



## Copenhagen Centre for Regulatory Science (CORS)

Medical Product Innovation - Research & Education

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# CORS Scientific Advisory Board meeting

May 30st 2017

9.00 – 11.00

University of Copenhagen, Universitets Parken 2, 4th floor, U12

## Agenda

- 1) Welcome
  - Adoption of the agenda
- 2) CORS Updates
  - Biosimilars PhD project (Marieke)
  - EMA Initiative on regulatory Science (Marieke)
  - Spring symposium (Marieke)
  - Fall event (Christine)
  - Upcoming meetings (Asbjørn and Mathias presentations)
- 3) AOB

## Minutes

- 1) CORS was informed that Janne Lehmann Knudsen has left the Danish Medicines Agency and that she will step down as a member of the CORS SAB.
- 2) Update from CORS
  - **Biosimilars PhD project** (MDB). The recommendation from SAB (dd March 3, 2017) to grant the project 'Similar but not identical: the changing landscape of biosimilars from the regulatory, industry, professional, and patient perspectives' was approved by the SC (written procedure dd March 16, 2017) and CORS Partner LEO Pharma has committed to finance the project. The position will be announced soon.  
Post meeting note: position was announced on June 20, 2017 with an application deadline of July 24, 2017.
  - **EMA Initiative on regulatory Science** (MDB). The European Medicines Agency (EMA) has developed a framework to formalize, structure and further develop interactions with the academic community. This was communicated on the EMA website and presented at the DIA meeting in Glasgow (March 2017). Marieke has met with Tony Humphreys ([Head of Scientific Committees Regulatory Science](#))

[Strategy](#) at EMA) to discuss the opportunities for collaboration between CORS and EMA, and will meet again on how to formalize this.

- **Spring symposium** (CH). The Copenhagen Centre for Regulatory Science and Denmark's Life Science Cluster, Biopeople, organised a symposium on research and education in regulatory science on 27 March 2017. The symposium had the pleasure of hosting a high-level delegation from Fudan University, Shanghai, China. With 46 participants in total (Academia n=23, Industry n=20, Regulatory Authorities n=3) and positive feedback, we look back to a successful meeting. Presentations held at the meeting can be found at the CORS website.
- **Fall symposium.** Title: "Transparency and regulatory science. Challenges, Opinions, examples." Date: October 2<sup>nd</sup> 2017. Save-the-date announcements have been sent out to the network soon. Confirmed speakers so far:
  - Ragnar Löfstedt (Professor of Risk Management at King's College London)
  - Dominic Way (Policy analyst, former research student at Risk Management at King's College London)
  - Other speakers are/will be invited.

The conference is announced on the CORS website: <https://cors.ku.dk/calendar/past-events/all-past-events/cors-annual-conference-2017/>

In conjunction to the annual conference a scientific & networking event for PhD students in Regulatory Science will be organized.

### 3) AOB

- **Seminar on Biosimilars.** Timo Minssen will host a seminar on biosimilars on June 1st 2017. <http://jura.ku.dk/ciir/english/calendar/biosimilar-dances/>
- **Regulatory Science at the University of Southern California.** Ongoing conversations with the Regulatory Science department at USC. Professor Frances Richmond gave an overview of activities in a recent meeting with Marieke de Bruin. UCPH and USC are in the process of signing a memorandum of understanding in regards to Regulatory Science.
- **CORS Network activities in Scandinavia.** SSJ proposes to communicate the existence and activities of CORS to potential collaborator university in Scandinavia. MDB will look into doing that.
- **New Pharmacovigilance professor at UCPH.** SK proposes to invite Morten Andersen to learn more about his professorship.