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	Air Force Specialized Hospital
Address of inspected CT site	EL-Tesseen St., Fifth Settlement, New Cairo
Inspection details	
Dates of inspection	30 October 2025
Type of inspection	Routine (Post Trial)
Introduction	
General information about the sponsor and CT site	- The inspected site is a Clinical Trial Site (**Air Force Specialized Hospital**) that conducts clinical studies for the sponsor (**AbbVie**). - PI name: **Prof. Dr. Hesham El Sawah** - 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 5 Week Maintenance and an Open-Label Extension Study of the Efficacy and Saf 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, investigational medicinal product (IMP) preparation and administration, laboratory sample processing, pharmacy (IMP storage), and document archiving. -Equipment maintenance, calibration, and emergency preparedness arrangements were verified during the inspection. -The medical equipment used during the trial, including a weight balance, sphygmomanometer, electrocardiogram (ECG) machine, endoscopy equipment, defibrillator (DC shock), centrifuges, incubator, laboratory refrigerator& freezer for bio sample storage, refrigerator for IMP storage, temperature monitoring devices, and an emergency trolley, was available and maintained. -One observation was identified during the inspection in accordance with ICH E6(R3), as inconsistencies were identified between calibration labels and calibration certificates for certain equipment, and the calibration labels attached to several devices did not include a device identification number linking them to the corresponding calibration certificates. Specifically, the calibration certificate for the sphygmomanometer did not specify the calibration due date reflected on the device label, the calibration label of the defibrillator (DC shock) contained dates that differed from those documented in the corresponding calibration certificate, and the identification field on the calibration labels of the weight balance, sphygmomanometer, ECG machine, defibrillator, centrifuges, and freezer was left blank. The site confirmed that equipment traceability was maintained through the Biomedical Engineering Department using the equipment serial number and equipment control number. In response for CAPA implementation, updated calibration documentation and supporting evidence were provided, a Note to File describing the site's calibration process and equipment identification procedures was filed, and the sponsor confirmed completion of the required documentation. The updated calibration certificate and corrected calibration label were accepted. The CAPA was further strengthened by requiring future calibration labels to include the equipment serial number and implementation of quality assurance verification to ensure consistency between calibration labels and calibration certificates. The submitted CAPA was subsequently reviewed and accepted by EDA. -The emergency trolley was available during the inspection, and emergency medicines were stored within their expiry dates. However, one observation was identified because the expiry dates documented in the emergency medication

	list for some medications did not correspond to the actual expiry dates of the stocked medicines. In response, the emergency medication list was corrected, a monthly reconciliation process was implemented to ensure consistency between physical stock and inventory records. The submitted CAPA was subsequently 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 (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.
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, investigational medicinal product management records, laboratory documentation, safety reporting procedures, monitoring reports, participant records, eCRFs, progress reports, and other study-specific essential documents. -Documents were controlled, periodically reviewed, and implemented. -One observation was identified during the inspection in accordance with Law No. 214/2020, as "Informed Consent Process" SOP had not been updated to require participants' fingerprints on the Informed Consent Form (ICF) template. In response for CAPA implementation, SOP was revised and updated to incorporate the participant fingerprint requirement, and the site committed to periodically review SOPs to ensure alignment with updated regulatory requirements. The submitted CAPA was reviewed and accepted by EDA. -Another observation was also 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, committed to submit the retrieved report to EDA once obtained, implemented electronic submission of progress reports where applicable, and retrained Clinical Research Associates (CRAs) on TMF management and regulatory filing requirements, including filing requirements for the Supreme Council and the Egyptian Drug Authority. The submitted CAPA was subsequently 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 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 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 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. - One observation was identified during the inspection in accordance with Law No. 214/2020, as the ICF for one of the verified participants did not include the participant's fingerprint. The site explained that the participant had signed the ICF before the implementation of Law No. 214/2020 and its Executive Regulation introducing the fingerprint requirement. In response for CAPA implementation, the site confirmed that all new informed consent forms and re-consent forms signed after implementation of the law include both the participant's signature and fingerprint. In addition, the site updated its informed consent SOP to incorporate the fingerprint requirement for future studies. The submitted CAPA was subsequently reviewed and accepted by EDA.
3.2. Ethics Committee Approval	- The inspection included verification of the regulatory and ethics documentation. - Approvals from IRB/IEC were available and verified during inspection: -**MOH approval(s)** on: 06/03/2019

	-**IRB approval(s)** on: 24/10/2018
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, adverse event (AE) and serious adverse event (SAE) documentation, eCRFs, medical records, and other study-related essential documents, together with verification of the clinical trial facilities, emergency preparedness arrangements, investigational medicinal product 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, 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 4, dated: 01/10/2020). -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 CRFs 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 CRFs 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. -One observation was identified during the inspection in accordance with ICH E6(R3), as some Investigational Product (IP) Dispatch Forms and Investigational Product Return for Destruction Forms were signed by a staff member who was listed in the Site Signature and Delegation of Responsibility Log but had not been delegated responsibility for IP receipt or return activities at the time the tasks were performed. In addition, discrepancies were identified between the signatures recorded on certain IP-related documents and those documented in the delegation log. The sponsor explained that some site personnel used different parts of their names in their signatures, which was not detected during monitoring. In response for CAPA implementation, the site documented the discrepancies through a Note to File, updated the relevant personnel records, and implemented refresher training on delegation requirements to ensure that no study-related activities are performed unless appropriately delegated. The sponsor also retrained Clinical Research Associates (CRAs) on delegation review requirements. The submitted CAPA was subsequently reviewed and accepted by EDA.
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.	
8. Safety Reporting (SAE)	

-Safety reporting procedures were reviewed during the inspection including adverse event (AE) and serious adverse event (SAE) documentation, safety-related records, applicable Standard Operating Procedures (SOPs), and other relevant study documentation. -SOPs for adverse event (AE) and serious adverse event (SAE) reporting was available. -The site was compliant with the safety reporting timelines.	
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 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
DC	Direct Current
ECG	Electrocardi ogram
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
TMF	Trial Master File
WHO	World Health Organization

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