Post-Approval Observational Cohort Study to Evaluate the Safety of the COMIRNATY 2023-2024 Formula in the United States

First published: 03/01/2024

Last updated: 06/05/2026

Study Finalised

Administrative details

EU PAS number

EUPAS108135

Study ID

108136

DARWIN EU® study

No

Study countries

United States

Study description

This study aims to answer the following research question: What is the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula in the United States?

In Phase 1, the primary objective is to estimate the incidence of pre-specified safety events of interest following vaccination with the COMIRNATY 2023-2024 Formula compared to the incidence of these events during a control window (i.e. expected rates of these events).

In Phase 2, the primary objective is to estimate the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula compared to individuals with no recorded vaccination with the COMIRNATY 2023-2024 Formula. The secondary objective is to estimate the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula compared to individuals with no recorded vaccination with the COMIRNATY 2023-2024 Formula among subgroups of individuals with concomitant administration of a non-COVID-19 vaccine, immunocompromised individuals, individuals with specific comorbidities, individuals with prior SARS-CoV-2 infection, individuals with prior COVID-19 vaccination, pregnant women, pediatric subjects, and the elderly, if sample size permits. This is a non-interventional observational study utilizing an administrative claims database in the US. Phase 1 will utilize a self-controlled risk interval (SCRI) design, and Phase 2 will utilize a matched comparative safety cohort design.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

OptumInsight Life Science, Inc.

Contact details

Study institution contact

Jenny Sun jenny.sun@pfizer.com

Study contact

jenny.sun@pfizer.com

Primary lead investigator

Ian Stryker

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/11/2023

Actual: 09/11/2023

Study start date
Planned: 15/01/2024

Actual: 15/01/2025

Date of interim report, if expected
Planned: 30/06/2024

Actual: 28/06/2025

Date of final study report
Planned: 30/04/2026

Actual: 30/04/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C4591062_PROTOCOL AND STATISTICAL ANALYSIS PLAN_V1.0_12DEC2023.pdf (682.6 KB)

C4591062_PROTOCOL AND STATISTICAL ANALYSIS PLAN V2.0_29AUG2025.pdf (716.96 KB)

C4591062_PROTOCOL AND STATISTICAL ANALYSIS PLAN_V3 AMENDMENT 2_18MAR2026.pdf (1.02 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Herbal 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 a non-interventional observational study utilizing an administrative claims database in the US. Phase 1 will utilize a self-controlled risk interval

(SCRI) design, and Phase 2 will utilize a matched comparative safety cohort design

Main study objective:
To estimate the incidence of pre-specified safety events of interest following vaccination with the COMIRNATY 2023-2024 Formula compared to the incidence of these events during a control window (i.e. expected rates of these events).

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

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

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

160.000

Study design details

Setting

The source population for this study will consist of all individuals with at least one medical or pharmacy claim from 11 September 2023 through 31 March 2024. The end date of 31 March 2024 was chosen based on the assumption that vaccine uptake will be similar to uptake during the 2022-2023 season. During the 2022-2023 COVID-19 season, the end of March reflected the time when uptake of the bivalent booster was no longer increasing (i.e., most individuals who received the bivalent booster dose had done so prior to March 2023), and COVID-19 cases declined substantially from their peak (CDC, 2020).

Outcomes

The pre-specified safety outcomes of interest include the following: acute disseminated encephalomyelitis (ADEM), anaphylaxis, Bell’s palsy, cerebral venous sinus thrombosis (CVST), convulsions/seizures (non-febrile), encephalomyelitis, glomerulonephritis, Guillain-Barré syndrome, herpes zoster, immune-mediated myositis,

immune thrombocytopenia, Kawasaki disease, multi inflammatory syndrome (in children and adults), multiple sclerosis (MS), myocardial infarction (MI), myocarditis/pericarditis, pulmonary embolism (PE), hemorrhagic stroke, ischemic stroke, and transverse myelitis. Study outcomes will be identified through claims indicators using published validated claims-based algorithms with high performance when available.

Data analysis plan

For the phase 1 SCRI design, the observed incidence rates of the pre-specified safety outcomes of interest will be estimated in the risk window and the control window. Among individuals who experience an outcome of interest, an exact conditional Poisson regression model with the natural logarithm of the person-time as the offset will be used to calculate the rate ratio and corresponding 95% confidence interval (CI) of events occurring during the risk period relative to the control period. The results from the SCRI utilizing the Optum pre-adjudicated claims database will be presented in the interim report, while results utilizing the ORD will be presented in the final report. Please see the protocol for a description of the data analysis plan for the phase 2 cohort study.

Data management

Data sources

Data source(s), other

Optum pre-adjudicated claims database United States, Optum Research Database United States

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Data sources (types)

Administrative healthcare records (e.g., claims)

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