For the Coordinating investigator (exercise) Yvonne Wengström

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Arm B: Action taken regarding the trial Intervention: No action taken ☐ Interrupted ☐ Withdrawn ☐

Arm A: Action taken regarding general exercise: No action taken ☐ Interrupted ☐ Withdrawn ☐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 2.0_19Sep2025*