



U.S. FOOD & DRUG
ADMINISTRATION

DATE: July 23, 2026

FROM: (b) (6)

THROUGH: (b) (6)

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TO: (b) (6)

SUBJECT: (b) (6) Final Discipline Review Memo

SPONSOR: ModernaTX, inc.

PRODUCT: mRNA-1010

BLA/STN 125869/0

REVIEW SUMMARY

Three (b) (6) inspections were issued for two domestic and one foreign clinical study investigators that participated in the conduct of clinical study mRNA-1010-P304. The inspections are complete but two of the Establishment Inspection Reports are pending review and final classification of the inspection. We will update the review as soon as all inspections have been reviewed and the inspections final classified.

BACKGROUND

(b) (6) inspection assignments were issued for two domestic and one foreign clinical investigator (CI) that conducted Protocol mRNA-1010-P304. The sites were selected based upon sponsor-reported adverse events, subject deaths, protocol deviations, total numbers of enrolled subjects, previous (b) (6) inspection histories, BLA clinical review team recommendations, and CI financial disclosures. The BLA review committee concurred with the proposed sites selected for inspection.

The (b) (6) inspections were conducted in accordance with FDA's Compliance Program (CP) 7348.811, Inspection Program for CIs. Information submitted in the BLA was compared to source documents at each inspected site. The inspection assignment also included specific questions concerning the clinical study.

PROTOCOL

Protocol mRNA-1010-P304, was a multicenter study conducted at 301 sites in 11 countries in North America, Europe, and East Asia for the prevention of influenza disease caused by any influenza A or B strains in the target population of adults greater than 50 years of age. A total of 40,805 participants were randomized, 20,402 to the mRNA-1010 group, and 20,403 to the standard dose (SD) comparator group. Of the total randomized subjects, 40,703 (99.8%) participants (20,349 [99.7%] in the mRNA-1010 group vs 20,354 [99.8%] in the SD comparator group) received a study injection. The inspections at the three clinical sites included 1,696 study subjects, which represented approximately 0.04% of the total number of study subjects.

(b) (6) INSPECTIONS SUMMARY

No significant (b) (6) inspectional findings were noted. No Form FDA-483s were issued, and all inspections were classified as No Action Indicated (NAI).

The table below summarizes site information and outcomes from the (b) (6) inspections:

Site Number	Protocol Number	CI/ Location	Form FDA-483 Issued?	Final Classification
US060	mRNA-1010-P304	Carlos Sesein, MD Hialeah, FL	No	NAI
EE001	mRNA-1010-P304	Airi Poder, MD Tartu, Estonia	No	NAI
US012	mRNA-1010-P304	Paul Bradley, MD Savannah, Georgia	No	NAI

INSPECTIONAL FINDINGS:

No significant objectionable inspectional findings were observed at the study sites, and a Form FDA 483 was not issued at close of any of the inspections. Safety and efficacy endpoints were verified without incident.

SIGNIFICANT INSPECTIONAL FINDINGS

No significant inspectional findings were observed.

SPONSOR/MONITORING ISSUES

An Information Request (IR) was issued to the firm on 1/20/2026 to obtain the telephone numbers and e-mail addresses of the CIs participating in the clinical trial mRNA-1010-P304. The sponsor submitted a written response to the IR on 1/23/2026. The response was reviewed and found to be acceptable.

No significant sponsor issues were noted. No significant sponsor-monitoring issues were identified during the above inspections.

FINANCIAL DISCLOSURE

The CI Compliance Program directs the FDA investigator to ask the CI if, and when, they disclosed information about their financial interests to the sponsor and/or interests of any sub-investigators, spouse(s) and dependent children, as well as if and when the information was updated. The information submitted to the BLA was verified for each of the inspected CIs.

ADMINISTRATIVE FOLLOW-UP

Should you have any questions or comments about the contents of this memo or any aspect of (b) (6), please contact me by email at (b) (6) or by phone at (b) (6).

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