## INTRODUCTION

The 10th Anniversary CoRE Scientific Conference marks a milestone in our journey as we celebrate a decade of achievements while looking ahead at emerging issues in the evolving field of health regulation. This year's Conference carries the theme: "Regulating the Future of Health: Converging Products & Services Regulation for Access, Innovation & Sustainability".

Focusing on four pivotal and pertinent themes – Regulating Artificial Intelligence & Digital Health, Regulating Precision Medicine, Regulating for Disease Prevention, and Partnerships for Effective Regulation, the Conference is envisioned to be a platform for key decision makers and stakeholders in the regulatory ecosystem to connect, engage, network, and be furthered empowered.

Session 1: Regulating Artificial Intelligence and Digital Health

Artificial Intelligence (AI) has emerged as a game-changer in the healthcare sector. AI-driven digital health technologies are redefining diagnosis, treatment, drug discovery, and the overall patient care landscape. Therefore, this transformative innovation necessitates robust regulation to ensure patient safety, ethical use, and responsible innovation.

This session, aims to answer the question **"How to develop AI and Digital Health regulations across different jurisdictions?"**
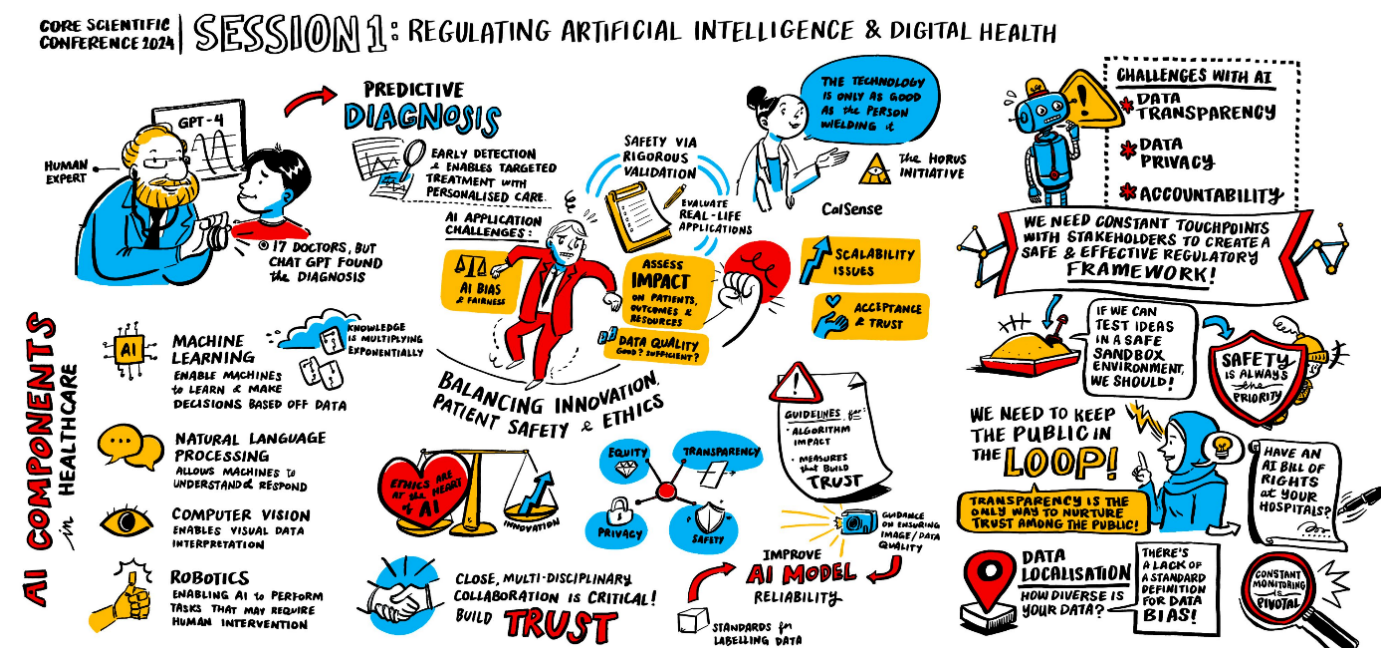
Snapshot of Session 1

As AI and digital health technologies rapidly evolve, their integration into healthcare systems offers unprecedented opportunities to transform care delivery. However, with great potential comes great responsibility, necessitating a balanced approach to innovation, regulation, and ethics. This session explored the multifaceted challenges and opportunities in regulating AI in healthcare, focusing on clinical applications, ethical considerations, operational strategies, and Singapore's regulatory roadmap. This session aimed to answer the question, how to develop AI and Digital Health regulations across different jurisdictions.

