

**IND Number 19745**  
**Sequence No. 0082**

December 02, 2020

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Document Control Center  
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**Submission Type: Response to FDA Requests for Information – CMC, Clinical  
Other – Updated P301 Data Blinding Plan (v4.0), Initial Pediatric Study  
Plan**

Dear Dr. Gruber:

Reference is made to Investigational New Drug Application (IND# 19745) for mRNA-1273, a messenger RNA (mRNA)-based active immunization to induce protective immunity against acute respiratory disease associated with the SARS-COV-2 virus (Sequence No. 0001, April 27, 2020). Reference is also made to the information request that was sent by FDA via email on November 28, 2020 (concerning comments and questions regarding IND 19745 SN0070). The purpose of this submission is to submit the response document with the requested information and amended Module 3 sections as provided in the following table.

CTD Section		Changes
3.2.P.3.5	Process Validation and/or Evaluation	<ul style="list-style-type: none"> <li>Addition of the mRNA-1273 Bacterial Challenge Filter Validation Report (EXT-0820)</li> </ul>

Also included in this submission is a response to comments regarding reporting of death of a trial participant received on November 27, 2020; an updated mRNA-1273-P301 data blinding plan (v4.0), and the Final version of the Initial Pediatric Study Plan (clean and tracked changes versions).

If FDA has any questions, please do not hesitate to contact me directly at (b) (6) or at (b) (6)@modernatx.com.

This eCTD submission has been prepared by PPD Development, Inc. in full compliance with ICH and FDA guidance. The eCTD has been verified and confirmed to be virus and spyware free. PPD utilizes Palo Alto Traps v4.2.2. All technical questions should be directed to (b) (6) at PPD (b) (6) or email at (b) (6)

Yours Sincerely,

Carlota Vinals

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