



Australian Government

Biotechnology in Australia

Strategic plan for health and medicine



Australian Government
Department of Health

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Title: Biotechnology in Australia - strategic plan for health and medicine

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Ministerial Foreword

Biotechnology is one of the most promising developments of our times. It has ushered in an era of new and improved therapeutics and treatments that are saving lives and improving well-being of everyday Australians.

The Australian Government is committed to nurturing a thriving and vibrant biotechnology sector that attracts global attention. We are building on the 2018 National Health and Medical Industry Growth Plan and looking ahead to the next decade. We are making significant investments in the ecosystem to encourage research – from blue-sky to applied – which can be translated and commercialised into medical products, including new drugs and devices.

Globally and within Australia, there are new challenges to delivering health and wellbeing needs. There are also opportunities to address those needs. We have a highly-skilled workforce, competitive and attractive clinical development capabilities, well-targeted tax incentives, secure and advanced infrastructures, growing manufacturing capacity, and a strong regulatory environment. This means we are positioned to accelerate the translation of research into real world outcomes.

This strategic plan represents the many ways in which the Australian Government will continue to support all parts of the research and development pipeline. It provides incentives to grow Australian sovereign capacity and capability to research and manufacture locally while embedding into a growing international supply-chain for advanced medical products. Australians have seen the growth of successful companies like the CSL, ResMed and Cochlear. I am confident that within the next decade we will see more such companies grow as shining examples of our success.

Greg Hunt



Introduction

Biotechnology has a track record of improving lives and with the right policies and investments, it will continue to do so.

Biotechnology uses living organisms, or their products to modify human health and the environment. The biotechnology sector is inherently disruptive, as shown by advances in genomics and it is increasingly being supported by other rapidly advancing technologies such as Artificial Intelligence and 3D bio printing.

The importance of biotechnology to the Australian government is emphasised by the range of biotechnologies included in the List of Critical Technologies in the National Interest¹ which is underpinned by the Blueprint and Action Plan for Critical Technologies.

While the applications of biotechnology are diverse, a vibrant and thriving biotechnology sector in areas of health and medicine is underpinned by specific investments, regulations, and policies to support three key areas – basic research, clinical development, and commercialisation. This decadal plan focuses on the health and medical applications of biotechnology in Australia.

Health and medical research is one of Australia's strongest research sectors.² Australian researchers have a proven track record in generating scientific discoveries of global significance, resulting in multiple Nobel Prizes in areas of Physiology and Medicine spanning over 60 years.³ Australian health and medical science research is in the best position to capitalise on emerging and disruptive technologies such as biotechnology. This presents a unique opportunity for the sector to generate transformative outcomes that will benefit health in Australia and globally.

Australia also has unique strengths in undertaking clinical trials to test the efficacy and safety of medical products. The availability of exceptional clinical trial researchers, diversity of patient pool, use of the English language, availability of value-adding infrastructure, a seasonal difference to northern hemisphere markets, a responsive regulatory system, and advanced digital capabilities makes Australia an attractive destination for international partners to undertake clinical studies.⁴

Translating research into commercial products involves partnerships and collaborations between industry, government science agencies (e.g. Commonwealth Scientific and Industrial Research Organisation (CSIRO), Australian Nuclear Science and Technology Organisation (ANSTO), Defence Science and Technology Group), and the academic sectors, particularly where manufacturers rely on publicly funded research to feed a pipeline of innovation. Manufacturing of products emerging from biotechnology is a complex pursuit and generally requires complicated supply chains. Onshore manufacturing helps position Australia as an exporter for biotechnology products and captures economic and job gains, as well as reducing the risk of supply disruptions.

Appropriate risk-mitigation strategies are adopted throughout our biotechnology ecosystem, including through protections for intellectual properties, cyber and data systems protects Australian talent, industry, and consumers from harm. A secure research and development and translation ecosystem also makes Australia an attractive destination for international collaborators.

This document provides an overview of the current landscape and identifies initiatives that will support and grow Australia's vibrant and thriving biotechnology ecosystem, ensuring our world-class research is effectively translated into high-value products of global standing. Given the blurring of traditional sector boundaries, the converging of technologies as seen in telemedicine, gene and cell therapies, and 3D bio-printing, as well as the opportunities for cross-sector collaboration the scope of this document includes the medical technology (including medical devices) and pharmaceutical sectors as well as medical biotechnology.

Opportunities and challenges facing the sector

In December 2021, the Australian Government through Department of Health along with Department of Industry, Science, Energy and Resources convened a roundtable discussion on the key challenges facing the sector, and opportunities for improving outcomes.

The discussion complemented consultations undertaken to support development of the AusBiotech's Biotech Blueprint, and research for MTPConnect's Sector Competitiveness Plans. Complementary consultations have also been undertaken across multiple Commonwealth agencies including on initiatives such as the Critical Technology Blueprint and Action Plan, the National Manufacturing Priorities under the Modern Manufacturing Initiative, and the Patent Box initiative.

Throughout these consultative forums, stakeholders have discussed the need for a strategic plan for the sector that provides meaningful articulation of how the Government will coordinate its efforts over the next decade. Key themes emerging through discussions were:

The biotechnology sector is limited by access to capital

Biotechnology and medical technologies are capital intensive, requiring investments in high-tech equipment, costly materials, and a highly skilled workforce. Biotechnology as a high-tech sector often incurs high establishment costs (e.g. regulatory, insurance, licences, patents) and high fixed operating costs (e.g. expensive equipment, highly-skilled workforce, specialised premises) compared to other industries.

Access to capital is often cited as the key barrier and enabler for the sector to translate innovative research into commercial outcomes. The Biomedical Translation Fund (BTF) was a key example cited of a successful tool for increasing access to capital. Stakeholders deliberated that the growing pool of funders and investors who understand the nuances of biomedical sciences, including the risks involved, could mean more chances that research is translated into real-world outcomes.

There are gaps in commercialisation and translation support for the sector

We heard that the Australian biotechnology sector is currently operating primarily in the early commercialisation space and translation (i.e. technology reaching patients) is limited. Participants suggested that commercialisation and translation could benefit from an ecosystem approach, including building awareness of enabling services and entities to support the sector. Ideas to further enhance the commercialisation and translation of research included establishing funding sources that help entities, particularly Small and Medium Enterprises (SMEs), to establish proof-of-concept of new and innovative ideas. Such proofs-of-concept could establish viability from a scientific, economic, and social benefit perspective.

Australia needs to think strategically to build sovereign capability

Participants noted that the global pandemic demonstrated that Australia benefits from being embedded within the global manufacturing and supply-chain for biopharmaceutical products, however we also need to develop self-sufficient capabilities where needed. Building sovereign capability to undertake biopharmaceutical research and manufacturing was noted to be in the national interest. We also heard that a way forward could be to examine Australia's unique strengths through a gap analysis in order to support a more targeted approach to building capabilities given our small size compared to global standards.

Greater coordination of incentives and support across the pipeline will break down silos

Stakeholders also suggested greater coordination and alignment of investments across the biotechnology ecosystem will help break down silos and eliminate duplicated efforts across many portfolios and between different jurisdictions. A greater understanding of the ecosystem through richer and targeted data collection efforts will help identify gaps for improvements.

Nurturing scientific and commercialisation skills across the biotechnology workforce is key

The biotechnology sector relies on a highly skilled workforce that can respond to global megatrends. Building and maintaining a vibrant biotechnology sector requires the availability of such a workforce in Australia. We heard long-term efforts are required to nurture the necessary skills in not only scientific development, but also in commercialisation and translation, as well as providing a supporting ecosystem.

Stakeholders expressed the view that accessing reliable data and measurements relevant to the sector is challenging, and there could be a role for all parts of the sector to contribute to metrics which will allow for coordinated government and industry support. A need also exists for horizon scanning for changing technologies and emerging opportunities.

This plan sets the framework and highlights initiatives to tackle issues through a strategic lens, offering a coordinated view of current and future Australian Government support to nurture the biotechnology sector.

Nurturing Australian biotechnology sector over the next decade

The **Biotechnology in Australia Plan** is a living document that articulates the range of Australian Government initiatives that support the entire biotechnology ecosystem. This plan sets out three pillars of Government support for health and medical applications of biotechnology and signals how current initiatives align. It also provides a framework to coordinate future commitments that identify and address gaps as they emerge across investments, infrastructures, skills and capabilities.

The long-term Australian Government's Plan for biotechnology in health and medicine focuses on three key Pillars:

- **Pillar 1 - Supporting world-class research and development** by strategically investing in areas of need and driving strong partnerships between academia, government science organisations, industry, health services, and consumers.
- **Pillar 2 - Facilitating high-quality and secure clinical development** that attracts global interest by continuously improving research capabilities, processes, and infrastructure thus ensuring they remain or become globally competitive.
- **Pillar 3 - Accelerating commercialisation** through partnerships and collaborations between academics, government science organisations, and industry; regulation that is fit-for-purpose; and by supporting the development of advanced manufacturing capabilities for biopharma and med-tech products.

These Pillars correspond to the development pathway that most medical products follow i.e. from the idea, through to its development with basic and preclinical research, followed by multi-staged clinical trials, before progressing through regulatory pathways and commercial manufacturing to be available for delivering care.

The Australian Government has a key role in delivering effective policies, regulation, and investments across this pipeline to address unmet needs and de-risk innovation. This provides a universally understood vocabulary to articulate government support for measures for the entire ecosystem.

