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	Neurology Department, Al-Manial Specialized Hospital, Cairo University
Address of inspected CT site	Abdel Aziz Al Saoud Street, Manial El Roda, Cairo, Egypt
Inspection details	
Dates of inspection	29 March 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 Al-Manial 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. Hatem Samir, supported by Co-Investigators and Clinical Coordinator 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 *eCRF*.
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 · Source documents and Case Report Forms (CRFs) · 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 at Al-Manial Specialized Hospital, Neurology Department, had adequate facilities and equipment to support the conduct of the trial. The site included a reception and waiting area, examination/consenting room, consultation room, counselling room, and procedure room. A combined examination, procedure, and consenting room was available. An archiving room and a dedicated IMP storage room (access-controlled) were in place. All trial equipment held valid calibration certificates. All equipment held valid calibration certificates An emergency trolley was available with medications within expiry dates and regular checking records available. Disposal containers were not applicable as no human sampling is performed at the site.
1.2. Computerized system	Electronic data capture as eCRF and randomization systems (using R software) were in use.
2. Pharmaceutical Quality System	
2.1.Quality Management System	The site had an established Quality Management System supported by SOPs: for PI Responsibilities; Site Initiation, Activation, Conduct and Close-out; Delegation of Authorities; Informed Consent; IMP Management, Safety Reporting and Source Documentation. -SOP-related deficiencies were identified: (1) site SOPs had not been updated to reflect recent ICH E6 R3 requirements and local EDA regulatory guidelines (EDA GCP Guideline V4, 26 March 2026), potentially impacting QMS effectiveness and participant protection; (2) no documented SOP existed describing the process for destruction of human biological samples, posing potential risks to subject confidentiality and biosafety; and (3) the Safety Reporting SOP had not been updated to align with EDA safety reporting timelines per the EDA Guideline V4.

	All deficiencies were identified, acknowledged, and addressed. The SOPs were updated to incorporate ICH E6 R3 requirements and EDA local regulatory guidelines, a new SOP for human biological sample destruction was developed and implemented, and the Safety Reporting SOP was revised to align with EDA reporting timelines, per ICH E6 R3, and EDA GCP Guideline V4.
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; sponsor-signed 25/09/2025); all EDA, IRB, and Supreme Council approvals; confidentiality agreements for PI, Co-Is; all contracts (CRO-PI, CRO-Alfa Lab, CRO-Sponsor, Sponsor destruction vendor); lab EGAC accreditation; SIVR; approved ICF; IB; eCRF; delegation log; administrative site approval (Faculty of Medicine, Qasr El Ainy); EDA submitted application and import license; study team contact list; site qualification and initiation visit reports; calibration certificates for all equipment; and GCP certificates for all staff. Progress reports to IRB and EDA progress report were available. -A note was identified that IRB progress reports did not include a specific time period covered; the CRO only informed the IRB of the approval status of the study.
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 Subject Protection	
3.1.Informed Consent Process	The informed consent process was reviewed with the PI, who explained the planned participant recruitment and consent procedures from Al-Manial Specialized Hospital. 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 20 /07/2025; 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. Subject Safety	The study not has been initiated yet, 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. -a Clinical Research Coordinator (CRC) was concurrently assigned across three study sites within the same trial (START24042025), presenting a risk of inadequate task distribution and potential operational inefficiencies. Both issues were identified, acknowledged, and corrected. The delegation log was updated to accurately reflect the staff member who performs randomisation, and a resource allocation plan was documented to confirm that the CRC had adequate capacity to fulfil responsibilities across all assigned sites, in accordance with ICH E6(R3) -Valid GCP certificates were confirmed for all delegated staff. All site staff were confirmed GCP trained. - The training system was adequate. All staff held valid GCP certificates. No training documentation gaps were identified. Staff training on the updated SOPs (including revised Safety Reporting SOP) was confirmed completed prior to trial initiation.
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 Neupro 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. The inspection concluded that Al-Manial Specialized Hospital, Neurology Department, was at an overall acceptable level of compliance for site readiness.

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. -A discrepancy was identified in the delegation log, where the individual responsible for performing randomisation was not accurately recorded — the activity was listed under a different assignee, while in practice it was carried out by the Data Management Specialist.

7. Laboratory and Bioanalytical Activities (if applicable)

- No site lab. To be inspected
- External accredited laboratories used with valid accreditation
- No human sampling was performed at the clinical trial site; all laboratory analyses were to be referred to the designated Laboratory. As the trial had not yet been initiated, no samples had been collected or processed.
- Laboratory procedures were defined. No on-site laboratory equipment was applicable as the site used an external laboratory and no human sampling was performed at the site.
- As no human sampling was to be performed at the clinical trial site and all blood analyses were to be conducted at the accredited external Alfa Laboratory, on-site sample handling, storage, and equipment were not applicable at this stage.

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.

- A finding was identified: the Safety Reporting SOP had not been updated to align with EDA safety reporting timelines per EDA GCP Guideline. This finding was identified, acknowledged, and

corrected: the SOP was updated to include all EDA-specified reporting timelines, and the revised SOP was implemented and staff were trained on its content prior to trial initiation.

- 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 Al-Manial Specialized Hospital, Neurology Department, on 29 March 2026, concluded that the site was at an overall acceptable level of compliance for trial readiness. Findings were classified as minor as no actual participant harm, data integrity breach, or safety reporting failure had occurred at the time of inspection, and the trial had not yet been initiated. All identified deficiencies were communicated to the site. Corrective and Preventive Actions were implemented and confirmed prior to trial activation

This EDA-GCP-PIR reflects the findings of the pre-initiation inspection conducted on 29 March 2026. The site is required to address all identified deficiencies and implement the required CAPAs prior to trial activation. The site is encouraged to focus on the root causes of deficiencies to strengthen its Quality Management System, ensure full alignment of 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.

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
ALCOA:	Attributable, Legible, Contemporaneous, Original, Accurate
CAPA:	Corrective and Preventive Action
CRF:	Case Report Form
CRC	Clinical research Center
CT	Clinical Trial
EDA	Egyptian Drug Authority
GCP:	Good Clinical Practice

ICF:	Informed Consent Form
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

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