Pfizer Global Regulatory Affairs
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Global Product Development

15 April 2021

Marion Gruber, Ph.D.
Director
Food and Drug Administration
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
c/o Central Document Room
10903 New Hampshire Avenue, WO71-G112
Silver Spring, MD 20993-0002

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

eCTD Sequence 0289 Serial No. 0288

IND Summary Monthly Safety Report: Reporting Period 01-MAR-2021 – 31-MAR-2021

Dear Dr. Gruber,

The provided report summarizes information associated with the subject IND during the reporting period. Please note that the format of the IND Annual Report for 2021 has been converted from the format described in 21 CFR 312.33 to the Summary Monthly Safety Report (SMSR) format described in International Conference on Harmonization; Guideline E2C (R2) Periodic benefit-risk evaluation report (PBRER), Step 5, January 2013.

In addition, as previously agreed with CBER, Pfizer/BioNTech are hereby submitting our plan for reporting Individual Case Serious Reports (ICSRs) and their relation to the SMSR. Following Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine on 11 December 2020 (EUA 27034), Pfizer processed and reported ICSRs on behalf of BioNTech to VAERS as spontaneous cases per the Postmarketing Adverse Drug Experience (PADE) Compliance Program reporting schedule. That is, serious and unlisted cases (foreign and domestic) were processed and submitted within 15 calendar days. Serious Listed domestic cases were submitted within 30 calendar days, not within 15calendar days as stipulated in the 11 December 2020 Letter of Authorization

(LOA). As stipulated in Section G of the February 25, 2020 Letter of Authorization, Pfizer/BioNTech have been submitting monthly periodic reports which summarize all spontaneous reports received, including all death cases, hospitalizations, multisystem inflammatory syndrome, serious and non-serious domestic/foreign cases, and administration errors. In addition, all cases received and uploaded in the safety database are included in weekly signal detection activities, regardless of seriousness or their status in the ICSR workflow. Effective 1 May 2020, we will also submit Serious Listed domestic cases within 15 days in accordance with the LOA.

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 please contact me via phone at at 212-733-2613; or via email at neda.aghajanimemar@pfizer.com.

Sincerely,

Neda Aghajani Memar, Pharm.D.
Director
Pfizer Global Regulatory Affairs