

PLACE IN SITE FILE #4.2.3

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

DSA version		Date of approval in CTIS Part I	Date of approval in CTIS Part II	Participant information	eCRF	
Start version: 1.1 Dated: 20-08-25		Date of approval: 29-08-25	Date of approval: 29-08-25	Start version: 1.0 Dated: 25-06-25	Start version: 2.0 Dated: 18-09-25	
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: 1.2 Dated: 01-04-2026	<ul style="list-style-type: none"> Added the Netherlands Thrombosis Foundation as funder (section 1 and section 11.2). Added statement that the use of biosimilar LMWHs subject to stricter monitoring, which is not allowed, will be assessed not only at site initiation, but also systematically and regularly during domain conduct (section 6.3). Clarifications with regards to what is included in the 'one or more domain-specific safety outcomes' outcomes 	Date of approval: 18.06.2026	Date of approval: 18.06.2026	☒ No ☐ Yes, new version: Dated:	☒ No ☐ Yes, new version: Dated:	

DSA change log for INCEPT-Thromboprophylaxis, version 1.1 – 2026-07-02

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	<p>(section 6.7), matching most recent version of the core protocol.</p> <ul style="list-style-type: none"> • Clarifications to justification for period of registration of HIT and handling of possible versus definitive HIT events in the 'one or more domain-specific safety outcomes' outcomes (Table 4, section 6.7). • Updates and clarifications of domain-specific feasibility outcomes (Table 5, section 6.9): clarification regarding 'recruitment proportion', consent to use of data replaced with consent to continued collection of data, and clarifications regarding how the separation-focused feasibility outcomes will be calculated. • Correction of typo in stopping rule for inferiority in section 7.3 (unchanged in all other places, where it was correct). • Added erroneously missing variable (sex) to the general model formula for 					
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	<p>analyses outlined in appendix 9, section 14.9 (the inclusion of this variable is defined in the core protocol).</p> <ul style="list-style-type: none"> • Clarifications and additional details on data the domain IDMSC will review at the annual meetings in addition to safety data and updates on how this will be presented (section 10.2). • Minor corrections, updates, and semantic edits in multiple places not leading to any changes in meaning. 					
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