0.67)	6 (1.17)	9 (0.84)
Received 3 doses, last dose ≥15 days ago	37 (12.17)	5 (13.89)	173 (31.86)	512 (36.65)	22 (29.33)	74 (24.50)	67 (17.36)	141 (15.77)	173 (33.72)	384 (35.82)
Received 4 doses, last dose <14 days ago	<5	0 (0)	6 (1.1)	11 (0.79)	0 (0)	<5	0 (0)	<5	<5	0 (0)
Received 4 doses, last dose ≥15 days ago	5 (1.64)	0 (0)	24 (4.42)	75 (5.37)	0 (0)	11 (3.64)	25 (6.48)	61 (6.82)	<20	30 (2.80)

10.3.2. Baseline characteristics of myocarditis and pericarditis cohorts (primary objective- natural history)

10.3.2.1. Myocarditis

The median age at diagnosis in the vaccinated cohort ranged between 36 years in CPRD Aurum to 53 years in NHR. In the unvaccinated cohort the median age was lower and ranged from 28 years in SIDIAP to 49 years in PHARMO. The median age at diagnosis of myocarditis was higher in the vaccinated cohort than in the unvaccinated cohort (vaccinated 13 years older than unvaccinated in NHR and 14 years older in SIDIAP), except in PHARMO. (Table 9). The percentage of very old (≥ 80 years of age) vaccinated individuals diagnosed with myocarditis was more than double that in unvaccinated individuals; in PHARMO 6.6% vs. 2.7%, NHR 7.7% vs. 2.9%, EpiChron 16% vs $<5/41$, SIDIAP 13.7% vs 3.8% and CPRD Aurum 3.3% vs 1.7%).

The percentages of females with myocarditis varied from 21.3% in EpiChron to 39.1% in SIDIAP in the vaccinated cohorts, and from 21.9% in EpiChron to 38.3% in SIDIAP in the unvaccinated cohorts (Table 9).

Current smoking status prevalence varied across the data sources among myocarditis cases, based on the ability to detect prior smoking status. Within data sources, smoking status was similar for the vaccinated and unvaccinated cohorts, however, the smoking status was mostly unknown, except in CPRD Aurum. The prevalence of obesity was highest in SIDIAP and CPRD Aurum, with a higher percentage of obesity in the vaccinated cohort versus the unvaccinated cohort in CPRD Aurum. Very few (≤ 5) vaccinated or unvaccinated individuals with a myocarditis diagnosis were pregnant, and those that were, varied in terms of their trimesters at the time of diagnosis.

10.3.2.2. Pericarditis

The median age at the time of pericarditis diagnosis in the vaccinated cohort ranged from 37 years in CPRD Aurum to 61 years in NHR. In the unvaccinated cohort, the median age ranged from 35 years in CPRD Aurum to 50 years in PHARMO. The median age at diagnosis of pericarditis was higher in the vaccinated cohort than in the unvaccinated cohorts (Table 10). The percentage of very old (80 years of age and older) in vaccinated individuals diagnosed with pericarditis was three times higher than in unvaccinated individuals; in NHR 9.5% vs. 3.1%, EpiChron 14.9% vs 5.3%, SIDIAP 25.6% vs 6.7% and CPRD Aurum 5.2% vs 1%. In all data sources there were more males diagnosed with pericarditis.

Current smoking status varied by data source, with more smokers in the unvaccinated cohorts. Obesity was most common in SIDIAP and CPRD Aurum, with higher rates in the vaccinated cohorts in both sources. Very few (<5) vaccinated or unvaccinated individuals with a pericarditis diagnosis were pregnant, and if they were these varied across trimesters.



Table 9. Demographic and lifestyle variables at baseline in the myocarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status by data source

	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Total, N	304	370	543	270	75	41	386	290	513	350
Age groups at time zero_{DX} (years), n (%)										
0-1	0 (0)	<5	0 (0)	<5	0 (0)	0 (0)	0 (0)	18 (6.21)	0 (0)	<5
2-4	0 (0)	<5	0 (0)	<5	0 (0)	0 (0)	0 (0)	36 (12.41)	0 (0)	<5
5-11	0 (0)	<5	0 (0)	7 (2.59)	<5	0 (0)	32 (8.29)	43 (14.83)	<5	18 (5.14)
12-15	<5	<5	<5	5 (1.85)	<5	<5	26 (6.74)	8 (2.76)	8 (1.56)	12 (3.43)
16-17	<5	<5	15 (2.76)	5 (1.85)	<5	<5	12 (3.11)	5 (1.72)	29 (5.65)	22 (6.29)
18-29	53 (17.43)	66 (17.84)	99 (18.23)	71 (26.3)	19 (25.33)	12 (29.27)	51 (13.21)	37 (12.76)	>161	116 (33.14)
30-39	55 (18.09)	59 (15.95)	60 (11.05)	41 (15.19)	10 (13.33)	7 (17.07)	55 (14.25)	31 (10.69)	99 (19.3)	61 (17.43)
40-49	49 (16.12)	55 (14.86)	60 (11.05)	45 (16.67)	9 (12.00)	5 (12.2)	54 (13.99)	32 (11.03)	71 (13.84)	53 (15.14)
50-59	56 (18.42)	77 (20.81)	89 (16.39)	37 (13.7)	5 (6.67)	<5	43 (11.14)	27 (9.31)	51 (9.94)	40 (11.43)
60-64	9 (2.96)	31 (8.38)	38 (7)	12 (4.44)	<5	0 (0)	5 (1.30)	8 (2.76)	18 (3.51)	6 (1.71)
65-69	18 (5.92)	35 (9.46)	46 (8.47)	15 (5.56)	<5	<5	7 (1.81)	12 (4.14)	26 (5.07)	8 (2.29)
70-79	39 (12.83)	27 (7.3)	90 (16.57)	19 (7.04)	9 (12.00)	<5	48 (12.44)	22 (7.59)	28 (5.46)	<5
80+	20 (6.58)	10 (2.7)	42 (7.73)	8 (2.96)	12 (16.00)	<5	53 (13.73)	11 (3.79)	17 (3.31)	6 (1.71)
Age at index date (years)										
Mean (SD)	48.49 (19.55)	47.24 (18.03)	51.37 (21.18)	41.47 (19.59)	47.63 (25.54)	42.44 (20.76)	45.85 (26.12)	32.23 (25.81)	39.23 (18.9)	33.13 (16.87)
Median (Q1, Q3)	46 (33 - 66)	49 (32 - 61)	53 (32 - 69)	40 (25 - 55)	43 (24 - 71)	39 (24 - 58)	42.50 (21 - 71)	28 (6 - 51)	36 (23 - 52)	30 (21 - 44)
Min, Max	14, 89	0, 94	13, 94	0, 86	11, 96	12, 84	5, 98	1, 90	9, 88	1, 89
Female, n (%)	97 (31.91)	120 (32.43)	191 (35.17)	77 (28.52)	16 (21.33)	9 (21.95)	151 (39.12)	111 (38.28)	179 (34.89)	102 (29.14)
Smoking status										
Unknown	293 (96.38)	364 (98.38)	539 (99.26)	269 (99.63)	72 (96.00)	39 (95.12)	359 (93.01)	267 (92.07)	185 (36.06)	163 (46.57)
Never or former	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Never	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	179 (34.89)	83 (23.71)
Former	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)



Table 9. Demographic and lifestyle variables at baseline in the myocarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status by data source

	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Current	11 (3.62)	6 (1.62)	<5 (0.74)	<5 (0.37)	<5	<5	27 (6.99)	23 (7.93)	149 (29.04)	104 (29.71)
Obese (diagnostic code or BMI >30 kg/m ² , n (%) ^a	5 (1.64)	<5	17 (3.13)	12 (4.44)	6 (8.00)	3 (7.32)	51 (13.21)	36 (12.41)	84 (16.37)	44 (12.57)
Pregnancy status, n (%)	<5	<5	0 (0)	<5	0 (0)	0 (0)	5 (7.69)	<5	0 (0)	0 (0)
Pregnancy trimester, n (%)										
First trimester	<5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Second trimester	0 (0)	<5	0 (0)	0 (0)	0 (0)	0 (0)	<5	<5	0 (0)	0 (0)
Third trimester	0 (0)	0 (0)	0 (0)	<5	0 (0)	0 (0)	<5	0 (0)	0 (0)	0 (0)

BMI: Body Mass Index; Q1: first quartile; Q3: third quartile; SD: standard deviation; Vac: vaccinated cohort; Unvac: unvaccinated cohort
^aClosest value to time zero_{ox} within three years. Time zero_{ox} is the date of myocarditis diagnosis that qualified to enter the cohort.



Table 10. Demographic and lifestyle characteristics at baseline in the pericarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status and data source

	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Total, N	36	66	1,397	544	302	133	894	770	1072	750
Age groups at time zero_{Dx} (years), n (%)										
0-1	0 (0)	0 (0)	0 (0)	<5	0 (0)	0 (0)	0 (0)	<5	0 (0)	0 (0)
2-4	0 (0)	0 (0)	0 (0)	6 (1.1)	0 (0)	0 (0)	0 (0)	7 (0.91)	0 (0)	0 (0)
5-11	0 (0)	<5	0 (0)	9 (1.65)	0 (0)	0 (0)	<5	14 (1.82)	<5	13 (1.73)
12-15	<5	0 (0)	7 (0.5)	11 (2.02)	9 (2.98)	5 (3.76)	14 (1.57)	9 (1.17)	16 (1.49)	15 (2.00)
16-17	<5	0 (0)	16 (1.15)	9 (1.65)	7 (2.32)	<5	21 (2.35)	14 (1.82)	32 (2.99)	33 (4.4)
18-29	8 (22.22)	13 (19.7)	156 (11.17)	83 (15.26)	46 (15.23)	24 (18.05)	80 (8.95)	130 (16.88)	>304	214 (28.53)
30-39	<5	10 (15.15)	123 (8.8)	89 (16.36)	41 (13.58)	17 (12.78)	80 (8.95)	96 (12.47)	223 (20.8)	173 (23.07)
40-49	<5	9 (13.64)	145 (10.38)	81 (14.89)	40 (13.25)	22 (16.54)	112 (12.53)	116 (15.06)	146 (13.62)	137 (18.27)
50-59	7 (19.44)	12 (18.18)	215 (15.39)	91 (16.73)	48 (15.89)	16 (12.03)	136 (15.21)	118 (15.32)	118 (11.01)	107 (14.27)
60-64	<5	7 (10.61)	129 (9.23)	42 (7.72)	8 (2.65)	14 (10.53)	14 (1.57)	47 (6.1)	52 (4.85)	26 (3.47)
65-69	<5	5 (7.58)	154 (11.02)	45 (8.27)	11 (3.64)	6 (4.51)	14 (1.57)	64 (8.31)	47 (4.38)	8 (1.07)
70-79	5 (13.89)	8 (12.12)	319 (22.83)	58 (10.66)	47 (15.56)	19 (14.29)	191 (21.36)	99 (12.86)	73 (6.81)	16 (2.13)
80+	<5	<5	133 (9.52)	17 (3.12)	45 (14.9)	7 (5.26)	229 (25.62)	52 (6.75)	56 (5.22)	8 (1.07)
Age at index date (years)										
Mean (SD)	50.69 (22.87)	48.17 (17.66)	57.05 (19.52)	46.72 (19.8)	52.05 (22.67)	48.17 (20.51)	59.54 (22.89)	48.55 (21.15)	42.08 (19.65)	36.93 (15.66)
Median (Q1, Q3)	56.50 (24 - 69)	50.50 (32 - 62)	61 (43 - 72)	48 (32 - 63)	51.50 (34 - 72)	49 (30 - 62)	60 (42 - 80)	49 (31 - 66)	37 (26 - 56)	35 (24 - 48)
Min, Max	15, 87	11, 83	13, 100	0, 91	12, 97	12, 91	6, 100	1, 92	8, 97	6, 90
Female, n (%)	10 (27.78)	22 (33.33)	467 (33.43)	159 (29.23)	87 (28.81)	34 (25.56)	320 (35.79)	271 (35.19)	353 (32.93)	195 (26.00)
Smoking status										
Unknown	33 (91.67)	62 (93.94)	1,385 (99.14)	538 (98.90)	285 (94.37)	123 (92.48)	834 (93.29)	700 (90.91)	360 (33.58)	296 (39.47)
Never or former	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Never	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	327 (30.50)	149 (19.87)
Former	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)



Table 10. Demographic and lifestyle characteristics at baseline in the pericarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status and data source

	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Current	<5	<5	12 (0.86)	6 (1.1)	17 (5.63)	10 (7.52)	60 (6.71)	70 (9.09)	385 (35.91)	305 (40.67)
Obese (diagnostic code or BMI >30 kg/m ²), n (%) ^a	<5	<5	54 (3.87)	16 (2.94)	24 (7.95)	9 (6.77)	136 (15.21)	106 (13.77)	140 (13.06)	82 (10.93)
Pregnancy status, n (%)	0 (0)	0 (0)	<5	<5	0 (0)	0 (0)	<5	<5	0 (0)	0 (0)
Pregnancy trimester, n (%)										
First trimester	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Second trimester	0 (0)	0 (0)	0 (0)	<5	0 (0)	0 (0)	<5	0 (0)	0 (0)	0 (0)
Third trimester	0 (0)	0 (0)	<5	<5	0 (0)	0 (0)	0 (0)	<5	0 (0)	0 (0)

BMI: Body Mass Index; Q1: first quartile; Q3: third quartile; SD: standard deviation; Vac: vaccinated cohort; unvac: unvaccinated cohort
a. Closest value to time zeroDx within three years. Time zeroDx is the date of myocarditis diagnosis that qualified to enter the cohort.

10.3.3. Healthcare utilisation in myocarditis cohort (primary objective natural history)

The data on healthcare utilisation in the previous 12 months in the myocarditis cohort are summarised by data source in [Appendix Table 1](#) and for the pericarditis cohorts in [Appendix Table 2](#). Results for healthcare utilisation were limited by the type of databases available for use in the different data sources. PHARMO had only partial hospital data and no emergency department data. NHR included primary care, hospitalisations, and COVID-19 tests, but not emergency visits. EpiChron captured all care settings; SIDIAP included primary care, hospitalisations, and tests; CPRD Aurum covered all settings via GP records. Missing data are marked as NA.

10.3.3.1. Myocarditis

Hospitalisation

Hospitalisation rates in the year prior to the myocarditis diagnosis differed between data sources, but not substantially between the vaccinated and unvaccinated cohorts within the data sources (Appendix Table 1). In NHR, about 35% had been hospitalised in the previous 12 months, in both the vaccinated and unvaccinated cohorts. In EpiChron, only a few vaccinated and no unvaccinated individuals had been hospitalised. In SIDIAP, 25.4% (vaccinated) and 23.5% (unvaccinated) had been hospitalised; and in CPRD Aurum, 18.7% and 20%, respectively, had been hospitalised.

Hospitalisation rates in the 2 weeks prior to diagnosis are summarised in Appendix Table 2. In the 2 weeks before diagnosis, hospitalisation rates were similar across cohorts, ranging from 12.0% vaccinated and 11.5% unvaccinated individuals in NHR to 1.3% vaccinated and 0% unvaccinated individuals in EpiChron.

Emergency department visits

In the year prior to myocarditis diagnosis in EpiChron, 55% of vaccinated cohort did not visit an emergency department in the year prior to diagnosis versus 51% of unvaccinated myocarditis cohort (Appendix Table 1).

In the 2 weeks before diagnosis, emergency visits occurred in 21.3% (vaccinated) and 17.1% (unvaccinated) in EpiChron, and 27.1% vs. 34.0% in CPRD Aurum. Other sources did not capture emergency visits (Appendix Table 2).

Primary care visits

In all data sources, primary care visits in the year prior to diagnosis were frequent in both the vaccinated and unvaccinated myocarditis cohorts (Appendix Table 1). In the year before diagnosis, most had at least one primary care visit: PHARMO (81.3% vaccinated, 73.0% unvaccinated), NHR (94.0% vs. 93.0%), EpiChron (92.0% vs.

nearly all), and SIDIAP (93.0% vs. 96.0%). GP visits were not assessable in CPRD Aurum due to an ETL issue.

In the 2 weeks before diagnosis, many had primary care visits: PHARMO (26% vaccinated, 25% unvaccinated), NHR (46% vs. 49%), EpiChron (56% vs. 49%), and SIDIAP (53% vs. 57%). ([Appendix Table 2](#)).

Cancer screening

Only CPRD Aurum captured cancer screening: 16.2% of vaccinated and 10.9% of unvaccinated individuals had screening in the year before diagnosis. Fewer than five individuals in each cohort were screened in the 2 weeks prior to diagnosis.

Recorded COVID-19 tests

Recorded COVID-19 tests in the year prior to myocarditis diagnosis were not frequent ([Appendix Table 1](#)). In PHARMO, COVID-19 tests could not be distinguished from vaccination or disease. Recorded testing varied from 11.4% vaccinated and 14.8% unvaccinated individuals in NHR to 50.5% vs. 44.3%, respectively in CPRD Aurum. Some individuals in SIDIAP and CPRD Aurum had three or more tests.

The percentages of recorded COVID-19 tests in the 2 weeks prior to diagnosis were low in all data sources ([Appendix Table 2](#)). In NHR, 98.3% of vaccinated and 97.8% of unvaccinated individuals had no recorded COVID-19 test. In EpiChron, these figures were 94.7% and 97.6%, respectively. In SIDIAP, nearly 100% of vaccinated and 97.6% of unvaccinated had no test recorded. In CPRD Aurum, 90.0% of vaccinated and 88.6% of unvaccinated individuals did not have a recorded test. ([Appendix Table 2](#)).

10.3.3.2. Pericarditis

Hospitalisation

In the year prior to pericarditis diagnosis, 42.2% and 36.4% of the vaccinated and unvaccinated pericarditis cohorts in NHR, had been hospitalised ([Appendix Table 3](#)). In EpiChron, 24.5% and 21.8% of vaccinated and unvaccinated cohorts had been hospitalised, vs. 34.9% and 25.2% respectively in SIDIAP and 13.1% and 10.7% in CPRD Aurum.

Hospitalisation within 2 weeks prior to pericarditis diagnosis was more common in vaccinated than unvaccinated individuals in NHR (13.2% vs. 10.3%), SIDIAP (12.0% vs. 6.9%), and CPRD Aurum (7.4% vs. 6.7%), but slightly lower in EpiChron (4.0% vs. 5.3%). ([Appendix Table 4](#)).

Emergency department visits

In EpiChron, 41% and 43% of the vaccinated and unvaccinated cohorts, respectively, had ≥ 1 emergency department visits in the year prior to diagnosis. In CPRD Aurum 48% of vaccinated and 47% of unvaccinated had one or more emergency department visit in the year prior ([Appendix Table 3](#)). For the other data sources, this data was not available.

In the 2 weeks prior to pericarditis diagnosis, in EpiChron, 18% of both the vaccinated and the unvaccinated cohorts, had one or more emergency department visit, in CPRD Aurum this was 27% and 26% in vaccinated and unvaccinated ([Appendix Table 4](#)).

Primary care visits

In all data sources, primary care visits in the year prior to diagnosis of pericarditis were frequent both in the vaccinated and unvaccinated cohorts ([Appendix Table 3](#)). In the year before diagnosis, ≥ 1 primary care visit was recorded for most cases, more frequently in vaccinated than unvaccinated individuals: PHARMO (86.1% vs. 51.5%), NHR (93.3% vs. 89.9%), EpiChron (93.1% vs. 90.2%), and SIDIAP (96.4% vs. 92.3%). Data were not available for CPRD Aurum.

In the 2 weeks prior to pericarditis diagnosis ([Appendix Table 4](#)) In the 2 weeks before diagnosis, ≥ 1 primary care visit was slightly more common in vaccinated than unvaccinated cohorts in most data sources: PHARMO (17.0% vs. 19.7%), NHR (47.5% vs. 48.2%), EpiChron (49% vs. 47%), and SIDIAP (63% vs. 58%). Data were not available for CPRD Aurum.

Cancer screening

Data on cancer screening was only available in CPRD Aurum, where 17.7% of the vaccinated cohort and 10.7% of the unvaccinated cohort had undergone cancer screening in the year prior to pericarditis diagnosis ([Appendix Table 3](#)). This was much lower in the 2 weeks prior to diagnosis ([Appendix Table 4](#)).

COVID-19 tests

Few COVID-19 tests were recorded in the year prior to pericarditis diagnosis ([Appendix Table 3](#)). Recorded COVID-19 tests were less frequent in the 2 weeks prior to the diagnosis of pericarditis ([Appendix Table 4](#)). In NHR 1.1% of the vaccinated cohort and 1% of unvaccinated cohort had a recorded COVID-19 test. In EpiChron, 4.0% and 3.8%, in SIDIAP, 2.0% and 2.7%. In CPRD Aurum this was 7.2% and 8.5% in vaccinated and unvaccinated cohorts, respectively.

10.3.4. Comorbidities and surrogates of frailty in myocarditis and pericarditis cohorts (primary objective - natural history)

Baseline comorbidities in the myocarditis and pericarditis cohorts are summarised in [Table 11](#) and [Table 12](#), respectively, for vaccinated and unvaccinated cohorts. These comorbidities were assessed for up to 10 years prior to diagnosis, with a minimum of one year.

The surrogates of frailty in the myocarditis and pericarditis cohorts are summarised in [Appendix Table 5](#) and [Appendix Table 6](#). These variables were assessed as present or absent in the year prior to time zero. Prevalence of frailty indicators was generally low except for lipid abnormalities and arthritis. Prevalence was generally higher in the vaccinated cohorts than in the unvaccinated cohorts.

10.3.4.1. Myocarditis

A history of cardiovascular disease was common in the myocarditis cohort and was generally higher in Pfizer-BioNTech vaccinated cases than unvaccinated across most data sources (e.g., NHR: 70.2% vs. 59.3%; EpiChron: 49.3% vs. 43.9%; SIDIAP: 49.5% vs. 40.7%; CPRD Aurum: 52.4% vs. 51.7%; PHARMO was an exception). Hypertension was frequent in both groups, with varying differences (10% in the vaccinated cohort in PHARMO and 32% in the vaccinated cohort in NHR and between 15 and 19% in the unvaccinated cohorts-(Table 11).

Diabetes prevalence ranged from 4.0% to 11.1% in vaccinated and 5.2% to 12.2% in unvaccinated cases. Respiratory disease was also prevalent, with rates between 24%-55% in vaccinated and 24.4%-48.3% in unvaccinated. Influenza diagnoses were more common in vaccinated cases. Connective tissue diseases and immunosuppressive conditions were relatively high, often more so in vaccinated individuals.

Vaccinated myocarditis cases tended to have more comorbidities, reflected in Charlson Comorbidity Index (CCI) scores: a lower proportion had a score of 0 and a higher proportion had scores ≥ 3 compared to unvaccinated across data sources. Median CCI scores were 0 or 1 in all datasets. Similarly, more vaccinated individuals had 2+ risk factors for severe COVID-19 per CDC criteria.

History of COVID-19 infection was similar between groups. Frailty indicators varied, but lipid abnormalities were consistently higher in vaccinated cohorts except in EpiChron.

10.3.4.2. Pericarditis

Cardiovascular disease was common in the pericarditis cohort and consistently higher in vaccinated individuals than in unvaccinated individuals in all data sources, e.g., PHARMO: 66.7% vs. 57.6%; NHR: 75.0% vs. 58.5%, respectively.

Hypertension was frequent in both groups, with higher prevalence in vaccinated cohorts, except in PHARMO ([Table 12](#)).

Diabetes ranged from 8.3% to 21.5% in vaccinated and 7.9% to 15.5% in unvaccinated cohorts. Respiratory disease was also prevalent (vaccinated: 30.3%–54.0%, unvaccinated: 25.6%–50.0%), generally higher in the vaccinated. Influenza history over the past 10 years was more common in vaccinated individuals, except in PHARMO and CPRD Aurum. Connective tissue diseases and immunosuppressive conditions were relatively common, and more frequent in vaccinated cohorts.

Overall, vaccinated individuals diagnosed with pericarditis tended to have more comorbidities. Fewer had a Charlson Comorbidity Index (CCI) score of 0, e.g., NHR: 30.6% vs. 42.3%, and more had scores ≥ 3 , e.g., SIDIAP: 32.4% vs. 18.7%. Median CCI scores were 0 or 1 in sources. Similarly, more vaccinated individuals had ≥ 2 CDC-defined risk conditions for severe COVID-19, e.g., PHARMO: 52.8% vs. 40.9%.

COVID-19 diagnosis or positive test was common, with higher test positivity in the vaccinated cohorts. Surrogates of frailty varied, but lipid abnormalities were consistently more prevalent in the vaccinated cohorts.



Table 11. Comorbidities at baseline in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status and by data source

	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Total, N	304	370	543	270	75	41	386	290	513	350
Comorbidities, n (%)	<5	0 (0)	17 (3.13)	<5	<5	0 (0)	<5	<5	7 (1.36)	5 (1.43)
History of anaphylaxis	19 (6.25)	22 (5.95)	71 (13.08)	25 (9.26)	20 (26.67)	7 (17.07)	90 (23.32)	49 (16.90)	77 (15.01)	49 (14.00)
History of allergies	21 (6.91)	30 (8.11)	57 (10.50)	14 (5.19)	3 (4)	5 (12.20)	43 (11.14)	26 (8.97)	52 (10.14)	32 (9.14)
Diabetes mellitus (types 1 and 2)	31 (10.2)	57 (15.41)	174 (32.04)	44 (16.30)	14 (18.67)	8 (19.51)	103 (26.68)	55 (18.97)	80 (15.59)	38 (10.86)
Hypertension (CDC risk group)	154 (50.66)	200 (54.05)	381 (70.17)	160 (59.26)	37 (49.33)	18 (43.90)	191 (49.48)	118 (40.69)	269 (52.44)	181 (51.71)
Cardiovascular disease	17 (5.59)	14 (3.78)	71 (13.08)	29 (10.74)	5 (6.67)	0 (0)	19 (4.92)	13 (4.48)	25 (4.87)	10 (2.86)
Myocardial infarction	10 (3.29)	13 (3.51)	85 (15.65)	32 (11.85)	8 (10.67)	5 (12.20)	53 (13.73)	34 (11.72)	35 (6.82)	23 (6.57)
Congestive heart failure	13 (4.28)	15 (4.05)	34 (6.26)	13 (4.81)	5 (6.67)	<5	30 (7.77)	7 (2.41)	12 (2.34)	<5
Cerebrovascular disease	14 (4.61)	14 (3.78)	66 (12.15)	30 (11.11)	5 (6.67)	<5	37 (9.59)	21 (7.24)	<5	0 (0)
Peripheral vascular disease	73 (24.01)	96 (25.95)	165 (30.39)	70 (25.93)	23 (30.67)	10 (24.39)	169 (43.78)	112 (38.62)	281 (54.78)	169 (48.29)
Chronic respiratory disease	16 (5.26)	11 (2.97)	5 (0.92)	0 (0)	8 (10.67)	<5	46 (11.92)	12 (4.14)	22 (4.29)	7 (2.00)
Chronic kidney disease	<5	6 (1.62)	<5	0 (0)	8 (10.67)	<5	43 (11.14)	11 (3.79)	19 (3.70)	<5
Mild to moderate renal disease	<5	<5	<5	<5	<5	<5	23 (5.96)	16 (5.52)	<5	<5
Chronic liver disease	<5	6 (1.62)	12 (2.21)	9 (3.33)	0 (0)	0 (0)	<5	<5	33 (6.43)	19 (5.43)
Moderate to severe liver disease	27 (8.88)	19 (5.14)	75 (13.81)	16 (5.93)	5 (6.67)	2 (4.88)	33 (8.55)	13 (4.48)	24 (4.68)	5 (1.43)
Any cancer diagnosis except non melanoma skin cancer	<5	0 (0)	0 (0)	0 (0)	<5	0 (0)	<5	<5	<5	0 (0)
Leukaemia	0 (0)	1 (0.27)	0 (0)	0 (0)	<5	0 (0)	<5	<5	0 (0)	0 (0)
Lymphoma	<5	1 (0.27)	15 (2.76)	7 (2.59)	<5	0 (0)	5 (1.30)	6 (2.07)	<5	0 (0)
Metastasis	32 (10.53)	51 (13.78)	155 (28.55)	73 (27.04)	5 (6.67)	5 (12.20)	37 (9.59)	26 (8.97)	55 (10.72)	42 (12)
Autoimmune disorders	43 (14.14)	47 (12.7)	200 (36.83)	95 (35.19)	19 (25.33)	7 (17.07)	201 (52.07)	127 (43.79)	68 (13.26)	31 (8.86)
Influenza infection or other respiratory infection	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	<5	0 (0)
HIV/AIDS	0 (0)	0 (0)	1 (0.18)	0 (0)	0 (0)	0 (0)	0 (0)	<5	<5	<5
Sickle cell disease (CDC risk group)	60 (19.74)	74 (20.00)	185 (34.07)	75 (27.78)	41 (54.67)	22 (53.66)	187 (48.45)	99 (34.14)	55 (10.72)	35 (10.00)
Connective tissue disease	<5 (0.66)	<5 (0.27)	<5 (0.18)	<5 (0.74)	<5	<5	<5	<5	0 (0)	0 (0)
Immunodeficiency except HIV	84 (27.63)	103 (27.84)	194 (35.73)	78 (28.89)	13 (17.33)	5 (12.20)	134 (34.72)	97 (33.45)	152 (29.63)	85 (24.29)
Human immunodeficiency virus (HIV) and other immunosuppressing conditions										



Table 11. Comorbidities at baseline in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status and by data source

	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Charlson Comorbidity Index										
0	185 (60.86)	246 (66.49)	203 (37.38)	130 (48.15)	24 (32.00)	13 (31.71)	132 (34.20)	128 (44.14)	249 (48.54)	174 (49.71)
1	62 (20.39)	66 (17.84)	146 (26.89)	74 (27.41)	32 (42.67)	20 (48.78)	111 (28.76)	93 (32.07)	128 (24.95)	109 (31.14)
2	24 (7.89)	29 (7.84)	79 (14.55)	27 (10.00)	4 (5.33)	6 (14.63)	51 (13.21)	28 (9.66)	53 (10.33)	31 (8.86)
3+	33 (10.86)	29 (7.84)	115 (21.18)	39 (14.44)	15 (20.00)	2 (4.88)	92 (23.83)	41 (14.14)	83 (16.18)	36 (10.29)
Mean (SD)	<5 (1)	<5 (1)	<5 (2)	<5 (2)	<5 (2)	<5 (1)	<5 (2)	<5 (2)	<5 (2)	<5 (1)
Median (Q1, Q3)	0 (0–1)	0 (0–1)	<5 (0–2)	<5 (0–1)	<5 (0–1)	<5 (0–1)	<5 (0–2)	<5 (0–1)	<5 (0–2)	<5 (0–1)
Min, Max	0, 10	0, 11	0, 14	0, 15	0, 11	0, 8	0, 14	0, 14	0, 11	0, 9
CDC at-risk groups										
Group 0 (no conditions)	103 (33.88)	124 (33.51)	102 (18.78)	70 (25.93)	26 (34.67)	16 (39.02)	114 (29.53)	83 (28.62)	124 (24.17)	86 (24.57)
Group 1 (1 condition)	85 (27.96)	116 (31.35)	164 (30.2)	98 (36.3)	25 (33.33)	15 (36.59)	82 (21.24)	82 (28.28)	144 (28.07)	112 (32.00)
Group 2 (>1 condition)	116 (38.16)	130 (35.14)	277 (51.01)	102 (37.78)	24 (32)	10 (24.39)	190 (49.22)	125 (43.1)	245 (47.76)	152 (43.43)
COVID-19 history										
Previous diagnosis of COVID-19	67 (22.04)	54 (14.59)	21 (3.87)	5 (1.85)	0 (0)	0 (0)	157 (40.67)	100 (34.48)	162 (31.58)	100 (28.57)
Positive test results for COVID-19	0 (0)	0 (0)	72 (13.26)	42 (15.56)	24 (32.00)	10 (24.39)	54 (13.99)	45 (15.52)	142 (27.68)	90 (25.71)



Table 12. Comorbidities at baseline in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status and by data source

	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Total, N	36	66	1,397	544	302	133	894	770	1,072	750
Comorbidities, n (%)										
History of anaphylaxis	<5	<5	36 (2.58)	13 (2.39)	9 (2.98)	<5	6 (0.67)	<5	20 (1.87)	<5
History of allergies	5 (13.89)	<5	155 (11.1)	77 (14.15)	81 (26.82)	38 (28.57)	179 (20.02)	144 (18.7)	188 (17.54)	101 (13.47)
Diabetes mellitus (types 1 and 2)	<5	10 (15.15)	199 (14.24)	43 (7.90)	45 (14.9)	16 (12.03)	192 (21.48)	86 (11.17)	138 (12.87)	72 (9.6)
Hypertension (CDC risk group)	8 (22.22)	16 (24.24)	524 (37.51)	120 (22.06)	88 (29.14)	24 (18.05)	369 (41.28)	169 (21.95)	204 (19.03)	80 (10.67)
Cardiovascular disease	24 (66.67)	38 (57.58)	1,048 (75.02)	318 (58.46)	155 (51.32)	62 (46.62)	585 (65.44)	387 (50.26)	568 (52.99)	348 (46.4)
Myocardial infarction	<5	10 (15.15)	131 (9.38)	35 (6.43)	19 (6.29)	<5	72 (8.05)	47 (6.1)	46 (4.29)	37 (4.93)
Congestive heart failure	<5	8 (12.12)	161 (11.52)	35 (6.43)	30 (9.93)	9 (6.77)	164 (18.34)	69 (8.96)	37 (3.45)	21 (2.80)
Cerebrovascular disease	<5	<5	135 (9.66)	44 (8.09)	11 (3.64)	<5	71 (7.94)	31 (4.03)	25 (2.33)	6 (0.8)
Peripheral vascular disease	5 (13.89)	12 (18.18)	271 (19.4)	61 (11.21)	18 (5.96)	7 (5.26)	134 (14.99)	79 (10.26)	10 (0.93)	<5
Chronic respiratory disease	11 (30.56)	17 (25.76)	466 (33.36)	148 (27.21)	96 (31.79)	34 (25.56)	390 (43.62)	260 (33.77)	579 (54.01)	375 (50.00)
Chronic kidney disease	<5	<5	21 (1.50)	<5	40 (13.25)	6 (4.51)	169 (18.9)	59 (7.66)	59 (5.50)	21 (2.80)
Mild to moderate renal disease	0 (0)	0 (0)	12 (0.86)	<5	40 (13.25)	6 (4.51)	168 (18.79)	59 (7.66)	42 (3.92)	15 (2.00)
Chronic liver disease	0 (0)	0 (0)	19 (1.36)	15 (2.76)	6 (1.99)	<5	65 (7.27)	47 (6.1)	6 (0.56)	<5
Moderate to severe liver disease	<5	<5	43 (3.08)	24 (4.41)	5 (1.66)	<5	11 (1.23)	9 (1.17)	97 (9.05)	67 (8.93)
Any cancer diagnosis except non melanoma skin cancer	<5	7 (10.61)	240 (17.18)	62 (11.4)	22 (7.28)	8 (6.02)	88 (9.84)	37 (4.81)	64 (5.97)	17 (2.27)
Leukaemia	0 (0)	<5	0 (0)	0 (0)	<5	0 (0)	9 (1.01)	5 (0.65)	5 (0.47)	5 (0.67)
Lymphoma	0 (0)	<5	0 (0)	0 (0)	<5	0 (0)	<5	5 (0.65)	0 (0)	0 (0)
Metastasis	0 (0)	<5	29 (2.08)	12 (2.21)	<5	<5	13 (1.45)	11 (1.43)	<5	<5
Autoimmune disorders	7 (19.44)	11 (16.67)	460 (32.93)	162 (29.78)	42 (13.91)	9 (6.77)	110 (12.3)	84 (10.91)	131 (12.22)	72 (9.6)
Influenza infection or other respiratory infection	<5	17 (25.76)	627 (44.88)	209 (38.42)	50 (16.56)	21 (15.79)	405 (45.3)	313 (40.65)	110 (10.26)	86 (11.47)
HIV/AIDS	0 (0)	0 (0)	<5	<5	<5	0 (0)	0 (0)	0 (0)	<5	<5
Sickle cell disease (CDC risk group)	0 (0)	<5	<5	<5	0 (0)	0 (0)	<5	<5	<5	<5
Connective tissue disease	12 (33.33)	16 (24.24)	601 (43.02)	183 (33.64)	219 (72.52)	69 (51.88)	478 (53.47)	356 (46.23)	156 (14.55)	71 (9.47)
Immunodeficiency except HIV	0 (0)	<5	11 (0.79)	<5	<5	0 (0)	13 (1.45)	22 (2.86)	0 (0)	<5
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	13 (36.11)	20 (30.3)	534 (38.22)	179 (32.9)	76 (25.17)	19 (14.29)	290 (32.44)	203 (26.36)	300 (27.99)	189 (25.2)



Table 12. Comorbidities at baseline in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status and by data source

	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Charlson Comorbidity Index										
0	18 (50.00)	33 (50.00)	427 (30.57)	230 (42.28)	59 (19.54)	41 (30.83)	250 (27.96)	296 (38.44)	421 (39.27)	353 (47.07)
1	7 (19.44)	12 (18.18)	348 (24.91)	135 (24.82)	130 (43.05)	60 (45.11)	230 (25.73)	227 (29.48)	317 (29.57)	211 (28.13)
2	<5	<5	206 (14.75)	71 (13.05)	44 (14.57)	15 (11.28)	124 (13.87)	103 (13.38)	102 (9.51)	60 (8.00)
3+	7 (19.44)	17 (25.76)	416 (29.78)	108 (19.85)	69 (22.85)	17 (12.78)	290 (32.44)	144 (18.7)	232 (21.64)	126 (16.80)
Mean (SD)	<5 (1)	<5 (1)	<5 (2)	<5 (2)	<5 (2)	<5 (1)	<5 (2)	<5 (2)	<5 (2)	<5 (1)
Median (Q1, Q3)	0 (0 - 1)	0 (0 - 1)	<5 (0 - 2)	<5 (0 - 1)	<5 (0 - 1)	<5 (0 - 1)	<5 (0 - 2)	<5 (0 - 1)	<5 (0 - 2)	<5 (0 - 1)
Min, Max	0, 10	0, 11	0, 14	0, 15	0, 11	0, 8	0, 14	0, 14	0, 11	0, 9
CDC at-risk groups										
Group 0 (no conditions)	10 (27.78)	21 (31.82)	203 (14.53)	143 (26.29)	108 (35.76)	52 (39.10)	199 (22.26)	256 (33.25)	251 (23.41)	208 (27.73)
Group 1 (1 condition)	7 (19.44)	18 (27.27)	362 (25.91)	165 (30.33)	62 (20.53)	38 (28.57)	194 (21.70)	200 (25.97)	291 (27.15)	220 (29.33)
Group 2 (>1 condition)	19 (52.78)	27 (40.91)	832 (59.56)	236 (43.38)	132 (43.71)	43 (32.33)	501 (56.04)	314 (40.78)	530 (49.44)	322 (42.93)
COVID-19 history										
Previous diagnosis of COVID-19	<5	11 (16.67)	31 (2.22)	8 (1.47)	11 (3.64)	9 (6.77)	232 (25.95)	147 (19.09)	321 (29.94)	133 (17.73)
Positive test results for COVID-19	0 (0)	0 (0)	151 (10.81)	52 (9.56)	91 (30.13)	26 (19.55)	101 (11.30)	50 (6.49)	294 (27.43)	119 (15.87)

10.3.5. Comedications and vaccinations myocarditis and pericarditis natural history study

Comedication in the year prior to diagnosis and anytime vaccination history for the myocarditis and pericarditis cohorts are summarised in [Appendix Table 7](#) and [Appendix Table 8](#), respectively.

10.3.5.1. Myocarditis

Comedication use in the year before myocarditis diagnosis was common, particularly for analgesics (15.4–45.3%), with generally higher rates in the vaccinated cohorts. Antibiotics, NSAIDs, psychotropics, statins, and novel anticoagulants were also frequently used, and were often higher in the vaccinated cohorts, which may be due to higher age of this group.

Influenza vaccination rates varied by data source but were consistently higher in vaccinated cohorts. Childhood vaccination data were limited, though in SIDIAP and CPRD Aurum, coverage for DTP-containing, MMR, Hepatitis B, polio, and meningitis vaccines was high in both cohorts, but was slightly higher in unvaccinated cohorts in SIDIAP.

10.3.5.2. Pericarditis

Comedication use before pericarditis diagnosis was higher than for myocarditis. Analgesic use ranged from 16.7% to 54.3% in vaccinated and 7.6% to 40.9% in unvaccinated cohorts. Antibiotic use ranged from 22.7% to 36.1% (vaccinated) across data sources and from 19.7% to 31.6% (unvaccinated), with higher use in vaccinated groups, consistent with the higher median age of that group.

NSAIDs, psychotropics, statins, and novel anticoagulants were also commonly used, generally more in vaccinated cohorts.

Influenza vaccination rates varied by data source but were consistently higher in vaccinated cohorts.

10.4. Main results for primary objective (natural history study)

10.4.1. COVID-19 vaccinations during follow-up

10.4.1.1. Myocarditis cohorts

COVID-19 vaccines received during follow-up are summarised in [Table 13](#). Across all databases, individuals unvaccinated at the time of myocarditis diagnosis were more likely to receive COVID-19 vaccines afterward. In PHARMO, 44.3% of previously unvaccinated and 40% of vaccinated individuals received at least one dose post-diagnosis, with half receiving non-Pfizer-BioNTech mRNA vaccines. In NHR, 60% of unvaccinated and 34% of vaccinated cases were vaccinated post-diagnosis, mostly with Pfizer-BioNTech. EpiChron showed 73.2% of unvaccinated and 17.3% of vaccinated cases received vaccines post-diagnosis. In SIDIAP, 34.8% of unvaccinated and 23.1% of vaccinated cases were vaccinated, with both Pfizer and non-Pfizer vaccines used. CPRD Aurum reported 41.4% of unvaccinated and 24.2% of vaccinated cases received further doses, primarily Pfizer-BioNTech. Sensitivity analyses in level 1 or level 1-3 cases confirmed consistent patterns of vaccination after diagnosis ([Appendix tables 9-12](#)).

10.4.1.2. Pericarditis cohorts

COVID-19 vaccines received during follow-up are summarised in [Table 13](#). Across all datasets, individuals unvaccinated at the time of pericarditis diagnosis were more likely to receive COVID-19 vaccines afterwards except in PHARMO. In PHARMO, 35% of unvaccinated and 55.6% of vaccinated individuals received at least one dose post-diagnosis. In NHR, 69.1% of unvaccinated and 40.5% of vaccinated cases were vaccinated, mostly with Pfizer-BioNTech. EpiChron showed 63.2% of unvaccinated and 26.2% of vaccinated cases received vaccines post-diagnosis. In SIDIAP, 69.9% of unvaccinated and 47.7% of vaccinated individuals were vaccinated, using both Pfizer and non-Pfizer vaccines. CPRD Aurum reported 48.3% of unvaccinated and 27.8% of vaccinated cases received further doses. Sensitivity analyses restricted to the individuals with level 1 or level 1-3 cases confirmed these vaccination patterns after first diagnosis ([Appendix tables 9-12](#)).



Table 13. COVID-19 vaccines received by individuals with myocarditis and pericarditis during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline

Part 1 (see Part 2 below)

	PHARMO				NHR				EpiChron			
	Myocarditis		Pericarditis		Myocarditis		Pericarditis		Myocarditis		Pericarditis	
Vaccination during follow-up, n (%)	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Total, N	304	370	36	66	270	1397	543	544	75	41	302	133
None	183 (60.20)	206 (55.68)	16 (44.44)	43 (65.15)	108 (40.00)	831 (59.48)	358 (65.93)	168 (30.88)	62 (82.67)	11 (26.83)	223 (73.84)	49 (36.84)
First Pfizer-BioNTech COVID-19 dose	0	93 (25.14)	0	13 (19.70)	142 (52.59)	0 (0)	0	325 (59.74)	0	19 (46.34)	0	63 (47.37)
Second Pfizer-BioNTech COVID-19 dose	34 (11.18)	75 (20.27)	6 (16.67)	9 (13.64)	117 (43.33)	90 (6.44)	32 (5.89)	286 (52.57)	<5	18 (43.90)	6 (1.99)	55 (41.35)
Third Pfizer-BioNTech COVID-19 dose	43 (14.14)	28 (7.57)	6 (16.67)	<5	93 (34.44)	326 (23.34)	100 (18.42)	228 (41.91)	5 (6.67)	11 (26.83)	35 (11.59)	24 (18.05)
Any non-Pfizer-BioNTech COVID-19 vaccine	75 (24.67)	107 (28.92)	12 (33.33)	16 (24.24)	48 (17.78)	80 (5.73)	28 (5.16)	112 (20.59)	7 (9.33)	14 (34.15)	31 (10.26)	37 (27.82)
mRNA COVID-19 vaccine	70 (93.33)	74 (69.16)	11 (91.67)	13 (81.25)	44 (91.67)	78 (97.50)	26 (92.86)	107 (95.54)	7 (100)	13 (92.86)	30 (96.77)	32 (86.49)
Non-mRNA COVID-19 vaccine	36 (48)	88 (82.24)	8 (66.67)	13 (81.25)	**	**	**	6 (5.36)	0 (0)	**	**	9 (24.32)

Vac: vaccinated; Unvac: unvaccinated; NA: not applicable

*Data on specific type was not available for CPRD Aurum ** information on the type of non -mRNA was not available



Table 13. COVID-19 vaccines received by individuals with myocarditis and pericarditis during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline
Part 2 (see Part 1 above)

Vaccination during follow-up, n (%)	SIDIAP						CPRD Aurum			
	Myocarditis			Pericarditis			Myocarditis		Pericarditis	
	Vac	Unvac		Vac	Unvac		Vac	Unvac	Vac	Unvac
Total, N	386	290		894	770		513	350	1072	750
None	297 (76.94)	189 (65.17)	468 (52.35)	232 (30.13)	389 (75.83)	205 (58.57)	774 (72.20)		388 (51.73)	
First Pfizer-BioNTech COVID-19 dose	0	64 (22.07)	0	342 (44.42)	0	75 (21.43)	0		183 (24.40)	
Second Pfizer-BioNTech COVID-19 dose	11 (2.85)	48 (16.55)	52 (5.82)	306 (39.74)	42 (8.19)	63 (18)	87 (8.12)		158 (21.07)	
Third Pfizer-BioNTech COVID-19 dose	19 (4.92)	15 (5.17)	108 (12.08)	101 (13.12)	73 (14.23)	57 (16.29)	194 (18.10)		153 (20.40)	
Any non-Pfizer-BioNTech COVID-19 vaccine	30 (7.77)	64 (22.07)	217 (24.27)	339 (44.03)	40 (7.80)	77 (22)	84 (7.84)		212 (28.27)	
mRNA COVID-19 vaccine	29 (96.67)	59 (92.19)	215 (99.08)	314 (92.63)	0 (0) *	0 (0) *	0 (0) *		0 (0) *	
Non-mRNA COVID-19 vaccine	**	12 (18.75)	**	82 (24.19)	0 (0) *	0 (0) *	0 (0) *		0 (0) *	

Vac: vaccinated; Unvac: unvaccinated; NA: not applicable

*Data on specific type was not available for CPRD Aurum ** information on the type of non -mRNA was not available

10.4.2. Tests performed for myocarditis and pericarditis diagnosis

10.4.2.1. Myocarditis cohorts

Tests performed to diagnose myocarditis are listed in [Table 14](#). For most data sources, these could not be retrieved directly from the electronic health records but were obtained through the natural history questionnaire and validation.

The natural history questionnaire was completed in REDCAP by the DEAPs, who validated myocarditis and pericarditis cases. [Appendix Table 13](#) shows the results of the natural history questionnaire for myocarditis cases, showing both how cases were diagnosed and what type of non-pharmacological treatment was provided. In data sources where original hospital data could be verified (NHR and EpiChron), which are more complete we saw that in NHR 155 out of the 227 cases (68.3%) had Cardiac magnetic resonance (CMR), and 42 out of 78 cases of myocarditis in EpiChron (53.9%). Also, echocardiograms were frequently conducted as part of the diagnosis. Very few individuals received a pacemaker or Implantable cardiac defibrillator, which is consistent with what we observed in the EHR data.

10.4.2.2. Pericarditis cohorts

Tests performed to diagnose pericarditis are listed in [Table 14](#). For most data sources, these could not be retrieved directly from the electronic health records but were obtained through the natural history questionnaire and validation.

[Appendix Table 14](#) shows the results for diagnostic tests and treatments from the natural history questionnaire for pericarditis cases. In data sources in which original hospital data could be verified, i.e., NHR and EpiChron, only 5.3% individuals in NHR and 9.7% in EpiChron had CMR compared with 68.3% and 53.9% of the myocarditis cases, respectively. Echocardiograms were frequently conducted as part of the diagnosis, 89% in NHR and 73.5% in EpiChron. Very few individuals received a pacemaker or Implantable cardiac defibrillator, which is consistent with what we observed in the EHR data. The most frequent non-pharmacological treatment was pericardial drainage, with 11.0% in NHR and 7.2% in EpiChron.

[Appendix Table 15](#) summarises the subgroup analyses for diagnostic tests in myocarditis and pericarditis cases.



Table 14. Number of individuals with at least one diagnostic test for myocarditis and pericarditis performed in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status at time of myocarditis diagnosis by data source

	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Diagnostic test, n (%)										
Myocarditis Total, N	304	370	543	270	75	41	386	290	513	350
Cardiac magnetic resonance(CMR)	NH	NH	NH	NH	NH	NH	NH	NH	45 (8.77)	25 (7.14)
Computed tomography(CT)	NH	NH	NH	NH	NH	NH	NH	NH	7 (1.36)	<5
Echocardiogram	NH	NH	NH	NH	NH	NH	NH	NH	119 (23.20)	71 (20.29)
Pericarditis Total, N	36	66	1397	544	302	133	894	770	1072	750
Cardiac magnetic resonance(CMR)	NH	NH	NH	NH	NH	NH	NH	NH	17 (1.59)	7 (0.93)
Computed tomography(CT)	NH	NH	NH	NH	NH	NH	NH	NH	7 (0.65)	6 (0.80)
Echocardiogram	NH	NH	NH	NH	NH	NH	NH	NH	187 (17.44)	139 (18.53)

NH: data were not available in electronic health record but obtained in natural history questionnaire (Appendix 5)

10.4.3. Treatments for myocarditis and pericarditis

10.4.3.1. Myocarditis cohort

Patterns of use of pharmacological treatments in myocarditis cases were similar between the vaccinated and unvaccinated myocarditis cohorts in the data sources ([Table 15](#)). Of note, this includes prevalent medication use and it is not incident use after diagnosis. The most frequent treatments were antibiotics, beta-blockers, ACE-I/ARBs, diuretics and immunosuppressant agents, paracetamol and glycosides/CCB. Non-pharmacological treatments such as transplants, defibrillators, and mechanical support that are supplied in the hospital could not be assessed using diagnostic codes. Subgroup analyses ([Appendix table 16](#)) shows that treatment was similar for all subgroups, except in individuals aged 15-30 years, where fewer cardiovascular medications were recorded. In the sensitivity analyses with definite cases only (level 1), and with level 1, 2 and 3 cases (definite, probable and possible cases) treatment patterns between the vaccinated and unvaccinated cohorts were similar ([Appendix Tables 17 to 20](#)).

10.4.3.2. Pericarditis cohort

Patterns of use of prevalent pharmacological treatments (not incident after diagnosis) in pericarditis cases were similar between the vaccinated and unvaccinated pericarditis cohorts and in the data sources ([Table 16](#)). The most frequently used was colchicine in both the vaccinated and unvaccinated cohorts, followed by NSAIDs and antibiotics. Non-pharmacological treatments that are supplied in the hospital could not be assessed adequately using diagnostic codes.

Subgroup analyses ([Appendix table 21](#)) shows that treatment was similar for all subgroups, except in individuals aged 15-30 years, who had more NSAIDs recorded.

In the sensitivity analysis of definite cases only (level 1), treatment patterns between vaccinated and unvaccinated were similar, with a higher percentage of definite cases received colchicine, as compared with all cases or cases with levels of certainty 1-3 ([Appendix Tables 22 to 25](#)).



Table 15. Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status and by data source

Treatment, n (%)	PHARMO		NHR		EpiChron		SIDIAF		CPRD Aurum	
	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Total, N	304	370	543	270	75	41	386	290	513	350
Paracetamol	<5	37 (10)	142 (26.15)	63 (23.33)	30 (40)	16 (39.02)	160 (41.45)	128 (44.14)	16 (3.12)	14 (4)
Antivirals	2 (0.66)	<5	10 (1.84)	10 (3.70)	<5	0 (0)	<5	<5	7 (1.36)	6 (1.71)
Antibiotics	96 (31.58)	122 (32.97)	186 (34.25)	84 (31.11)	36 (48)	15 (36.59)	137 (35.49)	104 (35.86)	106 (20.66)	61 (17.43)
Immunosuppressant agents	52 (17.11)	63 (17.03)	101 (18.60)	56 (20.74)	11 (14.67)	5 (12.20)	66 (17.10)	64 (22.07)	62 (12.09)	27 (7.71)
Beta-blockers	90 (29.61)	96 (25.95)	206 (37.94)	81 (30.00)	24 (32)	16 (39.02)	86 (22.28)	66 (22.76)	236 (46)	145 (41.43)
Diuretics	42 (13.82)	65 (17.57)	103 (18.97)	39 (14.44)	18 (24)	8 (19.51)	86 (22.28)	49 (16.90)	69 (13.45)	44 (12.57)
ACE inhibitor or ARB	62 (20.39)	100 (27.03)	182 (33.52)	72 (26.67)	18 (24)	14 (34.15)	106 (27.46)	63 (21.72)	191 (37.23)	106 (30.29)
Aldosterone antagonist	13 (4.28)	28 (7.57)	45 (8.29)	12 (4.44)	7 (9.33)	<5	29 (7.51)	27 (9.31)	0 (0)	0 (0)
Cardiac glycosides or calcium-channel blockers	41 (13.49)	52 (14.05)	56 (10.31)	18 (6.67)	8 (10.67)	<5	37 (9.59)	19 (6.55)	49 (9.55)	30 (8.57)
Antiarrhythmics	5 (1.64)	9 (2.43)	22 (4.05)	9 (3.33)	<5	<5	12 (3.11)	12 (4.14)	15 (2.92)	8 (2.29)
Pacemaker	0 (0)	0 (0)	6 (1.10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	8 (1.56)	<5
Implantable cardiac defibrillator	0 (0)	0 (0)	17 (3.13)	6 (2.22)	0 (0)	0 (0)	0 (0)	0 (0)	<5	5 (1.43)
Mechanical circulatory support	0 (0)	0 (0)	8 (1.47)	5 (1.85)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	<5
Heart transplantation	0 (0)	0 (0)	0 (0)	<5	0 (0)	0 (0)	0 (0)	0 (0)	<5	<5



Table 16. Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status and by data source

Treatment, n (%)	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac	Vac	Unvac
Total, N	36	66	1397	544	302	133	894	770	1072	750
Antibiotics	5 (13.89)	7 (10.61)	330 (23.62)	107 (19.67)	60 (19.87)	27 (20.30)	174 (19.46)	103 (13.38)	125 (11.66)	89 (11.87)
Antivirals	0 (0)	0 (0)	21 (1.50)	9 (1.65)	<5	0 (0)	7 (0.78)	<5	7 (0.65)	<5
Non-steroidal anti-inflammatory drugs (NSAIDs)	9 (25.00)	18 (27.27)	625 (44.74)	268 (49.26)	157 (51.99)	76 (57.14)	210 (23.49)	204 (26.49)	0 (0)	0 (0)
Colchicine	20 (55.56)	25 (37.88)	866 (61.99)	314 (57.72)	121 (40.07)	63 (47.37)	229 (25.62)	228 (29.61)	NA	NA
Intrapericardial administration of steroids	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)	1 (0.07)	<5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)	74 (5.30)	32 (5.88)	0 (0)	0 (0)	0 (0)	0 (0)	6 (0.56)	<5
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)	58 (4.15)	25 (4.60)	0 (0)	0 (0)	0 (0)	0 (0)	<5	<5
Pericardiocentesis	0 (0)	0 (0)	30 (2.15)	8 (1.47)	0 (0)	0 (0)	0 (0)	0 (0)	<5	<5
Cardiac catheterisation	0 (0)	0 (0)	18 (1.29)	8 (1.47)	<5	0 (0)	<5	0 (0)	9 (0.84)	8 (1.07)
Balloon pericardial window formation	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	<5	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)	<5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	<5

10.4.4. Outcomes for myocarditis and pericarditis cases

Outcomes in the year after diagnosis were assessed in the myocarditis and pericarditis cohorts. In PHARMO, individuals classified as myocarditis are a mixture of myocarditis and pericarditis cases, since it was not possible to distinguish between these two outcomes with the ICPC code. In all other data sources, a distinction could be made.

Since the study analyses were descriptive all risks shown in the Kaplan-Meier analyses were crude, and do not account for differences that may exist between vaccinated and unvaccinated individuals. Indeed, the median ages between the vaccinated and unvaccinated myocarditis cohorts differed substantially and also varied by data source. In NHR and SIDIAP, the median age difference was 13–14 years and 13–11 years, respectively (Table 17). Individuals were the youngest in CPRD Aurum and oldest in NHR. In the myocarditis and pericarditis cohorts the age differences between the vaccinated and unvaccinated individuals were about 13–14 years and 13–11 years in NHR and SIDIAP, respectively. These age differences could explain some of the heterogeneity observed in the crude risks of outcomes. The cumulative incidences for all outcomes with events can be found in [Section 15](#) – figures.

Table 17. Median age (years) of vaccinated and unvaccinated individuals by data source

	Myocarditis		Pericarditis	
	Vaccinated	Unvaccinated	Vaccinated	Unvaccinated
PHARMO	46	49	56.5	50.5
NHR	53	40	61	48
EpiChron	43	39	51.5	49
SIDIAP	42.5	28	60	49
CPRD Aurum	36	30	37	35

Post-hoc analyses

To explore observed differences in the risk of prespecified outcomes in vaccinated and unvaccinated individuals, we conducted *post-hoc* Cox-regression analyses, after adjustment for age, sex, and CDC and Charlson Comorbidity Index scores.

10.4.4.1. Hospitalisation

[Table 18](#) summarises the cumulative risk per 10,000 individuals for hospitalisations in the myocarditis and pericarditis cohorts in all data sources, except PHARMO, where this outcome could not be assessed. The risk for hospitalisations was very high immediately from the start of follow-up suggesting that most individuals were hospitalised following the diagnosis of myocarditis or pericarditis.

10.4.4.1.1. Myocarditis cohorts

The risk of hospitalisation for 10,000 individuals at 3 months after diagnosis was high. and lowest in CPRD Aurum, which did not comprehensively capture all hospitalisations (Table 18). In the sensitivity analyses of definitive cases only (Appendix Tables 26 and 29), the 12-month risks of hospitalisation were all above 9,000 per 10,000 individuals, however, the criteria for Brighton Collaboration level 1 is being hospitalised. Crude 3-month and 12-month risks for hospitalisation in those vaccinated and unvaccinated at baseline are presented in Appendix Figure 1. The risk at 12 months was not higher than the risk at 3 months, showing that hospitalisation occurred rapidly. However, these data are descriptive only, since vaccinated individuals were older, sicker and used more medications.

A *post-hoc* survival analysis comparing the risk over 12-months between vaccinated and unvaccinated cohorts with adjustment for age, sex and comorbidity scores showed a HR_{adj} of 1.04 (95% CI:0.90–1.20) for NHR, a HR_{adj} of 0.99 (95% CI:0.66–1.49) for EpiChron, a HR_{adj} of 0.77 (95% CI:0.64–0.91) in SIDIAP and a HR_{adj} of 1.04 (95% CI:0.69-1.56) in CPRD Aurum.

10.4.4.1.2. Pericarditis cohorts

The risk of hospitalisation in NHR was high in all data sources (Table 18) but lowest in CPRD Aurum (Appendix Tables 26 to 29) Crude 3-month and 12-month KM curves for hospitalisation in those vaccinated and unvaccinated at baseline are presented in Appendix Figure 2. These data should be interpreted as descriptive only, since vaccinated individuals were older and sicker.

Post-hoc survival analyses comparing the vaccinated with unvaccinated cohorts after adjustment for age, sex and comorbidity scores showed a HR_{adj} of 0.96 (95% CI:0.86-1.06) for NHR, a HR_{adj} of 0.66 (95% CI:0.50-0.86) for EpiChron, a HR_{adj} of 1.07 (95% CI:0.94-1.20) in SIDIAP and a HR_{adj} of 0.92 (95% CI:0.70-1.20) in CPRD Aurum for the 12-month risk.

10.4.4.2. Death

Table 18 shows the crude cumulative risk of death per 10,000 individuals in the myocarditis and pericarditis cohorts by data source.

10.4.4.2.1. Myocarditis cohorts

In PHARMO the 12-month cumulative risk of death was 364 (95% CI: 216-509) in myocarditis/pericarditis cases, but this should be interpreted with caution, since death dates are rounded and imputed in PHARMO. In other data sources the 12-month risk of death was higher see Table 18. In the sensitivity analyses of definitive cases only and definitive, probable and possible cases (Appendix Tables 30 to 33), the 12-month risk of death was lower than in all cases (not validated) together.

Crude 3- and 12-month cumulative risks in those vaccinated and unvaccinated at baseline are presented in [Appendix Figure 3](#). These data are descriptive only, since individuals in the vaccinated cohort were sicker and older, especially in NHR and SIDIAP.

Post-hoc survival analyses comparing the risk of death over 12 months between vaccinated and unvaccinated cohorts after adjusting for age, sex and comorbidity scores showed a HR_{adj} of 0.40 (95% CI: 0.16–1.01) in PHARMO, HR_{adj} of 0.74 (95% CI: 0.39–1.40) in NHR, a HR_{adj} of 3.25 (95% CI: 0.70–14.9) in EpiChron, a HR_{adj} of 0.66 (95% CI: 0.36–1.22) in SIDIAP and a HR_{adj} of 0.89 (95% CI: 0.28–2.85) in CPRD Aurum.

10.4.4.2.2. Pericarditis cohorts

In PHARMO the unadjusted 12-month cumulative risk of death per 10,000 individuals was 598 (95% CI: 122–1052), but this should be interpreted with caution, since death dates were rounded and imputed in PHARMO. In other data sources the risk was higher ([Table 18](#)). In the sensitivity analyses of definitive cases only ([Appendix Tables 30 to 33](#)), the 12-month risk of death was lower than in all cases (not validated) together.

Crude 3- and 12-month cumulative risks of death in those vaccinated and unvaccinated at baseline are presented in [Appendix Figure 4](#). These data are descriptive only, since vaccinated were sicker and older especially in NHR and SIDIAP.

Post-hoc survival analyses comparing risk of death between vaccinated and unvaccinated over 12 months after adjustment for age, sex and comorbidity scores showed a HR_{adj} of 0.25 (95% CI: 0.03–1.74) in PHARMO (only age adjusted), HR_{adj} of 1.06 (95% CI: 0.57–1.98) for NHR, a HR_{adj} of 1.13 (95% CI: 0.47–2.74) for EpiChron, a HR_{adj} of 0.84 (95% CI: 0.56–1.26) in SIDIAP and a HR_{adj} of 0.90 (95% CI: 0.69–1.19) in CPRD Aurum.



Table 18. Crude cumulative incidence (1-KM and 95% CI) of hospitalisation, death, heart failure, cardiogenic shock, fulminant myocarditis, and arrhythmia per 10,000 individuals at 3, 6, 9 and 12 months in the myocarditis and pericarditis cohorts by data source

	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Myocarditis	Pericarditis	Myocarditis	Pericarditis	Myocarditis	Pericarditis	Myocarditis	Pericarditis	Myocarditis	Pericarditis
Hospitalisation										
Total, N	NA	NA	813	1,941	116	435	676	1,664	863	1,822
3 months	NA	NA								
Events, n	NA	NA	640	1,568	98	222	426	1,047	86	182
Individuals at risk	NA	NA	146	337	13	183	241	595	682	1,462
Risk (95% CI)	NA	NA	7,907 (7,605 – 8,171)	8,090 (7,906 – 8,258)	8,448 (7,627 – 8,985)	5,123 (4,628 – 5,573)	6,307 (5,924 – 6,653)	6,296 (6,056 – 6,521)	1,010 (805 – 1,210)	1,009 (869 – 1,147)
12 months	NA	NA								
Events, n	NA	NA	661	1,622	98	231	438	1,088	107	218
Individuals at risk	NA	NA	94	175	7	108	109	523	415	946
Risk (95% CI)	NA	NA	8,242 (7,949 – 8,494)	8,450 (8,274 – 8,609)	8,448 (7,627 – 8,985)	5,427 (4,917 – 5,886)	6,547 (6,160 – 6,895)	6,559 (6,322 – 6,781)	1,346 (1,101 – 1,584)	1,282 (1,119 – 1,442)
Death										
3 months										
Events, n	15	5	37	42	11	22	42	69	9	11
Individuals at risk	618	94	704	1,744	100	384	604	1,515	754	1,628
Risk (95% CI)	228 (113 - 341)	490 (62 - 900)	462 (315 - 606)	221 (154 - 286)	958 (403 - 1,480)	515 (303 - 722)	630 (444 - 813)	424 (326 - 522)	106 (37 - 175)	63 (26 - 100)
12 months										
Events, n	23	6	52	73	14	35	61	116	14	24
Individuals at risk	477	73	461	1,108	80	286	363	1,264	482	1,085
Risk (95% CI)	364 (216 - 509)	598 (122 - 1052)	700 (513 - 884)	425 (328 - 520)	1,242 (610 - 1,831)	864 (585 - 1,135)	994 (750 - 1,232)	740 (609 - 869)	192 (89 - 294)	155 (92 - 216)
Heart failure										
3 months										
Events, n	29	13	129	177	21	55	91	300	64	37



Table 18. Crude cumulative incidence (1-KM and 95% CI) of hospitalisation, death, heart failure, cardiogenic shock, fulminant myocarditis, and arrhythmia per 10,000 individuals at 3, 6, 9 and 12 months in the myocarditis and pericarditis cohorts by data source

	PHARMO		NHR		EpiChron		SIDIAIP		CPRD Aurum	
	Myocarditis	Pericarditis	Myocarditis	Pericarditis	Myocarditis	Pericarditis	Myocarditis	Pericarditis	Myocarditis	Pericarditis
Individuals at risk	594	82	600	1,586	85	344	535	1,266	694	1,595
Risk (95% CI)	432 (277 - 584)	1284 (607 - 1912)	1602 (1345 - 1852)	926 (795 - 1055)	1810 (1079 - 2482)	1275 (955 - 1585)	1353 (1090 - 1608)	1814 (1626 - 1998)	756 (576 - 933)	208 (141 - 274)
12 months										
Events, n	31	14	148	217	23	59	104	336	78	50
Individuals at risk	455	64	387	992	67	254	313	1,065	431	1,055
Risk (95% CI)	467 (305 - 627)	1395 (689 - 2048)	1917 (1631 - 2193)	1198 (1045 - 1348)	2014 (1241 - 2719)	1395 (1057 - 1721)	1631 (1333 - 1918)	2062 (1862 - 2256)	977 (766 - 1183)	297 (215 - 378)
Cardiogenic shock										
3 months										
Events, n	5	0	8	7	<5	7	28	23	<5	0
Individuals at risk	616	94	702	1,740	100	381	588	1,502	<3334	1,628
Risk (95% CI)	74 (9 - 139)	0 (0 - 0)	98 (30 - 166)	36 (9 - 63)	86 (0 - 253)	161 (42 - 278)	417 (264 - 567)	138 (82 - 194)	12 (0 - 34)	0 (0 - 0)
12 months										
Events, n	5	0	8	7	<5	7	31	24	<5	0
Individuals at risk	475	73	461	1,105	80	285	348	1,252	<3334	1,085
Risk (95% CI)	74 (9 - 139)	0 (0 - 0)	98 (30 - 166)	36 (9 - 63)	86 (0 - 253)	161 (42 - 278)	489 (317 - 659)	146 (88 - 204)	12 (0 - 34)	0 (0 - 0)
Fulminant myocarditis										
3 months										
Events, n	11	35	<5	26	23	11	35	<5	26	23
Individuals at risk	611	679	99	590	734	611	679	99	590	734
Risk (95% CI)	164 (67 - 259)	433 (291 - 572)	172 (0 - 406)	385 (239 - 529)	268 (159 - 376)	164 (67 - 259)	433 (291 - 572)	172 (0 - 406)	385 (239 - 529)	268 (159 - 376)
12 months										
Events, n	11	36	<5	29	23	11	36	<5	29	23



Table 18. Crude cumulative incidence (1-KM and 95% CI) of hospitalisation, death, heart failure, cardiogenic shock, fulminant myocarditis, and arrhythmia per 10,000 individuals at 3, 6, 9 and 12 months in the myocarditis and pericarditis cohorts by data source

	PHARMO		NHR		EpiChron		SIDIAP		CPRD Aurum	
	Myocarditis	Pericarditis	Myocarditis	Pericarditis	Myocarditis	Pericarditis	Myocarditis	Pericarditis	Myocarditis	Pericarditis
Individuals at risk	471	441	79	349	464	471	441	79	349	464
Risk (95% CI)	164 (67 - 259)	447 (303 - 588)	172 (0 - 406)	457 (290 - 622)	268 (159 - 376)	164 (67 - 259)	447 (303 - 588)	172 (0 - 406)	457 (290 - 622)	268 (159 - 376)
Arrhythmia										
3 months										
Events, n	10	<5	57	95	<5	7	6	32	5	24
Individuals at risk	543	74	487	1,246	85	309	479	1,130	706	1,470
Risk (95% CI)	171 (65 - 276)	123 (0 - 361)	986 (739 - 1226)	657 (528 - 784)	220 (0 - 516)	209 (54 - 360)	118 (24 - 212)	268 (176 - 359)	64 (8 - 121)	149 (90 - 208)
12 months										
Events, n	27	<5	85	160	<5	18	15	79	21	43
Individuals at risk	386	56	275	724	67	215	272	927	422	966
Risk (95% CI)	513 (321 - 701)	402 (0 - 838)	1585 (1266 - 1893)	1219 (1038 - 1397)	454 (9 - 880)	609 (330 - 881)	376 (181 - 567)	701 (550 - 849)	353 (201 - 503)	298 (209 - 387)

10.4.4.3. Heart failure

[Table 18](#) summarises the cumulative risk of heart failure per 10,000 individuals in the myocarditis and pericarditis cohorts, these data do not exclude individuals with prior heart failure, and a post-hoc analysis is conducted in individuals without prior history of heart failure to look at the risk of new onset heart failure.

10.4.4.3.1. Myocarditis cohorts

The cumulative risk of visits /diagnosis of heart failure 12 months after diagnosis of myocarditis/pericarditis was lowest in PHARMO and highest in EpiChron ([Table 18](#)). In the sensitivity analyses of definitive cases only ([Appendix Tables 34 to 37](#)), the 12-month risk of visits /diagnosis of heart failure, was lower than in all cases (not validated) together. A *post hoc* analysis excluding individuals with pre-existing heart failure in the year prior to myocarditis diagnosis showed that the one year risk is much lower than in the main analysis, in PHARMO: 391 per 10,000 individuals (239 - 540) in EpiChron 1,544 (817 – 2,214), in NHR 1,228 (973 - 1476), in SIDIAP 1,049 (789 - 1302) and in CPRD Aurum 747 (555 - 936) per 10,000 individuals.

Crude 3- and 12-month cumulative risks of heart failure in those vaccinated and unvaccinated individuals at baseline are presented in [Appendix Figure 5](#). These data are descriptive only, since vaccinated individuals were sicker and older especially in NHR and SIDIAP.

Post-hoc survival analysis comparing 12-month risks of heart failure between vaccinated and unvaccinated cohorts after adjusting for age, sex and comorbidity scores showed a HR_{adj} of 0.51 95% CI: 0.24-1.07) in PHARMO, HR_{adj} of 0.92 (95% CI:0.64-1.32) in NHR, a HR_{adj} of 0.78 (95% CI:0.29-2.11) in EpiChron, a HR_{adj} of 0.68 (95% CI:0.46-1.01) in SIDIAP and a HR_{adj} of 0.83 (95% CI:0.53-1.29) in CPRD Aurum.

10.4.4.3.2. Pericarditis cohorts

The cumulative risk of visits/diagnosis of heart failure 12 months after diagnosis of pericarditis was lowest in CPRD Aurum and highest in SIDIAP ([Table 18](#)). The differences between data sources can be explained by differences in age distributions in the cohorts. In the sensitivity analyses of definitive cases only ([Appendix Tables 34 to 37](#)), the 12-month risk of heart failure was higher than in all cases (not validated) together.

A *post hoc* analysis excluding individuals with pre-existing heart failure in the year prior to pericarditis diagnosis showed that the 12-month risk was much lower than in the main analysis presented in [Table 18](#): 881 per 10,000 individuals (278 - 1447), 675 (549 – 800) in NHR, 957 (658 - 1246) in EpiChron, 1357 (1176 - 1534) in SIDIAP and 216 (144 - 287) in CPRD Aurum.

Crude 3- and 12-month cumulative risks of heart failure in those vaccinated and unvaccinated at baseline are presented in [Appendix Figure 6](#). These data are descriptive only, since vaccinated were sicker and older.

Post-hoc survival analyses comparing the risk of heart failure over 12 months between vaccinated and unvaccinated cohorts after adjustment for age, sex and comorbidity scores showed a HR_{adj} of 0.21 (95% CI: 0.03-1.36) in PHARMO (only age adjusted), HR_{adj} of 1.14 (95% CI:0.80-1.62) in NHR, a HR_{adj} of 0.99 (95% CI:0.54-1.81) in EpiChron, a HR_{adj} of 1.18 (95% CI:0.92-1.52) in SIDIAP and a HR_{adj} of 0.69 (95% CI:0.38-1.26) in CPRD Aurum.

10.4.4.4. Cardiogenic shock

[Table 18](#) summarises the cumulative risk of cardiogenic shock per 10,000 individuals in the myocarditis and pericarditis cohorts by data source. This risk was low in all data sources.

10.4.4.4.1. Myocarditis cohorts

In PHARMO the 12-month risk of cardiogenic shock was lowest in CPRD Aurum and highest in SIDIAP ([Table 18](#)). In Spanish data sources risks were higher than in other countries. In the sensitivity analyses of definitive cases only ([Appendix Tables 38 to 41](#)), the 12-months risk of cardiogenic shock, was comparable or lower than in all cases (not validated) together. Unadjusted 3- and 12-month cumulative risks of cardiogenic shock in those vaccinated and unvaccinated at baseline are presented in [Appendix Figure 7](#). These data are descriptive only, since vaccinated were sicker and older.

A *post-hoc* survival analysis comparing the risk of cardiogenic shock between the vaccinated and unvaccinated cohorts over a period of 12 months after adjusting for age, sex and comorbidity scores showed an HR_{adj} of 0.27 (95% CI: 0.03–2.28) in PHARMO, HR_{adj} of 1.67 (95% CI:0.34–8.13) in NHR (only age adjusted). In EpiChron the hazard ratio could not be estimated due to zero cases in the unvaccinated cohort. In SIDIAP the HR_{adj} was 0.40 (95% CI:0.19-0.82) and in CPRD Aurum the hazard ratio could not be estimated due to zero cases in the vaccinated cohort.

10.4.4.4.2. Pericarditis cohorts

In PHARMO and CPRD no cases were identified, and the 12-month risk was 0. Risks were lowest in NHR and highest in EpiChron ([Table 18](#)). In the Spanish data sources the risks were higher than in other countries. In the sensitivity analyses of definitive cases only ([Appendix Tables 38 to 41](#)), the 12-months risk of cardiogenic shock, was comparable or lower than in all cases (not validated) together. Unadjusted 3- and 12-months cumulative risks of cardiogenic shock in those vaccinated and unvaccinated at baseline are presented in [Appendix Figure 8](#). These data are descriptive only, since vaccinated were sicker and older.

Post-hoc survival analyses comparing risks of cardiogenic shock between the vaccinated and unvaccinated cohorts after adjustment for age, sex and comorbidity scores showed a HR_{adj} of 2.01 (95% CI:0.28-14.6) in NHR, a HR_{adj} of 3.14 (95% CI:0.43-23.2) in EpiChron, in SIDIAP the HR_{adj} was 0.77 (95% CI:0.33-1.84) and in CPRD Aurum no cases were identified.

10.4.4.5. Fulminant myocarditis for individuals with myocarditis

Table 18 summarises the cumulative risk of fulminant myocarditis in the myocarditis cohorts for different data sources. The risk was low in all data sources. In the sensitivity analyses of definitive cases only and definitive, probable and possible cases (Appendix Table 42 and 43), the 12-month risk of fulminant myocarditis was higher than in all cases (not validated) together.

Unadjusted 3- and 12-month cumulative risks of fulminant myocarditis in those vaccinated and unvaccinated at baseline are presented in Appendix Figure 9. These data are descriptive only, since vaccinated were sicker and older.

Post-hoc survival analyses comparing the 12-month risk of fulminant myocarditis between vaccinated and unvaccinated cohorts after adjusting for age, sex and comorbidity scores showed a HR_{adj} of 0.44 (95% CI: 0.12–1.56) in PHARMO, HR_{adj} of 0.93 (95% CI:0.47–1.81) in NHR, no estimate in EpiChron, in SIDIAP the HR_{adj} was 0.39 (95% CI: 0.18–0.83) and a HR_{adj} of 1.01 (95% CI:0.45-2.27) in CPRD Aurum.

10.4.4.6. Arrhythmia

Table 18 summarises the cumulative risk of arrhythmia per 10,000 individuals in the myocarditis and pericarditis cohorts by data source.

10.4.4.6.1. Myocarditis cohorts

We did not exclude pre-existing arrhythmia and therefore the data may include repeat visits of pre-existing conditions and not only incident events. The risk was highest in NHR (maybe due to age) and lowest in CPRD Aurum (Table 18). The sensitivity analyses with definite cases (level 1) showed that the risks of arrhythmia were higher in definite cases (Appendix tables 44 to 47).

A *post-hoc* analysis excluding individuals with arrhythmia recorded in the year prior to the myocarditis diagnosis showed that the 12-month risk was lower than in the main analyses: 480 (281 - 675) per 10,000 individuals in PHARMO, 1320 (993 - 1636) in NHR, 572 (71 - 1046) in EpiChron, 431 (224 - 634) in SIDIAP and 320 per 10,000 individuals (171 - 467) in CPRD Aurum.

Unadjusted 3 and 12-month cumulative risks of arrhythmia in those vaccinated and unvaccinated at baseline are presented in Appendix Figure 13.

Post-hoc survival analyses comparing risks of arrhythmia between vaccinated and unvaccinated cohorts after adjusting for age, sex and comorbidity scores showed a HR_{adj} of 0.71 (95% CI: 0.35–1.45) in PHARMO, HR_{adj} of 0.91 (95% CI: 0.61–1.34) in NHR, HR_{adj} of 0.75 (95% CI: 0.16–3.55) (age adjusted only) in EpiChron, in SIDIAP the HR_{adj} was 1.18 (95% CI: 0.57–2.44) and in CPRD Aurum the HR_{adj} was 0.75 (95% CI: 0.33–1.69).

10.4.4.6.2. Pericarditis cohorts

We did not exclude pre-existing arrhythmia and therefore the data may include repeat visits of pre-existing conditions and not only incident events. The risk was highest in NHR and was lowest in CPRD Aurum (Table 18). The sensitivity analyses with definite cases (level 1) showed that the risks of arrhythmia were higher in definite cases (Appendix tables 44 to 47).

A *post-hoc* analysis excluding individuals with arrhythmia recorded in the year prior to the diagnosis of pericarditis showed that the 12 months risk was lower than in the main analysis: 293 per 10,000 individuals (95%CI: 0 - 686) in PHARMO, 757 (593 - 918) in NHR, 559 (295 - 816) in EpiChron, 694 (539 - 847) in SIDIAP and 232 (153 - 311) in CPRD Aurum.

Unadjusted 3- and 12-month cumulative risks of arrhythmia in the vaccinated and unvaccinated cohorts at baseline are presented in Appendix Figure 14. These data are descriptive only, since the vaccinated individuals were sicker and older.

Post-hoc survival analyses comparing risks of arrhythmia between vaccinated and unvaccinated cohorts after adjusting for age, sex and comorbidity scores showed a HR_{adj} of 4.45 (95% CI: 0.46–42.8) in PHARMO (age-adjusted only), HR_{adj} of 0.85 (95% CI: 0.64–1.14) in NHR, HR_{adj} of 0.58 (95% CI: 0.24–1.41) in EpiChron. In SIDIAP the HR_{adj} was 1.01 (95% CI: 0.72–1.43) and in CPRD Aurum the HR_{adj} was 0.79 (95% CI: 0.44–1.42).

10.4.4.7. Sudden cardiac death

Data for sudden cardiac death could not be reliably extracted in all of the data sources, except EpiChron, since the cause of death was not available. In EpiChron there were <5 sudden cardiac deaths.

10.4.4.8. Chronic myocarditis in individuals with myocarditis

The risk of chronic myocarditis was low in all data sources. No chronic myocarditis was identified in PHARMO. In NHR the 12-month risk was 18 (95% CI: 0–133) per 10,000 individuals, in EpiChron 120 per 10,000 (95% CI: 0–352), in SIDIAP 85 per 10,000 individuals (95% CI: 0–183) and in CPRD Aurum 14 per 10,000 individuals (95% CI: 0–41). In the sensitivity analyses of definitive cases only and definitive, probable and possible cases (Appendix Tables 48 and 49), the 12-months risk of chronic myocarditis, was higher than in all cases (not validated) together.

Cumulative risks of chronic myocarditis in those vaccinated and unvaccinated at baseline are presented in [Appendix Figure 10](#). These data are descriptive only, since vaccinated were sicker and older. A post-hoc adjusted analysis could only be conducted in SIDIAP due to low number of cases, the HR_{adj} was 1.05 (95% CI: 0.28-3.87) for vaccinated compared to unvaccinated.

10.4.4.9. Heart transplant

Heart transplants were identified in NHR, SIDIAP and CPRD Aurum only ([Table 18](#)).

10.4.4.9.1. Myocarditis cohorts

In NHR the 12-month risk of a heart transplant was 13 per 10,000 individuals (95% CI: 0-38), in CPRD Aurum 42 (95% CI: 0-90) per 10,000 individuals the myocarditis cohort. In the sensitivity analyses of definitive cases only and definitive, probable and possible cases ([Appendix Tables 50 and 53](#)), the 12-month risk of heart transplant was comparable or lower than in all cases (not validated) together.

Unadjusted 3- and 12-month cumulative risks of heart transplants in those vaccinated and unvaccinated at baseline are presented in [Appendix Figure 11](#). These data are descriptive only, since vaccinated were sicker and older. A post-hoc adjusted analysis could not be conducted due to the low number of cases. Most cases occurred in the unvaccinated cohort.

10.4.4.9.2. Pericarditis cohorts

Heart transplants were only identified in the unvaccinated cohort in SIDIAP. The 12-month risk of a heart transplant was 7 per 10,000 individuals (95% CI: 0–21). The sensitivity analysis in definite cases, showed no case of heart transplant ([Appendix Tables 50 and 53](#)).

Unadjusted 3- and 12-month cumulative risks of heart transplants in those vaccinated and unvaccinated at baseline are presented in [Appendix Figure 12](#).

10.4.4.10. Chronic pericarditis for individuals with pericarditis

The cumulative risk of chronic pericarditis per 10,000 Individuals was low. No events were identified in PHARMO or EpiChron, in NHR the 12-month risk was 113 (95% CI: 57-168) per 10,000 Individuals, in SIDIAP 40 per 10,000 Individuals (95% CI: 0-71), in CPRD Aurum 45 per 10,000 Individuals (95% CI:12-79). The sensitivity analyses with definite cases (level 1) and definitive, probable and possible cases (levels 1-3) showed that the risks of chronic pericarditis were comparable in definite cases ([Appendix tables 54 and 55](#)).

Unadjusted 3-and 12-month cumulative risks of chronic pericarditis in those vaccinated at baseline and unvaccinated are presented in [Appendix Figure 15](#). These data are descriptive only, since the vaccinated individuals were sicker and older.

Post-hoc survival analyses comparing risk of chronic pericarditis between vaccinated and unvaccinated cohorts after adjusting for age, sex and comorbidity scores showed no cases in PHARMO, a HR_{adj} of 0.77 (95% CI: 0.29–1.99) in NHR and no cases in EpiChron. In SIDIAP the HR_{adj} could not be estimated and in CPRD Aurum the HR_{adj} was 0.86 (95% CI: 0.22–3.40).

10.4.4.11. Constrictive pericarditis for individuals with pericarditis

Constrictive pericarditis was only identified in EpiChron and SIDIAP ([Appendix Figure 16](#)). In EpiChron the 12-month risk of constrictive pericarditis was 46 per 10,000 Individuals (95% CI: 0–109) and in SIDIAP 81 per 10,000 (95% CI: 37–125). The sensitivity analyses with definite cases (level 1) showed that the risks of constrictive pericarditis were comparable or zero in definite cases ([Appendix tables 56 and 57](#)).

The comparison of risk of constrictive pericarditis over 12 months between vaccinated and unvaccinated cohorts could only be done in SIDIAP and showed an HR_{adj} of 0.50 (95% CI: 0.15–1.64).

10.4.4.12. Recurrent myocarditis (recording of myocarditis more than 30 days after first diagnosis) for individuals with myocarditis

The 12-month risk of recurrent myocarditis between 30 days after diagnosis until 12 months after first diagnosis was 1,429 per 10,000 Individuals in PHARMO (95% CI: 0–3,666), 2,569 in NHR (95% CI: 1,617–3,414), 638 per 10,000 Individuals in EpiChron (95% CI: 0–1,312), 2,455 in SIDIAP (95% CI: 443–4,44), and 2,222 per 10,000 Individuals (95% CI: 0–4,515) in CPRD Aurum. The sensitivity analyses with definite cases (level 1) showed that the risks of recurrent myocarditis were higher in definite cases ([Appendix tables 58 and 59](#)).

[Appendix Figure 17](#) shows the risks of recurrent myocarditis for vaccinated and unvaccinated. This is descriptive only.

Post hoc analyses comparing the risk of recurrent myocarditis between the vaccinated and unvaccinated cohorts showed a HR_{adj} of 1.07 (95% CI: 0.35–3.25) in PHARMO, HR_{adj} of 1.05 (95% CI: 0.75–1.46) in NHR, 0.40 (95% CI: 0.07–2.25), in EpiChron an HR_{adj} of 1.02 (95% CI: 0.44–2.39) in SIDIAP and 1.52 (95% CI: 0.99–2.34) in CPRD Aurum.

10.4.4.13. Recurrent pericarditis (new diagnosis of pericarditis during follow-up) for individuals with pericarditis

The 12-month risk of recurrent pericarditis between 30 days and up to 12 months after first diagnosis was 3,054 per 10,000 individuals (95% CI: 1,972–3,990) in NHR, 493 (95% CI: 130–843) in EpiChron, and 1,377 (95% CI: 23–2,547) in SIDIAP. No events were identified in PHARMO or CPRD. The sensitivity analyses with definite

cases (level 1) showed that the risks of recurrent pericarditis were higher in definite cases and definitive, probable and possible cases ([Appendix tables 60 and 61](#)).

[Appendix Figure 18](#) shows the risks of recurrent pericarditis in the vaccinated and unvaccinated cohorts. This is descriptive only.

Post hoc analyses comparing the risk of recurrent pericarditis between the vaccinated and unvaccinated cohorts over 12 months showed a HR_{adj} of 4.9 (95% CI: 0.90-25.9) in PHARMO, HR_{adj} of 1.04 (95% CI: 0.81-1.35) in NHR, 0.36 (95% CI: 0.11-1.19) in EpiChron), HR_{adj} of 0.92 (95% CI: 0.61-1.37) in SIDIAP and 1.24 (95% CI: 0.88-1.74) in CPRD Aurum.

10.4.4.14. Recovery

Recovery could not be estimated from the electronic health record data, because when individuals recover, this is not recorded. In definite cases, a sensitivity analysis was conducted, in which information from the natural history questionnaire was used as well. However, information about recovery was not available for all cases, which makes statements about recovery invalid ([Appendix Tables 62 and 63](#)).

10.5. Secondary objective: Risk factors for myocarditis and pericarditis

10.5.1. Overall study population for secondary objective (risk factors)

For assessment of risk factors, data from a source population of 34,470,945 individuals was included. Dose-specific cohorts were created and for each cohort eligible individuals had to have at least 12 months of look-back, to not have received a non-Pfizer-BioNTech COVID-19 vaccine before time zero, and to not have history of either pericarditis or myocarditis in the previous year ([Appendix table 64](#)).

10.5.2. Study populations for risk factor study

The matched study cohorts for Pfizer-BioNTech COVID-19 vaccine included 17,851,878 individuals for dose 1, among eligible persons after exclusions, 14,334,130 were successfully matched 1:1 to unvaccinated individuals, which was 80% of the initial cohort. In CPRD the percentage of the initial cohort that was eligible and matched was lower (71%). For the dose 2 cohort, 15,925,634 individuals were vaccinated with Pfizer-BioNTech COVID-19 vaccine dose 2 and had a prior dose 1, and 12,843,488 (81%) of this dose 2 cohort were eligible and could be matched. The dose 3 cohort included 4,872,424 individuals who received a third dose of Pfizer-BioNTech COVID-19 vaccine and had also received dose 1 and 2 of Pfizer-BioNTech vaccine, a total of 4,061,127 (83%) of the initial cohort was eligible and successfully matched.

Baseline characteristics and other details of the 3 dose cohorts are provided in the source tables ([Section 15 -Tables](#)). [Appendix table 65](#) summarises the follow-up and reasons for censoring for the primary risk window of 14-days after time zero for each

dose in the matched vaccinated and unvaccinated cohorts in the myocarditis cohorts.

[Appendix table 66](#) describes the follow-up and reasons for censoring for the primary risk window of 14-days after time zero of each dose. In all data sources, the median follow-up during the 14-day risk window after each vaccine dose was 14 days.

In **PEDIANET**, most censoring was due to reaching the 14-day limit or unvaccinated individuals receiving a Pfizer-BioNTech vaccine, particularly in the second and third dose cohorts. Fewer than five pericarditis events occurred after dose 1.

In **PHARMO**, 86% of censoring after dose 1 was due to reaching the 14-day window, followed by 10.5% due to Pfizer-BioNTech vaccination and 3.4% due to another vaccine. Over 95% were censored at 14 days for doses 2 and 3. Myocarditis events: 10 (vaccinated) and 7 (unvaccinated) after dose 1; 12 and <5 after dose 2; <5 and 0 after dose 3. Pericarditis: <5 events after doses 1 and 2; none after dose 3.

In **NHR**, censoring after dose 1 was 69.5% at 14 days, 27.6% due to Pfizer-BioNTech vaccination, and 2.9% due to another vaccine. For doses 2 and 3, 83.6% and 97.3% were censored at 14 days. Myocarditis: 9 (vaccinated) and 15 (unvaccinated) after dose 1; 10 and 9 after dose 2; 7 and 12 after dose 3. Pericarditis: 24 and 30 after dose 1; 42 and 30 after dose 2; 13 and 36 after dose 3.

In **EpiChron**, censoring after dose 1 was 65% at 14 days, 30% due to Pfizer-BioNTech vaccination, and 4.8% due to another vaccine. For doses 2 and 3, 89% and 99% were censored at 14 days. Myocarditis: <5 events in both groups after doses 1 and 2; 0 after dose 3. Pericarditis: 7 (vaccinated) and 5 (unvaccinated) after dose 1; 7 and <5 after dose 2; 0 in both groups after dose 3.

In **SIDIAP**, censoring after dose 1 was 68.6% at 14 days, 26.6% due to Pfizer-BioNTech vaccination, and 4.8% due to another vaccine. For doses 2 and 3, 84.6% and 98.7% were censored at 14 days. Myocarditis: <5 in both groups after dose 1; 11 and 10 after dose 2; 0 after dose 3. Pericarditis: 31 and 21 after dose 1; 21 and 19 after dose 2; <5 in both groups after dose 3.

In **CPRD Aurum**, censoring after dose 1 was 82.9% at 14 days, 10.2% due to Pfizer-BioNTech vaccination, and 6.6% due to another vaccine. For doses 2 and 3, 94.5% and >98% were censored at 14 days. Myocarditis: 12 (vaccinated) and 9 (unvaccinated) after dose 1; 19 and <5 after dose 2; <5 in both groups after dose 3. Pericarditis: 14 and 9 after dose 1; 18 and 29 after dose 2; 5 (vaccinated) and <5 (unvaccinated) after dose 3.

10.5.3. Identification of risk factors for myocarditis after each dose of Pfizer-BioNTech COVID-19 vaccine

Primary results focused on a 14-day risk window after each dose, with sensitivity analyses for 7 and 21 days that are included in the source tables ([Section 15 - tables](#)). Note to reader: Results in Section 15 – tables and below may change slightly since persons 80+ of age were excluded. This was discovered only during the final quality control and the data for this age could not be incorporated in this report. At this moment the results should be interpreted as for ages 0-79 years.

10.5.3.1. Pedianet

We could not estimate risk factors in Pedianet due to the absence of myocarditis cases in the different cohorts.

10.5.3.2. PHARMO

In PHARMO the diagnosis of myocarditis in the GP data source corresponds to both myocarditis and pericarditis, because the ICD code does not distinguish. Appendix table 67 provides an overview of the covariates and exposures that could be estimated. The third dose estimates are unstable because less than five cases of myocarditis were identified in the vaccinated cohort and none in the unvaccinated cohort. The first dose of the Pfizer-BioNTech COVID-19 vaccine was associated with a slightly increased risk of myocarditis although imprecise: OR=1.4 (95% CI: 0.5–3.8) compared with the unvaccinated cohort. The second dose of Pfizer-BioNTech COVID-19 vaccine was associated with an increase in risk OR=12.0 (95% CI: 1.6–92.3), with wide confidence intervals. Other risk factors included dementia and immunodeficiencies for first dose vaccinated cohort, and diabetes complications in the second dose cohort.

The final adjusted model showed that dose 2 of the Pfizer-BioNTech COVID-19 vaccine remains associated with myocarditis within 2 weeks after vaccination (OR=9.0 (95% CI: 1.1–71.1) ([Table 19](#)). For dose 1 an association with myocarditis and being vaccinated and being between 15 to 30 years old is suggested. The sensitivity analyses in confirmed cases did not yield any estimates, due to the lack of cases.

Table 19. Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort in PHARMO

Selected variables	First dose		Second dose		Third dose	
	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95% CI)
Sample size, N	2,525,102		1,909,034		508,938	
Vaccination status						
Unvaccinated	Ref	Ref	Ref	Ref	Ref	Ref
Pfizer-BioNTech COVID-19 vaccinated	0.0 (0.6)	1.0 (0.3–3.1)	2.2 (1.1)	9.0 (1.1–71.1)	NE	NE
Aged 15–30 years						
No	Ref	Ref	Ref	Ref		
Yes	0 (1.1)	0.6 (0.1–4.7)	NE	NE		
Vaccinated aged 15–30 years: Yes	1.4 (1.3)	4.0 (0.3–46.9)	NE	NE		
Marginal R ²	1		1		1	

NE: not estimable. Model selection based on methods described in SAP ([Appendix 4](#)).

10.5.3.3. NHR

NHR had several cases of myocarditis in the all the vaccinated and unvaccinated cohorts, resulting in many risk factors being associated with myocarditis within the 2-week risk window after each dose ([Appendix table 68](#)). Risk factors which had a statistically significant association are in bold. Risk factors were not consistent across the different dose cohorts, which may also be due to the number of cases. For dose 1, the risk factors associated with myocarditis were cardiovascular disease and conditions, some medications, as well as diabetes mellitus, 2 or more hospitalisations in the year prior to time zero, infections (COVID-19, influenza, sepsis), immunological disease and overall higher scores for comorbidities. For myocarditis occurring within 2 weeks after the second dose, the use of analgesics, corticosteroids, chronic liver disease, bladder incontinence, sepsis, immunosuppressive conditions and higher scores of comorbidities, were risk factors. For dose 3, heart failure, use of corticosteroids, NSAIDs, warfarin, prior hospitalisations, immunosuppressive conditions, cerebrovascular disease, vertigo and pregnancy were risk factors.

[Table 20](#) shows the final adjusted analyses and shows that exposure to Pfizer-BioNTech COVID-19 vaccine alone was not associated with an increased risk of myocarditis in any of the dose cohorts. However, for dose 2, an association between being vaccinated and being between 15 and 30 years old is suggested, but this estimate has very wide confidence intervals.

[Table 21](#) shows the results of the sensitivity analyses including only 'definitive' cases. This shows that dose 2 of Pfizer-BioNTech COVID-19 vaccine was associated with an OR of 3.0 (95% CI: 0.3–29.0), whereas dose 1 was not

associated with an increased risk. No dose 3 effect could be estimated using only confirmed cases of myocarditis.

Table 20. Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort in NHR

Selected variables	First dose		Second dose		Third dose	
	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95% CI)
Sample size	6,695,250		4,971,300		2,920,756	
Vaccination status						
Unvaccinated	Ref	Ref	Ref	Ref	Ref	Ref
Pfizer-BioNTech COVID-19	0 (0.5)	0.6 (0.2–1.5)	0 (0.6)	0.9 (0.3–2.6)	0 (0.5)	0.7 (0.2–1.9)
Aged 15–30 year						
No	Ref	Ref	Ref	Ref	Ref	Ref
Yes	0 (0.6)	0.8 (0.2–2.9)	0.1 (0.8)	1.1 (0.2–5.5)	0.7 (0.7)	2.1 (0.6–7.7)
Vaccinated and aged 15–30 years: Yes	0.1 (1.0)	1.1 (0.1–8.5)	0.8 (1.0)	2.3 (0.3–17.3)	0 (1.3)	0.5 (0.0–6.0)
Marginal R ²	1		1		1	

Model selection based on methods described in SAP (Appendix 4)

Table 21. Sensitivity analysis: Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort in NHR (definite cases)

Selected variables	First dose		Second dose		Third dose	
	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95% CI)
Sample size	6,695,250		4,971,300		2,920,756	
Vaccination status						
Unvaccinated	Ref	Ref	Ref	Ref	Ref	Ref
Pfizer-BioNTech COVID-19	0 (0.9)	0.7 (0.1–4.0)	1.1 (1.2)	3 (0.3–28.8)	NE	NE
Marginal R ²	1		1		1	

NE: not estimable. Model selection based on methods described in SAP (Appendix 4)

10.5.3.4. EpiChron

In EpiChron less than five cases of myocarditis were identified for the first dose and second dose cohorts, and none in the third dose cohorts (Appendix table 69). The strongest univariate risk factors for myocarditis occurring within 14 days after the first dose were being aged 15-30 years, influenza or other respiratory tract infection, comorbidities and MMR vaccination in the previous year. In the dose 2 cohort, vaccination with Pfizer-BioNTech COVID-19 vaccine was suggestive of increased risk for myocarditis but very imprecise. Being aged 15-30 years, analgesic use, NSAIDs and antibiotics use, more than two hospitalisations in the year prior to time zero, smoking and prior vaccination with DTP, MMR and meningitis vaccine were also associated with occurrence of myocarditis.

No adjusted analyses or sensitivity analyses with only definite cases could be run, due to the low number of cases identified.

10.5.3.5. SIDIAP

[Appendix table 70](#) shows the risk factors for the occurrence of myocarditis within 14 days after vaccination, for SIDIAP. No cases were observed in the dose 3 cohort; therefore, no risks could be estimated. Less than five cases occurred after dose 1 in the vaccinated and unvaccinated cohorts, but more cases were identified after dose 2. Conditions univariately associated with occurrence of myocarditis after dose 1 were heart failure, use of novel oral anticoagulants, diabetes complications, sepsis, immunological syndromes, cerebrovascular disease and indicators of comorbidity, as well as smoking. Vaccination with Pfizer-BioNTech COVID-19 vaccine was not associated with myocarditis in either dose 1 or dose 2. Other risk factors after dose 2 were diabetes mellitus and complications, autoimmune disorders and some non-COVID-19 vaccines.

Table 22. Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort in SIDIAP

	First dose		Second dose		Third dose	
Selected variables	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95%)
Sample size	6,162,810		5,610,762		968,264	
Vaccination status						
Control	Ref	Ref	Ref	Ref	Ref	Ref
Exposed	0 (0.8)	1 (0.2, 5.0)	0 (0.5)	0.8 (0.3, 2.0)	0 (0.0)	1 (1.0, 1.0)
Marginal R ²	1		1		NE	
Aged 15–30 years						
No			Ref	Ref		
Yes			NE (NE)	NE (NE, NE)		
Exposed and aged 15–30 years			NE (NE)	NE (NE, NE)		

The multivariable model (Table 22) did not produce an estimate for the interaction between Pfizer-BioNTech COVID-19 vaccine and being aged 15–30 years. The sensitivity analysis of definite cases did not have enough cases to produce an estimate for the vaccine.

10.5.3.6. CPRD Aurum

[Appendix table 71](#) shows the risk factors for myocarditis within 2 weeks after dose 1, 2 and 3 of Pfizer-BioNTech COVID-19 vaccine. Several risk factors were associated with myocarditis after dose 1, mostly heart failure, novel anticoagulants, chronic kidney disease, skin ulcer and psychotropics. Being aged 15–30 years, Pfizer-BioNTech COVID-19 vaccination, heart failure, sepsis and meningitis vaccination were associated with myocarditis after dose 2.

Results from the multivariable model are presented in [Table 23](#). Vaccination with Pfizer-BioNTech COVID-19 vaccine showed that for dose 1 and 2 there was interaction between exposure and age, with an imprecise but elevated vaccine

effect. Table 24 shows the results of the sensitivity analysis, showing lack of power to produce results estimates due to the low number of cases that could be ascertained to be definite based on CPRD Aurum source data.

Table 23. Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort in CPRD Aurum

	First dose		Second dose		Third dose	
Selected variables	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95% CI)
Cohort	6,463,712		5,825,424		2,787,902	
Cases	20		23		6	
Vaccination status						
Unvaccinated	Ref	Ref	Ref	Ref	Ref	Ref
Vaccination status Pfizer-BioNTech COVID-19 vaccine	1.0 (0.7)	2.7 (0.7, 10.1)	1.6 (1.1)	5.0 (0.6, 43.1)	0 (0.8)	1 (0.2, 5.0)
Aged 15–30-years						
No	Ref	Ref	Ref	Ref		
Yes	1.0 (0.7)	2.7 (0.6, 11.4)	1.6 (1.2)	5.0 (0.5, 48.3)		
Vaccinated and aged 15–30 years	-1.2 (1.0)	0.3 (0.0, 1.9)	-0.1 (1.3)	0.9 (0.1, 11.0)		
Marginal R ²	1		1		1	

Table 24. Sensitivity analysis: Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort in CPRD Aurum

	First dose		Second dose		Third dose	
Selected variables	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95% CI)	Beta (SE)	OR (95% CI)
Sample size	6,463,712		5,825,424		2,787,902	
Vaccination status						
Unvaccinated	Ref	Ref	Ref	Ref	Ref	Ref
Vaccination status Pfizer-BioNTech COVID-19 vaccine	0 (0.0)	1 (1.0, 1.0)	0 (0.0)	1 (1.0, 1.0)	0 (0.0)	1 (1.0, 1.0)
Marginal R ²	NE		NE		NE	

10.5.4. Identification of risk factors for pericarditis

Of note: these results can only be generalised to persons 0-80 years of age. During the final quality control it was noted that persons aged 80+ years had been erroneously excluded.

10.5.4.1. Pédianet

We could not estimate risk factors in Pédianet due to the low number of events.

10.5.4.2. PHARMO

In PHARMO the diagnosis of pericarditis in the GP data source was low, less than five in the vaccinated after the first, second and third dose, and none in the unvaccinated cohort. [Appendix Table 72](#) describes the univariate associations for the different dose cohorts. Use of analgesics and primary care visits were

associated with occurrence of pericarditis within 2 weeks after t0. Pfizer-BioNTech COVID-19 dose was not associated with occurrence of pericarditis after dose 1 and could not be analysed for dose 2 or 3.

Multivariate analyses could not be performed due to low number of cases, and we could not estimate the effect of Pfizer-BioNTech COVID-19 vaccine dose on the risk of pericarditis within 2 weeks after vaccination. The analyses with only confirmed cases could not be conducted due to the low number of confirmed cases.

10.5.4.3. NHR

[Appendix Table 73](#) shows the risk factors for pericarditis within 2 weeks after vaccination with first, second and third dose of Pfizer-BioNTech COVID-19 vaccine. Comorbidity in CDC risk group 2 was associated with pericarditis in each of the dose cohorts, as were many of the individual cardiovascular and immune-related conditions. Vaccination with the Pfizer-BioNTech COVID-19 vaccine was not associated with an increased risk of pericarditis in the univariate analysis, but there was evidence of interaction with being aged 15-30 years, especially after the second dose. None of the risk factors remained associated in the final multivariable logistic model ([Appendix Table 74](#)). In the confirmed cases analyses for dose 2, although the interaction was no longer found, the OR for the main effect of Pfizer-BioNTech vaccine was 5.0 (95% CI:1.1–22.9) ([Appendix Table 75](#)).

10.5.4.4. EpiChron

In EpiChron very few cases of pericarditis occurred in the 14-days risk window after t0 for dose 1 and 2 and none after dose 3 ([Appendix Table 76](#)). Risk factors in the first dose cohort included: heart failure, novel oral anticoagulants, statins, lipid abnormalities, increased healthcare utilisation, a higher Charlson comorbidity score and influenza/respiratory infections ([Appendix Table 76](#)). Risk factors for occurrence of pericarditis after the second dose included age 15-30 years of age, Pfizer-BioNTech COVID-19 vaccine (OR=7, 95% CI 0.9–56.9) and stroke/cerebrovascular disease. The final model could not produce an estimate for the interaction ([Appendix Table 77](#)). The sensitivity analysis with confirmed cases only showed an association with the second dose but with large confidence intervals OR=2 (95% CI:0.2–22.1) ([Appendix Table 78](#)).

10.5.4.5. SIDIAP

[Appendix Table 79](#) shows the risk factors for pericarditis within 14 days after t0 in SIDIAP. Risk factors in the first dose cohort included heart failure, analgesics, diabetes mellitus, use of statins, novel oral anticoagulants, diabetes and lipid abnormalities, hospitalisations, infections (COVID-19, influenza, sepsis, comorbidity). For dose 2 being aged 15-30 years as well as leukaemia and CDC score were associated with pericarditis. Fewer than five cases were identified in dose 3 cohort and only smoking and paralysis were significantly associated.

[Appendix Table 80](#) shows the results from the multivariate logistic regression model pointing to interaction between exposure to the Pfizer-BioNTech COVID-19 vaccine and being aged 15-30 years. No analyses were done on only confirmed cases due to the low number of cases.

The sensitivity analysis on definite cases did not yield effect estimates due to the low number of validated cases with a definite level of certainty.

10.5.4.6. CPRD Aurum

[Appendix Table 81](#) shows the risk factors for occurrence of pericarditis within 2 weeks after t0. Cardiovascular disease, corticosteroids, bladder incontinence, chronic kidney disease, ED visits, immunosuppressive conditions, infections (COVID-19, HIV, Influenza, sepsis), weakness, chronic respiratory disease, cancer and CDC risk group were associated with pericarditis. Risk factors for pericarditis after dose 2 were cardiovascular disease, warfarin, chronic kidney disease, mild to moderate kidney disease, hospitalisation, infections (influenza, sepsis) hypertension, and comorbidities/scores. Risk factors for pericarditis after dose 3 are sickle cell, preventive health services, obesity, infections (COVID-19) hepatitis B vaccine and peripheral vascular disease. [Appendix Table 82](#) shows the results of the multivariable model, and the impact of age/vaccination interaction. However, based on the interaction no effect is observed within 15-30 years of age, for Pfizer-BioNTech COVID-19 vaccine. Due to low number of definite cases in CPRD Aurum, the sensitivity analysis did not yield an effect estimate for the Pfizer-BioNTech COVID-19 vaccine.

Results for the external validation of the risk factors models are available for all DEAPs. However, Pédianet had no individuals with myocarditis and less than five with pericarditis and no models were developed. Calibration plots and receiver operating characteristics (ROC) curves are available on request.

10.6. Other analyses

None.

10.7. Adverse events / adverse reactions

This study involves a combination of existing structured data and unstructured data, which was converted to structured form during the implementation of the protocol solely by a computer using automated/algorithmic methods, such as natural language processing.

In these data sources, it is not possible to link, (i.e., identify a potential association between) a particular product and medical event for any individual. Thus, the minimum criteria for reporting an AE (i.e., identifiable patient, identifiable reporter, a suspect product, and event) cannot be met.

11. DISCUSSION

11.1. Key results

11.1.1. Summary of participating data sources

This final study report is based on data from six data sources in Italy (Pedianet, children only), The Netherlands (PHARMO), Norway (NHR), Spain (EpiChron and SIDIAP), and UK (CPRD Aurum) for both the primary and secondary objectives. The six data sources cover varying settings of care and have different lag times.

11.1.2. Validation

A total of 990 myocarditis and 1,250 pericarditis were sampled for validation. For myocarditis, 19% of the cases were classified as definite (level 1), and 36.2% were classified as level of certainty 1-3. For pericarditis, 20.5% of the cases were classified as level 1 and 38.6% as levels of certainty 1-3. The ability to reach a high level of certainty was dependent on the source data. GP-based data sources, such as Pedianet, PHARMO, and CPRD Aurum, could not access original results directly from laboratory tests or procedures conducted in hospital and relied on copies or transcripts of results reported back to the GPs. In these data sources, most cases were classified as level 4, i.e., diagnosis reported but insufficient information to meet level 1-3. In data sources that could access information on in-hospital measurements and procedures, the level of certainty was much higher. In CPRD Aurum or NHR no case of myocarditis or pericarditis was discarded (level 5) due to lack of information. Approximately 20-25% of all cases were classified as not being cases of myocarditis or pericarditis in EpiChron, SIDIAP and PHARMO.

Validated cases were used to create subpopulations for sensitivity analyses for the primary (natural history) and secondary (risk factors) objectives. However, due to differences in data instances and inclusion and exclusion criteria for the different objectives, not all validated cases could be matched in each of those studies, which reduced the power of the sensitivity analyses.

For most validated cases, natural history questionnaires were also completed. These showed better what type of diagnostics had been done, especially in the data sources that had access to hospital data. The natural history questionnaire data showed that most cases for which hospital data could be verified, both cardiac magnetic resonance and echocardiograms were performed, but this was less frequent for individuals with pericarditis.

11.1.3. Natural history of myocarditis and pericarditis (primary objective)

From among a source population of 34.4 million individuals, 5,674 myocarditis cases and 10,655 pericarditis cases were identified during the study period. After eligibility criteria were applied, 3,142 myocarditis cases and 5,966 pericarditis cases were included in the final cohort.

11.1.3.1. Characteristics at first diagnosis and comparisons between vaccinated and unvaccinated cohorts

In the myocarditis and pericarditis cohorts, 1821 (58.0%) individuals and 3701 pericarditis individuals (62.0%) had been vaccinated with the Pfizer-BioNTech COVID-19 vaccine prior to diagnosis respectively. Most myocarditis and pericarditis events occurred more than 22 days after the last dose in those who had received two doses.

The median age was higher for vaccinated myocarditis and pericarditis cases than unvaccinated cases, and the gender distribution differed between vaccinated and unvaccinated cases. In NHR and SIDIAP, in both the myocarditis and pericarditis cohorts, the difference was 11-14 years, with the vaccinated cohorts being older. The prevalence of comorbidities assessed in the 10 years prior to diagnosis was relatively high especially for cardiovascular and respiratory diseases, with a consistently higher prevalence for most conditions across data sources, and higher composite disease scores in vaccinated myocarditis and pericarditis cohorts than the unvaccinated cohorts. Since we excluded all individuals who had been vaccinated with a non -Pfizer BioNTech COVID-19 vaccine prior to diagnosis, we may have selected cases who were prioritised for early vaccination specifically with the Pfizer-BioNTech COVID-19 vaccine. Such individuals were typically older and frail or had comorbid conditions in many European countries, and the unvaccinated individuals were probably those who were targeted later.

Medication use in the prior year was relatively frequent in myocarditis cases, with the highest prevalences observed for antibiotics, NSAIDs and analgesics, and generally higher prevalences seen in vaccinated cohorts compared with unvaccinated cohorts, which can be explained by the higher age of vaccinated individuals. The same pattern was observed for the pericarditis cohorts. Any time prior vaccinations with non-COVID-19 vaccines varied between data sources, based on their ability to capture this and the available lookback period. The rates in CPRD Aurum were very high, reflecting the long lookback period for vaccination data and differences in vaccination policy between countries. Very few women were pregnant at diagnosis of myocarditis or pericarditis. The observed differences in age and comorbidities in the vaccinated and unvaccinated individuals means that unadjusted comparisons of outcomes between the vaccinated and unvaccinated cohorts are likely to be confounded.

Between 15% and 35% of the myocarditis cases had one or more hospitalisation in the year prior to myocarditis diagnoses and the majority of individuals had one or more GP visits in the prior year. Recorded COVID-19 tests varied between data sources, with the most frequent recording in CPRD Aurum (>50% of myocarditis cases) and the lowest in NHR. It should be recognised that COVID-19 test recording changed over the study period, with much lower levels of recording in 2023. In the 2 weeks prior to myocarditis, healthcare use was lower, but still around 10% of the individuals had a prior hospital visit, and around 0% to 15% had an emergency room

visit, where it could be measured. This healthcare use may have been for symptoms related to the diagnosis, and points to potential misclassification of the date of onset.

Hospitalisations in the year prior to diagnosis for pericarditis were more frequent than for myocarditis, especially in NHR where 43% had one or more hospitalisation. Also, emergency room visits were frequent in the data sources where they could be assessed, i.e., EpiChron and CPRD Aurum. Most of the individuals had one or more GP visits in the year prior to diagnosis, and this was higher for the vaccinated pericarditis cases than for the unvaccinated pericarditis cases. In the 2 weeks prior to diagnosis of pericarditis, healthcare use was low.

11.1.3.2. Comparison of vaccination and treatment after diagnosis in the vaccinated and unvaccinated cohorts

Although mRNA-based vaccines were recognised as risk factors for the development of myocarditis from September 2021, a substantial proportion of individuals with myocarditis and pericarditis were (re-)vaccinated after diagnosis.

Among the individuals with myocarditis that had been vaccinated with Pfizer-BioNTech COVID-19 vaccine prior to diagnosis, between 17.3% (EpiChron) and 40% (PHARMO) were vaccinated again with a COVID-19 vaccine after diagnosis, and these were both Pfizer-BioNTech and non-Pfizer-BioNTech vaccines. Myocarditis cases that had not been vaccinated with any COVID-19 vaccine at diagnosis were more frequently vaccinated after diagnosis (between 35% and 73%), with Pfizer-BioNTech and other vaccines. For pericarditis the same pattern was observed.

Patterns of recorded pharmacological treatments in the 365 days after diagnosis were similar between individuals who had been vaccinated and unvaccinated at baseline. However, these were not confined to new medications and could have included medications individuals were already taking. Following myocarditis diagnosis many individuals received antibiotics, cardiovascular medications, i.e., beta-blockers, ACE inhibitors or ARBs, and diuretics, and very few received invasive non-pharmacological treatments, although in most data sources this could not be assessed from the EHRs. These treatments were also frequently prescribed prior to diagnosis and may not have been given specifically for the myocarditis or pericarditis events observed in this study. However, the natural history questionnaire data showed that very few myocarditis cases had a pacemaker or cardiac defibrillator installed.

Patterns of pharmacological treatment of pericarditis in the 365 days after diagnosis were similar between individuals who had been vaccinated and unvaccinated at baseline. Following pericarditis diagnosis many individuals received colchicine, NSAIDs and antibiotics. These treatments (except colchicine) were also frequently prescribed prior to diagnosis and may not be given specifically for the myocarditis or pericarditis event in this study. Very few received invasive non-pharmacological

treatments, although in most data sources this could not be assessed from the EHRs. The natural history questionnaire data showed that very few other non-pharmacological interventions were given; in EpiChron 1.72% had a pacemaker, the most frequently identified non-pharmacological treatment in NHR and EpiChron was pericardial drainage.

11.1.3.3. Outcomes of myocarditis and pericarditis

Table 25 shows the overview of the 12-month unadjusted risk of outcomes between individuals who had been vaccinated and unvaccinated at baseline. These unadjusted risks are descriptive, but when presented for vaccinated and unvaccinated at baseline may lead to potential misinterpretation since these comparisons are confounded due to the higher age and comorbidities in vaccinated cases than unvaccinated. Also, we did not exclude individuals with prevalent disease, which was especially true for heart failure, and arrhythmia which was very common in the cohorts at baseline. To explore the impact of confounding on observed differences between vaccinated and unvaccinated individuals at baseline we conducted a post-hoc Cox-regression analysis adjusting for age, gender, and comorbidity scores. This analysis shows that the risks of different outcomes do not differ between those individuals who had been vaccinated with Pfizer BioNTech COVID-19 vaccine at first diagnosis of myocarditis or pericarditis, compared with unvaccinated. A post hoc analysis excluding individuals with pre-existing arrhythmia or heart failure showed lower 12- months risks of those outcomes after diagnosis.



Table 25. Summary of the 12-month unadjusted risk for recorded outcomes in the myocarditis and pericarditis cases who were vaccinated and unvaccinated at first diagnosis, with unadjusted and adjusted comparisons

Outcome	Myocarditis				Pericarditis			
	Vaccinated %	Unvaccinated %	HR crude	HRadj.* (95% CI)	Vaccinated %	Unvaccinated %	HR crude	HRadj.*
Hospitalisation								
PHARMO	NA	NA	NA	NA	NA	NA	NA	NA
NHR	82.21	82.71	1.01 (0.87-1.17)	1.04 (0.90-1.20)	85.27	82.96	1.04 (0.94-1.15)	0.96 (0.86-1.06)
EpiChron	85.33	82.93	1.02 (0.70-1.50)	0.99 (0.66-1.49)	51.14	60.93	0.79 (0.60-1.02)	0.66 (0.50-0.86)
SIDIAP	67.10	63.30	1.09 (0.90-1.31)	0.77 (0.64-0.91)	70.07	60.34	1.34 (1.19-1.50)	1.07 (0.94-1.20)
CPRD Aurum	13.71	12.99	1.11 (0.76-1.63)	1.04 (0.69-1.56)	12.74	12.93	0.98 (0.75-1.29)	0.92 (0.70-1.20)
Death								
PHARMO	2.53	4.51	0.55 (0.23-1.35)	0.40 (0.16-1.01)	2.78	7.74	0.36 (0.04-3.17)	0.25 (0.03-1.74)
NHR	7.72	5.77	1.38 (0.76-2.52)	0.74 (0.39-1.40)	5.16	2.29	2.09 (1.15-3.81)	1.06 (0.57-1.98)**
EpiChron	16.54	5.01	3.60 (0.82-15.79)	3.25 (0.7-14.9)***	10.27	5.34	1.90 (0.83-4.38)	1.13 (0.47-2.74)
SIDIAP	11.43	8.25	1.30 (0.77-2.19)	0.66 (0.36-1.22)	8.93	5.73	1.60 (1.10-2.33)	0.84 (0.56-1.26)
CPRD Aurum	2.21	1.57	1.31 (0.43-3.91)	0.89 (0.28-2.85)	2.19	0.71	3.06 (1.14-8.25)	0.90 (0.69-1.19)
Heart failure\$								
PHARMO	3.39	5.73	0.58 (0.27-1.23)	0.51 (0.24-1.07)	5.64	18.49	0.28 (0.06-1.25)	0.21 (0.03-1.36)***
NHR	20.22	17.42	1.15 (0.81-1.63)	0.92 (0.64-1.32)	13.80	7.73	1.83 (1.30-2.57)	1.14 (0.80-1.62)
EpiChron	21.63	17.30	1.31 (0.54-3.15)	0.78 (0.29-2.11)	15.85	9.87	1.65 (0.90-3.05)	0.99 (0.54-1.81)
SIDIAP	15.82	16.78	0.96 (0.65-1.42)	0.68 (0.46-1.01)	26.80	13.64	2.11 (1.67-2.66)	1.18 (0.92-1.52)
CPRD Aurum	9.72	9.992	0.94 (0.60-1.47)	0.83 (0.53-1.29)	3.02	2.88	1.09 (0.62-1.91)	0.69 (0.38-1.26)
Cardiogenic shock								
PHARMO	0.33	1.08	0.30 (0.03-2.72)	0.27 (0.03-2.28)***	0	0	NE	NE
NHR	1.10	0.74	1.49 (0.30-7.40)	1.67 (0.34-8.13)***	0.43	0.18	2.34 (0.28-19.42)	2.01 (0.28-14.6)
EpiChron	1.33	0	NE	NE	1.99	0.75	2.66 (0.32-22.0)	3.14 (0.43-23.2)
SIDIAP	3.30	7.09	0.41 (0.20-0.87)	0.40 (0.19-0.82)	1.35	1.58	0.87 (0.39-1.93)	0.77 (0.33-1.84)
CPRD Aurum	0	0.29	NE	NE	0	0	NE	NE
Fulminant myocarditis								
PHARMO	0.99	2.17	0.46 (0.12-1.72)	0.44 (0.12-1.56)	NR	NR	NR	NR



Table 25. Summary of the 12-month unadjusted risk for recorded outcomes in the myocarditis and pericarditis cases who were vaccinated and unvaccinated at first diagnosis, with unadjusted and adjusted comparisons

Outcome	Myocarditis				Pericarditis			
	Vaccinated	Unvaccinated	HR crude	HRadj.* (95% CI)	Vaccinated	Unvaccinated	HR crude	HRadj.*
NHR	4.48	4.46	1.00 (0.50-2.00)	0.93 (0.47-1.81)	NR	NR	NR	NR
EpiChron	2.57	0			NR	NR	NR	NR
SIDIAP	3.01	6.72	0.40 (0.18-0.86)	0.39 (0.18-0.83)	NR	NR	NR	NR
CPRD Aurum	2.75	2.59	1.06 (0.46-2.46)	1.01 (0.45-2.27)	NR	NR	NR	NR
Chronic myocarditis								
PHARMO	0	0	NE	NE	NR	NR	NR	NR
NHR	0	0.45	NE	NE	NR	NR	NR	NR
EpiChron	0	3.33	NE	NE	NR	NR	NR	NR
SIDIAP	0.52	1.22	1.09 (0.29-4.11)	1.05 (0.28-3.87)	NR	NR	NR	NR
CPRD Aurum	0	0.34	NE	NE	NR	NR	NR	NR
Heart transplant								
PHARMO	0	0	NE	NE	0	0	NE	NE
NHR	0	0.38	NE	NE	0	0	NE	NE
EpiChron	0	0	NE	NE	0	0	NE	NE
SIDIAP	0	0	NE	NE	0	0	NE	NE
CPRD Aurum	0.49	0.33	1.41 (0.13-15.8)	6.54 (0.41-103)***	0	0	NE	NE
Arrhythmia\$								
PHARMO	5.205	5.10	0.77 (0.38-1.58)	0.71 (0.35-1.45)	7.98	2.08	7.93 (0.92-68.6)	4.45 (0.46-42.8)***
NHR	15.40	16.76	1.06 (0.73-1.54)	0.91 (0.61-1.34)	12.10	12.29	1.18 (0.90-1.56)	0.85 (0.64-1.14)
EpiChron	3.89	2.86	0.85 (0.19-3.68)	0.75 (0.16-3.55)***	6.65	5.83	1.02 (0.47-2.20)	0.58 (0.24-1.41)
SIDIAP	4.83	2.88	1.58 (0.82-3.05)	1.18 (0.57-2.44)	8.44	5.64	1.82 (1.32-2.51)	1.01 (0.72-1.43)
CPRD Aurum	3.36	3.83	0.98 (0.43-2.44)	0.75 (0.33-1.69)	3.03	2.90	1.17 (0.66-2.07)	0.79 (0.44-1.42)
Chronic pericarditis								
PHARMO	NR	NR	NR	NR	0	0	NR	NR
NHR	NR	NR	NR	NR	0.89	1.48	0.73 (0.29-1.87)	0.77 (0.29-1.99)
EpiChron	NR	NR	NR	NR	0	0		
SIDIAP	NR	NR	NR	NR	0.25	0.42	1.24 (0.28-5.42)	NR
CPRD Aurum	NR	NR	NR	NR	0.36	0.59	0.74 (0.18-2.99)	0.86 (0.22-3.40)



Table 25. Summary of the 12-month unadjusted risk for recorded outcomes in the myocarditis and pericarditis cases who were vaccinated and unvaccinated at first diagnosis, with unadjusted and adjusted comparisons

Outcome	Myocarditis				Pericarditis			
	Vaccinated	Unvaccinated	HR crude	HRadj.* (95% CI)	Vaccinated	Unvaccinated	HR crude	HRadj.*
Constrictive pericarditis								
PHARMO	NR	NR	NR	NR	0	0	NR	NR
NHR	NR	NR	NR	NR	0	0	NR	NR
EpiChron	NR	NR	NR	NR	0	1.50	NR	NR
SIDIAP	NR	NR	NR	NR	0.58	1.06	0.56 (0.18-1.70)	0.50 (0.15-1.64)
CPRD Aurum	NR	NR	NR	NR	0	0	NE	NE
Recurrent myocarditis visits >30 days later								
PHARMO	2.56	2.13	1.10 (0.37-3.29)	1.07 (0.35-3.25)	NR	NR	NR	NR
NHR	24.34	29.28	0.84 (0.60-1.18)	1.05 (0.75-1.46)	NR	NR	NR	NR
EpiChron	4.06	9.19	0.42 (0.07- 2.50)	0.40 (0.07-2.25)	NR	NR	NR	NR
SIDIAP	5.13	3.69	1.20 (0.52-2.81)	1.02 (0.44-2.39)	NR	NR	NR	NR
CPRD Aurum	21.93	13.97	1.53 (1.01-2.33)	1.52 (0.99-2.34)	NR	NR	NR	NR
Recurrent pericarditis visits >30 days later								
PHARMO	NR	NR	NR	NR	13.72	11.07	3.71 (0.69-19.95)	4.9 (0.9 25.9)
NHR	NR	NR	NR	NR	23.78	23.73	1.04 (0.81-1.32)	1.04 (0.81-1.35)
EpiChron	NR	NR	NR	NR	3.29	8.17	0.40 (0.14-1.18)	0.36 (0.11-1.19)
SIDIAP	NR	NR	NR	NR	8.53	7.98	1.03 (0.71-1.52)	0.92 (0.61-1.37)
CPRD Aurum	NR	NR	NR	NR	13.29	11.07	1.16 (0.83-1.62)	1.24 (0.88-1.74)

HR=hazard ratio \$ analyses did not exclude prevalent cases, which had the greatest impact on arrhythmia and heart failure that had high prevalence at baseline, posthoc analyses excluding pre-existing conditions are reported in the text. *adjusted for age. age². Charlson index and CDC score. **adjusted for age. age². and Charlson index due to non-convergence with CDC score added as well. ***adjusted for age. age² only due to non-convergence NA: not available; NR: not relevant, NE not estimable

11.1.4. Risk factors for myocarditis and pericarditis after Pfizer-BioNTech COVID-19 vaccination (secondary objective)

Dose specific cohorts were created to identify risk factors for occurrence of myocarditis or pericarditis after dose 1, 2 or 3 of Pfizer-BioNTech COVID-19 vaccine. Vaccinated individuals were matched to unvaccinated individuals. The dose 1 matched cohort comprised of more than 14 million vaccinated individuals, the dose 2 cohort 12.8 million and dose 3 cohort had more than 4 million matched vaccinated individuals. Only very few cases of myocarditis or pericarditis occurred during the 14-day risk window.

Risk factors for the occurrence of myocarditis or pericarditis within 14 days after vaccination with Pfizer-BioNTech COVID-19 vaccine, were assessed using matched exposure cohorts for each dose of the vaccine. Vaccinated individuals were matched 1:1 with unvaccinated individuals. In the current report, risk factors were identified only for persons up to 80 years of age.

In general, being aged 15 to 30 years, cardio-and cerebrovascular disease or medications, immunological conditions, and infections were observed as risk factor for myocarditis, as well as indicators for comorbidity although we observed differences across data sources. Exposure to Pfizer-BioNTech COVID-19 vaccine dose 2 was associated with myocarditis and pericarditis, but in some data sources this was only observed in analyses of definite cases or after inclusion of the interaction with being aged 15 to 30 years. However, the association was very imprecise in all data sources where we had data, reflecting the rarity of the event. This points to the impact of misclassification, i.e., when non-cases are included, and masking if the total population is analysed instead of specific age groups. Some risk factors that were identified, e.g. medications or hospitalisation/healthcare use for doses 2 and 3 suggest protopathic bias: treatments/indicators for initial symptoms of the disease, which suggests that we may have had misclassification in the date of onset of the disease, with potential exposure misclassification.

In more detail the key findings about the association with Pfizer-BioNTech vaccine by data source for myocarditis and pericarditis are in Table 26.

Table 26. Summary table of the association between Pfizer-BioNTech vaccine by dose and occurrence of myocarditis or pericarditis

		Myocarditis			Pericarditis		
Data source	Pfizer-BioNTech	Dose 1 OR (95%CI)	Dose 2 OR (95%CI)	Dose 3 OR (95%CI)	Dose 1 OR (95%CI)	Dose 2 OR (95%CI)	Dose 3 OR (95%CI)
Univariate analysis (all cases)							
PHARMO	Vaccine	1.4 (0.5–3.8)	12.0 (1.6–92)	NA	1 (0.1-16)	NE	NE
NHR	Vaccine	0.6 (0.3–1.4)	1.1 (0.4–2.7)	0.6 (0.2–1.5)	0.8 (0.5–1.4)	1.3 (0.8–2.1)	0.4 (0.2–0.8)
EpiChron	Vaccine	1 (0.1–16.0)	2.0 (0.2–22.1)	NE	1.4 (0.4, 4.4)	7 (0.9, 56.9)	NE

Table 26. Summary table of the association between Pfizer-BioNTech vaccine by dose and occurrence of myocarditis or pericarditis

Data source	Pfizer-BioNTech	Myocarditis			Pericarditis		
		Dose 1 OR (95%CI)	Dose 2 OR (95%CI)	Dose 3 OR (95%CI)	Dose 1 OR (95%CI)	Dose 2 OR (95%CI)	Dose 3 OR (95%CI)
SIDIAP	Vaccine	1 (0.2, 5.0)	1.1 (0.5, 2.6)	NE	1.5 (0.8, 2.6)	1.1 (0.6, 2.1)	1.5 (0.2, 9.0)
CPRD	Vaccine	1.5 (0.6–3.7)	4.8 (1.6–14.0)	1 (0.2–5.0)	1.6 (0.7, 3.6)	0.6 (0.3, 1.1)	1.2 (0.4, 3.9)
Multivariate logistic regression with interaction (all cases)							
PHARMO	Vaccine	1.0 (0.3–3.1)	9.0 (1.1–71.1)		NE	NE	NE
	age 15-30 & vaccinated	4.0 (0.3–46.9)	NE		NE	NE	NE
NHR	Vaccine	0.6 (0.2–1.5)	0.9 (0.3–2.6)	0.7 (0.2–1.9)	0.7 (0.4–1.5)	1.3 (0.7–2.3)	0.3 (0.1–0.6)
	age 15-30 & vaccinated	1.1 (0.1–8.5)	2.3 (0.3–17.3)	0.5 (0.0–6.0)	2.6 (0.7–10.1)	4.5 (0.9–22.2)	NE
EpiChron	vaccine	NE	NE	NE	1.2 (0.4–3.9)	7 (0.9–56.9)	NE
SIDIAP	vaccine	NE	NE	NE	1.7 (0.8–3.5)	1.1 (0.5–2.5)	1.5 (0.3–9.0)
	age 15-30 & vaccinated				0.9 (0.2–3.4)	3.2 (0.7–14.3)	NE
CPRD	Vaccine	2.7 (0.7–10.1)	5.0 (0.6–43.1)	1 (0.2–5.0)	0.8 (0.3–2.2)	0.3 (0.1–0.6)	1.3 (0.3–4.7)
	age 15-30 & vaccinated	0.3 (0.0–1.9)	0.9 (0.1–11.0)	NE	10.6 (1.0–108.9)	3.3 (1.0–11.6)	0.8 (0.0–17.1)
Definite cases only							
PHARMO	Vaccine	NE	NE	NE	NE	NE	NE
NHR	Vaccine	0.7 (0.1–4.0)	3 (0.3–28.8)		0.8 (0.2–3.4)	5.0 (1.1–22.9)	NE
EpiChron	Vaccine	NE	NE	NE	0.5 (0.1–2.7)	2 (0.2–22.1)	
SIDIAP	Vaccine	NE	NE	NE	NE	NE	NE
CPRD	Vaccine	NE	NE	NE	NE	NE	NE

11.2. Limitations

11.2.1. Limitations of the data sources

Six data sources could provide data for this final report, but not all could provide data from all types of healthcare settings, e.g. CPRD Aurum, PHARMO and Pedianet only had GP databanks, that include data reported back from specialists and hospital, but it does not have the original data from those databanks. This limited assessment of healthcare utilisation and may have affected rates of outcomes, particularly hospital-based diagnoses and treatments.

For PHARMO the ICPC for diagnosis codes were used, but they lack the granularity to differentiate between myocarditis and pericarditis (infectious disease circulatory system), and those identified as such were labelled myocarditis. We could identify pericarditis diagnoses, using ICD-10 codes, only for the individuals in PHARMO who could be linked with hospital data. This means that cases called myocarditis are a mixture of myocarditis and pericarditis cases, which explains the differences in risks and treatments that we see in PHARMO. PHARMO also does not have the full date

for death, because this was rounded to the year and imputed at the mid-year. This impacts the risk of death which is misclassified in PHARMO.

For CPRD Aurum, we could obtain information on the outcomes only from GP recorded data, which means an underestimation, if it was not reported back from the hospital or coded into GP medical records. In general, we noted low risks of the outcomes in CPRD Aurum, e.g. hospitalisations which could be due to lack of recording (misclassification) or the younger age of the cohorts. There were several variables that could not be comprehensively identified in CPRD Aurum, such as recording of primary care visits and some vaccines.

Data on interventions/treatments in hospital were not typically captured in the electronic data sources; therefore, we analysed the data from the natural history questionnaire and focused on those data sources that could retrieve in-hospital data such as NHR and EpiChron; these showed that diagnostic procedures were conducted, and that the rate of non-pharmacological, invasive procedures was low.

History of vaccinations was retrieved any time prior, which resulted in large differences between data sources, some DEAPs could not extract other vaccines whereas CPRD Aurum had a long history of data, and much higher prevalences, especially for the childhood vaccines.

11.2.2. Limitations on validation

The validation study was built on the Brighton Collaboration case definitions, which are recognised standards for regulators and should be applicable to primary data collection and secondary use of data. VAC4EU developed a validation pipeline and tailored the BC case definition criteria to real world data, where lack of recording of information may mean absence of the criteria or lack of recording. Standardised data collection forms and explicit guidance was provided to abstractors in this study, especially on how to deal with lack of information. Although the abstractors were homogeneously trained on dummy cases, used the same data collection forms and system and had continuous support from the VAC4EU trainer, we cannot avoid differences in local decision making, and the source of information that was available for validation. Some data sources (NHR, EpiChron, SIDIAP) had access to source data where the patient was treated (hospital charts), whereas others (CPRD Aurum, PHARMO, PEDIANET), relied on information reported back and recorded in the computerised medical record of the primary care physicians, with (PHARMO, PEDIANET) or without free text (CPRD Aurum). We noted that that the source of data for validation impacted highly on the levels of certainty and the PPV values. Inability to reach high levels of certainty does not mean that a case was not a case but this had an impact on the power of the sensitivity analyses.

11.2.3. Limitations of the script

The two study objectives are complex and have different population selections, for the first objective a disease-based approach was taken to identify the cohorts, and

for the secondary objective selection was exposure-based. This means that the core data transformation steps were developed separately. Quality control was conducted by independent double-programming of the data transformation and analysis scripts. This relied on synthetic data, which did not always capture the complexity of the real-world data, leading to findings during the production of results, e.g. missing visits, missingness of data for some vaccines, which could not be corrected in time. An erratum was found in the application of exclusion criteria to the population for the study of risk factors during final QC, which left out individuals aged more than 80 years, which will be corrected prior to publication.

The script for the *post-hoc* adjusted survival analyses and analyses of the natural history questionnaire were peer-reviewed but not double programmed, as these analyses were included after a first view of the data.

11.2.4. Limitations of the methods

The analyses for all results are descriptive. No causal inference can be made. No comparative analyses were planned, but per SAP results are presented for vaccinated and unvaccinated individuals, which provide an opportunity for comparison of results that are not adjusted for confounding. To avoid conclusions based on confounded comparisons we conducted *post-hoc* analyses, adjusting for age, sex and comorbidity scores.

The cumulative risks of recorded clinical outcomes were based on recorded diagnosis codes, which did not always indicate a new event, but may also be related to repeat visits /recordings for an initial event, or prevalent disease. This may have affected conditions such as heart failure and arrhythmia, which were highly prevalent in the cohorts at baseline. To investigate sequelae of myocarditis or pericarditis unaffected by prevalent disease, these cases should have been excluded., these cases where prevalent.

Only a sample of the myocarditis and pericarditis cases could be validated, and the level of diagnostic certainty that could be assigned, depended greatly on the data that could be accessed to validate the cases. In data sources that could access original hospital records, the level of certainty was much higher than in data sources that only could review information recorded by the GP. False positive rates varied across data sources but may be at least 25% for myocarditis cases.

The number of validated cases that could be utilised for sensitivity analyses was not optimal. To start the lengthy process of validation, we had initially obtained cases from the data instances used for the interim report. However, we noted that some data sources lost GP practices or individuals in the subsequent data instances, for example when GPs no longer collaborate or change their software system, or when a patient withdraws passive consent. This led to losses of cases that were validated but could no longer be linked to the final data instance for this final report. Some data sources changed person identifiers between data instances, e.g. PHARMO and

SIDIAP, which required manual cross-mapping based on dates of birth and event dates.

For the larger data sources, i.e., NHR, SIDIAP and CPRD Aurum we had to sample cases for validation, since it was not feasible to validate all identified cases for the primary objective (natural history). To improve efficiency, these cases were sampled from the cohorts assembled for the secondary objective(risk factors), which used inclusion and exclusion criteria that differed from those used for the primary objective. Due to these decisions, not all validated cases could be used in the sensitivity analyses for both the primary and secondary objectives, which reduced power for those analyses.

Recovery was an outcome that could not be analysed in EHR data since individuals typically have recordings of healthcare seeking behaviour but not when they improve. Also, recovery is often a progressive process rather than a discrete event, and in many cases, individuals may experience partial or gradual improvement over time. Therefore, the exact date of recovery is rarely clearly defined or a clinically recorded time point. In this study, we only could assess recovery using the natural history questionnaire data, and therefore, this was done for a small population only.

Due to the low number of events across data sources, most risk factor models included only a few variables, typically one to five, that were selected based on the predefined algorithm in the SAP. As a result, odds ratios were often accompanied by wide confidence intervals.

External validation was assessed through calibration and discrimination. Calibration involved applying a model developed in one data source to others, comparing predicted versus observed outcome probabilities. However, the low event rates led to outcome probabilities clustering near zero, making calibration plots uninformative, even after adjusting axis scales.

Discrimination, measured by the area under the ROC curve (AUC), was generally poor (<0.7) across models. A few exceptions showed AUCs above 0.7, but these often reflected models with very few predictors and extremely low event counts. Overall, external validation was limited by the small number of events and the resulting sparse models.

11.3. Interpretation

A summary of the results from the literature review on the diagnosis, epidemiology, risk factors, treatments and outcomes are presented in [Appendix Table 83](#).

Our results on diagnosis modalities from the natural history questionnaire and validation align with reported case series which showed that electrocardiographic (ECG) changes were common in both vaccinated and unvaccinated myocarditis cases.^{3, 30, 42-48} Case series showed that CMR was a key diagnostic tool and

consistently revealed abnormalities including cardiac oedema in up to 82% of myocarditis cases.^{30, 42-46}

The results from our study also show that myocarditis and pericarditis occur infrequently in the source populations, which is consistent with known epidemiology in the same source population.⁶ Also, the risk factors we found are consistent.^{49, 50} Only a few published studies assessed myocarditis occurrence following a third dose,⁵¹ and also in our study we were not able to estimate risk factors properly after the third dose.

Although case series may suffer from selection bias, our study findings are consistent with the results of our systematic review of case series showing that up to 87% of myocarditis events following vaccination with Pfizer-BioNTech vaccine occurred after the second dose of the vaccine,^{17, 27, 30, 42-44, 49} with a median time to symptom onset of 3–4 days (range: 1–20 days).^{17, 30, 42-46, 48, 49, 52} These individuals were predominantly young males, with a median age ranging from 15 to 36 years.^{17, 30, 42-47}

Our data on treatment after diagnosis (mostly cardiovascular drugs, antibiotics and painkillers) was consistent with information obtained from our systematic review of case series.^{43, 30, 43, 45-48} Mechanical circulatory support (MCS), including ECMO and intra-aortic balloon pump, was required in a few vaccinated individuals (0%–2%),^{30, 45-48} but was used more frequently in unvaccinated individuals, reflecting more severe disease.^{3, 47, 48, 53, 54}

Our study showed that many myocarditis cases were hospitalised, and a substantial number of the pericarditis cases, which is consistent with data from the systematic review of case series; in that review the hospitalisation rate varied from 35% to 73% in case reports.¹⁷

In published population-based studies, the mortality rate was lower in vaccinated individuals (<0.2%) than in unvaccinated individuals (1.3%).^{53, 54} In our study, we had large differences in the mortality risks between data sources (mostly due to differences in age), and between vaccinated and unvaccinated. When we explored these differences (e.g., age and comorbidities) by adjusting for them, we observed that there was no difference in the risk of death in vaccinated and unvaccinated individuals with myocarditis.

Myocarditis reported in the case series of vaccinated individuals was mainly mild and self-limiting, which is consistent with the low risks of serious outcomes we observed in our study. In published case series a minority of individuals developed arrhythmias (0.5%–5%),^{45, 46, 49} pericardial effusion (3%–24%),^{42, 46, 47, 49} or required ICU care (3%–19%),^{17, 42, 43, 47} and mortality was rare (<0.2%).^{17, 30, 46, 52-54} No heart transplants were reported among vaccinated cases,⁴⁶ or in population-based

studies.⁵⁴ This is consistent with our findings, where we observed almost an absence of heart transplants within a year and low rates of pericardial effusion in pericarditis cases.

Our results showing a low frequency of cardiogenic shock align with the literature: in a study of 54 myocarditis cases who had received the Pfizer-BioNTech COVID-19 vaccine, only one patient developed cardiogenic shock.³

11.4. Generalizability

This study used national data from Norway, and regional data from Spain (Catalunya, Aragon) as well as a sample of paediatric data in Italy and general practice data in the Netherlands and the UK. The size of the source population was 34 million individuals. The study had two objectives and for the primary objective which studies the natural history of myocarditis and pericarditis cases, we excluded myocarditis and pericarditis cases, who had been vaccinated with non-Pfizer-BioNTech COVID-19 vaccines. Therefore, the natural history results, cannot be generalised to individuals who developed myocarditis or pericarditis after non-Pfizer-BioNTech COVID-19 vaccines. In the secondary objective, which aimed to assess risk factors for myocarditis or pericarditis following vaccination with different doses of Pfizer-BioNTech COVID-19 vaccines, the study included individuals based on exposure to different doses of the Pfizer-BioNTech COVID-19 vaccine and matched these individuals to unvaccinated individuals. Since individuals who had received a non-Pfizer-BioNTech COVID-19 vaccine were excluded, we cannot generalise the risk factors for myocarditis or pericarditis after Pfizer-BioNTech COVID-19 vaccines to individuals who develop myocarditis or pericarditis after receiving a non-Pfizer-BioNTech COVID-19 vaccine. For objective 2, we included subjects upon different doses of the Pfizer-BioNTech COVID-19 vaccine with large sample sizes (14.3 million vaccinated matched for dose 1, 12.8 million for dose 2 and 4.1 million for dose 3), however currently the population analysed for risk factors was restricted to individuals younger than 80.

12. OTHER INFORMATION

Not applicable.

13. CONCLUSIONS

The main objective of this study was to describe the clinical course of myocarditis and pericarditis among individuals diagnosed with myocarditis or pericarditis after receiving at least 1 dose of Pfizer-BioNTech COVID-19 vaccines and those developing these conditions who had not received any COVID-19 vaccine.

Our main conclusions are that in spite of the large population, myocarditis and pericarditis were very infrequent events, and cases occurred more frequently in males, which is consistent with known epidemiology. Myocarditis cases were mostly diagnosed with CMR and echocardiogram, but information on diagnostic procedures

could not always be obtained from the electronic health records, because these procedures were conducted in the hospital setting. For pericarditis an echocardiogram was often performed, based on information obtained for the validated cases.

Invasive non-pharmacological treatments were rarely given following the diagnosis. Most individuals received medicines, although we did not know the reason for prescription and many of the individuals were already on cardiovascular medications prior to diagnosis. Myocarditis cases often received antibiotics and cardiovascular medications (B-blockers, ACE inhibitor or ARB, cardiac glycosides or calcium channel blockers and diuretics), although the latter were less frequently used in young myocarditis cases. The pericarditis cases were mostly treated with colchicine and NSAIDs. Treatment patterns did not differ between individuals who had been vaccinated with Pfizer-BioNTech COVID-19 vaccines and those who were unvaccinated.

Many individuals who developed myocarditis or pericarditis were vaccinated with one or more doses of COVID-19 vaccine after diagnosis. As expected and consistent with vaccination campaigns, this was higher for those who were unvaccinated at the time of diagnosis. Most of those who were vaccinated received a mRNA-based COVID-19 vaccine.

We described the occurrence of different outcomes, and the unadjusted 12-month risks for these outcomes after diagnosis differed in absolute risks across data sources and within data source between the vaccinated and unvaccinated cohorts. Individuals with myocarditis and pericarditis were youngest in CPRD Aurum, and oldest in NHR, which is likely to be due to the COVID-19 vaccination campaigns, that prioritised older individuals and began with AstraZeneca COVID-19 vaccine in the UK, and with Pfizer-BioNTech COVID-19 vaccine in the Netherlands. The 12-month risks of clinical outcomes showed that serious outcomes were rare, except for heart failure and arrhythmia. The main analysis included persons with prior existence these conditions, a posthoc analyses excluding them lowered the risks.

The difference between vaccinated and unvaccinated individuals within data sources was mostly due to differences in age and potentially pre-existing disease. Within data sources, vaccinated individuals were much older than unvaccinated, by 13-14 years between the vaccinated and unvaccinated individuals in NHR and SIDIAP respectively. Vaccinated individuals were also sicker. Due to these differences in baseline risk a *post-hoc* analysis was conducted with adjustment for age and comorbidity scores. The results show that after adjustment, the 12-month risk of each of the clinical outcomes did not differ between individuals who were vaccinated and those who were unvaccinated at disease diagnosis. Also, the clinical course did not differ between cases classified as definite compared to all cases.

Our conclusions for the secondary objective, i.e., risk factors, for myocarditis or pericarditis after different doses of Pfizer-BioNTech COVID-19 vaccines are that age, cardiovascular and immunological conditions, as well as infections, are general risk factors for myocarditis mostly after dose 1. The results for the dose 2 cohorts varied between data sources but showed highly imprecise associations in several data sources. Results from some data sources suggested some effect modification of the vaccine by age. In some instances, the vaccine effect was highest in those aged 15 to 30 years, which is consistent with the published literature, although the estimates were imprecise.

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15. LIST OF SOURCE TABLES AND FIGURES

Standalone documents.

C4591038_Section15_Tables

This comprises all tables for objective 1 and 2 as per Tables shells

C4591038_Section15_Figures

This comprises all figures for objective 1 with information as per figure shells, tables with zero events and calibration plots for objective 2 have been removed, but are available upon request.

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Table 15.1.1 Attrition table for the primary objective myocarditis and pericarditis cohorts for PEDIANET

Pfizer-BioNTech vaccinated cohort	N	%
All individuals registered in the healthcare data source eligible to receive the Pfizer-BioNTech COVID-19 Vaccine	46,392	100
Myocarditis cohort		
Received a myocarditis diagnosis during the study period	0	0
12 months active enrolment at time zeroDx	0	
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	0	
No history of myocarditis in the 12 months before time zeroDx	0	
Total myocarditis cohort	0	
Pericarditis cohort		
Received a pericarditis diagnosis during the study period	<5	
12 months active enrolment at time zeroDx	<5	
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	<5	
No history of pericarditis in the 12 months before time zeroDx	<5	
Total pericarditis cohort	<5	

Table 15.1.2 Attrition table for the primary objective myocarditis and pericarditis cohorts for PHARMO

Pfizer-BioNTech vaccinated cohort	N	%
All individuals registered in the healthcare data source eligible to receive the Pfizer-BioNTech COVID-19 Vaccine	4,095,291	100
Myocarditis cohort		
Received a myocarditis diagnosis during the study period	1,118	0.03
12 months active enrolment at time zeroDx	1,112	99.46
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	698	62.43
No history of myocarditis in the 12 months before time zeroDx	1,090	97.5
Total myocarditis cohort	674	60.29
Pericarditis cohort		
Received a pericarditis diagnosis during the study period	191	0.01
12 months active enrolment at time zeroDx	191	100
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	115	60.21
No history of pericarditis in the 12 months before time zeroDx	171	89.53
Total pericarditis cohort	102	53.4

Table 15.1.3 Attrition table for the primary objective myocarditis and pericarditis cohorts for NHR

Pfizer-BioNTech vaccinated cohort	N	%
All individuals registered in the healthcare data source eligible to receive the Pfizer-BioNTech COVID-19 Vaccine	5,635,615	100
Myocarditis cohort		
Received a myocarditis diagnosis during the study period	1,204	0.02
12 months active enrolment at time zeroDx	1,200	99.67
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	906	75.25
No history of myocarditis in the 12 months before time zeroDx	1,098	91.2
Total myocarditis cohort	813	67.53
Pericarditis cohort		
Received a pericarditis diagnosis during the study period	2,832	0.05
12 months active enrolment at time zeroDx	2,818	99.51
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	2,174	76.77
No history of pericarditis in the 12 months before time zeroDx	2,599	91.77
Total pericarditis cohort	1,941	68.54

Table 15.1.4 Attrition table for the primary objective myocarditis and pericarditis cohorts for EPICHRON

Pfizer-BioNTech vaccinated cohort	N	%
All individuals registered in the healthcare data source eligible to receive the Pfizer-BioNTech COVID-19 Vaccine	1,420,230	100
Myocarditis cohort		
Received a myocarditis diagnosis during the study period	184	0.01
12 months active enrolment at time zeroDx	182	98.91
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	125	67.94
No history of myocarditis in the 12 months before time zeroDx	177	96.2
Total myocarditis cohort	116	63.04
Pericarditis cohort		
Received a pericarditis diagnosis during the study period	669	0.05
12 months active enrolment at time zeroDx	660	98.66
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	460	68.76
No history of pericarditis in the 12 months before time zeroDx	649	97.01
Total pericarditis cohort	435	65.02

Table 15.1.5 Attrition table for the primary objective myocarditis and pericarditis cohorts for SIDIAP

Pfizer-BioNTech vaccinated cohort	N	%
All individuals registered in the healthcare data source eligible to receive the Pfizer-BioNTech COVID-19 Vaccine	6,399,492	100
Myocarditis cohort		
Received a myocarditis diagnosis during the study period	1,274	0.02
12 months active enrolment at time zeroDx	1,234	96.86
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	742	58.24
No history of myocarditis in the 12 months before time zeroDx	1,229	96.47
Total myocarditis cohort	676	53.06
Pericarditis cohort		
Received a pericarditis diagnosis during the study period	2,880	0.05
12 months active enrolment at time zeroDx	2,818	97.85
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	1,794	62.29
No history of pericarditis in the 12 months before time zeroDx	2,787	96.77
Total pericarditis cohort	1,664	57.78

Table 15.1.6 Attrition table for the primary objective myocarditis and pericarditis cohorts for CPRD

Pfizer-BioNTech vaccinated cohort	N	%
All individuals registered in the healthcare data source eligible to receive the Pfizer-BioNTech COVID-19 Vaccine	16,873,925	100
Myocarditis cohort		
Received a myocarditis diagnosis during the study period	1,894	0.01
12 months active enrolment at time zeroDx	1,594	84.16
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	1,173	61.93
No history of myocarditis in the 12 months before time zeroDx	1,720	90.81
Total myocarditis cohort	863	45.57
Pericarditis cohort		
Received a pericarditis diagnosis during the study period	4,080	0.02
12 months active enrolment at time zeroDx	3,484	85.39
No non-Pfizer-BioNTech COVID-19 vaccine before time zeroDx	2,367	58.02
No history of pericarditis in the 12 months before time zeroDx	3,850	94.36
Total pericarditis cohort	1,822	44.66

Table 15.2.1 Cohort follow-up and reasons for censoring by study cohort for PEDIANET

Label	Myocarditis	Pericarditis
Total	0	2
Person-months of follow-up	NA	24.89
Median follow-up (Q1 - Q3)		12.45 (9.02-15.87)
Min, Max		(9.02, 16)
Reasons for censoring %		
End of the study period	0	<5
Exit from data source	0	<5
Death	0	0 (0)

Table 15.2.2 Cohort follow-up and reasons for censoring by study cohort for PHARMO

Label	Myocarditis	Pericarditis
Total	674	102
Person-months of follow-up	11 161.55	1694.28
Median follow-up (Q1 - Q3)	18.03 (9.75-23.44)	16.99 (10.74-23.01)
Min, Max	(0, 30.45)	(0.1, 30)
Reasons for censoring %		
End of the study period	465 (68.99)	59 (57.84)
Exit from data source	179 (26.56)	36 (35.29)
Death	30 (4.45)	7 (6.86)

Table 15.2.3 Cohort follow-up and reasons for censoring by study cohort for NHR

Label	Myocarditis	Pericarditis
Total	813	1941
Person-months of follow-up	10247.11	25336.26
Median follow-up (Q1 - Q3)	13.19 (6.21-18.64)	13.59 (6.91-19.07)
Min, Max	(0, 24.76)	(0, 25)
Reasons for censoring %		
End of the study period	752 (92.5)	1848 (95.21)
Exit from data source	<5	6 (0.31)
Death	58 (7.13)	87 (4.48)

Table 15.2.4 Cohort follow-up and reasons for censoring by study cohort for EPICHRON

Label	Myocarditis	Pericarditis
Total	116	435
Person-months of follow-up	1986.78	7232.86
Median follow-up (Q1 - Q3)	18.6 (9.39-24.98)	17.82 (8.43-24.89)
Min, Max	(0, 31.07)	(0, 31)
Reasons for censoring %		
End of the study period	101 (87.07)	398 (91.49)
Exit from data source	0 (0)	0 (0)
Death	15 (12.93)	37 (8.51)

Table 15.2.5 Cohort follow-up and reasons for censoring by study cohort for SIDIAP

Label	Myocarditis	Pericarditis
Total	676	1664
Person-months of follow-up	8904.07	31717.55
Median follow-up (Q1 - Q3)	13.67 (5.98-19.74)	21.74 (12.58-26.28)
Min, Max	(0, 30.21)	(0, 30)
Reasons for censoring %		
End of the study period	596 (88.17)	1486 (89.3)
Exit from data source	13 (1.92)	29 (1.74)
Death	67 (9.91)	149 (8.95)

Table 15.2.6 Cohort follow-up and reasons for censoring by study cohort for CPRD

Label	Myocarditis	Pericarditis
Total	863	1822
Person-months of follow-up	12227.97	27336.43
Median follow-up (Q1 - Q3)	13.98 (6.15-21.62)	14.93 (6.74-23.17)
Min, Max	(0, 30.25)	(0, 30)
Reasons for censoring %		
End of the study period	16 (1.85)	26 (1.43)
Exit from data source	830 (96.18)	1762 (96.71)
Death	17 (1.97)	34 (1.87)

Table 15.3.1 Demographic and lifestyle variables at baseline in the Myocarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Total	N =0	N =0
Age groups at time zeroDx (years), n (%)		
0-1	0	0
2-4	0	0
5-11	0	0
12-15	0	0
16-17	0	0
18-29	0	0
30-39	0	0
40-49	0	0
50-59	0	0
60-64	0	0
65-69	0	0
70-79	0	0
80+	0	0
Age at index date (years)		
Mean (SD)		
Median (Q1, Q3)		
Min, Max		
Female, n (%)	0	0
Smoking status, n (%)		
Never_or_Former	0	0
Never	0	0
Former	0	0
Current	0	0
Obese (diagnostic code or BMI >30 kg/m2), n (%) ^b	0	0
Socio economic status, n (%)		
Pregnancy status: yes, n (%) ^a	0	0
Pregnancy trimester, n (%) ^a		
First trimester	0	0
Second trimester	0	0
Third trimester	0	0

Table 15.3.1.1 Demographic and lifestyle variables at baseline in the Pericarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Total	N =1	N =1
Age groups at time zeroDx (years), n (%)		
0-1	0 (0)	0 (0)
2-4	0 (0)	0 (0)
5-11	0 (0)	0 (0)
12-15	<5	<5
16-17	0 (0)	0 (0)
18-29	0 (0)	0 (0)
30-39	0 (0)	0 (0)
40-49	0 (0)	0 (0)
50-59	0 (0)	0 (0)
60-64	0 (0)	0 (0)
65-69	0 (0)	0 (0)
70-79	0 (0)	0 (0)
80+	0 (0)	0 (0)
Age at index date (years)		
Mean (SD)	12	13
Median (Q1, Q3)	12 (12-12)	13 (13-13)
Min, Max	12, 12	13, 13
Female, n (%)	<5	0 (0)
Smoking status, n (%)		
Unknown	<5	<5
Never_or_Former	0 (0)	0 (0)
Never	0 (0)	0 (0)
Former	0 (0)	0 (0)
Current	0 (0)	0 (0)
Obese (diagnostic code or BMI >30 kg/m2), n (%) ^b	0 (0)	0 (0)
Socio economic status, n (%)		
Pregnancy status, n (%) ^a	0 (0)	0
Pregnancy trimester, n (%) ^a		
First trimester	0	0
Second trimester	0	0
Third trimester	0	0

Table 15.3.2 Demographic and lifestyle variables at baseline in the Myocarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Total	N =304	N =370
Age groups at time zeroDx (years), n (%)		
0-1	0 (0)	<5
2-4	0 (0)	<5
5-11	0 (0)	<5
12-15	<5	<5
16-17	<5	<5
18-29	53 (17.43)	66 (17.84)
30-39	55 (18.09)	59 (15.95)
40-49	49 (16.12)	55 (14.86)
50-59	56 (18.42)	77 (20.81)
60-64	9 (2.96)	31 (8.38)
65-69	18 (5.92)	35 (9.46)
70-79	39 (12.83)	27 (7.3)
80+	20 (6.58)	10 (2.7)
Age at index date (years)		
Mean (SD)	48 (19.55)	47 (18.03)
Median (Q1, Q3)	46 (33-66)	49 (32-61)
Min, Max	14, 89	0, 94
Female, n (%)	97 (31.91)	120 (32.43)
Smoking status, n (%)		
Unknown	293 (96.38)	364 (98.38)
Never_or_Former	0 (0)	0 (0)
Never	0 (0)	0 (0)
Former	0 (0)	0 (0)
Current	11 (3.62)	6 (1.62)
Obese (diagnostic code or BMI >30 kg/m2), n (%) ^b	5 (1.64)	<5
Socio economic status, n (%)		
Unknown	<5	<5
Pregnancy status: yes, n (%) ^a	<5	<5
Pregnancy trimester, n (%) ^a		
First trimester	<5	0 (0)
Second trimester	0 (0)	<5
Third trimester	0 (0)	0 (0)

Table 15.3.2.1 Demographic and lifestyle variables at baseline in the Pericarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Total	N =36	N =66
Age groups at time zeroDx (years), n (%)		
0-1	0 (0)	0 (0)
2-4	0 (0)	0 (0)
5-11	0 (0)	<5
12-15	<5	0 (0)
16-17	<5	0 (0)
18-29	8 (22.22)	13 (19.7)
30-39	<5	10 (15.15)
40-49	<5	9 (13.64)
50-59	7 (19.44)	12 (18.18)
60-64	<5	7 (10.61)
65-69	<5	5 (7.58)
70-79	5 (13.89)	8 (12.12)
80+	<5	<5
Age at index date (years)		
Mean (SD)	51 (22.87)	48 (17.66)
Median (Q1, Q3)	57 (24-69)	51 (32-62)
Min, Max	15, 87	11, 83
Female, n (%)	10 (27.78)	22 (33.33)
Smoking status, n (%)		
Unknown	>31	>61
Never_or_Former	0 (0)	0 (0)
Never	0 (0)	0 (0)
Former	0 (0)	0 (0)
Current	<5	<5
Obese (diagnostic code or BMI >30 kg/m2), n (%)b	<5	<5
Socio economic status, n (%)		
Unknown	0 (0)	0 (0)
Pregnancy status, n (%)a	0 (0)	0 (0)
Pregnancy trimester, n (%)a		
First trimester	0	0
Second trimester	0	0
Third trimester	0	0

Table 15.3.3 Demographic and lifestyle variables at baseline in the Myocarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Total	N =543	N =270
Age groups at time zeroDx (years), n (%)		
0-1	0 (0)	<5
2-4	0 (0)	<5
5-11	0 (0)	7 (2.59)
12-15	<5	5 (1.85)
16-17	15 (2.76)	5 (1.85)
18-29	>98	71 (26.3)
30-39	60 (11.05)	41 (15.19)
40-49	60 (11.05)	45 (16.67)
50-59	89 (16.39)	37 (13.7)
60-64	38 (7)	12 (4.44)
65-69	46 (8.47)	15 (5.56)
70-79	90 (16.57)	19 (7.04)
80+	42 (7.73)	8 (2.96)
Age at index date (years)		
Mean (SD)	51 (21.18)	41 (19.59)
Median (Q1, Q3)	53 (32-69)	40 (25-55)
Min, Max	13, 94	0, 86
Female, n (%)	191 (35.17)	77 (28.52)
Smoking status, n (%)		
Unknown	>538	>265
Never_or_Former	0 (0)	0 (0)
Never	0 (0)	0 (0)
Former	0 (0)	0 (0)
Current	<5	<5
Obese (diagnostic code or BMI >30 kg/m2), n (%)b	17 (3.13)	12 (4.44)
Socio economic status, n (%)		
Pregnancy status: yes, n (%)a	0 (0)	<5
Pregnancy trimester, n (%)a		
First trimester	0	0 (0)
Second trimester	0	0 (0)
Third trimester	0	<5

Table 15.3.3.1 Demographic and lifestyle variables at baseline in the Pericarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Total	N =1397	N =544
Age groups at time zeroDx (years), n (%)		
0-1	0 (0)	<5
2-4	0 (0)	6 (1.1)
5-11	0 (0)	9 (1.65)
12-15	7 (0.5)	11 (2.02)
16-17	16 (1.15)	9 (1.65)
18-29	156 (11.17)	83 (15.26)
30-39	123 (8.8)	89 (16.36)
40-49	145 (10.38)	81 (14.89)
50-59	215 (15.39)	>89
60-64	129 (9.23)	42 (7.72)
65-69	154 (11.02)	45 (8.27)
70-79	319 (22.83)	58 (10.66)
80+	133 (9.52)	17 (3.12)
Age at index date (years)		
Mean (SD)	57 (19.52)	47 (19.8)
Median (Q1, Q3)	61 (43-72)	48 (32-63)
Min, Max	13, 100	0, 91
Female, n (%)	467 (33.43)	159 (29.23)
Smoking status, n (%)		
Unknown	1,385 (99.14)	538 (98.9)
Never_or_Former	0 (0)	0 (0)
Never	0 (0)	0 (0)
Former	0 (0)	0 (0)
Current	12 (0.86)	6 (1.1)
Obese (diagnostic code or BMI >30 kg/m2), n (%)b	54 (3.87)	16 (2.94)
Socio economic status, n (%)		
Pregnancy status, n (%)a	<5	<5
Pregnancy trimester, n (%)a		
First trimester	0 (0)	0 (0)
Second trimester	0 (0)	<5
Third trimester	<5	<5

Table 15.3.4 Demographic and lifestyle variables at baseline in the Myocarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =75	N =41
Age groups at time zeroDx (years), n (%)		
0-1	0 (0)	0 (0)
2-4	0 (0)	0 (0)
5-11	<5	0 (0)
12-15	<5	<5
16-17	<5	<5
18-29	19 (25.33)	12 (29.27)
30-39	10 (13.33)	7 (17.07)
40-49	9 (12)	5 (12.2)
50-59	5 (6.67)	<5
60-64	<5	0 (0)
65-69	<5	<5
70-79	9 (12)	<5
80+	12 (16)	<5
Age at index date (years)		
Mean (SD)	48 (25.54)	42 (20.76)
Median (Q1, Q3)	43 (24-71)	39 (24-58)
Min, Max	11, 96	12, 84
Female, n (%)	16 (21.33)	9 (21.95)
Smoking status, n (%)		
Unknown	>70	>36
Never_or_Former	0 (0)	0 (0)
Never	0 (0)	0 (0)
Former	0 (0)	0 (0)
Current	<5	<5
Obese (diagnostic code or BMI >30 kg/m2), n (%) ^b	6 (8)	<5
Socio economic status, n (%)		
Pregnancy status: yes, n (%) ^a	0 (0)	0 (0)
Pregnancy trimester, n (%) ^a		
First trimester	0	0
Second trimester	0	0
Third trimester	0	0

Table 15.3.4.1 Demographic and lifestyle variables at baseline in the Pericarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =302	N =133
Age groups at time zeroDx (years), n (%)		
0-1	0 (0)	0 (0)
2-4	0 (0)	0 (0)
5-11	0 (0)	0 (0)
12-15	9 (2.98)	5 (3.76)
16-17	7 (2.32)	<5
18-29	46 (15.23)	>22
30-39	41 (13.58)	17 (12.78)
40-49	40 (13.25)	22 (16.54)
50-59	48 (15.89)	16 (12.03)
60-64	8 (2.65)	14 (10.53)
65-69	11 (3.64)	6 (4.51)
70-79	47 (15.56)	19 (14.29)
80+	45 (14.9)	7 (5.26)
Age at index date (years)		
Mean (SD)	52 (22.67)	48 (20.51)
Median (Q1, Q3)	52 (34-72)	49 (30-62)
Min, Max	12, 97	12, 91
Female, n (%)	87 (28.81)	34 (25.56)
Smoking status, n (%)		
Unknown	285 (94.37)	123 (92.48)
Never_or_Former	0 (0)	0 (0)
Never	0 (0)	0 (0)
Former	0 (0)	0 (0)
Current	17 (5.63)	10 (7.52)
Obese (diagnostic code or BMI >30 kg/m2), n (%)b	24 (7.95)	9 (6.77)
Socio economic status, n (%)		
Pregnancy status, n (%)a	0 (0)	0 (0)
Pregnancy trimester, n (%)a		
First trimester	0	0
Second trimester	0	0
Third trimester	0	0

Table 15.3.5 Demographic and lifestyle variables at baseline in the Myocarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =386	N =290
Age groups at time zeroDx (years), n (%)		
0-1	0 (0)	18 (6.21)
2-4	0 (0)	36 (12.41)
5-11	32 (8.29)	43 (14.83)
12-15	26 (6.74)	8 (2.76)
16-17	12 (3.11)	5 (1.72)
18-29	51 (13.21)	37 (12.76)
30-39	55 (14.25)	31 (10.69)
40-49	54 (13.99)	32 (11.03)
50-59	43 (11.14)	27 (9.31)
60-64	5 (1.3)	8 (2.76)
65-69	7 (1.81)	12 (4.14)
70-79	48 (12.44)	22 (7.59)
80+	53 (13.73)	11 (3.79)
Age at index date (years)		
Mean (SD)	46 (26.12)	32 (25.81)
Median (Q1, Q3)	43 (21-71)	28 (6-51)
Min, Max	5, 98	1, 90
Female, n (%)	151 (39.12)	111 (38.28)
Smoking status, n (%)		
Unknown	359 (93.01)	267 (92.07)
Never_or_Former	0 (0)	0 (0)
Never	0 (0)	0 (0)
Former	0 (0)	0 (0)
Current	27 (6.99)	23 (7.93)
Obese (diagnostic code or BMI >30 kg/m2), n (%)b	51 (13.21)	36 (12.41)
Socio economic status, n (%)		
Pregnancy status: yes, n (%)a	5 (7.69)	<5
Pregnancy trimester, n (%)a		
First trimester	0 (0)	0 (0)
Second trimester	<5	<5
Third trimester	<5	0 (0)

Table 15.3.5.1 Demographic and lifestyle variables at baseline in the Pericarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =894	N =770
Age groups at time zeroDx (years), n (%)		
0-1	0 (0)	<5
2-4	0 (0)	7 (0.91)
5-11	<5	14 (1.82)
12-15	14 (1.57)	9 (1.17)
16-17	21 (2.35)	14 (1.82)
18-29	80 (8.95)	>129
30-39	80 (8.95)	96 (12.47)
40-49	112 (12.53)	116 (15.06)
50-59	136 (15.21)	118 (15.32)
60-64	14 (1.57)	47 (6.1)
65-69	14 (1.57)	64 (8.31)
70-79	191 (21.36)	99 (12.86)
80+	>227	52 (6.75)
Age at index date (years)		
Mean (SD)	60 (22.89)	49 (21.15)
Median (Q1, Q3)	60 (42-80)	49 (31-66)
Min, Max	6, 100	1, 92
Female, n (%)	320 (35.79)	271 (35.19)
Smoking status, n (%)		
Unknown	834 (93.29)	700 (90.91)
Never_or_Former	0 (0)	0 (0)
Never	0 (0)	0 (0)
Former	0 (0)	0 (0)
Current	60 (6.71)	70 (9.09)
Obese (diagnostic code or BMI >30 kg/m2), n (%)b	136 (15.21)	106 (13.77)
Socio economic status, n (%)		
Pregnancy status, n (%)a	<5	<5
Pregnancy trimester, n (%)a		
First trimester	0 (0)	0 (0)
Second trimester	<5	0 (0)
Third trimester	0 (0)	<5

Table 15.3.6 Demographic and lifestyle variables at baseline in the Myocarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Total	N =513	N =350
Age groups at time zeroDx (years), n (%)		
0-1	0 (0)	<5
2-4	0 (0)	<5
5-11	<5	18 (5.14)
12-15	8 (1.56)	12 (3.43)
16-17	29 (5.65)	22 (6.29)
18-29	>161	116 (33.14)
30-39	99 (19.3)	61 (17.43)
40-49	71 (13.84)	53 (15.14)
50-59	51 (9.94)	40 (11.43)
60-64	18 (3.51)	6 (1.71)
65-69	26 (5.07)	8 (2.29)
70-79	28 (5.46)	<5
80+	17 (3.31)	6 (1.71)
Age at index date (years)		
Mean (SD)	39 (18.9)	33 (16.87)
Median (Q1, Q3)	36 (23-52)	30 (21-44)
Min, Max	9, 88	1, 89
Female, n (%)	179 (34.89)	102 (29.14)
Smoking status, n (%)		
Unknown	185 (36.06)	163 (46.57)
Never_or_Former	0 (0)	0 (0)
Never	179 (34.89)	83 (23.71)
Former	0 (0)	0 (0)
Current	149 (29.04)	104 (29.71)
Obese (diagnostic code or BMI >30 kg/m2), n (%) ^b	84 (16.37)	44 (12.57)
Socio economic status, n (%)		
Pregnancy status: yes, n (%) ^a	0 (0)	0 (0)
Pregnancy trimester, n (%) ^a		
First trimester	0	0
Second trimester	0	0
Third trimester	0	0

Table 15.3.6.1 Demographic and lifestyle variables at baseline in the Pericarditis overall and by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Total	N =1072	N =750
Age groups at time zeroDx (years), n (%)		
0-1	0 (0)	0 (0)
2-4	0 (0)	0 (0)
5-11	<5	13 (1.73)
12-15	16 (1.49)	15 (2)
16-17	32 (2.99)	33 (4.4)
18-29	>304	214 (28.53)
30-39	223 (20.8)	173 (23.07)
40-49	146 (13.62)	137 (18.27)
50-59	118 (11.01)	107 (14.27)
60-64	52 (4.85)	26 (3.47)
65-69	47 (4.38)	8 (1.07)
70-79	73 (6.81)	16 (2.13)
80+	56 (5.22)	8 (1.07)
Age at index date (years)		
Mean (SD)	42 (19.65)	37 (15.66)
Median (Q1, Q3)	37 (26-56)	35 (24-48)
Min, Max	8, 97	6, 90
Female, n (%)	353 (32.93)	195 (26)
Smoking status, n (%)		
Unknown	360 (33.58)	296 (39.47)
Never_or_Former	0 (0)	0 (0)
Never	327 (30.5)	149 (19.87)
Former	0 (0)	0 (0)
Current	385 (35.91)	305 (40.67)
Obese (diagnostic code or BMI >30 kg/m2), n (%)b	140 (13.06)	82 (10.93)
Socio economic status, n (%)		
Pregnancy status, n (%)a	0 (0)	0 (0)
Pregnancy trimester, n (%)a		
First trimester	0	0
Second trimester	0	0
Third trimester	0	0

Table 15.4.1 Healthcare utilisation in the 12 months prior to date of myocarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Total	N =0	N =0
Number of hospitalisations, n (%)		
0	0	0
1	0	0
> 1	0	0
Number of emergency department visits, n (%)		
0	0	0
1	0	0
>1	0	0
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0	0
Primary care utilisation, n (%)		
0	0	0
1	0	0
>1	0	0
Cancer screening, n (%)	0	0
Other preventive health services, n (%)	NA	NA
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	0	0
1-2	0	0
3-4	0	0
>=5	0	0

Table 15.4.1.1 Healthcare utilisation in the 12 months prior to date of pericarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Total	N =1	N =1
Number of hospitalisations, n (%)		
0	<5	<5
1	0 (0)	0 (0)
> 1	0 (0)	0 (0)
Number of emergency department visits, n (%)		
0	0 (0)	<5
1	0 (0)	0 (0)
>1	<5	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	0 (0)	0 (0)
1	0 (0)	0 (0)
>1	<5	<5
Cancer screening, n (%)	0 (0)	0 (0)
Other preventive health services, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	<5	0 (0)
1-2	0 (0)	<5
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.4.2 Healthcare utilisation in the 12 months prior to date of myocarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Total	N =304	N =370
Number of hospitalisations, n (%)		
0	304 (100)	370 (100)
1	0 (0)	0 (0)
> 1	0 (0)	0 (0)
Number of emergency department visits, n (%)		
0	304 (100)	370 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	57 (18.75)	100 (27.03)
1	39 (12.83)	44 (11.89)
>1	208 (68.42)	226 (61.08)
Cancer screening, n (%)	0 (0)	0 (0)
Other preventive health services, n (%)	NA	NA
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	304 (100)	370 (100)
1-2	0 (0)	0 (0)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.4.2.1 Healthcare utilisation in the 12 months prior to date of pericarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Total	N =36	N =66
Number of hospitalisations, n (%)		
0	36 (100)	66 (100)
1	0 (0)	0 (0)
> 1	0 (0)	0 (0)
Number of emergency department visits, n (%)		
0	36 (100)	66 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	5 (13.89)	32 (48.48)
1	<5	6 (9.09)
>1	>26	28 (42.42)
Cancer screening, n (%)	0 (0)	0 (0)
Other preventive health services, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	36 (100)	66 (100)
1-2	0 (0)	0 (0)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.4.3 Healthcare utilisation in the 12 months prior to date of myocarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Total	N =543	N =270
Number of hospitalisations, n (%)		
0	348 (64.09)	177 (65.56)
1	106 (19.52)	50 (18.52)
> 1	89 (16.39)	43 (15.93)
Number of emergency department visits, n (%)		
0	543 (100)	270 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	33 (6.08)	19 (7.04)
1	33 (6.08)	25 (9.26)
>1	477 (87.85)	226 (83.7)
Cancer screening, n (%)	0 (0)	0 (0)
Other preventive health services, n (%)	NA	NA
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	481 (88.58)	230 (85.19)
1-2	62 (11.42)	40 (14.81)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.4.3.1 Healthcare utilisation in the 12 months prior to date of pericarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Total	N =1397	N =544
Number of hospitalisations, n (%)		
0	808 (57.84)	346 (63.6)
1	247 (17.68)	93 (17.1)
> 1	342 (24.48)	105 (19.3)
Number of emergency department visits, n (%)		
0	1,397 (100)	544 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	94 (6.73)	55 (10.11)
1	84 (6.01)	38 (6.99)
>1	1,219 (87.26)	451 (82.9)
Cancer screening, n (%)	0 (0)	0 (0)
Other preventive health services, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	1,253 (89.69)	494 (90.81)
1-2	144 (10.31)	50 (9.19)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.4.4 Healthcare utilisation in the 12 months prior to date of myocarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =75	N =41
Number of hospitalisations, n (%)		
0	>57	35 (85.37)
1	13 (17.33)	6 (14.63)
> 1	<5	0 (0)
Number of emergency department visits, n (%)		
0	41 (54.67)	21 (51.22)
1	19 (25.33)	13 (31.71)
>1	15 (20)	7 (17.07)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	6 (8)	<5
1	<5	<5
>1	>64	36 (87.8)
Cancer screening, n (%)	0 (0)	0 (0)
Other preventive health services, n (%)	NA	NA
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	50 (66.67)	25 (60.98)
1-2	25 (33.33)	16 (39.02)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.4.4.1 Healthcare utilisation in the 12 months prior to date of pericarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =302	N =133
Number of hospitalisations, n (%)		
0	228 (75.5)	104 (78.2)
1	46 (15.23)	19 (14.29)
> 1	28 (9.27)	10 (7.52)
Number of emergency department visits, n (%)		
0	154 (50.99)	76 (57.14)
1	80 (26.49)	22 (16.54)
>1	68 (22.52)	35 (26.32)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	21 (6.95)	13 (9.77)
1	13 (4.3)	13 (9.77)
>1	268 (88.74)	107 (80.45)
Cancer screening, n (%)	0 (0)	0 (0)
Other preventive health services, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	199 (65.89)	80 (60.15)
1-2	103 (34.11)	53 (39.85)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.4.5 Healthcare utilisation in the 12 months prior to date of myocarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =386	N =290
Number of hospitalisations, n (%)		
0	288 (74.61)	222 (76.55)
1	62 (16.06)	45 (15.52)
> 1	36 (9.33)	23 (7.93)
Number of emergency department visits, n (%)		
0	386 (100)	290 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	26 (6.74)	12 (4.14)
1	24 (6.22)	11 (3.79)
>1	336 (87.05)	267 (92.07)
Cancer screening, n (%)	0 (0)	0 (0)
Other preventive health services, n (%)	NA	NA
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	291 (75.39)	202 (69.66)
1-2	72 (18.65)	63 (21.72)
3-4	18 (4.66)	14 (4.83)
>=5	5 (1.3)	11 (3.79)

Table 15.4.5.1 Healthcare utilisation in the 12 months prior to date of pericarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =894	N =770
Number of hospitalisations, n (%)		
0	582 (65.1)	576 (74.81)
1	164 (18.34)	117 (15.19)
> 1	148 (16.55)	77 (10)
Number of emergency department visits, n (%)		
0	894 (100)	770 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	32 (3.58)	59 (7.66)
1	26 (2.91)	42 (5.45)
>1	836 (93.51)	669 (86.88)
Cancer screening, n (%)	0 (0)	0 (0)
Other preventive health services, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	639 (71.48)	577 (74.94)
1-2	192 (21.48)	149 (19.35)
3-4	38 (4.25)	24 (3.12)
>=5	25 (2.8)	20 (2.6)

Table 15.4.6 Healthcare utilisation in the 12 months prior to date of myocarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Total	N =513	N =350
Number of hospitalisations, n (%)		
0	417 (81.29)	280 (80)
1	81 (15.79)	59 (16.86)
> 1	15 (2.92)	11 (3.14)
Number of emergency department visits, n (%)		
0	259 (50.49)	153 (43.71)
1	161 (31.38)	127 (36.29)
>1	93 (18.13)	70 (20)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	513 (100)	350 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Cancer screening, n (%)	83 (16.18)	38 (10.86)
Other preventive health services, n (%)	NA	NA
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	254 (49.51)	195 (55.71)
1-2	192 (37.43)	117 (33.43)
3-4	38 (7.41)	26 (7.43)
>=5	29 (5.65)	12 (3.43)

Table 15.4.6.1 Healthcare utilisation in the 12 months prior to date of pericarditis diagnosis (time zeroDX) by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Total	N =1072	N =750
Number of hospitalisations, n (%)		
0	931 (86.85)	669 (89.2)
1	102 (9.51)	59 (7.87)
> 1	39 (3.64)	22 (2.93)
Number of emergency department visits, n (%)		
0	556 (51.87)	398 (53.07)
1	312 (29.1)	213 (28.4)
>1	204 (19.03)	139 (18.53)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	1,072 (100)	750 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Cancer screening, n (%)	190 (17.72)	80 (10.67)
Other preventive health services, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	583 (54.38)	450 (60)
1-2	358 (33.4)	247 (32.93)
3-4	83 (7.74)	39 (5.2)
>=5	48 (4.48)	14 (1.87)

Table 15.5.1 Healthcare utilisation in the 2 weeks prior to date of myocarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Total	N =0	N =0
Number of hospitalisations, n (%)		
0	0	0
1	0	0
>1	0	0
Number of emergency department visits, n (%)		
0	0	0
1	0	0
>1	0	0
Primary care utilisation, n (%)		
0	0	0
1	0	0
>1	0	0
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0	0
Cancer screening, n (%)	0	0
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	0	0
1-2	0	0
3-4	0	0
>=5	0	0

Table 15.5.1.1 Healthcare utilisation in the 2 weeks prior to date of pericarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Total	N =1	N =1
Number of hospitalisations, n (%)		
0	<5	<5
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Number of emergency department visits, n (%)		
0	0 (0)	<5
1	0 (0)	0 (0)
>1	<5	0 (0)
Primary care utilisation, n (%)		
0	<5	<5
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Cancer screening, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	<5	<5
1-2	0 (0)	0 (0)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.5.2 Healthcare utilisation in the 2 weeks prior to date of myocarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Total	N =304	N =370
Number of hospitalisations, n (%)		
0	304 (100)	370 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Number of emergency department visits, n (%)		
0	304 (100)	370 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	223 (73.36)	278 (75.14)
1	57 (18.75)	51 (13.78)
>1	24 (7.89)	41 (11.08)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Cancer screening, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	304 (100)	370 (100)
1-2	0 (0)	0 (0)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.5.2.1 Healthcare utilisation in the 2 weeks prior to date of pericarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Total	N =36	N =66
Number of hospitalisations, n (%)		
0	36 (100)	66 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Number of emergency department visits, n (%)		
0	36 (100)	66 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	30 (83.33)	>51
1	<5	10 (15.15)
>1	<5	<5
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Cancer screening, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	36 (100)	66 (100)
1-2	0 (0)	0 (0)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.5.3 Healthcare utilisation in the 2 weeks prior to date of myocarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Total	N =543	N =270
Number of hospitalisations, n (%)		
0	477 (87.85)	239 (88.52)
1	55 (10.13)	26 (9.63)
>1	11 (2.03)	5 (1.85)
Number of emergency department visits, n (%)		
0	543 (100)	270 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	295 (54.33)	126 (46.67)
1	158 (29.1)	88 (32.59)
>1	90 (16.57)	56 (20.74)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Cancer screening, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	534 (98.34)	264 (97.78)
1-2	9 (1.66)	6 (2.22)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.5.3.1 Healthcare utilisation in the 2 weeks prior to date of pericarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Total	N =1397	N =544
Number of hospitalisations, n (%)		
0	1,212 (86.76)	488 (89.71)
1	154 (11.02)	46 (8.46)
>1	31 (2.22)	10 (1.84)
Number of emergency department visits, n (%)		
0	1,397 (100)	544 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	734 (52.54)	282 (51.84)
1	350 (25.05)	146 (26.84)
>1	313 (22.41)	116 (21.32)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Cancer screening, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	1,382 (98.93)	539 (99.08)
1-2	15 (1.07)	5 (0.92)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.5.4 Healthcare utilisation in the 2 weeks prior to date of myocarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =75	N =41
Number of hospitalisations, n (%)		
0	>70	41 (100)
1	<5	0 (0)
>1	0 (0)	0 (0)
Number of emergency department visits, n (%)		
0	>55	>31
1	15 (20)	5 (12.2)
>1	<5	<5
Primary care utilisation, n (%)		
0	33 (44)	21 (51.22)
1	18 (24)	10 (24.39)
>1	24 (32)	10 (24.39)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Cancer screening, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	>70	36 (87.8)
1-2	<5	5 (12.2)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.5.4.1 Healthcare utilisation in the 2 weeks prior to date of pericarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =302	N =133
Number of hospitalisations, n (%)		
0	>288	>122
1	9 (2.98)	6 (4.51)
>1	<5	<5
Number of emergency department visits, n (%)		
0	247 (81.79)	>107
1	50 (16.56)	21 (15.79)
>1	5 (1.66)	<5
Primary care utilisation, n (%)		
0	155 (51.32)	71 (53.38)
1	67 (22.19)	29 (21.8)
>1	80 (26.49)	33 (24.81)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Cancer screening, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	290 (96.03)	128 (96.24)
1-2	12 (3.97)	5 (3.76)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.5.5 Healthcare utilisation in the 2 weeks prior to date of myocarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =386	N =290
Number of hospitalisations, n (%)		
0	355 (91.97)	>264
1	31 (8.03)	21 (7.24)
>1	0 (0)	<5
Number of emergency department visits, n (%)		
0	386 (100)	290 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	181 (46.89)	124 (42.76)
1	103 (26.68)	80 (27.59)
>1	102 (26.42)	86 (29.66)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Cancer screening, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	>381	283 (97.59)
1-2	<5	7 (2.41)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.5.5.1 Healthcare utilisation in the 2 weeks prior to date of pericarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =894	N =770
Number of hospitalisations, n (%)		
0	787 (88.03)	717 (93.12)
1	98 (10.96)	48 (6.23)
>1	9 (1.01)	5 (0.65)
Number of emergency department visits, n (%)		
0	894 (100)	770 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Primary care utilisation, n (%)		
0	334 (37.36)	326 (42.34)
1	240 (26.85)	192 (24.94)
>1	320 (35.79)	252 (32.73)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Cancer screening, n (%)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	876 (97.99)	749 (97.27)
1-2	18 (2.01)	21 (2.73)
3-4	0 (0)	0 (0)
>=5	0 (0)	0 (0)

Table 15.5.6 Healthcare utilisation in the 2 weeks prior to date of myocarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Total	N =513	N =350
Number of hospitalisations, n (%)		
0	>454	>305
1	54 (10.53)	40 (11.43)
>1	<5	<5
Number of emergency department visits, n (%)		
0	374 (72.9)	231 (66)
1	122 (23.78)	107 (30.57)
>1	17 (3.31)	12 (3.43)
Primary care utilisation, n (%)		
0	513 (100)	350 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Cancer screening, n (%)	<5	<5
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	>460	>308
1-2	48 (9.36)	37 (10.57)
3-4	<5	<5
>=5	0 (0)	0 (0)

Table 15.5.6.1 Healthcare utilisation in the 2 weeks prior to date of pericarditis diagnosis by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Total	N =1072	N =750
Number of hospitalisations, n (%)		
0	>991	>697
1	76 (7.09)	48 (6.4)
>1	<5	<5
Number of emergency department visits, n (%)		
0	785 (73.23)	552 (73.6)
1	258 (24.07)	176 (23.47)
>1	29 (2.71)	22 (2.93)
Primary care utilisation, n (%)		
0	1,072 (100)	750 (100)
1	0 (0)	0 (0)
>1	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)	0 (0)	0 (0)
Cancer screening, n (%)	14 (1.31)	<5
Number of COVID-19 tests (PCR or antigenic), n (%)		
0	995 (92.82)	>682
1-2	70 (6.53)	63 (8.4)
3-4	7 (0.65)	<5
>=5	0 (0)	0 (0)

Table 15.6.1 Comorbidities at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N =0	N =0
History of Anaphylaxis	0	0
History of Allergies	0	0
Diabetes mellitus(types 1 and 2)	0	0
Hypertension (CDC risk group)	0	0
Cardiovascular disease	0	0
Myocardial infarction	0	0
Congestive heart failure	0	0
Cerebrovascular disease	0	0
Peripheral vascular disease	0	0
Chronic respiratory disease	0	0
Chronic kidney disease	0	0
Mild to moderate renal disease	0	0
Chronic liver disease	0	0
Moderate to severe liver disease	0	0
Any cancer diagnosis except non melanoma skin cancer	0	0
Leukemia	0	0
Lymphoma	0	0
Metastasis	0	0
Autoimmune disorders	0	0
Influenza infection or other respiratory infection	0	0
HIV/AIDS	0	0
Sickle cell disease (CDC risk group)	0	0
Connective tissue disease	0	0
Immunodeficiency except HIV	0	0
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	0	0
Charlson Comorbidity Index		
0	0	0
1	0	0
2	0	0
>=3	0	0
Mean(SD)		
Median (Q1, Q3)		
Min, Max		
CDC at-risk groups		
Group 0 (no conditions)	0	0
Group 1 (1 condition)	0	0
Group 2 (>1 condition)	0	0
COVID-19 history		

Table 15.6.1 Comorbidities at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	0	0
Positive test results for COVID-19	0	0

Table 15.6.1.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N < 5	N < 5
History of Anaphylaxis	0 (0)	0 (0)
History of Allergies	0 (0)	0 (0)
Diabetes mellitus(types 1 and 2)	0 (0)	0 (0)
Hypertension (CDC risk group)	0 (0)	0 (0)
Cardiovascular disease	0 (0)	0 (0)
Myocardial infarction	0 (0)	0 (0)
Congestive heart failure	0 (0)	0 (0)
Cerebrovascular disease	0 (0)	0 (0)
Peripheral vascular disease	0 (0)	0 (0)
Chronic respiratory disease	<5	0 (0)
Chronic kidney disease	0 (0)	0 (0)
Mild to moderate renal disease	0 (0)	0 (0)
Chronic liver disease	0 (0)	0 (0)
Moderate to severe liver disease	0 (0)	0 (0)
Any cancer diagnosis except non melanoma skin cancer	0 (0)	0 (0)
Leukemia	0 (0)	0 (0)
Lymphoma	0 (0)	0 (0)
Metastasis	0 (0)	0 (0)
Autoimmune disorders	0 (0)	0 (0)
Influenza infection or other respiratory infection	<5	<5
HIV/AIDS	0 (0)	0 (0)
Sickle cell disease (CDC risk group)	0 (0)	0 (0)
Connective tissue disease	0 (0)	0 (0)
Immunodeficiency except HIV	0 (0)	0 (0)
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	0 (0)	0 (0)
Charlson Comorbidity Index		
0	<5	<5
1	0 (0)	0 (0)
2	0 (0)	0 (0)
>=3	0 (0)	0 (0)
Mean(SD)	0	0
Median (Q1, Q3)	0 (0-0)	0 (0-0)
Min, Max	0, 0	0, 0
CDC at-risk groups		
Group 0 (no conditions)	0 (0)	<5
Group 1 (1 condition)	<5	0 (0)
Group 2 (>1 condition)	0 (0)	0 (0)
COVID-19 history		

Table 15.6.1.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	0 (0)	0 (0)
Positive test results for COVID-19	0 (0)	<5

Table 15.6.2 Comorbidities at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N =304	N =370
History of Anaphylaxis	<5	0 (0)
History of Allergies	19 (6.25)	22 (5.95)
Diabetes mellitus(types 1 and 2)	21 (6.91)	30 (8.11)
Hypertension (CDC risk group)	31 (10.2)	57 (15.41)
Cardiovascular disease	154 (50.66)	200 (54.05)
Myocardial infarction	17 (5.59)	14 (3.78)
Congestive heart failure	10 (3.29)	13 (3.51)
Cerebrovascular disease	13 (4.28)	15 (4.05)
Peripheral vascular disease	14 (4.61)	14 (3.78)
Chronic respiratory disease	73 (24.01)	96 (25.95)
Chronic kidney disease	16 (5.26)	11 (2.97)
Mild to moderate renal disease	<5	6 (1.62)
Chronic liver disease	<5	<5
Moderate to severe liver disease	<5	6 (1.62)
Any cancer diagnosis except non melanoma skin cancer	27 (8.88)	19 (5.14)
Leukemia	<5	0 (0)
Lymphoma	0 (0)	<5
Metastasis	<5	<5
Autoimmune disorders	32 (10.53)	51 (13.78)
Influenza infection or other respiratory infection	43 (14.14)	47 (12.7)
HIV/AIDS	0 (0)	0 (0)
Sickle cell disease (CDC risk group)	0 (0)	0 (0)
Connective tissue disease	60 (19.74)	74 (20)
Immunodeficiency except HIV	<5	<5
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	84 (27.63)	103 (27.84)
Charlson Comorbidity Index		
0	185 (60.86)	246 (66.49)
1	62 (20.39)	66 (17.84)
2	24 (7.89)	29 (7.84)
>=3	33 (10.86)	29 (7.84)
Mean(SD)	1 (1)	1 (1)
Median (Q1, Q3)	0 (0-1)	0 (0-1)
Min, Max	0, 10	0, 11
CDC at-risk groups		
Group 0 (no conditions)	103 (33.88)	124 (33.51)
Group 1 (1 condition)	85 (27.96)	116 (31.35)
Group 2 (>1 condition)	116 (38.16)	130 (35.14)
COVID-19 history		

Table 15.6.2 Comorbidities at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	67 (22.04)	54 (14.59)
Positive test results for COVID-19	0 (0)	0 (0)

Table 15.6.2.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N =36	N =66
History of Anaphylaxis	<5	<5
History of Allergies	5 (13.89)	<5
Diabetes mellitus(types 1 and 2)	<5	10 (15.15)
Hypertension (CDC risk group)	8 (22.22)	16 (24.24)
Cardiovascular disease	24 (66.67)	38 (57.58)
Myocardial infarction	<5	10 (15.15)
Congestive heart failure	<5	8 (12.12)
Cerebrovascular disease	<5	<5
Peripheral vascular disease	5 (13.89)	12 (18.18)
Chronic respiratory disease	11 (30.56)	17 (25.76)
Chronic kidney disease	<5	<5
Mild to moderate renal disease	0 (0)	0 (0)
Chronic liver disease	0 (0)	0 (0)
Moderate to severe liver disease	<5	<5
Any cancer diagnosis except non melanoma skin cancer	<5	7 (10.61)
Leukemia	0 (0)	<5
Lymphoma	0 (0)	<5
Metastasis	0 (0)	<5
Autoimmune disorders	7 (19.44)	11 (16.67)
Influenza infection or other respiratory infection	<5	17 (25.76)
HIV/AIDS	0 (0)	0 (0)
Sickle cell disease (CDC risk group)	0 (0)	<5
Connective tissue disease	12 (33.33)	16 (24.24)
Immunodeficiency except HIV	0 (0)	<5
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	13 (36.11)	20 (30.3)
Charlson Comorbidity Index		
0	>17	>32
1	7 (19.44)	12 (18.18)
2	<5	<5
>=3	7 (19.44)	17 (25.76)
Mean(SD)	1 (1)	2 (2)
Median (Q1, Q3)	0 (0-2)	0 (0-3)
Min, Max	0, 5	0, 14
CDC at-risk groups		
Group 0 (no conditions)	10 (27.78)	21 (31.82)
Group 1 (1 condition)	7 (19.44)	18 (27.27)
Group 2 (>1 condition)	19 (52.78)	27 (40.91)
COVID-19 history		

Table 15.6.2.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	<5	11 (16.67)
Positive test results for COVID-19	0 (0)	0 (0)

Table 15.6.3 Comorbidities at baseline in the Myocardites by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N =543	N =270
History of Anaphylaxis	17 (3.13)	<5
History of Allergies	71 (13.08)	25 (9.26)
Diabetes mellitus(types 1 and 2)	57 (10.5)	14 (5.19)
Hypertension (CDC risk group)	174 (32.04)	44 (16.3)
Cardiovascular disease	381 (70.17)	160 (59.26)
Myocardial infarction	71 (13.08)	29 (10.74)
Congestive heart failure	85 (15.65)	32 (11.85)
Cerebrovascular disease	34 (6.26)	13 (4.81)
Peripheral vascular disease	66 (12.15)	30 (11.11)
Chronic respiratory disease	165 (30.39)	70 (25.93)
Chronic kidney disease	5 (0.92)	0 (0)
Mild to moderate renal disease	<5	0 (0)
Chronic liver disease	<5	<5
Moderate to severe liver disease	12 (2.21)	9 (3.33)
Any cancer diagnosis except non melanoma skin cancer	75 (13.81)	16 (5.93)
Leukemia	0 (0)	0 (0)
Lymphoma	0 (0)	0 (0)
Metastasis	15 (2.76)	7 (2.59)
Autoimmune disorders	155 (28.55)	73 (27.04)
Influenza infection or other respiratory infection	200 (36.83)	95 (35.19)
HIV/AIDS	0 (0)	0 (0)
Sickle cell disease (CDC risk group)	<5	0 (0)
Connective tissue disease	185 (34.07)	75 (27.78)
Immunodeficiency except HIV	<5	<5
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	194 (35.73)	78 (28.89)
Charlson Comorbidity Index		
0	203 (37.38)	130 (48.15)
1	146 (26.89)	74 (27.41)
2	79 (14.55)	27 (10)
>=3	115 (21.18)	39 (14.44)
Mean(SD)	2 (2)	1 (2)
Median (Q1, Q3)	1 (0-2)	1 (0-1)
Min, Max	0, 14	0, 15
CDC at-risk groups		
Group 0 (no conditions)	102 (18.78)	70 (25.93)
Group 1 (1 condition)	164 (30.2)	98 (36.3)
Group 2 (>1 condition)	277 (51.01)	102 (37.78)
COVID-19 history		

Table 15.6.3 Comorbidities at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	21 (3.87)	5 (1.85)
Positive test results for COVID-19	72 (13.26)	42 (15.56)

Table 15.6.3.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N =1397	N =544
History of Anaphylaxis	36 (2.58)	13 (2.39)
History of Allergies	155 (11.1)	77 (14.15)
Diabetes mellitus(types 1 and 2)	199 (14.24)	43 (7.9)
Hypertension (CDC risk group)	524 (37.51)	120 (22.06)
Cardiovascular disease	1,048 (75.02)	318 (58.46)
Myocardial infarction	131 (9.38)	35 (6.43)
Congestive heart failure	161 (11.52)	35 (6.43)
Cerebrovascular disease	135 (9.66)	44 (8.09)
Peripheral vascular disease	271 (19.4)	61 (11.21)
Chronic respiratory disease	466 (33.36)	148 (27.21)
Chronic kidney disease	21 (1.5)	<5
Mild to moderate renal disease	12 (0.86)	<5
Chronic liver disease	19 (1.36)	15 (2.76)
Moderate to severe liver disease	43 (3.08)	24 (4.41)
Any cancer diagnosis except non melanoma skin cancer	240 (17.18)	62 (11.4)
Leukemia	0 (0)	0 (0)
Lymphoma	0 (0)	0 (0)
Metastasis	29 (2.08)	12 (2.21)
Autoimmune disorders	460 (32.93)	162 (29.78)
Influenza infection or other respiratory infection	627 (44.88)	209 (38.42)
HIV/AIDS	<5	<5
Sickle cell disease (CDC risk group)	<5	<5
Connective tissue disease	601 (43.02)	183 (33.64)
Immunodeficiency except HIV	11 (0.79)	<5
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	534 (38.22)	179 (32.9)
Charlson Comorbidity Index		
0	427 (30.57)	230 (42.28)
1	348 (24.91)	135 (24.82)
2	206 (14.75)	71 (13.05)
>=3	416 (29.78)	108 (19.85)
Mean(SD)	2 (2)	2 (2)
Median (Q1, Q3)	1 (0-3)	1 (0-2)
Min, Max	0, 13	0, 17
CDC at-risk groups		
Group 0 (no conditions)	203 (14.53)	143 (26.29)
Group 1 (1 condition)	362 (25.91)	165 (30.33)
Group 2 (>1 condition)	832 (59.56)	236 (43.38)
COVID-19 history		

Table 15.6.3.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	31 (2.22)	8 (1.47)
Positive test results for COVID-19	151 (10.81)	52 (9.56)

Table 15.6.4 Comorbidities at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N =75	N =41
History of Anaphylaxis	<5	0 (0)
History of Allergies	20 (26.67)	7 (17.07)
Diabetes mellitus(types 1 and 2)	<5	5 (12.2)
Hypertension (CDC risk group)	14 (18.67)	8 (19.51)
Cardiovascular disease	37 (49.33)	18 (43.9)
Myocardial infarction	5 (6.67)	0 (0)
Congestive heart failure	8 (10.67)	5 (12.2)
Cerebrovascular disease	5 (6.67)	<5
Peripheral vascular disease	5 (6.67)	<5
Chronic respiratory disease	23 (30.67)	10 (24.39)
Chronic kidney disease	8 (10.67)	<5
Mild to moderate renal disease	8 (10.67)	<5
Chronic liver disease	<5	<5
Moderate to severe liver disease	0 (0)	0 (0)
Any cancer diagnosis except non melanoma skin cancer	5 (6.67)	<5
Leukemia	<5	0 (0)
Lymphoma	<5	0 (0)
Metastasis	<5	0 (0)
Autoimmune disorders	5 (6.67)	5 (12.2)
Influenza infection or other respiratory infection	19 (25.33)	7 (17.07)
HIV/AIDS	0 (0)	0 (0)
Sickle cell disease (CDC risk group)	0 (0)	0 (0)
Connective tissue disease	41 (54.67)	22 (53.66)
Immunodeficiency except HIV	<5	<5
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	13 (17.33)	5 (12.2)
Charlson Comorbidity Index		
0	24 (32)	13 (31.71)
1	>31	>17
2	<5	6 (14.63)
>=3	15 (20)	<5
Mean(SD)	2 (2)	1 (1)
Median (Q1, Q3)	1 (0-1)	1 (0-1)
Min, Max	0, 11	0, 8
CDC at-risk groups		
Group 0 (no conditions)	26 (34.67)	16 (39.02)
Group 1 (1 condition)	25 (33.33)	15 (36.59)
Group 2 (>1 condition)	24 (32)	10 (24.39)
COVID-19 history		

Table 15.6.4 Comorbidities at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	0 (0)	0 (0)
Positive test results for COVID-19	24 (32)	10 (24.39)

