Investigator Site File

Study name

Physical exercise during neoadjuvant chemotherapy for breast cancer as a means to increase pathological complete response rates: the randomized Neo-ACT trial

Investigator Site File, ISF, Table of content

1.	**Study Contact List**
2.	**Protocol** - Current protocol (with Signature page) - Superseded protocols (signed and dated [valid from time of initiation])
3.	**Patient Information** - Patient screening form (optional) - Screening and enrolment log - Subject enrolment and identification log - Informed consent (blank copies all versions and patient information version log) - Signed informed consents (indicate if in a separate folder) - Other Patient Facing Material: Questionnaires
4.	**Safety** - SAE Form - SAE Instruction
5.	**Ethics Committee** - Approval/favourable opinion (including members list) - Amendments and approvals - Correspondence
6.	**Financial and legal** - Clinical trial agreement (site agreement) - Data processing agreement (if applicable) - Data Protection registration (if applicable)
7.	**Investigational site** - Site signature and delegation list - CV: s (staff on delegation list) - Training (e.g., certificates, attendance log)
8.	**Clinical supplies** - Fitbil log - Shipment Information
9.	**Study procedure manuals** - Vitala App Manual - Fitbit Manual
10.	**Laboratory and Biobank (only applicable for site collecting samples)** - Study Lab Manual - Biobank Agreement

11.	**Monitoring** - Monitoring visit log - Monitor's secrecy agreement - Initiation visits report (original) - Monitoring visits reports
12.	**Source Data & eCRF** - List of Source Data (Källdatalista) - CRF Completion Guidelines
13.	**Note to File** - Sponsor generated - Site generated
14.	**Correspondence** - To-From-Sponsor - Newsletters
15.	**Study reporting** - Publications - Clinical study report