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Building from a solid foundation:

The future of medtech in Australia

ACKNOWLEDGEMENT OF COUNTRY

RSM Australia acknowledges the Traditional Owners of the lands and waters on which we live and work. We pay respect to Elders past and present as the custodians of their culture and continuous connection to Country.

Artwork entitled "Koora-Benang-Bidi" by Michelle Kickett depicts Perth's waterways symbolising RSM's establishment on Whadjuk Country over 100 years ago, and captures the firm's growth across six states and territories of Australia.

Foreword

Australia has an opportunity to lead in many areas, one of which is the rapidly-growing medtech sector. Medtech already accounts for $5.4 billion of our GDP[1], a figure that is set to rise over time. Of course, this is as long as the already-secure foundations below the sector continue to receive support and prioritise innovation.

This report explores the Australian medtech sector, examining its current and future needs, as well as the barriers, challenges and the opportunities it is facing. It was prepared following interviews with local medtech leaders and drawing on a range of industry sources.

We have prepared the report to raise the profile of this important sector. Our hope is it will spark conversations to help further develop the sector and encourage interest and curiosity in a potential powerhouse for the Australian economy.

Mathavan Parameswaran
National Leader, Technology
RSM Australia

[1] The Value of Medtech Report, 2023, Medtech Association of Australia, p2

Key findings and recommendations

Below is a summary of the main report findings.

- Given the challenges to commercialise medtech innovations, funders working closely with other partners will assist aspiring medtech success stories to understand the potential for their innovations, the markets they address and returns that may be achieved.
- To aid with the above and noting that the National Reconstruction Fund (NRF) is designed to support the commercialisation of Australian innovation and technology, the NRF should help foster more partnerships between researchers, universities and funders.
- There is a need for more talent in the medtech industry. With the above initiatives, the medtech industry can prosper allowing the industry to attract more talent. In particular,the greater collaboration will provide confidence to international talent to make the move to work within the Australian medtech industry.

These initiatives will help Australia to encourage successful home grown medtech leaders to scale and grow the sector.

The scope of the local

Australia's medical technology – medtech – sector has a long and vibrant history and a stellar pedigree, with global healthcare leaders including hearing specialist Cochlear and medical equipment company ResMed having roots in Australia.

"Life sciences have had a higher profile since the COVID-19 pandemic. This is generating many opportunities for companies in the medtech industry. There are more people interested in working in the area and more people are interested in funding projects in the area. This is providing real momentum for the industry

Dr Rita Choueiri
National Director – Life Sciences, RSM Australia

The tools and devices covered by the term medtech include a wide range of technologies such as diagnostic machines, implantable devices, assistance technologies, surgical tools, consumables and software[2].

A diverse range of businesses operate in the medtech sector. At one end, there is an exciting range of early stage ventures. These entities need investment at the right time in their development to build their capacity. This funding is vital to support clinical trials, grow market share and invest in manufacturing. This will allow them to generate revenue to attract investment and do further R&D. At the other end of the scale is a range of mature, ASX-listed healthcare equipment and services businesses, with a combined market capitalisation of $139 billion[3]. As this shows, the public markets are a reliable source of funds for investment-grade medtech businesses.

The medtech sector benefits from extensive integration and collaboration between tertiary institutions and clinicians, medical institutes, healthcare providers and industry players of all sizes and levels of maturity. There are also many connections between the global and local medtech sectors, which supports an essential cross pollination of ideas across the worldwide health sector.

As a result, the Australian medtech sector is supported by a substantial innovation pipeline, a comprehensive body of locally registered intellectual property assets and ongoing clinical trials. All this activity can only take place thanks to a highly skilled workforce.

[2] The Value of Medtech Report, 2023, Medtech Association of Australia, p1
[3] The Value of Medtech Report, 2023, Medtech Association of Australia, p44

"We have access to world class researchers, facilities and universities. We also have a stable economic climate, political climate, we are English-speaking and accessible to the world. This is an ideal foundation for the medtech sector to build on," says Choueiri.

Importantly, the rise of medtech supports better health outcomes for Australians and a more effective, efficient healthcare system.

"Medtech innovation has the potential to significantly change patient care delivery pathways, impacting patient flow across the health sector and patient choice

Jayesh Kapitan
National Leader – Health Services, RSM Australia

The difficult COVID-19 pandemic years have been a galvanising force behind medtech. The entire health ecosystem came together to address the threat to global health. Governments, researchers, health providers and tertiary institutions worked alongside each other to achieve incredible outcomes in very short time frames. Advancements involving medical technologies, such as personal protective equipment, diagnostic test kits and ventilators, quickly entered everyday parlance and was key to overcoming barriers. During this period, models for collaboration were quickly developed across the global health sector.

