CMEL

THE UNIVERSITY OF HONG KONG
CENTRE FOR MEDICAL ETHICS AND LAW

10 ANNIVERSARY

Governance of Medical AI

9–11 May 2023
HKU Law & Zoom

The regulatory governance of medical devices with machine learning and artificial intelligence capabilities, and related application in genomic medicine is increasingly risk-based, context-specific, case-sensitive, decentralised, collaborative, and – in terms of its epistemic constituents – pluralistic. With focus on governance policies of the National Medical Products Administration of China, the European Medicines Agency and the US Food & Drug Administration, this international conference considers regulatory and ethical challenges for developers and users operating within the architecture of the Internet of Medical Things.

Simultaneous Interpretation in English and Mandarin will be available on day 1 and day 2.

11/F, Cheng Yu Tung Tower, Centennial Campus, HKU
or via ZOOM

Tuesday 9 May
Regulatory Governance of Medical AI

10:00-10:30 Welcome & Introduction

Prof Gilberto K.K. Leung
Li Ka Shing Faculty of Medicine, University of Hong Kong

Prof Calvin W.L. Ho
Centre for Medical Ethics and Law, Faculties of Law & Medicine, University of Hong Kong

10:30-11:00 Keynote Address:
China's AI Regulatory System and the Prospect of Ethical Governance of Medical AI

Prof Duan Weiwen
Institute of Philosophy, Chinese Academy of Social Sciences, Beijing

11:00-11:25 A Qualitative Analysis of Different Perspectives on Ethical Governance and Ethics Review of Medical AI Research and Development in Shenzhen, China

Dr Ji Ping
Clinical Research Institute, Shenzhen-PKU-HKUST Medical Center, Shenzhen

11:25-11:30 Intermission

11:30-11:55 Smartphone Crowdsourced Medical Data for Algorithm Training and Biomedical Research: Ethical and Legal Points to Consider

Dr Ma'n Zawati
Centre of Genomics and Policy, McGill University, Canada

11:55-12:20 Regulating AI Medical Devices

Dr Colin Mitchell
PHG Foundation, University of Cambridge, UK

12:20-12:45 Gaps & Trends in Medical AI Governance

Dr Barry Solaiman
College of Law, Hamad bin Khalifa University, Qatar

12:45-14:00 Lunch

14:00-14:25 The Clinical Governance of Medical AI: Addressing Ethical Gaps

Dr Alessandro Blasimme
Department of Health Sciences and Technology, ETH Zurich, Switzerland

14:25-14:50 Machine MD: Canada's Legal Governance of Safety and Privacy in Health AI

Prof Colleen M. Flood
Centre for Health Law, Policy and Ethics, Faculty of Law, University of Ottawa, Canada

14:50-15:15 Illustration of AI Adoption in Clinical Setting & Implications for Governance & Regulation

Dr Neeraj R. Mahboobani
Department of Radiology & Imaging, Queen Elizabeth Hospital, Hong Kong

15:15-16:30   **Round Table & Use Cases Discussion (Part I)**

Developers & Implementers

16:30-16:45   **Intermission**

16:45-18:45   **Round Table & Use Cases Discussion (Part II)**

18:45-19:00   **Summation**

Dr Karel Caals
NUS Centre for Biomedical Ethics, Singapore

Wednesday 10 May
Medical AI and Data Governance, with a Focus on Genomics

13:30-13:45 **Introductory Presentation**

Prof Calvin W.L. Ho
HKU Centre for Medical Ethics and Law, Hong Kong

13:45-14:15 **Impact of Different Regulations on the Secondary Use of Medical Data in Italy: Implications for AI Development and Use**

Prof Deborah Mascalzoni
Center for Research Ethics and Bioethics, Uppsala University, Sweden

14:15-14:45 **Data Governance and the FACILITATE Project: Defining the Elephant in the Room**

Dr Johanna M.C. Blom
Department of Biomedical, Metabolic and Neurosciences, University of Modena and Reggio Emilia, Italy

14:45-15:15 **European Health Data Space: The Panacea for Data Sharing in Europe?**

Dr Ciara Staunton
Institute of Biomedicine, Eurac Research, Italy

15:15-15:45 **The Impact of the UK and EU General Data Protection Regulation (GDPR) on International Genomic Data Sharing for Research**

