# EDA-GCP Public Inspection Report (PIR) of Clinical Trial Site

| Part 1 | General Information |
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| **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** | 20 December 2021 |
| **Type of inspection** | Trigger to verify the corrective and preventive actions implementation based on the previous inspection performed on 08 and 09 December 2021 and ensure implementation of suspension decision. |
| **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.<br>- PI name: **Dr\ Osama Azmy**<br>- 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 (screening, dosing, follow-up)<br>- Investigational Medicinal Product (IMP) management<br>- Pharmacy / IMP storage area<br>- Source documents and Case Report Forms (CRFs)<br>- Archiving and documentation system<br>- Quality management system |
| **Out of scope** | - Bioanalytical / laboratory facilities<br>- Informed Consent Process |
| **Inspected Clinical medical research** | The inspection focused on the following study(ies):<br>-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<br>-Protocol Number: COVID_VACC_1<br>-Phase I<br>- EDA Initial approval date: 09/11/2021 |

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| **Type of IMP** | Biological (Inactivated Vaccine) |
| **Part 2** | |
| **1. Facilities and equipment system** | |
| **1.1. Facilities and Trial Conduct** | - The site facilities relevant to the scope of the trigger inspection were reviewed. The pharmacy/investigational medicinal product (IMP) storage room was inspected.<br>- Emergency medical support and the investigational medicinal product (IMP) storage area were re-inspected. The retained IMP samples were stored in an access-controlled investigational product storage room, and access was restricted to delegated personnel. |
| **1.2. Computerized system** | Data capture, as CRF and randomization systems were in use. |
| **2. Pharmaceutical Quality System** | |
| **2.1. Quality Management System** | - The quality management system was reviewed with respect to the implementation of previous inspection recommendations and the control of quality system documentation. |
| **2.2. SOPs and Documentation** | - Standard operating procedures and quality system documentation were reviewed to verify document control and implementation of previous inspection recommendations. Deficiencies were identified, including failure to implement a previous inspection recommendation regarding periodic SOP review and inconsistencies between SOP titles, numbering, and the corresponding table of contents. All findings were acknowledged and fully addressed. A dedicated form was developed and implemented to document and track all IMP transfers within the clinical trial site, ensuring complete traceability of IMP movements. Two pharmacists were assigned responsibility for all IMP-related activities and the corresponding Personnel Information Sheets were updated accordingly. Documented evidence of any future IMP or placebo transfer from the pharmacy room to any other facility at the National Research Center was committed to and implemented. All submitted corrective and preventive actions were reviewed by EDA and confirmed to be acceptable, **in compliance with ICH E6(R2)** |
| **2.3. Deviation Management** | Deviation management was not assessed during this trigger inspection. The inspection did not include a review of the site's deviation management system, deviation records, or procedures for the identification, documentation, reporting, investigation, and management of protocol deviations. |

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| **2.4. CAPA System** | -The implementation of corrective actions arising from previous inspections was reviewed during the inspection. |
| **3. Ethics and participant Protection** | |
| **3.1. Informed Consent Process** | The informed consent process was not assessed during this trigger inspection. The inspection did not include a review of the informed consent process, informed consent forms, or documentation related to obtaining or maintaining informed consent from trial participants |
| **3.2. Ethics Committee Approval** | Approvals from IRB/IEC were available:<br>**-Supreme Council of University Hospitals:** 07/07/2021 |
| **3.3. Participant Safety** | Participant follow-up documentation was reviewed during this inspection to verify compliance with the decision regarding study suspension. |
| **4. Personnel and Training** | |
| **4.1. Training and qualifications** | Training and qualifications were not assessed during this trigger inspection. The inspection did not include a review of investigators 'or study staff qualifications, curriculum vitae, training records, or documentation of Good Clinical Practice (GCP) or protocol-specific training. |
| **5. Investigational Product (IMP) Management** | |
| **5.1. IMP handling** | - Investigational medicinal product (IMP) accountability, traceability, storage, and retained IMP inventory were reviewed during the inspection.<br>- The retained IMP was stored in a dedicated, access-controlled storage area under the required storage conditions.<br>- However, a deficiency was identified in IMP accountability and traceability, as a box of active vaccine vials was missing from the retained IMP inventory received by the principal investigator, indicating inadequate control of IMP accountability and traceability. This finding was acknowledged and fully addressed. A dedicated form was developed and implemented for tracking all IMP transfers within the clinical trial site to ensure complete documentation and traceability of IMP movements. Two pharmacists were assigned responsibility for all IMP-related activities and relevant Personnel Information Sheets were updated accordingly. All submitted corrective and preventive actions were reviewed by EDA and confirmed to be acceptable, **in compliance with ICH E6(R2) and applicable regulatory requirements.** |
| **6. Clinical Trial Conduct** | |
| **6.1. Protocol Compliance** | Protocol compliance was assessed with respect to investigational medicinal product (IMP) accountability, implementation of the study suspension decision, and participant follow-up. Deficiencies were identified in IMP accountability and participant follow-up documentation, indicating non- |