At the same time, these years brought Australia's sovereign capabilities, such as our ability to respond to health emergencies, our manufacturing capabilities and supply chain resilience into sharp focus. Consequently, there's now considerable emphasis on reinforcing these areas for the future. This is supporting what amounts to a boom in medtech across the country and around the world.

With such strong credentials and supporting infrastructure, there is scope for Australia to turbo-charge its medtech sector to create a significant and sizeable global industry and help bring important devices to market faster.

"There's capacity for Australia to develop a medtech equivalent to Silicon Valley here. This would involve the federal government investing in building a centre of excellence, pulling together universities, hospitals, clinicians and high-end manufacturers in one place. Developing such a precinct would underwrite greater collaboration and help attract the world's best talent to our shores," says Kapitan.

There's a precedent for this in other industries, for instance Melbourne's Biomedical Precinct (Parkville) for health services and Adelaide's Lot 14 for technology.

The definition of medtech

The term medtech covers a range of technologies, including medical hardware and software. These technologies may be used to diagnose, prevent, monitor, predict, treat or alleviate disease or other health concerns.

Medtech facts and stats (FY21/22)[4]

Accounts for **51,000** jobs across the economy

Produces gross annual revenue of **$11.4 bn**

Contributes **$5.4 bn** to GDP annually

Contributes to **$1.9 bn** in exports annually

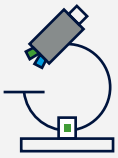
More than **$1 bn a year** invested by governments in health and medical research

851 Australian medtech manufacturers

71% of local medtech companies manufacture locally

4,169 new device registrations in 2022

56%
of Australian medtech companies do local clinical trials



65%
of medtech companies collaborate with universities and research institutes

64%
find it hard to employ good talent

[4] The Value of MedTech Report, 2023, MedTech Association of Australia, p2

The regulatory landscape

Australian boasts a robust regulatory framework around its medtech sector, with the Therapeutic Goods Administration (TGA) and the Australian Register of Therapeutic Goods at its centre. The Medical Technology Association of Australia (MTAA) is an active professional body, advocating for its members in a range of forums and publishing extensive research.

The TGA plays a central role in international regulatory harmonisation, which is a focus for the sector given the more markets in which a product has secured regulatory approvals, the greater the economies of scale. This has multiple benefits including lower cost of production, allowing new health tech to be accessed by more people, leading to a healthier world.

It's worth noting health regulations in Australia tend to follow Europe's. In 2021 the range of applications on the ARTG that can rely on decisions by European health regulators was expanded[5], an important step in the harmonisation process.

In a proactive step, the TGA has published an action plan to improve the regulatory structure around medical devices, while maintaining quality and safety standards[6].

The MTAA suggests[7] the TGA has a role to play developing regulatory dossiers for local and international contexts to help streamline the approval process around new medtech products and services.

Supporting advanced manufacturing

The development of a local advanced manufacturing sector is essential to medtech's ongoing success and there is substantial work taking place around this.

The national push to develop Australia's advanced manufacturing capabilities is also part of the shift to industry 4.0, which involves the integration of technology and manufacturing, incorporating emerging areas such as 3D printing. Its vital substantial emphasis continues to be placed on the development of manufacturing capabilities. A range of institutions and programs are likely to play a role, including the National Fabrication Facility, which gives researchers access to the latest fabrication technologies and the National Collaborative Research Infrastructure Capability, a program that manages Australia's national research infrastructure. This support will enable medtech firms to enhance their production capabilities and build expert skills.

The National Reconstruction Fund[8] (NRF), a $15 billion investment pool to revamp Australian industry, will also play a pivotal role. Medtech firms and manufacturers working with them are relying on these funds to continue to develop medical devices. In particular, small component manufacturers require NRF support to prevent this capability being offshored.

Funds are only one ingredient in a revitalised local manufacturing centre. Dedicated advanced manufacturing precincts could co-locate different parts of the ecosystem and encourage collaboration.

In terms of location, the Medical Technology Association of Australia (MTAA)s calling for advanced manufacturing centres to be built in areas where property prices are reasonable and there is access to low-cost labour[9]. This would encourage investment.

The MTAA says priority should be given[10] to developing the following sub-sectors in manufacturing:

- Electronics manufacturing
- Injectional moulding
- Manual (low volume) and automated (high volume) assembly
- Glass manufacturing
- Sterility treatments

[5] Comparable overseas regulators for medical device applications, 2022, Australian Department of Health and Aged Care
[6] Medical Devices Reform: An action plan for medical devices, 2022, Australian Department of Health and Aged Care
[7] MTAA Submission Paper, National Reconstruction Fund, 2023
[8] https://www.nrf.gov.au
[9] The Value of Medtech Report, 2023, Medtech Association of Australia, p7
[10] MTAA Submission Paper, National Reconstruction Fund, 2023

Case Study

Osteopore International's bright future as a regenerative medicine leader

Osteopore International was born when the company's founding members, three scientists and three surgeons, wanted to scientifically engineer better solutions to help patients regrow bone.

