

# Mall följebrev

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## About the document

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## About the cover letter template

This cover letter template should be used for applications for approval of clinical trials for medicinal products for human use according to EU-regulation no 536/2014.

The first page is an instruction to the person who will write the cover letter. The page should not be uploaded to CTIS but removed when using the template.

*Text written in red and cursive contains information on what should be described in each section, if not applicable the section should be deleted.*

This document should not contain personal data and should therefore not be signed.

According to CTR some clinical trials are defined as low-intervention clinical trials. There may be lower requirements on some levels of these trials, which are described in relevant sections of [the clinical trial protocol template](https://kliniskastudier.se/forskningsstod-och-radgivning/mallar-och-stoddokument/kliniska-lakemedelsprovningar) for medicinal products provided by Kliniska Studier Sverige.

The cover letter must end with a list indicating which documents are attached in the CTIS application, version number and date must be added to each document. It is not necessary to repeat information already in the EU-application form in the cover letter, unless it is *information to consider.*

CVs enclosed in the CTIS application will become public information.

**Application for approval of a clinical trial**

EU CT number: xxxx-xxxxxx-xx-xx

Sponsors organisation:

Trial-ID: *[Specific code number of sponsor]*

Trial title:

City: Date:

To: xxx

I hereby apply for approval to conduct the above-mentioned clinical trial.

### Characteristics of the clinical trial:

*Initial application*:

*[Provide a brief description of the trial’s characteristics; open/blinded, randomised, case-control, phase, how many study subjects are planned, what treatment they will receive.]*

*Re-application:*

State EU CT number for previous application*:*

*[Applicable if the application is resubmitted. Highlight the changes as compared to the previous submission and, if possible, specify how any unresolved issues in the first submission have been addressed.]*

*Low-Intervention Trial:*

*Leave a detailed justification: [Sponsor considers the clinical trial as a clinical low- intervention trial due to following xxxx]*

*Decentralised trial, DCT:*

*[Describe whether the trial is fully or partially decentralised and which parts are concerned.Justify the benefit of using decentralised elements in the clinical trial.]*

*Sponsor asks for assistance with reporting SUSAR:*

*[Sponsor is not able to report SUSAR in EudraVigilance and asks for assistance from the Swedish Medical Product Agency. Any SUSAR will be reported to the Swedish MPA on CIOMS-forms.]*

*Fee-reduction:*

*[The study is a non-commercial, academic clinical trial. Sponsor would like to apply for a fee-reduction on the following grounds xxxxxxxxxxx]*

### List of investigational medicinal product including placebo

*[An extensive list, including the legal status and handling of all IMPs, see also* [*EU regulation Appendix 1*](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0536&from=SV)*, for support]*

|  |  |  |
| --- | --- | --- |
| Investigational medicinal product and placebo | Reference safety information | Legal status |
|  | *[e.g.*   * *Summary of product characteristics/ SmPC* * *Investigators Brochure / /IMPD* * *Simplified IMPD]* | *[e.g. –The IMP has a marketing authorisation in Sweden/xxx*   * *the IMP will be prescribed to trial subjects and we therefore ask for an exception of the rule to label the product according to trial specific information. The IMP will be provided to trial subjects free of charge* * *The IMP will be handled by the hospital pharmacy X who will also label the packages with trial specific information before distributing them to sites* * *The IMP is under development* * *The IMP is given off label]* |

### List of Auxiliary products

*[An extensive list of all auxiliary products. Medicinal products given to the subjects that are not are called auxciliary products. These include background medication, rescue medication, diagnostic or challenge agents and other medicinal products that are used to measure outcomes]*

|  |  |  |
| --- | --- | --- |
| Auxiliary product | Reference safety information | Legal status and handling |
|  | *[e.g.*   * *Summary of product characteristics/SmPC* * Investigators Brochure*(IB)/IMPD* * *Simplified IMPD]* | *[e.g.*   * *The auxiliary product has a marketing authorisation in Sweden/xxx* * *The auxiliary product is under development* * *The auxiliary product is given off label]* |

### List of Medical Devices

*[An extensive list of all medical devices that will be investigated in the clinical trial but are not part of the IMP with a justification indicating whether the device is CE marked for the intended purpose.]*

|  |  |
| --- | --- |
| Medical device | Description/justification |
|  | *[For example. CE marked for intended purpose, not CE marked]* |

### ATTACHMENTS:

*All documents should contain the date and version number.*

#### Form:

* Compliance with Regulation (EU) 2016/679
* Proof of payment of fee. Available at: <https://www.lakemedelsverket.se/sv/blanketter/faktureringsunderlag-for-klinisk-provning>
* Cover letter

#### Part I: The following documents must always be attached to the application:

* Study protocol, version xx date xx
* Protocol synopsis in Swedish
* SmPC or IB/IMPD for the investigational medicinal product/products and placebo xx, version xx

***These documents should be attached if applicable:***

* *Justification of low-intervention clinical trial*
* *SmPC or Investigators Brochure/IMPD for the investigational medicinal product/products xx, version xx*
* *Labelling, Investigational Medicinal Product xxx, version xx (see annex VI of the CT Regulation)*
* *Documents from a scientific advice-meeting with an NCA*
* *Opinion on Paediatric Investigation Plan (PIP) from EMA*
* *Manufacturing license and GMP-certificate*

#### Part II: The following documents (in Swedish) must always be attached to the application:

* Description of the recruitment procedure
* Informed Consent form
* List of sites, including name and title workplace addresses and contact details to the responsible investigators, previous GCP education or previous experience of clinical trial. Principal Investigator’s financial interests should be stated.
* Site suitability including facilities, equipment, expert knowledge.
* Proof of insurance.
* Financing description of compensation to sites and trial subjects and a description of all other agreements.
* A statement from sponsor that data is handled in accordance with the GDPR and supplementary national legislation.

#### These documents should be attached if applicable.

* *Other documents targeted towards trial subjects such as recruitment ads, questionnaires, diaries*
* *Compliance with regulation for handling of biological samples.*

#### Information to consider

*Even if this information is described in the EU application form, the information must be repeated in the table below. In the table, it must be stated where in the application documents the information is found.*

*If any of the following is relevant, it must be described in the table below. Remove rows that are not relevant.*

### List of information to consider

*[If the clinical trial will include vulnerable subjects, e.g., pregnant or breastfeeding women.]*

*[If the clinical trial is a first-in-human trial]*

*[If the NCA, a member state or a third party country has given a scientific statement regarding the clinical trial or the IMP.]*

*[If the clinical trial is a part of or will be part of a paediatric investigation plan according to Regulation EC no 1901/2006 chapter II article 3 (if the NCA has published a decision regarding the paediatric investigation plan, the cover letter must entail a link to the decision on the NCA website).]*

*[If the IMP or auxiliary product is classified as a narcotic, psychotropic or radiopharmaceutical or if the IMP consist of or contains genetically modified organisms, GMO.]*

*[If Sponsor has obtained an orphan drug classification for the IMP for medical treatment of rare diseases.]*

*[The IMP is considered a prophylactic vaccine]*