MTPConnect
MedTech and Pharma Growth Centre

# Medical Technology, Biotechnology & Pharmaceutical Sector Competitiveness Plan

JUNE 2019

Australian Government
Department of Industry, Innovation and Science
Industry Growth Centres

# ACKNOWLEDGMENTS

This Sector Competitiveness Plan was developed with input from a broad cross section of sector participants, including industry associations, companies, regulatory bodies, research organisations, federal and state government representatives and investors. The open and constructive input has confirmed key elements of the 2016 SCP, and importantly identified areas of evolution and refinement as we look ahead to 2025. MTPConnect would like to thank all those who gave their time to participate in stakeholder consultations.

## LEGAL INFORMATION

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# FOREWORD FROM THE CHAIR AND MANAGING DIRECTOR & CEO

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In November of 2015, MTPConnect was established as an independent, not-for-profit organisation to drive connectivity, innovation, productivity and competitiveness in Australia's medical technology, biotechnology and pharmaceuticals (**MTP**) sector. In 2016 we published a foundation plan for the sector and MTPConnect; our first Sector Competitiveness Plan which was developed with input from hundreds of sector participants. The past three years have seen satisfying progress towards addressing the Sector Growth Priorities laid out in the 2016 plan.

One of MTPConnect's most valuable contributions has been our ability to foster connections and collaboration in the sector, increasing synergy between all participants ranging from industry and research to government. A headline achievement has been the investment of over $26 million into initiatives supporting the MTP sector which have attracted more than $39 million in co-contributions from industry. We aim to keep connectivity and collaboration as our focus, while continuing to support skills and workforce development, regulatory reform and bilateral international market access.

In 2019 we are releasing a refresh of our 2016 and 2018 Sector Competitiveness Plans, again with input from key sector participants. Our 2019 plan lays out a roadmap for MTPConnect's activities over the next three years, reflecting developments in the sector and achievements and lessons learned from our first years of operation. A key highlight of this report is the shortlist of Knowledge Priorities which represent areas where there is a high level of unmet need globally, and where Australia is, or has the potential to be, a leading global contributor. These Knowledge Priorities, developed in close consultation with the sector and through rigorous analysis of research and publication data, are intended to provide strategic focus to the sector's activities and we look forward to conversations with sector participants about how we can drive growth through these Priorities.

We thank you for your engagement in our efforts to promote some of the industries that are most central to Australia's future growth, health and prosperity. We look forward to working with you to drive further growth within the MTP sector over the next three years.

# EXECUTIVE SUMMARY

Technological developments and shifts in consumer behaviour are creating exciting opportunities within the MTP sector. Developments such as genomics, gene-editing, big data and analytics are accelerating the rise of precision medicine and digital health solutions. The ability to develop products and services tailored to individual / groups of consumers with seamless digital connectivity and integration is becoming increasingly feasible and holds great promise for enabling better health outcomes for consumers. Consumers are also increasingly aware of key issues affecting their overall health and wellbeing and are looking to take more responsibility for maintaining or improving their health. In this context, it is crucial for the Australian MTP sector to take a collective, coordinated response to these changes in the healthcare market in order to maximise value creation for the industry and consumers.

MTPConnect is a not-for-profit organisation that champions an industry-led approach to accelerating the rate of growth of the MTP sector, working collaboratively with all parts of the sector. The annual Sector Competitiveness Plan (**SCP**) is a living document through which MTPConnect communicates the sector-wide vision and priorities as well as its own priorities to support the achievement of the Sector Priorities. The 2019 SCP, which reflects input and feedback from a wide range of participants from across the MTP ecosystem, captures the evolving nature of the sector. It provides a roadmap that can be used for the whole sector to enhance collaboration and cohesion and is a unifying force in driving innovation and sector growth.

Since 2016, the MTP sector has achieved promising and steady growth. The sector added $4.9 billion in Gross Value Added (**GVA**) to the Australian economy, the same contribution as in 2016. The sector also supported a total of 70,000 industry and research jobs in 2018, an addition of c.8,000 jobs since 2016. There has been a c.2% p.a. increase in the total number of MTP companies since 2016, and a c.34% increase in the ASX market capitalisation of listed MTP companies from 2017 to 2018.

While the key metrics indicate steady growth for Australia's MTP sector, significant opportunities remain for Australia to expand its footprint in the global sector and increase economic and health contributions to the Australian economy. To achieve this accelerated rate of growth, Australia needs to focus on a number of Sector Priorities, with a clear Vision as outlined below.

MTPConnect's vision is for Australia to retain or increase the current and planned levels of expenditure in research and development (**R&D**) while achieving greater success in translation and commercialisation. This will deliver significant economic and jobs growth and improve the health and wellbeing of Australian and international consumers. This vision has multiple sub-components and will involve:

- Creating more products and solutions that reach proof-of-concept and early-stage commercialisation;
- Increasing employment in the sector and in particular the number of medium-sized to large companies with late-stage product successes;
- Maximising the value of any Intellectual Property (IP) monetisation events along the way; and
- Increasing the scale and sophistication of the supporting R&D ecosystem such as our clinical trials capabilities.

MTPConnect's original vision for the sector has been adapted to include a more explicit emphasis on driving better health outcomes for all Australians and international consumers with access to Australian MTP innovations. Implicit in any commercialisation and industry success is the imperative of improved healthcare outcomes. This Sector Vision will be achieved through seven Sector Growth Priorities.

| Sector Priorities | |
|---|---|
| Priority 1 | Align investment in Knowledge Priorities that meet current and future market needs |
| Priority 2 | Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials |
| Priority 3 | Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies |
| Priority 4 | Strengthen Australia as an attractive clinical trial research destination |
| Priority 5 | Support the development of digital healthcare solutions: devices and data analytics |
| Priority 6 | Position Australia as a preferred partner for international markets |
| Priority 7 | Support advanced manufacturing as a part of the broader Australian innovation system |

These Sector Priorities remain broadly consistent with the Sector Priorities highlighted in the 2016 SCP. The major update to the SCP is the identification of a shortlist of Knowledge Priorities (**KPs**) that are intended to provide strategic focus to the sector's activities.

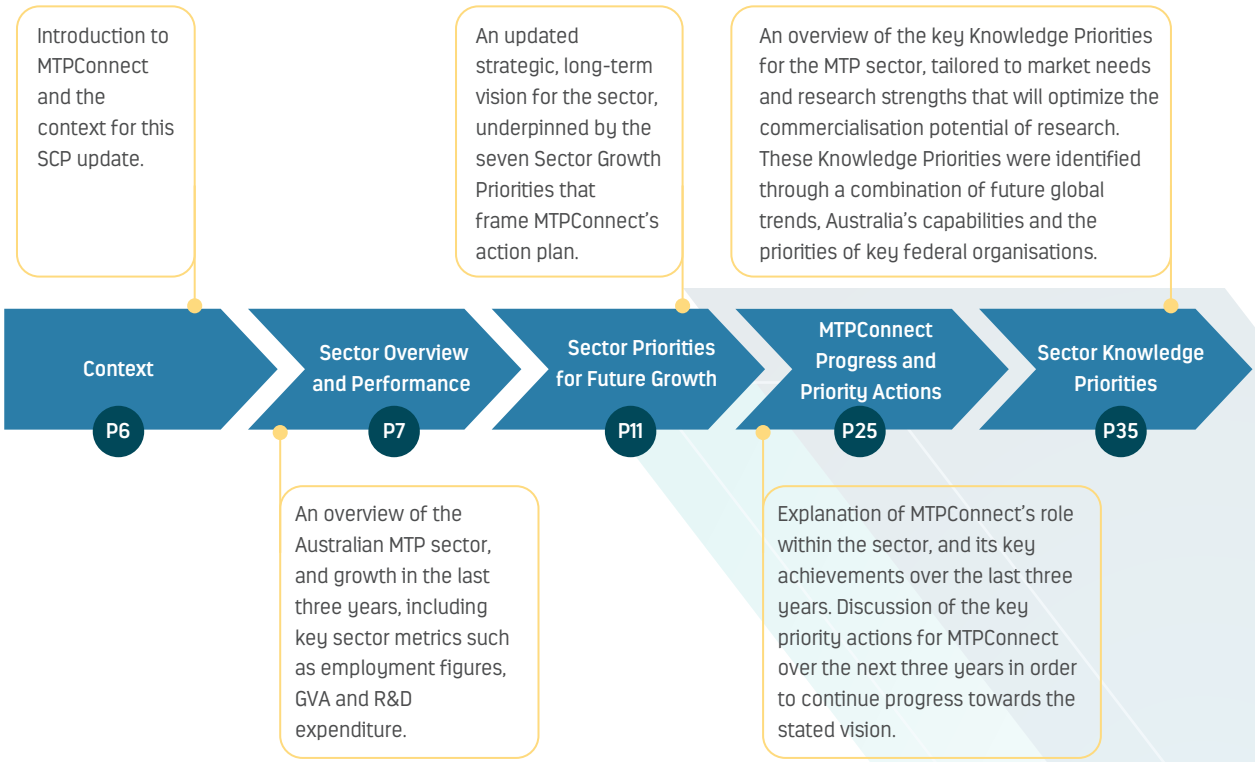
The KPs represent areas where there is a high level of unmet need globally, and where Australia is or has the potential to be a leading contributor globally. The KPs also capture the skills and capabilities required to be a leading contributor. A robust assessment has identified 24 current KPs across three major areas – areas of science, therapeutic areas, and device / diagnostic areas. In the coming months, MTPConnect will also undertake a comprehensive skills audit to identify key gaps in skills / capabilities that need to be addressed in order to drive greater sector growth. The KPs we've identified are not intended to be final, and they will be revisited and updated at regular intervals as they evolve over time. The intention is that a growing proportion of investment and activities in the sector are guided towards these KPs.

In addition, this report summarises the progress made by MTPConnect against its four Growth Centre objectives and also lays out a roadmap for its activities over the next three years. Overall, MTPConnect will continue to drive sector growth and achieve its Growth Centre objectives by:

- Deploying funding for strategic initiatives aimed at driving greater collaboration and commercialisation outcomes across the MTP sector;
- Working with sector participants across the MTP value chain to identify policy and regulatory barriers and provide independent advice and recommendations to government; and
- Delivering a suite of education, support and international outreach programs to build commercialisation expertise and increase international connectivity.

MTPConnect is committed to ensuring the Australian MTP sector evolves to meet the changing healthcare landscape globally and remains a strong and valuable contributor to the Australian economy. It looks forward to working closely with sector participants over the next three years towards achieving this goal.

## Document structure



# 1. CONTEXT

The Medical Technologies and Pharmaceuticals Industry Innovation Growth Centre (MTPII-GC Ltd), MTPConnect, was formed as a not-for-profit company in 2015 to champion the growth of Australia's MTP sector. MTPConnect represents and supports organisations, research entities and governments involved in the research, development, manufacturing or market commercialisation of innovative products along the MTP value chain. Key sector participants include patients and consumers, industry organisations and their representative bodies, federal and state government agencies, research organisations and funding agencies.

Consistent with the Industry Growth Centre initiative, MTPConnect has four key objectives that underpin its role in sector development and growth:

- Improving coordination and collaboration between research and industry, and within industry, to achieve stronger commercialisation outcomes;
- Improving management and workforce skills necessary for sector growth;
- Identifying and acting on opportunities to address regulations and policies that are unnecessary or overly burdensome and impede growth; and
- Improving the capability of the sector to engage with international markets and access global supply chains.

MTPConnect has been operating for three and a half years and a periodic review and update of the SCP is important to inform MTPConnect's ongoing priorities and areas of focus. This 2019 SCP builds on the initial plan published in December 2016 and the February 2018 update. The 2016 plan outlined a comprehensive 10-year strategic plan for the sector to boost the innovation, productivity and competitiveness of Australia's MTP sector. It also listed the key priorities and actions for MTPConnect to focus on over the period 2016-2025. While many of the priorities and megatrends defined in the 2016 SCP hold true, changing consumer demands and technological advances mean the sector is dynamic and is in an evolutionary state. The 2019 SCP reflects those evolutions. It has been developed with a view to the changes in the global and national MTP sector (including funding priorities), a review of MTPConnect's progress against its stated goals, and input from stakeholders from across Australia's MTP ecosystem, including medical technology (medtech), biotechnology (biotech) and pharmaceutical (pharma) companies, industry peak bodies, research institutions, investors, government agencies and federal and state government departments.

This SCP provides a roadmap by which MTPConnect will determine which actions to take and how it will direct its funding over the next three years, with a view to achieving the longer term 2025 sector goals. The SCP will continue to be updated on a periodic basis to reflect the changing environment and to assess progress against targets and performance metrics.

