Surveillance of an authorised clinical trial – step by step

Type of safety surveillance notification

Here you can indicate what type of notification you want to submit: Annual safety report, Change of trial status which comprises: The trial has been halted in Denmark or globally, Temporary halt of a trial, Premature trial closure. More information about types of notification.

Type of applicant

Please specify your role in the clinical trial. You have to represent the sponsor, investigator or CRO (Contract Research Organisation).

Applicant

Please fill in the fields marked with an asterisk. Applicant is the person submitting a safety surveillance notification. It may be the sponsor, the investigator or the applicant. Applicants apply on behalf of the sponsor and may be e.g. a CRO (contract research organisation), research assistant or another person to whom the sponsor has delegated the task. 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 (not applicable)

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.

Information on the trial, Information on investigational medicinal products

Please state the EudraCT number, protocol ID number etc. The fields marked with an asterisk are mandatory and used by the Danish Health and Medicines Authority and the Scientific Ethical Committee System to identify the notification. It is important that you add the EudraCT numbers if your notification concerns multiple trials in Denmark.

Information about the research ethics committee

Please select the relevant ethics committee from the drop-down menu.

If you have selected: Change of trial status

Here you select whether the clinical trial has ended in Denmark or globally, the clinical trial has been halted temporarily or the clinical trial has been ended earlier than planned. More information about change of clinical trial status.

If you have selected: Other safety-related information

The Danish Health and Medicines Authority and the Scientific Ethical Committee System must be informed if new knowledge of importance to the safety of trial subjects emerges while the trial is conducted. Examples could be toxicological findings of importance to patient safety or the briefing of investigators about aspects that they need to take into account during the conduct of a trial, etc. Please give a brief description of the reason for your notification.

Attached documentation to the safety surveillance notification

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. 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.