



# ANNUAL REPORT

2018

## 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 will work with integrity, collaboration, influence and leadership.



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## KEY FACTS AND FIGURES FOR THE YEAR

Global advances in medical technology over the past 20 years have resulted in

**56%**

reduction in hospital stays

**25%**

decline in disability rate

**16%**

decline in annual mortality and increased life expectancy of more than three years

For the 12 months to 30 June 2018 MTAA achieved an operating profit of

**\$497,189**

an increase in revenue to

**\$4,027,484**

a decrease in expenditure to

**\$3,530,295**

an increase in net assets to

**\$1,467,550**

**2**

Canberra events resulted in

**40**

**meetings with officials** and parliamentarians and the participation of over

**200**

people at our **keynote event** in Parliament House.

Support and participation of more than

**55**

**CEOs and senior representatives** of member companies, together with

**14**

patients and surgeons

In 2017-18, more than

**330**

people attended MTAA **Women in MedTech** events





over  
**200**

people attended  
**MedTech 2017** with

**46%**

of women as presenters  
as we seek to achieve

**50%**

in coming years

over **100**

healthcare leaders attended the  
**Value-Based Healthcare Summit**  
to help lead the debate on shifting  
from volume to value

**1<sup>st</sup>**

Inaugural **Women in  
MedTech** award

**10<sup>th</sup>**

anniversary of the  
**Kerrin Rennie Award**

**690**

people **enrolled** in Introduction to  
**Code of Practice** online training

**250**

new attendees took part  
in the Introduction to  
Operating Theatre training

MTAA issued

**24**

**press releases** and was  
mentioned in

**270**

separate mainstream  
media articles

**1,181**

**professionals** participated  
in **MTAA training courses**

**March**

**2018**

**PulseLine** launched  
providing news, commentary  
and insights on the  
Australian MedTech and  
healthcare landscape

social  
media  
reach



LinkedIn followers  
increasing by 860  
to 2,236



Twitter followers  
growing by 379 to  
1,143 followers



A photograph of two men in business suits engaged in a conversation at what appears to be a conference or trade show. The man on the right is bald, wears glasses, and has a mustache. He is smiling and gesturing with his hands while speaking. He wears a dark suit, a white shirt, a patterned tie, and a red lanyard. A name tag on his lapel reads "FAITHFULL STRYKER" and "DELEGATE". The man on the left is seen in profile, looking towards the first man. In the background, a woman in a light blue shirt and dark skirt is walking away. The setting is indoors with a dark wall and a bright light source on the right.

“ Every day,  
somewhere  
around Australia,  
someone’s life  
is improved by  
what we do. ”





# ABOUT MTAA

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MTAA REPRESENTS MANUFACTURERS AND SUPPLIERS OF MEDICAL TECHNOLOGY USED IN THE DIAGNOSIS, PREVENTION, TREATMENT AND MANAGEMENT OF DISEASE AND DISABILITY. MTAA MEMBERS SUPPLY THE MAJORITY OF NON-PHARMACEUTICAL PRODUCTS USED IN THE TREATMENT OF DISEASE AND DISABILITY IN AUSTRALIA.

The range of medical technology (MedTech) is diverse, from familiar items such as syringes, wound dressings and wheelchairs through to more complex technologies such as pacemakers, magnetic resonance imaging (MRI) machines, hip replacements, robotic surgery equipment and remote monitoring devices.

Our members play a vital role in providing healthcare professionals with essential education and training in the use of the more complex medical technologies to maximise patient health outcomes from the use of that technology. Industry-sponsored fellowships and funding for research and development in hospitals, universities and research facilities helps ensure the development and commercialisation of medical technology that meets contemporary healthcare needs and improves patient health and quality of life outcomes.

Associate members of MTAA are supporter or partner organisations and individuals who support the work of the sector along the entire MedTech value chain, all the way from product idea through to patient utilisation. They include legal, logistic and consulting practitioners, compliance agencies, health economists, researchers and universities, as well as industrial designers and product commercialisation specialists. They bring valuable expertise which enables MTAA to support its primary objective – to bring the benefits of technology to patients to ensure patient health outcomes and quality of life are improved.

## 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 will work with integrity, collaboration, influence and leadership

## OUR PEOPLE AT 30 JUNE 2018

**Ian Burgess** Chief Executive Officer

**Peter Tustin** Director of Business Operations

**Andrea Kunca** Director of Policy and Access

**Val Theisz** Director of Regulatory Affairs

**Polo Guilbert-Wright** Government Relations & Communications Manager

**Louie Radburnd** Marketing and Service Development Manager

**Lee Grow** Professional Development Manager

**Jennifer Ellis** Events and Engagement Manager

**Kristina Ek** Executive Assistant and Office Manager

**Sandra Marjanovic** Project Officer

**Neina Fahey** Code of Practice Coordinator

**Ranju Dhungel** Accounts Officer (part-time)

**David Ross** Policy Advisor

**Katherine Purcell** Human Resources Advisor

# CHAIR REPORT

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THE 2017–18 FINANCIAL YEAR HAS BEEN ONE OF CHALLENGE AND CHANGE FOR THE MEDICAL TECHNOLOGY INDUSTRY IN AUSTRALIA. I WANT TO THANK ALL OF YOU FOR YOUR CONTRIBUTION AND SUPPORT AS OUR INDUSTRY CONFRONTED A VERY DISRUPTIVE PERIOD.

The Australian healthcare system is world class and so is our MedTech industry, bringing research and innovation, improved health outcomes, manufacturing, employment, education and training to the Australian community and the economy, with positive impacts. Advances in healthcare and patient outcomes are simply not possible without our industry and our work reduces costs and recovery times in the healthcare space.

Global advances in medical technology over the past 20 years have resulted in a 56 per cent reduction in hospital stays, a 25 per cent decline in disability rates, a 16 per cent decline in annual mortality and increased life expectancy of more than 3 years. That is a record that the MedTech industry can be enormously proud of.

## AGREEMENT WITH THE FEDERAL GOVERNMENT

As Chair, I'd particularly like to highlight the Agreement with Federal Government on the Prostheses List, our major advocacy win this year. Following a period of continued pressure on the industry regarding the price of prostheses in the private sector and various Senate inquiries, MTAA negotiated this historic Agreement on behalf of the MedTech sector with the Government.

Under this Agreement, cuts to benefits on the Prostheses List were limited to \$303 million compared to the \$1 billion Government had put on the table. MTAA committed to work with the Government on a range of reforms to the Prostheses List Framework which will have significant medium and long-term ramifications for the sector.

In exchange, the sector received a commitment from Government to implement a large number of significantly overdue changes to improve the timeliness and efficiency of the Prostheses List process. MTAA will be focused over 2018–19 on ensuring that reforms to the Prostheses List Framework are well informed and appropriate for medical devices, the Government meets its timelines to commitments made, and that process reforms are put in place as soon as practicable, commencing by early 2019.

## HONOURING STEADFAST SUPPORT AND ACHIEVEMENT

The MTAA Board believes that a strong and supportive membership base is vital. We thank and recognise all our member companies for their contribution to the industry and their support through membership to further the important work of MTAA. Each year at the MedTech Industry Award Dinner, we take the opportunity to recognise those members who have been continuously committed to MTAA over the history of the organisation. We honoured the following members at this year's dinner:

### 5 years continuous membership

The SPD Company	BrainLab
Prism Surgical Design	Slate Hill Consulting

### 10 years continuous membership

Surgical Specialties

### 15 years continuous membership

Edwards LifeSciences	Covance
Regulatory Concepts	





### 30 years continuous membership

Baxter

### 35 years continuous membership

Medtronic

### WOMEN IN MEDTECH

As a Male Champion of Change in STEM, it gives me great pride to speak of the MTAA's Women in MedTech Board-led initiative which started in July 2015 in response to the gap of women in leadership positions across the industry. The support and engagement on this issue from members of our industry has been overwhelming, making it a clear issue of importance for MTAA to support. To acknowledge the support of these companies and individuals, MTAA introduced a new award this year, the Women in MedTech Champion. This is awarded to an individual or company who has contributed to advancing the mission and goals of the initiative. You can read more about the winners later in the annual report, but we're proud of and congratulate them: Emma Cleary, currently the Chief Operating Officer of Device Technologies Australia, and Johnson & Johnson Medical Devices, were the inaugural winners.

### HONORARY LIFE MEMBER

A very special MTAA membership category is that of the 'Honorary Life Member'. This is nominated and awarded on occasions by the Board to an individual who has provided long and meritorious service to the MedTech Industry in Australia. This year we recognised Gordon Stenning, who was responsible for the introduction of the first mechanical thrombectomy device into Australia. He still maintains a relationship with one of the first patient recipients of this technology.

### THANKS AND FAREWELL

In conclusion, I would like to say a huge thank you to my fellow MTAA Board members, all of our Committee members and to our management and staff led by Ian Burgess, for their steadfast support and wise counsel throughout the year.

I have had the privilege of working in the MedTech industry for over three decades, including the last four years as Chair of MTAA. This is my last year as Chair and I will be handing over the role at the Annual General Meeting in November. I'll leave you with the lessons I learned as Chair:

1. Patients should always remain our primary focus
2. The sun is shining for health in Australia and our industry has played a significant role
3. We must have a strong voice as an industry
4. Collaboration with all stakeholders is essential
5. MTAA must fully represent our membership and must be financially robust

I look forward to handing over the Chair role to a new leader who can help guide MTAA into the future. The value of medical technology for a healthier Australia is our mission and we will continue to advocate this in 2019 and beyond.



**GAVIN FOX-SMITH**  
CHAIR

# CEO REPORT

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2017-18 WAS A BUSY AND CHALLENGING PERIOD FOR OUR INDUSTRY AND I THANK OUR VALUED MEMBERS FOR THEIR SUPPORT, ADVICE AND SIGNIFICANT CONTRIBUTION TO MTAA'S ACTIVITIES.

We still have more to do as the MedTech industry faces ongoing challenges and pressures. We have earned a seat at the health policy debate, but it is one that we need to build on to ensure we remain in the future.