# 2. SECTOR OVERVIEW AND PERFORMANCE

## MTP sector definition and characteristics

The MTP sector is among the most innovative in the global economy.[1] It is a major contributor to R&D, both globally and within Australia. The MTP value chain encompasses a vibrant sector with a diverse range of participants, each with a critical role to play in the sector's growth and success. This value chain comprises consumers and patients, universities, other research organisations, small and large local and multinational companies, investors, service providers, industry organisations, infrastructure providers, governments, regulators, policymakers, funders and those involved in healthcare delivery, such as state health departments and private medical practice.

| | | Example participants | |
|---|---|---|---|
| Sector Participants | Private sector organisations | • SMEs and Start-ups<br>• Large medtech and pharma companies<br>• CROs | |
| | Institutions | • Universities<br>• Medical Research Institutes<br>• Governments<br>• CSIRO<br>• CRCs | • Hospitals<br>• Incubators<br>• AHRTC<br>• ADHA<br>• DMTC |
| | Industry organisations | • AAMRI<br>• ASMR<br>• AusBiotech<br>• AHMADA<br>• ANDHealth<br>• Austalian Dental Association | • ATSE<br>• Medicines Australia<br>• MTAA<br>• ARCS<br>• Australian Investment Council |
| | Service providers | • Research service providers<br>• Clinical research organisations<br>• Contract research organisations<br>• Regulatory consultants<br>• Health economists | • Professional advisers<br>- legal and IP<br>- financial<br>- regulatory |
| | Funders | • Government (including NHMRC and ARC)<br>• MNCs<br>• MRFF (including BTF)<br>• Philanthropic individuals and organisations<br>• NGOs | • Angel investors<br>• Venture capital<br>• ASX<br>• Customers |
| | Clinician groups | • Relevant clinical specialty associations (e.g. Haematology Society ANZ)<br>• Specialist medical colleges (e.g. RACS) | • AMA<br>• ACTA |
| | Consumer groups | • National Aboriginal Community Controlled Health Organisation (**NACCHO**)<br>• Australian Patients Association<br>• Charitable foundations (e.g. Cancer Council Australia, Leukaemia Foundation) | |

[1] Derwent World Patents Index, cited in Thomson Reuters 2017 State of Innovation Report

It is important to note that while the medtech and pharma markets are similar in many aspects, there is one distinctive difference – the time taken and investment required in the commercialisation pathway, and therefore, the extent to which globalisation becomes a necessity.

In pharma and biotech, the drug and biologics development pathways are long and expensive, but with success the value creation can be high. They may require between 10 and 15 years to complete, and the risk-adjusted average cost of bringing a new medicine or vaccine to market is cited as between US$760 million[2] and US$2.6 billion.[3] Products must be commercialised on a global scale to deliver the required return on investment. While innovation can start at a local level, often the commercialisation pathway will involve an Australian innovation being out-licensed or divested during pre-clinical or clinical development to a global partner that brings the development, regulatory, sales, marketing and distribution capabilities and resources to maximise its global reach and value as a product.

In medtech, the dynamic is often different. The development timeframe is typically shorter and the costs lower for medtech products (between four and 10 years, and c.US$30 million–150 million[4] in the United States). The product life cycle and investment return period are also shorter and IP protection can be more difficult. As a result, small and mid-sized medtech and digital health companies are more likely to be able to take a product all the way through to an in-market launch in Australia, with the need for global partners limited to suppliers. Nevertheless, as with the pharma and biotech subsectors, full value is only likely to be realised if global markets are accessed, either directly or through partnerships. Digital health applications using mobile phone sensors, smartwatches, fitness trackers, apps and artificial intelligence that were traditionally classified as medtech, are fast emerging as a distinct subsector, with characteristics which differentiate it from medtech; from regulatory pathways to commercial and remuneration models. In digital health, the timeframes are even shorter and investment amounts smaller.

As a consequence of the time and investment involved in the medtech and pharma pathways, there will be a considerable time lag between the inputs and stimulus provided by sector participants and the realisation of tangible outcomes and economic benefits.

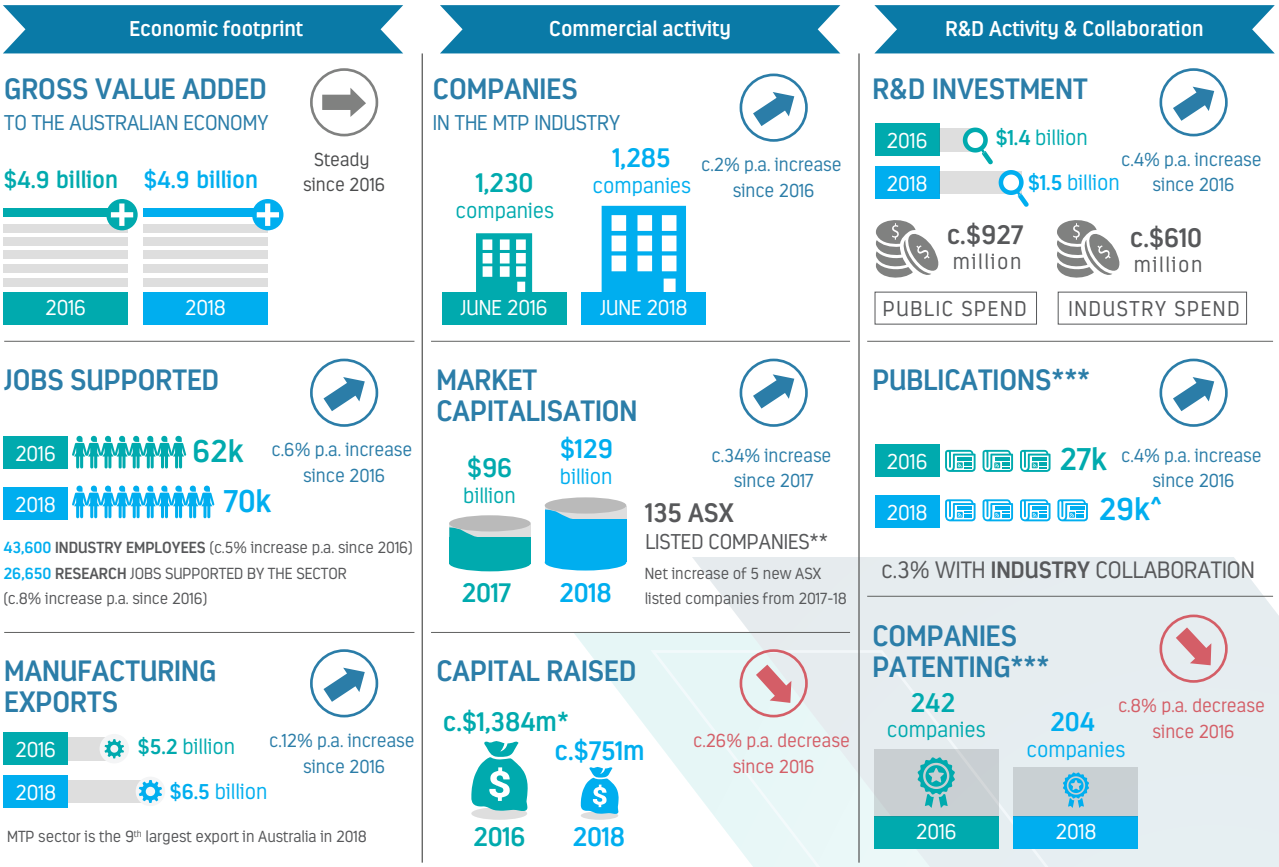
## MTP sector performance

MTPConnect has invested in creating a consistent set of sector wide metrics to track and measure competitiveness and growth over the long term. Prior to this effort, a consistent and holistic set of metrics for the entire MTP sector did not exist. MTPConnect will continue to measure and report these key metrics to provide a transparent measure of sector progress and performance over time, consistent with new methodologies adopted by the Australian Bureau of Statistics to reflect the changing composition of economic activity in Australia.

[2] Prasad V, Mailankody S., November 2017, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, JAMA Intern Med CBC, Canada

[3] In 2013 prices. DiMasi, Grabowski, Hansen, May 2016, *Innovation in the pharmaceutical industry: New estimates of R&D costs, Journal of Health Economics*

[4] Medscape – FDA Approval Process for Medical Devices; Josh Makower, Aabed Meer and Lyn Denend, *FDA Impact on U.S. Medical Technology Innovation*, November 2010; and Wendy Lee, "Lean Times for Venture Capital", *Minneapolis Star Tribune*, 20 April 2012. Figures are for medtech product development in the US. Costs may differ in other markets




Notes: * Capital raised in 2016 was artificially high due to a $888 million capital raise by Mayne Pharma

** The definition of ASX-listed MTP companies was broadened in the 2018 analysis to include companies to include medical software / digital health companies whose products are not necessarily regulated by the TGA

*** Data provided by Clarivate Analytics

^ There were an additional 77 reporting organisations whose publications output was included in the data from 2017 onwards.

Data collected by MTPConnect, Clarivate Analytics and L.E.K. Consulting 2018

In 2018, the MTP sector added $4.9 billion in GVA to the Australian economy, the same GVA as in 2016. The sector supported c.70,000 industry jobs in 2018, which is an increase of c.6% p.a. equivalent to an addition of c.8,000 jobs since 2016. Manufacturing exports grew by c.$1.3 billion increasing from $5.2 billion in 2016 to $6.5 billion in 2018, ranking the sector as the 9th most valuable export for Australia.

Commercial activity across the sector, as measured by the growth in number of current companies, capital raised, and market capitalisation of ASX listed companies, has seen solid growth across most metrics since 2016. The number of companies in the sector has grown moderately by c.2% p.a. with a net increase of c.55 companies since 2016. The number of ASX-listed MTP companies was 135 in November 2018, a net increase of 5 since 2017. The total market capitalisation of these ASX-listed MTP companies grew c.34% from c.$96 billion in Oct 2017 to $129 billion in November 2018, mainly driven by an increase of c.$30 billion in the market capitalisations of CSL, Cochlear and Resmed. The value of capital raised by the MTP sector has fallen by c.26% p.a. since 2016. However, it should be noted that the $1.38 billion of capital raised in 2016 included a very successful Mayne Pharma capital raising of $888 million.

Underlying R&D activity across the sector has seen strong growth. Total publications have grown by c.4% p.a. since 2016, with the share of publications involving industry collaborations remaining steady at c.3%. The estimated number of companies undertaking patenting activities has fallen by c.8%, equivalent to 20 / year since 2016 and indicating a consolidation in companies undertaking R&D. However, change is unlikely to represent a decline in innovation across the MTP ecosystem as academic patenting activities are not taken into account in this figure. R&D funding, as measured by the R&D investment made by both the public and private sector, has grown by c.4% p.a. from $1.4 billion in 2016 to c.$1.5 billion in 2018. Public R&D spend has increased by c.11% p.a. since 2016 to c.$930 million mainly driven by $200 million of BTF and MRFF funding, and a c.$180 million increase in NHMRC funding.

There have also been a number of notable events and milestones achieved within the MTP sector over the past 18 months, illustrating the significance and impact of the sector on the broader Australian economy at large, and the global potential for Australia's innovations. These include, but are not limited to:

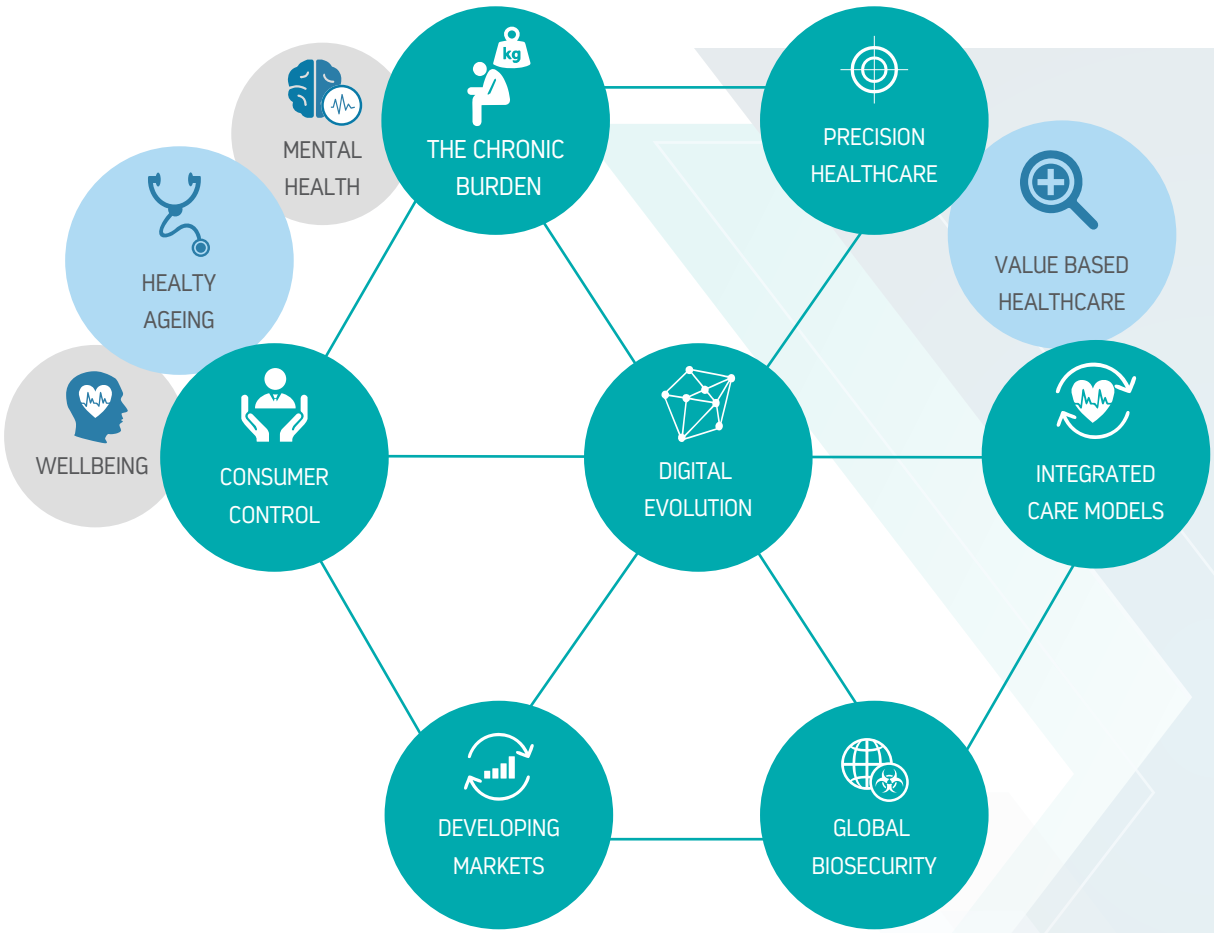
- $500 million Australian Genomics Health Futures Mission, funded through the Medical Research Future Fund, helping Australians live longer and better by genomics technology through funding research into better testing, diagnosis and treatment (May 2018);
- $1.9 billion acquisition of Sirtex Medical, a medical device company providing a radioactive treatment for inoperable liver cancer, by CDH Genetech, a large Chinese private equity firm, and Hong-Kong listed China Grand Pharmaceutical and Healthcare Holdings Limited, one of China's largest pharma and healthcare manufacturers (Jun 18);
- $500 million acquisition of Viralytics, a company focused on the development and commercialisation of oncolytic immunotherapies that harness the power of specific viruses to infect and kill cancer cells, by global pharma company Merck & Co., Inc. (Feb 2018); and
- Walter and Eliza Hall Institute sale of royalty stake in anti-cancer treatment Venetoclax, which was developed in Australia, for up to $424 million (Jul 2017).

