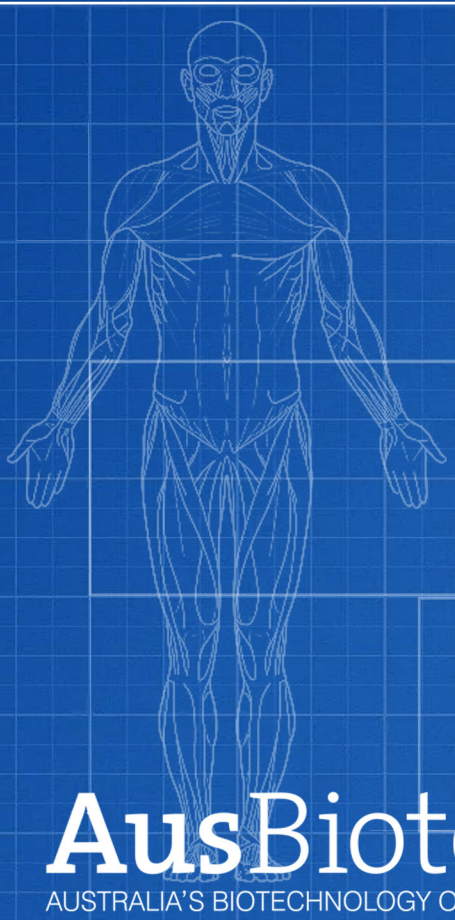
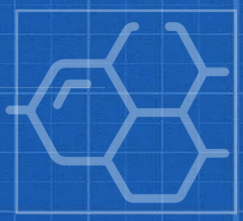


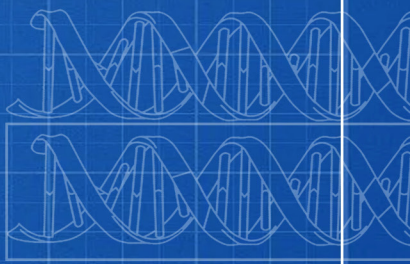
AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

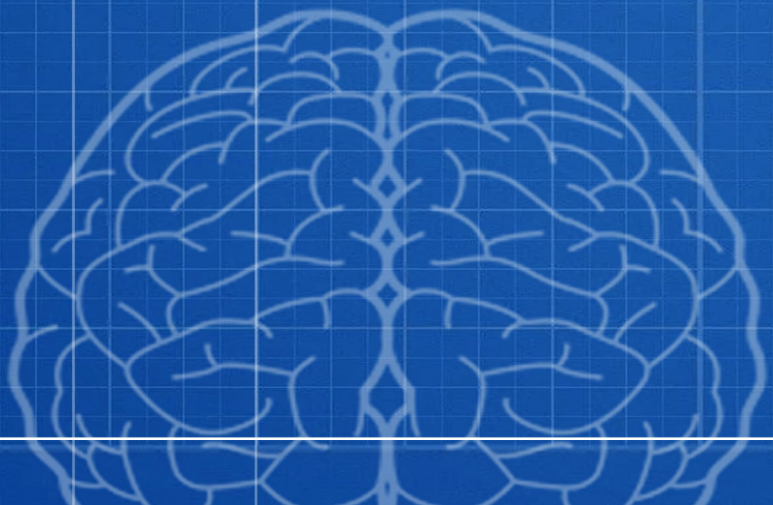
BIOTECHNOLOGY BLUEPRINT

A Decadal Strategy for the Australian Biotechnology Industry

2022 - 2032







CONTENTS

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FOREWORD

The biotechnology industry is pleased to present the Biotechnology *Blueprint: A Decadal Strategy for the Australian Biotechnology Industry* (Blueprint), which comprises the contribution of almost 350 individuals and organisations, all working to realise the potential of biotechnology in our society.

As economics collides with biology and epidemiology, the role of healthcare in modern society is in focus as never before.

Australia's medical and biotechnology industry has developed a critical mass over the past decades that is enabling the translation of ideas, technologies and health interventions to support and improve clinical practice and reach and benefit patients, to improve and extend human life. A focus on what clinicians need to help patients and what patients want and need to improve quality and length of life is critical.

COVID-19 served as an important reminder that Australia will need its biotechnology industry to help it face uncertain future threats, and that even as we overcome the acute phase of the pandemic, the chronic health challenges associated with ageing populations around the world, increasing burdens of disease, and growing health inequality, have not gone away.

That's why there has never been a more important, or opportune time to plan for the coming decade as a community and as an industry, noting the many options for Australia to proactively shape its future.

This is a valuable opportunity for us to put forward a clear and ambitious plan for our industry, contemplating what a vibrant and valuable Australian biotechnology industry could look like over the coming decade, and identifying the steps that should be taken in the near term to ensure that positive future is realised.

The Blueprint is a shared vision by industry, for the industry, and while AusBiotech led its development, it encompasses the entire ecosystem that enables biotechnology, its stakeholders and the work of numerous industry and advocacy organisation collaborators that will be required to deliver on the vision.

It is a time to be ambitious about how the biotechnology industry can help solve problems and generate the long-term economic growth and social capital that will be needed as we emerge from the current pandemic. Through its implementation, we can herald an era of Australian discovery, translation and innovation.

While the overarching three goals of the Blueprint will be vital in achieving the industry's vision, as they are inexorably interlinked, the impact of each to drive the industry towards outcomes is different.

From creating the right environment for companies to innovate and grow, to building the dedicated research infrastructure that supports the development of treatments and technologies, and enlisting the Australian healthcare system as an active partner to ensure that patients can benefit from cutting-edge innovations, the Blueprint is at its core, a 'blueprint' for societal good.

For industry, the Blueprint is an opportunity to look beyond the purview of individual technologies or firms, and consider the overall status and progression of the industry.

For governments, it's an opportunity to make the strategic investments that will solidify and strengthen Australia's sovereignty and global standing. In March 2022, the Federal Government launched '*Biotechnology in Australia – Strategic Plan for Health and Medicine*' which was developed in collaboration with the Blueprint, The Plan sets out three pillars of Government support for life sciences, and signals how its current initiatives align.

For us all, it's a chance to establish a shared sense of purpose and some common goals - a chance to achieve great things for Australian biotech, Australia, and Australians.

Lorraine Chiroiu
CEO, AusBiotech

Figure 1: Goals of the Biotechnology Blueprint

AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

ABOUT AUSBIOTECH

AusBiotech is Australia's biotechnology organisation, working on behalf of members for more than 35 years to provide representation and services to promote the global growth of the Australian biotechnology industry.

AusBiotech is a well-connected network of over 3,000 members in the biotechnology, including therapeutics, medical technology (devices and diagnostics), digital health and agribiotech sectors.

AusBiotech has representation in each major Australian state, providing a national network to support members and promote the commercialisation of Australian life science in national and international marketplaces.

AusBiotech is dedicated to the development, growth, and prosperity of the Australian life science industry, by providing initiatives to drive sustainability and growth, outreach and access to markets, and representation and support for members nationally and worldwide.

EXECUTIVE SUMMARY

The Australian biotechnology industry has made great strides to become a thriving community. Over 35 years, the industry has moved from a handful of companies to more than 1,427 today as part of an ecosystem of 2,654 organisations, employing more than 260,000 people.

The vast majority of companies developing therapeutics, diagnostics, devices, vaccines and other technologies in Australia are in the very early stages and are small and medium enterprises (more than 80 percent), the majority of which are pre-revenue, pre-market and on a journey of commercialisation.

As outstanding innovators on the global stage, the sector is seeking to continue and track this upward trajectory and maturation, as it continues to make an impactful contribution to Australia and the world.

Well-known Australian companies like Cochlear, CSL and ResMed are leading a trend of delivering for patients. This is supported by an ever-growing list of Australian inventions that are being licenced, partnered and acquired to support patient care across the globe.

For the first time in 20 years, the Blueprint presents a shared industry-developed vision for the next decade, that includes three goals, each with two sub-goals, which have helped define the 16 strategies, 43 objectives, and 109 tactics that will drive and shape the biotechnology industry's growth.

Goals and subgoals have been developed through the prism of six key sector enablers:

- Investment and funding;
- Supporting infrastructure and processes;
- Public sector science;
- Workforce and skills;
- Regulatory challenges and opportunities;
- Network, partnerships and collaborations.

The Blueprint responds to well-articulated, stubborn issues that the industry has grappled with for years, and presents a solutions-based approach. Consultation began with exploring issues and these are featured throughout the document as a starting point for each section. In summary, major issues include:

- **Access to capital to feed the need for commercialisation, clinical development and growth** remains key amid an expanding industry, and the diversity of investment sources is a pressing issue;
- **Growing companies through the commercialisation pathway and reaching market** remains the minority instead of the norm, (80 percent are pre-revenue and comparatively few Australian-developed products have reached market yet);
- **Gaps in technology transfer and commercialisation support** are complex issues that need to be addressed;
- **Incentives and structural supports along the pipeline are patchy, inconsistent and uncoordinated.**

The industry's vision is that over the coming decade, the Australian biotechnology industry will: (1) become a more mature, vibrant ecosystem; (2) with a more established global and domestic standing, and (3) be a stronger, more positive contributor to the Australian economy and its population.

These three goals, which have helped define objectives, steer strategies and craft tactics that will drive and shape the biotechnology industry's growth through to 2032 and beyond.

The Australian biotechnology industry will achieve these goals by:

- being a better connected and vibrant community able to create and grow high-value biotech companies consistently;

- providing a compelling range of jobs that attract and develop the best and brightest talent locally and convinces talented expatriates and international experts to make Australia their home;
- being an increasingly established and well-recognised global biotech participant;
- being an industry of greater influence, with leaders that are actively involved in biotechnology sector initiatives, and whose opinions are valued by the wider Australian community, and the Australian government;
- being a demonstrated and increasingly positive and sustainable contributor to the Australian economy; and
- improving more lives through the development of cutting-edge health technologies.

The Blueprint identifies metrics to track how the industry is progressing against these goals, with regular reviews scheduled to report on this progress.

Stakeholders interviewed for the Blueprint frequently urged for boldness and emphasised the need to grow and strengthen the industry, hear from diverse and knowledgeable voices, and openly track progress and outcomes.

Critical to the growth and vibrancy of the industry is the long-recognised need for Australia to improve the commercially focussed engagement between publicly funded research organisations and industry to develop more commercially viable assets and successfully create value from publicly-funded research.

Foundational elements of a thriving industry are viewed as being in place, including world-class research, robust regulatory frameworks, and a high-quality healthcare system. However, the development and introduction of crucial enablers is required to achieve the sector's ambitions.

From an improved investment and funding landscape, enhanced support for infrastructure and processes, global access to an appropriately skilled workforce, commitment to the continuous improvement of the regulatory environment and greater connection and collaboration across the sector, the Blueprint charts the way for industry and government to achieve a shared vision.

RECOMMENDATIONS

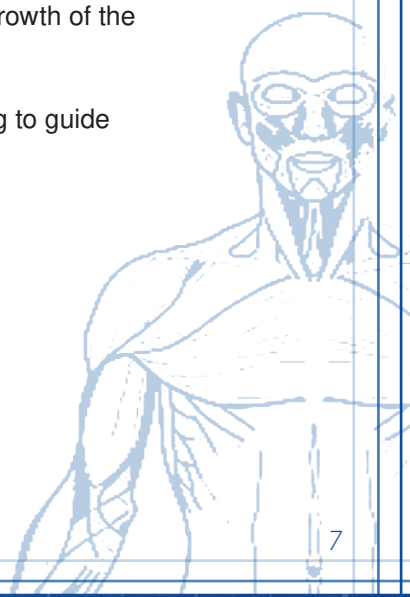
Delivering the Blueprint's shared vision for the Australian biotechnology ecosystem will deliver benefits and returns to all Australians.

Achieving that vision will require a partnership between governments and industry to create greater investment and funding opportunities, local infrastructure, translatable public sector science, workforce development, and the urgent sovereign capability Australia needs.

To this end, the Blueprint makes a series of strategic recommendations, some to government, others to the Australian biotechnology sector, which work simultaneously towards achieving that vision.

The Blueprint includes many significant and detailed recommendations uncovered through thorough consultation and discussion, building upon AusBiotech's existing knowledge from its more than 35 years operating as an industry leader. There are eight core, critical areas of focus.

1. Re-orient support for commercialisation to enable a dual focus on (academia and industry) commercialisation, through programs and initiatives incentivising partnerships, addressing key gaps, building awareness of roles, value and capabilities, and supporting collaborative structures.
2. Deliver specific programs aimed at transitioning small companies to medium-sized companies, and medium sized to large, addressing capability and skills gaps, and ensuring access to a diverse capital base and incentives, to allow companies to retain value creation in Australia.
3. Increase the competitiveness of the Australian operating environment relative to its overseas peers, using a mix of government and industry led initiatives while remaining open and accessible for inward investment.
4. Build sovereign capabilities in the biotechnology sector, including manufacturing and scale-up, core drug / device / product development expertise, supported by a robust service industry enabling local sourcing and partnering
5. Increase the knowledge, awareness and understanding of the contribution made by the biotechnology sector, including delivery of aligned metrics and reporting on delivery progress of the Blueprint.
6. Investment and capital: build, diversify and address gaps in access to capital across the variety of industry organisations, to significantly increase the flow of capital to the biotechnology sector by $1 billion annually.
7. Talent: Address the gaps in access to appropriate skills and talent, using proactive and resourced initiatives that attract, build and retain core talent essential for the growth of the industry.
8. Metrics and accountabilities: Deliver consistent momentum on the Blueprint recommendations, using aligned metrics and evidence-based decision-making to guide changes and updates, with shared accountabilities.



THE INDUSTRY TODAY

A SECTOR SNAPSHOT

In Australia, the COVID-19 pandemic has highlighted many strengths in our biotechnology sector. Australia's biomedical researchers continue to prove their world-class capability by leading efforts to analyse the virus and develop a response, while hundreds of Australia's biotechnology companies play key roles in developing technologies to address unmet medical needs, heal, protect, repair, and improve health outcomes.

Australian medical research, powered by the Medical Research Future Fund (MRFF) and ongoing investments through National Health and Medical Research Council (NHMRC) and Australian Research Council (ARC) to support scientific research, is starting to deliver an uplift in public benefit, providing the essential foundation for a thriving biotechnology industry. The MRFF's 2nd 10-year Investment Plan, has committed $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.

At the time of publication, the Australian Government support for the sector included:

- The $1.3 billion Modern Manufacturing Initiative, 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, when legislated, is a concessional tax treatment applied to profits derived from eligible new patents in the medical and biotechnology sector.
- The Biomedical Translation Fund (BTF), a $250 million co-investment (matched) program with government equity investment complementing private sector funding for promising biomedical discoveries, assisting in their commercialisation – delivering $500 million to the sector.
- 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 $5 million.