Long-term Vision for Australian Biotechnology

The long-term vision for Australian biotechnology is to create a vibrant and thriving ecosystem that promotes:

- a world-class research and innovation system supported by strong partnerships between academia, industry, health services, and consumers.
- a pipeline of innovative, high-quality biopharmaceuticals and medical technology products that attract global interest, while maintaining fit-for-purpose regulation.
- a globally recognised Australian medical products industry with the capability, capacity and expertise to locally manufacture advanced and high-value medical products using sophisticated and safe processes.
- access to national and international markets that facilitate product uptake and continuous cycles of product improvement.
- an ecosystem that supports high-quality research and its translation into commercial outcomes.

This vision aligns with the goals for the medical products manufacturing industry set out in the Medical Products Roadmap under the Modern Manufacturing Strategy (MMS).⁵

We will achieve significant growth in the sector through increased jobs and exports, and all Australians will benefit from access to leading-edge technologies. This means that over the next 10 years, the coordinated efforts across the medical and health biotechnology sector is expected to significantly contribute to our society and economy, with⁶:

- > \$8 billion in Gross Value Added
- > 1400 companies (>200 ASX listed)
- > 80,000 jobs supported
- > \$12 billion in manufacturing exports (50 per cent increase from 2019 figures) sustained growth in clinical trials (5 per cent p.a. achieved 2016-2019)

The following sections outline Australia's key strengths and the initiatives that will drive these outcomes and support the transformation of new ideas into products for patients.

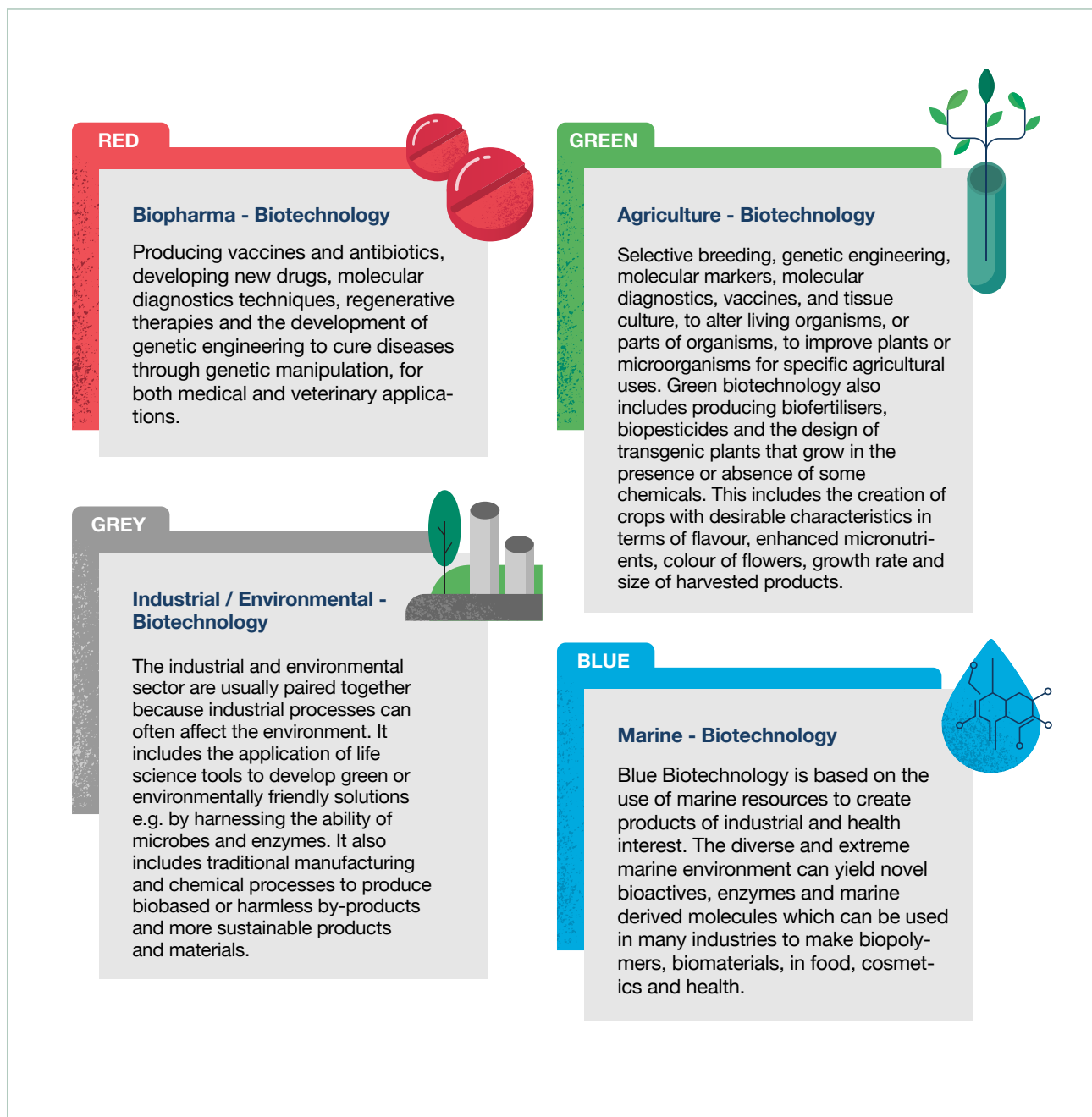
The Australian Government remains committed to the ecosystem that supports a thriving biotechnology sector, including:

- The Medical Research Future Fund (MRFF) 2nd 10-year Investment Plan, which commits \$6.3 billion between 2022-23 and 2031-32 to support lifesaving research, create jobs, strengthen the local industry base for commercialising research and innovation, and further grow Australia's reputation as a world leader in medical research.
- The \$1.3 billion Modern Manufacturing Initiative, a measure under the MMS, which identifies health and medical products as a key growth area.
- The University Research Commercialisation Package, which commits more than \$2.2 billion over 11 years to place university innovation and industry collaboration front and centre of Australia's economic recovery.
- The R&D Tax Incentive, which provides companies with tax offsets to encourage additional investment in R&D across all sectors and fields of research, including biotechnology, med-tech, and medical device development.
- The Patent Box initiative, which will apply to companies for income years commencing on or after 1 July 2022, is a concessional tax treatment applied to profits derived from eligible new patents in the medical and biotechnology sector.
- The \$501 million BTF, a co-investment program with government equity investment complementing private sector funding for promising biomedical discoveries, assisting in their commercialisation.
- Ongoing investments through National Health and Medical Research Council (NHMRC) and Australian Research Council (ARC) to support scientific research.



Biotechnology sector: overview and megatrends

Biotechnology at its simplest is technology based on biology. It harnesses cellular and biomolecular processes to develop technologies and products that can improve our health and well-being, economy, and environment (see Box 1 below for types of applications). Biotechnology includes the synthetic biology field of science that applies genetic technologies to rapidly design and build novel solutions such as engineered biosensors for rapid point-of-care tests, cell-based therapies, and vaccines.

