



Bioethics Seminar

Regulatory Governance of AI in Medicine in the Guangdong-Hong Kong-Macau Greater Bay Area in China

The main aim of this paper is to examine how a participatory and collaborative approach to the regulatory governance of medical devices based on artificial intelligence (AI) or machine learning (ML) is being developed and implemented in Hong Kong SAR, as part of the Guangdong – Hong Kong – Macau Greater Bay Area (GBA). In this connection, it also seeks to explicate what it means to be “participatory” and “collaborative”; these being regulatory principles that have been put forward by the International Medical Device Regulators Forum (IMDRF), and implicit in the “Guangdong-Hong Kong- Macau Greater Bay Area Pharmaceutical and Medical Device Regulatory Innovation and Development Work Plan” (GBA Medical Device Work Plan). The emerging regulatory governance is expected to support the development and uptake of AI/ML-based medical devices in a manner that is consistent with ethical and social values that sustain professional trustworthiness and public trust; and facilitate regulatory convergence within the GBA, thereby also promoting access to novel medical devices for residents in the GBA. Where applicable, comparative analysis is applied to contrast regulatory governance in the constituent jurisdictions of the GBA with those in the United States of America and the European Union.

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Monday, 22 August 2022

1:00-1:50 pm

**Bioethics Seminar Room (Room 119),
Level 1, 71 Frederick Street, Dunedin 9016**

Meeting ID: 922 351 556 | Password: 595584

To those joining online, we ask that you please mute yourselves upon arrival to avoid any accidental interruptions.

If you wish to attend the AV- linked venue at **University of Otago Christchurch (Room 7.11)**, please register your attendance to av.uoc@otago.ac.nz with your name, subject, and seminar date.

Please note that if no registration is received for this venue by the Thursday prior to the advertised seminar, the booking for that campus venue will be terminated.

Dunedin-based attendees in the Bioethics Seminar Room are not required to register.

Those attending in person are requested to please wear a mask, and to please not attend the seminar if you are experiencing any Covid-19 or flu-like symptoms.