Notice to applicant

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

Year 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. List of Required Documents for Clinical Trial Application Routine:

2.1. Cover letter directed to the General Manager of the General Administration of Clinical Trials, signed, dated, and stamped by the applicant, including the following items: Sponsor & CRO name, study title, study ID, and table of all submitted documents.

2.2. The Applicant Request to the Egyptian Drug Authority for Clinical Trial Authorization, filled, signed, and dated by the applicant.

2.3. Signed, stamped, and dated official delegation letter from the sponsor or the CRO to the company representative person who will submit the documents and deal with Bio-Inn EDA.

2.4. Detailed clinical trial protocol, signed by the sponsor and prepared according to the ICH guideline for Good Clinical Practice (GCP). The protocol should have the following:

2.4.1. Protocol Signature Page for each involved PI.

2.4.2. Public registry identification number, such as:

2.4.2.1. Clinicaltrials.gov (www. clinicaltrials.gov)

2.4.2.2. EudraCT Number (https://Eudract.ema.europa.eu)

2.4.2.3. Clinical Trials Information System (CTIS) (https://euclinicaltrials.eu/search-for-clinical-trials/)

2.4.2.4. International Clinical Trials Registry Platform (ICRTP) registry network.

2.4.2.5. Any National Database

2.5. Updated version of the Investigator's Brochure, with its version and date to document that relevant and current scientific information about the Investigational Product has been provided to the investigator.

2.6. Case Report Form, with its version and date. A printed or electronic document designed to record all the protocol-required information to be reported to the sponsor on each trial subject.

2.7. The finalized IRB approved Informed Consent Form (ICF), with its version and date:

2.7.1. For all involved age groups

2.7.2. For all special populations (e.g., pregnant partners)

2.7.3. For all special procedures (if applicable)

2.7.4. In English and Arabic Language.

2.8. Institutional Review Board Approval and/or MoH REC approval (if the clinical trial site is in a hospital affiliated to the Ministry of Health) for each involved site and its application form. To document that the trial has been subject to ethics review and given a favorable opinion. The IRB/MoH approval must be valid and with clear expiry date.

2.9. Questions raised by the IRB/MoH-REC to the applicant regarding the submitted protocol and their answers (if available)

2.10. The administrative approval (site's approval) of all involved sites.

2.11. The registration of the IRB, the license of the CRC, and the license of the CRO related to the protocol in the Supreme Council.

2.12. Valid insurance certificate, to document that compensation to subject(s) for trial-related injury will be available. It should include the name of the insured entity, the study name/ID, and the number of involved subjects, and the related annexes. The insurance company must be a local one or an international company that has a legal representative in the Arab Republic of Egypt. The insurance period should cover one year after the end of the trial.

2.13. Updated Curriculum Vitae and GCP Training certificate evidencing the qualifications of the Principal Investigator and Sub/Co-Investigator to document their eligibility to conduct the clinical trial and/or to provide medical supervision of subjects.

2.14. Signed and completed declarations by the Principal Investigators about compliance with the protocol, GCP guidelines, and local regulations.

2.15. Principal Investigators & Co-Investigators' conflict of interest and financial disclosure.

2.16. Signed agreement/contract between the involved parties:

2.16.1. Investigator/institution and sponsor or CRO &/or Commitment is required that they will be submitted before study activation

2.16.2. Sponsor and contract research organization (CRO) (if applicable)

2.16.3. Sponsor and all designated laboratories specifying the responsibilities and the tests to be performed, with the signature of both parties, or a commitment is required that they will be submitted before the EDA regulatory decision for clinical trial authorization.

2.16.3.1. In case the local lab related to the trial will be responsible for the destruction of biological samples like blood samples, this should be stated in the contract between the lab& sponsor/CRO

2.16.4. Sponsor /CRO & the vendor (in case of IP and/ or surplus human samples destruction, IP and/or human samples transportation, or depo for IP storage), or any another third party involved in the trial or Commitment is required that these contracts will be submitted before study activation

2.16.5. Sponsor and independent data monitoring committee (IDMC) members (If applicable)

2.17. Laboratory documents:

2.17.1. Simple clear list of tests that will be conducted in each lab.

2.17.2. Laboratory manual for each involved lab.

2.17.3. Normal values of each involved lab.

2.17.4. Accreditation certificate for each involved lab to document the competence of the facility to perform the required tests and to support the reliability of the results.

2.18. The Investigational Medicinal Product Dossier (IMPD) for both drug product and drug substance, to document the quality data of the IMP, drug specifications, drug composition, cold chain reports, stability study reports, …. etc.

