Minutes from the SafeBoosC Steering Committee Meeting the 26th of July

Present: Ebru Ergenekon, Jonathan Mintzer, Jakub Tkaczyk, Hans Fuschs, Gene Dempsey, Adelina Pellicer, Gorm Greisen, Mathias Lühr Hansen, Marie Rasmussen, Siv Fredly

Apologies: Christian Gluud, Janus Jakobsen, Gunnar Naulers, Gerhard Pichler, Gene Dempsey, Tomasz Szszapa, Saudamini Nesargi, Simon Hyttel-Sørensen, Maria Vestager

Absent: Cheng, Ana Vilan, Anne Marie Heuchan, Gabriel Dimitriou, Monica Fumagalli

Trial status update from Copenhagen

Overall, the trial is progressing well. Currently, 71 centres are open for randomisation. 68 centres have randomised participants. The national coordinator from France, Olivier Claris, has officially withdrawn from the SafeBoosC-III trial. Zürich has withdrawn from the trial after randomising 36 participants, due to having many additional ongoing studies. Chinese centres have started to catch up on randomisations after the COVID pandemic. Even though 71 centres are randomising, the randomisation rate has dropped to 2.1 per day, the last month. The randomisation has been decreasing since April. If this continues, we will not finish recruitment until February 2022. It is discussed whether some centres may be getting 'tired'. Hans Fch tells that same mechanism has been seen in COSGOD, as this trial, has also been recruiting for 3-4 years. There seems to be a trend with the newly randomising centres being more active than the centres that have been randomising for a while. Adelina mentions that the overall birth rate in Spain has been lower than ever, following the COVID pandemic.

National coordinators are urged to reach out to centres that are not randomising sufficiently, to encourage recruitment, ask if they need help in raising awareness of the trial, and to identify any reasons for the low recruitment rate.

Discussion on the eCRF and workflow for SafeBoosC-III follow-up study
The first participant randomised, will reach 24 months of corrected age in September 2021. 50 centres have declared participation in the follow-up study, so far. None have declined participation, however some sites have not responded to the invitation yet. Paperwork should be easier, hence the contracts will be covered by the extension of the SafeBoosC-III collaboration agreement. The protocol has been submitted to Danish ethics approval and the protocol paper will be drafted this fall.

The eCRF was presented in the OpenClinica Sandbox and was approved. The follow-up form can be found by randomising a new participant in the Sandbox.

Adelina presented the blinding procedure of the La Paz site, and examples of blinding procedures can be found shortly on the SafeBoosC website.

Discussion of new authorship criteria for the main trial
Up until today, 30 randomised babies have been required to become a co-author. However, it is clear that not all investigators will reach this, especially now when more than 70 centres are randomising. We believe that contribution to the trial should be acknowledged, regardless of failing

to randomise 30 babies. On the other hand, some centres will randomise more than 60 babies, while other centres will only randomise four or five. The extra contribution should also be rewarded.

Therefore, a suggestion for a new set of co-author requirements in the SafeBoosC-III trial, were presented and discussed at tonights (26th of July) SafeBoosC-III steering group meeting:

1) **All investigators that have randomised at least one baby will obtain co-authorship. We hereby acknowledge the effort in getting the trial up-and-running, which is quite an effort, and the contribution of one or more babies to the trial.**

2) **Investigators who randomise more than 30 babies, will be allowed to include one additional investigator from their centre as co-author on the main publication – on the condition that he or she has contributed substantially to the conduct of the trial.**

3) **Investigators who randomise more than 60 babies will be allowed to include two additional investigators from the centre as co-authors on the main publication – on the condition that they have contributed substantially to the conduct of the trial.**

Following the presentation and a short discussion in the group, a vote was taken. All nine members attending the meeting, as well as three additional members who voted per mail, voted in favour for the new co-author requirements. Thus 12 out of 22 steering committee members voted in favour.

Therefore, as from today (26th of July), the new co-author requirements as described above, applies for the SafeBoosC-III trial. The new criteria will also be written in a Standard Operation Procedure and uploaded to safeboosc.eu shortly.

Additionally, Gorm raised the question whether Marie Rasmussen should be a co-author on the main trial publication as well. She has contributed substantially to the development as well as conduct of the trial, by taking the lead on the development of SafeBoosC-III web-based training and certification program, as well as being the trial manager, when Mathias was/is unavailable. Due to less than 12 attending steering committee members, the discussion and vote on this was postponed until the next meeting.

Status on the SafeBoosC-IIIv trial

In April, we submitted a grant application to Innovation Fund Denmark, to cover the central study costs for the SafeBoosC-III follow-up study, and the SafeBoosC-IIIv trial. The total amount that we applied for, was 1.3 million euro. In June, we unfortunately received a rejection. Even though, the Innovation Fund described the two studies as “very intriguing and well described in comparison with the state of art” and considered the plan for implementation of the results to be “addressed in a satisfactory way”, the expected value creation was not considered sufficiently compelling for an investment, given the strong competition (many applications to the call). As for now, we intend to submit a grant application to the Novo Nordisk foundation (Investigator Initiated Trials call) before the deadline, which is the 1 st of September.

No further business