Public health and innovation – is regulation a friend or a foe?
CORS Annual Conference 2019, November 18, 2019

8:30 – 9:00 Arrival of the participants. Registration and coffee.
9:00 – 9:15 Welcome

9:15 – 11:30 SESSION 1
Session chair: Christine Hallgreen, Associate Professor, Copenhagen Centre for Regulatory Science, University of Copenhagen

9:15 Regulatory agencies: not only guardians, but also enablers of innovation?
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency

9:45 TBA
Dorte Strobel, Senior Regulatory Policy & Intelligence Manager, Leo Pharma

10:15 Ethics and Policy Surrounding Access to Experimental Interventions and Early Regulatory Approval
Jonathan Kimmelman, James McGill Professor of Biomedical Ethics, McGill University; Director, Biomedical Ethics Unit

11:00 Discussion

11:30 – 12:30 Lunch

12:30 – 14:30 SESSION 2
Session chair: Steffen Thirstrup, NDA Regulatory Services, and Adjunct Professor, University of Copenhagen.

12:30 Innovation, risk and regulation in postmarket settings
Jarno Hoekman, Assistant Professor in Science, Technology and Innovation Studies, Utrecht University

13:00 TBA
Bastian Hauck, Director, International Diabetes Federation

13:30 When regulation is set in place to foster drug development – the example of the paediatric regulation
Helle Christiansen, PhD fellow, Copenhagen Centre for Regulatory Science

14:00 Discussion
14:30 – 15:00  Coffee break

15:00 – 16:50  SESSION 3: INNOVATIVE THERAPEUTIC PRODUCT AND REGULATION  
Session chair: Professor Marieke De Bruin, Director of the Copenhagen Centre for Regulatory Science, University of Copenhagen

15:00  A clinical perspective on drug regulation: Some patients benefit, others do not – how to fix it?  
Anders Perner, Professor in intensive care at Rigshospitalet, University of Copenhagen

15:30  Innovative therapies call for innovative methods to support regulatory decision making  
Morten Andersen, Professor in Pharmacovigilance, Department of Drug Design and Pharmacology, University of Copenhagen

16:00  FDA initiatives – promoting and protecting the public health while supporting innovation  
Carolyn Wilson, Associate Director for Research, CBER, Food And Drug Administration

16:30  Discussion

16:50-17:00  Closing remarks: Professor Marieke De Bruin, Director of the Copenhagen Centre for Regulatory Science, University of Copenhagen