Overall, the MTP sector's performance over the last three years has been encouraging. The 8,000 jobs added by the sector since 2016 is greater than the aspirational growth target of 2,800 jobs / year over 10 years outlined in the 2016 SCP. The aspirational scenario assumed that the industry would reverse its decline from 2010-15, return to 2010 levels within 5 years and then continue to grow at an equivalent rate out to 2025. For GVA, which was relatively flat from 2016-2018, there is still room for improvement if we are to attain the 2016 SCP's aspirational target of $7.7 billion of GVA by 2025.

# 3. SECTOR PRIORITIES FOR FUTURE GROWTH

## Sector megatrends

Megatrends are the overarching social, economic, environmental, technological and geopolitical forces that will shape the future of industries. These megatrends are often disruptive; they change existing business models and present opportunities and challenges for organisations. In the 2016 SCP, seven megatrends were identified in collaboration with the CSIRO Futures group that will significantly affect the Australian MTP and broader health care sector over the next 20 years. These remain relevant, as the nature of megatrends are long term, and in some cases, new drivers under these seven megatrends have been identified. Two related megatrends have been added, namely: **healthy ageing** and **value-based healthcare**, where patients' health outcomes drive the choice, delivery and reimbursement of therapies. These additions reflect the evolving nature of the broader environment. Similarly, **mental health** and **wellbeing**, while not megatrends in their own right, have become increasingly important as underlying drivers in the **chronic burden** and **consumer control** megatrends respectively.



| Megatrend | Implications for the MTP sector |
|---|---|
| **Digital evolution** | |
| There will be a significant shift in how we exchange and process the significant amounts of data generated daily. Standardisation of data sharing will accelerate the development of new technologies and treatments that target individuals and the wider health system, particularly as artificial intelligence (**AI**)-based solutions become increasingly sophisticated. The upside will be improved efficiency for everything from R&D to patient-care coordination. Cybersecurity will be a growing challenge that will need to be addressed as more data is exchanged. | Data standardisation, AI and cybersecurity need to be central concerns for the MTP sector if it is to take full advantage of the digital world. There is an opportunity for agile countries to gain global advantage by setting and adopting global best practice standards around the rapid development and validation of digitally enabled health technologies and by developing the use of de-identified health datasets in healthcare research and practice. Fully integrated systems will allow continuous improvement in the MTP sector and in healthcare services more broadly, and ensure Australia keeps pace with the global digital frontier. |
| **Consumer control** | |
| Technology and information access are empowering patients to manage their healthcare more actively. Consumers are also increasingly aware of issues that impact their general wellbeing, such as sleep, mental health and nutrition, etc. As such, there will be growing demand for products and services that focus on prevention and enable the consumer to be more actively involved in the management of their health.<br>Patients will be able to track their health status via personal health records, wearable sensors and in-home monitors, gathering information that allows them to contribute more actively to healthcare decisions that concern them. Tomorrow's patients will be educated and informed decision-makers who take more responsibility and control for their own wellbeing. | This trend will see a change from the historical model of healthcare provision, based on consultation with medical specialists, to one where medical technologies are part of a consumer-driven, consumer-focused, digitally enabled ecosystem. Opportunities exist for Australia to build advanced clinical product development systems that support consumer-driven decisions and consumer-responsive products and services. Australia could become a preferred region for developing and testing this next generation of medical technology, with corresponding economic benefits. |
| **Healthy ageing** | |
| Healthy Ageing centres on maintaining good health for as long as possible and increasing the healthy lifespan. The WHO recently implemented an extension code for ageing-related diseases, an acknowledgement that ageing is a disease and hence can be treated. There is often assumption that ageing will lead to increased cost burden, but economic modelling by Deloitte Access Economics has shown that the health, societal and economic benefits of therapeutic interventions in an ageing population are significant, even greater than those of eliminating an entire disease. | This megatrend presents opportunities for new products and services that target healthy living and the prevention of diseases, rather than just treatment. It is closely related to the chronic burden and consumer control megatrends. Solutions for healthy ageing will include digital devices, sensors, and novel therapies, and will require companies to understand and respond to consumer needs effectively. Developing solutions will also require greater input from the social sciences and anthropology. |

| Megatrend | Implications for the MTP sector |
|---|---|
| **The chronic burden** | |
| Between 2015 and 2030, the proportion of the population aged 60 or over is projected to grow by 56%.[5] Modern medical and pharmaceutical technology allows us to manage chronic disease and live longer than ever before, but comes at an ever increasing cost to the public health system. Globally, health systems face the challenge of finding cost-effective models to cope with longer lifespans and maximise health and wellbeing at all ages.<br><br>In recent years, mental health conditions such as depression and anxiety are becoming increasingly prevalent. Mental health conditions impact Australians of all ages, and it is estimated that nearly half of all Australians will experience a mental health condition at some point in their lifetime.[6] The management of mental health will require a consumer-centric approach, and a focus on prevention as well as treatment. | This trend places significant pressure on the MTP sector. The public may demand new technologies, but access will be determined by governments' and healthcare providers' judgements about the economic sustainability of those technologies. Sector participants need to work with governments and healthcare providers to make sure research priorities and new technologies improve population health outcomes in a more cost-effective manner.<br><br>There will also be opportunities for novel products that support both the consumer and healthcare provider(s) and / or focus on prevention rather than treatment. The MTP sector will need to work closely with government, healthcare providers, and consumers in supporting patients in a holistic manner. |
| **Precision healthcare** | |
| Advances in science and technology are enabling more precise healthcare solutions. Targeted pharmaceuticals, biologicals and personalised medical technologies will be delivered that provide improved outcomes for cohorts of patients. The technologies advancing this trend include genomics, synthetic biology, gene-editing technologies, cell therapies, computational biology, medical imaging, 3D printing, data mining, and artificial intelligence.[7,8,9]<br><br>Biosensors are already providing clinicians and patients with real-time personalised data, regardless of location. In 2014, health wellness monitoring applications accounted for 66.3% of biosensor revenue globally.[10] | The growing trend for precision healthcare solutions will impact on the sector's supply chain, with an increasing focus on point-of-care optimisation. Real-time measurement and assessment of individual health will create demand for product and service providers that can offer integrated precision solutions, rather than single best-in-class products. A key implication for Australian developments is navigating the regulatory process in such a way that reimbursement for products is achieved. There will be a need for an innovation-oriented regulatory environment (adaptive regulation) and the development of novel business models. |
| **Value-based healthcare** | |
| The concept of value-based healthcare, where patients' health outcomes drive the choice, delivery and reimbursement of therapies, has been around for almost a decade.[11] The rise of precision medicine combined with the rising cost of traditional fee-for-service approach to healthcare is driving a paradigm shift towards this new patient-centric model. | This megatrend has enormous implications across multiple parts of the healthcare value chain. For example, the regulatory process for approving and reimbursing drugs and devices will need to adapt from the current volume-based approach to an outcome-based approach. There will need to be greater coordination among sector participants in the delivery of care and more efficient capturing of value delivered. MTP companies will need to rethink their operating models to cater for the more customer (and value) focused approach necessitated by value-based healthcare. |

5 United Nations, Dept. of Economic and Social Affairs Report "World Population Aging 2015"

6 https://www.beyondblue.org.au/about-us/research-projects/statistics-and-references

7 FDA, Oct 2013, Paving the way for personalized medicine

8 Frost & Sullivan, Feb 2016, 3D Printing in the Healthcare Industry

9 Australian Council of Learned Academies (ACOLA), Sep 2018, Synthetic Biology in Australia – An Outlook to 2030

10 Frost & Sullivan, May 2015, Analysis of the Global Biosensors Market

11 M.E. Porter, Jul 2009, New England Journal of Medicine, "A Strategy for Health Care Reform – Toward a Value-Based System"

| Megatrend | Implications for the MTP sector |
|---|---|
| **Integrated care models** | |
| Models for the delivery of healthcare are evolving to better address the context and specific needs of the patient. These integrated models reflect the whole of a patient's care needs, from prevention through to the end of life, across both physical and mental health, and in partnership with the patient, their carers and family. | Demand will increase for products and devices that are suited to integrated care models. Products will be required that can coexist and communicate with other products and information sources as part of an ongoing, continuous care ecosystem. As emphasis shifts from individual care episodes to ongoing patient management, products and devices will increasingly need to be packaged as part of a broader care proposition that attaches patient as well as economic benefits to the healthcare system. Devices will also play a role in connecting and monitoring the patient between formal care episodes. |
| **Global biosecurity** | |
| Recent pandemics highlight the globally transmissible nature of diseases and the threat these can have on human health. With more frequent travel, globalised trade and greater interconnectedness between countries, infectious disease outbreaks of international concern are becoming inevitable and unpredictable.[12]<br><br>Antimicrobial resistance is another complex global public health crisis that threatens the effective prevention and treatment of an ever-increasing range of infections.[13] The UK O'Neill Report estimated 10 million people will die annually from antibiotic resistant infections and cost the global economy up to $100 trillion.[14] There has been a 'discovery void' since the 1980s, with a limited pipeline of new antibacterial drugs.[15] | This megatrend presents growth in markets where the primary customer will be governments concerned with the rapid implementation of biosecurity solutions and long-term risk mitigation. For the sector, value will be lost if medicines become ineffective. Continued development of technologies to combat global threats will require an agile research, clinical development and manufacturing industry. Maintaining strong on-shore advanced manufacturing and research capabilities for biosecurity products will enable Australia to retain access to the products and know-how required to combat such risks. |
| **Developing markets** | |
| Demands for healthcare solutions are rising in developing countries. Today these markets are responsible for the majority of global sector growth (in percentage terms) and this trend will continue. However, it is important to note that the needs of these markets are at times distinct from developed economies. For example, there is demand for lower-cost solutions, or solutions delivered in different settings, such as point of care versus laboratory, cold chain considerations, etc. | Developing countries will continue to be an increasing market for the global MTP sector. Value can be created for the sector by partnering with developing countries to understand their unique needs and capabilities, and providing know-how and technology transfer to assist new product development, optimised manufacturing and distribution solutions for their local markets. There is an opportunity for Australia to leverage its high-quality facilities and production advantage in the short term and to collaborate over the longer term to develop innovative solutions that deliver sophisticated technologies, products and healthcare to developing countries in a cost-effective manner. |

[12] http://www.who.int/csr/research-and-development/strategy/en/

[13] http://apps.who.int/iris/bitstream/10665/112642/1/9789241564748_eng.pdf

[14] J. O'Neill, Dec 2014, Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations

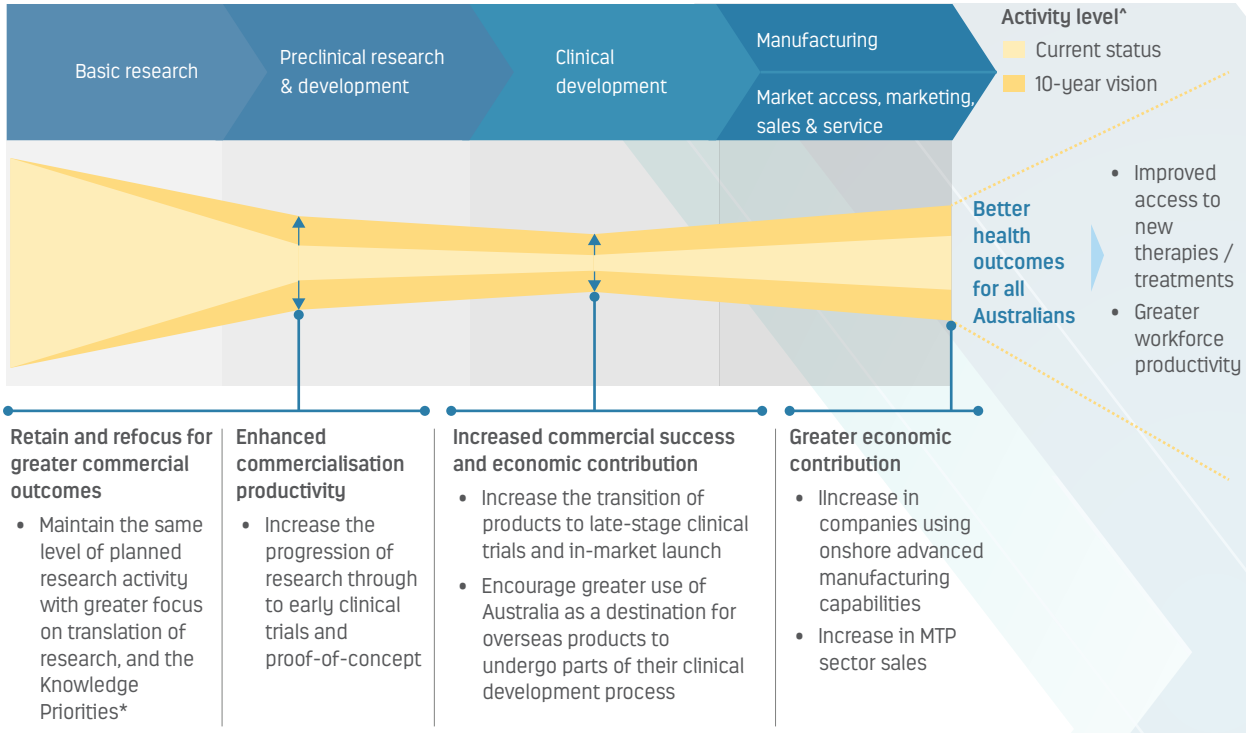
[15] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3021209/

## Sector vision

The Australian MTP sector has the potential to be a significant contributor to improving patient outcomes and also a key driver of economic and jobs growth over the next 10-20 years. However, there are important growth priorities that cannot be ignored if the sector is to remain sustainable, provide optimal health outcomes for Australians, and increase its contribution to the Australian economy.

