

PLACE IN SITE FILE #4.2.2

Domain specific appendix (DSA) change log for INCEPT-Albumin

DSA version		Date of approval in CTIS Part I	Date of approval in CTIS Part II	Participant information	eCRF	
Start version: 1.3 Dated: 13-02-25		Date of approval: 17-02-25	Date of approval: 14-02-25	Start version: 1.3 Dated: 07-02-25	Start version: 1.0 Dated: 12-06-25	
DSA version	Short description of DSA change	Date of approval in CTIS Part I	Date of approval in CTIS Part II	Changes in participant information	Correction in eCRF	What changes have been made in the eCRF
New version: 1.4 Dated: 20-08-25	- Updated to match updated core protocol version/date. - Clarification in the abstract that safety outcomes will be reported after 30 and 90 days (section 1). - Updated timeline (section 1 and section 13.5). - Updates to reporting checklists and their use: checklists now refer to sections instead of pages (to facilitate	Date of approval: 29-08-25	Date of approval: 29-08-25	☐ No ☒ Yes, new version: 1.4 Dated: 25-06-25 This new version only concern changes in wording not leading to any	☐ No ☒ Yes, new version: 2.0 Dated: 18-09-25	With the addition of INCEPT-Thromboprophylaxis, the registration of major bleeding in Day forms was expanded to give site of bleeding. This was to align the registration in the 2 domains

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	updating), and SPIRIT updated to 2025 version (and additional details have been to multiple sections to comply with the updated version, including specific contributions in section 2.2 and minor additional details elsewhere) (section 6.1, and appendix 1, section 14.1). • Clarification of the locations where domain-specific safety outcomes will be registered (section 6.7, section 8.1, and appendix 6, section 14.6). • All sensitivity analysis priors are now referred to in every relevant section (section 7.5, section 7.7, and section 7.9). • Added hypovolaemic shock due to fluid loss as a category under 'Other types of shock' (section 8.1 and section 14.6). • Updated Table S2 to display absolute differences before relative differences, due to the primary estimand being on			changes in meaning		
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	the absolute scale and changed the number of decimal points for some fields (appendix 3, section 14.3). • Minor corrections, updates, and semantic edits in multiple places not leading to any changes in meaning.					
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DSA version	Short description of DSA change	Date of approval in CTIS Part I	Date of approval in CTIS Part II	Changes in participant information	Correction in eCRF	What changes have been made in the eCRF
New version: 1.5 Dated: 01-04-2026	• Correction of rounding error in abstract (section 1). • Corrected wording regarding recommendation strength for 2024 ESICM guideline (“recommends” replaced with “suggests”) in section 5.3 and added explicit strengths of recommendations throughout this section. • Protocol adherence outcomes also listed in section 6.9 (in addition to Table 3), and the detailed definitions from Table 3 (section 6.9) are now also listed in appendix 6 (section 14.6). • Clarifications with regards to what is included in the ‘one or more domain-specific safety outcomes’ outcomes (section 6.7), matching most recent version of the core protocol.	Date of approval: 18.06.2026	Date of approval: 18.06.2026	☒ No ☐ Yes, new version: Dated:	☒ No ☐ Yes, new version: Dated:	

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	• Clarification that total volumes of albumin include all administered albumin, regardless of reasons for administering (including albumin administered in the <i>no albumin</i> arm under the special circumstances where this is permitted) in Table 3 (section 6.9) and Table S4 (appendix 3, section 14.3). • Added two feasibility outcomes: mean and median percentage of intervention days with a protocol violation (using the already defined protocol violations criteria) in Table 3 (section 6.9) and appendix 6 (section 14.3). These will also be reported under separation data (appendix 3, Table S4). • Clearer definition of the '<i>recruitment proportion</i>' feasibility outcome (Table 3, section 6.9 and appendix 6, section 14.6). • Clarifications and additional details on data the domain IDMSC will review at					
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	the annual meetings in addition to safety data and updates on how this will be presented (section 10.2). • Added erroneously missing variable (sex) to the general model formula for analyses outlined in appendix 4, section 14.4 (the inclusion of this variable is defined in the core protocol). Similarly, use of circulatory support is no longer listed as an adjustment variable in the same place, as the domain-specific eligibility criteria requires all participants to be on circulatory support at the time of domain inclusion. • Updated definition of the feasibility outcomes '<i>time to completion of the feasibility phase</i>' and '<i>recruitment proportion</i>' in appendix 6, section 14.6 to match the definition in Table 3 (section 6.9). • Updated definition of the '<i>participants without consent to continued collection of data</i>' feasibility criteria in Table 3					
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	(section 6.9) and appendix 6 (section 14.6); the definition now focuses on consent to continued collection of data instead of consent to the use of data. • Additional minor clarifications of feasibility outcomes in section 6.9 including Table 3. • Minor corrections/updates/semantic edits not leading to any changes in meaning.					
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