



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum

DATE March 21, 2025

FROM Triet M. Tran, PharmD, BCSCP, Regulatory Officer
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ)

THROUGH Kanaeko Ravenell, MS, Chief BMB

THROUGH Carrie M. Mampilly, MPH, Director DIS

TO Edward Wolfgang, PhD, 125817/0
Charles Line, MD, Clinical Reviewer
Amina White, MD, Clinical Reviewer
Donna Elhindi, PharmD, RPM
Paul Keller, PhD, RPM

SUBJECT Bioresearch Monitoring Final Discipline Review Memo

SPONSOR Novavax, Inc.

PRODUCT NUVAXOVID (Novavax's COVID-19 Vaccine, Adjuvanted)

sBLA STN 125817/0

FINAL SUMMARY STATEMENT

Bioresearch monitoring (BIMO) inspections were issued for two domestic clinical investigator (CI) sites participating in the conduct of Study 2019nCoV-301. The inspections did not reveal significant problems impacting the data submitted in support of this Biologics License Application (BLA).

BACKGROUND

BIMO inspection assignments were issued for two domestic CI sites that participated in the conduct the protocol entitled "A Phase 3, Randomized, Observer-Blinded, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1™ Adjuvant in Adult Participants ≥ 18 Years with a Pediatric Expansion in Adolescents (12 to < 18 Years)" (2019nCoV-301).

The sites were selected based on previous inspectional history, geographic location, and the data submitted in the BLA. The BLA review committee concurred with the sites selected for inspection. These inspections were conducted in accordance with FDA's

Compliance Program (CP) 7348.811, Inspection Program for CI and the inspection assignment included specific questions concerning the study protocol, and information submitted in the BLA was compared to source documents at the site. Study 2019nCoV-301 was conducted at 73 sites across The United States, enrolling a total of 2250 subjects. The two domestic CI sites inspected in support of this BLA covered approximately 7% of the subjects enrolled in the study.

INSPECTION SUMMARY AND OUTCOME

The inspections verified the data reported in the BLA, including but not limited to subject eligibility, protocol deviations, study drug administration, primary efficacy endpoint, and adverse events for all subjects enrolled at the inspected clinical sites. No significant objectionable inspectional findings were observed during the inspection. A Form FDA 483 was issued for one of the two inspected sites. The table below summarizes the BIMO inspections:

Site ID	Study Site Name and Location	Form FDA 483 Issued?	Final Inspection Classification
US012	Velocity Clinical Research Meridian, ID	Yes	No Action Indicated (NAI)*
US143	Research Your Health Plano, Texas	No	Voluntary Action Indicated (VAI)*

*Both classifications were changed by the Center. See details under Inspectional Findings.

Inspectional Findings:

The inspections did not reveal substantive issues that impact the data submitted in the BLA. However, the following issues were discussed during the inspections and shared with the BLA review committee.

- Study site US012: A Form FDA 483 was issued for this site with three observations related to verbal confirmation of medical history, temperature excursions, and protocol deviation reporting to the Institutional Review Board. Our review of the EIR and the site's explanations to the observations listed on the Form FDA 483 revealed that initial observations were not substantiated. The final classification was downgraded from VAI to NAI by the Center.
- Study site US143: A Form FDA 483 was not issued however we noted that protocol deviations were not being recorded by the site personnel, but rather by the monitor during their review. The final classification was escalated from NAI to VAI by the Center.

Sponsor Issues:

No significant sponsor issues were noted.

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 sites.

ADMINISTRATIVE FOLLOW-UP

No administrative follow-up is warranted at this time. Should you have any questions about the contents of this memo or any aspect of BIMO, please contact me at Triet.Tran@fda.hhs.gov.

Triet M. Tran, PharmD, BCSCP
Regulatory Officer

ELECTRONIC COPIES

EDR BLA STN 125817/0

Edward Wolfgang, PhD

Charles Line, MD, Clinical Reviewer

Amina White, MD, Clinical Reviewer

Donna Elhindi, PharmD, RPM

Paul Keller, PhD, RPM

Carrie M. Mampilly, MPH, Division Director

Kanaeko Ravenell, MS, Branch Chief

cberbimonotification@fda.hhs.gov,

Chron file

OII BIMO Division 3 Correspondence

OII BIMO Division 4 Correspondence

Cynthia J. Tsui, FDA Investigator

Travis M. Beard, FDA Investigator