



CeBIL symposium: Sustainable health innovation, grand challenges & the law, 14-15 June 2023

Agenda

Day 1 - 14 June 2023

9:00 Welcome & Opening remarks- [Timo Minssen](#), PI & NNF grant holder, Director of CeBIL, Faculty of Law, University of Copenhagen, LML Affiliate, University of Cambridge.

9:15 *Keynote presentation- CeBIL and the NNF's impact assessment framework* - [Thomas Alslev Christensen](#), Senior Vice President, Impact, Novo Nordisk Foundation

Study 1: Antibiotics

9:45 Chair: [Aaron Kesselheim](#), Professor of Medicine, Harvard Medical School/Brigham and Women's Hospital, PORTAL Director – *Highlights from the CeBIL's studies on AMR and Innovation.*

10:00 *Planning for Sustainability: Estimating global antibacterial funding required for a pipeline of 6 high-impact drugs per decade*– [Kevin Outterson](#), Professor of Law, Boston University, Director of CARB-X.

10:15 *Implementation of the UK's AMR National Action Plan* – [Rebecca Glover](#), Ass. Prof., Head of the Economic, Social, and Political Science, Antimicrobial Resistance Centre, London School of Hygiene & Tropical Medicine.

10:30 *Trends in the global antibiotics market*– [Jacob Madden](#), Postdoctoral research fellow, PORTAL, Harvard Medical School and Brigham & Women's Hospital.

10:45 Q&A and Debate

11:00 Break

Study 2: Orphan Drugs

11:15 Chair: [Timo Minssen](#), PI and NNF grant holder, CeBIL Director, Faculty of Law, University of Copenhagen, LML Affiliate, University of Cambridge - *CeBIL's orphan drug studies: Highlights and future opportunities and challenges*.

11:30 *The US Orphan Drug Act at 40* –[Michael S. Sinha](#), Ass. Professor, Center for Health Law Studies, Saint Louis University.

11:45 *The EU Orphan drug act at 23 - time to grow up?* - [Jakob Wested](#), Industrial Postdoc, Danish Medicines Agency & CeBIL, Faculty of Law, University of Copenhagen.

12:00 *Patient Engagement in Medicines R&D and in use – General and Rare Disease specific considerations*–[Merete Schmiegelow](#), Patient Advocate, Danish Cancer Society.

12:15 Q&A and Debate

12:30 Lunch

Study 3: Precision Medicine and AI

13:30 Chair: [Glenn Cohen](#), Faculty Director, James A. Attwood and Leslie Williams Professor of Law, and Deputy Dean, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School – *Precision Medicine and AI: Patients, Law, and Ethics*.

13:45 *Prioritizing JEDI (Justice, Equity, Diversity, Inclusion) in Precision Medicine and AI* – [Sonoo Thadaney Israni](#), Executive Director, Presence & Program in Bedside Medicine, Stanford University.

14:00 *Ethical issues in decentralized clinical trials* – [Effy Vayena](#), Professor of Bioethics, Deputy Head of the Institute of Translational Medicine, ETH Zurich.

14:15 *Who and How to Regulate Medical AI?* – [Carmel Shachar](#), Executive Director, The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School.

14:30 Q&A and Debate

Study 4: New Uses

14:45 Chair: [Kathy Liddell](#), Director, Centre for Law, Medicine and Life Sciences (LML), University of Cambridge– *An introduction to the CeBIL 'new uses' project*

15:00 *Patent-based challenges*- [Matt Fisher](#), Senior Lecturer, Faculty of Laws, University College London.

15:15 *Was the EU incentive for repurposing successful? And, should we think more about non-commercial incentives?*- [John Liddicoat](#)- Senior lecturer, The Dickson Poon School of Law, King's College London.

15:30 *US and UK government responses to the challenges*- [Marco Schito](#), Professor Practice in Law at Arizona Law & Executive Director of the Critical Path Institute's CURE Drug Repurposing Collaboratory.

