# 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 days 1 and 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)**

**Prof Walter Wai-Kay Seto**, Department of Medicine, University of Hong Kong
**Dr Keith Wan Hang Chiu**, Department of Radiology & Imaging, Queen Elizabeth Hospital
**Dr Wong Wai Kei**, Alpine Intelligent Medical Corporation Ltd
**Mrs Grace So**, AI InnoBio Ltd
**Ms Karen Poon**, Just A Moment Wellness Co Ltd
**Dr Jeffrey Pong**, Healfie Technology Ltd
**Mr Mark Szeto**, In Good Health Co Ltd
**Mr Ronald Tse**, MVisioner Ltd
**Mr Ivan Ng**, Time Creation Ltd (Brand name: FindDoc)

**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 & Data Governance, with a Focus on Genomics

**13:30-13:45   Introduction**

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

**13:45-14:15   Governing Health Data across Changing Contexts**

       **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 Artificial Intelligence in Genetic Testing: Regulatory Framework & 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**

## Keynote Address:
## China's AI Regulatory System & the Prospect of Ethical Governance of Medical AI
## Prof Duan Weiwen – 段偉文

Professor & Director, Department of Philosophy of Science and Technology, Institute of Philosophy, Chinese Academy of Social Sciences, Beijing, China
Director, Research Center for Science, Technology and Society, Chinese Academy of Social Sciences, Beijing, China

Prof Duan is doctoral supervisor at the University of the Chinese Academy of Social Sciences, and a special allowance expert of the State Council of China. He was a visiting scholar in Oxford University, Colorado School of Mines, and University of Pittsburgh. His main research areas are philosophy of science and technology, ethics of science and technology, social and ethical issues of ICTs, Big Data and AI. He is the chief researcher of "Philosophical Studies on Intelligence Revolution and Deepening Techno-scientific of Human Being (2017-2022)", supported by National Social Sciences Founding of China (NSSFC). He is the author of several books, including *The Ethical Foundation of Information Civilization* (2020, Shanghai People's Press). He is one of the deputy chairmen of the *Committee of Big Data Experts of China*; an academic advisor to the Support Center for Research on Scientific Norms and Ethics, Academic Division, *Chinese Academy of Sciences*; etc.

This presentation will focus on three aspects of the regulatory system and ethical governance of medical AI in China. First, the presentation will provide an overview of the existing AI and science and technology ethical regulatory system in China, including the AI and science and technology ethical governance system and its governance ideas constituted by ethical principles and standards, ethical review methods, and so forth. Second, the gap between possible ethical issues in medical AI and the existing regulatory provisions will be considered. Third, the presentation will put forward governance ideas and ethical strategies that should be in place to bridge this gap.

## A Qualitative Analysis of Different Perspectives on Ethical Governance and Ethics Review of Medical AI Research and Development in Shenzhen, China
## Dr Ji Ping –吉萍

Deputy Director, Clinical Research Institute, Shenzhen-Peking University-The Hong Kong University of Science and Technology Medical Center, Shenzhen, China

Dr Ping Ji began her clinical research career as medical writer and monitor for industry in China after obtaining her PhD in 2006 at Cardiff University, UK. She developed her interests in medical research ethical review and human subjects protection since 2010. She took the role as director of Quality Assurance Office in Peking University Human Research Protection Program by 2016. Since 2016, she moved to Shenzhen for building clinical research support and supervision platforms for education & training, technological support, ethical review, and policy development with the support from the local health authority. Together with her colleagues, her team has made great achievements on developing regional clinical research infrastructure.

A number of guidelines on AI development have been issued by international and national research institutes, government organizations and industries that give emphasis to different ethical values and considerations. Even when there is agreement on which ethical principles should apply, their implementation as real-world practices has been a big challenge. The Health Commission of Shenzhen and Peking University Clinical Research Institute (Shenzhen) designed and conducted the present qualitative study. Our primary objective was to learn about the ethical challenges, current status, barriers, needs and suggestions on Research and Development (R&D) projects on medical AI among multiple stakeholders, including sponsors, research teams, ethic committee members and institutes. We are also hoping to inform policy-makers on ethical governance and review based on the AI R&D activities' special features compared to traditional clinical research.

