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ANNUAL REPORT





2023-24 MTAA ANNUAL REPORT CONTENT

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OMMUNICATIONS

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INDUSTRY FACTS AND FIGURES

Advancements in medical technology have supported the health of Australians by contributing to:

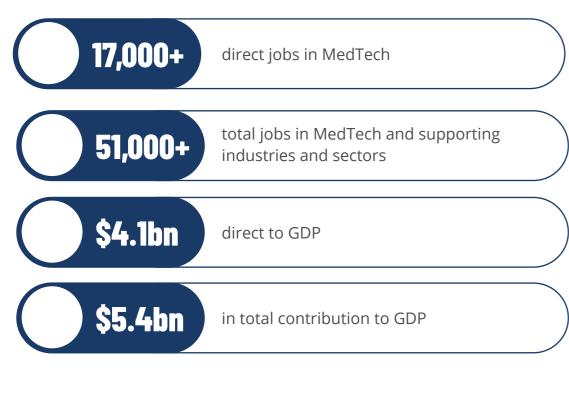
185,000,000+

pathology and diagnostic services per year - over **500,000** on average per day

128,083

surgeries on Australians to replace their hips, knees and other joints

Key highlights of MedTech's economic contribution include:



KEY ACHIEVEMENTS AND FIGURES





total members with 33 Associate Members

total representatives on 87 Industry Members and committees, forums, working groups and alliances







3,688

complete MTAA training

1.228

attendees to

MTAA events



participants



participants complete the OTP training



subscribers to MTAA communications











consultation and position papers



participants complete the Code of Practice (E13) training



increase in new followers bringing the total to 13,774



OUR MISSION, VISION AND VALUES

Our work is to champion medical technology for a healthier Australia. When our work is done, medical technology will be valued as a key driver of a healthier Australia. We work with integrity, collaboration, influence and leadership

The Medical Technology Association of Australia (MTAA) represents the manufacturers and suppliers of medical technology (MedTech) used across Australia to diagnose, prevent, treat, and manage disease and disability. MTAA members provide the majority of non-pharmaceutical products used in healthcare settings to address these needs.

MedTech covers a broad range of products, from everyday essentials like syringes, wound dressings, and wheelchairs to advanced technologies such as pacemakers, MRI machines, hip replacements, robotic surgery tools, and remote monitoring devices.

Our members play a vital role in equipping healthcare professionals with the skills and training required to make the most of complex medical technologies, helping to improve health outcomes for patients. They contribute to research and development by funding industry-sponsored fellowships and projects in hospitals, universities, and research centres, driving the innovation and commercialisation of medical technology that meets the healthcare needs of Australians and enhances quality of life.

MTAA's associate members include partner organisations and individuals supporting the MedTech sector across the whole value chain, from concept to patient use. This group includes legal and logistics experts, consultants, compliance agencies, health economists, researchers, universities, industrial designers, and product commercialisation specialists. Their valuable expertise enables MTAA to deliver on its goal of bringing technology to patients, improving health outcomes and quality of life across the nation.

SENIOR LEADERSHIP TEAM

Ian Burgess Chief Executive Officer

Paul Dale Director, Policy

Matthew Versi Director, External Affairs & Communications

Jasjit Baveja

POLICY

Toby Hodgson Digital Health Senior Manager **Omar Khan Policy Manager**

David Ross Policy Advisor

Pravin Siriwardena Policy Manager

ADVOCACY

Charlotte Carulli External Affairs & Content Manager

Justin Foster

OPERATIONS

Lee Harvey Jackie Lee Professional Development Manager Events & Engagement Manager

Ranju Dhungel Senior Finance Officer Seni Murni Administration Officer

EXECUTIVE ASSITANT

HUMAN RESOURCES

Kerrie Zocchi Executive Assistant to CEO

Rebecca Churchill HR Advisor



Karen De Leeuw Director, Finance & Administration

Associate Director, Regulatory

INDUSTRY DEVELOPMENT

Stuart Anderson CTC-M Program Manager

Teneille Murray MedTech Startup/SME Consultant

Louie Radburnd Advocacy & Communications Manager Marketing & Membership Manager

Carmel Rees Events Manager

Damla Guzel **Events Administrator**

MESSAGE CHAIR REPORT



SUSAN MARTIN

CHAIR MANAGING DIRECTOR, AUSTRALIA & NEW ZEALAND JOHNSON & JOHNSON MEDTECH

It has been another year of challenges and great opportunities in 2024 for the Australian MedTech Industry. We have seen our industry, like all businesses, affected by inflationary pressures in a much tougher reimbursement environment. There has been a direct impact from supply chain and labour shortages, geopolitical risks and macroeconomic trends. While MedTech providers adapt their business models to deal with these challenges our members have always rallied to deliver solutions which is best for industry and the Australian healthcare system.

While these pressures will remain for the foreseeable future, companies are getting on with bringing the latest medical technology to Australian patients. The sector pipeline is truly amazing, and we must continue to fight for access and reimbursement that rewards innovations and gives surgeons and patients the choice they need.

The external challenges we face have strengthened our relationship with the regulator, opening a more transparent and collaborative relationship between Industry and the Therapeutics Goods Administrator, which we hope will result in more timely access to technology.

And most importantly, we have worked hard to show the value our industry brings to the healthcare ecosystem which in turn has seen us increase our influence with key industry and political leaders to progress policies which will support, grow and sustain our industry.

The sector pipeline is truly amazing, and we must continue to fight for an access and reimbursement system that rewards innovations and gives surgeons and patients the choice they need.

||



CHAIR REPORT



message CHAIR REPORT







Honouring Member Support and Achievement

The MTAA Board recognises the vital role of a strong and supportive membership base for our industry association. We extend our gratitude to all member companies for their contributions to the industry and their support in advancing MTAA's important initiatives.

At the MedTech Industry Awards Dinner each year, we take a moment to express our appreciation and honour those members who have shown unwavering commitment to MTAA for 5, 15, 20, 25, and 30 years.

5 years

CircuitWise Electronics Manufacturing Pty Ltd Med El Implant Systems Australasia Pty Ltd

15 years Paragon Therapeutic Technologies Pty Ltd

20 years Gel Works Pty Ltd

25 years Abbott Medical Australasia Pty Ltd

30 years Bard Australia Pty Ltd

Honorary Members

MTAA also believes it is essential to recognise outstanding individuals who have dedicated their careers to the Medical Technology Industry in Australia. To this end, we occasionally award honorary member to deserving candidates of MTAA. This year, we honour Peter Abrahamson and Dr. Robert Kitchen for their significant contributions as MTAA industry representatives. Peter has built a distinguished career in pharmaceuticals and MedTech, while Robert is celebrated for his extensive regulatory expertise and leadership, making them both worthy recipients of MTAA Honorary membership.

Thank You and Farewell

As the outgoing Chair of MTAA, I want to express my gratitude to the MTAA Board, committee chairs and members for their commitment to the industry. I extend special thanks to Ian Burgess for his leadership in navigating the Association through numerous challenges. I have appreciated his guidance and great partnership.

Together with our members, we have made considerable strides in progressing our Strategic Plan, and I am confident that throughout 2025 the industry will keep advancing MedTech for an improved healthcare system. I approach the coming year with optimism and urge all MTAA members to continue showcasing the vital, lifesaving work our industry performs in Australia while celebrating our contributions and achievements.

Susan Martin CHAIR

MESSAGE CEO REPORT



IAN BURGESS CHIEF EXECUTIVE OFFICER MEDICAL TECHNOLOGY ASSOCIATION OF AUSTRALIA

This year, MTAA has again delivered on a highly productive advocacy and policy agenda. Our collective efforts have made substantial progress across a range of key issues affecting the MedTech industry and the Australian healthcare system.

<complex-block>

Advocacy Achievements

This year's MedTech on the Hill in Canberra was another resounding success. It raised the profile of our industry with government leaders, enabling engagement with MPs, Senators, and key government departments and agencies.

Our advocacy efforts have been central to significant policy wins including for:

- **Regulatory Reform:** Through ongoing collaboration with the Therapeutic Goods Administration (TGA), we continue to drive meaningful regulatory reform, this includes the regular RegTech meetings, establishment of the Quality Assurance Forum and frequent Member/TGA events which enhance regulatory collaboration.
- Prescribed List Advocacy: MTAA's persistent efforts, in collaboration with hospitals, doctors, and consumer groups, successfully convinced the Government to reverse previously negative decisions, including retaining General Use Items on the Prescribed List (PL), and preventing additional arbitrary cuts to PL benefits for General Use Items.

These outcomes underscore the value of consistent, constructive engagement with the Minister for Health and the Department of Health and Aged Care.

MTAA was also successful in securing funding for **Cardiac Technical Support Services** and preserved the Government's commitment to the Memorandum of Understanding (MOU) signed with the previous Health Minister, despite considerable pressure from private health insurers.

Demonstrating MedTech's Value

The **Value of MedTech Report** continues to underscore the significant contributions of our industry:

- Employing 17,000 people directly, and 51,000 when including those supporting the industry.
- Contributing \$5.4 billion to Australia's GDP.

We have continued our on-the-ground approach to communicating the vital role MedTech plays in improving patient outcomes, reducing mortality, and enhancing efficiencies within our healthcare system. Despite these contributions, challenges persist including fragmented legislative, reimbursement, and procurement frameworks, as well as financial pressures on private hospitals and industry revenue.





MESSAGE CEO REPORT



At the heart of everything we do is the purpose of our industry: to save lives. From enabling people to see, walk, or hear to extending and improving lives, MedTech touches every Australian from birth to their final moments.

Addressing Equity and Access

Equity of access remains a critical issue, as access to MedTech often depends on geographical location, demographics, and private health insurance coverage. Lengthy and complex approval and reimbursement processes further exacerbate these inequities, delaying time-to-market and shortening time-in-market for innovative technologies.

MTAA continues to advocate for improved regulatory, assessment, reimbursement, and procurement processes to ensure equitable access to life-saving medical technologies for all Australians.

The Purpose of MedTech

At the heart of everything we do is the purpose of our industry: **to save lives**. From enabling people to see, walk, or hear to extending and improving lives, MedTech touches every Australian from birth to their final moments.

That fundamental purpose drives the passion and commitment of all those who contribute to the lifechanging impact of our industry.

MTAA's Financial Performance

Total revenue grew by 14% in the twelve months to 30 June 2024. This was primarily a result of growth in membership, strong professional development and event attendance, and increased interest revenue.

Total expenses increased by 6.5%, reflecting MTAA's continued investment in additional resources to drive key strategic initiatives, including digital health.

4

As a result, MTAA achieved a net profit of \$348,863 for the twelve months to 30 June 2024 compared with the previous year's profit of \$13,104.

MTAA's balance sheet reflects a strong financial position with net assets of \$2,413,689 which is an increase of 17% year-on-year. This puts MTAA in a strong position to utilise reserves to support key strategic initiatives, if needed.

Conclusion

As we reflect on another year of progress, I want to thank the entire MTAA team—our Board, the MTAA staff, and the many committee and working group members—for your invaluable contributions. Together, we are driving the industry forward, addressing challenges, and maximising the impact of MedTech for patients, the economy, and the health system.

Thank you all for your dedication and commitment, and I look forward to continuing our work together into the future.

lan Burgess CHIEF EXECUTIVE OFFICER



POLICY, ADVOCACY & COMMUNICATION

MTAA has continued a robust and dynamic advocacy approach to championing industry's policy priorities. With the support of its policy and advocacy committees the Public Affairs Committees, Reimbursement Committee, Regulatory Committee and industry Policy Committee, MTAA has continued to achieve significant influence as a trusted partner and source of data-drive recommendations to government.

MTAA has continued its core advocacy activities guided by the Public Affairs Committee's Key Strategic Advocacy Pillars:



Value of MedTech;

A Partner in Health; and



Sustainable Access to MedTech.

The development of MTAA's Key Strategic Advocacy Pillars delivers for industry a forward advocacy plan for the duration of this Parliament, and beyond, guiding the activities of MTAA members and the broader industry by focusing on the policy priorities set out by the Board's Strategic Plan, and engaging with the stakeholders key to delivering on industry's commitment to patient access and doctor choice in the private health system.

