

NEWSLETTER

Dear friends and colleagues,

INCEPT is running well, many patients are being enrolled in the 7 active sites. Site initiation has been a bit slower than expected, mainly do to challenges with finding dates for training and GCP initiation.

There are many groups working with new domains, currently 10 altogether, within a broad range of interventions and hospitals.

Important notes

The eCRF has been updated for INCEPT-Albumin to align with a similar variable for INCEPT-Thromboprophylaxis:

The registration of major bleeding has been amended with questions about type and site of bleeding and any intervention used.

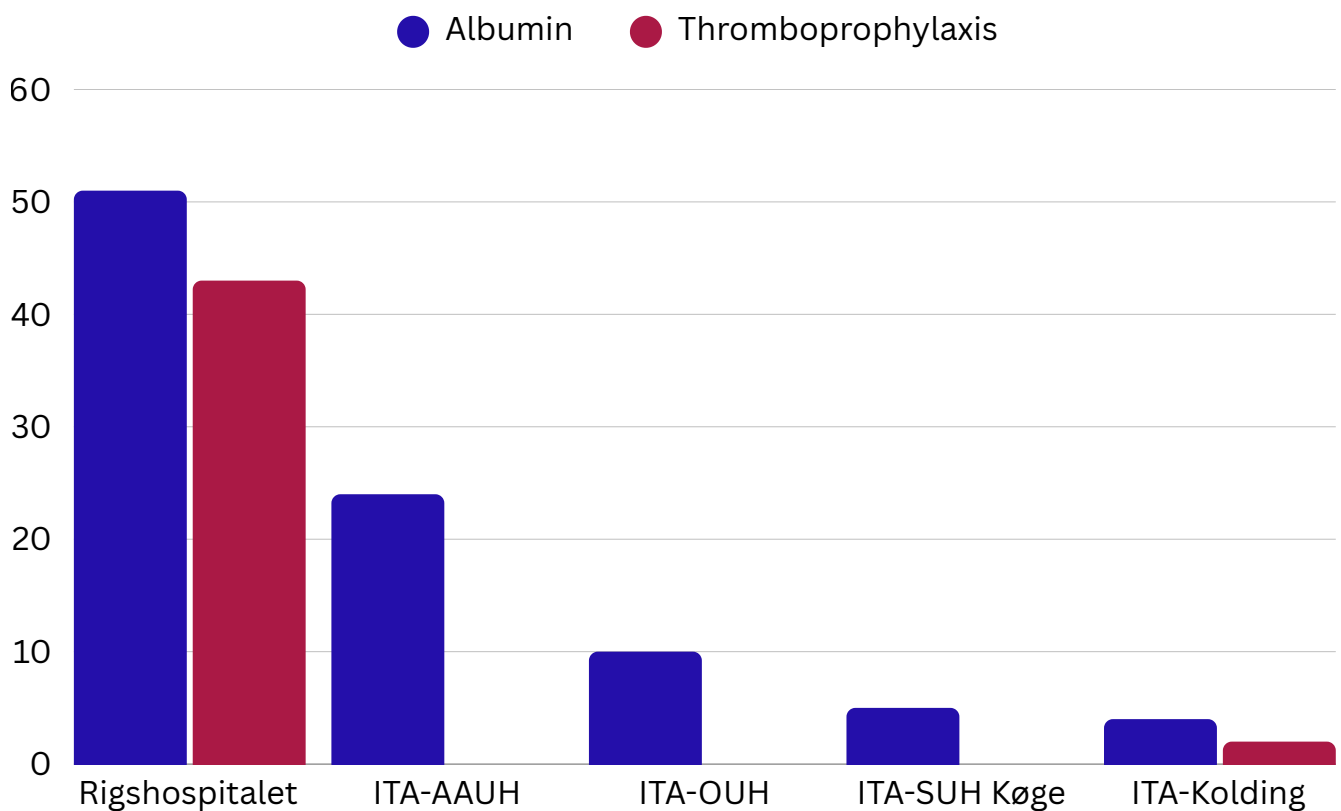
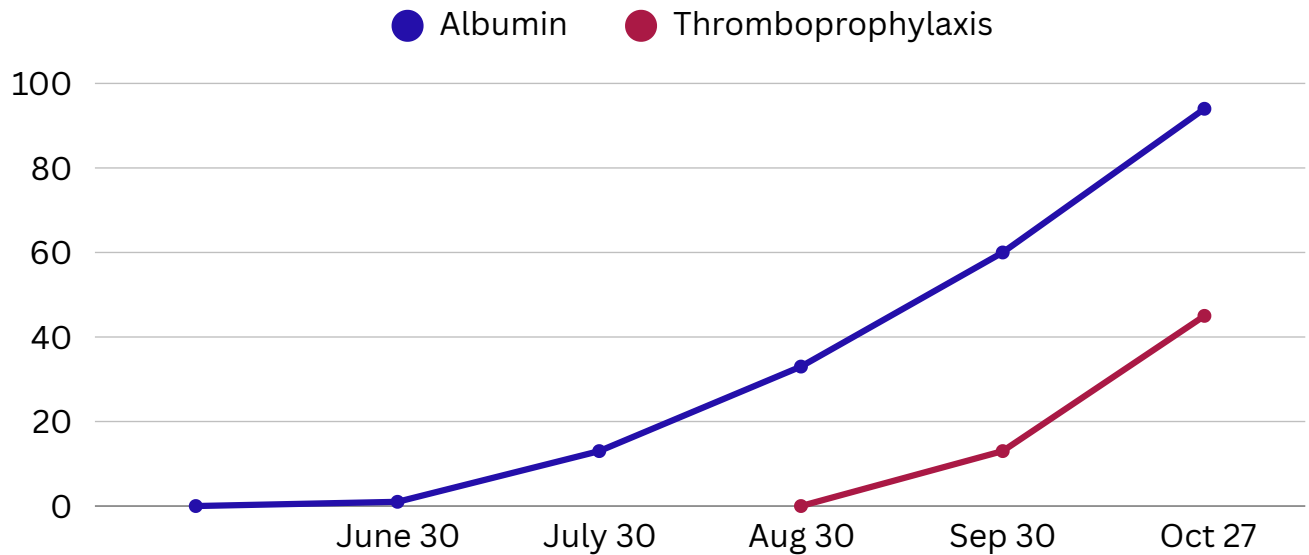
The update has been made so that all previously completed day-forms have now become red (meaning missing variable entry). Once you open one of the now red day-forms, you can see how the previous entry was (y/n).

