



Copenhagen Centre for Regulatory Science (CORS)

Medical Product Innovation - Research & Education

CORS Scientific Advisory Board meeting

June 28, 2019

9.00 – 11.00

University of Copenhagen, Mærsk Tower, 7.15.149

Present: Merete Schmiegelow, Susanne Kaae, Per Helboe, Helen Yu (replacement Timo Minssen), Steffen Thirstrup, Christine E. Hallgreen, Birthe B. Holm, Marieke De Bruin

Apologies: Ole J. Bjerrum, Theis Lange, Sukhwinder S. Jossan, Gunnar H. Gislason, Per Spindler, Lisa S. Villadsen, Nicolai C. Brun, Jens Heisterberg, Gitte Dyhr, Lene Jørgensen, Mette L. Bergenser, Trine M. Lund.

Guest speakers: Asbjørn Nøhr-Nielsen

Chair/minutes: Marieke De Bruin

Minutes

1. Welcome and adoption of the agenda
The agenda was adopted.
2. CORS news
 - SAB membership: LEO Pharma A/S representative
A name of a new LEO-representative has been announced, but we are awaiting documentation needed for the approval by the Steering Committee.
 - Staff: Christine is Associate Professor, new Postdoc in pharmacoepidemiology and health technology
Christine Hallgreen has been promoted to Associate Professor in a permanent position, and Richard Ofori-Asenso will start his 2-year post-doc on August 1st, working on the HTx and the SAFER project (What works best to protect public health? An international comparison of post-market regulatory risk communication on prescription drugs).
 - Follow-up EMA Regulatory Science strategy
CORS has submitted a written response to the public consultation of the EMA Regulatory Science Strategy 2025, taking into consideration the suggestions made by SAB.
3. Annual CORS conference
The Annual CORS conference is scheduled for Monday, November 18, Maersk tower, in the Henrik Dam Auditorium. The theme will be 'Public Health and Innovation – Is Regulation a Friend or a Foe?' The scientific program committee is confirming with potential speakers and finalizing the program. Registration is expected to open in July.

4. MRA program (Lene Jørgensen and Mette L. Bergenser)
The presentation about the MRA program is postponed to the September SAB meeting.
5. Break
6. Presentation of the CORS- funded PhD project on fixed-dose combinations
 - Asbjørn Nøhr-Nielsen presented his work. His first paper has recently been accepted (<https://bpspubs.onlinelibrary.wiley.com/doi/full/10.1111/bcp.13986>) and his other papers are underway. The thesis is expected to be submitted in December 2019. The SAB showed great interest and provided Asbjørn with numerous comments and recommendations.
 - According to the Terms for CORS-financed PhD projects, the candidate is expected to (co-)chair a stakeholder workshop when the project is finalized. The objective is to present and discuss the regulatory science perspectives and impact of the research project. SAB suggested to organize a workshop/roundtable discussion in spring (between handing in and the defence) with representatives from academia (modelers/statisticians), authorities (clinical assessors/modeling experts), industry (modeling/regulatory experts), and patients/health care professionals.
7. Any other business
None