

SafeBoosC-IIIv Steering Committee meeting

24 September 2026

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Janus Christian Jakobsen (Copenhagen Trial Unit), Georg Schmölzer (Canada), Adelina Pellicer (Spain), Zuzanna Owsiańska on behalf of Tomasz Szczapa (Poland), Andrés Daniel Nachari Shats on behalf of Jorge Fabres (Chile), Gabriel Dimitriou (Greece), Rong Yu on behalf of Laishuan Wang (China), Jakub Tkaczyk (Czech Republic), Lina Chalak (US), Hans Fuchs (Germany).

Apologies: Gitte Hahn (Denmark), Renato Procianoy (Brazil), Gerhard Pichler (Austria), Saudamini Nesargi (India), Gorm Greisen (Denmark), Cornelia Hagmann (Switzerland), Himanshu Popat (Australia), Livia Ognean (Romania), Mathias Lühr Hansen (Copenhagen Trial Unit).

Absent: Eugene Dempsey (Ireland), Merih Cetinkaya (Türkiye), Monica Fumagalli (Italy), Gunnar Naulaers (Belgium), Gabriel Musante (Argentina), Jyoti Lakhwani (Zambia).

Moderator: Caroline Kamp

Minute taker: Johanne Juul Petersen

1) Approval of the agenda

Agenda approved.

2) Members of the Steering Committee

Caroline presented the current members of the Steering Committee. No changes since the last Steering Committee meeting.

3) Central updates

Caroline gave an update on the central steps.

• Randomisation

22 centres have started randomisation in 10 countries. Seven additional centres are ready to randomise. 360 participants have been randomised. 40 additional centres are interested in joining the trial across 22 countries and six continents in total.

• Investigator Meeting in 2027

A SafeBoosC-IIIv Investigator Meeting will be hosted in Copenhagen on 5-6 April 2027. An invitation has been sent out. Please RSVP to caroline.kamp@ctu.dk.

• Dr Kosmas Sarafidis' substudy

The eCRF has been finalised, and sites are now able to participate. Caroline has invited all participating sites. Five sites are currently participating in the substudy.

• Step two – 2 year follow-up

Step two is being prepared, and more information will be shared with the Steering Committee shortly. Caroline will ask all national coordinators whether they would

like to participate and whether follow-up will be feasible. The additional time required to reach the sample size for step two is currently estimated at two years after the sample size for step one has been reached. This estimate will become more precise as more participants are randomised.

- **Central data monitoring meeting**

Central data monitoring has begun. Caroline and Johanne will contact investigators if any questions arise.

4) **National Coordinator update**

Many centres are making significant progress, as reflected in the Trial Preparations Log (available on the [website](#)).

- **Andrés, Chile:** Waiting for ethics approval.
- **Zuzanna, Poland:** Three sites are ready to randomise. One additional site is almost ready. Information material has been translated and shared with the Polish sites.
- **Adelina, Spain:** Eleven centres participating. All centres except two are currently randomising.
- **Gabriel, Greece:** Five centres are participating, and all centres are currently randomising. A sixth centre did not receive ethics approval.
- **Jakub, Czech Republic:** The collaboration agreement has been signed. Preparations for the initiation visit are currently underway, with the aim of beginning randomisation in October.
- **Laishuan, China:** One center is randomising with three participants currently included.
- **Lina, US:** One centre has started screening and inclusion.
- **Hans, Germany:** One centre is ready to randomise.
- **Livia, Romania:** Update by email. One centre is currently randomising. Another centre has recently received approval for the blinding procedure and has identified a local monitor. The site will finalise staff training in October and begin randomisation. Livia will participate in a national congress and follow up with the other participating centres.
- **Saudamini, India:** Update by email. Two centres are currently recruiting. Inclusion has slowed at one centre due to an outbreak of infections resulting in restricted admissions. Another centre will renew its insurance next week, after which randomisation will begin. The final centre is expected to begin randomisation in October.

5) **Substudies**

Three substudies are currently ongoing:

- **Substudy on renal outcomes – Saudamini Nesargi**
17 centres are currently participating in the substudy on renal outcomes.
- **Substudy on hypocapnia – María Carmen Bravo**
13 centres are currently participating in the substudy on hypocapnia.
- **Substudy on cardiovascular interventions – Kosmas Sarafidis**
5 centres are currently participating in the substudy on hypocapnia.

New substudies are welcome.

6) Any other business

Lina asked whether the inclusion criteria could be widened due to many newborns receiving non-invasive mechanical ventilation. Experiences and strategies for optimising recruitment were shared. The group agreed to maintain the current inclusion criteria. Non-invasive mechanical ventilation may be considered for future trials within the SafeBoosC platform.

The next Steering Committee meeting will be in November. The date will be announced by email.