

## INCEPT newsletter # 10 – January 2025

Dear friends and colleagues,

The core protocol + domain-specific appendix for the Albumin domain was submitted in November, the response from the authorities (medicines agency and ethics) came back in December and our response and the revised core protocol and DSA was submitted 13 January. The final decision (approve or reject) from the authorities is due 17 February. The plan is still to initiate INCEPT at Rigshospitalet in April 2025 and a few more sites before the summer holidays.

### **Stakeholder involvement:**

- The core outcome set study has been published. A lay summary disseminating the results, developed with the involvement of research panels in Denmark, has been finalised and will be shared with all stakeholders involved or participating in the study.
- The next step is to develop the core outcome measurement set, which will commence soon. If interested in being a part of this process, please contact Maj-Brit ([maj-Brit.noerregaard.kjaer@regionh.dk](mailto:maj-Brit.noerregaard.kjaer@regionh.dk)).

### **Methods:**

- Guide on design and simulation-based evaluation of advanced adaptive trials (the framework used for EMPRESS and all INCEPT domains currently being planned) is now available as a preprint (<https://doi.org/10.48550/arXiv.2501.08765>).
- Methodological systematic studies on aspects of other platform trials are being planned.
- If you have ideas or suggestions for methodologically focused projects within INCEPT or want to contribute to upcoming projects, please reach out to Anders ([anders.granholt@regionh.dk](mailto:anders.granholt@regionh.dk))

### **Data:**

- The work on the eCRF is progressing according to plan, with servers being set up and an intense 6-work sprint starting on 20 January to make the system as user friendly as possible while still serving the needs of our users, monitors and regulators.

### **Funding:**

- No updates

### **Clinical domains:**

- Albumin domain:
  - First patient expected to be randomised in *INCEPT-Albumin* on April 1, 2025
- Thromboprophylaxis domain:
  - No updates.

- Continuous glucose monitoring domain:
  - The management committee and the working group for the domain has been set up, and work on the DSA has started.
  - Survey and GEM-ICU cohort study are still in progress.
- Domains under consideration:
  - The process of forming a management committee of a future domain on anti-arrhythmic treatment of atrial fibrillation has started.
  - 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](mailto:morten.hylander.moeller@regionh.dk)).

**With collegial regards,**

Anders Granholm, Anders Perner, Morten Hylander Møller,  
Benjamin Skov Kaas-Hansen, Maj-Brit Nørregaard Kjær, Tine Sylvest Meyhoff, and Rikke Faebo Larsen  
on behalf of the INCEPT coordinating group