

SafeBoosC III steering committee meeting 15-04-2019, 22:00 PM CET

The first steering committee meeting was held through the online meeting platform Zoom. All participants found this format feasible for future steering committee meetings. We recommend that all members participating in future meetings use headphones with microphone.

Attending

Adelina Pellicer, Monica Fumagalli, Ana Vilan, Jakub Tkaczyk, Ebru Ergenekon, Gorm Greisen, Mathias Lühr Hansen

Moderator: Gorm Greisen

Referent: Mathias Lühr Hansen

Summary

Steering committee charter

The steering committee will have responsibility for the conduct of the SafeBoosC-III trial and may need to take some difficult decisions in the future. Gorm Greisen asked about the need for a charter to specify the standard ways of making decisions. All attendees agreed that this had to be discussed at a future meeting with better attendance.

Collaboration agreement

Gorm Greisen announced that the collaboration agreement will be bilateral – between his hospital on one side and each of the other hospitals on the other. We had unexpected delays particularly due to data protection issues but expect the collaboration agreement to be finished shortly after Easter. At first, it will be sent out to all national coordinators and all principal investigators who have directly asked for it. Based on this first experience with bilateral signatures, we will send it set it to all principal investigators. Several participants say that they need it as soon as possible for submitting their ethics application.

'Starters' before end of May

Rigshospitalet in Copenhagen may enrol the first baby before the end of May. Some hospitals in Greece may also be ready to do so.

Status on protocol amendments, SOPs and procedure updates – comments?

Multiple attendees requested that future protocol amendments should be kept to an absolute minimum, since it requires effort to communicate amendments to the respective research ethics board. Gorm Greisen and

Mathias Lühr Hansen will keep this in mind. It was also mentioned, that the description of ‘opt-out’ in the SOP ‘enrolment and randomisation’ was unclear. For the same SOP it was proposed that it was clearly stated, that a baby’s trial participation could be written in the day-to-day records. This has now been added. Please see the updated SOP at www.safeboosc.eu under ‘SOPs’.

Status on protocol paper and statistical analysis plan – comments?

All attendees were satisfied with the protocol paper which is now in review at the journal ‘Trials’, and with the statistical analysis plan paper which have been through revision by the steering committee members. The proposed changes are now being evaluated by Mathias, Gorm, Theis Lange (statistician) and Copenhagen Trial Unit.

Collaborative investigator certificate

Several principal investigators have asked for a collaborative investigator certificate for doctors at trial sites, who have assisted the principal investigator locally with the conduct of SafeBoosC III. Among attendees there was a general attitude towards this being a good idea. A draft will be made for approval in the next steering committee meeting.

Future meetings

All attendees agreed that 20:00 CET was a feasible time for future meetings. It was also decided that the next meeting should within approximately a month. In the future, we will aim to have a steering committee meetings approximately every month – focusing on decisions. They can be short. Summaries of steering committee meetings will be uploaded to www.safeboosc.eu under ‘Newsletters and steering group meetings’.

Best wishes

Gorm and Mathias