



SAB meeting Dec. 17th 2015

Members:

Present

Susanne Kaae
Ole J. Bjerrum
Christian B. Pipper
Per Spindler
Timo Minssen
Lisa S. Villadsen
Bjarke Oxlund
Merete Schmiegelov
Per Helboe
Steffen Thirstrup
Sukhwinder S. Jossan
Thomas Nedergaard Jensen (as substitute for Jesper Kihl)
Torbjörn Callréus

Absent:

Gitte Dyhr
Gunnar H. Gislason

Minutes

PART ONE:

Welcome to Bjarke Oxlund, Department of Anthropology, Faculty of Social Sciences and new member of SAB.

Status on the appointment of the CORS professor and administrative leader

Susanne Kaae informed on the progress of appointing the professor for CORS. Employment interviews have been conducted and one candidate has been singled out. Hopefully negotiations will result in an official appointment in the early spring 2016.

During the next year an administrative leader is also expected to be appointed. Until then Gitte Borup will continue as administrative assistant.

Status on proceedings from seminar/workshop on patient involvement.

The proceeding from the workshop in spring 2015? on patient involvement has been accepted for publication in the journal Therapeutic Innovation in Regulatory Science with the title: **A Paradigm Shift Towards Patient Involvement in Medicines Development and Regulatory Science: Workshop Proceedings and Commentary.** Published online first in January 2016.

New elective course on regulatory science: "Regulatory Science. Working with interdisciplinary challenges"

A new elective course has been approved on the master level of the pharmacist and master of pharmaceutical sciences education. The purpose of the course is for the students to dig deeper into the role of regulatory science, through the introduction to different topics and within RS, such as benefit-risk assessment, market access, patient involvement in drug development, and some of the problems relating to these. The students will also be introduced to RS through existing RS studies, and discussion of the implications of these in relation to drug development.

The course will have a clear distinction to the Regulatory affairs course. This course is an elective course just before the students initiate their master's thesis.

Involvement of patient organization in CORS

The Danish branch of rare diseases has expressed interest in participating in SAB. Susanne Kaae has arranged a meeting with the patient organization and Sven Frøkjær in January 2016 to discuss the role of the organisation and future cooperation.

Comments were made on the importance to reach beyond the Danish borders when establishing cooperation's, so that the research done within CORS will have an international impact. This is also the long term perspective of CORS, and will be initiated when the infrastructure of CORS is in place for initiating such international cooperation's.

Evaluation of CORS Research Seminar , October 2015?

The goal of the seminar was to establish a common interest between our collaborators, which was considered to be a success.

From the break-out sessions of the day research topics for CORS projects were proposed within Risk Minimization, Patient involvement and Off Label Use were proposed.

Comments were made on the seminar being an eye-opener for the broadness of RS. This also posed a challenge/consideration to how narrow or broad the definition of RS should be for CORS, to maintain focus and interest. This discussion might be raised again on a later stage.

CORS Inaugural Conference

The proposed agenda and budget was discussed and approved by the SAB and will now be discussed with the Board of Directors January 7th especially with regard to funding.

The initial plan is to have the CORS annual research seminar in the morning before the conference to give an introduction to the research being done.

This will also serve as an introduction to the outreach and the impact of RS along with the cooperation with the authorities and the industry. The presenters of the day will be asked to present within a theme of RS.

Sukhwinder Jossan suggested a poster walk during the lunch break the day of the conference.

Miscellaneous

It was discussed whether or not it was appropriate to include CORS as a co-organizer for the **Mini-symposium: Translational Safety Studies for Drug Induced Liver Injury (DILI)** co-organized by Ole J Bjerrum. There was a consensus that the symposium was relevant within the field of RS, and including CORS was more than appropriate.

This led to the discussion on when the SAB members could officially include CORS in various materials, and it was agreed that publications and events within RS were appropriate, but personal comments on e.g. changes in legislations should not be associated with CORS. A procedure for how to comment on guidelines etc. on behalf of CORS will be suggested at the next SAB meeting.

On this note it was suggested that information on events and presentations that included CORS should be sent to Gitte Borup, to contribute to getting a complete overview of the work being done by the SAB members on behalf of CORS.

A short generic Power Point presentation for CORS should be made for the SAB members to make use of.

Two versions of the meeting minutes should be made from now on. One official and one non-official to avoid project ideas being made public.

Ole Bjerrum proposed a seminar on healthy ageing

Part 2

Project proposal from Ole J Bjerrum And Christian B Pipper:

Project title:

There was a consensus on the relevance of the project within the CORS definition of RS. However the proposal was to be made clearer of its focus.

Project proposal from Susanne Kaae, Lisa Storm and Christine E Hallgreen:

Project title:

There was a consensus on the relevance of the project within the CORS definition of RS. However the proposal was to be made clearer on the methodological considerations that are planned to be investigated and a more thorough background search on research already done has to be included.

Both proposals will be re-evaluated at the next CORS meeting on February 4th.

Comments on the process:

Future applicants are to be invited to give a presentation of their project and participate in the initial discussion to answer questions from the SAB members before the SAB decide based on the developed 'Evaluation process of PhD/ post doc projects' on their recommendation for the proposal.

Next meetings:

February 4th 13.00-16.00

May 4th 13.00-16.00