16.2.7.2.3 Listing of Severe and Grade 4 Local Reactions – Subjects With Indeterminate Vaccine – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1 2 3 4 5 6 7	Stop Date[c]	Dur (Days)[d]

No subject meets the reporting criteria.

Abbreviation: Dur = duration.
a.   Relative day (Rel Day) = date of reaction - date of last vaccination + 1.
b.   The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21 caliper units are reported as >21. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).
c.   Stop date is the date the reaction was last reported.
d.   Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last e-diary day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered, which was used for the duration calculation.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:47)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_l004_sevlr_iv_all

16.2.7.3.3 Listing of Severe and Grade 4 Systemic Events – Subjects With Indeterminate Vaccine –
All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1 2 3 4 5 6 7	Stop Date[b]	Dur (Days)[c]
No subject meets the reporting criteria.							

Abbreviation: Dur = duration.
a. Relative day (Rel Day) = date of event - date of last vaccination + 1.
b. Stop date is the date the event was last reported.
c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was administered, which was used for the duration calculation.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:53)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_l004_sevse_iv_all

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16.2.7.4.3 Listing of Adverse Events – Subjects With Indeterminate Vaccine – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]/ Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1163 11631008	PSYCH	Anxiety/ ANXIETY	1	03NOV2020	96/C	1	No	O	NA/TC	N	N/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

a.   Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b.   Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c.   Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:53)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_l002_iv_all

FDA-CBER-2021-5683-0035324