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	MARC for Medical Services and Scientific Research (MARC CRE)
Address of inspected CT site	27 Northern Expansions, Polaris Complex, 4th Industrial Zone, 6th of October City, Giza, Egypt
Inspection details	
Dates of inspection	09 February 2026
Type of inspection	Routine – Pre-Initiation GCP Inspection to assess site readiness and capability to conduct trial activities in compliance with applicable regulatory requirements and GCP
Introduction	
General information about the sponsor and CT site	The inspected site is MARC for Medical Services and Scientific Research (MARC CRE), 6th of October City, Giza, 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. Ahmed Farag, supported by Co-Investigators This was a pre-initiation inspection. Planned activities include participant recruitment, rotigotine transdermal patch administration, clinical assessments, safety monitoring, IMP dispensing and accountability, and data documentation via CRF. The inspection covered the informed consent process area, housing area, examination room(s), archiving room, and IMP storage area.
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 signing, SAE reporting, CRF data, and dispensing records were not applicable as the trial had not yet been initiated at the time of inspection. No participant files

	were reviewed. Sample withdrawal at the site was not applicable as samples were to be processed at the external Alfa Laboratory by referral letter.
Inspected Clinical medical research	Adhesion and Safety of Rotigexole Compared to Neupro®: A Non-Inferiority Open-Labelled Crossover Randomized Controlled Trial Protocol No.: START24042025 Registry: NCT07015346 EDA approval: 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 MARC CRE had adequate facilities and equipment to support the conduct of the trial, including a reception and waiting area with 50 chairs, examination room, consultation room, counselling room, housing area, procedure/emergency room, pharmacy/IMP storage room, and archiving room. One combined room served for consenting, examination, IMP storage, dispensing, administration, and document archiving. Two emergency trolleys and an emergency medication cupboard were in place. All major equipment held valid calibration certificates; Temperature Data Logger; Emergency trolleys were available with medications within expiry dates and regular checking records available. Disposal containers were found, labeled, and color-coded per international color-coding system. - Calibration issues were identified: (1) No calibration certificate was found for the Weight Balance (2) a discrepancy existed between the calibration certificate and calibration label of Infra-red Thermometer These issues were identified, acknowledged, and corrected: a valid calibration certificate was obtained and filed for the weight balance; the thermometer calibration discrepancy was resolved with a new calibration performed and a corrected certificate filed
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 covering participant identification, entry/exit procedures, check-in/check-out, meals and fluids, IMP administration, cannulation, blood sample collection, hospitalization preparation, bio-sample numbering, vital signs recording, emergency care, centrifugation and sample segregation, and infection control. Two SAE/safety reporting SOPs were also verified

	- The current site SOPs did not adequately detail procedures specific to clinical trial conduct, nor did they clearly reference the applicable study protocol, pharmacy manual, laboratory manual, or other essential trial documents. They lacked explicit guidance on protocol-driven activities, documentation requirements, investigational product handling, sample management, and cross-referencing to relevant controlled documents, which posed a risk to operational clarity and regulatory compliance. This finding was identified, acknowledged, and addressed. The SOPs were reviewed and updated to include trial-specific detail, explicit cross-references to the study protocol and relevant controlled documents, and clear guidance on protocol-driven activities including IMP handling and sample management.
2.2.SOPs and Documentation	The site-maintained SOPs governing clinical trial activities. All essential ISF documents were verified and found at the site, including: signed protocol ; EDA approval; IRB approval; Supreme Council approval; confidentiality agreements for PI, Co-Is; CVs for PI and both Co-Is; insurance certificate; all contracts (MARC-PI; MARC-Alfa Lab; approved ICF; CRF; conflict of interest and financial disclosure forms; site delegation log ; CRO and IRB Supreme Council registration certificates; IMP identification form; administrative site approval ; EDA application; GCP certificates for all staff; CoA for all IMP batches; comparator pamphlets; calibration certificates; and temperature data logger records. progress reports were submitted to the IRB. Note: progress reports did not include specific coverage periods – only study status updates were provided as the trial had not yet been initiated. Note: The Site Initiation Visit Report (SIVR) was not available at the time of the inspection, as the site initiation visit had been conducted one day prior and the report was still under preparation. The SIVR was subsequently made available.
2.3. Deviation Management	As the trial had not yet been initiated, no protocol deviations had occurred at the time of inspection.
2.4. CAPA System	A CAPA system was established at the site.
3. Ethics and Participant Protection	
3.1.Informed Consent Process	The informed consent process was reviewed. As per the delegation log, PI and Co-I were confirmed responsible for explaining the participant recruitment process and obtaining informed consent. As the trial had not yet been initiated, no ICFs had been signed at the time of inspection. Approved ICF was available and verified at the site. As the trial had not yet been initiated, consent had not been obtained from any participant.