## Smartphone Crowdsourced Medical Data for Algorithm Training & Biomedical Research: Ethical and Legal Points to Consider
### Dr Ma'n H. Zawati

Assistant Professor & Executive Director, Centre of Genomics and Policy, Department of Human Genetics, Faculty of Medicine and Health Sciences, McGill University, Montreal, Québec, Canada

Ma'n H. Zawati (LL.B., LL.M., Ph.D. (DCL)) is also an Associate Member of the Faculty of Law, the Department of Equity, Ethics and Policy and the Department of Experimental Medicine. His research concentrates on the legal, ethical and policy dimensions of health research and clinical care, with a special focus on biobanking, data sharing & governance, professional liability, and the use of novel technologies (e.g. mHealth apps, WGS, WES) in both the clinical and research settings. His work is interdisciplinary, drawing together perspectives from law, ethics, genomics and policy. In 2022, Prof Zawati has published a book entitled "Reciprocity in Population Biobanks" (from Elsevier's Academic Press). He has also published 100+ book chapters and peer reviewed articles in leading publications. In 2015, he was awarded the Queen Elizabeth II Diamond Jubilee Scholarship (stay at Oxford University) and was named a Royal Society of Canada Delegate for the IAP Young Scientists of the Year international symposium. In 2014, the Young Bar Association of Montreal named him as one of its Lawyers of the Year. In 2023, he was elected as McGill University Senator, representing the Faculty of Medicine and Health Sciences.

This presentation will discuss the legal and ethical challenges that emerge with the growing use of Smartphone Crowdsourced Medical Data (SCMD) for Artificial Intelligence (AI) algorithm training and biomedical research. The applicability of current research regulations to this novel context remains ambiguous and limited, as issues of consent, inadequate privacy protections, anonymization challenges, and AI biases pose significant risks to user-protection. While utilizing SCMD to support innovative medical developments displays considerable potential, this presentation explores these ambiguities (by showcasing mhealth apps as case models) and proposes a research agenda that aims to preserve individuals' interests as SCMD and AI become increasingly prominent.

## Regulating AI Medical Devices
### Dr Colin Mitchell

Head of Humanities, PHG Foundation, University of Cambridge, Cambridge, UK

Dr Colin Mitchell is Head of Humanities at the UK based health policy think tank, the PHG Foundation, which is part of the University of Cambridge. He leads a team addressing legal and ethical issues that arise with genomics and other biomedical innovations. This includes challenges associated with genomic data processing, artificial intelligence and the obligations of health and scientific professionals in the contemporary biomedical landscape. Colin has a PhD in health law from the University of Amsterdam, a Masters of Studies in Legal Research from the University of Oxford and a BA in Law from the University of Cambridge.

This talk explores considers some of the challenges posed by current and near-future machine learning applications in healthcare, with a focus on the challenges of the opacity and adaptivity of some AI-driven technologies. A key element of the regulatory framework is medical device law. This presentation considers how existing EU and UK medical device regulations apply to AI and proposals for change to address gaps and improve certainty for manufacturers and users. Finally the talk addresses implications for health care professionals, regulators and policy makers, including gaps in the wider regulatory or ethical framework.

**Day 2: The Impact of the UK and EU General Data Protection Regulation (GDPR) on International Genomic Data Sharing for Research**

## Gaps & Trends in Medical AI Governance
## Dr Barry Solaiman

Assistant Professor, College of Law, Hamad bin Khalifa University, Doha, Qatar
Adjunct Assistant Professor of Medical Ethics in Clinical Medicine, Weill Cornell Medicine, Doha, Qatar

Barry Solaiman specialises in the law of AI in healthcare. He completed his PhD in law at the University of Cambridge. In Qatar, he is the Lead Project Investigator for a research project at HBKU and Project Investigator on another, both examining AI in healthcare. In addition to his journal publications in this space, he is co-editing a major book on Health, AI and the Law to be released in 2023.

This talk outlines gaps and trends in the governance of medical AI. A framework is provided for deciphering the governance trends around the world that tend to fall into either a hard or soft law category. Those categories are, in some countries, reflective of the free-market traditions espoused in their political traditions. To elucidate these considerations, reflections are provided on developments in the United States and the European Union as legal trend setters in this space alongside the legal responses of countries in East and Southeast Asia, and the Middle East.

### Book Talk (early preview): Research Handbook on Health, AI and the Law

Together with Prof I. Glenn Cohen on the evening of day 2.