2017-18 has been a year of significant challenge and change for the medical technology industry. By necessity, MTAA allocated substantial resources to activities related to the reform of the Prostheses List. However, MTAA also maintained broader advocacy and policy development, including regulatory reform, member services such as our professional development program, our annual conference and events, our Women in MedTech initiative, and regular provision of information and analysis of healthcare and industry issues.

## STRATEGIC PLAN

At our Annual General Meeting in November, we launched our new Strategic Plan 2017-2020. The strategic plan includes the core objective to: "communicate to the Government the economic value and benefits of the industry for Australia". This means more than the economic value and benefit the industry brings, but also how patients have benefited from the industry. This message is a great way to humanise our industry, which will play an important role in our advocacy and engagement work.

The strategic plan draws on extensive quantitative and qualitative research conducted with MTAA members in 2017. We surveyed 241 key contacts and commissioned 24 in-depth interviews. Two board workshops were held

to consider the results of the qualitative and quantitative research. An implementation workshop was conducted with members of the MTAA staff.

MTAA needs to grow in order to be financially sustainable and to achieve the strategic goals it has set for itself. The plan identifies that the best path to growth is in collaboration with a broad-based alliance that includes researchers, manufacturers, distributors, clinicians, providers, funders and consumers. Collaboration is at the heart of the plan. It widens engagement, expands a base for representation and advocacy, and brings benefits to members.

The plan has been developed at an important time. Healthcare policy and funding is in flux in Australia and the MedTech industry needs to ensure that it has a strong voice in policy debates that affect the future. The industry needs to continue to engage with the Government to move forward on a long list of issues.

The MTAA Strategic Plan 2017-2020 prioritises work in five strategic areas of activity and in this year's annual report, we're reporting on our work in each of these strategic areas.

- Advocacy
- Engagement
- Collaboration
- Integrity
- Member focus



## ADVOCACY

There is no doubt that the industry has achieved better results than it would otherwise have as a result of MTAA's engagement with the Minister for Health, our data-based advocacy, and the activism of individual member companies. Our Agreement with the Government for reform of the Prostheses List was a success in itself, and importantly, through that process, the MTAA engagement with the Government and the Shadow Ministry has increased our industry's profile and reputation in Canberra.

Shortly after the Agreement was announced, we held an inaugural two-day "Canberra delegation" in Parliament House in October last year that enabled us to move beyond stakeholders' scrutiny of the Prostheses List and promote the value of our industry more broadly. Then, with the support and participation of more than 55 CEOs and senior representatives of member companies, together with 14 patients and surgeons, our second Parliament House event held in June was even more successful, highlighting to Parliamentarians and key stakeholders the diversity of the life-saving medical technology provided by our members.

In all, the two Canberra events resulted in 40 meetings with officials and parliamentarians and had the participation of over 200 people. This further enhanced the profile of the industry and the understanding of

the enormous value we provide to patients and the healthcare system.

MTAA achieved more success from our advocacy. We obtained agreement from the Government that My Health Record (MyHR) data can be used by researchers and industry for research and development. We also gained a commitment from the Government that the Australian Digital Health Agency and the TGA will consult with MTAA towards utilising the MyHR as an alternative to patient implant cards (which will be required over the next few years).

Following the independent 2015 Review of Medicines and Medical Devices Regulation, MTAA has worked closely with the Therapeutic Goods Administration to deliver on the most comprehensive regulatory reforms since the Therapeutic Goods Act 1989. We have advocated on behalf of our members on over 20 public consultations leading to significant improvements of the regulatory framework, such as the introduction of a priority review pathway for novel medical devices, as well as enabling Australian-designated third-party bodies to perform conformity assessments for medical devices, streamlining the Special Access Scheme, expanding the use of market authorisation evidence from comparable overseas regulatory bodies for medical devices, and the revision of the Therapeutic Goods Advertising Code.

“ The work we do helps Australians live longer, healthier and more productive lives. ”

#### COLLABORATION

MTAA's collaborations have resulted in success in the last year. In collaboration with other associations, our advocacy successfully resulted in the retention of relevant occupations on the Skilled Migration List. We averted more substantive cutbacks to the R&D tax incentive. MTAA authored, in collaboration with IVD Australia, ADIA and AusBiotech, the MedTech industry policy paper on Unique Device Identifier (UDI) implementation in Australia, which has been positively received by the TGA and ADHA. At the core of the policy are the adoption of a globally harmonized UDI system; the alignment with international coding standards of UDI issuing agencies accredited in the US and the EU; and the establishment of an Australian UDI database (AusUDID) owned and managed by the TGA that allows sponsors to update information for their own products, and that has relevant data accessible to the general public free of charge.

#### ENGAGEMENT

As described above, the Board developed and adopted our new Strategic Plan, following a quantitative survey of members last year and qualitative interviews with members and external stakeholders. As part of the Strategic Plan, our new Committee structure was introduced at the start of 2018 and also new Forums have been established at the request of members, to progress initiatives directly relevant to those groups of members. The Forums established so far include Clinical Investigations, Ophthalmic, Orthopaedic and Regulatory

and also a Radiation Therapy Advisory Group.

Three years' work initiated and led by MTAA resulted in the Vendor Credentialing Standard, which will avoid duplication in credentialing; this will reduce complexity and cost for our industry. We also held a successful Value-Based Healthcare Summit with over 100 healthcare leaders to help lead the debate on shifting healthcare investment decisions from volume to value.

We launched the new online digital platform, PulseLine. This will be a key distribution channel for the Association and members to communicate and advocate to a wide range of stakeholders and decision makers. In addition, we've increased our media presence with coverage directly attributable to MTAA and also work "behind the scenes" to achieve specific media content that is beneficial to the industry.

#### MEMBER FOCUS

The total number of Memberships is in line with forecast and has reached 106, and includes 71 voting members and 35 Affiliate/Associate Members; this year we welcomed 8 new voting members and 10 new associate members. There are 9 committees currently operating in 2018 and there are 104 positions; 82 were vacant positions open to representatives of member companies. The 2018 committees are Public Affairs, Industry Policy, Reimbursement, Regulatory Affairs, Code Authority, Code Monitoring, Finance, Women in MedTech and the MedTech Conference. Your ongoing involvement is critical to the success of the industry





and I sincerely thank you and your staff for their contribution.

#### FINANCIAL PERFORMANCE

MTAA achieved a net profit of \$497,189 for the 12 months to 30 June 2018. The favourable result compared to the prior year profit of \$106,932 and losses in 2014-15 and 2015-16 and was primarily due to increased membership income, income from the annual conference and other events, revenue received from a payroll tax exemption and higher interest income earned on term deposits.

Total revenue in 2017-18 was \$4,027,484, an increase of 10.5% on the previous year. Total operating expenditure to 30 June 2018 was \$3,530,295, a decrease of 0.2% on the previous year. The balance sheet reflects a strong financial position and net assets of \$1,467,550 and reflects an increase since the prior year.

This is primarily due to the increased levels of cash from operating profit.

#### MTAA TEAM

I would like to recognise the extraordinary efforts of the entire MTAA staff during what has been a challenging period. Our dedicated and passionate staff have enabled MTAA to “punch above its weight” in terms of the quantity and quality of output from our small team.

**IAN BURGESS**  
CHIEF EXECUTIVE OFFICER



## ADVOCACY

# ADVOCACY

ADVOCACY IS AND WILL REMAIN A KEY ACTIVITY OF MTAA. WE CONTRIBUTE TO CURRENT REVIEWS AND CONSULTATIONS WITH A KEY FOCUS OF NEGOTIATING WITH THE AUSTRALIAN GOVERNMENT. AS A COLLABORATIVE ALLIANCE, WE COMMUNICATE TO THE GOVERNMENT THE ECONOMIC VALUE AND BENEFITS OF THE INDUSTRY FOR AUSTRALIA.

MTAA's engagement with the Government to secure an industry agreement to provide certainty and stability regarding the Prostheses List reimbursement was a key advocacy achievement in 2017-18. MTAA was also actively involved in the parliamentary process, including participating in four Senate inquiries.

MTAA was also present during this year's health budget lock-up and we've engaged in an increasing range of issues, including the MBS reviews,

the introduction of the My Health Record, and the workings of the Private Health Ministerial Advisory Committee.

With the Prostheses List Agreement, MTAA has earned a seat at the table of health policy debate, but we need to build on this success to ensure we remain at the table for all major health policy decisions in the future.

### PROSTHESES LIST REFORM AND AGREEMENT IMPLEMENTATION

Last year's annual report reported that a key deliverable for this financial year would be signing of the historic Agreement between MTAA and Government on 11 October 2017 on the Prostheses List. This was negotiated on behalf of the MedTech sector following a period of continued pressure on the industry and various Senate inquiries regarding the price of prostheses in the private

sector. Under this Agreement, cuts to benefits on the Prostheses List were limited to \$303 million (compared to the \$1 billion Government had put on the table).

MTAA committed to work with Government on a range of reforms to the Prostheses List Framework which will have significant medium and long-term ramifications for the sector. The process has enabled MTAA to have greater input into the reforms which had started prior to the Agreement but in which industry consultation and input was severely limited.

The Agreement provides the sector with financial stability for a four-year period and improvements in the efficacy and transparency of the Prostheses Listing Framework. It provides a pathway to formally broadening access to novel and cost-effective technologies that do not fit the antiquated criteria for listing on the Prostheses List. In exchange, the sector has agreed to accept significant cuts to benefits and participate in a process for reforming the Prostheses List Framework and how benefits are set and reviewed. MTAA's priority has been to ensure the benefits intended to flow on to the industry from this Agreement are realised (to partially offset the financial impact of the cuts), and also that reforms to the way benefits on the Prostheses List are set and reviewed are appropriate for medical devices (to ensure the future sustainability of the sector).

The next step for MTAA was to ensure appropriate representation on the three Industry Working Groups (IWGs) established under the Agreement to oversee the reforms and to ensure that the governance arrangements were appropriate. The Benefit Setting and Review IWG, the Cardiac Services IWG and the

Quality of Information IWG were established in March 2018 and held their first meetings in June 2018. The industry was well represented.