Dr Colin Mitchell
PHG Foundation, University of Cambridge, UK

15:45-15:50 **Intermission**

15:50-16:20 **The Use of AI in Genetic Testing: Regulatory Framework and Legal Issues**

Prof Du Li
Faculty of Law, University of Macau

16:20-16:50 **The Personal Information Protection Law and the 2023 Ethics Review Measures: Implications for Human Genomic Research and Medical AI R&D in China**

Dr Zhang Haihong
Human Research Protection Program, Health Science Center, Peking University, Beijing

16:50-17:20 **Digital Health, Data Governance and the Legal Framework**

Prof Ho Chih-Hsing
Institute of European and American Studies, Academia Sinica, Taipei

17:20-17:30 **Summation**

Dr Karel Caals, NUS Centre for Biomedical Ethics, Singapore

17:30-18:30 **Dinner**

Wednesday 10 May – Evening
Public Symposium: Governance of Medical AI

18:30-18:40 **Welcome**

Prof Calvin W.L. Ho
Centre for Medical Ethics and Law, Faculties of Law & Medicine, University of Hong Kong

Prof Gilberto K.K. Leung
Li Ka Shing Faculty of Medicine, University of Hong Kong

18:40-19:00 **Keynote Address: Adoption of Digital Technology to Facilitate Smart Living and Smart City Development in Hong Kong**

Ms Alice So
Head of Entrepreneurship, Hong Kong Cyberport Management Co Ltd

19:00-19:20 **Sharing Genetic Information for the Common Good**

Dr Derrick K.S. Au
Chair, Ethics Committee of the Hong Kong Genome Project

19:20-19:50 **Commentaries**

Dr Colin Mitchell
PHG Foundation, University of Cambridge, UK

Prof Du Li
Faculty of Law, University of Macau

Prof Deborah Mascalzoni
Center for Research Ethics and Bioethics, Uppsala University, Sweden

19:50-20:00 **Intermission**

20:00-20:30 **Book Talk (early preview): Research Handbook on Health, AI and the Law**

Dr Barry Solaiman
College of Law, Hamad bin Khalifa University, Qatar

Prof I. Glenn Cohen
Harvard Law School, Cambridge, Massachusetts, USA

20:30-20:50 **Commentaries and Q&A**

Dr Zhang Haihong
Human Research Protection Program, Health Science Center, Peking University, Beijing

Prof Colleen M. Flood
Centre for Health Law, Policy and Ethics, Faculty of Law, University of Ottawa, Canada

20:50-21:00 **Closing Remarks**

Thursday 11 May 2023
Collaboration and Participation in Ethical Governance

09:00-09:30 **Roundtable Discussion on Regulatory and Ethical Challenges in Medical AI (including Generative AI)**

Chairs: **Prof Calvin W.L. Ho and Dr Karel Caals**

09:30-10-00 **Artificial Intelligence Systems of the Hospital Authority of Hong Kong**

Mr Dennis Lee
Senior Systems Manager (AI Systems), Hospital Authority of Hong Kong

10:00-11:00 **Roundtable Discussion on Regulatory and Ethical Challenges in Data Governance**

Chair: **Dr Zhang Haihong**
Human Research Protection Programme, Health Science Center, Peking University, Beijing

Discussants:

Mr Henry Yau
Managing Director, HKU Clinical Trials Centre, Hong Kong

Dr Creany Wong
Deputy Managing Director, HKU Clinical Trials Centre, Hong Kong

11:00-11:15 **Intermission**

11:15-12:30 **Discussion on Next Steps for Research**

12:30-13:00 **Closing Remarks**

Organised by:

The Centre for Medical Ethics and Law (CMEL) develops new ideas and solutions in response to the big ethical, legal and policy questions of medicine and health. CMEL is the first cross-faculty interdisciplinary institution of its kind in the region. It was founded in 2012 by the LKS Faculty of Medicine and Faculty of Law at The University of Hong Kong as a joint inheritor of their vibrant intellectual traditions dating back to 1887 and 1969 respectively.

Today, CMEL brings together bioethicists, academic lawyers, medical scientists, and other scholars to conduct cutting edge bioethical and legal research and contribute to policy development in flagship areas like digital health and emergent technologies, mental health and capacity, and population and global health.

Research, teaching and knowledge exchange—CMEL's core initiatives—aim to ensure that developments in biomedicine and public health will be underpinned by ethical and legal considerations.

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