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, Faculty of Medicine, Alexandria University Hospital
Address of inspected CT site	Faculty of Medicine, Alexandria University, 17 Champollion Street, El Messalah, Alexandria, Egypt
Inspection details	
Dates of inspection	16 October 2025
Type of inspection	Routine
Introduction	
General information about the sponsor and CT site	-The inspected site is a Clinical Trial Site (**CRC, Faculty of Medicine, Alexandria University Hospital**) that conducts clinical studies for the sponsor (**AbbVie**). -PI name: **Prof. Dr. Osama Ebada** -Activities include participant recruitment, clinical conduct, sample collection, safety monitoring, and data documentation.
Brief report on inspection activities undertaken	
Scope and limitations	
Areas inspected	-Clinical operations (screening, dosing, follow-up) -Informed Consent Process -Investigational Medicinal Product (IMP) management -Pharmacy / IMP storage area -Bioanalytical / laboratory facilities (if applicable) -Source documents and Case Report Forms (CRFs) -Archiving and documentation system - Quality management system
Out of scope	Not defined
Inspected Clinical medical research	The inspection focused on the following study: -Protocol Title: A Multicenter, Randomized, Double-Blind, Placebo-Controlled 52-Week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Ulcerative Colitis -Protocol Number: M16-066 -Phase: III -EDA initial approval date: 17/04/2019

Type of IMP	Biological Monoclonal antibody (Risankizumab)
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, informed consent, examination, consultation, IMP preparation and administration, laboratory sample processing, pharmacy (IMP storage), and document archiving. - Equipment maintenance, calibration, and emergency preparedness arrangements were assessed for adequacy during the inspection. The medical equipment used during the trial, including a weight scale, sphygmomanometer, electrocardiogram (ECG) machine, endoscopy equipment, defibrillator, centrifuge, incubator, laboratory refrigerator, refrigerator for IMP storage, temperature data logger, calibrated thermometer, room temperature monitoring devices, was available and maintained with valid calibration. -The emergency trolley was available and inspected during the visit. Records demonstrated that routine checks were performed, and emergency medications were available within their expiry dates. -The pharmacy (IMP storage) area was secured with restricted access. Investigational medicinal products were stored under protocol-specified temperature conditions, continuous temperature monitoring was implemented using a calibrated data logger, and appropriate backup measures were available to maintain the required storage conditions.
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 (QMS) 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. -The study has been monitored according to the monitoring plan.
2.2. SOPs and Documentation	-The site maintains 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, IMP management records, laboratory documentation, safety reporting procedures,

	monitoring reports, participant records, eCRFs, progress reports, and other study-specific essential documents. -Study related documents were controlled, periodically reviewed, and implemented. -One observation was identified during the inspection in accordance with ICH E6(R3), as documentation supporting the Ministry of Health (MOH) one of the progress follow-up reports was not available in the Investigator Site File (ISF). In response for CAPA implementation, the sponsor requested retrieval of the submitted progress report from the MOH archives, documented the incident in a note-to-file that filed in the ISF, committed to submit the retrieved progress report to EDA once obtained, and implemented preventive measures by submitting progress reports electronically where applicable and retraining responsible personnel on Trial Master File (TMF) management requirements, including the filing of MOH progress reports in both the TMF and ISF. The submitted CAPA was reviewed and accepted by EDA.
2.3.Deviation Management	-Deviations were handled according to SOPs. Documentation of deviations, investigations, and CAPA was generally adequate. Some deficiencies were noted.
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 within defined timeline 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 reviewed during the inspection through the review of the approved 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 current Ethics Committee-approved versions of the informed consent forms, including the main ICF and, where applicable, the pregnant partner ICF as follows: • M16-066 Pregnant Partner Authorization for Data Release Egypt, version 1 dated 04 Aug 2018. • M16-066 OUS Main Study ICF Egypt, version 4, 27 November 2023. • M16-066 ICF (Continuous Treatment Extension), version 1, 27 November 2023.

3.2. Ethics Committee Approval	-Approvals from IRB/IEC were available and verified during inspection: • **MOH approval(s)** on: 06/03/2019 • **IRB approval(s)** on: 18\10\2018
3.3. Participant Safety	Safety monitoring procedures were in place. Participant safety was assessed during the inspection through the review of participant source records, informed consent documentation AE and SAE documentation, eCRFs, medical records, and other study-related essential documents, together with verification of the clinical trial facilities, emergency preparedness arrangements, IMP management process, pharmacy, and laboratory facilities.
4. Personnel and Training	
4.1. Training and qualifications	-Roles and responsibilities of study personnel were clearly defined. -GCP training records were available and reviewed. -The training system was generally adequate. -Current curriculum vitae (CVs) of the Principal Investigator and Sub-Investigators were available and appropriately maintained. -Study-specific training records, including trial initiation and investigator meeting documentation, were reviewed during the inspection and found to be available at the site, demonstrating that study personnel had received the required training to perform their assigned trial-related responsibilities.
5. Investigational Product (IMP) Management	
5.1. IMP handling	-IMP storage conditions, temperature monitoring, and accountability records were reviewed. -Shipping, receipt, and dispensing procedures were implemented. -Labeling and traceability were generally adequate. -The pharmacy (IMP storage area) was secured with restricted access, and IMPs were stored under the protocol-specified environmental conditions with appropriate temperature monitoring and documentation.
6. Clinical Trial Conduct	
6.1. Protocol Compliance	- The study was generally conducted according to the approved protocol (Version: Amendment 6, dated: 14/09/2023). -Based on the documents reviewed, facilities inspected, and the inspection findings, the study was conducted at an acceptable level of compliance with the approved protocol, GCP guidelines, and applicable regulatory requirements.
6.2. Source Data and CRFs	- Source documents and eCRFs were reviewed. - The inspection included comparison of participant source records with the corresponding eCRFs and other relevant study documentation. -Data were generally consistent.

	-Source data were found to be legible and well organized, and no discrepancies between the source documents and eCRFs were identified with compliance with ALCOA principles during the inspection.
6.3. Delegation of Duties	-The delegation of trial-related responsibilities was reviewed during the inspection through the review of the Site Signature and Delegation of Responsibilities Log and other relevant study documentation, and it was verified that trial-related duties had been appropriately assigned to qualified study personnel. -The delegation log was available, appropriately maintained, and clearly documented the responsibilities delegated by the Principal Investigator to qualified study personnel.
7. Laboratory and Bioanalytical Activities (if applicable)	
-An external central laboratory was used for analysis of bio samples. - Laboratory and bioanalytical activities were assessed during the inspection through the review of laboratory-related documentation, laboratory agreements, sample handling procedures, and blood sample transportation processes. -Laboratory procedures for sample collection, processing, storage, and transportation were implemented in accordance with the protocol and laboratory manuals. -The laboratories were accredited. Laboratory equipment used for sample processing and storage was considered appropriately calibrated through laboratory accreditation. -The laboratory facilities were inspected. Samples were processed, stored, and transported in accordance with the protocol and laboratory manual using calibrated equipment and temperature-controlled conditions.	
8. Safety Reporting (SAE)	
-Safety reporting procedures were available and reviewed during the inspection including adverse event (AE) and serious adverse event (SAE) documentation, safety-related records, applicable SOPs, and other relevant study documentation. -The site was compliant with the safety reporting timelines to the sponsor and regulatory authority.	
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 CAPA were 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 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
CRA	Clinical Research associate
CRF	Case Report Form
CT	Clinical Trial
CV	Curriculum Vitae
ECG	Electrocardiogram
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
ISF	Investigational site file
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