## The Clinical Governance of Medical AI: Addressing Ethical Gaps
## Dr Alessandro Blasimme

Senior Scientist, Health Ethics and Policy lab, Department of Health Sciences and Technology, Swiss Federal Institute of Technology, ETH Zurich, Switzerland

Alessandro Blasimme is a reader in bioethics at the Swiss Federal Institute of Technology (ETH Zürich). He has held research appointments at the French National Institute of Health and Medical Research (INSERM) as well as the University of Zürich, before joining ETH Zürich. In 2013 he received a Fulbright-Schuman Scholarship to undertake research at the Program on Science, Technology and Society, Harvard University (USA) where he was a fellow. His research focuses on ethical and policy issues in biomedical innovation and biotechnology. His areas of expertise include translational medicine, precision medicine, regenerative medicine, genetic engineering, digital health and ageing. He has published widely in leading bioethics and medical journals and he is a principal investigator in national as well as international research consortia. He is a visiting professor in bioethics at La Sapienza University of Rome (2022).

The regulatory landscape around AI is rapidly evolving. In this paper, I maintain that upstream models of regulation are unlikely to mitigate the specific ethical risks they are intended to address. In the case of medical AI, upstream regulation may actually undermine technological progress while failing to meet ethical needs. In particular I discuss three issues (the use of generative AI by patients and physicians, the mitigation of AI bias, and the requirements of explainability) to illustrate the shortcomings of upstream regulation and the advantages of more distributed governance models.

## Machine MD: Canada's Legal Governance of Safety and Privacy in Health AI
### Prof Colleen M. Flood

Professor & University Research Chair in Health Law & Policy, Faculty of Law, University of Ottawa, Ottawa, Canada
Director, University of Ottawa Centre for Health Law, Policy and Ethics, Ottawa, Canada

Colleen M. Flood FRSC, FCAHS is a University of Ottawa Research Chair in Health Law & Policy and inaugural director of the uOttawa Centre for Health Law, Policy and Ethics. Her research focuses on the role of law in shaping health care systems and the appropriate roles for the public and private sectors. She is the principal investigator of a CIHR grant on the governance of health-related AI and the author/editor of 13 books (several in multiple editions), editor of Halsbury's Laws of Canada - Public Health. 2019 and co-editor of Vulnerable: The Law, Policy & Ethics of COVID-19 (uOttawa Press 2020).

Professor Flood will discuss insights from six multi-disciplinary case-study workshops, which interrogated the sufficiency of existing Canadian laws to meet the challenges posed by various health-AI. The innovations workshopped included a suicide-prediction application, a surgical decision-support tool, a self-driving wheelchair, a triaging tool for a paediatric emergency room, "digital twin" technology, and a tool for assessing the risk of cardiac arrest in a paediatric ICU. She will explore whether existing privacy, liability, anti-discrimination and informed consent laws in Canada are sufficient to meet the challenges of various health-related AI and what these case-studies suggest are gaps and solutions. Specifically, she will explore the opportunities and challenges for Health Canada, in its role vis-à-vis medical devices, to develop regulations that sufficiently and efficiently regulates the safety and privacy of health-related AI.

## Illustration of AI Adoption in Clinical Setting and Implications for Governance and Regulation
### Dr Neeraj R. Mahboobani –馬承志

MBBS, FRCR, FHKCR, FHKAM (Radiology)
Consultant and Training Director, Department of Radiology & Imaging, Queen Elizabeth Hospital, Hong Kong, China
Convenor, Task Force on Artificial Intelligence, Professionalism & Ethics Committee, Hong Kong Academy of Medicine, Hong Kong, China

Dr Mahboobani's main area of work is in neuroradiology. In diagnostic neuroradiology, his interests are in MRI imaging of neurovascular and neuro-oncological diseases, as well as advanced MRI techniques including use of MR perfusion and functional MRI. In interventional neuroradiology, he performs a wide range of procedures for neurovascular diseases including carotid stenting, thrombectomy for acute ischaemic stroke, embolization of aneurysms and arteriovenous shunts including brain arteriovenous malformations. In recent years, he has been actively involved in the use and adoption of Artificial Intelligence in Radiology. He actively uses the RAPID AI software in the management of acute ischaemic stroke patients presenting to his hospital. His most recent project has been the implementation of DeepCT software for detection of acute intracranial haemorrhage and midline shift on non-contrast CT brain scans in his hospital.

The field of artificial intelligence has been booming in recent years. It has and will continue to impact numerous industries and spaces, healthcare included. There are many actors and players in the arena of artificial intelligence in healthcare, and successful deployment of AI in the clinical setting to achieve patient and healthcare system benefit requires intricate cohesiveness between various stakeholders. Governance and regulation are vital to attain beneficial adoption, and a framework for these will be proposed.