The regenerative medtech company focusing on tissue regeneration. It designs, develops and markets bioresorbable polymer implants for neurosurgical, orthopaedic and maxillofacial surgery use. The tissue-engineered product provides a scaffold for a patient's own bone cells to be regenerated. Its product lines are sold across 25 countries.

Osteopore's products are manufactured using its proprietary 3D printers. Its facility can run 24/7 using robots, while staff perform higher-value work such as quality assurance. The company was listed on the ASX in 2019 and is headquartered in Singapore.

While the company has a huge future, Osteopore has had to navigate many challenges since its IPO including geopolitical turmoil, high interest rates and inflation. The macroeconomic conditions of the pandemic were particularly difficult due to the importance of face-to-face connections in securing the trust of surgeons to adopt new products. Despite the challenges, Osteopore has achieved a significant milestone in the adoption of its products, crossing 100,000 implants globally — with ~80% achieved between 2019-2023.

A perennial challenge for businesses like Osteopore is encouraging hospitals to take up new technologies. Research shows reducing hospital readmissions by 20 per cent may save the US healthcare system about US$15 billion. So, on a cost benefit basis, it's possible to demonstrate Osteopore's products contribute solutions to eliminate unnecessary readmissions, to help reduce the economic burden on the healthcare system.

If we can develop products that create meaningful impact for patients, there's less concern about escalating costs

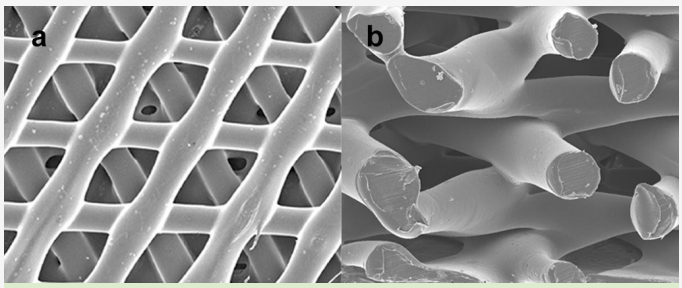
Dr Jing Lim
Chief Executive Officer and Chief Technology Officer, Osteopore

Another major hurdle is encouraging neurosurgeons and surgeons who are conditioned to use traditional technologies such as titanium and non-biodegradable plastics to use Osteopore's products.

"They are creatures of habit. So they take a bit of time to warm up to our technologies. But the good news is, once they get past that point, they tend to be a recurring customer," says Lim.

As a result, marketing is a priority, which involves additional resources to expand the distribution network. Events with professional societies and engaging key opinion leaders and encouraging them to speak to their peers are also important.

"Educating the medical field involves organising continuous medical education events. They give surgeons exposure to new technologies and allow Osteopore to share its products with them," says Lim.



Honeycomb microstructure of Osteopore's implant.
Top view (left) and side view (right)

Training is critical so surgeons get experience operating with Osteopore's products. This is in the form of workshops, as well as working on cadavers or anatomical models with a simulated implant.

This really helps the surgeons to de-risk how they use our products. Conducting workshops allows us to help them become familiar with the device, which gives them more assurance about outcomes," he adds.

The presentation of clinical data is also vital. This involves surgeons using the product, collecting the outcomes, submitting abstracts, publishing papers and attending conferences, sharing their clinical experience about using the product.

"We encourage them to speak from a point of clinical experience and a position of neutrality," says Lim.

One advantage is Osteopore's ability to tap into a talent pipeline of mechanical and bio engineering students, which ensures the business has access to the skillsets it needs.

At the same time, because of our network, we are able to attract more senior candidates to the company. So there's a balance in our team between senior people with experience and young people with drive and enthusiasm to make a difference in their career and in other people's lives," says Lim. The company will bring new talent with different skill sets into the business as it grows and expands.

Access to grants and incentives are essential for businesses such as Osteopore and some government grants are available in Singapore to help reimburse costs related to expanding the business. In Australia, Osteopore has access to tax rebates related to its research and development activities. It's currently sponsoring two clinical trials at Brisbane's Princess Alexandra Hospital and is looking to do more, to bring technology developed in Australia to the global market.

Osteopore also received a $19 million grant to develop its third generation product, which includes magnesium for bone growth.

Lim sees a big future for the Australian medtech sector. It's a very exciting, vibrant, dynamic space. If you look at a global medical device market, even though Australia is small relative to the US and other countries, the level of innovation and quality of clinical care is up there with the rest of the world, especially the US. Australian clinical data is always highly regarded and Australian surgeons are respected all over the world. Also, the medtech start-up environment is active and vibrant in Australia. We want to continue to collaborate with companies in Australia, support the ecosystem and accelerate the commercialisation pathway for everyone," says Lim.

