



**Welcome to the April 2024 issue of the SafeBoosC newsletter.**

### SafeBoosC-III follow-up

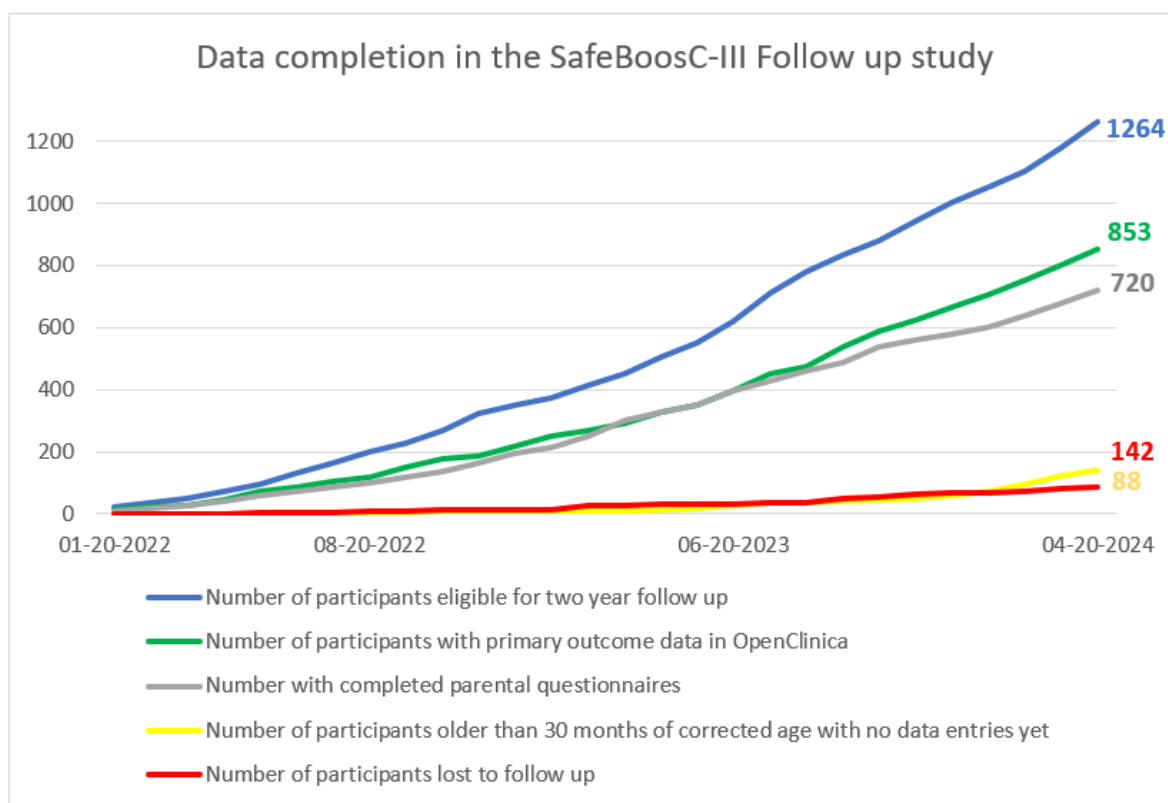
We are pleased to say that we have received a grant from the Louis Hansen foundation of 150.000 EUR meaning that the central costs of the SafeBoosC-III follow up is now fully funded including Marie's final PhD year and the fee for Copenhagen Trial Unit.

So far, 55 of 59 sites with eligible children are open for follow-up and 52 have entered data in OpenClinica. In total, 4 sites who have eligible children have not yet started the follow up and 11 sites have been excluded/withdrawn. All eligible infants (n=1264) have reached two years of corrected age.

**We therefore have entered the final phase of the study and we ask investigators to complete data entry as soon as possible.**

As of now, for 853 (67%) infants data entries in OpenClinica is done and 720 (57%) participants/families have completed the parental questionnaire. For the participants having reached 30 months of corrected age, 82% have enough data for the primary outcome. For an overview of data completion, please see figure 1. For an overview of each sites data completion see table 1. It is impressive that some hospitals are done already.

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



### SafeBoosC-IIIv

The first steering committee meeting was held on the 1st of May and a steering committee was constituted. The process of finding national coordinators is still underway. Interested sites are encouraged to reach out to trial manager Caroline ([caroline.kamp@ctu.dk](mailto:caroline.kamp@ctu.dk)).



