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: 2022.01.20 11:35:26 -05'00'

From: Smith, Michael (CBER)
Sent: Wednesday, January 19, 2022 5:30 PM
To: Mineo, Gosia (b) (6)
Cc: Collins, Kathleen Mary Catherine (b) (6); Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Stafford, Adrienne Kaye <Adrienne.Stafford@pfizer.com>
Subject: RE: [EXTERNAL] STN 125742/45: IR RE the datasets for adolescents 12 through 15 Years of Age

Gosia,

Thank you, please submit an amendment to the supplement by Wednesday, February 2nd with your response.

Regards,

Mike

From: Mineo, Gosia (b) (6)
Sent: Wednesday, January 19, 2022 5:28 PM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Cc: Collins, Kathleen Mary Catherine (b) (6); Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Stafford, Adrienne Kaye <Adrienne.Stafford@pfizer.com>
Subject: Re: [EXTERNAL] STN 125742/45: IR RE the datasets for adolescents 12 through 15 Years of Age

Hi Mike -

I confirm receipt of the below communication.

Thank you,
Gosia

On Jan 19, 2022, at 5:07 PM, Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov> wrote:

Kate,

The review team has the below information request for STN 125742/45 IR RE the datasets for adolescents 12 through 15 Years of Age

1. There are 2 subjects (10961068 and 11631062) with AE records that have AEACN = DRUG WITHDRAWN, but they only have COMPLETED records in DS. Please explain.

2. We have found that subject 11311279 was included in SDTM DM but not ADSL. Please explain.

3. As previously communicated and discussed under BLA 125742 and other BLAs/INDs reactogenicity events that begin within the prespecified assessment period should have been reported in FACE and summarized with the subject diary data in CE. Since this was not implemented, we request that:
    a. reactogenicity events that begin within the prespecified assessment period that are currently reported in the AE dataset be included in FACE, and then be flagged in AE so that we know that it is being included in the FACE dataset.
    b. Include all individual supporting assessments (daily e-diary and any unplanned assessments) and the assessor for each finding (identified using FAEVAL=STUDY SUBJECT or INVESTIGATOR) in the FACE domain.
    c. Maintain one row per subject/vaccination/symptom in the CE domain, with CE summarizing the duration of the event and maximum severity. Maximum severity (CESEV) should be based on the highest-level severity reported by the subject (via e-diary) or investigator (in the unplanned assessment CRF).
    d. Use SUPPCE CESEV1 and CEDIFFRS to show assessment of severity by study subject and reason investigator's assessment of severity differed from study subject as needed for events reported in CE.
    e. Update the analysis dataset(s) with records covering the entire event duration (which could go beyond the protocol-defined assessment period) with start/end dates and durations (based on first and last days the symptom was present as recorded in the e-diary and/or Symptom Resolved Dates CRF) derived from both the e-diary and CRF data.

Regards,

Mike

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

Mike Smith, Ph.D.
Captain, USPHS

Senior Regulatory Review Officer
Food and Drug Administration

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