Table 15.6.4.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N =302	N =133
History of Anaphylaxis	9 (2.98)	<5
History of Allergies	81 (26.82)	38 (28.57)
Diabetes mellitus(types 1 and 2)	45 (14.9)	16 (12.03)
Hypertension (CDC risk group)	88 (29.14)	24 (18.05)
Cardiovascular disease	155 (51.32)	62 (46.62)
Myocardial infarction	19 (6.29)	<5
Congestive heart failure	30 (9.93)	9 (6.77)
Cerebrovascular disease	11 (3.64)	<5
Peripheral vascular disease	18 (5.96)	7 (5.26)
Chronic respiratory disease	96 (31.79)	34 (25.56)
Chronic kidney disease	40 (13.25)	6 (4.51)
Mild to moderate renal disease	40 (13.25)	6 (4.51)
Chronic liver disease	6 (1.99)	<5
Moderate to severe liver disease	5 (1.66)	<5
Any cancer diagnosis except non melanoma skin cancer	22 (7.28)	8 (6.02)
Leukemia	<5	0 (0)
Lymphoma	<5	0 (0)
Metastasis	<5	<5
Autoimmune disorders	42 (13.91)	9 (6.77)
Influenza infection or other respiratory infection	50 (16.56)	21 (15.79)
HIV/AIDS	<5	0 (0)
Sickle cell disease (CDC risk group)	0 (0)	0 (0)
Connective tissue disease	219 (72.52)	69 (51.88)
Immunodeficiency except HIV	<5	0 (0)
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	76 (25.17)	19 (14.29)
Charlson Comorbidity Index		
0	59 (19.54)	41 (30.83)
1	130 (43.05)	60 (45.11)
2	44 (14.57)	15 (11.28)
>=3	69 (22.85)	17 (12.78)
Mean(SD)	2 (2)	1 (1)
Median (Q1, Q3)	1 (1-2)	1 (0-1)
Min, Max	0, 14	0, 9
CDC at-risk groups		
Group 0 (no conditions)	108 (35.76)	52 (39.1)
Group 1 (1 condition)	62 (20.53)	38 (28.57)
Group 2 (>1 condition)	132 (43.71)	43 (32.33)
COVID-19 history		

Table 15.6.4.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	11 (3.64)	9 (6.77)
Positive test results for COVID-19	91 (30.13)	26 (19.55)

Table 15.6.5 Comorbidities at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N =386	N =290
History of Anaphylaxis	<5	<5
History of Allergies	90 (23.32)	49 (16.9)
Diabetes mellitus(types 1 and 2)	43 (11.14)	26 (8.97)
Hypertension (CDC risk group)	103 (26.68)	55 (18.97)
Cardiovascular disease	191 (49.48)	118 (40.69)
Myocardial infarction	19 (4.92)	13 (4.48)
Congestive heart failure	53 (13.73)	34 (11.72)
Cerebrovascular disease	30 (7.77)	7 (2.41)
Peripheral vascular disease	37 (9.59)	21 (7.24)
Chronic respiratory disease	169 (43.78)	112 (38.62)
Chronic kidney disease	46 (11.92)	12 (4.14)
Mild to moderate renal disease	43 (11.14)	11 (3.79)
Chronic liver disease	23 (5.96)	16 (5.52)
Moderate to severe liver disease	<5	<5
Any cancer diagnosis except non melanoma skin cancer	33 (8.55)	13 (4.48)
Leukemia	<5	<5
Lymphoma	<5	<5
Metastasis	5 (1.3)	6 (2.07)
Autoimmune disorders	37 (9.59)	26 (8.97)
Influenza infection or other respiratory infection	201 (52.07)	127 (43.79)
HIV/AIDS	0 (0)	0 (0)
Sickle cell disease (CDC risk group)	0 (0)	<5
Connective tissue disease	187 (48.45)	99 (34.14)
Immunodeficiency except HIV	<5	<5
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	134 (34.72)	97 (33.45)
Charlson Comorbidity Index		
0	132 (34.2)	128 (44.14)
1	111 (28.76)	93 (32.07)
2	51 (13.21)	28 (9.66)
>=3	92 (23.83)	41 (14.14)
Mean(SD)	2 (2)	1 (2)
Median (Q1, Q3)	1 (0-2)	1 (0-1)
Min, Max	0, 14	0, 14
CDC at-risk groups		
Group 0 (no conditions)	114 (29.53)	83 (28.62)
Group 1 (1 condition)	82 (21.24)	82 (28.28)
Group 2 (>1 condition)	190 (49.22)	125 (43.1)
COVID-19 history		

Table 15.6.5 Comorbidities at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	157 (40.67)	100 (34.48)
Positive test results for COVID-19	54 (13.99)	45 (15.52)

Table 15.6.5.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N =894	N =770
History of Anaphylaxis	6 (0.67)	<5
History of Allergies	179 (20.02)	144 (18.7)
Diabetes mellitus(types 1 and 2)	192 (21.48)	86 (11.17)
Hypertension (CDC risk group)	369 (41.28)	169 (21.95)
Cardiovascular disease	585 (65.44)	387 (50.26)
Myocardial infarction	72 (8.05)	47 (6.1)
Congestive heart failure	164 (18.34)	69 (8.96)
Cerebrovascular disease	71 (7.94)	31 (4.03)
Peripheral vascular disease	134 (14.99)	79 (10.26)
Chronic respiratory disease	390 (43.62)	260 (33.77)
Chronic kidney disease	169 (18.9)	59 (7.66)
Mild to moderate renal disease	168 (18.79)	59 (7.66)
Chronic liver disease	65 (7.27)	47 (6.1)
Moderate to severe liver disease	11 (1.23)	9 (1.17)
Any cancer diagnosis except non melanoma skin cancer	88 (9.84)	37 (4.81)
Leukemia	9 (1.01)	5 (0.65)
Lymphoma	<5	5 (0.65)
Metastasis	13 (1.45)	11 (1.43)
Autoimmune disorders	110 (12.3)	84 (10.91)
Influenza infection or other respiratory infection	405 (45.3)	313 (40.65)
HIV/AIDS	0 (0)	0 (0)
Sickle cell disease (CDC risk group)	<5	<5
Connective tissue disease	478 (53.47)	356 (46.23)
Immunodeficiency except HIV	13 (1.45)	22 (2.86)
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	290 (32.44)	203 (26.36)
Charlson Comorbidity Index		
0	250 (27.96)	296 (38.44)
1	230 (25.73)	227 (29.48)
2	124 (13.87)	103 (13.38)
>=3	290 (32.44)	144 (18.7)
Mean(SD)	2 (3)	2 (2)
Median (Q1, Q3)	1 (0-3)	1 (0-2)
Min, Max	0, 15	0, 14
CDC at-risk groups		
Group 0 (no conditions)	199 (22.26)	256 (33.25)
Group 1 (1 condition)	194 (21.7)	200 (25.97)
Group 2 (>1 condition)	501 (56.04)	314 (40.78)
COVID-19 history		

Table 15.6.5.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	232 (25.95)	147 (19.09)
Positive test results for COVID-19	101 (11.3)	50 (6.49)

Table 15.6.6 Comorbidities at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N =513	N =350
History of Anaphylaxis	7 (1.36)	5 (1.43)
History of Allergies	77 (15.01)	49 (14)
Diabetes mellitus(types 1 and 2)	52 (10.14)	32 (9.14)
Hypertension (CDC risk group)	80 (15.59)	38 (10.86)
Cardiovascular disease	269 (52.44)	181 (51.71)
Myocardial infarction	25 (4.87)	10 (2.86)
Congestive heart failure	35 (6.82)	23 (6.57)
Cerebrovascular disease	12 (2.34)	<5
Peripheral vascular disease	<5	0 (0)
Chronic respiratory disease	281 (54.78)	169 (48.29)
Chronic kidney disease	22 (4.29)	7 (2)
Mild to moderate renal disease	19 (3.7)	<5
Chronic liver disease	<5	<5
Moderate to severe liver disease	33 (6.43)	19 (5.43)
Any cancer diagnosis except non melanoma skin cancer	24 (4.68)	5 (1.43)
Leukemia	<5	0 (0)
Lymphoma	0 (0)	0 (0)
Metastasis	<5	0 (0)
Autoimmune disorders	55 (10.72)	42 (12)
Influenza infection or other respiratory infection	68 (13.26)	31 (8.86)
HIV/AIDS	<5	0 (0)
Sickle cell disease (CDC risk group)	<5	<5
Connective tissue disease	55 (10.72)	35 (10)
Immunodeficiency except HIV	0 (0)	0 (0)
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	152 (29.63)	85 (24.29)
Charlson Comorbidity Index		
0	249 (48.54)	174 (49.71)
1	128 (24.95)	109 (31.14)
2	53 (10.33)	31 (8.86)
>=3	83 (16.18)	36 (10.29)
Mean(SD)	1 (2)	1 (1)
Median (Q1, Q3)	1 (0-2)	1 (0-1)
Min, Max	0, 11	0, 9
CDC at-risk groups		
Group 0 (no conditions)	124 (24.17)	86 (24.57)
Group 1 (1 condition)	144 (28.07)	112 (32)
Group 2 (>1 condition)	245 (47.76)	152 (43.43)
COVID-19 history		

Table 15.6.6 Comorbidities at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	162 (31.58)	100 (28.57)
Positive test results for COVID-19	142 (27.68)	90 (25.71)

Table 15.6.6.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Comorbidities, n (%)	N =1072	N =750
History of Anaphylaxis	20 (1.87)	<5
History of Allergies	188 (17.54)	101 (13.47)
Diabetes mellitus(types 1 and 2)	138 (12.87)	72 (9.6)
Hypertension (CDC risk group)	204 (19.03)	80 (10.67)
Cardiovascular disease	568 (52.99)	348 (46.4)
Myocardial infarction	46 (4.29)	37 (4.93)
Congestive heart failure	37 (3.45)	21 (2.8)
Cerebrovascular disease	25 (2.33)	6 (0.8)
Peripheral vascular disease	10 (0.93)	<5
Chronic respiratory disease	579 (54.01)	375 (50)
Chronic kidney disease	59 (5.5)	21 (2.8)
Mild to moderate renal disease	42 (3.92)	15 (2)
Chronic liver disease	6 (0.56)	<5
Moderate to severe liver disease	97 (9.05)	67 (8.93)
Any cancer diagnosis except non melanoma skin cancer	64 (5.97)	17 (2.27)
Leukemia	5 (0.47)	5 (0.67)
Lymphoma	0 (0)	0 (0)
Metastasis	<5	<5
Autoimmune disorders	131 (12.22)	72 (9.6)
Influenza infection or other respiratory infection	110 (10.26)	86 (11.47)
HIV/AIDS	<5	<5
Sickle cell disease (CDC risk group)	<5	<5
Connective tissue disease	156 (14.55)	71 (9.47)
Immunodeficiency except HIV	0 (0)	<5
Human immunodeficiency virus (HIV) and other immunosuppressing conditions	300 (27.99)	189 (25.2)
Charlson Comorbidity Index		
0	421 (39.27)	353 (47.07)
1	317 (29.57)	211 (28.13)
2	102 (9.51)	60 (8)
>=3	232 (21.64)	126 (16.8)
Mean(SD)	1 (2)	1 (2)
Median (Q1, Q3)	1 (0-2)	1 (0-1)
Min, Max	0, 11	0, 13
CDC at-risk groups		
Group 0 (no conditions)	251 (23.41)	208 (27.73)
Group 1 (1 condition)	291 (27.15)	220 (29.33)
Group 2 (>1 condition)	530 (49.44)	322 (42.93)
COVID-19 history		

Table 15.6.6.1 Comorbidities at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Previous diagnosis of COVID-19	321 (29.94)	133 (17.73)
Positive test results for COVID-19	294 (27.43)	119 (15.87)

Table 15.7.1 Surrogates of frailty at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =0	N =0
Wheelchair use	0	0
Home hospital bed	0	0
Paralysis	0	0
Hemiplegia or paraplegia	0	0
Parkinsons disease	0	0
Skin ulcer	0	0
Weakness	0	0
Stroke/brain injury	0	0
Ambulance transport	0	0
Dementia	0	0
Difficulty walking	0	0
Home oxygen	0	0
Rehabilitation care	0	0
Psychiatric illness	0	0
Sepsis	0	0
Heart failure	0	0
Podiatric care	0	0
Bladder incontinence	0	0
Diabetes with chronic complication	0	0
Arthritis	0	0
Coagulation deficiencies	0	0
Vertigo	0	0
Algorithm for Lipid abnormalities	0	0

Table 15.7.1.1 Surrogates of frailty at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for PEDIANET

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =1	N =1
Wheelchair use	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)
Paralysis	0 (0)	0 (0)
Hemiplegia or paraplegia	0 (0)	0 (0)
Parkinsons disease	0 (0)	0 (0)
Skin ulcer	0 (0)	0 (0)
Weakness	0 (0)	0 (0)
Stroke/brain injury	0 (0)	0 (0)
Ambulance transport	0 (0)	0 (0)
Dementia	0 (0)	0 (0)
Difficulty walking	0 (0)	0 (0)
Home oxygen	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)
Psychiatric illness	0 (0)	0 (0)
Sepsis	0 (0)	0 (0)
Heart failure	0 (0)	0 (0)
Podiatric care	0 (0)	0 (0)
Bladder incontinence	0 (0)	0 (0)
Diabetes with chronic complication	0 (0)	0 (0)
Arthritis	0 (0)	0 (0)
Coagulation deficiencies	0 (0)	0 (0)
Vertigo	0 (0)	0 (0)
Algorithm for Lipid abnormalities	0 (0)	0 (0)

Table 15.7.2 Surrogates of frailty at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =304	N =370
Wheelchair use	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)
Paralysis	0 (0)	<5
Hemiplegia or paraplegia	0 (0)	0 (0)
Parkinsons disease	0 (0)	0 (0)
Skin ulcer	<5	<5
Weakness	12 (3.95)	5 (1.35)
Stroke/brain injury	<5	5 (1.35)
Ambulance transport	0 (0)	0 (0)
Dementia	0 (0)	<5
Difficulty walking	0 (0)	0 (0)
Home oxygen	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)
Psychiatric illness	5 (1.64)	<5
Sepsis	<5	<5
Heart failure	<5	6 (1.62)
Podiatric care	0 (0)	0 (0)
Bladder incontinence	<5	<5
Diabetes with chronic complication	<5	<5
Arthritis	7 (2.3)	11 (2.97)
Coagulation deficiencies	0 (0)	<5
Vertigo	5 (1.64)	5 (1.35)
Algorithm for Lipid abnormalities	56 (18.42)	55 (14.86)

Table 15.7.2.1 Surrogates of frailty at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for PHARMO

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =36	N =66
Wheelchair use	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)
Paralysis	0 (0)	<5
Hemiplegia or paraplegia	0 (0)	<5
Parkinsons disease	0 (0)	0 (0)
Skin ulcer	0 (0)	0 (0)
Weakness	<5	0 (0)
Stroke/brain injury	<5	<5
Ambulance transport	0 (0)	0 (0)
Dementia	0 (0)	<5
Difficulty walking	0 (0)	0 (0)
Home oxygen	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)
Psychiatric illness	<5	<5
Sepsis	0 (0)	<5
Heart failure	<5	5 (7.58)
Podiatric care	0 (0)	0 (0)
Bladder incontinence	0 (0)	0 (0)
Diabetes with chronic complication	0 (0)	<5
Arthritis	<5	0 (0)
Coagulation deficiencies	<5	0 (0)
Vertigo	<5	<5
Algorithm for Lipid abnormalities	11 (30.56)	12 (18.18)

Table 15.7.3 Surrogates of frailty at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =543	N =270
Wheelchair use	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)
Paralysis	<5	0 (0)
Hemiplegia or paraplegia	0 (0)	0 (0)
Parkinsons disease	0 (0)	<5
Skin ulcer	12 (2.21)	<5
Weakness	24 (4.42)	13 (4.81)
Stroke/brain injury	14 (2.58)	<5
Ambulance transport	0 (0)	0 (0)
Dementia	<5	0 (0)
Difficulty walking	0 (0)	0 (0)
Home oxygen	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)
Psychiatric illness	35 (6.45)	28 (10.37)
Sepsis	11 (2.03)	<5
Heart failure	56 (10.31)	25 (9.26)
Podiatric care	0 (0)	0 (0)
Bladder incontinence	5 (0.92)	<5
Diabetes with chronic complication	6 (1.1)	<5
Arthritis	57 (10.5)	24 (8.89)
Coagulation deficiencies	<5	<5
Vertigo	18 (3.31)	11 (4.07)
Algorithm for Lipid abnormalities	148 (27.26)	41 (15.19)

Table 15.7.3.1 Surrogates of frailty at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =1397	N =544
Wheelchair use	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)
Paralysis	<5	<5
Hemiplegia or paraplegia	0 (0)	0 (0)
Parkinsons disease	<5	<5
Skin ulcer	29 (2.08)	7 (1.29)
Weakness	74 (5.3)	24 (4.41)
Stroke/brain injury	42 (3.01)	14 (2.57)
Ambulance transport	0 (0)	0 (0)
Dementia	8 (0.57)	<5
Difficulty walking	0 (0)	0 (0)
Home oxygen	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)
Psychiatric illness	78 (5.58)	44 (8.09)
Sepsis	26 (1.86)	7 (1.29)
Heart failure	114 (8.16)	27 (4.96)
Podiatric care	0 (0)	0 (0)
Bladder incontinence	13 (0.93)	<5
Diabetes with chronic complication	15 (1.07)	<5
Arthritis	183 (13.1)	56 (10.29)
Coagulation deficiencies	<5	<5
Vertigo	62 (4.44)	12 (2.21)
Algorithm for Lipid abnormalities	475 (34)	124 (22.79)

Table 15.7.4 Surrogates of frailty at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =75	N =41
Wheelchair use	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)
Paralysis	0 (0)	0 (0)
Hemiplegia or paraplegia	0 (0)	0 (0)
Parkinsons disease	0 (0)	<5
Skin ulcer	<5	0 (0)
Weakness	<5	0 (0)
Stroke/brain injury	0 (0)	0 (0)
Ambulance transport	0 (0)	0 (0)
Dementia	<5	0 (0)
Difficulty walking	0 (0)	0 (0)
Home oxygen	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)
Psychiatric illness	<5	<5
Sepsis	0 (0)	0 (0)
Heart failure	5 (6.67)	<5
Podiatric care	0 (0)	0 (0)
Bladder incontinence	0 (0)	0 (0)
Diabetes with chronic complication	0 (0)	<5
Arthritis	<5	<5
Coagulation deficiencies	<5	<5
Vertigo	<5	0 (0)
Algorithm for Lipid abnormalities	16 (21.33)	10 (24.39)

Table 15.7.4.1 Surrogates of frailty at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for EPICHRON

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =302	N =133
Wheelchair use	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)
Paralysis	<5	0 (0)
Hemiplegia or paraplegia	0 (0)	0 (0)
Parkinsons disease	<5	0 (0)
Skin ulcer	<5	<5
Weakness	<5	0 (0)
Stroke/brain injury	5 (1.66)	<5
Ambulance transport	0 (0)	0 (0)
Dementia	<5	0 (0)
Difficulty walking	0 (0)	0 (0)
Home oxygen	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)
Psychiatric illness	28 (9.27)	11 (8.27)
Sepsis	<5	<5
Heart failure	24 (7.95)	6 (4.51)
Podiatric care	0 (0)	0 (0)
Bladder incontinence	<5	0 (0)
Diabetes with chronic complication	8 (2.65)	<5
Arthritis	55 (18.21)	13 (9.77)
Coagulation deficiencies	5 (1.66)	<5
Vertigo	5 (1.66)	<5
Algorithm for Lipid abnormalities	90 (29.8)	36 (27.07)

Table 15.7.5 Surrogates of frailty at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =386	N =290
Wheelchair use	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)
Paralysis	<5	<5
Hemiplegia or paraplegia	<5	0 (0)
Parkinsons disease	<5	0 (0)
Skin ulcer	7 (1.81)	<5
Weakness	9 (2.33)	8 (2.76)
Stroke/brain injury	15 (3.89)	<5
Ambulance transport	0 (0)	0 (0)
Dementia	15 (3.89)	<5
Difficulty walking	<5	<5
Home oxygen	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)
Psychiatric illness	56 (14.51)	37 (12.76)
Sepsis	5 (1.3)	<5
Heart failure	31 (8.03)	19 (6.55)
Podiatric care	0 (0)	0 (0)
Bladder incontinence	18 (4.66)	<5
Diabetes with chronic complication	6 (1.55)	<5
Arthritis	53 (13.73)	21 (7.24)
Coagulation deficiencies	<5	<5
Vertigo	14 (3.63)	<5
Algorithm for Lipid abnormalities	85 (22.02)	34 (11.72)

Table 15.7.5.1 Surrogates of frailty at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =894	N =770
Wheelchair use	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)
Paralysis	7 (0.78)	<5
Hemiplegia or paraplegia	5 (0.56)	<5
Parkinsons disease	<5	<5
Skin ulcer	15 (1.68)	<5
Weakness	34 (3.8)	21 (2.73)
Stroke/brain injury	25 (2.8)	16 (2.08)
Ambulance transport	0 (0)	0 (0)
Dementia	21 (2.35)	5 (0.65)
Difficulty walking	11 (1.23)	<5
Home oxygen	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)
Psychiatric illness	141 (15.77)	91 (11.82)
Sepsis	17 (1.9)	8 (1.04)
Heart failure	116 (12.98)	40 (5.19)
Podiatric care	0 (0)	0 (0)
Bladder incontinence	37 (4.14)	14 (1.82)
Diabetes with chronic complication	42 (4.7)	18 (2.34)
Arthritis	148 (16.55)	75 (9.74)
Coagulation deficiencies	7 (0.78)	6 (0.78)
Vertigo	47 (5.26)	30 (3.9)
Algorithm for Lipid abnormalities	314 (35.12)	179 (23.25)

Table 15.7.6 Surrogates of frailty at baseline in the Myocarditis by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =513	N =350
Wheelchair use	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)
Paralysis	0 (0)	0 (0)
Hemiplegia or paraplegia	0 (0)	0 (0)
Parkinsons disease	<5	0 (0)
Skin ulcer	<5	0 (0)
Weakness	9 (1.75)	6 (1.71)
Stroke/brain injury	<5	<5
Ambulance transport	0 (0)	0 (0)
Dementia	<5	<5
Difficulty walking	0 (0)	0 (0)
Home oxygen	0 (0)	<5
Rehabilitation care	0 (0)	0 (0)
Psychiatric illness	26 (5.07)	18 (5.14)
Sepsis	7 (1.36)	<5
Heart failure	22 (4.29)	14 (4)
Podiatric care	7 (1.36)	5 (1.43)
Bladder incontinence	<5	<5
Diabetes with chronic complication	8 (1.56)	6 (1.71)
Arthritis	13 (2.53)	12 (3.43)
Coagulation deficiencies	0 (0)	<5
Vertigo	10 (1.95)	8 (2.29)
Algorithm for Lipid abnormalities	138 (26.9)	61 (17.43)

Table 15.7.6.1 Surrogates of frailty at baseline in the Pericarditis by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Characteristic, n (%)	N =1072	N =750
Wheelchair use	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)
Paralysis	0 (0)	0 (0)
Hemiplegia or paraplegia	0 (0)	0 (0)
Parkinsons disease	<5	0 (0)
Skin ulcer	<5	<5
Weakness	17 (1.59)	12 (1.6)
Stroke/brain injury	9 (0.84)	<5
Ambulance transport	0 (0)	0 (0)
Dementia	<5	0 (0)
Difficulty walking	<5	<5
Home oxygen	0 (0)	0 (0)
Rehabilitation care	<5	0 (0)
Psychiatric illness	59 (5.5)	42 (5.6)
Sepsis	5 (0.47)	5 (0.67)
Heart failure	21 (1.96)	14 (1.87)
Podiatric care	20 (1.87)	5 (0.67)
Bladder incontinence	6 (0.56)	<5
Diabetes with chronic complication	29 (2.71)	8 (1.07)
Arthritis	48 (4.48)	13 (1.73)
Coagulation deficiencies	<5	<5
Vertigo	32 (2.99)	10 (1.33)
Algorithm for Lipid abnormalities	250 (23.32)	120 (16)

Table 15.8.1 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the myocarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for Pedianet

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =0	N =0
Influenza	0	0
Pneumococcal vaccine	0	0
DTP (diphtheria tetanus and pertussis)	0	0
TPV (polio)	0	0
TV (MMR) (measles mumps and rubella)	0	0
Hib (Haemophilus influenzae type b)	0	0
HBV (hepatitis B virus)	0	0
VZV (varicella-zoster virus)	0	0
HPV (human papillomavirus)	0	0
Meningitis	0	0
Rotavirus	0	0
Medication, n (%)		
Analgesics	0	0
Antibiotics	0	0
Antivirals	0	0
Corticosteroids	0	0
Non-steroidal anti-inflammatory drugs (NS	0	0
Psychotropics	0	0
Statins	0	0
Novel oral anticoagulant	0	0
Warfarin	0	0

Table 15.8.1.1 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the pericarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for Pedianet

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =1	N =1
Influenza	0 (0)	0 (0)
Pneumococcal vaccine	0 (0)	0 (0)
DTP (diphtheria tetanus and pertussis)	0 (0)	0 (0)
TPV (polio)	0 (0)	0 (0)
TV (MMR) (measles mumps and rubella)	0 (0)	0 (0)
Hib (Haemophilus influenzae type b)	0 (0)	0 (0)
HBV (hepatitis B virus)	0 (0)	0 (0)
VZV (varicella-zoster virus)	0 (0)	0 (0)
HPV (human papillomavirus)	0 (0)	0 (0)
Meningitis	0 (0)	0 (0)
Rotavirus	0 (0)	0 (0)
Medication, n (%)		
Analgesics	0 (0)	0 (0)
Antibiotics	0 (0)	<5
Antivirals	0 (0)	0 (0)
Corticosteroids	0 (0)	0 (0)
Non-steroidal anti-inflammatory drugs (NS	0 (0)	0 (0)
Psychotropics	0 (0)	0 (0)
Statins	0 (0)	0 (0)
Novel oral anticoagulant	0 (0)	0 (0)
Warfarin	0 (0)	0 (0)

Table 15.8.2 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the myocarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for Pharmo

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =304	N =370
Influenza	0 (0)	0 (0)
Pneumococal vaccine	0 (0)	0 (0)
DTP (diphtheria tetanus and pertussis)	0 (0)	0 (0)
TPV (polio)	0 (0)	0 (0)
TV (MMR) (measles mumps and rubella)	0 (0)	0 (0)
Hib (Haemophilus influenzae type b)	0 (0)	0 (0)
HBV (hepatitis B virus)	0 (0)	0 (0)
VZV (varicella-zoster virus)	0 (0)	0 (0)
HPV (human papillomavirus)	0 (0)	0 (0)
Meningitis	0 (0)	0 (0)
Rotavirus	0 (0)	0 (0)
Medication, n (%)		
Analgesics	60 (19)	67 (18)
Antibiotics	71 (23)	93 (25)
Antivirals	<5	<5
Corticosteroids	33 (10)	41 (11)
Non-steroidal anti-inflammatory drugs (NS	71 (23)	98 (26)
Psychotropics	35 (11)	57 (15)
Statins	56 (18)	53 (14)
Novel oral anticoagulant	59 (19)	55 (14)
Warfarin	0 (0)	0 (0)

Table 15.8.2.1 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the pericarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for Pharmo

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =36	N =66
Influenza	0 (0)	0 (0)
Pneumococal vaccine	0 (0)	0 (0)
DTP (diphtheria tetanus and pertussis)	0 (0)	0 (0)
TPV (polio)	0 (0)	0 (0)
TV (MMR) (measles mumps and rubella)	0 (0)	0 (0)
Hib (Haemophilus influenzae type b)	0 (0)	0 (0)
HBV (hepatitis B virus)	0 (0)	0 (0)
VZV (varicella-zoster virus)	0 (0)	0 (0)
HPV (human papillomavirus)	0 (0)	0 (0)
Meningitis	0 (0)	0 (0)
Rotavirus	0 (0)	0 (0)
Medication, n (%)		
Analgesics	6 (16)	5 (7.5)
Antibiotics	11 (30)	15 (22)
Antivirals	0 (0)	0 (0)
Corticosteroids	5 (13)	<5
Non-steroidal anti-inflammatory drugs (NS	<5	9 (13)
Psychotropics	<5	7 (10)
Statins	11 (30)	12 (18)
Novel oral anticoagulant	8 (22)	9 (13)
Warfarin	0 (0)	0 (0)

Table 15.8.3 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the myocarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =543	N =270
Influenza	0 (0)	0 (0)
Pneumococcal vaccine	0 (0)	0 (0)
DTP (diphtheria tetanus and pertussis)	<5	13 (4.81)
TPV (polio)	<5	13 (4.81)
TV (MMR) (measles mumps and rubella)	0 (0)	0 (0)
Hib (Haemophilus influenzae type b)	5 (0.92)	13 (4.81)
HBV (hepatitis B virus)	21 (3.87)	14 (5.19)
VZV (varicella-zoster virus)	0 (0)	0 (0)
HPV (human papillomavirus)	0 (0)	0 (0)
Meningitis	0 (0)	0 (0)
Rotavirus	0 (0)	0 (0)
Medication, n (%)		
Analgesics	177 (32.6)	73 (27.04)
Antibiotics	168 (30.94)	77 (28.52)
Antivirals	8 (1.47)	5 (1.85)
Corticosteroids	83 (15.29)	36 (13.33)
Non-steroidal anti-inflammatory drugs (NS	130 (23.94)	61 (22.59)
Psychotropics	126 (23.2)	56 (20.74)
Statins	142 (26.15)	36 (13.33)
Novel oral anticoagulant	139 (25.6)	47 (17.41)
Warfarin	12 (2.21)	6 (2.22)

Table 15.8.3.1 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the pericarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for NHR

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =1397	N =544
Influenza	0 (0)	0 (0)
Pneumococcal vaccine	0 (0)	0 (0)
DTP (diphtheria tetanus and pertussis)	5 (0.36)	22 (4.04)
TPV (polio)	5 (0.36)	23 (4.23)
TV (MMR) (measles mumps and rubella)	0 (0)	0 (0)
Hib (Haemophilus influenzae type b)	6 (0.43)	23 (4.23)
HBV (hepatitis B virus)	60 (4.29)	23 (4.23)
VZV (varicella-zoster virus)	0 (0)	0 (0)
HPV (human papillomavirus)	0 (0)	0 (0)
Meningitis	0 (0)	0 (0)
Rotavirus	0 (0)	0 (0)
Medication, n (%)		
Analgesics	603 (43.16)	187 (34.38)
Antibiotics	489 (35)	147 (27.02)
Antivirals	37 (2.65)	15 (2.76)
Corticosteroids	200 (14.32)	64 (11.76)
Non-steroidal anti-inflammatory drugs (NS	341 (24.41)	133 (24.45)
Psychotropics	349 (24.98)	136 (25)
Statins	446 (31.93)	117 (21.51)
Novel oral anticoagulant	493 (35.29)	132 (24.26)
Warfarin	49 (3.51)	8 (1.47)

Table 15.8.4 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the myocarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for EpiChron

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =75	N =41
Influenza	30 (40)	9 (21.95)
Pneumococcal vaccine	8 (10.67)	<5
DTP (diphtheria tetanus and pertussis)	16 (21.33)	9 (21.95)
TPV (polio)	<5	0 (0)
TV (MMR) (measles mumps and rubella)	<5	<5
Hib (Haemophilus influenzae type b)	<5	0 (0)
HBV (hepatitis B virus)	<5	0 (0)
VZV (varicella-zoster virus)	0 (0)	0 (0)
HPV (human papillomavirus)	0 (0)	<5
Meningitis	15 (20)	<5
Rotavirus	0 (0)	0 (0)
Medication, n (%)		
Analgesics	34 (45.33)	18 (43.9)
Antibiotics	33 (44)	14 (34.15)
Antivirals	<5	0 (0)
Corticosteroids	8 (10.67)	<5
Non-steroidal anti-inflammatory drugs (NS	37 (49.33)	14 (34.15)
Psychotropics	21 (28)	9 (21.95)
Statins	14 (18.67)	10 (24.39)
Novel oral anticoagulant	14 (18.67)	6 (14.63)
Warfarin	0 (0)	0 (0)

Table 15.8.4.1 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the pericarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for EpiChron

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =302	N =133
Influenza	135 (44.7)	35 (26.32)
Pneumococal vaccine	37 (12.25)	7 (5.26)
DTP (diphtheria tetanus and pertussis)	80 (26.49)	33 (24.81)
TPV (polio)	0 (0)	0 (0)
TV (MMR) (measles mumps and rubella)	11 (3.64)	<5
Hib (Haemophilus influenzae type b)	<5	<5
HBV (hepatitis B virus)	9 (2.98)	<5
VZV (varicella-zoster virus)	6 (1.99)	<5
HPV (human papillomavirus)	8 (2.65)	6 (4.51)
Meningitis	38 (12.58)	15 (11.28)
Rotavirus	0 (0)	0 (0)
Medication, n (%)		
Analgesics	164 (54.3)	53 (39.85)
Antibiotics	109 (36.09)	42 (31.58)
Antivirals	<5	<5
Corticosteroids	53 (17.55)	17 (12.78)
Non-steroidal anti-inflammatory drugs (NS	148 (49.01)	61 (45.86)
Psychotropics	108 (35.76)	28 (21.05)
Statins	83 (27.48)	35 (26.32)
Novel oral anticoagulant	61 (20.2)	19 (14.29)
Warfarin	0 (0)	0 (0)

Table 15.8.5 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the myocarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =386	N =290
Influenza	135 (34.97)	64 (22.07)
Pneumococal vaccine	48 (12.44)	97 (33.45)
DTP (diphtheria tetanus and pertussis)	54 (13.99)	107 (36.9)
TPV (polio)	18 (4.66)	86 (29.66)
TV (MMR) (measles mumps and rubella)	44 (11.4)	101 (34.83)
Hib (Haemophilus influenzae type b)	19 (4.92)	85 (29.31)
HBV (hepatitis B virus)	20 (5.18)	85 (29.31)
VZV (varicella-zoster virus)	0 (0)	0 (0)
HPV (human papillomavirus)	0 (0)	0 (0)
Meningitis	84 (21.76)	110 (37.93)
Rotavirus	5 (1.3)	36 (12.41)
Medication, n (%)		
Analgesics	160 (41.45)	122 (42.07)
Antibiotics	121 (31.35)	84 (28.97)
Antivirals	<5	<5
Corticosteroids	50 (12.95)	40 (13.79)
Non-steroidal anti-inflammatory drugs (NS	107 (27.72)	84 (28.97)
Psychotropics	87 (22.54)	42 (14.48)
Statins	72 (18.65)	32 (11.03)
Novel oral anticoagulant	69 (17.88)	34 (11.72)
Warfarin	0 (0)	<5

Table 15.8.5.1 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the pericarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for SIDIAP

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =894	N =770
Influenza	466 (52.13)	235 (30.52)
Pneumococcal vaccine	127 (14.21)	104 (13.51)
DTP (diphtheria tetanus and pertussis)	23 (2.57)	47 (6.1)
TPV (polio)	5 (0.56)	26 (3.38)
TV (MMR) (measles mumps and rubella)	18 (2.01)	39 (5.06)
Hib (Haemophilus influenzae type b)	8 (0.89)	25 (3.25)
HBV (hepatitis B virus)	19 (2.13)	32 (4.16)
VZV (varicella-zoster virus)	0 (0)	0 (0)
HPV (human papillomavirus)	0 (0)	0 (0)
Meningitis	71 (7.94)	64 (8.31)
Rotavirus	0 (0)	8 (1.04)
Medication, n (%)		
Analgesics	472 (52.8)	315 (40.91)
Antibiotics	288 (32.21)	183 (23.77)
Antivirals	10 (1.12)	10 (1.3)
Corticosteroids	108 (12.08)	77 (10)
Non-steroidal anti-inflammatory drugs (NS	226 (25.28)	216 (28.05)
Psychotropics	266 (29.75)	157 (20.39)
Statins	272 (30.43)	146 (18.96)
Novel oral anticoagulant	238 (26.62)	118 (15.32)
Warfarin	<5	7 (0.91)

Table 15.8.6 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the myocarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =513	N =350
Influenza	246 (47.95)	117 (33.43)
Pneumococcal vaccine	0 (0)	0 (0)
DTP (diphtheria tetanus and pertussis)	304 (59.26)	194 (55.43)
TPV (polio)	313 (61.01)	193 (55.14)
TV (MMR) (measles mumps and rubella)	218 (42.5)	145 (41.43)
Hib (Haemophilus influenzae type b)	0 (0)	0 (0)
HBV (hepatitis B virus)	57 (11.11)	27 (7.71)
VZV (varicella-zoster virus)	<5	<5
HPV (human papillomavirus)	25 (4.87)	11 (3.14)
Meningitis	213 (41.52)	134 (38.29)
Rotavirus	<5	12 (3.43)
Medication, n (%)		
Analgesics	79 (15.4)	53 (15.14)
Antibiotics	99 (19.3)	51 (14.57)
Antivirals	7 (1.36)	5 (1.43)
Corticosteroids	44 (8.58)	27 (7.71)
Non-steroidal anti-inflammatory drugs (NS	0 (0)	0 (0)
Psychotropics	35 (6.82)	20 (5.71)
Statins	86 (16.76)	24 (6.86)
Novel oral anticoagulant	25 (4.87)	5 (1.43)
Warfarin	6 (1.17)	<5

Table 15.8.6.1 Comedications and vaccinations at baseline recorded in the year prior to time zeroDx in the pericarditis cohort overall by Pfizer-BioNTech COVID-19 vaccination status for CPRD

label	Vaccinated	Unvaccinated
Vaccine, n (%)	N =1072	N =750
Influenza	567 (52.89)	251 (33.47)
Pneumococcal vaccine	0 (0)	0 (0)
DTP (diphtheria tetanus and pertussis)	601 (56.06)	395 (52.67)
TPV (polio)	616 (57.46)	415 (55.33)
TV (MMR) (measles mumps and rubella)	381 (35.54)	262 (34.93)
Hib (Haemophilus influenzae type b)	0 (0)	0 (0)
HBV (hepatitis B virus)	129 (12.03)	73 (9.73)
VZV (varicella-zoster virus)	<5	<5
HPV (human papillomavirus)	74 (6.9)	31 (4.13)
Meningitis	386 (36.01)	259 (34.53)
Rotavirus	<5	<5
Medication, n (%)		
Analgesics	222 (20.71)	121 (16.13)
Antibiotics	243 (22.67)	148 (19.73)
Antivirals	10 (0.93)	6 (0.8)
Corticosteroids	98 (9.14)	49 (6.53)
Non-steroidal anti-inflammatory drugs (NS	0 (0)	0 (0)
Psychotropics	76 (7.09)	64 (8.53)
Statins	170 (15.86)	77 (10.27)
Novel oral anticoagulant	51 (4.76)	28 (3.73)
Warfarin	16 (1.49)	<5

Table 15.9.1 COVID-19 vaccination status at time zeroDX in Pfizer-BioNTech COVID-19 vaccinated individuals for PEDIANET

Characteristic, n (%)	Myocarditis	Pericarditis
Total	N =0	N =1
Time since last dose		
Received last dose in the previous 14 days	0 (NaN)	<5
Received last dose 15 or more days ago	0 (NaN)	0 (0)
Number of doses received		
1	0 (NaN)	<5
2	0 (NaN)	0 (0)
3	0 (NaN)	0 (0)
4+	0 (NaN)	0 (0)
Vaccination status		
Received 1 dose in previous 14 days	0 (NaN)	1 (100)
Received 1 dose, 15 or more days ago	0 (NaN)	0 (0)
Received 2 doses, last dose in previous 14 days	0 (NaN)	0 (0)
Received 2 doses, last dose >=15 days ago	0 (NaN)	0 (0)
Received 3 doses, last dose in previous 14 days	0 (NaN)	0 (0)
Received 3 doses, last dose >=15 days ago	0 (NaN)	0 (0)
Received 4 doses, last dose in previous 14 days	0 (NaN)	0 (0)
Received 4 doses, last dose >=15 days ago	0 (NaN)	0 (0)

Table 15.9.2 COVID-19 vaccination status at time zeroDX in Pfizer-BioNTech COVID-19 vaccinated individuals for PHARMO

Characteristic, n (%)	Myocarditis	Pericarditis
Total	N =304	N =36
Time since last dose		
Received last dose in the previous 14 days	27 (8.88)	<5
Received last dose 15 or more days ago	275 (90.46)	>31
Number of doses received		
1	100 (32.89)	13 (36.11)
2	158 (51.97)	17 (47.22)
3	40 (13.16)	6 (16.67)
4+	6 (1.97)	0 (0)
Vaccination status		
Received 1 dose in previous 14 days	12 (3.95)	2 (5.56)
Received 1 dose, 15 or more days ago	88 (28.95)	>31
Received 2 doses, last dose in previous 14 days	13 (4.28)	<5
Received 2 doses, last dose >=15 days ago	>299	>31
Received 3 doses, last dose in previous 14 days	<5	<5
Received 3 doses, last dose >=15 days ago	>299	<5
Received 4 doses, last dose in previous 14 days	<5	>31
Received 4 doses, last dose >=15 days ago	<5	0 (0)

Table 15.9.3 COVID-19 vaccination status at time zeroDX in Pfizer-BioNTech COVID-19 vaccinated individuals for NHR

Characteristic, n (%)	Myocarditis	Pericarditis
Total	N =543	N =1397
Time since last dose		
Received last dose in the previous 14 days	49 (9.02)	132 (9.45)
Received last dose 15 or more days ago	494 (90.98)	1265 (90.55)
Number of doses received		
1	85 (15.65)	183 (13.1)
2	242 (44.57)	592 (42.38)
3	186 (34.25)	536 (38.37)
4+	30 (5.52)	86 (6.16)
Vaccination status		
Received 1 dose in previous 14 days	18 (3.31)	49 (3.51)
Received 1 dose, 15 or more days ago	67 (12.34)	134 (9.59)
Received 2 doses, last dose in previous 14 days	12 (2.21)	59 (4.22)
Received 2 doses, last dose >=15 days ago	230 (42.36)	533 (38.15)
Received 3 doses, last dose in previous 14 days	13 (2.39)	24 (1.72)
Received 3 doses, last dose >=15 days ago	173 (31.86)	512 (36.65)
Received 4 doses, last dose in previous 14 days	6 (1.1)	11 (0.79)
Received 4 doses, last dose >=15 days ago	24 (4.42)	75 (5.37)

Table 15.9.4 COVID-19 vaccination status at time zeroDX in Pfizer-BioNTech COVID-19 vaccinated individuals for EPICHRON

Characteristic, n (%)	Myocarditis	Pericarditis
Total	N =75	N =302
Time since last dose		
Received last dose in the previous 14 days	6 (8)	20 (6.62)
Received last dose 15 or more days ago	69 (92)	281 (93.05)
Number of doses received		
1	14 (18.67)	29 (9.6)
2	38 (50.67)	184 (60.93)
3	23 (30.67)	77 (25.5)
4+	0 (0)	12 (3.97)
Vaccination status		
Received 1 dose in previous 14 days	2 (2.67)	9 (2.98)
Received 1 dose, 15 or more days ago	>70	20 (6.62)
Received 2 doses, last dose in previous 14 days	<5	8 (2.65)
Received 2 doses, last dose >=15 days ago	>70	>297
Received 3 doses, last dose in previous 14 days	<5	<5
Received 3 doses, last dose >=15 days ago	22 (29.33)	>297
Received 4 doses, last dose in previous 14 days	0 (0)	<5
Received 4 doses, last dose >=15 days ago	0 (0)	11 (3.64)

Table 15.9.5 COVID-19 vaccination status at time zeroDX in Pfizer-BioNTech COVID-19 vaccinated individuals for SIDIAP

Characteristic, n (%)	Myocarditis	Pericarditis
Total	N =386	N =894
Time since last dose		
Received last dose in the previous 14 days	21 (5.44)	82 (9.17)
Received last dose 15 or more days ago	365 (94.56)	810 (90.6)
Number of doses received		
1	56 (14.51)	111 (12.42)
2	238 (61.66)	571 (63.87)
3	67 (17.36)	148 (16.55)
4+	25 (6.48)	64 (7.16)
Vaccination status		
Received 1 dose in previous 14 days	8 (2.07)	41 (4.59)
Received 1 dose, 15 or more days ago	48 (12.44)	70 (7.83)
Received 2 doses, last dose in previous 14 days	13 (3.37)	35 (3.91)
Received 2 doses, last dose >=15 days ago	225 (58.29)	535 (59.84)
Received 3 doses, last dose in previous 14 days	0 (0)	6 (0.67)
Received 3 doses, last dose >=15 days ago	67 (17.36)	>889
Received 4 doses, last dose in previous 14 days	0 (0)	<5
Received 4 doses, last dose >=15 days ago	25 (6.48)	61 (6.82)

Table 15.9.6 COVID-19 vaccination status at time zeroDX in Pfizer-BioNTech COVID-19 vaccinated individuals for CPRD

Characteristic, n (%)	Myocarditis	Pericarditis
Total	N =513	N =1072
Time since last dose		
Received last dose in the previous 14 days	48 (9.36)	60 (5.6)
Received last dose 15 or more days ago	464 (90.45)	1011 (94.31)
Number of doses received		
1	100 (19.49)	208 (19.4)
2	223 (43.47)	441 (41.14)
3	179 (34.89)	393 (36.66)
4+	11 (2.14)	30 (2.8)
Vaccination status		
Received 1 dose in previous 14 days	17 (3.31)	26 (2.43)
Received 1 dose, 15 or more days ago	83 (16.18)	182 (16.98)
Received 2 doses, last dose in previous 14 days	24 (4.68)	25 (2.33)
Received 2 doses, last dose >=15 days ago	198 (38.6)	415 (38.71)
Received 3 doses, last dose in previous 14 days	6 (1.17)	9 (0.84)
Received 3 doses, last dose >=15 days ago	>508	384 (35.82)
Received 4 doses, last dose in previous 14 days	<5	0 (0)
Received 4 doses, last dose >=15 days ago	10 (1.95)	30 (2.8)

Table 15.11.1 COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N =0	N =0	N < 5	N < 5
None	0	0	<5	<5
First Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
Second Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
Thrid Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
Any Non-Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
mRNA COVID-19 vaccine	0	0	0	0
Non-mRNA COVID-19 vaccine	0	0	0	0

Table 15.11.2 COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N =304	N =370	N =36	N =66
None	183 (60.2)	206 (55.68)	16 (44.44)	>41
First Pfizer-BioNTech COVID-19 dose	0 (0)	93 (25.14)	0 (0)	13 (19.7)
Second Pfizer-BioNTech COVID-19 dose	34 (11.18)	75 (20.27)	6 (16.67)	9 (13.64)
Thrid Pfizer-BioNTech COVID-19 dose	43 (14.14)	28 (7.57)	6 (16.67)	<5
Any Non-Pfizer-BioNTech COVID-19 dose	75 (24.67)	107 (28.92)	12 (33.33)	16 (24.24)
mRNA COVID-19 vaccine	70 (93.33)	74 (69.16)	11 (91.67)	13 (81.25)
Non-mRNA COVID-19 vaccine	36 (48)	88 (82.24)	8 (66.67)	13 (81.25)

Table 15.11.3 COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N =543	N =270	N =1397	N =544
None	>355	108 (40)	>829	168 (30.88)
First Pfizer-BioNTech COVID-19 dose	0 (0)	>141	0 (0)	325 (59.74)
Second Pfizer-BioNTech COVID-19 dose	32 (5.89)	117 (43.33)	90 (6.44)	286 (52.57)
Thrid Pfizer-BioNTech COVID-19 dose	100 (18.42)	93 (34.44)	326 (23.34)	228 (41.91)
Any Non-Pfizer-BioNTech COVID-19 dose	28 (5.16)	48 (17.78)	80 (5.73)	112 (20.59)
mRNA COVID-19 vaccine	26 (92.86)	44 (91.67)	78 (97.5)	107 (95.54)
Non-mRNA COVID-19 vaccine	<5	<5	<5	6 (5.36)

Table 15.11.4 COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N =75	N =41	N =302	N =133
None	>58	11 (26.83)	>219	49 (36.84)
First Pfizer-BioNTech COVID-19 dose	0 (0)	>16	0 (0)	63 (47.37)
Second Pfizer-BioNTech COVID-19 dose	<5	18 (43.9)	6 (1.99)	55 (41.35)
Thrid Pfizer-BioNTech COVID-19 dose	5 (6.67)	11 (26.83)	35 (11.59)	24 (18.05)
Any Non-Pfizer-BioNTech COVID-19 dose	7 (9.33)	14 (34.15)	31 (10.26)	37 (27.82)
mRNA COVID-19 vaccine	7 (100)	13 (92.86)	30 (96.77)	32 (86.49)
Non-mRNA COVID-19 vaccine	0 (0)	<5	<5	9 (24.32)

Table 15.11.5 COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N =386	N =290	N =894	N =770
None	>293	189 (65.17)	>465	232 (30.13)
First Pfizer-BioNTech COVID-19 dose	0 (0)	64 (22.07)	0 (0)	342 (44.42)
Second Pfizer-BioNTech COVID-19 dose	11 (2.85)	48 (16.55)	52 (5.82)	306 (39.74)
Thrid Pfizer-BioNTech COVID-19 dose	19 (4.92)	15 (5.17)	108 (12.08)	101 (13.12)
Any Non-Pfizer-BioNTech COVID-19 dose	30 (7.77)	64 (22.07)	217 (24.27)	339 (44.03)
mRNA COVID-19 vaccine	29 (96.67)	59 (92.19)	215 (99.08)	314 (92.63)
Non-mRNA COVID-19 vaccine	<5	12 (18.75)	<5	82 (24.19)

Table 15.11.6 COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N =513	N =350	N =1072	N =750
None	389 (75.83)	205 (58.57)	774 (72.2)	388 (51.73)
First Pfizer-BioNTech COVID-19 dose	0 (0)	75 (21.43)	0 (0)	183 (24.4)
Second Pfizer-BioNTech COVID-19 dose	42 (8.19)	63 (18)	87 (8.12)	158 (21.07)
Thrid Pfizer-BioNTech COVID-19 dose	73 (14.23)	57 (16.29)	194 (18.1)	153 (20.4)
Any Non-Pfizer-BioNTech COVID-19 dose	40 (7.8)	77 (22)	84 (7.84)	212 (28.27)
mRNA COVID-19 vaccine	0 (0)	0 (0)	0 (0)	0 (0)
Non-mRNA COVID-19 vaccine	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.12.1 Number of patients with at least one diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)				
Cardiac magnetic resonance(CMR)	0	0	0 (0)	0 (0)
Computed tomography(CT)	0	0	0 (0)	0 (0)
Echocardiogram	0	0	0 (0)	0 (0)

Table 15.12.2 Number of patients with at least one diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)				
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.12.3 Number of patients with at least one diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)				
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.12.4 Number of patients with at least one diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)				
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.12.5 Number of patients with at least one diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)				
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.12.6 Number of patients with at least one diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

label	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)				
Cardiac magnetic resonance(CMR)	45 (8.77)	25 (7.14)	17 (1.59)	7 (0.93)
Computed tomography(CT)	7 (1.36)	<5	7 (0.65)	6 (0.8)
Echocardiogram	119 (23.2)	71 (20.29)	187 (17.44)	139 (18.53)

Table 15.13.1 Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

label	Vaccinated	Unvaccinated
Total	N =0	N =0
Treatment, n (%)		
Paracetamol	0	0
Antivirals	0	0
Antibiotics	0	0
Immunosuppressant agents	0	0
Beta-blockers	0	0
Diuretics	0	0
ACE inhibitor or ARB	0	0
Aldosterone Antagonist	0	0
Cardiac glycosides or calcium-channel blockers	0	0
Antiarrhythmics	0	0
Pacemaker	0	0
Implantable cardiac defibrillator	0	0
Mechanical circulatory support	0	0
Heart Transplantation	0	0

Table 15.13.2 Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

label	Vaccinated	Unvaccinated
Total	N =304	N =370
Treatment, n (%)		
Paracetamol	26 (8.55)	37 (10)
Antivirals	<5	<5
Antibiotics	96 (31.58)	122 (32.97)
Immunosuppressant agents	52 (17.11)	63 (17.03)
Beta-blockers	90 (29.61)	96 (25.95)
Diuretics	42 (13.82)	65 (17.57)
ACE inhibitor or ARB	62 (20.39)	100 (27.03)
Aldosterone Antagonist	13 (4.28)	28 (7.57)
Cardiac glycosides or calcium-channel blockers	41 (13.49)	52 (14.05)
Antiarrhythmics	5 (1.64)	9 (2.43)
Pacemaker	0 (0)	0 (0)
Implantable cardiac defibrillator	0 (0)	0 (0)
Mechanical circulatory support	0 (0)	0 (0)
Heart Transplantation	0 (0)	0 (0)

Table 15.13.3 Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

label	Vaccinated	Unvaccinated
Total	N =543	N =270
Treatment, n (%)		
Paracetamol	142 (26.15)	63 (23.33)
Antivirals	10 (1.84)	10 (3.7)
Antibiotics	186 (34.25)	84 (31.11)
Immunosuppressant agents	101 (18.6)	56 (20.74)
Beta-blockers	206 (37.94)	81 (30)
Diuretics	103 (18.97)	39 (14.44)
ACE inhibitor or ARB	182 (33.52)	72 (26.67)
Aldosterone Antagonist	45 (8.29)	12 (4.44)
Cardiac glycosides or calcium-channel blockers	56 (10.31)	18 (6.67)
Antiarrhythmics	22 (4.05)	9 (3.33)
Pacemaker	6 (1.1)	0 (0)
Implantable cardiac defibrillator	17 (3.13)	6 (2.22)
Mechanical circulatory support	8 (1.47)	5 (1.85)
Heart Transplantation	0 (0)	<5

Table 15.13.4 Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =75	N =41
Treatment, n (%)		
Paracetamol	30 (40)	16 (39.02)
Antivirals	<5	0 (0)
Antibiotics	36 (48)	15 (36.59)
Immunosuppressant agents	11 (14.67)	5 (12.2)
Beta-blockers	24 (32)	16 (39.02)
Diuretics	18 (24)	8 (19.51)
ACE inhibitor or ARB	18 (24)	14 (34.15)
Aldosterone Antagonist	7 (9.33)	<5
Cardiac glycosides or calcium-channel blockers	8 (10.67)	<5
Antiarrhythmics	<5	<5
Pacemaker	0 (0)	0 (0)
Implantable cardiac defibrillator	0 (0)	0 (0)
Mechanical circulatory support	0 (0)	0 (0)
Heart Transplantation	0 (0)	0 (0)

Table 15.13.5 Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =386	N =290
Treatment, n (%)		
Paracetamol	160 (41.45)	128 (44.14)
Antivirals	<5	<5
Antibiotics	137 (35.49)	104 (35.86)
Immunosuppressant agents	66 (17.1)	64 (22.07)
Beta-blockers	86 (22.28)	66 (22.76)
Diuretics	86 (22.28)	49 (16.9)
ACE inhibitor or ARB	106 (27.46)	63 (21.72)
Aldosterone Antagonist	29 (7.51)	27 (9.31)
Cardiac glycosides or calcium-channel blockers	37 (9.59)	19 (6.55)
Antiarrhythmics	12 (3.11)	12 (4.14)
Pacemaker	0 (0)	0 (0)
Implantable cardiac defibrillator	0 (0)	0 (0)
Mechanical circulatory support	0 (0)	0 (0)
Heart Transplantation	0 (0)	0 (0)

Table 15.13.6 Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

label	Vaccinated	Unvaccinated
Total	N =513	N =350
Treatment, n (%)		
Paracetamol	16 (3.12)	14 (4)
Antivirals	7 (1.36)	6 (1.71)
Antibiotics	106 (20.66)	61 (17.43)
Immunosuppressant agents	62 (12.09)	27 (7.71)
Beta-blockers	236 (46)	145 (41.43)
Diuretics	69 (13.45)	44 (12.57)
ACE inhibitor or ARB	191 (37.23)	106 (30.29)
Aldosterone Antagonist	0 (0)	0 (0)
Cardiac glycosides or calcium-channel blockers	49 (9.55)	30 (8.57)
Antiarrhythmics	15 (2.92)	8 (2.29)
Pacemaker	8 (1.56)	<5
Implantable cardiac defibrillator	<5	5 (1.43)
Mechanical circulatory support	0 (0)	<5
Heart Transplantation	<5	<5

Table 15.14.1 Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

label	Vaccinated	Unvaccinated
Total	N < 5	N < 5
Treatment, n (%)		
Antibiotics	0 (0)	0 (0)
Antivirals	0 (0)	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	<5	0 (0)
Colchicine	0 (0)	0 (0)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	0 (0)	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.14.2 Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

label	Vaccinated	Unvaccinated
Total	N =36	N =66
Treatment, n (%)		
Antibiotics	5 (13.89)	7 (10.61)
Antivirals	0 (0)	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	9 (25)	18 (27.27)
Colchicine	20 (55.56)	25 (37.88)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	0 (0)	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.14.3 Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

label	Vaccinated	Unvaccinated
Total	N =1397	N =544
Treatment, n (%)		
Antibiotics	330 (23.62)	107 (19.67)
Antivirals	21 (1.5)	9 (1.65)
Non-steroidal anti-inflammatory drugs (NSAIDs)	625 (44.74)	268 (49.26)
Colchicine	866 (61.99)	314 (57.72)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	<5	<5
Pericardial drainage	74 (5.3)	32 (5.88)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	58 (4.15)	25 (4.6)
Pericardiocentesis	30 (2.15)	8 (1.47)
Cardiac catheterization	18 (1.29)	8 (1.47)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	<5	0 (0)

Table 15.14.4 Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =302	N =133
Treatment, n (%)		
Antibiotics	60 (19.87)	27 (20.3)
Antivirals	<5	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	157 (51.99)	76 (57.14)
Colchicine	121 (40.07)	63 (47.37)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	<5	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.14.5 Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =894	N =770
Treatment, n (%)		
Antibiotics	174 (19.46)	103 (13.38)
Antivirals	7 (0.78)	<5
Non-steroidal anti-inflammatory drugs (NSAIDs)	210 (23.49)	204 (26.49)
Colchicine	229 (25.62)	228 (29.61)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	<5	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.14.6 Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

label	Vaccinated	Unvaccinated
Total	N =1072	N =750
Treatment, n (%)		
Antibiotics	125 (11.66)	89 (11.87)
Antivirals	7 (0.65)	<5
Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)	0 (0)
Colchicine	0 (0)	0 (0)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	6 (0.56)	<5
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	<5	<5
Pericardiocentesis	<5	<5
Cardiac catheterization	9 (0.84)	8 (1.07)
Balloon pericardial window formation	<5	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	<5

Table 15.15.1.1.1 Risk (1-KM and 95% CI) for Number Of Hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.1 Risk (1-KM and 95% CI) for Number Of Hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	674	370	304	102	66	36
3	Events, n	0	0	0	0	0	0
3	Persons at risk	618	347	271	94	61	33
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	572	325	247	91	59	32
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	518	302	216	84	53	31
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	477	282	195	73	47	26
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.3.1 Risk (1-KM and 95% CI) for Number Of Hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	813	270	543	1941	544	1397
3	Events, n	640	212	428	1568	438	1130
3	Persons at risk	146	53	93	337	102	235
3	Risk (95% CI)	7907 (7605 - 8171)	7868 (7317 - 8307)	7927 (7551 - 8246)	8090 (7906 - 8258)	8055 (7692 - 8361)	8104 (7886 - 8300)
6	Events, n	648	214	434	1597	445	1152
6	Persons at risk	129	51	78	274	92	182
6	Risk (95% CI)	8027 (7728 - 8287)	7949 (7402 - 8380)	8072 (7700 - 8384)	8263 (8084 - 8426)	8191 (7836 - 8488)	8294 (8081 - 8483)
9	Events, n	655	219	436	1609	445	1164
9	Persons at risk	113	46	67	227	90	137
9	Risk (95% CI)	8138 (7842 - 8393)	8150 (7617 - 8563)	8124 (7753 - 8434)	8345 (8167 - 8505)	8191 (7836 - 8488)	8419 (8208 - 8605)
12	Events, n	661	222	439	1622	450	1172
12	Persons at risk	94	43	51	175	76	99
12	Risk (95% CI)	8242 (7949 - 8494)	8271 (7747 - 8672)	8221 (7848 - 8529)	8450 (8274 - 8609)	8296 (7945 - 8586)	8527 (8315 - 8712)

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Table 15.15.4.1 Risk (1-KM and 95% CI) for Number Of Hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	116	41	75	435	133	302
3	Events, n	98	34	64	222	76	146
3	Persons at risk	13	5	8	183	50	133
3	Risk (95% CI)	8448 (7627 - 8985)	8293 (6648 - 9130)	8533 (7468 - 9150)	5123 (4628 - 5573)	5725 (4794 - 6490)	4855 (4257 - 5391)
6	Events, n	98	34	64	225	77	148
6	Persons at risk	10	5	5	154	47	107
6	Risk (95% CI)	8448 (7627 - 8985)	8293 (6648 - 9130)	8533 (7468 - 9150)	5208 (4710 - 5658)	5811 (4878 - 6574)	4938 (4336 - 5475)
9	Events, n	98	34	64	227	78	149
9	Persons at risk	7	5	<5	130	43	87
9	Risk (95% CI)	8448 (7627 - 8985)	8293 (6648 - 9130)	8533 (7468 - 9150)	5270 (4771 - 5722)	5900 (4965 - 6661)	4986 (4381 - 5525)
12	Events, n	98	34	64	231	80	151
12	Persons at risk	7	5	<5	108	40	68
12	Risk (95% CI)	8448 (7627 - 8985)	8293 (6648 - 9130)	8533 (7468 - 9150)	5427 (4917 - 5886)	6093 (5151 - 6852)	5114 (4494 - 5663)

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Table 15.15.5.1 Risk (1-KM and 95% CI) for Number Of Hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	676	290	386	1664	770	894
3	Events, n	426	178	248	1047	441	606
3	Persons at risk	241	109	132	595	325	270
3	Risk (95% CI)	6307 (5924 - 6653)	6141 (5537 - 6662)	6432 (5920 - 6880)	6296 (6056 - 6521)	5729 (5364 - 6064)	6783 (6461 - 7075)
6	Events, n	434	180	254	1063	447	616
6	Persons at risk	188	90	98	565	316	249
6	Risk (95% CI)	6437 (6055 - 6781)	6213 (5610 - 6732)	6608 (6098 - 7052)	6397 (6158 - 6620)	5808 (5444 - 6142)	6904 (6585 - 7194)
9	Events, n	437	181	256	1074	454	620
9	Persons at risk	121	63	58	544	309	235
9	Risk (95% CI)	6516 (6131 - 6863)	6267 (5662 - 6788)	6710 (6191 - 7158)	6467 (6229 - 6690)	5900 (5538 - 6234)	6954 (6636 - 7243)
12	Events, n	438	182	256	1088	464	624
12	Persons at risk	109	59	50	523	298	225
12	Risk (95% CI)	6547 (6160 - 6895)	6330 (5719 - 6853)	6710 (6191 - 7158)	6559 (6322 - 6781)	6034 (5672 - 6365)	7007 (6689 - 7294)

Table 15.15.6.1 Risk (1-KM and 95% CI) for Number Of Hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	863	350	513	1822	750	1072
3	Events, n	86	32	54	182	74	108
3	Persons at risk	682	275	407	1462	614	848
3	Risk (95% CI)	1010 (805 - 1210)	926 (615 - 1227)	1066 (793 - 1331)	1009 (869 - 1147)	995 (777 - 1208)	1019 (835 - 1199)
6	Events, n	95	37	58	194	81	113
6	Persons at risk	587	250	337	1266	553	713
6	Risk (95% CI)	1136 (918 - 1350)	1099 (757 - 1428)	1158 (872 - 1434)	1088 (942 - 1231)	1102 (872 - 1326)	1076 (886 - 1262)
9	Events, n	102	39	63	207	88	119
9	Persons at risk	492	224	268	1087	504	583
9	Risk (95% CI)	1253 (1020 - 1479)	1176 (820 - 1519)	1303 (994 - 1602)	1187 (1032 - 1338)	1220 (977 - 1457)	1158 (958 - 1353)
12	Events, n	107	42	65	218	92	126
12	Persons at risk	415	199	216	946	467	479
12	Risk (95% CI)	1346 (1101 - 1584)	1299 (920 - 1662)	1371 (1049 - 1680)	1282 (1119 - 1442)	1293 (1041 - 1538)	1274 (1059 - 1484)

Table 15.15.1.1.2 Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.2 Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	674	370	304	102	<67	<144
3	Events, n	15	10	5	5	<5	<5
3	Persons at risk	618	347	271	94	<67	<144
3	Risk (95% CI)	228 (113 - 341)	274 (105 - 441)	170 (21 - 316)	490 (62 - 900)	606 (12 - 1164)	278 (0 - 800)
6	Events, n	19	14	5	5	<5	<5
6	Persons at risk	572	325	247	91	<67	<144
6	Risk (95% CI)	293 (162 - 422)	389 (187 - 587)	170 (21 - 316)	490 (62 - 900)	606 (12 - 1164)	278 (0 - 800)
9	Events, n	23	16	7	6	5	<5
9	Persons at risk	518	302	216	84	53	<144
9	Risk (95% CI)	364 (216 - 509)	451 (232 - 664)	253 (65 - 437)	598 (122 - 1052)	774 (98 - 1404)	278 (0 - 800)
12	Events, n	23	16	7	6	5	<5
12	Persons at risk	477	282	195	73	47	<144
12	Risk (95% CI)	364 (216 - 509)	451 (232 - 664)	253 (65 - 437)	598 (122 - 1052)	774 (98 - 1404)	278 (0 - 800)

Table 15.15.3.2 Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	813	270	543	1941	544	1397
3	Events, n	37	10	27	42	7	35
3	Persons at risk	704	246	458	1744	517	1227
3	Risk (95% CI)	462 (315 - 606)	372 (143 - 596)	507 (319 - 692)	221 (154 - 286)	131 (34 - 226)	256 (172 - 339)
6	Events, n	43	13	30	57	10	47
6	Persons at risk	616	232	384	1520	501	1019
6	Risk (95% CI)	550 (389 - 709)	492 (228 - 750)	579 (375 - 779)	310 (230 - 389)	189 (72 - 304)	360 (258 - 461)
9	Events, n	49	14	35	67	12	55
9	Persons at risk	536	222	314	1318	481	837
9	Risk (95% CI)	645 (467 - 819)	534 (257 - 802)	706 (475 - 931)	378 (288 - 467)	229 (100 - 356)	441 (325 - 556)
12	Events, n	52	15	37	73	12	61
12	Persons at risk	461	210	251	1108	453	655
12	Risk (95% CI)	700 (513 - 884)	577 (289 - 857)	772 (524 - 1012)	425 (328 - 520)	229 (100 - 356)	516 (386 - 644)

Table 15.15.4.2 Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	116	<164	75	435	133	302
3	Events, n	11	<5	10	22	6	16
3	Persons at risk	100	<164	62	384	120	264
3	Risk (95% CI)	958 (403 - 1480)	244 (0 - 705)	1355 (537 - 2102)	515 (303 - 722)	453 (92 - 800)	542 (280 - 797)
6	Events, n	12	<5	11	30	7	23
6	Persons at risk	96	<164	58	351	117	234
6	Risk (95% CI)	1049 (469 - 1594)	244 (0 - 705)	1497 (640 - 2275)	720 (468 - 965)	534 (141 - 911)	805 (483 - 1116)
9	Events, n	14	<5	12	33	7	26
9	Persons at risk	89	<80	52	320	114	206
9	Risk (95% CI)	1242 (610 - 1831)	501 (0 - 1154)	1654 (751 - 2469)	804 (536 - 1064)	534 (141 - 911)	933 (583 - 1270)
12	Events, n	14	<5	12	35	7	28
12	Persons at risk	80	<80	46	286	113	173
12	Risk (95% CI)	1242 (610 - 1831)	501 (0 - 1154)	1654 (751 - 2469)	864 (585 - 1135)	534 (141 - 911)	1027 (656 - 1383)

Table 15.15.5.2 Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	676	290	386	1664	770	894
3	Events, n	42	18	24	69	21	48
3	Persons at risk	604	264	340	1515	733	782
3	Risk (95% CI)	630 (444 - 813)	622 (340 - 897)	638 (387 - 882)	424 (326 - 522)	275 (158 - 391)	556 (402 - 707)
6	Events, n	51	21	30	90	32	58
6	Persons at risk	512	232	280	1425	710	715
6	Risk (95% CI)	777 (570 - 980)	735 (427 - 1033)	811 (528 - 1086)	560 (447 - 672)	422 (278 - 565)	681 (510 - 849)
9	Events, n	56	22	34	103	38	65
9	Persons at risk	404	193	211	1348	693	655
9	Risk (95% CI)	875 (652 - 1092)	776 (459 - 1083)	958 (643 - 1261)	648 (526 - 768)	504 (346 - 659)	776 (592 - 956)
12	Events, n	61	23	38	116	43	73
12	Persons at risk	363	185	178	1264	674	590
12	Risk (95% CI)	994 (750 - 1232)	825 (494 - 1145)	1143 (784 - 1488)	740 (609 - 869)	573 (405 - 738)	893 (694 - 1087)

Table 15.15.6.2 Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	863	350	513	1822	750	1072
3	Events, n	9	<5	5	11	<5	7
3	Persons at risk	754	<345	452	1628	<741	945
3	Risk (95% CI)	106 (37 - 175)	116 (2 - 228)	99 (12 - 185)	63 (26 - 100)	54 (1 - 106)	69 (18 - 120)
6	Events, n	11	<5	7	16	<5	12
6	Persons at risk	659	<345	379	1419	<741	795
6	Risk (95% CI)	134 (55 - 212)	116 (2 - 228)	147 (38 - 255)	95 (48 - 141)	54 (1 - 106)	125 (54 - 195)
9	Events, n	11	<5	7	23	<5	19
9	Persons at risk	566	<345	311	1231	<741	655
9	Risk (95% CI)	134 (55 - 212)	116 (2 - 228)	147 (38 - 255)	146 (86 - 206)	54 (1 - 106)	219 (120 - 317)
12	Events, n	14	5	9	24	5	19
12	Persons at risk	482	229	253	1085	537	548
12	Risk (95% CI)	192 (89 - 294)	157 (18 - 294)	221 (71 - 368)	155 (92 - 216)	71 (8 - 134)	219 (120 - 317)

Table 15.15.1.3 Risk (1-KM and 95% CI) for Sudden Cardiac Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.3 Risk (1-KM and 95% CI) for Sudden Cardiac Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	674	370	304	102	66	36
3	Events, n	0	0	0	0	0	0
3	Persons at risk	618	347	271	94	61	33
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	572	325	247	91	59	32
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	518	302	216	84	53	31
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	477	282	195	73	47	26
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.3.3 Risk (1-KM and 95% CI) for Sudden Cardiac Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	813	270	543	1941	544	1397
3	Events, n	0	0	0	0	0	0
3	Persons at risk	704	246	458	1744	517	1227
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	616	232	384	1520	501	1019
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	536	222	314	1318	481	837
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	461	210	251	1108	453	655
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.4.3 Risk (1-KM and 95% CI) for Sudden Cardiac Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	116	41	75	435	133	302
3	Events, n	0	0	0	0	0	0
3	Persons at risk	100	38	62	384	120	264
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	96	38	58	351	117	234
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	89	37	52	320	114	206
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	80	34	46	286	113	173
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.5.3 Risk (1-KM and 95% CI) for Sudden Cardiac Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	676	290	386	1664	770	894
3	Events, n	0	0	0	0	0	0
3	Persons at risk	604	264	340	1515	733	782
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	512	232	280	1425	710	715
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	404	193	211	1348	693	655
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	363	185	178	1264	674	590
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.6.3 Risk (1-KM and 95% CI) for Sudden Cardiac Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	863	350	513	1822	750	1072
3	Events, n	0	0	0	0	0	0
3	Persons at risk	754	302	452	1628	683	945
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	659	280	379	1419	624	795
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	566	255	311	1231	576	655
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	482	229	253	1085	537	548
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.1.4 Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.4 Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	674	370	304	102	66	<71
3	Events, n	29	20	9	13	11	<5
3	Persons at risk	594	331	263	82	51	<71
3	Risk (95% CI)	432 (277 - 584)	541 (308 - 769)	298 (104 - 488)	1284 (607 - 1912)	1675 (721 - 2532)	564 (0 - 1293)
6	Events, n	29	20	9	13	11	<5
6	Persons at risk	548	309	239	80	50	<71
6	Risk (95% CI)	432 (277 - 584)	541 (308 - 769)	298 (104 - 488)	1284 (607 - 1912)	1675 (721 - 2532)	564 (0 - 1293)
9	Events, n	31	21	10	14	12	<5
9	Persons at risk	495	287	208	74	45	<71
9	Risk (95% CI)	467 (305 - 627)	573 (332 - 808)	339 (130 - 545)	1395 (689 - 2048)	1849 (845 - 2743)	564 (0 - 1293)
12	Events, n	31	21	10	14	12	<5
12	Persons at risk	455	267	188	64	40	<71
12	Risk (95% CI)	467 (305 - 627)	573 (332 - 808)	339 (130 - 545)	1395 (689 - 2048)	1849 (845 - 2743)	564 (0 - 1293)

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Table 15.15.3.4 Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	813	270	543	1941	544	1397
3	Events, n	129	42	87	177	33	144
3	Persons at risk	600	209	391	1586	487	1099
3	Risk (95% CI)	1602 (1345 - 1852)	1568 (1121 - 1993)	1620 (1302 - 1926)	926 (795 - 1055)	611 (407 - 811)	1050 (886 - 1211)
6	Events, n	136	42	94	198	37	161
6	Persons at risk	518	198	320	1370	468	902
6	Risk (95% CI)	1707 (1441 - 1965)	1568 (1121 - 1993)	1783 (1448 - 2106)	1054 (913 - 1192)	689 (472 - 901)	1201 (1024 - 1374)
9	Events, n	145	46	99	208	39	169
9	Persons at risk	449	185	264	1179	447	732
9	Risk (95% CI)	1857 (1577 - 2128)	1742 (1270 - 2188)	1918 (1567 - 2254)	1124 (978 - 1267)	730 (507 - 948)	1286 (1101 - 1467)
12	Events, n	148	46	102	217	41	176
12	Persons at risk	387	174	213	992	420	572
12	Risk (95% CI)	1917 (1631 - 2193)	1742 (1270 - 2188)	2022 (1655 - 2374)	1198 (1045 - 1348)	773 (543 - 998)	1380 (1184 - 1572)

Table 15.15.4.4 Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	116	41	75	435	133	302
3	Events, n	21	6	15	55	13	42
3	Persons at risk	85	33	52	344	110	234
3	Risk (95% CI)	1810 (1079 - 2482)	1463 (310 - 2480)	2000 (1042 - 2856)	1275 (955 - 1585)	987 (463 - 1482)	1401 (999 - 1785)
6	Events, n	22	6	16	55	13	42
6	Persons at risk	82	33	49	316	107	209
6	Risk (95% CI)	1910 (1158 - 2598)	1463 (310 - 2480)	2163 (1163 - 3051)	1275 (955 - 1585)	987 (463 - 1482)	1401 (999 - 1785)
9	Events, n	23	7	16	57	13	44
9	Persons at risk	76	31	45	287	104	183
9	Risk (95% CI)	2014 (1241 - 2719)	1730 (476 - 2819)	2163 (1163 - 3051)	1334 (1005 - 1652)	987 (463 - 1482)	1491 (1073 - 1890)
12	Events, n	23	7	16	59	13	46
12	Persons at risk	67	28	39	254	103	151
12	Risk (95% CI)	2014 (1241 - 2719)	1730 (476 - 2819)	2163 (1163 - 3051)	1395 (1057 - 1721)	987 (463 - 1482)	1585 (1150 - 1998)

Table 15.15.5.4 Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	676	290	386	1664	770	894
3	Events, n	91	40	51	300	92	208
3	Persons at risk	535	231	304	1266	653	613
3	Risk (95% CI)	1353 (1090 - 1608)	1386 (978 - 1776)	1328 (982 - 1661)	1814 (1626 - 1998)	1198 (965 - 1424)	2350 (2065 - 2625)
6	Events, n	95	41	54	313	96	217
6	Persons at risk	452	203	249	1193	631	562
6	Risk (95% CI)	1420 (1151 - 1681)	1424 (1010 - 1818)	1419 (1060 - 1763)	1900 (1708 - 2088)	1252 (1015 - 1484)	2466 (2175 - 2747)
9	Events, n	99	42	57	329	103	226
9	Persons at risk	347	167	180	1124	612	512
9	Risk (95% CI)	1502 (1224 - 1772)	1467 (1046 - 1868)	1534 (1156 - 1897)	2011 (1814 - 2203)	1350 (1104 - 1589)	2591 (2293 - 2878)
12	Events, n	104	46	58	336	104	232
12	Persons at risk	313	157	156	1065	597	468
12	Risk (95% CI)	1631 (1333 - 1918)	1678 (1216 - 2115)	1582 (1193 - 1953)	2062 (1862 - 2256)	1364 (1117 - 1605)	2680 (2377 - 2972)

Table 15.15.6.4 Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	863	350	513	1822	750	1072
3	Events, n	64	28	36	37	11	26
3	Persons at risk	694	277	417	1595	674	921
3	Risk (95% CI)	756 (576 - 933)	811 (518 - 1095)	719 (490 - 943)	208 (141 - 274)	151 (62 - 238)	248 (153 - 341)
6	Events, n	71	31	40	47	19	28
6	Persons at risk	601	254	347	1383	609	774
6	Risk (95% CI)	854 (662 - 1043)	914 (601 - 1217)	812 (567 - 1051)	272 (195 - 348)	270 (150 - 390)	270 (170 - 368)
9	Events, n	76	33	43	49	20	29
9	Persons at risk	510	230	280	1199	560	639
9	Risk (95% CI)	939 (734 - 1140)	992 (662 - 1309)	901 (638 - 1157)	288 (207 - 367)	288 (162 - 412)	284 (181 - 386)
12	Events, n	78	33	45	50	20	30
12	Persons at risk	431	207	224	1055	521	534
12	Risk (95% CI)	977 (766 - 1183)	992 (662 - 1309)	972 (692 - 1243)	297 (215 - 378)	288 (162 - 412)	302 (193 - 410)

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Table 15.15.1.5 Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.5 Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	674	<371	<1213	102	66	36
3	Events, n	5	<5	<5	0	0	0
3	Persons at risk	616	<371	<1213	94	61	33
3	Risk (95% CI)	74 (9 - 139)	108 (2 - 213)	33 (0 - 97)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	5	<5	<5	0	0	0
6	Persons at risk	570	<371	<1213	91	59	32
6	Risk (95% CI)	74 (9 - 139)	108 (2 - 213)	33 (0 - 97)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	5	<5	<5	0	0	0
9	Persons at risk	516	<371	<1213	84	53	31
9	Risk (95% CI)	74 (9 - 139)	108 (2 - 213)	33 (0 - 97)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	5	<5	<5	0	0	0
12	Persons at risk	475	<371	<1213	73	47	26
12	Risk (95% CI)	74 (9 - 139)	108 (2 - 213)	33 (0 - 97)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.3.5 Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	813	<541	543	1941	<2223	1397
3	Events, n	8	<5	6	7	<5	6
3	Persons at risk	702	<541	456	1740	<2223	1223
3	Risk (95% CI)	98 (30 - 166)	74 (0 - 176)	110 (22 - 198)	36 (9 - 63)	18 (0 - 54)	43 (9 - 77)
6	Events, n	8	<5	6	7	<5	6
6	Persons at risk	614	<541	382	1516	<2223	1015
6	Risk (95% CI)	98 (30 - 166)	74 (0 - 176)	110 (22 - 198)	36 (9 - 63)	18 (0 - 54)	43 (9 - 77)
9	Events, n	8	<5	6	7	<5	6
9	Persons at risk	534	<541	312	1314	<2223	833
9	Risk (95% CI)	98 (30 - 166)	74 (0 - 176)	110 (22 - 198)	36 (9 - 63)	18 (0 - 54)	43 (9 - 77)
12	Events, n	8	<5	6	7	<5	6
12	Persons at risk	461	<541	251	1105	<2223	652
12	Risk (95% CI)	98 (30 - 166)	74 (0 - 176)	110 (22 - 198)	36 (9 - 63)	18 (0 - 54)	43 (9 - 77)

Table 15.15.4.5 Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<466	41	<301	435	<534	302
3	Events, n	<5	0	<5	7	<5	6
3	Persons at risk	<466	38	<301	381	<534	261
3	Risk (95% CI)	86 (0 - 253)	0 (0 - 0)	133 (0 - 390)	161 (42 - 278)	75 (0 - 221)	199 (40 - 355)
6	Events, n	<5	0	<5	7	<5	6
6	Persons at risk	<466	38	<301	350	<534	233
6	Risk (95% CI)	86 (0 - 253)	0 (0 - 0)	133 (0 - 390)	161 (42 - 278)	75 (0 - 221)	199 (40 - 355)
9	Events, n	<5	0	<5	7	<5	6
9	Persons at risk	<466	37	<301	319	<534	205
9	Risk (95% CI)	86 (0 - 253)	0 (0 - 0)	133 (0 - 390)	161 (42 - 278)	75 (0 - 221)	199 (40 - 355)
12	Events, n	<5	0	<5	7	<5	6
12	Persons at risk	<466	34	<301	285	<534	172
12	Risk (95% CI)	86 (0 - 253)	0 (0 - 0)	133 (0 - 390)	161 (42 - 278)	75 (0 - 221)	199 (40 - 355)

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Table 15.15.5.5 Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	676	290	386	1664	770	894
3	Events, n	28	19	9	23	11	12
3	Persons at risk	588	252	336	1502	726	776
3	Risk (95% CI)	417 (264 - 567)	657 (367 - 939)	236 (82 - 387)	138 (82 - 194)	143 (59 - 226)	135 (59 - 210)
6	Events, n	28	19	9	23	11	12
6	Persons at risk	497	220	277	1413	703	710
6	Risk (95% CI)	417 (264 - 567)	657 (367 - 939)	236 (82 - 387)	138 (82 - 194)	143 (59 - 226)	135 (59 - 210)
9	Events, n	29	19	10	23	11	12
9	Persons at risk	391	183	208	1337	686	651
9	Risk (95% CI)	437 (280 - 592)	657 (367 - 939)	274 (103 - 442)	138 (82 - 194)	143 (59 - 226)	135 (59 - 210)
12	Events, n	31	20	11	24	12	12
12	Persons at risk	348	174	174	1252	666	586
12	Risk (95% CI)	489 (317 - 659)	709 (402 - 1005)	330 (127 - 528)	146 (88 - 204)	158 (69 - 246)	135 (59 - 210)

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Table 15.15.6.5 Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<3334	<1380	513	1822	750	1072
3	Events, n	<5	<5	0	0	0	0
3	Persons at risk	<3334	<1380	452	1628	683	945
3	Risk (95% CI)	12 (0 - 34)	29 (0 - 84)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	0	0	0	0
6	Persons at risk	<3334	<1380	379	1419	624	795
6	Risk (95% CI)	12 (0 - 34)	29 (0 - 84)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	0	0	0	0
9	Persons at risk	<3334	<1380	311	1231	576	655
9	Risk (95% CI)	12 (0 - 34)	29 (0 - 84)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	0	0	0	0
12	Persons at risk	<3334	<1380	253	1085	537	548
12	Risk (95% CI)	12 (0 - 34)	29 (0 - 84)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.1.6 Risk (1-KM and 95% CI) for Fulminant Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.6 Risk (1-KM and 95% CI) for Fulminant Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	674	370	<405	102	66	36
3	Events, n	11	8	<5	0	0	0
3	Persons at risk	611	341	<405	94	61	33
3	Risk (95% CI)	164 (67 - 259)	217 (67 - 365)	99 (0 - 209)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	11	8	<5	0	0	0
6	Persons at risk	565	319	<405	91	59	32
6	Risk (95% CI)	164 (67 - 259)	217 (67 - 365)	99 (0 - 209)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	11	8	<5	0	0	0
9	Persons at risk	512	297	<405	84	53	31
9	Risk (95% CI)	164 (67 - 259)	217 (67 - 365)	99 (0 - 209)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	11	8	<5	0	0	0
12	Persons at risk	471	277	<405	73	47	26
12	Risk (95% CI)	164 (67 - 259)	217 (67 - 365)	99 (0 - 209)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.3.6 Risk (1-KM and 95% CI) for Fulminant Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	813	270	543	<8000	544	<5715
3	Events, n	35	12	23	<5	0	<5
3	Persons at risk	679	236	443	<8000	517	<5715
3	Risk (95% CI)	433 (291 - 572)	446 (196 - 689)	426 (254 - 595)	5 (0 - 15)	0 (0 - 0)	7 (0 - 21)
6	Events, n	36	12	24	<5	0	<5
6	Persons at risk	591	223	368	<8000	501	<5715
6	Risk (95% CI)	447 (303 - 588)	446 (196 - 689)	448 (271 - 622)	5 (0 - 15)	0 (0 - 0)	7 (0 - 21)
9	Events, n	36	12	24	<5	0	<5
9	Persons at risk	513	213	300	<3334	481	<2353
9	Risk (95% CI)	447 (303 - 588)	446 (196 - 689)	448 (271 - 622)	12 (0 - 29)	0 (0 - 0)	17 (0 - 42)
12	Events, n	36	12	24	<5	0	<5
12	Persons at risk	441	201	240	<3334	453	<2353
12	Risk (95% CI)	447 (303 - 588)	446 (196 - 689)	448 (271 - 622)	12 (0 - 29)	0 (0 - 0)	17 (0 - 42)

Table 15.15.4.6 Risk (1-KM and 95% CI) for Fulminant Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<233	41	<150	<1740	133	<1213
3	Events, n	<5	0	<5	<5	0	<5
3	Persons at risk	<233	38	<150	<1740	120	<1213
3	Risk (95% CI)	172 (0 - 406)	0 (0 - 0)	267 (0 - 625)	23 (0 - 68)	0 (0 - 0)	33 (0 - 98)
6	Events, n	<5	0	<5	<5	0	<5
6	Persons at risk	<233	38	<150	<1740	117	<1213
6	Risk (95% CI)	172 (0 - 406)	0 (0 - 0)	267 (0 - 625)	23 (0 - 68)	0 (0 - 0)	33 (0 - 98)
9	Events, n	<5	0	<5	<5	0	<5
9	Persons at risk	<233	37	<150	<1740	114	<1213
9	Risk (95% CI)	172 (0 - 406)	0 (0 - 0)	267 (0 - 625)	23 (0 - 68)	0 (0 - 0)	33 (0 - 98)
12	Events, n	<5	0	<5	<5	0	<5
12	Persons at risk	<233	34	<150	<1740	113	<1213
12	Risk (95% CI)	172 (0 - 406)	0 (0 - 0)	267 (0 - 625)	23 (0 - 68)	0 (0 - 0)	33 (0 - 98)

Table 15.15.5.6 Risk (1-KM and 95% CI) for Fulminant Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	676	290	386	<6667	<3077	894
3	Events, n	26	18	8	<5	<5	0
3	Persons at risk	590	253	337	<6667	<3077	782
3	Risk (95% CI)	385 (239 - 529)	621 (339 - 894)	207 (64 - 348)	6 (0 - 18)	13 (0 - 38)	0 (0 - 0)
6	Events, n	26	18	8	<5	<5	0
6	Persons at risk	499	221	278	<6667	<3077	715
6	Risk (95% CI)	385 (239 - 529)	621 (339 - 894)	207 (64 - 348)	6 (0 - 18)	13 (0 - 38)	0 (0 - 0)
9	Events, n	27	18	9	<5	<5	0
9	Persons at risk	392	184	208	<6667	<3077	655
9	Risk (95% CI)	405 (254 - 554)	621 (339 - 894)	245 (84 - 404)	6 (0 - 18)	13 (0 - 38)	0 (0 - 0)
12	Events, n	29	19	10	<5	<5	0
12	Persons at risk	349	175	174	<6667	<3077	590
12	Risk (95% CI)	457 (290 - 622)	672 (373 - 961)	301 (106 - 492)	6 (0 - 18)	13 (0 - 38)	0 (0 - 0)

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Table 15.15.6.6 Risk (1-KM and 95% CI) for Fulminant Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	863	350	513	1822	750	1072
3	Events, n	23	9	14	0	0	0
3	Persons at risk	734	295	439	1628	683	945
3	Risk (95% CI)	268 (159 - 376)	259 (91 - 425)	275 (132 - 415)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	23	9	14	0	0	0
6	Persons at risk	640	274	366	1419	624	795
6	Risk (95% CI)	268 (159 - 376)	259 (91 - 425)	275 (132 - 415)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	23	9	14	0	0	0
9	Persons at risk	547	249	298	1231	576	655
9	Risk (95% CI)	268 (159 - 376)	259 (91 - 425)	275 (132 - 415)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	23	9	14	0	0	0
12	Persons at risk	464	223	241	1085	537	548
12	Risk (95% CI)	268 (159 - 376)	259 (91 - 425)	275 (132 - 415)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.1.7 Risk (1-KM and 95% CI) for Chronic Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.7 Risk (1-KM and 95% CI) for Chronic Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	651	362	289	97	62	35
3	Events, n	0	0	0	0	0	0
3	Persons at risk	602	337	265	91	59	32
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	553	316	237	89	57	32
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	503	293	210	78	49	29
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	451	270	181	72	46	26
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.3.7 Risk (1-KM and 95% CI) for Chronic Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<2223	<889	512	<6667	536	<5000
3	Events, n	0	0	0	<5	0	<5
3	Persons at risk	677	242	435	<6667	511	<5000
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	6 (0 - 17)	0 (0 - 0)	8 (0 - 25)
6	Events, n	0	0	0	<5	0	<5
6	Persons at risk	590	228	362	<1600	495	<1112
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	25 (0 - 49)	0 (0 - 0)	36 (1 - 71)
9	Events, n	<5	<5	0	9	<5	5
9	Persons at risk	<2223	<889	294	1245	<488	774
9	Risk (95% CI)	18 (0 - 55)	45 (0 - 133)	0 (0 - 0)	61 (21 - 102)	82 (2 - 162)	49 (5 - 91)
12	Events, n	<5	<5	0	10	5	5
12	Persons at risk	<2223	<889	223	1018	439	579
12	Risk (95% CI)	18 (0 - 55)	45 (0 - 133)	0 (0 - 0)	71 (27 - 115)	104 (13 - 195)	49 (5 - 91)

Table 15.15.4.7 Risk (1-KM and 95% CI) for Chronic Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<397	<149	65	411	129	282
3	Events, n	<5	<5	0	0	0	0
3	Persons at risk	<397	<149	61	377	120	257
3	Risk (95% CI)	101 (0 - 296)	270 (0 - 779)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	0	0	0	0
6	Persons at risk	<397	<149	56	340	116	224
6	Risk (95% CI)	101 (0 - 296)	270 (0 - 779)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	0	0	0	0
9	Persons at risk	<397	<149	49	309	113	196
9	Risk (95% CI)	101 (0 - 296)	270 (0 - 779)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	0	0	0	0
12	Persons at risk	<397	<149	45	278	110	168
12	Risk (95% CI)	101 (0 - 296)	270 (0 - 779)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.5.7 Risk (1-KM and 95% CI) for Chronic Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	625	<527	<690	<5715	<2858	<3077
3	Events, n	<5	<5	<5	<5	0	<5
3	Persons at risk	<607	<527	<690	<5715	727	<3077
3	Risk (95% CI)	66 (1 - 130)	76 (0 - 180)	58 (0 - 138)	7 (0 - 19)	0 (0 - 0)	13 (0 - 37)
6	Events, n	5	<5	<5	<5	0	<5
6	Persons at risk	430	<527	<413	<5715	703	<3077
6	Risk (95% CI)	87 (10 - 163)	76 (0 - 180)	97 (0 - 207)	7 (0 - 19)	0 (0 - 0)	13 (0 - 37)
9	Events, n	6	<5	<5	<5	<5	<5
9	Persons at risk	377	<313	<413	<1905	<2858	<1429
9	Risk (95% CI)	112 (21 - 203)	128 (0 - 273)	97 (0 - 207)	21 (0 - 45)	14 (0 - 42)	28 (0 - 67)
12	Events, n	9	<5	5	<5	<5	<5
12	Persons at risk	345	<220	165	<1380	<1380	<1429
12	Risk (95% CI)	194 (64 - 321)	182 (1 - 360)	208 (18 - 395)	29 (1 - 58)	29 (0 - 70)	28 (0 - 67)

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Table 15.15.6.7 Risk (1-KM and 95% CI) for Chronic Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<2858	<1177	491	<3334	727	<1905
3	Events, n	0	0	0	<5	0	<5
3	Persons at risk	734	300	434	<3334	665	<1905
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	12 (0 - 29)	0 (0 - 0)	21 (0 - 50)
6	Events, n	<5	<5	0	<5	0	<5
6	Persons at risk	<2858	<1177	349	<3334	606	<1905
6	Risk (95% CI)	14 (0 - 41)	34 (0 - 99)	0 (0 - 0)	12 (0 - 29)	0 (0 - 0)	21 (0 - 50)
9	Events, n	<5	<5	0	<5	0	<5
9	Persons at risk	<2858	<1177	293	<3334	560	<1905
9	Risk (95% CI)	14 (0 - 41)	34 (0 - 99)	0 (0 - 0)	12 (0 - 29)	0 (0 - 0)	21 (0 - 50)
12	Events, n	<5	<5	0	<5	0	<5
12	Persons at risk	<2858	<1177	234	<3334	521	<1905
12	Risk (95% CI)	14 (0 - 41)	34 (0 - 99)	0 (0 - 0)	12 (0 - 29)	0 (0 - 0)	21 (0 - 50)

Table 15.15.1.8 Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.8 Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	674	370	304	102	66	36
3	Events, n	0	0	0	0	0	0
3	Persons at risk	618	347	271	94	61	33
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	572	325	247	91	59	32
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	518	302	216	84	53	31
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	477	282	195	73	47	26
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.15.3.8 Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<3077	<1053	543	1941	544	1397
3	Events, n	<5	<5	0	0	0	0
3	Persons at risk	<3077	<1053	458	1744	517	1227
3	Risk (95% CI)	13 (0 - 38)	38 (0 - 112)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	0	0	0	0
6	Persons at risk	<3077	<1053	384	1520	501	1019
6	Risk (95% CI)	13 (0 - 38)	38 (0 - 112)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	0	0	0	0
9	Persons at risk	<3077	<1053	314	1318	481	837
9	Risk (95% CI)	13 (0 - 38)	38 (0 - 112)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	0	0	0	0
12	Persons at risk	<3077	<1053	251	1108	453	655
12	Risk (95% CI)	13 (0 - 38)	38 (0 - 112)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.15.4.8 Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	116	41	75	435	133	302
3	Events, n	0	0	0	0	0	0
3	Persons at risk	100	38	62	384	120	264
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	96	38	58	351	117	234
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	89	37	52	320	114	206
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	80	34	46	286	113	173
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.5.8 Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	676	290	386	<5715	<2858	894
3	Events, n	0	0	0	0	0	0
3	Persons at risk	604	264	340	1515	733	782
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	<5	<5	0
6	Persons at risk	512	232	280	<5715	<2858	715
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	7 (0 - 21)	14 (0 - 42)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	404	193	211	<5715	<2858	655
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	7 (0 - 21)	14 (0 - 42)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	363	185	178	<5715	<2858	590
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	7 (0 - 21)	14 (0 - 42)	0 (0 - 0)

Table 15.15.6.8 Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<3077	<1213	<1819	1822	750	1072
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<3077	302	<1819	1628	683	945
3	Risk (95% CI)	13 (0 - 38)	0 (0 - 0)	22 (0 - 64)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	<5	0	0	0
6	Persons at risk	<1482	<1213	<1819	1419	624	795
6	Risk (95% CI)	27 (0 - 63)	33 (0 - 98)	22 (0 - 64)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	<5	0	0	0
9	Persons at risk	<953	<1213	<817	1231	576	655
9	Risk (95% CI)	42 (0 - 90)	33 (0 - 98)	49 (0 - 118)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	<5	0	0	0
12	Persons at risk	<953	<1213	<817	1085	537	548
12	Risk (95% CI)	42 (0 - 90)	33 (0 - 98)	49 (0 - 118)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.1.9 Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.9 Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	633	351	282	<367	<217	<129
3	Events, n	12	8	<5	<5	0	<5
3	Persons at risk	574	319	<274	<367	57	<129
3	Risk (95% CI)	194 (85 - 302)	233 (72 - 391)	146 (3 - 287)	109 (0 - 318)	0 (0 - 0)	312 (0 - 897)
6	Events, n	22	15	7	<5	0	<5
6	Persons at risk	518	292	226	<177	55	<61
6	Risk (95% CI)	370 (217 - 521)	453 (226 - 674)	265 (69 - 457)	226 (0 - 532)	0 (0 - 0)	658 (0 - 1502)
9	Events, n	29	18	11	5	<5	<5
9	Persons at risk	465	268	197	69	<217	<30
9	Risk (95% CI)	506 (324 - 685)	555 (302 - 802)	447 (184 - 704)	592 (74 - 1082)	185 (0 - 538)	1350 (25 - 2500)
12	Events, n	32	20	12	5	<5	<5
12	Persons at risk	410	243	167	63	<217	<30
12	Risk (95% CI)	572 (376 - 764)	629 (357 - 893)	500 (218 - 775)	592 (74 - 1082)	185 (0 - 538)	1350 (25 - 2500)

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Table 15.15.3.9 Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	689	237	452	1686	494	1192
3	Events, n	84	31	53	162	41	121
3	Persons at risk	526	190	336	1330	431	899
3	Risk (95% CI)	1295 (1032 - 1550)	1348 (894 - 1778)	1272 (945 - 1587)	1006 (858 - 1152)	847 (595 - 1092)	1076 (893 - 1256)
6	Events, n	104	35	69	204	56	148
6	Persons at risk	435	176	259	1145	404	741
6	Risk (95% CI)	1646 (1350 - 1931)	1533 (1052 - 1988)	1725 (1343 - 2091)	1308 (1138 - 1475)	1172 (878 - 1455)	1365 (1156 - 1568)
9	Events, n	120	42	78	237	68	169
9	Persons at risk	364	161	203	947	371	576
9	Risk (95% CI)	1974 (1647 - 2289)	1878 (1348 - 2377)	2044 (1620 - 2447)	1575 (1387 - 1759)	1441 (1117 - 1752)	1630 (1398 - 1856)
12	Events, n	125	44	81	247	71	176
12	Persons at risk	294	148	146	765	347	418
12	Risk (95% CI)	2093 (1753 - 2419)	1982 (1437 - 2492)	2176 (1731 - 2597)	1675 (1479 - 1867)	1512 (1181 - 1831)	1752 (1506 - 1992)

Table 15.15.4.9 Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<140	<160	<130	391	122	269
3	Events, n	<5	<5	<5	16	8	8
3	Persons at risk	<140	<160	<130	346	107	239
3	Risk (95% CI)	287 (0 - 601)	250 (0 - 722)	310 (0 - 724)	420 (216 - 619)	664 (208 - 1098)	306 (95 - 513)
6	Events, n	6	<5	<5	21	9	12
6	Persons at risk	89	<78	<63	307	102	205
6	Risk (95% CI)	594 (121 - 1044)	514 (0 - 1182)	642 (12 - 1232)	565 (327 - 798)	751 (267 - 1212)	483 (211 - 747)
9	Events, n	7	<5	<5	28	10	18
9	Persons at risk	81	<51	<63	273	98	175
9	Risk (95% CI)	700 (185 - 1188)	785 (0 - 1600)	642 (12 - 1232)	792 (504 - 1071)	843 (328 - 1330)	784 (426 - 1129)
12	Events, n	7	<5	<5	31	10	21
12	Persons at risk	75	<51	<63	242	95	147
12	Risk (95% CI)	700 (185 - 1188)	785 (0 - 1600)	642 (12 - 1232)	899 (589 - 1198)	843 (328 - 1330)	955 (552 - 1342)

Table 15.15.5.9 Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	597	262	335	1474	713	761
3	Events, n	17	6	11	85	39	46
3	Persons at risk	538	242	296	1293	648	645
3	Risk (95% CI)	291 (153 - 426)	233 (47 - 416)	336 (139 - 529)	598 (474 - 721)	559 (387 - 728)	635 (455 - 811)
6	Events, n	32	13	19	121	51	70
6	Persons at risk	384	183	201	1192	621	571
6	Risk (95% CI)	599 (394 - 800)	553 (255 - 843)	632 (351 - 905)	867 (718 - 1014)	736 (540 - 929)	998 (773 - 1218)
9	Events, n	36	14	22	147	54	93
9	Persons at risk	331	164	167	1096	598	498
9	Risk (95% CI)	704 (476 - 927)	607 (291 - 912)	786 (457 - 1104)	1071 (905 - 1233)	781 (579 - 979)	1375 (1110 - 1632)
12	Events, n	40	14	26	165	60	105
12	Persons at risk	301	162	139	1028	584	444
12	Risk (95% CI)	825 (570 - 1072)	607 (291 - 912)	1036 (631 - 1424)	1222 (1044 - 1395)	875 (660 - 1084)	1593 (1306 - 1871)

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Table 15.15.6.9 Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	815	<417	487	1724	720	1004
3	Events, n	7	<5	<5	27	14	13
3	Persons at risk	717	<417	<482	1489	644	845
3	Risk (95% CI)	88 (23 - 153)	96 (0 - 204)	83 (2 - 163)	165 (103 - 226)	204 (98 - 309)	135 (62 - 207)
6	Events, n	15	6	9	39	17	22
6	Persons at risk	597	259	338	1301	587	714
6	Risk (95% CI)	215 (106 - 323)	208 (41 - 372)	220 (75 - 363)	248 (171 - 325)	252 (133 - 370)	246 (144 - 348)
9	Events, n	18	8	10	47	20	27
9	Persons at risk	512	230	282	1131	539	592
9	Risk (95% CI)	269 (144 - 392)	288 (88 - 483)	254 (95 - 411)	312 (223 - 401)	303 (171 - 434)	322 (200 - 442)
12	Events, n	23	10	13	50	20	30
12	Persons at risk	430	209	221	976	500	476
12	Risk (95% CI)	371 (218 - 522)	374 (142 - 601)	372 (165 - 575)	339 (245 - 432)	303 (171 - 434)	373 (239 - 506)

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Table 15.15.1.1.10 Risk (1-KM and 95% CI) for Chronic Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.10 Risk (1-KM and 95% CI) for Chronic Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	651	362	289	97	62	35
3	Events, n	0	0	0	0	0	0
3	Persons at risk	602	337	265	91	59	32
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	553	316	237	89	57	32
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	503	293	210	78	49	29
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	451	270	181	72	46	26
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.3.10 Risk (1-KM and 95% CI) for Chronic Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<2223	<889	512	1887	<2106	<1667
3	Events, n	0	0	0	<5	<5	<5
3	Persons at risk	677	242	435	<1740	<2106	<1667
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	23 (0 - 45)	19 (0 - 57)	24 (0 - 52)
6	Events, n	0	0	0	9	<5	8
6	Persons at risk	590	228	362	1443	<2106	950
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	54 (19 - 90)	19 (0 - 57)	70 (22 - 119)
9	Events, n	<5	<5	0	14	5	9
9	Persons at risk	<2223	<889	294	1239	469	770
9	Risk (95% CI)	18 (0 - 55)	45 (0 - 133)	0 (0 - 0)	91 (43 - 139)	102 (13 - 190)	83 (28 - 138)
12	Events, n	<5	<5	0	17	7	10
12	Persons at risk	<2223	<889	223	1012	436	576
12	Risk (95% CI)	18 (0 - 55)	45 (0 - 133)	0 (0 - 0)	118 (61 - 175)	146 (38 - 253)	97 (36 - 158)

Table 15.15.4.10 Risk (1-KM and 95% CI) for Chronic Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	105	40	65	411	129	282
3	Events, n	0	0	0	0	0	0
3	Persons at risk	99	38	61	377	120	257
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	94	38	56	340	116	224
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	85	36	49	309	113	196
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	79	34	45	278	110	168
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.5.10 Risk (1-KM and 95% CI) for Chronic Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	632	275	357	1603	<1482	848
3	Events, n	0	0	0	6	<5	<5
3	Persons at risk	583	259	324	1486	<1482	<817
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	39 (8 - 70)	27 (0 - 65)	49 (1 - 96)
6	Events, n	0	0	0	7	<5	<5
6	Persons at risk	437	206	231	1390	<953	<817
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	46 (12 - 80)	42 (0 - 89)	49 (1 - 96)
9	Events, n	0	0	0	7	<5	<5
9	Persons at risk	384	187	197	1296	<953	<817
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	46 (12 - 80)	42 (0 - 89)	49 (1 - 96)
12	Events, n	0	0	0	7	<5	<5
12	Persons at risk	354	185	169	1234	<953	<817
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	46 (12 - 80)	42 (0 - 89)	49 (1 - 96)

Table 15.15.6.10 Risk (1-KM and 95% CI) for Chronic Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<2858	<1177	491	1750	<931	<1291
3	Events, n	0	0	0	6	<5	<5
3	Persons at risk	734	300	434	1533	<931	<1291
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	36 (7 - 64)	43 (0 - 91)	31 (0 - 65)
6	Events, n	<5	<5	0	6	<5	<5
6	Persons at risk	<2858	<1177	349	1350	<931	<1291
6	Risk (95% CI)	14 (0 - 41)	34 (0 - 99)	0 (0 - 0)	36 (7 - 64)	43 (0 - 91)	31 (0 - 65)
9	Events, n	<5	<5	0	8	<5	<5
9	Persons at risk	<2858	<1177	293	1179	<678	<889
9	Risk (95% CI)	14 (0 - 41)	34 (0 - 99)	0 (0 - 0)	51 (15 - 87)	59 (1 - 117)	45 (0 - 91)
12	Events, n	<5	<5	0	8	<5	<5
12	Persons at risk	<2858	<1177	234	1020	<678	<889
12	Risk (95% CI)	14 (0 - 41)	34 (0 - 99)	0 (0 - 0)	51 (15 - 87)	59 (1 - 117)	45 (0 - 91)

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Table 15.15.1.11 Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.11 Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	674	370	304	102	66	36
3	Events, n	0	0	0	0	0	0
3	Persons at risk	618	347	271	94	61	33
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	572	325	247	91	59	32
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	518	302	216	84	53	31
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	477	282	195	73	47	26
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.3.11 Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	813	270	543	1941	544	1397
3	Events, n	0	0	0	0	0	0
3	Persons at risk	704	246	458	1744	517	1227
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	616	232	384	1520	501	1019
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	536	222	314	1318	481	837
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	461	210	251	1108	453	655
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.4.11 Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<466	41	<301	<870	<267	302
3	Events, n	<5	0	<5	<5	<5	0
3	Persons at risk	<466	38	<301	<870	<267	264
3	Risk (95% CI)	86 (0 - 253)	0 (0 - 0)	133 (0 - 390)	46 (0 - 109)	150 (0 - 355)	0 (0 - 0)
6	Events, n	<5	0	<5	<5	<5	0
6	Persons at risk	<466	38	<301	<870	<267	234
6	Risk (95% CI)	86 (0 - 253)	0 (0 - 0)	133 (0 - 390)	46 (0 - 109)	150 (0 - 355)	0 (0 - 0)
9	Events, n	<5	0	<5	<5	<5	0
9	Persons at risk	<466	37	<301	<870	<267	206
9	Risk (95% CI)	86 (0 - 253)	0 (0 - 0)	133 (0 - 390)	46 (0 - 109)	150 (0 - 355)	0 (0 - 0)
12	Events, n	<5	0	<5	<5	<5	0
12	Persons at risk	<466	34	<301	<870	<267	173
12	Risk (95% CI)	86 (0 - 253)	0 (0 - 0)	133 (0 - 390)	46 (0 - 109)	150 (0 - 355)	0 (0 - 0)

Table 15.15.5.11 Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<1334	290	<770	1664	770	894
3	Events, n	<5	0	<5	11	6	5
3	Persons at risk	<1334	264	<770	1507	729	778
3	Risk (95% CI)	30 (0 - 71)	0 (0 - 0)	52 (0 - 124)	68 (28 - 107)	79 (16 - 141)	58 (7 - 108)
6	Events, n	<5	0	<5	12	7	5
6	Persons at risk	<1334	232	<770	1416	705	711
6	Risk (95% CI)	30 (0 - 71)	0 (0 - 0)	52 (0 - 124)	74 (32 - 116)	92 (24 - 160)	58 (7 - 108)
9	Events, n	<5	0	<5	13	8	5
9	Persons at risk	<1334	193	<770	1339	687	652
9	Risk (95% CI)	30 (0 - 71)	0 (0 - 0)	52 (0 - 124)	81 (37 - 125)	106 (33 - 180)	58 (7 - 108)
12	Events, n	<5	0	<5	13	8	5
12	Persons at risk	<1334	185	<770	1257	668	589
12	Risk (95% CI)	30 (0 - 71)	0 (0 - 0)	52 (0 - 124)	81 (37 - 125)	106 (33 - 180)	58 (7 - 108)

Table 15.15.6.11 Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	863	350	513	1822	750	1072
3	Events, n	0	0	0	0	0	0
3	Persons at risk	754	302	452	1628	683	945
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	659	280	379	1419	624	795
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	566	255	311	1231	576	655
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	482	229	253	1085	537	548
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.15.1.1.12 Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.12 Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	621	344	<348	88	57	31
3	Events, n	9	6	<5	0	0	0
3	Persons at risk	564	314	<348	82	54	28
3	Risk (95% CI)	151 (52 - 248)	180 (36 - 322)	115 (0 - 243)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	12	7	5	0	0	0
6	Persons at risk	514	294	220	81	53	28
6	Risk (95% CI)	206 (90 - 321)	213 (55 - 368)	198 (24 - 369)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	12	7	5	0	0	0
9	Persons at risk	468	272	196	72	47	25
9	Risk (95% CI)	206 (90 - 321)	213 (55 - 368)	198 (24 - 369)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	13	7	6	0	0	0
12	Persons at risk	417	250	167	67	44	23
12	Risk (95% CI)	229 (105 - 353)	213 (55 - 368)	256 (49 - 460)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.15.3.12 Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	617	205	412	1859	523	1336
3	Events, n	108	36	72	26	10	16
3	Persons at risk	437	156	281	1605	489	1116
3	Risk (95% CI)	1855 (1532 - 2166)	1821 (1264 - 2342)	1876 (1474 - 2259)	148 (91 - 204)	196 (75 - 315)	129 (66 - 191)
6	Events, n	125	43	82	29	10	19
6	Persons at risk	366	144	222	1407	476	931
6	Risk (95% CI)	2189 (1840 - 2523)	2191 (1589 - 2750)	2191 (1757 - 2603)	168 (107 - 229)	196 (75 - 315)	159 (88 - 230)
9	Events, n	135	52	83	33	13	20
9	Persons at risk	310	128	182	1206	454	752
9	Risk (95% CI)	2413 (2046 - 2763)	2690 (2035 - 3292)	2231 (1791 - 2648)	198 (131 - 266)	259 (119 - 397)	172 (96 - 247)
12	Events, n	143	56	87	35	13	22
12	Persons at risk	254	115	139	981	424	557
12	Risk (95% CI)	2631 (2242 - 3000)	2928 (2248 - 3548)	2434 (1959 - 2882)	217 (145 - 289)	259 (119 - 397)	203 (116 - 290)

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Table 15.15.4.12 Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<113	<67	<209	401	125	276
3	Events, n	<5	<5	<5	0	0	0
3	Persons at risk	<113	<67	<209	368	117	251
3	Risk (95% CI)	354 (0 - 740)	606 (0 - 1386)	192 (0 - 559)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	5	<5	<5	0	0	0
6	Persons at risk	72	<44	<99	331	113	218
6	Risk (95% CI)	603 (76 - 1103)	919 (0 - 1859)	406 (0 - 941)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	5	<5	<5	0	0	0
9	Persons at risk	66	<44	<99	302	110	192
9	Risk (95% CI)	603 (76 - 1103)	919 (0 - 1859)	406 (0 - 941)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	5	<5	<5	0	0	0
12	Persons at risk	62	<44	<99	271	107	164
12	Risk (95% CI)	603 (76 - 1103)	919 (0 - 1859)	406 (0 - 941)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.15.5.12 Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	578	251	327	<2106	<1000	<2858
3	Events, n	11	<5	7	<5	<5	0
3	Persons at risk	523	<243	292	<2106	<1000	762
3	Risk (95% CI)	195 (80 - 309)	165 (3 - 324)	219 (57 - 378)	19 (0 - 41)	40 (0 - 86)	0 (0 - 0)
6	Events, n	17	7	10	<5	<5	<5
6	Persons at risk	379	178	201	<1539	<1000	<2858
6	Risk (95% CI)	325 (171 - 477)	306 (79 - 528)	338 (128 - 543)	26 (0 - 52)	40 (0 - 86)	14 (0 - 42)
9	Events, n	18	7	11	6	<5	<5
9	Persons at risk	329	159	170	1289	<728	<1334
9	Risk (95% CI)	352 (189 - 512)	306 (79 - 528)	389 (157 - 616)	41 (8 - 74)	55 (1 - 109)	30 (0 - 71)
12	Events, n	21	8	13	7	5	<5
12	Persons at risk	300	157	143	1226	657	<1334
12	Risk (95% CI)	443 (251 - 631)	367 (111 - 617)	513 (225 - 793)	49 (13 - 86)	70 (9 - 131)	30 (0 - 71)

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Table 15.15.6.12 Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	639	266	373	1737	723	1014
3	Events, n	64	23	41	12	<5	8
3	Persons at risk	511	221	290	1516	<702	859
3	Risk (95% CI)	1043 (797 - 1281)	902 (543 - 1248)	1143 (807 - 1467)	72 (31 - 112)	57 (1 - 113)	83 (25 - 140)
6	Events, n	87	31	56	16	6	10
6	Persons at risk	406	191	215	1331	598	733
6	Risk (95% CI)	1480 (1186 - 1764)	1248 (826 - 1651)	1655 (1245 - 2046)	100 (51 - 149)	89 (18 - 159)	108 (41 - 175)
9	Events, n	92	33	59	21	7	14
9	Persons at risk	348	172	176	1159	552	607
9	Risk (95% CI)	1590 (1283 - 1886)	1346 (906 - 1765)	1774 (1347 - 2181)	140 (80 - 200)	106 (27 - 184)	168 (79 - 256)
12	Events, n	101	34	67	22	8	14
12	Persons at risk	289	157	132	1001	512	489
12	Risk (95% CI)	1824 (1488 - 2146)	1397 (947 - 1825)	2193 (1690 - 2665)	149 (86 - 211)	125 (38 - 210)	168 (79 - 256)

Table 15.15.1.1.13 Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PEDIANET

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.15.2.13 Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	643	354	289	<122	<237	<64
3	Events, n	0	0	0	<5	<5	<5
3	Persons at risk	595	330	265	<122	<237	<64
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	330 (0 - 690)	169 (0 - 493)	626 (0 - 1431)
6	Events, n	0	0	0	<5	<5	<5
6	Persons at risk	546	309	237	<122	<237	<64
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	330 (0 - 690)	169 (0 - 493)	626 (0 - 1431)
9	Events, n	0	0	0	5	<5	<5
9	Persons at risk	496	286	210	68	<113	<42
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	572 (71 - 1047)	355 (0 - 827)	961 (0 - 1940)
12	Events, n	0	0	0	6	<5	<5
12	Persons at risk	444	263	181	62	<113	<30
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	719 (143 - 1261)	355 (0 - 827)	1372 (11 - 2547)

Table 15.15.3.13 Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	741	248	493	1425	392	1033
3	Events, n	25	6	19	247	61	186
3	Persons at risk	626	225	401	1016	314	702
3	Risk (95% CI)	360 (220 - 498)	251 (51 - 447)	418 (232 - 600)	1808 (1601 - 2010)	1588 (1214 - 1945)	1893 (1644 - 2135)
6	Events, n	29	8	21	290	79	211
6	Persons at risk	543	209	334	854	282	572
6	Risk (95% CI)	426 (273 - 578)	341 (106 - 570)	470 (271 - 664)	2174 (1948 - 2394)	2078 (1659 - 2477)	2205 (1935 - 2466)
9	Events, n	30	9	21	302	85	217
9	Persons at risk	471	200	271	710	265	445
9	Risk (95% CI)	444 (287 - 599)	388 (136 - 633)	470 (271 - 664)	2294 (2061 - 2520)	2251 (1816 - 2662)	2297 (2020 - 2564)
12	Events, n	32	9	23	310	89	221
12	Persons at risk	389	185	204	557	238	319
12	Risk (95% CI)	490 (321 - 656)	388 (136 - 633)	554 (324 - 778)	2390 (2150 - 2623)	2373 (1928 - 2793)	2378 (2092 - 2653)

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Table 15.15.4.13 Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EPICHRON

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<179	37	<109	305	93	212
3	Events, n	0	0	0	8	<5	<5
3	Persons at risk	91	35	56	270	<89	<200
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	277 (86 - 465)	453 (9 - 877)	200 (4 - 393)
6	Events, n	<5	0	<5	10	5	5
6	Persons at risk	<179	35	<109	243	78	165
6	Risk (95% CI)	224 (0 - 525)	0 (0 - 0)	367 (0 - 855)	353 (135 - 566)	572 (72 - 1047)	253 (32 - 470)
9	Events, n	<5	0	<5	10	5	5
9	Persons at risk	<179	33	<109	216	77	139
9	Risk (95% CI)	224 (0 - 525)	0 (0 - 0)	367 (0 - 855)	353 (135 - 566)	572 (72 - 1047)	253 (32 - 470)
12	Events, n	<5	0	<5	13	7	6
12	Persons at risk	<179	31	<109	192	72	120
12	Risk (95% CI)	224 (0 - 525)	0 (0 - 0)	367 (0 - 855)	493 (225 - 753)	817 (217 - 1380)	329 (62 - 588)

Table 15.15.5.13 Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<2500	267	<1380	1395	663	742
3	Events, n	<5	0	<5	60	33	27
3	Persons at risk	<2500	252	<1380	1238	594	644
3	Risk (95% CI)	16 (0 - 48)	0 (0 - 0)	29 (0 - 84)	445 (334 - 555)	516 (343 - 686)	383 (240 - 523)
6	Events, n	<5	0	<5	84	41	43
6	Persons at risk	<2500	200	<1380	1136	567	569
6	Risk (95% CI)	16 (0 - 48)	0 (0 - 0)	29 (0 - 84)	638 (505 - 769)	646 (453 - 836)	635 (449 - 818)
9	Events, n	<5	0	<5	95	46	49
9	Persons at risk	<2500	182	<1380	1043	541	502
9	Risk (95% CI)	16 (0 - 48)	0 (0 - 0)	29 (0 - 84)	730 (587 - 871)	729 (524 - 930)	738 (536 - 935)
12	Events, n	<5	0	<5	105	50	55
12	Persons at risk	<2500	180	<1380	981	530	451
12	Risk (95% CI)	16 (0 - 48)	0 (0 - 0)	29 (0 - 84)	820 (668 - 970)	798 (583 - 1008)	853 (633 - 1068)

Table 15.15.6.13 Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	802	<598	481	1300	541	759
3	Events, n	10	<5	8	108	42	66
3	Persons at risk	703	<598	417	1050	453	597
3	Risk (95% CI)	131 (50 - 211)	67 (0 - 159)	173 (53 - 291)	861 (704 - 1015)	797 (563 - 1025)	908 (696 - 1114)
6	Events, n	15	<5	12	127	51	76
6	Persons at risk	587	<389	331	900	403	497
6	Risk (95% CI)	207 (102 - 311)	103 (0 - 218)	279 (121 - 434)	1036 (863 - 1206)	988 (726 - 1243)	1069 (838 - 1295)
9	Events, n	16	<5	12	141	54	87
9	Persons at risk	506	<280	277	776	369	407
9	Risk (95% CI)	225 (115 - 334)	143 (2 - 282)	279 (121 - 434)	1183 (996 - 1366)	1057 (785 - 1321)	1282 (1023 - 1533)
12	Events, n	16	<5	12	145	56	89
12	Persons at risk	432	<280	221	666	339	327
12	Risk (95% CI)	225 (115 - 334)	143 (2 - 282)	279 (121 - 434)	1231 (1039 - 1419)	1107 (828 - 1378)	1329 (1063 - 1588)

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Table 15.16.1 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in Pedianet

subgroup	Characteristic	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Age: 15-30		N =0	N =0
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (NaN)
	Computed tomography(CT)	0 (NaN)	0 (NaN)
	Echocardiogram	0 (NaN)	0 (NaN)
Sex: Female		N =0	N < 5
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (0)
	Computed tomography(CT)	0 (NaN)	0 (0)
	Echocardiogram	0 (NaN)	0 (0)
Sex: Male		N =0	N < 5
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (0)
	Computed tomography(CT)	0 (NaN)	0 (0)
	Echocardiogram	0 (NaN)	0 (0)
Age and Sex: Females: 15-30		N =0	N =0
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (NaN)
	Computed tomography(CT)	0 (NaN)	0 (NaN)
	Echocardiogram	0 (NaN)	0 (NaN)
Age and Sex: Males: 15-30		N =0	N =0
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (NaN)
	Computed tomography(CT)	0 (NaN)	0 (NaN)
	Echocardiogram	0 (NaN)	0 (NaN)
COVID-19 history: Yes		N =0	N < 5
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (0)
	Computed tomography(CT)	0 (NaN)	0 (0)
	Echocardiogram	0 (NaN)	0 (0)
COVID-19 history: No		N =0	N < 5
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (0)
	Computed tomography(CT)	0 (NaN)	0 (0)
	Echocardiogram	0 (NaN)	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =0	N < 5

Table 15.16.1 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in Pedianet

subgroup	Characteristic	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (0)
	Computed tomography(CT)	0 (NaN)	0 (0)
	Echocardiogram	0 (NaN)	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =0	N =0
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (NaN)
	Computed tomography(CT)	0 (NaN)	0 (NaN)
	Echocardiogram	0 (NaN)	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Unvaccinated		N =0	N < 5
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (0)
	Computed tomography(CT)	0 (NaN)	0 (0)
	Echocardiogram	0 (NaN)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =0	N < 5
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (0)
	Computed tomography(CT)	0 (NaN)	0 (0)
	Echocardiogram	0 (NaN)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =0	N =0
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (NaN)
	Computed tomography(CT)	0 (NaN)	0 (NaN)
	Echocardiogram	0 (NaN)	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =0	N =0
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (NaN)
	Computed tomography(CT)	0 (NaN)	0 (NaN)
	Echocardiogram	0 (NaN)	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =0	N =0
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (NaN)

Table 15.16.1 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in Pedianet

subgroup	Characteristic	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
	Computed tomography(CT)	0 (NaN)	0 (NaN)
	Echocardiogram	0 (NaN)	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =0	N =0
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (NaN)
	Computed tomography(CT)	0 (NaN)	0 (NaN)
	Echocardiogram	0 (NaN)	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =0	N =0
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (NaN)
	Computed tomography(CT)	0 (NaN)	0 (NaN)
	Echocardiogram	0 (NaN)	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =0	N =0
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (NaN)
	Computed tomography(CT)	0 (NaN)	0 (NaN)
	Echocardiogram	0 (NaN)	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =0	N =0
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (NaN)
	Computed tomography(CT)	0 (NaN)	0 (NaN)
	Echocardiogram	0 (NaN)	0 (NaN)

Table 15.16.2 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in Pharmo

subgroup	Characteristic	Myocarditis cohort (N=674)	Pericarditis cohort (N=102)
Age: 15-30		N =135	N =23
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Sex: Female		N =217	N =32
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Sex: Male		N =457	N =70
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Age and Sex: Females: 15-30		N =42	N =5
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Age and Sex: Males: 15-30		N =93	N =18
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
COVID-19 history: Yes		N =121	N =15
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
COVID-19 history: No		N =553	N =87
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =36	N =5

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Table 15.16.2 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in Pharmo

subgroup	Characteristic	Myocarditis cohort (N=674)	Pericarditis cohort (N=102)
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =268	N =31
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
	Time since vaccination with Pfize	N > 364	N > 55
	Cardiac magnetic resonance(CMR)	>5 (>5)	>5 (>5)
	Computed tomography(CT)	>5 (>5)	>5 (>5)
	Echocardiogram	>5 (>5)	>5 (>5)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =12	N < 5
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =88	N =11
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =13	N < 5
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =145	N =16
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)

Table 15.16.2 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in Pharmo

subgroup	Characteristic	Myocarditis cohort (N=674)	Pericarditis cohort (N=102)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
	Time since vaccination with Pfize	N < 5	N < 5
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =37	N =5
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
	Time since vaccination with Pfize	N < 5	N =0
	Cardiac magnetic resonance(CMR)	0 (0)	0 (NaN)
	Computed tomography(CT)	0 (0)	0 (NaN)
	Echocardiogram	0 (0)	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =5	N =0
	Cardiac magnetic resonance(CMR)	0 (0)	0 (NaN)
	Computed tomography(CT)	0 (0)	0 (NaN)
	Echocardiogram	0 (0)	0 (NaN)

Table 15.16.3 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in NHR

subgroup	Characteristic	Myocarditis cohort (N=813)	Pericarditis cohort (N=1941)
Age: 15-30		N =204	N =289
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Sex: Female		N =268	N =626
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Sex: Male		N =545	N =1315
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Age and Sex: Females: 15-30		N =34	N =61
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Age and Sex: Males: 15-30		N =170	N =228
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
COVID-19 history: Yes		N =119	N =204
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
COVID-19 history: No		N =694	N =1737
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =66	N =195

Table 15.16.3 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in NHR

subgroup	Characteristic	Myocarditis cohort (N=813)	Pericarditis cohort (N=1941)
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =477	N =1202
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Unvaccinated		N =270	N =544
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =18	N =49
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =67	N =134
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =12	N =59
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =230	N =533
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)

Table 15.16.3 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in NHR

subgroup	Characteristic	Myocarditis cohort (N=813)	Pericarditis cohort (N=1941)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =13	N =24
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =173	N =512
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =6	N =11
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =24	N =75
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)

Table 15.16.4 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in EpiChron

subgroup	Characteristic	Myocarditis cohort (N=116)	Pericarditis cohort (N=435)
Age: 15-30		N =39	N =94
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Sex: Female		N =25	N =121
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Sex: Male		N =91	N =314
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
	Age and Sex: Females: 15-30	N < 5	N =16
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Age and Sex: Males: 15-30		N =37	N =78
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
COVID-19 history: Yes		N =34	N =118
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
COVID-19 history: No		N =82	N =317
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =10	N =30

Table 15.16.4 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in EpiChron

subgroup	Characteristic	Myocarditis cohort (N=116)	Pericarditis cohort (N=435)
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =65	N =272
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
	Time since vaccination with Pfizer	N > 32	N =133
	Cardiac magnetic resonance(CMR)	>5 (>5)	0 (0)
	Computed tomography(CT)	>5 (>5)	0 (0)
	Echocardiogram	>5 (>5)	0 (0)
	Time since vaccination with Pfizer	N < 5	N =9
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =12	N =20
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
	Time since vaccination with Pfizer	N < 5	N =9
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =35	N > 169
	Cardiac magnetic resonance(CMR)	0 (0)	>5 (>5)
	Computed tomography(CT)	0 (0)	>5 (>5)

Table 15.16.4 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in EpiChron

subgroup	Characteristic	Myocarditis cohort (N=116)	Pericarditis cohort (N=435)
	Echocardiogram	0 (0)	>5 (>5)
	Time since vaccination with Pfize	N < 5	N < 5
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =22	N =74
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =0	N < 5
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (0)
	Computed tomography(CT)	0 (NaN)	0 (0)
	Echocardiogram	0 (NaN)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =0	N =11
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (0)
	Computed tomography(CT)	0 (NaN)	0 (0)
	Echocardiogram	0 (NaN)	0 (0)

Table 15.16.5 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in SIDIAP

subgroup	Characteristic	Myocarditis cohort (N=676)	Pericarditis cohort (N=1664)
Age: 15-30		N =119	N =271
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Sex: Female		N =262	N =591
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Sex: Male		N =414	N =1073
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Age and Sex: Females: 15-30		N =24	N =57
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Age and Sex: Males: 15-30		N =95	N =214
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
COVID-19 history: Yes		N =316	N =477
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
COVID-19 history: No		N =360	N =1187
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =28	N =133

Table 15.16.5 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in SIDIAP

subgroup	Characteristic	Myocarditis cohort (N=676)	Pericarditis cohort (N=1664)
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =358	N =764
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Unvaccinated		N =290	N > 765
	Cardiac magnetic resonance(CMR)	0 (0)	>5 (>5)
	Computed tomography(CT)	0 (0)	>5 (>5)
	Echocardiogram	0 (0)	>5 (>5)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =8	N =44
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =48	N =70
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =13	N =36
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =225	N =535
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)

Table 15.16.5 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in SIDIAP

subgroup	Characteristic	Myocarditis cohort (N=676)	Pericarditis cohort (N=1664)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =0	N =7
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (0)
	Computed tomography(CT)	0 (NaN)	0 (0)
	Echocardiogram	0 (NaN)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =67	N =141
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =0	N < 5
	Cardiac magnetic resonance(CMR)	0 (NaN)	0 (0)
	Computed tomography(CT)	0 (NaN)	0 (0)
	Echocardiogram	0 (NaN)	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =25	N =61
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	0 (0)

Table 15.16.6 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in CPRD

subgroup	Characteristic	Myocarditis cohort (N=863)	Pericarditis cohort (N=1822)
Age: 15-30		N =356	N =644
	Cardiac magnetic resonance(CMR)	32 (8.99)	10 (1.55)
	Computed tomography(CT)	<5	<5
	Echocardiogram	78 (21.91)	100 (15.53)
Sex: Female		N =281	N =548
	Cardiac magnetic resonance(CMR)	16 (5.69)	10 (1.82)
	Computed tomography(CT)	<5	<5
	Echocardiogram	58 (20.64)	99 (18.07)
Sex: Male		N =582	N =1274
	Cardiac magnetic resonance(CMR)	54 (9.28)	14 (1.1)
	Computed tomography(CT)	6 (1.03)	9 (0.71)
	Echocardiogram	132 (22.68)	227 (17.82)
Age and Sex: Females: 15-30		N =64	N =159
	Cardiac magnetic resonance(CMR)	6 (9.38)	<5
	Computed tomography(CT)	<5	0 (0)
	Echocardiogram	16 (25)	16 (10.06)
Age and Sex: Males: 15-30		N =292	N =485
	Cardiac magnetic resonance(CMR)	26 (8.9)	8 (1.65)
	Computed tomography(CT)	0 (0)	<5
	Echocardiogram	62 (21.23)	84 (17.32)
COVID-19 history: Yes		N =262	N =454
	Cardiac magnetic resonance(CMR)	19 (7.25)	10 (2.2)
	Computed tomography(CT)	<5	<5
	Echocardiogram	52 (19.85)	75 (16.52)
COVID-19 history: No		N =601	N =1368
	Cardiac magnetic resonance(CMR)	51 (8.49)	14 (1.02)
	Computed tomography(CT)	5 (0.83)	12 (0.88)
	Echocardiogram	138 (22.96)	251 (18.35)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =62	N =100

Table 15.16.6 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in CPRD

subgroup	Characteristic	Myocarditis cohort (N=863)	Pericarditis cohort (N=1822)
	Cardiac magnetic resonance(CMR)	9 (14.52)	<5
	Computed tomography(CT)	<5	0 (0)
	Echocardiogram	15 (24.19)	9 (9)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =451	N =973
	Cardiac magnetic resonance(CMR)	36 (7.98)	16 (1.64)
	Computed tomography(CT)	<5	7 (0.72)
	Echocardiogram	104 (23.06)	178 (18.29)
	Time since vaccination with Pfize	N > 346	N =749
	Cardiac magnetic resonance(CMR)	>25 (>5)	7 (0.93)
	Computed tomography(CT)	<5	6 (0.8)
	Echocardiogram	>70 (>20)	139 (18.56)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =17	N =27
	Cardiac magnetic resonance(CMR)	<5	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	6 (35.29)	<5
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =83	N =182
	Cardiac magnetic resonance(CMR)	6 (7.23)	<5
	Computed tomography(CT)	<5	<5
	Echocardiogram	18 (21.69)	34 (18.68)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =25	N =26
	Cardiac magnetic resonance(CMR)	<5	0 (0)
	Computed tomography(CT)	<5	0 (0)
	Echocardiogram	7 (28)	<5
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =198	N =415
	Cardiac magnetic resonance(CMR)	16 (8.08)	6 (1.45)

Table 15.16.6 Tests performed for the diagnosis of myocarditis or pericarditis by subgroup in CPRD

subgroup	Characteristic	Myocarditis cohort (N=863)	Pericarditis cohort (N=1822)
	Computed tomography(CT)	<5	<5
	Echocardiogram	45 (22.73)	68 (16.39)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =6	N =9
	Cardiac magnetic resonance(CMR)	<5	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	0 (0)	<5
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =173	N =384
	Cardiac magnetic resonance(CMR)	15 (8.67)	9 (2.34)
	Computed tomography(CT)	<5	<5
	Echocardiogram	39 (22.54)	70 (18.23)
	Time since vaccination with Pfize	N < 5	N =0
	Cardiac magnetic resonance(CMR)	0 (0)	0 (NaN)
	Computed tomography(CT)	0 (0)	0 (NaN)
	Echocardiogram	0 (0)	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =10	N =30
	Cardiac magnetic resonance(CMR)	0 (0)	0 (0)
	Computed tomography(CT)	0 (0)	0 (0)
	Echocardiogram	<5	8 (26.67)

Table 15.17.1 Treatments for myocarditis by for Pedianet

subgroup	Characteristic	myocarditis cohort (N=0)
Age: 15-30		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Sex: Female		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Sex: Male		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)

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Table 15.17.1 Treatments for myocarditis by for Pedianet

subgroup	Characteristic	myocarditis cohort (N=0)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Age and Sex: Females: 15-30		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Age and Sex: Males: 15-30		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)

Table 15.17.1 Treatments for myocarditis by for Pedianet

subgroup	Characteristic	myocarditis cohort (N=0)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
COVID-19 history: Yes		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
COVID-19 history: No		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)

Table 15.17.1 Treatments for myocarditis by for Pedianet

subgroup	Characteristic	myocarditis cohort (N=0)
	Heart Transplantation	0 (NaN)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Unvaccinated		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)

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Table 15.17.1 Treatments for myocarditis by for Pedianet

subgroup	Characteristic	myocarditis cohort (N=0)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)

Table 15.17.1 Treatments for myocarditis by for Pedianet

subgroup	Characteristic	myocarditis cohort (N=0)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)

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Table 15.17.1 Treatments for myocarditis by for Pedianet

subgroup	Characteristic	myocarditis cohort (N=0)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)

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Table 15.17.1 Treatments for myocarditis by for Pedianet

subgroup	Characteristic	myocarditis cohort (N=0)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)

Table 15.17.2 Treatments for myocarditis by for Pharmo

subgroup	Characteristic	myocarditis cohort (N=674)
Age: 15-30		N =135
	Paracetamol	12 (8.89)
	Antivirals	<5
	Antibiotics	35 (25.93)
	Immunosuppressant agents	21 (15.56)
	Beta-blockers	10 (7.41)
	Diuretics	<5
	ACE inhibitor or ARB	10 (7.41)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Sex: Female		N =217
	Paracetamol	27 (12.44)
	Antivirals	<5
	Antibiotics	96 (44.24)
	Immunosuppressant agents	43 (19.82)
	Beta-blockers	72 (33.18)
	Diuretics	45 (20.74)
	ACE inhibitor or ARB	61 (28.11)
	Aldosterone Antagonist	23 (10.6)
	Cardiac glycosides or calcium-channel blockers	31 (14.29)
	Antiarrhythmics	8 (3.69)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Sex: Male		N =457
	Paracetamol	36 (7.88)
	Antivirals	<5
	Antibiotics	122 (26.7)
	Immunosuppressant agents	72 (15.75)
	Beta-blockers	114 (24.95)

Table 15.17.2 Treatments for myocarditis by for Pharmo

subgroup	Characteristic	myocarditis cohort (N=674)
	Diuretics	62 (13.57)
	ACE inhibitor or ARB	101 (22.1)
	Aldosterone Antagonist	18 (3.94)
	Cardiac glycosides or calcium-channel blockers	62 (13.57)
	Antiarrhythmics	6 (1.31)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Age and Sex: Females: 15-30		N =42
	Paracetamol	5 (11.9)
	Antivirals	<5
	Antibiotics	20 (47.62)
	Immunosuppressant agents	9 (21.43)
	Beta-blockers	<5
	Diuretics	<5
	ACE inhibitor or ARB	5 (11.9)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Age and Sex: Males: 15-30		N =93
	Paracetamol	7 (7.53)
	Antivirals	0 (0)
	Antibiotics	15 (16.13)
	Immunosuppressant agents	12 (12.9)
	Beta-blockers	6 (6.45)
	Diuretics	0 (0)
	ACE inhibitor or ARB	5 (5.38)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)

Table 15.17.2 Treatments for myocarditis by for Pharmo

subgroup	Characteristic	myocarditis cohort (N=674)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
COVID-19 history: Yes		N =121
	Paracetamol	7 (5.79)
	Antivirals	0 (0)
	Antibiotics	39 (32.23)
	Immunosuppressant agents	19 (15.7)
	Beta-blockers	29 (23.97)
	Diuretics	11 (9.09)
	ACE inhibitor or ARB	24 (19.83)
	Aldosterone Antagonist	6 (4.96)
	Cardiac glycosides or calcium-channel blockers	12 (9.92)
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
COVID-19 history: No		N =553
	Paracetamol	56 (10.13)
	Antivirals	6 (1.08)
	Antibiotics	179 (32.37)
	Immunosuppressant agents	96 (17.36)
	Beta-blockers	157 (28.39)
	Diuretics	96 (17.36)
	ACE inhibitor or ARB	138 (24.95)
	Aldosterone Antagonist	35 (6.33)
	Cardiac glycosides or calcium-channel blockers	81 (14.65)
	Antiarrhythmics	13 (2.35)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =36
	Paracetamol	<5

Table 15.17.2 Treatments for myocarditis by for Pharmo

subgroup	Characteristic	myocarditis cohort (N=674)
	Antivirals	0 (0)
	Antibiotics	6 (16.67)
	Immunosuppressant agents	<5
	Beta-blockers	5 (13.89)
	Diuretics	<5
	ACE inhibitor or ARB	6 (16.67)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =268
	Paracetamol	24 (8.96)
	Antivirals	<5
	Antibiotics	90 (33.58)
	Immunosuppressant agents	49 (18.28)
	Beta-blockers	85 (31.72)
	Diuretics	39 (14.55)
	ACE inhibitor or ARB	56 (20.9)
	Aldosterone Antagonist	13 (4.85)
	Cardiac glycosides or calcium-channel blockers	39 (14.55)
	Antiarrhythmics	5 (1.87)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
	Time since vaccination with Pfizer-BioNTech COVI	N > 364
	Paracetamol	>35 (>10)
	Antivirals	<5
	Antibiotics	>120 (>30)
	Immunosuppressant agents	>60 (>15)
	Beta-blockers	>95 (>25)
	Diuretics	>65 (>15)

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Table 15.17.2 Treatments for myocarditis by for Pharmo

subgroup	Characteristic	myocarditis cohort (N=674)
	ACE inhibitor or ARB	>100 (>25)
	Aldosterone Antagonist	>25 (>5)
	Cardiac glycosides or calcium-channel blockers	>50 (>10)
	Antiarrhythmics	>5 (>5)
	Pacemaker	>5 (>5)
	Implantable cardiac defibrillator	>5 (>5)
	Mechanical circulatory support	>5 (>5)
	Heart Transplantation	>5 (>5)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =12
	Paracetamol	<5
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	<5
	Beta-blockers	<5
	Diuretics	<5
	ACE inhibitor or ARB	<5
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =88
	Paracetamol	9 (10.23)
	Antivirals	<5
	Antibiotics	24 (27.27)
	Immunosuppressant agents	14 (15.91)
	Beta-blockers	25 (28.41)
	Diuretics	10 (11.36)
	ACE inhibitor or ARB	19 (21.59)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	10 (11.36)
	Antiarrhythmics	<5
	Pacemaker	0 (0)

Table 15.17.2 Treatments for myocarditis by for Pharmo

subgroup	Characteristic	myocarditis cohort (N=674)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =13
	Paracetamol	<5
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	0 (0)
	Beta-blockers	0 (0)
	Diuretics	0 (0)
	ACE inhibitor or ARB	0 (0)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =145
	Paracetamol	13 (8.97)
	Antivirals	<5
	Antibiotics	52 (35.86)
	Immunosuppressant agents	28 (19.31)
	Beta-blockers	52 (35.86)
	Diuretics	26 (17.93)
	ACE inhibitor or ARB	31 (21.38)
	Aldosterone Antagonist	10 (6.9)
	Cardiac glycosides or calcium-channel blockers	25 (17.24)
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
	Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago	N < 5

Table 15.17.2 Treatments for myocarditis by for Pharmo

subgroup	Characteristic	myocarditis cohort (N=674)
	Paracetamol	0 (0)
	Antivirals	0 (0)
	Antibiotics	0 (0)
	Immunosuppressant agents	<5
	Beta-blockers	0 (0)
	Diuretics	0 (0)
	ACE inhibitor or ARB	0 (0)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =37
	Paracetamol	<5
	Antivirals	0 (0)
	Antibiotics	13 (35.14)
	Immunosuppressant agents	6 (16.22)
	Beta-blockers	8 (21.62)
	Diuretics	<5
	ACE inhibitor or ARB	7 (18.92)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
	Time since vaccination with Pfizer-BioNTech COVI	N < 5
	Paracetamol	0 (0)
	Antivirals	0 (0)
	Antibiotics	0 (0)
	Immunosuppressant agents	0 (0)
	Beta-blockers	0 (0)

Table 15.17.2 Treatments for myocarditis by for Pharmo

subgroup	Characteristic	myocarditis cohort (N=674)
	Diuretics	0 (0)
	ACE inhibitor or ARB	0 (0)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =5
	Paracetamol	0 (0)
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	<5
	Beta-blockers	<5
	Diuretics	0 (0)
	ACE inhibitor or ARB	<5
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)

Table 15.17.3 Treatments for myocarditis by for NHR

subgroup	Characteristic	myocarditis cohort (N=813)
Age: 15-30		N =204
	Paracetamol	29 (14.22)
	Antivirals	<5
	Antibiotics	67 (32.84)
	Immunosuppressant agents	27 (13.24)
	Beta-blockers	39 (19.12)
	Diuretics	7 (3.43)
	ACE inhibitor or ARB	30 (14.71)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	<5
	Heart Transplantation	0 (0)
Sex: Female		N =268
	Paracetamol	90 (33.58)
	Antivirals	8 (2.99)
	Antibiotics	108 (40.3)
	Immunosuppressant agents	59 (22.01)
	Beta-blockers	112 (41.79)
	Diuretics	52 (19.4)
	ACE inhibitor or ARB	95 (35.45)
	Aldosterone Antagonist	18 (6.72)
	Cardiac glycosides or calcium-channel blockers	31 (11.57)
	Antiarrhythmics	8 (2.99)
	Pacemaker	<5
	Implantable cardiac defibrillator	7 (2.61)
	Mechanical circulatory support	5 (1.87)
	Heart Transplantation	0 (0)
Sex: Male		N =545
	Paracetamol	115 (21.1)
	Antivirals	12 (2.2)
	Antibiotics	162 (29.72)
	Immunosuppressant agents	98 (17.98)

Table 15.17.3 Treatments for myocarditis by for NHR

subgroup	Characteristic	myocarditis cohort (N=813)
	Beta-blockers	175 (32.11)
	Diuretics	90 (16.51)
	ACE inhibitor or ARB	159 (29.17)
	Aldosterone Antagonist	39 (7.16)
	Cardiac glycosides or calcium-channel blockers	43 (7.89)
	Antiarrhythmics	23 (4.22)
	Pacemaker	<5
	Implantable cardiac defibrillator	16 (2.94)
	Mechanical circulatory support	8 (1.47)
	Heart Transplantation	<5
Age and Sex: Females: 15-30		N =34
	Paracetamol	7 (20.59)
	Antivirals	<5
	Antibiotics	10 (29.41)
	Immunosuppressant agents	5 (14.71)
	Beta-blockers	9 (26.47)
	Diuretics	<5
	ACE inhibitor or ARB	5 (14.71)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	<5
	Heart Transplantation	0 (0)
Age and Sex: Males: 15-30		N =170
	Paracetamol	22 (12.94)
	Antivirals	<5
	Antibiotics	57 (33.53)
	Immunosuppressant agents	22 (12.94)
	Beta-blockers	30 (17.65)
	Diuretics	<5
	ACE inhibitor or ARB	25 (14.71)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5

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Table 15.17.3 Treatments for myocarditis by for NHR

subgroup	Characteristic	myocarditis cohort (N=813)
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	<5
	Heart Transplantation	0 (0)
COVID-19 history: Yes		N =119
	Paracetamol	27 (22.69)
	Antivirals	<5
	Antibiotics	43 (36.13)
	Immunosuppressant agents	21 (17.65)
	Beta-blockers	31 (26.05)
	Diuretics	16 (13.45)
	ACE inhibitor or ARB	28 (23.53)
	Aldosterone Antagonist	8 (6.72)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	<5
	Heart Transplantation	0 (0)
COVID-19 history: No		N =694
	Paracetamol	178 (25.65)
	Antivirals	18 (2.59)
	Antibiotics	227 (32.71)
	Immunosuppressant agents	136 (19.6)
	Beta-blockers	256 (36.89)
	Diuretics	126 (18.16)
	ACE inhibitor or ARB	226 (32.56)
	Aldosterone Antagonist	49 (7.06)
	Cardiac glycosides or calcium-channel blockers	72 (10.37)
	Antiarrhythmics	28 (4.03)
	Pacemaker	6 (0.86)
	Implantable cardiac defibrillator	20 (2.88)
	Mechanical circulatory support	10 (1.44)

Table 15.17.3 Treatments for myocarditis by for NHR

subgroup	Characteristic	myocarditis cohort (N=813)
	Heart Transplantation	<5
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =66
	Paracetamol	18 (27.27)
	Antivirals	0 (0)
	Antibiotics	25 (37.88)
	Immunosuppressant agents	15 (22.73)
	Beta-blockers	29 (43.94)
	Diuretics	10 (15.15)
	ACE inhibitor or ARB	24 (36.36)
	Aldosterone Antagonist	5 (7.58)
	Cardiac glycosides or calcium-channel blockers	11 (16.67)
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =477
	Paracetamol	124 (26)
	Antivirals	10 (2.1)
	Antibiotics	161 (33.75)
	Immunosuppressant agents	86 (18.03)
	Beta-blockers	177 (37.11)
	Diuretics	93 (19.5)
	ACE inhibitor or ARB	158 (33.12)
	Aldosterone Antagonist	40 (8.39)
	Cardiac glycosides or calcium-channel blockers	45 (9.43)
	Antiarrhythmics	21 (4.4)
	Pacemaker	6 (1.26)
	Implantable cardiac defibrillator	17 (3.56)
	Mechanical circulatory support	8 (1.68)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Unvaccinated		N =270
	Paracetamol	63 (23.33)
	Antivirals	10 (3.7)

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Table 15.17.3 Treatments for myocarditis by for NHR

subgroup	Characteristic	myocarditis cohort (N=813)
	Antibiotics	84 (31.11)
	Immunosuppressant agents	56 (20.74)
	Beta-blockers	81 (30)
	Diuretics	39 (14.44)
	ACE inhibitor or ARB	72 (26.67)
	Aldosterone Antagonist	12 (4.44)
	Cardiac glycosides or calcium-channel blockers	18 (6.67)
	Antiarrhythmics	9 (3.33)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	6 (2.22)
	Mechanical circulatory support	5 (1.85)
	Heart Transplantation	<5
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =18
	Paracetamol	7 (38.89)
	Antivirals	0 (0)
	Antibiotics	5 (27.78)
	Immunosuppressant agents	5 (27.78)
	Beta-blockers	6 (33.33)
	Diuretics	<5
	ACE inhibitor or ARB	<5
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =67
	Paracetamol	15 (22.39)
	Antivirals	<5
	Antibiotics	24 (35.82)
	Immunosuppressant agents	13 (19.4)
	Beta-blockers	19 (28.36)
	Diuretics	9 (13.43)

Table 15.17.3 Treatments for myocarditis by for NHR

subgroup	Characteristic	myocarditis cohort (N=813)
	ACE inhibitor or ARB	22 (32.84)
	Aldosterone Antagonist	7 (10.45)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	<5
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =12
	Paracetamol	0 (0)
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	<5
	Beta-blockers	<5
	Diuretics	<5
	ACE inhibitor or ARB	<5
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =230
	Paracetamol	59 (25.65)
	Antivirals	<5
	Antibiotics	74 (32.17)
	Immunosuppressant agents	39 (16.96)
	Beta-blockers	87 (37.83)
	Diuretics	42 (18.26)
	ACE inhibitor or ARB	73 (31.74)
	Aldosterone Antagonist	15 (6.52)
	Cardiac glycosides or calcium-channel blockers	18 (7.83)
	Antiarrhythmics	8 (3.48)

Table 15.17.3 Treatments for myocarditis by for NHR

subgroup	Characteristic	myocarditis cohort (N=813)
	Pacemaker	<5
	Implantable cardiac defibrillator	5 (2.17)
	Mechanical circulatory support	<5
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =13
	Paracetamol	<5
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	<5
	Beta-blockers	9 (69.23)
	Diuretics	<5
	ACE inhibitor or ARB	5 (38.46)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =173
	Paracetamol	49 (28.32)
	Antivirals	<5
	Antibiotics	61 (35.26)
	Immunosuppressant agents	32 (18.5)
	Beta-blockers	69 (39.88)
	Diuretics	38 (21.97)
	ACE inhibitor or ARB	60 (34.68)
	Aldosterone Antagonist	16 (9.25)
	Cardiac glycosides or calcium-channel blockers	22 (12.72)
	Antiarrhythmics	10 (5.78)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	9 (5.2)
	Mechanical circulatory support	<5

Table 15.17.3 Treatments for myocarditis by for NHR

subgroup	Characteristic	myocarditis cohort (N=813)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =6
	Paracetamol	<5
	Antivirals	0 (0)
	Antibiotics	5 (83.33)
	Immunosuppressant agents	<5
	Beta-blockers	<5
	Diuretics	<5
	ACE inhibitor or ARB	<5
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =24
	Paracetamol	7 (29.17)
	Antivirals	0 (0)
	Antibiotics	10 (41.67)
	Immunosuppressant agents	5 (20.83)
	Beta-blockers	12 (50)
	Diuretics	7 (29.17)
	ACE inhibitor or ARB	13 (54.17)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	6 (25)
	Antiarrhythmics	<5
	Pacemaker	<5
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)

Table 15.17.4 Treatments for myocarditis by for EpiChron

subgroup	Characteristic	myocarditis cohort (N=116)
Age: 15-30		N =39
	Paracetamol	14 (35.9)
	Antivirals	0 (0)
	Antibiotics	17 (43.59)
	Immunosuppressant agents	<5
	Beta-blockers	6 (15.38)
	Diuretics	<5
	ACE inhibitor or ARB	6 (15.38)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Sex: Female		N =25
	Paracetamol	11 (44)
	Antivirals	0 (0)
	Antibiotics	12 (48)
	Immunosuppressant agents	<5
	Beta-blockers	8 (32)
	Diuretics	10 (40)
	ACE inhibitor or ARB	8 (32)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Sex: Male		N =91
	Paracetamol	35 (38.46)
	Antivirals	<5
	Antibiotics	39 (42.86)
	Immunosuppressant agents	14 (15.38)
	Beta-blockers	32 (35.16)

Table 15.17.4 Treatments for myocarditis by for EpiChron

subgroup	Characteristic	myocarditis cohort (N=116)
	Diuretics	16 (17.58)
	ACE inhibitor or ARB	24 (26.37)
	Aldosterone Antagonist	9 (9.89)
	Cardiac glycosides or calcium-channel blockers	8 (8.79)
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
	Age and Sex: Females: 15-30	N < 5
	Paracetamol	<5
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	0 (0)
	Beta-blockers	0 (0)
	Diuretics	0 (0)
	ACE inhibitor or ARB	0 (0)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Age and Sex: Males: 15-30		N =37
	Paracetamol	13 (35.14)
	Antivirals	0 (0)
	Antibiotics	15 (40.54)
	Immunosuppressant agents	<5
	Beta-blockers	6 (16.22)
	Diuretics	<5
	ACE inhibitor or ARB	6 (16.22)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)

Table 15.17.4 Treatments for myocarditis by for EpiChron

subgroup	Characteristic	myocarditis cohort (N=116)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
COVID-19 history: Yes		N =34
	Paracetamol	14 (41.18)
	Antivirals	0 (0)
	Antibiotics	15 (44.12)
	Immunosuppressant agents	5 (14.71)
	Beta-blockers	9 (26.47)
	Diuretics	6 (17.65)
	ACE inhibitor or ARB	5 (14.71)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
COVID-19 history: No		N =82
	Paracetamol	32 (39.02)
	Antivirals	<5
	Antibiotics	36 (43.9)
	Immunosuppressant agents	11 (13.41)
	Beta-blockers	31 (37.8)
	Diuretics	20 (24.39)
	ACE inhibitor or ARB	27 (32.93)
	Aldosterone Antagonist	9 (10.98)
	Cardiac glycosides or calcium-channel blockers	9 (10.98)
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =10
	Paracetamol	<5

Table 15.17.4 Treatments for myocarditis by for EpiChron

subgroup	Characteristic	myocarditis cohort (N=116)
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	0 (0)
	Beta-blockers	<5
	Diuretics	<5
	ACE inhibitor or ARB	<5
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =65
	Paracetamol	28 (43.08)
	Antivirals	<5
	Antibiotics	32 (49.23)
	Immunosuppressant agents	11 (16.92)
	Beta-blockers	21 (32.31)
	Diuretics	17 (26.15)
	ACE inhibitor or ARB	15 (23.08)
	Aldosterone Antagonist	6 (9.23)
	Cardiac glycosides or calcium-channel blockers	6 (9.23)
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
	Time since vaccination with Pfizer-BioNTech COVI	N > 32
	Paracetamol	>15 (>35)
	Antivirals	>5 (>5)
	Antibiotics	>15 (>35)
	Immunosuppressant agents	>5 (>10)
	Beta-blockers	>15 (>35)
	Diuretics	>5 (>15)

Table 15.17.4 Treatments for myocarditis by for EpiChron

subgroup	Characteristic	myocarditis cohort (N=116)
	ACE inhibitor or ARB	>10 (>30)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	>5 (>5)
	Implantable cardiac defibrillator	>5 (>5)
	Mechanical circulatory support	>5 (>5)
	Heart Transplantation	>5 (>5)
	Time since vaccination with Pfizer-BioNTech COVI	N < 5
	Paracetamol	0 (0)
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	0 (0)
	Beta-blockers	<5
	Diuretics	0 (0)
	ACE inhibitor or ARB	<5
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =12
	Paracetamol	5 (41.67)
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	<5
	Beta-blockers	<5
	Diuretics	0 (0)
	ACE inhibitor or ARB	<5
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)

Table 15.17.4 Treatments for myocarditis by for EpiChron

subgroup	Characteristic	myocarditis cohort (N=116)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
	Time since vaccination with Pfizer-BioNTech COVI	N < 5
	Paracetamol	<5
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	0 (0)
	Beta-blockers	<5
	Diuretics	<5
	ACE inhibitor or ARB	0 (0)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =35
	Paracetamol	14 (40)
	Antivirals	<5
	Antibiotics	18 (51.43)
	Immunosuppressant agents	5 (14.29)
	Beta-blockers	9 (25.71)
	Diuretics	7 (20)
	ACE inhibitor or ARB	8 (22.86)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
	Time since vaccination with Pfizer-BioNTech COVI	N < 5

Table 15.17.4 Treatments for myocarditis by for EpiChron

subgroup	Characteristic	myocarditis cohort (N=116)
	Paracetamol	0 (0)
	Antivirals	0 (0)
	Antibiotics	0 (0)
	Immunosuppressant agents	0 (0)
	Beta-blockers	0 (0)
	Diuretics	0 (0)
	ACE inhibitor or ARB	0 (0)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =22
	Paracetamol	9 (40.91)
	Antivirals	0 (0)
	Antibiotics	12 (54.55)
	Immunosuppressant agents	<5
	Beta-blockers	9 (40.91)
	Diuretics	10 (45.45)
	ACE inhibitor or ARB	8 (36.36)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)

Table 15.17.4 Treatments for myocarditis by for EpiChron

subgroup	Characteristic	myocarditis cohort (N=116)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)

Table 15.17.5 Treatments for myocarditis by for SIDIAP

subgroup	Characteristic	myocarditis cohort (N=676)
Age: 15-30		N =119
	Paracetamol	29 (24.37)
	Antivirals	0 (0)
	Antibiotics	36 (30.25)
	Immunosuppressant agents	7 (5.88)
	Beta-blockers	15 (12.61)
	Diuretics	5 (4.2)
	ACE inhibitor or ARB	12 (10.08)
	Aldosterone Antagonist	5 (4.2)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Sex: Female		N =262
	Paracetamol	138 (52.67)
	Antivirals	5 (1.91)
	Antibiotics	103 (39.31)
	Immunosuppressant agents	61 (23.28)
	Beta-blockers	52 (19.85)
	Diuretics	59 (22.52)
	ACE inhibitor or ARB	67 (25.57)
	Aldosterone Antagonist	13 (4.96)
	Cardiac glycosides or calcium-channel blockers	28 (10.69)
	Antiarrhythmics	9 (3.44)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Sex: Male		N =414
	Paracetamol	150 (36.23)
	Antivirals	<5
	Antibiotics	138 (33.33)
	Immunosuppressant agents	69 (16.67)

Table 15.17.5 Treatments for myocarditis by for SIDIAP

subgroup	Characteristic	myocarditis cohort (N=676)
	Beta-blockers	100 (24.15)
	Diuretics	76 (18.36)
	ACE inhibitor or ARB	102 (24.64)
	Aldosterone Antagonist	43 (10.39)
	Cardiac glycosides or calcium-channel blockers	28 (6.76)
	Antiarrhythmics	15 (3.62)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Age and Sex: Females: 15-30		N =24
	Paracetamol	9 (37.5)
	Antivirals	0 (0)
	Antibiotics	10 (41.67)
	Immunosuppressant agents	<5
	Beta-blockers	<5
	Diuretics	0 (0)
	ACE inhibitor or ARB	0 (0)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Age and Sex: Males: 15-30		N =95
	Paracetamol	20 (21.05)
	Antivirals	0 (0)
	Antibiotics	26 (27.37)
	Immunosuppressant agents	6 (6.32)
	Beta-blockers	13 (13.68)
	Diuretics	5 (5.26)
	ACE inhibitor or ARB	12 (12.63)
	Aldosterone Antagonist	5 (5.26)
	Cardiac glycosides or calcium-channel blockers	0 (0)

Table 15.17.5 Treatments for myocarditis by for SIDIAP

subgroup	Characteristic	myocarditis cohort (N=676)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
COVID-19 history: Yes		N =316
	Paracetamol	134 (42.41)
	Antivirals	<5
	Antibiotics	125 (39.56)
	Immunosuppressant agents	70 (22.15)
	Beta-blockers	57 (18.04)
	Diuretics	48 (15.19)
	ACE inhibitor or ARB	61 (19.3)
	Aldosterone Antagonist	18 (5.7)
	Cardiac glycosides or calcium-channel blockers	26 (8.23)
	Antiarrhythmics	7 (2.22)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
COVID-19 history: No		N =360
	Paracetamol	154 (42.78)
	Antivirals	6 (1.67)
	Antibiotics	116 (32.22)
	Immunosuppressant agents	60 (16.67)
	Beta-blockers	95 (26.39)
	Diuretics	87 (24.17)
	ACE inhibitor or ARB	108 (30)
	Aldosterone Antagonist	38 (10.56)
	Cardiac glycosides or calcium-channel blockers	30 (8.33)
	Antiarrhythmics	17 (4.72)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)

Table 15.17.5 Treatments for myocarditis by for SIDIAP

subgroup	Characteristic	myocarditis cohort (N=676)
	Heart Transplantation	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =28
	Paracetamol	11 (39.29)
	Antivirals	0 (0)
	Antibiotics	8 (28.57)
	Immunosuppressant agents	<5
	Beta-blockers	7 (25)
	Diuretics	<5
	ACE inhibitor or ARB	8 (28.57)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =358
	Paracetamol	149 (41.62)
	Antivirals	<5
	Antibiotics	129 (36.03)
	Immunosuppressant agents	62 (17.32)
	Beta-blockers	79 (22.07)
	Diuretics	82 (22.91)
	ACE inhibitor or ARB	98 (27.37)
	Aldosterone Antagonist	26 (7.26)
	Cardiac glycosides or calcium-channel blockers	37 (10.34)
	Antiarrhythmics	12 (3.35)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Unvaccinated		N =290
	Paracetamol	128 (44.14)
	Antivirals	<5

Table 15.17.5 Treatments for myocarditis by for SIDIAP

subgroup	Characteristic	myocarditis cohort (N=676)
	Antibiotics	104 (35.86)
	Immunosuppressant agents	64 (22.07)
	Beta-blockers	66 (22.76)
	Diuretics	49 (16.9)
	ACE inhibitor or ARB	63 (21.72)
	Aldosterone Antagonist	27 (9.31)
	Cardiac glycosides or calcium-channel blockers	19 (6.55)
	Antiarrhythmics	12 (4.14)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =8
	Paracetamol	<5
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	<5
	Beta-blockers	<5
	Diuretics	<5
	ACE inhibitor or ARB	<5
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =48
	Paracetamol	17 (35.42)
	Antivirals	0 (0)
	Antibiotics	14 (29.17)
	Immunosuppressant agents	<5
	Beta-blockers	7 (14.58)
	Diuretics	<5

Table 15.17.5 Treatments for myocarditis by for SIDIAP

subgroup	Characteristic	myocarditis cohort (N=676)
	ACE inhibitor or ARB	5 (10.42)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =13
	Paracetamol	5 (38.46)
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	<5
	Beta-blockers	<5
	Diuretics	0 (0)
	ACE inhibitor or ARB	<5
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =225
	Paracetamol	77 (34.22)
	Antivirals	<5
	Antibiotics	69 (30.67)
	Immunosuppressant agents	28 (12.44)
	Beta-blockers	39 (17.33)
	Diuretics	39 (17.33)
	ACE inhibitor or ARB	55 (24.44)
	Aldosterone Antagonist	16 (7.11)
	Cardiac glycosides or calcium-channel blockers	14 (6.22)
	Antiarrhythmics	6 (2.67)

Table 15.17.5 Treatments for myocarditis by for SIDIAP

subgroup	Characteristic	myocarditis cohort (N=676)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =67
	Paracetamol	42 (62.69)
	Antivirals	<5
	Antibiotics	35 (52.24)
	Immunosuppressant agents	23 (34.33)
	Beta-blockers	30 (44.78)
	Diuretics	34 (50.75)
	ACE inhibitor or ARB	29 (43.28)
	Aldosterone Antagonist	8 (11.94)
	Cardiac glycosides or calcium-channel blockers	18 (26.87)
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)

Table 15.17.5 Treatments for myocarditis by for SIDIAP

subgroup	Characteristic	myocarditis cohort (N=676)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =0
	Paracetamol	0 (NaN)
	Antivirals	0 (NaN)
	Antibiotics	0 (NaN)
	Immunosuppressant agents	0 (NaN)
	Beta-blockers	0 (NaN)
	Diuretics	0 (NaN)
	ACE inhibitor or ARB	0 (NaN)
	Aldosterone Antagonist	0 (NaN)
	Cardiac glycosides or calcium-channel blockers	0 (NaN)
	Antiarrhythmics	0 (NaN)
	Pacemaker	0 (NaN)
	Implantable cardiac defibrillator	0 (NaN)
	Mechanical circulatory support	0 (NaN)
	Heart Transplantation	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =25
	Paracetamol	16 (64)
	Antivirals	0 (0)
	Antibiotics	14 (56)
	Immunosuppressant agents	9 (36)
	Beta-blockers	<5
	Diuretics	9 (36)
	ACE inhibitor or ARB	11 (44)
	Aldosterone Antagonist	<5
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)

Table 15.17.6 Treatments for myocarditis by for CPRD

subgroup	Characteristic	myocarditis cohort (N=863)
Age: 15-30		N =356
	Paracetamol	7 (1.97)
	Antivirals	<5
	Antibiotics	48 (13.48)
	Immunosuppressant agents	27 (7.58)
	Beta-blockers	106 (29.78)
	Diuretics	10 (2.81)
	ACE inhibitor or ARB	73 (20.51)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	5 (1.4)
	Antiarrhythmics	<5
	Pacemaker	<5
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	0 (0)
	Heart Transplantation	<5
Sex: Female		N =281
	Paracetamol	11 (3.91)
	Antivirals	8 (2.85)
	Antibiotics	83 (29.54)
	Immunosuppressant agents	43 (15.3)
	Beta-blockers	149 (53.02)
	Diuretics	51 (18.15)
	ACE inhibitor or ARB	109 (38.79)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	30 (10.68)
	Antiarrhythmics	11 (3.91)
	Pacemaker	6 (2.14)
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	<5
	Heart Transplantation	<5
Sex: Male		N =582
	Paracetamol	19 (3.26)
	Antivirals	5 (0.86)
	Antibiotics	84 (14.43)
	Immunosuppressant agents	46 (7.9)
	Beta-blockers	232 (39.86)

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Table 15.17.6 Treatments for myocarditis by for CPRD

subgroup	Characteristic	myocarditis cohort (N=863)
	Diuretics	62 (10.65)
	ACE inhibitor or ARB	188 (32.3)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	49 (8.42)
	Antiarrhythmics	12 (2.06)
	Pacemaker	<5
	Implantable cardiac defibrillator	5 (0.86)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	<5
Age and Sex: Females: 15-30		N =64
	Paracetamol	<5
	Antivirals	0 (0)
	Antibiotics	17 (26.56)
	Immunosuppressant agents	10 (15.62)
	Beta-blockers	22 (34.38)
	Diuretics	<5
	ACE inhibitor or ARB	14 (21.88)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	<5
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Age and Sex: Males: 15-30		N =292
	Paracetamol	6 (2.05)
	Antivirals	<5
	Antibiotics	31 (10.62)
	Immunosuppressant agents	17 (5.82)
	Beta-blockers	84 (28.77)
	Diuretics	7 (2.4)
	ACE inhibitor or ARB	59 (20.21)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)

Table 15.17.6 Treatments for myocarditis by for CPRD

subgroup	Characteristic	myocarditis cohort (N=863)
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	0 (0)
	Heart Transplantation	<5
COVID-19 history: Yes		N =262
	Paracetamol	8 (3.05)
	Antivirals	<5
	Antibiotics	47 (17.94)
	Immunosuppressant agents	26 (9.92)
	Beta-blockers	116 (44.27)
	Diuretics	34 (12.98)
	ACE inhibitor or ARB	78 (29.77)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	19 (7.25)
	Antiarrhythmics	10 (3.82)
	Pacemaker	<5
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	0 (0)
	Heart Transplantation	<5
COVID-19 history: No		N =601
	Paracetamol	22 (3.66)
	Antivirals	9 (1.5)
	Antibiotics	120 (19.97)
	Immunosuppressant agents	63 (10.48)
	Beta-blockers	265 (44.09)
	Diuretics	79 (13.14)
	ACE inhibitor or ARB	219 (36.44)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	60 (9.98)
	Antiarrhythmics	13 (2.16)
	Pacemaker	6 (1)
	Implantable cardiac defibrillator	7 (1.16)
	Mechanical circulatory support	<5
	Heart Transplantation	<5
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =62
	Paracetamol	<5

Table 15.17.6 Treatments for myocarditis by for CPRD

subgroup	Characteristic	myocarditis cohort (N=863)
	Antivirals	0 (0)
	Antibiotics	14 (22.58)
	Immunosuppressant agents	5 (8.06)
	Beta-blockers	33 (53.23)
	Diuretics	9 (14.52)
	ACE inhibitor or ARB	21 (33.87)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	6 (9.68)
	Antiarrhythmics	5 (8.06)
	Pacemaker	<5
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =451
	Paracetamol	14 (3.1)
	Antivirals	7 (1.55)
	Antibiotics	92 (20.4)
	Immunosuppressant agents	57 (12.64)
	Beta-blockers	203 (45.01)
	Diuretics	60 (13.3)
	ACE inhibitor or ARB	170 (37.69)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	43 (9.53)
	Antiarrhythmics	10 (2.22)
	Pacemaker	6 (1.33)
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	0 (0)
	Heart Transplantation	<5
	Time since vaccination with Pfizer-BioNTech COVI	N > 346
	Paracetamol	>10 (>5)
	Antivirals	>5 (>5)
	Antibiotics	>60 (>15)
	Immunosuppressant agents	>25 (>5)
	Beta-blockers	>145 (>40)
	Diuretics	>40 (>10)

Table 15.17.6 Treatments for myocarditis by for CPRD

subgroup	Characteristic	myocarditis cohort (N=863)
	ACE inhibitor or ARB	>105 (>30)
	Aldosterone Antagonist	>5 (>5)
	Cardiac glycosides or calcium-channel blockers	>30 (>5)
	Antiarrhythmics	>5 (>5)
	Pacemaker	<5
	Implantable cardiac defibrillator	>5 (>5)
	Mechanical circulatory support	<5
	Heart Transplantation	<5
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =17
	Paracetamol	0 (0)
	Antivirals	0 (0)
	Antibiotics	6 (35.29)
	Immunosuppressant agents	<5
	Beta-blockers	10 (58.82)
	Diuretics	<5
	ACE inhibitor or ARB	6 (35.29)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	0 (0)
	Pacemaker	<5
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =83
	Paracetamol	<5
	Antivirals	<5
	Antibiotics	16 (19.28)
	Immunosuppressant agents	7 (8.43)
	Beta-blockers	32 (38.55)
	Diuretics	12 (14.46)
	ACE inhibitor or ARB	32 (38.55)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	5 (6.02)
	Antiarrhythmics	<5
	Pacemaker	<5

Table 15.17.6 Treatments for myocarditis by for CPRD

subgroup	Characteristic	myocarditis cohort (N=863)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	<5
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =25
	Paracetamol	<5
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	0 (0)
	Beta-blockers	12 (48)
	Diuretics	<5
	ACE inhibitor or ARB	7 (28)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =198
	Paracetamol	<5
	Antivirals	<5
	Antibiotics	34 (17.17)
	Immunosuppressant agents	24 (12.12)
	Beta-blockers	82 (41.41)
	Diuretics	23 (11.62)
	ACE inhibitor or ARB	68 (34.34)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	13 (6.57)
	Antiarrhythmics	<5
	Pacemaker	<5
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =6

Table 15.17.6 Treatments for myocarditis by for CPRD

subgroup	Characteristic	myocarditis cohort (N=863)
	Paracetamol	0 (0)
	Antivirals	0 (0)
	Antibiotics	0 (0)
	Immunosuppressant agents	0 (0)
	Beta-blockers	<5
	Diuretics	0 (0)
	ACE inhibitor or ARB	<5
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =173
	Paracetamol	8 (4.62)
	Antivirals	<5
	Antibiotics	42 (24.28)
	Immunosuppressant agents	23 (13.29)
	Beta-blockers	91 (52.6)
	Diuretics	23 (13.29)
	ACE inhibitor or ARB	70 (40.46)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	23 (13.29)
	Antiarrhythmics	<5
	Pacemaker	<5
	Implantable cardiac defibrillator	<5
	Mechanical circulatory support	0 (0)
	Heart Transplantation	<5
	Time since vaccination with Pfizer-BioNTech COVI	N < 5
	Paracetamol	<5
	Antivirals	0 (0)
	Antibiotics	<5
	Immunosuppressant agents	0 (0)
	Beta-blockers	0 (0)

Table 15.17.6 Treatments for myocarditis by for CPRD

subgroup	Characteristic	myocarditis cohort (N=863)
	Diuretics	0 (0)
	ACE inhibitor or ARB	0 (0)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	0 (0)
	Antiarrhythmics	0 (0)
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =10
	Paracetamol	0 (0)
	Antivirals	<5
	Antibiotics	<5
	Immunosuppressant agents	<5
	Beta-blockers	7 (70)
	Diuretics	<5
	ACE inhibitor or ARB	7 (70)
	Aldosterone Antagonist	0 (0)
	Cardiac glycosides or calcium-channel blockers	<5
	Antiarrhythmics	<5
	Pacemaker	0 (0)
	Implantable cardiac defibrillator	0 (0)
	Mechanical circulatory support	0 (0)
	Heart Transplantation	0 (0)

Table 15.18.1 Treatments for pericarditis by for Pedianet

subgroup	Characteristic	pericarditis cohort (N<5)
Age: 15-30		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)
	Sex: Female	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.1 Treatments for pericarditis by for Pedianet

subgroup	Characteristic	pericarditis cohort (N<5)
	Sex: Male	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Age and Sex: Females: 15-30		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)

Table 15.18.1 Treatments for pericarditis by for Pedianet

subgroup	Characteristic	pericarditis cohort (N<5)
Age and Sex: Males: 15-30		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)
	COVID-19 history: Yes	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.1 Treatments for pericarditis by for Pedianet

subgroup	Characteristic	pericarditis cohort (N<5)
	COVID-19 history: No	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
	Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dos	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)

Table 15.18.1 Treatments for pericarditis by for Pedianet

subgroup	Characteristic	pericarditis cohort (N<5)
	Pericardiectomy	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)
	Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses:	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)

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Table 15.18.1 Treatments for pericarditis by for Pedianet

subgroup	Characteristic	pericarditis cohort (N<5)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
	Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses:	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)

Table 15.18.1 Treatments for pericarditis by for Pedianet

subgroup	Characteristic	pericarditis cohort (N<5)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)

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Table 15.18.1 Treatments for pericarditis by for Pedianet

subgroup	Characteristic	pericarditis cohort (N<5)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)

Table 15.18.1 Treatments for pericarditis by for Pedianet

subgroup	Characteristic	pericarditis cohort (N<5)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)

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Table 15.18.1 Treatments for pericarditis by for Pedianet

subgroup	Characteristic	pericarditis cohort (N<5)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)

Table 15.18.2 Treatments for pericarditis by for Pharmo

subgroup	Characteristic	pericarditis cohort (N=102)
Age: 15-30		N =23
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	10 (43.48)
	Colchicine	13 (56.52)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Sex: Female		N =32
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	12 (37.5)
	Colchicine	16 (50)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

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Table 15.18.2 Treatments for pericarditis by for Pharmo

subgroup	Characteristic	pericarditis cohort (N=102)
Sex: Male		N =70
	Antibiotics	9 (12.86)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	15 (21.43)
	Colchicine	29 (41.43)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Age and Sex: Females: 15-30		N =5
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	<5
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.2 Treatments for pericarditis by for Pharmo

subgroup	Characteristic	pericarditis cohort (N=102)
Age and Sex: Males: 15-30		N =18
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	8 (44.44)
	Colchicine	10 (55.56)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
COVID-19 history: Yes		N =15
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	6 (40)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.2 Treatments for pericarditis by for Pharmo

subgroup	Characteristic	pericarditis cohort (N=102)
COVID-19 history: No		N =87
	Antibiotics	9 (10.34)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	23 (26.44)
	Colchicine	39 (44.83)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	<5
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)

Table 15.18.2 Treatments for pericarditis by for Pharmo

subgroup	Characteristic	pericarditis cohort (N=102)
	Pericardiectomy	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =31
	Antibiotics	5 (16.13)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	7 (22.58)
	Colchicine	16 (51.61)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
	Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses:	N > 55
	Antibiotics	>5 (>10)
	Antivirals	>5 (>5)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	>15 (>25)
	Colchicine	>25 (>35)
	Intrapericardial administration of steroids	>5 (>5)
	Pericardioscopy for direct instillation of treatments into the pericardial space	>5 (>5)
	Pericardial drainage	>5 (>5)
	Subdiaphragmatic laparoscopic technique	>5 (>5)
	Video-assisted thoracoscopic technique	>5 (>5)
	Pericardioscopy for easy drainage of effusion	>5 (>5)
	Pericardiocentesis	>5 (>5)
	Cardiac catheterization	>5 (>5)
	Balloon pericardial window formation	>5 (>5)

Table 15.18.2 Treatments for pericarditis by for Pharmo

subgroup	Characteristic	pericarditis cohort (N=102)
	Instillation of sclerosing agents and fibrinolytic agents	>5 (>5)
	Pericardiectomy	>5 (>5)
	Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses:	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	<5
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =11
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	<5
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)

Table 15.18.2 Treatments for pericarditis by for Pharmo

subgroup	Characteristic	pericarditis cohort (N=102)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
	Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses:	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	<5
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =16
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	5 (31.25)
	Colchicine	9 (56.25)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)

Table 15.18.2 Treatments for pericarditis by for Pharmo

subgroup	Characteristic	pericarditis cohort (N=102)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
	Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses:	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	<5
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	<5
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)

Table 15.18.2 Treatments for pericarditis by for Pharmo

subgroup	Characteristic	pericarditis cohort (N=102)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)

Table 15.18.2 Treatments for pericarditis by for Pharmo

subgroup	Characteristic	pericarditis cohort (N=102)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)

Table 15.18.3 Treatments for pericarditis by for NHR

subgroup	Characteristic	pericarditis cohort (N=1941)
Age: 15-30		N =289
	Antibiotics	42 (14.53)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	180 (62.28)
	Colchicine	161 (55.71)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	<5
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Sex: Female		N =626
	Antibiotics	177 (28.27)
	Antivirals	16 (2.56)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	260 (41.53)
	Colchicine	367 (58.63)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	<5
	Pericardial drainage	40 (6.39)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	33 (5.27)
	Pericardiocentesis	18 (2.88)
	Cardiac catheterization	8 (1.28)
	Balloon pericardial window formation	0 (0)

Table 15.18.3 Treatments for pericarditis by for NHR

subgroup	Characteristic	pericarditis cohort (N=1941)
Sex: Male	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
		N =1315
	Antibiotics	260 (19.77)
	Antivirals	14 (1.06)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	633 (48.14)
	Colchicine	813 (61.83)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	<5
	Pericardial drainage	66 (5.02)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	50 (3.8)
	Pericardiocentesis	20 (1.52)
	Cardiac catheterization	18 (1.37)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	<5
Age and Sex: Females: 15-30		N =61
	Antibiotics	11 (18.03)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	46 (75.41)
	Colchicine	35 (57.38)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5

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Table 15.18.3 Treatments for pericarditis by for NHR

subgroup	Characteristic	pericarditis cohort (N=1941)
	Pericardiocentesis	<5
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Age and Sex: Males: 15-30		N =228
	Antibiotics	31 (13.6)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	134 (58.77)
	Colchicine	126 (55.26)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	<5
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
COVID-19 history: Yes		N =204
	Antibiotics	43 (21.08)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	94 (46.08)
	Colchicine	121 (59.31)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	11 (5.39)
	Subdiaphragmatic laparoscopic technique	0 (0)

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Table 15.18.3 Treatments for pericarditis by for NHR

subgroup	Characteristic	pericarditis cohort (N=1941)
	Video-assisted thoroscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	9 (4.41)
	Pericardiocentesis	<5
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
COVID-19 history: No		N =1737
	Antibiotics	394 (22.68)
	Antivirals	27 (1.55)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	799 (46)
	Colchicine	1059 (60.97)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	<5
	Pericardial drainage	95 (5.47)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoroscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	74 (4.26)
	Pericardiocentesis	35 (2.01)
	Cardiac catheterization	26 (1.5)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	<5
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =195
	Antibiotics	31 (15.9)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	102 (52.31)
	Colchicine	120 (61.54)
	Intrapericardial administration of steroids	0 (0)

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Table 15.18.3 Treatments for pericarditis by for NHR

subgroup	Characteristic	pericarditis cohort (N=1941)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	10 (5.13)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	10 (5.13)
	Pericardiocentesis	<5
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =1202
	Antibiotics	299 (24.88)
	Antivirals	19 (1.58)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	523 (43.51)
	Colchicine	746 (62.06)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	<5
	Pericardial drainage	64 (5.32)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	48 (3.99)
	Pericardiocentesis	27 (2.25)
	Cardiac catheterization	14 (1.16)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	<5
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Unvaccinated		N =544
	Antibiotics	107 (19.67)
	Antivirals	9 (1.65)

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Table 15.18.3 Treatments for pericarditis by for NHR

subgroup	Characteristic	pericarditis cohort (N=1941)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	268 (49.26)
	Colchicine	314 (57.72)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	<5
	Pericardial drainage	32 (5.88)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	25 (4.6)
	Pericardiocentesis	8 (1.47)
	Cardiac catheterization	8 (1.47)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =49
	Antibiotics	6 (12.24)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	26 (53.06)
	Colchicine	30 (61.22)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	<5
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.3 Treatments for pericarditis by for NHR

subgroup	Characteristic	pericarditis cohort (N=1941)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =134
	Antibiotics	26 (19.4)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	59 (44.03)
	Colchicine	73 (54.48)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	5 (3.73)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	5 (3.73)
	Pericardiocentesis	<5
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =59
	Antibiotics	8 (13.56)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	31 (52.54)
	Colchicine	34 (57.63)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5

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Table 15.18.3 Treatments for pericarditis by for NHR

subgroup	Characteristic	pericarditis cohort (N=1941)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =533
	Antibiotics	127 (23.83)
	Antivirals	5 (0.94)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	237 (44.47)
	Colchicine	325 (60.98)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	<5
	Pericardial drainage	32 (6)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	24 (4.5)
	Pericardiocentesis	12 (2.25)
	Cardiac catheterization	5 (0.94)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =24
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	14 (58.33)
	Colchicine	14 (58.33)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)

Table 15.18.3 Treatments for pericarditis by for NHR

subgroup	Characteristic	pericarditis cohort (N=1941)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =512
	Antibiotics	131 (25.59)
	Antivirals	9 (1.76)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	230 (44.92)
	Colchicine	336 (65.62)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	26 (5.08)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	19 (3.71)
	Pericardiocentesis	11 (2.15)
	Cardiac catheterization	6 (1.17)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	<5
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =11
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	9 (81.82)
	Intrapericardial administration of steroids	0 (0)

Table 15.18.3 Treatments for pericarditis by for NHR

subgroup	Characteristic	pericarditis cohort (N=1941)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =75
	Antibiotics	28 (37.33)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	25 (33.33)
	Colchicine	45 (60)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	<5
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.4 Treatments for pericarditis by for EpiChron

subgroup	Characteristic	pericarditis cohort (N=435)
Age: 15-30		N =94
	Antibiotics	16 (17.02)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	54 (57.45)
	Colchicine	45 (47.87)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Sex: Female		N =121
	Antibiotics	29 (23.97)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	59 (48.76)
	Colchicine	40 (33.06)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.4 Treatments for pericarditis by for EpiChron

subgroup	Characteristic	pericarditis cohort (N=435)
Sex: Male		N =314
	Antibiotics	58 (18.47)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	174 (55.41)
	Colchicine	144 (45.86)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Age and Sex: Females: 15-30		N =16
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	7 (43.75)
	Colchicine	5 (31.25)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.4 Treatments for pericarditis by for EpiChron

subgroup	Characteristic	pericarditis cohort (N=435)
Age and Sex: Males: 15-30		N =78
	Antibiotics	13 (16.67)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	47 (60.26)
	Colchicine	40 (51.28)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
COVID-19 history: Yes		N =118
	Antibiotics	22 (18.64)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	60 (50.85)
	Colchicine	47 (39.83)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.4 Treatments for pericarditis by for EpiChron

subgroup	Characteristic	pericarditis cohort (N=435)
COVID-19 history: No		N =317
	Antibiotics	65 (20.5)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	173 (54.57)
	Colchicine	137 (43.22)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =30
	Antibiotics	5 (16.67)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	14 (46.67)
	Colchicine	13 (43.33)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)

Table 15.18.4 Treatments for pericarditis by for EpiChron

subgroup	Characteristic	pericarditis cohort (N=435)
	Pericardiectomy	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =272
	Antibiotics	55 (20.22)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	143 (52.57)
	Colchicine	108 (39.71)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Unvaccinated		N =133
	Antibiotics	27 (20.3)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	76 (57.14)
	Colchicine	63 (47.37)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)

Table 15.18.4 Treatments for pericarditis by for EpiChron

subgroup	Characteristic	pericarditis cohort (N=435)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
		N =9
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	5 (55.56)
	Colchicine	<5
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
		N =20
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	13 (65)
	Colchicine	8 (40)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)

Table 15.18.4 Treatments for pericarditis by for EpiChron

subgroup	Characteristic	pericarditis cohort (N=435)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =9
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	5 (55.56)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses:		N > 169
	Antibiotics	>35 (>20)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	>85 (>50)
	Colchicine	>70 (>40)
	Intrapericardial administration of steroids	>5 (>5)
	Pericardioscopy for direct instillation of treatments into the pericardial space	>5 (>5)
	Pericardial drainage	>5 (>5)
	Subdiaphragmatic laparoscopic technique	>5 (>5)
	Video-assisted thoracoscopic technique	>5 (>5)

Table 15.18.4 Treatments for pericarditis by for EpiChron

subgroup	Characteristic	pericarditis cohort (N=435)
	Pericardioscopy for easy drainage of effusion	>5 (>5)
	Pericardiocentesis	>5 (>5)
	Cardiac catheterization	<5
	Balloon pericardial window formation	>5 (>5)
	Instillation of sclerosing agents and fibrinolytic agents	>5 (>5)
	Pericardiectomy	>5 (>5)
	Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses:	N < 5
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	<5
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =74
	Antibiotics	18 (24.32)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	40 (54.05)
	Colchicine	26 (35.14)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)

Table 15.18.4 Treatments for pericarditis by for EpiChron

subgroup	Characteristic	pericarditis cohort (N=435)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
	Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses:	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =11
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	<5
	Intrapericardial administration of steroids	0 (0)

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Table 15.18.4 Treatments for pericarditis by for EpiChron

subgroup	Characteristic	pericarditis cohort (N=435)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.5 Treatments for pericarditis by for SIDIAP

subgroup	Characteristic	pericarditis cohort (N=1664)
Age: 15-30		N =271
	Antibiotics	31 (11.44)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	89 (32.84)
	Colchicine	76 (28.04)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Sex: Female		N =591
	Antibiotics	118 (19.97)
	Antivirals	7 (1.18)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	163 (27.58)
	Colchicine	159 (26.9)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.5 Treatments for pericarditis by for SIDIAP

subgroup	Characteristic	pericarditis cohort (N=1664)
Sex: Male		N =1073
	Antibiotics	159 (14.82)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	251 (23.39)
	Colchicine	298 (27.77)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Age and Sex: Females: 15-30		N =57
	Antibiotics	9 (15.79)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	24 (42.11)
	Colchicine	14 (24.56)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.5 Treatments for pericarditis by for SIDIAP

subgroup	Characteristic	pericarditis cohort (N=1664)
Age and Sex: Males: 15-30		N =214
	Antibiotics	22 (10.28)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	65 (30.37)
	Colchicine	62 (28.97)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
COVID-19 history: Yes		N =477
	Antibiotics	79 (16.56)
	Antivirals	6 (1.26)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	127 (26.62)
	Colchicine	124 (26)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.5 Treatments for pericarditis by for SIDIAP

subgroup	Characteristic	pericarditis cohort (N=1664)
COVID-19 history: No		N =1187
	Antibiotics	198 (16.68)
	Antivirals	5 (0.42)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	287 (24.18)
	Colchicine	333 (28.05)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =133
	Antibiotics	23 (17.29)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	34 (25.56)
	Colchicine	31 (23.31)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)

Table 15.18.5 Treatments for pericarditis by for SIDIAP

subgroup	Characteristic	pericarditis cohort (N=1664)
	Pericardiectomy	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =764
	Antibiotics	152 (19.9)
	Antivirals	7 (0.92)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	176 (23.04)
	Colchicine	199 (26.05)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
	Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses:	N > 765
	Antibiotics	>100 (>10)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	>200 (>25)
	Colchicine	>225 (>25)
	Intrapericardial administration of steroids	>5 (>5)
	Pericardioscopy for direct instillation of treatments into the pericardial space	>5 (>5)
	Pericardial drainage	>5 (>5)
	Subdiaphragmatic laparoscopic technique	>5 (>5)
	Video-assisted thoracoscopic technique	>5 (>5)
	Pericardioscopy for easy drainage of effusion	>5 (>5)
	Pericardiocentesis	>5 (>5)
	Cardiac catheterization	>5 (>5)
	Balloon pericardial window formation	>5 (>5)

Table 15.18.5 Treatments for pericarditis by for SIDIAP

subgroup	Characteristic	pericarditis cohort (N=1664)
	Instillation of sclerosing agents and fibrinolytic agents	>5 (>5)
	Pericardiectomy	>5 (>5)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =44
	Antibiotics	6 (13.64)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	8 (18.18)
	Colchicine	9 (20.45)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =70
	Antibiotics	6 (8.57)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	22 (31.43)
	Colchicine	17 (24.29)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)

Table 15.18.5 Treatments for pericarditis by for SIDIAP

subgroup	Characteristic	pericarditis cohort (N=1664)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =36
	Antibiotics	5 (13.89)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	10 (27.78)
	Colchicine	10 (27.78)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =535
	Antibiotics	96 (17.94)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	144 (26.92)
	Colchicine	159 (29.72)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)

Table 15.18.5 Treatments for pericarditis by for SIDIAP

subgroup	Characteristic	pericarditis cohort (N=1664)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =7
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	<5
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =141
	Antibiotics	43 (30.5)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	20 (14.18)
	Colchicine	26 (18.44)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)

Table 15.18.5 Treatments for pericarditis by for SIDIAP

subgroup	Characteristic	pericarditis cohort (N=1664)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
	Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses:	N < 5
	Antibiotics	0 (0)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =61
	Antibiotics	16 (26.23)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	5 (8.2)
	Colchicine	9 (14.75)
	Intrapericardial administration of steroids	0 (0)

Table 15.18.5 Treatments for pericarditis by for SIDIAP

subgroup	Characteristic	pericarditis cohort (N=1664)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.6 Treatments for pericarditis by for CPRD

subgroup	Characteristic	pericarditis cohort (N=1822)
Age: 15-30		N =644
	Antibiotics	51 (7.92)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	<5
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Sex: Female		N =548
	Antibiotics	102 (18.61)
	Antivirals	6 (1.09)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	6 (1.09)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	<5
	Cardiac catheterization	<5
	Balloon pericardial window formation	<5

Table 15.18.6 Treatments for pericarditis by for CPRD

subgroup	Characteristic	pericarditis cohort (N=1822)
Sex: Male	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
		N =1274
	Antibiotics	112 (8.79)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	<5
	Cardiac catheterization	14 (1.1)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	<5
Age and Sex: Females: 15-30		N =159
	Antibiotics	18 (11.32)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5

Table 15.18.6 Treatments for pericarditis by for CPRD

subgroup	Characteristic	pericarditis cohort (N=1822)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	<5
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Age and Sex: Males: 15-30		N =485
	Antibiotics	33 (6.8)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
COVID-19 history: Yes		N =454
	Antibiotics	51 (11.23)
	Antivirals	5 (1.1)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)

Table 15.18.6 Treatments for pericarditis by for CPRD

subgroup	Characteristic	pericarditis cohort (N=1822)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	<5
	Cardiac catheterization	5 (1.1)
	Balloon pericardial window formation	<5
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
COVID-19 history: No		N =1368
	Antibiotics	163 (11.92)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	8 (0.58)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	5 (0.37)
	Cardiac catheterization	12 (0.88)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	<5
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose in the last 21 days		N =100
	Antibiotics	12 (12)
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)

Table 15.18.6 Treatments for pericarditis by for CPRD

subgroup	Characteristic	pericarditis cohort (N=1822)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero: Received last dose 22 or more days ago		N =973
	Antibiotics	113 (11.61)
	Antivirals	7 (0.72)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	6 (0.62)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	<5
	Cardiac catheterization	9 (0.92)
	Balloon pericardial window formation	<5
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Unvaccinated		N =749
	Antibiotics	89 (11.88)
	Antivirals	<5

Table 15.18.6 Treatments for pericarditis by for CPRD

subgroup	Characteristic	pericarditis cohort (N=1822)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	<5
	Cardiac catheterization	8 (1.07)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	<5
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose in the last 14 days		N =27
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.18.6 Treatments for pericarditis by for CPRD

subgroup	Characteristic	pericarditis cohort (N=1822)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 1 dose, 15 or more days ago		N =182
	Antibiotics	18 (9.89)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one in the last 14 days		N =26
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)

Table 15.18.6 Treatments for pericarditis by for CPRD

subgroup	Characteristic	pericarditis cohort (N=1822)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 2 doses, the last one 15 or more days ago		N =415
	Antibiotics	40 (9.64)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	5 (1.2)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	<5
	Cardiac catheterization	<5
	Balloon pericardial window formation	<5
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one in the last 14 days		N =9
	Antibiotics	<5
	Antivirals	0 (0)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)

Table 15.18.6 Treatments for pericarditis by for CPRD

subgroup	Characteristic	pericarditis cohort (N=1822)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	0 (0)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 3 doses, the last one 15 or more days ago		N =384
	Antibiotics	43 (11.2)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	0 (0)
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	0 (0)
	Pericardiocentesis	0 (0)
	Cardiac catheterization	5 (1.3)
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one in the last 14 days		N =0
	Antibiotics	0 (NaN)
	Antivirals	0 (NaN)
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (NaN)
	Colchicine	0 (NaN)
	Intrapericardial administration of steroids	0 (NaN)

Table 15.18.6 Treatments for pericarditis by for CPRD

subgroup	Characteristic	pericarditis cohort (N=1822)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (NaN)
	Pericardial drainage	0 (NaN)
	Subdiaphragmatic laparoscopic technique	0 (NaN)
	Video-assisted thoracoscopic technique	0 (NaN)
	Pericardioscopy for easy drainage of effusion	0 (NaN)
	Pericardiocentesis	0 (NaN)
	Cardiac catheterization	0 (NaN)
	Balloon pericardial window formation	0 (NaN)
	Instillation of sclerosing agents and fibrinolytic agents	0 (NaN)
	Pericardiectomy	0 (NaN)
Time since vaccination with Pfizer-BioNTech COVID-19 vaccine and number of doses: Received 4 doses, the last one 15 or more days ago		N =30
	Antibiotics	14 (46.67)
	Antivirals	<5
	Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)
	Colchicine	0 (0)
	Intrapericardial administration of steroids	0 (0)
	Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)
	Pericardial drainage	<5
	Subdiaphragmatic laparoscopic technique	0 (0)
	Video-assisted thoracoscopic technique	0 (0)
	Pericardioscopy for easy drainage of effusion	<5
	Pericardiocentesis	0 (0)
	Cardiac catheterization	<5
	Balloon pericardial window formation	0 (0)
	Instillation of sclerosing agents and fibrinolytic agents	0 (0)
	Pericardiectomy	0 (0)

Table 15.19.1.1.1 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	pericarditis cohort (N=1822)	Pericarditis cohort (N=1822)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.1.2 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.1.1.3 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.1.4 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.1.5 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.1.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.1.1.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

Table 15.19.1.1.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.1.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.2.1 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	127	22
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	118	21
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	108	19
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	96	17
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.1.2.2 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N=135)	Pericarditis cohort (N=23)
Male				
	Events, n	3	0	0
	Persons at risk	3	414	64
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	386	63
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	347	57
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	320	47
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	204	30
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	186	28
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	171	27
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	157	26
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.1.2.3 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N=217)	Pericarditis cohort (N=32)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	86	17
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	80	17
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	73	15
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	66	13
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	41	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	35	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.1.2.4 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N=42)	Pericarditis cohort (N=5)
No				
	Events, n	3	0	0
	Persons at risk	3	517	81
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	485	79
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	445	74
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	415	65
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	101	13
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	87	12
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	73	10
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	62	8
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.1.2.5 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=121)	Pericarditis cohort (N=15)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	36	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	35	5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	235	28
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	212	27
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	182	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	162	21
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.1.2.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	347	61
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	325	59
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	302	53
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	282	47
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	81	10
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	77	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	69	10
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.1.2.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Persons at risk	12	63	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	129	15
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	114	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	101	13
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	93	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.1.2.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	30	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	27	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	18	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.2.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.3.1 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N=5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	168	210
	Persons at risk	3	34	72
	Risk (95% CI)	3	8235 (7626 - 8688)	7270 (6704 - 7739)
	Events, n	6	170	215
	Persons at risk	6	29	60
	Risk (95% CI)	6	8344 (7744 - 8785)	7477 (6917 - 7936)
	Events, n	9	170	216
	Persons at risk	9	28	54
	Risk (95% CI)	9	8344 (7744 - 8785)	7521 (6961 - 7977)
	Events, n	12	171	218
	Persons at risk	12	22	41
	Risk (95% CI)	12	8403 (7807 - 8838)	7618 (7058 - 8071)

Table 15.19.1.3.2 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N=204)	Pericarditis cohort (N=289)
Male				
	Events, n	3	435	1087
	Persons at risk	3	94	202
	Risk (95% CI)	3	8008 (7639 - 8319)	8279 (8062 - 8472)
	Events, n	6	441	1101
	Persons at risk	6	81	170
	Risk (95% CI)	6	8142 (7778 - 8446)	8405 (8191 - 8593)
	Events, n	9	444	1112
	Persons at risk	9	73	136
	Risk (95% CI)	9	8213 (7852 - 8514)	8517 (8306 - 8701)
	Events, n	12	447	1118
	Persons at risk	12	64	108
	Risk (95% CI)	12	8288 (7929 - 8585)	8591 (8381 - 8773)
Female				
	Events, n	3	205	481
	Persons at risk	3	52	135
	Risk (95% CI)	3	7701 (7129 - 8159)	7693 (7337 - 8001)
	Events, n	6	207	496
	Persons at risk	6	48	104
	Risk (95% CI)	6	7793 (7225 - 8245)	7963 (7617 - 8258)
	Events, n	9	211	497
	Persons at risk	9	40	91
	Risk (95% CI)	9	7983 (7422 - 8423)	7983 (7638 - 8278)
	Events, n	12	214	504
	Persons at risk	12	30	67
	Risk (95% CI)	12	8154 (7593 - 8584)	8155 (7810 - 8445)

Table 15.19.1.3.3 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=626)
Male, 15-30 years				
	Events, n	3	138	167
	Persons at risk	3	30	54
	Risk (95% CI)	3	8118 (7428 - 8622)	7329 (6687 - 7846)
	Events, n	6	140	172
	Persons at risk	6	25	46
	Risk (95% CI)	6	8250 (7570 - 8740)	7586 (6953 - 8088)
	Events, n	9	140	173
	Persons at risk	9	24	41
	Risk (95% CI)	9	8250 (7570 - 8740)	7641 (7010 - 8139)
	Events, n	12	141	174
	Persons at risk	12	20	32
	Risk (95% CI)	12	8323 (7647 - 8805)	7703 (7072 - 8199)
Female, 15-30 years				
	Events, n	3	30	43
	Persons at risk	3	<5	18
	Risk (95% CI)	3	8824 (7046 - 9531)	7049 (5651 - 7998)
	Events, n	6	30	43
	Persons at risk	6	<5	14
	Risk (95% CI)	6	8824 (7046 - 9531)	7049 (5651 - 7998)
	Events, n	9	30	43
	Persons at risk	9	<5	13
	Risk (95% CI)	9	8824 (7046 - 9531)	7049 (5651 - 7998)
	Events, n	12	30	44
	Persons at risk	12	<5	9
	Risk (95% CI)	12	8824 (7046 - 9531)	7295 (5868 - 8229)

Table 15.19.1.3.4 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N=34)	Pericarditis cohort (N=61)
No				
	Events, n	3	536	1410
	Persons at risk	3	134	301
	Risk (95% CI)	3	7761 (7424 - 8053)	8129 (7936 - 8304)
	Events, n	6	544	1437
	Persons at risk	6	120	250
	Risk (95% CI)	6	7899 (7567 - 8185)	8303 (8115 - 8472)
	Events, n	9	551	1449
	Persons at risk	9	107	211
	Risk (95% CI)	9	8024 (7696 - 8306)	8390 (8204 - 8556)
	Events, n	12	557	1462
	Persons at risk	12	90	171
	Risk (95% CI)	12	8140 (7815 - 8417)	8497 (8313 - 8661)
Yes				
	Events, n	3	104	158
	Persons at risk	3	12	36
	Risk (95% CI)	3	8754 (7989 - 9229)	7746 (7093 - 8253)
	Events, n	6	104	160
	Persons at risk	6	9	24
	Risk (95% CI)	6	8754 (7989 - 9229)	7890 (7234 - 8390)
	Events, n	9	104	160
	Persons at risk	9	6	16
	Risk (95% CI)	9	8754 (7989 - 9229)	7890 (7234 - 8390)
	Events, n	12	104	160
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	8754 (7989 - 9229)	7890 (7234 - 8390)

Table 15.19.1.3.5 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N=204)
Vaccinated				
	Events, n	3	54	160
	Persons at risk	3	11	34
	Risk (95% CI)	3	8182 (6967 - 8910)	8208 (7579 - 8673)
	Events, n	6	54	163
	Persons at risk	6	10	28
	Risk (95% CI)	6	8182 (6967 - 8910)	8377 (7762 - 8822)
	Events, n	9	54	165
	Persons at risk	9	10	26
	Risk (95% CI)	9	8182 (6967 - 8910)	8493 (7889 - 8924)
	Events, n	12	54	167
	Persons at risk	12	10	21
	Risk (95% CI)	12	8182 (6967 - 8910)	8609 (8016 - 9024)
Unvaccinated				
	Events, n	3	374	970
	Persons at risk	3	82	201
	Risk (95% CI)	3	7892 (7486 - 8233)	8088 (7850 - 8299)
	Events, n	6	380	989
	Persons at risk	6	68	154
	Risk (95% CI)	6	8059 (7657 - 8392)	8281 (8049 - 8485)
	Events, n	9	382	999
	Persons at risk	9	57	111
	Risk (95% CI)	9	8119 (7718 - 8450)	8408 (8177 - 8609)
	Events, n	12	385	1005
	Persons at risk	12	41	78
	Risk (95% CI)	12	8237 (7832 - 8567)	8512 (8279 - 8714)

Table 15.19.1.3.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
Unvaccinated				
	Events, n	3	212	438
	Persons at risk	3	53	102
	Risk (95% CI)	3	7868 (7317 - 8307)	8055 (7692 - 8361)
	Events, n	6	214	445
	Persons at risk	6	51	92
	Risk (95% CI)	6	7949 (7402 - 8380)	8191 (7836 - 8488)
	Events, n	9	219	445
	Persons at risk	9	46	90
	Risk (95% CI)	9	8150 (7617 - 8563)	8191 (7836 - 8488)
	Events, n	12	222	450
	Persons at risk	12	43	76
	Risk (95% CI)	12	8271 (7747 - 8672)	8296 (7945 - 8586)
Received dose 1 in the last 14 days				
	Events, n	3	16	43
	Persons at risk	3	<5	6
	Risk (95% CI)	3	8889 (5896 - 9699)	8776 (7409 - 9421)
	Events, n	6	16	44
	Persons at risk	6	<5	5
	Risk (95% CI)	6	8889 (5896 - 9699)	8980 (7658 - 9555)
	Events, n	9	16	44
	Persons at risk	9	<5	5
	Risk (95% CI)	9	8889 (5896 - 9699)	8980 (7658 - 9555)
	Events, n	12	16	44
	Persons at risk	12	<5	5
	Risk (95% CI)	12	8889 (5896 - 9699)	8980 (7658 - 9555)
Received dose 1, 15 or more days ago				
	Events, n	3	52	108
	Persons at risk	3	15	25
	Risk (95% CI)	3	7761 (6503 - 8567)	8060 (7260 - 8626)
	Events, n	6	53	110
	Persons at risk	6	14	22
	Risk (95% CI)	6	7910 (6670 - 8689)	8221 (7436 - 8766)
	Events, n	9	54	111
	Persons at risk	9	12	19
	Risk (95% CI)	9	8060 (6839 - 8809)	8306 (7528 - 8839)
	Events, n	12	54	111