*Table 1: Open sites, number of eligible participants for two year follow up and data completion for each site up until the 30<sup>th</sup> of April 2024. Sites highlighted in light 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. Dark green indicate finished completing data.*

| Country               | Site                                                    | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|-----------------------|---------------------------------------------------------|----------------------------------------------|---------------------------------------|-----------------------------------|
| <b>Austria</b>        | University Hospital Graz                                | 15                                           | 12                                    | 10                                |
| <b>Belgium</b>        | UZ Leuven                                               | 30                                           | 29                                    | 22                                |
| <b>Belgium</b>        | Liege Rocourt                                           | 21                                           | 16                                    | 10                                |
| <b>Belgium</b>        | Grand Hospital de Charleroi                             | 18                                           | 12                                    | 13                                |
| <b>Belgium</b>        | AZ St. Jan University Hospital Brugge                   | 10                                           | 10                                    | 8                                 |
| <b>Belgium</b>        | CHU Tivoli                                              | 15                                           | 4                                     | 0                                 |
| <b>Czech Republic</b> | The Institute for the Care of Mother and Child          | 60                                           | 48                                    | 29                                |
| <b>Czech Republic</b> | Motol University Hospital                               | 9                                            | 9                                     | 8                                 |
| <b>China</b>          | Children's Hospital of Zhejiang, Hangzhou               | Excluded                                     |                                       |                                   |
| <b>China</b>          | Children's Hospital of Fudan University, Shanghai       | Excluded                                     |                                       |                                   |
| <b>China</b>          | Hainan Women and Children's Medical Center              | Excluded                                     |                                       |                                   |
| <b>China</b>          | Guangzhou Women and Children's Medical Center           | No data                                      |                                       |                                   |
| <b>China</b>          | Longgang District Central Hospital of Shenzhen          | Excluded                                     |                                       |                                   |
| <b>China</b>          | The People's Hospital of Dehong                         | Withdrawn                                    |                                       |                                   |
| <b>China</b>          | Guangxi Maternal and Child Healthcare Hospital, Nanning | Excluded                                     |                                       |                                   |



| Country        | Site                                          | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|----------------|-----------------------------------------------|----------------------------------------------|---------------------------------------|-----------------------------------|
| <b>China</b>   | Xiamen Children's Hospital                    | Excluded                                     |                                       |                                   |
| <b>Denmark</b> | Rigshospitalet                                | 87                                           | 82                                    | 44                                |
| <b>Denmark</b> | Odense University Hospital                    | 8                                            | 3                                     | 3                                 |
| <b>Denmark</b> | Aalborg University Hospital                   | 17                                           | 11                                    | 11                                |
| <b>Denmark</b> | Aarhus University Hospital                    | 20                                           | 18                                    | 14                                |
| <b>Germany</b> | Freiburg University Hospital                  | 16                                           | 5                                     | 5                                 |
| <b>Greece</b>  | Ippokrateion General Hospital of Thessaloniki | 20                                           | 20                                    | 11                                |
| <b>Greece</b>  | University of Patras General Hospital         | 7                                            | 6                                     | 2                                 |
| <b>Greece</b>  | Alexandra Univ. Hospital                      | 15                                           | 12                                    | 11                                |
| <b>Greece</b>  | University Hospital of Heraklion              | 9                                            | 8                                     | 7                                 |
| <b>India</b>   | St Johns Medical College Hospital, Bangalore  | 4                                            | 4                                     | 3                                 |
| <b>Ireland</b> | University Hospital Cork                      | 15                                           | 5                                     | 0                                 |
| <b>Ireland</b> | Rotunda Hospital Dublin                       | 13 (missing all three prep tasks)            |                                       |                                   |
| <b>Ireland</b> | NMH Holles St                                 | 11                                           | 2                                     | 4                                 |
| <b>Ireland</b> | Coombe Univ. Hospital                         | 15                                           | 3                                     | 0                                 |
| <b>Italy</b>   | Fondazione IRCCS Cà Granda Ospedale, Milano   | 35                                           | 35                                    | 32                                |
| <b>Italy</b>   | Presidio Ospedaliero S. Anna, Turin           | 8                                            | 1                                     | 1                                 |
| <b>Italy</b>   | Ospedale Fillipo del Ponte, Varese            | withdrawn                                    |                                       |                                   |
| <b>Italy</b>   | Fondazione Policlinico Univ. A. Gemelli, Roma | 9 (waiting for ethics approval)              |                                       |                                   |



