

SafeBoosC newsletter May 2022

Dear investigators

Welcome to the May 2022 issue of the SafeBoosC newsletter.

SafeBoosC investigator meeting in May

The third investigator meeting was held in Copenhagen from the 19th to 20th of May 2022.

Investigators from the 70 centres who randomised participants to the SafeBoosC-III trial were invited. Sixty people attended the meeting, either virtually and physically. The meeting focused on the results from the SafeBoosC-III trial, the progress of the SafeBoosC-III follow-up study, and the preparations for the SafeBoosC-IIIv trial.

The SafeBoosC-III trial were discussed, and it has been decided to keep the results confidential until the results have been published or presented at the EAPS congress in October. Therefore, minutes from these discussions will not be available in public space. Furthermore, the results were discussed in the session on the SafeBoosC-IIIv trial and therefore, discussions in this session will also be kept confidential. Please contact Marie (marie.isabel.skov.rasmussen@regionh.dk) or Mathias (mathias.luehr.hansen@regionh.dk) if you are a co-author of the SafeBoosC-III manuscript and wish to receive the minutes from the confidential sessions.

The presentations and minutes which did not mention the SafeBoosC-III results can be found here

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Sider/investigator-meetings.aspx>

SafeBoosC-III

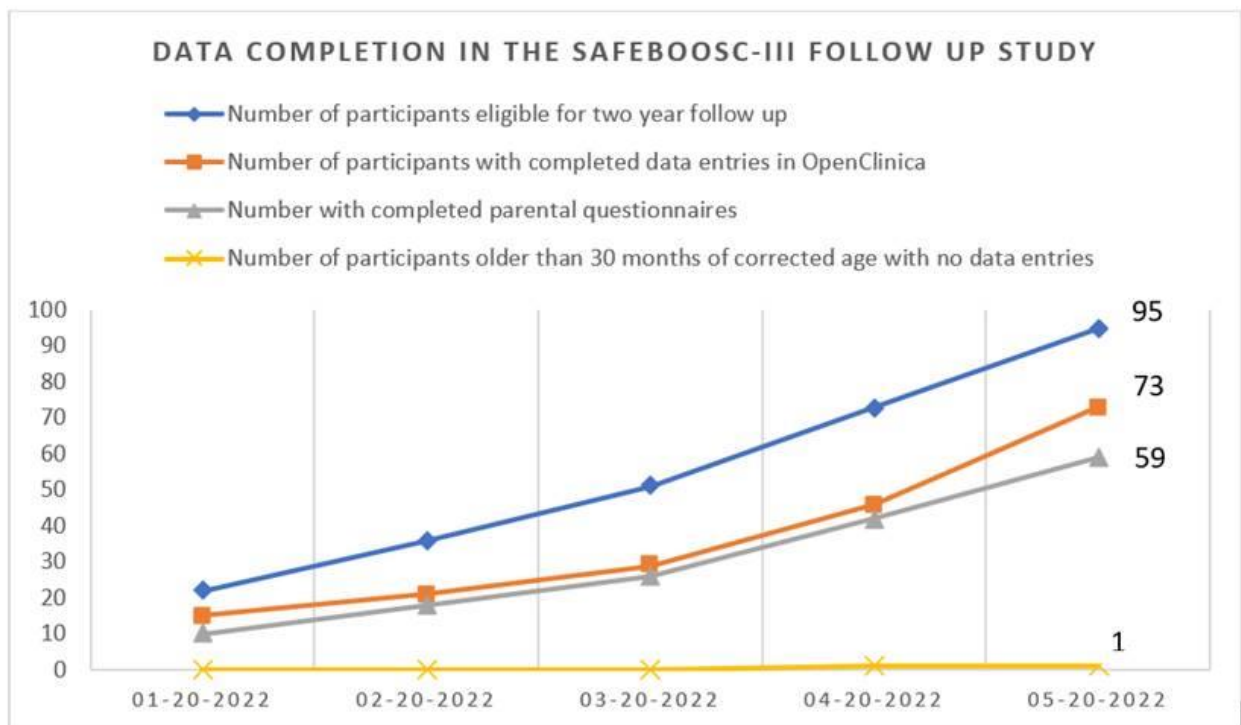
Following the investigator meeting with unblinding of data, Mathias and Gorm drafted the first version of the SafeBoosC-III manuscript, followed by subsequent rounds of revision by Janus and Christian from Copenhagen Trial Unit, Markus as statistician and Simon. On the 30th of May, the manuscript was sent all authors. We still expect to submit the manuscript before 10th of June as planned.

We have also been invited to submit the abstract as a 'late-breaker' for EAPS 2022.

SafeBoosC-III Follow-up

Twelve centers have participants that have reached two years of corrected age, and ten centers have started completing data entries in OpenClinica. A total of 73 participants have been followed up and 59 families have filled out the parental questionnaire. For an overview of data completion, please see figure 1.





SafeBoosC-IIIv

The SafeBoosC-IIIv project was presented at the investigator meeting and meet support by the present investigators. We still await approval of the trial protocol from the Danish Ethic Committee.

The next funding application will be for the Novo Nordisk Foundation late summer and we will have an answer from the Innovation Foundation in the winter. If funding is granted, we hope to start the trial in the end of 2022/beginning of 2023.

Thank you for your time,
Gorm, Marie, Maria and Mathias



SafeBoosC III
SAFEGUARDING THE BRAIN OF OUR SMALLEST CHILDREN