Michael J. Smith -S4
Digitally signed by Michael J. Smith -S4
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0014080934, cn=Michael J. Smith -S4
Date: 2022.03.08 16:03:49 -05'00'

From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Sent: Tuesday, March 8, 2022 3:38 PM
To: Collins, Kathleen Mary Catherine (b) (6)
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Mineo, Gosia (b) (6) Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: RE: [EXTERNAL] RE: STN 125742/45 – Comirnaty sBLA – Clinical-statistical comments regarding updated immunobridging analyses and solicited adverse reaction frequencies

Kate,

I checked with the review team and the comment pertains to reactogenicity data collected in the e-diary, as presented in Tables 5 and 6 of the draft package insert.

Regards,

Mike

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

From: Collins, Kathleen Mary Catherine (b) (6)
Sent: Tuesday, March 8, 2022 2:05 PM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Mineo, Gosia (b) (6) Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: [EXTERNAL] RE: STN 125742/45 – Comirnaty sBLA – Clinical-statistical comments regarding updated immunobridging analyses and solicited adverse reaction frequencies

Thanks again Mike for the query.

The team would like to clarify question 2 noted below:

FDA Question: Please clarify whether additional solicited adverse reaction data for adolescents 12 through 15 years of age in Study C4591001 have been collected up to the September 2, 2021 data cutoff since EUA issuance. Please submit updated solicited adverse reaction frequencies as appropriate, annotating any changes to the results.

In Study C4591001, in participants who originally received placebo, were unblinded (i.e. after EUA issuance) and then received BNT162b2 after unblinding, events related to reactogenicity were not reported using an e-diary but were instead reported as AEs. We would like clarify if

your question refers to reactogenicity data collected via the e-Diary or unsolicited AEs reported to the investigators?

We look forward to your clarification on this question at your earliest.

Kind regards

Kate