Simultaneously MTAA has also continued its engagement with the Federal Government for positive Prostheses List Reform that abides by the guardrails set out in the signed Agreement with the previous Government. Underpinning this engagement was MTAA's success in ensuring the guardrails of its MoU were upheld throughout the course of the new Government and current Parliament.

Underpinning this engagement was MTAA's success in securing a pre-election commitment from the future Labor Government to deliver on the Agreement while in office.

MTAA's productive relationship with Senators and Members of Parliament can best be seen through the continuation of the Parliamentary Friends of MedTech group, now chaired by the chair and deputy chair of the House of Representatives Standing Committee on Health, Aged Care and Sport, Dr Mike Freelander MP (Labor), and Melissa McIntosh MP (Liberal).

MTAA has continued its direct advocacy for memberspecific matters at the ministerial, parliamentary and committee levels of government, ensuring MedTech's voice is heard and included. This year also saw the continuation of the MedTech on the Hill initiative in Canberra, providing members with the unique opportunity to meet face-to-face with Ministers, Shadow Ministers, MPs and Senators from across the political spectrum.

In FY23/24, MTAA also took over the administration of the Radiation Oncology Access Coalition (ROAC) (formerly RTAG). This Alliance is a coalition of professionals and organisations who aspire to increase the public profile and accessibility of radiation therapy, to ensure it is adequately funded by government.

Member Communications

Digital media remains a vital tool for educating, informing and persuading stakeholders within MTAA's sphere of influence. In FY23/24, MTAA published 63 newsletters, including 18 Member Updates (exclusive to members) and 45 full database mailouts. Member feedback indicated that the content quality had notably improved with committees and third parties also contributing to a richer mix of news, opportunities, and insights.

MTAA's LinkedIn presence grew significantly with an additional 4,539 followers. Regular posting and commentary on relevant news aligned with MTAA's advocacy priorities boosted support for the channel and led to increased interaction from the online community. Outside of direct communication, LinkedIn continues an important medium to reach the broader healthcare sector, advocating to a targeted and engaged audience and promoting MTAA and industry activities effectively.



Medical Technology Association of Australia (MTAA) 12,144 followers

Funding for digital health faces several challenges at present. Unlike in some countries, there is no funding pathway for most regulated digital applications and services that patients can access and use at home. ➡ QUESTION: Do you believe that the introduction of a scheme to cover reimbursement for regulated digital health applications and services would see greater uptake? Would this make a significant difference to the way we deliver health and community care, adding value to the Australian economy?

#digitalhealth #funding

Do you believe a new scheme to cover reimbursement for regulated digital health applications and services would see greater uptake?

You can see how people vote. Learn more

Medical Technology

IARE

BREAKING: FEDERAL BUDGET NEWS @(site-clate-dc) @(site-clate-month) @(site-clate-syyy)

MTA

Building on last year's budget, Treasurer Jim Chalmers has delivered a second successive surplus of \$9.3 billion in this It-of-living relief without fueling inflation and commits to growing the number of Medicare Urgent Care

The focus of this cost-of-living relief is through tax cuts promised for all Australians, however other major relief inc

Yes	94%
No	6%
Unsure	0%
32 votes · Poll closed	



Earlybird Closes Soon for MedTech Conference

Earlybird registration is still available for the MTAA MedTech Conference.

Hosted at Sydney's ICC the 2-day event will focus on the prescribed list, digital health, value-based procurement, regulatory affairs. industry growth and much more.

Earlybird closes on Friday, 31 May 2024 at 5:00pm AEST.

Register

Date: 23-24 October 2024 Venue: Sydney ICC Earlybird Price: \$1,490 incl. GST Medical Technology Association of Australia (MTAA) 14,061 foll 6mo · 🕲

- The Federal Government's investment in Australian MedTech is paying dividends.
 - day. CathRx announced groundbreaking results from its first in-human f a new pulsed field ablation system for the treatment of atrial fibrillation.

tedTech was supported by the Federal Government's #CTCM Program tralian Medical Research Future Fund initiative delivered by MTPConnect) ws the importance of investment in Australian MedTech to generate rcial returns and high-paying jobs.

Anderson #MedTech #Innovation

CathRx 1,246 follow 6mo - 🕥

KING: It's a big week for CathRx this week as our initial first-in human / results evaluating #ElectroPulse - our next generation pulsed field ion (PFA) system - will be presented at the Heart Rhythm Societmore



ElectroPulse

First-in-Human Study Results Evaluating CathRx's next



Members Update

@(site-date-dd) @(site-date-month) @(site-date-yyyy)



New Face-to-face OTP Training Date Now Available

MTAA is now accepting enrolments for the new Introduction to OTP training taking place on Friday, 14 June 2024.

Operating Theatre P Fraining Course

OTP training is essential for Medical Company Representatives (In-House Technicians) wanting to enter the perioperative environment.

For those refreshing their certification, the selfpaced OTP Update is available online.

Price: \$950 incl. GST for 1.5 OTP Introduction \$195 incl. GST for 1.6 OTP Update

Register

MTAA encourages anyone with an interest in joining ROAC, collaborating or simply staying informed of ROAC's activities, to visit the ROAC website for more information and to follow ROAC on LinkedIn

radiation therapy.





es and making changes to student loan it

 GDP: Real GDP growth is forecast to grow by 2% in 2024-25, 2.25% in 2025-26, 2.50% in 2026-27, and 2.75% in 2027-28.

- Unemployment: Unemployment rate is expected to grow to 4.25% by 2027-28.
- Inflation: Inflation is ear cted to ease from 3.5% in 2023-24 to 2.5% in 2

KEY ECONOMIC INDICATORS







AVG. OPEN RATE FOR **NEWSLETTERS**









SUBSCRIBERS





INCREASE IN NEW FOLLOWERS BRINGING THE TOTAL TO 13,774

MTAA Supports ROAC to Increase **Radiation Therapy Access**

ROAC, Radiation Oncology Access Coalition, is a coalition of people and organisations who aspire to increase the public profile and accessibility of radiation therapy and to ensure it is adequately funded by government.

Join, Collaborate and Keep Updated

ROAC membership and collaboration opportunities are open to anyone with an interest in sustaining and increasing access to

Annual Report | FV23/24

PUBLIC SUBMISSIONS AND POSITION PAPERS

2023



Review of regulatory requirements for medical devices containing materials of animal, microbial or recombinant origin

Proposed application audit framework for medical devices



__**†**]

Conformity Assessment Timelines proposal



Prescribed List draft Guide



PL compliance consultation paper 7





(**†**)

t

PL post listing review framework

Authority

2024



Proposed regulatory clarifications to the exemption for Clinical Decision Support System (CDSS) software



Conformity Assessment certificate application process and timeframes



HTA Policy and Methods Review Consultation 2



Procurement policy (Inquiry into Procurement Practices across NSW government agencies)



Input into draft PL reform Baseline Evaluation Report

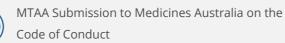


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Submission on Enhanced Consumer Engagement in Health Technology Assessment







Submission to the House Inquiry into Diabetes

Provision of industry data on Prescribed List items

to the Independent Health and Aged Care Pricing

Procurement policy (NSW Special Commission of

Further submission on updated draft Prescribed

Financial industry policy - examining consumer

Draft PL cost recovery implementation response

protections and flow on effects on MedTech

innovation (Wholesale investor thresholds)

Inquiry into HealthCare Funding)



Environmental Sustainability (SA Health Climate Change Framework)





Instructions for Use for Medical Devices -Consultation on availability of Instructions For Use (IFU) in more flexible formats

MTAA ACHIEVEMENTS



Successfully overturned the arbitrary 10% additional cut on General Use Items



Successfully influenced reforms for better access to high-quality clinical trials for patients, researchers, and industry representatives with government exclusively announcing the launch of the National One Stop Shop at the 2023 MedTech Conference



Ongoing funding for CIED services for FY24/25 at industry-assessed costs



Established the new Quality Assurance Forum to help better engaged with TGA on QA requirements



Parliamentary Friends of MedTech chairs presentation at conference panel and launch of the Digital Health Report



Ongoing collaboration and advocacy (doctors, hospitals, consumers)





Secured the continuation of Part D of the Prescribed List for General Use Items, with the opportunity for continuation of new listings



Advocated for Australia to adopt consistency with US/EU regarding Unique Device Identification to ensure no additional burdens to access TGA's UDI program leading to more approvals to market, and less resource-intensive work for regulatory teams.



Launched the MTAA Digital Health Report "Digital Health: Breaking Barriers to Deliver Better Patient Outcomes" aimed at identifying opportunities for digital health uptake and barriers that need to be overcome.



TGA agreed with MTAA's recommendations on how applications are selected for audits across all classifications providing an aligned and comparable approval process.



Continuing to successfully deliver TGA workshop collaborations and the inaugural RegConnect24 Symposium slated for Oct 2024

Reimbursement

MTAA remains committed to advocating for new reimbursement approaches to meet the demands of industry, improvoing processes related to the Prescribed List and to ensure better patient access to medical technology.

Prescribed List

The Prescribed List (PL) remained a challenging policy environment during FY23/24, and the industry contributed further savings to insurers through benefit reductions agreed with the previous Government. However, MTAA registered some important wins for the industry and played a key role in being the voice of industry on pending issues.

These included:

- Successfully maintaining around 500 General Use Items on the PL, which would have resulted in lower coverage
- Successfully reversed an announced additional arbitrary benefit reduction for General Use Items that would have decreased prices below the public average
- Ensured the benefit reductions required under PL reforms were implemented according to the Memorandum of Understanding signed with the previous Government
- Through the MTAA Cardiac Forum achieved ongoing payment of technical support services and consultation on a new model of provision/ funding
- Raised issues with the regrouping of the PL that would have resulted in significant benefit changes ultimately leading to the deferral of a flawed process

- Achieved removal of requirements for international and public prices from most PL applications
- Provided responses to 3 separate compliance consultations resulting in reconsideration of some negative proposals for industry
- Participated in the Department PL Reform
 Evaluation Advisory Group and provided feedback
 on reports to highlight industry perspectives
- Worked collaboratively with hospital, clinician and consumer peak bodies on PL reform issues to achieve aligned positions where possible
- Advocated for changes to the Health Products
 Portal following a highly problematic launch which
 has been recognised by the Department of Health
 and Aged Cage
- Ran a PL application training day with the Department of Health and Aged Care (first in over 10 years)
- Provided feedback on the draft PL Guide and listing processes which resulted in some practical improvements and further training resource
- Provided confidential feedback to meetings of the Medical Device and Human Tissue Advisory Committee (MDHTAC) to highlight industry perspectives



Other Reimbursement Initiatives

MTAA has been actively advancing efforts to improve reimbursement pathways for critical medical technologies, helping to ensure broader patient access and support for innovation across the healthcare sector.

These include:

- MTAA brought diabetes companies together for the first time to provide a unified position on expanding access to diabetes technology to the House of Representatives Committee inquiry resulting in an appearance at a public hearing and some of MTAA's recommendations being taken up.
- Submissions to the Health Technology Assessment (HTA) review and the Enhanced Consumer Engagement in HTA process which along with other stakeholders resulted in some positive recommendations for improvement that our industry can take forward into device HTA.

Regulatory and Clinical Issues

MTAA has continued to advocate for industry perspectives in the evolving regulatory landscape, ensuring that reforms, new regulations, and guidance documents align with the needs of members while minimising additional burdens. Through collaboration and advocacy, MTAA remains a trusted voice for the MedTech industry.

Highlights of FY23/24 include the following:

- Collaborated with TGA to deliver an expanded series of workshops, including a new session on Software as a Medical Device (SaMD), alongside pre- and post-market workshops.
- Successfully partnered with TGA on implementing Australia's UDI system, ensuring alignment with European and US requirements without additional data burdens for sponsors and manufacturers.
- Presented member feedback at the annual Medical Device Single Audit Program (MDSAP) forum, highlighting strategies for improving the program's effectiveness.
- Represented Australia at the MedTech EU annual conference, presenting on global regulatory matters and reliance practices, solidifying MTAA's international reputation and strong relationship with TGA.