The biotechnology sector, now comprising more than 2,654 organisations and employing at least 263,693 people, includes an industry segment that numbers over 1,427 ranging from small start-ups launching new therapies out of the lab, to global multinationals, like CSL, which recently achieved the status of Australia's most valuable listed company. Almost 80 percent of the industry is comprised of small and medium sized companies (SMEs), of which the majority are pre-revenue and in the process of commercialisation or translation of research.

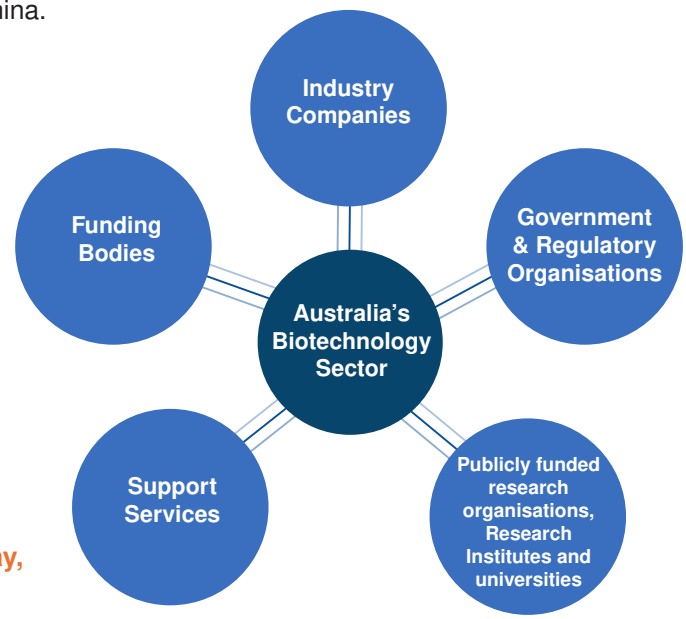
Against a backdrop of rapid change these are significant milestones and represent a substantial maturing of the industry over the past decades. In the 35 years since AusBiotech was founded as the Australian Biotechnology Association, the industry has grown from a mere handful of companies to have an ASX-listed market capitalisation of more than $242 billion in 196 of those companies and a further 1,231+ companies creating value.

The biotechnology industry is distinctive by virtue of the way it uses the latest advances in biomedical science to deliver potentially life-changing and life-saving therapies, vaccines, diagnostics and devices that have application in markets around the world.

The biotechnology industry is intrinsically global, and Australia's industry is strongly connected to the worldwide biotechnology sector through development partnerships and trade relationships.

While Australia enjoys a high international reputation for the quality of its research and clinical trials capability, its biotechnology industry is 'coming of age' with visibility on the global stage, having consistently ranked in the top countries globally for biotechnology innovation, when adjusted for population. However, there is undoubtedly intense competition for jobs and investment from other jurisdictions such as the US, UK, Singapore and China.

Figure 2 – Overview of Australia's Biotechnology Sector



As an industry, biotechnology can be characterised by long and costly product development cycles – for example, it can take 10-14 years and up to $2.5 billion to bring one biopharmaceutical from research to market. Medical devices typically take a shorter time to reach patients, but also require significant investment attraction during long periods of no revenue.

Figure 3 – A typical development pathway of a biotherapeutic

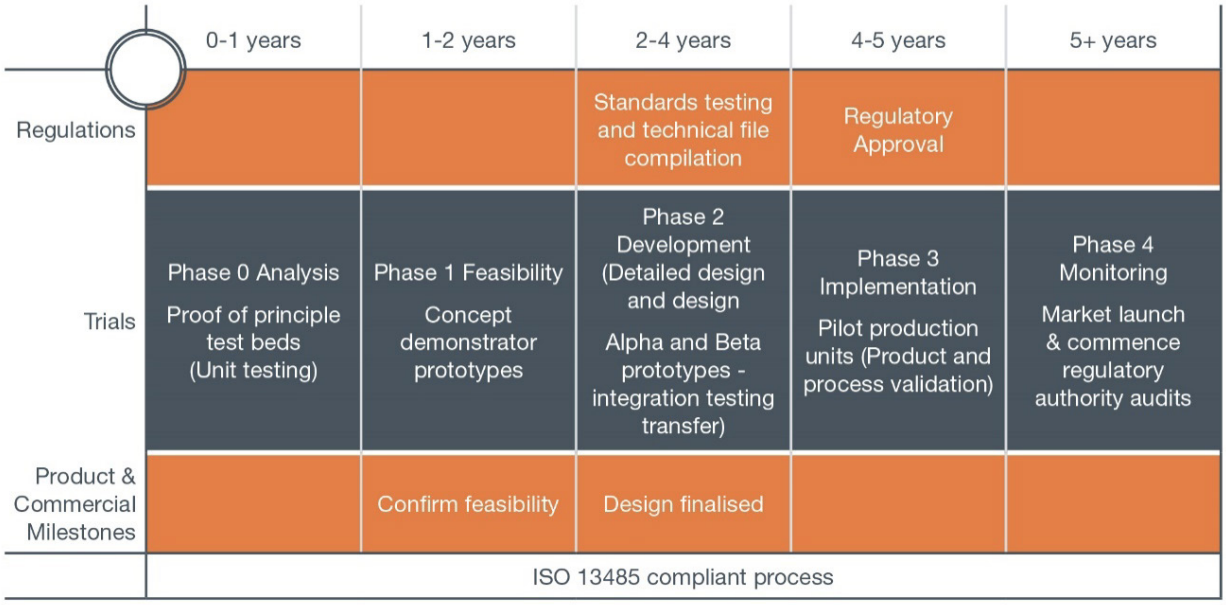
Schematic showing typical development pathway, specific to a bio-pharmaceutical

	0-2 years	2-4 years	4-6 years	6-8 years	8-10 years	10-12 years	12-14 years
Regulations	Patent Application	Clinical trials application			Regulatory Approval		Regulatory approval
Probability of success*			71% (71%)	44% (31.2%)	69% (21%)		
Trials	Basic Research/ Proof of Concept	Phase 0 Toxicology	Phase 1 a & b Dosing trials	Phase 2 a & b Small cohort trials	Phase 3 Large cohort trials		Phase 4 Post-marketing studies
Product & Commercial Milestones					Prepare data package	Submit data package and apply for re-imbursement	Market Launch

**Probability of success for each phase (and cumulative totals in brackets). Note that probabilities will differ between disease groups and from biologics to small molecule medicines*

Figure 4– A typical development pathway of a medical device

Schematic showing typical development pathway, specific to a medical device



The industry also operates in a highly regulated environment to underpin confidence in safety and efficacy, although the regulatory environments can vary substantially in different markets worldwide.

A key foundation of the biotechnology industry is research and development (R&D), which is conducted both in companies and in publicly funded research organisations, such as universities, medical research institutes and research agencies such as CSIRO and ANSTO.

R&D in publicly funded institutions provides a particularly important source of new intellectual property that can seed new companies or strengthen existing ones, while also delivering vital skills and training for the future workforce.

While Australia's performance in commercialising publicly funded R&D has historically been variable and a long-term undertaking, more recent success stories provide an example of the opportunity ahead if the sector can fill gaps and work together.

Australian success stories of commercialisation are many, but the most often cited examples of products that have reached commercialisation on a global scale include:

- Gardasil®, the human papillomavirus (HPV) vaccine originally developed for cervical cancer, now indicated for multiple diseases caused by HPV in both males and females, originated from ground-breaking research at the University of Queensland by Professor Ian Frazer from the Translational Research Institute. The technology was further developed with CSL before Merck & Co undertook long and large human clinical trials which ultimately led to its use in over 145 countries worldwide, saving the lives of more than 250,000 people every year.
- Cochlear has become the global leader in the cochlear implant or bionic ear, a technology based on the work of Professor Graeme Clark from the Bionic Ear Institute at the University of Melbourne.
- ResMed has become a global leader in continuous positive airway pressure (CPAP) devices, based on research by Professor Colin Sullivan and colleagues at the University of Sydney, on the first successful non-invasive treatment for obstructive sleep apnoea.

These examples have been joined in recent years by numerous examples that are reflective of an improving trend that needs to be extended:

- Venetoclax was developed by the Walter and Eliza Hall Institute, partnered with AbbVie.
- Queensland company Ellume developed the first rapid self-test for COVID-19 detection authorised by the US FDA and purchased for use.
- Cellestis' diagnostic test for tuberculosis, which was commercialised prior selling to Qiagen for $355 million, is still in market.
- Nanosonics is an Australian infection prevention company that has successfully developed and commercialised a unique automated disinfection technology, Trophon®, that is sold into more than 30 countries and protects 22 million patients per year.
- Microba has commercialised a microbiome analysis system, developed by scientists in Queensland.
- Global Kinetics commercialised technology the Florey Institute of Neuroscience & Mental Health, the Personal KinetiGraph® system (PKG®) movement recording is a unique and useful tool for neurologists in the management of Parkinson's disease.
- Avita Medical has commercialised a treatment for burn patients with its novel technology platform, the RECELL® System, based on technology developed by Perth researcher Dr Fiona Woods.
- Saluda Medical has received FDA and CE Mark approval for its Evoke® spinal cord stimulation system, after it developed from work at NICTA (now Data 61/CSIRO).

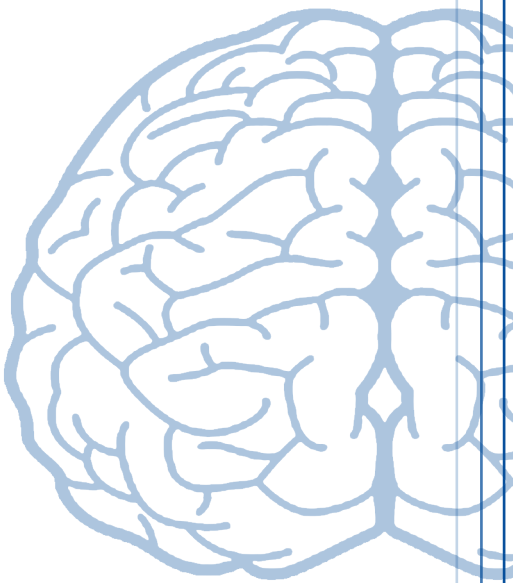
Governments at Commonwealth and State level have played an important role in the developing the biotechnology industry, ranging from investments in R&D and support for skills development, to the framing of regulatory and tax policies that impact the sector.

Even before the COVID-19 pandemic, the government identified medical technologies, biotechnology, and pharmaceuticals as a priority growth sector. This has proven to be a fortunate decision, with numerous Australian companies playing a part or taking the lead in the pandemic response.

While resolved in late 2020, a major headwind for the industry had been created by over four years of policy uncertainty around the status of the R&D Tax Incentive, which is a critical driver of investment in the industry.

In a globally mobile industry such as biotechnology, a strong and supportive policy environment is essential to attracting new investment and intellectual capital and retaining the value that has and can be created by companies and their investment.

With solid foundations like those outlined in this Blueprint, the Australian biotechnology industry is poised to accelerate its growth and benefit to the nation.



MACRO TRENDS

In thinking about the coming decade for the biotechnology industry, it can be helpful to keep in mind several macro trends – the overarching social, economic, environmental, technological, and geopolitical forces that will shape the future of industries.

In 2017 the CSIRO Futures group developed a set of seven megatrends that they anticipated would impact Australia's medical technologies and pharmaceutical industry.

MTPConnect, in their Sector Competitiveness Plan, augmented these with two additional trends to give the nine megatrends summarised in Table 1 below.

Recent experience of the COVID-19 pandemic, reflecting the "Global Biosecurity" macro trend, shows that these trends can be significantly accelerated in times of crisis. For example, the last two years have seen rapid adoption of telehealth during the crisis, and innovative use of digital tools to manage outbreaks.

More recently, trends around sovereign capability concerning manufacturing have come to the fore.

There is both a strength and a limitation to macro trends: while we can have a high degree of confidence that they will have some impact in the future, it is very difficult to know the precise quantum of impact, or when that impact will occur.

Their greatest value is thus as a tool to frame the discussion about possible future scenarios for the industry – a tool that this Blueprint has used to capture the opportunities for the Australian biotechnology industry over the coming decade.

Macro Trend	Brief Description
Digital Evolution	Greater creation, use and interchange of data will drive needs for standardisation, artificial intelligence and cybersecurity
Consumer Control	Technology and information access are empowering patients to proactively manage their healthcare
Healthy Ageing	Demographic trends in many economies will drive increased focus on maintaining good health for as long as possible
The Chronic Burden	Modern medical and pharmaceutical technology allows better management of chronic disease than ever before, but comes at ever increasing costs
Precision Healthcare	Advances in science and technology are enabling more precise healthcare solutions that are targeted to specific cohorts of patients, and even individuals
Value-based Healthcare	Rising health costs are driving an increased focus on using patients' health outcomes as the driver for choice, delivery and reimbursement of therapies
Integrated Care Models	Healthcare delivery models are increasingly integrating all the products and services required to address the whole of a patient's care needs
Global Biosecurity	Infectious disease pandemics, as well as rising antimicrobial resistance, are creating problems for governments worldwide, even in nations with strong healthcare systems
Developing Markets	Demands for healthcare solutions are rising in developing countries, but the needs of these markets are sometimes distinct from developed economies.

Table 1 – Megatrends affecting the medical technologies and pharmaceutical industries, as identified by MTPConnect in 2019, 2020, 2021 & 2022

BIOTECHNOLOGY SECTOR ENABLERS

Several enablers were identified as playing an important strategic role in helping the industry achieve the Biotech Blueprint's goals. The six key enablers that underpin the strategic framework necessary for achieving the Blueprint's goals:

- Investment and funding;
- Supporting infrastructure and processes;
- Public sector science;
- Workforce and skills;
- Regulatory challenges and opportunities;
- Networks, partnerships and collaboration.

DEFINITION AND SCOPE OF THIS REPORT

At its most simple explanation, biotechnology refers to technologies derived from or interfacing with biological systems or living organisms. Biotechnology is a science-driven industry sector that uses living organisms, molecular and synthetic biology to produce healthcare products, therapeutics or processes, devices, diagnostics, and such as genomics, food production, and biofuels.

Biotechnology has many applications in the health, agriculture, marine, industrial, and environmental sectors. In this Blueprint, biotechnology encompasses biotechnologies and medical technologies that are human medical and health-related.

THE ROLE OF GOVERNMENT(S)

The biotechnology and life sciences sectors have enjoyed bipartisan, solid support from governments over many years, including Federal and State governments. Industry continues to welcome and appreciate this support and it is considered that such ongoing support will be critical to the successful implementation of the Blueprint.

