Notice to applicant

Central Administration of Biological and Innovative products and clinical studies

General Administration of clinical trials

List of Required Documents in the Preclinical Package to be submitted to GA of CT for Scientific Opinion before First in Human Clinical Trial

2023

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1. Cover letter directed to the General Manager of the General Administration of Clinical Trials, signed, dated and stamped by the applicant, clarifying the followings: The applicant's name, table of all submitted documents, aim of submission, proposed human use, dosage, strength and route of administration with overview of the nonclinical testing strategy.

2. Official delegation letter signed, dated, and stamped by the sponsor to the representative person who will submit the documents and deal with Bio Inn-EDA.

3. IACUC Approval(s)/Ethical Approval for the conduction of preclinical animal studies.

4. Investigator's Brochure (IB):
Updated version of IB with its version and date to document that relevant and current scientific information about the investigational product has been provided to the investigator. Compilation of non-clinical data on the investigational product(s) that is relevant to the study of the product(s) in human subjects.

5. Signed **agreement/ contract** between involved parties, (To document agreements) e.g.:

- Sponsor/CRO and Investigator/institution
- Sponsor and Contract Research Organization (CRO).
- Sponsor and all designated laboratories.

6. Signed and completed **declarations** by the Investigators.

7. Curriculum vitae and/or other relevant documents evidencing qualifications of investigator(s) and/or supporting trial staff to whom the investigator tasks are delegated to document qualifications, GLP trainings and eligibility to conduct preclinical studies.

8. Investigational medicinal product dossier

To document the quality data of the IMP, cold chain reports, stability study reports, batch release certificate from NRA of country of origin for the batch of the concerned investigational product, etc.).

9. Certificate(s) of analysis of investigational product(s) e.g. identity, purity, and strength of Investigational medicinal product(s) to be used in the study.

10. The quality and safety of preclinical preparations should follow the strict control of the manufacturing process following the principles of Good Manufacturing Practice (GMP).

11. Name of the all laboratory (ies), address, telephone number(s) with list of all tests conducted in each laboratory.

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

13. Complete detailed preclinical studies reports (with raw data) for the investigational medicinal product are required to be submitted:

13.1 Good Laboratory Practice (GLP) compliance of the studies: studies are expected to be performed in compliance with Good Laboratory Practice (GLP), however, there may be situations where full compliance with GLP is not possible. If the study, or part of the study, was not conducted in compliance with GLP, areas of non-compliance should be defined and a statement of the reason for non-compliance should be drawn up.

13.2 Specification of the test material: In general, the product that is used in the definitive pharmacology and toxicology studies should be comparable to the product proposed for the initial clinical studies. However, it is recognized that during the course of development programs, changes normally occur in the manufacturing process in order to improve product quality and yields. The potential impact of such changes for extrapolation of the animal findings to humans should be considered.

13.3 Reports on studies:

A. Pharmacology

- Primary and secondary pharmacodynamics studies of the product.
- Safety pharmacology studies.

B. Pharmacokinetics

- Pharmacokinetic studies of product.

- Specific Pharmacokinetic studies.
- Toxicokinetic.

C. Toxicology

- Single-dose toxicity
- Repeat-dose toxicity
- Genotoxicity (if applicable)
- Carcinogenicity (Oncogenicity) (if applicable)
- Immunotoxicity.
- Local tolerance (may be incorporated in toxicology studies).
- Reproductive & developmental toxicity (if applicable).
- Tissue Cross reactivity studies (if applicable).

Note:

- ❖ Specific guidelines should be followed for each type of product (biological, pharmaceutical, vaccine…etc).
- ❖ International Guidelines e.g WHO, EMEA, FDA should be followed.
- ❖ Demonstration of relevance of the animal model; the relevance of the selected animal model should be justified in the application.
- ❖ Justification with documented evidence is required to be submitted when any of the abovementioned items is not fulfilled by the applicant.

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

15. Other supporting documents (if found).

16. The package should be submitted via email and on CD.

- 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)

➢ The following documents are required to be submitted as hard copy
- The cover letter (original)
- The Investigator(s) declaration (original)
- The IACUC approval(s) (certified copy of original)

17. Proof of payment of relevant fees.