## Round Table & Use Cases Discussion

### Prof Walter Wai-Kay Seto – 司徒偉基教授

MBBS(HK) MD(HK) AGAF FRCP (Edin, Glasg, Lond) FHKCP FHKAM (Medicine)
Department of Medicine, University of Hong Kong, Hong Kong, China

Prof Wai-Kay Seto is currently a specialist in Gastroenterology and Hepatology and Clinical Professor in the Department of Medicine; and Principal Investigator of the State Key Laboratory of Liver Research, the University of Hong Kong. Prof Seto is ranked by Clarivate Analytics in the top 1% worldwide by research in 2020, 2021 and 2022. He has published more than 250 international journal articles and book chapters, including first- or corresponding-authored articles in the Lancet, Journal of Clinical Oncology, Lancet Global Health, Journal of Hepatology, Gut, and Hepatology, majority related to research on chronic liver diseases. Prof Seto has been awarded the American Gastroenterological Association Fellowship (2021); the Asia-Pacific Digestive Week Emerging Leader from the APDW Federation (2018); Guangdong Province Outstanding Young Medical Talent Award (2017); and the Outstanding Young Research Award (2016-2017) from The University of Hong Kong.

### Dr Keith Wan Hang Chiu

Department of Radiology & Imaging, Queen Elizabeth Hospital, Hong Kong, China

### Dr Wong Wai Kei

Alpine Intelligent Medical Corporation Ltd, Hong Kong, China

### Mrs Grace So

AI InnoBio Ltd, Hong Kong, China

### Ms Karen Poon

Just A Moment Wellness Co Ltd, Hong Kong, China

### Dr Jeffrey Pong

Healfie Technology Ltd, Hong Kong, China

### Mr Mark Szeto

Founder & CEO, In Good Health Co Ltd, Hong Kong, China

Mark has over 28 years of investment banking, business management, and Telehealth experience. He is a Certified Public Accountant for both Hong Kong and the US, Chartered Global Management Accountant, member of the Greater Bay Area Think Tank, 2021 Asian Social Caring Leadership Awardee, and 2018 Asian Chinese Leader Awardee. Mark holds a Master of Business Administration and Bachelor of Science (Human Biology) degrees from University of Toronto. In Good Health Co. Ltd (IGH) is a patient driven startup that provides Chinese Medicine Telehealth services. IGH is a 1-stop shop for Chinese Medicine consultations. Its services include Appointment Making, Video Consultations, Prescriptions Making, Medicine Delivery, Medical Records Management, and Online Payment. Leveraging on technology, IGH commercializes, modernizes, and globalizes an industry which represents thousands of years of Chinese wisdom and culture. IGH was the 2022 Smart Living Partnership Awardee by ETnet, and the 2022 Most Outstanding Chinese Medicine Telehealth Platform Awardee by Corphub. IGH was nominated as the "Best and Most Innovative Digital Solution in Health and Wellbeing from China" for WSA2021 by the Internet Professional Association.

### Mr Ronald Tse

MVisioner Ltd, Hong Kong, China

### Mr Ivan Ng

Time Creation Ltd (Brand name: FindDoc), Hong Kong, China

## Impact of Different Regulations on the Secondary Use of Medical Data in Italy: Implications for AI Development and Use
### Prof Deborah Mascalzoni

Research group leader, ELSI group, Institute for Biomedicine, Eurac Research, Bozen, Italy
Associate Professor, Center for Research Ethics and Bioethics, Department of Public Health and Caring Sciences, Uppsala University, Uppsala, Sweden

Prof Deborah Mascalzoni's main research interests are genetics and new technologies including rare diseases and vulnerable community with special attention to human rights and privacy within the use of data. She is author of more than 60 peer reviewed articles. Deborah Mascalzoni developed, together with IT experts, the Dynamic Consent Platform for the Cooperative Health Research in South Tyrol (CHRIS) Study at Eurac Research, used by 13.500 individuals since 2011. She has been extensively working on projects focusing on research participant engagement and participant rights in biobanking. She serves as an advisor in different projects and is a member of different international and national advisory boards.

Large-scale data collections and biobanks are the natural data source for AI development and training in the biomedical field. AI-based diagnostics for cancer patients promise to deliver soon the first usable tools. To do so they need large access to EHR and good quality datasets. The legal and ethical landscape in different countries may heavily impact the ability to access and use data to develop and train AI. AI development needs to be embedded into a culture of trust supported by governance mechanisms that sustain the public Value of research. Using an Italian case, the CHRIS study as an example will showcase how even ethically advanced research scenarios could be damaged by different regulatory approaches in Europe.

