# New application for a 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.*

## 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.*

## Group of trial subjects

*Indicate the trial subjects included in the trial. You can tick more than one field. You have to fill in this field because this information is not available in the EudraCT form.*

## Design and First-in-Human

*The fields are 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.*

## Research on biological material

*Please state whether research on biological material will be conducted as part of the trial. You can tick more than one field. You have to fill in this field because this information is not available in the EudraCT form.*

## Phase and emergency trials

*The fields are 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.*

## Has the application been assessed through the VHP procedure, and is this the national application?

*VHP means Voluntary Harmonised Procedure. This is a procedure where the European drug regulatory authorities offer a coordinated assessment of an application for clinical trials. Read more about VHP here. In this field, please indicate whether the application for clinical trials has been assessed through the VHP procedure prior to the submission to the Danish Health and Medicines Authority.*

## Expected number of trial subjects in Denmark

*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.*

## Number of healthy trial subjects

*Please indicate the number of healthy trial subjects participating in the trial. You have to fill in this field because this information is not available in the EudraCT form.*

## Medical/health area

*Please select from the drop-down menu. You have to fill in this field because this information is not available in the EudraCT form.*

## Disease/code

*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.*

## ICD-10 code

*Please enter the ICD-10 code for the disease area that the trial is related to. You can find a list of ICD-10 codes by clicking this link*. You have to fill in this field because this information is not available in the EudraCT form.

## Multinational trial

*Please state if the trial is conducted in other countries than Denmark. You have to fill in this field because this information is not available in the EudraCT form.*

## 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.*

## End of trial

*Please state the expected end of trial date. You have to fill in this field because this information is not available in the EudraCT form.*

## Sites where trial is conducted

*Please state the sites where the trial is conducted. If you select a hospital department and need to find a hospital classification code, please click this link.*

## Address(es) of trial site(s) and name(S) of investigator(s)

*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.*

## 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.*

## Patient recruitment

*If you want to advertise for clinical trial subjects on sundhed.dk, you can enter the advert by clicking the link to the patient recruitment solution. Make sure the text for the advert is ready (in Danish). You have to provide information about the trial and enter the text for the advert. More information about patient*

*recruitment (link til patientrekruttering). The Scientific Ethical Committee System will handle the advert as part of the approval of the trial.*

## 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. Information about the signature page.*