
PLACE IN SITE FILE #0.3

Log for site file documents

Date: 2025.08.28		
Site file section	Changes	Need of action
# 1.5	Updated co-enrolment list are added	☒ Add ☐ Replace ☒ Inform ☐ Train/re-train

Date: 2025.08.29		
Site file section	Changes	Need of action
# 5.12	Added an overview of translated material to be used in DK; The following documents have been translated into Balkan languages, English, and German: - INCEPT, Information to patient (based on the Danish version 1.3) - INCEPT, Information to relative (based on the Danish version 1.3) - INCEPT-Albumin, Information to patient (based on the Danish version 1.3) - INCEPT-Albumin, Information to relative (based on the Danish version 1.3) - INCEPT-Albumin, Consent form to patient (based on the Danish version 1.3) - INCEPT-Albumin, Consent form to relative (based on the Danish version 1.3) Patient rights, 240202	☒ Add ☐ Replace ☒ Inform ☐ Train/re-train

Date: 2025.09.01		
Site file section	Changes	Need of action
# 0.2	- Updated training log site sub-investigator version 1.1 - Updated training log for medical doctors, version 1.1 - Updated training log for other trial staff version 1.1 <i>Remember to make the documents site-specific.</i>	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train

PLACE IN SITE FILE #0.3

Date: 2025.09.18		
Site file section	Changes	Need of action
# 0.2	- Updated training log site sub-investigator version 1.2 - Updated training log for medical doctors, version 1.2 - Updated training log for other trial staff version 1.2	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train
# 1 2.1	- Updated short guideline to staff version 1.1 in Danish (in black/white) - Updated short guideline to staff version 1.1 in Danish (in colour)	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
# 1.2.2	- Updated INCEPT operational guideline for Danish sites version 1.1 - Updated template for INCEPT praktisk procedure for informeret samtykke version 1.1 in Danish is added. <i>Remember to make the document site-specific.</i> - Updated INCEPT inklusionsnotat version 1.1 in Danish (site file 1.2.2) is added.	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
# 1.2.5	- Updated front page (forside) version 1.1 for the Danish version of the patient folder - Table of contents version (indholdsfortegnelse) version 1.1 for the Danish version of the patient folder INCEPT-platform - Updated pocket cards for INCEPT version 1.1 in Danish (version and date added on the cards). INCEPT-Albumin - Updated INCEPT-Albumin version 1.1 in Danish (version and date added on the cards).	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
	INCEPT-Thromboprophylaxis – new domain - Pocket cards for INCEPT-Thromboprophylaxis Fragmin version 1.0 in Danish - Thromboprophylaxis Innohep version 1.0 in Danish	☒ Add ☐ Replace ☐ Inform ☒ Train/re-train
# 2.1.2	Decision for first substantial modification (SM01) the initial application in CTIS	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train

PLACE IN SITE FILE #0.3

# 4.1.1	INCEPT-platform - Updated INCEPT core protocol version 1.4 - Updated INCEPT Core synopsis version 1.4 - Updated Signed front page of core protocol version 1.4	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train
# 4.1.2	INCEPT-Albumin - Updated domain specific appendix for INCEPT-Albumin version 1.4 - Updated INCEPT-Albumin synopsis version 1.4 - Updated signed front page of the domain specific appendix for INCEPT-Albumin version 1.4	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train
# 4.1.3	INCEPT-Thromboprophylaxis – new domain - Domain specific appendix for INCEPT-Thromboprophylaxis version 1.1 - INCEPT-Thromboprophylaxis synopsis version 1.1 - Signed front page of the domain specific appendix for INCEPT-Albumin version 1.1	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train
# 5.3	INCEPT-platform - Updated INCEPT information to guardian version 1.4 - Updated INCEPT information to relative version 1.4 - Updated INCEPT information to patient version 1.4 <i>Remember to make the documents site-specific.</i>	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
#5.4.1	INCEPT-Albumin - Updated INCEPT-Albumin information to guardian version 1.4 - Updated INCEPT information to relative version 1.4 - Updated INCEPT information to patient version 1.4	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
# 5.4.2	INCEPT-Thromboprophylaxis – new domain - INCEPT-Thromboprophylaxis information to guardian version 1.0 - INCEPT information to relative version 1.0 - INCEPT information to patient version 1.0 - INCEPT-Thromboprophylaxis consent form to guardian version. 1.0 - INCEPT-Thromboprophylaxis, consent form to relative version 1.0 - INCEPT-Thromboprophylaxis consent form to patient version 1.0	☒ Add ☐ Replace ☐ Inform ☒ Train/re-train

