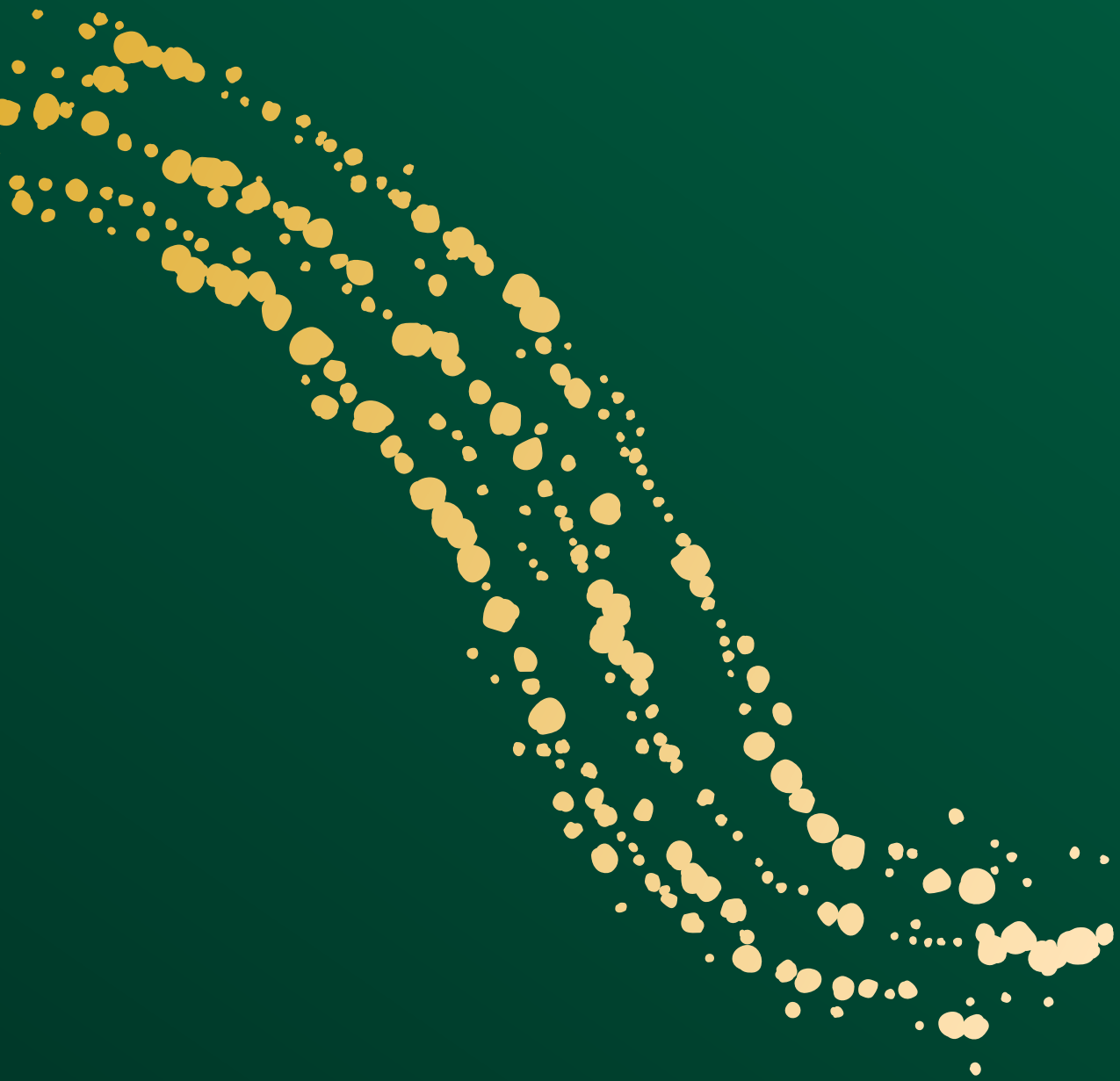
Australian Government
Australian Trade and Investment Commission

Medical Technology, Devices and Diagnostics

Industry Capability Report



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Acknowledgement of Country

In the spirit of reconciliation we acknowledge the Traditional Custodians of Country throughout Australia and their connections to land, sea and community. We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today.

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About us

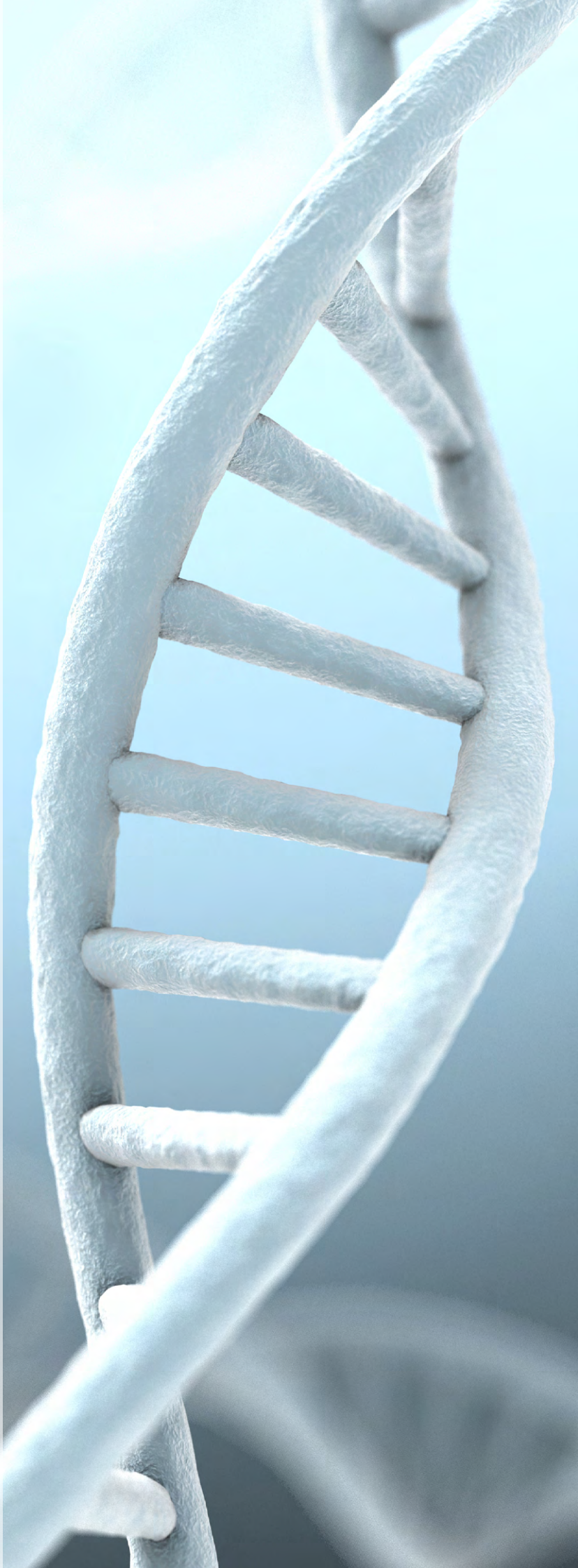
The Australian Trade and Investment Commission (Austrade) is Australia's national trade and investment promotion agency.

Austrade connects global businesses to Australian opportunities, helping foreign investors and buyers do business with Australia.

We help companies around the world source Australian goods and services for their global supply chains, as well as identify and capitalise on investment opportunities in Australia. For export needs, we can link Australian businesses to global markets.

We provide local and industry insights and make it easier for businesses to go global.

To discover how we can help you and your business, please click here.



Introduction

Australia has a long and distinguished track record of health and medical research excellence. Today, this continues with breakthrough discoveries, advancement of technologies into clinical trials and improvements in clinical practice.

Australian medical technology (MedTech) is an integral part of healthcare provision and is at the forefront of global innovation. MedTech supports patients and clinicians in providing medical care or monitoring of health through a range of technologies. These technologies include diagnostic machines, implantable devices, assistive technologies, surgical tools, consumables and software.

Australian MedTech companies are making a global impact. Solutions such as the Cochlear implant (bionic ear) and Resmed's continuous positive airway pressure (CPAP) devices for sleep apnoea are just two Australian innovations that have transformed the lives of people around the world.

The medical devices and diagnostics industry in Australia is developing rapidly. There is strong growth in digital health technologies and devices that utilise advanced materials, robotics, imaging, information technology (IT), design, and adaptive Artificial Intelligence (AI) diagnostic and therapeutic solutions. The industry is also evolving with the convergence of technology and skills from aligned innovation sectors, such as Information and Communications Technology (ICT), medical research and advanced materials.

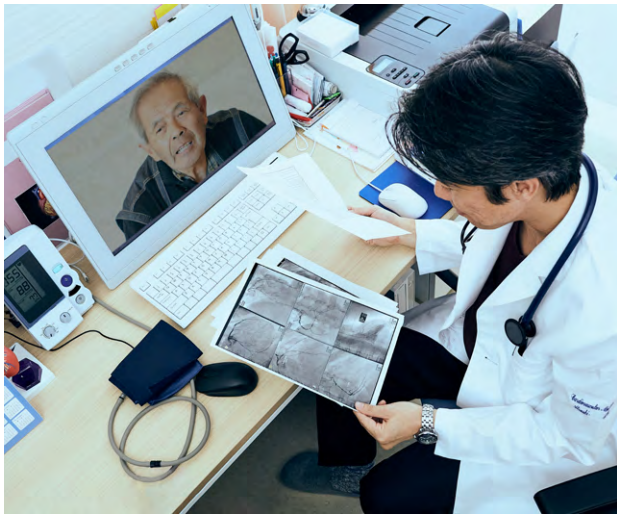
The health and medical sector in Australia benefit from a strong regulatory and funding system. This system includes a competitive research and development (R&D) tax incentive scheme and a world-class healthcare system, both of which foster favourable environment for innovation, investment and collaboration.

Australian MedTech companies are leading the way with pioneering breakthroughs that are transforming healthcare worldwide. They provide innovative solutions, including:

- Digital health technologies such as remote patient monitoring;
- Digital therapeutics providing real-time data and personalised care revolutionising the monitoring and management of health issues;
- X-ray machines and magnetic resonance imaging scanners aid cancer detection;
- Implantable devices such as pacemakers; and,
- Personal devices to manage diabetes.

This Report provides an overview of Australian capability in medical technologies and includes examples of some of the many companies with specialist expertise. These companies design, manufacture, and test tools and instruments, apparatus, and products used for diagnosis, prevention, monitoring and treatment of health issues worldwide. Many of these devices must receive approval from a regulatory body. In Australia, this body is the Therapeutic Goods Administration (TGA).

For tailored advice and information on connecting with and partnering in the Australian medical devices and diagnostics industry, contact your local Austrade representative.



Remote patient monitoring

Industry overview

Australia's MedTech ecosystem is characterised by innovative research, collaboration, and a strong commitment to enhancing healthcare outcomes. With a vast network of universities, research institutions, and entrepreneurial startups, we provide an environment that fosters the development of advanced medical technologies. Global innovators like Cochlear and ResMed demonstrate the high level of innovation and quality that Australian MedTech companies can offer.

Comprising of over 850 companies generating total revenue of A$11.4 billion, Australia's medical devices industry is exporting over $A2 billion each year since 2013. With a highly skilled integrated workforce, Australia employs over 17,000 people within MedTech companies and 34,000 people in supporting industries.

The Australian medical device, biotechnology, and pharmaceutical industries are distinct yet closely connected. They are characterised by strong interdependencies and a flow of ideas between medical research organisations, traditional and advanced manufacturing and the local healthcare system.

In Australia, the MedTech sector includes a significant number of small to medium-sized enterprises, which account for approximately 54 percent of the industry. In contrast, around 30-40 percent consists of global multinational companies and their subsidiaries. These companies are enhancing patient outcomes and improving efficiencies in healthcare systems worldwide, as nearly all of the medical devices and diagnostics manufactured are exported.

