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

PART 1: Administrative Details	
Title of Clinical Trial:	An Adaptive, Randomized, Placebo-controlled, Double-Blind, Multi-center Study of Oral FT-4202, a Pyruvate Kinase Activator in Patients with Sickle Cell Disease.
Protocol Version used for Inspection:	Version 4.0 dated 16th May 2022
FDA Clinical Trial Certificate number assigned:	FDA/CT/2215a(1) dated 2nd February 2024
Name of site Investigator:	Dr. Edeghonghon Olayemi
Clinical Trial Site Name and Address:	Ghana Institute of Clinical Genetics Korle Bu Teaching Hospital Greater Accra region
Sponsor Name and Address:	Forma Therapeutics, Inc. 300 North Beacon Street, Suite 501, Watertown, MA 02472, USA Attn: Irena Webster, MPH, MA Executive Director, Clinical Development Operations
Inspection Team:	Mrs. Amma Frempomaa Asare -Lead Inspector Ms. Jennifer Essilfie-Conduah -Regulatory Officer Ms. Nora Obodai -Regulatory Officer
Date(s) of inspection:	4th March – 5th March 2024
Date of report:	19th June 2024
FAPAR Number:	FDA/CT/PAR/GCP/245

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 Ghana Institute of Clinical Genetics, Korle Bu Teaching Hospital (KBTH), were the Consenting rooms, sample collection room, haematology laboratory, male and female wards, temporary storage for study documents and the pharmacy.

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. The total number of subjects consented and screened were sixteen (16) and the total number of subjects administered with the IP was thirteen (13). The number of participants who discontinued the trial by the Principal Investigator was two (2) and three (3) participants were left to be enrolled in the study.

PART 5: Inspection Findings & Regulatory Actions	
Findings:	Ten (10) Major findings and twenty-two (22) 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 5th 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.