

NEWSLETTER

Dear friends and colleagues,

INCEPT runs very well thanks to hard work from the core team and at sites!

The feasibility analyses of both domains will run over summer. We'll take care not to burden sites in July with queries about data.

We will evaluate the questions coming to the hotline to develop a FAQ list on the webpage of the most frequent themes. We will aim for hotline use being reserved for the more urgent questions.

You may have seen the new version of the webpage. It now also reads well on mobile phones thanks to Sasha, who is newly appointed web-developer in the core team.

Important notes

For those entering data:

Question from a site regarding the data field, "Any registered positive delirium score with a validated screening tool on this day".

No "validated screening tool" was used, but it reads in the patient files that the patient was delirious – what should we do?



Sponsor answer:

If the patient notes state that the patient has had delirium (and no anti-psychotics have been given or score used), you can answer 'yes' and write in the note field that the documentation is from the patient notes with the relevant date

Question from a monitor in relation to the entering of systolic blood pressure, we had difficulty verifying this, as the project nurse is looking for the lowest systolic blood pressure in several places.

This led to a talk that data should have one maximum two sources. We discussed where it is most correct to source?

If it is intensive charts, then there may only be data from a short time before the randomization.

If there has been an operation, then some very low systolic BP may have been registered.

Are there any input from the Sponsor site where it is most relevant?

Sponsor answer:

Your source data list should have written one (or two) places from where SBP should be registered.

Based on feedback for the safety committee in Albumin: In the day forms, please make sure that only albumin use in the ICU is registered and be aware of the allocation group when registering protocol violations.

INCEPT website

As you know our new [website](#) is now live.

Besides information you can also find site file documents (see under [Resources](#)).

Thus, the website is also a working tool – especially for the site investigators and project nurses. If you can't find specific documents, you can try the search function.

A missing document can also be our mistake, so please let us know if you think anything is missing.

Newsletter

All site investigators and project nurses must receive the newsletter. So please check at your site. If a person is missing on our email list, they must send an email to contact@incept.dk.

Case money

In the end of April, we calculate case money. We have built in the calculation in EasyRF. Around a week in advance of the calculation we send an email to remind you, and in that way give you time to enter data relevant for the calculation. In the end of the month, the site investigator receives an email with the calculation and instructions on how to invoice us.

Updates

Methods

New versions of the core protocol, both approved DSAs, and all national appendices submitted for evaluation in CTIS. Changes are overall minor. We will notify you when these have been approved.

Data

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Funding

INCEPT has been granted some internal funds at Rigshospitalet for project coordination. Additional funds are continuously being applied for.

Clinical domains

Albumin domain

337 participants included – a big thanks!
The 200 participants included in the feasibility phase will complete follow-up in May. Analyses of the feasibility phase will take place during summer.