- Secured \$61 million in additional funding for TGA through a pre-budget submission to support public good activities.
- Actively participated in key forums and committees, including RegTech (TGA-industry) Forum, TGA Advertising Consultative Committee (TGACC), TGA Industry Forum (TIF), and TGA Consultative Committee (TCC).
- Provided industry perspectives on four public TGA consultations.
- Launched the Quality Assurance Forum (QAF), engaging quality professionals from member companies to address shared challenges and drive improvements.
- Continued to collaborate with TGA to progress key issues raised by members, including approval timelines and regulatory efficiencies.









Industry Policy

The Industry Policy Committee, supported by the forums and working groups, has progressed key policy areas that have long-term impacts on member companies' ability to operate in the Australian market. Nurturing Australian innovation, building supply chain resilience and developing an innovative eco-system for commercialisation were a strategic priority for MTAA in FY23/24



Medical Technology Association of Australia (MTAA) 14,062 followers Ivr · 🕲

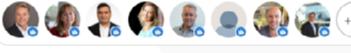
The Fresenius Medical Care Australia team presented an insightful look into their business today. Their work in environmental sustainability and innovative local manufacturing practices is a great example of how renal care is continuing to evolve and support Australian patients.

#MedTech #FMC #Sustainability #Environmental



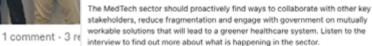
26





Medical Technology Association of Australia (MTAA) · (10)

On Earth Day 2024 (22 April 2024), the Albanese Labor Government signed a public statement of collaboration with the United States and the United Kingdom to decarbonise healthcare supply chains. Governments are increasingly focused on ways to decarbonise healthcare activities, which includes examining ways to reduce medical waste levels and procure with environmentally sustainable outcomes in mind. There is a need for the MedTech sector to understand its role in helping the Australian healthcare system become more environmentally sustainable



Rozalina Sarkezians Health Industry Hub #CardinalHealth #MTAA #ESG Jane Crowe, GAICD Pravin Siriwardena #EarthDay



1 comment - 4 reposts

Sustainability and ESG

MTAA has rapidly grown its activity and engagement on ESG-related issues through the formation of the Sustainability Working Group. Since its inception in May 2023, starting with 5 members, the working group has grown to 17 members and has been actively influencing policy activity at a State and Commonwealth level.

The MTAA Sustainability Working Group is crucial in driving change within the MedTech industry, ensuring that companies contribute to broader societal and environmental goals. Through active policy engagement at a state and commonwealth level, the group informs and influences regulations on reducing environmental impact.

The working group also serves as a place to share information on environmentally sustainable best practices and promotes aligning the Australian MedTech sector with global ESG standards. This growing collaboration strengthens Industry's collective voice allowing MedTech to develop sustainable practices that benefit patients and communities while supporting long-term resilience and global competitiveness.





Key achievements:

- Responses to National Health and Climate Strategy consultation, NSW Draft Roadmap, SA Health Climate Change Consultation, promoting harmonisation between State and Federal Government in reporting requirements and standards in procurement processes
- Developed strong partnerships with trade associations in promoting the awareness of ESG in the MedTech sector. Contributed to APACMed's 'Why ESG Matters for MedTech in the Asia-Pacific' and APACMed's dashboard for environmental regulations for MedTech in APAC.
- Established dialogue with NSW Health Climate Net Zero Unit to discuss opportunities to progress environmental sustainability initiatives.
- MTAA speaking at the APACMed MedTech Forum . on emerging trends around environmental sustainability from an Australian Perspective.
- Largest Plenary Sustainability Session at MTAA's . 2023 annual conference (bringing together Industry, government and Hospitals) and soft launched the APACMed ESG report.
- MTAA was interviewed by Health Industry Hub • to talk about activities occurring in MedTech, including the MTAA Sustainability working group activities.
- Strong engagement with National Health, . Sustainability and Climate Unit to understand how the National Health and Climate Strategy will be implemented going forward and building MTAA's relationship with the Unit as it continues to grow and influence Australia's greener healthcare direction.

Procurement and Value-Based

MTAA continues to advocate for industry-friendly terms related to public procurement processes. The level of policy and advocacy activity regarding procurement has been high with some notable activities, particularly across NSW and QLD.

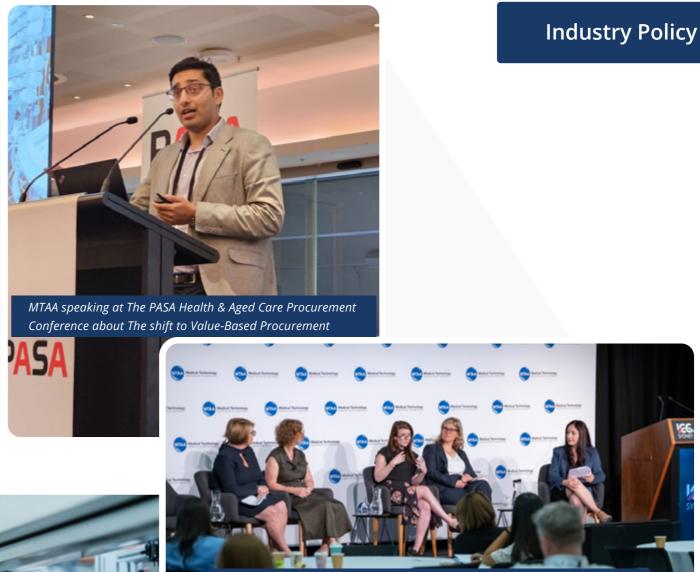
- MTAA was invited to speak on procurement processes in the NSW Health System as part of the Special Commission of Inquiry into Healthcare Funding. MTAA challenged the current ability of health services to adopt value-based options in procurement processes, with a lot of procurement still focused on the lowest price of technologies. The MTAA submission, which led to MTAA's invitation, was highly referenced during the State Inquiry by the Inquiry team with questions targeted at senior leaders within the NSW Health system on their current assessment of procurement practices NSW Health.
- MTAA was invited to speak at the NSW Legislative Council on current procurement practices within different NSW government agencies. MTAA's submission emphasised the use of unfavourable terms in contracts and the need to examine value-based procurement models to deliver better value-for-money outcomes through government procurement activity.
- MTAA presented at the Procurement and Supply Australasia conference discussing MTAA's Value-Based Procurement Report to a range of procurement stakeholders in healthcare.
- MTAA increased engagement between Industry and procurement leaders with an invitation to the HealthShare NSW senior leadership team, along with the Chief Procurement Officer, to discuss the latest version of the Standard Offer Arrangement and other procurement activities.
- MTAA sits on the QLD Health Industry Reference Group run by the QLD Health Chief Procurement Officer. This has been a useful mechanism to engage on QLD Health's major strategic procurement projects, raise procurement issues impacting MTAA members and understand QLD Health's future around environmental sustainability in procurement processes.

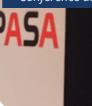
Supply Chain

The working group provides an opportunity for supply chain professionals from member companies to identify supply chain challenges to raise with government and provide input into MTAA activities and support advocacy.

Key Achievements:

- Providing input into the design of the 2024 MTAA Supply Chain Survey which included environmental sustainability trends. The survey has been used by a variety of member companies in their own conversations with key stakeholders on freight pressure challenges.
- Conversations with Department of Industry Roundtables with the Office of Supply Chain Resilience in Canberra giving an overview to members on how they identify and share information with other government agencies on supply chain events impacting different industries.
- The working groups provide a mechanism to discuss key industry supply challenges that can be raised with the Office of Supply Chain Resilience.













MTAA MedTech Conference session on Examining the 'E' in ESG for Healthcare

Digital Health

MTAA continues to drive the digitalisation of healthcare by leading policy discussions on its future and realising the potential of digital technologies to improve healthcare systems.

The MTAA Strategic Plan 2022-2025 leads policy discussions on the future of Connected Health in Australia and how digital health will transform the way Industry thinks about and interacts with healthcare. The ongoing efforts by the Digital Health Advisory Group and Cyber Security Working Group were joined by the establishment of the Privacy Working Group to progress many policy issues including specific work on digital health reimbursement in conjunction with the MTAA Reimbursement Committee.

Government and Wider Industry

The MTAA Digital Health Advisory Group addressed numerous pertinent digital health-related issues throughout FY23/24. MTAA engaged regularly with the Australian Digital Health Agency (ADHA), the Department of Health and Consultation and the Productivity Commission with work on their "Leveraging Digital Technology in Healthcare" report.

MTAA was represented in several key digital health groups and events including the Australian Digital Health Agency (ADHA), Australian Digital Health Standards Advisory Group, Standards Australia IT-014 Health Informatics Committee and numerous digital health workshops and events.

MTAA hosted the second edition of the Asia Pacific Medical Technology Association's (APACMed) Digital Health Reimbursement Policy Forum in June 2024 drawing international attendance from Singapore, Japan, South Korea, France, and the United States. This year's forum built on the previous year's inaugural discussions, with a focus on the reimbursement of Al-based platforms.

Cyber Security Working

The MTTA Cyber Security Working Group (CSWG) aims to bolster the medical technology sector's position as a leader in cyber security. Through stakeholder engagement with relevant government bodies (TGA, ACSC, State governments) and structured partnerships across the healthcare and cybersecurity sectors, the CSWG facilitates the development of improved practices and policy development for healthcare-based cybersecurity.

MTAA hosted a Privacy and Cybersecurity Training workshop for SMEs, run by elevenM, consulting to assist smaller companies in understanding the fundamental privacy and cybersecurity requirements as a MedTech company.

In addition, MTAA participated in the Department of Home Affairs Trusted Information Sharing Network (TSIN) Health Sector Group sessions and held specific cyber security discussions with the TGA and other key stakeholders.

Privacy Working

The MTAA Privacy Working Group (PWG) was established this year, stemming from the group of companies that were involved in the MTAA response to the Attorney-General's Privacy Act Review Report in 2023. This group is focused on the ongoing confusion around data collection, access, use, retention, sharing and consent across jurisdictions and internationally.



Breaking Barriers to Deliver Better Patient Outcomes

MTAA's Digital Health Advisory Group made strides to position MTAA as a leader in digital health via awareness, thought leadership, and reimbursement. The primary Digital Health Advisory Group focus of FY23/24 was the launch of the MTAA digital health report "Digital Health: Breaking Barriers to Deliver Better Patient Outcomes" the core collateral used for connected health advocacy and a baseline for MedTech digital health discussion.

The report was launched at the Australasian Institute of Digital Health (AIDH) MedInfo '23 conference in July 2023 at Sydney ICC. A dedicated session titled "Digital



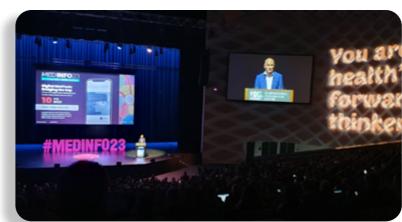




MedTech: Bridging the Gap" drew over 100 attendees during the 90-minute white paper launch. The session contained three sections:

- 1. The research team presented key findings from the report
- 2. A panel of digital health experts discussed pertinent topics identified within the report
- 3. The Co-Chairs of the House of Representatives Standing Committee on Health, Aged Care and Sport, Dr Mike Freelander MP and Mrs Melissa McIntosh MP endorsed Industry's efforts and recommendations in the paper.

MEMBER ENGAGEMENT



MedInfo23: Launch of the Digital Health Whitepaper 10 July 2023

MTAA leverage the large-scale attendance of MedInfo23 to launch the Report *Digital MedTech: Breaking Barriers* to Deliver Better Patient Outcomes. Organised by the Australasian Institute of Digital Health (AIDH), MedInfo23 attracts thousands of attendees across the globe and this year MTAA joined as a supporting session sponsor of the event.



Women in MedTech Mentoring Program Launch 27 July 2023

More than 50 attendees joined the launch of the Mentoring Program 2024. Members heard from the previous mentors and mentees of the Program who shared their advice and tips on how to facilitate a successful mentoring relationship including the importance of encouraging and empowering mentees in their development.

Events

MTAA leverages its connections and industry knowledge to provide keynotes and workshops relevant to the interests of members. The planning of these events is led by committees and working groups aiming to educate and advocate, and provide insights that are not available from other organisations. Importantly, these events facilitate conversations with decision-makers, influencers and like-minded professionals to engage in industry-specific discussions and encourage a supportive and collaborative approach to progressing initiatives and activities of MTAA.

