



CeBIL Annual Symposium 2018

Precision Medicine, Artificial Intelligence and the Law

7 September 2018

Christ's College, Cambridge

Black-box precision medicine is an exciting new frontier in health care diagnostics, harnessing the power of big data and artificial intelligence.

'In black-box medicine, machine-learning algorithms examine newly available troves of health data, including genomic sequences, patient clinical care records, and the results of diagnostic tests to make predictions and recommendations about care. An algorithm may be "black-box" either because it is based on unknowable machine-learning techniques or because the relationships it draws are too complex for explicit understanding. These algorithms, and artificial intelligence techniques more broadly, represent a point where health technology may outstrip human understanding.' (PMAIL, Harvard)

Black-box precision medicine raises challenging issues for legal and regulatory frameworks.

- What are the distinguishing features and added benefits of black-box medicine in comparison to traditional personalized medicine?
- What are the legal hurdles to the further development of black-box medicine?
- How does the IVD framework differ for black box medicine in the US and Europe?
- Does intellectual property law properly incentivize companies to share essential big data sets?
- What new evidence is there about the impact of the big intellectual property cases eg *Mayo v. Prometheus Labs* and *Association of Molecular Pathology v. Myriad*?
- How is the precision medicine industry (academic and commercial) responding to the regulatory and IP challenges?

CeBIL is a collaborative project spanning 5 years to investigate these and other issues on life science frontiers. It involves The Center for Advanced Studies in Biomedical Innovation Law (CeBIL) and the Department of Food and Resource Economics (IFRO) at the **University of Copenhagen**, The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at **Harvard Law School**, the **University of Michigan**, and the Centre for Law, Medicine and Life Sciences (LML) at the **University of Cambridge's** Law Faculty.

Join us for CeBIL Annual Symposium 2018—Knowledge exchange and networking

**An international showcase of speakers and panellists
from industry, academia, regulatory agencies, and legal services.**

Programme

08.45 Registration and Coffee

09.15 Introduction

Timo Minssen (Copenhagen) and Kathy Liddell (Cambridge)

9.30 Session 1: CeBIL's programme on Precision Medicine and AI

I. Glenn Cohen (Harvard)

Panellists

Chris Lowe (Cambridge Academy of Therapeutic Sciences)

Stuart Hogarth (Cambridge)

Richard Dybowski (Cambridge)

10.45 Morning Tea

11.15 Session 2: Intellectual Property and the Black Box

John Liddicoat (Cambridge)

Mateo Aboy (Cambridge)

Jacob Sherkow (New York Law School)

12.45 Lunch

13.45 Session 3: Regulating the Black Box as a Medical Device

Alberto Gutierrez (formerly FDA)

Nicholson Price (Michigan)

Stephen Lee (MHRA)

15.15 Afternoon tea

15.45 Session 4: The Future of Black Box Precision Medicine

Facilitator Tom Ling (RAND)

Panellists

Timo Minssen (Copenhagen)

Alison Dennis (Fieldfisher)

Manuel Corpas (Cambridge Precision Medicine)

Victoria Chico (Sheffield)

Jonathan Darrow (Harvard Medical School)

17.15 Close

Timo Minssen (Copenhagen) and Kathy Liddell (Cambridge)

Drinks Reception