INCEPT
The Intensive Care Platform Trial

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NEWSLETTER

Dear friends and colleagues,

It has been a good month for INCEPT with safety and feasibility meetings in both domains.

The first patients were enrolled in Iceland and in the Netherlands. A huge welcome to our Icelandic and Dutch colleagues.

Initiation meetings have been held in Stockholm and Finland. Hence, more Nordic participants are due from October and onwards.

Also INCEPT has been approved in Norway, Estonia and Austria. And the paperwork is ongoing in Switzerland and Saudi Arabia showing that the INCEPT-community is still growing.

New domains are on the way. INCEPT-Bicarbonate will likely commence in Q1 2027 and INCEPT-Insulin in Q2 2027.

Important notes

We all need to work on improving protocol adherence in the albumin domain, including remembering giving albumin in that arm when participants are in shock (i.e., at least immediately after randomization).

A short GCP-course for clinicians doing screening and consenting has been developed and will appear on the webpage soon. It's meant for training at new sites and for new colleagues at existing sites as a proportionate alternative to more extended GCP-courses.

Updates

Stakeholder involvement

After the development of the core outcome set, we evaluated the level of engagement among stakeholders in Denmark. The resulting paper, **'Evaluating meaningful patient and public involvement in intensive care research: a PEIRS-22 survey'**, has been accepted for publication in Nursing in Critical Care.

We hope to be able to share it with you soon.

We aim to use PEIRS-22 to evaluate the engagement in the core outcome measurement set as well.

Methods

New template for the upcoming DSA has been sent out to working groups for upcoming domains. If you are working on a new domain, and have not received the new template, please contact Anders Granholm

Data

A new data manager for INCEPT, Bolette Arildsen, has started mid-September. She has a master's degree in quantitative biology and disease modelling
and experience with clinical trials.
She will work mainly with data validation and analysis.

Upcoming events

- INCEPT/Easy-RF Workshop, October 23, 2026.
- INCEPT Platform management committee: November 25, 2026
- Introduction to advanced Bayesian adaptive trials: design and analysis, November 27-28, 2026

Clinical domains

Albumin domain

INCEPT-Albumin now also recruits in both Iceland and The Netherlands – thank you for initiating the domain at international sites!

Results from the integrated feasibility phase (covering the first 200 participants) have been shared with the domain and platform management committees and the domain IDMSC.
The overall conclusion is that the domain continues enrolment without modifications.
We are looking forward to sharing results more broadly!

One lesson learned from the feasibility data: please make sure to always keep allocation in mind for patients in INCEPT-Albumin. As they are in shock at time of randomisation, we expect that albumin is given following randomisation if they are allocated to the albumin arm, and vice versa if they are allocated to the no albumin arm.

We approach 600 participants - thanks a million for your contributions!

Thromboprophylaxis domain

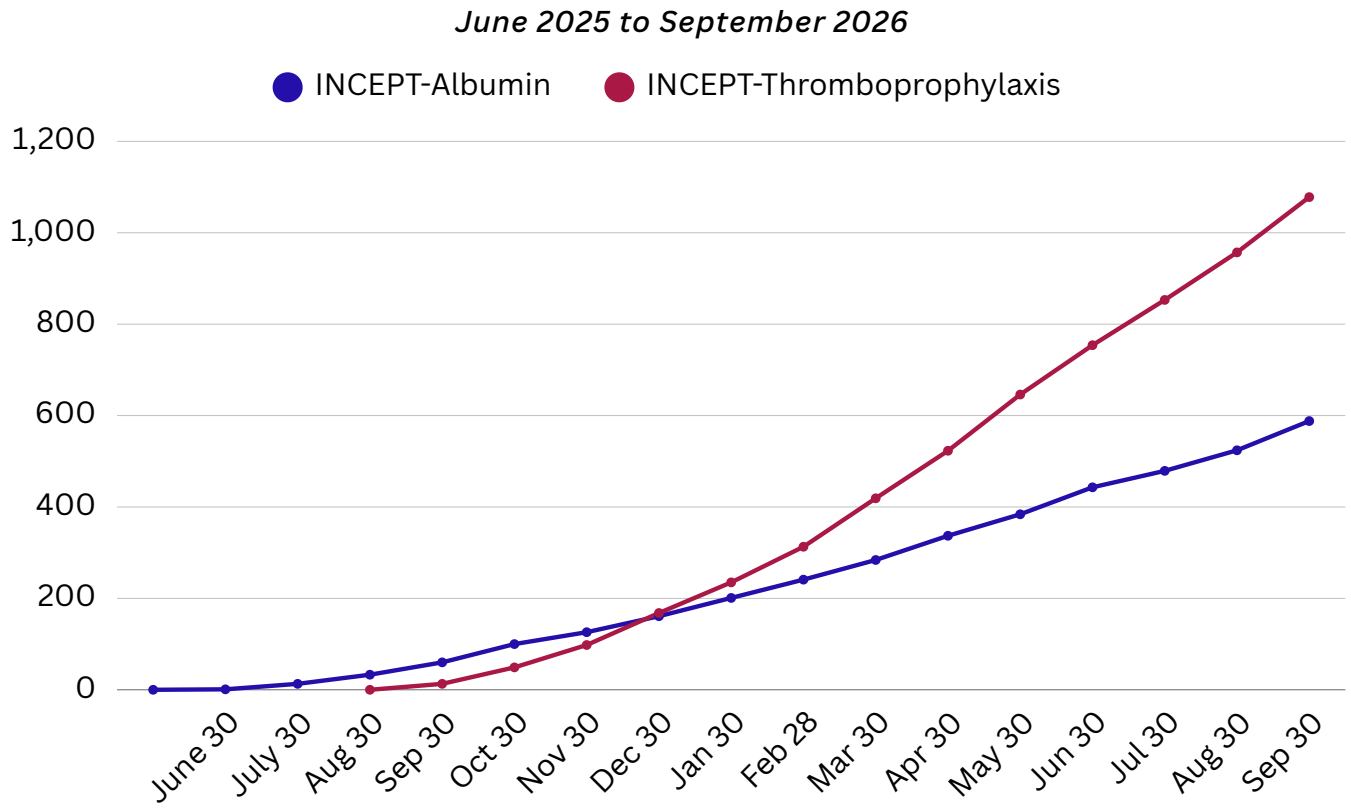
On September 3, the team in Iceland randomized their first participant, making INCEPT a truly international trial, and on September 10, participant number 1000 in the domain was randomized. These are both huge milestones and speak to the tremendous work on behalf of everybody involved.

