The Value of MedTech Report

20 June 2023

Prepared for:

MTAA Medical Technology Association of Australia

MTP Connect
MedTech and Pharma Growth Centre

nous

Nous Group acknowledges Aboriginal and Torres Strait Islander peoples as the First Australians and the Traditional Custodians of country throughout Australia. We pay our respect to Elders past, present and emerging, who maintain their culture, country and spiritual connection to the land, sea and community.

This artwork was developed by Marcus Lee Design to reflect Nous Group's Reconciliation Action Plan and our aspirations for respectful and productive engagement with Aboriginal and Torres Strait Islander peoples and communities.

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Contents

Glossary

Term	Description
ARTG	Australian Register of Therapeutic Goods – The list of approved therapeutic goods for use in Australia.
BioTech	Biotechnology – the use of technology to directly change or modify biological or cellular function or processes.
CAGR	Compound Annual Growth Rate – the mean annual growth rate of metric, over a specific period of time greater than one year.
Clinical Trial	A type of research that studies new tests and treatments and evaluates their effects on human health outcomes.
Operating Surplus	Otherwise referred to as Earnings before Interest, Taxes, Depreciation and Amortisation (EBITDA).
Financial Year (FY)	The Australian financial year occurs from July 1st to June 30th the following year.
GDP	Gross Domestic Product – standard measure of the value added through the production of goods and services in a country during a certain period.
HTA	Health Technology Assessment – a systematic evaluation of properties, effects and/or impacts of health technology.
ICU	Intensive Care Unit – specialised treatment given to patients who are severely unwell and require critical care.
IMDRF	International Medical Device Regulators Forum
IVD	*In Vitro* Diagnostic – a class of medical device where the device performs diagnostic functions on biological samples.
MBS	Medicare Benefits Schedule – this is the list of approved reimbursed goods and activities by the Australian government.
MedTech	Medical Technology
MSAC	Medical Services Advisory Committee – advises the Minister for Health and Aged Care about funding for new medical and health services and products.
MTAA	Medical Technology Association of Australia – national association representing companies in the medical technology industry.
OECD	Organisation for Economic Co-operation and Development – intergovernmental organisation to stimulate economic progress and trade.
Phase	The type of clinical defined by the aim
PLAC	Prostheses List Advisory Committee
Prescribed List	Prescribed List of Benefits for Medical Devices and Human Tissue Products – is a schedule that lists the benefits paid by private health insurers for certain medical devices and human tissue products. This replaces the Prostheses List.
Gross Revenue	The total turnover generated from MedTech activities (excluding GST).
TGA	Therapeutic Goods Administration
Additional economic terms	Presented in "Table 2 | Economic Metrics"

The Value of MedTech Report - 2023

What is MedTech?

Medical Technology (MedTech) is an integral part of healthcare provision around the world. MedTech supports patients and clinicians in providing medical care or monitoring health. MedTech covers a wide range of technologies such as diagnostic machines, implantable devices, assistive technologies, surgical tools, consumables, and software.

Areas of Focus

- Clinical training and use
- Patient benefits

185,000,000+ non-hospital pathology and diagnostics (FY20/21)

156,012 intensive care unit admissions (FY21/22)

128,083 hip, knee, shoulder, and other joint replacements (2022)

$8,617 avg spent per person on healthcare

KEY FINDINGS

Australia has a highly skilled workforce using MedTech who collaborate extensively

Top 5 therapeutic areas supported are:

- Cardiovascular surgery
- Orthopaedic surgery
- Obstetrics and gynaecology
- Ear, nose and throat (ENT)
- Intensive care and emergency

Areas of Focus

- Research
- Idea development
- Patenting
- Investment

7% annual growth in Australian MedTech patents (2010– 2020)

$1 bn+ government investment a year in health and medical research

2,300+ total MedTech clinical trials conducted in Australia (2002- onwards)

400+ clinical trial and/or research jobs

KEY FINDINGS

Australia has a robust innovation pipeline with increasing government supports for training and investment

Clinical trials are supporting local ideas and innovations

Australian companies are developing new MedTech, using a wide range of technologies and treating many different diseases

MedTech industry survey responses at a glance

88% of MedTech companies believe that **MedTech** is a **future growth sector**

56% of MedTech companies have local **clinical trials underway**

MedTech's economic value (FY21/22)

17,000+	51,000+	$11.4 bn	$4.1 bn	$5.4 bn
direct jobs	total jobs	MedTech Gross Revenue	direct GDP	total GDP

Areas of Focus

- Prototyping
- Regulatory approvals

79 countries have MedTech devices registered for use in Australia

851 Australian manufacturers

4,169 new device registrations (2022)

4,000+ manufacturing jobs

71% of companies have local product development

KEY FINDINGS

Market access in Australia requires safety, efficacy, and quality, whilst reimbursement requires cost-effectiveness assessments

Australian regulation is increasingly harmonised with international practice

COVID-19 provided Australia with valuable lessons on rapid MedTech development and spurred government investments into local MedTech manufacturing and sovereign capability

Areas of Focus

- Scaling of manufacturing
- Market access
- Distribution and sales

10% job growth since FY20/21

25% of companies are expecting 10%+ revenue growth in FY22/23

$139 bn Aust. Stock Exchange Healthcare Equipment and Services market capitalisation

KEY FINDINGS

Australian MedTech companies collaborate extensively with researchers, healthcare providers and clinicians

Top 5 occupations:

- Sales, marketing, and customer service
- Manufacturing
- Supply chain and logistics
- Product research and development
- Professional and consulting services

49% of MedTech companies are still **recovering from COVID-19**

65% of MedTech companies are collaborating with **universities and research institutes**

64% are finding it **difficult to find local talent** for their workforce

Executive Summary

At every step of our journey through life, medical technology (MedTech) is essential. From detecting, diagnosing, treating, and managing healthcare conditions, MedTech supports patients across the country to improve their health and wellbeing.

From implantable devices such as pacemakers, personal devices for the management of diabetes, X-ray machines and MRI scanners to uncover cancer, or surgical robots to aid surgery, to personal technologies that enable patients to effectively manage their chronic disease, the devices and equipment used in healthcare ensure Australians can live their life to its fullest.

This was never so evident as during the COVID-19 pandemic when Australia's MedTech sector was at the forefront of Australia's response, working in conjunction with government to invent, secure, and deliver, equipment such as testing kits, personal protective equipment (PPE), ventilators and vital equipment for intensive care units. From the earliest days of the pandemic MedTech provided life-saving support that enabled our healthcare staff, system and policy makers to respond.

Commissioned by the Medical Technology Association of Australia (MTAA), The Value of MedTech report outlines and quantifies the contributions the Australian MedTech industry makes to the Australian healthcare system and its economy each and every day. This report speaks to the opportunities to maximise the future benefits that MedTech can deliver to Australia's health, the strength of our healthcare system, and our economy. This report is based on survey data collected from Australian MedTech companies between Nov 2022 and Jan 2023, as well as secondary sources including economic reports and other publicly available information.

MedTech supports the health of Australians

Access to advanced medical technology is essential to the timely diagnosis and treatment of Australians experiencing health challenges. Between 1 July 2020 and 30th June 2021, over 185,000,000 pathology and diagnostic services – or over 500,000 on average per day – were delivered to detect and diagnose conditions such as cancer, cardiovascular disease, stroke, and diabetes and enable often critical treatment to begin that delivers the best opportunity to manage their condition. Additionally, 128,083 Australians – or over 350 on average per day – underwent surgeries to replace their hips, knees, and other joints that enable them to reclaim their quality of life.

MedTech is essential to the care for Australians, and increasingly, for the half of Australians living with a chronic disease such as diabetes, arthritis and kidney disease, innovations are strengthening the quality of care to improve health outcomes and ensure a better quality of life.

Importantly, the contribution of the sector to the health of Australians doesn't stop with the devices they create. MedTech businesses who participated in the survey collaborate extensively with the healthcare system, including with healthcare providers (45%), education and technical support (48%) and clinical trials sponsorships (53%). These partnerships drive, reimagine and transform the experiences of patients, to improve and save Australian lives, and ultimately save the Australian health system money.

MedTech supports Australia's innovation

The acceleration of product development during the pandemic demonstrated the innovation, capacity and flexibility of the Australian MedTech industry to identify, respond and deliver for Australian patients.

Australian MedTech companies and their collaborators in universities and institutions across Australia are responsible for a pipeline of innovation that is rapidly securing patents in the MedTech industry. Australian MedTech patents have grown at an average rate of 7% a year since 2010. In the same period, the proportion of global patents for MedTech that have originated from Australia have risen from 4.5% to 6%[1].

Australia ranks 14th among 55 global economies in the American Chamber of Commerce's 2023 International IP Index of intellectual property[2]. Australia scored particularly highly on commercialisation of IP assets, where it was in second place[3].

Seventy-one per cent of surveyed MedTech companies indicated their products had some level of local development. Since 2002 Australia has hosted over 2,300 MedTech clinical trials[4]. More than 60% of surveyed companies indicated they have trials starting in the next 12 months. Analysis for this report identified that MedTech supports over 400 jobs in the Australian clinical trials sector.

Clinical trials bring a range of flow-on benefits, including a strengthened research culture, an increasingly skilled clinical workforce, and improved outcomes for patients through early access to new technologies.

MedTech contributes to the Australian economy

Australia's MedTech sector is critical to the health of Australians, Australia's research and development sector, and the broader Australian economy.

Based upon the survey, analysis and the methodology developed as part of this engagement, an estimated 17,000 Australians were employed directly in Australia in 2021/22 in MedTech-related work and a further 34,000 employees supplied the inputs that the MedTech industry consumes. Over half (51 per cent) of the total MedTech workforce are women, and senior representation of women in the sector is above the Australian average.

MedTech gross revenues earned by Australian-based operations of organisations in the sector totalled $11.4 billion in 2021/22 (an annual growth rate of 6.2% over the previous two years). Allowing for input costs, the MedTech sector's total contribution to gross domestic product (GDP) in 2021/22 was $5.4 billion. This is made up of direct GDP from the MedTech industry of $4.1 billion, and indirect GDP (the value created throughout the MedTech supply chain) of $1.4 billion. This represents a nominal compound annual growth rate (CAGR) of 5.9% over the previous two years.

The future of Australia's MedTech industry

Advances in MedTech are critical to our nation's efforts to improve the health and wellbeing of every Australian and reduce the burden of disease that significantly impacts patients, their families, our healthcare system and our nation's productivity.

These advances are here now – driving improvements in detection to ensure we capture disease earlier and strengthening the way Australia manages conditions by putting greater tools in the hands of patients and their healthcare professionals.

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[1] World Intellectual property organisation, PATENTSCOPE database
[2] https://www.uschamber.com/intellectual-property/2023-international-ip-index
[3] https://www.uschamber.com/intellectual-property/2023-international-ip-index
[4] Clinicaltrials.gov and Australian and New Zealand Clinical Trials Registry data

To develop the future potential of Australian MedTech, there exists the opportunity to address current challenges.

Significant bottlenecks to market access: A majority of survey respondents suggested that the Australian healthcare market is not conducive to locally developing products and services or expanding market access. Delays in regulatory and reimbursement approval, total time to market, and lack of clear policy and guidance were common concerns. There was clear demand to develop a market access framework that streamlines regulatory and procurement processes that currently exist in the highly fragmented system.

Leveraging existing strengths in healthcare and innovation: The talent shortage – whether recruiting local or international talent – is an ongoing challenge. The survey found that the MedTech industry collaborates extensively with researchers, clinicians, and healthcare providers. Australia has the potential to overcome some of the talent shortages by using and fostering MedTech collaborations.

The MedTech industry can generate more value in the future: The MedTech industry is a key enabler to improve the health of Australians. Ensuring that a dollar spent on MedTech is a dollar well-spent will be key to the sustainability of the Australian healthcare system. By leveraging the strong innovation ecosystem, and in collaboration with our nation's world-class healthcare, Australian MedTech can deliver more and in doing so deliver efficiencies.

About this report

The primary data source for this report was an economic and sentiment survey sent to Australian MedTech companies from November 2022 to January 2023. Existing reports and publicly available data were incorporated to supplement the analysis where possible.

Broad stakeholder groups were engaged to provide additional insights, case studies and different perspectives. These groups included health service providers, regulators, patient representative groups, investors, and MedTech companies themselves. This report provides insights on the whole value chain of MedTech, from idea to patient, and it explores the social and economic benefits of MedTech to Australia.

The report's analysis of the economic contribution of the MedTech sector over the past three financial years is based on a survey supplemented by analysis of other data sources on government funding, international comparators, strategic partnerships, and MedTech-related education.

SECTION 1

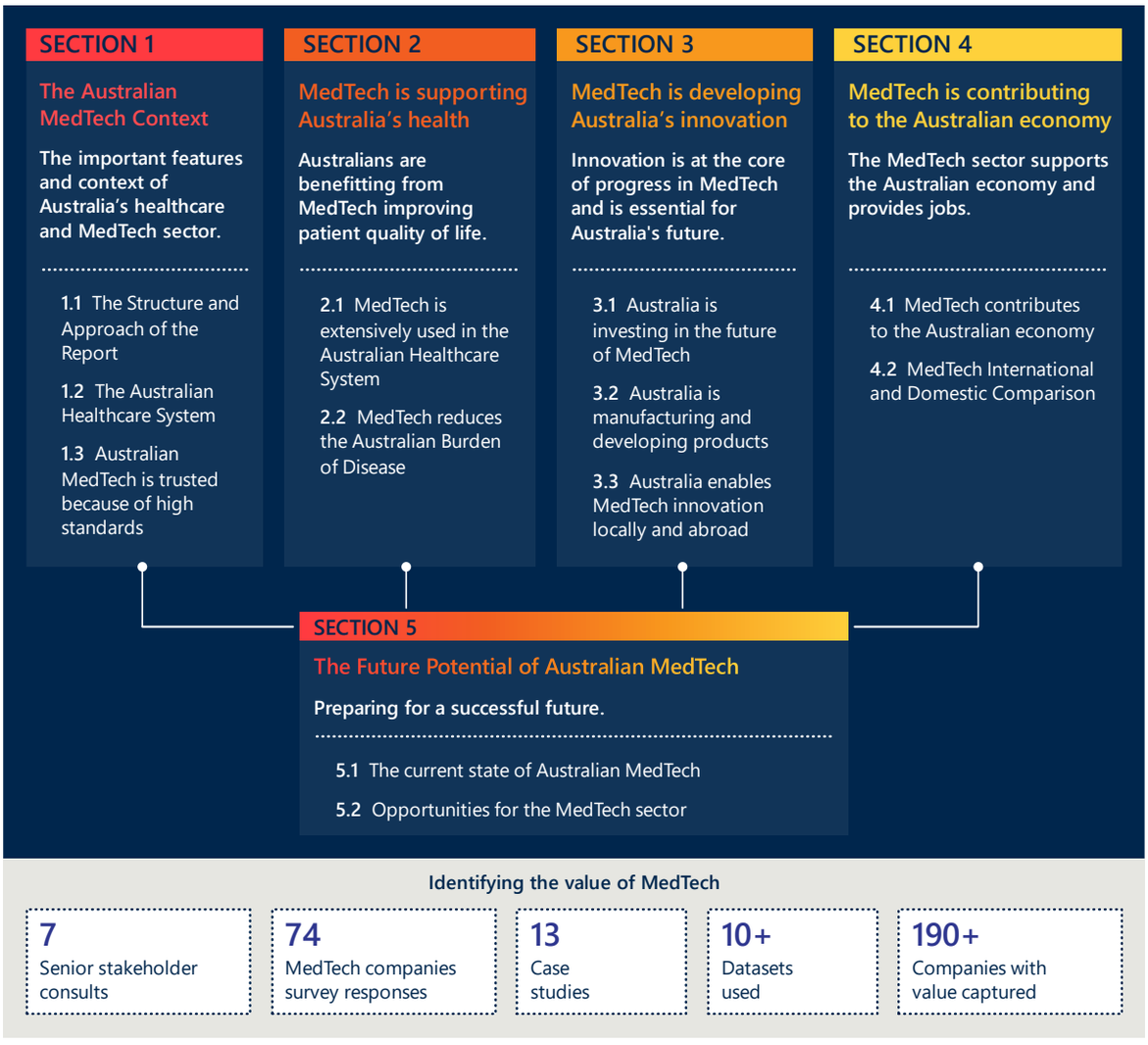
The Australian MedTech Context

1.1 The Structure and Approach of the Report

What is MedTech? Medical Technology (MedTech) is an integral part of healthcare systems around the world. MedTech supports patients and clinicians in providing medical care and monitoring health. MedTech covers a wide range of technologies such as diagnostic machines, implantable devices, assistive technologies, surgical tools, consumables and software.

MedTech generates many types of social and economic value, not only to patients and healthcare workers, but also to society more broadly. This report explores the value of MedTech to Australia along four major themes, followed by a discussion on the future of Australian MedTech (Figure 1).

Figure 1 | The structure and content of the report



This report represents a sector-wide analysis on the social and economic value that MedTech provides to Australia. The primary data source is an economic and sentiment survey the "MTAA Value of MedTech Survey" or "MTAA Survey" sent to MedTech companies from November 2022 to January 2023 (see Appendix A for more details). This survey generated valuable data on how companies are performing in Australia and gathered insights on the state of Australian MedTech. This work also identified existing reports and publicly available data to supplement the analysis where possible. Broad stakeholder groups were engaged with as part of this report, including health service providers, regulators, patient representative groups, investors and with MedTech companies directly. This context has provided additional insights which are shown throughout the report.

1.2 The Australian healthcare system

The MedTech industry aims to deliver financially sustainable positive impact for patients

Modern healthcare is built upon the history of continual advances in MedTech. Australia has a world-class healthcare system that provides exceptional care through the combination of quality health practitioners and access to many of the best technologies and medicines available. The Australian healthcare sector is a complex interaction between governments, healthcare providers and industry which are all aligned to the goal of improving patient lives. MedTech plays an important role in diagnosing, treating and monitoring the health of Australians, regardless of where and by whom they are treated.

What this means for patients:
MedTech is essential to the healthcare system and covers medical devices, from monitoring and diagnostic imaging machines, implantable devices such as pacemakers, to simpler use items such as scalpels, intranasal swabs and hypodermic needles. MedTech supports patients from all life stages. MedTech is helping Australians during pregnancy, supporting children to manage diabetes, treating chronic heart disease and replacing hips (Section 2).

The introduction of MedTech in these areas was transformative for patients and is now considered indispensable for current standards of care and improving quality of life. Australian MedTech companies are at the forefront of developing the next generation of care (Section 3).

The Therapeutic Goods Administration (TGA) regulates medical technology in Australia and serves as the main safeguard for MedTech use in Australia. It is a well-trusted and well-known institution[5] that provides patients and clinicians confidence in the technology they use.

Given the Australian context, this report has used the TGA definition of medical devices and technology as the basis of defining MedTech. In this report, MedTech is referred to as anything that falls under the Therapeutic Goods Administration 2022 definition of "Medical Devices" in Table 1.

Table 1 | Report definition of Medical Technology

Definition of Medical Technology: This report refers to Medical Technology as anything meeting the TGA definition of a "Medical Device" below.
"A medical device is: (a) any instrument, apparatus, appliance, software, implant, reagent, material or other article [excluding medicines] (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: (i) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; (iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; (iv) control or support of conception; (v) in vitro examination of a specimen derived from the human body for a specific medical purpose and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means…".[6]

[5] TGA stakeholder survey 2021 | Therapeutic Goods Administration (TGA)
[6] www.tga.gov.au/resources/resource/guidance/update-medical-device-definitions-and-requirements-system-or-procedure-packs

The social and economic value of MedTech accrues across society

The social and economic value of MedTech accrues to many stakeholders, including patients, clinicians, government and businesses (Figure 2). The primary benefit of MedTech is to patients, who experience better health outcomes, quality of life and opportunities for greater participation in society. The MedTech industry is supported by diverse industries and government regulators that ensure that critical medical goods from around the world are available to clinicians and patients.

Figure 2 | MedTech supports diverse stakeholders across Australia

Australia invests in the healthcare of its citizens and has good health outcomes

The Australian healthcare system consistently delivers quality care and is recognised as one of the best in the world[7]. The healthcare system is underpinned by significant investments (Figure 3) that equip Australia with modern technologies and treatments. There are also stringent regulatory safeguards and processes which help maintain healthcare system quality (Section 1.3). The combination of healthcare investment and modern technologies has enabled healthcare in Australia to achieve high-quality outcomes and serve as a hub for MedTech innovation (Case study 1).

[7] Mirror, Mirror 2021: Reflecting Poorly | Commonwealth Fund

Case study 1 | Australia has high-quality hospitals which help to develop MedTech for the world

LOCAL HEALTH SERVICES WORK CLOSELY WITH MEDTECH

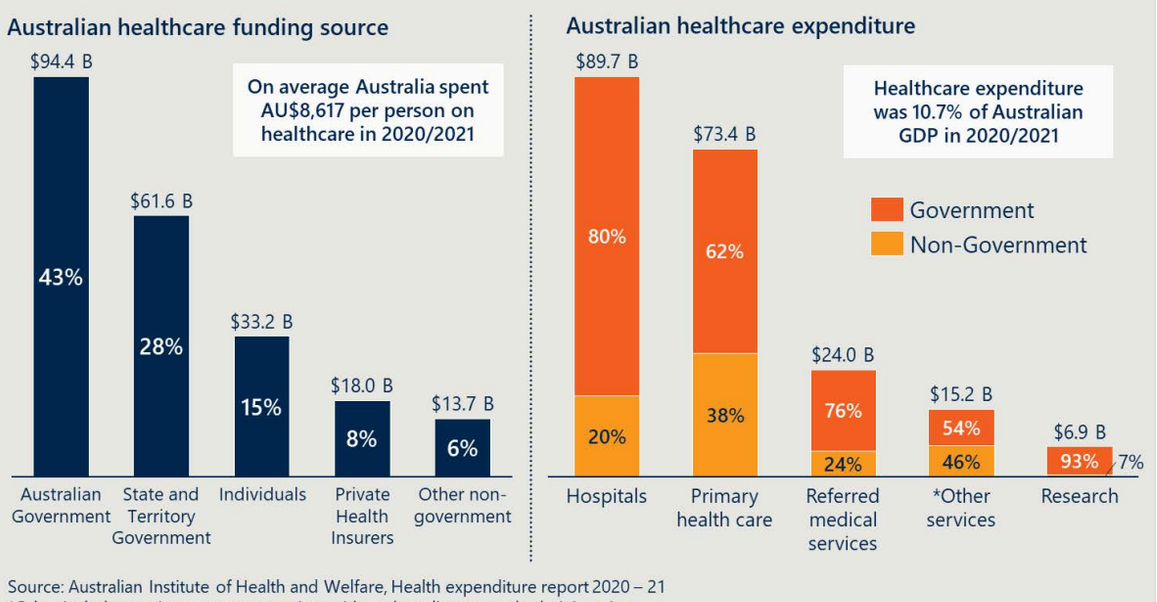
MedTech supports clinical services and innovation at local health services around Australia.

Sydney Local Health District (SLHD) is a network of public hospitals and other health facilities in Central and Inner Western Sydney. SLHD is integrated closely with the MedTech industry, leveraging strengths to improve research, teaching and clinical care. Many MedTech success stories in Australia, such as Cochlear and ResMed, have been built through collaborations with the healthcare system and universities. The SLHD has partnerships with established MedTech firms and played a key role in developing start-ups such as Perx with its digital health app and Baymatob which is supporting neonatal care. The SLHD has also launched the Sydney Biomedical Accelerator, a collaborative initiative with University of Sydney to combine clinical excellence with research expertise.

SLHD is home to the Royal Prince Alfred Hospital, recently named as Australia's top hospital[8]. Royal Prince Alfred Hospital is heavily involved in clinical trials and commercial partnerships. Strong innovation and medical research uphold its leading position and emphasis on patient care and outcomes is at the centre of the hospital's success.

The most recent health expenditure figures show an estimated $220.9 billion spent on health goods and services (2020 – 21)[9]. Australia has diversified pools of funding for healthcare, but a significant majority (71%) comes from public funding provided by Australian commonwealth, state and territory governments. Across all major areas of the healthcare system, government funding supports the majority of healthcare, including 80% of hospitals and 62% of primary health expenditure (Figure 3). Some of this funding also goes towards supporting the private healthcare system, which is subsidised by the Australian government.

Figure 3 | The sources of funding and expenditure in the Australian healthcare system



Source: Australian Institute of Health and Welfare, Health expenditure report 2020 – 21
*Other includes: patient transport services, aids and appliances, and administration

[8] https://www.newsweek.com/rankings/worlds-best-hospitals-2023/australia
[9] https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure-australia-2020-21/contents/summary

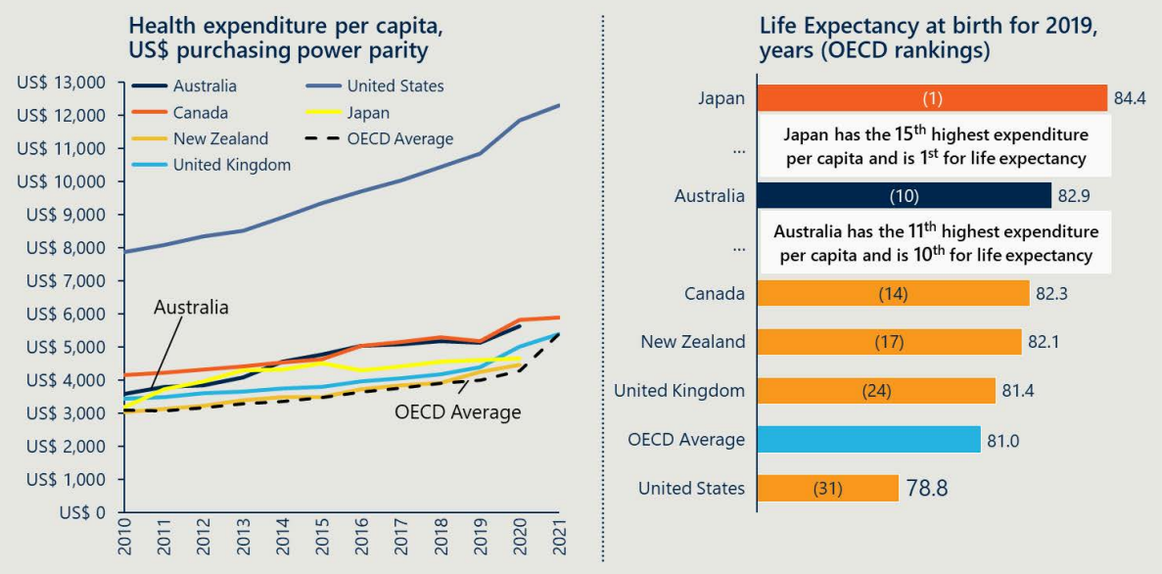
Expenditure on healthcare per person in Australia has steadily grown in the past two decades, which has coincided with improvements in health outcomes for Australian patients. From 2003 to 2022, the fatal burden of disease has decreased by 23% and the total burden of disease has decreased by 11% per person (age-standardised).[10]

Australia has significant healthcare expenditure per person compared to its Organisation for Economic Co-operation and Development (OECD) counterparts (Figure 4). In 2019, health spending equated to 10.2% of total gross domestic product (GDP). This places Australia 11 out of 38 OECD countries and above the median of 8.05% GDP.

As a percentage of GDP, Australia's healthcare expenditure is above that of the United Kingdom (9.9%), but below the United States (16.7%), Japan (11.0%) and Canada (11.0%).[11] Australia outperforms these countries in life expectancy except Japan, which ranked 1st in the OECD. However, Japan spends less per capita than Australia (Figure 4).

Investment in healthcare not only improves health outcomes but also creates operational efficiencies which reap cost-effectiveness benefits. For example, modern clinical communications technology is being deployed in Australian hospitals, enhancing service provider performance and improving patient experience (Case study 2).

Figure 4 | Australia has significant healthcare purchasing power and good life expectancy



Sources: OECD.stat, stats.oecd.org, health expenditure and life expectancy data

What this means for patients:

Australia outperforms many of its Western peers in life expectancy and has experienced significant reductions in the burden of disease since at least 2003. This means that patients are benefiting from the efficient delivery of healthcare which reduces the frequency and impact of disease. When comparing healthcare investment against outcomes, Australia appears to be faring well by both per-capita expenditure and % GDP spend.

[10] https://www.aihw.gov.au/reports/burden-of-disease/australian-burden-of-disease-study-2022/contents/interactive-data-on-disease-burden/burden-of-disease-in-australia

[11] https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure

Case study 2 | New digital technologies create efficiencies in hospital care

MEDTECH IS CREATING EFFICIENT HOSPITAL COMMUNICATION

Vocera is helping to provide efficiencies in hospital communication.

Traditional methods of hospital communication involve a central call operator to pass messages between clinicians, physicians, nurses and other hospital workers. Inefficiencies in this system lead medical workers to communicate via personal smartphones, raising issues around insecure messages and patient data confidentiality. Additionally, frontline nursing teams typically have no form of communication device beyond a fixed-line phone.

To address this, Vocera (now part of Stryker) has introduced a platform for direct communication. The platform provides real-time situational awareness, allowing all hospital workers and patients to communicate efficiently. Vocera has now been implemented in leading hospitals and aged care providers across Australia.

Overseas trials showed this system has been able to simplify workflows and reduce delays, resulting in patients receiving immediate benefit from the faster response times[12]. In another case, the Vocera system decreased delays in the peri-operative area, with a cycle time decreased by 5% resulting in a savings of roughly 15 minutes per case. These time savings allowed capacity to increase patient flow through the perioperative area by up to 253 cases peryear and increased overall patient and employee satisfaction[13].

In Australia, a wearable communication badge for medical personnel to attach to their scrubs is being utilised in Sydney Local Health Districts' Concord and RPA hospitals. The device has received positive feedback from employees, having created quicker staff response times and enhanced patient care.

[12] https://www.vocera.com/sites/default/files/VC-3032%20Halifax%20Health%20Case%20Study.pdf
[13] https://www.vocera.com/sites/default/files/VOC_7334_CS_CRMC_USA_R2.pdf

1.3 MedTech is trusted in Australia because of high standards

The Australian healthcare system must balance the potential benefits to patients with potential harms. Australia has a sophisticated healthcare regulatory system which is designed to only allow safe, efficacious and high-quality products to enter the market (Figure 5). Cost-effectiveness is also a key consideration when medical devices are being assessed for procurement and reimbursement decisions across the public and private healthcare systems. However, cost-effectiveness is not explicitly a requirement for MedTech to be approved for use in Australia.

