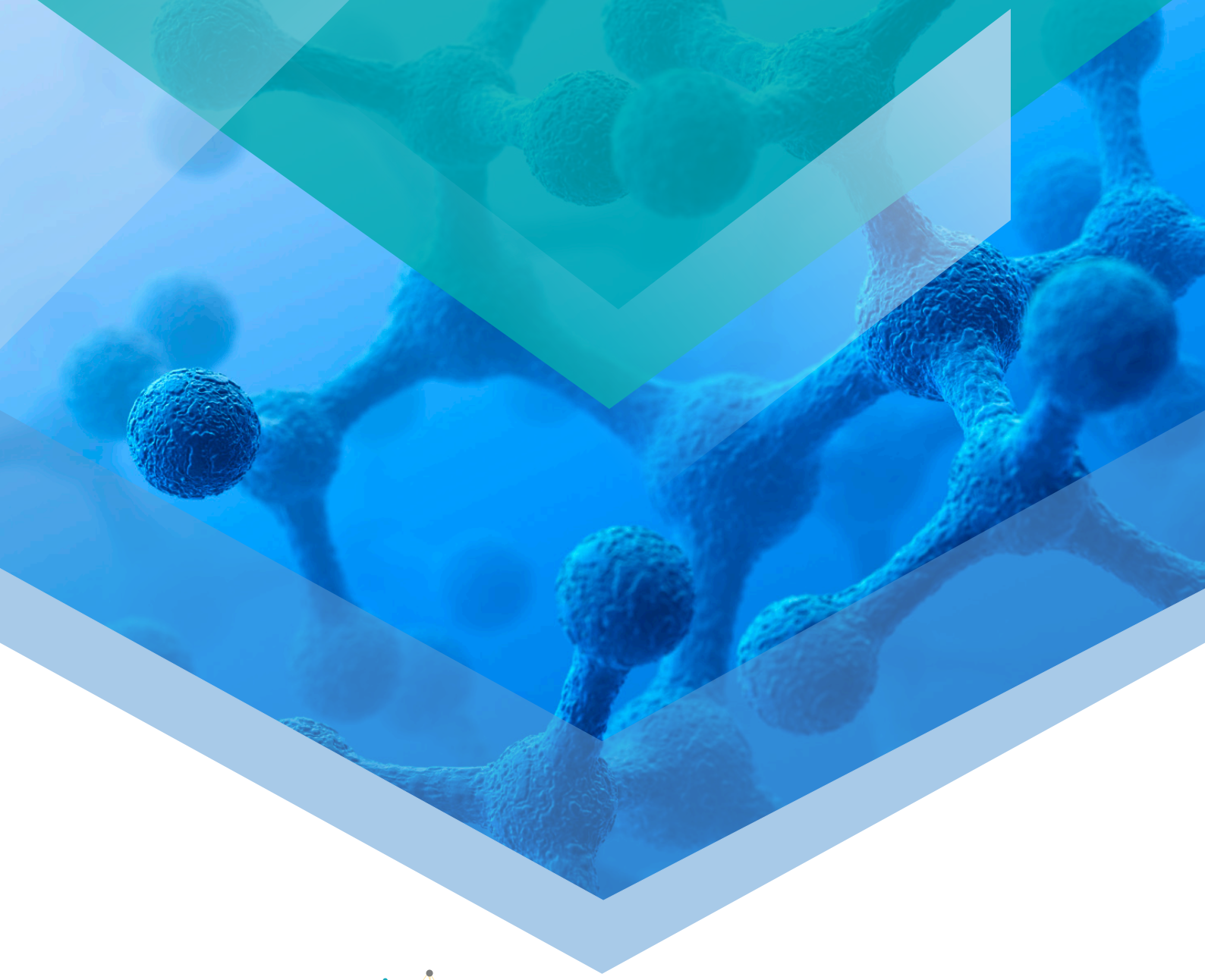

MTPConnect
MedTech and Pharma Growth Centre

Medical Technology, Biotechnology & Pharmaceutical Sector Competitiveness Plan

APRIL 2020

MTPConnect | Championing a sector-led approach to accelerating the growth of the medical technology, biotechnology and pharmaceutical ecosystem in Australia