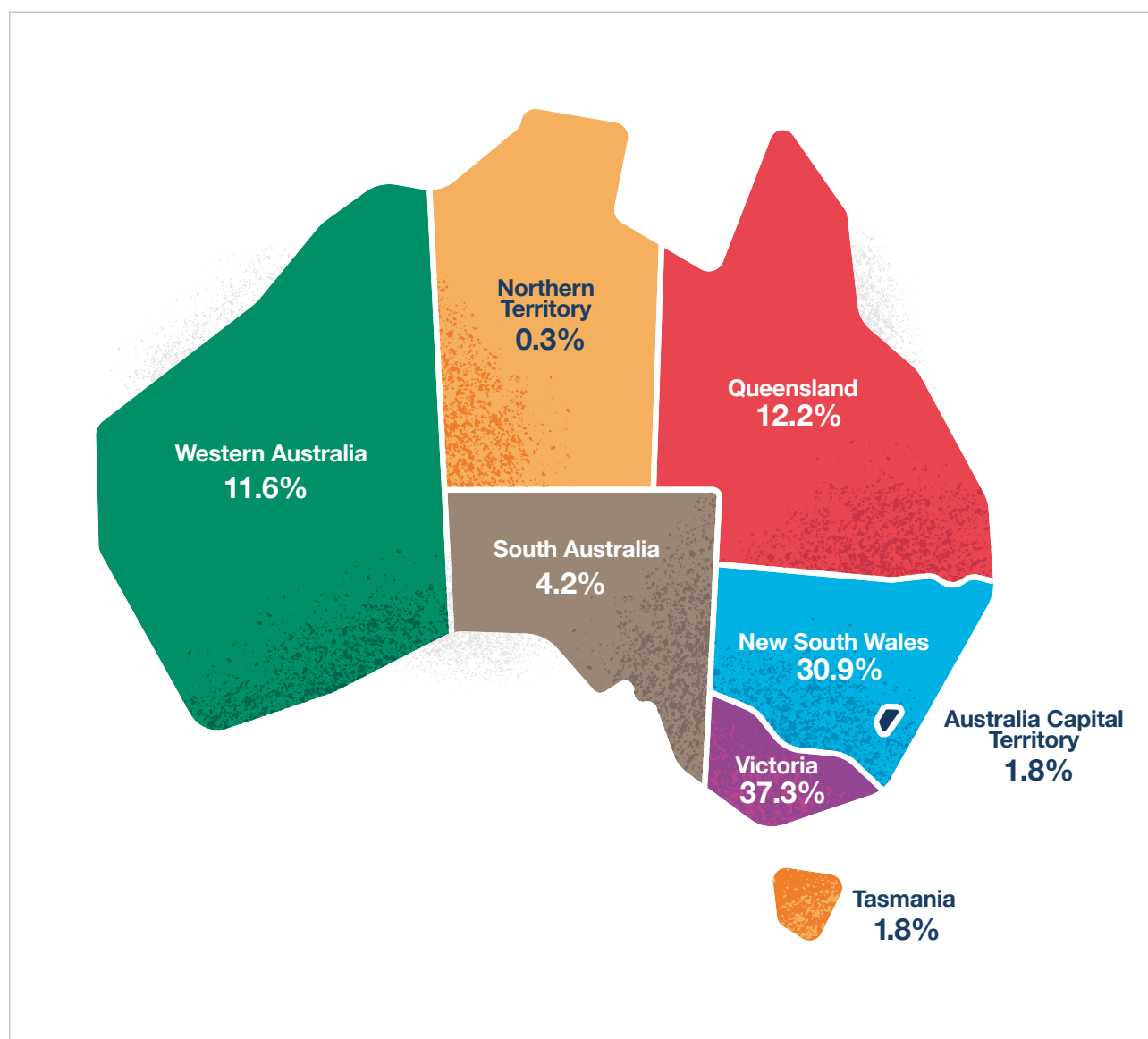


Box 1 – Biotechnology has diverse applications across sectors

Biotechnology has many applications in the health, agriculture, marine, industrial, and environmental sectors. The 2021 Australian biotechnology ecosystem is worth more than \$8 billion in annual revenue with annual growth projected at 3 per cent over 2021-2026. There are 540 businesses in the sector employing 16,310 staff, of which human health biotechnology represents more than 53 per cent of the product and services segmentation.⁷ Food and agriculture are likely to be the fastest-growing applications of biotechnology in the medium term, and the largest portion of the sector in terms of production and jobs.

The sector includes a range of players, including research organisations, smaller start-ups, and commercially viable operations that sell products in domestic and international markets. Their geographical distribution is largely determined by universities or other major research centres (Figure 1).

Figure 1 – Distribution of biotech establishments across Australia (per cent)



A focus on health and medicine

The health and medical applications of biotechnology are diverse. The age of synthetic biology is increasingly contributing to a wide variety of biological systems with the potential to improve human health such as vaccines, diagnostics approaches (such as synthetic biology-enabled reporter systems), and therapeutics (such as antivirals and genetic therapies). Globally, the health and medical applications of synthetic biology alone had a market worth of \$3.13 billion in 2019 and are expected to reach over \$241 billion by 2040. CSIRO's recent analysis projected that Australia could capture 3 per cent or over \$7 billion worth of this market by 2040.⁸

The opportunities and challenges across health and medicine and the applications of biotechnology are driven by megatrends observed across the sector.

Sector megatrends

The health and medical applications of biotechnology are heavily influenced by technology development, demographic shifts, and emerging health needs including those arising from unexpected or unpredictable weather events. The COVID-19 pandemic also continues to create widespread disruptions to health systems, generating new needs. In a post-pandemic future, there is a potential for changing burden of disease and workforce impact if new strains of the virus emerge or long-COVID proves common and long-lasting.

Changes in technology are also generating new opportunities. For instance, the transformational tool CRISPR/Cas9 ("clustered regularly interspaced short palindromic repeats") is increasingly adopted for gene-editing. Development of gene-drives, and the synthesis of mRNA-based vaccines and therapeutics provide innovative solutions to respond to health and medical needs. Australia's Synthetic Biology Roadmap identifies that global synthetic biology capabilities are maturing rapidly, with nations that invested early capturing greater market share. Australia could position itself to be a leader in synthetic biology in the Asia-Pacific region and maintain the competitiveness of critical national industries.⁹

These developments are coupled with a willingness of Australian consumers to accept new solutions. Australians are often early adopters of new health technology, driving demand and giving Australian companies a competitive advantage from an informed test market before they take their products global. A recent baseline survey of public attitudes to synthetic biology found that broadly *"Australians are "curious", "hopeful" and "excited" about how the emerging field of synthetic biology could address some of Australia's environmental, health and agricultural problems."*¹⁰

It is worth noting that the convergence of digital systems and human biology also creates new risks and the potential for new types of harms, particularly as health data can be particularly sensitive. The survey results included information about the types of risks and concerns people held, as well as their expectations of the management of the technology. This highlights the need for ongoing engagement with the community about new technologies.

In 2019 MTPConnect identified several megatrends impacting the medical technology, biotechnology, and pharmaceutical (MTP) industries (see Box 2),¹¹ with data being fundamental¹² to many of these megatrends.



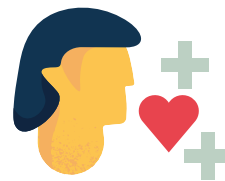
Digital evolution

Digital technology and big data is expanding worldwide including driving digital evolution in health such as telehealth.



Chronic burden

New innovations are allowing us to manage chronic disease and live longer than ever before.



Consumer control

Technology and information access are empowering patients to manage their own healthcare.



Healthy Ageing

Demographic shift in Australia and elsewhere is driving focus on maintaining good health for longer.



Developing markets

Developing countries and economies are fuelling a rising demand for healthcare solutions.



Precision Healthcare

Rise of targeted pharmaceuticals, biologicals, and personalised medical technologies.



Integrated Care Models

New models of care to better address the context and specific needs of the patient.



Global biosecurity

Pandemics, antimicrobial resistance, and other infectious diseases continue to threaten even well-developed healthcare system.



Value-based healthcare

Rising costs drive a patient-centric model where patient's health outcomes drive the choice, delivery, and reimbursement of therapies.

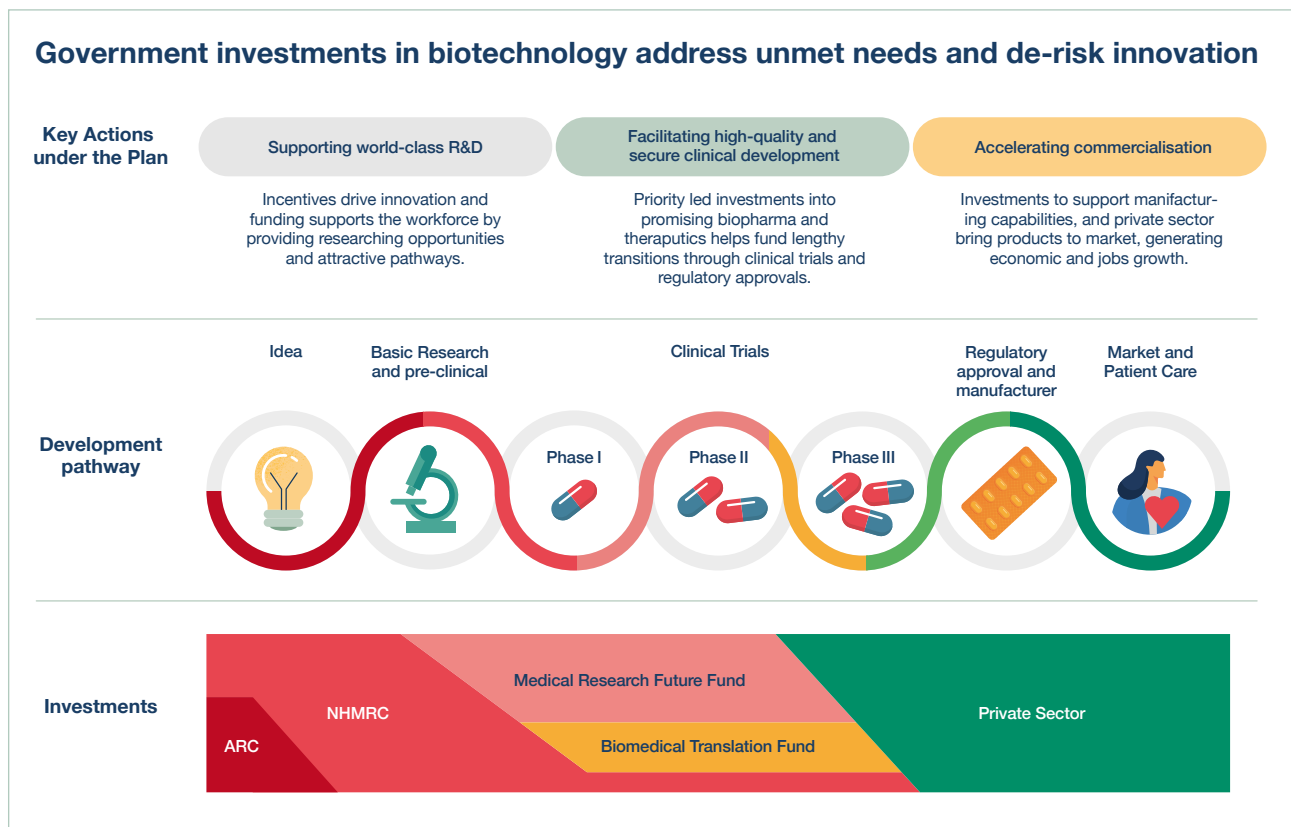
Policy and investment landscape: Developing a vibrant and thriving health and medical biotechnology ecosystem

Supporting the health and medical research and product development pathway

Translating an idea into patient care follows a highly regulated pathway (Figure 2) that is resource and time intensive. Analysis of clinical trials data over 2011-2021 has shown the overall probability of success for products transitioning from basic research into an approved product is at 7.9 per cent, and on average it takes 10.5 years for a Phase 1 asset to progress to regulatory approval.¹³

Supporting the pathway are a range of initiatives that are targeted to support a specific part of the pathway as well as those that have cross-purposes. These initiatives form the three key pillars under the Biotech 10 Year Plan, driving ideas through the pipeline from initial fundamental and applied research (such as through investments in research, including R&D tax incentives) while creating incentives to support industry development and manufacturing capability (such as through the patent box initiative, co-investment under the BTF and grants under the MMS).

