Minutes from Steering Committee Meeting the 6th of January 2020

Attendees: Hans Fuchs, Siv Fredly, Cornelia Hagmann, Tomasz Szczapa, Christian Gluud, Janus Christian Jakobsen, Simon Hyttel-Sørensen, Saudamini Nesargi, Jakub Tkaczyk, Anne Marie Heuchan, Gorm Greisen, Mathias Lühr Hansen, Marie Rasmussen

Apologies: Adelina Pellicer, Ebru Ergenekon, Jonathan Mintzer, Gerhard Pichler

News on funding and outside help

We have received 1,000,000 DKK (132,000 Euro) which will cover Mathias' fourth year as Trial Manager and (almost) all expenses for Copenhagen Trial Unit in the second enrolment year. This means that we are very close to have covered all central trial expenses.

Status and progress of trial preparations, by national coordinators

Germany – *Hans Fuchs*
So far only one center, Freiburg, will be participating. Freiburg has submitted ethics application and the collaboration agreement is with the legal department. The contract is the hold up right now, but because there is no money involved, it should be a speedy process. Hopeful to start randomising within the next month.

United Kingdom - *Anne Marie Heuchan*
Two sites will be able to join the trial. They expect ethics approval early in February and that they can start randomising in March.

Czech Republic - *Jakub Tkaczyk*
Two hospitals will participate, one has already started enrolling babies. The last hospital hope to start randomising in March, but need to deal with some internal organisational changes before they can proceed.

India – *Saudamini Nesgari*
As of right now, only one center will be participating. Have submitted for ethics approval. The contract is being reviewed. The biggest hold up in the contract is regarding the indemnity of patients. India is furthermore struggling with OxyPrem in concerns of responsibility of the devices. The wording used in the contracts is quite harsh, so therefore they might look for insurance for the OxyPrem devices. Optimistic that randomisation can start in April, at the latest.

Switzerland - *Cornelia Hagmann*
In Switzerland four units are taking part in the trial, two of them are open for randomisation. Zürich is already randomised two babies.

Norway – *Siv Fredly*
The two participating centers, Oslo and Bergen, have obtained ethical approval. Bergen is planning to start randomising in the near future. Oslo is currently waiting for another study to be finished, before they can start. Other departments might run into similar problems regarding competing trials and therefore this will be discussed on the Investigator Meeting in January.

Poland - *Tomasz Szczapa*
Four centers have received OxyPrem, two others are currently waiting for the shipment. The remaining centers will also receive from Oxyprem. There have been some problems to get the devices through customs. Most departments have signed the contracts and they expect that a handful of sites have completed all tasks and can start randomising early spring.

Denmark - *Simon Hyttel Sørensen*
Four departments are participating from Denmark, two are open for randomisation. The two others expect to start within the next month.

Overall trial progress
19 sites have opened for randomisation. Babies are being randomised almost every day and as of today we have randomised 100 babies to the trial

Final approval of agenda at the SafeBoosC Investigator Meeting in Copenhagen
No comments, all approved the agenda.

Problems or threats
Several sites are dependent on the OxyPrem devices and a possible problem could be external progress with delivering the sensors.
The heat in the OxyPrem sensor is not as high as other devices, so it might be worth discussing on a future SC meeting whether the sensor can be changed every 6 hours, since nurses have a minimal handling procedure. Investigators are prompted to gather some experience from staff regarding this concern.

CTU mentions that missing data is a big threat when conducting a large-scale trial like SafeBoosC. Problems begin with five percent missing data and after that the problems increases. A friendly reminder to continuously reduce the missing data and to also be aware of the quality of the data.

Mathias, Gorm and Marie