Table 15.19.1.3.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Persons at risk	12	9	17
	Risk (95% CI)	12	8060 (6839 - 8809)	8306 (7528 - 8839)
Received dose 2 in the last 14 days				
	Events, n	3	10	49
	Persons at risk	3	<5	10
	Risk (95% CI)	3	8333 (4094 - 9530)	8305 (7018 - 9037)
	Events, n	6	10	49
	Persons at risk	6	<5	10
	Risk (95% CI)	6	8333 (4094 - 9530)	8305 (7018 - 9037)
	Events, n	9	10	50
	Persons at risk	9	<5	9
	Risk (95% CI)	9	8333 (4094 - 9530)	8475 (7217 - 9164)
	Events, n	12	10	51
	Persons at risk	12	<5	8
	Risk (95% CI)	12	8333 (4094 - 9530)	8644 (7418 - 9288)
Received dose 2, 15 or more days ago				
	Events, n	3	179	417
	Persons at risk	3	45	110
	Risk (95% CI)	3	7821 (7209 - 8299)	7832 (7452 - 8156)
	Events, n	6	183	431
	Persons at risk	6	39	88
	Risk (95% CI)	6	8024 (7423 - 8484)	8120 (7753 - 8426)
	Events, n	9	184	433
	Persons at risk	9	37	77
	Risk (95% CI)	9	8076 (7478 - 8532)	8165 (7800 - 8470)
	Events, n	12	187	440
	Persons at risk	12	33	59
	Risk (95% CI)	12	8235 (7647 - 8676)	8350 (7989 - 8646)
Received dose 3 in the last 14 days				
	Events, n	3	9	17
	Persons at risk	3	<5	6
	Risk (95% CI)	3	6923 (3046 - 8639)	7083 (4559 - 8436)
	Events, n	6	9	18
	Persons at risk	6	<5	5
	Risk (95% CI)	6	6923 (3046 - 8639)	7569 (5012 - 8816)
	Events, n	9	9	19
	Persons at risk	9	<5	<5

Table 15.19.1.3.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Risk (95% CI)	9	6923 (3046 - 8639)	8056 (5487 - 9162)
	Events, n	12	9	19
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	6923 (3046 - 8639)	8056 (5487 - 9162)
Received dose 3, 15 or more days ago				
	Events, n	3	138	420
	Persons at risk	3	24	72
	Risk (95% CI)	3	8066 (7353 - 8587)	8231 (7864 - 8535)
	Events, n	6	139	424
	Persons at risk	6	17	51
	Risk (95% CI)	6	8150 (7438 - 8664)	8340 (7975 - 8639)
	Events, n	9	139	431
	Persons at risk	9	10	23
	Risk (95% CI)	9	8150 (7438 - 8664)	8628 (8248 - 8926)
	Events, n	12	139	431
	Persons at risk	12	<5	7
	Risk (95% CI)	12	8150 (7438 - 8664)	8628 (8248 - 8926)
Received dose 4 in the last 14 days				
	Events, n	3	5	8
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	8333 (26 - 9722)	7273 (2841 - 8961)
	Events, n	6	5	8
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	5	8
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	5	8
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	19	68
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	9321 (8206 - 9743)
	Events, n	6	19	68
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	9321 (8206 - 9743)

Table 15.19.1.3.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Events, n	9	19	68
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	19	68
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.4.1 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N=24)	Pericarditis cohort (N=75)
15-30				
	Events, n	3	32	33
	Persons at risk	3	5	54
	Risk (95% CI)	3	8205 (6489 - 9082)	3516 (2474 - 4414)
	Events, n	6	32	34
	Persons at risk	6	5	48
	Risk (95% CI)	6	8205 (6489 - 9082)	3641 (2583 - 4547)
	Events, n	9	32	34
	Persons at risk	9	<5	41
	Risk (95% CI)	9	8205 (6489 - 9082)	3641 (2583 - 4547)
	Events, n	12	32	34
	Persons at risk	12	<5	31
	Risk (95% CI)	12	8205 (6489 - 9082)	3641 (2583 - 4547)

Table 15.19.1.4.2 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N=39)	Pericarditis cohort (N=94)
Male				
	Events, n	3	76	153
	Persons at risk	3	11	137
	Risk (95% CI)	3	8352 (7382 - 8962)	4902 (4314 - 5429)
	Events, n	6	76	154
	Persons at risk	6	9	115
	Risk (95% CI)	6	8352 (7382 - 8962)	4940 (4351 - 5467)
	Events, n	9	76	154
	Persons at risk	9	6	102
	Risk (95% CI)	9	8352 (7382 - 8962)	4940 (4351 - 5467)
	Events, n	12	76	156
	Persons at risk	12	6	85
	Risk (95% CI)	12	8352 (7382 - 8962)	5046 (4448 - 5580)
Female				
	Events, n	3	22	69
	Persons at risk	3	<5	46
	Risk (95% CI)	3	8800 (6531 - 9585)	5706 (4726 - 6504)
	Events, n	6	22	71
	Persons at risk	6	<5	39
	Risk (95% CI)	6	8800 (6531 - 9585)	5903 (4917 - 6698)
	Events, n	9	22	73
	Persons at risk	9	<5	28
	Risk (95% CI)	9	8800 (6531 - 9585)	6119 (5124 - 6911)
	Events, n	12	22	75
	Persons at risk	12	<5	23
	Risk (95% CI)	12	8800 (6531 - 9585)	6414 (5380 - 7216)

Table 15.19.1.4.3 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=121)
Male, 15-30 years				
	Events, n	3	31	29
	Persons at risk	3	5	42
	Risk (95% CI)	3	8378 (6627 - 9220)	3726 (2553 - 4714)
	Events, n	6	31	29
	Persons at risk	6	5	39
	Risk (95% CI)	6	8378 (6627 - 9220)	3726 (2553 - 4714)
	Events, n	9	31	29
	Persons at risk	9	<5	34
	Risk (95% CI)	9	8378 (6627 - 9220)	3726 (2553 - 4714)
	Events, n	12	31	29
	Persons at risk	12	<5	25
	Risk (95% CI)	12	8378 (6627 - 9220)	3726 (2553 - 4714)
Female, 15-30 years				
	Events, n	3	<5	<5
	Persons at risk	3	0	<16
	Risk (95% CI)	3	NA (NA - NA)	2500 (48 - 4348)
	Events, n	6	<5	5
	Persons at risk	6	0	9
	Risk (95% CI)	6	NA (NA - NA)	3125 (434 - 5059)
	Events, n	9	<5	5
	Persons at risk	9	0	7
	Risk (95% CI)	9	NA (NA - NA)	3125 (434 - 5059)
	Events, n	12	<5	5
	Persons at risk	12	0	6
	Risk (95% CI)	12	NA (NA - NA)	3125 (434 - 5059)

Table 15.19.1.4.4 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	72	166
	Persons at risk	3	8	130
	Risk (95% CI)	3	8780 (7820 - 9318)	5258 (4672 - 5779)
	Events, n	6	72	169
	Persons at risk	6	7	112
	Risk (95% CI)	6	8780 (7820 - 9318)	5372 (4784 - 5894)
	Events, n	9	72	171
	Persons at risk	9	5	95
	Risk (95% CI)	9	8780 (7820 - 9318)	5456 (4864 - 5979)
	Events, n	12	72	174
	Persons at risk	12	5	83
	Risk (95% CI)	12	8780 (7820 - 9318)	5608 (5007 - 6136)
Yes				
	Events, n	3	26	56
	Persons at risk	3	5	53
	Risk (95% CI)	3	7647 (5687 - 8716)	4758 (3772 - 5588)
	Events, n	6	26	56
	Persons at risk	6	<5	42
	Risk (95% CI)	6	7647 (5687 - 8716)	4758 (3772 - 5588)
	Events, n	9	26	56
	Persons at risk	9	<5	35
	Risk (95% CI)	9	7647 (5687 - 8716)	4758 (3772 - 5588)
	Events, n	12	26	57
	Persons at risk	12	<5	25
	Risk (95% CI)	12	7647 (5687 - 8716)	4913 (3897 - 5759)

Table 15.19.1.4.5 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=34)	Pericarditis cohort (N=118)
Vaccinated				
	Events, n	3	10	18
	Persons at risk	3	0	12
	Risk (95% CI)	3	NA (NA - NA)	6000 (3800 - 7419)
	Events, n	6	10	18
	Persons at risk	6	0	12
	Risk (95% CI)	6	NA (NA - NA)	6000 (3800 - 7419)
	Events, n	9	10	18
	Persons at risk	9	0	12
	Risk (95% CI)	9	NA (NA - NA)	6000 (3800 - 7419)
	Events, n	12	10	18
	Persons at risk	12	0	12
	Risk (95% CI)	12	NA (NA - NA)	6000 (3800 - 7419)
Unvaccinated				
	Events, n	3	54	128
	Persons at risk	3	8	121
	Risk (95% CI)	3	8308 (7100 - 9012)	4730 (4099 - 5294)
	Events, n	6	54	130
	Persons at risk	6	5	95
	Risk (95% CI)	6	8308 (7100 - 9012)	4823 (4187 - 5390)
	Events, n	9	54	131
	Persons at risk	9	<5	75
	Risk (95% CI)	9	8308 (7100 - 9012)	4879 (4239 - 5448)
	Events, n	12	54	133
	Persons at risk	12	<5	56
	Risk (95% CI)	12	8308 (7100 - 9012)	5033 (4371 - 5618)

Table 15.19.1.4.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
Unvaccinated				
	Events, n	3	34	76
	Persons at risk	3	5	50
	Risk (95% CI)	3	8293 (6648 - 9130)	5725 (4794 - 6490)
	Events, n	6	34	77
	Persons at risk	6	5	47
	Risk (95% CI)	6	8293 (6648 - 9130)	5811 (4878 - 6574)
	Events, n	9	34	78
	Persons at risk	9	5	43
	Risk (95% CI)	9	8293 (6648 - 9130)	5900 (4965 - 6661)
	Events, n	12	34	80
	Persons at risk	12	5	40
	Risk (95% CI)	12	8293 (6648 - 9130)	6093 (5151 - 6852)
Received dose 1 in the last 14 days				
	Events, n	3	<5	5
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	5556 (773 - 7859)
	Events, n	6	<5	5
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	5556 (773 - 7859)
	Events, n	9	<5	5
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	5556 (773 - 7859)
	Events, n	12	<5	5
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	5556 (773 - 7859)
Received dose 1, 15 or more days ago				
	Events, n	3	9	7
	Persons at risk	3	<5	12
	Risk (95% CI)	3	7500 (3339 - 9062)	3500 (1034 - 5288)
	Events, n	6	9	7
	Persons at risk	6	<5	11
	Risk (95% CI)	6	7500 (3339 - 9062)	3500 (1034 - 5288)
	Events, n	9	9	7
	Persons at risk	9	0	10
	Risk (95% CI)	9	NA (NA - NA)	3500 (1034 - 5288)
	Events, n	12	9	7

Table 15.19.1.4.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Persons at risk	12	0	5
	Risk (95% CI)	12	NA (NA - NA)	3500 (1034 - 5288)
Received dose 2 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	0	<13
	Risk (95% CI)	3	NA (NA - NA)	3333 (0 - 5800)
	Events, n	6	<5	<5
	Persons at risk	6	0	<13
	Risk (95% CI)	6	NA (NA - NA)	3333 (0 - 5800)
	Events, n	9	<5	<5
	Persons at risk	9	0	<13
	Risk (95% CI)	9	NA (NA - NA)	3333 (0 - 5800)
	Events, n	12	<5	<5
	Persons at risk	12	0	<13
	Risk (95% CI)	12	NA (NA - NA)	3333 (0 - 5800)
Received dose 2, 15 or more days ago				
	Events, n	3	29	88
	Persons at risk	3	6	80
	Risk (95% CI)	3	8286 (6449 - 9172)	5049 (4247 - 5740)
	Events, n	6	29	90
	Persons at risk	6	<5	67
	Risk (95% CI)	6	8286 (6449 - 9172)	5179 (4372 - 5870)
	Events, n	9	29	90
	Persons at risk	9	<5	56
	Risk (95% CI)	9	8286 (6449 - 9172)	5179 (4372 - 5870)
	Events, n	12	29	92
	Persons at risk	12	<5	47
	Risk (95% CI)	12	8286 (6449 - 9172)	5363 (4538 - 6064)
Received dose 3 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	<5	<5
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	<5	<5
	Persons at risk	9	0	0

Table 15.19.1.4.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	<5	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	20	37
	Persons at risk	3	<5	27
	Risk (95% CI)	3	9091 (6592 - 9757)	5000 (3721 - 6019)
	Events, n	6	20	37
	Persons at risk	6	0	17
	Risk (95% CI)	6	NA (NA - NA)	5000 (3721 - 6019)
	Events, n	9	20	38
	Persons at risk	9	0	11
	Risk (95% CI)	9	NA (NA - NA)	5294 (3915 - 6361)
	Events, n	12	20	38
	Persons at risk	12	0	6
	Risk (95% CI)	12	NA (NA - NA)	5294 (3915 - 6361)
Received dose 4 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	<5
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	<5
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	1818 (0 - 3808)
	Events, n	6	0	<5
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	1818 (0 - 3808)

Table 15.19.1.4.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Events, n	9	0	<5
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.5.1 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<23)
15-30				
	Events, n	3	81	118
	Persons at risk	3	36	147
	Risk (95% CI)	3	6819 (5859 - 7557)	4354 (3732 - 4915)
	Events, n	6	81	119
	Persons at risk	6	31	143
	Risk (95% CI)	6	6819 (5859 - 7557)	4393 (3770 - 4954)
	Events, n	9	82	121
	Persons at risk	9	19	139
	Risk (95% CI)	9	6958 (5983 - 7696)	4472 (3846 - 5034)
	Events, n	12	82	125
	Persons at risk	12	15	134
	Risk (95% CI)	12	6958 (5983 - 7696)	4632 (4001 - 5196)

Table 15.19.1.5.2 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N=271)
Male				
	Events, n	3	288	663
	Persons at risk	3	121	396
	Risk (95% CI)	3	6962 (6484 - 7375)	6183 (5880 - 6463)
	Events, n	6	292	675
	Persons at risk	6	93	375
	Risk (95% CI)	6	7063 (6588 - 7471)	6299 (5998 - 6578)
	Events, n	9	295	684
	Persons at risk	9	61	358
	Risk (95% CI)	9	7189 (6709 - 7599)	6389 (6088 - 6666)
	Events, n	12	296	694
	Persons at risk	12	56	345
	Risk (95% CI)	12	7238 (6754 - 7649)	6490 (6191 - 6766)
Female				
	Events, n	3	138	384
	Persons at risk	3	120	199
	Risk (95% CI)	3	5271 (4625 - 5838)	6502 (6095 - 6867)
	Events, n	6	142	388
	Persons at risk	6	95	190
	Risk (95% CI)	6	5444 (4796 - 6012)	6573 (6168 - 6936)
	Events, n	9	142	390
	Persons at risk	9	60	186
	Risk (95% CI)	9	5444 (4796 - 6012)	6610 (6205 - 6971)
	Events, n	12	142	394
	Persons at risk	12	53	178
	Risk (95% CI)	12	5444 (4796 - 6012)	6684 (6280 - 7044)

Table 15.19.1.5.3 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N=591)
Male, 15-30 years				
	Events, n	3	70	92
	Persons at risk	3	23	117
	Risk (95% CI)	3	7377 (6322 - 8129)	4299 (3596 - 4926)
	Events, n	6	70	93
	Persons at risk	6	19	114
	Risk (95% CI)	6	7377 (6322 - 8129)	4348 (3643 - 4975)
	Events, n	9	71	95
	Persons at risk	9	11	110
	Risk (95% CI)	9	7564 (6481 - 8314)	4448 (3739 - 5076)
	Events, n	12	71	97
	Persons at risk	12	9	108
	Risk (95% CI)	12	7564 (6481 - 8314)	4549 (3837 - 5179)
Female, 15-30 years				
	Events, n	3	11	26
	Persons at risk	3	13	30
	Risk (95% CI)	3	4583 (2174 - 6251)	4561 (3102 - 5712)
	Events, n	6	11	26
	Persons at risk	6	12	29
	Risk (95% CI)	6	4583 (2174 - 6251)	4561 (3102 - 5712)
	Events, n	9	11	26
	Persons at risk	9	8	29
	Risk (95% CI)	9	4583 (2174 - 6251)	4561 (3102 - 5712)
	Events, n	12	11	28
	Persons at risk	12	6	26
	Risk (95% CI)	12	4583 (2174 - 6251)	4950 (3457 - 6102)

Table 15.19.1.5.4 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N=24)	Pericarditis cohort (N=57)
No				
	Events, n	3	251	742
	Persons at risk	3	105	436
	Risk (95% CI)	3	6977 (6463 - 7417)	6253 (5967 - 6518)
	Events, n	6	253	754
	Persons at risk	6	86	419
	Risk (95% CI)	6	7035 (6523 - 7472)	6356 (6072 - 6620)
	Events, n	9	255	759
	Persons at risk	9	60	409
	Risk (95% CI)	9	7124 (6608 - 7561)	6400 (6116 - 6663)
	Events, n	12	255	772
	Persons at risk	12	52	392
	Risk (95% CI)	12	7124 (6608 - 7561)	6515 (6232 - 6776)
Yes				
	Events, n	3	175	305
	Persons at risk	3	136	159
	Risk (95% CI)	3	5542 (4958 - 6058)	6402 (5944 - 6808)
	Events, n	6	181	309
	Persons at risk	6	102	146
	Risk (95% CI)	6	5757 (5172 - 6272)	6494 (6037 - 6898)
	Events, n	9	182	315
	Persons at risk	9	61	135
	Risk (95% CI)	9	5819 (5227 - 6337)	6640 (6184 - 7041)
	Events, n	12	183	316
	Persons at risk	12	57	131
	Risk (95% CI)	12	5890 (5288 - 6414)	6665 (6210 - 7066)

Table 15.19.1.5.5 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=316)	Pericarditis cohort (N=477)
Vaccinated				
	Events, n	3	20	69
	Persons at risk	3	8	64
	Risk (95% CI)	3	7143 (4868 - 8409)	5188 (4259 - 5966)
	Events, n	6	20	69
	Persons at risk	6	8	64
	Risk (95% CI)	6	7143 (4868 - 8409)	5188 (4259 - 5966)
	Events, n	9	20	70
	Persons at risk	9	8	63
	Risk (95% CI)	9	7143 (4868 - 8409)	5263 (4334 - 6040)
	Events, n	12	20	71
	Persons at risk	12	8	62
	Risk (95% CI)	12	7143 (4868 - 8409)	5338 (4409 - 6114)
Unvaccinated				
	Events, n	3	228	537
	Persons at risk	3	124	209
	Risk (95% CI)	3	6377 (5842 - 6843)	7035 (6692 - 7342)
	Events, n	6	234	547
	Persons at risk	6	90	188
	Risk (95% CI)	6	6568 (6035 - 7030)	7180 (6840 - 7483)
	Events, n	9	236	550
	Persons at risk	9	50	175
	Risk (95% CI)	9	6686 (6141 - 7154)	7225 (6887 - 7527)
	Events, n	12	236	553
	Persons at risk	12	42	166
	Risk (95% CI)	12	6686 (6141 - 7154)	7274 (6936 - 7575)

Table 15.19.1.5.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
Unvaccinated				
	Events, n	3	178	441
	Persons at risk	3	109	322
	Risk (95% CI)	3	6141 (5537 - 6662)	5751 (5386 - 6087)
	Events, n	6	180	447
	Persons at risk	6	90	313
	Risk (95% CI)	6	6213 (5610 - 6732)	5830 (5466 - 6165)
	Events, n	9	181	454
	Persons at risk	9	63	306
	Risk (95% CI)	9	6267 (5662 - 6788)	5924 (5560 - 6257)
	Events, n	12	182	464
	Persons at risk	12	59	295
	Risk (95% CI)	12	6330 (5719 - 6853)	6058 (5696 - 6389)
Received dose 1 in the last 14 days				
	Events, n	3	7	17
	Persons at risk	3	<5	27
	Risk (95% CI)	3	8750 (2181 - 9800)	3864 (2242 - 5146)
	Events, n	6	7	17
	Persons at risk	6	<5	27
	Risk (95% CI)	6	8750 (2181 - 9800)	3864 (2242 - 5146)
	Events, n	9	7	18
	Persons at risk	9	<5	26
	Risk (95% CI)	9	8750 (2181 - 9800)	4091 (2444 - 5379)
	Events, n	12	7	19
	Persons at risk	12	<5	25
	Risk (95% CI)	12	8750 (2181 - 9800)	4318 (2649 - 5608)
Received dose 1, 15 or more days ago				
	Events, n	3	25	30
	Persons at risk	3	22	36
	Risk (95% CI)	3	5217 (3570 - 6443)	4286 (3000 - 5335)
	Events, n	6	25	30
	Persons at risk	6	21	36
	Risk (95% CI)	6	5217 (3570 - 6443)	4286 (3000 - 5335)
	Events, n	9	25	30
	Persons at risk	9	14	36
	Risk (95% CI)	9	5217 (3570 - 6443)	4286 (3000 - 5335)
	Events, n	12	25	30

Table 15.19.1.5.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Persons at risk	12	14	36
	Risk (95% CI)	12	5217 (3570 - 6443)	4286 (3000 - 5335)
Received dose 2 in the last 14 days				
	Events, n	3	10	21
	Persons at risk	3	<5	15
	Risk (95% CI)	3	7692 (3774 - 9145)	5833 (3867 - 7169)
	Events, n	6	10	21
	Persons at risk	6	<5	15
	Risk (95% CI)	6	7692 (3774 - 9145)	5833 (3867 - 7169)
	Events, n	9	10	21
	Persons at risk	9	<5	15
	Risk (95% CI)	9	7692 (3774 - 9145)	5833 (3867 - 7169)
	Events, n	12	10	21
	Persons at risk	12	<5	15
	Risk (95% CI)	12	7692 (3774 - 9145)	5833 (3867 - 7169)
Received dose 2, 15 or more days ago				
	Events, n	3	137	351
	Persons at risk	3	85	175
	Risk (95% CI)	3	6095 (5402 - 6684)	6563 (6136 - 6943)
	Events, n	6	141	359
	Persons at risk	6	60	159
	Risk (95% CI)	6	6299 (5605 - 6883)	6725 (6300 - 7100)
	Events, n	9	143	362
	Persons at risk	9	31	148
	Risk (95% CI)	9	6505 (5777 - 7108)	6787 (6364 - 7161)
	Events, n	12	143	363
	Persons at risk	12	25	143
	Risk (95% CI)	12	6505 (5777 - 7108)	6809 (6386 - 7182)
Received dose 3 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	5714 (0 - 8178)
	Events, n	6	0	<5
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	5714 (0 - 8178)
	Events, n	9	0	<5
	Persons at risk	9	0	<5

Table 15.19.1.5.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Risk (95% CI)	9	NA (NA - NA)	5714 (0 - 8178)
	Events, n	12	0	<5
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	5714 (0 - 8178)
Received dose 3, 15 or more days ago				
	Events, n	3	49	125
	Persons at risk	3	17	15
	Risk (95% CI)	3	7313 (6012 - 8190)	8874 (8207 - 9293)
	Events, n	6	51	127
	Persons at risk	6	13	12
	Risk (95% CI)	6	7652 (6364 - 8484)	9024 (8381 - 9411)
	Events, n	9	51	127
	Persons at risk	9	9	10
	Risk (95% CI)	9	7652 (6364 - 8484)	9024 (8381 - 9411)
	Events, n	12	51	129
	Persons at risk	12	7	6
	Risk (95% CI)	12	7652 (6364 - 8484)	9268 (8605 - 9616)
Received dose 4 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	<5
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	<5
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	20	55
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	8133 (5651 - 9199)	9157 (7905 - 9661)
	Events, n	6	20	55
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.5.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Events, n	9	20	55
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	20	55
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.1.6.1 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=61)
15-30				
	Events, n	3	29	48
	Persons at risk	3	287	510
	Risk (95% CI)	3	820 (529 - 1101)	761 (551 - 966)
	Events, n	6	32	50
	Persons at risk	6	245	450
	Risk (95% CI)	6	922 (611 - 1222)	800 (584 - 1011)
	Events, n	9	34	52
	Persons at risk	9	202	396
	Risk (95% CI)	9	1004 (675 - 1321)	844 (620 - 1062)
	Events, n	12	34	56
	Persons at risk	12	168	329
	Risk (95% CI)	12	1004 (675 - 1321)	943 (701 - 1179)

Table 15.19.1.6.2 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N=356)	Pericarditis cohort (N=644)
Male				
	Events, n	3	60	126
	Persons at risk	3	451	1014
	Risk (95% CI)	3	1047 (792 - 1294)	1000 (833 - 1164)
	Events, n	6	63	136
	Persons at risk	6	393	872
	Risk (95% CI)	6	1109 (847 - 1365)	1096 (920 - 1268)
	Events, n	9	66	147
	Persons at risk	9	337	748
	Risk (95% CI)	9	1185 (911 - 1452)	1217 (1029 - 1401)
	Events, n	12	68	154
	Persons at risk	12	281	649
	Risk (95% CI)	12	1239 (955 - 1513)	1305 (1107 - 1498)
Female				
	Events, n	3	26	56
	Persons at risk	3	231	448
	Risk (95% CI)	3	934 (586 - 1270)	1030 (770 - 1282)
	Events, n	6	32	58
	Persons at risk	6	194	394
	Risk (95% CI)	6	1188 (791 - 1568)	1071 (806 - 1328)
	Events, n	9	36	60
	Persons at risk	9	155	339
	Risk (95% CI)	9	1385 (950 - 1800)	1120 (848 - 1384)
	Events, n	12	39	64
	Persons at risk	12	134	297
	Risk (95% CI)	12	1561 (1087 - 2009)	1232 (941 - 1513)

Table 15.19.1.6.3 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N=281)	Pericarditis cohort (N=548)
Male, 15-30 years				
	Events, n	3	26	39
	Persons at risk	3	230	377
	Risk (95% CI)	3	897 (562 - 1220)	822 (571 - 1067)
	Events, n	6	29	41
	Persons at risk	6	199	328
	Risk (95% CI)	6	1022 (661 - 1369)	876 (615 - 1129)
	Events, n	9	30	43
	Persons at risk	9	165	294
	Risk (95% CI)	9	1073 (700 - 1432)	934 (662 - 1198)
	Events, n	12	30	45
	Persons at risk	12	139	242
	Risk (95% CI)	12	1073 (700 - 1432)	1001 (715 - 1279)
Female, 15-30 years				
	Events, n	3	<5	9
	Persons at risk	3	<86	133
	Risk (95% CI)	3	469 (0 - 973)	574 (203 - 931)
	Events, n	6	<5	9
	Persons at risk	6	<86	122
	Risk (95% CI)	6	469 (0 - 973)	574 (203 - 931)
	Events, n	9	<5	9
	Persons at risk	9	<58	102
	Risk (95% CI)	9	690 (3 - 1331)	574 (203 - 931)
	Events, n	12	<5	11
	Persons at risk	12	<58	87
	Risk (95% CI)	12	690 (3 - 1331)	769 (312 - 1204)

Table 15.19.1.6.4 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N<86)	Pericarditis cohort (N=159)
No				
	Events, n	3	63	144
	Persons at risk	3	472	1101
	Risk (95% CI)	3	1062 (810 - 1307)	1062 (897 - 1225)
	Events, n	6	69	153
	Persons at risk	6	412	973
	Risk (95% CI)	6	1182 (915 - 1441)	1140 (968 - 1308)
	Events, n	9	72	162
	Persons at risk	9	356	857
	Risk (95% CI)	9	1252 (975 - 1520)	1226 (1047 - 1402)
	Events, n	12	76	173
	Persons at risk	12	308	759
	Risk (95% CI)	12	1354 (1062 - 1636)	1345 (1155 - 1532)
Yes				
	Events, n	3	23	38
	Persons at risk	3	210	361
	Risk (95% CI)	3	888 (535 - 1229)	848 (586 - 1103)
	Events, n	6	26	41
	Persons at risk	6	175	293
	Risk (95% CI)	6	1030 (646 - 1399)	933 (656 - 1202)
	Events, n	9	30	45
	Persons at risk	9	136	230
	Risk (95% CI)	9	1265 (822 - 1687)	1076 (768 - 1374)
	Events, n	12	31	45
	Persons at risk	12	107	187
	Risk (95% CI)	12	1333 (873 - 1770)	1076 (768 - 1374)

Table 15.19.1.6.5 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N=454)
Vaccinated				
	Events, n	3	13	<5
	Persons at risk	3	48	<100
	Risk (95% CI)	3	2103 (1019 - 3057)	401 (8 - 778)
	Events, n	6	13	5
	Persons at risk	6	47	91
	Risk (95% CI)	6	2103 (1019 - 3057)	504 (64 - 925)
	Events, n	9	14	6
	Persons at risk	9	44	90
	Risk (95% CI)	9	2279 (1154 - 3261)	609 (124 - 1069)
	Events, n	12	14	6
	Persons at risk	12	42	87
	Risk (95% CI)	12	2279 (1154 - 3261)	609 (124 - 1069)
Unvaccinated				
	Events, n	3	41	104
	Persons at risk	3	359	755
	Risk (95% CI)	3	923 (650 - 1189)	1082 (883 - 1277)
	Events, n	6	45	108
	Persons at risk	6	290	623
	Risk (95% CI)	6	1029 (739 - 1310)	1134 (930 - 1333)
	Events, n	9	49	113
	Persons at risk	9	224	494
	Risk (95% CI)	9	1169 (851 - 1476)	1213 (999 - 1423)
	Events, n	12	51	120
	Persons at risk	12	174	393
	Risk (95% CI)	12	1251 (915 - 1574)	1351 (1116 - 1580)

Table 15.19.1.6.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
Unvaccinated				
	Events, n	3	32	74
	Persons at risk	3	275	613
	Risk (95% CI)	3	926 (615 - 1227)	996 (778 - 1209)
	Events, n	6	37	81
	Persons at risk	6	250	552
	Risk (95% CI)	6	1099 (757 - 1428)	1104 (874 - 1328)
	Events, n	9	39	88
	Persons at risk	9	224	503
	Risk (95% CI)	9	1176 (820 - 1519)	1222 (978 - 1459)
	Events, n	12	42	92
	Persons at risk	12	199	466
	Risk (95% CI)	12	1299 (920 - 1662)	1295 (1042 - 1540)
Received dose 1 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<23	<109
	Risk (95% CI)	3	1765 (0 - 3391)	370 (0 - 1057)
	Events, n	6	<5	<5
	Persons at risk	6	<23	<109
	Risk (95% CI)	6	1765 (0 - 3391)	370 (0 - 1057)
	Events, n	9	<5	<5
	Persons at risk	9	<17	<53
	Risk (95% CI)	9	2353 (46 - 4125)	756 (0 - 1710)
	Events, n	12	<5	<5
	Persons at risk	12	<17	<53
	Risk (95% CI)	12	2353 (46 - 4125)	756 (0 - 1710)
Received dose 1, 15 or more days ago				
	Events, n	3	12	21
	Persons at risk	3	62	142
	Risk (95% CI)	3	1466 (663 - 2199)	1167 (685 - 1624)
	Events, n	6	12	23
	Persons at risk	6	54	128
	Risk (95% CI)	6	1466 (663 - 2199)	1297 (787 - 1779)
	Events, n	9	12	25
	Persons at risk	9	48	102
	Risk (95% CI)	9	1466 (663 - 2199)	1444 (900 - 1957)
	Events, n	12	12	27

Table 15.19.1.6.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Persons at risk	12	41	88
	Risk (95% CI)	12	1466 (663 - 2199)	1624 (1031 - 2177)
Received dose 2 in the last 14 days				
	Events, n	3	5	0
	Persons at risk	3	19	24
	Risk (95% CI)	3	2000 (268 - 3424)	0 (0 - 0)
	Events, n	6	5	<5
	Persons at risk	6	19	<96
	Risk (95% CI)	6	2000 (268 - 3424)	417 (0 - 1184)
	Events, n	9	5	<5
	Persons at risk	9	18	<96
	Risk (95% CI)	9	2000 (268 - 3424)	417 (0 - 1184)
	Events, n	12	5	<5
	Persons at risk	12	17	<96
	Risk (95% CI)	12	2000 (268 - 3424)	417 (0 - 1184)
Received dose 2, 15 or more days ago				
	Events, n	3	20	42
	Persons at risk	3	160	334
	Risk (95% CI)	3	1023 (588 - 1438)	1020 (722 - 1307)
	Events, n	6	23	44
	Persons at risk	6	135	286
	Risk (95% CI)	6	1195 (724 - 1643)	1078 (771 - 1374)
	Events, n	9	25	47
	Persons at risk	9	112	247
	Risk (95% CI)	9	1339 (831 - 1818)	1177 (853 - 1490)
	Events, n	12	25	50
	Persons at risk	12	100	216
	Risk (95% CI)	12	1339 (831 - 1818)	1290 (945 - 1623)
Received dose 3 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<24	<37
	Risk (95% CI)	3	1667 (0 - 4173)	1111 (0 - 2944)
	Events, n	6	<5	<5
	Persons at risk	6	<24	<37
	Risk (95% CI)	6	1667 (0 - 4173)	1111 (0 - 2944)
	Events, n	9	<5	<5
	Persons at risk	9	<5	<37

Table 15.19.1.6.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Risk (95% CI)	9	1667 (0 - 4173)	1111 (0 - 2944)
	Events, n	12	<5	<5
	Persons at risk	12	<5	<37
	Risk (95% CI)	12	1667 (0 - 4173)	1111 (0 - 2944)
Received dose 3, 15 or more days ago				
	Events, n	3	10	38
	Persons at risk	3	141	294
	Risk (95% CI)	3	582 (225 - 925)	1005 (696 - 1303)
	Events, n	6	11	38
	Persons at risk	6	107	231
	Risk (95% CI)	6	656 (272 - 1026)	1005 (696 - 1303)
	Events, n	9	12	38
	Persons at risk	9	73	174
	Risk (95% CI)	9	779 (327 - 1211)	1005 (696 - 1303)
	Events, n	12	14	40
	Persons at risk	12	42	120
	Risk (95% CI)	12	1049 (465 - 1597)	1126 (777 - 1463)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	<5	5
	Persons at risk	3	<13	21
	Risk (95% CI)	3	3143 (0 - 5553)	1667 (220 - 2899)
	Events, n	6	<5	5
	Persons at risk	6	<5	13
	Risk (95% CI)	6	3143 (0 - 5553)	1667 (220 - 2899)

Table 15.19.1.6.6 Risk (1-KM and 95% CI) for NUMBER OF HOSPITALISATIONS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Events, n	9	<5	5
	Persons at risk	9	0	6
	Risk (95% CI)	9	NA (NA - NA)	1667 (220 - 2899)
	Events, n	12	<5	5
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	1667 (220 - 2899)

Table 15.19.2.1.1 Risk (1-KM and 95% CI) for DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N<13)	Pericarditis cohort (N=30)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.2.1.2 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.2.1.3 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

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Table 15.19.2.1.4 Risk (1-KM and 95% CI) for DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.2.1.5 Risk (1-KM and 95% CI) for DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

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Table 15.19.2.1.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.2.1.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

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Table 15.19.2.1.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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Table 15.19.2.1.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.2.2.1 Risk (1-KM and 95% CI) for DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<513	22
	Risk (95% CI)	3	78 (0 - 228)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<513	21
	Risk (95% CI)	6	78 (0 - 228)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<513	19
	Risk (95% CI)	9	78 (0 - 228)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<513	17
	Risk (95% CI)	12	78 (0 - 228)	0 (0 - 0)

Table 15.19.2.2.2 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N<513)	Pericarditis cohort (N=23)
Male				
	Events, n	3	13	<5
	Persons at risk	3	414	<94
	Risk (95% CI)	3	292 (134 - 447)	429 (0 - 891)
	Events, n	6	16	<5
	Persons at risk	6	386	<94
	Risk (95% CI)	6	364 (187 - 538)	429 (0 - 891)
	Events, n	9	19	<5
	Persons at risk	9	347	<69
	Risk (95% CI)	9	443 (246 - 636)	588 (11 - 1132)
	Events, n	12	19	<5
	Persons at risk	12	320	<69
	Risk (95% CI)	12	443 (246 - 636)	588 (11 - 1132)
Female				
	Events, n	3	<5	<5
	Persons at risk	3	<426	<64
	Risk (95% CI)	3	94 (0 - 223)	625 (0 - 1427)
	Events, n	6	<5	<5
	Persons at risk	6	<280	<64
	Risk (95% CI)	6	143 (0 - 303)	625 (0 - 1427)
	Events, n	9	<5	<5
	Persons at risk	9	<203	<64
	Risk (95% CI)	9	198 (4 - 389)	625 (0 - 1427)
	Events, n	12	<5	<5
	Persons at risk	12	<203	<64
	Risk (95% CI)	12	198 (4 - 389)	625 (0 - 1427)

Table 15.19.2.2.3 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N<426)	Pericarditis cohort (N<64)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<351	17
	Risk (95% CI)	3	114 (0 - 333)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<351	17
	Risk (95% CI)	6	114 (0 - 333)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<351	15
	Risk (95% CI)	9	114 (0 - 333)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<351	13
	Risk (95% CI)	12	114 (0 - 333)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	41	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	35	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.2.2.4 Risk (1-KM and 95% CI) for DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N=42)	Pericarditis cohort (N=5)
No				
	Events, n	3	10	<5
	Persons at risk	3	517	<87
	Risk (95% CI)	3	185 (71 - 297)	460 (9 - 890)
	Events, n	6	14	<5
	Persons at risk	6	485	<87
	Risk (95% CI)	6	262 (126 - 397)	460 (9 - 890)
	Events, n	9	18	5
	Persons at risk	9	445	74
	Risk (95% CI)	9	346 (187 - 502)	584 (73 - 1068)
	Events, n	12	18	5
	Persons at risk	12	415	65
	Risk (95% CI)	12	346 (187 - 502)	584 (73 - 1068)
Yes				
	Events, n	3	5	<5
	Persons at risk	3	101	<60
	Risk (95% CI)	3	423 (53 - 779)	667 (0 - 1847)
	Events, n	6	5	<5
	Persons at risk	6	87	<60
	Risk (95% CI)	6	423 (53 - 779)	667 (0 - 1847)
	Events, n	9	5	<5
	Persons at risk	9	73	<60
	Risk (95% CI)	9	423 (53 - 779)	667 (0 - 1847)
	Events, n	12	5	<5
	Persons at risk	12	62	<60
	Risk (95% CI)	12	423 (53 - 779)	667 (0 - 1847)

Table 15.19.2.2.5 Risk (1-KM and 95% CI) for DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=121)	Pericarditis cohort (N<60)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	36	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	35	5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	5	<5
	Persons at risk	3	235	<124
	Risk (95% CI)	3	193 (24 - 360)	323 (0 - 925)
	Events, n	6	5	<5
	Persons at risk	6	212	<124
	Risk (95% CI)	6	193 (24 - 360)	323 (0 - 925)
	Events, n	9	7	<5
	Persons at risk	9	182	<124
	Risk (95% CI)	9	291 (75 - 502)	323 (0 - 925)
	Events, n	12	7	<5
	Persons at risk	12	162	<124
	Risk (95% CI)	12	291 (75 - 502)	323 (0 - 925)

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Table 15.19.2.2.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N<124)
Unvaccinated				
	Events, n	3	10	<5
	Persons at risk	3	347	<67
	Risk (95% CI)	3	274 (105 - 441)	606 (12 - 1164)
	Events, n	6	14	<5
	Persons at risk	6	325	<67
	Risk (95% CI)	6	389 (187 - 587)	606 (12 - 1164)
	Events, n	9	16	5
	Persons at risk	9	302	53
	Risk (95% CI)	9	451 (232 - 664)	774 (98 - 1404)
	Events, n	12	16	5
	Persons at risk	12	282	47
	Risk (95% CI)	12	451 (232 - 664)	774 (98 - 1404)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	81	10
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	77	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	69	10
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.2.2.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N<124)
	Persons at risk	12	63	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<142	15
	Risk (95% CI)	3	282 (6 - 550)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<142	14
	Risk (95% CI)	6	282 (6 - 550)	0 (0 - 0)
	Events, n	9	6	0
	Persons at risk	9	101	13
	Risk (95% CI)	9	456 (90 - 808)	0 (0 - 0)
	Events, n	12	6	0
	Persons at risk	12	93	11
	Risk (95% CI)	12	456 (90 - 808)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

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Table 15.19.2.2.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N<124)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<137	<5
	Risk (95% CI)	3	294 (0 - 846)	2000 (0 - 4839)
	Events, n	6	<5	<5
	Persons at risk	6	<137	<5
	Risk (95% CI)	6	294 (0 - 846)	2000 (0 - 4839)
	Events, n	9	<5	<5
	Persons at risk	9	<137	<5
	Risk (95% CI)	9	294 (0 - 846)	2000 (0 - 4839)
	Events, n	12	<5	<5
	Persons at risk	12	<137	<5
	Risk (95% CI)	12	294 (0 - 846)	2000 (0 - 4839)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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Table 15.19.2.2.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N<124)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.2.3.1 Risk (1-KM and 95% CI) for DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N=5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	<5	<5
	Persons at risk	3	<770	<1143
	Risk (95% CI)	3	52 (0 - 153)	35 (0 - 103)
	Events, n	6	<5	<5
	Persons at risk	6	<770	<534
	Risk (95% CI)	6	52 (0 - 153)	75 (0 - 179)
	Events, n	9	<5	<5
	Persons at risk	9	<770	<534
	Risk (95% CI)	9	52 (0 - 153)	75 (0 - 179)
	Events, n	12	<5	<5
	Persons at risk	12	<770	<320
	Risk (95% CI)	12	52 (0 - 153)	125 (0 - 265)

Table 15.19.2.3.2 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N<770)	Pericarditis cohort (N<1143)
Male				
	Events, n	3	15	23
	Persons at risk	3	480	1185
	Risk (95% CI)	3	277 (138 - 414)	178 (106 - 250)
	Events, n	6	19	30
	Persons at risk	6	414	1041
	Risk (95% CI)	6	366 (203 - 527)	240 (154 - 324)
	Events, n	9	23	38
	Persons at risk	9	360	894
	Risk (95% CI)	9	462 (274 - 645)	320 (219 - 420)
	Events, n	12	25	41
	Persons at risk	12	313	748
	Risk (95% CI)	12	519 (316 - 717)	355 (246 - 462)
Female				
	Events, n	3	22	19
	Persons at risk	3	224	559
	Risk (95% CI)	3	834 (494 - 1162)	310 (172 - 447)
	Events, n	6	24	27
	Persons at risk	6	202	479
	Risk (95% CI)	6	922 (563 - 1267)	458 (287 - 625)
	Events, n	9	26	29
	Persons at risk	9	176	424
	Risk (95% CI)	9	1015 (636 - 1378)	500 (320 - 676)
	Events, n	12	27	32
	Persons at risk	12	148	360
	Risk (95% CI)	12	1066 (675 - 1441)	571 (374 - 763)

Table 15.19.2.3.3 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=626)
Male, 15-30 years				
	Events, n	3	<5	<5
	Persons at risk	3	<646	<910
	Risk (95% CI)	3	62 (0 - 184)	44 (0 - 130)
	Events, n	6	<5	<5
	Persons at risk	6	<646	<910
	Risk (95% CI)	6	62 (0 - 184)	44 (0 - 130)
	Events, n	9	<5	<5
	Persons at risk	9	<646	<910
	Risk (95% CI)	9	62 (0 - 184)	44 (0 - 130)
	Events, n	12	<5	<5
	Persons at risk	12	<646	<910
	Risk (95% CI)	12	62 (0 - 184)	44 (0 - 130)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	32	58
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	29	<209
	Risk (95% CI)	6	0 (0 - 0)	192 (0 - 559)
	Events, n	9	0	<5
	Persons at risk	9	25	<209
	Risk (95% CI)	9	0 (0 - 0)	192 (0 - 559)
	Events, n	12	0	<5
	Persons at risk	12	19	<94
	Risk (95% CI)	12	0 (0 - 0)	426 (0 - 989)

Table 15.19.2.3.4 Risk (1-KM and 95% CI) for DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N=34)	Pericarditis cohort (N<209)
No				
	Events, n	3	33	39
	Persons at risk	3	607	1586
	Risk (95% CI)	3	482 (320 - 641)	228 (157 - 299)
	Events, n	6	39	54
	Persons at risk	6	542	1401
	Risk (95% CI)	6	583 (403 - 759)	326 (240 - 411)
	Events, n	9	45	64
	Persons at risk	9	482	1240
	Risk (95% CI)	9	690 (492 - 883)	398 (302 - 494)
	Events, n	12	48	70
	Persons at risk	12	429	1077
	Risk (95% CI)	12	750 (542 - 954)	447 (343 - 550)
Yes				
	Events, n	3	<5	<5
	Persons at risk	3	<117	<269
	Risk (95% CI)	3	342 (7 - 665)	149 (0 - 316)
	Events, n	6	<5	<5
	Persons at risk	6	<117	<269
	Risk (95% CI)	6	342 (7 - 665)	149 (0 - 316)
	Events, n	9	<5	<5
	Persons at risk	9	<117	<269
	Risk (95% CI)	9	342 (7 - 665)	149 (0 - 316)
	Events, n	12	<5	<5
	Persons at risk	12	<117	<269
	Risk (95% CI)	12	342 (7 - 665)	149 (0 - 316)

Table 15.19.2.3.5 Risk (1-KM and 95% CI) for DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N<269)
Vaccinated				
	Events, n	3	<5	5
	Persons at risk	3	<260	186
	Risk (95% CI)	3	154 (0 - 449)	259 (32 - 481)
	Events, n	6	<5	7
	Persons at risk	6	<124	178
	Risk (95% CI)	6	324 (0 - 756)	366 (96 - 628)
	Events, n	9	<5	9
	Persons at risk	9	<82	176
	Risk (95% CI)	9	493 (0 - 1023)	474 (167 - 772)
	Events, n	12	<5	9
	Persons at risk	12	<82	167
	Risk (95% CI)	12	493 (0 - 1023)	474 (167 - 772)
Unvaccinated				
	Events, n	3	26	30
	Persons at risk	3	396	1041
	Risk (95% CI)	3	556 (346 - 761)	255 (164 - 344)
	Events, n	6	28	40
	Persons at risk	6	327	841
	Risk (95% CI)	6	610 (388 - 828)	358 (248 - 467)
	Events, n	9	32	46
	Persons at risk	9	258	661
	Risk (95% CI)	9	729 (480 - 972)	435 (309 - 560)
	Events, n	12	34	52
	Persons at risk	12	197	488
	Risk (95% CI)	12	811 (538 - 1076)	532 (385 - 677)

Table 15.19.2.3.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
Unvaccinated				
	Events, n	3	10	7
	Persons at risk	3	246	517
	Risk (95% CI)	3	372 (143 - 596)	131 (34 - 226)
	Events, n	6	13	10
	Persons at risk	6	232	501
	Risk (95% CI)	6	492 (228 - 750)	189 (72 - 304)
	Events, n	9	14	12
	Persons at risk	9	222	481
	Risk (95% CI)	9	534 (257 - 802)	229 (100 - 356)
	Events, n	12	15	12
	Persons at risk	12	210	453
	Risk (95% CI)	12	577 (289 - 857)	229 (100 - 356)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	18	49
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<72	49
	Risk (95% CI)	6	556 (0 - 1557)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<37	49
	Risk (95% CI)	9	1111 (0 - 2451)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<37	48
	Risk (95% CI)	12	1111 (0 - 2451)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<133	<265
	Risk (95% CI)	3	303 (0 - 708)	151 (0 - 356)
	Events, n	6	<5	<5
	Persons at risk	6	<86	<265
	Risk (95% CI)	6	468 (0 - 971)	151 (0 - 356)
	Events, n	9	<5	<5
	Persons at risk	9	<86	<265
	Risk (95% CI)	9	468 (0 - 971)	151 (0 - 356)
	Events, n	12	<5	<5

Table 15.19.2.3.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Persons at risk	12	<86	<121
	Risk (95% CI)	12	468 (0 - 971)	332 (5 - 648)
Received dose 2 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	12	<237
	Risk (95% CI)	3	0 (0 - 0)	169 (0 - 493)
	Events, n	6	0	<5
	Persons at risk	6	12	<237
	Risk (95% CI)	6	0 (0 - 0)	169 (0 - 493)
	Events, n	9	0	<5
	Persons at risk	9	12	<237
	Risk (95% CI)	9	0 (0 - 0)	169 (0 - 493)
	Events, n	12	0	<5
	Persons at risk	12	12	<237
	Risk (95% CI)	12	0 (0 - 0)	169 (0 - 493)
Received dose 2, 15 or more days ago				
	Events, n	3	14	16
	Persons at risk	3	207	494
	Risk (95% CI)	3	611 (296 - 916)	302 (155 - 446)
	Events, n	6	14	20
	Persons at risk	6	189	458
	Risk (95% CI)	6	611 (296 - 916)	382 (216 - 545)
	Events, n	9	17	25
	Persons at risk	9	169	419
	Risk (95% CI)	9	761 (406 - 1104)	492 (302 - 679)
	Events, n	12	18	27
	Persons at risk	12	151	377
	Risk (95% CI)	12	817 (446 - 1173)	540 (339 - 736)
Received dose 3 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<53	<96
	Risk (95% CI)	3	769 (0 - 2110)	417 (0 - 1184)
	Events, n	6	<5	<5
	Persons at risk	6	<53	<49
	Risk (95% CI)	6	769 (0 - 2110)	833 (0 - 1875)
	Events, n	9	<5	<5
	Persons at risk	9	<53	<32

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Table 15.19.2.3.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Risk (95% CI)	9	769 (0 - 2110)	1250 (0 - 2478)
	Events, n	12	<5	<5
	Persons at risk	12	<53	<32
	Risk (95% CI)	12	769 (0 - 2110)	1250 (0 - 2478)
Received dose 3, 15 or more days ago				
	Events, n	3	9	12
	Persons at risk	3	134	427
	Risk (95% CI)	3	542 (190 - 880)	241 (105 - 375)
	Events, n	6	10	19
	Persons at risk	6	95	301
	Risk (95% CI)	6	625 (239 - 995)	426 (234 - 614)
	Events, n	9	11	20
	Persons at risk	9	53	172
	Risk (95% CI)	9	742 (293 - 1169)	466 (259 - 669)
	Events, n	12	12	22
	Persons at risk	12	17	50
	Risk (95% CI)	12	1183 (190 - 2075)	596 (322 - 862)
Received dose 4 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	<5	<45
	Risk (95% CI)	3	0 (0 - 0)	909 (0 - 2459)
	Events, n	6	0	<5
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	909 (0 - 2459)
	Events, n	9	0	<5
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	909 (0 - 2459)
	Events, n	12	0	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<96	<122
	Risk (95% CI)	3	417 (0 - 1184)	328 (0 - 766)
	Events, n	6	<5	<5
	Persons at risk	6	<5	<122
	Risk (95% CI)	6	417 (0 - 1184)	328 (0 - 766)

Table 15.19.2.3.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Events, n	9	<5	<5
	Persons at risk	9	<5	<29
	Risk (95% CI)	9	417 (0 - 1184)	1403 (0 - 3207)
	Events, n	12	<5	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.2.4.1 Risk (1-KM and 95% CI) for DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N<96)	Pericarditis cohort (N<122)
15-30				
	Events, n	3	0	0
	Persons at risk	3	37	87
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	37	82
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	75
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	62
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.2.4.2 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N=39)	Pericarditis cohort (N=94)
Male				
	Events, n	3	6	9
	Persons at risk	3	81	282
	Risk (95% CI)	3	668 (137 - 1171)	294 (103 - 481)
	Events, n	6	7	14
	Persons at risk	6	78	257
	Risk (95% CI)	6	784 (209 - 1324)	474 (228 - 714)
	Events, n	9	7	15
	Persons at risk	9	75	237
	Risk (95% CI)	9	784 (209 - 1324)	513 (256 - 763)
	Events, n	12	7	17
	Persons at risk	12	66	209
	Risk (95% CI)	12	784 (209 - 1324)	597 (316 - 869)
Female				
	Events, n	3	5	13
	Persons at risk	3	19	102
	Risk (95% CI)	3	2000 (268 - 3424)	1080 (508 - 1617)
	Events, n	6	5	16
	Persons at risk	6	18	94
	Risk (95% CI)	6	2000 (268 - 3424)	1347 (710 - 1941)
	Events, n	9	7	18
	Persons at risk	9	14	83
	Risk (95% CI)	9	2948 (825 - 4580)	1548 (861 - 2183)
	Events, n	12	7	18
	Persons at risk	12	14	77
	Risk (95% CI)	12	2948 (825 - 4580)	1548 (861 - 2183)

Table 15.19.2.4.3 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=121)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	36	71
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	36	68
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	33	63
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	51
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.2.4.4 Risk (1-KM and 95% CI) for DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	5	16
	Persons at risk	3	75	281
	Risk (95% CI)	3	611 (77 - 1116)	511 (264 - 753)
	Events, n	6	6	21
	Persons at risk	6	73	262
	Risk (95% CI)	6	737 (151 - 1287)	685 (397 - 963)
	Events, n	9	8	22
	Persons at risk	9	67	242
	Risk (95% CI)	9	998 (316 - 1631)	723 (427 - 1010)
	Events, n	12	8	24
	Persons at risk	12	61	222
	Risk (95% CI)	12	998 (316 - 1631)	803 (488 - 1107)
Yes				
	Events, n	3	6	6
	Persons at risk	3	25	103
	Risk (95% CI)	3	1814 (387 - 3029)	521 (106 - 919)
	Events, n	6	6	9
	Persons at risk	6	23	89
	Risk (95% CI)	6	1814 (387 - 3029)	821 (290 - 1322)
	Events, n	9	6	11
	Persons at risk	9	22	78
	Risk (95% CI)	9	1814 (387 - 3029)	1037 (433 - 1602)
	Events, n	12	6	11
	Persons at risk	12	19	64
	Risk (95% CI)	12	1814 (387 - 3029)	1037 (433 - 1602)

Table 15.19.2.4.5 Risk (1-KM and 95% CI) for DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=34)	Pericarditis cohort (N=118)
Vaccinated				
	Events, n	3	<5	<5
	Persons at risk	3	<40	<121
	Risk (95% CI)	3	1000 (0 - 2680)	333 (0 - 955)
	Events, n	6	<5	<5
	Persons at risk	6	<40	<121
	Risk (95% CI)	6	1000 (0 - 2680)	333 (0 - 955)
	Events, n	9	<5	<5
	Persons at risk	9	<40	<121
	Risk (95% CI)	9	1000 (0 - 2680)	333 (0 - 955)
	Events, n	12	<5	<5
	Persons at risk	12	<40	<121
	Risk (95% CI)	12	1000 (0 - 2680)	333 (0 - 955)
Unvaccinated				
	Events, n	3	9	15
	Persons at risk	3	53	235
	Risk (95% CI)	3	1413 (513 - 2228)	565 (283 - 839)
	Events, n	6	10	22
	Persons at risk	6	49	205
	Risk (95% CI)	6	1578 (630 - 2431)	862 (510 - 1201)
	Events, n	9	11	25
	Persons at risk	9	43	178
	Risk (95% CI)	9	1765 (758 - 2663)	1008 (623 - 1378)
	Events, n	12	11	27
	Persons at risk	12	37	146
	Risk (95% CI)	12	1765 (758 - 2663)	1117 (706 - 1510)

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Table 15.19.2.4.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
Unvaccinated				
	Events, n	3	<5	6
	Persons at risk	3	<164	120
	Risk (95% CI)	3	244 (0 - 705)	453 (92 - 800)
	Events, n	6	<5	7
	Persons at risk	6	<164	117
	Risk (95% CI)	6	244 (0 - 705)	534 (141 - 911)
	Events, n	9	<5	7
	Persons at risk	9	<80	114
	Risk (95% CI)	9	501 (0 - 1154)	534 (141 - 911)
	Events, n	12	<5	7
	Persons at risk	12	<80	113
	Risk (95% CI)	12	501 (0 - 1154)	534 (141 - 911)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<49	19
	Risk (95% CI)	3	833 (0 - 2271)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<49	18
	Risk (95% CI)	6	833 (0 - 2271)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<49	17
	Risk (95% CI)	9	833 (0 - 2271)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.2.4.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Persons at risk	12	<49	12
	Risk (95% CI)	12	833 (0 - 2271)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	7
	Persons at risk	3	<71	162
	Risk (95% CI)	3	571 (0 - 1310)	405 (107 - 695)
	Events, n	6	<5	11
	Persons at risk	6	<71	147
	Risk (95% CI)	6	571 (0 - 1310)	650 (271 - 1015)
	Events, n	9	<5	13
	Persons at risk	9	<45	129
	Risk (95% CI)	9	897 (0 - 1818)	789 (366 - 1193)
	Events, n	12	<5	15
	Persons at risk	12	<45	113
	Risk (95% CI)	12	897 (0 - 1818)	938 (471 - 1383)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

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Table 15.19.2.4.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	7	8
	Persons at risk	3	14	56
	Risk (95% CI)	3	3239 (940 - 4954)	1116 (355 - 1817)
	Events, n	6	8	11
	Persons at risk	6	12	44
	Risk (95% CI)	6	3759 (1300 - 5522)	1640 (694 - 2489)
	Events, n	9	8	12
	Persons at risk	9	11	38
	Risk (95% CI)	9	3759 (1300 - 5522)	1844 (826 - 2749)
	Events, n	12	8	12
	Persons at risk	12	9	27
	Risk (95% CI)	12	3759 (1300 - 5522)	1844 (826 - 2749)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	0	<32
	Risk (95% CI)	3	NA (NA - NA)	1250 (0 - 3266)
	Events, n	6	0	<5
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	1250 (0 - 3266)

Table 15.19.2.4.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Events, n	9	0	<5
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.2.5.1 Risk (1-KM and 95% CI) for DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<32)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<466	249
	Risk (95% CI)	3	86 (0 - 253)	0 (0 - 0)
	Events, n	6	<5	<5
	Persons at risk	6	<466	<976
	Risk (95% CI)	6	86 (0 - 253)	41 (0 - 120)
	Events, n	9	<5	<5
	Persons at risk	9	<466	<976
	Risk (95% CI)	9	86 (0 - 253)	41 (0 - 120)
	Events, n	12	<5	<5
	Persons at risk	12	<466	<976
	Risk (95% CI)	12	86 (0 - 253)	41 (0 - 120)

Table 15.19.2.5.2 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N<466)	Pericarditis cohort (N<976)
Male				
	Events, n	3	25	36
	Persons at risk	3	364	981
	Risk (95% CI)	3	618 (380 - 850)	344 (233 - 454)
	Events, n	6	30	51
	Persons at risk	6	309	922
	Risk (95% CI)	6	755 (491 - 1011)	495 (362 - 627)
	Events, n	9	32	58
	Persons at risk	9	252	875
	Risk (95% CI)	9	818 (541 - 1087)	569 (426 - 710)
	Events, n	12	34	68
	Persons at risk	12	228	821
	Risk (95% CI)	12	895 (600 - 1181)	679 (522 - 834)
Female				
	Events, n	3	17	33
	Persons at risk	3	240	534
	Risk (95% CI)	3	651 (347 - 945)	569 (378 - 755)
	Events, n	6	21	39
	Persons at risk	6	203	503
	Risk (95% CI)	6	812 (473 - 1140)	677 (470 - 880)
	Events, n	9	24	45
	Persons at risk	9	152	473
	Risk (95% CI)	9	965 (587 - 1327)	791 (566 - 1010)
	Events, n	12	27	48
	Persons at risk	12	135	443
	Risk (95% CI)	12	1154 (724 - 1563)	850 (617 - 1078)

Table 15.19.2.5.3 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N=591)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	86	196
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	73	188
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	59	181
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	55	175
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<96	53
	Risk (95% CI)	3	417 (0 - 1184)	0 (0 - 0)
	Events, n	6	<5	<5
	Persons at risk	6	<96	<205
	Risk (95% CI)	6	417 (0 - 1184)	196 (0 - 569)
	Events, n	9	<5	<5
	Persons at risk	9	<96	<205
	Risk (95% CI)	9	417 (0 - 1184)	196 (0 - 569)
	Events, n	12	<5	<5
	Persons at risk	12	<96	<205
	Risk (95% CI)	12	417 (0 - 1184)	196 (0 - 569)

Table 15.19.2.5.4 Risk (1-KM and 95% CI) for DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N<96)	Pericarditis cohort (N<205)
No				
	Events, n	3	23	50
	Persons at risk	3	322	1098
	Risk (95% CI)	3	649 (389 - 902)	428 (311 - 543)
	Events, n	6	28	64
	Persons at risk	6	282	1053
	Risk (95% CI)	6	804 (513 - 1086)	552 (420 - 683)
	Events, n	9	33	75
	Persons at risk	9	235	1010
	Risk (95% CI)	9	976 (653 - 1289)	652 (508 - 794)
	Events, n	12	37	86
	Persons at risk	12	214	964
	Risk (95% CI)	12	1136 (780 - 1478)	755 (600 - 908)
Yes				
	Events, n	3	19	19
	Persons at risk	3	282	417
	Risk (95% CI)	3	609 (340 - 871)	414 (230 - 595)
	Events, n	6	23	26
	Persons at risk	6	230	372
	Risk (95% CI)	6	745 (447 - 1034)	581 (361 - 795)
	Events, n	9	23	28
	Persons at risk	9	169	338
	Risk (95% CI)	9	745 (447 - 1034)	635 (404 - 860)
	Events, n	12	24	30
	Persons at risk	12	149	300
	Risk (95% CI)	12	805 (486 - 1114)	693 (449 - 930)

Table 15.19.2.5.5 Risk (1-KM and 95% CI) for DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=316)	Pericarditis cohort (N=477)
Vaccinated				
	Events, n	3	0	6
	Persons at risk	3	27	127
	Risk (95% CI)	3	0 (0 - 0)	451 (92 - 797)
	Events, n	6	0	7
	Persons at risk	6	27	125
	Risk (95% CI)	6	0 (0 - 0)	526 (139 - 898)
	Events, n	9	<5	8
	Persons at risk	9	<109	122
	Risk (95% CI)	9	370 (0 - 1057)	603 (189 - 999)
	Events, n	12	<5	9
	Persons at risk	12	<54	120
	Risk (95% CI)	12	741 (0 - 1678)	680 (241 - 1100)
Unvaccinated				
	Events, n	3	24	42
	Persons at risk	3	313	658
	Risk (95% CI)	3	688 (419 - 950)	573 (403 - 740)
	Events, n	6	30	51
	Persons at risk	6	253	593
	Risk (95% CI)	6	876 (571 - 1171)	708 (518 - 894)
	Events, n	9	33	57
	Persons at risk	9	185	536
	Risk (95% CI)	9	997 (665 - 1317)	806 (602 - 1005)
	Events, n	12	36	64
	Persons at risk	12	153	473
	Risk (95% CI)	12	1159 (783 - 1520)	932 (710 - 1149)

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Table 15.19.2.5.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
Unvaccinated				
	Events, n	3	18	21
	Persons at risk	3	264	730
	Risk (95% CI)	3	622 (340 - 897)	276 (159 - 392)
	Events, n	6	21	32
	Persons at risk	6	232	707
	Risk (95% CI)	6	735 (427 - 1033)	424 (279 - 567)
	Events, n	9	22	38
	Persons at risk	9	193	690
	Risk (95% CI)	9	776 (459 - 1083)	506 (348 - 661)
	Events, n	12	23	43
	Persons at risk	12	185	671
	Risk (95% CI)	12	825 (494 - 1145)	575 (407 - 741)
Received dose 1 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	7	<88
	Risk (95% CI)	3	0 (0 - 0)	455 (0 - 1051)
	Events, n	6	0	<5
	Persons at risk	6	7	<88
	Risk (95% CI)	6	0 (0 - 0)	455 (0 - 1051)
	Events, n	9	<5	<5
	Persons at risk	9	<28	<59
	Risk (95% CI)	9	1429 (0 - 3666)	682 (0 - 1398)
	Events, n	12	<5	<5
	Persons at risk	12	<28	<45
	Risk (95% CI)	12	1429 (0 - 3666)	909 (19 - 1720)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<188	61
	Risk (95% CI)	3	213 (0 - 617)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<92	59
	Risk (95% CI)	6	435 (0 - 1008)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<92	58
	Risk (95% CI)	9	435 (0 - 1008)	0 (0 - 0)
	Events, n	12	<5	0

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Table 15.19.2.5.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Persons at risk	12	<92	57
	Risk (95% CI)	12	435 (0 - 1008)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	13	<72
	Risk (95% CI)	3	0 (0 - 0)	556 (0 - 1275)
	Events, n	6	0	<5
	Persons at risk	6	13	<72
	Risk (95% CI)	6	0 (0 - 0)	556 (0 - 1275)
	Events, n	9	0	<5
	Persons at risk	9	13	<72
	Risk (95% CI)	9	0 (0 - 0)	556 (0 - 1275)
	Events, n	12	<5	<5
	Persons at risk	12	<53	<72
	Risk (95% CI)	12	769 (0 - 2110)	556 (0 - 1275)
Received dose 2, 15 or more days ago				
	Events, n	3	10	19
	Persons at risk	3	199	485
	Risk (95% CI)	3	457 (176 - 730)	364 (202 - 524)
	Events, n	6	13	25
	Persons at risk	6	166	454
	Risk (95% CI)	6	612 (283 - 930)	488 (299 - 672)
	Events, n	9	15	28
	Persons at risk	9	125	426
	Risk (95% CI)	9	734 (366 - 1088)	552 (351 - 748)
	Events, n	12	16	34
	Persons at risk	12	105	391
	Risk (95% CI)	12	821 (417 - 1208)	689 (462 - 911)
Received dose 3 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	0	<15
	Risk (95% CI)	3	NA (NA - NA)	2857 (0 - 5529)
	Events, n	6	0	<5
	Persons at risk	6	0	<15
	Risk (95% CI)	6	NA (NA - NA)	2857 (0 - 5529)
	Events, n	9	0	<5
	Persons at risk	9	0	<5

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Table 15.19.2.5.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Risk (95% CI)	9	NA (NA - NA)	2857 (0 - 5529)
	Events, n	12	0	<5
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	2857 (0 - 5529)
Received dose 3, 15 or more days ago				
	Events, n	3	7	14
	Persons at risk	3	58	121
	Risk (95% CI)	3	1050 (283 - 1756)	1006 (492 - 1493)
	Events, n	6	8	18
	Persons at risk	6	51	112
	Risk (95% CI)	6	1207 (386 - 1958)	1306 (724 - 1851)
	Events, n	9	9	21
	Persons at risk	9	38	93
	Risk (95% CI)	9	1407 (503 - 2224)	1559 (921 - 2153)
	Events, n	12	11	22
	Persons at risk	12	27	67
	Risk (95% CI)	12	1913 (783 - 2904)	1651 (992 - 2262)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	6	9
	Persons at risk	3	19	34
	Risk (95% CI)	3	2400 (527 - 3903)	1779 (642 - 2779)
	Events, n	6	7	9
	Persons at risk	6	5	10
	Risk (95% CI)	6	2847 (813 - 4431)	1779 (642 - 2779)

Table 15.19.2.5.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Events, n	9	7	9
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	1779 (642 - 2779)
	Events, n	12	7	9
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.2.6.1 Risk (1-KM and 95% CI) for DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=61)
15-30				
	Events, n	3	<5	<5
	Persons at risk	3	<690	<2500
	Risk (95% CI)	3	58 (0 - 138)	16 (0 - 46)
	Events, n	6	<5	<5
	Persons at risk	6	<690	<2500
	Risk (95% CI)	6	58 (0 - 138)	16 (0 - 46)
	Events, n	9	<5	<5
	Persons at risk	9	<690	<2500
	Risk (95% CI)	9	58 (0 - 138)	16 (0 - 46)
	Events, n	12	<5	<5
	Persons at risk	12	<690	<2500
	Risk (95% CI)	12	58 (0 - 138)	16 (0 - 46)

Table 15.19.2.6.2 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N<690)	Pericarditis cohort (N<2500)
Male				
	Events, n	3	8	8
	Persons at risk	3	501	1128
	Risk (95% CI)	3	140 (43 - 236)	66 (20 - 112)
	Events, n	6	9	10
	Persons at risk	6	440	977
	Risk (95% CI)	6	161 (56 - 264)	84 (32 - 136)
	Events, n	9	9	15
	Persons at risk	9	384	847
	Risk (95% CI)	9	161 (56 - 264)	138 (68 - 207)
	Events, n	12	12	16
	Persons at risk	12	322	744
	Risk (95% CI)	12	247 (104 - 388)	149 (76 - 223)
Female				
	Events, n	3	<5	<5
	Persons at risk	3	<1112	<728
	Risk (95% CI)	3	36 (0 - 106)	55 (0 - 118)
	Events, n	6	<5	6
	Persons at risk	6	<507	442
	Risk (95% CI)	6	79 (0 - 187)	118 (23 - 211)
	Events, n	9	<5	8
	Persons at risk	9	<507	384
	Risk (95% CI)	9	79 (0 - 187)	166 (51 - 281)
	Events, n	12	<5	8
	Persons at risk	12	<507	341
	Risk (95% CI)	12	79 (0 - 187)	166 (51 - 281)

Table 15.19.2.6.3 Risk (1-KM and 95% CI) for DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N<1112)	Pericarditis cohort (N<728)
Male, 15-30 years				
	Events, n	3	<5	<5
	Persons at risk	3	<564	<1905
	Risk (95% CI)	3	71 (0 - 169)	21 (0 - 61)
	Events, n	6	<5	<5
	Persons at risk	6	<564	<1905
	Risk (95% CI)	6	71 (0 - 169)	21 (0 - 61)
	Events, n	9	<5	<5
	Persons at risk	9	<564	<1905
	Risk (95% CI)	9	71 (0 - 169)	21 (0 - 61)
	Events, n	12	<5	<5
	Persons at risk	12	<564	<1905
	Risk (95% CI)	12	71 (0 - 169)	21 (0 - 61)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	60	142
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	49	129
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	41	108
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	95
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.2.6.4 Risk (1-KM and 95% CI) for DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N=64)	Pericarditis cohort (N=159)
No				
	Events, n	3	5	9
	Persons at risk	3	525	1231
	Risk (95% CI)	3	85 (10 - 158)	69 (24 - 114)
	Events, n	6	6	12
	Persons at risk	6	465	1096
	Risk (95% CI)	6	104 (21 - 187)	94 (41 - 146)
	Events, n	9	6	19
	Persons at risk	9	409	971
	Risk (95% CI)	9	104 (21 - 187)	160 (88 - 232)
	Events, n	12	8	20
	Persons at risk	12	358	874
	Risk (95% CI)	12	158 (46 - 269)	170 (96 - 245)
Yes				
	Events, n	3	<5	<5
	Persons at risk	3	<260	<910
	Risk (95% CI)	3	154 (3 - 304)	44 (0 - 105)
	Events, n	6	5	<5
	Persons at risk	6	194	<400
	Risk (95% CI)	6	201 (24 - 375)	100 (1 - 197)
	Events, n	9	5	<5
	Persons at risk	9	157	<400
	Risk (95% CI)	9	201 (24 - 375)	100 (1 - 197)
	Events, n	12	6	<5
	Persons at risk	12	124	<400
	Risk (95% CI)	12	270 (48 - 488)	100 (1 - 197)

Table 15.19.2.6.5 Risk (1-KM and 95% CI) for DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N<910)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	59	98
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	58	96
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	56	96
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<212	93
	Risk (95% CI)	12	189 (0 - 548)	0 (0 - 0)
Unvaccinated				
	Events, n	3	5	7
	Persons at risk	3	393	848
	Risk (95% CI)	3	113 (14 - 211)	77 (20 - 133)
	Events, n	6	7	12
	Persons at risk	6	321	700
	Risk (95% CI)	6	168 (43 - 292)	139 (60 - 217)
	Events, n	9	7	19
	Persons at risk	9	255	560
	Risk (95% CI)	9	168 (43 - 292)	247 (135 - 358)
	Events, n	12	8	19
	Persons at risk	12	201	456
	Risk (95% CI)	12	214 (60 - 365)	247 (135 - 358)

Table 15.19.2.6.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
Unvaccinated				
	Events, n	3	<5	<5
	Persons at risk	3	<345	<741
	Risk (95% CI)	3	116 (2 - 228)	54 (1 - 107)
	Events, n	6	<5	<5
	Persons at risk	6	<345	<741
	Risk (95% CI)	6	116 (2 - 228)	54 (1 - 107)
	Events, n	9	<5	<5
	Persons at risk	9	<345	<741
	Risk (95% CI)	9	116 (2 - 228)	54 (1 - 107)
	Events, n	12	5	5
	Persons at risk	12	229	536
	Risk (95% CI)	12	157 (18 - 294)	71 (8 - 134)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	17	27
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	26
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	17	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	17	25
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<334	<702
	Risk (95% CI)	3	120 (0 - 352)	57 (0 - 169)
	Events, n	6	<5	<5
	Persons at risk	6	<154	<320
	Risk (95% CI)	6	260 (0 - 609)	125 (0 - 297)
	Events, n	9	<5	<5
	Persons at risk	9	<154	<198
	Risk (95% CI)	9	260 (0 - 609)	203 (0 - 431)
	Events, n	12	<5	<5

Table 15.19.2.6.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Persons at risk	12	<154	<198
	Risk (95% CI)	12	260 (0 - 609)	203 (0 - 431)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	23	24
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	23	24
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	22	24
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	21	23
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<389	<770
	Risk (95% CI)	3	103 (0 - 243)	52 (0 - 123)
	Events, n	6	<5	<5
	Persons at risk	6	<389	<371
	Risk (95% CI)	6	103 (0 - 243)	108 (2 - 214)
	Events, n	9	<5	8
	Persons at risk	9	<389	279
	Risk (95% CI)	9	103 (0 - 243)	239 (73 - 402)
	Events, n	12	<5	8
	Persons at risk	12	<389	247
	Risk (95% CI)	12	103 (0 - 243)	239 (73 - 402)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	6	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	6	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	5	9

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Table 15.19.2.6.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	2500 (0 - 5741)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<334	<488
	Risk (95% CI)	3	120 (0 - 284)	82 (0 - 175)
	Events, n	6	<5	5
	Persons at risk	6	<334	258
	Risk (95% CI)	6	120 (0 - 284)	144 (18 - 269)
	Events, n	9	<5	7
	Persons at risk	9	<334	193
	Risk (95% CI)	9	120 (0 - 284)	225 (56 - 391)
	Events, n	12	<5	7
	Persons at risk	12	<138	137
	Risk (95% CI)	12	290 (0 - 652)	225 (56 - 391)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	8	<104
	Risk (95% CI)	3	0 (0 - 0)	385 (0 - 1096)
	Events, n	6	<5	<5
	Persons at risk	6	<5	<104
	Risk (95% CI)	6	1667 (0 - 4173)	385 (0 - 1096)

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Table 15.19.2.6.6 Risk (1-KM and 95% CI) for DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Events, n	9	<5	<5
	Persons at risk	9	<5	<104
	Risk (95% CI)	9	1667 (0 - 4173)	385 (0 - 1096)
	Events, n	12	<5	<5
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	1667 (0 - 4173)	385 (0 - 1096)

Table 15.19.4.1.1 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N<24)	Pericarditis cohort (N<104)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.4.1.2 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.4.1.3 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.4.1.4 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

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Table 15.19.4.1.5 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.4.1.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.4.1.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

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Table 15.19.4.1.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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Table 15.19.4.1.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.4.2.1 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	127	22
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	118	21
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	108	19
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	96	17
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.2.2 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N=135)	Pericarditis cohort (N=23)
Male				
	Events, n	3	0	0
	Persons at risk	3	414	64
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	386	63
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	347	57
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	320	47
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	204	30
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	186	28
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	171	27
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	157	26
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.2.3 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N=217)	Pericarditis cohort (N=32)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	86	17
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	80	17
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	73	15
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	66	13
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	41	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	35	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.2.4 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N=42)	Pericarditis cohort (N=5)
No				
	Events, n	3	0	0
	Persons at risk	3	517	81
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	485	79
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	445	74
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	415	65
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	101	13
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	87	12
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	73	10
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	62	8
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.2.5 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=121)	Pericarditis cohort (N=15)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	36	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	35	5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	235	28
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	212	27
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	182	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	162	21
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.2.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	347	61
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	325	59
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	302	53
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	282	47
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	81	10
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	77	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	69	10
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.4.2.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Persons at risk	12	63	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	129	15
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	114	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	101	13
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	93	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

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Table 15.19.4.2.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	30	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	27	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	18	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.4.2.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.4.3.1 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N=5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	186	261
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	159	233
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	136	205
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	113	176
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.3.2 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N=204)	Pericarditis cohort (N=289)
Male				
	Events, n	3	0	0
	Persons at risk	3	480	1185
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	414	1041
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	360	894
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	313	748
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	224	559
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	202	479
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	176	424
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	148	360
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.3.3 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=626)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	154	203
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	130	185
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	111	162
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	94	139
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	32	58
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	29	48
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	25	43
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	19	37
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.3.4 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N=34)	Pericarditis cohort (N=61)
No				
	Events, n	3	0	0
	Persons at risk	3	607	1586
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	542	1401
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	482	1240
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	429	1077
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	97	158
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	74	119
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	54	78
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	32	31
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.3.5 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N=204)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	62	186
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	57	178
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	56	176
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	54	167
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	396	1041
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	327	841
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	258	661
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	197	488
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.4.3.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	246	517
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	232	501
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	222	481
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	210	453
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	18	49
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	49
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	16	49
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	16	48
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	61	129
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	57	120
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	50	112
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.4.3.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Persons at risk	12	44	104
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	59
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	58
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	58
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	58
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	207	494
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	189	458
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	169	419
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	151	377
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	23
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	22
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	21

Table 15.19.4.3.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	11	18
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	134	427
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	95	301
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	53	172
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	17	50
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	10	41
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.3.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Events, n	9	0	0
	Persons at risk	9	<5	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.4.4.1 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N=24)	Pericarditis cohort (N=75)
15-30				
	Events, n	3	0	0
	Persons at risk	3	37	87
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	37	82
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	75
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	62
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.4.2 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N=39)	Pericarditis cohort (N=94)
Male				
	Events, n	3	0	0
	Persons at risk	3	81	282
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	78	257
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	75	237
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	66	209
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	19	102
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	18	94
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	14	83
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	14	77
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.4.3 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=121)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	36	71
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	36	68
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	33	63
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	51
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.4.4.4 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	0	0
	Persons at risk	3	75	281
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	73	262
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	67	242
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	61	222
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	25	103
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	23	89
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	22	78
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	19	64
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.4.5 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=34)	Pericarditis cohort (N=118)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	9	29
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	29
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	9	28
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	27
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	53	235
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	49	205
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	43	178
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	37	146
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.4.4.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	38	120
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	117
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	37	114
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	34	113
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	9	19
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	18
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	8	17
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.4.4.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Persons at risk	12	8	12
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	33	162
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	31	147
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	27	129
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	23	113
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.4.4.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	14	56
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	44
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	11	38
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	27
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)

Table 15.19.4.4.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.4.5.1 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=11)
15-30				
	Events, n	3	0	0
	Persons at risk	3	109	249
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	94	236
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	74	225
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	68	215
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.5.2 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N=271)
Male				
	Events, n	3	0	0
	Persons at risk	3	364	981
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	309	922
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	252	875
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	228	821
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	240	534
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	203	503
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	152	473
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	135	443
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.5.3 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N=591)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	86	196
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	73	188
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	59	181
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	55	175
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	23	53
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	21	48
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	15	44
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	40
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.5.4 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N=24)	Pericarditis cohort (N=57)
No				
	Events, n	3	0	0
	Persons at risk	3	322	1098
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	282	1053
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	235	1010
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	214	964
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	282	417
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	230	372
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	169	338
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	149	300
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.5.5 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=316)	Pericarditis cohort (N=477)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	27	127
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	27	125
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	26	122
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	25	120
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	313	658
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	253	593
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	185	536
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	153	473
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.4.5.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	264	730
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	232	707
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	193	690
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	185	671
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	7	42
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	7	42
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	6	41
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	6	40
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	44	61
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	59
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	29	58
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.4.5.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Persons at risk	12	28	57
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	34
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	34
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	34
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	199	485
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	166	454
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	125	426
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	105	391
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5

Table 15.19.4.5.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	58	121
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	51	112
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	38	93
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	27	67
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	19	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	5	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.5.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.4.6.1 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=61)
15-30				
	Events, n	3	0	0
	Persons at risk	3	311	555
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	269	490
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	226	431
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	189	366
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.6.2 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N=356)	Pericarditis cohort (N=644)
Male				
	Events, n	3	0	0
	Persons at risk	3	501	1128
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	440	977
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	384	847
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	322	744
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	253	500
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	219	442
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	182	384
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	160	341
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.6.3 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N=281)	Pericarditis cohort (N=548)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	251	413
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	220	361
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	185	323
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	156	271
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	60	142
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	49	129
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	41	108
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	95
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.6.4 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N=64)	Pericarditis cohort (N=159)
No				
	Events, n	3	0	0
	Persons at risk	3	525	1231
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	465	1096
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	409	971
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	358	874
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	229	397
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	194	323
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	157	260
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	124	211
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.6.5 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N=454)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	59	98
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	58	96
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	56	96
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	52	93
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	393	848
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	321	700
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	255	560
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	201	456
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.4.6.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	302	682
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	280	623
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	255	575
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	229	536
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	17	27
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	26
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	17	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	17	25
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	74	160
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	65	144
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	59	118
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.4.6.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Persons at risk	12	50	105
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	23	24
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	23	24
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	22	24
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	21	23
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	175	372
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	151	321
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	127	279
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	114	247
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	6	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	6	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	5	9

Table 15.19.4.6.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	148	329
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	113	258
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	80	193
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	47	137
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	8	25
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.4.6.6 Risk (1-KM and 95% CI) for SUDDEN CARDIAC DEATH at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Events, n	9	0	0
	Persons at risk	9	<5	7
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.5.1.1 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N=10)	Pericarditis cohort (N=30)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.5.1.2 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.5.1.3 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

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Table 15.19.5.1.4 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.5.1.5 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.5.1.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.5.1.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

Table 15.19.5.1.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.5.1.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.5.2.1 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	<5	<5
	Persons at risk	3	<541	<46
	Risk (95% CI)	3	74 (0 - 218)	870 (0 - 1951)
	Events, n	6	<5	<5
	Persons at risk	6	<541	<46
	Risk (95% CI)	6	74 (0 - 218)	870 (0 - 1951)
	Events, n	9	<5	<5
	Persons at risk	9	<541	<46
	Risk (95% CI)	9	74 (0 - 218)	870 (0 - 1951)
	Events, n	12	<5	<5
	Persons at risk	12	<541	<46
	Risk (95% CI)	12	74 (0 - 218)	870 (0 - 1951)

Table 15.19.5.2.2 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N<541)	Pericarditis cohort (N<46)
Male				
	Events, n	3	16	9
	Persons at risk	3	403	56
	Risk (95% CI)	3	352 (181 - 520)	1295 (468 - 2050)
	Events, n	6	16	9
	Persons at risk	6	375	56
	Risk (95% CI)	6	352 (181 - 520)	1295 (468 - 2050)
	Events, n	9	17	10
	Persons at risk	9	336	51
	Risk (95% CI)	9	378 (200 - 554)	1456 (578 - 2253)
	Events, n	12	17	10
	Persons at risk	12	309	42
	Risk (95% CI)	12	378 (200 - 554)	1456 (578 - 2253)
Female				
	Events, n	3	13	<5
	Persons at risk	3	191	<32
	Risk (95% CI)	3	600 (278 - 911)	1250 (26 - 2324)
	Events, n	6	13	<5
	Persons at risk	6	173	<32
	Risk (95% CI)	6	600 (278 - 911)	1250 (26 - 2324)
	Events, n	9	14	<5
	Persons at risk	9	159	<32
	Risk (95% CI)	9	655 (317 - 981)	1250 (26 - 2324)
	Events, n	12	14	<5
	Persons at risk	12	146	<32
	Risk (95% CI)	12	655 (317 - 981)	1250 (26 - 2324)

Table 15.19.5.2.3 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N=217)	Pericarditis cohort (N=32)
Male, 15-30 years				
	Events, n	3	0	<5
	Persons at risk	3	86	<72
	Risk (95% CI)	3	0 (0 - 0)	556 (0 - 1557)
	Events, n	6	0	<5
	Persons at risk	6	80	<72
	Risk (95% CI)	6	0 (0 - 0)	556 (0 - 1557)
	Events, n	9	0	<5
	Persons at risk	9	73	<72
	Risk (95% CI)	9	0 (0 - 0)	556 (0 - 1557)
	Events, n	12	0	<5
	Persons at risk	12	66	<72
	Risk (95% CI)	12	0 (0 - 0)	556 (0 - 1557)
Female, 15-30 years				
	Events, n	3	<5	<5
	Persons at risk	3	<169	<5
	Risk (95% CI)	3	238 (0 - 688)	2000 (0 - 4839)
	Events, n	6	<5	<5
	Persons at risk	6	<169	<5
	Risk (95% CI)	6	238 (0 - 688)	2000 (0 - 4839)
	Events, n	9	<5	<5
	Persons at risk	9	<169	<5
	Risk (95% CI)	9	238 (0 - 688)	2000 (0 - 4839)
	Events, n	12	<5	<5
	Persons at risk	12	<169	<5
	Risk (95% CI)	12	238 (0 - 688)	2000 (0 - 4839)

Table 15.19.5.2.4 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N<169)	Pericarditis cohort (N<20)
No				
	Events, n	3	24	10
	Persons at risk	3	495	72
	Risk (95% CI)	3	436 (264 - 605)	1158 (456 - 1809)
	Events, n	6	24	10
	Persons at risk	6	463	71
	Risk (95% CI)	6	436 (264 - 605)	1158 (456 - 1809)
	Events, n	9	26	11
	Persons at risk	9	424	66
	Risk (95% CI)	9	478 (297 - 656)	1285 (545 - 1966)
	Events, n	12	26	11
	Persons at risk	12	394	57
	Risk (95% CI)	12	478 (297 - 656)	1285 (545 - 1966)
Yes				
	Events, n	3	5	<5
	Persons at risk	3	99	<20
	Risk (95% CI)	3	413 (52 - 761)	2000 (0 - 3788)
	Events, n	6	5	<5
	Persons at risk	6	85	<20
	Risk (95% CI)	6	413 (52 - 761)	2000 (0 - 3788)
	Events, n	9	5	<5
	Persons at risk	9	71	<20
	Risk (95% CI)	9	413 (52 - 761)	2000 (0 - 3788)
	Events, n	12	5	<5
	Persons at risk	12	61	<20
	Risk (95% CI)	12	413 (52 - 761)	2000 (0 - 3788)

Table 15.19.5.2.5 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=121)	Pericarditis cohort (N<20)
Vaccinated				
	Events, n	3	<5	<5
	Persons at risk	3	<144	<5
	Risk (95% CI)	3	278 (0 - 800)	2000 (0 - 4839)
	Events, n	6	<5	<5
	Persons at risk	6	<144	<5
	Risk (95% CI)	6	278 (0 - 800)	2000 (0 - 4839)
	Events, n	9	<5	<5
	Persons at risk	9	<144	<5
	Risk (95% CI)	9	278 (0 - 800)	2000 (0 - 4839)
	Events, n	12	<5	<5
	Persons at risk	12	<144	<5
	Risk (95% CI)	12	278 (0 - 800)	2000 (0 - 4839)
Unvaccinated				
	Events, n	3	8	<5
	Persons at risk	3	228	<124
	Risk (95% CI)	3	301 (93 - 504)	323 (0 - 925)
	Events, n	6	8	<5
	Persons at risk	6	205	<124
	Risk (95% CI)	6	301 (93 - 504)	323 (0 - 925)
	Events, n	9	9	<5
	Persons at risk	9	175	<124
	Risk (95% CI)	9	349 (121 - 572)	323 (0 - 925)
	Events, n	12	9	<5
	Persons at risk	12	156	<124
	Risk (95% CI)	12	349 (121 - 572)	323 (0 - 925)

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Table 15.19.5.2.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N<124)
Unvaccinated				
	Events, n	3	20	11
	Persons at risk	3	331	51
	Risk (95% CI)	3	541 (308 - 769)	1675 (721 - 2532)
	Events, n	6	20	11
	Persons at risk	6	309	50
	Risk (95% CI)	6	541 (308 - 769)	1675 (721 - 2532)
	Events, n	9	21	12
	Persons at risk	9	287	45
	Risk (95% CI)	9	573 (332 - 808)	1849 (845 - 2743)
	Events, n	12	21	12
	Persons at risk	12	267	40
	Risk (95% CI)	12	573 (332 - 808)	1849 (845 - 2743)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<118	10
	Risk (95% CI)	3	341 (0 - 713)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<118	10
	Risk (95% CI)	6	341 (0 - 713)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<84	10
	Risk (95% CI)	9	477 (8 - 924)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.5.2.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N<124)
	Persons at risk	12	<84	9
	Risk (95% CI)	12	477 (8 - 924)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	6	<5
	Persons at risk	3	124	<64
	Risk (95% CI)	3	417 (85 - 738)	625 (0 - 1739)
	Events, n	6	6	<5
	Persons at risk	6	109	<64
	Risk (95% CI)	6	417 (85 - 738)	625 (0 - 1739)
	Events, n	9	6	<5
	Persons at risk	9	96	<64
	Risk (95% CI)	9	417 (85 - 738)	625 (0 - 1739)
	Events, n	12	6	<5
	Persons at risk	12	89	<64
	Risk (95% CI)	12	417 (85 - 738)	625 (0 - 1739)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.5.2.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N<124)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	30	<5
	Risk (95% CI)	3	0 (0 - 0)	2500 (0 - 5741)
	Events, n	6	0	<5
	Persons at risk	6	27	<5
	Risk (95% CI)	6	0 (0 - 0)	2500 (0 - 5741)
	Events, n	9	0	<5
	Persons at risk	9	18	<5
	Risk (95% CI)	9	0 (0 - 0)	2500 (0 - 5741)
	Events, n	12	0	<5
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	2500 (0 - 5741)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.5.2.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N<124)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.5.3.1 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N=5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	24	6
	Persons at risk	3	164	257
	Risk (95% CI)	3	1179 (724 - 1611)	214 (43 - 381)
	Events, n	6	24	6
	Persons at risk	6	139	229
	Risk (95% CI)	6	1179 (724 - 1611)	214 (43 - 381)
	Events, n	9	25	7
	Persons at risk	9	118	200
	Risk (95% CI)	9	1249 (776 - 1698)	257 (67 - 444)
	Events, n	12	25	8
	Persons at risk	12	98	172
	Risk (95% CI)	12	1249 (776 - 1698)	307 (93 - 515)

Table 15.19.5.3.2 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N=204)	Pericarditis cohort (N=289)
Male				
	Events, n	3	86	114
	Persons at risk	3	408	1082
	Risk (95% CI)	3	1590 (1276 - 1893)	881 (725 - 1034)
	Events, n	6	92	131
	Persons at risk	6	346	938
	Risk (95% CI)	6	1724 (1396 - 2039)	1033 (864 - 1200)
	Events, n	9	96	137
	Persons at risk	9	300	801
	Risk (95% CI)	9	1823 (1484 - 2149)	1096 (920 - 1269)
	Events, n	12	97	141
	Persons at risk	12	259	674
	Risk (95% CI)	12	1855 (1511 - 2184)	1144 (963 - 1322)
Female				
	Events, n	3	43	63
	Persons at risk	3	192	504
	Risk (95% CI)	3	1629 (1171 - 2064)	1020 (778 - 1256)
	Events, n	6	44	67
	Persons at risk	6	172	432
	Risk (95% CI)	6	1673 (1209 - 2113)	1095 (844 - 1340)
	Events, n	9	49	71
	Persons at risk	9	149	378
	Risk (95% CI)	9	1926 (1421 - 2401)	1181 (918 - 1437)
	Events, n	12	51	76
	Persons at risk	12	128	318
	Risk (95% CI)	12	2044 (1518 - 2537)	1310 (1026 - 1584)

Table 15.19.5.3.3 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=626)
Male, 15-30 years				
	Events, n	3	17	5
	Persons at risk	3	139	200
	Risk (95% CI)	3	1002 (539 - 1443)	225 (28 - 419)
	Events, n	6	17	5
	Persons at risk	6	116	182
	Risk (95% CI)	6	1002 (539 - 1443)	225 (28 - 419)
	Events, n	9	18	5
	Persons at risk	9	98	159
	Risk (95% CI)	9	1089 (597 - 1555)	225 (28 - 419)
	Events, n	12	18	6
	Persons at risk	12	81	136
	Risk (95% CI)	12	1089 (597 - 1555)	288 (56 - 515)
Female, 15-30 years				
	Events, n	3	7	<5
	Persons at risk	3	25	<240
	Risk (95% CI)	3	2059 (576 - 3308)	167 (0 - 485)
	Events, n	6	7	<5
	Persons at risk	6	23	<240
	Risk (95% CI)	6	2059 (576 - 3308)	167 (0 - 485)
	Events, n	9	7	<5
	Persons at risk	9	20	<107
	Risk (95% CI)	9	2059 (576 - 3308)	376 (0 - 877)
	Events, n	12	7	<5
	Persons at risk	12	17	<107
	Risk (95% CI)	12	2059 (576 - 3308)	376 (0 - 877)

Table 15.19.5.3.4 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N=34)	Pericarditis cohort (N<240)
No				
	Events, n	3	108	167
	Persons at risk	3	522	1434
	Risk (95% CI)	3	1573 (1296 - 1841)	975 (833 - 1114)
	Events, n	6	114	186
	Persons at risk	6	460	1257
	Risk (95% CI)	6	1675 (1389 - 1951)	1101 (950 - 1250)
	Events, n	9	123	195
	Persons at risk	9	406	1105
	Risk (95% CI)	9	1844 (1542 - 2135)	1169 (1013 - 1323)
	Events, n	12	126	204
	Persons at risk	12	361	964
	Risk (95% CI)	12	1909 (1600 - 2206)	1246 (1083 - 1406)
Yes				
	Events, n	3	21	10
	Persons at risk	3	78	152
	Risk (95% CI)	3	1774 (1056 - 2434)	491 (189 - 783)
	Events, n	6	22	12
	Persons at risk	6	58	113
	Risk (95% CI)	6	1900 (1146 - 2590)	628 (273 - 969)
	Events, n	9	22	13
	Persons at risk	9	43	74
	Risk (95% CI)	9	1900 (1146 - 2590)	723 (323 - 1106)
	Events, n	12	22	13
	Persons at risk	12	26	28
	Risk (95% CI)	12	1900 (1146 - 2590)	723 (323 - 1106)

Table 15.19.5.3.5 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N=204)
Vaccinated				
	Events, n	3	9	12
	Persons at risk	3	54	176
	Risk (95% CI)	3	1364 (495 - 2153)	620 (274 - 954)
	Events, n	6	9	16
	Persons at risk	6	50	164
	Risk (95% CI)	6	1364 (495 - 2153)	838 (436 - 1223)
	Events, n	9	9	17
	Persons at risk	9	50	162
	Risk (95% CI)	9	1364 (495 - 2153)	894 (479 - 1291)
	Events, n	12	9	18
	Persons at risk	12	48	153
	Risk (95% CI)	12	1364 (495 - 2153)	950 (522 - 1359)
Unvaccinated				
	Events, n	3	78	132
	Persons at risk	3	337	923
	Risk (95% CI)	3	1657 (1314 - 1986)	1120 (938 - 1299)
	Events, n	6	85	145
	Persons at risk	6	270	738
	Risk (95% CI)	6	1847 (1482 - 2197)	1259 (1064 - 1450)
	Events, n	9	90	152
	Persons at risk	9	214	570
	Risk (95% CI)	9	2006 (1621 - 2374)	1352 (1147 - 1552)
	Events, n	12	93	158
	Persons at risk	12	165	419
	Risk (95% CI)	12	2138 (1729 - 2527)	1460 (1239 - 1675)

Table 15.19.5.3.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
Unvaccinated				
	Events, n	3	42	33
	Persons at risk	3	209	487
	Risk (95% CI)	3	1568 (1121 - 1993)	611 (407 - 811)
	Events, n	6	42	37
	Persons at risk	6	198	468
	Risk (95% CI)	6	1568 (1121 - 1993)	689 (472 - 901)
	Events, n	9	46	39
	Persons at risk	9	185	447
	Risk (95% CI)	9	1742 (1270 - 2188)	730 (507 - 948)
	Events, n	12	46	41
	Persons at risk	12	174	420
	Risk (95% CI)	12	1742 (1270 - 2188)	773 (543 - 998)
Received dose 1 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<19	<66
	Risk (95% CI)	3	2222 (44 - 3924)	612 (0 - 1260)
	Events, n	6	<5	<5
	Persons at risk	6	<19	<50
	Risk (95% CI)	6	2222 (44 - 3924)	816 (17 - 1552)
	Events, n	9	<5	5
	Persons at risk	9	<19	44
	Risk (95% CI)	9	2222 (44 - 3924)	1020 (132 - 1829)
	Events, n	12	<5	5
	Persons at risk	12	<19	43
	Risk (95% CI)	12	2222 (44 - 3924)	1020 (132 - 1829)
Received dose 1, 15 or more days ago				
	Events, n	3	9	10
	Persons at risk	3	53	121
	Risk (95% CI)	3	1349 (489 - 2131)	752 (292 - 1189)
	Events, n	6	10	10
	Persons at risk	6	48	112
	Risk (95% CI)	6	1518 (604 - 2344)	752 (292 - 1189)
	Events, n	9	11	12
	Persons at risk	9	40	102
	Risk (95% CI)	9	1707 (729 - 2581)	927 (412 - 1415)
	Events, n	12	12	14

Table 15.19.5.3.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Persons at risk	12	36	95
	Risk (95% CI)	12	1931 (868 - 2870)	1111 (541 - 1647)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	59
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	12	<116
	Risk (95% CI)	6	0 (0 - 0)	345 (0 - 803)
	Events, n	9	0	<5
	Persons at risk	9	12	<116
	Risk (95% CI)	9	0 (0 - 0)	345 (0 - 803)
	Events, n	12	0	<5
	Persons at risk	12	12	<116
	Risk (95% CI)	12	0 (0 - 0)	345 (0 - 803)
Received dose 2, 15 or more days ago				
	Events, n	3	35	59
	Persons at risk	3	177	443
	Risk (95% CI)	3	1540 (1057 - 1997)	1117 (844 - 1382)
	Events, n	6	39	66
	Persons at risk	6	156	403
	Risk (95% CI)	6	1741 (1228 - 2225)	1262 (972 - 1542)
	Events, n	9	41	69
	Persons at risk	9	142	365
	Risk (95% CI)	9	1850 (1319 - 2348)	1328 (1030 - 1616)
	Events, n	12	42	72
	Persons at risk	12	128	321
	Risk (95% CI)	12	1912 (1370 - 2419)	1406 (1097 - 1703)
Received dose 3 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<18	<32
	Risk (95% CI)	3	2308 (0 - 4288)	1288 (0 - 2548)
	Events, n	6	<5	<5
	Persons at risk	6	<18	<23
	Risk (95% CI)	6	2308 (0 - 4288)	1746 (31 - 3167)
	Events, n	9	<5	<5
	Persons at risk	9	<18	<23

Table 15.19.5.3.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Risk (95% CI)	9	2308 (0 - 4288)	1746 (31 - 3167)
	Events, n	12	<5	<5
	Persons at risk	12	<18	<23
	Risk (95% CI)	12	2308 (0 - 4288)	1746 (31 - 3167)
Received dose 3, 15 or more days ago				
	Events, n	3	30	61
	Persons at risk	3	113	370
	Risk (95% CI)	3	1758 (1166 - 2311)	1218 (927 - 1501)
	Events, n	6	32	67
	Persons at risk	6	79	260
	Risk (95% CI)	6	1922 (1294 - 2505)	1393 (1073 - 1701)
	Events, n	9	34	69
	Persons at risk	9	45	144
	Risk (95% CI)	9	2146 (1454 - 2782)	1482 (1141 - 1810)
	Events, n	12	35	71
	Persons at risk	12	14	41
	Risk (95% CI)	12	2342 (1555 - 3057)	1617 (1230 - 1987)
Received dose 4 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	<5	<40
	Risk (95% CI)	3	0 (0 - 0)	1000 (0 - 2680)
	Events, n	6	0	<5
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	1000 (0 - 2680)
	Events, n	9	0	<5
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	1000 (0 - 2680)
	Events, n	12	0	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	6	7
	Persons at risk	3	8	35
	Risk (95% CI)	3	2549 (555 - 4122)	1080 (266 - 1827)
	Events, n	6	6	7
	Persons at risk	6	<5	7
	Risk (95% CI)	6	2549 (555 - 4122)	1080 (266 - 1827)

Table 15.19.5.3.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Events, n	9	6	7
	Persons at risk	9	<5	<5
	Risk (95% CI)	9	2549 (555 - 4122)	1080 (266 - 1827)
	Events, n	12	6	7
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.5.4.1 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N=24)	Pericarditis cohort (N=75)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<53	87
	Risk (95% CI)	3	769 (0 - 1569)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<53	82
	Risk (95% CI)	6	769 (0 - 1569)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<53	75
	Risk (95% CI)	9	769 (0 - 1569)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<53	62
	Risk (95% CI)	12	769 (0 - 1569)	0 (0 - 0)

Table 15.19.5.4.2 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N<53)	Pericarditis cohort (N=94)
Male				
	Events, n	3	14	31
	Persons at risk	3	71	257
	Risk (95% CI)	3	1538 (764 - 2248)	997 (658 - 1325)
	Events, n	6	14	31
	Persons at risk	6	69	235
	Risk (95% CI)	6	1538 (764 - 2248)	997 (658 - 1325)
	Events, n	9	15	33
	Persons at risk	9	65	215
	Risk (95% CI)	9	1665 (858 - 2401)	1078 (723 - 1421)
	Events, n	12	15	34
	Persons at risk	12	56	189
	Risk (95% CI)	12	1665 (858 - 2401)	1120 (756 - 1470)
Female				
	Events, n	3	7	24
	Persons at risk	3	14	87
	Risk (95% CI)	3	2800 (806 - 4361)	1997 (1248 - 2681)
	Events, n	6	8	24
	Persons at risk	6	13	81
	Risk (95% CI)	6	3354 (1114 - 5029)	1997 (1248 - 2681)
	Events, n	9	8	24
	Persons at risk	9	11	72
	Risk (95% CI)	9	3354 (1114 - 5029)	1997 (1248 - 2681)
	Events, n	12	8	25
	Persons at risk	12	11	65
	Risk (95% CI)	12	3354 (1114 - 5029)	2108 (1335 - 2813)

Table 15.19.5.4.3 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=121)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<50	71
	Risk (95% CI)	3	811 (0 - 1650)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<50	68
	Risk (95% CI)	6	811 (0 - 1650)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<50	63
	Risk (95% CI)	9	811 (0 - 1650)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<50	51
	Risk (95% CI)	12	811 (0 - 1650)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.5.4.4 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	18	36
	Persons at risk	3	61	255
	Risk (95% CI)	3	2195 (1246 - 3042)	1145 (786 - 1490)
	Events, n	6	19	36
	Persons at risk	6	60	238
	Risk (95% CI)	6	2325 (1352 - 3189)	1145 (786 - 1490)
	Events, n	9	20	38
	Persons at risk	9	55	217
	Risk (95% CI)	9	2460 (1461 - 3342)	1224 (851 - 1583)
	Events, n	12	20	40
	Persons at risk	12	49	198
	Risk (95% CI)	12	2460 (1461 - 3342)	1305 (918 - 1676)
Yes				
	Events, n	3	<5	19
	Persons at risk	3	<46	89
	Risk (95% CI)	3	882 (0 - 1788)	1623 (927 - 2266)
	Events, n	6	<5	19
	Persons at risk	6	<46	78
	Risk (95% CI)	6	882 (0 - 1788)	1623 (927 - 2266)
	Events, n	9	<5	19
	Persons at risk	9	<46	70
	Risk (95% CI)	9	882 (0 - 1788)	1623 (927 - 2266)
	Events, n	12	<5	19
	Persons at risk	12	<46	56
	Risk (95% CI)	12	882 (0 - 1788)	1623 (927 - 2266)

Table 15.19.5.4.5 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<46)	Pericarditis cohort (N=118)
Vaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<40	29
	Risk (95% CI)	3	1000 (0 - 2680)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<40	29
	Risk (95% CI)	6	1000 (0 - 2680)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<40	28
	Risk (95% CI)	9	1000 (0 - 2680)	0 (0 - 0)
	Events, n	12	<5	<5
	Persons at risk	12	<40	<113
	Risk (95% CI)	12	1000 (0 - 2680)	357 (0 - 1021)
Unvaccinated				
	Events, n	3	14	42
	Persons at risk	3	44	205
	Risk (95% CI)	3	2154 (1088 - 3092)	1556 (1112 - 1979)
	Events, n	6	15	42
	Persons at risk	6	41	180
	Risk (95% CI)	6	2345 (1228 - 3320)	1556 (1112 - 1979)
	Events, n	9	15	44
	Persons at risk	9	37	155
	Risk (95% CI)	9	2345 (1228 - 3320)	1660 (1197 - 2099)
	Events, n	12	15	45
	Persons at risk	12	31	125
	Risk (95% CI)	12	2345 (1228 - 3320)	1715 (1241 - 2162)

Table 15.19.5.4.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
Unvaccinated				
	Events, n	3	6	13
	Persons at risk	3	33	110
	Risk (95% CI)	3	1463 (310 - 2480)	987 (463 - 1482)
	Events, n	6	6	13
	Persons at risk	6	33	107
	Risk (95% CI)	6	1463 (310 - 2480)	987 (463 - 1482)
	Events, n	9	7	13
	Persons at risk	9	31	104
	Risk (95% CI)	9	1730 (476 - 2819)	987 (463 - 1482)
	Events, n	12	7	13
	Persons at risk	12	28	103
	Risk (95% CI)	12	1730 (476 - 2819)	987 (463 - 1482)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	<5
	Persons at risk	12	<5	<37
	Risk (95% CI)	12	0 (0 - 0)	1111 (0 - 2944)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	9	19
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	18
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	8	17
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.5.4.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Persons at risk	12	8	12
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	<5	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	3333 (0 - 7005)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	3333 (0 - 7005)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	3333 (0 - 7005)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	3333 (0 - 7005)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	6	24
	Persons at risk	3	28	144
	Risk (95% CI)	3	1714 (367 - 2873)	1377 (850 - 1874)
	Events, n	6	7	24
	Persons at risk	6	26	132
	Risk (95% CI)	6	2033 (564 - 3273)	1377 (850 - 1874)
	Events, n	9	7	26
	Persons at risk	9	23	115
	Risk (95% CI)	9	2033 (564 - 3273)	1519 (961 - 2042)
	Events, n	12	7	27
	Persons at risk	12	19	99
	Risk (95% CI)	12	2033 (564 - 3273)	1593 (1020 - 2130)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.5.4.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	8	18
	Persons at risk	3	10	44
	Risk (95% CI)	3	3636 (1273 - 5360)	2449 (1398 - 3372)
	Events, n	6	8	18
	Persons at risk	6	9	34
	Risk (95% CI)	6	3636 (1273 - 5360)	2449 (1398 - 3372)
	Events, n	9	8	18
	Persons at risk	9	9	29
	Risk (95% CI)	9	3636 (1273 - 5360)	2449 (1398 - 3372)
	Events, n	12	8	18
	Persons at risk	12	7	20
	Risk (95% CI)	12	3636 (1273 - 5360)	2449 (1398 - 3372)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)

Table 15.19.5.4.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.5.5.1 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=11)
15-30				
	Events, n	3	6	6
	Persons at risk	3	103	245
	Risk (95% CI)	3	505 (103 - 891)	222 (45 - 397)
	Events, n	6	6	6
	Persons at risk	6	89	233
	Risk (95% CI)	6	505 (103 - 891)	222 (45 - 397)
	Events, n	9	6	7
	Persons at risk	9	70	221
	Risk (95% CI)	9	505 (103 - 891)	265 (69 - 458)
	Events, n	12	6	7
	Persons at risk	12	65	211
	Risk (95% CI)	12	505 (103 - 891)	265 (69 - 458)

Table 15.19.5.5.2 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N=271)
Male				
	Events, n	3	63	169
	Persons at risk	3	317	835
	Risk (95% CI)	3	1530 (1175 - 1871)	1586 (1364 - 1803)
	Events, n	6	65	177
	Persons at risk	6	267	787
	Risk (95% CI)	6	1584 (1223 - 1930)	1668 (1441 - 1890)
	Events, n	9	66	187
	Persons at risk	9	213	744
	Risk (95% CI)	9	1617 (1251 - 1967)	1777 (1542 - 2005)
	Events, n	12	67	192
	Persons at risk	12	198	707
	Risk (95% CI)	12	1656 (1284 - 2013)	1833 (1594 - 2064)
Female				
	Events, n	3	28	131
	Persons at risk	3	218	431
	Risk (95% CI)	3	1074 (690 - 1442)	2227 (1883 - 2557)
	Events, n	6	30	136
	Persons at risk	6	185	406
	Risk (95% CI)	6	1162 (762 - 1545)	2320 (1970 - 2655)
	Events, n	9	33	142
	Persons at risk	9	134	380
	Risk (95% CI)	9	1324 (888 - 1739)	2435 (2078 - 2777)
	Events, n	12	37	144
	Persons at risk	12	115	358
	Risk (95% CI)	12	1603 (1096 - 2081)	2477 (2116 - 2821)

Table 15.19.5.5.3 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N=591)
Male, 15-30 years				
	Events, n	3	5	5
	Persons at risk	3	81	192
	Risk (95% CI)	3	527 (67 - 967)	235 (29 - 436)
	Events, n	6	5	5
	Persons at risk	6	69	185
	Risk (95% CI)	6	527 (67 - 967)	235 (29 - 436)
	Events, n	9	5	6
	Persons at risk	9	56	177
	Risk (95% CI)	9	527 (67 - 967)	289 (58 - 515)
	Events, n	12	5	6
	Persons at risk	12	53	171
	Risk (95% CI)	12	527 (67 - 967)	289 (58 - 515)
Female, 15-30 years				
	Events, n	3	<5	<5
	Persons at risk	3	<96	<229
	Risk (95% CI)	3	417 (0 - 1184)	175 (0 - 510)
	Events, n	6	<5	<5
	Persons at risk	6	<96	<229
	Risk (95% CI)	6	417 (0 - 1184)	175 (0 - 510)
	Events, n	9	<5	<5
	Persons at risk	9	<96	<229
	Risk (95% CI)	9	417 (0 - 1184)	175 (0 - 510)
	Events, n	12	<5	<5
	Persons at risk	12	<96	<229
	Risk (95% CI)	12	417 (0 - 1184)	175 (0 - 510)

Table 15.19.5.5.4 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N<96)	Pericarditis cohort (N<229)
No				
	Events, n	3	54	210
	Persons at risk	3	279	920
	Risk (95% CI)	3	1507 (1128 - 1870)	1777 (1556 - 1992)
	Events, n	6	55	220
	Persons at risk	6	244	876
	Risk (95% CI)	6	1538 (1155 - 1904)	1868 (1643 - 2088)
	Events, n	9	57	234
	Persons at risk	9	199	832
	Risk (95% CI)	9	1614 (1220 - 1991)	2001 (1768 - 2227)
	Events, n	12	61	239
	Persons at risk	12	181	803
	Risk (95% CI)	12	1790 (1365 - 2193)	2049 (1814 - 2278)
Yes				
	Events, n	3	37	90
	Persons at risk	3	256	346
	Risk (95% CI)	3	1177 (813 - 1526)	1909 (1545 - 2256)
	Events, n	6	40	93
	Persons at risk	6	208	317
	Risk (95% CI)	6	1287 (906 - 1652)	1980 (1610 - 2333)
	Events, n	9	42	95
	Persons at risk	9	148	292
	Risk (95% CI)	9	1374 (977 - 1754)	2031 (1657 - 2389)
	Events, n	12	43	97
	Persons at risk	12	132	262
	Risk (95% CI)	12	1436 (1022 - 1830)	2088 (1707 - 2451)

Table 15.19.5.5.5 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=316)	Pericarditis cohort (N=477)
Vaccinated				
	Events, n	3	<5	20
	Persons at risk	3	<113	109
	Risk (95% CI)	3	357 (0 - 1021)	1512 (879 - 2101)
	Events, n	6	<5	20
	Persons at risk	6	<113	108
	Risk (95% CI)	6	357 (0 - 1021)	1512 (879 - 2101)
	Events, n	9	<5	21
	Persons at risk	9	<113	106
	Risk (95% CI)	9	357 (0 - 1021)	1591 (943 - 2193)
	Events, n	12	<5	22
	Persons at risk	12	<113	104
	Risk (95% CI)	12	357 (0 - 1021)	1671 (1008 - 2285)
Unvaccinated				
	Events, n	3	50	188
	Persons at risk	3	278	507
	Risk (95% CI)	3	1404 (1035 - 1757)	2488 (2173 - 2791)
	Events, n	6	53	197
	Persons at risk	6	223	457
	Risk (95% CI)	6	1502 (1120 - 1868)	2627 (2304 - 2937)
	Events, n	9	56	205
	Persons at risk	9	155	409
	Risk (95% CI)	9	1632 (1226 - 2019)	2762 (2430 - 3078)
	Events, n	12	57	210
	Persons at risk	12	132	367
	Risk (95% CI)	12	1687 (1269 - 2085)	2852 (2515 - 3174)

Table 15.19.5.5.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
Unvaccinated				
	Events, n	3	40	92
	Persons at risk	3	231	650
	Risk (95% CI)	3	1386 (978 - 1776)	1202 (969 - 1430)
	Events, n	6	41	96
	Persons at risk	6	203	628
	Risk (95% CI)	6	1424 (1010 - 1818)	1257 (1019 - 1489)
	Events, n	9	42	103
	Persons at risk	9	167	609
	Risk (95% CI)	9	1467 (1046 - 1868)	1355 (1108 - 1596)
	Events, n	12	46	104
	Persons at risk	12	157	594
	Risk (95% CI)	12	1678 (1216 - 2115)	1370 (1121 - 1611)
Received dose 1 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<32	<59
	Risk (95% CI)	3	1250 (0 - 3266)	682 (0 - 1398)
	Events, n	6	<5	<5
	Persons at risk	6	<32	<59
	Risk (95% CI)	6	1250 (0 - 3266)	682 (0 - 1398)
	Events, n	9	<5	<5
	Persons at risk	9	<32	<44
	Risk (95% CI)	9	1250 (0 - 3266)	915 (19 - 1731)
	Events, n	12	<5	<5
	Persons at risk	12	<32	<44
	Risk (95% CI)	12	1250 (0 - 3266)	915 (19 - 1731)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	8
	Persons at risk	3	<96	53
	Risk (95% CI)	3	417 (0 - 966)	1178 (376 - 1914)
	Events, n	6	<5	8
	Persons at risk	6	<96	51
	Risk (95% CI)	6	417 (0 - 966)	1178 (376 - 1914)
	Events, n	9	<5	8
	Persons at risk	9	<96	50
	Risk (95% CI)	9	417 (0 - 966)	1178 (376 - 1914)
	Events, n	12	<5	8

Table 15.19.5.5.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Persons at risk	12	<96	50
	Risk (95% CI)	12	417 (0 - 966)	1178 (376 - 1914)
Received dose 2 in the last 14 days				
	Events, n	3	0	6
	Persons at risk	3	13	29
	Risk (95% CI)	3	0 (0 - 0)	1676 (357 - 2814)
	Events, n	6	0	6
	Persons at risk	6	13	29
	Risk (95% CI)	6	0 (0 - 0)	1676 (357 - 2814)
	Events, n	9	0	6
	Persons at risk	9	13	29
	Risk (95% CI)	9	0 (0 - 0)	1676 (357 - 2814)
	Events, n	12	0	6
	Persons at risk	12	12	29
	Risk (95% CI)	12	0 (0 - 0)	1676 (357 - 2814)
Received dose 2, 15 or more days ago				
	Events, n	3	25	98
	Persons at risk	3	181	402
	Risk (95% CI)	3	1118 (695 - 1522)	1840 (1504 - 2163)
	Events, n	6	26	103
	Persons at risk	6	149	373
	Risk (95% CI)	6	1170 (736 - 1583)	1944 (1599 - 2274)
	Events, n	9	28	108
	Persons at risk	9	106	345
	Risk (95% CI)	9	1293 (831 - 1732)	2054 (1700 - 2393)
	Events, n	12	28	110
	Persons at risk	12	91	316
	Risk (95% CI)	12	1293 (831 - 1732)	2103 (1744 - 2446)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5

Table 15.19.5.5.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	17	64
	Persons at risk	3	46	68
	Risk (95% CI)	3	2543 (1422 - 3518)	4565 (3672 - 5331)
	Events, n	6	18	66
	Persons at risk	6	40	62
	Risk (95% CI)	6	2706 (1554 - 3700)	4737 (3834 - 5508)
	Events, n	9	19	69
	Persons at risk	9	28	46
	Risk (95% CI)	9	2941 (1716 - 3985)	5027 (4099 - 5808)
	Events, n	12	20	73
	Persons at risk	12	21	33
	Risk (95% CI)	12	3193 (1890 - 4287)	5497 (4517 - 6302)
Received dose 4 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	6667 (0 - 9327)
	Events, n	6	0	<5
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	6667 (0 - 9327)
	Events, n	9	0	<5
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	6667 (0 - 9327)
	Events, n	12	0	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	6	27
	Persons at risk	3	15	18
	Risk (95% CI)	3	2421 (529 - 3935)	4965 (3332 - 6198)
	Events, n	6	7	29
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	3110 (785 - 4849)	5735 (3836 - 7049)

Table 15.19.5.5.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Events, n	9	7	29
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	5735 (3836 - 7049)
	Events, n	12	7	29
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.5.6.1 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=61)
15-30				
	Events, n	3	15	<5
	Persons at risk	3	298	<852
	Risk (95% CI)	3	425 (212 - 633)	47 (0 - 100)
	Events, n	6	17	<5
	Persons at risk	6	256	<598
	Risk (95% CI)	6	496 (262 - 724)	67 (1 - 133)
	Events, n	9	17	<5
	Persons at risk	9	217	<598
	Risk (95% CI)	9	496 (262 - 724)	67 (1 - 133)
	Events, n	12	17	5
	Persons at risk	12	182	362
	Risk (95% CI)	12	496 (262 - 724)	94 (9 - 178)

Table 15.19.5.6.2 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N=356)	Pericarditis cohort (N<852)
Male				
	Events, n	3	40	26
	Persons at risk	3	464	1104
	Risk (95% CI)	3	700 (488 - 908)	210 (129 - 289)
	Events, n	6	46	34
	Persons at risk	6	404	951
	Risk (95% CI)	6	827 (594 - 1054)	284 (189 - 378)
	Events, n	9	48	35
	Persons at risk	9	351	822
	Risk (95% CI)	9	878 (636 - 1114)	296 (198 - 392)
	Events, n	12	50	36
	Persons at risk	12	292	721
	Risk (95% CI)	12	934 (680 - 1180)	309 (208 - 409)
Female				
	Events, n	3	24	11
	Persons at risk	3	230	491
	Risk (95% CI)	3	870 (531 - 1197)	204 (84 - 322)
	Events, n	6	25	13
	Persons at risk	6	197	432
	Risk (95% CI)	6	911 (564 - 1246)	245 (112 - 375)
	Events, n	9	28	14
	Persons at risk	9	159	377
	Risk (95% CI)	9	1064 (679 - 1433)	270 (129 - 408)
	Events, n	12	28	14
	Persons at risk	12	139	334
	Risk (95% CI)	12	1064 (679 - 1433)	270 (129 - 408)

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Table 15.19.5.6.3 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N=281)	Pericarditis cohort (N=548)
Male, 15-30 years				
	Events, n	3	13	<5
	Persons at risk	3	240	<646
	Risk (95% CI)	3	450 (208 - 686)	62 (0 - 132)
	Events, n	6	15	<5
	Persons at risk	6	209	<445
	Risk (95% CI)	6	536 (267 - 797)	90 (1 - 178)
	Events, n	9	15	<5
	Persons at risk	9	177	<445
	Risk (95% CI)	9	536 (267 - 797)	90 (1 - 178)
	Events, n	12	15	5
	Persons at risk	12	150	267
	Risk (95% CI)	12	536 (267 - 797)	126 (12 - 239)
Female, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<127	142
	Risk (95% CI)	3	315 (0 - 735)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<127	129
	Risk (95% CI)	6	315 (0 - 735)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<127	108
	Risk (95% CI)	9	315 (0 - 735)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<127	95
	Risk (95% CI)	12	315 (0 - 735)	0 (0 - 0)

Table 15.19.5.6.4 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N<127)	Pericarditis cohort (N=159)
No				
	Events, n	3	46	26
	Persons at risk	3	483	1206
	Risk (95% CI)	3	780 (561 - 994)	196 (121 - 270)
	Events, n	6	52	35
	Persons at risk	6	423	1068
	Risk (95% CI)	6	899 (662 - 1130)	271 (182 - 359)
	Events, n	9	55	36
	Persons at risk	9	369	945
	Risk (95% CI)	9	968 (720 - 1210)	281 (190 - 371)
	Events, n	12	55	37
	Persons at risk	12	323	849
	Risk (95% CI)	12	968 (720 - 1210)	292 (198 - 385)
Yes				
	Events, n	3	18	11
	Persons at risk	3	211	389
	Risk (95% CI)	3	703 (384 - 1011)	244 (101 - 386)
	Events, n	6	19	12
	Persons at risk	6	178	315
	Risk (95% CI)	6	752 (420 - 1073)	272 (119 - 423)
	Events, n	9	21	13
	Persons at risk	9	141	254
	Risk (95% CI)	9	878 (505 - 1237)	310 (140 - 477)
	Events, n	12	23	13
	Persons at risk	12	108	206
	Risk (95% CI)	12	1018 (600 - 1418)	310 (140 - 477)

Table 15.19.5.6.5 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N=454)
Vaccinated				
	Events, n	3	5	<5
	Persons at risk	3	54	<100
	Risk (95% CI)	3	832 (106 - 1504)	404 (8 - 784)
	Events, n	6	7	<5
	Persons at risk	6	51	<100
	Risk (95% CI)	6	1171 (316 - 1951)	404 (8 - 784)
	Events, n	9	8	<5
	Persons at risk	9	48	<100
	Risk (95% CI)	9	1351 (434 - 2181)	404 (8 - 784)
	Events, n	12	8	5
	Persons at risk	12	45	88
	Risk (95% CI)	12	1351 (434 - 2181)	512 (64 - 940)
Unvaccinated				
	Events, n	3	31	22
	Persons at risk	3	363	828
	Risk (95% CI)	3	701 (460 - 936)	230 (134 - 324)
	Events, n	6	33	24
	Persons at risk	6	296	683
	Risk (95% CI)	6	756 (504 - 1002)	254 (153 - 354)
	Events, n	9	35	25
	Persons at risk	9	232	548
	Risk (95% CI)	9	824 (556 - 1085)	271 (165 - 376)
	Events, n	12	37	25
	Persons at risk	12	179	447
	Risk (95% CI)	12	911 (618 - 1195)	271 (165 - 376)

Table 15.19.5.6.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
Unvaccinated				
	Events, n	3	28	11
	Persons at risk	3	277	673
	Risk (95% CI)	3	811 (518 - 1095)	151 (62 - 239)
	Events, n	6	31	19
	Persons at risk	6	254	608
	Risk (95% CI)	6	914 (601 - 1217)	271 (150 - 391)
	Events, n	9	33	20
	Persons at risk	9	230	559
	Risk (95% CI)	9	992 (662 - 1309)	288 (163 - 412)
	Events, n	12	33	20
	Persons at risk	12	207	520
	Risk (95% CI)	12	992 (662 - 1309)	288 (163 - 412)
Received dose 1 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<35	<54
	Risk (95% CI)	3	1176 (0 - 2582)	741 (0 - 1678)
	Events, n	6	<5	<5
	Persons at risk	6	<23	<54
	Risk (95% CI)	6	1765 (0 - 3391)	741 (0 - 1678)
	Events, n	9	<5	<5
	Persons at risk	9	<23	<54
	Risk (95% CI)	9	1765 (0 - 3391)	741 (0 - 1678)
	Events, n	12	<5	<5
	Persons at risk	12	<23	<35
	Risk (95% CI)	12	1765 (0 - 3391)	1143 (0 - 2283)
Received dose 1, 15 or more days ago				
	Events, n	3	6	<5
	Persons at risk	3	68	<179
	Risk (95% CI)	3	743 (153 - 1299)	224 (4 - 438)
	Events, n	6	6	<5
	Persons at risk	6	59	<179
	Risk (95% CI)	6	743 (153 - 1299)	224 (4 - 438)
	Events, n	9	7	<5
	Persons at risk	9	52	<179
	Risk (95% CI)	9	912 (237 - 1539)	224 (4 - 438)
	Events, n	12	7	<5

Table 15.19.5.6.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Persons at risk	12	44	<179
	Risk (95% CI)	12	912 (237 - 1539)	224 (4 - 438)
Received dose 2 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<96	<96
	Risk (95% CI)	3	417 (0 - 1184)	417 (0 - 1184)
	Events, n	6	<5	<5
	Persons at risk	6	<96	<96
	Risk (95% CI)	6	417 (0 - 1184)	417 (0 - 1184)
	Events, n	9	<5	<5
	Persons at risk	9	<46	<96
	Risk (95% CI)	9	873 (0 - 1961)	417 (0 - 1184)
	Events, n	12	<5	<5
	Persons at risk	12	<46	<96
	Risk (95% CI)	12	873 (0 - 1961)	417 (0 - 1184)
Received dose 2, 15 or more days ago				
	Events, n	3	14	6
	Persons at risk	3	162	366
	Risk (95% CI)	3	716 (347 - 1071)	149 (30 - 267)
	Events, n	6	15	6
	Persons at risk	6	139	318
	Risk (95% CI)	6	774 (389 - 1143)	149 (30 - 267)
	Events, n	9	15	7
	Persons at risk	9	117	276
	Risk (95% CI)	9	774 (389 - 1143)	183 (47 - 318)
	Events, n	12	17	7
	Persons at risk	12	102	245
	Risk (95% CI)	12	938 (494 - 1361)	183 (47 - 318)
Received dose 3 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<5	<37
	Risk (95% CI)	3	3333 (0 - 6214)	1111 (0 - 2944)
	Events, n	6	<5	<5
	Persons at risk	6	<5	<37
	Risk (95% CI)	6	3333 (0 - 6214)	1111 (0 - 2944)
	Events, n	9	<5	<5
	Persons at risk	9	<5	<37

Table 15.19.5.6.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Risk (95% CI)	9	3333 (0 - 6214)	1111 (0 - 2944)
	Events, n	12	<5	<5
	Persons at risk	12	<5	<37
	Risk (95% CI)	12	3333 (0 - 6214)	1111 (0 - 2944)
Received dose 3, 15 or more days ago				
	Events, n	3	10	9
	Persons at risk	3	138	322
	Risk (95% CI)	3	592 (229 - 942)	235 (82 - 385)
	Events, n	6	12	11
	Persons at risk	6	105	250
	Risk (95% CI)	6	747 (327 - 1148)	298 (122 - 471)
	Events, n	9	13	11
	Persons at risk	9	73	188
	Risk (95% CI)	9	838 (384 - 1272)	298 (122 - 471)
	Events, n	12	13	11
	Persons at risk	12	42	134
	Risk (95% CI)	12	838 (384 - 1272)	298 (122 - 471)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<40	<40
	Risk (95% CI)	3	1000 (0 - 2680)	1000 (0 - 2012)
	Events, n	6	<5	<5
	Persons at risk	6	<5	<40
	Risk (95% CI)	6	1000 (0 - 2680)	1000 (0 - 2012)

Table 15.19.5.6.6 Risk (1-KM and 95% CI) for HEART FAILURE at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Events, n	9	<5	<5
	Persons at risk	9	<5	<40
	Risk (95% CI)	9	1000 (0 - 2680)	1000 (0 - 2012)
	Events, n	12	<5	<5
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	1000 (0 - 2680)	1000 (0 - 2012)

Table 15.19.6.1.1 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N<40)	Pericarditis cohort (N<40)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.6.1.2 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.6.1.3 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

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Table 15.19.6.1.4 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

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Table 15.19.6.1.5 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.6.1.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.6.1.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

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Table 15.19.6.1.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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**Table 15.19.6.1.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by
Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19
vaccination status at baseline for Pedianet**

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.6.2.1 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<541	22
	Risk (95% CI)	3	74 (0 - 218)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<541	21
	Risk (95% CI)	6	74 (0 - 218)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<541	19
	Risk (95% CI)	9	74 (0 - 218)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<541	17
	Risk (95% CI)	12	74 (0 - 218)	0 (0 - 0)

Table 15.19.6.2.2 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N<541)	Pericarditis cohort (N=23)
Male				
	Events, n	3	<5	0
	Persons at risk	3	<607	64
	Risk (95% CI)	3	66 (0 - 140)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<607	63
	Risk (95% CI)	6	66 (0 - 140)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<607	57
	Risk (95% CI)	9	66 (0 - 140)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<607	47
	Risk (95% CI)	12	66 (0 - 140)	0 (0 - 0)
Female				
	Events, n	3	<5	0
	Persons at risk	3	<435	30
	Risk (95% CI)	3	92 (0 - 218)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<435	28
	Risk (95% CI)	6	92 (0 - 218)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<435	27
	Risk (95% CI)	9	92 (0 - 218)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<435	26
	Risk (95% CI)	12	92 (0 - 218)	0 (0 - 0)

Table 15.19.6.2.3 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N<435)	Pericarditis cohort (N=32)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<371	17
	Risk (95% CI)	3	108 (0 - 315)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<371	17
	Risk (95% CI)	6	108 (0 - 315)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<371	15
	Risk (95% CI)	9	108 (0 - 315)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<371	13
	Risk (95% CI)	12	108 (0 - 315)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	41	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	35	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.6.2.4 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N=42)	Pericarditis cohort (N=5)
No				
	Events, n	3	<5	0
	Persons at risk	3	<741	81
	Risk (95% CI)	3	54 (0 - 115)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<741	79
	Risk (95% CI)	6	54 (0 - 115)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<741	74
	Risk (95% CI)	9	54 (0 - 115)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<741	65
	Risk (95% CI)	12	54 (0 - 115)	0 (0 - 0)
Yes				
	Events, n	3	<5	0
	Persons at risk	3	<243	13
	Risk (95% CI)	3	165 (0 - 390)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<243	12
	Risk (95% CI)	6	165 (0 - 390)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<243	10
	Risk (95% CI)	9	165 (0 - 390)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<243	8
	Risk (95% CI)	12	165 (0 - 390)	0 (0 - 0)

Table 15.19.6.2.5 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<243)	Pericarditis cohort (N=15)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	36	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	35	5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<1082	28
	Risk (95% CI)	3	37 (0 - 110)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1082	27
	Risk (95% CI)	6	37 (0 - 110)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<1082	26
	Risk (95% CI)	9	37 (0 - 110)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<1082	21
	Risk (95% CI)	12	37 (0 - 110)	0 (0 - 0)

Table 15.19.6.2.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<1082)	Pericarditis cohort (N=31)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<371	61
	Risk (95% CI)	3	108 (2 - 213)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<371	59
	Risk (95% CI)	6	108 (2 - 213)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<371	53
	Risk (95% CI)	9	108 (2 - 213)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<371	47
	Risk (95% CI)	12	108 (2 - 213)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	81	10
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	77	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	69	10
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.6.2.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<1082)	Pericarditis cohort (N=31)
	Persons at risk	12	63	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<580	15
	Risk (95% CI)	3	69 (0 - 203)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<580	14
	Risk (95% CI)	6	69 (0 - 203)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<580	13
	Risk (95% CI)	9	69 (0 - 203)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<580	11
	Risk (95% CI)	12	69 (0 - 203)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.6.2.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<1082)	Pericarditis cohort (N=31)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	30	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	27	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	18	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.6.2.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<1082)	Pericarditis cohort (N=31)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.6.3.1 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N=5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<409	261
	Risk (95% CI)	3	98 (0 - 232)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<409	233
	Risk (95% CI)	6	98 (0 - 232)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<409	205
	Risk (95% CI)	9	98 (0 - 232)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<409	176
	Risk (95% CI)	12	98 (0 - 232)	0 (0 - 0)

Table 15.19.6.3.2 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N<409)	Pericarditis cohort (N=289)
Male				
	Events, n	3	<5	5
	Persons at risk	3	<728	1182
	Risk (95% CI)	3	55 (0 - 117)	38 (5 - 71)
	Events, n	6	<5	5
	Persons at risk	6	<728	1038
	Risk (95% CI)	6	55 (0 - 117)	38 (5 - 71)
	Events, n	9	<5	5
	Persons at risk	9	<728	891
	Risk (95% CI)	9	55 (0 - 117)	38 (5 - 71)
	Events, n	12	<5	5
	Persons at risk	12	<728	746
	Risk (95% CI)	12	55 (0 - 117)	38 (5 - 71)
Female				
	Events, n	3	5	<5
	Persons at risk	3	223	<1250
	Risk (95% CI)	3	187 (23 - 347)	32 (0 - 76)
	Events, n	6	5	<5
	Persons at risk	6	201	<1250
	Risk (95% CI)	6	187 (23 - 347)	32 (0 - 76)
	Events, n	9	5	<5
	Persons at risk	9	175	<1250
	Risk (95% CI)	9	187 (23 - 347)	32 (0 - 76)
	Events, n	12	5	<5
	Persons at risk	12	148	<1250
	Risk (95% CI)	12	187 (23 - 347)	32 (0 - 76)

Table 15.19.6.3.3 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N<1250)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<678	203
	Risk (95% CI)	3	59 (0 - 173)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<678	185
	Risk (95% CI)	6	59 (0 - 173)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<678	162
	Risk (95% CI)	9	59 (0 - 173)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<678	139
	Risk (95% CI)	12	59 (0 - 173)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<137	58
	Risk (95% CI)	3	294 (0 - 846)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<137	48
	Risk (95% CI)	6	294 (0 - 846)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<137	43
	Risk (95% CI)	9	294 (0 - 846)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<137	37
	Risk (95% CI)	12	294 (0 - 846)	0 (0 - 0)

Table 15.19.6.3.4 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N<137)	Pericarditis cohort (N=61)
No				
	Events, n	3	5	5
	Persons at risk	3	606	1582
	Risk (95% CI)	3	72 (9 - 135)	29 (4 - 54)
	Events, n	6	5	5
	Persons at risk	6	541	1397
	Risk (95% CI)	6	72 (9 - 135)	29 (4 - 54)
	Events, n	9	5	5
	Persons at risk	9	481	1236
	Risk (95% CI)	9	72 (9 - 135)	29 (4 - 54)
	Events, n	12	5	5
	Persons at risk	12	429	1074
	Risk (95% CI)	12	72 (9 - 135)	29 (4 - 54)
Yes				
	Events, n	3	<5	<5
	Persons at risk	3	<159	<409
	Risk (95% CI)	3	252 (0 - 530)	98 (0 - 232)
	Events, n	6	<5	<5
	Persons at risk	6	<159	<409
	Risk (95% CI)	6	252 (0 - 530)	98 (0 - 232)
	Events, n	9	<5	<5
	Persons at risk	9	<159	<409
	Risk (95% CI)	9	252 (0 - 530)	98 (0 - 232)
	Events, n	12	<5	<5
	Persons at risk	12	<159	<409
	Risk (95% CI)	12	252 (0 - 530)	98 (0 - 232)

Table 15.19.6.3.5 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<159)	Pericarditis cohort (N<409)
Vaccinated				
	Events, n	3	0	<5
	Persons at risk	3	62	<389
	Risk (95% CI)	3	0 (0 - 0)	103 (0 - 243)
	Events, n	6	0	<5
	Persons at risk	6	57	<389
	Risk (95% CI)	6	0 (0 - 0)	103 (0 - 243)
	Events, n	9	0	<5
	Persons at risk	9	56	<389
	Risk (95% CI)	9	0 (0 - 0)	103 (0 - 243)
	Events, n	12	0	<5
	Persons at risk	12	54	<389
	Risk (95% CI)	12	0 (0 - 0)	103 (0 - 243)
Unvaccinated				
	Events, n	3	6	<5
	Persons at risk	3	394	<1213
	Risk (95% CI)	3	126 (25 - 225)	33 (1 - 66)
	Events, n	6	6	<5
	Persons at risk	6	325	<1213
	Risk (95% CI)	6	126 (25 - 225)	33 (1 - 66)
	Events, n	9	6	<5
	Persons at risk	9	256	<1213
	Risk (95% CI)	9	126 (25 - 225)	33 (1 - 66)
	Events, n	12	6	<5
	Persons at risk	12	197	<1213
	Risk (95% CI)	12	126 (25 - 225)	33 (1 - 66)

Table 15.19.6.3.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N<1213)
Unvaccinated				
	Events, n	3	<5	<5
	Persons at risk	3	<541	<2223
	Risk (95% CI)	3	74 (0 - 176)	18 (0 - 54)
	Events, n	6	<5	<5
	Persons at risk	6	<541	<2223
	Risk (95% CI)	6	74 (0 - 176)	18 (0 - 54)
	Events, n	9	<5	<5
	Persons at risk	9	<541	<2223
	Risk (95% CI)	9	74 (0 - 176)	18 (0 - 54)
	Events, n	12	<5	<5
	Persons at risk	12	<541	<2223
	Risk (95% CI)	12	74 (0 - 176)	18 (0 - 54)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	18	49
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	49
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	16	49
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	16	48
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<269	<534
	Risk (95% CI)	3	149 (0 - 435)	75 (0 - 219)
	Events, n	6	<5	<5
	Persons at risk	6	<269	<534
	Risk (95% CI)	6	149 (0 - 435)	75 (0 - 219)
	Events, n	9	<5	<5
	Persons at risk	9	<269	<534
	Risk (95% CI)	9	149 (0 - 435)	75 (0 - 219)
	Events, n	12	<5	<5

Table 15.19.6.3.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N<1213)
	Persons at risk	12	<269	<534
	Risk (95% CI)	12	149 (0 - 435)	75 (0 - 219)
Received dose 2 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	12	<237
	Risk (95% CI)	3	0 (0 - 0)	169 (0 - 493)
	Events, n	6	0	<5
	Persons at risk	6	12	<237
	Risk (95% CI)	6	0 (0 - 0)	169 (0 - 493)
	Events, n	9	0	<5
	Persons at risk	9	12	<237
	Risk (95% CI)	9	0 (0 - 0)	169 (0 - 493)
	Events, n	12	0	<5
	Persons at risk	12	12	<237
	Risk (95% CI)	12	0 (0 - 0)	169 (0 - 493)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<308	<715
	Risk (95% CI)	3	130 (0 - 276)	56 (0 - 120)
	Events, n	6	<5	<5
	Persons at risk	6	<308	<715
	Risk (95% CI)	6	130 (0 - 276)	56 (0 - 120)
	Events, n	9	<5	<5
	Persons at risk	9	<308	<715
	Risk (95% CI)	9	130 (0 - 276)	56 (0 - 120)
	Events, n	12	<5	<5
	Persons at risk	12	<308	<715
	Risk (95% CI)	12	130 (0 - 276)	56 (0 - 120)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	23
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	22
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	21

Table 15.19.6.3.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N<1213)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	11	18
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<345	<2000
	Risk (95% CI)	3	116 (0 - 274)	20 (0 - 58)
	Events, n	6	<5	<5
	Persons at risk	6	<345	<2000
	Risk (95% CI)	6	116 (0 - 274)	20 (0 - 58)
	Events, n	9	<5	<5
	Persons at risk	9	<345	<2000
	Risk (95% CI)	9	116 (0 - 274)	20 (0 - 58)
	Events, n	12	<5	<5
	Persons at risk	12	<345	<2000
	Risk (95% CI)	12	116 (0 - 274)	20 (0 - 58)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	10	41
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.6.3.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N<1213)
	Events, n	9	0	0
	Persons at risk	9	<5	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.6.4.1 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N=24)	Pericarditis cohort (N=75)
15-30				
	Events, n	3	0	0
	Persons at risk	3	37	87
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	37	82
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	75
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	62
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.6.4.2 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N=39)	Pericarditis cohort (N=94)
Male				
	Events, n	3	0	<5
	Persons at risk	3	81	<417
	Risk (95% CI)	3	0 (0 - 0)	96 (0 - 203)
	Events, n	6	0	<5
	Persons at risk	6	78	<417
	Risk (95% CI)	6	0 (0 - 0)	96 (0 - 203)
	Events, n	9	0	<5
	Persons at risk	9	75	<417
	Risk (95% CI)	9	0 (0 - 0)	96 (0 - 203)
	Events, n	12	0	<5
	Persons at risk	12	66	<417
	Risk (95% CI)	12	0 (0 - 0)	96 (0 - 203)
Female				
	Events, n	3	<5	<5
	Persons at risk	3	<100	<121
	Risk (95% CI)	3	400 (0 - 1138)	331 (7 - 644)
	Events, n	6	<5	<5
	Persons at risk	6	<100	<121
	Risk (95% CI)	6	400 (0 - 1138)	331 (7 - 644)
	Events, n	9	<5	<5
	Persons at risk	9	<100	<121
	Risk (95% CI)	9	400 (0 - 1138)	331 (7 - 644)
	Events, n	12	<5	<5
	Persons at risk	12	<100	<121
	Risk (95% CI)	12	400 (0 - 1138)	331 (7 - 644)

Table 15.19.6.4.3 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N<100)	Pericarditis cohort (N=121)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	36	71
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	36	68
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	33	63
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	51
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.6.4.4 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	<5	<5
	Persons at risk	3	<328	<422
	Risk (95% CI)	3	122 (0 - 357)	95 (0 - 201)
	Events, n	6	<5	<5
	Persons at risk	6	<328	<422
	Risk (95% CI)	6	122 (0 - 357)	95 (0 - 201)
	Events, n	9	<5	<5
	Persons at risk	9	<328	<422
	Risk (95% CI)	9	122 (0 - 357)	95 (0 - 201)
	Events, n	12	<5	<5
	Persons at risk	12	<328	<422
	Risk (95% CI)	12	122 (0 - 357)	95 (0 - 201)
Yes				
	Events, n	3	0	<5
	Persons at risk	3	25	<118
	Risk (95% CI)	3	0 (0 - 0)	339 (7 - 660)
	Events, n	6	0	<5
	Persons at risk	6	23	<118
	Risk (95% CI)	6	0 (0 - 0)	339 (7 - 660)
	Events, n	9	0	<5
	Persons at risk	9	22	<118
	Risk (95% CI)	9	0 (0 - 0)	339 (7 - 660)
	Events, n	12	0	<5
	Persons at risk	12	19	<118
	Risk (95% CI)	12	0 (0 - 0)	339 (7 - 660)

Table 15.19.6.4.5 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=34)	Pericarditis cohort (N=118)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	9	29
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	29
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	9	28
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	27
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	<5	6
	Persons at risk	3	<260	232
	Risk (95% CI)	3	154 (0 - 449)	221 (44 - 394)
	Events, n	6	<5	6
	Persons at risk	6	<260	204
	Risk (95% CI)	6	154 (0 - 449)	221 (44 - 394)
	Events, n	9	<5	6
	Persons at risk	9	<260	177
	Risk (95% CI)	9	154 (0 - 449)	221 (44 - 394)
	Events, n	12	<5	6
	Persons at risk	12	<260	145
	Risk (95% CI)	12	154 (0 - 449)	221 (44 - 394)

Table 15.19.6.4.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<260)	Pericarditis cohort (N=272)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	38	<534
	Risk (95% CI)	3	0 (0 - 0)	75 (0 - 221)
	Events, n	6	0	<5
	Persons at risk	6	38	<534
	Risk (95% CI)	6	0 (0 - 0)	75 (0 - 221)
	Events, n	9	0	<5
	Persons at risk	9	37	<534
	Risk (95% CI)	9	0 (0 - 0)	75 (0 - 221)
	Events, n	12	0	<5
	Persons at risk	12	34	<534
	Risk (95% CI)	12	0 (0 - 0)	75 (0 - 221)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	9	19
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	18
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	8	17
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.6.4.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<260)	Pericarditis cohort (N=272)
	Persons at risk	12	8	12
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	33	<234
	Risk (95% CI)	3	0 (0 - 0)	171 (0 - 362)
	Events, n	6	0	<5
	Persons at risk	6	31	<234
	Risk (95% CI)	6	0 (0 - 0)	171 (0 - 362)
	Events, n	9	0	<5
	Persons at risk	9	27	<234
	Risk (95% CI)	9	0 (0 - 0)	171 (0 - 362)
	Events, n	12	0	<5
	Persons at risk	12	23	<234
	Risk (95% CI)	12	0 (0 - 0)	171 (0 - 362)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.6.4.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<260)	Pericarditis cohort (N=272)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<88	<99
	Risk (95% CI)	3	455 (0 - 1286)	405 (0 - 844)
	Events, n	6	<5	<5
	Persons at risk	6	<88	<99
	Risk (95% CI)	6	455 (0 - 1286)	405 (0 - 844)
	Events, n	9	<5	<5
	Persons at risk	9	<88	<99
	Risk (95% CI)	9	455 (0 - 1286)	405 (0 - 844)
	Events, n	12	<5	<5
	Persons at risk	12	<88	<99
	Risk (95% CI)	12	455 (0 - 1286)	405 (0 - 844)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)

Table 15.19.6.4.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<260)	Pericarditis cohort (N=272)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.6.5.1 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=11)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<159	249
	Risk (95% CI)	3	253 (0 - 531)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<159	236
	Risk (95% CI)	6	253 (0 - 531)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<159	225
	Risk (95% CI)	9	253 (0 - 531)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<159	215
	Risk (95% CI)	12	253 (0 - 531)	0 (0 - 0)

Table 15.19.6.5.2 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N<159)	Pericarditis cohort (N=271)
Male				
	Events, n	3	20	15
	Persons at risk	3	352	972
	Risk (95% CI)	3	485 (275 - 690)	140 (69 - 210)
	Events, n	6	20	15
	Persons at risk	6	298	913
	Risk (95% CI)	6	485 (275 - 690)	140 (69 - 210)
	Events, n	9	20	15
	Persons at risk	9	243	867
	Risk (95% CI)	9	485 (275 - 690)	140 (69 - 210)
	Events, n	12	22	16
	Persons at risk	12	217	812
	Risk (95% CI)	12	568 (330 - 800)	152 (77 - 225)
Female				
	Events, n	3	8	8
	Persons at risk	3	236	530
	Risk (95% CI)	3	308 (96 - 516)	136 (42 - 229)
	Events, n	6	8	8
	Persons at risk	6	199	500
	Risk (95% CI)	6	308 (96 - 516)	136 (42 - 229)
	Events, n	9	9	8
	Persons at risk	9	148	470
	Risk (95% CI)	9	361 (125 - 591)	136 (42 - 229)
	Events, n	12	9	8
	Persons at risk	12	131	440
	Risk (95% CI)	12	361 (125 - 591)	136 (42 - 229)

Table 15.19.6.5.3 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N=591)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<378	196
	Risk (95% CI)	3	106 (0 - 312)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<378	188
	Risk (95% CI)	6	106 (0 - 312)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<378	181
	Risk (95% CI)	9	106 (0 - 312)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<378	175
	Risk (95% CI)	12	106 (0 - 312)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<49	53
	Risk (95% CI)	3	833 (0 - 1875)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<49	48
	Risk (95% CI)	6	833 (0 - 1875)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<49	44
	Risk (95% CI)	9	833 (0 - 1875)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<49	40
	Risk (95% CI)	12	833 (0 - 1875)	0 (0 - 0)

Table 15.19.6.5.4 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N<49)	Pericarditis cohort (N=57)
No				
	Events, n	3	16	16
	Persons at risk	3	313	1087
	Risk (95% CI)	3	447 (231 - 659)	135 (69 - 200)
	Events, n	6	16	16
	Persons at risk	6	273	1043
	Risk (95% CI)	6	447 (231 - 659)	135 (69 - 200)
	Events, n	9	17	16
	Persons at risk	9	228	1001
	Risk (95% CI)	9	484 (256 - 707)	135 (69 - 200)
	Events, n	12	19	17
	Persons at risk	12	205	954
	Risk (95% CI)	12	572 (314 - 823)	145 (76 - 213)
Yes				
	Events, n	3	12	7
	Persons at risk	3	275	415
	Risk (95% CI)	3	382 (168 - 592)	147 (38 - 254)
	Events, n	6	12	7
	Persons at risk	6	224	370
	Risk (95% CI)	6	382 (168 - 592)	147 (38 - 254)
	Events, n	9	12	7
	Persons at risk	9	163	336
	Risk (95% CI)	9	382 (168 - 592)	147 (38 - 254)
	Events, n	12	12	7
	Persons at risk	12	143	298
	Risk (95% CI)	12	382 (168 - 592)	147 (38 - 254)

Table 15.19.6.5.5 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=316)	Pericarditis cohort (N=477)
Vaccinated				
	Events, n	3	<5	<5
	Persons at risk	3	<113	<534
	Risk (95% CI)	3	357 (0 - 1021)	75 (0 - 221)
	Events, n	6	<5	<5
	Persons at risk	6	<113	<534
	Risk (95% CI)	6	357 (0 - 1021)	75 (0 - 221)
	Events, n	9	<5	<5
	Persons at risk	9	<113	<534
	Risk (95% CI)	9	357 (0 - 1021)	75 (0 - 221)
	Events, n	12	<5	<5
	Persons at risk	12	<113	<534
	Risk (95% CI)	12	357 (0 - 1021)	75 (0 - 221)
Unvaccinated				
	Events, n	3	8	11
	Persons at risk	3	309	652
	Risk (95% CI)	3	227 (70 - 381)	144 (59 - 229)
	Events, n	6	8	11
	Persons at risk	6	250	588
	Risk (95% CI)	6	227 (70 - 381)	144 (59 - 229)
	Events, n	9	9	11
	Persons at risk	9	182	532
	Risk (95% CI)	9	269 (92 - 444)	144 (59 - 229)
	Events, n	12	10	11
	Persons at risk	12	149	469
	Risk (95% CI)	12	334 (116 - 548)	144 (59 - 229)

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Table 15.19.6.5.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
Unvaccinated				
	Events, n	3	19	11
	Persons at risk	3	252	723
	Risk (95% CI)	3	657 (367 - 939)	143 (59 - 227)
	Events, n	6	19	11
	Persons at risk	6	220	700
	Risk (95% CI)	6	657 (367 - 939)	143 (59 - 227)
	Events, n	9	19	11
	Persons at risk	9	183	683
	Risk (95% CI)	9	657 (367 - 939)	143 (59 - 227)
	Events, n	12	20	12
	Persons at risk	12	174	663
	Risk (95% CI)	12	709 (402 - 1005)	158 (69 - 247)
Received dose 1 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<32	<177
	Risk (95% CI)	3	1250 (0 - 3266)	227 (0 - 658)
	Events, n	6	<5	<5
	Persons at risk	6	<32	<177
	Risk (95% CI)	6	1250 (0 - 3266)	227 (0 - 658)
	Events, n	9	<5	<5
	Persons at risk	9	<32	<177
	Risk (95% CI)	9	1250 (0 - 3266)	227 (0 - 658)
	Events, n	12	<5	<5
	Persons at risk	12	<32	<177
	Risk (95% CI)	12	1250 (0 - 3266)	227 (0 - 658)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<96	61
	Risk (95% CI)	3	417 (0 - 966)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<96	59
	Risk (95% CI)	6	417 (0 - 966)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<96	58
	Risk (95% CI)	9	417 (0 - 966)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.6.5.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Persons at risk	12	<96	57
	Risk (95% CI)	12	417 (0 - 966)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	34
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	34
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	34
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	6	6
	Persons at risk	3	196	482
	Risk (95% CI)	3	271 (55 - 483)	112 (23 - 201)
	Events, n	6	6	6
	Persons at risk	6	163	451
	Risk (95% CI)	6	271 (55 - 483)	112 (23 - 201)
	Events, n	9	7	6
	Persons at risk	9	122	424
	Risk (95% CI)	9	336 (85 - 581)	112 (23 - 201)
	Events, n	12	8	6
	Persons at risk	12	101	389
	Risk (95% CI)	12	431 (119 - 734)	112 (23 - 201)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5

Table 15.19.6.5.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	5
	Persons at risk	3	58	118
	Risk (95% CI)	3	0 (0 - 0)	355 (44 - 655)
	Events, n	6	0	5
	Persons at risk	6	51	110
	Risk (95% CI)	6	0 (0 - 0)	355 (44 - 655)
	Events, n	9	0	5
	Persons at risk	9	38	91
	Risk (95% CI)	9	0 (0 - 0)	355 (44 - 655)
	Events, n	12	0	5
	Persons at risk	12	27	65
	Risk (95% CI)	12	0 (0 - 0)	355 (44 - 655)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	19	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	5	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.6.5.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.6.6.1 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=61)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<1429	555
	Risk (95% CI)	3	28 (0 - 83)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1429	490
	Risk (95% CI)	6	28 (0 - 83)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<1429	431
	Risk (95% CI)	9	28 (0 - 83)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<1429	366
	Risk (95% CI)	12	28 (0 - 83)	0 (0 - 0)

Table 15.19.6.6.2 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N<1429)	Pericarditis cohort (N=644)
Male				
	Events, n	3	<5	0
	Persons at risk	3	<2353	1128
	Risk (95% CI)	3	17 (0 - 51)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<2353	977
	Risk (95% CI)	6	17 (0 - 51)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<2353	847
	Risk (95% CI)	9	17 (0 - 51)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<2353	744
	Risk (95% CI)	12	17 (0 - 51)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	253	500
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	219	442
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	182	384
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	160	341
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.6.6.3 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N=281)	Pericarditis cohort (N=548)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<1177	413
	Risk (95% CI)	3	34 (0 - 101)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1177	361
	Risk (95% CI)	6	34 (0 - 101)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<1177	323
	Risk (95% CI)	9	34 (0 - 101)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<1177	271
	Risk (95% CI)	12	34 (0 - 101)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	60	142
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	49	129
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	41	108
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	95
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.6.6.4 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N=64)	Pericarditis cohort (N=159)
No				
	Events, n	3	0	0
	Persons at risk	3	525	1231
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	465	1096
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	409	971
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	358	874
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	<5	0
	Persons at risk	3	<1053	397
	Risk (95% CI)	3	38 (0 - 113)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1053	323
	Risk (95% CI)	6	38 (0 - 113)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<1053	260
	Risk (95% CI)	9	38 (0 - 113)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<1053	211
	Risk (95% CI)	12	38 (0 - 113)	0 (0 - 0)

Table 15.19.6.6.5 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<1053)	Pericarditis cohort (N=454)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	59	98
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	58	96
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	56	96
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	52	93
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	393	848
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	321	700
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	255	560
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	201	456
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.6.6.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<1380	682
	Risk (95% CI)	3	29 (0 - 84)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1380	623
	Risk (95% CI)	6	29 (0 - 84)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<1380	575
	Risk (95% CI)	9	29 (0 - 84)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<1380	536
	Risk (95% CI)	12	29 (0 - 84)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	17	27
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	26
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	17	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	17	25
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	74	160
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	65	144
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	59	118
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.6.6.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Persons at risk	12	50	105
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	23	24
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	23	24
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	22	24
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	21	23
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	175	372
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	151	321
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	127	279
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	114	247
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	6	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	6	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	5	9

Table 15.19.6.6.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	148	329
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	113	258
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	80	193
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	47	137
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	8	25
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.6.6.6 Risk (1-KM and 95% CI) for CARDIOGENIC SHOCK at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Events, n	9	0	0
	Persons at risk	9	<5	7
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.7.1.1 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N=10)	Pericarditis cohort (N=30)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.7.1.2 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.7.1.3 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.7.1.4 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.7.1.5 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.7.1.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.7.1.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

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Table 15.19.7.1.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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Table 15.19.7.1.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.7.2.1 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<541	22
	Risk (95% CI)	3	74 (0 - 218)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<541	21
	Risk (95% CI)	6	74 (0 - 218)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<541	19
	Risk (95% CI)	9	74 (0 - 218)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<541	17
	Risk (95% CI)	12	74 (0 - 218)	0 (0 - 0)

Table 15.19.7.2.2 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N<541)	Pericarditis cohort (N=23)
Male				
	Events, n	3	8	0
	Persons at risk	3	409	64
	Risk (95% CI)	3	176 (54 - 297)	0 (0 - 0)
	Events, n	6	8	0
	Persons at risk	6	381	63
	Risk (95% CI)	6	176 (54 - 297)	0 (0 - 0)
	Events, n	9	8	0
	Persons at risk	9	343	57
	Risk (95% CI)	9	176 (54 - 297)	0 (0 - 0)
	Events, n	12	8	0
	Persons at risk	12	316	47
	Risk (95% CI)	12	176 (54 - 297)	0 (0 - 0)
Female				
	Events, n	3	<5	0
	Persons at risk	3	<290	30
	Risk (95% CI)	3	138 (0 - 292)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<290	28
	Risk (95% CI)	6	138 (0 - 292)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<290	27
	Risk (95% CI)	9	138 (0 - 292)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<290	26
	Risk (95% CI)	12	138 (0 - 292)	0 (0 - 0)

Table 15.19.7.2.3 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N<290)	Pericarditis cohort (N=32)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<371	17
	Risk (95% CI)	3	108 (0 - 315)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<371	17
	Risk (95% CI)	6	108 (0 - 315)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<371	15
	Risk (95% CI)	9	108 (0 - 315)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<371	13
	Risk (95% CI)	12	108 (0 - 315)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	41	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	35	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.7.2.4 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N=42)	Pericarditis cohort (N=5)
No				
	Events, n	3	8	0
	Persons at risk	3	510	81
	Risk (95% CI)	3	145 (45 - 245)	0 (0 - 0)
	Events, n	6	8	0
	Persons at risk	6	478	79
	Risk (95% CI)	6	145 (45 - 245)	0 (0 - 0)
	Events, n	9	8	0
	Persons at risk	9	439	74
	Risk (95% CI)	9	145 (45 - 245)	0 (0 - 0)
	Events, n	12	8	0
	Persons at risk	12	409	65
	Risk (95% CI)	12	145 (45 - 245)	0 (0 - 0)
Yes				
	Events, n	3	<5	0
	Persons at risk	3	<162	13
	Risk (95% CI)	3	248 (0 - 521)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<162	12
	Risk (95% CI)	6	248 (0 - 521)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<162	10
	Risk (95% CI)	9	248 (0 - 521)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<162	8
	Risk (95% CI)	12	248 (0 - 521)	0 (0 - 0)

Table 15.19.7.2.5 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<162)	Pericarditis cohort (N=15)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	36	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	35	5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<358	28
	Risk (95% CI)	3	112 (0 - 237)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<358	27
	Risk (95% CI)	6	112 (0 - 237)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<358	26
	Risk (95% CI)	9	112 (0 - 237)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<358	21
	Risk (95% CI)	12	112 (0 - 237)	0 (0 - 0)

Table 15.19.7.2.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<358)	Pericarditis cohort (N=31)
Unvaccinated				
	Events, n	3	8	0
	Persons at risk	3	341	61
	Risk (95% CI)	3	217 (67 - 365)	0 (0 - 0)
	Events, n	6	8	0
	Persons at risk	6	319	59
	Risk (95% CI)	6	217 (67 - 365)	0 (0 - 0)
	Events, n	9	8	0
	Persons at risk	9	297	53
	Risk (95% CI)	9	217 (67 - 365)	0 (0 - 0)
	Events, n	12	8	0
	Persons at risk	12	277	47
	Risk (95% CI)	12	217 (67 - 365)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<351	10
	Risk (95% CI)	3	114 (0 - 333)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<351	10
	Risk (95% CI)	6	114 (0 - 333)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<351	10
	Risk (95% CI)	9	114 (0 - 333)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.7.2.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<358)	Pericarditis cohort (N=31)
	Persons at risk	12	<351	9
	Risk (95% CI)	12	114 (0 - 333)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<580	15
	Risk (95% CI)	3	69 (0 - 203)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<580	14
	Risk (95% CI)	6	69 (0 - 203)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<580	13
	Risk (95% CI)	9	69 (0 - 203)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<580	11
	Risk (95% CI)	12	69 (0 - 203)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

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Table 15.19.7.2.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<358)	Pericarditis cohort (N=31)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<149	<5
	Risk (95% CI)	3	270 (0 - 779)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<149	<5
	Risk (95% CI)	6	270 (0 - 779)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<149	<5
	Risk (95% CI)	9	270 (0 - 779)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<149	<5
	Risk (95% CI)	12	270 (0 - 779)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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Table 15.19.7.2.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<358)	Pericarditis cohort (N=31)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.7.3.1 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N=5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	6	0
	Persons at risk	3	181	261
	Risk (95% CI)	3	294 (59 - 523)	0 (0 - 0)
	Events, n	6	6	0
	Persons at risk	6	155	233
	Risk (95% CI)	6	294 (59 - 523)	0 (0 - 0)
	Events, n	9	6	0
	Persons at risk	9	132	205
	Risk (95% CI)	9	294 (59 - 523)	0 (0 - 0)
	Events, n	12	6	0
	Persons at risk	12	110	176
	Risk (95% CI)	12	294 (59 - 523)	0 (0 - 0)

Table 15.19.7.3.2 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N=204)	Pericarditis cohort (N=289)
Male				
	Events, n	3	22	<5
	Persons at risk	3	463	<5000
	Risk (95% CI)	3	406 (239 - 571)	8 (0 - 22)
	Events, n	6	22	<5
	Persons at risk	6	397	<5000
	Risk (95% CI)	6	406 (239 - 571)	8 (0 - 22)
	Events, n	9	22	<5
	Persons at risk	9	344	<2223
	Risk (95% CI)	9	406 (239 - 571)	18 (0 - 42)
	Events, n	12	22	<5
	Persons at risk	12	299	<2223
	Risk (95% CI)	12	406 (239 - 571)	18 (0 - 42)
Female				
	Events, n	3	13	0
	Persons at risk	3	216	559
	Risk (95% CI)	3	485 (224 - 739)	0 (0 - 0)
	Events, n	6	14	0
	Persons at risk	6	194	479
	Risk (95% CI)	6	530 (255 - 796)	0 (0 - 0)
	Events, n	9	14	0
	Persons at risk	9	169	424
	Risk (95% CI)	9	530 (255 - 796)	0 (0 - 0)
	Events, n	12	14	0
	Persons at risk	12	142	360
	Risk (95% CI)	12	530 (255 - 796)	0 (0 - 0)

Table 15.19.7.3.3 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=626)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<171	203
	Risk (95% CI)	3	235 (5 - 461)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<171	185
	Risk (95% CI)	6	235 (5 - 461)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<171	162
	Risk (95% CI)	9	235 (5 - 461)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<171	139
	Risk (95% CI)	12	235 (5 - 461)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<69	58
	Risk (95% CI)	3	588 (0 - 1347)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<69	48
	Risk (95% CI)	6	588 (0 - 1347)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<69	43
	Risk (95% CI)	9	588 (0 - 1347)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<69	37
	Risk (95% CI)	12	588 (0 - 1347)	0 (0 - 0)

Table 15.19.7.3.4 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N<69)	Pericarditis cohort (N=61)
No				
	Events, n	3	29	0
	Persons at risk	3	585	1586
	Risk (95% CI)	3	420 (269 - 568)	0 (0 - 0)
	Events, n	6	30	0
	Persons at risk	6	520	1401
	Risk (95% CI)	6	437 (282 - 588)	0 (0 - 0)
	Events, n	9	30	<5
	Persons at risk	9	462	<5715
	Risk (95% CI)	9	437 (282 - 588)	7 (0 - 22)
	Events, n	12	30	<5
	Persons at risk	12	411	<5715
	Risk (95% CI)	12	437 (282 - 588)	7 (0 - 22)
Yes				
	Events, n	3	6	<5
	Persons at risk	3	94	<817
	Risk (95% CI)	3	505 (103 - 891)	49 (0 - 144)
	Events, n	6	6	<5
	Persons at risk	6	71	<817
	Risk (95% CI)	6	505 (103 - 891)	49 (0 - 144)
	Events, n	9	6	<5
	Persons at risk	9	51	<817
	Risk (95% CI)	9	505 (103 - 891)	49 (0 - 144)
	Events, n	12	6	<5
	Persons at risk	12	30	<817
	Risk (95% CI)	12	505 (103 - 891)	49 (0 - 144)

Table 15.19.7.3.5 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N<817)
Vaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<88	186
	Risk (95% CI)	3	455 (0 - 944)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<88	178
	Risk (95% CI)	6	455 (0 - 944)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<88	176
	Risk (95% CI)	9	455 (0 - 944)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<88	167
	Risk (95% CI)	12	455 (0 - 944)	0 (0 - 0)
Unvaccinated				
	Events, n	3	20	<5
	Persons at risk	3	384	<5000
	Risk (95% CI)	3	423 (239 - 602)	8 (0 - 25)
	Events, n	6	21	<5
	Persons at risk	6	314	<5000
	Risk (95% CI)	6	448 (258 - 633)	8 (0 - 25)
	Events, n	9	21	<5
	Persons at risk	9	247	<1905
	Risk (95% CI)	9	448 (258 - 633)	21 (0 - 50)
	Events, n	12	21	<5
	Persons at risk	12	189	<1905
	Risk (95% CI)	12	448 (258 - 633)	21 (0 - 50)

Table 15.19.7.3.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N<5000)
Unvaccinated				
	Events, n	3	12	0
	Persons at risk	3	236	517
	Risk (95% CI)	3	446 (196 - 689)	0 (0 - 0)
	Events, n	6	12	0
	Persons at risk	6	223	501
	Risk (95% CI)	6	446 (196 - 689)	0 (0 - 0)
	Events, n	9	12	0
	Persons at risk	9	213	481
	Risk (95% CI)	9	446 (196 - 689)	0 (0 - 0)
	Events, n	12	12	0
	Persons at risk	12	201	453
	Risk (95% CI)	12	446 (196 - 689)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	18	49
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	49
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	16	49
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	16	48
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<87	129
	Risk (95% CI)	3	460 (0 - 956)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<87	120
	Risk (95% CI)	6	460 (0 - 956)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<87	112
	Risk (95% CI)	9	460 (0 - 956)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.7.3.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N<5000)
	Persons at risk	12	<87	104
	Risk (95% CI)	12	460 (0 - 956)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	59
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	58
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	58
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	58
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	9	0
	Persons at risk	3	200	494
	Risk (95% CI)	3	391 (137 - 639)	0 (0 - 0)
	Events, n	6	9	0
	Persons at risk	6	182	458
	Risk (95% CI)	6	391 (137 - 639)	0 (0 - 0)
	Events, n	9	9	<5
	Persons at risk	9	163	<1819
	Risk (95% CI)	9	391 (137 - 639)	22 (0 - 66)
	Events, n	12	9	<5
	Persons at risk	12	146	<1819
	Risk (95% CI)	12	391 (137 - 639)	22 (0 - 66)
Received dose 3 in the last 14 days				
	Events, n	3	<5	0
	Persons at risk	3	<27	23
	Risk (95% CI)	3	1538 (0 - 3289)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<27	22
	Risk (95% CI)	6	1538 (0 - 3289)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<27	21

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Table 15.19.7.3.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N<5000)
	Risk (95% CI)	9	1538 (0 - 3289)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<27	18
	Risk (95% CI)	12	1538 (0 - 3289)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	7	<5
	Persons at risk	3	131	<2000
	Risk (95% CI)	3	406 (107 - 697)	20 (0 - 58)
	Events, n	6	8	<5
	Persons at risk	6	91	<2000
	Risk (95% CI)	6	480 (148 - 801)	20 (0 - 58)
	Events, n	9	8	<5
	Persons at risk	9	50	<2000
	Risk (95% CI)	9	480 (148 - 801)	20 (0 - 58)
	Events, n	12	8	<5
	Persons at risk	12	15	<2000
	Risk (95% CI)	12	480 (148 - 801)	20 (0 - 58)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<49	41
	Risk (95% CI)	3	833 (0 - 1875)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<5	10
	Risk (95% CI)	6	833 (0 - 1875)	0 (0 - 0)

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Table 15.19.7.3.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N<5000)
	Events, n	9	<5	0
	Persons at risk	9	<5	5
	Risk (95% CI)	9	833 (0 - 1875)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.7.4.1 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N<49)	Pericarditis cohort (N=75)
15-30				
	Events, n	3	0	0
	Persons at risk	3	37	87
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	37	82
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	75
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	62
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.7.4.2 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N=39)	Pericarditis cohort (N=94)
Male				
	Events, n	3	<5	0
	Persons at risk	3	<364	282
	Risk (95% CI)	3	110 (0 - 322)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<364	257
	Risk (95% CI)	6	110 (0 - 322)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<364	237
	Risk (95% CI)	9	110 (0 - 322)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<364	209
	Risk (95% CI)	12	110 (0 - 322)	0 (0 - 0)
Female				
	Events, n	3	<5	<5
	Persons at risk	3	<100	<482
	Risk (95% CI)	3	400 (0 - 1138)	83 (0 - 243)
	Events, n	6	<5	<5
	Persons at risk	6	<100	<482
	Risk (95% CI)	6	400 (0 - 1138)	83 (0 - 243)
	Events, n	9	<5	<5
	Persons at risk	9	<100	<482
	Risk (95% CI)	9	400 (0 - 1138)	83 (0 - 243)
	Events, n	12	<5	<5
	Persons at risk	12	<100	<482
	Risk (95% CI)	12	400 (0 - 1138)	83 (0 - 243)

Table 15.19.7.4.3 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N<100)	Pericarditis cohort (N<482)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	36	71
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	36	68
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	33	63
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	51
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.7.4.4 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	<5	<5
	Persons at risk	3	<328	<1250
	Risk (95% CI)	3	122 (0 - 357)	32 (0 - 93)
	Events, n	6	<5	<5
	Persons at risk	6	<328	<1250
	Risk (95% CI)	6	122 (0 - 357)	32 (0 - 93)
	Events, n	9	<5	<5
	Persons at risk	9	<328	<1250
	Risk (95% CI)	9	122 (0 - 357)	32 (0 - 93)
	Events, n	12	<5	<5
	Persons at risk	12	<328	<1250
	Risk (95% CI)	12	122 (0 - 357)	32 (0 - 93)
Yes				
	Events, n	3	<5	0
	Persons at risk	3	<137	103
	Risk (95% CI)	3	294 (0 - 846)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<137	89
	Risk (95% CI)	6	294 (0 - 846)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<137	78
	Risk (95% CI)	9	294 (0 - 846)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<137	64
	Risk (95% CI)	12	294 (0 - 846)	0 (0 - 0)

Table 15.19.7.4.5 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<137)	Pericarditis cohort (N=118)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	9	29
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	29
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	9	28
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	27
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	<5	<5
	Persons at risk	3	<130	<1082
	Risk (95% CI)	3	308 (0 - 719)	37 (0 - 108)
	Events, n	6	<5	<5
	Persons at risk	6	<130	<1082
	Risk (95% CI)	6	308 (0 - 719)	37 (0 - 108)
	Events, n	9	<5	<5
	Persons at risk	9	<130	<1082
	Risk (95% CI)	9	308 (0 - 719)	37 (0 - 108)
	Events, n	12	<5	<5
	Persons at risk	12	<130	<1082
	Risk (95% CI)	12	308 (0 - 719)	37 (0 - 108)

Table 15.19.7.4.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<130)	Pericarditis cohort (N<1082)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	38	120
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	117
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	37	114
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	34	113
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<49	19
	Risk (95% CI)	3	833 (0 - 2271)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<49	18
	Risk (95% CI)	6	833 (0 - 2271)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<49	17
	Risk (95% CI)	9	833 (0 - 2271)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.7.4.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<130)	Pericarditis cohort (N<1082)
	Persons at risk	12	<49	12
	Risk (95% CI)	12	833 (0 - 2271)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	33	162
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	31	147
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	27	129
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	23	113
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

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Table 15.19.7.4.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<130)	Pericarditis cohort (N<1082)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<88	<297
	Risk (95% CI)	3	455 (0 - 1286)	135 (0 - 395)
	Events, n	6	<5	<5
	Persons at risk	6	<88	<297
	Risk (95% CI)	6	455 (0 - 1286)	135 (0 - 395)
	Events, n	9	<5	<5
	Persons at risk	9	<88	<297
	Risk (95% CI)	9	455 (0 - 1286)	135 (0 - 395)
	Events, n	12	<5	<5
	Persons at risk	12	<88	<297
	Risk (95% CI)	12	455 (0 - 1286)	135 (0 - 395)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)

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Table 15.19.7.4.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<130)	Pericarditis cohort (N<1082)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.7.5.1 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=11)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<159	249
	Risk (95% CI)	3	253 (0 - 531)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<159	236
	Risk (95% CI)	6	253 (0 - 531)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<159	225
	Risk (95% CI)	9	253 (0 - 531)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<159	215
	Risk (95% CI)	12	253 (0 - 531)	0 (0 - 0)

Table 15.19.7.5.2 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N<159)	Pericarditis cohort (N=271)
Male				
	Events, n	3	19	0
	Persons at risk	3	353	981
	Risk (95% CI)	3	459 (255 - 659)	0 (0 - 0)
	Events, n	6	19	0
	Persons at risk	6	299	922
	Risk (95% CI)	6	459 (255 - 659)	0 (0 - 0)
	Events, n	9	19	0
	Persons at risk	9	244	875
	Risk (95% CI)	9	459 (255 - 659)	0 (0 - 0)
	Events, n	12	21	0
	Persons at risk	12	218	821
	Risk (95% CI)	12	542 (309 - 769)	0 (0 - 0)
Female				
	Events, n	3	7	<5
	Persons at risk	3	237	<2353
	Risk (95% CI)	3	267 (70 - 460)	17 (0 - 50)
	Events, n	6	7	<5
	Persons at risk	6	200	<2353
	Risk (95% CI)	6	267 (70 - 460)	17 (0 - 50)
	Events, n	9	8	<5
	Persons at risk	9	148	<2353
	Risk (95% CI)	9	320 (98 - 538)	17 (0 - 50)
	Events, n	12	8	<5
	Persons at risk	12	131	<2353
	Risk (95% CI)	12	320 (98 - 538)	17 (0 - 50)

Table 15.19.7.5.3 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N<2353)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<378	196
	Risk (95% CI)	3	106 (0 - 312)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<378	188
	Risk (95% CI)	6	106 (0 - 312)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<378	181
	Risk (95% CI)	9	106 (0 - 312)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<378	175
	Risk (95% CI)	12	106 (0 - 312)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<49	53
	Risk (95% CI)	3	833 (0 - 1875)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<49	48
	Risk (95% CI)	6	833 (0 - 1875)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<49	44
	Risk (95% CI)	9	833 (0 - 1875)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<49	40
	Risk (95% CI)	12	833 (0 - 1875)	0 (0 - 0)

Table 15.19.7.5.4 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N<49)	Pericarditis cohort (N=57)
No				
	Events, n	3	15	<5
	Persons at risk	3	314	<5000
	Risk (95% CI)	3	417 (208 - 621)	8 (0 - 25)
	Events, n	6	15	<5
	Persons at risk	6	274	<5000
	Risk (95% CI)	6	417 (208 - 621)	8 (0 - 25)
	Events, n	9	16	<5
	Persons at risk	9	228	<5000
	Risk (95% CI)	9	454 (233 - 669)	8 (0 - 25)
	Events, n	12	18	<5
	Persons at risk	12	205	<5000
	Risk (95% CI)	12	542 (291 - 787)	8 (0 - 25)
Yes				
	Events, n	3	11	0
	Persons at risk	3	276	417
	Risk (95% CI)	3	348 (144 - 548)	0 (0 - 0)
	Events, n	6	11	0
	Persons at risk	6	225	372
	Risk (95% CI)	6	348 (144 - 548)	0 (0 - 0)
	Events, n	9	11	0
	Persons at risk	9	164	338
	Risk (95% CI)	9	348 (144 - 548)	0 (0 - 0)
	Events, n	12	11	0
	Persons at risk	12	144	300
	Risk (95% CI)	12	348 (144 - 548)	0 (0 - 0)

Table 15.19.7.5.5 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=316)	Pericarditis cohort (N=477)
Vaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<113	127
	Risk (95% CI)	3	357 (0 - 1021)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<113	125
	Risk (95% CI)	6	357 (0 - 1021)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<113	122
	Risk (95% CI)	9	357 (0 - 1021)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<113	120
	Risk (95% CI)	12	357 (0 - 1021)	0 (0 - 0)
Unvaccinated				
	Events, n	3	7	0
	Persons at risk	3	310	658
	Risk (95% CI)	3	196 (51 - 338)	0 (0 - 0)
	Events, n	6	7	0
	Persons at risk	6	251	593
	Risk (95% CI)	6	196 (51 - 338)	0 (0 - 0)
	Events, n	9	8	0
	Persons at risk	9	182	536
	Risk (95% CI)	9	238 (71 - 402)	0 (0 - 0)
	Events, n	12	9	0
	Persons at risk	12	149	473
	Risk (95% CI)	12	303 (93 - 509)	0 (0 - 0)

Table 15.19.7.5.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
Unvaccinated				
	Events, n	3	18	<5
	Persons at risk	3	253	<3077
	Risk (95% CI)	3	621 (339 - 894)	13 (0 - 39)
	Events, n	6	18	<5
	Persons at risk	6	221	<3077
	Risk (95% CI)	6	621 (339 - 894)	13 (0 - 39)
	Events, n	9	18	<5
	Persons at risk	9	184	<3077
	Risk (95% CI)	9	621 (339 - 894)	13 (0 - 39)
	Events, n	12	19	<5
	Persons at risk	12	175	<3077
	Risk (95% CI)	12	672 (373 - 961)	13 (0 - 39)
Received dose 1 in the last 14 days				
	Events, n	3	<5	0
	Persons at risk	3	<32	42
	Risk (95% CI)	3	1250 (0 - 3266)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<32	42
	Risk (95% CI)	6	1250 (0 - 3266)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<32	41
	Risk (95% CI)	9	1250 (0 - 3266)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<32	40
	Risk (95% CI)	12	1250 (0 - 3266)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<96	61
	Risk (95% CI)	3	417 (0 - 966)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<96	59
	Risk (95% CI)	6	417 (0 - 966)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<96	58
	Risk (95% CI)	9	417 (0 - 966)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.7.5.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Persons at risk	12	<96	57
	Risk (95% CI)	12	417 (0 - 966)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	34
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	34
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	34
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	5	0
	Persons at risk	3	197	485
	Risk (95% CI)	3	222 (28 - 413)	0 (0 - 0)
	Events, n	6	5	0
	Persons at risk	6	164	454
	Risk (95% CI)	6	222 (28 - 413)	0 (0 - 0)
	Events, n	9	6	0
	Persons at risk	9	122	426
	Risk (95% CI)	9	288 (55 - 515)	0 (0 - 0)
	Events, n	12	7	0
	Persons at risk	12	101	391
	Risk (95% CI)	12	383 (84 - 673)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5

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Table 15.19.7.5.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	58	121
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	51	112
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	38	93
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	27	67
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	19	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	5	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.7.5.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.7.6.1 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=61)
15-30				
	Events, n	3	6	0
	Persons at risk	3	306	555
	Risk (95% CI)	3	169 (34 - 301)	0 (0 - 0)
	Events, n	6	6	0
	Persons at risk	6	264	490
	Risk (95% CI)	6	169 (34 - 301)	0 (0 - 0)
	Events, n	9	6	0
	Persons at risk	9	221	431
	Risk (95% CI)	9	169 (34 - 301)	0 (0 - 0)
	Events, n	12	6	0
	Persons at risk	12	184	366
	Risk (95% CI)	12	169 (34 - 301)	0 (0 - 0)

Table 15.19.7.6.2 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N=356)	Pericarditis cohort (N=644)
Male				
	Events, n	3	15	0
	Persons at risk	3	489	1128
	Risk (95% CI)	3	259 (129 - 388)	0 (0 - 0)
	Events, n	6	15	0
	Persons at risk	6	428	977
	Risk (95% CI)	6	259 (129 - 388)	0 (0 - 0)
	Events, n	9	15	0
	Persons at risk	9	372	847
	Risk (95% CI)	9	259 (129 - 388)	0 (0 - 0)
	Events, n	12	15	0
	Persons at risk	12	311	744
	Risk (95% CI)	12	259 (129 - 388)	0 (0 - 0)
Female				
	Events, n	3	8	0
	Persons at risk	3	245	500
	Risk (95% CI)	3	286 (89 - 479)	0 (0 - 0)
	Events, n	6	8	0
	Persons at risk	6	212	442
	Risk (95% CI)	6	286 (89 - 479)	0 (0 - 0)
	Events, n	9	8	0
	Persons at risk	9	175	384
	Risk (95% CI)	9	286 (89 - 479)	0 (0 - 0)
	Events, n	12	8	0
	Persons at risk	12	153	341
	Risk (95% CI)	12	286 (89 - 479)	0 (0 - 0)

Table 15.19.7.6.3 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N=281)	Pericarditis cohort (N=548)
Male, 15-30 years				
	Events, n	3	5	0
	Persons at risk	3	247	413
	Risk (95% CI)	3	171 (21 - 319)	0 (0 - 0)
	Events, n	6	5	0
	Persons at risk	6	216	361
	Risk (95% CI)	6	171 (21 - 319)	0 (0 - 0)
	Events, n	9	5	0
	Persons at risk	9	181	323
	Risk (95% CI)	9	171 (21 - 319)	0 (0 - 0)
	Events, n	12	5	0
	Persons at risk	12	152	271
	Risk (95% CI)	12	171 (21 - 319)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<257	142
	Risk (95% CI)	3	156 (0 - 455)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<257	129
	Risk (95% CI)	6	156 (0 - 455)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<257	108
	Risk (95% CI)	9	156 (0 - 455)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<257	95
	Risk (95% CI)	12	156 (0 - 455)	0 (0 - 0)

Table 15.19.7.6.4 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N<257)	Pericarditis cohort (N=159)
No				
	Events, n	3	13	0
	Persons at risk	3	514	1231
	Risk (95% CI)	3	218 (100 - 335)	0 (0 - 0)
	Events, n	6	13	0
	Persons at risk	6	454	1096
	Risk (95% CI)	6	218 (100 - 335)	0 (0 - 0)
	Events, n	9	13	0
	Persons at risk	9	398	971
	Risk (95% CI)	9	218 (100 - 335)	0 (0 - 0)
	Events, n	12	13	0
	Persons at risk	12	348	874
	Risk (95% CI)	12	218 (100 - 335)	0 (0 - 0)
Yes				
	Events, n	3	10	0
	Persons at risk	3	220	397
	Risk (95% CI)	3	382 (147 - 612)	0 (0 - 0)
	Events, n	6	10	0
	Persons at risk	6	186	323
	Risk (95% CI)	6	382 (147 - 612)	0 (0 - 0)
	Events, n	9	10	0
	Persons at risk	9	149	260
	Risk (95% CI)	9	382 (147 - 612)	0 (0 - 0)
	Events, n	12	10	0
	Persons at risk	12	116	211
	Risk (95% CI)	12	382 (147 - 612)	0 (0 - 0)

Table 15.19.7.6.5 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N=454)
Vaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<249	98
	Risk (95% CI)	3	161 (0 - 470)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<249	96
	Risk (95% CI)	6	161 (0 - 470)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<249	96
	Risk (95% CI)	9	161 (0 - 470)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<249	93
	Risk (95% CI)	12	161 (0 - 470)	0 (0 - 0)
Unvaccinated				
	Events, n	3	13	0
	Persons at risk	3	381	848
	Risk (95% CI)	3	290 (133 - 444)	0 (0 - 0)
	Events, n	6	13	0
	Persons at risk	6	309	700
	Risk (95% CI)	6	290 (133 - 444)	0 (0 - 0)
	Events, n	9	13	0
	Persons at risk	9	243	560
	Risk (95% CI)	9	290 (133 - 444)	0 (0 - 0)
	Events, n	12	13	0
	Persons at risk	12	190	456
	Risk (95% CI)	12	290 (133 - 444)	0 (0 - 0)

Table 15.19.7.6.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
Unvaccinated				
	Events, n	3	9	0
	Persons at risk	3	295	682
	Risk (95% CI)	3	259 (91 - 425)	0 (0 - 0)
	Events, n	6	9	0
	Persons at risk	6	274	623
	Risk (95% CI)	6	259 (91 - 425)	0 (0 - 0)
	Events, n	9	9	0
	Persons at risk	9	249	575
	Risk (95% CI)	9	259 (91 - 425)	0 (0 - 0)
	Events, n	12	9	0
	Persons at risk	12	223	536
	Risk (95% CI)	12	259 (91 - 425)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	17	27
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	26
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	17	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	17	25
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	6	0
	Persons at risk	3	68	160
	Risk (95% CI)	3	731 (150 - 1277)	0 (0 - 0)
	Events, n	6	6	0
	Persons at risk	6	59	144
	Risk (95% CI)	6	731 (150 - 1277)	0 (0 - 0)
	Events, n	9	6	0
	Persons at risk	9	53	118
	Risk (95% CI)	9	731 (150 - 1277)	0 (0 - 0)
	Events, n	12	6	0

Table 15.19.7.6.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Persons at risk	12	44	105
	Risk (95% CI)	12	731 (150 - 1277)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	<5	0
	Persons at risk	3	<100	24
	Risk (95% CI)	3	400 (0 - 1138)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<100	24
	Risk (95% CI)	6	400 (0 - 1138)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<100	24
	Risk (95% CI)	9	400 (0 - 1138)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<100	23
	Risk (95% CI)	12	400 (0 - 1138)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<198	372
	Risk (95% CI)	3	203 (4 - 398)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<198	321
	Risk (95% CI)	6	203 (4 - 398)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<198	279
	Risk (95% CI)	9	203 (4 - 398)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<198	247
	Risk (95% CI)	12	203 (4 - 398)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	6	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	6	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	5	9

Table 15.19.7.6.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<230	329
	Risk (95% CI)	3	174 (0 - 368)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<230	258
	Risk (95% CI)	6	174 (0 - 368)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<230	193
	Risk (95% CI)	9	174 (0 - 368)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<230	137
	Risk (95% CI)	12	174 (0 - 368)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	8	25
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.7.6.6 Risk (1-KM and 95% CI) for FULMINANT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Events, n	9	0	0
	Persons at risk	9	<5	7
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.1.1 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N=10)	Pericarditis cohort (N=30)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.8.1.2 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.8.1.3 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.8.1.4 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.8.1.5 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.8.1.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.8.1.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

Table 15.19.8.1.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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Table 15.19.8.1.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.8.2.1 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	123	21
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	113	20
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	103	18
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	93	17
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.2.2 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N=130)	Pericarditis cohort (N=23)
Male				
	Events, n	3	0	0
	Persons at risk	3	403	63
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	371	61
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	338	51
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	301	46
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	199	28
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	182	28
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	165	27
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	150	26
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.2.3 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N=213)	Pericarditis cohort (N=30)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	84	17
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	77	16
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	71	14
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	64	13
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	39	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	36	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	32	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.2.4 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N=41)	Pericarditis cohort (N=5)
No				
	Events, n	3	0	0
	Persons at risk	3	505	79
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	471	78
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	436	69
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	402	64
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	97	12
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	82	11
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	67	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	49	8
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.2.5 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=114)	Pericarditis cohort (N=14)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	36	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	35	5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	32	5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	229	27
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	202	27
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	176	24
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	149	21
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.2.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N=30)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	337	59
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	316	57
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	293	49
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	270	46
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	80	10
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	72	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	68	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.8.2.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N=30)
	Persons at risk	12	59	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	124	14
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	112	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	98	13
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	86	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

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Table 15.19.8.2.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N=30)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	30	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	24	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	16	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	10	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.8.2.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N=30)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.8.3.1 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	178	249
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	154	<976
	Risk (95% CI)	6	0 (0 - 0)	41 (0 - 121)
	Events, n	9	0	<5
	Persons at risk	9	131	<471
	Risk (95% CI)	9	0 (0 - 0)	85 (0 - 202)
	Events, n	12	0	<5
	Persons at risk	12	104	<471
	Risk (95% CI)	12	0 (0 - 0)	85 (0 - 202)

Table 15.19.8.3.2 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N=200)	Pericarditis cohort (N<976)
Male				
	Events, n	3	0	0
	Persons at risk	3	458	1124
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	399	<2223
	Risk (95% CI)	6	0 (0 - 0)	18 (0 - 43)
	Events, n	9	0	<5
	Persons at risk	9	347	<2223
	Risk (95% CI)	9	0 (0 - 0)	18 (0 - 43)
	Events, n	12	0	<5
	Persons at risk	12	293	<2223
	Risk (95% CI)	12	0 (0 - 0)	18 (0 - 43)
Female				
	Events, n	3	0	<5
	Persons at risk	3	219	<2223
	Risk (95% CI)	3	0 (0 - 0)	18 (0 - 54)
	Events, n	6	0	<5
	Persons at risk	6	191	<1026
	Risk (95% CI)	6	0 (0 - 0)	39 (0 - 92)
	Events, n	9	<5	7
	Persons at risk	9	<715	401
	Risk (95% CI)	9	56 (0 - 166)	153 (39 - 266)
	Events, n	12	<5	8
	Persons at risk	12	<715	328
	Risk (95% CI)	12	56 (0 - 166)	182 (55 - 308)

Table 15.19.8.3.3 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N<715)	Pericarditis cohort (N<2223)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	147	196
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	126	<770
	Risk (95% CI)	6	0 (0 - 0)	52 (0 - 153)
	Events, n	9	0	<5
	Persons at risk	9	108	<770
	Risk (95% CI)	9	0 (0 - 0)	52 (0 - 153)
	Events, n	12	0	<5
	Persons at risk	12	88	<770
	Risk (95% CI)	12	0 (0 - 0)	52 (0 - 153)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	31	53
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	28	46
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	<5
	Persons at risk	9	23	<185
	Risk (95% CI)	9	0 (0 - 0)	217 (0 - 630)
	Events, n	12	0	<5
	Persons at risk	12	16	<185
	Risk (95% CI)	12	0 (0 - 0)	217 (0 - 630)

Table 15.19.8.3.4 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N=33)	Pericarditis cohort (N<185)
No				
	Events, n	3	0	<5
	Persons at risk	3	586	<6667
	Risk (95% CI)	3	0 (0 - 0)	6 (0 - 19)
	Events, n	6	0	<5
	Persons at risk	6	520	<1482
	Risk (95% CI)	6	0 (0 - 0)	27 (1 - 53)
	Events, n	9	<5	9
	Persons at risk	9	<1905	1179
	Risk (95% CI)	9	21 (0 - 61)	66 (23 - 109)
	Events, n	12	<5	10
	Persons at risk	12	<1905	996
	Risk (95% CI)	12	21 (0 - 61)	76 (29 - 123)
Yes				
	Events, n	3	0	0
	Persons at risk	3	91	139
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	70	108
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	47	66
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	27	22
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.3.5 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=114)	Pericarditis cohort (N=197)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	62	183
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	57	<728
	Risk (95% CI)	6	0 (0 - 0)	55 (0 - 162)
	Events, n	9	0	<5
	Persons at risk	9	56	<728
	Risk (95% CI)	9	0 (0 - 0)	55 (0 - 162)
	Events, n	12	0	<5
	Persons at risk	12	48	<728
	Risk (95% CI)	12	0 (0 - 0)	55 (0 - 162)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	373	<4000
	Risk (95% CI)	3	0 (0 - 0)	10 (0 - 29)
	Events, n	6	0	<5
	Persons at risk	6	305	<1250
	Risk (95% CI)	6	0 (0 - 0)	32 (0 - 69)
	Events, n	9	0	<5
	Persons at risk	9	238	<817
	Risk (95% CI)	9	0 (0 - 0)	49 (0 - 97)
	Events, n	12	0	<5
	Persons at risk	12	175	<817
	Risk (95% CI)	12	0 (0 - 0)	49 (0 - 97)

Table 15.19.8.3.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=446)	Pericarditis cohort (N<4000)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	242	511
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	228	495
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	<5	<5
	Persons at risk	9	<889	<488
	Risk (95% CI)	9	45 (0 - 133)	82 (2 - 162)
	Events, n	12	<5	5
	Persons at risk	12	<889	439
	Risk (95% CI)	12	45 (0 - 133)	104 (13 - 195)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	18	49
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	49
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	16	49
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	16	47
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	59	124
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	56	118
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	49	110
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.8.3.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=446)	Pericarditis cohort (N<4000)
	Persons at risk	12	41	100
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	58
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	12	<233
	Risk (95% CI)	6	0 (0 - 0)	172 (0 - 502)
	Events, n	9	0	<5
	Persons at risk	9	12	<233
	Risk (95% CI)	9	0 (0 - 0)	172 (0 - 502)
	Events, n	12	0	<5
	Persons at risk	12	11	<233
	Risk (95% CI)	12	0 (0 - 0)	172 (0 - 502)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	201	478
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	181	<931
	Risk (95% CI)	6	0 (0 - 0)	43 (0 - 102)
	Events, n	9	0	<5
	Persons at risk	9	164	<931
	Risk (95% CI)	9	0 (0 - 0)	43 (0 - 102)
	Events, n	12	0	<5
	Persons at risk	12	138	<931
	Risk (95% CI)	12	0 (0 - 0)	43 (0 - 102)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	23
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	21
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	21

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Table 15.19.8.3.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=446)	Pericarditis cohort (N<4000)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	8	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	124	<1667
	Risk (95% CI)	3	0 (0 - 0)	24 (0 - 71)
	Events, n	6	0	<5
	Persons at risk	6	82	<1667
	Risk (95% CI)	6	0 (0 - 0)	24 (0 - 71)
	Events, n	9	0	<5
	Persons at risk	9	39	<413
	Risk (95% CI)	9	0 (0 - 0)	97 (0 - 247)
	Events, n	12	0	<5
	Persons at risk	12	9	<413
	Risk (95% CI)	12	0 (0 - 0)	97 (0 - 247)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	5	22
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	7
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.3.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=446)	Pericarditis cohort (N<4000)
	Events, n	9	0	0
	Persons at risk	9	<5	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.8.4.1 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N=21)	Pericarditis cohort (N=70)
15-30				
	Events, n	3	0	0
	Persons at risk	3	36	86
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	34	78
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	31	72
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	61
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.4.2 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N=38)	Pericarditis cohort (N=91)
Male				
	Events, n	3	<5	0
	Persons at risk	3	<320	277
	Risk (95% CI)	3	125 (0 - 365)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<320	251
	Risk (95% CI)	6	125 (0 - 365)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<320	228
	Risk (95% CI)	9	125 (0 - 365)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<320	205
	Risk (95% CI)	12	125 (0 - 365)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	18	100
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	18	89
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	14	81
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	73
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.4.3 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N=20)	Pericarditis cohort (N=111)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	35	70
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	33	65
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	30	60
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	50
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	13
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.4.4 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	0	0
	Persons at risk	3	75	277
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	72	255
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	64	234
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	61	217
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	<5	0
	Persons at risk	3	<96	100
	Risk (95% CI)	3	417 (0 - 1184)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<96	85
	Risk (95% CI)	6	417 (0 - 1184)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<96	75
	Risk (95% CI)	9	417 (0 - 1184)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<96	61
	Risk (95% CI)	12	417 (0 - 1184)	0 (0 - 0)

Table 15.19.8.4.5 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<96)	Pericarditis cohort (N=109)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	9	29
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	29
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	9	27
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	27
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	52	228
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	47	195
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	40	169
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	36	141
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.4.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=56)	Pericarditis cohort (N=253)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<149	120
	Risk (95% CI)	3	270 (0 - 779)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<149	116
	Risk (95% CI)	6	270 (0 - 779)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<149	113
	Risk (95% CI)	9	270 (0 - 779)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<149	110
	Risk (95% CI)	12	270 (0 - 779)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	9	19
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	8	18
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	8	17
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.8.4.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=56)	Pericarditis cohort (N=253)
	Persons at risk	12	7	12
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	33	157
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	30	142
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	25	125
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	23	110
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.8.4.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=56)	Pericarditis cohort (N=253)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	13	54
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	41
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	10	33
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	25
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)

Table 15.19.8.4.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=56)	Pericarditis cohort (N=253)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.8.5.1 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=7)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<413	245
	Risk (95% CI)	3	97 (0 - 285)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<413	233
	Risk (95% CI)	6	97 (0 - 285)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<413	219
	Risk (95% CI)	9	97 (0 - 285)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<100	208
	Risk (95% CI)	12	400 (0 - 841)	0 (0 - 0)

Table 15.19.8.5.2 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N<413)	Pericarditis cohort (N=264)
Male				
	Events, n	3	<5	0
	Persons at risk	3	<488	966
	Risk (95% CI)	3	82 (0 - 173)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<488	905
	Risk (95% CI)	6	82 (0 - 173)	0 (0 - 0)
	Events, n	9	<5	<5
	Persons at risk	9	<328	<3334
	Risk (95% CI)	9	122 (0 - 242)	12 (0 - 34)
	Events, n	12	6	<5
	Persons at risk	12	216	<1667
	Risk (95% CI)	12	209 (38 - 378)	24 (0 - 57)
Female				
	Events, n	3	<5	<5
	Persons at risk	3	<953	<2106
	Risk (95% CI)	3	42 (0 - 124)	19 (0 - 55)
	Events, n	6	<5	<5
	Persons at risk	6	<417	<2106
	Risk (95% CI)	6	96 (0 - 227)	19 (0 - 55)
	Events, n	9	<5	<5
	Persons at risk	9	<417	<1026
	Risk (95% CI)	9	96 (0 - 227)	39 (0 - 93)
	Events, n	12	<5	<5
	Persons at risk	12	<240	<1026
	Risk (95% CI)	12	167 (0 - 357)	39 (0 - 93)

Table 15.19.8.5.3 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N<953)	Pericarditis cohort (N<2106)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<326	193
	Risk (95% CI)	3	123 (0 - 361)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<326	185
	Risk (95% CI)	6	123 (0 - 361)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<326	178
	Risk (95% CI)	9	123 (0 - 361)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<128	168
	Risk (95% CI)	12	313 (0 - 741)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	20	52
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	15	48
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	41
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<53	40
	Risk (95% CI)	12	769 (0 - 2110)	0 (0 - 0)

Table 15.19.8.5.4 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N=53)	Pericarditis cohort (N=56)
No				
	Events, n	3	<5	<5
	Persons at risk	3	<431	<4445
	Risk (95% CI)	3	93 (0 - 197)	9 (0 - 27)
	Events, n	6	<5	<5
	Persons at risk	6	<306	<4445
	Risk (95% CI)	6	131 (2 - 258)	9 (0 - 27)
	Events, n	9	5	<5
	Persons at risk	9	217	<1380
	Risk (95% CI)	9	174 (20 - 326)	29 (0 - 61)
	Events, n	12	5	<5
	Persons at risk	12	206	<1026
	Risk (95% CI)	12	174 (20 - 326)	39 (1 - 78)
Yes				
	Events, n	3	<5	0
	Persons at risk	3	<1112	411
	Risk (95% CI)	3	36 (0 - 105)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1112	362
	Risk (95% CI)	6	36 (0 - 105)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<1112	319
	Risk (95% CI)	9	36 (0 - 105)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<173	288
	Risk (95% CI)	12	232 (0 - 459)	0 (0 - 0)

Table 15.19.8.5.5 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<1112)	Pericarditis cohort (N=455)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	27	127
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	26	124
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	25	120
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	25	120
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	<5	<5
	Persons at risk	3	<635	<2667
	Risk (95% CI)	3	63 (0 - 150)	15 (0 - 44)
	Events, n	6	<5	<5
	Persons at risk	6	<374	<2667
	Risk (95% CI)	6	107 (0 - 228)	15 (0 - 44)
	Events, n	9	<5	<5
	Persons at risk	9	<374	<1177
	Risk (95% CI)	9	107 (0 - 228)	34 (0 - 81)
	Events, n	12	5	<5
	Persons at risk	12	140	<1177
	Risk (95% CI)	12	236 (19 - 448)	34 (0 - 81)

Table 15.19.8.5.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<635)	Pericarditis cohort (N<2667)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<527	724
	Risk (95% CI)	3	76 (0 - 180)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<527	700
	Risk (95% CI)	6	76 (0 - 180)	0 (0 - 0)
	Events, n	9	<5	<5
	Persons at risk	9	<313	<2858
	Risk (95% CI)	9	128 (0 - 273)	14 (0 - 43)
	Events, n	12	<5	<5
	Persons at risk	12	<220	<1380
	Risk (95% CI)	12	182 (1 - 360)	29 (0 - 70)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	7	42
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	6	42
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	6	40
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	6	40
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	43	60
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	33	58
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	29	57
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.8.5.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<635)	Pericarditis cohort (N<2667)
	Persons at risk	12	<57	57
	Risk (95% CI)	12	702 (0 - 1596)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	34
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	34
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	34
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<400	<2000
	Risk (95% CI)	3	100 (0 - 237)	20 (0 - 61)
	Events, n	6	<5	<5
	Persons at risk	6	<239	<2000
	Risk (95% CI)	6	168 (0 - 357)	20 (0 - 61)
	Events, n	9	<5	<5
	Persons at risk	9	<239	<910
	Risk (95% CI)	9	168 (0 - 357)	44 (0 - 105)
	Events, n	12	<5	<5
	Persons at risk	12	<239	<910
	Risk (95% CI)	12	168 (0 - 357)	44 (0 - 105)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5

Table 15.19.8.5.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<635)	Pericarditis cohort (N<2667)
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	57	119
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	42	107
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	78
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	25	60
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	15	30
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

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Table 15.19.8.5.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<635)	Pericarditis cohort (N<2667)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.8.6.1 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N=22)	Pericarditis cohort (N=51)
15-30				
	Events, n	3	0	<5
	Persons at risk	3	301	<2223
	Risk (95% CI)	3	0 (0 - 0)	18 (0 - 53)
	Events, n	6	<5	<5
	Persons at risk	6	<1213	<2223
	Risk (95% CI)	6	33 (0 - 99)	18 (0 - 53)
	Events, n	9	<5	<5
	Persons at risk	9	<1213	<2223
	Risk (95% CI)	9	33 (0 - 99)	18 (0 - 53)
	Events, n	12	<5	<5
	Persons at risk	12	<1213	<2223
	Risk (95% CI)	12	33 (0 - 99)	18 (0 - 53)