It is of note that in March 2022, the Federal Government released its '*Biotechnology in Australia – Strategic Plan for Health and Medicine*', which notes: "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."

The plan can be found at: https://www.health.gov.au/resources/publications/biotechnology-in-australia-strategic-plan-for-health-and-medicine

The Plan 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.

The Plan 'dovetails' and aligns well with the Blueprint and its intentions.

Consistent with State Governments' various goals for each of their economies, initiatives aimed at supporting the biotechnology sector also continue to be important.

Ahead, the role of governments will be to continue existing support, particularly of enabling policy levers that enable ongoing attractiveness of the sector relative to competing markets and also to other sectors. Industry considers that the key recommendations for governments to consider include those which:

- Support the enablers of the sector as outlined in the strategy house, particularly including those related to access to skills and talent, infrastructure and capabilities, and regulatory frameworks.
- Foster cross-stakeholder initiatives such as those aimed at increasing industry commercialisation of research
- Build upon the recent surge in effort for sovereign capabilities development, acknowledging the identified need for capabilities in the medical sector for Australia's health.
- Build and deliver accurate reporting of the status of the sector to enable ongoing and evidence-based discussions about future endeavours.

We hope and request that governments take appropriate accountability for the relevant actions within the plan, and expect that governments will jointly reap the health, economic, and social rewards of a vibrant biotechnology sector.

OUR PLAN FOR THE FUTURE

STRATEGY HOUSE

The Strategy House below, offers a graphic representation of the 'top line' goal and sub goals of the Blueprint.

Australia: a global leader in biotechnology

In a decade, the industry will:

1. Be a more mature and vibrant ecosystem	**2. Have an increased local and global standing**	**3. Be a more positive contributor to Australian prosperity**
1.1 A better connected and vibrant community able to consistently create and grow high-value biotech companies	2.1 An increasingly established and well-recognised global biotech participant	3.1 A more demonstrated, positive and sustainable contributor to the Australian economy
1.2 Provide a compelling range of jobs that attract and develop the best and brightest talent locally and convinces talented expatriates and international experts to make Australia their home.	2.2 An industry of greater influence, with leaders whose opinions are valued by the wider Australian community and government and are actively involved in biotechnology sector initiatives.	3.2 Improve more lives through the development of cutting-edge health technologies

Sector Enablers

- Investment and funding
- Supporting infastructure and progress
- Public sector science
- Workforce and skills
- Regulatory challenges and opportunities
- Networks, partnerships, and collaborations

GOAL 1:

A MORE MATURE AND VIBRANT ECOSYSTEM

In a decade, the Australian biotechnology industry strives to be a more mature and vibrant sector, with the ability to attract and retain experts and deliver a higher degree of sector-wide connectivity critical to future successes.

The biotechnology development cycle, which is frequently collaborative in nature, requires access to different skill sets, expertise, and facilities throughout the R&D journey. This is particularly important given future growth opportunities and health innovations are likely to be characterised by a convergence of technologies and research fields.

Sub-goal 1.1: …a better connected and vibrant community that is able to consistently create and grow high-value biotech companies.

Capital and growth

While we emerge from the economic and health implications of the COVID-19 pandemic, many prominent forecasters expect that investment and growth will remain volatile and weaken for an extended period while there will also be a significant emphasis on strengthening healthcare systems against potential future pandemics.

Against that backdrop, biotechnology globally has seen record capital raising during the pandemic. This trend has been seen in the Australian biotechnology industry, making 2021 the highest year for capital attraction on record. With capital the lifeblood of the sector, rapidly increasing start-up and spinout company numbers, and a dearth of venture capital in Australia compared to other major countries, the thirst for capital is key.

Australia's industry is well placed to participate in the global growth but will need to develop a balanced community of companies at all stages/sizes. This will require that capital, and more of it, from a diversified and well-educated investor base is available for quality opportunities, and that the business environment is as attractive as possible compared to international competitors.

Issues:

While recent years have seen welcome growth in Australia's venture capital industry, the pools of genuinely patient and risk-tolerant capital remain too shallow to sustain available growth opportunities.

Inbound international capital is still limited, and there are concerns about a lack of diversity in the local investor base. This has meant that companies face continued challenges accessing private capital both at early (preclinical) and later stages (Phase II and beyond), often leading them to seek inappropriate commercialisation strategies such as premature public listing on the ASX.

Further, if we analyse the make-up of the sector, the vast majority of companies are small, early-stage, pre-revenue and pre-clinical. The industry has a shared desire to support the growth of depth and maturation of the industry by helping small companies become medium-sized and medium-sized companies to develop into large companies.

It is critical for ongoing success in accessing and deploying investor capital that Australia and Australian companies remain competitive, and that the business operating environment is conducive to biotechnology investment. This requires maintenance of the factors that attract investors, while staying ahead of investment trends likely to impact the sector. In this decadal plan, one continuing trend is that of the focus on ESG (Environment, Social, Governance) frameworks.

Community and stakeholder expectations are demanding conscious consideration of the impact of business operations, mitigatory actions, and a broader commitment to playing a positive role in the sustainability of the world. ESG performance is a competitive advantage for attracting and engaging employees, investors, and consumers.

Companies operating in the life science and medtech sectors are in a unique position where business foundations are often influenced by a strong purpose that has positive social impact. These companies therefore have an opportunity to infuse ESG into their business operations more organically and allow ESG focus and activity to evolve in natural alignment with company maturation.

There is growing evidence that companies that commit to ESG perform better. It is also fast becoming an expectation that all companies consider ESG at a foundational level. Multiple stakeholders drive this expectation – investors, consumers, and employees.

Strategy:

Develop a balanced community of Australian biotechnology companies at all stages and sizes of the company life cycle, which can access and understand the channels of engagement with sources of funding and investment.

Objectives and tactics:

1. Accelerate the scaling and growth of Australian biotechnology companies by expanding access to funding grants and programs:

    1.1. Advocating for a review, consultation and possible consideration of a new tranche of Biomedical Translation Fund to address gaps in commercialisation funding.

    1.2. Continue the “commercialisation” initiatives within the MRFF for early-stage research and development, ensuring that commercial entities have clear access and transparent decision-making.

    1.3. Where matching funds to grants are available, enable clear and equal access to grants for commercial entities.

    1.4. Build expertise in funding review panels, including potential need for international panellists, with the required development expertise to support funding of commercialisation.

    1.5. Consider if legislative or regulatory change is required to unlock funds into biotech start-ups and fledgling companies, including NCRIS and other programs.

    1.6. Consider what government support is needed to encourage greater private and public investment into life sciences companies (For example, superannuation funds)

2. Increase the flow of capital to the biotechnology sector by $1 billion per annom:

    2.1. Adding to existing total funds available to access through new or adjusted programmes, considering a total package competitive with other markets (For example, the UK). The package would consider the role of direct funding (research, scale-up, export), government support payments, incentives for investors including tax incentives and those applying disproportionately to life sciences.

    2.2. Recognising that success propels success, encourage the sharing and publicisation of life sciences successes. Equally assess means to stabilise and ensure appropriate, sophisticated responses to news flow to smooth the perceived volatility of Australian market.

    2.3. Grow the percentage of capital raised flowing to the biotech / life sciences sector and increase the number of deals done.

3. Grow the Australian pool of funders by:

    3.1. Developing a program and rollout strategy to increase biotechnology literacy for non-biotech investors.

    3.2. Work with the superannuation fund industry to develop and deliver a mechanism for superannuation funds to become funders of biotechnology companies.

    - Consider a mechanism for superannuation funds into VC or private equity, which builds private funding available for life sciences companies.
    - Consider a fund of sufficient size to enable phase-III-ready assets to access superannuation funds, redefining success to partner or sell later rather than currently after phase II.

    3.3. Attract new investors and build investments from existing investors

    - Consider incentives (including long term tax or income incentives, management of capital losses) for angel and private investors to overcome different risk profile and time to market.
    - Refining the “sophisticated investor” definitions to percentage of net worth rather than size of investable pool.
    - Develop connections with wealth management groups, to inform and communicate risk v opportunity proposition and enable the matching of criteria for funding to mandates of fund managers.

3.4. Increase the number of fund managers, with appropriate skills and capabilities, to increase new options for life sciences investing with confidence.

3.5. Consider expansion strategies for analysts reporting on life sciences companies, including accessing international talent and increasing provision (cover time spent) for analysing non-corporate clients and/or companies in which a position is not held. Aim to build capabilities in analyst reporting through expanding sponsored support.

3.6. Consider whether to support a subscription-based model for analyst reporting or specialist support to appeal to institutional analysts.

3.7. Enable platform for investors to register their interest, risk profile, type, size and nature of desired investments and/or mandates, and conduct gap analysis to assess if certain parts of the sector are underserved.

3.8. Using risk appetite and size of investments, develop mechanism for larger investors to invest in later stage clinical trials, akin to the Biomedical Translation Fund, but enabling a series of later stage development actions.

3.9 Build network of investors with the appropriate local and international connections, or ability to develop same for a particular area, so that less experienced founders can leverage this expertise to find the right investor partner/s.

4. Enhance education, communications and connections platforms that allow Australian companies to engage with local and international investors by:

4.1. Expanding the offering of investor meetings and conferences to involve more international investors and deepen relationships.

4.2. Establishing a program to build greater connections with local and international investors.

4.3. Developing a program and rollout strategy to increase biotechnology insights for investors, including updates of relevant AusBiotech resources.

4.4. Building a partnership between industry and government to develop a capital-raising education program.

4.5. Share new career scope of scientists as analysts to bridge business and science as career path for PhD graduates.

4.6. Build a Commercial Cluster, by increasing capabilities in managing and communicating market risk (articulating customer value and matching appropriate business models). Increase access to Australian healthcare professionals to test, try and buy – thereby collect the necessary data, test business models and earn initial revenues in Australia (possibly enabling them to remain based in Australia).

4.7. Investigate and share ongoing comparative "relative funding picture" of Australia's start-up, VC and deal flows compared with other life sciences hubs (for example, Israel), with the goal of identifying potential strategies for improving Australia's relative position. This should include talent, capital, number of accelerators, incubators and related programmes, government support (funds, grants, tax structures for founders, employees and investors), proximity of global companies, and cultural levers to grow the sector.

5. Increase the attractiveness of Australia's business environment to international investors and collaborators by:

5.1. Understanding and addressing real or perceived barriers for international investors to connect, invest and maintain relationships within the local biotech community.

5.2. Develop new initiatives that further increase the investment in Australia, including later stage investment into clinical trials, with goal of encouraging Australian companies to remain in Australia:

- Consideration of the role of advance purchasing, provisional approvals and prospective reimbursement cover if trials are conducted here.
- Active support for the accelerated talent acquisition in scale-up.
- Particular investment support for sovereign infrastructure (e.g. essential medicines, viral vector).
- Sustaining commitment to program funding for breakthrough commercial opportunities (breakthrough devices, digital health, therapeutics), including potential for co-investment by government(s).
- Consider programs from international markets (e.g. Catapult) that aim to remove high cost / risk barriers to entry, and to overcome high cost infrastructure investments needed to succeed.
- Backing or picking winners identified through robust means to differentially invest and deliver a strategic advantage for Australia.

5.3. Promoting the relative benefits of the Australian investment environment.

5.4. Build or leverage other investor initiatives from other markets and other sectors, to maximise attractiveness.

5.5. Capitalise on latest trends in investment vehicles and investor types, such as biotech-relevant listed investment vehicles.

5.6. Ensure that the sector is well-prepared to address sustainability, by leading the development of an 'environmental, social, and governance (ESG) framework' and reporting for the industry, as it is increasingly important to our employees, members and stakeholders, including investors, industry and consumer participants and is aligned with community expectations.

Building sovereign capability

The COVID-19 pandemic has placed in stark view the critical importance of Australian sovereign capability, exposing weaknesses in our manufacturing infrastructure and domestic supply chains.

Sovereign capability infers not only a degree of Australian-based manufacturing capability and associated domestic supply chains, but the appropriate research and development facilities and a skilled, experienced workforce[1].

In Australia, crucial medical supplies used by public and private hospitals, medical centres and other healthcare providers are mostly sourced from overseas. It is estimated that over 90 percent of medicines[1], not just 'medical kit', are imported, with over 68 percent of these supplies coming from the US and Europe alone[2].

While consumer products and medications are imported from the USA and Europe, the precursor components involved in their manufacture rely on supply from countries outside the US and Europe, such as India and China, creating a long and complex supply chain from product componentry to final goods[3].

With growing geopolitical tensions and continued uncertainty about the impact of future COVID-19 variants, there remains a real potential for disruption on a global scale, or regional supply chain disruptions that, in turn, could create flow-on global supply-chain disrupts.

Due to these factors, Australia's domestic supply chain of medical products is beholden to the stability of intricate and complex global networks, which themselves are vulnerable to disruption from issues in manufacturing and procurement, political instability, natural disasters, and pandemics. This was exemplified when in May 2020, the TGA reported shortages of 572 medicines, due to a reduction of outputs from manufacturers in China and India[4].

Without sovereign capability, Australian domestic supply will remain under pressure and uncertainty, posing a continued and unaddressed sovereign risk to the health and wellbeing of Australians.

This pressure and uncertainty, has highlighted the importance of resilient domestic supply chains, which can only be created though associated domestic manufacturing and workforce capabilities.

Limited access to a small number of local research and manufacturing facilities has also challenged Australian innovators with high-cost barriers and delayed the development phase of their research, driving them to conduct their research offshore. This takes the value creation for such work elsewhere and adds significant challenges and expense for pre-commercial companies and researchers.

In 2020, Australia ranked last on the OECD rankings for manufacturing self-sufficiency, a ranking that means Australia has the most underdeveloped manufacturing sector, and the greatest sovereign risk of any industrial country in the world[5]. But while manufacturing now comprises just 8 percent of the Australian economy, manufacturing remains one of Australia's major sources of innovation, responsible for a quarter of all investment in R&D.

Innovation and manufacturing are different sides of the same coin where a constant push-pull operates. Innovation in product design stimulates innovation in manufacturing processes, and innovation in manufacturing processes stimulates product design.

[1] Smart Sovereignty & Trusted Supply Chains, The Institute for Integrated Economic Research-Australia Ltd, April 2020
[2] Department of Foreign Affairs and Trade, Composition of Trade Australia 2018-19 - includes import of 'Pharm products (excl. medicaments), 'Medicaments (incl veterinary)', Medical electrodiagnostic apparatus' and 'Medical instruments (incl. veterinary)'
[3] Strengthening Australia's biotechnology sector and medical supply chain beyond COVID-19, Sarah Butler and Tom Sorrell, PWC Australia, July 2020.
[4] Hundreds of medications in short supply due to COVID-19 and panic buying, Cait Kelly, The New Daily, 10:00pm, May 2, 2020
[5] Federal Budget: a 10-year retrospective, Grant Thornton, November 2020

Building domestic capability in research and development, manufacturing and a skilled workforce not only addresses Australia's sovereign risk, but will also drive innovation and increase Australia's global competitiveness in the biotechnology. Currently, limited manufacturing infrastructure prevents the concurrent development of cutting-edge technologies, or critical responses to crises.

