

NEWSLETTER

Dear friends and colleagues,

INCEPT is doing well. Many sites are recruiting, several are initiated, and more Danish sites will be opened in the new year.

The GCP units have had the first monitoring at most sites (and second at some), the interaction appears good, and the comments are minor. One point has been about participants dying without consent being obtained from trial guardian and/or relatives; see the important note below.

Thanks to the data team for the nice and informative graphics on the frontpage of EasyRF.

The office work hard submitting the applications for the other countries (NL, SE, ISL and FI has been submitted, which is a major milestone).

BBH changes their site investigator January 1 to Nanna Reiter, welcome Nanna!



Important notes

- The updated procedure for obtaining consent in participants who died before relatives were informed has been circulated. Please ensure that any relatives to death participants not informed enrolled until now has been contacted as per the new procedure.

Please note trial guardian consent shall also be obtained for these participants.

- Upcoming deadlines where data entry should be final for participants enrolled before these dates:
 - INCEPT: 6/11 2025 annual safety report (the cut-off date is 18/2-26. With 90 days follow-up and 15 days for data entry and cleaning, this backtracks to early November 2025).
 - Albumin: 17/1 2026 (estim.) feasibility phase recruited (follow-up 90 days)
 - Thrombo: 11/2 2026 (estim.) feasibility phase recruited (follow-up 90 days)

We'll reach out if there are uncertainties; as always contact us (mail or hotline), if you have questions.

Updates

Workshops

We are excited to launch a new online, interactive workshop designed to help address common challenges with INCEPT and the EasyRF system.

This session will provide practical guidance, troubleshooting tips, and live Q&A to ensure smooth workflows and effective data management.

The first workshop, December 19, 2025, will be in Danish only, but from the beginning of 2026 the workshop will be available in English..

Funding

Additional funding has been obtained for INCEPT-Thromboprophylaxis (see below) and for the upcoming Bicarbonate domain.

Data

EasyRF has been slightly revised. A list of changes will be send directly from the team to site investigators and is also attached here as an appendix. Please archive it in Site File section 7.4 (eCRF; other).

Clinical domains

Albumin domain

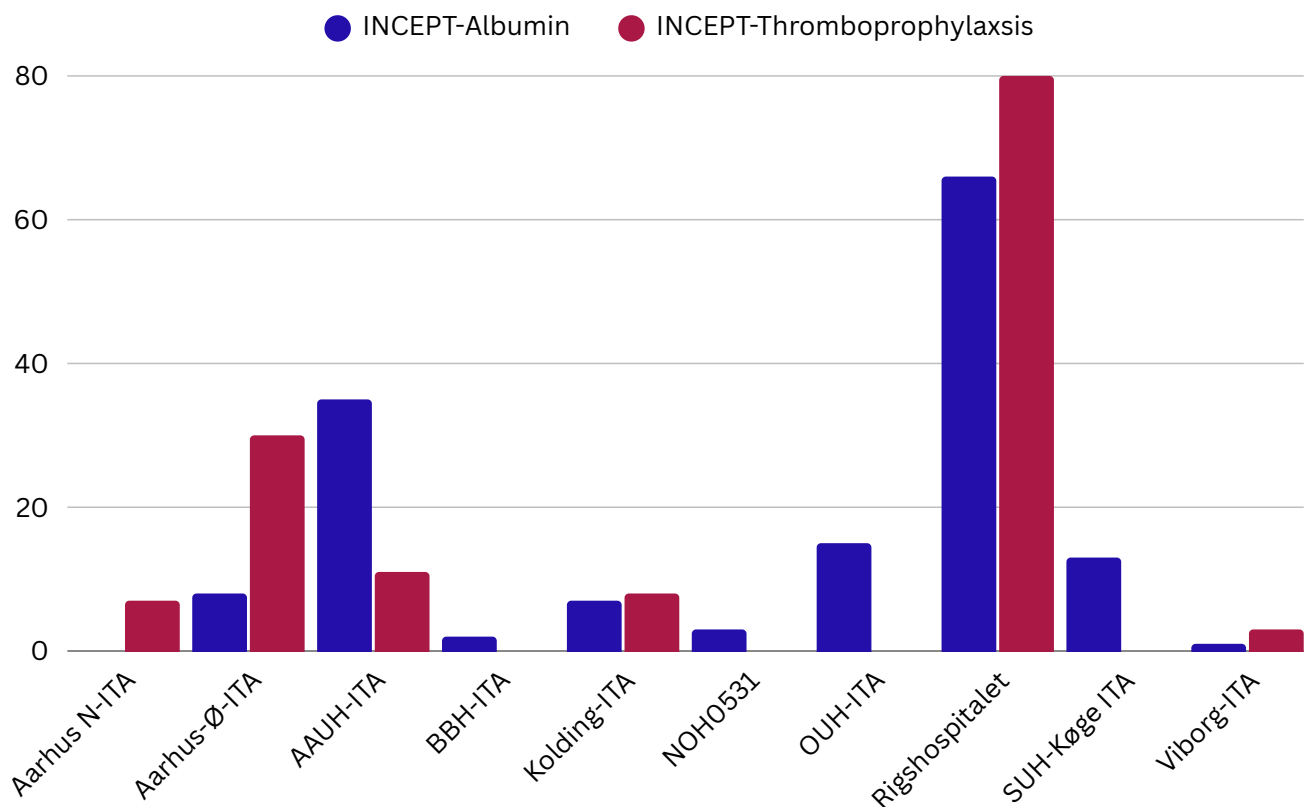
150 patients have been recruited at 10 active sites, which is as planned. 180-day follow-up is reached for the first participant around x-mas (enrolled at RH).

