

# Non-Interventional Postmarketing Safety Study to Evaluate the COMIRNATY 2024-2025 Formula (monovalent KP.2) in the United States

**First published:** 21/02/2025

**Last updated:** 01/08/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000476

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### Study ID

1000000476

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

The study will be conducted in two phases, each with its own specific objectives.

In Phase 1, the primary objective is to estimate the incidence of pre-specified AESIs in a risk window following vaccination with the COMIRNATY 2024-2025 Formula compared to the incidence of these events during a post-vaccination control window (ie, expected rates of these events).

In Phase 2, the primary objective is to estimate the incidence of pre-specified AESIs among individuals who receive the COMIRNATY 2024-2025 Formula compared to the incidence among individuals with no recorded vaccination with the COMIRNATY 2024-2025 Formula.

The secondary objective is to estimate the incidence of pre-specified AESIs among individuals who receive the COMIRNATY 2024-2025 Formula compared to the incidence among individuals with no recorded vaccination with the COMIRNATY 2024-2025 Formula within subgroups of immunocompromised individuals, individuals with specific comorbidities, individuals with prior SARS-CoV-2 infection, individuals with prior COVID-19 vaccination, individuals with concomitant administration of non-COVID-19 vaccines, pregnant individuals, children, 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.

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## **Study status**

Ongoing

## **Research institutions and networks**

### **Institutions**

Pfizer

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Institution

Optum - United States

## Contact details

### Study institution contact

Ian Stryker [Ian.Stryker@pfizer.com](mailto:Ian.Stryker@pfizer.com)

Study contact

[Ian.Stryker@pfizer.com](mailto:Ian.Stryker@pfizer.com)

### Primary lead investigator

Jenny Sun

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 23/08/2024

Actual: 23/08/2024

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**Study start date**

Planned: 11/03/2025

Actual: 11/03/2025

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**Date of interim report, if expected**

Planned: 30/06/2025

Actual: 30/06/2025

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**Date of final study report**

Planned: 28/02/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[C4591070 PROTOCOL AND STATISTICAL ANALYSIS PLAN\\_28OCT2024.pdf](#) (1.27 MB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Study design:**

This is a non-interventional observational study utilizing an administrative claims database in the US.

**Main study objective:**

To estimate the incidence of pre-specified AESIs in a risk window following vaccination with the COMIRNATY 2024-2025 Formula compared to the incidence of these events during a post vaccination 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)

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### **Anatomical Therapeutic Chemical (ATC) code**

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

## Population studied

### **Short description of the study population**

The study population will be drawn from a nationwide healthcare insurance claims database.

It will include all eligible individuals who receive the COMIRNATY 2024-2025 Formula from 22 August 2024 (the date of product approval/authorization) through 31 March 2025.

The end date of 31 March 2025 was chosen based on the assumption that vaccine uptake will be similar to uptake during the 2022-2023 and 2023-2024 vaccine seasons.

During the 2022-2023 and 2023-2024 COVID-19 seasons, the end of March reflected the time when uptake of the COVID-19 vaccine was no longer increasing (ie, most individuals who received the COVID-19 vaccine had done so prior to March), and COVID-19 cases declined substantially from their fall/winter peak.

The source population for this study will consist of all individuals with at least one medical or pharmacy claim from 22 August 2024 through 31 March 2025. In Phase 1, individuals age  $\geq 6$  months will be eligible for inclusion if they receive at least one dose of the COMIRNATY 2024-2025 Formula from 22 August 2024 through 31 March 2025, have continuous medical and pharmacy insurance coverage in the 365 days prior to their vaccination date, experience a safety outcome of interest during a risk or control period, and do not experience the safety event of interest during the clean period prior to vaccination. In Phase 2, individuals age  $\geq 6$  months will be eligible for inclusion in the exposed cohort if they receive a dose of the COMIRNATY 2024-2025 Formula and have continuous medical and pharmacy insurance coverage in the 365 days prior to their vaccination. Individuals age  $\geq 6$  months will be eligible for inclusion in the unexposed cohort if they do not receive a dose of the COMIRNATY 2024-2025 Formula but do have an outpatient physician visit with or without receipt of another vaccine and if they have continuous medical and pharmacy insurance coverage in the 365 days prior to their outpatient healthcare encounter. Individuals in the unexposed cohort will be matched to those in the exposed cohort if their outpatient healthcare encounter is within the same 14-day calendar period as the exposed individual's vaccination date and if they are in the same age group.

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### **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)

## Study design details

### Data analysis plan

Phase 1: For the SCRI design, the observed incidence rates of the pre-specified AEsIs will be estimated in the risk window and the control window.

Among individuals who experience an outcome of interest in either the risk window or the control window (but not both), an exact conditional Poisson regression model with the natural logarithm of the person-time as the offset will be used to calculate the relative incidence (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

### 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 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No