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  How Regulation can Help or Hinder Innovation – an industry perspective
Hans Hoogland, R&D Scientist, Senior Regulatory Intelligence Specialist, 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  When regulation gets in the way: Unmet needs, open source and patient-driven innovation – the #WeAreNotWaiting movement
Bastian Hauck, Director, #dedoc°

13:30  Right to Try Act: analysis of stakeholders’ values
Lourdes Cantarero Arevalo, Associate Professor, Social and Clinical Pharmacy, University of Copenhagen

14:00  Discussion
Coffee break

SESSION 3
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

Closing remarks: Professor Marieke De Bruin, Director of the Copenhagen Centre for Regulatory Science, University of Copenhagen