

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

Stephanie Ifayemi

Head of Policy

Partnership on AI (PAI)
United States of America

Stephanie Ifayemi is the Head of Policy at Partnership on AI (PAI). In this role, she has established a new public policy department for PAI. Stephanie drives the organization's engagement with global policy makers, aligns PAI research with policy, and facilitates dialogue between government, multilateral organizations and PAI's partner community of over 100 partners in 16 countries.

Prior to PAI, Stephanie was the Head of Digital Standards Policy in the UK government, where she built a new portfolio focused on technical standards for emerging technologies including AI and quantum. She was responsible for designing and building the UK's AI Standards Hub, and for setting the UK's first objectives on AI standards in the UK's National AI strategy.

Internationally, Stephanie sits on Chatham House's Taskforce for Al and Society, the OECD's Network of Expert on Al groups (AIGO and ONE AI), a member of EY's Global Al Advisory Council and a Schmidt Futures International Strategy Fellow. Stephanie holds a Master of Public Policy from the University of Oxford where she was a Duke of Cambridge Scholar.