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

Study ID

104404

DARWIN EU® study

No

Study countries

United States

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Institution | Outdated | Other | ENCePP partner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

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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: 24/05/2023

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

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

Medicinal product name

COMIRNATY

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

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

Anatomical Therapeutic Chemical (ATC) code

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

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.

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

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