Figure 2 – Development pathway for medical, biotech, and pharmaceutical, and major sources of funds across stages



Note – Establishing safety and efficacy of medical devices may not always require clinical trials stages.

Pillar 1 -Supporting world-class Research and Development

Basic research and discovery processes are at the core of a biotechnology ecosystem. A world-class research and innovation system supported by strong partnerships between academia, government science organisations, industry, health services, and consumers ensures there is a constant source of innovative ideas to solve contemporary challenges. Australia has rich biodiverse genetic resources and, as traditional custodians, Aboriginal and Torres Strait Islanders have a wealth of knowledge that could support the discovery process and lead to benefits-sharing agreements.

Australia's academic strength ranks in the top 10 global rankings in biological sciences, including biochemistry and cell biology, synthetic biology, genetics, and microbiology. Academic strengths in medical biotechnology and nanotechnology are also ranked 7th and 9th in the world.¹⁴

The Australian Government helps maintain world-class research by ensuring sustained investments are made including through foundational investments such as funding by NHMRC, ARC, and Research Block Grants; and targeted and priority-led investments such as through the MRFF. Researchers have access to cutting-edge research infrastructure through the National Collaborative Research Infrastructure Strategy (NCRIS) program.

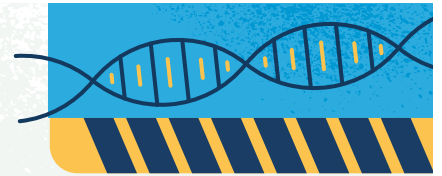
Successes emerging from basic research



Australian Government funded basic research has led to health and medical product developments such as:

- the world's first protein sequencing machine: the sequenator, whose design enabled the generation of vast amounts of biochemical data on proteins and the cloning of many molecules now used as drugs
- an anti-viral agent: zanamivir, one of the first drugs produced by 'rational design' informed by X-ray crystallography and the first specific anti-influenza drug
- new products for treating lung conditions, including mepolizumab, a monoclonal antibody used to treat severe asthma, and Bronchitol, which assists the breathing of patients whose lungs are inflamed or infected
- a topical treatment for pre-cancerous sun spots: Picato gel, which was developed after biochemical investigation of the sap of the Euphorbia peplus (milkweed) plant
- the world's first human papillomavirus vaccine: Gardasil, which provides protection against cervical cancer and which has been introduced into the national routine immunisation schedules of 110 countries
- a potent new anti-cancer drug: venetoclax, which causes the death of cancer cells and thereby slows down progression of the disease, and is currently approved for use against chronic lymphocytic leukaemia
- precision immunology: undertaken by the Centre for Personalised Immunology (CPI), which can identify harmful variants within a patient's genetic code and inform the development of patient-specific therapies.

CSIRO support for innovation in biotechnology



CSIRO is Australia's national science agency and plays a key role in driving innovation and technology development, and in fostering a strong science and research base. CSIRO is active in medical biotechnology research including:

- discovery research and non-clinical development for medical products including small molecule therapeutics, biological therapies, vaccines, diagnostic technologies, and medical devices
- disease models (animal models) and conducting pre-clinical validation (animal trials) of medical products, with a focus on those that require high levels of biocontainment
- digital platforms that support health and medical data interoperability and enable next-generation bioinformatics
- research into immunological techniques, innate immunity, inflammation, comparative immunology, immune cell effector function, integrated immune response, mucosal immunity, immunodeficiencies, host-pathogen interactions, and vaccines and therapeutic development.

CSIRO has many medical biotechnology infrastructure facilities including specialised laboratories and equipment to support cellular enumeration, multiparametric flow cytometry, phenotypic characterization assays, functional and serological profiling, and bioinformatics analysis.

The CSIRO BioFoundry at Dutton Park in Brisbane is a multimillion-dollar automated laboratory facility that enables rapid, high throughput engineering of biology, including microbial strains, enzymes, biosensors, and other biological components. Globally, BioFoundry facilities have been used for the rapid development and validation of diagnostics and vaccines for viruses, including SARS-CoV-2.

Biosecurity applications of biotechnology is also highly relevant, particularly responding to animal health needs and zoonotic diseases. Many technologies (including vaccine manufacturing) are aligned or are directly applicable to both human and animal health needs.

CSIRO's work in biosecurity applications of (medical) biotechnology includes:

- development of novel early disease diagnostic tools
- undertaking novel vaccine and anti-viral therapeutics development, testing, and early stage manufacture
- offering services in rapid gene screening and multiomics and bioinformatics relevant for understanding immune responses in detail – to better target therapeutics
- gene scanning and editing capability in disease vectors including for disease resilience/resistance.
- performing genome engineering in livestock to develop disease resilience and address welfare and ethics in production and issues of food safety, as well as genome engineering in pest animals to develop genetic biocontrol options to suppress and mitigate pest animal impacts on agriculture and the environment.

CSIRO also manages the Australian Centre for Disease Preparedness (ACDP) facility as a vital part of Australia's biosecurity infrastructure. It provides Australia's highest level of biocontainment within a purpose-built biosecurity infrastructure. The ACDP provides for research into new and emerging infectious diseases that affect both animals and people, as well as offering technical policy advice and training and providing diagnosis, surveillance, and response services.

Pillar 2 - Facilitating high-quality and secure clinical development

Clinical development is the next critical step in the research and development of medical technologies. It involves testing of the efficacy, toxicity, and safety of novel health products. Testing includes within laboratory settings, in animals and cell lines, and when demonstrated safe enough to progress, human trials.

The clinical trials sector employs 8,000 Australians. More than 95,000 Australians participated in clinical trials in 2019, which saw around 1,880 trials started. In 2019, \$1.4 billion was spent on clinical trials in Australia. The Australian Government supports investigator-initiated clinical trials through NHMRC and the MRFF, complementing private sector investment in industry-initiated trials. Since 2017, Australia has increased its competitive standing in early-stage clinical trials (Phase I and Phase II) and oncology, pneumology, neurology, and ophthalmology trials, while maintaining its share of late-stage trials (Phase III and Phase IV).¹⁵

Australia has a significant reputation as a 'go to' destination for conducting clinical trials¹⁶ owing to:

- availability of medical experts and research staff of global standing
- high quality of research and data, including high-quality publications
- compliance with Good Clinical Practice and high standards of data collection
- specialised and dedicated infrastructure including highly regarded Phase I specialised service providers and sites
- efforts to streamline regulatory and ethics approval including through the Clinical Trial Notification scheme by the Therapeutic Goods Administration (TGA) and reforms such as the National Mutual Acceptance scheme for efficient ethics processes, and
- R&D Tax incentives providing tax relief and cost competitiveness to encourage more private sector investment in R&D activities. AusIndustry, in consultation with the Australian Taxation Office and the Department of Health portfolio, are launching a determination to make it easier for companies to access the program if they are undertaking a phase 0, I, II, and/or III clinical trial for an unapproved therapeutic good.

Medical Research Future Fund

The MRFF was set up by the Australian Government in 2015. In July 2020, the fund grew to \$20 billion. The net interest earned from the fund invests into important health and medical research projects.

The MRFF operates within a broader context of Australian Government support for health and medical research that includes funding through NHMRC and the Biomedical Translation Fund, all seeking to improve health and wellbeing. The strategies and operations of the MRFF and NHMRC are aligned and complementary: whereas NHMRC supports national research activity and capability across all areas of health and medicine, MRFF research prioritises current and emerging health needs, addressing burden of disease and gaps in translation and health outcomes.

The Australian Government has committed \$6.3 billion for health and medical research through the 2nd 10-year Investment Plan for the MRFF. The 2nd 10-year Investment Plan provides funding to 2031-32 to support lifesaving research, create jobs, strengthen the local industry base for commercialising research and innovation, and further grow Australia's reputation as a world leader in medical research. MRFF funding is directed into 4 themes:

- **Patients (\$1.4 billion over 10 years)** - this theme aims to bring benefits to patients, including supporting life-changing clinical trials, funding innovative treatments and advanced health care and medical technologies.
- **Research missions (\$1.5 billion over 10 years)** are large programs of work that bring together key researchers, health professionals, stakeholders, industry partners and patients to tackle big health challenges.
- **Researchers (\$1.3 billion over 10 years)** - this theme aims to support Australian researchers, including to help build their skills and capacity, support their research in priority areas and assist them to develop and bring new research discoveries to the market.
- **Research translation (\$2.1 billion over 10 years)** - this theme aims to translate research outcomes into practice by building the evidence base to support the adoption of best practice care in to health care delivery.

Developing new drugs, devices, treatments and cures may take more than a decade. The 2nd 10-year Investment Plan gives researchers and industry certainty and direction so that they can address areas of unmet need and excel in collaborative and transformative research.

MRFF activities are based on areas of national priority identified by the Australian Medical Research Advisory Board following a national consultation process. Activities put patients at the core and focus on translating research into practice so that all Australians can benefit.

