



## Global Product Development

28 July 2021

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**Re: BLA 125742**

**COVID-19 mRNA Vaccine (BNT162/PF-07302048)**

**Follow-up Response to 22 July 2021 Information Request**

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 19 May 2021 for the COVID-19 mRNA Vaccine (BNT162/PF-07302048) developed by BioNTech and Pfizer under BB-IND 19736 for the prevention of COVID-19 caused by SARS-CoV-2 in individuals  $\geq 16$  years of age.

Further reference is made to CBER's 22 July 2021 Information Request to Pfizer, received via email from Laura Gottschalk, PhD (CBER) regarding clinical shell tables for Study C4591001 and Pfizer/BioNTech's initial response submitted 26 July 2021.

The present submission provides [Follow-up Response 1](#) for the Response to CBER 22 July 2021 Information Request Regarding Clinical Shell Tables for Study C4591001 in Module 1.11.3.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 215-280-5503; via facsimile at 845-474-3500; or via e-mail at [elisa.harkinstull@pfizer.com](mailto:elisa.harkinstull@pfizer.com).

Sincerely,

Elisa Harkins  
Global Regulatory Lead  
Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D.