## Public health and innovation – is regulation a friend or a foe?

CORS Annual Conference 2019, November 18, 2019

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30 – 9:00</td>
<td>Arrival of the participants. Registration and coffee.</td>
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<tr>
<td>9:00 – 9:15</td>
<td>Welcome</td>
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</tbody>
</table>
| 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 | **When regulation gets in the way: Unmet needs, open source and patient-driven innovation – the #WeAreNotWaiting movement**  
Bastian Hauck, Director, #dedoc° |
| 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
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