Minutes from the SafeBoosC Steering Committee Meeting the 24th of May 2023

Present: Tomasz Szczapa, Jakub Tcakzub, Janus Jakobsen, Simon Hyttel-Sørensen, Eugene Dempsey, Saudamini Nesargi, Gunnar Naulaers, Adelina Pellicer, Gerhard Pichler, Cornelia Hagmann, Anne Marie Heuchan, Gabriel Dimitriou, Marie Rasmussen, Maria Vestager, Mathias Lühr Hansen, Gorm Greisen.
From CTU: Markus Harboe Olsen, Faiza Siddique, Caroline Kamp Jørgensen

Apologies: Hans Fuchs, Jonathan Mintzer, Ebru Ergenekon, Christian Gluud, Siv Fredly, Monica Fumagalli

Absent: Guoqiang Cheng

The SafeBoosC-III follow up study
The study is progressing steadily. There is less than a year (April 2024) till the last randomised infant will reach two years of corrected age. The study will run 6 months after this i.e. till October 2024. So far, 42 of 52 sites with eligible children are open for follow-up and 38 have entered data in OpenClinica. A total of 550 infants have reached two years of corrected age. Of these, 351 infants have completed data entries in OpenClinica so far. A total of 5% (31 of 550) are lost to follow-up, i.e. data entry modules completed but with no data. In total, 350 participants/families have completed the parental questionnaires. About 76% of participants so far have data for the co-primary outcome meaning either clinical data or parental questionnaire We will start conducting central data quality monitoring shortly. We hope that national coordinators will help push this last stride to get data from as many participants as possible. There were no decisions to be made during this meeting regarding the FU study.

Ancillary study
Gorm presented the proposal of Lisbeth Thewissen on the use of advanced signal analysis on StO2/MABP recordings to estimate measures of cerebral autoregulation and relate those to the SafeBoosC-intervention and the outcomes we have recorded. Such data is available in infants enrolled in Leuven and in Madrid. He recommended approval with the note that other partners with recorded data of sufficient quality and quantity should also be invited. Enough members of the steering committee were present (>12) to constitute a quorum. This was unanimously approved.

The SafeBoosC-IIIv trial
Each national coordinator expressed their thoughts on the trial and possible participation. There is broad support for the trial and agreement on the relevance and need for the SafeBoosC-IIIv trial. Cornelia, Jonathan and Simon will try to find another to take over their position as national investigators. Ebru and Cheng will not participate. Gorm will step down as sponsor but still contribute to the trial. There will be a need for one or two “active” neonatologists to help with day-to-day management. In addition, the steering committee agreed on the possibility to launch the trial as a two-step process and thereby change the primary outcome to be assessed at 28 days e.g. “days alive outside hospital” and then a follow-up study assessed at two years of corrected age.

There is support for Janus to explore more funding opportunities. Some centres will need money to buy sensors. Ideally, it would be an overall funding approach to cover both central and local costs. If any other person succeeds to achieve to obtain the funding, they will be the sponsor.