| Country | Site                                             | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|---------|--------------------------------------------------|----------------------------------------------|---------------------------------------|-----------------------------------|
| Norway  | Oslo University Hospital                         | 30                                           | 0                                     | 19                                |
| Poland  | Medical Center UJASTEK, Krakow                   | 31                                           | Clinical data not available           | 24                                |
| Poland  | Szpital Uniwersytecki, Kraków                    | 19                                           | 1                                     | 0                                 |
| Poland  | Warsaw University of Medical Sciences            | 9                                            | 9                                     | 9                                 |
| Poland  | Poznan University of Medical Sciences            | 29                                           | Clinical data not available           | 26                                |
| Poland  | Specialist Hospital No. 2 in Bytom               | 7                                            | 0                                     | 0                                 |
| Poland  | Wroclaw Medical University                       | 3 (missing blinding procedure and assessor)  |                                       |                                   |
| Poland  | Jan Biziel University Hospital                   | 1 (missing blinding procedure and assessor)  |                                       |                                   |
| Poland  | Centre of Medical Postgraduate Education, Warsaw | 2 (missing blinding procedure and assessor)  |                                       |                                   |
| Spain   | H. Univ. Juan XXIII de Tarragona Hospital        | excluded                                     |                                       |                                   |
| Spain   | La Paz University Hospital                       | 59                                           | 55                                    | 49                                |
| Spain   | Hospital Clinic de Barcelona                     | 51                                           | 49                                    | 39                                |
| Spain   | University Hospital 12 de Octubre                | 60                                           | 53                                    | 32                                |
| Spain   | Hospital de Sant Joan de Deu                     | 24                                           | 19                                    | 14                                |
| Spain   | Hospital Clinico San Carlos                      | 27                                           | 27                                    | 23                                |
| Spain   | Hospital Universitarie Puerta del Mar            | 13                                           | 12                                    | 11                                |
| Spain   | H. Universitario Marqués de Valdecilla           | 13                                           | 11                                    | 8                                 |
| Spain   | H. U. Virgen de las Nieves, Granada              | excluded                                     |                                       |                                   |



| Country               | Site                                        | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|-----------------------|---------------------------------------------|----------------------------------------------|---------------------------------------|-----------------------------------|
| <b>Spain</b>          | Hospital Miguel Servet                      | 1 (missing all three prep tasks)             |                                       |                                   |
| <b>Spain</b>          | Hospital de Cruces                          | 3 (missing all three prep tasks)             |                                       |                                   |
| <b>Switzerland</b>    | Zürich University Hospital                  | 33                                           | 31                                    | 25                                |
| <b>Switzerland</b>    | Luzerner Kantonsspital                      | 37                                           | 34                                    | 19                                |
| <b>Switzerland</b>    | Geneva University Hospital                  | 9                                            | 9                                     | 7                                 |
| <b>Switzerland</b>    | Lausanne University Hospital                | 21                                           | 21                                    | 18                                |
| <b>Turkey</b>         | Gazi University Hospital                    | 7                                            | 7                                     | 8                                 |
| <b>Turkey</b>         | Marmara University Hospital                 | 23                                           | 23                                    | 17                                |
| <b>Turkey</b>         | Uludag University Hospital                  | 25                                           | 25                                    | 23                                |
| <b>Turkey</b>         | Kanuni Sultan University Hospital           | 8                                            | 8                                     | 8                                 |
| <b>Turkey</b>         | Bilkent Integrated Health Care Campus       | 19                                           | 19                                    | 19                                |
| <b>Turkey</b>         | Basaksehir City Hospital                    | 13                                           | 13                                    | 9                                 |
| <b>United Kingdom</b> | Royal Hospital for Children, Glasgow        | 15                                           | 4                                     | 2                                 |
| <b>United Kingdom</b> | NHS Lanarkshire Hospital, Wishaw            | 8                                            | 8                                     | 0                                 |
| <b>United States</b>  | University of Utah, Division of Neonatology | 26                                           | 23                                    | 25                                |
| <b>United States</b>  | Loma Linda University Hospital              | 28                                           | 8                                     | 0                                 |
| <b>United States</b>  | UT Southwestern Medical Center, Dallas      | 3                                            | 3                                     | 0                                 |
| <b>United States</b>  | Washington Univ. Hospital                   | 13                                           | 13                                    | 10                                |

Thank you for your time,

Marie and Gorm