

**RESPONSE TO CBER COMMUNICATION REGARDING CLINICAL TOPICS (IR #6)  
RECEIVED ON DECEMBER 05, 2020**

The Sponsor acknowledges CBER's communication regarding Clinical topics (IR #6).

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

**ITEM 1:**

**As soon as possible, we request that you submit narratives for all the severe COVID-19 cases from the November 25, 2020, data snapshot.**

**Follow-up e-mail from Carla Vinals, Sunday December 6, 9:11 AM**

*Regarding your request below:*

*As soon as possible, we request that you submit narratives for all the severe COVID-19 cases from the November 25, 2020, data snapshot.*

*We currently do not have narratives ready. In the interest of time, our proposal is to provide a summary table similar to the draft attached on this email, together with all the corresponding MedWatch forms.*

*Can you please let me know if this would be acceptable?*

**Follow-up e-mail from Goutam Sen, Sunday December 6, 2020, 10:16 AM**

*We agree with your proposal. Please see below our recommendation.*

*On the attached document (your 9:11AM email attachment), please clearly note which cases were included in the Nov 11 snapshot and which cases were included in the Nov 25 snapshot.*

*We still request you to submit narratives at least for the 11 adjudicated, per protocol severe COVID-19 cases from the Nov 11 snapshot, by Tuesday, December 8, 2020.*

**Sponsor Response:**

Included with this response are the n=11 narratives describing the severe COVID-19 cases at the time of the 11 Nov data snapshot. There is one case (US3312605) that we would like to bring to your attention since we have become aware of new information since the 11 and 25 November data snapshots. The Investigator at this site suspects that the information provided by this

participant may not be reliable and an investigation is currently ongoing. In light of the potential impact of this development, we expect to have resolution by December 11<sup>th</sup>, 2020.