

## SafeBoosC III newsletter April 2020

Dear investigators

Welcome to the April 2020 issue of the SafeBoosC newsletter.

### Status on randomisations and trial preparations

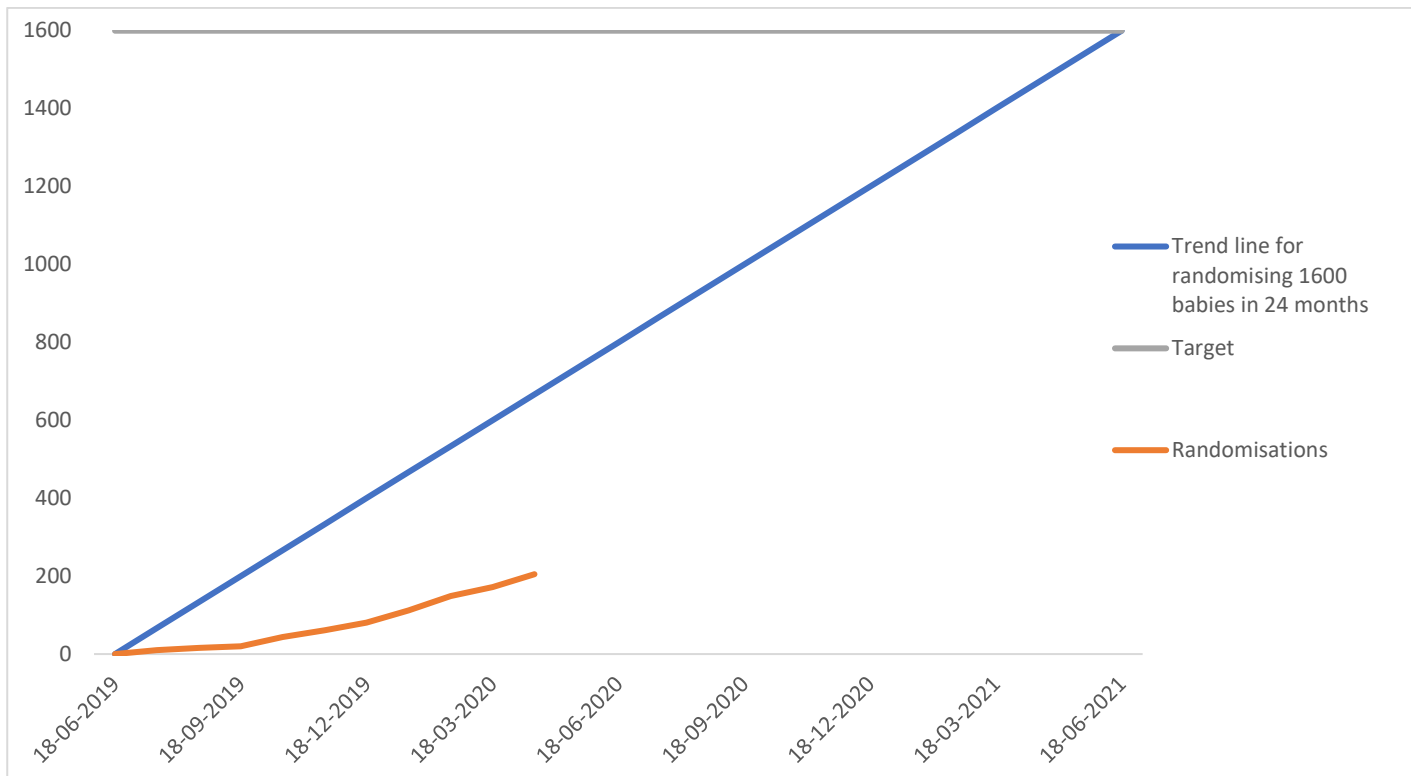
As was the case in March, the COVID-19 outbreak is still affecting the trial. Trial preparation activities as well as the randomisation rate is still lower than before the outbreak. Many sites are still active though, and since the last newsletter, 27 babies have been randomised. It is unlikely that the randomisation rate will increase significantly until the epidemic is under control, but we have high hopes that it will happen shortly after.

