

Notice to applicant for Public Dissemination of Clinical Trials Scientific and Regulatory data by Egyptian Drug Authority Year 2026

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1. List of Abbreviations:

- **AE:** Adverse Event
- **ALCOA:** Attributable, Legible, Contemporaneous, Original, Accurate.
- **Bio-Inn:** Central Administration of Biological and Innovative Products and clinical studies.
- **CAPA:** Corrective Action and Preventive Action
- **CT:** Clinical Trial
- **APASR:** Application_(s) Public Assessment Summary Report
- **AmPASR:** Amendment Public Assessment Summary Report
- **CRFs:** Case Report Form
- **CRO** Contract Research Organization
- **eCRF:** electronic Case Report Form
- **EDA:** Egyptian Drug Authority
- **EDA-CT:** Egyptian Drug Authority – Clinical Trial
- **GCP:** Good Clinical Practice
- **EMA:** European Medicines Agency
- **ICFs:** Informed Consent Forms
- **IB:** Investigational Brochure
- **ICH:** International Council for Harmonization
- **IMP:** Investigational Medicinal Product
- **PI:** Principal Investigator
- **PIR:** Public Inspection Report
- **SAE:** Serious Adverse Event
- **SOP:** Standard Operating Procedure
- **WHO:** World Health Organization

2. Introduction

As part of the cooperation between the Egyptian Drug Authority (EDA) and clinical trial specified entities, the Egyptian Drug Authority (EDA) publishes this guidance that included the rationale, approach, and procedure without the data confidentiality breaking for publishing the followings:

- **EDA-CT Application(s) Public Assessment Summary Report (CT-APASR)/ EDA-CT Amendment Public Assessment Summary Report CT-AmPASR)** for the clinical trial applications submitted to the EDA for evaluation and for which received a final EDA regulatory decision, whether approved or rejected.
- **EDA-GCP Public Inspection Report (PIR)** of Clinical Trial Site which will be developed based on the conducted GCP inspection.
- **EDA Clinical Trial / GCP Inspection Registry.**
- **GCP inspection metrics report.**

3. Rational

Through implementation of this guidance for publication of clinical trial application(s) as per WHO requirements and international agencies (e.g. EMA, ...) to publish summary reports of Clinical Trials Application (CT-APASR / CT-AmPASR), PIRs and EDA Clinical Trial / GCP Inspection Registry, the EDA aim to set the transparency that also led to:

- Increase public trustability and confidence in EDA scientific and enforcement of decision-making process.
- Avoidance of clinical trials duplication
- Encouragement of innovation and development of new investigational products.
- Public availability of the scientific data would enable independent secondary analysis of the scientific data reviewed by the Agency's scientific committees to determine investigational products' benefits and risks, which was expected to lead to public-health benefits.
- Increase awareness of regulatory inspection outcomes and common compliance findings, thereby supporting continuous quality improvement across the clinical research sector.
- Facilitate risk-based quality management by enabling stakeholders to identify recurring

compliance issues and implement corrective and preventive actions.

4. EDA-CT Application(s)/ Amendment Assessment Summary Publication:

Procedure:

The total time frame of the process after preparation of CT-APASR / CT-AmPASR to the final publishing is **20 days**.

4.1. Preparation of EDA-CT Application(s) Public Summary Assessment Report (CT- APSAR)/ EDA-CT Amendment Public Summary Assessment Report (CT-AmPASR)

- A comprehensive summary report will be prepared based on the assessment of submitted data/results from pre-clinical studies, previous clinical studies and the submitted clinical medical research (study protocol) after the submitted CT application(s) and its amendments have received a final EDA regulatory decision, whether approved or rejected, in Egypt.
- The prepared summary will be sent to the applicant(s) to be reviewed prior the publication.

4.2. Review by Sponsor or Legal Delegate (CRO / Service Provider)

- The applicant will review the summary CT-APASR / CT-AmPASR. This step allows them to provide feedback or comments regarding the content of the report.
- Any comment(s) regarding the content of the report should be sent to EDA Bio-Inn **within 10 days** from receiving the report.
- The applicant may request a timeline extension within this period including justification for the extension request, submitted via an official email, provided that the reasons and justifications are accepted by EDA.
- In case of receiving comments from the applicant, it will be reviewed by EDA. The publication timeline shall be temporarily suspended (stop clock) whenever discussion with the applicant is required regarding the submitted comments, until a final agreement is reached.

