

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 insurance certificate.
4. Changed documents (e.g., Protocol, ICF ...etc.).
5. Proof of payments for the determined fess.

➔ These documents should be submitted at least one month before expiry of EDA Approval.