

RESPONSE TO CBER COMMUNICATION REGARDING CLINICAL TOPICS (IR 11)  
RECEIVED ON DECEMBER 08, 2020

The Sponsor acknowledges CBER's communication regarding Clinical topics (IR 11).

This document provides the Sponsor's responses to CBER's requests (in **Bold**).

**ITEM 1:**

**In your executive summary of clinical safety, you indicate that 13 deaths have been reported during the study through December 3, 2020. Please submit narratives of the 5 additional deaths which were not included in the Nov 11 data cut.**

**Sponsor Response:**

The narratives are provided with this submission.

**ITEM 2:**

**Please submit narrative for the 1 additional related SAE (US3212326) that was included in the Nov 25 data cut, but not captured in the Nov 11 data cut.**

**Sponsor Response:**

The narrative is provided with this submission

**ITEM 3:**

**In the updated safety list from Nov 25 data cut, there is an SAE of COVID-19 in one vaccine participant (US 3492243). Please submit the narrative for this case.**

**Sponsor Response:**

A case narrative is provided. It is important to emphasize that as an SAE and case of COVID-19, the event is still in the process of being evaluated and is not complete. Diagnostic confirmation of COVID-19 and assessment of COVID-19 by the Investigator not complete.

**ITEM 4:**

**Please submit narratives for the 4 reported cases of facial paralysis/Bell's palsy for following participants (through Nov 25 data cut). Please include information on the laterality of the injection dose (s) and the laterality of the facial paralysis.**

**a. US3752245**

**b. US3182040**

**c. US3432056**

**d. US3382271**

**Sponsor Response:**

Case narratives are provided. Unfortunately the laterality of the facial paralysis has not been reported for any of these cases.

**ITEM 5:**

**Please submit a SAE summary excel sheet of all new SAEs that were included in the Nov 25 data cut and not in the Nov 11 data cut, similar to the one submitted on Dec 7 in response to IR #8.**

**Sponsor Response:**

The summary table is included in this submission