4.3. Publication on EDA Website

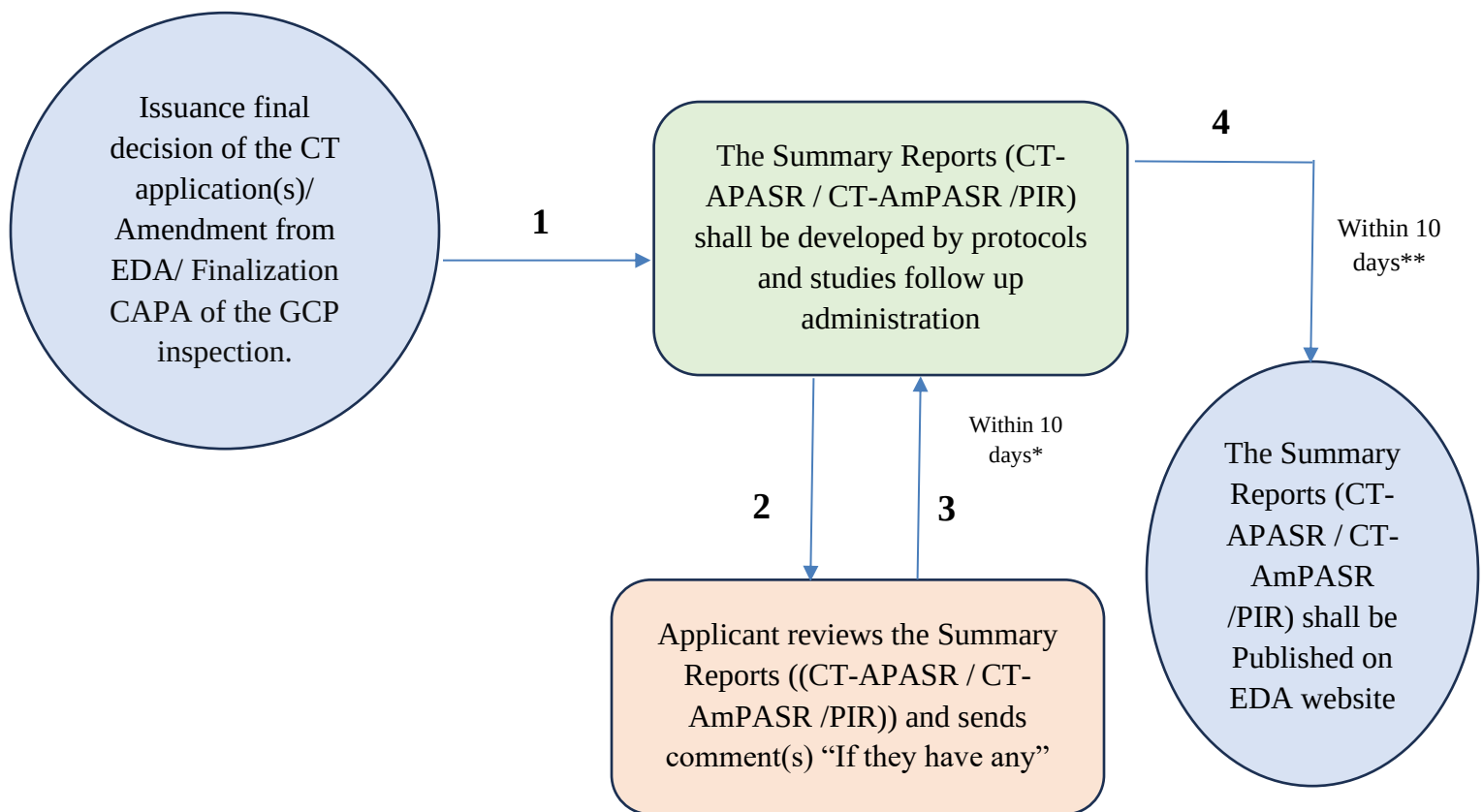
The EDA CT-APASR / CT-AmPASR for clinical trial application(s)/ amendments that have received a

final EDA regulatory decision, whether approved or rejected will be published on the EDA website **within 10 days**, making them accessible to the public and all relevant stakeholders.