Figure 5 | Key considerations for achieving regulatory approvals in the Australian MedTech market

The Therapeutic Goods Administration is the trusted regulator for MedTech access in Australia

The TGA maintains a register of all approved medical devices, medicines and biotherapeutics for use in Australia. For a product to be used in the market, it must be registered on the Australian Register of Therapeutic Goods (ARTG), which listed 62,381 devices and 34,291 medicines at the end of 2022[14]. Without listing on the ARTG, MedTech cannot be supplied in Australia.

Devices on the ARTG are placed into various classes based upon their intended use and risk profile. Each class has different requirements and assessment processes to be registered on the ARTG, ranging from self-assessment for conformity (i.e., Class I) to extensive documentation, evaluation of Quality Management Systems, and rigorous auditing by the TGA or registered conformity assessment bodies[15] (i.e., Class III). *In Vitro* diagnostics (IVDs) have classifications and requirements that are different from other medical devices due to different risks to the public. The detailed breakdown of these classes is shown in Appendix B, Table 11 and Table 12.

What this means for patients:

The Therapeutic Goods Administration (TGA) is the gatekeeper to MedTech reaching the market and patients. Before any MedTech product reaches a patient, it is the role of the TGA to ensure that patients can trust that it is safe, effective and of high quality.

[14] Therapeutic Goods Administration, Australian Register of Therapeutic Goods, data until 31st December 2022
[15] Australian conformity assessment bodies (Australian CABs) | Therapeutic Goods Administration (TGA)

The Australian Register of Therapeutic Goods (ARTG) is the list of medical devices and medicines that are approved for the Australian market. An ARTG listing is assessed based upon its risk profile. An individual ARTG ID has individual use conditions attached to their use and may be associated with whole medical devices or individual device components for use. A particular device may also be registered with new IDs for new use cases and conditions.

Awareness of the TGA has increased in Australia. A 2022 TGA stakeholder survey found that 7 out of 10 Australians had heard of the TGA, up by 17% from 2020[16]. Most survey respondents believe the TGA strikes the right balance between access to therapeutic goods and safety. Public trust in the TGA is important to help educate Australians about the benefits of medical devices and medicines. Information about TGA regulatory reform is on page 18.

What we've heard: The TGA is an important partner with the MedTech and healthcare sectors, providing trust for service providers, clinicians and patients. It oversees regular reform aligning Australia with international practices. This streamlines MedTech access while providing assurance that it is safe, effective and of high quality.

"Each product has risks and benefits. As the regulator we play a very valuable role – where TGA approves products on the basis that benefits significantly exceed risks it provides trust for MedTech products to clinicians and patients." -

Adj Prof John Skerritt, Former Deputy Secretary for Health Products Regulation
Australian Government Department of Health and Aged Care

Australia is increasingly aligned with international MedTech regulation

The TGA is increasing alignment between Australian and international MedTech regulations. Australia is an active participant in international regulatory harmonisation through the International Medical Device Regulators Forum (IMDRF), including hosting the 2022 meetings.[17] The ongoing work of the IMDRF means that devices approved in one jurisdiction are more likely to be approved in the other.

The International Medical Device Regulators Forum (IMDRF) represents many important MedTech market regulators. Its goal is to improve international regulatory harmonisation with regulators in economies including Australia, Brazil, Canada, China, the European Union, Japan, Russia, Singapore, South Korea, United Kingdom and the United States of America.

There is great diversity in the regulations surrounding medical devices internationally, however, MedTech regulation in Australia generally follows European Union regulations. A key change occurred on the 23rd July 2021, where changes in regulation expanded the number of therapeutic goods that could rely on evidence from European Union conformity assessment bodies to support their inclusion on the ARTG[18].

[16] https://www.tga.gov.au/resources/publication/publications/tga-stakeholder-survey-2022
[17] International Medical Device Regulators Forum (IMDRF) | International Medical Device Regulators Forum
[18] Comparable overseas regulators for medical device applications | Therapeutic Goods Administration (TGA)

Legislative and regulatory reform are active in these areas and are adapting to emerging technologies, such as software as a medical device, personalised devices and 3D printing. Reducing duplicative regulatory assessments remains a goal of high-quality regulation for Australia[19].

MedTech manufacturers need support from Australian sponsors

Manufacturers must have their device or components sponsored by an Australian entity to receive ARTG approval by the TGA. In some circumstances, the manufacturer may also be the sponsor. It is also common, however, for sponsors to support applications for many manufacturers.

Manufacturers may engage the services of regulatory consulting organisations to represent them as the TGA sponsor for listing their product on the ARTG. For example, Emergo Australia extensively sponsors MedTech devices for manufacturers from Australia and around the world to assist in navigating local regulatory processes.

Reimbursement and procurement decisions are separated across different healthcare systems

Several other regulatory processes are important for MedTech developers. Examples of this include the following:

- **Ensuring related services are listed on the Medicare Benefits Schedule,** which reimburses healthcare providers for part of the cost of the service;
- **Getting devices listed on the Prescribed List,** which enables patient access to medical technology in the private health system; and
- **Procurement processes of providers,** such as state/territory hospital services.

Government and private approvals and purchasing have different pathways

Medical devices are used in a variety of contexts, with many low-risk devices being available direct to consumers (e.g. diabetes monitoring kits). More complex MedTech such as medical imaging machines generally exist in larger clinical settings such as clinics or hospitals. For a medical device to be available for purchase in Australia, it first must meet TGA regulations. However, after TGA regulations there are many different pathways for MedTech to receive reimbursement approvals and be procured by the public and private healthcare systems (Figure 6).

Federal government reimbursement

Australia has a unique healthcare system with significant interrelation between the public and private systems regarding the use and reimbursement of medical technology. The government often reimburses medical professionals carrying out medical procedures and using MedTech in a private healthcare setting. For example, an X-ray conducted by a private radiology clinic may charge for a scan but the cost may be fully or partially covered by the government. Items that are reimbursed by the Australian government are listed on the Medicare Benefits Schedule (MBS) and are paid in the form of a "Medicare rebate". However, in a public hospital, there would typically be no fees to the patients undergoing a similar scan. The costs of care would be covered directly by public funding of the hospital's operations.

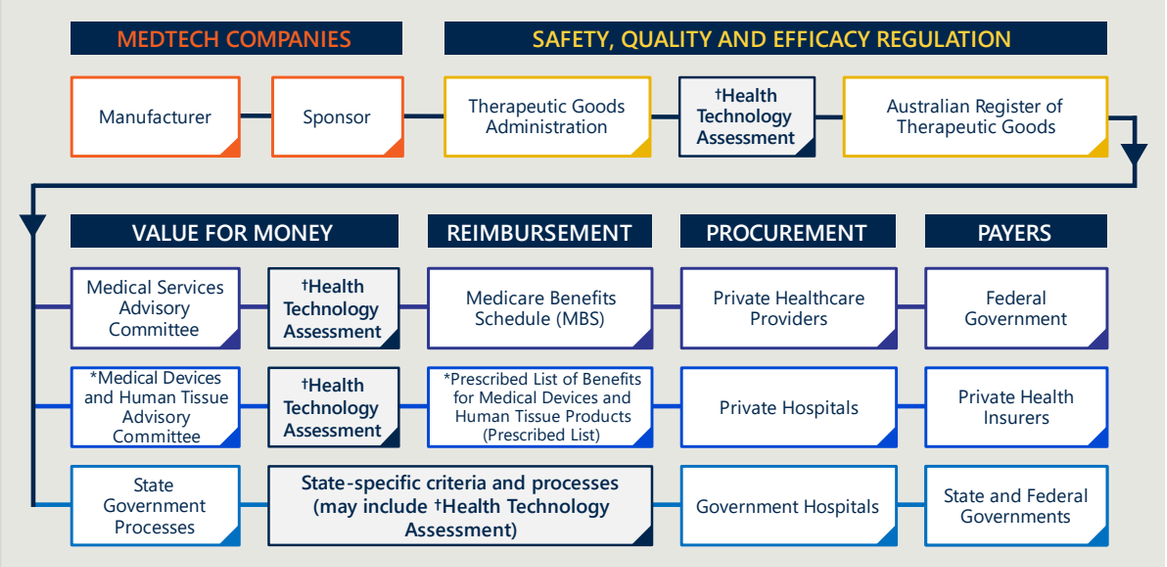
[19] Comparable overseas regulators for medical device applications | Therapeutic Goods Administration (TGA)

What this means for patients:

It is often the case that for MedTech-related procedures to reach broad patient populations, the procedure must be listed on the MBS. When a procedure is listed on the MBS, healthcare providers can be reimbursed by the amount set by the government which helps to cover their costs. Procedures without MBS listings often see patients pay the full cost of procedures, even if the medical devices used in the procedure are approved by the TGA as safe and efficacious. Therefore, delays in MBS listing have a direct impacts on the ability of patients to access the latest advancements in clinical care.

The main government body responsible for assessing medical technology for reimbursement through public funding is the Medical Services Advisory Committee. This is an independent non-statutory committee that advises the Government Department of Health and Aged Care.[20] New medical procedures, if they cannot be categorised under an existing MBS item number/category, undergo a Health Technology Assessment (HTA), to advise the Department on its suitability for public funding. While efficacy and safety are taken into consideration in this process, by this stage ARTG listing is approved or being performed in parallel with the TGA. The key consideration is therefore the economic case for the device being included in public reimbursement and for use in the private system. Following the assessment processes, a decision may be made to reimburse MedTech-related procedures. The procedures are then added to a list of MBS items and can be claimed.

Figure 6 | The pathways for MedTech entering the Australian gaining regulatory approval, gaining reimbursement, and entering the market.



This diagram is indicative and does not fully demonstrate the many complexities and cross -overs between pathways.
* As of 1st July 2023, the Medical Devices and Human Tissue Advisory Committee replace the Prothesis List Advisory Committee. This new committee will operate under a reformed process for listing medical devices on the prostheses list.
† Health technology assessment processes vary in their assessment criteria, including between states and federal governments.

[20] MSAC - About MSAC

Health Technology Assessments (HTAs) are part of the assessment process that determines the suitability of new MedTech devices to meet regulatory, reimbursement or procurement standards. The content and nature of HTAs varies across jurisdictions and assessment bodies. However, HTAs often focus on cost-effectiveness once a device is already approved for use by the TGA. Some organisations may use HTA outcomes from formal bodies as part of their decision-making process, such as for procurement, even when not explicitly required.

HTAs often assess: safety, efficacy, quality and economic business cases.

Private Healthcare Reimbursement

Private health insurance gives Australians options and control of their healthcare, opening more choice of clinician, hospitals and treatments with shorter wait times. Insurance may also provide access to a wider range of therapies and medical devices than what is supported by government reimbursement schemes.

Private health coverage of health procedure costs is dictated in part by an individual's private healthcare policy as well as the medical devices listing for access/use. There are recent reforms in the processes for having a medical device listed.[21] From the 1st July 2023, the Medical Devices and Human Tissue Advisory Committee will provide advice to the Australian Government on whether the devices should be listed on the Prescribed List of Benefits for Medical Devices and Human Tissue Products (Prescribed List) and may perform a HTA as part of that process. The reviews will operate under modernised review processes. Once a device is listed on the Prescribed List, private health insurers must meet the stipulated payment requirements for each product on the list and provide these devices to suitably insured patients.[22] The Medical Devices and Human Tissue Advisory Committee and Prescribed List replace the Prostheses List Advisory Committee and the Prostheses List, respectively.

State and Territory Procurement

States and territories in Australia administer funding to public hospitals but receive co-funding from the Federal government. At this level, states and territories must make their own decisions to maximise cost-effectiveness through a state-based HTA. However, in practice, states may make cost-effectiveness decisions based upon the HTAs already undertaken for the Prescribed List/Prostheses List or MBS.

Most states and/or territories have jurisdictional procurement offices that negotiate tenders and agreements for the health system. In some jurisdictions, there are health-specific procurement offices; in others, health procurement falls within a wider state government office. It is the long-term goal of the National Health Reform Agreement 2020-2025, that federal and state governments improve alignment on approaches to health technology assessment to encourage value in health procurement.[23]

Individual Purchasing

Medical devices may also be purchased directly by consumers, especially Class I devices which are generally considered low-risk. These can include items such as thermometers, diabetes test kits and rapid antigen tests.

[21] Modernising the prostheses list committee process | Health Portfolio Ministers and Aged Care
[22] The Prostheses List | Australian Government Department of Health and Aged Care
[23] 2020–25 National Health Reform Agreement (NHRA) | Australian Government Department of Health and Aged Care

What we've heard: The process for listing on the Medicare Benefits Schedule or Prescribed List/Prostheses List is a lengthy process that can occur over several years. It is often only after MedTech is listed that it is made widely available to patients. This means that even though a device may be classified as safe and effective by the TGA, it may not reach patients until much later.

Applying for and receiving approvals for reimbursement can create a major barrier for technology available for clinical use. Regulatory environment (74%) and regulator pricing (55%) was an operational challenge identified by survey respondents.

Variation in state and territory assessment processes can also be a barrier to access, with each jurisdiction having its own health technology assessment, procurement and tendering processes.

(MTAA survey respondents)

Australian regulation now and into the future

According to many survey respondents, the regulation of medical devices remains a concern and a barrier to future growth (see Section 5.1). There are recent and ongoing reforms in the TGA t¨at influence the regulatory burden into the future.

The TGA has released an action plan for medical devices to improve Australia's medical device regulatory system and prioritise patient safety[24]. The three-strategy plan focuses on improvements to device commercialisation, strengthening, the monitoring of devices currently available in Australia and providing detailed information on devices used by patients[25].

In 2019, the TGA performed international benchmarking for processes and timeframes against international regulators, including the USA, Canada, Japan, Brazil and the European Union. There was broad comparability of medical device regulation between each country, despite the distinct regulatory systems. It was noted that Australia is the only country to separate the pre-market approval (conformity assessment) and market authorisation steps (approval for sale). The separation of these steps makes Australian timeframes hard to compare with international performance. However, the TGA's timeframes for pre-market approval of high-risk devices are generally comparable with international benchmarks[26].

In response to the review, the TGA is currently undergoing a range of reforms to consolidate timeframes for pre-market approval of medical devices. As set out in the TGA international engagement strategy 2021-2025, the TGA is also focused on fostering international partnerships to enhance global policy alignment, pre-market global collaboration, post-market global monitoring and regional regulatory capabilities[27].

[24] https://www.tga.gov.au/resources/publication/publications/medical-devices-reforms-action-plan-medical-devices
[25] https://www.tga.gov.au/resources/publication/publications/medical-devices-reforms-action-plan-medical-devices
[26] https://www.tga.gov.au/sites/default/files/medical-device-application-processing-times-report.pdf
[27] https://www.tga.gov.au/resources/publication/publications/tga-international-engagement-strategy-2021-2025

Summary

Australia invests in the health of its citizens, with robust public and private healthcare systems. However, the pathway for MedTech to reach patients in Australia is complex.

There are many different processes and pathways for MedTech companies to navigate to get their technologies in the clinic.

Reforms to MedTech regulation, review processes and reimbursement approvals are ongoing. In the future, these reforms may simplify the process of getting MedTech into clinical use.

SECTION 2

MedTech is supporting Australia's healthcare

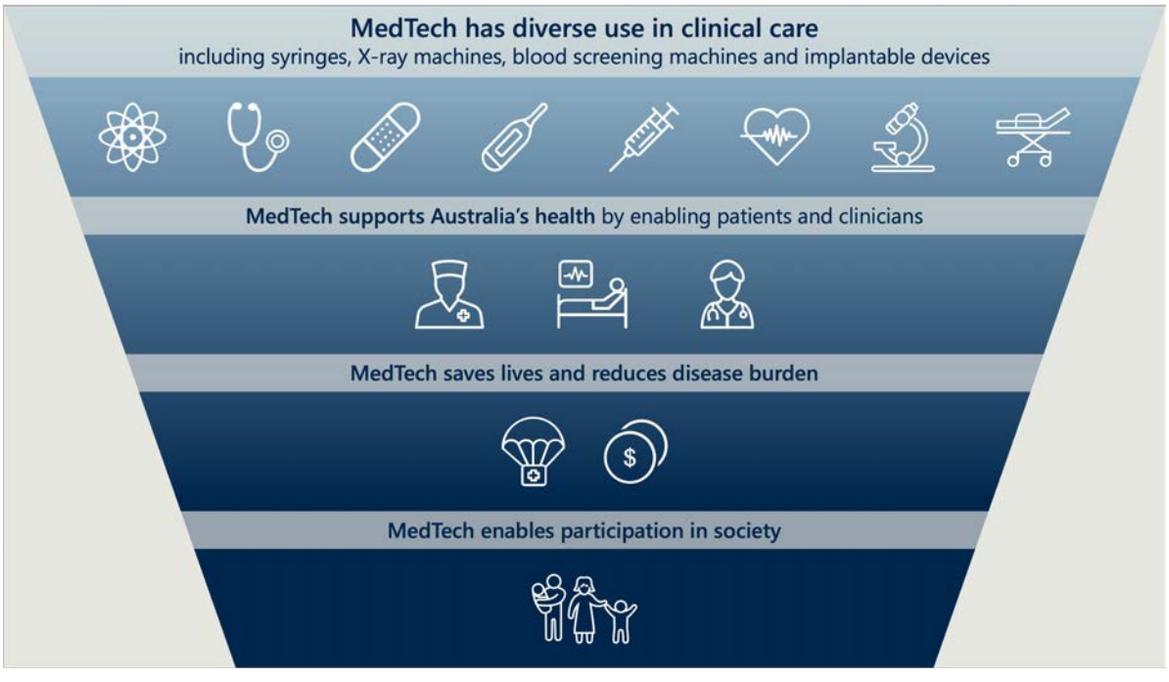
MedTech provides essential tools and capabilities for the Australian healthcare sector. MedTech is enabling patients to enjoy a better quality of life and broader participation in Australian society (Figure 7). Australia's healthcare system is enabled by a highly skilled workforce, making it a great location to deliver new MedTech.

2.1 MedTech is extensively used in the Australian healthcare system

MedTech provides integral goods, services and new technologies for the healthcare system to improve patient outcomes. The diversity of the Australian medical technology industry means that all Australians have interacted with MedTech, whether from standard diagnostic tests, surgery or even vaccinations with hypodermic needles. MedTech is supporting Australians from conception until end-of-life.

The MedTech industry provides essential medical equipment in all settings, ranging from large tertiary hospitals to small rural clinics and helps train healthcare professionals to ensure the safety and optimal use of MedTech products. Additionally, the MedTech industry provides professional development opportunities, such as training modules and webinars, to upskill staff and increase efficiency in the healthcare system.

Figure 7 | MedTech addresses the burden of disease on patients, enables improved participation in society

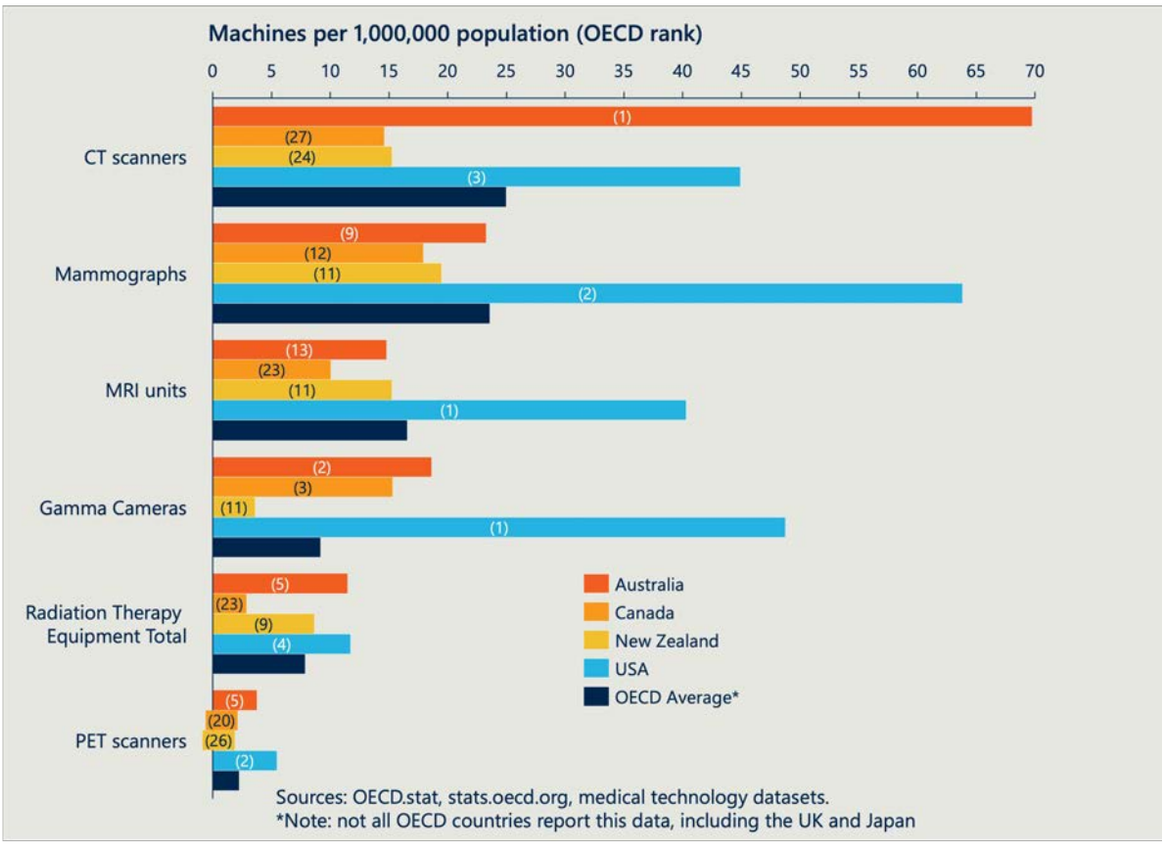


MedTech is successfully integrated into Australian healthcare

Access to safe and efficacious medical technology is a critical component of providing quality healthcare. MedTech provides the tools to diagnose, monitor and treat patients and the successful use of MedTech leads to a reduced burden of disease, better outcomes from healthcare interventions and improved quality of life. Australia is well-equipped with critical MedTech infrastructure, such as medical imaging technology and radiation therapy equipment that is the backbone of modern healthcare (Figure 8).

The use of medical devices must meet the needs of all healthcare stakeholders, from government to the patients receiving care. These needs include access to safe and effective care which is affordable to both the individual and to government. For this to be met, MedTech businesses must meet stringent standards to enter the market and even higher standards to be reimbursed by private and public healthcare funders and service providers.

Figure 8 | Australia is well-equipped with diagnostic and therapeutic MedTech infrastructure



What this means for patients:

From beginning to end of life, Australians have access to MedTech equipment and infrastructure that helps monitor health and diagnose disease.

In 2020, there were 295,976 babies born in Australia; 96% of these births occurred in hospitals. The support of MedTech, such as ultrasounds, to hearing tests in newborns, is essential during and after pregnancy[28]. The standardised use of these technologies gives babies the best chance at early intervention and a good start to life. Australian companies are developing new ways to improve detection and therapy in early life (see Case study 3).

Breast cancer is the most common cancer in women in Australia. Early screening and detection give a patient the best chance of survival. Breast Screen Australia is a national program that offers free mammograms for women over 40. 1.7 million women participated in the program from 2020-2021[29]. Women who were diagnosed with breast cancer through BreastScreen Australia between 2002 and 2012 had a 42% lower risk of dying from breast cancer by 2015 than women with breast cancer who had never been screened[30]. Breast cancer screening is one example of a medical intervention that is saving lives across Australia. Australian companies continue to innovate in testing and interventions for breast cancer (Case study 4).

[28] Mothers & babies Overview - Australian Institute of Health and Welfare (aihw.gov.au)
[29] https://www.aihw.gov.au/reports/australias-health/cancer-screening-and-treatment#How%20effective%20are%20the%20cancer%20screening%20programs?
[30] https://www.aihw.gov.au/reports/australias-health/cancer-screening-and-treatment#How%20effective%20are%20the%20cancer%20screening%20programs?

Case study 3 | Advanced technologies improve health outcomes for paediatric and maternal patients

AUSTRALIAN MEDICAL INNOVATION IS SUPPORTING THE START OF LIFE HEALTHCARE.

Australian companies Navi Medical Technologies and Baymatob have introduced cutting-edge technologies in paediatric care and maternal health, improving patient outcomes and clinical experience.

Central venous catheters are a common medical device used in intensive care unit (ICU) settings but face significant challenges for use in paediatric patients due to their age, size and mobility.

Melbourne start-up Navi Medical Technologies is developing a device to safely place and monitor central vascular catheters in paediatric patients. Its system will enable safer care for critically ill children by shortening procedure times and reducing complications with catheter misplacement or migration.

Postpartum haemorrhage (PPH) is the leading cause of preventable maternal death worldwide, with its current diagnosis methods leaving doctors with only minutes to administer life-saving treatments.

Sydney medical device company Baymatob has a world-first device that predicts if a woman is at risk of PPH before she gives birth. This early detection can significantly reduce PPH complications and the data acquired can be used for further research into maternal healthcare.

Case study 4 | Redefining cancer surgery with novel imaging technology

INNOVATIVE MEDICAL DEVICES ARE HELPING CANCER PATIENTS

OncoRes Medical are developing an imaging technology to assist surgeons with real-time assessment of tissue structure.

One in seven women are diagnosed with breast cancer in their lifetime[31]. The first stage of treatment involves complete surgical removal of the tumour, but sometimes part of the tumour gets left behind. This causes up to 35% of women to return for a second surgery, which can cause increased psychological trauma for patients, increased risk for complications and raise healthcare costs.

Perth-based start-up, OncoRes Medical, is developing a novel imaging device to help surgeons detect the difference between cancerous and healthy tissue. OncoRes has its origins at the University of Western Australia and the Western Australian Department of Health. Their device uses Quantitative Micro-Elastography technology, guiding surgeons with real-time decision-making to help remove all the cancer the first time. The device has demonstrated high diagnostic accuracy (96%) in detecting cancer in benchtop testing and a first in human proof-of-concept study has been done with 21 patients. A series of clinical trials are in progress to support the device receiving approval for more widespread clinical use. [32]

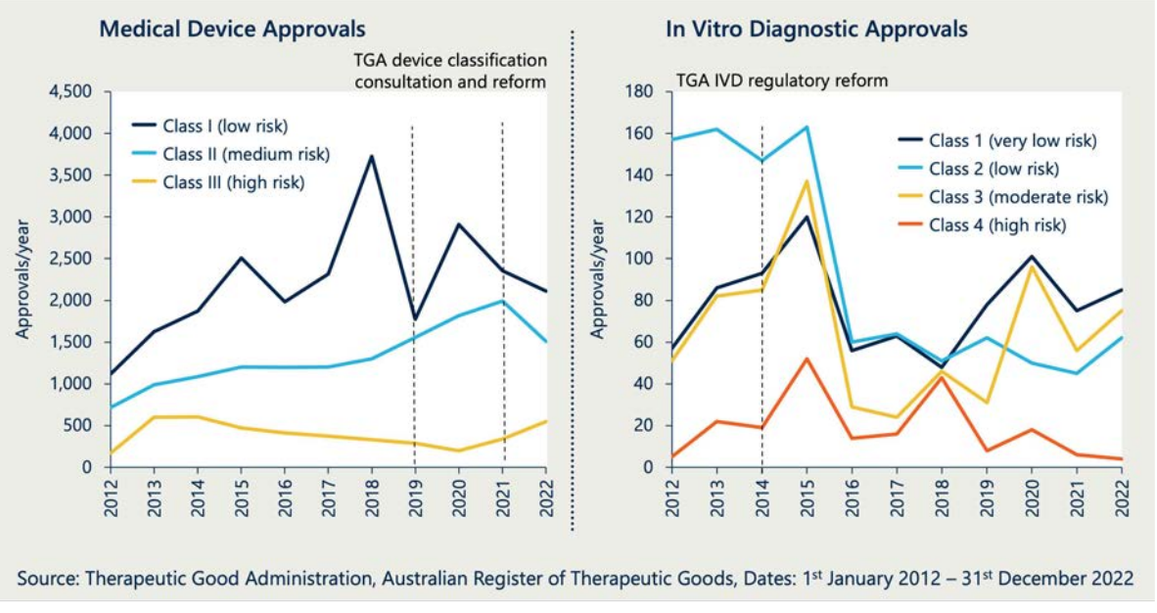
[31] https://nbcf.org.au/about-breast-cancer/breast-cancer-stats/
[32] https://nbcf.org.au/about-breast-cancer/breast-cancer-stats/#:~:text=Breast%20cancer%20is%20the%20most,breast%20cancer%20in%20their%20lifetime.

For more information about Australian MedTech Innovation see Appendix C "Clinical Trials and Innovation: The MedTech industry supports the healthcare workforce to achieve better patient outcomes"

Australia has new MedTech regularly entering the market

Approvals for MedTech devices in Australia have undergone patterns of change over the past 10 years (Figure 9). There has been a steady stream of approval on the ARTG for both medical devices and *in vitro* diagnostics (for medical sample testing), which have been shaped by reforms by the TGA. In 2022, there were over 4000 new medical device and 220 new *in vitro* diagnostic approvals. Less than 50% of these were for low-risk devices and diagnostics (Class 1/ Class I).

Figure 9 | MedTech approvals are enabling Australians to access the latest improvements in care



Source: Therapeutic Good Administration, Australian Register of Therapeutic Goods, Dates: 1st January 2012 – 31st December 2022

The approval of a new device requires many stakeholders to work together to create a solid evidence base. Australia has processes and infrastructure which support collaborations with MedTech companies, both big and small.

What we've heard: The high quality of research, clinicians, healthcare system and medical infrastructure makes Australia an attractive location for MedTech collaborations and for gathering evidence to support regulatory approvals.

"Genuine partnerships are valuable with both established MedTech companies, but also with start-ups."

Dr Teresa Anderson, Chief Executive, Sydney Local Health District

MedTech is enabling patients to have more fulfilling lives

Many of the diseases that MedTech treats are integrated into a broader program of health management. MedTech can leverage other clinical practice and innovations to help patients live more fulfilling lives.

Diabetes is highly prevalent in Australia, with almost 1.3 million (1 in 20) Australians living with the condition in 2020[33];11% of hospitalisation in Australia are associated with diabetes (2020-21)[34]. Diabetes has been associated with a high degree of self-management, with treatments typically involving diet monitoring, oral medication or insulin injection. The use of MedTech has revolutionised the way diabetes treatments are delivered, through the invention of the insulin pump and continuous glucose monitoring for Type 1 diabetes. An insulin pump is a small device that delivers continuous insulin and is attached to the body using a catheter, which is inserted under the skin of the abdomen. The pump gives patients more control over their blood sugar levels, removing the need for manual injections. A continuous glucose monitor is a small filament that sits under the skin and is connected to a sensor and chip that records and transmits real-time glucose measurements to either a smartphone application or a reader.