EVENTS. **BY NUMBERS IN THE LAST 12 MONTHS**









ATTENDEES AT THE MEDTECH CONFERENCE



16 FACE-TO-FACE **EVENTS IN FY23/24**

Annual Report | FY2





MedTech Annual Conference 23-24 October 2023 | Sydney

MTAA's MedTech Conference is Australia's premier event for medical technology, where pioneers, thought leaders, and innovators from across the globe gather to explore the latest breakthroughs and developments. As the healthcare industry undergoes rapid transformation, the MedTech Conference serves as the platform to discover cutting-edge solutions and strategies that are shaping the future.

This year saw 373 delegates attend the ICC Sydney venue with 79 presenters speaking in 20 sessions packed into a stellar two-day program.

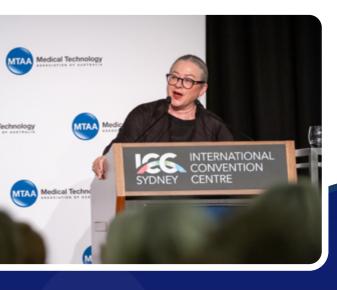
The event opened with an incredible story from TED Talk and MTAA keynote speaker, Dr Gill Hicks, a survivor of the 2005 London terrorist bombings. Her story is a tale of resilience, compassion and humanity. She recalls in vivid detail the moments that brought her so close to death, her realisation of the severity of her injuries and how she endured years of operations and emotional scars on her road to recovery. For 40 minutes she captivated the room and narrated a compelling and unique life story that immersed the audience as though they were right there by her side. Having turned her struggles into resilience and redemption, Dr Gills Hicks made it her mission to advocate for peace, embrace a positive outlook despite life's setbacks and reclaim her life as an artist and performer.

The day followed with sessions on regulatory harmonisation, identifying and overcoming cognitive bias in healthcare and a focus on how the Australian health system can address the long-term impacts of climate change and other environmental factors. MTAA continued its ongoing conversation reflecting on the practical tips for digital health uptake featuring patient groups, Local Health Districts and agencies, while concurrently running a session on the benefits of hybrid working environments to modernise today's workforce and hiring choices. Day 1 finished with a discussion on diversity and inclusion in the workplace, followed by an insightful panel into where private healthcare is headed in the future. Ian Opperman, NSW Government, closed the day with a thoughtprovoking exploration into the emerging cyber security challenges in healthcare in a growing and fast-paced digital age.

373 ATTENDEES

Day two brought an air of excitement and anticipation as Industry welcomed the Hon Mark Butler MP keynote address. The Health Minister praised Industry for its continuous contribution and ongoing service to Australian health and the economy when faced with cost-of-business and supply chain pressures. The Minister for Health and Aged Care used the occasion to announce the appointment of a new Chair of the Inter-Governmental Policy Reform Group (IGPRG) for health and medical research, including clinical trials, naming Emeritus Professor Ian Chubb AC, FAA FTSE to lead key reforms of the group. MTAA was fortunate to not only have the Minister make this announcement at the conference this year but to also have Professor Chubb in attendance as one of the panellists discussing the importance of a vibrant and efficient health and medical research operating environment in attracting more clinical trials to Australia.











Day two continued with special guest Joaquin Duato, Chairman and CEO, Johnson & Johnson, providing insights into the world's largest, most diversified healthcare products company with an exclusive fireside chat with Sue Martin, Managing Director of Australia and New Zealand, Johnson & Johnson MedTech. More sessions followed with Prescribed List Reforms and presentations from the Department of Health, sessions on growth opportunities for MedTech manufacturing, an update from TGA and concluded with a fascinating panel discussion on the evolution of Al in Healthcare.

The MedTech Conference 2023 was highly praised by attendees, speakers and supporting partners. The exceptional quality of presenters and topics, along with the well-organised logistics and event operations, created a memorable and insightful experience for attendees.

Australian MedTech Industry Awards 23 October 2023 | Sydney

The Australian MedTech Industry Awards brought together industry leaders to celebrate a year of innovation and leadership.

Held following day one of the MedTech Conference 2023, MTAA proudly announced the winners in five award categories. This year saw a record number of high-quality entries, reflecting an industry that continues to develop and deliver leadership and innovative solutions for Australian patients and the healthcare system.

Honorary Life Members: Peter Abrahamson and Dr Robert Kitchen

MTAA recognises the individuals who have dedicated their careers to the Medical Technology Industry in Australia. This year we recognised Peter Abrahamson and Dr Robert Kitchen for their roles as MTAA industry representatives.

Peter Abrahamson has led a successful career in the pharmaceutical, MedTech, and FMCG sectors, with significant roles in companies like Allergan and Unilever, and served as the inaugural industry representative for the Ophthalmic Clinical Advisory Group since 2004. His contributions to various clinical advisory groups over nearly two decades, along with his current role as Managing Director of Eye Co Pty Ltd and non-executive director at the Macular Disease Foundation of Australia, highlight his valuable impact on the MedTech sector and deserving of MTAA Honorary membership recognition.

Dr Robert Kitchen started his career in the pharmaceutical industry, specialising in technical advice and clinical trials, and actively contributed to Medicines Australia and government committees. Transitioning to MedTech in 1999, he became the Director of Scientific Affairs at Alcon Laboratories and held various leadership roles in MTAA, while also serving on the Clinical Advisory Group from 2014 to 2023, where his extensive regulatory expertise and collaborative approach earned him respect within the industry. His years of service and valuable contribution warrant his recognition as an Honorary Life Member.

Kerrin Rennie Award: Boston Scientific

Boston Scientific was awarded MTAA's most prestigious award and announced as the winner of the MTAA Kerrin Rennie Award 2023 for their FARAPULSE Pulsed Field Ablation System.

The FARAPULSE Pulsed Field Ablation (or PFA) System is intended to render targeted cardiac tissue electrically non-conductive to prevent cardiac arrhythmia initiation or maintenance. It is indicated for isolation of pulmonary veins for the treatment of drug-refractory paroxysmal atrial fibrillation (or PAF) in adults with cardiac arrhythmia adult patients up to 75 years of age.

Outstanding Achievement Award: Liz Carnabuci, Medtronic

Liz is an experienced strategic communicator with more than 25 years of sales and marketing experience in the healthcare industry in ANZ, China and APAC markets. She is committed to commercial excellence and is passionate about developing people and designing programmes to build talent, promote inclusion and drive organisational success. She is very passionate about healthcare and helping ensure that Australia continues to provide a sustainable and world-class healthcare system that can be accessed by everyone.

Liz is currently Vice President, Enterprise Accounts and Services for Medtronic ANZ and Japan and is also Vice President of Asia Pacific and Greater China for Medtronic's Diabetes business.

As one of MTAA's Board of Directors, she has a solid understanding of the duties and key governance principles and strategies to drive board success.









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Australian MedTech Industry Awards cont. 23 October 2023 | Sydney

Women in MedTech Company Champion Award: Stryker

Stryker is committed to advancing women both within the company and in the broader community. The company has made significant strides in female leadership representation, with 46.4% of its workforce being female, and women comprising 50% of senior leaders and 43% of people leaders. Stryker supports women and families through policies like parental leave, with 36% of primary caregivers being men, highlighting its commitment to gender equality.

The local Stryker Women's Network (SWN) promotes diverse representation and advocacy through various initiatives, including:

- Women Without Limits: An annual program that fosters personal growth and networking by providing challenging experiences.
- SWN Empowers: A program aimed at empowering leaders to support the advancement of women.
- Women to Women Peer Coaching: Launched globally in 2023, this initiative helps women achieve their goals through structured peer coaching.

Stryker also emphasises the importance of a diverse, equitable, and inclusive approach across the industry and engages with broader industry members at relevant events.

Women in MedTech Individual Champion Award: Dr Katharina Richter, RIBU Plasma & The University of Adelaide

Dr. Katharina Richter is a distinguished leader in the MedTech field, celebrated for her innovative contributions and commitment to gender diversity. She has received over 40 awards, including being named an MIT Innovator Under 35 Asia-Pacific and a finalist for the Prime Minister's Prize for New Innovator. Known for her pioneering work against antibiotic-resistant bacteria, she has developed six innovative treatments, three of which are patented.

Katharina serves as a role model for aspiring female leaders and actively promotes gender diversity in the industry. Her influence extends internationally as she represents Australian MedTech through various panels, collaborations, and media engagements. Additionally, she is involved in multiple committees and organizations, mentoring the next generation of MedTech leaders and fostering career development initiatives. Her remarkable contributions make her a true pioneer in both the MedTech industry and the advancement of women within it.

Women in MedTech Emerging Women in Leadership Award: Kate King, Medtronic Australasia

Kate King is a Government Affairs & Policy Director at Medtronic, where she plays a pivotal role in healthcare policy and advocacy. As Chair of the MTAA's Industry Policy Committee and Deputy Chair of the AmCham Health Policy Committee, she has been instrumental in addressing reform challenges in cardiac technical services and contributed significantly to the Value of Medtech Report.

Kate has cultivated strong relationships with patient organizations and other stakeholders to enhance the sector's advocacy efforts. She is also a member of Medtronic's Global Government Affairs Extended Leadership Team and has led the development of Reconciliation Action Plans, including a memorandum of understanding with Indigenous Health Australia. Additionally, she represents Medtronic on the ANZ Diversity Council.

Data and Compliance Training for MedTech SMEs 12 October 2024

MTAA has partnered with elevenM and their team specialising in privacy, cyber security and data governance to provide an introductory training course to data and compliance for SMEs. The 3-hour session helped SMEs gain an understanding of the requirements for businesses, an outline of the current laws on compliance, the risks of penalties and how to avoid them, and an action plan to prepare for future legislative changes.

Prescribed List **Application Training**

November

2.30pm - 4:30pm AlDT Puliman Sydney Airport, 191 O'Rierdan St, Mascot, NEW 2020

8 2023



Prescribed List Application Training – Sydney 8 November 2023

MTAA organised a training session in collaboration with the Department of Health and Aged Care for sponsors of Prescribed List products, following the introduction of new processes and the release of the new Prescribed List Guide. The session focused on understanding the application process and ensuring that sponsors meet the requirements for successful new and amendment applications. Presenters included Emeritus Professor Terry Campbell AM, Chair of the Medical Device and Human Tissue Advisory Committee, and Ms. Irina Tsyganova, Director of the Prescribed List Administration Section. Former industry representatives on Clinical Advisory Groups (CAGs) also participated to provide additional insights.

Post-Marketing Regulatory Affairs for Medical Devices Workshop – Melbourne 15 November 2023

MTAA Medical Technology

MTAA extended its MedTech regulatory workshop to Melbourne with a one-day workshop tailored to intermediate-to-advance professionals in the regulatory space. Co-hosted with TGA, the event opened with learnings on the structure of TGA with an emphasis on surveillance. This included discussions on adverse events, covering definitions, responsibilities of sponsors and manufacturers, and the TGA's report review process. Participants engaged in an activity involving examples of adverse events and appropriate responses.

The session also addressed recalls, detailing the flow, types, and decision-making processes involved. Immersing students with activities was important to allow participants to explore different types of recalls and how to process them.

Discussions on post-market reviews introduced recent reforms, highlighting key aspects such as reclassification, mandatory adverse event reporting, and Unique Device Identifiers (UDIs), along with the rationale and timelines for these reforms. An activity provided safety and reclassification examples and strategies for handling feedback on reforms.







Danny McDade + 2nd Life Sciences Growth Partner - Quality & Regulatory 9mo • Edited • 🕥

Great to be part of the MTAA Regulatory Affairs Networking Event in North Sydney last Thursday! ...more

> Medical Technology Association of Australia (MTAA) 14,061 followers 9mo - Edited - 🔇

Highlights from the Regulatory Affairs Networking Event at North Sydney

Jasjit Baveja, Ph.D.



Pre-Market Regulatory Affairs for Medical Devices Workshop – Melbourne 16-17 November 2023

This 2-day interactive workshop provided detailed coverage of the medical device regulations in Australia. Thirty-five individuals joined the face-to-face workshop and learned the basics of Australian medical device regulations, TGA structure and personnel, and QMS requirements, including ISO 13485 and MDSAP. The curriculum also provided learning on the intended use and classification of medical devices, market authorisation processes for the EU and FDA, and how to leverage approvals from comparable overseas regulators for TGA applications. The workshop also covered best practice guidelines for TGA applications and audits, essential principles, risk management, and clinical evidence requirements, with learning outcomes demonstrated with case studies.

