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HUGTiP REC SUBMISSION REQUIREMENTS: RESPONSE TO THE CLARIFICATIONS
CLINICAL RESEARCH WITH MEDICAL DEVICES (CLINICAL TRIAL)

Once the request for additional information is received, which is issued by the REC, you must ser an email to **ceic.germanstrias@gencat.cat** including the following documents:

1. **Cover letter.**
2. **Response letter to the REC's and/or AEMPS' clarification request,** in which new versions of any assessed document are specified: Protocol, Patient Information Sheet and Informed Consent Form, financial report, etc.
3. **New versions (including track changes, and updated version and date)** of the modified documents as a result of the clarifications: Protocol, Patient Information Sheet and Informed Consent Form, financial report, etc.
4. **New documentation.**

ⓘ If you need more information about the legislation applicable to this type of studies, you can visit the websit of the **Spanish Agency of Medicines and Medical Devices**.