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

Study ID

47010

DARWIN EU® study

No

Study countries

Germany

Italy

Spain

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.

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

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Study contact

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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

Medicinal product name

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

10.000

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

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