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Research Ethics Committee

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HUGTiP REC SUBMISSION REQUIREMENTS: RESPONSE TO A REQUEST FOR ADDITIONAL INFORMATION (CLINICAL TRIAL WITH MEDICINAL PRODUCTS)

Once you receive the request for additional information (Part I and/or Part II), which is issued by the AEMPS or the REC, you shall have 12 calendar days (according to Royal Decree 1090/2015) to reply via the **Clinical Trials with Medicinal Products Portal of the AEMPS**. Find below the documents that need to be attached:

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 resulting from responding to 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 website of the **Spanish Agency of Medicines and Medical Devices**.