EDA-GCP Public Inspection Report (PIR) of Clinical Trial Site

Part 1	General Information
Clinical medical research site details	
CT site information	
Name of CT site	MASRI CRC, Faculty of Medicine, Ain Shams University
Address of inspected CT site	El-Khalifa El-Mamoun Street, Abbasia, Cairo, Egypt
Inspection details	
Dates of inspection	02 December 2025
Type of inspection	Routine (Post Trial)
Introduction	
General information about the sponsor and CT site	- The inspected site is a Clinical Trial Site (**MASRI CRC, Ain shams University**) that conducts clinical studies for the sponsor (**Global Blood Therapeutics Inc. (GBT) is a wholly owned subsidiary of Pfizer Inc.).** - PI name: **Prof. Dr. Fatma Ebied** - Activities include participant recruitment, clinical conduct, sample collection, safety monitoring, and data documentation.
Brief report on inspection activities undertaken	
Scope and limitations	
Areas inspected	· Informed Consent Process · Investigational Medicinal Product (IMP) management · Source documents and Case Report Forms (CRFs) · Archiving and documentation system · Quality management system
Out of scope	The following areas were out of Scope: • Clinical Operations (Screening, dosing, follow-up): this was a post-trial GCP inspection conducted after the site's closure notification on 09 March 2025 and receipt of the close-out report on 15 May 2025. • Pharmacy / IMP storage area: The inspection was post-trial, and no at the site. • Site Laboratory: as no more blood sampling at this phase of the study.
Inspected Clinical medical research	The inspection focused on the following study: - Protocol Title: A randomized, double blind, placebo-controlled, multicenter study to assess the safety and efficacy of Inclacumab in

	participants with sickle anemia disease experiencing Vaso-occlusive crisis - Protocol Number: GBT2104-131 -Phase: III - EDA Initial approval date: 19\06\2022
Type of IMP	Biological Monoclonal antibody (Inclacumab)
Part 2	
1. Facilities and equipment system	
1.1. Facilities and Trial Conduct	-The site facilities were generally adequate for trial conduct. -Dedicated areas were available for participant reception and waiting, examination, consultation, and clinical procedures to support the conduct of the clinical trial. -Equipment maintenance, calibration, emergency preparedness was not verified during the inspection visit.
1.2. Computerized system	Electronic data capture, as eCRF and randomization systems were in use.
2. Pharmaceutical Quality System	
2.1. Quality Management System	-The site established a Quality Management System (QMS) supported by Standard Operating Procedures (SOPs) governing clinical trial conduct, documentation, participant safety, investigational medicinal product management, and quality oversight to ensure compliance with GCP, ethical principles, and applicable regulatory requirements. -An observation was identified **in accordance with ICHE6R3** regarding deficiencies in trial conduct and documentation, including failure to perform on of the required tests as per protocol, incorrect signatures on IMP dose preparation worksheets, failure to complete one of the questionnaires at the protocol-required visits, and lack of documented assessment of concomitant medications at specified visits for two participants. Corrective and preventive actions were implemented, including updating the affected dose preparation worksheets, training laboratory personnel and site staff on protocol-required procedures and documentation, and reinforcing documentation of concomitant medication assessment. The submitted CAPA was subsequently reviewed and accepted by EDA.
2.2.SOPs and Documentation	-The site-maintained SOPs governing clinical trial activities. During the inspection, the applicable SOPs and essential trial documents reviewed included the approved protocol and protocol amendments, Investigator's Brochure, informed consent forms, regulatory and

