Neo-Act - Guidlines for completing SAE-forms.

Serious Adverse Events (SAEs) related to the exercise intervention (Arm B) and to any general exercise performed by the patient without participating in the intervention (Arm A) must be reported within 24 hours after knowledge of the event. For definition of AEs to be reported/not reported see protocol.

Send the SAE-form to Yvonne Wengström, email:

neoact@mmk.ki.se

The SAE-form is to be completed in English; dates are entered in format: *dd-mm-yyyy*.

Initial report

Fill in as much as possible, but the following items have to be filled in for the initial report:

- Patient number, Centre name
- Type of report: Initial/Follow up
- Age gender
- Visit
- Arm A or Arm B
- If Arm B- Intervention Started on date (start date of the study related training)
- SAE-date (Date event became serious)
- Reason for considering the event serous
- Description of event
- Primary adverse event
- CTC grad (1-5)
- Relation to trial intervention (Arm B) **or** Relation to general exercise (Arm A)
- Action taken
- Outcome (”Outcome” is sometimes available first on the FU-report)
- Date event no longer serious.
  If not known when sending the initial report, a Follow-up report has to be sent, see below.
- Name and signature of person completing the form, Date

Please note, events reported on the SAE-form must be entered in the AE-section of the CRF.

Follow up-reports

If an incomplete report has been sent or if the SAE still is ongoing an updated SAE form has to be sent in with the “*Follow up*” box ticked, the Follow-up form must include all additions made as soon as new information is available.

A follow-up report has to be sent even when the event is completed. If single points have changed from the initial report, these can be changed on the same form, e.g., that the reason for hospitalization, grade etc. If multiple fields are changed, fill in and send a new completed SAE-form marked” Follow up”. The follow-up report (also additional supplementary follow-up reports) must be signed by the responsible investigator

Patient number
Patient study ID

Type of report

- The *Initial* box is ticked on the first report, this report does not have to be complete, i.e. all data not available, AE still ongoing etc.
- *The Follow up* box is ticked i when a completed report is sent in or the event is closed.

If the initial report is complete from the beginning, tick both *Initial* and *Follow up.*

Patient's age
Patient's age at the time of the SAE.

Patient's sex
Patient's gender.

Visit: E.g.," Pre surgery", "Post surgery", "Follow up 1 year" etc.

Date event became serious
Date when the AE progressed to a serious event/SAE (example: hospital admission), not when the AE itself started (example: infection).

Date event no longer serious
Date when the serious AE is no longer considered serious (for example, when the patient was discharged after an admission).

Reason for considering the event serious
The reason why the AE is serious according to the protocol definition

Description of event
Brief description of what happened. Complete the follow-up report.

Primary adverse event / grade
Identify the main AE causing the SAE. The AE must also be reported in the adverse event section in the CRF.

Arm B: Relation to study treatment
The responsible investigator must make an assessment of the causal relationship between the SAE and the study treatment, i.e., whether there is a reasonable possibility that the SAE is caused by the study treatment (exercise intervention) or not.
Arm A patients leave blank.

Arm A: Relation to study treatment
The responsible investigator must make an assessment of the causal relationship between the SAE and any general exercise, i.e., if there is a reasonable possibility that the SAE is caused by any general exercise or not.
Arm B patients leave blank

Arm B: Action taken…
No action taken: Tick if no action regarding the exercise intervention has been taken.
Interrupted: Tick if the SAE led to the exercise intervention being interrupted.
Withdrawn: Tick if the SAE has led to the decision to discontinue exercise intervention completely.
Arm A patients leave blank.

Arm A: Action taken…

No action taken: Tick if no action regarding any general exercise has been taken.
Interrupted: Tick if the SAE led to any general exercise being interrupted.

Withdrawn: Tick if the SAE has led to the decision to discontinue exercise intervention completely.
Arm B patients leave blank.

Outcome

Status of the main AE (Primary adverse event) when the SAE is no longer considered serious.If dead, date of death, Cause of death.
If the patient has died, the date of death must be filled in as well as the reason for the patient's death.

Name and signature of person completing the form

The initial report is signed by the person who filled in the form, which can be a research nurse, co-investigator or investigator. Name written, signature and date

Investigator's name and signature

The final report must be signed by the responsible investigator to verify that the investigator approves that the data is correct and complete. Name written, signature and date.