4.4. Updating After CT Amendments:

In case of any substantial amendment to the Clinical medical research (study protocol) & its related documents &/or the Investigator Brochure, the CT-AmPASR will be updated accordingly and subjected to the above-mentioned steps 4.1 - 4.3 for communication with the applicant to be published on EDA Website.

Flowchart of Publication Process



* In case of any further comments and/or clarifications arising from the review of the applicants' comments, these shall be communicated to the applicant, who shall have an additional 10 days to provide a response which could be extended the timelines.

** Starting from the date of receiving the initial reply from the applicant to the report.

EDA-CT Application(s) Public Assessment Summary Report (CT-APASR)

Part One: Administrative Details	
Protocol title / number:	
Protocol Version and Date	
Public Registry Identification Number:	
Type of Submission	New Submission: Resubmission (In case of resubmission, mention the date of previous submission):
Investigator's Brochure version (IB) and Date:	
Study Phase:	
Applicant:	
Sponsor:	
Study Site(s) & Name of Principal Investigator(s):	
IRB(s) Name(s) & Approval Dates:	
Number of Target Participants in Egypt:	
EDA regulatory decision with date:	Approval ☐ Date: Rejection ☐ Date and justification:
Part Two: Application Review Pathway	
Submission Pathway:	Routine ☐ Non-Routine ☐ Reliance ☐
Justification for the Review Pathway (if applicable)	
Regulatory Authority Relied Upon for the Reliance Pathway (if applicable)	
Part Three: Investigational Medicinal Product(s)	
Investigational Medicinal Product being tested:	Biological ☐ Pharmaceutical ☐ Innovative ☐ Herbal medicine ☐ Medical Device ☐
Name and Strength of Investigational Product(s) including Comparator(s):	
Dosage Form of Investigational Product(s) including Comparator(s):	

Part Four: Brief Summary

Brief description of IMPs:

Non-Clinical studies evaluation summary:

Assess whether the overall nonclinical evidence is scientifically adequate, appropriately conducted, and sufficient to support the proposed clinical development with respect to the investigational product, mechanism of action, indication, population, route, dose, exposure and treatment duration. The assessment should consider the totality of the nonclinical evidence, identify relevant risks and uncertainties, and determine how the findings support or limit the proposed clinical trial.

Based on the totality of the pharmacological, PK/TK, safety pharmacology and toxicological evidence, assess whether the nonclinical package adequately supports initiation or continuation of the proposed clinical trial at the proposed dose, route, population and treatment duration. The conclusion should integrate the findings rather than assess each study independently and should clearly identify any significant limitations, inconsistencies, uncertainties or unresolved risks and their implications for the proposed clinical trial.

metabolites or active metabolites have been adequately addressed and whether the available data support extrapolation of animal findings to the anticipated human exposure.

Integration of Nonclinical Findings & Clinical Risk Mitigation

Consider the nonclinical findings collectively and assess whether clinically relevant risks have been appropriately translated into the proposed clinical trial. For each important nonclinical finding, consider its relationship to the pharmacology, PK/TK, previous clinical experience and proposed clinical exposure. Assess whether the protocol adequately addresses identified risks through participant selection, dose selection, dose escalation, laboratory assessments, ECG/vital-sign monitoring, treatment interruption or discontinuation criteria, stopping rules, follow-up or other risk-mitigation measures.

Key Nonclinical Uncertainties & Knowledge Gaps

Identify important uncertainties or limitations remaining after consideration of the overall nonclinical evidence. Consider whether the uncertainty relates to mechanism, species relevance, exposure margins, toxicity, metabolites, duration, reproductive risk, long-term risk or another aspect of development. Assess whether the proposed clinical trial appropriately addresses these uncertainties or whether they could materially affect participant safety or interpretation of the study.

Summary of previous clinical experience:

Assess whether the available human experience provides adequate and relevant evidence regarding the safety, tolerability, pharmacology, efficacy and exposure of the investigational product to support the proposed clinical trial. The assessment should consider the totality of previous human evidence and its relevance to the proposed dose, regimen, population, duration and objectives.