3.2.Ethics Committee Approval	IRB approval: 27/10/2025. Supreme Council approval: 25/01/2026. All required regulatory and ethics approvals were available and complete at the site. All ICF versions were consistent with the approved protocol version.
3.3. Participant Safety	The study ~~not has~~has not been initiated yet, so no safety concern was identified
4. Personnel and Training	
4.1.Training and qualifications	GCP training records were available and reviewed. Valid GCP certificates were confirmed for study staff -no evidence was found for one of the Co-I had attended the protocol-specific training conducted by the PI. This was identified, acknowledged, and corrected: protocol-specific training was conducted for Co-I; attendance was documented and training records were filed, per ICH E6 R3. The training system was adequate following corrective action. All staff held valid GCP certificates. Protocol-specific training was completed for Co-I and training documentation was filed. No further training gaps were identified.
5. Investigational Product (IMP) Management	
5.1.1IMP handling	- IMP storage conditions, temperature monitoring, and accountability records were reviewed. IMP was stored separately in a fire- and waterproof metal cupboard per study protocol. A temperature data logger was installed inside the IMP cupboard with daily temperature logs available. The cupboard was connected to an alarm system in case of power failure (not applicable given the extractable data logger). Access-controlled IMP storage room was secured by delegated pharmacist Note – IMP Availability at Time of Inspection (Resolved during Inspection): At the start of the inspection, the IMP (Rotigotine 8 mg/24 hrs) was not present at the site. The site was immediately informed that no initiation or screening activities could be performed in the absence of the IMP. The site arranged for and received the complete IMP shipment on the same day (09/02/2026); receipt evidence was submitted during the inspection, and the issue was confirmed resolved. -Shipping records were available. As the trial had not yet been initiated, dispensing had not yet occurred. - IMP labelling was clear and readable, Comparator pamphlets for all Neupro strengths were available at the site. -The IMP availability gap (Rotigotine 8 mg absent at start of inspection) was resolved on the day of inspection with a full IMP shipment received and documented. No further IMP accountability deficiencies were identified.

6. Clinical Trial Conduct	
6.1.Protocol Compliance	As this was a pre-initiation inspection, the trial had not yet been initiated. The study (START24042025) was assessed for readiness and was at an acceptable level of compliance with the protocol, GCP guidelines, and applicable regulatory requirements.
6.2. Source Data and CRFs	- Source document templates and CRF were reviewed for readiness. As the trial had not yet been initiated -Participant records, screening log, and identification log were not applicable as the trial had not been initiated. Source data collection procedures were reviewed with site staff and confirmed to be in line with GCP requirements -Records storage infrastructure was in place. -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 systemati-cally 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.
6.3. Delegation of Duties	-The delegation log was available, -Findings that were identified and corrected: (1) the archiving task and adhesion assessment score were absent from the log – added; (2) certain responsibilities were not properly recorded – fully documented; (3) the delegation log assigned randomisation to the PI, who confirmed he does not perform this activity – corrected to reflect that randomisation is performed via "R" software, subsequently verified at the Ain Shams Specialized Hospital inspection on 18/02/2026
7. Laboratory and Bioanalytical Activities (if applicable	
-No site lab. To be inspected -External accredited laboratories: Alfa Laboratory with valid accreditation -No human sampling was performed at the clinical trial site; all laboratory analyses were to be referred to Alfa 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)
-Two SAE/safety reporting SOPs were available and verified: Adverse Event/SAE Monitoring, Recording and Reporting, and Management of Safety Reporting. No SAEs had occurred as the trial had not yet been initiated. No deficiencies were identified in the SAE reporting SOPs. -SAE reporting timelines and documentation requirements were confirmed in the available SOPs. No SAE reporting occurred as the trial had not yet been initiated. -No gaps in SAE reporting SOPs or documentation were identified. Both available SOPs were current and effective at the time of inspection.

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 MARC BE Centre on 9 February 2026 concluded that the site was at an overall acceptable level of compliance for trial readiness. All identified deficiencies were communicated to the site. Corrective and Preventive Actions were submitted and evaluated by EDA inspectors. The site was required to implement an adequate CAPA plan addressing all four findings and to demonstrate strengthened quality systems prior to trial initiation. The site is encouraged to ensure full alignment of SOPs with ICH E6 R3 principles, accurate and complete delegation log documentation, complete calibration records for all equipment, and documented evidence of protocol-specific training for all delegated staff, to ensure full compliance with GCP principles, data integrity standards (ALCOA+), 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 EDA Chairman Decree No.111 for 2022. 3. Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority "EDREX.GL.Bioinn.006". 4. Guideline for Good Clinical Practice ICH E6R3. 5. Declaration of Helsinki 6. 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
CRE	Clinical Research Entity

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