

SafeBoosC III newsletter January 2020

Dear investigators

Welcome to the first newsletter of 2020, which includes important information on document updates as well as an overall status of the trial progress.

Update to trial documents

- GCP monitor plan: elaboration of requirements for the diagnosis of death, i.e. death = death before 36 weeks + 0 days of postmenstrual age
- GCP monitoring visit report: same definition of death and Sponsor signature requirement

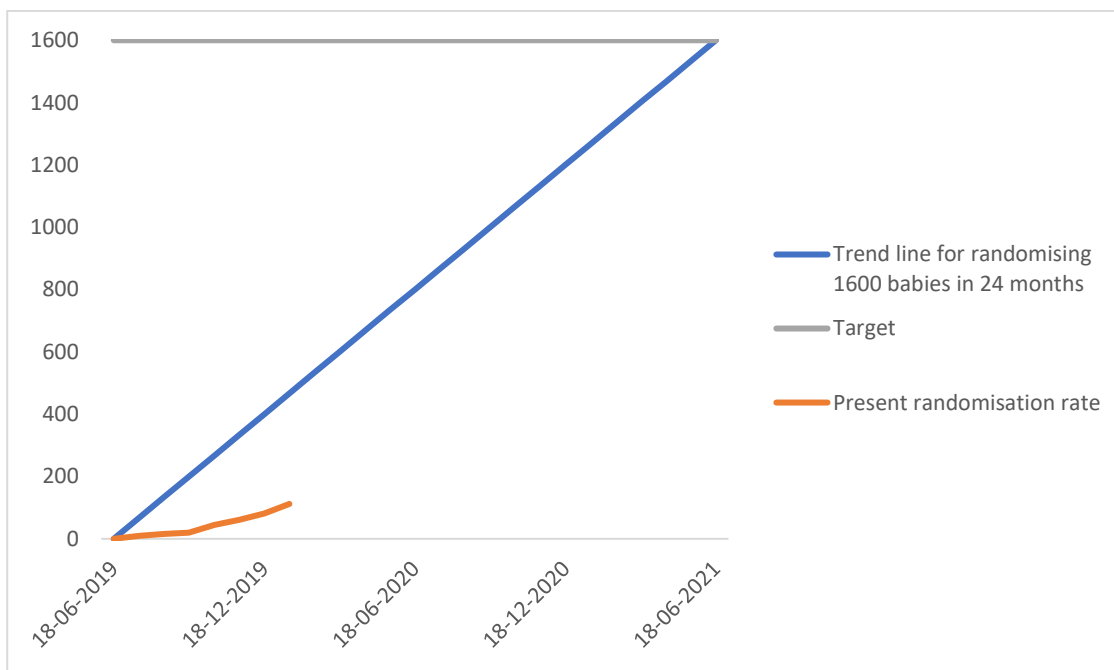
Status on randomisations and trial preparations

As of 28th of January, we have opened for randomisation in 25 sites. Furthermore, 33 additional sites have obtained ethics approval. Below you will find an overview of randomisations in each centre.

Country	Centre	Randomised since	Randomisations
Czech Republic	The Institute for the Care of Mother and Child	Sep 2019	11
China	Children's Hospital of Zhejiang, Hangzhou	Jan 2020	0
China	Children's Hospital of Fudan University, Shanghai	Jan 2020	0
Denmark	Rigshospitalet	Jun 2019	33
Denmark	Odense University Hospital	Dec 2019	0
Greece	Ippokrateion General Hospital of Thessaloniki	Oct 2019	4
Greece	University of Patras General Hospital	Jan 2020	0
Italy	Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milano	Nov 2019	4
Poland	Medical Center UJASTEK, Krakow	Jan 2020	0
Spain	La Paz University Hospital	Jul 2019	16
Spain	Hospital Clinic de Barcelona	Jul 2019	11
Spain	University Hospital 12 de Octubre	Jul 2019	21
Spain	Hospital de Sant Joan de Deu	Oct 2019	7
Spain	Hospital Clinico San Carlos	Sep 2019	4
Spain	Hospital Universitarie Puerta del Mar	Oct 2019	2
Spain	H. Universitario Marqués de Valdecilla	Dec 2019	2
Spain	H. U. Virgen de las Nieves, Granada	Jan 2020	0
Spain	C. U. Universitario de Santiago	Jan 2020	0

Country	Centre	Randomised since	Randomisations
Switzerland	Zürich University Hospital	Dec 2019	2
Switzerland	Luzerner Kantonsspital	Jan 2020	0
Turkey	Gazi University Hospital	Jan 2020	2
Turkey	Marmara University Hospital	Jan 2020	1
Turkey	Uludag University Hospital	Jan 2020	0
Turkey	Kanuni Sultan University Hospital	Jan 2020	0
Turkey	Bilkent Integrated Health Care Campus	Jan 2020	0
Total			120

As seen below, the randomisation rate is slowly increasing, and with opening of multiple new sites in January, we have high hopes for a stable increase over the next months.



Minutes from Steering Committee Meeting beginning of January

The fifth Steering Committee meeting was held online at 6th of January. During the meeting, national coordinators updated the group on trial progress, country by country was an update on trial progress country. Potential threats to the trial was also discussed and finally, the agenda for the 2nd SafeBoosC Investigator Meeting was approved. You can find the minutes here:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/minutes-from-steering-committee-meeting-6-january-2020.pdf>

2nd SafeBoosC Investigator Meeting in Copenhagen

The second SafeBoosC Investigator Meeting was held at AC Hotel Bella Sky in Copenhagen from 23rd to 24th of January. The meeting had four topics: 1) the process of getting the trial up and running in each country, 2) how to optimise the quality of the intervention – as it has to be delivered 24/7, 3) how to optimise the quality of the trial, as large-scale trials face several threats, and 4) ancillary studies. You can find the minutes from the meeting, the scientific agenda as well as all power-point presentations in the link below:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/departments-of-neonatology/research/SafeboosC-III/Sider/investigator-meeting-and-trial-information.aspx>

First central data monitoring report

We have completed the first round of central data monitoring and written a central monitoring report, which showed an overall good rate of data entry completion. However, we can still improve! Investigators with missing data have been contacted, and the monitoring report can be found below:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/departments-of-neonatology/research/SafeboosC-III/Sider/good-clinical-practice.aspx>

Thank you for your time,

Best wishes

Gorm and Mathias