The role of data in medtech

Data underpins everything in medtech and device manufacturing. Importantly, an array of positive patient outcomes can be achieved by collecting information on things like genetics, behaviours and pre-existing health conditions and connecting this information to medtech devices.

Over time, all this information will be used to assist in diagnostics, treatment and drug discovery. But this requires standards for data and data sharing

Dr Rita Choueiri
National Director – Life Sciences, RSM Australia

Digitisation of health is an ongoing mega trend. Devices and software are integral to the data collection required to drive research and better health outcomes.

Data plays an instrumental role when it comes to increasing clinical confidence, engaging patients and allocating resources. Medical devices generate substantial data to support efficient monitoring of patients and their care. Wearable devices like smart phones and smart watches generate substantial data for healthcare workers to monitor larger numbers of patients without sacrificing quality of care

Srdjan Dragutinovic
Director – Data Analytics, RSM Australia

AI, machine learning and big data are driving diagnostic and monitoring capabilities and these technologies will only become more sophisticated over time. Their algorithms will help identify high-risk patients and support healthcare providers to develop personalised treatment plans.

AI algorithms can integrate cellular imaging and CT scans to detect features and patterns that may have been overlooked by healthcare professionals. This allows for earlier detection and diagnosis and more effective treatments.

Data is also used to forecast and predict patient uptake in healthcare facilities. This is vital during epidemics and other disease outbreaks to help predict patient numbers so hospitals can properly plan staff rosters, taking into account the skills required to properly manage these situations.

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''A challenge is ensuring new technologies can interface with legacy systems to support collaboration, medical testing and trial outcomes. AI can help collate information into a universal data source, allowing data to be easily accessed by different healthcare professionals, departments and institutions,'' says Dragutinovic.

Privacy is a key issue. RSM Australia's Director – Management Consulting, Don Holley explains how the way data is used in medtech will change over time, taking this into account.

Interoperability of systems will improve, including safe usage and sharing of patient data

Don Holley
Director – Management Consulting, RSM Australia

Case Study

Rising global demand for medical imaging drives Mach7's future

Medical imaging leader Mach7 has developed through a mix of organic and inorganic growth. In 2016, a reverse merger with ASX-listed company 3DM brought Mach7 to the share market, which has been a sound growth platform.

"The rigour and transparency required of a listed company helped the business mature. In 2020, we completed a transformational acquisition in Client Outlook, which has led to the momentum we see today

Mike Lampron
Chief Executive Officer, Mach7 Technologies

Mach7 is an international business with customers across 16 countries. "This geographic diversity gave us traction through difficult global challenges like COVID," he adds.

Looking ahead, Mach7 is focused on delivering organic growth and continuing to build its business. It's well placed to meet modern requirements as the tech world transitions to cloud-focused and SaaS-based technology.

Overcoming hurdles

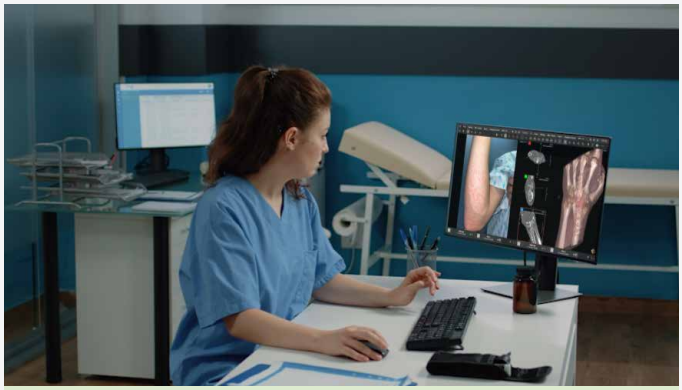
Like most businesses, talent management is a priority. As a software-only company, Mach7 has adapted to a modern workforce environment. "Technology and new management techniques mean we have a fully-remote workforce," says Lampron.

"Our ability to adapt and embrace this change has led to better employee engagement, better recruiting and lower attrition. The challenge has been how to embrace this change, while still building and maintaining a strong company culture," he adds. Lampron says company values are an important business driver. "We have established trust with our workforce by staying true to those values and supporting our employees as the world transitions to a new working environment. That trust, and ensuring our values are lived every day, has given us the ability to overcome the industry's biggest challenge, which we believe to be employee engagement."

Embracing growth

As Mach7's book of business has grown, so has the size and complexity of its customers. "The biggest challenge for us has been increasing the service and supportability of our products. This comes through innovation in our product, better processes and increasing the number of staff required to deploy and support our software," says Lampron.

