Notice to applicant

Central Administration of Biological and Innovative products and clinical studies
General Administration of clinical trials

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

2024

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Effective date: 14 October 2024

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

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

7- License of the Bioequivalence Center

8- 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.

9- 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.

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

11- Principal Investigator & Co-Investigator(s) confidentiality agreement.

12- 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 IP and/ or human samples destruction)

13- 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.

14- Valid GMP certificate of the Test product

15- Certificate(s) of Analysis of the Test product

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

17- Package insert/pamphlet for all trial medicines.

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

19- The bioequivalence center selection report by the sponsor.

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

21- EDA approved list of volunteers

22- Protocol deviation log.

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

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