Medical Research Commercialisation – the BioMedTech Incubator

The Medical Research Commercialisation Initiative under the MRFF supports innovative early-stage health and medical research, and helps researchers transform ideas into medical interventions provide important support for generating 'proof-of-concept' and opportunities for commercialisation. This initiative has provided \$67 million in funding to early stage SMEs through the BioMedTech Horizons and Biomedical Translation Bridge activities. It recently funded the \$79 million Early Stage Translation and Commercialisation activity, which provides funds to support early stage medical and research projects with commercial potential. It is also establishing the BioMedTech Incubator announced in January 2022. The BioMedTech Incubator will provide a suitable organisation up to \$50 million to establish a research incubator that nurtures Australian SMEs undertaking early-stage medical research projects with funds of up to \$5 million.



The Australian Government is working with all jurisdictions and key stakeholders to improve the operating environment for clinical trials and research

All jurisdictions are collaborating to further strengthen Australia's clinical trials sector and address issues of duplication and fragmentation under the Revitalised Clinical Trials Agenda endorsed by all Health Ministers and using stimulus from the Commonwealth's Encouraging more clinical trials in Australia initiative. A key focus has been redesigning trial operations around coordination hubs and central points of contact to improve system navigation for sponsors and participants, streamline trial processes and time to trial start-up, and improve workforce capacity. Significant improvements have been occurring across jurisdictions as a result of the initiative and the Australian Government announced a further investment of \$6 million over the next 4 years from 2021-22 to extend the measure, in recognition of the positive progress to date.

The development of the National Clinical Trials Governance Framework is a key element of the clinical trials reform agenda to ensure nationally consistent accreditation of health services undertaking trials. The Governance Framework will embed clinical trials into routine health care and strengthen clinical and corporate governance arrangements for governments, hospital administrators, health services, private companies, trials sponsors, and trials investigators that deliver clinical trials. The Governance Framework aligns with the existing National Safety and Quality Health Service Standards and regulations for the conduct of clinical trials and provides the actions essential for health service organisations to achieve accreditation, including operational measures of efficiency. Importantly, it will reduce duplication and increase efficiency, cohesion, and productivity across the sector. A maturity approach to implementation will be adopted and the Australian Commission on Safety and Quality in Health Care will continue to support sites throughout this process. Once embedded, responsibilities under the Governance Framework will be mandatory for health service organisations and trial sites providing clinical trial services.

In addition, progress is being made on the National One Stop Shop for Clinical Trials and Human Research Approvals, and a related National Clinical Trials Front Door (NCTFD). The One Stop Shop represents a significant opportunity to achieve an interconnected, rapidly responsive, streamlined, and intuitive platform to fast-track trial commencement and patient recruitment. It will facilitate rapid and streamlined approvals, support sites in meeting new accreditation requirements and address long-standing challenges with duplication, delays, and fragmentation, reduce investigator and sponsor administrative and navigation burden and expedite time to trial commencement. This functionality and its delivery will significantly progress Australia's agenda to position itself as a global leading destination for research and clinical trials and ensure better health for Australians. It will also enable increased investment in the sector and contribute to economic recovery in the COVID-19 pandemic environment. The One Stop Shop will assist all governments to respond to areas of need in a rapid, coordinated, and strategic manner, based on real-time, accurate information regarding trial activity and site capability. The One Stop Shop and NCTFD will also enable increased investment in the sector and contribute to economic recovery in the COVID-19 pandemic environment.

Pillar 3 - Accelerating commercialisation

Manufacturing is a key step to scale up successful products so that they can be made available to markets for use. In April 2021, the pharmaceutical manufacturing industry was worth \$12.7 billion, reporting a \$1.5 billion profit. Approximately 43 per cent of the revenue was generated through exports in 2020-21, reflecting the industry's global nature.¹⁷

The translation of research into commercial outcomes may be challenged by difficulties attracting early investment from the private sector. Furthermore, biotechnology products are likely to require investment in specialised skills and equipment which are not readily available to small and medium enterprises that make up most of the sector. Seeking early private sector investment (possibly through licensing or selling intellectual property rights) may also need to be traded off by the sector against the cost of adding further value to innovation through further publicly funded research prior to commercialisation.

To address these issues, the Australian Government is making strategic investments into research commercialisation:

- The \$501 million BTF was established as a co-investment program with government equity investment complementing private sector funding for promising biomedical discoveries, assisting in their commercialisation. It does so by addressing capital and management constraints to encourage the development of companies that are commercialising biomedical discoveries.
- The \$1.3 billion Modern Manufacturing Initiative, a measure under the MMS, identifies health and medical products as a key growth area and supports Australian manufacturers to become more competitive with successive rounds of funding under the Translation, Integration and Collaboration streams.
- The University Research Commercialisation package commits more than \$2.2 billion over 11 years across several initiatives, including providing incentives for research with commercial outcomes, and partnerships between universities and businesses.
- The Government has reached in-principle agreement with the Victorian Government and global mRNA company Moderna to establish a new sovereign vaccine manufacturing facility in Australia. It will produce respiratory mRNA vaccines for potential future pandemics and seasonal respiratory illnesses, and strengthen biopharmaceutical research and development, clinical trials and global supply chain access.

These measures complement existing government support in developing national research infrastructure – including the ANSTO's National Deuteration Facility¹⁸, which produces large quantities of deuterated biomolecules for both biomedical research and the pharmaceutical industry – that will support on-shore research and commercialisation of mRNA products into the future. CSIRO supports the industry with development and optimisation and novel processes for manufacturing medical products from concept up to phase I clinical trial quality and scale. CSIRO is also in the final stages of building a pilot production facility for biological drug and vaccine production, to enable companies to optimise and produce TGA-approved material for phase I and II clinical trials.

Synthetic Biology – A National BioFoundry



Synthetic biology is an emerging discipline in Australia that creates customised biological molecules and designs biological pathways. Synthetic biology uses a high throughput, cyclic workflow of designing, building, testing and improving genetic material to reach a goal. This cycle is completed at integrated facilities known as BioFoundries.

The Australian Government recently invested \$8.3 million to create Australia's first fully-integrated BioFoundry, under the Bioplatforms Australia NCRIS project. The BioFoundry will integrate existing investments in synthetic biology and provide additional equipment, technical expertise and data computation, all under a centralised service delivery model. This integrated service will also strengthen the research commercialisation pathway for biotechnology in Australia.

This new facility will increase the number of concurrent biological development research activities that can be undertaken with synthetic biology through automation, robotics, machine learning and artificial intelligence, accelerating research outcomes. This will help address national challenges – some outputs currently anticipated include:

- Manufacture of new vaccines and development of living therapeutics for conditions ranging from COVID-19 to Alzheimer's disease
- Life-saving corrections to diseased cells in patients through personalised gene therapies, treating conditions such as cancer
- Biosensors to detect disease in crops for early detection of food spoilage, reducing waste and increasing food security
- Producing plants and crops that can respond to the future drought and salinity impacts of a changing climate.

Regulation forms an important part of the product development pathway, ensuring safety and efficacy before a product can be used. The TGA is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood, and blood products.

Almost any product for which therapeutic claims are made must be entered in the Australian Register of Therapeutic Goods before it can be supplied in Australia. Before this registry action occurs, products are reviewed in the Australia's Health Technology Assessment (HTA) approval processes for new drugs and novel medical technologies, involving a range of processes and mechanisms relying on scientific evidence to assess their quality, safety, efficacy, effectiveness, and cost-effectiveness. Regular reviews and reforms of the HTA processes have delivered incremental and sustained improvements at the technical assessment and process levels. These provide an established and transparent approach for assessing a wide variety of health technologies that continue to deliver good outcomes for Australia.¹⁹

The TGA regulates therapeutic goods through pre-market assessment, post-market monitoring and enforcement of standards, licensing of Australian manufacturers, and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

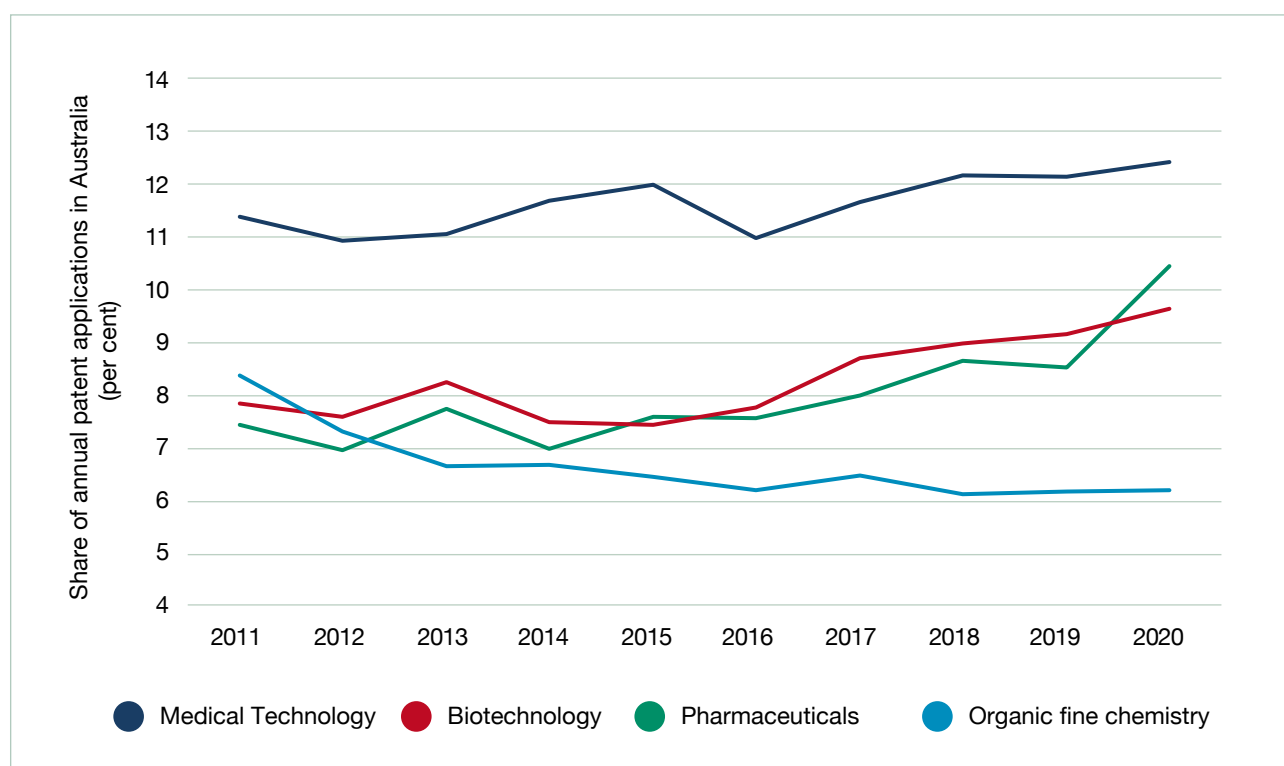
Therapeutic goods regulation can be challenging to navigate, particularly for small biotech startups. The TGA's SME Assist is a dedicated service to help small to medium enterprises, researchers, start-ups, and those unfamiliar with therapeutic goods regulation understand their regulatory and legislative obligations.

