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

PART 1: Administrative Details	
Title of Clinical Trial:	A Phase 1 Randomized, Blinded, Placebo-Controlled, Dose-Escalation and Dosing Regimen Selection Study to Evaluate the Safety and Immunogenicity of rVSV-Vectored Lassa Virus Vaccine in Healthy Adults at Multiple Sites in West Africa
Protocol Version used for Inspection:	Version 2.0, dated 04 March, 2022
FDA Clinical Trial Certificate number assigned:	FDA/CT/228b
Name of site Investigator:	Dr. Patrick Ansah
Clinical Trial Site Name and Address:	Navrongo Health Research Centre P. O. Box 114, Navrongo, Upper East Region Ghana
Sponsor Name and Address:	Emergent BioSolutions (EBS) 400 Professional Drive, Gaithersburg, Maryland, USA 20879
Inspection Team:	• Dr Yvonne Adu Boahen • Samiratu Yakubu • Daniel Boateng
Date(s) of inspection:	30th – 31st January 2024
Date of report:	5th February 2024
FAPAR Number:	FDA/CT/PAR/GCP/242

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:
	• The Clinical Trial Centre
	  ○ Consenting area
	  ○ Consulting rooms
	  ○ Sample collection room
	  ○ Vaccination area
	  ○ Resuscitation unit
	  ○ Room for audiometry tests
	  ○ Temporary archiving room
	• Archiving building

PART 4: Study Status at Time of Inspection	
Study Status:	At the time of the inspection, the site had closed enrolment. A total of eighteen (18) participants had been screened and administered the IP. The site was yet to undergo close-out procedures and all leftover IPs had been destroyed under FDA supervision.

PART 5: Inspection Findings & Regulatory Actions	
Findings:	Six (6) Major findings and twelve (12) 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 29th 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.