Medical and advanced manufacturing is an exemplar Australian innovation, and has been duly recognised in the Federal Government's *Modern Manufacturing Strategy*. The $1.5b strategy includes a significant $1.3b '*Modern Manufacturing Initiative*' has been welcomed by the sector, but more needs to be done to support Australian innovators and manufacturers through the expansion of local manufacturing infrastructure and the expansion of domestic market volume.

Expanded market volume, a necessity in any package of support, must come from a genuine commitment by state and federal governments to source and procure locally made products, materials, and services, creating economies of scale, and helping to deliver a necessary precursor to global competitiveness.

The key elements of sovereign capability that need addressing are defined as: Manufacturing capability; access to talent; and access to the elements needed to develop a pre-clinical package, including onshore toxicology capability and quality assurance.

Strategy

Increase the level of Australian self-reliance, building sovereign capability in Australian manufacturing infrastructure, domestic supply chains, research and development facilities and a skilled, experienced workforce.

Objectives and tactics:

6. Assess and address Australia's medical and bio-technological sovereign risks by working with the Australian Federal and State governments on an Australian biotechnology national sovereignty resilience framework, which:

6.1. Audits current capabilities and charts a strategy and action plan to address shortfalls and gaps, potentially by commissioning a sectoral view from the work of the DMTC. This framework should address mechanisms for:

- Identifying new and emerging gaps and opportunities;
- Prioritising or allocating to short - medium - long term strategies;
- Funding;
- Retention of the capability in medium term; and
- Support for training.

6.2. Includes a gap analysis that is specific to biotechnology and life sciences and has regard for the cross departmental reports and initiatives recently completed by and within the Federal Government, as well as those from State Governments. It should also link to sector competitiveness plans, and to government lists including critical technologies and priorities. It should also aim to capture capabilities "at risk" including any flow-on consequences for future local investment and ability to retain businesses in Australia.

6.3. Addresses the shortage and gaps in knowledge of local industry-specific capabilities by Identifying and publishing academic capabilities or areas of scientific endeavour, to enable prospective partners to target aligned institutions for particular strengths and expertise.

6.4. Increases meaningful industry engagement in government processes for review and assessment panels for both programs and individual projects

6.5. Identifies ways in which strategic investments in larger organisations or in key capability gaps can be made, to build ecosystems and propel capabilities e.g. large medtech companies.

7. Create, and improve access to local research and development facilities that local companies can use to reduce the cost and time inefficiencies of using overseas facilities, by:

7.1. Advocating for support programs seeking to fill capability gaps.

7.2. Bolstering access to Australia's world-class National Collaborative Research Infrastructure Strategy (NCRIS) / national R&D facilities.

7.3. Considering the role of incentives to source locally in order to deliver to local and global markets, noting:

- suggestions for fee waivers, vouchers or HECS-style funding for SMEs or low revenue companies developing orphan health solutions, payable on threshold revenue being reached

- suggestions for procurement at non-commercial rates (from universities), fees and charges for government processes and cost recovery mechanisms, procurement decisions, granting program decision criteria, hiring decisions

8. Industry to support and foster a national approach to understanding and bridging capability gaps and sovereign commercialisation opportunities, using established models to create industry solutions via consortia:

8.1. Creating national business plans for private/public partnerships or other models (e.g. Regenerative Medicines model).

8.2. Considering the role of incubators, accelerators and precincts in bringing together capabilities.

8.3. Using innovative sourcing models for talent and skills acquisition (and development), leveraging overseas links and landing posts for returning life sciences executives.

9. Industry to support the progress of key national infrastructure or capability gaps, with potential focal points:

9.1. Build capabilities in drug and other medical products development processes. This could include specific capability gaps such as medicinal chemistry, biologics development, manufacturing development (bridging to scale), IVD development, sourcing of critical (reference) materials, and be subject to findings in the gap analysis.

9.2. Bridge toxicology gaps by building a plan for remedy to barriers inhibiting growth of companies - understanding the role of regulation, ethics and reputational impacts, quality assurance, facility access and availability, as well as funding and costs.

10. Identify new areas of innovation, build the relevant stakeholder network, and articulate the specific support needed to build capabilities

10.1. Horizon scanning validated internationally to identify new areas of life sciences advances likely to be needed in Australia.

10.2. Identify areas requiring whole of pipeline capabilities and ecosystem approach to ensure translational projects can transcend to market, potentially using the regenerative medicine model as a template for way forward

11. Consider an appropriate model in support of Australian start-up or scale up companies looking to disrupt supply chains, establish new capabilities and/or services to those undertaking manufacturing, research and/or development, service delivery, including:

11.1. Create a “pull forward” of new growth areas, establish kick-off investment funding and support for training and skills development, and/or with incentives to build and retain companies in Australia with IP held locally:

11.2. Identify new approaches to the processes of bringing life sciences products to market, such as changes in regulatory approval recognition of new approaches for approval, e.g. microsimulations, repurposing, other modelling to reduce or avoid complex and risky development.

11.3. Consider a Grand Challenges or Expression of Interest approach based on national identification and publication of national challenges requiring industry solutions (akin to technological advances needed in anti-microbials, recycling, energy generation etc).

Diversity and inclusion for collective success

A vibrant industry starts with people. Building a diverse and inclusive Australian biotechnology workforce with the collective creativity to adapt, respond, and innovate is core to a thriving ecosystem.

In addition to overcoming stagnation by homogeny, in bringing new perspectives and life experiences to problem solving and innovation, diverse and inclusive workplaces have been shown to return a positive financial impact on businesses[6].

Companies that are more likely to have financial returns above their national industry medians were those that ranked in the top 25 percent for gender or racial and ethnic diversity, with a demonstrated inverse for companies in the bottom 25 percent, suggesting that workplace diversity is a competitive differentiator that shifts market share toward more diverse companies over time.

[6] *Diversity wins: How inclusion matters, McKinsey and Co, February 2015*

From gender parity and encouraging and supporting the participation of Australia's First Peoples, creating healthy workplaces and welcoming those with diverse perspectives, equity, diversity and inclusion plays a vital role in leading efforts to attract the best and brightest talent from diverse backgrounds and creating a vibrant Australian biotechnology ecosystem.

Issues:

Women have steadily been working towards equal participation, and having their contributions recognised in the biotechnology sector. However, recent figures show that efforts to support women across the sector are reaping results but still fall short of equity.

On average, women comprise 47.4 percent of all employed persons in Australia, but are under-represented across the biotechnology industry, representing a stagnant 32 percent of the industry's workforce; 25 percent of executives, 15 percent of board directors, and only 11 percent of CEOs. Data on the gender pay within the Australian biotechnology sector is lacking, and requires research.

Strategy:

Create an equitable and inclusive Australian biotechnology sector that respects, encourages broad participation and draws on the perspectives of a diverse workforce.

Objectives and tactics:

12. Building on the AusBiotech Diversity and Inclusion statement, develop a suite of sector-wide initiatives that address the 'leaky pipeline' of women's career progression, and encourages participation of all Australians, particularly our First Peoples, by:
    - 12.1. Advocating for a greater number of women in biotechnology company leadership positions, including boards and senior positions;
    - 12.2.Investigating the underlying drivers of equal career progression and remuneration in the biotechnology sector;
    - 12.3. Reporting on the level of indigenous peoples' participation and key barriers, and recommend initiatives to support participation.

Greater ecosystem connectivity

Heightened connectivity across the sector not only facilitates greater efficiencies by identifying duplication, but also creates opportunities for growth by bringing together the diverse array of industry stakeholders across the ecosystem.

These key stakeholders include patients, health providers, research institutes, small as well as multinational companies, support services, including clinical research organisations (CROs) and manufacturers, government, and regulatory organisations, and in particular, funding bodies and investors.

Many of these stakeholders are currently located within Australia's world leading and globally reputable biomedical and biotechnology precincts, such as the Melbourne Biomedical Precinct in Parkville Victoria and the Health and Innovation Precinct in Randwick NSW.

Issue:

Lack of coordination within and between these precincts can stifle sector growth and development, while enabling duplication across the ecosystem.

Strategy:

Support the establishment of high-impact, sustainable, physical, and virtual biotechnology hubs that enable connection, collaboration, and interaction.

Objectives and tactics:

13. Create, enable, and sustain linkages between entities that are undertaking and supporting the commercialisation of R&D by:
    - 13.1.Understanding a better way to define, build and develop biotechnology clusters.
    - 13.2. Building greater awareness of the enabling entities that support commercialisation efforts and facilitate connections to service providers.

14. Create an environment where entrepreneurs can develop their skills, and access talent, by:
    - 14.1. Creating an Australian 'Receiving Pad' program, modelled off the successful Austrade 'Landing Pad' program that would grant entrepreneurs access to, and residency within established biotechnology hubs in Australia. The program would provide pre-market and market-ready entrepreneurs and scaleups with an operational base and customised support for their future expansion goals.

Amplifying advocacy impact

Australia's broader biotechnology ecosystem, which consisting of around 2,558 organisations, is incredibly diverse and covers therapeutics, medical technology (devices and diagnostics), digital health, research organisations, investors, and service provision sectors.
Breadth and diversity underpin how robust a system can be when well established, but the life science ecosystem requires representative and coordinating organisations, advocacy bodies, and associations with defined scope and expertise specific to each of the unique facets of the broader sector.

Issue:

Currently, approximately 10 organisations[7] with representative and advocacy functions exist across the Australian biotechnology ecosystem. With most organisations being complementary in scope and function, it is inadvertent that some overlap will occur, which at times, causes a duplication of costs while misaligning efforts and advocacy across the ecosystem. Conversely, where alignment of intent exists, shared understanding can amplify common goals, through a variety of models including cross-promotion, consortia, and enabling supportive ballast behind leadership.

Strategy:

Break down silos, promote alignment and eliminate duplication of effort across the Australian biotechnology ecosystem to amplify and coordinate the biotechnology sector's voice.

Objectives and tactics

15. Enable the regular sharing of information, by:

    15.1. Building a communications forum between industry representative organisations and establish shared projects where it makes sense (and consider shared resources).

16. Create clarity around partnership models for different policy issues facing the sector by:

    16.1 Establishing agreements of scope between life science sector representative bodies, understanding areas of alignment, and engage in a proactive partnering model for headline issues.

Enhancing research commercialisation

Australia's public sector science and research is widely acknowledged for its quality, particularly in biomedical sciences. For example, Excellence in Research for Australia evaluations have shown that approximately 90 percent of the units of evaluation in medical and health sciences were rated above or well above world standard, while the same was true of approximately 80 percent of units in biological sciences.

However, the issues with commercialisation have been roundly discussed over many different fora and over a lengthy period. There is frustration that despite many consultations and discussion papers, solutions have not been proposed or actioned, or for other reasons have not been as successful as hoped and commercialisation of Australian research remains stubbornly low relative to peers.

It is apparent, however, that different stakeholders have different perspectives of the issues impeding optimal commercialisation or indeed what commercialisation is. In recognition of this, the Blueprint defines 'commercialisation' as the point of arrival in which a technology is commercially available to patients (i.e. it has reached commercialisation), and the commercialisation or translation pathway (refer figures 3 and 4) looks at the steps in reaching the arrival point. 'Early commercialisation' refers to the period from pre-spin-out, when a technology is still in the formative stages within a university or medical research institute setting and no legal structure had yet been registered to form a company or independent entity - A claim on IP has been lodged and/or granted – to post-spin-out/start-up when a legal entity has been formed to own the identified IP and a pathway towards clinical trials and investment has commenced. Some investment may have attracted but will likely be pre-series A in nature.

'Mid to late commercialisation' refers to the stage that commences once clinical trials have been initiated and early in this stage there is an increasing need for significant attraction of funds to execute the clinical research. This stage is lengthy, often a decade long.

[7] *Life Sciences Queensland, Bio-Melbourne Network, Life Sciences WA, ARCS, Medicines Australia, MTAA, Research Australia, MTP Connect, Australian Institute of Digital Health, CCRM Australia, ANDHealth*

Issues:

A lack of resources and experience, comprehensive understanding of the commercialisation process, and relatively few examples that can used as role models (approximately 20), have contributed to this point of weakness. While efforts to improve commercialisation arising from academic research have been significant, the programs are disparate, with progress considered to be slow and opaque, with uncertainty for changing the current dynamic. Initiatives have often been directed at universities and medical research institutions rather than at increasing industry's role in commercialising such research. There is an opportunity to additionally focus on the research and development efforts within the industry, noting that industry research (and that of other sources) can also be a powerful driver of innovation, particularly in areas such as digital health.

Whether from academic or industry-based research, the role of industry is imperative in the process. The industry knowledge of what is required for a technology or a company to be successful is patchy and inconsistent across organisations and academia-based technology transfer offices (TTOs). The encouragement of translation and description of research impact is only recently seen by granting bodies as being of high value. Commercialisation potential can also be difficult to apply a valuation at its early stages.

Further, for those intent on a commercialisation pathway, an enabling culture of rewarding entrepreneurs does not exist either in academia or in industry. Australia's higher education system does not incentivise or reward experts and academics who move between academia and industry, with such moves often coming at the career-limiting expense for example of academics not being able to publish.

Repeated feedback laments the lack of a 'Proof of Concept' (POC) Fund or other initiatives that help to improve early stage decisions to either instil confidence for advancement or abandon further investment. The nature and size of the gap in POC remains unclear regarding access to funds, quantum of opportunities, design and commercialisation focus.

An additional gap relates to access to commercialisation expertise, with existing models not perceived to have fulfilled the gap that some researchers, and some companies, continue to express. Having access to tailored early commercialisation support/advice, and resources for publicly-funded institutions and early commercial start-ups could increase the chance of innovations reaching market, as well as providing a clearer and faster pathway to get there.

Finally, feedback continues to raise the ongoing need for a cultural shift to drive collaboration across the commercialisation space. Despite a shift in narrative towards translation, the value of commercialisation could be better articulated and understood. There is reliance on overwhelmed TTOs and inward prospecting, with gaps in understanding capabilities existing within academic institutions / industry, opportunities available, and the technologies and infrastructure that may be accessed and leveraged. Attempts to bring organisations together through precincts, incubators and accelerators are highly valued – however constraints on achievements for the sector may arise from a lack of coordination (within and between) and/or duplication.

