

PS 3.3

ARTICULATING AND MITIGATING RISKS OF AI IN HEALTH

| BACKGROUND

The recent surge of AI innovation has led to the rapid development of AI-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 personalized care, optimizing care delivery, and providing support to an overstretched health workforce. In order to build trust in AI 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.

AI 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, AI 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 AI 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 AI 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

James Oughton

Chief Advisor Precision Health

Ministry of Health
New Zealand

James has extensive experience in both the public and private sectors and has returned to New Zealand after 7 years in the US working at the intersection of genomics and precision oncology. A pharmacist by training, James also holds postgraduate diplomas in both genomic medicine and public health. James is passionate about the intersection of health care and innovation and is excited about the opportunities new technologies can provide for patients.

In his role as Chief Advisor of Precision Health, James's role involves championing, liaising with stakeholders and advising on the Ministry of Health's precision health work programme to ensure the safe adoption of genomics and artificial intelligence in health care in New Zealand.