Arab Republic of Egypt Egyptian Drug Authority CA of Biological and Innovative products and clinical studies.





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

GA of Clinical Trials Protocols & Studies Follow up Administration

List of required documents from the investigator, sponsor&/or CRO to be submitted in case of Amendment

- 1. Cover letter to EDA requesting approval of Amendment(s) including list of all modified documents (Original hard copy).
 - IRB(s) Approval of sites at which the CT conducted (Certified original hard copy).
- 2. Table of changes for each modified document mentioning changes compared to original ones (previously approved by EDA) with rationale for each change.
- 3. Changed/modified documents (e.g., Protocol, ICF ...etc.).
- 4. Protocol signature page (in case of new version of protocol amendment) (Original hard copy).
- 5. Updated IMP accountability form (in case change number of doses or subjects...etc).
- 6. Quality data of IMPD (if any changes submitted).
- 7. Fees proof of payment (30.000 L.E).

► 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)