"This starts at the top, by making sure we have the right leadership team. It filters down the organisational chart to ensure we have the right people in the right roles, so we can responsibly scale." Data and data management have become increasingly key to Mach7's success. There are two main areas where data guides operations: within the ERP system for the accounting/finance team and in the CRM as a commercial tool.



Mach7's innovative solutions bring the entire patient record together, driving better health outcomes.

"We have made major investments in these tools over the past 18 months. It was a challenging process to find the right vendors for our business. But we are now coming out the other side of those deployments. These systems and the tools they provide make it much easier for us to use our data," Lampron says.

"I'm thankful we have fully implemented systems that can help us develop the business from this point forward," he says.

On the horizon

Demand for Mach7's technologies will only grow as medical imaging becomes an increasingly critical component of the healthcare spectrum.

"Most developed countries have adopted digital medical imaging. So now the emphasis is on making the process better and giving the industry the tools they need for big data and telemedicine," says Lampron. "Although every region is growing at a different rate, there is no doubt medtech as a whole continues to evolve and companies and investors will continue to fund this space."

When it comes to RSM Australia's support, Lampron notes the business is all about transparency.

"RSM has helped us provide our investors with meaningful information they know they can trust. We view our relationship with RSM as a partnership where our business can meet and exceed expectations. RSM helps ensure that we have the proper diligence in place so our customers and investors can have confidence in the information we provide," he says.

Public sector and policy support

The close integration of public sector health and research bodies and universities is essential to build and scale the next generation of medtech firms.

Numerous national and state-based institutions are involved in medical technologies, all of which have significant ties to tertiary institutions. The current primary national funding pool is the $20 billion Medical Research Future Fund (MRFF), which includes $450 million for the Medical Research Commercialisation initiative.

The Australian Government's Federal Research and Development Tax incentive (RDTI) also plays a pivotal role in early-stage funding. It can provide companies with an aggregated turnover below $20 million with a refundable tax offset of up to 43.5 per cent, or in limited circumstances 48.5 per cent, of the research and development (R&D) expenditure. Companies with an aggregated turnover above $20 million receive a tax offset ranging between the company tax rate plus 8.5 per cent to 16.5 per cent.

The RDTI provides the ability to use registered Australian Research Service Providers (RSPs) and other service providers and consultants to assist with the R&D. According to Choueiri, this results in many medtech claimants opting to engage with the services of universities and other specialised research institutions and claim their costs through the RDTI program.

MTAA offshoot, MTP Connect, is another important body. It was established as part of the federal government's Industry Growth Centres Initiative and fosters research and collaboration across the medtech ecosystem. MTP Connect has injected more than $141 million into 184 projects, as at end 2022, in combination with a $827 million contribution from industry.

Individual states are also investing in medtech. Some of the major state government-sponsored programs include: [11]

- Victorian Medical Device Prototyping and Scale-Up Facility at RMIT University
- Melbourne's $2 billion Biomedical Precinct.
- NSW Health's Medical Devices Fund's $8 million-plus annual grant program for commercialising medical devices.
- South Australia's Medical Devices Partnership Program at Flinders University.
- Western Australia's Life Sciences Innovation Hub and Manufacturing program.
- Queensland's BioPark Australia life and medical science hub.

Holley says it's essential for all parts of the medtech sector to continue to work together.

"We need to encourage more collaboration between local medtech firms and their overseas peers. Government-to-government collaboration is also needed to connect medtech firms that are solving global challenges, so they can share research findings and combine tax and funding incentives. This could include joint trade promotions to quickly grow markets. It's also critical to support business-to-business medtech ecosystems through formal collaboration, sharing resources and intellectual properly and by streamlining supply chains," says Holley.

To this end, Kapitan is calling on a new approach within the public health sector so local medtech firms can truly thrive.

> *"The public health sector funding roots and models are retrospective. We have collected lots of data based on specific DRG codes and activities, using this to determine future demand and fundings options. The focus is on funding what we have always done. We need a new way of doing things so medtech can take its rightful place in the public health sector. We also need a national focus. Public health is managed at a state level, with each state running its own race. Changing our approach to be more national would produce greater economies of scale*
>
> **Jayesh Kapitan**
> National Leader – Health Services, RSM Australia

[11] The Value of Medtech Report, 2023, MTAA. p42

Case Study

Trajan successfully scaling globally from Australia

Trajan Scientific and Medical was named for the thirteenth Roman emperor, one of its most successful, who led Rome to its peak, building infrastructure and doing social good. The business is focused on the analytical science of extracting quantitative information from a sample. Their purpose is to support science that benefits people.

