INCEPT
The Intensive Care Platform Trial

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www.incept.dk
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NEWSLETTER

Dear friends and colleagues,

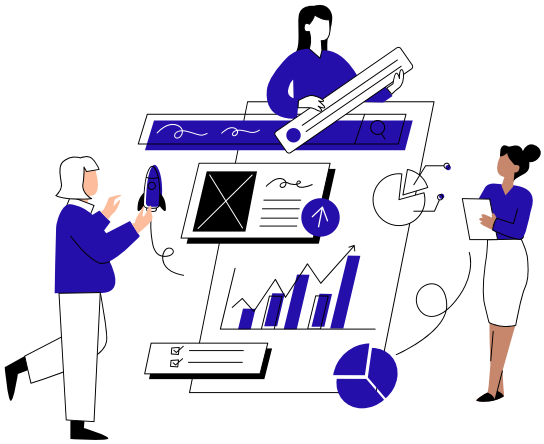
Through hard work at sites and centrally at the INCEPT core team 645 individual participants (752 randomisations) have been enrolled in INCEPT at 15 DK sites.
This is a major achievement in 9 months.

Welcome to Slagelse, now activated and first patient enrolled, and to Nanna Reiter, the newly appointed PI at Bispebjerg Hospital!

More countries and sites are CTIS-approved in INCEPT: Sweden (3 sites), the Netherlands (5 sites), Finland (4 sites) and Iceland (1 site), thanks to the hard work by the national investigators and the INCEPT-office.

The paperwork for Norway, Switzerland, Austria, Estonia, and Saudi Arabia is being prepared.

The GCP-reports are coming in – they look good with few issues around delegation logs and consents. A big thanks to everyone!



Central data quality assessment workflow has been established – you may have been involved in query solving, thanks for the very swift work!!

Data have been analysed for the 1st annual safety report (deadline for submission to the authorities is 19 April).
Timely entry and few queries and missing data = AMAZING JOB AT SITES!!!

The feasibility analyses for both domains are coming up this summer. More about the deadlines for data entry and query solving later.

Important notes

New webpage:
A newly designed version has been launched at www.incept.dk, including important new features. All relevant documents in updated versions are presented under Ressources and Key protocol documents and Site file. Sites will from now on receive an email when there are new documents or new versions existing document but will not receive the documents by email.

Regarding registration of relocation events after day 90:
You should not register "relocation events" (discharges/admissions) more than 90 days after the most recent domain inclusion in INCEPT. This is because discharges and admissions have no relevance after the 90 days follow-up period and therefore do not affect data collection. Moreover, registering these events after the 90 days period may in some cases influence what site is assigned responsibility for conducting the 180-day follow-up, which is inappropriate and may affect the payment of case money.

Data validation:
You've all been great at resolving the queries we recently sent out regarding validation of data.
Some of you have experienced that a query disappeared from your overview before you handled it and have asked why. This is usually not due to any problem, but simply happens because you resolved another query for the same participant in the meantime. It happens when you correct something in the same observation that the first query was concerned with (for example an erroneous registration on a dayform of the variable 'major bleeding').

On documentation of consents in easyRF:
When we document consents in easyRF we sometimes create an event of the type "Consent from…" to make a comment on the consent process – but before actual obtainment of the written consent.
Later, when we come back to upload the signed form as a file, we choose a date. **This date should be the date the form was signed by the consenting party**, (e.g., the relative) not the date the file is being uploaded.

Case money:
We will begin calculations for the first case money payment on April 30. Site investigators will receive an email one week in advance with amount to be paid to site. This is to give sites time to finalize participant data entry (e.g., consent has been concluded, data entered up to 90-day and 180-day follow-up).

Updates

Methods

A two-part series on the key considerations for planning adaptive platform trials has been published in the Journal of Clinical Epidemiology, click here for Part 1 and Part 2.

Clinical domains

Albumin domain

Enrolment is progressing well with 302 included participants. First IDMSC meeting with review of annual safety data has been held and the IDMSC recommends to continue the domain unchanged.

