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: 15/03/2024

Study Planned

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

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

OptumInsight Life Science, Inc.

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Katie Kendrick

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

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

Date of final study report
Planned: 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)

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:

Non-interventional study

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

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

1

Study design details

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

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