Australian Government
Department of Industry, Science, Energy and Resources

Industry Growth Centres

Acknowledgments

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Legal Information

Contents

Report creation led by:

Foreword from the Chair and Managing Director & CEO

Sue MacLeman
Chair

Dr Dan Grant
Managing Director & CEO

In November of 2015, MTPConnect was established as an independent, not-for-profit Growth Centre to drive connectivity, innovation, productivity and competitiveness in Australia's medical technology, biotechnology and pharmaceuticals (MTP) sector. In 2016 we published our first Sector Competitiveness Plan (SCP), a comprehensive sector snapshot and ten-year vision for growth developed following extensive consultation with and input from hundreds of sector participants.

In our 2020 SCP update, we revisit the MTP sector's knowledge priorities and review the growth achieved by the sector over the last four years - up until 31 December 2019, the period prior to the emergence of the novel coronavirus (SARS-CoV-2). While the impacts of the coronavirus disease (COVID-19) are developing and impossible to predict at the time of writing this update, we can report robust growth across many key metrics for the reporting period. Gross Value Added (GVA) has grown steadily at 2% p.a. since 2016, and exports have increased by 16% p.a. over the same period to be Australia's 8th largest export segment. MTPConnect will be directly addressing COVID-19 impacts on the MTP sector and the path to recovery in a series of reports to be released during 2020.

MTPConnect continues to make a valuable contribution to the growth of the MTP sector. Our Growth Centre work is now complemented by three Medical Research Future Fund programs worth nearly $100 million: BioMedTech Horizons (BMTH), Biomedical Translation Bridge (BTB) and the new Researcher Exchange and Development within Industry (REDI) Initiative. Through our work fostering collaboration, addressing workforce challenges, opening-up international markets and optimising regulatory and policy frameworks we are helping researchers, start-ups and SMEs develop into larger and more global players.

Our collective achievements are a clear demonstration of the importance of the MTP sector to Australia's health and economic wellbeing. Its resiliency in the face of global shocks, such as the COVID-19 crisis, is noteworthy. And while the sector had shown a strong upward trajectory at the time of writing, we acknowledge that it is now being tested like never before. Importantly, the sector is poised to play a key role in Australia's COVID-19 response and recovery.

We thank the many participants of the MTP sector for your engagement and collaboration to support the development and commercialisation of new biological, pharmaceutical, medical and health technology innovations. From vaccines to microwearables, your work underpins a sector that is central to Australia's future health and economic prosperity and we look forward to working with you further to sustain - and grow - our sector over the coming years.

Executive summary

The vision of better health outcomes for consumers through products and services tailored to individual needs and through seamless digital connectivity and integration is becoming increasingly tangible. Innovation and technological advancements in areas such as digital health solutions, precision and regenerative medicine supported by advanced manufacturing are driving this vision globally. In this context, the Australian MTP sector saw a number of key milestones in 2019, particularly in the areas of precision and regenerative medicine with the $500 million investment from the Medical Research Future Fund (MRFF) in the Genomics Health Futures Mission and the $150 million commitment to launch the Stem Cell Therapies Mission. We also saw a $105 million investment in a new CAR-T cell treatment centre at the Peter MacCallum Cancer Centre in Melbourne.

While 2020 has seen the onset of COVID-19, with impacts that are developing and impossible to predict at the time of writing, the Australian MTP sector rapidly mobilised to meet the pandemic challenge. Maintaining this momentum will be critical if the successes of 2019 are to be sustained.

