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	Abbassia, Cairo, Egypt
Inspection details	
Dates of inspection	16 December 2025
Type of inspection	Routine
Introduction	
General information about the sponsor and CT site	- The inspected site is a Clinical Trial Site (**MASRI CRC, Faculty of Medicine, Ain Shams University**) that conducts clinical studies for the sponsor (**Roche Egypt LLC**) in accordance with applicable regulatory requirements and ethical standards. - PI name: **Prof. Dr. Magd Zakaria** - 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 were out of scope: • Clinical Operations (Screening, dosing, follow-up) were not applicable as this phase of the trial (at time of inspection) no longer required these activities. • Pharmacy / IMP storage area as IMP were returned to the vendor for destruction • Bioanalytical / laboratory facilities as no further local laboratory will be performed for the patients within the study, as no safety follow-up and they are considered completed. No additional tests will be conducted for patients within the study based on this update.
Inspected Clinical medical research	The inspection focused on the following study:

	- Study Title: Single-arm, Open-label, 4-year study to evaluate the effectiveness and safety of Ocrelizumab treatment in patients with progressive multiple sclerosis - Protocol Number: MN39159 -Phase: III - EDA initial approval date: 20\09\2022
Type of IMP	Biological Monoclonal antibody (Ocrelizumab)
Part 2	
1. Facilities and equipment system	
1.1. Facilities and Trial Conduct	- The inspection included a tour of the site had the facilities, equipment, and infrastructure involved in the conduct of the study, including the archiving room and examination room. The site facilities were generally adequate for trial conduct. - Equipment maintenance, calibration, and emergency preparedness was in place during the inspection. Calibration certificates and maintenance records for the inspected equipment were verified, including maintenance documentation for the radiology center. -Emergency equipment available at the clinical trial site was reviewed as part of the inspection activities. * However, an observation was identified concerning the local laboratory **according to ICH E6R3,** as the CAP accreditation certificate was expired. In response, the site submitted a corrective and preventive action (CAPA), explaining that the delay resulted from ongoing laboratory facility modifications while valid ISO 15189 and GAHAR accreditation certificates remained available. The applicant subsequently submitted a CAP confirmation of continuity issued by the laboratory, and the submitted CAPA was reviewed and accepted by the Egyptian Drug Authority (EDA).
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 has established a Quality Management System supported by SOPs governing trial conduct, documentation, safety reporting, and IMP handling to ensure compliance with GCP principles, ethical standards, and regulatory requirements. The system aims to ensure participant safety, rights, and data integrity.
2.2. SOPs and Documentation	-SOPs and essential clinical trial documentation were reviewed during the inspection to verify their availability, implementation, and compliance with the approved protocol, GCP, and applicable regulatory requirements.

	-The documentation reviewed included the Investigator Site File (ISF), participant source records, informed consent forms (ICFs), case report forms (eCRFs), investigational medicinal product (IMP) documentation, regulatory and ethics approvals, laboratory accreditation records, equipment calibration certificates, and other study-related essential documents. - An observation was identified concerning the site's SOP system as one of the SOPs had not been updated to **reflect the requirements of ICH E6(R3),** and other one did not include procedures for obtaining participant fingerprints during the informed consent process. These observations indicated deficiencies in maintaining SOPs to ensure alignment with current regulatory requirements and site practices. - In response, the site revised the affected SOPs **to align with ICH E6(R3) requirements** and incorporated procedures for participant fingerprint documentation where applicable. Relevant study personnel received refresher training on the updated SOPs, and the submitted CAPA was reviewed and accepted by the Egyptian Drug Authority (EDA).
2.3. Deviation Management	Deviation management were reported and handled according to the site Standard Operating Procedures (SOPs). The inspection did not identify any protocol deviations or non-compliance that could affect participant safety, rights, or data integrity.
2.4. CAPA System	Following completion of the inspection, the site submitted a CAPA plan in response to the inspection observation . -The submitted CAPA, including the proposed corrective actions, preventive measures, root cause analysis, implementation timeline, and supporting documentation, was reviewed by the EDA . -The CAPA was considered adequate to address the identified observation and was accepted by EDA.
3. Ethics and participant Protection	
3.1. Informed Consent Process	The informed consent process was reviewed to verify compliance with the approved protocol, Good Clinical Practice (GCP), and applicable regulatory requirements. - Approved Informed Consent Forms (ICFs) were available and used as follows: • Main ICF (English version, V5.0) (09/09/2023) based on master ICF V6.0 (26/07/2023) • Main ICF (Arabic version, V5.0) (9/9/2023) based on Egypt ICF (English version, V5.0) (09/09/2023) • Main addendum 1 (Egypt, Arabic version, V4.0) (13/09/2023) based on addendum 1 to (Egypt, English version, V4.0) (9/9/2023)