As of 22<sup>nd</sup> of April, we have opened for randomisation in 36 centres and 205 babies have been randomised. Furthermore, 42 additional centres are actively preparing for the trial, meaning they have completed at least one of the trial preparation tasks. Below you will find an overview of randomisations in each of the 36 open centres.

| Country               | Centre   | Randomised since | Randomisations |
|-----------------------|--|------------------|----------------|
| <b>Czech Republic</b> | The Institute for the Care of Mother and Child                   | Sep 2019         | 13             |
| <b>China</b>          | Children's Hospital of Zhejiang, Hangzhou                        | Jan 2020         | 0              |
| <b>China</b>          | Children's Hospital of Fudan University, Shanghai                | Jan 2020         | 2              |
| <b>China</b>          | Hainan Women and Children's Medical Center                       | Mar 2020         | 0              |
| <b>China</b>          | Guangzhou Women and Children's Medical Center                    | Mar 2020         | 0              |
| <b>Denmark</b>        | Rigshospitalet   | Jun 2019         | 38             |
| <b>Denmark</b>        | Odense University Hospital                                       | Dec 2019         | 0              |
| <b>Denmark</b>        | Aalborg University Hospital                                      | Mar 2020         | 0              |
| <b>Greece</b>         | Ippokrateion General Hospital of Thessaloniki                    | Oct 2019         | 7              |
| <b>Greece</b>         | University of Patras General Hospital                            | Jan 2020         | 1              |
| <b>Greece</b>         | Alexandra Univ. Hospital   | March 2020       | 2              |
| <b>Greece</b>         | University Hospital of Heraklion                                 | March 2020       | 0              |
| <b>Italy</b>          | Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milano | Nov 2019         | 9              |
| <b>Poland</b>         | Medical Center UJASTEK, Krakow                                   | Jan 2020         | 5              |
| <b>Poland</b>         | Poznan University of Medical Sciences                            | Mar 2020         | 1              |
| <b>Poland</b>         | Specialist Hospital No. 2 in Bytow                               | Feb 2020         | 0              |
| <b>Poland</b>         | Wroclaw Medical University                                       | Apr 2020         | 0              |

| Country      | Centre                                    | Randomised since | Randomisations |
|--------------|---|------------------|----------------|
| Spain        | H. Univ. Juan XXIII de Tarragona Hospital | Feb 2020         | 5              |
| Spain        | La Paz University Hospital                | Jul 2019         | 22             |
| Spain        | Hospital Clinic de Barcelona              | Jul 2019         | 16             |
| Spain        | University Hospital 12 de Octubre         | Jul 2019         | 24             |
| Spain        | Hospital de Sant Joan de Deu              | Oct 2019         | 9              |
| Spain        | Hospital Clinico San Carlos               | Sep 2019         | 8              |
| Spain        | Hospital Universitarie Puerta del Mar     | Oct 2019         | 7              |
| Spain        | H. Universitario Marqués de Valdecilla    | Dec 2019         | 2              |
| Spain        | H. U. Virgen de las Nieves, Granada       | Jan 2020         | 3              |
| Spain        | C. U. Universitario de Santiago           | Jan 2020         | 0              |
| Spain        | Hospital Miguel Servet                    | Apr 2020         | 0              |
| Switzerland  | Zürich University Hospital                | Dec 2019         | 6              |
| Switzerland  | Luzerner Kantonsspital                    | Jan 2020         | 5              |
| Switzerland  | Geneva University Hospital                | Feb 2020         | 0              |
| Turkey       | Gazi University Hospital                  | Jan 2020         | 4              |
| Turkey       | Marmara University Hospital               | Jan 2020         | 5              |
| Turkey       | Uludag University Hospital                | Jan 2020         | 0              |
| Turkey       | Kanuni Sultan University Hospital         | Jan 2020         | 5              |
| Turkey       | Bilkent Integrated Health Care Campus     | Jan 2020         | 6              |
| <b>Total</b> |   |                  | 205            |

As you can see below, the randomisation rate in April is still lower than before the COVID-19 epidemic. However, the rate has increased slightly since March.



### Central monitoring report

In the link below you will find the central monitoring report from April 2020.

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/departments-of-neonatology/research/SafeboosC-III/Documents/for-professionals/data-completion-report-20-april-2020.pdf>

Completion of data entries has dropped a bit since last month (97% versus 98% for completion of end of monitoring module, 97% versus 100% completion of follow-up module, and 88% versus 99% completion of blinded follow-up module). We are aware that the COVID-19 epidemic makes it more difficult to complete data entries, especially for the blinded follow-up module since the principal investigators are dependent on the blinded assessor to complete these.

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

### Different thresholds for different sensors

We have been informed that some of you have been unsure which threshold to use for specific NIRS sensors. We would therefore like to remind you, that the standard operating procedure below describes the different threshold for each approved sensor, as calibrated in the blood-lipid phantom:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/departments-of-neonatology/research/SafeboosC-III/Documents/sop-hypoxic-threshold-oximeters.pdf>

Thank you for your time,

Best wishes  
Gorm and Mathias