



Minutes CRIC Scientific Steering Committee Meeting

Date: April 29th, 2016

Time: 1pm-3pm

Place: Forskningsenheden, Tagensvej 22, 2100 Copenhagen N

Invited members: Bodil Steen Rasmussen (BSR), John A. Myburgh (JAM), Ville Pettilä (VP), Thorbjørn Grøfte (TG), Ingrid Egerod (IE), Jakob Kjellberg (JK), Jan Bonde (JB), Christian Gluud (CG), Morten H Bestle (MHB), Hans-Henrik Bülow (HHB), Robert Winding (RW), Theis Lange (TL), Helle L. Nibro (HN), Morten H. Møller (MHM), Jens Winther (WIN), Jørn Wetterslev (WET), Anders Perner (AP).

Invited non-members: Lars Winther, Innovationsfonden (LW), Birgit Agerholm Larsen, CRIC project manager (BAL)

Participants: BSR, VP, IE, MHB, HHB, RW, MHM, WET, AP, BAL.

Declined: JAM, JB, JK, CG, TL.

Agenda

1. Welcome (by AP)
2. Presentation (new member, all)
 - a. Thorbjørn Grøfte is a new member of SSC.
3. CRIC office update (by BAL)
 - a. Helle is on maternal leave until March 2017 – there will be no substitute for Helle during her maternal leave.
 - b. The CRIC office/SUP-ICU have experienced some challenges.
 - i. Label-covered vials at sites identified without bottoms.

- ii. Bottom-check of all vials at sites and in storage/at distributors locations (Nomeco).
 - iii. Danish Medicine Agency supportively handled issues instantly when a dispute between Nomeco and CRIC threatened the on-going SUP-ICU trial - Nomeco found out that they had the overall responsibility for the IMP as the provider of final IMP QP release – an overall responsibility they were not aware of and did not want to take on their shoulders.
 - iv. Nomeco have on their own initiative announced IMP at clinical sites to be withhold until further notice, without the accept of SUP-ICU sponsor.
 - v. Final QP release is now in the hands of Pharma-Skan who also provided the placebo-production.
4. Status of started programs (5-10 min each)
- a. The program representatives gave a short oral/PowerPoint status/résumé of their ongoing programs. Please, see “Partner résumé” at the homepage for at written status.
5. Opening new research programs (5-10 min each)
- a. Oxygen program is on track.
 - b. Delirium program have experienced a draw back as the position as PhD-student became vacant.
6. Economy (by BAL)
- a. Yearly report and account for 2015 (Innovation Fund Denmark) (BAL)
 - i. CRIC (overall) have spent less on operating expenses than budgeted – this have been due to the delayed initiation of the SUP-ICU trial (delayed 3-5 months when finding a new company for placebo production instead of the regional pharmacy).
 - b. Fundraising plan (BAL)
 - i. We have applied Svend Andersen Fonden (HOT-ICU), Trygfonden (SUP-ICU) and Rigshospitalets Forskningsfond (SUP-ICU) – we only received a grant from Rigshospitalets Forskningsfond (900.000 Dkr. over 3 y).
 - c. Horizon2020 (AP)
 - i. The Horizon2020 topic: Comparing the effectiveness of existing healthcare intervention in the adult population (Topic identifier: SC1-PM-10-2017) was found to be relevant for CRIC and its partners – and the first initial meeting took place at CRIC’s facilities yesterday (April 28) with participants from London, Paris, Groningen, Bern/Helsinki and representatives from CRIC SSC.
 - ii. The participants agreed to start up the necessary procedures for a proposal.
7. Challenges in 2016 (AP)
- a. Fundraising – we still need more funds for the three clinical programs
 - b. GCP monitoring – as CRIC expect to spend close to 1.5 million Dkr for GCP monitoring it was suggested that it would be supportive if each department would consider applying for the local GCP monitoring expenses covered by CRIC.
 - c. Case-money for every 25 patients may be considered to encourage sites to raise their inclusion.
8. Next meeting is October 28, 2016 at 1 pm at CRIC facilities, Tagensvej 22, 2200 Copenhagen.