Market position

In 2023, the global advanced medical technologies market, including medical devices, medical imaging and patient monitoring, was valued at US$410.8 billion. Australia contributed US$6.5 billion, accounting for 1.6 percent of the total. Currently, there are 80 medical devices and diagnostics companies listed on the Australian Securities Exchange (ASX) with a total market share of US$181 Billion.

Australia's distinctive approach to problem-solving leads to products that foster the growth of innovative subsectors, including:

- Software-as-a-Medical-Device *(SaMD) (4D Medical)*
- AI applications *(TruScreen)*
- Robotics *(Convergence Medical)*
- Wrap-around digital and software services *(PropelHealthAI)*
- Sustainability, low-waste innovations *(180 Waste Group)*

Australia's MedTech and diagnostics industry benefits from a dynamic and globally competitive Precision Engineering Industry (PEI). The PEI encompasses the research, design, development, manufacture and verification of high-accuracy components, along with high-precision machines and systems.

Innovative niche products developed in Australia

3D customised titanium implants

Non-invasive blood glucose monitoring systems

Continuous positive airway pressure (CPAP) devices for sleep apnoea

Long-wearing night and day contact lenses

Melanoma detection devices

Diagnostic technologies for sleep disorders, neurophysiology and cardiology.

Export markets and key destinations

The top 10 destinations for Australian medical devices and diagnostics exports were the United States of America; New Zealand; the Netherlands; Germany; Japan; China; Singapore; India; Panama; and the Republic of Korea.

19.7% export growth in 2024

A **$12.8bn** projected 2028 export market value

7.0% projected compounded annual growth rate through 2028

Notable Australian innovations

Australia's MedTech sector has a strong history of delivering innovations that have both clinical and commercial significance. From initial biomedical breakthroughs to the latest digital technologies, these advancements have consistently addressed unmet needs, resulting in improved patient care and success in global markets. Leading Australian exporters such as Cochlear, Anatomics, and Nanosonics represent Australia's capability for innovation and are well-positioned to continue to provide solutions internationally for years to come.

1920 — 1930 — 1940 — 1950 — 1960 — 1970

Humidicrib (late 1930s) was developed in response to the polio epidemic, improving outcomes for premature infants through better temperature regulation.

Ultrasound scanner (1961) introduced safe, non-invasive imaging, transforming obstetrics and diagnostic medicine.

Electronic heart pacemaker (1926) enabled the controlled regulation of heart rhythm, laying the foundation for modern cardiac care.

Cochlear **implant (1978)** restored hearing to people with profound deafness and created an entirely new treatment pathway.

BioPen (2013) allows surgeons to 3D-print living cells directly into damaged tissue during operations - Axcelda.

Nanopatch™ (2015) a needle-free vaccination, improving uptake and reducing waste, now commercialising with Vaxxas.

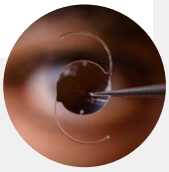
CPAP machine (1981) provided an effective treatment for sleep apnoea, improving sleep quality and reducing cardiovascular risk.

Spray-on skin (2005) allows rapid application of cultured skin cells, improving recovery outcomes for burns victims - Avita Medical.

Synchron **brain-computer interface (2016)** enables people with paralysis to control devices using thought, via a minimally invasive implant delivered through blood vessels.

1980 1990 2000 2010 2020 2030

Low-cost intraocular lens manufacturing (1990) improved global access to cataract surgery by reducing costs.

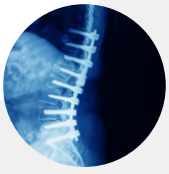


3D-printed titanium implants (2015) enable personalised bone reconstruction, improving surgical precision and outcomes. Anatomics and Additive Engineering.

AI diagnostic imaging (2024) will accelerate the interpretation of radiological scans, reducing diagnostic delays and supporting clinician workflow, provided by firms including 4D Medical, TruScreen and annalise.ai

Baby capsule (1984) was designed for vehicle use to improve infant safety during travel.

Additive Surgical **spinal implants (2020)** are 3D-printed titanium cages designed to enhance bone fusion and stability in spinal surgery.



Industry strengths

Australia has a well-established and internationally recognised medical technology, devices and diagnostics industry. The industry innovates and develops world-class MedTech solutions, supported by a dedicated ecosystem of stakeholders from research, industry, and government. This collaborative environment drives innovation and positions Australia as a leading destination for the development of globally impactful MedTech innovations.

Key strengths include:

- History of high-quality and pioneering MedTech development
- World-leading regulation and IP protections
- Competitive supporting industries
- Advanced industrial capabilities
- Global sector champions
- Strong investment trends
- Growing export opportunities
- Comprehensive health product design and prototyping capabilities

Australia's competitive advantage

Australia enables global partners to seamlessly advance innovations from the lab to manufacturing and clinical settings. Australian MedTech's competitive advantage is supported by:

- one of the largest healthcare markets in the Asia-Pacific region, with a sophisticated clinical environment; high standards of care; first-class clinical trials infrastructure and skills; and widespread use of high-end medical devices and diagnostics
- a robust regulatory environment with one of the most effective intellectual property (IP) rights protection systems in the world
- a competitive R&D tax incentive scheme that rewards investment in Australian research and development
- fast development cycles, fostered by a strong culture of collaboration and partnerships between the academic, research and corporate sectors
- a burgeoning national culture of innovation and entrepreneurship with matching government policy and program settings, that is fostering a strong small to medium enterprise (SME) and startup sector
- internationally recognised expertise in the design, development and manufacturing of medical devices, with the help of a strong and diverse manufacturing skills base and world-class infrastructure
- a strong Australian IT sector including world-class expertise in UX technologies, game design, bioinformatics, hardware and software development
- a highly skilled workforce and a globally competitive business environment
- an ideal market for prototyping and testing new medical products strong ties with the fast-growing Asia- Pacific region, supported by Free Trade Agreements.

Sophisticated public and private healthcare system

Australia has a world-class healthcare system that provides access to publicly subsidised services, pharmaceuticals, medical technologies and devices through various funding arrangements. In 2020-2021, approximately $220.9 billion was spent on health goods and services. In 2020-2021, Australians spent approximately $220.9 billion on health goods and services. Australia ranks sixth in the world with health expenditure of $8,617 per capita.

Key features of the Australian healthcare funding system include:

- universal access to benefits for medical services under the Medicare system
- eligibility for public hospital services, which is free at the point of service
- private health insurance, which largely funds private hospital activity.

The Australian Government offers subsidies for health care premiums through rebates, allowing insured patients to select treatment in either private or public hospitals. Over half of the Australian population, approximately 13.6 million people, is covered by private health insurance.

Australian MedTech workforce

Australia's MedTech workforce is growing due to a steady influx of local graduates in Science, Technology, Engineering, and Mathematics (STEM) from prestigious institutions worldwide. The roles available in the MedTech sector are diverse, including positions in marketing and sales, manufacturing, clinical trials, and supply chain and logistics. **Australian scientific institutions** rank among the top 1% in the world in 15 individual fields of research, including clinical medicine. This strong reputation, combined with Australia's excellent quality of life, helps us attract and retain skilled talent from around the world. Importantly, **this global workforce** enables Australia to develop MedTech solutions that address international health challenges, as graduates bring knowledge from their home countries and apply it within Australia's innovation ecosystem to create products suited to diverse global markets.

Agile, innovation-driven enterprises

The Australian medical device industry is primarily composed of SMEs. Approximately 41 percentof these companies employ fewer than 20 people, while 10 percent have more than 100 employees.

The Australian medical devices and diagnostics manufacturing sector is characterised by significant investment in R&D, strong protection of IP, and collaboration to foster innovation.

The industry plays a crucial role in addressing various challenges, such as an ageing population, an increased focus on wellness and preventative medicine, the emergence of new and chronic diseases. Additionally, the industry is responding to rising pressures on health systems, and growing lifestyle expectations.

For SMEs in this industry the typical path of entry into Global Value Chains often involve partnering with larger firms. Although SMEs face considerable challenges in funding the development of new devices, they continue to invest in new machinery, equipment and technology, as well as enhance management practices and engage in innovative marketing activities.

Excellence in research and development

Australia is home to Medical Research Institutes (MRIs) and universities backed by the Association of Australian Medical Research Institutes (AAMRI). The MRIs and the AAMRI are closely connected to industry and drive world-class MedTech innovation. Technology transfer offices at institutions similar to the University of Melbourne's Research, Innovation and Commercialisation (RIC) team and the University of New South Wales (UNSW) Founders act as fast-moving bridges between research and market. Notable Australian spinouts include Synchron, developing brain-computer interfaces based on University of Melbourne research, and Saluda Medical. This UNSW spinout is now delivering closed-loop spinal cord stimulation therapy.

55+ Medical Research Institutes

40+ Universities

Australia offers a variety of funding and government assistance opportunities for MedTech companies. Each state has initiatives aimed at supporting the growing medical device sector. Additionally, some local governments provide support programs to attract medical technology startups.

As global competition to attract clinical investigations increases, it is essential for Australia to remain competitive. As a preferred destination for conducting clinical investigations, Australia is renowned for its ability to solve cross-disciplinary problems.

This involves bringing together experts in computer science and mathematics to assist clinicians and medical researchers in addressing clinical needs. This collaborative approach has successfully fostered the convergence of healthcare and IT applications in areas such as urinary incontinence, cardiac monitoring and bone scaffolding replacement. These strengths also attract multinational companies like Cook Medical, GE Health, Medtronic, Fresenius Kabi and Baxter Healthcare to conduct R&D, as well as manufacturing, in Australia.

The clinical trials sector, particularly for medical devices, provides significant economic value to the country. In 2019, more than 1,800 clinical trials began, involving over 95,000 participants and contributing $1.4 billion to the Australian economy.

Major contract research organisations, including Novotech, Linear Clinical Research, and Emerald Clinical Trials, support both early- and late-phase trials. The Australian Clinical Trials Alliance (ACTA) plays a key role in national collaboration. Backed by a new $1.9 billion national research strategy announced in 2024, the sector continues to strengthen Australia's position as a launchpad for clinical validation and global expansion.

400+ MedTech clinical practice, trial, or research jobs

134 Medical Device trials are simultaneously ongoing*

40% of device trials are early stage or "first in human"**

*Indicative of sector capacity, based on MTAA data and estimates

**Based on MTAA data and estimates

Collaborating to find solutions

Collaboration intensity is a key indicator of both commercial and clinical impacts, and Australia recognises the importance of partnerships between industry and academia as a driver of innovation. New policies, programs and discussions are being implemented to enhance engagement rates, accelerate growth, and commercialise innovation.

Cameca Local Electrode Atom Probe, University of Sydney

While many companies specialise in one sub-field of medical devices, research conducted by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and Australian universities encompasses a broad range of topics. The advantages of collaboration, particularly in the fields of medical research and technologies space, are well-documented.

Australian R&D in medical devices and diagnostics involve numerous successful public-private partnerships. Examples of these collaborative efforts include:

Cooperative Research Centres (CRCs) is an Australian Government program designed to support industry-led collaborations between researchers, industry and the community. There are two CRCs currently working in advanced manufacturing and medical devices:

- **Digital Health Cooperative Research Centre (DHCRC)** is advancing digital health innovation by linking academia, industry and government to accelerate research implementation, enable effective use of data, connect care, empower the health workforce and support consumers to confidently be in control of their health and wellbeing.

- **Solutions for Manufacturing Advanced Regenerative Therapies CRC (SMART CRC)** is Australia's national centre for advancing regenerative therapy research, development, and manufacturing. Regenerative therapies include cell and gene therapies, tissue engineering solutions, and advanced medical devices, that enhance the body's ability to repair, regenerate, and even regrow tissues and organs, offering the potential to cure diseases rather than simply manage their symptoms.

