



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

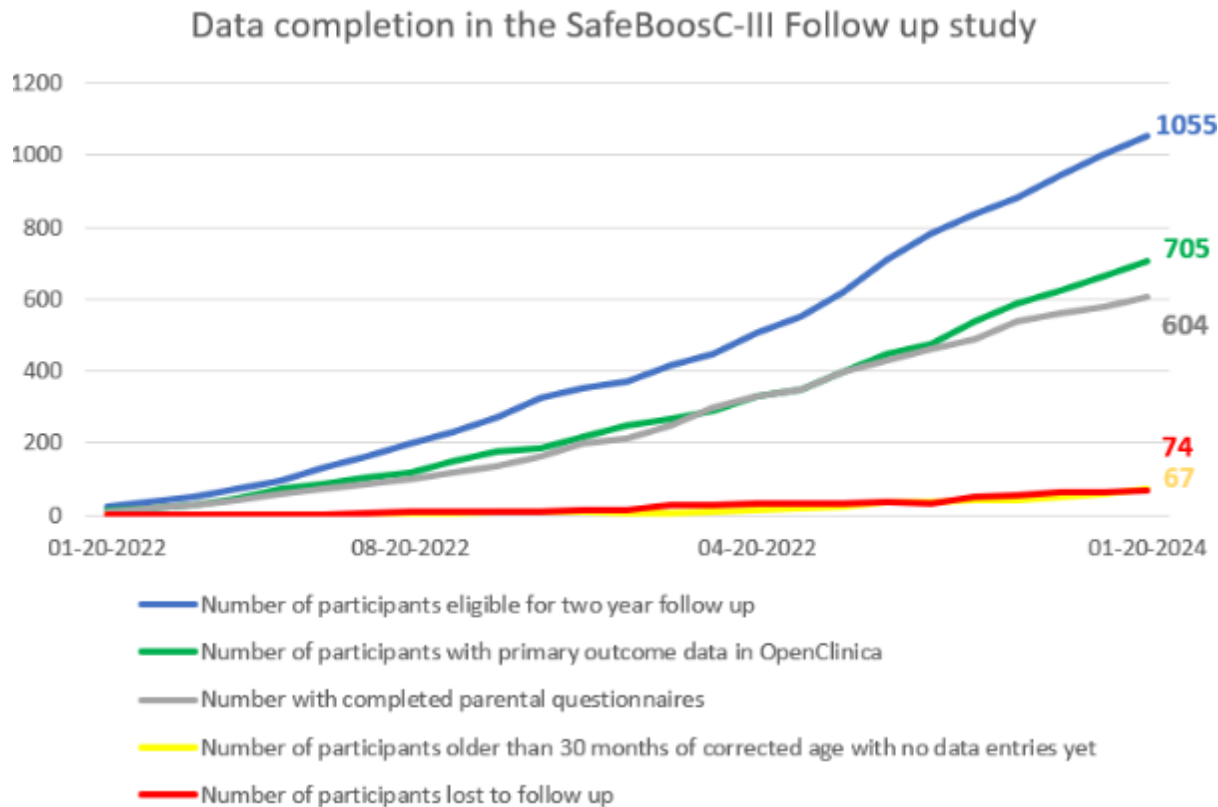
**SafeBoosC-IIIv**

Copenhagen Trial Unit has received a grant to cover the central costs for SafeBoosC-IIIv. The proposed primary outcome is hospital free days within 90 days from randomisation. In total, 1610 participants must be randomised. The hope is to start randomisation at the end of 2024. Please reach out to us if you are interested in participating.

**SafeBoosC-III follow-up**

So far, 52 of 59 sites with eligible children are open for follow-up and 45 have entered data in OpenClinica. In total, 7 sites who have eligible children have not yet started the follow up and 11 sites have been excluded/withdrawn. As a result, the follow-up rates have improved a bit since last month. A total of 1055 eligible infants have reached two years of corrected age. Of these, 705 (67%) infants have completed data entries in OpenClinica so far. In total, 604 (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.