Value-Based Procurement Networking Event

Thursday, 9 March 2023 | 4:00pm - 5:00pm AED MTAA Office, Level 4, 97 Waterloo Rooc Macquarie Park NSW 211

Regulatory EOY Networking Event - Sydney 29 November 2023

The regulatory end-of-year networking event provided a scenic atmosphere for regulatory professionals to connect with peers and industry leaders in front of Sydney's Darling Harbour. Fifty-five individuals gathered in the city centre to share knowledge and insights, amongst regulatory professionals.

Regulatory Affairs for SaMD Workshop - Sydney 30 November 2023

The SaMD (Software as a Medical Device) workshop focused on the development, regulation and best practices for software intended for medical purposes. This workshop covered topics on regulatory frameworks, including guidelines heard from the regulator, TGA. Participants explored the software development lifecycle, risk management, validation, and usability testing. The importance of clinical evaluation was discussed, emphasising the role of clinical data in demonstrating safety and effectiveness. Additionally, the workshops addressed Quality Management Systems (QMS) principles to ensure compliance and quality throughout the development process. Emerging trends, such as advancements in AI and machine learning and their implications for SaMD, were also highlighted.



Regulatory Networking Event 15 February 2024

MTAA invited the regulatory community to join its first regulatory networking event of 2024, hosted at Cardinal Health's office in North Sydney. Its purpose was to open interest for members to join the newly established Regulatory Affairs Professional Community and help formalise a network of followers and contributors in the space. Speaking on its goals and objectives, this community was designed specifically for professionals in the MedTech industry and provides



What an inspiration Dr Melina Georgousakis is! Franklin Women is making great strides, but there is definitely a way to go in breaking barriers for women making a difference to health outcomes. ...more



2

exclusive networking opportunities to connect with like-minded professionals, set up professional development opportunities, and inform members on regulatory updates and resources, while collaborating on discussions to share strategies for overcoming regulatory challenges.

International Women's Day Event 8 March 2024

Founder and Director of Franklin Women, Dr Melina Georgouska, hosted a special Women in MedTech event focused on this year's International Women's Day them: Count Her In: Invest in Women. Accelerate Progress. For the first time, MTAA hosted a hybrid event with more than 100 individuals join from Melbourne and Brisbane.

MTAA Quality Assurance Forum Networking Event 26 March 2024

The Quality Assurance Forum is a new event designed to unite Quality Assurance professionals, serving as a platform for information exchange to address key issues and meet the needs of the broader membership. Forty-five MedTech professionals attended this event offering an opportunity for members to connect, build stronger business relationships and share valuable advice and insights. This event also helped kick off the newly established MTAA Quality Assurance Forum, reporting to the Regulatory Committee, to encourage member participation and help shape its objective for the year.

. : : : : : ' **QUALITY ASSURANCE** FORUM MEETING AND NETWORKING EVENT 26 March 2024 Medical Technology

Regulatory Networking Event 30 May 2024

MTAA invited the MedTech community to a special Regulatory Networking event, sponsored by member company PPDSearch. This networking event focused on the interpersonal skills needed to progress the career of a regulatory professional and provided practical tips on successful communication to help succeed in today's regulatory environment.



HealthShare NSW – The New Standing Offer Arrangement (SOA) 10 April 2024

HealthShare NSW provided MTAA members with the latest updates on the Standing Offer Arrangement (SOA), providing clarity on the agreement, key changes and a refined implementation approach. The event was joined by HealthShare representatives Michael Gendy, Chief Procurement Officer, Alex Araujo, Executive Director, Procurement & Supply Chain, and Craig Turner, Specialist Advisor, who addressed questions from the 50+ procurement MedTech professionals present.





Introduction to Regulatory Affairs - Sydney 1 May 2024

MTAA continued its cycle of regulatory workshops with a one-day introductory level workshop for MedTech professionals hosted in collaboration with TGA. The workshop encouraged interactions between participants for an immersive learning experience while providing a comprehensive overview of pre- and post-market medical device regulations in Australia and setting the stage for future in-depth modules. The introductory workshop helped regulatory professionals understand the life cycle regulation of medical devices, insights into risk-based regulation, adverse event reporting, and Australia's position in global medical device regulation. Participants also learned about pathways to the Australian Register of Therapeutic Goods (ARTG), post-market review processes and TGA's regulatory refinement approach.

TRAINING BY NUMBERS

IN THE LAST 12 MONTHS



3,688

INDIVIDUALS COMPLETED MTAA TRAINING



1,168 INDIVIDUALS COMPLETED THE CODE OF PRACTICE TRAINING

1,336



INDIVIDUALS COMPLETED THE OPERATING THREATRE PROCOTOLS COURSE

Professional Development

Professional development training for the MedTech workforce is imperative to keep standards elevated, reduce risk, and grow the knowledge base of MedTech professionals.

The skill and engagement of the workforce is reflected in better patient outcomes, longevity of staff retention, and greater stability for the industry. MTAA is the recommended provider for the industry standard of Operating Theatre Protocols (OTP) training for visitors to the perioperative environment. Visitors to the perioperative environment include member companies' staff who interact with professionals in operating theatres and restricted hospital areas.

FY23/24 was another strong year of attendance in both formats of the OTP course. A total of 152 individuals participated in the Introduction to OTP course and 1,184 individuals in the updated online course. To increase convenience for interstate participants and to better manage internal resources all MTAA courses, including OTP training, have continued with a virtual format to meet the needs of the current working climate.

The Code of Practice training (Edition 13) entered its second year of a three-year cycle and was completed by 1,168 individuals in 2023-24. Completing Code Training is a mandatory requirement for all members who are medical device/technology suppliers. The Compliance and Competition Course was completed by 97 individuals, a requirement for all industry representatives who were part of MTAA's governing committees, forums, and working groups. To-date in this cycle, there have been 6,438 participants complete the training.



Women in MedTech

The MTAA Board initiated the concept of Women in MedTech (WiMT) to lead discussions and promote the benefits of gender diversity in the workplace and the MedTech sector. Entering its 9th year, the WiMT initiative continues to advocate this message and progress work that helps proactively support women in unlocking their potential.

The WiMT Committee was well represented with 14 members of different genders, roles and businesses, supporting a structured working plan that leveraged existing MTAA assets, resources and connections. A highlight of the WiMT calendar was the exclusive interview with Professor Jayashri Kulkarni AM, the founder and director of two research centres – HER Centre Australia and the Monash Alfred Psychiatry Research Centre. WiMT member, Alistair McKeon, sat down with Professor Kulkarni, a leader and expert in



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Medical Technology Association of Australia (MTAA)

12,144 followers 1mo • Edited • 🚯

Good mental health is vital to our overall health and well-being. Yet one in eight people globally are living with mental health conditions, which can impact their physical health, their well-being, how they connect with others and their livelihoods.

Vorld Mental Health Day MTAA encourage you to learn more about how al health issues are impacting Australia. The Mental Health Australia: t to the Nation 2023 brings to light key findings of Australian mental v, the demographic/geographic segments most vulnerable and the current s impacting Australians with mental health tions: https://inkd.in/gcEJUZ4e

ITAA's Women in MedTech Committee has been focused on women's al health and the challenges that can present at all ages. We sat down Professor Jayashri Kulkarni AM, a leader and expert in the field of in's mental health, for an exclusive interview on how the pandemic cacerbated mental health issues for many women, her ground-breaking al research of women's mental health, and her advice to industry on priate steps to raise awareness and support to tackle mental illness. In the full interview here: https://Inkd.in/gzPWVDcK

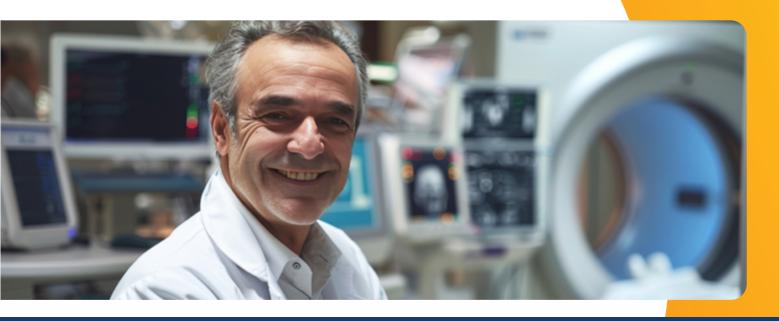
#WorldMentalHealthDay #MentalHealth #WomensHealth



the field of women's mental health, for an exclusive interview on how the pandemic has exacerbated mental health issues for many women, her groundbreaking clinical research of women's mental health, and her advice to industry on appropriate steps to raise awareness and support to tackle the illness.

WiMT continued its conversations with trailblazers and leaders in women in health with an event celebrating International Women's Day on 8 March 2024. The featured speaker, Founder and Director of Franklin Women, Dr Melina Georgouska, hosted a special hybrid event on Count Her In: Invest in Women. Accelerate Progress. A new format was introduced to attract an audience from across 3 states' borders, with satellite locations at Olympus' Sydney, Melbourne and Brisbane offices, providing visitors the opportunity to meet, interact and network amongst local attendees.

WORKING WITH INDUSTRY **COLLABORATION**



Working to unite the industry and engage a broader range of stakeholders is a way to strongly articulate and demonstrate the value proposition of the MedTech industry to the Australian community. Collaboration strengthens MTAA's leadership, representation and advocacy, as well as membership.

Clinical Translation and Commercialisation MedTech Program

MTAA is a program partner with MTPConnect, Australia's life sciences innovation accelerator for the medical technologies, biotechnologies and pharmaceuticals sector, which delivers the Clinical Translation and Commercialisation MedTech (CTCM) program, a \$19.75 million initiative funded by the Australian Government's Medical Research Future Fund (MRFF). The CTCM program seeks to identify and nurture high-quality medical device projects with strong commercial potential under development by start-ups and small-to-medium enterprises.

The CTCM program has generated \$7.2 million in funding to accelerate medical device innovation with Round 2 announced in July 2023 offering \$6.7 million investment to the following startups:

- 4DMedical Limited for the development of 4DMedical XV-Perfusion: A Contrast-free, Perfusion-enabled 4D lung scanner
- CathRx Ltd for the development of the CathRx Pulsed Field Ablation System for the treatment of atrial fibrillation

BioMedTech Horizons Program

MTAA partnered with MTPConnect to launch the BioMedTech Horizons (BMTH) program, an initiative of the Medical Research Future Fund (MRFF) introduced in 2017. The program was created to support research and development by small and medium enterprises focused on innovative, early-stage medical devices.

The impact report for the second, third, and fourth rounds of BMTH highlights \$30.3 million in funding awarded, which helped attract an additional \$36 million in industry contributions. This investment has supported 306 jobs, advanced 87 medical technologies toward commercialisation, initiated or completed 27 human clinical studies and trials, and resulted in 8

Australian Ethical Health Alliance

MTAA is a founding member of the Australian Ethical Health Alliance (AEHA). The Alliance aims to improve healthcare in Australia through the articulation and affirmation of ethical principles that promote the interests of patients and consumers, enhance access to safe and effective healthcare, encourage ethical collaboration in the healthcare sector and build public trust. MTAA is working with 71 other health sector organisations to achieve these goals.

- Medical Developments International Limited for the development of Medical Developments International Next Generation - a self-contained Rapid-release Penthrox Inhaler for safe, effective acute pain relief
- Rex Ortho Pty Ltd for the translation of the Rex Screw- A novel, expandable screw to improve surgical outcomes for hip fracture patients without compromising removability or surgical workflow
- Ventora Medical Pty Ltd for the development and clinical translation of a Neonatal Airway Pressure Monitor
- VitalTrace Pty Ltd for clinical translation of a VitalTrace novel continuous lactate biosensor for foetal monitoring
- Vivid White Pty Ltd to conduct the clinical study, manufacturing and registration of a medical device to treat glaucoma and prevent blindness.

technologies receiving marketing approval and being brought to market.

MTAA is proud to have played a key role in the discussions that led to the creation of the BMTH program. As a strong advocate for Australia's medical technologies sector MTAA's CEO, Ian Burgess, was pleased to serve as a founding member of the Steering Committee, providing guidance, advice, and governance support throughout all four rounds of funding.

