Notification regarding an authorised clinical trial – step by step

Upload of XML from EudraCT

Select the XML file you saved on your computer when you filled in the EudraCT form on the EudraCT website.

Documents to the DHMA and the Scientific Ethical Committee System:

Depending on the type of information you want to submit, you have to notify either the DHMA or the Scientific Ethical Committee System. We therefore ask you to assess to whom specific information is relevant.

See the list of amendments to determine which amendments you should submit to either the DHMA, the Scientific Ethical Committee System or both. The list is not exhaustive. The sponsor/investigator is at any time responsible for determining whether an amendment is so substantial that the DHMA and/or the Scientific Ethical Committee System must approve it. You should use the function "amendment to an authorised clinical trial" to submit substantial amendments for approval.

Please answer "yes" or "no" to indicate whether the amendment concerns the investigator, centres or an extension of the trial. The reason is that the DHMA and the Scientific Ethical Committee System handle amendments differently.

Depending on the type of information you want to submit, some of the pages (see the list on the left-hand side) are not relevant to fill in. They will be skipped when you fill in the form.

Type of notification

Please state one of the following reasons for submitting a notification.

- *Final clinical study report (summary of the trial results)*
- *Publication in relation to the trial*
- *Extension of trial period relative to the date approved on the Danish authorisation*
- *New sites/change of sites*
- *Change of principal/coordinating investigator*
- *Change of CRO/applicant*
- *Other information you want to submit.*

Please indicate if the notification concerns multiple trials with the same medicinal product. Remember to add all relevant EudraCT numbers in the form.

Applicant

Some of the fields are filled in with data from the XML file you have just uploaded. Please check the information in the pre-filled fields. If any of the information is incorrect, you must make the corrections in EudraCT and upload a new EudraCT XML file. Please fill in the fields marked with an asterisk. The applicant

is the person who submits a clinical trial application to the Danish Health and Medicines Authority. It may be the sponsor or the sponsor's representative, e.g. CRO (contract research organisation), research assistant or another person to whom the sponsor has delegated the task. The sponsor and the investigator must submit a joint application to the ethics committee system and therefore a signature page has to be filled in. If the applicant does not speak Danish, please add a Danish-speaking contact person under 'contact person' as the ethics committee system only communicates in Danish.

EAN number

The EAN number is an electronic address that we use to send an electronic invoice to a public institution. If you are a researcher and we are sending invoices to e.g. the hospital, please tick 'Public institution in Denmark' and fill in your EAN number for the hospital in this field.

Contact person

If you want us to contact another person than the applicant in connection with this application, please add a contact person by clicking here and filling in the fields. If the applicant does not speak Danish, please add a Danish-speaking contact person under 'contact person' as the ethics committee system only communicates in Danish. A field marked with an asterisk is mandatory.

Invoice recipient

If the invoice recipient is not the applicant, please tick the box and fill in the invoice recipient fields.

Sponsor

Some of the fields are filled in with data from the XML file you have just uploaded. Please check the information in the pre-filled fields. If any of the information is incorrect, you must make the corrections in EudraCT and upload a new EudraCT XML file. Please fill in the fields marked with an asterisk. The sponsor is the person, company or institution undertaking the responsibility for the initiation, management and possibly the financing of a clinical trial.

Investigator in Denmark

Some of the fields are filled in with data from the XML file you have just uploaded. Please check the information in the pre-filled fields. If any of the information is incorrect, you must make the corrections in EudraCT and upload a new EudraCT XML file. Please fill in the fields marked with an asterisk. The investigator or the investigator and the sponsor/the sponsor's representative must submit a joint application to the regional ethics committee located in the region where the investigator works. If the investigator is not the applicant, please use the signature page.

Trial information

The fields EudraCT number, Protocol ID number, title of the trial and the trial's main purpose are filled in automatically with data from the EudraCT XML file you have just uploaded. If any of the information is incorrect, you must make the corrections in EudraCT and upload a new EudraCT XML file. Please fill in the fields marked with an asterisk.

Information about the research ethics committee

The fields marked with an asterisk are mandatory. Please select the relevant ethics committee from the drop-down menu.

Information on investigational medicinal products

The field is filled in with data from the EudraCT XML file you have just uploaded. If any of the information is incorrect, you must make the corrections in EudraCT and upload a new EudraCT XML file.

Attached documentation to the application

Please attach the documentation about the trial that you want to submit to the Danish Health and Medicines Authority and the Scientific Ethical Committee System. List of documents to be submitted and list of the documents forwarded to the Danish Health and Medicines Authority and the Scientific Ethical Committee System, respectively. The mouse-over texts for each field indicate which documents to attach under the different headings. Remember that the documents should have a file size of maximum 10MB. The maximum size of the application is 80MB. How to minimise the size of PDF documents. Information about the signature page.