In Australia, the Juvenile Diabetes Research Foundation is an advocacy leader and research funder for Type I diabetes treatment[35]. Their work ranges from fundraising to funding research. Notably, they helped establish a nationwide insulin pump program for children and young adults to access[36]. The Juvenile Diabetes Research Program is a valued resource for patients, with 88% of insulin pump users from the program benefitting from better control over blood sugar levels and 67% having reported improved lifestyle flexibility.[37]

What we've heard: The development of new and advanced MedTech is enabling patients to live fuller lives. Personalised medicine is enabling customised and adaptable MedTech. ***"MedTech is the key to patient self-management"***
Mike Wilson, OAM, CEO, Juvenile Diabetes Research Foundation

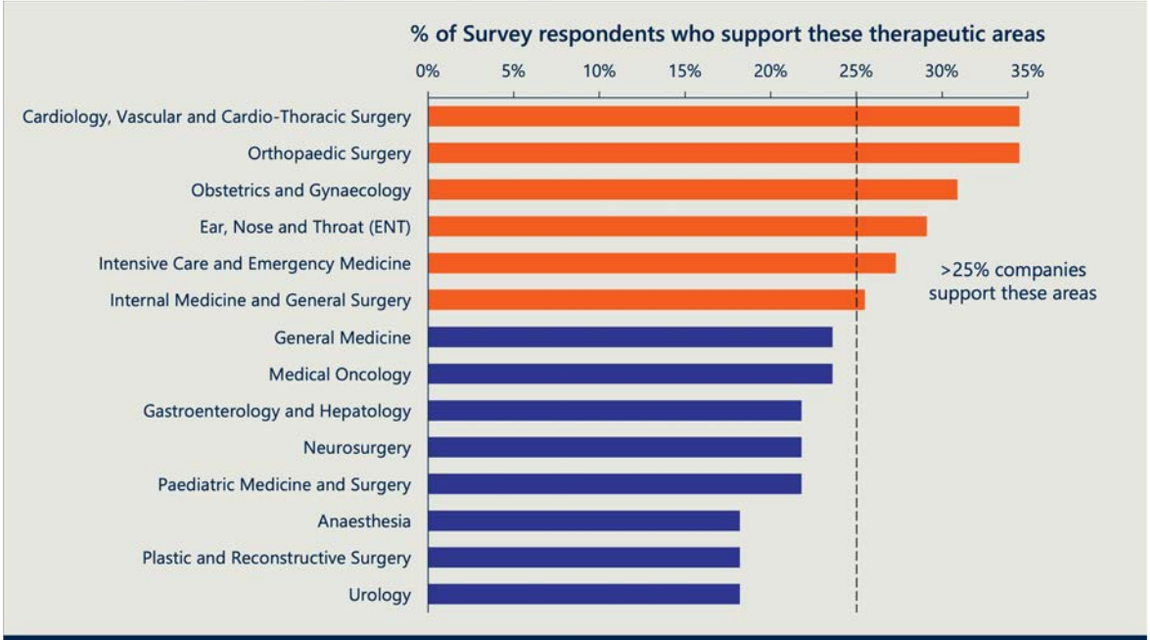
[33] https://www.aihw.gov.au/reports-data/health-conditions-disability-deaths/diabetes/overview
[34] Diabetes: Australian facts, Hospitalisations - Australian Institute of Health and Welfare (aihw.gov.au)
[35] https://jdrf.org.au/
[36] https://jdrf.org.au/living-with-t1d/insulin-pump-program/
[37] https://www.aihw.gov.au/getmedia/56686b65-b928-4076-a7cd-16661414b0fe/insulin-pump-use-pros-cons.pdf.aspx

2.2 MedTech reduces the Australian burden of disease

The burden of disease on patients is a combination of disease impact on quality of life and impact on longevity. The Australian Burden of Disease Study quantifies this and provides insight into what health problems impact Australians the most[38]. This study measures the impact on health through "Disability adjusted life years" (DALY) which considers the impacts of disease on quality of life and longevity. Advances in MedTech have been occurring in many areas of high disease burden. Over time, many serious conditions have reduced their burden on individuals, in part due to the improvements in MedTech. Early-life interventions are particularly important in reducing the burden of disease. Improving the health of a child or infant often has benefits that accrue throughout their life.

In 2022, the top five most burdensome disease groups included mostly chronic conditions including cancer, musculoskeletal conditions, cardio-vascular disease, mental health conditions and substance use disorders, and neurological conditions.[39] These top five accounted for close to two-thirds of the total burden. Australian MedTech companies are addressing many areas of disease burden, including the therapeutic areas of cardiovascular disease and neurological conditions (Figure 10).

Figure 10 | Top therapeutic areas supported by MTAA survey respondents



What this means for patients:

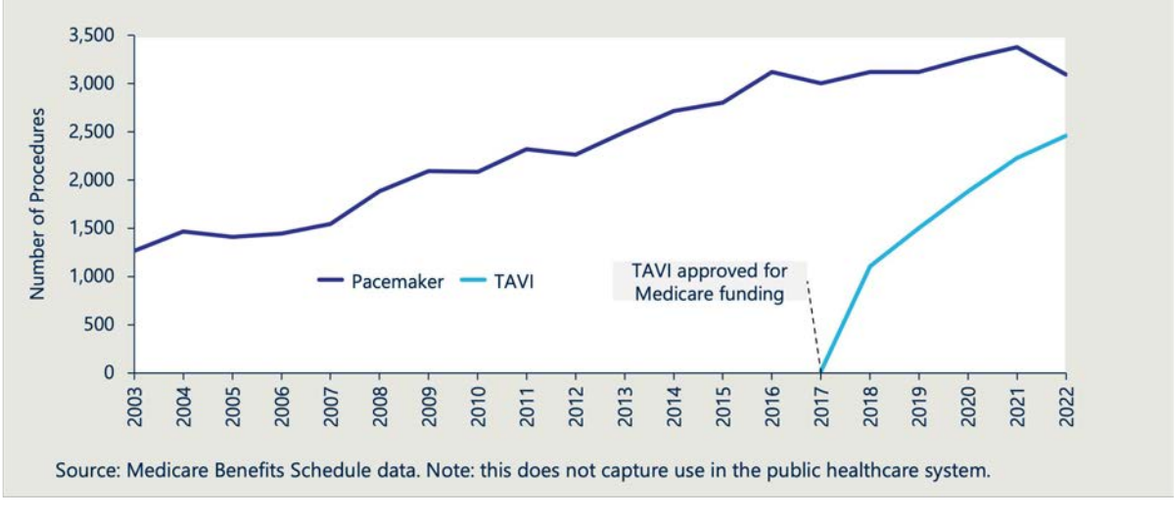
Patients are benefitting from surgeons using the latest techniques such as robotic surgery. The Royal Australasian College of Surgeons (RACS) is providing the world's first online robotic surgery course for surgeons, designed by surgeons.[40,41] The online course is part of a broader surgical training curriculum leveraging virtual reality, simulation and synthetic training materials.

[38] https://www.aihw.gov.au/reports/burden-of-disease/australian-burden-of-disease-study-2022/
[39] https://www.aihw.gov.au/reports/burden-of-disease/australian-burden-of-disease-study-2022/
[40] A new foundational course in surgical robotics | RACS (surgeons.org)
[41] World-first robotic surgery course for surgeons by surgeons | RACS

MedTech has been an important tool to complement a suite of medical and public health interventions for cardiovascular disease. MedTech and other interventions have ultimately led to a reduction in the burden of heart disease. There has been increased life expectancy for heart disease patients, with the fatal burden falling from 17.2 years lost per 1000 head of population in 2003 to 7.0 years lost in 2022.

Cardiovascular disease is the third largest burden of disease in Australia[42]. It includes a range of conditions such as coronary heart disease, cerebrovascular disease, rheumatic heart disease and other conditions. Advancements in pacemaker technology[43] and the introduction of Transcatheter Aortic Valve Implantations (TAVI)[44] has directly reduced the burden of the disease, along with other public health interventions (including reductions in smoking, low-salt food, medications and public access to defibrillators). These MedTech interventions are increasingly supporting the health of Australians (Figure 11). For more advanced degenerative cardiac conditions such as aortic stenosis, TAVI has been an important intervention. TAVI was only listed on the MBS in 2017 but has seen a steady rise in use and is improving patient outcomes (Case study 5). MedTech, along with a variety of factors, has made cardiovascular health a success story in Australian health. In 2003, coronary heart disease was the cause of an age standardised DALY rate of 20.9 years per 1000 population. Since then, the age-standardised DALY per 1000 population has fallen approximately to 9.0 years in 2022. Over time, many other serious cardiovascular conditions have reduced their burden, in part due to the improvements in MedTech.

Figure 11 | MedTech use for cardiac interventions has increased in Australia



Source: Medicare Benefits Schedule data. Note: this does not capture use in the public healthcare system.

[42] https://www.aihw.gov.au/reports/burden-of-disease/australian-burden-of-disease-study-2022/contents/summary#Significant
[43] Growing 37% over ten years to over 3,000 pacemaker insertions, removals or replacements in 2022 (MBS Data)
[44] 2,458 implantations of TAVI in 2022, reflecting a 10% increase from last year and a 123% increase from 2018 (MBS Data)

Case study 5 | MedTech is improving outcomes for patients with heart disease

MEDTECH IS SUPPORTING HEART DISEASE CARE

Low-risk and high tolerability of the transcatheter aortic valve implantation (TAVI) has led to earlier intervention for heart disease, improving patient outcomes and life expectancy.

Aortic stenosis is a heart valve disease severely affecting over 97,000 Australians and often requiring open heart surgery as treatment[45]. The disease leads to narrowing of the aortic valve opening, with symptoms including breathlessness, fatigue, chest pain and dizziness. Aortic stenosis is treated by fitting a replacement valve into the heart, traditionally through a surgical procedure. However, this invasive approach limits patient uptake.

Medical technology companies, including Edwards Lifesciences and Medtronic, are improving technologies for a procedure named transcatheter aortic valve implantation (TAVI)[46]. TAVI can treat aortic stenosis through a minimally invasive method of valve replacement. TAVI is performed through many small cuts instead of one large cut. Patients experience immediate benefits post-operation and reduced recovery when compared to surgical valve replacement. The procedure can also deliver broader health system optimisation through shorter stays in hospital.

"My TAVI procedure was painless; I had no idea what had been done; there was no pain or after-effects; the only effect was that I had never felt better in the previous 25 years." - Les Terrans, 85-year-old TAVI patient

The value of unpaid services provided by older Australians should be recognised. Older people's contribution to society through non-market activities, including volunteering, childcare and informal carer support helps to support the nation's economy. Offering TAVI to people aged over 65 could potentially prevent $117 million in productivity loss in a year due to withdrawal from productive activities[47].

Recently, the introduction of MBS item (38522) in Australia has widened accessibility for TAVI procedures as patients classed as low-risk for heart surgery can now access TAVI as non-invasive treatment option.

For more information about MedTech improving patient health see Appendix C "Patient Outcomes: MedTech innovation is improving patient outcomes".

[45] https://www.neda.net.au/_files/ugd/53defd_26301120845d48efaa789c04220a5155.pdf
[46] https://www.edwards.com/gb/procedures/aorticstenosis/TAVI
[47] Australian Government - Productivity Commission. An Ageing Australia: Preparing for the Future. 2013 [July 2021]; Available from: https://www.pc.gov.au/research/completed/ageing-australia. Available from: https://baker.edu.au/-/media/documents/impact/baker-institute_our-hidden-ageing-whitepaper.pdf

MedTech enables independence for people with chronic conditions

Australia has an ageing population, increasing the burden of disease and demand on the healthcare system. By 2053, those aged over 65 years are projected to account for 21% of the population (8.3 million people)[48].

As many of the leading causes of disease, including chronic conditions, result from an ageing population, the burden of disease in Australia is expected to increase over the coming years. Burden of disease refers to the impact of diseases and injuries on a population. Cancer, musculoskeletal and cardiovascular are the top three disease burdens, and targeting these groups is a priority for Australia[49]. MedTech companies are meeting this challenge by providing medical products to help individuals regain independence in their daily lives such as improving urinary function (see Case study 6) and restoring vision for the elderly (see Case study 7).

Case study 6 | Minimally invasive Medtech device relieves lower urinary tract symptoms

INNOVATIVE DEVICE RELIEVES URINARY SYMPTOMS

Olympus, a manufacturer of optical and digital precision technology, has developed a novel device to help patients experience from BPH symptoms.

Benign prostatic hyperplasia (BPH), which causes lower urinary tract symptoms, is a common condition among the ageing male population. Around 50% of men over age 50 have BPH compared to over 80% of men aged over 80[50]. This burden of disease is expected to grow with the ageing population.

BPH occurs when the prostate and surrounding tissue expands, with common symptoms including the need to urinate frequently and a weak urine stream. To address this, Olympus has developed a temporary implanted nickel-titanium device that delivers fast and effective relief from these symptoms shortly after the device is implanted.

The device can potentially reduce the burden of the cost of pharmaceuticals for BPH as it can be offered as an alternative to both surgical interventions and pharmaceuticals, which come with side-effects. Implantation can be performed as a day surgery, reducing demand on hospital staff, patient catheterisation and hospital beds.

Case study 7 | Intraocular lenses are restoring vision and independence for Australians

ADVANCED MEDICAL DEVICES ARE TRANSFORMING EYE CARE

The ophthalmic device industry has developed cutting-edge technologies to treat eye disease and conditions such as cataracts and glaucoma.

Over 1.1 million Australians are living with cataracts and more than 300,000 have glaucoma. As the population ages, the burden of cataracts is expected to rise.

Presbyopia-correcting intraocular lenses (PC-IOLs) are cutting-edge implantable artificial lenses for the eyes that allow patients to maintain their visual independence post-surgery. PC-IOLs provide clear vision at multiple distances, reducing or eliminating the need for glasses or contact lenses after cataract or lens replacement surgery.

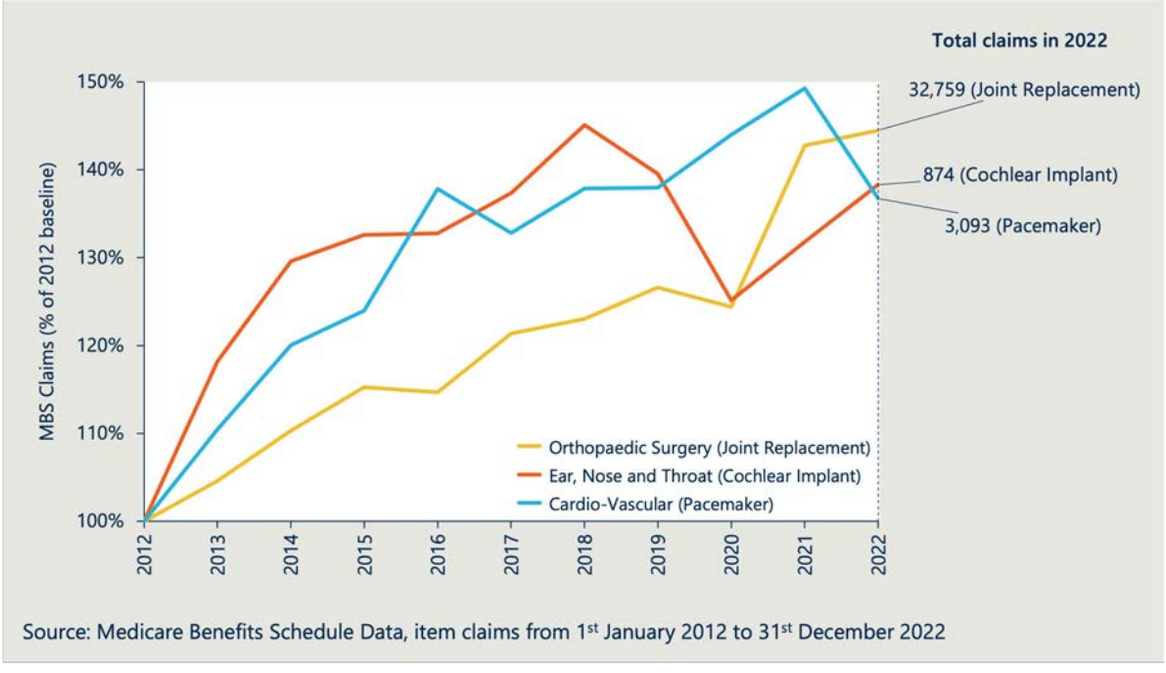
The impact of Intraocular lenses extends beyond improved visual outcomes, with clear vision essential for independent living, physical safety and mental health. Additionally, it allows individuals living with chronic conditions such as cataracts to resume daily activities such as reading, cooking and driving, leading to a healthier and happier life.

[48] https://www.aihw.gov.au/getmedia/19dbc591-b1ef-4485-80ce-029ff66d6930/6_9-health-ageing.pdf.aspx
[49] https://www.aihw.gov.au/reports/burden-of-disease/australian-burden-of-disease-study-2022/contents/summary
[50] Chughtai et al., 2016. Benign prostatic hyperplasia. Nature Reviews Disease Primers

Many complex devices used for chronic diseases have seen growth in use in the past 10 years (Figure 12). While data does not show the total number of devices being used in Australia, it illustrates a trend of steady growth in the use of complex implantable devices which provide sustained benefits. Each of these complex devices has seen a 30% increase in MBS claims (private sector claims) since 2012.

A particularly prevalent type of MedTech intervention is joint replacement. Because of the importance of this intervention, the Australian Orthopaedic Association maintains a register of the total number of joint replacements in Australia[51]. This shows that replacements are far more common than MBS data alone would indicate. Joint replacement is a complex procedure, however, Australian companies are assisting with the planning of joint replacement surgeries, and the training of surgeons (see Case study 8).

Figure 12 | MedTech use is increasingly enabling patients with complex needs



Source: Medicare Benefits Schedule Data, item claims from 1st January 2012 to 31st December 2022

What this means for patients:

MedTech is used to treat patients with chronic conditions to ensure they live an independent life and participate in society. Osteoarthritis is a chronic joint disease that affects mostly middle-aged to older adults. Joint replacement surgeries, commonly knee or hip, replace the damaged joint with an artificial joint to restore mobility for the patient. In 2022, Australia had 64,579 and 52,635 total knee and hip replacement elective surgeries, respectively[52]. Every surgery helps to relieve pain, correct deformity and allows the patient to resume normal activities. Advances in surgical materials and techniques have increased the effectiveness of joint replacement surgeries, allowing more Australians to be treated and live a better quality of life.

[51] Home - AOANJRR (sahmri.com)
[52] https://aoanjrr.sahmri.com/knees

Case study 8 | Australian start-up and global manufacturer create novel bio-model

PARTNERSHIPS BETWEEN GLOBAL COMPANIES AND START-UPS ENABLE FAST DEVELOPMENT

A collaboration between large medical device company Johnson & Johnson (J&J) and South Australian start-up Fusetec has fast-tracked the development of a novel surgical training model.

In partnership with J&J, Fusetec has developed a Total Knee Replacement (TKR) model using cutting-edge technology. TKR is a lifelike, anatomically accurate bone, skin and muscle model designed for surgical training, reducing the need for surgeons to practice on real patients or expensive cadavers[53]. J&J has supported Fusetec through access to global leaders, databases and large international markets.

The collaboration brings great social and economic value to Australia and worldwide. Globally, the bio-model can help train surgeons in developing nations with limited access to equipment. Fusetec is opening a world-first 3D Advanced Surgical Training Clinic in South Australia to serve as an education centre for their biomodel. This clinic will create 157 direct jobs and an additional 800 indirect positions, strengthening the local economy[54].

For more information about MedTech improving healthcare workforce productivity see Appendix C "Workforce and Operational Productivity: MedTech is upskilling the surgical workforce"

MedTech companies are providing broad social benefits for Australia

MedTech provides value to many parts of the healthcare sector beyond the direct benefits to patients (Figure 13). MedTech companies, as they develop new technologies and interventions, play an important role in providing information and training for best practice. MedTech companies also providing essential roles in managing patient care, where they support surgical operations, assist with maintenance of MedTech devices and manage after-patient care (Case study 9).

Respondents in the MTAA survey play many valuable social roles in the sector, providing: internships and training (65%); environment and sustainability initiatives (57%); patient advocacy (54%) and philanthropic initiatives (46%). From the social benefits identified in the survey, 8 out of 9 are expected to grow in the future.

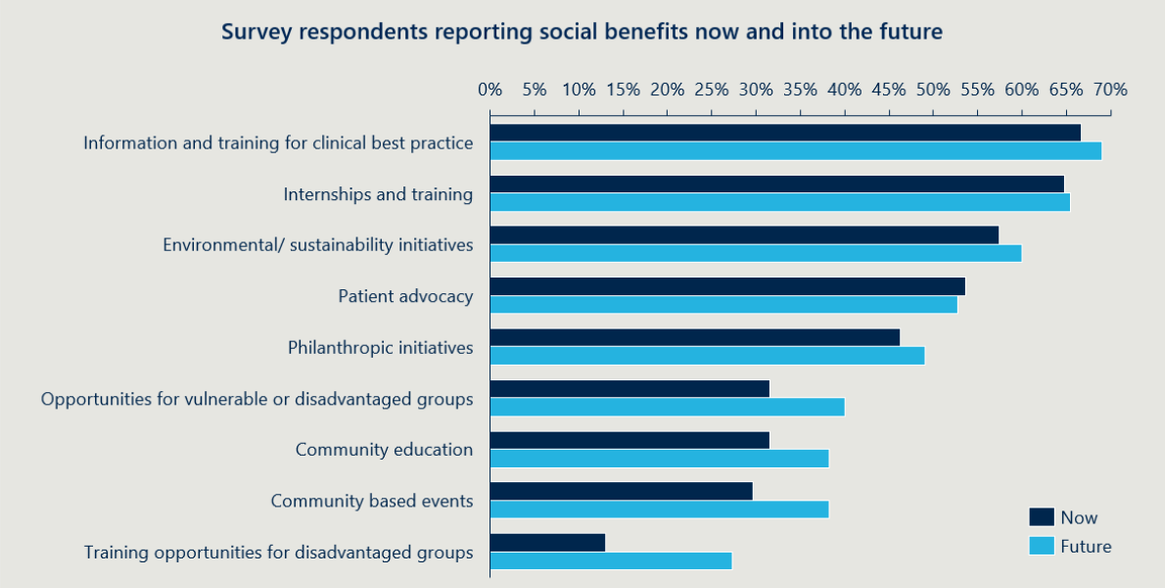
[53] https://fusetec.com.au/products
[54] https://www.aumanufacturing.com.au/fusetec-opens-3d-printed-body-part-surgery-training-clinic

What we've heard: MedTech companies provide valuable professional development and training opportunities. These opportunities are a great way to promote workforce retention in areas of high demand such as theatre nursing. By upskilling the workforce, there is potential to improve patient outcomes and retain healthcare staff.

What this means for patients:

The MedTech industry is actively helping clinicians and other medical staff to develop skills and improve patient care. Many roles employed by the MedTech industry support the healthcare workforce, thereby helping to alleviate the demands of the staffing crisis in hospitals. This means patients can receive the highest quality care, with reduced wait times and more personalised treatment plans. Improved patient outcomes from healthcare have a flow-on effect on society; when patients resume their daily activities they contribute to local communities and the wider economy. MedTech's continued support to the healthcare system improves Australia's health and wellbeing.

Figure 13 | The social benefits provided by MedTech companies



Source: MTAA Value of MedTech Survey. Questions: What social benefits does your organisation currently achieve? What social benefits does your organisation expect to achieve in the future? [Multiple selections possible from a list]

Case study 9 | MedTech is providing cardiac services that improve patient outcomes

MEDTECH IS IMPROVING PATIENT CARE AND REDUCING WORKFORCE SHORTAGES

Medtronic is a MedTech company enabling patient care and reducing workforce shortage through cardiac services.

Heart disease is the leading cause of death in Australia [55]. Incidents such as heart attacks or heart failure can result from this condition. This issue is met with medical interventions such as cardiac implantable electronic devices (CIEDs), that control and monitor a patient's heart rate. CIEDs are improving quality of life and survival rates for many patients, helping lower the burden of heart disease in Australia.

A cardiac technician is required to monitor and regulate CIEDs throughout their lifetime, ensuring the device is functioning properly and fixing any malfunctions. These services are delivered direct to patients face-to-face or via remote monitoring and can often require travel to rural or remote areas. As the number of CIED patients is predicted to grow, so too will demand for patient support services[56]. Medtronic and other MedTech firms including Abbott, Boston Scientific, Microport and Biotronik, are helping to address this shortage by offering cardiac services alongside their implantable devices. A diversified workforce means cardiac technicians can provide better care to patients, leading to better patient outcomes, such as better quality of life, fewer adverse events, less time in hospital and reduced device replacements.

Ongoing support from the medical technology sector is critical to ensuring demand for cardiac services are met and patients receive superior care.

For more information about the MedTech workforce see Appendix C "Health and Population Outcomes: The MedTech industry supports the healthcare workforce to achieve better patient outcomes"

MedTech and the response to COVID-19

Collaboration with MedTech companies was essential to Australia's pandemic response

Australia's MedTech industry played a vital role in the response to COVID-19. As the pandemic accelerated, new collaborative efforts between the MedTech industry and Australian government were formed in response to the rising case numbers. Medical Technology Association of Australia (MTAA) helped develop a framework to establish a COVID-19 Industry Working Group to support the Australian Government's Health Industry Coordination group[57]. The working group consisted of various MedTech

[55] https://www.aihw.gov.au/reports/heart-stroke-vascular-diseases/hsvd-facts/contents/summary-of-coronary-heart-disease-and-stroke/coronary-heart-disease

[56] KPMG 2021, Cardiac Implantable Electronic Device (CIED) service valuation

[57] https://www.mtpconnect.org.au/images/V3_MTPConnect%20MTAA%20Taskforce%20Ministerial%20Briefing%20Paper%20(Web%20version).pdf

companies in Australia from SMEs to large multinationals. MedTech companies manufacturing and supplying products in Australia are well-connected with the hospital system. This enabled them to have a crucial role in ramping up supply and delivery of vital equipment, such as ventilators, personal protective equipment, test kits and other hospital supplies.

The MedTech industry worked in collaboration with the federal government to ensure Australia secured its fair share of essential equipment in demand across the globe. For patients, this meant they could receive quicker diagnosis of COVID-19 through access to testing kits, which would further protect those around them and the wider community. The Australian industry collaboration was recognised as one of the best global responses to COVID-19, with other countries looking to replicate the working group strategy to prepare for future health challenges[58].

What this means for patients:

MedTech was an essential tool to monitor and manage the COVID-19 response. By 30th April 2022, there had been nearly 6 million COVID-19 diagnoses in Australia.[59] MedTech formed the backbone of these diagnoses, from the use of nasal swabs to the machines that performed the testing. The approval of Rapid Antigen Testing by the TGA enabled Australians to self-test and became a key tool to monitor the pandemic and allow more people to return to work.

Innovation during COVID-19 helped address global MedTech supply shortages

The COVID-19 pandemic stimulated innovation from Australian MedTech companies to meet new patient needs. Ventilators are a life-saving device for patients with severe respiratory COVID symptoms, supporting the patients' lungs while their bodies fight off the virus. Global demand for ventilators rapidly increased during the early months of the pandemic. To help Australia secure enough ventilators for the population, many global and local Australian MedTech firms turned to innovation.

One example is a collaboration between an JigSpace, an Australian MedTech company and global firm Medtronic. Medtronic released an open source of their ventilator design to boost global ventilator production. Victoria-based JigSpace saw an opportunity to further assist Medtronic, by creating 3D assembly guides that visualise the ventilator blueprint. This model allowed manufacturers to visually guide themselves through the assembling processes, speeding up production time. This helped manufacturers quickly learn how to assemble, operate and maintain ventilator specifications[60]. A larger supply of ventilators meant more patients with severe COVID-19 symptoms could be supported with the life-saving device. This partnership represents a valuable lesson in how companies can rapidly collaborate to create or scale-up devices that can save patients' lives.

What this means for patients:

The COVID-19 pandemic required rapid changes in clinical care around the world to deal with unprecedented patient demand. Many of the essential diagnosis tools, care equipment and hospital beds were designed and manufactured by the MedTech industry. The MedTech industry worked closely with government and the healthcare sector to ensure patients' needs were met.

[58] https://www.mtpconnect.org.au/images/V3_MTPConnect%20MTAA%20Taskforce%20Ministerial%20Briefing%20Paper%20(Web%20version).pdf
[59] COVID-19 Overview - Australian Institute of Health and Welfare (aihw.gov.au)
[60] https://biomelbourne.org/medtronic-partner-with-melbourne-company-to-accelerate-global-ventilator-knowledge/

The high demand for intensive care unit (ICU) beds was another pressing challenge Australia and the world faced during the COVID-19 pandemic. ICU beds were necessary to treat patients with severe symptoms who needed critical care. Stryker, a global MedTech firm, developed an emergency relief ICU bed in response to the growing demand for hospital beds[61]. The low-cost bed was made using innovative design and manufacturing to help healthcare staff move and position patients' efficiently. To manufacture the bed, Stryker used four small Australian companies from other manufacturing industries, who temporarily pivoted to "MedTech" manufacturing. This represents the impact of MedTech innovation in design and manufacturing during the COVID-19 pandemic.

Summary

Australians have access to MedTech which is well-integrated into standard clinical care. The use of MedTech has been one of many factors that has reduced the burden of disease on Australia that has been occurring over decades. MedTech has become increasingly important in managing chronic disease, such as diabetes and cardiovascular disease, where the benefits to patients are accruing over long periods of time.

MedTech became integral in Australia's response to the COVID-19 pandemic. The collaboration between governments and MedTech companies helped manage unprecedented demand on the healthcare system by providing essential supplies such as ventilators and intensive care unit beds. Patients in Australia continue to benefit from MedTech innovations in Australia and abroad.

[61] https://www.stryker.com/au/en/about/news/2020/australian-manufacturers-producing-emergency-hospital-beds.html

SECTION 3

MedTech is developing Australia's innovation

Innovation in MedTech has the potential to create new value for patients, the healthcare system, and economy. However, the full value of MedTech innovation is only achieved once it has reached clinical use. This requires that the innovation has met the key regulatory milestones that ensures the technology is safe and efficacious.