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| | compliance **with the study protocol, GCP, and applicable regulatory requirements**. All identified deficiencies were acknowledged and fully addressed. Corrective and preventive actions were developed, implemented, and submitted within the required timeframe through enhancement of IMP accountability and documentation practices, including implementation of documented procedures for IMP transfer, reinforcement of temperature monitoring and record maintenance, updating of study documentation where required, and strengthening oversight to ensure compliance with protocol requirements and applicable regulatory expectations. |
| **6.2. Source Data and CRFs** | - Participant records and source documents were reviewed to verify participant follow-up documentation.<br>- However, deficiency was identified, as one participant was documented as lost to follow-up without supporting evidence, and the corresponding visit log was incomplete. These observations indicated deficiencies in participant follow-up documentation and the maintenance of essential clinical trial records **in accordance with ICH E6(R2).** In response, the sponsor acknowledged the raised observation and committed to strengthening documentation practices to ensure the completeness and maintenance of essential clinical trial records in accordance with the study protocol and Good Clinical Practice (GCP). The corrective action performed was review the participant records and visit documentation to ensure the participant's lost to follow up status is supported by adequate documentation and as preventive action , site personnel was retrained on the good documentation practices and periodic quality reviews to verify completeness and accuracy of participants records and essential clinical trial documentation throughout the study. |
| **6.3. Delegation of Duties** | - Delegation of duties was not assessed during this trigger inspection. The inspection did not include a review of delegation logs, assignment of trial-related responsibilities, or documentation of delegated duties among study personnel. |
| **7. Laboratory and Bioanalytical Activities (if applicable)** | |
| - External and Internal Laboratories were used for analysis.<br>- Laboratory and bioanalytical activities were not assessed during this trigger inspection | |
| **8. Safety Reporting (SAE)** | |
| Safety reporting was not assessed during this trigger inspection. The inspection did not include a review of adverse event (AE) or serious adverse event (SAE) reporting procedures, safety reporting documentation, or compliance with applicable safety reporting requirements. | |

| Part 3 | Inspection outcome |
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| -Based on the reviewed documentation, inspected facilities, and observations identified during the inspection, clinical trial activities were suspended on 12 December 2021 following the trigger inspection.<br>Based on the critical deficiencies identified, the clinical trial site was not considered to be operating at an acceptable level of compliance with GCP guidelines and applicable regulatory requirements.<br>All identified deficiencies were communicated to the site and acknowledged. Corrective and preventive actions (CAPAs) were developed, implemented. However, the continuation of trial activities is contingent upon submission and approval of an amendment reflecting the change of manufacturer as corrective action regarding the IMP raised observations.<br>-This EDA-GCP-PIR remained valid and no further critical findings, safety concerns, or regulatory actions arose prior to the next scheduled inspection. | |
| **Part 4** | **List of national Laws and GCP Guidelines referenced in the inspection report** |
| 1. Law of Regulating Clinical Medical Research no.214/2020.<br>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<br>3. EDA Chairman Decree No.111 for 2022.<br>4. Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority "EDREX.GL.Bioinn.006".<br>5. Guideline for Good Clinical Practice ICH E6r2.<br>6. Declaration of Helsinki<br>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 |

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| 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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