



## Global Product Development

15 September 2021

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Director  
Food and Drug Administration  
Office of Vaccines Research and Review  
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**Re: COVID-19 Vaccine (BNT162/PF-07302048) BB-IND 19736**

**eCTD Sequence 0491      Serial No. 0491**

**IND Summary Monthly Safety Report: Reporting Period 01-AUG-2021 – 31-AUG-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 (PBREER), 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 214-918-5262; or via email at [Amitkumar.Patel@pfizer.com](mailto:Amitkumar.Patel@pfizer.com).

Sincerely,

Amit Patel  
Director  
Global Regulatory Affairs – Vaccines