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 4: Partnerships for Effective Regulation

Stakeholder partnerships and consumer education are vital for effective regulation. Involving diverse stakeholders such as industry representatives, advocacy groups, and experts in the regulatory process ensures well-informed and balanced regulations, while educating consumers promotes compliance and trust in the regulatory system.

This session will highlight **"How partnerships can create a more cohesive regulatory framework, address challenges and shape an innovative and responsive regulatory ecosystem."**

Snapshot of Session 4

As healthcare evolves with rapid advancements in technology and increasing complexity, the role of regulation becomes ever more critical. The path to effective regulation lies not in isolated efforts but in building robust partnerships among diverse stakeholders—regulators, industry leaders, healthcare providers, researchers, and, most importantly, patients. Collaboration, underpinned by shared goals and mutual trust, is the key to shaping a regulatory ecosystem that is safe, efficient, and innovative. This thematic session, co-chaired by A/Prof Raymond Chua and Dr Andy Greenfield, explored the power of partnerships in shaping effective regulatory frameworks. The discussions emphasized that regulation should not be a burden but an enabler of innovation, patient safety, and public trust. Stakeholders must work together to balance regulatory oversight with efficiency, ensuring that policies are transparent, adaptable, and aligned with real-world needs.

Key insights from the session revolved around the following perspectives:

- The regulator's role in fostering partnerships beyond enforcement
- Public engagement as a cornerstone of regulatory trust
- Industry partnerships with regulators for efficiency and compliance
- The role of industry associations in regulatory harmonization
- Patient organizations as key stakeholders in healthcare regulation
- International collaboration for regulatory effectiveness

As regulations evolve to accommodate precision medicine, AI in healthcare, and longevity-focused interventions, collaborative governance models will be essential to keep pace with innovation without compromising public safety.

Regulation as a partnership: moving beyond enforcement

Session Chair, A/Prof Raymond Chua opened the session on Effective collaboration and partnerships amongst stakeholders in the regulatory ecosystem from a Regulator perspective

A/Prof Raymond Chua opened the session by redefining the role of regulators in the modern healthcare ecosystem. Rather than functioning as enforcers, regulators should position themselves as facilitators—guiding industry and healthcare providers toward compliance through strategic partnerships, knowledge sharing, and transparency. He stressed that regulation should not be seen as a set of static legal contracts, but rather as an adaptive alliance among stakeholders, where both regulators and the regulated entities share a common goal—ensuring safety, efficacy, and quality in healthcare products and services.

A key takeaway from his presentation was the importance of effective communication in regulatory partnerships. Too often, regulations are buried in legal jargon, making compliance confusing and burdensome. He proposed that regulators should embrace simplified language, infographics, and digital tools to enhance engagement and understanding.

Beyond national frameworks, international collaboration is vital. The APAC regulatory network and partnerships with institutions like CoRE, provide a platform for horizon scanning, cross-border regulatory harmonization, and knowledge sharing. In the future, regulators must expand their engagement efforts to include a wider range of stakeholders, from startups and patient advocacy groups to digital health companies and AI developers, ensuring that compliance frameworks remain relevant, flexible, and innovation-friendly.

Public engagement: regulation with the people, not just for the people

Dr Andy Greenfield took the discussion further by emphasizing that effective regulation cannot exist in a vacuum—it must align with societal values, ethical concerns, and public trust.

Session Chair, Dr Andy Greenfield discussed further on the topic from a public engagement perspective

He argued that regulating technology is not just about the technology itself, but about its use cases and impact on society. Public engagement is critical in addressing societal concerns about AI, neurotechnology, human germline editing, and emerging biomedical advancements. Without early engagement with communities, regulators risk facing public backlash, ethical dilemmas, and a lack of trust in healthcare policies.

Dr Greenfield advocated for a mixed-methods approach to public engagement, incorporating workshops, surveys, focus groups, and ongoing consultations to gather diverse viewpoints. He shared case studies where public hesitation toward controversial medical innovations was mitigated through early, transparent, and science-driven engagement efforts. Regulatory frameworks must be built not just on scientific and technical expertise, but also on public consensus and ethical considerations. When the public is part of the regulatory process, compliance becomes voluntary rather than enforced, and trust in medical advancements increases.