External Representation

Some of the key representations this year were:

- AOA Presidential Line
- AOA Presidential Line Forum
- ARCS Advisory Board
- Australian Breast Device Registry (ABDR) Steering Committee
- Australian Digital Health Standards Advisory Group
- Australian Ethical Health Alliance (AEHA)
- Australian Medical Research and Innovation Strategy 2021-2026 (Australian Medical Research and Innovation Priorities)
- Australian Research Council's Research Hub for Connected Sensors for Health
- Bariatric Surgery Registry (BSR) Steering Committee
- **Beyond Science**
- **Clinical Trials Collaborative Forum**
- Continuity of Care Collaboration
- CT:IQ Executive Meetings
- **CT:IQ Steering Committee**
- Executive Committee Beyond Science Scientific Board
- Global Medical Technology Alliance (GMTA)
- GS1
- Healthy at Home (H@H)
- Independent Health and Aged Care Pricing Authority
- Industry Reference Group Qld Health Procurement
- MTPConnect Clinical Translation and Commercialisation (CTC-M) Steering Committee
- MTPConnect BioMedTech Horizons Steering Committee
- MTPConnect REDI Steering Committee
- NSW Smart Sensing Network (NSSN) Aging Taskforce
- NSW Medical Device Fund Selection Committee
- Peak Body CEO's Group
- Prescribed List Reform Evaluation Advisory Group
- Prescribed List Reform Stakeholder Advisory Group
- QLD Medical Category Council Industry Reference Group
- Regulatory & Technical Consultative Forum for Medical Devices (RegTech Forum)
- Research Development Task Force (RDTF)
- Royal Australian College of Surgeons Robotic Surgery Working Group
- Standards Australia
- Supply Chain Roundtable Department of Industry
- TGA Consultative Committee (TCC)
- Therapeutic Goods Advertising Consultative Committee (TGACC)
- TGA Industry Forum (TIF)
- Therapeutic Goods Advertising Consultative Committee (TGACC)
- UNSW ARC Research Hub for Connected Sensors for Health Industry Advisory Board

39 POSITIONS **REPRESENTATED BY MTAA STAFF AND MEMBERS**

MTAA works with government and health sector partners to articulate industry positions in key areas such as medical device regulations, health technology assessment, reimbursement in the public and private health sectors, clinical trials, MedTech industry development, standardisation and common technical specifications.



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1,168

INDIVIDUALS COMPLETED THE CODE OF PRACTICE **TRAINING IN 2023-24.**

MEDICAL TECHNOLOGY INDUSTRY CODE OF PRACTICE Administered by the Medical Technology Association of Australia Edition 13 – 2023

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CODE OF PRACTICE INTEGRITY

The objective of the MTAA Code of Practice is to help build and maintain the trust and confidence of, and accountability to, all communities with whom MTAA members engage.

The Medical Industry Code of Practice Edition 13 (Code), which is administered by MTAA, sets out the ethical framework within which MTAA member companies must work, both in their relationships with healthcare professionals and, where relevant, with consumers. All MTAA members are obliged, as a condition of membership, to comply with the Code.

The MTAA Code embodies among the strongest industry self-regulation regimes in Australia.

As a matter of course, MTAA continues to take steps to ensure that member companies and the relevant employees within them remain not only aware but are also demonstrably compliant with the required standards of ethical conduct.

In FY23/24, 1,168 individuals completed the Code training program, and a further 434 were in the process of doing so as of 30 June 2024. Since the launch of Edition 13 of the MTAA Code of Practice in January 2023, 5,701 individuals have completed the Online Updated Code training.

Separately, the Code Monitoring Committee oversaw two monitoring cycles during the year, each requiring member companies to report on:

- their internal guidelines that are intended to ensure relevant employees are provided adequate and up-to-date training on the Code, and
- comparative advertising (to healthcare professionals) conducted between 1 July 2023 and 31 December 2023.

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MEMBERSHIP **INDUSTRY & ASSOCIATE**

120 MEMBERS **87** Industry Members

33 Associate Members

Industry Members

3-D Matrix Medical Technology Pty Ltd 3DMorphic Pty Ltd Solventum (was 3M Australia Pty Ltd) Abbott Medical Australia Pty Ltd Additive Surgical Pty Ltd Alcon Laboratories (Australia) Pty Ltd Algostim Research and Development Pty Ltd AlphaXRT Ltd ARIA Research Pty Ltd Arthrex Australia Pty Ltd Avanos Medical Australia Pty Ltd Axonics Inc B. Braun Australia Pty Ltd Bard Australia Pty Ltd BellaSeno Pty Ltd Bausch & Lomb (Australia) Pty Limited Baxter Healthcare Pty Ltd **BIOTRONIK Australia Pty Ltd** Boston Scientific Pty Ltd Cardinal Health Australia 503 Pty Ltd CardioBionic Pty Ltd CathRX Ltd ConMed Linvatec Australia Pty Ltd Cook Australia Pty Ltd Corin (Australia) Pty Ltd Cortical Dynamics Limited Dentalife Australia Pty Ltd Dentroid Pty Ltd Device Technologies Australia Pty Ltd

Industry Members

DJO Global Pty Ltd t/a Enovis EBR Systems (Aust) Pty Ltd Edwards Lifesciences Pty Ltd Elekta Pty Ltd Eudaemon Technologies Pty Ltd Evolution Surgical Pty Ltd Exactech Australia Pty Ltd Field Orthopaedics Pty Ltd Fresenius Medical Care Australia Pty Ltd Gamma Gurus Gel Works Pty Ltd Getz Healthcare Pty Ltd Heraeus Medical Australia Pty Ltd Hologic (Australia & New Zealand) Pty Ltd Horten Medical Pty Ltd Hydrix Limited Integra Neurosciences Pty Ltd InterMed Medical Pty Ltd JiffyStent Pty Ltd Johnson & Johnson Medical Pty Ltd Karl Storz Endoscopy Australia Pty Ltd KLS Martin Australia Pty Ltd Laminar Air Flow Pty Ltd LifeHealthcare Distribution Pty Ltd Ligo Medical Pty Ltd Lima Orthopaedics Australia Pty Ltd LivaNova Australia Pty Ltd Mainstay Medical (Australia) Pty Ltd Materialise Australia Pty Ltd

This year, we welcomed 15 new industry members: Additive Surgical, ARIA Research, Axonics, CardioBionic, CathRx, Dentalife Australia, Dentriod, JiffyStent, Karl Storz Endoscopy Australia, Ligo Medical, Mainstay Medical, Microbio, Organon Pharma, Sample Assist, and Presidio Medical AU. Additionally, we welcomed 6 new associate members: AUDIENCED, Health Technology Analysts, IVDEXEL, Linfox Australia, Neo-Bionica, and Transcience.

Industry Members

MatOrtho Australia Pty Ltd Medacta Australia Pty Ltd MED-EL Implant Systems Australasia Pty Ltd Medical Specialties Australasia Pty Ltd Medistar Medtronic Australasia Pty Ltd Microbio Ltd MicroPort CRM Pty Ltd Molnlycke Health Care Pty Ltd Nevro Medical Pty Ltd NL-Tec Pty Ltd NuVasive (Aust/NZ) Pty Ltd Olympus Australia Pty Ltd Organon Pharma Pty Ltd Paragon Therapeutic Technologies Pty Ltd Presidio Medical AU Pty Ltd Prism Surgical Designs Pty Ltd Sample Assist Pty Ltd Smith & Nephew Pty Ltd Spectrum Surgical Pty Ltd Stratos MedTech Pty Ltd Stryker Australia Pty Ltd Tasman Medtech Pty Ltd Teleflex Medical Australia Pty Ltd Terumo Australia Pty Ltd Tunstall Australasia Pty Ltd t/a Tunstall Healthcare Varian Medical Systems Australasia Pty Ltd W L Gore & Associates (Australia) Pty Ltd Zimmer Biomet Pty Ltd

Associate Members Amazon Web Services Pty Ltd Avania Pty Ltd AUDIENCED Pty Ltd Circuitwise Electronics Manufacturing Commercial Eyes Pty Ltd DHL Supply Chain (Australia) Pty Ltd Expeditors International Pty Ltd GeorgeFaithfull Advisory Pty Ltd Health and Technology Advisory Group (HTAG) Health Technology Analysts Pty Ltd Healthcare Professionals Group Pty Ltd Heng & Hurst Pty Ltd Hogan Lovells Australia HTRAK Pty Ltd Icon Cancer Care IDE Group Illuminate Health Consulting Pty Ltd

- IVDEXEL Pty Ltd KD&A Pty Ltd Linfox Healthcare Logistics Lucid Health Consulting Pty Ltd Medtechnique Consulting MTPConnect Neo-Bionica Pty Ltd NSW Smart Sensing Network OneMD Pty Ltd Pettit Pharma & Device Search Pty Ltd PharmaLex Pty Ltd Regulatory Concepts Pty Ltd Smartways Logistics Holdings Pty Ltd Transcience Pty Ltd
- Value-Based Access Pty Ltd
- Veranex

BOARD OF DIRECTORS





ELIZABETH CARNABUCI



REBECCA CORTIULA

VICE-CHAIR

SENIOR MANAGING DIRECTOR, VARIAN MEDICAL SYSTEMS, AUSTRALASIA

CHAIR MANAGING DIRECTOR, JOHNSON & JOHNSON MEDTECH ANZ

VICE-CHAIR VP AND MANAGING DIRECTOR ANZ | VP DIABETES APAC, MEDTRONIC AUSTRALASIA

Monash University, Bachelor of Nursing, GAICD.

Susan started her career as a critical care nurse and has spent two decades working in the medical device sector. Throughout her career, she has taken increasingly senior local, regional and global commercial and people leadership roles culminating in her current appointment as Managing Director of Johnson & Johnson Medical Devices (JJMD) for Australia and New Zealand in January 2018. Before being appointed Managing Director, she was most recently the Asia Pacific Franchise Lead for IIMD's Cardiovascular Specialty Solutions business and was responsible for providing leadership to drive the business's global franchise strategy and pipeline.

Susan was elected to the Board in November 2018, was re-elected in November 2020 and 2022. She was appointed as Chair in November 2023. Bachelor of Commerce (UNSW Sydney), MBA (MGSM), GAICD

Liz joined Medtronic in November 2019 as VP, Diabetes Group APAC. In May 2020, Liz added VP & MD Australasia to her remit. Medtronic offers technologies and solutions to treat a wide range of medical conditions. Liz is an experienced strategic commercial leader with more than 25 years of sales and marketing experience in the healthcare industry. Liz holds a Bachelor of Commerce degree from UNSW Sydney as well as an MBA from Macquarie Graduate School of Management in Australia, and Graduate Diploma AICD. She is currently pursuing a Bachelor of Psychology at the University of Central Queensland.

Liz was first appointed to the Board in August 2020. She was elected in November 2021 and appointed Vice Chair in November 2023.

B.Sc (UTS), MBA (AGSM), GAICD

Rebecca has been working within the Australian Healthcare system for more than 25 years. Rebecca's career started in the Australian hospital system and Australian Red Cross Blood Service as a Hospital Scientist. Her MedTech journey began in Terumo Corporation ANZ spanning over 20 years where she advanced her career before her appointed as Managing Director. She currently leads the Varian Medical Systems ANZ team as Senior Managing Director of Australasia. Currently Chair of the Women in MedTech Committee, Rebecca leads Industry's progression of equity, advocating for women in MedTech, supporting a diverse and inclusive workplace, and shares a passion for healthcare to help ensure Australia has a sustainable healthcare system that can be readily accessed by all.

Rebecca first joined the Board in November 2015. She was re-elected in November 2022 and appointed as Vice-Chair in November 2023.



WARREN BALLINGER

VICE PRESIDENT & MANAGING DIRECTOR ANZ, BOSTON SCIENTIFIC

Bachelor of Economics (Accounting Major) Macquarie University, ICAA

PRESIDENT, AUSTRALIA & NEW

ZEALAND, ZIMMER BIOMET

With 20 years of experience within the orthopaedic device industry with a variety of connections from International, Regional and within Australia & New Zealand.

With the experience of leading two major Orthopaedic companies, Biomet and now Zimmer Biomet, Warren has been successfully involved and exposed to government price negotiations on various formats since 2001. Currently, Warren holds the position as the Chair of the Orthopaedic Sub Committee Forum with the MTAA.