In 2016, MTPConnect's vision was for Australia to retain all current and planned levels of R&D expenditure[16] while achieving greater commercialisation success, creating more products that reach proof-of-concept and early-stage commercialisation, increasing the number of medium to large companies with late-stage product successes, and maximising the value of any intellectual-property (**IP**) monetisation events along the way.

## The long-term vision for research and commercial activity in the MTP sector, by value-chain stage




Note: * These are areas of high unmet need and in which a sizeable commercial opportunity exists, where Australia can develop world class research excellence;
^ Activity level includes all forms of activity and economic value creation in Australia regardless of whether it originates from Australia or overseas. Diagram is intended to be illustrative only and is not to scale

This vision remains relevant today. Widening the funnel, i.e. increasing the activities and the number of products flowing through each stage of the MTP value chain, is still critical. However, an explicit focus on improved health outcomes and the growth of funding have been added. The overall effect would be better health outcomes for all Australians (and patients globally), which will drive greater workforce productivity, greater employment and wealth creation for Australia.

[16] This includes new funding initiatives such as the BTF and the MRFF

It is also important to note that while this value chain for MTP innovation – stretching from basic science to manufacturing and market launch – remains the core pathway for the development of MTP products, there are increasing examples of innovations that require alternative development models. In particular, some digital innovations and advanced manufacturing technologies (e.g. 3D printing) follow a more iterative pathway with rapid prototyping and frequent revisions.

The successful achievement of this vision will result in considerable benefits for Australia, through both improved healthcare and economic contributions. Estimates developed by MTPConnect in 2016 indicated that by reversing the sector's decline in recent years, the following economic growth could be achieved by 2025:

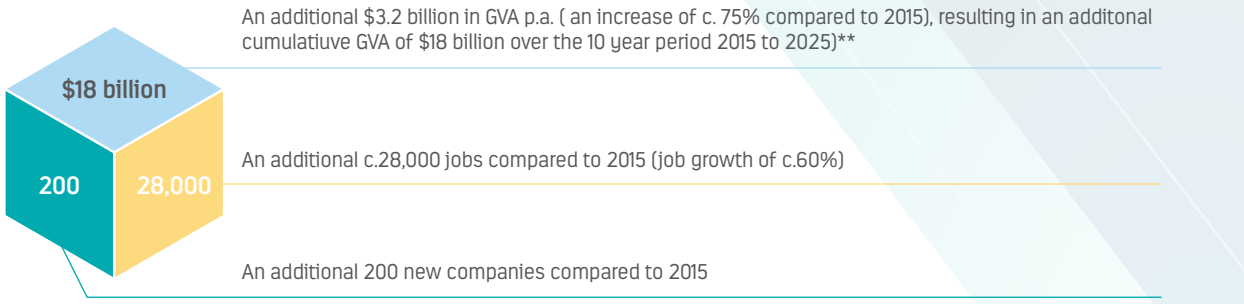
- An additional c.28,000 jobs compared to 2015 (job growth of c.60%); and
- An additional c.$3.2 billion in GVA per annum (an increase of c.75% compared to 2015), resulting in an additional cumulative GVA of c.$18 billion over the 10 year period 2015 to 2025.

In addition, consumers and their families, both in Australia and internationally, will benefit from enhanced healthcare innovation, leading to enhanced healthcare outcomes.

For the 2020 update of the SCP, five years into the original 10-year vision, MTPConnect intends to examine and reassess these targets, taking into account sector performance, changes in consumer demands and technological advances, as well as policy settings, assumptions and implementation.

Further details of MTPConnect's sector growth potential and benefits estimates are available in the 2016 SCP.

## MTP Sector by 2025*




Notes: * Estimated additional GVA, employment and companies assumes the decline from over the past five years can be reversed, with the industry returning to 2010 levels within 5 years and then continuing to grow at an equivalent rate out to 2025. This scenario reflects the full potential of the government's incremental investment in the sector including MTPConnect, the BTF and the MRFF;
** Compared to the baseline forecast

Source: MTPConnect Sector Competitiveness Plan 2016; L.E.K. Analysis

## Sector Priorities

The 2016 SCP identified seven priorities for the sector which underpin the achievement of the sector vision of enhanced healthcare and economic outcomes for Australia. These seven priorities remain relevant today and are summarised below. Changes have been made to Priorities 1, 5 and 6 respectively, namely:

- The KPs in Priority 1 have been reviewed with the objective of identifying a more targeted set of priorities based on independent metrics. They are described in this report in Section 5, and Priority 1 has been modified to reflect this;

- Priority 5 has been modified to reflect the rise of digital healthcare solutions broadly, rather than just digitally enabled MTP solutions; and
- Priority 6 has been modified to have a more global focus as stakeholder consultations have identified the United States, Europe and Asia as key markets for the MTP sector.

A more detailed description of these Sector Priorities, and their origins, can be found in the 2016 SCP.

## Priority 1: Align investment in Knowledge Priorities that meet current and future market needs

Australia will be better positioned to maximise the commercial results and health outcomes of its R&D investment by complementing investigator-led research with a top-down, strategic approach that focuses on areas with strong market need and commercial potential and draws on Australia's competitive advantages. While there is value in blue sky research, aligning strategically around key KPs will enable Australia to build long term world-class positions in targeted areas of research and commercialisation.

MTPConnect has undertaken a robust, independent assessment to define the KPs, tailored to market needs and Australia's research strengths that will optimise the commercialisation potential of research. These KPs and the methodology applied in identifying the KPs are described in Section 5.

| | |
|---|---|
| **Current Constraints & Gaps** | • Until the recent implementation of the MRFF, there has been a lack of strategic focus on investing in research with a strong likelihood of commercial outcomes. Grant funding and application criteria often do not currently align with prioritisation of commercially-focused research<br>• Lack of collaboration between researchers, industry and clinicians, small-scale collaboration hubs and a lack of focus on the commercialisation potential of research activities<br>• Difficulty in attracting and retaining talented researchers due to lack of certainty over long-term funding<br>• Lack of awareness of appropriate IP and other relevant regulations among researchers |
| **Description / purpose of this priority** | • To align R&D investment in KPs that have been identified to optimise commercialisation potential of research based on current and future market needs and Australian research strengths<br>• To ensure sufficient percentage of R&D spending (not 100%) is allocated and targeted to these areas, and to build a full ecosystem of research skills and industry links to support KPs while ensuring ongoing support for blue sky research |
| **Outcomes** | • Increased strategic allocation of public R&D funding channelled towards identified KP areas<br>• A greater number of successful commercialisation opportunities arising from research will drive better patient outcomes, sector GVA and employment |

| Growth Centre objectives addressed | | | |
|---|---|---|---|
| Improving coordination and collaboration | Improving management and workforce skills | Identifying opportunities to address regulations | Improving access to global supply chains & markets |
| ✓✓✓ | ✓✓ | ✓ | ✓ |

## Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials

Australia has a world-leading health and medical research capability, both in quality and quantity of output. However, there is not the same level of research commercialisation as some of Australia's major R&D peers and efforts at early-stage commercialisation are often hindered during the transition from discovery to proof-of-concept.[17] Australia must become more effective in translating research to commercial outcomes that benefit patients. It is only in this way that Australia will see sustainable economic growth in the MTP sector. Achieving this outcome requires not only effective research and start-up sub-sectors, but a healthy, full value-chain ecosystem from research through to commercial marketing and sales of products. Developing entrepreneurial capabilities across the full value-chain will be a key step towards realising greater economic benefits in the sector. The recently announced Research Exchange and Development within Industry Initiative (**REDI**) is a promising step towards facilitating collaborations across researchers, industry and clinicians and driving entrepreneurship within the MTP sector.

| | |
|---|---|
| **Current Constraints & Gaps** | • Need to optimise and leverage funding available for advancing innovations from discovery to proof-of-concept phase<br>• Australia's researchers and clinicians are not sufficiently incentivised to focus on commercialisation / translation<br>• Lack of knowledge regarding regulatory and clinical pathways to market, and lack of skills in crucial areas of research support<br>• TGA is not resourced / required to provide pre-submission support to SMEs in navigating regulatory hurdles |
| **Description / purpose of this priority** | • To develop a healthy, full value-chain ecosystem from research through to commercial marketing and sales of products. Collaboration and sharing of skills between industry, support services and research is critical<br>• To ensure important foundations such as aligned and available funding, a strong IP regime, and a local MTP ecosystem including researchers and commercialisation service providers<br>• To ensure necessary focus on skills / support required to provide clear value propositions to funders and investors, a lower risk path to translation and commercialisation, and a greater focus on consumer and market needs will accelerate product development |
| **Outcomes** | • Significant economic benefits, including high-value jobs and inflows of royalties and returns to investors<br>• Better health outcomes for patients<br>• Incentives and rewards for researchers and clinicians |

| Growth Centre objectives addressed | | | |
|---|---|---|---|
| Improving coordination and collaboration | Improving management and workforce skills | Identifying opportunities to address regulations | Improving access to global supply chains & markets |
| ✓✓✓ | ✓✓✓ | ✓ | ✓ |

[17] McKeon Review, 2013, Chapter 6

## Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies

The majority of companies in Australia's MTP sector are start-ups and small biotechnology and medtech firms with products in early-stage development. These companies often struggle to access sufficient long-term funding to commercialise their products, and either fail before reaching a major milestone, or have to make compromises on the development pathway due to lack of access to appropriate skills, resources and experts. Mid-sized companies are often able to weather greater risk and advance their products to a later stage of development than start-ups, leading to more favourable licensing arrangements and returns as the company increases its bargaining strength and commercialisation astuteness. As described in Section 2, the pharma development pathway is typically long and requires global partnerships for successful commercialisation. In contrast, the medtech and digital health development pathways are usually shorter and more likely to be commercialised locally. Therefore, transforming the medtech and digital health SME sector is likely to have more immediate impact in terms of new product launches and local companies compared to the pharma / biotech SME sector.

| | |
|---|---|
| **Current Constraints & Gaps** | • Funding of later stage clinical development is often insufficient to meet the high cost of clinical trials and gaining market access<br>• Lack of business management skills related to product commercialisation and monetisation<br>• Processes related to clinical trials and regulatory approvals are complex and present challenges for SMEs who lack resources and experience in navigating these hurdles<br>• Lack of knowledge and skills to navigate international regulations when launching products globally |
| **Description / purpose of this priority** | • To develop relevant commercialisation skills and expertise in SMEs<br>• To ensure policy stability, predictability and international alignment with regards to R&D tax incentives, reimbursement policies and intellectual property protections<br>• To provide support for SMEs looking for funding and advice to commercialise their early-stage assets / products |
| **Outcomes** | • Increase in private sector investment and a larger, high-skilled workforce<br>• Increase in the number of products that are brought to Phase II and III clinical trials by local pharma companies and to product launch by Australian medtech companies<br>• Direct economic benefit will be greater MTP sector employment and GVA |

| Growth Centre objectives addressed | | | |
|---|---|---|---|
| Improving coordination and collaboration | Improving management and workforce skills | Identifying opportunities to address regulations | Improving access to global supply chains & markets |
| ✓✓ | ✓✓ | ✓✓ | ✓✓ |

## Priority 4: Strengthen Australia as an attractive clinical trial research destination

Australia's clinical trial industry is facing competition from more populous regions in Europe, South America and Asia that are looking to expand their clinical trials footprint, offering access to large patient populations. Establishing a single ethics approval for multi-site private / public clinical trials with uniform governance across jurisdictions and sites, and embedding clinical research as a priority activity within hospitals are keys to ensuring Australia continues to be an attractive clinical trials destination. This will also provide more Australian patients with access to best-in-class therapies earlier. As global competition for clinical trials increases, regulatory bodies will need to ensure they create an attractive and workable environment for both local and international trials, e.g. harmonised ethics reviews across states and predictable approval timelines. Progress has been made in recent years to strengthen clinical trials in Australia, including development of a National Clinical Trials Governance Framework and a framework for collection of national aggregate statistics on clinical trials. However, there is broad consensus that more work is required if we are to address the known issues and stay ahead of the competition.

