APACMed
The voice of MedTech

AI REVOLUTIONISING MEDTECH SYMPOSIUM AUSTRALIA

SUMMARY REPORT | NOV 2025

ARTIFICIAL INTELLIGENCE

JOINTLY ORGANISED BY MTAA Medical Technology Association of Australia

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EXECUTIVE SUMMARY

APACMed and the Medical Technology Association of Australia (MTAA), supported by L.E.K. Consulting, collaborated to organize the AI Revolutionising MedTech Symposium on 19 November 2025 in Sydney, Australia. The symposium highlighted a clear and urgent message: Australia is on the cusp of a transformative shift in healthcare, driven by the convergence of AI, modern data infrastructure, and evolving regulatory and policy frameworks. Across government, providers, industry and patient groups, consensus emerged that realising the potential of AI, which is no longer just a vision but reality, requires coordinated system change built on trust, interoperability and capability uplift.

Sessions throughout the day, which consisted of 5 speaker presentations and 3 panel discussions, highlighted several unifying themes.

First, governance maturity - including adaptive regulation, transparent data stewardship, and fit-for-purpose cybersecurity - was repeatedly identified as the essential foundation for safe and scalable AI deployment for the MedTech and healthcare industry. Second, the discussions reinforced that Australia's greatest opportunity lies not in developing more algorithms but in unlocking the latent value of health data through harmonised standards, dynamic consent models, and cross-sector collaboration. Third, participants emphasised the critical importance of workforce readiness and workflow redesign, noting that successful AI adoption depends on empowering clinicians and operational teams with the skills, tools and confidence to integrate AI into care pathways.

Across the panels and presentations, there was strong alignment that the future of healthcare will be predictive, personalised and preventative, underpinned by federated data architectures, real-world evidence ecosystems, and AI systems embedded seamlessly into clinical decision-making and patient engagement. Yet achieving this vision will require sustained investment in shared infrastructure, regulatory coherence across jurisdictions, and a national approach to capability development.

The day closed with a collective call to action: industry, government and the clinical community must move together - deliberately and with pace—to build the digital and governance foundations that will enable AI to deliver safer, more equitable and more efficient healthcare for all Australians.

SESSION 1

AI IN PRACTICE FOR MEDTECH

Manoj Sridhar, Partner, L.E.K. Consulting

Overview

Manoj covered how AI, particularly generative AI, is already reshaping MedTech, separating near-term, value-creating use cases from hype and outlining the conditions that are typically required for successful adoption of AI solutions.

Key insights

- **AI capability inflection point is real, not theoretical**
  GenAI performance has improved dramatically in just two years (e.g., ~200% increase in model "IQ", ~97% reduction in hallucination rates, >6,000% increase in context handling, and ~96% cost reduction), enabling clinically meaningful applications rather than experimental pilots.

- **Value is concentrated in specific MedTech domains today**
  Radiology, cardiovascular, and neurology account for ~90% of FDA-approved AI-enabled devices, reflecting where data density, workflow integration, and regulatory clarity are strongest.

- **Adoption hinges on trust and lifecycle governance**
  Successful AI MedTech solutions consistently demonstrate (i) rigorous clinical and economic evidence across the total product lifecycle, (ii) deep workflow integration for clinicians, and (iii) strong governance covering safety, transparency, and regulatory alignment.

SESSION 2

OVERVIEW OF DOHDA INITIATIVES TO SUPPORT AI IN MEDTECH

Penny Shakespeare, Deputy Secretary, Department of Health, Disability and Ageing

Overview

Penny provided an outline of how the Australian Government is approaching AI in MedTech as a system-wide reform lever - seeking to enable innovation while safeguarding patient safety, equity, and long-term sustainability of the health system.

Key insights

- **AI must solve system problems, not add burden**
  Adoption will be constrained unless AI demonstrably reduces workforce pressure and integrates cleanly into clinical workflows. Solutions that increase complexity or cognitive load are unlikely to scale in an already overstretched system.

- **Evidence, value and equity drive government support**
  Beyond technical performance, AI solutions must show system-level value - improved outcomes, productivity, or sustainability - and equitable distribution of benefits across populations and providers.

- **Progress depends on co-design with industry and regulators**
  Government does not seek to be an AI expert or developer; effective AI adoption will rely on early, structured collaboration with industry to align on evidence expectations, policy settings, and national digital health priorities.