Warren was elected to the Board in November 2020 and re-elected in November 2022.

Bachelor of Human Movement (Honours), Charles Sturt University Master of Business Administration, Charles Sturt University

Michael is responsible for strategy, commercial operations, and talent development across both countries. He is a member of the Asia Pacific regional leadership team. With an allied health background, Michael joined Boston Scientific in 2003 as Clinical Specialist, Cardiac Rhythm Management. Prior to his current role he served as Business Unit Director, Endoscopy and earlier as Business Unit Director, Rhythm Management. He has previously held regional responsibility as Marketing Director, Rhythm Management for Asia Pacific, Middle East and Africa.

Michael Baulch was elected to the Board in November 2023.





MICHAEL BAULCH

WARREN BINGHAM

GradCertMgt Macquarie University, PGDipMgmt Macquarie University, Certificate in Business Administration, GAICD

Warren Bingham is renowned for his founding role at MedTech International and executive positions across companies like ARIA Research, OmnisOva, and Agscent. With over 30 years of experience, Warren specialises in guiding organisations toward innovation, particularly in the strategic execution and commercialisation of medical technologies. Warren is also deeply committed to philanthropy, serving as an ambassador for Vinnies CEO Sleepout and Diabetes Australia, and supporting accelerators like the Cerebral Palsy Alliance's Remarkable.

Warren was appointed to the Board in February 2024.

BOARD OF DIRECTORS







MANAGING DIRECTOR, CARDINAL HEALTH AUSTRALIA

B.A. B. Comm

With a career spanning over 25 years in healthcare, Jane has worked across Australia, New Zealand, and China, including medical devices, over-thecounter and pharmaceuticals, with organisations such as 3M, Roche and Johnson & Johnson. To build her strategic and creative thinking, Jane spent four years in healthcare advertising, and took the leap into the not-for-profit sector, as Executive Director for the peak body for community care and contract holder for the delivery of home care services for the Commonwealth and State Governments.

lane is an advocate for Environmental and Social Governance, with a passion for Diversity Equity and Inclusion.

Jane is currently the Managing Director for Cardinal Health ANZ and President of a not-for-profit childcare.

Jane joined the Board in September 2022

Masters of Business Administration (Healthcare Strategies Concentration) *Cambridge University, MA Honours*

(Management) University of St Andrews

JACK LANCASTER

CHIEF EXECUTIVE OFFICER,

EVOLUTION SURGICAL

Jack is an experienced healthcare leader and has been CEO of Australian MedTech manufacturer Evolution Surgical since 2020. Jack spent the early part of his career advising the NHS on strategy and turnarounds, developing a passion for value-based healthcare, and the role the private sector can play in supporting value for patients. He is a passionate advocate for the importance of a strong sovereign Australian MedTech ecosystem. Prior to Evolution Surgical, Jack was in the healthcare practice at Boston Consulting Group in Sydney.

lack was elected to the Board in November 2023.

Masters of Business Administration - AGSM, Bachlor of Communications - University of

Canberra

JEFF SOO

MANAGING DIRECTOR.

TERUMO AUSTRALIA

With 18 years of medical device industry experience in ANZ and APAC, Jeff brings skills in general management, strategic planning and execution, and experience in sales and marketing gained from leading Australian med-tech and US-based MNCs. He has a passion for the benefits of medical technology and working with members of an industry responsible for facilitating their availability to improve health outcomes for all Australians. Jeff has experience across ENT, cardiology, radiology, cardiac surgery, endovascular, TAVR, and medical consumables gained locally and abroad working in small companies to among the largest in the world.

Jeff joined the Board in October 2021.



CHIEF EXECUTIVE OFFICER,

DEVICE TECHNOLOGIES

Diploma of Health Science – Nursing,

Bachelor of Health Science - Nursing

Mick has over 26 years' experience

in medical devices across Australia

Technologies in 1998 and held many

leadership and senior management

Mick has completed the Company of

the Advanced Management Program

at INSEAD in Fontainebleau, France.

Currently, Mick sits on the Board of

Directors for Device Technologies also

leading the company in his role as CEO.

Mick serving his sixth year on the MTAA

Board spanning over 10 years with 2

Michael joined the Board in 2009,

re-elected in 2011, retired in 2013 and re-joined the Board in November 2022.

years serving as Treasury.

Directors course at AICD and completed

positions, which placed him well to lead

and overseas. Mick joined Device

the company into the future.

Latrobe University

MICHAEL TREVASKIS

MANAGING DIRECTOR, EDWARDS LIFESCIENCES ANZ & KOREA

Master of Business (UTS)

Being in the medical device industry for more than 32 years now, Pat started his career at Medtronic where he held several roles including Territory Management, Sales Management, Marketing and General Management. Pat proudly joined Edwards Lifesciences in 2011 where he initially started his career as the Business Unit Manager of Critical Care.

In April 2013, Pat was then appointed as the Managing Director of the Australia and New Zealand Business and in 2020 he also assumed responsibility for Korea.

Pat joined the board in October 2019, reelected in November 2021 and elected vice chair in November 2022.





PATRICK WILLIAMS

FORMER **BOARD** DIRECTORS

CHRIS SZELECZKY

GENERAL MANAGER - SERVICE AND **OPERATIONS, OLYMPUS AUSTRALIA**

LYN DAVIES MANAGING DIRECTOR, TUNSTALL AUSTRALASIA

MATTHEW MUSCIO

CHIEF EXECUTIVE OFFICER, EBOS MEDTECH

MARK TAFFA FOUNDER & CEO, HORTEN MEDICAL

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TOTAL REPRESENTATIVES

ON COMMITTEES, FORUMS, WORKING **GROUPS AND ADVISORY GROUPS**

MTAA GOVERNANCE COMMITTEES

Active participation of members is essential to MTAA achieving success and important. This year saw 328 representatives contribute to the work of MTAA committees, forums and working groups. MTAA forums and alliances have progressed key initiatives relevant to participating members.

Public Affairs Committee

The Public Affairs Committee (PAC) is responsible for providing strategic advice, shared intelligence and coordinated activities to support MTAA's advocacy efforts on behalf of its members. The PAC is currently supporting MTAA's direct engagement and media campaign activities for positive reforms, including providing patient stories, data and insights on the effects of negative reform.

The PAC is also responsible for overseeing the execution of the Advocacy Strategy and its activities, including active stakeholder engagement to promote priorities of the industry and the strategic issues identified by other MTAA committees including Reimbursement, Regulatory Affairs and Industry Policy.

PAC members are also tasked with supporting the amplification of MTAA's advocacy content.



Regulatory Affairs Committee

The Regulatory Affairs Committee (RAC) is responsible for supporting the strategic development and delivery of MTAA's regulatory policy priorities. The RAC is also the body that discusses the operational issues facing the association's members in their interactions with the Therapeutic Goods Administration (TGA) in meeting the regulatory requirements for supplying MedTech in Australia.

The RAC's other objectives are to develop regulatoryfocused strategic initiatives for the MTAA including:

- Reviewing the effectiveness of the regulatory • system for MedTech in Australia,
- Contributing to MTAA's involvement with . international regulatory organisations,
- Liaising with Commonwealth departments and . industry associations in Australia and overseas, and
- Providing advice on the professional development of regulatory staff in the medical

MTAA GOVERNANCE COMMITTEES

Reimbursement Committee

The role of the Reimbursement Committee is to promote the MedTech industry's access to funding and reimbursement pathways that enable timely public and private market access. This includes:

- Providing effective advice and support to the . MTAA to achieve the best possible outcomes on Prescribed List (PL) reform
- Where applicable, creating working groups to jointly draft submissions in response to PL consultations
- Identify PL listing issues and solutions for MTAA communication with the Department
- Monitor and where necessary comment on other reimbursement/funding issues at a federal or state level
- Inform work on reimbursement of digital health by the Digital Health Advisory Group

Industry Policy Committee

The Industry Policy Committee is responsible for developing policy positions and engaging with stakeholders on local industry development and workforce initiatives and provides oversight on key procurement and supply chain challenges impacting members. The IPC is also focused on developing positions in response to current and emerging Environmental, Social, and Governance (ESG) activities impacting the MedTech sector.

Code Authority

The Code Authority is responsible for overseeing the administration of the MTAA Code of Practice. Amongst other things, it:

- reviews and periodically recommends updates to the Code to ensure it remains fit for purpose,
- oversees the work of the Code Monitoring Committee, and
- oversees and facilitates the investigation and resolution of Code-related complaints.

The Code Authority is headed by an independent chair, and consists of up to two MTAA board members, a healthcare professional, a health consumer representative and up to seven industry representatives.

The Committee's focus during FY23/24 was to assist MTAA in developing new guidance materials for member companies on:

- rules for social media marketing, ٠
- scope of training and education permitted by the . Code of Practice at third-party events,
- use of URLs for foreign-domiciled websites in Australian advertising,
- use of "gates" to prevent unauthorised access to company websites, and
- vendor credentialing.

Code Monitoring Committee

The Code Monitoring Committee, which reports to the Code Authority, is responsible for ensuring compliance with the MTAA Code of Practice. It does this by collecting and reviewing information from member companies on different aspects of their interactions with healthcare professionals and consumers to ensure these activities comply with the Code.

The Monitoring Committee is headed by an independent chair, and consists of a health consumer representative, a healthcare professional and up to seven industry representatives.

In FY23/24, the Committee oversaw two monitoring cycles during the year, each requiring member companies to report on:

- Their internal guidelines are intended to ensure relevant employees are provided adequate and up-to-date training on the Code, and
- Comparative advertising (to healthcare professionals) conducted between 1 July 2023 and 31 December 2023.



Finance

To assist the Board in the effective discharge of its responsibilities for financial reporting, internal controls, audit, compliance and risk management.

MedTech Conference

To drive the agenda, sponsorship and attendance of the MedTech Conference that appeals to MedTech industry leaders and executives.

Women-in-MedTech

The Women in MedTech Committee was established to drive and fulfil a number of objectives, including to continue to promote the WiMT initiative to the wider MedTech industry.

MTAA GOVERNANCE FORUMS

Cardiac Forum

The Forum is a collaboration of five cardiac rhythm device companies primarily intended to address the issue of funding for cardiac technical support services associated with cardiac implantable electronic devices in the context of PL reforms. The Forum has met weekly through the year and at the request of the Department of Health and Aged Care made a joint submission to the Medical Services Advisory Committee on the value and funding for these services. The Forum has also engaged with multiple stakeholders including the Department on related issues.

Neuromodulation Forum

The Neuromodulation Forum brings together companies that develop, manufacture and distribute implantable medical devices that use electrical pulses to treat chronic pain. It met numerous times during FY23/24, including to advise MTAA on its public response to media reports on the use of spinal cord stimulators (SCS) in Australia.

The Forum monitored and respond to two separate post-market reviews of ARTG and PL-listed SCS devices. Additionally, the Forum continues to liaise with the Faculty of Pain Medicine, the Neuromodulation Society of Australia and New Zealand, and other stakeholders, to reach an agreement on governance and funding arrangements for a new neuromodulation registry in Australia.

Clinical Investigations Forum

The Clinical Investigations Forum (CIF) is made up of industry members who conduct and support clinical trials in Australia. The CIF believes that clinical trials are an area of focus of the current Government, and by becoming the expert voice on clinical trials with medical devices the CIF can play a significant role in making the voice of the MedTech industry heard with stakeholders. The CIF aims to establish the value of MedTech clinical trials for the industry and establish the CIF as the body of experts in MTAA to cover this topic.

Regulatory Forum

The Regulatory Affairs Forum is an extension of the Regulatory Affairs Committee and acts as an information-sharing space to ensure the broad membership is covered and issues are passed up to the committee and subsequently to the TGA and RegTech Committee.

Orthopaedic Forum

The MTAA Orthopaedic Forum provides members with the opportunity to discuss and address issues of mutual interest and concern to those companies involved in the orthopaedic sector, in an environment respectful of competition values.

The Forum offers collective linkages to the Australian Orthopaedic Association (AOA) in circumstances where an industry voice is more appropriate and provides AOA members the opportunity to be abreast of significant industry issues, activities and concerns. The output of the MTAA Orthopaedic Forum also informs relevant MTAA committees and provides the MTAA Secretariat with aggregated input on key industry policy matters.

