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	Hematology Department, Nasser Institute for research and Treatment Hospital (Site no.3004)
Address of inspected CT site	1351 Nile Kornish, Shubra, Cairo
Inspection details	
Dates of inspection	15 February 2026
Type of inspection	Routine
Introduction	
General information about the sponsor and CT site	- The inspected site is a Clinical Trial Site (**Hematology Department, Nasser Institute for research and Treatment Hospital**) that conducts clinical studies for the sponsor (**Janssen Research & Development, LLC**). - PI name: **Prof. Dr. Raafat Abd El Fattah** - 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) - Informed Consent Process - Bioanalytical / laboratory facilities (if applicable) - Source documents and Case Report Forms (CRFs) - Archiving and documentation system - Quality management system
Out of scope	The following area were out of the Inspection Scope: - Clinical operations (dosing, follow-up) as no participants were randomized or received IMP at this site. - Investigational Medicinal Product (IMP) management as no participants were enrolled and no IMP was shipped to the site. - Pharmacy / IMP storage area as no IMP was shipped to the site.
Inspected Clinical medical research	The inspection focused on the following study: Study Title: Efficacy and Safety of M281 in Adults with Warm Autoimmune Hemolytic Anemia: A Multicenter, Randomized, Double-blind, Placebo-controlled Study with a long-term Open-label Extension

	- Protocol Number: MOM-M281-0006 -Phase: II/III - EDA initial approval date: 19/07/2023
Type of IMP	Biological Monoclonal antibody (Nipocalimab)
Part 2	
1. Facilities and equipment system	
1.1. Facilities and Trial Conduct	- The site facilities were generally adequate for trial conduct. - Equipment maintenance, calibration, and emergency preparedness were in place. - Dedicated consenting, examination and procedure rooms were available for study-related activities. - One observation was identified during the inspection, as no safety sharps disposal containers (yellow safety boxes) were available in the examination room **in accordance with the internationally recognized colour-coding system.** In response, the site restored the supply of yellow sharps disposal containers and ensured their availability in the examination room. Furthermore, the inventory checklist and inventory management SOP were updated to incorporate weekly monitoring of sharps disposal container stock to prevent future shortages, relevant personnel were trained on the updated procedures, and supporting evidence demonstrating implementation was submitted to the Egyptian Drug Authority (EDA). The submitted CAPA was reviewed and accepted by the EDA. - Study files were stored in a secure, access-controlled, fire- and water-resistant cabinet. - A dedicated investigational medicinal product (IMP) storage room was available, and the IMP storage conditions were maintained in accordance with the Pharmacy Manual. - Equipment, calibration records, emergency equipment preparedness, IMP storage conditions, temperature monitoring records, and laboratory facilities were reviewed and verified for adequacy and compliance with the approved protocol, Good Clinical Practice (GCP), and applicable regulatory requirements during the inspection. - One observation was identified during the inspection, as calibration certificates demonstrating coverage during the study conduct period were unavailable for the ECG and centrifuge, and expired calibration labels were identified on the sphygmomanometer, weight balance, and ECG during the inspection visit **in ICH E6R3.** The sponsor attributed these observations to delays in the issuance and filing of calibration certificates and labels by the site's medical engineering department. In response, the provided the missing

	calibration certificates and updated calibration labels, implemented a periodic quality review process for calibration activities, updated the equipment calibration SOP, and training relevant personnel on the revised procedure. 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 Quality Management System (QMS) was assessed during the inspection to verify that quality processes supporting the conduct of the clinical trial were established and implemented in accordance with the approved protocol, GCP, and applicable regulatory requirements.
2.2. SOPs and Documentation	- The site-maintained SOPs governing clinical trial activities. The applicable SOPs were reviewed during the inspection to assess document control, periodic review, and implementation. The inspection included review of SOPs related to informed consent, adverse event (AE) and serious adverse event (SAE) reporting, participant rights, investigational medicinal product (IMP) management, medical equipment calibration and maintenance, inventory management, and other study-related quality procedures. - One observation was identified during the inspection **in accordance with CT law 214/2020, ICH E6R3, and Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority**, as several site SOPs were not fully aligned with current regulatory requirements, including deficiencies in procedures related to participant rights, serious adverse event (SAE) reporting, IMP management, and document control. The sponsor attributed these observations primarily to delays in the scheduled review and update of site SOPs. In response, the site committed to revising and updating the affected SOPs, developing an SOP for IMP management, correcting documentation control deficiencies, and training relevant site personnel on the updated procedures. The submitted CAPA was reviewed and accepted by the EDA.
2.3.Deviation Management	- Protocol deviations were handled according to SOPs and were documented in progress reports submitted to EDA. - The procedures and documentation related to the identification, reporting, assessment, and management of protocol deviations, including associated investigations and CAPA reviewed and insured compliance with GCP.
2.4. CAPA System	- A CAPA system was established at the site. - A Comprehensive CAPA responses addressing all findings and recommendations were prepared and submitted within defined timeline