Australia's MTP sector delivered robust and steady growth across many key metrics to 31 December 2019. The sector added $5.2 billion in GVA to the Australian economy in 2019, a 2% p.a. increase since 2016. Manufacturing exports have grown 16% p.a. since 2016 to be worth $8.2 billion, making the MTP sector the 8th largest export segment in Australia. There has been a 1% p.a. increase in the total number of MTP companies since 2016 and a 28% p.a. increase in the ASX market capitalisation of listed MTP companies from 2016, a rate that is more than three times the 9% p.a. growth observed in the overall S&P / ASX growth over the same period.

During 2019, Australia continued to cement its reputation as a 'go to' destination for companies wanting to conduct clinical trials, with 1,820 ongoing trials - a 22% increase on 2015. As well as contributing an estimated $1.1 billion a year to the economy, more clinical trials means more patients getting increasing access to new therapies. Sustaining our successes in this area in the years ahead will be a particular challenge.

These outcomes are explored in detail in the 2020 Sector Competitiveness Plan (SCP), a living document through which MTPConnect communicates the sector-wide vision and priorities as well as its own priorities to support the achievement of these shared objectives. The 2020 SCP captures the advances made by the sector both globally and nationally over the last year. 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 sustaining sector growth.

While Australia's MTP sector has been delivering strong growth, significant opportunities remain to build the capabilities of the MTP sector workforce. MTPConnect is stepping-up on this front, having recently been selected by the Department of Health to deliver the $32 million REDI Initiative, which is focused on systematically addressing gaps in sector skills and ensuring Australia has an industry-ready MTP workforce. Investment in local talent and jobs will enable Australia to expand its footprint in the global sector, seize opportunities created by emerging megatrends in health and medical research and improve health outcomes.

MTPConnect's vision is for Australia to increase the current planned levels of expenditure on Research and Development (R&D) to deliver 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. MTPConnect's seven Sector Growth Priorities, identified in 2016 and refined in 2019 remain relevant today if the sector is to achieve this Sector Vision.

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

This SCP updates the shortlist of Knowledge Priorities (KPs) that MTPConnect identified in 2019 and they are intended to provide greater strategic focus to the sector's activities. These KPs are based on a robust assessment framework and input from key stakeholders across the sector and represent areas where there is a high level of unmet need globally and where Australia is or has the potential to be a world leader. The KPs also recognise that skills and capabilities will be required to succeed. Two new Emerging KPs, biomedical engineering and dermatologicals, have been added to the seven KPs identified in 2019 (regenerative medicine, human movement and sports science, medical physiology, medical biotechnology, nanotechnology, pain management, optometry and ophthalmology). Together, these emerging KPs are areas that are expected to grow rapidly over the next five years and are areas where Australia could strategically build strength and capability in order to sustain sector growth during the next decade.

The 2020 SCP also summarises the progress made by MTPConnect against its four Growth Centre 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.

With the clear vision outlined in this 2020 SCP and a focus on a number of sector priorities, Australia is well-positioned to sustain and grow the MTP sector so it can continue contributing to the protection of the health of Australians and economic growth. The role of the MTP sector, on the front line for research, diagnosis, management, prevention and treatment of infectious diseases, has never been more important in driving Australia's COVID-19 response and recovery.

Many researchers, start-ups and SMEs are working in vaccine design and manufacture, diagnostics and imaging, bioprocessing technologies, ventilation technology, telemedicine, infection control and protection and immune system-directed therapeutics. Industry has, and will continue to be, integral to securing essential supplies of ventilators, testing kits and other personal protective equipment (PPE) required by the healthcare system and building sovereign capabilities for future pandemic resilience.