Aikenhead Centre for Medical Discovery (ACMD) is a collaborative biomedical engineering centre accelerating the translation and commercialisation of research. This includes the delivery of much-needed, cutting-edge medical and healthcare solutions with a focus on MedTech, biotech and digital health.

Medical Devices Research Institute (MDRI) is an industry and research engagement program and an ideas incubator supporting early-stage innovation and technology development, from proof-of-concept and prototyping, to clinical evaluation and commercialisation planning.

Medical Devices Partnering Program (MDPP) fosters collaborations between researchers, industry, end-users and government to develop medical technologies with global market potential, and provides a mechanism to develop proof of concept, prototyping, clinical evaluation and commercialisation planning.

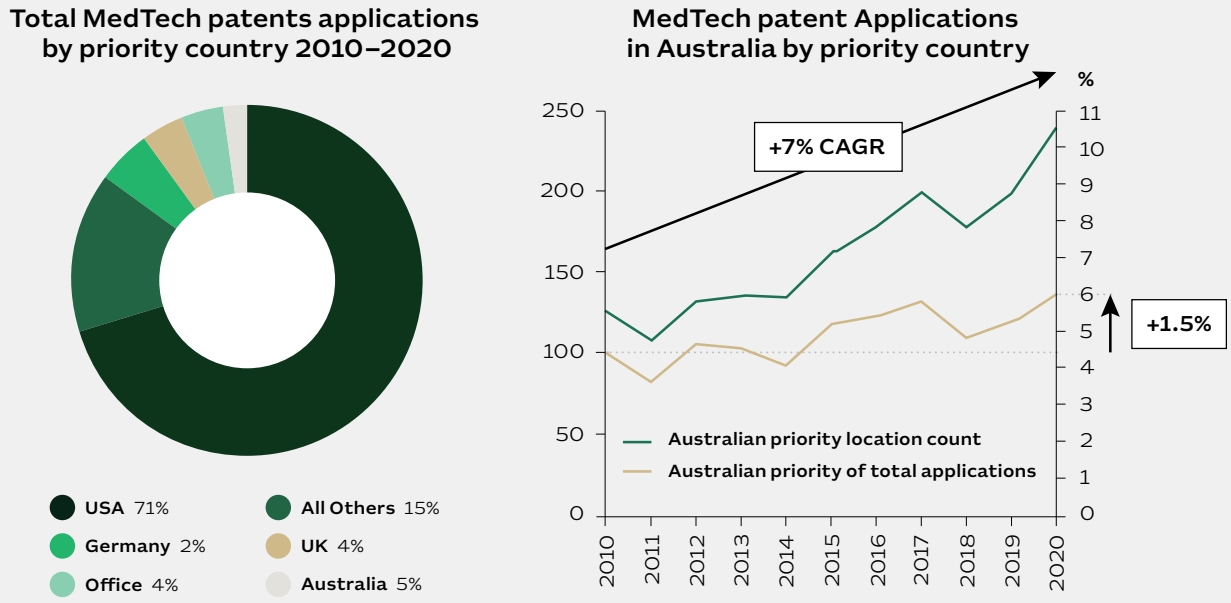
MTPConnect is Australia's Life Sciences Innovation Accelerator – an independent, not-for-profit organisation established by the Australian Government to champion the continuing growth of Australia's vibrant medical products sector.

The WA Life Sciences Innovation Hub is a partnership between MTPConnect, the Western Australian Government and the University of Western Australia (UWA) to accelerate the growth of the state's health and medical life sciences sector, create new jobs and support economic diversification.

An active patent environment

Australia is a global leader in MedTech patents, with strengths in diagnostics, implants and digital health. Australian MedTech patents have grown at an average rate of 7% per year since 2010, with Australia now holding a 6% share of global MedTech patents. In 2023, 3,690 Australian MedTech standard patent applications were filed, second only to pharmaceuticals, placing Australia 2nd in medical device patents globally.

Figure 1. Australian 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 pulishing of patents, therefore 2021–2023 data is incomplete.
Patents incuded are international Patent Classes (IPC): A61B, A61C, A61F, A61H, A61J, A61M, A61N.

Commercialisation and regulatory support

Australia offers an excellent environment for developing and commercialising medical devices, and it is a global leader in health and medical research.

In 2023, the Australian Government established the National Reconstruction Fund Corporation (NRFC) to support seven priority areas of the Australian economy, including medical science. The NRFC can provide finance in the form of debt and equity, aiming to promote innovation in the medical manufacturing industry and secure Australia's sovereign capabilities in medical science.

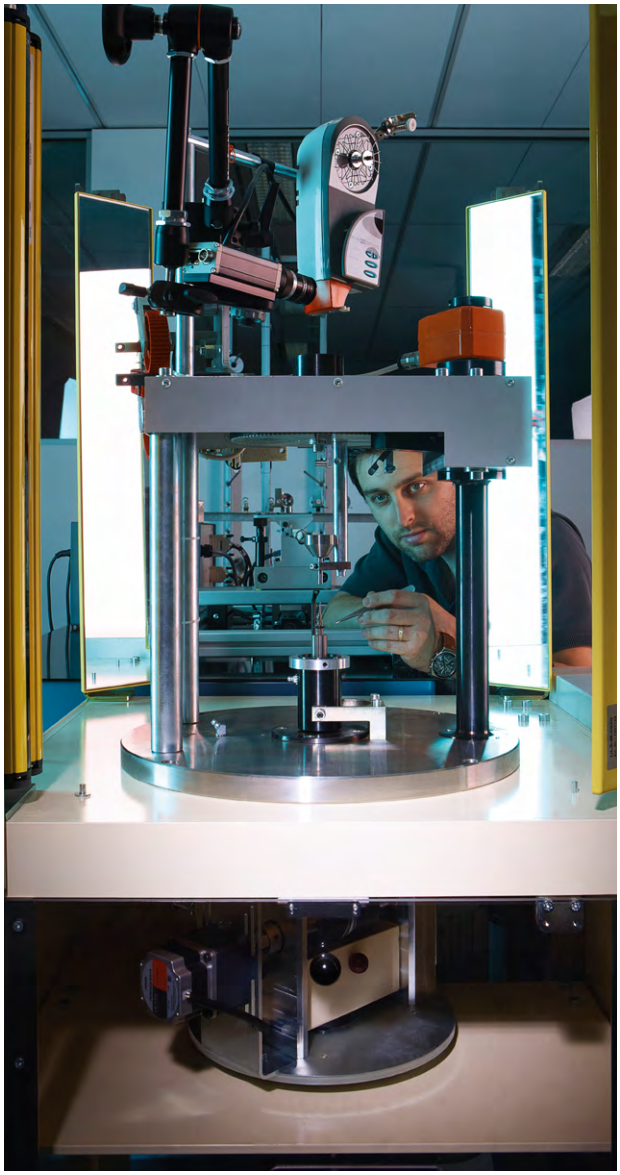
Our globally recognised regulatory body, the Therapeutic Goods Administration (TGA) was a founding member of the International Medical Device Regulators Forum (IMDRF). The IMDRF was established in 2011 and builds on the strong foundational work of the Global Harmonisation Task Force (GHTF) on Medical Devices.

Supporting startup technology companies is vital for the growth of the MedTech sector. Both the Australian Government and state governments provide various funding opportunities in science and technology which promotes discovery, collaboration, commercialisation, and skills development.

One key initiative is the Research and Development Tax Incentive, which supports investment in research and development activities; further details are available here.

Additionally, governments recognise crowdfunding as an attractive and essential driver for startups in the innovation technology sector in Australia. In support of a platform of initiatives to foster innovation and SMEs, a review of equity crowdfunding regulations has improved access to capital.

To support export opportunities, Australia is committed to promoting business and investment through Free Trade Agreements (FTAs). These agreements eliminate tariffs, address non-tariff barriers that hinder the flow of goods and services between parties, and enhance cooperation. Australia's strategic positioning within the wider APAC region and strong trade connections through FTAs, including with ASEAN (2010), South Korea (2014), China (2015), and Indonesia (2020).



Bionic Eye Research at NICTA
© The Kitchen 2010

Digital health, AI and precision medicine

Australian MedTech companies are using artificial intelligence (AI) to transform the healthcare sector by developing advanced diagnostic and therapeutic solutions.

These platforms utilise machine learning and data analytics to enhance medical diagnostics, treatment planning, and personalised care. With diagnostic accuracy rates of 93% for AI imaging tools (annalise.ai) and improved patient outcomes in IVF success (Vitrolife), the potential and transformative power of AI in this sector are evident.

Examples of leading AI technologies include:

- **Harrison.ai** Deep learning technology applied to comprehensive radiology solutions across chest X-rays and head CT images.
- **Synchron** Brain-computer interfaces that enable paralysed patients to control devices.

Precision engineering is fundamental to Australia's role in pioneering assistive technologies for healthcare, emphasising the precise design and manufacturing of medical devices, including prosthetics and imaging systems.

Practical applications of precision engineering include:

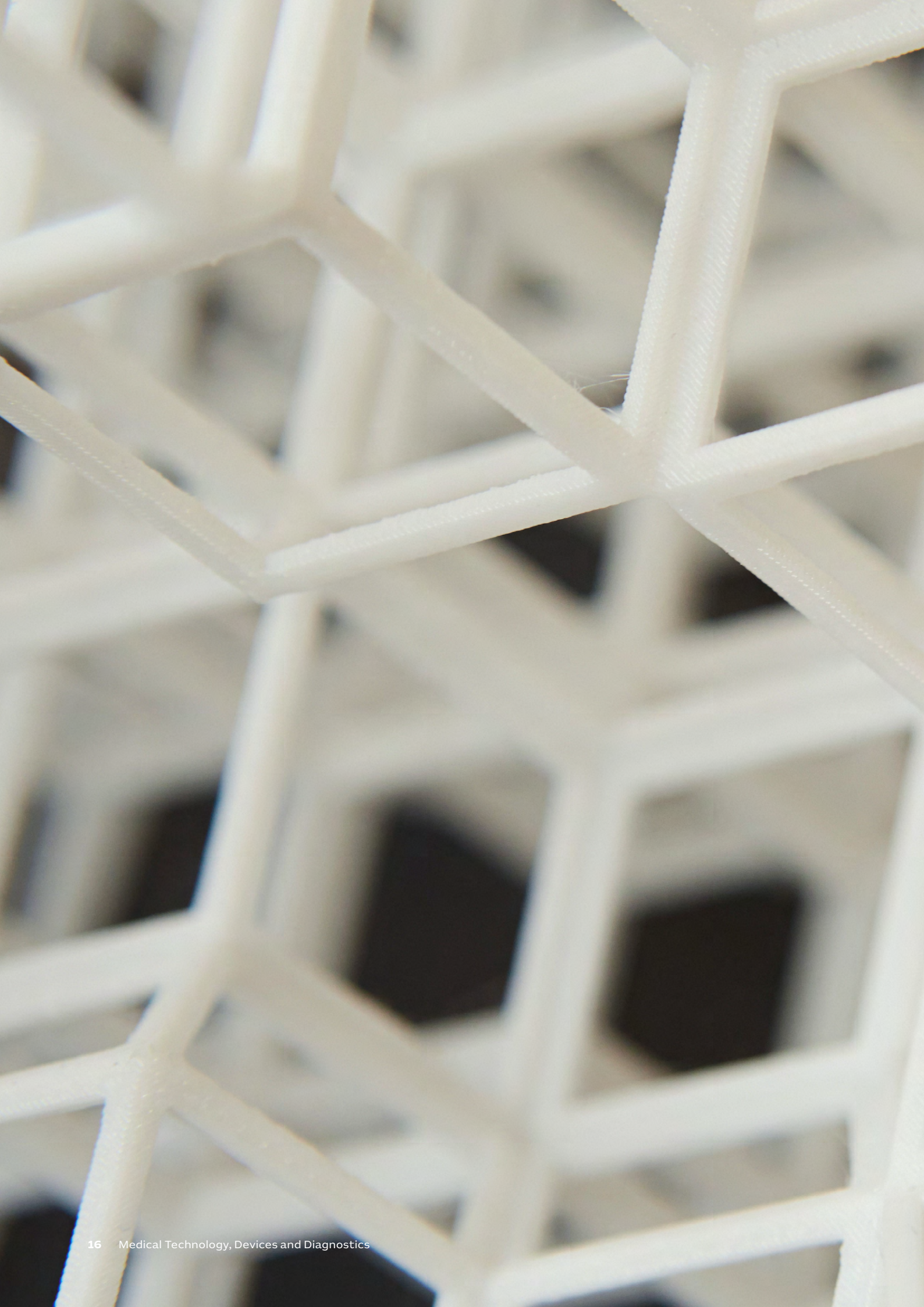
- **Optiscan** biopsy-free imaging technology, which can reduce patient discomfort across clinical settings, including cancer diagnosis and treatment.
- **Design+Industry** part of Capgemini, is a globally leading product design and development consultancy company.
- **LenexaCARE** is a fabric-based sensor system that utilises AI to prevent pressure injuries in real-time.

