



MEMORANDUM

DATE: May 6, 2025

FROM: Haecin Chun, MS, Consumer Safety Officer
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ)

THROUGH: Kanaeko Ravenell, MS, Branch Chief, BMB

THROUGH: Carrie M. Mampilly, MPH, Division Director, DIS

TO: Joseph Kulinski, PhD, Chair, BLA 125835/0
Timothy Brennan, MD, Clinical Reviewer
Brittany Shepherd, MD, Clinical Reviewer
Sylvia Park, PharmD, RPM
Donna Elhindi, PharmD, RPM

SUBJECT: BIMO Final Review Memo

SPONSOR: ModernaTX, Inc.

PRODUCT: Moderna COVID-19 Vaccine, mRNA (MNEXSPIKE)

BLA: BLA STN 125835/0

FINAL SUMMARY STATEMENT

Bioresearch Monitoring (BIMO) inspections were issued for the sponsor and five clinical investigator (CI) study sites that participated in the conduct of Study mRNA-1283-P301. The inspections did not reveal significant issues impacting the data submitted in this original Biologics License Application (BLA).

BACKGROUND

A sponsor and five (two foreign and three domestic) clinical investigator BIMO inspection assignments were issued to review the study conduct of the following clinical study entitled, "A Randomized, Observer-blind, Active-controlled Phase 3 Study to Investigate the Safety, Immunogenicity, and Relative Vaccine Efficacy of mRNA-1283 Compared with mRNA-1273 in Participants Aged ≥12 Years for the Prevention of COVID-19" (Protocol mRNA-1283-P301).

Protocol mRNA-1283-P301 has a country specific protocol for Japan and a global protocol for all other study sites located in multiple countries, including the U.S. The five clinical study sites were selected based on subject enrollment, previous inspection history, and the data/information submitted in the BLA. The inspections were conducted in accordance with CP 7348.811, Inspection Program for Clinical Investigators (CIs). Information submitted in the BLA was compared to source documents at each inspected site. The inspection assignments also included specific questions concerning the clinical study.

The sponsor inspection included reviewing ModernaTx's study conduct of Protocol mRNA-1283-P301, and also their adequacy in accomplishing their responsibilities as a sponsor according to the applicable regulations governing the proper conduct of the clinical investigation. The inspection was conducted in accordance with FDA's Compliance Program (CP) 7348.810, Inspection Program for Sponsors and Contract Research Organizations.

INSPECTION SUMMARY AND FINDINGS

The table below summarizes the results of the BIMO inspections:

Entity	Site ID	Location	Issued FDA Form 483?	Final Inspection Classification
Sponsor	N/A	Cambridge, MA	No	No Action Indicated (NAI)
CI	US005	Velocity Clinical Research Greenville Greenville, South Carolina	No	NAI
CI	US064	Noble Clinical Research Tucson, Arizona	No	NAI
CI	US108	Clinical Research Partners, LLC Richmond, Virginia	No	NAI
CI	JP005	Dojinkinenkai Meiwa Hospital Chiyoda-ku, Tokyo, Japan	No	NAI
CI	JP008	Shinei Medical Healthcare Clinic Suginami-ku, Tokyo, Japan	No	NAI

Clinical Investigator Issues

No significant objectionable inspectional findings were observed.

Sponsor Issues

No significant sponsor issues were observed; however, two discussion items were conveyed at the conclusion of the inspection in regard to the adequate process for qualification and initiation of investigator sites and the hybrid approach to training (both on-line and in-person trainings) for the study. ModernaTx provided their post-inspection response on 3/31/2025, adequately addressing these two discussion items, as well as demonstrating their commitment to complete their responsibilities as a sponsor.

FINANCIAL DISCLOSURE

The CI CP directs the FDA investigators to ask the CI 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 last updated. The information submitted to the BLA was verified at the inspected/assessed clinical sites no deviations were found in the submitted data.

ADMINISTRATIVE FOLLOW-UP

Should you have any questions about the contents of this memo or any aspect of BIMO, please contact me at haecin.chun@fda.hhs.gov.

Haecin Chun, MS,
Consumer Safety Officer

Distribution:

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History:

Draft: Chun: 04/28/2025

Review: Ravenell: 5/5/2025