

Copenhagen Centre for Regulatory Science (CORS)

Medical Product Innovation - Research & Education



Minutes from:

Meeting CORS Scientific Advisory Board

February 4th 2016 13.00 – 16.00

University of Copenhagen, Nørre Alle 71, building 17, 4th floor meeting room 17- 411

Members:

Present

Susanne Kaae
Ole J. Bjerrum
Christian B. Pipper
Per Spindler
(Timo Minssen) Ana Nordberg
Lisa S. Villadsen
Merete Schmiegelow
Per Helboe
Sukhwinder S. Jossan
Torbjörn Callréus
Gunnar H. Gislason

Absent:

Gitte Dyhr
Jesper Kihl
Bjarke Oxlund
Steffen Thirstrup

CORS:

Christine Hallgreen
Gitte Borup

Agenda

PART 1 – Ordinary meeting

1. Welcome and CORS news
 - Minutes from BoD meeting, Jan. 7th
 - A brief status on the appointment of the new professor
 - Approval of minutes from Dec. 17th
2. Possibility for cooperation within risk minimization with EMA
3. Procedure for SAB members to comment on hearings
4. Any other business, next meetings
 - Input to Biopeople workshop on 21 April. See separate mail (sent 02.02.2016).
 - Biopeople hosts a visit from Katsura Tsukamoto, Professor of Global Regulatory Science at Gifu Pharmaceutical University on 11 April. We would like to offer that he spends part of the day presenting/discussing with the staff at CORS, and possible one or more representative from the SAB.

PART 2 – Discussion of Proposals

1. Re-evaluation of PhD proposal by Ole Bjerrum et al
2. Re-evaluation of PhD proposal by Susanne Kaae et al
3. The next step for the PhD-proposals

Minutes

PART ONE:

1. CORS news

The new professor and Centre head Marieke de Bruin will officially begin her position at CORS on August 15th. Marieke de Bruin will maintain her position at PRAC at EMA. Also, she will keep a 10% position at the University of Utrecht

The upcoming meeting with the patient organization of rare diseases was discussed. Initiatives to include/invite other patient organizations that represent broader patient groups were proposed. Gunnar Gislason who is also chief of research at the Danish Heart Association proposed to invite the Association of Danish Patients.

Joint meeting of SAB and CORS Board of Directors was proposed to take place in the third quarter of 2016. Topics for the agenda should be discussed at the next meeting on May 4th.

2. Possibility for cooperation within risk minimization with EMA

As Marieke de Bruin is an expert member of PRAC, a discussion of the opportunity for a joint/shared PhD with PRAC regarding collecting and analysing data. Possible projects are to be discussed on the next meeting, May 4th, where Marieke will also participate.

3. Procedure for SAB members to comment on hearings

The conclusion was that CORS should be the sole consignor of any comments that are associated with CORS, and not the individual SAB members on behalf of CORS. Individual members may draft comments within the area of 'science' and forward the comments to CORS.

4. Any other business, next meeting

Biopeople are hosting a visit from dr. Katsura Tsukamoto from Japan on April 10th with the intent of discussing common interest within research and educational aspects of regulatory science. Apart from meeting with Biopeople, dr. Tsukamoto will also meet with CORS, and Per Spindler invited interested members of SAB to participate. Merete Schmiegelow accepted the invitation.

Biopeople workshop on 21 April

Biopeople is hosting a workshop on collaboration with visiting guests from the International Center for Regulatory Science, University of Southern California (USC), School of Pharmacy, USA. The aim of the workshop is to share knowledge between academic and industrial professionals in regulatory science. Per Spindler invited members of SAB to participate in the program. CORS SAB members to participate: Merete Schmiegelow, Timo Minssen and Ole Bjerrum. Marieke De Bruin will also participate and contribute to the program. Please visit Biopeoples website to register for the workshop and view the full program.

PART TWO

Project proposal from Ole J Bjerrum and Christian B Pipper and the proposal from Susanne Kaae, Lisa Storm and Christine E Hallgreen were approved by SAB and will be forwarded to the CORS Board of Directors for further assessment.

The next steps for the PhD-proposals:

The proposals will be discussed by the Board of Directors on the April 20th. The procedure for financing the projects will also be discussed.

Next meetings:

May 4th 13.00-16.00

September 15th 13.00-16.00