CoRE Scientific Conference 2024
Regulating the Future of Health
Converging Health Products & Services Regulation for Access, Innovation & Sustainability
14 - 15 October 2024

INTRODUCTION

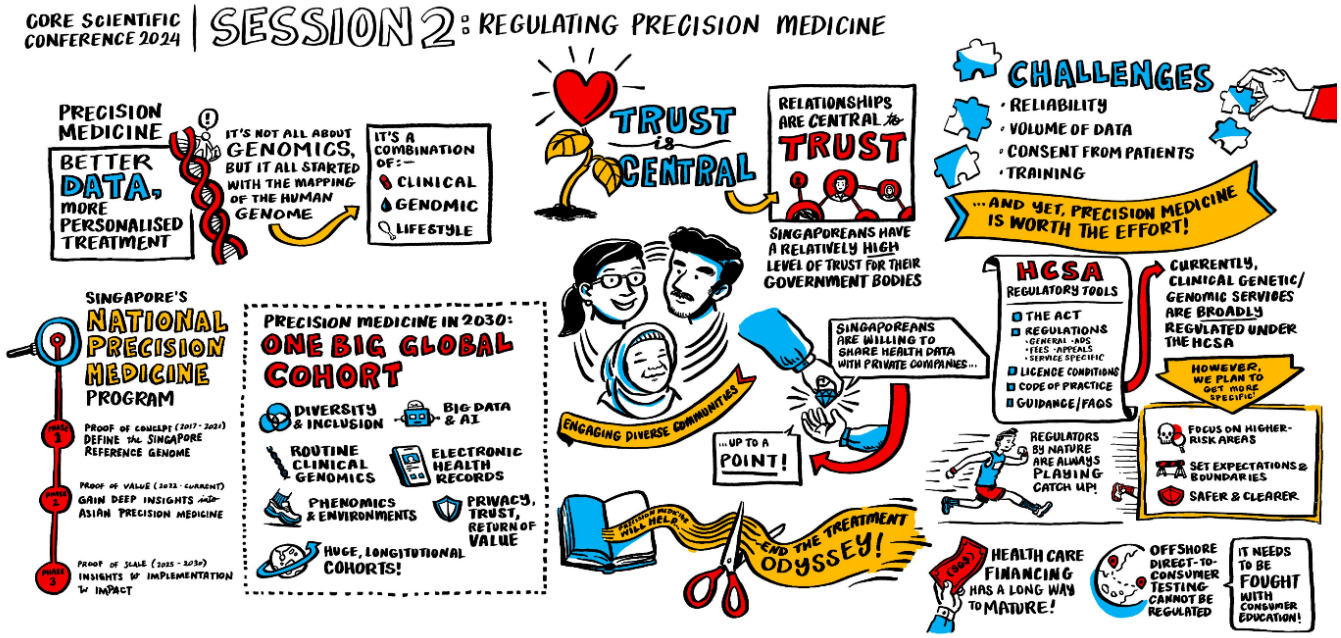
The 10th Anniversary CoRE Scientific Conference marks a milestone in our journey as we celebrate a decade of achievements while looking ahead at emerging issues in the evolving field of health regulation. This year's Conference carries the theme: "Regulating the Future of Health: Converging Products & 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 2: Regulating Precision Medicine

Precision Medicine holds immense promise for personalizing healthcare and enhancing patient outcomes. From wearable devices to genomics, these technologies are reshaping healthcare delivery and regulatory frameworks must evolve in parallel with these advancements.

This session will explore how regulations can keep pace with advancements in genomics, personalized therapies and data-driven healthcare, ensuring safety, efficacy and equitable access to these innovative treatments and facilitate answering the question **"Precision Medicine – what is the regulatory paradigm?"**



Snapshot of Session 2

Healthcare has long been structured around one-size-fits-all approaches where treatments and interventions are largely standardized across populations. However, Precision Medicine (PM) aims to disrupt this traditional model by offering highly personalized care based on an individual's genetic, physiological, and lifestyle data. This transformation, however, brings with it challenges in implementation, ethics, and regulations that were explored in this conference's second thematic session on Regulating Precision Medicine (PM).

Chaired by **Prof John Chambers**, the discussion revolved around four key areas:

- The evolution of Precision Medicine by 2030
- Ethical and societal concerns surrounding genomic data
- The integration of PM into clinical practice
- Regulatory challenges in genetic testing and patient consent

At the heart of the discussion was a key takeaway: PM is no longer just a vision for the future—it is already reshaping modern medicine. The challenge now is how to implement it responsibly, ensuring that innovation does not outpace ethical and regulatory safeguards.

Precision medicine in 2030: a new era of personalized healthcare

A/Prof Tan Ee Shien on topic "How will Precision Medicine look like in 2030?"

A/Prof Tan Ee Shien painted a compelling vision of what Precision Medicine might look like by 2030, highlighting its transformative impact on medical practice and healthcare delivery.

One of the most significant advancements enabling the rise of PM has been the Human Genome Project, which dramatically reduced the cost and time required for genome sequencing. Singapore's National Precision Medicine Program is already taking steps to sequence a significant portion of the population, allowing researchers to better understand disease risks and improve treatment strategies. The ability to map genetic predispositions means that medical interventions can be preemptive rather than reactive, marking a fundamental shift in disease prevention and management.

