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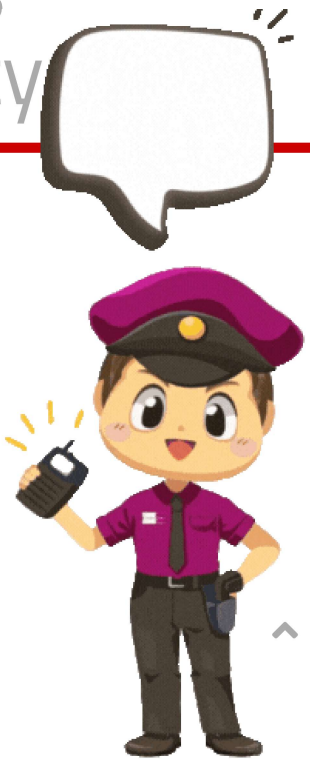
Futurise Lead RegTalk 2025: AI Medical Devices in Malaysia - Balancing Innovation and Safety



PRESS RELEASE

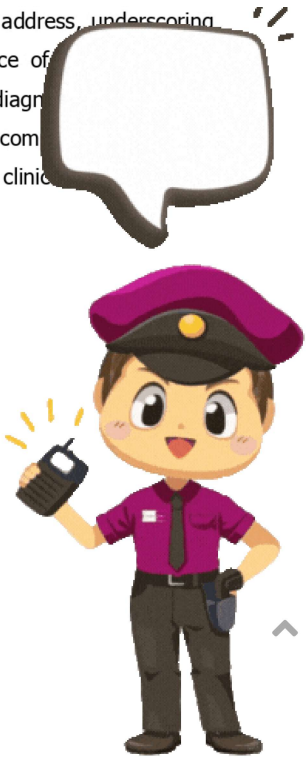
FOR IMMEDIATE RELEASE

Futurise Lead RegTalk 2025: AI Medical Devices in Malaysia - Balancing Innovation and Safety

Kuala Lumpur, Malaysia – 28 August 2025 – Futurise Sdn Bhd (Futurise), in collaboration with the Medical Device Authority (MDA), hosted the latest edition of RegTalk at the Siemens Healthineers Experience Center, focusing on "AI Medical Devices in Malaysia – Balancing Innovation & Safety."

The session brought together regulators, industry leaders, and policy experts to explore the opportunities and challenges of artificial intelligence in healthcare. The discussion highlighted the critical balance between fostering innovation and ensuring patient safety, clinical validation and ethical data use.

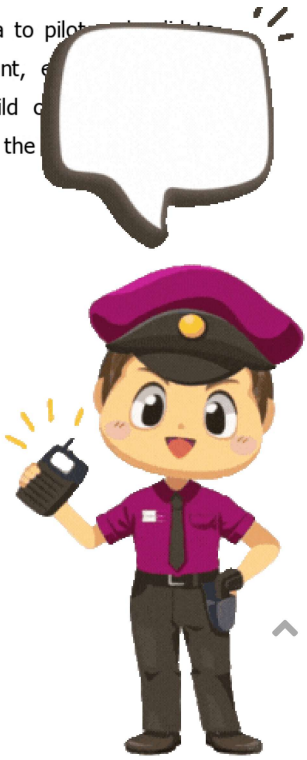
Shafinaz Salim, Acting CEO of Futurise, delivered the welcome address, underscoring Malaysia's pivotal moment in digital health. "The convergence of technology presents extraordinary opportunities from predictive diagn patient monitoring. Yet, these advancements also introduce new com be navigated carefully especially when it comes to public safety, clinic ethical data use," said Shafinaz.



She also announced plans to collaborate with MDA in establishing Malaysia's first regulatory sandbox for medical devices. "This proposed regulatory sandbox is more than a testing mechanism. It is a strategic platform to accelerate responsible innovation, by allowing innovators to safely trial AI-driven medical technologies within a controlled environment under the oversight of MDA. Our aim is clear and that is to support industry growth while safeguarding public health, in full alignment with MDA's mandate," she added.

Shafinaz further emphasised the importance of enabling innovation through progressive regulatory frameworks. "To achieve this vision, we must address a crucial challenge: regulation. Innovation thrives in environments that allow experimentation, and this is where regulatory sandboxes can play a transformative role. The sandbox framework allows industries to experiment with new ideas without the immediate constraints of existing regulations, enabling rapid prototyping and faster scaling. As Futurise is mandated by the Government to drive the National Regulatory Sandbox, we believe the regulatory sandbox is the perfect enabler and plays a crucial role in this."

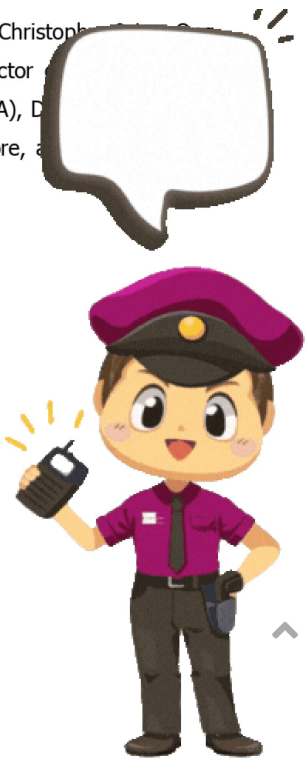
A regulatory sandbox for medical devices would allow Malaysia to pilot
AI-driven medical technologies in a risk-managed environment,
bodies to observe and respond to real-time challenges, build
innovators, clinicians, and the public, and ultimately fast-track the
patient-centric innovations into the healthcare ecosystem.



