Notice to applicant

List of Required Documents in The Preclinical Studies Results Package Data to be Submitted to GA of CT at Bio Inn-EDA for Scientific Opinion Before First in Human Clinical Trial

Year 2026

Code: EDREX.NP.Bioinn.005

Version No: 3.0

Issue Date: 06 August 2026

Effective date: 06 August 2026

Table of Contents

1. List of Abbreviations:

- **Bio-Inn:** Central Administration of Biological and Innovative Products and Clinical Studies
- **CT:** Clinical Trials
- **CRC:** Clinical Research Center
- **CRO:** Contract Research Organization
- **GLP:** Good Laboratory Practice
- **IB:** Investigator's Brochure

2. List of Required Documents in The Preclinical Studies Results Package Data

2.1. Cover letter directed to the General Manager of the General Administration of Clinical Trials, signed, dated, and stamped by the applicant, clarifying the following: 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.

2.2. 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.

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

2.4. 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.

2.5. 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.

2.6. Signed and completed declarations by Principal Investigator

2.7. 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.

2.8. 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.).

2.8.1. In case of medical device protocols, 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.

2.8.2. In case of Herbal product protocols, IMPD should include (reference monograph, pharmacopeia, handbook, specifications of the raw material and the finished product, etc.)

2.9. 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.

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

2.11. Name of the all laboratory(ies), **address**, **telephone number**(s) with list of all tests conducted in each laboratory. 1

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

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

2.13.1. 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.

2.13.2. 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.

2.13.3. Reports on studies:

2.13.3.1. Pharmacology

2.13.3.1.1. Primary and secondary pharmacodynamics studies of the product.
2.13.3.1.2. Safety pharmacology studies.

2.13.3.2. Pharmacokinetics

2.13.3.2.1. Pharmacokinetic studies of product.
2.13.3.2.2. Specific Pharmacokinetic studies.
2.13.3.2.3 Toxicokinetic.

2.13.3.3. Toxicology

2.13.3.3.1. Single-dose toxicity
2.13.3.3.2. Repeat-dose toxicity
2.13.3.3.3. Genotoxicity (if applicable)
2.13.3.3.4. Carcinogenicity (Oncogenicity) (if applicable)
2.13.3.3.5. Immunotoxicity.
2.13.3.3.6. Immunogenicity
2.13.3.3.7. Local tolerance (may be incorporated in toxicology studies).
2.13.3.3.8. Reproductive & developmental toxicity (if applicable).
2.13.3.3.9. Tissue cross-reactivity studies (if applicable).

2.13.4. Other toxicity studies, if available. Any other related toxicity studies that were not listed above, including but not limited to:

2.13.4.1. Antigenicity
2.13.4.2. Immunotoxicity
2.13.4.3. Mechanistic studies (if not included elsewhere)
2.13.4.4. Dependence
2.13.4.5. Metabolites
2.13.4.6. Impurities
2.13.4.7. Other

2.13.5. In case of Investigational Medical Device - Biological Evaluation:

2.13.5.1. In-vitro cytotoxicity.
2.13.5.2. Hemocompatibility.
2.13.5.3. Pyrogenicity.
2.13.5.4. Systemic Toxicity.
2.13.5.5. Irritation & Sensitization.
2.13.5.6. Implantation effects.
2.13.5.7. Genotoxicity.
2.13.5.8. Carcinogenicity.
2.13.5.9. Reproductive and Developmental Toxicity.
2.13.5.10. Degradation.
2.13.5.11. Neurotoxicity and Immunotoxicity
2.13.5.12. Chemical Characterization
2.13.5.13. Extractables and Leachable Studies

Notes:

- 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 i not fulfilled by the applicant.

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

2.15. Other **supporting documents** (if found).

2.16. 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)

2.17. 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	06 August 2026	• Enhancing criteria description of required documents for more clarification to adopt with guideline for regulatory oversight of clinical trials by Egyptian Drug Authority version 05 • Addition EDA Clinical Trials Platform