Strategy:

Foster and encourage an enduring collaboration-to-commercialisation partnerships between Australian universities, industry, and funders.

Objectives and tactics:

Re-orient support for commercialisation to enable a dual focus on efforts and collaborations across both academia and industry, through programs and initiatives incentivising partnerships, addressing key gaps, building awareness of roles, value and capabilities, and supporting collaborative structures.

17. Facilitate and incentivise collaboration and partnerships between industry-academia by developing industry and academia collaboration incentives.

    17.1. For academia / MRIs incentives, accelerate and enhance early commercialisation of publicly-funded research based on an Australian-first 'gold standard' framework for university-industry partnerships, developed by AusBiotech, the University of Sydney's Faculty of Medicine and Health, and the University of Sydney Business School. Transcending individual companies and institutions, the opportunities are outlined in the 2022-released *Accelerating Health and Medical Research Commercialisation in Australia* report (See https://www.ausbiotech.org/news/gold-standard-commercialisation-for-biotech):

- Support university moves to adjust (or include to) standard EBAs and KPIs for academic researchers exploring the commercialisation potential of their research.
- Consider accommodation of publication requirements as part of industry-funded research, as academic journal publication remains an important criterion for grant funding and career progression.
- Encourage published progress towards increasing intent to translate and commercialise, including metric of the ratio of the number of TTO disclosures per original research academic publication, number of partnerships and collaborations established.
- Support review of the Category 1 - 4 funding model in a way that places more emphasis on industry income, resulting in direct financial incentive to universities and their researchers.
- Introduce an academic / industry engagement and impact evaluation mechanism to routinely fit within block funding considerations (considering existing ARC and research block grants processes and programs (for example at https://www.arc.gov.au/engagement-and-impact-assessment and https://www.dese.gov.au/research-block-grants/calculating-research-block-grants)
- Tie follow-on research funding from university / MRI for researcher, funding of protected time, and promotion and increase incentives with demonstrated and advanced progress toward commercialisation.

17.2. For industry incentives, accelerate and enhance commercialisation by:

- Ensure incentives (or no disincentives) for industry to choose Australian centres for collaborations.
- Ensure industry access to commercialisation support programs, such as Commercialisation Action Plans.
- Access external funding to support commercialisation progress, to support partnering, researcher, funding of protected time, and delivery of milestones.
- Design collaboration incentives for industry to participate in commercialisation assessments of publicly funded research, including vouchers or other mechanisms .
- Introduce a new funding pool available to industry for new collaborations with publicly funded research organisations (e.g.CSIRO, MRIs, universities) to increase the uptake of basic research into industrial R&D pipelines.
- Recognise the role of industry to “pull” clinical gaps and problems into solutions available to patients, by focusing on the development to market needs alongside the research needed to gain approvals. Where the solution has a value to payers, including governments, investigate models to share costs of collecting data needed to prove value and solve the clinical problem.

18. Continue and expand the new / fledgling support and funding for early, clinical stage companies to source seed funding (through a stage-gated approach) and broaden accessibility

18.1. Explore the development of an Australian version of the successful Small Business Innovation Research program from the United States, Canada and/or UK based programs with similar goals and long term sustainability.

18.2. Work with federal government on the continuation (and scale) of the Research Business Innovation program, Accelerating Commercialisation program, to maximise value and customisation for biotech.

18.3. Using industry inputs, develop set of desired principles for industry programs aimed at SMEs.

18.4. Assess and disseminate information about programs arising from Federal and State-based initiatives.

19. Address pivotal existing gaps in access to funds and expertise in commercialisation:

19.1. Proof of Concept (POC): Accelerate and enhance the translation and commercialisation of research by undertaking a comprehensive scoping study on an Australian ‘ POC fund for the biotechnology sector to better understand and refine the critical gaps in POC funding. This should capture both preclinical, clinical and commercial activities. Based on the above, pursue and implement the recommendations of the POC fund scoping study:

- Track and project the sustainable pipeline of commercialisable opportunities and seek to describe number and type that have not proceeded due to lack of partner or funding.

- Increase access to existing POC support (funds and funders).
- Address identified gaps in POC using both researcher and industry inputs, clearly define the concepts of, and need for, POC work, potentially seen as a "cost of entry" to certain follow-on work or partnerships
- Advocate, develop and implement a POC program or fund(s) to which industry or academic researchers may apply, to conduct activity required for POC.
- Include design features recommended throughout Blueprint consultations (AusBiotech) such as defined purpose, national reach, limiting duplication with existing programs, cover for therapeutics, medical devices and digital health, push from researcher and pull from partner.
- Customise for requisite factors and funding (high number of small, early projects versus low number of larger POC work).

19.2. Access to expertise and advisory support: Establishing a virtual 'Australian Biotechnology Commercialisation Advisory Service', housed on and/or accssed via AusBiotech's website that increases access to industry knowledge and transcends borders, boundaries and agendas tasked with:

- Reviewing existing models, programs and ascertain forecast level of support and use, verifying gaps and ability to address.
- Developing commercialisation resources and case studies to support researchers and spinouts on the commercialisation process, typical pathways in biotech, medtech and digital health, and provide access regardless of where research originated.
- On an as needs basis, providing intensive support 'wrap around' services that bring together key industry experts to review and advise on the commercialisation progress of a technology or asset (point-in-time advisory)
- Aid value description in readiness for next stage investment (via pitch deck or other).
- Link to new AusBiotech-produced resources and to existing (non-AusBiotech) resources, including relevant grant, funding and investment programs.
- Hold an exhaustive list of the available external programs and services such as incubators, accelerators and/or specialist services.
- Enabling a sustainable, funded concierge or valet service available at a national level, having regard to existing models and programs.

19.3. Support sponsored programs (e.g. from governments) including stage-gated schemes for commercialisation.

- Ensure new and existing initiatives are appropriately designed to ensure access for industry participation and collaboration e.g. Action Plan for University Research Commercialisation.
- Provide ongoing support for the continuation of proven programs, including BTF, incubator programs, REDI, Bridge and Bridge-tech and list "supported programs" that continue to meet needs of biotech companies.

20. Increase awareness of the value of commercialisation of research.

20.1. Support university / MRI deployment of programs that educate early career researchers about commercialisation and debunk many of the myths/misperceptions about commercialisation, the role of researchers in the process, and the importance of commercialisation in bringing the knowledge they generate to bear on the world's challenges.

20.2. Continue to frame research value in both clinical (health and social) and economic and commercial outcomes.

20.3. Advocacy on the value of commercialisation, distinct from translation, to reframe the long-term endpoint / value of commercialisation.

20.4.Define programs with commercialisation outcomes, including POC and other initiatives to ensure a balance of R&D initiatives have an appropriate commercialisation lens.

20.5. Advocate for key government programs to increase accessibility for industry research projects.

21.Enable collaborative structures in support of commercialisation:

21.1. Facilitate the exchange of knowledge, skills and experience through an integrated industry and academia relationship, by:

- incentivising companies training emerging leaders.
- Incentivising universities to encourage industry fellowships, which also should consider global placements in order to access international R&D infrastructure and maximise the learning opportunity.
- Movement between industry and academia should also consider secondments for TTO staff within private equity/venture capital firms to understand their approach to valuing pre-clinical invention disclosures/IP (an extension of current programs focused on researchers).

21.2. Showcase (share) national capabilities to facilitate the leveraging of capabilities (and opportunities) between industry and academia by:

- delivering a national industry and academia collaboration, technology transfer education program or conference or creating a dedicated stream within an existing conference, complemented by an Australian association of university technology managers with an annual forum for sharing ideas, trends and best practices.
- Facilitating linkages: engage directly with university / MRI commercialisation / tech transfer teams, document issues, position AusBiotech as expert partner and gateway to investor and industry networks.
- Develop a proforma capability map that universities could use, publish and track over time, that when collated shows where there are university research capabilities. This will provide industry with visibility into university research and provide a scalable (i.e., not just person-to-person) approach to business development.

21.3. Encourage new and best practice methods for identifying outcome-driven ideas or problems requiring solutions, and encourage industry insights and inputs.

- Clinicians, researchers, industry, cross-sectoral inputs to solve identified clinical gaps, leveraging expertise by forming industry / academic strategic partnerships to access more sophisticated insights into the commercial potential of university research.

21.4. Increase support for the key interface roles between industry and academic institutions:

- improved training and professional development opportunities for commercialisation offices within Australian universities, including annual TTO forum.
- Develop metrics to assist TTOs in tracking their commercialisation progress, complemented by Toolkit (see glossary), a toolkit of template contracts, model agreements, decision guides, and guidance notes for universities and companies that wish to undertake collaborative research projects with each other.
- Access the global pipeline of TTO talent by creating opportunities commensurate with those in the US and UK. This may require re-evaluating the optimal personnel size and resourcing requirements for Australian TTOs.

21.5. Create, enable, and sustain linkages between entities that are undertaking and supporting the commercialisation of R&D by:

- Understanding a better way to define, build and develop biotechnology clusters.
- Building greater awareness of the enabling entities that support commercialisation efforts and facilitate connections to service providers.

Sub-goal 1.2: …provide a compelling range of jobs that attract and develop the best and brightest talent locally and convinces talented expatriates and international experts to make Australia their home.

Attracting and retaining the best and brightest

As a high-skilled industry, attracting the best and brightest from wherever they may be, is imperative to growing and sustaining a successful, vibrant, and world-class biotechnology ecosystem.

Key factors in increasing the industry's resilience and sustaining a vibrant ecosystem across the value chain relate to quality, scale, and accessibility.

Increasing the number of high-quality medium and large companies will attract talented and skilled people to the local industry by providing career paths and opportunities, as well as on-the-job-training in management and industry-specific skills.

Issues:

Complexity in Australia's visa application processes has tended to discourage talent and expertise from relocating to Australia. This complexity, coupled with a lack of understanding of Australia's visa system, has acted as a barrier to attracting new talent and meeting skills shortages across the sector, creating little opportunity to tap into expertise without having to overcome obstructive red tape.

Strategy:

Develop resources and a contact point so that the Australian biotechnology industry can reap the benefits of streamlined pathways to immigration and the exchange of personnel, information, and ideas.

Objectives and tactics:

22. Provide ease of entry programs for people with specialist skills and experience, by:

22.1. Working with Global Talent Officers in the Federal Government's Global Business and Talent Attraction Taskforce to promote Australia's Global Talent Visa Program in key biotechnology ecosystems globally.

22.2. Working with locally-stationed Global Talent Officers to promote the Global Talent Visa program amongst the Australian biotechnology ecosystem.

23. Bolster industry awareness of permanent residency visa pathways for biotechnology c-suite executives, by:

23.1. Increasing clarify and education on visa programs, applicable to the sector.

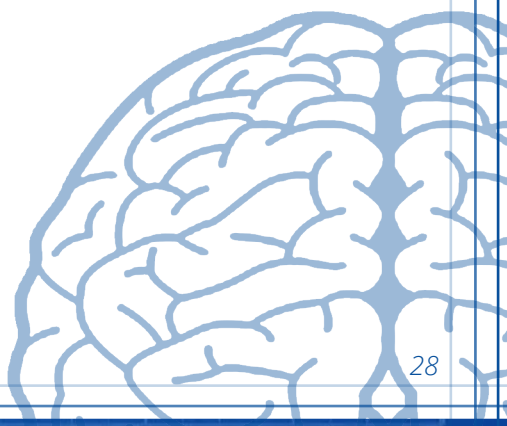
23.2. Setting up and regular tracking mechanism and providing ongoing advocacy for specific skills in shortage to be included in the skills priority list.

24. Remove challenges around intra-company transfers and recruitment from overseas parent/sister companies, by:

24.1. Working with the Department of Immigration to enhance the accessibility of the 'Sub-class 188, Business Innovation and Investment (Provisional) visa' by introducing a stream to allow greater intra-company-based personnel exchanges for employees of companies with operations in Australia, or partnerships with Australian based companies.

25. Build effective connections and opportunities for Australian expatriates to contribute to Australian biotech companies, by:

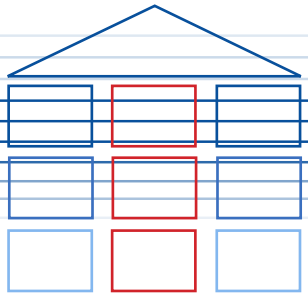
25.1. Partnering with Australian trade commissions and embassies in relevant jurisdictions to establish a network of 'Australians in biotech abroad', creating a platform that Australian based companies can access for knowledge exchange, guidance, and partnerships with expatriates.



Key metrics to track the growth of maturity and vibrancy in the ecosystem

Metric	Rationale	Current reporting
M1.1: Number of companies in the sector	The scale of the industry is a key factor for the industry's sustainability and ability to attract and retain talent.	As at 2022, there are at least 2,654 organisations in the Australian biotechnology ecosystem, growing ~43 percent since 2019 and 60 percent since 2017.
M1.2: Number of companies in each sub-sector	Current collection of sub-section data is medtech and digital health/pharma and biotech/agricultural biotech/services. Digital health to be separated from medtech and services to be more granular (manufacturing/clinical trials/regulatory/IP).	Industry comprises of at least 1,427 companies, making up around 54 percent of the biotechnology sector in Australia. Of this, medtech and digital health comprise of around 40 percent, pharma 38 percent, and agri-biotech 22 percent.
M1.3: Number of small, medium and large sized biotech companies	The number of small, medium and large size companies is an indicator of the industry's sustainability, stability and depth of the industry and the industry's job market. Tracking Australia's ability to grow companies is a measure of its vibrancy.	Approximately 79 percent of biotech companies are SMEs (less than 100 employees).
M1.4: Percentage of ASX biotech companies valued over $100 million	The proportion of biotech companies achieving market valuations greater than $100 million measures the industry's ability to create companies of significant future value.	There are 196 biotech companies listed on the ASX, worth about $242 billion combined. Around 38 percent (74 of the 196) of these companies are valued over $100 million.
M1.5: Revenue versus non-revenue companies	This is a key indicator of commercialisation, of whether the company has reached market or not.	
M1.6: Capital raised (private, public and government)	This is a leading indicator of future growth and a measure of support for industry. Could also capture series A and B funding.	
M1.7: Number of collaborations, partnerships and licencing deals across the sector.	Greater connection and coordination across the sector will drive efficiencies and better facilitate commercially viable innovations.	
M1.8: Number of jobs (FTE) and their geographic locality	Depth and liquidity of the job market across Australia is necessary to attract people to the industry.	There are at least 263,693 employees working across Australia; this has increased by at least 8 percent since 2019 (up from 243,406).
M1.9: Skills gaps	Skills gaps in Australia, plus gaps segmented geographically and by size of gap.	
M1.10: Remuneration	Together with job availability, remuneration is a factor that will attract and retain talent to the local sector.	
M1.11: Percentage of employees with international experience or education	The percentage of talent within a company who hold international experience or education is a measure of being able to provide compelling jobs in the global market and also facilitates knowledge transfer from overseas markets, driving a vibrant and competitive Australian industry.	
M1.12: Business expenditure on R&D (BERD) relative to turnover and country BERD.	This is a leading indicator of future growth and a measure of contribution to country.	
M1.13: Diversity in sector	Commencing with gender diversity, with a view to other important forms of diversity.	Women form 53 percent of the workforce across the biotechnology sector and this has not varied markedly since 2017 (50 percent). However, female representation on industry boards remains low at 17 percent, and as CEO/Founders (16 percent).

