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	Ain Shams specialized hospital (Neurology Department)
Address of inspected CT site	Al-Khalifa Al-Ma'mun Street, El-Abaseya
Inspection details	
Dates of inspection	18 February 2026
Type of inspection	Routine – Pre-Initiation (Pre-Activation) GCP Inspection to verify site readiness prior to trial initiation
Introduction	
General information about the sponsor and CT site	The inspected site is Ain Shams specialized Hospital (Neurology Department), Cairo, Egypt, conducting clinical studies for the sponsor EVA Pharma, Egypt, in accordance with applicable regulatory requirements and ethical standards. The CRO was MARC for Medical Services and Scientific Research. The Principal Investigator was Prof. Dr. Ali Shalsh This was a pre-initiation inspection. Planned activities include participant recruitment from the Neurology Department, Rotigotine transdermal patch application, clinical assessments, safety monitoring, IMP dispensing and accountability, and data documentation via CRF.
Brief report on inspection activities undertaken	
Scope and limitations	
Areas inspected	• Clinical operations (screening, dosing, follow-up) • Informed Consent Process • Investigational Medicinal Product (IMP) management • Pharmacy / IMP storage area • Archiving and documentation system • Quality management system
Out of scope	• Participant records, screening/identification logs, informed consent review, SAE reporting, eCRF review, and dispensing records were not applicable as the trial had not yet been initiated at the time of inspection. • Human sampling is not performed at the site; participants are referred to Alfa Laboratory. • Disposal containers were not applicable for the same reason.
Inspected Clinical medical research	The pre-initiation inspection focused on the following study:

	Adhesion and Safety of Rotigexole Compared to Neupro®: A Non-Inferiority Open-Labelled Crossover Randomized Controlled Trial Protocol No.: START24042025| Registry: NCT07015346 EDA approval on: 13/11/2025.
Type of IMP	Transdermal patches – Rotigotine (Rotigexole) 8 mg/24 hrs (IMP) and Neupro® 4 mg, 6 mg, and 8 mg/24 hrs (comparator).
Part 2	
1. Facilities and equipment system	
1.1. Facilities and Trial Conduct	The **trial site** (Ain Shams specialized hospital.) had (adequate facilities, equipment to support the conduct of the trial, reception and waiting area, an examination room, a consultation room, a counseling room, a procedure room ….etc). However, the inspection found that the calibration of medical equipment for the trial procedures had been performed internally at Ain Shams Specialized Hospital rather than by a certified third-party provider, and that the patient monitor's calibration certificate had not been verified. This raised GCP concerns about the suitability, accuracy and maintenance of trial equipment and, in turn, the reliability of the clinical data. A regulatory decision was therefore taken at the end of the inspection to suspend the start of screening until the calibration issues were resolved. MARC CRO then implemented immediate corrective actions: a certified third party performed the calibration, and the calibration certificates and labels were submitted to EDA. The issue was considered resolved • An archiving room and a dedicated IMP storage room (access-controlled) were in place. • An emergency trolley was available with medications within expiry dates and regular checking records available.
1.2. Computerized system	Electronic data capture as eCRF will be used during the study and randomization systems (using R software) were used to the master randomization list.
2. Pharmaceutical Quality System	
2.1. Quality Management System	The site had a quality assurance system described in SOP(s) in place: for Good Clinical Practice; Investigational Products Management, Records/Essential Documents and Archiving Procedures in Case of Emergency which includes safety reporting for SAEs; Informed Consent procedure SOP-related deficiencies were identified: -The Consenting SOP states that minors are individuals under the age of 18 years. However, in accordance with Egyptian civil law, minors are defined as

