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 December 2021
Type of inspection	Routine
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 - Clinical operations (screening, dosing, follow-up) - Informed Consent Process
Out of scope	Not defined
Inspected Clinical medical research	The inspection focused on the following study: -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: 09/11/2021

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. - Dedicated reception, waiting, examination, consultation, consulting, procedure, and observation rooms were available to support study-related activities. - Equipment maintenance, calibration, and emergency preparedness was in place. - Emergency medical support was available through qualified physicians, nurses, and laboratory personnel. Emergency equipment, including a defibrillator, intubation and resuscitation equipment, and oxygen supply devices, was available and maintained in a state of readiness. - A dedicated investigational medicinal product (IMP) storage room was available with controlled access, and laboratory facilities were available to support protocol-required testing. - However, Deficiencies were identified during the inspection, including expired medications in the emergency trolley, absent documented routine inspection records for the emergency trolley, used sharps not appropriately disposed of in the sampling room, and calibration deficiencies affecting some equipment with missing or unreadable calibration labels. All findings were acknowledged and fully addressed. Expired emergency medications were replaced, a delegated pharmacist was assigned to perform and document routine monthly inspections of the emergency trolley, and a dedicated checklist for monitoring emergency medications and expiry dates was introduced. Used sharps were properly disposed of in compliance with applicable procedures. All affected equipment was calibrated and valid calibration labels were affixed. A dedicated emergency medicine box for the clinical trial was maintained, and procedures for routine verification of emergency equipment readiness were implemented. All submitted corrective and preventive actions were reviewed by EDA and confirmed to be acceptable, **in compliance with ICH E6(R2).**
1.2. Computerized system	CRF 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 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. -Documents were controlled, periodically reviewed, and implemented. -During the inspection, essential trial documents were reviewed and verified, including the approved protocol and amendments, Investigator's Brochure, regulatory and ethics committee approvals, investigator qualifications and training records, delegation logs, confidentiality agreements, informed consent forms, investigational medicinal product (IMP) management records, pharmacy and laboratory manuals, monitoring reports, safety reports, laboratory accreditation certificates, and participant records. However, deficiencies related to documentation practices were identified, including missing pages in some Chemistry, Manufacturing and Controls (CMC) documents, indicating deficiencies in document completeness and control **in accordance with ICH E6(R2).** In response, the sponsor reviewed and completed the Chemistry, Manufacturing and Controls (CMC) documentation by providing the missing pages and verifying the completeness of the essential trial documents. The submitted corrective and preventive actions were reviewed by EDA and considered acceptable.
2.3. Deviation Management	-Deviation management procedures were established through site SOPs. -During the inspection, protocol and Good Clinical Practice (GCP) deviations were identified and documented as inspection observations for corrective and preventive action (CAPA).
2.4. CAPA System	A CAPA system was established, and it were requested to address the inspection observations. The sponsor/site was requested to investigate the identified deficiencies and implement appropriate corrective and preventive actions to ensure **compliance with Good Clinical Practice (GCP) and applicable regulatory requirements.**
3. Ethics and participant Protection	
3.1. Informed Consent Process	-The informed consent process was reviewed. - Approved Informed Consent Forms (ICFs) were available and used throughout the study.

	-The correct Research Ethics Committee (REC)-approved versions of the informed consent forms were used, and participants signed the approved ICFs prior to the performance of any study-related procedures. The informed consent process was found to be **in accordance with Good Clinical Practice (GCP) requirements.**
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 to ensure the protection of study participants. No Serious Adverse Events (SAEs) had been reported at the time of the inspection.
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. -Current curriculum vitae (CVs), GCP certificates, delegation records, and protocol-specific training documentation for study personnel were available and reviewed during the inspection. -Interviews with study personnel confirmed adequate knowledge of the study protocol and assigned trial-related responsibilities.
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. - Deficiencies related to IMP management were identified, including unreadable vial labels, inadequate segregation of used and unused IMP vials, incomplete labelling of IMP storage boxes, and deficiencies in documentation of batch identification and expiry information. All findings were acknowledged and fully addressed. Unreadable IMP vial labels were replaced, used and unused IMP vials were appropriately segregated, IMP storage box labels were updated to clearly distinguish the investigational medicinal product from placebo, and corresponding batch numbers, manufacturing dates, and expiry dates were documented. All submitted corrective and preventive actions were reviewed by EDA and confirmed to be acceptable, **in compliance with ICH E6(R2).** - Deficiencies related to IMP storage and transportation were identified, including inadequate temperature monitoring and the absence of