Based on the totality of the available human safety, tolerability, PK/PD and efficacy evidence, assess whether the existing clinical experience adequately supports the proposed dose, regimen, population, duration and objectives of the current trial. Clearly identify unresolved safety signals, limitations, inconsistencies and uncertainties and explain how they influence the overall benefit–risk assessment.

Integration of Clinical Safety Findings with Protocol Risk Mitigation

Assess whether important safety findings from previous clinical experience have been appropriately translated into the proposed protocol. Consider eligibility criteria, baseline assessments, monitoring

requirements, laboratory and cardiac assessments, concomitant medication restrictions, dose modification/interruption criteria, stopping rules, follow-up and other risk-mitigation measures. Assess whether the proposed monitoring is proportionate to the identified risks.

Key Clinical Uncertainties & Knowledge Gaps

Identify important uncertainties remaining after consideration of the previous human evidence. Consider uncertainties relating to safety, efficacy, dose/exposure, treatment duration, specific populations, long-term effects or other clinically relevant areas. Assess whether the proposed study is appropriately designed to address these uncertainties.

Summary of the submitted clinical medical research (study protocol)

Based on the totality of the scientific, nonclinical and clinical evidence, assess whether the proposed protocol is appropriately designed to answer its stated research questions while adequately protecting participants. The assessment should integrate the identified risks, benefits, uncertainties and mitigation measures and should clearly identify any deficiencies that could materially affect participant safety, scientific validity or reliability of the study results.

Arms and Interventions	Experimental:
	Comparator:
Study Indication	
Study Design:	Allocation:
	Interventional Model:
	Blinding:
Study Population:	
Study Objective(s):	
Scientific Rationale:	
Study Outcomes	Primary end points/ Outcome Measures
	Secondary endpoints/Outcome Measures

Risk-Based Assessment of Eligibility & Exclusion Criteria of the submitted protocol:

Assess whether exclusion criteria are proportionate to identified risks and supported by the available nonclinical and clinical evidence. Consider organ-function restrictions, cardiovascular risk, concomitant diseases, prior therapies, concomitant medications, reproductive considerations and other relevant factors. Determine whether each important restriction contributes meaningfully to participant safety or study interpretability.

Concomitant & Rescue Medications

Assess whether permitted and prohibited concomitant medications are scientifically and clinically justified. Consider potential pharmacokinetic or pharmacodynamic interactions, effects on efficacy endpoints, confounding, rescue therapy, background standard of care and participant safety. Assess whether the protocol appropriately manages medications that could materially influence the study results or risk profile.

Safety Monitoring & Safety Assessments

Assess whether the safety monitoring strategy is proportionate to the known and anticipated risks of the

investigational product. Consider the safety findings from nonclinical studies and previous clinical experience and whether the proposed clinical, laboratory, ECG, imaging or other assessments are adequate to detect clinically important risks in a timely manner.

Assess whether the protocol provides adequate definitions, monitoring, management and follow-up of adverse events and serious adverse events. Consider whether anticipated adverse events and important potential risks have appropriate management algorithms, dose-modification criteria, treatment discontinuation criteria and follow-up requirements.

Overall Integrated Benefit-Risk Assessment

Assess the overall benefit–risk balance of the proposed clinical trial by integrating the totality of the nonclinical evidence, previous clinical experience, and the proposed protocol. Consider whether the available findings across the different stages of development are consistent and collectively support the proposed mechanism, dose, regimen, population, and treatment duration, and whether any individual finding becomes more or less significant when interpreted in the context of the totality of evidence. Weigh the anticipated benefits against the identified and potential risks and remaining uncertainties, taking into account the disease severity, available treatment alternatives, unmet medical need, strength and limitations of the supporting evidence, magnitude and clinical relevance of the anticipated benefit, and the likelihood, severity, and reversibility of potential harms. Assess whether the proposed protocol includes adequate and proportionate measures to address the identified risks and uncertainties, including appropriate participant selection, dosing, safety monitoring, treatment interruption or discontinuation criteria, stopping rules, rescue therapy, and follow-up. Conclude whether the anticipated benefits justify the identified and potential risks and remaining uncertainties and whether the available evidence and proposed safeguards adequately support the conduct of the clinical trial.

