



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

Joint meeting Steering Committee and Scientific Advisory Board
December 15th 2016
14.00 – 16.00

University of Copenhagen, Universitetsparken 2, Meeting room A, 3rd floor (down the hall to your right)

Present

Susanne Kaae
Ole J. Bjerrum
Christian B. Pipper
Per Spindler
Timo Minsen
Merete Schmiegelow
Jens Heisterberg
Per Helboe
Sukhwinder S. Jossan
Torbjörn Callréus
Gunnar H. Gislason
Birthe Holm
Steffen Thirstrup
Jesper Kihl
Sven Frøkjær
Flemming Madsen
Karsten Vrangbæk

Absent:

Bjarke Oxlund
Gitte Dyhr
Lisa S. Villadsen
Robin Evers

Guest:

Janne Lehmann Knudsen

CORS:

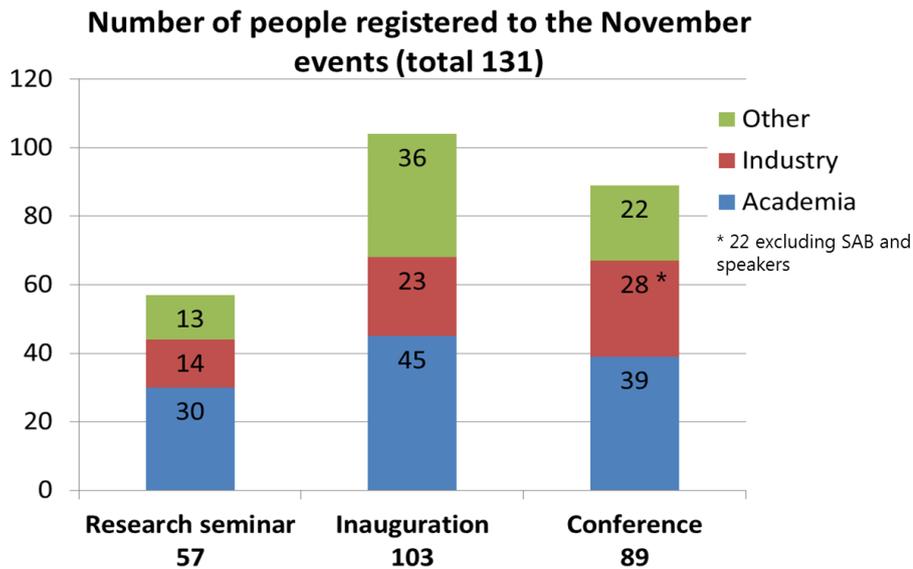
Marie Louise De Bruin
Christine Erikstrup Hallgreen
Stense Vestergaard

Agenda

1. Welcome
 - Adoption of the agenda
2. CORS News
 - Conference
 - Update PhD projects
 - Candidates (Susanne Kaae & Ole Bjerrum)
 - Open call (see annex)
 - Topics agreed in May 2016: a) Impact of regulatory instruments: Investigating series of decisions, b) Uncertainty: benefit and risk.
 - Affiliations & acknowledgements (attached)
 - Input for annual rapport
 - Terms for Ph.D. (will be circulated before the meeting)
3. Roles and responsibilities
 - SAB/BoD
 - DKMA
4. Annual cycle: Next year's activities
 - Spring event (visit from Japan – Gifu University)
 - Research seminar and conference
5. AOB and date for next meeting
 - Visit to Fudan University (Sven Frøkjær / Flemming Madsen)

Minutes

1. Welcome
 - Adoption of the agenda
 - Agenda was adopted with the addition of 'Future funding' under AOB
 - Welcome to new member from Novo Nordisk Jens Heisterberg and guest from DKMA Janne Lehman Knudsen
2. CORS News
 - Conference
 - General impression was satisfaction among participant – no formal evaluation was conducted
 - Number of participants in the three events, see figure below.



