Notice to applicant

List of Required Documents for Clinical Trial Application Amendment submitted to GA of CT at Bio Inn- EDA

Year 2026

Code: EDREX.NP.Bioinn.004

Version No: 5.0

Issue Date: 06 August 2026

Effective date: 06 August 2026

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1. List of Abbreviations:

- **Bio-Inn:** Central Administration of Biological and Innovative Products and Clinical Studies
- **CT:** Clinical Trials
- **EDA:** Egyptian Drug Authority
- **GA of CT:** General Administration of Clinical Trials
- **ICF:** Informed consent form
- **IMP:** Investigational Medicinal Product.
- **IMPD:** Investigational Medicinal Product Dossier
- **IRB:** Institutional Review Board

2. The required documents for Submission of Clinical Trial Application Amendment:

2.1 Cover letter to EDA requesting approval of the submitted Amendment(s), including a list of all modified documents (Original hard copy).

2.2 IRB(s) Approval of site(s) at which the CT is conducted (Certified original hard copy).

2.3 Table changes for each modified document describes the changes from the newly submitted one(s) and original one(s) (previously approved by EDA) with rationale for each change in the following format.

Section	Description of Change	Rational for Change

2.4 Changed/ modified documents (e.g., Protocol, ICF …etc.).

2.5 Protocol signature page (in case of a new version of the protocol amendment) (Original hard copy).

2.6 Updated IMP accountability form (in case the number of doses or participants …etc).

2.7 Quality data of IMPD (if any changes are submitted).

2.8 A declaration letter by the applicant stating that the submitted changes in amendment(s) are identical to that submitted, evaluated, and approved by the regulatory authority of the reference countries (in case of Reliance submission).

2.9 Approval or rejection of the submitted changes in the amendment(s) by the regulatory authority of the reference countries with full detailed clarifications (in case of reliance submission).

2.10 Full assessment report from the regulatory authority of the reference countries about the submitted amendment(s), including comments and recommendation(s) (in case of reliance submission).

2.11 The Questions & Answers documents &\or any correspondence between the sponsor and the regulatory authority of the reference countries relating to safety and efficacy or queries, the risk management plan, or benefit- risk decisions applicants (in case of reliance).

2.12 Proof of fees payment.

2.13 The CT package Amendment(s) should be submitted via:
EDA Clinical Trials Platform (ctprotocol.edaegypt.gov.eg) and by e-mail:

- For IMPs of **biological** origin via email ctpro.bio@edaegypt.gov.eg and cc for (bio.ct@edaegypt.gov.eg)
- For IMPs of **chemical** origin via email ctpro.pharma@edaegypt.gov.eg and cc for (bio.ct@edaegypt.gov.eg)
- For **other types of IMPs and Medical Device** via email (bio.ct@edaegypt.gov.eg)

3. History Table

Version No.	Issue date	Summary of Changes
1	February 2022	New Version
2	5 January 2023	More clarification due to issuance of guideline for regulatory oversight of clinical trials by Egyptian Drug Authority (version 2.1)
3	14 October 2024	Some clarification due to issuance of supreme council construction prime minister decree 746/2024
4	06 August 2026	• Enhancing criteria description/ timing of required documents for more clarification to adopt with guideline for regulatory oversight of clinical trials by Egyptian Drug Authority version 05 • Addition EDA Clinical Trials Platform