| | |
|---|---|
| **Current Constraints & Gaps** | • Longitudinal patient datasets and patient registries currently fractured across multiple collecting agencies and in some instances proprietary<br>• Current regulatory framework for clinical trials is complex, with state and local health networks having duplicated and differing governance and ethics requirements<br>• Lack of cost competitiveness compared with other jurisdictions<br>• Comparatively small patient base that is geographically dispersed increases difficulty of recruiting sufficient patients for trials |
| **Description / purpose of this priority** | • To improve the efficiency and cost-effectiveness of patient recruitment for clinical trials in Australia<br>• To streamline the regulatory and ethics review process across states to make multi-site trials more competitive with international markets<br>• To continue to promote Australia globally as a specialist clinical trial destination |
| **Outcomes** | • Robust clinical trial industry which provides Australians participating in local trials with early, free access to new healthcare technologies<br>• Create skilled employment and transfer knowledge to the health sector on new trends in medicine and devices<br>• Improve the profile of Australia as a destination for international medical research and assists in the development of an internationally competitive MTP ecosystem |

| Growth Centre objectives addressed | | | |
|---|---|---|---|
| Improving coordination and collaboration | Improving management and workforce skills | Identifying opportunities to address regulations | Improving access to global supply chains & markets |
| ✓✓✓ | ✓ | ✓✓✓ | ✓✓ |

## Priority 5: Support the development of digital healthcare solutions: devices and data analytics

The digital world has, and will continue to have, a substantial impact on the healthcare landscape. The development of digital devices and datasets will enable new software solutions and healthcare platforms that will change how healthcare providers diagnose and administer health solutions and how consumers choose to be treated. Digital technologies will also change how new products and therapeutics are discovered and developed. They are the crucial elements needed as the sector moves towards greater adoption of precision healthcare. The success of these new solutions also relies on educating end users, such as state health departments and public and private healthcare providers, on the potential of digital innovations.

This priority directly reflects the importance of the digital evolution megatrend, but it is also reinforced by the role that digital healthcare solutions play in several other megatrends, including delivering precision healthcare, providing greater consumer control, and delivering better integrated end-to-end care (which is often supported by digital diagnostics and monitoring devices).

| | |
|---|---|
| **Current Constraints & Gaps** | • Lack of funding for research support services such as bioinformatics, computational biology and data analytics to meet the next wave of health innovation<br>• Health data sets are underutilised due to inaccessibility, lack of sophisticated investors for digital health, lack of linkages between them and policy restrictions regarding the use of records<br>• Shortage of biomedical engineering, bioinformatics, health informatics and data analytics skills<br>• Australia's regulatory system is designed to take a risk-based approach which does not suit the new wave of digital devices, 'apps' and algorithms being developed |
| **Description / purpose of this priority** | • **Digital devices:** To identify and encourage the development opportunities available in digital technology, and the skills and regulatory stance that are required to respond to them<br>• **Data analytics:** To encourage the development and sharing of standardised data assets with better data linkages across Australia to provide a platform for greater collaboration and investment. To support regulatory capability and technology developments to appropriately safe keep patient information records |
| **Outcomes** | • Greater rate of development and commercialisation of digital solutions and MTP products based on a deeper and more rapid understanding of biological and patient data<br>• This will in turn benefit patients, driving better health outcomes for them, while enhancing Australia's relevance in a fast, growing area of the global economy |

| Growth Centre objectives addressed | | | |
|---|---|---|---|
| Improving coordination and collaboration | Improving management and workforce skills | Identifying opportunities to address regulations | Improving access to global supply chains & markets |
| ✓✓✓ | ✓✓✓ | ✓✓ | ✓ |

## Priority 6: Position Australia as a preferred partner for international markets

International markets such as the United States, Europe and Asia present a number of unique opportunities for Australian researchers and developers. Certain healthcare markets (e.g. China, South-east Asia) have particular needs arising out of cultural, regulatory, demographic and resourcing differences. These may arise in the clinical setting, for example, due to differences in resources available to meet care needs, or in particular therapeutic areas as a result of regional diseases. Australia can address these needs by understanding these differences and tailoring R&D and product development to meet them. In addition, the increasing integration of many developing markets into the global economy introduces new global biosecurity threats which Australia is well positioned to play a role in managing. Success overseas will not only bring direct revenue to Australia through licensing or distribution deals, but it will also open up new partnerships for research or investment.

| | |
|---|---|
| **Current Constraints & Gaps** | • Need for stronger links with research, trade and investment partners globally with a focus on the US, Europe and Asia<br>• Current instability of policy and need to ensure ongoing international competitiveness of IP laws<br>• Insufficient support for SMEs seeking to navigate regulatory requirements for approval in Australia, which is required for medical devices prior to market access being provided in a large number of overseas countries<br>• Lack of knowledge and understanding of commercial and regulatory processes in international markets |
| **Description / purpose of this priority** | • To develop partnerships with key overseas investors, companies, industry bodies, universities and institutes<br>• To continue to work with government to ensure a stable policy environment and IP protection that are consistent with international best practice (e.g. exclusivity arrangements, transaction costs)<br>• To develop systems and tools that can help local companies better understand and navigate overseas markets and regulatory processes |
| **Outcomes** | • For researchers, start-ups and SMEs, increased cross-border collaborations will improve prospects of uncovering new insights and tapping international funding pools<br>• SMEs and larger companies will gain accelerated access to export markets that are aligned to the fastest growing region for healthcare demand through partnerships, and support systems and tools<br>• Overall outcomes will be increased funding, research collaboration and value of exports |

| Growth Centre objectives addressed | | | |
|---|---|---|---|
| Improving coordination and collaboration | Improving management and workforce skills | Identifying opportunities to address regulations | Improving access to global supply chains & markets |
| ✓✓ | ✓ | ✓✓ | ✓✓✓ |

## Priority 7: Support advanced manufacturing as part of the broader Australian innovation ecosystem

The Advanced Manufacturing Growth Centre (**AMGC**) defines advanced manufacturers as those who "typically use a combination of three factors to remain competitive: advanced knowledge, advanced processes, and advanced business models". Pursuit of advanced manufacturing can involve numerous elements of best practice including cost reduction, value differentiation and market focus. Some medical technologies and new pharma products (e.g. biologics, cell therapies, assistive technologies) require highly specialised manufacturing that is well suited to those countries with a reputation for clean, safe and high-quality manufacturing. In fact, Australia is already positioned as a high-value, lower-volume manufacturer, as evidenced by a growing demand from Asia for Australian-manufactured products, including pharmaceuticals. Expanding Australia's advanced manufacturing capabilities within the MTP sector and the broader innovation ecosystem will strengthen Australia's reputation and open up additional opportunities for integrating more fully with global markets up and down the manufacturing value chain.

| | |
|---|---|
| **Current Constraints & Gaps** | • Lack of targeted R&D funding that is market-led and considers commercial potential of projects<br>• Failure to have a global perspective and focus only on a small market makes it challenging for local companies to achieve scale and cost advantages<br>• Shortage of advanced manufacturing skills specific to the MTP sector<br>• Australian production costs are often uncompetitive for lower-skilled and well-established manufacturing processes |
| **Description / purpose of this priority** | • To leverage Australia's reputation as a high-value, lower-volume manufacturer, and expand the country's advanced manufacturing capabilities within the MTP sector and the broader innovation ecosystem<br>• To encourage local manufacturers to forge strong collaborative relationships with Australia-based researchers and MTP companies at the early development stages, positioning Australia as a known and reputable destination for prototyping and testing |
| **Outcomes** | • Increase the value of advanced manufacturing in the MTP sector, supporting the next generation of Australia's evolved manufacturing economy<br>• Provide an opportunity for the re-skilling and redeployment of Australia's existing manufacturing workforce into highly-skilled jobs along the value chain |

| Growth Centre objectives addressed | | | |
|---|---|---|---|
| Improving coordination and collaboration | Improving management and workforce skills | Identifying opportunities to address regulations | Improving access to global supply chains & markets |
| ✓✓ | ✓✓✓ | ✓✓ | ✓✓✓ |

The seven MTP Sector Priorities identified are strongly aligned with the four defined Growth Centre objectives, as illustrated in the diagram below. Each Sector Priority will benefit from actions under more than one of the Growth Centre objectives. The following section outlines the key priority actions that MTPConnect will undertake over the next three years in order to address the key Growth Centre objectives and Sector Priorities.

| Sector Priorities | | Growth Centre objectives: Improving coordination and collaboration | Improving management and workforce skills | Identifying opportunities to address regulations | Improving access to global supply chains & markets |
|---|---|---|---|---|---|
| P1 | Align investment in Knowledge Priorities identified based on current and future market trends | ✓✓✓ | ✓✓ | ✓ | ✓ |
| P2 | Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials | ✓✓✓ | ✓✓✓ | ✓ | ✓ |
| P3 | Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies | ✓✓ | ✓✓ | ✓✓ | ✓✓ |
| P4 | Strengthen Australia as an attractive clinical trial research destination | ✓✓✓ | ✓ | ✓✓✓ | ✓✓ |
| P5 | Support the development of digital healthcare solutions: devices and data analytics | ✓✓✓ | ✓✓✓ | ✓✓ | ✓ |
| P6 | Position Australia as the preferred partner for international markets | ✓✓ | ✓ | ✓✓ | ✓✓✓ |
| P7 | Support advanced manufacturing as a part of the Australian innovation ecosystem | ✓✓ | ✓✓✓ | ✓✓ | ✓✓✓ |

**Key:** ✓✓✓ Greater focus on addressing particular Growth Centre objective
✓ Less focus on addressing particular Growth Centre objective

# 4. MTPCONNECT PROGRESS AND PRIORITY ACTIONS

## Role of MTPConnect as a Growth Centre

The Industry Growth Centres Initiative, administered by the Australian Government Department of Industry, Innovation and Science (DIIS), aims to drive innovation, productivity and competitiveness, generating local wealth and employment in Australia.

MTPConnect is working to forge stronger connections between research and industry, maximising opportunities for Australians to not only make scientific and technological breakthroughs to improve the health of Australians, but to see them developed through the proof-of-concept stage and successfully translated and commericalised. MTPConnect and its Program Partners are working to achieve these outcomes by improving collaboration, providing and facilitating funding, developing skills, informing policy and promoting regulatory reform.

Over the past three years, MTPConnect has focused its efforts and achieved significant outcomes against each of the four Growth Centre objective areas and developed a strong foundation from which to continue driving growth in the MTP sector.

### MTPConnect Growth Centre objectives

- **Improving coordination and collaboration** between research and industry, and within industry, to achieve stronger commercialisation outcomes;
- **Improving management and workforce skills** necessary for sector growth;
- **Identifying and acting on opportunities to address regulations** and policies that are unnecessary or overly burdensome and impede growth; and
- **Improving the capability** of the sector to engage with **international markets and access global supply chains.**

## Overview of MTPConnect's progress

Over the past three years, MTPConnect and its Program Partners have achieved significant outcomes, a summary of which is highlighted in this section. MTPConnect has invested a total of $26 million across 48 projects through MTPConnect's project funds and the BioMedTech Horizons (**BMTH**) program. These projects have leveraged $39 million of matching funding by industry. A full list and details of MTPConnect co-funded projects can be found on its website.

As a result of MTPConnect's expertise in delivering impactful funding programs, it has been successful in securing c.$90 million in funding from various sources, including the BMTH ($45 million) and Biomedical Translation Bridge ($22.3 million) programs. MTPConnect will continue to guide these funds to nurture early stage health and medical research ventures to reach proof-of-concept stage with potential to attract further capital and support.

# Projects Overview

## GROWTH CENTRE PROJECT FUND PROGRAM

(Department of Industry Innovation and Science)

**36** Projects

**15** University led

**22** Industry led

**$15.6M** MTPConnect grants
**$25.7M** Industry funding committed
**$3.7M** in kind so far

**161** TOTAL number of PARTNERS

**$25.6M**
in grant funding deployed across two programs

**$39M**
in matched funding secured from industry

## MRFF BIOMEDTECH HORIZONS PROGRAM

(Department of Health)

**11** Projects

**7** Precision medicine

**4** 3D printing

**$10M** BMTH fund
**$13.3M** Industry contribution

**39** TOTAL number of PARTNERS

Note: Date as at 30/06/2018

| Key funding programs | Allocated funding value |
|---|---|
| MTPConnect project funding | $15.6m |
| Growth Centres renewal | $10m* |
| BioMedTech Horizons program | $40m |
| Biomedical Translation Bridge program | $22.3m |

Note: * Only a percentage of the total $10 million will be made available for additional project funding over the next two years from Oct 2019 (this percentage is still yet to be determined).

MTPConnect's key achievements against each of its Growth Centre objectives are summarised below, including the outcomes arising from the project funds invested.

## Growth Centre Objective 1: Improving coordination and collaboration

MTPConnect has successfully deployed project funding through its Growth Centre project funds as well as BMTH across a wide range of project areas, ranging from 3D anatomical printing and precision medicine to clinical trials, advanced manufacturing and industry mentoring. As at 30 June 2018, these projects have driven cross-sector collaborations with 60% of MTPConnect projects involving industry-research collaborations.

