UNIVERSITY OF COPENHAGEN
DEPARTMENT OF PHARMACY

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

MINUTES

18 JUNE 2020

COPENHAGEN CENTRE FOR REGULATORY SCIENCE

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Forum CORS SAB Meeting

Meeting held 18-06-2020, 9:00-11:00

Place Zoom meeting

Minutes-taker Selene Bornati

Present
Christine Hallgreen, Per Helboe, Eskild Colding-Jørgensen, Steffen Thirstrup, Per Spindler, Lisa Villadsen, Birthe Holm, Jens Heisterberg, Nina Christiansen, Theis Lange, Gunnar H. Gíslason, Timo Minssen, Sukhwinder S. Jossan, Mathias Møllebæk, Richard Ofori-Asenso, Selene Bornati.
Chair: Marieke De Bruin

Agenda

1. Welcome and adoption of the agenda
   The agenda was adopted, no further items were added.

2. CORS-funded PhDs and post-docs
   a. Upcoming PhD defences
   Several PhD projects are coming to an end this year. Asbjørn Nøhr-Nielsen is due to defend his thesis soon, while Mathias Møllebæk and Louise C. Druedhal are expected to hand in their theses at the end of the year.

   b. New post-doc/ PhD
      i) Mathias presented a potential postdoc project titled *Regulation of diagnostic tests under COVID-19*.

SAB approved of the project and discussed various aspects of the scope of the project, the approach of the questions and its timeframe. The project will be developed into a research proposal as soon as possible. The project will require one postdoc position for 18 months.

ii) Christine Hallgreen pitched a second postdoc project named *Data Collection Interface for Regulatory Data and Analytics*

SAB was very positive about this project as well, and reflected about the maturation and aspects of the project. SAB members who have additional comments or questions are free to contact CORS.

3. Annual conference
   a. Conference Committee established

The Conference Committee is composed of Per Spindler, Per Helboe, Nina Christiansen, Marieke De Bruin and Selene Bornati.

b. Date and format

The date is confirmed on 23 November, in the second half of the day. The preferred format is a hybrid of online and face-to-face conference, with few audience members present and the rest online. The live panel should be in the room.
Considering the possibility to hire a professional studio and/or a professional moderator, it might be necessary to implement participation fees for industry stakeholders, although they would be greatly reduced compared to the former conferences. No final decision has been reached yet.

c. Potential topics

Tentative title: *The pandemic as a driver for regulatory innovation*

1. Digitalisation, use of AI and translation of data for regulatory decision-making
2. Repurposing of drugs
3. Communication channels and links to forgotten stakeholder.

These topics will be narrowed down further before the summer break.

Promotion of the event will start as soon as possible.

SAB discussed the involvement of stakeholders, prepublications, use of data in repercussion drugs, issues about data validity, pressure on control and review processes, connection to supply chain. This theme offers many interesting potential sub-topics, which is why we should focus most on the regulatory system.

4. AOB
   a. COVID projects
   The CURB project was unfortunately rejected, as projects related to clinical impact were prioritised by the funding bodies.

5. Presentation by Richard Ofori-Asenso (HTx project)
   Richard completed his first study, and has compiled a report currently under review for publication.

   SAB discussed the scope and the outcomes of the study, and potential collaborations associated with the project.

The next SAB meeting is scheduled to take place on 17 September.