**Metrics highlighted in grey represent metrics for which data is currently collected.*
**Of the 27 metrics in the Blueprint, data to measure against only six of those metrics is currently collected.*



GOAL 2:

AN INCREASED LOCAL AND GLOBAL STANDING

The biotechnology industry is intrinsically global in character. Australia's industry is connected to the worldwide sector through development partnerships and trade relationships. The global biotechnology industry is also intensely competitive, with a highly mobile workforce, mobile capital and intellectual property, and a global marketplace.

The competitive and global nature of the industry requires that Australia consistently meets international standards, and be seamlessly connected to the global ecosystem in order to achieve success.

Sub-goal 2.1: …will be an increasingly established and well-recognised global biotech participant.

A global player, with globally comparable incentives

An important goal over the coming decade is to remain committed to delivering highly-valued commercial products and services for the global market. Establishing the industry as a more active global player will stimulate growth and vibrancy in the Australian ecosystem to attract talent and capital from both local and international sources. However, being globally competitive requires comparability in business environments and incentives with comparable ecosystems.

Issue:

Currently, Australia lacks cohesive policies, programs, and incentives across the pipeline, which are becoming global standard, preventing Australia from being an active global player.

Our R&D Tax Incentive (RDTI) is world class and creating the additionality for our sector that was intended, but it has rarely over the last decade been without review, threat, or uncertainty. The industry has been advocating for end-to-end tax incentives for years, where a suite of interlinked programs would work together and complement each other. For example, advocacy for a patent box for Australia, to complement the RDTI started more than eight years ago, and with the announcement in the 2021 May budget, has provided an opportunity for the design to assist global competitiveness.

Strategy:

Create an Australian business environment conducive to the entire research, development, and commercial pipeline. Looking to comparable countries and learning what we can from their initiatives, to apply here without reinventing programs.

Objectives and tactics:

26. Bring Australia's biotechnology industry incentives in line with global standards by:

    26.1. Creating and advocating for a policy position that integrates relevant tax measures to work together, articulates the value of this for Australia and considers the unique characteristics of biotechnology (including but not limited to, an Australian patent box, the ESIC Incentive / ESVCLP / VCLP, ESOP/ ESS and RDTI).

27. Look to relevant comparable countries, such as the UK, to understand the key enablers that have driven their innovation success, by:

    27.1. Conducting a project to analyse programs directly related to this sector and determining which should be established in Australia.

Sub-goal 2.2: …an industry of greater influence, with leaders whose opinions are valued by the wider Australian community and government and are actively involved in biotechnology sector initiatives.

Working 'hand in glove' with government

High visibility and an established global standing must be founded on solid footing on local soil. Yet, while Australian academic institutes are widely celebrated and consulted by government, the Australian biotechnology industry is under-represented as part of the policy and decision-making process.

For example, where there is an initiative to drive commercialisation in the sector, the depth of knowledge within the industry must be consulted and involved in design and implementation. Broad experience and expertise are required to ensure that any initiative will be successful. The role of the industry is often not considered when new and innovative ideas and approaches are brought to the policy 'table', potentially locking out key pathways of future success.

Issue:

There is a noticeable lack of biotechnology and biotechnology industry knowledge and representation on federal government and agency committees, and stakeholder reference groups.

There is an opportunity for better outcomes if governments and industry can be more proactive in identifying and engaging biotechnology expertise on key committees.

Strategy:

Maximise contribution of industry knowledge and expertise in assistance of relevant government and agency bodies, committees, and stakeholder reference groups.

Objectives and tactics:

28. Draw on the expertise within the AusBiotech membership to amplify the sector's voice and aid with lived experience with discussions with government, by:

    28.1. Establishing a formal and standing advisory group to support government efforts at state and federal levels to provide a contribution from industry that can inform the policy and decision-making process.

    28.2. Supporting AusBiotech State Branch Committees to interact and work with state governments alongside state-based industry organisations.

29. Ensure appropriate and effective representation/s for the sector at all levels and mechanisms of government, by:

    29.1. Determining key government, departmental and agency committees relevant to the industry, and advocating for industry membership to them.

Nurturing local talent into future leaders and advocates

The development and growth of home-grown, Australian policy leadership for the biotechnology sector is vital for the sector's future.

With over 2,654 organisations employing over 263,693 people across a broad and diverse sector that has talent across the biotechnology pipeline, cultivating and nurturing talent into future leaders will arm the sector with leadership that possesses a rich and invaluable practical understanding, and a lived appreciation for the realities facing Australia's biotechnology ecosystem.

Issue:

The sector is young, at the cutting edge of new technologies, and few have a sector-wide view. There is lack of a coordinated approach to leverage learning within the sector, and lack of a mechanism to increase biotechnology 'literacy' to cultivate and support emerging leaders in shaping the future of the biotechnology industry.

Strategy:

Establish an Australian biotechnology workforce program that can nurture emerging leaders across the industry for the future and stands ready to assist and work effectively with the Australian Government to deliver for Australian biotech while aiming to lift the biotechnology 'literacy' levels amongst policymakers and decision makers.

Objectives and tactics:

30. Enshrine a deep understanding of the machinery of government, and the policy and political processes, amongst the biotechnology sectors' talent and emerging leaders by:

30.1. Developing and delivering a leadership program for biotechnology sectors' talent and emerging leaders that upskills the sector on the workings of government in policy and economic development.

31. Foster the growth and development of the next generation of policy champions and leaders within government decision making and policy roles that are relevant to the Australian biotechnology sector, by:

31.1. Developing an education and information program to support Parliamentarians, and government employees

Growing local talent and capability, for greater global visibility

Australia has lots to boast about and our reputation is growing. From our reliable research sector to our world leading hospital system, and reliable clinical trials sector, to our R&D capabilities and notable expertise, the success of Australian biotechnology is an important story to share when demonstrating the value of companies from across the globe establishing in Australia.

Issue:

Currently, there is a lack of direct and targeted promotional marketing to markets of interest, and to companies looking to establish in Australia. It is expensive for a trade organisation to promote the successes of the Australian biotechnology industry. For example, a country Pavilion at the world's largest congress costs in the order of $250,000 and is up to not-for-profit outfits to carry the risk that costs will be covered.

Australia would benefit from stories being told to the global ecosystem. Partnership opportunities would enable Australia to be seen as a trusted partner, and as an attractor of R&D, investment, and manufacturing destination of choice. Austrade and state-based trade offices are supportive, but often have broad remits and little direct funding to support efforts. Export Market Development Grants from the Australian Federal Government are helpful, but small.

Strategy:

Position Australia's successful biotechnology ecosystem internationally as the natural destination of choice for partnering, clinical trials, establishing new businesses and investing.

Objectives and tactics:

32. Increase awareness of Australia's strengths amongst biotech companies globally and attract companies and investment to locate within Australia, by:

32.1. Partnering with the Australian Government to undertake a targeted, international campaign to promote and demonstrate the merits of the Australian biotechnology ecosystem. Taking any opportunity to highlight Australia's:

- R&D and patent-based tax incentives;
- World class healthcare system and clinical trials capability;
- Ground-breaking basic and applied research;
- Commercialisation potential.

32.2. Continuing annual promotion at BIO and other significant global events, based on an agreed calendar with Austrade and others, where support is agreed/committed over multiple years to create certainly and momentum.

Transcending geopolitical tensions

Most notably uncovered by the COVID-19 pandemic, our inter-connected world is vulnerable to disruptions in trade, official communications, and political relations, which can come with great consequences for a sector that is quintessentially global in nature.

Issue:

Political tensions between governments at an international and a domestic level, can affect the industry and its interests abroad.

Strategy:

Build direct partnerships within key markets, that can transcend geopolitical volatility and conflicting political developments.

Objectives and tactics:

33. Build strategic partnerships with industry bodies and business councils across the globe to create enduring opportunities for the Australian biotechnology sector, by:

33.1.Continuing engagement with the International Council of Biotechnology

Associations (ICBA) and participate in its global policy forums on global issues.

33.2.Building on established memorandums of understanding with international trade organisations.

34.Strengthen the prospects of business-to-business partnerships and investment opportunities between Australia and markets of interest, by:

34.1.Establishing collaborative events/ opportunities in key markets.

34.2.Strengthening bonds with industry bodies in other jurisdictions (peak body to peak body), and focusing efforts on identified key markets for:

- Investment attraction;
- Sales and distribution;
- Regulatory approvals;
- Preclinical and clinical development;
- Partnering; and
- Manufacturing.

Key metrics that measure the Australian biotechnology industry's global and local standing

Metric	Rationale
M2.1: Direct foreign investment in Australian companies	Global capital is mobile, and therefore the level of foreign investment is a strong indicator of the industry's position as a global leader. It should be tracked in tranche size location from which it comes and seed v series A, B or C.
M2.2: Venture capital invested in the Australian sector versus venture capital invested in Australia.	This will give a measure of how much biotech is attracting in the pool of venture capital investment.
M2.3: Number and value of global partnerships, licencing deals, and mergers and acquisitions.	Global partnerships, licencing deals, and M&A are important measures of whether the quality of our R&D, intellectual property and service capabilities meet or exceed international standards.
M2.4: Key industry opinion leaders represented on decisive government committees	The industry's growth and success will require effective, industry-specific government policies and initiatives driven by industry consultation and involvement. This should track key committees and whether biotech expertise is involved.
M2.5: Capital raised	See above table for the same metric
M2.6: MRFF funds applied to commercialisation	While the MRFF is cognisant of the importance of translation, tracking the amount invested once research is transferred could provide fresh insight.

GOAL 3:

A MORE POSITIVE CONTRIBUTOR TO AUSTRALIAN PROSPERITY

In a decade, the Australian biotechnology industry will be a more positive contributor to Australian prosperity – in economic, social and in health terms. A strong and relevant Australian biotechnology industry must be sustainable and consistently demonstrate value as a net positive contributor to the country's economy.

The ultimate purpose of the biotechnology industry is to develop technologies to save and improve lives. Therefore, the Australian biotechnology industry will continue to try and demonstrate its ability to consistently achieve this outcome through improved products, services and therapies that address unmet and health needs.

The Australian biotechnology industry has a developing record of successfully commercialising new products, services, and therapies for the global market. However, the long-term nature of development in this sector means that progress to market requires patience.

Commercialisation pathways will often involve overcoming complex and prohibitive barriers. Whether an Australian biotech company brings a new technology to market directly or indirectly, both pathways are successful outcomes that generate positive economic and social impact and achieve the industry's mandate to contribute to Australian prosperity.

Sub-goal 3.1: … a more demonstrated positive and sustainable contributor to the Australian economy.

Remaining competitive by delivering global best practice

The Australian biotechnology sector is committed to becoming a more positive economic contributor to Australia. First however, we must improve Australia's ability to translate early-stage research into promising commercial candidates, consistently progressing IP assets along the development and commercialisation pipeline.

Being able to demonstrate the ability to consistently create value and a return on investment will attract more knowledgeable investors, garner broader support from the government and generate greater economic returns, but amongst other enablers, this is in part dependent on the workability of Australia's regulatory environment.

Issue:

A notable impediment to effective commercialisation is the disbursement of regulatory responsibilities and the lack of harmonisation across Commonwealth, State and Territory agencies. The inconsistent programs and infrastructure across state jurisdictions can result in an associated lack of coordination and harmony in policies designed to encourage the progress of research from bench to bedside at a national level.

Further, with a constant stream of new and emerging trends, biotechnologies that Australian patients can benefit from are thick on the horizon.

Australia's therapeutics goods regulator - the Therapeutic Goods Administration (TGA), is doing an admirable job in responding to the evolving landscape and has taken an active role in harmonising Australia's regulatory frameworks with key international jurisdictions.

The TGA however, currently operates under cost-constraints defined by an industry cost-recovery business model, and in an environment where new technologies are providing challenges in traditional regulatory pathways around the globe.

Additionally, the role of the TGA in consumer education, public relations and other worthy activities has appropriately increased in recent years. The TGA, the industry – and by extension - the Australian public, would benefit from a better-resourced regulator that has public funding to continually refine existing regulatory frameworks, and address – and support, the emergence of new technologies[8].

Strategy:

Create greater harmonisation between jurisdictions and provide sufficient resourcing for Australian regulators and regulating bodies.

Objective and tactics:

35. Enhance Australia's ability to reap the full benefit of our domestic R&D capabilities when regulating current technologies and responding to new and emerging trends by:

32.1. Take a sector-wide approach, working across industry organisations, to support and improve regulatory harmonisation in terms of frameworks and pathways across Commonwealth, State and Territory jurisdictions and agencies to recommend the requisite refinement, or alignment for nationwide harmonisation and consistency with international standards.

36. Support the TGA in further harmonising current regulatory frameworks and preparing for new and emerging trends and technologies, by:

36.1. Advocating for publicly-funded resources for the TGA to add to the current funding available.

33.2. Hosting forums to support understanding of issues and potential solutions.

33.3. Investigating opportunities for fast-tracking regulatory approvals for Australian technologies where products are approved by a comparable regulator.

33.4. Investigating options for emergency approvals in times of dire need for technologies that have received approvals from regulators in comparable jurisdictions.

Industry data collection to drive industry insights

While the strategies and tactics will be vital in achieving the Blueprint's goals, the impact of each to drive the industry towards the overarching vision is different, and will require a set of specific metrics to evaluate the industry's progress towards achieving that vision.

The metrics identified for each of the Blueprint's goals have been developed to track the industry's progress and growth over the coming decade.

Issue:

The current lack of consistent and industry-specific data makes it difficult to evaluate the industry against those metrics. Of the 25 metrics identified in Blueprint, only six can be sufficiently reported against using industry-specific data that is currently collected.

Strategy:

Harness the insight provided by industry specific data collection capabilities to measure and accelerate the growth and progress of the Australian biotechnology sector.

