



Copenhagen Centre for Regulatory Science (CORS)
Medical Product Innovation - Research & Education

Minutes from meeting in the Scientific Advisory Board (SAB)

September 3rd 2015, 14.00-16.00

Participants

- Susanne Kaae, Head of Section for Social Pharmacy, Dept. of Pharmacy, SUND
- Ole J. Bjerrum Prof. Emeritus, Dept. of Drug Design and Pharmacology, SUND
- Gunnar H. Gislason, Prof. MD, PhD, FESC, FACC, FAHA. The Cardiovascular Research Centre, Gentofte University Hospital, and The Danish Heart Foundation.
- Lisa Villadsen, PhD, Associate Professor. Department of Media, Cognition and Communication, HUM
- Per Spindler, Director Biopeople and president of DIA (Drug Information Association)
- Jesper Kihl, Vice President, Regulatory Affairs, LEO Pharma A/S
- Merete Schmiegelow, MSc Pharm, Senior Director Regulatory Policies & Intelligence, Novo Nordisk A/S and Honorary Industrial Ambassador Dept. of Pharmacy, SUND
- Adjunct Professor Per Helboe, PhD. MSc Pharm. Dept. of Pharmacy, SUND
- Steffen Thirstrup, PhD, MD, Medical Advisor and Advisory Board Member, NDA Regulatory Services, and adjunct professor at Dept. of Pharmacy, SUND
- Sukhwinder Jossan, Associate Vice President, Regulatory Affairs, Ferring Pharmaceuticals
- Torbjörn Callréus, Chief Medical Officer, Pharmacovigilance and Medical Devices, Danish Health and Medicines Authorities
- Christine Erikstrup Hallgreen, Assistant Prof., CORS
- Gitte Borup, Assistant, CORS
- Karin Friis Bach, Project Manager, CORS

1. Welcome and 'Round of Introduction'

The meeting was opened by Susanne Kaae from the department of Pharmacy. The department is hosting CORS and Susanne will be chairing the Scientific Advisory Board (SAB) meetings until a professor has been employed.

A short presentation was made by each of the attending SAB members.

2. CORS news

A brief orientation was made by Karin Friis Bach covering the following topics:

- The announcement for the Professorship in Regulatory Science is just about to be posted. Deadline for application will be late September.
- Karin Friis Bach and Sven Frøkjær visited the Dutch Medicines Evaluation Board who has established a structured collaboration with several national universities within the field of Regulatory Science. The purpose of the meeting was mutual information about ongoing activities and discussion of a possible future cooperation.
- The concept of the Master Program in “Medicines Regulatory Affairs” as a university-based education has been approved by the Danish Health Authorities. Further planning is now ongoing. First courses will take place in September 2016.
- The proceedings from the Session “New Partnerships in Regulatory Science” on the DIA EuroMeeting 2015 has been accepted for publication: <http://m.dij.sagepub.com/content/early/2015/08/10/2168479015599810>. The session was arranged by BioPeople, Novo Nordisk and CORS in cooperation.
- The proceedings from the workshop “Patient involvement in medicines development and approvals” in May 2015 are expected to be ready for submission as a commentary to the journal “Therapeutic Innovation and Regulatory Science” within a few weeks.
- CORS, BioPeople and the Section for Social and Clinical Pharmacy are part of an international consortium applying for the IMI Call “Patient SMART”. The application has reached stage II.
- Karin Friis Bach has resigned from her position as project manager at CORS by the end of September. The vacant position as administrative manager will be posted as soon as possible.

3. CORS Research Seminar 2015

A yearly research seminar with the purpose of discussing CORS-projects and ideas is planned to take place every autumn. The first seminar will be November 23rd 2015 in Copenhagen (KU Main Building, Frue Plads). All CORS partners are called to present one or more research projects/ideas related to Regulatory Science. The seminar and call for presenters was introduced by Christine Hallgreen.

4. Terms of Reference

A new version of “Terms of Reference” for SAB was discussed at the meeting. No further modifications were suggested. The proposal will be sent to the legal department of the faculty for final review.

5. Evaluation of CORS research projects

A new proposal for evaluation procedure, criteria for approval and an overall research strategy was discussed.

It was pointed out, that the evaluation of proposed projects should be a systematic and transparent process. For this purpose a scoring system could be developed, e.g. inspired by other scoring systems used by the University. Also the research strategy could involve a tool

that provides an overview of all partner competencies in order to ensure diversity of the selected projects.

Emphasis was made on the process of evaluation not being only a simple yes/no – evaluation but merely a process of qualification of proposals.

A new proposal which includes the different views and ideas raised at the meeting is attached to these minutes. Comments to this proposal may be sent to **karin.bach@sund.ku.dk** before **September 28th**.

6. Proposal of project

A brief description of a proposed CORS research project was discussed at the meeting. The overall subject was evaluation of risk minimization interventions. Torbjörn Callreus explained why the authorities have recognized this as an important topic and how they already are participating in research activities. It was agreed that the proposal could be a relevant project for CORS to elaborate further. Christine Hallgreen will contact possible collaborators in order to proceed with the work and prepare an application for the next SAB meeting.

7. Planning of a Symposium/Kick-off event spring 2016

Several themes for a symposium planned for the spring 2016 were discussed at the meeting, e.g. “Coordination of HTA activities across Europe” or “Efficiency of Regulatory Science from a worldwide perspective – how can different universities work together?”

A working group was established with the purpose of preparing a proposal for the next SAB meeting. Members of the group are: Merete Schmiegelow, Sukhwinder Jossan, Per Spindler, Gitte Borup.

8. Next Meeting

The next meeting will be on **Thursday 17th of December, 14.00 -16.00** at the same venue, Nørre Allé 71.

15. sept 2015