The Intensive Care Platform Trial (INCEPT)

Austria

National appendix

National appendix version and date
Version 1.0, 2026-06-30

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Version 1.5, 2026-04-01

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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 coordinating centre

National coordinating centre
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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 Austria 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.

Austrian informed consent procedure
First, patients fulfilling all platform inclusion criteria will be screened. If screened patients fulfil any platform exclusion criteria, they will be excluded. Otherwise, they will be randomised to domains for which they fulfil all platform and domain-specific eligibility criteria by trained trial staff.

Participants will be asked for informed consent as soon as possible thereafter. Since acutely ill patients are unable to provide consent before trial inclusion, a deferred consent model is used. For participants, both oral and written information will be given in person by a medical doctor trained and certified in the trial protocol. The participant has the right to bring a companion to the conversation. Following the briefing, the patient may consent to continued inclusion in the trial and the continuation of assessments and data processing by providing a handwritten signature or may refuse to give consent.

If the participant is clearly able to understand the informed consent discussion but is unable to give their informed consent in writing, consent may be given and recorded in the presence of an impartial witness. In this case, the witness shall sign and date the informed consent document. The witness must not be part of the trial team. The physical inability to sign must be documented by the trial investigator in a credible manner.

Unlike in other EU-countries, Austrian law does not automatically entitle a participant's relatives to give consent to clinical trials. However, patients may appoint a legal representative prior to treatment. If a participant has appointed such a representative, the trial staff will attempt to contact them as soon as possible after treatment and arrange an appointment to obtain informed consent. If contact is successfully established by telephone, the legal representative will be given the opportunity to make an appointment at the study centre with a medical doctor who is trained and certified in the trial protocol and certified in obtaining informed consent.

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 and all relevant domains. Written information and the consent form will be subject to review and approval by the applicable competent authorities (e.g., the relevant

ethical committees). 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 must have sufficient time to consider their decision 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.

In the event of the patient's death

If the participant deceases before written informed consent is obtained, the consent procedure will be stopped. If the participant has been correctly included in the trial, 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 single 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. The same regulations apply in Austria, except that relatives cannot withdraw participants from the trial (see section 3).

5 | Outcomes and safety

5.1 | EQ-5D-5L value set

For the EQ-5D-5L instrument [1] used to assess health-related quality of life (HRQoL) at day 180, we will use the Austrian national EQ-5D-5L value set [2] for participants enrolled in Austria to calculate EQ-5D-5L index values for the primary analyses.

5.2 | Safety outcomes

The *INCEPT* core protocol outlines the handling of safety outcomes in *INCEPT* domains based on European Union (EU) regulations [3] for the assessment of safety outcomes for pharmacological interventions (investigational medicinal products); this procedure applies to Austria with no country-specific adaptations and no additional collection or reporting of additional safety data.

6 | Other considerations

Insurance

Trial participants in Austria have to be covered by an insurance. The contract with the platform sponsor site will regulate this point for each site. For the Medical University of Vienna, the standard insurance used by the university will be contracted, paid by the platform sponsor site.

7 | Summary of changes

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

Version 1.0, 2026-06-30: first version submitted for approval.

8 | References

[1] Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res 2011;20:1727–36. https://doi.org/10.1007/s11136-011-9903-x.

[2] Jensen CE, Sørensen SS, Gudex C, Jensen MB, Pedersen KM, Ehlers LH. The Danish EQ-5D-5L Value Set: A Hybrid Model Using cTTO and DCE Data. Appl Health Econ Health Policy 2021;19:579–91. https://doi.org/10.1007/s40258-021-00639-3.

[3] EudraLex - EU Legislation. Risk proportionate approaches in clinical trials - Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use. EudraLex - Vol 10 - Clinical Trials Guideline 2017. https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en (accessed December 20, 2023).