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 Centre of Excellence-National Research Center "NRC"
Address of inspected CT site	El Noor Street from Research Street, El-Dokki, Giza
Inspection details	
Dates of inspection	02 November 2021
Type of inspection	Pre-initiation
Introduction	
General information about the sponsor and CT site	- The inspected site is a Clinical Trial Site (**Medical Research Centre of Excellence-National Research Center**) that conducts clinical studies for the sponsor (**National Research Center**) in accordance with applicable regulatory requirements and ethical standards. - PI name: **Dr\ Osama Azmy** - Activities include participant recruitment, clinical conduct, sample collection, safety monitoring, and data documentation.
Brief report on inspection activities undertaken	
Scope and limitations	
Areas inspected	- Investigational Medicinal Product (IMP) management - Pharmacy / IMP storage area - Bioanalytical / laboratory facilities (if applicable) - Source documents and Case Report Forms (CRFs) - Archiving and documentation system - Quality management system
Out of scope	This inspection was performed to ensure the suitability of the clinical trial site as applicable facilities, verify compliance with Good Clinical practices (GCP) and procedures at the trial sites to ensure safety of volunteers. Therefore, the following were out of scope as the study was not initiated yet: - Clinical operations (screening, dosing, follow-up) - Informed Consent Process
Inspected Clinical medical research	The inspection focused on the following study(ies): -Protocol Title: A Phase 1 Clinical Trial to Evaluate the Safety,

	Tolerability, and Immunogenicity of Inactivated SARS-CoV-2 Vaccine Against COVID-19 in Healthy Adults -Protocol Number: COVID_VACC_1 -Phase I - EDA Initial approval date: NA as the inspection was performed before obtained regulatory decision for study conduction to ensure suitability of submitted trial site to phase I clinical trial
Type of IMP	Biological (Inactivated Vaccine)
Part 2	
1. Facilities and equipment system	
1.1. Facilities and Trial Conduct	- The site facilities were generally adequate for trial conduct of the Phase I clinical trial, including reception and waiting areas, examination, consultation, consulting, and procedure rooms, as well as observation rooms for post-dose participant monitoring. - Equipment maintenance, calibration, and emergency preparedness was in place. -An emergency trolley was available at the clinical trial unit with qualified medical support personnel. However, the emergency trolley was not dedicated to the Phase I clinical trial, and routine verification of documented records were not available **in compliance with ICH E6(R2).** In addition, formal agreements with nearby hospitals and a dedicated ambulance for trial participants were not in place at the time of inspection. These findings were acknowledged; In response, a dedicated emergency trolley and ambulance were provided , a formal agreements for emergency referral with nearby hospitals were established , and procedures to ensure routine inspection and documentation of the emergency trolley to support site readiness prior to study initiation were implemented.
1.2. Computerized system	Randomization systems were in use.
2. Pharmaceutical Quality System	
2.1.Quality Management System	The site has established a Quality Management System supported by 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.

2.2.SOPs and Documentation	- The site maintains SOPs governing clinical trial activities. TMF Documents are controlled, periodically reviewed, and implemented. - The following documentation were verified including study-specific procedures and the investigational medicinal product (IMP) destruction procedure, were available and reviewed during the inspection. - The site's documentation system was generally adequate to support the conduct of the clinical trial. However, the IMP destruction procedure did not specify the external entity responsible for destruction or include the corresponding contractual agreement, which was requested to be finalized before study initiation **in compliance with ICH E6(R2).** In response, the site finalized the investigational medicinal product (IMP) destruction procedure by identifying the external entity responsible for IMP destruction and establishing the corresponding contractual agreement prior to study initiation, ensuring compliance with the applicable regulatory and Good Clinical Practice (GCP) requirements.
2.3. Deviation Management	No deviations were observed as the study was not initiated yet.
2.4. CAPA System	The site was required to address all observations and submit CAPA and supportive documentation as proof of correction, in the proposed time schedule for corrections. The identified findings were appropriately addressed by the site through corrective and preventive actions before initiation.
3. Ethics and participant Protection	
3.1. Informed Consent Process	The informed consent process was reviewed as part of the site readiness assessment. Approved Informed Consent Forms (ICFs) were available for use in the study. As the inspection was conducted prior to study initiation, the implementation of the informed consent process could not be verified.
3.2. Ethics Committee Approval	Approvals from IRB/IEC were available: **-Supreme Council of University Hospitals:** 07/07/2021
3.3. Participant Safety	Safety monitoring procedures were in place. But no SAE/AE reporting as the study not initiated yet.
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. - The training system was generally adequate.

	- Training records and qualification documents for study personnel, including curriculum vitae (CVs), GCP certificates, and study-specific training documentation, were reviewed during the inspection**.** - It is recommended to maintain up-to-date curriculum vitae (CVs) and relevant training records, including training on study-specific procedures, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and other trial-related training, for all personnel participating in the clinical trial.
5. Investigational Product (IMP) Management	
5.1. 1IMP handling	- IMP storage conditions, temperature monitoring, and accountability records were reviewed. - Shipping, receipt, and dispensing procedures were implemented. - Labeling and traceability were generally adequate. - The investigational medicinal product (IMP) was stored in a dedicated, access-controlled storage room. However, deficiencies were identified in the environmental conditions of the storage area, temperature monitoring , and documentation, including the absence of documented daily temperature records and evidence of a calibrated temperature data logger indicating inadequate control and monitoring of IMP storage conditions **in compliance with ICH E6(R2).** In response, the site relocated the IMP storage refrigerator to a suitable controlled environment, routine temperature monitoring using a calibrated thermometer and data logger with documented daily temperature records and all equipment and instruments used in the clinical trial were calibrated and identified with valid calibration labels prior to study initiation. - ~~Minor~~ Deficiencies related to IMP transportation and documentation were also identified **according to ICH E6(R2),** including the absence of a documented transportation procedure and lack of evidence of temperature monitoring during transportation, indicating inadequate control of IMP transportation conditions. In response, a transportation procedure was established and documented temperature monitoring during IMP transportation was implemented to ensure the required storage conditions were maintained.
6. Clinical Trial Conduct	
6.1. Protocol Compliance	- The clinical trial site was assessed for readiness to conduct the study in accordance with the approved protocol.

6.2. Source Data and CRFs	- Source document templates and Case Report Forms (CRFs) templates were reviewed as part of the site readiness assessment. - The documentation system for recording trial data was available and considered adequate to support the conduct of the clinical trial. - As the inspection was conducted prior to study initiation, no participant source data or completed CRFs were available for verification.
6.3. Delegation of Duties	- Delegation logs were available and reviewed during the inspection. - Roles and responsibilities of study personnel were documented through the delegation log. - It was recommended to ensure that the delegation log clearly defines the roles and responsibilities of all study personnel participating in the clinical trial. In addition, confidentiality agreements should be signed by all study personnel before undertaking any trial-related activities and maintained as part of the essential study records.
7. Laboratory and Bioanalytical Activities (if applicable)	
- External and Internal Laboratories were used for analysis. - Laboratory procedures for Sample handling and analysis were generally defined. - External laboratory accreditation and qualifications were confirmed to be appropriate for the study requirements.	
8. Safety Reporting (SAE)	
-SOPs for SAE reporting were available and confirmed to be ready for implementation upon trial initiation. -Reporting timelines and documentation procedures were reviewed and confirmed to be in place in preparation for study commencement.	
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. All identified deficiencies were communicated to the site. Corrective and preventive actions (CAPA) were be 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 202
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 E6r2.
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
GCP	Good Clinical Practice
IB	Investigator Brochure
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
WHO	World Health Organization