

NEWSLETTER

Dear friends and colleagues,

INCEPT is continuously enrolling very well.

We have crossed the 1000 randomisation mark. VERY WELL DONE!!!

Fewer participants than expected are co-enrolled in the 2 domains, which increases the overall workload (one main benefit of platform trials is re-use, including that among co-enrolled participants).

The INCEPT community is growing - more sites will be opening in Sweden, Finland, and Iceland after August; in the Netherlands it may be before the summer holidays.

The paperwork for approvals in Norway, Estonia and Austria is far in the process.

An ethics application for INCEPT has been submitted by colleagues in Saudi Arabia after a very effective process.

The INCEPT office presently works with case money payout, so that all your good work is supported.



Important notes

Newsletter

It is important that all site investigators and project nurses receive the newsletter. So please check at your site.

If a person is missing on our email list, they can sign up on the [website](#) or send an email to contact@incept.dk.

Updates

Data

About the use of the 'Unknown' button in EasyRF

As part of our ongoing monitoring of data entry, we have noticed that the 'Unknown' button is sometimes used inappropriately.

The 'Unknown' button exists for all variables on baseline and day forms, but it should only be used when the value of the variable is truly non-existent/impossible to obtain.

Specific attention to the following variables is needed: "Any registered coma" (rarely 'Unknown' in an ICU setting, even if the electronic health record contains for example no RASS or GCS score), "Any registered positive delirium score" (if the health record contains no registered score, the value is 'No' and not 'Unknown'), Clinical Frailty Scale (even if CFS is not registered in the health record, investigator/the one doing data entry should assess frailty and assign a value based on information available about the patient), and height and weight (if they have not been measured, an estimate should be registered – and such almost always exist, because they are used for dosing of drugs etc.).

Funding

The funding team continuously apply for funding because of the unique features of INCEPT (a platform trial without a stopping date, domains with very high maximum sample sizes, high resource use centrally and high number of enrolments at sites).

Clinical domains

Albumin domain

Thank you for nice discussions on the domain at the CRIC network meeting!
Welcome to the ICU in Svendborg, DK.

Analyses for the feasibility phase (n=200) will be conducted over summer, and we are looking forward to sharing results with you.



Thromboprophylaxis domain

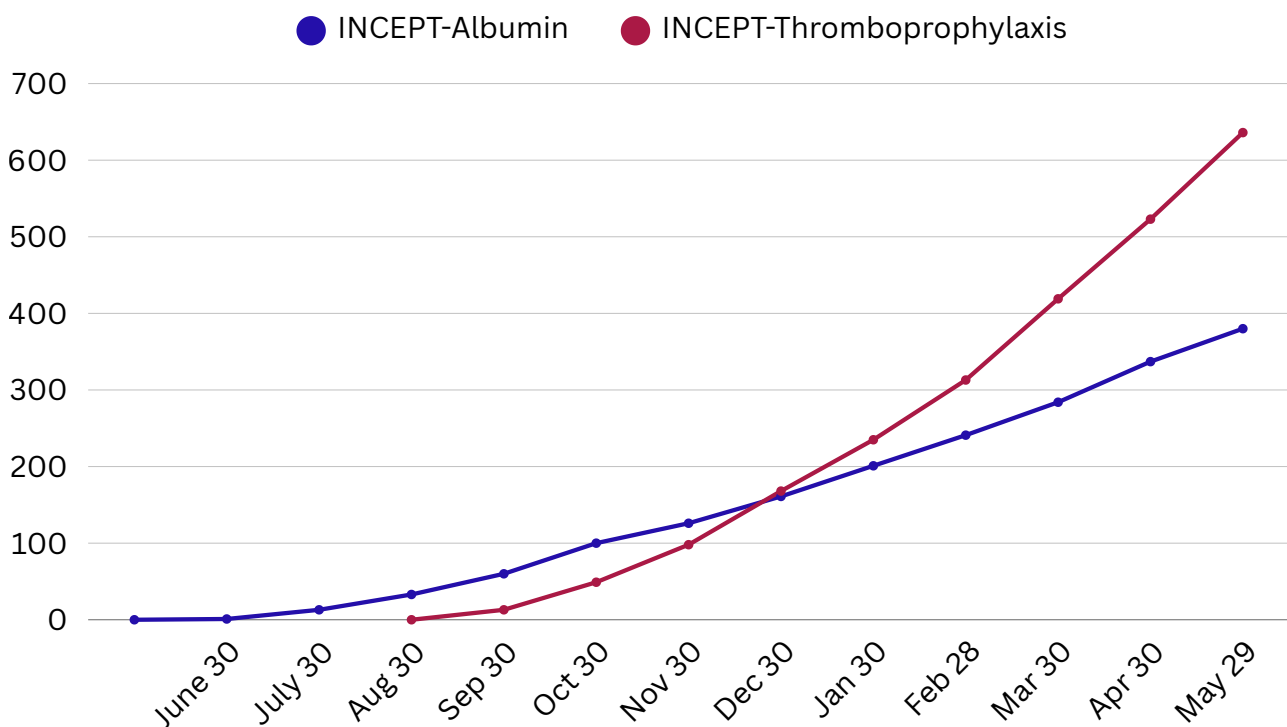
We have implemented a change in the EasyRF for the protocol adherence variable in INCEPT-Thromboprophylaxis "Administration of the site-preferred LMWH in the allocated dose" (yes/no).

