Germans Trias i Pujol Hospital

Institut Català de la Salut

**Research Ethics Committee**
Crta. De Canyet, s/n - 08916 Badalona
Tel. 93 497 89 56
E-mail: ceic.germanstrias@gencat.cat

# CLINICAL TRIAL WITH MEDICINAL PRODUCTS
# SUBMISSION REQUIREMENTS: INITIAL APPLICATIONS

Before submitting a clinical trial through CTIS, sponsors must contact the Technical Secretariat at ceic.germanstrias@gencat.cat to request evaluation by the HUGTiP CEIm. The request should include the basic study information, the number of participating sites, the anticipated submission date, and the proposed Reporting Member State (RMS).

If submission is postponed, a new request for evaluation must be made to ensure the HUGTiP CEIm's availability on the proposed submission date.

In parallel, the Site Suitability Declaration must be obtained by contacting: fu.clinicalresearch.hugtip@igtp.cat

**Evaluation fees:** Evaluation fees must be paid to the Spanish Agency of Medicines and Medical Devices AEMPS no more than 30 days before the initial CTIS submission. Exemption from payment applies to non-commercial sponsors that meet the criteria established in Article 2.2 of Royal Decree 1090/2015 and the relevant AEMPS guidance documents, provided that a signed declaration certifying compliance with these requirements is submitted.

Finally, the application for ethical review must be submitted through the **Clinical Trials Information System (CTIS)** in accordance with the **Sponsors Guidance** and the **Official documents templates**

## PART I DOCUMENTATION (REC and AEMPS)

1. **Cover letter**
2. **Form 317** requesting payment of the AEMPS fee together with proof of payment.
3. **Statement of Compliance with Regulation (EU) 2016/679.**
4. **Sponsor Authorisation for the Applicant** (where applicable).
5. **Protocol** structured in accordance with current legislation.
6. **Synospsis protocol for laypersons** *(in Spanish)*
7. **Investigator's Brochure** for the Investigational Medicinal Product.
8. **Investigator's Brochure** for Auxiliary Medicinal Products.
9. **Scientific Advice and Paediatric Investigation Plan** (where applicable).
10. **Justification of the Low-Intervention Clinical Trial Classification** (if not included in the cover letter).

## PART II DOCUMENTATION (REC)

11. **Documents related to participant recruitment procedures and recruitment materials.**
12. **Patient Information Sheet(s) and Informed Consent Form(s).**
13. **Evidence of insurance coverage or financial guarantee** including all participating sites and Principal Investigators..
14. **Financial Report and Participant Compensation Document.**
15. **Declaration of Compliance with Applicable Rules for Biological Samples.**
16. **Declaration of Compliance with National Data Protection Requirements** (covered by Appendix 1 of the Patient Information Sheet and Informed Consent Form template, Anexo VIIIA of the AEMPS Instructions).
17. **Documents required for each participating site:**
    - **Currículum Vitae** of the Principal Investigator
    - **Declaration of Interest (DOI)** of the Principal Investigator.
    - **Site Suitability**

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## CLINICAL TRIAL WITH MEDICINAL PRODUCTS
## SUBMISSION REQUIREMENTS: RESPONSES TO REQUESTS FOR CLARIFICATION

Responses must be submitted through the Clinical Trials Information System (CTIS) following the Sponsors Guidance and the Official documents templates

## CLINICAL TRIAL WITH MEDICINAL PRODUCTS
## SUBMISSION REQUIREMENTS: SUBSTANTIAL AMENDMENT

Substantial Amendments must be submitted through the Clinical Trials Information System (CTIS) following the Sponsors Guidance and the Official documents templates

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