

SafeBoosC newsletter April 2022

Dear investigators

Welcome to the April 2022 issue of the SafeBoosC newsletter.

Statistical analyses have been initiated

The possibility to enter new data into OpenClinica was closed on 1st of April. Since then, local and central GCP monitoring has been completed as well. On the 19th of April, OpenClinica was locked for further data modifications, data was extracted, and the statistical analyses were initiated.

The statistical analyses will be performed independently by Markus Harboe Olsen, MD, from Copenhagen Trial Unit, Copenhagen University Hospital, and Aksel Karl Georg Jensen, MSc, PhD, from the Section of Biostatistics at University of Copenhagen.

Details on the statistical analyses can be found in the published statistical analysis plan, which is available on the SafeBoosC publication webpage (safeboosc.eu):

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/safeboosc/Sider/publications.aspx>

SafeBoosC hybrid investigator meeting in May

A total of 55 colleagues will attend the SafeBoosC investigator meeting from 19th to 20th of May – 31 will be present in Copenhagen and 24 will attend online. We look very much forward to host this first, post COVID, investigator meeting.

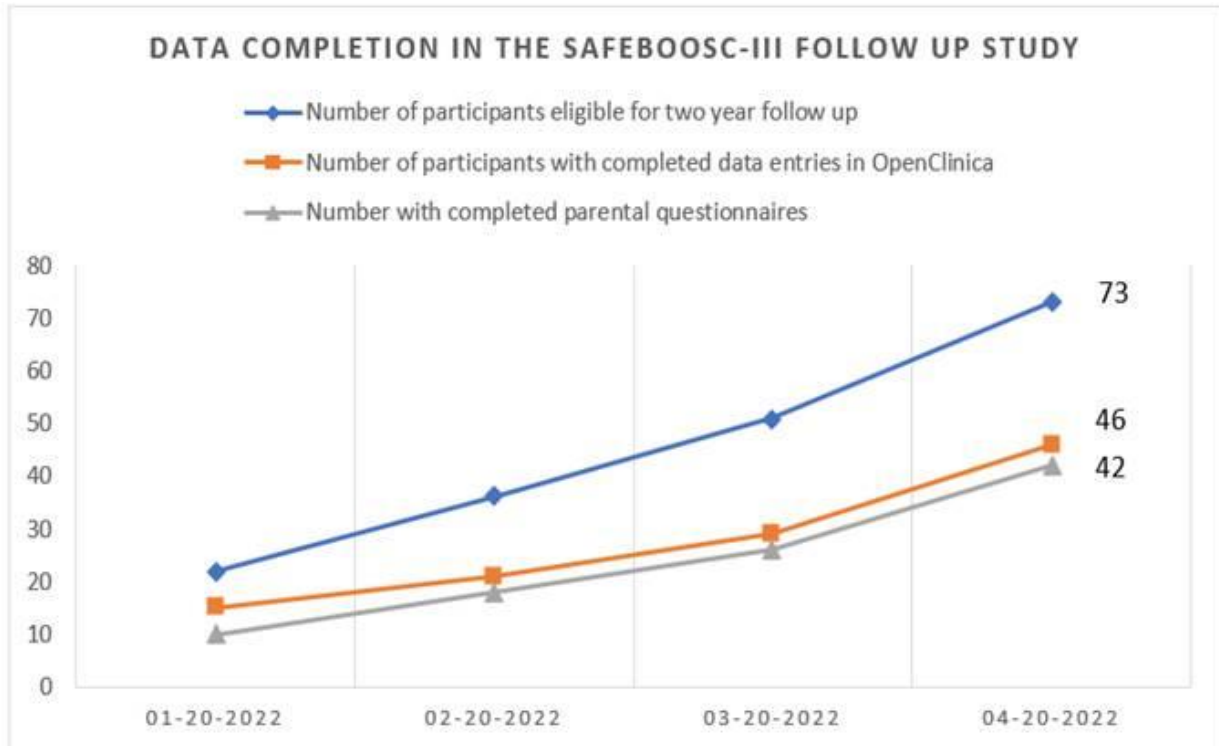
Details on how to attend online, including relevant links for the meeting, will be sent out once we get closer to the meeting.

The informational letter, including agenda, can be found on safeboosc.eu:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/informational-letter-for-3rd-investigator-meeting.pdf>

SafeBoosC-III Follow-up

In eleven centres, one or more participants have reached two years of corrected age. Of these eleven centres, nine have started to enter two-year follow-up data in OpenClinica. For 46 participants, data entries have been completed in OpenClinica, and 42 families have completed the parental questionnaire.



SafeBoosc-III

We have applied for funding to cover the central trial costs from the Innovation Foundation and the Tryg Foundation and will receive decisions late summer/early fall.

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