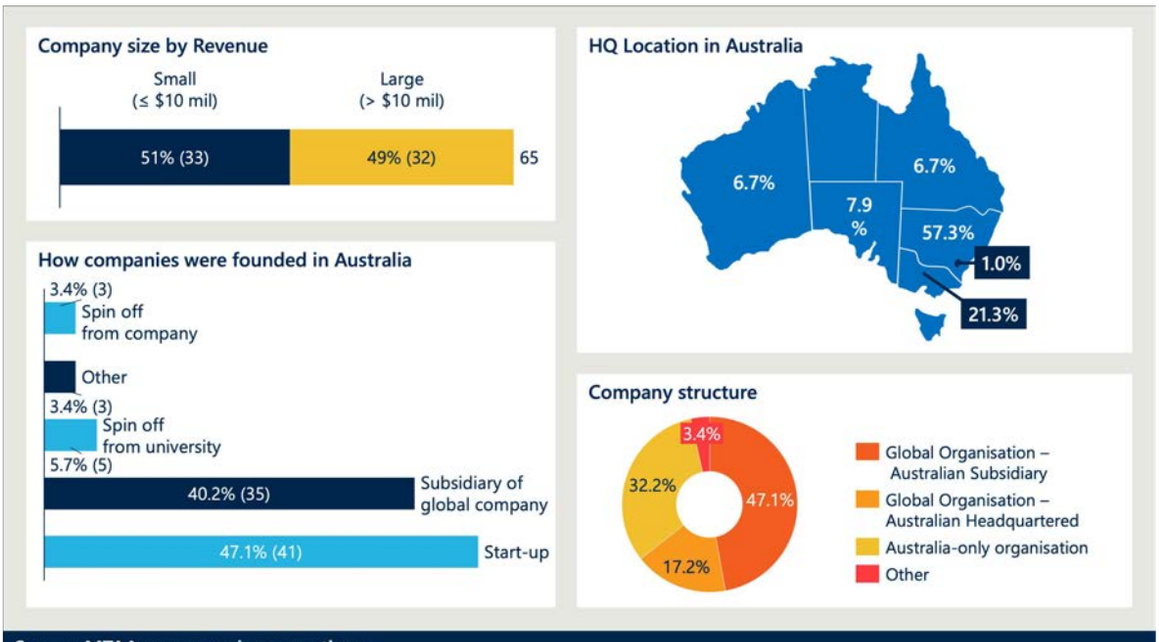
3.1 Australia is investing in the future of MedTech

MedTech innovations are at the core of improving clinical care, and come from a variety of sources including universities, start-ups and established MedTech organisations. These innovations must be validated and protected through intellectual property protections before they can undergo the full development process. Innovations in MedTech are expensive but are finding increasing levels of support in Australia.

The Australian MedTech industry is diverse

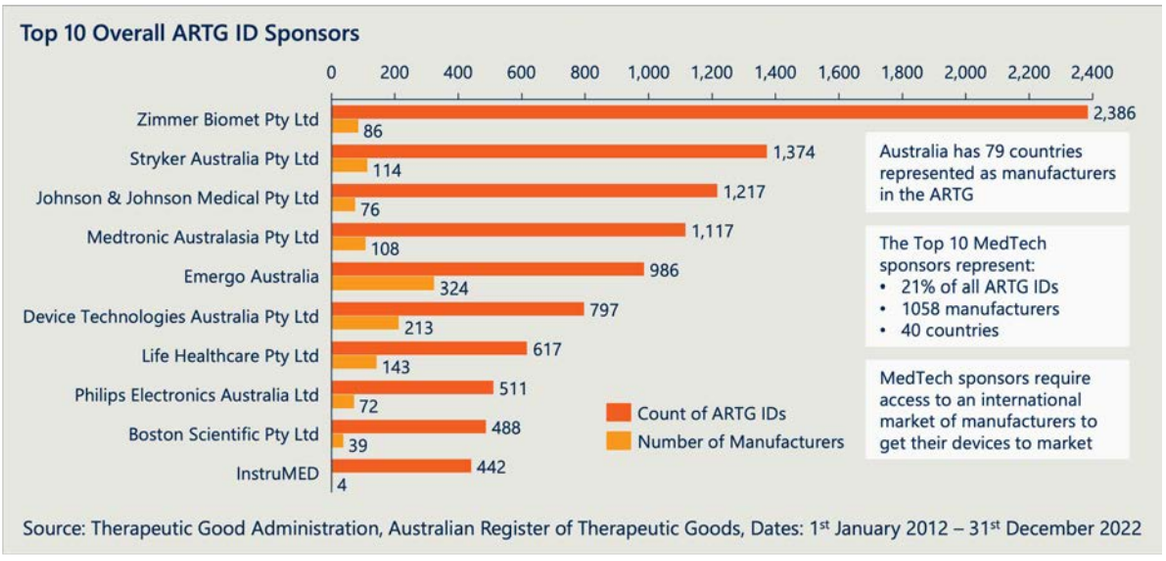
MedTech companies are present across Australia and come in a variety of sizes (Figure 14). These organisations have their origins as spin-offs, start-ups, universities and as subsidiaries of global organisations.

Figure 14 | MTAA Value of MedTech survey respondent demographics



There is a wide diversity in MedTech products being delivered in Australia (Figure 10), with organisations of different sizes and roles in the sector. Many global organisations support the sponsorship of MedTech devices sourced from manufacturers around the world. The top 10 ARTG sponsors represent over 1000 manufacturers from 40 countries, and 21% of all medical device listings (Figure 15). Therefore, the listing of medical devices is very concentrated in relatively few organisations, and there are many small organisations that have only 1 or 2 on the ARTG.

Figure 15 | The top 10 MedTech sponsors represent thousands of devices and use components coming from many manufacturers around the world



The Australian MedTech industry is collaborative

Collaboration is a key feature of the Australian MedTech ecosystem and enables MedTech companies to develop sector capability. Australian MedTech companies benefit from a strong research and health ecosystem, enabling extensive and valuable collaborations. The survey showed that the majority of MedTech companies are actively collaborating and perform some of their product development in Australia (Figure 16). Furthermore, MedTech companies are engaging with researchers and healthcare providers to develop and enhance products, resulting in improvement to patient outcomes.

What we've heard: The MedTech industry has valuable collaborations with healthcare providers. These collaborations include research that provides opportunities to improve clinical care and patient outcomes. Furthermore, links between global MedTech companies and the local Australian MedTech ecosystem provide essential skills transferral in areas such as regulatory affairs, technical services, and clinical practice.

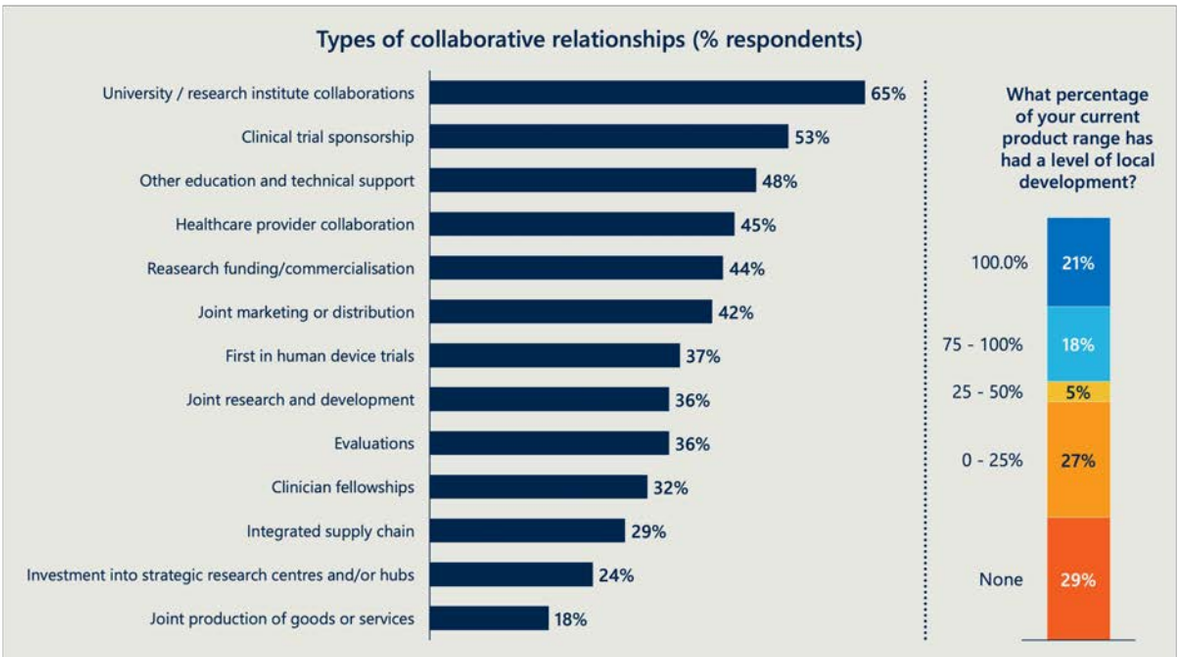
"The MedTech industry represents a high potential growth opportunity for Australia, given the strengths of the medical research ecosystem, engineering and design capabilities as well as an innovative start-up economy. Australian SMEs can benefit from accessing new partners and markets through networks that have a broad range of international and domestic players."

Dr. Craig B. Neylon, MedTech Industry Advisor, Industry Capability Network Victoria

What this means for patients

Medical technology development is a collaboration between industry, healthcare providers and the Australian government. All the work towards product development ultimately improves patient outcomes. There is a long time between an idea and getting the product to patients, however, collaboration efforts can help shorten this process.

Figure 16 | MedTech Organisations are highly collaborative which enables the development and commercialisation of innovation



Source: MTAA Survey data, Question: Which, if any, of the following types of collaborative relationships does your organisation partake in with other organisations? What percentage of your current product range has had a level of local development (including research, manufacturing) aside from regulatory approval?

One example of an Australian state government supporting MedTech innovation is the Stryker R&D Lab which opened in Brisbane in 2022.[62] Principal financial assistance was provided through the Advance Queensland Industry Attraction Fund, which enabled multi-national MedTech company Stryker to develop the Lab in partnership with the Queensland government, healthcare providers and research partners University of Queensland[63] and Queensland University of Technology[64].

There are four main areas of focus for the R&D Lab - digital health, robotics, clinical software applications, and advanced manufacturing. It brings international resourcing, capabilities and expertise to Australia, and Stryker's expanded presence will generate opportunities for local researchers, universities and industry, creating new skilled jobs and pathways for collaboration.

MedTech businesses require different supports across their lifecycle

There is substantial scope for innovation in the MedTech industry that leverages existing strengths in Australia's collaborative approach (Figure 16) and world-class medical research. However, there is a long journey for MedTech innovations to reach the market (Figure 17). For MedTech companies to succeed, they require tailored support that is suited to their stage on the innovation and commercialisation journey.

MedTech, unlike many other industries, required significant investment before there are any potential financial returns. A common struggle for Australian researchers is to overcome the funding 'valley of death' before research can progress into clinical trials and beyond. Therefore, many small MedTech companies operate at a significant loss.

[62] https://www.statedevelopment.qld.gov.au/industry/industry-support/advance-queensland-industry-attraction-fund
[63] https://www.uq.edu.au/news/article/2021/10/partnership-ignites-new-medical-rd-lab
[64] https://research.qut.edu.au/cbt/2022/09/26/stryker-and-brisbane-partners-opens-rd-lab/

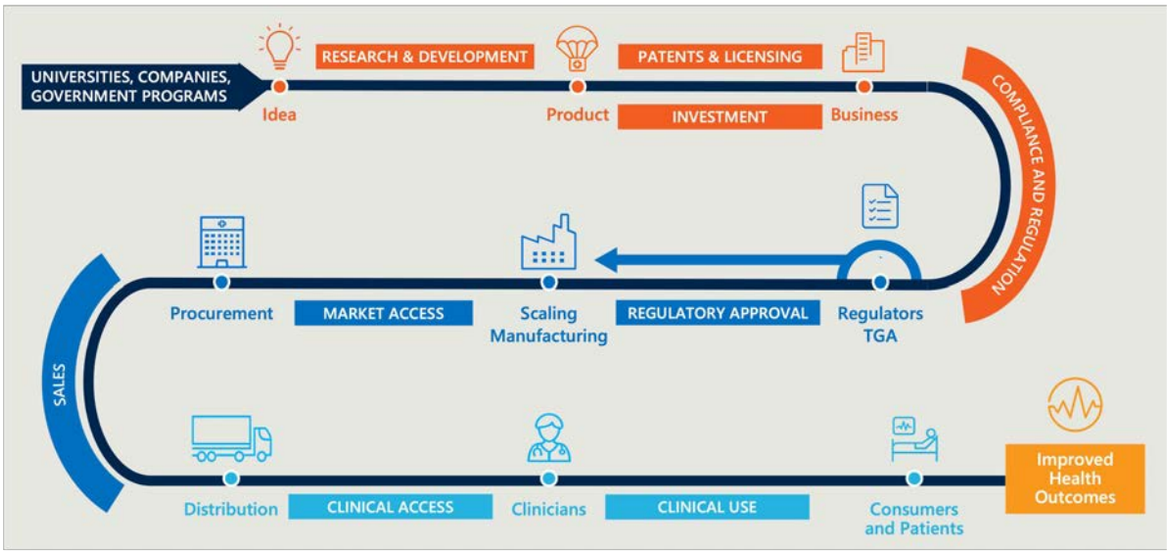
Over 80% of small MedTech companies (revenue < $10 mil/year) operated at a loss in our analysis.*

Source: MTAA Value MedTech survey, desktop research. *Loss as defined by a deficit in operating surplus.

There is a clear need for "patient capital" to enable new MedTech businesses to perfect product design, scale production, and conduct clinical trials to generate the evidence necessary for regulatory approval. That capital can be supplied from several sources - venture capital, investment from international MedTech companies, or government financing - and the composition of funding depends on having appropriate incentives in place to foster the investment that leads to innovative products.

Innovative ideas which originate from a variety of sources must have substantive research and development before a product can be generated. At this stage, the idea needs to be protected through intellectual property registration, such as patents, and must take onboard substantial capital to develop the product to meet the efficacy, safety and quality regulatory standards (see Section 1). Typically, only after regulatory approval is achieved are innovations able to generate revenue, where innovative companies now have rights to enter the market and engage with the healthcare system to improve health outcomes.

Figure 17 | The MedTech innovation and commercialisation value chain. The journey from idea to improved health outcomes.



The MedTech industry is a priority to jurisdictions across Australia

Australia places great emphasis on investing in innovation, developing both the healthcare system and the economy. Federal and State governments have invested heavily to accelerate the growth of the MedTech industry and promote collaboration and a diverse research environment that is competitive in the Asia-Pacific region.

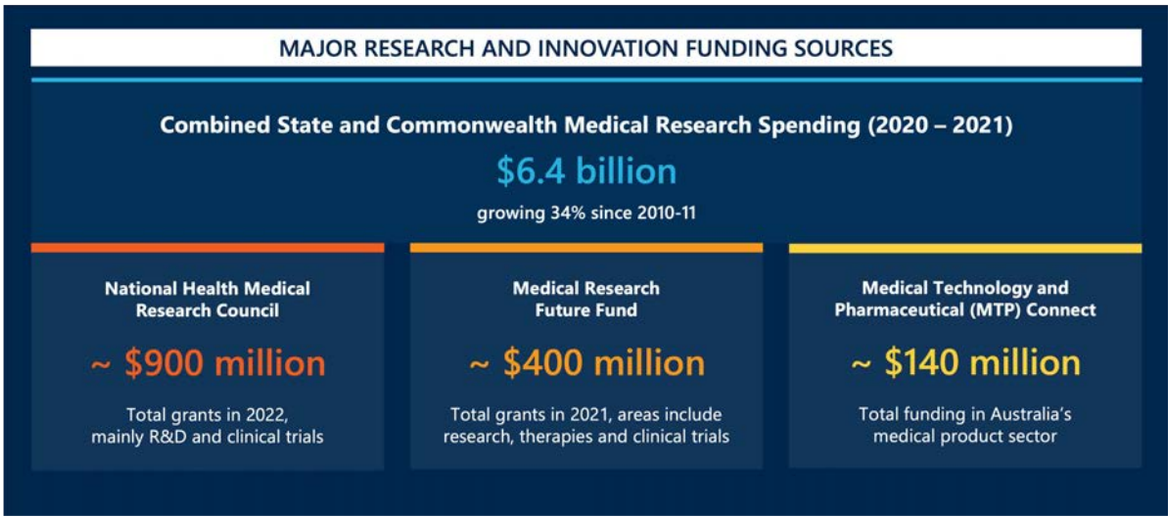
MedTech is constantly evolving, and it is growing increasingly important that advanced healthcare systems stay up-to-date with developments in MedTech to provide world-class treatment. Australia understands this and places great emphasis on investing in innovation, developing both the healthcare system and the economy. In 2020-21, Australian State and Commonwealth governments spent approximately $6.4 billion on medical research, growing 34% since 2010-11[65]. Individual spending on aids and appliances such as

[65] Health expenditure Australia 2020-21, Research - Australian Institute of Health and Welfare (aihw.gov.au)

hearing aids, orthopaedic appliances and prostheses fitted externally has grown 16% over the same period to approximately $3.2 billion.[66] Capital Spending, which includes large-scale fixed assets such as buildings and equipment with a multi-year useful life, also increased 37% since 2010-11 to $11.7 billion.

The major government medical research funds are shown in Figure 18, which primarily support research institute and healthcare system innovation. A more complete picture of the Australian funding landscape available to MedTech companies is shown in Figure 19, with additional details of these programs in Appendix B, Table 13.

Figure 18 | Major Australian public funding for MedTech innovation



Federal programs are enabling and upskilling the Australian MedTech industry

There are many national bodies supporting MedTech in Australia (Figure 19). A key organisation fuelling innovation has been MTPConnect, established in 2015 as part of the Federal Government's Industry Growth Centres Initiative. MTPConnect has been focussed in fostering research, improving researcher capabilities, and allowing increased collaboration between researchers, investors and government. Alongside patient improvement, this has led to increased job creation and new innovative products. MTPConnect has injected more than $141 million as at the end of 2022, supporting 184 different projects. Industry support has led to an additional contribution of $827 million. From all programs and initiatives, MTPConnect has contributed $1.3 billion into the sector, resulting in a return of $5.1 billion to the economy.[67]

Selected MTPConnect programs[68]:

- **Clinical Translation and Commercialisation MedTech (CTCM):** This program is focused on high-quality medical device projects and supports their translation through clinical trials to bolster chances of commercialisation. Initiatives such as these have supported an additional 796 clinical trials and 2,517 patients have been recruited for those trials. This has ultimately led to the increase in patients treated by 240,754.
- **BioMedTech Horizons Program:** This program has funded 49 projects to support health technologies, drive discoveries and encourage commercialisation.

[66] AIHW datasets – check aids/appliances
[67] MTPConnect 2022 Annual report
[68] PROGRAMS : MTPConnect

- **Researcher Exchange and Development within Industry (REDI) fellowship:** Researchers, clinicians and professionals are provided with funded industry placements to work with leading companies in the sector.
- **BridgeTech program:** This development program involves training researchers and entrepreneurs to navigate the commercialisation pathway for MedTech. This includes content on how to navigate the full commercialisation journey.

State programs are focused on building their local commercialisation and manufacturing

State Governments have similarly prioritised the MedTech industry as a future growth market. There are also research institutes and innovation centres across Australia which are supporting MedTech. These include the Bionics Institute[69], which supports the development of advanced MedTech. The institute was founded by Professor Graeme Clark, who led Australia's development of the cochlear implant, and led to the creation of the company Cochlear, one of Australia's biggest MedTech success stories and highly valued companies (Figure 20).

Selected state programs:

- In 2022, the Victorian Government pledged $12.7 million toward the $16.7 million **Victorian Medical Device Prototyping and Scale-Up Facility** at RMIT University, with the goal to develop Australian-made medical devices and encourage researchers and companies to remain local.
- For almost 10 years, NSW Health has run the **Medical Devices Fund**, a grant program currently awarding over $8 million per year to encourage investment and the commercialisation of medical devices in NSW. Since inception, the fund has invested more than $78 million for 43 technologies, with some achieving notable success.
- The South-Australia based **Medical Devices Partnership Program** at Flinders University, which supports the development on new MedTech and collaboration in the sector[70].
- Western Australia has recently announced a **Life Sciences Innovation Hub and Manufacturing program**[71].

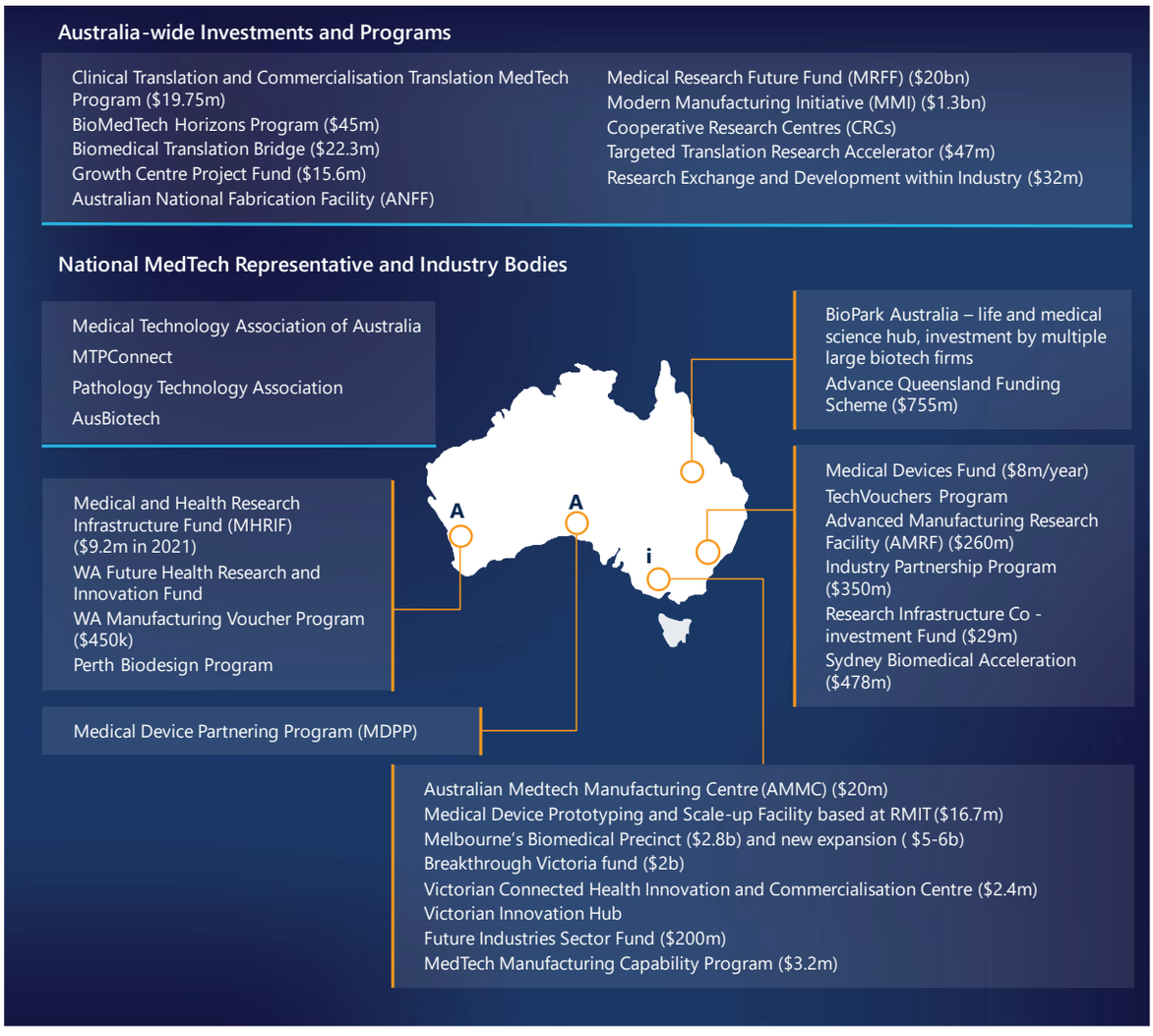
What we've heard: There is a good pipeline of MedTech early-stage companies. However, the limited size of the Australian venture capital market and other high-risk investment markets means that many companies struggle to gain access to the funds to validate their products and as a result move overseas. However, if Australian MedTech companies do meet the high demands required, they have opportunities for local investment.

"For investment in the OneVentures Healthcare fund, we want to see the company proposition as first in class or best in class, and that they understand the regulatory environment for the future."

Dr. Jeannie Joughin, Principal, OneVentures

[69] Home - Bionics Institute
[70] https://mdpp.org.au/
[71] WA Life Sciences Innovation Hub : MTPConnect

Figure 19 | Across Australia MedTech is seen a priority strategic area with investments helping innovations at different stages of the development pipeline



3.2 Australia is manufacturing and developing products

Healthcare is an essential service, that is highly susceptible to global supply chain shocks. Common essential items ranging from gloves to complex ventilator machines may be in short supply worldwide. Medical devices require components from around the world and even prominent Australian manufacturers still require globally integrated supply chains. However, the change in healthcare demands and supply chains during the COVID-19 pandemic has emphasised that supply chains are vulnerable to shocks, and therefore there is value in considering having the sovereign MedTech capacity and Australia's ability to meet these challenges. Vaxxas is one Australian company that is addressing these challenges by locally manufacturing technologies to deliver vaccines (Case study 10). Vaxxas is an excellent example of a university innovation being developed and spun-out by ongoing government and private investment.

Case study 10 | Innovative technology and manufacturing create needle-free vaccines

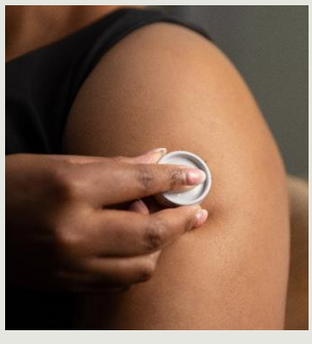
REVOLUTIONARY TECHNOLOGY TO WIDEN VACCINE ACCESS

Australian Vaxxas are commercialising a novel vaccination technology to enhance performance of existing and next-generation vaccines.

Vaxxas, a Brisbane-based biotechnology company, is commercialising a novel vaccination technology that could redefine where and how vaccines are administered in future.

Currently, vaccination is associated with traditional needle and syringe, which for some can cause discomfort and even avoidance. Since this 170-year-old technology was invented, scientists have discovered that the highest density of the body's immune response cells are in the skin, and that there are better ways of delivering a vaccine's life-saving contents.

The high-density microarray patch (HD-MAP) technology that Vaxxas is producing can be delivered just under the skin's surface via a small patch covered in thousands of tiny vaccine-coated microprojections. The proprietary dry-coating technology, based on initial research out of The University of Queensland, also has the potential to eliminate or significantly reduce the need for 'cold chain' storage and be administered with minimal training, leading to increased access to vaccines, particularly in lower to middle-income countries.



For more information about the MedTech manufacturing see Appendix C "Manufacturing: MedTech is advancing Australian Manufacturing"

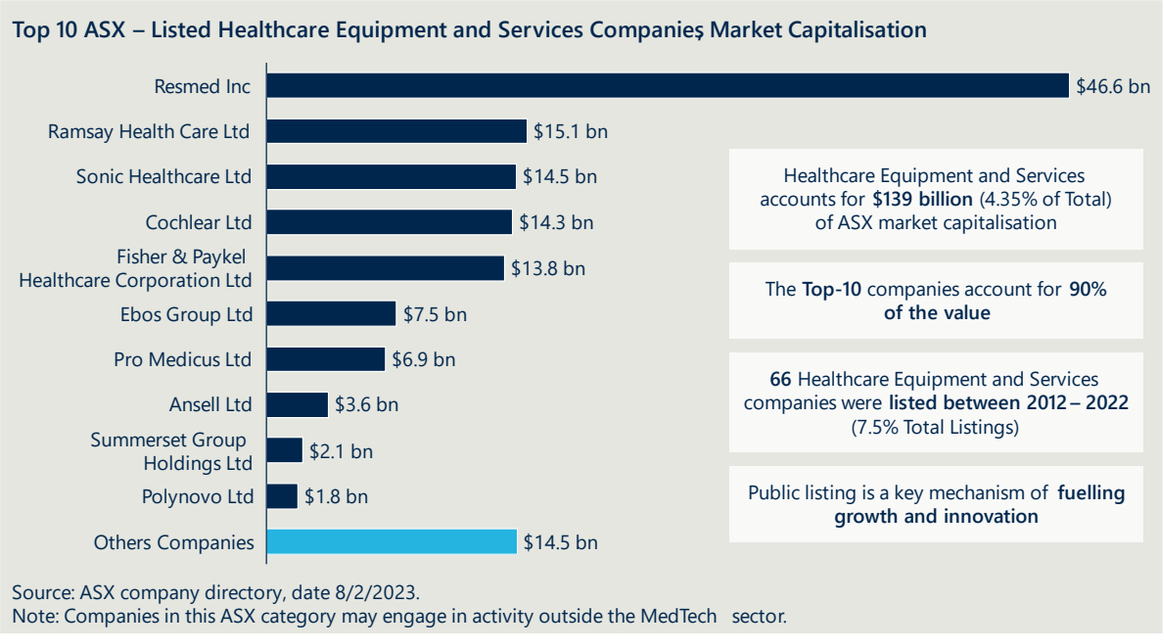
Australia has a growing innovation ecosystem

Australia has developed important MedTech products that have been exported throughout the world. The market capitalisation of healthcare equipment and services on the Australian Stock Exchange (ASX) is over $139 billion (Figure 20). These companies include prominent MedTech success stories such as ResMed, Cochlear, Fisher and Paykel Healthcare, and Ansell. Public listings of companies are an important

mechanism for obtaining investment for future growth, and this segment of the ASX has seen 66 companies listed from 2012 – 2022, representing 7.5% of total listings on the exchange [72].

Australian manufacturers are supporting MedTech use across the full spectrum of manufacturing and use case complexity. There is a steady stream of MedTech ideas being developed in Australia with a supportive ecosystem to promote them. There are upcoming MedTech start-ups that are in the process of scaling their manufacturing and product development. Australian MedTech manufacturers are producing the full range of medical device and *in vitro* diagnostic classes, and account for 7% of all ARTG listings (Figure 21).

