# SafeBoosC newsletter May 2023

Dear investigators
Welcome to the May 2023 issue of the SafeBoosC newsletter.

**SafeBoosC-III follow-up**

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. 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 75% 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. For an overview of data completion, please see figure 1. For an overview of each centre's data completion see table 1.

*Figure 1: Overall data completion in the SafeBoosC-III follow up study*

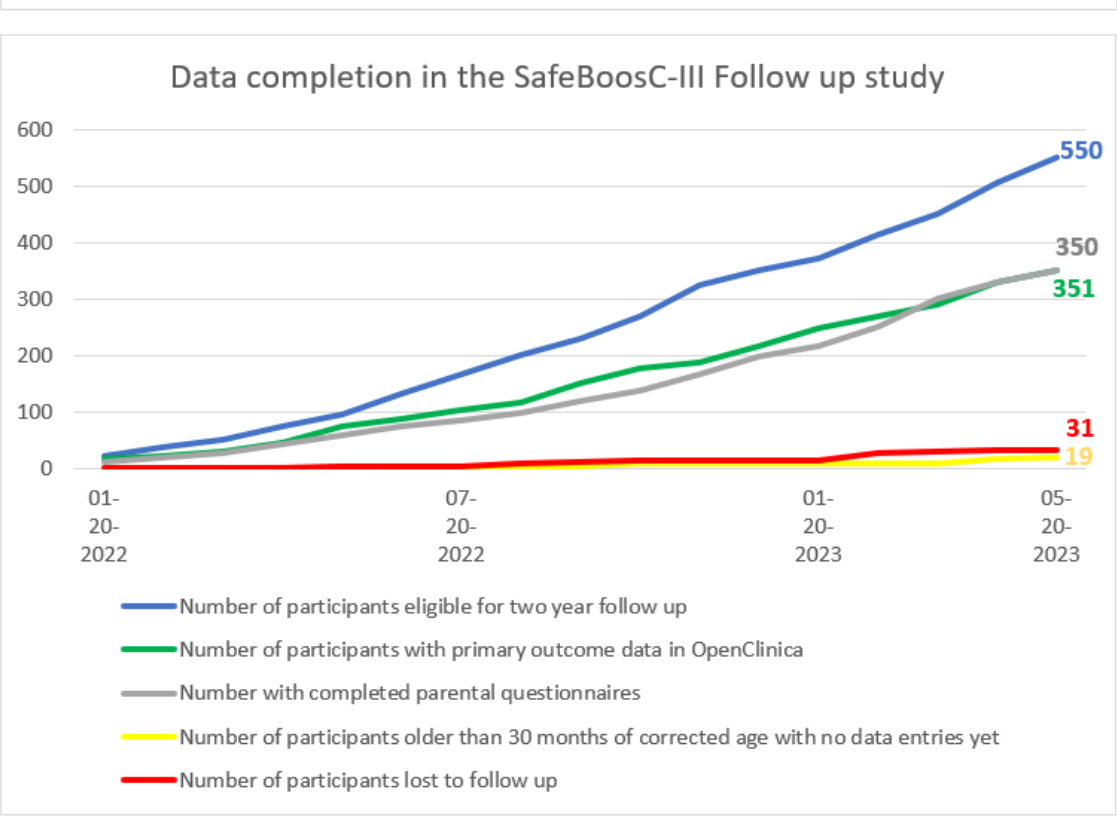


*Table 1: Open centres, number of eligible participants for two year follow up and data completion for each centre up until the 30th of May 2023. Centres highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed in order to start the follow up study.*

| Country | Centre | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|---|---|---|---|---|
| **Austria** | University Hospital Graz | 8 | 6 | 5 |
| **Belgium** | UZ Leuven | 19 | 14 | 13 |
| **Belgium** | Liege Rocourt | 8 | 1 | 2 |
| **Belgium** | Grand Hospital de Charleroi | 5 | 4 | 4 |
| **Belgium** | AZ St. Jan University Hospital Brugge | 6 | 0 | 0 |
| **Belgium** | CHU Tivoli | Dec 2022 (missing blinded assessor) | | |
| **Czech Republic** | The Institute for the Care of Mother and Child | 40 | 27 | 23 |
| **Czech Republic** | Motol University Hospital | May 2023 (missing all three prep tasks) | | |
| **China** | Children's Hospital of Zhejiang, Hangzhou | (unknown if they will participate due to COVID surge) | | |
| **China** | Children's Hospital of Fudan University, Shanghai | (unknown if they will participate due to COVID surge) | | |
| **China** | Hainan Women and Children's Medical Center | Aug 2023 | | |
| **China** | Guangzhou Women and Children's Medical Center | No data | | |
| **China** | Longgang District Central Hospital of Shenzen | (unknown if they will participate due to COVID surge) | | |
| **China** | The People's Hospital of Dehong | (unknown if they will participate due to COVID surge) | | |
| **China** | Guangxi Maternal and Child Healthcare Hospital, Nanning | (unknown if they will participate due to COVID surge) | | |
| **China** | Xiamen Children's Hospital | (unknown if they will participate due to COVID surge) | | |