Marketing of products is underpinned by business confidence that the value of research and innovation is protected. The biotechnology sector is a research-intensive sector with significant costs associated with the development of new products and processes. Patents protect commercial rights for new inventions, and are of interest to investors. Patents also can be licensed, particularly for smaller biotechnology companies, to larger companies who have the manufacturing capabilities to scale production and compete in consumer markets. While these strategic alliances are one option, the Australian Government is seeking to develop other options for SME manufacturing of their intellectual property, set out under the Modern Manufacturing Strategy.

IP Australia administers patent rights in Australia for new, inventive, and useful devices, substances, methods or processes. Australia's intellectual property arrangements rank 11th in the world for security making it an attractive business operational environment.²⁰

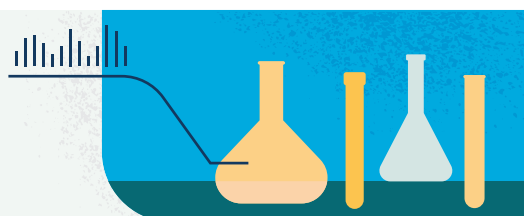
Three leading classes of patent applications filed in Australia in 2020 were in medical technology (3701), pharmaceuticals (3106), and biotechnology (2865) (Figure 3). In 2019 (latest data), Australians increased their number of patents filed overseas by six per cent – nearly four times as many applications were filed by Australians overseas compared to domestically. The US remains the primary destination country, receiving 37 per cent of Australians' international filings.²¹

Figure 3 – Leading classes of patent applications in Australia



Supporting the pathway are organisations such as the MTPConnect, established as an Industry Growth Centre. This Industry Growth Centre has a broad mandate which includes increasing collaboration and commercialisation across the sector, improving management and workforce skills, improving access to global supply chains and international markets and optimising the regulatory environment.

mRNA's great potential



mRNA vaccines have emerged as some of the best vaccines to fight COVID-19. The COVID-19 mRNA vaccines, developed by Pfizer/BioNTech and Moderna, use part of the RNA code from the SARS-CoV-2 virus (the virus that causes COVID-19) to spark the production of the coronavirus' specific spike protein. Immune cells recognise the spike protein as foreign and begin building an immune response against it and creating memory cells and antibodies that protect against future infection.²²

The Australian Government recognises that mRNA technology is part of the next generation in advanced healthcare. Building on the success of COVID-19 mRNA vaccines, the Government announced it had reached an in-principle agreement with the Victorian Government and global mRNA company Moderna to establish a new sovereign vaccine manufacturing facility in Australia. It will produce respiratory mRNA vaccines for potential future pandemics and seasonal health issues, and strengthen biopharmaceutical research and development, clinical trials and global supply chain. This will help ensure Australia is prepared for future health crises by investing in a transformational technology platform that can deliver population-scale health responses for ourselves and our region. This investment will also leverage our highly skilled and highly trained workforce to deliver high-paying jobs and economic growth.

The in-principle agreement builds on the Government's \$1.5 billion MMS and opportunities in the Medical Products National Manufacturing Priority Road Map.

The potential application of mRNA platform go beyond COVID-19 vaccines, as the technology has significant potential to combat many other diseases including cancers, HIV, tuberculosis, cystic fibrosis, muscular dystrophy, malaria, and influenza.

The Australian Government, through the MRFF is providing further support to establish mRNA research capability. An investment of up to \$25 million from 2022-23 in the 2021 mRNA Clinical Trials Enabling Infrastructure grants will directly support Australian medical research and medical innovation projects that leverage and enhance emerging technologies, platforms, equipment and infrastructure to conduct clinical trials of mRNA-based vaccines and therapeutics. Funding to establish, extend and enhance the capacity, capability and effective use of Australia's health and medical research infrastructure will help Australian researchers remain at the forefront of health and medical research, and strengthen our response to the COVID-19 pandemic and future health emergencies by accelerating clinical trials of novel mRNA treatments and therapeutics.

Development and commercialisation of medical devices in Australia

The TGA describes medical devices as having therapeutic benefits, which either affect the body in a physical way or are used to measure or monitor functions of the body. Examples of medical devices include artificial hips, blood pressure monitors, and orthodontics.

Biotechnology has increasing applications within the medical devices sector such as through the incorporation of biosensors. Development of medical devices also leverages many of the facilities and processes associated with the drug development pathway (Figure 2), including to demonstrate the safety and efficacy of devices.

Research incentives and funding across the medical biotechnology sector often overlap with medical device development and commercialisation. For example, the R&D Tax Incentive provides companies with tax offsets to encourage additional investment in R&D across all sectors and most fields of research, including biotechnology, med-tech, and medical device development. Also, the BTF and the MRFF provide a boost for research and its commercialisation in health technologies covering both sectors. CSIRO has an ISO accredited facility (in collaboration with Monash University) that produces polymer and cellular materials for medical devices. This facility is available for companies to develop prototypes and short-run production of medical devices that would be accredited for clinical trials.

Approximately 80 per cent of the medical devices used in Australia are imported. The market was valued at USD 4 billion in 2016. Goldstein Market Intelligence analysis forecast the Australian medical device market size as growing at a cumulative annual growth rate of 10 per cent through the forecast years (2017-2030).²³

Government investments into research and commercialisation

The Australian Government spent over \$2 billion in the 2020-21 financial year to directly support research and development activities in health.²⁴ Australian Government investment de-risks ideas, supports innovation, and addresses unmet needs.

Foundational investments such as those provided by NHMRC, ARC, Research Block Grants, Cooperative Research Centres Program, and the MRFF help drive research in public institutions. Notably, the MRFF is a \$20 billion long-term investment in supporting Australian health and medical research to transform health and medical innovation, including innovations through biotechnology. The Australian Medical Research and Innovation Strategy and Priorities for funding from the MRFF are determined every 5 years and 2 years respectively, following national consultations to ensure focus is on areas of maximum impact.

The ARC's Industrial Transformation Research Program (ITRP) funds research hubs and training centres. The program includes Industrial Transformation Priorities that reflect the Australian Government's commitment to developing critical industry sectors and to supporting collaboration between universities and industry. Medical Technologies and Pharmaceuticals has been an ITRP Priority since 2015.

Tax measures are likely to be one of the contributing factors in incentivising R&D and attracting clinical research to Australia. A 2016 report found that clinical trials were up to 60 per cent more cost-effective compared to in the United States after tax incentives.²⁵

By reducing the costs of cutting-edge R&D, the R&D Tax Incentive encourages companies to undertake additional R&D, which delivers spillover benefits to the broader economy. Established for more than a decade, the program has delivered on average more than \$2.5 billion each year in tax offsets to over 11,000 companies conducting cutting-edge R&D. With the introduction of enhanced reforms on 1 July 2021, the program is expected to deliver increased support for business R&D in future years.

The Patent Box initiative (announced in May 2021 and will apply to companies for income years commencing on or after 1 July 2022) is a concessional tax treatment applied to profits derived from eligible new patents in the medical and biotechnology sector. The Patent Box applies to the other end of the innovation spectrum to encourage companies to base their medical and biotechnology research and development operations, and commercialise innovation, in Australia. It also aims to retain the ownership of eligible patented inventions in Australia.²⁶

The Cooperative Research Centres (CRC) Program supports Australian industries to partner with the research sector to solve industry-identified problems through CRC grants and CRC Projects grants that offers up to 50% matched funding for industry-led research.²⁷ For example, \$2.1 million was awarded through a CRC Projects grant in 2018, to develop a suite of technologies and enable CAR-T therapy for solid cancers. Carina Biotech, one of the partners on this project, announced on 1 September 2021 that it raised \$5.4 million to undertake the required studies to initiate a clinical trial of their lead LGR5-targeted CAR-T program for the treatment of advanced colorectal (bowel) cancer in late 2022.²⁸

The Defence Innovation Hub, one of the Australian Government's flagship Defence innovation programs, invests in innovative technologies that can enhance Defence capability and grow the Australian defence industry and innovation sector. As part of the 2020 Force Structure Plan, \$800 million is being invested in the Defence Innovation Hub through to 2030. The Innovation Hub provides sponsorship and funding to a variety of innovative proposals that include in biotechnology. For example, it has funded the biotech start-up GLIA to develop a microRNA based device for diagnosis and ongoing assessment of concussion, in partnership with Alfred hospital, and CSIRO.²⁹

