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

PART 1: Administrative Details	
Title of Clinical Trial:	Novel vacuum-induced Haemorrhage control for postpartum Haemorrhage: a multicentre randomised trial. (NOVIC)
Protocol Version used for Inspection:	Version 2.3 dated 16th June 2023
FDA Clinical Trial Certificate number assigned:	FDA/CT/235 dated 4th July 2023
Name of site Investigator:	Dr. Samuel A. Oppong
Clinical Trial Site Name and Address:	Korle Bu Teaching Hospital Greater Accra region
Sponsor Name and Address:	Women and Infant Hospital of Island 101 Dudley Street, Providence, Rhode Island 02905 Email: kfarnum@wihri.org Phone: +1 401 430 1575
Inspection Team:	Mrs. Amma Frempomaa Asare -Lead Inspector Ms. Jennifer Essilfie-Conduah -Regulatory Officer Ms. Pearl Entsua-Mensah -Regulatory Officer
Date(s) of inspection:	14th March – 15th March 2024
Date of report:	19th June 2024
FAPAR Number:	FDA/CT/PAR/GCP/244

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 at the Maternity Center (Korle-Bu Teaching Hospital) were: • Consenting Area • Labour and Delivery Wards • Storeroom for Investigational Products (IP)

PART 4: Study Status at Time of Inspection	
Study Status:	At the time of the inspection, the site was actively enrolling participants for the study. Per the study design, the total number of subjects consented who were eligible was one hundred and thirty-one (131). Seven (7) participants were randomized; three (3) to Jada arm and four (4) to the standard of care.

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 6th June 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.