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	CRC, Air Force Specialized Hospital
Address of inspected CT site	EL, N Teseen St, 5th settlement, Cairo, Egypt
Inspection details	
Dates of inspection	02 September 2025
Type of inspection	Routine
Introduction	
General information about the sponsor and CT site	- The inspected site is a Clinical Trial Site (**CRC, Air Force Specialized Hospital**) that conducts clinical studies for the sponsor (**F. Hoffmann-La Roche Ltd**) - PI name: **Prof. Dr. Tarek Hesham** - Activities include participant recruitment, clinical conduct, sample collection, safety monitoring, and data documentation.
Brief report on inspection activities undertaken	
Scope and limitations	
Areas inspected	· Informed Consent Process · Investigational Medicinal Product (IMP) management · Source documents and Case Report Forms (CRFs) · Archiving and documentation system · Quality management system
Out of scope	The following were out of scope: · Clinical Operations (Screening, dosing, follow-up) were not applicable as this phase of the trial (at time of inspection) no longer required these activities. · Bioanalytical / laboratory facilities were not applicable as no further local laboratory testing will be performed for the participants within the study. As at this phase, the Participants were followed up and referred to an external radiology center for tumor assessment.
Inspected Clinical medical research	The inspection focused on the following study: Study Title: A Phase III, Open-Label, Randomized Study of Atezolizumab with Lenvatinib or Sorafenib Versus Lenvatinib or Sorafenib alone in Hepatocellular Carcinoma Previously Treated with Atezolizumab and Bevacizumab Protocol Number: M042541

	-Phase: III - EDA initial approval date: 31\01\2022
Type of IMP	Biological Monoclonal antibody (Atezolizumab)
Part 2	
1. Facilities and equipment system	
1.1. Facilities and Trial Conduct	- The inspection visit included a tout at the site facilities relevant to the conduct of the study. The inspected facilities were generally adequate for trial conduct. - The inspected areas included the pharmacy/investigational medicinal product (IMP) storage room and laboratory-related facilities, while the consenting/examination room and procedure room were outside the scope of the inspection as no trial-related procedures or IMP administration were being performed during the inspection. - Equipment maintenance, calibration, and emergency preparedness was in place as the inspection also included verification of the emergency trolley, emergency equipment readiness, disposal containers, IMP storage arrangements, and temperature monitoring records associated with IMP storage and transportation. Laboratory accreditation and documentation supporting equipment calibration were also reviewed as part of the assessment of laboratory activities.
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 was assessed through the review of quality-related processes and essential clinical trial documentation. - The inspection verified that the site had a quality assurance system supported by Standard Operating Procedures (SOPs), including procedures for the informed consent process, data monitoring and integrity, biological sample handling, risk-based monitoring, and quality management in clinical research. - The inspection also confirmed that the study was monitored according to the monitoring plan and that Good Clinical Practice (GCP) training records for the study personnel were available for verification.
2.2. SOPs and Documentation	-SOPs and essential clinical trial documentation were reviewed during the inspection to verify compliance with the approved protocol, GCP, and applicable regulatory requirements. The inspection verified the availability of SOPs covering the informed consent process, data monitoring and integrity, biological sample handling, risk-based monitoring, quality management in clinical research, and safety reporting. -One observation was identified during the inspection in accordance with ICH E6R3. An inconsistency was observed in the tumor assessment reports (CT scan

