

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: 2026.10.12  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                            |
|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Site file section | Changes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Need of action                                                                                                                                                                                             |
| #1.2.2            | <p>Praktisk procedure for informeret samtykke, version 1.3 (update).</p> <p>The Danish template is revised, so it is clear how to handle informed consent when a patient is not able to sign. Please, inform medical doctors who screen and inform for consent.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input type="checkbox"/> Add<br><input checked="" type="checkbox"/> Replace and archive former version<br><input checked="" type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train            |
| #10.2             | <p>Info about GCP-training, version 1.0 (new document that replaces the former document INCEPT_CV and GCP course, version 1.1).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input type="checkbox"/> Add<br><input checked="" type="checkbox"/> Replace and archive former version<br><input checked="" type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train            |
| #10.2             | <p>All trial staff need GCP-training/certification, but at different levels depending on delegated roles.</p> <p>Info with links to relevant GCP courses for three groups:<br/> GCP course_site investigators_DK, version 1.0<br/> GCP course_site investigators (international), version 1.0<br/> GCP course_other trial staff, version 1.0</p> <p>A course for Danish medical doctors who screen patients and inform for consent is available (Staff_medical doctors). This is a simple course in two parts.<br/> Part 1: Slideshow (GCP_kursus_Part 1, version 1.0)<br/> Part 2: Written material, including certification (GCP_kursus_Part 2, version 1.0)<br/> The course can be used for medical doctors that are not yet delegated to any tasks. Both parts are mandatory.</p> <p>The course is available as English templates which can be adapted to be used in countries outside DK.<br/> GCP_course_Part 1_template_EN, version 1.0<br/> GCP_course_Part 2_template_EN, version 1.0</p> | <input checked="" type="checkbox"/> Add<br><input type="checkbox"/> Replace and archive former version<br><input checked="" type="checkbox"/> Inform<br><input checked="" type="checkbox"/> Train/re-train |

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|  | <p>If a national investigator adapts the course to a national setting the version will be available in #10.2. Currently, available to a Swedish setting.</p> <p><i>Note: There is no need for re-training, but training of new staff must follow these guidelines.</i></p> |  |
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| Date: 2026.09.24  |                                                                                                                                       |                                                                                                                                                                                      |
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| Site file section | Changes                                                                                                                               | Need of action                                                                                                                                                                       |
| #5.3              | <p>The document "Patient rights" has been updated. New version is dated 28.08.2026.</p> <p><i>Only relevant for Danish sites.</i></p> | <input type="checkbox"/> Add<br><input checked="" type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train |

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

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

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| Date: 2026.07.09  |                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                 |
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| 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><i>Note:</i><br><i>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.</i>                                                                                                | <input checked="" type="checkbox"/> Add<br><input type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input checked="" type="checkbox"/> Train/re-train |
| #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><i>Note:</i><br><i>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.</i> | <input checked="" type="checkbox"/> Add<br><input type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input checked="" type="checkbox"/> 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><i>Note: This document must be printed for Danish site files.</i>                                                                                                                                                                                                     | <input type="checkbox"/> Add<br><input checked="" type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> 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)                                                                                                                                                                                                                            | <input checked="" type="checkbox"/> Add<br><input type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> 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)                                                                                                                                                                                       | <input checked="" type="checkbox"/> Add<br><input type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train            |
| #4.1.1            | Core protocol, version 1.5 updated.                                                                                                                                                                                                                                                                                                                                                               | <input type="checkbox"/> Add<br><input checked="" type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train            |
| #4.1.1            | Frontpage core protocol_signed, version 1.5 updated.<br>(must be signed by site investigator)                                                                                                                                                                                                                                                                                                     | <input checked="" type="checkbox"/> Add<br><input type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train            |
| #4.1.1            | Core protocol synopsis, version 1.5 updated.                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> Add                                                                                                                                                                    |

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| #4.1.2 | INCEPT-Albumin, domain specific appendix, version 1.5 updated                                                    | <input type="checkbox"/> Add<br><input checked="" type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train |
| #4.1.2 | Frontpage INCEPT-Albumin_signed, version 1.5 updated.<br><i>(must be signed by site investigator)</i>            | <input checked="" type="checkbox"/> Add<br><input type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train |
| #4.1.2 | INCEPT-Albumin synopsis, version 1.5 updated                                                                     | <input type="checkbox"/> Add<br><input checked="" type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train |
| #4.1.3 | INCEPT-Thromboprophylaxis, domain specific appendix, version 1.2 updated                                         | <input type="checkbox"/> Add<br><input checked="" type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train |
| #4.1.3 | Frontpage INCEPT-Thromboprophylaxis_signed, version 1.2 updated.<br><i>(must be signed by site investigator)</i> | <input checked="" type="checkbox"/> Add<br><input type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train |
| #4.1.3 | INCEPT-Thromboprophylaxis synopsis, version 1.2 updated                                                          | <input type="checkbox"/> Add<br><input checked="" type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> 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)                                                                                                                           | <input type="checkbox"/> Add<br><input checked="" type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> 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) | <input type="checkbox"/> Add<br><input checked="" type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train |
| #15.5  | Annual Safety Report_01, new document<br><br><i>Note: The Annual Safety Report was finalized by CTIS 26.06.26.</i>                                                                                                                                                                                                             | <input checked="" type="checkbox"/> Add<br><input type="checkbox"/> Replace and archive former version<br><input type="checkbox"/> Inform<br><input type="checkbox"/> Train/re-train |