The Australian Government is also investing \$4 billion over 12 years (2018 – 2029) through the NCRIS program to support the research infrastructure biotechnology relies on, and make sure Australian researchers can access them.³⁰ For example, Bioplatforms Australia helps researchers access equipment to study DNA, proteins, small biological molecules and ways to redesign organisms for new purposes; Therapeutic Innovation Australia helps research products to develop and navigate the commercialisation pathway; Phenomics Australia provides researchers with cell, tissue, and animal models to study diseases; Pawsey and the National Computational Infrastructure provides high-performance computing to Australian researchers, government and industry; the National Deuteration Facility provides biomolecules for research and the pharmaceuticals industry; and the new Synthetic Biology (Bio-Foundry) will design, build and test genetic material to address critical gaps in high-throughput bioengineering capability to the R&D community.³¹

Table1 – Annual investments in R&D activities in health

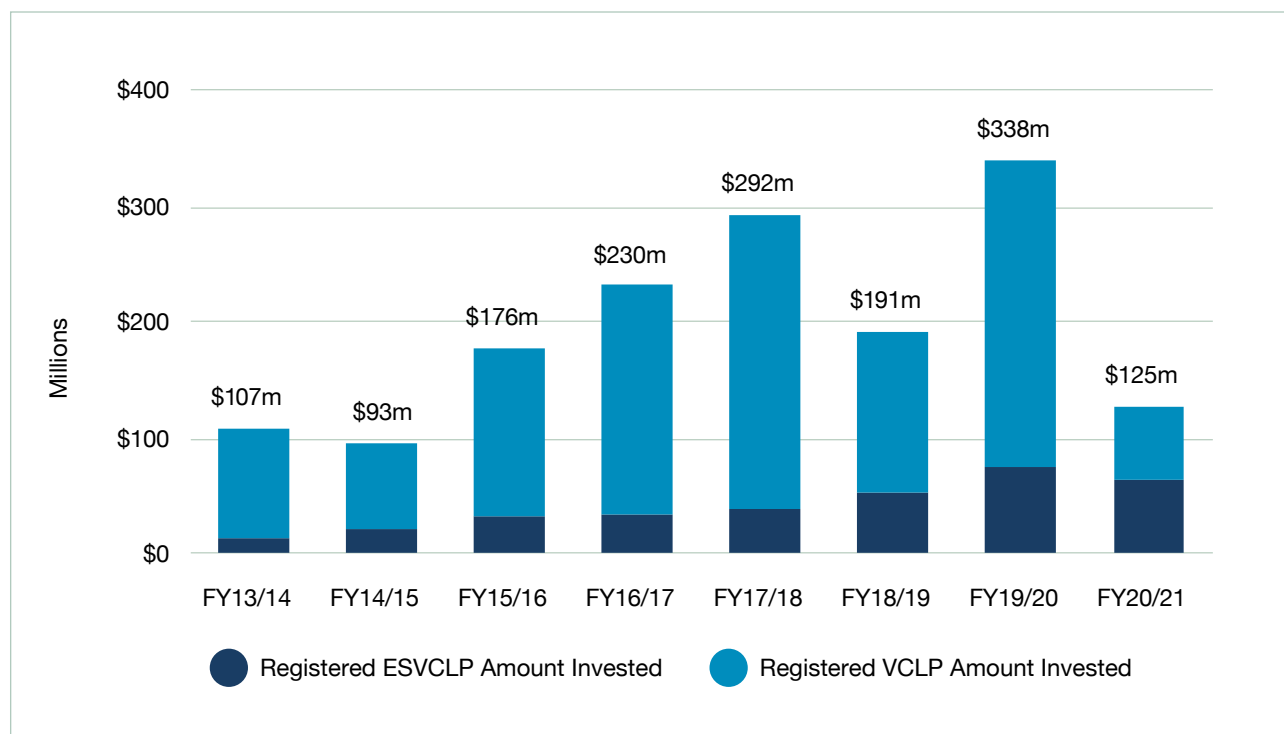
	2018–2019 (\$m)	2019–2020 (\$m)	2020–2021 (\$m)	2021–2022 (\$m)
NHMRC research grants	846	901	891	870
MRFF	222	393	580	646
BTF investments	54	29	58	25 [^]
R&D Tax Incentive	223	246	251	267
Other initiatives	119	112	99	114

Figures based on Australian Government's Science, Research and Innovation Budget Tables 2021–2022, including:

- NHMRC research grants and MRFF based on R&D investment by program/activity under the Health Portfolio
- R&D Tax incentive based on R&D investment by Socio-Economic Objective (SEO)- Industry R&D Tax measures (Health)
- Other initiatives aggregate R&D investment by program/activity under the Health Portfolio, excluding the MRFF, the NHMRC and the BTF
- BTF investments ([^]data as of 3 March 2022) provided by Department of Industry, Science, Energy and Resources.

Venture capital companies provide risk capital to innovative early-stage businesses to fund commercialisation activities. These businesses help convert research and development into commercial outcomes. They support job-creation, improved productivity, competitiveness, and economic diversification. The Australian Government attracts venture capital investments through Early Stage Venture Capital Limited Partnerships (ESVCLP), Venture Capital Limited Partnerships (VCLP), and Australian Venture Capital Fund of Funds (AFOF) programs by providing an internationally recognisable investment vehicle and incentives such as tax exemptions and offsets.³² Over the last five years, investment through venture capital in the healthcare and social assistance sector has been slowly growing (see Figure 4).

The \$501 million BTF is an equity co-investment venture capital program announced in the National Innovation and Science Agenda to support the development of biomedical ventures in Australia. The BTF policy objectives are to invest in promising biomedical discoveries and assist in their commercialisation. Furthermore, by addressing capital and management constraints, the program aims to encourage the development of companies that are commercialising biomedical discoveries. BTF funds have been invested in early research through to clinical trials and commercialisation.

Figure 4 - ESVCLP and VCLP investments in healthcare and social assistance sector in Australia

Further, the manufacturing of health and medical products has been identified as one of the six National Manufacturing Priority (NMP) areas under the Australian Government's \$1.5 billion MMS. The Government is working closely with industry on the implementation of the MMS.

The Medical Products Roadmap provides a framework, developed in consultation with industry, for opportunities in high value-add medicines (such as sophisticated pharmaceuticals, biologics and complementary medicines), cutting-edge treatments, digitally integrated products and platforms, as well as medical device and animal health. The strategy's focus is on developing the capability, capacity and expertise to locally manufacture advanced and high-value medical products using sophisticated processes.

The Government is supporting medical products manufacturing with successive funding rounds pursuant to the Translation, Integration and Collaboration streams in accordance with the Modern Manufacturing Initiative.

The MMS also includes \$107.2 million for the Supply Chain Resilience Initiative (SCRI). The SCRI is strengthening Australia's ability to access critical necessities, better positioning Australia to respond to future supply chain disruptions. The first round of the SCRI grants program sought applications to address vulnerabilities for critical products including medicines. Successful grant applicants under round 1 of the SCRI grants program were announced in December 2021; this included \$7.8 million announced for 6 projects to address identified supply chain vulnerabilities for medicines.

The Government is also protecting Australia's capability to manufacture nuclear medicines and through a \$30 million project to design a new world-leading manufacturing facility at ANSTO's Lucas Heights campus in Sydney. Once built, the new facility will not only safeguard Australia's supply of these important medicines, but will also support radiopharmaceutical research and collaboration with industry on potential new radiopharmaceuticals for diagnosis and treatment.

Developing workforce and skills

The biotechnology sector requires specialised skills to undertake cutting-edge research and translate to successful commercial outcomes. The strong growth trajectory will continually require the attraction and retention of a skilled workforce. The workforce also needs to continuously evolve and develop new skills in areas as priorities and areas of competitive advantage change.



“As the shape of the post-COVID world emerges, it is already apparent that access to global research talent and skills in emerging technologies is increasingly fiercely competitive, and that access to a range of partnerships between domestic and international industry, Government, and research networks will become increasingly important.”

Group of Eight - Submission to the Senate Standing Committee on Economics Inquiry on The Australian Manufacturing Industry, 9 September 2021³³

A 2020 survey analysed the workforce in the medical, biotechnology, and pharmaceutical sectors and identified 20 priority skills gaps. These skills gaps span seven key themes: advanced manufacturing and supply chains; business operations; clinical trials; health data and cybersecurity; health economics and regulatory affairs; product development and commercialisation; and specialist and technical skills.³⁴

Examples of how Australian Government supports skills development and retention

The NHMRC provides funding through Investigator Grants that offer flexible funding for researchers working at the pre-commercial stage in the public sector, where many researchers first learn about IP protection, regulatory processes, clinical trials among others. They offer 5 years' flexible funding to support their research and – at the senior levels – to support research teams.

On 4 September 2020, the Global Business and Talent Attraction Taskforce (Taskforce) was established to fast track Australia's post-COVID-19 economic recovery by attracting high-value businesses and exceptionally talented individuals in future-focussed sectors to Australia. The Taskforce attracts businesses and individuals from priority growth sectors such as advanced manufacturing, digitech, health industries, and life sciences³⁵. Fields of specialisation in which exceptionally talented individuals are being supported include biotechnology, biomedicine, bioengineering, cell and gene therapies, biochemistry, and cell biology.