Key Protocol Uncertainties & Deficiencies

Identify the protocol elements where uncertainty remains regarding scientific validity, participant safety, feasibility or interpretability. Consider whether the identified issue is adequately addressed elsewhere in the protocol or whether modification, clarification, additional information or additional risk mitigation is required

Part Five: Abbreviation(s):

EDA-CT Amendment Public Assessment Summary Report (CT-AmPASR)

Part One: Administrative Details	
Protocol title / number:	
Protocol Version and Date	
Public Registry Identification Number:	
Type of Submission	New Submission: Resubmission (In case of resubmission, mention the date of previous submission):
Investigator's Brochure version (IB) and Date:	
Study Phase:	
Applicant:	
Sponsor:	
Study Site(s) & Name of Principal Investigator(s):	
IRB(s) Name(s) & Approval Dates:	
EDA regulatory decision with date:	
Part Two: Application Review Pathway	
Review Pathway:	Routine ☐ Non-Routine ☐ Reliance ☐
Justification for the Review Pathway (if applicable)	
In case of reliance, Name of the reference county(ies):	
Part Three: Investigational Medicinal Product(s)	
Investigational Medicinal Product being tested:	Biological ☐ Pharmaceutical ☐ Innovative ☐ Herbal medicine ☐ Medical Device ☐
Name and Strength of Investigational Product(s) including Comparator(s):	
Dosage Form of Investigational Product(s) including Comparator(s):	
Part Four: Brief Summary	



Brief description of IMPs:	
Study Indication:	
List of Changed Documents	
Scientific Rationale of the submitted Amendment:	
Summary Description of Changes:	
Part Five: Abbreviation(s):	

5. EDA-GCP Public Inspection Report (PIR)

5.1. Preparation of CT Application Summary Report

EDA-GCP Public Inspection Report (PIR) of Clinical Trial Site which will be developed based on the conducted GCP inspection of the inspected clinical trial site and/or the related entities. The PIR shall be prepared after the finalization and closure of the corresponding CAPA.

5.2. Review by Sponsor or Legal Delegate (CRO / Service Provider)

The applicant shall review the PIR and sharing it with the sponsor and the clinical trial site relevant to the GCP inspection, including the relevant Principal Investigator, as applicable, and provide any comments **within 10 days** from the date of receipt. The applicant may request a timeline extension within this period, including justification for the extension request, submitted via an official email, provided that the reasons and justifications are accepted and approved by EDA. Any comments received from the applicant will be assessed by EDA. The publication timeline shall be temporarily suspended (stop clock) if additional discussion with the applicant is required, until a final agreement is reached.

5.3. Publication on EDA Website

Upon completion of the comments review process, the finalized PIR shall be published on the EDA website within 10 days. The applicant may request an extension within this period including justification for the extension request, submitted via an official email, provided that the reasons and justifications are accepted and approved by EDA.

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	
Address of inspected CT site	
Inspection details	
Dates of inspection	
Type of inspection	
Introduction	
General information about the sponsor and CT site	<i>The inspected site is Clinical Trial Site (.....) conducting clinical studies for the sponsor (.....) in accordance with applicable regulatory requirements and ethical standards.</i> <i>PI name</i> <i>Activities include participant recruitment, clinical conduct, sample collection, safety monitoring, and data documentation.</i>
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 • Bioanalytical / laboratory facilities (if applicable) • Source documents and Case Report Forms (CRFs) • Archiving and documentation system • Quality management system
Out of scope	<i>[Specify if any with reason]</i>
Inspected Clinical medical research	<i>The inspection focused on the following study(ies):</i> <i>[Study Title / Protocol Number \ Phase]</i> <i>EDA initial approval date</i>
Type of IMP	

Part 2	
1. Facilities and equipment system	
1.1. Facilities and Trial Conduct	• The site facilities were generally adequate for trial conduct Equipment maintenance, calibration, and emergency preparedness were in place.
1.2. Computerized system	Electronic data capture as eCRF 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 are controlled, periodically reviewed, and implemented. However, some deficiencies were identified.
2.3. Deviation Management	Deviations were handled according to SOPs. Documentation of deviations, investigations, and CAPA were generally adequate. Some deficiencies were noted
2.4. CAPA System	A CAPA system was established; however, effectiveness tracking required improvement for deviations
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. • However, deficiencies were noted regarding documentation, re-consenting, and/or verification during inspection.
3.2. Ethics Committee Approval	Approvals from IRB/IEC was available; date of approval However, documentation completeness and version control required improvement.
3.3. Participant Safety	Safety monitoring procedures were in place. AE/SAE reporting was generally compliant, with minor deficiencies observed.
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; however, some gaps in training documentation and completeness were identified.

