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



Global Product Development

16 June 2021

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IND No. 19,736 for COVID-19 Vaccine (BNT162, PF-07302048) eCTD Sequence 0369 Serial No. 0368

IND Annual Report: Reporting Period 22-APR-2020 – 21-APR-2021

Dear Director:

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 Development Safety Updated Report (DSUR) format described in *International Conference on Harmonization; Guidance for Industry E2F Development Safety Update Report (ICHE2F), August 2011.*

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, PharmD Senior Manager Global Regulatory Affairs - Vaccines