Michael J. Smith -S4 Digitally signed by Michael J. Smith -S4 Date: 2022.04.22 14:57:33 -04'00'

From: Smith, Michael (CBER)
Sent: Friday, April 22, 2022 2:52 PM
To: Collins, Kathleen Mary Catherine (b) (6); Mineo, Gosia (b) (6)
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; MaguireThon, Meghan <Meghan.MaguireThon@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: STN 125742/45 & IND 19736: IR RE request for a revised study protocol for Study C4591022 - pregnancy registry study (postmarketing commitment (PMC) #10 as described in the STN 125742/0 approval letter)

Kate and Gosia,

The review team has the below Information Request regarding Study C4591022, the pregnancy registry study.

The current version (version 3.0, dated November 29, 2021) of your protocol for the pregnancy registry study (postmarketing commitment (PMC) #10 as described in the STN 125742/0 approval letter, dated August 23, 2021) includes individuals aged 18 years and older. In the context of the Pharmacovigilance Plan (PVP, version 1.4) submitted with sBLA 125742/45 to extend the use of COMIRNATY to individuals 12 years of age and older, please revise the study protocol for C4591022 to include pregnant individuals of all ages. Please respond to this Information Request under sBLA 125742/45 and submit a revised final study protocol and statistical analysis plan (both tracked changes and clean running versions) to IND 19736 by May 6, 2022.

Regards,

Mike

- Please confirm receipt of this email and let us know if you have any questions.

Mike Smith, Ph.D.
Captain, USPHS

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