	- All corrective actions were implemented and supported with documentation as proof of correction in compliance with applicable GCP and regulatory standards.
3. Ethics and participant Protection	
3.1.Informed Consent Process	- The informed consent process was assessed through the review of the approved ICFs, participant source records, informed consent documentation, and other relevant essential trial documents to verify compliance with the approved protocol, GCP, and applicable regulatory requirements. Approved Informed Consent Forms (ICFs) were available and used as follows: • Main Adult ICF Version 0.1 (dated 3/11/2022) • ICF for pregnant participant or pregnant partner: version 0.1 (3/11/2022) - All informed consents were signed by participants prior to the performance of any study-related procedures, in full compliance with GCP guidelines. The procedure for obtaining informed consent from participants was confirmed to be fully in line with the requirements of GCP guidelines.
3.2.Ethics Committee Approval	Approval from IEC were available, date of approval: • **MOH approval** on: 31/05/2023 Approval from the Ministry of Health (MOH)-Independent Ethics Committee (IEC) the, as applicable, was reviewed during the inspection and verified the compliance with the EDA approved protocol, GCP, and applicable regulatory requirements.
3.3.Participant Safety	- Participant safety was assessed during the inspection through the review of participant source records, informed consent documentation, adverse event (AE) and SAE records, eCRFs, and other relevant essential clinical trial documentation to verify that participants' rights, safety, and well-being were protected in accordance with the approved protocol, GCP, and applicable regulatory requirements. - The inspection confirmed that the SAEs were reported at the inspected site during the conduct of the clinical trial.
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. - Personnel qualifications and training were assessed during the inspection to verify that study personnel were appropriately qualified, trained, and delegated to perform their assigned trial-related responsibilities in accordance with the approved protocol, Good Clinical Practice (GCP), and applicable regulatory requirements.

	- The inspection included a review of curriculum vitae (CVs), training records, delegation documentation, and other relevant personnel records.
5. Investigational Product (IMP) Management	
5.1. IMP handling	- As no participants were randomized, no IMP was shipped to the site, and no IMP handling activities were performed.
6. Clinical Trial Conduct	
6.1. Protocol Compliance	- Protocol compliance was assessed during the inspection through the review of the approved protocol (Version: Amendmnet6.0, dated: 18/08/2022), participant source records, eCRFs, and other relevant essential clinical trial documentation to verify compliance with the approved protocol, GCP, and applicable regulatory requirements.
6.2. Source Data and CRFs	- Source documents and eCRFs were reviewed during the inspection to verify the completeness, accuracy, consistency, and traceability of clinical trial data in accordance with the approved protocol, GCP, and applicable regulatory requirements. - The inspection included a comparison of participant source records with the corresponding study documentation, as applicable.
6.3. Delegation of Duties	- The delegation of trial-related responsibilities was assessed during the inspection to verify that study duties had been appropriately assigned to qualified study personnel in accordance with the approved protocol, GCP, and applicable regulatory requirements. - The inspection included a review of the delegation of responsibilities log, supporting personnel records, and access to essential clinical trial documentation. - One minor observation was identified during the inspection in accordance with ICH-E6R3, as the study nurse had access to archived participant records without formal delegation or documented authorization. In response, the site revised its archiving procedure to clearly define authorized personnel and access requirements, implemented appropriate access control measures, and provided training to the relevant study personnel on the updated procedure. The submitted CAPA was reviewed and accepted by EDA.
7. Laboratory and Bioanalytical Activities (if applicable)	
- An External Central and Local laboratory were used for biosamples analysis. - Laboratory and bioanalytical activities were assessed during the inspection through the review of laboratory-related documentation and a visit to the laboratory facilities involved in the clinical trial, as applicable, and verified the compliance with the approved protocol, GCP, and applicable regulatory requirements.	
8. Safety Reporting (SAE)	

- SOP for SAE reporting was available.
- Safety reporting was assessed during the inspection through the review of AE and SAE documentation, safety-related records, applicable SOPs, and other relevant study documentation to verify compliance with the approved protocol, GCP, and applicable regulatory requirements.

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 the identified deficiencies were communicated to the site and Corrective and preventive actions (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
CAPA	Corrective and Preventive Action
CRF	Case Report Form
CT	Clinical Trial
CV	Curriculum Vitae
EDA	Egyptian Drug Authority
ECG	Electrocardiogram
GCP	Good Clinical Practice
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

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