

List of required documents to be submitted to GA of CT at Bio Inn- EDA for CT package data amendment(s)

**Year
2025**

Code: EDREX.NP.Bioinn.004
Version No.4
Issue Date: 5 Sep. 2025
Effective date: 16 Nov. 2025

1. **Cover letter** to EDA requesting approval of the submitted Amendment(s) including list of all modified documents (Original hard copy).
2. **IRB(s) Approval** of site(s) at which the CT conducted (Certified original hard copy).
3. **Table of changes** for each modified document stating each changed content in all sections between newly submitted one(s) and original one(s) (previously approved by EDA) with rationale for each change in the following format.

Section	Old	New	Rationale for change

4. Changed/ modified documents (e.g., Protocol, ICF ...etc.).
5. **Protocol signature page** (in case of new version of protocol amendment) (Original hard copy).
6. Updated **IMP accountability** form (in case change number of doses or subjects...etc).
7. **Quality data** of IMPD (if any changes submitted).
8. **A declaration letter** by the applicant (sponsor, PI, CRO) stating that 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).
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).
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).
11. The **Questions & Answers documents** & \or any correspondence between the sponsor and 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).

12. Proof of fees payment.

➔ **The CT package should be submitted via email:**

- 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)