At this session, experts from across medicine, technology, and policy convened to explore the question: Can AI be integrated into healthcare without compromising patient safety, ethical integrity, and trust? The discussions centred on four key presentations:

- AI's Expanding Role in Clinical Practice
- Ethical and Regulatory Challenges in AI Governance
- Operational Realities of AI in Hospital and Health Systems
- Singapore's Strategic Path for AI Regulation

The dialogue underscored that the challenge is no longer whether AI should be implemented in healthcare—it already is. The challenge is how to regulate it effectively, ensuring it serves humanity without unintended harm.

AI's growing influence in clinical practice

Session chair, Dr Harvey Castro opening session 1 on topic Clinical Applications of Artificial Intelligence

The session opened with **Dr Harvey Castro**, who illustrated the vast potential of AI in personalized medicine, early disease detection, and predictive analytics. AI is no longer just an experimental tool—it is already assisting radiologists in medical imaging, supporting diagnostics, and even offering second opinions for complex cases.

A particularly striking example was a mother who used AI to analyze her child's test results and symptoms, leading to a diagnosis of her child's condition that had eluded doctors. This raises a fundamental question: What happens when AI outperforms human expertise? While such cases highlight AI's promise, they also raise concerns about accuracy, liability, and patient data privacy.

Perhaps most intriguingly, Dr Castro pointed out that AI may offer a surprising advantage in patient engagement. Some studies suggest that patients perceive AI as more empathetic than human doctors—not

because AI has emotions, but because it has unlimited time and patience to explain conditions in detail, whereas human doctors are often constrained by packed schedules. Does this mean AI could redefine the doctor-patient relationship? The discussion leaned towards a hybrid future, where AI is not a replacement but a tool that enhances human expertise, giving physicians more time for complex decision-making and direct patient care.

The ethical dilemmas of ai in healthcare

While AI's capabilities are impressive, they also bring ethical challenges. **A/Prof Liu Nan** explored these concerns, framing AI as a double-edged sword—an enabler of medical breakthroughs, yet a potential source of bias, privacy risks, and unintended consequences. One particularly controversial example involved AI interpreting a patient's thoughts, an experiment that raises urgent concerns about consent, cognitive privacy, and the boundaries of AI capabilities.
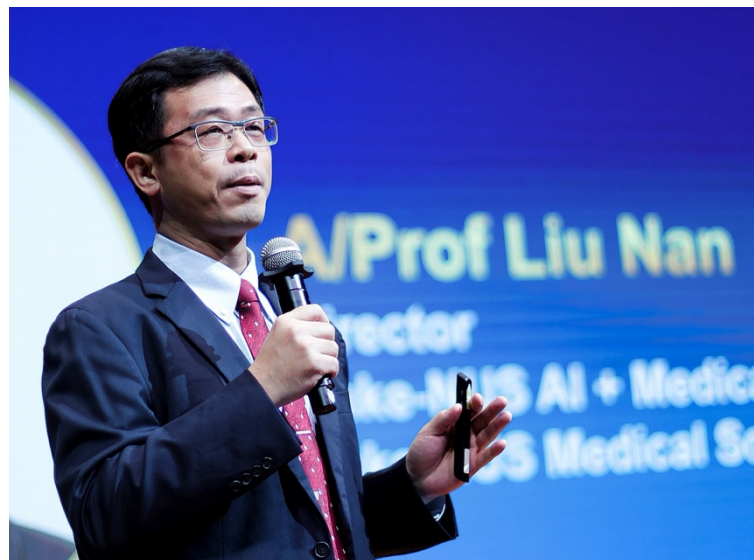
A/Prof Liu Nan on Balancing Innovation, patient safety and ethical considerations for AI in healthcare.