In December 2020, the Researcher Exchange and Development within Industry (REDI) Fellowship Program was launched to provide grants of up to \$250,000 for the industry to secure Fellows from academia. Funded through the MRFF, this unique workforce initiative aims to give the industry an opportunity to accelerate collaboration with a researcher, academic, clinician, or MTP professional, and address existing skills gaps.



Improving partnerships and collaboration

The innovation pipeline for health and medical applications of biotechnology is fuelled by R&D efforts across public and private sectors including universities, research organisations including government research organisations, SMEs, and large companies. Partnership and collaboration for innovation often transcend national boundaries with research often conducted by international research teams.

In 2015, the Australian Government established MTPConnect, an independent, not-for-profit organisation to accelerate the rate of growth of the MTP sector in Australia. MTPConnect was part of the Industry Growth Centres Initiative and has a key focus on increasing collaboration and commercialisation across the sector.

University Research Commercialisation Action Plan

On 1 February 2022, the Prime Minister announced investments of \$2.2 billion over 11 years to place university innovation and industry collaboration front and centre of Australia's economic recovery.

The goal of the University Research Commercialisation Action Plan is for universities, industry and Government to partner on effective research through an aligned and prioritised investment across sectors. To achieve this the University Research Commercialisation reforms will focus research effort on the 6 National Manufacturing Priorities (of which Medical Products is a priority) identified in the MMS. This will align research focus and industry demand and reduce fragmentation of research and development (R&D) activity across the country.

The Action Plan outlines key initiatives to reform Australia's commercialisation landscape including:

- establishing Australia's Economic Accelerator – a \$1.6 billion stage-gated program dedicated to funding translation and commercialisation in national priority areas
- expanding CSIRO's Main Sequence Ventures – with an additional \$150 million of Commonwealth funding for a co-investment fund with the private sector to catalyse venture capital investment in high-value opportunities to be taken to market.
- establishment of the Trailblazer Universities Program – through an injection of \$243.5 million to support select universities to boost prioritised R&D and drive commercialisation outcomes with industry partners.
- introduction of a National Industry PhD Program – through investments of \$296 million to establish a new suite of industry PhDs and fellowships that span the research career pathway, adding 1,800 industry PhDs and over 800 industry fellows over 10 years.





Entrepreneurs' Programme

Since June 2014, the Entrepreneurs' Programme (EP) has delivered advice and grants to enable high potential businesses to grow, innovate and commercialise nationally and globally. Through a network of over 170 independent, expert facilitators across Australia, EP works closely with its clients to determine the business's needs and how to best achieve them in the short, medium, and long term. In addition to improving outcomes for clients, EP also improves outcomes for the broader economy, regions, industry sectors, and communities. The program is delivered through a suite of offerings tailored to businesses depending on their strengths, the outcomes they are seeking and the sectors they are in. The EP offerings which have produced outcomes for clients in biotechnology are:

- Accelerating Commercialisation, where expert commercialisation facilitators work with businesses, entrepreneurs, and researchers to develop and commercialise novel products, processes, or services so they are investment ready and can get to market. From October 2014 to December 2021, Accelerating Commercialisation has invested in 100 grants worth \$54 million in the Medical Technologies and Pharmaceuticals Growth Sector, and specifically 57 grants worth \$28 million have been awarded to Australian businesses developing a project within the Biotechnology space.
- Growth, where expert facilitators work with businesses to help them grow by improving their management capability, capacity to trade and export in global markets, and their supply chain performance
- Innovation Connections, where expert facilitators work to connect businesses with the research sector and support them to undertake collaborative research projects to develop innovative solutions.

HeadSafelP was founded to develop "NuroChek," a brain scanner in a briefcase, when its founder, Dr Adrian Cohen, injured his own head and neck and wanted to find a better tool than the largely subjective tests utilised in sport medicine. In 2019, HeadsafelP was awarded a \$745,080 Accelerating Commercialisation grant to complete the necessary commercialisation activities and achieve the first sales of its Nurochek device. HeadsafelP was also supported through the Growth Service offering of the Entrepreneurs' Programme with a business evaluation and a \$20,000 Business Growth Grant. Through EP help, HeadsafelP was invited for six months into Texas Medical Center's Innovation Lab, an internationally renowned incubator of medical technology. This resulted in multi-centre clinical trials in the US, New Zealand and Australia.

Complementary Initiatives

The investments and initiatives directly impacting the biotechnology applications in health and medicine also benefit from other complementary initiatives. These initiatives may have a different focus but often lead to direct impacts within the biotechnology ecosystem.

The biotechnology ecosystem is also shaped by considerations around security and risks posed by technology. A secure ecosystem builds confidence in institutions handling potentially sensitive data and discoveries related to health and medicine. The Australian Government has developed guidelines for, and in partnership with, Australian university sector to manage and engage with risk to deepen resilience against foreign interference in the university sector.³⁶ The Parliamentary Joint Committee on Intelligence and Security is also considering national security risks in Australian higher education and research sector.³⁷ In August 2020, the Australian Cyber Security Strategy was released, which invests \$1.67 billion over 10 years to create a more secure online world for Australians, their businesses, and the essential services upon which we all depend.³⁸

Applications in space medicine

The Australian Space Agency is developing the *Advancing Space: Leapfrog R&D - Applied Space Medicine and Life Sciences Roadmap 2021-2030* under the *Australian Civil Space Strategy 2019-2028*. This roadmap will include areas of biotechnology including health and medical applications as identified in the Biotechnology Plan.



Looking to the future

The Australian Biotechnology sector has a promising future. A thriving and vibrant biotechnology sector will support the economy and well-being of all Australians.

The Australian Government remains fully committed to continuing to support the sector and this plan provides the framework to align its current and future initiatives, as well as attracting global interest in our sovereign capabilities.

The plan presented here articulates how the Australian Government is supporting the sector achieve this future across initiatives under three broad pillars. These pillars and initiatives align to the health and medical research and development pipeline ensuring a common standard can be used to identify gaps and opportunities. It provides an internationally understood vocabulary to articulate a coherent message of commitment across the ecosystem, and attract new partnerships and collaborations of the future.



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The Australian Government is promoting the development of the Australian biotechnology sector through initiatives that support foundational research, high-quality clinical trials, and accelerate commercialisation.

A Plan for Biotechn

We have an opportunity to build on our research strengths to deliver health, social and economic benefits



Australia has world-class research institutions, a skilled workforce, and a competitive clinical trials sector to drive research and development activities in healthcare. In 2020-21 the Australian Government provided over \$2 billion directly for health related R&D and build strong foundations to support its translation.



Australia is well placed to deliver the next generation of innovative biotechnology medical products. Drawing on our national strengths, Australian manufacturers are poised to compete globally on value rather than cost alone.



Our strong regulatory environment builds confidence in the safety and efficacy of research applications in healthcare, our secure business operational environment attracts new inventions, and our national safeguards across research and data protects the ecosystem from threats.

Pillar 1

Supporting world-cl
by strategically invest
strong partnerships b
science organisations
consumers.

Pillar 2

Facilitating high-qua
development that attr
improving research ca
infrastructure thus en
globally competitive.

Pillar 3

Accelerating comm
through partnerships a
academics, governme
industry; regulation tha
supporting the develop
capabilities for biophar

2019 p.a.

\$5.2 billion
Gross Value Added

1278
Companies, 135 ASX listed

68,000
Jobs supported

\$8.2 billion
Manufacturing exports

1820
Clinical Trials

Projections based on targets set by the
Industry Growth Plan, and growth tra
by the MTPConnect 2020 Se

Biotechnology in Australia

World-class research and development

Investing in areas of need and driving innovation through partnerships between academia, government, industry, health services, and consumers.

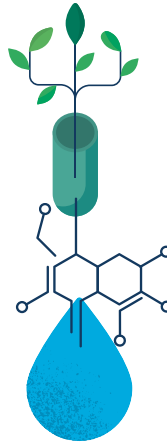
High quality and secure clinical development

Attracts global interest by continuously improving capabilities, processes, and standards, ensuring they remain or become best in class.

Commercialisation

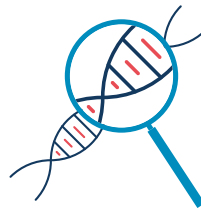
Encourages partnerships and collaborations between academia, government, science organisations, and industry that is fit-for-purpose; and by supporting the development of advanced manufacturing for pharmaceutical and med-tech products.

Our long-term vision is to build a vibrant and thriving biotechnology ecosystem that drives life-science research and its translation, and attracts global interest.



A vibrant and thriving ecosystem promotes:

- a world-class research and innovation system supported by strong partnerships between academia, industry, health services, and consumers.
- a pipeline of innovative, high-quality biopharmaceuticals and medical technology products that attract global interest, while maintaining fit-for-purpose regulation.
- a globally recognised Australian medical products industry with the capability, capacity and expertise to locally manufacture advanced and high value medical products using sophisticated and safe processes.
- access to national and international markets that facilitate product uptake and continuous cycles of product improvement.
- an ecosystem that supports high-quality research and its translation into commercial outcomes.



Our targets align with Australia's Long Term National Health Plan to invest in medical research and boost the economy, and the 'Modern Manufacturing Strategy' which sets out a pathway to be globally competitive by achieving strong rates of commercialisation, integration, and collaboration. The biotechnology sector can grow the manufacturing sector through increased jobs and exports, and all Australians will benefit from access to cutting edge new technologies.

Source: 2018 Health and Medical Research Sector Competitiveness Plan.

p.a. 2030

>1400
Companies, 135 ASX listed

>\$8 billion
Gross Value Added

>80,000
Jobs supported

>\$12 billion
Manufacturing exports

Sustained growth in Clinical Trials