SESSION 3

OVERVIEW OF TGA INITIATIVES TO SUPPORT AI IN MEDTECH

John Jamieson, Assistant Secretary, Medical Devices Authorisation Branch, Australian Government, Department of Health, Disability and Ageing, Therapeutic Goods Administration

Overview

John provided an update on Australia's regulatory approach to AI and Software as a Medical Device (SaMD), outlining review outcomes, priority reforms, and how the TGA intends to balance innovation with patient safety.

Key insights

- **Australia's SaMD framework is largely fit-for-purpose, with targeted refinements**
  Rather than wholesale reform, the TGA is pursuing incremental changes - clarifying definitions, responsibilities, and exclusions - to better capture AI-specific risks while remaining technology-agnostic.

- **Five strategic regulatory priorities guide AI oversight**
  These include supporting stakeholders with clearer guidance, reinforcing accountability, improving transparency of AI use (e.g., clearer ARTG information), strengthening compliance, and refining regulation as AI capabilities evolve.

- **Early and proactive engagement is critical for sponsors**
  The TGA strongly encourages pre-submission engagement for AI-enabled products to clarify classification, evidence expectations, and lifecycle change management (including international alignment via IMDRF and Predetermined Change Control Plans).

ENABLING AI THROUGH POLICY & REGULATIONS

PANEL 1

Panellists

Mahesh Datar | Senior Manager Regulatory Affairs, Medtronic (Moderator)
Joern Lubadel | Global Head of Product Security, B. Braun
Ashley Mancuso | Vice President, MedTech BISO & Product Security, Johnson & Johnson MedTech
Dalvin Chien | Partner, Mills Oakley
John Jamieson | Assistant Secretary, Medical Devices Authorisation Branch, Australian Government, Department of Health, Disability and Ageing, Therapeutic Goods Administration

Overview

This panel covered the importance of fit-for-purpose policy and regulatory frameworks to enable the adoption of AI and discussed international perspectives to inform what Australia can do to balance innovation with patient safety.

Key insights

- **AI Is Not a Product; It Is Part of a Product**
  Speakers highlighted the need to view AI as an embedded capability requiring lifecycle stewardship, not a standalone module. Consequently, regulations need to be risk-based when regulating AI to ensure innovation gets to the patient.

- **Cybersecurity = Patient Safety**
  Consensus that cybersecurity risks translate directly into clinical risks. Companies have to build digital trust by building cybersecurity into products ("secure by design") and manage them across the entire product lifecycle, not just during development.

- **International Alignment**
  Acceptance of international standards through reliance frameworks and mutual recognition can accelerate safe adoption.

Calls to Action

Standards and harmonisation are essential for ensuring patient safety, which is ultimately a critical element in healthcare. Industry and regulators need to think intergenerationally about AI because AI's long-term impact is intergenerational; decisions today will shape healthcare for decades. Strengthen regulatory–industry co-design to clarify evidence expectations for adaptive and continuously learning AI.

SESSION 4

VOLUNATRY CODE OF CONDUCT FOR AI

Chelsea Gordon, Legal Lead – AI Advisory, MinterEllison

Overview

Chelsea provided an overview of the MTAA–MSIA Voluntary AI Code of Conduct, designed to fill a governance gap for AI-enabled health software that is not regulated as a medical device.

Key insights

- **A governance gap exists outside TGA-regulated devices**
  Many AI-enabled health software solutions fall outside SaMD regulation, creating legal, operational, and trust risks that the voluntary code is designed to address.

- **Focus is on organisational governance, not product certification**
  The code emphasises accountability, risk management, data governance, human oversight, transparency, and record-keeping - aligned with Australia's AI Safety Standard (AISix).

- **Industry self-regulation as a strategic signal**
  Signatory and accreditation pathways allow organisations to demonstrate responsible AI practices proactively, building trust with consumers, partners, and regulators while formal AI legislation continues to evolve.

SESSION 5

BEYOND THE PILOT – INTERNATIONAL LEARNINGS ON SCALING AI INNOVATION

Stephanie Owen, Health Industry Consulting & Services Lead, Microsoft ANZ

Overview

Stephanie highlighted global lessons from Microsoft's healthcare engagements on why AI initiatives stall at pilot stage - and how organisations can systematically scale AI into production and sustained value.