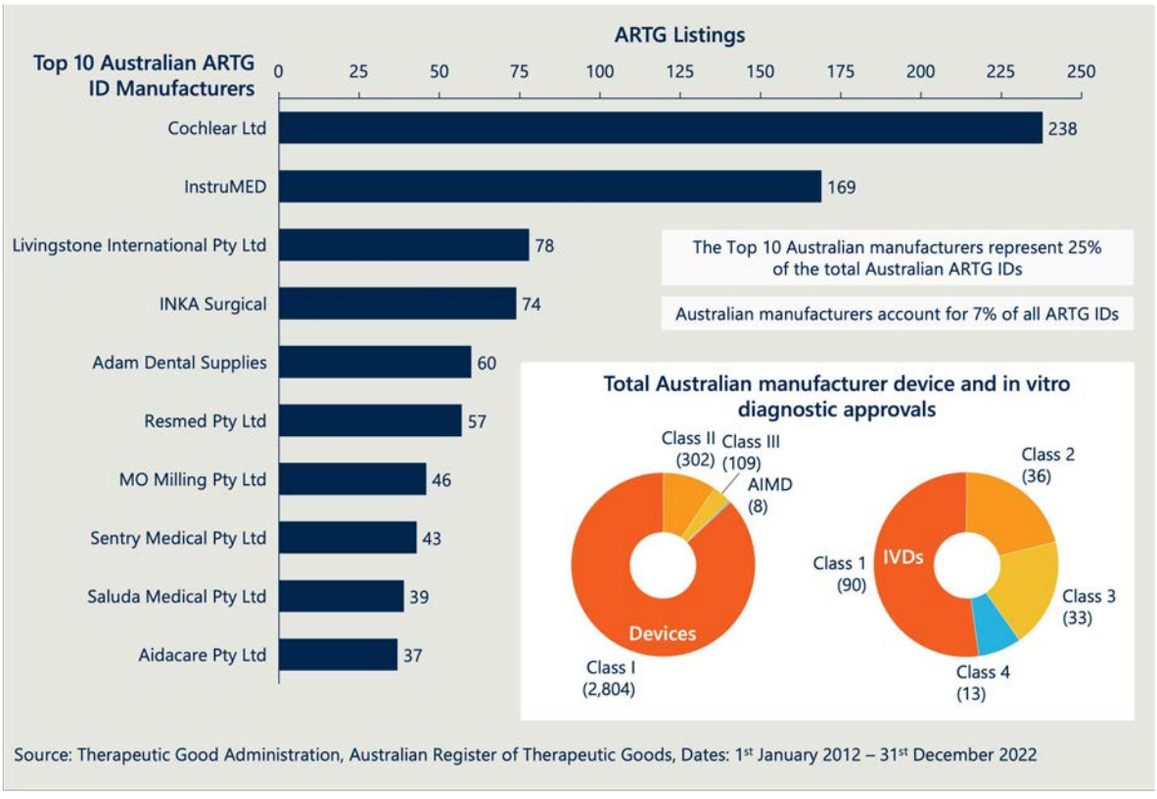
Figure 20 | Publicly listed healthcare equipment and services market capitalisation



Source: ASX company directory, date 8/2/2023.
Note: Companies in this ASX category may engage in activity outside the MedTech sector.

[72] Company directory (asx.com.au)

Figure 21 | Manufacturers registered in Australia support many ARTG listings and types of products



Developing a digital health future

Digital health technologies in Australia's health system have experienced transformative change over recent years. Digital health is an important tool to better manage health outcomes and strengthen data systems across the health sector, such as mobile health, telehealth and IT systems. Digital health solutions for hospital management are already showing success and creating operational efficiencies (Case study 2).

Recent developments in Australia's digital health services include electronic prescriptions, Medicare online, COVID-19 digital certificates, digital health records and many more[73]. Gaps in Australia's digital health sector have been identified by Australia's National Digital Health Initiative (ANDHealth), the leading provider of support programs for digital health technology companies[74]. ANDHealth has supported over 400 companies with development, commercialisation, and implementation of digital health technologies, creating value for the Australian health system and economy.

The integrating of electronic medical records, patient monitoring devices, mobile apps and analytics presents many risks and opportunities for the sector. There have been prominent success stories such as Perx Health[75] which is leveraging behavioural science to help manage chronic health conditions. It has been the beneficiaries of leveraging Australia's collaborative healthcare system, working with clinicians to validate their product with clinical trials. This has enabled them to gain a competitive edge in the Australian and international markets.

[73] https://www.aihw.gov.au/reports/australias-health/digital-health
[74] https://www.andhealth.com.au/
[75] Perx Health: better health engagement and outcomes

What we've heard: Digital health provides a new avenue to improve health outcomes in patients. This is an area of active reform around the world, and digital health apps are increasingly being treated as "Software as a medical device", with their own set of regulatory requirements. There are unresolved issues surrounding cybersecurity and data ownership. This is currently an area of active reform and is likely to be in the future.

What this means for patients:

Digital health products are becoming increasingly integrated in patient lives to provide information and monitor disease. There are rapid developments, with emergent technologies such as AI providing new opportunities and challenges. For patients, digital health initiatives can streamline access to their healthcare data and information, such as accessing Medicare records online. Digital health can also efficiently connect patients to doctors. One example is telehealth consultations, which allow patients to receive quicker treatment plans or advice through virtual doctor appointments, which can be supplemented with remote patient monitoring using medical devices. There are also many digital health apps that can monitor patients medical care or give general healthcare advice. In the future digital health apps will require a strong evidence base to ensure patients receive the most up-to date information.

Rapid manufacturing and product development success during COVID-19

Australia's response to the COVID-19 pandemic benefitted from strong collaboration efforts between the MedTech industry and the Federal government. Throughout the pandemic, MedTech was at the forefront, with priority placed on securing equipment such as testing kits, personal protective equipment (PPE), ventilators and vital ICU equipment. The pandemic identified critical weaknesses in Australia's procurement and sovereign capability, but also led to important innovations. The acceleration of product development during the pandemic demonstrated the innovation, capacity, and flexibility of the Australian MedTech industry.

IP Australia's reports on innovation during COVID-19[76] have identified key areas of MedTech patent filing and innovation during the pandemic including:

- respiratory support devices
- facial shields and filters
- surgical goggles and gowns
- medical diagnostics.

Leading companies in this space included publicly listed Australian companies. For example, ResMed and Fisher and Paykel Healthcare ranked 2nd and 3rd in patent applications for respiratory support devices since 2000.[77]

The complex and technical regulatory and IP requirements for manufacturing medical devices means that there are significant difficulties in upscaling sovereign capacity using existing resources and infrastructure. However innovative solutions helped overcome these challenges.

Many of these rapid innovations over the pandemic have been fostered and enabled by MedTech funding programs, government coordination and regulatory reforms around Australia (Figure 19).

[76] https://www.ipaustralia.gov.au/tools-and-research/professional-resources/data-research-and-reports/publications-and-reports/2022/09/30/01/37/covid19-technology-resources
[77] https://public.tableau.com/app/profile/patent.analytics.hub/viz/Ventilatorsanalysis/Intro

MTPConnect administered the "Biomedical Translation Bridge Program", which supported the accelerated commercialisation of five products designed to help improve Australia's COVID-19 response.[78] One of the recipients were a team of researchers at the University of Melbourne. The researchers were able to develop a "Ventilation hood" to reduce the risk of infection to healthcare workers by containing airborne droplets.[79]

COVID-19 led to the development of innovative ideas that are transforming the future of MedTech manufacturing and disrupting traditional business models. For example, 3DMEDiTech was able to address shortages in nasal swabs for COVID-19 testing by using advanced 3D manufacturing in Australia. Advanced manufacturing posed a solution for a low-tech and large-scale problem.[80]

The rapid advances in MedTech during COVID-19 pandemic have demonstrated how Australia can do better to support MedTech into the future.

What we've heard: The rapid advances in Australian MedTech during the COVID-19 pandemic have demonstrated how well Australia can do, and what it can do to perform better in the future.

[78] BTB Funds COVID-19 Research Efforts In Australia: MTPConnect
[79] Researchers design ventilation hoods for hospital beds to help contain COVID-19 spread (unimelb.edu.au)
[80] 3DMeditech - COVID19 Testing swabs - Advanced Manufacturing - Australian Made

3.3 Australia enables MedTech innovation locally and abroad

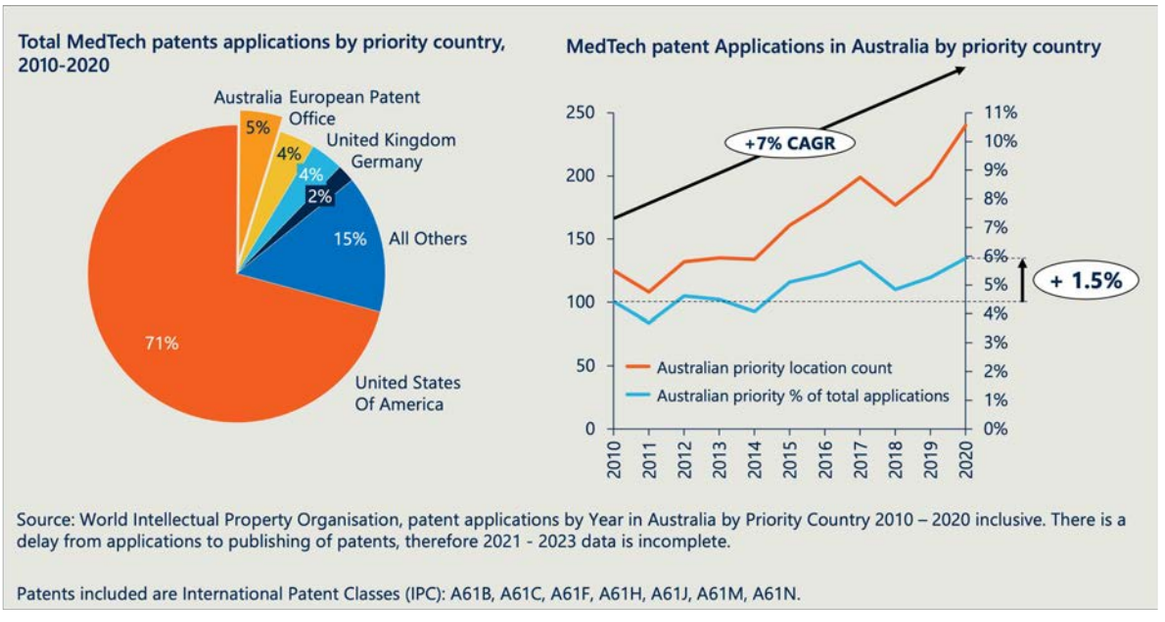
MedTech is a sophisticated and global market, which is built upon the development and protection of innovation. The global ecosystem relies on diverse supply chains and distributed stages for the product development lifecycle. The idea, product development, clinical testing and first-in-market approval may occur around the world. Australia has distinct and growing advantages for enabling MedTech innovation.

The MedTech industry is built upon the protection of innovative ideas

Australia has an impressive pipeline of ideas built upon world-class higher education, research, and a growing list of innovative MedTech companies. Patents are a key tool to protect innovative intellectual property (IP) and provide exclusive rights to inventions for the patent holders in the region they are registered. IP Australia manages patent registration in Australia and, of the MedTech patents registered, Australia ranks 2nd only to the United States of America (Figure 22). The number of Australian MedTech patents has been growing at 7% compound annual growth rate between 2010 and 2020 and has grown from a proportion of global patents 4.5% to 6%.

Australia ranks 14th on the International IP Index 2023, a report that benchmarks the IP frameworks across 55 global economies[81]. Receiving an overall score of 80.68%, Australia also places 4th in the Asia region. Australia scored particularly high in commercialisation of IP assets (2nd place at 95.83%)[82], patents, copyrights, membership and ratification of international treaties. Key strengths for Australia include its global lead on online copyright enforcement, patentability of biotechnology inventions and ease of IP licensing activity.

Figure 22 | Australia's MedTech intellectual property is growing rapidly and is performing internationally



Source: World Intellectual Property Organisation, patent applications by Year in Australia by Priority Country 2010 – 2020 inclusive. There is a delay from applications to publishing of patents, therefore 2021 - 2023 data is incomplete.

Patents included are International Patent Classes (IPC): A61B, A61C, A61F, A61H, A61J, A61M, A61N.

[81] https://www.uschamber.com/intellectual-property/2023-international-ip-index
[82] https://www.uschamber.com/intellectual-property/2023-international-ip-index

Clinical trials support local and international MedTech innovation understanding the effectiveness of new technology

Clinical trials in Australia have a strong global reputation. Australia makes an attractive destination for international companies due to its quality research and data, excellent health professionals, streamlined regulatory approvals and stable socio-political environment. Clinical trials are typically split into four phases. Phase I tests a new medical invention in a small cohort to determine safety and side effects. Phase II is conducted among a larger group of participants to determine efficacy and further evaluate safety, followed by Phase III to compare the new treatment to standard treatment/s. Phase IV monitors the intervention among the general population after it enters the market[83]. Australia is developing its competitive position in early-stage trials (Phase I and II), and specialising in oncology, pneumology, neurology and ophthalmology trials[84]. Australia is a preferred destination for these early-stage trials, including "first in human trials", because of this simplified regulatory stream that enables new interventions to be evaluated in patients.

What we've heard: MedTech collaborating with clinicians is a win-win. When MedTech companies work with clinicians they can better identify and serve patients' needs, and clinicians are equipped better/earlier access to tools that improve patient outcomes.

Clinical trials bring a range of benefits, including greater patient care outcomes through early treatment access, strengthened research culture and a highly skilled workforce. More broadly, the economy experiences a boost from personal spending by healthier trial patients and those employed in the sector. Government expenditure is also supported through the tax revenue associated with the trial employee income.

The clinical trials sector brings high economic value to Australia, employing over 8000 Australians. In 2019, more than 1800 clinical trials started, involving over 95,000 participants and $1.4 billion contributed to the economy[85]. For Australian clinical trials starting in 2022, 9.2% were for MedTech[86]. Our analysis suggests that clinical trials support over 400 MedTech clinical practice, trials and/or research jobs[87].

Some of these clinical trials are investigational and are supporting the earlier stages of product development. However, in many cases, these trials (Phase I, II, and III) provide the supporting evidence for regulatory approval demonstrating safety, efficacy and quality. In the survey 38% of companies said they are supporting "first in human" clinical trials, which are in the first stages in providing evidence for regulation. The data from the Medical Technology Association Australia estimates, identified 134 medical device clinical trials taking place in Australia of which 40% are early stage or "first in human" trials.

There is significant growth in MedTech clinical trial activity in Australia, with 63% of survey respondents reporting starting new clinical trials in the next 12 months and 268 clinical trials being underway (Figure 23). Data from clinical trial registries supports the finding that Australia has a strong and growing clinical trial sector (Figure 24).

[83] https://www.australianclinicaltrials.gov.au/what-clinical-trial/phases-clinical-trials
[84] https://www.mtpconnect.org.au/reports/clinicaltrialsreports2021
[85] https://www.mtpconnect.org.au/images/MTPConnect_Australia's%20Clinical%20Trials%20Sector%20report%202021.pdf
[86] Nous analysis of Australian and New Zealand Clinical Trials Registry (ANZCTR) and Clinicaltrials.gov data
[87] Nous analysis of the MTAA Value of MedTech survey, see Section 4 of the report for more details.

Figure 23 | MedTech organisations are conducting clinical trials in Australia

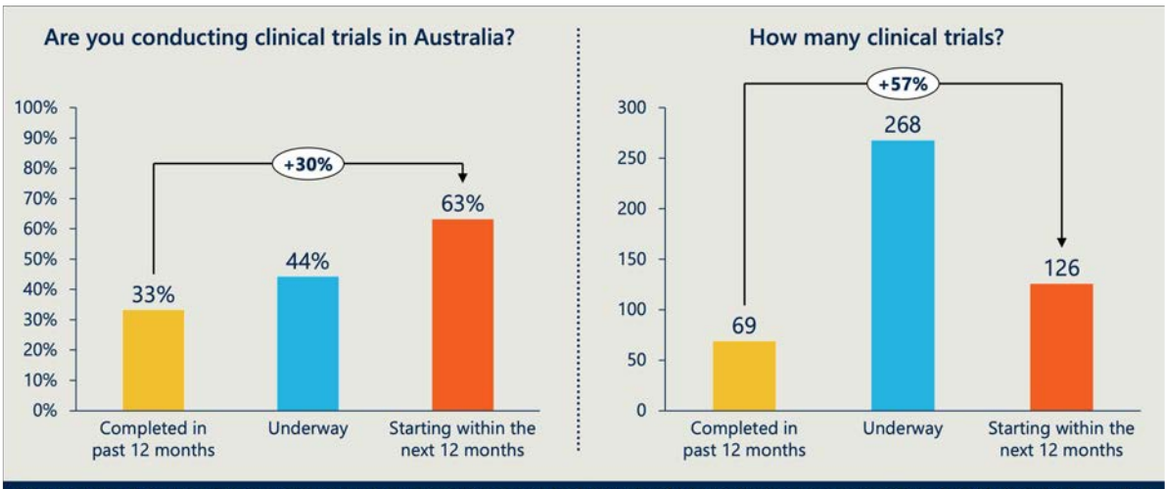
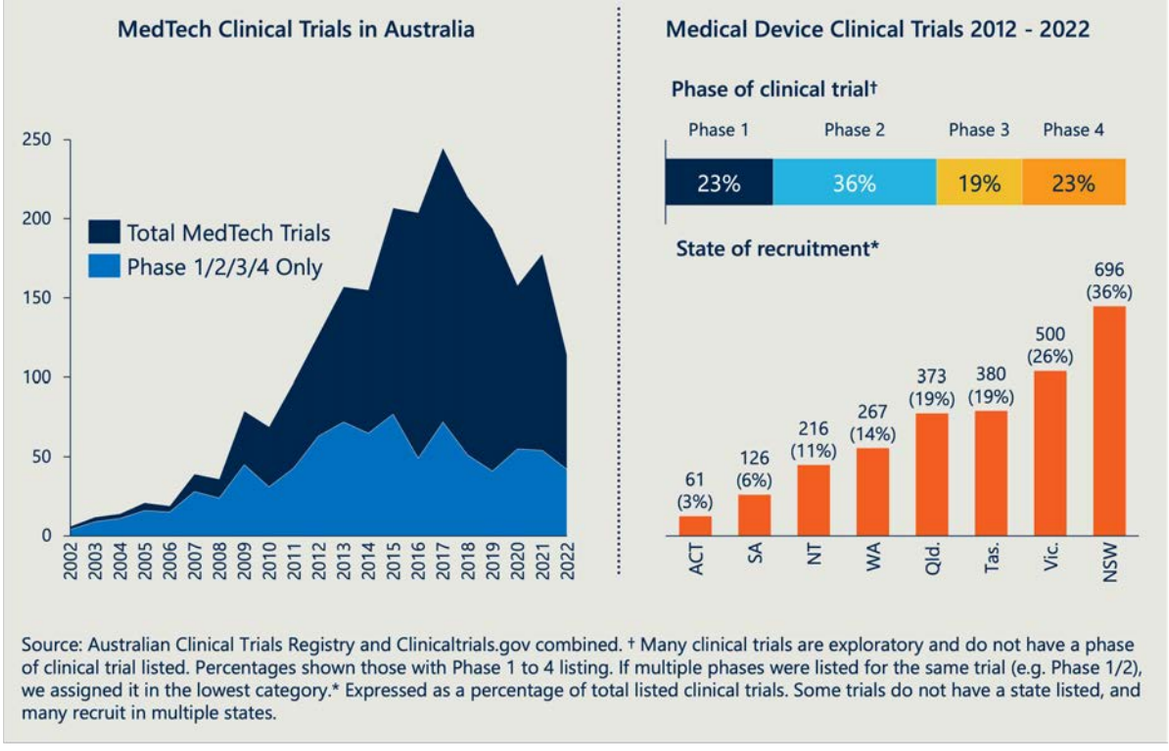


Figure 24 | An overview of MedTech clinical trials in Australia



What this means for patients

Clinical trials are important to ensure the benefits of innovative MedTech can be delivered effectively to improve health outcomes for all Australians. Clinical trials give patients early access to treatments, therapies and diagnostic tests. These new interventions may be better than what is currently available for a patient's condition or may have fewer side effects. Clinical trials give patients the opportunity to have an active role in their personal healthcare and receive extra advice and medical care from clinicians involved in the trial. Socially, patients may benefit from support groups and resources during the trial and get the chance to connect with other participants experiencing similar health issues.

Early-stage MedTech innovation

There are many innovative MedTech companies in Australia developing new solutions to a range of important problems. Innovative MedTech companies in Australia are finding new ways to treat and diagnose disease. These include companies such as MAXONIQ which is using advanced manufacturing to create custom prostheses (Case study 11), and NeuralDx which are developing new ways to diagnose and measure brain disease (Case study 12).

Summary

Australia has a rich MedTech innovation system with prominent examples of Australian global MedTech success stories, and a rich pipeline of new companies. MedTech innovation is a high-priority area for governments across Australia, which has resulted in significant investments in local research, development, and manufacturing. The partnerships between start-ups, global MedTech organisations, academic and healthcare providers have been essential to the development and growth of the Australian MedTech industry.

Case study 11 | Advanced manufacturing techniques deliver positive outcomes for patients requiring complex surgical intervention

CUSTOM-MADE DEVICES IMPROVE PATIENT OUTCOMES

MedTech company MAXONIQ has the manufacturing ability to personalise medical products and devices for patients, improving treatment outcomes.

Medical prostheses are medical devices commonly used by surgeons but often require tailoring to the patient to be effective. MAXONIQ is a Victoria-based manufacturing company that develops custom-made surgical products for patients undergoing jaw surgery. Patients experiencing this require complex mandibular reconstruction to rebuild the missing jaw, often causing discomfort and problems eating as they are left unable to chew. This device was created through a collaboration between MAXONIQ, the University of Melbourne and industry partners.

Their patient specific 3D printed titanium mandibular prostheses is designed to replicate the patients jawbone providing restored, pain-free function and greater quality of life. The personalised jaw joint has been implanted in over 280 patients and expected to help more once MAXONIQ finalises FDA (US) and MDR (Europe) approvals.

Case study 12 | Biomarkers of brain function help clinicians make faster and more accurate diagnosis

CLINICAL TRIALS AND INNOVATION IMPROVE PATIENT OUTCOMES

NeuralDx Ltd are developing advanced technology to increase accurate diagnosis and treatment of mental and neurological disorders.

There is a global need for breakthrough innovation with respect to the diagnosis and treatment of mental and neurological disorders. Current diagnostic practises have an absence of objective technology. NeuralDx Ltd is a Victorian-based start-up commercialising a Monash University "break-through" innovation in the above field, which measures a unique signal of "deep brain function" from structures directly associated with the control of emotions, behaviours, movement and cognition. The device has potential to diagnose and identify different mental and neurological disorders.

NeuralDx has tested the patented technology on more than 600 patients covering over 8 clinical applications and has successfully published 25 peer-reviewed papers. If commercialised, this innovation could lead to greater patient outcomes through a superior diagnostic performance and fill expected workforce shortages through identifying earlier intervention paths.

For more information about Australian MedTech Innovation see Appendix C, "Clinical Trials and Innovation: The MedTech industry supports the healthcare workforce to achieve better patient outcomes"

SECTION 4

MedTech is contributing to the Australian economy

4.1 MedTech contributes to the Australian Economy

This report is based on an extensive survey and research to estimate the significant contribution that the MedTech industry provides to the Australian economy. An overview of MedTech's contribution to the Australian economy is in Figure 25. The following section outlines the results of this analysis, paying particular attention to the key metrics listed below. Full definitions of the metrics used are listed in Table 2.

MedTech industry gross revenue

MedTech gross revenues earned by Australia-based operations of the sector totalled $11.4 billion in 2021/22. Not all of this, however, translates into value-add due to a large proportion of that revenue accounting for inputs.

Total contribution to GDP

Allowing for input costs, the MedTech industries total (direct + indirect) contribution to gross domestic product (GDP, or "gross value added") in 2021/22 was $5.4 billion. Total contribution to GDP is made up of direct GDP of the MedTech industry of $4.1 billion and indirect GDP (indirect is the value add created by suppliers to the MedTech industry, who then create additional value added in those supplying industries) of $1.4 billion.

Employment

17,028 persons were employed directly in Australia in MedTech-related work, and including indirect employment, the total employment supported by MedTech is 51,309 in 2021/22.

Figure 25 | The overview of MedTech's contribution to the Australian economy[88]

Source: MTAA survey, desktop research, and modelling (see methods in Appendix A).
Utilising the income approach to calculating Gross Domestic Product:
GDP = Employee Remuneration + Earnings Before Interest, Taxes, Depreciation and Amortisation + Indirect Taxes - Subsidies

The framework to measure economic contribution of MedTech companies to Australia

This report provides an economic snapshot of the MedTech industry within Australia. A collection of economic metrics utilised together to determine the sector's value and size and is detailed in Table 2.

[88] Numbers may not sum exactly due to rounding

Table 2 | Economic Metrics

Economic Metric	Description
Gross Revenue	**Gross Revenue** is the total turnover generated from MedTech activities (excluding GST). It provides an indication of the total demand for MedTech, based on the expenditure on MedTech products. It should also be noted that gross revenue is distinct from profit. Gross revenue is the total funds invested into purchases of MedTech, whereas profit (Operating Surplus or EBITDA) is the gross revenue generated less the expenses and labour costs incurred to generate that revenue. An industry or organisation's gross revenue is usually significantly more than its contribution to gross domestic product. However, gross revenue is easier to measure and interpret and is a fair and pragmatic measure of business activity (or total sales). Gross Revenue was determined through a combination of desktop research of publicly available information and the outputs of the survey.
Total Contribution to GDP	Total contribution of the MedTech industry is the summation of the direct and indirect contribution to GDP. GDP is a standard concept in economic statistics used to measure economic activity. It is also referred to as "value added".
Direct GDP	**Direct GDP** is the direct contribution of companies in the MedTech industry to Australia's GDP and a standard measurement utilised to show the economic contribution of a sector more precisely. In broad terms, it is the gross operating surplus (or EBIDTA) plus the compensation of employees attributable to MedTech related activity and indirect taxes on production[89]. **Gross Operating Surplus** measures the income generated from MedTech activities before accrual adjustments such as depreciation and tax, after subtracting the cost of intermediate goods and compensation of employees. It is equivalent to the concept of earnings before interest, depreciation, taxes and amortisation (EBIDTA). Gross operating surplus is a main component of GDP when measured from the income side. **Compensation of employees** is the total salary, superannuation and other costs of labour engaged in MedTech industry activity. It is a main component of the sector's contribution to GDP. Both the Gross Operating Surplus and compensation of employees were determined through the survey and desktop analysis of financial statements of listed MedTech companies.
Indirect GDP	Indirect GDP is the value added from purchases by MedTech firms from their Australian suppliers (intermediate inputs) that create additional value added in those supplying industries (e.g. supplying businesses that provide equipment, insurance and services, or rent offices to businesses in the MedTech industry). Indirect GDP was determined by examining ratios derived from the ABS' input output tables and calculating the indirect contribution to GDP of Australian firms providing intermediate inputs to the firms involved directly in the MedTech industry. Indirect GDP related to the upstream suppliers only holds at a point in time – if the MedTech industry were to grow, it does not automatically follow that the historical proportion of indirect GDP will grow in the same way.
Employment	This is the total number of people engaged in MedTech activities. It includes all employees (including people on paid leave), long-term contract workers, regular casuals, working directors and proprietors. The employment figures were derived by determining the headcount of MedTech employees through both surveying individual firms and desktop research.
Exports	This is the total value of goods and services exported overseas to which the MedTech industry contributes. Exports are a component of GDP when measured from the expenditure and so are not additional to the contribution of GDP from the income side (i.e. just a different way of

[89] This is known as the Income Approach to measuring GDP. Further detail can be found here https://www.abs.gov.au/statistics/detailed-methodology-information/concepts-sources-methods/australian-system-national-accounts-concepts-sources-and-methods/2020-21/chapter-11-gross-domestic-product-income-approach-gdpi

Economic Metric	Description
	measuring the same thing, so not additive). However, exports data illustrates the contribution made to world trade markets and global competitiveness of the Australian sector and so is a valuable proxy to measure the characteristics of the sector.

The economic analysis outlined in this report combines and analyses multiple data sources. The primary data source for the economic metrics was a comprehensive survey of MedTech organisations. Complementary data sources were used to validate the survey responses, sense-check the results and address any potential gaps in the survey. Further detail of the approach and methodology undertaken for the survey is found in Appendix A.1.

The MedTech industry generates $11.4 billion in gross revenue in Australia from its activities

The gross revenue generated by the MedTech industry in 2022 was estimated to be $11.4 billion. Gross Revenue captures the total demand (i.e. total sales) generated from purchases of MedTech by hospitals, clinics and other users of MedTech. Gross Revenue provides an indication of the gross volume of economic activity related to this sector based on transactions[90]. When compared to total health expenditure ($220.9 billion) [91], this represents approximately 5% of overall expenditure. An overview of Australia's MedTech gross revenue growth is shown below (Figure 26).

Figure 26 | Australian MedTech gross revenue growth

Source: MTAA survey economic modelling, and survey questions. Questions: Over the next financial year we predict our MedTech revenue to grow by [multi-choice], Over the next financial year we predict our MedTech expenditure (including salaries) to grow by. [multi-choice].

As indicated in the graph above, the gross revenue of the MedTech industry has increased and represents a CAGR of approximately 6.2%. It is important to note that these survey results have been compiled encompassing a period of time where the COVID-19 pandemic had occurred and should be interpreted accordingly.

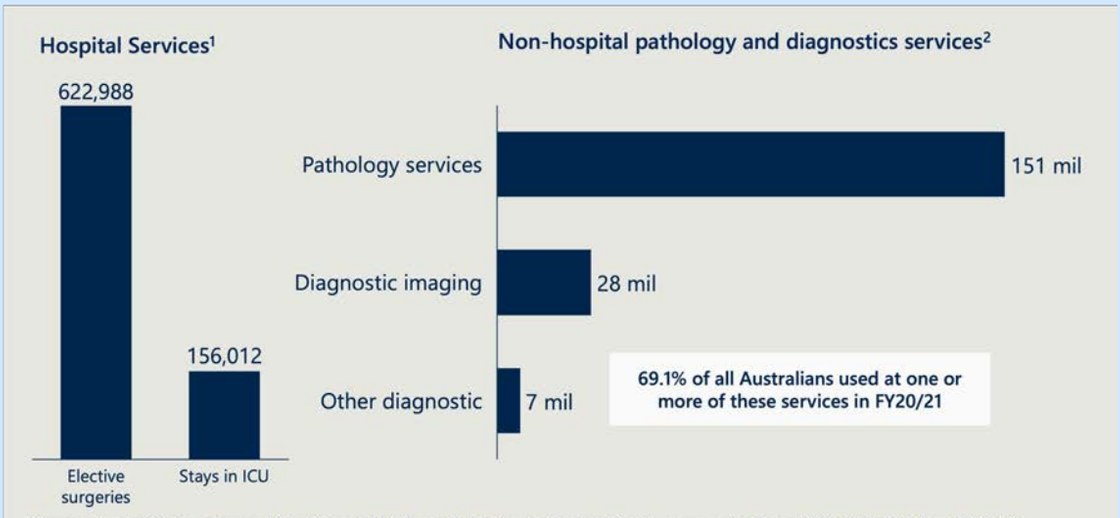
However, results from the survey indicated that respondents feel confident in the ability to rebound from this period of volatility and believe they are expected to either return or exceed pre-COVID projections.