## Data Governance and the FACILITATE Project: Defining the Elephant in the Room
### Prof Johanna M.C. Blom

Associate Professor in Psychobiology and Behavioral Neuroscience & Vice-Coordinator of FACILITATE, Department of Biomedical, Metabolic and Neural Sciences, School of Medicine, University of Modena and Reggio Emilia, Modena, Italy

Prof Johanna Blom is Chair of the Ethical Committee for Research of the University of Modena and Reggio Emilia, and former Associate Director of the Part-time Graduate Program in Developmental Psychology and Behavioral Brain Sciences, Johns Hopkins University, USA, as well as the Vice-Coordinator of the IMI2-JU supported project FACILITATE. She is an expert in the generation of individualized networks to refine diagnoses, tailor treatment, and identify variants correlated with adverse drug reactions. Her research focuses on engaging young patients as (digital) data contributors necessitating the establishment of a robust ethical, legal, and trusted ecosystem with well-defined guidelines.

Building sound data governance in the FACILITATE project can only happen by promoting cohesion among all stakeholders involved in clinical trials and needs a shared sense of purpose, trust, and collaboration. This can be achieved through open communication, transparency, and mutual respect. Stakeholders need to recognize that they all have a common goal if they want to improve patient outcomes, which is to advance data sharing, return, and reuse. By fostering a culture of accountability, stakeholders are held responsible for their actions, decisions and contributions to the trial which is essential for successful governance and innovation in clinical trials.

## European Health Data Space: The Panacea for Data Sharing in Europe?
## Dr Ciara Staunton

Senior Researcher, Institute of Biomedicine, Eurac Research, Bolzano, Italy

Dr Ciara Staunton has expertise on the legal and ethical issues in the field of biobanks, genomics, stem cells, health data, data protection and governance, and public health. She has been involved in the development of policy in Ireland, Bahrain and Africa and in 2021, led the development of the Framework for the Governance of Personal Data for the Access to COVID-19 Tools Accelerator. She is a member of several international advisory boards providing ethico-legal oversight on these topics and is a member of the National Irish COVID-19 Biobank – Research Ethics Committee (NICB-REC).

The development of medical AI is reliant on access to high quality and diverse data sets. The fragmented implementation of the General Data Protection Regulation (GDPR) in the context of scientific research has hindered the sharing of sensitive personal data, thus the proposed European Health Data Space (EHDS) will be welcomed. If passed, the EHDS will create an obligation to share electronic health data and thereby "unleash the benefits of the secondary use of electronic health data". However, will it really solve Europe's data sharing challenges? This paper will discuss the EHDS, what it means for medical AI, and offer reflections on how to address anticipated ethico-legal governance gaps in the current text.

## The Impact of the UK and EU General Data Protection Regulation (GDPR) on International Genomic Data Sharing for Research
## Dr Colin Mitchell

*Biography see day 1 (above)*

This presentation will discuss the challenges for international genomic data sharing raised by the European Union's General Data Protection Regulation (GDPR) and the UK's closely aligned version of the same regulation. It will draw on PHG Foundation research on the impact of the GDPR on genomic healthcare and research and provide an updated assessment of how the specific rules in Chapter V of the Regulation apply to international transfers of genomic data. We will also consider potential solutions and mechanisms to facilitate the sharing of genomic data between the EU/EEA and the rest of the world.

## The Use of AI in Genetic Testing: Regulatory Framework and Legal Issues
## Prof Du Li – 杜立

Associate Professor, Faculty of Law, University of Macau, Macau, China

Prof Du holds dual bachelor's degrees in both clinical medicine and law (Wuhan University, China) and a PhD. in law (University of Alberta, Canada). His teaching and research interests include international law, food law, biotechnology law and policy, and privacy law. Prof Du Li has led many research projects on legal and ethical implications of novel and emerging biotechnologies, e.g., genetic testing, stem cells, synthetic biotechnology, etc. He frequently shares his research findings at international conferences frequently and publishes articles in leading academic journals.

While artificial intelligence (AI) holds promise to revolutionize the genetic testing industry, the development of AI-assisted genome interpretation tools is subject to rules and regulations on personal information and human genetic data (HGD) protection. This presentation will explore the regulatory framework of the use of AI in genetic testing in China and examine legal issues associated with HGD access and sharing, HGD cross-border transfer, and privacy protection.