	ethics approvals, investigator qualifications and training records, delegation logs, investigational medicinal product management records, laboratory documentation, pharmacy manual, monitoring reports, participant records, eCRFs, source documents, contracts and agreements, safety reporting documentation, and other study-specific essential documents. -Study related Documents were appropriately controlled, maintained, periodically reviewed, and available. -One observation was identified **in accordance with ICH E6R3** regarding missing required signatures from the sponsor on essential trial documents, as Protocol Amendment and missing signature by CRA on the Site Recruitment and Activation Plan. In response for CAPA implementation, the investigator protocol acceptance form for Protocol Amendment was already filed in the Investigator Site File (ISF) and the signed Site Recruitment and activation plan**.** -Another observation was identified regarding deficiencies in the site's SOPs, as some SOPs had not been updated to reflect the current requirements of ICH E6(R3), did not address notification to EDA in case of IMP destruction, did not adequately describe safety reporting procedures and timelines to EDA, and did not address participant fingerprint documentation **in accordance with the Clinical Trials Law and EDA Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority**. In response for CAPA implementation, the site updated the identified SOPs and added a requirement that SOPs be reviewed and updated annually or whenever required due to regulatory changes. The CAPA related to the SOP deficiencies was reviewed by EDA and considered acceptable.
2.3. Deviation Management	Deviations were not handled according to SOPs as one observation was identified regarding protocol deviation management as mentioned above.
2.4. CAPA System	-A CAPA system was established at the site. -CAPA responses for findings identified during this inspection were submitted by the site and evaluated by EDA inspectors. -The identified findings were appropriately addressed by the site through corrective and preventive actions.
3. Ethics and participant Protection	
3.1.Informed Consent Process	-The informed consent process was verified during the inspection through the review of the approved Informed Consent Forms (ICFs),

	participant source records, and other relevant essential trial documents. -The inspection confirmed that informed consent was obtained from all participants before the performance of any study-related procedures using the approved Ethics Committee-approved versions of the informed consent forms, including the following: • Main Adul Paret ICF, V 3.0, dated 07 Dec 2023 • Adolescent assent (12-17 years old) ICF, Version 0.1, dated 1 March 2021 • Partner pregnancy ICF, V 1.0, dated 1 March 2021
3.2. Ethics Committee Approval	Approvals from IRB/IEC were available: **-MOH approval:** 07/07/2021 **-IRB approval:** 13/06/2021 -One observation was identified regarding a missing coverage period in progress reports submitted to MOH, for which no separate documentation was available. The CAPA response explained that the period was included in a subsequent progress report, but the start date had been entered incorrectly due to a typographical error. The submitted CAPA was reviewed by EDA and considered acceptable.
3.3. Participant Safety	-Participant safety was verified during the inspection through the review of participant source records, informed consent documentation, adverse event (AE) and serious adverse event (SAE) documentation, eCRFs, medical records, and other study-related essential documents. - The inspection report confirmed that the SAE was reported to the sponsor within the protocol-specified timeline and to EDA within the specified timeframe. -The inspection identified findings related to missed protocol-required assessments and incomplete documentation in participant records as described above; however, the CAPA response stated that the missed test did not affect participant enrolment or participant safety.
4. Personnel and Training	
4.1. Training and qualifications	-Roles and responsibilities of study personnel were clearly defined. -Current curriculum vitae (CVs), professional qualifications, and training records of the Principal Investigator and delegated study personnel were available and appropriately maintained. -GCP training records for the study team were reviewed and found to be available at the site. -Protocol-specific training records had been completed and were retained in the Investigator Site File.