By the time of the first meetings, MTAA had developed the majority of the initial industry positions, with the input of the relevant policy committees, to inform the work of these IWGs. MTAA acknowledges the extraordinary work of the Reimbursement Committee and other MTAA policy committee members that enabled the MTAA to be on the front foot at IWG meetings. More than 10 meetings of teams comprising MTAA committee members were held to undertake specific activities to address the various areas of reform, in addition to the already scheduled meetings of these Committees.

MTAA will continue to work with its members through 2018–19 to develop new policy and advocacy positions that may be required as the IWGs continue to discuss reform options. We will also work with the Department of Health and the Government to ensure the timely delivery of commitments under the Agreement.

#### PRE-ELECTION SUMMIT

On 27 March 2018, MTAA joined Research Australia, along with AusBiotech, the Association of Australian Medical Research Institutes, Australian Clinical Trials Alliance, ARCS Australia, Consumers Health Forum of Australia and other healthcare and medical research stakeholders, at a pre-election summit at Old Parliament House in Canberra. In anticipation of the next Federal Election, participants discussed common public policy issues that unite our sector and why health and medical research and innovation is important to the health and wealth of Australians.





#### WOMEN IN MEDTECH

Women in MedTech (WiMT) is an exciting and important initiative that was developed by MTAA in 2015, to lead the debate and promote the benefits of women's leadership in the workplace and within the MedTech industry. The Women in MedTech Committee, started in 2018, aims to achieve success in diversity and inclusion and to aspire to a level of excellence as an industry leader in Australia, and support the initiative within MTAA, the industry and the wider community. In 2017-18, more than 330 people attended MTAA Women in MedTech events.

The Women in MedTech initiative has developed an industry White Paper to share current practices, tools, resources and insights, as a practical resource to assist MTAA members accelerate their progress in gender diversity.

A Women in MedTech section has been added to MTAA website to provide resources including the White Paper; encourage diversity, leadership and inclusion; and promote relevant events, projects and link to stakeholder websites.



### PRIVATE HEALTH INSURANCE

In 2017–18, MTAA has been actively advocating on behalf of the sector in relation to the Private Health Insurance Reforms announced by the Government. MTAA has repeatedly raised concerns about the categorisation of insurance policies into gold, silver, bronze and basic categories, initially through the Ministerially appointed Private Health Ministerial Advisory Committee (PHMAC) and subsequently directly with Government. While MTAA supports the intent of the Government's reforms to deliver greater transparency for consumers and to make private health insurance more attractive and valuable to policyholders, the 'gold' categorisation of services has been of significant concern.

Firstly, many of the services classified into 'gold' (and therefore associated with the highest premiums) correspond to common chronic conditions with a growing incidence of disease. Secondly, many are associated with the use of relatively expensive prostheses, potentially impacting on patient out-of-pocket costs or public hospital costs. MTAA will continue to advocate to minimise any unintended consequences of the reforms on patients, industry and public hospitals. MTAA has been actively reminding the media and stakeholders that lower-than-expected Private Health Insurance premium increases were the direct result of an agreement struck between the Government and MTAA members.

### HEALTHCARE POLICY

MTAA successfully advocated with Government to allow for the data from the MyHR system to be used by researchers and industry to better help them target research and development activities as well as identify areas requiring improvement. To build on this significant win, MTAA will work with policymakers in 2018–19 to identify the medical

device data that needs to be collected under MyHR.

MTAA has also led in the national debate on value-based healthcare and is identifying what this would mean for the MedTech sector in a range of areas, including the impact on company business models, marketing approval and reimbursement decisions. This will continue to be an area of focus in 2018–19.

### BUDGET

MTAA monitors the health budget and advocates on areas of interest for our members. The current budget builds on the Government's investment in health, which is expected to increase from \$78.8 billion in 2018–19 to \$85 billion in 2021–22. The health portfolio now accounts for 16.13 per cent of overall government expenditure. With Australia's improving fiscal situation, MTAA believes that Government should continue to prioritise health expenditure. However, the current service delivery system in Australia provides fragmented care and Australia needs to transform its healthcare system to be fit for the 21st century. Unfortunately, the budget did not provide any further commitments to reforming our healthcare system to align with a shift away from volume to value. This will be something that MTAA will continue to pursue with decision-makers.

The Government will deliver a record \$6 billion in funding for Australia's health and medical research sector, including \$3.5 billion for the National Health and Medical Research Council, \$2 billion in disbursements from the Medical Research Future Fund and \$500 million from the Biomedical Translation Fund, including an additional \$10 million towards the BioMedtech Horizons program for which MTAA through its Agreement ensured an additional \$30 million.

“ MTAA, in collaboration with AusBiotech, Medicines Australia, Research Australia and BioMelbourne, successfully advocated for the Budget to recognise the importance of clinical trials and research and development.”

#### REGULATORY AND CLINICAL ISSUES

During 2017–18, MTAA continued to work closely with the TGA in progressing regulatory reforms and ensuring that the new and revised regulations and guidelines are workable for the MedTech industry and aligned with international best practice.

MTAA has successfully argued that product information leaflets should be allowed to be provided in electronic format on a company's website and that they should be excluded from the scope of the Therapeutic Goods Advertising Code 2018 and related restricted and prohibited representations, because they are a form of product labelling covered by the medical device regulations.

MTAA has also advocated for alignment with EU regulatory requirements for clinical evidence and for improvements in clinical trials governance in Australia. MTAA is an active participant in the Research & Development Taskforce alongside Medicines Australia, and the Clinical Trials Collaborative Forum.

#### RESEARCH & DEVELOPMENT TAX INCENTIVE

MTAA, in collaboration with AusBiotech, Medicines Australia, Research Australia and BioMelbourne, successfully advocated for the Budget to recognise the importance of clinical trials and research and development.

The decision to exclude R&D expenditure on clinical

trials towards the \$4 million refundable R&D tax offsets announced in May 2018 was a key demand from the medical technology research community and MTAA will continue to work with the Commonwealth to ensure that any unintended consequences from this decision are minimised.

With the Australian clinical trials industry estimated to be worth \$1 billion to the economy, and the number of clinical trials involving medical devices having increased from 119 to over 160 in just three years, this advocacy win was important. Collaboration was essential to this victory.

#### SKILLED MIGRATION

In 2017, the Government announced the Temporary Work (Skilled) visa (subclass 457 visa) would be abolished and replaced with the completely new Temporary Skill Shortage (TSS) visa in March 2018.

MTAA in collaboration with Medicines Australia, AusBiotech and other healthcare and medical research peak bodies continue to advocate for a skilled visa system that complements the Australian workforce and adds additional skills, capacity and attractiveness to invest in the Australian industry. We advocate for sensible changes to ensure our skilled migration is flexible and capable of attracting the overseas talent needed. We achieved some concessions for skilled migration, including the introduction of a pilot that could see highly skilled workers being able to access permanent residency.



## SUBMISSIONS

MTAA has submitted the following formal responses to Senate inquiries and Commonwealth consultations:

- Alignment with EU Medical Device Regulatory Framework (TGA Consultation)
- 3D Printing Technology in the Medical Device Field – Australian Regulatory Considerations (TGA Discussion Paper)
- Value and Affordability of Private Health Insurance and out-of-pocket Medical Costs (Senate inquiry)
- Development of a Framework for Secondary Use of My Health Record system data (DoH Consultation)
- Proposed Regulatory Changes related to personalised and 3D-printed Medical Devices (TGA Consultation)
- The Effect of Red Tape on Health Services (Senate inquiry)
- Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 (Senate inquiry)

- Therapeutic Goods Advertising Code 2018 (TGA Consultation)
- Joint MTAA, IVD Australia, ADIA and AusBiotech Policy Paper: UDI in Australia
- Complaints Handling – Advertising of Therapeutic Goods (TGA Consultation)

In addition, MTAA has submitted formal responses to consultations related to clinical trials by the DoH Clinical Trials Collaborative Forum and the R&D Taskforce:

- Establishing an Australian Coordinating Body for Clinical Trials
- ANZ Clinical Trials Registry governance and improvements





## ENGAGEMENT

# ENGAGEMENT

INCREASING ENGAGEMENT IS A WAY FOR MTAA TO BENEFIT FROM THE BEST TALENT THE INDUSTRY HAS TO OFFER NOW AND IN THE FUTURE. MTAA ENGAGES WITH CURRENT AND POTENTIAL MEMBERS AND KEY STAKEHOLDERS, INVOLVING INDUSTRY LEADERS AND CREATING OPPORTUNITIES FOR FUTURE INDUSTRY LEADERS. FOCUSING ON ISSUES OF SPECIAL INTEREST TO MEMBER COMPANIES AND COMPANY REPRESENTATIVES INCREASES

Throughout 2017–18, MTAA held various forums and workshops for members including the MedTech Annual Conference, Women in MedTech networking and workshop events, the Value-Based Healthcare Summit, MedTech Forums and CEO Networking Functions. Engagement with our members also ties in with our work of advocacy and representation. Members also value being kept up to date with information and developments within the industry

and being able to demonstrate a commitment to the industry through MTAA. With our members support, MTAA is well-placed to represent and promote the MedTech industry's interests, and to meet the challenges facing the industry.

### MEDTECH 2017 ANNUAL CONFERENCE | 1–2 NOVEMBER 2017

*The Value of Medical Technology to a Healthier Australia*

Over 200 people attended MedTech 2017 at Doltone House, Jones Bay Wharf, Sydney, for inspiring discussions and presentations on the future of MedTech. The program was built around five themes: the customer, the patient, systems, the future of healthcare, and human resources with 29 men and 25 women as presenters including featured international guest speakers, Dr Dora Hughes and Mr Richie Etwaru.



Over 200 people attended MedTech 2017 at Doltone House, Jones Bay Wharf, Sydney.



### THE MEDTECH 2017 INDUSTRY AWARDS DINNER | 1 NOVEMBER 2017

Once again, the annual Medtech industry awards dinner brought together industry leaders to celebrate and pay tribute to a year of innovation and leadership. Held at the end of Day One of MedTech 2017, MTA was proud to announce the winners in three awards categories, chosen from a record number of high-quality entries, a testament to an industry that is developing and providing the Australian healthcare system with innovative solutions for patients.

