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

PART 1: Administrative Details	
Title of Clinical Trial:	A Phase IIa observer-blind, randomized, controlled, age-de-escalation, single centre interventional study to evaluate the safety, reactogenicity, and immune response of the GVGH iNTS vaccine against S. Typhimurium and S. Enteritidis, in adults, children and infants, including dose-finding in infants, in Africa.
Protocol Version used for Inspection:	Protocol Amendment 2 Final dated 30th October 2023
FDA Clinical Trial Certificate number assigned:	FDA/CT/2313
Name of Principal Investigator:	Prof. Ellis Owusu-Dabo School of Public Health, College of Health Sciences, University Post Office, Kwame Nkrumah University of Technology, Kumasi E-mail: eowusu-dabo.chs@knust.edu.gh Telephone Number: +233201964425
Clinical Trial Site Name and Address:	KNUST-IVI Collaborative Centre
Sponsor Name and Address:	GlaxoSmithKline Biologicals SA Rue de l'Institut, 89 B-1330 Rixensart Belgium
Inspection Team:	Mrs. Amma Frempomaa Asare (Lead Inspector) Dr. Edwin Nkansah Mr. Jesse Kojo Kuntoh
Date(s) of inspection:	27th to 28th February 2024
Date of report:	19th June 2024
FAPAR Number:	FDA/CT/PAR/GCP/243

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 during the inspection at the study site, which is the KNUST-IVI Collaborative Centre, Agogo, were the consenting room, screening room, Phlebotomy room, vaccine preparation room, vaccine administration area, resuscitation/observation room, pharmacy unit, KNUST-IVI Laboratory and the archiving area. The inspection team also inspected the Public Health Laboratory/EOD laboatory at the KNUST School of Public Health.

PART 4: Study Status at Time of Inspection	
Study Status:	At the time of the inspection, the study was actively enrolling participants, and the following details were noted: a) Total number of participants consented screened = 30 adults b) Total number of participants who failed screening = 10 adults c) Total number of participants eligible = 20 adults d) Total number of subjects randomized and had been administered study IPs = 20 adults

PART 5: Inspection Findings & Regulatory Actions	
Findings:	Twelve (12) Major findings and eighteen (18) Minor findings were observed during the inspection.
Regulatory Actions:	Enrolment of new participants in the study was suspended as a regulatory action.

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 24th May 2024 and all outstanding issues deemed satisfactory.
Current Status of the study:	The suspension of new enrolment of participants into the study has been released. The study is now in substantial compliance with GCP and all FDA-applicable 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.