

# 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:** 15/07/2024

Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/47709>

### EU PAS number

EUPAS47708

### Study ID

47709

### DARWIN EU® study

No

## 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

Ongoing

## 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

**Last updated:** 22/09/2020

**Network**

**ENCePP partner**

## Contact details

### Study institution contact

Cynthia de Luise

**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: 30/09/2024

## 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)

## 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 type:

Non-interventional study

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#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

#### 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

### Name of medicine

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

(J07BX03) covid-19 vaccines

covid-19 vaccines

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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)

## Data management

## Data sources

### Data source(s)

Clinical Practice Research Datalink

The Information System for Research in Primary Care (SIDIAP)

PHARMO Data Network

ARS Toscana

Pedianet network

EpiChron Cohort

Norwegian Health Registers

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### Data sources (types)

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

[Disease registry](#)

Drug dispensing/prescription data  
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