

# Post-Authorisation Safety Study of Comirnaty Original/Omicron BA.1 and Comirnaty Original/Omicron BA.4-5 in Europe

**First published:** 22/01/2024

**Last updated:** 15/07/2024

Study

Ongoing

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/199012>

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### **EU PAS number**

EUPAS108847

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### **Study ID**

199012

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### **DARWIN EU® study**

No

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## Study countries

- Italy
  - Netherlands
  - Norway
  - Spain
  - United Kingdom
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## Study description

This study aims to answer the research question is there an increased risk of pre-specified adverse events of special interest (AESIs) after vaccination with bivalent BA.1 or bivalent BA.4-5 compared with no vaccination against COVID-19 among individuals with comparable vaccination histories? The primary study objective is to determine whether there is an increased risk of pre-specified AESIs following the administration of bivalent BA.1 or bivalent BA.4-5 compared with not receiving any COVID-19 vaccine during follow-up. A retrospective cohort design will be used to estimate the incidence of AESIs after receiving a Pfizer-BioNTech COVID-19 bivalent vaccine, and these incidences will be compared with those in a comparator group that did not receive any COVID-19 vaccine during follow-up. Exposed individuals will be matched to unexposed individuals using relevant individual characteristics. For selected AESIs a self-controlled risk interval (SCRI) study design will also be used, when appropriate. The source population will comprise all individuals registered in each of the health care data sources who are eligible to receive bivalent BA.1 or bivalent BA.4-5. The study period will start on the date of availability of the bivalent BA.1, which was the first bivalent vaccine to receive authorisation in the EU (on 01 Sep 2022), in each participating country and will end on 31 Aug 2024 or the date of the latest data availability. BA.4-5 received authorisation in the EU on 12 Sep 2022. Individuals will be evaluated for eligibility and time zero will be determined as the date of exposure (vaccination with bivalent BA.1 or bivalent BA.4-5). Matching will occur at time zero and follow-up will begin at time zero.

Individuals who have received at least one dose of bivalent BA.1 or bivalent BA.4-5 will be included in the exposed cohort. Individuals who have not received a dose of any COVID-19 vaccine at time zero will be included in the unexposed cohort.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

#### Pfizer

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

#### University Medical Center Utrecht (UMCU)

Netherlands

**First published:** 24/11/2021

**Last updated:** 22/02/2024

**Institution**

**Educational Institution**

**Hospital/Clinic/Other health care facility**

**ENCePP partner**

## RTI Health Solutions (RTI-HS)

- France
- Spain
- Sweden
- United Kingdom
- United Kingdom (Northern Ireland)
- United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025

**Institution**

**Not-for-profit**

**ENCePP partner**

## Teamit Institute

- Spain

**First published:** 12/03/2024

**Last updated:** 12/03/2024

**Institution**

**Other**

**ENCePP partner**

## Fondaziione Penta ONLUS

## Networks

## Vaccine monitoring Collaboration for Europe (VAC4EU)

- Belgium
- Denmark
- Finland
- France
- Germany
- Italy
- Netherlands
- Norway
- Spain
- United Kingdom

**First published:** 22/09/2020

**Last updated:** 22/09/2020

Network

ENCePP partner

## Contact details

### Study institution contact

Cynthia de Luise

Study contact

[cynthia.deluise@pfizer.com](mailto:cynthia.deluise@pfizer.com)

### Primary lead investigator

Cynthia de Luise

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 31/01/2024

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### **Study start date**

Planned: 31/03/2024

Actual: 13/06/2024

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### **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

[C4591052\\_PROTOCOL AMENDMENT 2\\_V3.0\\_08JAN2024.pdf](#)(1.02 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)?

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

To determine whether there is an increased risk of pre-specified AESIs following the administration of bivalent BA.1 or bivalent BA.4-5 compared with not receiving any COVID-19 vaccine during follow-up.

## Study Design

### **Non-interventional study design**

Cohort

Other

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### **Non-interventional study design, other**

Self-controlled risk interval

## Study drug and medical condition

### **Name of medicine**

COMIRNATY

COMIRNATY 15/15  $\hat{\text{A}}\mu\text{G}$  - ORIGINAL/OMICRON BA.1 (--) - DISPERSION FOR INJECTION

COMIRNATY 15/15  $\hat{\text{A}}\mu\text{G}$  - ORIGINAL/OMICRON BA.4-5 (--) - DISPERSION FOR INJECTION

COMIRNATY 5/5  $\hat{\text{A}}\mu\text{G}$  - ORIGINAL/OMICRON BA.4-5 (--) - CONCENTRATE FOR DISPERSION FOR INJECTION

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

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

FAMTOZINAMERAN

RAXTOZINAMERAN

RILTOZINAMERAN

TOZINAMERAN

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

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

(J07BX) Other viral vaccines

Other viral vaccines

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## **Medical condition to be studied**

Adverse event following immunisation

# Population studied

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

The study size will be determined by the uptake of the bivalent BA.1 and bivalent BA.4-5 vaccines in the contributing data sources during the study period.

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## **Age groups**

Preterm newborn infants (0 - 27 days)

Term newborn infants (0 - 27 days)

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)

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## **Special population of interest**

Immunocompromised

Pregnant women

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## **Estimated number of subjects**

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# Study design details

## **Outcomes**

Risk of pre-specified AESIs following the administration of bivalent BA.1 or bivalent BA.4-5 compared with not receiving any COVID-19 vaccine during follow-up.

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## **Data analysis plan**

Data from the matched cohort design will be analysed as follows: Conditional exchangeability: The pairs will be matched using several variables considered as potential confounders to ensure conditional exchangeability. Additional standard epidemiological methods, based on propensity scores, will be used to improve adjustment for confounding, if necessary. The effect estimates will be reported as risk ratios and risk differences (and their corresponding 95% confidence intervals) for those exposed to a Pfizer-BioNTech COVID-19 bivalent vaccine compared with those not exposed to any COVID-19 vaccine during follow-up. Appropriate data analysis models will be used to estimate the incidence rate ratios of AESIs in the risk and the control windows in the SCRI study.

# Data management

## Data sources

### **Data source(s)**

Pedinet network

PHARMO Data Network

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink

EpiChron Cohort

Norwegian Health Registers

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### **Data sources (types)**

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Other

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### **Data sources (types), other**

Routine primary care electronic patient registry

## 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