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**HUGTiP REC SUBMISSION REQUIREMENTS: RESPONSE TO THE CLARIFICATIONS
OBSERVATIONAL STUDY WITH MEDICINAL PRODUCT**

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

- 1. Letter in response to the clarifications requested by the REC.**
- 2. 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.
- 3. New documentation.**