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 personlized 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.

Speaker

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Founder & President of 'UNITE Parliamentarians Network for Global Health'. Chair of the 'Harvard-Charité Global Health Policy Lab', an academic collaborative between Harvard University and Charité – University Medicine Berlin, based in Berlin. Chair of the 'Centre for Global Health' at NOVA IMS – Data Science School. Former 4-term Member of the Portuguese Parliament and former Vice President of the Social Democrats Parliamentary Board. Current opposition City Councilor of Sintra and Former Deputy Mayor of Cascais. Medical Doctor trained in Infectious Diseases, with nearly a decade of clinical practice and in health tech advisory services. Post-graduate studies Johns Hopkins University, Harvard Kennedy School of Government and Harvard Medical School. Founder of 'CREATING HEALTH – Research and Innovation Funding'. Author of the book "A Road to the Cure – Proposals to Fix the Portuguese Health System", among others.