

RESPONSE TO CBER COMMUNICATION REGARDING CLARIFICATION OF PREGNANCY STUDY AND ACTIVE SURVEILLANCE STUDY RECEIVED ON DECEMBER 02, 2020

The Sponsor acknowledges CBER's communication regarding the clarification of pregnancy study and active surveillance study.

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

Item 1:

Clarification of your pregnancy study

In your EUA you have stated that you are, "...planning to establish an observational pregnancy cohort study, (e.g., with the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) Mother to Baby cohort)" and that "Moderna would not establish a separate pregnancy registry relying on passive contact," while your proposed prescribing information states that, "There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy." Please provide clarification on this discrepancy.

Sponsor Response:

This question has been addressed in our [PVP](#).

Item 2:

Active surveillance study details submission for review

Post Authorization active surveillance: As conveyed in the guidance (Guidance for Industry: Emergency Use Authorization for Vaccines to Prevent COVID-19 (October 2020) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19>), please propose your plan for active surveillance of safety for individuals who receive your vaccine under an EUA as the "active follow-up for safety." Specifically, please supply the following details on your proposed pregnancy study and other planned EUA surveillance studies for FDA review:

- **Specific pregnancy or other study design(s), including clarification of the type of comparator group to be used to assess vaccine safety**
- **Details on follow-up of patients and the identification of specific outcomes, and whether these data will be collected in a prospective manner or retrospectively**
- **Whether safety outcomes will be pre-specified, or if methods will allow for the evaluation of outcomes that are not predetermined**

- **The minimum sample size for each study population and the study's approximate power to detect outcomes related to vaccination (which may be expected to occur at varying rates).**

Sponsor Response:

This question has been addressed in our [PVP](#).