## 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 – 张海洪

Office Director, Human Research Protection Programme, Health Science Center, Peking University, Beijing, China

Dr Zhang received her PhD in research ethics from Peking University (PKU) and is now working at PKU Human Research Protection Program. In the past ten years, she and her team developed institutional ethics review working procedures and policies at PKU. She is in-charge of the PKU investigators' research ethics training program and teaches medical students clinical research ethics. Her research interests are protection of vulnerable research subject, IRB capacity building and data ethics.

On 18 February 2023, the Ethics Review Measures for Life Science and Medical Research Involving Human Subject was issued jointly by the National Health Commission, Ministry of Education, Ministry of Science and Technology, and the National Administration of Traditional Chinese Medicine. Along with the Personal Information Protection Law of China that came into effective in 2021 and an updated regulatory framework on using personal data for research purposes, these developments have significant implications on the ethical governance of medical research and development (R&D) across the country. This presentation will specifically focus on the latest ethics review and informed consent requirements of research that involve health data and genomic information, explore possible challenges of implementing ethical requirements, and finally, advocate for more engagement, as well as highlight the need for concerted effort among all stakeholders, particularly, the institutions and investigators.

## Digital Health, Data Governance and the Legal Framework
### Dr Ho Chih-hsing - 何之行

Associate Professor, Institute of European and American Studies & Research Center for Information Technology Innovation (joint appointment). Academia Sinica, Taipei.

Dr Ho's (LLM (Columbia) JSM (Stanford) PhD Law (LSE)) research focuses on the intersection of law, medicine and data science, with particular attention to the governance of genomics and newly emerging technologies. She has been appointed to the Advisory Committee on Digital Health, and the Advisory Committee on the Law for Biotech Development for the Ministry of Health and Welfare (MOHW) in Taiwan. She is also a member of the Consultation and Review Board of the National Biobank Consortium in Taiwan (NBCT), and has been appointed to the Taiwan Ministry of Health and Welfare's Biobank Ethics and Governance Council.

Digital health has rapidly advanced in recent years, with technology playing an increasingly important role in healthcare. On the other hand, advancements in genomics research have created vast amounts of data, leading to exciting possibilities for personalized medicine and targeted therapies. However, genomics and health data present unique challenges for data governance and legal frameworks due to their sensitive and identifiable nature. Robust policies are necessary to address issues such as consent, privacy, and public-private partnership, while also enabling research and innovation. Establishing appropriate data governance and legal frameworks is crucial and it is essential to balance the need for access to data for research and innovation while protecting patients' privacy and maintaining trust in the healthcare system.

## Keynote Address: Adoption of digital technology to facilitate smart living & smart city development in Hong Kong
## Ms Alice So

Head of Entrepreneurship, Hong Kong Cyberport Management Co Ltd, Hong Kong, China

As a passionate, strategic and result-driven leader with regional exposure, Alice has been dedicated to providing supports to Hong Kong start-ups for more than a decade. She leads the Entrepreneurship Team to nurture talents and assist start-ups at different life stages to accelerate in the digital tech industry worldwide, through the Cyberport Creative Micro Fund and the Cyberport Incubation Programme with financial support and professional services. Alice has been in the judging and assessment panels for signature technology awards and innovation funding schemes including the Hong Kong ICT Awards, the Jump-starter of Alibaba Entrepreneurs Fund, 2019 MIT Inclusive Innovation Challenge, the Technovation and the TSSSU funding of universities, etc. She is a Council Member of the Hong Kong Computer Society, an Honorary Board Member of Hong Kong Medical & Healthcare Device Industries, and a member of the Design Discipline Advisory Board of Hong Kong Design Institute.
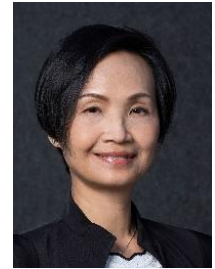
Human need is the mother of innovation. All digital technologies that have thrived so far are created for solving people's pain points. As technologies and societies are indivisible, all related stakeholders play significant roles in driving successful technology adoption to enhance the living standard in the society, targeting a better world together.

## Sharing Genetic Information for the Common Good
## Dr Derrick K.S. Au – 區結成

Honorary Advisor, CUHK Centre for Bioethics, Faculty of Medicine, Chinese University of Hong Kong, Hong Kong, China
Chair, Ethics Committee of the Hong Kong Genome Project

Dr Derrick Au is Ex-Director and current Advisor of the CUHK Centre for Bioethics at the Chinese University of Hong Kong. Dr Au served in clinical geriatric and rehabilitation services for two decades before taking up executive positions in the Hong Kong Hospital Authority. As Director of Quality & Safety (2014-16) his portfolio included overseeing clinical ethics, research ethics and technology assessment. Dr Au is current Convenor of the Ethics Advisory Committee of the Hong Kong Genome Institute and Ex-chairman of the HA Clinical Ethics Committee (2017-2020).