Document structure

Context	Sector overview and performance	Sector Priorities for future growth	MTPConnect progress and priority actions	Sector Knowledge Priorities
Introduction to MTPConnect and the context for this SCP update.	An overview of the Australian MTP sector, and growth in the last three years, including key sector metrics such as employment figures, GVA and R&D expenditure.	An updated strategic, long-term vision for the sector, underpinned by the seven Sector Growth Priorities that frame MTPConnect's action plan.	Explanation of MTPConnect's role within the sector, and its key achievements over the last four years. Discussion of the key priority actions for MTPConnect over the next three years in order to continue progress towards the stated vision.	An overview of the key KPs for the MTP sector, tailored to market needs and research strengths that will optimize the commercialisation potential of research. These KPs were identified by considering future global trends, Australia's capabilities and the priorities of key federal organisations.
P6	P7	P15	P30	P38

1. Context

MTPConnect, a not for profit organisation that champions an industry-led approach to accelerating the growth of Australia's MTP sector, has been operating for four and a half years. Its first SCP, published in 2016, outlined a comprehensive 10-year strategic plan through to 2025 to boost the innovation, productivity and competitiveness of the MTP sector. A periodic review and update of the SCP is important to track sector priorities and outcomes. The 2020 SCP takes a forward-looking view to inform and refine sector priorities and within those, MTPConnect's organisational areas of focus.

In 2019, MTPConnect invested in a more extensive "refresh" of the 2016 and 2018 plans. The 2019 SCP refined the key priorities for the MTP sector in light of the evolution in the megatrends impacting on the sector, drawing on input from sector participants. For the first time it also included a comprehensive analysis and selection of KPs. As a result, this 2020 SCP is a lighter edition, which focuses on sector metrics and outcomes, a refinement of the KPs and a summary of MTPConnect's achievements and future focus areas to support the sector's goals for 2025 and beyond. This document also refers to the MTPConnect 2019 Annual Report and FY2020 Business Plan which contain more detailed information regarding MTPConnect progress and activities as well as MTPConnect's plan for the upcoming year.

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 where the *Professional*, *Scientific and Technical Services* and *Manufacturing industries* are the two strongest performing sectors in business expenditure on R&D (BERD)[2]. The sector's inherent resiliency and global market diversification make it less vulnerable to external shocks, such as the COVID-19 pandemic. As a key knowledge-intensive industry, the MTP sector has a critical role to play in Australia's response to COVID-19 and in rebuilding the economy in the post-COVID-19 era.

The MTP value chain encompasses a vibrant sector with a diverse range of participants, each playing a critical role 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, clinicians and others involved in healthcare delivery, such as state health departments and private medical practice.

	Example participants	
Private sector organisations	▪ SMEs and start-ups ▪ Large medtech and pharma companies ▪ CROs	
Institutions	▪ Universities ▪ Medical Research Institutes ▪ Government (departments & agencies including Department of Industry, Science, Energy & Resources, Department of Health, Australian Digital Health Agency, Australian Space Agency, Australian Nuclear Science and Technology Organisation, Department of Education) ▪ CSIRO ▪ CRCs	▪ Hospitals ▪ Incubators ▪ AHRTC ▪ DMTC
Industry organisations	▪ AAMRI ▪ ASMR ▪ AusBiotech ▪ AHMADA ▪ Australian Dental Association ▪ Australian Investment Council	▪ ATSE ▪ Medicines Australia ▪ MTAA ▪ ARCS ▪ PTA
Service providers	▪ Research service providers ▪ Clinical research organisations ▪ Contract research organisations ▪ Regulatory consultants ▪ Health economists	▪ Professional advisers ▪ Legal and IP ▪ Financial ▪ Regulatory ▪ Incubators (e.g. ANDHealth, Cicada)

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

[2] Australian Bureau of Statistics, 8104.0 - Research and Experimental Development, 2017-18

	Example participants	
Funders	▪ Government (including NHMRC and ARC) ▪ MNCs ▪ MRFF (including BTF) ▪ Philanthropic individuals and organisations ▪ NGOs	▪ Angel investors ▪ Venture capital ▪ ASX ▪ Customers
Clinician groups	▪ Relevant clinical specialty associations (e.g. Haematology Society ANZ, COSA) ▪ Specialist medical colleges (e.g. RACS)	▪ AMA ▪ ACTA
Consumer groups	▪ National Aboriginal Community Controlled Health Organisation (NACCHO) ▪ Australian Patients Association ▪ Charitable foundations (e.g. Cancer Council Australia, Leukaemia Foundation)	

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 ten and fifteen years to complete, and the risk-adjusted average cost of bringing a new medicine or vaccine to market is cited as between US$648 million[3] and US$2.6 billion[4]. 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 ten years, and US$30 million– US$150 million[5] 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.