Objectives and tactics:

37. Build a culture of industry data harvesting that enables data collection and analysis capability by:

37.1. Benchmarking the sector in an auditing exercise to determine data requirements and identifying the necessary partnerships and collaborations needed to meet them.

37.2. Determining what data is currently collected across the sector and agreeing specific data set collection goals across multiple interested organisations – and coordinating to partner where possible.

37.3. Assessing which metrics outlined in the Blueprint can be feasibly collected, and which may need to be adjusted.

37.4. Identify, align, resource and track key metrics required to appropriately measure progress towards the vision and plan outlined in the Blueprint.

[8] Looking to comparable jurisdictions, the US FDA's funding is generated through a 50 percent industry/50 percent government split, and the EU's EMA is funded via a 75/25 percent split.

Sub-goal 3.2: …improve more lives through the development of cutting-edge health technologies.

New areas of health technologies that are developing as sub sectors, with unique needs, are regenerative medicine (RM), digital health (including digital therapeutics), and synthetic biology, including mRNA.

RM harnesses cells and tissues, often combined with gene therapy and devices, to enable the body to regenerate and heal itself. As a market, RM has grown rapidly in the past decade, and is expected to reach A$120b in revenues by 2035.[9]

Australia has established a good initial position in this market, with 32 companies having a strong focus on RM and around 1,200 researchers working in labs, but continued focus will be required to capture an outsized share globally. The Australian RM community has outlined a vision for the sectoral opportunities in a report published in 2018[10], and since then a consortium of seven organisations have banded together to research, benchmark and produce nine reports that will act as a foundational body of evidence on which to build the sector. As at May 2022, a newly-launched Cell and Gene Catalyst, co-led by AusBiotech and Medicines Australia, has called for expressions of interest to continue the work of the Consortium.

For the biotechnology industry, the shift to digital health is expected to transform how product development is managed and financed as therapeutics, diagnostics and devices become increasingly dependent on digital inputs and technologies. However, the nascent digital health sector frequently relies on new business models that are unfamiliar for investors, and which are playing out against a fluid regulatory backdrop, putting a premium on domain-specific skills and experience.

ANDHealth's report on the strengths, opportunities, constraints and barriers to the commercialisation of evidence based digital health technologies in Australia demonstrates that Australia's healthcare system will need to accelerate its adoption of digital technologies if it is to tackle the challenges of the coming decade[11].

As outlined in the CSIRO's National Synthetic Biology Roadmap[12], recent attention has turned to the potential of synthetic biotechnology and its emerging capability, including RNA-based products. Since the pandemic mRNA technology has come into the spotlight for its successful role in the rapid development of safe and effective vaccines for COVID-19. It has also triggered public and private investment to establish capabilities from fundamental scientific research through to clinical and commercial onshore mRNA manufacturing.

Developing RNA technology could yield advancements in vaccines for autoimmune deficiencies, brain function and disorders, and products with agricultural application that could be essential for Australian biosecurity, with considerable potential for more advanced uses in treating disorders such as arthritis, cancer, and malaria.[1]

Smoothing the path to new technologies

The maturation of Australian biotechnology companies into revenue generating businesses indicates that a treatment, vaccine, device or diagnostic has reached a patient. It indicates that research has been translated, commercialised, and has begun to create value. But this rests on the technology having access to a reliant and supportive pathway to patients.

Issues:

There are key challenges for patients achieving access to new technologies.

Although some challenges may be unique to individual technologies, challenges that are structural in nature, and therefore, far more complex, require addressing through sectorial and systems policy approaches.

One such structural challenge is market access, a key systemic issue for the Australian biotechnology industry that directly impacts patient access to breakthrough treatments.

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[9] Regenerative Medicine Opportunities for Australia, MTP Connect, 2018
[10] Regenerative Medicine: Opportunities for Australia, MTPConnect, 2018
[11] Digital Health: Creating a new growth industry for Australia, ANDHealth, 2020
[12] CSIRO Futures (2021) "A National Synthetic Biology Roadmap: Identifying commercial and economic opportunities for Australia" CSIRO, 2021
[1] "Statement – National RNA science and technology priorities", published by Academy of Science, July 2021

The issues surrounding market access, health technology assessment and reimbursement, are often seen as blockages that impede the progress of technologies from benchtop to bedside. Researchers and SMEs often see market access as an issue to deal with further down the development pipeline. Often, the greater blockage is clinical practice, with no supports currently available to SMEs or researchers on the research, direction and planning for market access early enough in the development journey.

Strategy:

Support the value creation of new technologies and their pathway to patients.

Objectives and tactics:

38. Develop market access support for SMEs and researchers, by:

38.1. Scoping a project to commence a (possibly virtual) 'market access institute' for SMEs and researchers that enables education on market access (including clinical practice change, quality/GCP and HTA processes and reimbursement) in early-stage development.

39. Identify and support the specific challenges and opportunities faced by sub-sectors within the biotechnology ecosystem, by:

39.1. Creating new sub-sector-specific strategies to overcome the challenges that stifle the growth and smooth adoption of new technologies, or where they exist, supporting the implementation of existing strategies such as the RM Consortium's '*Catalysing Regenerative Medicine in Australia: A Strategic Roadmap', ANDHealth's 'Digital Health: Creating a New Growth Industry for Australia', and the CSIRO Future's 'A National Synthetic Biology Roadmap: Identifying commercial and economic opportunities for Australia'.*

Clinical trials in Australia, for Australians

Australia has a world-class ranking in regard to the quality of its clinical research, with a number of advantages that lend to this global standing, such as high-quality infrastructure, an ethnically diverse population, high quality regulators, and globally recognised clinicians.

Clinical trials provide benefits to Australian patients, the healthcare system and the broader medical research industry. They provide a mechanism for patients to gain early, no-cost access to innovative treatments across a broad range of diseases while contributing to better healthcare outcomes by generating evidence that drives improvements in clinical practice and therapies.

It is recognised that Australia's medical research sector makes a significant contribution to the economy. For every $1 invested in medical research in Australia, $3.90 is returned to the broader economy.[13]

Issues:

Since 2006 the need for clinical trial reform in Australia has been well recognised. As a result, many committees, working groups, consultation forums and other initiatives have been implemented at Federal and State levels, many with positive and impactful outcomes.

However, until a recent, welcomed, announcement by the Federal Government to create a Clinical Trials One-Stop-Shop, and to consider options for a National Clinical Trials Front Door, lack of coordination, harmonisation across jurisdictions, and a single point of access to the sector would have continued to go unaddressed.

Strategy:

Support work by Federal and State governments, and the Clinical Trials Project Reference Group (CTPRG) to create an effective, efficient and world-leading Australian clinical trials sector.

Objectives and tactics:

40. Work with the Federal Government and the Australian Commission on Safety and Quality in Health Care to deliver a Clinical Trials One-Stop-Shop and a Clinical Trials National Front Door that is fit for purpose by:

40.1. Coordinating stakeholder views from industry and supporting efforts to develop platform/s that will deliver single coordinated point/s of entry, notably:

- a platform for participant expression of interest, participant matching to trials, a database of nationally available trials; and

[13] *Economic Impact of Medical Research in Australia, a KPMG study commissioned by the Association of Australian Medical Research Institutes (AAMRI) October 2018.*

- resources for overseas companies interested in conducting trials here in Australia.

Protecting intellectual property

Intellectual property (IP) - and its protection - is the most fundamental source of value used by Australian biotechnology companies to attract the substantial, multi-million-dollar investment it takes to bring test, treatments, devices and cures to patients.

Unlike tangible goods, the portability of IP makes it especially easy to move its management to another, more competitive jurisdiction, with management, manufacture, registration and sale of the IP's products often dictated by the business and public policy environment of its locality.

As biotechnology is a global undertaking, globally-competitive IP system that fosters and encourages the development of new biotechnologies through globally competitive IP protection terms, data exclusivity provisions, and IP commercialisation incentives, is key to Australia's future health and wealth.

At a global level, the recent debate at the World Trade Organization on waiving the Trade Related Aspects of the IP Rights (TRIPS) agreement to allow for forced technology transfer has re-ignited concerns about compulsory licensing and acquisitions.

Issues:

Areas of note that warrant attentions are Australia's lack of provision of data exclusivity, a niche but critical component of our IP system, and other areas where we currently lag behind comparable and important jurisdictions.

For example, the current five-year data exclusivity provision trails collaborators such as the United States (up to 12 years), Canada (eight years), the EU (up to 11 years), Japan (eight years) as well as countries like Russia and China (six years). This puts at risk investment in Australia's rapidly growing domestic biotechnology sector.

The most recent review of Australia's patent term lengths and patent term extensions (PTEs) was last conducted in 2012 and, having been specific to pharmaceutical patents, did not include a review of comparable protections for Australia versus other key jurisdictional markets.

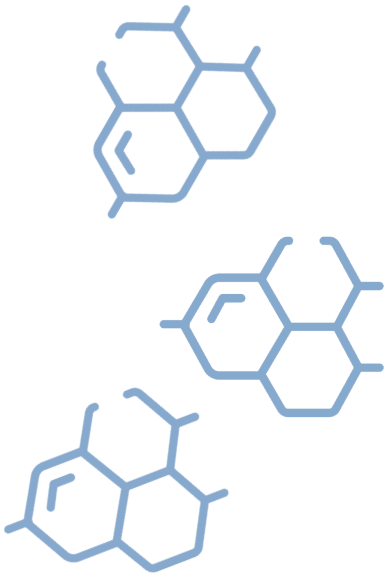
While IP protection is not the only factor considered by investors when making investment decisions, the total protection term available and the potential for investment return is absolutely critical. The length and nature of protections significantly influence the risk assessment of investors, and the registration of multi-national companies' IP, here in Australia.

Strategy:

Advocate for an Australian biotechnology ecosystem where IP is protected, valued and regulated in a manner comparable to world-best international jurisdictions.

Objectives and tactics:

41. Protect Australian IP and attract more companies to register their IP here in Australia by:
    - 41.1. Working with the Federal Government and IP Australia to review the Australian patent system in relation to world best practice.
    - 41.2. Advocating for the harmonisation of data exclusivity term lengths with global best practice;
    - 41.3. Oppose plans that undermine value and force companies to relinquish IP protection without due compensation, compulsory acquisition or forced tech transfer, such as the TRIPS waiver.



Key metrics that measure the industry's positive contribution to Australian prosperity

Metric	Rationale
M3.1: Return on Investment (ROI)	Determining the dollar amount returned for every dollar invested into the biotechnology sector will help demonstrate the amplification of investment and the value add the industry has on the Australian economy.
M3.2: Number of patents granted in overseas and local markets by Australian companies	Patenting is a value creation activity and an indication of future economic activity and global competitiveness. The patent landscape is illustrative, not as a stand-alone measure, but when taken with other metrics. Granular capture of Australian companies patenting in overseas markets and at home is recommended.
M3.3: Revenue	Revenue generation indicates sustainability, commercialisation success and a positive contribution to the Australian economy.
M3.4: Deal flow	Deal flow indicates inflection points have been met and monetised, e.g., a measure of commercialisation success.
M3.5: Manufacturing export	Exporting capacity is a measure of contribution to the Australian economy.
M3.6: Gross value-added amount	A measure of the value of all goods and services produced by the industry. Is a measure of the contribution to the Australian economy.
M3.7: Development progression made (e.g., percentage of companies that progressed to next phase in clinical trials)	Progression through the development pipeline is a short-term measure of commercialisation success.
M3.8: Number of products brought to market + which are available in Australian market	A measure of both direct and continuing human impact and realising value from IP.

TRACKING PROGRESS

Throughout the Blueprint, the Australian biotechnology community presents a strategic plan to help deliver its ambitions over the coming decade.

The Blueprint looks to the future by identifying the obstacles currently faced by the sector, proposing the strategic government investments and greater sector coordination needed to overcome them.

The plan includes strategies and tactics that work hand-in-hand to deliver the three goals that underpin the sector's vision for Australian biotechnology.

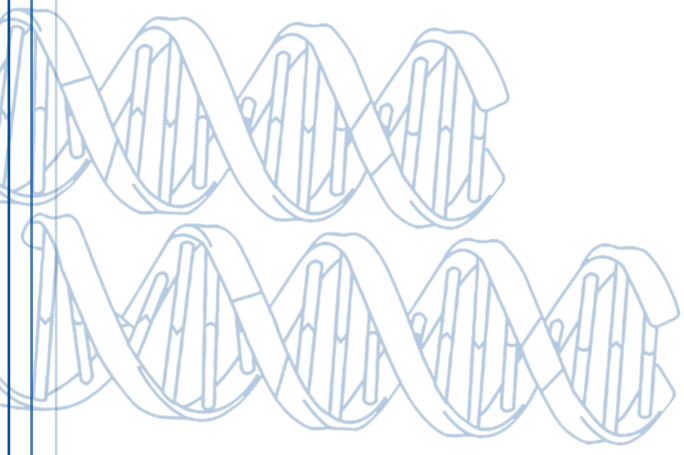
To track implementation of those tactics, a series of checkpoints at two and a half years, five years, and seven years will be used to ensure appropriate progress is being made.

Further, in acknowledgement that the Blueprint was written during what will undoubtedly be recalled as a monumental period throughout history, the five-year checkpoint will also include a midterm review of the Blueprint itself, examining its strategies, objectives, and tactics, to evaluate their suitability to that time, adjusting and where necessary proposing new strategies, objectives, and tactics.

Tracking and reporting of progress will mitigate for distractions, changing agendas and different stakeholder priorities. It is envisaged that the blueprint will be supported in whole or in part, by the stakeholders for whom the recommendations are both relevant and resonate. There are two additional recommendations considered critical for delivering on the vision and strategies outlined in this blueprint. Firstly, the recommendations within this report do not all have sufficient data sources to track progress; there is a need to build up the resources and mechanisms needed to understand progress and therefore to address shortfalls and gaps that are evidenced by the data. Secondly, with such an ambitious and fulsome plan, it will be critical to align on key priorities, timelines and actions, given that some recommendations intersect across stakeholders.

At the outset it is intended that the Blueprint be one for industry to judge progress, but there is a necessity for other stakeholders to not only join in and collaborate for success, but also to actively pursue aligned approaches and importantly to accept appropriate accountabilities. A joint, oversight group, akin to that previously used but now aligned to execution of the Blueprint, is proposed to foster the collaboration needed to deliver Blueprint success, to:

42. Establish a body such as a joint industry council, with appropriate representation from key stakeholders such as governments, to provide collaborative input to the execution of the Blueprint.



IMPLEMENTATION AND INTENTION TIMELINE

While most tactics in the Blueprint will be executed consistently or on an 'as needed' basis over the coming decade, some tactics outlined within this document will act as an enabler for implementing other tactics, and will therefore require priority status or phasing.

