



**U.S. FOOD & DRUG**  
ADMINISTRATION

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## Memorandum

DATE: April 4, 2023

TO: Santosh Nanda, PhD, Committee Chair  
Nicholas Geagan, MD, Clinical Reviewer  
Edward Wolfgang, PhD, RPM  
Nikunj Sharma, PhD, ORPM

FROM: Malcolm Nasirah, PharmD, MS, Regulatory Reviewer  
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Division of Inspections and Surveillance (DIS)  
Office of Compliance and Biologics Quality (OCBQ)

THROUGH: Dennis T. Cato, Chief BMB

THROUGH: Carrie M. Mampilly, MPH, Director DIS

SUBJECT: Bioresearch Monitoring Discipline Review Memo

PRODUCT: Respiratory Syncytial Virus Vaccine

SPONSOR: GlaxoSmithKline Biologicals SA  
BLA STN: 125775/0

### REVIEW SUMMARY

Bioresearch Monitoring (BIMO) Clinical Investigator (CI) inspections were issued for two foreign and two domestic clinical study sites that participated in the conduct of study protocol 212494. The inspections did not reveal substantive issues that impact the data submitted in this Biologics License Application (BLA).

### BACKGROUND

Four clinical study sites conducting the study protocol 212494 were identified for BIMO CI inspections. The sites were selected based upon the inspectional history, sponsor-reported adverse events, protocol deviations, and total number of subjects enrolled.

The 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 212494.

## PROTOCOL

Protocol 212494: *A Phase 3, randomized, placebo-controlled, observer-blind, multi-country study to demonstrate the efficacy of a single dose and annual revaccination doses of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above.*

The study enrolled a total of 26,664 subjects with approximately 23,000 participants in the Northern Hemisphere and approximately 2000 participants in the Southern Hemisphere, in 17 countries, with a planned study duration of several years. The inspected sites comprised of approximately 4.6% of the total subjects enrolled under protocol 212494 for the Northern Hemisphere. No Southern Hemisphere sites were inspected.

## BIMO INSPECTIONS SUMMARY

No significant BIMO inspectional findings were noted. The below table summarizes site information and outcomes from the BIMO inspections.

Study Site #	Firm Name	Location	FDA Form 483 Issued	Inspectional Final Classification
249411	Carol Pretzwell, MD	United Kingdom	No	NAI
249254	Natalie Duric, MD	United Kingdom	No	NAI
251406	Ghazaleh Bahrami, MD	Cerritos, California	No	NAI
251481	Jill Miracle, MD	Akron, Ohio	No	NAI

NAI = No Action Indicated

## INSPECTIONAL FINDINGS:

For Sites 249411, 249254, and 251406 there were no significant observations, and a Form FDA 483 was not issued at close of these inspections.

Site 251481 did not receive a Form FDA 483, but the OBIMO investigator noted that Subject files were not organized in appropriate binders, and a progress note dated 8/20/2021 located in the unblinded folder for subject (b) (6) did not contain any identifying information. This occurred during the oversight of the first principal investigator, Jeffery Klein, who (b) (6).

## SPONSOR/MONITORING ISSUES

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

## FINANCIAL DISCLOSURE

The CI CP directs the FDA investigator 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, spouse(s) and dependent children, as well as if and when the information was last updated. The information submitted to the BLA was verified for each of the inspected clinical study sites.

ADMINISTRATIVE FOLLOW-UP

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at 301-796-6667.

Malcolm Nasirah, PharmD, MS, BCGP  
Consumer Safety Officer