Notice to applicant for public dissemination of Clinical Trials scientific and regulatory data by Egyptian Drug Authority

Year 2025

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1. 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 for publishing a summary clinical trial application (CTA) report which is summarized from the pre-clinical studies and the previous clinical studies reports for the clinical trial submitted to EDA for evaluation after the grantee approval(s) in Egypt without the data confidentiality breaking.

2. 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, 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.

3. Procedure:

The total time frame of the process after preparation of CT Application Summary Report to final publishing is 20 days.

3.1 Preparation of CT Application Summary Report

- A comprehensive summary report is created based on data from pre-clinical studies and previous clinical studies. This report serves as part of the clinical trial package submitted to the Egyptian Drug Authority (EDA) for review.
- The report is sent to the applicants through their legal delegates for review before it is published.

3.2 Review by Sponsor or Legal Delegate

- The sponsor or his/her legal delegate reviews the CT application summary report. This step allows them to provide feedback or comments regarding the content of the report.

• **Timeline:** Any comments must be submitted to the administration of protocols and studies follow-up at EDA **within 10 days** of receiving the report, if no response is received, then the report will be considered accepted and to be published.

3.3 Publication on EDA Website

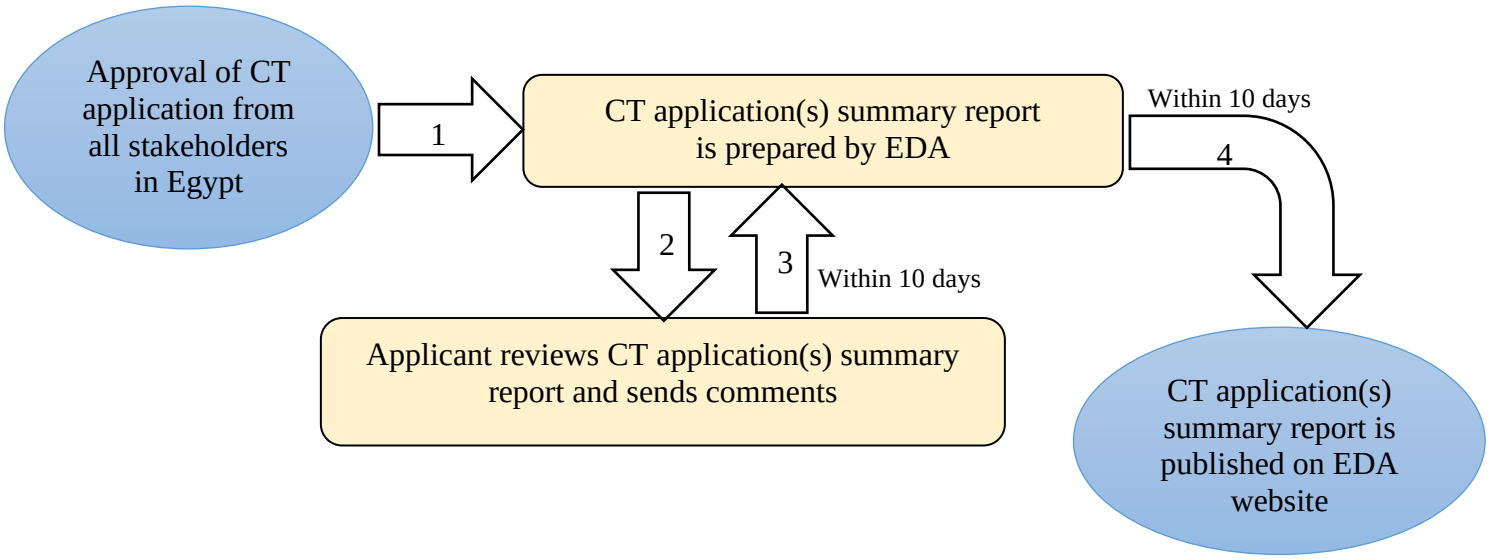
- The protocols and studies follow-up administration at the General Administration (GA) of CT at EDA reviews the received comments from the sponsor or legal delegate for consideration and final publishing on EDA website within 10 days, making them accessible to relevant stakeholders.

➔ N.B. Taken in consideration that the final CT summary reports will be sent to sponsor or legal delegate for notification and receiving further comments (if any) before publishing within the same period, if no response is received, then the final report will be considered accepted and to be published on EDA website.

3.4 Updating After Amendments

- If there are any substantial amendments made to the clinical medical research (study protocol) that have been approved by EDA, the CT application summary report will be updated accordingly.
- The updated report is then published to reflect these changes, ensuring that all information remains current and accurate.

Flowchart of publication process



CT application(s) summary report

- **Protocol title:**
- **Protocol code number:**
- **Public Registry Number:**
- **Version:**
- **Date:**
- **Investigational Product being tested:**

Biological ☐ **Pharmaceutical** ☐ **Innovative** ☐

Herbal medicine ☐ **Medical device** ☐

- **Sponsor:**
- **Indication:**
- **Investigator's brochure (IB)**
  Version:
  Date:
- **Name of all Sites:**
- **Name of PI(s):**
- **EDA approval date:**

- **Summary of pre-clinical studies:**
- **Summary of previous clinical studies:**
- **Protocol:**
  Phase:
  Objective(s):
  Rationale:
  Design:
- **Recommendation &/or Questions & Answers:**

- **Abbreviation:**