Industry partnerships: efficiency, compliance, and trust-building

The pharmaceutical and MedTech industries are not just entities to be regulated—they are active partners in healthcare innovation. Representatives from the Singapore Association of Pharmaceutical Industries (SAPI) and APACMed emphasized that strong industry-regulator relationships lead to better compliance, improved product quality, and faster regulatory approvals.

Ms Celine Ting highlighted how SAPI's engagement with Singapore's Health Sciences Authority (HSA) has evolved from a rigid compliance-driven approach to a trust-based collaboration. Regular dialogues, capacity-building workshops, and shared objectives have led to higher-quality dossier submissions and reduced approval timelines.

Similarly, **Dr Cindy Pelou** from APACMed showcased the role of trade associations in harmonizing regulations across Asia-Pacific markets. With medical device regulations varying

significantly between Singapore, Thailand, Malaysia, and Indonesia, APACMed has been instrumental in promoting regulatory harmonization and reliance mechanisms. Both industry leaders emphasized that effective regulation is not about reducing oversight but about making compliance more structured, predictable, and innovation-friendly.

Patients as partners: regulation must reflect real-world healthcare needs

Ms Nidhi Swarup on patient group perspective

A perspective that is often overlooked in regulatory discussions is that of patients—the very people for whom these regulations are designed. **Ms Nidhi Swarup**, a patient advocate and founder of the Crohn's & Colitis Society of Singapore, emphasized that patients should not just be passive recipients of healthcare but active contributors to regulatory policies.

She shared her personal journey navigating the healthcare system, highlighting significant gaps in patient education, mental wellness initiatives, and access to preventive care. Many patients struggle to understand the healthcare system, leading to misinformed decisions, anxiety about treatment options, and challenges in accessing the right care at the right time.

Her argument was that regulators, industry leaders, and healthcare providers must actively engage with patient groups to ensure that regulations reflect real-world healthcare needs. This includes:

- Simplifying regulatory guidelines for patients and caregivers
- Promoting shared decision-making in treatment choices
- Expanding patient advocacy groups' role in clinical trials and drug approvals

Her insights reinforced that patients are not just end-users of medical products—they are key stakeholders who should have a voice in shaping healthcare policies.

International collaboration: a globalized approach to regulation

Dr Florentin Blanc concluded the session by taking a global perspective on regulatory innovation. He argued that modern regulation should move away from rigid, rule-heavy oversight to outcome-driven, risk-based approaches.

In many countries, regulatory agencies focus too much on enforcement and not enough on facilitation. However, successful regulatory models worldwide have demonstrated that when compliance is framed as a partnership rather than an obligation, outcomes improve.

His presentation emphasized that global collaboration is essential, particularly in areas like pandemic preparedness, AI regulation, and pharmaceutical innovation. The regulatory landscape is no longer confined within national borders, and international partnerships will determine how effectively regulations can adapt to global healthcare challenges.

Panel discussion featuring (from left to right): A/Prof Raymond Chua, Ms Celine Ting, Dr Cindy Pelou, Ms Nidhi Swarup, Dr Florentin Blanc and Dr Andy Greenfield on topic "How do we envision the regulatory ecosystem and partnerships by 2030?"

Panel Discussion - How do we envision the regulatory ecosystem and partnerships by 2030?

The panel was moderated by the Session Chairs **A/Prof Chua & Dr Greenfield** with the speakers being the panellists. A very critical aspect as to *how partnerships can create a more cohesive regulatory framework, address challenges and shape an innovative and responsive regulatory ecosystem* was discussed during this panel discussion.

Key Takeaways from the panel discussion were:

- Regulators must evolve into facilitators, engaging with industries, healthcare providers patients, and international networks to enhance compliance and trust.
- Public engagement must be embedded into regulatory processes to ensure that medical advancements align with societal values and ethical considerations.
- Strong partnerships between industry and regulators lead to better compliance, faster approvals, and improved patient outcomes.

- Patient voices must be amplified in regulatory discussions to create more inclusive and effective healthcare policies.
- International collaboration is essential in creating harmonized, efficient regulatory frameworks that adapt to the fast-changing landscape of medical innovation.
- Capacity building should be provided to upskill and create future-ready stakeholders across the entire healthcare ecosystem.

The panellists concluded that the challenge ahead is clear: Regulation should not be seen as a barrier—it should be a bridge that connects industry, regulators, patients, and global stakeholders in shaping a healthcare system that is safer, more efficient, and more inclusive.