Received (date, sign):	SAE-nr:

Neo-Act	**SAE**	

Patient number	**Centre** _____	Type of report: Initial ☐	Follow up ☐

INSTRUCTIONS: *Please send this form by email to Yvonne Wengström, coordinating investigator exercise, Karolinska Institutet* neoact@mmk.ki.se **within 24 hours after notification.**
Keep the original at your site until monitoring.

Patient's age (years) |__|__|	Patient's sex: Male ☐ Female ☐	Visit: ....

Arm A – Control group ☐   **Arm B – Intervention** ☐

Arm B- Intervention started on date: __ __/__ __/__ __ __ __

Date event became serious: __ __/__ __/__ __ __ __

Reason for considering the event serious: Death ☐   Life-threatening ☐
       Hospitalisation/prolonged hospital stay ☐   Permanent disabling/incapacitating ☐
       Resulted in congenital abnormality ☐   Other medically important events   ☐
If other, specify:...

Description of event

....

....

Primary adverse event: .... CTC Grade1 ☐   2 ☐   3 ☐   4 ☐   5 ☐

Arm B: Relation to trial Intervention: Possibly ☐   Probably ☐   Definitely ☐

Arm A: Relation to general exercise: Possibly ☐   Probably ☐   Definitely ☐

Arm B: Action taken regarding the trial Intervention: No action taken ☐   Interrupted ☐   Withdrawn ☐

Arm A: Action taken regarding general exercise: No action taken ☐   Interrupted ☐   Withdrawn ☐

Outcome: ☐ Recovered   ☐ Ongoing   ☐ Unknown   ☐ Dead, Cause of death: ....

Date event no longer serious: __ __/__ __/__ __ __ __   If dead, date of death: __ __/__ __/__ __ __ __

Name and signature of person completing the form	Date __ __/__ __/__ __ __ __
Investigator's name and signature	Date __ __/__ __/__ __ __ __

All dates as ddmmyyyy   *Neo-Act SAE form Version 1.0*