[3] Prasad, Mailankody, November 2017, Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval, JAMA Intern Med

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

[5] Medscape – FDA Approval Process for Medical Devices; Makower, Meer and Denend, FDA Impact on U.S. Medical Technology Innovation, November 2010; and 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

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. However, due to the relatively shorter timeframes and smaller investment required, it may be possible to realise benefits in the short term by focusing on digital health innovation.

MTP sector performance

MTPConnect has invested in creating a consistent set of sector wide metrics to track and measure competitiveness and growth. 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 (ABS) to reflect the changing composition of economic activity in Australia. Overall, the MTP sector has made good progress across most metrics and achieved some key milestones in 2019.

The economic contribution of the MTP sector as measured by GVA grew by 5% from 2018 adding $5.2 billion in GVA to the Australian economy. This represents an increase of 2% p.a. from 2016. Manufacturing exports grew to $8.2b, representing an increase of 16% p.a. from 2016 and ranking the sector as the 8th most valuable exporter for the nation. Further, the sector supported approximately 68,000 jobs in 2019, an increase of 4% p.a. since 2016.

Commercial activity across the sector, as measured by growth in the number of companies, capital raised and the market capitalisation of ASX listed companies, has seen steady growth since 2016. The number of companies in the sector has grown by around 1% p.a. with a net increase of 50 companies since 2016. The number of ASX-listed MTP companies was 135 in November 2019, a net increase of five since 2018.

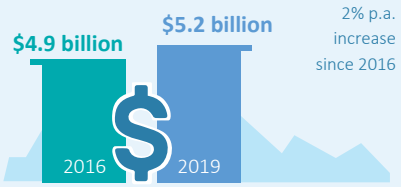
The market capitalisation of these ASX-listed MTP companies increased considerably in 2019; growing 39% from $129 billion in November 2018 to $179 billion in November 2019. There has also been substantial growth over the longer term, with a 28% p.a. increase from June 2016 to November 2019 (there was a 9% p.a. increase in the S&P / ASX 200 index over the same period). CSL, Resmed and Cochlear made up almost 90% of market capitalisation in 2019 and contributed 87% of the increase in market capitalisation from 2018 to 2019.

The value of capital raised by the MTP sector has also increased; growing 41% on 2018 raisings to $1.06 billion in 2019. Excluding the atypical $888 million capital raising by Mayne Pharma, capital raised would have grown at 29% p.a. from 2016.

R&D activity has continued to grow across the sector. Total publications have increased by 7% p.a. since 2016. Further, the share of these publications involving industry collaborations increased from 3% to 4% in 2019, a promising sign of increasing collaboration between industry and researchers. The estimated number of companies undertaking patenting activities increased by 44% from 2018 to 2019 after a period of decline over the 2016-18 period. Compared to 2016, the number of companies patenting has increased 7% p.a. over the four year period. R&D funding, as measured by the R&D investment made by both the public and private sector, has also grown by 5% p.a. from $1.4 billion in 2016 to $1.6 billion in 2019. In particular, public R&D spend has increased by 11% p.a. since 2016 to $1,022 million, driven primarily by the commitment of MRFF and BTF funding over the period.

