Germans Trias i Pujol Hospital

Institut Català de la Salut

Research Ethics Committee
Crta. De Canyet, s/n - 08916 Badalona
Tel. +34 93 497 89 56
Email: ceic.germanstrias@gencat.cat
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NOTIFICATIONS RELATING TO CLINICAL TRIALS WITH MEDICINAL PRODUCTS/MEDICAL DEVICES

Notifications should be sent only regarding clinical trials with medicinal products/medical devices in which the HUGTiP REC acts as the evaluating REC.

Notifications that the REC MUST receive

The HUGTiP REC must receive the following notifications:

- **Start of the clinical trial** (date of opening of the first site in Spain, and date of the first visit of the first subject included in Spain).
- **Annual follow-up report** of the clinical trial (Annex XI-**Instructions of the Spanish Agency of Medicines and Medical Devices (AEMPS) for conducting clinical trials in Spain**).
- **Serious breaches** occurred in Spain.
- Renewal of the **insurance certificate**.
- **Interim report** of results.
- Temporary **halt/interruption** of a clinical trial.
- **Restart** of the clinical trial after a halt/interruption.
- **End of the recruitment** (date on which subject selection in Spain is concluded).
- **End** of the trial in **Spain** (Annex 1D) and **global end** (date of the last visit of the last subject).
- Summary **report of final results** of the clinical trial.
- **Publication of results.**
- **Annual Safety Reporting** (DSUR).
- **Ad hoc report** or initial notification of urgent safety measures already taken.
- **Changes and/or updates** of **contact person** with the REC, **CRO, study monitor,** etc. **not specified** in substantial amendments.
- **Update of this site's research team (collaborators).** The study must be active and the corresponding annual follow-up reports must have been submitted.
  To add new collaborators, the notification must be accompanied by the **Principal Investigator and collaborators statement of responsibilities** signed by the Principal Investigator and the new collaborators.

Notifications that the REC MUST NOT receive

The REC HUGTiP shall not accept the following notifications:

- **Non-substantial modifications**
- Changes in the **summary of product characteristics and/or package leaflet** of the investigational and/or auxiliary medicinal product.

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- Updates to the **Investigator's Brochure** that do not imply a substantial modification. You may send it attached to the Annual Safety Report (DSUR).
- Suspected unexpected serious adverse reactions **(SUSARS)** occurred in Spain or in another country. These may be notified exclusively to the AEMPS.
- Serious Adverse Event (SAE) reporting form for **medical devices** not related to the investigational medical device and/or SAE occurred in other countries.
- **Notifications on product quality** if they do not involve a modification or security problem that affects the participants of the study.
- **Notifications addressed to researchers:** Dear Investigator Letter (DIL), *Note to files* from the researcher's records, protocol clarification letters, memos, etc.
- **Material for patients that does not belong to part II of the trial:** patient ID card, questionnaires, medication use control cards, etc.
- **Trial materials that do not belong to part I or II of the trial:** Case Report Forms (CRF), leaflets for researchers, etc.
- **Non-substantial modifications for the REC in the financial report.** Assessment by the REC is considered necessary only for those modifications that imply changes in the compensations for the participants and the investigators submitted in the initial financial report.
- **Translation of Patient Information Sheets and Informed Consent Forms (PIS-ICF) into other languages:** the Sponsor will be responsible for providing an accurate translation of this information into other languages. If the REC deems it necessary, the Sponsor will be asked to provide a translation.