PLACE IN SITE FILE #0.3

Date: 2025.09.18		
Site file section	Changes	Need of action
# 9.1	Updated template for source data list version 1.1	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train

Date: 2025.09.26		
Site file section	Changes	Need of action
# 4.2.2	INCEPT-platform - Updated protocol change log for INCEPT version 1.1 INCEPT-Albumin - Updated protocol change log for INCEPT-Albumin version 1.1	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
	INCEPT-Thromboprophylaxis – new domain Protocol change log for INCEPT-Thromboprophylaxis version 1.0	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train

Date: 2025.10.10		
Site file section	Changes	Need of action
Table of content	Updated Table of content, version 1.2 The following are added: 0.3 Log for site file documents 1.5.3 Quarterly quality check <i>Remember to make the table of content site-specific.</i>	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
# 0.3	Updated Log for site trial documents version 2.0, but with former content (version 1.0) in the new document. This document will now be part of the site file and will be a continuous document.	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train
# 1.5.1	INCEPT-Albumin Updated co-enrolment list for INCEPT-Albumin, version 4.0	☒ Add ☐ Replace ☒ Inform ☐ Train/re-train
	INCEPT-Thromboprophylaxis – new domain Co-enrolment list for INCEPT-Thromboprophylaxis, version 1.0	☒ Add ☐ Replace ☒ Inform ☐ Train/re-train

PLACE IN SITE FILE #0.3

# 10.1	Updated the document CV and GCP course version 1.1	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
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Date: 2025.10.28		
Site file section	Changes	Need of action
# 5.12	Updated overview of translated material to be used in DK	☒ Add ☐ Replace ☒ Inform ☐ Train/re-train
	The following documents have been translated into Balkan languages, English, and German: - INCEPT-Thromboprophylaxis, Information to patient (based on the Danish version 1.0) - INCEPT-Thromboprophylaxis, Information to relative (based on the Danish version 1.0) - INCEPT-Thromboprophylaxis, Consent form to patient (based on the Danish version 1.0) - INCEPT-Thromboprophylaxis, Consent form to relative (based on the Danish version 1.0)	☒ Add ☐ Replace ☒ Inform ☐ Train/re-train

Date: 2025.11.17		
Site file section	Changes	Need of action
Table of content	Updated Table of content, version 1.3 The following is added: 1.5.4 Gap-analysis 5.12.1 Post mortem consent <i>Remember to make add this in your site-specific table of content</i>	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
# 1.2.2	Updated template for INCEPT praktisk procedure for informeret samtykke version 1.2 in Danish. The changes are in the section: "Hvad gør jeg hvis" "... patienten er død inden de pårørende er informeret om forsøget?" <i>Remember to replace this section in your site-specific procedure.</i>	☒ Add ☐ Replace ☒ Inform ☐ Train/re-train
# 1.5.3	Gap-analysis version 1.0 <i>Remember to fill in and sign.</i>	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train
# 5.12.1	Post mortem samtykke, instruks version 1.0 Template for Post mortem samtykke følgebrev version 1.0	☒ Add ☐ Replace ☒ Inform ☐ Train/re-train

PLACE IN SITE FILE #0.3

Date: 2025.12.19		
Site file section	Changes	Need of action
Table of content	Updated Table of content, version 1.4 The following are added: 5.12.2 Translations to be used in DK 4.4.2 Substudy proposals <i>Remember to add this in your site-specific table of content</i>	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
#4.4.2	Substudy proposal template, version 1.0	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train
#1.5.3	Updated Quarterly quality check, version 1.1 (site name is added). The document was sent out to active sites 01.12.25 asking them to fill it out as described in the document. Generally, the document will continue to be part of the site file.	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
#1.3.4	Updated Guideline for obtaining 180-day follow-up, version 1.1 The 180-day follow-up guideline explains the procedure in order to reduce the risk of bias.	☐ Add ☒ Replace ☒ Inform ☐ Train/re-train