	individuals less than 21 years of age. Therefore, the SOP requires revision to align with the applicable legal framework -The IMP Management: Investigational Products Management does not include procedures for investigational product (IMP) destruction. Therefore, the SOP requires revision to incorporate detailed IMP destruction procedures and to align with Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority -Review of SOP titled "Standard Operating Procedures in Case of Emergency," revealed that the safety reporting timelines specified therein are not aligned with the current Egyptian Drug Authority (EDA) guidelines for clinical trial oversight The SOPs were updated by MASRI CRC to address all EDA requirements as part of the corrective action. In addition, MARC CRO submitted the site qualification checklist as evidence that the delegated entity will review selected site SOPs during the site qualification assessment process for future studies. This checklist is required to be submitted as a preventive action deliverable.
2.2. SOPs and Documentation	-The site-maintained SOPs governing all clinical trial activities -All essential ISF documents were verified and found at the site, including: signed protocol by PI & sponsor; all EDA, IRB, and Supreme Council approvals; confidentiality agreements for PI, Co-Is; all contracts (CRO-PI, CRO-External Lab, CRO-Sponsor) lab EGAC accreditation, approved ICF; IB; eCRF; delegation log; and GCP certificates for all staff. Progress reports to IRB and EDA progress report were available. -However, the contract between Sponsor /CRO and IMP destruction vendor was not found in the ISF at the time of inspection, however it was received from MARC (CRO) in trial package -Trial initiation monitoring report was not at found at the site during the inspection as it was confirmed by site staff that the monitoring visit was conducted however, the report had not been finalized at the time of the inspection. -There was an error in the Conflict-of-Interest form signed by one of the Co-Investigators. She mistakenly checked the box indicating that she or a relative has a financial or other interest in the work she will be involved This issue has been addressed. MARC CRO submitted the corrected Conflict of Interest Form, duly signed by the Co-Investigator, as the corrective action. Additionally, the QA professional at MARC CRO conducted Good Documentation Practice (GDP) training for the study personnel as a preventive action.

2.3. Deviation Management	As the trial had not yet been initiated, no protocol deviations had occurred at the time of inspection. The protocol deviation log was in place and ready.
2.4. CAPA System	A CAPA system was established at the site.
3. Ethics and participant Protection	
3.1.Informed Consent Process	As the trial had not yet been initiated, no ICFs had been signed at the time of inspection. The procedure for obtaining informed consent was explained by the PI and was in line with GCP requirements. As the trial had not yet been initiated, consent had not yet been obtained from any participant.
3.2. Ethics Committee Approval	IRB: on 09/11/2025; EDA approval on: 13/11/2025. Supreme Council approval on: 25/01/2026. All required regulatory and ethics approvals were available and complete at the site. A note was identified: IRB progress reports did not include a specific time period covered; the CRO only informed the IRB of the approval status. This was acknowledged and future progress reports were confirmed to include specific coverage periods.
3.3. Participant Safety	The study has not been initiated yet at the time of the inspection so no safety concern was identified
4. Personnel and Training	
4.1. Training and qualifications	- Roles and responsibilities of study personnel were clearly defined in the delegation log. - Valid GCP certificates were confirmed for all delegated staff. All site staff were confirmed GCP trained. - CV of (delegated Radiology Technician) & (delegated Study nurse) were not found in the ISF **The absence of these documents prevents verification of their qualifications and training in accordance with GCP requirements.** - This issue has been addressed. MARC CRO submitted staff CVs, to the EDA as corrective action. - The site coordinator will ensure careful review of the ISF and confirm that all required staff qualification documents, including CVs, are obtained and filed in the ISF prior to delegation of any new staff to study-related activities as preventive action
5. Investigational Product (IMP) Management	