The orthopaedic sector has continued to provide much-needed implant supply support to surgical procedures across Australia in both the public and private sectors. Despite health funds' scepticism of the need and the occasional circulation of misinformation, companies continue to respond to surgeons' and hospitals' demands and offer orthopaedic technicians' support in theatre in accordance with established ethical practice.



The forum meets quarterly and is open to membership by all MTAA companies supplying orthopaedic products, with discussion pitched at the CEO level. Twenty member companies participate in the activities of the Forum. Regular activities include:

- Scheduled meetings with the Australian Orthopaedic Association (AOA) Presidential Line, the AOA CEO and the Director of the AOA National Joint Replacement Registry, are usually held guarterly. Topical subjects have included the "two-year evidence rule" for Prescribed List (PL) items related to hips and knees and funding of the AOA NJRR required by government from sponsors of orthopaedics on the PL.
- MTAA works closely with KPMG in the conduct of the MTAA Orthopaedic Market Survey. The survey has 17 companies contributing data in the categories of hips, knees, shoulders, spine, trauma, sports and bone cement products with six-monthly aggregated data reports and "dashboards" being provided to contributors.
- Receiving orthopaedic-specific PL updates and guidance to members on how to navigate the demands of PL processes.

WORKING & ADVISORY GROUPS

Digital Health Advisory Group

The Digital Health Advisory Group (DHAG) advocates for information and communications technology (ICT) enabled health system for Australia. The purpose of the Digital Health Advisory Group is to identify necessary policy changes for digital health and drive the implementation of an ICT-enabled service delivery framework for a healthier Australia through advocacy to influence new models of healthcare, facilitated by technology-enabled services. The group engages with key decision-makers, stakeholders and peak bodies to help establish the foundations for service delivery improvements.

The Digital Health Advisory Group membership includes representation from the broadest spectrum of the healthcare ecosystem in Australia. Members come from health and community care, the medical device industry, peak bodies, research institutes, associations and advocacy groups. The group is focused on developing communications and forums that bring to light the wider scale opportunities that are possible in the delivery of alternative models of care towards a healthier Australia.

Radiational Oncology Alliance Coalition

MTAA provides support to the Radiation Oncology Access Coalition (ROAC) (formerly RTAG), which is a coalition of people and organisations who aspire to increase the public profile and accessibility of radiation therapy, to ensure it is adequately funded by government.

Key achievements:

- Creating newly re-branded coalition, including improved internal governance structures and external presence (e.g. new logo, website and social media).
- Updating the coalition's core objectives and planning advocacy initiatives.
- Leveraging MTAA's infrastructure and network to access key government decision makers, including through MTAA's MedTech on the Hill advocacy initiative.
- Advocating and securing a change to Department of Health and Aged Care back-dated bulk-billing requirements.
- Providing key consultation input to Ernest Young on Department of Health and Aged Care's Private Sector Viability Review of non-public radiation oncology treatment providers.

Research Development Taskforce

The Research Development Taskforce is a joint membership between of MTAA, MA and AusBiotech members with the goal to work with government on their various initiatives and to shape the Clinical Trials space in Australia to ensure Australia becomes a preferred location to conduct Clinical Trials.

Key achievements:

- Developed the Clinical Trial Indemnity Guidelines, including a structured approach to address compensation for adverse events in collaboration with insurance companies
- Established new CT:IQ projects relating to informed consent
- Supported updated on Defence Trade Controls
- Developed Regional, Rural and Remote Clinical Trial Enabling Program

Sustainability Working Group

The Sustainability Working Group is focused on understanding and contributing to MTAA's policy activities on environmental policies impact on Industry. This work includes understanding policy opportunities activities around health system decarbonisation, circular economy and how Industry can collaborate with government and clinical groups in addressing these different challenges.

Supply Chain Working Group

The working group provides an opportunity for supply chain professionals from member companies to identify supply chain challenges to raise with government and provide input into activities that can support MTAA's advocacy activities.

Key achievements:

- Providing input into the design of the 2024
 MTAA Supply Chain Survey, which included on environmental sustainability trends. The survey has been able to be used by different member companies in their own conversations with key stakeholders on freight pressure challenges.
- Department of Industry Roundtables with the Office of Supply Chain Resilience in Canberra giving an overview to members on how they identify and share information with other government agencies on supply chain events impacting different industries.
- The working group provided a mechanism to discuss key industry supply challenges which can be raised with the Office of Supply Chain Resilience.

Value-Based Procurement Working Group

Subset of the Procurement Forum and members of the Public Affairs Committee oversee how to implement innovative procurement models across the Australian healthcare system.

COMMITTEE MEMBERS REPRESENTATION

Code Authority

Peter Abrahamson (Chair)	Independent
eff Soo (Board Director)	Terumo
Rebecca Arraj	Johnson & Johnson
Dr. John Quinn	Royal Australasian College Surgeons
lenry Ko	Consumer Health Forum
Arishma Singh	Cook Medical
Georgia Marshall	Medtronic
kta Shandil	Stryker
aura Tompkins	Boston Scientific
Dominica McCann	Zimmer Biomet
Rebecca Arraj	Johnson & Johnson MedTeo
Dominica McCann	Zimmer Biomet
Retired/Resigned:	

Pam Davis, independent Chris Szeleczky, Olympus Emma Press, Medtronic Adam Wood, EBOS MedTech Kenneth Wong, Arthrex Michael Baulch, Boston Scientific Dawn de Cruz, Allergan

Code Monitoring

Peter Abrahamson	Independent Chair
Jenny Chau	Smith & Nephew
Rebecca Arthur	Medtronic
Henry Ko	Consumer Health Forum
Rochelle Harris	Stryker
Helen Roch	Johnson & Johnson
Michelle Stewart	Device Technologies
Mandy Horn	Cook Medical
Julian Herrera	Olympus
Retired/Resigned:	

Pam Davis, independent Megan Guy, Non Pareil Nursing Allison Fox, Boston Scientific Stuart Hayes, Bard Australia

Finance Warren Ballinger (Board Director & Chair) Zimmer Biomet Pat Williams (Board Director) Edwards Lifesciences Joel Stuhler LifeHealthcare

Retired/Resigned: Mark Taffa, Horton Medical

Industry Policy	
Kirk Kikirekov (Chair)	HTRAK Pty Ltd
Mahiyar Hira (Vice Chair)	Karl Storz Australia
Michael Baulch (Board Director)	Boston Scientific
Rebecca Cortiula (Board Director)	Varian Medical Systems Australasia
Michael Reynolds	BIOTRONIK Australia
Alessandra Doolan	Health and Technology Advisory Group (HTAG)
Tansy Michael	Fresenius Medical Care Australia
Darin Kottege	Johnson & Johnson MedTec
Nicola McNeil	Stryker
Con Constantinou	Getz Healthcare
Gabrielle Challis	Medtronic Australasia
Neroli Manning	Cardinal Health Australia 50
Jeroen Mangelmans	Linfox
Michael Gardner	DHL Supply Chain (Australia
Stuart Hayes	Bard Australia
Retired/Resigned: Jon Michael, NuVasive	

MedTech Conference

Daniel Kildea, Johnson & Johnson Ross Lane, Cook Medical

George Sidis, IDE Group

Jane Crowe (Chair and Board Director)	Cardinal Health Australia 503
Mick Trevaskis (Board Director)	Device Technologies Australia
Kirstyn Pickering	Device Technologies Australia
Christina Machado	Edwards Lifesciences
Christine Leung	Cardinal Health Australia 503
Hardeep Girn	AUDIENCED
lan Hyam	Smith & Nephew
Jenny Pawlowski	Medtronic Australasia
Retired/Resigned: n/a	

Public Affairs

Elizabeth Carnabuci (Chair and Board Director)	Medtronic Australasia
Patrick Williams (Board Director)	Edwards Lifesciences
Mark Taffa (Board Director)	Horten Medical
Kristy Hardy (Chair of RC)	Johnson & Johnson MedTech
Kirk Kikirekov (Chair of IPC)	HTRAK Pty Ltd
Mahesh Datar (Chair of RAC)	Medtronic Australasia
Daniel Kildea	Johnson & Johnson MedTech
Gareth Trickey	
Justin Keenan	Cook Australia
Polo Guilbert-Wright	Edwards Lifesciences
Robyn Chu	Alcon Laboratories (Australia)
Beth Roberts	KLS Martin
Michael Reynolds	BIOTRONIK Australia
Kate King	Medtronic Australasia
David Brezzo	Zimmer Biomet
Edwina Sharrock	Device Technologies
Jane Yanco	B. Braun Australia
Clinton Lubcke	Stryker
Kushagra Gupta	LifeHealthcare
Michael Simmonds	Boston Scientific
Paul Davies	Abbott Medical Australia
Retired/Resigned: n/a	

Regulatory Affairs

Gary Burgess, Commercial Eyes Romit Singh, Arthrex Australia

Regulatory Allairs	
Mahesh Datar (Chair)	Medtronic Australasia
George Faithful (Vice Chair)	GeorgeFaithfull Advisory
Elizabeth Van Den Akker	Abbott Medical Australia
Ruth Shennan	Device Technologies
Maneesha Pillay	Edwards Lifesciences
Sarah Botros	Stryker Australia
Rebecca Gaudin	Johnson & Johnson MedTech
Fleur Winslade	Terumo Australia
Hugh Cameron	Bard Australia
Hemangi Malde	Cook Australia
Rachel Patrick	
Katie-Lou Buscher	NuVasive (Aus/NZ)
Falko Thiele	BIOTRONIK Australia
Kellie Shaw	Olympus Australia
Jillianne McKenzie	Field Orthopaedics
Giselle Rayman	Cardinal Health Australia 503
Ramakrishnan Kannan	LivaNova Australia
Iriny Ibrahem	Baxter Healthcare
Leanne Hartge	Solventum
Romit Singh	Zimmer Biomet
Retired/Resigned: Iriny Ibrahem, Zimmer Biomet Peter Austen, Evolution Surgical Morteza Yousefi, Solventum	



Reimbursement	
Kristy Hardy (Chair)	Johnson & Johnson MedTech
Michael Reynolds	BIOTRONIK Australia
Joel Parrish	Elekta
Maggie Dowrick	Cook Australia
Sebnem Erdol	Abbott Medical Australia
Jane Yanco	B. Braun Australia
Georgia Psarros	Baxter Healthcare
Rachael Todd	Edwards Lifesciences
Sheryl Dunlop	Zimmer Biomet
Anne Rossi	LifeHealthcare
Sarah Botros	Stryker
Tracey Doman	Boston Scientific
Blaise Agresta	Lucid Health Consulting
Joanne Burnett	Commercial Eyes
Doug Symonds	Medtronic Australasia
Colman Taylor	HTAnalysts
Hugh Cameron	Bard Australia
Angela Chang	Device Technology Australia
Dominic Langforrd	Evolution Surgical
Retired/Resigned Members Susan McKensey, Device Technologies Australia	

Oona Reardon, Economics George Papadopoulos, Lucid Consulting Lisa McDonald, Smith + Nephew Paul Sim, AMSL

Women in MedTech

Rebecca Cortiula (Chair and Board Director)	Varian Medical Systems Australasia
Jack Lancaster (Board Director)	Evolution Surgical
Sofia Hernandez	LifeHealthcare
Michelle Stewart	Device Technologies Australia
Breanna Peck	Baxter Healthcare
Beth Roberts	KLS Martin
Josh McLellan	Medtronic Australasia
Naeema Mohamed	Smith + Nephew
Alistair McKeon	Teleflex Medical Australia
Julia Ellis	Johnson & Johnson MedTech
Sue Hansford	Integra Lifesciences
Megan Keeble	Zimmer Biomet
Patrick Callanan	Boston Scientific
Bronwyn Calvert	Molnlycke
Grace Woods	Edwards Lifesciences
Janie Fonua	Arthrex Australia
Rupa Vignesh	
Kylie Pearce	Olympus Australia
Elizabeth Pettit	Pettit Pharma & Device Search
Retired/Resigned:	

Matt Muscio, Lifehealthcare



CHAMPIONING MEDTECH

Our work is to champion medical technology for a healthier Australia. When our work is done, medical technology will be valued as a key driver of a healthier Australia.





MTAA Medical Technology

Medical Technology Association of Australia

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