

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

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

Programme

- 11:00-12:15 Session 2 **Communicating well, communicating better**
Session chair: Lisa Storm Villadsen, Department of Media, Cognition and Communication, University of Copenhagen
- According to the WHO, the COVID-19 pandemic is accompanied by an 'infodemic' that poses significant global health risks, with the general public doubting both disease and treatment. The pressure to identify treatments has generated an extraordinary amount of hopeful and misinformed news coverage. Navigating information flows can be a challenge for all stakeholders in unprecedented conditions. In this session, communication experts from industry, patient organisations and regulatory authorities will examine their recent experiences on building trust in the regulatory system. How to keep confidence in the system, when nothing seems certain?
- 11:00 Keynote **Fighting pandemics with enhanced risk communication?**
Frederic Boudier, Department of Safety, Economics and Planning, University of Stavanger
- 11:20 Pitch **Dilemma Between Learning, Doing and Saying in a Pandemic**
François Houyez, EURORDIS
- Pitch **EMA's communication and enhanced transparency measures for COVID-19**
Melanie Carr, European Medicines Agency
- Pitch **COVID-19 - Questions Inspire Solutions**
Andy Powrie-Smith, European Federation of Pharmaceutical Industries and Associations (EFPIA)
- 11:45 Debate Discussion
- 12:15 Conclusion With Marie Louise (Marieke) De Bruin, CORS