Overall, as a result of MTPConnect project fund investments, there have been 79 technologies invented or progressed, 37 new patents/trademark applications and licenses, 11 new start-up companies, 45 direct jobs


Note: Date as at 30/06/2018

being created and more than $6 million of investment flowing into incubator companies. An additional $125.8 million in funding has also been secured for the MTP sector through 26 MTPConnect-assisted grant applications (this does not include round five and six CRC-Ps, or the 2018 ARC ITRPs).

MTPConnect has also fostered greater connectivity and collaboration between industry and researchers through programs such as the Bridge Program and the Medical Device Partnering Program (**MDPP**), which partners medtech companies with a need for product development with designers or engineers at research institutes who can help them develop their devices. For FY2018 there were 88 collaboration events organised by MTPConnect and its partners, attended by more than 4,400 people.

## Growth Centre Objective 2: Improving management and workforce skills

MTPConnect, in collaboration with Program Partners, has played an important role in upskilling industry participants. MTPConnect has maintained strong engagement across the sector and supported Project Partners to deliver activities such as workshops, networking events and inbound and outbound trade missions, connecting with over 3,750 companies, universities, research organisations and industry associations. More than 7,700 people have attended 307 training and information seminars.

Examples of successful programs supported by MTPConnect include:

- The Bridge Program, a consortium of 16 companies, universities and industry associations aiming to transfer practical skills on pharmaceutical commercialisation to Australia's early career researchers;
- Industry Mentor Network in STEM (**IMNIS**) program, an award-winning mentoring initiative to enhance students' understanding of industry and career opportunities;
- Centre for Entrepreneurial Research and Innovation (**CERI**), working with local researchers to develop their entrepreneurial skills; and
- ANDHealth+ program, focused on assisting Australian mid-stage digital health companies to meet key investor, partner and customer requirements around clinical and commercial validation. Since October 2017, ANDHealth+ cohorts have raised over $14 million, undertaken 9 new market launches, generated $2.4 million in revenue, created 63 new jobs, commenced 10 clinical trials and studies, secured 115 new customers, and served 12,857 patients.

**Information Sharing and Workforce Skills Development**

**1,103** **individuals** received targeted **workforce skills / commercialisation training**

**7,730** **individuals** attended **307 training events** and **seminars**

**4,418** **individuals** attended **88 collaboration events**

Note: Date as at 30/06/2018

## Growth Centre Objective 3: Identifying opportunities to address regulations

MTPConnect has represented the MTP sector with a strong independent voice, working with numerous agencies and industry bodies to better streamline regulation pathways and promote the best interests of the sector as a whole. MTPConnect's work in this area spans numerous regulatory areas, including 3D printing, an importation

regime for clinical trial placebo kits and R&D tax reform. MTPConnect's work with the Therapeutic Goods Administration (**TGA**) and other agencies on adaptive regulation for new technologies is one such example.

| Regulatory area | Example MTPconnect activities |
|---|---|
| 3D printing | Reviewed the draft paper on 3D Printing legislation for the TGA before it was released and highlighted areas of potential concern and engaged in industry roundtables and specific meetings. |
| Events and workshops | MTPConnect coordinated a Regulatory Convergence workshop with speakers from TGA, US FDA and UK MHRA, in addition to API sector representatives. |
| Review of Medicines and Medical Devices Regulation | MTPConnect worked directly with DIIS and the TGA in the development of a response to the Expert Review of Medicines and Medical Devices Regulation (MMDR Sansom Review). MTPConnect reviewed both draft papers on "Designation of Australian Conformity Assessment Bodies for Medical Devices" and "Accelerated Assessment of Medical Devices – Priority Review Pathway" and identified key sector issues, which were then provided to government before any public circulation of the document. MTPConnect continues to work closely with the sector, DIIS, DoH and TGA on the issue of Conformity Assessment Bodies.<br><br>MTPConnect is working with regulatory consultants and the TGA regarding the designation of Australian conformity assessment bodies for medical devices and the accelerated assessment of medical devices – priority pathway implementation plan. |
| Clinical trials | MTPConnect has provided inputs into TGA's new Clinical Trials Handbook, provided feedback on TGA's regulatory reform proposal and contributes to the Clinical Trials Governance Framework Consultation, an initiative aimed at strengthening governance arrangements for clinical trials in Australia and to support the delivery of safe and high-quality care for patients and consumers. |
| Digital health | ANDHealth and MTPConnect have worked together to generate a discussion paper on the potential of digital health in Australia. In November 2017, there were a series of four C-suite industry roundtable consultations aimed at capturing the voice of industry in identifying the opportunities, constraints and barriers facing Australia as it looks to build a world class digital health sector. These roundtables informed the Digital Health Whitepaper and has a section on regulation. MTPConnect also engages strongly with the recently established Digital Health CRC. |
| Placebo | Provided key government agencies with advice on policy options for an importation regime for clinical trial placebo kits strengthening Australia's reputation for high quality clinical trials processes. |
| Regenerative medicine | In collaboration with key stakeholders, MTPConnect led a sector-wide effort to develop a national regenerative medicine opportunity paper, outlining key regulatory reform areas. |
| Precision medicine | Coordinated an industry roundtable event highlighting the impact of this megatrend on the sector, including that on regulation and reimbursement. A white paper has also been prepared for the sector. |
| Adaptive regulation | One of the Project Fund Programs focusses on Adaptive clinical trials. In partnership with industry stakeholders, MTPConnect has also initiated a program to explore adaptive regulatory frameworks as they relate to Digital Health. |
| Delay in AQIS permits | MTPConnect continues to direct companies with issues of delay due to AQIS permits to register these on the 'non-tariff barrier register', while keeping DIIS and Austrade informed. |
| R&D Tax incentive | Actively engaged in the consultation process, specifically:<br>• The calculation of R&D intensity under the R&D premium; and<br>• The process for implementing a 'clinical trials' exemption under the $4 million cap on annual cash refunds. |
| Medicinal cannabis | In Quarter 4 of 2016, MTPConnect worked with DIIS, the TGA and the Office of Drug Control to engage with the sector on the new legislation and the respective departments' positions on the issues of medicinal cannabis, via a white paper and a roundtable of sector experts. Responses to MTPConnect from both sector and government stated that the facilitations and outcomes were highly positive and productive and headed off potential hostile media coverage on patient access issues. The work on medicinal cannabis has continued with a focus on investment, regulation, manufacturing and patient access initiatives. |

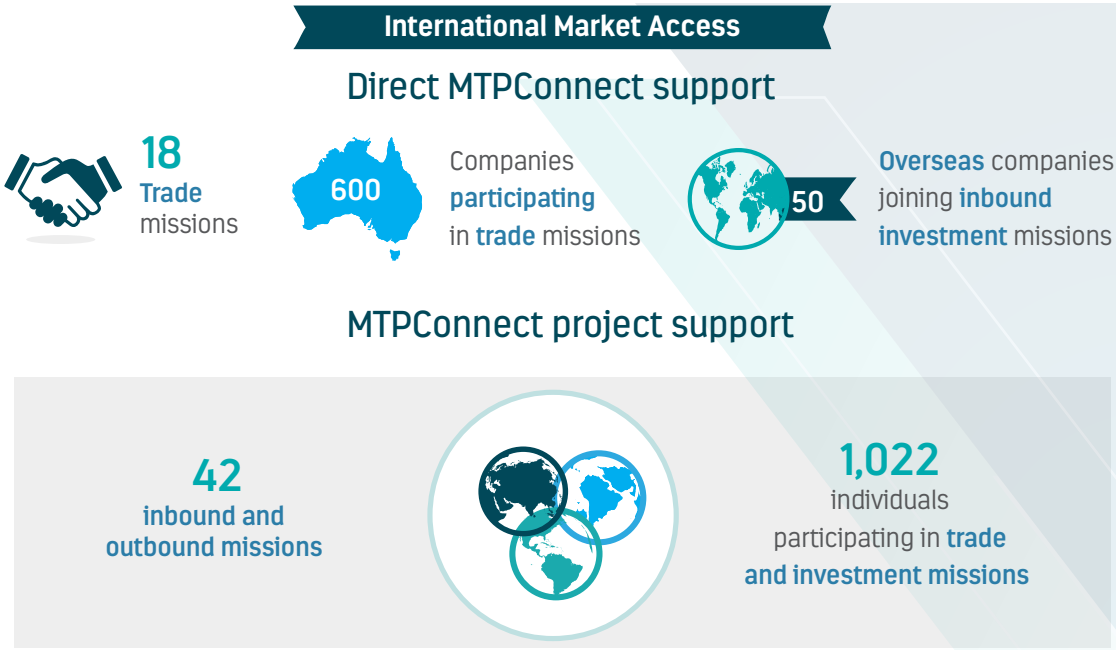
Source: MTPConnect Annual Report FY2018

The development of SME Assist, an education and training web portal to enhance the sector's understanding of regulatory issues, has gained considerable traction. MTPConnect has worked with the TGA to integrate the portal with MTPConnect's Bridge Program to ensure broader awareness and uptake for the portal.

## Growth Centre Objective 4: Improving access to global supply chains & markets

MTPConnect has successfully engaged with international markets to promote the strengths and capabilities of the Australian MTP sector and its participants. The facilitation of both inbound and outbound trade and investment missions has prompted vibrant collaboration and linkages on an international scale.

MTPConnect has partnered with Austrade and peak bodies such as AusBiotech to put Australian MTP stakeholders in front of international customers and investors. MTPConnect has led or supported 18 trade missions, including the 2018 BIO MedTech Conference delegations, with 600 companies participating across all missions. Fifty overseas companies have joined MTPConnect-supported inbound investment missions, which have recently included inbound missions from China.




Note: Date as at 30/06/2018

## MTPConnect priority actions for the next three years

MTPConnect's priority actions for the next three years will build on its achievements since inception in 2015 and continue addressing the key challenges of the sector and align with the four key objectives of the Growth Centre Initiative. MTPConnect's priority actions can be broadly categorised into three themes:

1. Deploy strategic initiative funding;
2. Provide industry thought leadership through an independent voice; and
3. Taking direct action focused on the four Growth Centre objectives.

**Our three themes**

**Deploy strategic initiative funding**

Deliver funding for strategic initiatives through Commonwealth and State funding programs, such as BMTH and BTB, as well as MTPConnect project funds

1

**Independent voice**

Work with sector participants across the MTP value chain to identify policy and regulatory barriers and provide independent advice and recommendations to government

2

**Taking direct action**

Deliver education events and support programs to build commercialisation expertise

Deliver and support programs aimed at driving greater collaboration and commercialisation outcomes

Facilitate national and international connections and collaborations for Australian researchers and companies

3

Under Theme One, MTPConnect's expertise has enabled it to expand its role in delivering strategic initiative funding to include MRFF and state government funded programs, in addition to its own Growth Centre programs. MTPConnect continues to leverage its social license as a trusted independent voice in the sector to inform government policies and regulatory reforms, consistent with Theme Two, while direct action activities continue under Theme Three to develop workforce skills and expertise and foster greater international interactions and connections for the Australian MTP sector.

### Growth Centre Objective 1: Improving coordination and collaboration

MTPConnect plays a leading role in addressing the challenges faced by the MTP sector in translating research through to commercial outputs, and in doing so, contributes to the broader national policy objective of transitioning to a knowledge-based economy that supports creation of high-paying jobs. This work will continue through the deployment of strategic initiative funding and provision of specialist skills and services

to develop greater commercialisation expertise. A selection of key MTPConnect priority actions addressing this Growth Centre objective are listed in the table below.

**Summary of MTPConnect key priority actions to address Growth Centre Objective 1**

| Deploy strategic initiative funding | Provide industry thought leadership through an independent voice | Taking direct action | |
|---|---|---|---|
| | | Provide specialist skills / services | Promote and connect Australia globally |
| • Deploy DIIS Project Funding<br>• Secure and deliver additional non-GC sourced funding to key initiatives in the sector, such as BMTH and BTB<br>• Help ensure appropriate and quality MTP projects are funded through alternative programs such as CRC, CRC-P programs) | • Engage with funding bodies such as NHMRC, ARC, MRFF to encourage inclusion of commercialisation factors in sector rankings and grant assessment criteria, and encouraging increases to translation and commercialisation-focused grant programs<br>• Continue to refine Knowledge Priorities in light of market pull or science push<br>• Continue to monitor, assess and promote international best practice approaches to funding SMEs | • Develop programs that link large research-intensive Multinational Companies to Australia's researchers and SMEs<br>• Expand activity in existing state-based Hubs (NSW, VIC, SA, WA) and build new Hubs (QLD) by leveraging additional state government funding<br>• Expand communications and engagement with the general public, including patients<br>• Enhance effectiveness of TTOs by sharing best practices<br>• Collate and report on a consistent set of sector metrics on behalf of the sector | • Continue to promote Australia as a specialist clinical trial destination and develop case studies of local trials that showcase Australia's expertise and niche experience<br>• Continue working with accelerators, including ANDHealth and the Actuator |

## Growth Centre Objective 2: Improving management and workforce skills

Developing and refining workforce commercialisation skills remains a key priority for the MTP sector if it is to realise its full potential in the future. MTPConnect will continue to support skills development across the sector (standalone or in collaboration with sector partners), from VET through to Early Career Researcher training, internships and mentoring. By effectively blurring the lines between industry, research and teaching, MTPConnect will help ensure that Australia develops an industry-ready workforce. A selection of key MTPConnect priority actions addressing this Growth Centre objective are listed in the table below.