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



*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 Jan 2024. Sites 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               | Site                                                    | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|-----------------------|---------------------------------------------------------|----------------------------------------------|---------------------------------------|-----------------------------------|
| <b>Austria</b>        | University Hospital Graz                                | 13                                           | 12                                    | 7                                 |
| <b>Belgium</b>        | UZ Leuven                                               | 27                                           | 24                                    | 20                                |
| <b>Belgium</b>        | Liege Rocourt                                           | 19                                           | 16                                    | 10                                |
| <b>Belgium</b>        | Grand Hospital de Charleroi                             | 13                                           | 5                                     | 6                                 |
| <b>Belgium</b>        | AZ St. Jan University Hospital Brugge                   | 10                                           | 10                                    | 8                                 |
| <b>Belgium</b>        | CHU Tivoli                                              | 14                                           | 0                                     | 0                                 |
| <b>Czech Republic</b> | The Institute for the Care of Mother and Child          | 57                                           | 42                                    | 26                                |
| <b>Czech Republic</b> | Motol University Hospital                               | 7                                            | 3                                     | 5                                 |
| <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                                     |                                       |                                   |
| <b>China</b>          | Xiamen Children's Hospital                              | Excluded                                     |                                       |                                   |
| <b>Denmark</b>        | Rigshospitalet                                          | 80                                           | 66                                    | 40                                |



| Country        | Site                                          | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|----------------|-----------------------------------------------|----------------------------------------------|---------------------------------------|-----------------------------------|
| <b>Denmark</b> | Odense University Hospital                    | 8                                            | 3                                     | 3                                 |
| <b>Denmark</b> | Aalborg University Hospital                   | 15                                           | 11                                    | 10                                |
| <b>Denmark</b> | Aarhus University Hospital                    | 17                                           | 12                                    | 10                                |
| <b>Germany</b> | Freiburg University Hospital                  | 13                                           | 5                                     | 5                                 |
| <b>Greece</b>  | Ippokrateion General Hospital of Thessaloniki | 20                                           | 20                                    | 8                                 |
| <b>Greece</b>  | University of Patras General Hospital         | 6                                            | 6                                     | 2                                 |
| <b>Greece</b>  | Alexandra Univ. Hospital                      | 13                                           | 12                                    | 11                                |
| <b>Greece</b>  | University Hospital of Heraklion              | 8                                            | 7                                     | 6                                 |
| <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                                 | 4                                            | 1                                     | 0                                 |
| <b>Ireland</b> | Coombe Univ. Hospital                         | 7 (missing all three prep tasks)             |                                       |                                   |
| <b>Italy</b>   | Fondazione IRCCS Cà Granda Ospedale, Milano   | 31                                           | 30                                    | 26                                |
| <b>Italy</b>   | Presidio Ospedaliero S. Anna, Turin           | 7                                            | 1                                     | 1                                 |
| <b>Italy</b>   | Ospedale Fillipo del Ponte, Varese            | withdrawn                                    |                                       |                                   |
| <b>Italy</b>   | Fondazione Policlinico Univ. A. Gemelli, Roma | 4 (missing all three prep tasks)             |                                       |                                   |
| <b>Norway</b>  | Oslo University Hospital                      | 23                                           | 0                                     | 4                                 |
| <b>Poland</b>  | Medical Center UJASTEK, Krakow                | 31                                           | Clinical data not available           | 24                                |