Key insights

- **"Pilot purgatory" is a structural problem, not a technology problem**
  The main barriers to scale are weak data foundations, fragmented governance, legacy infrastructure, unclear ownership, and lack of AI-ready operating models - not model performance.

- **Scaling AI requires a multi-dimensional operating model**
  Successful organisations align AI initiatives across five dimensions - business strategy, data & technology foundations, AI experience design, organisational culture, and continuous AI governance (including monitoring for drift and incidents).

- **Sequence matters for value creation**
  International experience shows the highest success when organisations start with internal productivity and workflow use cases, then progress to patient-facing applications and advanced clinical innovation as capability maturity increases.

UNLOCKING AI THROUGH DATA & COLLABORATION PANEL 2

Panellists

Stephanie Owen | Health Industry Consulting & Services Lead, Microsoft ANZ (Moderator)
Tam C. Nguyen | Director of Research & Innovation, Monash Health
Timothy Panoho | Branch Manager – Architecture, Australian Digital Health Agency
Dr Julian Adler | CEO Radiology, Sonic Healthcare
Chelsea Gordon | Legal Lead – AI Advisory, MinterEllison

Overview

This panel covered cross-sector and cross-border data sharing, consent, privacy and collaboration as enablers for scaling trustworthy AI use in healthcare.

Key insights

- **Data - not algorithms - is the critical bottleneck in scaling AI across Australia**
  With fragmentation, inconsistent privacy rules and poor interoperability limiting value realisation.

- **Digital maturity remains uneven**
  Without investment in data infrastructure, shared standards and modern cloud environments, AI cannot scale safely beyond pilots.

- **Trust hinges on modernising consent models**
  Dynamic, granular and consumer-mediated approaches are required to enable meaningful data use.

- **Federated data-sharing models are emerging as the most viable architecture**
  Enabling cross-organisation insight generation while maintaining security and sovereignty.

Calls to Action

Mandate interoperability standards (FHIR and open APIs) to accelerate safe data liquidity across the health ecosystem. Develop a national consent framework that supports dynamic, patient-controlled data sharing. Establish cross-sector data collaboratives and secure federated data platforms to accelerate research, AI model development and system-wide efficiency.

BUILDING INDUSTRY READINESS FOR AI

PANEL 3

Panellists

Minta Chen | Head of Regulatory Affairs & Quality Assurance, Harrison.ai (Moderator)
Madeline O'Donoghue | Chief Corporate Affairs Officer, Pathology Technology Australia
Bettina McMahon | CEO, Healthdirect
Suneeta Mall | Head of AI Engineering, Harrison.ai
Miang Tanakasemsub | Regional Regulatory Affairs Head, APJ, Johnson & Johnson
Penny Shakespeare | Deputy Secretary, Department of Health, Disability and Ageing

Overview

This panel covered the barriers to adoption of AI in healthcare including workforce skills gaps, policy and system-level barriers, and the need for proper change management.

Key insights

- **AI readiness is fundamentally a people and workflow challenge**
  Requiring capability uplift in digital literacy, critical reasoning and AI supervision.

- **Workflow redesign is the critical determinant of successful AI deployment**
  AI layered on top of existing processes increases risk and reduces adoption.

- **Clinicians and the healthcare workforce more broadly require support and training**
  To shift from deterministic to probabilistic reasoning, along with tools that embed explainability and usability.

- **Infrastructure gaps**
  Including cybersecurity, interoperability and data platforms—remain material barriers to scaling AI safely and sustainably.

Calls to Action / Future Outlook

Industry needs to move away from point solutions to more broad-based applications and work out how to bring this into the healthcare system. Empower patients with AI-enabled tools that help them self-manage, reducing pressure on the health system. Focus on proactive, outcomes-focused healthcare rather than the reactive, episodic system we have today.

CLOSING REFLECTIONS

Overall, it was an excellent day of practical, actionable insight. Attendees gained clarity on regulatory pathways, real-world AI use cases, and the collaborative frameworks required for safe adoption. Collective ownership and cross-sector collaboration is essential to capturing the full potential of AI where AI becomes a trusted, enabler of better health outcomes for all Australians and it was reassuring to see great participation from both industry and Government throughout the day.

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About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. For more information, visit **www.apacmed.org**