Table 15.19.8.6.2 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N<1213)	Pericarditis cohort (N<2223)
Male				
	Events, n	3	0	<5
	Persons at risk	3	489	<2353
	Risk (95% CI)	3	0 (0 - 0)	17 (0 - 42)
	Events, n	6	<5	<5
	Persons at risk	6	<1905	<2353
	Risk (95% CI)	6	21 (0 - 61)	17 (0 - 42)
	Events, n	9	<5	<5
	Persons at risk	9	<1905	<2353
	Risk (95% CI)	9	21 (0 - 61)	17 (0 - 42)
	Events, n	12	<5	<5
	Persons at risk	12	<1905	<2353
	Risk (95% CI)	12	21 (0 - 61)	17 (0 - 42)
Female				
	Events, n	3	0	0
	Persons at risk	3	245	475
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	204	424
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	174	370
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	149	325
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.6.3 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N=274)	Pericarditis cohort (N=532)
Male, 15-30 years				
	Events, n	3	0	<5
	Persons at risk	3	244	<1667
	Risk (95% CI)	3	0 (0 - 0)	24 (0 - 71)
	Events, n	6	<5	<5
	Persons at risk	6	<976	<1667
	Risk (95% CI)	6	41 (0 - 122)	24 (0 - 71)
	Events, n	9	<5	<5
	Persons at risk	9	<976	<1667
	Risk (95% CI)	9	41 (0 - 122)	24 (0 - 71)
	Events, n	12	<5	<5
	Persons at risk	12	<976	<1667
	Risk (95% CI)	12	41 (0 - 122)	24 (0 - 71)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	57	134
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	46	121
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	37	102
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	32	87
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.6.4 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N=61)	Pericarditis cohort (N=152)
No				
	Events, n	3	0	<5
	Persons at risk	3	512	<5000
	Risk (95% CI)	3	0 (0 - 0)	8 (0 - 23)
	Events, n	6	<5	<5
	Persons at risk	6	<2000	<5000
	Risk (95% CI)	6	20 (0 - 58)	8 (0 - 23)
	Events, n	9	<5	<5
	Persons at risk	9	<2000	<5000
	Risk (95% CI)	9	20 (0 - 58)	8 (0 - 23)
	Events, n	12	<5	<5
	Persons at risk	12	<2000	<5000
	Risk (95% CI)	12	20 (0 - 58)	8 (0 - 23)
Yes				
	Events, n	3	0	<5
	Persons at risk	3	222	<1600
	Risk (95% CI)	3	0 (0 - 0)	25 (0 - 74)
	Events, n	6	0	<5
	Persons at risk	6	179	<1600
	Risk (95% CI)	6	0 (0 - 0)	25 (0 - 74)
	Events, n	9	0	<5
	Persons at risk	9	148	<1600
	Risk (95% CI)	9	0 (0 - 0)	25 (0 - 74)
	Events, n	12	0	<5
	Persons at risk	12	113	<1600
	Risk (95% CI)	12	0 (0 - 0)	25 (0 - 74)

Table 15.19.8.6.5 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=252)	Pericarditis cohort (N<1600)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	59	97
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	56	96
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	55	95
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	52	92
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	375	<1740
	Risk (95% CI)	3	0 (0 - 0)	23 (0 - 55)
	Events, n	6	0	<5
	Persons at risk	6	293	<1740
	Risk (95% CI)	6	0 (0 - 0)	23 (0 - 55)
	Events, n	9	0	<5
	Persons at risk	9	238	<1740
	Risk (95% CI)	9	0 (0 - 0)	23 (0 - 55)
	Events, n	12	0	<5
	Persons at risk	12	182	<1740
	Risk (95% CI)	12	0 (0 - 0)	23 (0 - 55)

Table 15.19.8.6.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=431)	Pericarditis cohort (N<1740)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	300	664
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1177	605
	Risk (95% CI)	6	34 (0 - 99)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<1177	559
	Risk (95% CI)	9	34 (0 - 99)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<1177	520
	Risk (95% CI)	12	34 (0 - 99)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	17	27
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	26
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	17	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	17	25
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	73	151
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	63	140
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	53	113
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.8.6.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=431)	Pericarditis cohort (N<1740)
	Persons at risk	12	46	97
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	23	24
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	22	24
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	21	23
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	21	22
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	170	<755
	Risk (95% CI)	3	0 (0 - 0)	53 (0 - 126)
	Events, n	6	0	<5
	Persons at risk	6	140	<755
	Risk (95% CI)	6	0 (0 - 0)	53 (0 - 126)
	Events, n	9	0	<5
	Persons at risk	9	124	<755
	Risk (95% CI)	9	0 (0 - 0)	53 (0 - 126)
	Events, n	12	0	<5
	Persons at risk	12	108	<755
	Risk (95% CI)	12	0 (0 - 0)	53 (0 - 126)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	6	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	5	9

Table 15.19.8.6.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=431)	Pericarditis cohort (N<1740)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	137	297
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	99	229
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	72	175
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	39	115
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	7	22
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	12
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.8.6.6 Risk (1-KM and 95% CI) for CHRONIC MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=431)	Pericarditis cohort (N<1740)
	Events, n	9	0	0
	Persons at risk	9	<5	7
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.9.1.1 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N=10)	Pericarditis cohort (N=30)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.9.1.2 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.9.1.3 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.9.1.4 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.9.1.5 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.9.1.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.9.1.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

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Table 15.19.9.1.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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Table 15.19.9.1.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.9.2.1 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	127	22
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	118	21
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	108	19
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	96	17
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.2.2 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N=135)	Pericarditis cohort (N=23)
Male				
	Events, n	3	0	0
	Persons at risk	3	414	64
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	386	63
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	347	57
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	320	47
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	204	30
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	186	28
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	171	27
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	157	26
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.2.3 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N=217)	Pericarditis cohort (N=32)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	86	17
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	80	17
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	73	15
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	66	13
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	41	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	35	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.2.4 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N=42)	Pericarditis cohort (N=5)
No				
	Events, n	3	0	0
	Persons at risk	3	517	81
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	485	79
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	445	74
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	415	65
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	101	13
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	87	12
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	73	10
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	62	8
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.2.5 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=121)	Pericarditis cohort (N=15)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	36	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	35	5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	235	28
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	212	27
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	182	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	162	21
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.2.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	347	61
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	325	59
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	302	53
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	282	47
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	81	10
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	77	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	69	10
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.9.2.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Persons at risk	12	63	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	129	15
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	114	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	101	13
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	93	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

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Table 15.19.9.2.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	30	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	27	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	18	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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Table 15.19.9.2.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.9.3.1 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N=5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	186	261
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	159	233
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	136	205
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	113	176
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.3.2 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N=204)	Pericarditis cohort (N=289)
Male				
	Events, n	3	<5	0
	Persons at risk	3	<2106	1185
	Risk (95% CI)	3	19 (0 - 56)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<2106	1041
	Risk (95% CI)	6	19 (0 - 56)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<2106	894
	Risk (95% CI)	9	19 (0 - 56)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<2106	748
	Risk (95% CI)	12	19 (0 - 56)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	224	559
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	202	479
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	176	424
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	148	360
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.3.3 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=626)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	154	203
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	130	185
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	111	162
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	94	139
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	32	58
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	29	48
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	25	43
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	19	37
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.3.4 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N=34)	Pericarditis cohort (N=61)
No				
	Events, n	3	<5	0
	Persons at risk	3	<2667	1586
	Risk (95% CI)	3	15 (0 - 44)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<2667	1401
	Risk (95% CI)	6	15 (0 - 44)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<2667	1240
	Risk (95% CI)	9	15 (0 - 44)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<2667	1077
	Risk (95% CI)	12	15 (0 - 44)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	97	158
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	74	119
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	54	78
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	32	31
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.3.5 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N=204)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	62	186
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	57	178
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	56	176
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	54	167
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	396	1041
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	327	841
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	258	661
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	197	488
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.3.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<1053	517
	Risk (95% CI)	3	38 (0 - 112)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1053	501
	Risk (95% CI)	6	38 (0 - 112)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<1053	481
	Risk (95% CI)	9	38 (0 - 112)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<1053	453
	Risk (95% CI)	12	38 (0 - 112)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	18	49
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	49
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	16	49
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	16	48
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	61	129
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	57	120
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	50	112
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.9.3.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Persons at risk	12	44	104
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	59
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	58
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	58
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	58
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	207	494
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	189	458
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	169	419
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	151	377
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	23
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	22
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	21

Table 15.19.9.3.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	11	18
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	134	427
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	95	301
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	53	172
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	17	50
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	10	41
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.3.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Events, n	9	0	0
	Persons at risk	9	<5	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.9.4.1 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N=24)	Pericarditis cohort (N=75)
15-30				
	Events, n	3	0	0
	Persons at risk	3	37	87
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	37	82
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	75
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	62
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.4.2 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N=39)	Pericarditis cohort (N=94)
Male				
	Events, n	3	0	0
	Persons at risk	3	81	282
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	78	257
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	75	237
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	66	209
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	19	102
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	18	94
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	14	83
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	14	77
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.4.3 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=121)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	36	71
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	36	68
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	33	63
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	51
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.4.4 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	0	0
	Persons at risk	3	75	281
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	73	262
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	67	242
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	61	222
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	25	103
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	23	89
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	22	78
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	19	64
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.4.5 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=34)	Pericarditis cohort (N=118)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	9	29
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	29
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	9	28
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	27
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	53	235
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	49	205
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	43	178
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	37	146
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.4.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	38	120
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	117
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	37	114
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	34	113
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	9	19
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	18
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	8	17
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.9.4.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Persons at risk	12	8	12
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	33	162
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	31	147
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	27	129
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	23	113
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

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Table 15.19.9.4.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	14	56
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	44
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	11	38
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	27
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)

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Table 15.19.9.4.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=65)	Pericarditis cohort (N=272)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.9.5.1 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=11)
15-30				
	Events, n	3	0	0
	Persons at risk	3	109	249
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	94	236
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	74	225
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	68	215
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.5.2 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N=271)
Male				
	Events, n	3	0	0
	Persons at risk	3	364	981
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	309	922
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	252	875
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	228	821
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	240	534
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	203	<2000
	Risk (95% CI)	6	0 (0 - 0)	20 (0 - 58)
	Events, n	9	0	<5
	Persons at risk	9	152	<2000
	Risk (95% CI)	9	0 (0 - 0)	20 (0 - 58)
	Events, n	12	0	<5
	Persons at risk	12	135	<2000
	Risk (95% CI)	12	0 (0 - 0)	20 (0 - 58)

Table 15.19.9.5.3 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N<2000)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	86	196
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	73	188
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	59	181
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	55	175
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	23	53
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	21	48
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	15	44
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	40
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.9.5.4 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N=24)	Pericarditis cohort (N=57)
No				
	Events, n	3	0	0
	Persons at risk	3	322	1098
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	282	<4445
	Risk (95% CI)	6	0 (0 - 0)	9 (0 - 28)
	Events, n	9	0	<5
	Persons at risk	9	235	<4445
	Risk (95% CI)	9	0 (0 - 0)	9 (0 - 28)
	Events, n	12	0	<5
	Persons at risk	12	214	<4445
	Risk (95% CI)	12	0 (0 - 0)	9 (0 - 28)
Yes				
	Events, n	3	0	0
	Persons at risk	3	282	417
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	230	372
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	169	338
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	149	300
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.5.5 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=316)	Pericarditis cohort (N=477)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	27	127
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	27	125
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	26	122
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	25	120
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	313	658
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	253	593
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	185	536
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	153	473
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.5.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	264	730
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	232	<2858
	Risk (95% CI)	6	0 (0 - 0)	14 (0 - 42)
	Events, n	9	0	<5
	Persons at risk	9	193	<2858
	Risk (95% CI)	9	0 (0 - 0)	14 (0 - 42)
	Events, n	12	0	<5
	Persons at risk	12	185	<2858
	Risk (95% CI)	12	0 (0 - 0)	14 (0 - 42)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	7	42
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	7	42
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	6	41
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	6	40
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	44	61
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	59
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	29	58
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.9.5.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Persons at risk	12	28	57
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	34
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	34
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	34
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	199	485
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	166	454
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	125	426
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	105	391
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5

Table 15.19.9.5.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	58	121
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	51	112
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	38	93
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	27	67
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	19	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	5	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.5.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=358)	Pericarditis cohort (N=764)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.9.6.1 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=61)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<1291	555
	Risk (95% CI)	3	31 (0 - 92)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1291	490
	Risk (95% CI)	6	31 (0 - 92)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<1291	431
	Risk (95% CI)	9	31 (0 - 92)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<1291	366
	Risk (95% CI)	12	31 (0 - 92)	0 (0 - 0)

Table 15.19.9.6.2 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N<1291)	Pericarditis cohort (N=644)
Male				
	Events, n	3	<5	0
	Persons at risk	3	<2106	1128
	Risk (95% CI)	3	19 (0 - 58)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<2106	977
	Risk (95% CI)	6	19 (0 - 58)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<2106	847
	Risk (95% CI)	9	19 (0 - 58)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<2106	744
	Risk (95% CI)	12	19 (0 - 58)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	253	500
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<976	442
	Risk (95% CI)	6	41 (0 - 120)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<455	384
	Risk (95% CI)	9	88 (0 - 209)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<455	341
	Risk (95% CI)	12	88 (0 - 209)	0 (0 - 0)

Table 15.19.9.6.3 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N=976)	Pericarditis cohort (N=548)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<1026	413
	Risk (95% CI)	3	39 (0 - 114)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1026	361
	Risk (95% CI)	6	39 (0 - 114)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<1026	323
	Risk (95% CI)	9	39 (0 - 114)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<1026	271
	Risk (95% CI)	12	39 (0 - 114)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	60	142
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	49	129
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	41	108
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	95
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.6.4 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N=64)	Pericarditis cohort (N=159)
No				
	Events, n	3	<5	0
	Persons at risk	3	<2106	1231
	Risk (95% CI)	3	19 (0 - 55)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<2106	1096
	Risk (95% CI)	6	19 (0 - 55)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<2106	971
	Risk (95% CI)	9	19 (0 - 55)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<2106	874
	Risk (95% CI)	12	19 (0 - 55)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	229	397
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<889	323
	Risk (95% CI)	6	45 (0 - 133)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<405	260
	Risk (95% CI)	9	99 (0 - 236)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<405	211
	Risk (95% CI)	12	99 (0 - 236)	0 (0 - 0)

Table 15.19.9.6.5 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=889)	Pericarditis cohort (N=454)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	59	98
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	58	96
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	56	96
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	52	93
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<1600	848
	Risk (95% CI)	3	25 (0 - 73)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1600	700
	Risk (95% CI)	6	25 (0 - 73)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<690	560
	Risk (95% CI)	9	58 (0 - 138)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<690	456
	Risk (95% CI)	12	58 (0 - 138)	0 (0 - 0)

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Table 15.19.9.6.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N<1600)	Pericarditis cohort (N=973)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	302	682
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<1213	623
	Risk (95% CI)	6	33 (0 - 98)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<1213	575
	Risk (95% CI)	9	33 (0 - 98)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<1213	536
	Risk (95% CI)	12	33 (0 - 98)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	17	27
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	26
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	17	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	17	25
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	74	160
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	65	144
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<260	118
	Risk (95% CI)	9	154 (0 - 449)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.9.6.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N<1600)	Pericarditis cohort (N=973)
	Persons at risk	12	<260	105
	Risk (95% CI)	12	154 (0 - 449)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	23	24
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	23	24
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	22	24
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	21	23
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	175	372
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	151	321
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	127	279
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	114	247
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	6	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	6	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	5	9

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Table 15.19.9.6.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N<1600)	Pericarditis cohort (N=973)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<607	329
	Risk (95% CI)	3	66 (0 - 193)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<607	258
	Risk (95% CI)	6	66 (0 - 193)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<607	193
	Risk (95% CI)	9	66 (0 - 193)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<607	137
	Risk (95% CI)	12	66 (0 - 193)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	8	25
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.9.6.6 Risk (1-KM and 95% CI) for HEART TRANSPLANTATION at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N<1600)	Pericarditis cohort (N=973)
	Events, n	9	0	0
	Persons at risk	9	<5	7
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.10.1.1 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N=10)	Pericarditis cohort (N=30)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.10.1.2 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.10.1.3 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

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Table 15.19.10.1.4 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

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Table 15.19.10.1.5 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.10.1.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.10.1.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

Table 15.19.10.1.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.10.1.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.10.2.1 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<507	21
	Risk (95% CI)	3	79 (0 - 233)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<507	20
	Risk (95% CI)	6	79 (0 - 233)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<507	18
	Risk (95% CI)	9	79 (0 - 233)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<507	17
	Risk (95% CI)	12	79 (0 - 233)	0 (0 - 0)

Table 15.19.10.2.2 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N<507)	Pericarditis cohort (N=23)
Male				
	Events, n	3	11	0
	Persons at risk	3	380	59
	Risk (95% CI)	3	266 (110 - 420)	0 (0 - 0)
	Events, n	6	18	0
	Persons at risk	6	344	57
	Risk (95% CI)	6	452 (245 - 654)	0 (0 - 0)
	Events, n	9	22	<5
	Persons at risk	9	310	<112
	Risk (95% CI)	9	569 (334 - 798)	360 (0 - 839)
	Events, n	12	24	<5
	Persons at risk	12	271	<112
	Risk (95% CI)	12	634 (383 - 877)	360 (0 - 839)
Female				
	Events, n	3	<5	<5
	Persons at risk	3	<834	<116
	Risk (95% CI)	3	48 (0 - 142)	345 (0 - 987)
	Events, n	6	<5	<5
	Persons at risk	6	<197	<56
	Risk (95% CI)	6	204 (4 - 399)	716 (0 - 1626)
	Events, n	9	7	<5
	Persons at risk	9	155	<37
	Risk (95% CI)	9	380 (99 - 653)	1088 (0 - 2178)
	Events, n	12	8	<5
	Persons at risk	12	139	<37
	Risk (95% CI)	12	446 (137 - 746)	1088 (0 - 2178)

Table 15.19.10.2.3 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N<834)	Pericarditis cohort (N<116)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<339	17
	Risk (95% CI)	3	118 (0 - 344)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<339	16
	Risk (95% CI)	6	118 (0 - 344)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<339	14
	Risk (95% CI)	9	118 (0 - 344)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<339	13
	Risk (95% CI)	12	118 (0 - 344)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	39	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	36	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	32	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.10.2.4 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N=41)	Pericarditis cohort (N=5)
No				
	Events, n	3	12	<5
	Persons at risk	3	477	<315
	Risk (95% CI)	3	235 (103 - 365)	127 (0 - 370)
	Events, n	6	21	<5
	Persons at risk	6	437	<153
	Risk (95% CI)	6	424 (245 - 600)	262 (0 - 614)
	Events, n	9	26	5
	Persons at risk	9	401	61
	Risk (95% CI)	9	538 (334 - 738)	677 (85 - 1234)
	Events, n	12	29	5
	Persons at risk	12	364	56
	Risk (95% CI)	12	613 (393 - 828)	677 (85 - 1234)
Yes				
	Events, n	3	0	0
	Persons at risk	3	97	11
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<385	10
	Risk (95% CI)	6	104 (0 - 305)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<108	8
	Risk (95% CI)	9	372 (0 - 779)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<108	7
	Risk (95% CI)	12	372 (0 - 779)	0 (0 - 0)

Table 15.19.10.2.5 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<385)	Pericarditis cohort (N=13)
Vaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<144	5
	Risk (95% CI)	3	278 (0 - 800)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<144	5
	Risk (95% CI)	6	278 (0 - 800)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<144	5
	Risk (95% CI)	9	278 (0 - 800)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<144	5
	Risk (95% CI)	12	278 (0 - 800)	0 (0 - 0)
Unvaccinated				
	Events, n	3	<5	<5
	Persons at risk	3	<315	<109
	Risk (95% CI)	3	127 (0 - 269)	370 (0 - 1057)
	Events, n	6	6	<5
	Persons at risk	6	192	<51
	Risk (95% CI)	6	266 (53 - 474)	789 (0 - 1784)
	Events, n	9	10	<5
	Persons at risk	9	164	<25
	Risk (95% CI)	9	483 (184 - 772)	1626 (28 - 2969)
	Events, n	12	11	<5
	Persons at risk	12	136	<25
	Risk (95% CI)	12	546 (224 - 859)	1626 (28 - 2969)

Table 15.19.10.2.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<315)	Pericarditis cohort (N<109)
Unvaccinated				
	Events, n	3	8	0
	Persons at risk	3	319	57
	Risk (95% CI)	3	233 (72 - 391)	0 (0 - 0)
	Events, n	6	15	0
	Persons at risk	6	292	55
	Risk (95% CI)	6	453 (226 - 674)	0 (0 - 0)
	Events, n	9	18	<5
	Persons at risk	9	268	<217
	Risk (95% CI)	9	555 (302 - 802)	185 (0 - 538)
	Events, n	12	20	<5
	Persons at risk	12	243	<217
	Risk (95% CI)	12	629 (357 - 893)	185 (0 - 538)
Received dose 1 in the last 14 days				
	Events, n	3	<5	0
	Persons at risk	3	<49	<5
	Risk (95% CI)	3	833 (0 - 2271)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<49	<5
	Risk (95% CI)	6	833 (0 - 2271)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<49	<5
	Risk (95% CI)	9	833 (0 - 2271)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<49	<5
	Risk (95% CI)	12	833 (0 - 2271)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	79	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<315	9
	Risk (95% CI)	6	127 (0 - 370)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<150	8
	Risk (95% CI)	9	268 (0 - 627)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.10.2.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<315)	Pericarditis cohort (N<109)
	Persons at risk	12	<150	8
	Risk (95% CI)	12	268 (0 - 627)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<494	<57
	Risk (95% CI)	3	81 (0 - 239)	714 (0 - 1970)
	Events, n	6	<5	<5
	Persons at risk	6	<157	<26
	Risk (95% CI)	6	256 (0 - 538)	1558 (0 - 3338)
	Events, n	9	5	<5
	Persons at risk	9	89	<13
	Risk (95% CI)	9	456 (56 - 840)	3247 (26 - 5427)
	Events, n	12	6	<5
	Persons at risk	12	76	<13
	Risk (95% CI)	12	571 (113 - 1008)	3247 (26 - 5427)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.10.2.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<315)	Pericarditis cohort (N<109)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<64	<5
	Risk (95% CI)	3	625 (0 - 1427)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<64	<5
	Risk (95% CI)	6	625 (0 - 1427)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<35	<5
	Risk (95% CI)	9	1176 (0 - 2396)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<35	<5
	Risk (95% CI)	12	1176 (0 - 2396)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.10.2.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<315)	Pericarditis cohort (N<109)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.10.3.1 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	16	12
	Persons at risk	3	153	229
	Risk (95% CI)	3	895 (466 - 1305)	457 (201 - 707)
	Events, n	6	20	22
	Persons at risk	6	130	200
	Risk (95% CI)	6	1146 (659 - 1608)	895 (530 - 1247)
	Events, n	9	21	25
	Persons at risk	9	107	173
	Risk (95% CI)	9	1215 (712 - 1691)	1043 (644 - 1425)
	Events, n	12	22	26
	Persons at risk	12	85	140
	Risk (95% CI)	12	1308 (775 - 1811)	1098 (686 - 1491)

Table 15.19.10.3.2 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N=190)	Pericarditis cohort (N=273)
Male				
	Events, n	3	54	105
	Persons at risk	3	366	919
	Risk (95% CI)	3	1213 (904 - 1512)	955 (779 - 1127)
	Events, n	6	64	137
	Persons at risk	6	307	798
	Risk (95% CI)	6	1464 (1125 - 1790)	1289 (1084 - 1489)
	Events, n	9	76	159
	Persons at risk	9	257	656
	Risk (95% CI)	9	1825 (1440 - 2193)	1546 (1319 - 1766)
	Events, n	12	79	166
	Persons at risk	12	212	532
	Risk (95% CI)	12	1925 (1527 - 2304)	1645 (1409 - 1874)
Female				
	Events, n	3	30	57
	Persons at risk	3	160	411
	Risk (95% CI)	3	1478 (973 - 1954)	1117 (839 - 1387)
	Events, n	6	40	67
	Persons at risk	6	128	347
	Risk (95% CI)	6	2049 (1457 - 2601)	1347 (1040 - 1643)
	Events, n	9	44	78
	Persons at risk	9	107	291
	Risk (95% CI)	9	2306 (1675 - 2888)	1637 (1293 - 1967)
	Events, n	12	46	81
	Persons at risk	12	82	233
	Risk (95% CI)	12	2470 (1809 - 3078)	1738 (1379 - 2083)

Table 15.19.10.3.3 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N=216)	Pericarditis cohort (N=534)
Male, 15-30 years				
	Events, n	3	12	10
	Persons at risk	3	131	180
	Risk (95% CI)	3	794 (352 - 1215)	482 (186 - 769)
	Events, n	6	16	17
	Persons at risk	6	110	160
	Risk (95% CI)	6	1093 (571 - 1586)	870 (464 - 1259)
	Events, n	9	16	18
	Persons at risk	9	92	138
	Risk (95% CI)	9	1093 (571 - 1586)	935 (511 - 1339)
	Events, n	12	16	19
	Persons at risk	12	75	111
	Risk (95% CI)	12	1093 (571 - 1586)	1003 (561 - 1425)
Female, 15-30 years				
	Events, n	3	<5	<5
	Persons at risk	3	<28	<108
	Risk (95% CI)	3	1460 (27 - 2687)	372 (0 - 866)
	Events, n	6	<5	5
	Persons at risk	6	<28	40
	Risk (95% CI)	6	1460 (27 - 2687)	996 (125 - 1791)
	Events, n	9	5	7
	Persons at risk	9	15	35
	Risk (95% CI)	9	1887 (239 - 3256)	1458 (391 - 2407)
	Events, n	12	6	7
	Persons at risk	12	10	29
	Risk (95% CI)	12	2466 (469 - 4045)	1458 (391 - 2407)

Table 15.19.10.3.4 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N=28)	Pericarditis cohort (N<108)
No				
	Events, n	3	79	149
	Persons at risk	3	448	1213
	Risk (95% CI)	3	1422 (1126 - 1708)	1026 (868 - 1181)
	Events, n	6	97	191
	Persons at risk	6	376	1055
	Risk (95% CI)	6	1786 (1456 - 2103)	1354 (1172 - 1531)
	Events, n	9	112	222
	Persons at risk	9	325	893
	Risk (95% CI)	9	2129 (1767 - 2474)	1622 (1422 - 1816)
	Events, n	12	117	231
	Persons at risk	12	270	749
	Risk (95% CI)	12	2257 (1883 - 2614)	1714 (1508 - 1916)
Yes				
	Events, n	3	5	13
	Persons at risk	3	78	117
	Risk (95% CI)	3	546 (67 - 1001)	824 (381 - 1247)
	Events, n	6	7	13
	Persons at risk	6	59	90
	Risk (95% CI)	6	803 (210 - 1360)	824 (381 - 1247)
	Events, n	9	8	15
	Persons at risk	9	39	54
	Risk (95% CI)	9	1022 (291 - 1698)	1068 (512 - 1592)
	Events, n	12	8	16
	Persons at risk	12	24	16
	Risk (95% CI)	12	1022 (291 - 1698)	1310 (578 - 1984)

Table 15.19.10.3.5 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=105)	Pericarditis cohort (N=179)
Vaccinated				
	Events, n	3	9	9
	Persons at risk	3	46	155
	Risk (95% CI)	3	1636 (599 - 2559)	533 (188 - 866)
	Events, n	6	13	16
	Persons at risk	6	37	144
	Risk (95% CI)	6	2422 (1179 - 3490)	967 (504 - 1406)
	Events, n	9	14	19
	Persons at risk	9	35	141
	Risk (95% CI)	9	2633 (1341 - 3732)	1155 (652 - 1630)
	Events, n	12	15	19
	Persons at risk	12	27	117
	Risk (95% CI)	12	2856 (1511 - 3988)	1155 (652 - 1630)
Unvaccinated				
	Events, n	3	44	112
	Persons at risk	3	290	744
	Risk (95% CI)	3	1214 (870 - 1545)	1173 (966 - 1375)
	Events, n	6	56	132
	Persons at risk	6	222	597
	Risk (95% CI)	6	1614 (1214 - 1996)	1432 (1201 - 1657)
	Events, n	9	64	150
	Persons at risk	9	168	435
	Risk (95% CI)	9	1951 (1499 - 2379)	1721 (1460 - 1973)
	Events, n	12	66	157
	Persons at risk	12	119	301
	Risk (95% CI)	12	2056 (1585 - 2501)	1887 (1602 - 2162)

Table 15.19.10.3.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=393)	Pericarditis cohort (N=1020)
Unvaccinated				
	Events, n	3	31	41
	Persons at risk	3	190	431
	Risk (95% CI)	3	1348 (894 - 1778)	847 (595 - 1092)
	Events, n	6	35	56
	Persons at risk	6	176	404
	Risk (95% CI)	6	1533 (1052 - 1988)	1172 (878 - 1455)
	Events, n	9	42	68
	Persons at risk	9	161	371
	Risk (95% CI)	9	1878 (1348 - 2377)	1441 (1117 - 1752)
	Events, n	12	44	71
	Persons at risk	12	148	347
	Risk (95% CI)	12	1982 (1437 - 2492)	1512 (1181 - 1831)
Received dose 1 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<20	<59
	Risk (95% CI)	3	2000 (0 - 3788)	682 (0 - 1398)
	Events, n	6	5	6
	Persons at risk	6	9	38
	Risk (95% CI)	6	3400 (459 - 5434)	1364 (288 - 2320)
	Events, n	9	5	6
	Persons at risk	9	8	38
	Risk (95% CI)	9	3400 (459 - 5434)	1364 (288 - 2320)
	Events, n	12	5	6
	Persons at risk	12	8	36
	Risk (95% CI)	12	3400 (459 - 5434)	1364 (288 - 2320)
Received dose 1, 15 or more days ago				
	Events, n	3	9	8
	Persons at risk	3	44	108
	Risk (95% CI)	3	1628 (594 - 2548)	659 (207 - 1090)
	Events, n	6	12	14
	Persons at risk	6	38	97
	Risk (95% CI)	6	2213 (1021 - 3247)	1196 (587 - 1766)
	Events, n	9	14	18
	Persons at risk	9	31	85
	Risk (95% CI)	9	2660 (1348 - 3774)	1575 (877 - 2220)
	Events, n	12	14	18

Table 15.19.10.3.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=393)	Pericarditis cohort (N=1020)
	Persons at risk	12	25	76
	Risk (95% CI)	12	2660 (1348 - 3774)	1575 (877 - 2220)
Received dose 2 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<45	<109
	Risk (95% CI)	3	909 (0 - 2459)	370 (0 - 861)
	Events, n	6	<5	<5
	Persons at risk	6	<45	<109
	Risk (95% CI)	6	909 (0 - 2459)	370 (0 - 861)
	Events, n	9	<5	<5
	Persons at risk	9	<23	<54
	Risk (95% CI)	9	1818 (0 - 3808)	748 (15 - 1427)
	Events, n	12	<5	<5
	Persons at risk	12	<23	<54
	Risk (95% CI)	12	1818 (0 - 3808)	748 (15 - 1427)
Received dose 2, 15 or more days ago				
	Events, n	3	20	50
	Persons at risk	3	161	370
	Risk (95% CI)	3	1070 (615 - 1503)	1126 (827 - 1415)
	Events, n	6	29	58
	Persons at risk	6	136	336
	Risk (95% CI)	6	1584 (1036 - 2097)	1323 (999 - 1636)
	Events, n	9	34	66
	Persons at risk	9	115	294
	Risk (95% CI)	9	1911 (1307 - 2473)	1539 (1188 - 1875)
	Events, n	12	36	73
	Persons at risk	12	94	243
	Risk (95% CI)	12	2056 (1427 - 2639)	1759 (1379 - 2122)
Received dose 3 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	9	<43
	Risk (95% CI)	3	0 (0 - 0)	952 (0 - 2125)
	Events, n	6	0	<5
	Persons at risk	6	9	<28
	Risk (95% CI)	6	0 (0 - 0)	1429 (0 - 2802)
	Events, n	9	0	<5
	Persons at risk	9	9	<21

Table 15.19.10.3.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=393)	Pericarditis cohort (N=1020)
	Risk (95% CI)	9	0 (0 - 0)	1964 (31 - 3523)
	Events, n	12	<5	<5
	Persons at risk	12	<5	<21
	Risk (95% CI)	12	1250 (0 - 3266)	1964 (31 - 3523)
Received dose 3, 15 or more days ago				
	Events, n	3	18	46
	Persons at risk	3	93	293
	Risk (95% CI)	3	1415 (783 - 2004)	1185 (856 - 1502)
	Events, n	6	20	54
	Persons at risk	6	56	197
	Risk (95% CI)	6	1654 (948 - 2305)	1466 (1090 - 1826)
	Events, n	9	21	60
	Persons at risk	9	30	91
	Risk (95% CI)	9	1839 (1049 - 2559)	1807 (1350 - 2241)
	Events, n	12	21	60
	Persons at risk	12	7	11
	Risk (95% CI)	12	1839 (1049 - 2559)	1807 (1350 - 2241)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	<5	10
	Persons at risk	3	<5	14
	Risk (95% CI)	3	2041 (0 - 4309)	2056 (796 - 3143)
	Events, n	6	<5	11
	Persons at risk	6	<5	5
	Risk (95% CI)	6	2041 (0 - 4309)	3191 (468 - 5136)

Table 15.19.10.3.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=393)	Pericarditis cohort (N=1020)
	Events, n	9	<5	11
	Persons at risk	9	<5	<5
	Risk (95% CI)	9	2041 (0 - 4309)	3191 (468 - 5136)
	Events, n	12	<5	11
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.10.4.1 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N<20)	Pericarditis cohort (N=58)
15-30				
	Events, n	3	0	<5
	Persons at risk	3	37	<351
	Risk (95% CI)	3	0 (0 - 0)	114 (0 - 333)
	Events, n	6	<5	<5
	Persons at risk	6	<149	<174
	Risk (95% CI)	6	270 (0 - 779)	230 (0 - 540)
	Events, n	9	<5	<5
	Persons at risk	9	<149	<174
	Risk (95% CI)	9	270 (0 - 779)	230 (0 - 540)
	Events, n	12	<5	<5
	Persons at risk	12	<149	<174
	Risk (95% CI)	12	270 (0 - 779)	230 (0 - 540)

Table 15.19.10.4.2 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N<149)	Pericarditis cohort (N<351)
Male				
	Events, n	3	<5	13
	Persons at risk	3	<113	253
	Risk (95% CI)	3	354 (0 - 740)	466 (215 - 711)
	Events, n	6	5	17
	Persons at risk	6	72	225
	Risk (95% CI)	6	603 (76 - 1103)	626 (332 - 910)
	Events, n	9	6	22
	Persons at risk	9	67	200
	Risk (95% CI)	9	734 (150 - 1283)	844 (498 - 1177)
	Events, n	12	6	23
	Persons at risk	12	62	178
	Risk (95% CI)	12	734 (150 - 1283)	891 (534 - 1234)
Female				
	Events, n	3	0	<5
	Persons at risk	3	18	<139
	Risk (95% CI)	3	0 (0 - 0)	289 (0 - 607)
	Events, n	6	<5	<5
	Persons at risk	6	<72	<101
	Risk (95% CI)	6	556 (0 - 1557)	397 (7 - 772)
	Events, n	9	<5	6
	Persons at risk	9	<72	73
	Risk (95% CI)	9	556 (0 - 1557)	647 (128 - 1138)
	Events, n	12	<5	8
	Persons at risk	12	<72	64
	Risk (95% CI)	12	556 (0 - 1557)	918 (282 - 1512)

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Table 15.19.10.4.3 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N<72)	Pericarditis cohort (N<139)
Male, 15-30 years				
	Events, n	3	0	<5
	Persons at risk	3	36	<288
	Risk (95% CI)	3	0 (0 - 0)	139 (0 - 406)
	Events, n	6	<5	<5
	Persons at risk	6	<144	<142
	Risk (95% CI)	6	278 (0 - 800)	282 (0 - 659)
	Events, n	9	<5	<5
	Persons at risk	9	<144	<142
	Risk (95% CI)	9	278 (0 - 800)	282 (0 - 659)
	Events, n	12	<5	<5
	Persons at risk	12	<144	<142
	Risk (95% CI)	12	278 (0 - 800)	282 (0 - 659)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	13
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.10.4.4 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	0	14
	Persons at risk	3	75	251
	Risk (95% CI)	3	0 (0 - 0)	504 (243 - 758)
	Events, n	6	<5	18
	Persons at risk	6	<149	228
	Risk (95% CI)	6	270 (0 - 633)	662 (361 - 954)
	Events, n	9	<5	23
	Persons at risk	9	<98	204
	Risk (95% CI)	9	411 (0 - 857)	878 (527 - 1216)
	Events, n	12	<5	25
	Persons at risk	12	<98	188
	Risk (95% CI)	12	411 (0 - 857)	971 (599 - 1328)
Yes				
	Events, n	3	<5	<5
	Persons at risk	3	<38	<210
	Risk (95% CI)	3	1071 (0 - 2147)	191 (0 - 451)
	Events, n	6	<5	<5
	Persons at risk	6	<27	<134
	Risk (95% CI)	6	1497 (21 - 2754)	299 (0 - 628)
	Events, n	9	<5	5
	Persons at risk	9	<27	69
	Risk (95% CI)	9	1497 (21 - 2754)	558 (65 - 1028)
	Events, n	12	<5	6
	Persons at risk	12	<27	54
	Risk (95% CI)	12	1497 (21 - 2754)	708 (135 - 1248)

Table 15.19.10.4.5 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<38)	Pericarditis cohort (N<210)
Vaccinated				
	Events, n	3	0	<5
	Persons at risk	3	9	<113
	Risk (95% CI)	3	0 (0 - 0)	357 (0 - 1021)
	Events, n	6	0	<5
	Persons at risk	6	9	<113
	Risk (95% CI)	6	0 (0 - 0)	357 (0 - 1021)
	Events, n	9	0	<5
	Persons at risk	9	9	<113
	Risk (95% CI)	9	0 (0 - 0)	357 (0 - 1021)
	Events, n	12	0	<5
	Persons at risk	12	9	<113
	Risk (95% CI)	12	0 (0 - 0)	357 (0 - 1021)
Unvaccinated				
	Events, n	3	<5	7
	Persons at risk	3	<112	212
	Risk (95% CI)	3	360 (0 - 839)	299 (78 - 515)
	Events, n	6	<5	11
	Persons at risk	6	<54	178
	Risk (95% CI)	6	751 (14 - 1433)	501 (206 - 786)
	Events, n	9	<5	17
	Persons at risk	9	<54	150
	Risk (95% CI)	9	751 (14 - 1433)	849 (449 - 1231)
	Events, n	12	<5	20
	Persons at risk	12	<54	122
	Risk (95% CI)	12	751 (14 - 1433)	1050 (595 - 1483)

Table 15.19.10.4.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<112)	Pericarditis cohort (N=241)
Unvaccinated				
	Events, n	3	<5	8
	Persons at risk	3	<160	107
	Risk (95% CI)	3	250 (0 - 722)	664 (208 - 1098)
	Events, n	6	<5	9
	Persons at risk	6	<78	102
	Risk (95% CI)	6	514 (0 - 1182)	751 (267 - 1212)
	Events, n	9	<5	10
	Persons at risk	9	<51	98
	Risk (95% CI)	9	785 (0 - 1600)	843 (328 - 1330)
	Events, n	12	<5	10
	Persons at risk	12	<51	95
	Risk (95% CI)	12	785 (0 - 1600)	843 (328 - 1330)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<40	17
	Risk (95% CI)	3	1000 (0 - 2680)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<40	16
	Risk (95% CI)	6	1000 (0 - 2680)	0 (0 - 0)
	Events, n	9	<5	<5
	Persons at risk	9	<40	<60
	Risk (95% CI)	9	1000 (0 - 2680)	667 (0 - 1847)
	Events, n	12	<5	<5

Table 15.19.10.4.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<112)	Pericarditis cohort (N=241)
	Persons at risk	12	<40	<60
	Risk (95% CI)	12	1000 (0 - 2680)	667 (0 - 1847)
Received dose 2 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	<5	<37
	Risk (95% CI)	3	0 (0 - 0)	1111 (0 - 2944)
	Events, n	6	0	<5
	Persons at risk	6	<5	<37
	Risk (95% CI)	6	0 (0 - 0)	1111 (0 - 2944)
	Events, n	9	0	<5
	Persons at risk	9	<5	<37
	Risk (95% CI)	9	0 (0 - 0)	1111 (0 - 2944)
	Events, n	12	0	<5
	Persons at risk	12	<5	<37
	Risk (95% CI)	12	0 (0 - 0)	1111 (0 - 2944)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	5
	Persons at risk	3	<137	148
	Risk (95% CI)	3	294 (0 - 846)	313 (39 - 579)
	Events, n	6	<5	7
	Persons at risk	6	<45	132
	Risk (95% CI)	6	902 (0 - 1826)	451 (118 - 773)
	Events, n	9	<5	11
	Persons at risk	9	<45	113
	Risk (95% CI)	9	902 (0 - 1826)	773 (319 - 1206)
	Events, n	12	<5	13
	Persons at risk	12	<45	97
	Risk (95% CI)	12	902 (0 - 1826)	944 (436 - 1425)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.10.4.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<112)	Pericarditis cohort (N=241)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	13	<121
	Risk (95% CI)	3	0 (0 - 0)	333 (0 - 777)
	Events, n	6	0	<5
	Persons at risk	6	12	<51
	Risk (95% CI)	6	0 (0 - 0)	795 (0 - 1527)
	Events, n	9	0	5
	Persons at risk	9	10	29
	Risk (95% CI)	9	0 (0 - 0)	1050 (113 - 1899)
	Events, n	12	0	6
	Persons at risk	12	9	22
	Risk (95% CI)	12	0 (0 - 0)	1423 (234 - 2468)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)

Table 15.19.10.4.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<112)	Pericarditis cohort (N=241)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.10.5.1 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=5)
15-30				
	Events, n	3	<5	5
	Persons at risk	3	<431	240
	Risk (95% CI)	3	93 (0 - 274)	196 (24 - 365)
	Events, n	6	<5	5
	Persons at risk	6	<431	229
	Risk (95% CI)	6	93 (0 - 274)	196 (24 - 365)
	Events, n	9	<5	5
	Persons at risk	9	<431	215
	Risk (95% CI)	9	93 (0 - 274)	196 (24 - 365)
	Events, n	12	<5	5
	Persons at risk	12	<99	204
	Risk (95% CI)	12	406 (0 - 855)	196 (24 - 365)

Table 15.19.10.5.2 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N<431)	Pericarditis cohort (N=263)
Male				
	Events, n	3	8	50
	Persons at risk	3	333	849
	Risk (95% CI)	3	225 (70 - 378)	538 (392 - 682)
	Events, n	6	19	71
	Persons at risk	6	241	788
	Risk (95% CI)	6	589 (327 - 844)	777 (602 - 949)
	Events, n	9	20	90
	Persons at risk	9	212	726
	Risk (95% CI)	9	628 (355 - 893)	1004 (805 - 1199)
	Events, n	12	24	101
	Persons at risk	12	192	679
	Risk (95% CI)	12	817 (490 - 1132)	1144 (930 - 1352)
Female				
	Events, n	3	9	35
	Persons at risk	3	205	444
	Risk (95% CI)	3	393 (138 - 642)	713 (482 - 938)
	Events, n	6	13	50
	Persons at risk	6	143	404
	Risk (95% CI)	6	618 (283 - 941)	1037 (760 - 1306)
	Events, n	9	16	57
	Persons at risk	9	119	370
	Risk (95% CI)	9	837 (424 - 1233)	1197 (900 - 1485)
	Events, n	12	16	64
	Persons at risk	12	109	349
	Risk (95% CI)	12	837 (424 - 1233)	1369 (1050 - 1677)

Table 15.19.10.5.3 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N=231)	Pericarditis cohort (N=511)
Male, 15-30 years				
	Events, n	3	0	<5
	Persons at risk	3	81	<200
	Risk (95% CI)	3	0 (0 - 0)	201 (4 - 394)
	Events, n	6	0	<5
	Persons at risk	6	61	<200
	Risk (95% CI)	6	0 (0 - 0)	201 (4 - 394)
	Events, n	9	0	<5
	Persons at risk	9	55	<200
	Risk (95% CI)	9	0 (0 - 0)	201 (4 - 394)
	Events, n	12	<5	<5
	Persons at risk	12	<104	<200
	Risk (95% CI)	12	385 (0 - 893)	201 (4 - 394)
Female, 15-30 years				
	Events, n	3	<5	<5
	Persons at risk	3	<92	<220
	Risk (95% CI)	3	435 (0 - 1233)	182 (0 - 529)
	Events, n	6	<5	<5
	Persons at risk	6	<92	<220
	Risk (95% CI)	6	435 (0 - 1233)	182 (0 - 529)
	Events, n	9	<5	<5
	Persons at risk	9	<92	<220
	Risk (95% CI)	9	435 (0 - 1233)	182 (0 - 529)
	Events, n	12	<5	<5
	Persons at risk	12	<92	<220
	Risk (95% CI)	12	435 (0 - 1233)	182 (0 - 529)

Table 15.19.10.5.4 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N<92)	Pericarditis cohort (N<220)
No				
	Events, n	3	9	63
	Persons at risk	3	284	930
	Risk (95% CI)	3	293 (103 - 480)	619 (470 - 766)
	Events, n	6	16	88
	Persons at risk	6	217	876
	Risk (95% CI)	6	560 (288 - 824)	876 (699 - 1049)
	Events, n	9	19	104
	Persons at risk	9	192	822
	Risk (95% CI)	9	695 (385 - 995)	1044 (852 - 1233)
	Events, n	12	22	119
	Persons at risk	12	178	783
	Risk (95% CI)	12	848 (496 - 1187)	1211 (1004 - 1413)
Yes				
	Events, n	3	8	22
	Persons at risk	3	254	363
	Risk (95% CI)	3	287 (89 - 481)	546 (321 - 766)
	Events, n	6	16	33
	Persons at risk	6	167	316
	Risk (95% CI)	6	644 (330 - 948)	848 (566 - 1121)
	Events, n	9	17	43
	Persons at risk	9	139	274
	Risk (95% CI)	9	711 (372 - 1038)	1154 (821 - 1474)
	Events, n	12	18	46
	Persons at risk	12	123	245
	Risk (95% CI)	12	785 (417 - 1139)	1257 (907 - 1594)

Table 15.19.10.5.5 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=284)	Pericarditis cohort (N=425)
Vaccinated				
	Events, n	3	<5	<5
	Persons at risk	3	<54	<466
	Risk (95% CI)	3	741 (0 - 1678)	86 (0 - 253)
	Events, n	6	<5	<5
	Persons at risk	6	<54	<115
	Risk (95% CI)	6	741 (0 - 1678)	349 (7 - 680)
	Events, n	9	<5	8
	Persons at risk	9	<54	104
	Risk (95% CI)	9	741 (0 - 1678)	704 (221 - 1162)
	Events, n	12	<5	9
	Persons at risk	12	<35	103
	Risk (95% CI)	12	1143 (0 - 2283)	793 (282 - 1277)
Unvaccinated				
	Events, n	3	9	45
	Persons at risk	3	271	533
	Risk (95% CI)	3	300 (105 - 491)	737 (527 - 942)
	Events, n	6	17	66
	Persons at risk	6	177	465
	Risk (95% CI)	6	629 (332 - 917)	1119 (860 - 1371)
	Events, n	9	20	85
	Persons at risk	9	144	397
	Risk (95% CI)	9	807 (451 - 1150)	1500 (1198 - 1792)
	Events, n	12	23	96
	Persons at risk	12	117	344
	Risk (95% CI)	12	1029 (597 - 1442)	1751 (1422 - 2067)

Table 15.19.10.5.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=308)	Pericarditis cohort (N=646)
Unvaccinated				
	Events, n	3	6	39
	Persons at risk	3	242	645
	Risk (95% CI)	3	233 (47 - 416)	562 (389 - 732)
	Events, n	6	13	51
	Persons at risk	6	183	618
	Risk (95% CI)	6	553 (255 - 843)	740 (542 - 933)
	Events, n	9	14	54
	Persons at risk	9	164	595
	Risk (95% CI)	9	607 (291 - 912)	785 (581 - 984)
	Events, n	12	14	60
	Persons at risk	12	162	581
	Risk (95% CI)	12	607 (291 - 912)	878 (663 - 1088)
Received dose 1 in the last 14 days				
	Events, n	3	<5	0
	Persons at risk	3	<28	41
	Risk (95% CI)	3	1429 (0 - 3666)	0 (0 - 0)
	Events, n	6	<5	<5
	Persons at risk	6	<28	<82
	Risk (95% CI)	6	1429 (0 - 3666)	488 (0 - 1125)
	Events, n	9	<5	<5
	Persons at risk	9	<28	<41
	Risk (95% CI)	9	1429 (0 - 3666)	976 (20 - 1840)
	Events, n	12	<5	<5
	Persons at risk	12	<5	<41
	Risk (95% CI)	12	3143 (0 - 5974)	976 (20 - 1840)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<177	<249
	Risk (95% CI)	3	227 (0 - 658)	161 (0 - 470)
	Events, n	6	<5	<5
	Persons at risk	6	<177	<78
	Risk (95% CI)	6	227 (0 - 658)	513 (0 - 1062)
	Events, n	9	<5	7
	Persons at risk	9	<177	49
	Risk (95% CI)	9	227 (0 - 658)	1229 (332 - 2042)
	Events, n	12	<5	7

Table 15.19.10.5.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=308)	Pericarditis cohort (N=646)
	Persons at risk	12	<67	49
	Risk (95% CI)	12	603 (0 - 1404)	1229 (332 - 2042)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	32
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	32
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	32
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	<5
	Persons at risk	12	12	<129
	Risk (95% CI)	12	0 (0 - 0)	312 (0 - 897)
Received dose 2, 15 or more days ago				
	Events, n	3	5	24
	Persons at risk	3	173	414
	Risk (95% CI)	3	263 (33 - 488)	528 (320 - 732)
	Events, n	6	9	36
	Persons at risk	6	120	377
	Risk (95% CI)	6	512 (178 - 835)	812 (553 - 1063)
	Events, n	9	11	48
	Persons at risk	9	99	337
	Risk (95% CI)	9	685 (275 - 1077)	1115 (812 - 1409)
	Events, n	12	12	55
	Persons at risk	12	81	300
	Risk (95% CI)	12	793 (333 - 1231)	1310 (979 - 1629)
Received dose 3 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	2000 (0 - 4839)
	Events, n	6	0	<5
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	2000 (0 - 4839)
	Events, n	9	0	<5
	Persons at risk	9	0	<5

Table 15.19.10.5.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=308)	Pericarditis cohort (N=646)
	Risk (95% CI)	9	NA (NA - NA)	2000 (0 - 4839)
	Events, n	12	0	<5
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	2000 (0 - 4839)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	16
	Persons at risk	3	<108	81
	Risk (95% CI)	3	371 (0 - 863)	1552 (822 - 2224)
	Events, n	6	6	23
	Persons at risk	6	31	68
	Risk (95% CI)	6	1246 (256 - 2136)	2317 (1435 - 3109)
	Events, n	9	7	28
	Persons at risk	9	24	42
	Risk (95% CI)	9	1571 (398 - 2600)	2977 (1965 - 3861)
	Events, n	12	8	32
	Persons at risk	12	17	27
	Risk (95% CI)	12	2014 (554 - 3249)	3737 (2530 - 4749)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<40	<26
	Risk (95% CI)	3	1000 (0 - 2223)	1565 (7 - 2879)
	Events, n	6	<5	5
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	1000 (0 - 2223)	2061 (235 - 3545)

Table 15.19.10.5.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=308)	Pericarditis cohort (N=646)
	Events, n	9	<5	5
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	2061 (235 - 3545)
	Events, n	12	<5	5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.10.6.1 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N<40)	Pericarditis cohort (N=41)
15-30				
	Events, n	3	<5	6
	Persons at risk	3	<1334	518
	Risk (95% CI)	3	30 (0 - 90)	102 (20 - 183)
	Events, n	6	<5	8
	Persons at risk	6	<367	464
	Risk (95% CI)	6	109 (0 - 232)	142 (44 - 240)
	Events, n	9	<5	9
	Persons at risk	9	<367	400
	Risk (95% CI)	9	109 (0 - 232)	166 (57 - 274)
	Events, n	12	<5	9
	Persons at risk	12	<367	331
	Risk (95% CI)	12	109 (0 - 232)	166 (57 - 274)

Table 15.19.10.6.2 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N<1334)	Pericarditis cohort (N=605)
Male				
	Events, n	3	5	23
	Persons at risk	3	480	1024
	Risk (95% CI)	3	94 (12 - 175)	201 (119 - 282)
	Events, n	6	9	28
	Persons at risk	6	403	893
	Risk (95% CI)	6	189 (65 - 312)	252 (159 - 345)
	Events, n	9	11	33
	Persons at risk	9	349	777
	Risk (95% CI)	9	241 (98 - 383)	311 (205 - 416)
	Events, n	12	12	35
	Persons at risk	12	295	668
	Risk (95% CI)	12	269 (116 - 421)	337 (225 - 447)
Female				
	Events, n	3	<5	<5
	Persons at risk	3	<520	<494
	Risk (95% CI)	3	77 (0 - 182)	81 (2 - 159)
	Events, n	6	6	11
	Persons at risk	6	194	408
	Risk (95% CI)	6	268 (53 - 478)	237 (97 - 374)
	Events, n	9	7	14
	Persons at risk	9	163	354
	Risk (95% CI)	9	326 (83 - 563)	312 (149 - 472)
	Events, n	12	11	15
	Persons at risk	12	135	308
	Risk (95% CI)	12	583 (235 - 918)	342 (169 - 512)

Table 15.19.10.6.3 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N=520)	Pericarditis cohort (N=523)
Male, 15-30 years				
	Events, n	3	<5	<5
	Persons at risk	3	<1082	<445
	Risk (95% CI)	3	37 (0 - 109)	90 (2 - 178)
	Events, n	6	<5	<5
	Persons at risk	6	<471	<445
	Risk (95% CI)	6	85 (0 - 203)	90 (2 - 178)
	Events, n	9	<5	5
	Persons at risk	9	<471	299
	Risk (95% CI)	9	85 (0 - 203)	122 (14 - 230)
	Events, n	12	<5	5
	Persons at risk	12	<471	245
	Risk (95% CI)	12	85 (0 - 203)	122 (14 - 230)
Female, 15-30 years				
	Events, n	3	0	<5
	Persons at risk	3	55	<297
	Risk (95% CI)	3	0 (0 - 0)	135 (0 - 320)
	Events, n	6	<5	<5
	Persons at risk	6	<177	<140
	Risk (95% CI)	6	227 (0 - 658)	286 (5 - 560)
	Events, n	9	<5	<5
	Persons at risk	9	<177	<140
	Risk (95% CI)	9	227 (0 - 658)	286 (5 - 560)
	Events, n	12	<5	<5
	Persons at risk	12	<177	<140
	Risk (95% CI)	12	227 (0 - 658)	286 (5 - 560)

Table 15.19.10.6.4 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N<177)	Pericarditis cohort (N<297)
No				
	Events, n	3	5	23
	Persons at risk	3	502	1139
	Risk (95% CI)	3	90 (11 - 167)	186 (110 - 261)
	Events, n	6	8	34
	Persons at risk	6	429	1011
	Risk (95% CI)	6	157 (48 - 265)	285 (190 - 380)
	Events, n	9	8	39
	Persons at risk	9	377	894
	Risk (95% CI)	9	157 (48 - 265)	337 (232 - 442)
	Events, n	12	10	42
	Persons at risk	12	332	796
	Risk (95% CI)	12	212 (79 - 344)	371 (259 - 481)
Yes				
	Events, n	3	<5	<5
	Persons at risk	3	<471	<397
	Risk (95% CI)	3	85 (0 - 202)	101 (2 - 199)
	Events, n	6	7	5
	Persons at risk	6	168	290
	Risk (95% CI)	6	360 (92 - 620)	132 (16 - 246)
	Events, n	9	10	8
	Persons at risk	9	135	237
	Risk (95% CI)	9	557 (211 - 890)	237 (71 - 401)
	Events, n	12	13	8
	Persons at risk	12	98	180
	Risk (95% CI)	12	792 (359 - 1206)	237 (71 - 401)

Table 15.19.10.6.5 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<471)	Pericarditis cohort (N=436)
Vaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<240	97
	Risk (95% CI)	3	167 (0 - 485)	0 (0 - 0)
	Events, n	6	<5	<5
	Persons at risk	6	<240	<97
	Risk (95% CI)	6	167 (0 - 485)	416 (8 - 806)
	Events, n	9	<5	<5
	Persons at risk	9	<240	<97
	Risk (95% CI)	9	167 (0 - 485)	416 (8 - 806)
	Events, n	12	<5	<5
	Persons at risk	12	<240	<97
	Risk (95% CI)	12	167 (0 - 485)	416 (8 - 806)
Unvaccinated				
	Events, n	3	<5	13
	Persons at risk	3	<564	749
	Risk (95% CI)	3	71 (0 - 150)	150 (69 - 230)
	Events, n	6	8	18
	Persons at risk	6	283	623
	Risk (95% CI)	6	234 (70 - 395)	220 (118 - 321)
	Events, n	9	9	23
	Persons at risk	9	228	502
	Risk (95% CI)	9	276 (93 - 455)	308 (181 - 434)
	Events, n	12	12	26
	Persons at risk	12	170	389
	Risk (95% CI)	12	425 (176 - 667)	369 (225 - 512)

Table 15.19.10.6.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N<564)	Pericarditis cohort (N=906)
Unvaccinated				
	Events, n	3	<5	14
	Persons at risk	3	<417	643
	Risk (95% CI)	3	96 (0 - 204)	204 (98 - 310)
	Events, n	6	6	17
	Persons at risk	6	259	586
	Risk (95% CI)	6	208 (41 - 372)	253 (133 - 371)
	Events, n	9	8	20
	Persons at risk	9	230	538
	Risk (95% CI)	9	288 (88 - 483)	304 (171 - 435)
	Events, n	12	10	20
	Persons at risk	12	209	499
	Risk (95% CI)	12	374 (142 - 601)	304 (171 - 435)
Received dose 1 in the last 14 days				
	Events, n	3	<5	0
	Persons at risk	3	<69	27
	Risk (95% CI)	3	588 (0 - 1643)	0 (0 - 0)
	Events, n	6	<5	<5
	Persons at risk	6	<69	<104
	Risk (95% CI)	6	588 (0 - 1643)	385 (0 - 1096)
	Events, n	9	<5	<5
	Persons at risk	9	<69	<104
	Risk (95% CI)	9	588 (0 - 1643)	385 (0 - 1096)
	Events, n	12	<5	<5
	Persons at risk	12	<69	<104
	Risk (95% CI)	12	588 (0 - 1643)	385 (0 - 1096)
Received dose 1, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	71	<690
	Risk (95% CI)	3	0 (0 - 0)	58 (0 - 171)
	Events, n	6	<5	<5
	Persons at risk	6	<252	<204
	Risk (95% CI)	6	159 (0 - 463)	197 (0 - 416)
	Events, n	9	<5	<5
	Persons at risk	9	<252	<204
	Risk (95% CI)	9	159 (0 - 463)	197 (0 - 416)
	Events, n	12	<5	<5

Table 15.19.10.6.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N<564)	Pericarditis cohort (N=906)
	Persons at risk	12	<252	<204
	Risk (95% CI)	12	159 (0 - 463)	197 (0 - 416)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	23	24
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	22	24
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	21	23
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	21	22
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	6
	Persons at risk	3	<378	332
	Risk (95% CI)	3	106 (0 - 251)	160 (32 - 286)
	Events, n	6	5	9
	Persons at risk	6	135	294
	Risk (95% CI)	6	312 (37 - 579)	253 (88 - 416)
	Events, n	9	5	11
	Persons at risk	9	119	256
	Risk (95% CI)	9	312 (37 - 579)	324 (132 - 511)
	Events, n	12	8	13
	Persons at risk	12	100	220
	Risk (95% CI)	12	578 (172 - 967)	403 (183 - 618)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	6	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	5	9

Table 15.19.10.6.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N<564)	Pericarditis cohort (N=906)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<646	<339
	Risk (95% CI)	3	62 (0 - 182)	118 (2 - 233)
	Events, n	6	<5	7
	Persons at risk	6	<247	219
	Risk (95% CI)	6	162 (0 - 389)	233 (59 - 403)
	Events, n	9	<5	10
	Persons at risk	9	<134	165
	Risk (95% CI)	9	299 (0 - 642)	392 (142 - 637)
	Events, n	12	<5	10
	Persons at risk	12	<134	108
	Risk (95% CI)	12	299 (0 - 642)	392 (142 - 637)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	7	<51
	Risk (95% CI)	3	0 (0 - 0)	785 (0 - 1773)
	Events, n	6	0	<5
	Persons at risk	6	<5	<51
	Risk (95% CI)	6	0 (0 - 0)	785 (0 - 1773)

Table 15.19.10.6.6 Risk (1-KM and 95% CI) for ARRHYTHMIA at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N<564)	Pericarditis cohort (N=906)
	Events, n	9	0	<5
	Persons at risk	9	<5	<51
	Risk (95% CI)	9	0 (0 - 0)	785 (0 - 1773)
	Events, n	12	0	<5
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	2321 (0 - 4724)

Table 15.19.11.1.1 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N=10)	Pericarditis cohort (N<51)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.11.1.2 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.11.1.3 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.11.1.4 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

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Table 15.19.11.1.5 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

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Table 15.19.11.1.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.11.1.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

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Table 15.19.11.1.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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Table 15.19.11.1.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.11.2.1 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	123	21
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	113	20
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	103	18
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	93	17
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.2.2 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N=130)	Pericarditis cohort (N=23)
Male				
	Events, n	3	0	0
	Persons at risk	3	403	63
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	371	61
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	338	51
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	301	46
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	199	28
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	182	28
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	165	27
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	150	26
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.2.3 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N=213)	Pericarditis cohort (N=30)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	84	17
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	77	16
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	71	14
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	64	13
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	39	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	36	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	32	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.11.2.4 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N=41)	Pericarditis cohort (N=5)
No				
	Events, n	3	0	0
	Persons at risk	3	505	79
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	471	78
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	436	69
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	402	64
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	97	12
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	82	11
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	67	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	49	8
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.2.5 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=114)	Pericarditis cohort (N=14)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	36	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	35	5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	32	5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	229	27
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	202	27
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	176	24
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	149	21
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.2.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N=30)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	337	59
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	316	57
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	293	49
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	270	46
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	80	10
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	72	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	68	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.11.2.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N=30)
	Persons at risk	12	59	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	124	14
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	112	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	98	13
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	86	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

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Table 15.19.11.2.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N=30)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	30	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	24	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	16	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	10	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.11.2.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N=30)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.11.3.1 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	178	249
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	154	<976
	Risk (95% CI)	6	0 (0 - 0)	41 (0 - 121)
	Events, n	9	0	<5
	Persons at risk	9	131	<471
	Risk (95% CI)	9	0 (0 - 0)	85 (0 - 202)
	Events, n	12	0	<5
	Persons at risk	12	104	<471
	Risk (95% CI)	12	0 (0 - 0)	85 (0 - 202)

Table 15.19.11.3.2 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N=200)	Pericarditis cohort (N<976)
Male				
	Events, n	3	0	<5
	Persons at risk	3	458	<5000
	Risk (95% CI)	3	0 (0 - 0)	8 (0 - 25)
	Events, n	6	0	<5
	Persons at risk	6	399	<1112
	Risk (95% CI)	6	0 (0 - 0)	36 (1 - 71)
	Events, n	9	0	<5
	Persons at risk	9	347	<1112
	Risk (95% CI)	9	0 (0 - 0)	36 (1 - 71)
	Events, n	12	0	5
	Persons at risk	12	293	689
	Risk (95% CI)	12	0 (0 - 0)	48 (6 - 91)
Female				
	Events, n	3	0	<5
	Persons at risk	3	219	<741
	Risk (95% CI)	3	0 (0 - 0)	54 (0 - 115)
	Events, n	6	0	5
	Persons at risk	6	191	455
	Risk (95% CI)	6	0 (0 - 0)	94 (11 - 175)
	Events, n	9	<5	10
	Persons at risk	9	<715	397
	Risk (95% CI)	9	56 (0 - 166)	209 (79 - 337)
	Events, n	12	<5	12
	Persons at risk	12	<715	323
	Risk (95% CI)	12	56 (0 - 166)	266 (114 - 415)

Table 15.19.11.3.3 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N<715)	Pericarditis cohort (N<741)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	147	196
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	126	<770
	Risk (95% CI)	6	0 (0 - 0)	52 (0 - 153)
	Events, n	9	0	<5
	Persons at risk	9	108	<770
	Risk (95% CI)	9	0 (0 - 0)	52 (0 - 153)
	Events, n	12	0	<5
	Persons at risk	12	88	<770
	Risk (95% CI)	12	0 (0 - 0)	52 (0 - 153)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	31	53
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	28	46
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	<5
	Persons at risk	9	23	<185
	Risk (95% CI)	9	0 (0 - 0)	217 (0 - 630)
	Events, n	12	0	<5
	Persons at risk	12	16	<185
	Risk (95% CI)	12	0 (0 - 0)	217 (0 - 630)

Table 15.19.11.3.4 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N=33)	Pericarditis cohort (N<185)
No				
	Events, n	3	0	<5
	Persons at risk	3	586	<1600
	Risk (95% CI)	3	0 (0 - 0)	25 (1 - 50)
	Events, n	6	0	8
	Persons at risk	6	520	1336
	Risk (95% CI)	6	0 (0 - 0)	52 (16 - 89)
	Events, n	9	<5	13
	Persons at risk	9	<1905	1174
	Risk (95% CI)	9	21 (0 - 61)	92 (42 - 142)
	Events, n	12	<5	16
	Persons at risk	12	<1905	990
	Risk (95% CI)	12	21 (0 - 61)	119 (60 - 178)
Yes				
	Events, n	3	0	0
	Persons at risk	3	91	139
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	70	<482
	Risk (95% CI)	6	0 (0 - 0)	83 (0 - 243)
	Events, n	9	0	<5
	Persons at risk	9	47	<482
	Risk (95% CI)	9	0 (0 - 0)	83 (0 - 243)
	Events, n	12	0	<5
	Persons at risk	12	27	<482
	Risk (95% CI)	12	0 (0 - 0)	83 (0 - 243)

Table 15.19.11.3.5 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=114)	Pericarditis cohort (N<482)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	62	183
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	57	<728
	Risk (95% CI)	6	0 (0 - 0)	55 (0 - 162)
	Events, n	9	0	<5
	Persons at risk	9	56	<728
	Risk (95% CI)	9	0 (0 - 0)	55 (0 - 162)
	Events, n	12	0	<5
	Persons at risk	12	48	<728
	Risk (95% CI)	12	0 (0 - 0)	55 (0 - 162)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	373	<1380
	Risk (95% CI)	3	0 (0 - 0)	29 (0 - 61)
	Events, n	6	0	7
	Persons at risk	6	305	775
	Risk (95% CI)	6	0 (0 - 0)	73 (19 - 128)
	Events, n	9	0	8
	Persons at risk	9	238	595
	Risk (95% CI)	9	0 (0 - 0)	90 (27 - 153)
	Events, n	12	0	9
	Persons at risk	12	175	427
	Risk (95% CI)	12	0 (0 - 0)	108 (35 - 180)

Table 15.19.11.3.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=446)	Pericarditis cohort (N<1380)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	242	<2106
	Risk (95% CI)	3	0 (0 - 0)	19 (0 - 57)
	Events, n	6	0	<5
	Persons at risk	6	228	<2106
	Risk (95% CI)	6	0 (0 - 0)	19 (0 - 57)
	Events, n	9	<5	5
	Persons at risk	9	<889	469
	Risk (95% CI)	9	45 (0 - 133)	102 (13 - 190)
	Events, n	12	<5	7
	Persons at risk	12	<889	436
	Risk (95% CI)	12	45 (0 - 133)	146 (38 - 253)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	18	49
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	49
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	16	49
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	16	47
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	59	124
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	56	118
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	49	110
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.11.3.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=446)	Pericarditis cohort (N<1380)
	Persons at risk	12	41	100
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	58
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	12	<233
	Risk (95% CI)	6	0 (0 - 0)	172 (0 - 502)
	Events, n	9	0	<5
	Persons at risk	9	12	<233
	Risk (95% CI)	9	0 (0 - 0)	172 (0 - 502)
	Events, n	12	0	<5
	Persons at risk	12	11	<233
	Risk (95% CI)	12	0 (0 - 0)	172 (0 - 502)
Received dose 2, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	201	<2000
	Risk (95% CI)	3	0 (0 - 0)	20 (0 - 60)
	Events, n	6	0	<5
	Persons at risk	6	181	<471
	Risk (95% CI)	6	0 (0 - 0)	85 (2 - 167)
	Events, n	9	0	<5
	Persons at risk	9	164	<471
	Risk (95% CI)	9	0 (0 - 0)	85 (2 - 167)
	Events, n	12	0	5
	Persons at risk	12	138	350
	Risk (95% CI)	12	0 (0 - 0)	110 (13 - 207)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	23
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	21
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	21

Table 15.19.11.3.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=446)	Pericarditis cohort (N<1380)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	8	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	124	<852
	Risk (95% CI)	3	0 (0 - 0)	47 (0 - 111)
	Events, n	6	0	<5
	Persons at risk	6	82	<548
	Risk (95% CI)	6	0 (0 - 0)	73 (0 - 155)
	Events, n	9	0	<5
	Persons at risk	9	39	<274
	Risk (95% CI)	9	0 (0 - 0)	146 (0 - 310)
	Events, n	12	0	<5
	Persons at risk	12	9	<274
	Risk (95% CI)	12	0 (0 - 0)	146 (0 - 310)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	5	22
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	7
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.3.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=446)	Pericarditis cohort (N<1380)
	Events, n	9	0	0
	Persons at risk	9	<5	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.11.4.1 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N=21)	Pericarditis cohort (N=70)
15-30				
	Events, n	3	0	0
	Persons at risk	3	37	86
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	35	78
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	32	72
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	61
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.4.2 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N=39)	Pericarditis cohort (N=91)
Male				
	Events, n	3	0	0
	Persons at risk	3	81	277
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	76	251
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	71	228
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	66	205
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	18	100
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	18	89
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	14	81
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	73
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.4.3 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N=20)	Pericarditis cohort (N=111)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	36	70
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	34	65
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	31	60
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	50
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	13
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.11.4.4 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	0	0
	Persons at risk	3	75	277
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	72	255
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	64	234
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	61	217
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	24	100
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	22	85
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	21	75
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	18	61
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.4.5 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=28)	Pericarditis cohort (N=109)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	9	29
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	29
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	9	27
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	27
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	52	228
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	47	195
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	40	169
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	36	141
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.4.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=56)	Pericarditis cohort (N=253)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	38	120
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	116
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	36	113
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	34	110
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	9	19
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	8	18
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	8	17
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.11.4.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=56)	Pericarditis cohort (N=253)
	Persons at risk	12	7	12
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	33	157
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	30	142
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	25	125
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	23	110
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.11.4.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=56)	Pericarditis cohort (N=253)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	13	54
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	41
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	10	33
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	25
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)

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Table 15.19.11.4.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N=56)	Pericarditis cohort (N=253)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.11.5.1 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=7)
15-30				
	Events, n	3	0	<5
	Persons at risk	3	105	<1026
	Risk (95% CI)	3	0 (0 - 0)	39 (0 - 116)
	Events, n	6	0	<5
	Persons at risk	6	80	<1026
	Risk (95% CI)	6	0 (0 - 0)	39 (0 - 116)
	Events, n	9	0	<5
	Persons at risk	9	71	<1026
	Risk (95% CI)	9	0 (0 - 0)	39 (0 - 116)
	Events, n	12	0	<5
	Persons at risk	12	66	<1026
	Risk (95% CI)	12	0 (0 - 0)	39 (0 - 116)

Table 15.19.11.5.2 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N=112)	Pericarditis cohort (N<1026)
Male				
	Events, n	3	0	<5
	Persons at risk	3	356	<1334
	Risk (95% CI)	3	0 (0 - 0)	30 (0 - 64)
	Events, n	6	0	<5
	Persons at risk	6	272	<976
	Risk (95% CI)	6	0 (0 - 0)	41 (1 - 81)
	Events, n	9	0	<5
	Persons at risk	9	241	<976
	Risk (95% CI)	9	0 (0 - 0)	41 (1 - 81)
	Events, n	12	0	<5
	Persons at risk	12	223	<976
	Risk (95% CI)	12	0 (0 - 0)	41 (1 - 81)
Female				
	Events, n	3	0	<5
	Persons at risk	3	227	<728
	Risk (95% CI)	3	0 (0 - 0)	55 (0 - 116)
	Events, n	6	0	<5
	Persons at risk	6	165	<728
	Risk (95% CI)	6	0 (0 - 0)	55 (0 - 116)
	Events, n	9	0	<5
	Persons at risk	9	143	<728
	Risk (95% CI)	9	0 (0 - 0)	55 (0 - 116)
	Events, n	12	0	<5
	Persons at risk	12	131	<728
	Risk (95% CI)	12	0 (0 - 0)	55 (0 - 116)

Table 15.19.11.5.3 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N=248)	Pericarditis cohort (N<728)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	84	194
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	64	186
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	57	179
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	54	169
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	<5
	Persons at risk	3	21	<217
	Risk (95% CI)	3	0 (0 - 0)	185 (0 - 538)
	Events, n	6	0	<5
	Persons at risk	6	16	<217
	Risk (95% CI)	6	0 (0 - 0)	185 (0 - 538)
	Events, n	9	0	<5
	Persons at risk	9	14	<217
	Risk (95% CI)	9	0 (0 - 0)	185 (0 - 538)
	Events, n	12	0	<5
	Persons at risk	12	12	<217
	Risk (95% CI)	12	0 (0 - 0)	185 (0 - 538)

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Table 15.19.11.5.4 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N=23)	Pericarditis cohort (N<217)
No				
	Events, n	3	0	6
	Persons at risk	3	313	1079
	Risk (95% CI)	3	0 (0 - 0)	54 (11 - 96)
	Events, n	6	0	7
	Persons at risk	6	248	1032
	Risk (95% CI)	6	0 (0 - 0)	63 (16 - 110)
	Events, n	9	0	7
	Persons at risk	9	223	981
	Risk (95% CI)	9	0 (0 - 0)	63 (16 - 110)
	Events, n	12	0	7
	Persons at risk	12	211	950
	Risk (95% CI)	12	0 (0 - 0)	63 (16 - 110)
Yes				
	Events, n	3	0	0
	Persons at risk	3	270	407
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	189	358
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	161	315
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	143	284
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.5.5 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=297)	Pericarditis cohort (N=451)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	27	127
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	26	124
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	25	120
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	25	120
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	297	<702
	Risk (95% CI)	3	0 (0 - 0)	57 (1 - 113)
	Events, n	6	0	<5
	Persons at risk	6	205	<702
	Risk (95% CI)	6	0 (0 - 0)	57 (1 - 113)
	Events, n	9	0	<5
	Persons at risk	9	172	<702
	Risk (95% CI)	9	0 (0 - 0)	57 (1 - 113)
	Events, n	12	0	<5
	Persons at risk	12	144	<702
	Risk (95% CI)	12	0 (0 - 0)	57 (1 - 113)

Table 15.19.11.5.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=330)	Pericarditis cohort (N=722)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	259	<1429
	Risk (95% CI)	3	0 (0 - 0)	28 (0 - 66)
	Events, n	6	0	<5
	Persons at risk	6	206	<953
	Risk (95% CI)	6	0 (0 - 0)	42 (0 - 89)
	Events, n	9	0	<5
	Persons at risk	9	187	<953
	Risk (95% CI)	9	0 (0 - 0)	42 (0 - 89)
	Events, n	12	0	<5
	Persons at risk	12	185	<953
	Risk (95% CI)	12	0 (0 - 0)	42 (0 - 89)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	7	42
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	6	42
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	6	40
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	6	40
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	43	60
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	33	58
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	29	57
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.11.5.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=330)	Pericarditis cohort (N=722)
	Persons at risk	12	28	57
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	34
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	34
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	34
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	189	<667
	Risk (95% CI)	3	0 (0 - 0)	60 (0 - 128)
	Events, n	6	0	<5
	Persons at risk	6	137	<667
	Risk (95% CI)	6	0 (0 - 0)	60 (0 - 128)
	Events, n	9	0	<5
	Persons at risk	9	117	<667
	Risk (95% CI)	9	0 (0 - 0)	60 (0 - 128)
	Events, n	12	0	<5
	Persons at risk	12	98	<667
	Risk (95% CI)	12	0 (0 - 0)	60 (0 - 128)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5

Table 15.19.11.5.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=330)	Pericarditis cohort (N=722)
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	57	<527
	Risk (95% CI)	3	0 (0 - 0)	76 (0 - 223)
	Events, n	6	0	<5
	Persons at risk	6	41	<527
	Risk (95% CI)	6	0 (0 - 0)	76 (0 - 223)
	Events, n	9	0	<5
	Persons at risk	9	33	<527
	Risk (95% CI)	9	0 (0 - 0)	76 (0 - 223)
	Events, n	12	0	<5
	Persons at risk	12	25	<527
	Risk (95% CI)	12	0 (0 - 0)	76 (0 - 223)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	15	30
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.5.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=330)	Pericarditis cohort (N=722)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.11.6.1 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N=22)	Pericarditis cohort (N=51)
15-30				
	Events, n	3	0	<5
	Persons at risk	3	301	<1143
	Risk (95% CI)	3	0 (0 - 0)	35 (0 - 84)
	Events, n	6	<5	<5
	Persons at risk	6	<1213	<1143
	Risk (95% CI)	6	33 (0 - 99)	35 (0 - 84)
	Events, n	9	<5	<5
	Persons at risk	9	<1213	<1143
	Risk (95% CI)	9	33 (0 - 99)	35 (0 - 84)
	Events, n	12	<5	<5
	Persons at risk	12	<1213	<1143
	Risk (95% CI)	12	33 (0 - 99)	35 (0 - 84)

Table 15.19.11.6.2 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N<1213)	Pericarditis cohort (N<1143)
Male				
	Events, n	3	0	<5
	Persons at risk	3	489	<1539
	Risk (95% CI)	3	0 (0 - 0)	26 (0 - 55)
	Events, n	6	<5	<5
	Persons at risk	6	<1905	<1539
	Risk (95% CI)	6	21 (0 - 61)	26 (0 - 55)
	Events, n	9	<5	<5
	Persons at risk	9	<1905	<1539
	Risk (95% CI)	9	21 (0 - 61)	26 (0 - 55)
	Events, n	12	<5	<5
	Persons at risk	12	<1905	<1539
	Risk (95% CI)	12	21 (0 - 61)	26 (0 - 55)
Female				
	Events, n	3	0	<5
	Persons at risk	3	245	<690
	Risk (95% CI)	3	0 (0 - 0)	58 (0 - 124)
	Events, n	6	0	<5
	Persons at risk	6	204	<690
	Risk (95% CI)	6	0 (0 - 0)	58 (0 - 124)
	Events, n	9	0	5
	Persons at risk	9	174	365
	Risk (95% CI)	9	0 (0 - 0)	108 (13 - 202)
	Events, n	12	0	5
	Persons at risk	12	149	320
	Risk (95% CI)	12	0 (0 - 0)	108 (13 - 202)

Table 15.19.11.6.3 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N=274)	Pericarditis cohort (N<690)
Male, 15-30 years				
	Events, n	3	0	<5
	Persons at risk	3	244	<1667
	Risk (95% CI)	3	0 (0 - 0)	24 (0 - 71)
	Events, n	6	<5	<5
	Persons at risk	6	<976	<1667
	Risk (95% CI)	6	41 (0 - 122)	24 (0 - 71)
	Events, n	9	<5	<5
	Persons at risk	9	<976	<1667
	Risk (95% CI)	9	41 (0 - 122)	24 (0 - 71)
	Events, n	12	<5	<5
	Persons at risk	12	<976	<1667
	Risk (95% CI)	12	41 (0 - 122)	24 (0 - 71)
Female, 15-30 years				
	Events, n	3	0	<5
	Persons at risk	3	57	<589
	Risk (95% CI)	3	0 (0 - 0)	68 (0 - 201)
	Events, n	6	0	<5
	Persons at risk	6	46	<589
	Risk (95% CI)	6	0 (0 - 0)	68 (0 - 201)
	Events, n	9	0	<5
	Persons at risk	9	37	<589
	Risk (95% CI)	9	0 (0 - 0)	68 (0 - 201)
	Events, n	12	0	<5
	Persons at risk	12	32	<589
	Risk (95% CI)	12	0 (0 - 0)	68 (0 - 201)

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Table 15.19.11.6.4 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N=61)	Pericarditis cohort (N<589)
No				
	Events, n	3	0	<5
	Persons at risk	3	512	<1291
	Risk (95% CI)	3	0 (0 - 0)	31 (1 - 62)
	Events, n	6	<5	<5
	Persons at risk	6	<2000	<1291
	Risk (95% CI)	6	20 (0 - 58)	31 (1 - 62)
	Events, n	9	<5	5
	Persons at risk	9	<2000	937
	Risk (95% CI)	9	20 (0 - 58)	41 (5 - 78)
	Events, n	12	<5	5
	Persons at risk	12	<2000	838
	Risk (95% CI)	12	20 (0 - 58)	41 (5 - 78)
Yes				
	Events, n	3	0	<5
	Persons at risk	3	222	<817
	Risk (95% CI)	3	0 (0 - 0)	49 (0 - 117)
	Events, n	6	0	<5
	Persons at risk	6	179	<817
	Risk (95% CI)	6	0 (0 - 0)	49 (0 - 117)
	Events, n	9	0	<5
	Persons at risk	9	148	<482
	Risk (95% CI)	9	0 (0 - 0)	83 (0 - 178)
	Events, n	12	0	<5
	Persons at risk	12	113	<482
	Risk (95% CI)	12	0 (0 - 0)	83 (0 - 178)

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Table 15.19.11.6.5 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=252)	Pericarditis cohort (N<817)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	59	97
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	56	96
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	<5
	Persons at risk	9	55	<385
	Risk (95% CI)	9	0 (0 - 0)	104 (0 - 305)
	Events, n	12	0	<5
	Persons at risk	12	52	<385
	Risk (95% CI)	12	0 (0 - 0)	104 (0 - 305)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	375	<1177
	Risk (95% CI)	3	0 (0 - 0)	34 (0 - 72)
	Events, n	6	0	<5
	Persons at risk	6	293	<1177
	Risk (95% CI)	6	0 (0 - 0)	34 (0 - 72)
	Events, n	9	0	<5
	Persons at risk	9	238	<1177
	Risk (95% CI)	9	0 (0 - 0)	34 (0 - 72)
	Events, n	12	0	<5
	Persons at risk	12	182	<1177
	Risk (95% CI)	12	0 (0 - 0)	34 (0 - 72)

Table 15.19.11.6.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=431)	Pericarditis cohort (N<1177)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	300	<931
	Risk (95% CI)	3	0 (0 - 0)	43 (0 - 91)
	Events, n	6	<5	<5
	Persons at risk	6	<1177	<931
	Risk (95% CI)	6	34 (0 - 99)	43 (0 - 91)
	Events, n	9	<5	<5
	Persons at risk	9	<1177	<678
	Risk (95% CI)	9	34 (0 - 99)	59 (1 - 117)
	Events, n	12	<5	<5
	Persons at risk	12	<1177	<678
	Risk (95% CI)	12	34 (0 - 99)	59 (1 - 117)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	17	27
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	26
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	17	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	17	25
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	73	151
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	63	140
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	<5
	Persons at risk	9	53	<482
	Risk (95% CI)	9	0 (0 - 0)	83 (0 - 245)
	Events, n	12	0	<5

Table 15.19.11.6.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=431)	Pericarditis cohort (N<1177)
	Persons at risk	12	46	<482
	Risk (95% CI)	12	0 (0 - 0)	83 (0 - 245)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	23	24
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	22	24
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	21	23
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	21	22
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	170	<755
	Risk (95% CI)	3	0 (0 - 0)	53 (0 - 126)
	Events, n	6	0	<5
	Persons at risk	6	140	<755
	Risk (95% CI)	6	0 (0 - 0)	53 (0 - 126)
	Events, n	9	0	<5
	Persons at risk	9	124	<755
	Risk (95% CI)	9	0 (0 - 0)	53 (0 - 126)
	Events, n	12	0	<5
	Persons at risk	12	108	<755
	Risk (95% CI)	12	0 (0 - 0)	53 (0 - 126)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	6	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	5	9

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Table 15.19.11.6.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=431)	Pericarditis cohort (N<1177)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	137	<1429
	Risk (95% CI)	3	0 (0 - 0)	28 (0 - 82)
	Events, n	6	0	<5
	Persons at risk	6	99	<1429
	Risk (95% CI)	6	0 (0 - 0)	28 (0 - 82)
	Events, n	9	0	<5
	Persons at risk	9	72	<1429
	Risk (95% CI)	9	0 (0 - 0)	28 (0 - 82)
	Events, n	12	0	<5
	Persons at risk	12	39	<1429
	Risk (95% CI)	12	0 (0 - 0)	28 (0 - 82)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	7	22
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	12
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.11.6.6 Risk (1-KM and 95% CI) for CHRONIC PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=431)	Pericarditis cohort (N<1177)
	Events, n	9	0	0
	Persons at risk	9	<5	7
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.12.1.1 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N=10)	Pericarditis cohort (N=30)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.12.1.2 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.12.1.3 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.12.1.4 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.12.1.5 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

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Table 15.19.12.1.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.12.1.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

Table 15.19.12.1.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.12.1.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.12.2.1 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	127	22
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	118	21
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	108	19
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	96	17
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.2.2 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N=135)	Pericarditis cohort (N=23)
Male				
	Events, n	3	0	0
	Persons at risk	3	414	64
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	386	63
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	347	57
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	320	47
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	204	30
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	186	28
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	171	27
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	157	26
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.2.3 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N=217)	Pericarditis cohort (N=32)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	86	17
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	80	17
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	73	15
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	66	13
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	41	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	35	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.2.4 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N=42)	Pericarditis cohort (N=5)
No				
	Events, n	3	0	0
	Persons at risk	3	517	81
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	485	79
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	445	74
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	415	65
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	101	13
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	87	12
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	73	10
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	62	8
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.2.5 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=121)	Pericarditis cohort (N=15)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	36	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	35	5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	235	28
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	212	27
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	182	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	162	21
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.2.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	347	61
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	325	59
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	302	53
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	282	47
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	81	10
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	77	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	69	10
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.12.2.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Persons at risk	12	63	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	13	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	129	15
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	114	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	101	13
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	93	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.12.2.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	30	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	27	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	18	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.12.2.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=31)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.12.3.1 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N=5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	186	261
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	159	233
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	136	205
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	113	176
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.3.2 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N=204)	Pericarditis cohort (N=289)
Male				
	Events, n	3	0	0
	Persons at risk	3	480	1185
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	414	1041
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	360	894
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	313	748
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	224	559
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	202	479
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	176	424
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	148	360
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.3.3 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N=268)	Pericarditis cohort (N=626)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	154	203
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	130	185
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	111	162
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	94	139
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	32	58
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	29	48
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	25	43
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	19	37
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.3.4 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N=34)	Pericarditis cohort (N=61)
No				
	Events, n	3	0	0
	Persons at risk	3	607	1586
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	542	1401
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	482	1240
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	429	1077
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	97	158
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	74	119
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	54	78
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	32	31
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.3.5 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N=204)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	62	186
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	57	178
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	56	176
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	54	167
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	396	1041
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	327	841
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	258	661
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	197	488
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.12.3.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	246	517
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	232	501
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	222	481
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	210	453
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	18	49
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	49
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	16	49
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	16	48
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	61	129
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	57	120
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	50	112
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.12.3.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Persons at risk	12	44	104
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	59
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	58
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	58
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	58
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	207	494
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	189	458
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	169	419
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	151	377
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	23
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	22
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	21

Table 15.19.12.3.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	11	18
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	134	427
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	95	301
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	53	172
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	17	50
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	10	41
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.3.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=477)	Pericarditis cohort (N=1202)
	Events, n	9	0	0
	Persons at risk	9	<5	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.12.4.1 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N=24)	Pericarditis cohort (N=75)
15-30				
	Events, n	3	0	0
	Persons at risk	3	37	87
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	37	82
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	34	75
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	30	62
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.4.2 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N=39)	Pericarditis cohort (N=94)
Male				
	Events, n	3	<5	<5
	Persons at risk	3	<364	<1250
	Risk (95% CI)	3	110 (0 - 322)	32 (0 - 94)
	Events, n	6	<5	<5
	Persons at risk	6	<364	<1250
	Risk (95% CI)	6	110 (0 - 322)	32 (0 - 94)
	Events, n	9	<5	<5
	Persons at risk	9	<364	<1250
	Risk (95% CI)	9	110 (0 - 322)	32 (0 - 94)
	Events, n	12	<5	<5
	Persons at risk	12	<364	<1250
	Risk (95% CI)	12	110 (0 - 322)	32 (0 - 94)
Female				
	Events, n	3	0	<5
	Persons at risk	3	19	<482
	Risk (95% CI)	3	0 (0 - 0)	83 (0 - 243)
	Events, n	6	0	<5
	Persons at risk	6	18	<482
	Risk (95% CI)	6	0 (0 - 0)	83 (0 - 243)
	Events, n	9	0	<5
	Persons at risk	9	14	<482
	Risk (95% CI)	9	0 (0 - 0)	83 (0 - 243)
	Events, n	12	0	<5
	Persons at risk	12	14	<482
	Risk (95% CI)	12	0 (0 - 0)	83 (0 - 243)

Table 15.19.12.4.3 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N<482)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	36	71
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	36	68
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	33	63
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	51
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.12.4.4 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	0	<5
	Persons at risk	3	75	<635
	Risk (95% CI)	3	0 (0 - 0)	63 (0 - 150)
	Events, n	6	0	<5
	Persons at risk	6	73	<635
	Risk (95% CI)	6	0 (0 - 0)	63 (0 - 150)
	Events, n	9	0	<5
	Persons at risk	9	67	<635
	Risk (95% CI)	9	0 (0 - 0)	63 (0 - 150)
	Events, n	12	0	<5
	Persons at risk	12	61	<635
	Risk (95% CI)	12	0 (0 - 0)	63 (0 - 150)
Yes				
	Events, n	3	<5	0
	Persons at risk	3	<137	103
	Risk (95% CI)	3	294 (0 - 846)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<137	89
	Risk (95% CI)	6	294 (0 - 846)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<137	78
	Risk (95% CI)	9	294 (0 - 846)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<137	64
	Risk (95% CI)	12	294 (0 - 846)	0 (0 - 0)

Table 15.19.12.4.5 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<137)	Pericarditis cohort (N=118)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	9	29
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	29
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	9	28
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	27
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<260	235
	Risk (95% CI)	3	154 (0 - 449)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<260	205
	Risk (95% CI)	6	154 (0 - 449)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<260	178
	Risk (95% CI)	9	154 (0 - 449)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<260	146
	Risk (95% CI)	12	154 (0 - 449)	0 (0 - 0)

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Table 15.19.12.4.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<260)	Pericarditis cohort (N=272)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	38	<267
	Risk (95% CI)	3	0 (0 - 0)	150 (0 - 355)
	Events, n	6	0	<5
	Persons at risk	6	38	<267
	Risk (95% CI)	6	0 (0 - 0)	150 (0 - 355)
	Events, n	9	0	<5
	Persons at risk	9	37	<267
	Risk (95% CI)	9	0 (0 - 0)	150 (0 - 355)
	Events, n	12	0	<5
	Persons at risk	12	34	<267
	Risk (95% CI)	12	0 (0 - 0)	150 (0 - 355)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	9	19
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	18
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	8	17
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.12.4.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<260)	Pericarditis cohort (N=272)
	Persons at risk	12	8	12
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<140	162
	Risk (95% CI)	3	286 (0 - 822)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<140	147
	Risk (95% CI)	6	286 (0 - 822)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<140	129
	Risk (95% CI)	9	286 (0 - 822)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<140	113
	Risk (95% CI)	12	286 (0 - 822)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.12.4.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<260)	Pericarditis cohort (N=272)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	14	56
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	44
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	11	38
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	27
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)

Table 15.19.12.4.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<260)	Pericarditis cohort (N=272)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.12.5.1 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=11)
15-30				
	Events, n	3	0	<5
	Persons at risk	3	109	<1026
	Risk (95% CI)	3	0 (0 - 0)	39 (0 - 116)
	Events, n	6	0	<5
	Persons at risk	6	94	<1026
	Risk (95% CI)	6	0 (0 - 0)	39 (0 - 116)
	Events, n	9	0	<5
	Persons at risk	9	74	<1026
	Risk (95% CI)	9	0 (0 - 0)	39 (0 - 116)
	Events, n	12	0	<5
	Persons at risk	12	68	<1026
	Risk (95% CI)	12	0 (0 - 0)	39 (0 - 116)

Table 15.19.12.5.2 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N=119)	Pericarditis cohort (N<1026)
Male				
	Events, n	3	<5	7
	Persons at risk	3	<817	974
	Risk (95% CI)	3	49 (0 - 116)	67 (17 - 116)
	Events, n	6	<5	8
	Persons at risk	6	<817	914
	Risk (95% CI)	6	49 (0 - 116)	77 (24 - 130)
	Events, n	9	<5	9
	Persons at risk	9	<817	867
	Risk (95% CI)	9	49 (0 - 116)	88 (30 - 145)
	Events, n	12	<5	9
	Persons at risk	12	<817	815
	Risk (95% CI)	12	49 (0 - 116)	88 (30 - 145)
Female				
	Events, n	3	0	<5
	Persons at risk	3	240	<580
	Risk (95% CI)	3	0 (0 - 0)	69 (1 - 137)
	Events, n	6	0	<5
	Persons at risk	6	203	<580
	Risk (95% CI)	6	0 (0 - 0)	69 (1 - 137)
	Events, n	9	0	<5
	Persons at risk	9	152	<580
	Risk (95% CI)	9	0 (0 - 0)	69 (1 - 137)
	Events, n	12	0	<5
	Persons at risk	12	135	<580
	Risk (95% CI)	12	0 (0 - 0)	69 (1 - 137)

Table 15.19.12.5.3 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N=591)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	86	196
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	73	188
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	59	181
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	55	175
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	<5
	Persons at risk	3	23	<217
	Risk (95% CI)	3	0 (0 - 0)	185 (0 - 538)
	Events, n	6	0	<5
	Persons at risk	6	21	<217
	Risk (95% CI)	6	0 (0 - 0)	185 (0 - 538)
	Events, n	9	0	<5
	Persons at risk	9	15	<217
	Risk (95% CI)	9	0 (0 - 0)	185 (0 - 538)
	Events, n	12	0	<5
	Persons at risk	12	13	<217
	Risk (95% CI)	12	0 (0 - 0)	185 (0 - 538)

Table 15.19.12.5.4 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N=24)	Pericarditis cohort (N<217)
No				
	Events, n	3	<5	6
	Persons at risk	3	<715	1095
	Risk (95% CI)	3	56 (0 - 133)	52 (10 - 93)
	Events, n	6	<5	7
	Persons at risk	6	<715	1049
	Risk (95% CI)	6	56 (0 - 133)	61 (16 - 106)
	Events, n	9	<5	8
	Persons at risk	9	<715	1005
	Risk (95% CI)	9	56 (0 - 133)	71 (22 - 119)
	Events, n	12	<5	8
	Persons at risk	12	<715	961
	Risk (95% CI)	12	56 (0 - 133)	71 (22 - 119)
Yes				
	Events, n	3	0	5
	Persons at risk	3	282	412
	Risk (95% CI)	3	0 (0 - 0)	106 (13 - 199)
	Events, n	6	0	5
	Persons at risk	6	230	367
	Risk (95% CI)	6	0 (0 - 0)	106 (13 - 199)
	Events, n	9	0	5
	Persons at risk	9	169	334
	Risk (95% CI)	9	0 (0 - 0)	106 (13 - 199)
	Events, n	12	0	5
	Persons at risk	12	149	296
	Risk (95% CI)	12	0 (0 - 0)	106 (13 - 199)

Table 15.19.12.5.5 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=316)	Pericarditis cohort (N=477)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	27	127
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	27	125
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	26	122
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	25	120
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	<5	5
	Persons at risk	3	<715	654
	Risk (95% CI)	3	56 (0 - 134)	68 (8 - 127)
	Events, n	6	<5	5
	Persons at risk	6	<715	589
	Risk (95% CI)	6	56 (0 - 134)	68 (8 - 127)
	Events, n	9	<5	5
	Persons at risk	9	<715	533
	Risk (95% CI)	9	56 (0 - 134)	68 (8 - 127)
	Events, n	12	<5	5
	Persons at risk	12	<715	472
	Risk (95% CI)	12	56 (0 - 134)	68 (8 - 127)

Table 15.19.12.5.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<715)	Pericarditis cohort (N=764)
Unvaccinated				
	Events, n	3	0	6
	Persons at risk	3	264	726
	Risk (95% CI)	3	0 (0 - 0)	79 (16 - 142)
	Events, n	6	0	7
	Persons at risk	6	232	702
	Risk (95% CI)	6	0 (0 - 0)	93 (24 - 161)
	Events, n	9	0	8
	Persons at risk	9	193	684
	Risk (95% CI)	9	0 (0 - 0)	107 (33 - 180)
	Events, n	12	0	8
	Persons at risk	12	185	665
	Risk (95% CI)	12	0 (0 - 0)	107 (33 - 180)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	7	42
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	7	42
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	6	41
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	6	40
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	44	61
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	38	59
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	29	58
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.12.5.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<715)	Pericarditis cohort (N=764)
	Persons at risk	12	28	57
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	34
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	34
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	34
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<889	<690
	Risk (95% CI)	3	45 (0 - 132)	58 (0 - 124)
	Events, n	6	<5	<5
	Persons at risk	6	<889	<690
	Risk (95% CI)	6	45 (0 - 132)	58 (0 - 124)
	Events, n	9	<5	<5
	Persons at risk	9	<889	<690
	Risk (95% CI)	9	45 (0 - 132)	58 (0 - 124)
	Events, n	12	<5	<5
	Persons at risk	12	<889	<690
	Risk (95% CI)	12	45 (0 - 132)	58 (0 - 124)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5

Table 15.19.12.5.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<715)	Pericarditis cohort (N=764)
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	<5
	Persons at risk	3	<269	<282
	Risk (95% CI)	3	149 (0 - 435)	142 (0 - 335)
	Events, n	6	<5	<5
	Persons at risk	6	<269	<282
	Risk (95% CI)	6	149 (0 - 435)	142 (0 - 335)
	Events, n	9	<5	<5
	Persons at risk	9	<269	<282
	Risk (95% CI)	9	149 (0 - 435)	142 (0 - 335)
	Events, n	12	<5	<5
	Persons at risk	12	<269	<282
	Risk (95% CI)	12	149 (0 - 435)	142 (0 - 335)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	19	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	5	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.5.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<715)	Pericarditis cohort (N=764)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.12.6.1 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N=25)	Pericarditis cohort (N=61)
15-30				
	Events, n	3	0	0
	Persons at risk	3	311	555
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	269	490
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	226	431
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	189	366
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.6.2 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N=356)	Pericarditis cohort (N=644)
Male				
	Events, n	3	0	0
	Persons at risk	3	501	1128
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	440	977
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	384	847
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	322	744
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	253	500
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	219	442
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	182	384
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	160	341
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.6.3 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N=281)	Pericarditis cohort (N=548)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	251	413
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	220	361
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	185	323
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	156	271
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	60	142
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	49	129
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	41	108
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	33	95
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.6.4 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N=64)	Pericarditis cohort (N=159)
No				
	Events, n	3	0	0
	Persons at risk	3	525	1231
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	465	1096
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	409	971
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	358	874
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	229	397
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	194	323
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	157	260
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	124	211
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.6.5 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=262)	Pericarditis cohort (N=454)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	59	98
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	58	96
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	56	96
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	52	93
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	393	848
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	321	700
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	255	560
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	201	456
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.6.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	302	682
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	280	623
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	255	575
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	229	536
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	17	27
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	17	26
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	17	26
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	17	25
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	74	160
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	65	144
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	59	118
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.12.6.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Persons at risk	12	50	105
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	23	24
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	23	24
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	22	24
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	21	23
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	175	372
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	151	321
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	127	279
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	114	247
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	6	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	6	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	5	9

Table 15.19.12.6.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	148	329
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	113	258
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	80	193
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	47	137
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	8	25
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	14
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.12.6.6 Risk (1-KM and 95% CI) for CONSTRICTIVE PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=451)	Pericarditis cohort (N=973)
	Events, n	9	0	0
	Persons at risk	9	<5	7
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.13.1.1 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N=10)	Pericarditis cohort (N=30)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.13.1.2 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.13.1.3 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.13.1.4 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.13.1.5 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.13.1.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.13.1.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

Table 15.19.13.1.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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Table 15.19.13.1.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.13.2.1 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	<5	0
	Persons at risk	3	<466	18
	Risk (95% CI)	3	86 (0 - 253)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<150	18
	Risk (95% CI)	6	268 (0 - 562)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<150	17
	Risk (95% CI)	9	268 (0 - 562)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<150	16
	Risk (95% CI)	12	268 (0 - 562)	0 (0 - 0)

Table 15.19.13.2.2 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N<466)	Pericarditis cohort (N=20)
Male				
	Events, n	3	7	0
	Persons at risk	3	377	57
	Risk (95% CI)	3	176 (46 - 305)	0 (0 - 0)
	Events, n	6	8	0
	Persons at risk	6	346	56
	Risk (95% CI)	6	204 (63 - 343)	0 (0 - 0)
	Events, n	9	8	0
	Persons at risk	9	316	48
	Risk (95% CI)	9	204 (63 - 343)	0 (0 - 0)
	Events, n	12	8	0
	Persons at risk	12	280	43
	Risk (95% CI)	12	204 (63 - 343)	0 (0 - 0)
Female				
	Events, n	3	<5	0
	Persons at risk	3	<405	25
	Risk (95% CI)	3	99 (0 - 235)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<190	25
	Risk (95% CI)	6	211 (4 - 413)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<190	24
	Risk (95% CI)	9	211 (4 - 413)	0 (0 - 0)
	Events, n	12	5	0
	Persons at risk	12	137	24
	Risk (95% CI)	12	282 (32 - 525)	0 (0 - 0)

Table 15.19.13.2.3 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N<405)	Pericarditis cohort (N=27)
Male, 15-30 years				
	Events, n	3	<5	0
	Persons at risk	3	<313	14
	Risk (95% CI)	3	128 (0 - 375)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<313	14
	Risk (95% CI)	6	128 (0 - 375)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<313	13
	Risk (95% CI)	9	128 (0 - 375)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<313	12
	Risk (95% CI)	12	128 (0 - 375)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	38	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<72	<5
	Risk (95% CI)	6	556 (0 - 1277)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<72	<5
	Risk (95% CI)	9	556 (0 - 1277)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<72	<5
	Risk (95% CI)	12	556 (0 - 1277)	0 (0 - 0)

Table 15.19.13.2.4 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N<72)	Pericarditis cohort (N=5)
No				
	Events, n	3	9	0
	Persons at risk	3	472	71
	Risk (95% CI)	3	181 (63 - 298)	0 (0 - 0)
	Events, n	6	12	0
	Persons at risk	6	436	71
	Risk (95% CI)	6	246 (108 - 383)	0 (0 - 0)
	Events, n	9	12	0
	Persons at risk	9	403	63
	Risk (95% CI)	9	246 (108 - 383)	0 (0 - 0)
	Events, n	12	13	0
	Persons at risk	12	370	59
	Risk (95% CI)	12	273 (125 - 418)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	92	11
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	78	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	65	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	47	8
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.13.2.5 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=109)	Pericarditis cohort (N=13)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	35	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	34	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	33	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	31	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<304	24
	Risk (95% CI)	3	132 (0 - 280)	0 (0 - 0)
	Events, n	6	5	0
	Persons at risk	6	186	24
	Risk (95% CI)	6	230 (28 - 428)	0 (0 - 0)
	Events, n	9	5	0
	Persons at risk	9	163	21
	Risk (95% CI)	9	230 (28 - 428)	0 (0 - 0)
	Events, n	12	6	0
	Persons at risk	12	136	19
	Risk (95% CI)	12	301 (56 - 540)	0 (0 - 0)

Table 15.19.13.2.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<304)	Pericarditis cohort (N=27)
Unvaccinated				
	Events, n	3	6	0
	Persons at risk	3	314	54
	Risk (95% CI)	3	180 (36 - 322)	0 (0 - 0)
	Events, n	6	7	0
	Persons at risk	6	294	53
	Risk (95% CI)	6	213 (55 - 368)	0 (0 - 0)
	Events, n	9	7	0
	Persons at risk	9	272	47
	Risk (95% CI)	9	213 (55 - 368)	0 (0 - 0)
	Events, n	12	7	0
	Persons at risk	12	250	44
	Risk (95% CI)	12	213 (55 - 368)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	11	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	11	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	11	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	11	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<164	10
	Risk (95% CI)	3	244 (0 - 573)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<164	10
	Risk (95% CI)	6	244 (0 - 573)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<164	9
	Risk (95% CI)	9	244 (0 - 573)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.13.2.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<304)	Pericarditis cohort (N=27)
	Persons at risk	12	<97	9
	Risk (95% CI)	12	415 (0 - 871)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	13	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	13	0
	Risk (95% CI)	9	0 (0 - 0)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	13	0
	Risk (95% CI)	12	0 (0 - 0)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<455	13
	Risk (95% CI)	3	88 (0 - 257)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<226	13
	Risk (95% CI)	6	177 (0 - 417)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<226	12
	Risk (95% CI)	9	177 (0 - 417)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<226	10
	Risk (95% CI)	12	177 (0 - 417)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

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Table 15.19.13.2.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<304)	Pericarditis cohort (N=27)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	30	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<104	<5
	Risk (95% CI)	6	385 (0 - 1096)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<104	<5
	Risk (95% CI)	9	385 (0 - 1096)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<104	<5
	Risk (95% CI)	12	385 (0 - 1096)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

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Table 15.19.13.2.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N<304)	Pericarditis cohort (N=27)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.13.3.1 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	45	11
	Persons at risk	3	91	232
	Risk (95% CI)	3	3153 (2343 - 3877)	427 (177 - 671)
	Events, n	6	48	12
	Persons at risk	6	75	210
	Risk (95% CI)	6	3398 (2562 - 4139)	472 (207 - 730)
	Events, n	9	51	13
	Persons at risk	9	61	182
	Risk (95% CI)	9	3678 (2808 - 4442)	524 (241 - 798)
	Events, n	12	55	15
	Persons at risk	12	43	147
	Risk (95% CI)	12	4174 (3218 - 4995)	642 (316 - 957)

Table 15.19.13.3.2 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N=152)	Pericarditis cohort (N=275)
Male				
	Events, n	3	78	21
	Persons at risk	3	292	1090
	Risk (95% CI)	3	1976 (1573 - 2361)	176 (101 - 250)
	Events, n	6	92	24
	Persons at risk	6	241	960
	Risk (95% CI)	6	2381 (1942 - 2797)	205 (123 - 286)
	Events, n	9	100	27
	Persons at risk	9	199	816
	Risk (95% CI)	9	2651 (2186 - 3089)	240 (149 - 329)
	Events, n	12	107	29
	Persons at risk	12	165	662
	Risk (95% CI)	12	2934 (2437 - 3399)	267 (169 - 364)
Female				
	Events, n	3	30	5
	Persons at risk	3	145	515
	Risk (95% CI)	3	1598 (1055 - 2108)	88 (11 - 164)
	Events, n	6	33	5
	Persons at risk	6	125	447
	Risk (95% CI)	6	1782 (1209 - 2319)	88 (11 - 164)
	Events, n	9	35	6
	Persons at risk	9	111	390
	Risk (95% CI)	9	1915 (1319 - 2470)	110 (22 - 198)
	Events, n	12	36	6
	Persons at risk	12	89	319
	Risk (95% CI)	12	2001 (1385 - 2573)	110 (22 - 198)

Table 15.19.13.3.3 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N=199)	Pericarditis cohort (N=598)
Male, 15-30 years				
	Events, n	3	38	9
	Persons at risk	3	76	183
	Risk (95% CI)	3	3176 (2286 - 3964)	445 (156 - 725)
	Events, n	6	41	10
	Persons at risk	6	62	168
	Risk (95% CI)	6	3471 (2546 - 4281)	501 (193 - 799)
	Events, n	9	44	11
	Persons at risk	9	49	145
	Risk (95% CI)	9	3811 (2840 - 4650)	566 (233 - 887)
	Events, n	12	48	13
	Persons at risk	12	35	116
	Risk (95% CI)	12	4404 (3326 - 5309)	714 (325 - 1087)
Female, 15-30 years				
	Events, n	3	7	<5
	Persons at risk	3	15	<113
	Risk (95% CI)	3	3051 (874 - 4710)	357 (0 - 831)
	Events, n	6	7	<5
	Persons at risk	6	13	<113
	Risk (95% CI)	6	3051 (874 - 4710)	357 (0 - 831)
	Events, n	9	7	<5
	Persons at risk	9	12	<113
	Risk (95% CI)	9	3051 (874 - 4710)	357 (0 - 831)
	Events, n	12	7	<5
	Persons at risk	12	8	<113
	Risk (95% CI)	12	3051 (874 - 4710)	357 (0 - 831)

Table 15.19.13.3.4 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N=24)	Pericarditis cohort (N<113)
No				
	Events, n	3	97	22
	Persons at risk	3	376	1474
	Risk (95% CI)	3	1941 (1586 - 2281)	138 (81 - 195)
	Events, n	6	108	23
	Persons at risk	6	323	1308
	Risk (95% CI)	6	2190 (1814 - 2548)	146 (86 - 205)
	Events, n	9	118	27
	Persons at risk	9	281	1145
	Risk (95% CI)	9	2441 (2044 - 2818)	178 (111 - 245)
	Events, n	12	125	29
	Persons at risk	12	238	962
	Risk (95% CI)	12	2647 (2230 - 3041)	197 (125 - 269)
Yes				
	Events, n	3	11	<5
	Persons at risk	3	61	<173
	Risk (95% CI)	3	1343 (567 - 2055)	232 (4 - 455)
	Events, n	6	17	6
	Persons at risk	6	43	99
	Risk (95% CI)	6	2261 (1237 - 3166)	411 (74 - 736)
	Events, n	9	17	6
	Persons at risk	9	29	61
	Risk (95% CI)	9	2261 (1237 - 3166)	411 (74 - 736)
	Events, n	12	18	6
	Persons at risk	12	16	19
	Risk (95% CI)	12	2613 (1381 - 3669)	411 (74 - 736)

Table 15.19.13.3.5 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=94)	Pericarditis cohort (N=193)
Vaccinated				
	Events, n	3	13	7
	Persons at risk	3	38	172
	Risk (95% CI)	3	2518 (1232 - 3615)	384 (101 - 659)
	Events, n	6	13	7
	Persons at risk	6	33	165
	Risk (95% CI)	6	2518 (1232 - 3615)	384 (101 - 659)
	Events, n	9	14	7
	Persons at risk	9	32	165
	Risk (95% CI)	9	2745 (1403 - 3877)	384 (101 - 659)
	Events, n	12	14	7
	Persons at risk	12	27	140
	Risk (95% CI)	12	2745 (1403 - 3877)	384 (101 - 659)
Unvaccinated				
	Events, n	3	59	9
	Persons at risk	3	243	944
	Risk (95% CI)	3	1766 (1345 - 2166)	84 (29 - 138)
	Events, n	6	69	12
	Persons at risk	6	189	766
	Risk (95% CI)	6	2134 (1669 - 2573)	120 (52 - 189)
	Events, n	9	69	13
	Persons at risk	9	150	587
	Risk (95% CI)	9	2134 (1669 - 2573)	137 (61 - 212)
	Events, n	12	73	15
	Persons at risk	12	112	417
	Risk (95% CI)	12	2387 (1870 - 2872)	178 (83 - 273)

Table 15.19.13.3.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=357)	Pericarditis cohort (N=1148)
Unvaccinated				
	Events, n	3	36	10
	Persons at risk	3	156	489
	Risk (95% CI)	3	1821 (1264 - 2342)	196 (75 - 315)
	Events, n	6	43	10
	Persons at risk	6	144	476
	Risk (95% CI)	6	2191 (1589 - 2750)	196 (75 - 315)
	Events, n	9	52	13
	Persons at risk	9	128	454
	Risk (95% CI)	9	2690 (2035 - 3292)	259 (119 - 397)
	Events, n	12	56	13
	Persons at risk	12	115	424
	Risk (95% CI)	12	2928 (2248 - 3548)	259 (119 - 397)
Received dose 1 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<14	<96
	Risk (95% CI)	3	3000 (0 - 5335)	417 (0 - 966)
	Events, n	6	<5	<5
	Persons at risk	6	<14	<96
	Risk (95% CI)	6	3000 (0 - 5335)	417 (0 - 966)
	Events, n	9	<5	<5
	Persons at risk	9	<14	<96
	Risk (95% CI)	9	3000 (0 - 5335)	417 (0 - 966)
	Events, n	12	<5	<5
	Persons at risk	12	<14	<96
	Risk (95% CI)	12	3000 (0 - 5335)	417 (0 - 966)
Received dose 1, 15 or more days ago				
	Events, n	3	7	<5
	Persons at risk	3	43	<260
	Risk (95% CI)	3	1342 (364 - 2221)	154 (0 - 365)
	Events, n	6	10	<5
	Persons at risk	6	37	<260
	Risk (95% CI)	6	1946 (785 - 2962)	154 (0 - 365)
	Events, n	9	10	<5
	Persons at risk	9	33	<260
	Risk (95% CI)	9	1946 (785 - 2962)	154 (0 - 365)
	Events, n	12	12	<5

Table 15.19.13.3.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=357)	Pericarditis cohort (N=1148)
	Persons at risk	12	26	<114
	Risk (95% CI)	12	2487 (1132 - 3635)	351 (4 - 685)
Received dose 2 in the last 14 days				
	Events, n	3	5	<5
	Persons at risk	3	7	<77
	Risk (95% CI)	3	4167 (590 - 6384)	520 (0 - 1077)
	Events, n	6	5	<5
	Persons at risk	6	7	<77
	Risk (95% CI)	6	4167 (590 - 6384)	520 (0 - 1077)
	Events, n	9	5	<5
	Persons at risk	9	7	<77
	Risk (95% CI)	9	4167 (590 - 6384)	520 (0 - 1077)
	Events, n	12	5	<5
	Persons at risk	12	6	<77
	Risk (95% CI)	12	4167 (590 - 6384)	520 (0 - 1077)
Received dose 2, 15 or more days ago				
	Events, n	3	42	7
	Persons at risk	3	124	464
	Risk (95% CI)	3	2423 (1756 - 3036)	141 (37 - 245)
	Events, n	6	45	9
	Persons at risk	6	110	428
	Risk (95% CI)	6	2617 (1927 - 3247)	187 (65 - 307)
	Events, n	9	45	10
	Persons at risk	9	102	388
	Risk (95% CI)	9	2617 (1927 - 3247)	212 (81 - 341)
	Events, n	12	47	10
	Persons at risk	12	88	342
	Risk (95% CI)	12	2774 (2060 - 3423)	212 (81 - 341)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	10	22
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	10	20
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<40	20

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Table 15.19.13.3.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=357)	Pericarditis cohort (N=1148)
	Risk (95% CI)	9	1000 (0 - 2680)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<40	9
	Risk (95% CI)	12	1000 (0 - 2680)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	15	<5
	Persons at risk	3	83	<870
	Risk (95% CI)	3	1318 (670 - 1921)	46 (0 - 109)
	Events, n	6	19	<5
	Persons at risk	6	51	<527
	Risk (95% CI)	6	1823 (1024 - 2550)	76 (0 - 162)
	Events, n	9	19	<5
	Persons at risk	9	24	<527
	Risk (95% CI)	9	1823 (1024 - 2550)	76 (0 - 162)
	Events, n	12	19	<5
	Persons at risk	12	6	<527
	Risk (95% CI)	12	1823 (1024 - 2550)	76 (0 - 162)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	22
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	7
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.13.3.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=357)	Pericarditis cohort (N=1148)
	Events, n	9	0	0
	Persons at risk	9	<5	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.13.4.1 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N=15)	Pericarditis cohort (N=67)
15-30				
	Events, n	3	0	0
	Persons at risk	3	27	82
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	25	74
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	23	68
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	22	57
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.13.4.2 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N=27)	Pericarditis cohort (N=87)
Male				
	Events, n	3	<5	0
	Persons at risk	3	<92	268
	Risk (95% CI)	3	437 (0 - 909)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<69	242
	Risk (95% CI)	6	586 (12 - 1128)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<69	221
	Risk (95% CI)	9	586 (12 - 1128)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<69	198
	Risk (95% CI)	12	586 (12 - 1128)	0 (0 - 0)
Female				
	Events, n	3	0	0
	Persons at risk	3	15	100
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<60	89
	Risk (95% CI)	6	667 (0 - 1847)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<60	81
	Risk (95% CI)	9	667 (0 - 1847)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<60	73
	Risk (95% CI)	12	667 (0 - 1847)	0 (0 - 0)

Table 15.19.13.4.3 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N<60)	Pericarditis cohort (N=110)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	26	66
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	24	61
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	22	56
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	21	46
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	13
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.13.4.4 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=16)
No				
	Events, n	3	0	0
	Persons at risk	3	62	270
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<122	248
	Risk (95% CI)	6	328 (0 - 765)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<122	229
	Risk (95% CI)	9	328 (0 - 765)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<122	212
	Risk (95% CI)	12	328 (0 - 765)	0 (0 - 0)
Yes				
	Events, n	3	<5	0
	Persons at risk	3	<28	98
	Risk (95% CI)	3	1429 (0 - 2802)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<28	83
	Risk (95% CI)	6	1429 (0 - 2802)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<28	73
	Risk (95% CI)	9	1429 (0 - 2802)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<28	59
	Risk (95% CI)	12	1429 (0 - 2802)	0 (0 - 0)

Table 15.19.13.4.5 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<28)	Pericarditis cohort (N=107)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	8	29
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	8	29
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	8	27
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	8	27
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<177	222
	Risk (95% CI)	3	227 (0 - 658)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<83	189
	Risk (95% CI)	6	484 (0 - 1119)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<83	165
	Risk (95% CI)	9	484 (0 - 1119)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<83	137
	Risk (95% CI)	12	484 (0 - 1119)	0 (0 - 0)

Table 15.19.13.4.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<177)	Pericarditis cohort (N=247)
Unvaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<67	117
	Risk (95% CI)	3	606 (0 - 1386)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<44	113
	Risk (95% CI)	6	919 (0 - 1859)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<44	110
	Risk (95% CI)	9	919 (0 - 1859)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<44	107
	Risk (95% CI)	12	919 (0 - 1859)	0 (0 - 0)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	7	18
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	6	17
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	6	16
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

Table 15.19.13.4.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<177)	Pericarditis cohort (N=247)
	Persons at risk	12	6	11
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<109	152
	Risk (95% CI)	3	370 (0 - 1057)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<52	137
	Risk (95% CI)	6	772 (0 - 1745)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<52	122
	Risk (95% CI)	9	772 (0 - 1745)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<52	107
	Risk (95% CI)	12	772 (0 - 1745)	0 (0 - 0)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.13.4.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<177)	Pericarditis cohort (N=247)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	11	54
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	10	41
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	8	33
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	7	25
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)

Table 15.19.13.4.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<177)	Pericarditis cohort (N=247)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.13.5.1 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=7)
15-30				
	Events, n	3	<5	<5
	Persons at risk	3	<345	<513
	Risk (95% CI)	3	116 (0 - 340)	78 (0 - 184)
	Events, n	6	<5	<5
	Persons at risk	6	<345	<513
	Risk (95% CI)	6	116 (0 - 340)	78 (0 - 184)
	Events, n	9	<5	<5
	Persons at risk	9	<345	<513
	Risk (95% CI)	9	116 (0 - 340)	78 (0 - 184)
	Events, n	12	<5	<5
	Persons at risk	12	<80	<513
	Risk (95% CI)	12	501 (0 - 1050)	78 (0 - 184)

Table 15.19.13.5.2 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N<345)	Pericarditis cohort (N<513)
Male				
	Events, n	3	8	<5
	Persons at risk	3	310	<2000
	Risk (95% CI)	3	240 (74 - 403)	20 (0 - 47)
	Events, n	6	11	<5
	Persons at risk	6	229	<2000
	Risk (95% CI)	6	352 (144 - 556)	20 (0 - 47)
	Events, n	9	12	<5
	Persons at risk	9	200	<1291
	Risk (95% CI)	9	397 (171 - 616)	31 (0 - 67)
	Events, n	12	14	<5
	Persons at risk	12	183	<910
	Risk (95% CI)	12	497 (233 - 753)	44 (1 - 86)
Female				
	Events, n	3	<5	<5
	Persons at risk	3	<308	<2106
	Risk (95% CI)	3	130 (0 - 276)	19 (0 - 55)
	Events, n	6	6	<5
	Persons at risk	6	150	<1026
	Risk (95% CI)	6	285 (56 - 509)	39 (0 - 92)
	Events, n	9	6	<5
	Persons at risk	9	129	<678
	Risk (95% CI)	9	285 (56 - 509)	59 (0 - 126)
	Events, n	12	7	<5
	Persons at risk	12	117	<678
	Risk (95% CI)	12	362 (88 - 628)	59 (0 - 126)

Table 15.19.13.5.3 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N<308)	Pericarditis cohort (N<2106)
Male, 15-30 years				
	Events, n	3	<5	<5
	Persons at risk	3	<257	<405
	Risk (95% CI)	3	156 (0 - 455)	99 (0 - 235)
	Events, n	6	<5	<5
	Persons at risk	6	<257	<405
	Risk (95% CI)	6	156 (0 - 455)	99 (0 - 235)
	Events, n	9	<5	<5
	Persons at risk	9	<257	<405
	Risk (95% CI)	9	156 (0 - 455)	99 (0 - 235)
	Events, n	12	<5	<5
	Persons at risk	12	<97	<405
	Risk (95% CI)	12	415 (0 - 980)	99 (0 - 235)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	20	52
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	15	48
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	13	41
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<53	40
	Risk (95% CI)	12	769 (0 - 2110)	0 (0 - 0)

Table 15.19.13.5.4 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N=53)	Pericarditis cohort (N=56)
No				
	Events, n	3	9	<5
	Persons at risk	3	276	<1482
	Risk (95% CI)	3	301 (105 - 493)	27 (0 - 57)
	Events, n	6	13	<5
	Persons at risk	6	212	<1482
	Risk (95% CI)	6	456 (210 - 696)	27 (0 - 57)
	Events, n	9	13	5
	Persons at risk	9	188	976
	Risk (95% CI)	9	456 (210 - 696)	47 (6 - 87)
	Events, n	12	13	6
	Persons at risk	12	178	943
	Risk (95% CI)	12	456 (210 - 696)	57 (11 - 102)
Yes				
	Events, n	3	<5	0
	Persons at risk	3	<513	406
	Risk (95% CI)	3	78 (0 - 184)	0 (0 - 0)
	Events, n	6	<5	<5
	Persons at risk	6	<225	<1482
	Risk (95% CI)	6	178 (2 - 351)	27 (0 - 81)
	Events, n	9	5	<5
	Persons at risk	9	141	<1482
	Risk (95% CI)	9	242 (26 - 453)	27 (0 - 81)
	Events, n	12	8	<5
	Persons at risk	12	122	<1482
	Risk (95% CI)	12	461 (133 - 777)	27 (0 - 81)

Table 15.19.13.5.5 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<513)	Pericarditis cohort (N<1482)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	25	126
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	24	123
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	23	119
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	23	119
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	7	0
	Persons at risk	3	267	639
	Risk (95% CI)	3	238 (62 - 410)	0 (0 - 0)
	Events, n	6	10	<5
	Persons at risk	6	177	<2353
	Risk (95% CI)	6	370 (140 - 594)	17 (0 - 50)
	Events, n	9	11	<5
	Persons at risk	9	147	<1112
	Risk (95% CI)	9	428 (172 - 678)	36 (0 - 86)
	Events, n	12	13	<5
	Persons at risk	12	120	<1112
	Risk (95% CI)	12	573 (248 - 888)	36 (0 - 86)

Table 15.19.13.5.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=302)	Pericarditis cohort (N<2353)
Unvaccinated				
	Events, n	3	<5	<5
	Persons at risk	3	<243	<976
	Risk (95% CI)	3	165 (3 - 324)	41 (0 - 86)
	Events, n	6	7	<5
	Persons at risk	6	178	<976
	Risk (95% CI)	6	306 (79 - 528)	41 (0 - 86)
	Events, n	9	7	<5
	Persons at risk	9	159	<728
	Risk (95% CI)	9	306 (79 - 528)	55 (1 - 109)
	Events, n	12	8	5
	Persons at risk	12	157	654
	Risk (95% CI)	12	367 (111 - 617)	70 (9 - 132)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	6	41
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	5	41
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	5	39
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	5	39
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	41	60
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	31	58
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	27	57
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	<5	0

Table 15.19.13.5.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=302)	Pericarditis cohort (N<2353)
	Persons at risk	12	<53	57
	Risk (95% CI)	12	756 (0 - 1710)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	34
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	34
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	11	34
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	11	34
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<181	473
	Risk (95% CI)	3	222 (4 - 435)	0 (0 - 0)
	Events, n	6	6	<5
	Persons at risk	6	113	<1819
	Risk (95% CI)	6	365 (71 - 650)	22 (0 - 66)
	Events, n	9	6	<5
	Persons at risk	9	97	<870
	Risk (95% CI)	9	365 (71 - 650)	46 (0 - 110)
	Events, n	12	6	<5
	Persons at risk	12	81	<870
	Risk (95% CI)	12	365 (71 - 650)	46 (0 - 110)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5

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Table 15.19.13.5.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=302)	Pericarditis cohort (N<2353)
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<117	119
	Risk (95% CI)	3	342 (0 - 798)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<75	107
	Risk (95% CI)	6	539 (0 - 1117)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<51	78
	Risk (95% CI)	9	795 (1 - 1526)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<51	60
	Risk (95% CI)	12	795 (1 - 1526)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	<5	0
	Persons at risk	3	<88	30
	Risk (95% CI)	3	455 (0 - 1286)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	455 (0 - 1286)	0 (0 - 0)

Table 15.19.13.5.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N=302)	Pericarditis cohort (N<2353)
	Events, n	9	<5	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.13.6.1 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N<88)	Pericarditis cohort (N=51)
15-30				
	Events, n	3	31	8
	Persons at risk	3	203	511
	Risk (95% CI)	3	1251 (828 - 1654)	141 (43 - 238)
	Events, n	6	36	11
	Persons at risk	6	160	456
	Risk (95% CI)	6	1482 (1021 - 1919)	202 (83 - 319)
	Events, n	9	36	14
	Persons at risk	9	130	391
	Risk (95% CI)	9	1482 (1021 - 1919)	271 (129 - 411)
	Events, n	12	38	14
	Persons at risk	12	113	323
	Risk (95% CI)	12	1623 (1126 - 2091)	271 (129 - 411)

Table 15.19.13.6.2 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N=256)	Pericarditis cohort (N=598)
Male				
	Events, n	3	42	10
	Persons at risk	3	346	1043
	Risk (95% CI)	3	1021 (723 - 1309)	87 (33 - 140)
	Events, n	6	54	14
	Persons at risk	6	282	909
	Risk (95% CI)	6	1358 (1013 - 1690)	128 (61 - 194)
	Events, n	9	58	16
	Persons at risk	9	244	794
	Risk (95% CI)	9	1487 (1123 - 1835)	151 (77 - 225)
	Events, n	12	64	17
	Persons at risk	12	203	680
	Risk (95% CI)	12	1711 (1312 - 2092)	164 (86 - 242)
Female				
	Events, n	3	22	<5
	Persons at risk	3	165	<1053
	Risk (95% CI)	3	1085 (645 - 1503)	38 (0 - 91)
	Events, n	6	33	<5
	Persons at risk	6	124	<1053
	Risk (95% CI)	6	1732 (1171 - 2258)	38 (0 - 91)
	Events, n	9	34	5
	Persons at risk	9	104	365
	Risk (95% CI)	9	1800 (1226 - 2337)	115 (13 - 216)
	Events, n	12	37	5
	Persons at risk	12	86	321
	Risk (95% CI)	12	2052 (1422 - 2636)	115 (13 - 216)

Table 15.19.13.6.3 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N=211)	Pericarditis cohort (N<1053)
Male, 15-30 years				
	Events, n	3	23	8
	Persons at risk	3	168	376
	Risk (95% CI)	3	1142 (691 - 1572)	190 (59 - 320)
	Events, n	6	27	11
	Persons at risk	6	135	334
	Risk (95% CI)	6	1368 (873 - 1837)	273 (112 - 431)
	Events, n	9	27	12
	Persons at risk	9	112	290
	Risk (95% CI)	9	1368 (873 - 1837)	304 (132 - 473)
	Events, n	12	29	12
	Persons at risk	12	96	236
	Risk (95% CI)	12	1535 (993 - 2044)	304 (132 - 473)
Female, 15-30 years				
	Events, n	3	8	0
	Persons at risk	3	35	135
	Risk (95% CI)	3	1730 (563 - 2753)	0 (0 - 0)
	Events, n	6	9	0
	Persons at risk	6	25	122
	Risk (95% CI)	6	1981 (728 - 3064)	0 (0 - 0)
	Events, n	9	9	<5
	Persons at risk	9	18	<225
	Risk (95% CI)	9	1981 (728 - 3064)	178 (0 - 420)
	Events, n	12	9	<5
	Persons at risk	12	17	<225
	Risk (95% CI)	12	1981 (728 - 3064)	178 (0 - 420)

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Table 15.19.13.6.4 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N=47)	Pericarditis cohort (N<225)
No				
	Events, n	3	47	8
	Persons at risk	3	354	1162
	Risk (95% CI)	3	1103 (800 - 1397)	64 (20 - 108)
	Events, n	6	60	11
	Persons at risk	6	290	1037
	Risk (95% CI)	6	1458 (1108 - 1794)	91 (37 - 145)
	Events, n	9	64	13
	Persons at risk	9	251	919
	Risk (95% CI)	9	1580 (1214 - 1931)	112 (51 - 172)
	Events, n	12	71	14
	Persons at risk	12	217	820
	Risk (95% CI)	12	1826 (1425 - 2209)	123 (58 - 187)
Yes				
	Events, n	3	17	<5
	Persons at risk	3	157	<413
	Risk (95% CI)	3	908 (486 - 1311)	97 (2 - 191)
	Events, n	6	27	5
	Persons at risk	6	116	294
	Risk (95% CI)	6	1537 (982 - 2059)	126 (15 - 235)
	Events, n	9	28	8
	Persons at risk	9	97	240
	Risk (95% CI)	9	1619 (1044 - 2157)	238 (70 - 404)
	Events, n	12	30	8
	Persons at risk	12	72	181
	Risk (95% CI)	12	1831 (1192 - 2423)	238 (70 - 404)

Table 15.19.13.6.5 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=197)	Pericarditis cohort (N=440)
Vaccinated				
	Events, n	3	<5	0
	Persons at risk	3	<44	96
	Risk (95% CI)	3	920 (19 - 1740)	0 (0 - 0)
	Events, n	6	6	0
	Persons at risk	6	34	95
	Risk (95% CI)	6	1411 (296 - 2398)	0 (0 - 0)
	Events, n	9	8	0
	Persons at risk	9	31	94
	Risk (95% CI)	9	1916 (625 - 3030)	0 (0 - 0)
	Events, n	12	12	0
	Persons at risk	12	27	91
	Risk (95% CI)	12	2959 (1394 - 4240)	0 (0 - 0)
Unvaccinated				
	Events, n	3	37	8
	Persons at risk	3	251	764
	Risk (95% CI)	3	1173 (810 - 1522)	92 (28 - 155)
	Events, n	6	50	10
	Persons at risk	6	181	639
	Risk (95% CI)	6	1687 (1244 - 2109)	121 (46 - 195)
	Events, n	9	51	14
	Persons at risk	9	145	514
	Risk (95% CI)	9	1734 (1283 - 2162)	190 (89 - 290)
	Events, n	12	55	14
	Persons at risk	12	105	399
	Risk (95% CI)	12	1995 (1484 - 2474)	190 (89 - 290)

Table 15.19.13.6.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=329)	Pericarditis cohort (N=917)
Unvaccinated				
	Events, n	3	23	<5
	Persons at risk	3	221	<702
	Risk (95% CI)	3	902 (543 - 1248)	57 (1 - 113)
	Events, n	6	31	6
	Persons at risk	6	191	597
	Risk (95% CI)	6	1248 (826 - 1651)	89 (18 - 160)
	Events, n	9	33	7
	Persons at risk	9	172	551
	Risk (95% CI)	9	1346 (906 - 1765)	106 (27 - 185)
	Events, n	12	34	8
	Persons at risk	12	157	511
	Risk (95% CI)	12	1397 (947 - 1825)	125 (38 - 211)
Received dose 1 in the last 14 days				
	Events, n	3	<5	0
	Persons at risk	3	<18	27
	Risk (95% CI)	3	2308 (0 - 4288)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<18	26
	Risk (95% CI)	6	2308 (0 - 4288)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<13	26
	Risk (95% CI)	9	3077 (53 - 5182)	0 (0 - 0)
	Events, n	12	6	0
	Persons at risk	12	7	25
	Risk (95% CI)	12	4615 (1093 - 6745)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	8	<5
	Persons at risk	3	42	<326
	Risk (95% CI)	3	1486 (479 - 2387)	123 (0 - 290)
	Events, n	6	10	<5
	Persons at risk	6	33	<326
	Risk (95% CI)	6	1966 (780 - 3000)	123 (0 - 290)
	Events, n	9	10	<5
	Persons at risk	9	27	<326
	Risk (95% CI)	9	1966 (780 - 3000)	123 (0 - 290)
	Events, n	12	11	<5

Table 15.19.13.6.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=329)	Pericarditis cohort (N=917)
	Persons at risk	12	25	<326
	Risk (95% CI)	12	2264 (954 - 3384)	123 (0 - 290)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	16	24
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	15	24
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	14	23
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<57	22
	Risk (95% CI)	12	714 (0 - 1970)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	19	<5
	Persons at risk	3	111	<500
	Risk (95% CI)	3	1364 (773 - 1917)	80 (0 - 170)
	Events, n	6	27	5
	Persons at risk	6	85	303
	Risk (95% CI)	6	2036 (1313 - 2700)	142 (17 - 265)
	Events, n	9	28	8
	Persons at risk	9	73	263
	Risk (95% CI)	9	2132 (1390 - 2811)	250 (76 - 420)
	Events, n	12	30	8
	Persons at risk	12	59	227
	Risk (95% CI)	12	2374 (1571 - 3100)	250 (76 - 420)
Received dose 3 in the last 14 days				
	Events, n	3	<5	0
	Persons at risk	3	<5	9
	Risk (95% CI)	3	2000 (0 - 4839)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<5	9
	Risk (95% CI)	6	4667 (0 - 7858)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<5	9

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Table 15.19.13.6.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=329)	Pericarditis cohort (N=917)
	Risk (95% CI)	9	7333 (0 - 9493)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	7333 (0 - 9493)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	10	<5
	Persons at risk	3	100	<455
	Risk (95% CI)	3	814 (317 - 1287)	88 (0 - 186)
	Events, n	6	14	<5
	Persons at risk	6	67	<455
	Risk (95% CI)	6	1222 (594 - 1808)	88 (0 - 186)
	Events, n	9	14	<5
	Persons at risk	9	51	<301
	Risk (95% CI)	9	1222 (594 - 1808)	133 (0 - 264)
	Events, n	12	16	<5
	Persons at risk	12	27	<301
	Risk (95% CI)	12	1658 (782 - 2451)	133 (0 - 264)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	6	22
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	12
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)

Table 15.19.13.6.6 Risk (1-KM and 95% CI) for RECURRENT MYOCARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=329)	Pericarditis cohort (N=917)
	Events, n	9	0	0
	Persons at risk	9	<5	7
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.14.1.1 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Age	measure	months	Myocarditis cohort (N=8)	Pericarditis cohort (N=30)
15-30				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.14.1.2 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Male				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)

Table 15.19.14.1.3 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Sex and age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.14.1.4 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

COVID-19 History	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
No				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Yes				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.14.1.5 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N<5)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.14.1.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
Unvaccinated				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0

Table 15.19.14.1.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0

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Table 15.19.14.1.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	0
	Risk (95% CI)	3	NA (NA - NA)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.14.1.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for Pedianet

Vaccination history	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.14.2.1 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	0	0
	Persons at risk	3	120	18
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	110	17
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	<5
	Persons at risk	9	100	<69
	Risk (95% CI)	9	0 (0 - 0)	588 (0 - 1643)
	Events, n	12	0	<5
	Persons at risk	12	90	<69
	Risk (95% CI)	12	0 (0 - 0)	588 (0 - 1643)

Table 15.19.14.2.2 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex	measure	months	Myocarditis cohort (N=127)	Pericarditis cohort (N<69)
Male				
	Events, n	3	0	<5
	Persons at risk	3	396	<127
	Risk (95% CI)	3	0 (0 - 0)	315 (0 - 736)
	Events, n	6	0	<5
	Persons at risk	6	364	<127
	Risk (95% CI)	6	0 (0 - 0)	315 (0 - 736)
	Events, n	9	0	<5
	Persons at risk	9	331	<61
	Risk (95% CI)	9	0 (0 - 0)	661 (12 - 1268)
	Events, n	12	0	5
	Persons at risk	12	294	40
	Risk (95% CI)	12	0 (0 - 0)	884 (103 - 1603)
Female				
	Events, n	3	0	<5
	Persons at risk	3	199	<109
	Risk (95% CI)	3	0 (0 - 0)	370 (0 - 1057)
	Events, n	6	0	<5
	Persons at risk	6	182	<109
	Risk (95% CI)	6	0 (0 - 0)	370 (0 - 1057)
	Events, n	9	0	<5
	Persons at risk	9	165	<109
	Risk (95% CI)	9	0 (0 - 0)	370 (0 - 1057)
	Events, n	12	0	<5
	Persons at risk	12	150	<109
	Risk (95% CI)	12	0 (0 - 0)	370 (0 - 1057)

Table 15.19.14.2.3 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Sex and age	measure	months	Myocarditis cohort (N=212)	Pericarditis cohort (N<109)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	81	16
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	74	15
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	<5
	Persons at risk	9	68	<60
	Risk (95% CI)	9	0 (0 - 0)	667 (0 - 1847)
	Events, n	12	0	<5
	Persons at risk	12	61	<60
	Risk (95% CI)	12	0 (0 - 0)	667 (0 - 1847)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	39	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	36	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	32	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	29	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.14.2.4 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

COVID-19 History	measure	months	Myocarditis cohort (N=41)	Pericarditis cohort (N<5)
No				
	Events, n	3	0	<5
	Persons at risk	3	499	<157
	Risk (95% CI)	3	0 (0 - 0)	256 (0 - 601)
	Events, n	6	0	<5
	Persons at risk	6	465	<157
	Risk (95% CI)	6	0 (0 - 0)	256 (0 - 601)
	Events, n	9	0	<5
	Persons at risk	9	430	<75
	Risk (95% CI)	9	0 (0 - 0)	535 (10 - 1032)
	Events, n	12	0	5
	Persons at risk	12	396	55
	Risk (95% CI)	12	0 (0 - 0)	701 (85 - 1279)
Yes				
	Events, n	3	0	<5
	Persons at risk	3	96	<53
	Risk (95% CI)	3	0 (0 - 0)	769 (0 - 2110)
	Events, n	6	0	<5
	Persons at risk	6	81	<53
	Risk (95% CI)	6	0 (0 - 0)	769 (0 - 2110)
	Events, n	9	0	<5
	Persons at risk	9	66	<53
	Risk (95% CI)	9	0 (0 - 0)	769 (0 - 2110)
	Events, n	12	0	<5
	Persons at risk	12	48	<53
	Risk (95% CI)	12	0 (0 - 0)	769 (0 - 2110)

Table 15.19.14.2.5 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=112)	Pericarditis cohort (N<53)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	36	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	35	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	<5
	Persons at risk	9	34	<5
	Risk (95% CI)	9	0 (0 - 0)	2500 (0 - 5741)
	Events, n	12	0	<5
	Persons at risk	12	32	<5
	Risk (95% CI)	12	0 (0 - 0)	5000 (0 - 8123)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	229	<56
	Risk (95% CI)	3	0 (0 - 0)	716 (0 - 1626)
	Events, n	6	0	<5
	Persons at risk	6	202	<56
	Risk (95% CI)	6	0 (0 - 0)	716 (0 - 1626)
	Events, n	9	0	<5
	Persons at risk	9	176	<56
	Risk (95% CI)	9	0 (0 - 0)	716 (0 - 1626)
	Events, n	12	0	<5
	Persons at risk	12	149	<56
	Risk (95% CI)	12	0 (0 - 0)	716 (0 - 1626)

Table 15.19.14.2.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N<56)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	330	<237
	Risk (95% CI)	3	0 (0 - 0)	169 (0 - 493)
	Events, n	6	0	<5
	Persons at risk	6	309	<237
	Risk (95% CI)	6	0 (0 - 0)	169 (0 - 493)
	Events, n	9	0	<5
	Persons at risk	9	286	<113
	Risk (95% CI)	9	0 (0 - 0)	355 (0 - 827)
	Events, n	12	0	<5
	Persons at risk	12	263	<113
	Risk (95% CI)	12	0 (0 - 0)	355 (0 - 827)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	12	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	12	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	12	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	<5
	Persons at risk	12	12	<5
	Risk (95% CI)	12	0 (0 - 0)	5000 (0 - 8750)
Received dose 1, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	80	<40
	Risk (95% CI)	3	0 (0 - 0)	1000 (0 - 2680)
	Events, n	6	0	<5
	Persons at risk	6	72	<40
	Risk (95% CI)	6	0 (0 - 0)	1000 (0 - 2680)
	Events, n	9	0	<5
	Persons at risk	9	68	<40
	Risk (95% CI)	9	0 (0 - 0)	1000 (0 - 2680)
	Events, n	12	0	<5

Table 15.19.14.2.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N<56)
	Persons at risk	12	59	<40
	Risk (95% CI)	12	0 (0 - 0)	1000 (0 - 2680)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	13	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	13	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	<5
	Persons at risk	9	13	0
	Risk (95% CI)	9	0 (0 - 0)	NA (NA - NA)
	Events, n	12	0	<5
	Persons at risk	12	13	0
	Risk (95% CI)	12	0 (0 - 0)	NA (NA - NA)
Received dose 2, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	124	<60
	Risk (95% CI)	3	0 (0 - 0)	667 (0 - 1847)
	Events, n	6	0	<5
	Persons at risk	6	112	<60
	Risk (95% CI)	6	0 (0 - 0)	667 (0 - 1847)
	Events, n	9	0	<5
	Persons at risk	9	98	<60
	Risk (95% CI)	9	0 (0 - 0)	667 (0 - 1847)
	Events, n	12	0	<5
	Persons at risk	12	86	<60
	Risk (95% CI)	12	0 (0 - 0)	667 (0 - 1847)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.14.2.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N<56)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	30	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	24	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	16	<5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	10	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	<5	0
	Risk (95% CI)	6	0 (0 - 0)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)

Table 15.19.14.2.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for PHARMO

Vaccination history	measure	months	Myocarditis cohort (N=253)	Pericarditis cohort (N<56)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.14.3.1 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Age	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=0)
15-30				
	Events, n	3	10	37
	Persons at risk	3	162	160
	Risk (95% CI)	3	552 (213 - 879)	1759 (1227 - 2260)
	Events, n	6	12	50
	Persons at risk	6	138	130
	Risk (95% CI)	6	676 (298 - 1039)	2468 (1845 - 3044)
	Events, n	9	13	52
	Persons at risk	9	117	105
	Risk (95% CI)	9	745 (345 - 1128)	2593 (1953 - 3182)
	Events, n	12	14	54
	Persons at risk	12	90	83
	Risk (95% CI)	12	846 (401 - 1271)	2754 (2085 - 3366)

Table 15.19.14.3.2 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex	measure	months	Myocarditis cohort (N=192)	Pericarditis cohort (N=222)
Male				
	Events, n	3	19	162
	Persons at risk	3	424	714
	Risk (95% CI)	3	400 (222 - 575)	1705 (1462 - 1942)
	Events, n	6	21	190
	Persons at risk	6	370	610
	Risk (95% CI)	6	451 (260 - 638)	2046 (1781 - 2303)
	Events, n	9	22	199
	Persons at risk	9	320	502
	Risk (95% CI)	9	477 (280 - 671)	2177 (1902 - 2443)
	Events, n	12	24	206
	Persons at risk	12	267	395
	Risk (95% CI)	12	544 (327 - 756)	2298 (2012 - 2574)
Female				
	Events, n	3	6	85
	Persons at risk	3	202	302
	Risk (95% CI)	3	276 (56 - 491)	2043 (1645 - 2422)
	Events, n	6	8	100
	Persons at risk	6	173	244
	Risk (95% CI)	6	377 (117 - 631)	2468 (2033 - 2880)
	Events, n	9	8	103
	Persons at risk	9	151	208
	Risk (95% CI)	9	377 (117 - 631)	2563 (2119 - 2982)
	Events, n	12	8	104
	Persons at risk	12	122	162
	Risk (95% CI)	12	377 (117 - 631)	2601 (2152 - 3024)

Table 15.19.14.3.3 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Sex and age	measure	months	Myocarditis cohort (N=239)	Pericarditis cohort (N=433)
Male, 15-30 years				
	Events, n	3	8	30
	Persons at risk	3	136	133
	Risk (95% CI)	3	526 (164 - 874)	1746 (1157 - 2296)
	Events, n	6	9	40
	Persons at risk	6	116	111
	Risk (95% CI)	6	603 (212 - 979)	2399 (1718 - 3024)
	Events, n	9	10	42
	Persons at risk	9	98	90
	Risk (95% CI)	9	686 (264 - 1089)	2547 (1845 - 3189)
	Events, n	12	11	44
	Persons at risk	12	77	71
	Risk (95% CI)	12	805 (324 - 1262)	2735 (1996 - 3406)
Female, 15-30 years				
	Events, n	3	<5	7
	Persons at risk	3	<58	27
	Risk (95% CI)	3	690 (0 - 1568)	1818 (500 - 2953)
	Events, n	6	<5	10
	Persons at risk	6	<38	19
	Risk (95% CI)	6	1062 (0 - 2131)	2800 (1135 - 4152)
	Events, n	9	<5	10
	Persons at risk	9	<38	15
	Risk (95% CI)	9	1062 (0 - 2131)	2800 (1135 - 4152)
	Events, n	12	<5	10
	Persons at risk	12	<38	12
	Risk (95% CI)	12	1062 (0 - 2131)	2800 (1135 - 4152)

Table 15.19.14.3.4 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

COVID-19 History	measure	months	Myocarditis cohort (N<58)	Pericarditis cohort (N=40)
No				
	Events, n	3	22	232
	Persons at risk	3	540	920
	Risk (95% CI)	3	369 (216 - 519)	1888 (1666 - 2105)
	Events, n	6	26	269
	Persons at risk	6	477	783
	Risk (95% CI)	6	445 (276 - 611)	2230 (1991 - 2463)
	Events, n	9	27	280
	Persons at risk	9	425	671
	Risk (95% CI)	9	465 (292 - 636)	2348 (2102 - 2587)
	Events, n	12	29	288
	Persons at risk	12	363	547
	Risk (95% CI)	12	515 (329 - 697)	2446 (2193 - 2691)
Yes				
	Events, n	3	<5	15
	Persons at risk	3	<130	96
	Risk (95% CI)	3	310 (0 - 650)	1102 (556 - 1617)
	Events, n	6	<5	21
	Persons at risk	6	<130	71
	Risk (95% CI)	6	310 (0 - 650)	1733 (1010 - 2397)
	Events, n	9	<5	22
	Persons at risk	9	<130	39
	Risk (95% CI)	9	310 (0 - 650)	1860 (1101 - 2554)
	Events, n	12	<5	22
	Persons at risk	12	<130	10
	Risk (95% CI)	12	310 (0 - 650)	1860 (1101 - 2554)

Table 15.19.14.3.5 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<130)	Pericarditis cohort (N=155)
Vaccinated				
	Events, n	3	<5	39
	Persons at risk	3	<83	108
	Risk (95% CI)	3	482 (0 - 1000)	2577 (1845 - 3243)
	Events, n	6	<5	47
	Persons at risk	6	<61	96
	Risk (95% CI)	6	662 (12 - 1269)	3140 (2352 - 3847)
	Events, n	9	<5	48
	Persons at risk	9	<61	95
	Risk (95% CI)	9	662 (12 - 1269)	3212 (2417 - 3923)
	Events, n	12	5	49
	Persons at risk	12	44	78
	Risk (95% CI)	12	848 (105 - 1536)	3285 (2484 - 4001)
Unvaccinated				
	Events, n	3	16	147
	Persons at risk	3	344	594
	Risk (95% CI)	3	407 (209 - 600)	1766 (1502 - 2022)
	Events, n	6	17	164
	Persons at risk	6	282	476
	Risk (95% CI)	6	436 (231 - 637)	2024 (1739 - 2298)
	Events, n	9	17	169
	Persons at risk	9	220	350
	Risk (95% CI)	9	436 (231 - 637)	2119 (1826 - 2402)
	Events, n	12	18	172
	Persons at risk	12	160	241
	Risk (95% CI)	12	495 (260 - 725)	2203 (1896 - 2498)

Table 15.19.14.3.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=429)	Pericarditis cohort (N=879)
Unvaccinated				
	Events, n	3	6	61
	Persons at risk	3	225	314
	Risk (95% CI)	3	251 (51 - 447)	1588 (1214 - 1945)
	Events, n	6	8	79
	Persons at risk	6	209	282
	Risk (95% CI)	6	341 (106 - 570)	2078 (1659 - 2477)
	Events, n	9	9	85
	Persons at risk	9	200	265
	Risk (95% CI)	9	388 (136 - 633)	2251 (1816 - 2662)
	Events, n	12	9	89
	Persons at risk	12	185	238
	Risk (95% CI)	12	388 (136 - 633)	2373 (1928 - 2793)
Received dose 1 in the last 14 days				
	Events, n	3	0	15
	Persons at risk	3	17	26
	Risk (95% CI)	3	0 (0 - 0)	3659 (1999 - 4974)
	Events, n	6	0	18
	Persons at risk	6	16	23
	Risk (95% CI)	6	0 (0 - 0)	4390 (2646 - 5721)
	Events, n	9	0	19
	Persons at risk	9	15	22
	Risk (95% CI)	9	0 (0 - 0)	4634 (2869 - 5963)
	Events, n	12	0	19
	Persons at risk	12	15	21
	Risk (95% CI)	12	0 (0 - 0)	4634 (2869 - 5963)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	21
	Persons at risk	3	<79	78
	Risk (95% CI)	3	509 (0 - 1054)	2021 (1209 - 2757)
	Events, n	6	<5	23
	Persons at risk	6	<79	71
	Risk (95% CI)	6	509 (0 - 1054)	2236 (1385 - 3004)
	Events, n	9	<5	23
	Persons at risk	9	<79	64
	Risk (95% CI)	9	509 (0 - 1054)	2236 (1385 - 3004)
	Events, n	12	<5	25

Table 15.19.14.3.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=429)	Pericarditis cohort (N=879)
	Persons at risk	12	<53	52
	Risk (95% CI)	12	766 (0 - 1475)	2505 (1592 - 3319)
Received dose 2 in the last 14 days				
	Events, n	3	<5	10
	Persons at risk	3	<24	35
	Risk (95% CI)	3	1667 (0 - 3530)	2222 (908 - 3347)
	Events, n	6	<5	11
	Persons at risk	6	<24	34
	Risk (95% CI)	6	1667 (0 - 3530)	2444 (1078 - 3601)
	Events, n	9	<5	11
	Persons at risk	9	<24	34
	Risk (95% CI)	9	1667 (0 - 3530)	2444 (1078 - 3601)
	Events, n	12	<5	11
	Persons at risk	12	<24	32
	Risk (95% CI)	12	1667 (0 - 3530)	2444 (1078 - 3601)
Received dose 2, 15 or more days ago				
	Events, n	3	10	71
	Persons at risk	3	184	291
	Risk (95% CI)	3	498 (192 - 795)	1846 (1449 - 2226)
	Events, n	6	11	82
	Persons at risk	6	166	263
	Risk (95% CI)	6	553 (230 - 866)	2161 (1734 - 2566)
	Events, n	9	11	84
	Persons at risk	9	151	230
	Risk (95% CI)	9	553 (230 - 866)	2223 (1790 - 2633)
	Events, n	12	11	86
	Persons at risk	12	127	201
	Risk (95% CI)	12	553 (230 - 866)	2293 (1853 - 2710)
Received dose 3 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	11	<21
	Risk (95% CI)	3	0 (0 - 0)	1905 (38 - 3421)
	Events, n	6	0	6
	Persons at risk	6	11	13
	Risk (95% CI)	6	0 (0 - 0)	2857 (638 - 4550)
	Events, n	9	0	6
	Persons at risk	9	11	13

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Table 15.19.14.3.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=429)	Pericarditis cohort (N=879)
	Risk (95% CI)	9	0 (0 - 0)	2857 (638 - 4550)
	Events, n	12	<5	6
	Persons at risk	12	<45	6
	Risk (95% CI)	12	909 (0 - 2459)	2857 (638 - 4550)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	61
	Persons at risk	3	<189	239
	Risk (95% CI)	3	212 (0 - 447)	1777 (1361 - 2174)
	Events, n	6	<5	67
	Persons at risk	6	<133	162
	Risk (95% CI)	6	301 (4 - 589)	2021 (1569 - 2448)
	Events, n	9	<5	70
	Persons at risk	9	<133	78
	Risk (95% CI)	9	301 (4 - 589)	2234 (1727 - 2710)
	Events, n	12	<5	70
	Persons at risk	12	<133	7
	Risk (95% CI)	12	301 (4 - 589)	2234 (1727 - 2710)
Received dose 4 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	1667 (0 - 4173)	2000 (0 - 4839)
	Events, n	6	<5	<5
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	<5	<5
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	<5	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	5	<54
	Risk (95% CI)	3	0 (0 - 0)	749 (0 - 1531)
	Events, n	6	0	<5
	Persons at risk	6	<5	<54
	Risk (95% CI)	6	0 (0 - 0)	749 (0 - 1531)

Table 15.19.14.3.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for NHR

Vaccination history	measure	months	Myocarditis cohort (N=429)	Pericarditis cohort (N=879)
	Events, n	9	0	<5
	Persons at risk	9	<5	<5
	Risk (95% CI)	9	0 (0 - 0)	749 (0 - 1531)
	Events, n	12	0	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.14.4.1 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Age	measure	months	Myocarditis cohort (N=20)	Pericarditis cohort (N=54)
15-30				
	Events, n	3	0	0
	Persons at risk	3	32	58
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	<5
	Persons at risk	6	<129	<112
	Risk (95% CI)	6	312 (0 - 897)	358 (0 - 833)
	Events, n	9	<5	<5
	Persons at risk	9	<129	<112
	Risk (95% CI)	9	312 (0 - 897)	358 (0 - 833)
	Events, n	12	<5	<5
	Persons at risk	12	<129	<49
	Risk (95% CI)	12	312 (0 - 897)	823 (7 - 1572)

Table 15.19.14.4.2 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex	measure	months	Myocarditis cohort (N<129)	Pericarditis cohort (N<112)
Male				
	Events, n	3	0	6
	Persons at risk	3	76	198
	Risk (95% CI)	3	0 (0 - 0)	284 (57 - 506)
	Events, n	6	<5	8
	Persons at risk	6	<149	179
	Risk (95% CI)	6	269 (0 - 629)	387 (120 - 647)
	Events, n	9	<5	8
	Persons at risk	9	<149	159
	Risk (95% CI)	9	269 (0 - 629)	387 (120 - 647)
	Events, n	12	<5	10
	Persons at risk	12	<149	142
	Risk (95% CI)	12	269 (0 - 629)	515 (196 - 824)
Female				
	Events, n	3	0	<5
	Persons at risk	3	15	<154
	Risk (95% CI)	3	0 (0 - 0)	260 (0 - 609)
	Events, n	6	0	<5
	Persons at risk	6	15	<154
	Risk (95% CI)	6	0 (0 - 0)	260 (0 - 609)
	Events, n	9	0	<5
	Persons at risk	9	11	<154
	Risk (95% CI)	9	0 (0 - 0)	260 (0 - 609)
	Events, n	12	0	<5
	Persons at risk	12	11	<92
	Risk (95% CI)	12	0 (0 - 0)	437 (0 - 914)

Table 15.19.14.4.3 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Sex and age	measure	months	Myocarditis cohort (N=17)	Pericarditis cohort (N<154)
Male, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	31	46
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	<5
	Persons at risk	6	<124	<89
	Risk (95% CI)	6	323 (0 - 925)	450 (0 - 1042)
	Events, n	9	<5	<5
	Persons at risk	9	<124	<89
	Risk (95% CI)	9	323 (0 - 925)	450 (0 - 1042)
	Events, n	12	<5	<5
	Persons at risk	12	<124	<39
	Risk (95% CI)	12	323 (0 - 925)	1038 (8 - 1963)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	<5	12
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	10
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	9
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	9
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

Table 15.19.14.4.4 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

COVID-19 History	measure	months	Myocarditis cohort (N<5)	Pericarditis cohort (N=12)
No				
	Events, n	3	0	6
	Persons at risk	3	68	197
	Risk (95% CI)	3	0 (0 - 0)	288 (58 - 512)
	Events, n	6	<5	7
	Persons at risk	6	<134	182
	Risk (95% CI)	6	299 (0 - 698)	337 (88 - 580)
	Events, n	9	<5	7
	Persons at risk	9	<134	163
	Risk (95% CI)	9	299 (0 - 698)	337 (88 - 580)
	Events, n	12	<5	10
	Persons at risk	12	<134	147
	Risk (95% CI)	12	299 (0 - 698)	521 (199 - 832)
Yes				
	Events, n	3	0	<5
	Persons at risk	3	23	<160
	Risk (95% CI)	3	0 (0 - 0)	250 (0 - 587)
	Events, n	6	0	<5
	Persons at risk	6	21	<100
	Risk (95% CI)	6	0 (0 - 0)	403 (0 - 841)
	Events, n	9	0	<5
	Persons at risk	9	20	<100
	Risk (95% CI)	9	0 (0 - 0)	403 (0 - 841)
	Events, n	12	0	<5
	Persons at risk	12	18	<100
	Risk (95% CI)	12	0 (0 - 0)	403 (0 - 841)

Table 15.19.14.4.5 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=27)	Pericarditis cohort (N<160)
Vaccinated				
	Events, n	3	0	0
	Persons at risk	3	9	21
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	9	21
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	9	19
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	9	19
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	47	<179
	Risk (95% CI)	3	0 (0 - 0)	224 (5 - 438)
	Events, n	6	<5	5
	Persons at risk	6	<91	144
	Risk (95% CI)	6	440 (0 - 1019)	283 (35 - 525)
	Events, n	9	<5	5
	Persons at risk	9	<91	120
	Risk (95% CI)	9	440 (0 - 1019)	283 (35 - 525)
	Events, n	12	<5	6
	Persons at risk	12	<91	101
	Risk (95% CI)	12	440 (0 - 1019)	372 (69 - 665)

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Table 15.19.14.4.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<91)	Pericarditis cohort (N=191)
Unvaccinated				
	Events, n	3	0	<5
	Persons at risk	3	35	<89
	Risk (95% CI)	3	0 (0 - 0)	453 (9 - 877)
	Events, n	6	0	5
	Persons at risk	6	35	78
	Risk (95% CI)	6	0 (0 - 0)	572 (72 - 1047)
	Events, n	9	0	5
	Persons at risk	9	33	77
	Risk (95% CI)	9	0 (0 - 0)	572 (72 - 1047)
	Events, n	12	0	7
	Persons at risk	12	31	72
	Risk (95% CI)	12	0 (0 - 0)	817 (217 - 1380)
Received dose 1 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	7
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	7
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	7
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	7
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 1, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	8	14
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	7	13
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	7	12
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0

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Table 15.19.14.4.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<91)	Pericarditis cohort (N=191)
	Persons at risk	12	7	8
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	5
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 2, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	30	<252
	Risk (95% CI)	3	0 (0 - 0)	159 (0 - 376)
	Events, n	6	<5	<5
	Persons at risk	6	<58	<165
	Risk (95% CI)	6	691 (0 - 1572)	243 (0 - 510)
	Events, n	9	<5	<5
	Persons at risk	9	<58	<165
	Risk (95% CI)	9	691 (0 - 1572)	243 (0 - 510)
	Events, n	12	<5	<5
	Persons at risk	12	<58	<113
	Risk (95% CI)	12	691 (0 - 1572)	356 (2 - 698)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	<5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	<5	<5

Table 15.19.14.4.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<91)	Pericarditis cohort (N=191)
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	<5	<5
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	12	<82
	Risk (95% CI)	3	0 (0 - 0)	488 (0 - 1125)
	Events, n	6	0	<5
	Persons at risk	6	11	<82
	Risk (95% CI)	6	0 (0 - 0)	488 (0 - 1125)
	Events, n	9	0	<5
	Persons at risk	9	9	<82
	Risk (95% CI)	9	0 (0 - 0)	488 (0 - 1125)
	Events, n	12	0	<5
	Persons at risk	12	8	<82
	Risk (95% CI)	12	0 (0 - 0)	488 (0 - 1125)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)

Table 15.19.14.4.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for EpiChron

Vaccination history	measure	months	Myocarditis cohort (N<91)	Pericarditis cohort (N=191)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.14.5.1 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Age	measure	months	Myocarditis cohort (N=0)	Pericarditis cohort (N=5)
15-30				
	Events, n	3	0	<5
	Persons at risk	3	99	<233
	Risk (95% CI)	3	0 (0 - 0)	172 (3 - 338)
	Events, n	6	0	5
	Persons at risk	6	75	210
	Risk (95% CI)	6	0 (0 - 0)	218 (27 - 406)
	Events, n	9	0	6
	Persons at risk	9	67	195
	Risk (95% CI)	9	0 (0 - 0)	266 (53 - 473)
	Events, n	12	0	6
	Persons at risk	12	62	185
	Risk (95% CI)	12	0 (0 - 0)	266 (53 - 473)

Table 15.19.14.5.2 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex	measure	months	Myocarditis cohort (N=106)	Pericarditis cohort (N=242)
Male				
	Events, n	3	<5	33
	Persons at risk	3	<1482	800
	Risk (95% CI)	3	27 (0 - 80)	382 (253 - 509)
	Events, n	6	<5	47
	Persons at risk	6	<1482	735
	Risk (95% CI)	6	27 (0 - 80)	556 (400 - 709)
	Events, n	9	<5	53
	Persons at risk	9	<1482	682
	Risk (95% CI)	9	27 (0 - 80)	635 (468 - 799)
	Events, n	12	<5	58
	Persons at risk	12	<1482	640
	Risk (95% CI)	12	27 (0 - 80)	705 (527 - 878)
Female				
	Events, n	3	0	27
	Persons at risk	3	226	438
	Risk (95% CI)	3	0 (0 - 0)	559 (352 - 761)
	Events, n	6	0	37
	Persons at risk	6	164	401
	Risk (95% CI)	6	0 (0 - 0)	784 (538 - 1024)
	Events, n	9	0	42
	Persons at risk	9	142	361
	Risk (95% CI)	9	0 (0 - 0)	901 (637 - 1158)
	Events, n	12	0	47
	Persons at risk	12	130	341
	Risk (95% CI)	12	0 (0 - 0)	1029 (744 - 1305)

Table 15.19.14.5.3 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Sex and age	measure	months	Myocarditis cohort (N=246)	Pericarditis cohort (N=500)
Male, 15-30 years				
	Events, n	3	0	<5
	Persons at risk	3	78	<182
	Risk (95% CI)	3	0 (0 - 0)	220 (4 - 431)
	Events, n	6	0	5
	Persons at risk	6	59	164
	Risk (95% CI)	6	0 (0 - 0)	279 (35 - 516)
	Events, n	9	0	6
	Persons at risk	9	53	156
	Risk (95% CI)	9	0 (0 - 0)	339 (68 - 602)
	Events, n	12	0	6
	Persons at risk	12	50	147
	Risk (95% CI)	12	0 (0 - 0)	339 (68 - 602)
Female, 15-30 years				
	Events, n	3	0	0
	Persons at risk	3	21	49
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	16	46
	Risk (95% CI)	6	0 (0 - 0)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	14	39
	Risk (95% CI)	9	0 (0 - 0)	0 (0 - 0)
	Events, n	12	0	0
	Persons at risk	12	12	38
	Risk (95% CI)	12	0 (0 - 0)	0 (0 - 0)

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Table 15.19.14.5.4 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

COVID-19 History	measure	months	Myocarditis cohort (N=23)	Pericarditis cohort (N=52)
No				
	Events, n	3	<5	42
	Persons at risk	3	<1291	880
	Risk (95% CI)	3	31 (0 - 91)	441 (310 - 570)
	Events, n	6	<5	64
	Persons at risk	6	<1291	823
	Risk (95% CI)	6	31 (0 - 91)	686 (522 - 846)
	Events, n	9	<5	73
	Persons at risk	9	<1291	768
	Risk (95% CI)	9	31 (0 - 91)	789 (613 - 961)
	Events, n	12	<5	81
	Persons at risk	12	<1291	733
	Risk (95% CI)	12	31 (0 - 91)	886 (699 - 1069)
Yes				
	Events, n	3	0	18
	Persons at risk	3	266	358
	Risk (95% CI)	3	0 (0 - 0)	457 (248 - 661)
	Events, n	6	0	20
	Persons at risk	6	186	313
	Risk (95% CI)	6	0 (0 - 0)	515 (292 - 733)
	Events, n	9	0	22
	Persons at risk	9	158	275
	Risk (95% CI)	9	0 (0 - 0)	577 (339 - 810)
	Events, n	12	0	24
	Persons at risk	12	141	248
	Risk (95% CI)	12	0 (0 - 0)	648 (392 - 898)

Table 15.19.14.5.5 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N=291)	Pericarditis cohort (N=415)
Vaccinated				
	Events, n	3	0	<5
	Persons at risk	3	25	<145
	Risk (95% CI)	3	0 (0 - 0)	276 (0 - 579)
	Events, n	6	0	8
	Persons at risk	6	24	98
	Risk (95% CI)	6	0 (0 - 0)	746 (235 - 1231)
	Events, n	9	0	8
	Persons at risk	9	23	94
	Risk (95% CI)	9	0 (0 - 0)	746 (235 - 1231)
	Events, n	12	0	9
	Persons at risk	12	23	93
	Risk (95% CI)	12	0 (0 - 0)	845 (301 - 1358)
Unvaccinated				
	Events, n	3	<5	24
	Persons at risk	3	<1291	542
	Risk (95% CI)	3	31 (0 - 91)	400 (242 - 556)
	Events, n	6	<5	35
	Persons at risk	6	<1291	474
	Risk (95% CI)	6	31 (0 - 91)	607 (409 - 800)
	Events, n	9	<5	41
	Persons at risk	9	<1291	411
	Risk (95% CI)	9	31 (0 - 91)	731 (512 - 945)
	Events, n	12	<5	46
	Persons at risk	12	<1291	361
	Risk (95% CI)	12	31 (0 - 91)	851 (609 - 1085)

Table 15.19.14.5.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<1291)	Pericarditis cohort (N=635)
Unvaccinated				
	Events, n	3	0	33
	Persons at risk	3	252	591
	Risk (95% CI)	3	0 (0 - 0)	518 (345 - 689)
	Events, n	6	0	41
	Persons at risk	6	200	564
	Risk (95% CI)	6	0 (0 - 0)	649 (455 - 840)
	Events, n	9	0	46
	Persons at risk	9	182	538
	Risk (95% CI)	9	0 (0 - 0)	733 (526 - 935)
	Events, n	12	0	50
	Persons at risk	12	180	527
	Risk (95% CI)	12	0 (0 - 0)	802 (586 - 1013)
Received dose 1 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	7	<160
	Risk (95% CI)	3	0 (0 - 0)	250 (0 - 722)
	Events, n	6	0	<5
	Persons at risk	6	6	<160
	Risk (95% CI)	6	0 (0 - 0)	250 (0 - 722)
	Events, n	9	0	<5
	Persons at risk	9	6	<160
	Risk (95% CI)	9	0 (0 - 0)	250 (0 - 722)
	Events, n	12	0	<5
	Persons at risk	12	6	<160
	Risk (95% CI)	12	0 (0 - 0)	250 (0 - 722)
Received dose 1, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	43	<240
	Risk (95% CI)	3	0 (0 - 0)	167 (0 - 485)
	Events, n	6	0	<5
	Persons at risk	6	33	<115
	Risk (95% CI)	6	0 (0 - 0)	349 (0 - 813)
	Events, n	9	0	<5
	Persons at risk	9	29	<115
	Risk (95% CI)	9	0 (0 - 0)	349 (0 - 813)
	Events, n	12	0	<5

Table 15.19.14.5.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<1291)	Pericarditis cohort (N=635)
	Persons at risk	12	28	<115
	Risk (95% CI)	12	0 (0 - 0)	349 (0 - 813)
Received dose 2 in the last 14 days				
	Events, n	3	0	<5
	Persons at risk	3	11	<121
	Risk (95% CI)	3	0 (0 - 0)	333 (0 - 955)
	Events, n	6	0	<5
	Persons at risk	6	11	<40
	Risk (95% CI)	6	0 (0 - 0)	1000 (0 - 2012)
	Events, n	9	0	<5
	Persons at risk	9	10	<40
	Risk (95% CI)	9	0 (0 - 0)	1000 (0 - 2012)
	Events, n	12	0	<5
	Persons at risk	12	10	<31
	Risk (95% CI)	12	0 (0 - 0)	1333 (27 - 2468)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	16
	Persons at risk	3	<800	394
	Risk (95% CI)	3	50 (0 - 146)	374 (193 - 553)
	Events, n	6	<5	24
	Persons at risk	6	<800	360
	Risk (95% CI)	6	50 (0 - 146)	577 (350 - 799)
	Events, n	9	<5	30
	Persons at risk	9	<800	326
	Risk (95% CI)	9	50 (0 - 146)	739 (480 - 991)
	Events, n	12	<5	34
	Persons at risk	12	<800	293
	Risk (95% CI)	12	50 (0 - 146)	858 (576 - 1131)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	<5
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	3333 (0 - 7005)
	Events, n	9	0	<5
	Persons at risk	9	0	<5

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Table 15.19.14.5.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<1291)	Pericarditis cohort (N=635)
	Risk (95% CI)	9	NA (NA - NA)	3333 (0 - 7005)
	Events, n	12	0	<5
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	3333 (0 - 7005)
Received dose 3, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	58	<114
	Risk (95% CI)	3	0 (0 - 0)	353 (7 - 688)
	Events, n	6	0	8
	Persons at risk	6	42	88
	Risk (95% CI)	6	0 (0 - 0)	747 (234 - 1234)
	Events, n	9	0	8
	Persons at risk	9	34	62
	Risk (95% CI)	9	0 (0 - 0)	747 (234 - 1234)
	Events, n	12	0	9
	Persons at risk	12	25	46
	Risk (95% CI)	12	0 (0 - 0)	913 (307 - 1481)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	0	<5
	Risk (95% CI)	3	NA (NA - NA)	0 (0 - 0)
	Events, n	6	0	0
	Persons at risk	6	0	<5
	Risk (95% CI)	6	NA (NA - NA)	0 (0 - 0)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	15	<33
	Risk (95% CI)	3	0 (0 - 0)	1227 (2 - 2301)
	Events, n	6	0	<5
	Persons at risk	6	<5	<5
	Risk (95% CI)	6	0 (0 - 0)	1227 (2 - 2301)

Table 15.19.14.5.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for SIDIAP

Vaccination history	measure	months	Myocarditis cohort (N<1291)	Pericarditis cohort (N=635)
	Events, n	9	0	<5
	Persons at risk	9	0	<5
	Risk (95% CI)	9	NA (NA - NA)	1227 (2 - 2301)
	Events, n	12	0	<5
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)

Table 15.19.14.6.1 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Age	measure	months	Myocarditis cohort (N=22)	Pericarditis cohort (N=45)
15-30				
	Events, n	3	5	48
	Persons at risk	3	283	360
	Risk (95% CI)	3	162 (20 - 302)	1104 (804 - 1394)
	Events, n	6	7	55
	Persons at risk	6	233	314
	Risk (95% CI)	6	234 (61 - 405)	1282 (959 - 1594)
	Events, n	9	7	61
	Persons at risk	9	195	264
	Risk (95% CI)	9	234 (61 - 405)	1459 (1111 - 1793)
	Events, n	12	7	61
	Persons at risk	12	169	217
	Risk (95% CI)	12	234 (61 - 405)	1459 (1111 - 1793)

Table 15.19.14.6.2 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex	measure	months	Myocarditis cohort (N=321)	Pericarditis cohort (N=452)
Male				
	Events, n	3	8	72
	Persons at risk	3	465	723
	Risk (95% CI)	3	158 (49 - 267)	833 (647 - 1016)
	Events, n	6	10	83
	Persons at risk	6	393	612
	Risk (95% CI)	6	203 (77 - 328)	982 (778 - 1181)
	Events, n	9	11	94
	Persons at risk	9	342	530
	Risk (95% CI)	9	230 (94 - 364)	1152 (928 - 1371)
	Events, n	12	11	97
	Persons at risk	12	292	456
	Risk (95% CI)	12	230 (94 - 364)	1206 (975 - 1431)
Female				
	Events, n	3	<5	36
	Persons at risk	3	<520	327
	Risk (95% CI)	3	77 (0 - 182)	924 (632 - 1208)
	Events, n	6	5	44
	Persons at risk	6	194	288
	Risk (95% CI)	6	214 (26 - 399)	1155 (827 - 1471)
	Events, n	9	5	47
	Persons at risk	9	164	246
	Risk (95% CI)	9	214 (26 - 399)	1252 (908 - 1582)
	Events, n	12	5	48
	Persons at risk	12	140	210
	Risk (95% CI)	12	214 (26 - 399)	1288 (938 - 1624)

Table 15.19.14.6.3 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Sex and age during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Sex and age	measure	months	Myocarditis cohort (N<520)	Pericarditis cohort (N=401)
Male, 15-30 years				
	Events, n	3	<5	33
	Persons at risk	3	<250	265
	Risk (95% CI)	3	160 (3 - 314)	1032 (692 - 1360)
	Events, n	6	5	39
	Persons at risk	6	191	232
	Risk (95% CI)	6	203 (25 - 378)	1243 (869 - 1602)
	Events, n	9	5	43
	Persons at risk	9	162	197
	Risk (95% CI)	9	203 (25 - 378)	1402 (1002 - 1785)
	Events, n	12	5	43
	Persons at risk	12	141	161
	Risk (95% CI)	12	203 (25 - 378)	1402 (1002 - 1785)
Female, 15-30 years				
	Events, n	3	<5	15
	Persons at risk	3	<237	95
	Risk (95% CI)	3	169 (0 - 493)	1300 (664 - 1894)
	Events, n	6	<5	16
	Persons at risk	6	<110	82
	Risk (95% CI)	6	366 (0 - 853)	1393 (735 - 2004)
	Events, n	9	<5	18
	Persons at risk	9	<110	67
	Risk (95% CI)	9	366 (0 - 853)	1619 (899 - 2283)
	Events, n	12	<5	18
	Persons at risk	12	<110	56
	Risk (95% CI)	12	366 (0 - 853)	1619 (899 - 2283)

Table 15.19.14.6.4 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by COVID-19 History during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

COVID-19 History	measure	months	Myocarditis cohort (N<237)	Pericarditis cohort (N=118)
No				
	Events, n	3	7	74
	Persons at risk	3	489	810
	Risk (95% CI)	3	132 (34 - 230)	787 (613 - 957)
	Events, n	6	9	87
	Persons at risk	6	418	713
	Risk (95% CI)	6	177 (61 - 292)	943 (752 - 1130)
	Events, n	9	9	98
	Persons at risk	9	367	620
	Risk (95% CI)	9	177 (61 - 292)	1088 (881 - 1290)
	Events, n	12	9	101
	Persons at risk	12	326	551
	Risk (95% CI)	12	177 (61 - 292)	1133 (920 - 1340)
Yes				
	Events, n	3	<5	34
	Persons at risk	3	<315	240
	Risk (95% CI)	3	127 (0 - 269)	1084 (732 - 1422)
	Events, n	6	6	40
	Persons at risk	6	169	187
	Risk (95% CI)	6	276 (55 - 493)	1322 (928 - 1698)
	Events, n	9	7	43
	Persons at risk	9	139	156
	Risk (95% CI)	9	339 (86 - 585)	1476 (1050 - 1882)
	Events, n	12	7	44
	Persons at risk	12	106	115
	Risk (95% CI)	12	339 (86 - 585)	1540 (1098 - 1960)

Table 15.19.14.6.5 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Pfizer-BioNTech COVID-19 vaccine within 21 days after time zero for myocarditis or pericarditis	measure	months	Myocarditis cohort (N<315)	Pericarditis cohort (N=326)
Vaccinated				
	Events, n	3	<5	10
	Persons at risk	3	<120	60
	Risk (95% CI)	3	336 (0 - 784)	1413 (562 - 2188)
	Events, n	6	<5	11
	Persons at risk	6	<79	58
	Risk (95% CI)	6	512 (0 - 1060)	1559 (668 - 2364)
	Events, n	9	<5	13
	Persons at risk	9	<79	55
	Risk (95% CI)	9	512 (0 - 1060)	1850 (889 - 2709)
	Events, n	12	<5	13
	Persons at risk	12	<79	55
	Risk (95% CI)	12	512 (0 - 1060)	1850 (889 - 2709)
Unvaccinated				
	Events, n	3	6	56
	Persons at risk	3	360	538
	Risk (95% CI)	3	149 (30 - 266)	852 (635 - 1063)
	Events, n	6	9	65
	Persons at risk	6	278	440
	Risk (95% CI)	6	241 (83 - 397)	1015 (777 - 1247)
	Events, n	9	9	74
	Persons at risk	9	225	353
	Risk (95% CI)	9	241 (83 - 397)	1217 (949 - 1478)
	Events, n	12	9	76
	Persons at risk	12	172	273
	Risk (95% CI)	12	241 (83 - 397)	1273 (995 - 1543)

Table 15.19.14.6.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=421)	Pericarditis cohort (N=689)
Unvaccinated				
	Events, n	3	<5	42
	Persons at risk	3	<598	452
	Risk (95% CI)	3	67 (0 - 159)	798 (564 - 1027)
	Events, n	6	<5	51
	Persons at risk	6	<389	402
	Risk (95% CI)	6	103 (0 - 218)	990 (728 - 1245)
	Events, n	9	<5	54
	Persons at risk	9	<280	368
	Risk (95% CI)	9	143 (2 - 282)	1059 (787 - 1324)
	Events, n	12	<5	56
	Persons at risk	12	<280	338
	Risk (95% CI)	12	143 (2 - 282)	1109 (829 - 1380)
Received dose 1 in the last 14 days				
	Events, n	3	<5	<5
	Persons at risk	3	<35	<45
	Risk (95% CI)	3	1176 (0 - 2582)	909 (0 - 2034)
	Events, n	6	<5	<5
	Persons at risk	6	<35	<45
	Risk (95% CI)	6	1176 (0 - 2582)	909 (0 - 2034)
	Events, n	9	<5	<5
	Persons at risk	9	<35	<29
	Risk (95% CI)	9	1176 (0 - 2582)	1388 (0 - 2730)
	Events, n	12	<5	<5
	Persons at risk	12	<35	<29
	Risk (95% CI)	12	1176 (0 - 2582)	1388 (0 - 2730)
Received dose 1, 15 or more days ago				
	Events, n	3	<5	16
	Persons at risk	3	<308	106
	Risk (95% CI)	3	130 (0 - 380)	1192 (625 - 1725)
	Events, n	6	<5	18
	Persons at risk	6	<148	94
	Risk (95% CI)	6	271 (0 - 635)	1363 (755 - 1931)
	Events, n	9	<5	20
	Persons at risk	9	<148	71
	Risk (95% CI)	9	271 (0 - 635)	1574 (907 - 2192)
	Events, n	12	<5	20

Table 15.19.14.6.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=421)	Pericarditis cohort (N=689)
	Persons at risk	12	<148	64
	Risk (95% CI)	12	271 (0 - 635)	1574 (907 - 2192)
Received dose 2 in the last 14 days				
	Events, n	3	0	6
	Persons at risk	3	23	14
	Risk (95% CI)	3	0 (0 - 0)	3000 (674 - 4746)
	Events, n	6	0	6
	Persons at risk	6	22	14
	Risk (95% CI)	6	0 (0 - 0)	3000 (674 - 4746)
	Events, n	9	0	6
	Persons at risk	9	21	13
	Risk (95% CI)	9	0 (0 - 0)	3000 (674 - 4746)
	Events, n	12	0	6
	Persons at risk	12	21	13
	Risk (95% CI)	12	0 (0 - 0)	3000 (674 - 4746)
Received dose 2, 15 or more days ago				
	Events, n	3	<5	24
	Persons at risk	3	<177	221
	Risk (95% CI)	3	226 (4 - 442)	902 (551 - 1240)
	Events, n	6	6	27
	Persons at risk	6	129	193
	Risk (95% CI)	6	365 (72 - 650)	1029 (653 - 1389)
	Events, n	9	6	31
	Persons at risk	9	113	171
	Risk (95% CI)	9	365 (72 - 650)	1217 (804 - 1612)
	Events, n	12	6	32
	Persons at risk	12	100	146
	Risk (95% CI)	12	365 (72 - 650)	1274 (847 - 1680)
Received dose 3 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	6	5
	Risk (95% CI)	3	0 (0 - 0)	0 (0 - 0)
	Events, n	6	<5	0
	Persons at risk	6	<5	5
	Risk (95% CI)	6	2000 (0 - 4839)	0 (0 - 0)
	Events, n	9	<5	0
	Persons at risk	9	<5	5

Table 15.19.14.6.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=421)	Pericarditis cohort (N=689)
	Risk (95% CI)	9	2000 (0 - 4839)	0 (0 - 0)
	Events, n	12	<5	0
	Persons at risk	12	<5	5
	Risk (95% CI)	12	2000 (0 - 4839)	0 (0 - 0)
Received dose 3, 15 or more days ago				
	Events, n	3	<5	17
	Persons at risk	3	<598	217
	Risk (95% CI)	3	67 (0 - 196)	653 (348 - 949)
	Events, n	6	<5	21
	Persons at risk	6	<598	165
	Risk (95% CI)	6	67 (0 - 196)	841 (488 - 1182)
	Events, n	9	<5	25
	Persons at risk	9	<598	125
	Risk (95% CI)	9	67 (0 - 196)	1104 (672 - 1516)
	Events, n	12	<5	26
	Persons at risk	12	<598	80
	Risk (95% CI)	12	67 (0 - 196)	1194 (729 - 1635)
Received dose 4 in the last 14 days				
	Events, n	3	0	0
	Persons at risk	3	<5	0
	Risk (95% CI)	3	0 (0 - 0)	NA (NA - NA)
	Events, n	6	0	0
	Persons at risk	6	0	0
	Risk (95% CI)	6	NA (NA - NA)	NA (NA - NA)
	Events, n	9	0	0
	Persons at risk	9	0	0
	Risk (95% CI)	9	NA (NA - NA)	NA (NA - NA)
	Events, n	12	0	0
	Persons at risk	12	0	0
	Risk (95% CI)	12	NA (NA - NA)	NA (NA - NA)
Received dose 4, 15 or more days ago				
	Events, n	3	0	<5
	Persons at risk	3	7	<69
	Risk (95% CI)	3	0 (0 - 0)	588 (0 - 1643)
	Events, n	6	0	<5
	Persons at risk	6	<5	<25
	Risk (95% CI)	6	0 (0 - 0)	1634 (0 - 3548)

Table 15.19.14.6.6 Risk (1-KM and 95% CI) for RECURRENT PERICARDITIS at different timepoints by Vaccination history during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for CPRD

Vaccination history	measure	months	Myocarditis cohort (N=421)	Pericarditis cohort (N=689)
	Events, n	9	0	<5
	Persons at risk	9	<5	<25
	Risk (95% CI)	9	0 (0 - 0)	1634 (0 - 3548)
	Events, n	12	0	<5
	Persons at risk	12	0	<5
	Risk (95% CI)	12	NA (NA - NA)	1634 (0 - 3548)

Table 15.20.1.a Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=0	N=0	N<5	N<5
None	0	0	<5	<5
First Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
Second Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
Thrid Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
Any Non-Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
mRNA COVID-19 vaccine	0	0	0	0
Non-mRNA COVID-19 vaccine	0	0	0	0

Table 15.20.1.b Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=0	N=0	N<5	N<5
None	0	0	<5	<5
First Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
Second Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
Thrid Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
Any Non-Pfizer-BioNTech COVID-19 dose	0	0	0 (0)	0 (0)
mRNA COVID-19 vaccine	0	0	0	0
Non-mRNA COVID-19 vaccine	0	0	0	0

Table 15.20.2.a Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=9	N<5	N<5	N=6
None	5 (55.56)	0 (0)	<5	<5
First Pfizer-BioNTech COVID-19 dose	0 (0)	<5	0 (0)	<5
Second Pfizer-BioNTech COVID-19 dose	<5	<5	0 (0)	<5
Thrid Pfizer-BioNTech COVID-19 dose	<5	0 (0)	<5	0 (0)
Any Non-Pfizer-BioNTech COVID-19 dose	<5	<5	<5	<5
mRNA COVID-19 vaccine	0 (0)	<5	<5	<5
Non-mRNA COVID-19 vaccine	<5	<5	<5	<5

Table 15.20.2.b Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=19	N=18	N=25	N=32
None	12 (63.16)	10 (55.56)	>10	>17
First Pfizer-BioNTech COVID-19 dose	0 (0)	6 (33.33)	0 (0)	9 (28.12)
Second Pfizer-BioNTech COVID-19 dose	<5	7 (38.89)	<5	5 (15.62)
Thrid Pfizer-BioNTech COVID-19 dose	<5	<5	5 (20)	<5
Any Non-Pfizer-BioNTech COVID-19 dose	<5	<5	8 (32)	6 (18.75)
mRNA COVID-19 vaccine	<5	<5	7 (87.5)	5 (83.33)
Non-mRNA COVID-19 vaccine	<5	<5	5 (62.5)	5 (83.33)

Table 15.20.3.a Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=95	N=22	N=99	N=29
None	66 (69.47)	10 (45.45)	55 (55.56)	7 (24.14)
First Pfizer-BioNTech COVID-19 dose	0 (0)	11 (50)	0 (0)	19 (65.52)
Second Pfizer-BioNTech COVID-19 dose	5 (5.26)	9 (40.91)	16 (16.16)	17 (58.62)
Thrid Pfizer-BioNTech COVID-19 dose	17 (17.89)	6 (27.27)	25 (25.25)	10 (34.48)
Any Non-Pfizer-BioNTech COVID-19 dose	7 (7.37)	<5	9 (9.09)	6 (20.69)
mRNA COVID-19 vaccine	7 (100)	<5	9 (100)	6 (100)
Non-mRNA COVID-19 vaccine	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.20.3.b Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=137	N=29	N=178	N=37
None	84 (61.31)	14 (48.28)	>100	11 (29.73)
First Pfizer-BioNTech COVID-19 dose	0 (0)	14 (48.28)	0 (0)	23 (62.16)
Second Pfizer-BioNTech COVID-19 dose	9 (6.57)	11 (37.93)	24 (13.48)	21 (56.76)
Thrid Pfizer-BioNTech COVID-19 dose	32 (23.36)	9 (31.03)	44 (24.72)	11 (29.73)
Any Non-Pfizer-BioNTech COVID-19 dose	9 (6.57)	<5	17 (9.55)	7 (18.92)
mRNA COVID-19 vaccine	9 (100)	<5	16 (94.12)	7 (100)
Non-mRNA COVID-19 vaccine	0 (0)	0 (0)	<5	0 (0)

Table 15.20.4.a Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=34	N=24	N=127	N=76
None	25 (73.53)	<5	72 (56.69)	21 (27.63)
First Pfizer-BioNTech COVID-19 dose	0 (0)	12 (50)	0 (0)	>43
Second Pfizer-BioNTech COVID-19 dose	<5	11 (45.83)	<5	38 (50)
Thrid Pfizer-BioNTech COVID-19 dose	<5	9 (37.5)	28 (22.05)	17 (22.37)
Any Non-Pfizer-BioNTech COVID-19 dose	5 (14.71)	11 (45.83)	22 (17.32)	21 (27.63)
mRNA COVID-19 vaccine	5 (100)	10 (90.91)	21 (95.45)	18 (85.71)
Non-mRNA COVID-19 vaccine	0 (0)	<5	<5	<5

Table 15.20.4.b Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=34	N=26	N=161	N=103
None	25 (73.53)	<5	99 (61.49)	26 (25.24)
First Pfizer-BioNTech COVID-19 dose	0 (0)	14 (53.85)	0 (0)	59 (57.28)
Second Pfizer-BioNTech COVID-19 dose	<5	13 (50)	<5	53 (51.46)
Thrid Pfizer-BioNTech COVID-19 dose	<5	9 (34.62)	30 (18.63)	23 (22.33)
Any Non-Pfizer-BioNTech COVID-19 dose	5 (14.71)	12 (46.15)	26 (16.15)	33 (32.04)
mRNA COVID-19 vaccine	5 (100)	11 (91.67)	25 (96.15)	28 (84.85)
Non-mRNA COVID-19 vaccine	0 (0)	<5	<5	8 (24.24)

Table 15.20.5.a Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=28	N=9	N=31	N=8
None	23 (82.14)	5 (55.56)	>8	5 (62.5)
First Pfizer-BioNTech COVID-19 dose	0 (0)	<5	0 (0)	<5
Second Pfizer-BioNTech COVID-19 dose	0 (0)	<5	<5	<5
Thrid Pfizer-BioNTech COVID-19 dose	<5	0 (0)	5 (16.13)	<5
Any Non-Pfizer-BioNTech COVID-19 dose	<5	<5	11 (35.48)	<5
mRNA COVID-19 vaccine	<5	<5	11 (100)	<5
Non-mRNA COVID-19 vaccine	0 (0)	0 (0)	0 (0)	<5

Table 15.20.5.b Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=91	N=21	N=88	N=26
None	>71	17 (80.95)	44 (50)	15 (57.69)
First Pfizer-BioNTech COVID-19 dose	0 (0)	<5	0 (0)	9 (34.62)
Second Pfizer-BioNTech COVID-19 dose	<5	<5	5 (5.68)	10 (38.46)
Thrid Pfizer-BioNTech COVID-19 dose	5 (5.49)	0 (0)	10 (11.36)	<5
Any Non-Pfizer-BioNTech COVID-19 dose	6 (6.59)	<5	23 (26.14)	5 (19.23)
mRNA COVID-19 vaccine	6 (100)	<5	23 (100)	5 (100)
Non-mRNA COVID-19 vaccine	0 (0)	0 (0)	0 (0)	<5

Table 15.20.6.a Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=10	N<5	N=9	N<5
None	7 (70)	<5	>=5	<5
First Pfizer-BioNTech COVID-19 dose	0 (0)	0 (0)	0 (0)	0 (0)
Second Pfizer-BioNTech COVID-19 dose	<5	0 (0)	0 (0)	0 (0)
Thrid Pfizer-BioNTech COVID-19 dose	<5	0 (0)	<5	<5
Any Non-Pfizer-BioNTech COVID-19 dose	<5	0 (0)	0 (0)	<5
mRNA COVID-19 vaccine	0 (0)	0	0	0 (0)
Non-mRNA COVID-19 vaccine	0 (0)	0	0	0 (0)

Table 15.20.6.b Sensitivity analysis: COVID-19 vaccines received during follow-up by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Vaccination during follow-up, n (%)	N=171	N=49	N=179	N=52
None	126 (73.68)	38 (77.55)	125 (69.83)	>36
First Pfizer-BioNTech COVID-19 dose	0 (0)	6 (12.24)	0 (0)	8 (15.38)
Second Pfizer-BioNTech COVID-19 dose	16 (9.36)	5 (10.2)	23 (12.85)	7 (13.46)
Thrid Pfizer-BioNTech COVID-19 dose	25 (14.62)	5 (10.2)	35 (19.55)	<5
Any Non-Pfizer-BioNTech COVID-19 dose	16 (9.36)	5 (10.2)	11 (6.15)	10 (19.23)
mRNA COVID-19 vaccine	0 (0)	0 (0)	0 (0)	0 (0)
Non-mRNA COVID-19 vaccine	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.21.1.a Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive cases of myocarditis or pericarditis only, for PEDIANET

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=0	N=0	N<5	N<5
Cardiac magnetic resonance(CMR)	0	0	0 (0)	0 (0)
Computed tomography(CT)	0	0	0 (0)	0 (0)
Echocardiogram	0	0	0 (0)	0 (0)

Table 15.21.1.b Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=0	N=0	N<5	N<5
Cardiac magnetic resonance(CMR)	0	0	0 (0)	0 (0)
Computed tomography(CT)	0	0	0 (0)	0 (0)
Echocardiogram	0	0	0 (0)	0 (0)

Table 15.21.2.a Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive cases of myocarditis or pericarditis only, for PHARMO

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=9	N<5	N<5	N=6
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.21.2.b Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=19	N=18	N=25	N=32
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.21.3.a Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive cases of myocarditis or pericarditis only, for NHR

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=95	N=22	N=99	N=29
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.21.3.b Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=137	N=29	N=178	N=37
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.21.4.a Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive cases of myocarditis or pericarditis only, for EPICHRON

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=34	N=24	N=127	N=76
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.21.4.b Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=34	N=26	N=161	N=103
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.21.5.a Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive cases of myocarditis or pericarditis only, for SIDIAP

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=28	N=9	N=31	N=8
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.21.5.b Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=91	N=21	N=88	N=26
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.21.6.a Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive cases of myocarditis or pericarditis only, for CPRD

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=10	N<5	N=9	N<5
Cardiac magnetic resonance(CMR)	0 (0)	0 (0)	0 (0)	0 (0)
Computed tomography(CT)	0 (0)	0 (0)	0 (0)	0 (0)
Echocardiogram	<5	<5	<5	<5

Table 15.21.6.b Sensitivity analysis: Diagnostic tests performed for the diagnosis of myocarditis or pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline using for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Characteristic	Myocarditis vaccinated	Myocarditis unvaccinated	Pericarditis vaccinated	Pericarditis unvaccinated
Diagnostic test, n (%)	N=171	N=49	N=179	N=52
Cardiac magnetic resonance(CMR)	14 (8.19)	0 (0)	<5	<5
Computed tomography(CT)	<5	0 (0)	0 (0)	<5
Echocardiogram	42 (24.56)	6 (12.24)	21 (11.73)	13 (25)

Table 15.22.1.a Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis only, for PEDIANET

label	Vaccinated	Unvaccinated
Total	N =0	N =0
Treatment, n (%)		
Paracetamol	0	0
Antivirals	0	0
Antibiotics	0	0
Immunosuppressant agents	0	0
Beta-blockers	0	0
Diuretics	0	0
ACE inhibitor or ARB	0	0
Aldosterone Antagonist	0	0
Cardiac glycosides or calcium-channel blockers	0	0
Antiarrhythmics	0	0
Pacemaker	0	0
Implantable cardiac defibrillator	0	0
Mechanical circulatory support	0	0
Heart Transplantation	0	0

Table 15.22.1.b Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis only, for PEDIANET

label	Vaccinated	Unvaccinated
Total	N =0	N =0
Treatment, n (%)		
Paracetamol	0	0
Antivirals	0	0
Antibiotics	0	0
Immunosuppressant agents	0	0
Beta-blockers	0	0
Diuretics	0	0
ACE inhibitor or ARB	0	0
Aldosterone Antagonist	0	0
Cardiac glycosides or calcium-channel blockers	0	0
Antiarrhythmics	0	0
Pacemaker	0	0
Implantable cardiac defibrillator	0	0
Mechanical circulatory support	0	0
Heart Transplantation	0	0

Table 15.22.2.a Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis only, for PHARMO

label	Vaccinated	Unvaccinated
Total	N =9	N < 5
Treatment, n (%)		
Paracetamol	<5	0 (0)
Antivirals	0 (0)	0 (0)
Antibiotics	<5	<5
Immunosuppressant agents	<5	0 (0)
Beta-blockers	<5	<5
Diuretics	<5	<5
ACE inhibitor or ARB	<5	<5
Aldosterone Antagonist	0 (0)	<5
Cardiac glycosides or calcium-channel blockers	<5	<5
Antiarrhythmics	0 (0)	<5
Pacemaker	0 (0)	0 (0)
Implantable cardiac defibrillator	0 (0)	0 (0)
Mechanical circulatory support	0 (0)	0 (0)
Heart Transplantation	0 (0)	0 (0)

Table 15.22.2.b Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis only, for PHARMO

label	Vaccinated	Unvaccinated
Total	N =19	N =18
Treatment, n (%)		
Paracetamol	<5	0 (0)
Antivirals	0 (0)	0 (0)
Antibiotics	<5	<5
Immunosuppressant agents	<5	<5
Beta-blockers	<5	<5
Diuretics	<5	<5
ACE inhibitor or ARB	<5	<5
Aldosterone Antagonist	0 (0)	<5
Cardiac glycosides or calcium-channel blockers	<5	<5
Antiarrhythmics	0 (0)	<5
Pacemaker	0 (0)	0 (0)
Implantable cardiac defibrillator	0 (0)	0 (0)
Mechanical circulatory support	0 (0)	0 (0)
Heart Transplantation	0 (0)	0 (0)

Table 15.22.3.a Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis only, for NHR

label	Vaccinated	Unvaccinated
Total	N =95	N =22
Treatment, n (%)		
Paracetamol	25 (26.32)	5 (22.73)
Antivirals	<5	<5
Antibiotics	35 (36.84)	10 (45.45)
Immunosuppressant agents	17 (17.89)	6 (27.27)
Beta-blockers	31 (32.63)	6 (27.27)
Diuretics	20 (21.05)	<5
ACE inhibitor or ARB	25 (26.32)	6 (27.27)
Aldosterone Antagonist	7 (7.37)	0 (0)
Cardiac glycosides or calcium-channel blockers	9 (9.47)	<5
Antiarrhythmics	0 (0)	<5
Pacemaker	<5	0 (0)
Implantable cardiac defibrillator	0 (0)	<5
Mechanical circulatory support	<5	<5
Heart Transplantation	0 (0)	<5

Table 15.22.3.b Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis only, for NHR

label	Vaccinated	Unvaccinated
Total	N =137	N =29
Treatment, n (%)		
Paracetamol	33 (24.09)	6 (20.69)
Antivirals	<5	<5
Antibiotics	50 (36.5)	14 (48.28)
Immunosuppressant agents	25 (18.25)	9 (31.03)
Beta-blockers	47 (34.31)	10 (34.48)
Diuretics	25 (18.25)	5 (17.24)
ACE inhibitor or ARB	37 (27.01)	9 (31.03)
Aldosterone Antagonist	9 (6.57)	<5
Cardiac glycosides or calcium-channel blockers	12 (8.76)	<5
Antiarrhythmics	<5	<5
Pacemaker	<5	0 (0)
Implantable cardiac defibrillator	<5	<5
Mechanical circulatory support	<5	<5
Heart Transplantation	0 (0)	<5

Table 15.22.4.a Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis only, for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =34	N =24
Treatment, n (%)		
Paracetamol	17 (50)	8 (33.33)
Antivirals	<5	0 (0)
Antibiotics	17 (50)	9 (37.5)
Immunosuppressant agents	5 (14.71)	<5
Beta-blockers	12 (35.29)	11 (45.83)
Diuretics	<5	5 (20.83)
ACE inhibitor or ARB	5 (14.71)	11 (45.83)
Aldosterone Antagonist	<5	<5
Cardiac glycosides or calcium-channel blockers	<5	<5
Antiarrhythmics	<5	<5
Pacemaker	0 (0)	0 (0)
Implantable cardiac defibrillator	0 (0)	0 (0)
Mechanical circulatory support	0 (0)	0 (0)
Heart Transplantation	0 (0)	0 (0)

Table 15.22.4.b Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis only, for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =34	N =26
Treatment, n (%)		
Paracetamol	17 (50)	8 (30.77)
Antivirals	<5	0 (0)
Antibiotics	17 (50)	10 (38.46)
Immunosuppressant agents	5 (14.71)	<5
Beta-blockers	12 (35.29)	11 (42.31)
Diuretics	<5	5 (19.23)
ACE inhibitor or ARB	5 (14.71)	11 (42.31)
Aldosterone Antagonist	<5	<5
Cardiac glycosides or calcium-channel blockers	<5	<5
Antiarrhythmics	<5	<5
Pacemaker	0 (0)	0 (0)
Implantable cardiac defibrillator	0 (0)	0 (0)
Mechanical circulatory support	0 (0)	0 (0)
Heart Transplantation	0 (0)	0 (0)

Table 15.22.5.a Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis only, for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =28	N =9
Treatment, n (%)		
Paracetamol	11 (39.29)	<5
Antivirals	<5	0 (0)
Antibiotics	6 (21.43)	<5
Immunosuppressant agents	<5	<5
Beta-blockers	9 (32.14)	<5
Diuretics	<5	<5
ACE inhibitor or ARB	7 (25)	<5
Aldosterone Antagonist	<5	<5
Cardiac glycosides or calcium-channel blockers	<5	0 (0)
Antiarrhythmics	<5	0 (0)
Pacemaker	0 (0)	0 (0)
Implantable cardiac defibrillator	0 (0)	0 (0)
Mechanical circulatory support	0 (0)	0 (0)
Heart Transplantation	0 (0)	0 (0)

Table 15.22.5.b Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis only, for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =91	N =21
Treatment, n (%)		
Paracetamol	35 (38.46)	7 (33.33)
Antivirals	<5	0 (0)
Antibiotics	28 (30.77)	6 (28.57)
Immunosuppressant agents	15 (16.48)	<5
Beta-blockers	14 (15.38)	<5
Diuretics	9 (9.89)	<5
ACE inhibitor or ARB	20 (21.98)	<5
Aldosterone Antagonist	<5	<5
Cardiac glycosides or calcium-channel blockers	6 (6.59)	<5
Antiarrhythmics	<5	<5
Pacemaker	0 (0)	0 (0)
Implantable cardiac defibrillator	0 (0)	0 (0)
Mechanical circulatory support	0 (0)	0 (0)
Heart Transplantation	0 (0)	0 (0)

Table 15.22.6.a Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis only, for CPRD

label	Vaccinated	Unvaccinated
Total	N =10	N < 5
Treatment, n (%)		
Paracetamol	<5	0 (0)
Antivirals	0 (0)	0 (0)
Antibiotics	5 (50)	0 (0)
Immunosuppressant agents	<5	0 (0)
Beta-blockers	7 (70)	<5
Diuretics	<5	0 (0)
ACE inhibitor or ARB	5 (50)	<5
Aldosterone Antagonist	0 (0)	0 (0)
Cardiac glycosides or calcium-channel blockers	<5	0 (0)
Antiarrhythmics	0 (0)	0 (0)
Pacemaker	<5	0 (0)
Implantable cardiac defibrillator	0 (0)	0 (0)
Mechanical circulatory support	0 (0)	0 (0)
Heart Transplantation	0 (0)	0 (0)