**Summary of MTPConnect key priority actions to address Growth Centre Objective 2**

| Provide industry thought leadership through an independent voice | Taking direct action – provide specialist skills / services |
|---|---|
| • Continue to engage the sector and government to develop skills-training packages specifically applicable to the MTP sector (e.g. digital health, regenerative medicine, precision medicine) | • Continue ongoing work to establish best practice graduate and internship programs that link researchers and industry to encourage exchange of information and skills, drive SME employment, and promote roles in advanced manufacturing<br>• Promote programs to support early stages of start-up and company formation<br>• Promote an SME education program to maximise negotiated funding outcomes, out-licensing arrangements or divestment<br>• Work with AusBiotech to develop a comprehensive commercialisation guide to assist early-stage medtech companies in navigating the commercialisation pathway for medical devices<br>• Explore opportunities for provision of coordinated professional development programs for TTOs |

## Growth Centre Objective 3: Identifying and acting on opportunities to address regulations

MTPConnect has been involved in a number of cross-sector forums seeking to identify and address areas of regulatory burden within the MTP sector. It will continue to drive progress against this objective by focusing on generating independent insights regarding emerging areas, such as digital health, adaptive clinical trials and precision medicine. In addition, MTPConnect will work with sector participants and government to develop appropriate frameworks to position Australia as an efficient and cost-effective destination for investment. A summary of key MTPConnect priority actions addressing this Growth Centre objective are listed in the table below.

**Summary of MTPConnect key priority actions to address Growth Centre Objective 3**

| Deploy strategic initiative funding | Provide industry thought leadership through an independent voice |
|---|---|
| • Continue using the Project Fund Program to co-fund projects to improve regulation and clinical trials in Australia | • Adopt 'horizon scanning' as a focus to effectively anticipate the need for change and position Australia favourably<br>• Hold roundtables and 'future forums', and deliver white papers on future trends and significant growth areas including digital health, precision medicine, 3D printing, and adaptive clinical trials to help government develop appropriate responses and identify areas for regulatory renewal<br>• Continue to work with relevant government bodies such as TGA on streamlining and harmonising the regulatory regime for clinical trials<br>• Continue to engage with CSIRO on sector specific initiatives such as the Adaptive Regulatory Project. We will also build on our work as part of the CSIRO's Health and Biosecurity Advisory Board and engagement with the roadmap projects, including Future of Health report<br>• Work with the government on review of and guidance for the MTP sector on the R&D Tax Incentive program |

## Growth Centre Objective 4: Improving access to global supply chains & markets

To succeed in a highly competitive global marketplace, Australia needs to continue to engage with international markets to attract inbound collaborations and investments from overseas, and to develop partnerships with international companies and institutions to commercialise Australian products and services globally. Links to global markets are also necessary to understand international unmet needs, the development and regulatory requirements, market opportunities and access strategies. To achieve this objective, MTPConnect will continue to promote Australia's capabilities internationally and foster connections between international companies and institutions and Australian businesses and researchers. A summary of key MTPConnect priority actions addressing this Growth Centre objective are listed in the table below.

**Summary of MTPConnect key priority actions to address Growth Centre Objective 4**

| Taking direct action – promote and connect australia globally |
| --- |
| • Continue to work with Austrade and peak industry bodies to develop a cohesive approach to promoting Australia's MTP sector internationally (e.g. MedTech / BIO conferences, inbound / outbound trade missions) in order to maximise SME connections |
| • Conduct seminars and information sessions regarding the comprehensive global investment education program for the Australian life science sector |
| • Continue to attend and present at focused conferences and exhibitions domestically and internationally to develop MTPConnect and Australia's MTP sector's in-market presence |
| • Continue to evaluate global best practice around international engagement strategies and translate into Australian initiatives, including CIMIT, MaRS Innovation, Catapult UK and Fraunhofer Institute |
| • Provide advice, guidance and connections to international market experts to help prepare Australian companies for international expansion |

# 5. SECTOR KNOWLEDGE PRIORITIES

## Introduction

Knowledge Priorities are intended to provide strategic focus to the sector's activities. They represent areas where there is a high level of unmet need globally and where Australia is or has the potential to be a leading contributor. It is intended that a growing proportion of investment and activities in the sector should be guided towards these KPs where patient outcomes can be realised and opportunities exist for strong returns.

KPs are divided into five key areas:

- Areas of science: areas of basic research that underpin biological discovery, and provide early-stage ideas;
- Therapeutic areas: knowledge areas that focus on R&D of specific treatments for diseases and pathologic findings, as well as prevention of conditions that negatively impact the health of individuals;
- Device / diagnostic areas: areas of technology, medical devices and diagnostic tools that provide solutions for medical conditions;
- Skills / capabilities: specialist skills and capabilities that are critical to enhancing the pipeline of products advancing through the MTP value chain, and realise greater commercialisation outcomes; and
- Other existing national priorities.

The categorisation of priorities into these four areas is to some degree discretionary and priorities may be defined through a combination of the above four areas. For example, success in developing immuno-oncology drugs will rely on focusing on immunology (area of science) and oncology (therapeutic area).

## Methodology

MTPConnect has carried out a robust, independent assessment of KPs and tested these KPs with key stakeholders across the broad MTP sector. KPs in each of the three areas mentioned above have been shortlisted by considering:

- Global trends, such as forecast global sales in therapeutic and device areas as indicators of areas with significant global market need and commercial potential;
- Australia's strength and capability in basic research, clinical trials and past/ existing commercial success as indicators of Australia's competitive strengths; and
- Strategic priorities of key national organisations and initiatives, such as the NHMRC and MRFF.

KPs are then segmented into:

- **Current KPs:** KPs that reflect current areas of unmet market need and / or competitive strength for Australia, and
- **Emerging KPs:** KPs that reflect areas with future commercial potential and / or potential for Australia to build competitive strength.

The detailed methodology and data used to identify KPs are laid out in Appendix 2.

## Knowledge Priorities identified

Overall, six areas of science, nine therapeutic areas, five device / diagnostic areas and four other existing national priorities have been identified as **Current KPs**, as shown in the diagram below. Seven KPs have also been identified as **Emerging KPs**. These are regenerative medicine, human movement and sports science, medical physiology, medical biotechnology, nanotechnology, pain management, and optometry and ophthalmology. A comprehensive audit of skills and capabilities across the sector to define skill-based KPs, e.g. big data analytics, and commercialisation skills will be undertaken during 2019 and the KPs updated accordingly.

| | Areas of science | Therapeutic areas | Device / diagnostic areas | Skills / capabilities | Other existing national priorities |
|---|---|---|---|---|---|
| Current | Biochemistry and cell biology (including synthetic biology) | Oncology | Diagnostic device – POC / lab | Certain skills / capabilities have been identified through prior work, including advanced manufacturing, clinical trials expertise and big data analytics | Drug repurposing |
| | Psychology and cognitive sciences | Infectious disease (including antimicrobial resistance) | Surgical devices and consumables | MTPConnect to lead a skills audit in 2019 along with sector participants to identify KPs | Biosecurity |
| | Genetics and precision medicine | Neurosciences and neurology | Implantables (including 3D printed custom devices and bionics) | | Data science |
| | Microbiology | Cardiac and cardiovascular systems | Wearable devices | | Rare diseases |
| | Immunology | Diabetes, endocrinology and metabolism | Digital health and monitoring | | |
| | Paediatrics and reproductive medicine | Respiratory disorders (e.g. asthma) | | | |
| | | Arthritis and musculoskeletal conditions | | | |
| | | Aged and palliative care | | | |
| | | Aboriginal and Torres Strait Islander Health | | | |
| Emerging | Human movement and sports science | Regenerative medicine | | | |
| | Medical physiology | Optometry and ophthalmology | | | |
| | Medical biotechnology | Pain management | | | |
| | Nanotechnology | | | | |

## Areas of science

The six current areas of science identified reflect areas where Australia is among the top 10 in both high-quality research publications internationally and national competitive grant funding (over the past three years). Many of these areas reflect fundamental research priorities that underpin biological discovery and are the basis for generating commercialisation opportunities in relevant therapeutic and device / diagnostic areas. It should be noted that immunology is included in this list due to its particular relevance in supporting oncology, which is a priority therapeutic area. Oncology, and more specifically immuno-oncology, is widely regarded as the therapeutic area representing the largest future commercial potential globally.

Human movement and sports science, medical physiology, medical biotechnology, and nanotechnology are classified as emerging KPs because Australia is very strong in terms of high-quality publications in these areas (5th, 8th, 8th and 9th in the world respectively), but these areas have not attracted a lot of national competitive grant funding in recent years. These Emerging KPs should be considered as candidates for additional funding.

## Therapeutic areas

Nine therapeutic areas have been identified as current KPs. Oncology, infectious diseases (including antimicrobial resistance); neurosciences; cardiovascular disease; diabetes, endocrinology & metabolism; respiratory disorders; and arthritis & musculoskeletal conditions are all diseases that are among the most prevalent globally and have the most impact on healthcare systems. In addition, a focus on aged and palliative care as a KP is particularly relevant in the context of the ageing population, a global megatrend. The Aboriginal and Torres Strait Islander Health has been included as a current KP, consistent with the national priorities laid out by the NHMRC and the MRFF.

Optometry and ophthalmology, pain management and regenerative medicine are classified as Emerging KPs as Australia is currently building strong capability and reputation in each of these three therapeutic areas in terms of research capability, clinical trials and commercial success. Of these emerging KPs, regenerative medicine in particular represents significant commercial potential, estimated to be a c.$120 billion global market in 2035, and is an area where Australia has competitive strengths in R&D.

## Device / diagnostic areas

Five device / diagnostic areas have been identified as KPs:

- Diagnostic device (POC / lab) refers to technologies / devices that are used to diagnose specific medical conditions. These devices are typically used at the point-of-care or laboratory setting. Examples include medical imaging devices and in-lab testing kits;
- Surgical devices and consumables refer to devices and tools used within a hospital or surgical environment, including in-surgery monitoring devices, wound care instruments and robotics;
- Implantables include custom-made 3D printed implants and bionics, that are used as prosthetics in surgical environments;
- Wearable sensors include portable devices such as blood pressure sensors, hearing and sleeping aids; and
- Digital health / monitoring refers to big data analytics, portable devices and smartphone apps that provide consumers and healthcare professionals with instantaneous access to patient's health status, including smart inhalers, diabetes management apps and mental health management apps.

## Skills / capabilities

Previous reports that have specifically looked at the regenerative medicine and clinical trials landscape in Australia have identified a few key focus areas across the MTP value chain, where there is a need for Australia to develop greater skills / capabilities. These include:

- Commercialisation expertise, including the ability to identify an unmet market need, develop proof-of-concept and a product development plan, access relevant development capabilities both locally and internationally and the related timeline and budget, create appropriate IP strategies, navigate regulatory requirements, design clinical trials, access optimum funding pathways and establish strategic partnerships;
- Advanced manufacturing skills and capabilities (e.g. cell and tissue manufacturing, 3D printing);
- Clinical trials expertise, particularly in early stage biopharma trials (e.g. immunotherapy) that involve novel trial designs and those that focus on translational medicine; and
- Big data analytics, including both the software and skills to synthesise and analyse big data sets.

There is a need for a comprehensive skills audit to be undertaken across the entire MTP sector to identify current skills gaps, and to subsequently prioritise KPs accordingly. MTPConnect is planning to lead such a skills audit in 2019 along with major sector participants.

## Other existing national priorities

Four other KPs have been identified - drug repurposing, biosecurity, data science and rare diseases. These areas have been shortlisted as they have been identified as national priorities by the MRFF and do not fit into any of the three areas above.

Drug repurposing refers to identifying new uses for approved or investigational drugs that are outside the scope of the original medical indication. Biosecurity refers to the procedures or measures designed to protect the population against biological or biochemical threats / substances (developments to be informed by MTPConnect's work with the Defence Materials Technology Centre's Strategic Advisory Committee). Data science refers to the use of scientific methods, processes, algorithms and systems to extract knowledge and insights from data, and rare diseases refer to life-threatening or chronically debilitating, statistically rare and complex diseases with low survival rates. The MRFF has prioritised rare diseases including brain and other rare cancers to extend and enhance the quality of life for Australians living with these devastating conditions.

The KPs identified above are not intended to be final, and they will be revisited and updated at regular intervals as they evolve over time.

# APPENDICES

## Appendix 1: Glossary of terms

| | |
|---|---|
| AAMRI | Association of Australian Medical Research Institutes |
| ACOLA | Australian Council of Learned Academies |
| AHMADA | Australian Health Manufacturers and Development Association |
| AHRTC | Advanced Health Research and Translation Centre |
| AI | Artificial Intelligence |
| AMA | Australian Medical Association |
| ARC | Australian Research Council |
| AMGC | Advanced Manufacturing Growth Centre |
| ARCS | Association of Regulatory and Clinical Scientists |
| ARTG | Australian Register of Therapeutic Goods |
| ASMR | Australian Society for Medical Research |
| ASX | Australian Securities Exchange |
| ATSE | Australian Academy of Technological Sciences and Engineering |
| BMTH | BioMedTech Horizons project |
| BTB | Biomedical Translation Bridge |
| BTF | Biomedical Translation Fund |
| CERI | Centre for Entrepreneurial Research and Innovation |
| CRC | Cooperative Research Centre |
| CRO | Contract Research Organisation |
| CSIRO | Commonwealth Scientific and Industrial Research Organisation |
| DIIS | Department of Industry, Innovation and Science |
| GVA | Gross Value Added |
| HMR | Health and Medical Research |
| IMNIS | Industry Mentoring Network in STEM |
| IP | Intellectual property |
| KPs | Knowledge Priorities |
| MA | Medicines Australia |
| MDPP | Medical Device Partnering Program |
| MNC | Multinational corporation |
| MRFF | Medical Research Future Fund |
| MRI | Medical Research Institute |
| MSAC | Medical Services Advisory Committee |
| MTAA | Medical Technology Association of Australia |
| MTP | Medical technology, biotechnology and pharmaceutical |
| NACCHO | National Aboriginal Community Controlled Health Organisation |
| NGO | Non-government organisation |
| NHMRC | National Health and Medical Research Council |

| | |
|---|---|
| PBAC | Pharmaceutical Benefits Advisory Committee |
| PBS | Pharmaceutical Benefits Scheme |
| REDI | Research Exchange and Development with Industry Initiative |
| R&D | Research and Development |
| SCP | Sector Competitiveness Plan |
| SME | Small and medium-sized enterprises |
| STEM | Science, Technology, Engineering and Mathematics |
| TGA | Therapeutic Goods Administration |
| TTO | Technology Transfer Office |
| VC | Venture Capital |

## Appendix 2: Detailed methodology for Knowledge Priorities

The methodology and data used to identify KPs in each of the three key areas: 1) areas of science, 2) therapeutic areas, and 3) device / diagnostic areas – are detailed below.

