



DATE November 17, 2021

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Division of Inspections and Surveillance (DIS)  
Office of Compliance and Biologics Quality (OCBQ)

THROUGH Dennis Cato, Chief, BMB

THROUGH Carrie Mampilly, MPH, Director, DIS

THROUGH Mary Malarkey, Director, OCBQ

TO Sudhakar Agnihothram, PhD, Chair, STN 125752/0  
Rachel Zhang, MD, Clinical Reviewer  
Josephine Resnick, PhD, RPM  
Joseph Kulinski, PhD, RPM

SUBJECT Bioresearch Monitoring Final Review Memo  
SPONSOR ModernaTX, Inc.  
PRODUCT mRNA-1273 COVID-19 vaccine (SPIKEVAX)  
BLA STN 125752/0

### **FINAL SUMMARY STATEMENT**

One Bioresearch Monitoring (BIMO) inspection was conducted at a domestic Clinical Investigator (CI) site participating in the conduct of study protocol mRNA-1273-P301. The inspection did not reveal problems impacting the data submitted in support of this Biologics License Application (BLA).

### **Background**

One CI study site was inspected in support of this BLA. The inspection was conducted in accordance with FDA's Compliance Program (CP) 7348.811, Inspection Program for Clinical Investigators. The inspection assignment was issued for the following study protocol, which included Parts A and B:

**mRNA-1273-P301:** A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older

The site was selected based on previous inspectional history, geographic location, and the data submitted in this BLA. The inspection assignment included specific questions concerning the study protocol and requested the investigators to compare source documents at the site with information submitted in this BLA. The domestic CI site inspected in support of this BLA covered 3% of the subjects enrolled in the study inclusive

of Parts A and B. Study mRNA-1273-P301 was conducted at 99 study centers enrolling a total of 30,346 subjects aged 18 years and older in Part A; of these subjects that participated in Part A, a total of 28,964 subjects started Part B.

### **Inspection Outcome**

<b>Site ID</b>	<b>Number of subjects enrolled</b>	<b>Location</b>	<b>Form FDA 483 issued</b>	<b>Final Inspection Classification</b>
319	928	Quality of Life Medical & Research Center, LLC Tucson, Arizona	No	No Action Indicated

The inspection verified the data reported in the BLA, including but not limited to subject's eligibility, protocol deviations, study drug administration, immunogenicity data, safety and reactogenicity events, concomitant medication administration, and adverse events for the randomly and equitably selected subjects enrolled at the inspected clinical site. The inspection further evaluated the adequacy of the study and site monitoring by the sponsor. No Form FDA 483 was issued at the conclusion of the inspection.

### **Noteworthy inspectional findings**

None.

### **Sponsor Issues**

No significant sponsor issues were noted.

### **Financial Disclosure**

The Clinical Investigator Compliance Program directs the FDA investigators to ask the clinical investigator if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any sub-investigators, spouses and dependent children, and if and when the information was updated. The information submitted to the BLA was verified at the inspected clinical site and found no deviations in the submitted data.

### **Administrative follow-up**

No administrative follow-up is warranted at this time from BIMO for the inspected clinical investigator. Should you have any questions about the contents of this memo or any aspect of BIMO, please contact me at 240-402-8979.

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Bhanu Kannan, M.S.  
Consumer Safety Officer