



## Copenhagen Centre for Regulatory Science (CORS)

Medical Product Innovation - Research & Education

### CORS Scientific Advisory Board meeting

March 19, 2019

9.00 – 12.00

University of Copenhagen, Mærsk Tower, 7.15.149

## Minutes

**Present:** Merete Schmiegelow, Susanne Kaae, Per Helboe, Ole J. Bjerrum, Theis Lange, Jesper Kihl, Nicolai C. Brun, Christine E. Hallgreen, Jens Heisterberg, Per Spindler

**Apologies:** Gitte Dyhr, Timo Minssen, Sukhwinder S. Jossan, Gunnar H. Gislason, Birthe B. Holm, Steffen Thirstrup, Lisa S. Villadsen

**Chair:** Marieke De Bruin

**CORS/Minute taker:** Selene Bornati

**Guest:** Louise Druedahl

#### 1. Welcome and adoption of the agenda

The agenda was adopted.

It was Jesper Kihl's last meeting, as he is retiring. A new representative from LEO Pharma will be brought forward. The appointment has to be adopted by the steering committee.

#### 2. CORS news

- new staff
  - Selene Bornati will provide administrative support at CORS. She is reachable via the regular CORS email. She is in charge of developing the new website.
  - Helle Christiansen (PhD) and Arnela Boskovic (Research assistant) have started their work in December and January, respectively.
  - The recruitment process of a postdoc is underway. The person will work on two projects, Horizon 2020 HTx Project and Drug utilization studies for the safety communication project in collaboration with the University of Sydney.
- Visits from Japan and China
  - Professor Urushihara visited CORS and CeBil as part of a diplomatic mission between Japan and Denmark. The discussion included paediatric drug development and deep learning techniques in signal development. We hope this meeting started a future collaboration.

- Professor Ming-Wei Wang from University of Fudan will visit Denmark in May as part of the Memorandum of Understanding between UCPH and Fudan. The Professor will teach on the elective course Regulatory Science. Jens Heisterberg will visit the Queenstown molecular biology meeting in Shanghai (March 21-22) to present the topic “how should drug regulators be involved in early-stage research?” within this context.
  - joint CORS/CeBIL symposium March 4, 2019
    - Feng Zhang from the Broad Institute came to present his work on CRISPR technology in a joint CeBil/CORS symposium on March 4. While there were not many who attended the event, it enabled to establish excellent contact.
  - New data centre at DKMA  
Nikolai Brun presented the new data centre to be established at DKMA. CORS expressed strong interest in this ambitious project. There was an extended discussion on the numerous aspects of the new data centre.
3. Annual CORS conference
- Date: week 47  
The next conference will likely take place in the third week of November, at a date that does not coincide with other events in the Mærsk tower.
  - Program committee  
An email will be sent out for people to manifest their interest. It is important to assess the available resources, as setting up a conference takes time and dedication.  
A short brainstorm about possible topics mentioned “outcomes of directions of regulatory science” and experiences linked to agencies like DKMA.
4. International Symposium for Young Researchers in Regulatory Science (Utrecht, February 13-14, 2019)  
Louise Druedahl presented her work as an organizer of the symposium, which brought together researchers from throughout Europe. The theme was “maneuvering with and among stakeholders”. The next meeting will take place in Denmark, in spring 2020.
5. Presentation of the CORS funded PhD project on biosimilars  
Louise Druedahl presented her work. The SAB showed great interest and provided Louise with numerous comments and recommendations.
6. EMA regulatory science strategy  
It was decided that CORS will take the matter further with EMA, and will draft the response for the public consultation with advice from SAB.
7. Any other business
- The next SAB meetings will take place on June 28 and September 27, from 9 to 12.
  - The workshop about communication resulted in a communication strategy chart that will be developed and presented at a later date.