

SafeBoosC newsletter December 2019

Dear investigators

Welcome to the last newsletter of 2019. We hope that you will take your time to read it, since it contains valuable information and good news!

Update to trial documents

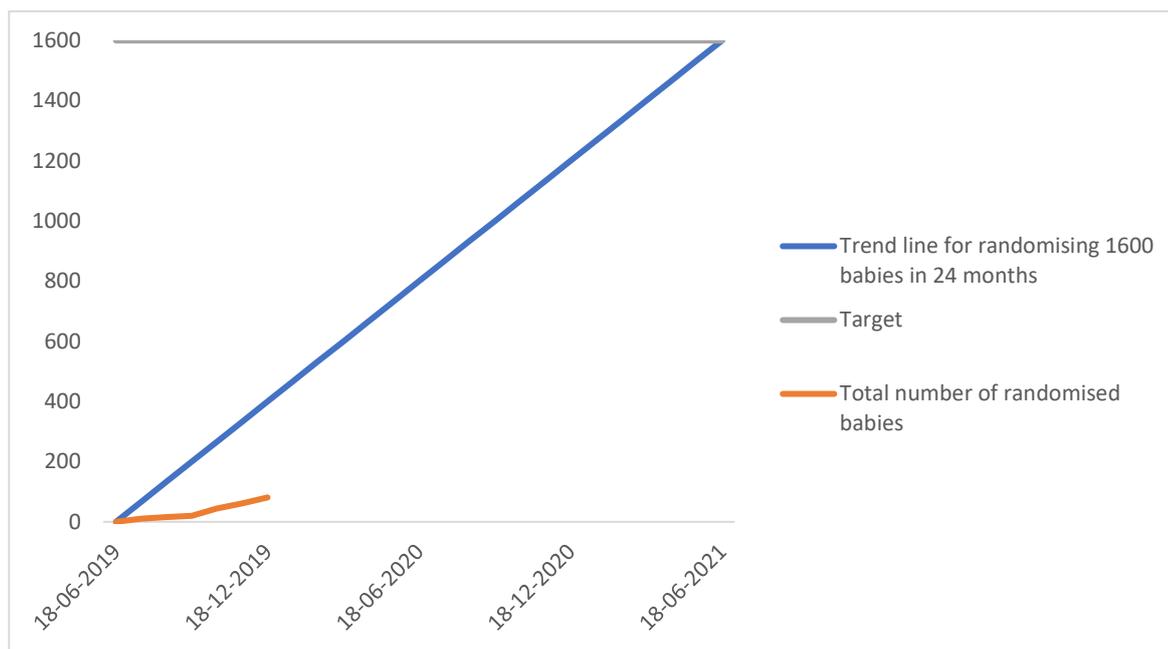
- GCP monitor plan: “Login information to eCRF” not needed in Trial Master File

Status on randomisation and trial preparations

As of 11th of December, we have opened for randomisation in 18 sites. Below you will find an overview of the randomisations in each centre. Please note that in some sites we have opened for randomisation, but the principal investigators have reported to us that they will not officially start randomising before late December/early January.

Country	Centre	Opened for randomisation	Randomisation
Czech Republic	The Institute for the Care of Mother and Child	9-sept 2019	10
Denmark	Rigshospitalet	18-jun 2019	26
Denmark	Odense University Hospital	10-dec 2019	0
Greece	Ippokrateion General Hospital of Thessaloniki	3-oct 2019	2
Italy	Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milano	18-nov 2019	0
Spain	La Paz University Hospital	18-jul 2019	10
Spain	Hospital Clinic de Barcelona	9-jul 2019	11
Spain	University Hospital 12 de Octubre	8-jul 2019	14
Spain	Hospital de Sant Joan de Deu	2-oct 2019	5
Spain	Hospital Clinico San Carlos	30-sep 2019	2
Spain	Hospital Universitarie Puerta del Mar	21-oct 2019	1
Spain	H. Universitario Marqués de Valdecilla	5-dec 2019	0
Switzerland	Zürich University Hospital	23-oct 2019	0
Switzerland	Luzerner Kantonsspital	11-dec 2019	0
Turkey	Gazi University Hospital	1-nov 2019	0
Turkey	Marmara University Hospital	28-nov 2019	0
Turkey	Uludag University Hospital	23-nov 2019	0
Turkey	Kanuni Sultan University Hospital	25-nov 2019	0
Total			81

The randomisation rate has also been stable since jENS, and since we expect a large number of sites (including some of the sites above) will start enrolling babies within the next month, we expect the rate to increase significantly over the next months (see figure next page).



New grant received from Louis-Hansen foundation

We are happy to announce that the Louis-Hansen foundation has granted us 1,000,000 DKK (150,000 Euro). This means that we only need to find an additional 600,000 DKK (80,000 Euro) to cover the remaining central trial costs. We have high hopes!

New SafeBoosC publication

As mentioned in the October newsletter, the manuscript on the statistical analysis plan has been accepted for publication in Trials Journal, and it is now available online:

Late November, the manuscript on the protocol has also been accepted for publication in Trials Journal. We will upload it to www.safeboosc.eu as soon as it is available.

Minutes from Steering committee meeting including approval of central monitoring plan and collaborative investigator certificate

The fourth online steering committee meeting was held in November. You will 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-18-nov.pdf>

During the meeting, the Central monitoring plan was also approved and we will start the process of monitoring all data entries within the next months: You will find the plan here:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/central-monitoring-plan.pdf>

At the steering committee meeting, it was also decided that a collaborative investigator certificate will be available to colleagues in local hospitals, who have supported the principal investigator substantially with the conduct of the trial. For more details, please see Minutes from the steering committee meeting above.

Web-based training certificate

Marie Rasmussen has started the process of sending out certificates on web-based training to all staff members, who have completed relevant training modules. Staff members will receive their certificates, once their respective hospitals have randomised babies for six months. In case some staff members train later (or new staff are hired), they must contact Marie directly (marie.isabel.skov.rasmussen@rh.regionh.dk) to get their certificate.

SafeBoosC meetings in China and Poland

At 12th of November we attended the SafeBoosC investigator meeting in Shanghai, China, where 10 of the 11 Chinese principal investigators participated. The meeting was fruitful, and we are confident, that the first baby will be randomised in China early spring. During our trip to China, Gorm also presented the SafeBoosC project at two Chinese conferences in Hefei and Wuhan.

From 28-30th of November we also attended the Neonatal Emergencies Symposium in Poland, where a Polish SafeBoosC investigator meeting was held. The meeting mainly focused on trial preparations as well as how to manage OpenClinica. It was a positive meeting and the first Polish Sites are planned to start randomising in January.

Thank you for a great year, and we are looking forward to seeing many of you at the 2nd SafeBoosC Investigator meeting in Copenhagen in January.

Merry Christmas and a happy new year,
Gorm and Mathias