

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.



Keynote

Jiho Cha

Member of Parliament

Korean National Assembly
Republic of Korea

Jiho Cha, M.D. Ph.D., a Member of Parliament (Congressman) in the National Assembly of the Republic of Korea serving on the Committee on Foreign Affairs and Unification is a physician, global health scholar, and field humanitarian. After completing clinical training in 2005, he has worked for North Korean and other marginalized populations around the world (North Korea, Papua New Guinea, Pakistan, Indonesia, China, Afghanistan, Ukraine, Bangladesh, Nigeria, Libya etc.) through non-governmental (MSF, Human Rights Watch), governmental (South Korean Ministry of Unification), international organizations (WHO, IOM), and academia (Univ. of Manchester, Johns Hopkins Univ. and KAIST). His research interests lie in global response to future crises specifically related to complex humanitarian crises, climate change and human mobility, and AI for humanitarian system. He was also affiliated with Feinstein International Center, Tufts University, and Center for Humanitarian Health, Johns Hopkins University.