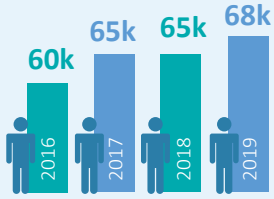
Economic footprint

GROSS VALUE ADDED
TO THE AUSTRALIAN ECONOMY



2% p.a. increase since 2016

JOBS SUPPORTED*



4% p.a. increase since 2016

Includes industry and research jobs

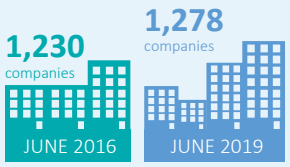
MANUFACTURING EXPORTS

16% p.a. increase since 2016

MTP sector is the 8th largest export in Australia in 2019

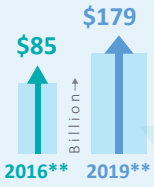
Commercial activity

COMPANIES
IN THE MTP INDUSTRY



1% p.a. increase since 2016

MARKET CAPITALISATION

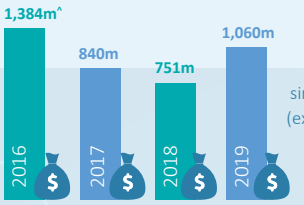


28% p.a. increase since 2016

135 ASX
LISTED COMPANIES***

Net increase of 5 new ASX listed companies from 2018-19****

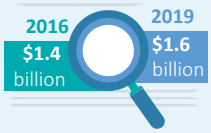
CAPITAL RAISED



29% p.a. increase since 2016 (ex. $888m Mayne Pharma raise)

R&D activity & collaboration

R&D INVESTMENT



5% p.a. increase since 2016

$1^^ billion public spend

$619 million industry spend

PUBLICATIONS^^^

7% p.a. increase since 2016

4% with **industry** collaboration

COMPANIES PATENTING^^^

7% p.a. increase since 2016

CLINICAL TRAILS

5% p.a. increase since 2016

Notes: * Due to the volatile nature of quarterly employment metrics, the industry job portion of the presented figures is calculated as a rolling 2-year average of the quarterly data. In the 2019 SCP, industry jobs was calculated as an annual average.

** 2016 market cap as at 2016, 2019 market cap as at November 2019.

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

**** 2018 figure for ASX listed companies adjusted from 135 to 130 for the 5 companies that were de-listed during the year.

^ Capital raised in 2016 was artificially high due to a $888 million capital raise by Mayne Pharma.

^^ Public spend analysis comprises grants made by ARC, NHMRC, BTF and MRFF; NHMRC and ARC (announced before August 2018) grant funding per year assumes grant funding distributed equally in each year of the grant; ARC funding estimates for grants announced after August 2018 assume a) the duration of each of these grants is the average duration of a grant of equivalent type (e.g., Linkage Project, Discovery Project) over the period from January 2016 to August 2018, and b) grant funding is distributed equally across each year of the assumed grant duration; MRFF funding is FY2019 committed funding per 2018-20 Priorities Discussion Paper; BTF funding assumes increase between previous announcement and current grant funding occurred in 2019.

^^^ Data provided by Clarivate Analytics.

^^^^ There were an additional 79 reporting organisations whose publications output was included in the data from 2017 onwards.

The total number of clinical trials in Australia grew from 1,576 in 2016 to 1,820 in 2019[6], an increase of 5% p.a. during this period. About 530 of these trials were sponsored by industry, an increase of 54 trials since 2016. In 2015, these clinical trials were estimated to correspond with $1.1 billion of industry investment[7]. The number of Phase I and II trials in Australia grew the fastest over the period 2016-19 at 7.3% p.a. and 7.4% p.a. respectively. In addition, clinical trials involving medical devices grew at 8% p.a. In comparison, the number of Phase III trials contracted by 25 trials, and Phase IV trials remained steady at 80 trials. The relative growth in early stage trials suggests that Australia is leveraging its strength and expertise in running these trials whilst maintaining the volume of later stage trials that are key to providing access to novel therapies to Australian patients.