Table 15.22.6.b Sensitivity analysis: Treatments for myocarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis only, for CPRD

label	Vaccinated	Unvaccinated
Total	N =171	N =49
Treatment, n (%)		
Paracetamol	<5	<5
Antivirals	0 (0)	0 (0)
Antibiotics	38 (22.22)	7 (14.29)
Immunosuppressant agents	14 (8.19)	<5
Beta-blockers	80 (46.78)	21 (42.86)
Diuretics	20 (11.7)	8 (16.33)
ACE inhibitor or ARB	62 (36.26)	14 (28.57)
Aldosterone Antagonist	0 (0)	0 (0)
Cardiac glycosides or calcium-channel blockers	18 (10.53)	<5
Antiarrhythmics	6 (3.51)	<5
Pacemaker	<5	0 (0)
Implantable cardiac defibrillator	0 (0)	0 (0)
Mechanical circulatory support	0 (0)	0 (0)
Heart Transplantation	0 (0)	0 (0)

Table 15.23.1.a Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of pericarditis only, for PEDIANET

label	Vaccinated	Unvaccinated
Total	N < 5	N < 5
Treatment, n (%)		
Antibiotics	0 (0)	0 (0)
Antivirals	0 (0)	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	<5	0 (0)
Colchicine	0 (0)	0 (0)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	0 (0)	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.23.1.b Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of pericarditis only, for PEDIANET

label	Vaccinated	Unvaccinated
Total	N < 5	N < 5
Treatment, n (%)		
Antibiotics	0 (0)	0 (0)
Antivirals	0 (0)	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	<5	0 (0)
Colchicine	0 (0)	0 (0)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	0 (0)	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.23.2.a Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of pericarditis only, for PHARMO

label	Vaccinated	Unvaccinated
Total	N < 5	N =6
Treatment, n (%)		
Antibiotics	<5	<5
Antivirals	0 (0)	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	<5	<5
Colchicine	<5	<5
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	0 (0)	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.23.2.b Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of pericarditis only, for PHARMO

label	Vaccinated	Unvaccinated
Total	N =25	N =32
Treatment, n (%)		
Antibiotics	<5	<5
Antivirals	0 (0)	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	8 (32)	10 (31.25)
Colchicine	15 (60)	15 (46.88)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	0 (0)	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

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Table 15.23.3.a Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of pericarditis only, for NHR

label	Vaccinated	Unvaccinated
Total	N =99	N =29
Treatment, n (%)		
Antibiotics	22 (22.22)	9 (31.03)
Antivirals	<5	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	47 (47.47)	15 (51.72)
Colchicine	76 (76.77)	23 (79.31)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	7 (7.07)	<5
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	6 (6.06)	<5
Pericardiocentesis	<5	<5
Cardiac catheterization	<5	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.23.3.b Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of pericarditis only, for NHR

label	Vaccinated	Unvaccinated
Total	N =178	N =37
Treatment, n (%)		
Antibiotics	30 (16.85)	10 (27.03)
Antivirals	<5	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	85 (47.75)	17 (45.95)
Colchicine	116 (65.17)	28 (75.68)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	11 (6.18)	<5
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	8 (4.49)	<5
Pericardiocentesis	<5	<5
Cardiac catheterization	<5	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

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Table 15.23.4.a Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of pericarditis only, for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =127	N =76
Treatment, n (%)		
Antibiotics	24 (18.9)	20 (26.32)
Antivirals	<5	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	62 (48.82)	49 (64.47)
Colchicine	60 (47.24)	42 (55.26)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	<5	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.23.4.b Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of pericarditis only, for EPICHRON

label	Vaccinated	Unvaccinated
Total	N =161	N =103
Treatment, n (%)		
Antibiotics	26 (16.15)	24 (23.3)
Antivirals	<5	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	81 (50.31)	65 (63.11)
Colchicine	69 (42.86)	54 (52.43)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	<5	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.23.5.a Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of pericarditis only, for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =31	N =8
Treatment, n (%)		
Antibiotics	<5	<5
Antivirals	0 (0)	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	8 (25.81)	<5
Colchicine	10 (32.26)	<5
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	0 (0)	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.23.5.b Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of pericarditis only, for SIDIAP

label	Vaccinated	Unvaccinated
Total	N =88	N =26
Treatment, n (%)		
Antibiotics	20 (22.73)	<5
Antivirals	<5	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	28 (31.82)	<5
Colchicine	31 (35.23)	10 (38.46)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	0 (0)	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	0 (0)	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	0 (0)	0 (0)
Balloon pericardial window formation	0 (0)	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.23.6.a Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of pericarditis only, for CPRD

label	Vaccinated	Unvaccinated
Total	N =9	N < 5
Treatment, n (%)		
Antibiotics	<5	<5
Antivirals	0 (0)	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)	0 (0)
Colchicine	0 (0)	0 (0)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	<5	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	<5	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	0 (0)	0 (0)
Balloon pericardial window formation	<5	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.23.6.b Sensitivity analysis: Treatments for pericarditis by Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of pericarditis only, for CPRD

label	Vaccinated	Unvaccinated
Total	N =179	N =52
Treatment, n (%)		
Antibiotics	20 (11.17)	9 (17.31)
Antivirals	0 (0)	0 (0)
Non-steroidal anti-inflammatory drugs (NSAIDs)	0 (0)	0 (0)
Colchicine	0 (0)	0 (0)
Intrapericardial administration of steroids	0 (0)	0 (0)
Pericardioscopy for direct instillation of treatments into the pericardial space	0 (0)	0 (0)
Pericardial drainage	<5	0 (0)
Subdiaphragmatic laparoscopic technique	0 (0)	0 (0)
Video-assisted thoracoscopic technique	0 (0)	0 (0)
Pericardioscopy for easy drainage of effusion	<5	0 (0)
Pericardiocentesis	0 (0)	0 (0)
Cardiac catheterization	<5	<5
Balloon pericardial window formation	<5	0 (0)
Instillation of sclerosing agents and fibrinolytic agents	0 (0)	0 (0)
Pericardiectomy	0 (0)	0 (0)

Table 15.24.6.a.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<27	<5	<20	<12	<5	<19
3	Events, n	<5	0	<5	<5	<5	<5
3	Persons at risk	<27	<5	<20	<12	0	<19
3	Risk (95% CI)	1538 (0 - 3289)	0 (0 - 0)	2000 (0 - 4132)	3636 (53 - 5929)	NA (NA - NA)	2222 (0 - 4515)
6	Events, n	<5	0	<5	<5	<5	<5
6	Persons at risk	<27	<5	<20	<12	0	<19
6	Risk (95% CI)	1538 (0 - 3289)	0 (0 - 0)	2000 (0 - 4132)	3636 (53 - 5929)	NA (NA - NA)	2222 (0 - 4515)
9	Events, n	<5	0	<5	5	<5	<5
9	Persons at risk	<27	<5	<20	5	0	<12
9	Risk (95% CI)	1538 (0 - 3289)	0 (0 - 0)	2000 (0 - 4132)	4697 (601 - 7008)	NA (NA - NA)	3519 (0 - 6069)
12	Events, n	<5	0	<5	5	<5	<5
12	Persons at risk	<27	<5	<20	5	0	<12
12	Risk (95% CI)	1538 (0 - 3289)	0 (0 - 0)	2000 (0 - 4132)	4697 (601 - 7008)	NA (NA - NA)	3519 (0 - 6069)

Table 15.24.6.a.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	13	<5	10	11	<5	9
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	11	<5	9
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	11	<5	9	10	<5	8
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	10	<5	8
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	8	<5	7	8	<5	6
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.6.a.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<45	<5	<37	11	<5	9
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	11	<5	9
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	11	<5	9	10	<5	8
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	0	<5	0	0	0
9	Persons at risk	<45	<5	<37	10	<5	8
9	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	0	<5	0	0	0
12	Persons at risk	<45	<5	<37	8	<5	6
12	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.6.a.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	13	<5	10	11	<5	9
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	11	<5	9
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	11	<5	9	10	<5	8
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	10	<5	8
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	8	<5	7	8	<5	6
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.6.a.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	13	<5	<13	11	<5	9
3	Events, n	<5	<5	<5	0	0	0
3	Persons at risk	<12	<5	<13	11	<5	9
3	Risk (95% CI)	3337 (0 - 5561)	3333 (0 - 7005)	3143 (0 - 5553)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	<5	0	0	0
6	Persons at risk	<12	<5	<13	10	<5	8
6	Risk (95% CI)	3337 (0 - 5561)	3333 (0 - 7005)	3143 (0 - 5553)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	<5	0	0	0
9	Persons at risk	<12	<5	<13	10	<5	8
9	Risk (95% CI)	3337 (0 - 5561)	3333 (0 - 7005)	3143 (0 - 5553)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	<5	0	0	0
12	Persons at risk	<12	<5	<5	8	<5	6
12	Risk (95% CI)	3337 (0 - 5561)	3333 (0 - 7005)	3143 (0 - 5553)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.6.a.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	13	<5	10	11	<5	9
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	11	<5	9
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	11	<5	9	10	<5	8
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	10	<5	8
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	8	<5	7	8	<5	6
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.6.a.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	13	<5	10	11	<5	9
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	11	<5	9
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	11	<5	9	10	<5	8
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	10	<5	8
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	8	<5	7	8	<5	6
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.6.a.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	13	<5	10	11	<5	9
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	10	<5	8
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	10	<5	8	10	<5	8
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	10	<5	8
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	8	<5	7	6	<5	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.6.a.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	13	<5	10	11	<5	9
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	11	<5	9
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	11	<5	9	10	<5	8
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	10	<5	8
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	8	<5	7	8	<5	6
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.6.a.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<37	<5	<28	<40	<5	<32
3	Events, n	0	0	0	<5	0	<5
3	Persons at risk	10	<5	8	<40	<5	<32
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	1000 (0 - 2680)	0 (0 - 0)	1250 (0 - 3266)
6	Events, n	<5	0	<5	<5	0	<5
6	Persons at risk	<37	<5	<28	<40	<5	<32
6	Risk (95% CI)	1111 (0 - 2944)	0 (0 - 0)	1429 (0 - 3666)	1000 (0 - 2680)	0 (0 - 0)	1250 (0 - 3266)
9	Events, n	<5	0	<5	<5	0	<5
9	Persons at risk	<37	<5	<28	<40	<5	<32
9	Risk (95% CI)	1111 (0 - 2944)	0 (0 - 0)	1429 (0 - 3666)	1000 (0 - 2680)	0 (0 - 0)	1250 (0 - 3266)
12	Events, n	<5	0	<5	<5	0	<5
12	Persons at risk	<37	<5	<28	<40	<5	<5
12	Risk (95% CI)	1111 (0 - 2944)	0 (0 - 0)	1429 (0 - 3666)	1000 (0 - 2680)	0 (0 - 0)	1250 (0 - 3266)

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Table 15.24.6.a.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	13	<5	10	11	<5	9
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	10	<5	8
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	10	<5	8	10	<5	8
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	10	<5	8
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	8	<5	7	6	<5	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.6.a.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	13	<5	10	11	<5	9
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	11	<5	9
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	11	<5	9	10	<5	8
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	10	<5	8
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	8	<5	7	8	<5	6
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.6.a.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<19	<5	<13	11	<5	9
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<19	<5	<5	10	<5	8
3	Risk (95% CI)	2222 (0 - 4515)	0 (0 - 0)	3333 (0 - 6214)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	0	0	0
6	Persons at risk	<5	<5	<5	10	<5	8
6	Risk (95% CI)	2222 (0 - 4515)	0 (0 - 0)	3333 (0 - 6214)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	0	<5	0	0	0
9	Persons at risk	<5	<5	<5	10	<5	8
9	Risk (95% CI)	2222 (0 - 4515)	0 (0 - 0)	3333 (0 - 6214)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	0	<5	0	0	0
12	Persons at risk	<5	<5	<5	6	<5	<5
12	Risk (95% CI)	2222 (0 - 4515)	0 (0 - 0)	3333 (0 - 6214)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.6.a.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<45	<5	<37	8	<5	7
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<45	<5	<37	8	<5	7
3	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	0	0	0
6	Persons at risk	<45	<5	<37	8	<5	7
6	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	0	<5	0	0	0
9	Persons at risk	<45	<5	<37	8	<5	7
9	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	0	<5	0	0	0
12	Persons at risk	<45	<5	<37	5	<5	<5
12	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

1094

Table 15.24.6.b.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	220	49	171	231	52	179
3	Events, n	56	16	40	51	15	36
3	Persons at risk	142	25	117	163	32	131
3	Risk (95% CI)	2578 (1972 - 3139)	3343 (1855 - 4559)	2363 (1695 - 2978)	2226 (1688 - 2747)	2958 (1577 - 4113)	2020 (1408 - 2589)
6	Events, n	57	16	41	53	15	38
6	Persons at risk	123	22	101	144	30	114
6	Risk (95% CI)	2633 (2021 - 3199)	3343 (1855 - 4559)	2433 (1755 - 3055)	2323 (1754 - 2853)	2958 (1577 - 4113)	2145 (1516 - 2728)
9	Events, n	58	16	42	56	15	41
9	Persons at risk	102	21	81	130	26	104
9	Risk (95% CI)	2696 (2075 - 3268)	3343 (1855 - 4559)	2511 (1820 - 3143)	2487 (1897 - 3034)	2958 (1577 - 4113)	2356 (1694 - 2965)
12	Events, n	59	17	42	56	15	41
12	Persons at risk	84	16	68	121	25	96
12	Risk (95% CI)	2779 (2141 - 3365)	3713 (2081 - 5008)	2511 (1820 - 3143)	2487 (1897 - 3034)	2958 (1577 - 4113)	2356 (1694 - 2965)

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Table 15.24.6.b.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<870	49	<678	<460	<104	<607
3	Events, n	<5	0	<5	<5	<5	0
3	Persons at risk	<870	38	<678	<460	<104	164
3	Risk (95% CI)	46 (0 - 135)	0 (0 - 0)	59 (0 - 173)	87 (0 - 206)	388 (0 - 902)	0 (0 - 0)
6	Events, n	<5	0	<5	<5	<5	<5
6	Persons at risk	<393	33	<311	<290	<104	<607
6	Risk (95% CI)	102 (0 - 241)	0 (0 - 0)	129 (0 - 307)	138 (0 - 293)	388 (0 - 902)	66 (0 - 193)
9	Events, n	<5	0	<5	<5	<5	<5
9	Persons at risk	<393	31	<311	<290	<104	<607
9	Risk (95% CI)	102 (0 - 241)	0 (0 - 0)	129 (0 - 307)	138 (0 - 293)	388 (0 - 902)	66 (0 - 193)
12	Events, n	<5	0	<5	<5	<5	<5
12	Persons at risk	<393	27	<311	<290	<104	<607
12	Risk (95% CI)	102 (0 - 241)	0 (0 - 0)	129 (0 - 307)	138 (0 - 293)	388 (0 - 902)	66 (0 - 193)

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Table 15.24.6.b.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	220	49	171	231	52	179
3	Events, n	11	<5	7	0	0	0
3	Persons at risk	191	<46	153	209	45	164
3	Risk (95% CI)	523 (217 - 819)	881 (17 - 1671)	425 (112 - 728)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	24	7	17	0	0	0
6	Persons at risk	168	33	135	184	39	145
6	Risk (95% CI)	1183 (727 - 1618)	1629 (442 - 2669)	1067 (574 - 1534)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	41	9	32	0	0	0
9	Persons at risk	142	31	111	170	35	135
9	Risk (95% CI)	2102 (1506 - 2656)	2136 (786 - 3288)	2097 (1421 - 2720)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	53	11	42	0	0	0
12	Persons at risk	119	27	92	155	33	122
12	Risk (95% CI)	2799 (2124 - 3416)	2660 (1168 - 3900)	2843 (2070 - 3541)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.6.b.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	220	49	171	231	52	179
3	Events, n	0	0	0	0	0	0
3	Persons at risk	191	38	153	209	45	164
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	168	33	135	184	39	145
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	142	31	111	170	35	135
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	119	27	92	155	33	122
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.6.b.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	220	49	171	231	52	179
3	Events, n	18	5	13	5	0	5
3	Persons at risk	175	35	140	204	45	159
3	Risk (95% CI)	846 (463 - 1213)	1064 (135 - 1905)	783 (364 - 1183)	225 (28 - 418)	0 (0 - 0)	289 (36 - 536)
6	Events, n	21	6	15	5	0	5
6	Persons at risk	152	30	122	179	39	140
6	Risk (95% CI)	1008 (588 - 1410)	1326 (271 - 2268)	917 (463 - 1351)	225 (28 - 418)	0 (0 - 0)	289 (36 - 536)
9	Events, n	22	6	16	5	0	5
9	Persons at risk	126	28	98	165	35	130
9	Risk (95% CI)	1076 (637 - 1495)	1326 (271 - 2268)	1005 (521 - 1464)	225 (28 - 418)	0 (0 - 0)	289 (36 - 536)
12	Events, n	23	6	17	6	0	6
12	Persons at risk	104	25	79	150	33	117
12	Risk (95% CI)	1148 (689 - 1585)	1326 (271 - 2268)	1098 (583 - 1586)	290 (55 - 518)	0 (0 - 0)	371 (71 - 662)

Table 15.24.6.b.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	220	49	171	231	52	179
3	Events, n	0	0	0	0	0	0
3	Persons at risk	191	38	153	209	45	164
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	168	33	135	184	39	145
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	142	31	111	170	35	135
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	119	27	92	155	33	122
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.6.b.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	220	<197	171	231	52	179
3	Events, n	5	<5	<5	0	0	0
3	Persons at risk	187	<197	<171	209	45	164
3	Risk (95% CI)	227 (28 - 423)	204 (0 - 592)	234 (5 - 459)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	5	<5	<5	0	0	0
6	Persons at risk	164	<197	<171	184	39	145
6	Risk (95% CI)	227 (28 - 423)	204 (0 - 592)	234 (5 - 459)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	5	<5	<5	0	0	0
9	Persons at risk	138	<197	<171	170	35	135
9	Risk (95% CI)	227 (28 - 423)	204 (0 - 592)	234 (5 - 459)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	5	<5	<5	0	0	0
12	Persons at risk	115	<197	<171	155	33	122
12	Risk (95% CI)	227 (28 - 423)	204 (0 - 592)	234 (5 - 459)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.6.b.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	211	46	165	222	48	174
3	Events, n	0	0	0	0	0	0
3	Persons at risk	184	37	147	199	42	157
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	158	31	127	179	38	141
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	134	30	104	164	33	131
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	114	25	89	146	31	115
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.6.b.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	220	49	171	231	52	179
3	Events, n	0	0	0	0	0	0
3	Persons at risk	191	38	153	209	45	164
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	168	33	135	184	39	145
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	142	31	111	170	35	135
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	119	27	92	155	33	122
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.6.b.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<413	45	<326	<286	<164	<223
3	Events, n	<5	0	<5	<5	0	<5
3	Persons at risk	<413	36	<326	<286	42	<223
3	Risk (95% CI)	97 (0 - 229)	0 (0 - 0)	123 (0 - 292)	140 (0 - 297)	0 (0 - 0)	180 (0 - 379)
6	Events, n	7	0	7	8	<5	7
6	Persons at risk	149	30	119	171	<164	134
6	Risk (95% CI)	406 (105 - 699)	0 (0 - 0)	508 (132 - 870)	405 (125 - 677)	244 (0 - 705)	450 (118 - 771)
9	Events, n	8	0	8	9	<5	8
9	Persons at risk	124	29	95	157	<164	124
9	Risk (95% CI)	473 (145 - 791)	0 (0 - 0)	592 (183 - 985)	461 (161 - 752)	244 (0 - 705)	521 (162 - 868)
12	Events, n	9	0	9	9	<5	8
12	Persons at risk	104	24	80	140	<164	109
12	Risk (95% CI)	559 (191 - 913)	0 (0 - 0)	704 (241 - 1146)	461 (161 - 752)	244 (0 - 705)	521 (162 - 868)

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Table 15.24.6.b.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	211	46	165	<690	48	<541
3	Events, n	0	0	0	0	0	0
3	Persons at risk	184	37	147	199	42	157
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	158	31	127	179	38	141
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	<5	0	<5
9	Persons at risk	134	30	104	<690	33	<541
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	58 (0 - 171)	0 (0 - 0)	74 (0 - 216)
12	Events, n	0	0	0	<5	0	<5
12	Persons at risk	114	25	89	<690	31	<541
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	58 (0 - 171)	0 (0 - 0)	74 (0 - 216)

Table 15.24.6.b.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	220	49	171	<931	52	<715
3	Events, n	0	0	0	<5	0	<5
3	Persons at risk	191	38	153	<931	45	<715
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	43 (0 - 128)	0 (0 - 0)	56 (0 - 164)
6	Events, n	0	0	0	<5	0	<5
6	Persons at risk	168	33	135	<931	39	<715
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	43 (0 - 128)	0 (0 - 0)	56 (0 - 164)
9	Events, n	0	0	0	<5	0	<5
9	Persons at risk	142	31	111	<931	35	<715
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	43 (0 - 128)	0 (0 - 0)	56 (0 - 164)
12	Events, n	0	0	0	<5	0	<5
12	Persons at risk	119	27	92	<931	33	<715
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	43 (0 - 128)	0 (0 - 0)	56 (0 - 164)

Table 15.24.6.b.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	157	<65	120	<834	<181	172
3	Events, n	17	<5	15	<5	<5	0
3	Persons at risk	120	<65	92	<834	<181	155
3	Risk (95% CI)	1137 (612 - 1633)	618 (0 - 1413)	1299 (662 - 1892)	48 (0 - 142)	222 (0 - 644)	0 (0 - 0)
6	Events, n	21	<5	18	<5	<5	0
6	Persons at risk	97	<42	72	<834	<181	139
6	Risk (95% CI)	1450 (853 - 2009)	953 (0 - 1925)	1606 (892 - 2263)	48 (0 - 142)	222 (0 - 644)	0 (0 - 0)
9	Events, n	22	<5	19	<5	<5	0
9	Persons at risk	80	<42	56	<834	<181	129
9	Risk (95% CI)	1540 (921 - 2117)	953 (0 - 1925)	1726 (980 - 2410)	48 (0 - 142)	222 (0 - 644)	0 (0 - 0)
12	Events, n	26	<5	23	<5	<5	0
12	Persons at risk	64	<42	44	<834	<181	113
12	Risk (95% CI)	2003 (1252 - 2690)	953 (0 - 1925)	2378 (1422 - 3228)	48 (0 - 142)	222 (0 - 644)	0 (0 - 0)

Table 15.24.6.b.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for CPRD

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	205	<144	160	161	<129	128
3	Events, n	5	<5	<5	15	<5	14
3	Persons at risk	173	<144	<156	130	<129	103
3	Risk (95% CI)	259 (32 - 480)	278 (0 - 800)	257 (5 - 503)	956 (484 - 1405)	312 (0 - 897)	1121 (549 - 1658)
6	Events, n	7	<5	5	16	<5	15
6	Persons at risk	147	<72	119	114	<129	89
6	Risk (95% CI)	373 (97 - 641)	556 (0 - 1275)	328 (41 - 608)	1030 (538 - 1497)	312 (0 - 897)	1212 (617 - 1770)
9	Events, n	7	<5	5	19	<5	18
9	Persons at risk	125	<72	98	100	<129	79
9	Risk (95% CI)	373 (97 - 641)	556 (0 - 1275)	328 (41 - 608)	1268 (714 - 1788)	312 (0 - 897)	1510 (837 - 2134)
12	Events, n	7	<5	5	19	<5	18
12	Persons at risk	107	<72	84	91	<129	71
12	Risk (95% CI)	373 (97 - 641)	556 (0 - 1275)	328 (41 - 608)	1268 (714 - 1788)	312 (0 - 897)	1510 (837 - 2134)

Table 15.24.4.a.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	58	24	34	203	76	127
3	Events, n	55	22	33	139	54	85
3	Persons at risk	<5	<5	<5	63	22	41
3	Risk (95% CI)	9483 (8443 - 9828)	9167 (6859 - 9779)	9706 (7972 - 9957)	6851 (6142 - 7430)	7105 (5883 - 7965)	6698 (5769 - 7423)
6	Events, n	55	22	33	141	54	87
6	Persons at risk	<5	<5	<5	61	22	39
6	Risk (95% CI)	9483 (8443 - 9828)	9167 (6859 - 9779)	9706 (7972 - 9957)	6951 (6246 - 7523)	7105 (5883 - 7965)	6859 (5937 - 7572)
9	Events, n	55	22	33	142	54	88
9	Persons at risk	<5	<5	<5	60	22	38
9	Risk (95% CI)	9483 (8443 - 9828)	9167 (6859 - 9779)	9706 (7972 - 9957)	7001 (6298 - 7570)	7105 (5883 - 7965)	6940 (6021 - 7646)
12	Events, n	55	22	33	145	55	90
12	Persons at risk	<5	<5	<5	57	21	36
12	Risk (95% CI)	9483 (8443 - 9828)	9167 (6859 - 9779)	9706 (7972 - 9957)	7151 (6456 - 7710)	7237 (6024 - 8080)	7101 (6191 - 7794)

Table 15.24.4.a.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<233	24	<137	203	<102	127
3	Events, n	<5	0	<5	13	<5	10
3	Persons at risk	<233	24	<137	190	<102	117
3	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	640 (297 - 971)	395 (0 - 823)	787 (307 - 1244)
6	Events, n	<5	0	<5	15	<5	11
6	Persons at risk	<233	24	<137	188	<77	116
6	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	739 (372 - 1092)	526 (11 - 1015)	866 (364 - 1342)
9	Events, n	<5	0	<5	17	<5	13
9	Persons at risk	<233	24	<137	186	<77	114
9	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	837 (448 - 1211)	526 (11 - 1015)	1024 (481 - 1536)
12	Events, n	<5	0	<5	19	<5	15
12	Persons at risk	<233	24	<137	184	<77	112
12	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	936 (526 - 1328)	526 (11 - 1015)	1181 (602 - 1725)

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Table 15.24.4.a.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<233	24	<137	203	76	127
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<233	24	<137	191	74	117
3	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	0	0	0
6	Persons at risk	<233	24	<137	189	73	116
6	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	0	<5	0	0	0
9	Persons at risk	<233	24	<137	187	73	114
9	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	0	<5	0	0	0
12	Persons at risk	<233	24	<137	185	73	112
12	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.4.a.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	58	24	34	<405	76	<252
3	Events, n	0	0	0	<5	0	<5
3	Persons at risk	57	24	33	<405	74	<252
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	99 (0 - 235)	0 (0 - 0)	159 (0 - 375)
6	Events, n	0	0	0	<5	0	<5
6	Persons at risk	57	24	33	<405	73	<252
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	99 (0 - 235)	0 (0 - 0)	159 (0 - 375)
9	Events, n	0	0	0	<5	0	<5
9	Persons at risk	57	24	33	<405	73	<252
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	99 (0 - 235)	0 (0 - 0)	159 (0 - 375)
12	Events, n	0	0	0	<5	0	<5
12	Persons at risk	57	24	33	<405	73	<252
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	99 (0 - 235)	0 (0 - 0)	159 (0 - 375)

Table 15.24.4.a.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	58	<32	<46	203	76	127
3	Events, n	6	<5	<5	37	10	27
3	Persons at risk	52	<32	<46	163	65	98
3	Risk (95% CI)	1034 (215 - 1785)	1250 (0 - 2478)	882 (0 - 1788)	1826 (1276 - 2341)	1316 (522 - 2043)	2130 (1384 - 2811)
6	Events, n	6	<5	<5	37	10	27
6	Persons at risk	52	<32	<46	162	64	98
6	Risk (95% CI)	1034 (215 - 1785)	1250 (0 - 2478)	882 (0 - 1788)	1826 (1276 - 2341)	1316 (522 - 2043)	2130 (1384 - 2811)
9	Events, n	7	<5	<5	38	10	28
9	Persons at risk	51	<24	<46	161	64	97
9	Risk (95% CI)	1207 (327 - 2007)	1667 (34 - 3032)	882 (0 - 1788)	1876 (1320 - 2397)	1316 (522 - 2043)	2210 (1453 - 2900)
12	Events, n	7	<5	<5	41	10	31
12	Persons at risk	51	<24	<46	157	64	93
12	Risk (95% CI)	1207 (327 - 2007)	1667 (34 - 3032)	882 (0 - 1788)	2028 (1454 - 2564)	1316 (522 - 2043)	2452 (1663 - 3166)

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Table 15.24.4.a.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	58	24	34	<271	76	<170
3	Events, n	0	0	0	<5	0	<5
3	Persons at risk	57	24	33	<271	74	<170
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	148 (0 - 312)	0 (0 - 0)	236 (0 - 497)
6	Events, n	0	0	0	<5	0	<5
6	Persons at risk	57	24	33	<271	73	<170
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	148 (0 - 312)	0 (0 - 0)	236 (0 - 497)
9	Events, n	0	0	0	<5	0	<5
9	Persons at risk	57	24	33	<271	73	<170
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	148 (0 - 312)	0 (0 - 0)	236 (0 - 497)
12	Events, n	0	0	0	<5	0	<5
12	Persons at risk	57	24	33	<271	73	<170
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	148 (0 - 312)	0 (0 - 0)	236 (0 - 497)

Table 15.24.4.a.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<233	24	<137	<817	76	<507
3	Events, n	<5	0	<5	<5	0	<5
3	Persons at risk	<233	24	<137	<817	74	<507
3	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	49 (0 - 145)	0 (0 - 0)	79 (0 - 231)
6	Events, n	<5	0	<5	<5	0	<5
6	Persons at risk	<233	24	<137	<817	73	<507
6	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	49 (0 - 145)	0 (0 - 0)	79 (0 - 231)
9	Events, n	<5	0	<5	<5	0	<5
9	Persons at risk	<233	24	<137	<817	73	<507
9	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	49 (0 - 145)	0 (0 - 0)	79 (0 - 231)
12	Events, n	<5	0	<5	<5	0	<5
12	Persons at risk	<233	24	<137	<817	73	<507
12	Risk (95% CI)	172 (0 - 502)	0 (0 - 0)	294 (0 - 846)	49 (0 - 145)	0 (0 - 0)	79 (0 - 231)

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Table 15.24.4.a.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<229	<96	33	196	76	120
3	Events, n	<5	<5	0	0	0	0
3	Persons at risk	<229	<96	33	191	74	117
3	Risk (95% CI)	175 (0 - 510)	417 (0 - 1184)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	0	0	0	0
6	Persons at risk	<229	<96	33	189	73	116
6	Risk (95% CI)	175 (0 - 510)	417 (0 - 1184)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	0	0	0	0
9	Persons at risk	<229	<96	33	186	73	113
9	Risk (95% CI)	175 (0 - 510)	417 (0 - 1184)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	0	0	0	0
12	Persons at risk	<229	<96	33	183	73	110
12	Risk (95% CI)	175 (0 - 510)	417 (0 - 1184)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.4.a.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	58	24	34	203	76	127
3	Events, n	0	0	0	0	0	0
3	Persons at risk	57	24	33	191	74	117
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	57	24	33	189	73	116
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	57	24	33	187	73	114
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	57	24	33	185	73	112
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.4.a.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<114	<96	<133	183	70	113
3	Events, n	<5	<5	<5	9	5	<5
3	Persons at risk	<114	<96	<133	170	64	<112
3	Risk (95% CI)	351 (0 - 817)	417 (0 - 1184)	303 (0 - 871)	497 (175 - 809)	716 (91 - 1302)	360 (7 - 700)
6	Events, n	<5	<5	<5	12	6	6
6	Persons at risk	<77	<49	<133	166	62	104
6	Risk (95% CI)	526 (0 - 1089)	833 (0 - 1875)	303 (0 - 871)	666 (295 - 1023)	862 (178 - 1497)	542 (111 - 955)
9	Events, n	<5	<5	<5	17	6	11
9	Persons at risk	<57	<32	<133	159	62	97
9	Risk (95% CI)	702 (14 - 1342)	1250 (0 - 2478)	303 (0 - 871)	950 (510 - 1370)	862 (178 - 1497)	1006 (424 - 1553)
12	Events, n	<5	<5	<5	18	6	12
12	Persons at risk	<57	<32	<133	156	62	94
12	Risk (95% CI)	702 (14 - 1342)	1250 (0 - 2478)	303 (0 - 871)	1007 (555 - 1438)	862 (178 - 1497)	1099 (492 - 1667)

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Table 15.24.4.a.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	57	24	33	196	76	120
3	Events, n	0	0	0	0	0	0
3	Persons at risk	57	24	33	191	74	117
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	57	24	33	189	73	116
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	57	24	33	186	73	113
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	57	24	33	183	73	110
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.4.a.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	58	24	34	<817	<304	127
3	Events, n	0	0	0	<5	<5	0
3	Persons at risk	57	24	33	<817	<304	117
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	49 (0 - 145)	132 (0 - 384)	0 (0 - 0)
6	Events, n	0	0	0	<5	<5	0
6	Persons at risk	57	24	33	<817	<304	116
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	49 (0 - 145)	132 (0 - 384)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	57	24	33	<817	<304	114
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	49 (0 - 145)	132 (0 - 384)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	57	24	33	<817	<304	112
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	49 (0 - 145)	132 (0 - 384)	0 (0 - 0)

Table 15.24.4.a.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<63	<43	<104	190	73	117
3	Events, n	<5	<5	<5	0	0	0
3	Persons at risk	<63	<43	<104	185	71	114
3	Risk (95% CI)	638 (0 - 1312)	952 (0 - 2125)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	<5	0	0	0
6	Persons at risk	<63	<43	<104	183	70	113
6	Risk (95% CI)	638 (0 - 1312)	952 (0 - 2125)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	<5	0	0	0
9	Persons at risk	<63	<43	<104	180	70	110
9	Risk (95% CI)	638 (0 - 1312)	952 (0 - 2125)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	<5	0	0	0
12	Persons at risk	<63	<43	<104	177	70	107
12	Risk (95% CI)	638 (0 - 1312)	952 (0 - 2125)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.4.a.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<107	23	<60	146	<108	91
3	Events, n	0	0	0	6	<5	<5
3	Persons at risk	53	23	30	135	<108	<89
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	422 (86 - 747)	371 (0 - 862)	453 (9 - 878)
6	Events, n	<5	0	<5	7	<5	5
6	Persons at risk	<107	23	<60	132	<108	82
6	Risk (95% CI)	377 (0 - 877)	0 (0 - 0)	667 (0 - 1518)	493 (130 - 843)	371 (0 - 862)	567 (72 - 1038)
9	Events, n	<5	0	<5	7	<5	5
9	Persons at risk	<107	23	<60	131	<108	81
9	Risk (95% CI)	377 (0 - 877)	0 (0 - 0)	667 (0 - 1518)	493 (130 - 843)	371 (0 - 862)	567 (72 - 1038)
12	Events, n	<5	0	<5	10	<5	6
12	Persons at risk	<107	23	<60	126	<53	78
12	Risk (95% CI)	377 (0 - 877)	0 (0 - 0)	667 (0 - 1518)	711 (276 - 1126)	756 (15 - 1442)	683 (140 - 1197)

Table 15.24.4.b.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	60	26	34	264	103	161
3	Events, n	56	23	33	155	62	93
3	Persons at risk	<5	<5	<5	108	41	67
3	Risk (95% CI)	9333 (8282 - 9741)	8846 (6655 - 9602)	9706 (7972 - 9957)	5874 (5235 - 6427)	6019 (4952 - 6861)	5780 (4943 - 6478)
6	Events, n	56	23	33	158	63	95
6	Persons at risk	<5	<5	<5	105	40	65
6	Risk (95% CI)	9333 (8282 - 9741)	8846 (6655 - 9602)	9706 (7972 - 9957)	5988 (5351 - 6539)	6116 (5051 - 6952)	5906 (5070 - 6600)
9	Events, n	56	23	33	159	63	96
9	Persons at risk	<5	<5	<5	104	40	64
9	Risk (95% CI)	9333 (8282 - 9741)	8846 (6655 - 9602)	9706 (7972 - 9957)	6027 (5390 - 6576)	6116 (5051 - 6952)	5969 (5134 - 6660)
12	Events, n	56	23	33	163	65	98
12	Persons at risk	<5	<5	<5	100	38	62
12	Risk (95% CI)	9333 (8282 - 9741)	8846 (6655 - 9602)	9706 (7972 - 9957)	6179 (5545 - 6723)	6311 (5251 - 7134)	6095 (5262 - 6781)

Table 15.24.4.b.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<240	26	<137	264	<138	161
3	Events, n	<5	0	<5	13	<5	10
3	Persons at risk	<240	26	<137	251	<138	151
3	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	492 (228 - 750)	291 (0 - 611)	621 (241 - 987)
6	Events, n	<5	0	<5	15	<5	11
6	Persons at risk	<240	26	<137	249	<104	150
6	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	568 (285 - 843)	388 (8 - 754)	683 (285 - 1065)
9	Events, n	<5	0	<5	17	<5	13
9	Persons at risk	<240	26	<137	247	<104	148
9	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	644 (343 - 935)	388 (8 - 754)	807 (377 - 1219)
12	Events, n	<5	0	<5	19	<5	15
12	Persons at risk	<240	26	<137	245	<104	146
12	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	720 (403 - 1026)	388 (8 - 754)	932 (471 - 1370)

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Table 15.24.4.b.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<240	26	<137	264	103	161
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<240	26	<137	252	101	151
3	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	0	0	0
6	Persons at risk	<240	26	<137	250	100	150
6	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	0	<5	0	0	0
9	Persons at risk	<240	26	<137	248	100	148
9	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	0	<5	0	0	0
12	Persons at risk	<240	26	<137	246	100	146
12	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.4.b.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	60	26	34	<527	103	<320
3	Events, n	0	0	0	<5	0	<5
3	Persons at risk	59	26	33	<527	101	<320
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	76 (0 - 180)	0 (0 - 0)	125 (0 - 296)
6	Events, n	0	0	0	<5	0	<5
6	Persons at risk	59	26	33	<527	100	<320
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	76 (0 - 180)	0 (0 - 0)	125 (0 - 296)
9	Events, n	0	0	0	<5	0	<5
9	Persons at risk	59	26	33	<527	100	<320
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	76 (0 - 180)	0 (0 - 0)	125 (0 - 296)
12	Events, n	0	0	0	<5	0	<5
12	Persons at risk	59	26	33	<527	100	<320
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	76 (0 - 180)	0 (0 - 0)	125 (0 - 296)

Table 15.24.4.b.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	60	<35	<46	264	103	161
3	Events, n	6	<5	<5	38	11	27
3	Persons at risk	54	<35	<46	223	91	132
3	Risk (95% CI)	1000 (208 - 1728)	1154 (0 - 2300)	882 (0 - 1788)	1442 (1007 - 1855)	1069 (452 - 1647)	1679 (1081 - 2238)
6	Events, n	6	<5	<5	38	11	27
6	Persons at risk	54	<35	<46	222	90	132
6	Risk (95% CI)	1000 (208 - 1728)	1154 (0 - 2300)	882 (0 - 1788)	1442 (1007 - 1855)	1069 (452 - 1647)	1679 (1081 - 2238)
9	Events, n	7	<5	<5	39	11	28
9	Persons at risk	53	<27	<46	221	90	131
9	Risk (95% CI)	1167 (316 - 1943)	1538 (31 - 2818)	882 (0 - 1788)	1480 (1040 - 1898)	1069 (452 - 1647)	1742 (1134 - 2309)
12	Events, n	7	<5	<5	42	11	31
12	Persons at risk	53	<27	<46	217	90	127
12	Risk (95% CI)	1167 (316 - 1943)	1538 (31 - 2818)	882 (0 - 1788)	1596 (1142 - 2027)	1069 (452 - 1647)	1932 (1297 - 2520)

Table 15.24.4.b.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	60	26	34	<351	103	<216
3	Events, n	0	0	0	<5	0	<5
3	Persons at risk	59	26	33	<351	101	<216
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	114 (0 - 241)	0 (0 - 0)	186 (0 - 393)
6	Events, n	0	0	0	<5	0	<5
6	Persons at risk	59	26	33	<351	100	<216
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	114 (0 - 241)	0 (0 - 0)	186 (0 - 393)
9	Events, n	0	0	0	<5	0	<5
9	Persons at risk	59	26	33	<351	100	<216
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	114 (0 - 241)	0 (0 - 0)	186 (0 - 393)
12	Events, n	0	0	0	<5	0	<5
12	Persons at risk	59	26	33	<351	100	<216
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	114 (0 - 241)	0 (0 - 0)	186 (0 - 393)

Table 15.24.4.b.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<240	26	<137	<1053	103	<646
3	Events, n	<5	0	<5	<5	0	<5
3	Persons at risk	<240	26	<137	<1053	101	<646
3	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	38 (0 - 112)	0 (0 - 0)	62 (0 - 183)
6	Events, n	<5	0	<5	<5	0	<5
6	Persons at risk	<240	26	<137	<1053	100	<646
6	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	38 (0 - 112)	0 (0 - 0)	62 (0 - 183)
9	Events, n	<5	0	<5	<5	0	<5
9	Persons at risk	<240	26	<137	<1053	100	<646
9	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	38 (0 - 112)	0 (0 - 0)	62 (0 - 183)
12	Events, n	<5	0	<5	<5	0	<5
12	Persons at risk	<240	26	<137	<1053	100	<646
12	Risk (95% CI)	167 (0 - 485)	0 (0 - 0)	294 (0 - 846)	38 (0 - 112)	0 (0 - 0)	62 (0 - 183)

Table 15.24.4.b.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<237	<104	33	257	103	154
3	Events, n	<5	<5	0	0	0	0
3	Persons at risk	<237	<104	33	252	101	151
3	Risk (95% CI)	169 (0 - 493)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	0	0	0	0
6	Persons at risk	<237	<104	33	250	100	150
6	Risk (95% CI)	169 (0 - 493)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	0	0	0	0
9	Persons at risk	<237	<104	33	247	100	147
9	Risk (95% CI)	169 (0 - 493)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	0	0	0	0
12	Persons at risk	<237	<104	33	242	99	143
12	Risk (95% CI)	169 (0 - 493)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.4.b.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	60	26	34	264	103	161
3	Events, n	0	0	0	0	0	0
3	Persons at risk	59	26	33	252	101	151
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	59	26	33	250	100	150
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	59	26	33	248	100	148
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	59	26	33	246	100	146
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.4.b.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<118	<104	<133	243	96	147
3	Events, n	<5	<5	<5	11	6	5
3	Persons at risk	<118	<104	<133	228	89	139
3	Risk (95% CI)	339 (0 - 790)	385 (0 - 1096)	303 (0 - 871)	457 (190 - 718)	627 (128 - 1101)	345 (43 - 637)
6	Events, n	<5	<5	<5	14	7	7
6	Persons at risk	<79	<53	<133	224	87	137
6	Risk (95% CI)	508 (0 - 1053)	769 (0 - 1739)	303 (0 - 871)	583 (282 - 875)	733 (195 - 1241)	484 (128 - 828)
9	Events, n	<5	<5	<5	19	7	12
9	Persons at risk	<59	<35	<133	217	87	130
9	Risk (95% CI)	678 (14 - 1298)	1154 (0 - 2300)	303 (0 - 871)	795 (446 - 1132)	733 (195 - 1241)	837 (372 - 1279)
12	Events, n	<5	<5	<5	21	7	14
12	Persons at risk	<59	<35	<133	211	86	125
12	Risk (95% CI)	678 (14 - 1298)	1154 (0 - 2300)	303 (0 - 871)	880 (513 - 1233)	733 (195 - 1241)	978 (478 - 1451)

Table 15.24.4.b.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	59	26	33	257	103	154
3	Events, n	0	0	0	0	0	0
3	Persons at risk	59	26	33	252	101	151
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	59	26	33	250	100	150
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	59	26	33	247	100	147
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	59	26	33	242	99	143
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.4.b.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPICHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	60	26	34	<1053	<413	161
3	Events, n	0	0	0	<5	<5	0
3	Persons at risk	59	26	33	<1053	<413	151
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	38 (0 - 112)	97 (0 - 285)	0 (0 - 0)
6	Events, n	0	0	0	<5	<5	0
6	Persons at risk	59	26	33	<1053	<413	150
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	38 (0 - 112)	97 (0 - 285)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	59	26	33	<1053	<413	148
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	38 (0 - 112)	97 (0 - 285)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	59	26	33	<1053	<413	146
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	38 (0 - 112)	97 (0 - 285)	0 (0 - 0)

Table 15.24.4.b.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPOCHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<64	<45	<104	251	100	151
3	Events, n	<5	<5	<5	0	0	0
3	Persons at risk	<64	<45	<104	246	98	148
3	Risk (95% CI)	625 (0 - 1285)	909 (0 - 2034)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	<5	0	0	0
6	Persons at risk	<64	<45	<104	244	97	147
6	Risk (95% CI)	625 (0 - 1285)	909 (0 - 2034)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	<5	0	0	0
9	Persons at risk	<64	<45	<104	241	97	144
9	Risk (95% CI)	625 (0 - 1285)	909 (0 - 2034)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	<5	0	0	0
12	Persons at risk	<64	<45	<104	236	96	140
12	Risk (95% CI)	625 (0 - 1285)	909 (0 - 2034)	385 (0 - 1096)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.4.b.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for EPOCHRON

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<109	24	<60	190	<99	115
3	Events, n	0	0	0	7	<5	<5
3	Persons at risk	54	24	30	178	<99	<113
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	376 (99 - 646)	407 (0 - 849)	356 (7 - 693)
6	Events, n	<5	0	<5	9	<5	5
6	Persons at risk	<109	24	<60	174	<74	106
6	Risk (95% CI)	370 (0 - 861)	0 (0 - 0)	667 (0 - 1518)	485 (171 - 789)	546 (11 - 1053)	446 (56 - 820)
9	Events, n	<5	0	<5	9	<5	5
9	Persons at risk	<109	24	<60	173	<74	105
9	Risk (95% CI)	370 (0 - 861)	0 (0 - 0)	667 (0 - 1518)	485 (171 - 789)	546 (11 - 1053)	446 (56 - 820)
12	Events, n	<5	0	<5	12	6	6
12	Persons at risk	<109	24	<60	167	65	102
12	Risk (95% CI)	370 (0 - 861)	0 (0 - 0)	667 (0 - 1518)	650 (288 - 999)	824 (170 - 1435)	537 (110 - 945)

Table 15.24.3.a.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	117	22	95	128	29	99
3	Events, n	107	21	86	116	28	88
3	Persons at risk	9	<5	8	10	<5	9
3	Risk (95% CI)	9145 (8454 - 9528)	9545 (6915 - 9933)	9053 (8236 - 9491)	9077 (8403 - 9466)	9655 (7634 - 9950)	8909 (8072 - 9383)
6	Events, n	108	22	86	117	28	89
6	Persons at risk	8	0	8	9	<5	8
6	Risk (95% CI)	9240 (8565 - 9598)	NA (NA - NA)	9053 (8236 - 9491)	9169 (8507 - 9537)	9655 (7634 - 9950)	9030 (8208 - 9475)
9	Events, n	108	22	86	117	28	89
9	Persons at risk	6	0	6	8	<5	7
9	Risk (95% CI)	9240 (8565 - 9598)	NA (NA - NA)	9053 (8236 - 9491)	9169 (8507 - 9537)	9655 (7634 - 9950)	9030 (8208 - 9475)
12	Events, n	108	22	86	117	28	89
12	Persons at risk	5	0	5	8	<5	7
12	Risk (95% CI)	9240 (8565 - 9598)	NA (NA - NA)	9053 (8236 - 9491)	9169 (8507 - 9537)	9655 (7634 - 9950)	9030 (8208 - 9475)

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Table 15.24.3.a.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<371	22	<297	<450	29	<345
3	Events, n	0	0	0	0	0	0
3	Persons at risk	109	20	89	116	26	90
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	<5	0	<5
6	Persons at risk	<371	19	<297	<450	26	<345
6	Risk (95% CI)	108 (0 - 315)	0 (0 - 0)	135 (0 - 395)	89 (0 - 262)	0 (0 - 0)	116 (0 - 340)
9	Events, n	<5	0	<5	<5	0	<5
9	Persons at risk	<185	19	<146	<223	24	<171
9	Risk (95% CI)	217 (0 - 511)	0 (0 - 0)	274 (0 - 642)	180 (0 - 425)	0 (0 - 0)	235 (0 - 552)
12	Events, n	<5	0	<5	<5	0	<5
12	Persons at risk	<185	16	<146	<141	23	<108
12	Risk (95% CI)	217 (0 - 511)	0 (0 - 0)	274 (0 - 642)	285 (0 - 598)	0 (0 - 0)	373 (0 - 780)

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Table 15.24.3.a.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	117	<45	<124	128	29	99
3	Events, n	5	<5	<5	0	0	0
3	Persons at risk	109	<45	<124	116	26	90
3	Risk (95% CI)	434 (55 - 799)	909 (0 - 2034)	323 (0 - 675)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	10	<5	8	0	0	0
6	Persons at risk	91	<45	72	111	26	85
6	Risk (95% CI)	920 (358 - 1449)	909 (0 - 2034)	933 (293 - 1531)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	14	<5	12	0	0	0
9	Persons at risk	79	<45	60	98	24	74
9	Risk (95% CI)	1344 (659 - 1979)	909 (0 - 2034)	1478 (663 - 2222)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	21	<5	17	0	0	0
12	Persons at risk	68	<21	52	91	23	68
12	Risk (95% CI)	2131 (1269 - 2907)	1919 (30 - 3450)	2204 (1208 - 3087)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.3.a.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	117	22	95	128	29	99
3	Events, n	0	0	0	0	0	0
3	Persons at risk	109	20	89	116	26	90
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	91	19	72	111	26	85
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	79	19	60	98	24	74
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	68	16	52	91	23	68
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.3.a.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	117	<45	95	128	<39	99
3	Events, n	17	<5	15	11	<5	8
3	Persons at risk	92	<45	74	106	<39	82
3	Risk (95% CI)	1457 (792 - 2073)	909 (0 - 2034)	1582 (814 - 2285)	875 (367 - 1357)	1034 (0 - 2077)	828 (261 - 1362)
6	Events, n	20	<5	18	12	<5	9
6	Persons at risk	75	<45	58	100	<39	76
6	Risk (95% CI)	1764 (1028 - 2440)	909 (0 - 2034)	1963 (1101 - 2740)	963 (429 - 1468)	1034 (0 - 2077)	942 (336 - 1511)
9	Events, n	21	<5	19	12	<5	9
9	Persons at risk	65	<45	48	87	<39	65
9	Risk (95% CI)	1879 (1114 - 2577)	909 (0 - 2034)	2109 (1209 - 2916)	963 (429 - 1468)	1034 (0 - 2077)	942 (336 - 1511)
12	Events, n	21	<5	19	12	<5	9
12	Persons at risk	57	<45	43	83	<39	61
12	Risk (95% CI)	1879 (1114 - 2577)	909 (0 - 2034)	2109 (1209 - 2916)	963 (429 - 1468)	1034 (0 - 2077)	942 (336 - 1511)

Table 15.24.3.a.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<471	22	<381	<257	<116	<397
3	Events, n	<5	0	<5	<5	<5	<5
3	Persons at risk	<471	20	<381	<257	<116	<397
3	Risk (95% CI)	85 (0 - 251)	0 (0 - 0)	105 (0 - 308)	156 (0 - 369)	345 (0 - 987)	101 (0 - 296)
6	Events, n	<5	0	<5	<5	<5	<5
6	Persons at risk	<471	19	<381	<257	<116	<397
6	Risk (95% CI)	85 (0 - 251)	0 (0 - 0)	105 (0 - 308)	156 (0 - 369)	345 (0 - 987)	101 (0 - 296)
9	Events, n	<5	0	<5	<5	<5	<5
9	Persons at risk	<471	19	<381	<257	<116	<397
9	Risk (95% CI)	85 (0 - 251)	0 (0 - 0)	105 (0 - 308)	156 (0 - 369)	345 (0 - 987)	101 (0 - 296)
12	Events, n	<5	0	<5	<5	<5	<5
12	Persons at risk	<471	16	<381	<257	<116	<397
12	Risk (95% CI)	85 (0 - 251)	0 (0 - 0)	105 (0 - 308)	156 (0 - 369)	345 (0 - 987)	101 (0 - 296)

Table 15.24.3.a.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	117	<30	<96	128	29	99
3	Events, n	7	<5	<5	0	0	0
3	Persons at risk	102	<30	<96	116	26	90
3	Risk (95% CI)	598 (159 - 1018)	1364 (0 - 2685)	421 (9 - 816)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	7	<5	<5	0	0	0
6	Persons at risk	85	<30	<96	111	26	85
6	Risk (95% CI)	598 (159 - 1018)	1364 (0 - 2685)	421 (9 - 816)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	7	<5	<5	0	0	0
9	Persons at risk	73	<30	<96	98	24	74
9	Risk (95% CI)	598 (159 - 1018)	1364 (0 - 2685)	421 (9 - 816)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	7	<5	<5	0	0	0
12	Persons at risk	63	<30	<96	91	23	68
12	Risk (95% CI)	598 (159 - 1018)	1364 (0 - 2685)	421 (9 - 816)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.3.a.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	116	22	94	<413	<100	96
3	Events, n	0	0	0	0	0	0
3	Persons at risk	106	20	86	112	26	86
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	87	19	68	104	25	79
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	76	18	58	<413	<100	72
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	97 (0 - 285)	400 (0 - 1138)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	60	14	46	<413	<100	61
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	97 (0 - 285)	400 (0 - 1138)	0 (0 - 0)

Table 15.24.3.a.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<471	<88	95	128	29	99
3	Events, n	<5	<5	0	0	0	0
3	Persons at risk	<471	<88	89	116	26	90
3	Risk (95% CI)	85 (0 - 251)	455 (0 - 1286)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	0	0	0	0
6	Persons at risk	<471	<88	72	111	26	85
6	Risk (95% CI)	85 (0 - 251)	455 (0 - 1286)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	0	0	0	0
9	Persons at risk	<471	<88	60	98	24	74
9	Risk (95% CI)	85 (0 - 251)	455 (0 - 1286)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	0	0	0	0
12	Persons at risk	<471	<88	52	91	23	68
12	Risk (95% CI)	85 (0 - 251)	455 (0 - 1286)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.3.a.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	107	<35	88	110	25	85
3	Events, n	13	<5	11	13	<5	9
3	Persons at risk	85	<35	70	87	<24	67
3	Risk (95% CI)	1278 (604 - 1905)	1146 (0 - 2523)	1310 (556 - 2003)	1241 (585 - 1850)	1667 (34 - 3032)	1123 (403 - 1789)
6	Events, n	19	<5	16	17	<5	13
6	Persons at risk	65	<24	51	79	<24	60
6	Risk (95% CI)	1921 (1103 - 2664)	1736 (0 - 3345)	1963 (1048 - 2784)	1649 (899 - 2338)	1667 (34 - 3032)	1664 (793 - 2452)
9	Events, n	22	<5	18	20	<5	16
9	Persons at risk	54	<18	41	68	<24	51
9	Risk (95% CI)	2302 (1399 - 3110)	2326 (41 - 4087)	2291 (1288 - 3179)	1990 (1164 - 2738)	1667 (34 - 3032)	2111 (1128 - 2984)
12	Events, n	23	<5	19	21	5	16
12	Persons at risk	41	<18	32	57	16	41
12	Risk (95% CI)	2459 (1514 - 3299)	2326 (41 - 4087)	2494 (1426 - 3429)	2115 (1261 - 2885)	2157 (278 - 3673)	2111 (1128 - 2984)

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Table 15.24.3.a.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	116	22	94	<409	<100	95
3	Events, n	0	0	0	0	0	0
3	Persons at risk	106	20	86	111	26	85
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	87	19	68	103	25	78
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	76	18	58	<409	<100	71
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	98 (0 - 287)	400 (0 - 1138)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	60	14	46	<409	<100	60
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	98 (0 - 287)	400 (0 - 1138)	0 (0 - 0)

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Table 15.24.3.a.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	117	22	95	128	29	99
3	Events, n	0	0	0	0	0	0
3	Persons at risk	109	20	89	116	26	90
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	91	19	72	111	26	85
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	79	19	60	98	24	74
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	68	16	52	91	23	68
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.3.a.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	101	19	82	125	28	97
3	Events, n	22	5	17	0	0	0
3	Persons at risk	70	12	58	113	26	87
3	Risk (95% CI)	2295 (1403 - 3095)	2867 (381 - 4710)	2164 (1196 - 3026)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	23	5	18	0	0	0
6	Persons at risk	56	12	44	105	25	80
6	Risk (95% CI)	2418 (1502 - 3235)	2867 (381 - 4710)	2318 (1314 - 3206)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	24	5	19	0	0	0
9	Persons at risk	46	11	35	96	23	73
9	Risk (95% CI)	2569 (1617 - 3414)	2867 (381 - 4710)	2520 (1452 - 3455)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	24	5	19	0	0	0
12	Persons at risk	36	8	28	84	23	61
12	Risk (95% CI)	2569 (1617 - 3414)	2867 (381 - 4710)	2520 (1452 - 3455)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.3.a.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	113	<77	91	88	<57	72
3	Events, n	5	0	5	21	<5	20
3	Persons at risk	99	20	79	57	<57	44
3	Risk (95% CI)	454 (57 - 835)	0 (0 - 0)	558 (70 - 1022)	2516 (1520 - 3395)	714 (0 - 1970)	2908 (1743 - 3908)
6	Events, n	7	<5	6	25	<5	24
6	Persons at risk	82	<77	64	47	<57	35
6	Risk (95% CI)	665 (175 - 1131)	526 (0 - 1479)	695 (140 - 1219)	3054 (1972 - 3990)	714 (0 - 1970)	3574 (2304 - 4634)
9	Events, n	7	<5	6	25	<5	24
9	Persons at risk	71	<77	54	40	<57	30
9	Risk (95% CI)	665 (175 - 1131)	526 (0 - 1479)	695 (140 - 1219)	3054 (1972 - 3990)	714 (0 - 1970)	3574 (2304 - 4634)
12	Events, n	8	<5	7	26	<5	25
12	Persons at risk	56	<77	43	34	<57	24
12	Risk (95% CI)	799 (245 - 1321)	526 (0 - 1479)	868 (220 - 1473)	3232 (2109 - 4195)	714 (0 - 1970)	3795 (2475 - 4884)

1150

Table 15.24.3.b.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	166	29	137	215	37	178
3	Events, n	142	28	114	177	33	144
3	Persons at risk	21	<5	20	35	<5	31
3	Risk (95% CI)	8590 (7938 - 9036)	9655 (7634 - 9950)	8355 (7590 - 8877)	8240 (7648 - 8683)	8919 (7272 - 9572)	8100 (7424 - 8599)
6	Events, n	143	29	114	180	33	147
6	Persons at risk	19	0	19	31	<5	27
6	Risk (95% CI)	8657 (8013 - 9093)	NA (NA - NA)	8355 (7590 - 8877)	8393 (7814 - 8818)	8919 (7272 - 9572)	8286 (7626 - 8763)
9	Events, n	143	29	114	181	33	148
9	Persons at risk	17	0	17	28	<5	24
9	Risk (95% CI)	8657 (8013 - 9093)	NA (NA - NA)	8355 (7590 - 8877)	8446 (7871 - 8866)	8919 (7272 - 9572)	8352 (7696 - 8821)
12	Events, n	143	29	114	182	33	149
12	Persons at risk	15	0	15	21	<5	18
12	Risk (95% CI)	8657 (8013 - 9093)	NA (NA - NA)	8355 (7590 - 8877)	8517 (7942 - 8931)	8919 (7272 - 9572)	8439 (7782 - 8901)

1151

Table 15.24.3.b.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	166	29	137	<389	37	<323
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<164	26	<136	200	34	166
3	Risk (95% CI)	244 (5 - 477)	0 (0 - 0)	295 (6 - 575)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	5	0	5	<5	0	<5
6	Persons at risk	130	25	105	<389	34	<323
6	Risk (95% CI)	318 (39 - 589)	0 (0 - 0)	385 (47 - 713)	103 (0 - 243)	0 (0 - 0)	124 (0 - 294)
9	Events, n	6	0	6	<5	0	<5
9	Persons at risk	113	23	90	<257	32	<212
9	Risk (95% CI)	393 (78 - 698)	0 (0 - 0)	478 (95 - 846)	156 (0 - 329)	0 (0 - 0)	189 (0 - 398)
12	Events, n	7	0	7	<5	0	<5
12	Persons at risk	94	19	75	<186	28	<153
12	Risk (95% CI)	489 (123 - 842)	0 (0 - 0)	597 (149 - 1024)	216 (4 - 423)	0 (0 - 0)	262 (5 - 513)

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Table 15.24.3.b.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	166	<39	137	215	37	178
3	Events, n	9	<5	6	0	0	0
3	Persons at risk	151	<39	125	200	34	166
3	Risk (95% CI)	555 (196 - 901)	1034 (0 - 2077)	451 (92 - 797)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	15	<5	12	0	0	0
6	Persons at risk	130	<39	105	189	34	155
6	Risk (95% CI)	964 (487 - 1417)	1034 (0 - 2077)	956 (425 - 1458)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	21	<5	17	0	0	0
9	Persons at risk	113	<29	90	173	32	141
9	Risk (95% CI)	1404 (825 - 1946)	1408 (26 - 2598)	1415 (764 - 2020)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	33	7	26	0	0	0
12	Persons at risk	94	19	75	152	28	124
12	Risk (95% CI)	2339 (1599 - 3015)	2580 (724 - 4064)	2291 (1467 - 3035)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

1153

Table 15.24.3.b.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	166	29	137	215	37	178
3	Events, n	0	0	0	0	0	0
3	Persons at risk	151	26	125	200	34	166
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	130	25	105	189	34	155
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	113	23	90	173	32	141
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	94	19	75	152	28	124
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.3.b.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	166	<30	137	215	<50	178
3	Events, n	28	<5	24	17	<5	14
3	Persons at risk	125	<30	103	184	<50	152
3	Risk (95% CI)	1696 (1103 - 2249)	1379 (28 - 2547)	1761 (1096 - 2376)	804 (430 - 1163)	811 (0 - 1650)	801 (389 - 1195)
6	Events, n	31	<5	27	20	<5	17
6	Persons at risk	105	<30	84	172	<50	140
6	Risk (95% CI)	1913 (1282 - 2500)	1379 (28 - 2547)	2026 (1310 - 2683)	956 (548 - 1346)	811 (0 - 1650)	986 (529 - 1421)
9	Events, n	33	<5	29	20	<5	17
9	Persons at risk	90	<30	71	156	<50	126
9	Risk (95% CI)	2074 (1412 - 2685)	1379 (28 - 2547)	2223 (1467 - 2912)	956 (548 - 1346)	811 (0 - 1650)	986 (529 - 1421)
12	Events, n	33	<5	29	21	<5	18
12	Persons at risk	78	<30	62	138	<50	111
12	Risk (95% CI)	2074 (1412 - 2685)	1379 (28 - 2547)	2223 (1467 - 2912)	1021 (595 - 1427)	811 (0 - 1650)	1066 (585 - 1523)

1155

Table 15.24.3.b.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<667	29	<548	<431	<149	<715
3	Events, n	<5	0	<5	<5	<5	<5
3	Persons at risk	<667	26	<548	<431	<149	<715
3	Risk (95% CI)	60 (0 - 177)	0 (0 - 0)	73 (0 - 215)	93 (0 - 221)	270 (0 - 779)	56 (0 - 165)
6	Events, n	<5	0	<5	<5	<5	<5
6	Persons at risk	<667	25	<548	<431	<149	<715
6	Risk (95% CI)	60 (0 - 177)	0 (0 - 0)	73 (0 - 215)	93 (0 - 221)	270 (0 - 779)	56 (0 - 165)
9	Events, n	<5	0	<5	<5	<5	<5
9	Persons at risk	<667	23	<548	<431	<149	<715
9	Risk (95% CI)	60 (0 - 177)	0 (0 - 0)	73 (0 - 215)	93 (0 - 221)	270 (0 - 779)	56 (0 - 165)
12	Events, n	<5	0	<5	<5	<5	<5
12	Persons at risk	<667	19	<548	<431	<149	<715
12	Risk (95% CI)	60 (0 - 177)	0 (0 - 0)	73 (0 - 215)	93 (0 - 221)	270 (0 - 779)	56 (0 - 165)

1156

Table 15.24.3.b.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	166	<39	137	215	37	178
3	Events, n	7	<5	<5	0	0	0
3	Persons at risk	144	<39	<137	200	34	166
3	Risk (95% CI)	423 (111 - 725)	1034 (0 - 2077)	292 (6 - 570)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	7	<5	<5	0	0	0
6	Persons at risk	124	<39	<137	189	34	155
6	Risk (95% CI)	423 (111 - 725)	1034 (0 - 2077)	292 (6 - 570)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	7	<5	<5	0	0	0
9	Persons at risk	107	<39	<137	173	32	141
9	Risk (95% CI)	423 (111 - 725)	1034 (0 - 2077)	292 (6 - 570)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	7	<5	<5	0	0	0
12	Persons at risk	89	<39	<137	152	28	124
12	Risk (95% CI)	423 (111 - 725)	1034 (0 - 2077)	292 (6 - 570)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

1157

Table 15.24.3.b.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	161	29	132	<728	<133	175
3	Events, n	0	0	0	0	0	0
3	Persons at risk	147	26	121	192	34	158
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	122	23	99	182	33	149
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	108	22	86	<728	<133	135
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	55 (0 - 163)	303 (0 - 871)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	85	17	68	<728	<133	112
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	55 (0 - 163)	303 (0 - 871)	0 (0 - 0)

1158

Table 15.24.3.b.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<656	<116	137	215	37	178
3	Events, n	<5	<5	0	0	0	0
3	Persons at risk	<656	<116	125	200	34	166
3	Risk (95% CI)	61 (0 - 180)	345 (0 - 987)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	0	0	0	0
6	Persons at risk	<656	<116	105	189	34	155
6	Risk (95% CI)	61 (0 - 180)	345 (0 - 987)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	0	0	0	0
9	Persons at risk	<656	<116	90	173	32	141
9	Risk (95% CI)	61 (0 - 180)	345 (0 - 987)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	0	0	0	0
12	Persons at risk	<656	<116	75	152	28	124
12	Risk (95% CI)	61 (0 - 180)	345 (0 - 987)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.3.b.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	147	25	122	192	33	159
3	Events, n	22	<5	18	23	6	17
3	Persons at risk	112	<24	94	153	26	127
3	Risk (95% CI)	1571 (945 - 2154)	1711 (29 - 3108)	1544 (860 - 2177)	1242 (753 - 1704)	1875 (404 - 3121)	1108 (597 - 1592)
6	Events, n	30	5	25	30	6	24
6	Persons at risk	86	15	71	141	25	116
6	Risk (95% CI)	2199 (1468 - 2867)	2171 (284 - 3692)	2205 (1399 - 2936)	1646 (1088 - 2168)	1875 (404 - 3121)	1604 (993 - 2173)
9	Events, n	35	6	29	35	7	28
9	Persons at risk	72	14	58	122	22	100
9	Risk (95% CI)	2666 (1857 - 3395)	2693 (572 - 4337)	2665 (1770 - 3463)	1958 (1351 - 2522)	2214 (620 - 3536)	1910 (1244 - 2525)
12	Events, n	37	6	31	37	8	29
12	Persons at risk	52	10	42	98	19	79
12	Risk (95% CI)	2884 (2035 - 3643)	2693 (572 - 4337)	2935 (1984 - 3774)	2100 (1469 - 2684)	2567 (855 - 3959)	1998 (1314 - 2628)

1160

Table 15.24.3.b.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	161	29	132	<715	<133	174
3	Events, n	0	0	0	0	0	0
3	Persons at risk	147	26	121	191	34	157
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	122	23	99	181	33	148
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	108	22	86	<715	<133	134
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	56 (0 - 164)	303 (0 - 871)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	85	17	68	<715	<133	111
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	56 (0 - 164)	303 (0 - 871)	0 (0 - 0)

Table 15.24.3.b.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	166	29	137	215	37	178
3	Events, n	0	0	0	0	0	0
3	Persons at risk	151	26	125	200	34	166
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	130	25	105	189	34	155
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	113	23	90	173	32	141
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	94	19	75	152	28	124
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.3.b.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	141	25	116	<265	36	<220
3	Events, n	27	6	21	<5	0	<5
3	Persons at risk	102	16	86	<265	34	<220
3	Risk (95% CI)	2009 (1300 - 2660)	2636 (571 - 4248)	1880 (1120 - 2574)	151 (0 - 319)	0 (0 - 0)	182 (0 - 385)
6	Events, n	28	6	22	<5	0	<5
6	Persons at risk	84	16	68	<265	33	<220
6	Risk (95% CI)	2094 (1371 - 2757)	2636 (571 - 4248)	1984 (1203 - 2695)	151 (0 - 319)	0 (0 - 0)	182 (0 - 385)
9	Events, n	29	6	23	<5	0	<5
9	Persons at risk	71	15	56	<265	31	<220
9	Risk (95% CI)	2197 (1452 - 2877)	2636 (571 - 4248)	2115 (1300 - 2854)	151 (0 - 319)	0 (0 - 0)	182 (0 - 385)
12	Events, n	29	6	23	<5	0	<5
12	Persons at risk	59	11	48	<265	28	<220
12	Risk (95% CI)	2197 (1452 - 2877)	2636 (571 - 4248)	2115 (1300 - 2854)	151 (0 - 319)	0 (0 - 0)	182 (0 - 385)

1163

Table 15.24.3.b.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for NHR

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	158	<100	129	164	<88	140
3	Events, n	6	0	6	32	<5	31
3	Persons at risk	139	26	113	117	<88	96
3	Risk (95% CI)	387 (79 - 687)	0 (0 - 0)	471 (96 - 832)	2025 (1372 - 2629)	455 (0 - 1286)	2289 (1546 - 2966)
6	Events, n	8	<5	7	40	<5	38
6	Persons at risk	117	<100	95	101	<45	82
6	Risk (95% CI)	536 (167 - 892)	400 (0 - 1138)	565 (148 - 965)	2581 (1855 - 3242)	909 (0 - 2034)	2866 (2048 - 3600)
9	Events, n	8	<5	7	40	<5	38
9	Persons at risk	103	<100	82	91	<45	74
9	Risk (95% CI)	536 (167 - 892)	400 (0 - 1138)	565 (148 - 965)	2581 (1855 - 3242)	909 (0 - 2034)	2866 (2048 - 3600)
12	Events, n	9	<5	8	41	<5	39
12	Persons at risk	81	<100	65	73	<45	59
12	Risk (95% CI)	631 (218 - 1026)	400 (0 - 1138)	683 (208 - 1136)	2668 (1928 - 3340)	909 (0 - 2034)	2968 (2133 - 3714)

1164

Table 15.24.2.a.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	11	<5	9	11	6	5
3	Events, n	11	<5	9	10	6	<5
3	Persons at risk	0	0	0	<5	0	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	9091 (4109 - 9860)	NA (NA - NA)	8000 (0 - 9654)
6	Events, n	11	<5	9	10	6	<5
6	Persons at risk	0	0	0	<5	0	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	9091 (4109 - 9860)	NA (NA - NA)	8000 (0 - 9654)
9	Events, n	11	<5	9	10	6	<5
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	9091 (4109 - 9860)	NA (NA - NA)	8000 (0 - 9654)
12	Events, n	11	<5	9	10	6	<5
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	9091 (4109 - 9860)	NA (NA - NA)	8000 (0 - 9654)

1165

Table 15.24.2.a.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	11	<5	9	11	6	5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	11	6	5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	10	<5	8	11	6	5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	10	5	5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	9	<5	7	9	5	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.2.a.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<45	<5	<37	11	6	5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	11	6	5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	0	0	0
6	Persons at risk	<45	<5	<37	11	6	5
6	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	0	<5	0	0	0
9	Persons at risk	<45	<5	<37	10	5	5
9	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	0	<5	0	0	0
12	Persons at risk	<23	<5	<19	9	5	<5
12	Risk (95% CI)	1818 (0 - 3808)	0 (0 - 0)	2222 (0 - 4515)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

1167

Table 15.24.2.a.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	11	<5	9	11	6	5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	11	6	5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	10	<5	8	11	6	5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	10	5	5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	9	<5	7	9	5	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.2.a.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<45	<5	9	<23	<13	5
3	Events, n	<5	<5	0	<5	<5	0
3	Persons at risk	<45	<5	9	<23	<5	5
3	Risk (95% CI)	909 (0 - 2459)	5000 (0 - 8750)	0 (0 - 0)	1818 (0 - 3808)	3333 (0 - 6214)	0 (0 - 0)
6	Events, n	<5	<5	0	<5	<5	0
6	Persons at risk	<45	<5	8	<23	<5	5
6	Risk (95% CI)	909 (0 - 2459)	5000 (0 - 8750)	0 (0 - 0)	1818 (0 - 3808)	3333 (0 - 6214)	0 (0 - 0)
9	Events, n	<5	<5	0	<5	<5	0
9	Persons at risk	<45	<5	8	<23	<5	5
9	Risk (95% CI)	909 (0 - 2459)	5000 (0 - 8750)	0 (0 - 0)	1818 (0 - 3808)	3333 (0 - 6214)	0 (0 - 0)
12	Events, n	<5	<5	0	<5	<5	0
12	Persons at risk	<45	<5	7	<23	<5	<5
12	Risk (95% CI)	909 (0 - 2459)	5000 (0 - 8750)	0 (0 - 0)	1818 (0 - 3808)	3333 (0 - 6214)	0 (0 - 0)

Table 15.24.2.a.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	11	<5	9	<45	<24	5
3	Events, n	0	0	0	<5	<5	0
3	Persons at risk	11	<5	9	<45	<24	5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	909 (0 - 2459)	1667 (0 - 4173)	0 (0 - 0)
6	Events, n	0	0	0	<5	<5	0
6	Persons at risk	10	<5	8	<45	<24	5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	909 (0 - 2459)	1667 (0 - 4173)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	10	<5	8	<45	<5	5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	909 (0 - 2459)	1667 (0 - 4173)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	9	<5	7	<45	<5	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	909 (0 - 2459)	1667 (0 - 4173)	0 (0 - 0)

Table 15.24.2.a.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<45	<5	9	11	6	5
3	Events, n	<5	<5	0	0	0	0
3	Persons at risk	<45	<5	9	11	6	5
3	Risk (95% CI)	909 (0 - 2459)	5000 (0 - 8750)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	0	0	0	0
6	Persons at risk	<45	<5	8	11	6	5
6	Risk (95% CI)	909 (0 - 2459)	5000 (0 - 8750)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	0	0	0	0
9	Persons at risk	<45	<5	8	10	5	5
9	Risk (95% CI)	909 (0 - 2459)	5000 (0 - 8750)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	0	0	0	0
12	Persons at risk	<45	<5	7	9	5	<5
12	Risk (95% CI)	909 (0 - 2459)	5000 (0 - 8750)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.2.a.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<45	<5	<37	11	6	5
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<45	<5	<37	11	6	5
3	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	0	0	0
6	Persons at risk	<45	<5	<37	10	5	5
6	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	0	<5	0	0	0
9	Persons at risk	<45	<5	<37	10	5	5
9	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	0	<5	0	0	0
12	Persons at risk	<45	<5	<37	9	5	<5
12	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.2.a.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	11	<5	9	11	6	5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	11	6	5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	10	<5	8	11	6	5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	10	5	5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	9	<5	7	9	5	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.2.a.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	11	<5	9	<37	5	<5
3	Events, n	0	0	0	<5	0	<5
3	Persons at risk	11	<5	9	<37	5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	2500 (0 - 5741)
6	Events, n	0	0	0	<5	0	<5
6	Persons at risk	10	<5	8	<37	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	2500 (0 - 5741)
9	Events, n	0	0	0	<5	0	<5
9	Persons at risk	10	<5	8	<37	<5	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	2500 (0 - 5741)
12	Events, n	0	0	0	<5	0	<5
12	Persons at risk	9	<5	7	<37	<5	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	2500 (0 - 5741)

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Table 15.24.2.a.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<45	<5	<37	<40	6	<20
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<45	<5	<37	11	6	5
3	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	0	0	0
6	Persons at risk	<45	<5	<37	10	5	5
6	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	0	<5	0	0	0
9	Persons at risk	<45	<5	<37	10	5	5
9	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	0	<5	<5	0	<5
12	Persons at risk	<45	<5	<37	<40	5	<5
12	Risk (95% CI)	909 (0 - 2459)	0 (0 - 0)	1111 (0 - 2944)	1000 (0 - 2680)	0 (0 - 0)	2000 (0 - 4839)

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Table 15.24.2.a.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or perdicarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	11	<5	9	<45	<24	5
3	Events, n	0	0	0	<5	<5	0
3	Persons at risk	11	<5	9	<45	<24	5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	909 (0 - 2459)	1667 (0 - 4173)	0 (0 - 0)
6	Events, n	0	0	0	<5	<5	0
6	Persons at risk	10	<5	8	<45	<24	5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	909 (0 - 2459)	1667 (0 - 4173)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	10	<5	8	<45	<5	5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	909 (0 - 2459)	1667 (0 - 4173)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	9	<5	7	<45	<5	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	909 (0 - 2459)	1667 (0 - 4173)	0 (0 - 0)

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Table 15.24.2.a.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<28	<5	<24	10	5	5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	9	<5	8	10	5	5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	8	<5	7	10	5	5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	8	<5	7	10	5	5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	0	<5	0	0	0
12	Persons at risk	<28	<5	<24	9	5	<5
12	Risk (95% CI)	1429 (0 - 3666)	0 (0 - 0)	1667 (0 - 4173)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

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Table 15.24.2.a.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	11	<5	9	8	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	11	<5	9	8	<5	<5
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	10	<5	8	7	<5	<5
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	10	<5	8	7	<5	<5
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	9	<5	7	6	<5	<5
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.2.b.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	18	19	57	32	25
3	Events, n	36	17	19	52	28	24
3	Persons at risk	<5	<5	0	<5	<5	<5
3	Risk (95% CI)	9730 (8132 - 9961)	9444 (6268 - 9917)	NA (NA - NA)	9123 (7974 - 9620)	8750 (6874 - 9500)	9600 (7271 - 9941)
6	Events, n	36	17	19	52	28	24
6	Persons at risk	<5	<5	0	<5	<5	<5
6	Risk (95% CI)	9730 (8132 - 9961)	9444 (6268 - 9917)	NA (NA - NA)	9123 (7974 - 9620)	8750 (6874 - 9500)	9600 (7271 - 9941)
9	Events, n	36	17	19	52	28	24
9	Persons at risk	<5	<5	0	<5	<5	<5
9	Risk (95% CI)	9730 (8132 - 9961)	9444 (6268 - 9917)	NA (NA - NA)	9123 (7974 - 9620)	8750 (6874 - 9500)	9600 (7271 - 9941)
12	Events, n	36	17	19	52	28	24
12	Persons at risk	<5	<5	0	<5	<5	<5
12	Risk (95% CI)	9730 (8132 - 9961)	9444 (6268 - 9917)	NA (NA - NA)	9123 (7974 - 9620)	8750 (6874 - 9500)	9600 (7271 - 9941)

Table 15.24.2.b.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<140	18	<69	<114	<64	25
3	Events, n	<5	0	<5	<5	<5	0
3	Persons at risk	<140	17	<69	<114	<64	24
3	Risk (95% CI)	286 (0 - 822)	0 (0 - 0)	588 (0 - 1643)	351 (0 - 817)	625 (0 - 1427)	0 (0 - 0)
6	Events, n	<5	0	<5	<5	<5	0
6	Persons at risk	<140	17	<69	<114	<64	23
6	Risk (95% CI)	286 (0 - 822)	0 (0 - 0)	588 (0 - 1643)	351 (0 - 817)	625 (0 - 1427)	0 (0 - 0)
9	Events, n	<5	0	<5	<5	<5	0
9	Persons at risk	<140	16	<69	<75	<42	23
9	Risk (95% CI)	286 (0 - 822)	0 (0 - 0)	588 (0 - 1643)	540 (0 - 1117)	960 (0 - 1937)	0 (0 - 0)
12	Events, n	<5	0	<5	<5	<5	0
12	Persons at risk	<140	15	<69	<75	<42	18
12	Risk (95% CI)	286 (0 - 822)	0 (0 - 0)	588 (0 - 1643)	540 (0 - 1117)	960 (0 - 1937)	0 (0 - 0)

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Table 15.24.2.b.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	<72	<25	<113	<53	<50
3	Events, n	<5	<5	<5	<5	0	<5
3	Persons at risk	<37	<72	<25	<113	30	<50
3	Risk (95% CI)	1097 (22 - 2056)	556 (0 - 1557)	1612 (0 - 3129)	357 (0 - 832)	0 (0 - 0)	800 (0 - 1804)
6	Events, n	6	<5	5	<5	0	<5
6	Persons at risk	30	<72	13	<113	30	<50
6	Risk (95% CI)	1653 (352 - 2779)	556 (0 - 1557)	2730 (368 - 4513)	357 (0 - 832)	0 (0 - 0)	800 (0 - 1804)
9	Events, n	8	<5	6	<5	0	<5
9	Persons at risk	28	<37	12	<113	27	<50
9	Risk (95% CI)	2210 (733 - 3451)	1111 (0 - 2451)	3289 (738 - 5138)	357 (0 - 832)	0 (0 - 0)	800 (0 - 1804)
12	Events, n	10	<5	7	<5	<5	<5
12	Persons at risk	26	<24	11	<53	<53	<50
12	Risk (95% CI)	2766 (1149 - 4088)	1667 (0 - 3222)	3849 (1143 - 5728)	768 (12 - 1466)	769 (0 - 1739)	800 (0 - 1804)

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Table 15.24.2.b.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	18	19	57	32	25
3	Events, n	0	0	0	0	0	0
3	Persons at risk	32	17	15	54	30	24
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	30	17	13	53	30	23
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	28	16	12	50	27	23
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	26	15	11	42	24	18
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.2.b.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<50	<37	<77	<77	<43	25
3	Events, n	<5	<5	<5	<5	<5	0
3	Persons at risk	<50	<37	<77	<77	<43	24
3	Risk (95% CI)	811 (0 - 1650)	1111 (0 - 2451)	526 (0 - 1479)	526 (0 - 1089)	938 (0 - 1893)	0 (0 - 0)
6	Events, n	<5	<5	<5	<5	<5	0
6	Persons at risk	<50	<37	<77	<77	<43	23
6	Risk (95% CI)	811 (0 - 1650)	1111 (0 - 2451)	526 (0 - 1479)	526 (0 - 1089)	938 (0 - 1893)	0 (0 - 0)
9	Events, n	<5	<5	<5	<5	<5	0
9	Persons at risk	<50	<37	<77	<56	<31	23
9	Risk (95% CI)	811 (0 - 1650)	1111 (0 - 2451)	526 (0 - 1479)	724 (13 - 1384)	1300 (21 - 2415)	0 (0 - 0)
12	Events, n	<5	<5	<5	<5	<5	0
12	Persons at risk	<50	<37	<77	<56	<31	18
12	Risk (95% CI)	811 (0 - 1650)	1111 (0 - 2451)	526 (0 - 1479)	724 (13 - 1384)	1300 (21 - 2415)	0 (0 - 0)

Table 15.24.2.b.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	18	19	<229	<129	25
3	Events, n	0	0	0	<5	<5	0
3	Persons at risk	32	17	15	<229	<129	24
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	175 (0 - 510)	312 (0 - 897)	0 (0 - 0)
6	Events, n	0	0	0	<5	<5	0
6	Persons at risk	30	17	13	<229	<129	23
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	175 (0 - 510)	312 (0 - 897)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	28	16	12	<229	<129	23
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	175 (0 - 510)	312 (0 - 897)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	26	15	11	<229	<129	18
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	175 (0 - 510)	312 (0 - 897)	0 (0 - 0)

Table 15.24.2.b.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<74	<72	<77	57	32	25
3	Events, n	<5	<5	<5	0	0	0
3	Persons at risk	<74	<72	<77	54	30	24
3	Risk (95% CI)	541 (0 - 1242)	556 (0 - 1557)	526 (0 - 1479)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	<5	<5	0	0	0
6	Persons at risk	<74	<72	<77	53	30	23
6	Risk (95% CI)	541 (0 - 1242)	556 (0 - 1557)	526 (0 - 1479)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	<5	0	0	0
9	Persons at risk	<74	<72	<77	50	27	23
9	Risk (95% CI)	541 (0 - 1242)	556 (0 - 1557)	526 (0 - 1479)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	<5	0	0	0
12	Persons at risk	<74	<72	<77	42	24	18
12	Risk (95% CI)	541 (0 - 1242)	556 (0 - 1557)	526 (0 - 1479)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.2.b.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<129	18	<60	<212	30	<92
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<129	17	<60	53	30	23
3	Risk (95% CI)	312 (0 - 897)	0 (0 - 0)	667 (0 - 1847)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	<5	0	<5
6	Persons at risk	<129	17	<60	<212	28	<92
6	Risk (95% CI)	312 (0 - 897)	0 (0 - 0)	667 (0 - 1847)	189 (0 - 548)	0 (0 - 0)	435 (0 - 1233)
9	Events, n	<5	0	<5	<5	0	<5
9	Persons at risk	<129	15	<60	<212	25	<92
9	Risk (95% CI)	312 (0 - 897)	0 (0 - 0)	667 (0 - 1847)	189 (0 - 548)	0 (0 - 0)	435 (0 - 1233)
12	Events, n	<5	0	<5	<5	0	<5
12	Persons at risk	<129	15	<60	<212	24	<92
12	Risk (95% CI)	312 (0 - 897)	0 (0 - 0)	667 (0 - 1847)	189 (0 - 548)	0 (0 - 0)	435 (0 - 1233)

Table 15.24.2.b.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	18	19	57	32	25
3	Events, n	0	0	0	0	0	0
3	Persons at risk	32	17	15	54	30	24
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	30	17	13	53	30	23
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	28	16	12	50	27	23
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	26	15	11	42	24	18
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.2.b.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<109	17	<49	<205	29	<88
3	Events, n	0	0	0	<5	0	<5
3	Persons at risk	31	16	15	<205	29	<88
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	196 (0 - 569)	0 (0 - 0)	455 (0 - 1286)
6	Events, n	0	0	0	<5	0	<5
6	Persons at risk	29	16	13	<205	27	<88
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	196 (0 - 569)	0 (0 - 0)	455 (0 - 1286)
9	Events, n	<5	0	<5	<5	0	<5
9	Persons at risk	<109	14	<49	<64	24	<28
9	Risk (95% CI)	370 (0 - 1057)	0 (0 - 0)	833 (0 - 2271)	627 (0 - 1291)	0 (0 - 0)	1459 (0 - 2860)
12	Events, n	<5	0	<5	<5	0	<5
12	Persons at risk	<109	14	<49	<64	23	<28
12	Risk (95% CI)	370 (0 - 1057)	0 (0 - 0)	833 (0 - 2271)	627 (0 - 1291)	0 (0 - 0)	1459 (0 - 2860)

Table 15.24.2.b.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<129	18	<60	<212	30	<92
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<129	17	<60	53	30	23
3	Risk (95% CI)	312 (0 - 897)	0 (0 - 0)	667 (0 - 1847)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	<5	0	<5
6	Persons at risk	<129	17	<60	<212	28	<92
6	Risk (95% CI)	312 (0 - 897)	0 (0 - 0)	667 (0 - 1847)	189 (0 - 548)	0 (0 - 0)	435 (0 - 1233)
9	Events, n	<5	0	<5	<5	0	<5
9	Persons at risk	<129	15	<60	<212	25	<92
9	Risk (95% CI)	312 (0 - 897)	0 (0 - 0)	667 (0 - 1847)	189 (0 - 548)	0 (0 - 0)	435 (0 - 1233)
12	Events, n	<5	0	<5	<5	0	<5
12	Persons at risk	<129	15	<60	<95	24	<42
12	Risk (95% CI)	312 (0 - 897)	0 (0 - 0)	667 (0 - 1847)	422 (0 - 982)	0 (0 - 0)	966 (0 - 2162)

Table 15.24.2.b.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	18	19	<229	<129	25
3	Events, n	0	0	0	<5	<5	0
3	Persons at risk	32	17	15	<229	<129	24
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	175 (0 - 510)	312 (0 - 897)	0 (0 - 0)
6	Events, n	0	0	0	<5	<5	0
6	Persons at risk	30	17	13	<229	<129	23
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	175 (0 - 510)	312 (0 - 897)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	28	16	12	<229	<129	23
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	175 (0 - 510)	312 (0 - 897)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	26	15	11	<229	<129	18
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	175 (0 - 510)	312 (0 - 897)	0 (0 - 0)

Table 15.24.2.b.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<72	12	<37	<157	27	<64
3	Events, n	0	0	0	0	0	0
3	Persons at risk	24	11	13	47	27	20
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	22	11	11	46	26	20
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	19	9	10	42	24	18
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	0	<5	<5	0	<5
12	Persons at risk	<72	9	<37	<157	23	<64
12	Risk (95% CI)	556 (0 - 1557)	0 (0 - 0)	1111 (0 - 2944)	256 (0 - 740)	0 (0 - 0)	625 (0 - 1739)

Table 15.24.2.b.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PHARMO

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	33	17	16	<69	<113	<47
3	Events, n	0	0	0	<5	<5	<5
3	Persons at risk	31	16	15	<69	<113	<47
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	585 (0 - 1205)	357 (0 - 1021)	852 (0 - 1916)
6	Events, n	0	0	0	<5	<5	<5
6	Persons at risk	29	16	13	<69	<113	<47
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	585 (0 - 1205)	357 (0 - 1021)	852 (0 - 1916)
9	Events, n	0	0	0	5	<5	<5
9	Persons at risk	26	14	12	39	<55	<31
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	999 (127 - 1793)	728 (0 - 1651)	1310 (0 - 2590)
12	Events, n	0	0	0	6	<5	<5
12	Persons at risk	25	14	11	35	<55	<22
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	1242 (254 - 2130)	728 (0 - 1651)	1853 (15 - 3353)

Table 15.24.1.a.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.a.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.a.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.a.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.a.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.a.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.a.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.a.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

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Table 15.24.1.a.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

1201

Table 15.24.1.a.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.a.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.a.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.a.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.a.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.1.b.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.b.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.b.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.1.b.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.1.b.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.b.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.1.b.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.b.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.b.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.b.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.b.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.b.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	<5	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.b.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.1.1.b.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for PEDIANET

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	0	0	0	<5	<5	<5
3	Events, n	0	0	0	0	0	0
3	Persons at risk	0	0	0	<5	<5	<5
3	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	0	0	0	<5	<5	<5
6	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	0	0	0	<5	0	<5
9	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	0	0	0	<5	0	<5
12	Risk (95% CI)	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)	0 (0 - 0)	NA (NA - NA)	0 (0 - 0)

Table 15.24.5.a.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	9	28	39	8	31
3	Events, n	34	7	27	30	6	24
3	Persons at risk	<5	<5	<5	8	<5	6
3	Risk (95% CI)	9189 (7601 - 9726)	7778 (2456 - 9345)	9643 (7553 - 9948)	7692 (5907 - 8699)	7500 (1698 - 9247)	7742 (5667 - 8823)
6	Events, n	34	7	27	30	6	24
6	Persons at risk	<5	<5	0	7	<5	5
6	Risk (95% CI)	9189 (7601 - 9726)	7778 (2456 - 9345)	NA (NA - NA)	7692 (5907 - 8699)	7500 (1698 - 9247)	7742 (5667 - 8823)
9	Events, n	34	7	27	30	6	24
9	Persons at risk	<5	<5	0	7	<5	5
9	Risk (95% CI)	9189 (7601 - 9726)	7778 (2456 - 9345)	NA (NA - NA)	7692 (5907 - 8699)	7500 (1698 - 9247)	7742 (5667 - 8823)
12	Events, n	34	7	27	30	6	24
12	Persons at risk	<5	<5	0	7	<5	5
12	Risk (95% CI)	9189 (7601 - 9726)	7778 (2456 - 9345)	NA (NA - NA)	7692 (5907 - 8699)	7500 (1698 - 9247)	7742 (5667 - 8823)

1221

Table 15.24.5.a.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	9	28	39	8	31
3	Events, n	0	0	0	0	0	0
3	Persons at risk	33	8	25	37	7	30
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	25	7	18	35	7	28
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	25	7	18	35	7	28
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	21	6	15	33	7	26
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

1222

Table 15.24.5.a.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<38	<37	<38	39	8	31
3	Events, n	<5	<5	<5	0	0	0
3	Persons at risk	<38	<37	<38	37	7	30
3	Risk (95% CI)	1081 (22 - 2028)	1111 (0 - 2944)	1071 (0 - 2147)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	11	<5	9	0	0	0
6	Persons at risk	25	<19	18	35	7	28
6	Risk (95% CI)	3002 (1346 - 4341)	2222 (0 - 4515)	3265 (1260 - 4810)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	12	<5	10	0	0	0
9	Persons at risk	25	<19	18	35	7	28
9	Risk (95% CI)	3282 (1570 - 4646)	2222 (0 - 4515)	3639 (1553 - 5210)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	14	<5	11	0	0	0
12	Persons at risk	21	<13	15	33	7	26
12	Risk (95% CI)	3842 (2037 - 5237)	3333 (0 - 5800)	4014 (1858 - 5598)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

1223

Table 15.24.5.a.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	9	28	39	8	31
3	Events, n	0	0	0	0	0	0
3	Persons at risk	33	8	25	37	7	30
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	25	7	18	35	7	28
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	25	7	18	35	7	28
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	21	6	15	33	7	26
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.5.a.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<38	<37	<38	39	<11	31
3	Events, n	<5	<5	<5	12	<5	9
3	Persons at risk	<38	<37	<38	25	<5	21
3	Risk (95% CI)	1081 (22 - 2028)	1111 (0 - 2944)	1071 (0 - 2147)	3077 (1466 - 4384)	3750 (0 - 6346)	2903 (1111 - 4334)
6	Events, n	5	<5	<5	12	<5	9
6	Persons at risk	23	<37	<27	23	<5	19
6	Risk (95% CI)	1424 (175 - 2515)	1111 (0 - 2944)	1518 (16 - 2794)	3077 (1466 - 4384)	3750 (0 - 6346)	2903 (1111 - 4334)
9	Events, n	6	<5	5	12	<5	9
9	Persons at risk	22	<37	16	23	<5	19
9	Risk (95% CI)	1797 (359 - 3020)	1111 (0 - 2944)	2017 (232 - 3475)	3077 (1466 - 4384)	3750 (0 - 6346)	2903 (1111 - 4334)
12	Events, n	6	<5	5	13	<5	10
12	Persons at risk	19	<37	14	21	<5	17
12	Risk (95% CI)	1797 (359 - 3020)	1111 (0 - 2944)	2017 (232 - 3475)	3378 (1693 - 4721)	3750 (0 - 6346)	3277 (1377 - 4758)

1225

Table 15.24.5.a.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<50	<28	<38	<157	<32	31
3	Events, n	<5	0	<5	<5	<5	0
3	Persons at risk	<50	8	<38	<157	<32	30
3	Risk (95% CI)	811 (0 - 1650)	0 (0 - 0)	1071 (0 - 2147)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)
6	Events, n	<5	0	<5	<5	<5	0
6	Persons at risk	<50	7	<38	<157	<32	28
6	Risk (95% CI)	811 (0 - 1650)	0 (0 - 0)	1071 (0 - 2147)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)
9	Events, n	<5	0	<5	<5	<5	0
9	Persons at risk	<50	7	<38	<157	<32	28
9	Risk (95% CI)	811 (0 - 1650)	0 (0 - 0)	1071 (0 - 2147)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)
12	Events, n	<5	<5	<5	<5	<5	0
12	Persons at risk	<33	<28	<38	<157	<32	26
12	Risk (95% CI)	1228 (0 - 2315)	1429 (0 - 3666)	1071 (0 - 2147)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)

1226

Table 15.24.5.a.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<74	<28	<57	<157	<32	31
3	Events, n	<5	0	<5	<5	<5	0
3	Persons at risk	<74	8	<57	<157	<32	30
3	Risk (95% CI)	541 (0 - 1242)	0 (0 - 0)	714 (0 - 1621)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)
6	Events, n	<5	0	<5	<5	<5	0
6	Persons at risk	<74	7	<57	<157	<32	28
6	Risk (95% CI)	541 (0 - 1242)	0 (0 - 0)	714 (0 - 1621)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)
9	Events, n	<5	0	<5	<5	<5	0
9	Persons at risk	<74	7	<57	<157	<32	28
9	Risk (95% CI)	541 (0 - 1242)	0 (0 - 0)	714 (0 - 1621)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)
12	Events, n	<5	<5	<5	<5	<5	0
12	Persons at risk	<43	<28	<57	<157	<32	26
12	Risk (95% CI)	952 (0 - 1945)	1429 (0 - 3666)	714 (0 - 1621)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)

1227

Table 15.24.5.a.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<133	<28	<100	39	8	31
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<133	7	<100	37	7	30
3	Risk (95% CI)	303 (0 - 871)	0 (0 - 0)	400 (0 - 1138)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	0	0	0
6	Persons at risk	<133	7	<100	35	7	28
6	Risk (95% CI)	303 (0 - 871)	0 (0 - 0)	400 (0 - 1138)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	<5	0	0	0
9	Persons at risk	<57	<28	<100	34	7	27
9	Risk (95% CI)	707 (0 - 1616)	1429 (0 - 3666)	400 (0 - 1138)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	<5	0	0	0
12	Persons at risk	<34	<28	<37	33	7	26
12	Risk (95% CI)	1196 (0 - 2405)	1429 (0 - 3666)	1086 (0 - 2448)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

1228

Table 15.24.5.a.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	9	28	39	8	31
3	Events, n	0	0	0	0	0	0
3	Persons at risk	33	8	25	37	7	30
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	25	7	18	35	7	28
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	25	7	18	35	7	28
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	21	6	15	33	7	26
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.5.a.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<121	9	<88	35	8	27
3	Events, n	<5	0	<5	<5	0	<5
3	Persons at risk	<121	7	<88	<35	7	<27
3	Risk (95% CI)	333 (0 - 955)	0 (0 - 0)	455 (0 - 1286)	1171 (23 - 2186)	0 (0 - 0)	1512 (29 - 2775)
6	Events, n	<5	0	<5	<5	0	<5
6	Persons at risk	<52	7	<37	<35	7	<27
6	Risk (95% CI)	773 (0 - 1757)	0 (0 - 0)	1091 (0 - 2432)	1171 (23 - 2186)	0 (0 - 0)	1512 (29 - 2775)
9	Events, n	<5	0	<5	6	0	6
9	Persons at risk	<32	6	<23	25	7	18
9	Risk (95% CI)	1258 (0 - 2512)	0 (0 - 0)	1776 (0 - 3442)	1825 (385 - 3049)	0 (0 - 0)	2361 (506 - 3854)
12	Events, n	<5	0	<5	7	0	7
12	Persons at risk	<23	6	<16	23	7	16
12	Risk (95% CI)	1805 (0 - 3290)	0 (0 - 0)	2599 (0 - 4552)	2152 (595 - 3450)	0 (0 - 0)	2785 (786 - 4351)

1230

Table 15.24.5.a.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	9	28	<157	<32	31
3	Events, n	0	0	0	<5	<5	0
3	Persons at risk	30	7	23	<157	<32	30
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)
6	Events, n	0	0	0	<5	<5	0
6	Persons at risk	25	7	18	<157	<32	28
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	23	6	17	<157	<32	27
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	20	6	14	<157	<32	26
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	256 (0 - 740)	1250 (0 - 3266)	0 (0 - 0)

1231

Table 15.24.5.a.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	37	9	28	39	8	31
3	Events, n	0	0	0	0	0	0
3	Persons at risk	33	8	25	37	7	30
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	25	7	18	35	7	28
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	25	7	18	35	7	28
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	21	6	15	33	7	26
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

1232

Table 15.24.5.a.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<42	<28	<30	<153	<32	31
3	Events, n	<5	0	<5	<5	<5	0
3	Persons at risk	<42	7	<30	<153	<32	30
3	Risk (95% CI)	972 (0 - 1962)	0 (0 - 0)	1350 (0 - 2664)	263 (0 - 759)	1250 (0 - 3266)	0 (0 - 0)
6	Events, n	<5	<5	<5	<5	<5	0
6	Persons at risk	<29	<28	<30	<153	<32	28
6	Risk (95% CI)	1424 (0 - 2645)	1429 (0 - 3666)	1350 (0 - 2664)	263 (0 - 759)	1250 (0 - 3266)	0 (0 - 0)
9	Events, n	5	<5	<5	<5	<5	0
9	Persons at risk	17	<28	<20	<153	<32	27
9	Risk (95% CI)	1875 (208 - 3258)	1429 (0 - 3666)	2015 (0 - 3640)	263 (0 - 759)	1250 (0 - 3266)	0 (0 - 0)
12	Events, n	6	<5	5	<5	<5	0
12	Persons at risk	13	<28	8	<153	<32	26
12	Risk (95% CI)	2455 (443 - 4044)	1429 (0 - 3666)	2903 (185 - 4868)	263 (0 - 759)	1250 (0 - 3266)	0 (0 - 0)

1233

Table 15.24.5.a.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	36	9	27	<129	<20	<104
3	Events, n	0	0	0	<5	0	<5
3	Persons at risk	29	7	22	<129	5	<104
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	312 (0 - 897)	0 (0 - 0)	385 (0 - 1096)
6	Events, n	0	0	0	<5	<5	<5
6	Persons at risk	24	7	17	<40	<5	<50
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	1018 (0 - 2049)	2000 (0 - 4839)	803 (0 - 1812)
9	Events, n	0	0	0	<5	<5	<5
9	Persons at risk	22	6	16	<30	<5	<33
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	1377 (23 - 2547)	2000 (0 - 4839)	1241 (0 - 2464)
12	Events, n	0	0	0	<5	<5	<5
12	Persons at risk	19	6	13	<30	<5	<33
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	1377 (23 - 2547)	2000 (0 - 4839)	1241 (0 - 2464)

Table 15.24.5.b.1 Sensitivity analysis: Risk (1-KM and 95% CI) for Number of hospitalisations at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	112	21	91	114	26	88
3	Events, n	65	14	51	80	16	64
3	Persons at risk	46	6	40	32	10	22
3	Risk (95% CI)	5804 (4782 - 6625)	6667 (3897 - 8179)	5604 (4457 - 6515)	7018 (6048 - 7749)	6154 (3746 - 7635)	7273 (6164 - 8061)
6	Events, n	65	14	51	80	16	64
6	Persons at risk	38	6	32	31	10	21
6	Risk (95% CI)	5804 (4782 - 6625)	6667 (3897 - 8179)	5604 (4457 - 6515)	7018 (6048 - 7749)	6154 (3746 - 7635)	7273 (6164 - 8061)
9	Events, n	65	14	51	80	16	64
9	Persons at risk	18	<5	14	29	10	19
9	Risk (95% CI)	5804 (4782 - 6625)	6667 (3897 - 8179)	5604 (4457 - 6515)	7018 (6048 - 7749)	6154 (3746 - 7635)	7273 (6164 - 8061)
12	Events, n	65	14	51	80	16	64
12	Persons at risk	15	<5	11	28	9	19
12	Risk (95% CI)	5804 (4782 - 6625)	6667 (3897 - 8179)	5604 (4457 - 6515)	7018 (6048 - 7749)	6154 (3746 - 7635)	7273 (6164 - 8061)

1235

Table 15.24.5.b.2 Sensitivity analysis: Risk (1-KM and 95% CI) for Death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	112	21	91	114	26	88
3	Events, n	0	0	0	0	0	0
3	Persons at risk	105	18	87	110	25	85
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	88	17	71	106	25	81
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	63	15	48	100	24	76
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	51	14	37	88	20	68
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

1236

Table 15.24.5.b.3 Sensitivity analysis: Risk (1-KM and 95% CI) for Recovery at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	112	<28	91	<389	<88	88
3	Events, n	7	<5	<5	0	0	0
3	Persons at risk	105	<28	<91	110	25	85
3	Risk (95% CI)	625 (166 - 1063)	1429 (0 - 2802)	440 (9 - 852)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	23	<5	19	0	0	0
6	Persons at risk	88	<21	71	106	25	81
6	Risk (95% CI)	2061 (1274 - 2777)	1905 (38 - 3421)	2099 (1214 - 2895)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	49	6	43	0	0	0
9	Persons at risk	63	15	48	100	24	76
9	Risk (95% CI)	4433 (3424 - 5287)	2857 (638 - 4550)	4807 (3659 - 5747)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	56	7	49	<5	<5	0
12	Persons at risk	51	14	37	<389	<88	68
12	Risk (95% CI)	5083 (4052 - 5935)	3333 (979 - 5073)	5501 (4335 - 6427)	103 (0 - 302)	455 (0 - 1286)	0 (0 - 0)

Table 15.24.5.b.4 Sensitivity analysis: Risk (1-KM and 95% CI) for Sudden cardiac death at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	112	21	91	114	26	88
3	Events, n	0	0	0	0	0	0
3	Persons at risk	105	18	87	110	25	85
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	88	17	71	106	25	81
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	63	15	48	100	24	76
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	51	14	37	88	20	68
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.5.b.5 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Failure at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	112	<85	91	114	26	88
3	Events, n	8	<5	7	18	5	13
3	Persons at risk	99	<85	82	93	20	73
3	Risk (95% CI)	715 (225 - 1181)	476 (0 - 1345)	771 (206 - 1303)	1583 (884 - 2228)	1923 (257 - 3304)	1482 (705 - 2194)
6	Events, n	9	<5	8	19	5	14
6	Persons at risk	82	<85	66	89	20	69
6	Risk (95% CI)	821 (291 - 1321)	476 (0 - 1345)	899 (283 - 1475)	1673 (957 - 2332)	1923 (257 - 3304)	1599 (795 - 2332)
9	Events, n	10	<5	9	20	5	15
9	Persons at risk	56	<85	42	82	19	63
9	Risk (95% CI)	935 (363 - 1474)	476 (0 - 1345)	1041 (369 - 1666)	1772 (1036 - 2448)	1923 (257 - 3304)	1730 (892 - 2490)
12	Events, n	10	<5	9	21	5	16
12	Persons at risk	48	<85	35	73	16	57
12	Risk (95% CI)	935 (363 - 1474)	476 (0 - 1345)	1041 (369 - 1666)	1876 (1118 - 2571)	1923 (257 - 3304)	1863 (993 - 2649)

1239

Table 15.24.5.b.6 Sensitivity analysis: Risk (1-KM and 95% CI) for Cardiogenic Shock at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<150	<60	<122	<455	<104	88
3	Events, n	<5	0	<5	<5	<5	0
3	Persons at risk	<150	18	<122	<455	<104	85
3	Risk (95% CI)	268 (0 - 562)	0 (0 - 0)	330 (0 - 690)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)
6	Events, n	<5	0	<5	<5	<5	0
6	Persons at risk	<150	17	<122	<455	<104	81
6	Risk (95% CI)	268 (0 - 562)	0 (0 - 0)	330 (0 - 690)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)
9	Events, n	<5	0	<5	<5	<5	0
9	Persons at risk	<150	15	<122	<455	<104	76
9	Risk (95% CI)	268 (0 - 562)	0 (0 - 0)	330 (0 - 690)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)
12	Events, n	<5	<5	<5	<5	<5	0
12	Persons at risk	<93	<60	<122	<455	<104	68
12	Risk (95% CI)	433 (0 - 858)	667 (0 - 1847)	330 (0 - 690)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)

1240

Table 15.24.5.b.7 Sensitivity analysis: Risk (1-KM and 95% CI) for Fulminant myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<224	<60	<182	<455	<104	88
3	Events, n	<5	0	<5	<5	<5	0
3	Persons at risk	<224	18	<182	<455	<104	85
3	Risk (95% CI)	179 (0 - 421)	0 (0 - 0)	220 (0 - 516)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)
6	Events, n	<5	0	<5	<5	<5	0
6	Persons at risk	<224	17	<182	<455	<104	81
6	Risk (95% CI)	179 (0 - 421)	0 (0 - 0)	220 (0 - 516)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)
9	Events, n	<5	0	<5	<5	<5	0
9	Persons at risk	<224	15	<182	<455	<104	76
9	Risk (95% CI)	179 (0 - 421)	0 (0 - 0)	220 (0 - 516)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)
12	Events, n	<5	<5	<5	<5	<5	0
12	Persons at risk	<117	<60	<182	<455	<104	68
12	Risk (95% CI)	342 (0 - 733)	667 (0 - 1847)	220 (0 - 516)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)

1241

Table 15.24.5.b.8 Sensitivity analysis: Risk (1-KM and 95% CI) for Chronic myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<422	<60	<348	114	26	88
3	Events, n	<5	0	<5	0	0	0
3	Persons at risk	<422	17	<348	110	25	85
3	Risk (95% CI)	95 (0 - 279)	0 (0 - 0)	115 (0 - 336)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	<5	0	<5	0	0	0
6	Persons at risk	<422	15	<348	103	25	78
6	Risk (95% CI)	95 (0 - 279)	0 (0 - 0)	115 (0 - 336)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	<5	<5	<5	0	0	0
9	Persons at risk	<156	<60	<348	95	21	74
9	Risk (95% CI)	258 (0 - 616)	667 (0 - 1847)	115 (0 - 336)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	<5	<5	<5	0	0	0
12	Persons at risk	<88	<60	<103	86	18	68
12	Risk (95% CI)	456 (0 - 968)	667 (0 - 1847)	390 (0 - 946)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

1242

Table 15.24.5.b.9 Sensitivity analysis: Risk (1-KM and 95% CI) for Heart Transplantation at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	112	21	91	114	26	88
3	Events, n	0	0	0	0	0	0
3	Persons at risk	105	18	87	110	25	85
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
6	Events, n	0	0	0	0	0	0
6	Persons at risk	88	17	71	106	25	81
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
9	Events, n	0	0	0	0	0	0
9	Persons at risk	63	15	48	100	24	76
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
12	Events, n	0	0	0	0	0	0
12	Persons at risk	51	14	37	88	20	68
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table 15.24.5.b.10 Sensitivity analysis: Risk (1-KM and 95% CI) for Arrhythmia at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<207	21	<169	103	25	78
3	Events, n	<5	0	<5	5	0	5
3	Persons at risk	<207	17	<169	94	24	70
3	Risk (95% CI)	194 (0 - 457)	0 (0 - 0)	238 (0 - 559)	492 (62 - 904)	0 (0 - 0)	652 (82 - 1188)
6	Events, n	<5	0	<5	7	0	7
6	Persons at risk	<129	15	<104	85	24	61
6	Risk (95% CI)	312 (0 - 656)	0 (0 - 0)	386 (0 - 808)	702 (186 - 1190)	0 (0 - 0)	931 (249 - 1566)
9	Events, n	<5	0	<5	9	0	9
9	Persons at risk	<80	14	<62	76	20	56
9	Risk (95% CI)	506 (0 - 1002)	0 (0 - 0)	653 (0 - 1295)	934 (331 - 1500)	0 (0 - 0)	1241 (444 - 1973)
12	Events, n	5	0	5	11	0	11
12	Persons at risk	44	14	30	66	17	49
12	Risk (95% CI)	717 (50 - 1339)	0 (0 - 0)	955 (45 - 1782)	1183 (496 - 1821)	0 (0 - 0)	1570 (664 - 2388)

1244

Table 15.24.5.b.11 Sensitivity analysis: Risk (1-KM and 95% CI) for chronic pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	109	21	88	<455	<104	88
3	Events, n	0	0	0	<5	<5	0
3	Persons at risk	97	17	80	<455	<104	85
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)
6	Events, n	0	0	0	<5	<5	0
6	Persons at risk	66	15	51	<455	<104	78
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)
9	Events, n	0	0	0	<5	<5	0
9	Persons at risk	54	14	40	<455	<104	74
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)
12	Events, n	0	0	0	<5	<5	0
12	Persons at risk	50	14	36	<455	<104	68
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	88 (0 - 257)	385 (0 - 1096)	0 (0 - 0)

Table 15.24.5.b.12 Sensitivity analysis: Risk (1-KM and 95% CI) for Constrictive Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<224	21	<182	<455	26	<351
3	Events, n	<5	0	<5	<5	0	<5
3	Persons at risk	<224	18	<182	<455	25	<351
3	Risk (95% CI)	179 (0 - 421)	0 (0 - 0)	220 (0 - 516)	88 (0 - 257)	0 (0 - 0)	114 (0 - 333)
6	Events, n	<5	0	<5	<5	0	<5
6	Persons at risk	<224	17	<182	<455	25	<351
6	Risk (95% CI)	179 (0 - 421)	0 (0 - 0)	220 (0 - 516)	88 (0 - 257)	0 (0 - 0)	114 (0 - 333)
9	Events, n	<5	0	<5	<5	0	<5
9	Persons at risk	<224	15	<182	<455	24	<351
9	Risk (95% CI)	179 (0 - 421)	0 (0 - 0)	220 (0 - 516)	88 (0 - 257)	0 (0 - 0)	114 (0 - 333)
12	Events, n	<5	0	<5	<5	0	<5
12	Persons at risk	<224	14	<182	<455	20	<351
12	Risk (95% CI)	179 (0 - 421)	0 (0 - 0)	220 (0 - 516)	88 (0 - 257)	0 (0 - 0)	114 (0 - 333)

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Table 15.24.5.b.13 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Myocarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	<133	<69	<107	<435	<100	86
3	Events, n	<5	0	<5	<5	<5	0
3	Persons at risk	<133	17	<107	<435	<100	83
3	Risk (95% CI)	301 (0 - 631)	0 (0 - 0)	374 (0 - 780)	92 (0 - 269)	400 (0 - 1138)	0 (0 - 0)
6	Events, n	<5	<5	<5	<5	<5	0
6	Persons at risk	<95	<69	<107	<435	<100	76
6	Risk (95% CI)	424 (6 - 824)	588 (0 - 1643)	374 (0 - 780)	92 (0 - 269)	400 (0 - 1138)	0 (0 - 0)
9	Events, n	5	<5	<5	<5	<5	0
9	Persons at risk	47	<69	<68	<435	<100	72
9	Risk (95% CI)	592 (60 - 1095)	588 (0 - 1643)	597 (0 - 1173)	92 (0 - 269)	400 (0 - 1138)	0 (0 - 0)
12	Events, n	6	<5	5	<5	<5	0
12	Persons at risk	40	<69	27	<435	<100	66
12	Risk (95% CI)	821 (124 - 1470)	588 (0 - 1643)	933 (28 - 1757)	92 (0 - 269)	400 (0 - 1138)	0 (0 - 0)

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Table 15.24.5.b.14 Sensitivity analysis: Risk (1-KM and 95% CI) for Recurrent Pericarditis at different timepoints during follow-up by study cohort and Pfizer-BioNTech COVID-19 vaccination status at baseline for definitive, probable or possible cases of myocarditis or pericarditis only, for SIDIAP

Months	measure	Myocarditis Overall	Myocarditis Unvaccinated	Myocarditis Vaccinated	Pericarditis Overall	Pericarditis Unvaccinated	Pericarditis Vaccinated
	N	110	21	89	<127	<88	<145
3	Events, n	0	0	0	<5	<5	<5
3	Persons at risk	98	17	81	<127	<88	<145
3	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	317 (0 - 664)	455 (0 - 1286)	276 (0 - 646)
6	Events, n	0	0	0	6	<5	<5
6	Persons at risk	67	15	52	80	<45	<70
6	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	655 (134 - 1149)	909 (0 - 2034)	573 (11 - 1104)
9	Events, n	0	0	0	7	<5	5
9	Persons at risk	55	14	41	73	<45	57
9	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	775 (205 - 1311)	909 (0 - 2034)	736 (92 - 1338)
12	Events, n	0	0	0	8	<5	6
12	Persons at risk	49	14	35	65	<45	51
12	Risk (95% CI)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	915 (286 - 1503)	909 (0 - 2034)	914 (184 - 1589)

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Table 15.25.1 Attrition table for the secondary objective by database for the myocarditis cohort in Pedianet

Label	N	%
Received Pfizer-BioNTech COVID-19 Vaccine Dose 1 as first vaccine shot	11,278	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose1	10,547	93.52
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose1	10,547	93.52
Excluding subjects with history of myocarditis or pericarditis before time zeroDose1	10,546	93.51
Total first dose vaccinee cohort (Matching variables without missing)	10,546	93.51
Total first dose matched vaccinee cohort	10,500	93.1
Received Pfizer-BioNTech COVID-19 Vaccine Dose 2 as the second dose, following a first Pfizer dose	9,529	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose2	8,992	94.36
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose2	8,992	94.36
Excluding subjects with history of myocarditis or pericarditis before time zeroDose2	8,991	94.35
Total second dose vaccinee cohort (Matching variables without missing)	8,991	94.35
Total second dose matched vaccinee cohort	8,944	93.86
Received Pfizer-BioNTech COVID-19 Vaccine Dose 3 as the third dose, following a first and second Pfizer dose	1,118	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose3	1,088	97.32
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose3	1,088	97.32
Excluding subjects with history of myocarditis or pericarditis before time zeroDose3	1,088	97.32
Total third dose vaccinee cohort (Matching variables without missing)	1,088	97.32
Total third dose matched vaccinee cohort	1,055	94.36

Table 15.25.2 Attrition table for the secondary objective by database for the myocarditis cohort in PHARMO

Label	N	%
Received Pfizer-BioNTech COVID-19 Vaccine Dose 1 as first vaccine shot	1,367,112	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose1	1,363,879	99.76
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose1	1,363,879	99.76
Excluding subjects with history of myocarditis or pericarditis before time zeroDose1	1,361,588	99.6
Total first dose vaccinee cohort (Matching variables without missing)	1,361,588	99.6
Total first dose matched vaccinee cohort	1,361,488	99.59
Received Pfizer-BioNTech COVID-19 Vaccine Dose 2 as the second dose, following a first Pfizer dose	1,041,486	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose2	1,039,936	99.85
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose2	1,039,936	99.85
Excluding subjects with history of myocarditis or pericarditis before time zeroDose2	1,038,196	99.68
Total second dose vaccinee cohort (Matching variables without missing)	1,038,196	99.68
Total second dose matched vaccinee cohort	1,038,107	99.68
Received Pfizer-BioNTech COVID-19 Vaccine Dose 3 as the third dose, following a first and second Pfizer dose	274,882	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose3	274,544	99.88
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose3	274,544	99.88
Excluding subjects with history of myocarditis or pericarditis before time zeroDose3	274,078	99.71
Total third dose vaccinee cohort (Matching variables without missing)	274,078	99.71
Total third dose matched vaccinee cohort	273,981	99.67

Table 15.25.3 Attrition table for the secondary objective by database for the myocarditis cohort in NHR

Label	N	%
Received Pfizer-BioNTech COVID-19 Vaccine Dose 1 as first vaccine shot	3,612,375	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose1	3,587,933	99.32
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose1	3,587,933	99.32
Excluding subjects with history of myocarditis or pericarditis before time zeroDose1	3,579,098	99.08
Total first dose vaccinee cohort (Matching variables without missing)	3,578,891	99.07
Total first dose matched vaccinee cohort	3,566,893	98.74
Received Pfizer-BioNTech COVID-19 Vaccine Dose 2 as the second dose, following a first Pfizer dose	2,765,584	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose2	2,753,276	99.55
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose2	2,753,276	99.55
Excluding subjects with history of myocarditis or pericarditis before time zeroDose2	2,745,507	99.27
Total second dose vaccinee cohort (Matching variables without missing)	2,745,383	99.27
Total second dose matched vaccinee cohort	2,703,959	97.77
Received Pfizer-BioNTech COVID-19 Vaccine Dose 3 as the third dose, following a first and second Pfizer dose	1,787,566	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose3	1,785,719	99.9
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose3	1,785,719	99.9
Excluding subjects with history of myocarditis or pericarditis before time zeroDose3	1,779,828	99.57
Total third dose vaccinee cohort (Matching variables without missing)	1,779,787	99.56
Total third dose matched vaccinee cohort	1,657,666	92.73

Table 15.25.4 Attrition table for the secondary objective by database for the myocarditis cohort in EpiChron

Label	N	%
Received Pfizer-BioNTech COVID-19 Vaccine Dose 1 as first vaccine shot	802,310	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose1	786,987	98.09
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose1	786,987	98.09
Excluding subjects with history of myocarditis or pericarditis before time zeroDose1	786,169	97.99
Total first dose vaccinee cohort (Matching variables without missing)	786,147	97.99
Total first dose matched vaccinee cohort	674,158	84.03
Received Pfizer-BioNTech COVID-19 Vaccine Dose 2 as the second dose, following a first Pfizer dose	732,312	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose2	721,043	98.46
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose2	721,043	98.46
Excluding subjects with history of myocarditis or pericarditis before time zeroDose2	720,291	98.36
Total second dose vaccinee cohort (Matching variables without missing)	720,272	98.36
Total second dose matched vaccinee cohort	535,683	73.15
Received Pfizer-BioNTech COVID-19 Vaccine Dose 3 as the third dose, following a first and second Pfizer dose	239,926	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose3	238,997	99.61
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose3	238,997	99.61
Excluding subjects with history of myocarditis or pericarditis before time zeroDose3	238,720	99.5
Total third dose vaccinee cohort (Matching variables without missing)	238,713	99.49
Total third dose matched vaccinee cohort	101,339	42.24

Table 15.25.5 Attrition table for the secondary objective by database for the myocarditis cohort in SIDIAP

Label	N	%
Received Pfizer-BioNTech COVID-19 Vaccine Dose 1 as first vaccine shot	3,305,180	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose1	3,233,191	97.82
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose1	3,233,191	97.82
Excluding subjects with history of myocarditis or pericarditis before time zeroDose1	3,226,899	97.63
Total first dose vaccinee cohort (Matching variables without missing)	3,083,837	93.3
Total first dose matched vaccinee cohort	3,081,405	93.23
Received Pfizer-BioNTech COVID-19 Vaccine Dose 2 as the second dose, following a first Pfizer dose	2,998,561	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose2	2,948,814	98.34
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose2	2,948,814	98.34
Excluding subjects with history of myocarditis or pericarditis before time zeroDose2	2,942,941	98.15
Total second dose vaccinee cohort (Matching variables without missing)	2,810,285	93.72
Total second dose matched vaccinee cohort	2,805,381	93.56
Received Pfizer-BioNTech COVID-19 Vaccine Dose 3 as the third dose, following a first and second Pfizer dose	541,223	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose3	538,480	99.49
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose3	538,480	99.49
Excluding subjects with history of myocarditis or pericarditis before time zeroDose3	536,758	99.18
Total third dose vaccinee cohort (Matching variables without missing)	492,701	91.03
Total third dose matched vaccinee cohort	484,132	89.45

Table 15.25.6 Attrition table for the secondary objective by database for the myocarditis cohort in CPRD

Label	N	%
Received Pfizer-BioNTech COVID-19 Vaccine Dose 1 as first vaccine shot	4,818,449	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose1	4,107,568	85.25
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose1	4,107,568	85.25
Excluding subjects with history of myocarditis or pericarditis before time zeroDose1	4,102,272	85.14
Total first dose vaccinee cohort (Matching variables without missing)	3,419,004	70.96
Total first dose matched vaccinee cohort	3,411,502	70.8
Received Pfizer-BioNTech COVID-19 Vaccine Dose 2 as the second dose, following a first Pfizer dose	4,231,944	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose2	3,726,265	88.05
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose2	3,726,265	88.05
Excluding subjects with history of myocarditis or pericarditis before time zeroDose2	3,721,186	87.93
Total second dose vaccinee cohort (Matching variables without missing)	3,113,293	73.57
Total second dose matched vaccinee cohort	3,080,680	72.8
Received Pfizer-BioNTech COVID-19 Vaccine Dose 3 as the third dose, following a first and second Pfizer dose	2,027,709	100
Excluding subjects with <12 months continuous enrolment ^a at time zeroDose3	1,905,083	93.95
Excluding subjects with non-Pfizer-BioNTech COVID-19 vaccine before time zeroDose3	1,905,083	93.95
Excluding subjects with history of myocarditis or pericarditis before time zeroDose3	1,901,756	93.79
Total third dose vaccinee cohort (Matching variables without missing)	1,596,454	78.73
Total third dose matched vaccinee cohort	1,542,954	76.09

Table 15.26.1.1.1.1 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (7-days risk window) in Pedianet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	10,500	10,500	8,944	8,944	1,055	1,055
Person-months of follow-up						
Total	2,376	2,376	2,042	2,042	240	240
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	6 (0.1)	8 (0.1)	12 (0.1)	10 (0.1)	9 (0.9)	5 (0.5)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	22 (0.2)	22 (0.2)	19 (0.2)	19 (0.2)	<5	<5
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	502 (4.8)	503 (4.8)	234 (2.6)	234 (2.6)	27 (2.6)	27 (2.6)
End of risk window	9,970 (95)	9,967 (94.9)	8,679 (97)	8,681 (97.1)	1,018 (96.5)	1,022 (96.9)
Myocarditis (outcome)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diagnosis of pericarditis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

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Table 15.26.1.1.2 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (7-days risk window) in PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	1,262,551	1,268,216	954,517	958,957	254,469	255,074
Person-months of follow-up						
Total	282,087	283,311	218,765	219,686	58,692	58,759
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	<5	<5	<5	<5	<5
Exit from data source or migration	36 (<0.1)	267 (<0.1)	62 (<0.1)	455 (<0.1)	61 (<0.1)	594 (0.2)
Death	32 (<0.1)	152 (<0.1)	25 (<0.1)	143 (<0.1)	8 (<0.1)	21 (<0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	22,284 (1.8)	22,332 (1.8)	5,486 (0.6)	5,584 (0.6)	867 (0.3)	873 (0.3)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	73,393 (5.8)	73,808 (5.8)	16,070 (1.7)	16,390 (1.7)	1,004 (0.4)	1,005 (0.4)
End of risk window	1,166,798 (92.4)	1,171,652 (92.4)	932,859 (97.7)	936,381 (97.6)	252,525 (99.2)	252,579 (99)
Myocarditis (outcome)	8 (<0.1)	<5	11 (<0.1)	<5	<5	0 (0)
Diagnosis of pericarditis	0 (0)	0 (0)	<5	0 (0)	0 (0)	0 (0)

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Table 15.26.1.1.3 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (7-days risk window) in NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,347,625	3,358,768	2,485,686	2,496,717	1,460,378	1,468,667
Person-months of follow-up						
Total	725,392	727,716	554,632	556,865	336,231	338,051
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	49 (<0.1)	329 (<0.1)	106 (<0.1)	463 (<0.1)	42 (<0.1)	237 (<0.1)
Death	62 (<0.1)	426 (<0.1)	72 (<0.1)	1,313 (0.1)	79 (<0.1)	736 (0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	45,815 (1.4)	45,915 (1.4)	30,862 (1.2)	30,934 (1.2)	1,825 (0.1)	1,840 (0.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	439,099 (13.1)	440,763 (13.1)	168,898 (6.8)	170,262 (6.8)	15,076 (1)	15,143 (1)
End of risk window	2,862,582 (85.5)	2,871,314 (85.5)	2,285,719 (92)	2,293,729 (91.9)	1,443,345 (98.8)	1,450,684 (98.8)
Myocarditis (outcome)	6 (<0.1)	9 (<0.1)	6 (<0.1)	<5	<5	6 (<0.1)
Diagnosis of pericarditis	12 (<0.1)	12 (<0.1)	23 (<0.1)	12 (<0.1)	8 (<0.1)	21 (<0.1)

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Table 15.26.1.1.4 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (7-days risk window) in EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	611,210	614,989	489,239	491,151	92,041	92,273
Person-months of follow-up						
Total	129,756	130,440	110,408	110,802	21,264	21,315
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	5 (<0.1)	5 (<0.1)	<5	<5	<5	<5
Death	13 (<0.1)	88 (<0.1)	9 (<0.1)	173 (<0.1)	<5	29 (<0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	15,539 (2.5)	15,562 (2.5)	5,069 (1)	5,083 (1)	42 (<0.1)	42 (<0.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	82,812 (13.5)	84,136 (13.7)	18,256 (3.7)	18,455 (3.8)	262 (0.3)	263 (0.3)
End of risk window	512,836 (83.9)	515,194 (83.8)	465,896 (95.2)	467,437 (95.2)	91,732 (99.7)	91,936 (99.6)
Myocarditis (outcome)	<5	<5	<5	<5	0 (0)	0 (0)
Diagnosis of pericarditis	<5	<5	6 (<0.1)	<5	0 (0)	0 (0)

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Table 15.26.1.1.5 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (7-days risk window) in SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,081,405	3,081,405	2,805,381	2,805,381	484,132	484,132
Person-months of follow-up						
Total	653,968	653,968	626,305	626,305	111,780	111,780
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	18 (<0.1)	18 (<0.1)	33 (<0.1)	33 (<0.1)	67 (<0.1)	67 (<0.1)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	74,163 (2.4)	74,163 (2.4)	50,885 (1.8)	50,885 (1.8)	862 (0.2)	862 (0.2)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	453,520 (14.7)	453,524 (14.7)	161,283 (5.7)	161,283 (5.7)	1,389 (0.3)	1,389 (0.3)
End of risk window	2,553,687 (82.9)	2,553,684 (82.9)	2,593,162 (92.4)	2,593,165 (92.4)	481,812 (99.5)	481,813 (99.5)
Myocarditis (outcome)	0 (0)	<5	6 (<0.1)	5 (<0.1)	0 (0)	0 (0)
Diagnosis of pericarditis	17 (<0.1)	14 (<0.1)	12 (<0.1)	10 (<0.1)	<5	<5

Table 15.26.1.1.1.6 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (7-days risk window) in CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,231,856	3,240,799	2,912,712	2,918,333	1,393,951	1,398,427
Person-months of follow-up						
Total	719,376	720,996	666,186	667,035	321,579	322,403
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	4,615 (0.1)	6,300 (0.2)	3,745 (0.1)	6,417 (0.2)	1,405 (0.1)	2,705 (0.2)
Death	28 (<0.1)	410 (0)	31 (<0.1)	428 (0)	29 (<0.1)	264 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	102,127 (3.2)	102,855 (3.2)	38,413 (1.3)	38,512 (1.3)	1,112 (0.1)	1,113 (0.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	163,546 (5.1)	164,305 (5.1)	33,006 (1.1)	33,211 (1.1)	7,304 (0.5)	7,316 (0.5)
End of risk window	2,961,524 (91.6)	2,966,921 (91.5)	2,837,493 (97.4)	2,839,744 (97.3)	1,384,098 (99.3)	1,387,024 (99.2)
Myocarditis (outcome)	7 (<0.1)	<5	13 (<0.1)	<5	<5	<5
Diagnosis of pericarditis	9 (<0.1)	<5	11 (<0.1)	20 (<0.1)	<5	<5

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Table 15.26.2.1.1 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (14-days risk window) in Peditanet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	10,500	10,500	8,944	8,944	1,055	1,055
Person-months of follow-up						
Total	4,583	4,583	4,014	4,016	473	475
Median (Q1,Q3)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	17 (0.2)	13 (0.1)	27 (0.3)	12 (0.1)	17 (1.6)	8 (0.8)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	55 (0.5)	54 (0.5)	38 (0.4)	38 (0.4)	<5	<5
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	1,158 (11)	1,159 (11)	456 (5.1)	456 (5.1)	36 (3.4)	36 (3.4)
End of risk window	9,269 (88.3)	9,274 (88.3)	8,423 (94.2)	8,438 (94.3)	999 (94.7)	1,008 (95.5)
Myocarditis (outcome)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diagnosis of pericarditis	<5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.26.2.1.2 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (14-days risk window) in PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	1,262,551	1,268,216	954,517	958,957	254,469	255,074
Person-months of follow-up						
Total	540,713	542,939	430,946	432,563	116,825	116,817
Median (Q1,Q3)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	<5	<5	6 (<0.1)	6 (<0.1)	7 (<0.1)	6 (<0.1)
Exit from data source or migration	104 (<0.1)	595 (<0.1)	118 (<0.1)	894 (0.1)	115 (<0.1)	1,234 (0.5)
Death	73 (<0.1)	265 (<0.1)	54 (<0.1)	289 (<0.1)	22 (<0.1)	43 (<0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	42,553 (3.4)	42,657 (3.4)	11,945 (1.3)	12,135 (1.3)	1,948 (0.8)	1,958 (0.8)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	132,586 (10.5)	133,527 (10.5)	35,926 (3.8)	36,532 (3.8)	2,043 (0.8)	2,046 (0.8)
End of risk window	1,087,220 (86.1)	1,091,161 (86)	906,455 (95)	909,100 (94.8)	250,332 (98.4)	249,787 (97.9)
Myocarditis (outcome)	10 (<0.1)	7 (<0.1)	12 (<0.1)	<5	<5	0 (0)
Diagnosis of pericarditis	<5	0 (0)	<5	0 (0)	0 (0)	0 (0)

1262

Table 15.26.2.1.3 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (14-days risk window) in NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,347,625	3,358,768	2,485,686	2,496,717	1,460,378	1,468,667
Person-months of follow-up						
Total	1,313,811	1,317,809	1,054,873	1,058,593	667,261	670,670
Median (Q1,Q3)	1 (0.4, 0.5)	1 (0.4, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	118 (<0.1)	709 (<0.1)	277 (<0.1)	979 (<0.1)	130 (<0.1)	542 (<0.1)
Death	179 (<0.1)	823 (<0.1)	195 (<0.1)	2,463 (0.1)	196 (<0.1)	1,434 (0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	97,892 (2.9)	98,086 (2.9)	66,569 (2.7)	66,715 (2.7)	4,090 (0.3)	4,126 (0.3)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	923,222 (27.6)	926,830 (27.6)	339,454 (13.7)	342,353 (13.7)	34,638 (2.4)	34,850 (2.4)
End of risk window	2,326,181 (69.5)	2,332,275 (69.4)	2,079,139 (83.6)	2,084,168 (83.5)	1,421,304 (97.3)	1,427,667 (97.2)
Myocarditis (outcome)	9 (<0.1)	15 (<0.1)	10 (<0.1)	9 (<0.1)	7 (<0.1)	12 (<0.1)
Diagnosis of pericarditis	24 (<0.1)	30 (<0.1)	42 (<0.1)	30 (<0.1)	13 (<0.1)	36 (<0.1)

1263

Table 15.26.2.1.4 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (14-days risk window) in EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	611,210	614,989	489,239	491,151	92,041	92,273
Person-months of follow-up						
Total	228,176	229,191	213,157	213,847	42,407	42,504
Median (Q1,Q3)	1 (0.3, 0.5)	1 (0.3, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	6 (<0.1)	6 (<0.1)	<5	<5	<5	<5
Death	32 (<0.1)	176 (<0.1)	33 (<0.1)	310 (0.1)	5 (<0.1)	46 (<0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	29,500 (4.8)	29,550 (4.8)	10,708 (2.2)	10,741 (2.2)	89 (0.1)	89 (0.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	182,652 (29.9)	185,080 (30.1)	42,538 (8.7)	43,011 (8.8)	714 (0.8)	718 (0.8)
End of risk window	399,012 (65.3)	400,171 (65.1)	435,948 (89.1)	437,084 (89)	91,230 (99.1)	91,417 (99.1)
Myocarditis (outcome)	<5	<5	<5	<5	0 (0)	0 (0)
Diagnosis of pericarditis	7 (<0.1)	5 (<0.1)	7 (<0.1)	<5	0 (0)	0 (0)

1264

Table 15.26.2.1.5 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (14-days risk window) in SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,081,405	3,081,405	2,805,381	2,805,381	484,132	484,132
Person-months of follow-up						
Total	1,176,091	1,176,090	1,193,746	1,193,746	222,710	222,710
Median (Q1,Q3)	1 (0.3, 0.5)	1 (0.3, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	47 (<0.1)	47 (<0.1)	79 (<0.1)	79 (<0.1)	174 (<0.1)	174 (<0.1)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	147,885 (4.8)	147,885 (4.8)	111,731 (4)	111,733 (4)	2,624 (0.5)	2,624 (0.5)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	820,234 (26.6)	820,239 (26.6)	321,443 (11.5)	321,445 (11.5)	3,475 (0.7)	3,475 (0.7)
End of risk window	2,113,205 (68.6)	2,113,210 (68.6)	2,372,096 (84.6)	2,372,095 (84.6)	477,856 (98.7)	477,857 (98.7)
Myocarditis (outcome)	<5	<5	11 (<0.1)	10 (<0.1)	0 (0)	0 (0)
Diagnosis of pericarditis	31 (<0.1)	21 (<0.1)	21 (<0.1)	19 (<0.1)	<5	<5

1265

Table 15.26.2.1.6 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (14-days risk window) in CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,231,856	3,240,799	2,912,712	2,918,333	1,393,951	1,398,427
Person-months of follow-up						
Total	1,364,282	1,366,610	1,310,961	1,312,030	640,126	641,494
Median (Q1,Q3)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	10,102 (0.3)	13,077 (0.4)	9,725 (0.3)	13,739 (0.5)	3,571 (0.3)	5,700 (0.4)
Death	70 (<0.1)	728 (0)	104 (<0.1)	891 (0)	86 (0)	507 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	213,294 (6.6)	215,354 (6.6)	75,128 (2.6)	75,436 (2.6)	2,561 (0.2)	2,564 (0.2)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	328,571 (10.2)	330,473 (10.2)	75,633 (2.6)	76,157 (2.6)	16,660 (1.2)	16,694 (1.2)
End of risk window	2,679,793 (82.9)	2,681,149 (82.7)	2,752,085 (94.5)	2,752,077 (94.3)	1,371,065 (98.4)	1,372,955 (98.2)
Myocarditis (outcome)	12 (<0.1)	9 (<0.1)	19 (<0.1)	<5	<5	<5
Diagnosis of pericarditis	14 (<0.1)	9 (<0.1)	18 (<0.1)	29 (<0.1)	5 (<0.1)	<5

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Table 15.26.3.1.1 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (21-days risk window) in Peditanet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	10,500	10,500	8,944	8,944	1,055	1,055
Person-months of follow-up						
Total	6,663	6,664	5,936	5,942	700	706
Median (Q1,Q3)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	27 (0.3)	23 (0.2)	45 (0.5)	22 (0.2)	32 (3)	17 (1.6)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	78 (0.7)	77 (0.7)	58 (0.6)	59 (0.7)	<5	<5
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	1,590 (15.1)	1,592 (15.2)	621 (6.9)	623 (7)	46 (4.4)	46 (4.4)
End of risk window	8,804 (83.8)	8,808 (83.9)	8,220 (91.9)	8,240 (92.1)	974 (92.3)	989 (93.7)
Myocarditis (outcome)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diagnosis of pericarditis	<5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.26.3.1.2 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (21-days risk window) in PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	1,262,551	1,268,216	954,517	958,957	254,469	255,074
Person-months of follow-up						
Total	785,499	788,531	638,153	640,301	174,529	174,350
Median (Q1,Q3)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	6 (<0.1)	6 (<0.1)	17 (<0.1)	16 (<0.1)	13 (<0.1)	12 (<0.1)
Exit from data source or migration	161 (<0.1)	837 (0.1)	183 (<0.1)	1,218 (0.1)	195 (0.1)	1,660 (0.7)
Death	131 (<0.1)	386 (<0.1)	77 (<0.1)	399 (<0.1)	33 (<0.1)	52 (<0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	56,875 (4.5)	57,047 (4.5)	16,757 (1.8)	17,010 (1.8)	2,700 (1.1)	2,720 (1.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	167,229 (13.2)	168,656 (13.3)	49,281 (5.2)	50,067 (5.2)	2,819 (1.1)	2,824 (1.1)
End of risk window	1,038,138 (82.2)	1,041,274 (82.1)	888,187 (93.1)	890,244 (92.8)	248,704 (97.7)	247,805 (97.2)
Myocarditis (outcome)	10 (<0.1)	10 (<0.1)	14 (<0.1)	<5	5 (<0.1)	<5
Diagnosis of pericarditis	<5	0 (0)	<5	<5	0 (0)	0 (0)

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Table 15.26.3.1.3 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (21-days risk window) in NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,347,625	3,358,768	2,485,686	2,496,717	1,460,378	1,468,667
Person-months of follow-up						
Total	1,798,328	1,803,470	1,514,961	1,519,529	993,557	998,315
Median (Q1,Q3)	1 (0.4, 0.7)	1 (0.4, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	208 (<0.1)	1,058 (<0.1)	465 (<0.1)	1,555 (0.1)	359 (<0.1)	1,023 (0.1)
Death	317 (<0.1)	1,166 (<0.1)	334 (<0.1)	3,395 (0.1)	323 (<0.1)	2,231 (0.2)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	137,827 (4.1)	138,107 (4.1)	95,933 (3.9)	96,123 (3.8)	5,993 (0.4)	6,046 (0.4)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	1,270,364 (37.9)	1,275,437 (38)	462,094 (18.6)	466,258 (18.7)	51,685 (3.5)	52,055 (3.5)
End of risk window	1,938,855 (57.9)	1,942,932 (57.8)	1,926,790 (77.5)	1,929,331 (77.3)	1,401,992 (96)	1,407,229 (95.8)
Myocarditis (outcome)	14 (<0.1)	28 (<0.1)	15 (<0.1)	10 (<0.1)	8 (<0.1)	15 (<0.1)
Diagnosis of pericarditis	40 (<0.1)	40 (<0.1)	55 (<0.1)	45 (<0.1)	18 (<0.1)	68 (<0.1)

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Table 15.26.3.1.4 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (21-days risk window) in EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	611,210	614,989	489,239	491,151	92,041	92,273
Person-months of follow-up						
Total	312,570	313,795	310,792	311,697	63,458	63,596
Median (Q1,Q3)	1 (0.3, 0.7)	1 (0.3, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	7 (<0.1)	7 (<0.1)	6 (<0.1)	12 (<0.1)	5 (<0.1)	5 (<0.1)
Death	55 (<0.1)	262 (<0.1)	49 (<0.1)	414 (0.1)	9 (<0.1)	69 (0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	36,846 (6)	36,921 (6)	14,750 (3)	14,794 (3)	126 (0.1)	128 (0.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	221,628 (36.3)	224,323 (36.5)	57,736 (11.8)	58,430 (11.9)	1,026 (1.1)	1,033 (1.1)
End of risk window	352,665 (57.7)	353,470 (57.5)	416,686 (85.2)	417,498 (85)	90,874 (98.7)	91,038 (98.7)
Myocarditis (outcome)	<5	<5	<5	<5	0 (0)	0 (0)
Diagnosis of pericarditis	7 (<0.1)	5 (<0.1)	9 (<0.1)	<5	<5	0 (0)

Table 15.26.3.1.5 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (21-days risk window) in SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,081,405	3,081,405	2,805,381	2,805,381	484,132	484,132
Person-months of follow-up						
Total	1,631,498	1,631,498	1,719,196	1,719,197	332,683	332,684
Median (Q1,Q3)	1 (0.3, 0.7)	1 (0.3, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	62 (<0.1)	62 (<0.1)	134 (<0.1)	134 (<0.1)	281 (0.1)	281 (0.1)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	201,026 (6.5)	201,026 (6.5)	156,749 (5.6)	156,752 (5.6)	5,033 (1)	5,033 (1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	995,232 (32.3)	995,237 (32.3)	433,441 (15.5)	433,446 (15.5)	5,086 (1.1)	5,086 (1.1)
End of risk window	1,885,046 (61.2)	1,885,044 (61.2)	2,215,010 (79)	2,215,013 (79)	473,725 (97.9)	473,730 (97.9)
Myocarditis (outcome)	<5	6 (<0.1)	14 (<0.1)	11 (<0.1)	0 (0)	0 (0)
Diagnosis of pericarditis	35 (<0.1)	30 (<0.1)	33 (<0.1)	25 (<0.1)	7 (<0.1)	<5

1271

Table 15.26.3.1.6 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated myocarditis cohort (21-days risk window) in CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,231,856	3,240,799	2,912,712	2,918,333	1,393,951	1,398,427
Person-months of follow-up						
Total	1,957,028	1,959,134	1,938,146	1,938,946	955,731	957,360
Median (Q1,Q3)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	14,623 (0.5)	19,159 (0.6)	15,457 (0.5)	20,434 (0.7)	5,629 (0.4)	8,806 (0.6)
Death	125 (<0.1)	1,032 (0)	171 (0)	1,346 (0)	166 (0)	769 (0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	297,466 (9.2)	300,594 (9.3)	102,817 (3.5)	103,520 (3.5)	4,012 (0.3)	4,022 (0.3)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	434,531 (13.4)	437,330 (13.5)	112,296 (3.9)	113,103 (3.9)	25,691 (1.8)	25,770 (1.8)
End of risk window	2,485,071 (76.9)	2,482,659 (76.6)	2,681,922 (92.1)	2,679,889 (91.8)	1,358,440 (97.5)	1,359,052 (97.2)
Myocarditis (outcome)	15 (<0.1)	13 (<0.1)	21 (<0.1)	7 (<0.1)	<5	<5
Diagnosis of pericarditis	25 (<0.1)	12 (<0.1)	28 (<0.1)	34 (<0.1)	10 (<0.1)	5 (<0.1)

1272

Table 15.26.1.2.1 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (7-days risk window) in Peditanet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	10,500	10,500	8,944	8,944	1,055	1,055
Person-months of follow-up						
Total	2,376	2,376	2,042	2,042	240	240
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	6 (0.1)	8 (0.1)	12 (0.1)	10 (0.1)	9 (0.9)	5 (0.5)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	22 (0.2)	22 (0.2)	19 (0.2)	19 (0.2)	<5	<5
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	502 (4.8)	503 (4.8)	234 (2.6)	234 (2.6)	27 (2.6)	27 (2.6)
End of risk window	9,970 (95)	9,967 (94.9)	8,679 (97)	8,681 (97.1)	1,018 (96.5)	1,022 (96.9)
Pericarditis (outcome)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diagnosis of myocarditis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.26.1.2.2 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (7-days risk window) in PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	1,262,551	1,268,216	954,517	958,957	254,469	255,074
Person-months of follow-up						
Total	282,087	283,311	218,765	219,686	58,692	58,759
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	<5	<5	<5	<5	<5
Exit from data source or migration	36 (<0.1)	267 (<0.1)	62 (<0.1)	455 (<0.1)	61 (<0.1)	594 (0.2)
Death	32 (<0.1)	152 (<0.1)	25 (<0.1)	143 (<0.1)	8 (<0.1)	21 (<0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	22,284 (1.8)	22,332 (1.8)	5,486 (0.6)	5,584 (0.6)	867 (0.3)	873 (0.3)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	73,393 (5.8)	73,808 (5.8)	16,070 (1.7)	16,390 (1.7)	1,004 (0.4)	1,005 (0.4)
End of risk window	1,166,798 (92.4)	1,171,652 (92.4)	932,859 (97.7)	936,381 (97.6)	252,525 (99.2)	252,579 (99)
Pericarditis (outcome)	0 (0)	<5	<5	0 (0)	0 (0)	0 (0)
Diagnosis of myocarditis	8 (<0.1)	<5	11 (<0.1)	<5	<5	0 (0)

1274

Table 15.26.1.2.3 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (7-days risk window) in NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,347,625	3,358,768	2,485,686	2,496,717	1,460,378	1,468,667
Person-months of follow-up						
Total	725,392	727,716	554,632	556,865	336,231	338,051
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	49 (<0.1)	329 (<0.1)	106 (<0.1)	463 (<0.1)	42 (<0.1)	237 (<0.1)
Death	62 (<0.1)	426 (<0.1)	72 (<0.1)	1,313 (0.1)	79 (<0.1)	736 (0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	45,815 (1.4)	45,915 (1.4)	30,862 (1.2)	30,934 (1.2)	1,825 (0.1)	1,840 (0.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	439,099 (13.1)	440,763 (13.1)	168,898 (6.8)	170,262 (6.8)	15,076 (1)	15,143 (1)
End of risk window	2,862,582 (85.5)	2,871,314 (85.5)	2,285,719 (92)	2,293,729 (91.9)	1,443,345 (98.8)	1,450,684 (98.8)
Pericarditis (outcome)	13 (<0.1)	12 (<0.1)	24 (<0.1)	15 (<0.1)	9 (<0.1)	21 (<0.1)
Diagnosis of myocarditis	5 (<0.1)	9 (<0.1)	5 (<0.1)	<5	<5	6 (<0.1)

Table 15.26.1.2.4 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (7-days risk window) in EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	611,210	614,989	489,239	491,151	92,041	92,273
Person-months of follow-up						
Total	129,756	130,440	110,408	110,802	21,264	21,315
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	5 (<0.1)	5 (<0.1)	<5	<5	<5	<5
Death	13 (<0.1)	88 (<0.1)	9 (<0.1)	173 (<0.1)	<5	29 (<0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	15,539 (2.5)	15,562 (2.5)	5,069 (1)	5,083 (1)	42 (<0.1)	42 (<0.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	82,812 (13.5)	84,136 (13.7)	18,256 (3.7)	18,455 (3.8)	262 (0.3)	263 (0.3)
End of risk window	512,836 (83.9)	515,194 (83.8)	465,896 (95.2)	467,437 (95.2)	91,732 (99.7)	91,936 (99.6)
Pericarditis (outcome)	<5	<5	6 (<0.1)	<5	0 (0)	0 (0)
Diagnosis of myocarditis	<5	<5	<5	<5	0 (0)	0 (0)

1276

Table 15.26.1.2.5 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (7-days risk window) in SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,081,405	3,081,405	2,805,381	2,805,381	484,132	484,132
Person-months of follow-up						
Total	653,968	653,968	626,305	626,305	111,780	111,780
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	18 (<0.1)	18 (<0.1)	33 (<0.1)	33 (<0.1)	67 (<0.1)	67 (<0.1)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	74,163 (2.4)	74,163 (2.4)	50,885 (1.8)	50,885 (1.8)	862 (0.2)	862 (0.2)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	453,520 (14.7)	453,524 (14.7)	161,283 (5.7)	161,283 (5.7)	1,389 (0.3)	1,389 (0.3)
End of risk window	2,553,687 (82.9)	2,553,684 (82.9)	2,593,162 (92.4)	2,593,165 (92.4)	481,812 (99.5)	481,813 (99.5)
Pericarditis (outcome)	17 (<0.1)	14 (<0.1)	12 (<0.1)	10 (<0.1)	<5	<5
Diagnosis of myocarditis	0 (0)	<5	6 (<0.1)	5 (<0.1)	0 (0)	0 (0)

Table 15.26.1.2.6 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (7-days risk window) in CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,231,856	3,240,799	2,912,712	2,918,333	1,393,951	1,398,427
Person-months of follow-up						
Total	719,376	720,996	666,186	667,035	321,579	322,403
Median (Q1,Q3)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)	0 (0.2, 0.2)
Min, Max	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2	0, 0.2
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	4,615 (0.1)	6,300 (0.2)	3,745 (0.1)	6,417 (0.2)	1,405 (0.1)	2,705 (0.2)
Death	28 (<0.1)	410 (0)	31 (<0.1)	428 (0)	29 (<0.1)	264 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	102,127 (3.2)	102,855 (3.2)	38,413 (1.3)	38,512 (1.3)	1,112 (0.1)	1,113 (0.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	163,546 (5.1)	164,305 (5.1)	33,006 (1.1)	33,211 (1.1)	7,304 (0.5)	7,316 (0.5)
End of risk window	2,961,524 (91.6)	2,966,921 (91.5)	2,837,493 (97.4)	2,839,744 (97.3)	1,384,098 (99.3)	1,387,024 (99.2)
Pericarditis (outcome)	9 (<0.1)	<5	11 (<0.1)	20 (<0.1)	<5	<5
Diagnosis of myocarditis	7 (<0.1)	<5	13 (<0.1)	<5	<5	<5

1278

Table 15.26.2.2.1 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (14-days risk window) in Pedianet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	10,500	10,500	8,944	8,944	1,055	1,055
Person-months of follow-up						
Total	4,583	4,583	4,014	4,016	473	475
Median (Q1,Q3)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	17 (0.2)	13 (0.1)	27 (0.3)	12 (0.1)	17 (1.6)	8 (0.8)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	55 (0.5)	54 (0.5)	38 (0.4)	38 (0.4)	<5	<5
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	1,158 (11)	1,159 (11)	456 (5.1)	456 (5.1)	36 (3.4)	36 (3.4)
End of risk window	9,269 (88.3)	9,274 (88.3)	8,423 (94.2)	8,438 (94.3)	999 (94.7)	1,008 (95.5)
Pericarditis (outcome)	<5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diagnosis of myocarditis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.26.2.2.2 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (14-days risk window) in PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	1,262,551	1,268,216	954,517	958,957	254,469	255,074
Person-months of follow-up						
Total	540,713	542,939	430,946	432,563	116,825	116,817
Median (Q1,Q3)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	<5	<5	6 (<0.1)	6 (<0.1)	7 (<0.1)	6 (<0.1)
Exit from data source or migration	104 (<0.1)	595 (<0.1)	118 (<0.1)	894 (0.1)	115 (<0.1)	1,234 (0.5)
Death	73 (<0.1)	265 (<0.1)	54 (<0.1)	289 (<0.1)	22 (<0.1)	43 (<0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	42,553 (3.4)	42,657 (3.4)	11,945 (1.3)	12,135 (1.3)	1,948 (0.8)	1,958 (0.8)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	132,586 (10.5)	133,527 (10.5)	35,926 (3.8)	36,532 (3.8)	2,043 (0.8)	2,046 (0.8)
End of risk window	1,087,220 (86.1)	1,091,161 (86)	906,455 (95)	909,100 (94.8)	250,332 (98.4)	249,787 (97.9)
Pericarditis (outcome)	<5	<5	<5	0 (0)	0 (0)	0 (0)
Diagnosis of myocarditis	10 (<0.1)	6 (<0.1)	12 (<0.1)	<5	<5	0 (0)

1280

Table 15.26.2.2.3 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (14-days risk window) in NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,347,625	3,358,768	2,485,686	2,496,717	1,460,378	1,468,667
Person-months of follow-up						
Total	1,313,811	1,317,809	1,054,873	1,058,593	667,261	670,670
Median (Q1,Q3)	1 (0.4, 0.5)	1 (0.4, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	118 (<0.1)	709 (<0.1)	277 (<0.1)	979 (<0.1)	130 (<0.1)	542 (<0.1)
Death	179 (<0.1)	823 (<0.1)	195 (<0.1)	2,463 (0.1)	196 (<0.1)	1,434 (0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	97,892 (2.9)	98,086 (2.9)	66,569 (2.7)	66,715 (2.7)	4,090 (0.3)	4,126 (0.3)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	923,222 (27.6)	926,830 (27.6)	339,454 (13.7)	342,353 (13.7)	34,638 (2.4)	34,850 (2.4)
End of risk window	2,326,181 (69.5)	2,332,275 (69.4)	2,079,139 (83.6)	2,084,168 (83.5)	1,421,304 (97.3)	1,427,667 (97.2)
Pericarditis (outcome)	25 (<0.1)	31 (<0.1)	45 (<0.1)	34 (<0.1)	15 (<0.1)	38 (<0.1)
Diagnosis of myocarditis	8 (<0.1)	14 (<0.1)	7 (<0.1)	5 (<0.1)	5 (<0.1)	10 (<0.1)

1281

Table 15.26.2.2.4 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (14-days risk window) in EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	611,210	614,989	489,239	491,151	92,041	92,273
Person-months of follow-up						
Total	228,176	229,191	213,157	213,847	42,407	42,504
Median (Q1,Q3)	1 (0.3, 0.5)	1 (0.3, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	6 (<0.1)	6 (<0.1)	<5	<5	<5	<5
Death	32 (<0.1)	176 (<0.1)	33 (<0.1)	310 (0.1)	5 (<0.1)	46 (<0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	29,500 (4.8)	29,550 (4.8)	10,708 (2.2)	10,741 (2.2)	89 (0.1)	89 (0.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	182,652 (29.9)	185,080 (30.1)	42,538 (8.7)	43,011 (8.8)	714 (0.8)	718 (0.8)
End of risk window	399,012 (65.3)	400,171 (65.1)	435,948 (89.1)	437,084 (89)	91,230 (99.1)	91,417 (99.1)
Pericarditis (outcome)	7 (<0.1)	5 (<0.1)	7 (<0.1)	<5	0 (0)	0 (0)
Diagnosis of myocarditis	<5	<5	<5	<5	0 (0)	0 (0)

Table 15.26.2.2.5 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (14-days risk window) in SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,081,405	3,081,405	2,805,381	2,805,381	484,132	484,132
Person-months of follow-up						
Total	1,176,091	1,176,090	1,193,746	1,193,746	222,710	222,710
Median (Q1,Q3)	1 (0.3, 0.5)	1 (0.3, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	47 (<0.1)	47 (<0.1)	79 (<0.1)	79 (<0.1)	174 (<0.1)	174 (<0.1)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	147,885 (4.8)	147,885 (4.8)	111,731 (4)	111,733 (4)	2,624 (0.5)	2,624 (0.5)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	820,234 (26.6)	820,239 (26.6)	321,443 (11.5)	321,445 (11.5)	3,475 (0.7)	3,475 (0.7)
End of risk window	2,113,205 (68.6)	2,113,210 (68.6)	2,372,096 (84.6)	2,372,095 (84.6)	477,856 (98.7)	477,857 (98.7)
Pericarditis (outcome)	31 (<0.1)	21 (<0.1)	21 (<0.1)	19 (<0.1)	<5	<5
Diagnosis of myocarditis	<5	<5	11 (<0.1)	10 (<0.1)	0 (0)	0 (0)

Table 15.26.2.2.6 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (14-days risk window) in CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,231,856	3,240,799	2,912,712	2,918,333	1,393,951	1,398,427
Person-months of follow-up						
Total	1,364,282	1,366,610	1,310,961	1,312,030	640,126	641,494
Median (Q1,Q3)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)	1 (0.5, 0.5)
Min, Max	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5	0, 0.5
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	10,102 (0.3)	13,077 (0.4)	9,725 (0.3)	13,739 (0.5)	3,571 (0.3)	5,700 (0.4)
Death	70 (<0.1)	728 (0)	104 (<0.1)	891 (0)	86 (0)	507 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	213,294 (6.6)	215,354 (6.6)	75,128 (2.6)	75,436 (2.6)	2,561 (0.2)	2,564 (0.2)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	328,571 (10.2)	330,473 (10.2)	75,633 (2.6)	76,157 (2.6)	16,660 (1.2)	16,694 (1.2)
End of risk window	2,679,793 (82.9)	2,681,149 (82.7)	2,752,085 (94.5)	2,752,077 (94.3)	1,371,065 (98.4)	1,372,955 (98.2)
Pericarditis (outcome)	14 (<0.1)	9 (<0.1)	18 (<0.1)	30 (<0.1)	6 (<0.1)	5 (<0.1)
Diagnosis of myocarditis	12 (<0.1)	9 (<0.1)	19 (<0.1)	<5	<5	<5

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Table 15.26.3.2.1 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (21-days risk window) in Pedianet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	10,500	10,500	8,944	8,944	1,055	1,055
Person-months of follow-up						
Total	6,663	6,664	5,936	5,942	700	706
Median (Q1,Q3)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	27 (0.3)	23 (0.2)	45 (0.5)	22 (0.2)	32 (3)	17 (1.6)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	78 (0.7)	77 (0.7)	58 (0.6)	59 (0.7)	<5	<5
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	1,590 (15.1)	1,592 (15.2)	621 (6.9)	623 (7)	46 (4.4)	46 (4.4)
End of risk window	8,804 (83.8)	8,808 (83.9)	8,220 (91.9)	8,240 (92.1)	974 (92.3)	989 (93.7)
Pericarditis (outcome)	<5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diagnosis of myocarditis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.26.3.2.2 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (21-days risk window) in PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	1,262,551	1,268,216	954,517	958,957	254,469	255,074
Person-months of follow-up						
Total	785,499	788,531	638,153	640,301	174,529	174,350
Median (Q1,Q3)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	6 (<0.1)	6 (<0.1)	17 (<0.1)	16 (<0.1)	13 (<0.1)	12 (<0.1)
Exit from data source or migration	161 (<0.1)	837 (0.1)	183 (<0.1)	1,218 (0.1)	195 (0.1)	1,660 (0.7)
Death	131 (<0.1)	386 (<0.1)	77 (<0.1)	399 (<0.1)	33 (<0.1)	52 (<0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	56,875 (4.5)	57,047 (4.5)	16,757 (1.8)	17,010 (1.8)	2,700 (1.1)	2,720 (1.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	167,229 (13.2)	168,656 (13.3)	49,281 (5.2)	50,067 (5.2)	2,819 (1.1)	2,824 (1.1)
End of risk window	1,038,138 (82.2)	1,041,274 (82.1)	888,187 (93.1)	890,244 (92.8)	248,704 (97.7)	247,805 (97.2)
Pericarditis (outcome)	<5	<5	<5	<5	0 (0)	0 (0)
Diagnosis of myocarditis	10 (<0.1)	9 (<0.1)	14 (<0.1)	<5	5 (<0.1)	<5

Table 15.26.3.2.3 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (21-days risk window) in NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,347,625	3,358,768	2,485,686	2,496,717	1,460,378	1,468,667
Person-months of follow-up						
Total	1,798,328	1,803,470	1,514,961	1,519,529	993,557	998,315
Median (Q1,Q3)	1 (0.4, 0.7)	1 (0.4, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	208 (<0.1)	1,058 (<0.1)	465 (<0.1)	1,555 (0.1)	359 (<0.1)	1,023 (0.1)
Death	317 (<0.1)	1,166 (<0.1)	334 (<0.1)	3,395 (0.1)	323 (<0.1)	2,231 (0.2)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	137,827 (4.1)	138,107 (4.1)	95,933 (3.9)	96,123 (3.8)	5,993 (0.4)	6,046 (0.4)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	1,270,364 (37.9)	1,275,437 (38)	462,094 (18.6)	466,258 (18.7)	51,685 (3.5)	52,055 (3.5)
End of risk window	1,938,855 (57.9)	1,942,932 (57.8)	1,926,790 (77.5)	1,929,331 (77.3)	1,401,992 (96)	1,407,229 (95.8)
Pericarditis (outcome)	42 (<0.1)	43 (<0.1)	61 (<0.1)	49 (<0.1)	20 (<0.1)	71 (<0.1)
Diagnosis of myocarditis	12 (<0.1)	25 (<0.1)	9 (<0.1)	6 (<0.1)	6 (<0.1)	12 (<0.1)

Table 15.26.3.2.4 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (21-days risk window) in EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	611,210	614,989	489,239	491,151	92,041	92,273
Person-months of follow-up						
Total	312,570	313,795	310,792	311,697	63,458	63,596
Median (Q1,Q3)	1 (0.3, 0.7)	1 (0.3, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	7 (<0.1)	7 (<0.1)	6 (<0.1)	12 (<0.1)	5 (<0.1)	5 (<0.1)
Death	55 (<0.1)	262 (<0.1)	49 (<0.1)	414 (0.1)	9 (<0.1)	69 (0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	36,846 (6)	36,921 (6)	14,750 (3)	14,794 (3)	126 (0.1)	128 (0.1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	221,628 (36.3)	224,323 (36.5)	57,736 (11.8)	58,430 (11.9)	1,026 (1.1)	1,033 (1.1)
End of risk window	352,665 (57.7)	353,470 (57.5)	416,686 (85.2)	417,498 (85)	90,874 (98.7)	91,038 (98.7)
Pericarditis (outcome)	7 (<0.1)	5 (<0.1)	10 (<0.1)	<5	<5	0 (0)
Diagnosis of myocarditis	<5	<5	<5	<5	0 (0)	0 (0)

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Table 15.26.3.2.5 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (21-days risk window) in SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,081,405	3,081,405	2,805,381	2,805,381	484,132	484,132
Person-months of follow-up						
Total	1,631,498	1,631,498	1,719,196	1,719,197	332,683	332,684
Median (Q1,Q3)	1 (0.3, 0.7)	1 (0.3, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	62 (<0.1)	62 (<0.1)	134 (<0.1)	134 (<0.1)	281 (0.1)	281 (0.1)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	201,026 (6.5)	201,026 (6.5)	156,749 (5.6)	156,752 (5.6)	5,033 (1)	5,033 (1)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	995,232 (32.3)	995,237 (32.3)	433,441 (15.5)	433,446 (15.5)	5,086 (1.1)	5,086 (1.1)
End of risk window	1,885,046 (61.2)	1,885,044 (61.2)	2,215,010 (79)	2,215,013 (79)	473,725 (97.9)	473,730 (97.9)
Pericarditis (outcome)	35 (<0.1)	30 (<0.1)	33 (<0.1)	25 (<0.1)	7 (<0.1)	<5
Diagnosis of myocarditis	<5	6 (<0.1)	14 (<0.1)	11 (<0.1)	0 (0)	0 (0)

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Table 15.26.3.2.6 Cohort follow-up and reasons for censoring in the matched vaccinated and unvaccinated pericarditis cohort (21-days risk window) in CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N	3,231,856	3,240,799	2,912,712	2,918,333	1,393,951	1,398,427
Person-months of follow-up						
Total	1,957,028	1,959,134	1,938,146	1,938,946	955,731	957,360
Median (Q1,Q3)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)	1 (0.7, 0.7)
Min, Max	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7	0, 0.7
Reasons for censoring						
End of the study period	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Exit from data source or migration	14,623 (0.5)	19,159 (0.6)	15,457 (0.5)	20,434 (0.7)	5,629 (0.4)	8,806 (0.6)
Death	125 (<0.1)	1,032 (0)	171 (0)	1,346 (0)	166 (0)	769 (0.1)
Receipt of a non-Pfizer-BioNTech COVID-19 vaccine	297,466 (9.2)	300,594 (9.3)	102,817 (3.5)	103,520 (3.5)	4,012 (0.3)	4,022 (0.3)
Unvaccinated matched individual vaccinated with Pfizer-BioNTech COVID-19 vaccine	434,531 (13.4)	437,330 (13.5)	112,296 (3.9)	113,103 (3.9)	25,691 (1.8)	25,770 (1.8)
End of risk window	2,485,071 (76.9)	2,482,659 (76.6)	2,681,922 (92.1)	2,679,889 (91.8)	1,358,440 (97.5)	1,359,052 (97.2)
Pericarditis (outcome)	25 (<0.1)	12 (<0.1)	28 (<0.1)	35 (<0.1)	11 (<0.1)	6 (<0.1)
Diagnosis of myocarditis	15 (<0.1)	13 (<0.1)	21 (<0.1)	6 (<0.1)	<5	<5

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Table 15.27.1 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for Pedianet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	10,500 (50)	10,500 (50)	8,944 (50)	8,944 (50)	1,055 (50)	1,055 (50)
Age groups at index date (years) n (%)						
00-01	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
02-04	17 (0.16)	347 (3.3)	<5	288 (3.22)	0 (0)	0 (0)
05-11	7,735 (73.67)	8,260 (78.67)	6,239 (69.76)	6,859 (76.69)	0 (0)	287 (27.2)
12-15	2,748 (26.17)	1,893 (18.03)	2,703 (30.22)	1,797 (20.09)	1,055 (100)	768 (72.8)
16-17	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
18-29	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
30-39	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
40-49	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
50-59	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
60-64	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
65-69	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
70-79	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
80+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Age at index date (years)						
Mean (SD)	9 (2.5)	9 (2.4)	10 (2.5)	9 (2.5)	13 (0.5)	12 (0.8)
Median (Q1,Q3)	10 (7, 12)	10 (7, 11)	10 (7, 12)	10 (7, 11)	13 (12, 13)	12 (11, 13)
Min, Max	3, 13	3, 13	3, 13	3, 13	12, 13	10, 13
Female, n (%)	5,155 (49.1)	5,155 (49.1)	4,418 (49.4)	4,418 (49.4)	511 (48.44)	511 (48.44)
Race/ethnicity, n (%)						
SES, n (%)						
low	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)

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Table 15.27.1 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for Pedianet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
middle	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
high	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
Pregnancy status, n (%) ^a						
Pregnancy trimester, n (%) ^b						
Residency in a long-term care facility, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Healthcare worker or essential worker status, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Smoking status, n (%)						
Never	10,500 (100)	10,500 (100)	8,944 (100)	8,944 (100)	1,055 (100)	1,055 (100)
Current	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Former	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Obese (diagnostic code or BMI >30 kg/m ²) ^c	270 (2.57)	279 (2.66)	229 (2.56)	250 (2.8)	34 (3.22)	45 (4.27)

Table 15.27.2 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	1,262,551 (50)	1,262,551 (50)	954,517 (50)	954,517 (50)	254,469 (50)	254,469 (50)
Age groups at index date (years) n (%)						
00-01	6 (<0.1)	<5	0 (0)	0 (0)	0 (0)	0 (0)
02-04	122 (<0.1)	420 (<0.1)	45 (<0.1)	201 (<0.1)	0 (0)	0 (0)
05-11	13,022 (1.03)	18,763 (1.49)	5,916 (0.62)	11,321 (1.19)	17 (<0.1)	253 (0.1)
12-15	75,775 (6)	70,543 (5.59)	65,088 (6.82)	59,979 (6.28)	4,316 (1.7)	4,194 (1.65)
16-17	46,500 (3.68)	44,893 (3.56)	37,385 (3.92)	36,574 (3.83)	4,725 (1.86)	6,282 (2.47)
18-29	203,270 (16.1)	204,000 (16.16)	164,454 (17.23)	164,774 (17.26)	75,547 (29.69)	73,756 (28.98)
30-39	184,814 (14.64)	185,399 (14.68)	154,332 (16.17)	154,248 (16.16)	74,185 (29.15)	74,012 (29.08)
40-49	186,521 (14.77)	185,952 (14.73)	123,002 (12.89)	123,324 (12.92)	32,641 (12.83)	32,882 (12.92)
50-59	219,518 (17.39)	213,881 (16.94)	166,727 (17.47)	161,621 (16.93)	24,838 (9.76)	24,850 (9.77)
60-64	16,052 (1.27)	25,679 (2.03)	12,793 (1.34)	21,141 (2.21)	5,386 (2.12)	5,429 (2.13)
65-69	110,705 (8.77)	107,676 (8.53)	69,847 (7.32)	66,849 (7)	8,891 (3.49)	9,049 (3.56)
70-79	206,246 (16.34)	205,341 (16.26)	154,928 (16.23)	154,485 (16.18)	23,923 (9.4)	23,762 (9.34)
80+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Age at index date (years)						
Mean (SD)	45 (20)	45 (20)	44 (20.1)	44 (20.1)	39 (17)	39 (17)
Median (Q1, Q3)	46 (28, 65)	46 (28, 64)	43 (27, 59)	43 (27, 60)	35 (27, 49)	35 (27, 49)
Min, Max	0, 79	1, 79	3, 79	3, 79	8, 79	9, 79
Female, n (%)	638,819 (50.6)	638,819 (50.6)	482,835 (50.58)	482,835 (50.58)	130,423 (51.25)	130,423 (51.25)
Race/ethnicity, n (%)						
SES, n (%)						
low	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)

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Table 15.27.2 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
middle	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
high	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
Pregnancy status, n (%) ^a						
Yes	3,092 (0.93)	3,093 (0.93)	2,643 (1.03)	2,643 (1.03)	1,211 (1.26)	1,211 (1.26)
No	331,134 (99.07)	330,518 (99.07)	253,725 (98.97)	253,449 (98.97)	94,682 (98.74)	94,606 (98.74)
Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pregnancy trimester, n (%) ^b						
Residency in a long-term care facility, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Healthcare worker or essential worker status, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Smoking status, n (%)						
Never	1,240,271 (100)	1,243,803 (100)	937,674 (100)	941,189 (100)	250,210 (100)	251,063 (100)
Current	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Former	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Obese (diagnostic code or BMI >30 kg/m ²) ^c	33,355 (2.64)	31,836 (2.52)	25,074 (2.63)	23,727 (2.49)	6,851 (2.69)	6,224 (2.45)

Table 15.27.3 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,347,625 (50)	3,347,625 (50)	2,485,650 (50)	2,485,650 (50)	1,460,378 (50)	1,460,378 (50)
Age groups at index date (years) n (%)						
00-01	5 (<0.1)	<5	<5	<5	0 (0)	0 (0)
02-04	6 (<0.1)	241 (<0.1)	<5	35 (<0.1)	0 (0)	0 (0)
05-11	10,274 (0.31)	41,358 (1.24)	1,429 (0.06)	4,125 (0.17)	17 (<0.1)	38 (<0.1)
12-15	209,701 (6.26)	193,201 (5.77)	32,601 (1.31)	48,649 (1.96)	249 (<0.1)	304 (<0.1)
16-17	119,284 (3.56)	119,441 (3.57)	102,282 (4.11)	92,576 (3.72)	946 (0.06)	8,584 (0.59)
18-29	575,944 (17.2)	560,131 (16.73)	357,083 (14.37)	347,295 (13.97)	188,380 (12.9)	179,779 (12.31)
30-39	487,379 (14.56)	490,462 (14.65)	308,339 (12.4)	310,659 (12.5)	135,046 (9.25)	136,869 (9.37)
40-49	513,896 (15.35)	513,729 (15.35)	374,080 (15.05)	374,455 (15.06)	190,729 (13.06)	190,218 (13.03)
50-59	548,019 (16.37)	548,894 (16.4)	463,026 (18.63)	463,850 (18.66)	276,971 (18.97)	277,920 (19.03)
60-64	242,281 (7.24)	249,490 (7.45)	221,940 (8.93)	233,530 (9.4)	139,694 (9.57)	141,355 (9.68)
65-69	239,601 (7.16)	233,313 (6.97)	231,225 (9.3)	218,496 (8.79)	182,194 (12.48)	179,703 (12.31)
70-79	401,235 (11.99)	397,363 (11.87)	393,642 (15.84)	391,978 (15.77)	346,152 (23.7)	345,608 (23.67)
80+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Age at index date (years)						
Mean (SD)	44 (19.2)	44 (19.2)	49 (18.4)	49 (18.4)	54 (17.3)	54 (17.3)
Median (Q1,Q3)	45 (28, 60)	45 (28, 60)	51 (34, 65)	51 (34, 64)	57 (42, 69)	57 (42, 69)
Min, Max	0, 79	1, 79	0, 79	1, 79	5, 79	5, 79
Female, n (%)	1,639,264 (48.97)	1,639,264 (48.97)	1,249,039 (50.25)	1,249,039 (50.25)	745,701 (51.06)	745,701 (51.06)
Race/ethnicity, n (%)						
SES, n (%)						
low	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)

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Table 15.27.3 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
middle	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
high	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
Pregnancy status, n (%)a						
Yes	12,930 (1.47)	12,931 (1.48)	10,467 (1.71)	10,467 (1.72)	4,220 (1.48)	4,220 (1.48)
No	867,207 (98.53)	863,722 (98.52)	600,860 (98.29)	599,012 (98.28)	280,633 (98.52)	280,418 (98.52)
Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pregnancy trimester, n (%)b						
Residency in a long-term care facility, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Healthcare worker or essential worker status, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Smoking status, n (%)						
Never	3,347,625 (100)	3,347,625 (100)	2,485,650 (100)	2,485,650 (100)	1,460,378 (100)	1,460,378 (100)
Current	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Former	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Obese (diagnostic code or BMI >30 kg/m2)c	117,684 (3.52)	97,933 (2.93)	102,044 (4.11)	83,696 (3.37)	67,512 (4.62)	59,779 (4.09)

Table 15.27.4 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	611,210 (50)	611,210 (50)	489,239 (50)	489,239 (50)	92,041 (50)	92,041 (50)
Age groups at index date (years) n (%)						
00-01	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
02-04	0 (0)	1,411 (0.23)	0 (0)	978 (0.2)	0 (0)	0 (0)
05-11	49,239 (8.06)	49,942 (8.17)	30,045 (6.14)	31,863 (6.51)	64 (0.07)	69 (0.07)
12-15	33,030 (5.4)	32,012 (5.24)	28,517 (5.83)	26,465 (5.41)	583 (0.63)	606 (0.66)
16-17	15,600 (2.55)	15,139 (2.48)	12,841 (2.62)	12,193 (2.49)	1,127 (1.22)	1,131 (1.23)
18-29	72,158 (11.81)	71,794 (11.75)	59,901 (12.24)	59,811 (12.23)	10,211 (11.09)	10,209 (11.09)
30-39	81,278 (13.3)	81,815 (13.39)	70,728 (14.46)	70,956 (14.5)	13,835 (15.03)	13,772 (14.96)
40-49	129,105 (21.12)	129,679 (21.22)	111,907 (22.87)	111,870 (22.87)	25,480 (27.68)	25,496 (27.7)
50-59	108,246 (17.71)	106,256 (17.38)	91,504 (18.7)	90,377 (18.47)	25,554 (27.76)	25,080 (27.25)
60-64	10,538 (1.72)	11,120 (1.82)	9,450 (1.93)	10,356 (2.12)	1,857 (2.02)	2,324 (2.52)
65-69	27,181 (4.45)	29,896 (4.89)	19,102 (3.9)	19,871 (4.06)	3,325 (3.61)	3,461 (3.76)
70-79	84,835 (13.88)	82,146 (13.44)	55,244 (11.29)	54,499 (11.14)	10,005 (10.87)	9,893 (10.75)
80+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Age at index date (years)						
Mean (SD)	43 (20.3)	43 (20.2)	42 (19.1)	42 (19.2)	47 (14.9)	47 (14.9)
Median (Q1,Q3)	44 (27, 56)	44 (27, 56)	44 (28, 55)	44 (28, 55)	48 (38, 56)	48 (38, 56)
Min, Max	5, 79	4, 79	5, 79	4, 79	6, 79	5, 79
Female, n (%)	308,186 (50.42)	308,186 (50.42)	246,605 (50.41)	246,605 (50.41)	44,233 (48.06)	44,233 (48.06)
Race/ethnicity, n (%)						
SES, n (%)						
low	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)

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Table 15.27.4 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
middle	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
high	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
Pregnancy status, n (%)a						
Yes	1,330 (0.85)	1,330 (0.84)	1,127 (0.84)	1,127 (0.84)	21 (0.08)	21 (0.08)
No	155,898 (99.15)	156,177 (99.16)	133,513 (99.16)	133,309 (99.16)	25,972 (99.92)	25,958 (99.92)
Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pregnancy trimester, n (%)b						
Residency in a long-term care facility, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Healthcare worker or essential worker status, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Smoking status, n (%)						
Never	498,924 (81.63)	508,597 (83.21)	399,427 (81.64)	412,319 (84.28)	72,381 (78.64)	77,936 (84.68)
Current	84,693 (13.86)	76,947 (12.59)	66,522 (13.6)	56,880 (11.63)	14,496 (15.75)	10,348 (11.24)
Former	27,593 (4.51)	25,666 (4.2)	23,290 (4.76)	20,040 (4.1)	5,164 (5.61)	3,757 (4.08)
Obese (diagnostic code or BMI >30 kg/m2)c	33,826 (5.53)	34,165 (5.59)	25,570 (5.23)	25,724 (5.26)	4,698 (5.1)	4,270 (4.64)

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Table 15.27.5 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,081,405 (50)	3,081,405 (50)	2,805,381 (50)	2,805,381 (50)	484,132 (50)	484,132 (50)
Age groups at index date (years) n (%)						
00-01	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
02-04	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
05-11	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
12-15	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
16-17	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
18-29	348,435 (13.87)	350,524 (14.02)	299,915 (12.79)	302,025 (12.99)	55,342 (11.89)	52,402 (11.39)
30-39	401,746 (16)	403,919 (16.15)	361,986 (15.43)	363,418 (15.63)	42,812 (9.2)	42,804 (9.31)
40-49	609,500 (24.27)	612,034 (24.47)	563,826 (24.04)	564,065 (24.27)	50,464 (10.84)	50,784 (11.04)
50-59	514,988 (20.51)	503,981 (20.15)	485,167 (20.69)	473,559 (20.37)	42,222 (9.07)	41,533 (9.03)
60-64	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
65-69	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
70-79	385,566 (15.35)	391,184 (15.64)	384,281 (16.39)	376,692 (16.21)	126,029 (27.07)	123,325 (26.81)
80+	251,149 (10)	239,076 (9.56)	250,057 (10.66)	244,739 (10.53)	148,703 (31.94)	149,154 (32.42)
Age at index date (years)						
Mean (SD)	45 (22.6)	45 (22.6)	47 (22.4)	47 (22.4)	63 (23.1)	63 (23.1)
Median (Q1,Q3)	45 (27, 58)	45 (27, 58)	46 (30, 61)	46 (30, 61)	74 (43, 81)	73 (43, 81)
Min, Max	1, 106	1, 107	1, 106	1, 107	2, 107	1, 107
Female, n (%)	1,600,933 (51.95)	1,600,933 (51.95)	1,464,298 (52.2)	1,464,298 (52.2)	275,508 (56.91)	275,508 (56.91)
Race/ethnicity, n (%)						
SES, n (%)						
low	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)

Table 15.27.5 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
middle	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
high	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
Pregnancy status, n (%)a						
Yes	9,817 (1.26)	9,816 (1.26)	8,734 (1.25)	8,732 (1.25)	869 (1.04)	869 (1.04)
No	769,706 (98.74)	767,644 (98.74)	692,736 (98.75)	691,395 (98.75)	82,510 (98.96)	82,291 (98.96)
Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pregnancy trimester, n (%)b						
Residency in a long-term care facility, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Healthcare worker or essential worker status, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Smoking status, n (%)						
Never	2,327,153 (77.43)	2,329,144 (77.48)	2,119,907 (77.47)	2,126,144 (77.67)	373,187 (78.94)	371,720 (78.65)
Current	465,852 (15.5)	461,121 (15.34)	422,111 (15.43)	410,129 (14.98)	69,410 (14.68)	68,077 (14.4)
Former	212,332 (7.07)	215,724 (7.18)	194,400 (7.1)	201,176 (7.35)	30,176 (6.38)	32,816 (6.94)
Obese (diagnostic code or BMI >30 kg/m2)c	460,042 (14.93)	465,668 (15.11)	426,916 (15.22)	432,212 (15.41)	101,491 (20.96)	96,144 (19.86)

1300

Table 15.27.6 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,231,856 (50)	3,231,856 (50)	2,912,712 (50)	2,912,712 (50)	1,393,951 (50)	1,393,951 (50)
Age groups at index date (years) n (%)						
00-01	<5	<5	<5	<5	0 (0)	0 (0)
02-04	134 (<0.1)	5,424 (0.17)	<5	2,423 (0.08)	0 (0)	22 (<0.1)
05-11	136,544 (4.22)	183,563 (5.68)	84,038 (2.89)	119,305 (4.1)	3,044 (0.22)	3,597 (0.26)
12-15	367,733 (11.38)	335,368 (10.38)	281,869 (9.68)	263,334 (9.04)	9,680 (0.69)	19,024 (1.36)
16-17	197,012 (6.1)	195,522 (6.05)	163,979 (5.63)	161,281 (5.54)	55,111 (3.95)	50,343 (3.61)
18-29	875,237 (27.08)	858,714 (26.57)	803,793 (27.6)	787,659 (27.04)	334,767 (24.02)	329,533 (23.64)
30-39	714,590 (22.11)	709,519 (21.95)	659,577 (22.64)	656,700 (22.55)	321,317 (23.05)	319,977 (22.95)
40-49	300,773 (9.31)	302,858 (9.37)	308,506 (10.59)	314,579 (10.8)	174,357 (12.51)	176,163 (12.64)
50-59	248,128 (7.68)	250,336 (7.75)	238,895 (8.2)	236,840 (8.13)	175,289 (12.57)	175,012 (12.56)
60-64	104,459 (3.23)	107,466 (3.33)	99,977 (3.43)	99,323 (3.41)	80,397 (5.77)	80,459 (5.77)
65-69	95,475 (2.95)	95,857 (2.97)	91,263 (3.13)	92,217 (3.17)	76,173 (5.46)	76,019 (5.45)
70-79	191,767 (5.93)	187,226 (5.79)	180,811 (6.21)	179,050 (6.15)	163,816 (11.75)	163,802 (11.75)
80+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Age at index date (years)						
Mean (SD)	34 (18.1)	33 (18.1)	35 (17.9)	35 (18)	43 (18.4)	43 (18.4)
Median (Q1,Q3)	30 (19, 43)	30 (19, 43)	31 (20, 45)	31 (20, 45)	39 (28, 58)	39 (27, 58)
Min, Max	1, 79	1, 79	1, 79	1, 79	5, 79	3, 79
Female, n (%)	1,672,136 (51.74)	1,672,136 (51.74)	1,520,690 (52.21)	1,520,690 (52.21)	770,494 (55.27)	770,494 (55.27)
Race/ethnicity, n (%)						
SES, n (%)						
low	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)

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Table 15.27.6 Demographic and lifestyle variables at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
middle	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
high	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
Pregnancy status, n (%)a						
Yes	17,045 (1.49)	17,041 (1.5)	16,703 (1.57)	16,705 (1.58)	8,942 (1.76)	8,942 (1.77)
No	1,124,760 (98.51)	1,121,004 (98.5)	1,045,429 (98.43)	1,040,825 (98.42)	498,114 (98.24)	497,228 (98.23)
Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pregnancy trimester, n (%)b						
Residency in a long-term care facility, n (%)	1,505 (<0.1)	942 (<0.1)	1,430 (<0.1)	1,546 (0.05)	1,226 (0.09)	1,628 (0.12)
Healthcare worker or essential worker status, n (%)	3,476 (0.11)	1,232 (<0.1)	3,543 (0.12)	1,251 (<0.1)	2,791 (0.2)	770 (0.06)
Smoking status, n (%)						
Never	3,231,856 (100)	3,231,856 (100)	2,912,712 (100)	2,912,712 (100)	1,393,951 (100)	1,393,951 (100)
Current	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Former	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Obese (diagnostic code or BMI >30 kg/m2)c	114,204 (3.53)	108,297 (3.35)	108,324 (3.72)	101,003 (3.47)	71,989 (5.16)	68,047 (4.88)

Table 15.28.1 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for Pedianet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	10,500 (50)	10,500 (50)	8,944 (50)	8,944 (50)	1,055 (50)	1,055 (50)
Number of hospitalisations, n (%)						
0	10,116 (96.34)	10,144 (96.61)	8,613 (96.3)	8,612 (96.29)	1,016 (96.3)	1,017 (96.4)
1	296 (2.82)	276 (2.63)	261 (2.92)	240 (2.68)	33 (3.13)	31 (2.94)
2+	88 (0.84)	80 (0.76)	70 (0.78)	92 (1.03)	6 (0.57)	7 (0.66)
Number of emergency department visits, n (%)						
0	9,265 (88.24)	9,304 (88.61)	7,878 (88.08)	7,905 (88.38)	914 (86.64)	941 (89.19)
1	976 (9.3)	962 (9.16)	844 (9.44)	814 (9.1)	110 (10.43)	93 (8.82)
2+	259 (2.47)	234 (2.23)	222 (2.48)	225 (2.52)	31 (2.94)	21 (1.99)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)						
0	10,500 (100)	10,500 (100)	8,944 (100)	8,944 (100)	1,055 (100)	1,055 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Primary care utilisation, n (%)						
0	1,294 (12.32)	1,438 (13.7)	1,026 (11.47)	1,185 (13.25)	132 (12.51)	151 (14.31)
1	1,744 (16.61)	1,733 (16.5)	1,438 (16.08)	1,489 (16.65)	180 (17.06)	154 (14.6)
2+	7,462 (71.07)	7,329 (69.8)	6,480 (72.45)	6,270 (70.1)	743 (70.43)	750 (71.09)
Cancer screening, n (%)						
0	10,500 (100)	10,500 (100)	8,944 (100)	8,944 (100)	1,055 (100)	1,055 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Other preventive health services, n (%)						
No	7,177 (68.35)	7,709 (73.42)	0 (0)	6,508 (72.76)	0 (0)	592 (56.11)

1303

Table 15.28.1 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PediaNet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Yes	3,323 (31.65)	2,791 (26.58)	8,944 (100)	2,436 (27.24)	1,055 (100)	463 (43.89)
Number of COVID-19 tests (PCR or antigenic), n (%)						
0	2,966 (28.25)	3,301 (31.44)	1,901 (21.25)	2,335 (26.11)	140 (13.27)	192 (18.2)
1-2	7,449 (70.94)	7,129 (67.9)	6,927 (77.45)	6,512 (72.81)	901 (85.4)	843 (79.91)
3-4	85 (0.81)	70 (0.67)	116 (1.3)	97 (1.08)	14 (1.33)	20 (1.9)
5+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.28.2 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	1,262,551 (50)	1,262,551 (50)	954,517 (50)	954,517 (50)	254,469 (50)	254,469 (50)
Number of hospitalisations, n (%)						
0	1,262,551 (100)	1,262,551 (100)	954,517 (100)	954,517 (100)	254,469 (100)	254,469 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Number of emergency department visits, n (%)						
0	1,262,551 (100)	1,262,551 (100)	954,517 (100)	954,517 (100)	254,469 (100)	254,469 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)						
0	1,262,551 (100)	1,262,551 (100)	954,517 (100)	954,517 (100)	254,469 (100)	254,469 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Primary care utilisation, n (%)						
0	1,262,551 (100)	1,262,551 (100)	954,517 (100)	954,517 (100)	254,469 (100)	254,469 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Primary care utilisation, n (%)						
0	400,597 (31.73)	679,768 (53.84)	298,367 (31.26)	583,579 (61.14)	77,460 (30.44)	169,440 (66.59)
1	178,111 (14.11)	120,703 (9.56)	135,073 (14.15)	79,409 (8.32)	37,403 (14.7)	18,371 (7.22)
2+	683,843 (54.16)	462,080 (36.6)	521,077 (54.59)	291,529 (30.54)	139,606 (54.86)	66,658 (26.19)
Cancer screening, n (%)						
0	1,262,551 (100)	1,262,551 (100)	954,517 (100)	954,517 (100)	254,469 (100)	254,469 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Other preventive health services, n (%)						
No	1,262,551 (100)	1,262,551 (100)	954,517 (100)	954,517 (100)	254,469 (100)	254,469 (100)

1305

Table 15.28.2 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Yes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)						
0	1,262,551 (100)	1,262,551 (100)	954,517 (100)	954,517 (100)	254,469 (100)	254,469 (100)
1-2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
3-4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
5+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.28.3 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,347,625 (50)	3,347,625 (50)	2,485,650 (50)	2,485,650 (50)	1,460,378 (50)	1,460,378 (50)
Number of hospitalisations, n (%)						
0	3,043,025 (90.9)	3,047,226 (91.03)	2,234,317 (89.89)	2,187,467 (88)	1,299,740 (89)	1,258,250 (86.16)
1	221,785 (6.63)	221,648 (6.62)	178,230 (7.17)	196,420 (7.9)	110,470 (7.56)	130,769 (8.95)
2+	82,815 (2.47)	78,751 (2.35)	73,103 (2.94)	101,763 (4.09)	50,168 (3.44)	71,359 (4.89)
Number of emergency department visits, n (%)						
0	3,347,625 (100)	3,347,625 (100)	2,485,650 (100)	2,485,650 (100)	1,460,378 (100)	1,460,378 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)						
0	3,347,625 (100)	3,347,625 (100)	2,485,650 (100)	2,485,650 (100)	1,460,378 (100)	1,460,378 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Primary care utilisation, n (%)						
0	484,625 (14.48)	591,037 (17.66)	322,201 (12.96)	458,811 (18.46)	189,790 (13)	281,000 (19.24)
1	354,174 (10.58)	366,497 (10.95)	237,082 (9.54)	252,322 (10.15)	127,172 (8.71)	138,844 (9.51)
2+	2,508,826 (74.94)	2,390,091 (71.4)	1,926,367 (77.5)	1,774,517 (71.39)	1,143,416 (78.3)	1,040,534 (71.25)
Cancer screening, n (%)						
0	3,347,625 (100)	3,347,625 (100)	2,485,650 (100)	2,485,650 (100)	1,460,378 (100)	1,460,378 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Other preventive health services, n (%)						
No	3,347,625 (100)	3,347,625 (100)	2,485,650 (100)	2,485,650 (100)	1,460,378 (100)	1,460,378 (100)

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Table 15.28.3 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Yes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)						
0	3,276,431 (97.87)	3,276,191 (97.87)	2,440,316 (98.18)	2,439,994 (98.16)	1,430,736 (97.97)	1,430,701 (97.97)
1-2	71,194 (2.13)	71,434 (2.13)	45,334 (1.82)	45,656 (1.84)	29,642 (2.03)	29,677 (2.03)
3-4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
5+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.28.4 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	611,210 (50)	611,210 (50)	489,239 (50)	489,239 (50)	92,041 (50)	92,041 (50)
Number of hospitalisations, n (%)						
0	575,452 (94.15)	576,808 (94.37)	462,310 (94.5)	462,304 (94.49)	86,577 (94.06)	88,348 (95.99)
1	29,703 (4.86)	27,969 (4.58)	22,508 (4.6)	21,165 (4.33)	4,539 (4.93)	2,973 (3.23)
2+	6,055 (0.99)	6,433 (1.05)	4,421 (0.9)	5,770 (1.18)	925 (1)	720 (0.78)
Number of emergency department visits, n (%)						
0	505,943 (82.78)	511,657 (83.71)	407,882 (83.37)	413,480 (84.51)	78,099 (84.85)	81,264 (88.29)
1	73,680 (12.05)	67,966 (11.12)	57,265 (11.7)	50,851 (10.39)	10,039 (10.91)	7,345 (7.98)
2+	31,587 (5.17)	31,587 (5.17)	24,092 (4.92)	24,908 (5.09)	3,903 (4.24)	3,432 (3.73)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)						
0	611,210 (100)	611,210 (100)	489,239 (100)	489,239 (100)	92,041 (100)	92,041 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Primary care utilisation, n (%)						
0	85,873 (14.05)	150,725 (24.66)	78,431 (16.03)	168,389 (34.42)	12,977 (14.1)	41,455 (45.04)
1	52,044 (8.51)	49,251 (8.06)	45,999 (9.4)	41,707 (8.52)	8,966 (9.74)	8,275 (8.99)
2+	473,293 (77.44)	411,234 (67.28)	364,809 (74.57)	279,143 (57.06)	70,098 (76.16)	42,311 (45.97)
Cancer screening, n (%)						
0	611,210 (100)	611,210 (100)	489,239 (100)	489,239 (100)	92,041 (100)	92,041 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Other preventive health services, n (%)						
No	611,210 (100)	611,210 (100)	489,239 (100)	489,239 (100)	92,041 (100)	92,041 (100)

1309

Table 15.28.4 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Yes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)						
0	436,355 (71.39)	461,627 (75.53)	357,794 (73.13)	392,189 (80.16)	53,167 (57.76)	67,788 (73.65)
1-2	174,855 (28.61)	149,583 (24.47)	131,445 (26.87)	97,050 (19.84)	38,874 (42.24)	24,253 (26.35)
3-4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
5+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.28.5 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,081,405 (50)	3,081,405 (50)	2,805,381 (50)	2,805,381 (50)	484,132 (50)	484,132 (50)
Number of hospitalisations, n (%)						
0	2,862,364 (92.89)	2,858,274 (92.76)	2,602,243 (92.76)	2,582,496 (92.06)	421,167 (86.99)	432,606 (89.36)
1	175,752 (5.7)	178,046 (5.78)	160,900 (5.74)	168,860 (6.02)	45,700 (9.44)	37,052 (7.65)
2+	43,289 (1.4)	45,085 (1.46)	42,238 (1.51)	54,025 (1.93)	17,265 (3.57)	14,474 (2.99)
Number of emergency department visits, n (%)						
0	3,081,405 (100)	3,081,405 (100)	2,805,381 (100)	2,805,381 (100)	484,132 (100)	484,132 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)						
0	3,081,405 (100)	3,081,405 (100)	2,805,381 (100)	2,805,381 (100)	484,132 (100)	484,132 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Primary care utilisation, n (%)						
0	399,947 (12.98)	568,260 (18.44)	297,907 (10.62)	630,790 (22.49)	22,398 (4.63)	100,569 (20.77)
1	235,025 (7.63)	230,200 (7.47)	240,810 (8.58)	220,380 (7.86)	16,236 (3.35)	36,045 (7.45)
2+	2,446,433 (79.39)	2,282,945 (74.09)	2,266,664 (80.8)	1,954,211 (69.66)	445,498 (92.02)	347,518 (71.78)
Cancer screening, n (%)						
0	3,081,405 (100)	3,081,405 (100)	2,805,381 (100)	2,805,381 (100)	484,132 (100)	484,132 (100)
1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Other preventive health services, n (%)						
No	3,081,405 (100)	3,081,405 (100)	2,805,381 (100)	2,805,381 (100)	484,132 (100)	484,132 (100)

Table 15.28.5 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Yes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Number of COVID-19 tests (PCR or antigenic), n (%)						
0	2,132,470 (69.2)	2,141,774 (69.51)	1,916,652 (68.32)	1,960,014 (69.87)	302,239 (62.43)	297,374 (61.42)
1-2	863,935 (28.04)	855,849 (27.77)	803,490 (28.64)	767,504 (27.36)	154,478 (31.91)	156,965 (32.42)
3-4	85,000 (2.76)	83,782 (2.72)	85,239 (3.04)	77,863 (2.78)	27,415 (5.66)	29,793 (6.15)
5+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.28.6 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,231,856 (50)	50 (2912712)	2,912,712 (50)	50 (1393951)	. (.)	. (.)
Number of hospitalisations, n (%)						
0	3,185,417 (98.56)	99 (2870920)	2,868,031 (98.47)	98 (1369273)	. (.)	. (.)
1	37,509 (1.16)	1 (33779)	34,184 (1.17)	1 (18417)	. (.)	. (.)
2+	8,930 (0.28)	0 (8013)	10,497 (0.36)	0 (6261)	. (.)	. (.)
Number of emergency department visits, n (%)						
0	2,886,507 (89.31)	90 (2596674)	2,613,295 (89.72)	89 (1250779)	. (.)	. (.)
1	260,095 (8.05)	7 (238755)	211,086 (7.25)	8 (97662)	. (.)	. (.)
2+	85,254 (2.64)	3 (77283)	88,331 (3.03)	3 (45510)	. (.)	. (.)
Skilled nursing facility, nursing home, or extended care facility stay, n (%)						
0	3,230,778 (99.97)	100 (2911696)	2,911,253 (99.95)	100 (1392847)	. (.)	. (.)
1	745 (0.02)	0 (729)	1,115 (0.04)	0 (860)	. (.)	. (.)
2+	333 (0.01)	-1,111 (287)	344 (0.01)	0 (244)	. (.)	. (.)
Primary care utilisation, n (%)						
0	3,231,856 (100)	100 (2912712)	2,912,712 (100)	100 (1393951)	. (.)	. (.)
1	0 (0)	0 (0)	0 (0)	0 (0)	. (.)	. (.)
2+	0 (0)	0 (0)	0 (0)	0 (0)	. (.)	. (.)
Cancer screening, n (%)						
0	2,930,080 (90.66)	92 (2605712)	2,698,141 (92.63)	80 (1198779)	. (.)	. (.)
1	256,456 (7.94)	7 (257927)	189,601 (6.51)	16 (167252)	. (.)	. (.)
2+	45,320 (1.4)	1 (49073)	24,970 (0.86)	4 (27920)	. (.)	. (.)
Other preventive health services, n (%)						
No	3,206,066 (99.2)	99 (2889439)	2,895,159 (99.4)	99 (1383085)	. (.)	. (.)

Table 15.28.6 Healthcare utilisation at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Yes	25,790 (0.8)	1 (23273)	17,553 (0.6)	1 (10866)	. (.)	. (.)
Number of COVID-19 tests (PCR or antigenic), n (%)						
0	1,905,228 (58.95)	67 (1560725)	1,962,003 (67.36)	47 (978935)	. (.)	. (.)
1-2	1,223,101 (37.85)	31 (1220465)	883,741 (30.34)	46 (378026)	. (.)	. (.)
3-4	103,527 (3.2)	2 (131522)	66,968 (2.3)	7 (36990)	. (.)	. (.)
5+	0 (0)	0 (0)	0 (0)	0 (0)	. (.)	. (.)