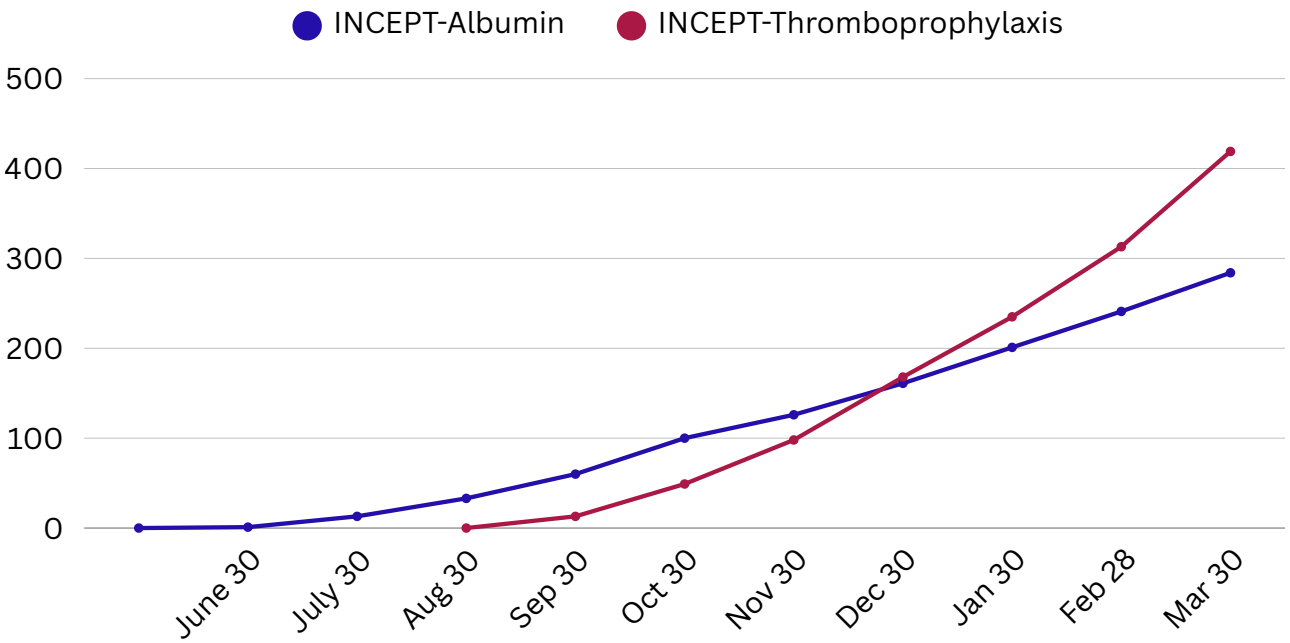
One note from IDMSC: 22% of participants in the No albumin-arm was registered to receive albumin in the ICU, but only 6 % had a protocol violation registered. Please make sure that only albumin use in the ICU is registered, and be aware of the allocation group when registering protocol violations.

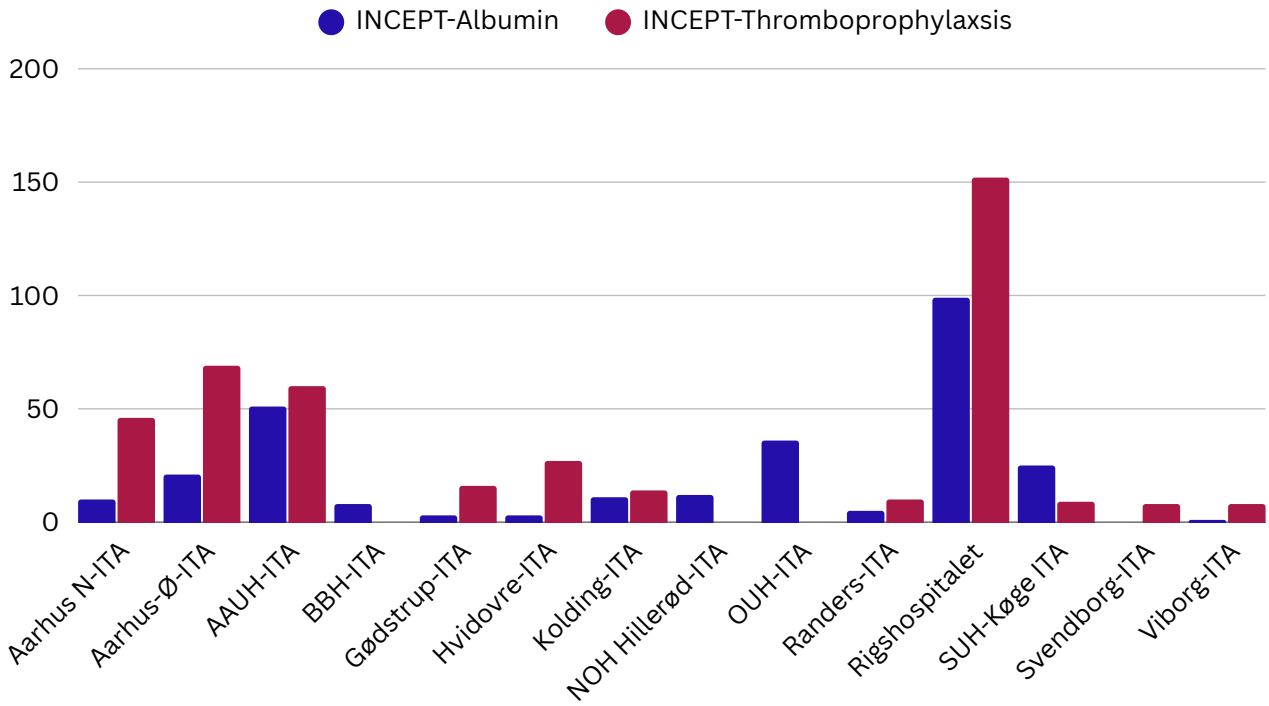
Protocol article describing the domain published in Acta Anaesthesiologica Scandinavica, *link*.

Thromboprophylaxis domain

Enrolment in INCEPT-Thromboprophylaxis is progressing well with 449 included participants.

First IDMSC meeting with review of annual safety data has been held and the IDMSC recommends to continue the domain unchanged.





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Upcoming events

- The next INCEPT/EasyRF workshop will be held April 24, 2026. Click here to register for participation.
- CRIC Network Meeting, Panum. May 13, 2026.
- From Research to Practice – Implementation in Health Sciences. May 19-20, 2026. Click here to read more and register.
- INCEPT Platform management committee meeting. May 27, 2026, 15.00-16.00.
- PhD course in advanced Bayesian adaptive trial design, June 3-4, 2026. Click here to register.
- INCEPT Network meeting. June 24, 2026, 15.00-16.00.

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