For most patients, bleeding have not occurred, and then it is just a matter of selecting “no” for the new bleeding variable.

For the few who have had a major bleeding, you must go into the medical record of the participant and find the information about the bleeding (type and site) and then fill in the question about how it was managed.



Current enrolment status across all sites



Updates

Stakeholder involvement

We are currently conducting research panel meetings to discuss and define the core outcomes. This is the first step in developing the core outcome measurement set (COMS).

In November, we will hold an expert panel meeting with key stakeholders, including specialists experienced in COMS, clinical trialists, and methodologists. Together, we aim to refine the definitions and hopefully reach consensus on the core outcome concepts.

A patient from the research panel meeting in Copenhagen and Anders P participated in a short video produced for the Copenhagen Life Science Summit.

The Summit aims to deliver concrete EU recommendations and practical proposals to ensure Europe's new life science vision benefits patients and strengthen Europe's competitiveness. To watch the video, [click here](#).

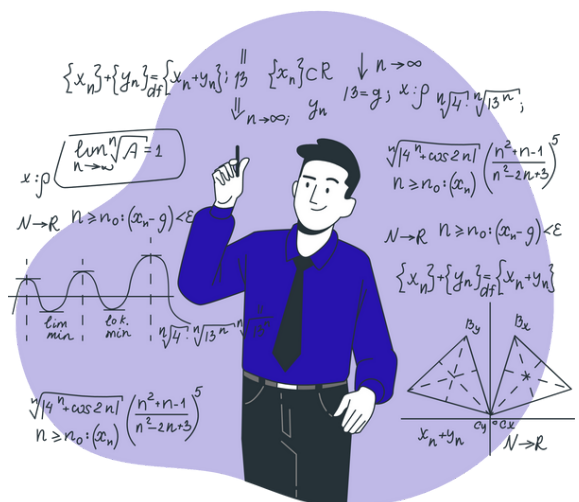
Methods

Tutorial on designing and evaluating Bayesian advanced adaptive clinical trials has recently been published in Pharmaceutical Statistics, ([link](#)). This tutorial is a walk-through of the framework used in the design phase of both active INCEPT domains (and EMPRESS).

We have developed a new PhD course: **"Introduction to advanced Bayesian adaptive trials: design and analysis"** to be held December 3-4, 2025.

The course is an introduction to statistical methods used in INCEPT (planning and analysis stages) and may be relevant for PhD-students involved in upcoming domains – please share.

Non-PhD-students may sign up for the waiting list and can attend if all seats are not taken by PhD-students.



Funding

Prof. Asger Granfeldt from AUH (Denmark) has received funding from DFF for a NaHCO₃- domain, which is another important milestone for INCEPT.

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

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