

NEWSLETTER

Dear friends and colleagues,

INCEPT has been active for 7 weeks since the enrolment of the first participant 30 June in INCEPT-Albumin at Rigshospitalet.

We have learned a lot. Screening was initially done by trial staff, but increasingly by clinicians, which largely has been uncomplicated.

The electronic case report form, EasyRF, works very well, and the few updates have been implemented smoothly.

At this time, 9 participants has been co-enrolled in EMPRESS. The reuse of data between the 2 trials has also worked well. We have had no major issues with consent.



Updates

Data:

- EasyRF was launched before the summer holiday and has been running smoothly since after a few hiccups during the first days
- We have 21 participants enrolled as of 21 August
- Few bugs emerge but at a manageable pace and nothing has been disruptive so far
- The next couple of weeks, our focus is on consolidation of the code and finalizing the technical documentation. Then, we turn our focus to data extraction for analytics and central data quality monitoring
- The work on automatic data extraction has been revived now that we have a functional system in production

Stakeholder involvement:

From September/October 2025, we will involve our research panels in the first step of developing the core outcome measurement set. This step focuses on defining and conceptualizing the six core outcomes.

Clinical domains

Albumin domain:

Rigshospitalet and Aalborg University Hospital screens actively, and Zealand University Hospital (Køge) has been initiated. North Zealand Hospital, Bispebjerg Hospital, Viborg Regional Hospital, Kolding Hospital and Odense University Hospital will be trained and initiated in August/September followed by the remaining DK sites in autumn/winter. For the other countries, the CTIS (regulatory) submissions will be done when the Thromboprophylaxis domain has been approved.

As of now, 28 patients have been screened and 21 included, most of whom have had septic shock. Those excluded had had albumin before screening. There have been few violations (e.g., one participant allocated to albumin never received albumin).

Thromboprophylaxis domain:

The INCEPT-Thromboprophylaxis DSA is currently pending review by the Danish authorities.

Calcium domain:

A survey to inform a future RCT and assess current treatment practices for hypocalcemia in critically ill patients will be launched in week 34 and will remain open for six weeks.



No updates:

Funding
Methods
Continuous glucose monitoring domain
Bicarbonate domain
Atrial fibrillation domain
Vasopressin domain

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,

Anders Granholm, Anders Perner, Morten Hylander Møller,
Benjamin Skov Kaas-Hansen, Maj-Brit Nørregaard Kjær, and Rikke Faebo Larsen

on behalf of the INCEPT Coordinating Group