	of the abdomen and pelvis after contrast) regarding the documented route of contrast administration (oral and/or intravenous), which was inconsistent across the study records. The sponsor's root cause analysis concluded that the inconsistency resulted from a repeated typographical error in the tumor assessment reports, while the corresponding tumor requisition forms consistently documented intravenous contrast administration. In response, the site prepared and filed a Note-to-File describing the issue, documented the event in the clinical trial management system, and implemented refresher training for the study staff on Good Documentation Practice (GDP), focusing on accurate recording, handling, and correction of clinical trial documentation in accordance with GCP and regulatory requirements. The submitted Corrective and Preventive Action (CAPA) was reviewed and accepted by the Egyptian Drug Authority (EDA).
2.3. Deviation Management	Deviation management procedures were available. Deviations were handled per available SOPs.
2.4. CAPA System	A CAPA system was established at the site. The inspection findings were communicated to the sponsor and the clinical trial site. CAPA responses for findings identified during this inspection were submitted within defined timeline and evaluated by EDA. 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 through the verification of the approved Informed Consent Forms (ICFs), participant source records, and informed consent documentation to assess compliance with the approved protocol, GCP, and applicable regulatory requirements. -Approved ICFs were available and used as follows: • Country Main ICF V3.1, Dated: 05/11/2023 • Country Main ICF V4, Dated: 24/12/2023 • Country Main ICF V5, Dated: 03/04/2024 - 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 IRB/IEC were available, date of approval: • **IRB approval** on: 26\05\2021 • **MOH approval(s)** on: 08\07\2021 • **Supreme Council Renewal Approval** on: 20\04\2025
3.3. Participant Safety	-Participants safety was assessed through the review of participant source records, safety-related documentation, adverse event (AE) and serious adverse

	event (SAE) records, case report forms (eCRFs), and other essential clinical trial documentation to verify compliance with the approved protocol, GCP, and applicable regulatory requirements. -One SAE involving a death case of the study participant was reported during the conduct of the trial. The event was assessed by the investigator as not related to the IMP. The SAE was reported to the sponsor within the protocol-specified timeline and to the EDA within the applicable regulatory reporting timeframe. -Site SOPs and monitoring visit logs were reviewed and confirmed the sponsor's active oversight of participant safety through structured follow-up and timely emergency response, reinforcing the site's preparedness to detect, escalate, and manage adverse events.
4. Personnel and Training	
4.1. Training and qualifications	- Roles and responsibilities of study personnel were clearly defined. - The qualifications and training of the investigator and study personnel were reviewed during the inspection to verify that delegated trial-related responsibilities were supported by appropriate qualifications and training. -The inspection included verification of curriculum vitae (CVs), GCP training records, protocol-specific training documentation, delegation of responsibilities records, and other relevant personnel qualification records.
5. Investigational Product (IMP) Management	
5.1. IMP handling	- IMP management was assessed through the review of IMP-related documentation to verify compliance with the approved protocol, GCP, and applicable regulatory requirements. -The inspection included verification of IMP shipping, receipt, storage, dispensing, return, accountability, temperature monitoring records, and associated documentation. -IMP storage conditions, including temperature monitoring records, were reviewed during the inspection.
6. Clinical Trial Conduct	
6.1. Protocol Compliance	- Protocol compliance was assessed through the review of the approved protocol (Version: 6.0, dated: 23/02/2024), participant source records, case report forms (eCRFs), tumor assessment documentation, monitoring records, and other 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 Case Report Forms (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 comparison of participant source records, tumor assessment reports, case report forms (eCRFs), and other relevant study documentation.
6.3. Delegation of Duties	-Site signature and delegation of responsibilities log was confirmed to be available, accurately completed, signed by the PI, and reflective of the actual roles, qualifications and responsibilities assigned to each study team member.

7. Laboratory and Bioanalytical Activities (if applicable)

-An External Central and Local Laboratories were used for analysis of bio samples.
-Laboratory and bioanalytical activities were assessed through the review of laboratory-related documentation relevant to the conduct of the clinical trial. The inspection included verification of central and local laboratory accreditation, laboratory manuals, sample handling procedures, equipment calibration records, and other laboratory-related essential documentation to assess compliance with the approved protocol, Good Clinical Practice (GCP), and applicable regulatory requirements.

8. Safety Reporting (SAE)

-Safety reporting was assessed through the review of the SOP) for safety reporting, participant safety records, SAE documentation, and related essential clinical trial records to verify compliance with the approved protocol, GCP, and applicable regulatory requirements.
-The SAE was reported to the sponsor within the protocol-specified timeline and to the EDA within the applicable regulatory reporting timeframe.

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 submitted 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

CAPA	Corrective and Preventive Action
CRF	Case Report Form
CRC	Clinical Research Center
CT	Clinical Trial
CV	Curriculum Vitae
EDA	Egyptian Drug Authority
GCP	Good Clinical Practice
GDP	Good Documentation Practice
ICF	Informed Consent Form
ICH	International Council for 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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