Table 15.29.1 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for Peditanet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	10,500 (50)	10,500 (50)	8,944 (50)	8,944 (50)	1,055 (50)	1,055 (50)
History of anaphylaxis	49 (0.47)	44 (0.42)	42 (0.47)	36 (0.4)	<5	5 (0.47)
History of allergies	1,588 (15.12)	1,582 (15.07)	1,365 (15.26)	1,390 (15.54)	144 (13.65)	167 (15.83)
Diabetes mellitus (types 1 and 2)	28 (0.27)	29 (0.28)	23 (0.26)	32 (0.36)	<5	10 (0.95)
Hypertension (CDC risk group)	<5	<5	<5	9 (0.1)	<5	6 (0.57)
Cardiovascular disease	367 (3.5)	346 (3.3)	321 (3.59)	271 (3.03)	41 (3.89)	45 (4.27)
Myocardial infarct	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Congestive heart failure	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Cerebrovascular disease	64 (0.61)	69 (0.66)	56 (0.63)	45 (0.5)	10 (0.95)	6 (0.57)
Peripheral vascular disease	25 (0.24)	28 (0.27)	25 (0.28)	15 (0.17)	<5	5 (0.47)
Chronic respiratory disease	6,159 (58.66)	6,221 (59.25)	5,179 (57.9)	5,243 (58.62)	564 (53.46)	563 (53.36)
Chronic kidney disease	<5	<5	<5	<5	0 (0)	<5
Mild or moderate kidney disease	<5	<5	<5	<5	0 (0)	<5
Chronic liver disease	<5	<5	<5	<5	0 (0)	0 (0)
Moderate or severe liver disease	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Cancer any cancer diagnosis except non melanoma skin cancer	49 (0.47)	37 (0.35)	44 (0.49)	31 (0.35)	5 (0.47)	<5
Leukemia	<5	<5	<5	0 (0)	<5	0 (0)
Lymphoma	40 (0.38)	29 (0.28)	35 (0.39)	27 (0.3)	<5	<5
Metastasis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Autoimmune disorders	235 (2.24)	202 (1.92)	199 (2.22)	198 (2.21)	29 (2.75)	48 (4.55)
Influenza infection or other respiratory infection	5,610 (53.43)	5,645 (53.76)	4,709 (52.65)	4,656 (52.06)	474 (44.93)	533 (50.52)
HIV/AIDS	6 (0.06)	<5	5 (0.06)	<5	0 (0)	0 (0)
Sickle Cell Disease (CDC risk group)	5 (0.05)	7 (0.07)	5 (0.06)	14 (0.16)	0 (0)	0 (0)

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Table 15.29.1 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for Peditanet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Connective tissue disease	20 (0.19)	26 (0.25)	17 (0.19)	14 (0.16)	<5	0 (0)
Charlson Comorbidity Index						
0	10,432 (99.35)	10,439 (99.42)	8,884 (99.33)	8,893 (99.43)	1,047 (99.24)	1,052 (99.72)
1	57 (0.54)	57 (0.54)	51 (0.57)	48 (0.54)	7 (0.66)	<5
2	11 (0.1)	<5	9 (0.1)	<5	<5	0 (0)
3 or more	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mean (SD)	0 (0.1)	0 (0.1)	0 (0.1)	0 (0.1)	0 (0.1)	0 (0.1)
Median (Q1,Q3)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Min, Max	0, 2	0, 2	0, 2	0, 2	0, 2	0, 1
CDC at-risk groupsb						
Group 0	3,569 (33.99)	3,569 (33.99)	3,087 (34.51)	3,087 (34.51)	371 (35.17)	371 (35.17)
Group 1	3,868 (36.84)	3,833 (36.5)	3,290 (36.78)	3,248 (36.31)	392 (37.16)	384 (36.4)
Group 2	3,063 (29.17)	3,098 (29.5)	2,567 (28.7)	2,609 (29.17)	292 (27.68)	300 (28.44)
Immunodeficiencies	6 (0.06)	5 (0.05)	5 (0.06)	6 (0.07)	0 (0)	0 (0)
Human immunodeficiency virus and other immunosuppressing conditions	3,056 (29.1)	3,056 (29.1)	2,546 (28.47)	2,546 (28.47)	270 (25.59)	270 (25.59)
Previous diagnosis of COVID-19	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Positive test result for COVID-19	1,053 (10.03)	1,053 (10.03)	661 (7.39)	661 (7.39)	44 (4.17)	44 (4.17)

Table 15.29.2 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	1,262,551 (50)	1,262,551 (50)	954,517 (50)	954,517 (50)	254,469 (50)	254,469 (50)
History of anaphylaxis	10,248 (0.81)	9,888 (0.78)	7,862 (0.82)	7,505 (0.79)	2,396 (0.94)	2,167 (0.85)
History of allergies	86,242 (6.83)	78,274 (6.2)	66,027 (6.92)	57,604 (6.03)	18,609 (7.31)	15,494 (6.09)
Diabetes mellitus (types 1 and 2)	82,460 (6.53)	84,985 (6.73)	60,590 (6.35)	63,607 (6.66)	12,216 (4.8)	12,465 (4.9)
Hypertension (CDC risk group)	125,123 (9.91)	119,868 (9.49)	89,895 (9.42)	84,938 (8.9)	16,396 (6.44)	15,039 (5.91)
Cardiovascular disease	488,320 (38.68)	477,741 (37.84)	360,759 (37.79)	349,028 (36.57)	80,698 (31.71)	77,014 (30.26)
Myocardial infarct	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Congestive heart failure	10,939 (0.87)	12,361 (0.98)	8,013 (0.84)	9,586 (1)	1,530 (0.6)	1,668 (0.66)
Cerebrovascular disease	29,889 (2.37)	31,375 (2.49)	21,760 (2.28)	23,634 (2.48)	3,817 (1.5)	4,069 (1.6)
Peripheral vascular disease	39,544 (3.13)	33,709 (2.67)	28,732 (3.01)	23,355 (2.45)	5,174 (2.03)	3,398 (1.34)
Chronic respiratory disease	253,649 (20.09)	248,648 (19.69)	191,182 (20.03)	187,149 (19.61)	48,563 (19.08)	47,726 (18.76)
Chronic kidney disease	31,770 (2.52)	30,390 (2.41)	23,154 (2.43)	21,436 (2.25)	4,148 (1.63)	3,484 (1.37)
Mild or moderate kidney disease	2,573 (0.2)	3,055 (0.24)	1,775 (0.19)	2,480 (0.26)	428 (0.17)	507 (0.2)
Chronic liver disease	1,002 (0.08)	1,164 (0.09)	748 (0.08)	973 (0.1)	178 (0.07)	216 (0.08)
Moderate or severe liver disease	12,990 (1.03)	12,548 (0.99)	9,597 (1.01)	9,013 (0.94)	2,394 (0.94)	2,188 (0.86)
Cancer any cancer diagnosis except non melanoma skin cancer	54,436 (4.31)	54,566 (4.32)	39,412 (4.13)	40,156 (4.21)	8,660 (3.4)	7,011 (2.76)
Leukemia	1,701 (0.13)	2,295 (0.18)	1,001 (0.1)	2,140 (0.22)	408 (0.16)	333 (0.13)
Lymphoma	1,087 (0.09)	1,414 (0.11)	645 (0.07)	1,238 (0.13)	258 (0.1)	244 (0.1)
Metastasis	4,719 (0.37)	5,367 (0.43)	3,535 (0.37)	4,363 (0.46)	911 (0.36)	740 (0.29)
Autoimmune disorders	107,078 (8.48)	97,116 (7.69)	79,460 (8.32)	69,753 (7.31)	18,735 (7.36)	15,502 (6.09)
Influenza infection or other respiratory infection	120,394 (9.54)	110,565 (8.76)	87,885 (9.21)	79,238 (8.3)	18,261 (7.18)	16,960 (6.66)
HIV/AIDS	2,492 (0.2)	3,230 (0.26)	1,854 (0.19)	2,530 (0.27)	706 (0.28)	813 (0.32)
Sickle Cell Disease (CDC risk group)	29 (<0.1)	52 (<0.1)	22 (<0.1)	35 (<0.1)	5 (<0.1)	12 (<0.1)

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Table 15.29.2 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Connective tissue disease	164,809 (13.05)	141,271 (11.19)	120,900 (12.67)	96,417 (10.1)	23,583 (9.27)	17,939 (7.05)
Charlson Comorbidity Index						
0	1,137,588 (90.1)	1,140,486 (90.33)	863,290 (90.44)	865,413 (90.67)	235,797 (92.66)	238,168 (93.59)
1	66,279 (5.25)	63,792 (5.05)	48,285 (5.06)	45,923 (4.81)	9,495 (3.73)	8,367 (3.29)
2	58,684 (4.65)	58,273 (4.62)	42,942 (4.5)	43,181 (4.52)	9,177 (3.61)	7,934 (3.12)
3 or more	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mean (SD)	0 (0.5)	0 (0.5)	0 (0.5)	0 (0.5)	0 (0.4)	0 (0.4)
Median (Q1,Q3)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Min, Max	0, 2	0, 2	0, 2	0, 2	0, 2	0, 2
CDC at-risk groupsb						
Group 0	537,799 (42.6)	537,799 (42.6)	412,567 (43.22)	412,567 (43.22)	122,265 (48.05)	122,265 (48.05)
Group 1	327,744 (25.96)	333,698 (26.43)	248,200 (26)	253,298 (26.54)	66,824 (26.26)	68,548 (26.94)
Group 2	397,008 (31.44)	391,054 (30.97)	293,750 (30.77)	288,652 (30.24)	65,380 (25.69)	63,656 (25.02)
Immunodeficiencies	2,447 (0.19)	2,284 (0.18)	1,793 (0.19)	1,794 (0.19)	493 (0.19)	428 (0.17)
Human immunodeficiency virus and other immunosuppressing conditions	241,677 (19.14)	241,677 (19.14)	178,680 (18.72)	178,680 (18.72)	42,789 (16.82)	42,789 (16.82)
Previous diagnosis of COVID-19	81,630 (6.47)	81,653 (6.47)	54,504 (5.71)	54,552 (5.72)	36,624 (14.39)	36,633 (14.4)
Positive test result for COVID-19	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.29.3 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,347,625 (50)	3,347,625 (50)	2,485,650 (50)	2,485,650 (50)	1,460,378 (50)	1,460,378 (50)
History of anaphylaxis	54,081 (1.62)	53,842 (1.61)	41,924 (1.69)	41,808 (1.68)	25,044 (1.71)	27,004 (1.85)
History of allergies	76,606 (2.29)	75,655 (2.26)	57,201 (2.3)	57,024 (2.29)	32,756 (2.24)	35,034 (2.4)
Diabetes mellitus (types 1 and 2)	226,936 (6.78)	199,652 (5.96)	213,421 (8.59)	208,725 (8.4)	162,715 (11.14)	183,134 (12.54)
Hypertension (CDC risk group)	611,087 (18.25)	600,871 (17.95)	564,229 (22.7)	554,298 (22.3)	425,770 (29.15)	419,886 (28.75)
Cardiovascular disease	1,355,641 (40.5)	1,350,164 (40.33)	1,172,761 (47.18)	1,169,995 (47.07)	812,318 (55.62)	813,342 (55.69)
Myocardial infarct	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Congestive heart failure	51,047 (1.52)	48,896 (1.46)	49,205 (1.98)	62,691 (2.52)	39,539 (2.71)	63,584 (4.35)
Cerebrovascular disease	107,386 (3.21)	101,953 (3.05)	101,535 (4.08)	106,372 (4.28)	79,116 (5.42)	86,641 (5.93)
Peripheral vascular disease	173,113 (5.17)	161,733 (4.83)	164,590 (6.62)	159,372 (6.41)	129,516 (8.87)	139,855 (9.58)
Chronic respiratory disease	756,427 (22.6)	741,875 (22.16)	594,624 (23.92)	592,177 (23.82)	372,281 (25.49)	397,633 (27.23)
Chronic kidney disease	6,509 (0.19)	4,769 (0.14)	5,981 (0.24)	4,907 (0.2)	4,028 (0.28)	4,264 (0.29)
Mild or moderate kidney disease	4,977 (0.15)	3,076 (0.09)	4,743 (0.19)	3,604 (0.14)	2,888 (0.2)	3,964 (0.27)
Chronic liver disease	25,836 (0.77)	29,346 (0.88)	21,561 (0.87)	32,468 (1.31)	12,964 (0.89)	24,075 (1.65)
Moderate or severe liver disease	49,863 (1.49)	51,364 (1.53)	42,767 (1.72)	51,806 (2.08)	27,571 (1.89)	39,329 (2.69)
Cancer any cancer diagnosis except non melanoma skin cancer	187,863 (5.61)	166,765 (4.98)	176,373 (7.1)	156,978 (6.32)	136,684 (9.36)	118,564 (8.12)
Leukemia	8,146 (0.24)	6,750 (0.2)	7,460 (0.3)	8,793 (0.35)	5,649 (0.39)	8,725 (0.6)
Lymphoma	12,173 (0.36)	10,325 (0.31)	11,369 (0.46)	12,053 (0.48)	8,617 (0.59)	8,810 (0.6)
Metastasis	20,881 (0.62)	17,680 (0.53)	19,967 (0.8)	18,775 (0.76)	15,388 (1.05)	13,966 (0.96)
Autoimmune disorders	631,641 (18.87)	598,180 (17.87)	535,015 (21.52)	514,182 (20.69)	349,567 (23.94)	353,198 (24.19)
Influenza infection or other respiratory infection	674,273 (20.14)	650,096 (19.42)	536,706 (21.59)	513,548 (20.66)	331,537 (22.7)	336,383 (23.03)
HIV/AIDS	7,006 (0.21)	7,427 (0.22)	5,457 (0.22)	7,415 (0.3)	2,921 (0.2)	5,454 (0.37)
Sickle Cell Disease (CDC risk group)	208 (0.01)	242 (0.01)	165 (0.01)	300 (0.01)	96 (0.01)	431 (0.03)

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Table 15.29.3 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Connective tissue disease	807,632 (24.13)	780,404 (23.31)	697,501 (28.06)	650,212 (26.16)	477,288 (32.68)	437,892 (29.98)
Charlson Comorbidity Index						
0	2,784,785 (83.19)	2,829,025 (84.51)	1,963,933 (79.01)	1,981,764 (79.73)	1,071,938 (73.4)	1,049,394 (71.86)
1	269,321 (8.05)	250,587 (7.49)	245,843 (9.89)	225,767 (9.08)	177,744 (12.17)	172,760 (11.83)
2	293,519 (8.77)	268,013 (8.01)	275,874 (11.1)	278,119 (11.19)	210,696 (14.43)	238,224 (16.31)
3 or more	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mean (SD)	0 (0.6)	0 (0.6)	0 (0.7)	0 (0.7)	0 (0.7)	0 (0.8)
Median (Q1,Q3)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 1)	0 (0, 1)
Min, Max	0, 2	0, 2	0, 2	0, 2	0, 2	0, 2
CDC at-risk groupsb						
Group 0	1,276,069 (38.12)	1,276,069 (38.12)	812,980 (32.71)	812,980 (32.71)	383,143 (26.24)	383,143 (26.24)
Group 1	881,341 (26.33)	904,300 (27.01)	619,526 (24.92)	639,626 (25.73)	328,303 (22.48)	334,116 (22.88)
Group 2	1,190,215 (35.55)	1,167,256 (34.87)	1,053,144 (42.37)	1,033,044 (41.56)	748,932 (51.28)	743,119 (50.89)
Immunodeficiencies	5,185 (0.15)	3,974 (0.12)	4,498 (0.18)	3,722 (0.15)	2,909 (0.2)	2,656 (0.18)
Human immunodeficiency virus and other immunosuppressing conditions	668,073 (19.96)	668,073 (19.96)	566,982 (22.81)	566,982 (22.81)	375,204 (25.69)	375,204 (25.69)
Previous diagnosis of COVID-19	4,516 (0.13)	4,088 (0.12)	2,790 (0.11)	2,610 (0.11)	1,423 (0.1)	2,414 (0.17)
Positive test result for COVID-19	71,194 (2.13)	71,434 (2.13)	45,334 (1.82)	45,656 (1.84)	29,642 (2.03)	29,677 (2.03)

Table 15.29.4 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	611,210 (50)	611,210 (50)	489,239 (50)	489,239 (50)	92,041 (50)	92,041 (50)
History of anaphylaxis	3,165 (0.52)	2,859 (0.47)	2,492 (0.51)	2,080 (0.43)	516 (0.56)	373 (0.41)
History of allergies	139,189 (22.77)	126,192 (20.65)	111,797 (22.85)	93,393 (19.09)	22,096 (24.01)	15,792 (17.16)
Diabetes mellitus (types 1 and 2)	39,062 (6.39)	42,133 (6.89)	28,023 (5.73)	33,051 (6.76)	5,754 (6.25)	6,538 (7.1)
Hypertension (CDC risk group)	76,467 (12.51)	79,590 (13.02)	56,871 (11.62)	61,681 (12.61)	11,890 (12.92)	12,974 (14.1)
Cardiovascular disease	168,793 (27.62)	162,456 (26.58)	124,340 (25.41)	114,081 (23.32)	26,446 (28.73)	22,685 (24.65)
Myocardial infarct	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Congestive heart failure	5,438 (0.89)	6,306 (1.03)	3,748 (0.77)	5,861 (1.2)	710 (0.77)	1,145 (1.24)
Cerebrovascular disease	6,800 (1.11)	6,906 (1.13)	5,099 (1.04)	6,011 (1.23)	980 (1.06)	1,339 (1.45)
Peripheral vascular disease	7,267 (1.19)	7,321 (1.2)	5,291 (1.08)	5,660 (1.16)	1,052 (1.14)	922 (1)
Chronic respiratory disease	68,855 (11.27)	69,445 (11.36)	49,384 (10.09)	50,788 (10.38)	9,588 (10.42)	9,277 (10.08)
Chronic kidney disease	9,811 (1.61)	9,868 (1.61)	6,812 (1.39)	7,457 (1.52)	1,473 (1.6)	1,389 (1.51)
Mild or moderate kidney disease	9,890 (1.62)	9,943 (1.63)	6,873 (1.4)	7,493 (1.53)	1,486 (1.61)	1,387 (1.51)
Chronic liver disease	2,000 (0.33)	2,275 (0.37)	1,468 (0.3)	2,018 (0.41)	324 (0.35)	415 (0.45)
Moderate or severe liver disease	2,536 (0.41)	2,884 (0.47)	1,974 (0.4)	2,365 (0.48)	369 (0.4)	349 (0.38)
Cancer any cancer diagnosis except non melanoma skin cancer	16,804 (2.75)	16,844 (2.76)	12,247 (2.5)	12,962 (2.65)	2,448 (2.66)	2,092 (2.27)
Leukemia	270 (0.04)	307 (0.05)	127 (0.03)	188 (0.04)	23 (0.02)	36 (0.04)
Lymphoma	456 (0.07)	511 (0.08)	262 (0.05)	387 (0.08)	58 (0.06)	72 (0.08)
Metastasis	1,491 (0.24)	1,697 (0.28)	1,076 (0.22)	1,586 (0.32)	315 (0.34)	225 (0.24)
Autoimmune disorders	33,802 (5.53)	33,151 (5.42)	25,056 (5.12)	24,366 (4.98)	5,126 (5.57)	4,388 (4.77)
Influenza infection or other respiratory infection	53,240 (8.71)	48,317 (7.91)	42,794 (8.75)	36,411 (7.44)	7,713 (8.38)	6,426 (6.98)
HIV/AIDS	56 (0.01)	59 (0.01)	36 (0.01)	53 (0.01)	<5	16 (0.02)
Sickle Cell Disease (CDC risk group)	51 (0.01)	86 (0.01)	35 (0.01)	92 (0.02)	6 (0.01)	9 (0.01)

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Table 15.29.4 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Connective tissue disease	272,473 (44.58)	250,658 (41.01)	216,948 (44.34)	184,717 (37.76)	46,940 (51)	34,534 (37.52)
Charlson Comorbidity Index						
0	539,799 (88.32)	538,154 (88.05)	437,181 (89.36)	433,836 (88.68)	81,498 (88.55)	81,934 (89.02)
1	43,575 (7.13)	44,182 (7.23)	32,148 (6.57)	32,798 (6.7)	6,517 (7.08)	6,213 (6.75)
2	27,836 (4.55)	28,874 (4.72)	19,910 (4.07)	22,605 (4.62)	4,026 (4.37)	3,894 (4.23)
3 or more	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mean (SD)	0 (0.5)	0 (0.5)	0 (0.5)	0 (0.5)	0 (0.5)	0 (0.5)
Median (Q1,Q3)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Min, Max	0, 2	0, 2	0, 2	0, 2	0, 2	0, 2
CDC at-risk groupsb						
Group 0	345,104 (56.46)	345,104 (56.46)	291,110 (59.5)	291,110 (59.5)	52,510 (57.05)	52,510 (57.05)
Group 1	112,822 (18.46)	113,397 (18.55)	86,224 (17.62)	87,083 (17.8)	16,225 (17.63)	16,810 (18.26)
Group 2	153,284 (25.08)	152,709 (24.98)	111,905 (22.87)	111,046 (22.7)	23,306 (25.32)	22,721 (24.69)
Immunodeficiencies	585 (0.1)	581 (0.1)	319 (0.07)	360 (0.07)	46 (0.05)	56 (0.06)
Human immunodeficiency virus and other immunosuppressing conditions	36,783 (6.02)	36,783 (6.02)	22,471 (4.59)	22,471 (4.59)	5,141 (5.59)	5,141 (5.59)
Previous diagnosis of COVID-19	2,550 (0.42)	2,925 (0.48)	1,033 (0.21)	1,325 (0.27)	187 (0.2)	579 (0.63)
Positive test result for COVID-19	49,791 (8.15)	49,776 (8.14)	20,617 (4.21)	20,621 (4.21)	12,344 (13.41)	12,338 (13.4)

Table 15.29.5 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,081,405 (50)	3,081,405 (50)	2,805,381 (50)	2,805,381 (50)	484,132 (50)	484,132 (50)
History of anaphylaxis	18,572 (0.6)	16,237 (0.53)	16,590 (0.59)	14,287 (0.51)	2,574 (0.53)	1,932 (0.4)
History of allergies	442,311 (14.35)	436,011 (14.15)	403,497 (14.38)	392,480 (13.99)	84,205 (17.39)	74,801 (15.45)
Diabetes mellitus (types 1 and 2)	247,873 (8.04)	257,957 (8.37)	241,869 (8.62)	267,274 (9.53)	89,049 (18.39)	92,289 (19.06)
Hypertension (CDC risk group)	417,487 (13.55)	415,978 (13.5)	408,123 (14.55)	410,873 (14.65)	153,303 (31.67)	142,617 (29.46)
Cardiovascular disease	974,814 (31.64)	960,293 (31.16)	942,250 (33.59)	919,198 (32.77)	294,990 (60.93)	285,452 (58.96)
Myocardial infarct	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Congestive heart failure	56,805 (1.84)	57,817 (1.88)	56,742 (2.02)	67,093 (2.39)	30,734 (6.35)	34,322 (7.09)
Cerebrovascular disease	68,160 (2.21)	66,025 (2.14)	67,574 (2.41)	71,935 (2.56)	32,666 (6.75)	31,518 (6.51)
Peripheral vascular disease	84,472 (2.74)	84,712 (2.75)	83,025 (2.96)	87,905 (3.13)	32,970 (6.81)	31,552 (6.52)
Chronic respiratory disease	810,953 (26.32)	810,940 (26.32)	737,685 (26.3)	737,118 (26.28)	173,009 (35.74)	170,502 (35.22)
Chronic kidney disease	120,516 (3.91)	118,409 (3.84)	120,271 (4.29)	123,488 (4.4)	61,729 (12.75)	59,714 (12.33)
Mild or moderate kidney disease	119,857 (3.89)	117,736 (3.82)	119,631 (4.26)	122,688 (4.37)	61,497 (12.7)	59,626 (12.32)
Chronic liver disease	83,495 (2.71)	89,064 (2.89)	80,123 (2.86)	89,936 (3.21)	21,925 (4.53)	22,237 (4.59)
Moderate or severe liver disease	6,674 (0.22)	7,696 (0.25)	6,449 (0.23)	8,504 (0.3)	2,326 (0.48)	2,416 (0.5)
Cancer any cancer diagnosis except non melanoma skin cancer	87,014 (2.82)	88,154 (2.86)	85,520 (3.05)	89,562 (3.19)	32,105 (6.63)	30,020 (6.2)
Leukemia	3,486 (0.11)	4,401 (0.14)	3,404 (0.12)	5,445 (0.19)	1,626 (0.34)	2,876 (0.59)
Lymphoma	3,766 (0.12)	4,842 (0.16)	3,683 (0.13)	6,404 (0.23)	1,595 (0.33)	2,566 (0.53)
Metastasis	8,956 (0.29)	10,097 (0.33)	8,822 (0.31)	12,066 (0.43)	3,252 (0.67)	4,063 (0.84)
Autoimmune disorders	189,326 (6.14)	189,486 (6.15)	182,359 (6.5)	190,177 (6.78)	59,901 (12.37)	57,723 (11.92)
Influenza infection or other respiratory infection	885,874 (28.75)	861,398 (27.95)	793,474 (28.28)	758,099 (27.02)	167,293 (34.56)	158,754 (32.79)
HIV/AIDS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sickle Cell Disease (CDC risk group)	864 (0.03)	1,354 (0.04)	700 (0.02)	1,375 (0.05)	105 (0.02)	146 (0.03)

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Table 15.29.5 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Connective tissue disease	1,042,573 (33.83)	1,029,551 (33.41)	974,461 (34.74)	932,726 (33.25)	236,954 (48.94)	210,648 (43.51)
Charlson Comorbidity Index						
0	2,578,385 (83.68)	2,571,034 (83.44)	2,317,814 (82.62)	2,295,848 (81.84)	304,305 (62.86)	310,185 (64.07)
1	264,152 (8.57)	269,156 (8.73)	251,567 (8.97)	251,897 (8.98)	73,898 (15.26)	71,460 (14.76)
2	238,868 (7.75)	241,215 (7.83)	236,000 (8.41)	257,636 (9.18)	105,929 (21.88)	102,487 (21.17)
3 or more	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mean (SD)	0 (0.6)	0 (0.6)	0 (0.6)	0 (0.6)	1 (0.8)	1 (0.8)
Median (Q1,Q3)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 1)	0 (0, 1)
Min, Max	0, 2	0, 2	0, 2	0, 2	0, 2	0, 2
CDC at-risk groupsb						
Group 0	1,348,120 (43.75)	1,348,120 (43.75)	1,203,074 (42.88)	1,203,074 (42.88)	118,671 (24.51)	118,671 (24.51)
Group 1	690,400 (22.41)	690,343 (22.4)	620,127 (22.1)	620,307 (22.11)	81,119 (16.76)	83,970 (17.34)
Group 2	1,042,885 (33.84)	1,042,942 (33.85)	982,180 (35.01)	982,000 (35)	284,342 (58.73)	281,491 (58.14)
Immunodeficiencies	21,603 (0.7)	23,116 (0.75)	19,457 (0.69)	22,172 (0.79)	4,840 (1)	4,885 (1.01)
Human immunodeficiency virus and other immunosuppressing conditions	613,398 (19.91)	613,398 (19.91)	557,216 (19.86)	557,216 (19.86)	130,872 (27.03)	130,872 (27.03)
Previous diagnosis of COVID-19	377,959 (12.27)	391,992 (12.72)	218,013 (7.77)	279,642 (9.97)	107,781 (22.26)	94,156 (19.45)
Positive test result for COVID-19	165,621 (5.37)	152,335 (4.94)	167,695 (5.98)	109,104 (3.89)	52,102 (10.76)	63,113 (13.04)

Table 15.29.6 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,231,856 (50)	3,231,856 (50)	2,912,712 (50)	2,912,712 (50)	1,393,951 (50)	1,393,951 (50)
History of anaphylaxis	42,784 (1.32)	40,278 (1.25)	40,552 (1.39)	33,117 (1.14)	24,955 (1.79)	18,483 (1.33)
History of allergies	439,020 (13.58)	420,144 (13)	398,943 (13.7)	368,462 (12.65)	198,035 (14.21)	176,002 (12.63)
Diabetes mellitus (types 1 and 2)	334,565 (10.35)	306,617 (9.49)	320,196 (10.99)	309,264 (10.62)	233,283 (16.74)	230,869 (16.56)
Hypertension (CDC risk group)	314,430 (9.73)	302,952 (9.37)	303,772 (10.43)	285,723 (9.81)	236,114 (16.94)	220,998 (15.85)
Cardiovascular disease	1,134,546 (35.11)	1,133,491 (35.07)	1,032,765 (35.46)	1,043,634 (35.83)	582,351 (41.78)	588,502 (42.22)
Myocardial infarct	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Congestive heart failure	14,541 (0.45)	13,064 (0.4)	14,087 (0.48)	14,321 (0.49)	11,486 (0.82)	11,612 (0.83)
Cerebrovascular disease	31,759 (0.98)	29,282 (0.91)	30,582 (1.05)	31,914 (1.1)	24,309 (1.74)	26,440 (1.9)
Peripheral vascular disease	7,581 (0.23)	6,964 (0.22)	7,284 (0.25)	7,308 (0.25)	5,967 (0.43)	6,397 (0.46)
Chronic respiratory disease	1,420,684 (43.96)	1,413,943 (43.75)	1,289,592 (44.27)	1,264,015 (43.4)	662,762 (47.55)	639,926 (45.91)
Chronic kidney disease	53,279 (1.65)	47,477 (1.47)	51,715 (1.78)	47,050 (1.62)	42,350 (3.04)	37,889 (2.72)
Mild or moderate kidney disease	44,988 (1.39)	40,099 (1.24)	43,867 (1.51)	39,133 (1.34)	36,310 (2.6)	31,968 (2.29)
Chronic liver disease	9,250 (0.29)	9,268 (0.29)	8,808 (0.3)	10,982 (0.38)	6,427 (0.46)	8,914 (0.64)
Moderate or severe liver disease	192,981 (5.97)	225,616 (6.98)	174,371 (5.99)	238,975 (8.2)	92,169 (6.61)	142,601 (10.23)
Cancer any cancer diagnosis except non melanoma skin cancer	80,810 (2.5)	67,887 (2.1)	77,726 (2.67)	58,808 (2.02)	61,744 (4.43)	44,211 (3.17)
Leukemia	2,765 (0.09)	1,966 (0.06)	2,517 (0.09)	2,400 (0.08)	1,951 (0.14)	1,514 (0.11)
Lymphoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Metastasis	1,311 (0.04)	1,003 (0.03)	1,307 (0.04)	1,190 (0.04)	1,162 (0.08)	800 (0.06)
Autoimmune disorders	215,010 (6.65)	192,591 (5.96)	204,177 (7.01)	175,244 (6.02)	138,411 (9.93)	118,342 (8.49)
Influenza infection or other respiratory infection	226,074 (7)	219,237 (6.78)	198,593 (6.82)	189,937 (6.52)	106,803 (7.66)	100,178 (7.19)
HIV/AIDS	3,509 (0.11)	3,089 (0.1)	3,345 (0.11)	3,858 (0.13)	2,591 (0.19)	3,224 (0.23)
Sickle Cell Disease (CDC risk group)	3,650 (0.11)	4,681 (0.14)	3,208 (0.11)	5,491 (0.19)	1,393 (0.1)	3,158 (0.23)

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Table 15.29.6 Comorbidities at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Connective tissue disease	223,919 (6.93)	209,495 (6.48)	214,844 (7.38)	180,905 (6.21)	163,534 (11.73)	133,048 (9.54)
Charlson Comorbidity Index						
0	2,644,212 (81.82)	2,659,295 (82.28)	2,363,305 (81.14)	2,350,415 (80.7)	1,039,864 (74.6)	1,028,322 (73.77)
1	236,218 (7.31)	212,432 (6.57)	221,898 (7.62)	190,147 (6.53)	140,840 (10.1)	118,112 (8.47)
2	351,426 (10.87)	360,129 (11.14)	327,509 (11.24)	372,150 (12.78)	213,247 (15.3)	247,517 (17.76)
3 or more	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Mean (SD)	0 (0.7)	0 (0.7)	0 (0.7)	0 (0.7)	0 (0.7)	0 (0.8)
Median (Q1,Q3)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 1)	0 (0, 1)
Min, Max	0, 2	0, 2	0, 2	0, 2	0, 2	0, 2
CDC at-risk groupsb						
Group 0	1,021,541 (31.61)	1,021,541 (31.61)	900,443 (30.91)	900,443 (30.91)	359,066 (25.76)	359,066 (25.76)
Group 1	942,608 (29.17)	946,324 (29.28)	840,547 (28.86)	847,279 (29.09)	358,562 (25.72)	364,167 (26.12)
Group 2	1,267,707 (39.23)	1,263,991 (39.11)	1,171,722 (40.23)	1,164,990 (40)	676,323 (48.52)	670,718 (48.12)
Immunodeficiencies	878 (0.03)	528 (0.02)	795 (0.03)	497 (0.02)	554 (0.04)	331 (0.02)
Human immunodeficiency virus and other immunosuppressing conditions	530,256 (16.41)	530,256 (16.41)	483,143 (16.59)	483,143 (16.59)	274,363 (19.68)	274,363 (19.68)
Previous diagnosis of COVID-19	401,170 (12.41)	401,166 (12.41)	448,109 (15.38)	448,106 (15.38)	211,092 (15.14)	211,091 (15.14)
Positive test result for COVID-19	372,179 (11.52)	374,023 (11.57)	420,534 (14.44)	419,396 (14.4)	193,900 (13.91)	191,657 (13.75)

Table 15.30.1 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PediaNet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	10,500 (50)	10,500 (50)	8,944 (50)	8,944 (50)	1,055 (50)	1,055 (50)
Wheelchair use	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paralysis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Hemiplegia	7 (0.07)	12 (0.11)	7 (0.08)	12 (0.13)	<5	0 (0)
Parkinson's disease	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin ulcer	<5	<5	0 (0)	<5	0 (0)	0 (0)
Weakness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Stroke/brain injury	64 (0.61)	69 (0.66)	56 (0.63)	45 (0.5)	10 (0.95)	6 (0.57)
Ambulance transport	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dementia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Difficulty walking	8 (0.08)	8 (0.08)	7 (0.08)	8 (0.09)	0 (0)	<5
Home oxygen	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric illness	118 (1.12)	89 (0.85)	98 (1.1)	74 (0.83)	22 (2.09)	7 (0.66)
Sepsis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Heart failure	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Podiatric care	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder incontinence	32 (0.3)	28 (0.27)	24 (0.27)	32 (0.36)	<5	9 (0.85)
Diabetes complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Arthritis	132 (1.26)	132 (1.26)	111 (1.24)	99 (1.11)	14 (1.33)	14 (1.33)
Coagulation deficiencies	<5	<5	0 (0)	<5	0 (0)	<5

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Table 15.30.1 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for Pedianet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Vertigo	24 (0.23)	16 (0.15)	21 (0.23)	15 (0.17)	<5	5 (0.47)
Lipid abnormalities	0 (0)	<5	0 (0)	<5	0 (0)	0 (0)

Table 15.30.2 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	1,262,551 (50)	1,262,551 (50)	954,517 (50)	954,517 (50)	254,469 (50)	254,469 (50)
Wheelchair use	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paralysis	6,168 (0.49)	6,191 (0.49)	4,700 (0.49)	4,701 (0.49)	1,097 (0.43)	1,042 (0.41)
Hemiplegia	1,603 (0.13)	1,912 (0.15)	1,232 (0.13)	1,515 (0.16)	275 (0.11)	310 (0.12)
Parkinson's disease	3,501 (0.28)	3,589 (0.28)	2,548 (0.27)	2,730 (0.29)	445 (0.17)	411 (0.16)
Skin ulcer	9,561 (0.76)	10,060 (0.8)	7,051 (0.74)	7,705 (0.81)	1,479 (0.58)	1,347 (0.53)
Weakness	22,220 (1.76)	15,848 (1.26)	17,045 (1.79)	11,059 (1.16)	4,932 (1.94)	2,841 (1.12)
Stroke/brain injury	29,793 (2.36)	31,263 (2.48)	21,697 (2.27)	23,567 (2.47)	3,811 (1.5)	4,063 (1.6)
Ambulance transport	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dementia	1,461 (0.12)	1,606 (0.13)	1,098 (0.12)	1,324 (0.14)	187 (0.07)	219 (0.09)
Difficulty walking	186 (0.01)	176 (0.01)	142 (0.01)	149 (0.02)	32 (0.01)	33 (0.01)
Home oxygen	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric illness	121,802 (9.65)	117,570 (9.31)	91,282 (9.56)	86,711 (9.08)	24,765 (9.73)	23,149 (9.1)
Sepsis	4,229 (0.33)	3,198 (0.25)	3,222 (0.34)	2,044 (0.21)	773 (0.3)	433 (0.17)
Heart failure	10,939 (0.87)	12,361 (0.98)	8,013 (0.84)	9,586 (1)	1,530 (0.6)	1,668 (0.66)
Podiatric care	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder incontinence	3,445 (0.27)	2,689 (0.21)	2,538 (0.27)	1,826 (0.19)	642 (0.25)	365 (0.14)
Diabetes complications	8,343 (0.66)	8,195 (0.65)	6,258 (0.66)	5,882 (0.62)	1,244 (0.49)	1,100 (0.43)
Arthritis	148,257 (11.74)	127,706 (10.11)	108,549 (11.37)	87,010 (9.12)	20,374 (8.01)	15,855 (6.23)
Coagulation deficiencies	957 (0.08)	746 (0.06)	744 (0.08)	539 (0.06)	221 (0.09)	108 (0.04)

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Table 15.30.2 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Vertigo	19,449 (1.54)	13,357 (1.06)	14,743 (1.54)	8,427 (0.88)	3,463 (1.36)	1,733 (0.68)
Lipid abnormalities	72,277 (5.72)	63,600 (5.04)	51,931 (5.44)	43,160 (4.52)	9,468 (3.72)	7,644 (3)

Table 15.30.3 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,347,625 (50)	3,347,625 (50)	2,485,650 (50)	2,485,650 (50)	1,460,378 (50)	1,460,378 (50)
Wheelchair use	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paralysis	6,412 (0.19)	5,898 (0.18)	5,593 (0.23)	5,554 (0.22)	3,847 (0.26)	3,958 (0.27)
Hemiplegia	10 (<0.1)	<5	10 (<0.1)	6 (<0.1)	7 (<0.1)	0 (0)
Parkinson's disease	8,900 (0.27)	7,124 (0.21)	8,687 (0.35)	7,501 (0.3)	7,064 (0.48)	7,627 (0.52)
Skin ulcer	96,140 (2.87)	92,297 (2.76)	78,613 (3.16)	79,019 (3.18)	54,680 (3.74)	56,624 (3.88)
Weakness	111,468 (3.33)	110,125 (3.29)	83,379 (3.35)	88,514 (3.56)	45,579 (3.12)	52,444 (3.59)
Stroke/brain injury	107,386 (3.21)	101,953 (3.05)	101,535 (4.08)	106,372 (4.28)	79,116 (5.42)	86,641 (5.93)
Ambulance transport	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dementia	8,281 (0.25)	6,244 (0.19)	8,138 (0.33)	10,625 (0.43)	6,714 (0.46)	10,677 (0.73)
Difficulty walking	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Home oxygen	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric illness	550,277 (16.44)	570,267 (17.03)	424,613 (17.08)	508,163 (20.44)	245,561 (16.81)	338,979 (23.21)
Sepsis	17,451 (0.52)	16,174 (0.48)	15,817 (0.64)	15,497 (0.62)	11,409 (0.78)	11,806 (0.81)
Heart failure	51,047 (1.52)	48,896 (1.46)	49,205 (1.98)	62,691 (2.52)	39,539 (2.71)	63,584 (4.35)
Podiatric care	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder incontinence	21,339 (0.64)	19,850 (0.59)	18,367 (0.74)	17,717 (0.71)	13,184 (0.9)	13,352 (0.91)
Diabetes complications	28,673 (0.86)	21,671 (0.65)	27,045 (1.09)	22,512 (0.91)	19,143 (1.31)	21,259 (1.46)
Arthritis	742,081 (22.17)	717,919 (21.45)	645,622 (25.97)	602,189 (24.23)	445,909 (30.53)	407,313 (27.89)
Coagulation deficiencies	3,938 (0.12)	3,664 (0.11)	3,431 (0.14)	3,783 (0.15)	2,301 (0.16)	3,316 (0.23)

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Table 15.30.3 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Vertigo	72,759 (2.17)	70,880 (2.12)	60,037 (2.42)	57,944 (2.33)	38,429 (2.63)	35,865 (2.46)
Lipid abnormalities	277,066 (8.28)	264,228 (7.89)	251,408 (10.11)	216,880 (8.73)	183,220 (12.55)	154,503 (10.58)

Table 15.30.4 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	611,210 (50)	611,210 (50)	489,239 (50)	489,239 (50)	92,041 (50)	92,041 (50)
Wheelchair use	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paralysis	2,279 (0.37)	2,104 (0.34)	1,823 (0.37)	1,739 (0.36)	349 (0.38)	310 (0.34)
Hemiplegia	1,636 (0.27)	1,517 (0.25)	1,321 (0.27)	1,202 (0.25)	257 (0.28)	189 (0.21)
Parkinson's disease	1,283 (0.21)	1,153 (0.19)	921 (0.19)	753 (0.15)	159 (0.17)	85 (0.09)
Skin ulcer	2,242 (0.37)	2,025 (0.33)	1,713 (0.35)	1,923 (0.39)	333 (0.36)	522 (0.57)
Weakness	1,007 (0.16)	1,058 (0.17)	747 (0.15)	915 (0.19)	148 (0.16)	113 (0.12)
Stroke/brain injury	4,642 (0.76)	4,777 (0.78)	3,526 (0.72)	4,216 (0.86)	705 (0.77)	882 (0.96)
Ambulance transport	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dementia	660 (0.11)	619 (0.1)	497 (0.1)	807 (0.16)	90 (0.1)	111 (0.12)
Difficulty walking	285 (0.05)	276 (0.05)	226 (0.05)	205 (0.04)	46 (0.05)	30 (0.03)
Home oxygen	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric illness	148,783 (24.34)	140,853 (23.04)	121,070 (24.75)	109,579 (22.4)	24,402 (26.51)	20,570 (22.35)
Sepsis	715 (0.12)	831 (0.14)	513 (0.1)	886 (0.18)	96 (0.1)	123 (0.13)
Heart failure	5,438 (0.89)	6,306 (1.03)	3,748 (0.77)	5,861 (1.2)	710 (0.77)	1,145 (1.24)
Podiatric care	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder incontinence	2,420 (0.4)	2,309 (0.38)	1,813 (0.37)	1,997 (0.41)	378 (0.41)	311 (0.34)
Diabetes complications	2,840 (0.46)	3,242 (0.53)	1,950 (0.4)	2,894 (0.59)	399 (0.43)	562 (0.61)
Arthritis	198,360 (32.45)	182,211 (29.81)	156,799 (32.05)	133,522 (27.29)	34,200 (37.16)	25,017 (27.18)
Coagulation deficiencies	1,137 (0.19)	1,224 (0.2)	785 (0.16)	926 (0.19)	157 (0.17)	212 (0.23)

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Table 15.30.4 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Vertigo	2,752 (0.45)	2,640 (0.43)	2,169 (0.44)	1,936 (0.4)	428 (0.47)	324 (0.35)
Lipid abnormalities	25,929 (4.24)	25,745 (4.21)	19,378 (3.96)	19,324 (3.95)	4,374 (4.75)	3,418 (3.71)

Table 15.30.5 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,081,405 (50)	3,081,405 (50)	2,805,381 (50)	2,805,381 (50)	484,132 (50)	484,132 (50)
Wheelchair use	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Home hospital bed	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paralysis	16,171 (0.52)	14,233 (0.46)	15,821 (0.56)	17,459 (0.62)	6,983 (1.44)	7,171 (1.48)
Hemiplegia	14,351 (0.47)	12,641 (0.41)	13,986 (0.5)	15,365 (0.55)	5,804 (1.2)	5,859 (1.21)
Parkinson's disease	10,413 (0.34)	9,300 (0.3)	10,452 (0.37)	10,133 (0.36)	6,048 (1.25)	5,197 (1.07)
Skin ulcer	12,781 (0.41)	10,065 (0.33)	12,777 (0.46)	12,863 (0.46)	8,720 (1.8)	7,904 (1.63)
Weakness	39,899 (1.29)	39,172 (1.27)	36,218 (1.29)	35,909 (1.28)	8,126 (1.68)	6,564 (1.36)
Stroke/brain injury	67,810 (2.2)	65,651 (2.13)	67,226 (2.4)	71,629 (2.55)	32,505 (6.71)	31,408 (6.49)
Ambulance transport	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dementia	12,620 (0.41)	10,628 (0.34)	12,842 (0.46)	13,120 (0.47)	8,833 (1.82)	6,542 (1.35)
Difficulty walking	5,392 (0.17)	5,121 (0.17)	5,249 (0.19)	5,689 (0.2)	3,059 (0.63)	2,597 (0.54)
Home oxygen	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Rehabilitation care	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric illness	830,742 (26.96)	844,186 (27.4)	775,057 (27.63)	792,459 (28.25)	160,722 (33.2)	158,573 (32.75)
Sepsis	3,422 (0.11)	3,727 (0.12)	3,235 (0.12)	5,605 (0.2)	1,609 (0.33)	1,376 (0.28)
Heart failure	56,805 (1.84)	57,817 (1.88)	56,742 (2.02)	67,093 (2.39)	30,734 (6.35)	34,322 (7.09)
Podiatric care	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder incontinence	27,420 (0.89)	24,753 (0.8)	27,347 (0.97)	26,880 (0.96)	16,286 (3.36)	12,570 (2.6)
Diabetes complications	48,162 (1.56)	50,065 (1.62)	47,295 (1.69)	57,464 (2.05)	21,013 (4.34)	22,398 (4.63)
Arthritis	785,437 (25.49)	780,783 (25.34)	743,532 (26.5)	716,192 (25.53)	201,268 (41.57)	177,199 (36.6)
Coagulation deficiencies	2,371 (0.08)	2,234 (0.07)	2,144 (0.08)	2,506 (0.09)	524 (0.11)	297 (0.06)

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Table 15.30.5 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Vertigo	69,537 (2.26)	66,912 (2.17)	65,995 (2.35)	59,512 (2.12)	19,414 (4.01)	13,104 (2.71)
Lipid abnormalities	266,185 (8.64)	264,079 (8.57)	259,204 (9.24)	254,953 (9.09)	92,977 (19.2)	79,858 (16.5)

Table 15.30.6 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,231,856 (50)	3,231,856 (50)	2,912,712 (50)	2,912,712 (50)	1,393,951 (50)	1,393,951 (50)
Wheelchair use	432 (0.01)	516 (0.02)	436 (0.01)	519 (0.02)	365 (0.03)	383 (0.03)
Home hospital bed	<5	5 (<0.1)	<5	<5	<5	0 (0)
Paralysis	3,751 (0.12)	3,538 (0.11)	3,491 (0.12)	3,564 (0.12)	2,354 (0.17)	2,363 (0.17)
Hemiplegia	1,976 (0.06)	1,696 (0.05)	1,775 (0.06)	1,754 (0.06)	1,078 (0.08)	948 (0.07)
Parkinson's disease	3,397 (0.11)	3,082 (0.1)	3,214 (0.11)	2,498 (0.09)	2,760 (0.2)	1,942 (0.14)
Skin ulcer	7,958 (0.25)	7,770 (0.24)	7,635 (0.26)	8,396 (0.29)	5,891 (0.42)	6,242 (0.45)
Weakness	14,618 (0.45)	12,347 (0.38)	14,589 (0.5)	11,209 (0.38)	8,954 (0.64)	6,284 (0.45)
Stroke/brain injury	32,659 (1.01)	30,201 (0.93)	31,468 (1.08)	32,846 (1.13)	24,973 (1.79)	27,135 (1.95)
Ambulance transport	408 (0.01)	431 (0.01)	354 (0.01)	508 (0.02)	206 (0.01)	148 (0.01)
Dementia	4,098 (0.13)	4,370 (0.14)	3,594 (0.12)	4,311 (0.15)	3,156 (0.23)	3,163 (0.23)
Difficulty walking	1,578 (0.05)	1,738 (0.05)	1,465 (0.05)	1,623 (0.06)	1,215 (0.09)	1,115 (0.08)
Home oxygen	242 (0.01)	263 (0.01)	222 (0.01)	210 (0.01)	212 (0.02)	234 (0.02)
Rehabilitation care	1,349 (0.04)	1,030 (0.03)	1,118 (0.04)	781 (0.03)	1,110 (0.08)	664 (0.05)
Psychiatric illness	417,673 (12.92)	404,083 (12.5)	391,301 (13.43)	389,341 (13.37)	213,090 (15.29)	219,087 (15.72)
Sepsis	2,181 (0.07)	2,155 (0.07)	1,882 (0.06)	2,627 (0.09)	1,217 (0.09)	1,430 (0.1)
Heart failure	14,541 (0.45)	13,064 (0.4)	14,087 (0.48)	14,321 (0.49)	11,486 (0.82)	11,612 (0.83)
Podiatric care	22,623 (0.7)	19,213 (0.59)	21,623 (0.74)	15,866 (0.54)	16,509 (1.18)	9,639 (0.69)
Bladder incontinence	6,029 (0.19)	5,789 (0.18)	5,834 (0.2)	5,418 (0.19)	4,389 (0.31)	3,601 (0.26)
Diabetes complications	73,883 (2.29)	63,522 (1.97)	71,879 (2.47)	70,888 (2.43)	57,457 (4.12)	57,575 (4.13)
Arthritis	281,268 (8.7)	261,192 (8.08)	268,034 (9.2)	224,609 (7.71)	194,003 (13.92)	156,804 (11.25)
Coagulation deficiencies	1,879 (0.06)	1,428 (0.04)	1,808 (0.06)	1,264 (0.04)	1,051 (0.08)	630 (0.05)

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Table 15.30.6 Surrogates of frailty at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
Vertigo	33,263 (1.03)	29,282 (0.91)	32,126 (1.1)	23,956 (0.82)	19,858 (1.42)	12,655 (0.91)
Lipid abnormalities	36,290 (1.12)	33,885 (1.05)	35,022 (1.2)	30,915 (1.06)	26,466 (1.9)	22,139 (1.59)

Table 15.31.1 Vaccination history at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for Pedianet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	10,500 (50)	10,500 (50)	8,944 (50)	8,944 (50)	1,055 (50)	1,055 (50)
Influenza	1,981 (18.87)	1,981 (18.87)	1,661 (18.57)	1,661 (18.57)	167 (15.83)	167 (15.83)
Pneumococcal	5,275 (50.24)	5,253 (50.03)	4,252 (47.54)	4,227 (47.26)	26 (2.46)	91 (8.63)
DTP (diphtheria, tetanus, and pertussis)	2,696 (25.68)	2,575 (24.52)	2,239 (25.03)	2,184 (24.42)	<5	16 (1.52)
TPV (polio)	8,683 (82.7)	8,565 (81.57)	7,332 (81.98)	7,211 (80.62)	745 (70.62)	579 (54.88)
TV (MMR) (measles, mumps, and rubella)	7 (0.07)	7 (0.07)	<5	6 (0.07)	0 (0)	0 (0)
Hib (Haemophilus influenzae type b)	4,609 (43.9)	4,736 (45.1)	3,737 (41.78)	3,858 (43.14)	<5	24 (2.27)
HBV (hepatitis B virus)	54 (0.51)	206 (1.96)	45 (0.5)	160 (1.79)	<5	9 (0.85)
VZV (varicella-zoster virus)	8,310 (79.14)	8,025 (76.43)	7,004 (78.31)	6,700 (74.91)	687 (65.12)	533 (50.52)
HPV (human papillomavirus)	98 (0.93)	50 (0.48)	89 (1)	62 (0.69)	87 (8.25)	33 (3.13)
Meningitis	5,523 (52.6)	5,302 (50.5)	4,542 (50.78)	4,249 (47.51)	162 (15.36)	93 (8.82)
Rotavirus	496 (4.72)	534 (5.09)	388 (4.34)	393 (4.39)	0 (0)	0 (0)

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Table 15.31.2 Vaccination history at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	1,262,551 (50)	1,262,551 (50)	954,517 (50)	954,517 (50)	254,469 (50)	254,469 (50)
Influenza	60,596 (4.8)	60,596 (4.8)	37,092 (3.89)	37,092 (3.89)	18,195 (7.15)	18,195 (7.15)
Pneumococcal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
DTP (diphtheria, tetanus, and pertussis)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
TPV (polio)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
TV (MMR) (measles, mumps, and rubella)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Hib (Haemophilus influenzae type b)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HBV (hepatitis B virus)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
VZV (varicella-zoster virus)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HPV (human papillomavirus)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Meningitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Rotavirus	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 15.31.3 Vaccination history at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,347,625 (50)	3,347,625 (50)	2,485,650 (50)	2,485,650 (50)	1,460,378 (50)	1,460,378 (50)
Influenza	922,540 (27.56)	922,540 (27.56)	813,215 (32.72)	813,215 (32.72)	688,149 (47.12)	688,149 (47.12)
Pneumococcal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
DTP (diphtheria, tetanus, and pertussis)	22,823 (0.68)	29,541 (0.88)	12,372 (0.5)	12,264 (0.49)	6,550 (0.45)	6,357 (0.44)
TPV (polio)	23,000 (0.69)	29,698 (0.89)	12,521 (0.5)	12,421 (0.5)	6,658 (0.46)	6,551 (0.45)
TV (MMR) (measles, mumps, and rubella)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Hib (Haemophilus influenzae type b)	25,287 (0.76)	31,519 (0.94)	14,703 (0.59)	14,287 (0.57)	8,548 (0.59)	8,553 (0.59)
HBV (hepatitis B virus)	131,477 (3.93)	125,947 (3.76)	94,340 (3.8)	87,917 (3.54)	50,096 (3.43)	44,967 (3.08)
VZV (varicella-zoster virus)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HPV (human papillomavirus)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Meningitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Rotavirus	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

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Table 15.31.4 Vaccination history at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	611,210 (50)	611,210 (50)	489,239 (50)	489,239 (50)	92,041 (50)	92,041 (50)
Influenza	127,957 (20.94)	127,957 (20.94)	79,314 (16.21)	79,314 (16.21)	11,388 (12.37)	11,388 (12.37)
Pneumococcal	40,803 (6.68)	36,987 (6.05)	26,200 (5.36)	20,112 (4.11)	2,905 (3.16)	1,781 (1.94)
DTP (diphtheria, tetanus, and pertussis)	170,140 (27.84)	151,255 (24.75)	129,247 (26.42)	104,584 (21.38)	18,074 (19.64)	12,283 (13.35)
TPV (polio)	1,720 (0.28)	2,312 (0.38)	1,281 (0.26)	1,983 (0.41)	89 (0.1)	98 (0.11)
TV (MMR) (measles, mumps, and rubella)	69,859 (11.43)	63,834 (10.44)	49,051 (10.03)	42,012 (8.59)	1,913 (2.08)	1,206 (1.31)
Hib (Haemophilus influenzae type b)	747 (0.12)	775 (0.13)	462 (0.09)	532 (0.11)	72 (0.08)	67 (0.07)
HBV (hepatitis B virus)	20,392 (3.34)	18,505 (3.03)	13,810 (2.82)	12,134 (2.48)	978 (1.06)	805 (0.87)
VZV (varicella-zoster virus)	28,449 (4.65)	23,644 (3.87)	19,870 (4.06)	14,440 (2.95)	712 (0.77)	470 (0.51)
HPV (human papillomavirus)	35,046 (5.73)	27,761 (4.54)	29,276 (5.98)	19,527 (3.99)	3,344 (3.63)	1,857 (2.02)
Meningitis	97,602 (15.97)	81,125 (13.27)	73,645 (15.05)	52,996 (10.83)	4,806 (5.22)	2,600 (2.82)
Rotavirus	9,725 (1.59)	7,439 (1.22)	6,018 (1.23)	3,667 (0.75)	29 (0.03)	15 (0.02)

Table 15.31.5 Vaccination history at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,081,405 (50)	3,081,405 (50)	2,805,381 (50)	2,805,381 (50)	484,132 (50)	484,132 (50)
Influenza	817,436 (26.53)	817,436 (26.53)	784,314 (27.96)	784,314 (27.96)	279,190 (57.67)	279,190 (57.67)
Pneumococcal	290,401 (9.42)	282,635 (9.17)	261,104 (9.31)	251,169 (8.95)	71,586 (14.79)	75,208 (15.53)
DTP (diphtheria, tetanus, and pertussis)	384,137 (12.47)	381,431 (12.38)	303,440 (10.82)	301,596 (10.75)	16,231 (3.35)	18,788 (3.88)
TPV (polio)	115,530 (3.75)	120,213 (3.9)	79,372 (2.83)	86,520 (3.08)	1,802 (0.37)	2,168 (0.45)
TV (MMR) (measles, mumps, and rubella)	252,321 (8.19)	269,476 (8.75)	185,139 (6.6)	206,643 (7.37)	9,352 (1.93)	8,020 (1.66)
Hib (Haemophilus influenzae type b)	105,325 (3.42)	105,626 (3.43)	70,988 (2.53)	72,104 (2.57)	1,173 (0.24)	997 (0.21)
HBV (hepatitis B virus)	107,617 (3.49)	110,774 (3.59)	79,654 (2.84)	84,849 (3.02)	6,508 (1.34)	5,249 (1.08)
VZV (varicella-zoster virus)	<5	0 (0)	<5	0 (0)	0 (0)	0 (0)
HPV (human papillomavirus)	23 (<0.1)	17 (<0.1)	19 (<0.1)	9 (<0.1)	5 (<0.1)	0 (0)
Meningitis	459,214 (14.9)	423,597 (13.75)	386,685 (13.78)	337,860 (12.04)	24,196 (5)	18,851 (3.89)
Rotavirus	28,144 (0.91)	20,449 (0.66)	19,134 (0.68)	12,151 (0.43)	45 (0.01)	37 (0.01)

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Table 15.31.6 Vaccination history at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,231,856 (50)	3,231,856 (50)	2,912,712 (50)	2,912,712 (50)	1,393,951 (50)	1,393,951 (50)
Influenza	1,149,902 (35.58)	1,149,902 (35.58)	1,095,779 (37.62)	1,095,779 (37.62)	631,503 (45.3)	631,503 (45.3)
Pneumococcal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
DTP (diphtheria, tetanus, and pertussis)	1,018,692 (31.52)	909,238 (28.13)	879,861 (30.21)	723,408 (24.84)	356,689 (25.59)	258,804 (18.57)
TPV (polio)	1,201,324 (37.17)	1,060,706 (32.82)	1,025,022 (35.19)	826,312 (28.37)	388,857 (27.9)	263,625 (18.91)
TV (MMR) (measles, mumps, and rubella)	450,891 (13.95)	445,411 (13.78)	337,354 (11.58)	341,992 (11.74)	75,776 (5.44)	63,854 (4.58)
Hib (Haemophilus influenzae type b)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HBV (hepatitis B virus)	144,919 (4.48)	115,176 (3.56)	129,023 (4.43)	93,529 (3.21)	61,776 (4.43)	37,480 (2.69)
VZV (varicella-zoster virus)	6,742 (0.21)	5,427 (0.17)	5,293 (0.18)	4,165 (0.14)	1,380 (0.1)	924 (0.07)
HPV (human papillomavirus)	334,897 (10.36)	279,979 (8.66)	293,989 (10.09)	219,847 (7.55)	76,238 (5.47)	56,619 (4.06)
Meningitis	691,905 (21.41)	598,888 (18.53)	595,747 (20.45)	454,129 (15.59)	200,866 (14.41)	128,742 (9.24)
Rotavirus	57,199 (1.77)	58,371 (1.81)	38,301 (1.31)	38,992 (1.34)	1,505 (0.11)	1,562 (0.11)

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Table 15.32.1 Comedications at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PediaNet

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	10,500 (50)	10,500 (50)	8,944 (50)	8,944 (50)	1,055 (50)	1,055 (50)
Analgesics	19 (0.18)	25 (0.24)	21 (0.23)	32 (0.36)	<5	<5
Antibiotics	1,049 (9.99)	1,179 (11.23)	874 (9.77)	1,005 (11.24)	93 (8.82)	88 (8.34)
Antiviral medications	25 (0.24)	28 (0.27)	23 (0.26)	25 (0.28)	<5	<5
Corticosteroids	3,018 (28.74)	3,031 (28.87)	2,512 (28.09)	2,526 (28.24)	266 (25.21)	270 (25.59)
Non-steroidal anti-inflammatory drugs	113 (1.08)	159 (1.51)	104 (1.16)	135 (1.51)	20 (1.9)	18 (1.71)
Psychotropics	61 (0.58)	65 (0.62)	49 (0.55)	58 (0.65)	<5	12 (1.14)
Statins	0 (0)	0 (0)	0 (0)	<5	0 (0)	0 (0)
Novel oral anticoagulants	<5	7 (0.07)	0 (0)	5 (0.06)	0 (0)	0 (0)
Warfarin	<5	6 (0.06)	<5	0 (0)	<5	0 (0)

Table 15.32.2 Comedications at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for PHARMO

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	1,262,551 (50)	1,262,551 (50)	954,517 (50)	954,517 (50)	254,469 (50)	254,469 (50)
Analgesics	101,895 (8.07)	77,486 (6.14)	76,106 (7.97)	50,130 (5.25)	19,814 (7.79)	10,623 (4.17)
Antibiotics	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Antiviral medications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Corticosteroids	227,444 (18.01)	226,940 (17.97)	168,107 (17.61)	167,397 (17.54)	39,468 (15.51)	39,626 (15.57)
Non-steroidal anti-inflammatory drugs	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychotropics	104,584 (8.28)	82,522 (6.54)	77,456 (8.11)	54,122 (5.67)	19,348 (7.6)	11,358 (4.46)
Statins	163,161 (12.92)	118,827 (9.41)	119,417 (12.51)	68,373 (7.16)	19,962 (7.84)	8,349 (3.28)
Novel oral anticoagulants	114,688 (9.08)	88,074 (6.98)	84,201 (8.82)	53,452 (5.6)	15,067 (5.92)	7,172 (2.82)
Warfarin	5 (<0.1)	<5	<5	<5	<5	0 (0)

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Table 15.32.3 Comedications at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for NHR

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,347,625 (50)	3,347,625 (50)	2,485,650 (50)	2,485,650 (50)	1,460,378 (50)	1,460,378 (50)
Analgesics	698,907 (20.88)	659,029 (19.69)	589,879 (23.73)	554,989 (22.33)	396,643 (27.16)	363,696 (24.9)
Antibiotics	544,690 (16.27)	518,175 (15.48)	437,517 (17.6)	419,904 (16.89)	286,979 (19.65)	266,471 (18.25)
Antiviral medications	43,439 (1.3)	41,275 (1.23)	34,509 (1.39)	37,008 (1.49)	20,707 (1.42)	31,949 (2.19)
Corticosteroids	626,425 (18.71)	630,606 (18.84)	531,736 (21.39)	535,217 (21.53)	353,454 (24.2)	353,121 (24.18)
Non-steroidal anti-inflammatory drugs	625,660 (18.69)	588,436 (17.58)	506,775 (20.39)	435,385 (17.52)	317,535 (21.74)	240,706 (16.48)
Psychotropics	433,164 (12.94)	425,634 (12.71)	367,159 (14.77)	395,567 (15.91)	248,360 (17.01)	286,044 (19.59)
Statins	425,585 (12.71)	386,924 (11.56)	405,687 (16.32)	323,228 (13)	320,399 (21.94)	237,555 (16.27)
Novel oral anticoagulants	318,018 (9.5)	295,063 (8.81)	305,924 (12.31)	283,081 (11.39)	245,336 (16.8)	234,291 (16.04)
Warfarin	15,868 (0.47)	14,160 (0.42)	15,094 (0.61)	15,396 (0.62)	11,247 (0.77)	13,951 (0.96)

Table 15.32.4 Comedications at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for EpiChron

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	611,210 (50)	611,210 (50)	489,239 (50)	489,239 (50)	92,041 (50)	92,041 (50)
Analgesics	148,659 (24.32)	135,736 (22.21)	111,873 (22.87)	92,685 (18.94)	26,085 (28.34)	15,883 (17.26)
Antibiotics	104,772 (17.14)	93,296 (15.26)	80,621 (16.48)	64,539 (13.19)	18,489 (20.09)	11,144 (12.11)
Antiviral medications	3,320 (0.54)	3,025 (0.49)	2,514 (0.51)	2,247 (0.46)	567 (0.62)	278 (0.3)
Corticosteroids	32,473 (5.31)	32,196 (5.27)	20,105 (4.11)	19,875 (4.06)	4,790 (5.2)	4,621 (5.02)
Non-steroidal anti-inflammatory drugs	161,688 (26.45)	140,036 (22.91)	127,396 (26.04)	94,586 (19.33)	29,226 (31.75)	15,285 (16.61)
Psychotropics	107,585 (17.6)	94,657 (15.49)	83,088 (16.98)	65,975 (13.49)	17,425 (18.93)	10,910 (11.85)
Statins	88,822 (14.53)	82,981 (13.58)	63,675 (13.02)	52,691 (10.77)	13,595 (14.77)	8,920 (9.69)
Novel oral anticoagulants	32,540 (5.32)	32,066 (5.25)	22,681 (4.64)	23,192 (4.74)	4,137 (4.49)	3,946 (4.29)
Warfarin	113 (0.02)	109 (0.02)	81 (0.02)	117 (0.02)	13 (0.01)	28 (0.03)

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Table 15.32.5 Comedications at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for SIDIAP

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,081,405 (50)	3,081,405 (50)	2,805,381 (50)	2,805,381 (50)	484,132 (50)	484,132 (50)
Analgesics	751,454 (24.39)	742,704 (24.1)	698,571 (24.9)	666,681 (23.76)	218,755 (45.18)	161,934 (33.45)
Antibiotics	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Antiviral medications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Corticosteroids	586,255 (19.03)	584,547 (18.97)	532,339 (18.98)	528,240 (18.83)	124,413 (25.7)	123,286 (25.47)
Non-steroidal anti-inflammatory drugs	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychotropics	468,637 (15.21)	438,816 (14.24)	449,193 (16.01)	397,292 (14.16)	135,140 (27.91)	96,604 (19.95)
Statins	346,348 (11.24)	326,978 (10.61)	341,628 (12.18)	290,486 (10.35)	129,021 (26.65)	89,030 (18.39)
Novel oral anticoagulants	212,848 (6.91)	206,780 (6.71)	210,906 (7.52)	203,364 (7.25)	92,653 (19.14)	77,042 (15.91)
Warfarin	4,069 (0.13)	4,034 (0.13)	4,027 (0.14)	4,475 (0.16)	1,811 (0.37)	1,586 (0.33)

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Table 15.32.6 Comedications at each Pfizer-BioNTechCOVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccination status for CPRD

factor	first dose vaccinated	first dose unvaccinated	second dose vaccinated	second dose unvaccinated	third dose vaccinated	third dose unvaccinated
N (%)	3,231,856 (50)	3,231,856 (50)	2,912,712 (50)	2,912,712 (50)	1,393,951 (50)	1,393,951 (50)
Analgesics	262,806 (8.13)	246,783 (7.64)	246,390 (8.46)	224,173 (7.7)	163,971 (11.76)	141,754 (10.17)
Antibiotics	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Antiviral medications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Corticosteroids	464,573 (14.37)	467,278 (14.46)	429,593 (14.75)	430,702 (14.79)	251,808 (18.06)	253,415 (18.18)
Non-steroidal anti-inflammatory drugs	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychotropics	124,535 (3.85)	119,526 (3.7)	115,050 (3.95)	117,233 (4.02)	71,108 (5.1)	69,124 (4.96)
Statins	241,965 (7.49)	210,619 (6.52)	234,799 (8.06)	168,669 (5.79)	193,591 (13.89)	126,976 (9.11)
Novel oral anticoagulants	30,464 (0.94)	26,310 (0.81)	29,414 (1.01)	26,047 (0.89)	23,556 (1.69)	20,774 (1.49)
Warfarin	9,791 (0.3)	8,216 (0.25)	8,777 (0.3)	6,039 (0.21)	6,664 (0.48)	4,350 (0.31)

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Table 15.33.1.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Heart failure			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antibiotics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antiviral medications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Corticosteroids			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	NE	NE	NE

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Table 15.33.1.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Psychotropics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Statins			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Warfarin			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes complications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	NE	NE	NE
Bladder incontinence			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Ambulance transport			

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Table 15.33.1.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of emergency department visits			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Primary care utilisation			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			

Table 15.33.1.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HIV/AIDS			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sepsis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of allergies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Autoimmune disorders			
No	Ref	Ref	Ref

Table 15.33.1.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	NE	NE	NE
Smoking status			
Never	Ref	Ref	Ref
Current	NE	NE	NE
Former	NE	NE	NE
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			

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Table 15.33.1.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Arthritis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Connective tissue disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Psychiatric illness			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Dementia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vertigo			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Comorbidities			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref

Table 15.33.1.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Leukemia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lymphoma			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref

Table 15.33.1.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Meningitis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pneumococcal			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groupsb			
Group 0	Ref	Ref	Ref
Group 1	NE	NE	NE
Group 2	NE	NE	NE
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Calendar period			

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Table 15.33.2.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Heart failure			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antibiotics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antiviral medications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Corticosteroids			
No	Ref	Ref	Ref
Yes	1 (0, 3)	1 (0, 3)	1 (0, 3)
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	2 (0, 7)	2 (0, 7)	2 (0, 7)
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	NE	NE	NE

Table 15.33.2.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Psychotropics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Statins			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Warfarin			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	1 (0, 7)	1 (0, 7)	1 (0, 7)
Diabetes complications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	1 (1, 4)	1 (1, 4)	1 (1, 4)
Bladder incontinence			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Ambulance transport			

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Table 15.33.2.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of emergency department visits			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Primary care utilisation			
0	Ref	Ref	Ref
1	2 (1, 9)	2 (1, 9)	2 (1, 9)
2+	1 (0, 3)	1 (0, 3)	1 (0, 3)
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			

Table 15.33.2.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	1 (0, 3)	1 (0, 3)	1 (0, 3)
Influenza			
No	Ref	Ref	Ref
Yes	1 (0, 9)	1 (0, 9)	1 (0, 9)
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	1 (0, 7)	1 (0, 7)	1 (0, 7)
COVID-19			
No	Ref	Ref	Ref
Yes	1 (0, 7)	1 (0, 7)	1 (0, 7)
HIV/AIDS			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sepsis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of allergies			
No	Ref	Ref	Ref
Yes	1 (0, 7)	1 (0, 7)	1 (0, 7)
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Autoimmune disorders			
No	Ref	Ref	Ref

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Table 15.33.2.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	2 (0, 7)	2 (0, 7)	2 (0, 7)
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	33 (4, 251)	33 (4, 251)	33 (4, 251)
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	5 (1, 35)	5 (1, 35)	5 (1, 35)
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	0 (0, 1)	0 (0, 1)	0 (0, 1)
Smoking status			
Never	Ref	Ref	Ref
Current	NE	NE	NE
Former	NE	NE	NE
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			

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Table 15.33.2.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Arthritis			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Connective tissue disease			
No	Ref	Ref	Ref
Yes	0 (0, 3)	0 (0, 3)	0 (0, 3)
Psychiatric illness			
No	Ref	Ref	Ref
Yes	1 (0, 5)	1 (0, 5)	1 (0, 5)
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Dementia			
No	Ref	Ref	Ref
Yes	51 (7, 388)	51 (7, 388)	51 (7, 388)
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vertigo			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Comorbidities			
No	Ref	Ref	Ref
Yes	0 (0, 2)	0 (0, 2)	0 (0, 2)
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref

Table 15.33.2.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Leukemia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lymphoma			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	0 (0, 2)	0 (0, 2)	0 (0, 2)
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref

Table 15.33.2.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Meningitis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pneumococcal			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groupsb			
Group 0	Ref	Ref	Ref
Group 1	1 (1, 4)	1 (1, 4)	1 (1, 4)
Group 2	0 (0, 2)	0 (0, 2)	0 (0, 2)
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Calendar period			

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Table 15.33.3.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	3 (1, 7)	3 (1, 7)	3 (1, 7)
Heart failure			
No	Ref	Ref	Ref
Yes	22 (9, 55)	22 (9, 55)	22 (9, 55)
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	1 (0, 3)	1 (0, 3)	1 (0, 3)
Antibiotics			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Antiviral medications			
No	Ref	Ref	Ref
Yes	3 (0, 25)	3 (0, 25)	3 (0, 25)
Corticosteroids			
No	Ref	Ref	Ref
Yes	3 (1, 6)	3 (1, 6)	3 (1, 6)
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	7 (3, 16)	7 (3, 16)	7 (3, 16)
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)

Table 15.33.3.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Psychotropics			
No	Ref	Ref	Ref
Yes	2 (1, 6)	2 (1, 6)	2 (1, 6)
Statins			
No	Ref	Ref	Ref
Yes	5 (2, 12)	5 (2, 12)	5 (2, 12)
Warfarin			
No	Ref	Ref	Ref
Yes	10 (1, 71)	10 (1, 71)	10 (1, 71)
Chronic liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	3 (0, 21)	3 (0, 21)	3 (0, 21)
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	6 (3, 15)	6 (3, 15)	6 (3, 15)
Diabetes complications			
No	Ref	Ref	Ref
Yes	6 (1, 43)	6 (1, 43)	6 (1, 43)
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	1 (0, 1)	1 (0, 1)	1 (0, 1)
Bladder incontinence			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Ambulance transport			

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Table 15.33.3.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of emergency department visits			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	3 (1, 9)	3 (1, 9)	3 (1, 9)
2+	15 (6, 39)	15 (6, 39)	15 (6, 39)
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Primary care utilisation			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			

Table 15.33.3.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	3 (1, 6)	3 (1, 6)	3 (1, 6)
Influenza			
No	Ref	Ref	Ref
Yes	3 (1, 6)	3 (1, 6)	3 (1, 6)
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
COVID-19			
No	Ref	Ref	Ref
Yes	4 (1, 18)	4 (1, 18)	4 (1, 18)
HIV/AIDS			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Sepsis			
No	Ref	Ref	Ref
Yes	9 (1, 64)	9 (1, 64)	9 (1, 64)
History of allergies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Autoimmune disorders			
No	Ref	Ref	Ref

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Table 15.33.3.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	4 (2, 10)	4 (2, 10)	4 (2, 10)
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	12 (5, 29)	12 (5, 29)	12 (5, 29)
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	1 (0, 10)	1 (0, 10)	1 (0, 10)
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	0 (0, 1)	0 (0, 1)	0 (0, 1)
Smoking status			
Never	Ref	Ref	Ref
Current	NE	NE	NE
Former	NE	NE	NE
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			

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Table 15.33.3.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	3 (1, 11)	3 (1, 11)	3 (1, 11)
Arthritis			
No	Ref	Ref	Ref
Yes	1 (0, 3)	1 (0, 3)	1 (0, 3)
Connective tissue disease			
No	Ref	Ref	Ref
Yes	1 (1, 3)	1 (1, 3)	1 (1, 3)
Psychiatric illness			
No	Ref	Ref	Ref
Yes	2 (1, 5)	2 (1, 5)	2 (1, 5)
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	1 (0, 10)	1 (0, 10)	1 (0, 10)
Dementia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	1 (0, 10)	1 (0, 10)	1 (0, 10)
Vertigo			
No	Ref	Ref	Ref
Yes	2 (0, 15)	2 (0, 15)	2 (0, 15)
Comorbidities			
No	Ref	Ref	Ref
Yes	2 (1, 5)	2 (1, 5)	2 (1, 5)
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref

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Table 15.33.3.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	3 (1, 9)	3 (1, 9)	3 (1, 9)
Leukemia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lymphoma			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	8 (1, 56)	8 (1, 56)	8 (1, 56)
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	2 (0, 11)	2 (0, 11)	2 (0, 11)
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	4 (1, 18)	4 (1, 18)	4 (1, 18)
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref

Table 15.33.3.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Meningitis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pneumococcal			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groupsb			
Group 0	Ref	Ref	Ref
Group 1	1 (0, 5)	1 (0, 5)	1 (0, 5)
Group 2	3 (1, 8)	3 (1, 8)	3 (1, 8)
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	2 (1, 5)	2 (1, 5)	2 (1, 5)
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	6 (3, 16)	6 (3, 16)	6 (3, 16)
Calendar period			

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Table 15.33.4.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	5 (0, 80)	5 (0, 80)	5 (0, 80)
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Heart failure			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antibiotics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antiviral medications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Corticosteroids			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	NE	NE	NE

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Table 15.33.4.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Psychotropics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Statins			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Warfarin			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes complications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	1 (0, 16)	1 (0, 16)	1 (0, 16)
Bladder incontinence			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Ambulance transport			

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Table 15.33.4.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of emergency department visits			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Primary care utilisation			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			

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Table 15.33.4.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HIV/AIDS			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	11 (1, 176)	11 (1, 176)	11 (1, 176)
Sepsis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of allergies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Autoimmune disorders			
No	Ref	Ref	Ref

Table 15.33.4.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	NE	NE	NE
Smoking status			
Never	Ref	Ref	Ref
Current	NE	NE	NE
Former	NE	NE	NE
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			

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Table 15.33.4.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Arthritis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Connective tissue disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Psychiatric illness			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Dementia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vertigo			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Comorbidities			
No	Ref	Ref	Ref
Yes	2 (0, 39)	2 (0, 39)	2 (0, 39)
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref

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Table 15.33.4.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Leukemia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lymphoma			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	3 (0, 45)	3 (0, 45)	3 (0, 45)
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref

Table 15.33.4.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	8 (1, 130)	8 (1, 130)	8 (1, 130)
Meningitis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pneumococcal			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groupsb			
Group 0	Ref	Ref	Ref
Group 1	NE	NE	NE
Group 2	NE	NE	NE
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Calendar period			

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Table 15.33.5.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	2 (0, 13)	2 (0, 13)	2 (0, 13)
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	4 (1, 24)	4 (1, 24)	4 (1, 24)
Heart failure			
No	Ref	Ref	Ref
Yes	26 (5, 144)	26 (5, 144)	26 (5, 144)
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	2 (0, 9)	2 (0, 9)	2 (0, 9)
Antibiotics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antiviral medications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Corticosteroids			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	7 (1, 37)	7 (1, 37)	7 (1, 37)
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Psychotropics			

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Table 15.33.5.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Statins			
No	Ref	Ref	Ref
Yes	4 (1, 22)	4 (1, 22)	4 (1, 22)
Warfarin			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic liver disease			
No	Ref	Ref	Ref
Yes	7 (1, 59)	7 (1, 59)	7 (1, 59)
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	2 (0, 19)	2 (0, 19)	2 (0, 19)
Diabetes complications			
No	Ref	Ref	Ref
Yes	12 (1, 106)	12 (1, 106)	12 (1, 106)
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	2 (0, 18)	2 (0, 18)	2 (0, 18)
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	1 (0, 5)	1 (0, 5)	1 (0, 5)
Bladder incontinence			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Ambulance transport			
No	Ref	Ref	Ref
Yes	NE	NE	NE

Table 15.33.5.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Number of emergency department visits			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Primary care utilisation			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			

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Table 15.33.5.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	1 (0, 7)	1 (0, 7)	1 (0, 7)
Influenza			
No	Ref	Ref	Ref
Yes	1 (0, 8)	1 (0, 8)	1 (0, 8)
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
COVID-19			
No	Ref	Ref	Ref
Yes	1 (0, 8)	1 (0, 8)	1 (0, 8)
HIV/AIDS			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Sepsis			
No	Ref	Ref	Ref
Yes	172 (20, 1,474)	172 (20, 1,474)	172 (20, 1,474)
History of allergies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Autoimmune disorders			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	NE	NE	NE

Table 15.33.5.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	11 (1, 96)	11 (1, 96)	11 (1, 96)
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	1 (0, 10)	1 (0, 10)	1 (0, 10)
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	0 (0, 2)	0 (0, 2)	0 (0, 2)
Smoking status			
Never	Ref	Ref	Ref
Current	5 (1, 36)	5 (1, 36)	5 (1, 36)
Former	11 (2, 77)	11 (2, 77)	11 (2, 77)
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Arthritis			
No	Ref	Ref	Ref
Yes	1 (0, 8)	1 (0, 8)	1 (0, 8)

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Table 15.33.5.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Connective tissue disease			
No	Ref	Ref	Ref
Yes	2 (0, 10)	2 (0, 10)	2 (0, 10)
Psychiatric illness			
No	Ref	Ref	Ref
Yes	1 (0, 7)	1 (0, 7)	1 (0, 7)
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	9 (1, 77)	9 (1, 77)	9 (1, 77)
Dementia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	9 (1, 77)	9 (1, 77)	9 (1, 77)
Vertigo			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Comorbidities			
No	Ref	Ref	Ref
Yes	6 (1, 33)	6 (1, 33)	6 (1, 33)
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Leukemia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lymphoma			
No	Ref	Ref	Ref

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Table 15.33.5.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	1 (0, 8)	1 (0, 8)	1 (0, 8)
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	4 (0, 31)	4 (0, 31)	4 (0, 31)
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	1 (0, 12)	1 (0, 12)	1 (0, 12)
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE

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Table 15.33.5.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Meningitis			
No	Ref	Ref	Ref
Yes	3 (1, 16)	3 (1, 16)	3 (1, 16)
Pneumococcal			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groups ^b			
Group 0	Ref	Ref	Ref
Group 1	2 (0, 31)	2 (0, 31)	2 (0, 31)
Group 2	5 (1, 46)	5 (1, 46)	5 (1, 46)
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	1 (0, 11)	1 (0, 11)	1 (0, 11)
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	7 (1, 61)	7 (1, 61)	7 (1, 61)
Calendar period			

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Table 15.33.6.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	1 (1, 3)	1 (1, 3)	1 (1, 3)
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	1 (1, 3)	1 (1, 3)	1 (1, 3)
Heart failure			
No	Ref	Ref	Ref
Yes	12 (2, 92)	12 (2, 92)	12 (2, 92)
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	2 (1, 7)	2 (1, 7)	2 (1, 7)
Antibiotics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antiviral medications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Corticosteroids			
No	Ref	Ref	Ref
Yes	2 (1, 5)	2 (1, 5)	2 (1, 5)
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	13 (3, 54)	13 (3, 54)	13 (3, 54)
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	NE	NE	NE

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Table 15.33.6.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Psychotropics			
No	Ref	Ref	Ref
Yes	5 (1, 15)	5 (1, 15)	5 (1, 15)
Statins			
No	Ref	Ref	Ref
Yes	2 (1, 8)	2 (1, 8)	2 (1, 8)
Warfarin			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	1 (0, 6)	1 (0, 6)	1 (0, 6)
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	2 (0, 5)	2 (0, 5)	2 (0, 5)
Diabetes complications			
No	Ref	Ref	Ref
Yes	5 (1, 22)	5 (1, 22)	5 (1, 22)
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	2 (1, 4)	2 (1, 4)	2 (1, 4)
Bladder incontinence			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	11 (3, 38)	11 (3, 38)	11 (3, 38)
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	4 (1, 29)	4 (1, 29)	4 (1, 29)
Ambulance transport			

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Table 15.33.6.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of emergency department visits			
0	Ref	Ref	Ref
1	2 (1, 7)	2 (1, 7)	2 (1, 7)
2+	2 (0, 16)	2 (0, 16)	2 (0, 16)
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Primary care utilisation			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			

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Table 15.33.6.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	2 (1, 5)	2 (1, 5)	2 (1, 5)
Influenza			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
COVID-19			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
HIV/AIDS			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	2 (0, 6)	2 (0, 6)	2 (0, 6)
Sepsis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of allergies			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Autoimmune disorders			
No	Ref	Ref	Ref

Table 15.33.6.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	2 (0, 7)	2 (0, 7)	2 (0, 7)
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	6 (1, 25)	6 (1, 25)	6 (1, 25)
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	3 (1, 13)	3 (1, 13)	3 (1, 13)
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	0 (0, 1)	0 (0, 1)	0 (0, 1)
Smoking status			
Never	Ref	Ref	Ref
Current	NE	NE	NE
Former	NE	NE	NE
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			

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Table 15.33.6.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Arthritis			
No	Ref	Ref	Ref
Yes	2 (1, 7)	2 (1, 7)	2 (1, 7)
Connective tissue disease			
No	Ref	Ref	Ref
Yes	1 (0, 5)	1 (0, 5)	1 (0, 5)
Psychiatric illness			
No	Ref	Ref	Ref
Yes	0 (0, 3)	0 (0, 3)	0 (0, 3)
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Dementia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vertigo			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Comorbidities			
No	Ref	Ref	Ref
Yes	1 (0, 3)	1 (0, 3)	1 (0, 3)
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref

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Table 15.33.6.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Leukemia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lymphoma			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	22 (3, 161)	22 (3, 161)	22 (3, 161)
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	8 (1, 60)	8 (1, 60)	8 (1, 60)
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref

Table 15.33.6.1 Univariable odds ratio and 95% confidence interval for myocarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	1 (0, 5)	1 (0, 5)	1 (0, 5)
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Meningitis			
No	Ref	Ref	Ref
Yes	2 (1, 5)	2 (1, 5)	2 (1, 5)
Pneumococcal			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	1 (1, 3)	1 (1, 3)	1 (1, 3)
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groupsb			
Group 0	Ref	Ref	Ref
Group 1	2 (1, 9)	2 (1, 9)	2 (1, 9)
Group 2	3 (1, 11)	3 (1, 11)	3 (1, 11)
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	1 (0, 5)	1 (0, 5)	1 (0, 5)
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Calendar period			

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Table 15.33.1.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Heart failure			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antibiotics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antiviral medications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Corticosteroids			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	NE	NE	NE

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Table 15.33.1.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Psychotropics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Statins			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Warfarin			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes complications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	NE	NE	NE
Bladder incontinence			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Ambulance transport			

Table 15.33.1.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of emergency department visits			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Primary care utilisation			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			

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Table 15.33.1.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HIV/AIDS			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sepsis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of allergies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Autoimmune disorders			
No	Ref	Ref	Ref

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Table 15.33.1.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	NE	NE	NE
Smoking status			
Never	Ref	Ref	Ref
Current	NE	NE	NE
Former	NE	NE	NE
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			

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Table 15.33.1.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pédianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Arthritis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Connective tissue disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Psychiatric illness			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Dementia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vertigo			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Comorbidities			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref

Table 15.33.1.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Leukemia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lymphoma			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref

Table 15.33.1.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for Pedianet

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Meningitis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pneumococcal			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groups ^b			
Group 0	Ref	Ref	Ref
Group 1	NE	NE	NE
Group 2	NE	NE	NE
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Calendar period			

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Table 15.33.2.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Heart failure			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	13 (1, 209)	13 (1, 209)	13 (1, 209)
Antibiotics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antiviral medications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Corticosteroids			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	NE	NE	NE

Table 15.33.2.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Psychotropics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Statins			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Warfarin			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes complications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	1 (0, 16)	1 (0, 16)	1 (0, 16)
Bladder incontinence			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Ambulance transport			

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Table 15.33.2.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of emergency department visits			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Primary care utilisation			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			

Table 15.33.2.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HIV/AIDS			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sepsis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of allergies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Autoimmune disorders			
No	Ref	Ref	Ref

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Table 15.33.2.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	NE	NE	NE
Smoking status			
Never	Ref	Ref	Ref
Current	NE	NE	NE
Former	NE	NE	NE
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			

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Table 15.33.2.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Arthritis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Connective tissue disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Psychiatric illness			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Dementia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vertigo			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Comorbidities			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref

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Table 15.33.2.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Leukemia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lymphoma			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref

Table 15.33.2.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for PHARMO

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Meningitis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pneumococcal			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groupsb			
Group 0	Ref	Ref	Ref
Group 1	NE	NE	NE
Group 2	NE	NE	NE
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Calendar period			

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Table 15.33.3.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Heart failure			
No	Ref	Ref	Ref
Yes	6 (3, 16)	6 (3, 16)	6 (3, 16)
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	4 (2, 6)	4 (2, 6)	4 (2, 6)
Antibiotics			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Antiviral medications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Corticosteroids			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	5 (3, 8)	5 (3, 8)	5 (3, 8)
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	2 (1, 3)	2 (1, 3)	2 (1, 3)

Table 15.33.3.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Psychotropics			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Statins			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Warfarin			
No	Ref	Ref	Ref
Yes	8 (2, 34)	8 (2, 34)	8 (2, 34)
Chronic liver disease			
No	Ref	Ref	Ref
Yes	2 (0, 16)	2 (0, 16)	2 (0, 16)
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	1 (0, 9)	1 (0, 9)	1 (0, 9)
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	1 (0, 3)	1 (0, 3)	1 (0, 3)
Diabetes complications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	1 (0, 1)	1 (0, 1)	1 (0, 1)
Bladder incontinence			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	11 (1, 78)	11 (1, 78)	11 (1, 78)
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	15 (2, 109)	15 (2, 109)	15 (2, 109)
Ambulance transport			

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Table 15.33.3.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of emergency department visits			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	2 (1, 6)	2 (1, 6)	2 (1, 6)
2+	18 (10, 32)	18 (10, 32)	18 (10, 32)
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Primary care utilisation			
0	Ref	Ref	Ref
1	1 (0, 3)	1 (0, 3)	1 (0, 3)
2+	1 (1, 3)	1 (1, 3)	1 (1, 3)
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			

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Table 15.33.3.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Influenza			
No	Ref	Ref	Ref
Yes	3 (2, 5)	3 (2, 5)	3 (2, 5)
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
COVID-19			
No	Ref	Ref	Ref
Yes	2 (0, 7)	2 (0, 7)	2 (0, 7)
HIV/AIDS			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	2 (1, 3)	2 (1, 3)	2 (1, 3)
Sepsis			
No	Ref	Ref	Ref
Yes	4 (1, 26)	4 (1, 26)	4 (1, 26)
History of allergies			
No	Ref	Ref	Ref
Yes	1 (0, 6)	1 (0, 6)	1 (0, 6)
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	1 (0, 8)	1 (0, 8)	1 (0, 8)
Autoimmune disorders			
No	Ref	Ref	Ref

Table 15.33.3.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	2 (1, 3)	2 (1, 3)	2 (1, 3)
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	3 (1, 7)	3 (1, 7)	3 (1, 7)
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	1 (0, 5)	1 (0, 5)	1 (0, 5)
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	1 (0, 1)	1 (0, 1)	1 (0, 1)
Smoking status			
Never	Ref	Ref	Ref
Current	NE	NE	NE
Former	NE	NE	NE
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			

Table 15.33.3.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	2 (1, 5)	2 (1, 5)	2 (1, 5)
Arthritis			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Connective tissue disease			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Psychiatric illness			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	4 (2, 9)	4 (2, 9)	4 (2, 9)
Dementia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	4 (2, 9)	4 (2, 9)	4 (2, 9)
Vertigo			
No	Ref	Ref	Ref
Yes	2 (0, 7)	2 (0, 7)	2 (0, 7)
Comorbidities			
No	Ref	Ref	Ref
Yes	1 (1, 2)	1 (1, 2)	1 (1, 2)
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref

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Table 15.33.3.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	2 (1, 5)	2 (1, 5)	2 (1, 5)
Leukemia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lymphoma			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	6 (2, 26)	6 (2, 26)	6 (2, 26)
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	1 (1, 2)	1 (1, 2)	1 (1, 2)
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	2 (1, 6)	2 (1, 6)	2 (1, 6)
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	2 (0, 7)	2 (0, 7)	2 (0, 7)
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref

Table 15.33.3.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for NHR

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Meningitis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Pneumococcal			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groupsb			
Group 0	Ref	Ref	Ref
Group 1	2 (1, 3)	2 (1, 3)	2 (1, 3)
Group 2	2 (1, 5)	2 (1, 5)	2 (1, 5)
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	2 (1, 3)	2 (1, 3)	2 (1, 3)
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	3 (1, 6)	3 (1, 6)	3 (1, 6)
Calendar period			

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Table 15.33.4.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	0 (0, 4)	0 (0, 4)	0 (0, 4)
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	2 (1, 6)	2 (1, 6)	2 (1, 6)
Heart failure			
No	Ref	Ref	Ref
Yes	34 (9, 127)	34 (9, 127)	34 (9, 127)
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Antibiotics			
No	Ref	Ref	Ref
Yes	2 (0, 6)	2 (0, 6)	2 (0, 6)
Antiviral medications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Corticosteroids			
No	Ref	Ref	Ref
Yes	2 (0, 13)	2 (0, 13)	2 (0, 13)
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	4 (1, 16)	4 (1, 16)	4 (1, 16)
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)

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Table 15.33.4.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Psychotropics			
No	Ref	Ref	Ref
Yes	2 (0, 6)	2 (0, 6)	2 (0, 6)
Statins			
No	Ref	Ref	Ref
Yes	4 (1, 14)	4 (1, 14)	4 (1, 14)
Warfarin			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	7 (2, 23)	7 (2, 23)	7 (2, 23)
Diabetes complications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	8 (2, 28)	8 (2, 28)	8 (2, 28)
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	1 (0, 4)	1 (0, 4)	1 (0, 4)
Bladder incontinence			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Ambulance transport			

Table 15.33.4.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of emergency department visits			
0	Ref	Ref	Ref
1	4 (1, 14)	4 (1, 14)	4 (1, 14)
2+	8 (2, 32)	8 (2, 32)	8 (2, 32)
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Primary care utilisation			
0	Ref	Ref	Ref
1	1 (0, 6)	1 (0, 6)	1 (0, 6)
2+	0 (0, 1)	0 (0, 1)	0 (0, 1)
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			

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Table 15.33.4.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	1 (0, 11)	1 (0, 11)	1 (0, 11)
Influenza			
No	Ref	Ref	Ref
Yes	3 (1, 9)	3 (1, 9)	3 (1, 9)
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HIV/AIDS			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	4 (1, 14)	4 (1, 14)	4 (1, 14)
Sepsis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
History of allergies			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Autoimmune disorders			
No	Ref	Ref	Ref

Table 15.33.4.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	2 (0, 12)	2 (0, 12)	2 (0, 12)
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	6 (2, 21)	6 (2, 21)	6 (2, 21)
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	0 (0, 2)	0 (0, 2)	0 (0, 2)
Smoking status			
Never	Ref	Ref	Ref
Current	NE	NE	NE
Former	NE	NE	NE
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			

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Table 15.33.4.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Arthritis			
No	Ref	Ref	Ref
Yes	1 (0, 3)	1 (0, 3)	1 (0, 3)
Connective tissue disease			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Psychiatric illness			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Dementia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vertigo			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Comorbidities			
No	Ref	Ref	Ref
Yes	2 (1, 6)	2 (1, 6)	2 (1, 6)
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref

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Table 15.33.4.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Leukemia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lymphoma			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	3 (1, 10)	3 (1, 10)	3 (1, 10)
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	1 (0, 3)	1 (0, 3)	1 (0, 3)
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref

Table 15.33.4.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for EpiChron

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	2 (0, 13)	2 (0, 13)	2 (0, 13)
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	1 (0, 6)	1 (0, 6)	1 (0, 6)
Meningitis			
No	Ref	Ref	Ref
Yes	1 (0, 5)	1 (0, 5)	1 (0, 5)
Pneumococcal			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groups ^b			
Group 0	Ref	Ref	Ref
Group 1	NE	NE	NE
Group 2	NE	NE	NE
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	1 (0, 6)	1 (0, 6)	1 (0, 6)
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Calendar period			

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Table 15.33.5.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	1 (1, 3)	1 (1, 3)	1 (1, 3)
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	2 (1, 3)	2 (1, 3)	2 (1, 3)
Heart failure			
No	Ref	Ref	Ref
Yes	6 (2, 14)	6 (2, 14)	6 (2, 14)
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	2 (1, 3)	2 (1, 3)	2 (1, 3)
Antibiotics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antiviral medications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Corticosteroids			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	4 (2, 7)	4 (2, 7)	4 (2, 7)
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	NE	NE	NE

Table 15.33.5.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Psychotropics			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Statins			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Warfarin			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic liver disease			
No	Ref	Ref	Ref
Yes	1 (0, 6)	1 (0, 6)	1 (0, 6)
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Diabetes complications			
No	Ref	Ref	Ref
Yes	4 (1, 12)	4 (1, 12)	4 (1, 12)
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	2 (1, 5)	2 (1, 5)	2 (1, 5)
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	1 (1, 3)	1 (1, 3)	1 (1, 3)
Bladder incontinence			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	2 (0, 5)	2 (0, 5)	2 (0, 5)
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	2 (0, 5)	2 (0, 5)	2 (0, 5)
Ambulance transport			

Table 15.33.5.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of emergency department visits			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	2 (1, 5)	2 (1, 5)	2 (1, 5)
2+	6 (2, 17)	6 (2, 17)	6 (2, 17)
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Primary care utilisation			
0	Ref	Ref	Ref
1	1 (0, 6)	1 (0, 6)	1 (0, 6)
2+	2 (1, 7)	2 (1, 7)	2 (1, 7)
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			

Table 15.33.5.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Influenza			
No	Ref	Ref	Ref
Yes	2 (1, 3)	2 (1, 3)	2 (1, 3)
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
COVID-19			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
HIV/AIDS			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	2 (1, 3)	2 (1, 3)	2 (1, 3)
Sepsis			
No	Ref	Ref	Ref
Yes	17 (2, 122)	17 (2, 122)	17 (2, 122)
History of allergies			
No	Ref	Ref	Ref
Yes	1 (1, 2)	1 (1, 2)	1 (1, 2)
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Autoimmune disorders			
No	Ref	Ref	Ref

Table 15.33.5.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	4 (2, 10)	4 (2, 10)	4 (2, 10)
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	0 (0, 1)	0 (0, 1)	0 (0, 1)
Smoking status			
Never	Ref	Ref	Ref
Current	1 (1, 3)	1 (1, 3)	1 (1, 3)
Former	1 (0, 3)	1 (0, 3)	1 (0, 3)
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			

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Table 15.33.5.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	5 (1, 15)	5 (1, 15)	5 (1, 15)
Arthritis			
No	Ref	Ref	Ref
Yes	2 (1, 3)	2 (1, 3)	2 (1, 3)
Connective tissue disease			
No	Ref	Ref	Ref
Yes	1 (1, 3)	1 (1, 3)	1 (1, 3)
Psychiatric illness			
No	Ref	Ref	Ref
Yes	1 (1, 2)	1 (1, 2)	1 (1, 2)
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	1 (0, 6)	1 (0, 6)	1 (0, 6)
Dementia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	1 (0, 6)	1 (0, 6)	1 (0, 6)
Vertigo			
No	Ref	Ref	Ref
Yes	2 (0, 7)	2 (0, 7)	2 (0, 7)
Comorbidities			
No	Ref	Ref	Ref
Yes	3 (2, 4)	3 (2, 4)	3 (2, 4)
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref

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Table 15.33.5.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Leukemia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Lymphoma			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	1 (1, 3)	1 (1, 3)	1 (1, 3)
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref

Table 15.33.5.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for SIDIAP

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	1 (0, 4)	1 (0, 4)	1 (0, 4)
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	0 (0, 2)	0 (0, 2)	0 (0, 2)
Meningitis			
No	Ref	Ref	Ref
Yes	1 (0, 1)	1 (0, 1)	1 (0, 1)
Pneumococcal			
No	Ref	Ref	Ref
Yes	2 (1, 3)	2 (1, 3)	2 (1, 3)
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	0 (0, 4)	0 (0, 4)	0 (0, 4)
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groupsb			
Group 0	Ref	Ref	Ref
Group 1	1 (0, 2)	1 (0, 2)	1 (0, 2)
Group 2	1 (1, 3)	1 (1, 3)	1 (1, 3)
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	2 (1, 3)	2 (1, 3)	2 (1, 3)
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	2 (1, 7)	2 (1, 7)	2 (1, 7)
Calendar period			

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Table 15.33.6.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Age 15 to 30 year age group			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
Age at index date (years)			
Coagulation deficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sickle Cell Disease (CDC risk group)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cardiovascular disease			
No	Ref	Ref	Ref
Yes	2 (1, 5)	2 (1, 5)	2 (1, 5)
Heart failure			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Myocardial infarct			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Analgesics			
No	Ref	Ref	Ref
Yes	2 (1, 7)	2 (1, 7)	2 (1, 7)
Antibiotics			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Antiviral medications			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Corticosteroids			
No	Ref	Ref	Ref
Yes	4 (2, 9)	4 (2, 9)	4 (2, 9)
Novel oral anticoagulants			
No	Ref	Ref	Ref
Yes	5 (1, 38)	5 (1, 38)	5 (1, 38)
Non-steroidal anti-inflammatory drugs			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Psychotropics			

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Table 15.33.6.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Statins			
No	Ref	Ref	Ref
Yes	1 (0, 5)	1 (0, 5)	1 (0, 5)
Warfarin			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Moderate or severe liver disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Diabetes mellitus (types 1 and 2)			
No	Ref	Ref	Ref
Yes	0 (0, 3)	0 (0, 3)	0 (0, 3)
Diabetes complications			
No	Ref	Ref	Ref
Yes	2 (0, 16)	2 (0, 16)	2 (0, 16)
Lipid abnormalities			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vaccination status			
CONTROL	Ref	Ref	Ref
EXPOSED	2 (1, 4)	2 (1, 4)	2 (1, 4)
Bladder incontinence			
No	Ref	Ref	Ref
Yes	25 (3, 184)	25 (3, 184)	25 (3, 184)
Chronic kidney disease			
No	Ref	Ref	Ref
Yes	6 (1, 26)	6 (1, 26)	6 (1, 26)
Mild or moderate kidney disease			
No	Ref	Ref	Ref
Yes	3 (0, 25)	3 (0, 25)	3 (0, 25)
Ambulance transport			
No	Ref	Ref	Ref
Yes	NE	NE	NE

Table 15.33.6.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Number of emergency department visits			
0	Ref	Ref	Ref
1	5 (2, 13)	5 (2, 13)	5 (2, 13)
2+	2 (0, 17)	2 (0, 17)	2 (0, 17)
Healthcare worker or essential worker status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Home hospital bed			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Number of hospitalisations			
0	Ref	Ref	Ref
1	9 (2, 37)	9 (2, 37)	9 (2, 37)
2+	18 (2, 131)	18 (2, 131)	18 (2, 131)
Skilled nursing facility, nursing home, or extended care facility stay			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Home oxygen			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Other preventive health services			
No	Ref	Ref	Ref
Yes	6 (1, 44)	6 (1, 44)	6 (1, 44)
Primary care utilisation			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Rehabilitation care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Residency in a long-term care facility			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Wheelchair use			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to Pfizer COVID-19 vaccines			

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Table 15.33.6.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hypersensitivity to smallpox vaccine			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Human immunodeficiency virus and other immunosuppressing conditions			
No	Ref	Ref	Ref
Yes	4 (2, 9)	4 (2, 9)	4 (2, 9)
Influenza			
No	Ref	Ref	Ref
Yes	2 (1, 4)	2 (1, 4)	2 (1, 4)
Previous diagnosis of COVID-19			
No	Ref	Ref	Ref
Yes	4 (2, 9)	4 (2, 9)	4 (2, 9)
COVID-19			
No	Ref	Ref	Ref
Yes	4 (2, 9)	4 (2, 9)	4 (2, 9)
HIV/AIDS			
No	Ref	Ref	Ref
Yes	44 (6, 330)	44 (6, 330)	44 (6, 330)
Influenza infection or other respiratory infection			
No	Ref	Ref	Ref
Yes	3 (1, 8)	3 (1, 8)	3 (1, 8)
Sepsis			
No	Ref	Ref	Ref
Yes	142 (33, 606)	142 (33, 606)	142 (33, 606)
History of allergies			
No	Ref	Ref	Ref
Yes	1 (0, 3)	1 (0, 3)	1 (0, 3)
History of anaphylaxis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Autoimmune disorders			
No	Ref	Ref	Ref
Yes	1 (0, 5)	1 (0, 5)	1 (0, 5)
Hypersensitivity to drugs and substances			
No	Ref	Ref	Ref
Yes	NE	NE	NE

Table 15.33.6.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Immunodeficiencies			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Immunological syndromes (rheumatoid arthritis,)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Charlson Comorbidity Index			
0	Ref	Ref	Ref
1	NE	NE	NE
2	NE	NE	NE
3 or more	NE	NE	NE
Charlson Comorbidity Index			
Obese (diagnostic code or BMI >30 kg/m2)			
No	Ref	Ref	Ref
Yes	1 (0, 9)	1 (0, 9)	1 (0, 9)
Pregnancy status			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Sex			
Male	Ref	Ref	Ref
Female	1 (0, 1)	1 (0, 1)	1 (0, 1)
Smoking status			
Never	Ref	Ref	Ref
Current	NE	NE	NE
Former	NE	NE	NE
SES			
low	Ref	Ref	Ref
middle	NE	NE	NE
high	NE	NE	NE
Difficulty walking			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Weakness			
No	Ref	Ref	Ref
Yes	11 (1, 81)	11 (1, 81)	11 (1, 81)
Arthritis			
No	Ref	Ref	Ref
Yes	2 (0, 6)	2 (0, 6)	2 (0, 6)

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Table 15.33.6.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTechCOVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Connective tissue disease			
No	Ref	Ref	Ref
Yes	1 (0, 6)	1 (0, 6)	1 (0, 6)
Psychiatric illness			
No	Ref	Ref	Ref
Yes	2 (1, 5)	2 (1, 5)	2 (1, 5)
Cerebrovascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Dementia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Hemiplegia			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Paralysis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Parkinson disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Stroke/brain injury			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Vertigo			
No	Ref	Ref	Ref
Yes	5 (1, 35)	5 (1, 35)	5 (1, 35)
Comorbidities			
No	Ref	Ref	Ref
Yes	3 (1, 7)	3 (1, 7)	3 (1, 7)
Cancer any cancer diagnosis except non melanoma skin cancer			
No	Ref	Ref	Ref
Yes	6 (2, 21)	6 (2, 21)	6 (2, 21)
Leukemia			
No	Ref	Ref	Ref
Yes	130 (30, 555)	130 (30, 555)	130 (30, 555)
Lymphoma			
No	Ref	Ref	Ref

Table 15.33.6.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
Yes	NE	NE	NE
Metastasis			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Chronic respiratory disease			
No	Ref	Ref	Ref
Yes	4 (1, 9)	4 (1, 9)	4 (1, 9)
Pregnancy trimester			
Skin ulcer			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Cancer screening			
0	Ref	Ref	Ref
1	NE	NE	NE
2+	NE	NE	NE
Positive test result for COVID-19			
No	Ref	Ref	Ref
Yes	3 (1, 8)	3 (1, 8)	3 (1, 8)
Number of COVID-19 tests (PCR or antigenic)			
0	Ref	Ref	Ref
1-2	NE	NE	NE
3-4	NE	NE	NE
5+	NE	NE	NE
Podiatric care			
No	Ref	Ref	Ref
Yes	NE	NE	NE
DTP (diphtheria, tetanus, and pertussis)			
No	Ref	Ref	Ref
Yes	1 (0, 3)	1 (0, 3)	1 (0, 3)
Hib (Haemophilus influenzae type b)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
HPV (human papillomavirus)			
No	Ref	Ref	Ref
Yes	1 (0, 5)	1 (0, 5)	1 (0, 5)
HBV (hepatitis B virus)			
No	Ref	Ref	Ref
Yes	1 (0, 8)	1 (0, 8)	1 (0, 8)

Table 15.33.6.2 Univariable odds ratio and 95% confidence interval for pericarditis for covariates at each Pfizer-BioNTech COVID-19 dose date in the matched cohort by Pfizer-BioNTech COVID-19 vaccine dose for CPRD

factor	first dose vaccinated	second dose vaccinated	third dose vaccinated
TV (MMR) (measles, mumps, and rubella)			
No	Ref	Ref	Ref
Yes	1 (0, 3)	1 (0, 3)	1 (0, 3)
Meningitis			
No	Ref	Ref	Ref
Yes	0 (0, 2)	0 (0, 2)	0 (0, 2)
Pneumococcal			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Rotavirus			
No	Ref	Ref	Ref
Yes	NE	NE	NE
TPV (polio)			
No	Ref	Ref	Ref
Yes	1 (0, 2)	1 (0, 2)	1 (0, 2)
VZV (varicella-zoster virus)			
No	Ref	Ref	Ref
Yes	NE	NE	NE
CDC at-risk groups ^b			
Group 0	Ref	Ref	Ref
Group 1	3 (1, 16)	3 (1, 16)	3 (1, 16)
Group 2	6 (1, 26)	6 (1, 26)	6 (1, 26)
Hypertension (CDC risk group)			
No	Ref	Ref	Ref
Yes	2 (1, 6)	2 (1, 6)	2 (1, 6)
Peripheral vascular disease			
No	Ref	Ref	Ref
Yes	NE	NE	NE
Calendar period			

Table 15.34.1.1 Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for Pedianet

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	21,000		17,888		2,110	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0.01)	1 (1, 1)	0 (0.02)	1 (1, 1)	0 (0.04)	1 (1, 1)
Marginal R ₂	NE		NE		NE	

Table 15.34.2.1 Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for PHARMO

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	2,525,102		1,909,034		508,938	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0.58)	1 (0, 3)	2 (1.05)	9 (1, 71)	NE	NE
Age 15 to 30 year age group						
No	Ref	Ref	Ref	Ref		
Yes	0 (1.08)	1 (0, 5)	NE	NE		
GROUPEXPOSED:AGE_1530Yes	1 (1.26)	4 (0, 47)	NE	NE		
Marginal R_	1		1		1	

Table 15.34.3.1 Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for NHR

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,695,250		4,971,300		2,920,756	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0.48)	1 (0, 1)	0 (0.56)	1 (0, 3)	0 (0.53)	1 (0, 2)
Age 15 to 30 year age group						
No	Ref	Ref	Ref	Ref	Ref	Ref
Yes	0 (0.65)	1 (0, 3)	0 (0.8)	1 (0, 5)	1 (0.67)	2 (1, 8)
GROUPEXPOSED:AGE_1530Yes	0 (1.03)	1 (0, 8)	1 (1.03)	2 (0, 17)	0 (1.27)	1 (0, 6)
Marginal R_	1		1		1	

Table 15.34.4.1 Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for EpiChron

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	1,222,420		978,478		184,082	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (1.41)	1 (0, 16)	1 (1.23)	2 (0, 22)	0 (0.01)	1 (1, 1)
Marginal R_	1		1		NE	

Table 15.34.5.1 Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for SIDIAP

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,162,810		5,610,762		968,264	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0.82)	1 (0, 5)	0 (0.47)	1 (0, 2)	0 (0)	1 (1, 1)
Marginal R ₂	1		1		NE	
Age 15 to 30 year age group						
No			Ref	Ref		
Yes			NE	NE		
GROUPEXPOSED:AGE_1530Yes			NE	NE		

Table 15.34.6.1 Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for CPRD

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,463,712		5,825,424		2,787,902	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	1 (0.68)	3 (1, 10)	2 (1.1)	5 (1, 43)	0 (0.82)	1 (0, 5)
Age 15 to 30 year age group						
No	Ref	Ref	Ref	Ref		
Yes	1 (0.73)	3 (1, 11)	2 (1.16)	5 (1, 48)		
GROUPEXPOSED:AGE_1530Yes	-1 (0.95)	0 (0, 2)	-0 (1.27)	1 (0, 11)		
Marginal R_	1		1		1	

Table 15.34.1.2 Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for Pedianet

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	21,000		17,888		2,110	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	NE	NE	0 (0.02)	1 (1, 1)	0 (0.04)	1 (1, 1)
Marginal R_	1		NE		NE	

Table 15.34.2.2 Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for PHARMO

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	2,525,102		1,909,034		508,938	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (1.41)	1 (0, 16)	NE	NE	0 (0)	1 (1, 1)
Marginal R ₂	1		1		NE	

Table 15.34.3.2 Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for NHR

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,695,250		4,971,300		2,920,756	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0.36)	1 (0, 2)	0 (0.29)	1 (1, 2)	-1 (0.39)	0 (0, 1)
Age 15 to 30 year age group						
No	Ref	Ref	Ref	Ref	Ref	Ref
Yes	0 (0.54)	0 (0, 1)	-1 (0.75)	0 (0, 1)	NE	NE
Sex						
Male	Ref	Ref	Ref	Ref	Ref	Ref
Female	0 (0.37)	1 (0, 1)	0 (0.35)	1 (0, 1)	-2 (0.53)	0 (0, 0)
COVID-19						
No	Ref	Ref	Ref	Ref	Ref	Ref
Yes	1 (0.72)	2 (0, 7)	0 (1.02)	1 (0, 5)	NE	NE
Hypersensitivity to drugs and substances						
0	Ref	Ref	Ref	Ref	Ref	Ref
1	NE	NE	NE	NE	NE	NE
GROUPEXPOSED:AGE_1530Yes	1 (0.7)	3 (1, 10)	2 (0.81)	5 (1, 22)	NE	NE
GROUPEXPOSED:L_SEX_COVFemale	0 (0.57)	1 (0, 2)	0 (0.48)	1 (0, 2)	1 (0.76)	4 (1, 16)
Marginal R_	1		1		1	
Immunological syndromes (rheumatoid arthritis,)						
No			Ref	Ref		
Yes			1 (0.46)	2 (1, 5)		
Comorbidities						
No			Ref	Ref		
Yes			0 (0.23)	1 (1, 2)		

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Table 15.34.4.2 Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for EpiChron

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	1,222,420		978,478		184,082	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0.61)	1 (0, 4)	2 (1.07)	7 (1, 57)	0 (0.01)	1 (1, 1)
Age 15 to 30 year age group						
No	Ref	Ref				
Yes	NE	NE				
GROUPEXPOSED:AGE_1530Yes	NE	NE				
Marginal R_	1		1		NE	

Table 15.34.5.2 Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for SIDIAP

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,162,810		5,610,762		968,264	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	1 (0.37)	2 (1, 3)	0 (0.42)	1 (0, 3)	0 (0.91)	2 (0, 9)
Age 15 to 30 year age group						
No	Ref	Ref	Ref	Ref		
Yes	0 (0.51)	1 (1, 4)	0 (0.63)	1 (0, 3)		
Sex						
Male	Ref	Ref	Ref	Ref		
Female	0 (0.46)	0 (0, 1)	0 (0.46)	1 (0, 2)		
COVID-19						
No	Ref	Ref				
Yes	1 (0.3)	2 (1, 4)				
Hypersensitivity to Pfizer COVID-19 vaccines						
No	Ref	Ref				
Yes	NE	NE				
GROUPEXPOSED:AGE_1530Yes	0 (0.67)	1 (0, 3)	1 (0.77)	3 (1, 14)		
GROUPEXPOSED:L_SEX_COVFemale	0 (0.62)	1 (0, 2)	0 (0.66)	0 (0, 2)		
Marginal R_	1		1		1	

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Table 15.34.6.2 Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for CPRD

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,463,712		5,825,392		2,787,902	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	-0 (0.54)	1 (0, 2)	-1 (0.39)	0 (0, 1)	0 (0.67)	1 (0, 5)
Age 15 to 30 year age group						
No	Ref	Ref	Ref	Ref	Ref	Ref
Yes	-2 (1.06)	0 (0, 2)	-1 (0.43)	1 (0, 1)	-1 (1.12)	1 (0, 5)
Sex						
Male			Ref	Ref		
Female			-2 (0.54)	0 (0, 0)		
COVID-19						
No			Ref	Ref		
Yes			-1 (0.6)	0 (0, 1)		
GROUPEXPOSED:AGE_1530Yes	2 (1.19)	11 (1, 109)	1 (0.64)	3 (1, 12)	-0 (1.57)	1 (0, 17)
GROUPEXPOSED:L_SEX_COVFemale			1 (0.73)	3 (1, 14)		
Marginal R_	1		1		1	

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Table 15.35.1.1 Sensitivity analysis: Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for Pedianet

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	21,000		17,888		2,110	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0.01)	1 (1, 1)	0 (0.02)	1 (1, 1)	0 (0.04)	1 (1, 1)
Marginal R ₂	NE		NE		NE	

Table 15.35.2.1 Sensitivity analysis: Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for PHARMO

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	2,525,102		1,909,034		508,938	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0)	1 (1, 1)	0 (0)	1 (1, 1)	0 (0)	1 (1, 1)
Marginal R ₂	NE		NE		NE	

Table 15.35.3.1 Sensitivity analysis: Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for NHR

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,695,250		4,971,300		2,920,756	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0.91)	1 (0, 4)	1 (1.16)	3 (0, 29)	NE	NE
Marginal R_	1		1		1	

Table 15.35.4.1 Sensitivity analysis: Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for EpiChron

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	1,222,420		978,478		184,082	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	NE	NE	NE	NE	0 (0.01)	1 (1, 1)
Marginal R_	1		1		NE	

Table 15.35.5.1 Sensitivity analysis: Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for SIDIAP

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,162,810		5,610,762		968,264	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0)	1 (1, 1)	NE	NE	0 (0)	1 (1, 1)
Marginal R ₂	NE		1		NE	

Table 15.35.6.1 Sensitivity analysis: Final multivariable logistic model for myocarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for CPRD

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,463,712		5,825,424		2,787,902	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0)	1 (1, 1)	0 (0)	1 (1, 1)	0 (0)	1 (1, 1)
Marginal R_	NE		NE		NE	

Table 15.35.1.2 Sensitivity analysis: Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for Pedianet

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	21,000		17,888		2,110	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	NE	NE	0 (0.02)	1 (1, 1)	0 (0.04)	1 (1, 1)
Marginal R_	1		NE		NE	

Table 15.35.2.2 Sensitivity analysis: Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for PHARMO

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	2,525,102		1,909,034		508,938	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0)	1 (1, 1)	0 (0)	1 (1, 1)	0 (0)	1 (1, 1)
Marginal R ₂	NE		NE		NE	

Table 15.35.3.2 Sensitivity analysis: Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for NHR

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,695,250		4,971,300		2,920,756	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0.76)	1 (0, 3)	2 (0.78)	5 (1, 23)	NE	NE
Age 15 to 30 year age group						
No	Ref	Ref	Ref	Ref		
Yes	0 (1.12)	1 (0, 7)	NE	NE		
GROUPEXPOSED:AGE_1530Yes	0 (1.61)	1 (0, 31)	NE	NE		
Marginal R_	1		1		1	

Table 15.35.4.2 Sensitivity analysis: Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for EpiChron

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	1,222,420		978,478		184,082	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0.87)	1 (0, 3)	1 (1.23)	2 (0, 22)	0 (0.01)	1 (1, 1)
Marginal R ₂	1		1		NE	

Table 15.35.5.2 Sensitivity analysis: Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for SIDIAP

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,162,810		5,610,762		968,264	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	-1 (1.16)	0 (0, 3)	NE	NE	0 (0)	1 (1, 1)
Marginal R ₂	1		1		NE	

Table 15.35.6.2 Sensitivity analysis: Final multivariable logistic model for pericarditis by Pfizer-BioNTech COVID-19 vaccine dose in the matched cohort for CPRD

Selected variables	First dose beta (SE)	First dose OR (95% CI)	Second dose beta (SE)	Second dose OR (95% CI)	Third dose beta (SE)	Third dose OR (95% CI)
Sample size	6,463,712		5,825,424		2,787,902	
Vaccination status						
CONTROL	Ref	Ref	Ref	Ref	Ref	Ref
EXPOSED	0 (0)	1 (1, 1)	NE	NE	0 (0)	1 (1, 1)
Marginal R_	NE		1		NE	

Table 15.36.1 Summary of results for validation of myocarditis and pericarditis cases by level of diagnostic certainty, exposure group for Pedianet

Characteristic	Vaccinated n(%)	Vaccinated PPV	Unvaccinated n(%)	Unvaccinated PPV
Myocarditis cases detected by electronic algorithm	0		0	
Cases subject to validation n, (%)	0 (NaN)		0 (NaN)	
Level 1	0 (NaN)		0 (NaN)	
Level 2	0 (NaN)		0 (NaN)	
Level 3	0 (NaN)		0 (NaN)	
Level 1-3 (PPV-strict)	0 (NaN)		0 (NaN)	
Level 4	0 (NaN)		0 (NaN)	
Level 1-4 (PPV-broad)	0 (NaN)		0 (NaN)	
Level 5	0 (NaN)		0 (NaN)	
Pericarditis cases detected by electronic algorithm	<5		<5	
Cases subject to validation n, (%)	<5		<5	
Level 1	<5		<5	
Level 2	0 (NaN)		0 (NaN)	
Level 3	0 (NaN)		0 (NaN)	
Level 1-3 (PPV-strict)	<5	100	<5	100
Level 4	0 (NaN)		0 (NaN)	
Level 1-4 (PPV-broad)	<5	100	<5	100
Level 5	0 (0)		0 (0)	

Table 15.36.2 Summary of results for validation of myocarditis and pericarditis cases by level of diagnostic certainty, exposure group for PHARMO

Characteristic	Vaccinated n(%)	Vaccinated PPV	Unvaccinated n(%)	Unvaccinated PPV
Myocarditis cases detected by electronic algorithm	304		370	
Cases subject to validation n, (%)	25 (8.22)		24 (6.49)	
Level 1	<5		<5	
Level 2			<5	
Level 3	0 (NaN)		0 (NaN)	
Level 1-3 (PPV-strict)	9 (100)	100	<5	100
Level 4	10 (40)		16 (66.67)	
Level 1-4 (PPV-broad)	19 (100)	100	18 (100)	100
Level 5	6 (24)		6 (25)	
Pericarditis cases detected by electronic algorithm	36		66	
Cases subject to validation n, (%)	28 (77.78)		43 (65.15)	
Level 1	<5			
Level 2	<5		<5	
Level 3	0 (NaN)		0 (NaN)	
Level 1-3 (PPV-strict)	5 (100)	100	6 (100)	100
Level 4	20 (71.43)		26 (60.47)	
Level 1-4 (PPV-broad)	25 (100)	100	32 (100)	100
Level 5	<5		10 (23.26)	

Table 15.36.3 Summary of results for validation of myocarditis and pericarditis cases by level of diagnostic certainty, exposure group for NHR

Characteristic	Vaccinated n(%)	Vaccinated PPV	Unvaccinated n(%)	Unvaccinated PPV
Myocarditis cases detected by electronic algorithm	543		270	
Cases subject to validation n, (%)	137 (25.23)		29 (10.74)	
Level 1	59 (43.07)			
Level 2	36 (26.28)		<5	
Level 3	0 (NaN)		0 (NaN)	
Level 1-3 (PPV-strict)	95 (100)	100	22 (100)	100
Level 4	42 (30.66)		7 (24.14)	
Level 1-4 (PPV-broad)	137 (100)	100	29 (100)	100
Level 5	0 (0)		0 (0)	
Pericarditis cases detected by electronic algorithm	1,397		544	
Cases subject to validation n, (%)	179 (12.81)		37 (6.8)	
Level 1	40 (22.35)			
Level 2	31 (17.32)		<5	
Level 3	28 (100)		9 (100)	
Level 1-3 (PPV-strict)	99 (100)	100	29 (100)	100
Level 4	79 (44.13)		8 (21.62)	
Level 1-4 (PPV-broad)	178 (100)	100	37 (100)	100
Level 5	0 (0)		0 (0)	

Table 15.36.4 Summary of results for validation of myocarditis and pericarditis cases by level of diagnostic certainty, exposure group for EpiChron

Characteristic	Vaccinated n(%)	Vaccinated PPV	Unvaccinated n(%)	Unvaccinated PPV
Myocarditis cases detected by electronic algorithm	75		41	
Cases subject to validation n, (%)	43 (57.33)		35 (85.37)	
Level 1	22 (51.16)			
Level 2	12 (100)		<5	
Level 3	0 (NaN)		0 (NaN)	
Level 1-3 (PPV-strict)	34 (100)	100	24 (100)	100
Level 4	0 (0)		<5	
Level 1-4 (PPV-broad)	34 (100)	100	26 (100)	100
Level 5	9 (20.93)		9 (25.71)	
Pericarditis cases detected by electronic algorithm	302		133	
Cases subject to validation n, (%)	178 (58.94)		112 (84.21)	
Level 1				
Level 2	40 (100)		30 (100)	
Level 3	<5		<5	
Level 1-3 (PPV-strict)	127 (100)	100	76 (100)	100
Level 4	34 (19.1)		27 (24.11)	
Level 1-4 (PPV-broad)	161 (100)	100	103 (100)	100
Level 5	17 (9.55)		9 (8.04)	

Table 15.36.5 Summary of results for validation of myocarditis and pericarditis cases by level of diagnostic certainty, exposure group for SIDIAP

Characteristic	Vaccinated n(%)	Vaccinated PPV	Unvaccinated n(%)	Unvaccinated PPV
Myocarditis cases detected by electronic algorithm	386		290	
Cases subject to validation n, (%)	114 (29.53)		32 (11.03)	
Level 1	<5		<5	
Level 2			<5	
Level 3	7 (100)		<5	
Level 1-3 (PPV-strict)	28 (100)	100	9 (100)	100
Level 4	63 (55.26)		12 (37.5)	
Level 1-4 (PPV-broad)	91 (100)	100	21 (100)	100
Level 5	23 (20.18)		11 (34.38)	
Pericarditis cases detected by electronic algorithm	894		770	
Cases subject to validation n, (%)	128 (14.32)		34 (4.42)	
Level 1	27 (21.09)			
Level 2	<5		<5	
Level 3	<5		0 (NaN)	
Level 1-3 (PPV-strict)	31 (100)	100	8 (100)	100
Level 4	57 (44.53)		18 (52.94)	
Level 1-4 (PPV-broad)	88 (100)	100	26 (100)	100
Level 5	40 (31.25)		8 (23.53)	

Table 15.36.6 Summary of results for validation of myocarditis and pericarditis cases by level of diagnostic certainty, exposure group for CPRD

Characteristic	Vaccinated n(%)	Vaccinated PPV	Unvaccinated n(%)	Unvaccinated PPV
Myocarditis cases detected by electronic algorithm	513		350	
Cases subject to validation n, (%)	178 (34.7)		50 (14.29)	
Level 1	0 (0)		<5	
Level 2			<5	
Level 3	<5		<5	
Level 1-3 (PPV-strict)	10 (100)	100	<5	100
Level 4	161 (90.45)		46 (92)	
Level 1-4 (PPV-broad)	171 (100)	100	49 (100)	100
Level 5	0 (0)		0 (0)	
Pericarditis cases detected by electronic algorithm	1,072		750	
Cases subject to validation n, (%)	207 (19.31)		64 (8.53)	
Level 1	9 (4.35)		<5	
Level 2	0 (0)		0 (0)	
Level 3	0 (NaN)		0 (NaN)	
Level 1-3 (PPV-strict)	9 (100)	100	<5	100
Level 4	170 (82.13)			
Level 1-4 (PPV-broad)	179 (100)	100	52 (100)	100
Level 5	0 (0)		0 (0)	

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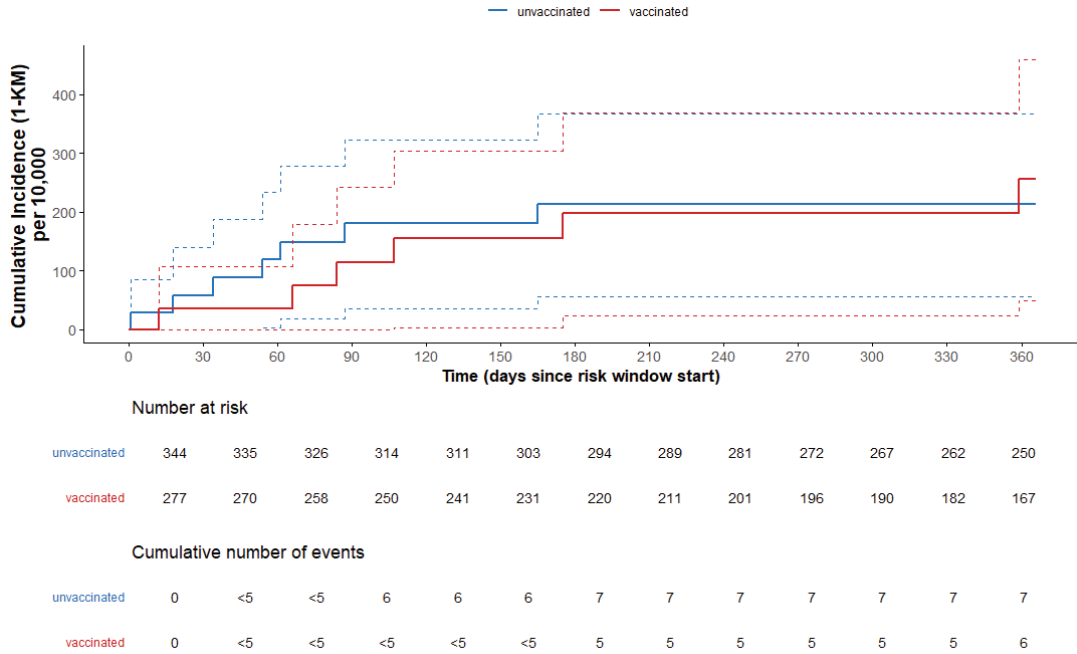
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15.1 **Figure 1: Overall cumulative incidence by outcome in the myocarditis and pericarditis cohorts by data source**

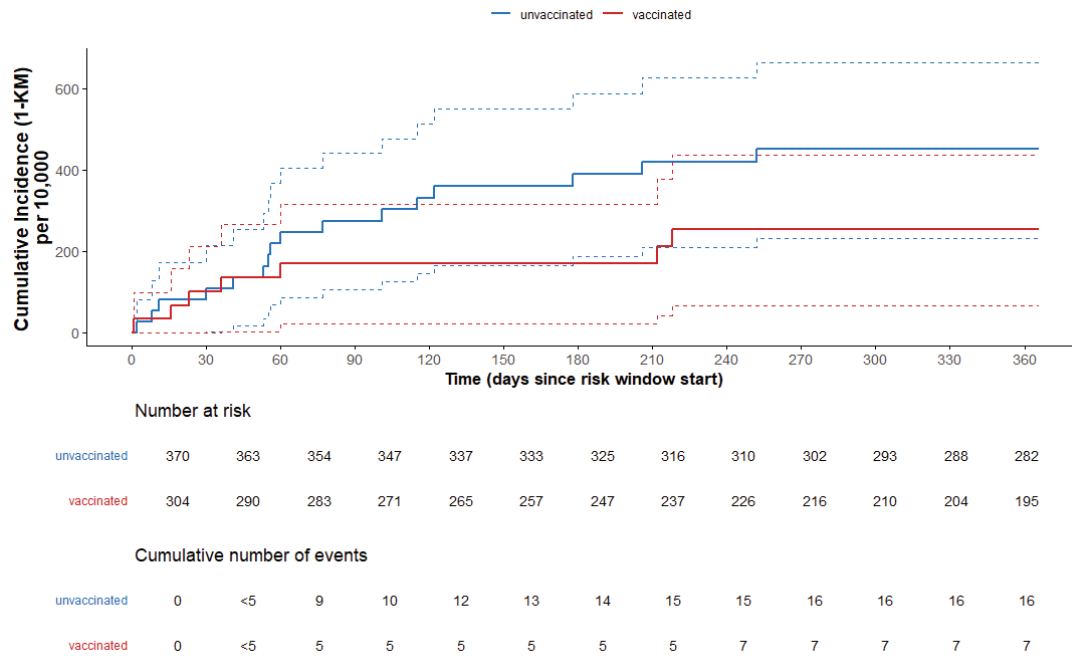
15.1.1 **PHARMO myocarditis cohort**

15.1.1.1 **Cumulative incidence of recurrent myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**

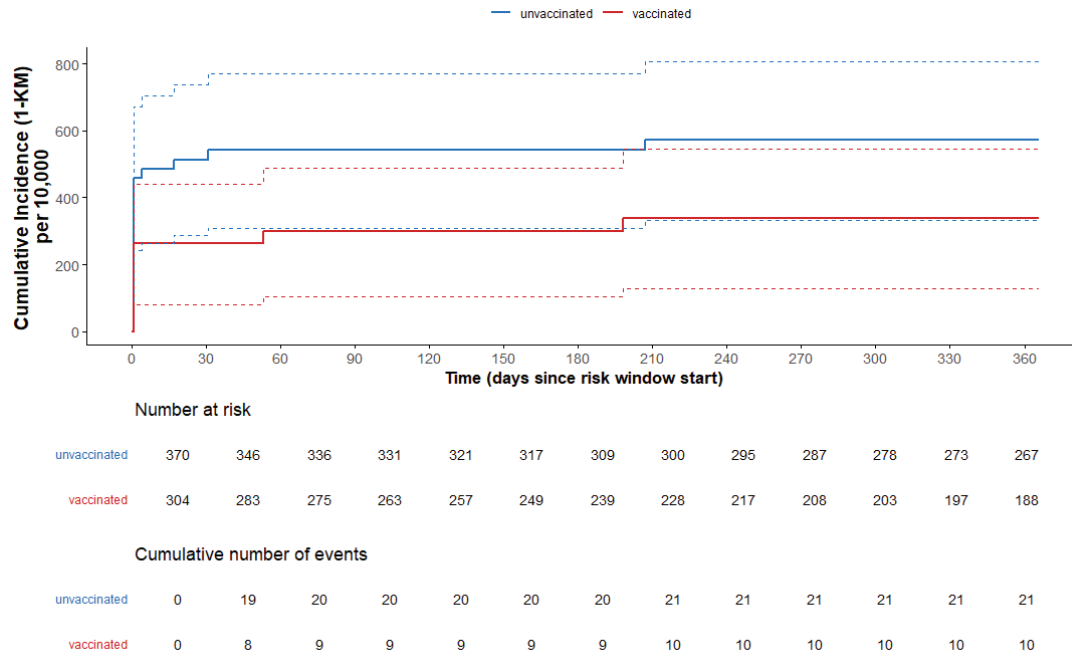


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15.1.1.2 Cumulative incidence of death in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

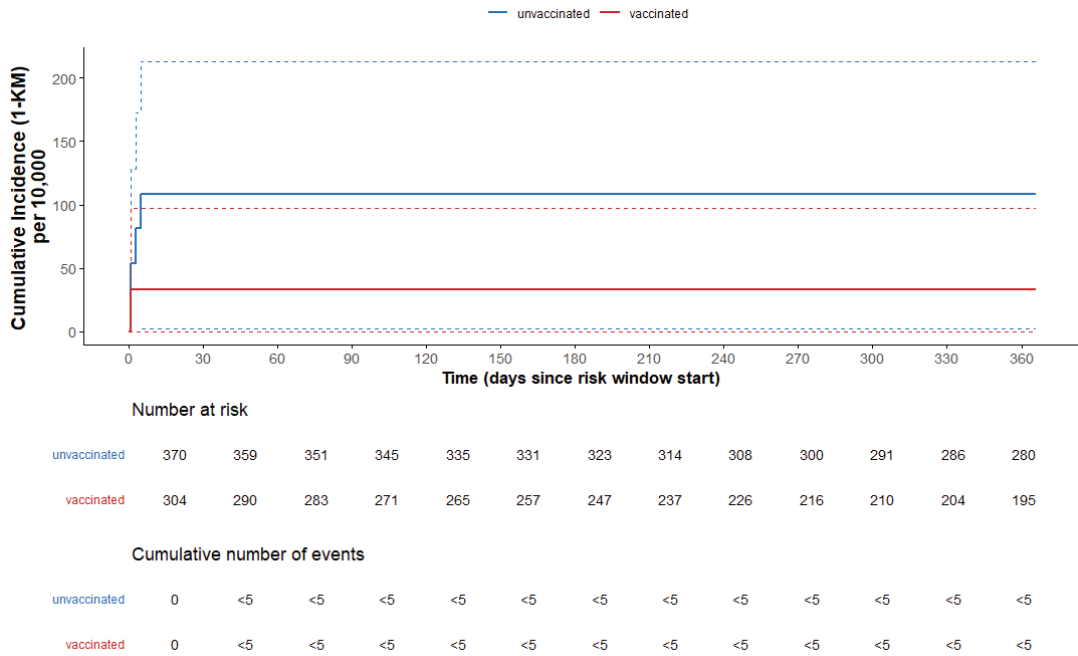


15.1.1.3 Cumulative incidence of heart failure in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



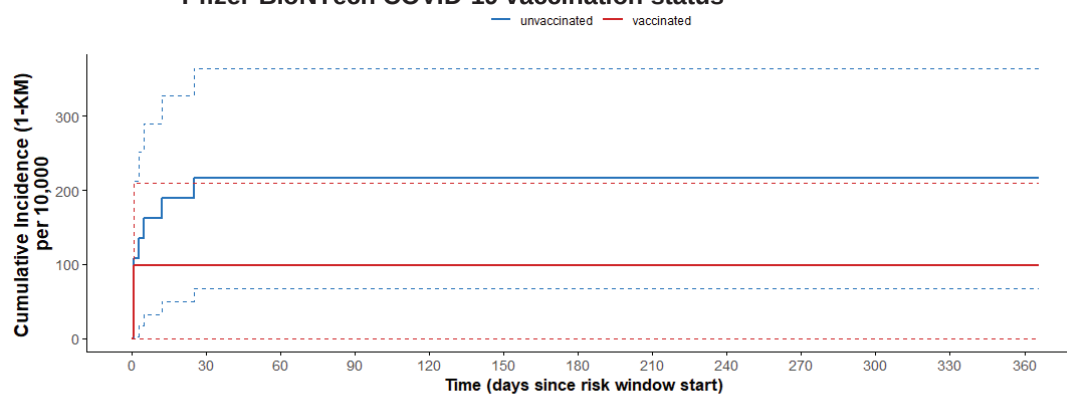
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15.1.1.4 Cumulative incidence of cardiogenic shock in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



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15.1.1.5 Cumulative incidence of fulminant myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



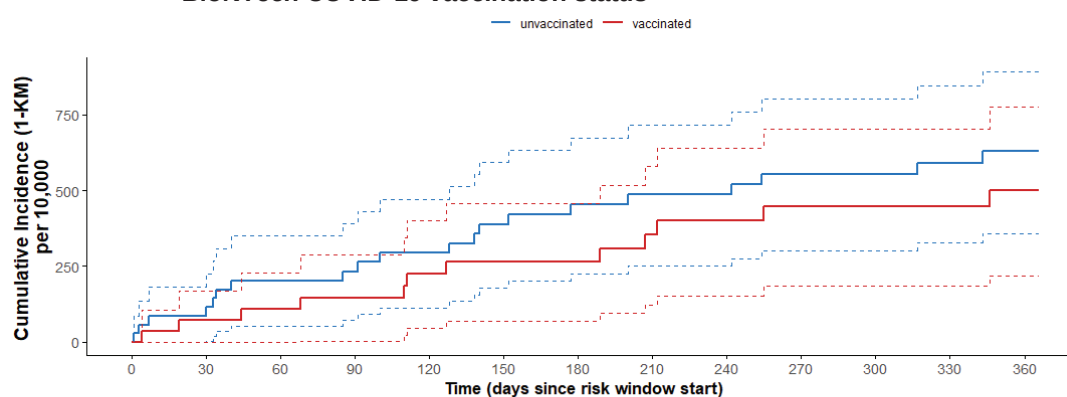
Number at risk

unvaccinated	370	355	347	341	331	327	319	310	305	297	288	283	277
vaccinated	304	289	282	270	264	256	246	236	225	215	209	203	194

Cumulative number of events

unvaccinated	0	8	8	8	8	8	8	8	8	8	8	8	8
vaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5

15.1.1.6 Cumulative incidence of arrhythmia in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



Number at risk

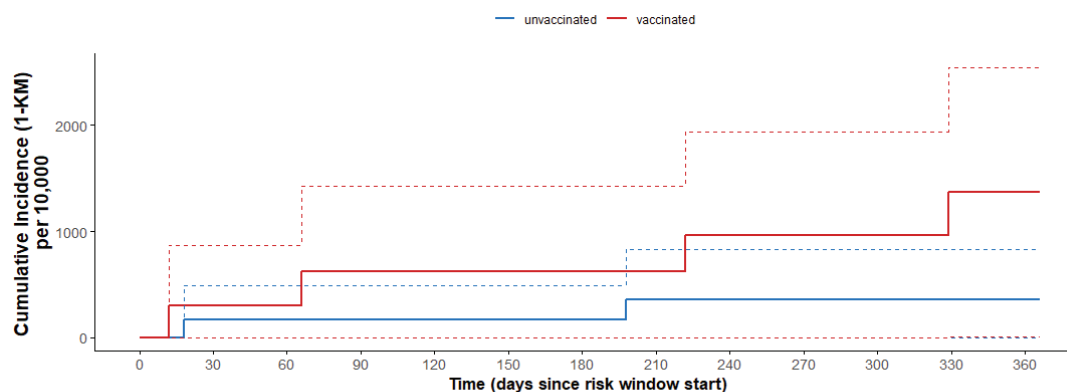
unvaccinated	351	341	330	319	313	302	292	286	279	268	263	256	243
vaccinated	282	275	262	255	245	235	226	213	203	197	191	182	167

Cumulative number of events

unvaccinated	0	<5	7	8	10	13	15	16	16	18	18	19	20
vaccinated	0	<5	<5	<5	6	7	7	9	10	11	11	11	12

15.1.2 PHARMO pericarditis cohort

15.1.2.1 Cumulative incidence of recurrent pericarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



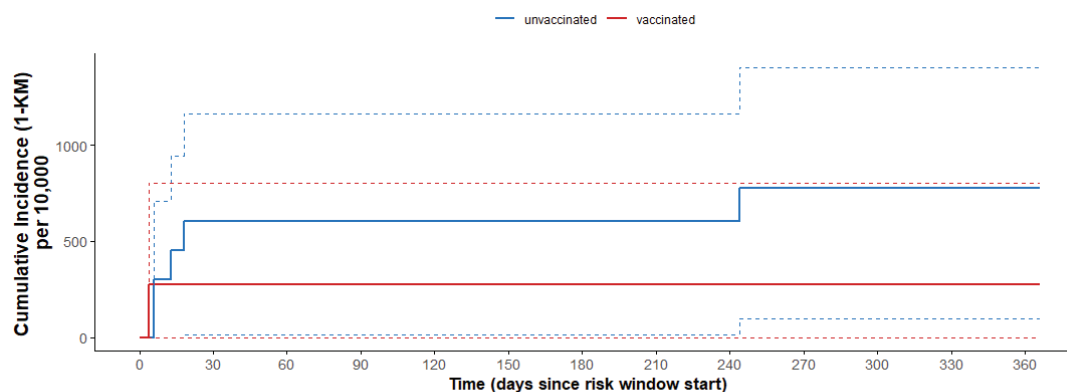
Number at risk

unvaccinated	59	58	57	55	55	55	53	51	48	44	43	42	41
vaccinated	33	32	30	28	28	28	28	28	26	24	24	21	21

Cumulative number of events

unvaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5
vaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5

15.1.2.2 Cumulative incidence of death in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



Number at risk

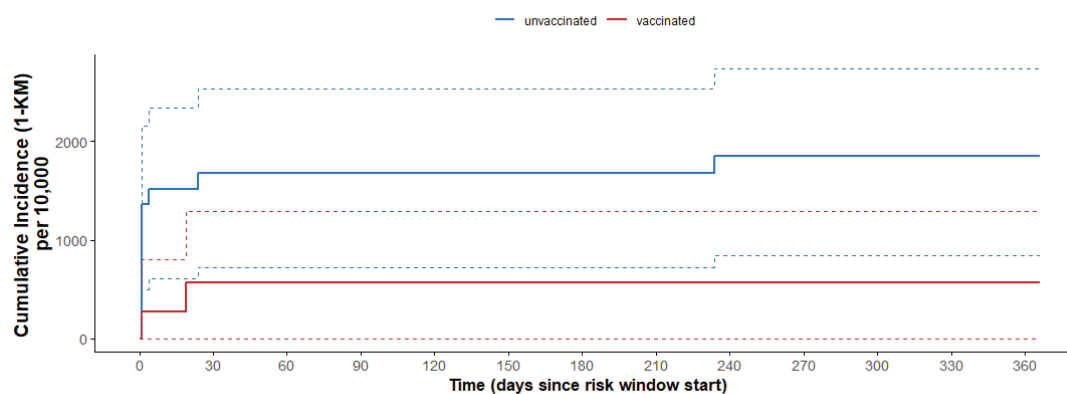
unvaccinated	66	62	62	61	59	59	59	57	56	53	49	48	47
vaccinated	36	35	35	33	32	32	32	32	32	31	29	28	26

Cumulative number of events

unvaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	5	5	5	5
vaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5

15.1.2.3 Cumulative incidence of heart failure in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

Pericarditis - Heart Failure



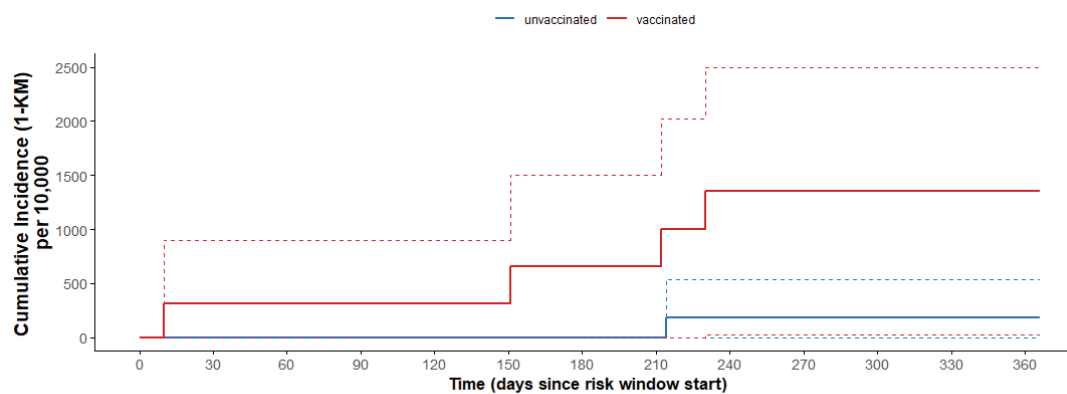
Number at risk

unvaccinated	66	52	52	51	50	50	50	48	46	45	42	41	40
vaccinated	36	33	33	31	30	30	30	30	30	29	27	26	24

Cumulative number of events

unvaccinated	0	11	11	11	11	11	11	11	12	12	12	12	12
vaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5

15.1.2.4 Cumulative incidence of arrhythmia in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



Number at risk

unvaccinated	60	60	59	57	57	57	55	54	50	47	46	45	44
vaccinated	32	31	29	28	28	28	27	27	24	22	21	19	19

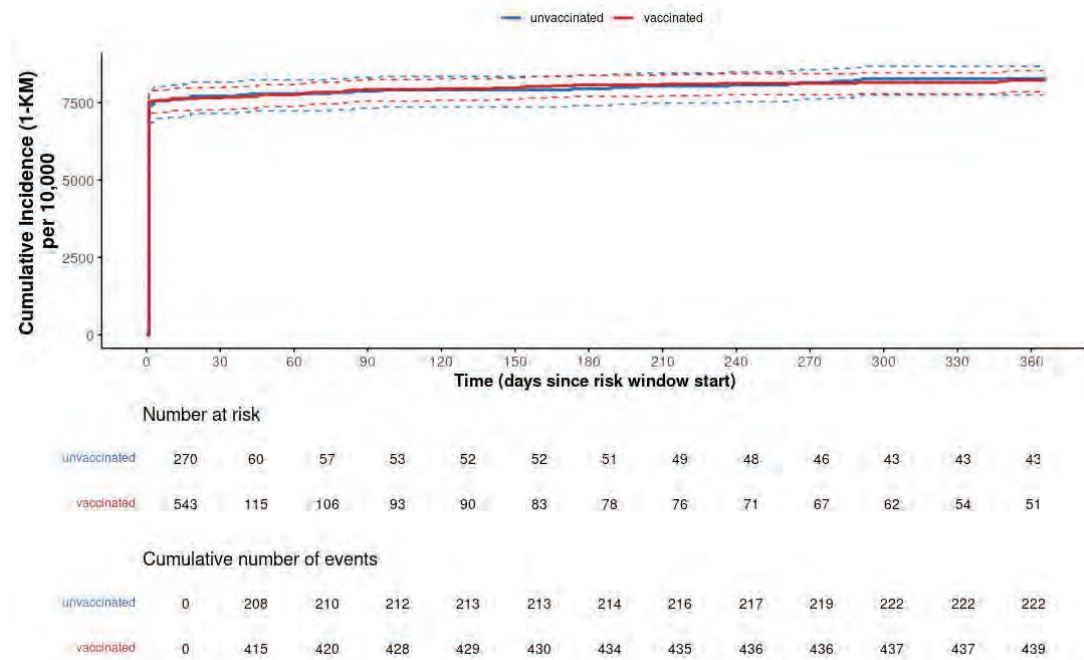
Cumulative number of events

unvaccinated	0	0	0	0	0	0	0	0	<5	<5	<5	<5	<5
vaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5

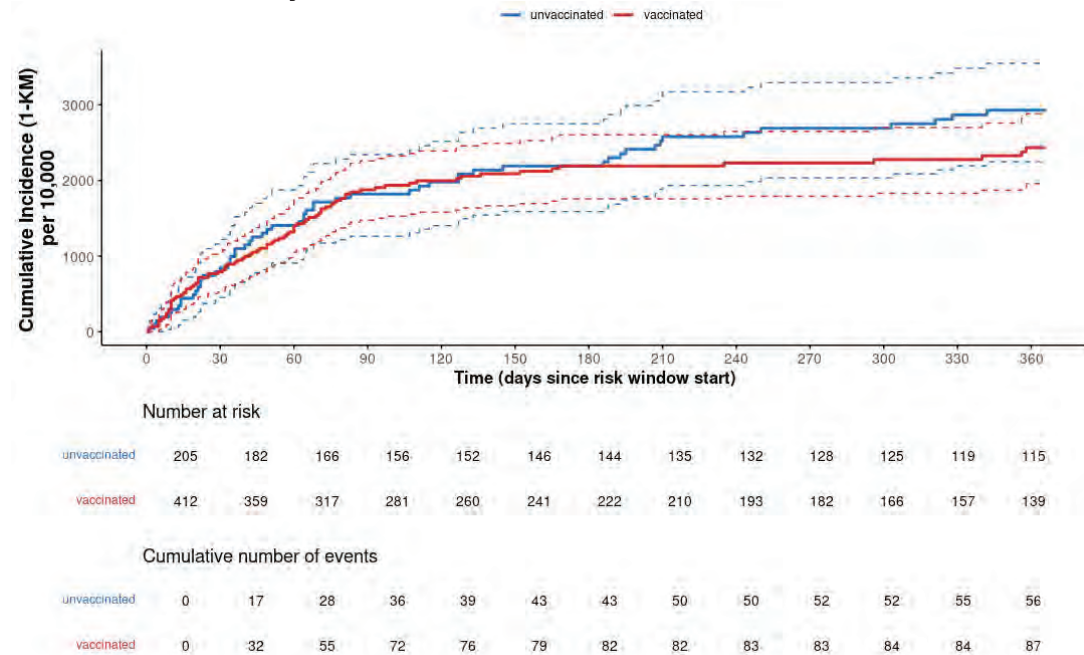
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15.1.3 NHR myocarditis cohort

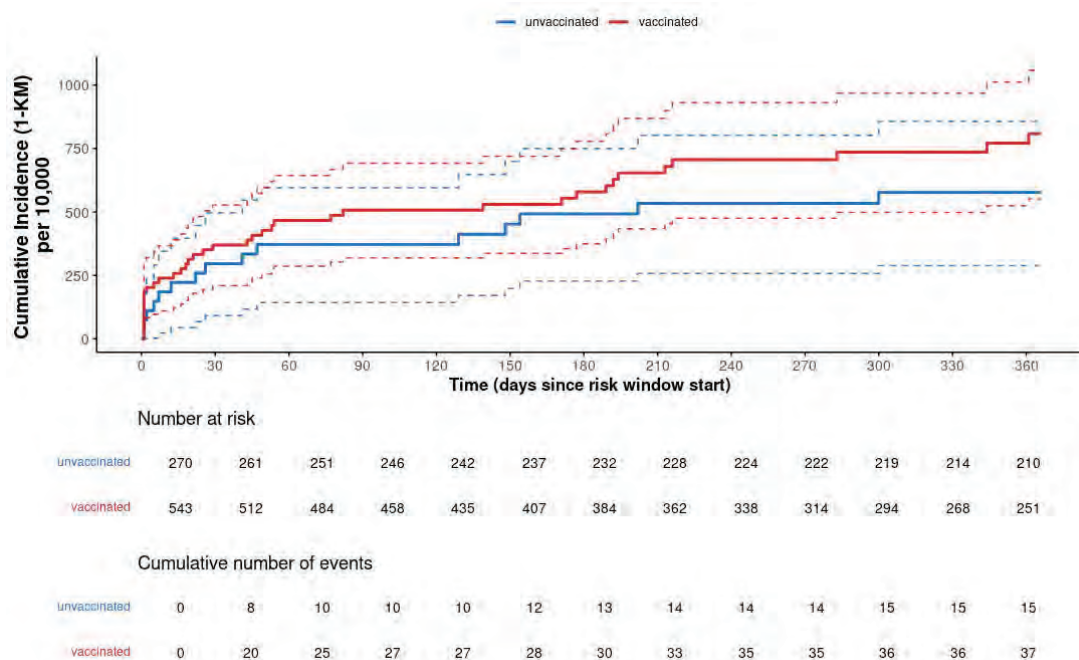
15.1.3.1 NHR: Cumulative incidence of the number of hospitalisations in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



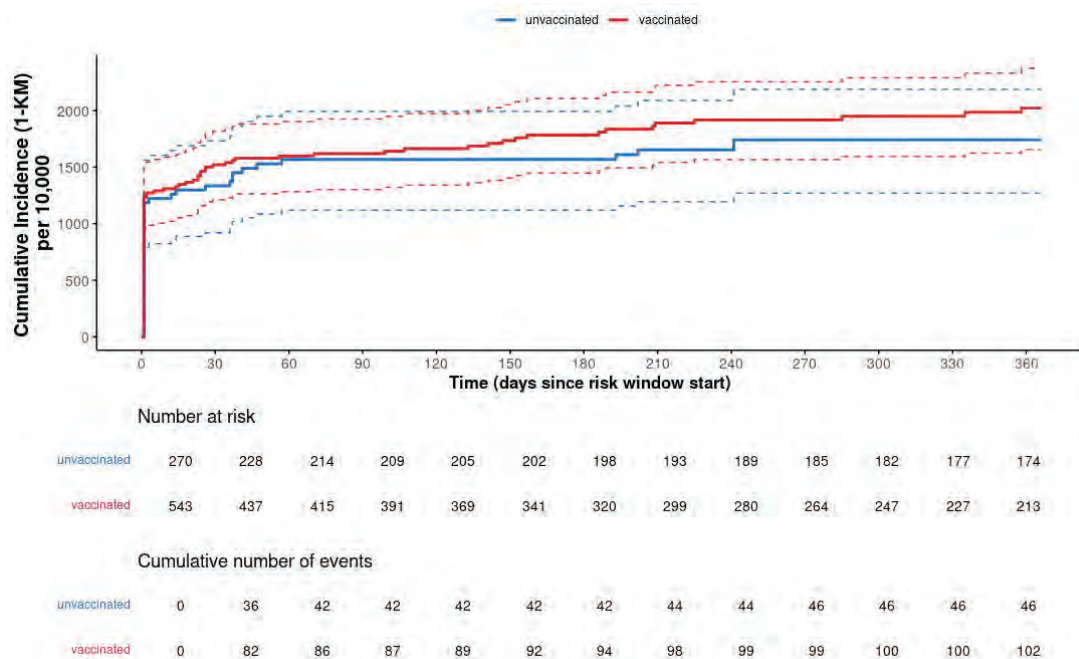
15.1.3.2 NHR: Cumulative incidence of recurrent myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



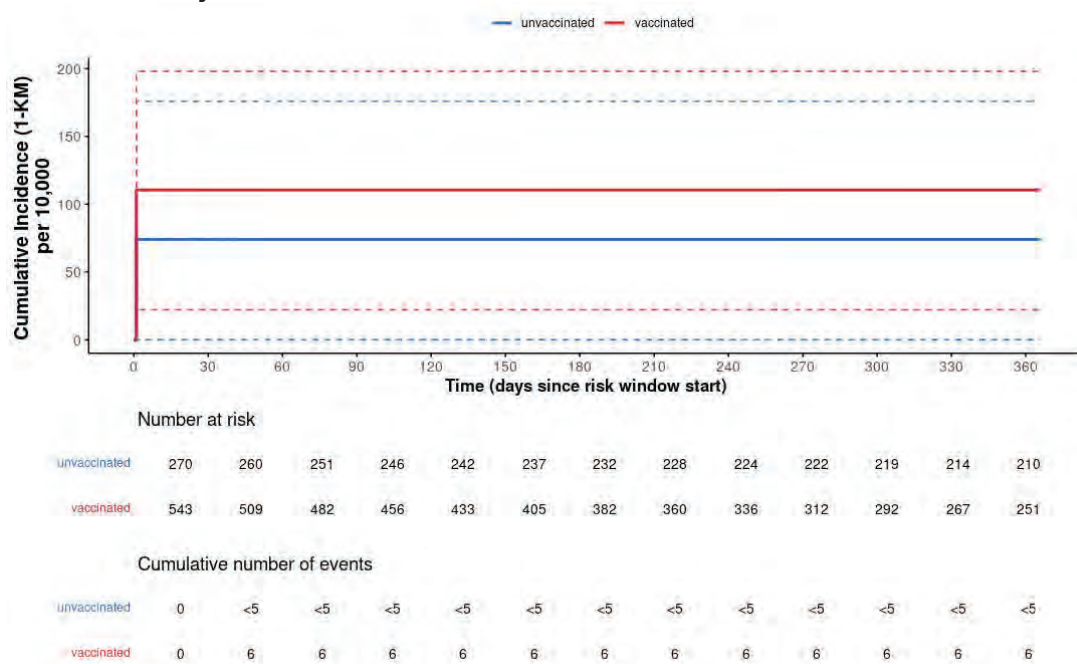
15.1.3.3 NHR: Cumulative incidence of death in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



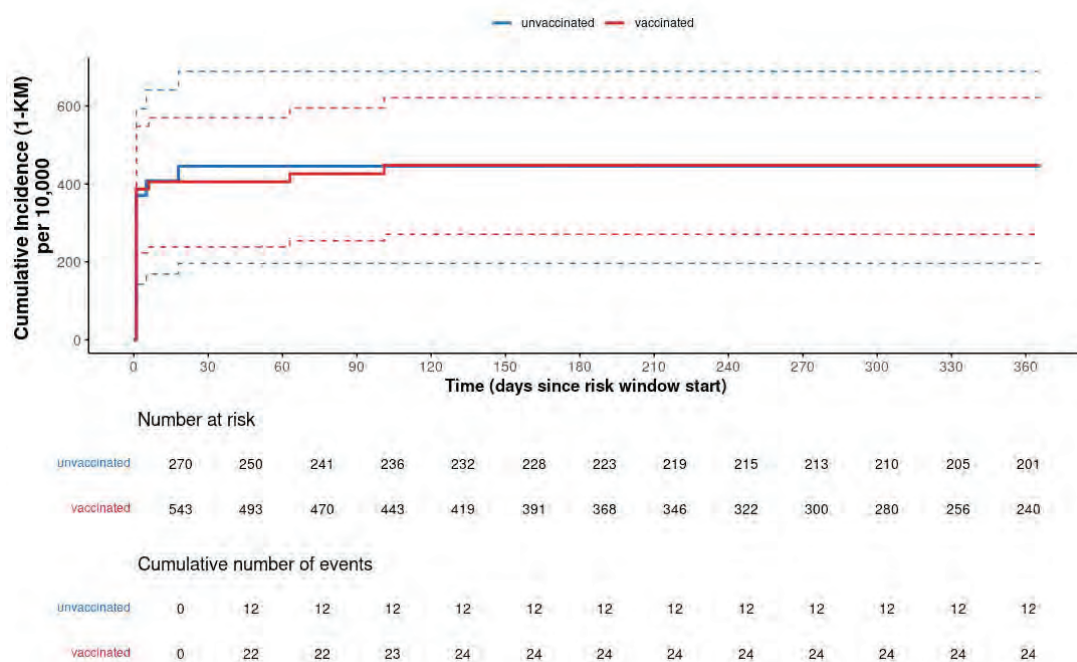
15.1.3.4 NHR: Cumulative incidence of heart failure in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



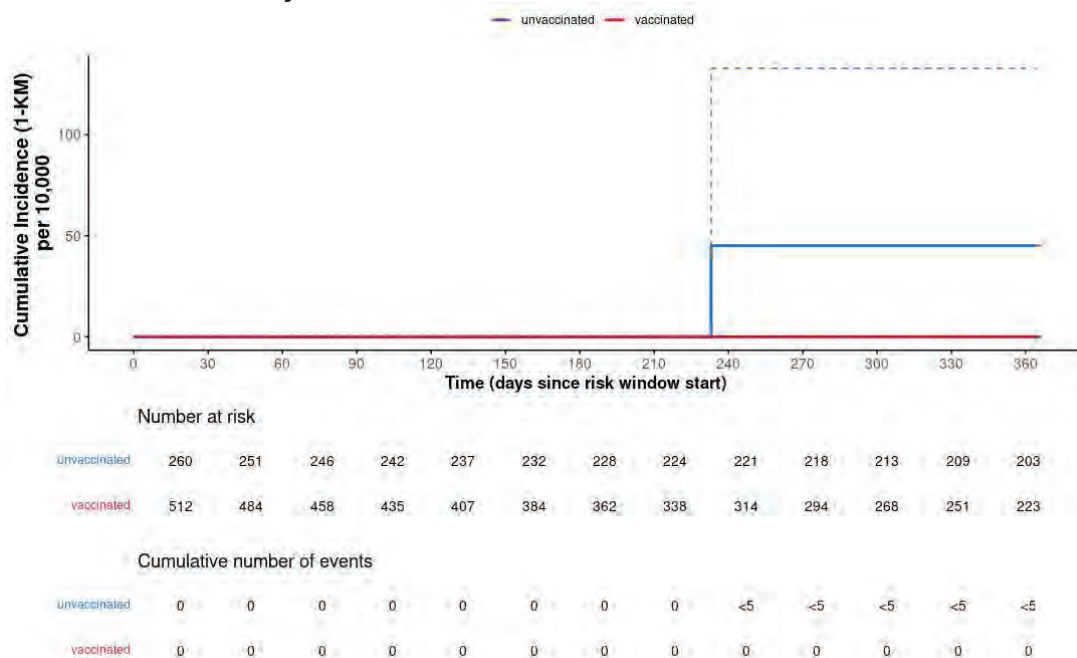
15.1.3.5 NHR: Cumulative incidence of cardiogenic shock in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



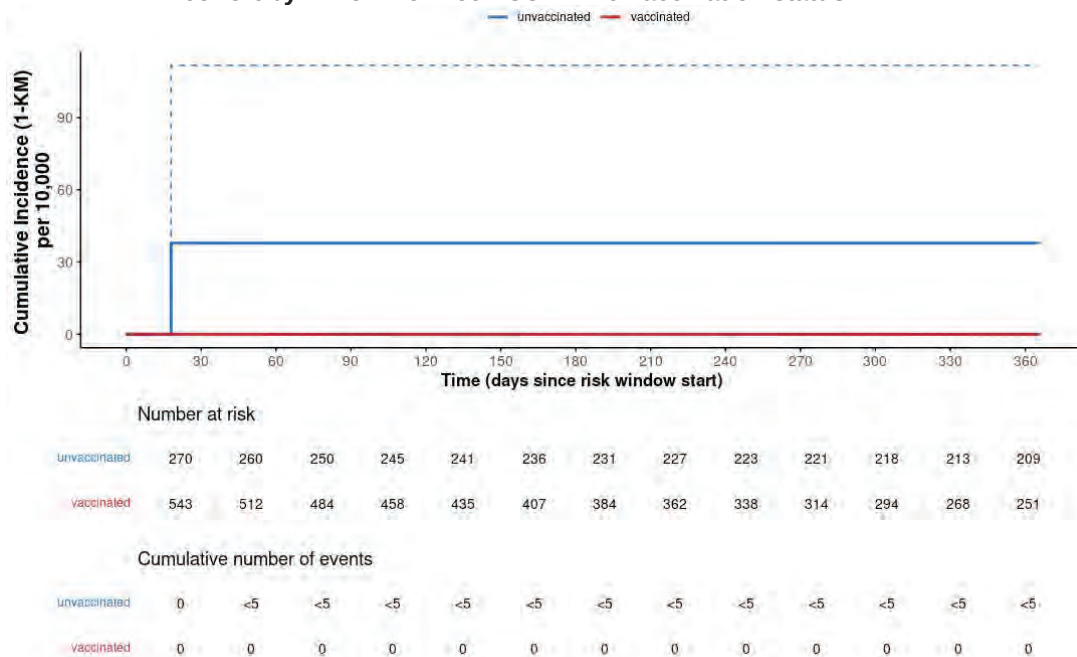
15.1.3.6 NHR: Cumulative incidence of fulminant myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



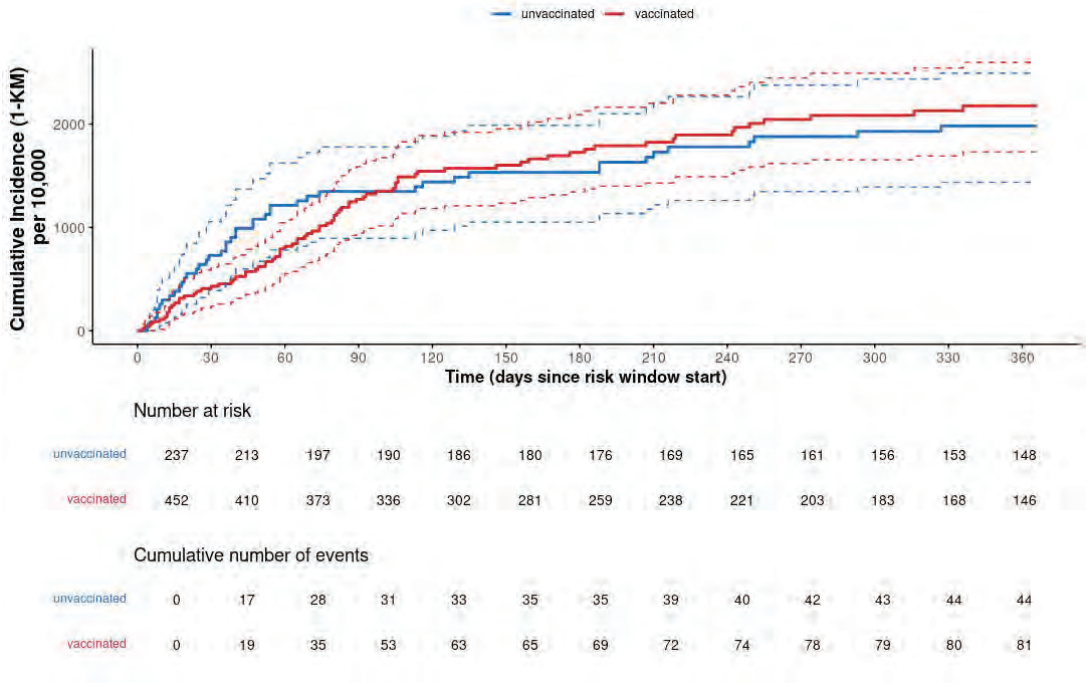
15.1.3.7 NHR: Cumulative incidence of chronic myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



15.1.3.8 NHR: Cumulative incidence of heart transplantations in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



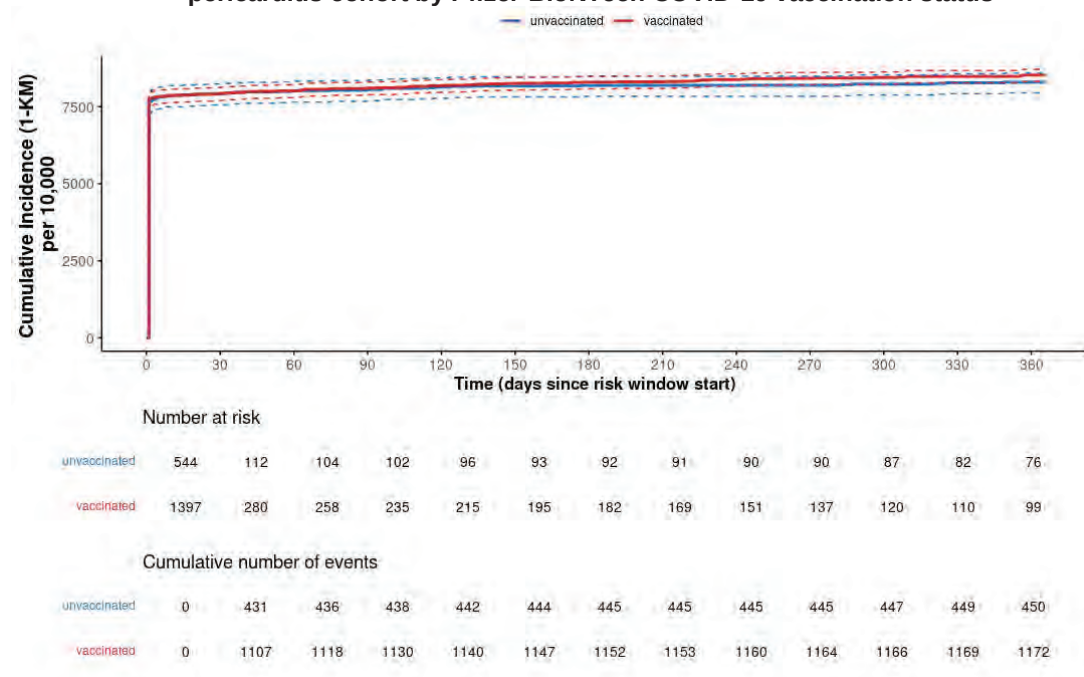
15.1.3.9 NHR: Cumulative incidence of arrhythmia in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



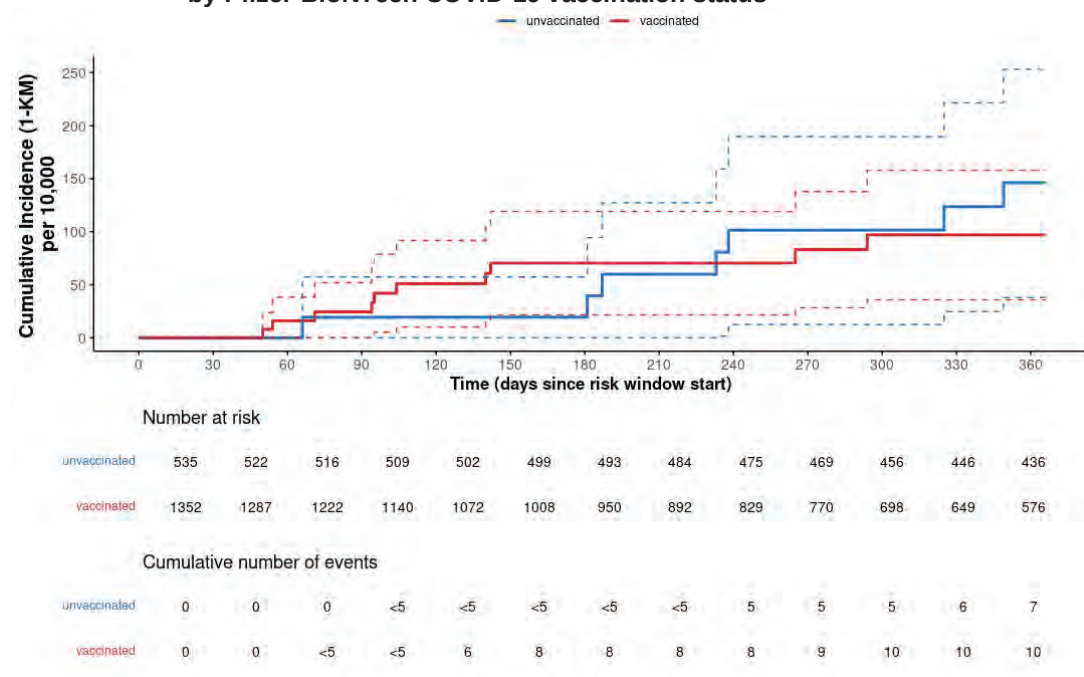
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15.1.4 NHR pericarditis cohort

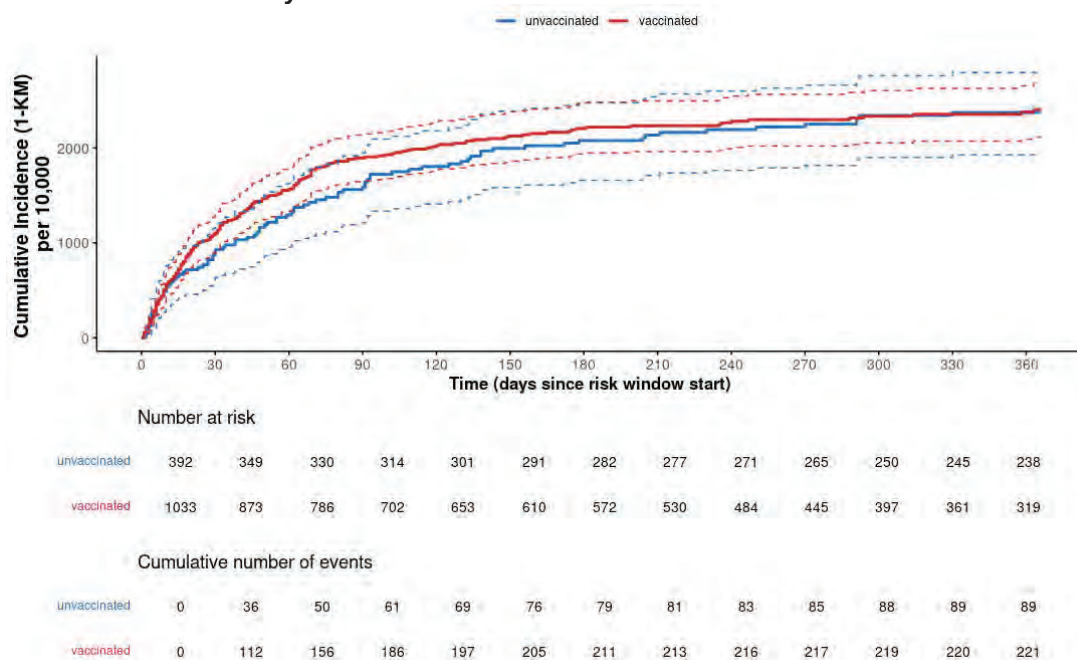
15.1.4.1 NHR: Cumulative incidence of the number of hospitalisations in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



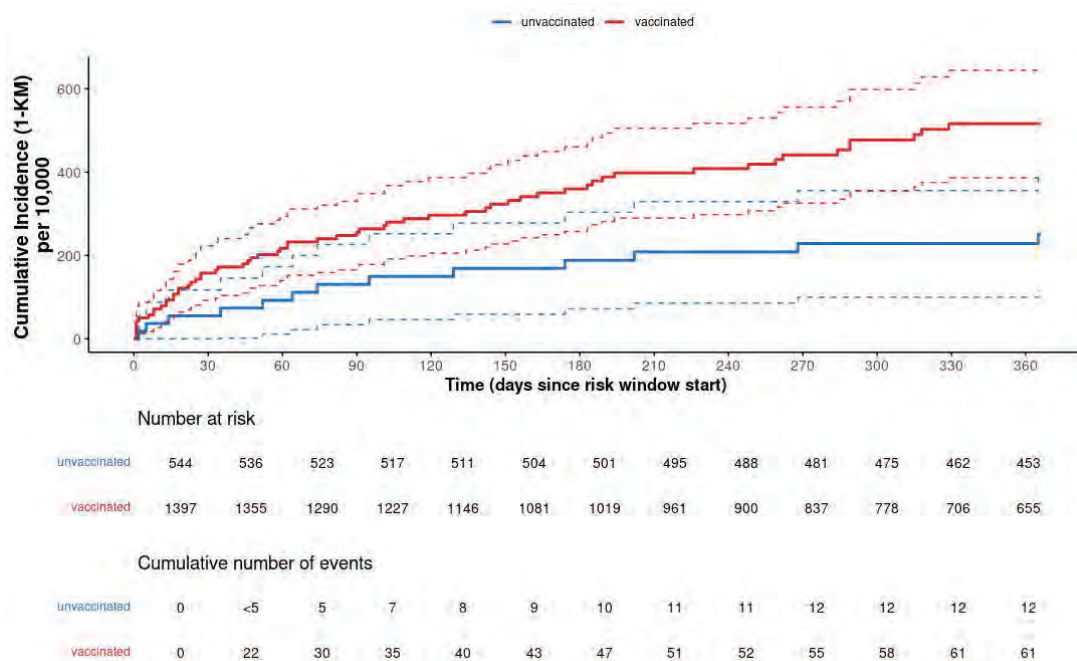
15.1.4.2 NHR: Cumulative incidence of chronic pericarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



15.1.4.3 NHR: Cumulative incidence of recurrent pericarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

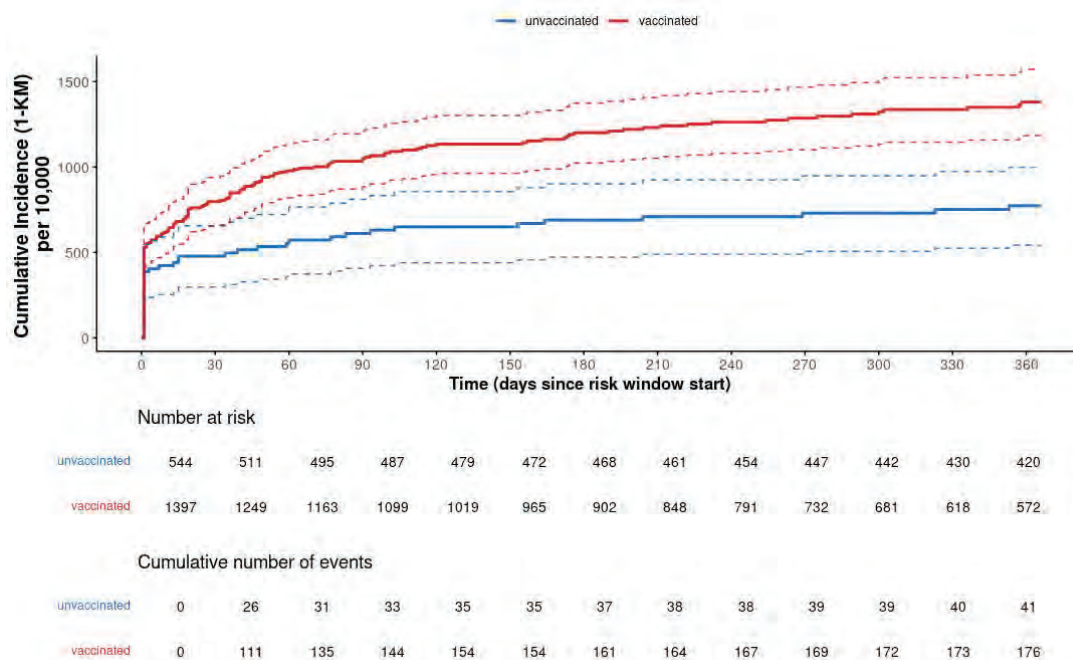


15.1.4.4 NHR: Cumulative incidence of death in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



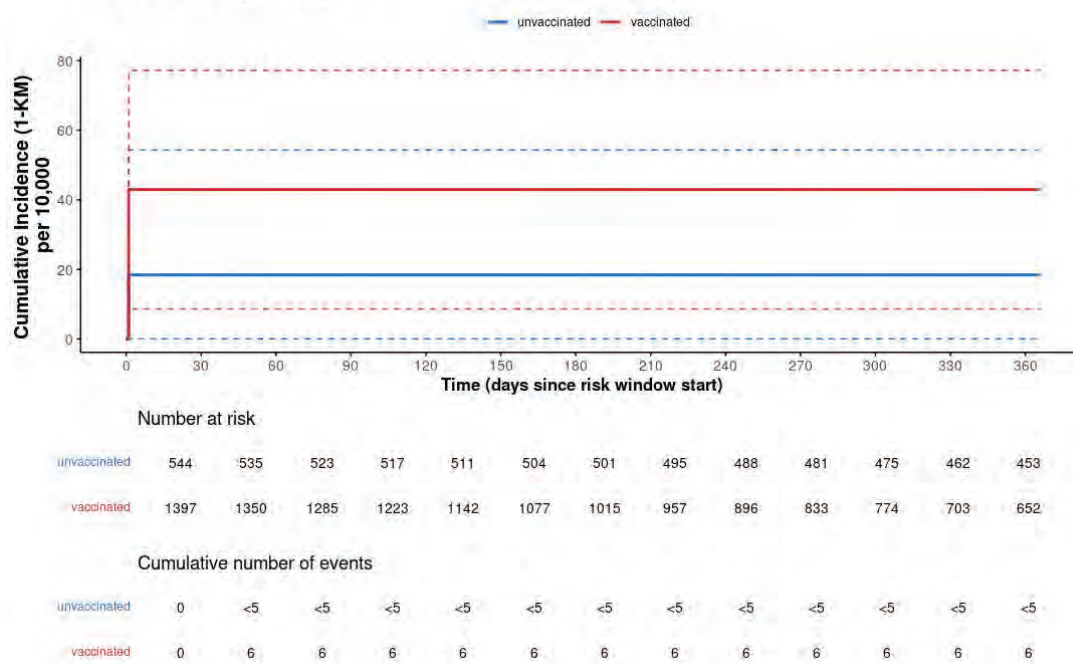
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15.1.4.5 NHR: Cumulative incidence of heart failure in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



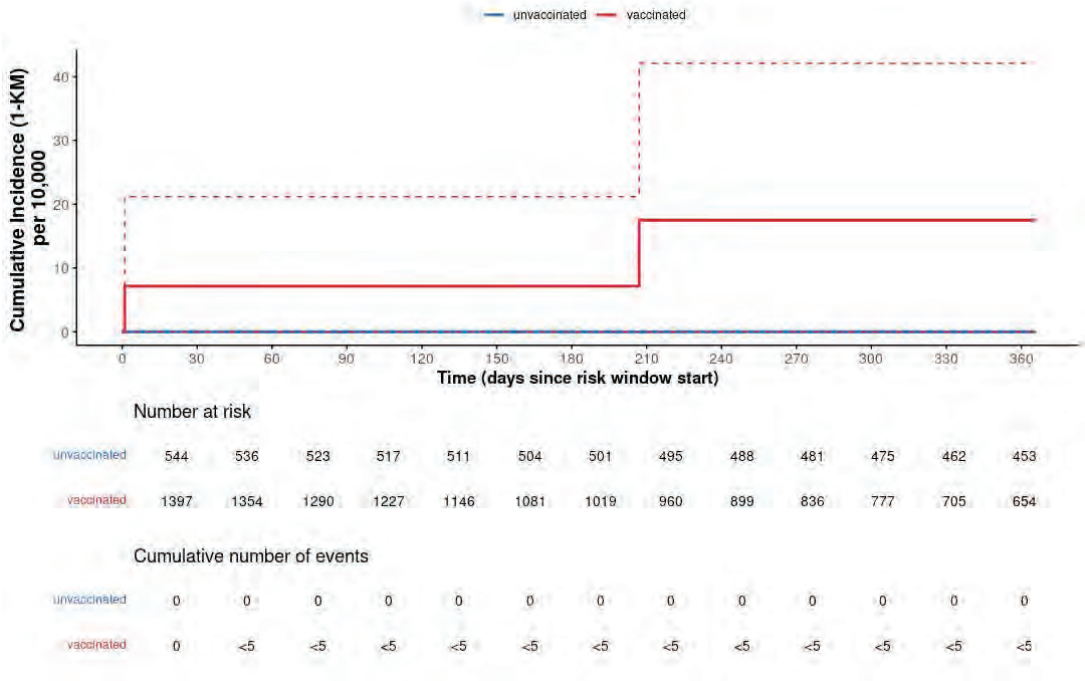
15.1.4.6 NHR: Cumulative incidence of cardiogenic shock in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

Pericarditis - Cardiogenic Shock



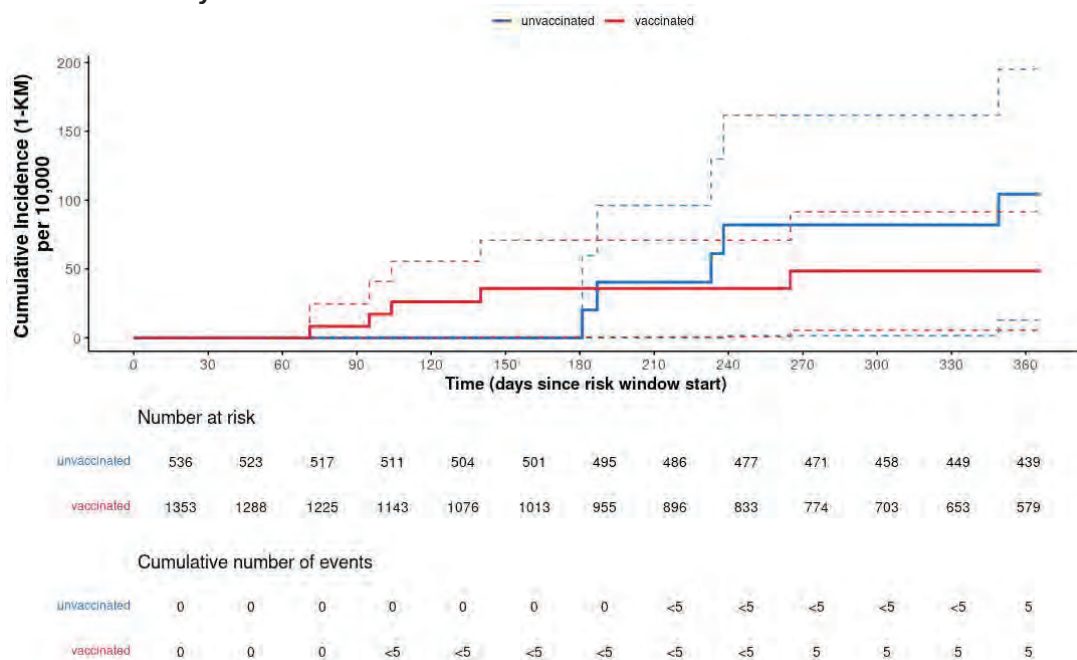
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15.1.4.7 NHR: Cumulative incidence of fulminant myocarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

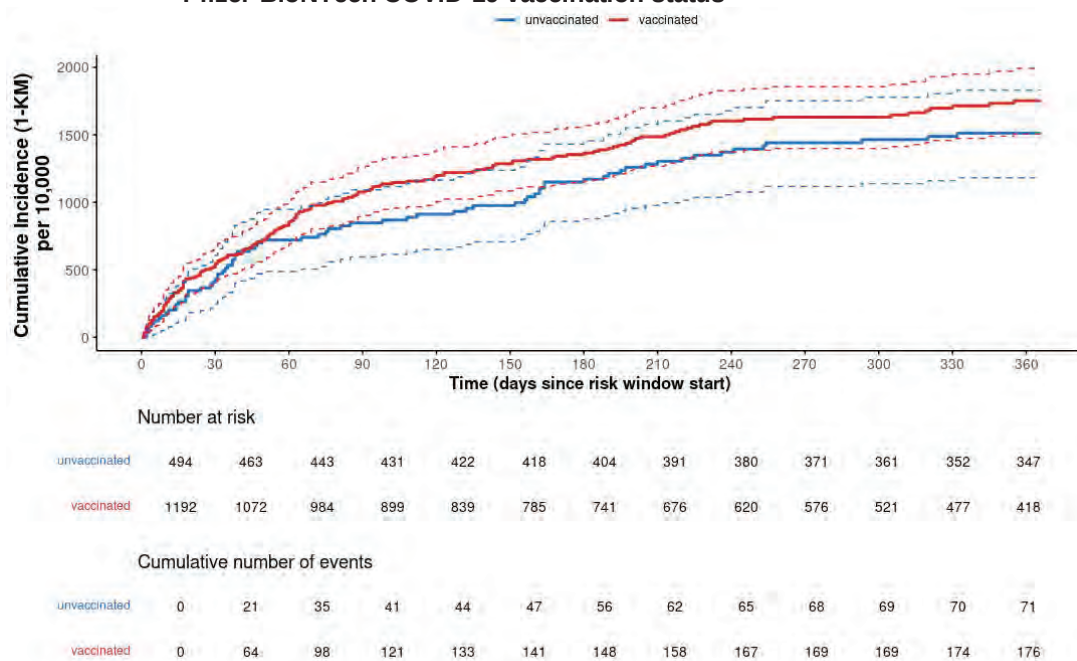


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15.1.4.8 NHR: Cumulative incidence of chronic myocarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

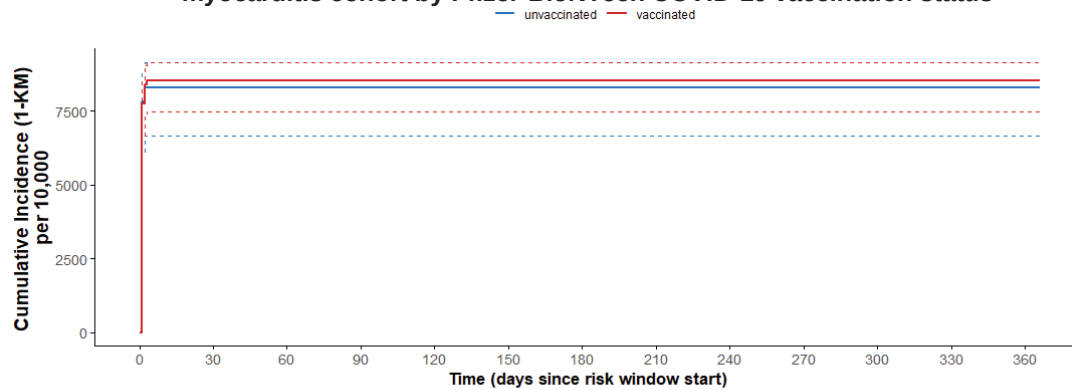


15.1.4.9 NHR: Cumulative incidence of arrhythmia in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



15.1.5 EpiChron myocarditis cohort

15.1.5.1 EpiChron: Cumulative incidence of the number of hospitalisations in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



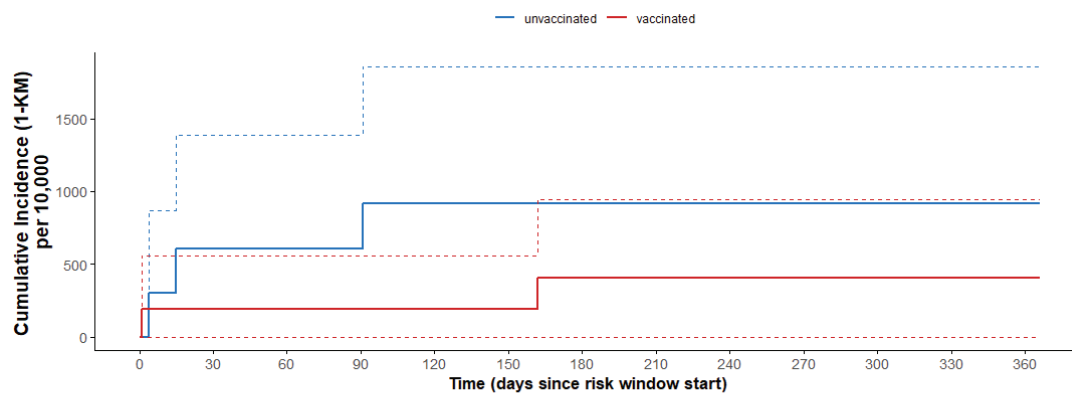
Number at risk

unvaccinated	41	7	7	5	5	5	5	5	5	5	5	5
vaccinated	75	9	8	8	7	7	5	<5	<5	<5	<5	<5

Cumulative number of events

unvaccinated	0	34	34	34	34	34	34	34	34	34	34	34
vaccinated	0	64	64	64	64	64	64	64	64	64	64	64

15.1.5.2 EpiChron: Cumulative incidence of recurrent myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



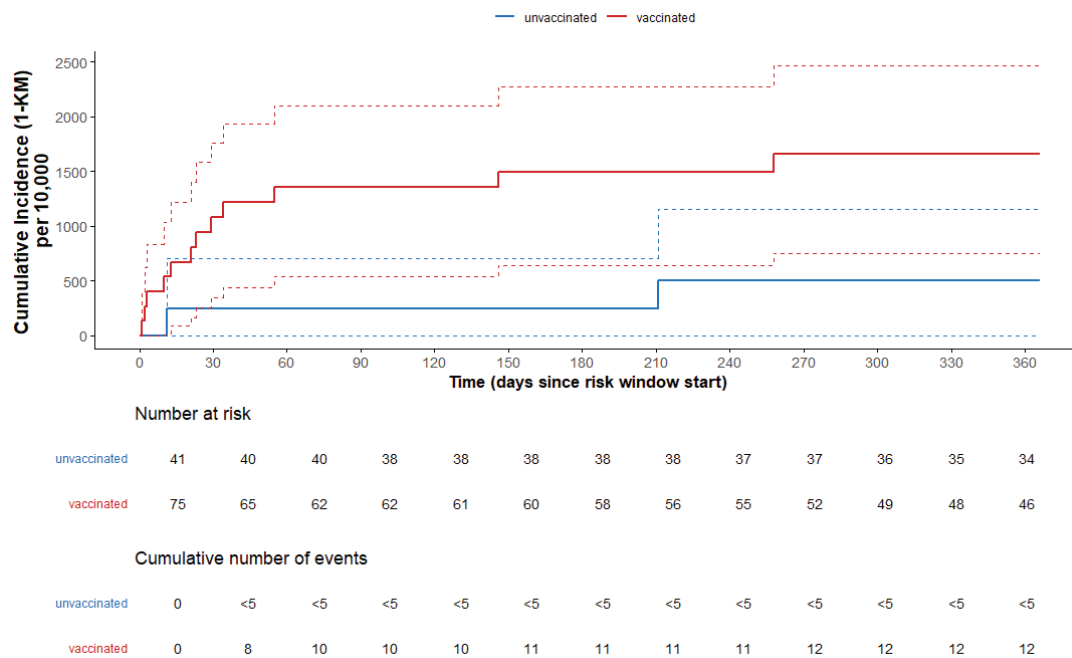
Number at risk

unvaccinated	33	31	30	30	29	29	29	28	28	28	27	27	27
vaccinated	52	50	50	49	48	46	43	42	40	38	37	35	35

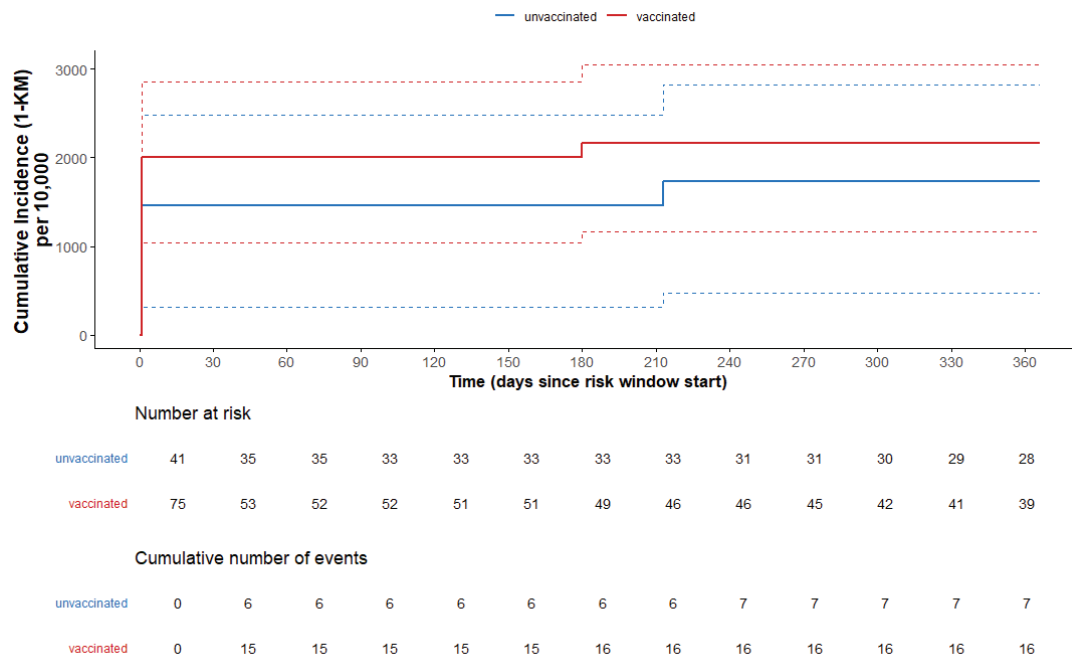
Cumulative number of events

unvaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5
vaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5

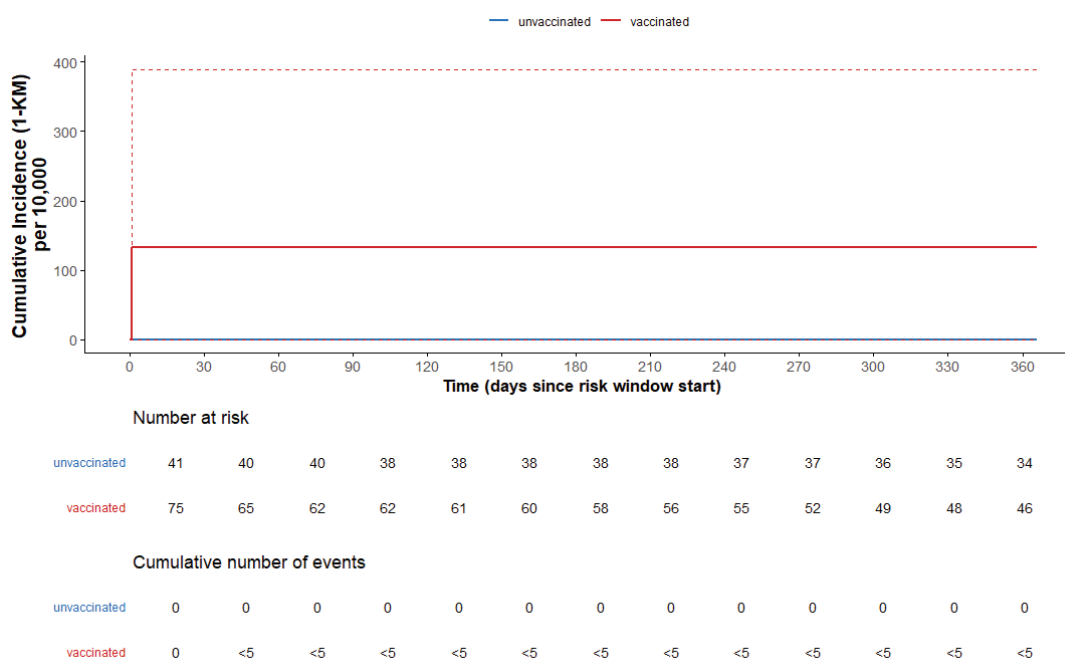
15.1.5.3 EpiChron: Cumulative incidence of deaths in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



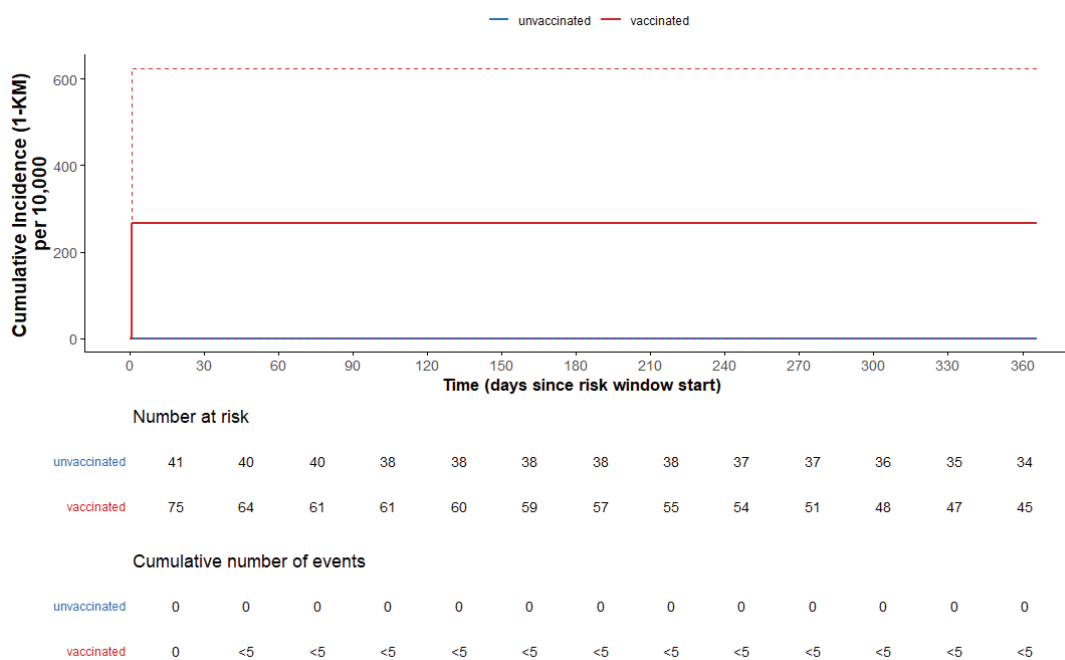
15.1.5.4 EpiChron: Cumulative incidence of heart failure in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

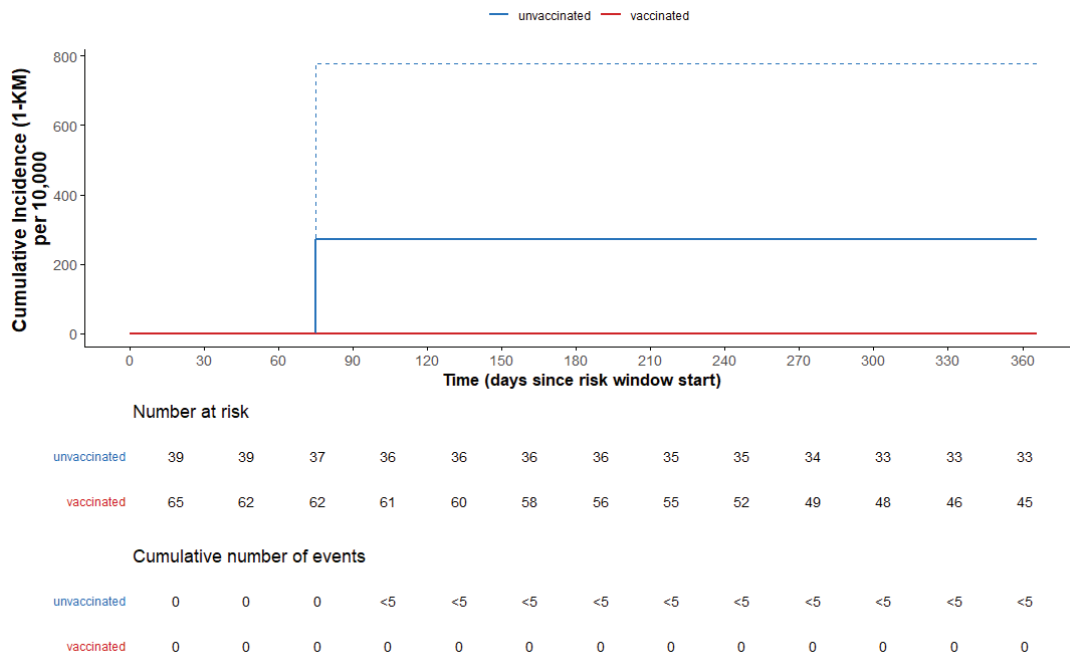
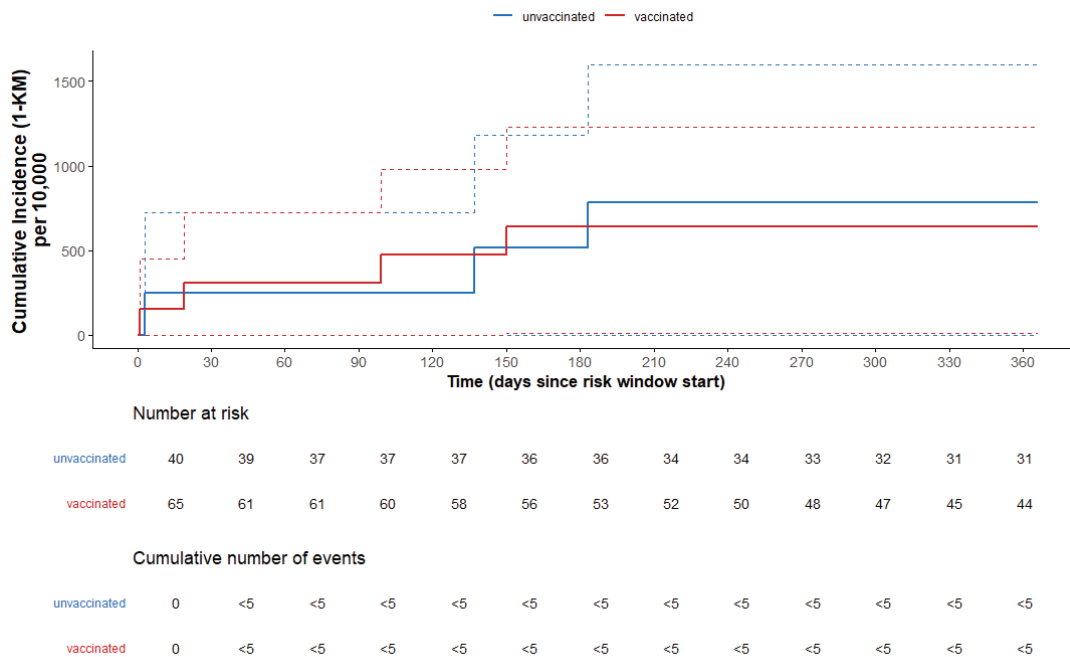


