Notice to applicant

List of Required Documents for Renewal of EDA Approval of Clinical Trial Application submitted to GA of CT at Bio Inn- EDA

Year 2026

Code: EDREX.NP.Bioinn.001

Version No: 4.0

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Effective date: 06 August 2026

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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
- **EDA:** Egyptian Drug Authority
- **GA of CT:** General Administration of Clinical Trials
- **GLP:** Good Laboratory Practice
- **IMP:** Investigational Medicinal Product.
- **IRB:** Institutional Review Board

2. List of Required Documents for Renewal of EDA Approval of Clinical Trial Application:

2.1. **A renewal request letter** addressed to EDA signed and dated by the applicant (sponsor or CRO).

2.2. **Renewal of IRB(s)** of the site(s) of the clinical trial.

2.3. **Renewal of administrative approvals** of the site(s) of the clinical trial (if found).

2.4. **Valid insurance certificate** covering the entire duration of the medical research, including the follow-up period, and remaining valid for one year after completion of the study.

2.5. **Valid GLP accreditation certificates** for the designated laboratory(ies) used for analysis.

2.6. **Valid registration and licensing documents**, including IRB registration, CRC license, and CRO license.

2.7. **Updated versions** of any previously submitted documents that have expired.

2.8. **Investigational Medicinal Product (IMP) Identification Form** (specifying the quantity of IMP requested for approval by the Central Administration of Pharmaceutical Policies and Market Access for the upcoming year. The requested quantity shall be justified with a clear calculation based on the number of participants (planned &/or ongoing), the dosing regimen, and the duration.)

2.9. **Proof of payments** of the determined fees.

The renewal request shall be submitted to EDA at least one month before the end of the validity.

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	14 October 2024	Some clarification due to issuance of supreme council construction prime minister decree 746/2024
4	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