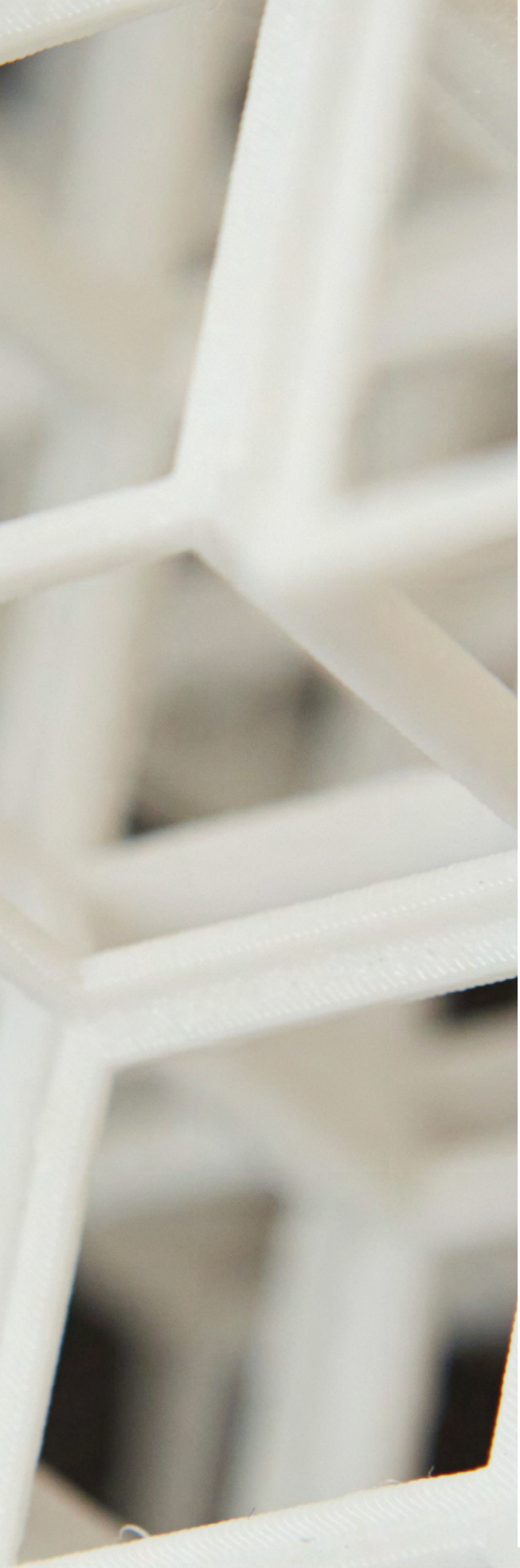
Software as a Medical Device (SaMD) is transforming Australia's digital health landscape by offering innovative software solutions intended for medical purposes, such as diagnosis and monitoring. These solutions operate independently on platforms like smartphones and regulated medical devices approved by the TGA. The sector is positioned for growth both domestically and internationally, striking a balance between innovation and safety.

Examples of practical applications of SaMD and digital health include:

- **MedTech Artia** provides medical practice management software that streamlines administration and improves efficiency for general practice, hospitals, specialists, and government departments.
- **Vively** offers a wearable-enabled application that delivers real-time metabolic health insights, helping users track and manage their health more effectively.
- **Beamtree** delivers smart software that improves clinical decision-making by helping doctors and hospitals diagnose conditions, prioritise treatments, and reduce safety risks.
- **XRHealth** develops virtual reality therapy platforms that enable patients to complete rehabilitation and mental health treatments at home while clinicians monitor their progress.
- **Cardihab** provides a digital cardiac rehabilitation program that supports safe recovery at home and keeps patients connected with their healthcare team.

Optiscan Machine





Manufacturing and supply chain capabilities

The Australian Government's co-investment plans aim to strengthen advanced manufacturing and diversify medical supply chains. For example, The Medical Science Co-investment Plan supports local production of medical products and ensures supply chains can meet future innovation needs.

Australia's MedTech industry thrives on advanced manufacturing, offering cutting-edge technologies such as 3D printing, robotics, and automation to create high-quality, customised medical devices and components. Local manufacturing capabilities include:

- **Zeal 3D** offers 3D scanning, printing, batch and mass manufacturing, machining, and laser cutting.
- **Additive Engineering** Metal 3D Printing and Manufacturing, specialising in bio-compatible titanium 3D printing
- **Australian Research Council Training Centre for Medical Implant Technologies (ARC CMIT)** provides training to develop workforce skills in the latest technologies, specialised in personalised 3D printed orthopaedic and maxillofacial implants.
- **Australian National Fabrication Facility (ANFF)** is a national network of 21 university-based nodes that provide access to advanced fabrication tools and expertise. The network supports researchers and industry in developing micro- and nanotechnology-enabled devices, including MedTech innovations.
- **Fusetec** is an advanced manufacturing company specialising in the design and development of fully operable, anatomically accurate soft tissue surgical training models.

Regulatory and commercialisation landscape

Australia is a trusted and reliable trading partner that provides MedTech solutions developed within strong regulatory and policy frameworks.

- **Australia's strong IP protection environment** aligns with international standards, supports MedTech innovation through leadership in online copyright enforcement, patentability of biotechnology, and ease of IP licensing.
- **Supportive policy and regulatory environment** that significantly impacts company development, enabling businesses to navigate challenges, access funding, and bring innovative solutions to market efficiently, while adhering to rigorous safety and efficacy standards. These strengths also attract multinationals such as Cook Medical, GE Healthcare, Medtronic, and Baxter Healthcare to undertake R&D and/or manufacturing in Australia.

Government organisations

The following are some of the government and industry bodies involved in the Australian medical devices and diagnostics industry.

The Department of Industry, Science and Resources is the Australian Government department that helps the industry to become more efficient, competitive and innovative through engagement with business, research bodies, tertiary education sectors, government and the broader community.

Therapeutic Goods Administration (TGA) is Australia's main regulator for medical devices and other therapeutic products. It is internationally recognised for maintaining high standards of safety and quality.

Key industry associations

Medical Technology Association of Australia (MTAA) is the peak association representing companies in the medical technology industry.

MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

AusBiotech a leading Australian industry body representing and advocating for organisations doing business in and with the global life sciences economy.

ARCS Australia is a professional body supporting individuals working in the development of medicines, medical devices, and diagnostics.

Pathology Technology Australia represents manufacturers and suppliers of diagnostic tests and technologies. Its report *Unleashing the Hidden Potential* outlines the sector's contribution.

Australian Dental Industry Association (ADIA) is the peak body for suppliers of dental products, including manufacturers, importers, and distributors.

Consumer Healthcare Products Australia (CHP Australia) is the peak body for companies making and distributing non-prescription healthcare products.

Science Industry Australia (SIA) is the national body for organisations in the science industry, including life sciences suppliers, scientific equipment makers, and diagnostic technology providers.

Accelerators and commercialisation launchpads

Accelerator programs provide Australian companies with information and the right connections to fast-track and international approval pathways ready to export their products in global markets.

Accelerators

- **Medical Device Partnering Program:** Flinders University program offering early-stage device development and prototyping support.
- **Health 10x Accelerator:** Accelerator program run by UNSW and The George Institute for Global Health.
- **Cicada Innovations:** Deep tech incubator operator.
- **MedTech Actuator:** APAC MedTech accelerator.
- **ANDHealth:** ANDHealth Activate accelerator program.
- **Perth Biodesign:** Multidisciplinary training program for MedTech and digital health innovation.
- **BridgeTech Program:** National professional development program for MedTech commercialisation run by Queensland University of Technology.
- **MTPConnect:** National industry growth centre accelerating MedTech, biotech, and pharmaceutical innovation through funding, collaboration, and ecosystem development.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Investment and capital environment

Angels and specialist investors are shaping Australian MedTech by combining funding with expertise and networks, helping research grow into global businesses. Early-stage capital remains limited, creating opportunities for investors to back promising ventures before larger funds enter.

As institutional investors and private equity follow, strong exit pathways are emerging. For international investors, Australia offers a trusted ecosystem of research, clinical trials, and government support, together with direct access to rapidly expanding healthcare markets across the Asia-Pacific region.

Foreign direct investment (FDI) opportunities

Australia presents compelling opportunities for foreign direct investment, with global MedTech leaders increasingly choosing to base R&D and manufacturing operations locally. By tapping into Australia's innovation ecosystem, international firms gain access to world-class research institutions, clinical trial networks, advanced manufacturing capabilities, and strong government support. Investment in local facilities not only strengthens sovereign supply and sustainability but also provides investors with a strategic launchpad into APAC's fast-growing healthcare markets.

Stryker has established a Brisbane R&D Lab within the Herston Health Precinct to co-develop digital health and robotics solutions with clinicians.

Baxter Healthcare is investing A$40 million, alongside the Australian Government, to expand IV fluid production in Western Sydney.

Cardinal Health has launched its first medical device remanufacturing facility outside the US in Newcastle to cut waste and boost sustainability.

Strategic government grants and co-investment initiatives

The Australian Commonwealth and State Governments, actively support the MedTech sector through initiatives aimed at boosting investment and innovation.

Key initiatives include:

Australia's investments and programs

National Health and Medical Research Council (NHMRC) disburses A$800 million in grants for medical research and clinical development.

Medical Research Future Fund (MRFF) is a A$22 billion fund targeted at emerging needs. Programs include the Targeted Translation Research Accelerator (TTRA) and the Clinical Translation and Commercialisation Medtech Program (CTC-M).

MHRIF: Supports indirect research costs to sustain long-term medical research efforts.

ARC ITTC and SRI: National co-investment schemes that connect academia with industry to develop future-ready research capabilities.

State initiatives and programs

New South Wales

- NSW Health: Medical Devices Fund.
- Investment NSW: Going Global Export Program, MVP Ventures Program.
- •NSW Health Commercialisation Training Program

Queensland

- Department of Environment, Tourism, Science and Innovation: Overall state roadmap and innovation planning, coordination of initiatives, including innovation precincts.
- Advance Queensland: Ignite Programs, Corporate Innovation Network.

Victoria

- Department of Jobs, Skills, Industry and Regions: Australian MedTech Manufacturing Centre (AMMC), MedTech Manufacturing Capability Program (MMCP).
- LaunchVIC: Funds programs and networks across pre-accelerator and accelerator programs, angel networks and VC funds.
- Victorian Medical Device Prototyping and Scale-Up Facility.
- Victorian Medical Research Acceleration Fund: State-led initiative driving local innovation and commercialisation.

South Australia

- Department of State Development.
- Seed-Start program, Research and Innovation Fund.
- Medical Device Partnering Program (MDPP).

