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

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## Administrative details

### **EU PAS number**

EUPAS104403

### Study ID

104404

#### DARWIN EU® study

No

#### **Study countries**

United States

#### **Study status**

Ongoing

### Research institutions and networks

### Institutions

### Pfizer

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Germany

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# Contact details

### Study institution contact

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Study contact

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**Primary lead investigator** Scott Kelly

Primary lead investigator

## Study timelines

Date when funding contract was signed Planned: 29/11/2022 Actual: 29/11/2022

Study start date Planned: 26/05/2023 Actual: 19/01/2023

**Date of final study report** Planned: 30/11/2025

## 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

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

Not applicable

## Methodological aspects

## Study type

## Study type list

### Study topic:

Disease /health condition

### Study type:

Non-interventional study

### 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

Name of medicine COMIRNATY

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)

### 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.

### 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.

### 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

### Data sources

### Data source(s), other

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

### 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

#### **Check completeness**

Unknown

#### **Check stability**

Unknown

### **Check logical consistency**

Unknown

## Data characterisation

### Data characterisation conducted

No