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	CRC, Alexandria university Hospital (Site no.: 303973)
Address of inspected CT site	17 Champlin Street, Azarita Alex, Alexandria, Egypt
Inspection details	
Dates of inspection	31 December 2025
Type of inspection	Routine
Introduction	
General information about the sponsor and CT site	- The inspected site is a Clinical Trial Site (**CRC, Alexandria University Hospital**) that conducts clinical studies for the sponsor (**Roche**) in accordance with applicable regulatory requirements and ethical standards. - PI name**: Prof. Dr. Farouk Talaat** - 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 safety follow-up and the participants were 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 site facilities were generally adequate for trial conduct as the inspection included a tour of the relevant areas of the clinical trial site involved in the conduct of the study, including the archiving room and examination room. Based on the documents reviewed and the facilities inspected, the study was conducted at an acceptable level of compliance with the protocol, GCP guidelines, and applicable regulatory requirements. - Equipment maintenance, calibration, and emergency preparedness was in place. - Calibration certificates for the inspected equipment were reviewed and verified to be current at the time of the inspection. No deficiencies related to equipment maintenance or calibration were identified.
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	-The site maintains SOPs governing clinical trial activities. - Essential trial documentation was reviewed during the inspection, including participant source records, the Investigator Site File (ISF), informed consent forms, case report forms (CRFs), investigational medicinal product (IMP) records, and Good Clinical Practice (GCP) training records. The reviewed documentation was assessed to verify compliance with the approved protocol, Good Clinical Practice (GCP), and applicable regulatory requirements.
2.3. Deviation Management	The inspection included a review of the clinical trial documentation to verify whether protocol deviations were identified, reported, handled and

	managed according to the site Standard Operating Procedures (SOPs) throughout the conduct of the study.
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 during the inspection. - 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)

3.2. Ethics Committee Approval	Approvals from IRB/IEC were available, date of approval: • **IRB approval** on: 21/06/2018 • **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 review of participant source records, informed consent documentation, eCRFs, medical records, and other study-related essential documents including safety-related assessments, as applicable to the study protocol to verify that participant rights, safety, and well-being were protected in accordance with the approved protocol, GCP, and applicable regulatory requirements. -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. - No participant safety-related deficiencies were identified during the inspection.
4. Personnel and Training	
4.1. Training and qualifications	- The qualifications and training records of the investigator and study personnel involved in the conduct of the clinical trial were reviewed during the inspection verified that delegated staff were appropriately qualified and trained to perform their assigned trial-related responsibilities. - Roles and responsibilities were assigned in accordance with the conduct of the clinical trial, and Good Clinical Practice (GCP) training records were available for review. - The inspection included verification of curriculum vitae (CVs), GCP training records, protocol-specific training documentation, delegation of responsibilities log, and other relevant personnel qualification records.
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. - No deficiencies related to IMP management were identified during the inspection.

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 documents and corresponding trial records were reviewed to assess the accuracy, completeness, and integrity of the recorded data. -One observation was identified related to source documentation practices, as corrections in source records were not fully documented **in accordance with ALCOAC principles and ICH E6R3 guideline** and a documentation error was identified in the recording of source data. The site acknowledged the observation and corrected the affected source documentation as corrective action and implemented preventive measures by retraining the responsible Co-personnel on ALCOAC source documentation principles. Evidence of the training was submitted as part of the CAPA, which was reviewed and accepted by the Egyptian Drug Authority (EDA).
6.3. Delegation of Duties	- Delegation logs were available and verified, during the inspection, visit that assignment of study responsibilities among the study personnel involved in the conduct of the clinical trial and to confirm that delegated trial-related activities were appropriately documented and performed by authorized personnel.
7. Laboratory and Bioanalytical Activities (if applicable	
- An external central & local Laboratory were used for analysis of bio samples. - Laboratory and bioanalytical activities were not within the scope of this inspection. Therefore, no assessment of laboratory facilities, sample handling, or bioanalytical procedures was performed.	
8. Safety Reporting (SAE)	
- SOPs for SAE reporting were available. - Safety reporting documentation relevant to the conduct of the clinical trial was reviewed during the inspection to verify compliance with the approved protocol, Good Clinical Practice (GCP), and applicable regulatory requirements. - No deficiencies related to safety reporting were identified during the inspection.	
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
CAPA	Corrective and Preventive Action
CRF	Case Report Form
CRC	Clinical Research Center
CT	Clinical Trial
EDA	Egyptian Drug Authority
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
MOH	Ministry of Health
PI	Principal Investigator
PIR	Public Inspection Report
SAE	Serious Adverse Event
SOP	Standard Operating Procedure

WHO	World Health Organization

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