

**List of required documents from the investigator, sponsor&/or CRO to be submitted in case of
Amendment**

1. Letter to EDA requesting approval of Amendment(s) including list of all modified documents.
2. Fees proof of payment (30.000 L.E).
3. Ethics approval on the submitted amendment.
4. IRB Approval of sites at which the CT conducted.
5. Table of changes for each modified document mentioning changes with rationale.
6. Changed documents (e.g., Protocol, ICF ...etc.).

➔ Documents must be submitted as **hard** and **soft** copies (CD & E-mail).