5.1. 1IMP handling	-IMP storage conditions, temperature monitoring, and accountability records were reviewed. IMP was stored in an access-controlled IMP storage room in a metal cupboard per study protocol. No special storage conditions were required; patches were kept in the outer packaging protected from light. A temperature data logger was in place inside the IMP cupboard with daily temperature logs available. -Shipping records detailing quantity and batch numbers were available. As the trial had not yet been initiated, dispensing was not yet applicable. -IMP labelling was clear and readable. Pamphlets of comparator were available. -No IMP-specific deficiencies were identified. All IMP quantities received were accounted for and reconciliation records were in place. As the trial had not yet been initiated, no dispensing had occurred.
6. Clinical Trial Conduct	
6.1. Protocol Compliance	As this was a pre-initiation inspection, the trial had not yet been initiated. The site was assessed for readiness to conduct the study in compliance with the approved protocol, GCP guidelines, and applicable regulatory requirements.
6.2. Source Data and CRFs	- Source document templates and the eCRF were reviewed for readiness. As the trial had not yet been initiated: - Participant records, screening log, and identification log were not yet applicable as the trial had not been initiated. Records storage infrastructure was in place; IMP was stored in an access-controlled room. Confidentiality of future records was confirmed to be maintained. Source data collection processes were reviewed with site staff and confirmed to be in line with GCP requirements for trial readiness. -All study data will first be documented in the source documents, in accordance with the site's standard system and clinical practice. To ensure that every required assessment and procedure is systematically captured for the trial, paper case report forms (CRFs) have been prepared. Paper CRFs will serve as the primary data-collection instrument across all sites. -Once completed and signed by the investigator or a delegated staff member, the paper CRFs will be securely transferred to MARC CRO for transcription into the validated electronic data-capture (EDC) system. - As no data had been collected at time of inspection, no data integrity issues were identified.
6.3. Delegation of Duties	- The delegation log was available.However**,** the randomization list was prepared by the Data Management Specialist, who was not delegated this responsibility by the PI. According to the Site Staff Signature and Delegation of Authority Log, signed by the PI, the responsibility for randomization was

	delegated to the Clinical Coordinator. As a corrective action, MARC CRO submitted documented evidence confirming that the Data Management Specialist was authorized to generate the central randomization list for the study, while the delegated Clinical Coordinator was responsible for coordinating the randomization process at the site. As a preventive action, MARC CRO submitted the relevant Randomization SOP, which provides clear and detailed instructions governing the randomization process, including both manual and automated randomization list generation.

7. Laboratory and Bioanalytical Activities (if applicable

-No laboratory facilities were available at the clinical trial site for inspection.
-An external accredited laboratory was used (Alpha Lab.) with valid accreditation according to EGAC under ISO 15189:2022, valid from 08 January 2025 to 08 March 2028.
-No human biological samples were collected at the clinical trial site.
-All laboratory analyses were planned to be conducted at the designated external laboratory.
- As the clinical trial had not yet commenced, no samples had been collected or processed at the time of inspection.

8. Safety Reporting (SAE)

A Safety Reporting SOP was available at the site. As the trial had not yet been initiated, no SAEs had been reported.

- Review of SOP titled "Standard Operating Procedures in Case of Emergency," revealed that the safety reporting timelines specified therein are not aligned with the current Egyptian Drug Authority (EDA) guidelines for clinical trial oversight
- No actual SAE reporting gaps existed as the trial had not been initiated.

Part 3	**Inspection outcome**

Based on the reviewed documentation, inspected facilities, and observations identified during the inspection: The routine pre-initiation GCP inspection conducted at Ain Shams Specialized hospital, Neurology Department, on 18 February 2026, concluded that the site was at an overall acceptable level of compliance for trial readiness. No actual participant harm, data integrity breaches, or safety reporting failures had occurred at the time of the inspection. Furthermore, the clinical trial had not yet commenced.

- The site had addressed the identified deficiencies and implemented the required CAPAs. The site had also taken steps to address the root causes of the deficiencies, strengthen its Quality Management System, ensure alignment of its SOPs with ICH E6(R3) and EDA regulatory guidelines, and maintain adequate resource allocation for all trial-related activities in accordance with GCP principles and participant protection requirements.
- This EDA-GCP-PIR reflects the findings of the pre-initiation inspection conducted on 18 February 2026.

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
COI	Conflict of Interest
CPL	Clinical Project Leader
CRF	Case Report Form
CRC	Clinical Research Center
CT	Clinical Trial
EDA	Egyptian Drug Authority
EDC	Electronic Data Capture
EGAC	Egyptian Accreditation Council
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
ISF	Investigator Site File
NCT	ClinicalTrials.gov Registry Identifier
PI	Principal Investigator
PIR	Public Inspection Report
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
WHO	World Health Organization