### Areas of science

Areas of science are segmented by the Australian Research Council (**ARC**) into 4-digit codes that are relevant to the MTP sector. Areas have been shortlisted as KPs based on:

- Metrics that provide an indication of academic strength; and
- The level of competitive grant funding attracted over the last three years.

Academic strength has been assessed based on Australia's global ranking in terms of the number of quality published documents within each area of science over the last three years. The number of quality published documents within each area of science is calculated by multiplying the total number of published documents by the percentage of publications that placed in the top 10% based on citations by category, year and document type. Australia's global ranking in each area of science is shown in the data table below. Data from the Clarivate Analytics' Web of Science database was used for these calculations.

Competitive grant funding has been calculated by adding the total amount of ARC and NHMRC competitive grants announced for each area of science over the last three years. This total includes funding for future years that were announced in 2018 or earlier.

Areas of science were then shortlisted if ranked in the top 10 for both of the above metrics. This was combined with stakeholder consultation to arrive at the final agreed list (highlighted in blue below). Those areas not shortlisted, but identified with strong potential for future growth, have been classified as emerging areas - these areas are ranked in the top 10 for academic strength, but are yet to receive significant grant funding (highlighted in yellow below).

## Table 1: Analysis of areas of science KPs

| Areas of science | | Australia's capability | | Shortlisted as KP? |
|---|---|---|---|---|
| Relevant MTP ARC 2-digit codes | Relevant MTP ARC 4-digit codes | Academic strength (2016-18) | Competitive grants (2016-18) | |
| | | Aus global ranking in each area of science (1) | Total funding ranking – NHMRC + ARC (2) | |
| Biological Sciences | Biochemistry and cell biology (including synthetic biology) | 10 | 1 | Yes |
| | Genetics | 7 | 5 | Yes |
| | Microbiology | 10 | 15 | No |
| Chemical sciences | Medicinal and biomolecular chemistry | 12 | 13 | No |
| Engineering | Biomedical engineering | 9 | 14 | No |
| Medical and Health Sciences | Cardiovascular medicine and haematology | 12 | 8 | No |
| | Clinical sciences (3) | 9 | 2 | Yes |
| | Dentistry | 13 | 22 | No |
| | Human movement and sports science | 3 | 21 | Yes (emerging) |
| | Immunology (4) | 12 | 6 | Yes |
| | Medical biochemistry and metabolomics | 10 | 20 | No |
| | Medical microbiology | 7 | 7 | Yes |
| | Medical physiology | 8 | 19 | Yes (emerging) |
| | Neurosciences (5) | 10 | 3 | Yes |
| | Oncology and carcinogenesis | 12 | 4 | No |
| | Optometry and ophthalmology (6) | 5 | 16 | Yes |
| | Paediatrics and reproductive medicine | 6 | 9 | Yes |
| | Pharmacology and pharmaceutical sciences | 9 | 12 | No |
| Psychology and cognitive sciences | Cognitive science | 9 | 18 | No |
| | Other psychology and cognitive sciences (5) | 7 | 23 | No |
| | Psychology (5) | 5 | 10 | Yes |
| Technology | Industrial biotechnology | 24 | 24 | No |
| | Medical biotechnology | 8 | 17 | Yes (emerging) |
| | Nanotechnology | 9 | 11 | Yes (emerging) |

**Keys** Current area of science | Emerging area of science | Overlapping with therapeutic area

Notes:

1. Australia's global ranking in terms of the number of quality published documents within each area of science over the last three years, calculated by multiplying the total number of published documents by the percentage of publications that placed in the top 10% based on citations by category, year and document type.
2. Total funding ranking refers to the ranking for funding for the particular area of science out of the list of areas of science tagged as relevant to the MTP sector.

3. The ARC 6-digit codes within Clinical Sciences predominantly relate to therapeutic areas which have already been considered in the therapeutic area analysis below.
4. Immunology has been included despite being ranked outside of the top 10 for Academic Strength given its particular relevance in supporting oncology, which is a priority therapeutic area. Oncology, and more specifically immuno-oncology, is widely regarded as the therapeutic area representing the largest future commercial potential globally.
5. Neurosciences, Psychology and Other psychology and cognitive sciences have been combined into one category, namely: Psychology and Cognitive Sciences.
6. Optometry and ophthalmology has been included as an emerging therapeutic area due to its overlap across areas of science and therapeutic areas.

## Therapeutic areas

Therapeutic areas have been shortlisted as KPs based on three key groups of metrics, with relevant data sources analysed under each:

1. Size of the future global market opportunity
    a. Global sales, by therapeutic area in 2024 from relevant market research reports
2. Australia's capability
    a. Number of ASX companies in each area
    b. Number of companies identified as commercialisation 'success stories' by relevant industry bodies in each area
    c. Number of licensing deals in each area
    d. Number of Major Research Institutions (MRIs) focusing their research efforts in each area
    e. Number of clinical trials initiated in each area in Australia
3. Existing priorities of key national bodies
    a. MRFF priorities and initiatives (listed in the Australian Medical Research and Innovation Priorities 2018-20 report and on the MRFF website)
    b. NHMRC priorities (listed in the NHMRC Corporate Plan 2018-19)

For each metric, a threshold was assigned which triggered its inclusion in the shortlisting process. Overall, a therapeutic area was shortlisted as a KP if:

- The global sales in 2024 was › $40 billion; and
- The sum of all its Australian capability metrics was greater than a defined threshold (2); or
- It was an existing priority of one of either the NHMRC or the MRFF.

Those areas not shortlisted, but identified with strong potential for future growth, have been classified as emerging areas (highlighted in yellow below).

## Table 2: Analysis of therapeutic areas KPs

| Therapeutic areas | Source | Global trends | Australia's capability | | | | | Existing priorities | | Short-listed as KP? |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Global Sales 2024 ($bn) | # ASX companies | Success Stories | Licensing deals | # MRIs researching | # Clinical trials (% of global trials) | MRFF | NHMRC | |
| Cardiac and cardiovascular sys | SCP '16 | 90 | 7 | 3 | 0 | 17 | 40 (34%) | 1 | 0 | Yes |
| Diabetes, endocrinology & metabolism | | 60 | 5 | 2 | 1 | 14 | 0 | 1 | 0 | Yes |
| Immunology (1) | | 38 | 5 | 0 | 0 | 18 | 0 | 0 | 0 | Yes |
| Neurosciences & neurology | SCP '16 | 35 | 15 | 2 | 0 | 23 | 49 (30%) | 1 | 0 | Yes |
| Obesity | | 16 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | No |
| Oncology | | 233 | 23 | 8 | 3 | 25 | 294 (42%) | 1 | 0 | Yes |
| Ophthalmology and optometry | | 30 | 5 | 0 | 0 | 7 | 9 (31%) | 0 | 0 | Yes (emerging) |
| Pain management | | 80 | 13 | 1 | 1 | 3 | 0 | 0 | 0 | Yes (emerging) |
| Respiratory disorders (asthma) | | 43 | 7 | 0 | 0 | 6 | 65 (35%) | 0 | 0 | Yes |
| Sleep | | 3 | 4 | 0 | 1 | 3 | 0 | 0 | 0 | No |
| Arthritis & musculoskeletal conditions | | 78 | 4 | 0 | 0 | 8 | 43 (36%) | 0 | 0 | Yes |
| Haematology | | 47 | 5 | 0 | 0 | 1 | 0 | 0 | 0 | No |
| Infectious disease (inc. antimicrobial resistance) | | 85 | 10 | 3 | 1 | 12 | 84 (46%) | 1 | 0 | Yes |
| Otorhinolaryngology | | 12 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | No |
| Paediatrics and reproductive medicine (1) | | 149 | 7 | 0 | 0 | 9 | 0 | 0 | 0 | Yes |
| Reproductive endocrinology | | 20 | 0 | 0 | 0 | 0 | 38 (27%) | 0 | 0 | No |
| Surgery | | 22 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | No |
| Regenerative medicine (3) | New | 120 (2) | 6 | 1 | 0 | 2 | 0 | 0 | 0 | Yes (emerging) |
| Dermatologicals | Evaluate Pharma | 30 | 7 | 1 | 0 | 1 | 0 | 0 | 0 | No |
| Nephrology | Evaluate MedTech | 15 (4) | 6 | 1 | 0 | 2 | 12 (40%) | 0 | 0 | No |
| Aboriginal and Torres Strait Islander Health | MRFF; NHMRC | 7 (5) | 0 | 0 | 0 | 5 | 0 | 1 | 1 | Yes |
| Aged, supportive and palliative care | MRFF; NHMRC | 1,017 | 0 | 1 | 0 | 5 | 0 | 1 | 1 | Yes |

| Keys | Current therapeutic area | Emerging therapeutic area | Overlapping with area of science |
|---|---|---|---|

Notes:

1. Immunology and Paediatrics and reproductive medicine have already been included as areas of science.
2. Refers to AUD forecast by 2035 from Catapult and Gene Therapy, UK.
3. Regenerative medicine has been included as an emerging therapeutic area as it represents significant commercial potential, estimated to be a c.$120 billion global market in 20135, and is an area where Australia has competitive strengths in R&D.
4. Refers to 2022 forecast from Evaluate MedTech.
5. Using health expenditure, by Indigenous status in 2010-11. This has been forecasted using the CAGR for Indigenous population growth between 2011-16.

## Device / diagnostic areas

Device / diagnostic areas are areas of technology, medical devices and diagnostic tools that provide solutions for medical conditions.

As above with therapeutic areas, device / diagnostic areas have been shortlisted based on three key groups of metrics, with relevant data sources analysed under each:

1. Size of the future global market opportunity
    a. Global sales, by device area in 2022 from relevant market research reports
2. Australia's capability
    a. Number of ASX companies in each therapeutic area
    b. Number of companies identified as commercialisation 'success stories' by relevant industry bodies in each therapeutic area
3. Existing priorities of key national bodies
    a. MRFF priorities and initiatives (listed in the Australian Medical Research and Innovation Priorities 2018-20 report and on the MRFF website)
    b. NHMRC priorities (listed in the NHMRC Corporate Plan 2018-19)

As above, for each metric a threshold was assigned which triggered its inclusion in the shortlisting process. A device / diagnostic area was shortlisted as a KP if:

- The global sales in 2022 was › $40 billion; and
- The sum of all its Australian capability metrics was greater than a defined threshold (1); or
- It was an existing priority of either the NHMRC or the MRFF

Table 3: Analysis of device / diagnostic area KPs

| Device / diagnositc areas | Source | Global trends | Australia's capability | | Existing priorities | | Shortlisted as KP? |
|---|---|---|---|---|---|---|---|
| | | Global sales 2022 ($bn) | # ASX companies | Success stories | MRFF | NHMRC | |
| Wearable device | SCP '16 | 50 | 14 | 4 | 0 | 0 | Yes |
| Diagnostic device – patient | SCP '16 | 5 | 6 | 2 | 0 | 0 | No |
| Diagnostic device – POC / lab | SCP '16 | 70 | 19 | 5 | 0 | 0 | Yes |
| Drug delivery | SCP '16 | 25 | 7 | 1 | 0 | 0 | No |
| Sterile / protective equipment | SCP '16 | 10 | 4 | 1 | 0 | 0 | No |
| Implantables and bionics | SCP '16 | 107 | 6 | 3 | 0 | 0 | Yes |
| Surgical devices and consumables | SCP '16 | 88* | 8 | 3 | 0 | 0 | Yes |
| Digital health / monitoring | MRFF; NHMRC | 297 | 14 | 2 | 1 | 1 | Yes |

Keys Current device / diagnostic area

## Other existing national priorities

Four other KPs have been shortlisted as they have been identified as national priorities by the MRFF, and do not fit into any of the three areas above.

Table 4: Analysis of broader landscape area KPs

| Broader landscape areas | Source | Existing priorities | | Shortlisted? |
|---|---|---|---|---|
| | | MRFF | NHMRC | |
| Drug repurposing | MRFF | 1 | 0 | Yes |
| Biosecurity | MRFF | 1 | 0 | Yes |
| Data science | MRFF; NHMRC | 1 | 1 | Yes |
| Rare diseases | MRFF | 1 | 0 | Yes |

Keys Current 'other' area

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Note: In addition to these sources, MTPConnect has drawn on a number of internal documents provided by sector participants that have not been released publicly. We thank all participants for their input.

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