The Kerrin Rennie Award was established in 2007 to recognise and profile the innovative and extraordinary contribution of medical technology in improving health outcomes of patients and this year's award was sponsored by the Department of Industry, Innovation and Science. It was won by Medtronic Australasia Pty Ltd for their Solitaire Platinum, which restores the flow of blood to the brain by allowing the clot to be removed and withdrawing it from the body. With almost 1,000 cases of strokes each week in Australia, this is life-saving and life-changing technology.

The Outstanding Achievement Award is open to individuals who have contributed in a significant way to the development of the medical technology industry through improvement to patient outcomes or excellence in leadership and innovation. This year's winner, Dr Elisa Mokany, is co-founder and Chief Technology Officer at SpeedX, an Australian molecular diagnostics company, where she leads the development of innovative diagnostic technologies and commercialization of infectious disease and antibiotic resistance tests. Her effort, talent and

Highlights included presentations on artificial intelligence and MedTech, private health insurance reform, the future of value-based healthcare, the use of blockchain technology by the healthcare sector, and how other technology will transform the MedTech workforce. Engaging stakeholders outside of the industry was another theme: Daily Telegraph Health Editor, Sue Dunlevy and Health Dispatch's Paul Cross provided insights and tips for the MedTech industry to work with the media, while Member for North Sydney, Trent Zimmerman MP and NSW Senator Sam Dastyari advised on government engagement.

Comments from attendees indicated that some thought this was the best MedTech conference yet, with a great balance of topics, excellent speakers, worthwhile content and representing good value for money.

dedication have driven the continued growth of SpeedX which now has its sights set on the US market.

A new award, the Women in MedTech Champion, was awarded to an individual or a company who has contributed to advancing the mission and goals of MTAA's initiative, Women in MedTech. The inaugural award went to two winners. Emma Cleary, currently the Chief Operating Officer of Device Technologies Australia and until recently a Director on the MTAA Board was recognised for playing a significant role in driving the Women in MedTech agenda within MTAA, and in keeping it on the industry's radar as a critical issue. Johnson & Johnson Medical Devices was recognised for their employee programs and policies, and achievements such as female representation of 57 per cent of their Board, 46 per cent of their executive, 47 per cent of their management and 65 per cent of their non-management staff.

George Faithful from Stryker provided for the second year running his unique musical and comedic talents as MC and started off the night with an original, comic song relating to the industry. And MTAA recognised long-time MTAA members, Baxter with their 30-year certificate and Medtronic with their 35-year certificate. A Life Member certificate was given to Gordon Stenning by Gavin Fox-Smith.

“MTAA effectively engages with members inside the association and stakeholders across the industry.”

#### WEBINAR ON ENFORCING RESTRAINTS AGAINST FORMER EMPLOYEES | 17 AUGUST 2017

MTAA hosted a webinar on enforcing restraints against former employees. In discussion with Caitilin Watson of Atkinson Vinden Lawyers, an MTAA Associate Member, webinar participants learned how to protect their business when employees move on, with case studies and a review of the basics of restraints. As nearly one-quarter of all new employees in Australia leave their job within their first year, it's important to avoid problems in the workplace from employees taking company's confidential information and sharing it with a competitor.

#### MTAA AND AUSBIOTECH BRIEFING ON THE PROSTHESES LIST REFORM | 15 SEPTEMBER 2017

As part of our work on Prostheses List reform, MTAA co-hosted with AusBiotech a briefing about the reform with Minister Hunt's Senior Advisor. This industry briefing provided an update on the current discussions with the Federal Government regarding Prostheses List pricing reform and status of the industry agreement with the Government – and what benefit reductions would mean for MTAA members.

#### TGA MEDICAL DEVICES SPONSOR INFORMATION DAY | 11 OCTOBER 2017

MTAA is proud to have supported the TGA Medical Devices Sponsor Information Day, which focused on new regulatory staff within the industry. The program highlighted clinical evidence, the life cycle of a medical device, conformity assessment, pre-market assessment and audit, post-market responsibilities and the future of medical device regulation.





### LIFE-CHANGING IMPACT OF MEDICAL TECHNOLOGY | 17 OCTOBER 2017

Approximately 50 MTAA members attended the special event *Life-Changing Impact of Medical Technology*, with Government MPs and Senators in Canberra to hear from patients on the positive and life-changing impact of medical technology. Both the Minister for Health, Greg Hunt MP, and Shadow Minister of Health, Catherine King MP, heard from our patients including mother Leah Bohm whose seven-year-old has lived with an aggressive form of epilepsy since just before his first birthday. She spoke about how medical technology has changed their lives, allowing Leah to finally discover her son's personality, hidden for so many years because of his condition.

### WEBINAR ON CHRISTMAS PARTY CASES | 28 NOVEMBER 2017

Conducted by Caitilin Watson of Atkinson Vinden Lawyers, this webinar was targeted to HR managers and management, to learn how to avoid what is meant to be a happy occasion from turning nasty. They reviewed classic examples of what has occurred at and around workplace Christmas parties.

### INTERNATIONAL WOMEN'S DAY EVENT | 6 MARCH 2018

This event focused on the importance of gender diversity within Australian MedTech and translating the conversation on women in STEM into action. 100 industry representatives heard from an inspiring female leader, NSW Minister for Women, the Honourable Tanya Davies MP, who spoke in recognition of International Women's Day and its 2018 theme, 'Press for Progress', asking every person how they will press forward and progress gender parity.

### VALUE-BASED HEALTHCARE SUMMIT | 24 APRIL 2018

MTAA hosted the Value-Based Healthcare Summit on 24 April 2018, attended by over 100 people including policymakers, patient advocates, payers, providers and industry leaders for a day-long program to discuss this new health paradigm and how the shift towards value-based healthcare agenda will impact the medical device sector. The concept of value-based healthcare has the potential to transform how healthcare is delivered by moving away from a volume-based to value-based care models focusing on health outcomes that matter to patients. As Australia, like most countries, is in the preliminary stages of using this model, implementation is fragmented across jurisdictions, so it is important that MTAA remains involved in the policy debate around this issue.

### WHITE PAPER LAUNCH – WOMEN IN MEDTECH | 3 MAY 2018

MTAA was pleased to support this event in line with the objectives of the Women in MedTech initiative to launch a White Paper developed to support best practice within the industry on promoting women in leadership. Julie Burton of Workplace Gender Equality Agency (WGEA) presented with a panel session with Julie Burton, Emma Cleary, Sue Martin, Nicki Luther and Rebecca Cortiula sharing success stories.

### LIFE-CHANGING IMPACT OF MEDICAL TECHNOLOGY | 19 JUNE 2018

MTAA hosted its second *Life-Changing Impact of Medical Technology* event in Parliament House on 19 June 2018. The event was a tremendous success with well over 100 people including key members of Parliament such as

Minister for Health, Greg Hunt MP, Shadow Health Minister, Catherine King MP, Shadow Treasurer, Chris Bowen MP, John Alexander MP, Trent Zimmerman MP, Tony Zappia, Senator Kristina Keneally, Jason Clare MP and many others. MTAA member companies provided an array of medical devices to be on display during the event. The highlights of the event were the personal stories of patients and healthcare professionals. We heard from Dianne Sloan whose husband benefited from medical technology after he suffered a devastating stroke which his surgeon said would normally have either killed him or left him severely incapacitated. Instead, he has had an excellent recovery thanks to mechanical thrombectomy. Former NSW Deputy Premier, John Watkins AM, was diagnosed with Parkinson's disease seven years ago but kept his condition private until earlier this year. He agreed to undergo a seven-hour operation to attach a pacemaker device with leads into his brain, better known as deep brain stimulation, which has had a life-changing impact.

#### PROFESSIONAL DEVELOPMENT

Professional development is an essential way for healthcare professionals to stay up to date on the latest standards, reduce risk and advance better practices in the healthcare environment. The skills and engagement of our workforce is reflected in better medical outcomes for patients, longer staff retention, and greater stability for our industry.

The Operating Theatre Protocols (OTP) course was the most attended facilitated face-to-face training course by MTAA with 257 registrations in the 2017-18 financial year. This year, new ACORN standards introduce changes to direct patient care, handwashing and the aseptic field so a new course was launched in October 2018. This program is key for safety in the operating theatre, as well as best practice knowledge for new and existing medical company representatives. Some hospitals are now asking for the MTAA OTP card as part of their vendor credentialing process, for visitor identification and standards verification.

**1,181**

professionals participated  
in MTAA training courses

**250**

new attendees took part  
in the Introduction to  
Operating Theatre training

**280**

logged in to update their  
Operating Theatre training  
knowledge

**690**

people enrolled in  
Introduction to Code of  
Practice online training







“ Increasing engagement is a way for MTAA to benefit from the best talent the industry has to offer. ”

#### COMMUNICATIONS

MTAA continues to engage and develop strong networks and relationships with key journalists. These relationships have enabled MTAA to be made aware of media stories before they are printed and have allowed MTAA to respond to them proactively, increasing public and stakeholder awareness of the issues that matter to us.

In 2017–18, MTAA issued 24 press releases and was mentioned in 270 separate mainstream media articles. Our social media reach has continued to grow with the number of LinkedIn followers increasing by 860 to 2,236, and our Twitter followers growing by 379 to 1,143 followers.

In March 2018, MTAA launched PulseLine, a digital-first publication dedicated to providing news, commentary and insights on the Australian MedTech and healthcare landscape. PulseLine continues to grow in readership and is now a key distribution channel used by MTAA and members to communicate to the wider Australian MedTech community and decision-makers. MTAA also secured funding from the NSW Department of Industry under its Knowledge Hub Program to support the development of PulseLine content and provide opportunities to showcase the NSW medical device industry to the public. Under this initiative, we developed 10 separate pieces of digital video content from an animated infographic showcasing the NSW MedTech landscape.





## COLLABORATION

# COLLABORATION

WORKING TO UNITE THE INDUSTRY AND ENGAGE A BROADER RANGE OF STAKEHOLDERS IS A WAY TO MORE STRONGLY ARTICULATE AND DEMONSTRATE THE VALUE PROPOSITION OF THE MEDICAL TECHNOLOGY INDUSTRY TO THE AUSTRALIAN COMMUNITY. COLLABORATION STRENGTHENS MTAA ITSELF IN TERMS OF LEADERSHIP, REPRESENTATION AND ADVOCACY, AS WELL AS MTAA'S MEMBERSHIP.