Trajan CEO Stephen Tomisich at the Company's Global Headquarters in Ringwood, Australia

Trajan Scientific and Medical manufacturing site in Penang, Malaysia

> *If we think about laboratories, samples come in every day for blood, water, soil, food and more. The purpose of those labs is to understand the composition of those samples, such as a biomarker in blood or a contaminant in soil. Trajan designs and develops the core technologies that allow those measurements to happen*

Stephen Tomisich
Chief Executive Officer, Trajan Scientific and Medical

Trajan has acquired 12 businesses since it was founded in 2011. Considerable work is taking place right now to integrate these businesses and realise synergies in terms of revenue, growth, costs and operationally. Work is ongoing to transition the footprint of the business to optimise performance, which involves developing its operations in Penang, Malaysia as a centre of excellence, with a 150-strong team already based there. In Melbourne, the focus has been on developing robotic production platforms to take the variability and labour intensity out of production processes. Production capability is also being expanded at Trajan's facility in the US in Austin, Texas, in addition to consolidating operations at its robotics business in North Carolina. "Our aim has been to scale science engineering at a global level to become an industry supplier," says Tomisich. Another focus is rounding out the company's in house technology development capacity. This involves extending and growing the existing portfolio of businesses with product line extensions.

Alongside this is a program to invest in disruptive technologies such as microsampling devices and microsampling workflows to service future markets. This has significance for clinical research, helping to make it easier for trial patients to supply samples without having to attend a health facility. "We are developing a range of tools that allow people to take a blood or skin sample with analytical credibility that would otherwise require you to go to a clinic. Downstream from that is to develop laboratory workflows, physical tools and robotic automation," says Tomisich. Central to Trajan's growth strategy is challenging the current healthcare model, which is based on centralised, diagnostic-based sick care."The way the healthcare system works, we wait until we have symptoms, then get diagnosed and treated. Yet, if we understand someone's genetics and the biomarkers we should be looking for, we can become far more proactive and preventative when it comes to illness," says Tomisich.

Trajan has a partnership with The Baker Institute in Melbourne, a world leading research centre for cardiovascular disease and diabetes. The institute is undertaking ground-breaking research into cardiovascular events that happen to people who are not classified as high risk, looking at hundreds of measurements about lipids. Trajan's expertise in microsamples has been instrumental to the research and the future of predictive healthcare. An important part of this work is challenging barriers of adoption for new technologies across the healthcare system, an impetus for Trajan's acquisition strategy. After acquiring My Health Test in 2021 it now has a medically-accredited pathology laboratory in Melbourne which has been accredited in the field of medical testing (ISO 15189) by the National Association for Testing Authorities, Australia (NATA) in conjunction with the Royal College of Pathologists of Australasia (RCPA). This is key to developing an accredited, medical-pathology workflow other labs can replicate, which will support industry-wide adoption of Trajan's innovations.As for the future, the emphasis is on continuing to scale the business and deliver emerging medical technologies to the world and improving health outcomes for the global population.

Closing the grant gap

The primary pool of grant funding for medical sector projects is the $20 billion MRFF. However, the grants are typically received by universities or, occasionally, by large medical-sector foundations or research institutes.

"It is rare for funds to be provided directly to industry under the MRFF, so there is a gap in the market for medtech grant funding for industry

Dr Rebecca Barnes
National Grants Manager – RSM Australia

Hala Zreiqat, The University of Sydney's Payne-Scott Professor of Biomedical Engineering, says better access to grants and funding for medtech researchers would drive innovation. "With more resources, researchers and start-ups can explore new ideas and technologies that could lead to breakthroughs in medical technology."

Zreiqat's research focuses on developing better man-made materials for the treatment of injuries involving bone, meniscus and tendon injuries. She says enhanced funding could support commercialisation of research findings by covering the cost of patenting, regulatory navigation and business development.

Alongside her colleagues at the University of Sydney, Zreiqat has developed a bioceramic material, recently acquired by Allegra Orthopaedics. The material is being developed as a spinal fusion device, and is currently being assessed by the US Food and Drug Administration.

"More funds would mean research institutions and start-ups could invest in the latest equipment and facilities. Funding can mean the product and technology can be developed in Australia, which only enhances the reputation of our medtech industry globally."

Better funding would also allow for more comprehensive and larger-scale clinical trials. Although the RDTI program can help subsidise the costs, a company must still have enough upfront funding to initiate costly clinical trials which can be a barrier. Upfront funding could expedite the approval process for new technologies and ensure a higher level of safety and efficacy.

"This will lead to new jobs and support the long-term sustainability of the medtech sector. It would also allow for ongoing research and development, even in areas that might not provide immediate financial returns but have potential for significant future impact, such as regenerative medicine or nanotechnology. says Zreiqat.

A bigger pool of funds could also boost Australia's capabilities in emerging technologies such as digital health, personalised medicine and methods to address chronic diseases prevalent to patients living in remote regions of Australia.

