

INCEPT newsletter #11 – February 2025

Dear friends and colleagues,

INCEPT, including the INCEPT-Albumin domain, has been approved by the Danish authorities. This is a major milestone! The key protocol documents will be made publicly available on the INCEPT website shortly and can be freely shared following that.

During the approval process, some changes have been made – most are relatively minor, but two important changes were required:

1) The approach to informed consent has been changed slightly. The procedure itself is unchanged, including the modular approach to information materials and the procedure being simultaneous and combined for all domains that a participant has been included to or may be included to later during the same ICU stay. We have, however, been required to obtain separate signatures for each domain during the consent procedure (alternatively, withdrawal or denial of consent to a single domain would require us to withdraw participants from all domains, which was a worse alternative). We hope that this procedure can be simplified further in the future, but this was not an option at this time.

2) We have been required to send annual updates on progress, consent status, etc. to the authorities for each domain. This will be done in conjunction with the annual IDMSC meetings and the previously planned safety reporting as most of the information requested was already planned to be assessed on these occasions.

We are working hard on the eCRF. Together with the legal department at Rigshospitalet we are progressing with clinical trial agreements and data processing agreements. And we're working on the trial master file and monitoring plan with the GCP-unit. So, everything is moving forward, and we expect to be able to start inclusion at Rigshospitalet in April.

We have discussed that it may be time to rethink our meetings. We'll maintain the INCEPT meetings, but they may develop into network meetings every third month where new clinical, methodological, or other ideas are discussed. In addition, they'll serve as a forum for feedback for the relevant working groups. These meetings will be scheduled at the same time as we are used to, but only every third month. Furthermore, one of the INCEPT meetings (within a three-month period) will be converted to management committee meetings, as the project now moves into a new phase. We will send new/updated calendar invitations for both meetings.

Stakeholder involvement:

- The process of developing a core outcome measurement set has begun, however, it is still in a very early phase. We have agreed to involve the research panels in the first step, where we will define the outcomes and provide them with the opportunity to participate throughout the process. Additionally, it would be beneficial to involve them in the final step to reach consensus on the recommended measurements.

Methods:

- The *domain-specific appendix* template has been updated following the changes made to the core protocol and *INCEPT-Albumin* during the approval process. Whenever you are ready to start actively writing the 'protocol' for a domain, please reach out and we will provide you with the newest version and assist you in the process.
- A manuscript describing INCEPT, focusing on the core protocol and general methodology, will be submitted to *Acta Anaesthesiologica Scandinavica* shortly. All core protocol contributors have been invited as co-authors.

Data:

- Intense work on getting the workflows and design right so the eCRF is as user friendly as possible.
- We expect the first beta version to be ready for testing by real users (read: you) around 1 March. If you want to help, make sure to send Benjamin or Rikke an email, so we can let you know when we are ready.
- Great progress in setting up automatic data capture, starting with the EPIC system in the Capital Region of Denmark. We do our best to create a scalable setup that can integrate with other systems as well with as little additional development as possible.

Funding:

- The MC will on one of the first meetings discuss the financial/budgetary expectations for new domains.

Clinical domains:

- Albumin domain:
 - First participant expected to be randomised in domain at Rigshospitalet in April 2025. Stepwise initiation of Danish sites will occur from May 2025 onwards. For sites also participating in EMPRESS, we will cover both trials at the initiation visits.
 - Plans for INCEPT and INCEPT-Albumin implementation in the other countries are being developed.
- Thromboprophylaxis domain:
 - No updates.
- Continuous glucose monitoring domain:
 - We have presented the domain to the research panel, and the DSA is being developed in the working group.
- Domains under consideration:
 - No updates
 - If you have any ideas, suggestions, or updates to coming or previously discussed domains not listed above (i.e., domains that are early in the planning phase) that you would like to discuss at future meetings, please reach out to Morten (morten.hylander.moeller@regionh.dk).

With collegial regards,

Anders Granholm, Anders Perner, Morten Hylander Møller,
Benjamin Skov Kaas-Hansen, Maj-Brit Nørregaard Kjær, Tine Sylvest Meyhoff, and Rikke Faebø Larsen
on behalf of the INCEPT coordinating group