Interim Analysis of Myocarditis and Pericarditis Associated with COMIRNATY in Persons Less Than 21 Years of Age

First published: 21/08/2025

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Study Planned

Administrative details

EU PAS number

EUPAS1000000600

Study ID

1000000600

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ United States

Study description

This protocol (C4591079) is an interim analysis based on data from the ongoing C4591036 study titled "Low-interventional Study of Myocarditis and Pericarditis Associated with COMIRNATY in Persons Less Than 21 Years of Age" This is a non-interventional study designated as a PASS.
The research objective of this study (C4591079) is as follows:
What are the acute and long term sequalae associated with myocarditis and pericarditis
following vaccination with COMIRNATY?

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

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Study contact

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Primary lead investigator

Cynthia de Luise

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/06/2025

Study start date
Planned: 01/09/2025

Data analysis start date
Planned: 01/09/2025

Date of final study report
Planned: 31/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer 100%

Study protocol

C4591079_PROTOCOL_31JUL2025.pdf (1.12 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

C4591079

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is an interim analysis based on data from the ongoing C4591036 study, “Low- interventional Study of Myocarditis and Pericarditis Associated with COMIRNATY in Persons Less Than 21 Years of Age.”

Main study objective:

Primary objective:

The primary objective of this study is to characterize the potential long-term sequelae associated with myocarditis/pericarditis following COMIRNATY vaccination in persons <21 years old.

Secondary objectives:

1) To characterize the acute course (hospital admission/emergency room (ER) evaluation to discharge) of COMIRNATY-associated myocarditis/pericarditis in persons <21 years old.

2) To compare acute and long-term cardiac outcomes of COMIRNATY-associated myocarditis/pericarditis with those of myocarditis/pericarditis associated with COVID-19, including the multisystem inflammatory syndrome in children associated with COVID-19 in persons <21 years old (MIS-C).

3) To identify possible sociodemographic and medical risk factors, such as age, sex assigned at birth, race, ethnicity, insurance, and zip code, for greater frequency and severity of long-term cardiac sequelae in persons <21 years old.

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

Population studied

Short description of the study population

This study uses data from three cohorts of participants in the ongoing C4591036 study:

Cohort 1: Prospectively ascertained cases of probable or confirmed myocarditis/pericarditis associated with COMIRNATY, i.e., participants enrolled under the protocol during hospitalization or ≤ 2 weeks after hospital discharge.

Cohort 2: Retrospectively ascertained cases of probable or confirmed myocarditis /
pericarditis associated with COMIRNATY, i.e., participants enrolled >2 weeks after

hospital discharge (combination of retrospective data collection from electronic medical records (EMRs) and prospective data from the time that the participant signs
informed consent/assent). Participants can be retrospectively or prospectively ascertained and enrolled at any time from their COMIRNATY-associated myocarditis/pericarditis.

Cohort 3: Comparator cohort of COVID-19-related myocarditis/pericarditis, including
MIS-C. Participants can be retrospectively or prospectively ascertained and enrolled
at any time from their COVID-19 or MIS-C-associated myocarditis/pericarditis. Cohort 3 participants will not be separated into COVID-19-associated myocarditis/pericarditis with or without MIS-C because of the rarity of myocardial
involvement in children with acute severe COVID-19.

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.

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