

PS 3.3



| BACKGROUND

The recent surge of Al innovation has led to the rapid development of Al-driven health solutions with immense potential to improve the health and well-being of individuals and communities around the world, by accelerating drug discovery and development, increasing access to care, delivering personlized care, optimizing care delivery, and providing support to an overstretched health workforce. In order to build trust in Al systems, as well as further accelerate innovation and equitable access to these technologies, a regulatory ecosystem with effective guardrails and safety brakes need to be in place to safeguard individuals and communities.

Al technologies bring a unique set of risks and challenges, such as unethical data collection, cybersecurity threats and amplifying biases, that must be addressed. Without effective and robust regulatory and enforcement systems in place, Al health solutions could have access to sensitive personal information, compromising privacy, health security, and undermining collaboration. This results in biases, mistrust, inaccuracies, and ineffectiveness in health systems. The lack of governance mechanisms also contributes to the slow adoption of Al solutions within health systems. Governments are hesitant to approve technologies without evidence of safety and efficacy; technology developers do not have clear pathways to certification or regulatory approval; and private sector companies are left to develop ethical frameworks without a governmental mandate to protect the public good.

Therefore, strong, responsive governance frameworks and regulatory mechanisms are required to establish AI systems' safety and effectiveness by putting Responsible AI standards into actual practice. The use of regulatory sandboxes for safe innovation, promotion of open AI models and the use of AI in compliance tech present interesting options to explore as one establish a regulatory ecosystem for AI in health. A robust ecosystem will help mitigate risks, ensure AI's foundation remains firmly rooted in ethical principles and respect for human rights, as well as build trust for long-term acceptability and success of AI-enabled progress in the health sector.

| OBJECTIVES

This session seeks to:

- Provide a clear articulation of risks associated with the rise of Al systems in health
- Discuss the regulatory balance between ethical and economic incentives needed to safeguard patient safety and privacy while fostering innovation
- Draw lessons from current regulations for medical devices in the regulation of predictive and generative AI in health
- Explore engagement of diverse stakeholder groups in the regulatory process

Keynote speaker and panelists will explore the need for Responsible AI in health, consequences of not having regulatory mechanisms in place and how an agile and effective regulatory ecosystem can mitigate risks, accelerate innovation, increase access to healthcare and promote health equity.





Panelist

Raymond Chua

Deputy Director-General of Health, Health Regulation | Chief Executive Officer-Designate

Ministry of Health | Health Sciences Authority Singapore

Adjunct Associate Professor (Dr) Raymond Chua is the Chief Executive Officer-Designate of the Health Sciences Authority responsible for safeguarding and advancing public health through securing the national blood supply, administering national justice through its forensic medicine and scientific testing capabilities and regulating the health products. He is also the Deputy Director-General of Health (Health Regulation) at the Ministry of Health overseeing the regulations of healthcare services and information. With these 2 concurrent positions, he will better synergize regulatory policies, operations and enforcement across healthcare services, information and products in Singapore. He has extensive regulatory, management and operational experience in both the public healthcare and private pharmaceutical sectors in the past 25 years, contributing to the advancing developments of the healthcare landscape.

Adj A/Prof (Dr) Raymond holds adjunct professorships at the NUS Saw Swee Hock School of Public Health, and the Centre of Regulatory Excellence in Duke-NUS. He also holds a Bachelor of Medicine and Bachelor of Surgery from NUS Yong Loo Lin School of Medicine, a Master of Science in Public Health from the London School of Hygiene and Tropical Medicine and a Master of Business Administration from the University of Nottingham.