List of Essential required documents in the file of the investigator and/or sponsor/CROto be submitted to EDA for clinical trials to be conducted in Egypt

1. **Ethical committee approval**
   Approval on the C.T. protocol/amendments from the Research Ethics committee/ Research & Health Development at Egyptian Ministry of Health &Population (REC-RHD/MoHp) with its application form containing: (Exp date, protocol version, protocol amendment (if found), ICF version & its amendment (if found) and if any conditional approvals are stated.

2. **Investigator's Brochure(IB):**

   Updated version of IB with its version and dateTo document that relevant and current scientific information about the investigational product has been provided to the investigator. Compilation of the clinical & nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects

3. **SignedDetailed clinical Trial protocol/Amendments(s) prepared according to ICH Guideline for Good Clinical Practice (GCP)**

To document investigator and sponsor agreement to the protocol/amendment(s)

4. **Information given to trial subjects**

   Informed consent form with its **version number and date** (including all recruited age groups and applicable translations Arabic & English).

   - Any other written information

   To document those subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent.

   - Advertisement for subject recruitment (if used)

   To document that recruitment measures are appropriate and not coercive.

5. **Valid Insurance statement**

To document that compensation to subject(s) for trial-related injury will be available.

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6. **Signed agreement/ contract between involved parties,(To document agreements) e.g.:**
   - Investigator/institution and sponsor
   - Investigator/institution and contract research organization (CRO)
   - Sponsor and contract research organization (CRO)

7. **Dated, documented favorable opinion of Ethics Committee of national registered IRB(s) :**
   -Institutional review board (IRB) of the site at which the C.T. will be conducted with its updates

   - Must be valid and illustrating its approval, expiry dates.

   -Copy of the IRB application form; that include all the documents to be submitted to EDA and REC-RHD/MOHpwith its dates and version numbers (protocol and any amendments, case report form , informed consent form(s), any other written information to be provided to the subject(s), advertisement for subject recruitment (if used), insurance certificate, any other documents given favorable opinion…. Etc)

   To document that the trial has been subject to Ethics Committees review and given favourableopinion.To identify the version number and date of the document(s).

8. **Registered Institutional Review Board (IRB) by Research & Health Development at Ministry of Health and Population (RHD/MOHp): if found**

To document that the Ethics Committee (IRB)is constituted in agreement with Good Clinical Practice.

9. **Other NRAsauthorization/ approval/notification of protocol**

   To document appropriate authorisation/approval/notification by the regulatory authorities in case of multi-centric clinical trials.

10. **Curriculum vitae and/or other relevant documents evidencing qualifications of investigator(s) and/or supporting trial staff to whom investigator tasks are delegated**

    To document qualifications, GCP trainings and eligibility to conduct trial and/or provide medical supervision of subjects.

11. Normal value(s)/range(s) for medical/laboratory/technical procedure(s) and/or test(s) included in the protocol , laboratory manual

To document normal values and/or ranges of the tests.
To document competence of facility to perform required test(s), and support reliability of results.

12. Sample of label(s) attached to investigational medicinal product container(s)

To document compliance with applicable labeling regulations and appropriateness of instructions provided to the subjects.

13. Instructions or SOPs for handling, accountability, destruction of investigational medicinal product(s) and trial related materials

To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational medicinal products and trial-related materials.(may be found separate or included in the protocol or investigational brochure).

14. Shipping records for investigational medicinal product(s) and trial related materials (if found)

To document distribution dates, batch numbers and method of distribution of investigational medicinal product(s) and trial-related materials. To allow tracking of product batch, review of distribution conditions, and accountability.

15. Certificate(s) of analysis of investigational product(s)

To document identity, purity, and strength of investigational medicinal product(s) to be used in the trial.

16. Decoding procedures for blinded trials

To document how, in case of an emergency, identity of blinded investigational medicinal product can be revealed without breaking the blind for the remaining subjects' treatment.(In case of blind trials)

17. Quality data ofinvestigational medicinal product;
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) .

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18. Master Randomization List for randomized trials

To document method for randomization of trial population(In case of randomized Trial)

19. Pre/ Initiation –Trial Monitoring Report

To document that the site is suitable for the trial.

To document that trial procedures were reviewed with the investigator and the investigator's trial staff

20. Acceptablevalid certificate of GMP manufacturing of the investigational products

21. Certificate of GMP manufacture of Placebo/Comparator (when available)

22. Name of the laboratory , address, telephone number(s).

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

Certification or accreditation or established quality control and/or external quality assessment or other validation (where required).

24. Preclinical studies for the investigational product (summaries of non-clinical pharmacology and toxicology data for any IMP used in the clinical trial).

25. Report summaries of prior clinical trials (as phase I, II...) (if found) with the investigational product(s). All studies should have been conducted in accordance with the principles of Good Clinical Practice (GCP).

26. Signed and completed declarations by Investigators.

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

28. Case report form; with its version number and date.

29. Package insert(s) for other trial medicines (If applicable).

30. Fees proof of payment:

Fees are 50,000 LE in case of protocol submission and 30,000 LE in case of Amendment submission.

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31. **Scientific advice opinion requirements from other regulatory authorities in case of multicentric trials.**
32. **Questions and answers between regulatory authorities and sponsor/applicant (if found).**
33. **On-site Inspection Reports of previous studiesin case of Phase II, III, IV to be conducted in Egypt (previous studies conducted outside Egypt.**
34. **Applicant should fulfill, sign, dated and submit the "Applicant request to the Egyptian Drug Authority For Clinical Trial Authorization on a medicinal product for Human use"with the CT package data.**
35. **The CT package data should be submitted as two hardcopies and two soft copies (CD-ROM).**
36. **Other supporting documents (if found)**

Head of C.T.E. department

Chairman of NORCB