15.1.5.5 EpiChron: Cumulative incidence of cardiogenic shock in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



15.1.5.6 EpiChron: incidence number of fulminant myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

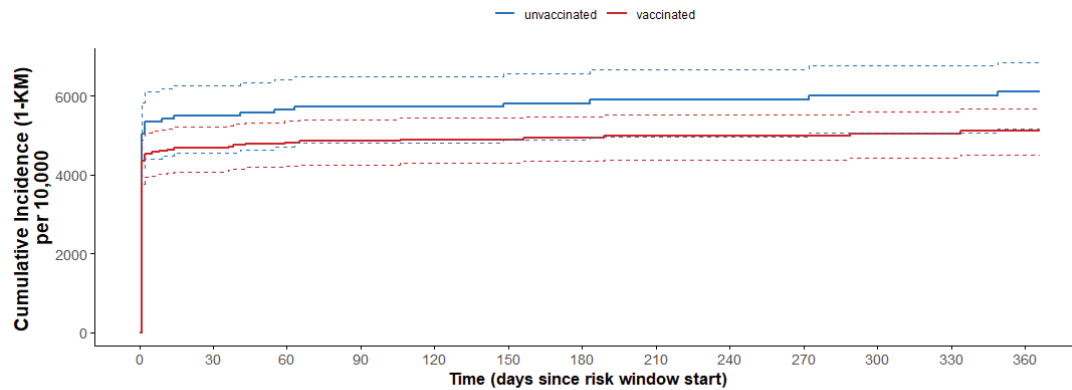


15.1.5.7 EpiChron: Cumulative incidence of chronic myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**15.1.5.8 EpiChron: Cumulative incidence of arrhythmia in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**

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15.1.6 EpiChron pericarditis cohort

15.1.6.1 EpiChron: Cumulative incidence of the number of hospitalisations in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



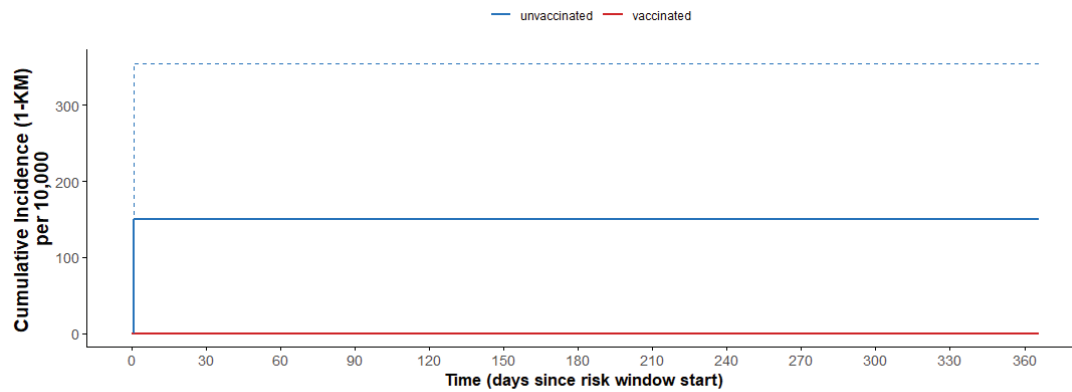
Number at risk

unvaccinated	133	59	54	50	50	49	47	45	44	43	41	41	40
vaccinated	302	151	138	133	126	118	107	96	93	87	83	73	68

Cumulative number of events

unvaccinated	0	73	75	76	76	77	77	78	78	78	79	79	80
vaccinated	0	141	145	146	147	147	148	149	149	149	150	150	151

15.1.6.2 EpiChron: Cumulative incidence of constrictive pericarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



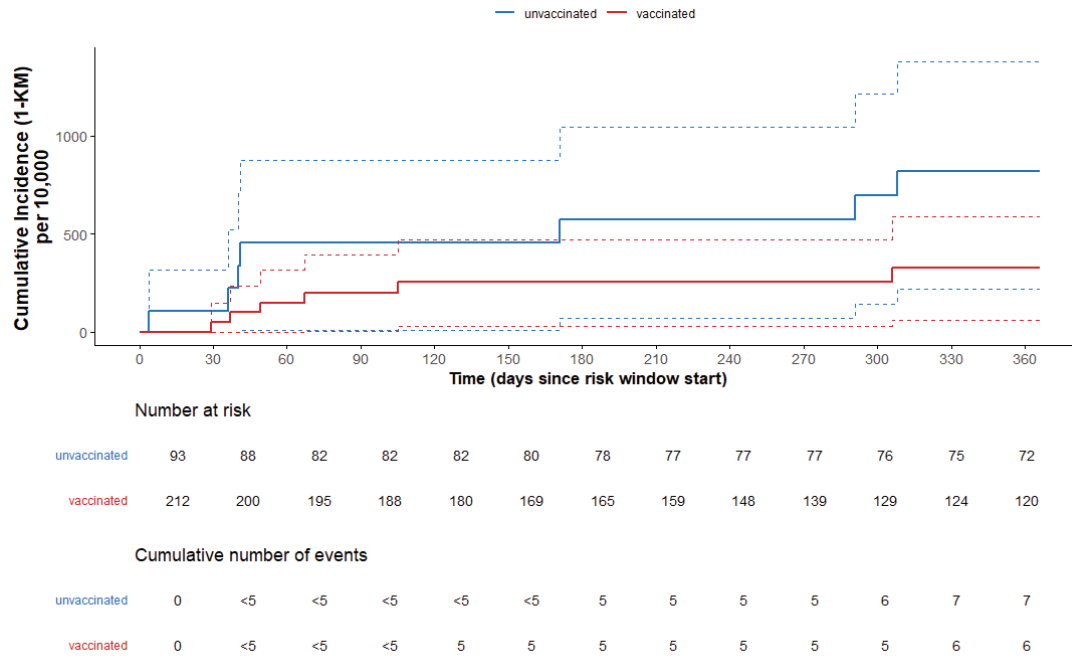
Number at risk

unvaccinated	133	127	121	118	118	118	115	114	113	112	111	111	111
vaccinated	302	282	268	264	257	247	234	224	217	206	196	179	173

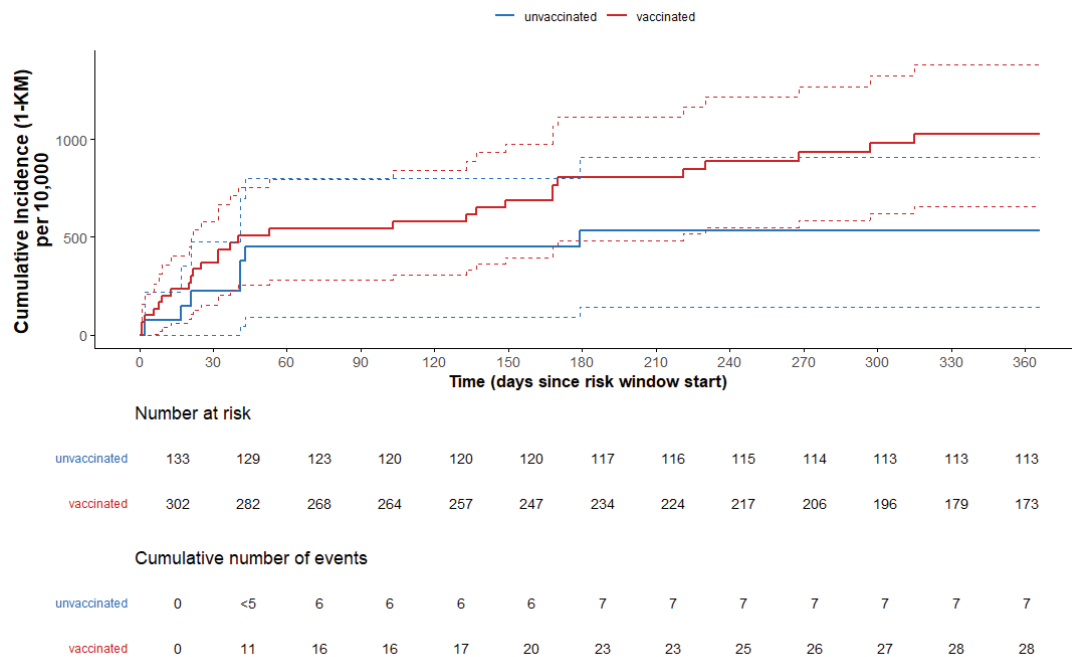
Cumulative number of events

unvaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5
vaccinated	0	0	0	0	0	0	0	0	0	0	0	0	0

15.1.6.3 EpiChron: Cumulative incidence of recurrent pericarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

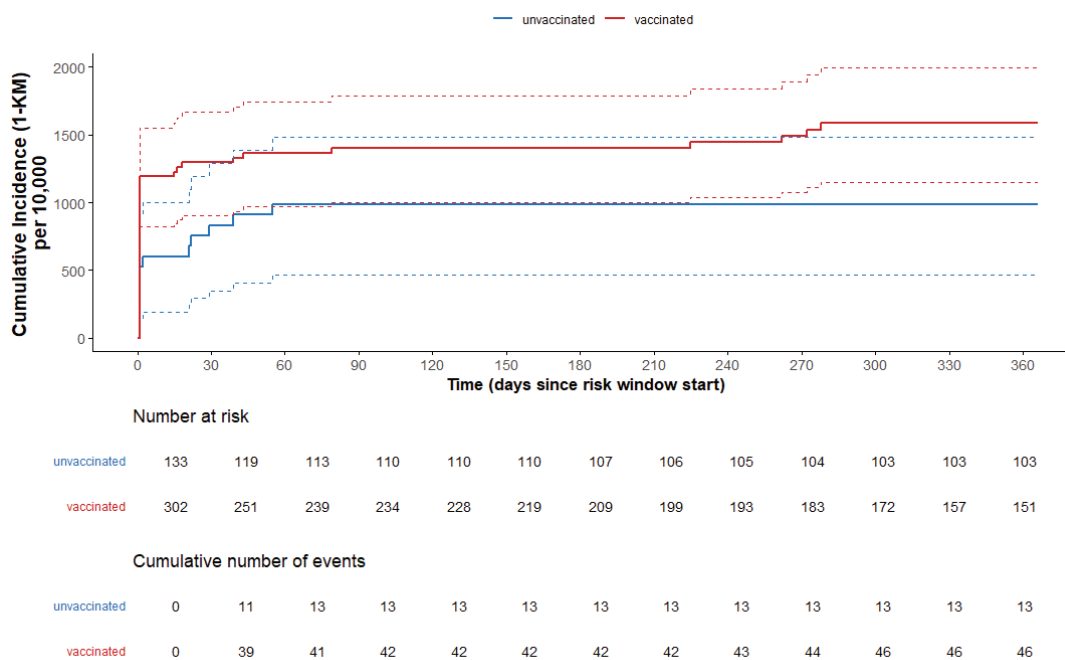


15.1.6.4 EpiChron: Cumulative incidence of death in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

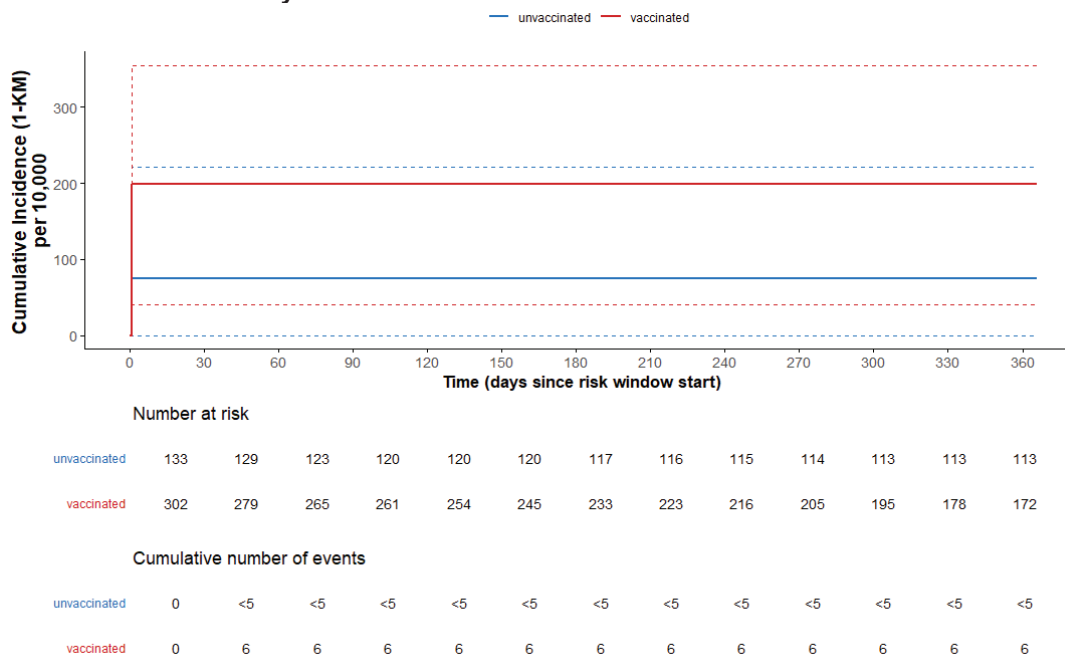


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15.1.6.5 EpiChron: Cumulative incidence of heart failure in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

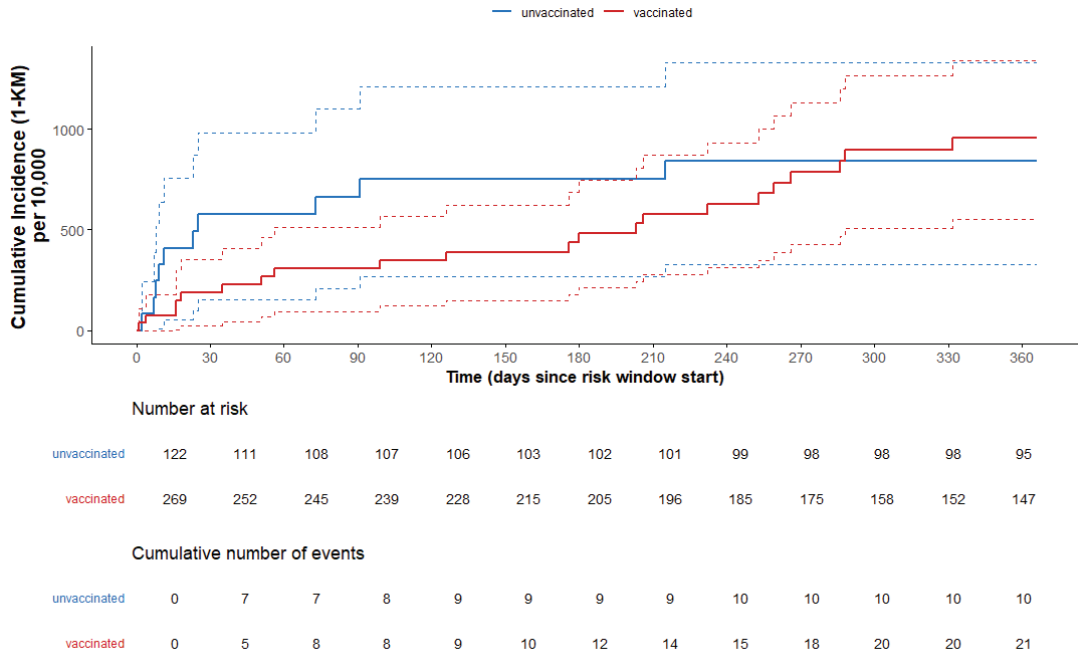


15.1.6.6 EpiChron: Cumulative incidence of cardiogenic shock in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



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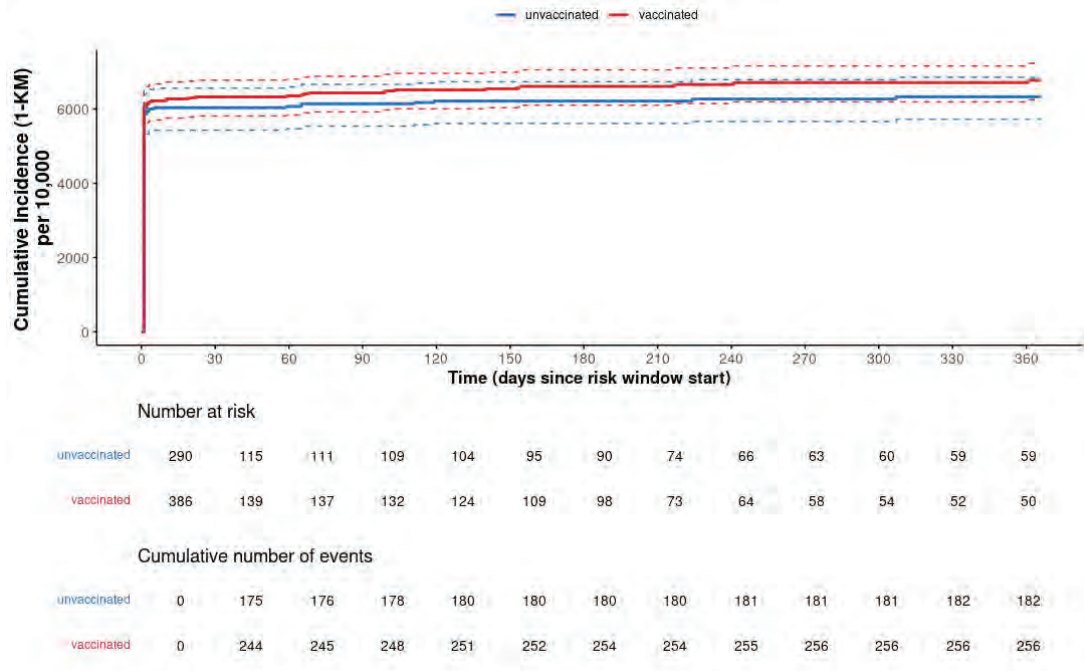
15.1.6.7 EpiChron: Cumulative incidence of arrhythmia in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



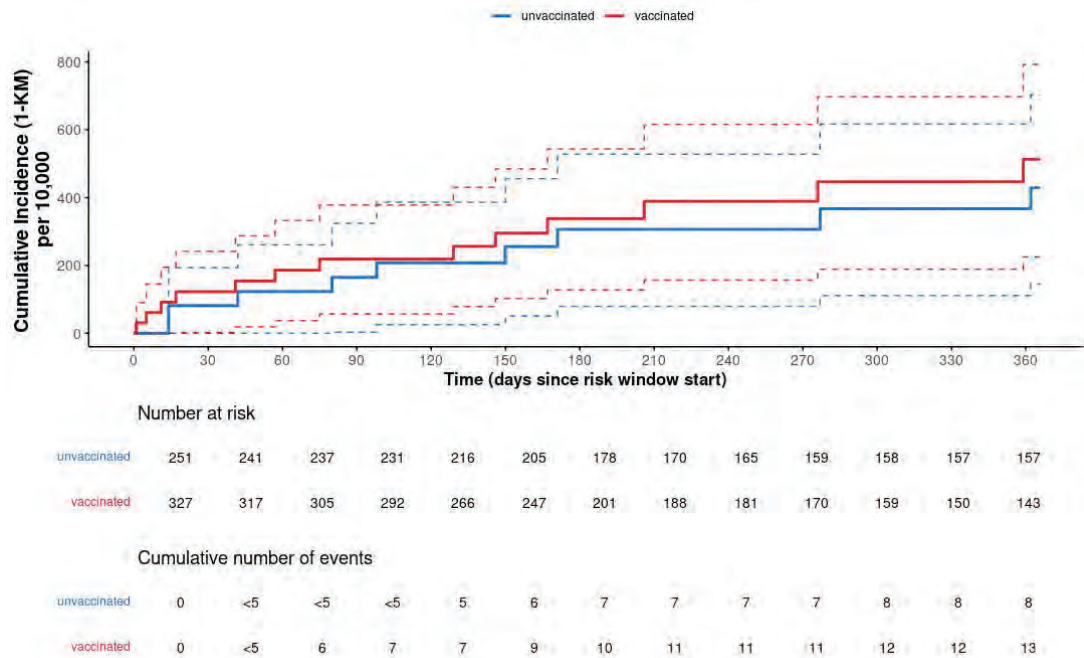
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15.1.7 SIDIAP myocarditis cohort

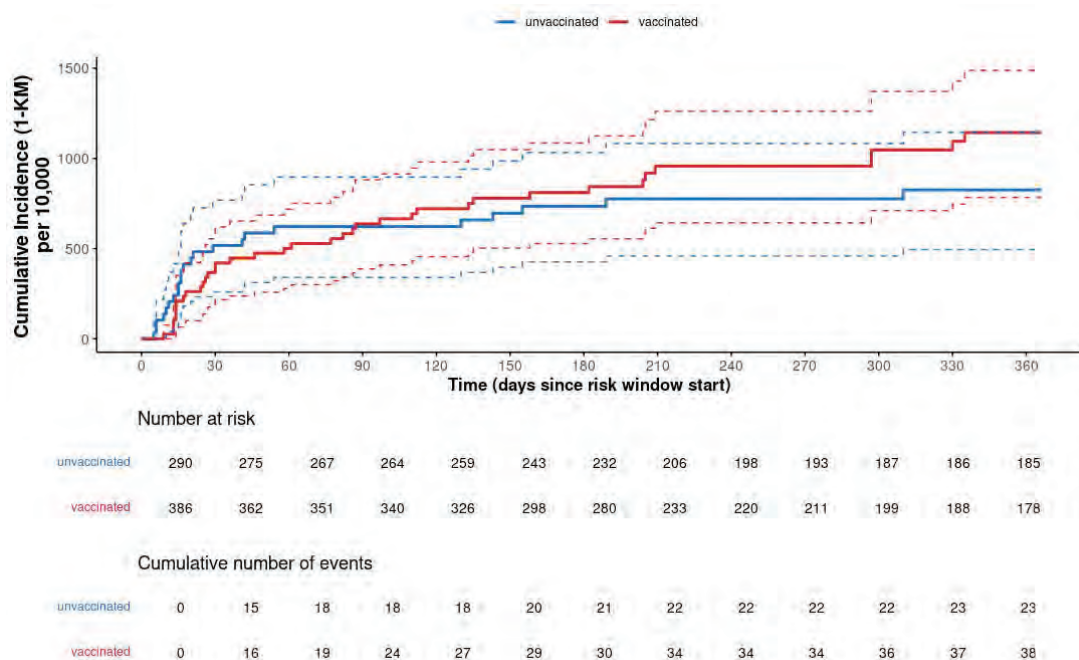
15.1.7.1 SIDIAP: Cumulative incidence of the number of hospitalisations in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



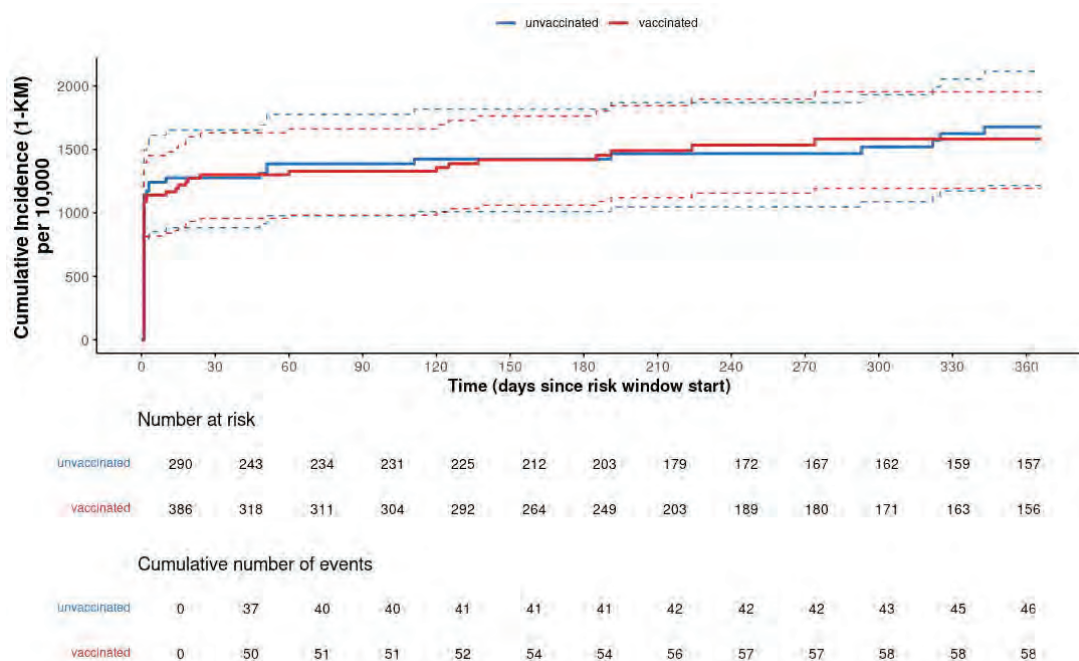
15.1.7.2 SIDIAP: Cumulative incidence of recurrent myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



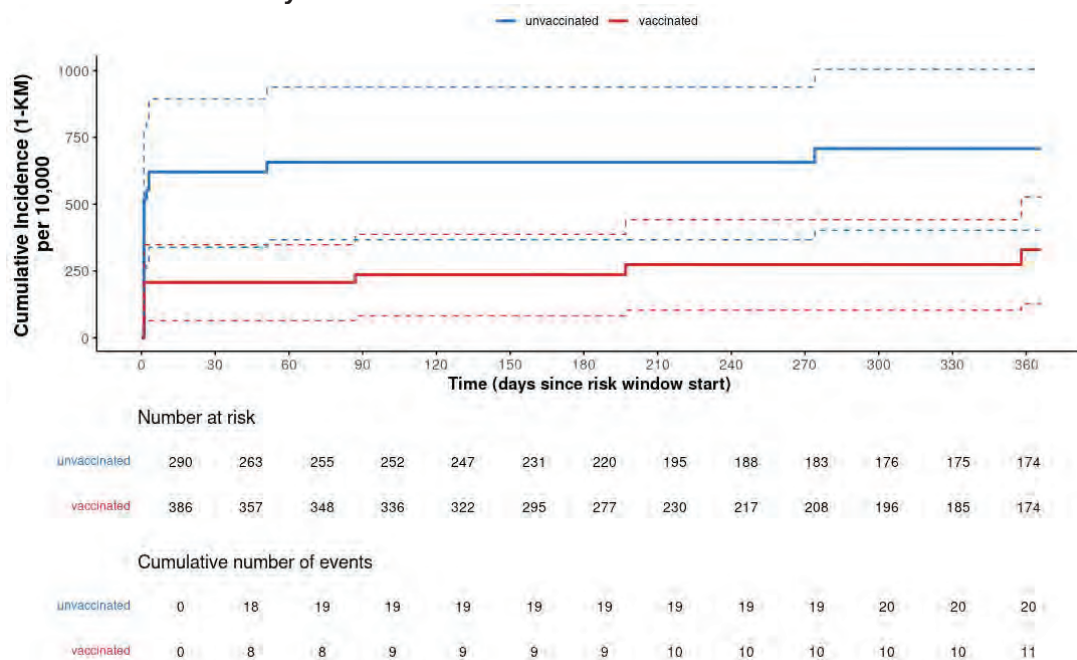
15.1.7.3 SIDIAP: Cumulative incidence of death in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



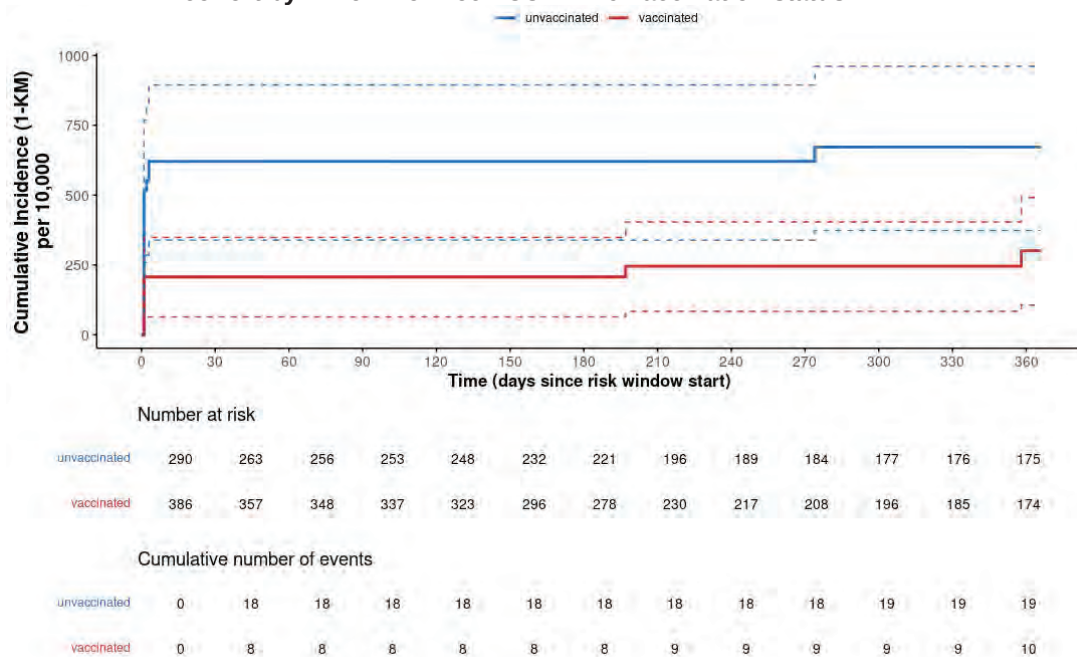
15.1.7.4 SIDIAP: Cumulative incidence of heart failure in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



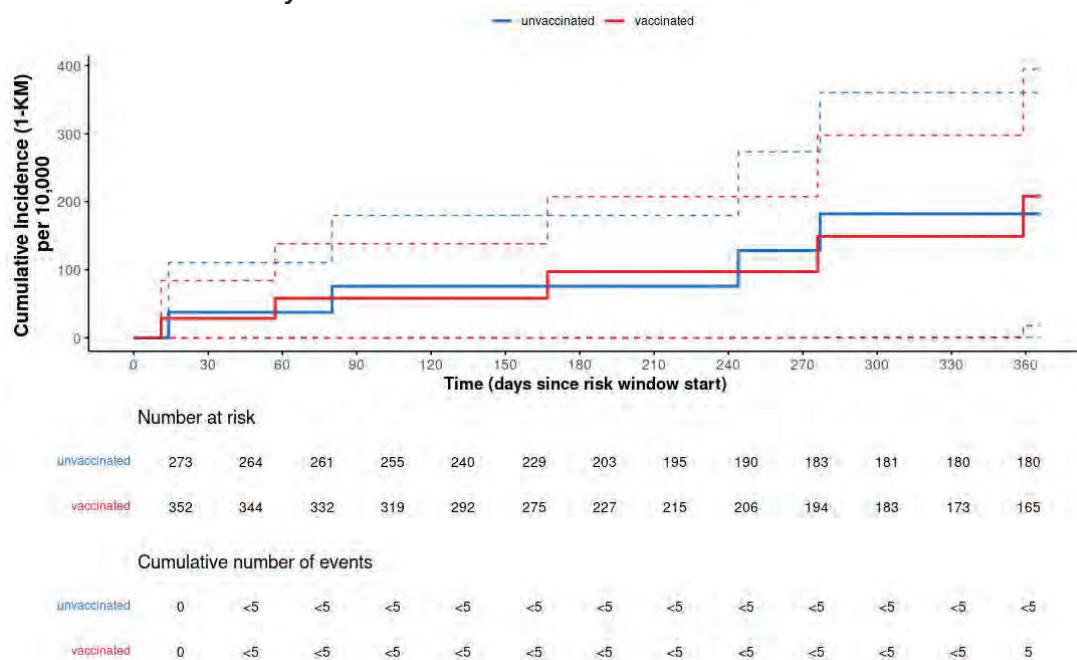
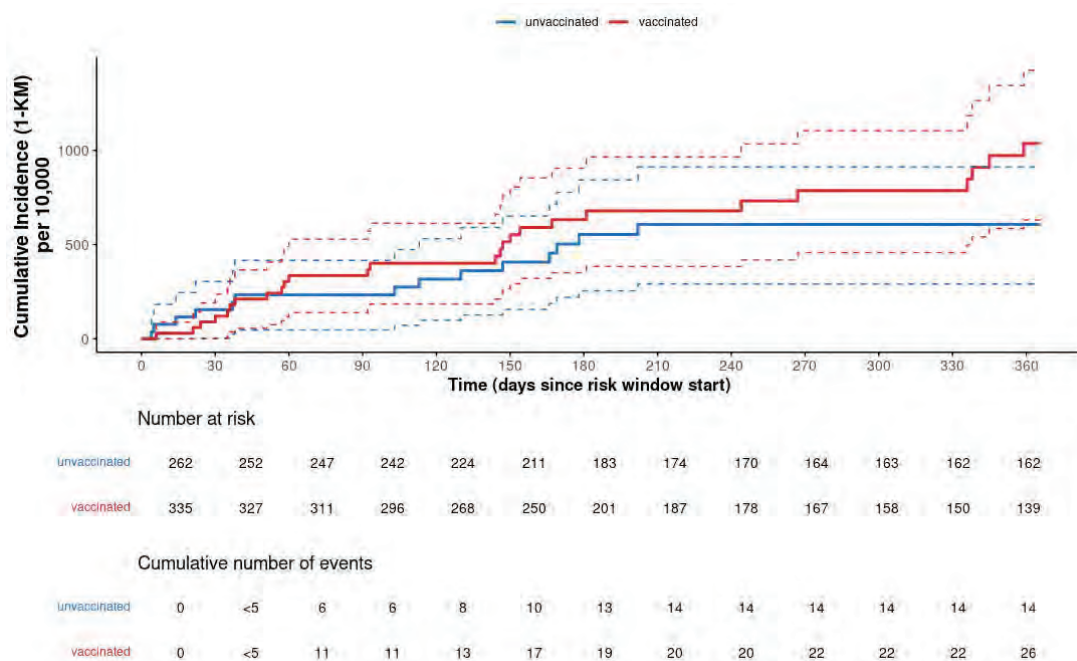
15.1.7.5 SIDIAP: Cumulative incidence of cardiogenic shock in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



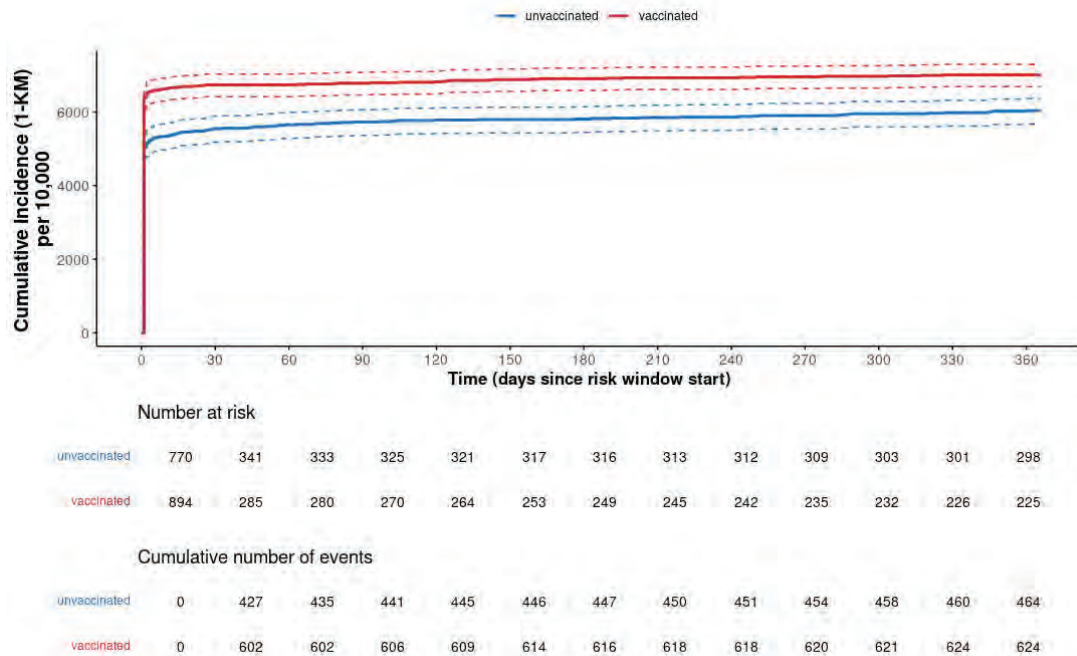
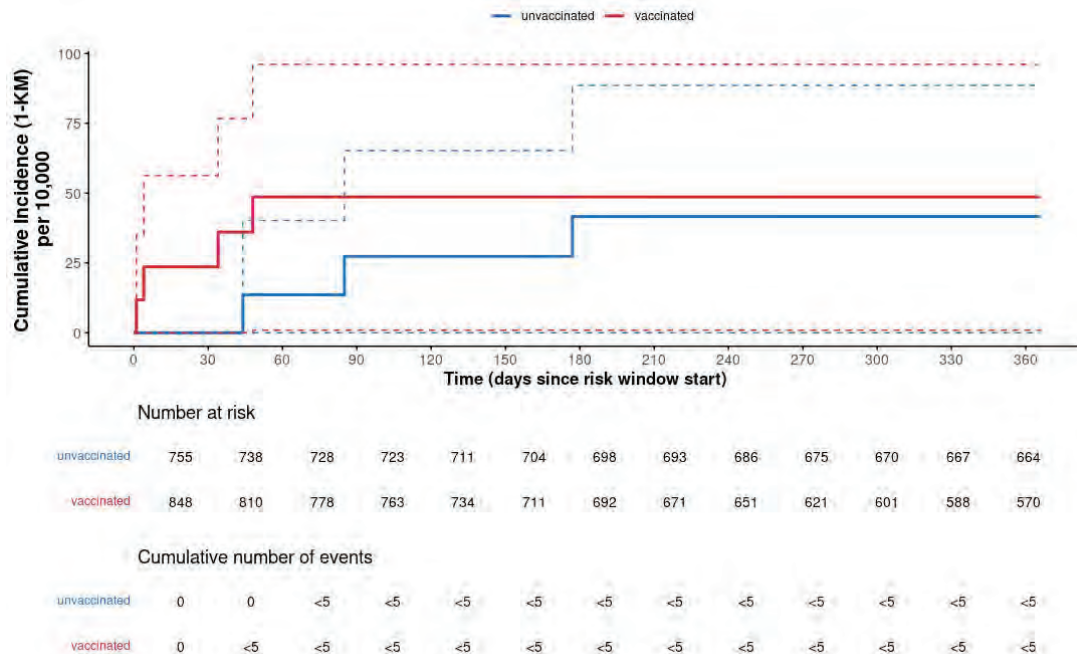
15.1.7.6 SIDIAP: Cumulative incidence of fulminant myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



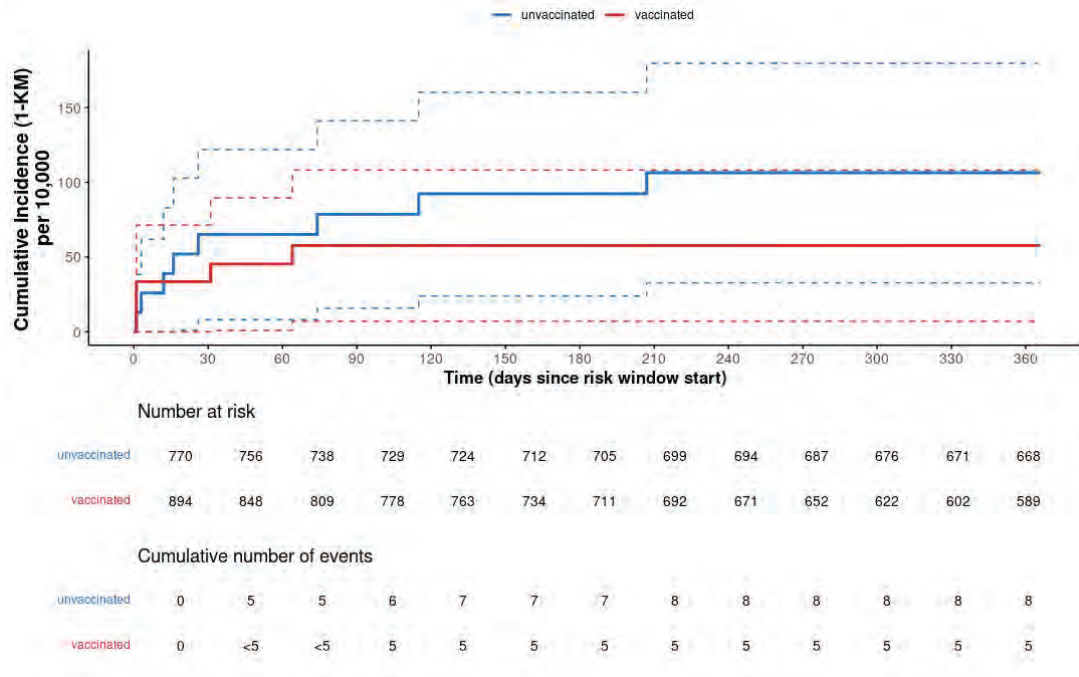
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15.1.7.7 SIDIAP: Cumulative incidence of chronic myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**15.1.7.8 SIDIAP: Cumulative incidence of arrhythmia in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**

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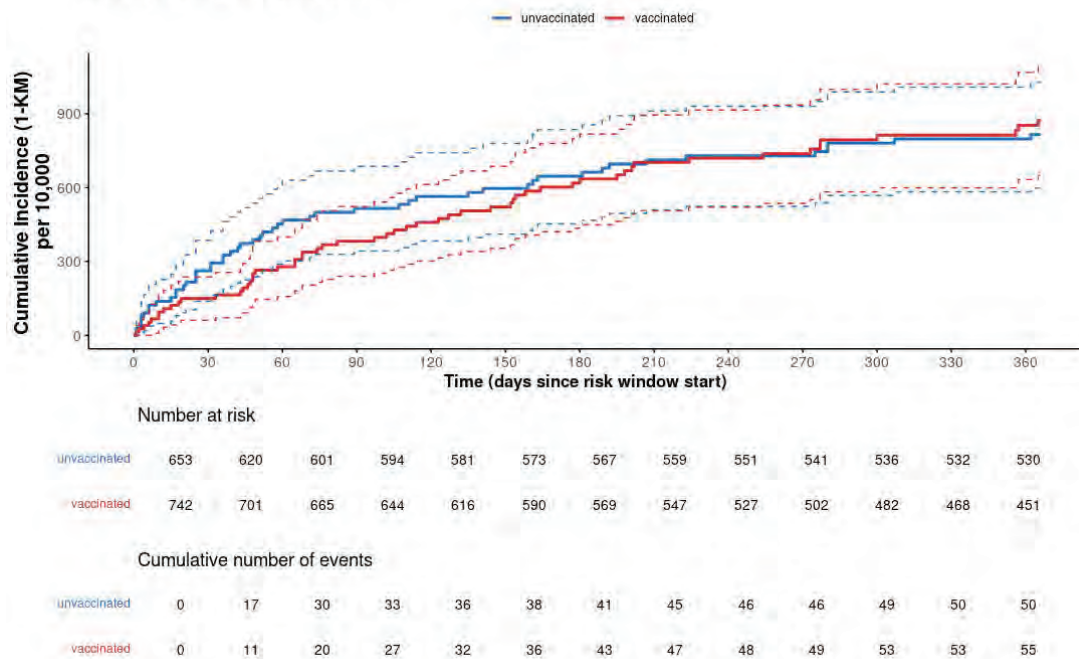
15.1.8 SIDIAP pericarditis cohort**15.1.8.1 SIDIAP: Cumulative incidence of the number of hospitalisations in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status****15.1.8.2 SIDIAP: Cumulative incidence of chronic pericarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**

15.1.8.3 SIDIAP: Cumulative incidence of constrictive pericarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



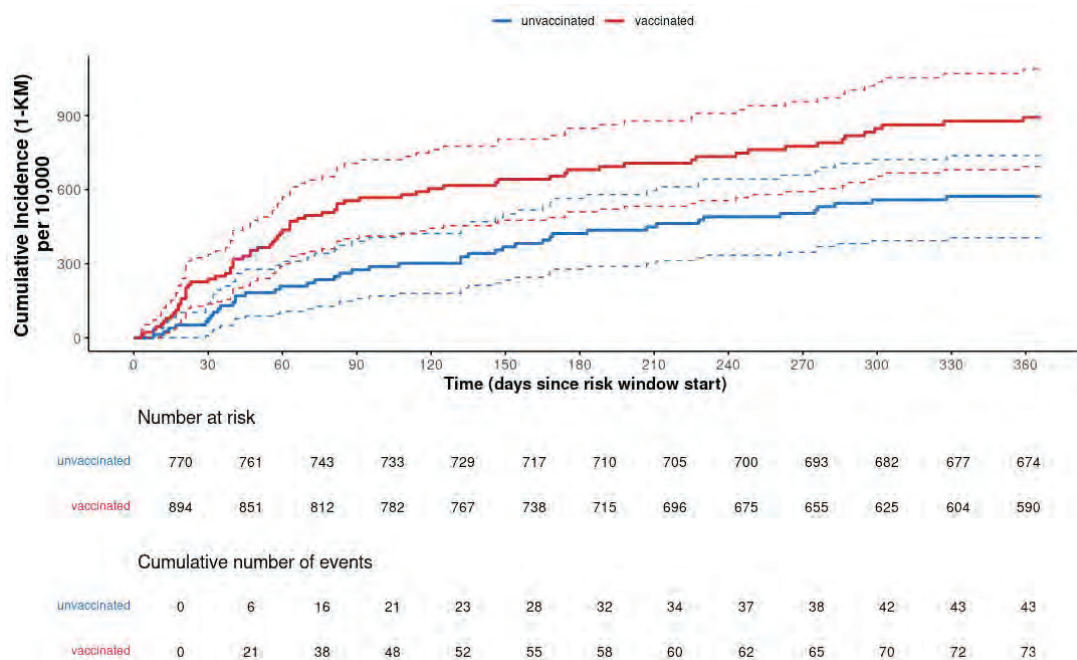
15.1.8.4 SIDIAP: Cumulative incidence of recurrent pericarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

Pericarditis - Recurrent Pericarditis

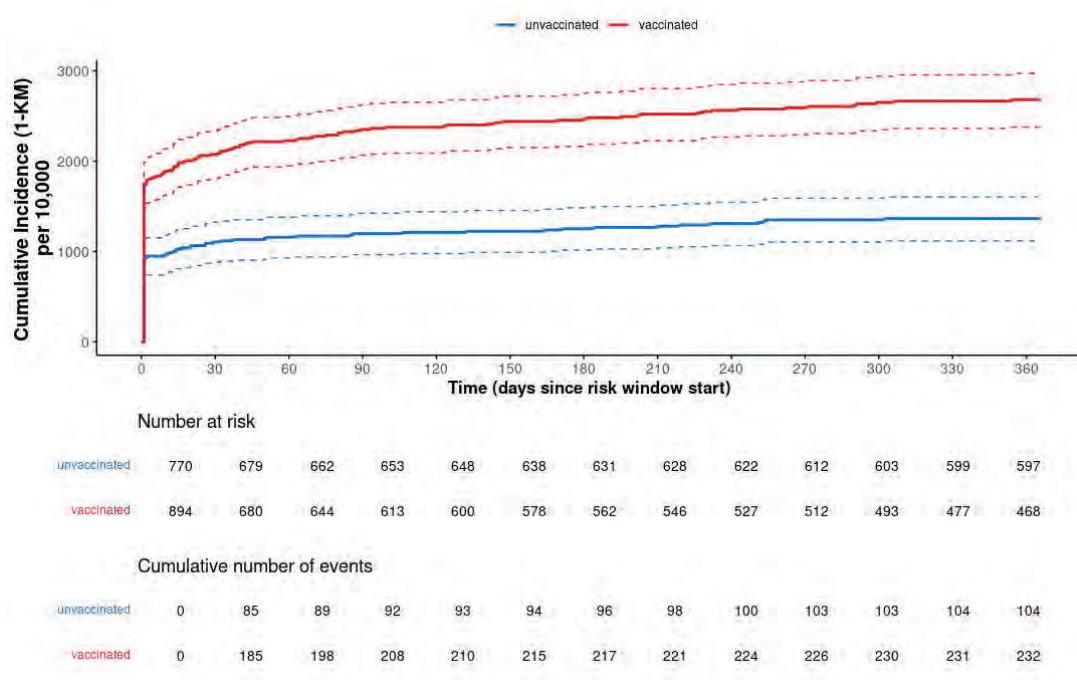


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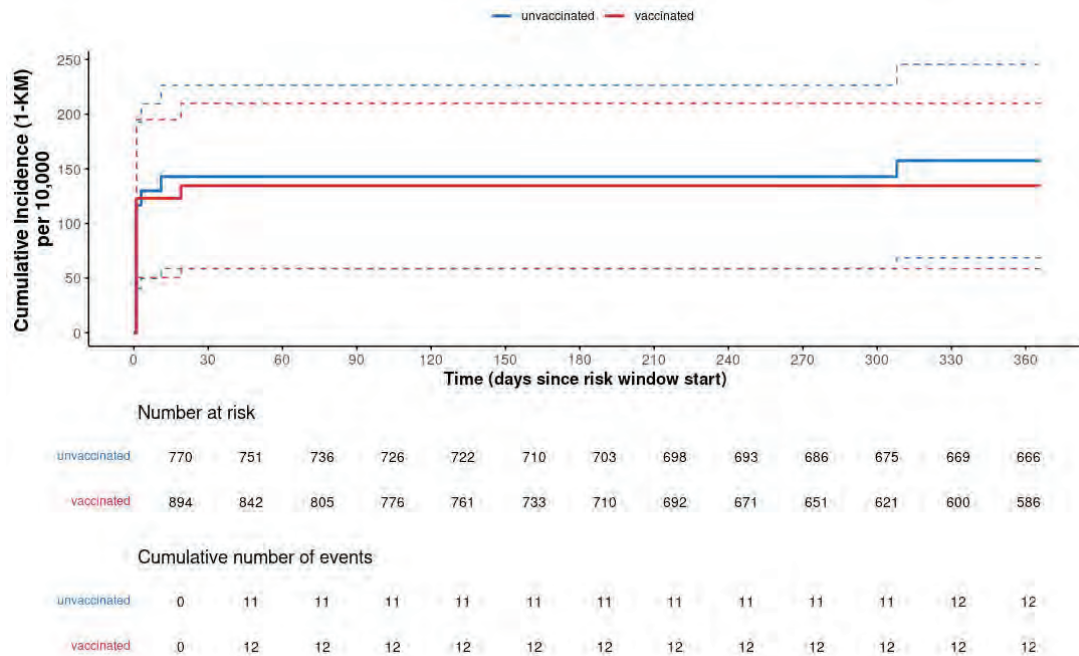
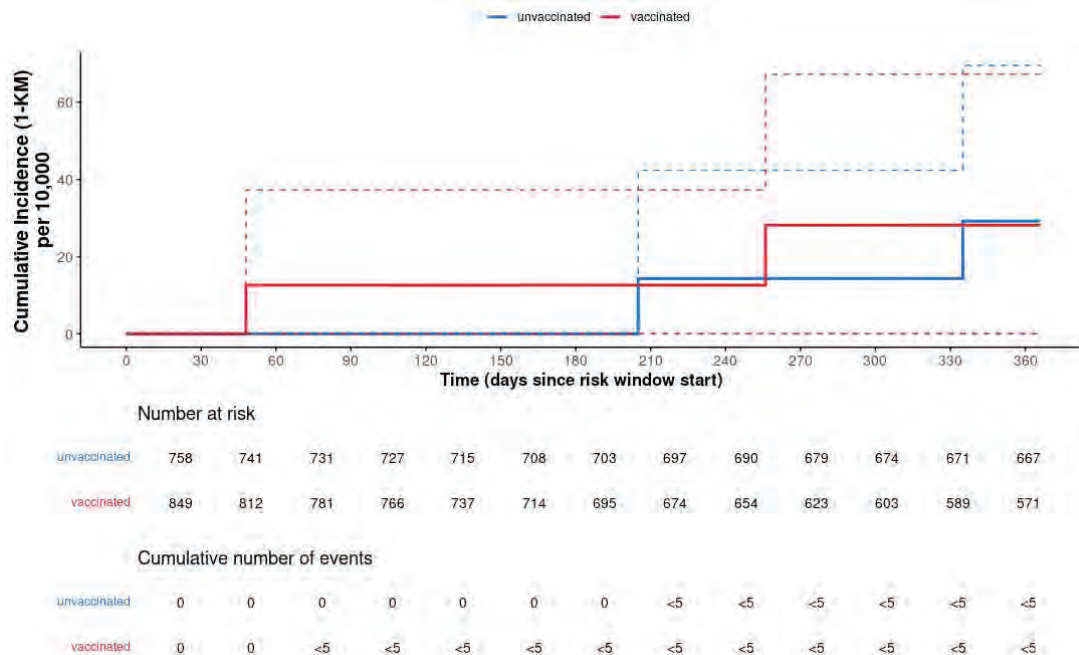
15.1.8.5 SIDIAP: Cumulative incidence of death in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



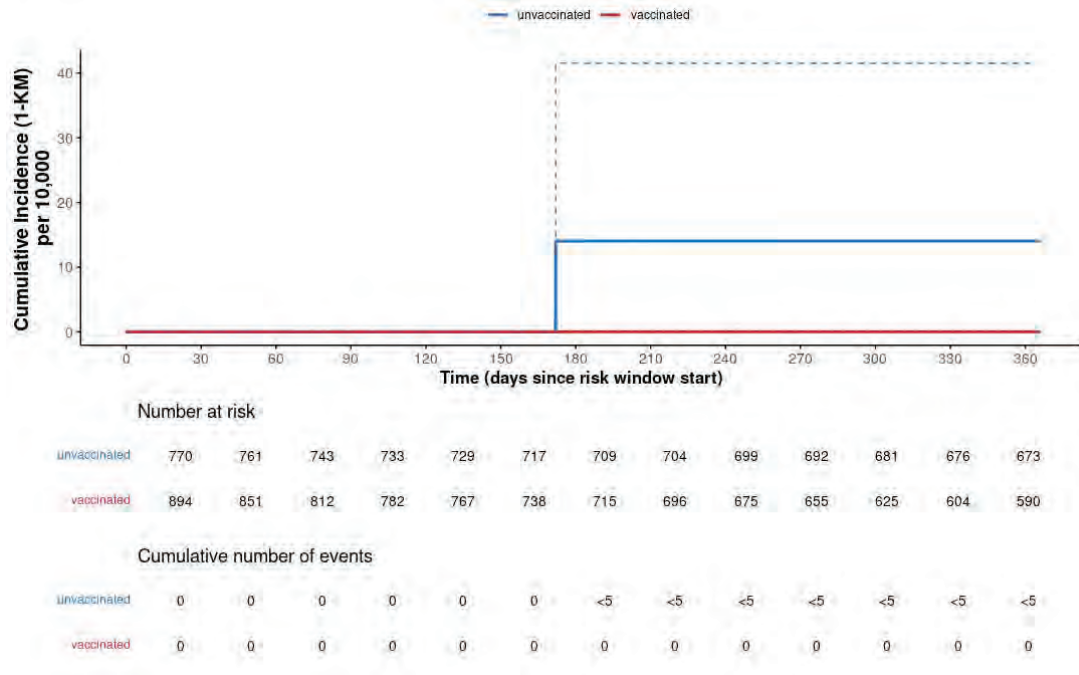
15.1.8.6 SIDIAP: Cumulative incidence of heart failure in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



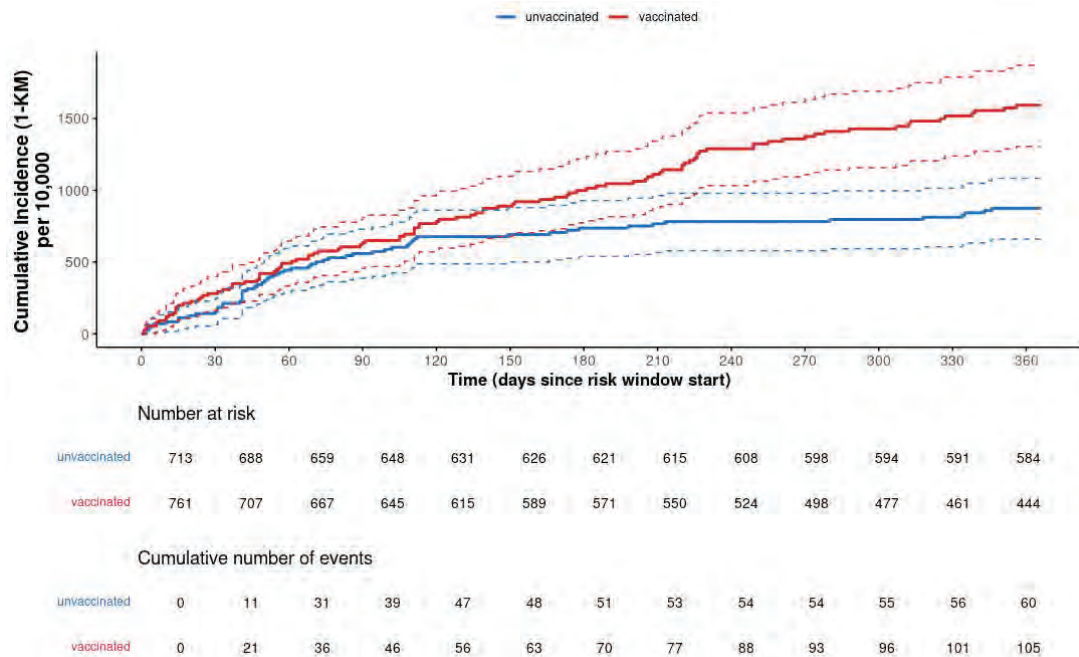
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15.1.8.7 SIDIAP: Cumulative incidence of cardiogenic shock in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**15.1.8.8 SIDIAP: Cumulative incidence of chronic myocarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**

15.1.8.9 SIDIAP: Cumulative incidence of heart transplantation in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



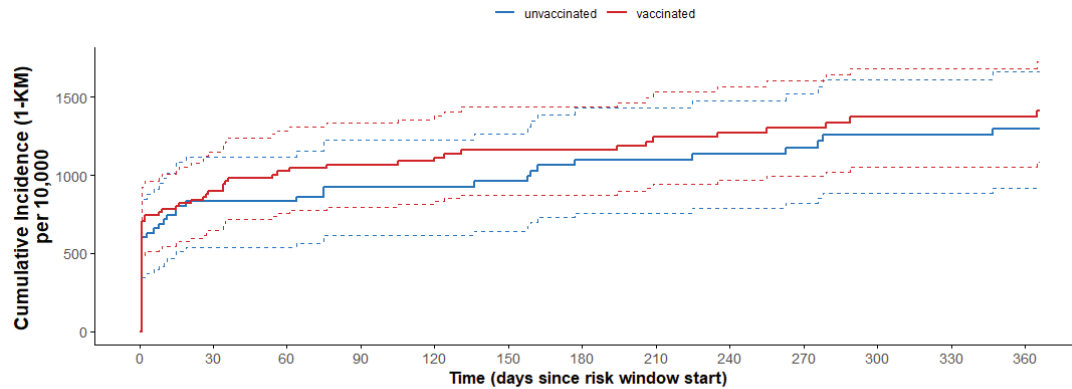
15.1.8.10 SIDIAP: Cumulative incidence of arrhythmia in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



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15.1.9 CPRD Aurum myocarditis cohort

15.1.9.1 CPRD Aurum: Cumulative incidence of the number of hospitalisations in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



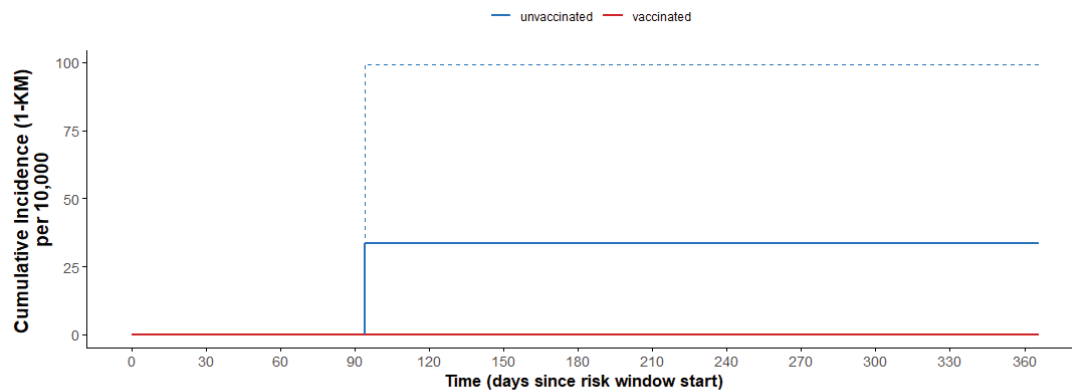
Number at risk

unvaccinated	350	308	293	275	273	264	250	240	230	224	213	209	199
vaccinated	513	448	429	407	390	360	337	308	283	268	250	235	216

Cumulative number of events

unvaccinated	0	29	29	32	32	33	37	37	38	39	41	41	42
vaccinated	0	46	52	54	56	58	58	61	62	63	65	65	65

15.1.9.2 CPRD Aurum: Cumulative incidence of chronic pericarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



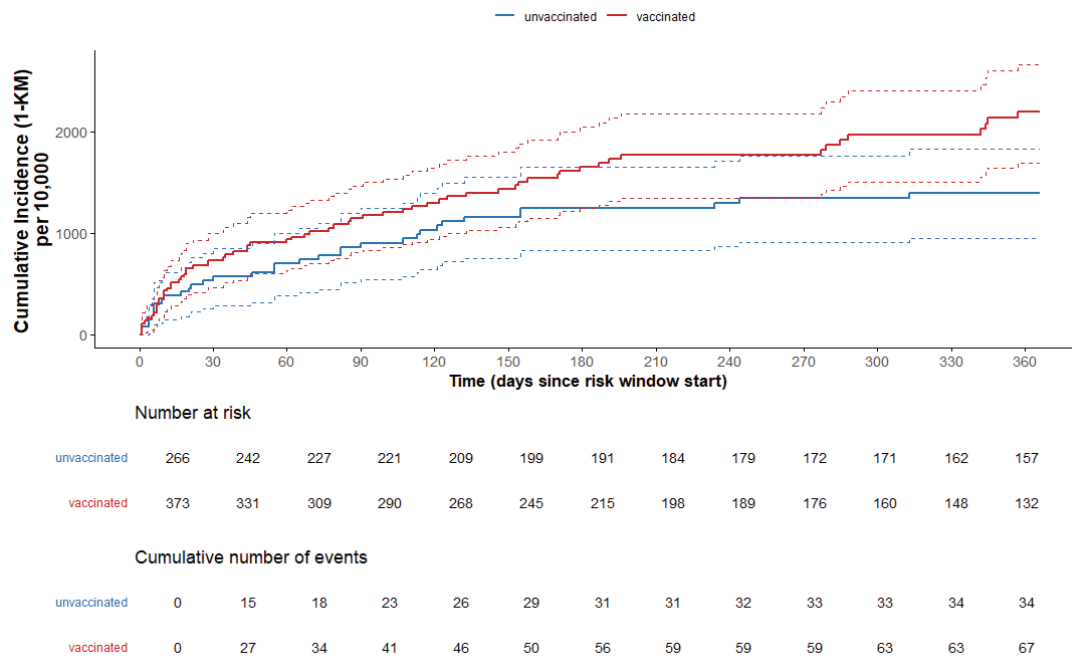
Number at risk

unvaccinated	335	319	302	300	290	279	269	259	254	242	238	228	222
vaccinated	491	474	451	434	405	378	349	325	310	293	274	252	234

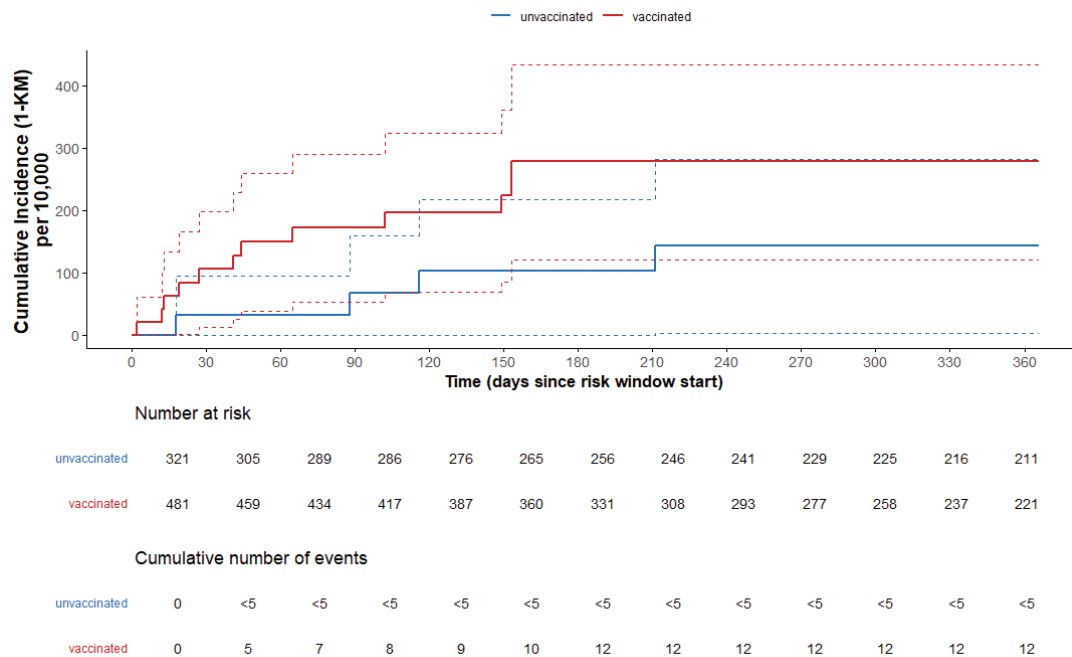
Cumulative number of events

unvaccinated	0	0	0	0	<5	<5	<5	<5	<5	<5	<5	<5	<5
vaccinated	0	0	0	0	0	0	0	0	0	0	0	0	0

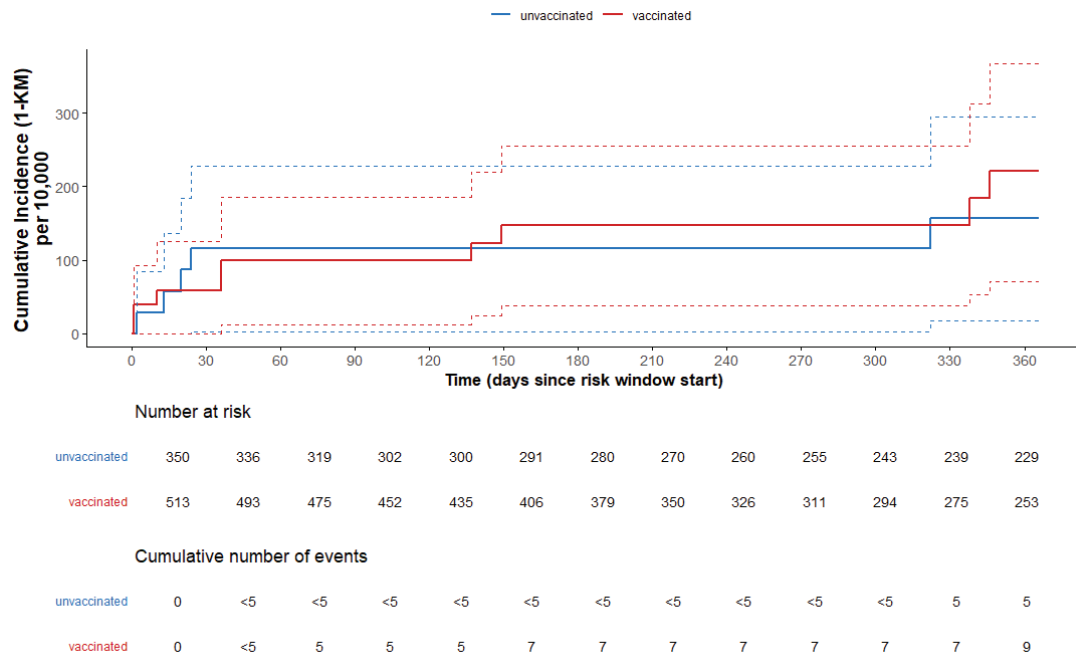
15.1.9.3 CPRD Aurum: Cumulative incidence of recurrent myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



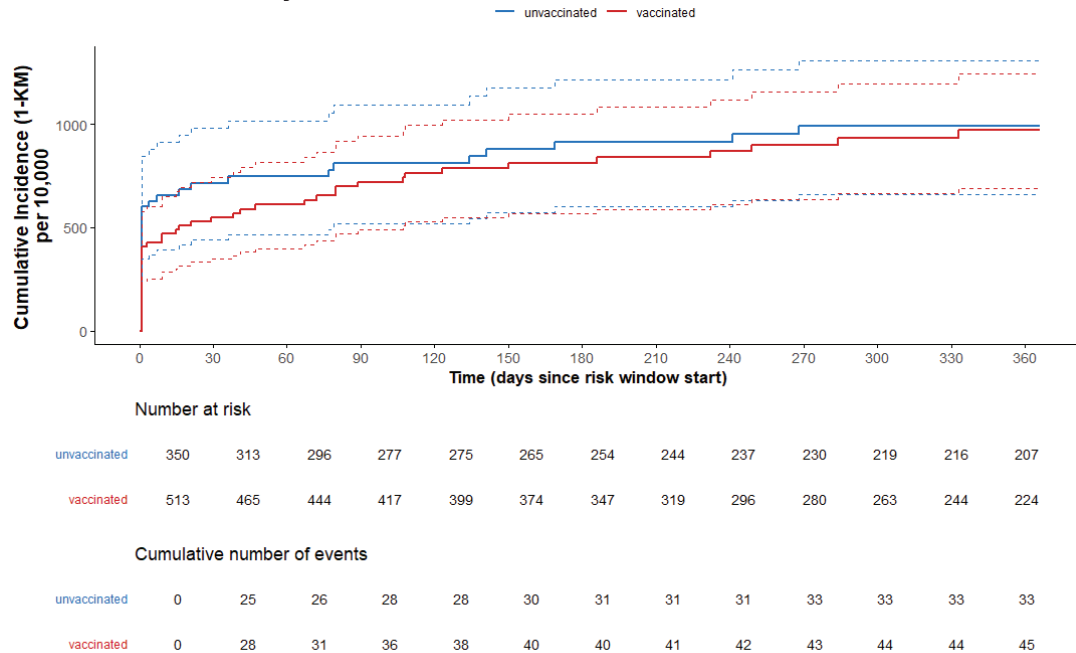
15.1.9.4 CPRD Aurum: Cumulative incidence of recurrent pericarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



15.1.9.5 CPRD Aurum: Cumulative incidence of death in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



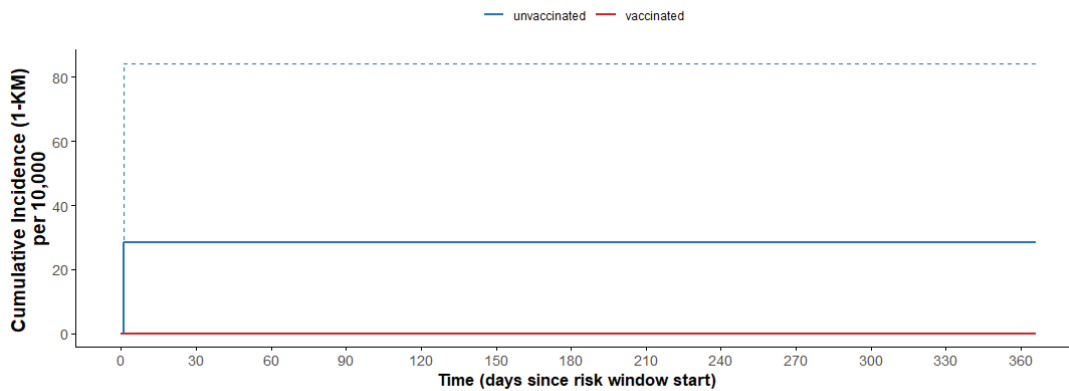
15.1.9.6 CPRD Aurum: Cumulative incidence of heart failure in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



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15.1.9.7 CPRD Aurum: Cumulative incidence of recurrent myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

Myocarditis - Cardiogenic Shock

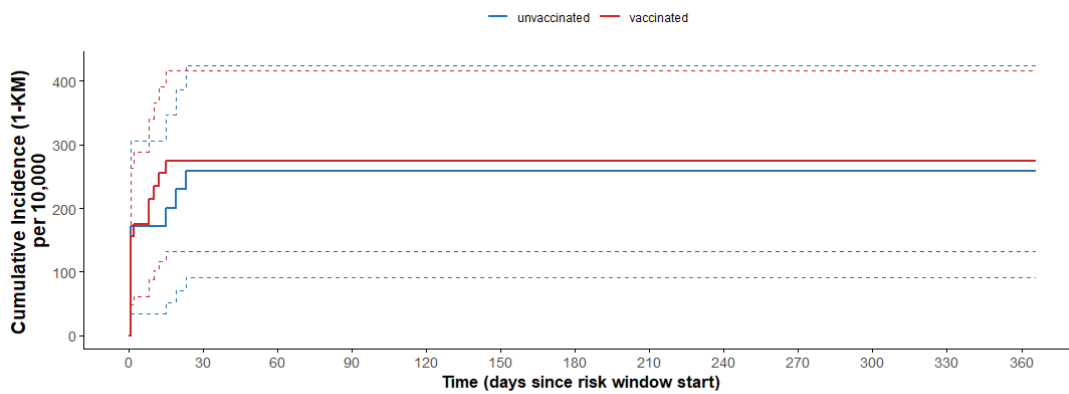


Number at risk

unvaccinated	350	335	318	301	299	290	279	269	259	254	242	238	228
vaccinated	513	493	475	452	435	406	379	350	326	311	294	275	253

Cumulative number of events

unvaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5
vaccinated	0	0	0	0	0	0	0	0	0	0	0	0	0

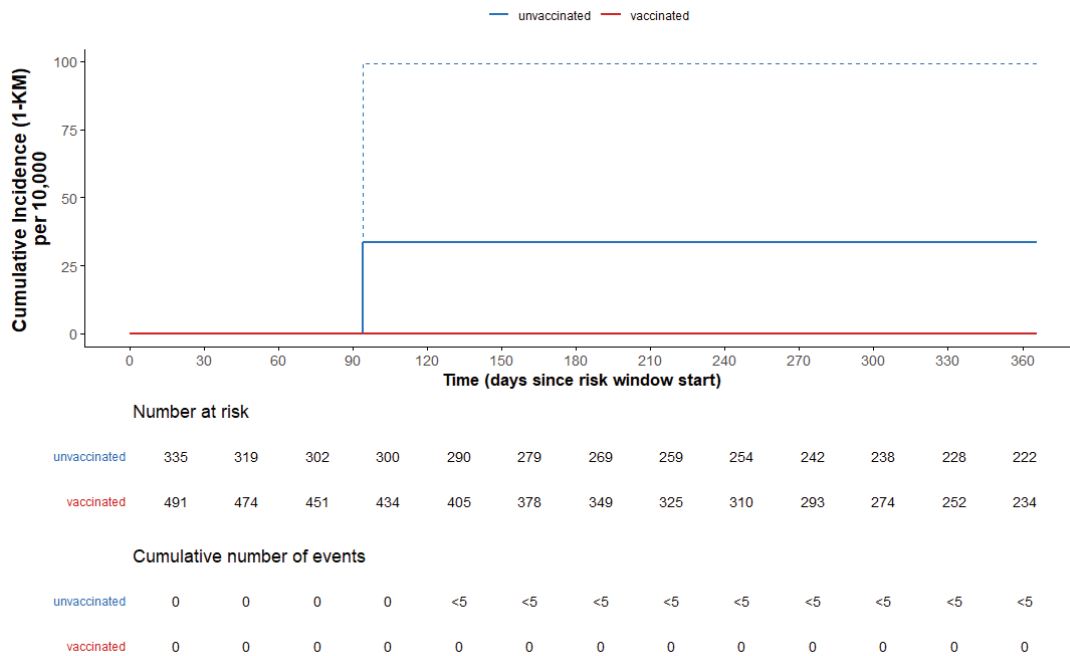
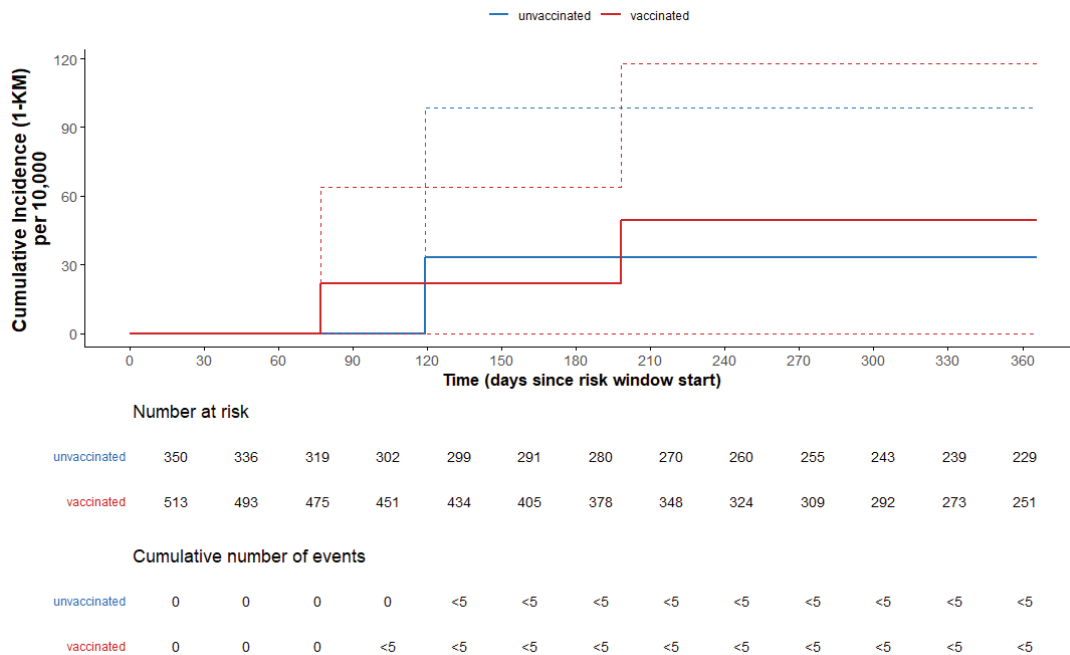
15.1.9.8 CPRD Aurum: Cumulative incidence of fulminant myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

Number at risk

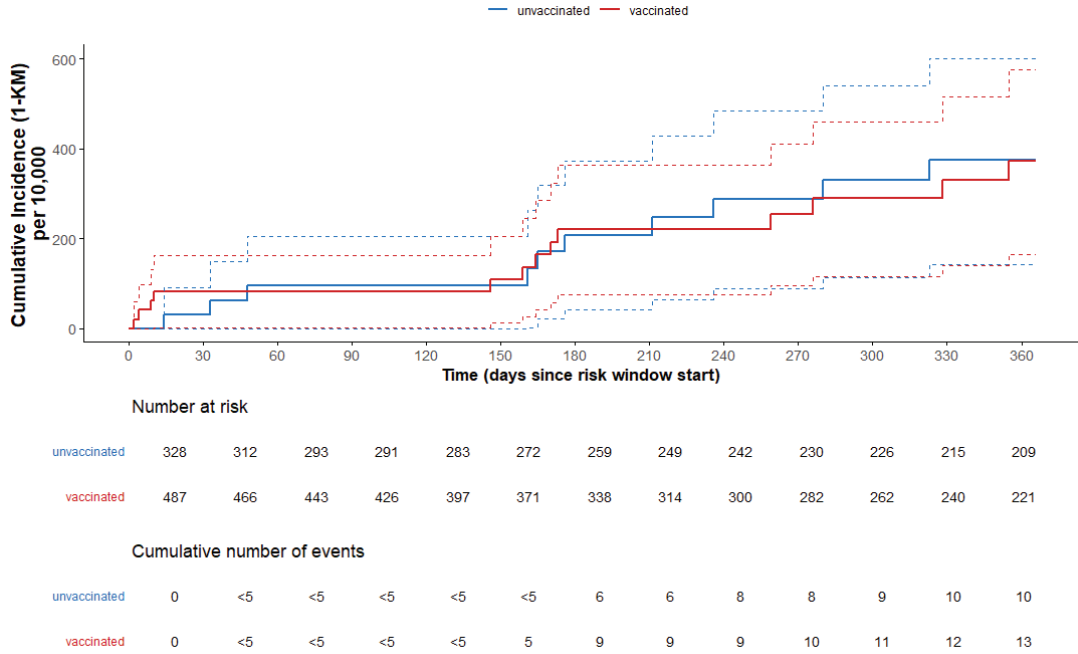
unvaccinated	350	327	311	295	293	285	274	264	254	249	237	233	223
vaccinated	513	479	461	439	422	393	366	337	313	298	281	262	241

Cumulative number of events

unvaccinated	0	9	9	9	9	9	9	9	9	9	9	9	9
vaccinated	0	14	14	14	14	14	14	14	14	14	14	14	14

15.1.9.9 CPRD Aurum: Cumulative incidence of chronic myocarditis in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**15.1.9.10 CPRD Aurum: Cumulative incidence of heart transplantation in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**

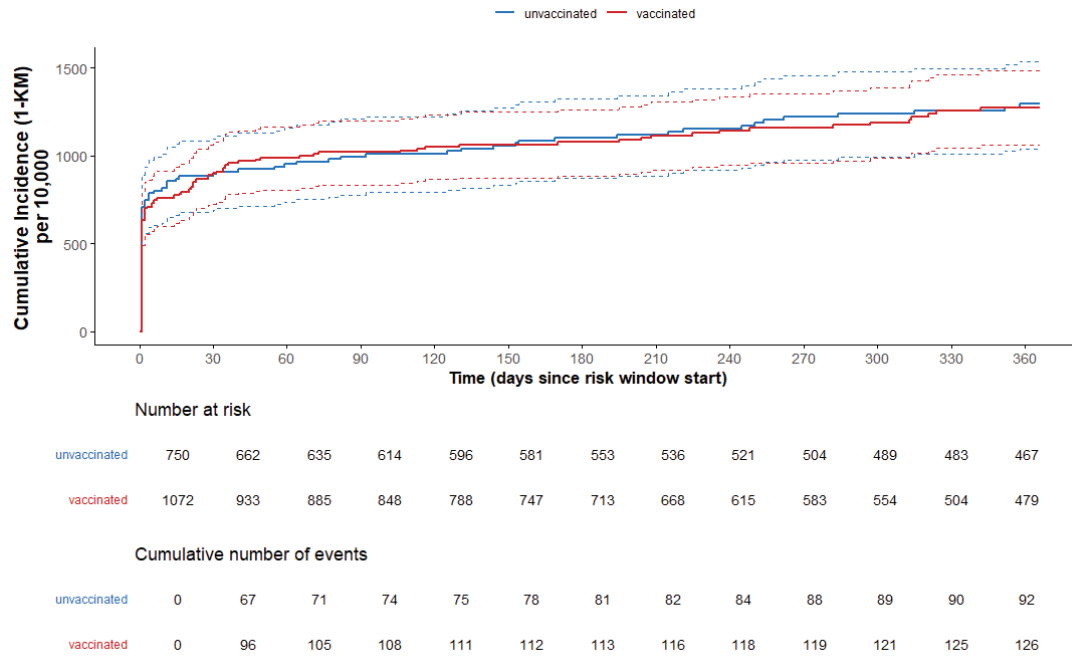
15.1.9.11 CPRD Aurum: Cumulative incidence of arrhythmia in the myocarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



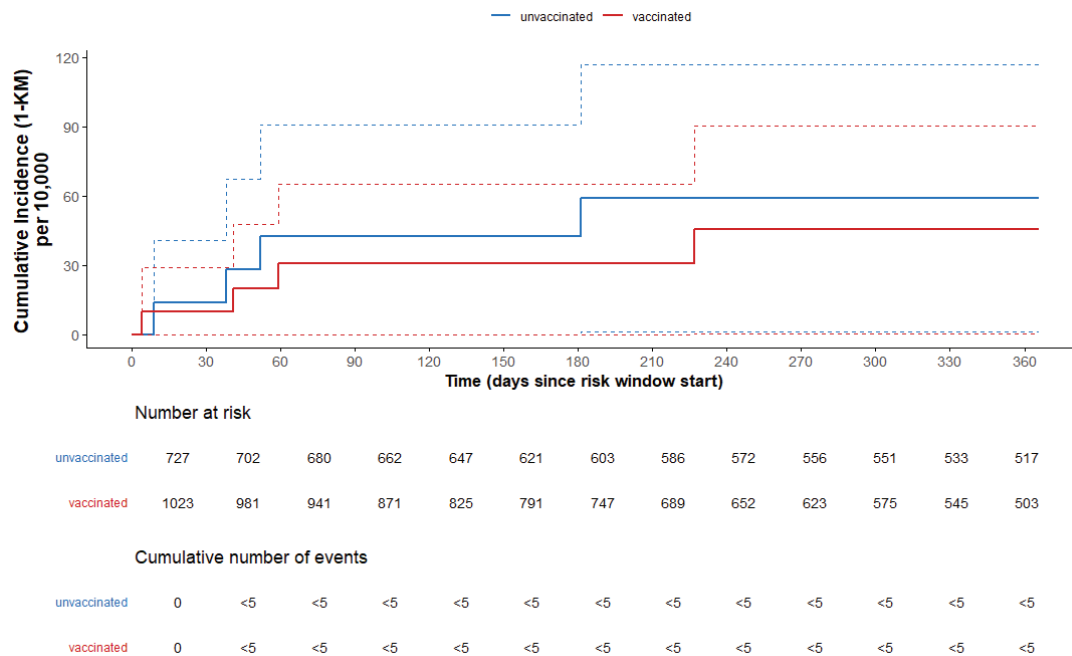
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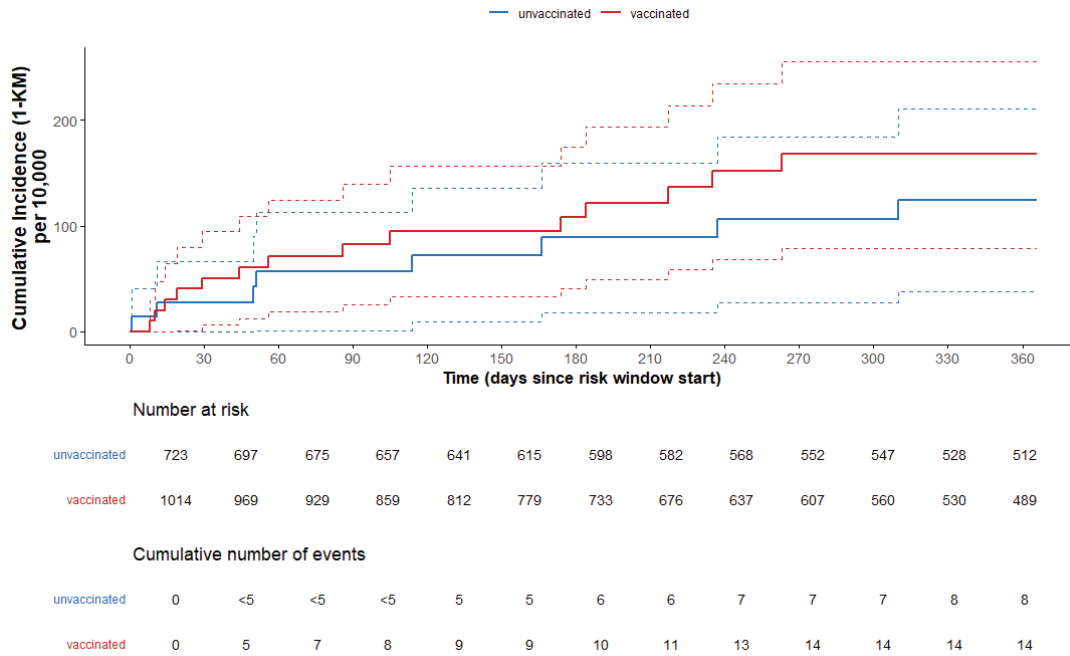
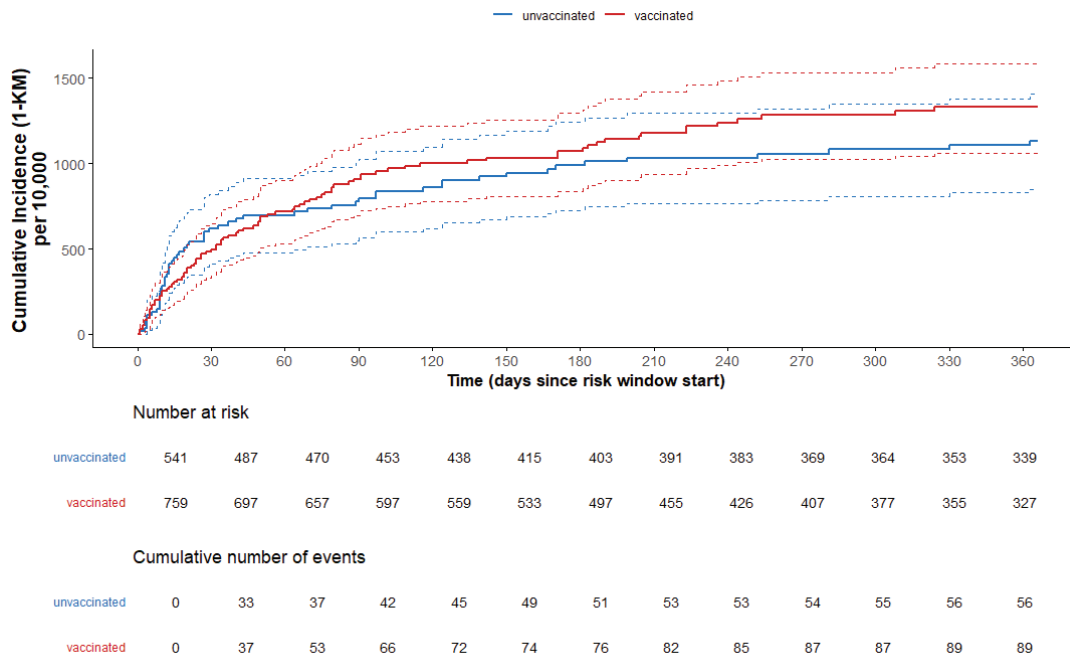
15.1.10 CPRD Aurum pericarditis cohort

15.1.10.1 CPRD Aurum: Cumulative incidence of the number of hospitalisations in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



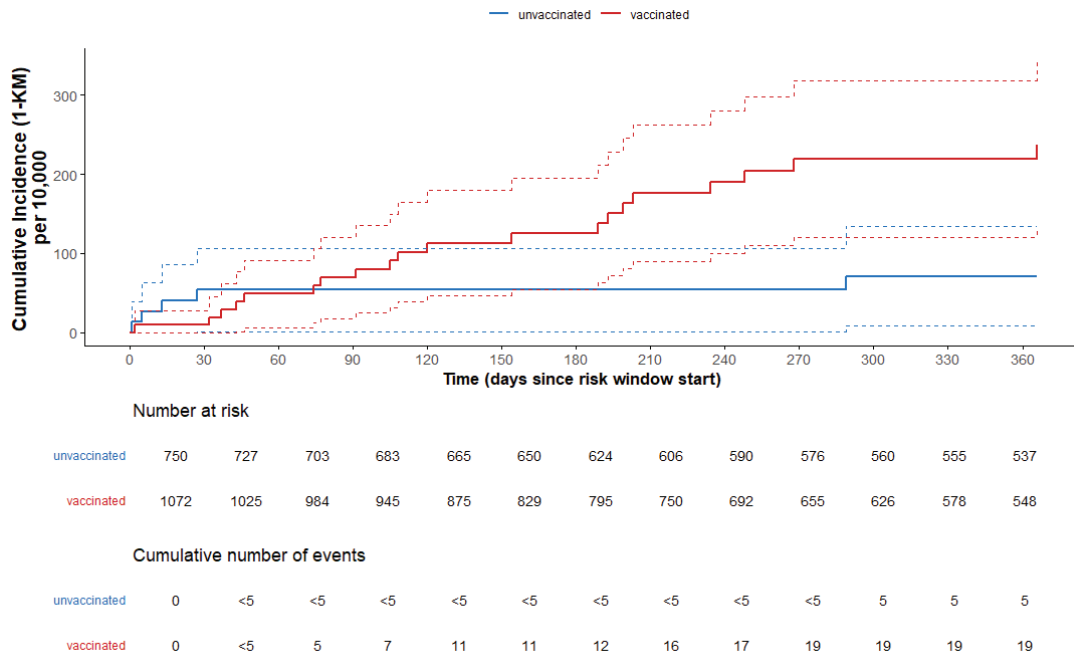
15.1.10.2 CPRD Aurum: Cumulative incidence of chronic pericarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



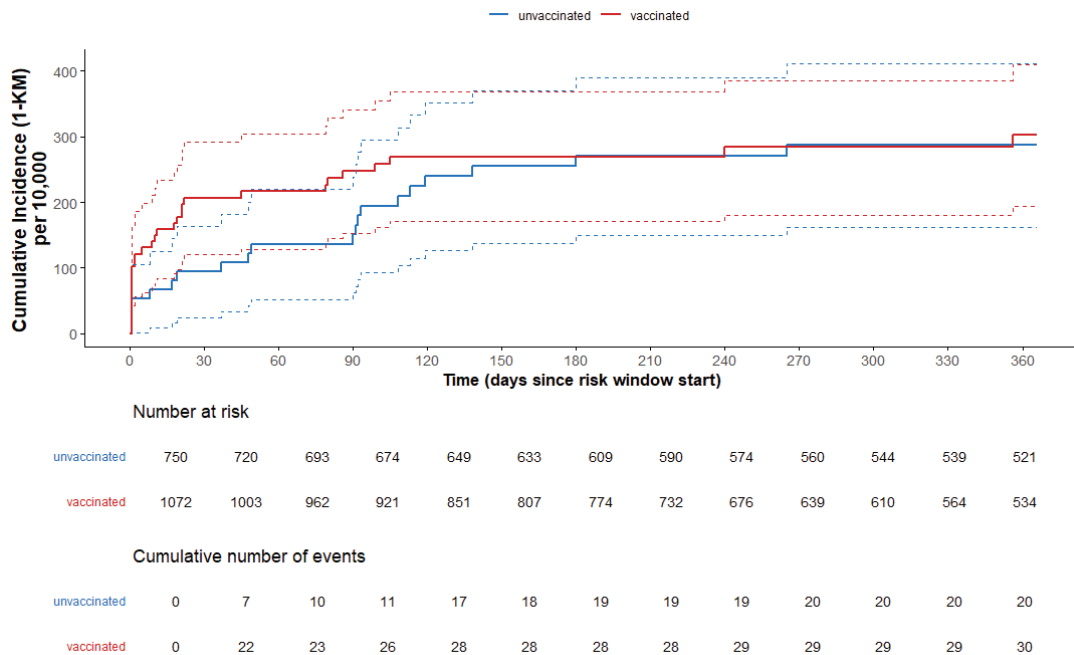
15.1.10.3 CPRD Aurum: Cumulative incidence of recurrent myocarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**15.1.10.4 CPRD Aurum: Cumulative incidence of recurrent pericarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**

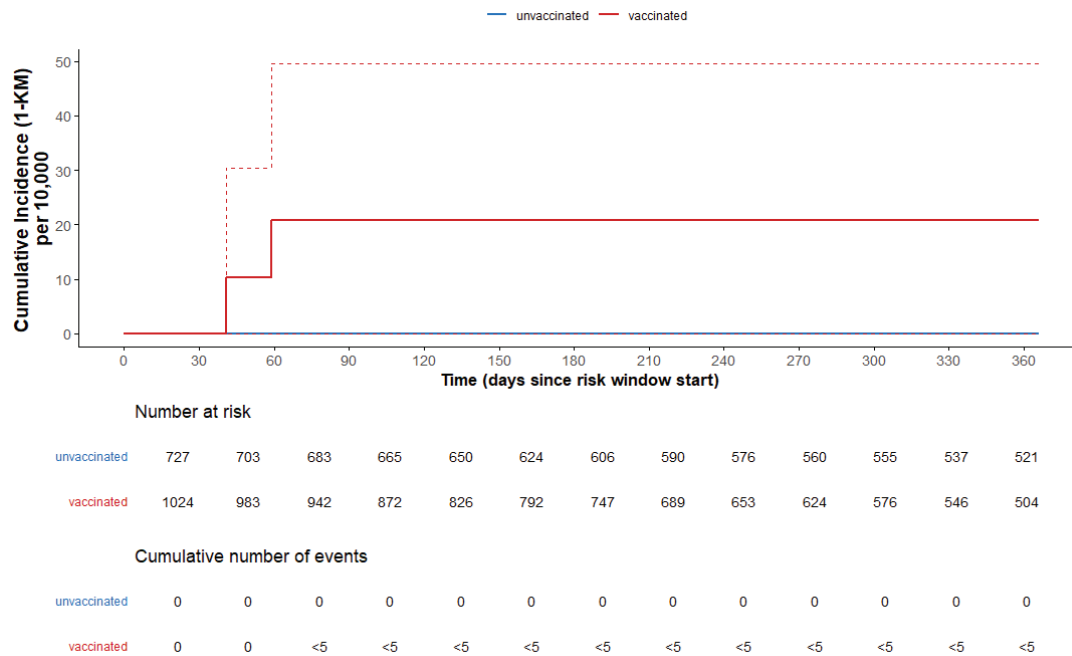
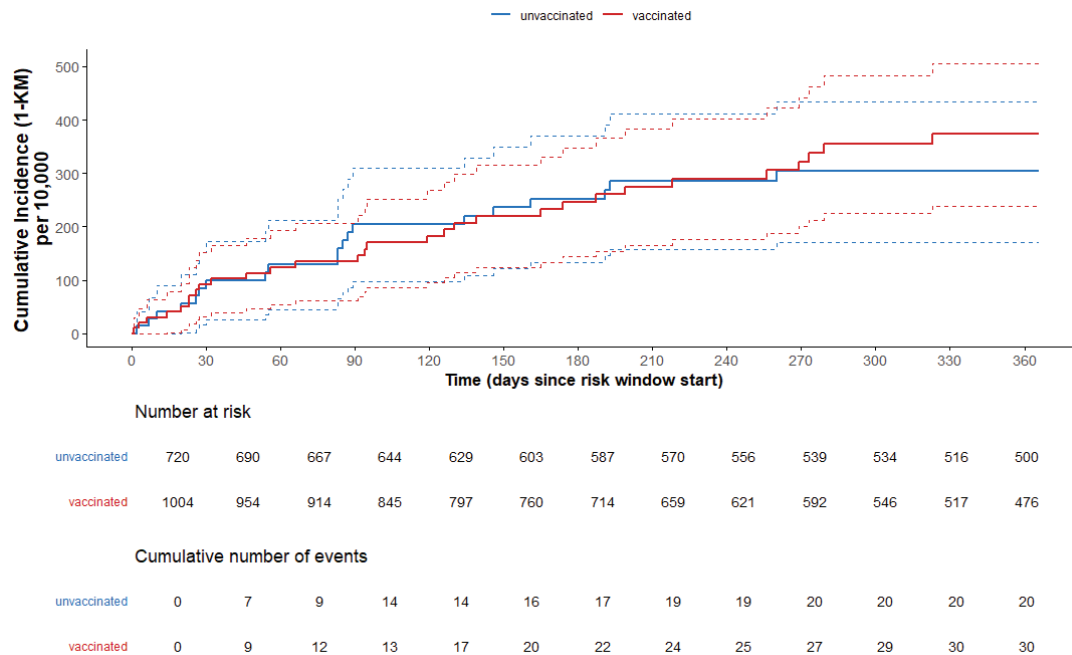
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15.1.10.5 CPRD Aurum: Cumulative incidence of death in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status



15.1.10.6 CPRD Aurum: Cumulative incidence of heart failure in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status

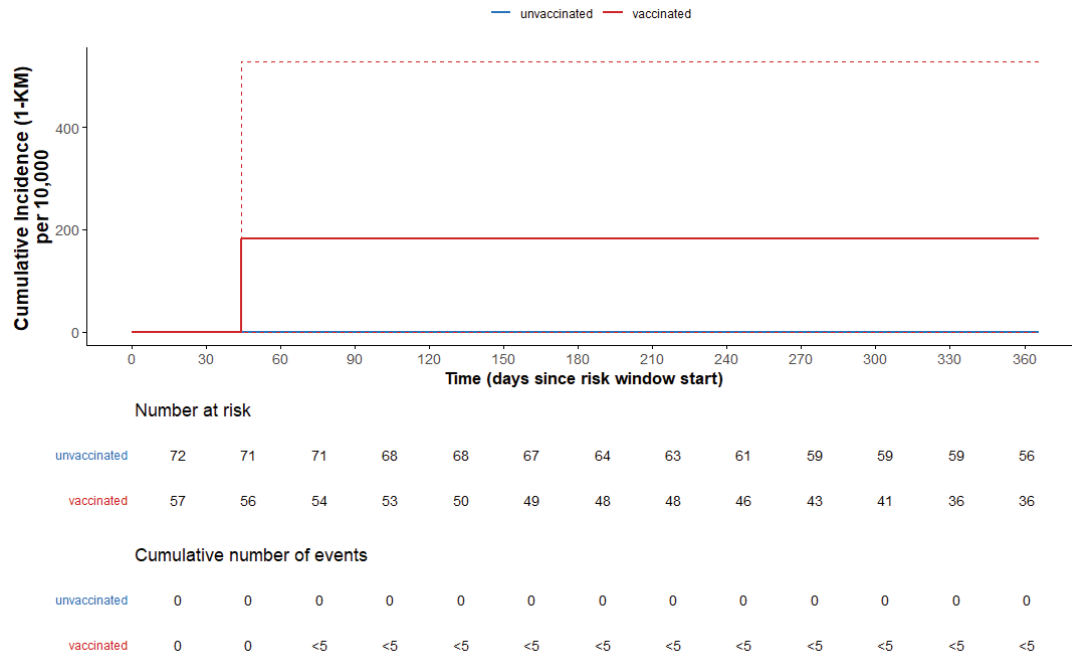


15.1.10.7 CPRD Aurum: Cumulative incidence of chronic myocarditis in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**15.1.10.8 CPRD Aurum: Cumulative incidence of arrhythmia in the pericarditis cohort by Pfizer-BioNTech COVID-19 vaccination status**

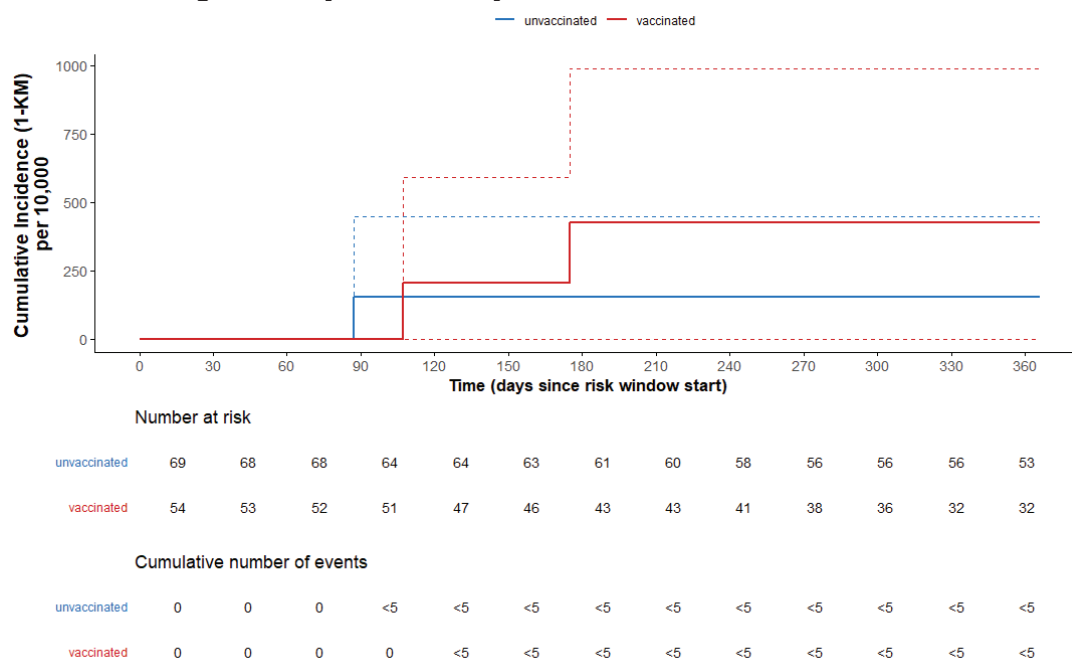
15.2 Figure 2: Cumulative incidence by outcome in subgroups in the myocarditis and pericarditis cohorts by data source

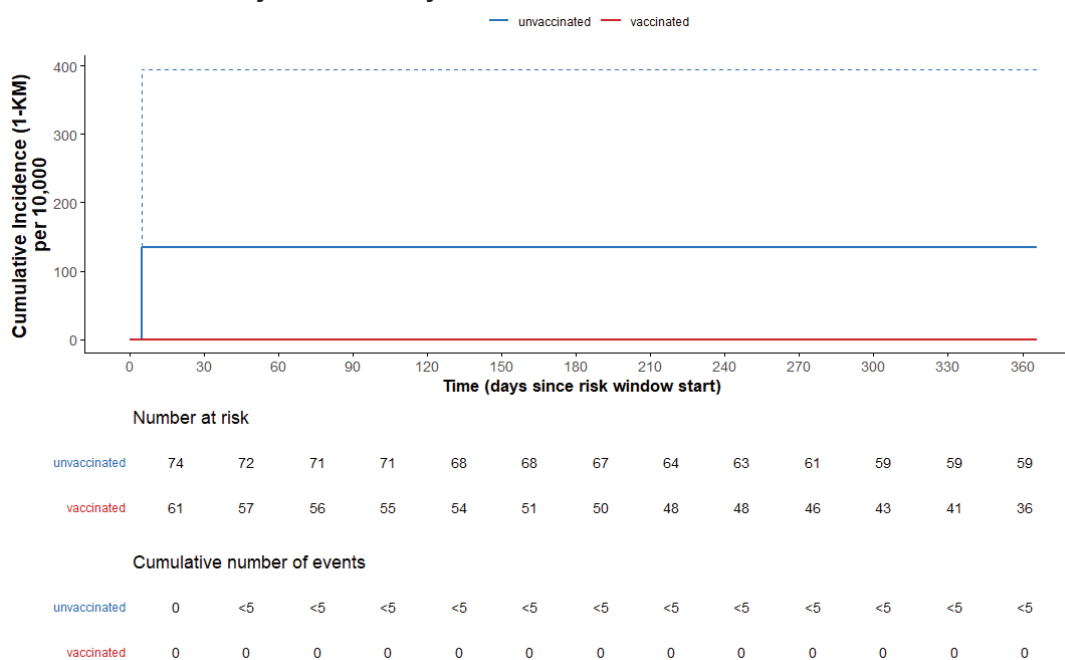
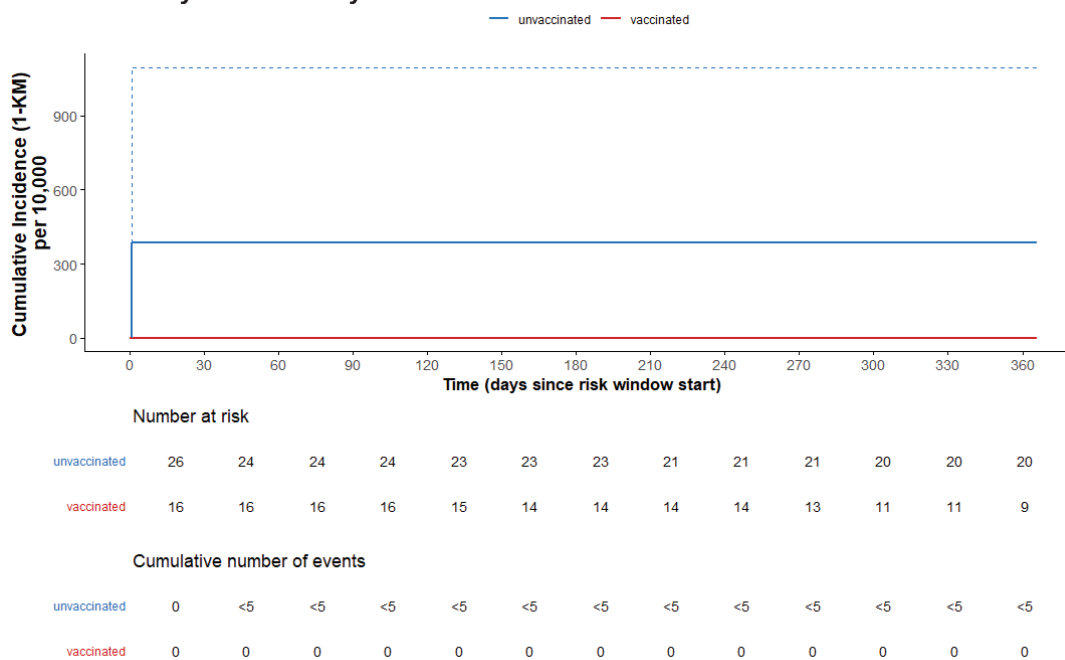
15.2.1 PHARMO myocarditis cohort

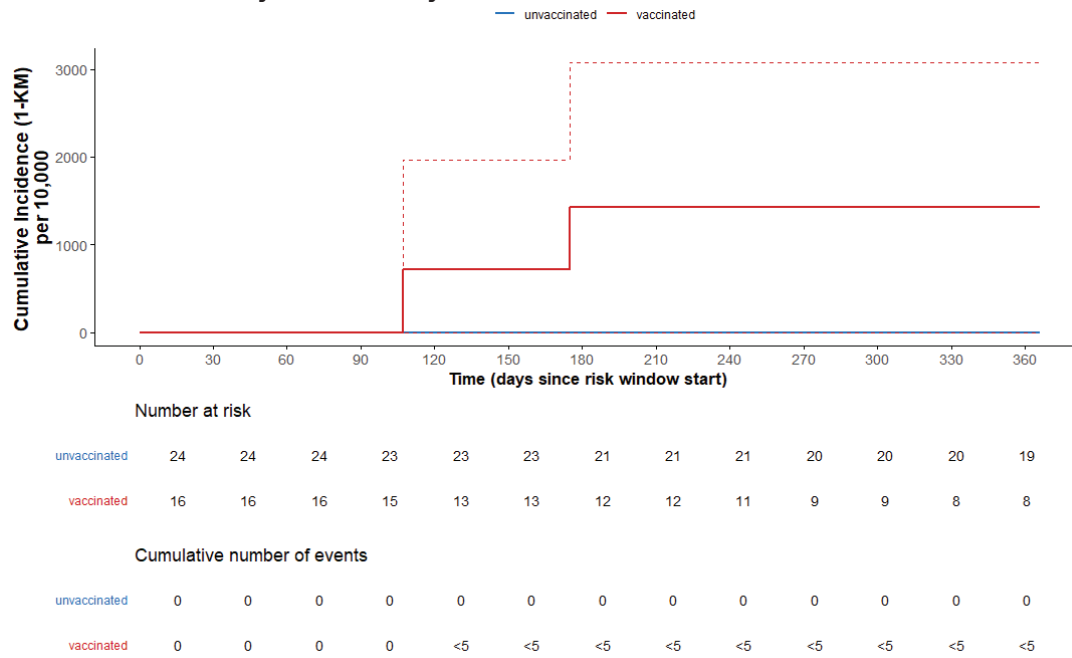
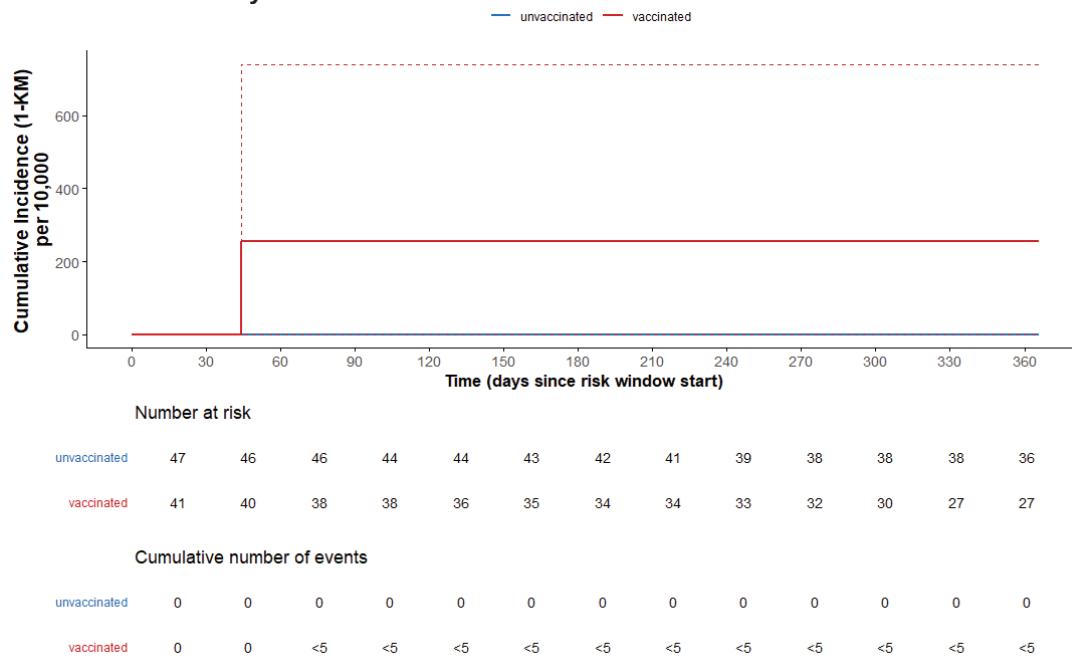
15.2.1.1 PHARMO: Cumulative incidence of arrhythmia in individuals aged 15–30 years in the myocarditis cohort



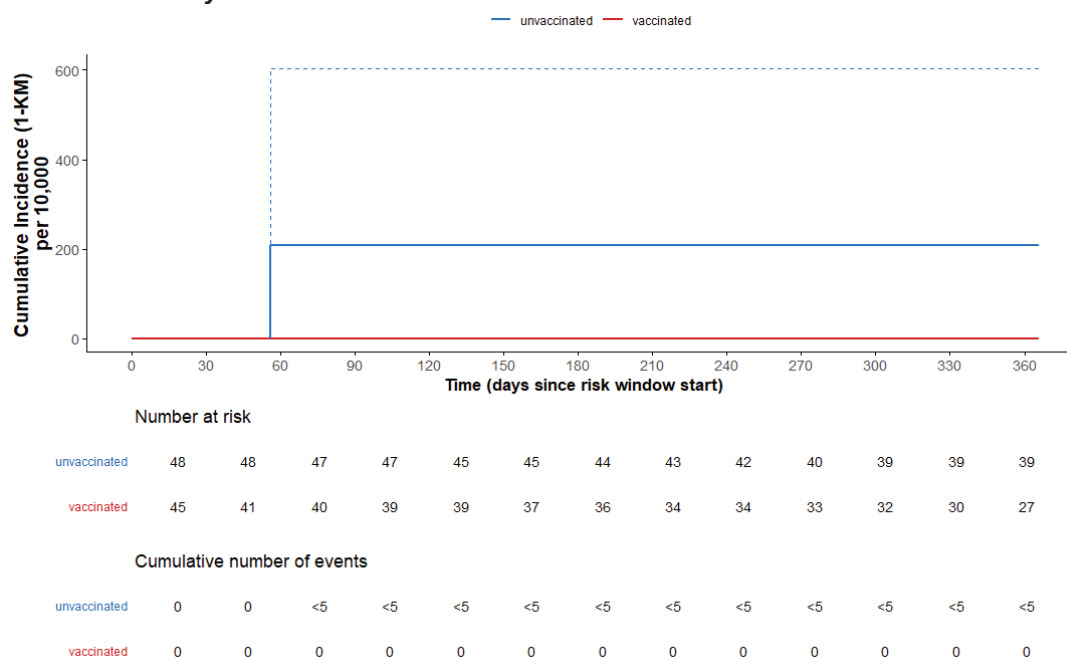
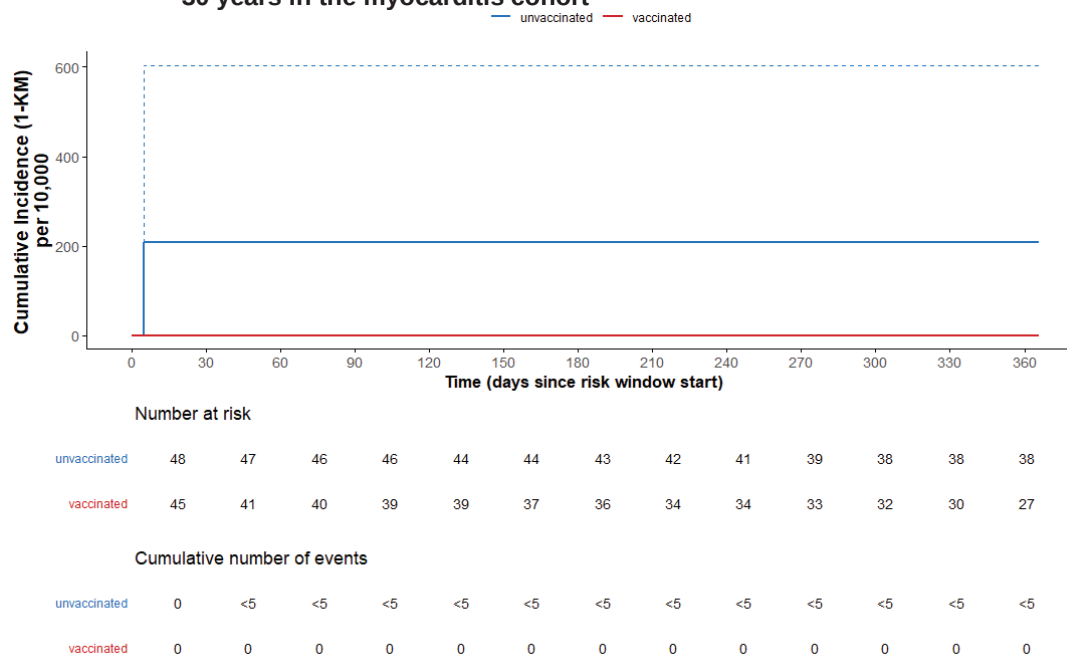
15.2.1.2 PHARMO: Cumulative incidence of recurrent myocarditis in individuals aged 15–30 years in the myocarditis cohort



15.2.1.3 PHARMO: Cumulative incidence of cardiogenic shock in individuals aged 15–30 years in the myocarditis cohort**15.2.1.4 PHARMO: Cumulative incidence of heart failure in females aged 15–30 years in the myocarditis cohort**

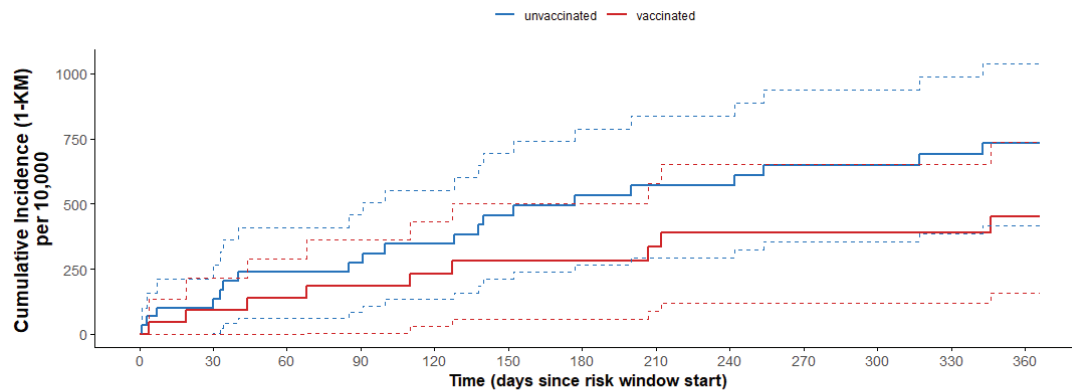
15.2.1.5 PHARMO: Cumulative incidence of recurrent myocarditis in females aged 15–30 years in the myocarditis cohort**15.2.1.6 PHARMO: Cumulative incidence of arrhythmia in males aged 15–30 years in the myocarditis cohort**

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15.2.1.7 PHARMO: Cumulative incidence of death in males aged 15–30 years in the myocarditis cohort**15.2.1.8 PHARMO: Cumulative incidence of fulminant myocarditis in males aged 15–30 years in the myocarditis cohort**

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15.2.1.9 PHARMO: Cumulative incidence of arrhythmia in individuals with no history of COVID-19 in the myocarditis cohort



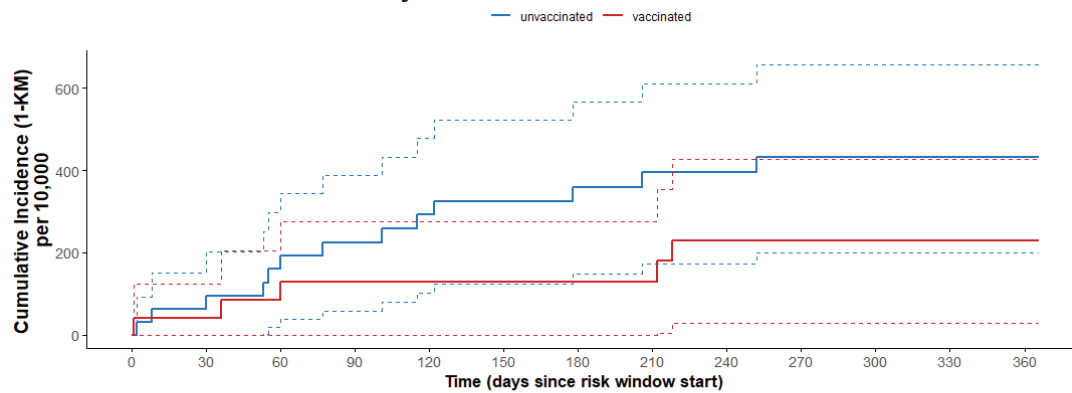
Number at risk

unvaccinated	299	291	281	271	265	257	249	243	238	230	227	222	215
vaccinated	221	217	210	206	200	194	188	178	173	171	165	157	149

Cumulative number of events

unvaccinated	0	<5	7	8	10	13	15	16	16	18	18	19	20
vaccinated	0	<5	<5	<5	5	6	6	7	8	8	8	8	9

15.2.1.10 PHARMO: Cumulative incidence of death in individuals with no history of COVID-19 in the myocarditis cohort

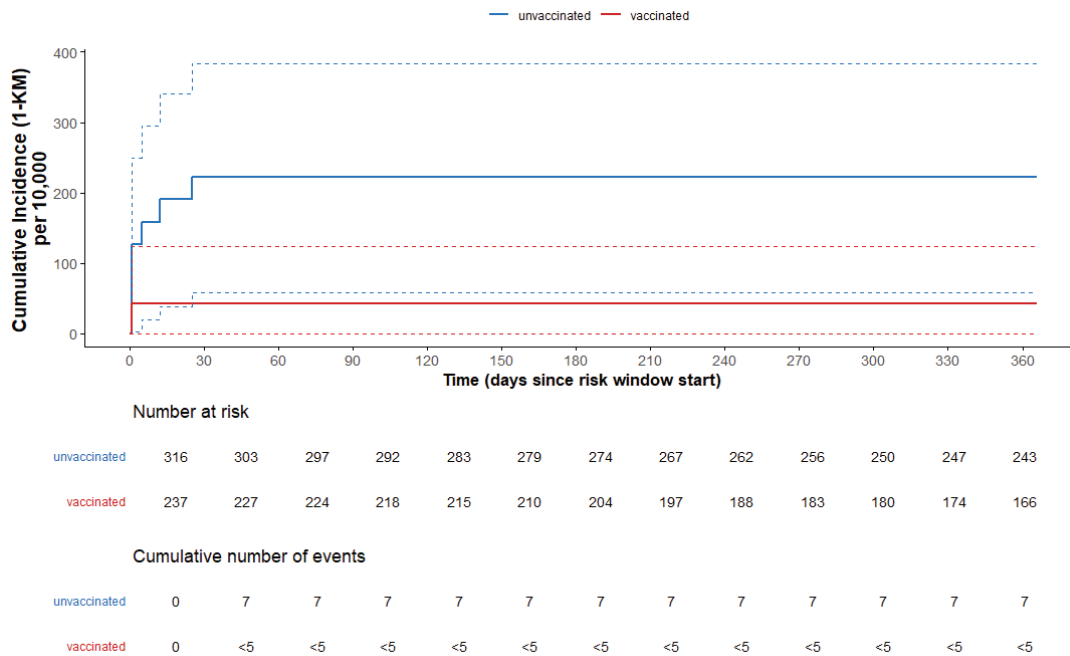
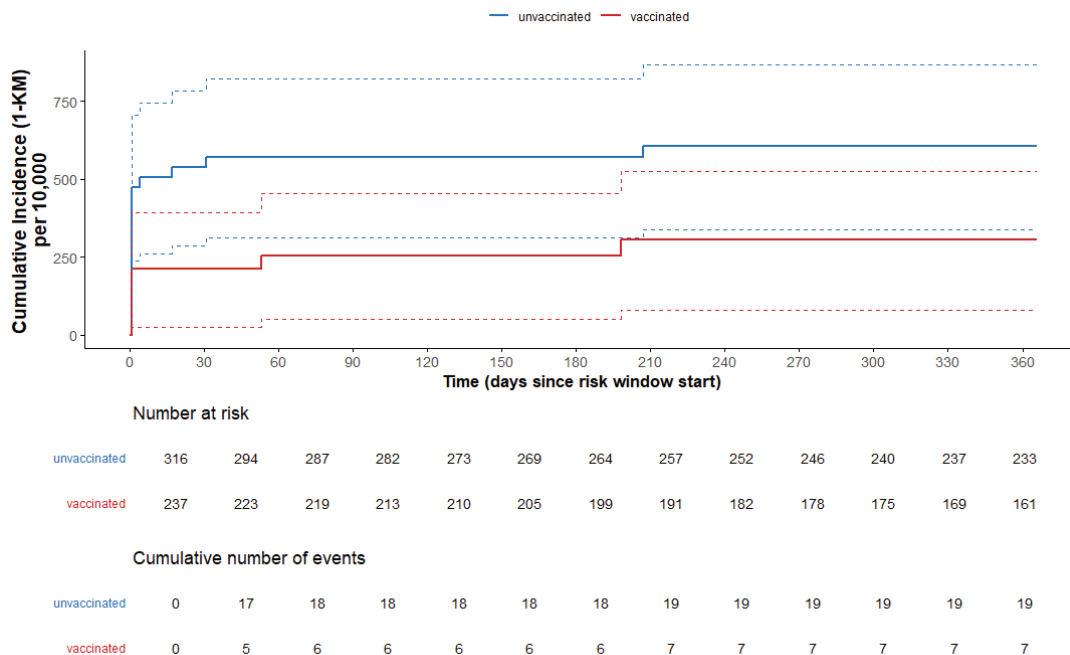


Number at risk

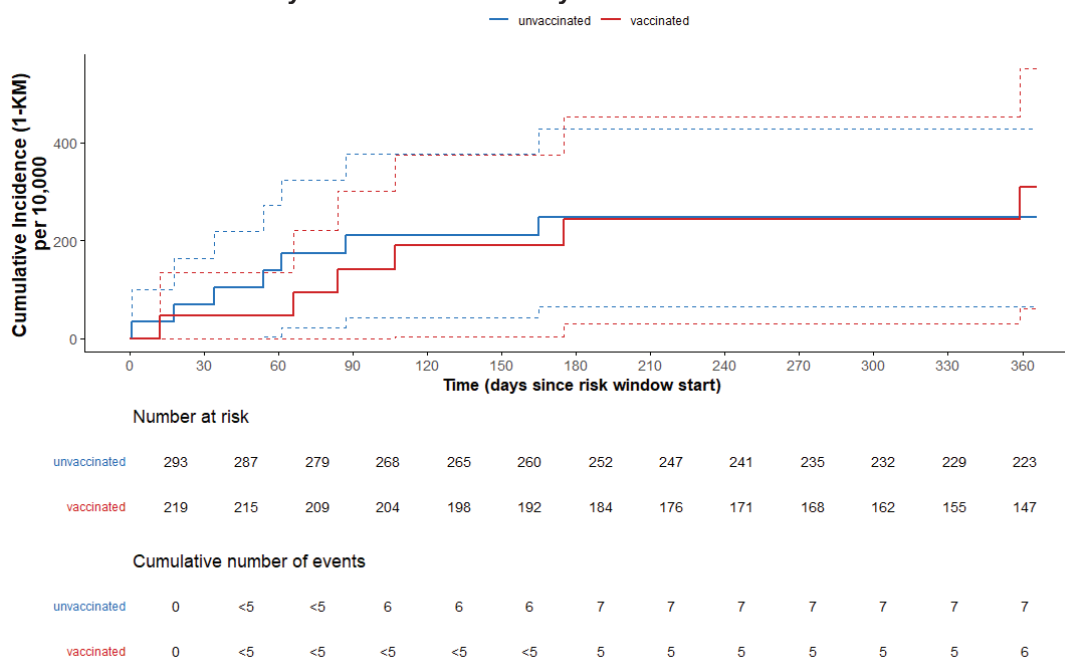
unvaccinated	316	310	304	298	289	285	280	273	267	261	255	252	248
vaccinated	237	228	225	219	216	211	205	198	189	184	181	175	167

Cumulative number of events

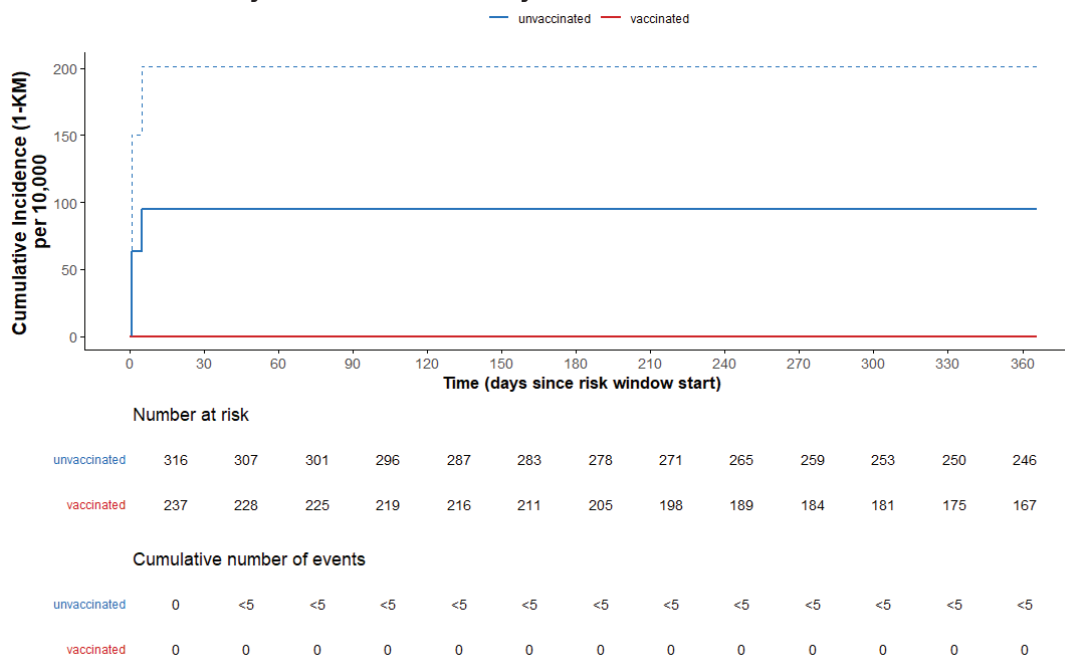
unvaccinated	0	<5	6	7	9	10	11	12	12	13	13	13	13
vaccinated	0	<5	<5	<5	<5	<5	<5	<5	5	5	5	5	5

15.2.1.11 PHARMO: Cumulative incidence of fulminant myocarditis in individuals with no history of COVID-19 in the myocarditis cohort**15.2.1.12 PHARMO: Cumulative incidence of heart failure in individuals with no history of COVID-19 in the myocarditis cohort**

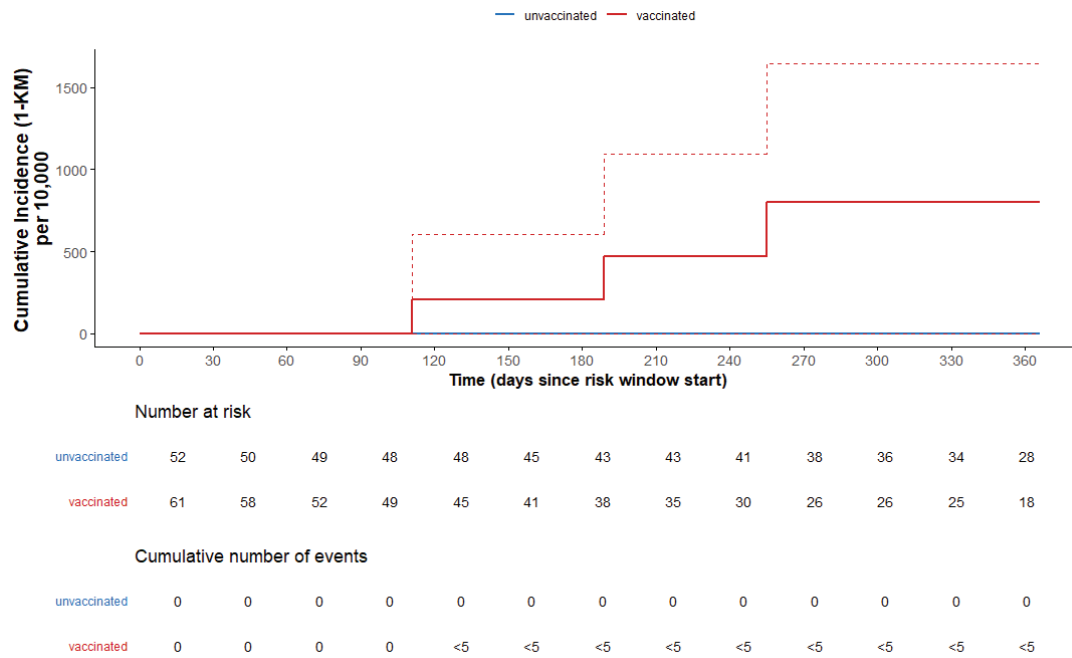
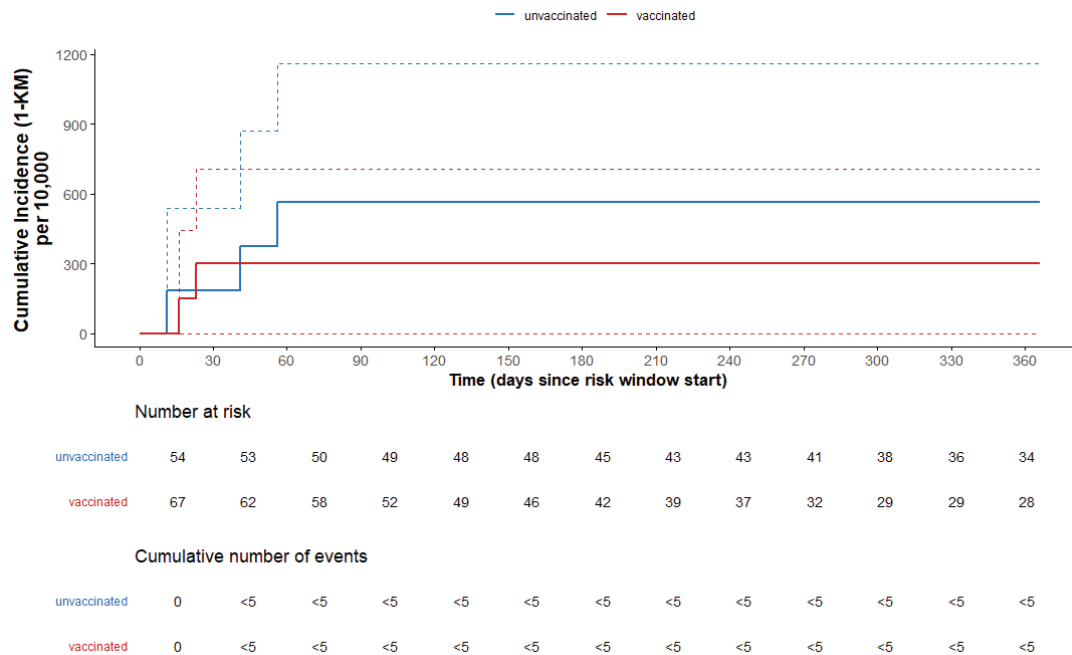
15.2.1.13 PHARMO: Cumulative incidence of recurrent myocarditis in individuals with no history of COVID-19 in the myocarditis cohort



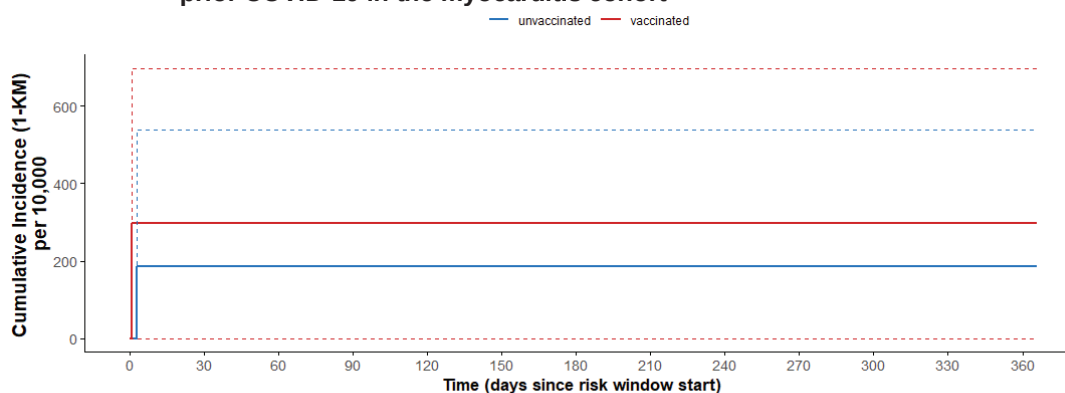
15.2.1.14 PHARMO: Cumulative incidence of cardiogenic shock in individuals with no history of COVID-19 in the myocarditis cohort



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15.2.1.15 PHARMO: Cumulative incidence of arrhythmia in individuals with prior COVID-19 in the myocarditis cohort**15.2.1.16 PHARMO: Cumulative incidence of death in individuals with prior COVID-19 in the myocarditis cohort**

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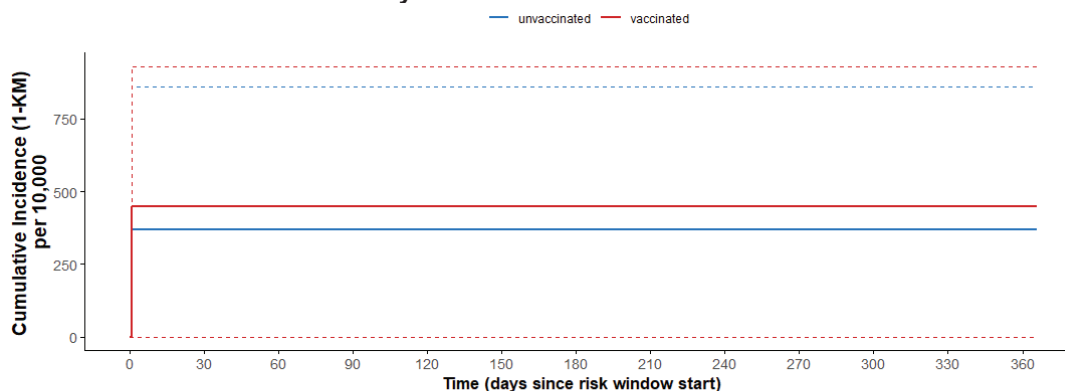
15.2.1.17 PHARMO: Cumulative incidence of fulminant myocarditis in individuals with prior COVID-19 in the myocarditis cohort

Number at risk

unvaccinated	54	52	50	49	48	48	45	43	43	41	38	36	34
vaccinated	67	62	58	52	49	46	42	39	37	32	29	29	28

Cumulative number of events

unvaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5
vaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5

15.2.1.18 PHARMO: Cumulative incidence of heart failure in individuals with prior COVID-19 in the myocarditis cohort

Number at risk

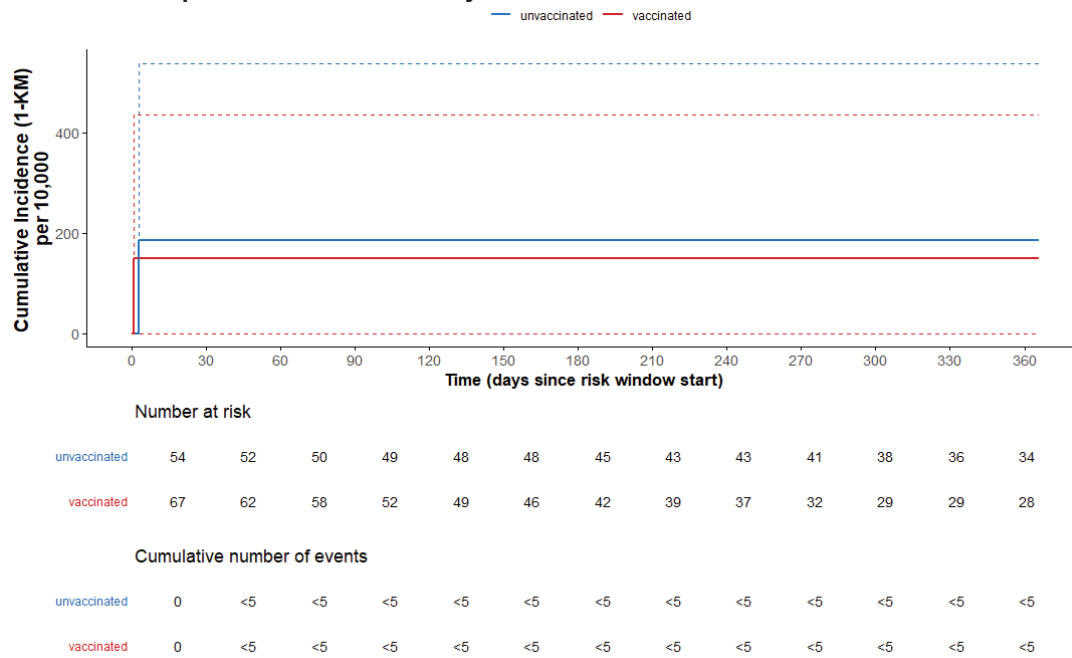
unvaccinated	54	52	49	49	48	48	45	43	43	41	38	36	34
vaccinated	67	60	56	50	47	44	40	37	35	30	28	28	27

Cumulative number of events

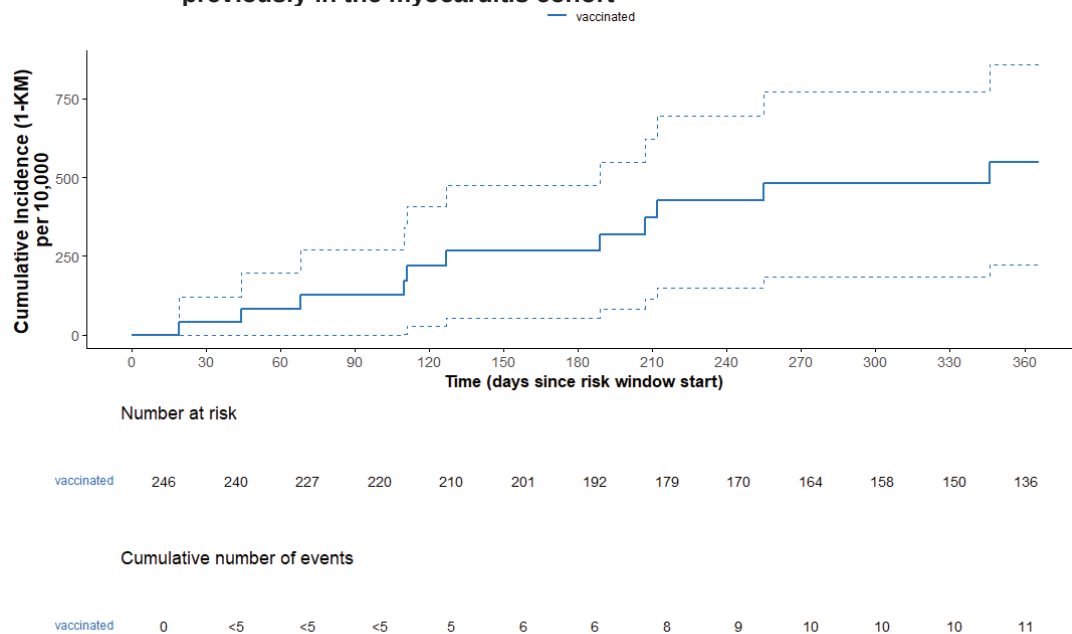
unvaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5
vaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5

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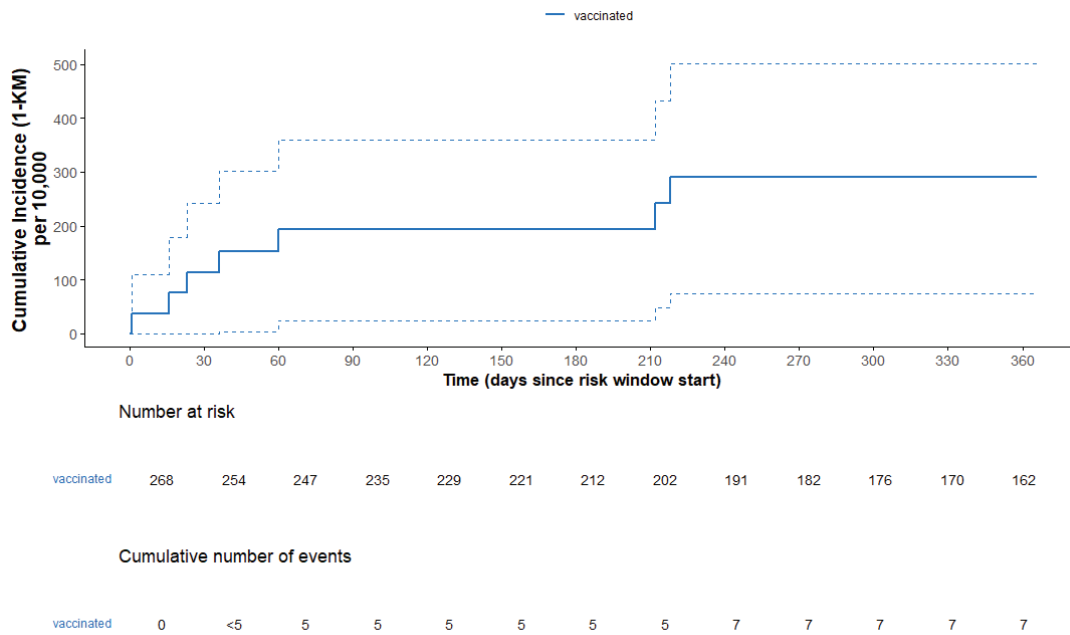
15.2.1.19 PHARMO: Cumulative incidence of cardiogenic shock in individuals with prior COVID-19 in the myocarditis cohort



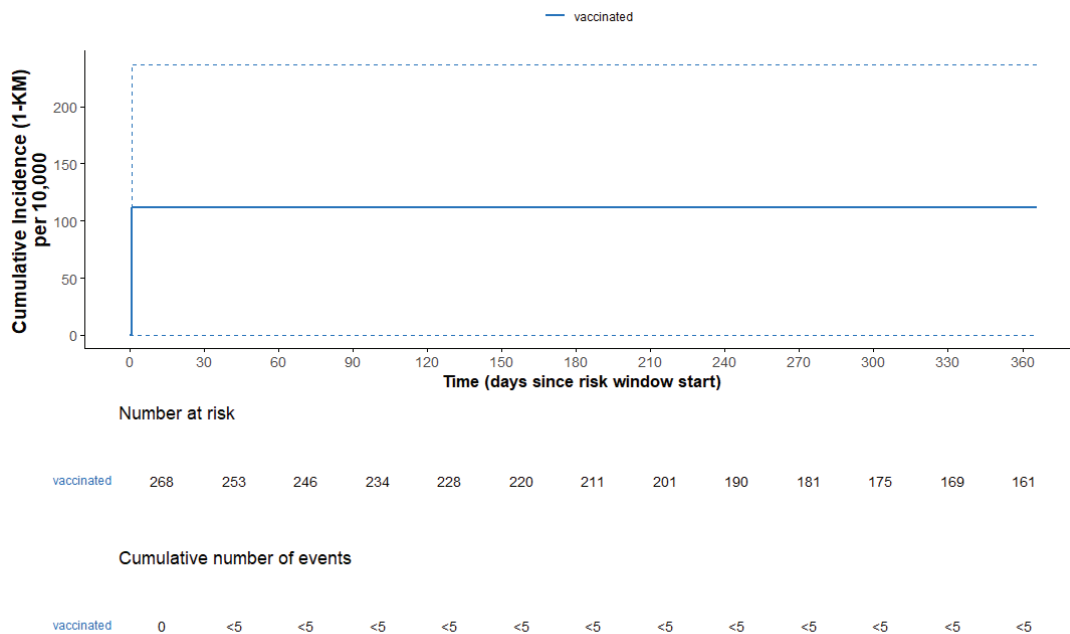
15.2.1.20 PHARMO: Cumulative incidence of arrhythmia in vaccinated individuals who received their last dose of Pfizer-BioNTech COVID-19 vaccine ≥ 22 days previously in the myocarditis cohort



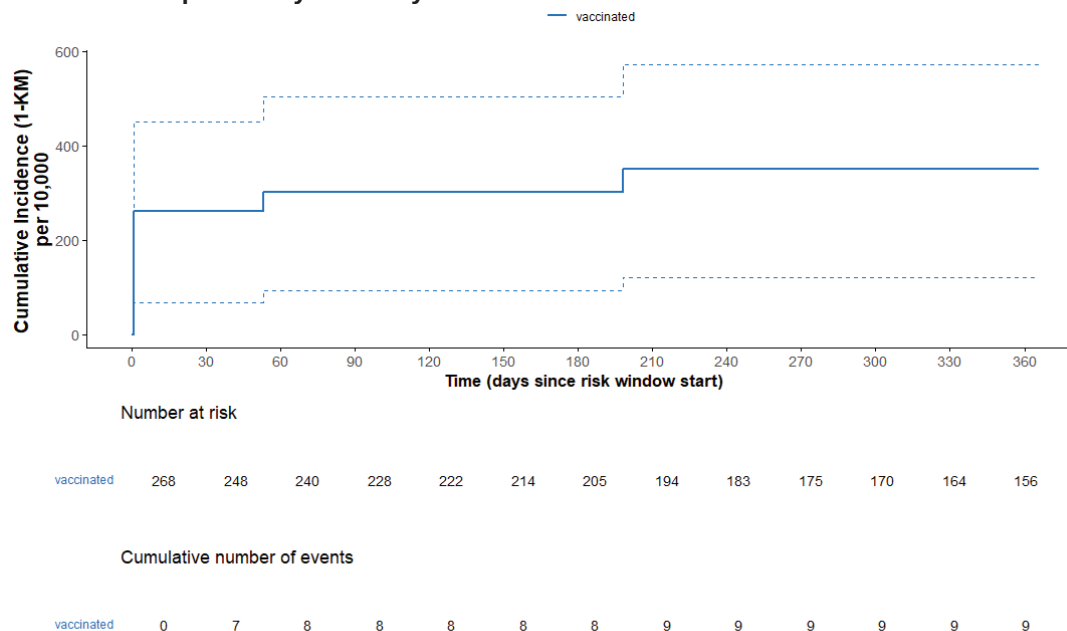
15.2.1.21 PHARMO: Cumulative incidence of death in vaccinated individuals who received their last dose of Pfizer-BioNTech COVID-19 vaccine ≥ 22 days previously in the myocarditis cohort



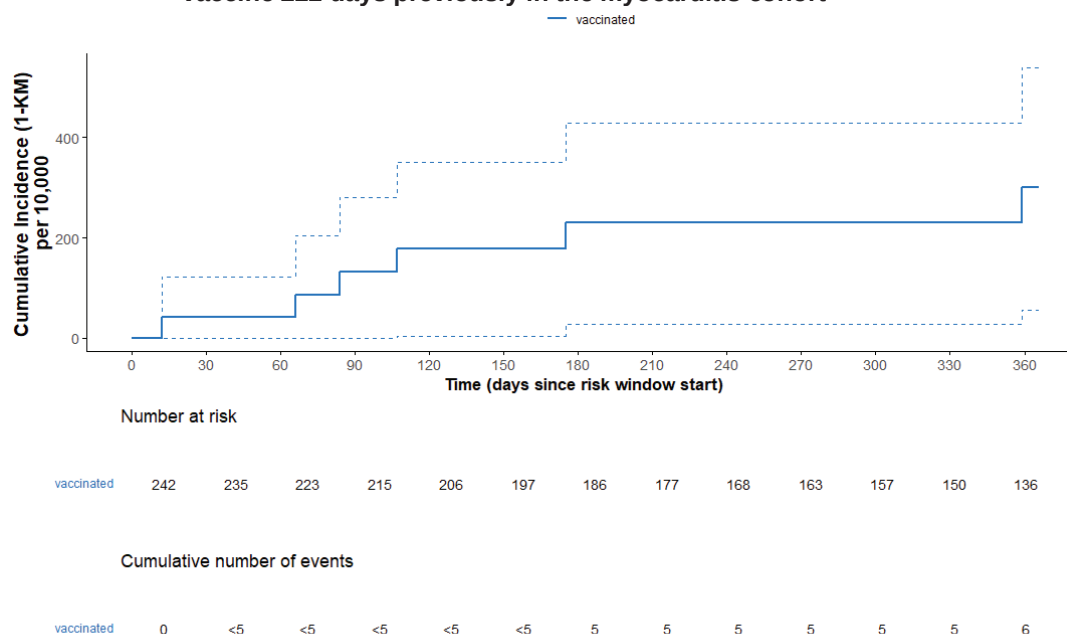
15.2.1.22 PHARMO: Cumulative incidence of fulminant myocarditis in vaccinated individuals who received their last dose of Pfizer-BioNTech COVID-19 vaccine ≥ 22 days previously in the myocarditis cohort



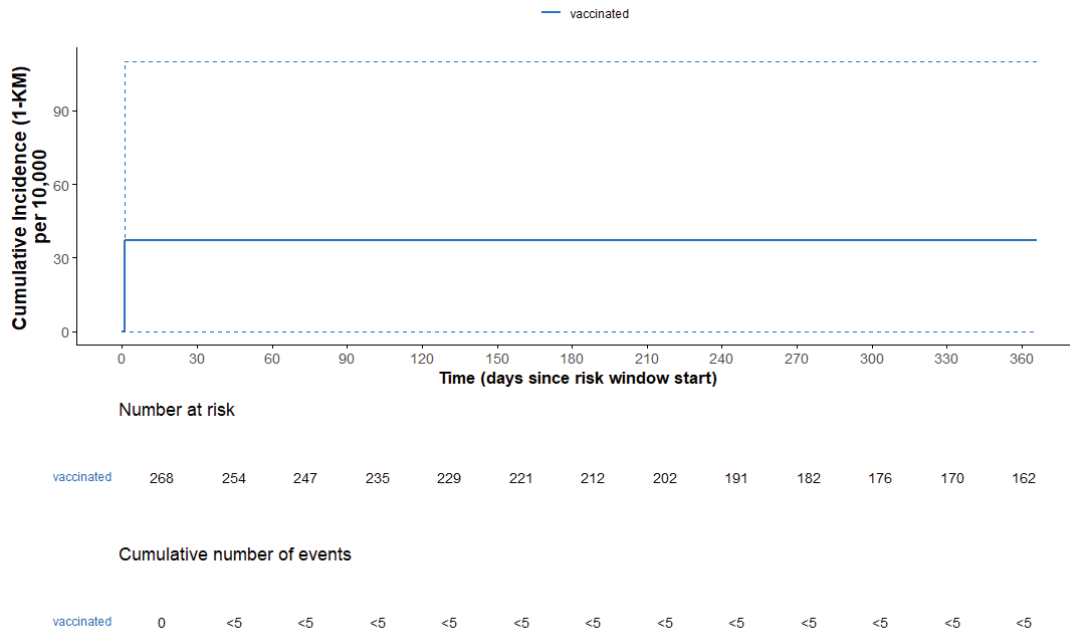
15.2.1.23 PHARMO: Cumulative incidence of heart failure in vaccinated individuals who received their last dose of Pfizer-BioNTech COVID-19 vaccine ≥ 22 days previously in the myocarditis cohort



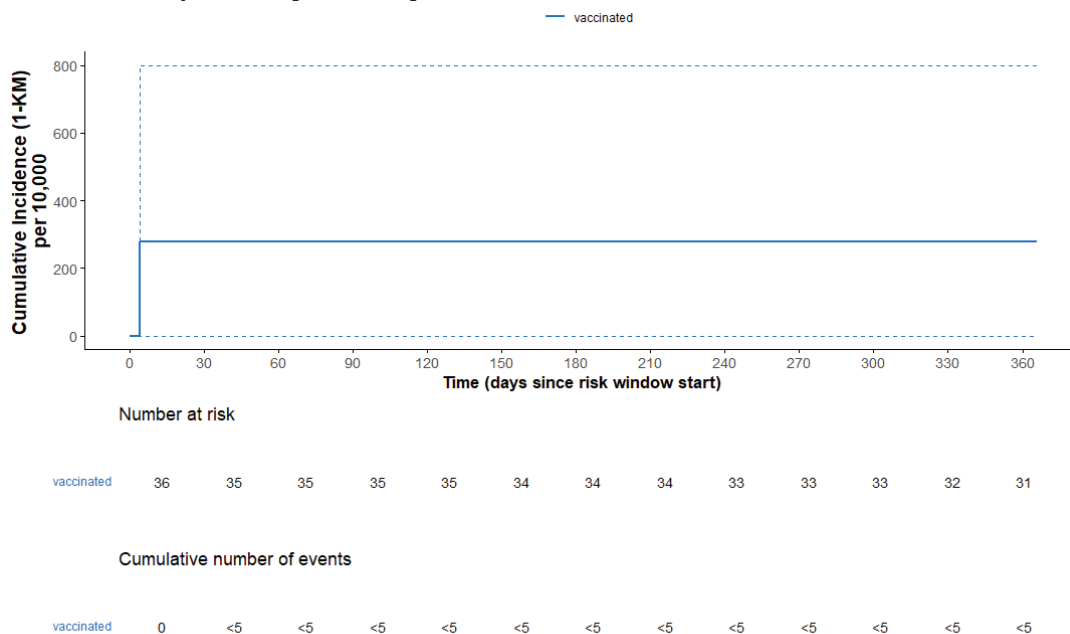
15.2.1.24 PHARMO: Cumulative incidence of recurrent myocarditis in vaccinated individuals who received their last dose of Pfizer-BioNTech COVID-19 vaccine ≥ 22 days previously in the myocarditis cohort



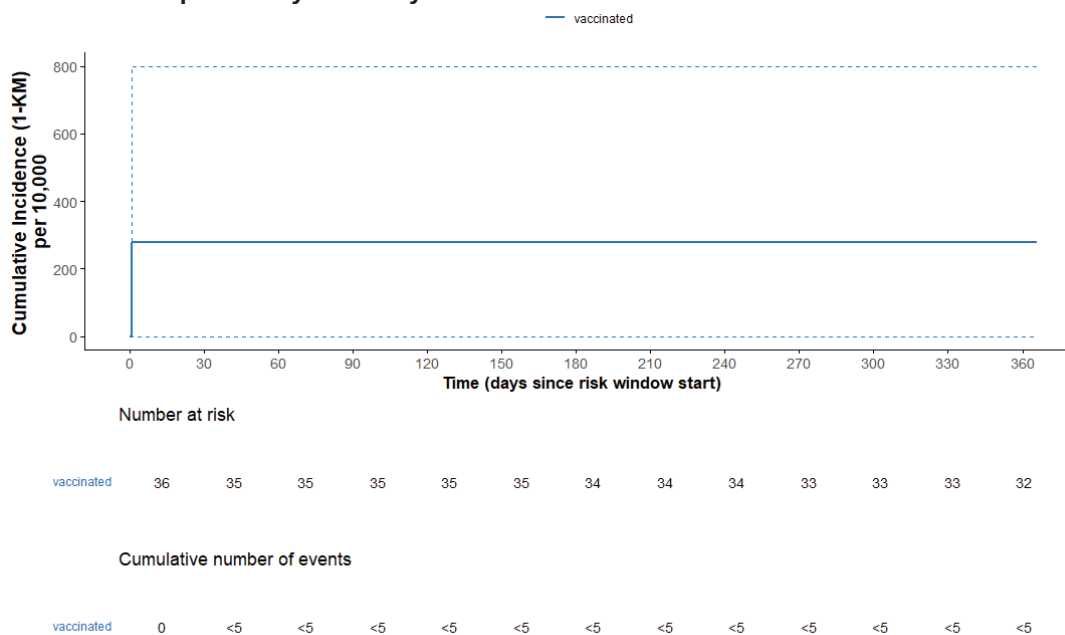
15.2.1.25 PHARMO: Cumulative incidence of cardiogenic shock in vaccinated individuals who received their last dose of Pfizer-BioNTech COVID-19 vaccine ≥ 22 days previously in the myocarditis cohort



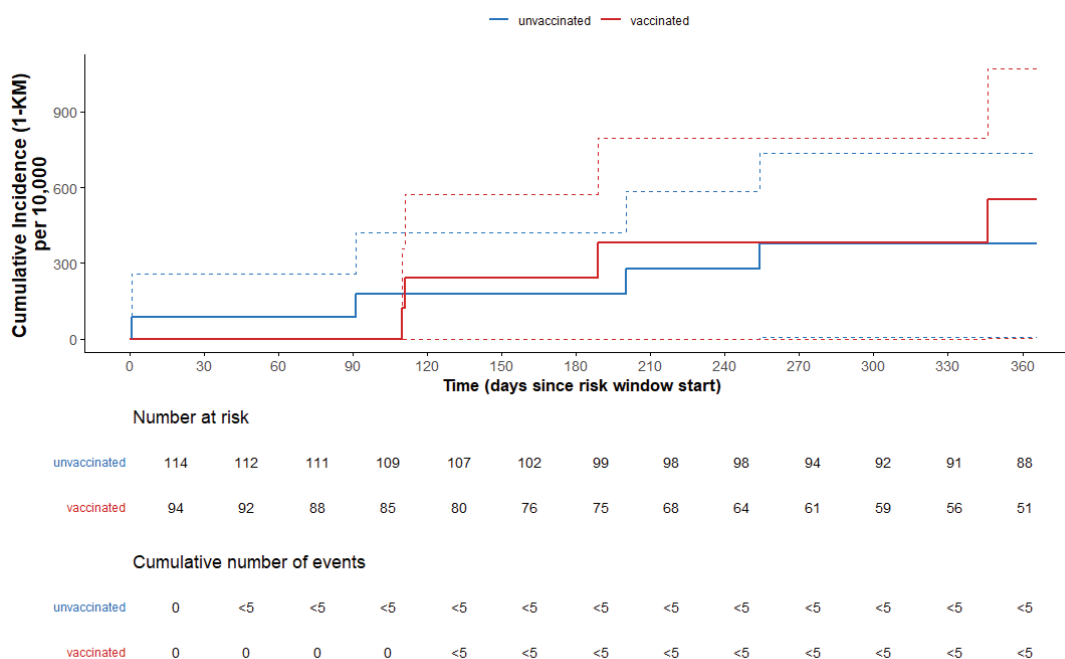
15.2.1.26 PHARMO: Cumulative incidence of arrhythmia in vaccinated individuals who received their last dose of Pfizer-BioNTech COVID-19 vaccine <22 days previously in the myocarditis cohort



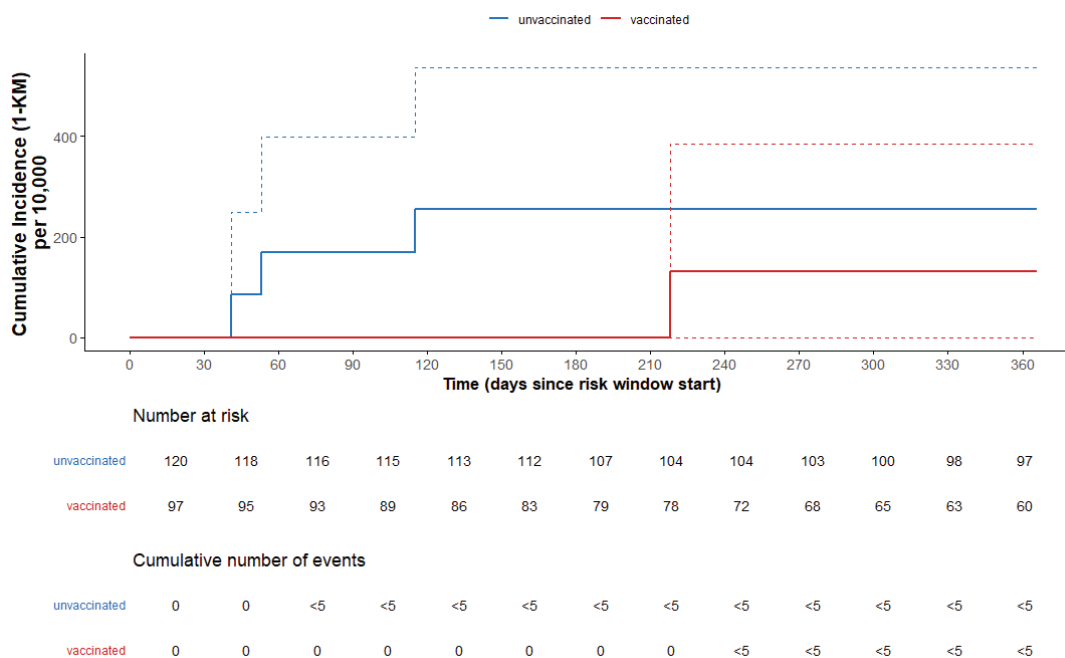
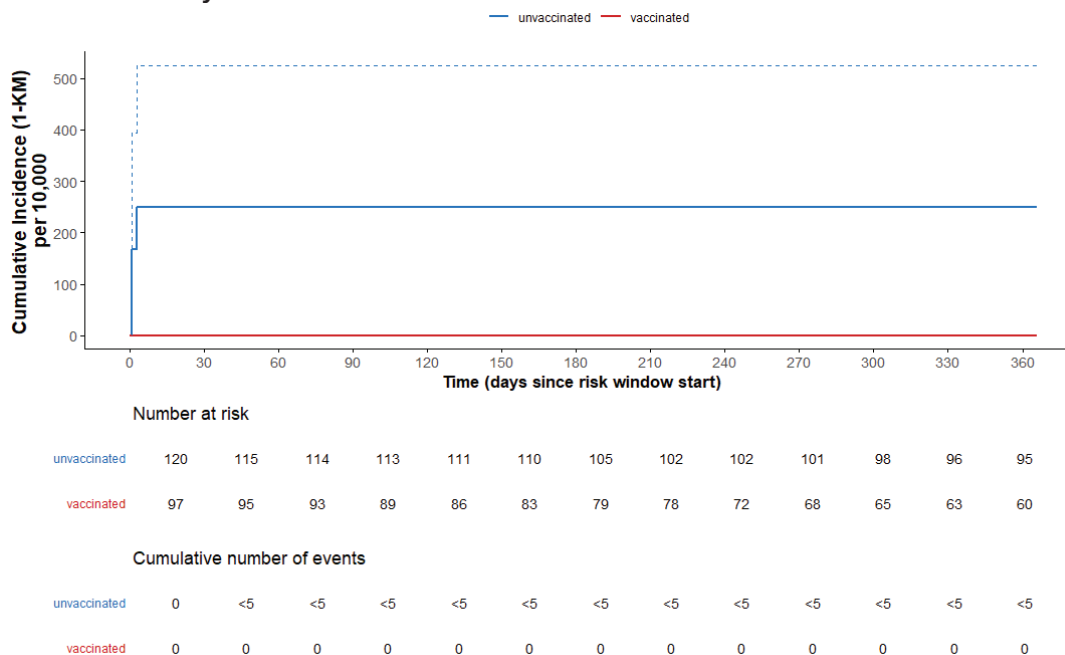
15.2.1.27 PHARMO: Cumulative incidence of heart failure in vaccinated individuals who received their last dose of Pfizer-BioNTech COVID-19 vaccine <22 days previously in the myocarditis cohort



15.2.1.28 PHARMO: Cumulative incidence of arrhythmia in females in the myocarditis cohort

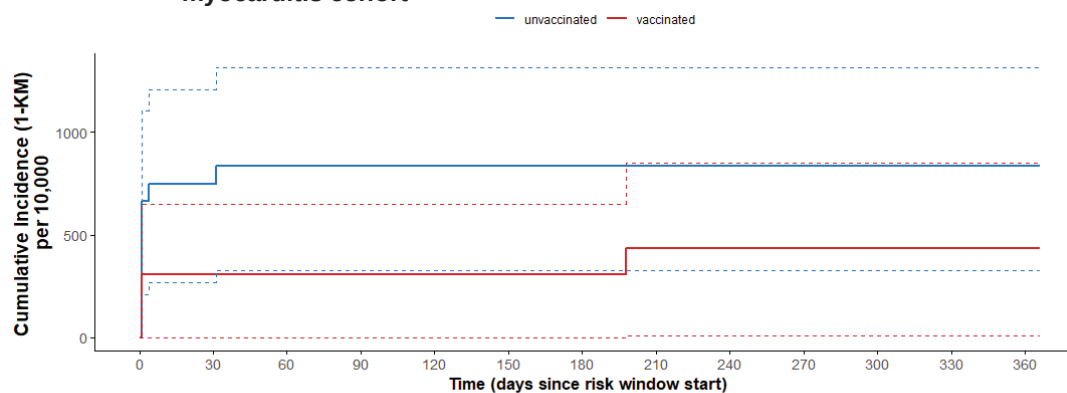


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15.2.1.29 PHARMO: Cumulative incidence of death in females in the myocarditis cohort**15.2.1.30 PHARMO: Cumulative incidence of fulminant myocarditis in females in the myocarditis cohort**

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15.2.1.31 PHARMO: Cumulative incidence of heart failure in females in the myocarditis cohort



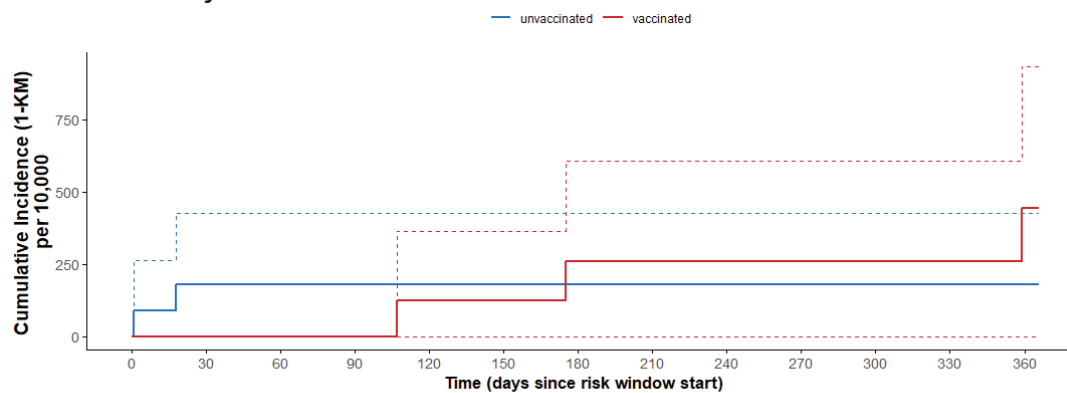
Number at risk

unvaccinated	120	109	106	105	103	102	97	95	95	94	91	89	88
vaccinated	97	92	90	86	83	80	76	74	68	65	63	61	58

Cumulative number of events

unvaccinated	0	9	10	10	10	10	10	10	10	10	10	10	10
vaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5

15.2.1.32 PHARMO: Cumulative incidence of recurrent myocarditis in females in the myocarditis cohort



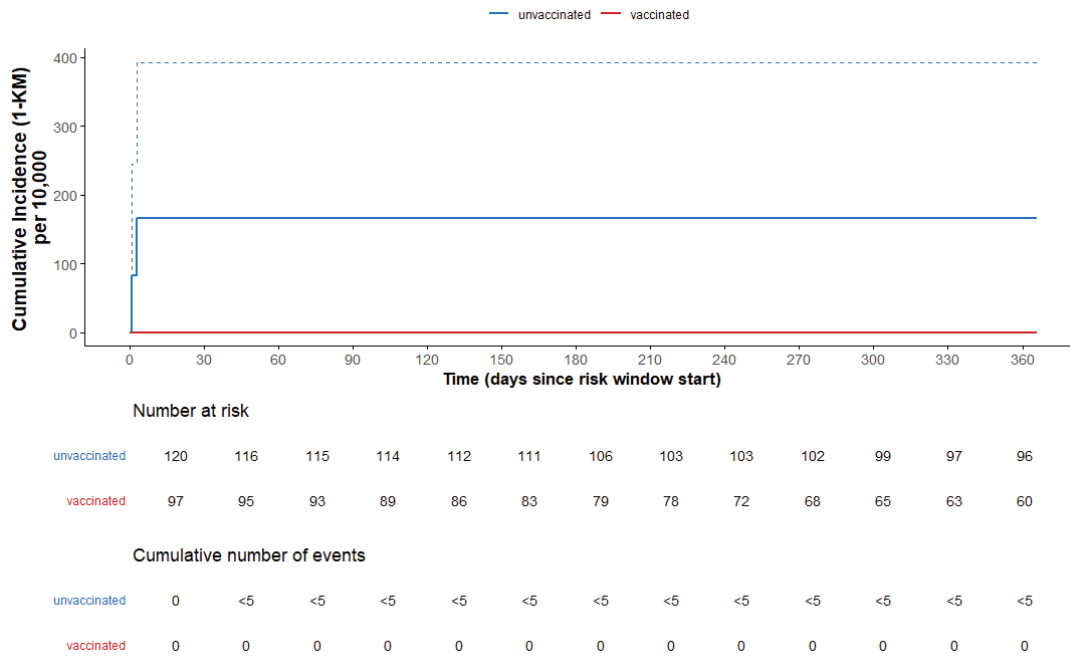
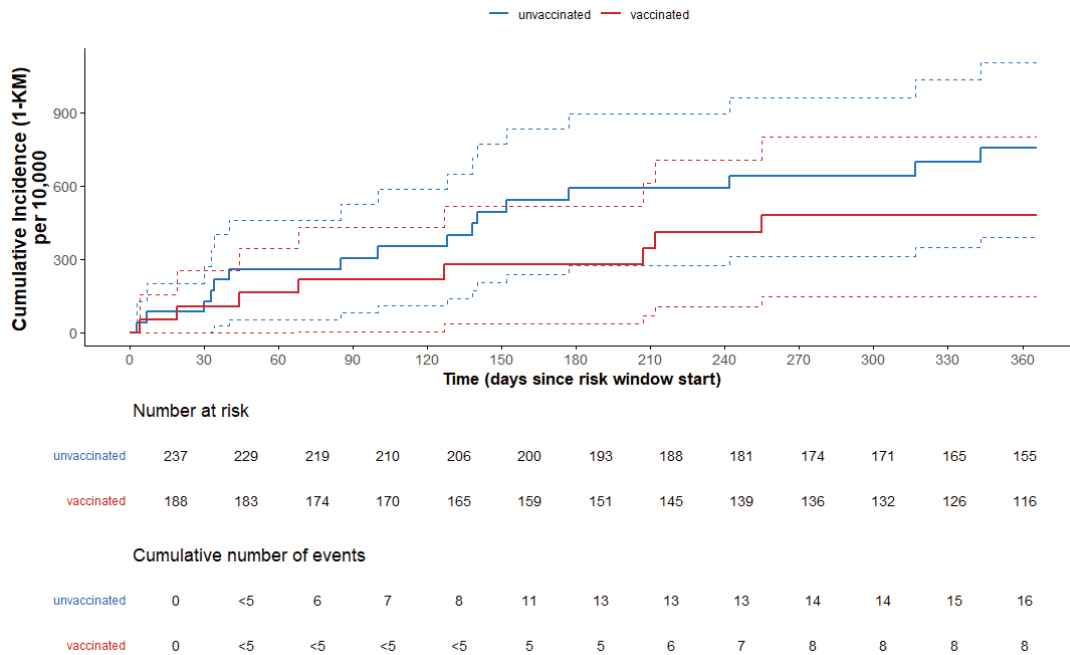
Number at risk

unvaccinated	111	108	107	105	104	99	96	96	95	92	90	89	86
vaccinated	91	89	85	82	78	74	72	66	62	60	58	56	51

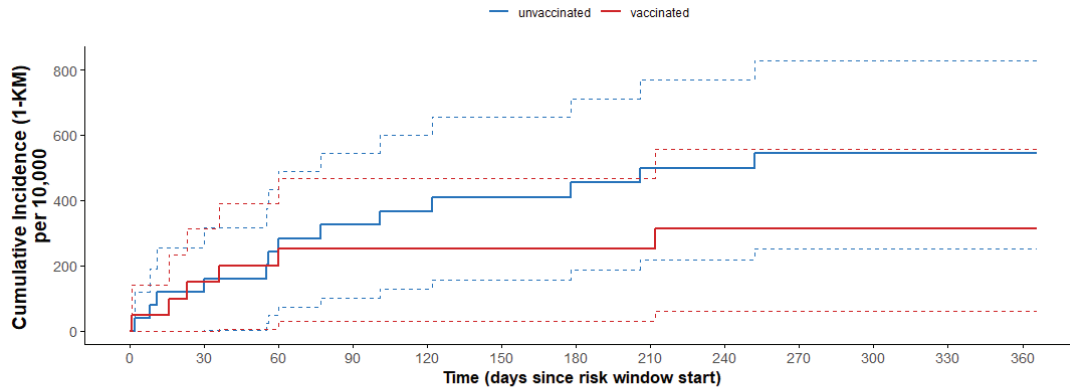
Cumulative number of events

unvaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5
vaccinated	0	0	0	0	<5	<5	<5	<5	<5	<5	<5	<5	<5

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15.2.1.33 PHARMO: Cumulative incidence of cardiogenic shock in females in the myocarditis cohort**15.2.1.34 PHARMO: Cumulative incidence of arrhythmia in males in the myocarditis cohort**

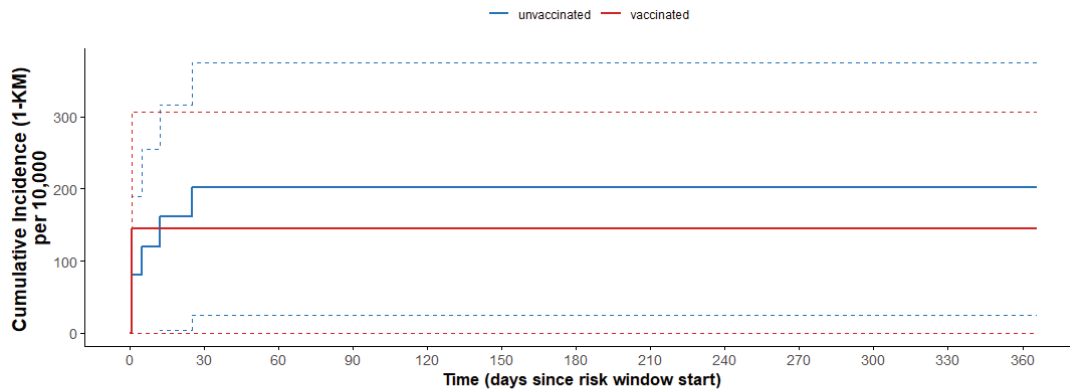
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15.2.1.35 PHARMO: Cumulative incidence of death in males in the myocarditis cohort**Number at risk**

unvaccinated	250	245	238	232	224	221	218	212	206	199	193	190	185
vaccinated	207	195	190	182	179	174	168	159	154	148	145	141	135

Cumulative number of events

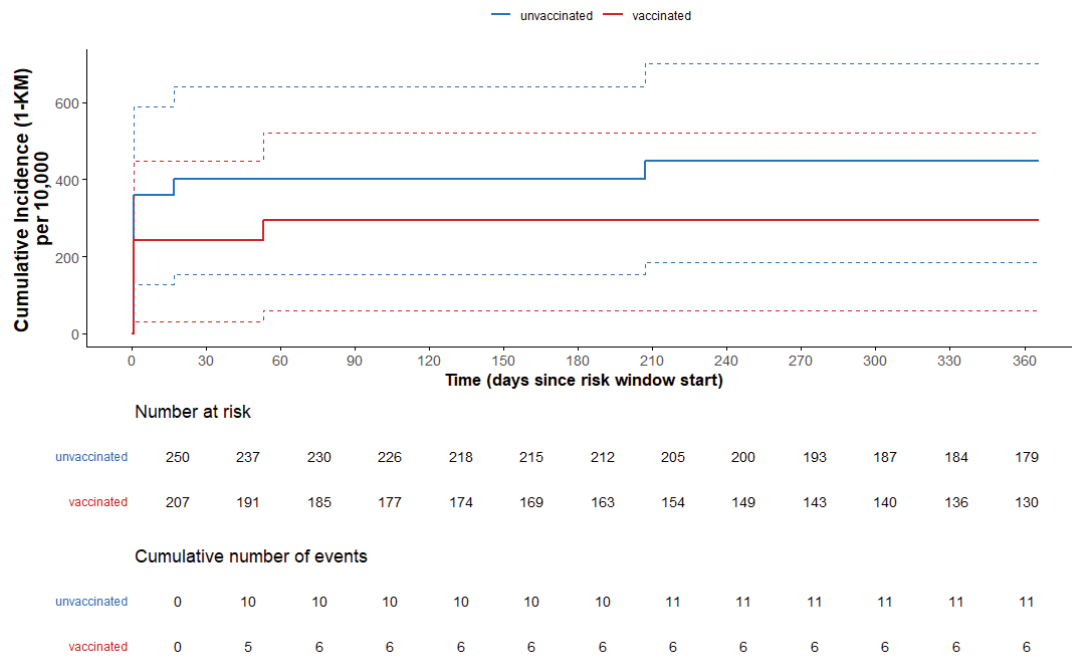
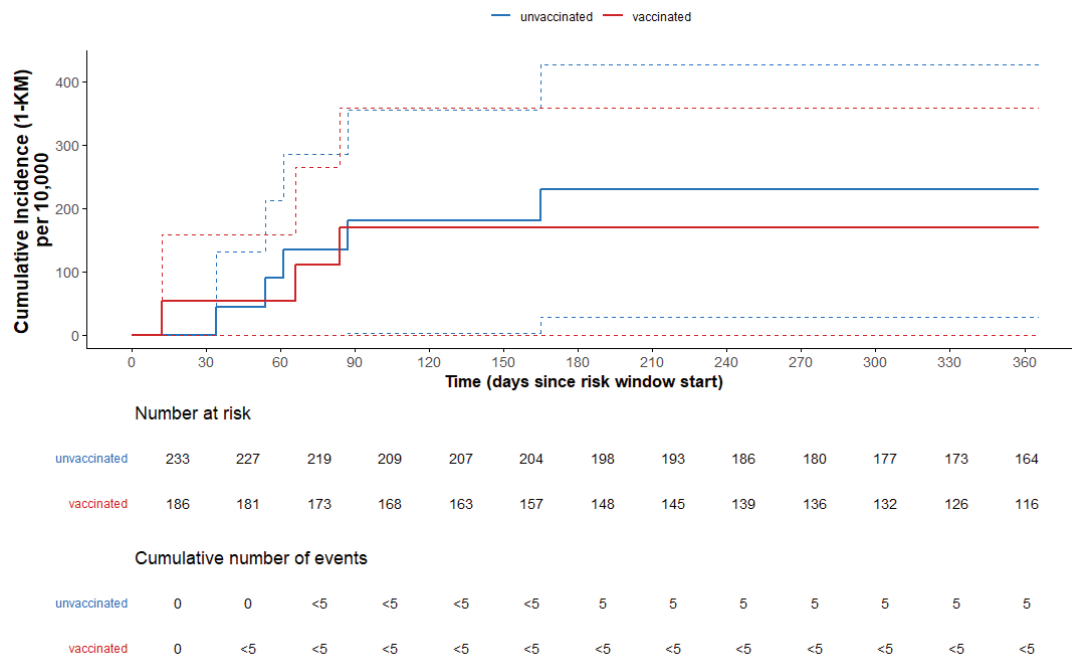
unvaccinated	0	<5	7	8	9	10	11	12	12	13	13	13	13
vaccinated	0	<5	5	5	5	5	5	5	6	6	6	6	6

15.2.1.36 PHARMO: Cumulative incidence of fulminant myocarditis in males in the myocarditis cohort**Number at risk**

unvaccinated	250	240	233	228	220	217	214	208	203	196	190	187	182
vaccinated	207	194	189	181	178	173	167	158	153	147	144	140	134

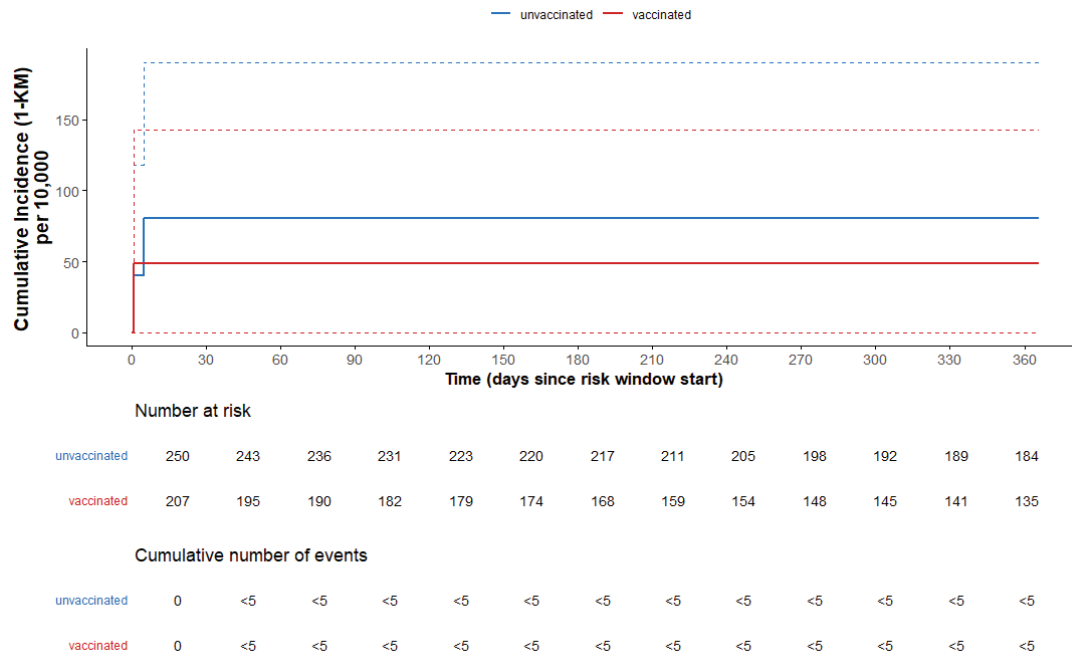
Cumulative number of events

unvaccinated	0	5	5	5	5	5	5	5	5	5	5	5	5
vaccinated	0	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5

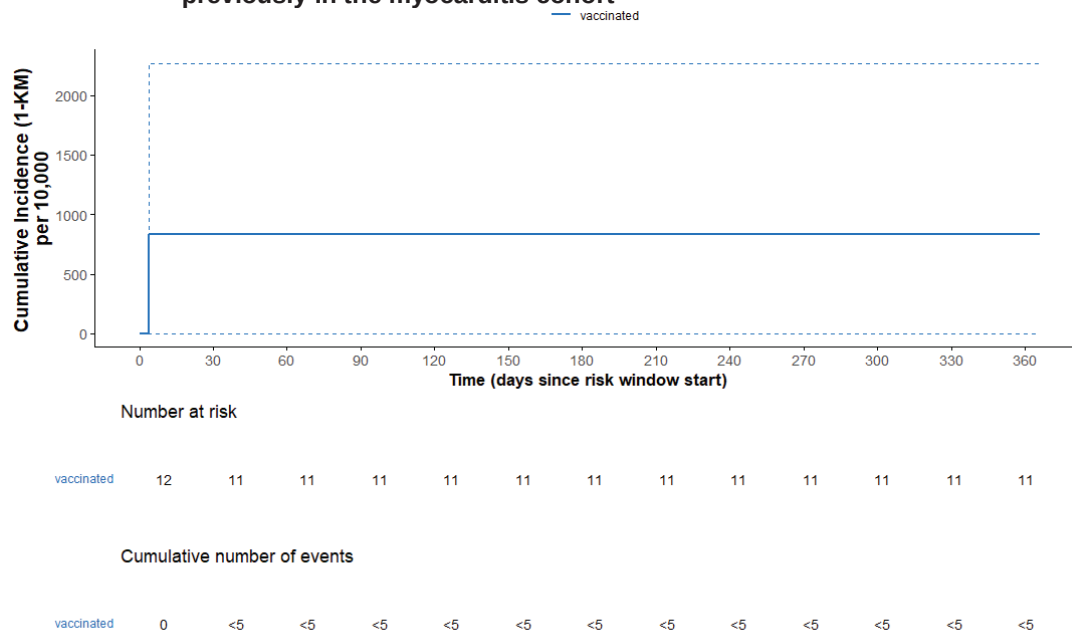
15.2.1.37 PHARMO: Cumulative incidence of heart failure in males in the myocarditis cohort**15.2.1.38 PHARMO: Cumulative incidence of recurrent myocarditis in males in the myocarditis cohort**

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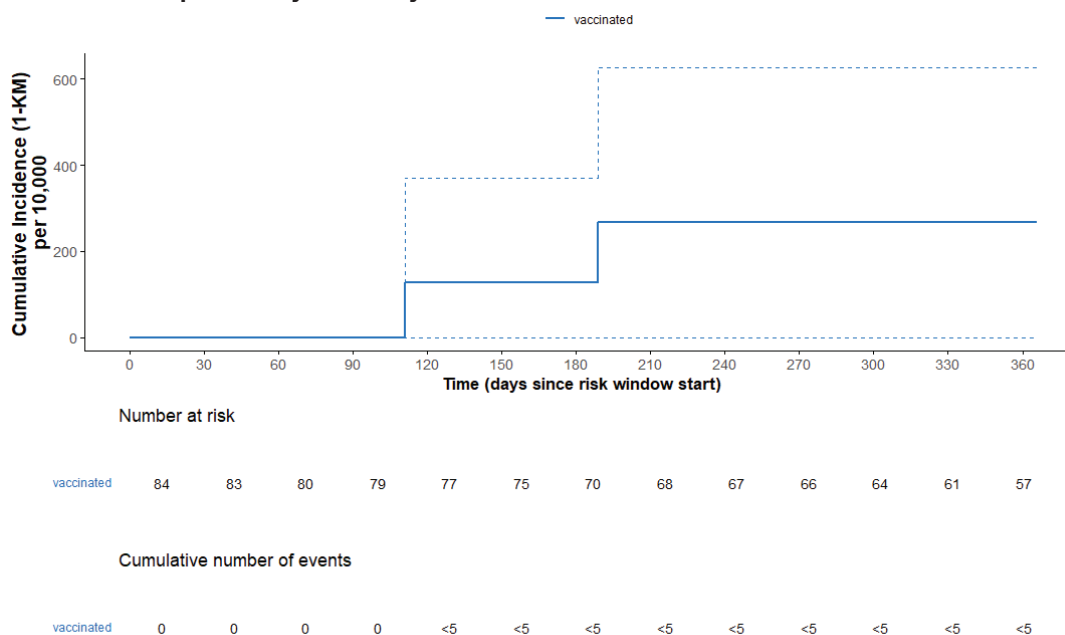
15.2.1.39 PHARMO: Cumulative incidence of cardiogenic shock in males in the myocarditis cohort



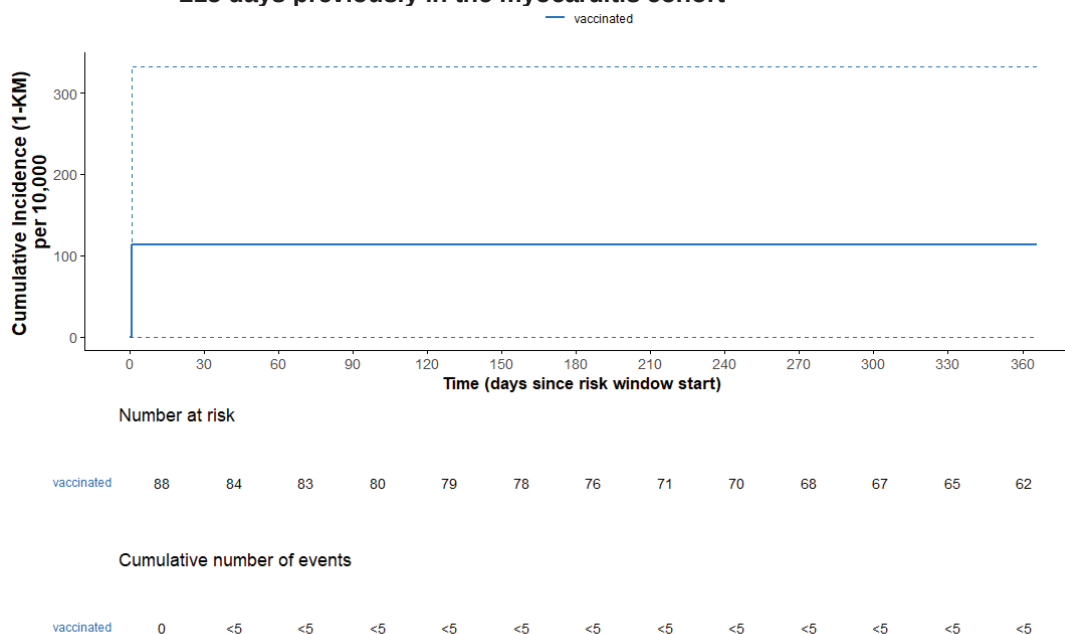
15.2.1.40 PHARMO: Cumulative incidence of arrhythmia in vaccinated individuals who received one dose of Pfizer-BioNTech COVID-19 vaccine <15 days previously in the myocarditis cohort



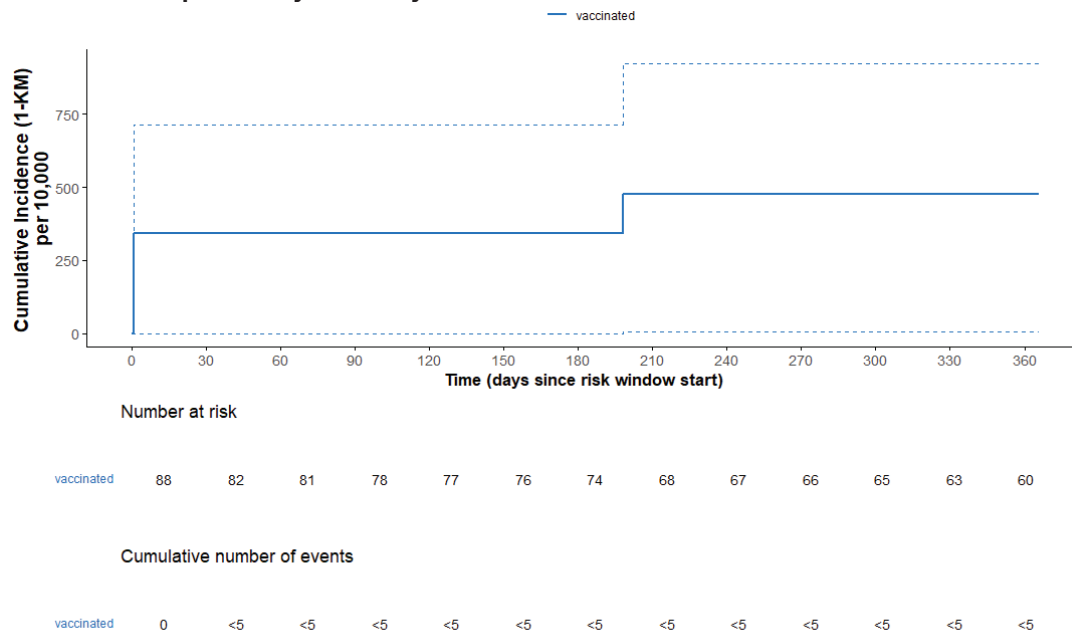
15.2.1.41 PHARMO: Cumulative incidence of arrhythmia in vaccinated individuals who received one dose of Pfizer-BioNTech COVID-19 vaccine ≥ 15 days previously in the myocarditis cohort



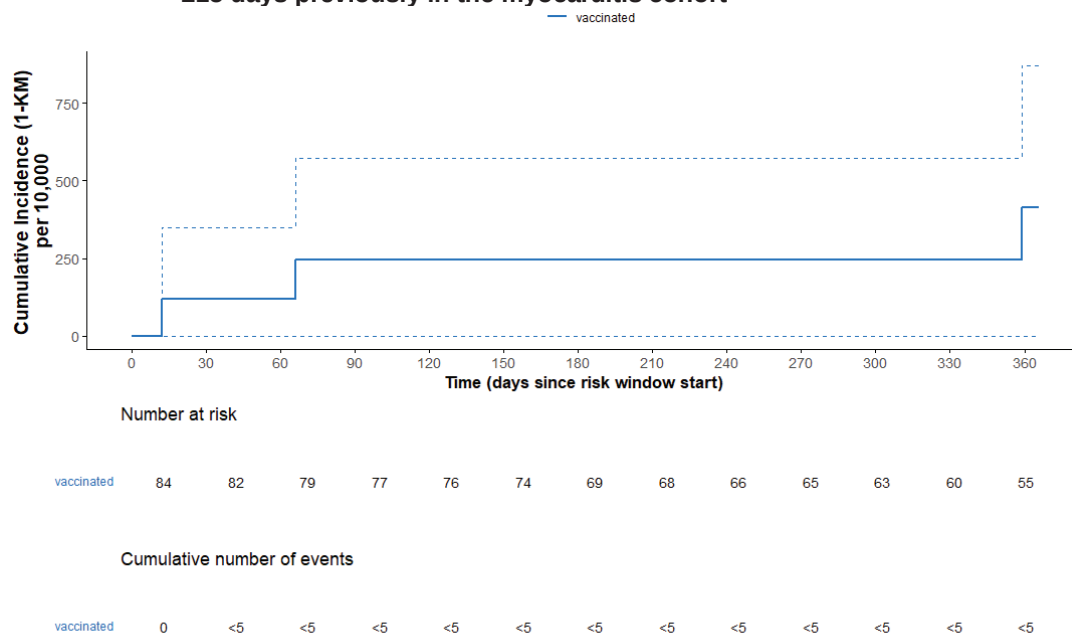
15.2.1.42 PHARMO: Cumulative incidence of fulminant myocarditis in vaccinated individuals who received one dose of Pfizer-BioNTech COVID-19 vaccine ≥ 15 days previously in the myocarditis cohort



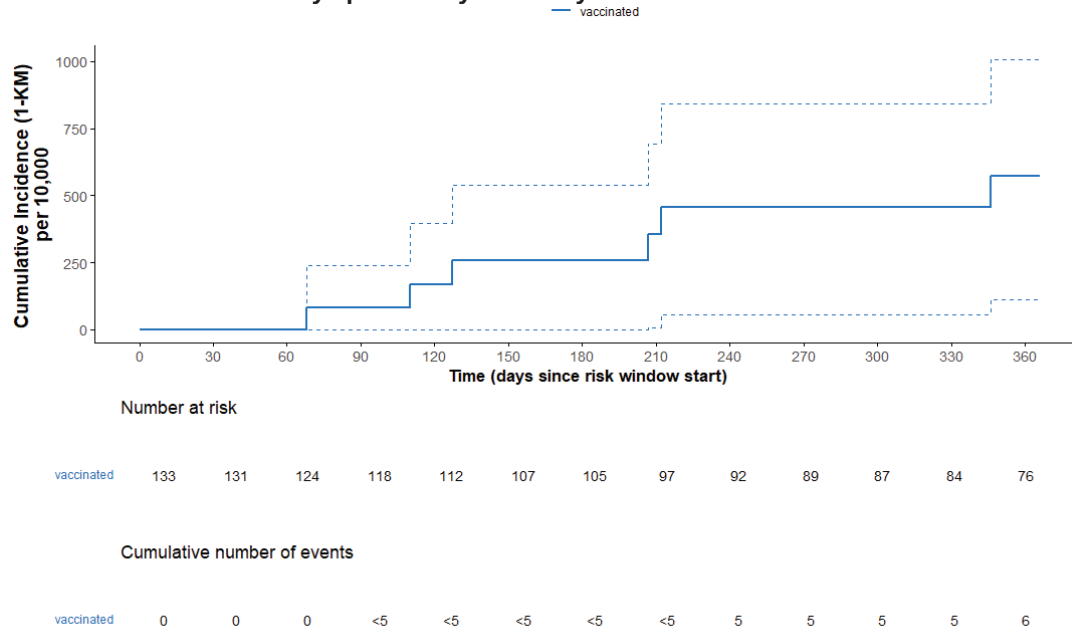
15.2.1.43 PHARMO: Cumulative incidence of heart failure in vaccinated individuals who received one dose of Pfizer-BioNTech COVID-19 vaccine ≥ 15 days previously in the myocarditis cohort



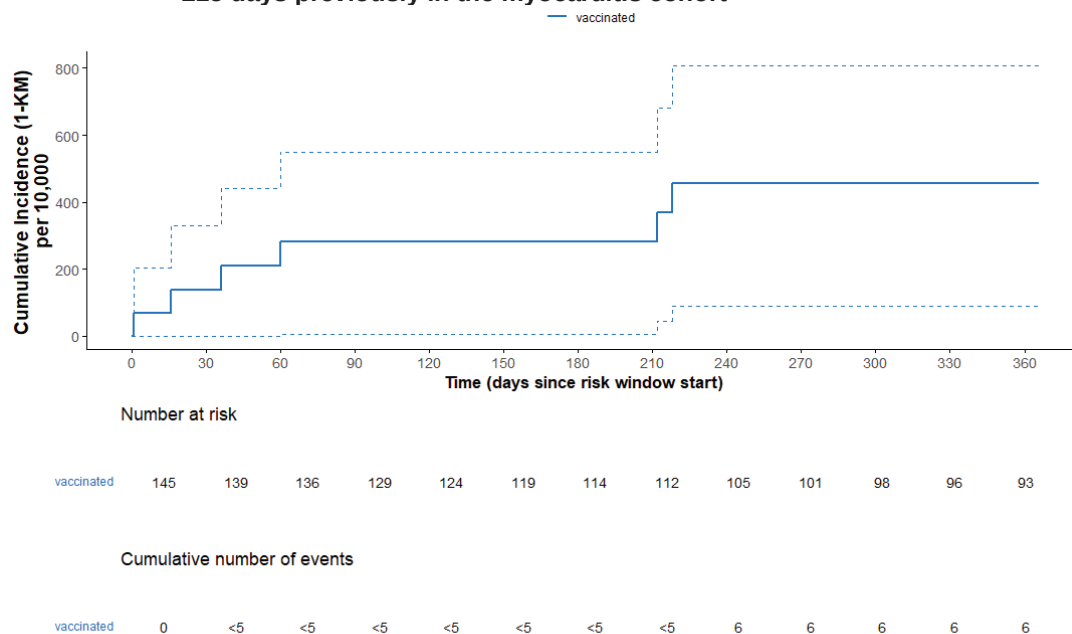
15.2.1.44 PHARMO: Cumulative incidence of recurrent myocarditis in vaccinated individuals who received one dose of Pfizer-BioNTech COVID-19 vaccine ≥ 15 days previously in the myocarditis cohort



