



# SafeBoosC III

SAFEGUARDING THE BRAIN OF OUR SMALLEST CHILDREN

## SafeBoosC III newsletter, August 2019

Dear investigators

Welcome to the August version of SafeBoosC III newsletters. Below you will find important information and updates on the trial, including updates to trial documents.

### Status on randomisation

As mentioned in our last newsletter, the first baby was randomised in Copenhagen in the end of June. Since then, three other sites from Spain have started randomising and so far, ten babies have been included. In Copenhagen, the trial has been well received by parents. We use prior informed consent.

### Status on trial preparations

We have a positive feeling, that trial preparations are progressing well in most countries. So far, 35 sites have achieved REB/IRB approval and nine investigators have signed and returned the collaboration agreement. We encourage you all to continue with trial preparations, especially local approval and signing of the collaboration agreement, since this might take some time in some centres.

You can follow trial preparations across all participating sites on the training and delegation log:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/safeboosc-iii-preparation-log.pdf>

### Updates to GCP documents

- 'Report template for GCP initiation visits' has been updated. At the last page, a column for signature by principal investigator has been added. By signing the report, principal investigators assume responsibility to handle follow ups until the next GCP visit.
- 'Good Clinical Practice monitoring plan' has been updated. It has been added that the first monitoring visit should be performed after follow-up data has been entered for the first baby.

The updated documents should be used from now on, meaning already filled-out reports does not need to be changed. The documents can be found under Good Clinical Practice at [ww.safeboosc.eu](http://ww.safeboosc.eu).

### [SafeBoosC meeting at jENS in Maastricht, Holland in September](#)

A separate invitation for the SafeBoosC meeting at jENS in Maastricht has been sent out by e-mail. The meeting will be held in the ESPR room at Thursday 19th of September from 9 - 10:30 AM. It is primarily meant as a forum to share and discuss experiences with trial preparations, the web-based training and certification system, as well as the first randomised babies. However, if you wish to discuss any other matters, please let us know and we will add it to the agenda. We hope to see many of you there!

### [SafeBoosC meeting in Shanghai, China in November](#)

In May, Mathias was present at PAS 2019 in Baltimore, US. During the conference, he met with fifteen US principal investigators to discuss SafeBoosC participation, the elements of preparing for the trial, as well as answering questions. We found these meetings of great value for the future collaboration with US sites, and therefore, we have decided to conduct similar meetings in China. Therefore, we will go to Shanghai and Wuhan in November, to meet with the Chinese principal investigators. China is moving fast with trial preparations and have started training their staff in the Chinese version of the SafeBoosC web-based training program.

### [SafeBoosC meeting at PAS, Philadelphia, US in 2020](#)

The preparations for hosting a SafeBoosC meeting at PAS in 2020 have started in close collaboration with US national coordinator Jonathan Mintzer. More info will follow.

Thank you for your time.

Best wishes

Gorm and Mathias