[90] It should be noted that revenue does not mean profit – whilst it is a measure of the turnover generated, it does not take into account the expenditure incurred (as profit is the difference of revenue and expenditure).
[91] https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure-australia-2020-21/contents/summary

What this means for patients:

This gross revenue represents the level of activity that MedTech companies deliver through the facilitation of clinical care and diagnostic services to Australian patients. MedTech enables hospitals to perform surgeries and care for patients in intensive care units (ICUs). MedTech also enables the delivery of pathology and other diagnostics outside of the hospital (Figure 27).

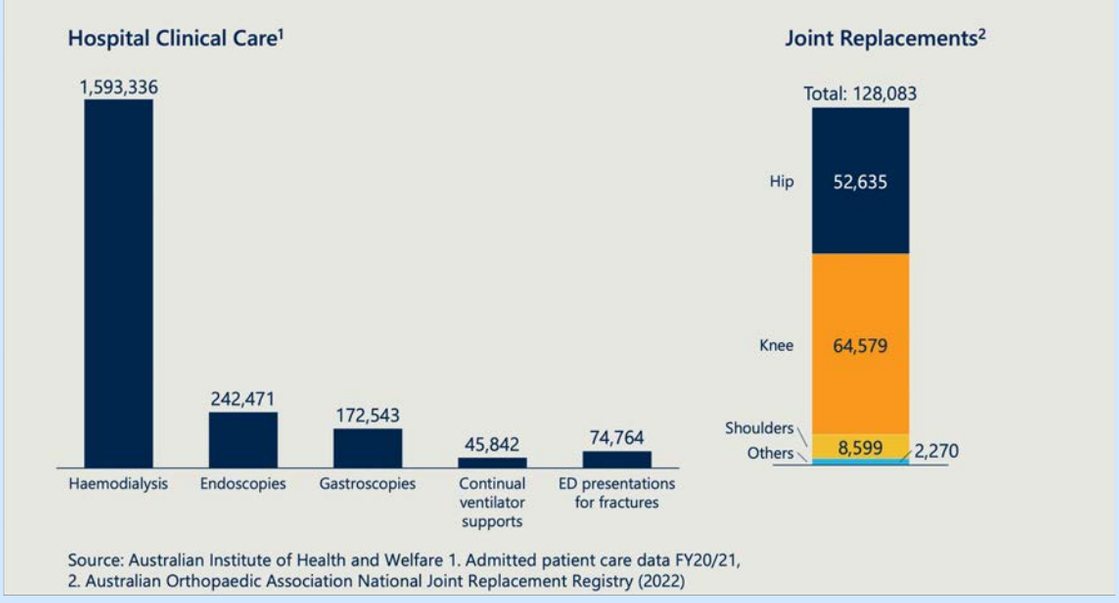
Figure 27 | Selected types of services events involving MedTech



Source: Australian Institute of Health and Welfare 1. MyHospitals data Elective surgeries from FY21/22, ICU stays FY20/21, 2. Medicare Benefits Schedule data from FY20/21.

There are types of clinical procedures that are heavily reliant on the use of MedTech (Figure 28). Particularly high-volume procedures such as haemodialysis support patients over long periods of time and are required for the continued health of Australian patients. Procedures such as endoscopies and gastroscopies are essential medical investigations that help diagnose and plan for future therapy. Continual ventilator supports in intensive care units actively keep patients alive and breathing. Joint replacements are key procedures which use prostheses to enable continual mobility and function for Australians. The benefits of these procedures include enabling patients to participate in the economy.

Figure 28 | Selected types of clinical procedures involving intensive use of MedTech



Source: Australian Institute of Health and Welfare 1. Admitted patient care data FY20/21, 2. Australian Orthopaedic Association National Joint Replacement Registry (2022)

The MedTech industry in total contributes $5.4 billion to GDP

The total contribution to GDP from the Australian MedTech industry to the Australian economy is comprised of both the direct and indirect contribution. For clarity, direct contribution refers to the direct contribution to GDP from companies in the MedTech industry, whereas indirect contribution reflects the purchases from upstream Australian suppliers (i.e. intermediate inputs) that create additional value added in those supplying industries (e.g. organisations that provide equipment and services to businesses in the MedTech industry). Details of MedTech GDP are in Table 3, noting that the figures do not sum exactly due to rounding.

Table 3 | Estimates of total, direct and indirect contribution to GDP

GDP Metric	2020 ($b)	2021 ($b)	2022[92] ($b)
Total contribution to GDP	4.9	5.2	5.4
Direct contribution GDP	3.6	3.9	4.1
Indirect contribution GDP	1.2	1.3	1.4

The total contribution to GDP for 2022 was $5.4 billion, which is equivalent to 0.33% of Australia's GDP. As indicated in the graph below, the contribution of the MedTech sector to Australia's GDP has increased and represents a CAGR of approximately 5.9%. Additional details on GDP growth are shown below (Figure 29).

Figure 29 | Australian MedTech GDP growth

As noted above, the indirect contribution measures the intermediate inputs produced by other sectors of the economy (which can include primary inputs, raw materials, components, rent, insurance) that are utilised by the MedTech industry to manufacture and sell its products. This captures the 'upstream' contribution to GDP to which the MedTech industry indirectly contributes. The indirect employment is discussed in the following section.

Similarly, MedTech products and services are utilised by other sectors of the economy. Based on an analysis of the 'downstream' use of MedTech products from the ABS Input Output tables, Health Care

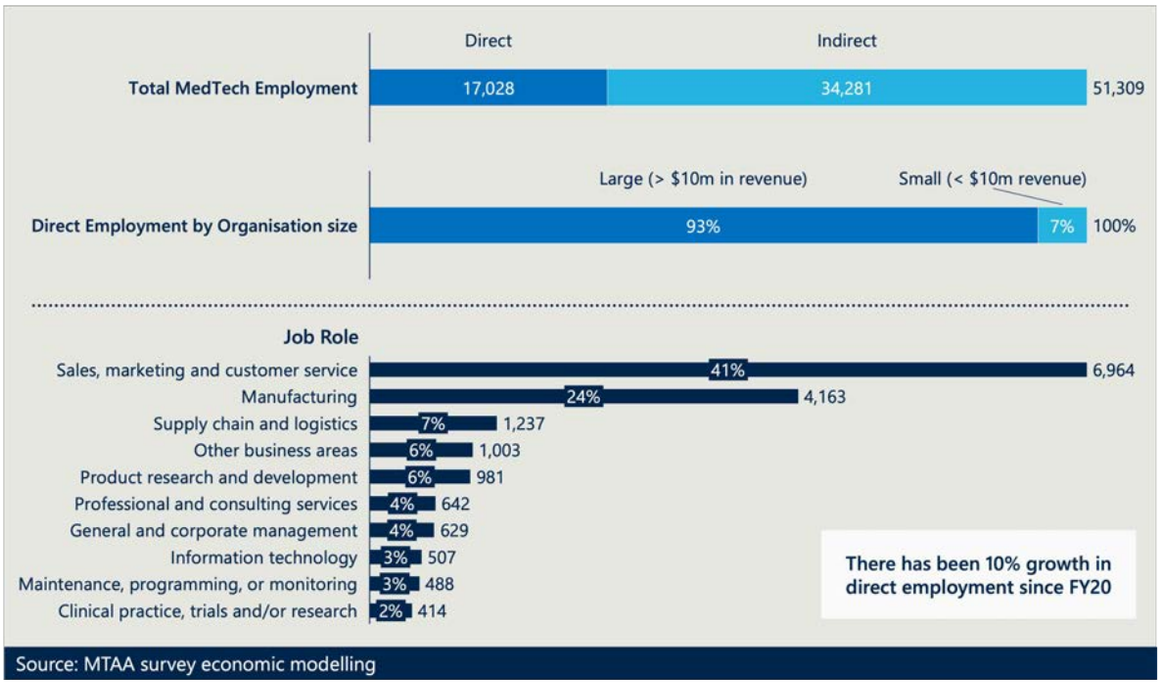
[92] Note: difference in values due to rounding.

Services, Residential Care and Assistance and the Education industries are significant consumers of MedTech products[93]. Complimentary analysis of other datasets indicates that for MedTech manufacturing, 46.7% of the downstream use is through purchases by wholesalers, 34.5% is to export markets and 18.8% directly to hospitals[94]. For MedTech wholesaling activities, 28.9% of output flows to Public Hospitals and 25.5% to Private Medical Practices and Hospitals[95]. These industries align with the MedTech sector's focus in delivering better patient outcomes.

The Australian MedTech Sector directly employs over 17,000 people

Based on the results of the survey and noting the limitations discussed in the methodology in Appendix A.2, the Australian MedTech industry employed 17,028 people in 2022[96]. A detailed breakdown of employment in the sector is shown in Figure 30.

Figure 30 | MedTech employment and job roles for FY21/22



It is estimated that most of these employees were in Sales and Marketing followed by Manufacturing. Analysis was also undertaken to determine the indirect employment. This analysis was undertaken by examining ABS input-output tables and determining the employment headcount per million dollars of value added generated by the industry. This analysis noted that in total the MedTech industry supports 51,309 employees and subtracting the 17,028 derived from the survey yields an estimate of 34,281 indirect employees. Indirect employment would be workers in industries that supply the indirect inputs that the MedTech industry consumes. The survey also asked respondents to classify their workers into specific employment categories to provide a more detailed picture of where in the value chain MedTech workers reside. The estimates of employment for each category over the three years the survey assessed are outlined in Table 4.

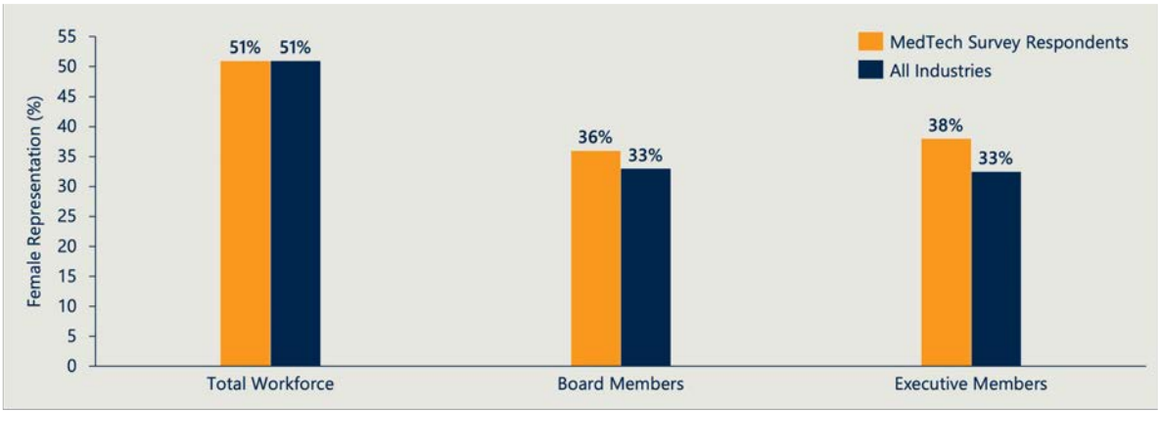
[93] ABS Input Output Tables
[94] IBISWorld, Medical and Surgical Equipment Manufacturing in Australia Industry Report
[95] IBISWorld, Medical and Scientific Equipment Wholesaling in Australia Industry Report
[96] This is the total number of people engaged in direct MedTech activities. It includes all employees (including staff on paid leave), long-term contract workers, regular casuals, working directors and proprietors. It does not include 'indirect employment' – people employed in the supply chain for the MedTech industry.

Table 4 | Estimates of MedTech employment for each specific employment category

Employment Category	2020 Headcount	2021 Headcount	2022 Headcount
Clinical practice, trials and/or research	449	448	414
General and corporate management	606	600	629
Information technology	177	179	507
Manufacturing	3,430	3,491	4,163
Medical device maintenance	475	509	488
Product research and development	1,027	1,091	981
Professional and consulting services	500	561	642
Sales, marketing and customer service	6,840	7,169	6,964
Supply chain & logistics	1,032	1,146	1,237
Other business area	914	907	1,003
Total	**15,450**	**16,101**	**17,028**

The survey also sought to canvas employment through the lens of gender diversity. The level of female representation in the MedTech industry is presented below (Figure 31). The results of the survey indicated that the MedTech industry was aligned with all industries overall. However, MedTech female representation was greater at both the Board and Executive levels when compared to all industries. This result was even more favourable when compared to corporate Australia with only 42% of total workforce being represented by women and only 24% of executives[97].

Figure 31 | Survey responses on gender diversity in MedTech industry[98]



[97] https://www.wgea.gov.au/sites/default/files/documents/Women-in-Leadership%20report-BCA.pdf
[98] https://www.wgea.gov.au/women-in-leadership

Outside of employment, there are many initiatives underway to improve female engagement with MedTech. One example is explored below (Case study 13), that highlights the need for a female design focus when creating surgical equipment.

Case study 13 | Re-designing surgical instruments to better suit women in orthopaedics

EMPOWERING WOMEN IN MEDICAL PROFESSIONS

MedTech is remodelling surgical tools to create an inclusive medical environment for female orthopaedics.

Although women account for 50% of medical school students, only 5% of practicing orthopaedic surgeons in Australia are female[99]. One factor that contributes to this gender disparity is instrumentation that is ill-designed for female anatomy. Work by Antoni Chen (Brigham & Women's Hospital) and colleagues, hypothesise that instrumentation size is a leading cause of work-related injuries suffered by female orthopaedic surgeons.

DePuy Synthes, the orthopaedics business unit of Johnson & Johnson MedTech has developed the DePuy Synthes Women of Orthopaedics group to support Diversity, Equity, & Inclusion'. The project partnered with female surgeons to re-design commonly used orthopaedics instruments to increase the usability, ergonomics of instruments and reduce the risk of injury for females in orthopaedics.

With the number of female orthopaedic surgeons expected to grow, this program contributes to a more inclusive medical environment that both encourages female representation in orthopaedics and provides proper instruments for them to best serve patients.

The survey also captured the sentiment of respondents and noted that one of the key barriers to growth was the fact that they had found it increasingly difficult to attract the right staff as shown by the following figures.

- 64% of survey respondents agreed it was difficult to find local talent for their workforce.
- Over 50% of respondents also agreed it was difficult to bring international talent to Australia.

To examine the potential implications on sourcing future employment in the sector, it is important to understand the potential pool of employees.

MedTech in Australia is not separately classified as its own industry with its own ANZSIC code to measure employment growth and projections. To ground truth in the results of this report, it is worth considering the ANZSIC codes that are identified to most likely contribute to the employment in this sector and subsequent changes in these industries over time. The following outlines the growth of employment industries over time for those ANSZSIC industry categories that best contribute to the pool of employees MedTech firms would seek to employ.

It is important to clarify that this analysis is an estimation regarding employment. While the identified industries are likely to contribute to the MedTech industry, it is important to note the following:

- There is not a one-to-one relationship between the data in these industries and MedTech – not all employment in each will be MedTech.
- There are other industries that do contribute to MedTech that are not listed here, as MedTech only draws upon a limited number of employees from these industries.

At a high level, this analysis allows us to understand how broader changes in industries estimated to most likely contribute to MedTech are changing over time.

[99] https://eor.bioscientifica.com/view/journals/eor/5/10/2058-5241.5.200022.xml

In conducting the analysis, it was also valuable to consider the broader employment trends of the chosen industries over a longer period (2011-2026). This approach was taken to increase the accuracy of broader macro-economic trends that may be associated with the MedTech industry, rather than choosing a small period in isolation that is not reflective of national trends. Table 5 provides an overview of the changes in employment for the identified industry categories.

Overall, the industries most closely related to MedTech and thus representing the pool of potential employees to draw upon, have grown historically at a CAGR of 3.2% and are forecast to grow further over the next five years to 3.8%. From this we can determine the following:

- Those firms seeking to expand manufacturing capabilities in the future may face difficulty in recruitment, with Professional and Scientific Manufacturing forecast to decrease by 1.5% per year over the forecast period.
- Potential growth in digital health opportunities would be supported by the forecast increase in Computer System Design and Related Services category.

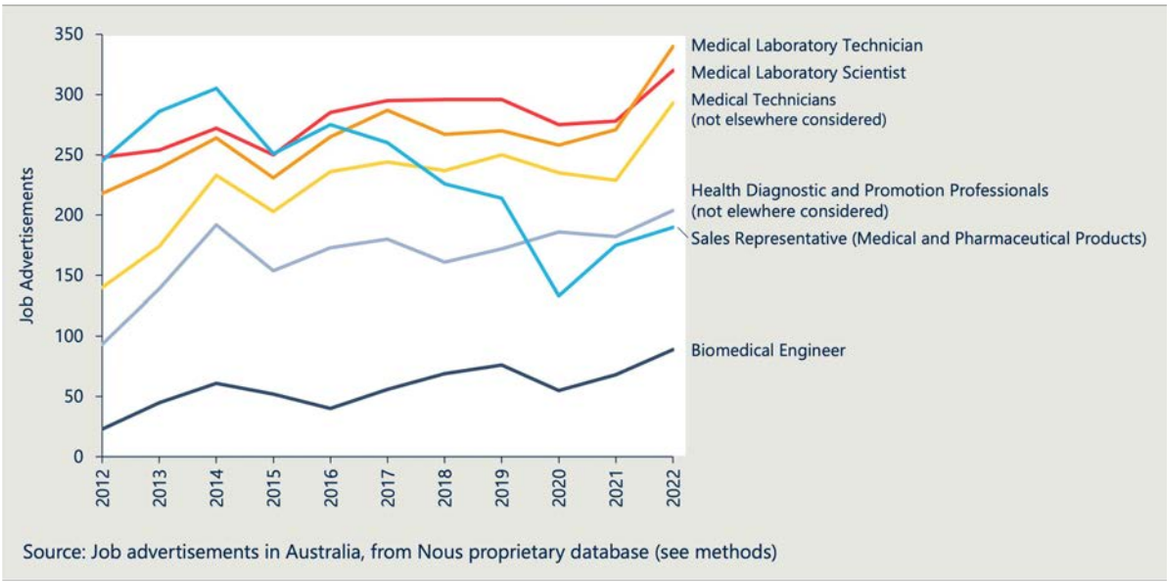
The number of job advertisements for occupations that support and/or use MedTech had been relatively stable over time but saw a recent 19% increase from 2021-2022 (Figure 32). There is also expected growth in employment in industries related to MedTech of 7% from 2021 to 2026 (Figure 33). Therefore, the sustained growth in Australia's MedTech sector will require a stable pipeline of qualified people with skills relevant to the sector.

Table 5 | Growth of industry categories estimated to contribute to the MedTech industry, measured by employment levels (2011-2026)[100]

Industry Categories	2011	2016	2021	2026	Historical CAGR	Forecast CAGR
ANZSIC 241 Professional and Scientific Equipment Manufacturing (includes Code 2412 and 2419)	15,661	23,437	18,403	17,039	1.6%	-1.5%
ANZIC 349 Other Machinery and Equipment Wholesaling (includes Code 3491)	82,120	69,675	58,153	61,914	-3.4%	1.3%
ANZSIC Code 852 Pathology and Diagnostic Imaging Services	49,828	48,345	60,078	66,833	1.9%	2.2%
ANZSIC Code 691 Scientific Research Services	33,278	39,472	43,721	47,607	2.8%	1.7%
ANZSIC Code 700 Computer System Design and Related Services	180,299	211,703	315,797	406,276	5.8%	5.2%
Total	**363,197**	**394,648**	**498,173**	**601,695**	**3.2%**	**3.8%**

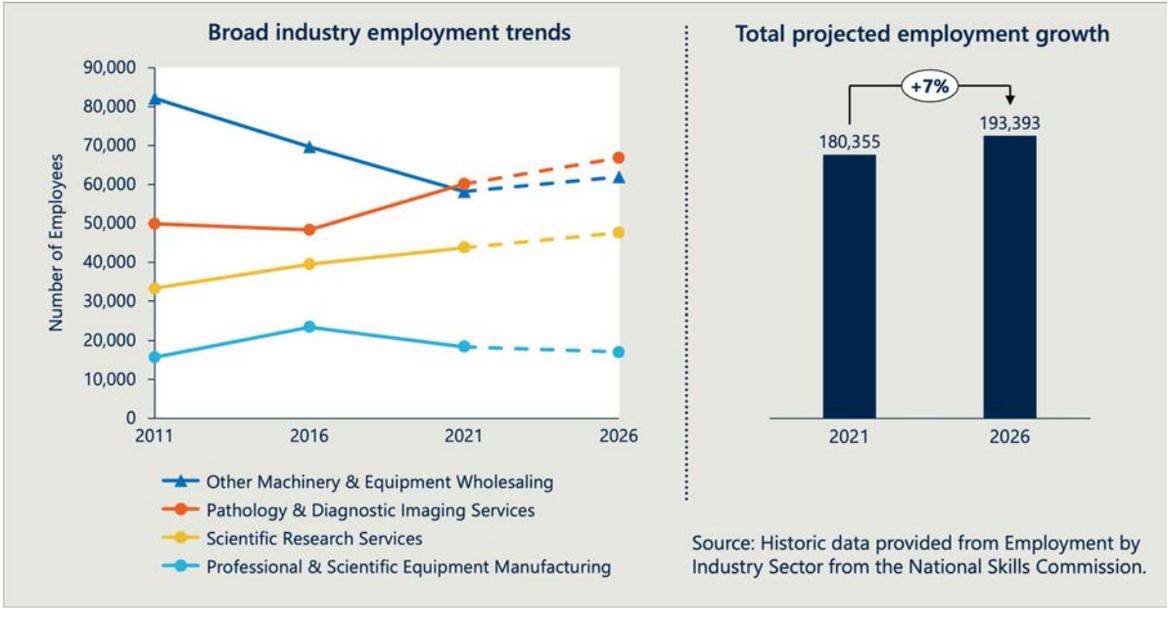
[100] Historic data provided from Employment by Industry Sector - National and State/Territory, Quarterly Time Series: November 1984 to August 2022 from the National Skills Commission. Projections provided https://labourmarketinsights.gov.au/our-research/employment-projections/

Figure 32 | Jobs advertisements for selected occupations that use and/or support MedTech



Australia's MedTech sector has benefited from strong growth in the supply of higher education science, technology, engineering and mathematics (STEM) skills. There is a steady pipeline of STEM graduates entering the workforce. However, as noted, MedTech companies surveyed found that it was hard to find both local and international talent.

Figure 33 | Employment in MedTech-related industries are projected to grow



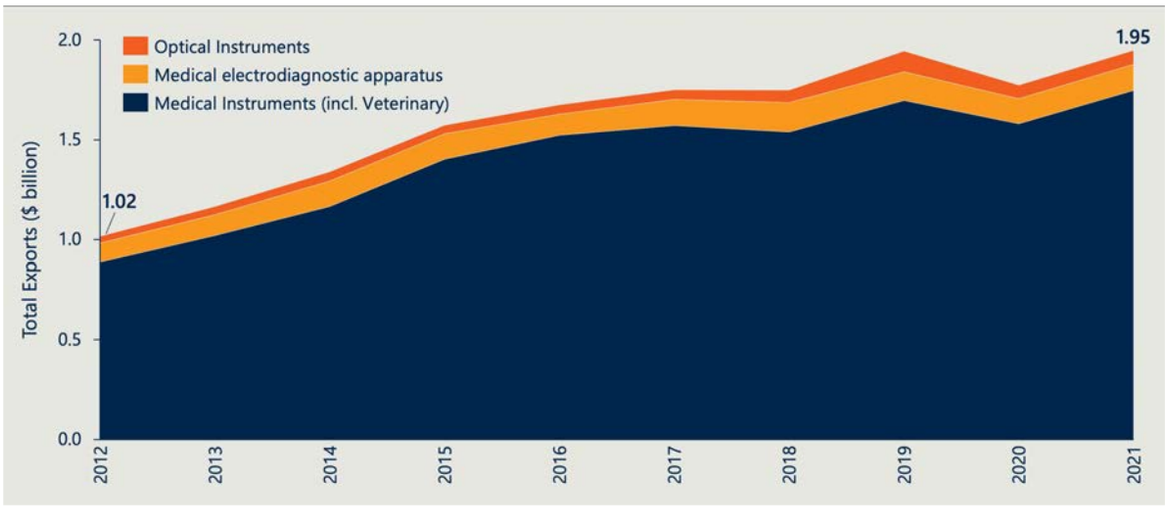
MedTech contributes to $1.9 billion in exports

Exports provide another lens by which the impact of the MedTech industry can be examined (Figure 34). However, caution should be maintained – exports are already a component of GDP (when measured from the expenditure side) and so are not additional to the contribution of GDP (when measured from the income side) with the latter used to estimate GDP earlier in the report.

Exports are a valuable proxy to measure the overall size of the MedTech industry, and to understand global competitiveness and linkages of the sector.

Examining export datasets developed by the Department of Foreign Affairs and Trade provides an indication of the contribution that MedTech makes to Australia's exports. Figure 34 outlines the three export categories that most closely align to the definition of MedTech products and the relative export value from 2011-2021.

Figure 34 | Exports of MedTech related products from Australia



The three Standard International Trade Classification (SITC) categories selected in the above chart are those that MedTech would most likely contribute to. They include:

- medical electrodiagnostic apparatus;
- optical instruments; and
- medical instruments (including veterinary).

In total these, three categories contributed $1.9 billion of Australia's exports in 2021, roughly 3.9% of the total value for that year. While MedTech would contribute significantly to these figures, the total value cannot be wholly attributed to this sector. There would be other industries that also would manufacture and export products within these categories. Similarly, there would likely be other SITC categories to which MedTech contributes but are not presented in the above figure as the proportion derived by MedTech would be relatively small and difficult to disaggregate.

Australia's largest export market for MedTech products is New Zealand, with the United States second (noting the US is the largest MedTech market in the world). Austrade notes that there is potential growth in the US markets as Australia's outstanding medical science, strong intellectual property protection, robust regulatory regime, fast-tracked clinical trials and expertise in successful commercialising medical science and technologies result in high-quality products that are attractive to this market[101].

[101] https://www.austrade.gov.au/australian/export/export-markets/countries/united-states-of-america/industries/medtech-to-the-united-states

4.2 MedTech International and Domestic Comparison

International Comparisons

Benchmarking Australia's MedTech sector against other countries helps to sense-check the results in this report. While the countries selected for this comparison are at different stages of industry maturity and are focused on different components of the value chain, they still provide a useful contrast.

The analysis primarily compares Australia against the United States, the United Kingdom and Canada. These countries have been chosen given their similarity in GDP per capita and maturity of their healthcare sector. The observations made, however, are not an analysis of the accuracy of this report's estimate of the value of the Australian MedTech industry relative to other economies.

While figures for Australia are drawn from the survey and analysis undertaken, the data for the comparator countries is drawn from IBISWorld industry reports[102].

Table 6 | International Comparisons of the MedTech industry

Country	Direct GDP ($AUD, Billion) 2022[103]	Direct GDP as a % of total GDP[104]	Employees[105]	Employees as a % of working age population[106]
United States	$52.6	0.22%	382,254	0.18%
United Kingdom	$3.3	0.09%	48,466	0.11%
Canada	$5.4	0.25%	49,295	0.20%
Australia	$4.1	0.24%	17,028	0.11%

Recognising there are key differences between the MedTech industry in each country (e.g. across sector maturity, sector composition, sector funding and targeted initiatives) and key differences in the industry definitions and data collation methodologies, Table 6 shows that the results included in this report are not unreasonable compared with these other economies.

Domestic Comparisons

Other domestic-focussed reports that have estimated the economic value of the Australian MedTech industry provide valuable context. Comparing findings across studies is beneficial in generating a more comprehensive understanding of the value of the sector and how methodological differences may influence the respective outcomes reported.

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[102] For America and Canada this is comprised of two reports which cover Medical Device Manufacturing and Medical Instrument & Supply Manufacturing in each respective country. For the UK this Medical & Dental Instrument Manufacturing and Electromedical & Imaging Equipment Manufacturing.

[103] Industry Value Add figures and are the equivalent of Direct GDP. These are for 2022 are sourced from IBISWORLD reports for America, Canada and UK. All values provided are in AUD using OECD using purchasing power parity conversion. For more information see: https://stats.oecd.org/Index.aspx?DataSetCode=CPL, accessed on 23 Feb 2023

[104] All data is for 2021. OECD GDP figures converted to AUD by PPP from https://data.oecd.org/gdp/gross-domestic-product-gdp.htm, accessed on 23 Feb 2023

[105] Employment figures for 2022 are sourced from IBISWORLD reports for America, Canada and UK, accessed on 23 Feb 2023

[106] All data is for 2021, with percentage of working age population and total population from https://data.oecd.org/pop/working-age-population.htm#indicator-chart and https://data.oecd.org/pop/population.htm#indicator-chart respectively, accessed on 23 Feb 2023

The following outline some of these reports:

- Medical and Surgical Equipment Manufacturing in Australia Industry Report (IBISWorld)
- Medical and Scientific Equipment Wholesaling in Australia Industry Report (IBISWorld).

These reports are a useful comparison to ground truth the survey and research analysis undertaken as a component of this study. Table 7 highlights what types of activities that each report captures, with those bolded reflecting activities that fall within the definition of MedTech adopted for this study.

Table 7 | Activities in domestic reporting equivalent to this study's definition of MedTech

Report	Activities captured in the report
Medical and Surgical Equipment Manufacturing in Australia	• **Artificial eye, limb and joint manufacturing** • **Dental amalgam, instrument, chair, plaster and equipment manufacturing** • **Pacemaker and respirator manufacturing** • **First-aid equipment manufacturing** • **Hearing aid manufacturing** • **Hypodermic needle and syringe manufacturing** • **Magnetic resonance imaging equipment manufacturing** • **Medical diagnostic apparatus, equipment and ultrasound manufacturing** • **Surgical and electromedical equipment manufacturing** • Veterinary instrument manufacturing
Medical and Scientific Equipment Wholesaling in Australia	• Aeronautical instruments wholesaling • **Dental instruments or equipment wholesaling** • Mathematical instruments wholesaling • **Medical equipment and instruments wholesaling** • Meteorological instruments or equipment wholesaling • Nautical instruments wholesaling • **Ophthalmic instruments wholesaling** • Seismic instruments wholesaling • Surveying instruments wholesaling • Veterinary instruments or equipment wholesaling

Key economic metrics were extracted from these reports and compared to those derived through this study (Table 8). The majority of the activities of the manufacturing report were closely aligned to those that comprised the definition of MedTech for this study. However, an approach to apportion wholesaling to provide a more accurate, and MedTech-specific representation of this industry segment was adopted for the analysis.

Table 8 | Domestic comparisons of the MedTech industry

Report	Gross Revenue ($b)	Direct GDP ($b)[107]	Employment
Medical and Surgical Equipment Manufacturing in Australia	6.8	2.0	12,364
Medical and Scientific Equipment Wholesaling in Australia[108]	12.6	3.0	18,772
Total	**19.4**	**5.0**	**31,136**
This Report	**11.4**	**4.1**	**17,028**

As outlined in the methodology, there are limitations to all studies that have sought to measure the value of the Australian MedTech industry. When considering the differences between the IBISWorld report and this report, one should keep in mind each report's focus, methods and limitations/caveats. Without knowing the details of the IBISWorld methodology, the values outlined above provide a helpful sense-check. But caution should be taken to draw definitive conclusions about the value of Australian MedTech by combining the results from each study.

