Pfizer Global Regulatory Affairs
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Global Product Development

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Director
Office of Vaccines Research and Review
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

SN 0267

Re: Covid-19 Vaccine (BNT162/PF-07302048) BB-IND 19736

IND Amendment –

- **Post-authorization Vaccine Effectiveness Studies: Study C4591014, WI235284, WI255886 Protocols**
- **Statistical Analysis Plan for Study WI255886**

Dear Dr. Gruber,

Reference is made to BB-IND 19736 for the COVID-19 vaccine (BNT162; PF-07302048), which Pfizer and BioNTech are developing for the prevention of COVID-19 in adults ≥16 years of age. The IND was effective on April 29, 2020. Further references is made to the Emergency Use Authorization (EUA 27034) that was granted for this vaccine (Pfizer-BioNTech COVID-19 Vaccine) on 11 December 2020, the agreed Pharmacovigilence Plan, and the Request for Comments and Advice submitted 22 February 2021 to BB-IND 19736 (SN 224) regarding Pfizer-BioNTech's commitment to evaluate vaccine effectiveness.

The present submission provides final protocols for three post-authorization studies to evaluate vaccine effectiveness (test negative design) of BNT162b2, as described in the 22 February 2021 Request, in Module 5.3.5.4. Pfizer/BioNTech have incorporated feedback received from CBER's 05 March 2021 Response to the 22 February 2021 Request.

- WI235284 entitled, "*Respiratory Syncytial Virus (RSV) in Older Adults and Pregnant Women Study (ROAPS)"* Amendment for BNT162b2 Post-authorization Vaccine Effectiveness - Pfizer-Emory Research Collaboration
    - Pfizer has been engaged in a research collaboration with Emory University, who is the sponsor of the study, to conduct prospective surveillance for RSV

in older adults and pregnant women hospitalized with acute respiratory infection (ROAPS) since 2018. Study WI235284 is a proposed amendment to the ROAPS protocol which includes the required study design elements necessary to perform the test-negative design VE analyses of BNT162b2 that Pfizer has planned. To maintain document continuity for the Emory IRB, the COVID VE study design elements have been incorporated and labeled as ***COVID VE / Substudy 6***. The aim of this amendment is to continue the ROAPS study and the associated Substudies 1-5, and to implement the COVID VE Substudy 6 pending agreement with the Regulatory Authorities and approval from the Emory IRB.

- WI255886 entitled, "*A Pan-pandemic Acute Lower Respiratory Tract Disease (LRTD) Surveillance Study (AVONCap)"* Amendment for BNT162b2 Post-authorization Vaccine Effectiveness - University of Bristol (UK): Pfizer-Emory Research Collaboration
    - Pfizer has also been engaged in a research collaboration with the University of Bristol, a site that was deemed a *Vaccine Research Centre of Excellence* by Pfizer as an expression of the intention to form a longstanding research partnership. The first study in this collaboration was of adults hospitalized with lower respiratory tract disease which has been recruiting participants since 2020. The University of Bristol is the sponsor of the study. Study WI255886 is a proposed amendment to the AVONCap protocol which includes the required study design elements necessary to perform the test-negative design VE analyses of BNT162b2 that Pfizer has planned. Alongside the protocol, which contains summary information in accordance with site-defined requirements, the statistical analysis plan for this study is also enclosed in this submission. ***Chapter 2*** of the statistical analysis plan includes detailed information about the planned BNT162b2 VE analyses.

- C4591014 entitled, "*Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California"*
    - Pfizer is the sponsor of Study C4591014

The same information is being submitted to BB-IND 19736 and EUA 27034 in parallel.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 212-733-2613; via facsimile at 845-474-3500; or via e-mail at neda.aghajanimemar@pfizer.com.

Sincerely,

Neda Aghajani Memar, Pharm.D.
Director

Pfizer Global Regulatory Affairs

CC: Ramachandra S. Naik, Ph.D.