

FOLLOW-UP TO RESPONSE TO CBER COMMUNICATION REGARDING EUA 27073 (IR #1) RECEIVED ON DECEMBER 01, 2020

The Sponsor responded to EUA 27073 IR #1 Item H on December 06, 2020 (EUA27073 SN0004).

This document provides additional information to the previous Sponsor's responses to CBER's request (in **Bold**).

Item H:

A Form FDA 483 was issued after inspection of study site 387 (Dr. Michael Levine, Las Vegas, NV) by FDA's Bioresearch Monitoring team. Given the concern for data integrity at this site, please conduct a sensitivity analysis for the primary efficacy endpoint (overall and by the protocol specified age and risk subgroups) excluding all data from this study site, along with data from study site 393 as we previously requested. This should be done both for the interim analysis (Nov 11 snapshot) as well as for the primary analysis.

Sponsor Response:

This is a follow-up of the response to IR#1 item H provided in EUA SN0004. In its initial response Moderna proposed to submit an additional sensitivity analysis of efficacy excluding the 2 study sites that were issued 483s as a result of the BIMO site inspection, based on the data snapshot of November 25.

At data snapshot 2 (25-Nov-2020), there were no new cases reported starting 14 days after the 2nd injection based on the adjudication committee assessment in participants enrolled at site 387 and site 393 compared to data snapshot 1 (11-Nov-2020). Therefore, sensitivity analyses were not performed given there was only one case (from site 393) in participants enrolled at site 387 and 393. If sensitivity analyses were performed, the results would be consistent with that from the primary analysis.