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





# Administrative details

EU PAS number	
EUPAS41302	
Study ID	
47010	
DARWIN EU® study	
No	
Study countries	
Germany	
Italy	

Spain
-------

#### Study description

This prospective, observational cohort study is a multi-center, noninterventional 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.

#### **Study status**

## 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
<b>Last updated:</b> 22/04/2024
Institution Non-Pharmaceutical company ENCePP partner

## **Networks**

**Self Care Catalysts** 

## Contact details

### **Study institution contact**

## Cherise Wong cherise.wong@pfizer.com

**Study contact** 

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

#### Study start date

Planned: 31/08/2021

Actual: 28/09/2021

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

Planned: 30/09/2024

Actual: 10/05/2023

## 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

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

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

#### Name of medicine

**COMIRNATY** 

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

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

**FAMTOZINAMERAN** 

**RAXTOZINAMERAN** 

**RILTOZINAMERAN** 

**TOZINAMERAN** 

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

(J07BN01) covid-19, RNA-based vaccine covid-19, RNA-based vaccine (J07BX03) covid-19 vaccines covid-19 vaccines

#### 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)

### Special population of interest

**Immunocompromised** 

Pregnant women

#### **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

### 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

### 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

### **Check completeness**

Unknown

### **Check stability**

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No