Western Australia

- Future Health Research and Innovation Fund (FHRI).

Strategic growth opportunities

The major export markets for Australian MedTech firms remain in North America and Western Europe. The US and Netherlands comprise over 30% and 12% of exports respectively.

There is growing opportunity in Asian markets, which represent half of Australia's top 20 export markets, notably Japan (#5, 6.1%) and China (#6, 4.9%). As East Asia ages, and South East Asia's middle class expands and experience an increase in the prevalence of chronic conditions, there are strong export opportunities for high quality healthcare products and services, which Australia is well positioned to supply.

Appendices

Definitions and sector classifications

The MedTech industry is rapidly growing in complexity and innovation. Existing and new products, along with sub-segments, have become more interconnected and dependent. However, they remain distinct yet closely related.

Medical Technology (MedTech) A broad field of healthcare innovations including devices, diagnostics, software, and tools that support prevention, diagnosis, treatment, and monitoring of health and disability.

Medical Devices Instruments, machines, materials, or software used for medical purposes such as diagnosis, treatment, monitoring, or supporting life and physiological processes.

Diagnostics Technologies, including in-vitro and in-vivo tools, that identify diseases or conditions to guide clinical decisions and treatment.

Software-as-a-Medical-Device (SaMD) is software that can function on a digital device, and has an intended purpose consistent with the definition of a medical device. This is distinct from Software-in-a-Medical-Device (SiMD) and Software-as-an-Accessory-to-a-Medical-Device, which cannot operate separately from their associated devices.

AI Applications (including generative AI) can be considered a medical device if the intended use is: diagnosis, prevention, monitoring, prediction, prognosis or treatment of a disease, injury, or disability, alleviation of, or compensation for, an injury or disability, investigation of the anatomy or of a physiological process, or control or support of conception.

Robotics in the context of medical devices are “smart” machines that can perform actions that healthcare provider might. Some robots operate autonomously, whilst others operate with some monitoring or control by a person, and others are fully controlled by a person. They can perform minimally invasive surgery, endoscopic procedures, or even be worn as exoskeletons.

Cardiac Monitor

AI Machine

Acknowledgements

Our partners

This report has been prepared in collaboration with the Medical Technology Association of Australia (MTAA).

MTAA is the peak association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA's membership spans Australian start-ups through to global MedTech leaders. Its members develop, manufacture and supply medical technologies used in the diagnosis, prevention, treatment and management of disease and disability.

The range of medical technology is diverse, with products ranging from familiar items such as syringes and wound dressings to high technology implantable devices such as pacemakers, defibrillators, and orthopaedic implants. Products also include hospital and diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines, as well as digital health technologies such as remote monitoring devices and digital therapeutics.

MTAA members distribute the majority of non-pharmaceutical products used in the diagnosis and treatment of disease and disability in Australia. It's member companies also play a vital role in providing healthcare professionals with essential education and training to ensure the safe and effective use of medical technology.

Australia's Medtech innovation showcase

23 Strands

AI-powered precision medicine for women's health

Headquartered in Australia, 23Strands is a leading innovator in clinical artificial intelligence and precision medicine, with a particular focus on hormone-related treatments throughout a woman's life course. The company develops advanced AI-driven tools that support accurate diagnosis, improved treatment outcomes, and more efficient clinical workflows, positioning it as a key player in Australia's next-generation diagnostics landscape.

At the core of its offering is a proprietary AI platform that enables precision medicine through Whole Genome Sequencing. The system processes large-scale clinical data to deliver real-time, actionable insights across specialties, including oncology, cardiology, and neurology. The company's global partnerships, including a collaboration with Merck KGaA, reflect the scalability of its solutions. 23Strands also supports device manufacturing through strategic international collaborations.

Female scientist examining DNA sequence results

The company has secured over $25 million in competitive grants as an industry partner, in recognition of its leadership in AI and women's health. With support from Austrade and export programs, it has expanded into markets including India, Asia, and North America. Ongoing projects include a collaboration with Bioplatforms Australia to enable secure, nation-wide genome sequencing and storage capabilities for Australian patients.

23Strands recently signed its first global biopharma contract to provide Whole Genome Sequencing and precision health insights in women's health, strengthening its commercial reach.

"23Strands' journey has been made possible by the robust clinical, research and technology ecosystem in Australia. Our ability to leverage local expertise while accessing global markets has positioned us as a trusted partner in advancing precision medicine solutions worldwide."

Mark Grosser, CEO and Co-founder, 23Strands

www.23strands.com

Atomo Diagnostics

Empowering Decentralised Testing

Atomo Diagnostics is a publicly listed Australian company headquartered in Sydney and a global leader in point-of-care diagnostics. The company applies user-centred engineering to diagnostic design, developing integrated platforms that improve usability and reduce error rates in both clinical and at-home testing.

Diagnostic scientist

Pipetting HIV infected cells from petri dish

Atomo's Pascal platform combines multiple testing steps, including skin prick, sample collection, and buffer delivery, into a single easy-to-use device, making rapid tests easier and faster to use. This platform is used in Lumos Diagnostics' FebriDxTM test, which helps tell the difference between viral and bacterial infections. Atomo's Galileo platform powers its HIV self-test, the first and only test of its kind registered in Australia. The test is CE marked, WHO prequalified, and sold in pharmacies and retail stores across Australia, New Zealand, the United Kingdom, and more than 40 countries.

Atomo was awarded a $2.44 million Australian Government grant to develop a rapid syphilis test in partnership with the Burnet Institute. The company has also expanded its HIV self-testing vending machine program across Australia, increasing access in key locations.

Independent studies have shown that Atomo's Pascal platform significantly improves test performance, reduces blood collection errors by 90%, eliminates buffer delivery errors entirely, and decreases test completion time by over 40%. With results like these, Atomo is well-positioned to improve testing outcomes across both over-the-counter and point-of-care settings.

"Being part of the Australian MedTech ecosystem has been key to our growth and global expansion. The combination of research, skilled talent, and a supportive environment has enabled us to innovate locally and compete confidently on the world stage."

John Kelly, Managing Director, Atomo Diagnostics

www.atomodiagnostics.com

Baymatob

Care that knows what's coming

Baymatob is a Sydney-based MedTech company developing Oli, a wearable sensor and digital platform designed to improve safety in pregnancy and childbirth. Oli enables early detection and monitoring of serious, treatable complications in maternal and fetal health. Baymatob is active in Australia and the United States.

Oli's patent-protected sensor and machine learning algorithims provide predictive, personalised insights across a range of maternal conditions. Its first application targets postpartum haemorrhage (PPH), the leading cause of maternal mortality worldwide. There is currently no early-warning system for PPH on the market, and Oli is the most advanced solution in development, offering a validated, data-driven tool to improve outcomes and reduce healthcare costs. Baymatob has secured over $8 million in grant funding and was named "AI Innovator in Healthcare" at the 2024 Australian AI Awards.

Following a successful commercial simulation in Illinois, the company is advancing pivotal studies in both Australia and the US. Oli has received FDA Breakthrough Device designation and is now in limited manufacturing with ISO-certified partners. Early results suggest it could halve the need for emergency hysterectomies and major transfusions and reduce up to 35% of the US$1.8B in annual PPH-related costs. With clinical validation already supporting over 15 future digital health products, Baymatob is well-positioned to achieve its goal of improving maternal care on a global scale.

"Australia's MedTech ecosystem has been a catalyst for execution of our vision—to redefine what's possible at the intersection of healthcare and technology. By harnessing Australia's deep clinical and manufacturing expertise, we've been able to pioneer first-in-class applications of machine learning and next-generation wearable technologies that are shaping the future of maternal health."

Tara Croft, CEO, Baymatob

www.baymatob.com

CathRx

Redefining catheter innovation in cardiac care

CathRx Ltd is an Australian medical device company specialising in cardiac electrophysiology. It designs and manufactures innovative catheter systems for diagnosing and treating cardiac arrhythmias. Based in Sydney, its ISO 13485-certified facility supplies products globally, with active operations across Korea and manufacturing partnerships in Taiwan. CathRx is focused on research and development (R&D) led growth to expand access to safer, more effective cardiac treatments.

Its flagship product, the ElectroPulse PFA System, is a next-generation ablation platform for atrial fibrillation. Unlike traditional methods that use heat or cold, ElectroPulse delivers short electrical pulses to target heart tissue precisely, reducing the risk of damage to nearby structures. The system includes three single-use catheters that allow doctors to diagnose and treat a broad range of heart rhythm conditions, including in patients with pacemakers. It also works with existing hospital equipment, reducing training needs.

Over the past year, CathRx has commercialised diagnostic catheters in Korea and is now present in nearly 50% of hospitals nationwide. With support from a $1.5 million CTCM grant, a 75-patient first-in-human clinical study of the ElectroPulse System was conducted, reporting no device-related adverse events and strong early results. The company has recently increased its production capacity from 3,000–4,000 to 20,000 units annually through a contract manufacturer based in Taiwan.

"The combination of world-class clinical expertise and targeted government support has created an ideal environment for developing and commercialising advanced technologies like our ElectroPulse Pulsed Field Ablation (PFA) System. Government-backed initiatives like the CTCM program have provided critical funding and validation, allowing us to accelerate development timelines."

Milanjot Singh Assi, Head of Operations, CathRx Ltd

www.cathrx.com

Khelix diagnostic catheta

D+I™ Part of Capgemini

D+I

From concept to commercialisation

D+I, Part of Capgemini, delivers complete product development - from concept to production - for complex medical, scientific, and wellness devices.

Certified to ISO 13485:2016, D+I supports global leaders and startups alike in launching new technologies and enhancing existing products. Its 80-person team across Australian studios integrates industrial design, human factors, mechanical and electronics engineering, software, DFMA, production transfer, and project management into a single, quality-driven workflow.

International clients – such as Siemens, Enovis, and Zeta Surgical - turn to D+I for Australia's design and engineering expertise. Validated designs are transferred into production with manufacturers in Australia and worldwide.

D+I applies a stage-gated process, Discovery • Concept • Development • Production - to de-risk innovation, meet regulatory requirements, and deliver scalable production packages. Services include research, concept creation, engineering, verification, regulatory support, pilot builds, and production management, underpinned by ISO 13485, ISO 9001, and ISO/IEC 27001 certifications.–With 270+ design and engineering awards and a 95% market-entry rate, D+I has helped bring to life innovations like Inventia's RASTRUM bioprinter, AdvanCell's Lead-212 generators, and Cochlear's hearing technologies.

As part of Capgemini Engineering, D+I offers local delivery with global reach - backed by 62,000 engineers, 90+ R&D labs, and advanced digital capabilities across 50+ countries.

"Australia's MedTech ecosystem has been instrumental in helping us guide established companies, entrepreneurs, and startups through the journey of transforming innovative ideas into globally launched products."

David Jones, VP, Head of D+I Part of Capgemini

www.design-industry.com.au

Device Technologies

Pioneering possibility

Device Technologies is a leading supplier of advanced medical technologies, supporting hospitals and healthcare professionals across Australia, New Zealand, and key Asian markets. With more than 200 global brands and over 30,000 products across 15 specialties, the company plays a critical role in introducing cutting-edge medical technologies across the region.

Operating in nine countries including Singapore, Malaysia, the Philippines, Vietnam, Thailand, Indonesia, and Hong Kong, Device Technologies provides end-to-end commercial support for international MedTech companies. Its services span regulatory affairs, clinical education, technical support, marketing, and digital learning—enabling rapid market entry and sustained growth.

Device Technologies has launched transformative technologies including Intuitive's surgical robotics, MMI's microsurgical systems, and Insightec's incisionless brain therapies. It has also expanded Australian-developed innovations like Orthocell's Remplir into Asia and the U.S., helping companies scale globally from a strong local foundation.

