UNIVERSITY OF COPENHAGEN
DEPARTMENT OF PHARMACY

Copenhagen Centre for Regulatory Science (CORS)
Medical Product Innovation - Research & Education

CORS Scientific Advisory Board meeting

September 27, 2019
9.00 – 11.00

University of Copenhagen, Mærsk Tower, 7.15.122

Minutes

Presents: Merete Schmiegelow, Per Helboe, Jens Heisterberg, Eskild Colding-Jørgensen, Christine Hallgreen, Nina Christiansen, Steffen Thirstrup, Helle Christiansen, Susanne Kaae, Birthe Holm, Per Spindler.

Absents: Gitte Dyhr, Gunnar H. Gíslason, Lisa Storm Villadsen, Ole Jannik Bjerrum, Sukhwinder S. Jossan, Theis Lange, Timo Minssen.

Chair: Marieke De Bruin

Minute taker: Selene Bornati

1. Welcome and adoption of the agenda

The agenda was accepted. One topic was added under AOB.

2. CORS news
    a. Welcome to Nina Christiansen and Eskild Colding-Jørgensen

SAB welcomes two new members: Nina Christiansen (LEO Pharma) and Eskild Colding-Jørgensen (DKMA).
It was also Merete Schmiegelow's last meeting as a SAB member. Her position will not be replaced.

    b. Update on Conference

The programme and the speakers are now all confirmed, with an unexpected and welcomed addition in the person of Carolyn Wilson from FDA. The Conference is moved to Nielsine Nielsen auditorium and will be broadcasted live.
The members of SAB are encouraged to communicate about the conference and advertise it to their colleagues. There will be LinkedIn messages to share.

3. Honorarium to patients representatives invited as speakers

SAB discussed the possibility to offer an honorarium to patient representatives who are invited as speakers to the conference, considering that dissemination is not necessarily a part of a patient representative's compensated tasks.
Several options were assessed. Birthe Holm will help us draft a policy that resembles EMA's approach to reimbursement of patient representatives (a small allowance that speakers are free to refuse) while complying with the University's policy. The draft must be approved by the steering committee.

4. MRA program (guests: Lene Jørgensen, Mette L. Bergenser and Vibeke Petersen)

Presentation of the MRA program, its development and outcomes. The programme is developing well, with 12 satisfied enrolled students.
SAB's input was requested about raising interest in the course 'Transparency and Trustworthiness in Drug Development'. SAB provided advice about the format, its content, the outcomes and even the title. It also discussed opportunities for on-site visits, where the MRA program will be presented at companies with potentially interested students. SAB provided very positive feedback.

5. Presentation of the CORS-funded PhD project on impact of paediatric regulations on drug development (Helle Christiansen)

Helle gave a status on her project, presenting her latest progress. The discussion focused on impact, background, goals and advancements. Special attention was given to external influences.
SAB showed great interest and provided with input on new aspects and perspectives.

6. Any other business (AOB)
    a. EMA consultation

Merete Schmiegelow asked about the status of the public consultation of EMA Regulatory Science Strategy to 2025. CORS has submitted their input in June and EMA will have a stakeholder meeting in November. So far, no results from the consultation have been published.