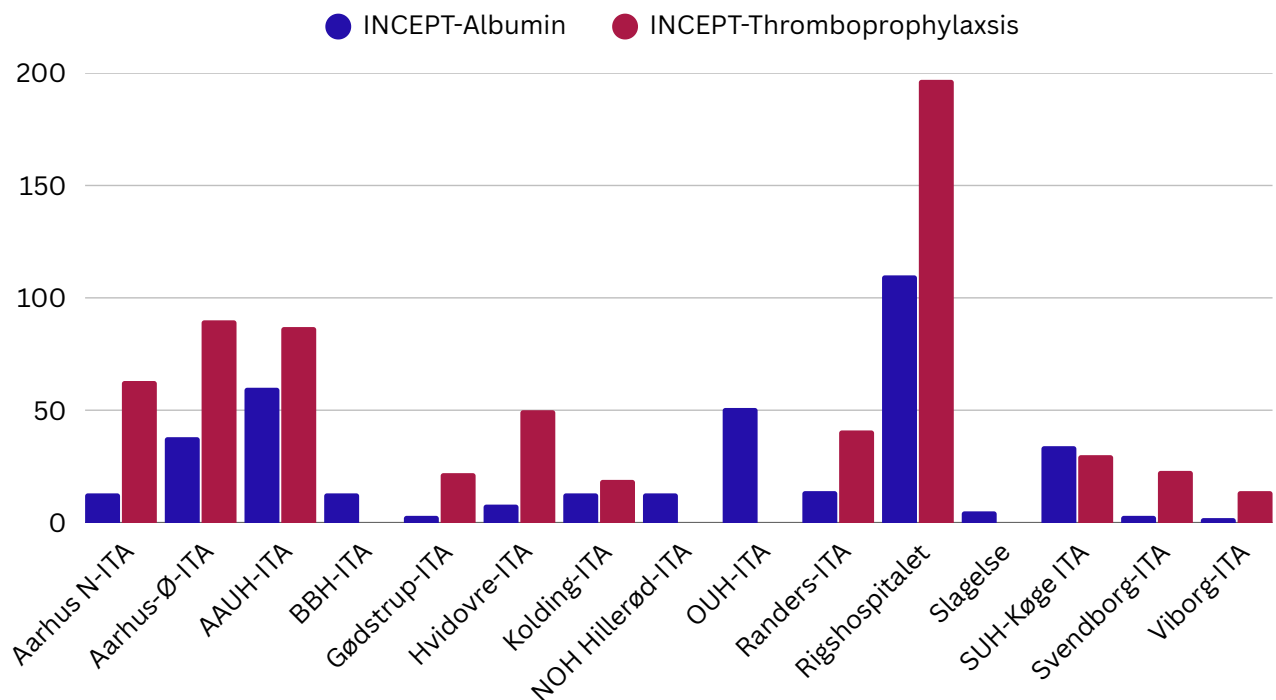
There were logistical situations in which filling in this variable created problems. We have solved this by adding three separate options under the "reason" for deviation in the EasyRF, each describing a situation in which administration has become irrelevant: when a dose was scheduled but not administered because the participant was admitted after or discharged before the scheduled dosing time, an 'End of participation' event such as withdrawal of consent has happened already, or the participant was at an INCEPT trial site not active in the Thromboprophylaxis-domain.

As for INCEPT-Albumin, analyses for the feasibility phase (n=300) will be conducted over summer, and we are looking forward to sharing results with you.

Enrolment overview

June 2025 to May 2026





Upcoming events

- PhD course in advanced Bayesian adaptive trial design, June 3-4, 2026.
Click [here](#) to register.
- INCEPT Platform management committee meeting. June 15, 2026, 15.00-16.00.
- The next INCEPT/EasyRF workshop will be held June 19, 2026.
Click [here](#) to register for participation.
- INCEPT Network meeting. June 24, 2026, 15.00-16.00.
- PhD course “Patient and public involvement in health research”, August 25-26, 2026.
Click [here](#) to register.

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

