



## Minutes of CRIC Scientific Steering Committee Meeting”

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**Date:** October 28<sup>th</sup>, 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:** Bodil Steen Rasmussen (BSR), Thorbjørn Grøfte (TG), Jakob Kjellberg (JK), Jan Bonde (JB), Christian Gluud (CG), Morten H Bestle (MHB), Hans-Henrik Bülow (HHB), Theis Lange via Skype (TL), Morten H. Møller (MHM), Jørn Wetterslev left at 1.45 (WET), Anders Perner (AP), Birgit Agerholm Larsen, CRIC project manager (BAL).

**Non-participants:** John A. Myburgh (JAM), Ville Pettilä (VP), Ingrid Egerod (IE), Robert Winding (RW), Helle L. Nibro (HN), Jens Winther (WIN), Lars Winther, Innovationsfonden (LW), Birgit Agerholm Larsen, CRIC project manager (BAL)

## Minutes according to agenda

1. Welcome (by AP)
2. Presentation (all)
  - a. A short presentation and a welcome to the new member of the Steering Committee, Thorbjørn Grøfte.
3. SUP-ICU (MHM)
  - a. A power point presentation of status ([www.sup-icu.com](http://www.sup-icu.com))

- b. Discussion of low-recruiting sites which has been and will be encouraged to improve recruitment.
  - c. Suggestion to announce that recruitment prior to the interim analyses at 1675 patients will be taken into account - as well as personal contact with the site - when evaluating the clinical sites continuation in the trial.
  - d. At present there is an estimated 10% higher vial administration in one of the arms (blinded which one).
  - e. At present an estimate based on the first 1000 patients in SUP-ICU foresee that we may be short of SUP-ICU medicine, which support efforts to reduce medicine stocks at sites not recruiting.
4. HOT-ICU (BSR)
- a. A protocol draft for HOT-ICU is to be released within days/weeks
  - b. A power point presentation of clinical issues from the drafted protocol was presented and discussed, and will be approached further when the protocol draft is distributed among stakeholders in the project.
  - c. Inclusion/exclusion criteria's were discussed and will be discussed further during the internal protocol-approval process.
  - d. Cohort study was presented
  - e. BSR hoped to be able to include the first patient in HOT-ICU in march 2017, whereas members of the Steering Committee found it to be too optimistic.
5. AID-ICU (AP)
- a. Cohort study performed by Marie Oxenbøll-Collet – preliminary result: haloperidol was the most used drug, some olanzapine and a fair amount of dexmedetomidine was used in acutely ill patients admitted to ICU.
  - b. General discussion of the complexity of doing an RCT in the time of a potentially increasing off-label use of dex. A discussion on three arm (haloperidol and "dex" and placebo) vs two arm (halo vs placebo) –incl. the advantages and dis-advantages from a clinical and trial-related point of view – a discussion that will be continued but must be settled soon to be able to progress in the planning of the RCT.
6. Opening new research programs (5-10 min each)
- a. CRIC is open for new projects from members, but it should be emphasized that any new project must be full finances by fundraising since CRIC is already short of funding for the present studies.
7. Horizon2020 (AP)
- a. A project entitled "IMPACTIC" has been submitted to phase 1 of the H2020 program. It includes a very large RCT on restrictive vs standard care fluid therapy in ICU and CRIC is the coordinator for the consortium, which includes Finnish, Swedish, British, Dutch, French and Swiss colleagues. We will know if we pass to phase 2 in January 2017.
  - b. EUopSTART grant of app. 50.000 Dkr. was obtained to prepare the application for Horizon2020
8. CRIC Conference Q2 (Q3) 2017
- a. Several inputs to how to approach a conference; written and oral media, patient organizations, politicians, authorities,.....
  - b. The aim of the conference – health economy in ICU, highest mortality, poor evidence based treatment, the value of independent interventional research
  - c. the CRIC management group will provide suggestion to a conference,
9. Economy (by BAL)
- a. Fundraising (BAL)

- i. Medicin-puljen (SUP-ICU x 2, HOT-ICU x 1)
- ii. Trygfonden (SUP-ICU)
- iii. Linde-fonden (HOT-ICU)
- iv. Local/regional research funds
  - 1. Grants to SUP-ICU: Rigshospitalet 900.000, Region Hovedstaden 1.140.000
  - 2. Grants to HOT-IC: Obelske Familiefond 800.000

b. Budget/account

- i. All three clinical trials have been delayed and we therefore have an excess of money on our account for 2015 and 2016. Innovationsfonden/Forsknings og Innovationsstyrelsen has requested a new profile/budget for the grant (re-allocation of *when* the money is needed to prevent a local accumulation of money – the amount granted is unaffected).

10. Challenges in 2016/2017 (AP)

- a. Fundraising. Based on the experience of SUP-ICU, each clinical program need to find approx. 5M DKK from external or internal sources. SUP-ICU has done this as 2M DKK from foundations and 3M DDK from the ICU at RH that have paid Anders', Mortens and Mettes salary (2M DKK) and not claimed the case money for the patients recruited at the ICU (estm. 1M DKK) . Thus SUP-ICU has this as a buffer, if no more external funds are obtained.
- b. HOT-ICU and AID-ICU are both facing intensive work loads ahead before their first patient can be recruited. A meeting should be arranged between the SUP-ICU team members and the team members of HOT-ICU and AID-ICU as soon as possible to hand over experiences from the SUP-ICU trial.

11. Next meeting

- a. Friday May 5, 2017
- b. All Stakeholder Meeting 10-12 am, and Scientific Steering Committee meeting 1-3 pm