

Required actions after authorisation of a clinical trial

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After the trial has been authorised, please pay attention to the sponsor’s obligations to report to Fimea through the CTIS portal during and after the clinical drug trial. Help is always available from Fimea by email: clinicaltrials@fimea.fi.

Please note that it is the responsibility of the applicant to monitor and maintain the information in the CTIS portal.

1. Submission of notifications concerning Finland through the CTIS portal

The program will not send an acknowledgement of these after the information has been recorded.

1.1 Mandatory notifications

Start of trial: means the first phase of the recruitment of subjects, unless otherwise specified in the protocol. The trial and its recruitment can be considered to have started when, for example, the permits and agreements concerning the trial site are in order and subjects can be admitted to the trial, i.e. recruitment can be started. For example, this may be when the recruitment notification or an advertisement for the trial has been published. The notification must be submitted within 15 days in each country participating in the trial.

Start of recruitment: means the first visit of the first subject and, at the same time, the point in time when the first subject has signed the consent form. The notification must be submitted within 15 days in each country participating in the trial.

- If the date of the first visit has not been entered in the CTIS portal within 2 years of receiving the clinical trial authorisation, the application will expire.
- If recruitment has not properly started within 2 years, a substantial modification must be submitted using a combined Part I and Part II application or only Part II application, and an extension of the recruitment start date must be given as the reason. In addition, a new estimated date for starting recruitment must be provided and the situation and the reasons must be explained in a free-form cover letter. The modification application is easier to submit before the two-year deadline, but it is also possible to submit it later, if necessary.
- Instructions for submitting a substantial modification can be found on Fimea's [website](#) and in the Sponsor [handbook](#) prepared by the EMA.

End of recruitment: means that recruitment is stopped. The notification must be submitted within 15 days in each country participating in the trial.

- This notification is submitted if recruitment is terminated or suspended for reasons other than safety.
- If recruitment is restarted, the Start of recruitment section will be applied.

End of trial: the end of a clinical trial refers to the last visit of the last subject or a later date specified in the protocol. The notification must be submitted within 15 days in each country participating in the trial.

- If recruitment is restarted, a new start of trial notification must be submitted.
- In case of premature end of the trial, "early termination" is selected.
- In case of early termination for safety-related reasons, a substantial modification application (SM, see section 2) must also be submitted, describing how the treatment of the subjects will continue after the end of the trial, if this has not already been specified. The application must be submitted before the trial is reported as completed.
- If early termination related to safety is notified, an unexpected event notification must be submitted prior to it once a safety concern has been established.
- If the trial is multinational, an end of trial notification must also be submitted after the trial has ended in all countries (globally).

1.2 Notifications submitted as necessary

Temporary halt of the clinical trial: means a temporary interruption of the trial. The notification must be made within 15 days of the temporary interruption of the clinical trial in each country participating in the trial and must state the reasons for such action. In addition, it must be stated whether the interruption concerns only recruitment or also treatment with the investigational medicinal product.

- If recruitment is interrupted because of a potential change in the benefit-risk balance (e.g., a problem related to safety), this must be notified as a temporary halt of the clinical trial.
- If recruitment is interrupted because it is difficult to find subjects for the trial, this must be notified as end of recruitment. The sponsor may later decide to restart recruitment and notify it (Restart of recruitment, see below).
- When notifying a temporary halt of the clinical trial, a notification of the end of recruitment must usually be submitted at the same time.

Restart of trial / Restart of recruitment: If a temporarily interrupted clinical trial is restarted, the sponsor must notify all Member States concerned through the CTIS portal. The notification must be submitted within 15 days of the restart of the temporarily halted clinical trial in each country participating in the trial. The restart of recruitment is always notified separately to each Member State.

- If the trial has been interrupted for safety reasons, a substantial modification application must first be submitted in the CTIS portal (SM, see section 2).

2. Substantial modifications (SM) and Non-substantial modifications (NSM) submitted as necessary

- Substantial modifications to the trial (SM) require an application for authorisation to be submitted in the portal.
- Non-substantial modifications (NSM) must be notified in the portal. An NSM does not require an authorisation. Instead, the portal approves it immediately.
- The EMA's [Q&A document](#), Annex IV (Classification of changes to ongoing clinical trials) helps with the classification of modifications (SM or NSM).
- Instructions for submitting a substantial modification can be found on Fimea's [website](#) and in the Sponsor [handbook](#) prepared by the EMA.

3. Safety reporting

3.1 Unexpected adverse reactions

- The sponsor has an obligation to report to Fimea any SUSARs, i.e. suspected unexpected serious adverse reactions related to the investigational medicinal product.
- Non-commercial sponsors may submit a free-form notification of SUSAR to Fimea in a secure email (Eudralink or [Fimea's secure mail service](#)) to FI-CTA (a) fimea.fi, after which Fimea will report it to the EMA's EudraVigilance database.

3.2 Annual report

- The Annual Safety Report (ASR) must be submitted in the CTIS portal once a year during the trial. The obligation begins one year from the clinical trial authorisation and

ends with the end of the trial, which is usually the last visit of the last patient. The report must be submitted within two months of the annual date (the date on which one year has passed from the authorisation of the trial).

- Simplified annual report templates for trials conducted by non-commercial sponsors and using medicines subject to a marketing authorisation are available on Fimea's website.
- Information about safety reporting on Fimea's website:
https://fimea.fi/en/supervision/clinical_drug_trials/safety-reporting-in-clinical-trials

3.3. Unexpected event (UE)

A UE is an incident that may influence the benefit-risk balance of the medicinal product or lead to changes in the administration of the medicinal product or in the clinical trial as a whole (e.g., a significant hazard to patients). Such notifications must be made without delay, but no later than 15 days after the sponsor of the trial became aware of the incident. In other words, a UE may precede the notification of early termination.

4. Trial results

- The summary of the trial results must be submitted in the CTIS portal within one year of the end of the trial.
- Additionally, the sponsor shall submit a summary of the results for laypersons (Annex V to the EU Clinical Trials Regulation). General guidelines on preparing summaries of results for laypersons are available on the European Commission's [website](#) EudraLex - Volume 10.

More information on Fimea's website: https://fimea.fi/en/supervision/clinical_drug_trials

If you have any questions, please contact clinicaltrials@fimea.fi