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.
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
& via ZOOM

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

IN PERSON ONLY

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
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.

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