

## Copenhagen Centre for Regulatory Science (CORS)

*Medical Product Innovation. Research & Education*



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### Minutes from Board of Directors Meeting

16 September 2015, 14.00 - 15.00

#### Participants:

- Sven Frøkjær, Vice-Dean, Faculty of Health and Medical Sciences
- Flemming Madsen, Head of Department, Department of Pharmacy, Faculty of Health and Medical Sciences
- Karsten Vrangbæk, Director of Center for Health Economics and Policy
- Karin Friis Bach, Project Manager, CORS

#### Absent:

- Robin Evers, Senior Vice President for Global Regulatory Affairs, Novo Nordisk A/S

#### 1. Welcome by Sven Frøkjær

Sven Frøkjær opened the meeting of the board with a word of welcome.

#### 2. Activities since last meeting.

Karin Friis Bach summarized the current status and activities of CORS. Since last meeting the preparations for the new professorship have been finalized – including the work of the search committee who has identified three potential candidates. The position is now open for applicants. Deadline for applications is October 4<sup>th</sup> and job interviews are scheduled for December 17<sup>th</sup>.

In July Sven Frøkjær and Karin Friis Bach visited the Medicines Evaluation Board (MEB) in Utrecht. The MEB has a strong scientifically founded collaboration with all major Dutch universities within the field of Regulatory Science. They have several Ph.D. students within the field, but lack the closer cooperation with pharmaceutical companies with regard to both research and education. Future possibility of common research- and educational activities was discussed.

Two meetings have been held in the Scientific Advisory Board (SAB). Minutes from both meetings are attached. The group has now agreed upon a set of “Terms of Reference” and has proposed a process for evaluation of new CORS-financed projects. A CORS research seminar has been planned and will take place on November 23<sup>rd</sup> and a symposium or workshop will be arranged in spring 2016.

Karin Friis Bach will end her position as a project manager at CORS by the end of September. A new administrative manager will be employed.

### 3. Research activities

A proposed project regarding evaluation of risk minimisation interventions required by the Authorities was discussed at the last meeting in the Scientific Advisory Board (SAB). Several partners including researchers from the Faculty of Humanity, The DHMA, the section of Social and Clinical Pharmacy (SUND) and at least one pharmaceutical company was interested in pursuing this project. A more detailed project description will be made for the next SAB-meeting and will be evaluated according to the agreed procedure.

The CORS secretariat has called the partners for more research ideas since 2-3 Ph.D. projects are planned to be initialized in 2016.

CORS is still part of the international applicant-consortium trying to be chosen for the IMI project PATIENT-SMART (establishment of a patient knowledge hub to be used for medicines development processes). The consortium has reached stage II and will submit the final application by the end of the year. If approved CORS will together with Biopeople and the section of Social and Clinical Pharmacy from august 2016 be part of the initial mapping phase, test case selection and description of user needs and requirements.

Publications:

- Proceedings from the Session “New Partnerships in Regulatory Science” on the DIA EuroMeeting 2015 have been accepted for publication:

<http://m.dij.sagepub.com/content/early/2015/08/10/2168479015599810>.

The session was arranged by BioPeople, Novo Nordisk and CORS in cooperation.

- Proceedings from the workshop “Patient involvement in medicines development and approvals” have been submitted as a commentary to the journal “Therapeutic Innovation and Regulatory Science”.

### 4. Educational activities

The basic elective course, “Drug Regulatory Affairs – from discovery to approval and marketing”, for students in pharmacy or pharmaceutical science is already being organized by CORS. One more elective course, “Interdisciplinary challenges within Regulatory Sciences” is planned, and will probably be conducted first time in autumn 2016. It is the intention to organise teaching at this course together with some of the CORS-partners.

Further to this, CORS is actively involved in the establishment of the new master programme

“Medicines Regulatory Affairs” which is being described and applied for in collaboration with Medicademy. The programme consists of several courses and CORS will be responsible for 1-2 of these.

CORS is also involved in the supervision of a number of master thesis projects, as several students wish to do their master thesis within the field of Regulatory Science.

#### 5. Economy and Legal Agreements

An updated budget was discussed and approved. Only minor changes have been made since last meeting. An overview of running costs since the establishment of CORS in March was also presented. Until now expenditure has reached 31.833 DKK. This amount covers the workshop in May, conference attendances and meeting in Utrecht. (Both documents are attached).

A proposal for legal agreements concerning the CORS collaboration has been sent to all four pharmaceutical companies, who have agreed to contribute to the research at the centre. So far an agreement has been signed with Novo Nordisk A/S whereas the other three are still pending.

#### 6. Procedure for initiation of CORS projects

The Scientific Advisory Board has during the last two meetings discussed a document describing the procedure for initiation of CORS financed projects (document attached). This includes:

- The application procedure
- The evaluation procedure
- The research strategy

The document was discussed and approved by the Board.

#### 7. Miscellaneous

Next meeting will be January 7<sup>th</sup>.