

# Assessment of risk factors for Myocarditis in the United States (US) using Electronic Health Records and Claims data

**First published:** 23/05/2023

**Last updated:** 26/11/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS104403

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### Study ID

104404

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study status

Finalised

## Research institutions and networks

## Institutions

### Pfizer

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

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

Institution

### Optum



Germany

**First published:** 03/01/2012

**Last updated:** 07/02/2014

Institution

Outdated

Other

ENCePP partner

## Contact details

### Study institution contact

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Study contact

[jing.liu10341e@pfizer.com](mailto:jing.liu10341e@pfizer.com)

### Primary lead investigator

Scott Kelly

Primary lead investigator

# Study timelines

## **Date when funding contract was signed**

Planned: 29/11/2022

Actual: 29/11/2022

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## **Study start date**

Planned: 26/05/2023

Actual: 24/05/2023

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## **Date of final study report**

Planned: 30/11/2025

Actual: 28/10/2025

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[C4591055 NI study protocol\\_v1.0\\_11 May 2023\\_final.pdf](#) (362.88 KB)

[C4591055 NI study protocol\\_v2.0\\_11 Jan 2025\\_clean.pdf](#) (427.77 KB)

## Regulatory

## Was the study required by a regulatory body?

No

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

Not applicable

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

#### **Main study objective:**

Assess and compare demographic, medical history, and comorbidities that may be risk factors for myocarditis.

## 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)

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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

COVID-19

COVID-19 immunisation

# Population studied

## Age groups

- 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)
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## **Estimated number of subjects**

1

# Study design details

## **Outcomes**

To assess and compare demographic, medical history, and comorbidities that may be risk factors for myocarditis in each of three cohorts: 1) Myocarditis after mRNA COVID-19 vaccine, 2) Myocarditis after SARS-CoV-2 infection (2020-2022), or 3) Acute/viral myocarditis prior to the COVID-19 era (pre-2020).

1. To examine the risk factors in each myocarditis cohort stratified by age group at diagnosis, sex, time period and follow-up time (years).
  2. To assess and compare the validity of myocarditis diagnosis case definitions in administrative data for each cohort, via calculating the PPV(Positive predictive value) using electronic medical record review.
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## **Data analysis plan**

In primary analyses, descriptive statistics will be presented to characterize myocarditis patients in terms of demographic and clinical characteristics as of the index date. Additionally, we will examine clinical characteristics, including patient's history for myocarditis pre-2020, post SARS-CoV-2 infection, and post mRNA COVID-19 vaccine cohorts, through utilization of logistic regression models will be used to estimate odds ratios (ORs) and 95% CIs of associations between demographics, clinical characteristics, and empirical model identified risk factor and myocarditis.

# Documents

## Study report

[C4591055 Non-Interventional Study Report\\_Redacted.pdf](#) (2.61 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), other

Optum's Electronic Health Record (EHR) data United States

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### Data sources (types)

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

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

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No