Notice to applicant

List of required documents to be submitted to GA of CT at Bio Inn-EDA for Bioequivalence Studies

Year 2025

Code: EDREX.NP.Bioinn.12
Version No.2
Issue Date: 24 Sep. 2025
Effective date: 16 Nov. 2025

1- **Signed, stamped and dated official delegation letter** from the Bioequivalence Center to the representative person who will submit the documents and deal with Bio-Inn EDA.

2- **Detailed Study protocol** with version number and date. The protocol should be signed and dated by the sponsor and the PI.

3- **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.

4- **The finalized IRB approved Informed Consent Form (ICF),** with its version and date.

5- **Evidence document of accreditation** of BE center by any accrediting entities **(if available)**

6- **Institutional Review Board approval including list of reviewed documents.** The IRB approval must be valid and with clear expiry date.

7- **Questions raised by the IRB to the applicant regarding the submitted protocol and their answers (if available)**

8- **License of the Bioequivalence Center**

9- **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, and the number of involved subjects and the related annexes. The insurance company must be a local one or an international company that have a legal representative in the Arab Republic of Egypt.

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

11- **Principal Investigator & Co-Investigator(s) conflict of interest and financial disclosure with the study sponsor.**

12- **Principal Investigator & Co-Investigator(s) confidentiality agreement.**

13- Signed contracts to document the agreements between the involved parties:

- Between the Sponsor and the Bioequivalence Center
- Between the Bioequivalence Center and the PI
- Between the Bioequivalence Center and the Laboratory
- Between the Bioequivalence Center &the vendor (in case of IMP and/ or human samples destruction)

14- Laboratory documents:

- Laboratory manual for the involved lab.
- Normal values of the involved lab.
- Accreditation certificate for the involved lab to document the competence of the facility to perform the required tests and to support the reliability of the results.

15- Valid GMP certificate of the manufacturing site of the IMP (Test product)

16- Certificate(s) of Analysis of the IMP (Test product)

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

18- Package insert/pamphlet for all trial medicines.

19- IMP (Test product) samples withdrawal records (محضر سحب عينات المستحضر الجنيس)

20- The bioequivalence center selection report by the sponsor.

21- Calibration certificates and SOPs of equipment used in the center.

22- EDA approved list of volunteers

23- Protocol deviation log.

24- Delegation and signature log of site staff involved in the study.

25- Site selection report&/or monitoring report (if available)