Summary

MedTech has upstream and downstream benefits that produce indirect benefits across the economy. The MedTech industry contributes a total of $5.4 billion GDP to the Australian economy. Currently, the sector supports over 17,000 direct and 51,000 total jobs. MedTech is exporting $1.95 billion overseas and contributes to over 4,000 jobs in manufacturing. Australian MedTech has been experiencing revenue and employment growth over the past 3 years, which is projected to continue.

[107] The IBIS world reports report an industry value add (IVA) figure for each of the manufacturing and wholesaling industries. IVA measures the market value of goods and services produced by the industry minus the cost of goods and services used in production. IVA is also described as the industry's contribution to GDP, or profit plus wages and depreciation. This is equivalent to direct GDP as recorded in this report.

[108] Figures for the Wholesaling industry report were prorated to only incorporate those categories which were closely related to MedTech activities. This included surgical and medical instruments and supplies, dental equipment and supplies, and surgical and medical appliances and apparatus, which together represented 65.4% of the industry.

SECTION 5

The Future Potential of Australian MedTech

5.1 The current state of Australian MedTech

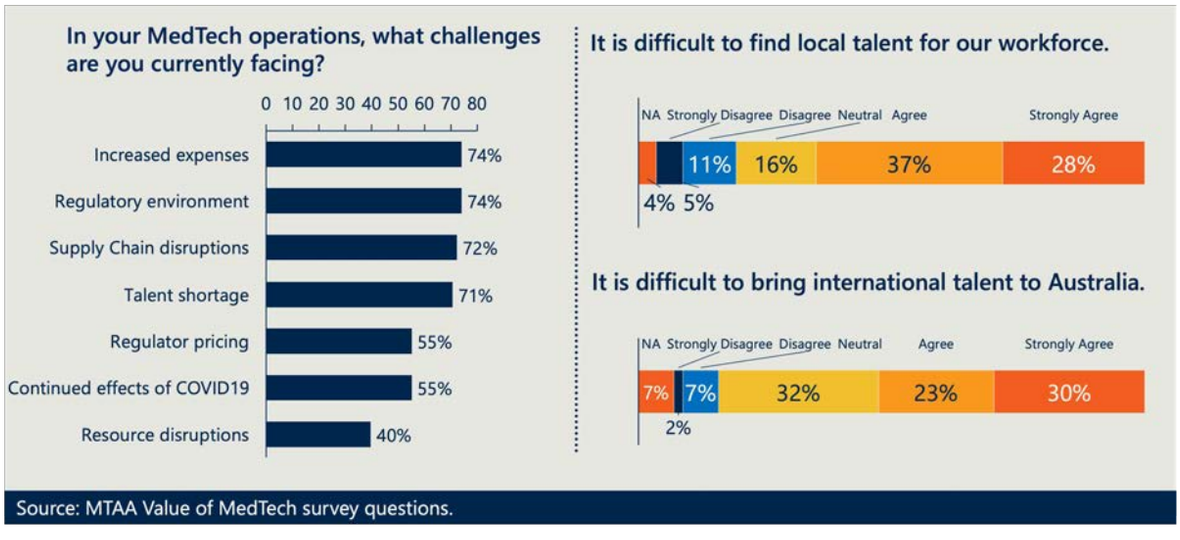
To develop the future potential of Australian MedTech, it is essential to understand the current challenges that MedTech organisations face. If these challenges are well-understood, Australia has the potential to overcome any barriers limiting the growth of the sector and create more value by improving patient lives.

Ongoing challenges to MedTech operations

There are many challenges that are affecting MedTech operations (Figure 35), which may be exacerbated by recent growth. There is a predicted strong growth in job demand for the MedTech industry and adjacent industries (see Section 4). MTAA survey respondents are finding that talent shortage is an ongoing operational challenge (71%), and this is true for local (65%) and international (53%) talent (Figure 35).

Some of the challenges that the MedTech industry faces appear to be more systemic economic or global issues. These include challenges with increased expenses, supply chain disruptions, continued effects of COVID-19, and resource disruptions (Figure 35).

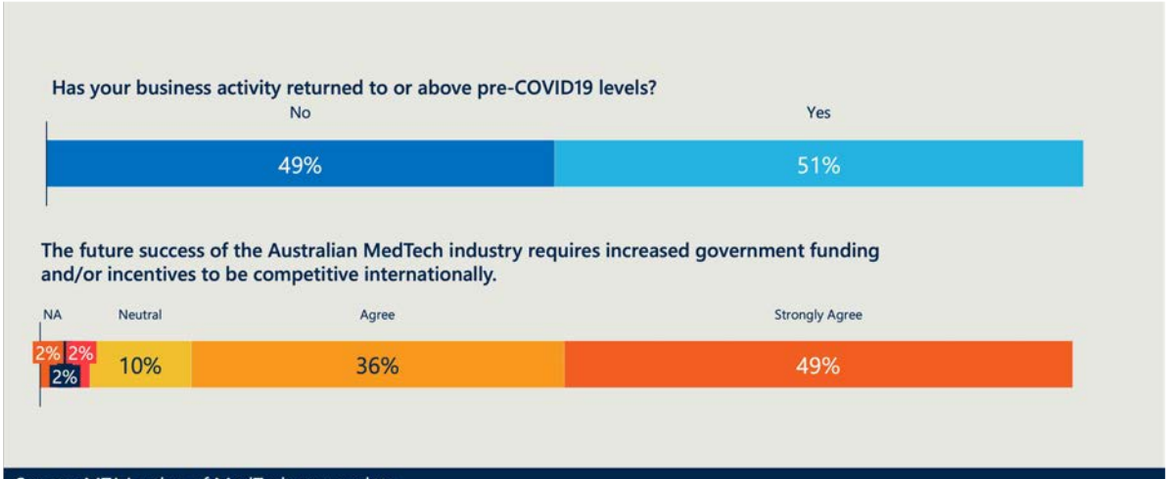
Figure 35 | Ongoing challenges facing Australian MedTech operations



Source: MTAA Value of MedTech survey questions.

Many MedTech businesses are still recovering from COVID-19. Forty-nine percent of MTAA survey respondents report that their business activities have not returned to, or exceeded, pre-COVID-19 levels (Figure 36). Furthermore, 85% of survey respondents believe that they require more government support to be competitive internationally.

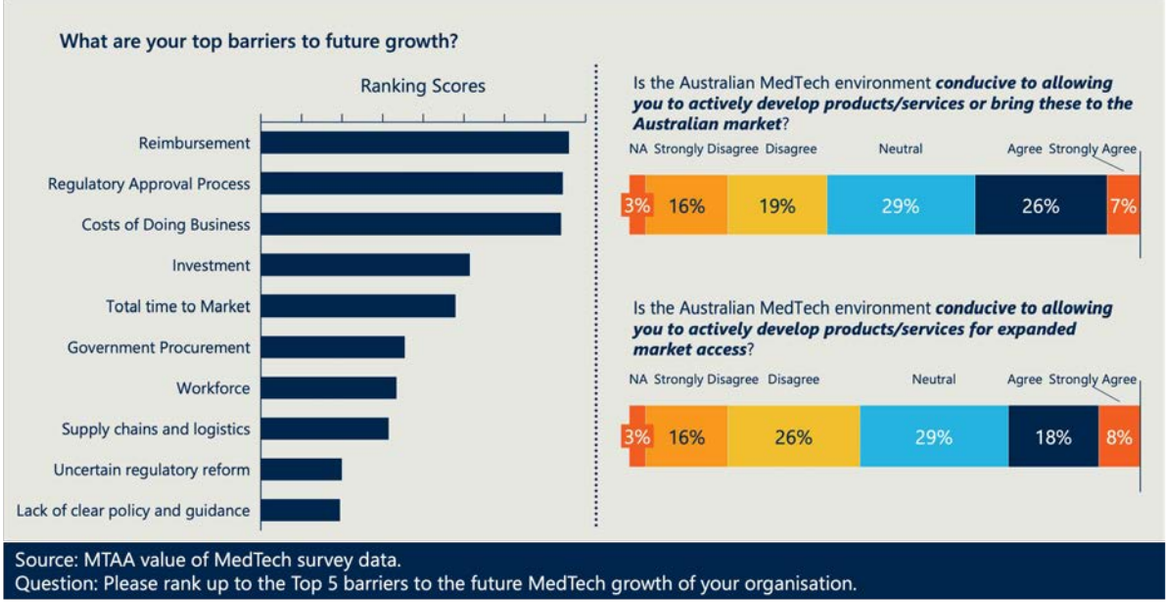
Figure 36 | MedTech business recovery and support



Barriers to future growth

MedTech companies have identified key barriers to the future growth of their organisation (Figure 37). A common theme from consultation and the MTAA survey is that there are significant bottlenecks to accessing the market. The top two barriers to growth are reimbursement and regulatory approval process, which are critical components of access to the Australian market. Also included in the top barriers were total time to market, government procurement, uncertain regulatory reform and lack of clear policy and guidance. These barriers are likely contributors to the current state, where few companies feel that the Australian environment is conducive to develop products, services, or expand market access (Figure 37).

Figure 37 | Barriers to future growth



5.2 Opportunities for the MedTech industry

Providing clarity in regulation and the pathways to market

The pathways to market are complex and unclear for MedTech. Regulation and pathways for procurement were both rated as challenges for operations and barriers to growth (Figure 35 and Figure 37). The barriers that regulation presents must be balanced by the safety and value that these barriers provide (Figure 38). For example the TGA is highly trusted in Australia but can be perceived as overly conservative by the MedTech industry.[109]

"The New Frontier: Delivering better health for all Australians" report by the Australian parliament[110] identified the strengths and challenges facing the medicines and health technology. Regulation and reimbursements keeping pace with rapid technological and therapeutic development was identified as an ongoing challenge for Australia. In February 2023 the UK government published a "Medical technology strategy"[111], which provided a strategy to address many of the same issues Australia faces.

There is an opportunity in Australia to preserve the quality, safety and trust in MedTech regulation, while improving market access. Providing clarity to stakeholders about the regulatory pathways, processes and timelines may be a key enabler of reducing regulatory burden and potentially enabling a faster time to market. An additional possibility is that a unifying framework for MedTech market access is developed in Australia. Streamlining the existing regulatory processes with reimbursement approvals and procurement processes that vary between jurisdictions has the potential to provide efficiencies for the healthcare sector and benefit the MedTech industry by reducing regulatory burden.

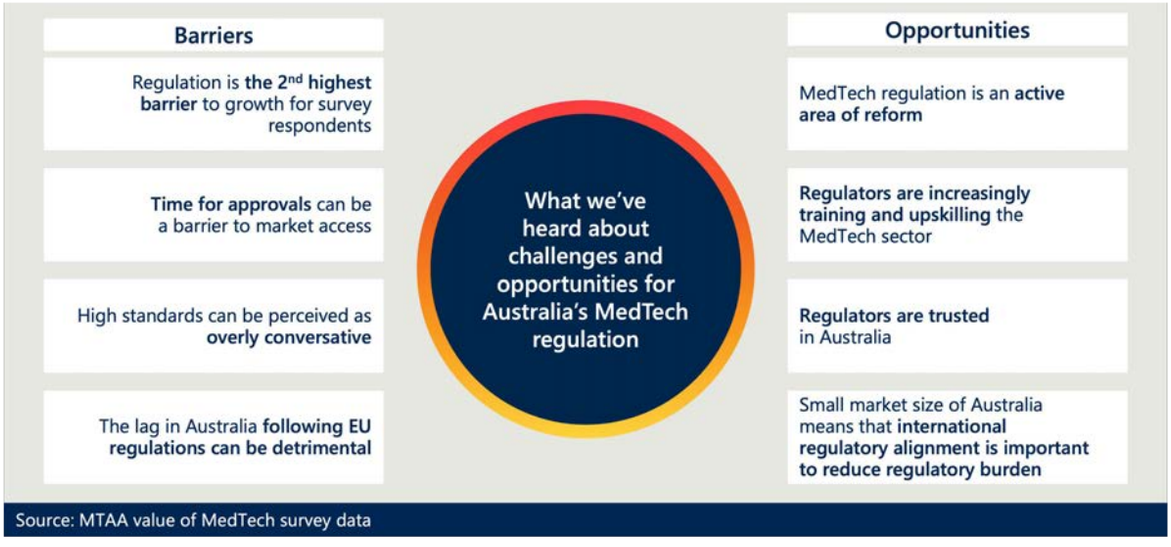
Value-based approach to healthcare presents an alternative

Decision-making processes surrounding healthcare have typically focused on narrowly minimising the financial cost of the provision of care and therapeutics. However, an alternative overarching framework for healthcare decision-making is value-based healthcare. The "value" in value-based healthcare is derived from measuring health outcomes (including non-financial benefits such as improved quality of life outcomes and broader flow-on savings elsewhere in the system) against the cost of delivering outcomes.

An application of value-based healthcare is value-based procurement, in which healthcare procurement decisions are informed by the total benefits of providing care, rather than just the immediate outcomes for the Health Department's budget or hospitals' budget.[112] Value-based procurement decisions can be made by quantifying the relative cost of delivery and the benefit to patients for different tenders. For example, in the UK a pilot used value-based procurement to reduce the rate of catheter-associated urinary tract infections.[113] The success of the pilot demonstrated that reduced rates of infections had flow-on savings on the costs of consumables, costs of treating infections, improvement in operational productivity and reductions in patient length of stay.

[109] MTAA Value of MedTech survey comments
[110] Preparing for Health Cares New Frontier – Parliament of Australia (aph.gov.au)
[111] Medical technology strategy - GOV.UK (www.gov.uk)
[112] Value-based procurement, Alira Health
[113] Value Based Procurement Pilot Reduces Catheter Associated Urinary Tract Infections (CAUTI) » NHS Supply Chain

Figure 38 | Barriers and opportunities for Australian regulation



Leveraging Existing Innovation and Skills Pipeline

There are many lessons to be learned from programs and reforms over the pandemic period. COVID-19, while disruptive, was a time of accelerated MedTech innovation in Australia, where rapid regulatory changes and directed investments developed new MedTech and benefits for patients.

The changes that occurred during COVID-19 demonstrated that targeted and sensible reform and funding can yield substantial benefits. During this period, partnerships between MedTech organisations, research institutions, hospitals, government, and regulators demonstrated that a coordinated response to a problem can yield rapid solutions.

Australia has the potential to overcome the existing challenge of talent shortages by using and fostering MedTech collaborations. Collaborations have an important role in upskilling workers and creating opportunities in the sector (Figure 39).

Figure 39 | What we've heard about collaboration in MedTech

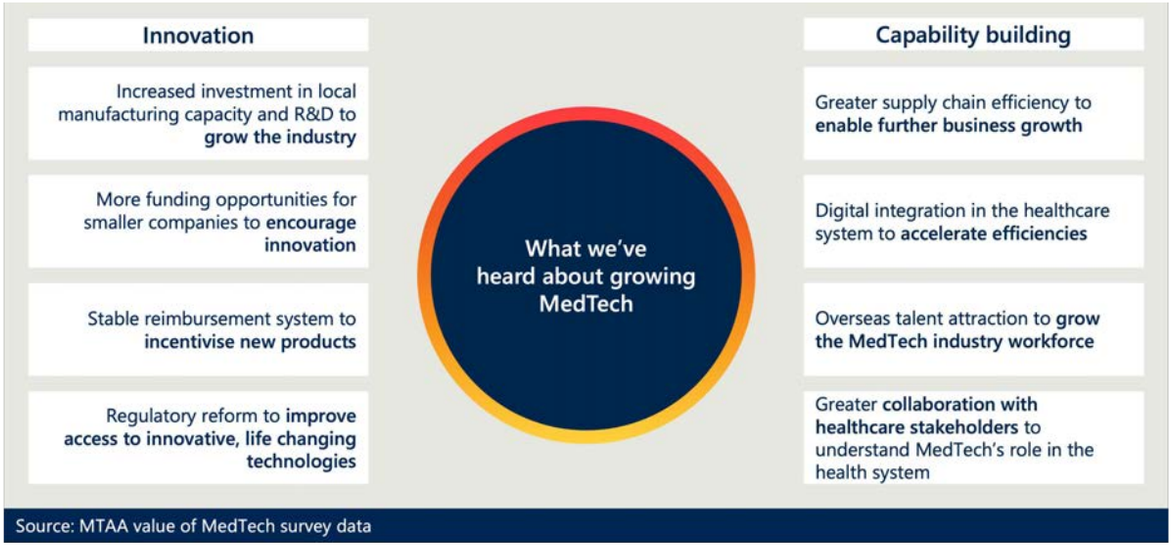
Generating future value

The Australian MedTech industry is undergoing a significant period of growth. Companies, both large and small, are feeling positive about the future of Australian MedTech (Figure 40). This sentiment comes from growth in Australian MedTech gross revenue (6.2% CAGR) and jobs (5.0% CAGR) from FY20/21 to FY21/22. The MTAA survey has generated many ideas about how to sustain growth in the MedTech industry. Two key themes emerged from the analysis, namely growth through innovation and through capability development (Figure 41).

The future growth of MedTech will hinge on the sector being able to articulate value for money to stakeholders across the value chain. However, the most important stakeholders will be the payers in the Australian healthcare sector (such as state and federal governments and health insurers), who are given the task of sustainably providing the best outcomes for patients. Whilst existing processes, such as health technology assessments, go part way to quantifying this value, different processes are applied by payers and policy makers across healthcare systems and state and territory jurisdictions. A clear framework for demonstrating the benefit of individual MedTech devices in Australia would be valuable to MedTech sponsors, payers, clinicians and ultimately patients.

Figure 40 | Future growth in the Australian MedTech industry

Figure 41 | What we've heard about growing MedTech



Summary

The MedTech industry is a key enabler for improving the health of Australians. The growth of the MedTech industry is tied to its ability to articulate the value it provides to Australia. Ensuring that a dollar spent on MedTech is a dollar well-spent will be key to the sustainability of the Australian healthcare system and ensure that patients continue to benefit from the use of medical devices.

The MedTech industry is growing, employing thousands of workers around Australia and contributing billions to the economy. However, Australia can better capture the value of MedTech to patients by fostering more local development, exports and improving pathways to clinical use. By leveraging the strong innovation ecosystem and world-class healthcare, Australian MedTech has an opportunity to secure future growth and better patient outcomes well into the future.

Appendix A Data Figures and Tables

A.1 Methodology

Table 9 | Definition of the MedTech industry

Definition of Australian MedTech industry:
Entities that support the research and development; manufacturing; distribution; sales and marketing; and/or service and support of Medical Technology. These can be broadly defined in the following ANZSIC codes: • Code: 2412 Medical and Surgical Equipment Manufacturing • Code: 2419 Other Professional and Scientific Equipment Manufacturing • Code: 3491 Professional and Scientific Goods Wholesaling • Code: 8520 Pathology and Diagnostic Imaging Services • Code: 6910 Scientific Research Services • Code: 7000 Computer System Design and Related Services • Other: Consultancy and Advisory Services This definition explicitly excludes end-users of MedTech such as hospitals and clinics as meeting the definition of the MedTech industry, as their primary function is to provide services to patients, rather than the use of MedTech per se.

Method

The economic analysis outlined in this report combines and analyses multiple data sources. The primary data source for the economic metrics was a national survey of MedTech organisations. Complementary data sources were used to triangulate the survey and sense-check the results. All the data sources used in this report were also chosen for their repeatability so that the growth of the MedTech industry can be monitored consistently over the coming decade.

Surveying the Australian MedTech industry

The sampling frame for this survey was informal, due to the lack of a definitive population of MedTech-businesses to draw on. The population comprised organisations that were provided to Nous by the MTAA and complemented through identifying those self-disclosed MedTech businesses through ASX listings.

The primary data source for the economic analysis of the MedTech industry and its growth was a survey of the Australian MedTech industry (the survey). Through consultation with the MTAA, Nous identified MedTech organisations which were the recipients of the survey through the following methods:

- MTAA Member list
- MTPConnect Member list
- Pathology Technology Australia Member list

- desktop research from the Australian Register of Therapeutic Goods of Australia-based sponsors and/or manufacturers of MedTech
- desktop research of ASX listed organisations which were not in the above lists, but which were identified as being MedTech industry businesses.

The survey was designed to gather organisational information that could be used to measure key economic metrics. Prior to the launch, the survey was extensively developed through consultation with the MTAA, with this feedback being incorporated into the final design.

The effectiveness of the survey in collecting data to analyse the economic metrics identified relies on having good responses to each of the respective questions. It was a requirement for submitting the survey that all sections were complete, with a particular focus on company demographics, revenue and headcount data. Although an organisation might have only partially completed the survey, submitted surveys had, at a minimum, aggregated this data in these sections.

During the quality control processes the survey participants were contacted to clarify any concerns raised about the quality of their survey data. In the event that responses were not able to be gathered, secondary data sources were sought, such as company annual reports, or otherwise were excluded from the data.

Table 10 | MedTech company sources of data used in analysis

Items	Companies Responding
Survey – General	64
Survey – Pathology Technology Association (Headcount data only)	10
Pathology Technology Association – Summary Data	51
ASX – Desktop research	52
MTAA Members – Desktop Research	14
Total Companies	**191**

Additional data sources to support the economic analysis

To support the economic estimates from the national survey, a range of additional data sources were used to triangulate and sense-check the results. The additional data sources identified were used for the following purposes:

- to increase the validity and reliability of any conclusions drawn by comparing the survey analysis against other identified proxies
- to supplement survey responses by increasing coverage through publicly available data, such as annual reports and IBISWorld reports
- to position the current results within the broader economic context by understanding changes in the labour force and how these external metrics compare to the estimated value of the MedTech industry
- examining trade and export data to capture the impact that the MedTech industry provides to these key metrics.

The additional data sources identified to support the analysis are outlined below. It is important to recognise that reliance on each varies; dependent on the quality of the data available and the methodologies used to collate and measure them.

- Tracking changes in the industries that are most likely to contribute to the MedTech industry
  As attribution is a primary challenge for measuring the MedTech industry, and because MedTech is not a separate ANZSIC code, it is beneficial to track changes in the industries that are more closely aligned with the MedTech industry and which are likely to be contributing to respective components of the value chain. That is, there are specific ANZSIC codes that are likely to be more closely aligned with the MedTech industry than others, which can be used to sense-check the reported growth and size of the sector. For example, when examining forecast growth in the MedTech industry several ANZSIC categories were investigated, to present an overall picture.
- Utilising publicly available data to identify and fill gaps
  The survey itself was initially sent through to the respective member lists of the MTAA, MTPConnect and PTA. Other MedTech organisations, who did not happen to fall within the above lists were identified and subsequently surveys emailed through to them, increasing the overall reach of the evidence gathering task. Where there were instances of respondents who didn't respond to the survey, and there was publicly available financial information available (annual and financial reports), this information was captured and included in the analysis to present as wide a view as possible.
- Comparison to previous estimates for the Australian MedTech industry
  Other reports that have attempted to quantify the economic value of the Australian MedTech industry can provide valuable sense-checks. Reports considered in this review included:
    - Medical and Surgical Equipment Manufacturing in Australia Industry Report (IBISWorld)
    - Medical and Scientific Equipment Wholesaling in Australia Industry Report (IBISWorld).

  These reports provide a useful comparison to ground-truth the survey and research analysis undertaken as a component of this study. When considering the differences between the IBISWorld report and this report, one should keep in mind each reports' focus, method and the respective limitations/caveats. Without knowing the details of the IBISWorld methodology, the values can provide a helpful sense-check; but caution should be taken to draw definitive conclusions about the value of Australian MedTech by combining the results from each study.
- Assessment of MedTech industry exports
  Exports provide another lens by which the impact of the MedTech industry can be examined. Acknowledging the distinction between the income and expenditure methods of calculating GDP and examining export datasets developed by the Department of Foreign Affairs and Trade, provides an indication of the contribution that MedTech makes to Australia's export markets.

A.2 Analytical limitations

Given the usual limitations of survey work, Nous went to extra lengths to cross-check and triangulate data to ensure stakeholders can have confidence in the estimates in this report. In common with all data analysis, the estimates derived from the survey incorporate uncertainty. There are three main sources of potential error for this particular study: measurement, processing and sampling.

Measurement uncertainty comes from survey respondents having difficulties in answering some questions and in some cases being provided with deliberately imprecise answer options to encourage response on confidential variables. For example, this could be where instead of an ability to provide a free text response a survey recipient is asked to allocate a range from a selection (e.g. "0-2.5%, 2.5 -5%, >5%").

A balance is struck between ensuring an adequate response rate and accuracy of responses. For the key economic variables, (gross revenue, workers compensation, gross operating surplus, and headcount) free text responses were asked to be provided.

Processing is the stage in survey management that involves cleaning, tidying, de-duplicating and inputting missing responses. Processing was particularly complex for this survey in order to mitigate sampling and measurement challenges. Where there were responses that could be identified as obvious errors, engagement with the respondent was undertaken to clarify the correct response and updates applied accordingly. Where there were instances of an absence of responses, or particular metrics were unable to be gleaned from publicly available information, then estimates utilising other existing survey data and calculated ratios were determined.

The two particularly important sources of **sampling uncertainty** relate to the limited number of responses and biases in those who responded to the survey. These are discussed in a little more detail below.

Limited number or partially answered survey responses

It is expected that the number and completion of responses for the survey was impacted by three major factors:

- The commercially sensitive questions asked (particularly those regarding gross revenue and remuneration)
- A lack of any legal requirement to answer the survey (as would be the case for an ABS-administered survey)
- The timing of the survey over the December-January period where firms may not have had all relevant members or capacity to respond.

This analysis incorporated auxiliary data and statistical estimation to compensate for gaps in survey data. Auxiliary information (sourced from publicly available annual and financial reports) was available in some cases to mitigate this issue.

Systematic bias in responses

There was not a single, comprehensive and exhaustive list of the whole MedTech industry for use in distributing the survey. Initial survey distribution lists were built up through a combination of known members of the MTAA, PTA and MTPConnect, as well as desktop research to identify ASX listed companies that undertake MedTech activities. As the population of relevant organisations is not defined there is minimal auxiliary information for the sector that could be used to weight results. It is reasonable to assume that:

- the firms who responded to the survey are not typical of the firms in the statistical population (that is, the Australian economy) which is response bias
- recruitment was not done at random but was heavily targeted at firms believed to be most involved in the MedTech industry. For example, the targeting of ASX listed companies (as these are publicly available) means that there is the potential for there to be smaller MedTech companies that are not listed and missed which is sampling bias.

While there were challenges in obtained a representative sample, Nous is confident that we have captured the vast majority of the industry.

Statistical Imputation of auxiliary information

This analysis incorporated auxiliary data and statistical imputation in order to compensate for gaps in survey data. Auxiliary information (annual reports and company websites) was available on public companies to address gaps in the survey response. The key limitation with desktop research is the minimal level of data publicly available. Company reports provide revenue and occasionally headcount, but a disaggregation rarely occurred. To overcome this, a ratio-extrapolation of existing survey data was used to impute missing data.

This overall statistical approach was necessary due to these factors:

- Not all desired organisations answered the survey, partly due to the limitations outlined above
- Not all respondents answered every question in the survey or provided their financial data for every financial year sought. For example, dependent on the timing of the survey response, those organisations with a 30 June financial year end may not have had accounts finalised to report on 2021/22 financial information
- Some data was not publicly available. For example, annual and financial reports may have provided headline revenue, and employee expenditure data, yet headcount data was not as readily disclosed.

In undertaking this estimation, the bimodal nature of the MedTech industry as represented in the survey data was taken into account. From the survey results it became apparent that there were large clusters of extremely large, and small businesses. Each presented unique characteristics based on the stark differences between "Small" and "Large" companies. In order to account for this, when ratios were calculated to aid the imputation of data, a bimodal approach was undertaken to develop two sets of ratios for each metric, and dependent on whether the organisation was small or large applied accordingly.

For each metric, the following ratios were applied:

- **Operating Surplus**: Calculated the ratio of gross revenue to operating surplus of complete data and divided available revenue data to estimate missing figures.
- **MedTech Operating Surplus**: Calculated the ratio of gross MedTech Revenue to Total Revenue and applied to Operating Surplus to estimate missing figures.
- **Total Remuneration:** Calculated the ratio of gross revenue per employee of complete data and multiplied available headcount data by ratio to estimate missing figures.
- **MedTech Remuneration:** Calculated the ratio of MedTech remuneration per MedTech employee using only survey data and multiplied available MedTech headcount data to estimate missing figures.
- **Total Headcount:** Calculated the ratio of gross revenue per employee and divided available revenue data to estimate missing figures.
- **MedTech Headcount:** Calculated the ratio percentage of total employees from MedTech taken from solely survey data and multiplied the total headcount figures to estimate missing data.
- Where two years of data was available, analytical techniques were used to estimate the third year. If organisations had publicly available data, these were also used to estimate. Where data didn't exist, analysis was enhanced by using ASX-listed and companies that were clearly MedTech.

Furthermore, in obvious cases, such as small companies or due to the nature of the company, total revenue was used to substitute for MedTech revenue.

Note the key limitation of a ratio-extrapolation is that companies that have minimal to no available data still cannot be estimated. Company reports that provided regional data (e.g. APAC) with no disaggregation were also excluded.

Ratio-extrapolation is also dependant on the robustness of actual data. Where there is insufficient or inaccurate actual data, the ratios and any estimates calculated with those ratios will lose accuracy. A quality check was performed to ensure that any unfeasible figures estimated by the ratio-extrapolation were amended appropriately. For example, if MedTech remuneration exceeded total remuneration, a check into the company's profile showed whether the entirety of total remuneration was MedTech-related.

With gross revenue and headcount variables being largely imputed for many MedTech organisations, there is considerable uncertainty. Estimates of revenue were more stable due to better data from survey respondents.

Despite the estimates detailed above there are still limitations with this report, namely the gaps identified and estimated and the desktop research may not have picked up the rest of the sector, resulting in the estimations being relatively conservative. Should this process be repeated, expanding the number of potential respondents identified and improving the response rate will lead to a more comprehensive, accurate and reflective dataset.

Nonetheless, the current data depicts that the sector is extremely 'top-heavy'. Estimations show that the top ten companies (as per revenue in FY22) represented approximately 70% of the sector. Through desktop research, there is a high degree of confidence that the largest companies, and thus the largest contributors to the economic metrics outlining in this report, have been captured.

Direct and Indirect Value Added

The data from the responses provided a clear indication of the direct GDP and employment produced by the MedTech industry. Each firm's direct GDP was estimated as the sum of its gross operating surplus and employee remuneration, noting that indirect taxes and subsidies for this sector would be relatively nominal.

