

Minutes from the SafeBoosC-III follow up Steering Committee Meeting 28th of August 2024

Attendees: Ebru Ergenekon, Janus Jakobsen, Markus Harboe Olsen, Jakub Tkaczyk, Gabriel Dimitriou, Tomasz Szczapa, Siv Fredly, Gene Dempsey, Mathias Luhr Hansen, Marie Isabel S Rasmussen, Gorm Greisen

Apologies: Christian Gluud, Gunnar Naulers, Saudamini Nesargi, Jonathan Mintzer, Monica Fumagalli,

Absent: Gerhard Pichler, Adelina Pellicer, Guoqiang Cheng, Cornelia Hagmann, Anne Marie Heuchan, Simon Hüttel Sørensen

Marie and Gorm explain that the two sites that were to be discussed regarding exclusion, have both delivered data now, and therefore cannot be excluded from the study. Therefore, no decisions were to be made on this meeting.

Marie gave a status on the follow up study. The last participant in the study reached 24 months of corrected age in April 2024. A total of 13 sites have either withdrawn or been excluded from the study. Currently, there are 2 sites pending ethics approval, and have their data ready as soon as ethics is granted. There are 55 sites participating in the follow-up study. Out of these, 37 sites have completed data collection. Meanwhile, 11 sites have only 1-2 participants with missing data, and 7 sites have more than 10% of their participants' data missing. The data completion rates for the co-primary outcomes in the study are currently 85% for death or moderate-to-severe neurodevelopmental disability (1251/1485 participants). It is predicted that this completion rate may increase to 88% by the end of the study, totaling 1310 participants evaluated for this outcome. For the mean Bayley III/IV cognitive score, the current data completion rate is 43%, with (503/1163 participants). It is predicted that we will reach 45% by the end of the study, covering 525 participants evaluated with Bayley assessments. The denominator is different in the outcomes, as mortality is included in the dichotomous outcome, but not in the continuous outcome. The timeline for completion of the study was presented and national coordinators were encouraged to take note of key dates.