### MTPCONNECT

In 2017–18, MTAA continued to increase our collaboration with MTPConnect, the Australian Government's Medical Technology, Biotechnology, and Pharmaceutical (MTP) Industry Growth Centre. At the MedTech conference in November 2017, we formalised our partnership by signing a memorandum of understanding to work collaboratively to boost the growing MedTech industry in Australia.

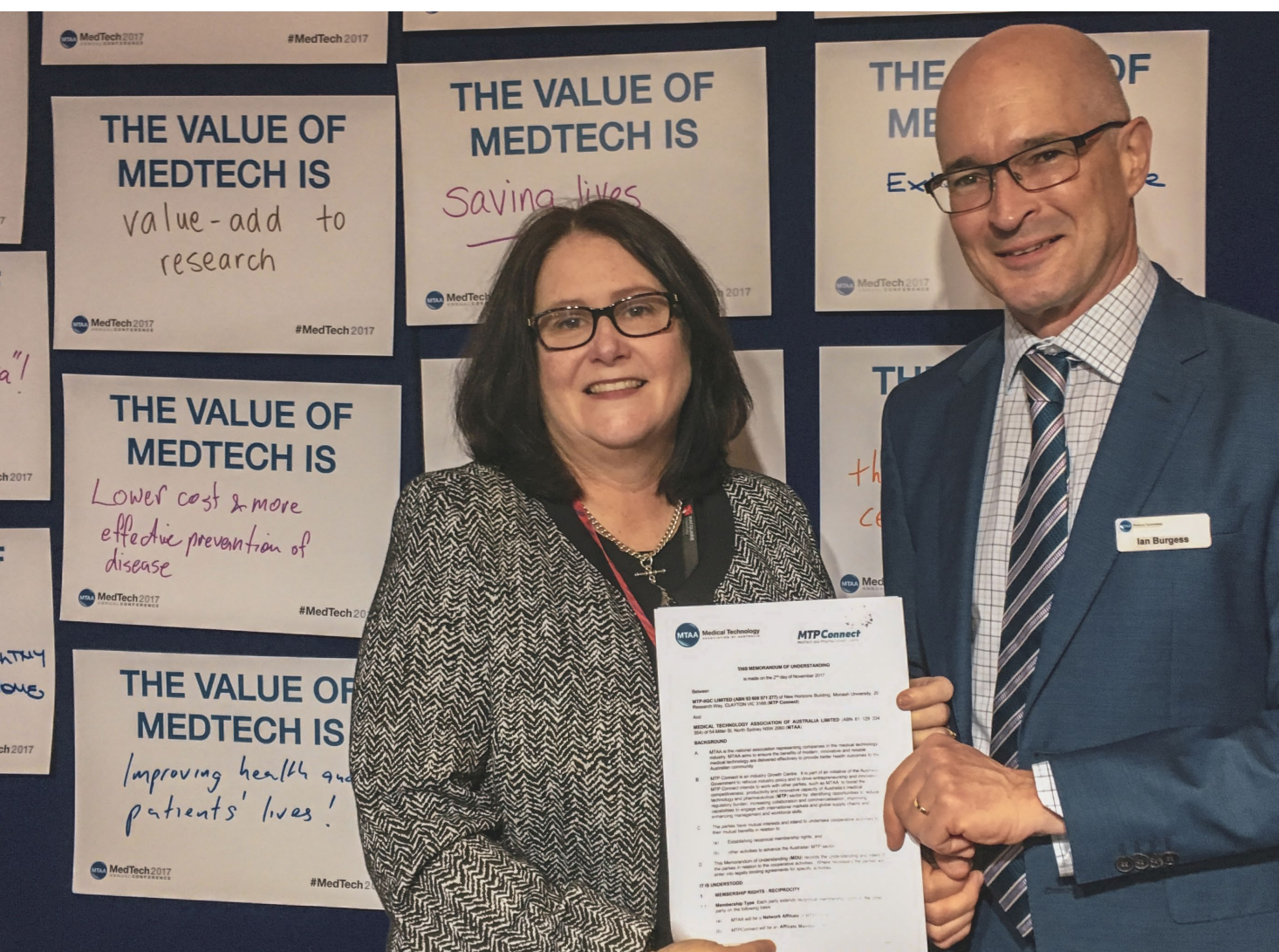
Sue MacLeman, CEO of MTPConnect,

said, "MTPConnect is excited to work closely with MTAA to ensure the continued growth and innovation of MedTech in Australia. Under the direction of its CEO, Ian Burgess, the Medical Technology Association of Australia is set to continue to provide outstanding advocacy on behalf of the sector and those patients set to benefit from its innovative and life-saving outputs."

In April 2018, MTAA, with MTPConnect and the Minister for Health, Greg Hunt MP announced the 11 recipients

of \$10 million investment from the Australian Government's \$35 million BioMedTech Horizons program, which aims to help Australia move cutting-edge ideas and breakthrough discoveries towards proof-of-concept and commercialisation, and stimulate collaboration across disciplines and between the research, industry and technology sectors. \$5 million of this funding was provided by the Government as a direct result of MTAA's Agreement with the Government to reform the Prostheses List.





### BRIDGETECH PROGRAM

The BridgeTech Program is a new professional development program on the commercialisation of medical technology and was formally launched in April 2018.

The BridgeTech Program is open to mid-career entrepreneurs, researchers, business development professionals, IP lawyers, regulatory officers and others in the med-tech ecosystem.

Led by QUT, The BridgeTech Program involves a consortium of partners including MTA, medical technology companies, universities, AusBiotech and other associations.

The first round of the program enrolled 77 participants from around Australia.

### HEALTH HORIZONS

In February 2018, Health Horizon launched an online collection of hundreds of Australian health innovations to unlock the possibility of collaboration on a national scale.

The platform is the first milestone in an MTPConnect-funded project to develop a National MedTech, Pharmaceutical and Digital Health Showcase, the culmination of effort from a consortium of national organisations and industry and academic innovation leaders including MTA, Health Informatics Society of Australia, Medical Software Industry of Australia, Health, Hospital and Health Services IP Ltd, Novartis Pharmaceuticals Australia, Queensland University of Technology and University of Newcastle. The project will provide a 'living' showcase of health innovations in Australia, identifying, cataloguing and tracking in real-time innovations under development in Australia.





#### PEAK BODIES

The CEOs of several health sector associations meet as a group to ensure effective communication and identify issues of common interest and potential collaboration.

Along with MTAA, this group includes Research Australia, Medicines Australia, Australian Self Medication Industry, Complementary Medicines Australia, IVD Australia, Generic and Biosimilar Medicines Association, AusBiotech and ARCS Australia.

Collaboration has included joint advocacy in relation to the Research & Development Tax Incentive, Skilled Migration and support for MTPConnect.

#### AUSTRALIAN CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION IN THE HEALTHCARE SECTOR

MTAA was one of five organisations that led the development of the Australian Consensus Framework, which aims to increase ethical behaviour characterised by values and principles such as honesty, integrity, transparency, accountability and oversight. That work was led by MTAA, the Australian Orthopaedic Association, Medicines Australia, Royal Australasian College of Surgeons and the Australian Healthcare & Hospitals Association.

Subsequently, the framework has been developed with input and collaboration from 60 healthcare entities who are now signatories to the Australian Consensus Framework, including professional health bodies, industry organisations, hospital and health services associations, universities, regulators, patient and advocacy groups, and other related organisations.





#### NSW KNOWLEDGE HUB

MTAA has been collaborating and co-funding projects with the NSW Department of Industry on an annual basis to promote business development in the MedTech sector.

The Department of Industry provides a maximum amount of \$50,000 and MTAA provides in-kind funding of up to \$150,000. In 2017–18, the funds were used to develop an animated infographic along with a factsheet to highlight the value of the industry to the Australian and NSW

economy and our healthcare system. In addition, a range of video content was developed. We worked with the University of Sydney and its biomedical engineering faculty to highlight Stryker's internship program. And we worked with the Vinyl Council of Australia to showcase Baxter's end-to-end recycling program for its PVC materials from hospitals across Australia and to showcase the secondary use of PVC and Baxter's commitment to sustainability. All the content was deployed through MTAA's online digital platform, PulseLine.



## INTEGRITY

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ONE OF MTAA'S KEY STRATEGIC AREAS OF ACTIVITY IS OUR FIRM COMMITMENT TO ETHICAL LEADERSHIP AND INTEGRITY. THIS IS UNDERPINNED AND EVIDENCED BY THE MEDICAL TECHNOLOGY INDUSTRY CODE OF PRACTICE (THE CODE), WHICH IS ADMINISTERED BY THE CODE AUTHORITY AND THE CODE MONITORING COMMITTEE.





**The Code Authority (CA)** meets six times per year and is responsible for oversight and effective administration of the Code including complaints and monitoring.

During 2017-18, the CA undertook an editorial revision of the current MTAA Code of Practice (9th Edition, 1 January 2015) to improve clarity and readability.

The editorial revision of the MTAA Code will be presented for approval by MTAA members at the 2018 Annual General Meeting. As the Code needs to be fully reviewed by members every three years, the Code Authority will proceed with a full review in 2018-19.

In 2017-18, the CA reviewed a total of three complaints. The CA concluded that two of the complaints were not a breach of the Code and the third complaint is pending due to legal matters.

**The Code Monitoring Committee (CMC)** meets five times per year and is responsible for reviewing company monitoring reports to determine compliance with the Code.

Each year the CMC will review approximately 70 monitoring reports from companies who are members of MTAA. The reports provide transparency between MTAA and its members and allow recognition of opportunities to provide education on the Code and support where it is required.

In 2018, the Code Monitoring Committee reviewed companies' responses to how they ensure they are meeting the provisions relating to Comparative Advertising (clause 8.4), Arrangements with Healthcare Professionals acting as Consultants (clause 9.8) and company representatives (clause 10).





## FINANCES

# FINANCES

THE FINANCIAL OPERATING RESULTS REFLECT THAT MTAA ACHIEVED A NET PROFIT OF \$497,189 FOR THE TWELVE MONTHS TO 30 JUNE 2018.