	documented transportation procedures. All findings were acknowledged and fully addressed. Documented procedures for IMP transportation were established, temperature monitoring during storage and transportation was implemented using calibrated monitoring devices, and documented temperature records were maintained to ensure required storage conditions throughout transit. All submitted corrective and preventive actions were reviewed by EDA and confirmed to be acceptable, **in compliance with ICH E6(R2).**
6. Clinical Trial Conduct	
6.1. Protocol Compliance	- The study was generally conducted according to the approved protocol. - Protocol-required study procedures, participant eligibility, investigational medicinal product (IMP) management, safety reporting, and study documentation were reviewed during the inspection. - Protocol compliance was generally acceptable. However, deficiencies were identified in the implementation and documentation of certain study procedures, including IMP management, laboratory notification requirements, and documentation practices, which were considered deviations from Good Clinical Practice (GCP) and applicable regulatory requirements. In response, the sponsor investigated the identified protocol-related observations, implemented appropriate corrective and preventive actions to address the deficiencies, and submitted supporting documentation to the Egyptian Drug Authority (EDA) for review. The submitted corrective and preventive actions were reviewed by EDA and considered acceptable.
6.2. Source Data and CRFs	-Source document templates and Case Report Forms (CRFs) were reviewed. -Participant records were available for verification and maintained in an organized and accessible manner throughout the inspection. -Data were generally consistent between the reviewed source documents and CRFs. However, Deficiencies in source documentation were identified, including overwriting in participant records and incomplete Chemistry, Manufacturing and Controls (CMC) documentation due to missing pages. All findings were acknowledged and fully addressed. The CMC documentation was completed through submission of the missing pages, and measures were implemented to ensure all source document corrections complied with ALCOA principles and GCP requirements, with corrections made without obscuring original entries and appropriately dated and signed. All submitted corrective and preventive

	actions were reviewed by EDA and confirmed to be acceptable, in compliance with ICH E6(R2).
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. However, deficiencies were identified in the delegation and documentation of study responsibilities, including incomplete documentation of study roles, inconsistencies in personnel identification, and performance of investigational medicinal product (IMP)-related activities by personnel who had not been delegated those responsibilities, indicating deficiencies in the management and documentation of delegated trial duties in accordance with ICH E6(R2). In response, the sponsor updated the delegation log to clearly define the roles and responsibilities of all study personnel, corrected inconsistencies in personnel identification, and ensured that investigational medicinal product (IMP)-related activities were delegated only to appropriately authorized personnel. In addition, the delegation documentation was updated to assign the designated registered pharmacist responsibility for IMP receipt, inspection, and dispensing in accordance with the study protocol. The submitted corrective and preventive actions were reviewed by EDA and considered acceptable.
7. Laboratory and Bioanalytical Activities (if applicable	
-External and Internal Laboratories were used for analysis. -Laboratory procedures were generally defined. -Sample handling and analysis were reviewed. However, deficiencies were identified in laboratory-related documentation and regulatory compliance, including the use of an external laboratory to perform delegated laboratory testing without prior notification to the Egyptian Drug Authority (EDA), indicating non-compliance with applicable regulatory requirements**.** In response, the sponsor implemented corrective actions by notifying the Egyptian Drug Authority (EDA) of the use of the external laboratory for delegated laboratory testing, updating the relevant study documentation, and submitting the required supporting documents related to the external laboratory. The submitted corrective and preventive actions were reviewed by EDA and considered acceptable.	
8. Safety Reporting (SAE)	
SOPs for SAE reporting were available. Adverse Event (AE) and Serious Adverse Event (SAE) documentation was reviewed. No Serious Adverse Events (SAEs) had been reported during the inspection period, and safety reporting	

activities were generally conducted in accordance with the study protocol and Good Clinical Practice (GCP) requirements.	
Part 3	**Inspection outcome**
-Based on the reviewed documentation, inspected facilities, and observations identified during the inspection, the clinical trial site was confirmed to be operating at an acceptable level of compliance with GCP guidelines and applicable regulatory requirements. -All identified deficiencies were communicated to the site, acknowledged, and fully addressed. Corrective and preventive actions (CAPAs) were developed, implemented, and confirmed to be acceptable by EDA. -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 E6r2. 6. Declaration of Helsinki 7. WHO Handbook for Good Clinical Research Practice (GCP) -Guidance for Implementation	
Abbreviation	
AE	Adverse Event
ALCOA	Attributable, Legible, Contemporaneous, Original, Accurate
CAPA	Corrective and Preventive Action
CMC	Chemistry, Manufacturing and Controls
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

PI	Principal Investigator
PIR	Public Inspection Report
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
WHO	World Health Organization

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