	-The inspection identified an observation **in accordance with ICHE6R3**, regarding IMP dose preparation documentation, as certain dose preparation worksheets were signed by Co-Investigators as the IMP preparers, although the delegation log indicated that the study pharmacist was responsible for IMP preparation. The site clarified that the IMP was in fact prepared by the pharmacist and that the Co-Investigator signatures were intended to confirm review of the IMP preparation; however, the signatures had been entered in the IMP preparer field. In response for CAPA implementation, the PI clarified and signed and dated the affected worksheets during the inspection, and updated dose preparation worksheets identifying the pharmacist, as the correct IMP preparer were subsequently submitted. As a preventive action, site staff were retrained on completion of dose preparation worksheets and related training documentation for IMP preparation and handling. The submitted CAPA was reviewed and accepted by EDA.
5. Investigational Product (IMP) Management	
5.1. IMP handling	-IMP storage conditions, temperature monitoring, shipment, receipt, dispensing, accountability, return, and destruction procedures, as applicable, were reviewed during the inspection.
6. Clinical Trial Conduct	
6.1. Protocol Compliance	- The study was generally conducted according to the approved protocol (Protocol Amendment 4 (Version 5), dated: 13 July 2023). -Protocol compliance was verified during the inspection through the review of the approved protocol, participant source records, eCRFs, informed consent documentation, IMP records, laboratory documentation, safety reporting records, monitoring documentation, and other essential trial documents.
6.2. Source Data and CRFs	- Source documents and eCRFs were reviewed during the inspection. - The inspection included comparison of participant source records with the corresponding eCRFs and other relevant study documentation which were found to be complete, legible, contemporaneous, and appropriately maintained.
6.3. Delegation of Duties	- The Delegation of Responsibility Log was confirmed to be available at the site, accurately completed, signed by the Principal Investigator, and reflective of the actual roles and responsibilities assigned to each study team member. - Roles and responsibilities of study personnel were documented through the delegation log.

7. Laboratory and Bioanalytical Activities (if applicable)
- An external local Laboratory was used for analysis. - Laboratory procedures for Sample handling and analysis were generally defined. - External laboratory accreditation and qualifications were confirmed to be appropriate for the study requirements. - Laboratory procedures for sample collection, processing, storage, and transportation were implemented in accordance with the study protocol and laboratory manuals.
8. Safety Reporting (SAE)
- Safety reporting procedures were verified during the inspection through the review of AE and SAE documentation, safety-related records, applicable SOPs, and other relevant study documentation. - Reporting timelines and documentation procedures were reviewed and confirmed to be in place in preparation for study commencement.

Part 3	**Inspection outcome**
- Based on the reviewed documentation, inspected facilities, and observations identified during the inspection: The clinical trial site was considered to be operating at an acceptable level of compliance with GCP guidelines and applicable regulatory requirements as All identified deficiencies were communicated to the site and the Corrective and preventive actions (CAPA) were be implemented to address the observations. -This EDA-GCP-PIR remained valid until the next inspection, provided no critical findings, safety concerns, or regulatory actions arise.	
Part 4	**List of national Laws and GCP Guidelines referenced in the inspection report**
1. Law of Regulating Clinical Medical Research no.214/2020. 2. Prime Minister's Decree No. 927 of 2022 On Promulgating the Executive Regulation of Law on Regulating Clinical Medical Research Promulgated by Law No. 214 of 202 3. EDA Chairman Decree No.111 for 2022. 4. Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority "EDREX.GL.Bioinn.006". 5. Guideline for Good Clinical Practice ICH E6r3. 6. Declaration of Helsinki 7. WHO Handbook for Good Clinical Research Practice (GCP) -Guidance for Implementation	

Abbreviation	
AE	Adverse Event
CAPA	Corrective and Preventive Action
CRC	Clinical Research Center
CRF	Case Report Form
CT	Clinical Trial
CV	Curriculum Vitae

EDA	Egyptian Drug Authority
GCP	Good Clinical Practice
IB	Investigator Brochure
ICF	Informed Consent Form
ICH	International Conference of Harmonization
IMP	Investigational Medicinal Product
IRB/IEC	Institutional Review Board / Ethics Committee
MOH	Ministry of Health
PI	Principal Investigator
PIR	Public Inspection Report
QMS	Quality Management System
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
WHO	World Health Organization

العنـــــــــــوان: 51 شارع وزارة الزراعة، العجوزة - الجيزة
البـريد الإلـكـتـرونـي: المكتب الفني / bio.tech@edaegypt.gov.eg، المكتب الإداري /bio.admin@edaegypt.gov.eg
التـــلـيـــفـــون: 0237484988
موقع الهيئة: www.edaegypt.gov.eg