HERO-Together Boost: A post-Emergency Use Authorization observational cohort study to evaluate the safety of the Pfizer-BioNTech COVID-19 vaccine

First published: 08/08/2023

Last updated: 10/03/2026

Study | Finalised

Administrative details

EU PAS number

EUPAS105791

Study ID

106796

DARWIN EU® study

No

Study countries

United States

Study description

The research question addressed by this study is: what are the incidence rates of safety events of interest among persons vaccinated with the Pfizer-BioNTech COVID 19 vaccine in a United States (US) cohort? The primary study objective is to estimate the real-world incidence of safety events of interest among recipients of the Pfizer-BioNTech COVID-19 vaccine following Emergency Use Authorization (EUA). The secondary objective is to estimate the incidence rates of safety events of interest among subcohorts of interest, including individuals who are pregnant, individuals who are immunocompromised, and stratified by age. This is a prospective observational cohort study of US residents, in which data are collected from participant self-report at regular intervals following vaccination, primarily using a secure web portal. Safety event occurrence will be confirmed by medical record review and/or linked claims/electronic health record (EHR) data. The study period will be 18 months.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Duke Clinical Research Institute (DCRI)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Verily Life Sciences, CVS Health Clinical Trial Services

Contact details

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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: 19/04/2023

Actual: 19/04/2023

Study start date
Planned: 30/06/2023

Actual: 24/08/2023

Date of final study report
Planned: 28/02/2026

Actual: 05/02/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C4591049_PROTOCOL AMENDMENT 1_V2_08MAR2023.pdf (562.38 KB)

C4591049_PROTOCOL AMENDMENT 2 V3_25APR2025.pdf (653.73 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Prospective, observational, voluntary safety study

Main study objective:

To estimate the real-world incidence of safety events of interest among recipients of the Pfizer-BioNTech COVID-19 vaccine following EUA

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Pfizer-BioNTech COVID-19 vaccine

Anatomical Therapeutic Chemical (ATC) code

(J07BN) 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

Setting

The source population will be adults living in the US, whereby after enrollment study participants are followed for up to 18 months. Given the broad source

population, the study will apply multiple recruitment strategies to ensure enrollment of a diverse sample to support generalizability of results. The primary study recruitment strategy (pharmacy email invitations) may leverage oversampling of traditionally underrepresented populations to ensure adequate representation in the final analytic population.

Outcomes

Incidence of safety events of interest among recipients of the Pfizer-BioNTech COVID-19 vaccine following EUA, Incidence rates of safety events of interest among subcohorts of interest, including individuals who are pregnant, individuals who are immunocompromised, and stratified by age

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Data analysis plan

Vaccination and baseline characteristics will be summarized using descriptive statistics, including measures of central tendency and dispersion (means, medians, standard deviations) for continuous variables and percentages for categorical variables. The primary analysis for each objective will be restricted to participants who enrolled within 10 days of vaccination to mitigate the risk of selective enrollment and disproportionate representation of higher risk participants. The number and incidence rate for each safety event of interest will be calculated overall, and within subgroups of interest, including pregnant women, immunocompromised individuals, and within age groups. Rates will also be stratified by other baseline characteristics, such as race/ethnicity, work setting, prior COVID-19, and geographic region, data permitting.

Summary results

The study population was primarily White (82.2%), female (58.7%), not Hispanic or Latino (87.6%) with a mean age of 5 4.3 years ranging from 18 to 88 years and had a low prevalence of comorbidity at Baseline. The incidence proportions of both non-adjudicated (< 1.0%) and confirmed hospitalizations (< 1.0%) due

to AESIs was low. Non-hospitalized AESIs were also relatively uncommon, reported by approximately 5.2% of study participants, with non-severe allergic reactions being the most frequent event (1.5% of study participants). All other non-hospitalized AESIs occurred in < 1.0% of participants. Analysis of incidence rates of AESI among subgroups of interest estimate higher rates of confirmed hospitalization among recipients of the Pfizer-BioNTech COVID-19 vaccine who were in the subgroups of immunosuppressed or 70+ years of age, than in strata of immunocompetent or younger ages, respectively.

There was poor concordance (kappa=0.26) and a low positive specific agreement (0.33) between claims-based methods and medical record review adjudication for safety event
confirmation.

Documents

Abstract of study report

c4591049-abstract.pdf (649.41 KB)

Study report

c4591049-report-body.pdf (6.14 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 source(s), other

Event confirmation via data linkage andor medical record review United States

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