15:45 Q&A and Debate

16:00 Break

Study 5: Biologics and biologics manufacturing

16:15 Chair: [Nicholson Price](#), Professor of Law, Michigan Law, University of Michigan– *The CeBIL Biologics Manufacturing Study*.

16:30 *Biosimilars and Follow-On Products: Adoption, Prices, And Users* – [Ariel Stern](#), Associate Professor of Business Administration, Technology and Operations Management Unit, Harvard Business School.

16:45 *Intellectual Property, Public Funding, and Innovation in Biomanufacturing Platforms* – [Arti Raj](#), Elvin R. Latty Professor of Law, Faculty Director, The Center for Innovation Policy, Duke Law.

17:00 *Knowledge Sharing of Biologics - A qualitative study* – [Louise C. Druedahl](#), PhD, since 01, June 2023, Global Regulatory Affairs, Novo Nordisk, fmr. Postdoc, CeBIL, Faculty of Law, University of Copenhagen

17:15 Q&A and Debate

Concluding session

17:30 Chair: [Timo Minssen](#), PI and NNF grant holder, CeBIL Director, Faculty of Law, University of Copenhagen LML Research Affiliate, University of Cambridge - *Open discussion for all studies & Closing remarks*

18:00 Reception

19:00 Dinner for speakers

Day 2 - 15 June 2023

9:00 *Summary of Day 1 & Plan for Day 2* - [Timo Minssen](#), PI and NNF grant holder, CeBIL, Faculty of Law, University of Copenhagen

9:15 Keynote presentation- *Transforming Healthcare: Leveraging the potential of AI Digital Solutions to Conquer the Grand Challenges in Health*, [Ryan Dos Santos](#), Technical Officer - Digital Health at the World Health Organization (Europe), Division of Country Health Policies and Systems.

Study 6: Synergy

9:45 Chair: [Timo Minssen](#), PI and NNF grant holder, CeBIL, Faculty of Law, University of Copenhagen– *The CeBIL Synergy Study*

10:00 *Technology Specificity, Vaccine R&D and Pandemic/Epidemic Preparedness* – [Ana Santos Rutschman](#), Professor of Law, Villanova University Charles Widger School of Law (virtual talk)

10:15 *Sustainable competition & regulatory sandboxes in pharma & health* – [Ioannis Lianos](#), President of the Hellenic Competition Commission/ Professor of Global Competition Law and Public Policy, UCL Law

10:30 *Managing Privacy Risks in International Data Transfers for Biomedical Research* – [Marcelo Corrales Compagnucci](#), Associate Professor and Deputy Director, CeBIL, Faculty of Law, University of Copenhagen

10:45 Q&A and Debate

11:00 Break

Future Research Directions

11:15 Chair: [Timo Minssen](#), PI and NNF grant holder, CeBIL, Faculty of Law, University of Copenhagen – *Future plans of the CeBIL team*

11:25 *Advanced Medical Computing & Quantum Technology*- [Mateo Aboy](#) - Principal Research Scholar, Centre for Law, Medicine and Life Sciences (LML), University of Cambridge

11:40 *Pandemic Preparedness & AMR* - [Jyoti Joshi](#), AMR Advisor, The International Centre for Antimicrobial Resistance Solutions (ICARS)

11:55 *Sustainable Biomedical Innovation & Global South Perspectives* - [Kshitij Kumar Singh](#), Assistant Professor, Campus Law Centre, Faculty of Law, University of Delhi

12:10 *Can health innovation be inclusive and equitable? Ways forward and obstacles with antibiotics*- [Rohit Malpani](#), Senior Advisor, GARDP

12:25 *Panel discussion*

12:45 *Closing remarks*- [Timo Minssen](#), PI and NNF grant holder, CeBIL, Faculty of Law, University of Copenhagen

12:50 Lunch

13:50-15:50 *Internal CeBIL program meeting with speakers*

