

RESPONSE TO CBER COMMUNICATION REGARDING CLINICAL TOPICS (IR 18)
RECEIVED ON DECEMBER 13, 2020

The Sponsor acknowledges CBER's communication regarding Clinical topics (IR 18).

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

ITEM 1:

Please provide the case narratives for the facial swelling adverse events for each of the 3 following participants. Please include all additional information, including prior medications/treatments and confirm vaccine or placebo dosing.

- I. Subject #348-2155**
- II. Subject # 367-2261**
- III. Subject #360-2084**

Sponsor Response:

The requested narratives are included in this submission.