

SafeBoosC-IIIv Steering Committee meeting

19th March 2025

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Janus Christian Jakobsen (Copenhagen Trial Unit), Mathias Lühr Hansen (Copenhagen Trial Unit), Gorm Greisen (Denmark), Adelina Pellicer (Spain), Gabriel Dimitriou (Greece), Livia Ognean (Romania), Tomasz Szczapa (Poland), Jakub Tkaczyk (Czech Republic).

Apologies: Monica Fumagalli (Italy), Gitte Hahn (Denmark), Saudamini Nesargi (India), Gerhard Pichler (Austria), Hans Fuchs (Germany), Renato Procianoy (Brazil), Jorge Fabres (Chile), Gunnar Naulaers (Belgium), Siv Fredly (Norway).

Absent: Merih Cetinkaya (Turkey), Jyoti Lakhwani (Zambia), Eugene Dempsey (Ireland), Cornelia Hagmann (Switzerland), Lina Chalak (US), Laishuan Wang (China), Daniel Virella (Portugal), Gabriel Musante (Argentina), Himanshu Popat (Australia).

Moderator: Caroline Kamp

Minute taker: Johanne Juul Petersen

1) Approval of the agenda

Agenda approved.

2) Members of the Steering Committee

We received several apologies for the meeting. For the next meeting, we will suggest 16.30 CEST.

Caroline, Johanne, and Mathias will meet with Massimo Di Maio from France, who might take on the role as National Coordinator. No National Coordinator from UK has been found. At last Steering Committee meeting, Gene offered to reach out to a contact in Liverpool. Caroline will follow up on this, and Tomasz will reach out to another contact in UK. Fernando from Uruguay has withdrawn as National Coordinator for Uruguay, and we have asked Fernando to suggest a new National Coordinator. Gabriel has reached out to a centre in Cyprus, who might be interested in joining the trial.

3) Central updates

Caroline gave an update the central steps including:

a. eCRF

The eCRF has been finalised. Access for each centre will be granted, once all local steps before randomisation have been completed.

b. Web-based training

Web-based training is available online.

c. Ready for randomisation

All central steps are now ready for randomisation.

d. Central data monitoring plan and DMSC charter

Copenhagen Trial Unit has finalised the central data monitoring, which is available on the website. The DMSC charter will be finalised shortly.

e. Statistical analysis plan and protocol paper

Copenhagen Trial Unit will work on the statistical analysis plan and protocol paper in the following month.

4) National Coordinator update

Many centres are making great progress, which can be followed in the Trial Preparations Log (available on the website).

- **Adelina, Spain:** Finalising the web-based training. Adelina will work on Spanish translations of the training material. The aim is to start randomisation in the first week of April.
- **Tomasz, Poland:** Interest from 13 centres. Ethical approval is expected within a month. Contracts might be a challenge, but it has succeeded in one centre. OxyPrem will likely support the Polish centres.
- **Gabriel, Greece:** Interest from five centres. Finalising the web-based training. OxyPrem will likely support the Greek centres.
- **Livia, Romania:** Finalising the web-based training. The centres are still waiting for equipment.
- **Jakub, Czech Republic:** Waiting for ethical approval. Approval might be challenging, if the trial needs to be approved as a device trial.
- **India:** Not present. Updated on email. One centre is waiting for access to web-based training. The remaining centres are finalising the collaboration agreement and ethics approvals.

5) Substudies

Two substudies were presented at the Substudy meeting on the 5th of February 2025.

- **Substudy proposal on renal outcomes – Saudamini Nesargi**
The substudy on renal outcomes was briefly discussed. All participants present voted to approve the substudy. An additional vote will be sent out by email for the Steering Committee participants not attending the meeting.
- **Substudy proposal on hypocapnia – María Carmen Bravo**
The substudy on hypocapnia was briefly discussed. All participants present voted to approve the substudy. An additional vote will be sent out by email for the Steering Committee participants not attending the meeting.

6) Any other business

Next Steering Committee meeting will be on 21st of May 2025.