Arab Republic of Egypt
Egyptian Drug Authority
CA of Biological and Innovative products and clinical studies.
GA of Clinical Trials
Protocols & Studies Follow up Administration

جمهورية مصر العربية
هيئة الدواء المصرية
الادارة المركزية للمستحضرات الحيوية و المبتكرة والدراسات الاكلينيكية
الإدارة العامة للدراسات الإكلينيكية
إدارة البروتوكولات و متابعة إجراء الدراسات

List of required documents for protocol amendment reliance submission from the investigator, sponsor &/or CRO to be submitted to Bio Inn-EDA for clinical trials in Egypt

1. **Cover letter** to EDA requesting approval of Amendment(s) including list of all modified documents. (**Original hard copy)**
2. **A declaration letter** by the applicant (Sponsor, PI, CRO) stating that C.T package data (protocol, IB, nonclinical reports, previous study reports and other relevant documents) are identical to that submitted, evaluated and approved by the Regulatory authority of the reference countries.
3. **Approval or rejection** of clinical trials by the Regulatory authority of the reference countries with full detailed clarifications.
4. Status of the protocol in all centers.
5. **Full assessment report** from the Regulatory authority of the reference countries about submitted amendment including comments and recommendation.
6. **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.
7. **IRBs/MoH-REC Approval** of sites at which the CT conducted. (**Certified hard copies of original)**
8. **The Questions & Answers** documents between the Sponsor and IRBs/MoH-REC in Egypt (if found).
9. Table of changes for each modified document mentioning changes compared to original ones (previously approved by EDA) **with rationale**
10. Changed/ modified documents (e.g., Protocol, ICF …etc.).
11. **Protocol signature page** (in case of new version of protocol amendment). (**Original hard copy**)
12. All information relevant to risk-benefit assessment and the safety of the investigational product, obtained during the investigation or otherwise received from any source, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers (If applicable).
13. Reports in the scientific literature, and unpublished scientific papers (If available).
14. Updated IMP accountability form (in case change number of doses or subjects…etc.).
15. Quality data of IMPD (if any changes submitted).
16. Fees proof of payment (30.000 L.E).

➡ **Documents must be submitted via official 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)