Recent results include a 75% increase in robotic surgery capital installations in Southeast Asia, a 150% year-on-year increase in insufflation system sales, and the onboarding of nine new suppliers and over 8,600 products across Australia and New Zealand. The company has also trained more than 760 new robotic surgeons across Australia, New Zealand, and Asia in the past financial year.

With the largest independent clinical education team in Australia and New Zealand and a trusted track record of commercialisation, Device Technologies continues to deliver scalable, high-impact growth for MedTech innovators across the Asia-Pacific.

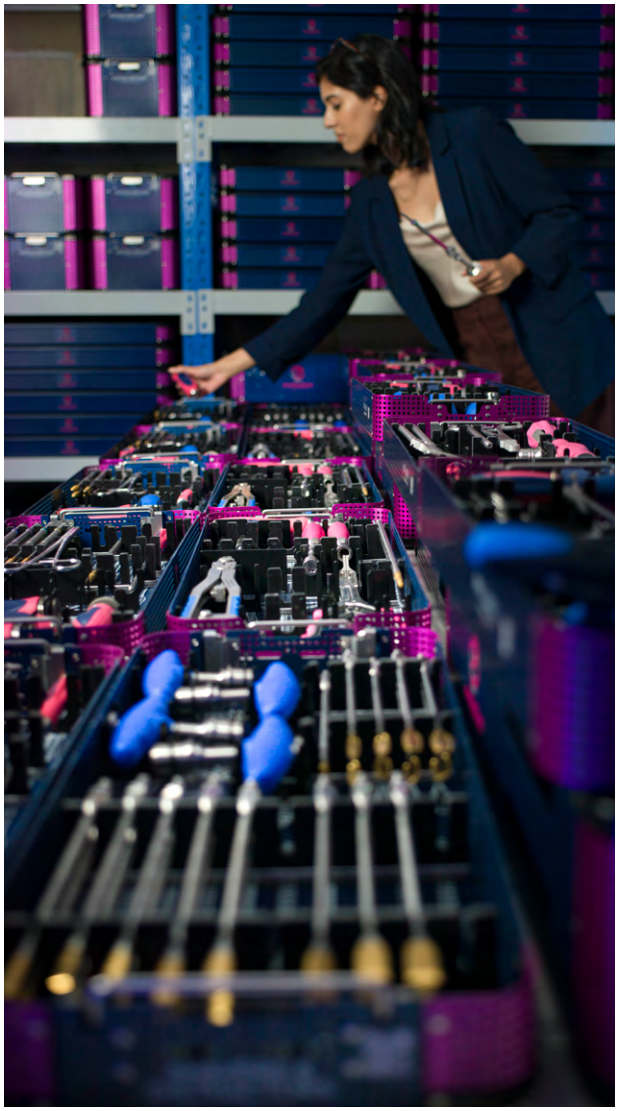
www.device.com.au

Evolution Surgical

Advancing spinal surgery through Australian innovation

Evolution Surgical is an Australian MedTech company transforming spinal surgery through locally designed and manufactured technologies. Headquartered in New South Wales, with offices across Queensland, Victoria, and South Australia, the company specialises exclusively in spinal care, delivering clinician-led innovation from design to distribution.

Focused on complex spinal conditions such as tumours, trauma, deformities, and degenerative disc disease, Evolution Surgical offers a comprehensive portfolio of implants, surgical instruments, biologics, and enabling technologies. Its flagship systems—such as the Katana thoracolumbar stabilisation platform and the BA Posterior Cervical system—are developed in close collaboration with Australian surgeons to improve precision and outcomes in high-acuity procedures.



By retaining full control over the product lifecycle, Evolution Surgical delivers rapid, locally driven innovation while strengthening Australia's sovereign capability in medical manufacturing. The company's solutions are now used in thousands of spinal procedures each year.

With a focus on depth rather than breadth, Evolution Surgical has built a reputation for excellence in one of the most demanding areas of surgery. By combining engineering precision with close clinical collaboration, the company is redefining what locally led innovation in spinal care can achieve—setting a benchmark for Australian-made surgical technology.

"Australia's MedTech ecosystem has been instrumental in our success. It has allowed us to design and manufacture world-class spinal technologies, leveraging local clinical expertise, strong regulatory frameworks and export support. Being based in Australia has helped us stay agile, innovate rapidly and deliver meaningful clinical impact."

Jack Lancaster, CEO & Founder, Evolution Surgical

www.evolutionsurgical.com.au

Harrison.ai

Harrison.ai

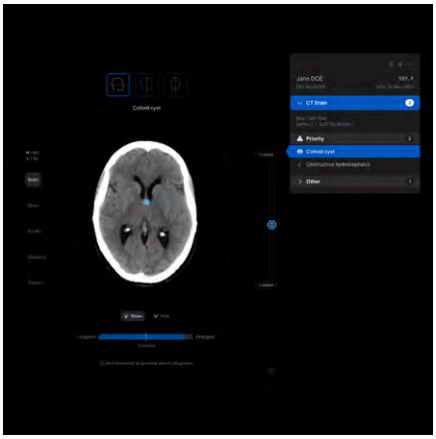
Smarter radiology

Harrison.ai is an Australian health technology company that develops advanced artificial intelligence solutions for medical imaging, with regulatory clearance in 40 countries.

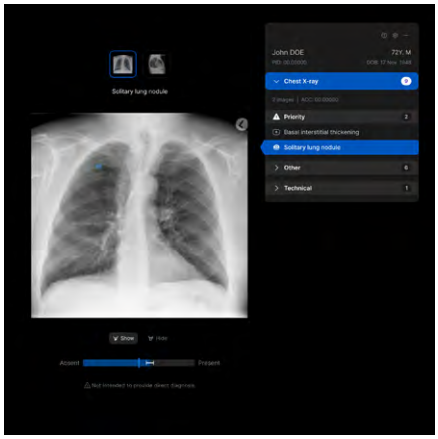
Their comprehensive AI-powered products help clinicians rapidly and accurately interpret chest X-rays and head CT scans, enabling faster diagnoses, prioritisation of critical cases, and improved patient outcomes across healthcare systems worldwide.

Harrison.aichest X-ray solution detects up to 124 findings on chest x-rays and Harrison.ai Brain CT solution detects up to 130 radiological findings on non-contrast head CT studies in under a minute. Harrison's AI models are trained on some of the world's largest and most rigorously annotated medical imaging datasets, with input from over 150 qualified radiologists. The company's products have received regulatory clearances in multiple regions and are robustly validated in real-world clinical settings.

www.harrison.ai



Harrison.ai CT Brain



Harrison.ai Chest X-ray

Hydrix

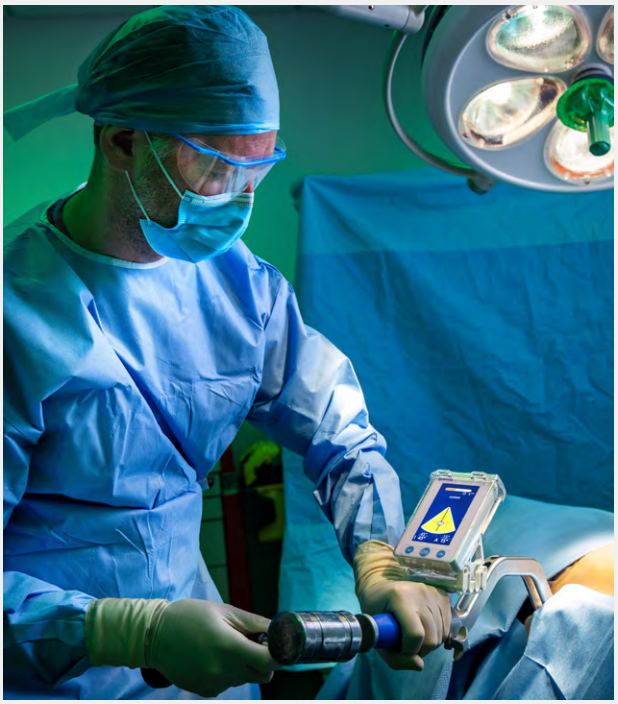
Enabling breakthrough MedTech innovation from concept to clinic

Hydrix is a specialist advisory and product development firm that helps MedTech innovators design, engineer, and commercialise high-risk, high-impact medical technologies. The company provides end-to-end support across the development lifecycle, including market strategy, product design and systems engineering, regulatory guidance, clinical trial facilitation, and investor readiness.

Hydrix is an internationally recognised leader in medical device development that helps innovators design, engineer and commercialise transformative technologies. The company provides end-to-end support across the development lifecycle, including market strategy, product design and systems engineering, regulatory guidance, clinical trial facilitation, and investor readiness.

Headquartered in Melbourne, Hydrix works with clients across North America, Europe, Asia, and Australia, with 70% of revenue generated from international markets. Its multidisciplinary team has supported over 100 MedTech companies to accelerate time to market, meet global regulatory requirements, and bring life-changing technologies to patients.

Hydrix's experience spans complex Class II and Class III devices, including implantables, wearables and sensors, diagnostics, robotics, and cardiac systems. They are a global leader in cardiac platform technologies, including safety-critical controller systems for Ventricular Assist Device and Total Artificial Heart clients in Australia and throughout the world, development of a chronic pacing platform now in human trials, the FDA- and TGA-cleared Gyder Surgical Hip Navigation System, and the Micro-X mobile X-ray system. Hydrix has also developed LUDO, a proprietary simulation platform supporting Australia's leadership in artificial heart and circulatory support innovation.



Gyder Surgical Hip Navigation System

Hydrix played a critical role in the awarding of the $50 million MRFF-funded Australian Heart Frontiers Program, leveraging their cardiac and ventricular assist expertise and strategic insights to influence outcomes that shape Australia's MedTech leadership internationally.

www.hydrix.com

ide.group

IDE Group

Create meaningful MedTech venture

IDE Group is an entrepreneurial partner that discovers, develops, and commercialises breakthrough medical technologies. Based in Sydney with global operations across the United States, European Union, China, and Australia, IDE helps clients turn early-stage ideas into high-value ventures through a unique combination of strategy, design, development, and manufacturing services.

IDE works with a broad spectrum of MedTech innovators, from pre-seed startups to global corporations, specialising in areas such as diagnostics, drug delivery, respiratory care, surgical tools, radiology, and connected health. The team applies a risk-based methodology to guide each project through a structured development path—identifying and resolving commercial, technical, and regulatory risks to improve efficiency and reduce time to market.

The firm has led over 500 projects, contributed to 85 patents, and supported more than 50 products, now improving patient outcomes in global markets. Notable success stories include Bayer Radiology's MEDRAD Centargo CT injector, Atomo Diagnostics' rapid HIV self-test now sold in over 30 countries, and ResMed's Pixi Mask, developed to serve global paediatric sleep therapy markets.

IDE also runs the Building Better Futures for Health Challenge, a flagship innovation competition supporting health professionals and entrepreneurs to launch new MedTech ventures.