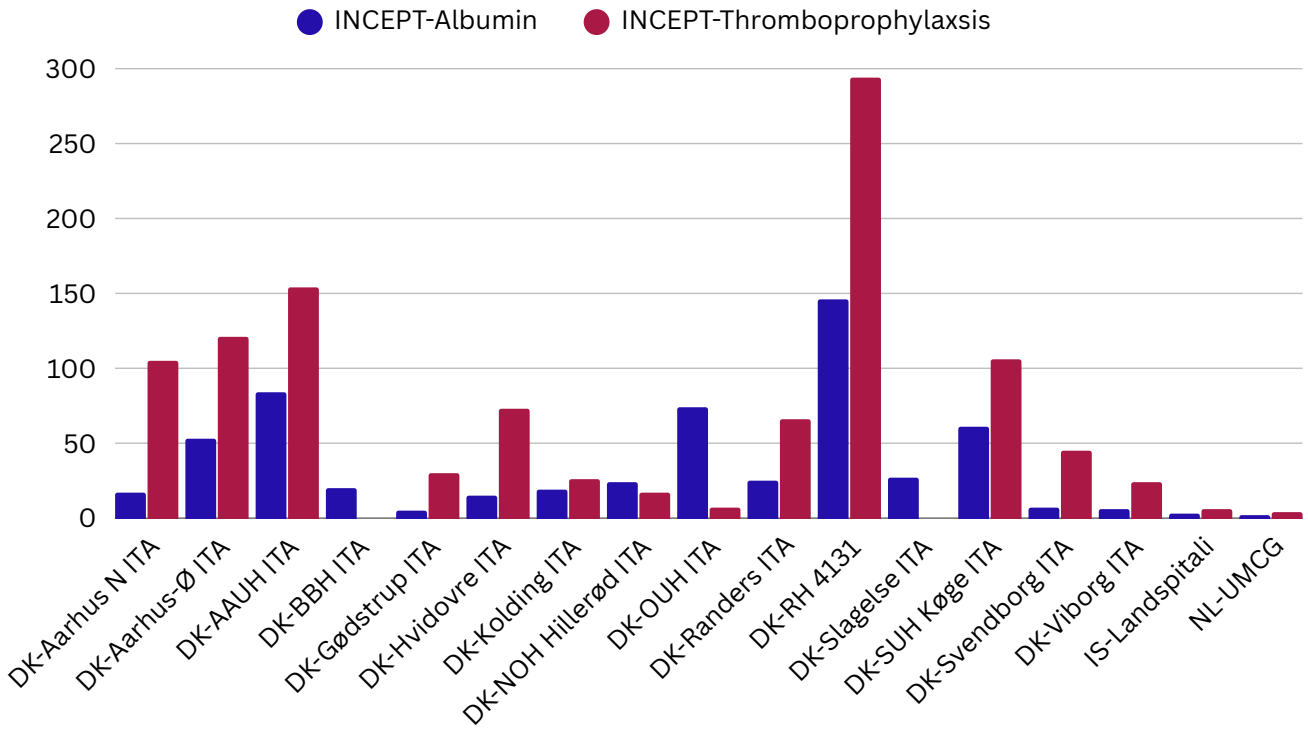
Based on current enrolment rates (100+ participants per months), by the beginning of January 2027 we will have included the 1500 participants for the first adaptive analysis, which will be our next common milestone.

Results from the integrated feasibility phase (covering participants enrolled until late February 2026) are now in and have been shared with the IDMSC. The IDMSC congratulated the whole team on a well-conducted domain and recommended continuing unchanged.

Thank you all for making it happen!

Enrolment overview





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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,

The INCEPT Coordinating Group

Anders Granholm, Anders Perner, Morten Hylander Møller, Maj-Brit Nørregaard Kjær, and Rikke Faebo Larsen