



MINUTES

20 MARCH 2020

Forum CORS SAB Meeting
Meeting date 20-03-2020, 8:30-10:30
Place Adobe Connect
Minutes-taker Selene Bornati

**COPENHAGEN CENTRE FOR
REGULATORY SCIENCE**

UNIVERSITETSPARKEN 2
DK-2100 COPENHAGEN

DIR 45 35 32 52 48

Present

Marieke De Bruin (chair), Christine Hallgreen, Selene Bornati, Mathias Møllebæk, Jens Heisterberg, Nina Christiansen, Per Spindler, Steffen Thirstrup, Susanne Kaae, Lisa Storm Villadsen, Per Helboe, Timo Minssen, Ole Bjerrum.

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Apologies

Birthe Holm, Gitte Dyhr, Gunnar H. Gíslason, Sukhwinder S. Jossan, Eskild Colding-Jørgensen

Agenda

1. Christine Hallgreen: PhD pitch (20 min)

A project idea for a new to-be CORS-funded project was presented. SAB discussed the scope of the project, the aim and its relevance and agreed that the idea of interest to CORS and should be worked out in more detail.

2. Annual Conference 2020 (30 min)

As a reminder, the Conference is scheduled to take place on November 23, 2020.

a. Establishment of the Conference Committee

Per Spindler has accepted to be part of the organising committee, which Marieke De Bruin will chair. Two additional members are needed and CORS SAB members were encouraged to volunteer. Interest can be expressed via email before April 15.

b. Discussion of tentative themes for 2020

From the poll, the most interesting themes are:

1. Regulation of AI components intended for evidence generation in medicines/medtech development
2. How regulations / regulators can stimulate innovation, if a business case is not commercially attractive on its own
3. Regulation in medtech & digital
4. Patients alignment and RS, interface regulatory-HTA
5. How treatments for small patients groups are reviewed for use and reimbursement once the MA has been granted.
6. Postmarketing pharmacovigilance methodologies

Naturally, a Covid19-themed conference is also considered. It will be difficult to speak about anything else at that point, but maybe it is possible to integrate the subject into a wider discussion.

The Conference Committee will make the final decision, but input is welcome from the whole of SAB.

3. Ad-hoc (10 min)

- a. Two publications became public. They are both the result of Master projects at CORS and will be listed on the CORS publications page (<https://cors.ku.dk/research/cors-publications/>)
- b. The PhD defense of Asbjørn Nøhr-Nielsen has been postponed until further notice, because of COVID-19. The planned symposium ahead of the defense, will also be postponed. The topic is *Modeling and simulation in drug development and regulation*. The panel included two guests speakers, Janet Mifsud, Professor Clinical Pharmacology & Therapeutics, University of Malta, and Henrik Agersø, Head of Quantitative Clinical Pharmacology at Novo Nordisk), as well as to of Asbjørn's co-supervisors, Ole J. Bjerrum and Theis Lange.

4. Presentation by Mathias Møllebæk (30+20 min)

PAGE 3 OF 3

Mathias presented the latest developments of his PhD project 'Factors ensuring effective Direct to Healthcare Professional Communication of Risk Minimization Initiatives'. SAB praised Mathias for the great work and importance for the field. He was encouraged to expand his work to address COVID-19 related issues. The slides of his presentation were circulated to SAB members.

Next Meeting: June 18, 2020, 9.00-12.00