In the 'genomic era', genetic information has become increasingly important in research and development. The aims are to improve healthcare through precise diagnosis, personalized treatments, and health preventions. However, sharing genetic information is not a simple matter, even when there is good cause. This presentation considers the issues of and tension between the common good and individual rights, at healthcare level and in genome data-banking.

Commentaries:

### Dr Colin Mitchell
Head of Humanities, PHG Foundation, University of Cambridge, Cambridge, UK

### Prof Du Li – 杜立
Associate Professor, Faculty of Law, University of Macau, Macau, China

### Prof Deborah Mascalzoni
Research group leader, ELSI group, Institute for Biomedicine, Eurac Research, Bozen, Italy
Associate Professor, Center for Research Ethics and Bioethics, Department of Public Health and Caring Sciences, Uppsala University, Uppsala, Sweden

## Book Talk (early preview): Research Handbook on Health, AI and the Law
## Prof I. Glenn Cohen & Dr Barry Solaiman

### Prof I. Glenn Cohen

James A. Attwood and Leslie Williams Professor of Law & Deputy Dean, Harvard Law School, Cambridge, Massachusetts, USA
Faculty Director, Petrie-Flom Center for Health Law Policy, Biotechnology & Bioethics, Harvard Law School, Cambridge, Massachusetts, USA

Prof Cohen is one of the world's leading experts on the intersection of bioethics (sometimes also called "medical ethics") and the law, as well as health law. He also teaches civil procedure. He has advised the U.S. Vice President on reproductive rights, discussed medical AI policy with members of the Korean Congress, and lectured to legal, medical, and industry conferences around the world. His work has been frequently covered by or appeared in PBS, NPR, ABC, NBC, CBS, CNN, MSNBC, Mother Jones, the New York Times, The Washington Post, the Boston Globe, and many other media venues.

### Dr Barry Solaiman – *Biography Dr Barry Solaiman see day 1 (above)*

In this presentation, we will discuss our ground-breaking book exploring the legal implications surrounding the use of artificial intelligence (AI) in healthcare. This will be the first book to comprehensively examine core legal issues surrounding data discrimination and privacy, informed consent, medical liability, IP, and data security, in the healthcare AI context, while examining secular and religious perspectives. The book also provides an overview of regulations as derived from international organisations, the United States, United Kingdom, China, Singapore, South Korea, the European Union, and the Middle East. We will discuss interesting trends that have arisen and the implications of new technologies on the law like ChatGPT and beyond.

Commentaries:

### Dr Zhang Haihong - 张海洪
Office Director, Human Research Protection Programme, Health Science Center, Peking University, Beijing, China

### Prof Colleen M. Flood
Professor & University Research Chair in Health Law & Policy, Faculty of Law, University of Ottawa, Ottawa, Canada
Director, University of Ottawa Centre for Health Law, Policy and Ethics, Ottawa, Canada

## Artificial Intelligence Systems of the Hospital Authority of Hong Kong
## Mr Dennis Lee

Senior Systems Manager (AI Systems), Hospital Authority of Hong Kong, Hong Kong, China

Mr Dennis Lee currently serves as the Senior System Manager for Artificial Intelligence Systems of the Hong Kong Hospital Authority. His work involves developing the Artificial Intelligence and Big Data Platform to streamline data acquisition for facilitating HA data analysis, develop Hospital Command Center dashboards, and solution deployment for Artificial Intelligence. Mr Lee leads the Corporate Project management office and as program managers for several large scale system implementations under IT&HI division.

## Roundtable Discussion on Regulatory and Ethical Challenges in Data Governance
## Dr Zhang Haihong 张海洪 – Mr Henry Yau 游广智 – Dr Creany Wong 黄嘉慧

Chair:

### Dr Zhang Haihong – 张海洪

Office Director, Human Research Protection Programme, Health Science Center, Peking University, Beijing, China

Discussants:

### Mr Henry Yau – 游广智

BSc (Biochemistry), MBA (Finance)
Managing Director, HKU Clinical Trials Centre, Hong Kong

Henry Yau is the Managing Director of The University of Hong Kong Clinical Trials Centre (HKU-CTC) and Honorary Assistant Professor of Faculty of Medicine of Macau University of Science and Technology (MUST). He holds a B.Sc. in Biochemistry and an MBA in Finance. Started his service in the pharmaceutical industry in the early-1990s, he joined HKU-CTC in 2000. Henry also undertakes roles in many local and international bodies such as Steering Board Member and Past Chairperson of the International Clinical Trial Center Network (ICN), Member of the Working Group on Good Governance Practice for Research Institutions of the Council for International Organizations of Medical Sciences (CIOMS), and Advisor (Asia) of Training and Resources in Research Ethics Evaluation Program (TRREE).

