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

# Global Product Development



14 August 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 0453 Serial No. 0452**

**IND Summary Monthly Safety Report: Reporting Period 01-JUL-2021 – 31-JUl-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.*

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 212-733-2613; or via email at neda.aghajanimemar@pfizer.com.

Sincerely,

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