5. Investigational Product (IMP) Management	
5.1. IMP handling	- IMP storage conditions, temperature monitoring, and accountability records were reviewed. - Shipping, receipt, and dispensing procedures were implemented. - Labeling and traceability were generally adequate. - Minor deficiencies related to documentation and verification were noted.
6. Clinical Trial Conduct	
6.1. Protocol Compliance	The study was generally conducted according to the approved protocol. Some deviations were identified.
6.2. Source Data and CRFs	- Source documents and CRFs were reviewed: - Data were generally consistent. - Some issues related to ALCOA principles were identified.
6.3. Delegation of Duties	Delegation logs were available; however, completeness and accuracy required improvement.
7. Laboratory and Bioanalytical Activities (if applicable)	
- Name of labs - Laboratory procedures were generally defined. - Sample handling and analysis were reviewed. - Some deficiencies related to documentation and validation were noted	
8. Safety Reporting (SAE)	
- SOPs for SAE reporting were available. - Reporting timelines and documentation were generally followed. - Minor gaps in documentation or completeness were identified	
Part 3	Inspection outcome
- Based on the reviewed documentation, inspected facilities, and observations identified during the inspection: - The clinical trial site was considered to be operating at an acceptable level of compliance with GCP guidelines and applicable regulatory requirements. - All identified deficiencies were communicated to the site. Corrective and preventive actions (CAPA) should be implemented to address the observations. - This EDA-GCP-PIR remains 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
- Law of Regulating Clinical Medical Research no.214/2020. - 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.	

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.**

Abbreviations:

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

6. EDA Clinical Trial / GCP Inspection Registry

All CT application(s) granted EDA regulatory decision for interventional study protocol(s) of clinical trials include the use of new compounds (biological, pharmaceutical, herbal, innovative products, and medical devices), or new indications for use, or new dosage forms that were never used on human body and other interventional study protocol(s) shall be filled &/or updated quarterly on a regular basis and/or updated immediately in case of any significant change(s) to the status of any clinical trial such as suspension/termination/withdrawal.

All data related to the GCP inspection(s) conducted by the GCP inspection team at EDA on clinical medical research site(s) and its related entities conducted inside/outside Egypt should be filled &/ or updated quarterly on a regular basis and/or updated in case of any significant change(s) related to the conducted inspection(s) immediate regulatory decision(s).

A web portal link has been developed and utilized for updating the “GCP Inspections Registry”. This portal enables the prompt electronic recording, updating, and tracking of GCP inspection data, ensuring accurate documentation, enhanced data integrity, and more efficient management of inspection records.

7. GCP Inspection Metrics

The GCP Inspection Metrics Report is an annual publicly available report that summarizes Good Clinical Practice (GCP) inspection activities conducted during a one-year reporting period. It provides an overview of inspection metrics, including the characteristics of the inspections performed, the types and classifications of identified deficiencies, their distribution across different inspection categories, and trends in inspection findings and regulatory compliance. The report serves as a valuable resource for identifying recurring deficiencies and compliance gaps, supporting continuous quality improvement, enhancing inspection preparedness, and promoting adherence to GCP principles and applicable regulatory requirements.



8. History Table:

Version Number	Issue Date	Summary of Change
1	January 2025	New version
2	July 2026	Addition of the followings: - GCP Public Inspection Report (PIR) of Clinical Trial Site. - EDA Clinical Trial / GCP Inspection Registry - GCP Inspection Metrics
3	August 2026	More clarification about a mechanism for requesting an extension of the applicant review period
4	October 2026	- Updating EDA-CT Application(s) Public Summary Assessment Report (CT- APSAR)/ EDA-CT Amendment Public Summary Assessment Report (CT-AmPSAR) templates. - Addition of Publication of Rejected Clinical Trials Applications