# EDA-GCP Public Inspection Report (PIR) of Clinical Trial Site

| Part 1 | General information |
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| **Clinical medical research site details** | |
| **CT site information** | |
| **Name of CT site** | CRC, Faculty of Medicine, Alexandria University Hospital |
| **Address of inspected CT site** | 17 Champlion Street, Azarita Alex, Alexandria, Egypt |
| **Inspection details** | |
| **Dates of inspection** | 23 September 2025 |
| **Type of inspection** | Routine (Post-trial) inspection |
| **Introduction** | |
| **General information about the sponsor and CT site** | The inspected site is CRC, Faculty of Medicine, Alexandria University Hospital, conducting clinical studies for the sponsor Janssen Research & Development (CRO: MCT) in accordance with applicable regulatory requirements and ethical standards. The Principal Investigator was Dr. Ashraf El. Ghandour, supported by Co-Investigators<br>Activities included participant recruitment, clinical conduct (screening, randomisation, dosing, follow-up), sample collection, safety monitoring, SAE reporting, and data documentation in the eCRF system. |
| **Brief report on inspection activities undertaken** | |
| **Scope and limitations** | |
| **Areas inspected** | · Informed Consent Process<br>· Investigational Medicinal Product (IMP) management<br>· Pharmacy / IMP storage area<br>· Source documents and Case Report Forms (CRFs)<br>· Archiving and documentation system<br>· Quality management system |
| **Out of scope** | Consenting/Examination and Procedure Rooms were not applicable for inspection, as this was a post-trial inspection and no further clinical activities were performed at the site. |
| **Inspected Clinical medical research** | Phase III 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<br>Protocol No.: MOM-M281-006<br>Phase: III<br>EudraCT: 2019-000720-17<br>EDA approval on: 19/07/2023. |

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| **Type of IMP** | Biological- Monoclonal Antibody (M281 Nipocalimab– IV infusion) &Placebo |
| **Part 2** | |
| **1. Facilities and equipment system** | |
| **1.1.Facilities and Trial Conduct** | The site facilities were adequate for trial conduct.<br>- A designated examination room, consultation room, and procedure room were all available and rendered operational.<br>- Procedure Room: An emergency trolley equipped with emergency medications was placed and made readily available at the procedure area.<br>- Calibration labels and certificates for all equipment involved in the clinical trial were available and valid during study conduct. All relevant calibration labels were attached to the equipment, and the certificates were filed in the site master file.<br>- The study records were safely kept in a fire & waterproof (metal) cupboard and were secured against unauthorized access.<br>-A dedicated Pharmacy (Investigational product storage room) was established at the site<br>-Emergency preparedness, resuscitation equipment, and disposal containers were present and compliant with international colour-coding standards. |
| **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 had an established Quality Management System supported by SOPs governing trial conduct, documentation, safety reporting, and IMP handling, ensuring compliance with GCP principles, ethical standards, regulatory requirements Management and Control of Adverse Event Reporting Procedure; Management and Control of Informed Consent Process; and GCP Audit and Inspection. The system aimed to ensure participant safety, rights, and data integrity<br>-The study has been monitored according to the monitoring plan. |
| **2.2. SOPs and Documentation** | -The site-maintained SOPs governing all clinical trial activities. Documents were controlled, periodically reviewed, and implemented. |
| **2.3. Deviation Management** | -Protocol deviations were handled according to SOPs and were documented in progress reports submitted to EDA. |
| **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<br>- All corrective actions were implemented and supported with documentation as proof of correction in compliance with applicable GCP and regulatory |

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| | standards. |
| **3. Ethics and Participant Protection** | |
| **3.1.Informed Consent Process** | -The informed consent process was reviewed and confirmed compliant with GCP guidelines.<br>-Approved Informed Consent Forms (V2.1 dated 26/08/2024) were available<br>-Verified informed consent forms were signed before any study-related procedures were performed for all three participants. Advertisements were not used for participant recruitment. No deficiencies were identified in the informed consent process. |
| **3.2.Ethics Committee Approval** | IRB approval on: 19/01/2023<br>MOH Conditional approval on: 31/05/2023<br>All regulatory approvals were available at the site. Documentation completeness and version control were adequate. ICF was correctly withheld from use as Supreme Council approval was not obtained. |
| **3.3. Participant Safety** | -Site SOP (Management and Control of Adverse Event Reporting Procedure) and monitoring visit logs were reviewed and confirmed the sponsor's active oversight of participant safety through structured follow-up and timely emergency response.<br>-SAEs events were reported to the sponsor within the protocol-specified timeline, demonstrating that the sponsor maintained effective oversight of participant safety through robust follow-up mechanisms and readiness to respond to emergencies, and, per ICH GCP E6(R2)<br>-SAE reported within protocol-specified and EDA timelines. |
| **4. Personnel and Training** | |
| **4.1.Training and qualifications** | -Roles and responsibilities of study personnel were clearly defined and documented in the delegation log.<br>-GCP training records were available and reviewed. All site-delegated staff held valid GCP certificates.<br>-The training system was adequate. Training logs, agendas, and materials (covering study protocol, blinding plan, SAE reporting, etc.) were verified. |
| **5. Investigational Product (IMP) Management** | |
| **5.1. IMP handling** | - IMP storage conditions, temperature monitoring, and accountability records were reviewed. IMP was stored separately in a water- and fireproof metal cupboard per study protocol.<br>-Shipping, receipt, and dispensing procedures were implemented. Temperature during transportation was monitored via data logger<br>-Two temperature excursion events were identified and reviewed by the sponsor; both batches were approved for use following confirmation that product stability was unaffected. |

