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

Year 2026

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Table of Contents

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
- **CT-ASPR:** Clinical Trial - Assessment Summary Publication Report
- **CRFs:** Case Report Form
- **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) Assessment Summary Publication Report (CT-ASPR) for the clinical trial submitted to EDA for evaluation after the grantee approval(s) in Egypt.
- 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.

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, Public inspection reports and EDA Clinical Trial / GCP Inspection Registry, the Egyptian Drug Authority (EDA) aim to set the transparency that also led to:

- Increase public trustability and confidence in EDA scientific and enforcement of decision-making operation.
- 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 preventive and corrective actions.

4. EDA-CT Application(s) Assessment Summary Publication Report

Procedure:

The total time frame of the process after preparation of EDA-CT Application(s) Assessment Summary Publication Report (CT-ASPR) to final publishing is 20 days.

4.1.Preparation of CT Application Summary Report

- A comprehensive summary report will be prepared based on the approved data from pre-clinical studies, previous clinical studies and the submitted study protocol after the submitted CT application(s) granted final approval from all concerned stakeholders 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

- The applicant will review the summary "CT-ASPR "report. 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 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.
- 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.

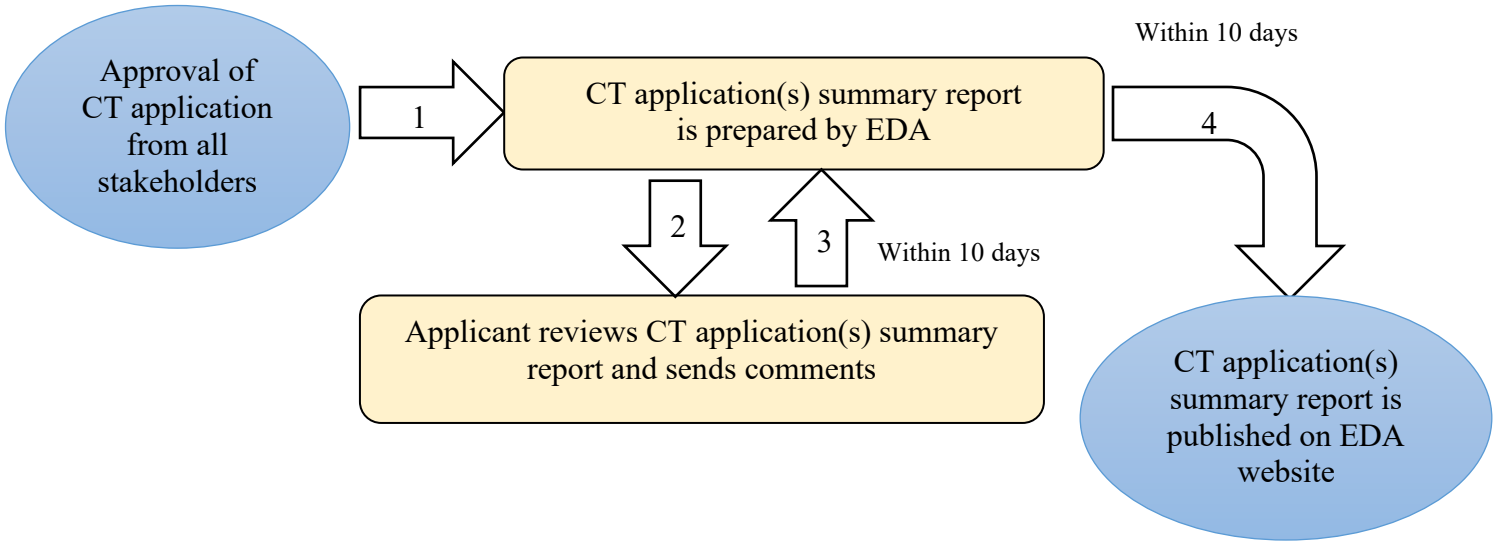
4.3. Publication on EDA Website

The EDA-CT Application(s) Assessment Summary Publication Report (CT-ASPR) will be published on the EDA website within 10 days, making them accessible to the public and all relevant stakeholders.

4.4. Updating After Amendments

In case of any substantial amendment to the Clinical medical research (study protocol) & its related documents and the Investigator Brochure, the CT application(s) Assessment Summary Publication Report will be updated accordingly, then published on EDA Website.

Flowchart of publication process



EDA-CT Application(s) Assessment Summary Publication Report (CT-ASPR)

• **Protocol title:** • **Protocol code number:** • **Public Registry Number:** • **Version:** • **Date:**
• **Investigational Product being tested:** **Biological** ☐ **Pharmaceutical** ☐ **Innovative** ☐ **Medical device** ☐ **Herbal Medicine** ☐
• **Sponsor:**
• **Indication:**
• **Investigator's brochure (IB)** **Version:** **Date:**
• **Name of all Sites:** • **Name of PI(s):**
• **EDA approval date:**
• **Brief Description of Investigational Medicinal Product(s) (IMPs):**
• **Summary of pre-clinical studies:**
• **Summary of previous clinical studies:**
• **Protocol:** ▪ **Phase:** ▪ **Objective(s):** ▪ **Rationale:** ▪ **Design:**
• **Abbreviation:**

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

The applicant shall review the PIR and provide any comments **within 10 days** from the date of receipt. 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	*The inspected site is Clinical Trial Site (.....) conducting clinical studies for the sponsor (.....) in accordance with applicable regulatory requirements and ethical standards.* *PI name* *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)* · *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	*[Specify if any with reason]*
Inspected Clinical medical research	*The inspection focused on the following study(ies):* *[Study Title / Protocol Number \ Phase]* *EDA initial approval date*
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**
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.** **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.

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