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

جمهورية مصر العربية
هيئة الدواء المصرية
الادارة المركزية للمستحضرات الحيوية و المبتكرة والدراسات الاكلينيكية
الإدارة العامة للدراسات الإكلينيكية

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

1. Cover letter directed to the general manager of general administration of clinical trials from the applicant signed, dated and stamped
Included the following items: Sponsor &/or CRO name, study title, study ID and table of all submitted documents.

2. Stamped, signed and dated "Official Delegation" from sponsor &/ or to the company representative person that will submit the documents and deal with the Bio Inn-EDA.

3. Applicant should fulfill, signed, dated and submit the "Applicant request to the Egyptian Drug Authority for Clinical Trial Authorization on a medicinal product for Human use" with the CT package data.

4. Institutional review board (IRB) approval
- To document that the trial has been subject to Ethics Committees review and given favorable opinion.
- It must be valid and illustrating its approval, expiry dates.

5. Administrative approvals for all sites at which the clinical trial protocol conducted (IF found).

6. Signed Detailed clinical Trial protocol/Amendments(s) prepared according to ICH Guideline for Good Clinical Practice (GCP)
A document describe design, objective, methodology, and statistical consideration of the submitted clinical trial.

العنـــــــــــوان: 51 شارع وزارة الزراعة، العجوزة - الجيزة
البريد الإلكتروني: المكتب الفني / bio.tech@edaegypt.gov.eg، المكتبالإداري /bio.admin@edaegypt.gov.eg
التـــلـيـــفـــــون: 0237484988

7. **Informed consent form** with its **version number and date** (including all recruited age groups and applicable translations Arabic & English).
To document those subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent.

8. **Investigator's Brochure (IB):**
Updated and dated version of IB to document that relevant and current scientific information about the investigational product has been provided to the investigator. Including the previous data on the investigational product(s) that are relevant to the study of the product(s) in human subjects regarding the non-clinical and clinical studies (which is may be found as a separate report).

9. **Valid Insurance certificate**
- To document that compensation to subject(s) for trial-related injury will be available.
- It should include name of insured entity, study name/ID and number of subjects.
- The insurance company must be a local one.

10. **Signed and completed declarations by Investigators.**

11. **Signed agreement/ contract between involved parties, (To document agreements) e.g.:**
- Investigator/institution and sponsor
- Investigator/institution and contract research organization (CRO)
- Sponsor and contract research organization (CRO)
- Contract(s) with all designated laboratories

12. **Case report form; with its version number and date.**
A printed or electronic questionnaire designed to record all product required information to be reported to sponsor on each participant subjects.

13. **Curriculum vitae and/or other relevant documents (e.g.: GCP certificate) evidencing qualifications of investigator(s) and/or supporting trial staff to whom investigator tasks are delegated**
To document qualifications, trainings and eligibility to conduct trial and/or provide medical supervision of subjects.

14. Name of the all laboratory (ies), address, telephone number(s) with list of all tests / technical procedures to be conducted in each laboratory.

15. Evidence of accreditation and documented evidence of GLP compliance of the designated laboratories to be used for the assay of clinical samples.

Certification or accreditation or established quality control and/or external quality assessment or other validation (where required).

16. Normal value(s)/range(s) for medical/laboratory/technical procedure(s) and/or test(s) included in the protocol, laboratory manual

- To document normal values and/or ranges of the tests.
- To document competence of facility to perform required test(s), and support reliability of results.

17. Sample of label(s) attached to investigational medicinal product container(s)

To document compliance with applicable labeling regulations and appropriateness of instructions provided to the subjects.

18. Package insert(s)/ pamphlet for other trial medicines (If applicable).

19. Written procedures include instructions for handling, accountability, destruction of investigational medicinal product(s) and trial related materials

To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational medicinal products and trial-related materials. (May be found separate or included in the protocol or investigational brochure).

20. Shipping records for investigational medicinal product(s) and trial related materials (if found).

To document distribution dates, batch numbers and method of distribution of investigational medicinal product(s) and trial-related materials. To allow tracking of product batch, review of distribution conditions, and accountability.

21. Investigational medicinal product dossier.

To document the quality data of the IMP, drug specifications, drug composition, cold chain reports, stability study reports ...etc.

22. Acceptable valid certificate of GMP manufacturing of the investigational products.

23. Certificate of GMP manufacture of Placebo/Comparator (when available).

24. Certificate(s) of analysis of investigational product(s)

To document identity, purity, and strength of investigational medicinal product(s) to be used in the trial.

25. Pre/ Initiation –Trial Monitoring Report (submitted before trial initiation)

It is a written report to document that:

- The site is suitable before initiation of the trial.
- The trial procedures were reviewed with the investigator and the investigator's trial staff.

26. Other NRAs authorization/ approval/notification of protocol(if found)

To document appropriate authorization/approval/notification by the regulatory authorities in case of multi-centric clinical trials.

27. Scientific advice opinion &/or Questions and answers between regulatory authorities and sponsor/applicant (if found).

28. Evidence show the previous studies conducted outside Egypt in case of phase II, III, IV in Egypt comply with stringent NRA regulations and GCP principles.

29. A summary of safety reports of marketed authorized product(s), in case of Submitting Phase 4 Protocol.

30. Full, legible copies of key, peer-reviewed published articles supporting the application (when available).

31. Other supporting documents (if found) such as: Advertisement for subject recruitment" to document that recruitment measures are appropriate and not coercive".

32. The CT package data should be submitted as one hard copy and one soft copy (CD-ROM) and also send to the official e-mail.Bio.ct@edaegypt.gov.eg.

33. Fees proof of payment:

Fees are **50,000** LE in case of protocol initial submission and **30,000** LE in case of Amendment submission and **20,000** in case of evaluation of clinical study results.