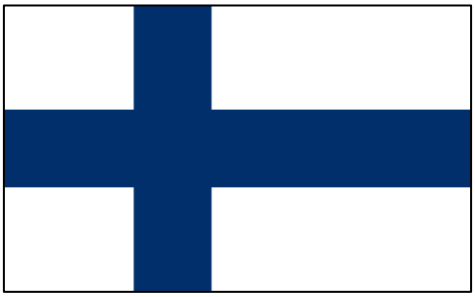
The Intensive Care Platform Trial (INCEPT)

Finland



National appendix

National appendix version and date
Version 1.1, 2026-04-01

Corresponding core protocol version and date
Version 1.5, 2026-04-01

Website: www.incept.dk

Applicable core protocol registration numbers
European Union Clinical Trials Information System (CTIS) EUCT number: 2024-516208-41-00.
ClinicalTrials.gov identifier: NCT06667999.
Universal Trial Number: U1111-1313-8171.

Table of contents

1 | Administrative information 3
1.1 | Protocol and national appendix structure 3
1.2 | National coordinator 3
2 | Abbreviations 4
3 | Screening, inclusion, and informed consent procedures 5
4 | Discontinuation and withdrawals 8
5 | Outcomes and safety 9
5.1 | EQ-5D-5L value set 9
5.2 | Safety outcomes 9
6 | Other considerations 10
7 | Summary of changes 11
8 | References 12

1 | Administrative information

1.1 | Protocol and national appendix structure

This is a national appendix to the *Intensive Care Platform Trial (INCEPT)* core protocol. Everything described in the version of the core protocol listed on the front page applies except where explicitly stated otherwise. This national appendix only covers details that are specific to this country and not otherwise covered by the *INCEPT* core protocol. The national appendix should be read along with the core protocol.

1.2 | National coordinator

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A list of national coordinating investigators in all participating countries will be made available on the *INCEPT* website prior to first inclusion in each country and continuously updated.

2 | Abbreviations

CTIS: *Clinical Trials Information System*
eCRF: *electronic case report form*
EU: *European Union*
EUCT number: *European Union Clinical Trials Information System (CTIS) number*
GCP: *Good Clinical Practice*
HRQoL: *health-related quality of life*
INCEPT: *the Intensive Care Platform Trial*

3 | Screening, inclusion, and informed consent procedures

The following section contains specific procedures that apply for Finland in addition to the generic principles outlined in the core protocol, including the use of a modular approach to the informed consent procedure with information only given for the domains that are relevant for a specific participant.

Finnish informed consent procedure
First, patients fulfilling all platform inclusion criteria and no exclusion criteria will be screened and randomised to domains for which they fulfil all domain-specific eligibility criteria by trained trial staff. As soon as possible hereafter, informed consent for continuation in the platform trial (including all applicable domains) will be obtained from a legally designated representative (in Finland a close relative). All informed consents will be obtained by medical doctors trained and certified in the trial protocol and follow all applicable regulations.

Written information can be delivered either in paper form or electronically, using a platform with strong identification. For the relatives, verbal information will be given either in person or by a video call according to the relative's preferences. Video calls, where used, will be individual, direct, and with simultaneous dialogue following adequate identification of the participant and relatives, and the right to confidentiality will be ensured by ensuring that all involved parties are in a place and time where they can talk privately prior to discussing the trial. Relatives may be contacted by regular phone calls to arrange the meeting in person or via video call, according to personal preferences. The relative has the right to bring a companion. During this conversation, we will arrange how to send the written information to the relative (i.e., via email or by physical mail) or inform the relative about how to access the digital information. We will encourage the relative to read the written information before the next conversation, during which the relative has a possibility to ask questions. After we have informed the relative about the trial, and he or she is willing to consent, we will ask the relative to sign the consent form and return the signed consent form personally or by post. Alternatively, the relative will log in to the platform containing the trial information by using a strong identification system and sign the consent form digitally. A PDF copy of the signed consent form is printed, saved and a copy is delivered to the relative.

Participants will be asked for informed consent as soon as possible hereafter. For participants, both oral and written information will be given preferably in person by a medical doctor trained and certified in the trial protocol. If this is not possible (e.g., the participant has been discharged to another hospital without participating sites), we will inform the participant by video call and proceed as described above. Either way, the participant has the right to bring a companion to the conversation. This conversation may similarly be arranged by contact through regular phone calls,

and the participants can choose to receive the oral information in accordance with personal preferences.