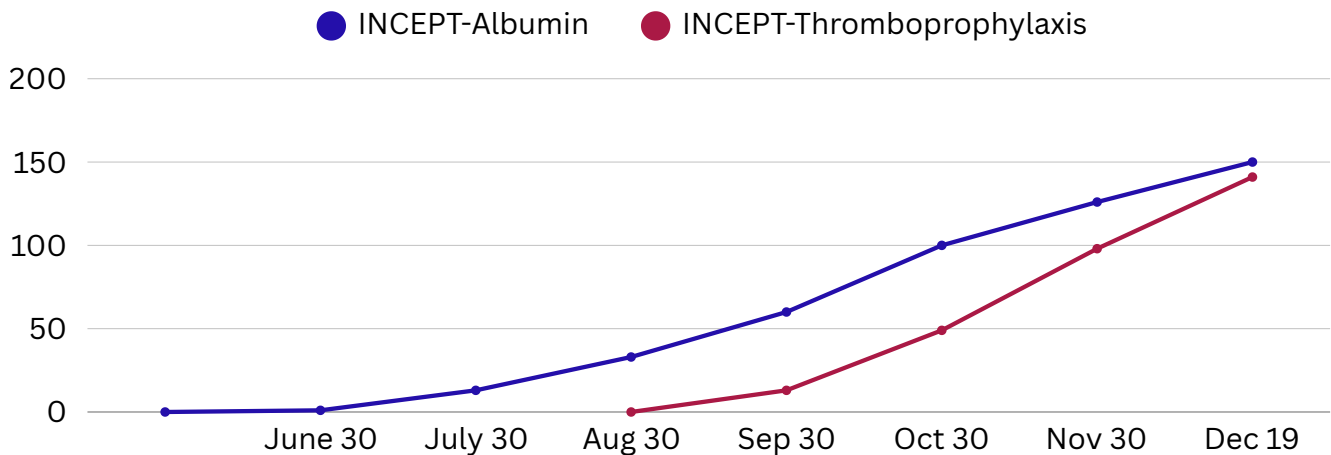
Thromboprophylaxis domain

141 participants have been included in the domain to date.

The paperwork has been submitted to add the Netherlands as a participating country in INCEPT, and anticipate expanding recruitment there in Q1 2026.

The domain was granted 300.000 € funding from the Thrombosis Foundation Netherlands.





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



Appendix:

Hello everyone,

We have recently release v0.11.x, with some new features and important fixes.

Data extraction

- Data now should be filtered correctly when selecting specific events and observations
- Date of creation for events was added
- Date of first value change for observation was added

Events, files and remarks

- Remarks can be edited after being entered in the system (not deleted) by some users (some roles cannot do that)
- In the contact information for the participant detail, there is a new box that can be used to add comments specific for a given participation. You decide what to write there, it could be language spoken or how to contact the participant at follow-up. Just remember that if the same person is in both trials, the comments will not be shared so you will have to write them separately (if they apply for both trials).
- Transfer will only be allowed to sites that have at least one domain running
- Now you can set the date and time when a file is uploaded. I would suggest using the time the consent was actually obtained when entering that field, since in this way we can estimate the time it takes to get the consent, and not only the time that it takes to upload the consent in the system . Also, this would allow to register two different times for two consents if obtained at different time points. In the following releases we will update the UI to make it more intuitive
- Many UI fixes and improvements

Long term follow-up

- All 180 days follow-up forms have been recreated according to protocols
- Blinded registrar should be able to login and simply edit the observations which are supposed to be edited by the blinded. If while entering blinded data you believe some information should not be visible to that user, please let us know (a bug with the blinded made all forms disappear, but that has now been fixed).
- Please note that part of the 180 days follow-up form (hrqol) have a 14 days slack so that data can be entered earlier. Standard registrar will be able to see the form fields as well, but the fields will appear as blocked - in case you wonder why you cannot edit.

Let us know if anything does not work as expected (support@easyrf.dk)

On behalf of the EasyRF team

Davide