More funding would also bolster the talent pipeline. MTAA research found 64 per cent of a survey of 191 respondents agreed it was difficult to find local talent for their workforce and more than 50 per cent agreed it was difficult to bring international talent to Australia.

"Brain drain is a serious issue in Australia and better funding would make the sector more attractive for top talent, including researchers, engineers and industry leaders. This will strengthen collaboration and drive the medtech sector forward," says Zreiqat.

Establishing strong links between medtech researchers and industry players is also crucial. "These partnerships provide researchers with insights into market needs, regulatory pathways and commercial strategies. Venture capital in Australia can also offer financial support and resources for product development," says Hala Zreiqat.

This might include grants, tax incentives, and programs that connect researchers with industry mentors and investors. Navigating the regulatory landscape can be a major challenge for medtech researchers. Simplifying and clarifying regulatory processes and providing guidance and support for researchers to get through these processes can significantly aid commercialisation efforts.

"This process should involve all stakeholders including hospitals, clinics and healthcare professionals, who can provide valuable feedback on the practical applications and efficacy of new technologies, guiding researchers in refining their products for the market," says Zreiqat.

Implementing these strategies would create a more conducive environment for the transition of medtech innovations from research to commercial success, boosting the sector's overall growth and impact in Australia and beyond.

Use technology to enable operational excellence

Case Study

Specialised Therapeutics benefits from a lean business model

Specialised Therapeutics is a privately-held biopharmaceutical company that partners with international biotech and pharmaceutical businesses without a presence in Oceania. It then in-licenses, commercialises and champions partners' products, as if they were their own.

As its name suggests, Specialised Therapeutics focuses on products that have a unique proposition in fulfilling a unmet medical need. The medicines are typically low-volume, high-value products. For example, even if only 100 units are sold each year, this could represent revenue in excess of a million dollars.

"We are very selective in the products we take on. We must know and understand a product intimately before we make the decision to license and our team can spend months undertaking appropriate due diligence, which involves not only knowing how a therapy works, but who it will benefit, what other products are its competitors and at what stage of the disease do patients need this therapy

Carlo Montagner
Chief Executive Officer, Specialised Therapeutics

Specialised Therapeutics looks after all the medical, regulatory and commercialisation activities for these products, including logistics, distribution and marketing.

"So, while we don't conduct the original the research and development underpinning our products, we treat all of them as if they were developed by us. "We don't want 'me-too' therapies. We always look to license products where there is a genuine an unmet clinical need." The first product Specialised Therapeutics commercialised 15 years ago was Abraxane, which today is a standard treatment for breast and pancreatic cancer – becoming one of the most successful chemotherapies ever commercialised in Australia. Since then, the business has formed relationships with more than 10 partners spanning Europe, the US and Asia and expanded its product portfolio across a number of diseases.

China represents a huge opportunity for the business, with companies based in this jurisdiction disrupting the global pharmaceutical market with high tech drugs at low price points.

"We want to be at the forefront of this. We have a partnership with a Chinese company which will evolve into taking on several of their other pipeline products. We are also talking to other Chinese companies to bring their products to market," says Montagner.

Specialised Therapeutics constantly faces challenges bringing products to market, the most significant of which is patients' capacity to afford specialist therapies and technologies. Consequently, registering its products with the Pharmaceutical Benefits Scheme (PBS) is a priority, given patients are only required to make a small co-payment to access drugs on the PBS, which may otherwise cost many thousands.

Another challenge is each product's lengthy payback period. The business invests between $1 million and $2 million per product applying for regulatory and reimbursement approvals, and even then, there is no guarantee of success. It can take several years between the time a drug is approved by the TGA and it being fully commercialised, generating meaningful revenue.

"There are many barriers to entry for newcomers and these can only be overcome by having a solid capital base, positive cash flow and disciplined business management selecting and commercialising medicines," says Montagner, who explains the business suffers what he calls 'leaky bucket syndrome'. Our products have finite patent lives of between 10 and 15 years. There are always new competitors taking market share, as well as price erosion to consider. So we have to keep topping up the bucket with new products," he adds.

The business has always been cash flow positive and profitable, and has never relied on debt or other investors. ''Our cash flow has funded our growth and sustainability,'' says Montagner. Finding the right products that are available for licensing for this region, which are commercially viable, and which can be sold at a reasonable price with reasonable market uptake, is another hurdle.

To this end, Montagner spends up to 60 per cent of his time on business development to bring in new products. ''This is very resource intensive and not all products will be commercially feasible,'' he says.

Foreign exchange risk poses another barrier and future revenue streams are adjusted for commercial, regulatory, price and product risk. The team operates a zero-based budgeting model, working on a rolling 18-month budget, reviewed monthly and quarterly.

''We run the organisation as if it's a listed, multinational company. That has been the key to our longevity and survival,'' says Montagner. While access to talent is a typical challenge for health businesses, Specialised Therapeutics has put together a stellar team of highly experienced people with outstanding capability and expertise.

