FACULTY OF HEALTH AND MEDICAL SCIENCES UNIVERSITY OF COPENHAGEN

Copenhagen Centre for Regulatory Science (CORS)

Medical Product Innovation - Research & Education



CORS Scientific Advisory Board meeting Sep 15, 2017 13.00 – 15.00

University of Copenhagen, Universitetsparken 2, 3rd floor, UP2 (Mødesal A)

Present

Marieke De Bruin
Anna Birna Almarsdottir (substitute Susanne Kaae)
Ole J. Bjerrum
Gunnar H. Gislason
Christian B. Pipper
Per Spindler
Timo Minsen
Merete Schmiegelow
Per Helboe
Birthe Holm
Jens Heisterberg
Gitte Dyhr

Apologies

Bjarke Oxlund Lisa S. Villadsen Steffen Thirstrup Torbjörn Callréus Sukhwinder S. Jossan Jesper Kihl Nikolai C. Brun

CORS

Christine Hallgreen

Guest

Morten Andersen

Agenda

- 1) Welcome
- Adoption of the agenda
- 2) CORS Updates
- Biosimilars PhD project (Marieke)
- MRA awareness about courses (Merete)
- Annual conference update (Christine)
- 3) Meet Morten Andersen, professor in Pharmacovigilance
- · Research plan PhV group at ILF
- Opportunities for collaboration in research & education
- 4) AOB

Minutes

1) CORS was informed that Torbjörn Callréus has resigned from the Danish Medicines Agency as of September 30th. Furthermore, Bjarke Oxlund has resigned from his position at the University of Copenhagen in favor of a position at the Danish Institute for Human Rights. Both will step down as members of the CORS SAB and replacements are sought.

2) CORS updates

- **Biosimilars PhD project** (MDB/ABA). Recruitment for the PhD position was successful and the candidate will be employed as of November 1, 2017.
- MRA awareness about courses (MS). Challenges on development of and recruitment for individual courses within the MRA program were discussed, as well as future actions to improve it.
- Annual conference update (CH). With 2 weeks to go before the event, all speakers are confirmed and registration is still ongoing. Additional awareness resulted in a recent increase in registrations, but there are still some seats available.

3) Meet Morten Andersen, professor in Pharmacovigilance

Morten Anderson gave a presentation about his research plan for the Pharmacovigilance group at the department of Drug Design and Pharmacology and opportunities for collaboration in education and research with CORS were discussed. Both groups expect to collaborate on projects where regulatory science meets pharmacovigilance. First outputs of this collaboration were a presentation of a joint systematic review on methods used to evaluate effectiveness of Risk Minimisation Measures at the International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) in Montreal by Christine Hallgreen, as well as the establishment of the Pharmacoepidemiology Research Collaboration.

4) AOB

Collaborations: The memorandum of understanding with the University of Southern California has been signed and plans for collaborative events will be made. In October 2017, a delegation from CORS will visit Fudan University to discuss the progress in the establishment in the Regulatory Science Centre and opportunities for collaboration in education.

Strategy: CORS will reevaluate its strategy and plans for the upcoming years. As part of this exercise visits to all partners will be planned before the end of the year.

Topics for joint SAB-SC meeting: SAB members are asked to provide topics in writing

Next meetings: joint SAB-SC meeting, December 5, 13-16 h; for the SAB meeting Q1 2018 a doodle will be circulated