



## Minutes of CRIC Scientific Steering Committee Meeting”

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**Date:** Mai 5<sup>th</sup>, 2017

**Time:** 1pm-3pm

**Place:** Juliane Marie Centret, 2rd floor, 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), Lone Musaeus Poulsen (LMP), Jørn Wetterslev (WET), Anders Perner (AP).

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

**Non-attendees:** JAM, VP, TG, HN, WIN, LW

## Minutes according to agenda

1. Welcome (AP)
  - a. A welcome to all attendees.
2. Presentation (all)
  - a. *Lone Musaeus Poulsen, Sjællands Universitetshospital, Køge presented as a new member of the steering committee.*
3. Sjællands Universitetshospital, Køge – new partner in CRIC (AP/LMP)
  - a. *AP presented the new partner in CRIC, Køge, and complimented on the two candidates - Hillerød and Køge - being equally qualified in this close run for the AID-ICU program.*
  - b. *Lone Museaus Poulsen from Sjællands Universitetshospital Køge expressed her gratitude and the acknowledgement of being elected to take over the AID-ICU trial.*
  - c. *Morten Bestle, Nordsjællands Hospital, Hillerød, congratulated Køge and expressed his full support to Køge.*
4. SUP-ICU (MHM)
  - a. SUP-ICU inclusion is ahead of the plan, but it has also turned out to be a necessity.
  - b. *SUP-ICU has experienced some challenges about medicine expire that have forced the team to plan for the trial to end already at end of August 2017 to ensure medicine for the 90-days follow-up before it expires end of November 2017.*



- c. *CRIC can't get new supplies from Actavis as they have stopped import to Denmark, and when asked they would not provide us with durability data on Pantoprazole for Lægemiddelstyrelsen to act on to legitimate a dispensation of 1-2 months.*
  - d. *Potential encouragements to speed up the inclusion was discussed:*
    - i. *Show up in person on sites*
    - ii. *Bring project nurses when visiting sites to encourage nurses on sites*
    - iii. *Confront/contact the head of department team at the sites*
    - iv. *Less patients for a co-authorship*
  - e. *Interim analysis is on its way*
5. **HOT-ICU (BSR)**
- a. *The protocol - in which oxygen is handled as a drug - has been a challenge – also for Lægemiddelstyrelsen.*
  - b. *SAE – SAR – SUSAR are still “negotiated” with Lægemiddelstyrelsen, but it is expected to be settled soon.*
  - c. *Medicine student(s) are hired to take part in the daily work when HOT-ICU starts inclusion of patients.*
  - d. *HOT-ICU was encouraged to approach Italian sites – they have invested a lot of efforts on administrative issues – not in time to be part of SUP-ICU - but they can take advantage of their efforts for upcoming trials.*
  - e. *Olav have started recruitment of sites – Aalborg Universitetshospital will be the first to start, then Rigshospitalet, and then the rest of the sites recruited.*
  - f. *HOT-ICU will also include Swedish sites where the legislation has been changed in favor of intensive care patients being allowed to participate in trials.*
6. **AID-ICU (LMP)**
- a. *Concerns about being the last study in a row of three consecutive studies with overlap between HOT-ICU and AID-ICU.*
  - b. *A PhD-student has been hired, as well as a substitute for when the PhD- student is going on maternal leave.*
  - c. *An application will be forwarded to Medicinpuljen and will hold a description of the trial to be used later on when writing the actual protocol.*
7. **Copenhagen Trial Unit (WET)**
- a. *Systematic reviews are on track – Sara has replaced Marija who is on maternal leave.*
  - b. *Literature search results revealed suspicion of fraud, and the involved authors and journals have been advised of the suspicion of fraud (re-use of data).*
  - c. *The e-CRF for HOT-ICU is in progress and take advantage of the features developed for SUP-ICU.*
8. **How do we keep up enthusiasm and maintain high inclusion rates? Suggestions and points of view from “the battlefield” outside the large university hospitals.**
- a. *Several Danish sites in SUP-ICU may not make it for the 50 patients that is the limit for a co-authorship, and it is suggested to lower the limit.*
  - b. *A lowering of the limit to gain co-authorship was also suggested to encourage the sites to increase recruitment at this important stage in the SUP-ICU trial.*
  - c. *The SUP-ICU team argues to keep the existing limits as they do not support changes to be made during the trial, and changing at this point may seem inappropriate to investigators adhering to the present limits.*

9. Opening new research programs (5-10 min each)
  - a. *Rigshospitalet suggests one new program and 2 in pipeline – CLASSIC II (IV fluid), antibiotics and atrial fibrillation.*
  - b. *Discussion of how to ensure a widespread national representation of partners and programs i.e. CRIC suggested programs offered to CRIC partners, or CRIC partners suggest new programs for themselves to run.*
  - c. *Efforts should be done to encourage all intensive care units in the five regions in Denmark to join CRIC.*
10. CRIC Conference Q2 (Q3) 2017
  - a. *A conference is planned for Autumn 2017 and AP is promoting a clinical trial conference for national politicians.*
11. Economy in CRIC (AP/BAL)
  - a. Fundraising (BAL)
    - i. *SUP-ICU has received financial support from Rigshospitalets Forskningsråd, Region Hovedstadens Forskningsfond, Medicinpuljen og Innovationsfonden -*
    - ii. *HOT-ICU has received financial support from Den Obelske Familie Fond, DASAIM and Innovationsfonden.*
    - iii. *AID-ICU has received financial support from Innovationsfonden*
  - b. Budget/account (BAL)
    - i. *For the first two years we have experienced to have less expenditures than expected but only due to expenditures postponed to the coming years. We therefore have applied Innovationfonden for a new payout profile adjusted to this new situation.*
    - ii. *We are on track with the expenditures provided HOT-ICU and AID-ICU will find the financial support stated in their budgets.*
12. Challenges in 2017/2018 (AP)
  - a. *Financial support is by far the biggest challenge in 2017/2018, as increasingly reduced opportunities and grant sizes are available for independent research/investigator-initiated clinical trials.*
13. Next meeting
  - a. *Next meeting is to be held October 27, 2017, at 12-15 at Tagensvej 22, ground floor (same building, same entrance, but this time at ground floor).*
  - b. *Lunch/sandwich 11.30-12 at the 3<sup>rd</sup> floor.*

Referent: BAL