### Dr Creany Wong – 黄嘉慧

BSc (Food and Nutritional Science), MPhil, PhD
Deputy Managing Director, HKU Clinical Trials Centre, Hong Kong

Creany Wong is the Deputy Managing Director of The University of Hong Kong Clinical Trials Centre (HKU-CTC) and Honorary Assistant Professor of Faculty of Medicine of Macau University of Science and Technology (MUST). She holds a B.Sc. in Food and Nutritional Science, MPhil and PhD degree. She joined HKU-CTC in 2006 and has diversified expertise and experience in clinical research management. Creany also undertakes roles in many local and international bodies such as Member of the Working Group on Good Governance Practice for Research Institutions of the Council for International Organizations of Medical Sciences (CIOMS), Member of Genetically Modified Organisms (Control of Release) Expert Group of Agriculture, Fisheries and Conservation Department (AFCD), HKSAR and Advisor (Asia) of Training and Resources in Research Ethics Evaluation Program (TRREE).

## Conference Chair
## Professor Gilberto Ka-kit Leung – 梁嘉傑

Tsang Wing-Hing Professor in Clinical Neuroscience & Associate Dean (Teaching & Learning), Li Ka Shing Faculty of Medicine, The University of Hong Kong, Hong Kong, China
Co-Director, Centre for Medical Ethics and Law, Faculties of Law & Li Ka Shing Faculty of Medicine, The University of Hong Kong, Hong Kong, China

Professor Gilberto K.K. Leung is Tsang Wing-Hing Professor in Clinical Neuroscience at the University of Hong Kong (HKU) and Honorary Consultant Neurosurgeon at Queen Mary Hospital. He graduated from the University of London with M.B.B.S. and Intercalated BSc in Physical Anthropology in 1992. He joined HKU in 2005 where he obtained his MS and PhD. He holds an LLB from the University of London, and an LLM in Medical Law and Ethics with Distinction from the University of Edinburgh. He is currently President of the Hong Kong Academy of Medicine, Associate Dean (Teaching & Learning) of his medical faculty, and Co-Director of the Centre for Medical Ethics and Law at HKU. His clinical and research interests cover endoscopic neurosurgery, molecular biology of brain tumours, neuroprotective therapy, medical education, and medical law and ethics.

## Conference Chair
## Dr Calvin W.L Ho – 何維倫

Associate Professor of Law & Co-Director, Centre for Medical Ethics and Law, Faculties of Law and Medicine, The University of Hong Kong, Hong Kong, China

Dr Calvin Ho's research is on global health law and ethics, and the governance of health and biomedical technologies (with focus on health technologies based on Artificial Intelligence and data analytics). He is Co-Chair of the Expert Group on the Ethics of Social Listening and Infodemic Management, as well as a member of the COVID-19 Ethics & Governance Working Group of the World Health Organization (WHO). Calvin is also an Ethics Board member of Médecins Sans Frontières (Doctors Without Borders), and a member of the Regulation and Ethics Work Stream of the Global Alliance for Genomics & Health. He was one of the contributing authors of the WHO's *Guidelines on Ethical Issues in Public Health Surveillance* that was published in 2017.

## Summary
## Dr Karel Caals

Research Fellow, Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore
Assistant Editor, Asian Bioethics Review

Karel obtained a PhD in Health Geography, after qualitative field research on the training of healthcare professionals in Timor-Leste to establish the concept of the 'More-than-National Health System'. As part of his interest in health systems, he researches the digitalisation of health, working on topics such as the ethics of artificial intelligence in healthcare and digital health surveillance. Additional interests include various topics in the field of research ethics, as well as stakeholder engagement. As Assistant Editor, he manages and promotes the Asian Bioethics Review, an academic journal established and hosted by CBmE, and published by Springer Nature. Additionally, he promotes the NUS Centre for Biomedical Ethics and its various initiatives via social media.

**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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