Minutes from the SafeBoosC Steering Committee Meeting the 18th of May 2020, at 20:00 CET

Present: Anne Marie Heuchan, Jonathan Mintzer, Saudamini Nesargi, Jakub Tkaczyk, Monica Fumagalli, Hans Fuchs, Gene Dempsey, Gerhard Pichler, Adelina Pellicer, Janus Jakobsen, Christian Gluud, Gunnar Naulers, Gabriel Dimitriou, Gorm Greisen, Mathias Lühr Hansen, Marie Rasmussen

Apologies: Tomasz Szczapa, Cornelia Hagmann

Absent: Siv Fredly, Simon Hyttel-Sørensen, Ebru Ergenekon, Guoqiang Cheng, Ana Vilan

Trial status update from Copenhagen
40 hospitals have started randomising and more than 240 babies have been included. An additional 32 hospitals have ethics approval and are preparing for participation as well. Despite a 60% increase in the number of hospitals open for randomization from January to May, the randomisation rate has not increased. Several investigators report that the rate of extremely preterm infants has declined in their respective centres during the COVID-19 outbreak. Thus, there is confidence that the rate will increase in the near future.

News on trial preparations, by national coordinators

Anne Marie – Great Britain
Obtained ethics approval in March. Have gotten an exemption to proceed with research, due to all research was put on hold due to Covid-19.

Jonathan Mintzer - USA
The CPARF funding application is put on hold since they are re-prioritizing their grant distributions due to COVID-19. Three centers are moving forward without funding and are expected to start randomising before summer.

Saudamini Nesargi - India
Have received final ethics approval. The collaboration agreement is approved as well as the contract with OxyPrem.

Jakub Tzackub – Czech Republic
One center is randomising and the other is still dealing with internal issues.

Hans Fuchs - Germany
The center in Freiberg is very close to opening up for randomization.

Monica Fumagalli - Italy
Milan has been recruiting despite Covid-19. Three more centers are working on trial preparations and one has ethics approval.

Gene Dempsey - Ireland

Since the university is serving as a sponsor for the country and has been shut down, the contracts have not been able to be processed and signed. As soon as the contracts are signed, the GCP initiation will proceed.

Gerhard Pichler - Austria
Plan on having the GCP initiation visit at the end of May.

Adelina Pellicer - Spain
Elven departments are open for randomisation and three additional departments are still working on trial preparations. Adelina has been in contact with the departments, that have not randomised babies yet, but can report about very few extremely preterm infants born in Spain.

Gunnar Naulers - Belgium
Have obtained ethics approval and contracts are almost in place. GCP initiation visit will take place at the end of May or the beginning of June.

Gabriel Dimitriou – Greece
Four departments randomising.

Re-booting after the Corona crisis. What are the challenges?
The departments that have been forced to shut down research are slowing starting to open up again. Hopes are high that the randomisation rate will pick up soon, as the Covid-19 situation normalises, and more sites open for randomisation.

Update and discussion on the SafeBoosC III follow-up study
A synopsis was circulated with the preliminary draft of the SafeBoosC follow-up study. The Steering Committee shared their knowledge of how routine follow-up is conducted in their respective countries. Most countries have a systematic follow-up of extremely preterm infants at two years, with the majority using the Bayley test. In Germany it is required by law to follow up on high-risk infants and in Belgium the departments will only receive shares of the national SafeBoosC-III grant, if infants are followed up. All national coordinators in the steering committee were positive towards participating in the follow-up study. The primary outcome was discussed and Janus Jakobsen (CTU) shared his concerns regarding using standardized mean difference as a primary outcome, since this method may incorrectly adjust for differences in variability among study populations. The Mental Developmental Index (MDI) could also be used as a continuous outcome, which would require approximately n=500 with a minimal relevant difference of 5 points and a power of 80%. The next step in planning the follow-up study is to send out a survey to all principal investigators, to gather information regarding routine follow-up, so the decision on the final study is based on feasibility.

Discussion and potential approval of Gerhards' ancillary study on General Movement Assessments
Enough members (n=12, > 50%) of the steering committee (n=21) are present to constitute a quorum. All members (12/12) voted in favour of the approval of Gerhards' GMA study protocol.

24-hour number for urgent issues regarding randomisation
Some departments have requested a 24-hour phone number in case of urgent questions. The steering committee agreed that this would be valuable, and Mathias will proceed with this.

Other business

Adelina - GCP Monitoring
If the GCP person is not currently working in the hospital due to Covid-19, they can contact Mathias. The SafeBoosC GCP monitoring is quite simple and a solution could be, to conduct the visit through Zoom by screen sharing.

Gorm - Website
To follow the policy of transparancy, all sources of funding will be published on the website. The steering committee agrees. Mathias will proceed with gathering information from all investigators.