PLACE IN SITE FILE #0.3

# Log for site file documents

## Period: 2026–H2
## (1 July 2026 to 31 December 2026)

The latest changes are from the top of the document,
structured by date and follow site file section number.

The log will within the period be updated by date in the table.

| **Date: 2026.09.08** | | |
|---|---|---|
| **Site file section** | **Changes** | **Need of action** |
| #1.5.1 | Co-enrolment list for INCEPT-Albumin version 5.0 is updated with a new trial (HOT-NSTI Trial).<br><br>Co-enrolment list for INCEPT-Thromboprophylaxis version 2.0 is updated with a new trial (HOT-NSTI Trial). | ☐ Add<br>☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #10.5.1 | Educational material.<br>The English presentation have been updated.<br><br>*Primarily, relevant for sites outside Denmark, but if a Danish site needs it, the presentation is available at www.incept.dk.* | ☐ Add<br>☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |

| **Date: 2026.07.10** | | |
|---|---|---|
| **Site file section** | **Changes** | **Need of action** |
| #10.5.1 | Educational material.<br>The following presentations have been updated.<br>Part 5 (in Danish)<br>Initiation (in English)<br><br>*Note: Updates are related to supportive information material. It does not require re-training, since it is not new knowledge to site staff.* | ☐ Add<br>☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |

| **Date: 2026.07.09** | | |
|---|---|---|
| **Site file section** | **Changes** | **Need of action** |
| #0.1 | Delegation log version 2.0 updated according to the new structure of the training log.<br><br>*Note:* | ☒ Add<br>☐ Replace and archive former version<br>☐ Inform<br>☒Train/re-train |

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| | *The content of the delegation log is compressed/reduced. Already delegated staff do not have to be delegated again, but new staff must be delegated according to version 2.0.* | |
| #0.3 | Training logs, version 2.0 (H2-2026) for sub-investigators, medical doctors, and other trial staff.<br>These new versions follow a more simple and generic structure to make it easier to handle across countries.<br><br>*Note:*<br>*The content of the training log is compressed and do not require retraining, but training of new staff must be trained according to version 2.0.* | ☒ Add<br>☐ Replace and archive former version<br>☐ Inform<br>☒Train/re-train |
| #1.5.2 | Recruiting sites per domain, version 1.1 updated.<br>Updated with Slagelse Hospital (information in newsletter #22).<br><br>*Note: This document must be printed for Danish site files.* | ☐ Add<br>☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #2.1.1 | Decisions for the initial applications:<br>Finland (only sites in FI)<br>Iceland (only sites in IS)<br>Sweden (only sites in SE)<br>The Netherlands (only sites in NL) | ☒ Add<br>☐ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #2.1.2 | Decision for SM03 for the following countries:<br>Denmark (only sites in DK)<br>Finland (only sites in FI)<br>Iceland (only sites in IS)<br>Sweden (only sites in SE)<br>The Netherlands (only sites in NL) | ☒ Add<br>☐ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #4.1.1 | Core protocol, version 1.5 updated. | ☐ Add<br>☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #4.1.1 | Frontpage core protocol_signed, version 1.5 updated.<br>*(must be signed by site investigator)* | ☒ Add<br>☐ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #4.1.1 | Core protocol synopsis, version 1.5 updated. | ☐ Add<br>☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #4.1.2 | INCEPT-Albumin, domain specific appendix, version 1.5 updated | ☐ Add |

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| | | ☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #4.1.2 | Frontpage INCEPT-Albumin_signed, version 1.5 updated.<br>*(must be signed by site investigator)* | ☒ Add<br>☐ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #4.1.2 | INCEPT-Albumin synopsis, version 1.5 updated | ☐ Add<br>☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #4.1.3 | INCEPT-Thromboprophylaxis, domain specific appendix, version 1.2 updated | ☐ Add<br>☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #4.1.3 | Frontpage INCEPT-Thromboprophylaxis_signed, version 1.2 updated.<br>*(must be signed by site investigator)* | ☒ Add<br>☐ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #4.1.3 | INCEPT-Thromboprophylaxis synopsis, version 1.2 updated | ☐ Add<br>☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |

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| #4.2 | Protocol changes log and domain specific changes log<br>For INCEPT protocol, version 1.2 (#4.2.1)<br>For INCEPT-Albumin, version 1.2 (#4.2.2)<br>For INCEPT-Thromboprophylaxis, version 1.1 (#4.2.3) | ☐ Add<br>☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #4.4.1 | National appendix – Denmark, version 1.5 (only sites in DK)<br>National appendix – Finland, version 1.1 (only sites in FI)<br>National appendix – Iceland, version 1.3 (only sites in IS)<br>National appendix – Sweden, version 1.2 (only sites in SE)<br>National appendix – The Netherlands, version 1.0 (only sites in NL) | ☐ Add<br>☒ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |
| #15.5 | Annual Safety Report_01, new document<br><br>*Note: The Annual Safety Report was finalized by CTIS 26.06.26.* | ☒ Add<br>☐ Replace and archive former version<br>☐ Inform<br>☐Train/re-train |