| Country | Centre | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|---|---|---|---|---|
| **Denmark** | Rigshospitalet | 58 | 44 | 29 |
| **Denmark** | Odense University Hospital | 5 | 0 | 1 |
| **Denmark** | Aalborg University Hospital | 6 | 1 | 4 |
| **Denmark** | Aarhus University Hospital | 8 | 6 | 7 |
| **Germany** | Freiburg University Hospital | 7 | 5 | 2 |
| **Greece** | Ippokrateion General Hospital of Thessaloniki | 13 | 13 | 6 |
| **Greece** | University of Patras General Hospital | 5 | 2 | 1 |
| **Greece** | Alexandra Univ. Hospital | 11 | 8 | 8 |
| **Greece** | University Hospital of Heraklion | 8 | 6 | 6 |
| **India** | St Johns Medical College Hospital, Bangalore | 2 | 1 | 1 |
| **Ireland** | University Hospital Cork | May 2023 (missing all three prep tasks) | | |
| **Ireland** | Rotunda Hospital Dublin | Aug 2023 | | |
| **Ireland** | NMH Holles St | Aug 2023 | | |
| **Ireland** | Coombe Univ. Hospital | Sep 2023 | | |
| **Italy** | Fondazione IRCCS Cà Granda Ospedale, Milano | 21 | 20 | 16 |
| **Italy** | Presidio Ospedaliero S. Anna, Turin | 3 | 0 | 0 |
| **Italy** | Ospedale Fillipo del Ponte, Varese | Apr 2023 (missing all three prep tasks) | | |
| **Italy** | Fondazione Policlinico Univ. A. Gemelli, Roma | May 2023 (missing all three prep tasks) | | |
| **Norway** | Oslo University Hospital | July 2023 | | |

| Country | Centre | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|---|---|---|---|---|
| **Poland** | Medical Center UJASTEK, Krakow | 21 | Clinical data not available | 17 |
| **Poland** | Szpital Uniwersytecki, Kraków | Mar 2023 (missing blinding procedure and assessor) | | |
| **Poland** | Warsaw University of Medical Sciences | 4 | 1 | 2 |
| **Poland** | Poznan University of Medical Sciences | 21 | Clinical data not available | 18 |
| **Poland** | Specialist Hospital No. 2 in Bytom | 4 | 0 | 0 |
| **Poland** | Wroclaw Medical University | Oct 2023 | | |
| **Poland** | Jan Biziel University Hospital | Dec 2023 | | |
| **Poland** | Centre of Medical Postgraduate Education, Warsaw | July 2023 | | |
| **Spain** | H. Univ. Juan XXIII de Tarragona Hospital | excluded | | |
| **Spain** | La Paz University Hospital | 50 | 41 | 40 |
| **Spain** | Hospital Clinic de Barcelona | 33 | 30 | 28 |
| **Spain** | University Hospital 12 de Octubre | 30 | 26 | 14 |
| **Spain** | Hospital de Sant Joan de Deu | 18 | 16 | 17 |
| **Spain** | Hospital Clinico San Carlos | 16 | 13 | 13 |
| **Spain** | Hospital Universitarie Puerta del Mar | 10 | 8 | 5 |
| **Spain** | H. Universitario Marqués de Valdecilla | 10 | 0 | 1 |
| **Spain** | H. U. Virgen de las Nieves, Granada | excluded | | |
| **Spain** | Hospital Miguel Servet | Dec 2023 | | |
| **Spain** | Hospital de Cruces | June 2023 | | |

| Country | Centre | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|---|---|---|---|---|
| **Switzerland** | Zürich University Hospital | 28 | 13 | 21 |
| **Switzerland** | Luzerner Kantonsspital | 21 | 15 | 10 |
| **Switzerland** | Geneva University Hospital | 6 | 6 | 5 |
| **Switzerland** | Lausanne University Hospital | 11 | 8 | 8 |
| **Turkey** | Gazi University Hospital | 2 | 2 | 2 |
| **Turkey** | Marmara University Hospital | 13 | 10 | 7 |
| **Turkey** | Uludag University Hospital | 1 | 11 | 8 |
| **Turkey** | Kanuni Sultan University Hospital | 8 | 8 | 6 |
| **Turkey** | Bilkent Integrated Health Care Campus | 14 | 7 | 7 |
| **Turkey** | Basaksehir City Hospital | 1 | 1 | 1 |
| **United Kingdom** | Royal Hospital for Children, Glasgow | June 2023 | | |
| **United Kingdom** | NHS Lanarkshire Hospital, Wishaw | June 2023 | | |
| **United States** | University of Utah, Division of Neonatology | 10 | 5 | 5 |
| **United States** | Loma Linda University Hospital | Nov 2022 (working on contracts) | | |
| **United States** | UT Southwestern Medical Center, Dallas | 1 | 0 | 0 |
| **United States** | Washington Univ. Hospital | Sep 2023 | | |

**SafeBoosC-IIIv**

The SafeBoosC-IIIv trial was discussed on the steering committee meeting on the 24th of May. There is broad support for the trial and agreement on the relevance and need for the SafeBoosC-IIIv trial. 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 Jakbsen from Copenhagen Trial Unit 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. The minutes from the meeting can be found here.

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