List of documents submitted for EDA Approval Renewal

1. A renewal request letter addressed to EDA signed and dated by the applicant (sponsor or CRO).
2. Renewal of IRB(s) of the site(s) of the clinical trial.
3. Renewal of administrative approvals of the site(s) of the clinical trial (if found).
4. Renewal of insurance certificate, GLP accreditation of designated laboratory(ies) used for analysis, and any other expired documents were previously submitted to EDA.
   --Insurance certificate shall cover the entire period of the medical research and the follow-up period provided however that it shall be valid for one year after the completion of the medical research.
5. Last follow up/Progress report.
6. Proof of payments of the determined fees (15.000 l.e).

➡ **These request for renewal and required documents should be submitted at least one month before expiry of EDA Approval.**