The COVID-19 pandemic offered another cautionary tale. Many AI models developed for predicting patient outcomes failed spectacularly, largely due to biased or poor-quality data. This failure exposed AI's dependency on high-quality datasets—if the data is flawed, AI becomes a liability rather than an asset. To navigate these risks, A/Prof Liu outlined nine fundamental ethical principles for AI in healthcare: accountability, autonomy, equity, integrity, non-maleficence, trust, transparency, privacy and security. Among the proposed solutions was federated learning, a technology that allows AI to train on decentralized data while preserving privacy.

However, ethics alone will not resolve AI's challenges—strong governance is required. This led to the next theme: how AI can be effectively deployed in real-world hospitals without compromising security and efficiency.

From theory to practice: deploying AI in healthcare systems

While the theoretical benefits of AI are widely recognized, its real-world implementation remains a challenge. **Asst Prof James Lee Wai Kit** offered an insider's perspective on how AI is being deployed in hospitals, highlighting both groundbreaking advancements and logistical hurdles. The NUHS Discovery AI Tribid System was introduced as an innovative approach to managing de-identified and identifiable patient data securely, facilitating AI-driven diagnostics while maintaining patient privacy. However, even with such systems, integrating AI into legacy electronic medical records (EMRs) remains a major challenge.

Several practical AI applications were discussed, including:

- Predicting Appendicitis – AI models using natural language processing (NLP) to improve emergency diagnostics.
- CardioSight – Mapping cardiovascular health metrics for early risk detection.
- Champs Initiative – AI-enhanced chatbot support for patient monitoring via WhatsApp.
- Speech-to-Text AI (Russell-GPT) – Improving clinical documentation efficiency through live transcription.

Despite these advancements, many AI tools struggle to integrate seamlessly with outdated hospital IT systems, proving that technology alone is not enough—system-wide readiness is crucial for AI success.

One of the key takeaways was that AI implementation cannot be a one-size-fits-all approach. Hospitals need customized solutions tailored to their specific infrastructure, workflows, and patient demographics.

Singapore's strategic approach to AI governance

Singapore has emerged as a thought leader in AI governance, aiming to balance innovation with safety. **Asst Prof Kavitha Palaniappan** outlined the country's regulatory strategy, followed by how it is being continuously reviewed and refined to ensure it remains responsive to emerging challenges and aligned with global best practices. This ongoing review is done in collaboration with MOH and CoRE.

A global review of AI regulations was conducted, revealing gaps in risk classification, data security, and trust-building. Two high-level roundtable discussions followed, focusing on:

- Identifying AI challenges and needs in healthcare, and
- Analyzing real-world AI use cases and potential risks

Singapore's approach is not to introduce new legislation, but to enhance existing regulatory frameworks with additional AI-specific guidelines.

Challenges and Unresolved Questions:

- Who is responsible for AI errors in clinical decision-making?
- How do we ensure AI models remain relevant as medical knowledge evolves?
- Where does accountability lie when AI-driven patient interactions lead to misinformation?

The consensus was that regulation must evolve alongside AI itself, requiring continuous dialogue between policymakers, developers, and healthcare professionals.

Panel discussion featuring (from left to right): Dr Harvey Castro, Dr Boitumelo, Ms Idamazura Idris, Asst Prof James Lee Wai Kit, and Asst Prof Liu Nan on developing AI and digital health regulation across different jurisdictions

Panel Discussion - Developing AI and Digital Health regulations across different Jurisdictions

The panel was moderated by the Session Chair **Dr Castro** with the speakers being panellists. There were additionally two more panellists; **Ms Idamazura Idris** from Medical Device Authority, Malaysia and **Dr Boitumelo Semete-Makokotlela** from The South African Health Products Regulatory Authority who are both regulators themselves. The panel deep dived into the key question, *How to Develop AI and Digital Health regulations across different Jurisdictions?*

It was pointed out that healthcare professionals raise concerns over transparency of data, protection of personal information and accuracy of AI generated diagnosis and hence adequate stakeholder engagement is imperative. The other issue that was highlighted was the necessity to make AI regulations applicable and implementable to address safety, performance and effective change management.

It was agreed by the panellists that as AI's role in medicine expands, its successful adoption depends not just on technological advancements, but on governance, ethics, trust and effective regulations.

Key Takeaways from the Session:

- AI should complement, not replace human expertise.
- Ethical AI requires bias mitigation, high-quality data, and strong accountability.
- AI regulation must be flexible and context-specific, ensuring alignment with real-world clinical needs.