

RESPONSE TO CBER COMMUNICATION REGARDING CLINICAL TOPICS (IR 14)  
RECEIVED ON DECEMBER 09, 2020

The Sponsor acknowledges CBER's communication regarding Clinical topics (IR 14).

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

**ITEM 1:**

**Interval for Periodic Safety Reports:**

**In your pharmacovigilance plan (PVP) submitted under EUA 27073, you propose quarterly submission of periodic safety reports. Please note, that as communicated in FDA response to Question 8 of IND IND19745/78, we expect that the sponsor will be required to submit to the IND periodic safety reports at monthly intervals.**

**Sponsor Response:**

The sponsor will submit periodic safety reports to the IND at monthly intervals.

**ITEM 2:**

**AESI - Multisystem Inflammatory Syndrome in Children (MIS-C) and Bell's Palsy:**

**In your PVP, you provide a list of predefined AESIs to be studied post market. Included in this list is multi-system inflammatory syndrome in children (MIS-C). Please change this to MIS in adults, consistent with the proposed authorization indication. In addition, please add Bell's Palsy to the current list of 23 AESI to be evaluated.**

**Sponsor Response:**

The sponsor will change MIS-C to MIS. The sponsor will also add Bell's Palsy to the current list of AESI to be evaluated.

**ITEM 3:**

**Concept protocols for proposed Active Surveillance studies:**

**Please provide concept protocols for the following proposed active surveillance studies that were summarized in your PVP for FDA review:**

- **Pregnancy Registry**
- **Pregnancy Observational Cohort Study**
- **Active Surveillance Activity**
- **Real World Effectiveness Study**

**For each of the studies, please provide the following study milestone dates:**

- **Final protocol submission date**
- **Study completion date**
- **Final study report submission date**

**Sponsor Response:**

The concept protocols of the following studies are provided with this submission:

- The Pregnancy Observational Cohort which includes the passive pregnancy registry
- The Active Surveillance Activity: Post-approval safety of SARS-CoV-2 mRNA-1273 vaccine: Active surveillance, signal refinement and self-controlled risk interval (SCRI) signal evaluation in HealthVerity (Previously referred to as Active Follow-up for Safety in the Pharmacovigilance Plan)
- Real World Effectiveness Study

Timelines for the Pregnancy Observational Cohort (including the passive pregnancy registry):

- Final protocol submission date: December 21, 2020
- Study completion date: December 31, 2023
- Final study report submission date: June 30, 2024

Timelines for the Active Surveillance Activity (Active Follow-up for Safety)

- Final protocol submission date: December 21, 2020
- Study completion date: December 31, 2022
- Final study report submission date: June 30, 2023

Timelines for the Real World Effectiveness study:

- Final protocol submission date: March 1, 2021
- Study completion date: September 30, 2024
- Final study report submission date: June 30, 2025