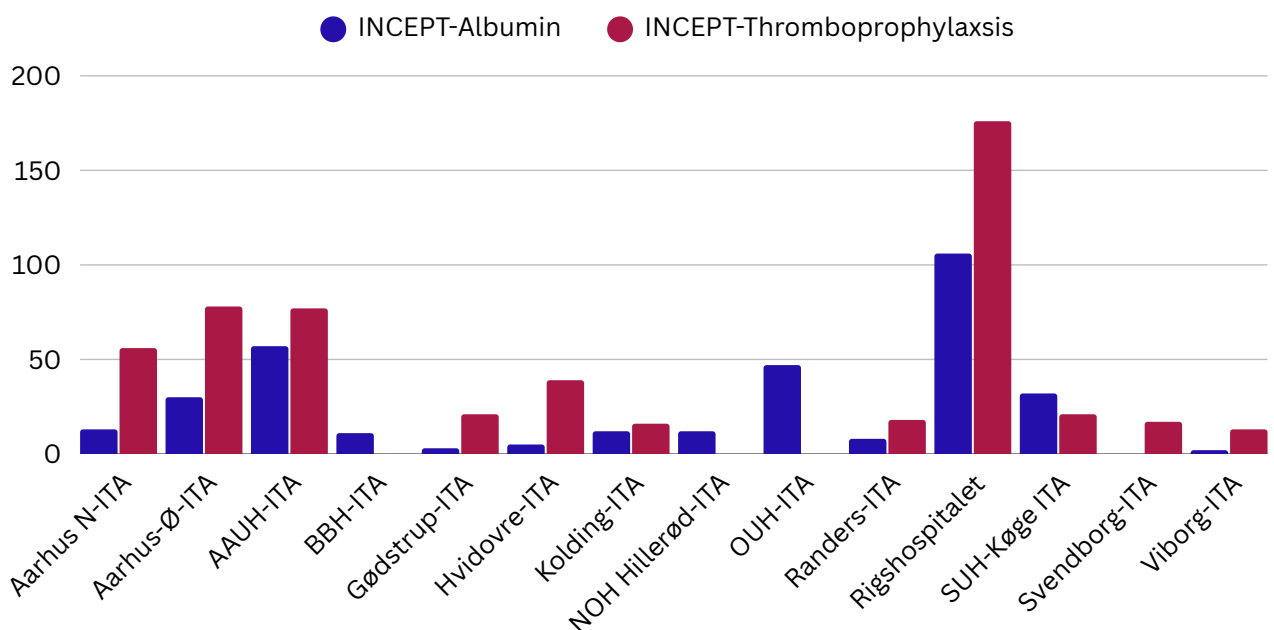
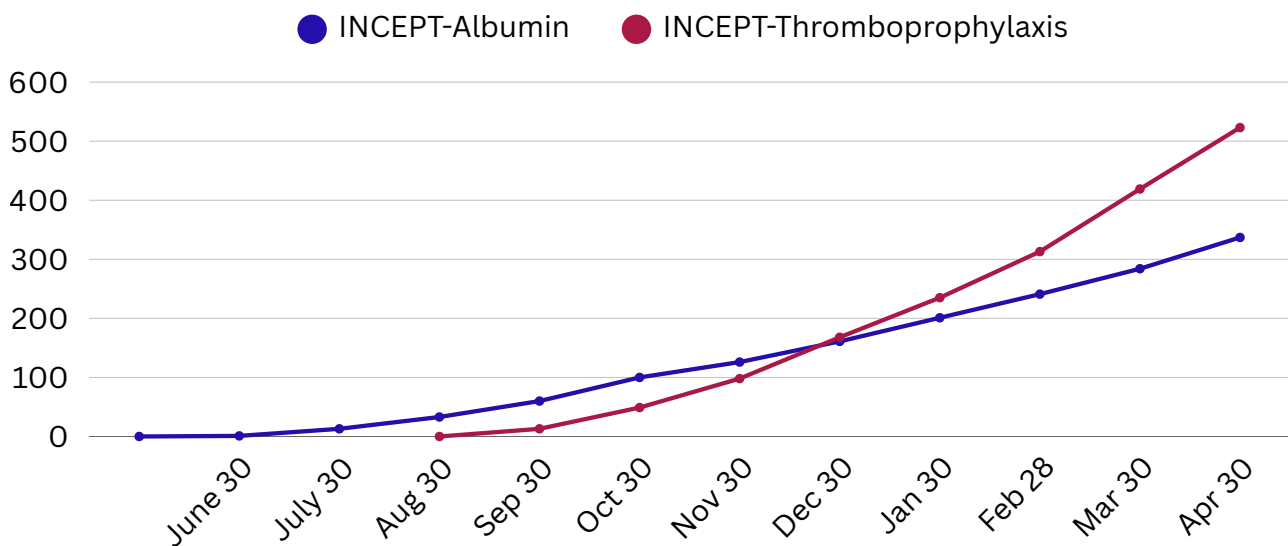


In first the report of annual safety data, 22% of participants in the No albumin-arm was registered to receive albumin in the ICU, but only 6 % had a protocol violation registered.

Please make sure that only albumin use in the ICU is registered, and be aware of the allocation group when registering protocol violations.

Thromboprophylaxis domain

A total of 523 patients have been included in the INCEPT-Thromboprophylaxis domain with over 100 new enrolments in April already. We thank you all for your hard work!



Upcoming events

- CRIC Network Meeting, Panum.
May 13, 2026.
- The next INCEPT/EasyRF workshop will be held
May 29, 2026.
Click [here](#) to register for participation.
- From Research to Practice – Implementation in
Health Sciences, May 19-20, 2026.
Click [here](#) to read more and register.
- PhD course in advanced Bayesian adaptive trial
design, June 3-4, 2026.
Click [here](#) to register.
- INCEPT Platform management committee
meeting. May 27, 2026, 15.00-16.00.
- 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