Yet, Precision Medicine extends beyond genetics. With the increasing integration of wearable technology and electronic health records (EHRs), healthcare professionals now have access to continuous streams of real-time patient data. This data, when combined with AI-driven predictive analytics, could revolutionize how diseases are diagnosed, monitored, and treated. For instance, AI is already being used to automate screening processes for retinal diseases and optimize medication dosing based on individual metabolic responses.

A particularly promising application of PM lies in newborn screening initiatives, currently being explored in countries such as the UK, Australia, and the US. Early genomic screening at birth

could allow for the identification of potential health risks long before symptoms manifest, enabling preventive care tailored to an individual's genetic predispositions.

Ethical considerations: can precision medicine earn public trust?

The promise of Precision Medicine relies heavily on the availability of patient data, but data is deeply personal. **Dr Tamra Lysaght** delved into the ethical considerations of genomic research and precision medicine, emphasizing that public trust is a prerequisite for progress. Trust in PM is not a given - it must be earned and maintained. Patients are often wary of sharing their genetic information, fearing misuse, data breaches, and corporate exploitation. The reality is that genomic data, once collected, has long-term implications for both individuals and their families, raising concerns about privacy, informed consent, and ownership of genetic information.

Dr Tamra Lysaght delved on Ethical Considerations in Precision Medicine Regulation

A particularly insightful discussion revolved around social license initiatives in Singapore, where public engagement efforts have been underway since 2019. Through surveys and workshops, researchers sought to understand public sentiment on data sharing. Findings revealed that while a majority - 64% of respondents - were open to sharing their data, this willingness was conditional on transparency and accountability. The study underscored that if PM is to succeed, researchers and policymakers must ensure that participation remains voluntary and that patients have full control over their data.

Another key ethical dilemma involves corporate involvement in genomic research. While pharmaceutical companies play a critical role in advancing PM, concerns persist about profiteering and monopolization of genetic data. There is a fine line between incentivizing innovation and preventing commercial exploitation of patient information, making regulatory oversight absolutely essential.

Bringing precision medicine into clinical practice: opportunities and barriers

Moving beyond research, **A/Prof Denise Goh** explored how Precision Medicine is being integrated into real-world healthcare settings, shedding light on both exciting breakthroughs and the challenges that lie ahead.

Traditionally, genetic testing and personalized treatment plans were confined to specialized hospitals and research centers. However, PM is gradually expanding beyond hospitals to include primary care settings, pharmacies, and even community health programs. This expansion means that genetic counselors, nurses, and pharmacists will play an increasingly vital role in guiding patients through genomic testing and personalized treatment plans.

Despite these advancements, challenges in implementation remain significant. PM is technologically intensive, requiring state-of-the-art sequencing tools, AI integration, and secure data storage infrastructure - all of which demand substantial financial and human resources. Compounding these challenges is the underrepresentation of Asian populations in global genomic studies, raising concerns about the applicability of existing genetic models to Asian communities.

Another major hurdle is cost. Genetic testing is expensive, and many patients are forced to pay out-of-pocket due to limited insurance coverage. Insurance companies are hesitant to cover genomic testing and precision therapies, citing concerns about long-term financial sustainability and the potential for genetic data to impact insurance premiums. There is also resistance among healthcare professionals, many of whom struggle to keep pace with rapidly evolving genomic knowledge. Without ongoing education and training, PM risks remaining a niche field rather than becoming standard practice.

Regulating genetic testing: a work in progress

Ms Jahara Ibrahim from the Ministry of Health (MOH) provided an overview of Singapore's evolving regulatory framework for PM, focusing on the regulation of genetic testing services under the Healthcare Services Act (HCSA).

Rather than adopting rigid, one-size-fits-all regulations, Singapore has opted for a flexible, tiered risk-based system. Genetic tests are classified into three levels, with high-risk Level 3 tests requiring additional regulatory approval before implementation.

While the regulatory framework provides a structured approach to managing genomic services, key concerns remain, such as:

- Who is responsible for medical errors in AI-driven genetic predictions?
- How do we prevent misuse of genetic data in insurance underwriting and employment screening?
- How do we ensure global data-sharing frameworks align across different legal systems?

These are pressing questions that will require ongoing policy refinement and stakeholder collaboration.

Panel discussion featuring (from left to right): Ms Jahara Ibrahim, A/Prof Denise Goh, A/Prof Tan Ee Shien, Dr Tamra Lysaght, Ms Indri Rooslamiati and Session Chair, Prof John Chambers on Precision Medicine – what is the regulatory paradigm?

Panel Discussion - Precision Medicine – what is the regulatory paradigm?

The panel was moderated by the Session Chair **Prof Chambers** with the speakers being panellists. There was one additional panellist; **Ms Indri Rooslamiati** from Ministry of Health, Indonesia. The panel addressed the key question, *Precision Medicine – what is the regulatory paradigm how will it look like in 2030?*

As the precision medicine regulatory paradigm moves towards 2030, it was opined that precision medicine still is in an exploratory stage and is not in the healthcare system, atleast in Singapore, at the moment. Even clinical genomic based diagnostic tests for common diseases don't fall under the standard of care at present. Implementation of Precision Medicine, looking into regulations, pricing and healthcare financing should be carried out as a use case progressing towards 2030.

The session concluded with a clear message: Precision Medicine is not a distant dream - it is already here in some form. However, its success depends on more than just scientific breakthroughs. Moving forward, policymakers, researchers, and clinicians must work together to ensure that it is accessible, ethical, and rigorously regulated. As we move towards 2030, the challenge will not be whether Precision Medicine can work but rather, how to make it work for everyone.