



Minutes from the initial meeting in the

Scientific Advisory Board (SAB)

June 23rd 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
- Christian Bressen Pippner, Associate Professor, Section for Biostatistics, Dept. of Public Health, SUND
- Per Spindler, Director Biopeople and president of DIA (Drug Information Association)
- Timo Minssen, Associate Professor, Centre for Information and Innovation Law, LAW
- Trine Moulvad, Vice President, Regulatory Policies & Intelligence, Novo Nordisk A/S
- Gitte Dyhr, Chief Specialist, Regulatory Affairs, Pharmacovigilance and CQA, H. Lundbeck A/S
- Jens Ekelund, Associate Vice President, Global Regulatory Affairs, Ferring Pharmaceuticals A/S
- Jesper Kihl, Vice President, Regulatory Affairs, LEO Pharma A/S - *from 14-14.45*
- 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. By then it is expected that the professor will take over the leadership of SAB.

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

2. CORS status and future plans

A brief presentation by Karin Friis Bach. The presentation is attached. The preparation of an advertisement for a new professor is in process. A search committee has been proposed (Sven Frøkjær, Steffen Thirstrup, Karin Friis Bach).

A question was raised regarding a webpage for CORS. This was established a few days after the meeting and can be reached at: <http://pharmacy.ku.dk/cors/>. Possibilities for new partners and collaborators was discussed, e.g. patient organizations and the EMA committee on Pharmacovigilance, PRAC.

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 take place November 23rd 2015. For further planning a working group has been established. The group is still open for participants!

4. Terms of Reference

The proposed "Terms of Reference" was discussed and a new version of the document is attached. Major changes to the document included omission of the phrase that allowed for the possibility of substitutes to participate if a SAB-member was unable to attend. Substitutes will still be welcomed if a member is prevented from participating, but since the SAB-members are personally announced; personal mandate and participation should be the main rule.

It was also agreed that SABs aim and duties should be more clearly defined.

Terms of Reference should be approved by CORS Board of Directors and reviewed once a year.

5. Proposed principal research areas

The document with the proposed "CORS Research Areas" was discussed. It was agreed, that this should be a living document that can be improved/developed continuously. It was also agreed that the description of research areas to a greater extent should emphasize that Regulatory Science is an impact-science and therefore it should be a specific interest to involve Regulatory Agencies. These agencies also often have great amount of data that could be of relevance for e.g. Ph.D. projects.

It was also mentioned that the heading "Benefit-Risk Assessment" should be rephrased, as this is a very general term. Subjects should be a little more specific as e.g. "patient involvement in benefit-risk assessment"

The section regarding "Regulatory Pathways" should also involve pathways for safety-assessment (e.g. requirements for PAS studies), requirements for pre-clinical testing and hurdles to be overcome for actually reaching the market and the patients.

The section on Personalized Medicine was regarded as too specific and a change to "Hot Topics within Regulatory Science" was proposed instead. This could e.g. include areas as data-transparency, patent requirements and a possible paradigm shift within the methodologies used for creating evidence of the efficacy and effectiveness of drugs.

A proposal for a new document describing the “CORS Research Areas” will be prepared before the next meeting.

6. Procedure and recommendations for establishment of CORS projects

The proposed procedure and recommendations for CORS projects was discussed at the meeting. Overall it was agreed, that the proposed pathway for discussion and approval of projects could be used. However it was also agreed, that it should not be the responsibility of SAB to prioritize between proposed projects, but rather to give advice on the scientific value on each project.

In case of disagreement between members, the different opinions should be stated in the minutes from the meeting. If a member of SAB has proposed a specific project, that member cannot take part in the final discussions of the project.

Lastly, some minor changes to the wording of the document were proposed.

A new version of the document is attached. This can be discussed at the next meeting.

7. Any other business

It was discussed, that Regulatory Science is an “applied research” area and may be difficult to communicate to researchers who are used to work within the field of natural sciences. Participation at staff meetings at the university departments etc was recommended.

8. Next Meeting

The next meeting will be on **Thursday 3rd of September, 14.00 -16.00** at the same venue, Nørre Allé 71.