Of note, all consenting parties will be provided with written and oral information about the platform trial (including all relevant domains) allowing them to make an informed decision about participation in the trial. Written information and the consent forms will be subject to review and approval by the applicable competent authorities (e.g., the relevant ethical committees). The written information material will be in modular format and consist of general information about *INCEPT* and additional information sheets about all relevant domains. The informed consent procedure will be common and simultaneous for *INCEPT* including all applicable domains, with explicit, written informed consent to each specific domain using separate informed consent forms, and with consent to one or more domains constituting consent to *INCEPT* including all elements that are common between domains. All consent forms will be signed by the consenting party and the medical doctor who has provided trial information for the consenting party. We will emphasise that the consenting party has at least 24 hours to decide whether to give consent or not. The consenting party can, at any time and without further explanation, withdraw consent to continued participation in the platform trial or specific domains.

Lack of informed consent from the participant's relatives

If information about the participant's relatives is not available after inclusion, the investigator will do his/her best to seek information in all reasonable ways, e. g., from the police. In these situations, it may take, e.g., 1-2 weeks to conclude that no relative can be identified. If a relative is not identified and the participant remains unable to consent themselves, the trial intervention(s) will be discontinued but data collection will be continued. All initiatives to identify the participant's relatives will be documented in patient files, logs or similar. The same procedure has been used in other approved related trials [1–5] .

Lack of informed consent from the participant's relative and the participant deceases

If the participant deceases before informed consent is obtained (due to rapid progression of critical illness or because the participant's relative is not yet identified), the consent procedure will be stopped. If the participant has been correctly included in the trial and reasonable attempts to identify relatives and obtain their informed consent have been made, the collected data will be kept and analysed, and additional data from the electronic patient record may similarly be collected and analysed.

Trial personnel

The screening will be done by trained trial staff in collaboration with the treating clinical doctor, who ultimately decides if a patient can be enrolled in the trial and individual domains. When a candidate patient is identified, a member of the trained trial staff will screen the patients in the electronic case report form (eCRF). Collection of informed consent will be performed by medical

doctors who are trained and certified in the trial protocol. If questions arise during the informed consent procedure, coordinating trial staff (including the sponsor) can be reached through the 24-h trial hotline. All medical doctors with consent functions in the *INCEPT* trial will be trained and approved according to *Good Clinical Practice* (GCP) guidelines before engaging in the trial.

4 | Discontinuation and withdrawals

The core protocol outlines the procedure for handling discontinuations and withdrawals in *INCEPT* according to the applicable Danish regulations as well as EU Clinical Trial Regulation 536/2014 [10].

In Finland, the EU Clinical Trial Regulation 536/2014 [10] applies as well as the applicable Finnish legislation, National Act on Clinical Trials (983/2021) [9].

5 | Outcomes and safety

5.1 | EQ-5D-5L value set

For the EQ-5D-5L instrument [6] used to assess health-related quality of life (HRQoL) at day 180, we will use the Danish national EQ-5D-5L national value set [7] for participants enrolled in Finland to calculate EQ-5D-5L index values for the primary analyses. Currently, no Finnish national value set is available.

5.2 | Safety outcomes

The *INCEPT* core protocol outlines the handling of safety outcomes in *INCEPT* domains based on European Union (EU) regulations [8] for the assessment of safety outcomes for pharmacological interventions (investigational medicinal products); this procedure applies to Finland with no country-specific adaptations and no additional collection or reporting of additional safety data.

6 | Other considerations

Insurance

Trial participants in Finland are covered by the "*Pharmaceutical injuries insurance regarding bodily injuries resulting from a pharmaceutical product marketed in Finland"* [11]. Other types of injuries are covered by "*Patient insurance"* [12].

7 | Summary of changes

This section summarises all changes to the national appendix after initial submission for approval.

Version 1.1, 2026-04-01:

- Updated to change core protocol version.

Version 1.0, 2025-12-18: first version submitted for approval.

8 | References

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[9] Act on Clinical Trials on Medicinal Products. https://www.finlex.fi/api/media/statute-foreign-language-translation/687537/mainPdf/main.pdf?timestamp=2021-11-18T22%3A00%3A00.000Z. Accessed December 01, 2025

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[11] Insurance coverage for users of medicinal products https://www.laakevahinko.fi/en/https://www.laakevahinko.fi/en/tietoa-laakevahinkovakuutuksesta/. Accessed 26 Jun 2025

[12] The Finnish Patient Insurance Centre.https://www.pvk.fi/en/Accessed 20 Nov 2025