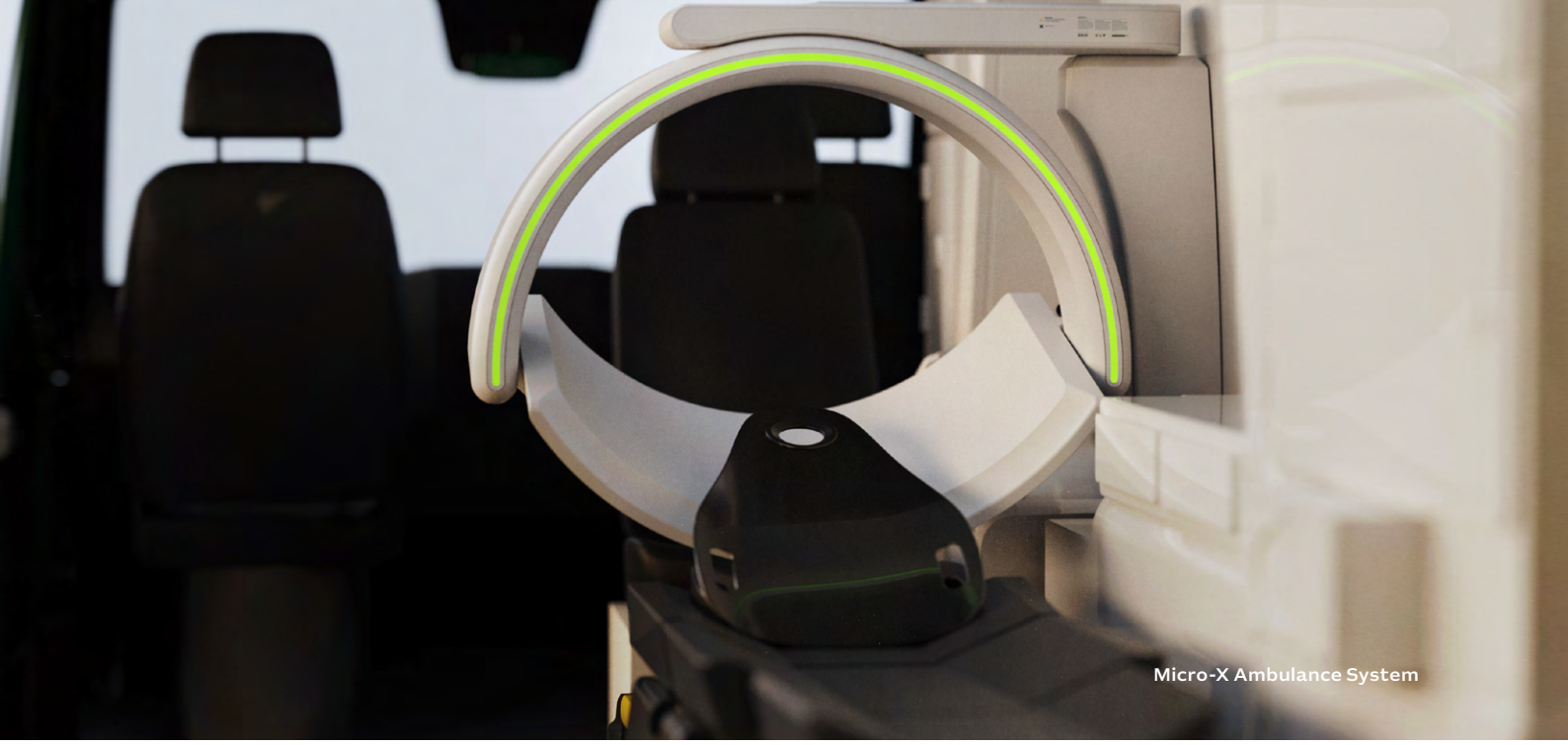
MRI Scanner

Surgical tools

"We believe the best outcomes in the MedTech industry emerge from true partnership. By bringing bold ideas, strategic insights, and strong capabilities to the forefront, and working closely with ambitious founders, health innovators, and industry leaders, we challenge convention and co-create scalable new MedTech ventures."

George Sidis, Managing Director, IDE Group

www.ide.group



Micro-X Ambulance System

MICRO-X

Micro-X

World-leading Nano Electronic X-ray Technology

Access to X-ray and CT imaging remains limited in many care settings, particularly in homes, ambulances, and rural areas. Traditional CT machines weigh over a tonne and require dedicated infrastructure. Micro-X is taking on this challenge with breakthrough X-ray technology that drastically reduces size, weight, and complexity—redefining what's possible in diagnostic imaging.

Built on proprietary Nano Electronic X-ray (NEX) technology, Micro-X replaces the filament cathode found in traditional X-ray systems with carbon nanotubes. This eliminates cathode heat, enables instant control, and reduces energy needs—allowing high-quality imaging in compact form factors. NEX underpins a growing suite of products, including a mobile X-ray cart used in over 400 locations across 39 countries and a new ultra-compact CT system in development.

A curved emitter array replaces the need to rotate heavy tubes, enabling fixed-position CT scanning in ambulances and mobile clinics. Micro-X is developing vehicle-based CT scanners under multi-year partnerships with ARPA-H and the Australian Stroke Alliance, and has secured funding from the U.S. Department of Homeland Security to build next-generation airport scanners.

Recognised with multiple iF and Good Design Awards, and named one of Australia's Top 10 Most Innovative Manufacturers in 2025, Micro-X continues to deliver novel imaging technologies.

With strong investor backing and national R&D programs, Micro-X is building advanced manufacturing capability in South Australia with global impact in sight.

"Australia's MedTech ecosystem—from investor support to university partnerships—has been essential to our growth. Collaborating with Flinders University has helped us accelerate innovation and develop talent locally."

Anthony Skeats, Chief Operating Officer, Micro-X

www.micro-x.com

Multigate

Custom procedure packs supporting sustainable healthcare across the region

Multigate is a family-owned Australian company and leading manufacturer of Procedure Packs and single-use medical consumables for hospitals across Australia and New Zealand. Headquartered in Sydney, the company employs around 500 people and operates a purpose-built ISO Class 7 clean room and warehouse facility. Multigate will open a new state-of-the-art Head Office, production and automated distribution facility, in late 2025 which includes a fully automated 30,000m^2 warehouse and an automated goods-to-person production capability.

With over 25 years of experience in procedure pack development, Multigate supplies more than 2,000 custom and standard procedure pack configurations, designed in collaboration with clinical teams. The company designs and manufactures a wide range of consumables, providing control over product quality, innovation speed, and supply chain resilience. During the COVID-19 pandemic, Multigate led the supply of PPE to Australian Federal and State Governments.

In 2023, Multigate expanded its regional presence with the launch of Multigate NZ Limited. Beyond Australia and New Zealand, Multigate exports to eight countries in Asia and Europe.
The company's robust global supply chain is supported by joint ventures in China and the UK, and trusted partnerships across multiple regions.

Multigate is the first and only Procedure Pack provider in the region to achieve Climate Neutral validation, with every pack supplied to Australia and New Zealand offset through registered projects that help tackle climate change.
The company continues to invest in operational excellence and sustainability as it supports healthcare systems across the region and beyond.

www.multigate.com.au

Nanosonics

Infection prevention. For life.

Nanosonics is an Australian infection prevention company that pioneered the trophon device, the first major innovation in high-level disinfection for ultrasound probes in more than two decades. Headquartered in Sydney, the company now operates across key markets with offices in North America, Europe, Japan, and Australia.

The trophon platform provides fully automated, consistent, and traceable disinfection for ultrasound probes, helping reduce the risk of cross-contamination in clinical environments. It is currently the only automated high-level disinfection technology for transvaginal, transrectal, and surface probes that meets the microbial efficacy standards required for both FDA clearance and CE marking. The latest generation, trophon2, supports infection prevention teams with improved workflow integration, compliance traceability, and enhanced ease of use.

More than 25,000 trophon systems are installed globally, protecting over 106,000 patients every day—equating to more than 26 million protected annually. The technology is used widely by leading hospitals and imaging providers in over 30 countries.

To support growing international demand, Nanosonics has built a strong global infrastructure including regional offices, a distributor network, and dedicated logistics and service operations. With revenue exceeding 170 million Australian dollars in the last financial year and continued growth across North America, Europe, and Asia, the company is well-positioned to scale its infection prevention technologies worldwide.

www.nanosonics.com

Navbit

Cutting edge technology for surgical precision

Traditional navigation systems for orthopaedic surgery are often bulky, expensive, and inaccessible to smaller hospitals and day surgery centres. Navbit is addressing this with purpose-built, miniaturised surgical navigation technologies that are affordable, precise, and scalable across global healthcare systems.

Headquartered at Cicada Innovations in Sydney, Navbit designs and manufactures high-precision electronic and software-based devices for the surgical environment. Its lead product, Navbit SPRINT, is a compact, sterile, single-use device that supports accurate alignment of the acetabular cup during hip replacement surgery. Unlike traditional systems, SPRINT integrates advanced MEMS sensor technology into a disposable format—offering high performance without the overhead of capital-intensive equipment.

Navbit RAPID, a pre-operative software device, analyses spinal and pelvic anatomy using proprietary algorithms applied to standard X-rays. The system simplifies complex calculations and presents results in a clear, actionable format, supporting faster, patient-specific decisions.

Navbit technologies have been used in thousands of surgeries and are commercially distributed by global orthopaedic leaders including Johnson & Johnson MedTech and Smith+Nephew. The company has secured regulatory approvals across major markets including CE Mark, FDA 510(k), PMDA Japan, and ARTG listing in Australia. With ISO 13485 and MDSAP certification, Navbit is preparing for broader international rollout in 2026.

"Medtech is not something you can do alone. It takes a village—brilliant individuals, merit-based government grants, and organisations like AusBiotech, MTAA, and Austrade. For Navbit, that village also includes partners such as J&J MedTech and Smith+Nephew, the hospitals that support innovation, and the surgeons who put technology to work where it matters most."

Lynette Walter, CEO & Founder, Navbit

www.navbit.com

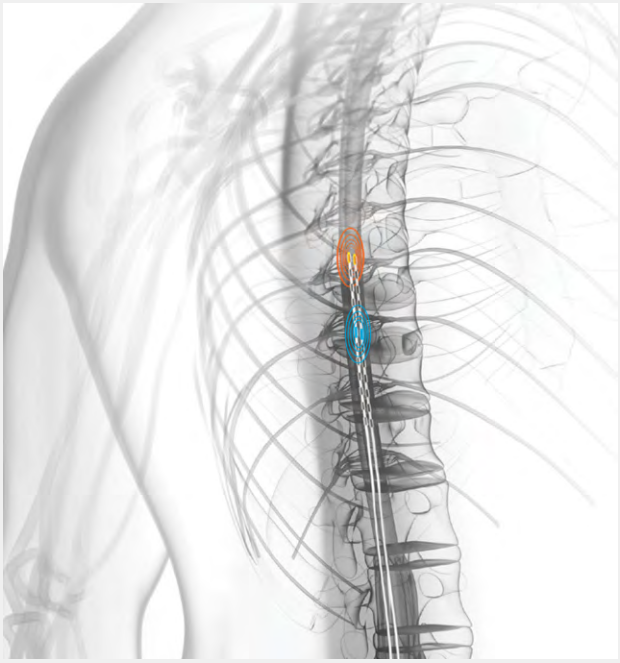
Saluda Medical

Saluda Medical is an Australian-founded medical technology company providing therapies for treating chronic pain using spinal cord stimulation (SCS). Saluda has transformed SCS therapy making it objective, prescriptive, validated and lasting.

The foundation of Saluda was laid 17 years ago with a research grant from NICTA (now part of CSIRO). Saluda was incorporated in 2013 and has its Research and Development Headquarters in Sydney and Commercial Headquarters in Minnesota, USA. The company is tapping the US market – the largest in the world – with innovations having deep roots in Australian medical technology. The company has obtained the key regulatory approvals (TGA, CE Mark, FDA PMA) to allow a strong commercial presence throughout Australia, UK, Europe and the USA, in a world market with a value of approximately $4B AUD.

Saluda has shown in a rigorous prospective double-blind clinical trial that a closed-loop algorithm using the evoked response of the spinal cord as a biomarker offers superior performance to open-loop operation such as that utilized in traditional SCS devices. As the evoked response is unique to each patient, Saluda's therapy can be individually tailored to provide precise and accurate therapy that automatically adjusts to meet the patient's needs. Saluda follows in the footsteps of a long line of pioneering Australian companies driving ground-breaking innovation in medical technology, like Telectronics (Lane Cove) and Cochlear (Macquarie Park). Saluda continues to innovate and improve its products with its recent US launch of EVA – an assisted programming platform whose design is informed by data obtained from records of trillions of evoked response recordings.