Date: 2026.01.30		
Site file section	Changes	Need of action
# 5.12	Updated overview of translated material to be used in DK, version 1.3	☒ Add ☐ Replace ☒ Inform ☐ Train/re-train
	The following documents have been translated into Arabic, Romanian, Spanish, and Ukrainian: - INCEPT, Information to patient (based on the Danish version 1.4) - INCEPT, Information to relative (based on the Danish version 1.4) - Patient rights, 240202 - INCEPT-Albumin, Information to patient (based on the Danish version 1.4) - INCEPT-Albumin, Information to relative (based on the Danish version 1.4) - INCEPT-Albumin, Consent form to patient (based on the Danish version 1.1)* - INCEPT-Albumin, Consent form to relative (based on the Danish version 1.1)* - INCEPT-Thromboprophylaxis, Information to patient (based on the Danish version 1.0)	☒ Add ☐ Replace ☒ Inform ☐ Train/re-train

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	• INCEPT-Thromboprophylaxis, Information to relative (based on the Danish version 1.0) • INCEPT-Thromboprophylaxis, Consent form to patient (based on the Danish version 1.0) • INCEPT-Thromboprophylaxis, Consent form to relative (based on the Danish version 1.0) <i>*2025.08.29 it was noted that version 1.3 was translated. This was a typing error in this log for site file documents. Version 1.1 is the current version and translations are based on this both in August 2025 and in January 2026..</i>	
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Date: 2026.03.05		
Site file section	Changes	Need of action
Table of content	Updated Table of content, version 1.5 The following has been changed: • 5.12.2 if you archive the translations to be used in DK electronically, then add the specific placeholder in the Table of content • 6.5.1 SOP for co-authorship is added • 7.4.1 Site user list is added. The template is added as part of the site file. Can be archived electronically. • 14.2 Change in heading <i>Remember to add this in your site-specific table of content</i>	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
#1.5.3	Updated Quarterly quality check version 1.2	☒ Add ☒ Replace ☐ Inform ☐ Train/re-train
#6.5.1	SOP for co-authorship version 1.0	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train
#7.4.1	Site user list, version 2. This is now part of the site file and two new roles as well a short information about blinded registrar are added.	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train

Date: 2026.03.19		
Site file section	Changes	Need of action
#7.4.1	Site user list, version 3. A minor (but important) correction regarding The "B" in the blinded registrar username. The B should be at the end of the username.	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train

PLACE IN SITE FILE #0.3

Date: 2026.04.23		
Site file section	Changes	Need of action
#16.1.1	Case money model, 260423. New version with updated information about invoice process. Amounts are unchanged.	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train

Date: 2026.05.15		
Site file section	Changes	Need of action
#1.2.3	Guideline for data entry. "For Danish sites" is deleted, since this guideline will be used at all sites.	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
#1.5.3	Quarterly quality check, version 1.3. New version where check of EasyRF users is changed from "delete" to "remove roles".	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train
#5.12.2	Updated the overview of translated material to be used in DK, version 1.4. The following documents have been translated into Italian, Russian, and Turkish languages: • INCEPT, Information to patient (based on the Danish version 1.4 – the Italian version based on the English version 1.3) • INCEPT, Information to relative (based on the Danish version 1.4 – the Italian version based on the English version 1.3) • INCEPT-Albumin, Information to patient (based on the Danish version 1.4 – the Italian version based on the English version 1.3) • INCEPT-Albumin, Information to relative (based on the Danish version 1.4 – the Italian version based on the English version 1.3) • INCEPT-Albumin, Consent form to patient (based on the Danish version 1.1) • INCEPT-Albumin, Consent form to relative (based on the Danish version 1.1) • INCEPT-Thromboprophylaxis, Information to patient (based on the Danish version 1.0) • INCEPT-Thromboprophylaxis, Information to relative (based on the Danish version 1.0) • INCEPT-Thromboprophylaxis, Consent form to patient (based on the Danish version 1.0) • INCEPT-Thromboprophylaxis, Consent form to relative (based on the Danish version 1.0) Patient rights, 240202	☐ Add ☒ Replace ☐ Inform ☐ Train/re-train

PLACE IN SITE FILE #0.3

#7.1	Updated eCRF due to: 1. Expansion on data on protocol adherence in INCEPT-Thromboprophylaxis 2. Version and date are added to the document	☒ Add ☐ Replace ☐ Inform ☐ Train/re-train
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