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
Web: www.ceicgermanstrias.cat

CLINICAL INVESTIGATION OF A MEDICAL DEVICE
SUBMISSION REQUIREMENTS: INITIAL APPLICATIONS

Any clinical investigation of a medical device must be reviewed by a single Research Ethics Committee accredited in Spain to assess clinical investigations involving medical devices. The opinion issued by that Committee shall be valid throughout Spain.

In addition, for clinical investigations conducted to assess the conformity of a medical device **without CE marking**, or **with CE marking but used outside its intended purpose**, authorisation from the Spanish Agency of Medicines and Medical Devices (AEMPS) is also required.

For Clinical investigatios involving **CE-marked medical device used within its intended purpose but requiring participants to undergo additional invasive or burdensome procedures**, notification to the AEMPS is required.

Where a clinical investigation involving a medical device to be conducted at HUGTiP has already obtained a **favourable opinion from another Spanish REC**, local contractual arrangements should be managed through fu.clinicalresearch.hugtip@igtp.cat.In accordance with Royal Decree 192/2023, **no further review by the HUGTiP CEIm is required.**

For **multicentre clinical investigations involving medical devices**, prior consultation with the Technical Secretariat is required. Requests should be sent to ceic.germanstrias@gencat.cat and should include the basic study details, the number of participating centres, and the anticipated submission date. Following confirmation by the HUGTiP REC that it is able to undertake the ethical review, the complete application package should be submitted to avaluacionsceic.germanstrias@gencat.cat

1. **Cover Letter including:** Study title; protocol code; list of submitted documents; list of sites and principal investigators
2. **Clinical Investigation Plan,** structured in accordance with current legislation and including the protocol code, version number and date in the header or footer of the document.
3. **Summary of the Clinical Investigation Plan, in Spanish or Catalan.**
4. **Patient Information Sheet(s) and Informed Consent Form(s)**
5. **Investigator's Brochure,** or alternatively the Instructions for Use/Technical Documentation, including approved intended purpose, risks and contraindications
6. Information on the conformity assessment and **regulatory status of the medical device**, including its CE-marking status and any relevant regulatory approvals.
7. **Documents relating to participant recruitment procedures and recruitment materials**.
8. **Investigator Suitability Form** including: participating centres; principal investigators; number of participants to be recruited at each centre
9. **Proof of insurance coverage or financial guarantee,** listing all participating centres and Principal Investigators (for investigations involving non-CE-marked devices or CE-marked devices used outside their intended purpose).
10. **Financial Report.**
11. **Documents Required for Each Participating Centre (Multicentre Studies)**
    - **Abbreviated Curriculum Vitae of the Principal Investigator**
    - Declaration of Interest **(DOI)** for each participating Principal Investigator (Eudralex – Volumen 10 – Capitulo I.)
    - **Site Suitability.**
12. **Invoice Request Form** (where applicable)

ⓘ	If additional information on the applicable legislation is needed, please consult the website **Agencia Española de Medicamentos y Productos Sanitarios.**
ⓘ	The Site Suitability Declaration for HUGTiP must be requested from: fu.clinicalresearch.hugtip@igtp.cat.

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CLINICAL INVESTIGATION OF A MEDICAL DEVICE
SUBMISSION REQUIREMENTS: RESPONSE TO REQUESTS FOR CLARIFICATION

If the HUGTiP CEIm requests clarifications, the following documentation should be submitted to avaluacionsceic.germanstrias@gencat.cat:

1. **Point-by-Point Response letter** specifying any new versions generated for the reviewed documents
2. **Updated documents** (all revised documents must include: tracked changes and updated version and date)
3. **Any new documentation** generated as a consequence of the responses provided

CLINICAL INVESTIGATION OF A MEDICAL DEVICE
SUBMISSION REQUIREMENTS: SUBSTANTIAL AMENDMENT

Applications for substantial amendments must be submitted to avaluacionsceic.germanstrias@gencat.cat and include the following documentation:

1. **Application Letter for a Substantial Amendment, including a complete list of the submitted documentation**
2. **Summary and Justification of Changes.**
3. **Updated versions (**with track changes, updated version number and date) of all documents modified as a consequence of the amendment
4. **Any new documentation generated** as a consequence of the amendment.
5. **Invoice Request Form** (where applicable)

Additional documentation required for specific substantial amendments

>> If the substantial amendment relates exclusively to a site addition, change of Principal Investigator, or change of Sponsor, the following documentation must be submitted:

1. **Cover letter**
2. **Updated proof of insurance** (where applicable)
3. **Invoice Request Form** (where applicable)

The following additional documents are also required

SITE ADDITION	CHANGE PI	CHANGE SPONSOR
4. Updated Financial Report. (where applicable) **5.** Updated **Investigator Suitability Form.** **6.** Documents for each additional site: ▪ **Abbreviated Curriculum Vitae of the Principal Investigator.** ▪ **Site Suitability**	**4.** Updated **Investigator Suitability Form.** **5. Abbreviated Curriculum Vitae of the new Principal Investigator**	**4. Sponsor Transfer Letter**