TITLE: FOOD AND DRUGS AUTHORITY PUBLIC ASSESSMENT REPORT ON GCP INSPECTIONS

PART 1: Administrative Details	
Title of Clinical Trial:	A parallel-group, Phase III, multi-stage, modified double-blind, multi-armed study to assess the efficacy, safety, and immunogenicity of two SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (monovalent and bivalent) for prevention against COVID-19 in adults 18 years of age and older as a primary series and open-label extension to assess immunogenicity, safety, efficacy of a monovalent booster dose of SARS-CoV2 Adjuvanted Recombinant Protein Vaccine.
Protocol Version used for Inspection:	Version 8 dated 18th September 2022
FDA Clinical Trial Certificate number assigned:	FDA/CT/2112c (2 ext 1)
Name of site Investigator:	Dr. Nana Akosua Ansah
Clinical Trial Site Name and Address:	Navrongo Health Research Centre P. O. Box 114, Navrongo, Upper East Region Ghana
Sponsor Name and Address:	Sanofi Pasteur Inc. Discovery Drive, Swiftwater, PA 18370-0187, USA.
Inspection Team:	• Dr Yvonne Adu Boahen • Samiratu Yakubu • Daniel Boateng
Date(s) of inspection:	31st January – 1st February 2024
Date of report:	6th February 2024
FAPAR Number:	FDA/CT/PAR/GCP/246

PART 2: Purpose of Inspection

Purpose:	The inspection was conducted as part of the FDA's mandate to ensure that all approved clinical trials are conducted in compliance with international best practice; the approved protocol, Good Clinical Practice (GCP), ICH E6 R2 standards and applicable regulatory requirements. The conduct of the inspection was as per FDA/CTD/SOP - 06 (SOP for Conducting GCP Inspections)

PART 3: Documents Reviewed and Facilities Inspected	
Documents Reviewed:	Documents reviewed included the version of the trial protocol available on site, Logs (delegation, screening, enrolment, training), Informed Consent Forms (ICFs), Standard Operating Procedures (SOPs) and Ethics Review Board (IRB) approval. These documents were reviewed to verify traceability, accuracy, consistency, completeness, and reliability of the study data.

Facilities Inspected:	Areas visited were:
	• NHRC – Clinical Trial Centre
	  ○ Clinical Trial area
	  ○ Consenting area
	  ○ Sample collection rooms
	  ○ Data room
	  ○ Resuscitation room/ICU
	  ○ Pre-screening area
	  ○ Post-screening room
	  ○ Temporary and permanent archiving rooms
	  ○ Pharmacy

PART 4: Study Status at Time of Inspection	
Study Status:	At the time of the inspection, the site had closed enrolment for the first phase of the study and started the second phase (crossover/booster phase). The total number of subjects administered with the IP was one thousand, two hundred and eighteen (1218). The number expected for the booster only vaccination was five hundred and twenty-one (521) and out of this, four hundred and twenty-seven (427) had been given the booster dose. Four hundred and twenty-three (423) participants had

	received the crossover dose 01 and four hundred and sixteen (416) participants had received crossover dose 02.

PART 5: Inspection Findings & Regulatory Actions	
Findings:	Seven (7) Major findings and twelve (10) Minor findings were observed during the inspection.
Regulatory Actions:	It was recommended that the sponsor and the study team take steps to resolve all the findings during the inspection to improve the site's compliance with GCP as per the FDA's guidelines and ICH E6 R2 guidelines.

PART 6: Status of Corrective and Preventive Actions (CAPA) & Current Status of Study	
Status of CAPA:	Corrective and preventive actions have been instituted as of 26th March 2024 and all outstanding issues deemed satisfactory.
Current Status of the study:	The study was found in substantial compliance with the principles of GCP as per the FDA's guidelines and ICH E6 R2 guidelines. The Sponsor and the Investigator site staff have been directed to ensure and maintain compliance with all applicable laws during the entire duration of the study.