



7.3.3 C4591011: Active safety surveillance of the Pfizer-BioNTech COVID-19 vaccine in the U.S. Department of Defense population following Emergency Use Authorization

The primary objective of this study is to assess whether individuals and sub-cohorts of interest (i.e., 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) in the Department of Defense (DoD) military health system (MHS) experience increased risk of safety events of interest following receipt of the Pfizer-BioNTech COVID-19 vaccine. Secondary objectives are to characterize utilization patterns of the Pfizer-BioNTech COVID-19 vaccine among individuals within the DoD MHS.

This active safety surveillance study will utilize a rapid-cycle, longitudinal, observational cohort study design to assess real-world safety of the Pfizer-BioNTech COVID-19 vaccine using a self-controlled risk interval design and a cohort design with two comparator populations (2018/2019 season influenza vaccine recipients and unvaccinated matched controls). Safety events of interest are aligned with AESIs from the Brighton Collaboration's SPEAC Project, FDA, and CDC's Advisory Committee on Immunization Practices (ACIP) enhanced safety monitoring recommendations. A stepwise data analysis process will include signal detection, evaluation, and verification. The study will use coding and medical record data from the DoD MHS Data Repository and will be conducted for 30-months post-EUA.

The proposed study milestones are:

Interim report submissions: June 30, 2021; December 31, 2021; June 30, 2022; December 31, 2022

Final study report submission: December 31, 2023

Reviewer comment: This study was proposed in the original EUA submission (EUA 27034/0). The final study protocol was submitted to EUA 27034/68 and reviewed by the CBER BEST team. An IR response (EUA 27034/186) indicated that the start date for C4591011 is delayed due to a change in study collaborators and the first interim report will be submitted by December 31, 2021 rather than June 30, 2021. Please see previous review memorandums for additional details.

7.3.4 C4591012: Post-emergency use authorization active safety surveillance study among individuals in the Veteran's Affairs Health System receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) vaccine

The primary objective of this study is to assess whether individuals and sub-cohorts of interest (i.e., 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) in the Veterans Health Administration