SafeBoosC-III newsletter February 2022

Dear investigators

Welcome to the February 2022 issue of the SafeBoosC-III newsletter.

Investigator meeting in Copenhagen 19-20 of May 2022
As mentioned previously, the next SafeBoosC investigator meeting will take place in Copenhagen from 19th to 20th of May 2022. The meeting will be held as a hybrid meeting. This means, that those who cannot attend physically, will be able to join online. Details on how to attend virtually will be sent out later.

The meeting will focus on 1) the results from the SafeBoosC-III trial, 2) the progress of the SafeBoosC-III follow-up study, and 3) the preparations for the SafeBoosC-IIIv trial.

Please recall that the session on the results from SafeBoosC-III, where two alternative abstracts will be discussed and the results will be unblinded, is confidential. This means that only investigators who will co-author the main publication can attend this session – this is relevant for those who intend to send a delegate to the meeting.

The deadline for registration to the investigator meeting is 1st of April 2022. Please send an e-mail to mathias.luehr.hansen@regionh.dk if you intend to participate, including whether you will attend physically or virtually.

An information letter including an agenda and practical information will be sent out within the next week.

Secondary publications
As mentioned previously, all principal investigators are allowed to plan and conduct secondary studies and subsequent publications based on SafeBoosC-III trial data. However, the study must be approved by the steering committee 'up-front'. If a single or a group of principal investigators, or members of the steering committee intend to do so, **a description of the study must be sent to mathias.luehr.hansen@regionh.dk before 17th of March 2022.**

The investigator(s) shall then present the study at the online meeting on 24th of March (link has been sent by e-mail) for discussion. After the investigator meeting, the steering committee will discuss the suggested studies and develop and decide on a 'secondary study and publication plan'.

More details can be found in the SOP "Secondary publications in SafeBoosC-III", which is available on safeboosc.eu:

https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/sops/sop-secondary-publications-240122.pdf

Status on data completion

As we have initiated the trial completion phase, data completion monitoring will be conducted every 14th day. All reports are available on safeboosc.eu: https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/safeboosc-iii-data-completion-report-210222.pdf

We also changed the definition of 'missing data' so that an incomplete data entry is registered as missing, as soon as the data entry is eligible, i.e., three days after birth for the end of monitoring and SARs forms and at 36+0 weeks of postmenstrual age for the follow-up and blinded follow-up forms. This is to ensure completion of the remaining data entry forms as soon as possible.

For the end of monitoring and follow-up form, data completion is still 99% as was the case two weeks ago. For the SAR form and blinded follow-up form, data completion has increased from 97% to 99% and from 94% to 96%, respectively.

Investigators with missing data entries have been contacted and urged to complete data entries.

SafeBoosC-III Follow-up

In seven centres, the first participants have reached two years of corrected age, and five of these centres have started completing data entries in OpenClinica. For an overview of data completion, please see figure 1. The completion of parental questionnaires is progressing steadily. Based on information from principal investigators, the parents are willing to complete the questionnaire when approached, either in the follow up clinic, by telephone or by email.

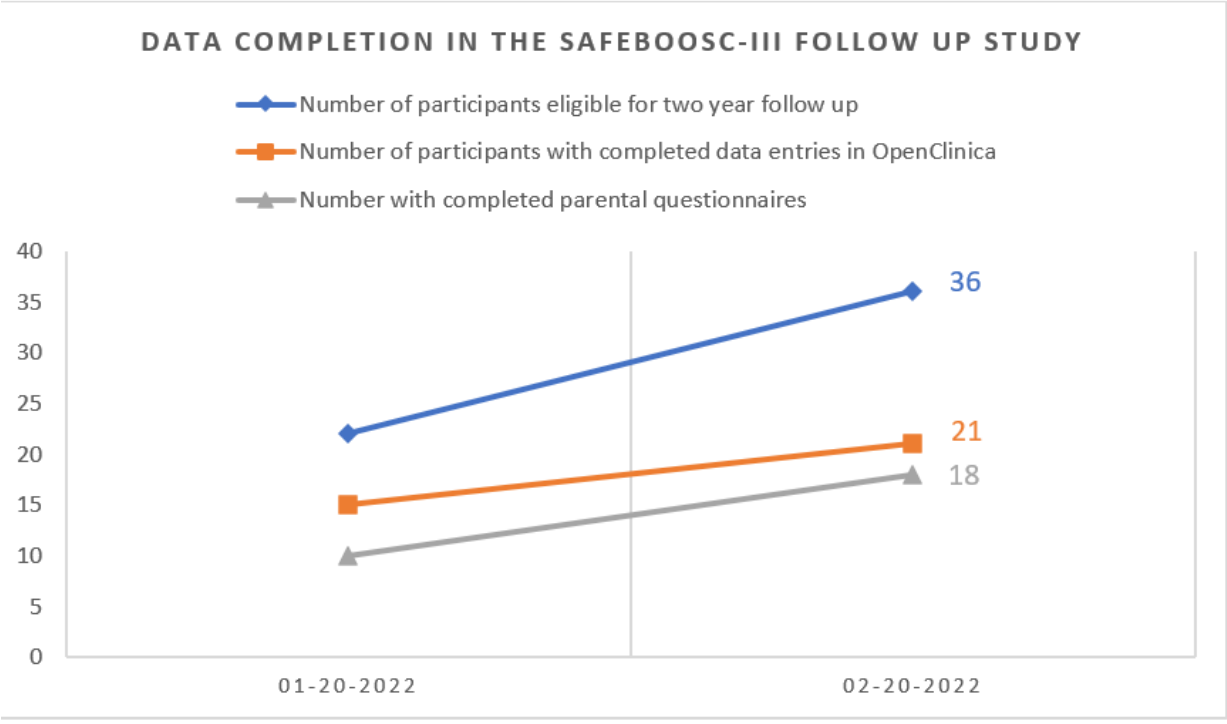

Figure 1.

SafeBoosC-IIIv

We're in an ongoing process of applying for funding to cover the trial center costs in Copenhagen and still awaiting the decision from the ethics committee in Denmark regarding the trial protocol. We expect the protocol to be approved during spring.

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