For example:

2.18.1. In case of medical device protocols, the technical file should include (clinical equivalence form, ISO certificate related to the device, reference ISOs, or any international quality certification if found (ex: CE mark,5(10)K or PMA in FDA, …. etc.), risk file, and performance test.

2.18.2. In case of herbal medicine protocols, IMPD should include (reference monograph, pharmacopeia, handbook, specifications of the raw material and the finished product…..etc.)

2.18.3. For IMPs which are market authorized in Egypt.

2.18.3.1. The SMPC (or its equivalent) and a commitment letter from the Sponsor stating that there is no difference between the IMP used in the clinical trial and the authorized one regarding quality specifications of the drug product, drug substance, and packaging material are required

2.18.3.2. If there is a difference between the IMP used in the clinical trial and the

authorized one, IMPD & the table of changes shall be submitted.

2.18.4. For IMPs with marketing authorization in a reference country

2.18.4.1. The IMPD and a commitment letter from the sponsor stating that there is no difference between the marketed product & the IMP that will be used in the clinical trial regarding quality specifications of the drug product, drug substance, and packaging material are required.

2.18.4.2. If there is a difference between the IMP used and the authorized one, a table of changes shall be submitted along with the full IMPD

2.19. **Valid GMP certificate** of the Investigational Medicinal Product(s) including the placebo/ Comparator (if applicable).

2.20 Certificate(s) of Analysis of the Investigational Medicinal Product(s) including the placebo/ Comparator (if applicable).

2.21. Registration license in case of Investigational Medicinal Product(s) with marketing authorization in Egypt.

2.22. Sample of label attached to the IMP, in compliance with applicable labeling regulations and appropriateness of instructions provided to the subjects.

2.23. Written procedures, including instructions for handling, accountability, and transportation (e.g., Pharmacy Manual). This may be separate or detailed in the protocol.

****In case of medical devices, instruction for use (IFU) & operator's manual.**

2.24. Package insert/pamphlet for all trial medicines (if applicable).

2.25. Shipment records of the Investigational Medicinal Product(s) and trial related materials (if found). To document distribution dates, batch numbers, and method of distribution of the IMP and trial-related materials, to allow tracking of the product batch, review of distribution conditions and accountability.

****(Commitment is required that they will be submitted before site's activation)**

2.26. Site qualification/site selection visit reports. To document that the site is suitable for the trial and that the trial procedures were reviewed with the investigator and trial's staff.

2.27. The protocol monitoring plan

2.28. Calibration certificates of equipment used in the involved clinical trial site(s) or Commitment is required that they will be submitted before the site's activation.

2.29. SOPs for equipment and clinical trial operations in the clinical trial site(s) or Commitment is required that they will be submitted before the site's activation.

2.30. Other National Regulatory Authorities approvals of the protocol (status of the protocol in other countries). To document that the submitted protocol is currently being conducted in at least one of the reference countries mentioned in the list published on the EDA website

2.31. Scientific advice opinion by other regulatory authorities to the applicant regarding the IMP or the submitted protocol in case of multi-centric trials (if available)

2.32. Detailed clinical study reports of previous studies (e.g., Phase I, II, …) with evidence show the previous studies comply with GCP principles

2.33. Plan for post-trial benefit, clarifying the sponsor's plan regarding providing the IMP after the end of the trial.

2.34. Statistical Analysis Plan (SAP) once finalized.

2.35. DSMB Charter (if applicable)

2.36. Summary of safety reports of marketed product(s).
****(In case of submitting Phase IV protocols).**

2.37. Key peer-reviewed published articles supporting the application (when available).

2.38. Other supporting documents, such as: Advertisement for subject recruitment, to document that recruitment measures are appropriate and not coercive. (If available) sample of data acquisition tools (e.g., diaries, clinical outcome assessments, patient-reported outcomes) that are provided to the investigator and/or IRB/IEC (If applicable).

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

39.1. For IMPs of **biological origin** via email ctpro.bio@edaegypt.gov.eg and cc for (bio.ct@edaegypt.gov.eg)

39.2. For IMPs of **chemical origin** via email ctpro.pharma@edaegypt.gov.eg and cc for (bio.ct@edaegypt.gov.eg)

39.3. For **other types of IMPs** and **Medical Devices** via email (bio.ct@edaegypt.gov.eg)

2.40. Proof of payment of relevant fees.

➢ The following documents are required to be submitted as a **hard copy:**

- The cover letter (**original**)
- The application form (**original**)
- The Protocol Signature Page by involved PI(s) (**original**)
- The PI(s) declaration (**original**)
- The IRB(s) (**certified copy of original**)
- The site(s)' administrative approval(s) (**certified copy of original**)
- Proof of payment of relevant fees

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	• Separate non-routine pathway from routine pathway • Addition EDA Clinical Trials Platform