Indirect GDP was calculated using ratios derived from the Input-Output tables.[114] In this case, the ratios were for the average relationship in each industry of total GDP add to gross revenue. Indirect GDP – in effect the contribution of Australian firms providing intermediate inputs to the MedTech activities of firms involved directly in the MedTech industry – was calculated as the difference between total GDP (derived using the input output tables) and direct GDP (derived from the survey).

Input-Output tables were similarly used to calculate indirect employment. Employment per output ratios were calculated using employment figures from ABS data.[115] This was multiplied by total revenue to estimate total headcount. Similarly to the methodology above, the indirect headcount was then calculated by the difference between total headcount (derived using the input output tables) and direct headcount (derived from the survey).

The key limitation here was that there was no one ANZSIC code that directly related to MedTech and ANZSIC2401 was used as a proxy for the above analysis as it was the industry code that the majority of the activity would be attributed to.

Geographical Segmentation

Survey respondents were asked to provide a breakdown of their total MedTech headcount on a state level. The high response rate with regards to this provided robust ratios which were used to calculate metrics such as gross revenue, GDP and total headcount at a geographical level. The key limitation here was that the survey was very heavily skewed towards New South Wales, resulting in states such as Victoria being under-estimated, as per other data sources.

[114] 5209.0.55.001 - Australian National Accounts: Input-Output Tables, 2019-20. Also see *Information Paper Australian National Accounts Introduction to Input-Output Multipliers*: *Catalogue No. 5246*

[115] 6291.0.55.001 Labour Force, Australia, Detailed - Table 06. Employed persons by Industry sub-division of main job (ANZSIC) and Sex

Appendix B Supporting data and tables

Table 11 | Therapeutic Goods Administration, classes of medical devices for regulation

Definition of TGA Device Classes:[116]		
Risk	**Classification(s)**	**Examples**
Low	Class I	• Surgical retractors • Tongue depressors
Low to Medium	Class Is - supplied sterile Class Im - with a measuring function Class IIa	• Sterile surgical gloves, hypodermic needles, suction unit • Medicine cup with specific units of measurement • Dental drills; ultrasound machines; digital or infrared thermometers
Medium to High	Class IIb	• Surgical lasers • Diagnostic X-ray • Lung ventilator • Blood bags • Condoms
High	Class III	• Prosthetic heart valves • Absorbable surgical sutures • Hip prostheses (for example, replacement of hip joint) • Pacemakers
High	AIMD (Active Implantable Medical Devices)	• Implantable defibrillator

Table 12 | Therapeutic Goods Administration, In Vitro Diagnostic regulatory classes

Definition of TGA IVD medical device classes: [117]		
Class	**Risk level/description**	**Examples**
Class 1 IVD	No public health risk or low personal risk	• Sample collection container • Microbiological culture media
Class 2 IVD	Low public health risk or moderate personal risk	• Pregnancy and fertility self-testing kits • Cholesterol test
Class 3 IVD	Moderate public health risk or high personal risk	• Tests to detect a sexually transmitted disease (e.g., chlamydia, gonorrhoea) • Human genetic tests
Class 4 IVD	High public health risk	• Blood donor screening tests for HIV • Test for Ebola

[116] Medical devices overview | Therapeutic Goods Administration (TGA)
[117] Overview of medical devices and IVD regulation | Therapeutic Goods Administration (TGA)

Table 13 | Investment in MedTech programs and grants details

Name of program	Location (state info /federal)	Description	Recent Funding AUD$
AusBiotech	Federal	Not-for-profit industry group providing representation and services to promote global growth of Australia's life sciences industry	
MTPConnect	Federal	Not-for-profit organisation aiming to accelerate growth in the medical technology, biotechnology and pharmaceutical sectors in Australia	
BridgeTech	Federal	Development program training researchers and entrepreneurs on navigating the commercialisation pathway of new medical technologies	
Clinical Translation and Commercialisation MedTech Program	Federal	Nurturing medical device projects with commercial potential and supporting their translation through early clinical trials	$19.75m
BioMedTech Horizons Program	Federal	Initiative supporting the commercial development of biomedical and medical technologies	$45m
BioMedical Translation Bridge	Federal	Funds early-stage health and medical research to reach proof-of-concept with the potential to attract further capital	$22.3m
Growth Centre Project Fund	Federal	Department of Industry, Science and Resources. - funding support	$15.6m
Targeted Translation Research Accelerator	Federal	Research program targeting diabetes and cardiovascular disease, establishing research centres, funding program and promotion of commercial translation of devices etc.	$47m
Researcher Exchange and Development within Industry	Federal	Initiative focused on improving workforce skills and driving jobs growth. Led to 46 training programs and 7 industry fellowships	$32m
National and Medical Research Council Centres of Research Excellence	Federal	Scheme to promote medical research, build capacity in research workforce and provide collaboration between teams	
Australian National Fabrication Facility	Federal	Supports research, development and commercialisation potential by providing access to micro and nanofabrication tools	
Medical Research Future Fund	Federal	Long-term investment supporting health and medical research	$20bn
Commonwealth Scientific and Industrial Research Organisation	Federal	Government agency driving innovation	
Modern Manufacturing Initiative (MMI)	Federal	Grant for manufacturers in Priority Sectors which includes Medical Products	$1.3bn
Australian MedTech Manufacturing Centre	Victoria	Initiative supporting growth of MedTech manufacturing, supporting procurement opportunities and strengthening capabilities	$20m
Future Industries Sector Fund	Victoria	Grant funding for sectors that have potential to drive job growth including MedTech industry	$200m
MedTech Manufacturing Capability Program	Victoria	Grant funding to assist MedTech manufacturers to expand production and connect with suppliers	$3.2m
LaunchVic	Victoria	Established by Victorian government to fuel start-ups in all high growth sectors including MedTech	
Medical Device Prototyping and Scale-Up Facility at RMIT	Victoria	Medical research and device translation lab developing and commercialising medical devices	$16.7m

Name of program	Location (state info /federal)	Description	Recent Funding AUD$
Breakthrough Victoria fund	Victoria	Independent company set up by Victorian government to support innovation in emerging industries including MedTech	$2bn
Victorian Connected Health Innovation and Commercialisation Centre	Victoria	Centre supporting MedTech manufacturers by connecting them with healthcare professionals, innovators and investors	$2.4m
Victorian Innovation Hub	Victoria	Brings together start-ups from growing sectors including MedTech	
Medical Devices Fund	New South Wales	Investing in the development and commercialisation of medical devices and related technologies in NSW	$8m per year
TechVouchers Program	New South Wales	Program driving opportunities between SMEs and public sector research organisations	$15k Voucher
Advanced Manufacturing Research Facility	New South Wales	Research facility connecting NSW manufacturers with newest technology and research in electronics and manufacturing	$260m
Sydney Biomedical Accelerator	New South Wales	Proposed research complex focussing on high growth areas in healthcare including medical device development	$478m
WA Manufacturing Voucher Program	Western Australia	Funding to support medical products manufacturing	$450k
Medical and Health Research Infrastructure Fund (MHRIF)	Western Australia	Scheme supporting medical and health researchers with funding for indirect costs of research	$9.2m
Future Health Research and Innovation Fund	Western Australia	Fund driving health and medical research, innovation and commercialisation	
WA Life Sciences Innovation Hub	Western Australia	Hub delivering programs to connect innovation community, attract investment and foster commercialisation	
BioPark Australia	Queensland	Life and medical science hub promoting industries including MedTech	
Advance Queensland Funding Scheme	Queensland	Government initiative to support QLD scientists, researchers, innovators and businesses	$755m
Herston Health Precinct	Queensland	Research institute promoting health innovation, education, research, training and clinical care	
South Australian Health and Medical Research Institute	South Australia	Health and medical research institute	$200m
Medical Device Partnering Program	South Australia	Facilitates collaboration between researchers, industry and other stakeholders with research projects to demonstrate proof of concept	$150k

Appendix C Complementary Report Handouts

HEALTH AND POPULATION OUTCOMES

The MedTech sector supports the healthcare workforce to achieve better patient outcomes

Challenge: Australia is facing a healthcare workforce shortage

How MedTech helps: The MedTech industry is helping to manage the growing demand for cardiac support services

Australia's healthcare workers often need complex and technical skillsets. There are ongoing challenges in finding enough of the right people. A stretched healthcare system means patients face longer wait times and reduced services. These stresses are expected to increase as demand for health care increases because of the ageing population.

What is MedTech?

Medical Technology (MedTech) supports patients and clinicians in providing medical care or monitoring health. MedTech covers a wide range of technologies such as diagnostic machines, implantable devices, assistive technologies, surgical tools, consumables and software.

The MedTech sector is working in partnership with Australia's health care services to provide the personnel and technical skills required to address some of these ongoing challenges.

of MedTech companies are providing **education and technical support**.[1]

The MedTech sector is helping to manage the growing demand for cardiac support services

The MedTech sector is increasingly supporting the treatment of cardiovascular disease by servicing cardiac implantable electronic devices such as pacemakers, implantable cardioverter-defibrillators and implantable loop recorders. These devices need ongoing optimisation and monitoring.

Cardiac technicians ensure the device is operating properly from the time of implant to device expiry. They use specialist equipment to provide data for cardiologists and help review diagnostic information.

Cardiovascular disease is the **3rd largest burden** of disease **in Australia** and accounts for **1 in 4** of annual deaths.[2]

[1] "Value of MedTech Report"
[2] Australian Institute of Health and Welfare, Australian Burden of Disease Study 2023

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Australia is currently facing a shortage of cardiac technicians. MedTech companies are helping fill the workforce shortage by offering their own cardiac services alongside their implantable devices. These 'industry-employed cardiac technicians' perform 56% of cardiac support servicing, mainly in private settings.

Demand for CIEDs has increased **7%** each year

56% of cardiac services are **supplied by MedTech**

Medtronic is a MedTech firm offering highly trained cardiac technicians to support their implantable devices. They travel to rural and remote clinics, MRI centres and emergency departments, giving around-the-clock support to private patients – on demand, universal, at no cost to patient, regardless of where they live. Medtronic is just one company providing these services. Others include Abbott, Boston Scientific, Biotronik and Microport.

Medtronic

MedTech is enabling patients to have access to high quality services and care

MedTech innovation and servicing support for implantable devices enable clinicians to improve patient outcomes. Examples include better targeted cardiac pacing algorithms, improved battery life leading to fewer replacement devices and remote monitoring enabling faster intervention when issues arise.

Patients benefit by[1]:

- **Better quality of life**
- **Fewer adverse events**
- **Less time in hospital**
- **Reduced device replacements**

The MedTech sector is providing an essential workforce for the care of patients

The MedTech sector is helping to manage the burden of cardiovascular disease by providing extra support services. This alleviates pressure on the resources of the healthcare system. This is just one example of a broader integration of MedTech in supporting the healthcare workforce to improve patient outcomes.

For more information on MedTech, Health and Population Outcomes see: "Value of MedTech Report"

[1] Cardiac Implantable Electronic Device (CIED) service valuation, KPMG, 2021

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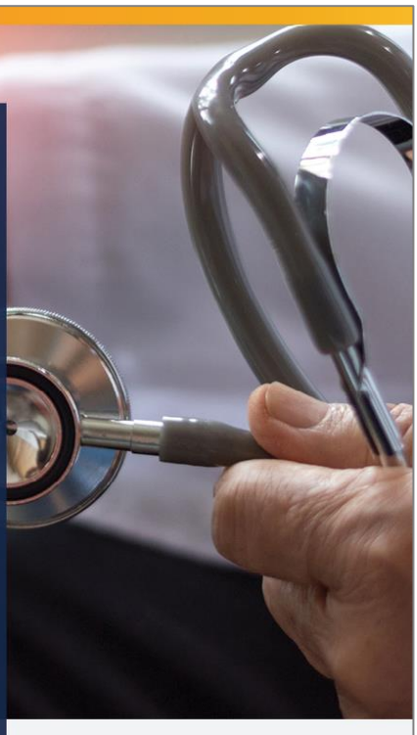

PATIENT OUTCOMES

MedTech innovation is improving patient outcomes

Challenge: Australia is facing challenges in treating chronic disease

How MedTech helps: MedTech is providing safer and more effective options for cardiovascular disease

Australia's healthcare system faces challenges in providing quality care cost-effectively. The average cost of a patient's stay in a major public hospital is around $5,000. MedTech innovations can improve patients' outcomes and reduce costs for the healthcare system. Quicker recovery helps patients to return to their daily life sooner and frees up hospital resources for other patients.

What is MedTech?

Medical Technology (MedTech) supports patients and clinicians in providing medical care or monitoring health. MedTech covers a wide range of technologies such as diagnostic machines, implantable devices, assistive technologies, surgical tools, consumables and software.

MedTech innovation helps Australia to provide quality health care for patients more cost effectively.

MedTech innovation offers alternatives to invasive open-heart surgery

Treatment of aortic stenosis has historically required open-heart surgery. This is risky, invasive and expensive, requiring a hospital stay of up to a week.

MedTech companies have been working to develop alternative procedures that improve outcomes for patients with aortic stenosis. A new therapy called transcatheter aortic valve implantation (TAVI) has emerged as a low-risk alternative to open-heart surgery.

TAVI is a minimally invasive procedure. Edwards Lifesciences and Medtronic are some of the MedTech firms improving technologies for transcatheter aortic valve implantation (TAVI), to establish it as a strong alternative to open heart surgery. Recent developments in TAVI therapies are providing better outcomes than surgery for patients with severe aortic stenosis.

MedTech can reduce the burden of heart valve disease

The burden of Aortic Stenosis heart disease is growing in Australia. Aortic Stenosis damages the aortic valve, one of 4 valves in the heart that work together to keep blood flowing. It is common in elderly people. Its prevalence is predicted to grow as the population ages and diagnostic methods improve.

97,000 Australians are living with severe aortic stenosis

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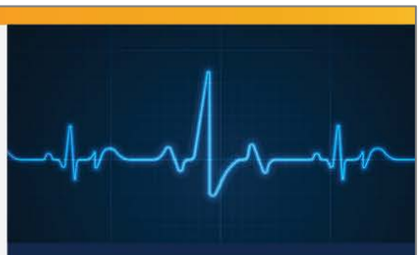
MedTech innovations help patients to recover faster with minimally invasive procedures

TAVI can offer immediate benefits, depending on the patient, such as increased energy levels, breathing ability and less pain. Since the replacement valve is placed using minimally invasive techniques, patients experience a much more rapid recovery than with open heart surgery. Earlier intervention with TAVI is expected to provide better long-term outcomes, including a better quality of life and increased life expectancy.

TAVI reduces the strain on hospital resources due to its short procedure length. TAVI requires minimal hospital resourcing than open heart surgery, freeing up hospital operating theatres and staff for more complex procedures.

1 hour procedure
4-48 hours patients are walking after the operation
3 day average hospital stay



MedTech is giving patients a **wider range of treatment options**.

"My TAVI procedure was painless; I had no idea what had been done; there was no pain or after-effects; the only effect was that I had never felt better in the previous 25 years."

Les Terrans, an 85-year-old patient

Cost of heart valve disease in those aged 65+ to the community and economy

The value of unpaid services provided by older Australians should be recognised. Their contribution to society through non-market activities, including volunteering, childcare and informal carer support helps to support the nation's economy. Offering TAVI as an effective intervention to heart disease can not only benefit patients on an individual level, but also more broadly to society.

A recent study found that TAVI is cost-effective compared with open heart surgery from the perspective of the Australian health care system. The higher procedural costs for TAVI compared to heart surgery are offset by a shorter length of hospitalisation and lower complication costs.

TAVI was estimated to reduce lifetime costs by **US$10,000**[1]

Offering TAVI to people aged over 65+ could save **AUD$117 million** a year[2]

MedTech innovation is improving patient health and recovery

The use of medical technologies has potential to be a net benefit to patients and to the healthcare system by improving patient outcomes and recovery compared to current practice. TAVI is but one example of MedTech innovation that is helping improve patient outcomes while also reducing the burden on Australia's healthcare system.

For more information on MedTech and Patient Outcomes see: "Value of MedTech Report"

[1] Baron SJ, Wang K, House JA, Magnuson EA, Reynolds M, Makkar R,et al. Cost-effectiveness of transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at intermediate risk. Circulation. 2019;139(7):877-88

[2] https://baker.edu.au/impact/advocacy/valve-disease

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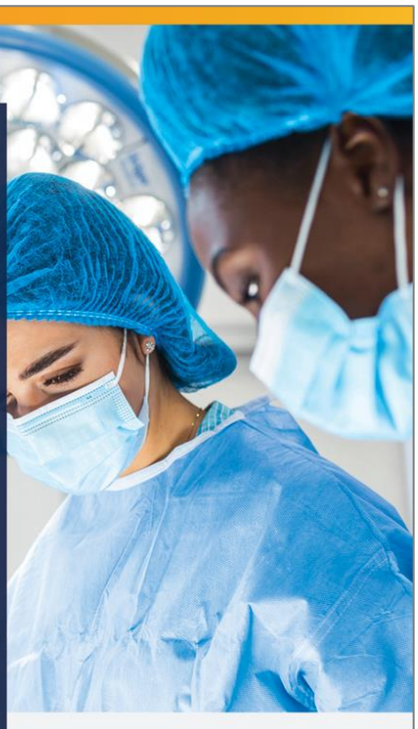


WORKFORCE AND OPERATIONAL PRODUCTIVITY

MedTech is upskilling the surgical workforce

Challenge: The healthcare workforce faces the need for constant upskilling

How MedTech helps: MedTech is providing new ways for surgeons to train for complex surgeries

The healthcare workforce deals with complex challenges and the need to maintain standards in line with emerging best practise. MedTech plays an important role in the training of healthcare workers, to ensure they are up to date with the newest devices, procedures, and medical technologies.

What is MedTech?

Medical Technology (MedTech) supports patients and clinicians in providing medical care or monitoring health. MedTech covers a wide range of technologies such as diagnostic machines, implantable devices, assistive technologies, surgical tools, consumables and software.

Collaborations between universities, hospitals and other industry partners can help upskill the health workforce.

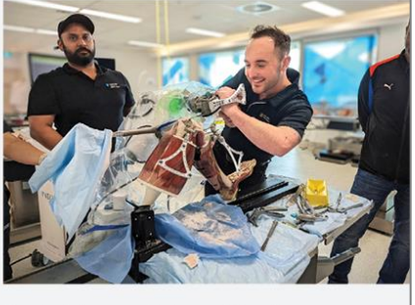
MedTech collaborations with industry, start-ups and academia is creating surgical training products

Collaborations between universities, hospitals and other industry partners are common in the MedTech sector. They are essential to upskill the industry and develop capability in the sector.

One example of a valuable collaboration is that between MedTech company Johnson & Johnson, South Australian biotechnology start-up Fusetec, and Flinders University. This collaboration has revolutionised training of surgeons.

Surgical training products enable surgeons to refine their skills before going into theatre. In this collaboration the partners have designed 3D surgical training models for improved knee, hip and spine surgeries.

The bio-models are made from synthetic replicate lifelike bone, skin and muscle. This gives trainee surgeons predictable and repeated training experiences.



Training Johnson and Johnson staff on the bio-models at Fusetecs' Advanced Surgical Training Clinic

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All parties in the collaboration played a key role to product development

fusetec	designed and manufactured the bio-model.
Johnson & Johnson	provided access to global leaders, databases, sponsorship and commercialisation advice.
Flinders University	provided research and data to validate the models' functionality.

MedTech and Australian surgeries at a glance[1]

128,083 hip, knee, shoulder and other joint replacements in 2022

622,988 elective surgeries 2021/22

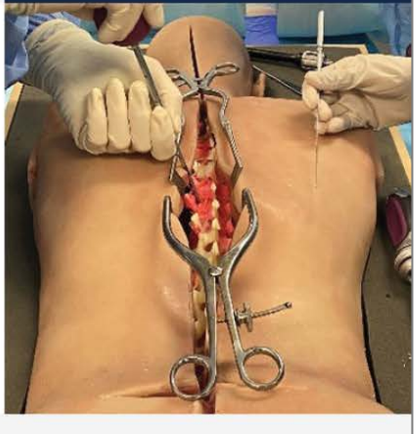
32% of surveyed MedTech companies **collaborate on clinician fellowships**

65% of surveyed MedTech companies **collaborate with Universities** or research institutes

MedTech is helping surgeons to be better prepared for complex surgeries

The outcomes of this project have a wide range of benefits. The bio-model can safely train surgeons in an environment free from potentially harmful bacteria, as it reduces the need for in-theatre learning or the use of expensive cadavers.

There are many benefits for patients. Surgeons can practice on realistic models, ensuring that patients receive the best trained surgeons when it comes to their own surgery.



Spine training using the biomodel

Partnerships can create new jobs and strengthen local economies

Fusetec have established a unique 3D Advanced Surgical Training Clinic in South Australia to train surgeons and other medical personnel with their bio-model. Fusetec expects that this precinct will create 157 new direct jobs in areas like research, production and administration, as well as potentially 800 indirect jobs in South Australia's supply chain, medical tourism and higher education industries.

The clinic is expected to attract surgeons and medical staff from around the world to practise and upskill on rare and complex pathologies.

MedTech collaborations bring value to Australia's healthcare system and patients

This collaboration brings value to Australia's hospital workforce and surgical staff, to patients and to the broader economy. This example shows how all MedTech companies can collaborate, ranging from start-ups to international corporations. These collaborations help train the workforce and develop the local innovation sector.

For more information on MedTech and the healthcare workforce see: "Value of MedTech Report"

[1] "Value of MedTech Report"

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MANUFACTURING

MedTech is advancing Australian Manufacturing

Challenge: Australia has a strong innovation pipeline that must have global reach to realise its tremendous value

How MedTech helps: MedTech manufacturing enables Australia's innovative MedTech ideas to reach the world

There is a stream of MedTech ideas being developed in Australia with the number of MedTech patents growing at 7% per year on average between 2010 and 2020. The acceleration of domestic product development during the COVID-19 pandemic shined a light on the innovation, capacity, and flexibility of the Australian MedTech sector to respond to emerging global health needs.

What is MedTech?

Medical Technology (MedTech) supports patients and clinicians in providing medical care or monitoring health. MedTech covers a wide range of technologies such as diagnostic machines, implantable devices, assistive technologies, surgical tools, consumables and software.

MedTech manufacturing helps to retain the value of Australian innovation onshore and is important for ensuring sovereign capability.

Australian MedTech manufacturing is helping to address some of the world's most pressing health challenges

Routine and pandemic vaccinations play an important role in protecting the health of communities around the globe. However, the benefits of vaccination are compromised by several factors, including a hesitancy around needle and syringe which can be as high as 25% in some populations. Complexities including cold-chain storage and skilled administration also threaten efficient and effective distribution to many communities.

Vaxxas is an Australian-based biotechnology company developing a vaccine platform technology that could overcome these and other challenges in the vaccination space, resulting in increased equitable access across the globe. More specifically Vaxxas' high-density microarray patch (HD-MAP), covered by thousands of tiny vaccine-coated microprojections, has been designed to deliver a vaccine directly to the abundant amount of immune cells located just under the skin's surface, often resulting in a faster and stronger immune response.

Australian MedTech manufacturing at a glance[1]

4,000+ MedTech manufacturing jobs in Australia

850+ registered Australian MedTech manufacturers

71% of MedTech survey respondents had local product development

[1] "Value of MedTech Report"

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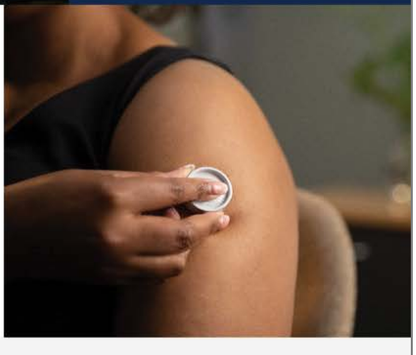
Local MedTech manufacturing has potential for global reach

Vaxxas will manufacture its vaccination technology for late stage clinical trials and early commercial purposes in a new state-of-the-art biomedical facility in Brisbane, Queensland. The facility will also serve as the company's global headquarters.



A recent study published in Human Vaccines & Immunotherapeutics[1] demonstrates for the first-time the potential of Vaxxas' device to deliver vaccines effectively by either a trained professional or self-administration[1]

This promising initial validation of the technology's potential for self- and lower-skilled administration could be impactful in pandemic response and increase access to vaccination in hard-to-reach areas, particularly lower- and middle-income countries.

vaxxas

MedTech manufacturing retains value in Australia

Traditionally, MedTech manufacturing has had to overcome regulatory and financial challenges to ensure patient safety and commercial viability. Once these challenges are met there is potential for large benefits here in Australia, and globally, by building this manufacturing capacity locally.

Vaxxas has received significant support from the Queensland Government by way of funding for its new facility and from the Australian Government through its Modern Manufacturing Initiative grants to support the build of specialised biomedical manufacturing and production infrastructure.

The company has a growing workforce of 130 people, many of whom are highly specialised and experienced engineering and science experts. Investing in local manufacturing has the potential to help secure the ongoing growth and development of the MedTech sector here in Australia for years to come.

$90+ million estimated contribution by Vaxxas to Queensland economy since 2011

$12+ million from Australian Government in Modern Manufacturing Initiative grants for specialised manufacturing infrastructure

Australia benefits from MedTech manufacturing

The MedTech sector has a sophisticated and global market which relies on diverse supply chains. Australian MedTech manufacturing is already providing benefits to patients and to the economy. MedTech development and manufacturing has many safeguards in place. Once regulatory requirements are met there is potential for accessing markets globally.

For more information on MedTech and manufacturing see: "Value of MedTech Report"

[1] Baker et al. 2023, Human Vaccines & Immunotherapeutics, Evaluation of the self-administration potential of high-density microarray patches to human skin: A preliminary study

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CLINICAL TRIALS AND INNOVATION

Australian clinical trials are supporting MedTech innovation

Challenge: MedTech innovations require extensive validation before they can be used in patient

How MedTech helps: The Australian healthcare sector is supporting the development of new MedTech

Clinical trials are studies that test how well new medical treatments work in patients and healthy volunteers. Regulators in Australia and around the world require clinical evidence of MedTech safety and effectiveness before it reaches the market. Australia has growing clinical trial sector, with a strong global reputation.

The clinical trial sector is supporting Australian researchers and start-ups to develop value in Australia, whilst providing patients with the latest advances in care.

Australian companies are developing innovations across many types of medical fields and technologies.

Early detection for postpartum haemorrhage reduces patient complications

Postpartum haemorrhage – bleeding after giving birth – is the leading cause of preventable maternal death worldwide. Current diagnosis methods give doctors only minutes to administer life-saving treatments. Sydney medical device company Baymatob have developed a world-first device intended to predict if a woman is at risk of postpartum haemorrhage before she gives birth.

Early clinical data indicates that the device can provide at least one hour of warning prior to birth for over 80% of postpartum haemorrhages.

Knowing who is at higher risk will help doctors to prepare better and provide prompt treatment
- Pilot study Clinical Investigators.

Australian MedTech is developing safer care for critically ill children

Central venous catheters are used in intensive care units to provide drugs, fluids or blood. There are significant challenges in using them with children due to their size and mobility. Melbourne start-up Navi Medical Technologies are developing a device to safely place and monitor these catheters in paediatric patients. They are performing clinical research which demonstrated the technology is able to achieve at least 90% accuracy in positioning central venous catheters. Navi is working to perform more validation trials to secure international approvals.

The device will enable safer care for critically ill children by shortening procedure times and reducing complications

Clinical trials at a glance[1]

$1bn Australian government invests per year in health and medical research

56% of MedTech companies surveyed have clinical trials underway

23,000+ of MedTech clinical trials in Australia since 2002

[1] "Value of MedTech Report"

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MedTech innovation improves of brain disorders

Current diagnostic practises in neurology, psychology and psychiatry lack objective technology for diagnosing brain disorders. This can lead to misdiagnosis and delayed treatment for patients. MedTech innovation is helping to improve this situation.

NeuralDx Ltd is a Victorian based start-up commercialising a Monash University research innovation that measures a unique signal of deep brain function from structures directly associated with the control of emotions, behaviours, movement and cognition. The device has the potential to objectively diagnose different mental and neurological disorders. NeuralDx is pursuing further clinical validation and regulatory approvals in Australia.

NeuraLDx has trialled the devices in **600+** patients

NeuralDx

Tailored prosthesis promote better outcomes of surgery

Medical prostheses often require tailoring to the patient to be effective. MAXONIQ is a Victorian based manufacturing company that develops custom-made surgical products for patients undergoing jaw surgery. This device was created through a collaboration between MAXONIQ, the University of Melbourne and industry partners. Their patient-specific 3D printed titanium mandibular prosthesis is designed to replicate the patient's jawbone, providing restored pain-free function and better quality of life. The personalised jaw joint and is expected to help more patients once MAXONIQ finalises FDA (US) and MDR (Europe) approvals.

MAXONIQ

Prosthesis implanted in a patient

Implanted in **260+** patients

Cancer detection technology is reducing repeated breast cancer surgeries

One in 7 women are diagnosed with breast cancer in their lifetime. Sometimes during surgery, part of the tumour gets left behind. As a result, up to a third of patients who have breast-conserving surgery, called a lumpectomy, require a second surgery. This can cause increased psychological trauma for patients and increased risk of complications.

Perth based start-up, OncoRes Medical, are developing a novel imaging device to help surgeons detect the difference between cancerous and healthy tissue. OncoRes has its origins at the University of Western Australia, and the Western Australian Department of Health. Their handheld probe uses Quantitative Micro-Elastography technology, guiding surgeons with real-time decision-making to help remove all the cancer the first time.

The device has demonstrated high diagnostic accuracy (96%) in detecting cancer in benchtop testing and a first in human proof of concept study has been done with 21 patients. A series of clinical trials are ongoing to support the device receiving regulatory approvals for more widespread clinical use.

1 in 3 breast cancer patients having lumpectomy require a second surgery

50+ patients are in clinical trials

Clinical trials in Australia enable innovative companies to improve patient care and develop the local MedTech sector

Australian start-ups, research institutions and the healthcare system are working together to improve patient outcomes through clinical trials. They are providing new types of ways to diagnose, monitor and treat disease. These innovations are supporting the development of best-in-class clinical care. Clinical trials in Australia are providing the evidence for local MedTech innovators to continue their progression to monitoring and treating patients in the global market. MedTech companies are delivering new therapies and growing thanks to a robust clinical trial sector.

For more information on MedTech and innovation see: "Value of MedTech Report"

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A bigger idea of success

Nous Group is an international management consultancy operating across Australia, New Zealand, the United Kingdom, Ireland and Canada. We are inspired and determined to improve people's lives in significant ways. When our strengths complement yours and we think big together, we can transform businesses, governments, and communities. We realise a bigger idea of success.