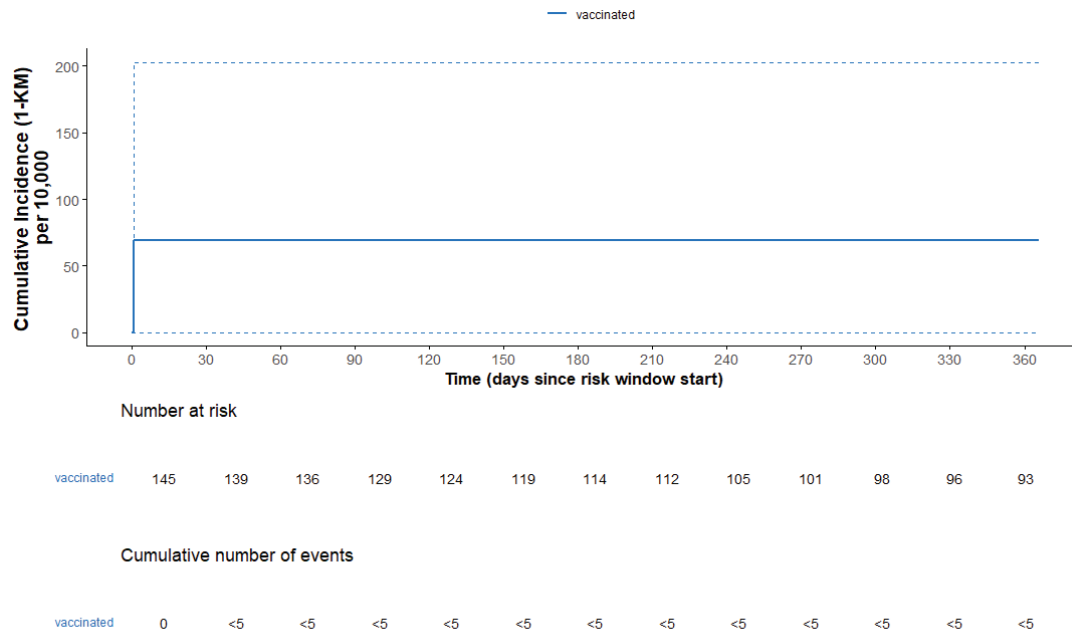
15.2.1.45 PHARMO: Cumulative incidence of arrhythmia in vaccinated individuals who received two doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the myocarditis cohort



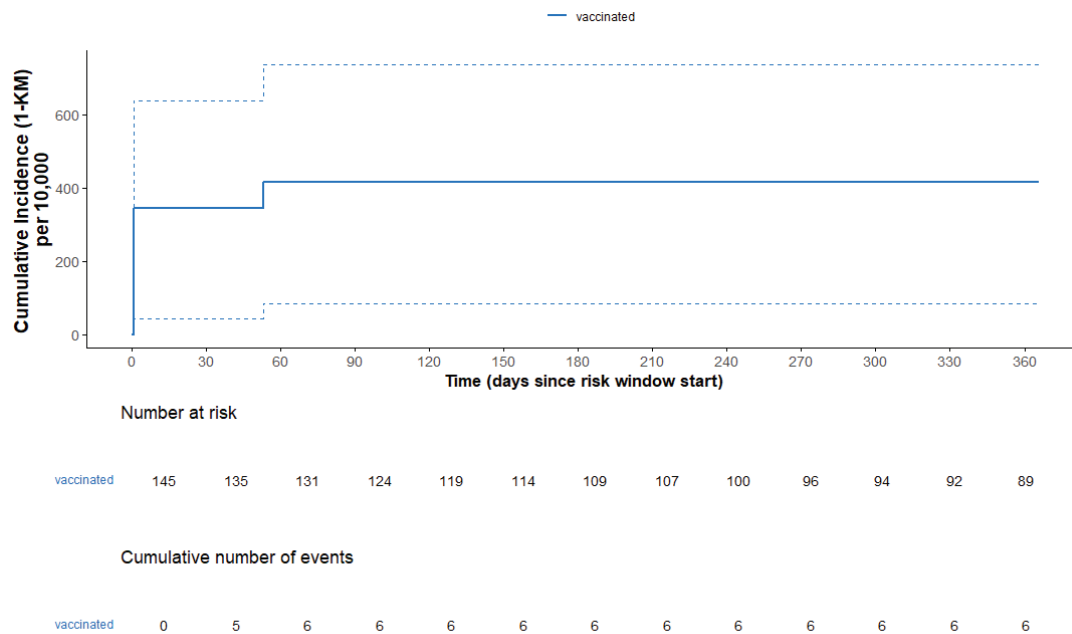
15.2.1.46 PHARMO: Cumulative incidence of death in vaccinated individuals who received two doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the myocarditis cohort



15.2.1.47 PHARMO: Cumulative incidence of fulminant myocarditis in vaccinated individuals who received two doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the myocarditis cohort

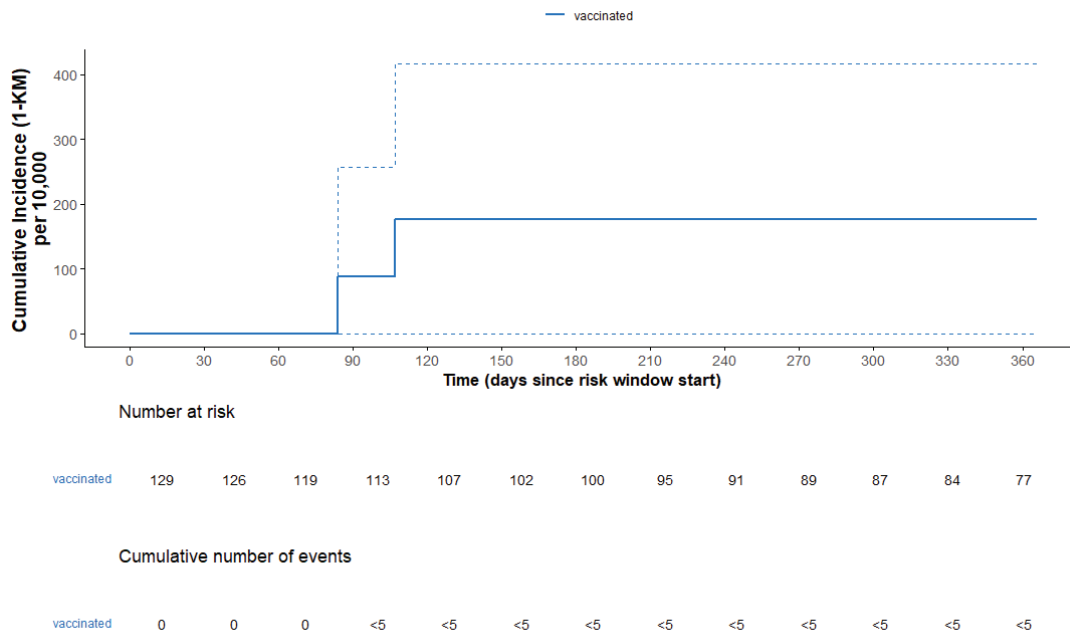


15.2.1.48 PHARMO: Cumulative incidence of heart failure in vaccinated individuals who received two doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the myocarditis cohort

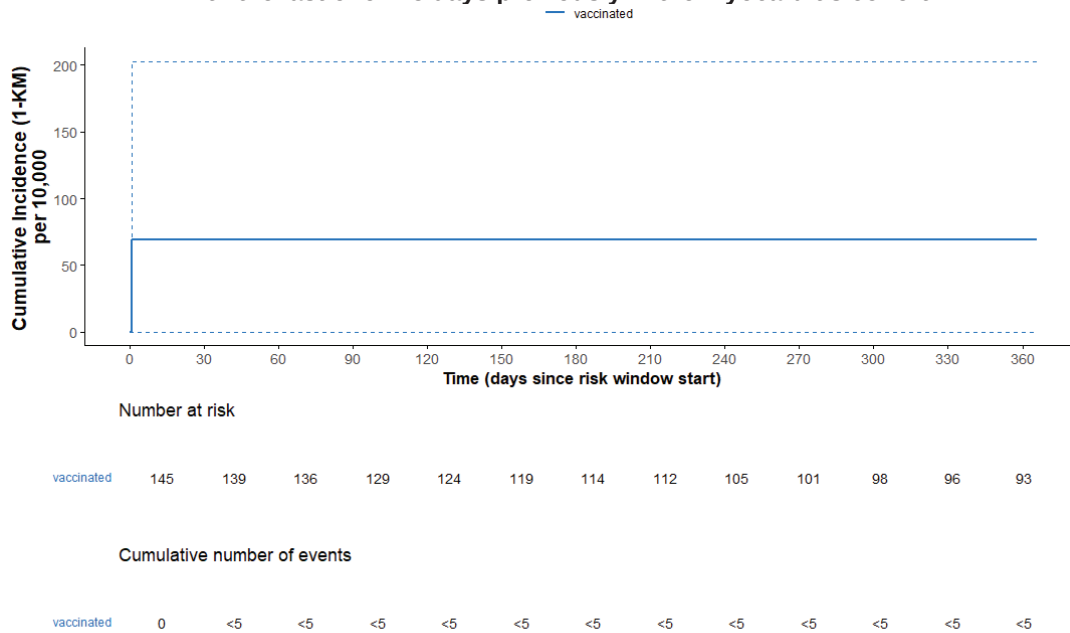


15.2.1.49 PHARMO: Cumulative incidence of recurrent myocarditis in vaccinated individuals who received two doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the myocarditis cohort

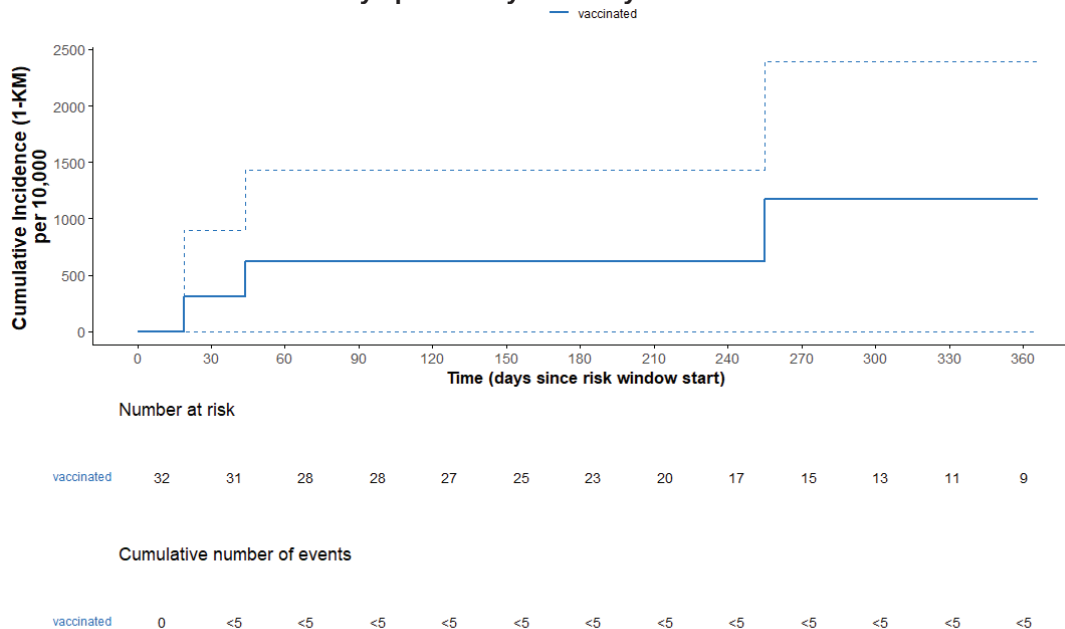
Myocarditis - Recurrent Myocarditis - Time Since Pfizer Vaccination: Received 2 doses, the last one 15 or more days ago



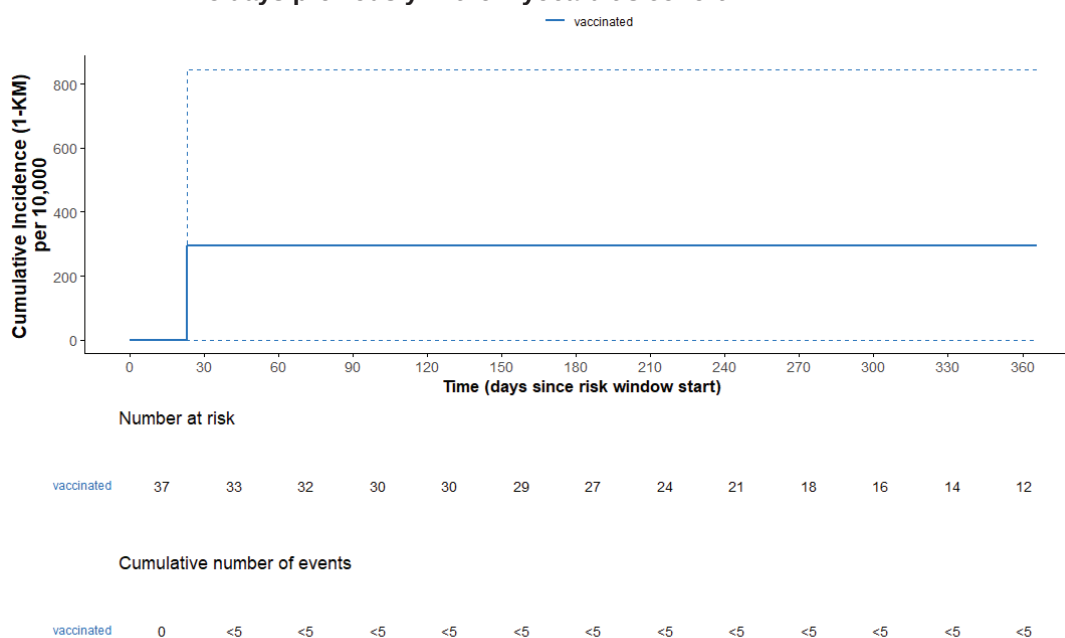
15.2.1.50 PHARMO: Cumulative incidence of cardiogenic shock in vaccinated individuals who received two doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the myocarditis cohort



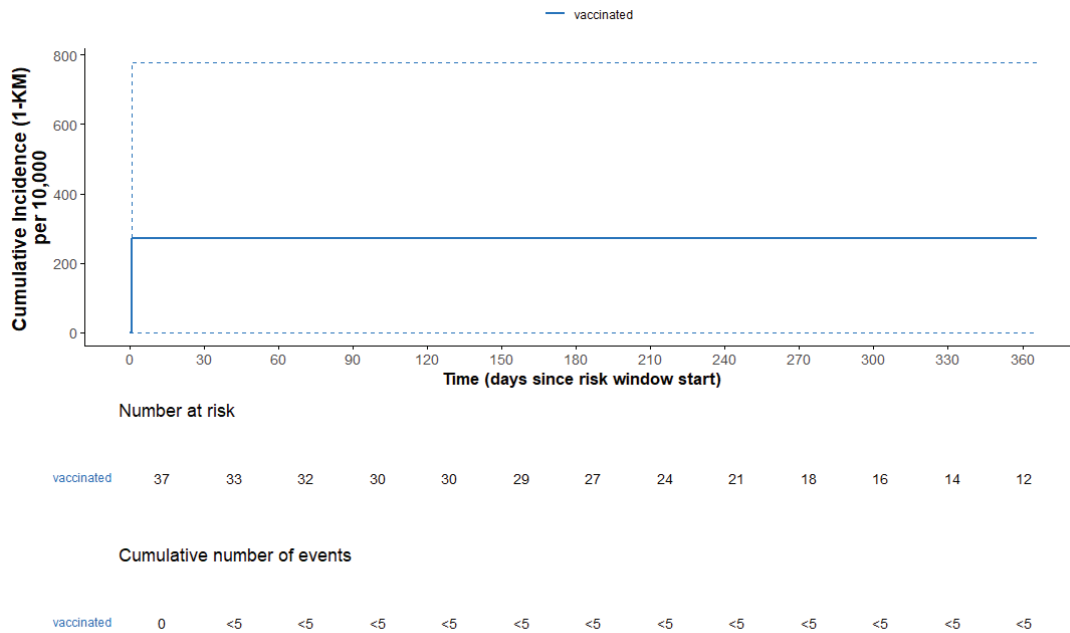
15.2.1.51 PHARMO: Cumulative incidence of arrhythmia in vaccinated individuals who received three doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the myocarditis cohort



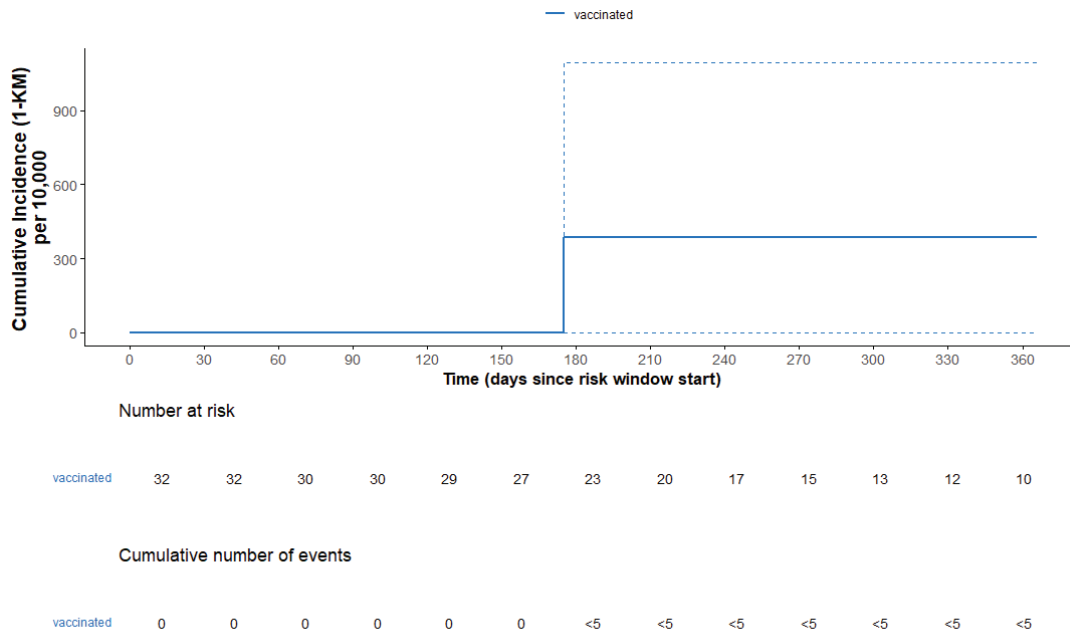
15.2.1.52 PHARMO: Cumulative incidence of death in vaccinated individuals who received three doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the myocarditis cohort



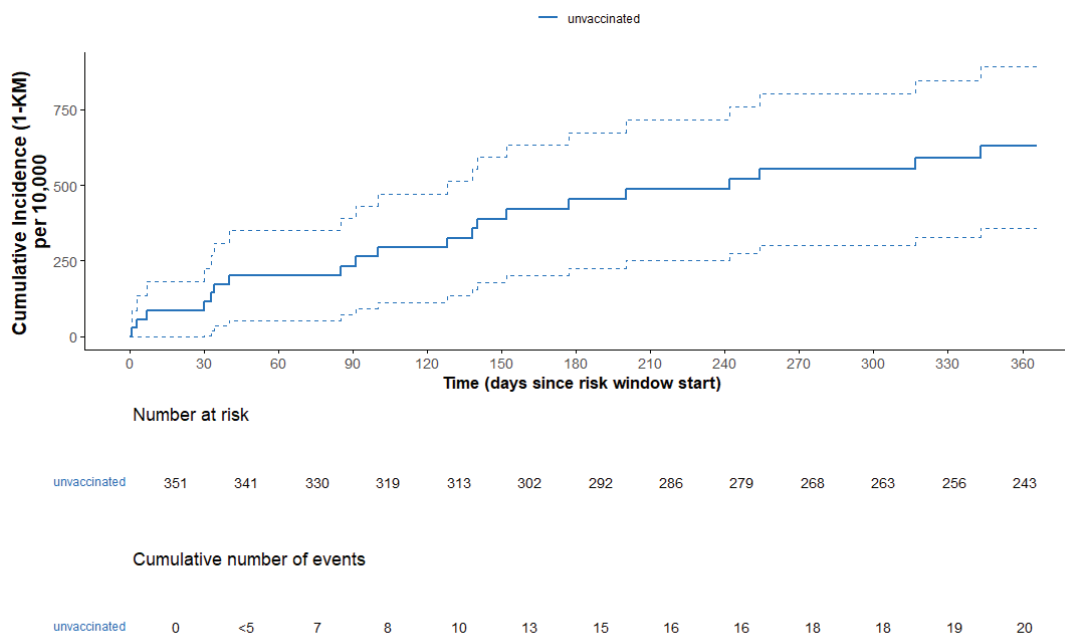
15.2.1.53 PHARMO: Cumulative incidence of fulminant myocarditis in vaccinated individuals who received three doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the myocarditis cohort



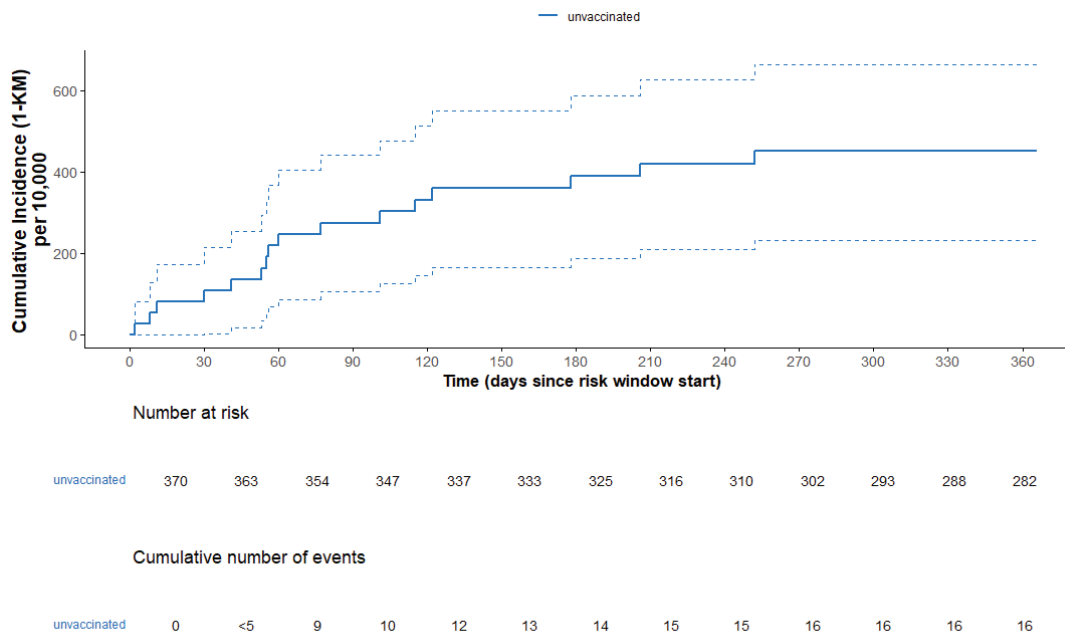
15.2.1.54 PHARMO: Cumulative incidence of recurrent myocarditis in vaccinated individuals who received three doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the myocarditis cohort



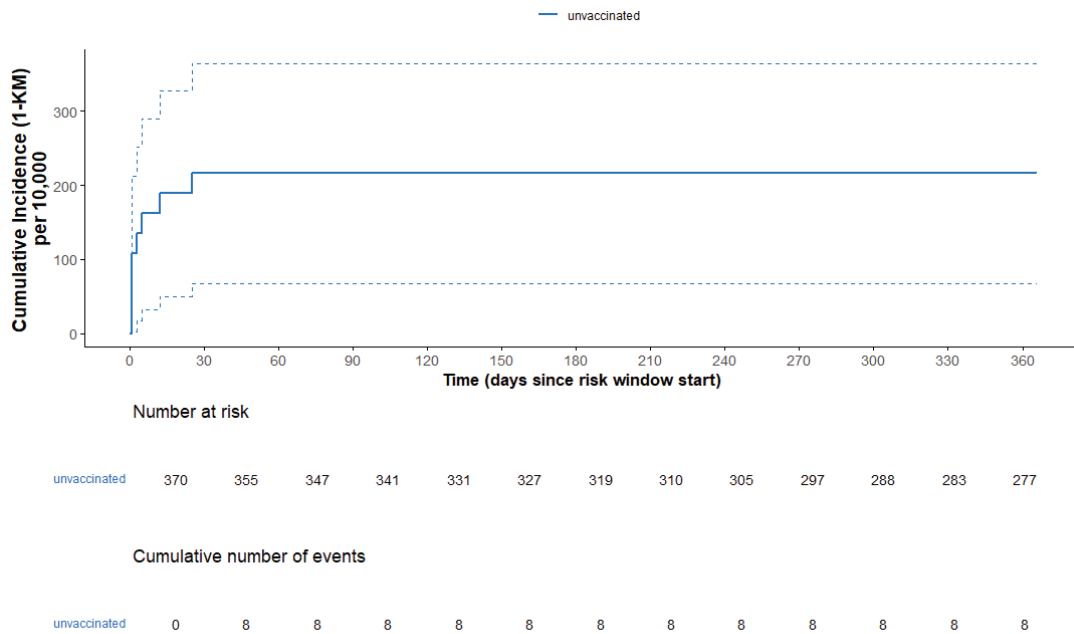
15.2.1.55 PHARMO: Cumulative incidence of arrhythmia in unvaccinated individuals in the myocarditis cohort



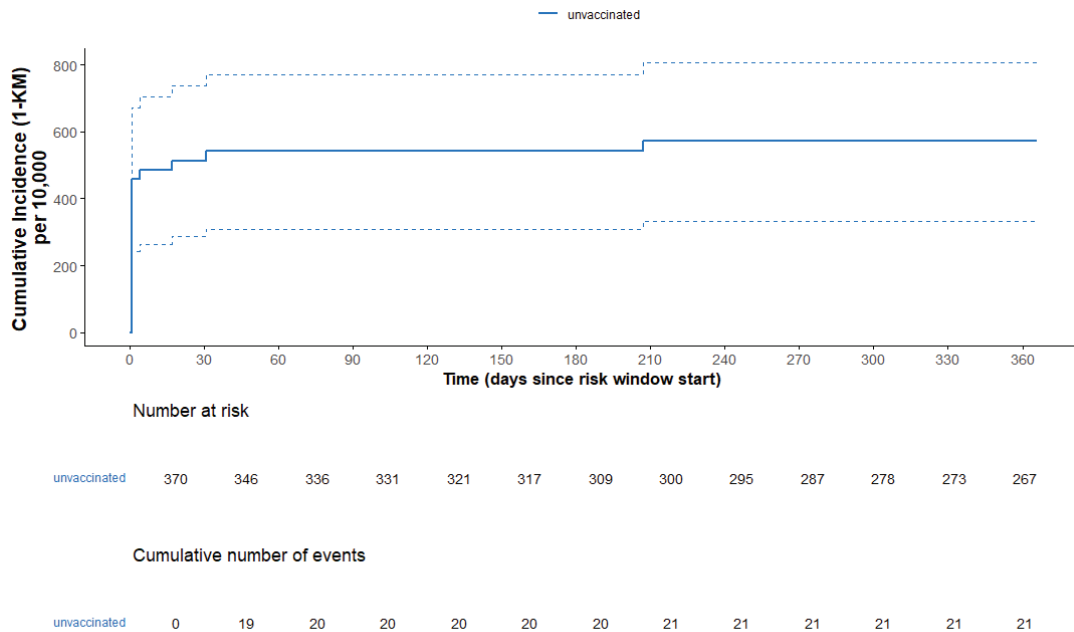
15.2.1.56 PHARMO: Cumulative incidence of death in unvaccinated individuals in the myocarditis cohort



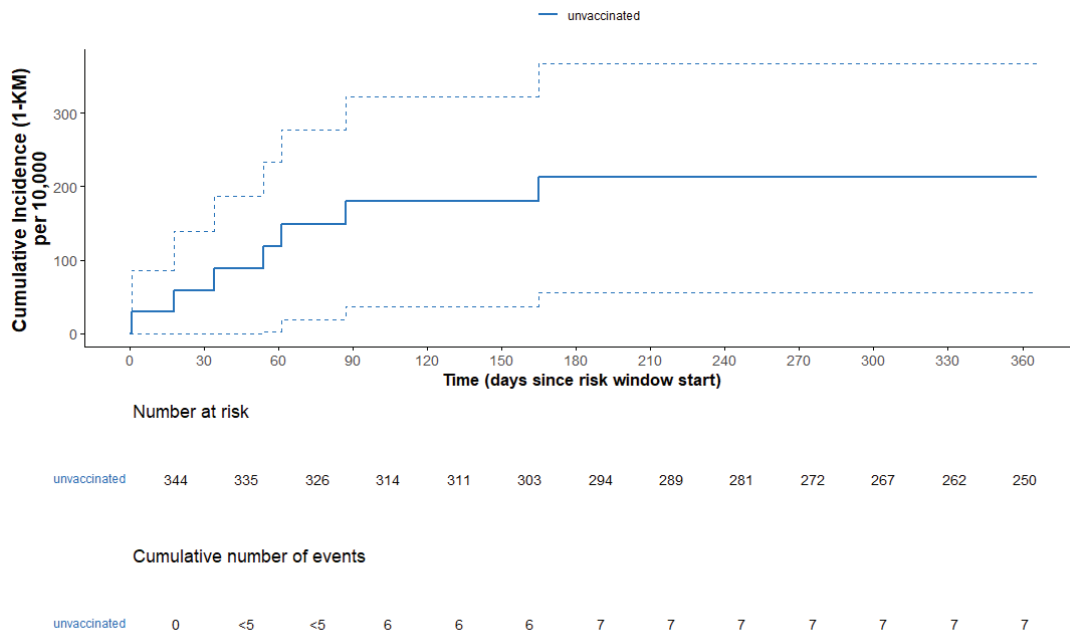
15.2.1.57 PHARMO: Cumulative incidence of fulminant myocarditis in unvaccinated individuals in the myocarditis cohort



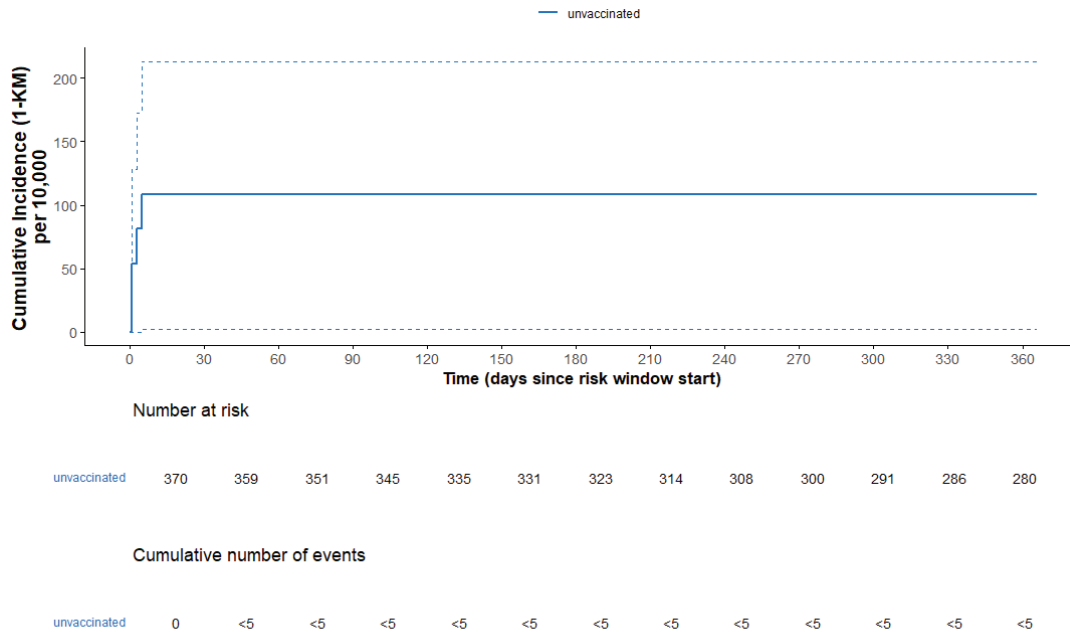
15.2.1.58 PHARMO: Cumulative incidence of heart failure in unvaccinated individuals in the myocarditis cohort



15.2.1.59 PHARMO: Cumulative incidence of recurrent myocarditis in unvaccinated individuals in the myocarditis cohort



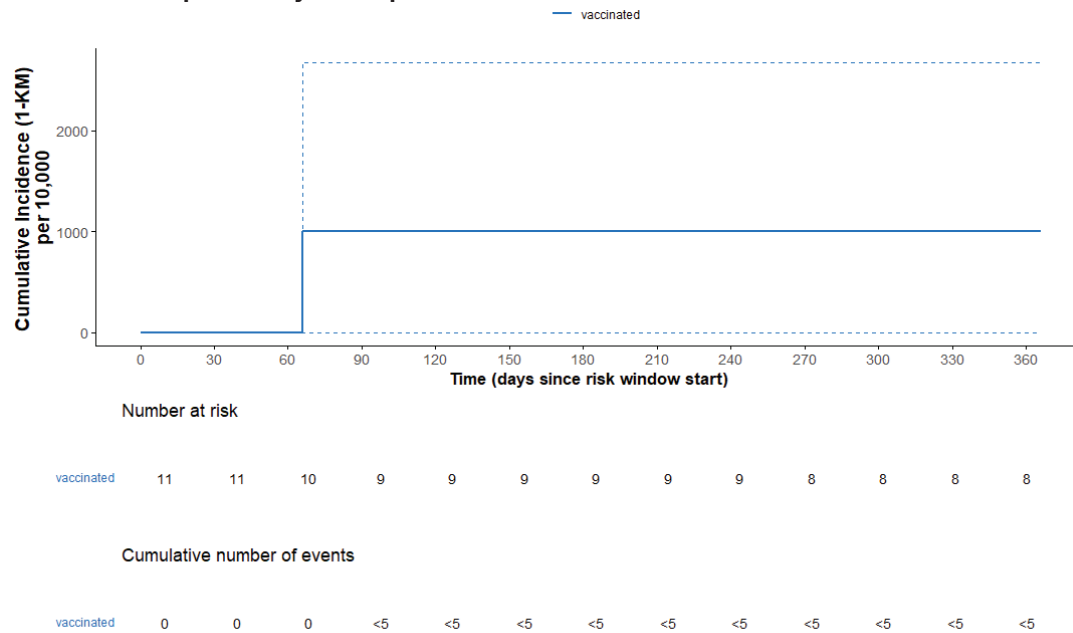
15.2.1.60 PHARMO: Cumulative incidence of cardiogenic shock in unvaccinated individuals in the myocarditis cohort



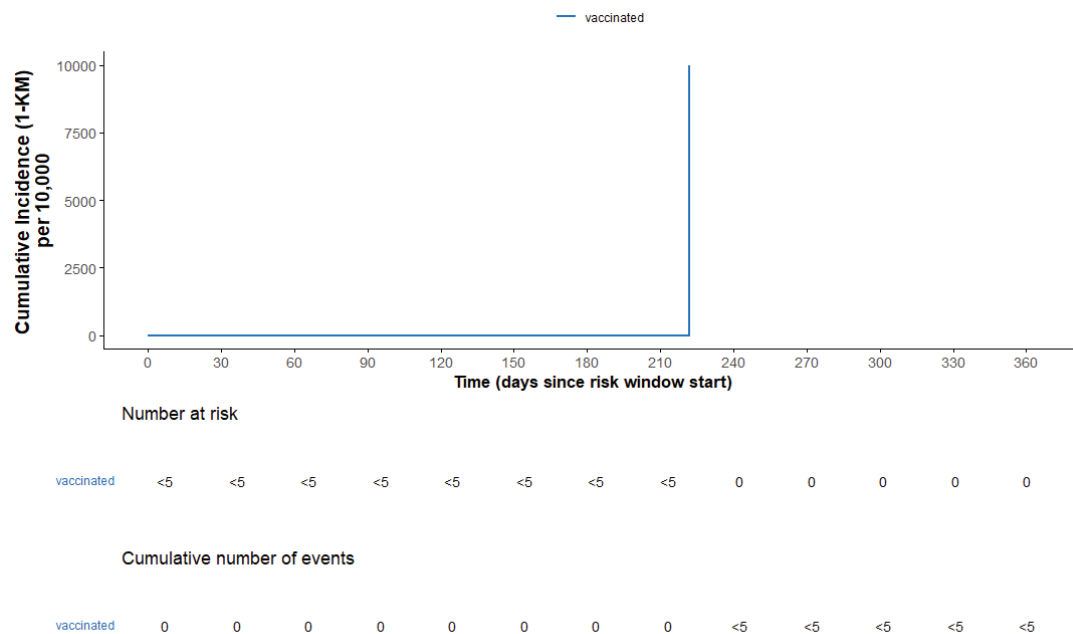
15.2.2 PHARMO pericarditis cohort

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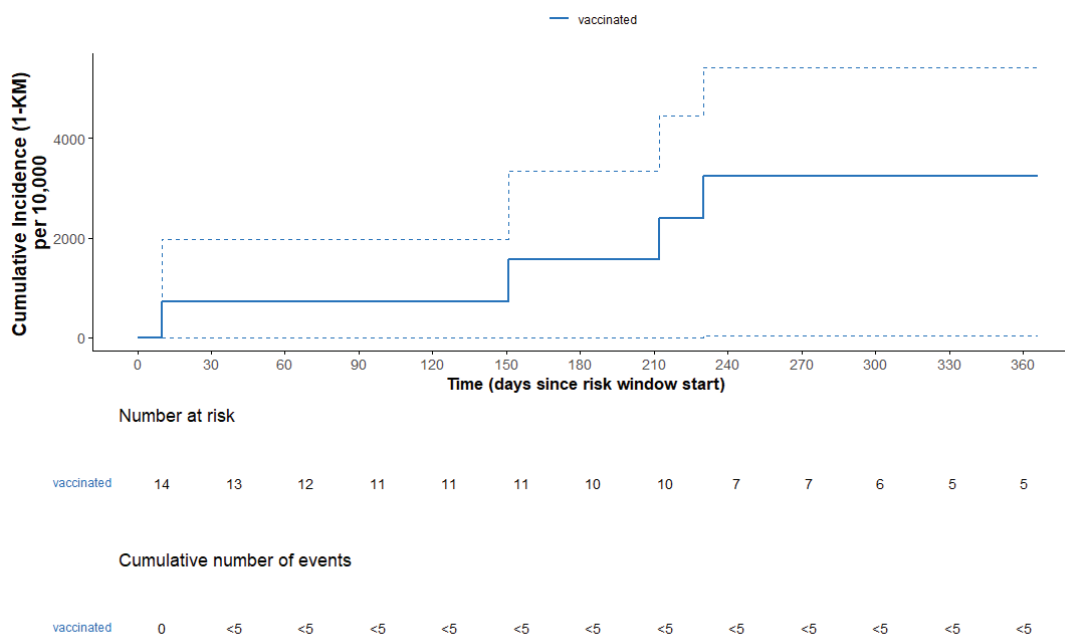
15.2.2.1 PHARMO: Cumulative incidence of recurrent pericarditis in individuals who received one dose of Pfizer-BioNTech COVID-19 vaccine ≥ 15 days previously in the pericarditis cohort



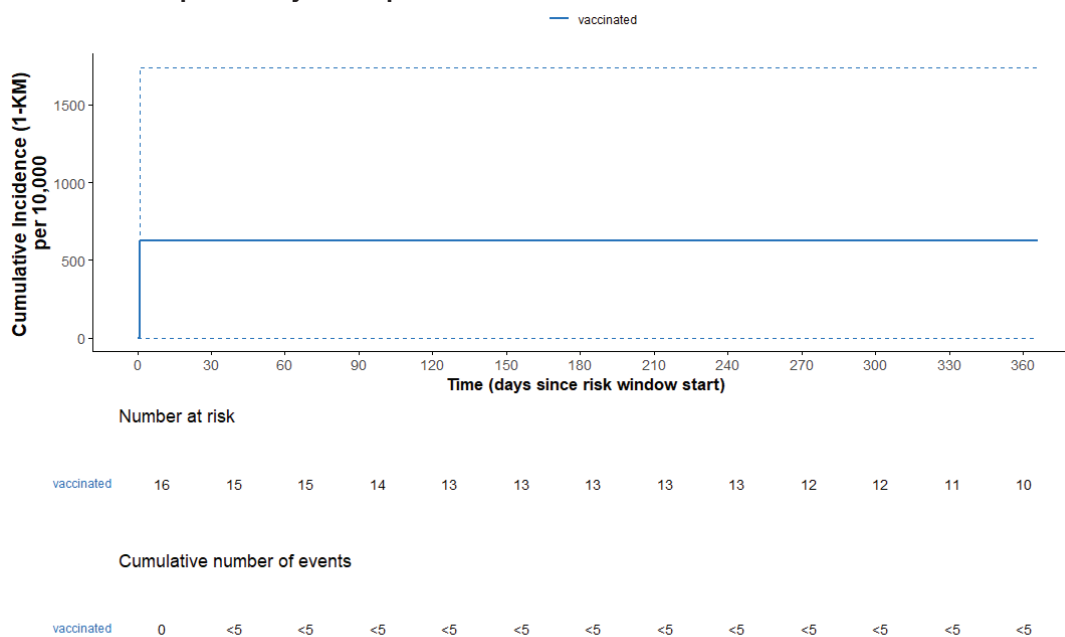
15.2.2.2 PHARMO: Cumulative incidence of recurrent pericarditis in individuals who received two doses of Pfizer-BioNTech COVID-19 vaccine with the last one within 14 days in the pericarditis cohort



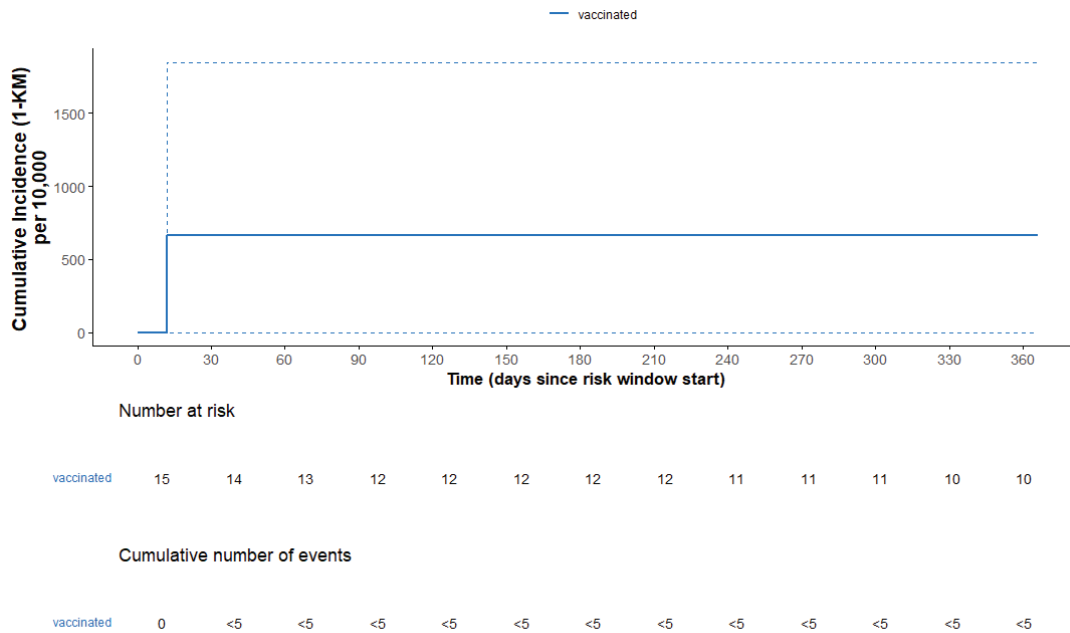
15.2.2.3 PHARMO: Cumulative incidence of arrhythmia in individuals who received two doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the pericarditis cohort



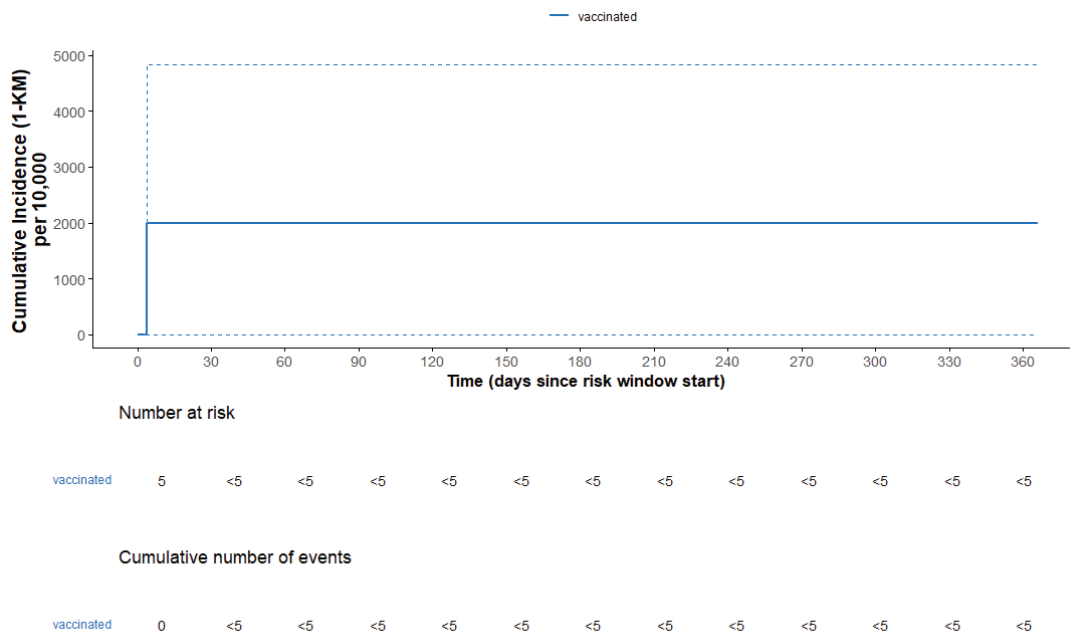
15.2.2.4 PHARMO: Cumulative incidence of heart failure in individuals who received two doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the pericarditis cohort

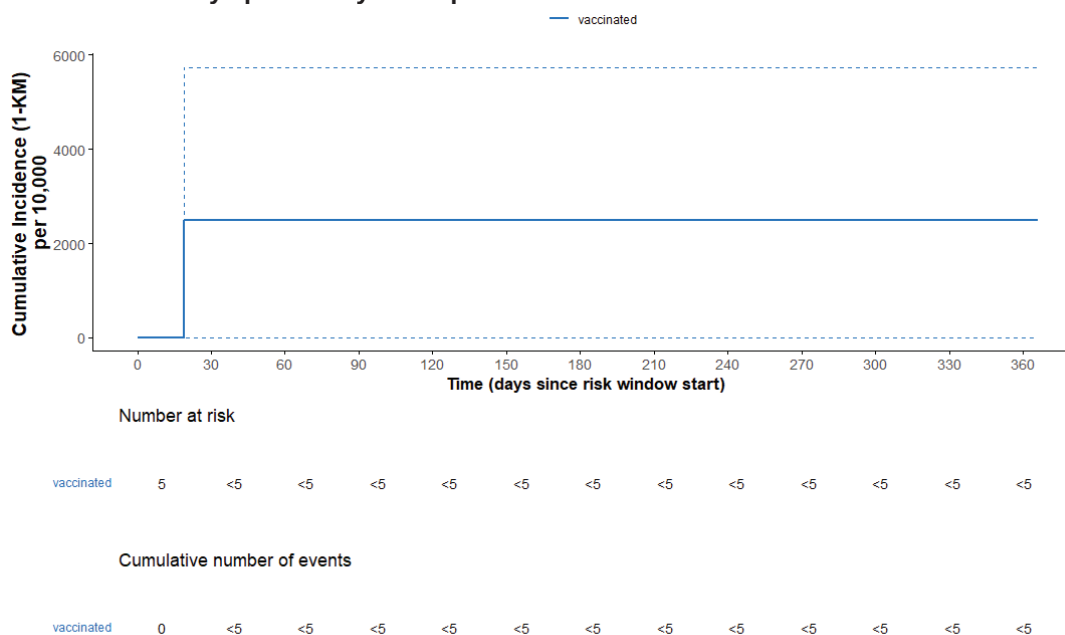
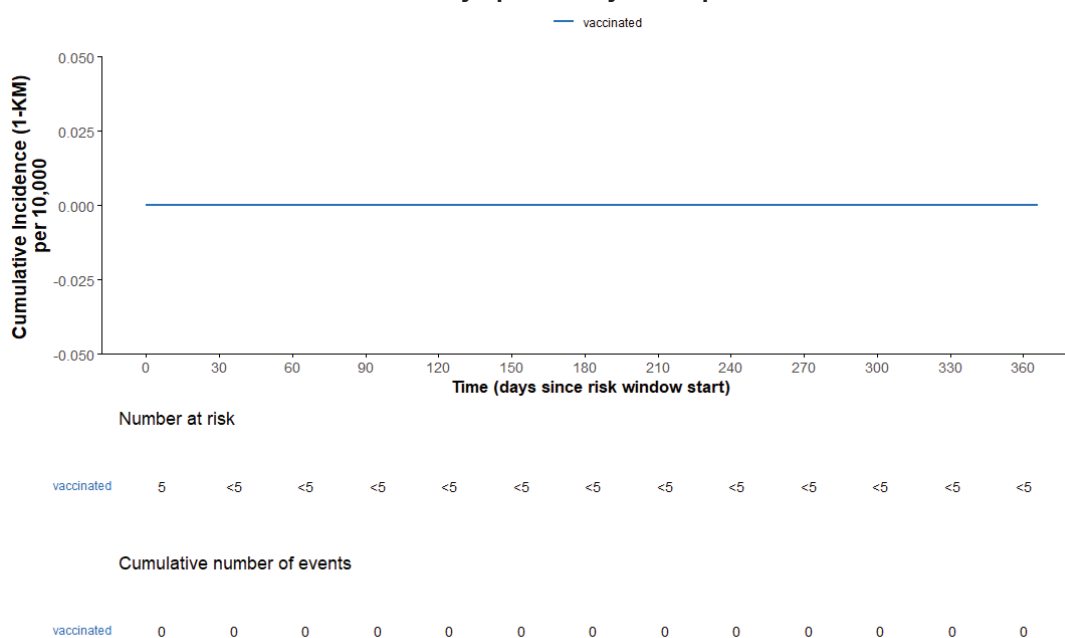


15.2.2.5 PHARMO: Cumulative incidence of recurrent pericarditis in individuals who received two doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the pericarditis cohort

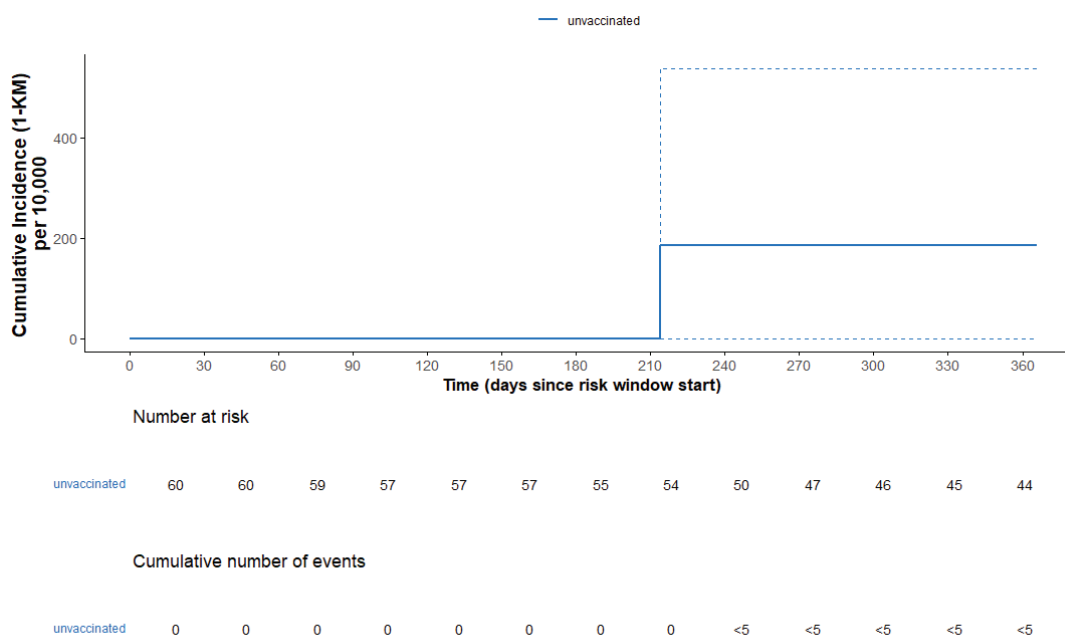


15.2.2.6 PHARMO: Cumulative incidence of death in individuals who received two doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the pericarditis cohort

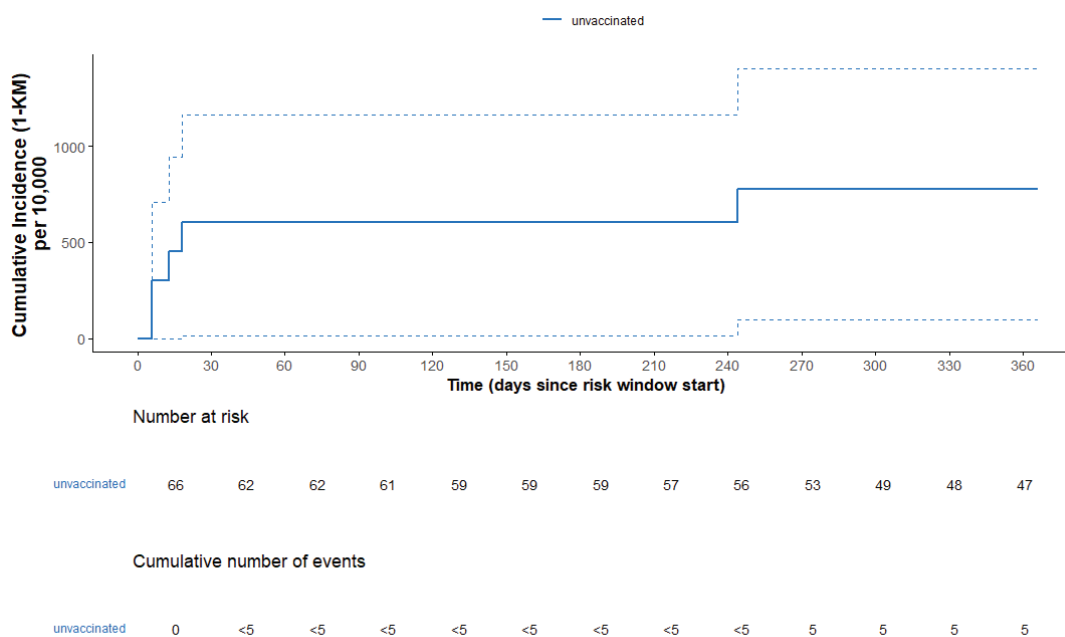


15.2.2.7 PHARMO: Cumulative incidence of heart failure in individuals who received three doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the pericarditis cohort**15.2.2.8 PHARMO: Cumulative incidence of the number of hospitalisations in individuals who received three doses of Pfizer-BioNTech COVID-19 vaccine with the last one ≥ 15 days previously in the pericarditis cohort**

15.2.2.9 PHARMO: Cumulative incidence of arrhythmia in unvaccinated individuals in the pericarditis cohort

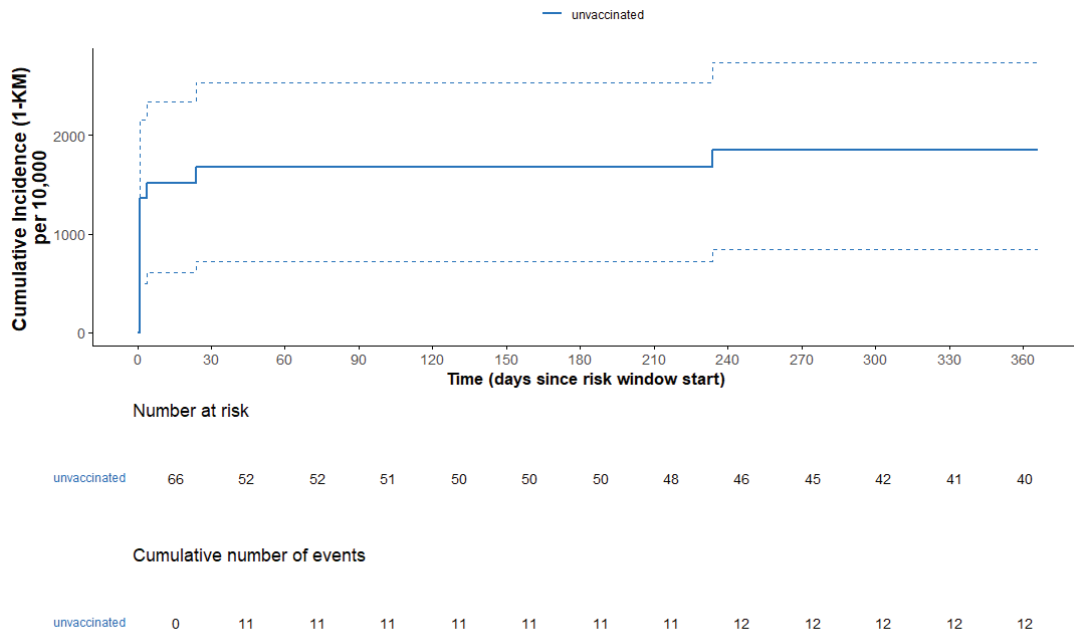


15.2.2.10 PHARMO: Cumulative incidence of death in unvaccinated individuals in the pericarditis cohort

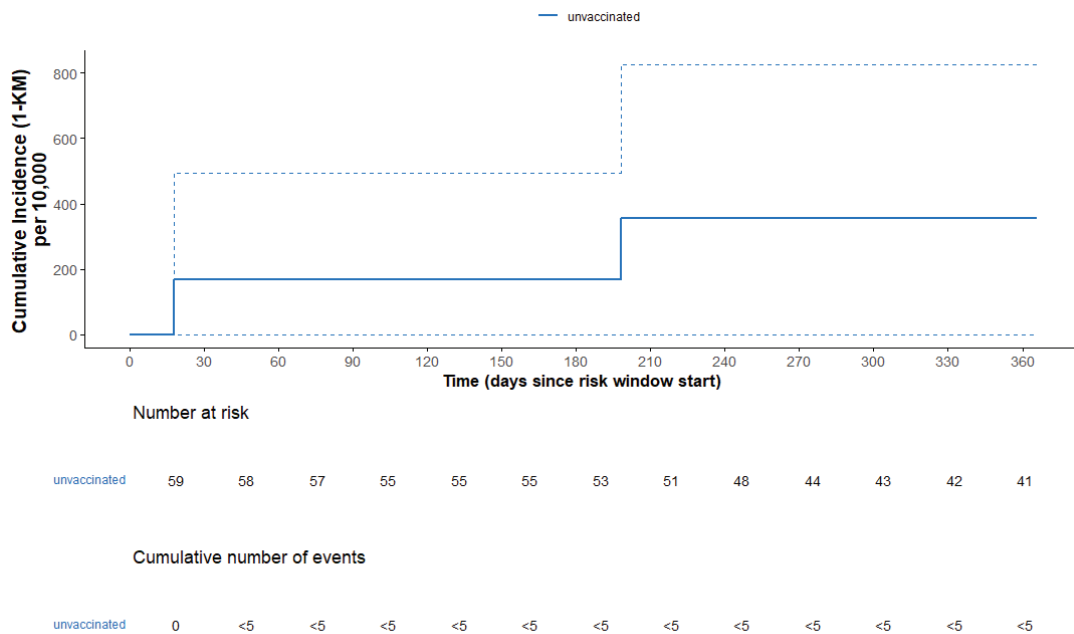


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15.2.2.11 PHARMO: Cumulative incidence of heart failure in unvaccinated individuals in the pericarditis cohort

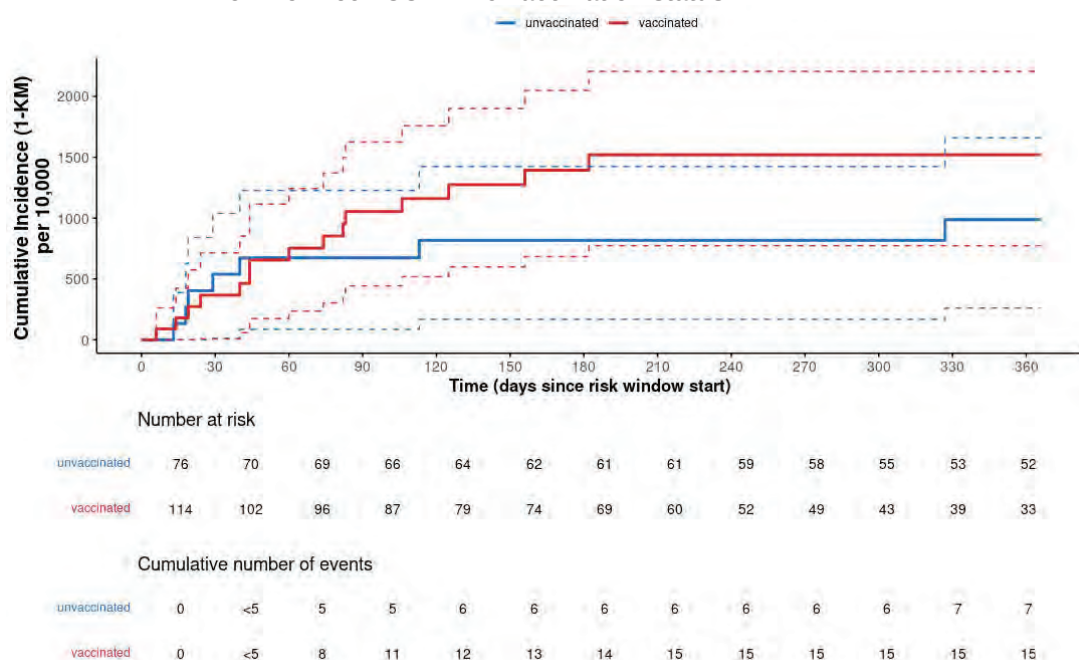


15.2.2.12 PHARMO: Cumulative incidence of recurrent pericarditis in unvaccinated individuals in the pericarditis cohort

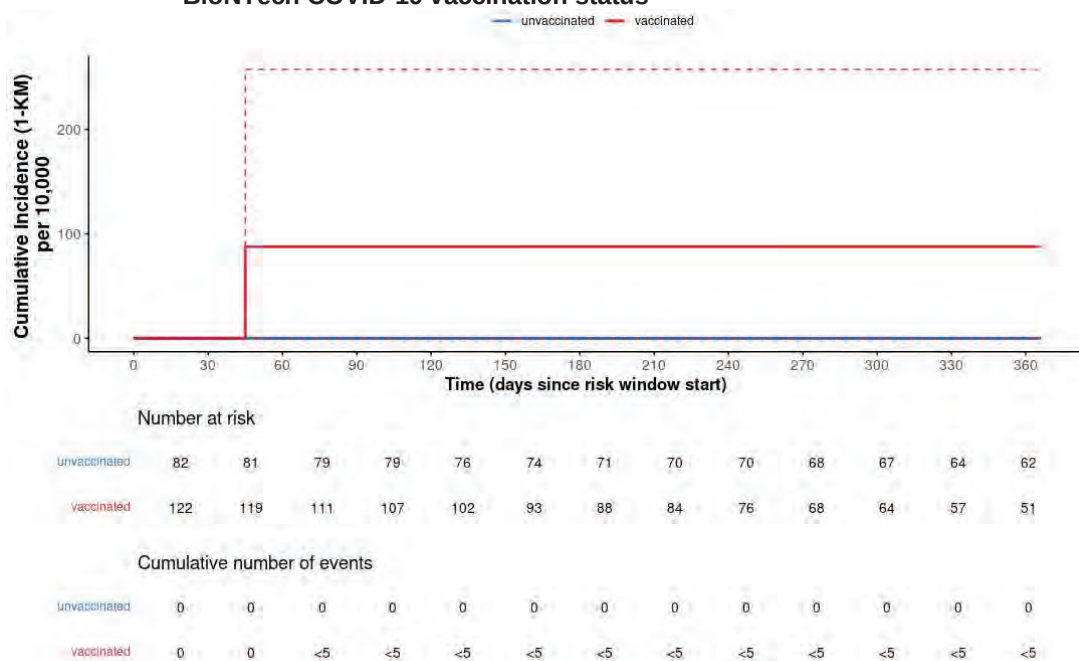


15.2.3 NHR myocarditis cohort

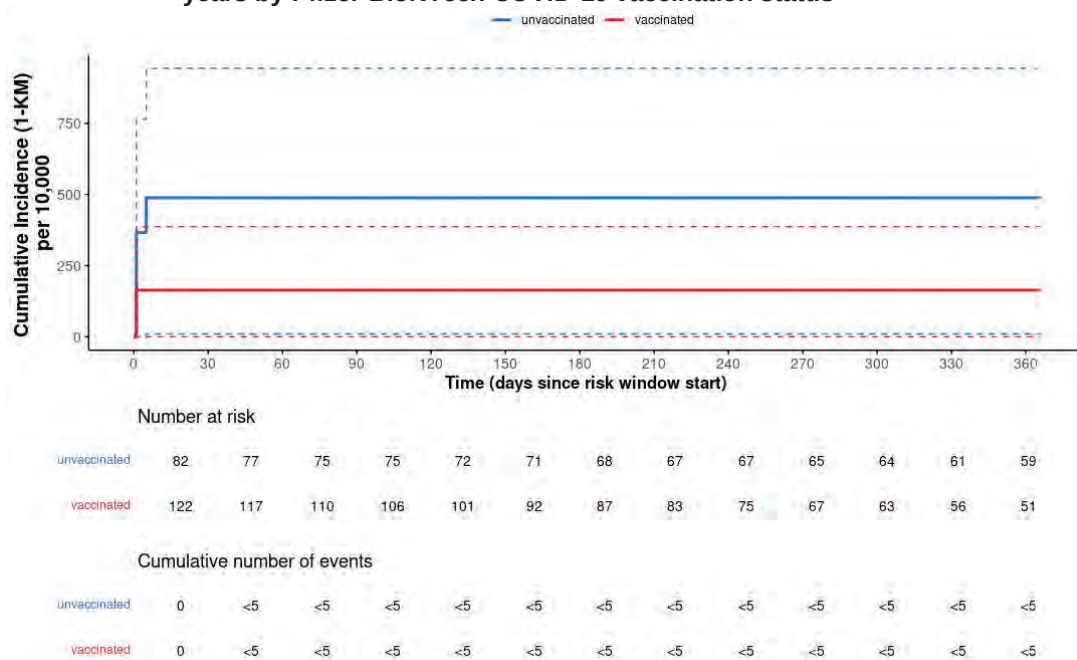
15.2.3.1 NHR: Cumulative incidence of arrhythmia in individuals aged 15–years by Pfizer-BioNTech COVID-19 vaccination status



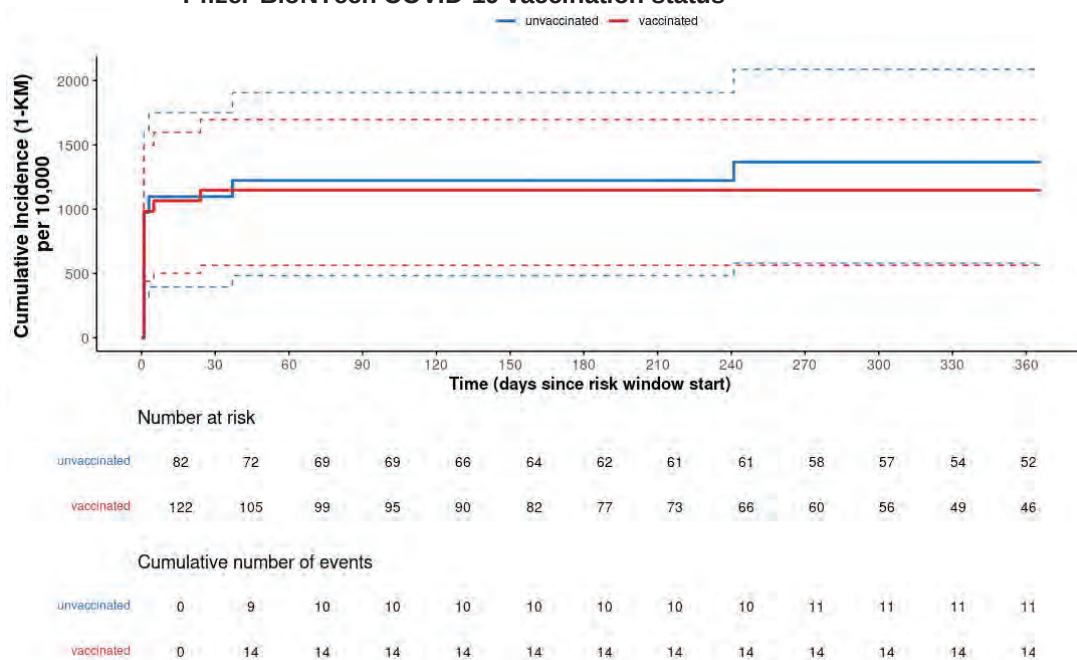
15.2.3.2 NHR: Cumulative incidence of death in individuals aged 15–years by Pfizer-BioNTech COVID-19 vaccination status



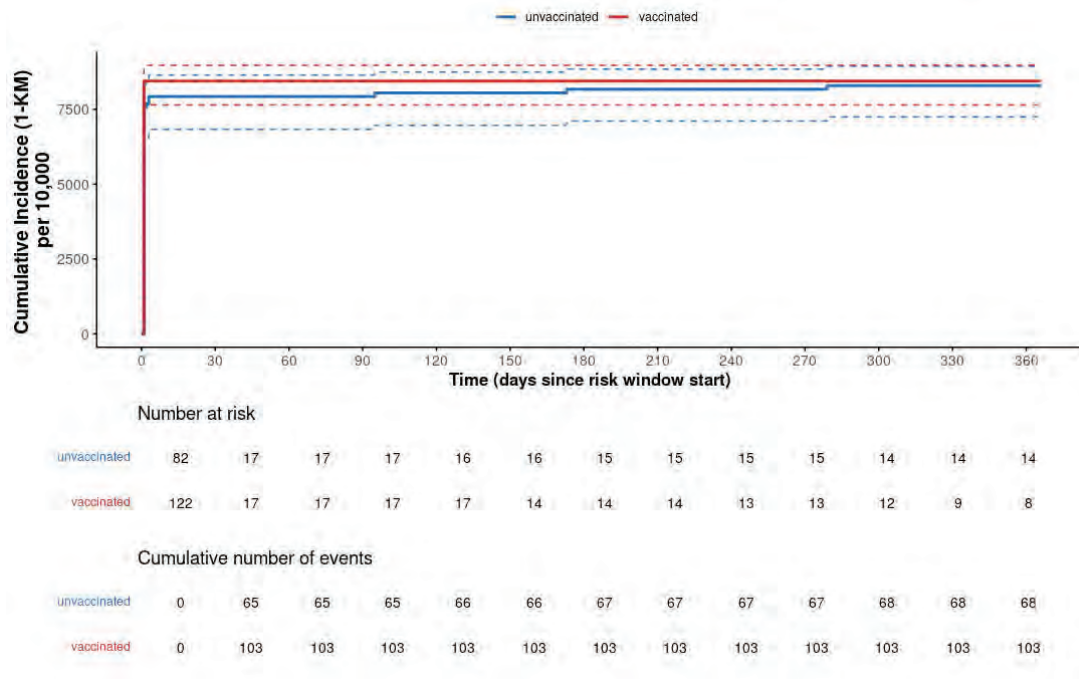
15.2.3.3 NHR: Cumulative incidence of fulminant myocarditis in individuals aged 15–years by Pfizer-BioNTech COVID-19 vaccination status



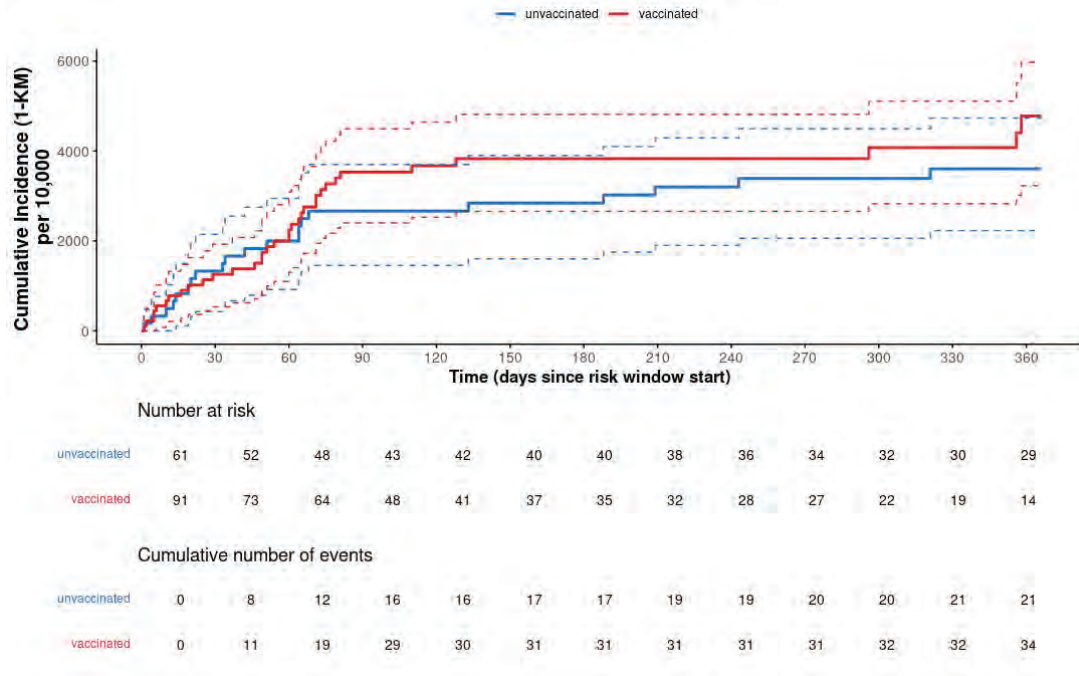
15.2.3.4 NHR: Cumulative incidence of heart failure in individuals aged 15–years by Pfizer-BioNTech COVID-19 vaccination status



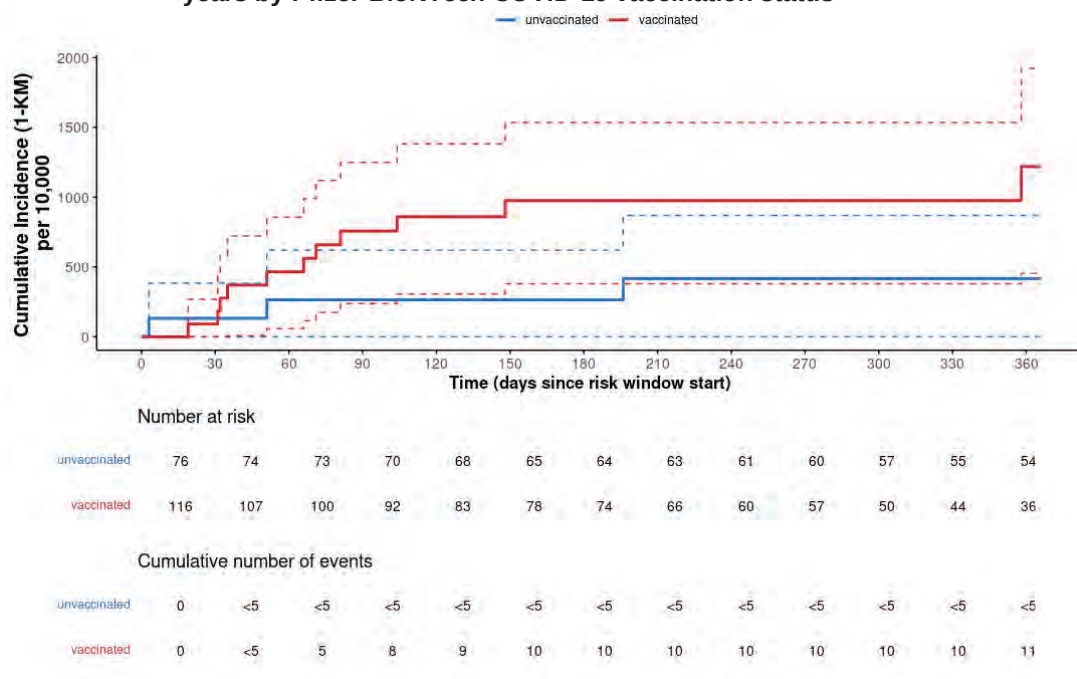
15.2.3.5 NHR: Cumulative incidence of the number of hospitalisations in individuals aged 15–years by Pfizer-BioNTech COVID-19 vaccination status



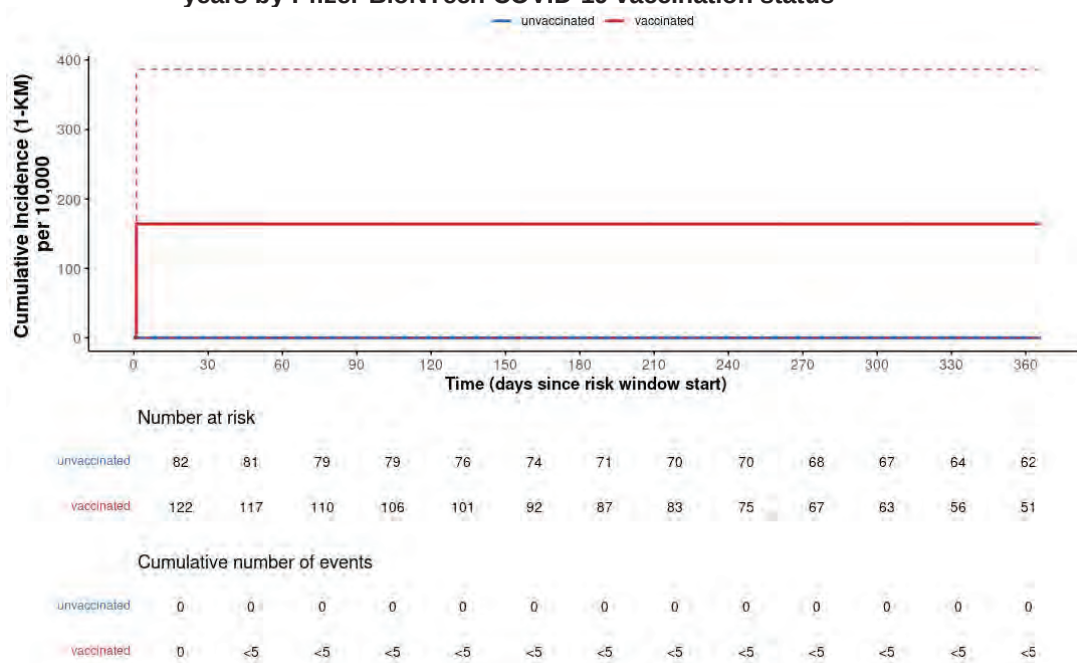
15.2.3.6 NHR: Cumulative incidence of recurrent myocarditis in individuals aged 15–years by Pfizer-BioNTech COVID-19 vaccination status

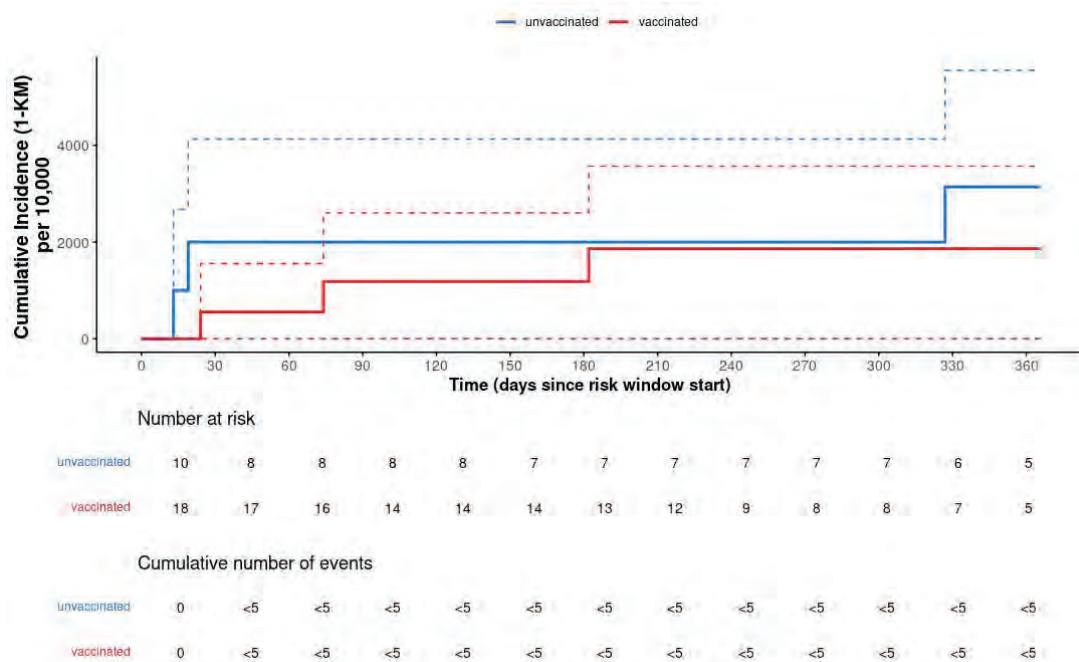
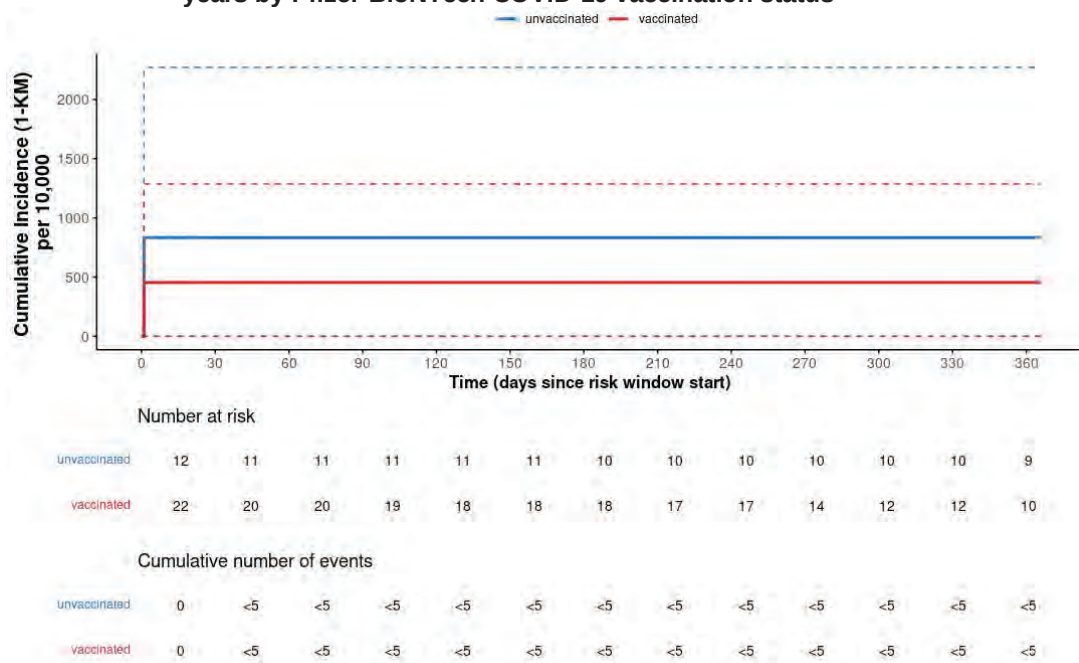


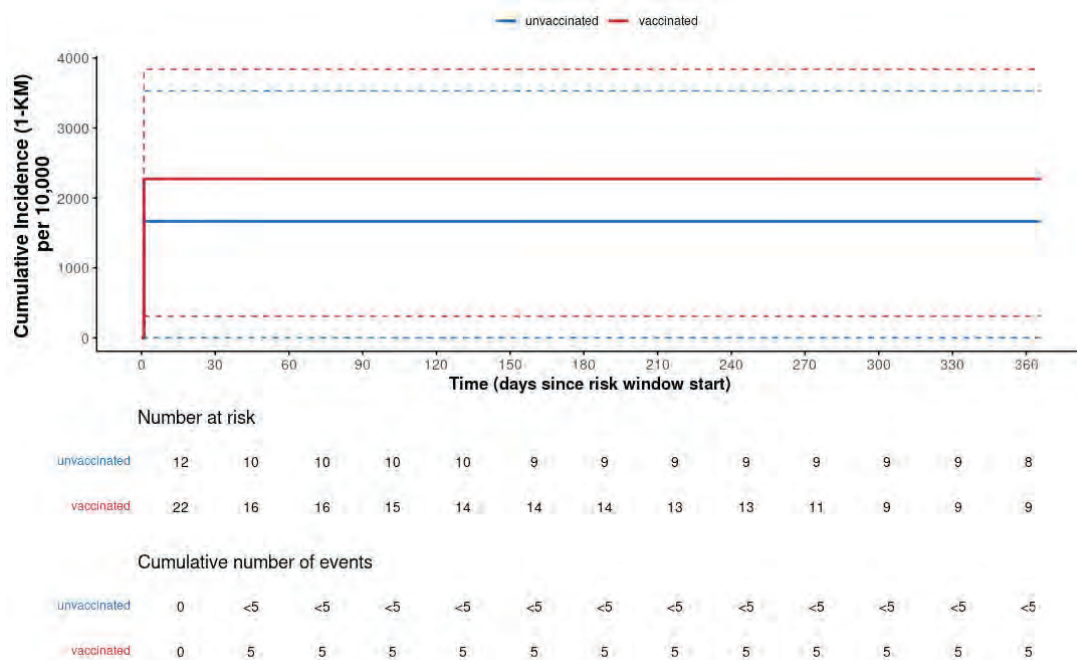
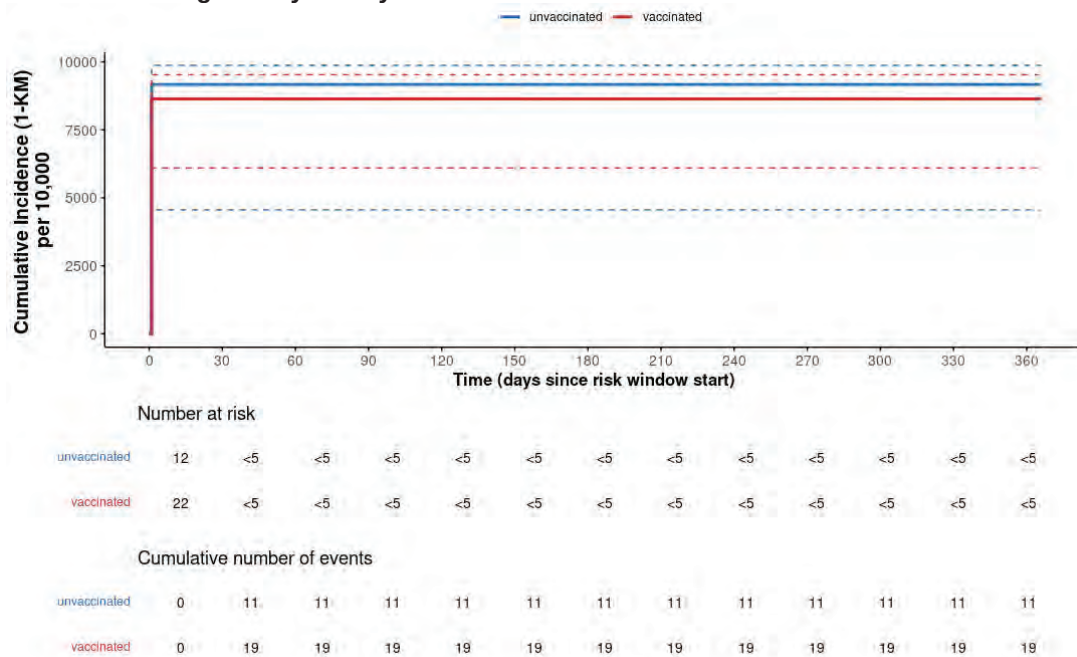
15.2.3.7 NHR: Cumulative incidence of recurrent pericarditis in individuals aged 15–years by Pfizer-BioNTech COVID-19 vaccination status

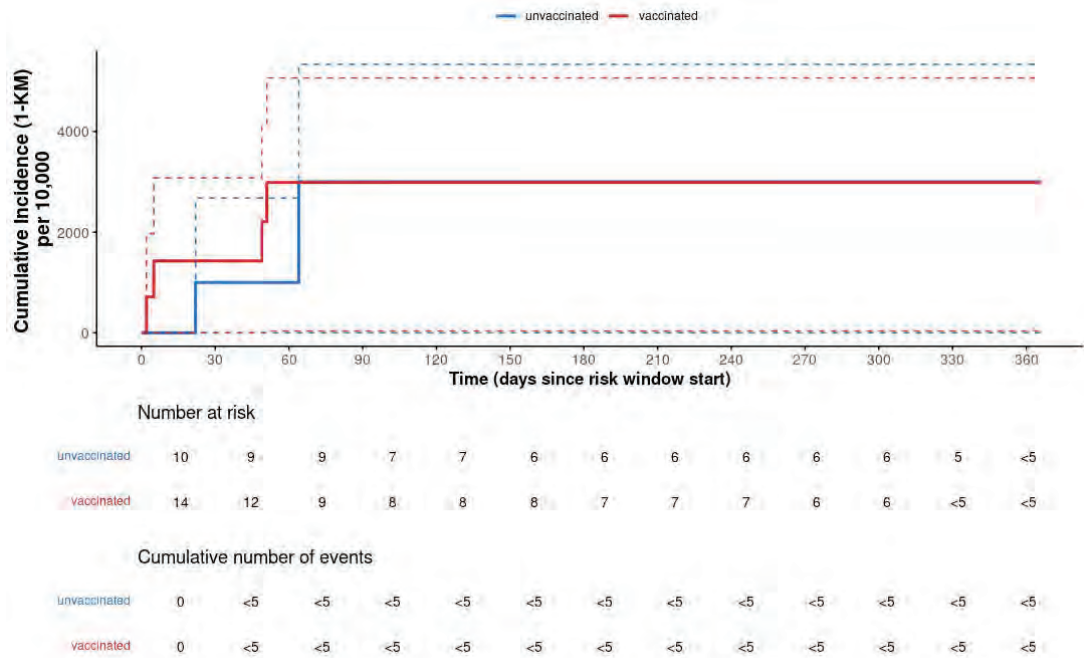
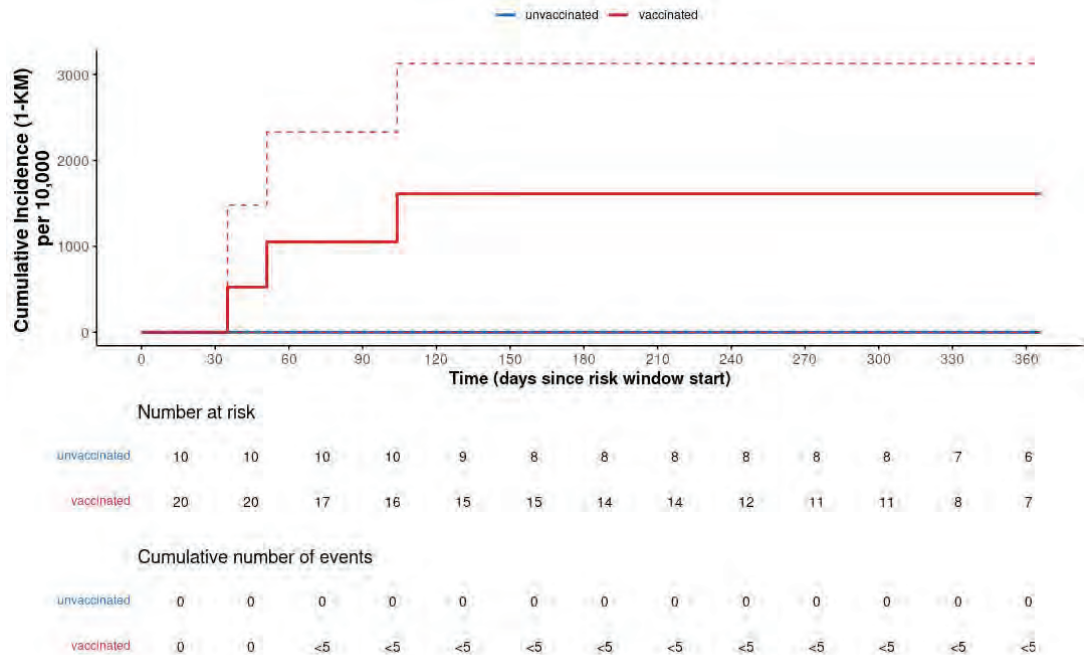


15.2.3.8 NHR: Cumulative incidence of cardiogenic shock in individuals aged 15–years by Pfizer-BioNTech COVID-19 vaccination status

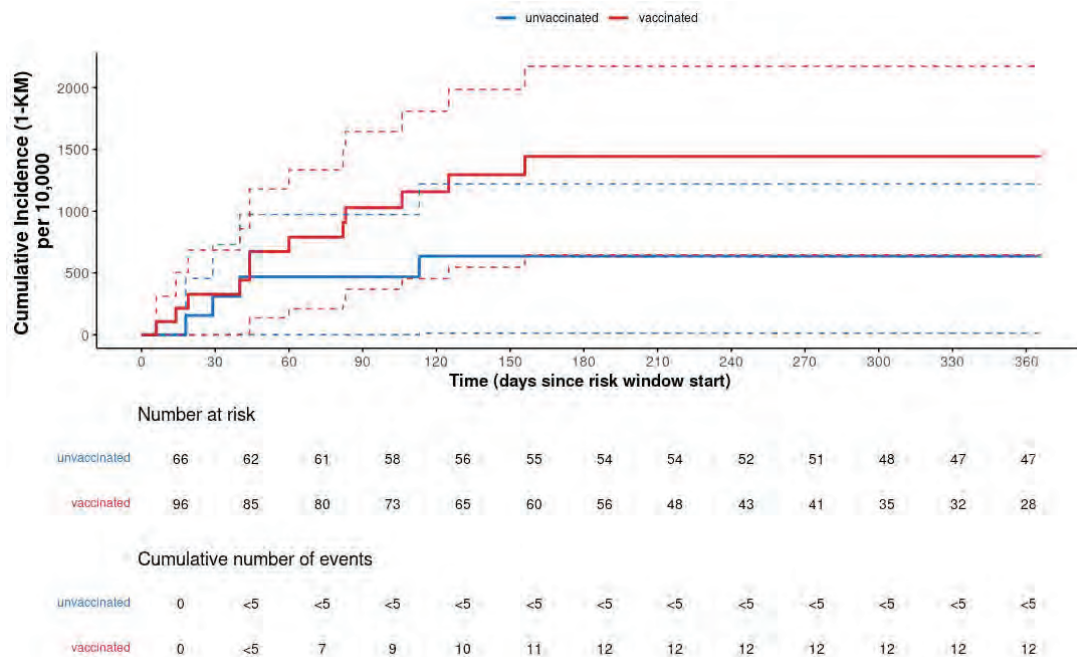


15.2.3.9 NHR: Cumulative incidence of arrhythmia in females aged 15–years by Pfizer-BioNTech COVID-19 vaccination status**15.2.3.10 NHR: Cumulative incidence of fulminant myocarditis in females aged 15–years by Pfizer-BioNTech COVID-19 vaccination status**

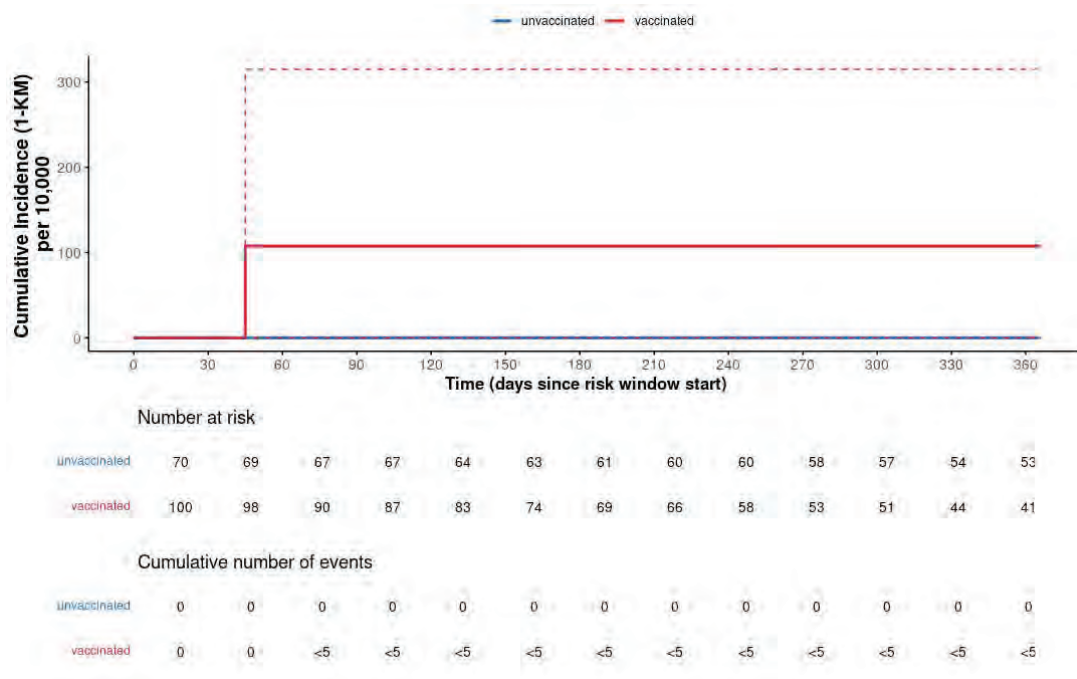
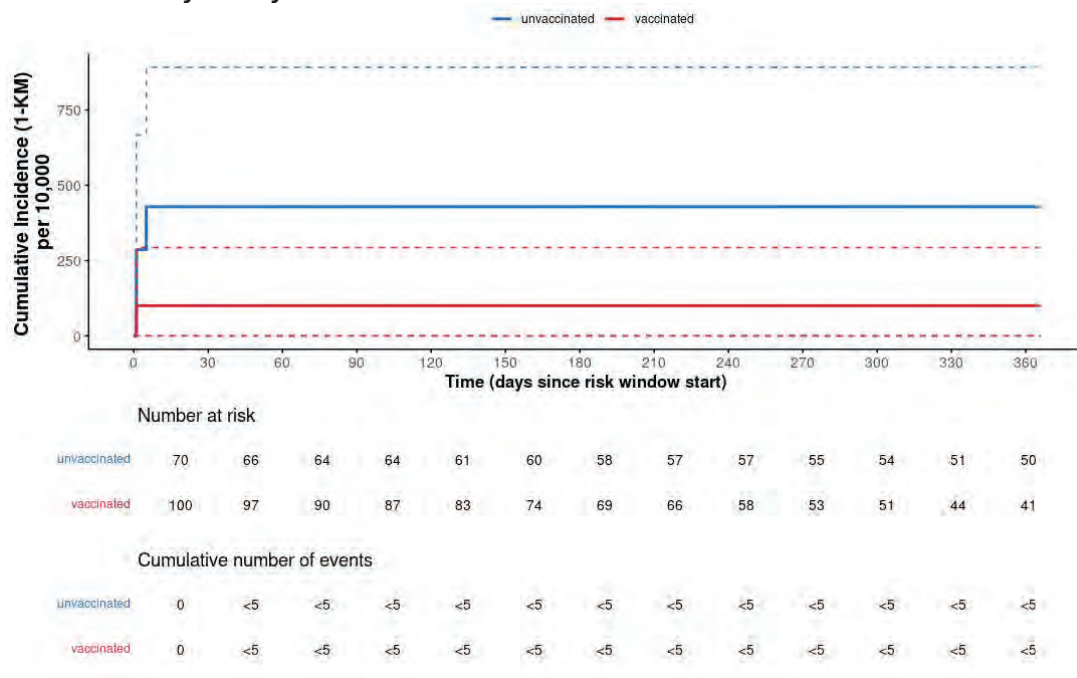
15.2.3.11 NHR: Cumulative incidence of heart failure in females aged 15–years by Pfizer-BioNTech COVID-19 vaccination status**15.2.3.12 NHR: Cumulative incidence of the number of hospitalisation in females aged 15–years by Pfizer-BioNTech COVID-19 vaccination status**

15.2.3.13 NHR: Cumulative incidence of recurrent myocarditis in females aged 15–years by Pfizer-BioNTech COVID-19 vaccination status**15.2.3.14 NHR: Cumulative incidence of recurrent pericarditis in females aged 15–years by Pfizer-BioNTech COVID-19 vaccination status**

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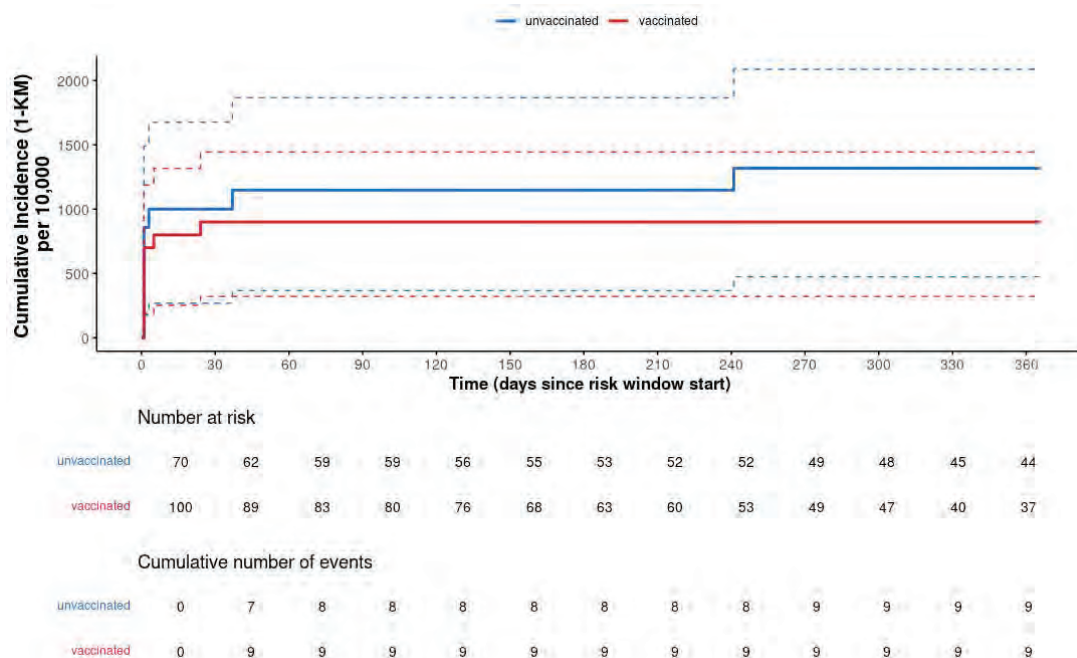
15.2.3.15 NHR: Cumulative incidence of cardiogenic shock in females aged 15–years by Pfizer-BioNTech COVID-19 vaccination status**15.2.3.16 NHR: Cumulative incidence of arrhythmia in males aged 15–years by Pfizer-BioNTech COVID-19 vaccination status**

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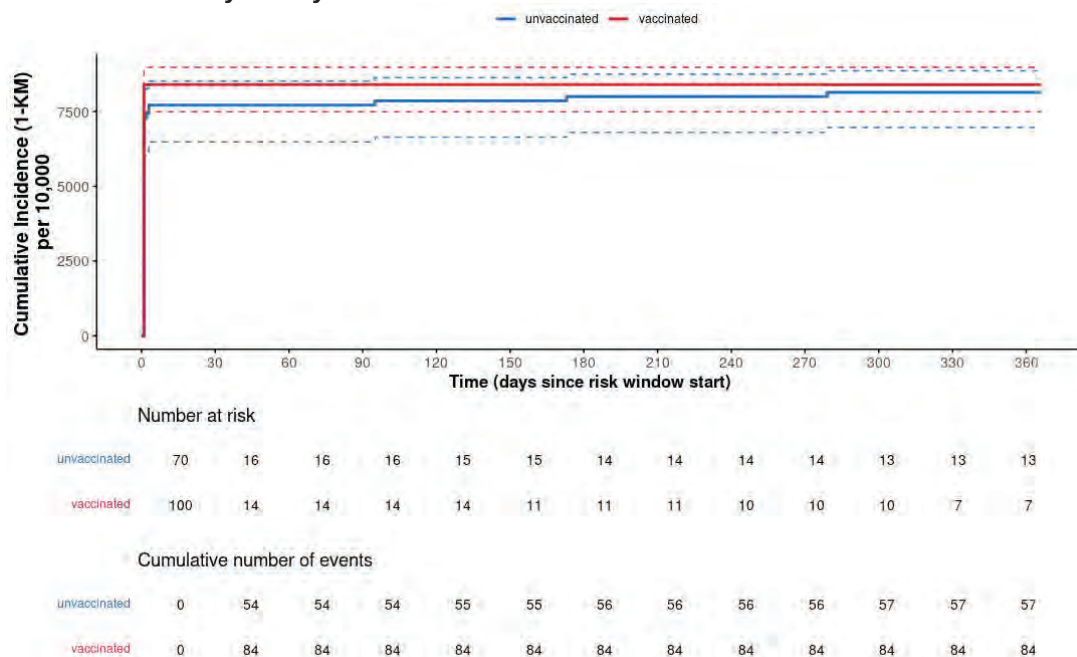
15.2.3.17 NHR: Cumulative incidence of death in males aged 15–years by Pfizer-BioNTech COVID-19 vaccination status**15.2.3.18 NHR: Cumulative incidence of fulminant myocarditis in males aged 15–years by Pfizer-BioNTech COVID-19 vaccination status**

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15.2.3.19 NHR: Cumulative incidence of heart failure in males aged 15–years by Pfizer-BioNTech COVID-19 vaccination status

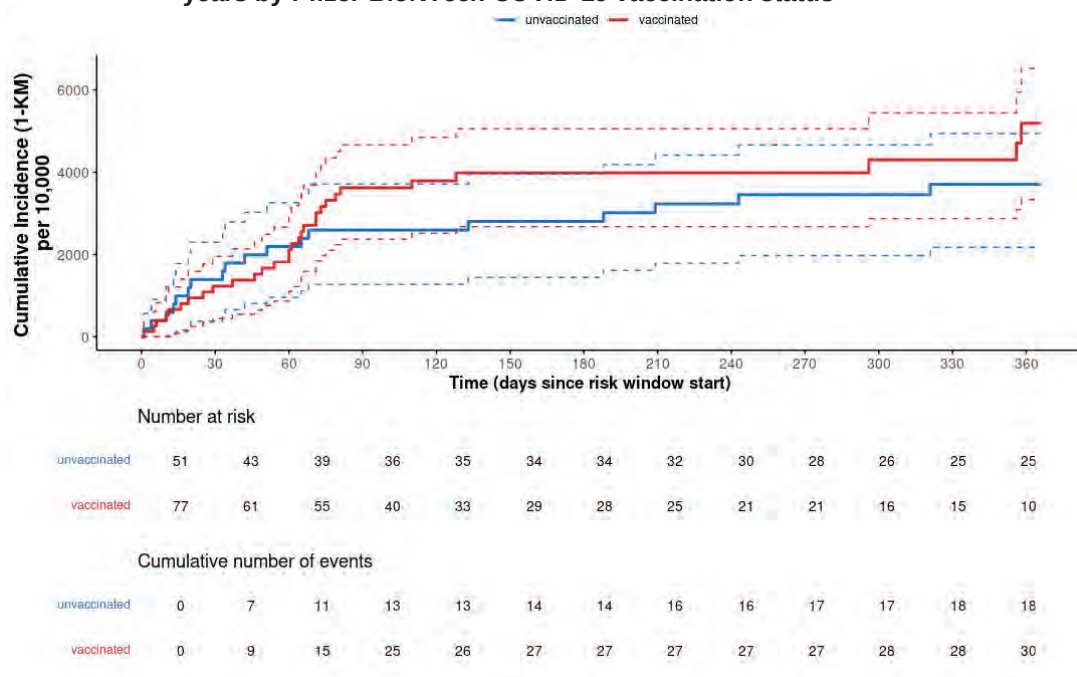


15.2.3.20 NHR: Cumulative incidence of the number of hospitalisations in males aged 15–years by Pfizer-BioNTech COVID-19 vaccination status

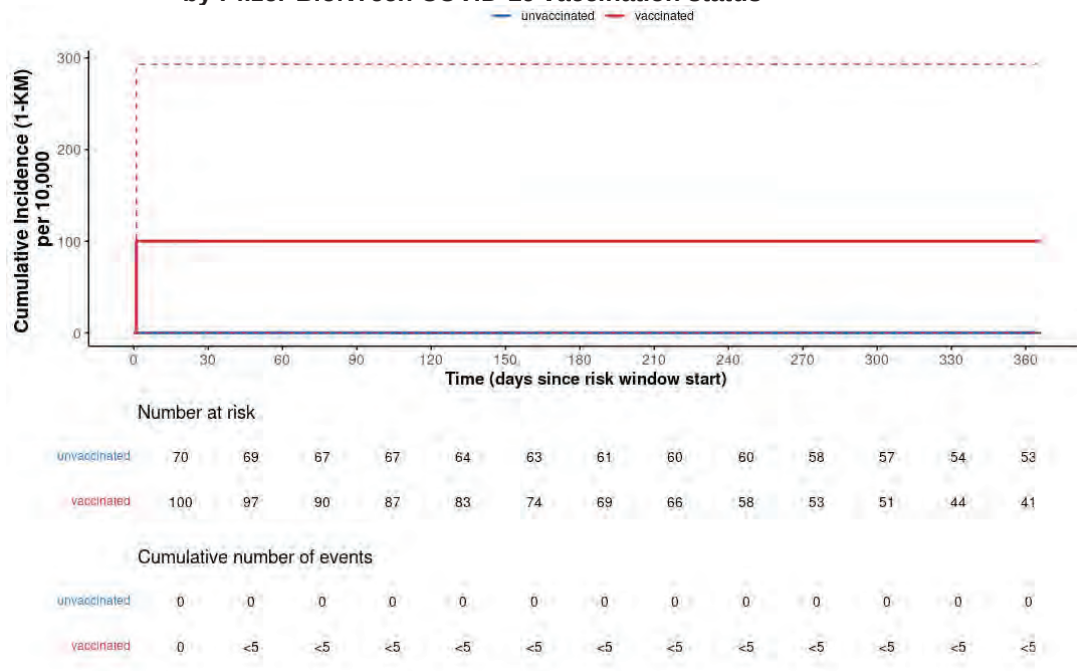


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15.2.3.21 NHR: Cumulative incidence of recurrent myocarditis in males aged 15–years by Pfizer-BioNTech COVID-19 vaccination status

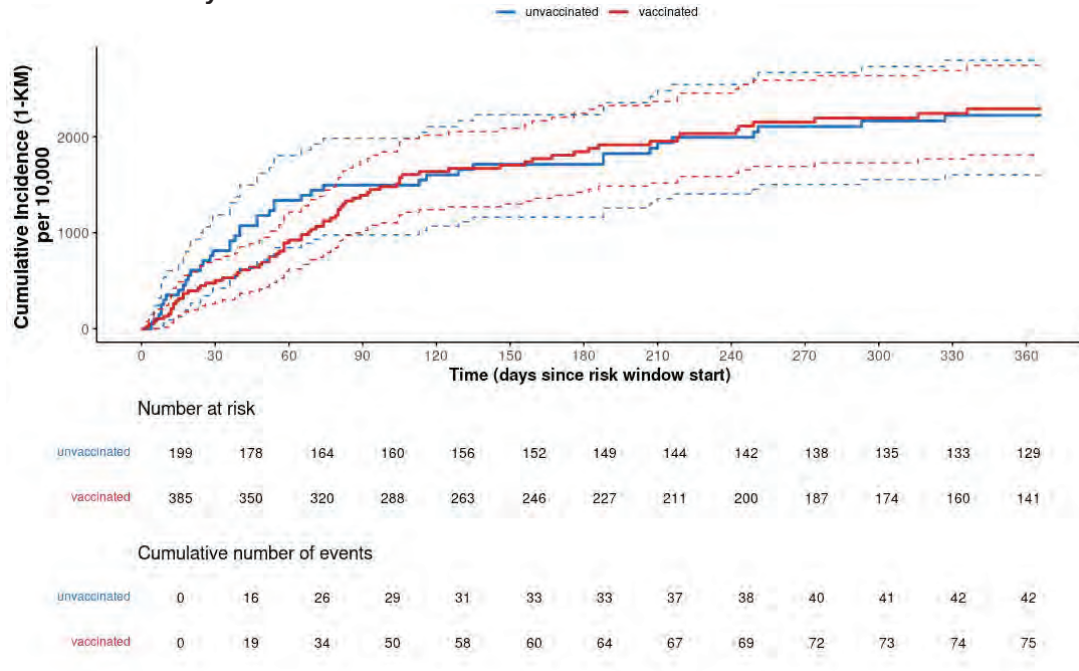


15.2.3.22 NHR: Cumulative incidence of cardiogenic shock in males aged 15–years by Pfizer-BioNTech COVID-19 vaccination status

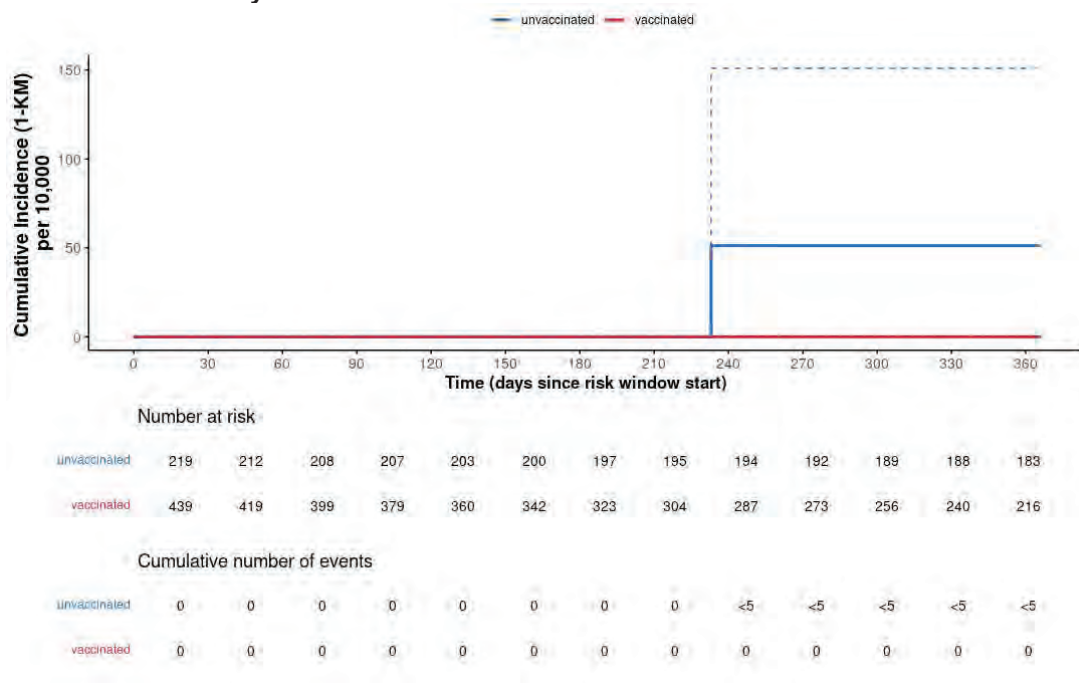


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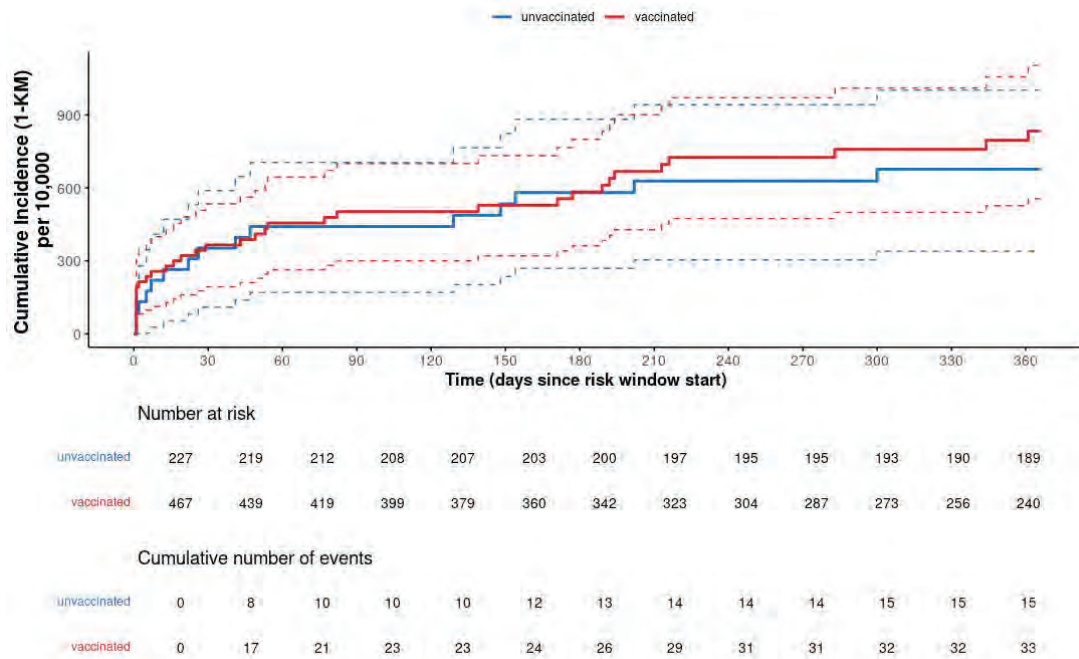
15.2.3.23 NHR: Cumulative incidence of arrhythmia in individuals who have no history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort



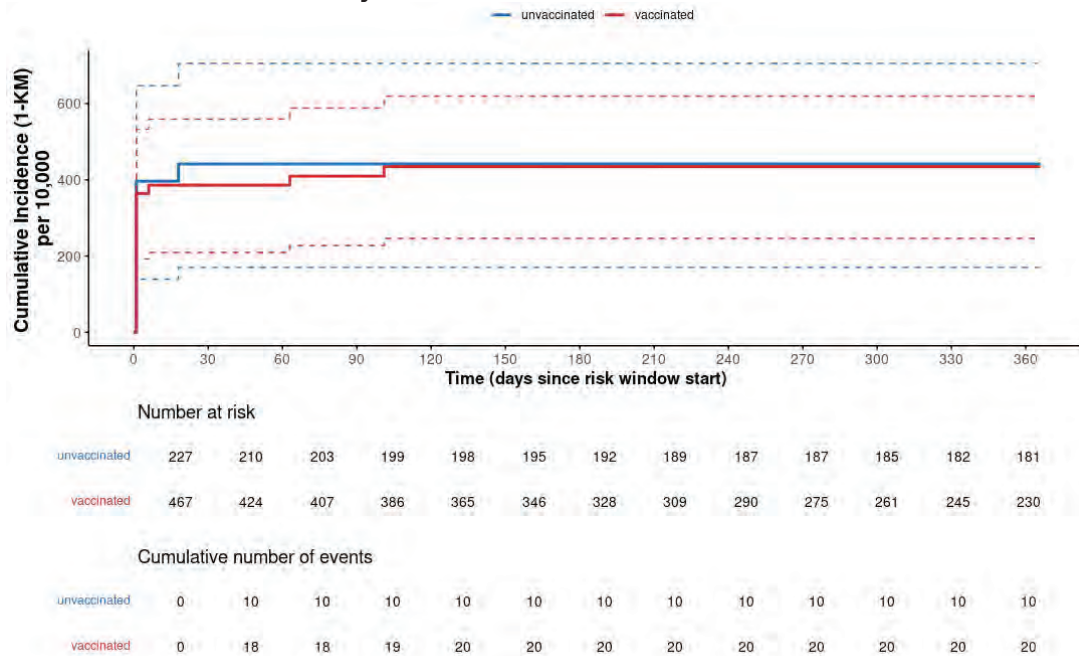
15.2.3.24 NHR: Cumulative incidence of chronic myocarditis in individuals who have no history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort

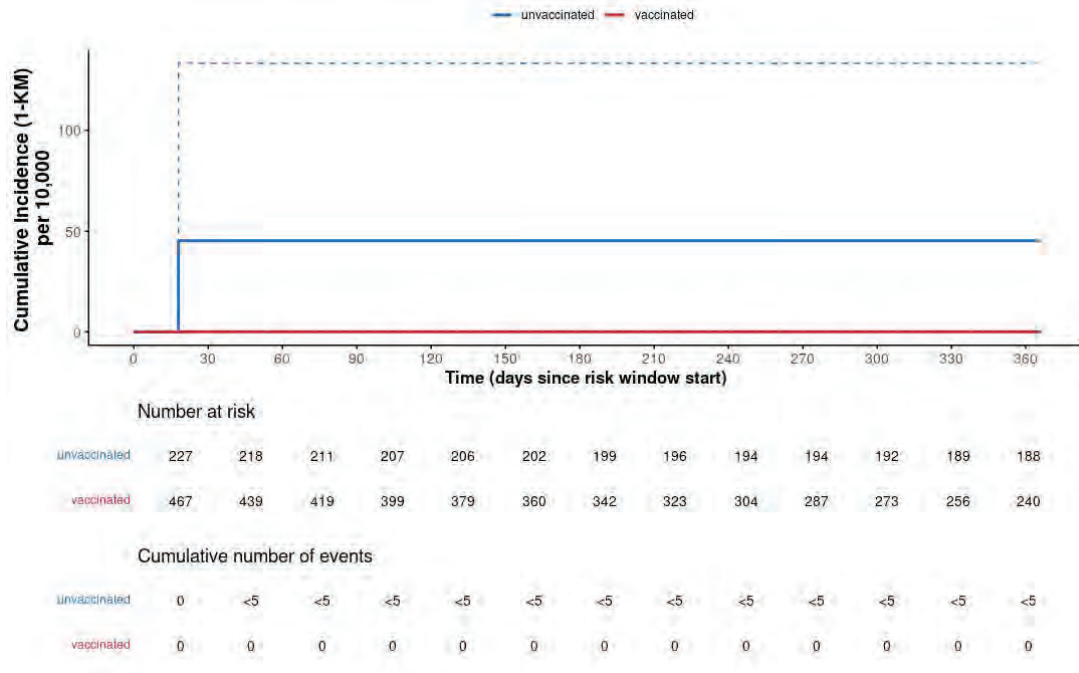
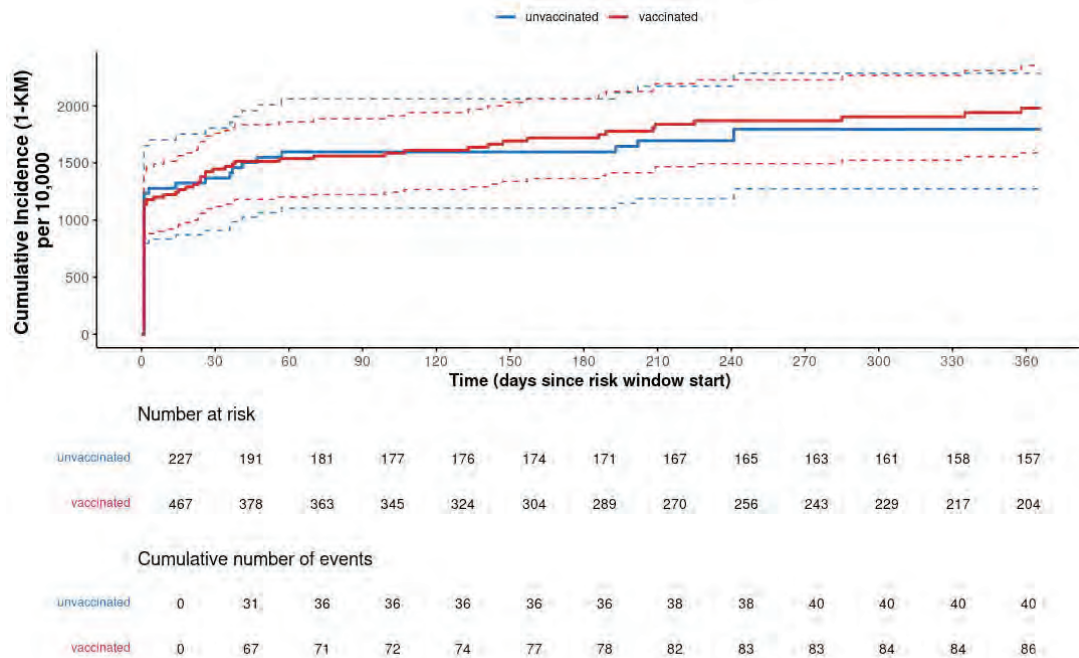


15.2.3.25 NHR: Cumulative incidence of death in individuals who have no history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort

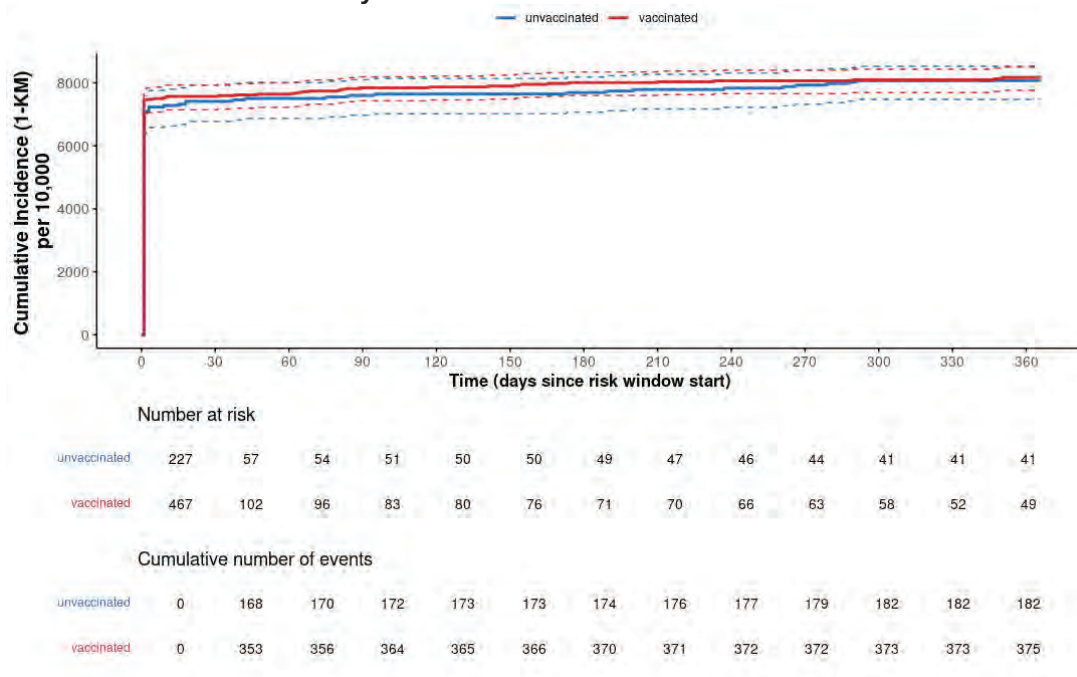


15.2.3.26 NHR: Cumulative incidence of fulminant myocarditis in individuals who have no history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort

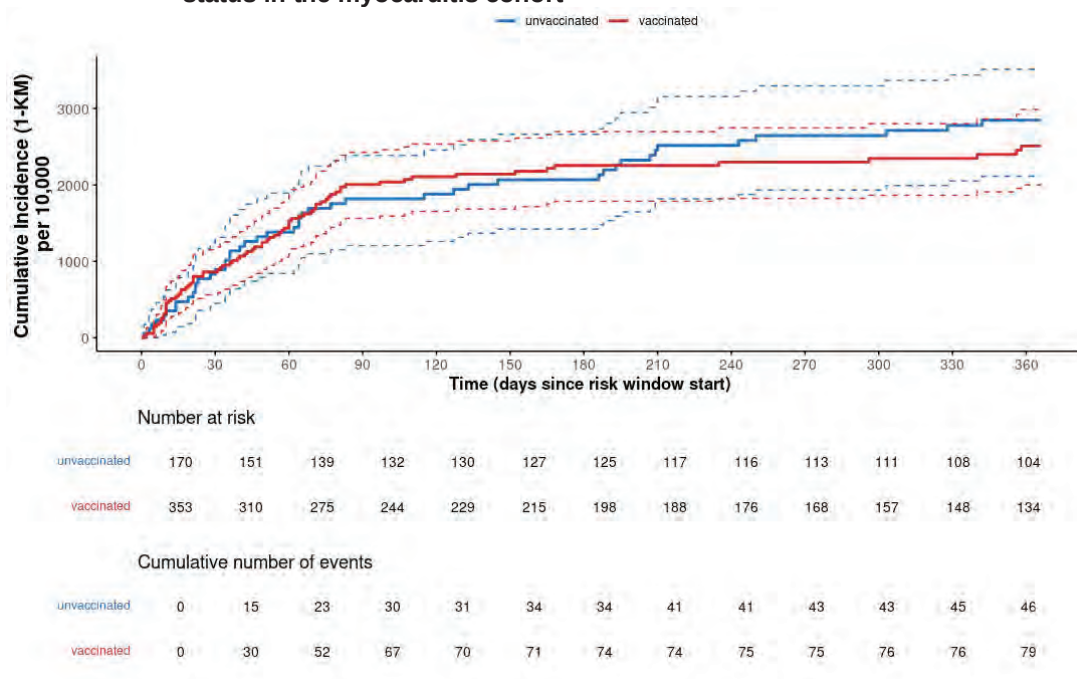


15.2.3.27 NHR: Cumulative incidence of heart transplant in individuals who have no history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort**15.2.3.28 NHR: Cumulative incidence of heart failure in individuals who have no history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort**

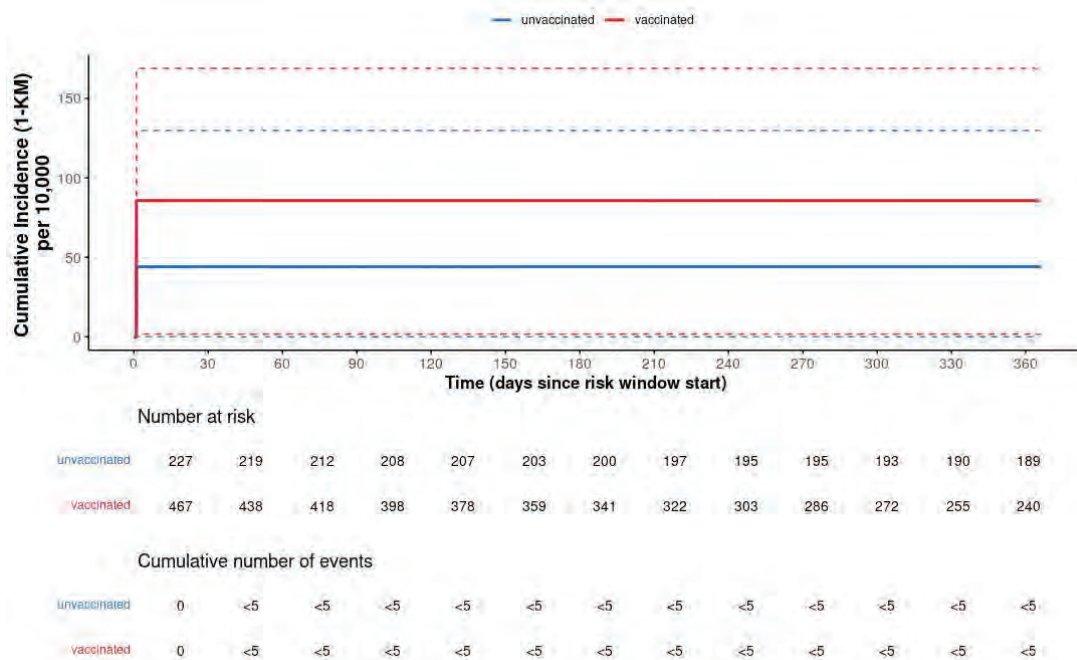
15.2.3.29 NHR: Cumulative incidence of the number of hospitalisations in individuals who have no history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort



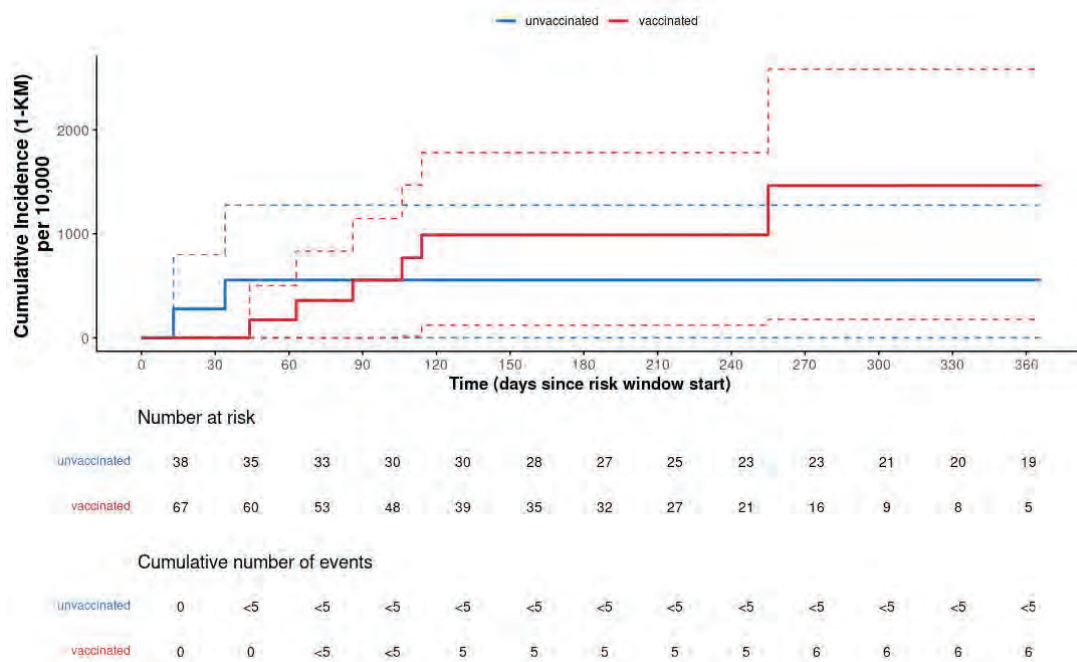
15.2.3.30 NHR: Cumulative incidence of recurrent myocarditis in individuals who have no history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort

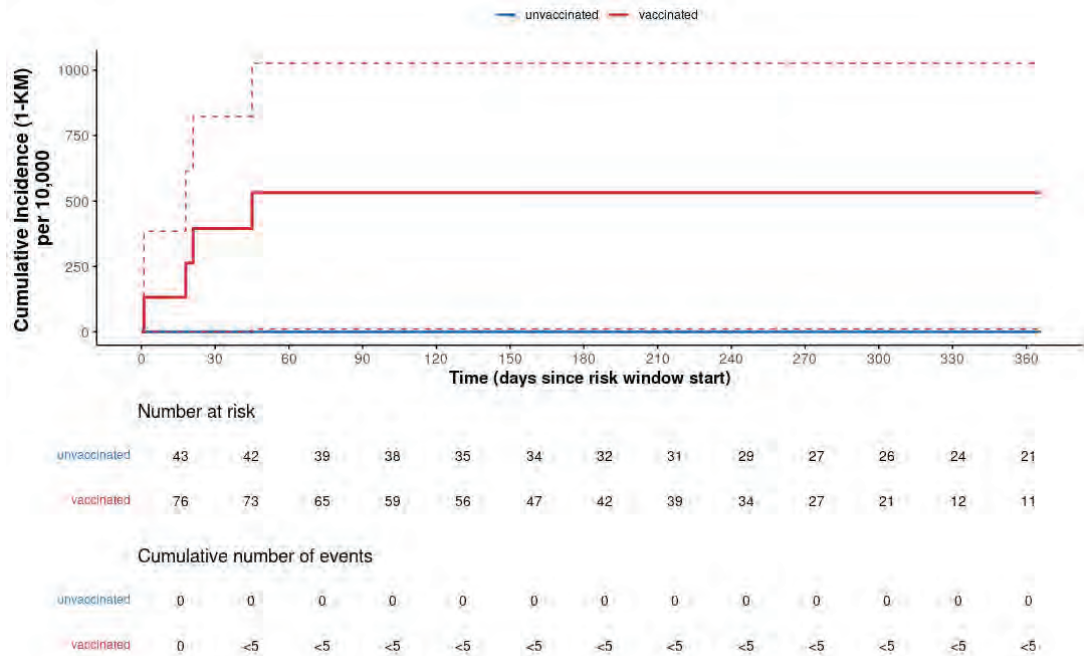
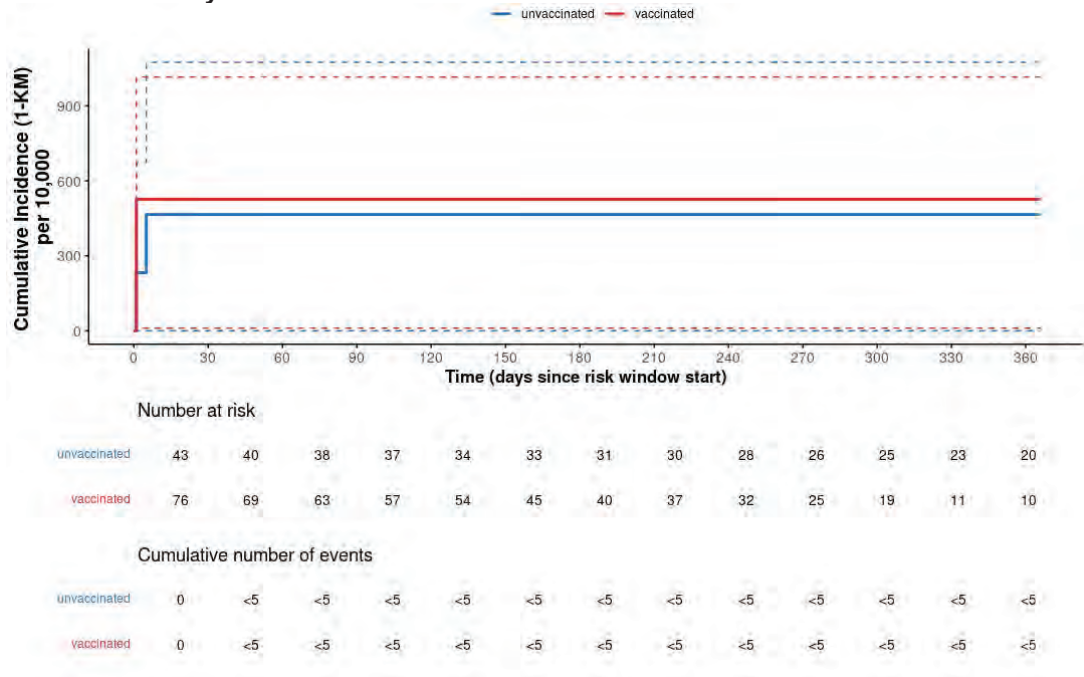


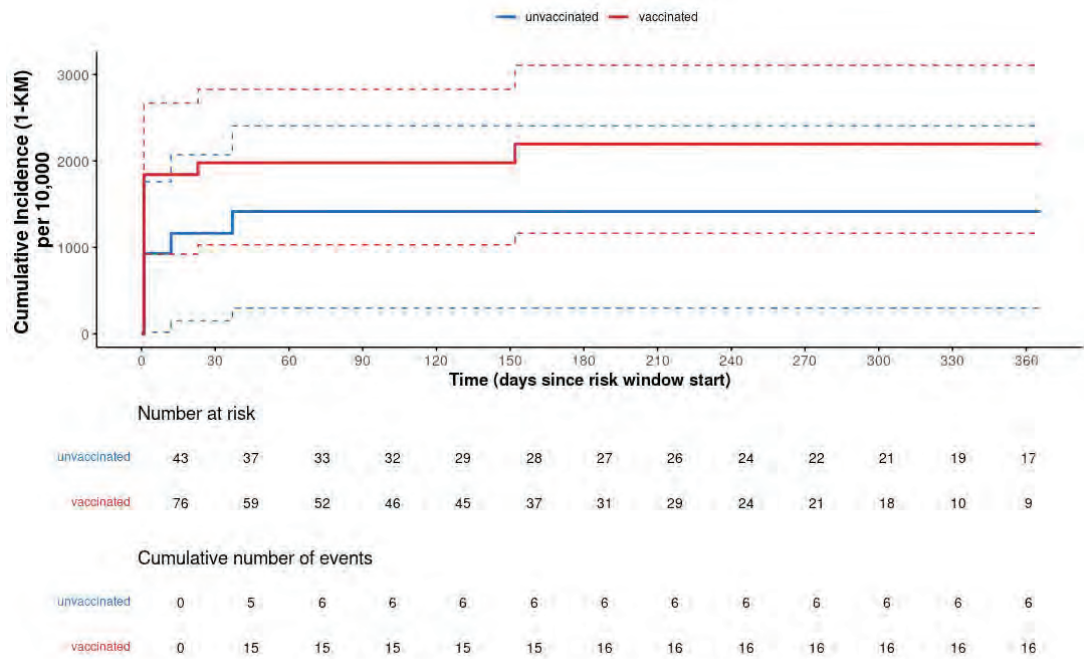
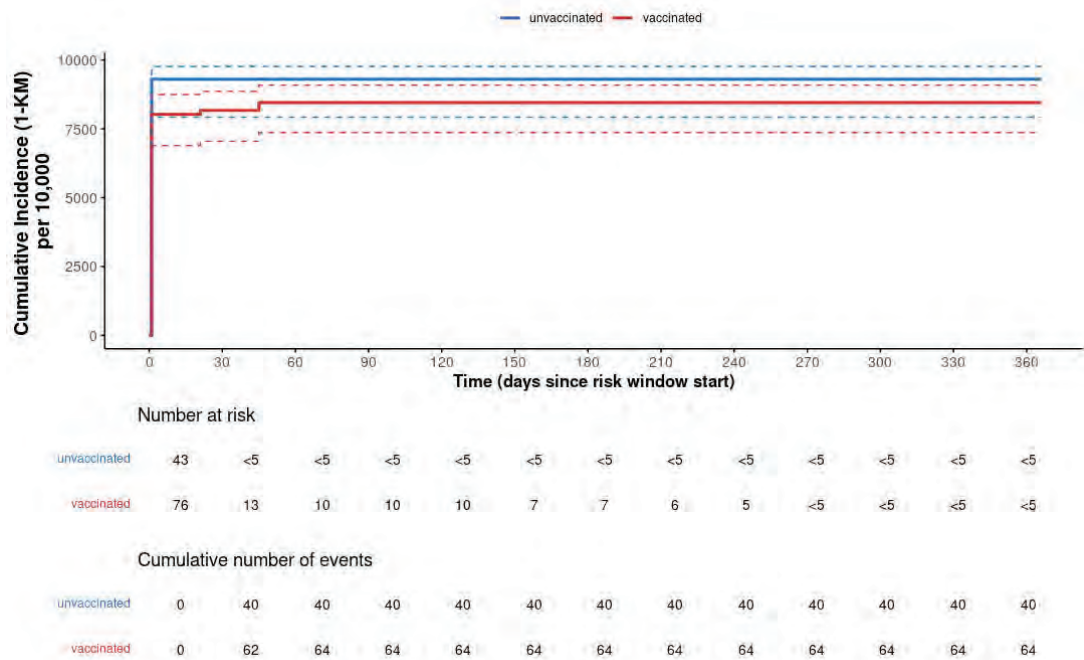
15.2.3.31 NHR: Cumulative incidence of cardiogenic shock in individuals who have no history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort

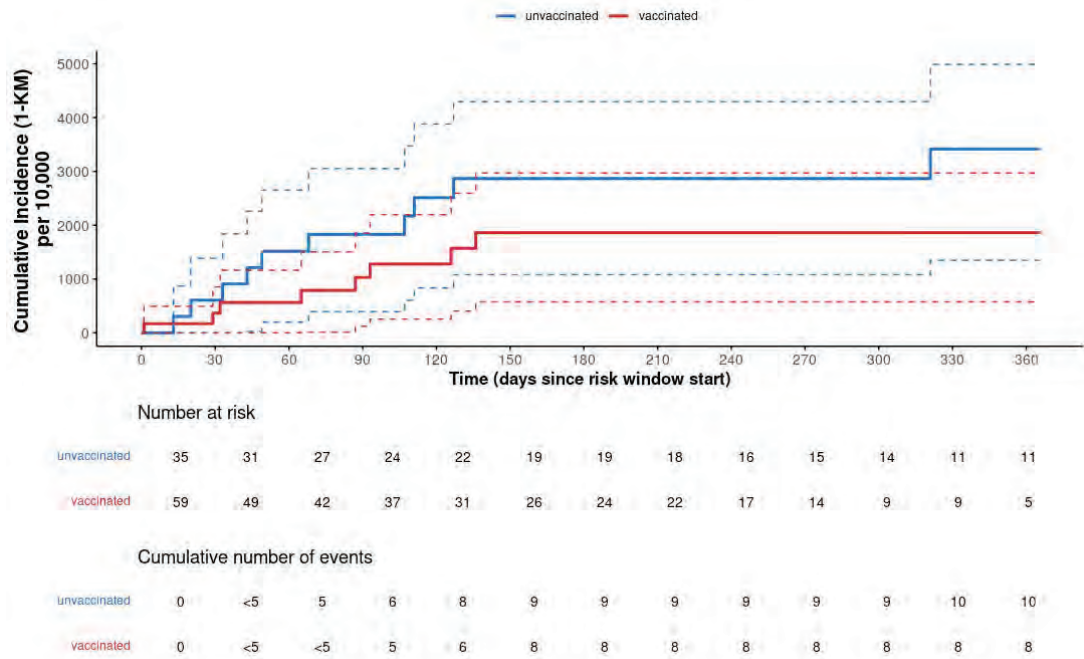
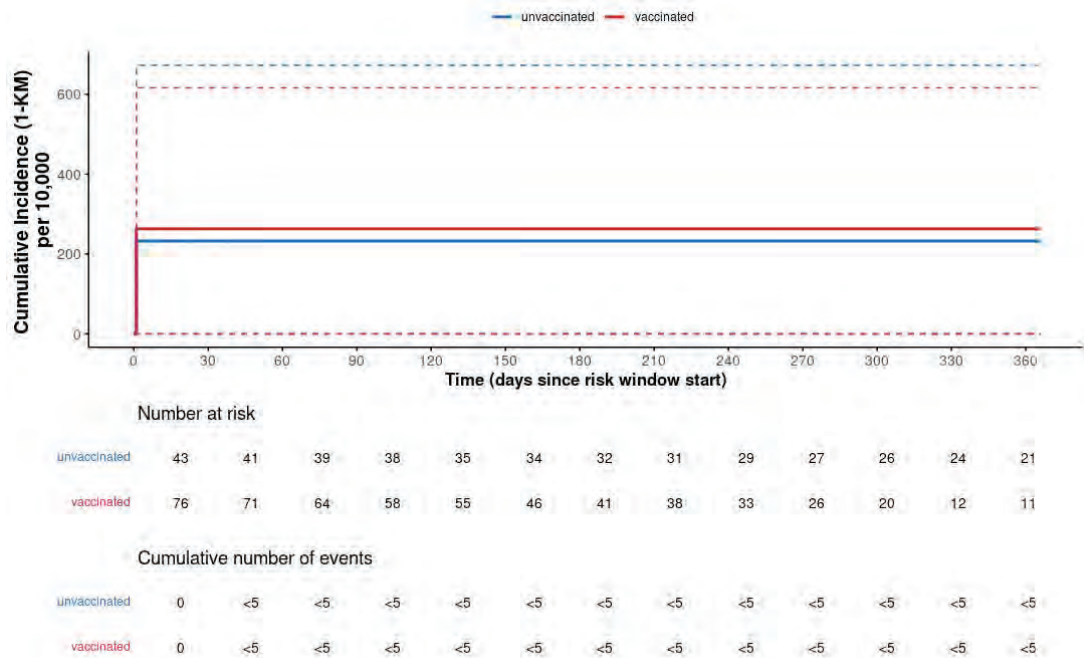


15.2.3.32 NHR: Cumulative incidence of arrhythmia in individuals with history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort

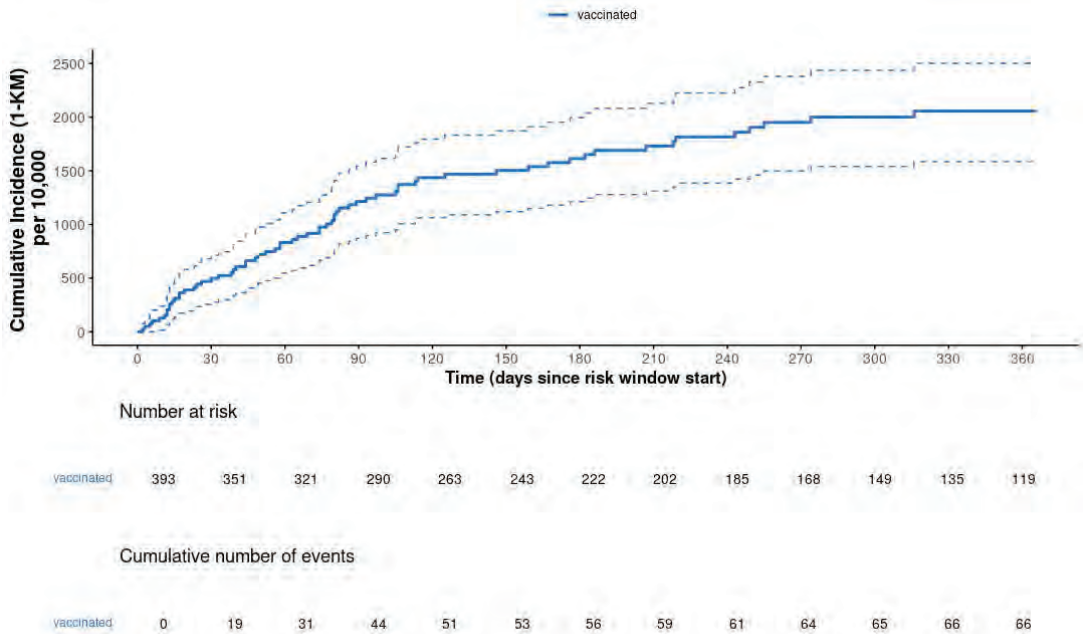


15.2.3.33 NHR: Cumulative incidence of death in individuals with history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort**15.2.3.34 NHR: Cumulative incidence of fulminant myocarditis in individuals with history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort**

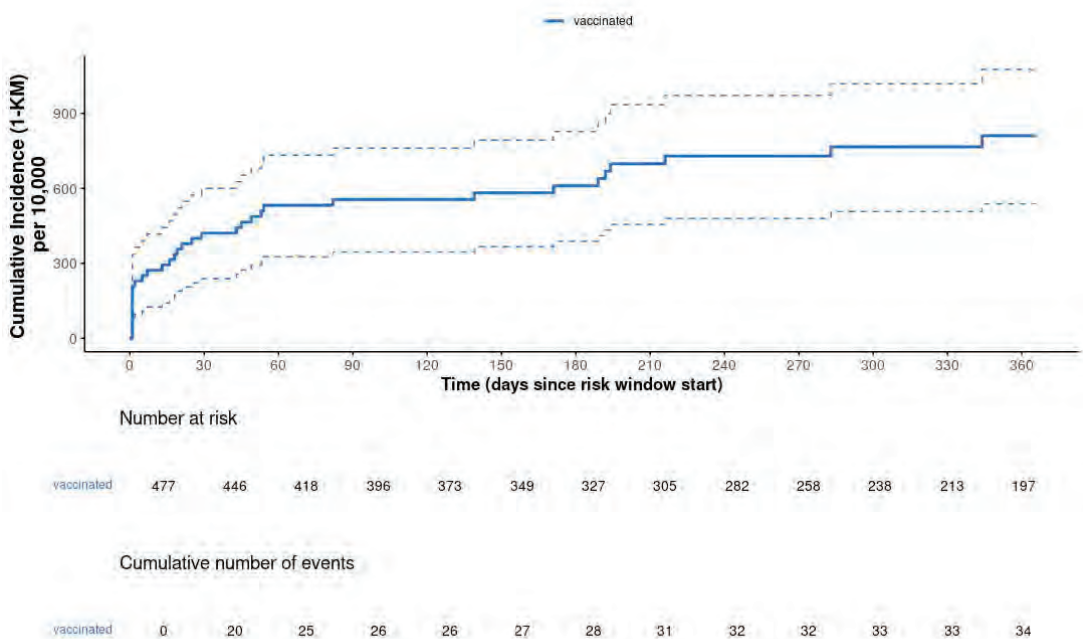
15.2.3.35 NHR: Cumulative incidence of heart failure in individuals with history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort**15.2.3.36 NHR: Cumulative incidence of number of hospitalisation in individuals with history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort**

15.2.3.37 NHR: Cumulative incidence of recurrent myocarditis in individuals with history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort**15.2.3.38 NHR: Cumulative incidence of cardiogenic shock in individuals with history of COVID-19 by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort**

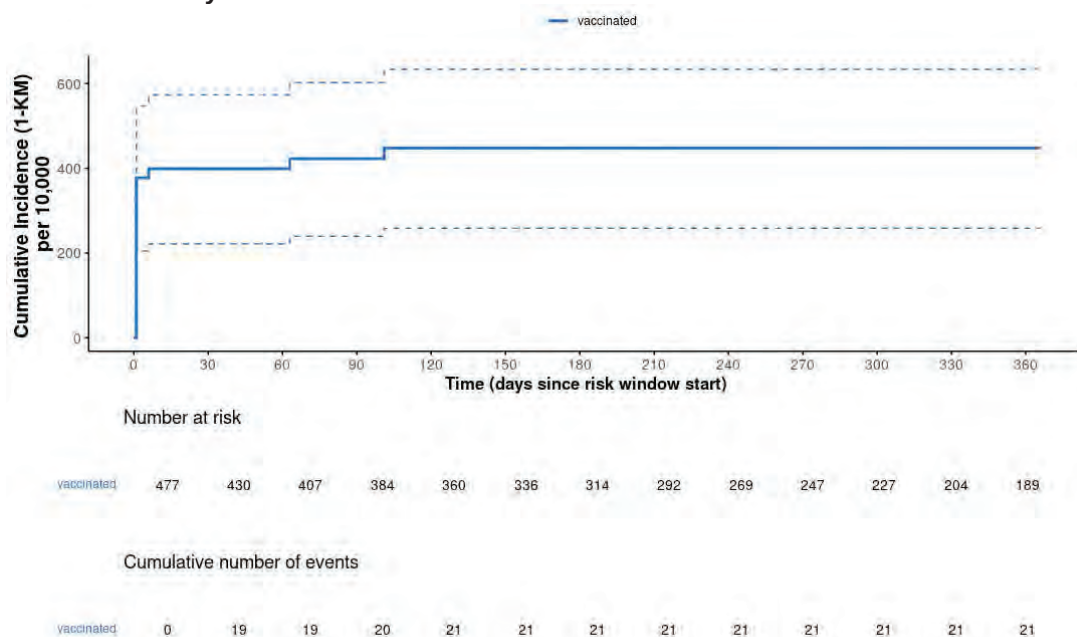
15.2.3.39 NHR: Cumulative incidence of arrhythmia in vaccinated individuals who received the last dose ≥ 22 days previously in the myocarditis cohort



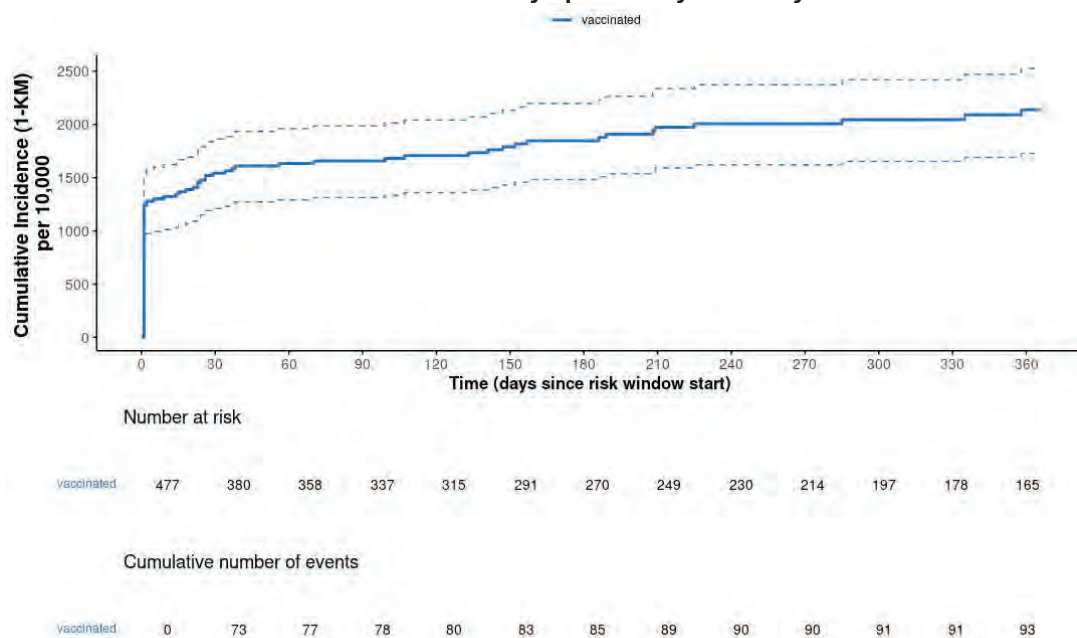
15.2.3.40 NHR: Cumulative incidence of death in vaccinated individuals who received the last dose ≥ 22 days previously in the myocarditis cohort



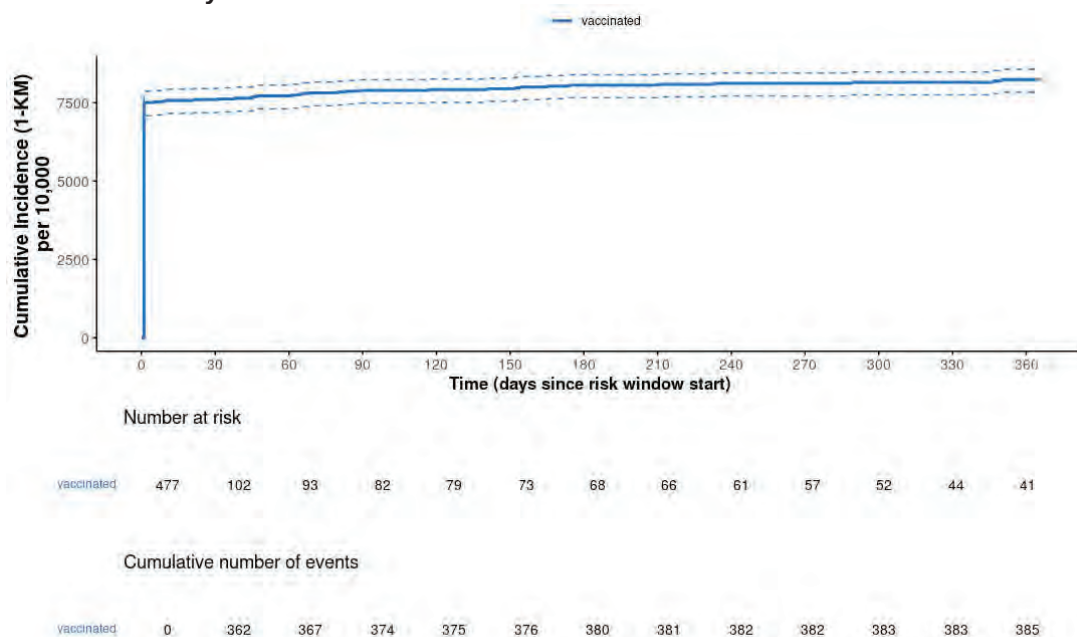
15.2.3.41 NHR: Cumulative incidence of fulminant myocarditis in vaccinated individuals who received the last dose ≥ 22 days previously in the myocarditis cohort



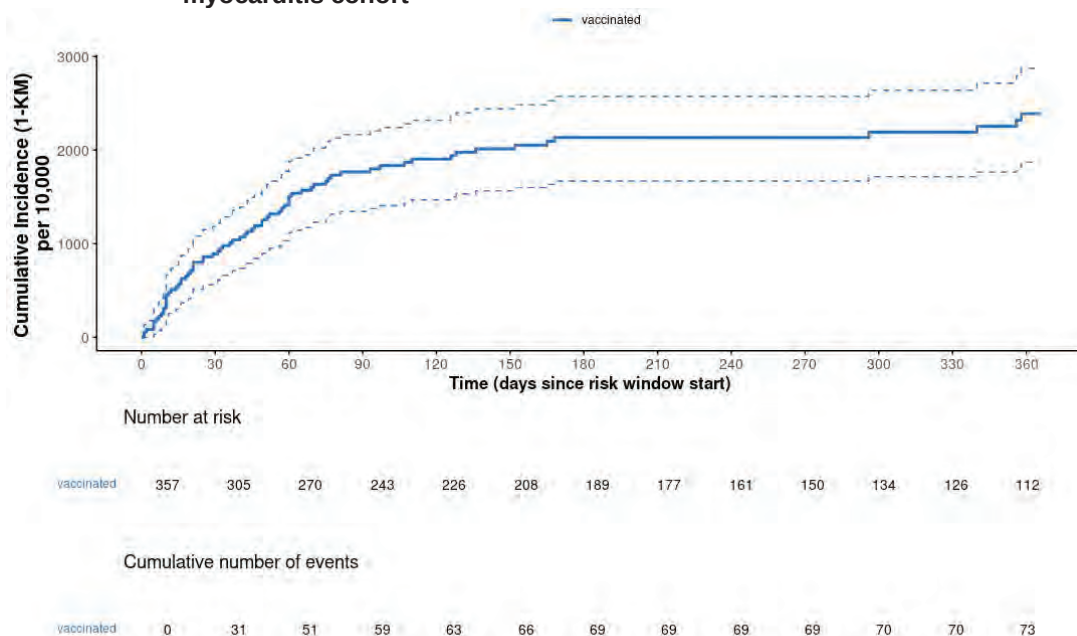
15.2.3.42 NHR: Cumulative incidence of heart failure in vaccinated individuals who received the last dose ≥ 22 days previously in the myocarditis cohort



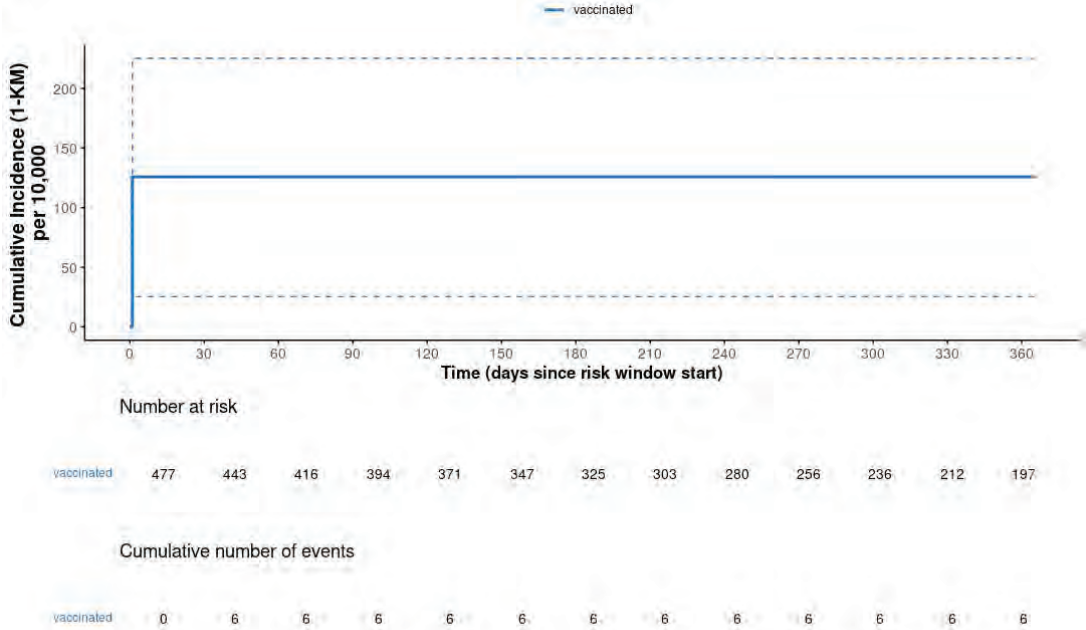
15.2.3.43 NHR: Cumulative incidence of the number of hospitalisations in vaccinated individuals who received the last dose ≥ 22 days previously in the myocarditis cohort



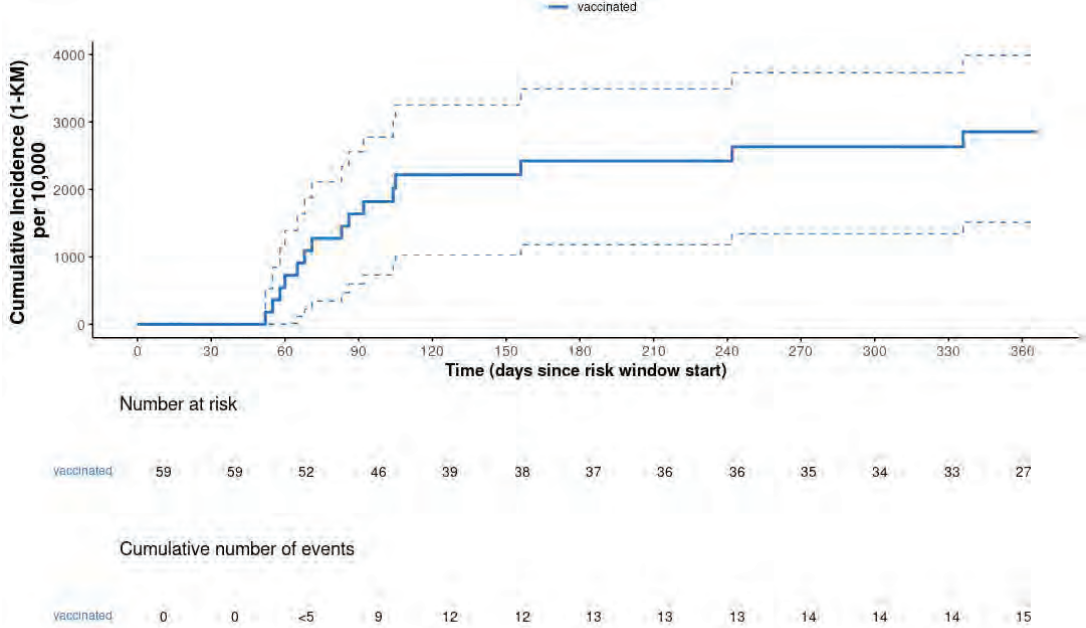
15.2.3.44 NHR: Cumulative incidence of recurrent myocarditis in vaccinated individuals who received the last dose ≥ 22 days previously in the myocarditis cohort



15.2.3.45 NHR: Cumulative incidence of cardiogenic shock in vaccinated individuals who received the last dose ≥ 22 days previously in the myocarditis cohort

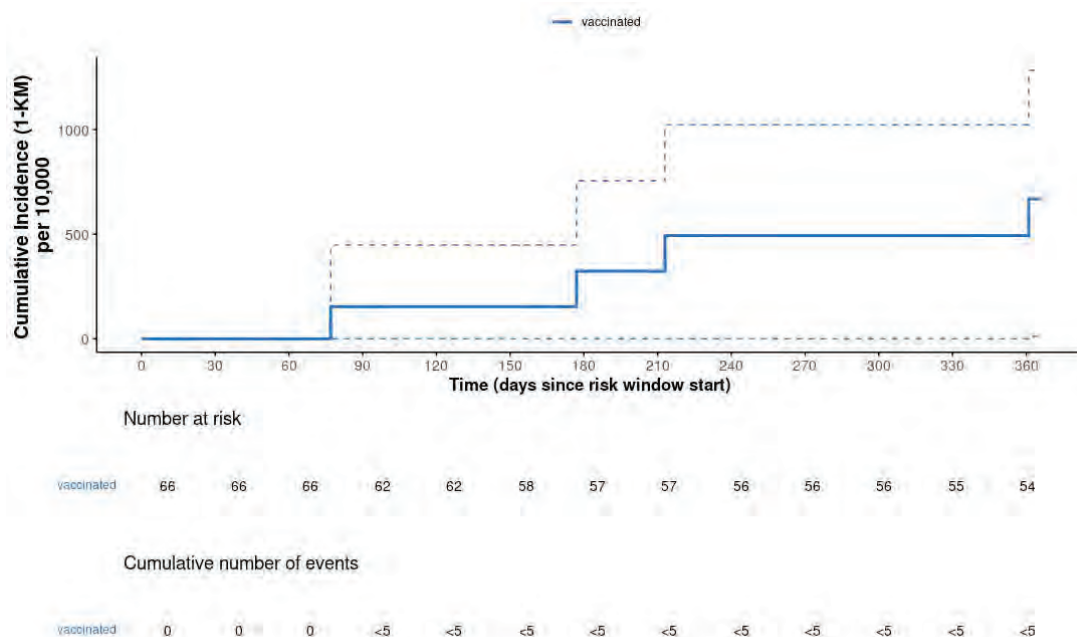


15.2.3.46 NHR: Cumulative incidence of arrhythmia in vaccinated individuals who received the last dose < 22 days previously in the myocarditis cohort

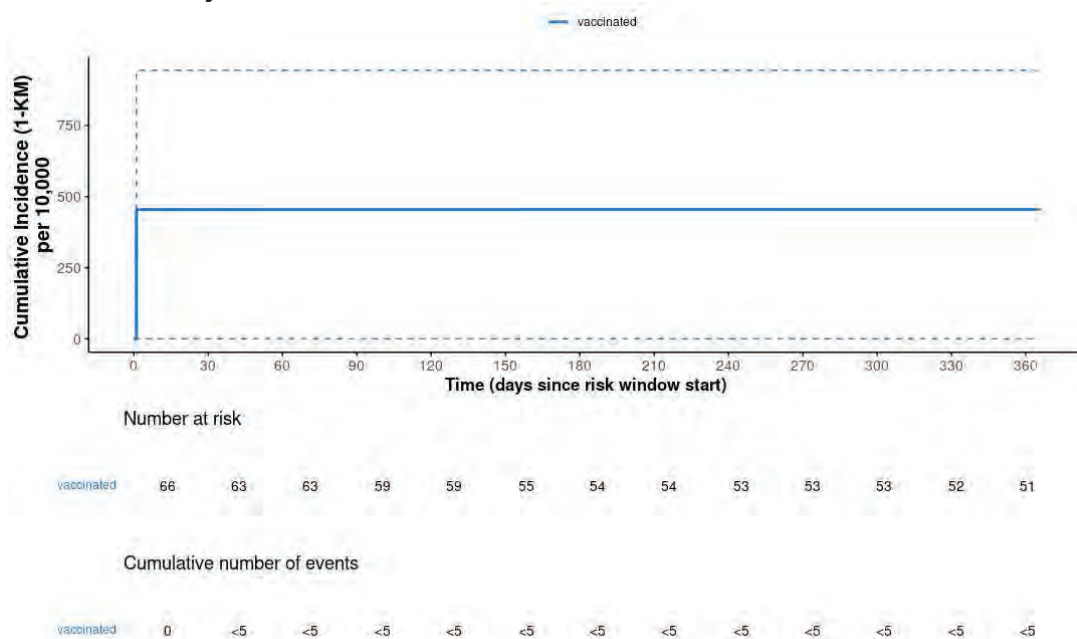


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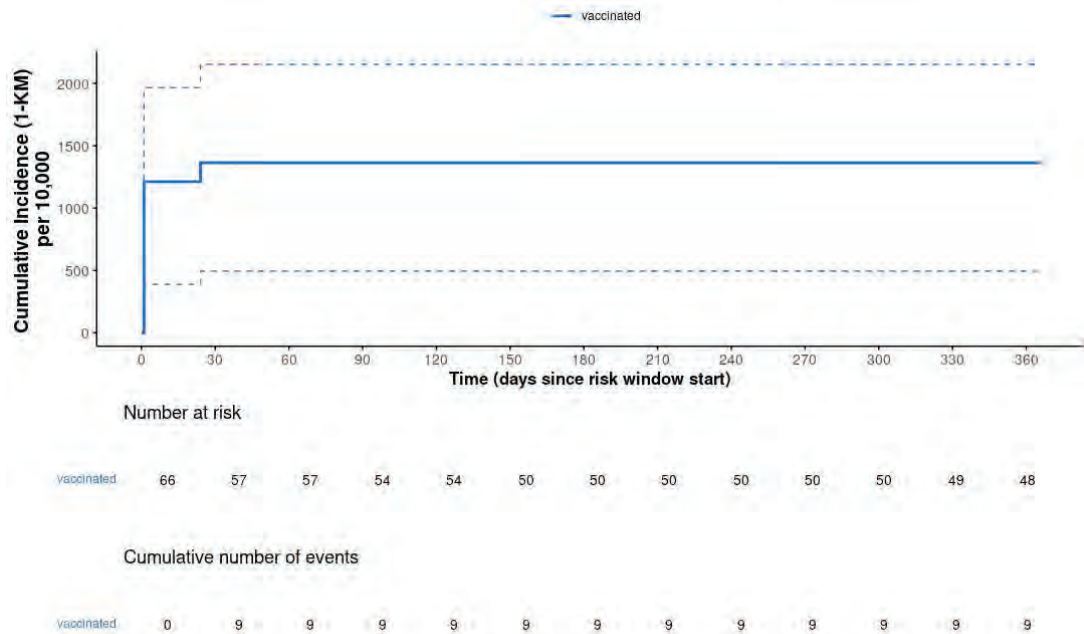
15.2.3.47 NHR: Cumulative incidence of death in vaccinated individuals who received the last dose <22 days previously in the myocarditis cohort



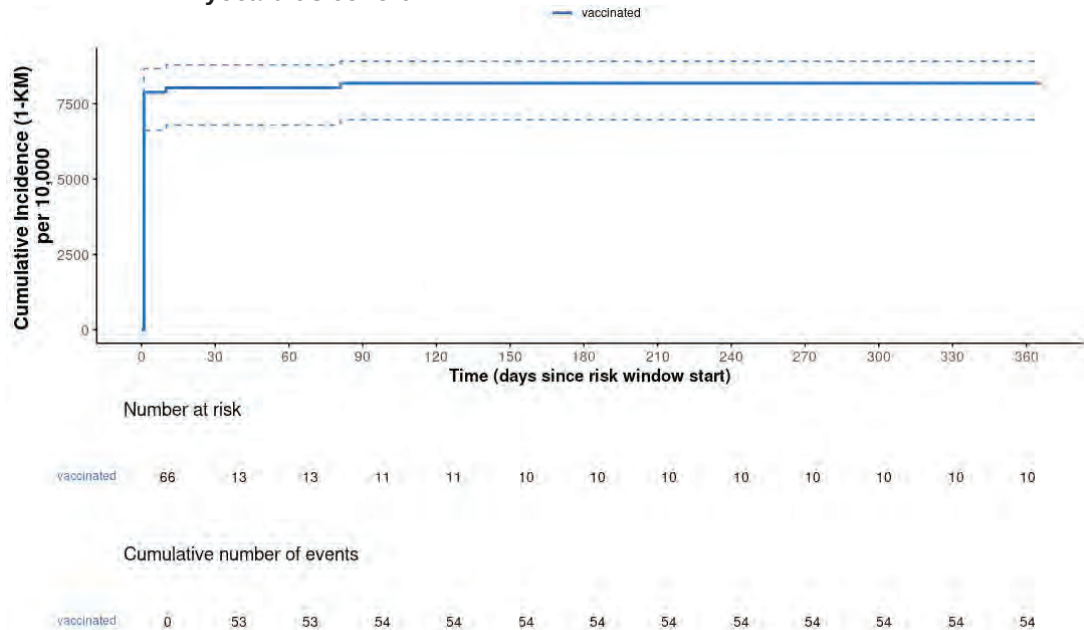
15.2.3.48 NHR: Cumulative incidence of fulminant myocarditis in vaccinated individuals who received the last dose <22 days previously in the myocarditis cohort



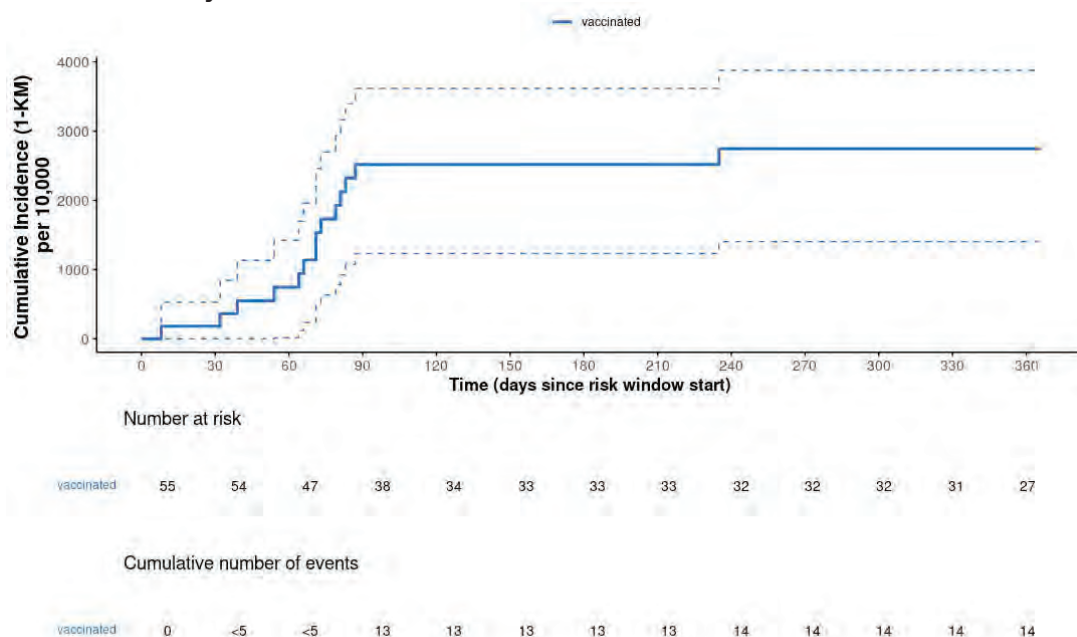
15.2.3.49 NHR: Cumulative incidence of heart failure in vaccinated individuals who received the last dose <22 days previously in the myocarditis cohort



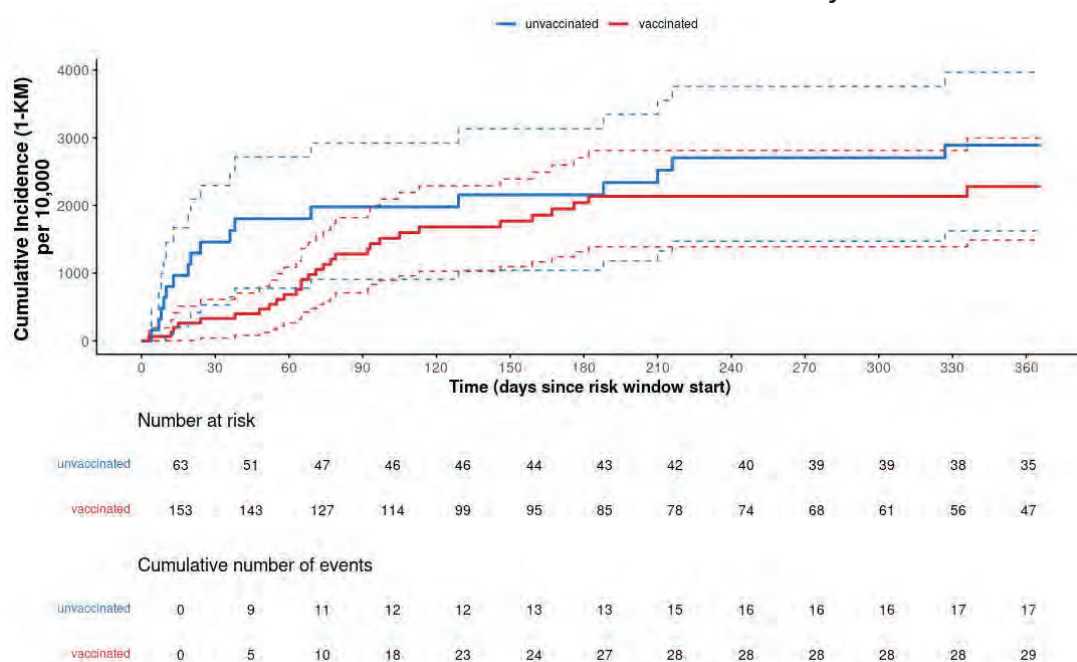
15.2.3.50 NHR: Cumulative incidence of the number of hospitalisations in vaccinated individuals who received the last dose <22 days previously in the myocarditis cohort



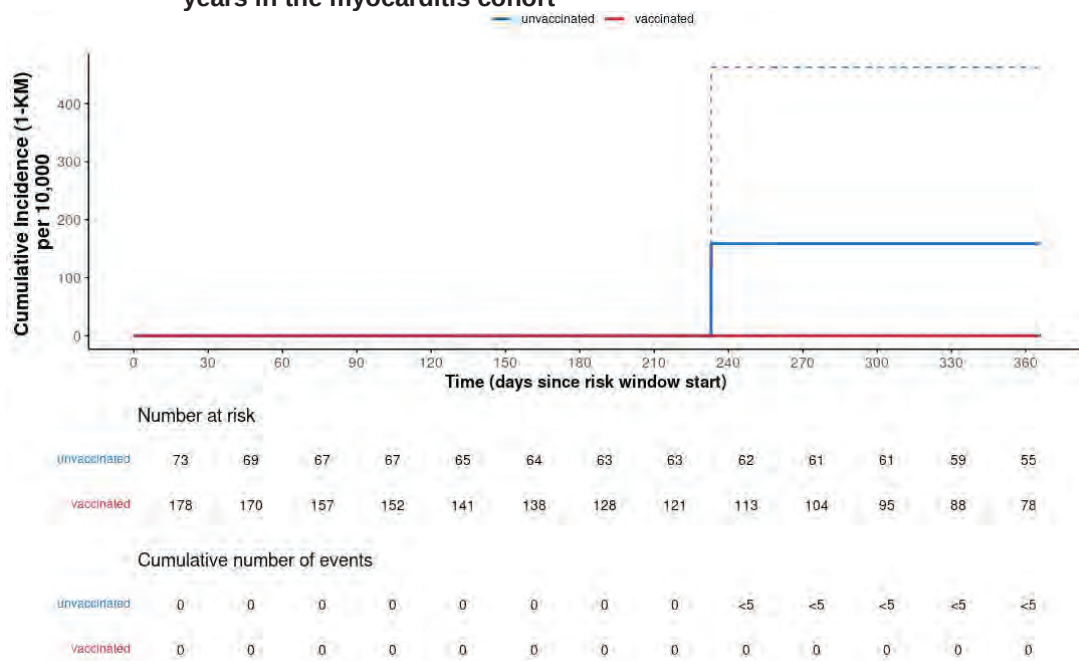
15.2.3.51 NHR: Cumulative incidence of recurrent myocarditis in vaccinated individuals who received the last dose <22 days previously in the myocarditis cohort



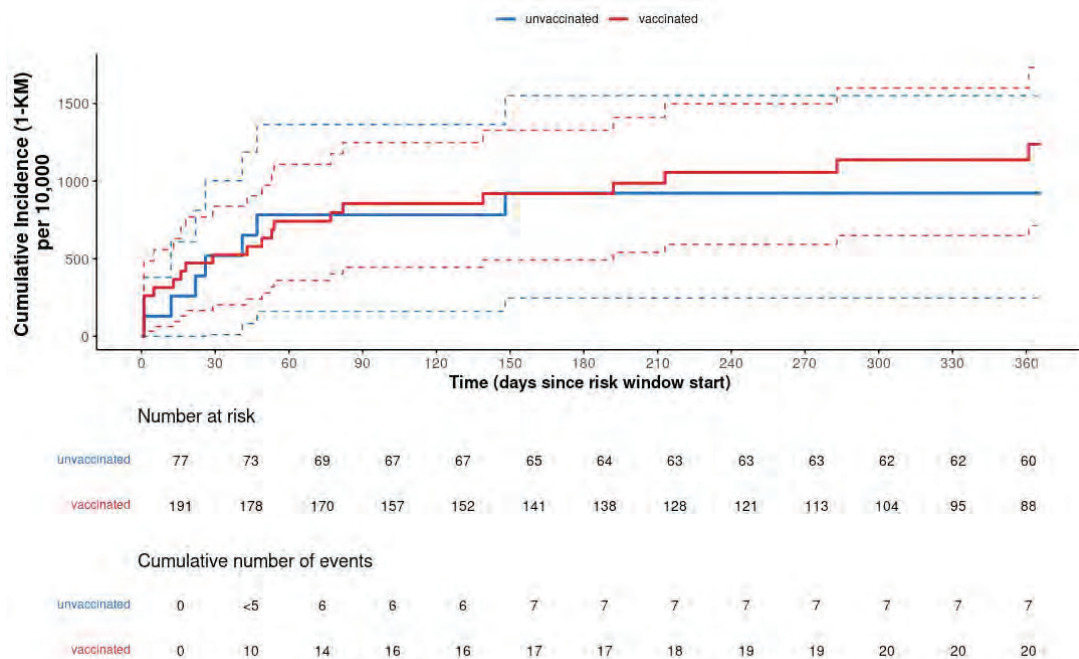
15.2.3.52 NHR: Cumulative incidence of arrhythmia in females aged 15–30 years by Pfizer-BioNTech COVID-19 vaccination status in the myocarditis cohort



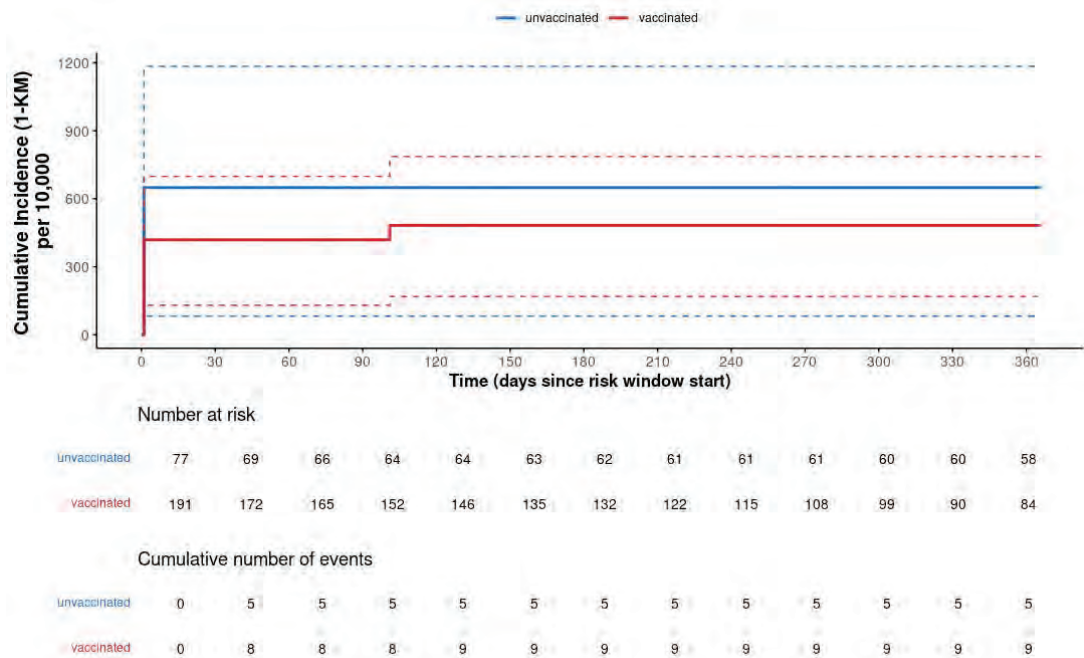
15.2.3.53 NHR: Cumulative incidence of chronic myocarditis in females aged 15–30 years in the myocarditis cohort



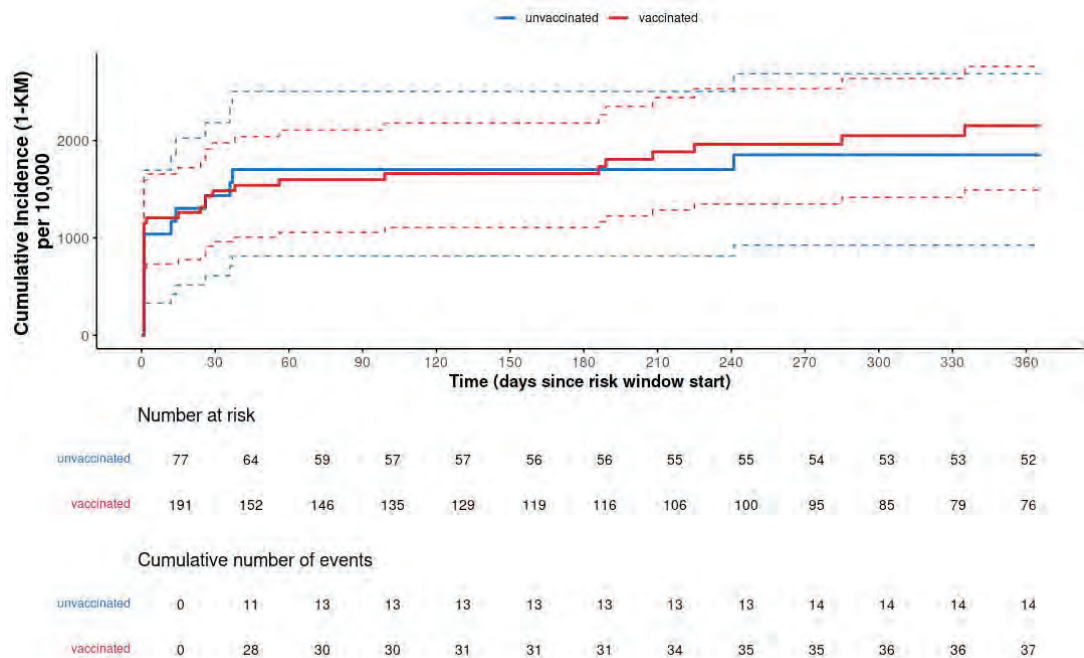
15.2.3.54 NHR: Cumulative incidence of death in females aged 15–30 years in the myocarditis cohort



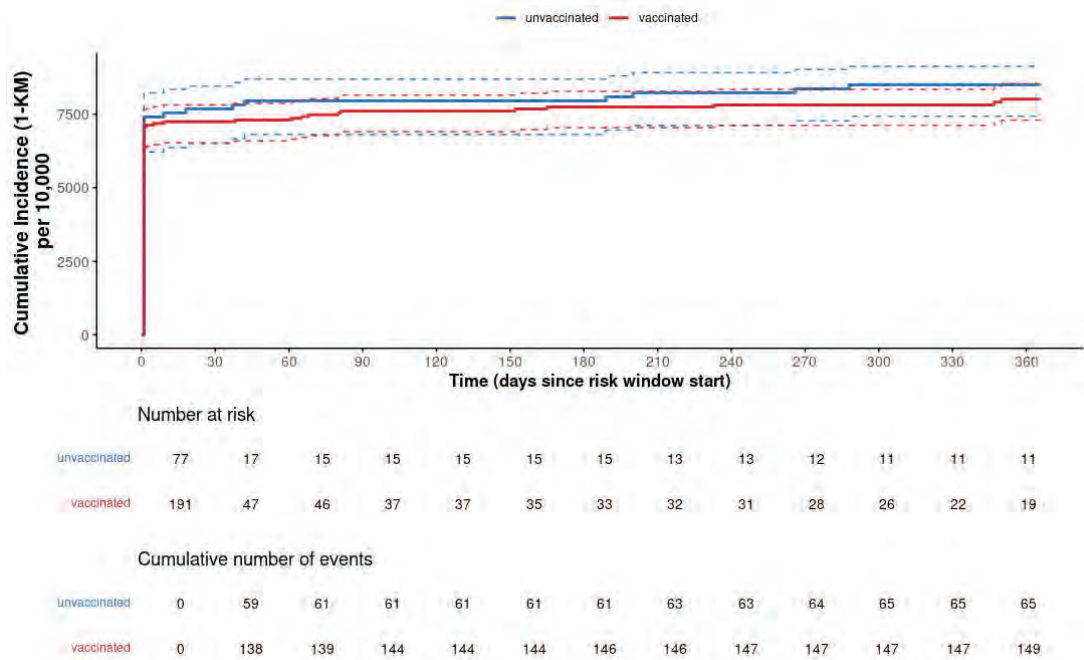
15.2.3.55 NHR: Cumulative incidence of fulminant myocarditis in females aged 15–30 years in the myocarditis cohort



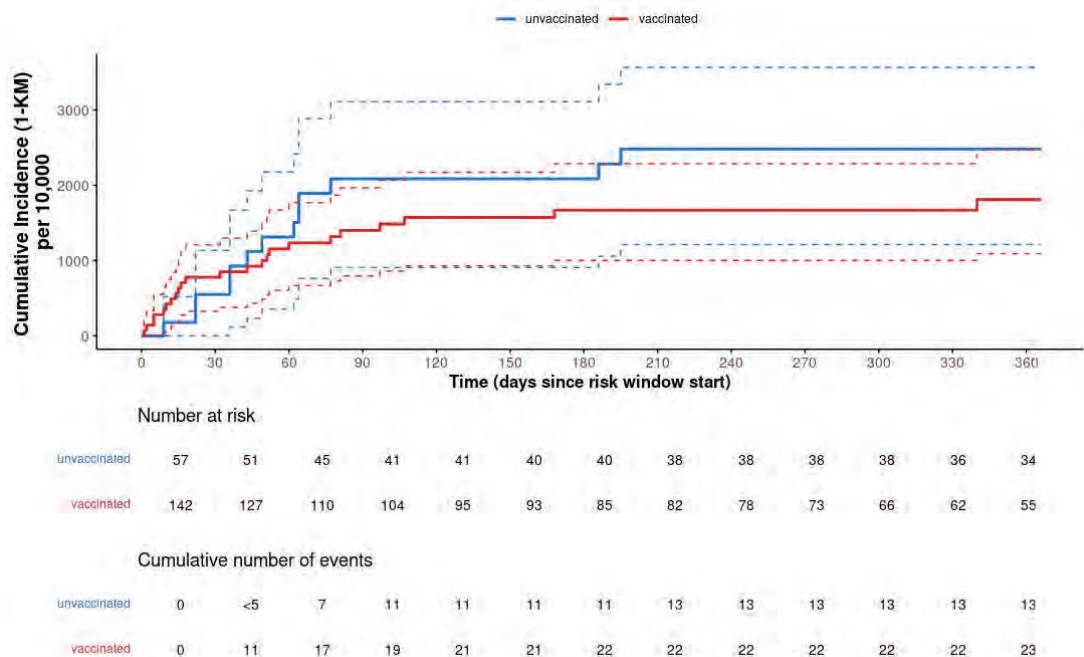
15.2.3.56 NHR: Cumulative incidence of heart failure in females aged 15–30 years in the myocarditis cohort



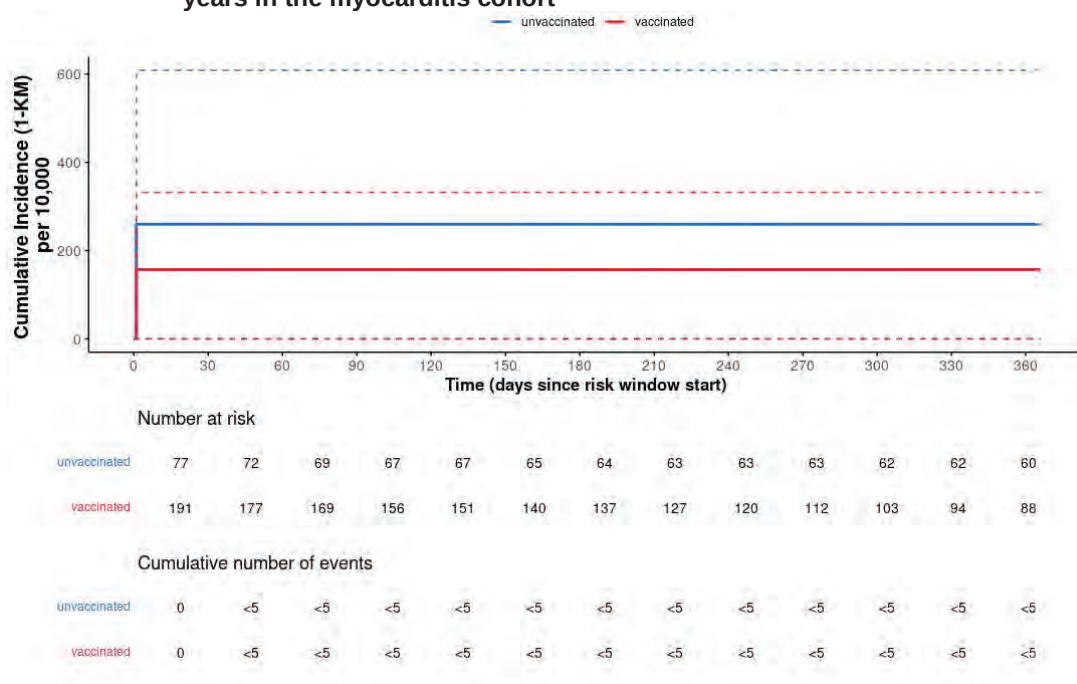
15.2.3.57 NHR: Cumulative incidence of the number of hospitalisations in females aged 15–30 years in the myocarditis cohort



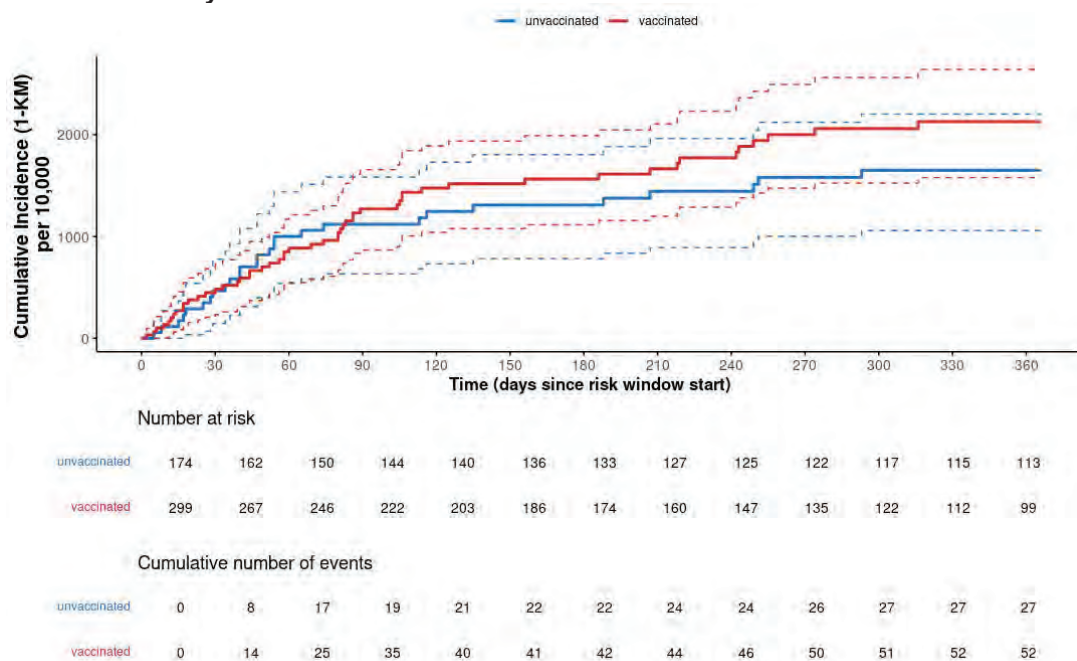
15.2.3.58 NHR: Cumulative incidence of recurrent myocarditis in females aged 15–30 years in the myocarditis cohort

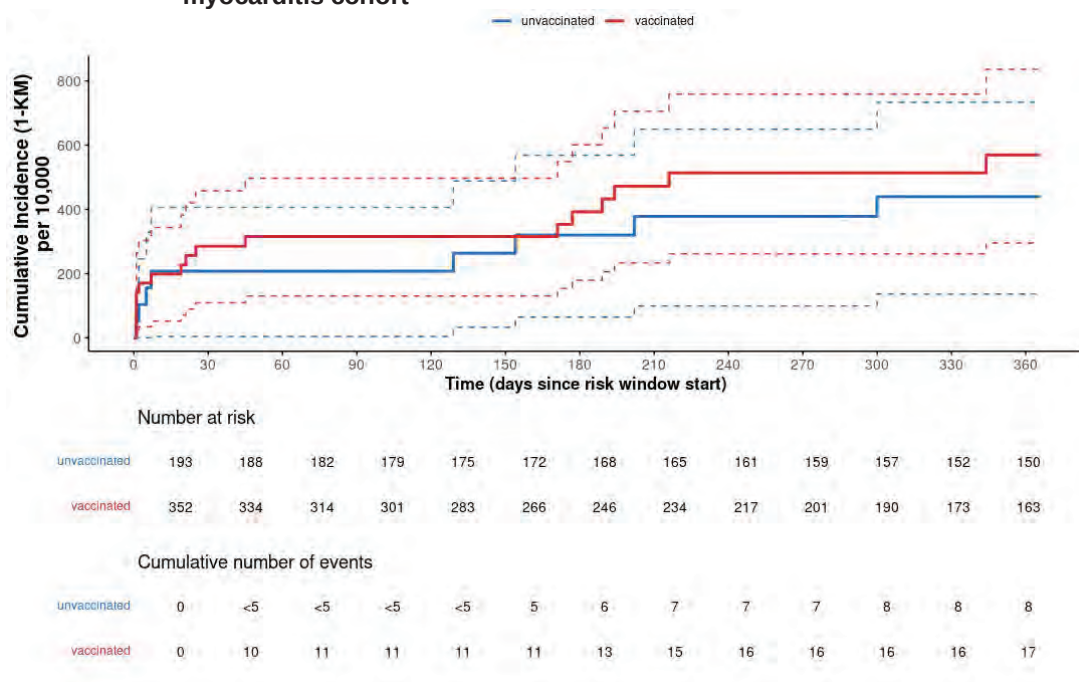


15.2.3.59 NHR: Cumulative incidence of cardiogenic shock in females aged 15–30 years in the myocarditis cohort



15.2.3.60 NHR: Cumulative incidence of arrhythmia in males aged 15–30 years in the myocarditis cohort



15.2.3.61 NHR: Cumulative incidence of death in males aged 15–30 years in the myocarditis cohort**15.2.3.62 NHR: Cumulative incidence of fulminant myocarditis in males aged 15–30 years in the myocarditis cohort**