	• Main ICF (Egypt, English version, V4.0) (08/11/2021) based on master ICF (V5.0) (22/09/2021) (Superseded) • Main addendum 1 to the master ICF (V4.0) (Arabic & English version, V1.0) (16/01/2022) (Superseded) • Main ICF (Arabic version, V4.0 based on Egypt ICF) (27/11/2021) and English version (V4.0) (08/11/2021) (Superseded) • Main Egypt ICF (English & Arabic, V3.1) (19/10/2021) (Superseded) • Pregnancy Outcome and Infant Health Information on First Year of Life Authorization Form (English V2.0) (18-05-2021) (Superseded) and (Arabic V2.0) (25/05/2021) (Superseded) • Main Egypt ICF (English version, V2.0) (13/03/2020) (Superseded) and (Arabic version, V2.0) (17/03/2020) (Superseded) • Main ICF (English version, V1.1) (22/02/2018) (Superseded) and (Arabic version, V1.0) (07/05/2018) (Superseded) • Dry run ICF (English version, V2.0) (08/03/2020) and (Arabic version, V2.0) (17/03/2020) • Dry run ICF (English version, V1.0) (17/03/2020) and (Arabic version, V1.0) (24/03/2020) - The inspection included verification of the approved informed consent forms (ICFs), participant consent documentation, and participant source records to confirm that informed consent was appropriately documented before the conduct of study-related procedures.
3.2. Ethics Committee Approval	Approvals from IRB/IEC were available, date of approval: • **IRB approval** on: 22/01/2019 • **MOH approval(s)** on: 31/10/2018 • **Supreme Council Approval** on: 06/01/2025
3.3. Participant Safety	-Participant safety was assessed during the inspection through the review of participant source records, informed consent documentation, eCRFs, and other study-related essential documents to verify that participant rights, safety, and well-being were adequately protected throughout the conduct of the clinical trial. -The inspection also assessed the preparedness of the investigator site and sponsor to ensure participant safety through the verification of safety reporting procedures, qualified study personnel, protocol-specific training, pharmacy and laboratory support, investigational medicinal product accountability and storage, calibrated study equipment, and monitoring activities performed throughout the conduct of the clinical trial.
4. Personnel and Training	

4.1. Training and qualifications	- Roles and responsibilities of study personnel were clearly defined. - The qualifications and training of the investigator and study personnel were reviewed during the inspection verified that delegated staff were appropriately qualified and trained to perform their assigned trial-related responsibilities. -The inspection included verification of curriculum vitae (CVs), GCP training records, protocol-specific training documentation, delegation records, and other relevant personnel qualification documents.
5. Investigational Product (IMP) Management	
5.1. IMP handling	- The management of the IMP was reviewed during the inspection, including IMP shipment, receipt, dispensing, accountability, and destruction records as well as certificates of analysis and other related documentation. -IMP handling was assessed for compliance with the approved protocol, GCP, and applicable regulatory requirements.
6. Clinical Trial Conduct	
6.1. Protocol Compliance	The conduct of the clinical trial was reviewed to assess compliance with the approved protocol (Version: 6.0, dated: 26/07/2023), GCP, and applicable regulatory requirements . The study was conducted at an acceptable level of compliance with the approved protocol, and no protocol deviations were identified during the inspection.
6.2. Source Data and CRFs	-Source data and Case Report Forms (eCRFs) were reviewed during the inspection to verify the completeness, accuracy, and consistency of clinical trial data with the participant source records. -The inspection included comparison of participant source documents with the corresponding eCRFs and review of study documentation to assess compliance with the approved protocol, GCP, and applicable regulatory requirements.
6.3. Delegation of Duties	The study personnel documentation was reviewed and verified that trial-related responsibilities were assigned to qualified and appropriately trained personnel. Documentation reviewed included study personnel qualification records, GCP training records, and other relevant essential documents supporting the conduct of the clinical trial activities
7. Laboratory and Bioanalytical Activities (if applicable)	
- An external central and local Laboratory (Local) were used for analysis of bio samples. - The inspection included a review of laboratory-related documentation relevant to the conduct of the clinical trial, including laboratory accreditation records, as part of the verification of essential trial documentation.	

- Some deficiencies related to documentation and lab accreditation were noted. An observation was identified, as the Clinical Pathology local Laboratory CAP accreditation certificate had expired at the time of the inspection. In response, the site provided a valid CAP accreditation certificate as CAPA, which was reviewed and accepted by EDA.
8. Safety Reporting (SAE)
- Safety reporting documentation was reviewed as part of the inspection of essential trial records to assess compliance with the approved protocol, Good Clinical Practice (GCP), and applicable regulatory requirements. - The inspection included a review of participant source records, case report forms (eCRFs), and other relevant study documentation supporting participant safety oversight Based on the Clinical trial activities performed.

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 CAPA were implemented to address the observations. This EDA-GCP-PIR remains 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 2020 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
ALCOA	Attributable, Legible, Contemporaneous, Original, Accurate
CAP	College of American Pathologist
CAPA	Corrective and Preventive Action
CRF	Case Report Form
CRC	Clinical Research Center
CT	Clinical Trial
EDA	Egyptian Drug Authority
GAHAR	General Authority for Healthcare Accreditation and Regulation

GCP	Good Clinical Practice
ICF	Informed Consent Form
IB	Investigator Brochure
ICH	International Conference of Harmonization
IMP	Investigational Medicinal Product
IRB/IEC	Institutional Review Board / Ethics Committee
ISF	Investigator Site File
ISO	International Organization for Standardization
MOH	Ministry of Health
PI	Principal Investigator
PIR	Public Inspection Report
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
WHO	World Health Organization

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