With a global supply chain, Saluda builds its products using some of the best technologies and skills available in the world. As of 2025, Saluda has approximately 150 employees in its Sydney facility and over 450 employees world-wide.



"The local availability of managerial, technical and clinical staff with outstanding qualifications and experience in active implantable medical devices has enabled us to develop groundbreaking therapies and products that treat chronic pain in global markets."

Peter Single, CTO, Saluda Medical

www.saludamedical.com

Southern Star Research

Home of Australian clinical trials

Southern Star Research is a full-service Contract Research Organisation (CRO) dedicated to navigating the complexities of bringing new medical products to market. Founded 14 years ago in Sydney, it has grown from a small team into a global network delivering services in medical writing, clinical monitoring, project management, biostatistics, data management, safety, and quality assurance.

The company has received multiple accolades, including the Frost & Sullivan 2024 Asia-Pacific Competitive Strategy Leadership Award and a Great Place to Work certification in Australia. Its international team delivers innovative trial solutions across diverse therapeutic areas.

Southern Star Research specialises in supporting emerging biotech's, where lean teams and limited funding require maximum return on investment. By compressing the clinical value chain, removing unnecessary steps, optimising workflows, and applying automation, the company ensures trials run faster and more efficiently.

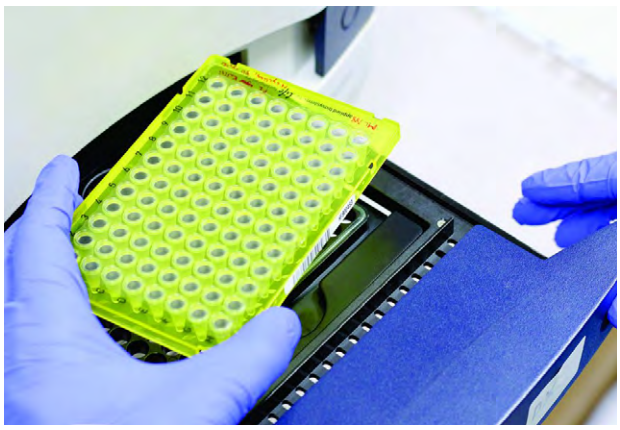
With a focus on early-phase trials, Southern Star leverages Australia's Clinical Trial Notification (CTN) scheme and R&D tax incentives to accelerate study launch, often within weeks, making it a preferred destination for U.S.-based biotech firms seeking early data.

While headquartered in Australia, Southern Star is expanding into South Korea and Singapore, unlocking access to diverse patient populations and efficient healthcare infrastructure. In each market, the company partners with local investigators and regulatory experts, ensuring every trial benefits from both global standards and local insight, a critical success factor in cross-border studies.

With growing reach and deep expertise, Southern Star Research is helping the next generation of medical innovators succeed on the global stage.

www.southernstarresearch.com

Laboratory researcher



Test kit

SpeeDx

Superior PCR multiplexing transforming diagnostics

Australian MedTech company since 2009, SpeeDx develop advanced technologies for diagnosing infectious diseases, combatting antimicrobial resistance (AMR), and oncology applications, with test kits supplied to laboratories locally and overseas, including the US, UK and Europe.

SpeeDx specialise in molecular diagnostic solutions that go beyond simple detection. They pioneered the first STI PCR test that simultaneously detects an infecting organism and its antibiotic resistance status, thus empowering clinicians to make informed clinical decisions. Their suite of patented PCR technologies enable highly accurate mutation detection, and market-leading multiplexing that double the number of results per sample, compared to standard methods.

Global commercialisation and manufacturing scale-up has been supported by significant awards, including $4.3M from the NSW Health Medical Device Fund (2014/2017), and the Manufacturing Modernisation Fund (2021). In recognition of their innovation, SpeeDx were named Australian Company of the Year by AusBiotech and Johnson&Johnson (2021), and founders Alison Todd and Elisa Mokany, received the Prime Minister's Award for Innovation (2022).

Since 2019, SpeeDx expanded AMR market access through a collaboration with Cepheid, developed clinical trial tests for GSK and are facilitating vaccine efficacy testing for another pharmaceutical giant. With key partnerships, supply of IVD products to three major European laboratory groups (Synlab, Eurofins and Cerba), and strong kit demand from a leading US laboratory, SpeeDx is a growing force in the global molecular diagnostics market.

"Over the past five years, Austrade have provided critical support for our global success,"

Elisa Mokany, CTO and Founder, SpeeDx.

www.plexpcr.com

TruScreen

Transforming cervical screening for underserved markets

TruScreen is an Australian MedTech company that has developed a real-time, AI-enabled device for cervical cancer screening. Unlike many other technologies that are used alongside traditional methods, TruScreen is approved as a primary screening tool. The company is focused on emerging markets, including China, Mexico, Vietnam, Saudi Arabia, and Central and Eastern Europe, where access to large-scale screening programs is limited.

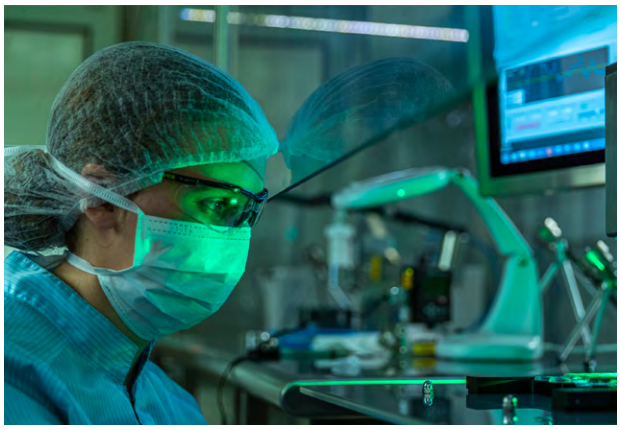
By analysing electrical and optical signals from cervical tissue, TruScreen eliminates the need for laboratory infrastructure and addresses common challenges associated with traditional cytology, including failed samples, follow-up delays, and patient discomfort. In clinical trials, TruScreen demonstrated improved outcomes compared to both cytology and HPV testing, supporting its use as a standalone effective screening option. The device is CE-marked, approved by China's NMPA, and registered in over 10 countries. TruScreen has also been recognised by the WHO, Unitaid, and the Clinton Health Access Initiative.

The company is expanding across Asia, Africa, and Latin America, helping improve access to cervical cancer screening in regions where it is most needed.

"TruScreen is fortunate to be located in Australia and in an industry which provides ready access to highly skilled Scientists, Engineers and Technicians. Being a device that is incredibly complicated to manufacture and requires engineering tolerances beyond the scope of most countries, TruScreen would not be able to proceed if we were in most other countries in the world."

Martin Dillon, CEO, TruScreen

www.truscreen.com



University research student

Vaxxas delivery of vaccine

Vaxxas

Rethinking what's possible with vaccines

Vaxxas is an Australian-based biotechnology company leading the development of microarray patch technology for the delivery of vaccines. Born from research at the University of Queensland in 2011, the company relocated from the Translational Research Institute in 2023 to a custom-built biomedical manufacturing facility in Brisbane's Northshore precinct, now home to its 130+ strong team.

Vaxxas intends to transform vaccination by replacing the needle and syringe with a small patch that delivers vaccines in a more efficient and patient-preferred manner. HD-MAP-delivered vaccines also have the potential to be stored and transported at elevated temperatures, making them more accessible, and require less vaccine to achieve a stronger, faster immune response.

Vaxxas' HD-MAP technology has completed five successful Phase I clinical trials involving over 500 participants, with vaccines addressing some of the world's biggest health challenges, including COVID-19, flu, measles, and rubella.

The company is also conducting its first US IND-enabled Phase 1 clinical study for an avian influenza vaccine in collaboration with the US Government and is advancing the scale-up of its biomedical facility to manufacture products for late-stage clinical trials and first commercial products.

"Australia is innovative by nature and has credibility and history on the global stage. Its vibrant and supportive ecosystem, including world-class research from our universities, exceptional STEM talent and a growing infrastructure, makes it a great place for companies like Vaxxas to thrive."

Michael Junger, Director – Industry and Government Relations, Vaxxas

www.vaxxas.com

Orthocell

Novel solutions to regenerate mobility

Peripheral nerve injuries can have serious impacts on movement and quality of life. In many cases, recovery is slow and incomplete. Orthocell is addressing this challenge with regenerative technologies that support the body's natural healing process, helping surgeons repair damaged nerves more effectively.

Headquartered in Perth, Orthocell develops and manufactures collagen-based medical devices designed to restore function and improve surgical outcomes. Its lead product, Remplir™, is a soft, flexible wrap used to protect and support injured nerves during surgery. By creating a protective environment around the nerve, Remplir helps reduce scarring and encourages faster, more reliable healing. The product is manufactured using Orthocell's proprietary SMRT™ process, which preserves the natural collagen structure to support tissue integration.

To date, more than 70,000 patients have been treated with Orthocell's collagen products, with no reported adverse events. Since receiving TGA approval and reimbursement in 2022, Remplir has been adopted by more than 200 surgeons across over 100 hospitals in Australia. In 2025, the product received regulatory approval in the United States, Thailand, and Canada, unlocking access to three fast-growing nerve repair markets worth over US$1.7 billion combined.

Backed by strong clinical uptake and a growing global footprint, Orthocell is demonstrating how Australian innovation can lead in regenerative medicine.

"Australia's MedTech ecosystem has provided Orthocell with the necessary support—ranging from local market success and manufacturing infrastructure to strategic partnerships and financial backing—to facilitate its growth and successful expansion into global markets."

Paul Anderson, CEO, Orthocell

www.orthocell.com

Orthocell Laboratory

Remplir

Neo-Bionica

Advancing global neurotech from the heart of Melbourne

As the demand for next-generation implantable devices grows, medical innovators face significant challenges in rapidly translating ideas into functional, clinically ready prototypes. Neo-Bionica is helping bridge that gap. Based in Melbourne and co-located within St Vincent's Hospital, the company provides end-to-end neurotechnology development and manufacturing services for startups and established MedTech firms alike.

Neo-Bionica offers a rare combination of design, engineering, regulatory, and manufacturing capabilities under one roof. This integrated, full-service model accelerates development timelines, reduces risk, and ensures that new devices are informed by daily, face-to-face engagement with clinicians. The company is also the only contract manufacturer in Australia offering hermitization services, a critical capability for sealing implantable devices such as pacemakers, deep brain stimulators, and biosensors.

Led by a team with deep experience at global leaders like Medtronic, Cochlear, Siemens, Synchron, and Advanced Bionics, Neo-Bionica has quickly earned a reputation for quality and reliability in a highly specialised field. Since launching, it has supported neurotech and bioelectronic device development in areas such as epilepsy, spinal cord stimulation, fetal monitoring, nerve regrowth, cardiovascular health, and more.

Today, around 75% of Neo-Bionica's revenue comes from international clients, with active projects in the US, UK, Germany, Japan, Spain, and Switzerland. By enabling faster, safer development of complex implantable technologies, Neo-Bionica is exporting Australia's advanced neurotech capabilities to the world.

"Our location within the hospital is unique globally. We interact with clinicians daily, gaining real-time feedback on prototypes, designs and concepts. This face-to-face engagement accelerates development cycles and ensures devices are clinically relevant and effective, which ultimately improves patient outcomes."

Dr Ludovic Labat, CEO, Neo-Bionica

www.neobionica.com

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This report was prepared in partnership with the Medical Technology Association of Australia (MTAA)

The Medical Technology Association of Australia (MTAA) is the national peak industry association representing manufactures and suppliers of medical technology across devices and digital health (MedTech) used in the diagnosis, prevention, treatment and management of disease and disability. MTAA's membership encompasses a diverse range of Medtech companies including established global Medtech companies all the way to emerging start-ups seeking to commercially translate Australia's world class research into market leading concepts.

www.mtaa.org.au/

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