The keynote was delivered by Aidahwaty M. Olaybal, Senior Director of the Pre-Market Control Division, Medical Device Authority (MDA), who emphasised the importance of regulatory frameworks in ensuring innovation is aligned with patient safety and trust. She highlighted that as AI-driven technologies continue to evolve, regulatory oversight must remain adaptive and forward-looking to address emerging risks. Aidahwaty also stressed that collaboration between regulators, industry, and healthcare professionals is essential to build a resilient ecosystem that balances innovation with public confidence.

"Striking the right balance between innovation and safety requires centring collaboration, bringing together developers, clinicians, ethicists, and regulators in a shared space of co-creation. It also demands rigorous real-world validation, beyond lab environments, to ensure AI devices perform reliably in diverse clinical settings. Regulatory sandboxes offer the ideal environment to test and iterate safely. And importantly, education must remain continuous for developers, users, and decision-makers alike, so that we evolve alongside our technology," said Aidahwaty.

The panel discussion was moderated by Deepak Pillai, Partner at Christoph
Malaysia, and featured Idamazura Idris @ Harun, Senior Director
Strategic Planning Division at the Medical Device Authority (MDA), D
Head of Research Collaboration at Siemens Healthcare Singapore,
Associate at Asia Group Advisors.



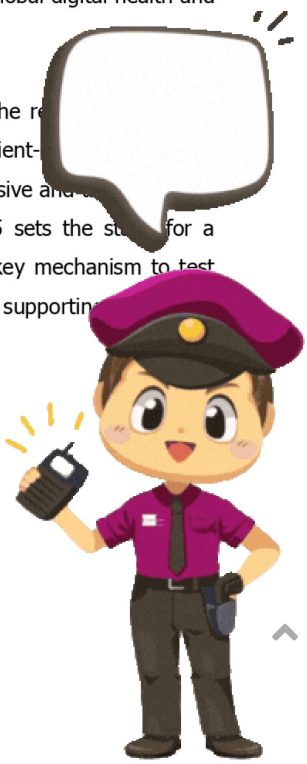
The panel explored key issues such as regulatory harmonisation, international best practices, ethical considerations in AI deployment, and strategies to accelerate the adoption of AI-powered medical devices responsibly.

The event reaffirmed the importance of public-private collaboration to ensure Malaysia strengthens its position as a leader in digital health innovation, while maintaining the highest standards of safety and trust.

Looking ahead, Futurise highlighted that building an enabling ecosystem will require active participation from stakeholders across the healthcare value chain including regulators, clinicians, innovators, investors, and patients. By fostering open dialogue, knowledge-sharing, and capacity-building, Malaysia can establish a strong foundation for AI-driven medical technologies to thrive.

Futurise remains committed to advancing a safe and progressive digital health ecosystem. By working hand-in-hand with government and industry partners, the organisation aims to shape a regulatory landscape that not only empowers businesses and drives innovation, but also positions Malaysia as a leader in global digital health and industrial growth.

As Futurise and MDA move forward with the development of the r framework, the priority will be to align innovation with patient- ensuring that Malaysia's healthcare system remains both progressive and the age of artificial intelligence. This outcome of RegTalk 2025 sets the st for a broader roadmap where regulatory sandboxes will serve as a key mechanism to test and refine breakthrough innovations in a structured environment, supportin



ambitions in digital health while contributing to ASEAN's collective effort in shaping safe and sustainable healthcare solutions powered by technology.

For more information, please visit www.futurise.com.my.

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About Futurise
Futurise is a wholly-owned subsidiary of Cyberview Sdn Bhd under the Ministry of Finance. It is mandated by the Government of Malaysia to manage the National Regulatory Sandbox, providing public policy advisory and acting as a key enabler of regulatory solutions to expedite innovation and future-proof Malaysia's economy.

About Medical Device Authority (MDA)
MDA is the government agency entrusted to serve the Malaysia medical device industry. It is a federal statutory agency under the Ministry of Health Malaysia to implement and enforce the Medical Device Act 2012 (Act 737). The main objectives of the Act are to address public health and safety issues related to medical devices and to facilitate medical device trade and industry.

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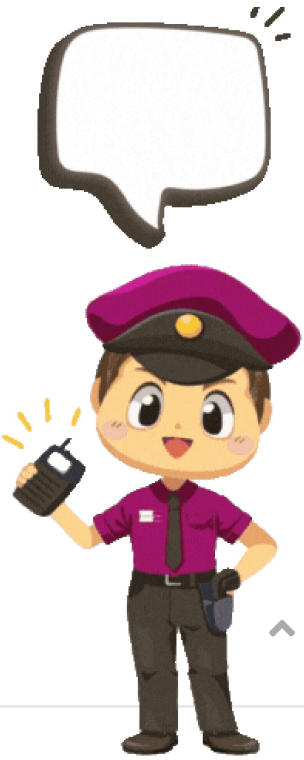

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