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| | -Dispensing and drug accountability records were maintained by the Unblinded Pharmacist<br>-Labelling and traceability were adequate.<br>- IMP accountability was fully reconciled and verified during inspection. |
| **6. Clinical Trial Conduct** | |
| **6.1.Protocol Compliance** | -The study was conducted at an acceptable level of compliance with the approved protocol (Amendment V.6 dated 18/08/2022) and GCP guidelines. |
| **6.2. Source Data and CRFs** | - Source documents and eCRFs; eCRF completion guideline was reviewed for compliance<br>-Data were generally consistent between eCRF and source documents. Source data were legible, well-organized, and confidentiality of all records was maintained. Records were securely kept in a fire- and waterproof metal cupboard, with access controlled<br>-Two ALCOA-related issues were identified and subsequently corrected:<br>(1) PRO Measures at all visits were completed but had not been signed by the PI as evidence of verification – the PI signed all forms as per CAPA implementation;<br>(2) A deficiency was identified related to Good Documentation Practices: corrections made to source document narratives (e.g., investigational product procedure records) were initialed rather than dated and signed with the full name of the investigator or Co-Investigators. This finding was addressed; and source document correction procedures were updated, and targeted GDP retraining was conducted for all relevant staff. |
| **6.3. Delegation of Duties** | -The Delegation of Responsibility Log was confirmed to be available at the site, accurately completed, signed by the Principal Investigator, and reflective of the actual roles and responsibilities assigned to each study team member.<br>-A deviation was identified: both Co-Investigators commenced their trial activities before the EDA-approved protocol amendment formally including them in trial activities. This deviation did not affect patient safety or data integrity and was corrected with a process update requiring regulatory approval prior to any role commencement. This was acknowledged by the sponsor and corrected: the amendment was submitted and approved by EDA on 30/09/2024, regularizing both Co-Investigators' roles. |
| **7. Laboratory and Bioanalytical Activities (if applicable** | |
| -No site lab. To be inspected<br>-External Central Laboratories had valid accreditation.<br>-Laboratory procedures were defined and available at the site using Lab Manual | |

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| -Sample handling and analysis procedures were reviewed. Withdrawn samples were stored at protocol-specified temperatures. A centrifuge was used for blood sample separation; calibration was valid during study conduct. Samples were stored in a freezer with valid calibration records. Daily temperature records were maintained.<br>-No deficiencies related to laboratory documentation or sample validation were identified. All laboratory equipment held valid accreditation and calibration certificates at the time of the inspection |
| **8. Safety Reporting (SAE)** |
| -An SOP for SAE reporting was available and verified (Management and Control of Adverse Event Reporting Procedure,<br>-All SAEs were reported to the sponsor within the protocol-specified timeline. SAE reporting to the Ethics committee and Bio Inn-EDA was within the specified timeframe. No deficiencies were identified in safety reporting.<br>-No gaps in SAE documentation or completeness were identified. All SAE documentation was complete and consistent. |

| **Part 3** | **Inspection outcome** |
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| Based on the reviewed documentation, inspected facilities, and observations identified during the inspection: The GCP inspection conducted at CRC, Faculty of Medicine, Alexandria University Hospital resulted in an overall acceptable level of compliance as All identified deficiencies were communicated to the site and Corrective and Preventive Actions (CAPA) were submitted by the site within defined timeline of receipt of the inspection report and were evaluated by EDA inspectors. CAPAs were confirmed as appropriate and were implemented<br>This EDA-GCP-PIR remained valid until the next inspection, provided no critical findings, safety concerns, or regulatory actions arise. The site is encouraged to continue strengthening its Quality Assurance System and to use its internal audit programme to monitor ongoing GCP compliance. | |

| **Part 4** | **List of national Laws and GCP Guidelines referenced in the inspection report** |
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| 1. Law of Regulating Clinical Medical Research no.214/2020.<br>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<br>3. EDA Chairman Decree No.111 for 2022.<br>4. Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority "EDREX.GL.Bioinn.006".<br>5. Guideline for Good Clinical Practice ICH E6R3.<br>6. Declaration of Helsinki<br>7. WHO Handbook for Good Clinical Research Practice (GCP) -Guidance for Implementation | |

| **Abbreviation** | |
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| AE: | Adverse Event |
| ALCOA: | Attributable, Legible, Contemporaneous, Original, Accurate |
| CAPA: | Corrective and Preventive Action |

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| CRF: | Case Report Form |
| CRC | Clinical research Center |
| CT | Clinical Trial |
| EDA | Egyptian Drug Authority |
| GCP: | Good Clinical Practice |
| ICF: | Informed Consent Form |
| 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 |
| SAE: | Serious Adverse Event |
| SOP: | Standard Operating Procedure |

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