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/228a
Name of site Investigator:	Dr. Seyram Kaali
Clinical Trial Site Name and Address:	Kintampo Health Research Center P. O. Box 200, Kintampo, Bono-East Ghana
Sponsor Name and Address:	Emergent BioSolutions (EBS) 400 Professional Drive, Gaithersburg, Maryland, USA 20879
Inspection Team:	• Richard Osei Buabeng, Principal Regulatory Officer (Inspection Lead) • Harriet Fianko, Regulatory Officer • Lindsay Addae, Regulatory Officer
Date(s) of inspection:	5th – 7th February 2024
Date of report:	13th February 2024
FAPAR Number:	FDA/CT/PAR/GCP/241

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 signed Protocol, Informed Consent Forms, Investigators' Brochure, Calibration records, Screening and Enrolment Logs, Sponsors reports and Communications with the investigator.
Facilities Inspected:	o Pharmacy unit o Cold room o Sample Collection room o Laboratory o Waiting area o Consulting rooms o Consenting area o Vaccine preparation, vaccination and post-vaccination rooms o Audiometry testing room o Resuscitation room/ICU o Archiving unit

PART 4: Study Status at Time of Inspection	
Study Status:	Enrolment was closed at the time of inspection with the last follow up date for the last participant being 5th July 2023, however, the study was yet to close-out activities on site. A total of 37 participants were screened and consented.

PART 5: Inspection Findings & Regulatory Actions	
Findings:	A total of eighteen (18) findings were observed during the inspection, one (1) critical, ten (10) major and seven (7) minor findings.
Regulatory Actions:	It was recommended that the sponsor and the study team take steps to find effective ways of correcting the non-compliances found during the

	inspection to improve the site's compliance with Good Clinical Practice (GCP) as per the FDA and ICH E6R2 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 10th May 2024 and all outstanding issues were satisfactorily resolved.
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 study was also reminded to submit the final study report, conforming to the ICH E3 Guideline for the Structure and Content of Clinical Study Reports per section 3.6.4.1 of the FDA's Guidelines for Authorization of Clinical Trials.