Summary of steering committee meeting May 27th 20.00 CET 2019

Present: Mathias, Gorm, Janus, Simon, Adelina, Gene, Tomasz, Gabriel, Jakub, Karen, Ebru, Anne Marie
Apologies: Gunnar, Jonathan, Siv, Monica, Cornelia
Missing response: Gerhard, Cheng, Olivier, Ana Vilan

News from Rigshospitalet, Copenhagen

Collaboration agreement
Despite the process started more than four months ago, the collaboration agreement is still not ready. However, we push hard for our hospitals upper management to approve our final draft, and we hope to have it ready within a week or two. Until then, we encourage all principal investigators to consider who should revise and sign the agreement locally (head of department or hospital director).

Ethics approvals and trial preparations
As for now, 13 departments from seven different countries have been given REB approval. In Copenhagen, our REB application including the use of deferred consent was rejected. Our parallel REB application including the use of prior informed consent has been partially approved – minor adjustments were needed, and we have now resubmitted our application. We expect final approval within few days and will send it out to all participating departments when it is obtained.

Status and demonstration of the web-based training and certification program
We apologize for the delay, but we're back on track with new people behind the programming. The module on NIRS monitoring module is ready and the rest are in the pipeline. All modules will be available within the next weeks. When all modules are ready, we will start the process of translating it into various languages according to local needs.

In case investigators wants to train staff before the online training program is ready, we are in the process of uploading all learning material and questions for the module on NIRS monitoring and the treatment guideline to www.safeboosc.eu. We will inform investigators as soon as it is online.

News from Copenhagen Trial Unit

Statistical analysis plan and electronic case report form
The statistical analysis plan is currently in review at Trials journal. We have opted in for the journal's new In Review system, meaning that the draft manuscript will be made available online very soon.

The eCRF is ready. As soon as the collaboration agreement has been signed and returned and GCP initiation visit report has been received, we will open up for randomisation for individual departments.

News from national coordinators

Tomasz Szczapa – using pediatric Masimo sensor in SafeBoosC despite not being CE-marked for babies below 4 kgs. For decision by the SC.

Since the neonatal sensors from Masimo are not available before autumn, Tomasz Szczapa, as the national coordinator in Poland, asked for the steering committees take on the use of Masimo's pediatric sensor, to prevent further delays. As of now, the pediatric sensor is CE-marked to be used in newborns in Europe. Since the pediatric sensor is primarily meant to be used in larger children, there has been worries whether the adhesiveness was too strong for the skin of preterm babies. However, Tomasz has previously used the pediatric sensor on preterm babies and have had no skin complications. Furthermore, the polish REB approved that Tomasz' department could use the pediatric sensor in SafeBoosC. Based on this, the steering committee decided to favor the use of pediatric Masimo sensors until the neonatal sensors are ready.

Using NIRS sensors without removing the white paper
A question was raised regarding the differences in rStO2 value, when the white paper on the sensor is left on, in order to avoid the adhesive effect, since this method is used some places. Gorm and Simon preliminarily tested it for the INVOS adult sensor during the SafeBoosC-II trial and found little effect. Mathias will try to include a study of this issue in the blood-lipid phantom tests to be done in Zürich next week.

New SafeBoosC logo

A new SafeBoosC logo has been designed. The Steering Committee voted whether or not the logo should include a figure or only consist of the text. The majority agreed on, that the figure should be included in the logo (see below).

SafeBoosC III
SAFEGUARDING THE BRAIN OF OUR SMALLEST CHILDREN

Other business

Since we in Copenhagen do not need to sign a collaboration agreement, we expect to randomise the first baby within one or two weeks. We only need the final ethics approval in order to start, since the GCP initiation visit has been completed and staff has been informed.

Regarding the GCP initiation visit, it was clarified, that it is solely the GCP person themselves who are required to have GCP experience/training.