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	National Liver Institute- Menoufia University
Address of inspected CT site	National Liver Institute-Shebin El Kom-Menoufia, Egypt
Inspection details	
Dates of inspection	05 August 2025
Type of inspection	Routine
Introduction	
General information about the sponsor and CT site	- The inspected site is a Clinical Trial Site (**National Liver Institute- Menoufia University**) that conducts clinical studies for the sponsor (**AstraZeneca**) in accordance with applicable regulatory requirements and ethical standards. - PI name: **Prof. Dr. Imam Waked** - 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 (follow-up) - Informed Consent Process - Investigational Medicinal Product (IMP) management - Bioanalytical / laboratory facilities (if applicable) - Source documents and Case Report Forms (CRFs) - Archiving and documentation system - Quality management system
Out of scope	The following - Clinical operations (screening, dosing) - Pharmacy / IMP storage area were out of scope no trial-related procedures or IMP administration were being performed as all enrolled participants were in the long-term follow-up phase and all IMP kits had already been returned to the sponsor for destruction
Inspected Clinical medical research	The inspection focused on the following study(ies): -Study Title: A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter study of Durvalumab monotherapy or in combination with

	Bevacizumab as adjuvant therapy in patients with hepatocellular carcinoma who are at high risk of recurrent after curative hepatic resection or ablation - **Protocol Number**: D910DC00001 (EMERALD-2) -**Phase:** III - **EDA initial approval date:** 12/12/20221
Type of IMP	Biological (Monoclonal antibody)
Part 2	
1. Facilities and equipment system	
1.1. Facilities and Trial Conduct	- The site facilities were generally adequate to support the clinical trial conduct. The site included dedicated areas for participant reception and waiting, examination, consultation, clinical procedures, and pharmacy/investigational medicinal product (IMP) storage area. All enrolled participants were in the long term follow up phase and all IMP kits has been returned the sponsor for destruction. Therefore, those areas (Consenting and examination rooms, procedure room, and Pharmacy) were out of the inspection scope. - Emergency preparedness was in place. -The calibration status of the CT scanner used for participant follow-up was verified and found to be valid.
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 supported by Standard Operating Procedures (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 quality management system was considered adequate to support participant safety, data integrity, and the overall conduct of the clinical trial.
2.2. SOPs and Documentation	-The site maintains SOPs governing clinical trial activities were available and implemented. - Essential trial documentation was reviewed during the inspection, including the approved protocol and amendments, Investigator's Brochure, regulatory and ethics committee approvals, informed consent forms, investigator qualifications and training records, delegation logs, monitoring reports, safety documentation, investigational medicinal product (IMP) records, laboratory documentation, participant records, and other study-specific essential documents.

	-Documentation was generally complete, controlled, and maintained **in accordance with Good Clinical Practice (GCP) requirements.**
2.3. Deviation Management	No protocol deviations were identified during the inspection. Based on the documents reviewed and participant records verified, the inspection did not identify any non-compliance requiring corrective or preventive actions.
2.4. CAPA System	No deficiencies were identified during the inspection; therefore, no corrective and preventive actions (CAPAs) were required.
3. Ethics and participant Protection	
3.1.Informed Consent Process	-The informed consent process was reviewed through a review of the approved informed consent forms and participants signed informed consent documentation. -The inspected participant records confirmed that informed consent had been appropriately obtained and documented before trial participation.
3.2. Ethics Committee Approval	Approvals from IRB/IEC were available, date of approval: • **IRB approval** on: 13/01/2021 • **MOH approval(s)** on: 09/06/2021
3.3. Participant Safety	Participant safety was assessed through the review of participant source documents, safety-related records, serious adverse event (SAE) documentation, and protocol compliance. Participants were in the long-term follow-up phase at the time of the inspection, and safety follow-up was documented as required by the protocol.
4. Personnel and Training	
4.1. Training and qualifications	-The qualifications, training, and delegation of study personnel were reviewed during the inspection. The investigator and study staff were appropriately qualified to perform their trial-related responsibilities, and delegated duties were documented. -Valid Good Clinical Practice (GCP) training records were available for all study personnel involved in the conduct of the clinical trial**.**
5. Investigational Product (IMP) Management	
5.1. IMP handling	- IMP temperature monitoring, and accountability records were reviewed. - Shipping, receipt, dispensing, return, and destruction procedures and records were implemented. - At the time of the inspection, all IMP kits had been returned to the sponsor for destruction; therefore, physical storage and dispensing activities were not within the inspection scope. -The reviewed IMP documentation demonstrated appropriate management of the investigational medicinal product.

6. Clinical Trial Conduct	
6.1. Protocol Compliance	- The study was generally conducted according to the approved protocol (Version 3.0 , dated: 19/05/2021). -Protocol compliance was assessed through the review of essential documents, participant source records, Case Report Forms (CRFs), safety documentation, and study conduct.
6.2. Source Data and CRFs	- Source documents and eCRFs were reviewed through the review of participant source documents and corresponding trial records to verify the accuracy, completeness, and consistency of the recorded data. -The inspected documentation supported the integrity of the clinical trial data and compliance with the protocol and Good Clinical Practice (GCP) requirements.
6.3. Delegation of Duties	- Delegation logs were available. The delegation of trial-related duties was appropriately documented, and study personnel were assigned responsibilities consistent with their qualifications and trial roles.
7. Laboratory and Bioanalytical Activities (if applicable)	
• External central laboratory used for analysis of bio samples and National radiology center for nuclear medicine services. • Laboratory procedures were generally defined. • Laboratory accreditation was verified during the inspection visit. • Sample handling and analysis were reviewed.	
8. Safety Reporting (SAE)	
• SOPs for SAE reporting was available. • Reporting timelines and documentation were generally followed.	
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. No deficiencies were identified. -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	
CAPA	Corrective and Preventive Action
eCRF	Electronic Case Report Form
CT	Clinical Trial
EDA	Egyptian Drug Authority
GCP	Good Clinical Practice
ICF	Informed Consent Form
IB	Investigator Brochure
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
WHO	World Health Organization

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