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	Medical Research Institute (MRI)-Alexandria University
Address of Inspected CT Site	165, Horreya Avenue, Hadara, Alexandria
Inspection Details	
Dates of Inspection	**Inspection Duration:** One-day inspection **Start Date:** 03 February 2026 **End Date:** 03 February 2026
Type of Inspection	Routine GCP Inspection
Introduction	
General Information about the Sponsor and the CT Site	The inspected site is a Clinical Trial Site (Medical Research Institute (MRI)-Alexandria University) participating in the conduct of the inspected clinical study sponsored by (F. Hoffmann-La Roche Ltd) in accordance with applicable regulatory requirements and ethical standards. **PI Name:** Prof. Dr. Hanaa Kohail The inspection included verification of the study site's conduct of clinical trial activities, including the informed consent process, protocol compliance, participant source documentation, safety reporting, maintenance of the Investigator Site File, data documentation, and verification of IMP management and accountability to assess compliance with the study protocol, GCP principles, and applicable local regulations.
Brief Report on Inspection Activities Undertaken	
Scope and Limitations	
Areas Inspected	· Informed Consent Forms · Source documents and Electronic Case Report Forms (eCRFs) . Investigator Site File (ISF) and Essential Documents . Quality Management/Quality Assurance System . Archiving and Document Control System · Safety reporting . IMP Management Related Documents . Site Facilities and Study-Relevant Areas
Out of Scope	Non identified.

Inspected Clinical Medical Research	A Phase III, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of Adjuvant Giredestrant Compared with Physician's Choice of Adjuvant Endocrine Monotherapy in Patients with Estrogen Receptor-Positive, HER2-Negative Early Breast Cancer. **Protocol Number:** GO42784 **Trial ID:** lidERA, **EU CT Number:** 2021-000129-28 **Phase:** III **EDA Initial Approval Date:** 04 Dec 2022
Type of IMP	The IMPs are small molecules including: Tested Product: Giredestrant 30 mg capsules; Comparators: Letrozole 2.5 mg tablets, Tamoxifen 20 mg tablets.
Part 2	
1. Facilities and Equipment System	
1.1. Facilities and Trial Conduct	- The trial site had adequate facilities and equipment to support the conduct of the trial. - A designated reception and waiting area, examination room, consultation room, and procedure room were all available and rendered operational. - Procedure Room: An emergency trolley equipped with emergency medications was placed and made readily available at the procedure area. - Calibration labels and certificates for all equipment involved in the clinical trial were available. All relevant calibration labels were attached to the equipment, and the certificates were filed in the Investigator Site File. However, the calibration certificates did not include sufficient details of the calibration process (e.g., reference standards used and calibration results). As a corrective action, the sponsor had contracted an external accredited vendor who performed calibration for all equipment used in the trial and issued calibration certificates that included the details of the calibration process. In addition, preventive measures were implemented to avoid recurrence. Supporting documentation was compiled and submitted as proof of correction, in compliance with GCP requirements. - A dedicated Pharmacy/Investigational product storage room was established at the site. - Appropriate storage conditions for the IMPs were maintained on-site, ensuring that the investigational product was stored under the required conditions prior to administration, in compliance with protocol and GCP requirements.
1.2. Computerized System	Electronic data capture, such as eCRF and randomization systems, were in use.

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2. Pharmaceutical Quality System	
2.1. Quality Management System	- The site had a quality assurance system described in SOPs, including Recording, Management & Reporting of AEs, Obtaining Informed Consent, and IMP Management SOPs. - The study has been monitored according to the monitoring plan. - All study personnel were GCP trained (certificates were found at the site).
2.2. SOPs and Documentation	-SOPs governing all clinical trial activities were maintained, implemented, and confirmed to be in full compliance with GCP requirements -Essential documents were available and reviewed, including study approvals, source documents, ICFs, eCRF, contracts, insurance, CVs, GCP certificates, IB, safety reports, progress reports, IMP records, and calibration records.
2.3.Deviation Management	Clinical trial-related deviations were managed and documented in accordance with the sponsor's applicable procedures.
2.4. CAPA System	The site was required to address all observations and submit CAPA and supporting documentation as proof of correction, in the proposed time schedule for corrections. The identified minor finding was appropriately addressed by the applicant through corrective and preventive actions that were assessed and accepted by EDA.
3. Ethics and Participant Protection	
3.1. Informed Consent Process	-The informed consent process was reviewed. The approved informed consent forms were used throughout the study and were confirmed to be the correct, IRB-approved versions. 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	Approvals from the IRB were available. - Initial IRB Approval dated 23/01/2022
3.3. Participant Safety	-Safety reporting procedure was in place. -Verified SAEs were reported to the sponsor and Bio Inn-EDA within the specified timelines. -Participants who experienced SAEs were appropriately followed up by the Principal Investigator/delegated site staff until resolution of the SAEs.
4. Personnel and Training	

4.1. Training and Qualifications	-Curriculum Vitae of the Principal Investigator, Co-Investigator(s), Pharmacist and Site Coordinator were confirmed to be available at the site, up to date, and filed appropriately in the Investigator Site File in compliance with GCP requirements. -GCP training records and workloads for all staff who took part in the conduct of the clinical trial were verified and filed at the site. Protocol-specific training records were reviewed and retained in the Investigator Site File.
5. Investigational Product (IMP) Management	
5.1. IMP Handling	-Shipping records detailing the quantity and the batch numbers of the IMPs received at the site were available. -Printout of the temperature data logger during transportation of IMP from the depot to the clinical trial site was verified. -The IMPs were stored in a refrigerator below 25°C according to the pharmacy manual. -Dispensing and accountability records were verified during the inspection. -The IMP labeling was compliant with regulatory requirements
6. Clinical Trial Conduct	
6.1. Protocol Compliance	- The study was conducted in compliance with the approved study protocol. - Based on the documents reviewed, facilities inspected, and considering the one finding of the inspection, the study (GO42784), was conducted at an acceptable level of compliance with the protocol, GCP guidelines, and applicable regulatory requirements
6.2. Source Data and CRFs	- Participant records were available for verification and were maintained in an organized and accessible manner throughout the inspection period. - Source data were confirmed to be legible, well organized, and maintained in full compliance with ALCOA principles throughout the study.
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.
7. Laboratory and Bioanalytical Activities (if applicable)	
-The study site utilized an external local laboratory. -The laboratory was accredited. -The laboratory procedures were defined in the laboratory manual filed in the Investigator Site File, along with the reference ranges to be accessible to the study staff.	
8. Safety Reporting (SAE)	
Safety reporting procedure was in place. Verified SAEs were reported to the sponsor and Bio Inn-EDA within the specified 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. - The identified deficiency was communicated to the applicant and was subsequently addressed through appropriate corrective and preventive actions, which were evaluated and accepted by the EDA. - This EDA-GCP-PIR remained valid until the next GCP inspection of the site.	
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	

Abbreviations	
CAPA:	Corrective and Preventive Action
CRF:	Case Report Form
CT	Clinical Trial
EDA	Egyptian Drug Authority
GCP:	Good Clinical Practice
IB	Investigator Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IMP:	Investigational Medicinal Product
IRB:	Institutional Review Board
ISF:	Investigator Site File
PI:	Principal Investigator
PIR	Public Inspection Report
SAE:	Serious Adverse Event
SOP:	Standard Operating Procedure
WHO	World Health Organization

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