

SafeBoosC-IIIv Steering Committee meeting

30th October 2024

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Janus Christian Jakobsen (Copenhagen Trial Unit), Gorm Greisen (Denmark), Lina Chalak/Asmahan Ahmed (US), Renato Procianoy (Brazil), Saudamini Nesargi (India), Gabriel Dimitriou (Greece), Livia Ognean (Romania), Laishuan Wang (China), Jakub Tkaczyk (Czech Republic), Adelina Pellicer (Spain).

Apologies: Siv Fredly (Norway), Jorge Fabres (Chile), Gunnar Naulaers (Belgium), Monica Fumagalli (Italy), Fernando Silvera (Uruguay), Cornelia Hagmann (Switzerland), Tomasz Szczapa (Poland), Merih Cetinkaya (Turkey), Gitte Hahn (Denmark), Gerhard Pichler (Austria), Hans Fuchs (Germany), Eugene Dempsey (Ireland), Daniel Virella (Portugal), Olivier Baud (France), Mathias Lühr Hansen (Copenhagen Trial Unit).

Absent: Gabriel Musante (Argentina), Atul Malhotra/Himanshu Popat (Australia), Anne Marie Heuchan (UK), 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 went through the list of national coordinators. Since the last Steering Committee meeting, Olivier from France has withdrawn from the trial. Members of the Steering Committee (Adelina, Gorm, and Lina) will think of any other contacts in France and reach out. Adelina has reached out to a contact in Colombia, who might be interested in joining as national coordinator.

3) Central updates

a. Ethical approval and central steps before randomisation

Caroline gave an update on the ethics approval in Denmark and the final central steps before randomisation. The protocol version 2.0 is still awaiting ethical approval in Denmark. All central documents including Standard Operation Procedures for the trial are being finalised centrally and will be presented to the Steering Committee when they are ready. Due to a change in the process of ethical approval, as discussed at the last Steering Committee meeting, there is a small delay. The aim is for all central steps to be ready for randomisation to begin in January 2025.

b. Local monitoring plan

Caroline gave an update on the local monitoring plan. Since the GCP unit in Denmark cannot go through the local monitor plan, the 'GCP plan' will change name

to 'Local monitoring based on ICH-GCP principles'. This is only a change of the name, as all procedures will remain the same.

c. Substudy meeting

Caroline went through the process of substudies. A substudy meeting will be held online on the 5th of February 2025. Substudies can be presented at this meeting. After the online meeting, the Steering Committee will discuss the suggested studies and develop and decide on a 'secondary study and publication plan'. A Standard Operating Procedure on substudies will be sent to the Steering Committee within a few weeks.

4) National Coordinator update

- **Adelina, Spain:** 12 centres are joining. One centre has all approvals, while the remaining centres are waiting for the final regulatory steps.
- **Saudamini, India:** Three centres are joining with potentially two other centres. Final regulatory steps are underway before randomisation.
- **Gabriel, Greece:** Five centres are joining. Final regulatory steps are underway before randomisation.
- **Lina, US:** One centre is joining and awaiting ethical approval. More centres will be contacted, once this centre has obtained ethical approval.
- **Jakub, Czech Republic:** One centre is joining and awaiting ethical approval.
- **Ling Zhao, China:** Ten centres are joining. Ethical approval has been obtained for some centres.
- **Livia, Romania:** Five centres are joining. Some centres received ethical approval, and some centres are waiting for approval. All documents have been translated.
- **Renato, Brazil:** Nine centres are joining and awaiting ethical approval.

5) Any other business

Next Steering Committee meeting will be on 15th of January 2025, 20:30 CET.

Substudy meeting on 5th of February 2025, 20:30 CET.