



## Copenhagen Centre for Regulatory Science (CORS)

Medical Product Innovation - Research & Education

### Annual CORS Conference 2018

## Impact of drug regulation on health and society

19.11.2018

9:00 – 9:30 | *Arrival of the participants. Registration and coffee.*

9:30 – 9:45 | *Welcome: Professor Marieke De Bruin, Director of the Copenhagen Centre for Regulatory Science, University of Copenhagen, Denmark*

### 9:45 – 11:45 | **Session 1. Impact of innovation on drug regulation**

- 9:45-10:15 | *Louise Druedahl, Copenhagen Centre for Regulatory Science*  
"Investigating the biosimilar route: How is the European regulatory route being used?"
- 10:15-10:45 | *David Martin, FDA*  
"Novel data approaches"
- 10:45-11:15 | *Bert Leufkens, Utrecht University, Affiliate Professor at CORS*  
"A responsive regulatory system, myth or reality?"
- 11:15-11:45 | *Discussion: **What will the future regulatory system look like?***

Session chair: Nikolai Brun, Medical Evaluation and Biostatistics, Danish Medicines Agency

11:45 – 12:45 | *Lunch*

### 12:45 – 14:15 | **Session 2. How and why to measure the impact of regulation on society and public health?**

- 12:45-13:15 | *Mette Gørtz, Centre for Health Economics and Policy, UCPH, Denmark*  
"Health, innovations and economic behavior"
- 13:15-13:45 | *Christine E. Hallgreen, Copenhagen Centre for Regulatory Science*

	“Use of complexity science methods in regulatory science”
13:45-14:15	<b>Discussion: Are we geared up to evaluate regulatory systems?</b>
Session chair: Nancy Pire-Smerkanich, Regulatory & Quality Sciences, University of Southern California, USA	
14:15 – 14:45	<i>Coffee break</i>
<b>14:45 – 16:45</b>	<b>Session 3: How do policy instruments affect society and public health?</b>
14:45-15:15	<i>Mathias Møllebæk</i> , Copenhagen Centre for Regulatory Science “How do Danish GPs read regulatory safety advisories? A protocol analysis”
15:15-15:45	<i>Per Sindahl</i> , Danish Medicines Agency, “Added value of pharmacovigilance instruments”
15:45-16:15	Patient representative ( <i>tba</i> )
16:15-16:45	<b>Discussion: Drug regulation - does it really matter?</b>
Session chair: Jens Heisterberg, Regulatory Intelligence, Novo Nordisk, Denmark	
16:45-17:00	Closing remarks: <i>Professor Marieke De Bruin</i> , Director of the Copenhagen Centre for Regulatory Science, University of Copenhagen, Denmark
17:00	<i>End of the conference</i>

Note: the time slots are approximate, and they might be slightly changed in the final draft.