



## Global Product Development

2 July 2021

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**Re: BLA 125742**

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

**Response to 29 June 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.

The purpose of the current document is to respond to CBER's 29 June 2021 Information Request regarding datasets that was provided by Captain Michael Smith, PhD (CBER) to Pfizer via email. The [Response to CBER's 29 June 2021 Information Request](#) regarding datasets is provided 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.