The favourable result achieved was ahead of Budget, FY18 Forecast and the prior year primarily due to increased membership income, Annual Conference Income and Other Event Income, revenue received from the Payroll Tax exemption (\$175k) and higher interest income earned on Term Deposits. The result reflects strong financial management and cost control.

The Balance Sheet reflects a strong financial position and

net assets of \$1,467,550 reflect an increase since the prior year. This is primarily due to the increased levels of cash from operating profit.

The Statement of Cash Flows reflects a strong cash position and an improvement on prior years due to profits returning to retained earnings at 30 June, cash received from the Payroll Tax refund and the levies for Prostheses List and Radiation Therapy sector members.



“ At the heart of MTAA’s work is a patient-centred approach, putting the needs of patients foremost, involving them in healthcare decisions and finding ways for patients to get better, look after themselves and stay independent.”



MEMBERSHIP

## MEMBERSHIP

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MTAA EXISTS TO SERVE THE NEEDS OF MEMBERS. THESE NEEDS DRIVE PLANNING EVERYTHING FROM SERVICE LINES OF THE ORGANISATION TO ADVOCACY AND PROFESSIONAL DEVELOPMENT COURSES.



## BOARD OF DIRECTORS



### **Gavin Fox-Smith (Chair)**

*B.Sci (USyd), Grad Cert Mktg (CSU), MBA (Deakin) AFAMI, CPM, GAICD*

Vice President – Global Education Solutions, Johnson & Johnson Medical Devices, Asia Pacific. With more than 30 years' experience in the medical devices industry, including 21 years at Johnson & Johnson, Gavin has an extensive background as a senior executive in the Asia Pacific region. Gavin was recently appointed Vice President for Johnson & Johnson Medical Devices Asia Pacific, leading Global Education Solutions. Prior to this, he was Managing Director of Johnson & Johnson Medical Devices for Australia and New Zealand, a role he held for six years. He is a member of the Johnson & Johnson Medical Devices Asia Pacific Regional Leadership Team.

As Chair of MTAA, Gavin helped to shape industry dialogue with Government and ensure stable and beneficial policy settings for the industry, customers and patients into the future. Gavin's philosophy of collaboration and service extends to community. He is a passionate advocate for efforts that improve health, literacy and education, particularly for Indigenous communities. Gavin is a Governor of the American Chamber of Commerce, a member of the Male Champions of Change in STEM and an ambassador for Bowel Cancer Australia and Rotary Oceania Medical Aid for Children. Gavin joined the Board in April 2012 and was elected Chair in December 2014.



### **Rebecca Cortiula**

*B.Sc (UTS), MBA (AGSM), MAICD*

Managing Director, Terumo Australia Pty Ltd.

Rebecca has been working within the Australian healthcare system for more than 20 years. Prior to joining Terumo, she worked within the Australian hospital system as a hospital scientist in scientific areas including biochemistry, microbiology, haematology and blood banking. She also worked for the Australian Red Cross Blood Service in the serology laboratories. Rebecca has a broad range of experience, with the specialty areas laboratory science, cardiovascular surgery, interventional radiology and cardiology, transfusion, and general hospital medical devices, both consumables and capital equipment.

Rebecca joined the board in November 2015 and was elected Vice-Chair in December 2016.



### **Steven Flynn**

*BEng, Mech, Grad Dip Management, MEI (Swinburne)*

General Manager, Australia/New Zealand, Baxter Healthcare

Steven is responsible for over 1,100 employees and oversees a significant commercial, manufacturing and compounding pharmacy footprint across Australia and New Zealand. As the current Vice-Chair of the MTAA board, Steven has ensured that Baxter is active in advocating directly for the MTAA policy platform to deliver benefits to the entire membership. Since 2006, Steven has held senior executive roles in Baxter Australia, New Zealand and Asia Pacific. Prior to working in health care, Steven worked at TNT and GM Holden Limited.

Steven joined the board in November 2015 and was elected Vice-Chair in 2017.

## BOARD OF DIRECTORS



### **Maurice Ben-Mayor**

*B.SC (UNSW), Exec MBA (AGSM)*

President, Stryker South Pacific

Maurice has over 20 years of experience in the MedTech industry across senior roles in sales, management, marketing and market access. Maurice has been at Stryker for 15 years and is currently the President of Stryker's South Pacific division.

Maurice joined the board in December 2016.



### **Lyn Davies**

*Dip Bus Mgt, PERSA, AMACs, MAICD*

Managing Director, Tunstall Australasia Pty Ltd

Commencing with Tunstall in October 2004, Lyn is a seasoned executive with over 25 years in senior leadership roles across the private and public sectors. Prior to Tunstall, Lyn had worked with well-known organisations such as Logan City Council, Mater Hospitals QLD and CITEC Queensland State Government.

Lyn joined the Board in December 2013.



### **Andrew Fox-Smith**

*B.Bus (Charles Sturt), AMP (Harvard), AICD*

Chief Executive Officer & Director, Global Orthopaedic Technology Pty Ltd

Andrew has over 20 years' experience in the medical technology industry and brings broad experience from senior jobs in both multinational corporations and Australian small and medium-sized enterprises. Andrew was previously Chairman at Optimized Ortho up until its acquisition by Corin and prior to that was Group President International for Stryker where he also sat on the Executive Committee. He joined Global Orthopaedic in July 2014 when he led a management buy-in with other investors.

Andrew joined the board in April 2017.



### **Matthew Muscio**

*B.Bus (QUT), Melbourne Business School,  
Post-Graduate Degree in Management*

Chief Executive Office, LifeHealthcare

Matthew has 18 years' experience in the medical device industry across sales, marketing and management functions for private, multinational and ASX-listed entities. He is Chief Executive Officer of LifeHealthcare and prior to this held the position of Chief Operating Officer from 2013, responsible for the company's sales, marketing and commercial operations, playing a key role in LifeHealthcare's initial public offering in December 2013. Prior to LifeHealthcare, Matt spent 13 years working with Johnson & Johnson Medical's orthopaedic business DePuy Synthes, leading their spine and neurological surgical divisions.

Matthew joined the board in November 2017.



### **Samih Nabulsi**

*PhD Mechanical Engineering/Material  
Science (QU). MEng Research, Mechanical  
Engineering (QU), BSc Mechanical  
Engineering, University of Sussex*

General Manager – Cook Medical Australia

Samih has worked in the medical device industry for 20 years, both internationally and in Australia, and has led the development of innovative medical solutions through in-house R&D, the growth of domestic and international partnerships, collaborations with research partners and the development of new technologies with industry leaders. An engineer and scientist by training, he holds a PhD in engineering combined with an extensive and practical background in the medical device industry.

Samih joined the board in November 2017.



### **Vassie Ponsamy**

*B Comm, Diploma in Engineering*

Managing Director, Smith & Nephew Pty Ltd,  
Australia and New Zealand (ANZ)

Vassie joined Smith & Nephew in July 2014 as Regional Managing Director for Sub-Saharan Africa. Prior to Smith & Nephew, he was Managing Director, Middle East and Africa for Getinge Healthcare and before this, Executive Director, International Business for AECL and Managing Director, Africa Region for GE Healthcare. He has extensive experience across many industries around the world, including in Africa, the Middle East, South America, South East Asia and Australia.

Vassie joined the Board in January 2018.



## BOARD OF DIRECTORS



### **Craig Stamp**

*Bachelor of Optometry (UNSW) and a Graduate Diploma in Marketing*

General Manager, Device Technologies

Craig has over 25 years of experience in health care, pharmaceuticals and medical devices in Australia and Asia. He has held senior leadership positions at Allergan and Bausch & Lomb where he was Managing Director and VP Commercial Operations, Asia-Pacific. He has also served as CEO and Managing Director at a publicly listed company, Vision Group Holdings Ltd, a former ASX-listed company which is now privately held.

Craig joined the board in November 2017.



### **Mark Taffa**

*B.Bus (CSU)*

Managing Director, Horten Medical Pty Ltd

Mark is the founder and Managing Director of Horten Medical, a company distributing medical devices, established in 2005. Actively involved in the healthcare industry for over 15 years, Mark has worked with both large multinationals and small businesses. At GE Medical, Mark had product responsibility for all of Asia in digital imaging, which included living in Singapore and consulting to the Brunei government on e-health. Mark also has experience in running small-scale local manufacturing of complex medical equipment for local and export sales.

Mark joined the board in December 2013 and was Vice-Chair until November 2017.

## FORMER BOARD OF DIRECTORS

### Michele Blanshard

*Griffith University, Bachelor of Health Science.  
Macquarie University - Graduate School of  
Business, MBA.*

Country Director for Diabetes, ANZ,  
Medtronic

Michele is a member of 2 NFP Boards. She has a unique insight into one of the region's greatest health priorities. Responsible for all business initiatives across Australia & New Zealand, Michele knows what's important in addressing Diabetes – now and in the future. Member of the Medtronic Australia Executive Leadership Team and an Executive Sponsor of the Medtronic Women's Network. Prior to joining Medtronic, she held senior sales, marketing and product roles at Johnson & Johnson including Global Product Director and Asia Pacific Marketing Manager, as well as ran her own business.

Michele joined the board in November 2017 and resigned in May 2018.

### Paul Braico

*B.Eng. (UNSW), MBA (MGSM), GAICD*

Vice President and Managing Director,  
Boston Scientific

Paul has 30 years experience in the medical technology industry, working in diverse organisations including Australian manufacturing, medical equipment, medical distribution, and medical device multinationals. Prior to his current role, Paul has held several senior leadership roles in Australia and Japan.

Paul joined the board in June 2012 and resigned in November 2017.

### Tanja Brycker

*Post Grad Dip Marketing & Business (UTS),  
General Management Program (AGSM), GAICD*

Managing Director & General Manager,  
Teleflex Medical Australia & New Zealand

Tanja has been involved in the Australian Healthcare industry for over 30 years, contributing as a registered nurse, midwife and intensive care nurse specialist for 12 years. For the past 20 years Tanja's involvement in MedTech has evolved through sales, marketing and general management where she spent 16 years building up an Australian owned family business, Mayo Healthcare until it was acquired by Teleflex Medical in 2014.

