NATIONAL COMMITTEE ON HEALTH RESEARCH ETHICS

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When to report side effects (adverse reactions)?

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Location: http://en.nvk.dk/general-guidelines/when-to-report-side-effects

1. Reporting of adverse reactions (clinical trials on medicinal products)

Serious unexpected adverse reactions

The investigator or sponsor must notify the committee immediately if during the clinical trial suspected unexpected serious adverse reactions (SUSARs) occur.

SUSARs that are fatal or life-threatening must be reported to the committee (and the Danish Medicines Agency) as soon as possible and no later than 7 days after the sponsor or the investigator became aware of a suspected adverse reaction. No later than 8 days after reporting, the sponsor must inform the committee (and the Danish Medicines Agency) of all relevant information about the sponsor's and the investigator's follow-up on the report.

Any other suspected unexpected serious adverse reactions must be reported to the Danish Medicines Agency and the committee no later than 15 days from the time the sponsor became aware of them.

The report must be submitted along with comments on any consequences for the clinical trial in question.

The duty to submit reports to the committee covers SUSARs having occurred in Denmark.

It is only the unexpected adverse reactions that must be reported immediately. An unexpected adverse reaction is an adverse reaction whose nature or severity is not consistent with the activity's risk described in the trial protocol.

SUSARs reported to the committee system must otherwise include the content specified in the Danish Medicines Agency's clinical trials guideline, sections 12.1 and 12.3 on the reporting of adverse reactions. Please see the Danish Medicines Agency's guideline

The committee must receive SUSARs and annual reports in PDF report format. The report must be submitted electronically (encrypted), (note that the required submission format may vary between the regional research ethics committees).

SUSAR reports in PDF format can be generated either in the process of submitting reports to the EudraVigilance database (e.g. CIOMS report) or by using the Danish Medicines Agency's e-form for reporting of suspected unexpected serious adverse reactions (SUSARs) seen in clinical trials on medicinal products (before submitting the e-form, you can print it out and then submit it in PDF-format).

It is the Danish Medicines Agency, which supervises clinical trials on medicinal products.

Annual report

Once a year throughout the trial period, the sponsor or the investigator must submit a list of all suspected serious adverse reactions (expected and unexpected) that occurred in the period. The report must include an assessment of the safety of the trial subject.

It is possible to replace the annual report and list of all suspected serious adverse reactions by the Development Safety Update Report (DSUR), please see ICH E2F).

The annual report submitted to the committee system must otherwise comply with the Danish Medicines Agency's "Guideline for applications for authorisation of clinical trials of medicinal products in humans", section 12.4 on the reporting of adverse reactions.

Annual reports must be submitted as a report in PDF format. The report must be submitted electronically (encrypted). (Note that the required submission format may vary between the regional research ethics committees).

2. Reporting of adverse reactions (trials not involving medicinal products)

Serious unexpected adverse reactions and adverse events

The investigator or sponsor must notify the committee immediately if during the trial suspected unexpected serious adverse reactions or adverse events occur. The report must be submitted along with comments on any consequences for the trial in question.

Only adverse reactions and adverse events having occurred in Denmark need to be reported.

A report must be submitted no later than 7 days after the sponsor or the investigator became aware of an occurrence.

In case of serious adverse reactions or serious adverse events resulting from the project, the investigator must provide the information the committee asks for.

A reporting form designed by the committee system can be used. The form along with appendices can be submitted electronically to the regional research ethics committee using digital signature, (note that the required submission format may vary between the regional research ethics committees). Download the form here: Reporting form (in Danish only).

Annual report

Once a year throughout the trial period, the sponsor or the investigator must submit a list of all serious expected and unexpected adverse reactions and all serious adverse events that occurred during the period. The report must include an assessment of the safety of the research participants.

The material submitted must be in Danish or in English.

The report must be submitted using this Reporting form (in Danish only). The form along with appendices can be submitted electronically to the regional research ethics committee using digital signature. (Note that the required submission format may vary between the regional research ethics committees).

The reporting duty also applies to trials with medical devices.