Notice to applicant

Central Administration of Biological and Innovative products and clinical studies

General Administration of clinical trials

List of required documents to be submitted to GA of CT for CT package data amendment(s)

2024

Code: EDREX.NP.Bioinn.004
Version No: 3
Issue Date: 14 October 2024
Effective date: 14 October 2024

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 refence 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. **Fees proof of 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)