CRIC Board Member Meeting August 26th, 2021 at Rigshospitalet

Participants

Anders Perner (AP), Morten Hylander (MH), Bodil Steen Rasmussen (BSR), Morten Bestle (MB), Anne Craveiro Brøchner (ACB), Maria Cronhjort (MC), Gitte Kingo Vesterlund (GKV), Maj-Brit Nørregaard Kjær (MNK)

Online participants

Theis Lange (TL), Robert Winding (RW), Christian Gluud (CG), Matthew Morgan (MM), Marlies Ostermann (MO), Erik Keus (EK), Jon Henrik Laake (JHL), Joerg Schefold (JS), Carmen Pfortmüller (CP)

Agenda

1. Review of 'About' CRIC as written on our website
2. Open discussion about the visions and strategies for CRIC

Review of 'About' CRIC as written on our website

What is CRIC

We went through the text on the website and found it covering CRIC.

For the planning of the COVID STEROID trials all were not included in the process. It may be that the network and the trial would have benefitted from a more including process. Obviously, this will be easier without the time pressure and travel restrictions caused by COVID-19.

Open discussion about the visions and strategies for CRIC

Discussion points

How do we ensure that there are trials to run?
How does a trial program enter CRIC?
How do we ensure that there are trials to run?
How do we prioritize among programs?
How do we ensure continued clinical and methodological support?
How do we develop CRIC?

Summary of the discussion:

Eight trials have been initiated; several are finalized. CLASSIC likely finalizes recruitment in November, AID-ICU in Jan/Feb next year. Then we have GODIF and HOT-COVID. Usually we think in prioritizing between trials. But now it is important to think about having trials to run. We have not planned what to do post COVID-19. We need to run trials to maintain the network.

How to plan and use the 'office' at Rigshospitalet (RH) was discussed. From the 'office' services are offered based on the resources available. Knowledge will eagerly be shared and help provided and some work done. If resources are lower, sponsor sites will be asked to do more of the tasks (work around contracts, insurance was mentioned as examples where RH often helps). The 'office' at RH is sometimes challenged on resources since Gitte and Maj-Brit both do part time PhDs.

How to plan and use the methodological sites (e.g. CTU and biostatistics) was discussed. Funding will most often be the main barrier. Thus, early involvement of the method sites will be essential to obtain funding for the methodological support from grants.

It is also fine to use local methodological support if certain 'CRIC quality standards' are met. In that way CRIC may be seen as a quality stamp – we shall ensure that high quality research is done within the network no matter which method center is used. Thus, available resources should be pragmatically fitted in - CRIC should be open and inclusive. You can use both the 'office', meet with CTU and/or use other resources. The core eCRF may be important to use. In Aalborg they made agreement with CTU to use e-CRF, and other parts they have elsewhere. The CRIC network has found a model that trial sites seem to be happy with, it is likely important to mimic that in new trials, thereby motivating sites to be involved and include patients. E.g. a new e-CRF with too much data may lead sites to say no. We had 12 new sites from India in CS2, they were very happy with our model as they were used to much more difficult trials. So, this model can expand. India was very collaborative.

GC outlined CTUs 'stand'. CTU has functioned for 25 years, is government funded and not specially oriented. They do SRs and RCTs. To get their collaboration, send an email, present the idea, then we say start the systematic review. One or more reviews will show that it is important to do the trial, and then we look for funding. Most trials are not large enough. Methodology often not good. Always start with the review. Also, we should share data for our trials.

It was discussed how a new research question/program enters CRIC, and whether it is possible for all to come up with trials, or if specific sites are prioritized in the future? All members are welcome to come up with ideas for trials.

A doable structure will be that the Board is contacted early, likely through the 'Office'. After initial email contact to the board, a group will likely be formed within the board to develop the question/program. This process should lead to a grant application with a budget to ensure the scientific process, feasibility and methodological support. The present CRIC trials (SUP, HOT, AID, CLASSIC, CS-2, GODIF) have had a budget between 1 and 2 million Euros. Suggestions are more than welcome from anybody within the network. Any research question that may improve the care of patients, relatives, staff, anything relevant for the ICU setting, may be relevant. For now, the board should not decide, which questions/programs/trials shall 'graduate' to be done in the network. Those who get funding have proved their worth. Trials should though meet a certain standard to be a 'CRIC trial' that is to run with assistance of CRIC and using the network. Both CTU and biostatistics would like to be a part of the program/trial planning as early as possible. The more brains going into it the better chance of getting funding.

Across countries there are interest in using the CRIC infrastructure and model though there may be barriers as conflicts between trials, when there are several trials asking similar questions. For UK it wouldn't be easier if the trials were initiated in UK instead of Copenhagen. If funding is available, there has not been problems. UK are keen to collaborate with successful trial networks.

Aggregates from the discussion

- The description of CRIC on http://www.cric.nu/about-cric/ covers what we aim for
- For new trial programs early involvement of the board is essential to develop the research question and together form a grant application with a realistic budget
- CRIC is a quality stamp, a model to do trial programs, but the methodological resources may be obtained locally and used as long as the quality has the standard.

- The CRIC Board should meet twice per year (hybrid physical and web) and include the CRIC Network once per year.

AP briefly presents The Intensive Care Platform Trial (INCEPT), which is a new research program that aims to prepare, initiate and run an adaptive platform trial. There are four ongoing work groups:

- Stakeholder involvement (patients, relatives, clinicians), incl. the building a Core outcome set for ICU patients
- Statistical modelling/Methods
- Data infrastructure within the EPRs
- Funding