Tanja joined the board in August 2016 and resigned in October 2017.

### Andrew Wiltshire RN (Qld)

*BA (Media Studies) Griffith, MBA (UNE), GAICD*

Senior Director, Corporate Affairs, Medtronic  
Australasia Pty Ltd

Andrew has over 20 years experience in the Australian medical technology and pharmaceutical sectors. As Senior Director, Corporate Affairs Andrew is actively engaged in efforts to positively promote industry to government, healthcare providers and the community for appropriate access to medical technologies. He oversees Medtronic's government affairs, PR, quality, regulatory and reimbursement initiatives in Australia and New Zealand.

Andrew joined the board in October 2013 and resigned in November 2017.

### Emma Cleary

*B.Bus (Deakin), ICAA, MAICD*

Chief Operating Officer, Device Technologies  
Australia Pty Ltd

Emma has over 25 years experience within the Medical Device, Managed Services, Professional Accounting and other industries, Emma has held a number of senior management roles both in Australia and overseas. Emma is a Chartered Accountant and joined Device Technologies as CFO in 2005. In addition to her group financial management responsibility, Emma is also responsible for the global operations of Device Technologies. More recently, Emma developed and launched Device Solutions, the Managed Services division of the company that focusses on improving patient diagnostics and care through the use of digital technology. Prior to joining Device Technologies, Emma held leadership positions with Pioneer International, Tenix Group, Ericsson and Bosch across Asia and Australia.

Emma joined the board in October 2013 and was Vice Chair between December 2014 and December 2016. She resigned in November 2017.

## COMMITTEES

As part of the MTAA Strategic Plan 2017–2020, several committees and sub-committees were abolished and replaced with member forums focused on special interests. It was decided that by jettisoning the old committee structure, and opening forums to all members and associate members, it would increase opportunities for companies of all types to engage with MTAA. Plus, reforming the MTAA committee system provides more effective decision-making and greater engagement. Four new Strategic Committees were created including a new Public Affairs Committee to provide oversight of the three policy and regulatory committees to ensure that MTAA's communications and government affairs are coordinated for maximum impact. The Regulatory Affairs Committee and Sub-Committee were replaced with a single Regulatory Affairs Committee. The Reimbursement and Access Committee and Sub-Committee were replaced with a single Reimbursement Committee. The Industry Policy Committee is a newly created committee that seeks to capture issues outside the remit of the other committees. As described above, a new form of engagement was created, known as the Member Forum, and open to all member company representatives who choose to attend.

### PUBLIC AFFAIRS COMMITTEE

The Public Affairs Committee (PAC) is the most senior MTAA Committee and provides oversight of the Reimbursement, Regulatory and Industry Policy Committees to ensure a coordinated and aligned strategy and communications. PAC sets the advocacy direction for the MedTech industry with relevant stakeholders across key areas in healthcare policy, reimbursement, regulatory and industry development. The objective for the past financial year has been the development and implementation of an advocacy program which includes active stakeholder engagement to promote the policy positions and strategic issues identified by their Committees. PAC has also overseen the successful launch and implementation of PulseLine, the new digital platform that provides insights for the Australian MedTech sector.

As a new Committee that merged the previous Government Affairs and Access Committee, PAC met four times in 2017–18. Its key deliverable was the development of a comprehensive advocacy strategy that included key priorities, messaging and implementation plans. It has also been involved in providing direction to the industry on private health insurance reform including making several submissions to both a Senate inquiry and the Department of Health. It was also involved in the Canberra events described above, including two days of doorknocking in Parliament that involved over 20 individual one-on-one meetings with MPs, Senators and Senior Advisers.



### REIMBURSEMENT COMMITTEE

The role of the Reimbursement Committee is to promote funding and reimbursement pathways for medical devices to enable timely access to these technologies in the public and private markets.

The committee met four times in 2017–18 with its work primarily focused on supporting the implementation of the MTAA-Government Agreement. The committee's achievements include:

- Developing the terms of reference for the three Industry Working Groups under the Agreement
- Developing options for undertaking Prostheses List benefit reviews, reforming how benefits are set under the Prostheses List, and expedited pathways to listing on the Prostheses List
- Identifying issues with the operation of the existing Prostheses List framework to improve clarity, transparency, consistency of decision-making and reduce duplication between Health Technology Assessment Bodies
- Identifying options for broadening access to cost-effective technologies that do not meet the criteria for listing on the Prostheses List.

### INDUSTRY POLICY COMMITTEE

The role of the Industry Policy Committee (IPC) is to promote initiatives which impact on the development and sustainability of the industry and health care. This Committee was newly established in January 2018 under the MTAA Strategic Plan to enable input from the industry on these issues. The committee met three times to 30 June 2018 and identified an ambitious workplan to enable the industry to be well-placed to engage in shaping policy on emerging issues such as digital

healthcare and cybersecurity, as well as in initiatives to support SMEs such as through the reforms to the R&D Tax Incentive and the SME grant elements of the MTAA-Government Agreement. The IPC also provided guidance on the industry environment to enable the Public Affairs Committee to develop its advocacy strategy.

### REGULATORY AFFAIRS COMMITTEE

The Regulatory Affairs Committee (RAC) meets eight times per year, before and after each of the four TGA RegTech meetings each calendar year. RAC is responsible for formulating MTAA positions and the strategic direction of MTAA on regulatory matters within the scope of the Therapeutic Goods Act, the Medical Devices Regulations and the Advertising Code. RAC drives MTAA advocacy on all regulatory reform issues. During 2017–18, the advocacy work of RAC included:

- Progressing the regulatory framework for personalised medical devices including 3D-printed medical devices to ensure a level playing field between the MedTech industry and other entities engaging in mass production of patient-specific devices such as 3D-printed orthopaedic implants.
- Ensuring that patient information leaflets for implants, required to be handed out to patients as part of informed consent, can be provided in electronic format on a company's website.
- Contributing to TGA guidance documents on electronic instructions for use (eIFU), on designation of Australian conformity assessment bodies, and on wider use of market authorisation evidence from comparable overseas regulatory bodies.
- Coordinating membership feedback to the revision of the Therapeutic Goods Advertising Code and related guidelines.

## MEMBER FORUMS

The **Regulatory Forum (RF)** meets at least four times per year, with additional ad hoc meetings as requested. The RF raises awareness on regulatory issues that members face in their day-to-day work. The RF represents an opportunity for members to interact and exchange ideas, discuss specific topics of interest, and provide an opportunity for learning and development for professionals starting in regulatory roles.

The **Clinical Investigations Forum (CIF)** meets six times per year with additional ad hoc meetings as requested. The CIF provides an opportunity to members who share an interest in advancing clinical investigations in Australia to discuss, share information, network and consult, and to progress relevant issues. With the new MTAA committee structure, the Industry Policy Committee will now be responsible for policy development in relation to clinical trials. Among the CIF activities during 2017–18 were monitoring of and engaging with national

initiatives in the clinical trials space, and participating in and contributing to relevant state initiatives.

The **Orthopaedic Forum** offers MTAA orthopaedic members the opportunity to discuss and address issues of mutual interest and concern. The orthopaedic sector is vibrant and innovative, and the forum provides members with a medium to address the dynamics of their environment. The forum meets quarterly and is open to membership by all MTAA orthopaedic companies. Currently, 14 companies participate. Activities during 2017–18 include regular representative meetings with the Australian Orthopaedic Association when issues of combined interest are discussed and addressed, and a move towards the re-establishment of the Orthopaedic Market Survey covering hips, knees, shoulders, spine, trauma and sports medicine products. A working group has progressed preparation and planning to the point where it is expected that the market survey will be operational in early 2019.

The **Ophthalmic Forum** was established by the Board at the request of member companies in April 2018. The Forum will progress issues of common interest and will initially undertake an analysis of the value to patients and Government of accessing ophthalmic devices through the Prostheses List. The Forum will also undertake advocacy to communicate with and educate the Government on the economic and health benefits generated by the ophthalmic device industry.

The **Radiation Therapy Advisory Group (RTAG)** is an alliance of cancer patient advocates, healthcare providers, medical technology vendors and oncology professionals, who are aligned in their desire to raise the profile of radiation therapy and ensure it is adequately funded by government by providing highly informed and expert advice. Radiation therapy and the many different specialised treatments it involves are not always simple to understand. RTAG's initial focus

is on highlighting the lack of access to radiation therapy in regional and rural Australia. RTAG also offers advice and information on a range of relevant issues to the sector and how radiation therapy affects cancer patients and communities.

### **This year there will be over 130,000 new diagnoses of cancer in Australia**

The **role of radiation therapy in palliative care** and **pain relief** for cancer patients is **crucial**

1 in 2 cancer patients **should receive radiation therapy** but only 1 in 3 do so

**Several regional areas** are also **underserved** by the capacity of existing treatment centres

**Significant regional population centres** such as NSW South Coast, Gladstone, Sunraysia, Shepparton, Mt Gambier and Broken Hill **do not have radiation therapy services**



## COMMITTEE MEMBERS

### PUBLIC AFFAIRS COMMITTEE

Maurice Ben-Mayor (PAC Chair)	Stryker
Paul Davies (IPC Chair)	Abbott
George Faithfull (RAC Chair)	Stryker
Michael Simmonds (Reim Chair)	Boston Scientific
Carolyn Cameron	Allergan
Robyn Chu	Alcon
Fraser Cleave	LifeHealthCare
Libby Day	Baxter Healthcare
Carey Jackson	Johnson & Johnson Medical
Will Knox	Device Technologies
Natalie Lawandi	Medtronic
Michael Reynolds	Biotronik
Mark Taffa	Horten Medical
Emily Williams	Cook Medical

**Resigned committee member:** Jim Crompton Johnson & Johnson Medical

### REIMBURSEMENT COMMITTEE

Michael Simmonds (Chair)	Boston Scientific
Sarah Botros	Stryker
Michelle Costa	Johnson & Johnson Medical
Sheryl Dunlop	Zimmer Biomet
Laurence Fong	Smith & Nephew
Sarah Griffin	Medtechnique Consulting
Kevin Guinee	Bard
Peggy McBride	St Jude Medical
Kieran Murphy	Nevro
Georgia Psarros	Baxter Healthcare
Rebecca Schnabel	Allergan
Doug Symonds	Medtronic
Rachael Todd	LivaNova

