

# A Non-Interventional Post-Authorization Safety Study (PASS) for Active Safety Surveillance of Recipients of the Pfizer-BioNTech COVID-19 mRNA vaccine in the EU

**First published:** 08/06/2021

**Last updated:** 14/05/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS41302

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### Study ID

47010

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### DARWIN EU® study

No

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### Study countries

 Germany

 Italy

## **Study description**

This prospective, observational cohort study is a multi-center, non-interventional post-authorization safety study conducted to evaluate safety of study participants receiving the Pfizer-BioNTech COVID-19 mRNA vaccine. The study period is 30 months. Each participant will be followed from baseline (vaccination dose received at index date, where index date is defined as the date of Pfizer-BioNTech COVID-19 mRNA vaccine dose received within the 5 days prior to enrolment, regardless of dose number) until death, withdrawal of consent, loss to follow-up, 24 months or end of study period, whichever occurs first. Data will be collected at baseline directly from the participants receiving the vaccine and/or their designee, this may include a health care provider (HCP) or study staff at the site administering the vaccine. This study will collect information on all reported occurrences of the medically attended safety events of interest, which is based on the adverse events of special interest lists specified by ACCESS and SPEAC/Brighton Collaboration, for which the participant sought medical care during the study period. Data collection will be performed at baseline (vaccination dose received at index date) and at weeks 1, 2, 4, 6, 8, 12 and every three months thereafter, through 24 months following index date. In addition, data will be collected on any subsequent vaccine doses received during the study period. Participant reported medically attended safety events of interest will be confirmed by the treating HCPs or through medical record documentation if needed to validate or establish the diagnosis associated with the event and validate the occurrence of a safety event of interest, or other clinically significant event. This primary data collection study will aim for up to 10,000 vaccine recipients with 2 years of follow-up data from a total of approximately 20 centers. The study will be conducted in Germany, Italy and Spain.

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## **Study status**

Finalised

## Research institutions and networks

### Institutions


Pfizer

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

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

Institution

IQVIA

 United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

Institution

Non-Pharmaceutical company

ENCePP partner

### Networks

Self Care Catalysts

### Contact details

### **Study institution contact**

Cherise Wong [cherise.wong@pfizer.com](mailto:cherise.wong@pfizer.com)

Study contact

[cherise.wong@pfizer.com](mailto:cherise.wong@pfizer.com)

### **Primary lead investigator**

Cherise Wong

Primary lead investigator

## Study timelines

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

Planned: 27/10/2020

Actual: 27/10/2020

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### **Study start date**

Planned: 31/08/2021

Actual: 28/09/2021

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### **Date of final study report**

Planned: 30/09/2024

Actual: 10/05/2023

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## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[C4591010\\_FINAL APPROVED PROTOCOL\\_20MAY2021.pdf](#) (3.25 MB)

[C4591010\\_PROTOCOL AMENDMENT 2\\_07JAN2022.pdf](#) (3.62 MB)

## Regulatory

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

No

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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

Disease epidemiology

Drug utilisation

**Main study objective:**

Estimate the real-world incidence of medically attended safety events of interest and other clinically significant events among individuals vaccinated with the Pfizer-BioNTech COVID-19 mRNA vaccine after authorization in the European Union (EU).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

COMIRNATY

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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

(J07BX03) covid-19 vaccines

covid-19 vaccines

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### **Medical condition to be studied**

COVID-19 immunisation

## Population studied

### **Age groups**

- 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**

10000

## Study design details

### **Outcomes**

Real-world incidence of medically attended safety events of interest and other clinically significant events among individuals vaccinated with the Pfizer-BioNTech COVID-19 mRNA vaccine after authorization in the European Union, Whether the vaccine recipients experience increased risk of medically attended safety events of interest (SEIs) post vaccination, via comparison with expected background rates and, as feasible, by self-controlled risk interval analysis  
Incidence rates of medically attended SEIs among subcohorts of interest such as pregnant vaccine recipients, immunocompromised participants, and stratified by age

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### **Data analysis plan**

The study population of Pfizer-BioNTech COVID-19 vaccine recipients will be described in terms of demographic and health history characteristics, along with vaccination characteristics such as number of doses received and interval between doses. The incidence rates of medically attended safety events of interest will be estimated in the primary safety dataset of participants who enroll within 2 days of vaccination. Rates will also be estimated for the overall study population and within subcohorts of interest such as pregnant vaccine recipients, immunocompromised participants, and within age categories. The final analysis will also include subcohorts for heterologous vaccination courses. For events with a sufficient number of cases, the observed rate will be compared with expected rates where available from historical or concurrent rates as reported in the scientific literature or other sources. For selected endpoints a SCRI analysis will be implemented if case counts are sufficient.

## Documents

### **Study report**

[C4591010\\_PROGRESS REPORT\\_31AUG2021.pdf](#) (1.8 MB)

## 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 sources (types)

Other

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### Data sources (types), other

Prospective patient-based data collection

## 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