It is envisioned that the above-mentioned joint industry council will determine timelines, seeking to work towards along term view, but accepting the need for early and ongoing progress and momentum.

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The Board of AusBiotech

Name	Oragnisation
Ms Michelle Burke	Chair, AusBiotech (to Nov 2021 and Principal and Director, Indigo Advisory Pty Ltd
Geoffrey Kempler	Chair AusBiotech (from Nov 2021) and Chair Alterity
Ms Lorraine Chiroiu	Chief Executive Officer and Managing Director, AusBiotech Ltd
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Dr James Campbell	Chief Executive Officer, Patrys Ltd

The Biotechnology Blueprint's Leadership Forum

Name	Organisation
Ms Michelle Burke	Principal and Director, Indigo Advisory
Dr Andrew Nash	Chief Scientific Officer, Senior Vice President, Head of Research, CSL Limited
Dr Mary-Beth Brinson	Vice President Global Clinical Affairs, Cochlear Ltd (no longer in role)
Ms Julie Phillips	Chief Executive Officer and Managing Director, BioDiem Ltd
Dr Siro Perez	Head of Life Sciences, IP Group Australia
Mr Silvio Tiziani	Director, External Strategy and Planning, Australian Regenerative Medicine Institute
Dr Ryan Parlett	Director Business Management, Pharma Services, Patheon
Ms Helen Fisher	Chief Executive Officer and Managing Director Bio Capital Impact Fund and non-executive director Paradigm Biopharmaceuticals Ltd
Ms Marilyn Jones	Director, mexec
Prof Trent Munro	Senior Group Leader, Institute for Bioengineering and Nanotechnology, University of Queensland
Mr Warren Bingham	Chief Executive Officer, BioAnalytics Holdings Pty Ltd
Dr James Campbell	Chief Executive Officer, Patrys Ltd
Dr Chris Davis	General Manager, Institute for Glycomics, Griffith University
Mr Colin La Galia	Chief Executive Officer, Epichem (no longer in role)
Dr Mark Ashton	Executive Director, IP Commercialisation, UniQuest Pty Ltd
Ms Jane Kelly	Chief Executive Officer, CMAX Clinical Trials Pty Ltd
Mr Mark Glover	General Manager, Biointelect Pty Ltd

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AusBiotech Advisory Groups:

- The Investor Advisory Group
- The AusMedtech Advisory Group
- The AusMedtech Regulatory Affairs Advisory Group
- The Regenerative Medicine Advisory Group
- The Clinical Trials Advisory Group
- The Intellectual Property Advisory Group

GLOSSARY OF TERMS

ARTG	Australian Register of Therapeutic Goods
Biotechnology clusters, precincts	A model of integrating, through close proximity and co-location, highly skilled researchers and research institutes, clinicians, hospitals, technologists, developers, and manufacturers
BTF	The Biomedical Translation Fund, funded through the Australian Government's Medical Research Future Fund provides companies with matched venture capital through licensed private sector fund managers. The BTF is intended to help Australian biotechnology companies develop biomedical discoveries into tangible products, services and outcomes.
Clinical Trials National Front Door	A proposed platform for improving patient recruitment to Australian clinical trials
Clinical Trials One-Stop-Shop	A proposed national online portal for all health and medical research will make it easier for researchers, industry representatives and sponsors to find, conduct, participate and invest in research in Australia
Commercialisation	The process of developing scientific knowledge into a profitable, tangible product, service or outcome that has a commercial return.
CROs	Clinical Research Organisations, also known as contract research organisations, are companies that provide outsourced research services to the biotechnology, pharmaceutical and medical device industries.
CSIRO	Commonwealth Scientific and Industrial Research Organisation.
Data Exclusivity	Data exclusivity refers to protection of clinical trial data provided to a regulatory agency to prove safety and efficacy of a new drug. Data exclusivity prevents manufacturers for generic brand therapeutics from referencing this data as proof of efficacy in their own applications
Diagnostics	A practice, device or apparatus used in medical assessments, or the diagnosis of medical ailments
Digital health	Digital health technologies use computing platforms, connectivity, software, and sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products.[14]
EMDG grants	Export Market Development Grants form a program by the Australian Federal Government that helps Australian businesses grow their exports in international markets. These grants encourage small to medium enterprises to market and promote their goods and services globally.

[14] US Food and Drug Administration, 2020, *What is Digital Health?*, accessed 19 October 2021

Emerging technologies	Emerging technologies can be broadly characterised by five attributes: radical novelty, fast growth, coherence, prominent impact, and uncertainty and ambiguity.
ESIC Incentive	The Early Stage Investment Company Incentive, is a tac incentive provided by the Australian Federal Government to T eligible investors, who purchase new shares, with: a non-refundable carry forward tax offset equal to 20 percent of the value of their qualifying investments. This is capped at a maximum tax offset amount of $200,000; a modified capital gains tax (CGT) treatment, under which capital gains made or accrued on qualifying shares that are continuously held for at least 12 months and less than ten years are exempt from CGT. Capital losses made or accrued on shares held less than ten years are also disregarded.
ESS	Employee Share Schemes give employees a benefit such as: shares in the company they work for at a discounted price; the opportunity to buy shares in the company in the future (this is called a right or option). In most cases, employees will be eligible for special tax treatment.
ESVCLP	Early Stage Venture Capital Limited Partnerships are tax incentives provided by the Australian Federal Government that include: flow-through tax treatment for ESVCLP; an exemption for Australian and foreign venture capital partners from income tax on capital and revenue profits from the disposal of eligible venture capital investments made by the ESVCLP and any other income earned on these investments; that fund managers are taxed on their carried interest in the partnership on capital account, rather than as income.
FDA	United States Food and Drug Administration, the US equivalent of the Australian Therapeutic Drug Administration.
Intellectual property	As defined by IP Australia, is the is the property of your mind or proprietary knowledge.
Lambert review	The Lambert Review of Business-University Collaboration was a report by Richard Lambert published by Her Majesty's Treasury in the United Kingdom in 2003, which made "a series of recommendations aimed at smoothing out the path between Britain's strong science base and the business community" [HM Treasury 2003a].
Lambert toolkit	The Lambert toolkit is a toolkit of template contracts, model agreements, decision guides, and guidance notes for universities and companies that wish to undertake collaborative research projects with each other.
Modern Manufacturing Initiative (MMI)	A $1.3 billion Australian Federal Government initiative to drive lasting change for Australian manufacturers that meet the National Manufacturing Priorities, by helping them scale-up, collaborate, and commercialise.
Modern Manufacturing Strategy	The Modern Manufacturing Strategy is a whole-of-government strategy of the Australian Federal Government "to help Australian manufacturing scale-up, become more competitive and resilient — creating jobs for now and future generations".
MRFF	Medical Research Future Fund
MTPConnect	Australia's Growth Centre for the medical technologies, biotechnologies and pharmaceuticals sector.

NCRIS	National Collaborative Research Infrastructure Strategy
Patent box incentive	A tax concession for Australian medical and biotechnology innovations announced in the 2021-22 Federal Budget. The incentive which is proposed to tax corporate income derived from eligible Australian patents in the medical and biotechnology sectors, at a concessional rate of 17 per cent, effective from 1 July 2022.
Proof of concept funding	Funding provided to SMEs and researchers intended to examine whether an idea has the potential for becoming a tangible, marketable product.
Reimbursement	The process of fully reimbursing a company or entity for the cost of a health technology. In Australia, Health Technology Assessments (HTAs) for reimbursement assesses health technologies and procedures in regard to their quality, safety, comparative effectiveness, clinical effectiveness and cost effectiveness. Current health technologies assessed include: medical services, surgical interventions, medical procedures, diagnostic technologies (including pathology), medical devices, vaccines and pharmaceuticals, as well as combinations of these health technologies including hybrid and co-dependent technologies.
Regenerative medicine	Regenerative medicine represents the possibility of revolutionary, lifelong, and curative therapies include gene therapies, cell therapies (such as CAR-T), and tissue-engineered products (TEPs), to regenerate or replace injured, diseased, or defective cells, tissues, or organs to restore or establish function and structure.
SME	Small and medium enterprise
Sovereign capability / Sovereign manufacturing capability	The ability to design, build, sustain, upgrade and export Australian made products that don't rely on complex global supply chains.
TGA	The Therapeutic Goods Administration is the medicine and therapeutic regulatory agency of the Australian Government. As part of the Department of Health, the TGA regulates the quality, supply and advertising of medicines, pathology devices, medical devices, blood products and most other therapeutics.
TRIPS Agreement	The Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international treaty which regulates intellectual property rights
TTO	Refers to a Technology Transfer Office that resides in a university and is responsible for technology transfer and other aspects of the commercialisation of research. TTOs engage in a variety of commercial activities and aim to facilitate the process of bringing research developments to market. Most major research universities have established TTOs in the past decades, although there are many presentations, styles and sizes..
VCLP Incentive	Venture Capital Limited Partnerships are tax incentives provided by the Australian Federal Government that include: flow-through tax treatment for a VCLP; an exemption for eligible foreign venture capital limited partners from income tax on capital and revenue profits from the disposal of eligible venture capital investments by the VCLP; that fund managers are taxed on their carried interest in the partnership on capital account, rather than as income.
Venture capital	Funds invested in a project that carries a certain degree of risk, and is typically a new or expanding business.

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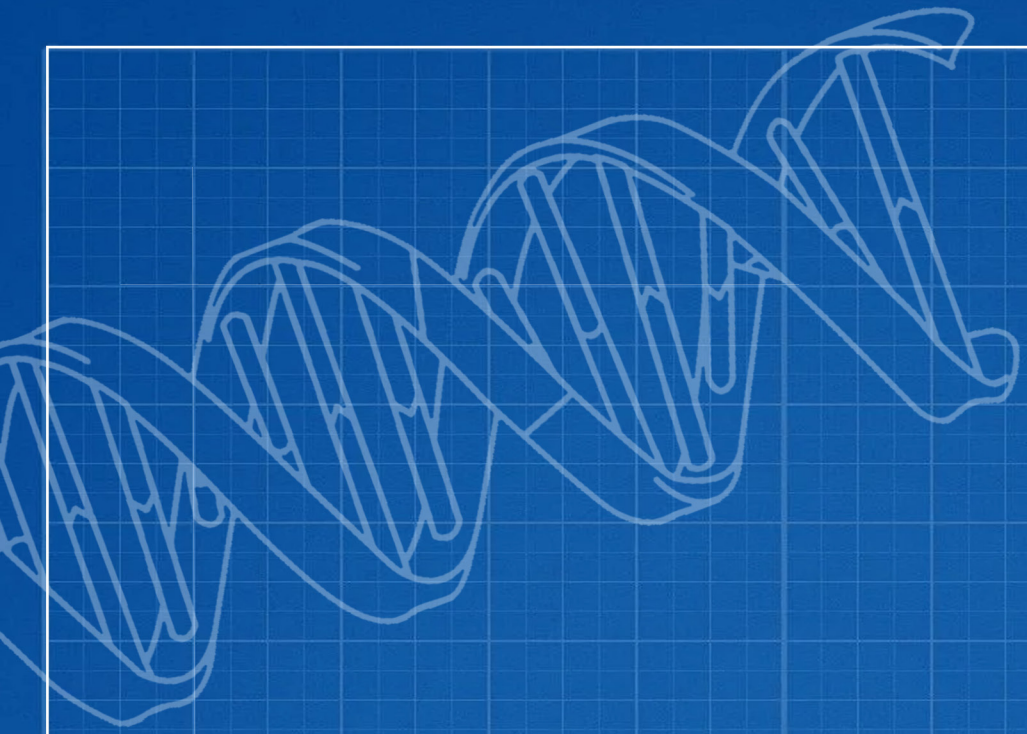

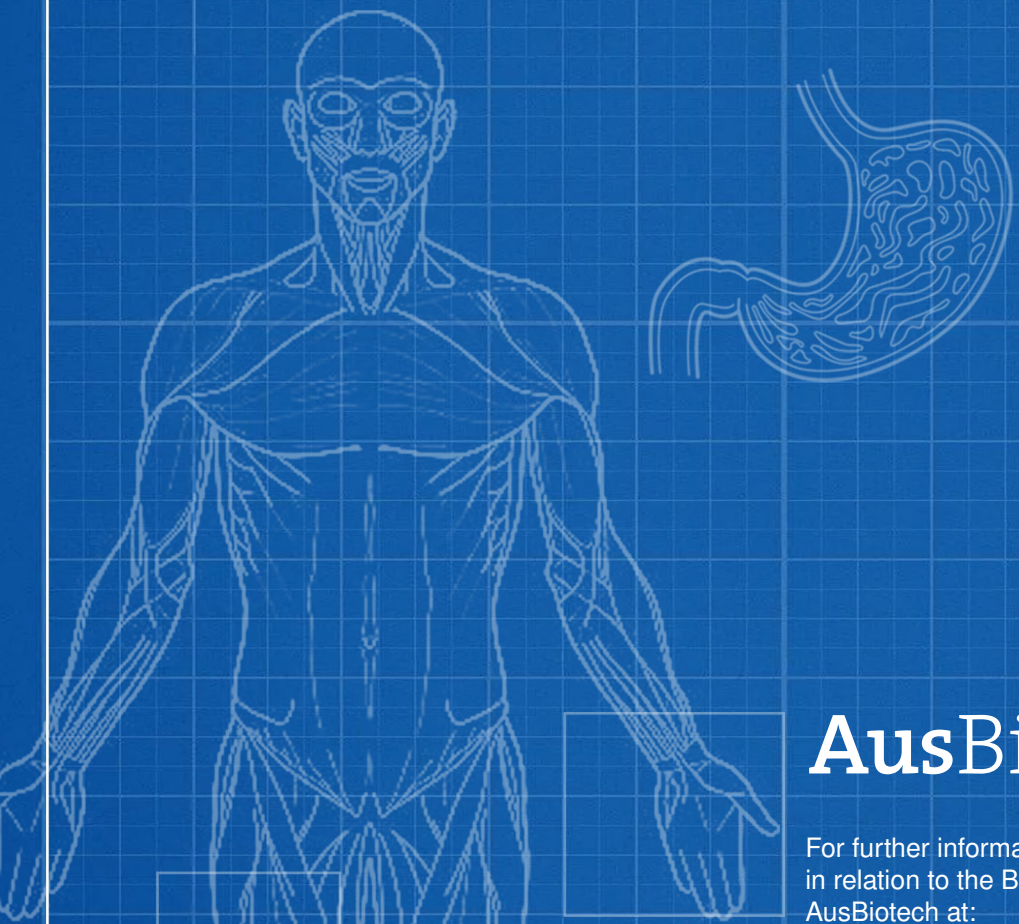

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