### INDUSTRY POLICY COMMITTEE

Paul Davies (Chair)	Abbott
Alex Best	Johnson & Johnson Medical
Matthew Malone	Stryker
Juliet Spencer	3M

#### Resigned committee members:

Jim Crompton Johnson & Johnson Medical  
 Ross Lane Cook Medical  
 Todd Pironis Stryker  
 Tamara Searant Medtronic  
 Robert Webb Cook Medical

### REGULATORY AFFAIRS COMMITTEE

George Faithfull (Chair)	Stryker
Jason Aldworth	3DMEDITEch
Katie-Lou Buscher	Cook Medical
Hugh Cameron	BD
Renee Cotta	Boston Scientific
Mahesh Datar	Medtronic
Cheryl Davey	Alcon
Kea Dent	KD&A
Laleetha Devi	Halyard Australia
Rebecca Gaudin	Johnson & Johnson Medical
Sue Hunter	Abbott/St Jude
Suhayl Khan	AMSL
Meryl Musson	Edwards Lifesciences
Ruth Shennan	Device Technologies
Samantha Tham	Smith & Nephew
Falko Thiele	Biotronik
Elizabeth Van Den Akker	Abbott Vascular
Fleur Winslade	Terumo

## CODE AUTHORITY

Paul Gibbeson (Chair)	Independent
Hugh Cameron	Becton Dickson
Dawn DeCruz	Allergan
Steven Flynn	Baxter Healthcare
Andrew Fox-Smith	Global Orthopaedic Technology
Henry Ko	Consumer Health Forum
Carol Mazzella	Stryker
Jason Neal	W.L. Gore
John Quin	Royal Australasian College of Surgeons
Dean Taylor	LifeHealthcare
Michelle Wagner	Johnson & Johnson Medical

## FINANCE COMMITTEE

Craig Stamp (Chair)	Device Technologies
Matt Muscio	LifeHealthcare
<b>Resigned committee member:</b> Kerry Lawson Baxter Healthcare	

## MEDTECH CONFERENCE COMMITTEE

Samih Nabulsi (Chair)	Cook Medical
Donna McCann	Medtronic
James Boyce	Johnson & Johnson Medical
Emily Williams	Cook Medical
<b>Resigned committee members:</b>	
Michele Blanshard Medtronic	
Charlotte Hart LifeHealthcare	

## CODE MONITORING COMMITTEE

Paul Gibbeson (Chair)	Independent
Leonardo Cevallos	Cook Medical
Nadine Crimson	Alcon
Pam Davis	Independent
Trent Enright	Terumo
Mark Flynn	Independent
Megan Guy	Independent HCP
Glen Mason	Johnson & Johnson
Jennifer Mew-Sum	Medtronic
Chloe Meyer	Smith & Nephew

## WOMEN IN MEDTECH

Rebecca Cortiula (Chair)	Terumo
Lyn Davies	Tunstall Australasia
Lauren Goodridge	Zimmer Biomet
Sauming Ho	Varian
Nicki Luther	Stryker
Belinda Ramirez	Medtronic
Samantha Russell	3M
Katrina Symons	Johnson & Johnson Medical
Glenn Whittaker	Device Technologies
<b>Resigned committee member:</b> Glenn Whittaker Device Technologies	

## MTAA MEMBERS

MTAA MEMBERS
3DMEDiTech
3M Healthcare Pty Ltd
Abbott (Vascular) Australasia Pty Ltd
Abbott Vision (AMO Australia Pty Ltd)
Admedus (Australia) Pty Ltd
Alcon Laboratories (Australia) Pty Ltd
Allergan Australia Pty Ltd
AlphaXRT
Analytica Ltd
Australasian Medical & Scientific Ltd
Australian Dermatology Equipment P/L
B Braun Australia Pty Ltd
Bard Australia Pty Ltd
Baxter Healthcare Pty Ltd
Becton Dickinson Pty Ltd
Biotronik Australia Pty Ltd
Boston Scientific Pty Ltd
Brainlab Australia Pty Ltd
ConMed Australia
Cook Australia
Corin (Australia) Pty Ltd
Culpan Medical Australia Pty Ltd
Deutsch Medical
Device Technologies Australia Pty Ltd
EBR Systems
Edwards Lifesciences Pty Ltd
Elekta
Fresenius Kabi Australia Pty Ltd
Gel Works Pty Ltd
Global Orthopaedic Technology Pty Ltd
Grey Innovation
Halyard Australia
Hologic (Australia) Pty Ltd
Horten Medical
iNova Pharmaceuticals (Australia) Pty Ltd

MTAA MEMBERS
Johnson & Johnson Medical Pty Ltd
Keystone Healthcare Supplies
KLS Martin Australia Pty LTD
Laminar Air Flow Pty Ltd
LifeHealthcare Pty Ltd
LivaNova Australia Pty Ltd
Materialise Australia P/L
Matrix Surgical Pty Ltd
Medacta
Medical Specialties Australia Pty Ltd
Medigroup Australia Pty Ltd
Medtronic Australasia Pty Ltd
Molnlycke Healthcare
Nevro Medical Pty Ltd
NL-Tech
Olympus Australia Pty Ltd
Paragon Therapeutic Technologies
Powervision Inc
Prism Surgical Designs Pty Ltd
REM Systems Pty Ltd
Sirtex Medical Limited
Smith & Nephew Pty Ltd
Smiths Medical Australasia Pty Ltd
Spectrum Surgical Pty Ltd
St. Jude Medical Australia Pty Ltd
Stryker Australia Pty Ltd
Surgical Specialties Pty Ltd
Teleflex Medical Australia Pty Ltd
Terumo Australia Pty Ltd
Tomi Australia Pty Ltd
Tunstall Australasia Pty Ltd
United Healthcare Imaging
Varian Medical Systems Australasia Pty Ltd
W. L. Gore and Associates (Aust) Pty Ltd
Wright Medical Australia
Zimmer Biomet

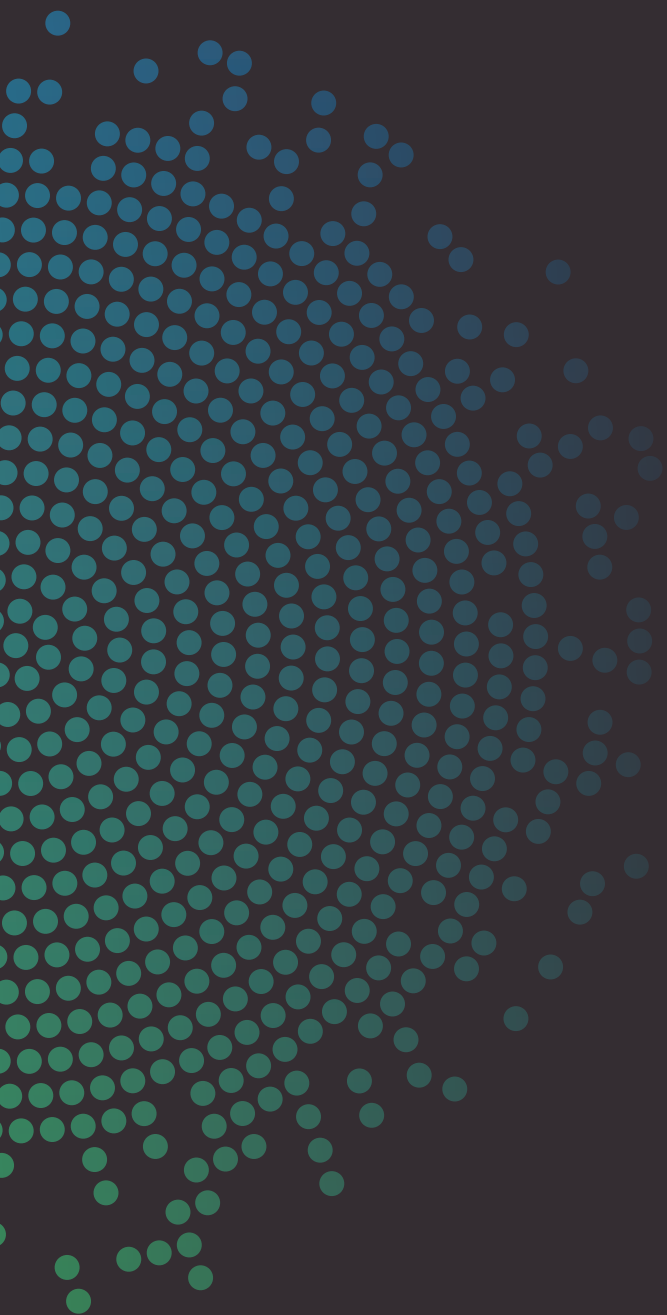


**MTAA ASSOCIATE MEMBERS**

Atkinson Vinden Lawyers
Bizcaps Software
Brandwood Biomedical Pty Ltd
Cancer Care Associates
Certification Body Australia
Circuitwise Electronics
Clinical Research Corporation
Covance Pty Ltd
Cutlass Pharmed Regulatory Services
Dentons (previously Gadens)
DHL Supply Chain (Australia) Pty Ltd
Elementum Advisory
Evolution Clinical
Five Corners Pty Ltd
GenesisCare
Healthcare Placement Solutions Pty Ltd
hTrak Pty Ltd
ICON Cancer Care
IDE Group
Illuminate Health Consulting Pty Ltd
Insight Strategy
KD&A
Lucid Health Consulting
Medtechnique
MTP Connect (Affiliate)
NetDimensions (Australia) Pty Ltd
Oliver Healthcare Packaging
Open Sesame Consulting
Regulatory Concepts Pty Ltd
SJ Alder Pty Ltd
Slate Hill Consulting Pty Ltd
Smartways Logistics
Sue Akeroyd & Associates
The SPD Company Pty Ltd
The University of Newcastle

**MTAA HONORARY MEMBERS**

Ms Pam Davis
Mr Stephen Fogarty
Mr Barry Jones
Mr Graham Murphy
Mr Bernard O'Connor
Mr Brian Vale
Mr John Whiteford
Mr Peter Ord
Mr David Ross
Mr Gordon Stenning



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