Pandemics as driver for regulatory innovation - regulatory changes in times of disaster

Programme

9:00 – 9:05 Welcome  With Marie Louise (Marieke) De Bruin, CORS

9:05 – 10:20 Session 1  Thinking differently - new data, new techniques, new ways of decision-making
Session chair: Theis Lange, Department of Public Health, University of Copenhagen.

Regulators are finding ways to support the expedited development and distribution of novel coronavirus-related vaccines, tests and treatments. Novel data techniques are being used for generating evidence on therapy performance and assist regulatory decision making. How can these new techniques help us progress? And how does society respond to the fast-changing world?

9:05 Keynote  Made by Disasters: On the Social, Cultural and Political Responses to Extreme Events and the Changes that Follow in their Wake
Kristoffer Albris, Department of Anthropology, University of Copenhagen

9:25 Pitch  Being bold to lead – how the Danish Medicines Agency is going first in data analytics in Europe
Jesper Kjaer, Danish Medicines Agency

Pitch  Personalizing Treatment Development
John Zibert, Studies&Me A/S

Pitch  Accelerating digital transformation of regulatory affairs in the time of COVID-19
Niels Buch Leander, NNIT A/S

9:50 Debate  Discussion

10:20-10:30 Break

10:30-11:00 Keynote and QA  Responsive Regulatory Systems: A Post-Pandemic Gap Analysis
Andrea Julsing Keyter, South African Health Products Regulatory Authority
## Programme

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<td>11:00</td>
<td>Keynote</td>
<td>Fighting pandemics with enhanced risk communication?</td>
<td>Frederic Bouder, Department of Safety, Economics and Planning, University of Stavanger</td>
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<td>11:20</td>
<td>Pitch</td>
<td>Dilemma Between Learning, Doing and Saying in a Pandemic</td>
<td>François Houÿez, EURORDIS</td>
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<td>Pitch</td>
<td>EMA's communication and enhanced transparency measures for COVID-19</td>
<td>Melanie Carr, European Medicines Agency</td>
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<td>COVID-19 - Questions Inspire Solutions</td>
<td>Andy Powrie-Smith, European Federation of Pharmaceutical Industries and Associations (EFPIA)</td>
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<td>Conclusion</td>
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