A summary is being drafted to share the experience from the conference (by Merete Schmiegelow, Marieke De Bruin and Per Spindler)

Big thanks to the planning committee - Merete Schmiegelow, Per Spindler and Sukhwinder S. Jossan

- Update PhD projects
 - Candidates (Susanne Kaae & Ole Bjerrum)

Two candidates has been appointed, starting 31st of december

PhD project: Factors ensuring effective Direct to Healthcare Professional Communication impact on physician's behaviour

Candidate: Mathias Møllebæk, Master of Arts, Rhetoric

Main supervisor: Susanne Kaae, IF

PhD project: The development of fixed-dose combinations through improved methodology

Candidate: Asbjørn Nøhr-Nielsen, Cand. Scient. Molecular Biomedicine

Main supervisor Trine Meldgard, ILF

Co-supervisor; Ole Bjerrum, ILF

- Open call

The call text was adopted including the proposed changes from the steering committee and adding of the terms interdisciplinary or multidisciplinary as a pre-request.

The call will have two phases. First phase is the assessment of the project second phase is the assessment of the candidate.

The call for the project will be posted before Christmas on CORS website with submission deadline on February the 17th.
(<http://pharmacy.ku.dk/research/cors/dokumenter/PhD-project-in-Regulatory-Science-Open-call-2017.pdf>)

The call will also be distributed to partners at other faculties to make sure of circulation. CORS staff will screen the submissions and depending on quantity and topics distribute the project descriptions to the relevant partners for assessment. The projects will be discussed at the SAB meeting 3rd of March 2017.

- Topics agreed in May 2016: a) Impact of regulatory instruments: Investigating series of decisions, b) Uncertainty: benefit and risk.

Marieke presents a short description of the topics of the next PhD and a post-doc proposal – to be defined in detail once the open call PhD project has been decided.

- Affiliations & acknowledgements

The idea is for associates, partners and PhDs to have access to a standardized text to acknowledge the role of CORS. In addition, a template for a Declaration of Interest statement was drafted. The proposed wording of the DoI can be used when suitable otherwise moderations are accepted as well. The revised version will be published on the CORS website.

- Input for annual rapport

Stense Vestergaard requested that all send an overview of activities related to CORS including publications, presentations, teaching etc. before February the 1st 2017. It was agreed that the annual report for 2016 will show a cumulative overview of CORS activities for all previous years.

- Terms for CORS financed PhD projects

The terms were adopted including the proposed changes from the steering committee. The revised version will be published on CORS website.
(http://pharmacy.ku.dk/research/cors/dokumenter/Terms_for_CORS_PhDs_2016_12_20.pdf)

3. Roles and responsibilities

- SAB/Steering Committee

Marieke De Bruin presented the CORS organisation diagram – it was proposed to leave out the role and obligations as professor outside CORS to make it easier to understand. The revised version will be published on the CORS website.

- DKMA

Briefing on collaboration with DKMA (see minutes steering committee meeting)

4. Annual cycle: Next year's activities

- Spring event (visit from Japan – Gifu University)

Due to the Japanese academic year (April 2017 – March 2018) the joint event will be planned for spring event 2018. Another CORS spring event needs to be organised for 2017, perhaps in conjunction with the visit from the delegates from Fudan University (see AOB).

- Research seminar and conference

Transparency and Data disclosure were discussed as potential topics for the next conference in fall 2017, as well as the organisation with few key speakers and more research driven presentations.

Merete Schmiegelow and Birthe Holm volunteered for the program/planning committee and Timo Minsen expressed interest.

5. AOB and date for next meeting

- Visit to Fudan University (Sven Frøkjær / Flemming Madsen)

Sven Frøkjær and Flemming Madsen explained about their trip to Fudan University in China and the collaboration emerging (http://spfdu.fudan.edu.cn/NewsInfo_list.aspx?BID=66&SID=68&ShowID=1975) A return visit from the Chinese delegation is planned for March/April 20.

An overview of titles and short course description of all CORS/regulatory related courses at all faculties is to be shared with the collaborators at Fudan University. SAB members are requested to send a list to Sven Frøkjær

- Future Funding

The topic was postponed to next meeting

- Next Meeting

The next SAB meeting is planned for March 3, 2017. A doodle will be circulated to plan a meeting in Q2 2017.