''We position ourselves as an attractive and enjoyable place to work. We're focused on bringing people into the business we think would enjoy working with each other because they are aligned to our values,'' says Montagner.

RSM has provided invaluable assistance to Specialised Therapeutics with general compliance advice, as well as expert knowledge on transfer pricing and working internationally.

''As our business grew and expanded internationally, we realised we needed accountants like RSM with broad, multi-country expertise who were adept at navigating complex global markets,'' says Montagner.

''At the moment, RSM is helping us with a corporate restructure. The team also has the expertise to work on our long-term positioning on a local and a strategic level and they understand our business. They have expertise in Asia, so they tick all our boxes and have been extremely helpful,'' he adds.

''Our business relationship with RSM is enduring. We are always impressed by how responsive they are. If we need an answer to what may be a complex query, we know we can just pick up the phone and ask. Our account manager is fantastic and always makes himself available. Our transition to RSM was seamless and they rapidly developed an understanding of our business model, operating in very complex markets.''

Access to growth funding

Research funding aside, medtech faces significant challenges accessing private sector funding in Australia. Despite a handful of exceptions, local venture capital firms have avoided funding early-stage companies developing medical devices, leaving the RDTI as the main funding lifeline for these companies.

Most Australian venture capital funds typically flow to pharmacology and biologic projects due to the nature of return and exit pathways, typically focused on research via phase I to III clinical trials. MTAA's figures indicate medical devices represent just 25.3 per cent, or $255 million, of the $1.7 billion of venture capital invested into the health technology sector between 2018 and 2022. The majority of funding for medical device technologies comes from high-net worth family office or angel/seed investors.

Medical devices tend to be acquired after first major market validation and require upfront funding support through the research, product engineering and development phases. This includes animal model studies and first in human, pilot and pivotal clinical trials and commercialisation across reimbursement, market access and procurement.

The exit horizon for medtech is around eight to ten years, versus 12 to 15 years for pharmacology projects, which require less capital and deliver more consistent aggregate portfolio returns. This leads to different risk return profiles that require further insights for investors to better understand the attractiveness of medical devices. In general, devices that are funded have a clear clinical need and a differentiated solution that benefits patient outcomes and contribute towards overall health economic benefits.

> MTAA believes companies looking to secure financing need good science, a strong clinical need and a comprehensive understanding of the path to market. This includes clinician-led insights into the medical problems to be solved, together with a clearly-defined pathway to market through regulatory, reimbursement, market access and procurement hurdles.

As the MTAA suggests, there is an opportunity for the federal government to support open-ended and fund-of-fund investment models for medtech. This could complement venture capital and private equity options. Alternate funding structures could also provide capital for early stage ventures that have not yet validated their market.

It is also important for governments to recognise not every successful business is going to be an attractive proposition for venture capital funds. Successful medtech companies that might not provide a large return but still employ Australians, manufacture locally and research and develop products onshore are still extremely valuable to Australia's future.

What areas of medtech have the most potential?

There is huge potential for the local medtech sector across many fronts

For instance, Australia does well in rapid-start clinical trials, thanks to our Clinical Trial Notification Scheme. We also have the ability to manufacture activate implantable cardiac and neuro stimulation Class III devices, along with personalised devices, relative to high volume Class I and Class II devices and related lifestyle consumer electronics.

Evidenced by various strategic distribution partnerships and acquisitions, Australia benefits from growing interest among multinational medtech companies in our local innovation ecosystem, supported by collaborative research partnership through to acquiring market validated start-ups.

While Australian manufacturing has its limits, the MTAA says stipulating grant recipients conduct prototyping in Australia will help to build and scale advanced manufacturing locally. This could also help diversify the pool of local grant recipients and help build scale locally. More government incentives to support buying Australian-made products is also needed. The MTAA says grant programs could be supported by health department procurement initiatives to validate market demand, a common request from international partners.

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Looking ahead

There is much to be positive about for the future of the local medtech sector. A bedrock of long-term industry development, interconnectedness between various parts of the ecosystem and an impressive body of home-grown research is a solid starting block.

There's an equal number of challenges to resolve that are potential barriers to future growth. These include more diverse funding sources, fast-tracked regulatory approvals that don't compromise quality and safety and better government incentives. This will help support the right environment to develop products, services and expand market share and create export opportunities.

As the medtech sector develops, it will need to navigate many of the same issues all businesses are facing, such as appropriate product stewardship in a world moving towards circular economy. How to move towards sustainability in an industry replete with necessarily disposable products is especially challenging.

Nevertheless, as long as the sector continues to attract financial and government support, and the challenges it needs to face are addressed, medtech should take its place at the heart of the Australian health system.

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