

# Post-Authorisation Active Surveillance Study of Myocarditis and Pericarditis Among Individuals in Europe Receiving the Pfizer- BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

**First published:** 22/08/2022

**Last updated:** 05/11/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS47708

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### Study ID

47709

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### DARWIN EU® study


No

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### Study countries

 Italy

 Netherlands

 Norway

 Spain

 United Kingdom

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## **Study description**

This study will address the following research question, “What is the clinical course of myocarditis and pericarditis cases after being vaccinated with the Pfizer-BioNTech COVID-19 vaccine in European countries?”.

This cohort study is nested in the ongoing retrospective cohort study (EUPAS41623) titled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine." The parent study includes individuals across 5 European countries who receive at least 1 dose of the Pfizer-BioNTech COVID-19 vaccine, as well as individuals who did not receive a COVID-19 vaccine. For the primary objective (natural history), the study will be conducted in the cohort of cases of myocarditis and of pericarditis identified in the full population of the parent study. For the secondary objective (risk factors), the study will be conducted using the population from the parent study component in which vaccinated and unvaccinated individuals are matched 1:1 on date of vaccination in the vaccinated group and date of study eligibility in the unvaccinated group. Individuals are also matched on age, sex, history of COVID-19, place of residence, history of influenza vaccination, pregnancy status, immunocompromised status, presence of pre-existing medical conditions, and socioeconomic status/education level. The matching variables, vaccination status, and other baseline variables to be identified in a review of the medical literature will be considered as potential risk factors for the development of myocarditis and of pericarditis.

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## **Study status**

Finalised

## **Research institutions and networks**

## Institutions


### Pfizer

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

### University Medical Center Utrecht (UMCU)

 Netherlands

**First published:** 24/11/2021

**Last updated:** 22/02/2024


**Institution**

**Educational Institution**


**Hospital/Clinic/Other health care facility**


**ENCePP partner**


### RTI Health Solutions (RTI-HS)

 France

 Spain

 Sweden

 United Kingdom

 United Kingdom (Northern Ireland)

 United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025

**Institution**

**Not-for-profit**

**ENCePP partner**

## Teamit Institute

 Spain

**First published:** 12/03/2024

**Last updated:** 12/03/2024

**Institution**


**Other**


**ENCePP partner**


## Fondazione Penta ONLUS

## Networks


### Vaccine monitoring Collaboration for Europe (VAC4EU)

 Belgium


 Denmark


 Finland

 France


 Germany

 Italy

 Netherlands

 Norway

 Spain

 United Kingdom

**First published:** 22/09/2020

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Network

Outdated

ENCePP partner

## Contact details

### Study institution contact

Cynthia de Luise [cynthia.deluise@pfizer.com](mailto:cynthia.deluise@pfizer.com)

Study contact

[cynthia.deluise@pfizer.com](mailto:cynthia.deluise@pfizer.com)

### Primary lead investigator

Cynthia de Luise

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 27/10/2021

Actual: 27/10/2021

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### Study start date

Planned: 31/12/2022

Actual: 10/02/2023

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**Data analysis start date**

Planned: 31/03/2024

Actual: 31/03/2024

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**Date of interim report, if expected**

Planned: 22/09/2023

Actual: 29/09/2023

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**Date of final study report**

Planned: 30/06/2025

Actual: 30/06/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[C4591038\\_PROTOCOL AMENDMENT 2\\_V3\\_13MAY2022.pdf](#) (4.52 MB)

[C4591038\\_PROTOCOL AMENDMENT 4 V5.0\\_11JUN2025.pdf](#) (3.08 MB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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## Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Other

**If 'other', further details on the scope of the study**

natural history and risk factors

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To describe the clinical course (treatment, survival, hospitalisations, long-term cardiac outcomes) of myocarditis or 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 and/or pericarditis who had no prior COVID-19 vaccination, using a cohort study.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medicinal product name**

COMIRNATY

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### **Study drug International non-proprietary name (INN) or common name**

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

FAMTOZINAMERAN

RAXTOZINAMERAN

RILTOZINAMERAN

TOZINAMERAN

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### **Anatomical Therapeutic Chemical (ATC) code**

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

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### **Medical condition to be studied**

Myocarditis

Pericarditis

## Population studied

## **Age groups**

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

## **Study design details**

### **Outcomes**

Potential outcomes for myocarditis are treatment, recovery, survival, hospitalisations, sudden cardiac death, heart failure, cardiogenic shock, fulminant myocarditis, inflammatory cardiomyopathy, heart transplant, and arrhythmia.

Potential outcomes for pericarditis are treatment, recovery, survival, hospitalisations, and chronic, restrictive, and recurrent pericarditis. 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.

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### **Data analysis plan**

For the primary objective, the distributions of vaccination status and other baseline characteristics will be described. For continuous variables, means,

standard deviations and quartiles will be estimated. For categorical variables, counts and proportions will be estimated. The missingness of variables will also be described. The occurrence of the different treatments and outcomes during follow-up will be described using counts and proportions. Continuous variables (e.g. length of stay) will be described using means, standard deviations and quartiles. When appropriate, the occurrence of time-to-event outcomes (e.g. death) will be described using the Kaplan-Meier estimator or curve. Analysis will be performed overall by sex and age, COVID-19 history, vaccination status, and time since vaccination.

## Documents

### Study report

[C4591038\\_INTERIM REPORT ABSTRACT\\_18SEP2023.pdf](#) (189.71 KB)

[c4591038-interim-report-body.pdf](#) (5.56 MB)

[c4591038-final report abstract.pdf](#) (699.96 KB)

[C4591038\\_FINAL REPORT PART 1\\_11JUN2025.pdf](#) (18.12 MB)

[C4591038\\_FINAL REPORT PART 2\\_11JUN2025.pdf](#) (19.12 MB)

### Study, other information

[C4591038\\_PROTOCOL AMENDMENT 3 V4.0\\_08AUG2024.pdf](#) (1 MB)

## Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency

but are no longer maintained.

## Data sources

### Data source(s)

Clinical Practice Research Datalink

The Information System for Research in Primary Care (SIDIAP)

PHARMO Data Network

ARS Toscana

Pedianet

EpiChron Cohort

Norwegian Health Registers

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Disease registry](#)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

Yes

### CDM Mappings

### CDM name

ConcepTION CDM

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**CDM website**

<https://www.imi-conception.eu/>

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**CDM release frequency**

6 months

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## Data quality specifications

**Check conformance**

Yes

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**Check completeness**

Yes

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**Check stability**

Yes

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**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

No