| Country       | Site                                             | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|---------------|--------------------------------------------------|----------------------------------------------|---------------------------------------|-----------------------------------|
| <b>Poland</b> | Szpital Uniwersytecki, Kraków                    | 17                                           | 1                                     | 0                                 |
| <b>Poland</b> | Warsaw University of Medical Sciences            | 9                                            | 9                                     | 9                                 |
| <b>Poland</b> | Poznan University of Medical Sciences            | 28                                           | Clinical data not available           | 24                                |
| <b>Poland</b> | Specialist Hospital No. 2 in Bytom               | 6                                            | 0                                     | 0                                 |
| <b>Poland</b> | Wroclaw Medical University                       | 3 (missing blinding procedure and assessor)  |                                       |                                   |
| <b>Poland</b> | Jan Biziel University Hospital                   | 1 (missing blinding procedure and assessor)  |                                       |                                   |
| <b>Poland</b> | Centre of Medical Postgraduate Education, Warsaw | 2 (missing blinding procedure and assessor)  |                                       |                                   |
| <b>Spain</b>  | H. Univ. Juan XXIII de Tarragona Hospital        | excluded                                     |                                       |                                   |
| <b>Spain</b>  | La Paz University Hospital                       | 58                                           | 51                                    | 46                                |
| <b>Spain</b>  | Hospital Clinic de Barcelona                     | 46                                           | 42                                    | 32                                |
| <b>Spain</b>  | University Hospital 12 de Octubre                | 53                                           | 49                                    | 23                                |
| <b>Spain</b>  | Hospital de Sant Joan de Deu                     | 23                                           | 19                                    | 14                                |
| <b>Spain</b>  | Hospital Clinico San Carlos                      | 27                                           | 24                                    | 22                                |
| <b>Spain</b>  | Hospital Universitarie Puerta del Mar            | 12                                           | 10                                    | 9                                 |
| <b>Spain</b>  | H. Universitario Marqués de Valdecilla           | 13                                           | 11                                    | 8                                 |
| <b>Spain</b>  | H. U. Virgen de las Nieves, Granada              | excluded                                     |                                       |                                   |
| <b>Spain</b>  | Hospital Miguel Servet                           | 1 (missing all three prep tasks)             |                                       |                                   |
| <b>Spain</b>  | Hospital de Cruces                               | 3 (missing all three prep tasks)             |                                       |                                   |



| Country               | Site                                        | Participants eligible for two year follow up | Completed data entries in OpenClinica | Completed parental questionnaires |
|-----------------------|---------------------------------------------|----------------------------------------------|---------------------------------------|-----------------------------------|
| <b>Switzerland</b>    | Zürich University Hospital                  | 33                                           | 25                                    | 25                                |
| <b>Switzerland</b>    | Luzerner Kantonsspital                      | 34                                           | 32                                    | 17                                |
| <b>Switzerland</b>    | Geneva University Hospital                  | 9                                            | 9                                     | 7                                 |
| <b>Switzerland</b>    | Lausanne University Hospital                | 18                                           | 14                                    | 16                                |
| <b>Turkey</b>         | Gazi University Hospital                    | 7                                            | 5                                     | 6                                 |
| <b>Turkey</b>         | Marmara University Hospital                 | 22                                           | 21                                    | 17                                |
| <b>Turkey</b>         | Uludag University Hospital                  | 23                                           | 20                                    | 15                                |
| <b>Turkey</b>         | Kanuni Sultan University Hospital           | 8                                            | 8                                     | 6                                 |
| <b>Turkey</b>         | Bilkent Integrated Health Care Campus       | 19                                           | 11                                    | 8                                 |
| <b>Turkey</b>         | Basaksehir City Hospital                    | 10                                           | 11                                    | 5                                 |
| <b>United Kingdom</b> | Royal Hospital for Children, Glasgow        | 13                                           | 0                                     | 0                                 |
| <b>United Kingdom</b> | NHS Lanarkshire Hospital, Wishaw            | 4                                            | 0                                     | 0                                 |
| <b>United States</b>  | University of Utah, Division of Neonatology | 22                                           | 14                                    | 14                                |
| <b>United States</b>  | Loma Linda University Hospital              | 26                                           | 7                                     | 0                                 |
| <b>United States</b>  | UT Southwestern Medical Center, Dallas      | 3                                            | 1                                     | 0                                 |
| <b>United States</b>  | Washington Univ. Hospital                   | 7                                            | 8                                     | 5                                 |

Thank you for your time,

Marie and Gorm