

# Active Safety Surveillance of the Pfizer-BioNTech COVID-19 Vaccine in the United States

## Department of Defense Population Following Emergency Use Authorization

**First published:** 03/07/2023

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/107862>

### EU PAS number

EUPAS50375

### Study ID

107862

### DARWIN EU® study

No

### Study countries

United States

### Study description

This study aims to answer the research question: What are the incidence rates of safety events of interest (based on adverse events of special interest AESI), overall and in sub-cohorts of interest, among individuals in the United States DoD Military Health System (MHS) vaccinated with the Pfizer-BioNTech COVID-19 Vaccine as compared to expected rates of those events? The primary objectives are 1) to assess whether individuals identified in the DoD MHS experience increased risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 Vaccine, specifically in the following groups:

individuals receiving at least one dose, individuals receiving the primary series, and individuals receiving approved booster dose(s) of the Pfizer-BioNTech COVID-19 Vaccine after the primary series and 2) to assess whether sub-cohorts of interest (ie, pregnant women, immunocompromised, elderly, individuals with specific comorbidities, individuals receiving only one dose of the Pfizer-BioNTech COVID-19 Vaccine, and individuals with prior SARS-CoV-2 infection) identified in the DoD MHS experience increased risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 Vaccine. This post-EUA active safety surveillance study will employ a retrospective, longitudinal, observational cohort study design. The observed safety event of interest rates in the cohort of individuals who received the Pfizer-BioNTech Vaccine between 11 December 2020 and 30 June 2023 will be compared to expected rates derived in 3 control groups: active comparator cohort, general population comparator cohort, and self-controls. Update: Study C4591011 was terminated in 14 September 2023, the study objectives were addressed by earlier availability of data from multiple other studies with similar study endpoints and analyses. No study reports were prepared.

## Study status

Finalised

## Research institution and networks

### Institutions

**Pfizer**

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

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Institution

Analysis Group, Inc., The Henry M. Jackson Foundation for the Advancement of Military Medicine Inc., Defense Health Agency

## Contact details

### Study institution contact

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Study contact

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**Primary lead investigator**

Heather Ward

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned:

28/01/2021

Actual:

28/01/2021

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### Study start date

Planned:

31/01/2023

Actual:

14/09/2023

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### Date of final study report

Planned:

31/01/2025

Actual:

14/09/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[C4591011\\_PROTOCOL AMENDMENT 2\\_09AUG2022.pdf\(3.41 MB\)](#)

## 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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**Main study objective:**

To assess whether individuals identified in the DoD MHS experience increased risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 Vaccine, specifically in the following groups: individuals receiving at least 1 dose, individuals receiving the primary series, individuals receiving approved booster dose(s) of the Pfizer-BioNTech COVID-19 Vaccine after the primary series

### Study Design

**Non-interventional study design**

Cohort

### Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J07BX03) covid-19 vaccines

### Population studied

**Age groups**

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)  
Children (2 to < 12 years)  
Adolescents (12 to < 18 years)  
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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### **Estimated number of subjects**

1

## **Study design details**

### **Outcomes**

Risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 vaccine among various groups of individuals and sub-cohorts of interest in the DoD MHS, The proportion of individuals receiving at least 1 dose of the vaccine, 2-dose and 3-dose vaccine completion rates, booster dose(s) completion rate, distribution of time gaps between doses for the primary series and between completion of the primary series and booster dose(s), demographics and health histories of recipients, overall and among the sub-cohorts of interest

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### **Data analysis plan**

The cohort design will compare the incidence of the safety event of interest between a COVID-19 vaccine recipient cohort and the respective comparator cohorts as follows: Multivariate adjustment using Poisson regression will be conducted for the selected safety events of interest, comparing incidence rates of safety events in individuals receiving COVID-19 vaccine to active comparators. Risk of safety events among COVID-19 vaccinated individuals and contemporary unvaccinated controls will be compared using inverse probability of treatment weighting. SCCS design with a post-vaccination control time period will be conducted for the selected safety events of interest. Case validation/adjudication through medical records review may be conducted if a statistically significant finding of association is found. Descriptive statistics will be used to summarize baseline demographics, clinical characteristics, and vaccine utilization patterns. Various subgroup analyses will also be conducted

## **Data management**

### **Data sources**

**Data source(s), other**

United States Department of Defense Military Health System United States

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**Data sources (types)**

Administrative data (e.g. claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

## 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