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

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## Administrative details

**Study description** 

EU PAS number	
EUPAS105791	
Study ID	
106796	
DARWIN EU® study	
No	
Study countries	
United States	

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**

Ongoing

## Research institutions and networks

## Institutions

## Pfizer

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## Duke Clinical Research Institute (DCRI)

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Verily Life Sciences, CVS Health Clinical Trial Services

## Contact details

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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

# 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)

## 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 type

Study type list

#### Study type:

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

#### 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

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

(J07BX) Other viral vaccines
Other viral vaccines

#### Medical condition to be studied

COVID-19 immunisation

## Population studied

#### Age groups

- Adults (18 to < 46 years)</li>
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)</li>
- Adults (75 to < 85 years)</li>
- Adults (85 years and over)

#### **Special population of interest**

Immunocompromised

Pregnant women

#### **Estimated number of subjects**

500

## Study design details

#### **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

#### 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.

## 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 stability**

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No