There have also been a number of notable events and milestones achieved within the MTP sector over the past 12 months, particularly in the areas of precision and regenerative medicine. Both areas have attracted significant attention and investment globally, and the developments in Australia illustrate the strength of the local MTP sector and the potential impact it can have on the broader Australian economy. These include, but are not limited to:

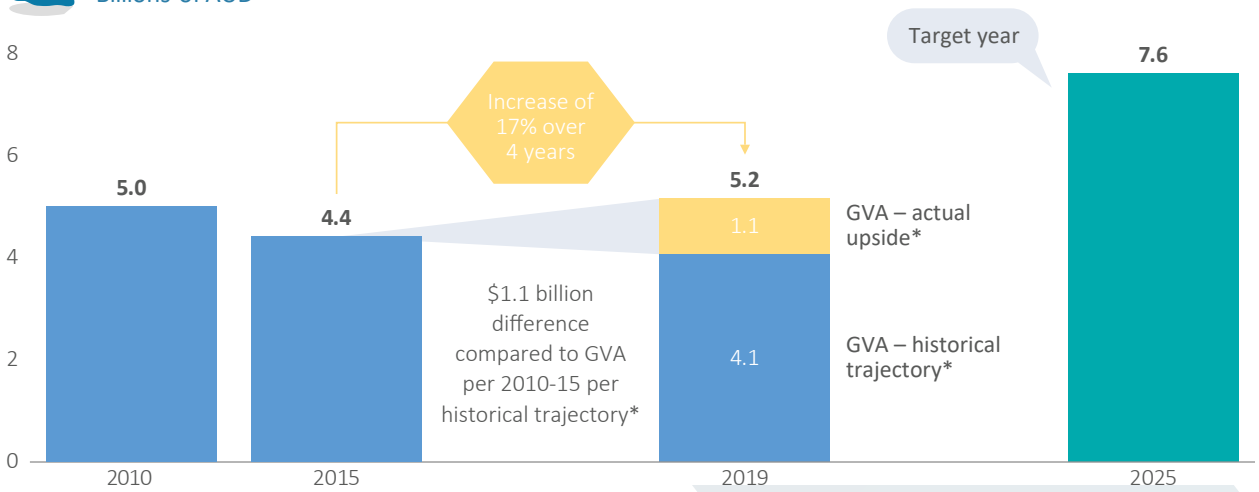
- announced establishment of a $105 million CAR-T cell manufacturing and treatment centre at Melbourne's Peter McCallum Cancer Centre, the first of its kind in the Southern Hemisphere (March 2019);
- $150 million commitment from the MRFF to launch the Stem Cell Therapies Mission, a research funding program that aims to accelerate the investigation of stem cell-related treatments and therapies (October 2019);
- $75 million capital raising by Mesoblast, a Melbourne-based regenerative medicine company focused on cellular therapies for inflammatory and cardiovascular applications (October 2019);
- $120 million capital raising by Avita Medical, a regenerative medicine company specialising in spray-on skin cell therapy (November 2019); and
- $100 million acquisition of Ellex Medical Lasers' lasers and ultra-sound business by French company Lumibird Group SA (December 2019).

Overall, the MTP sector's performance over the last four years has been encouraging. MTP sector GVA has increased by 4% p.a. from 2015 to 2019, slightly above the GVA growth rate for the Australian economy overall (3.2% p.a.). Importantly growth in MTP sector GVA is a reversal of the decline that was experienced between 2010 to 2015. If the MTP sector is to reach the upside growth potential outlined in the initial SCP in 2016 GVA growth will need to lift to 6.7% p.a. between 2019 and 2025. This is a 'stretch' goal but possible given the payoff from the investment undertaken over the 2015-19 period will take several years to be fully realised given the length of commercialisation timeframes in medtech and pharma.

[6] Clinical trial data provided by the NHMRC Clinical Trial Centre

[7] MTPConnect, June 2017, Clinical Trials in Australia: the economic profile and competitive position of the sector

Gross value added, per annum
Billions of AUD

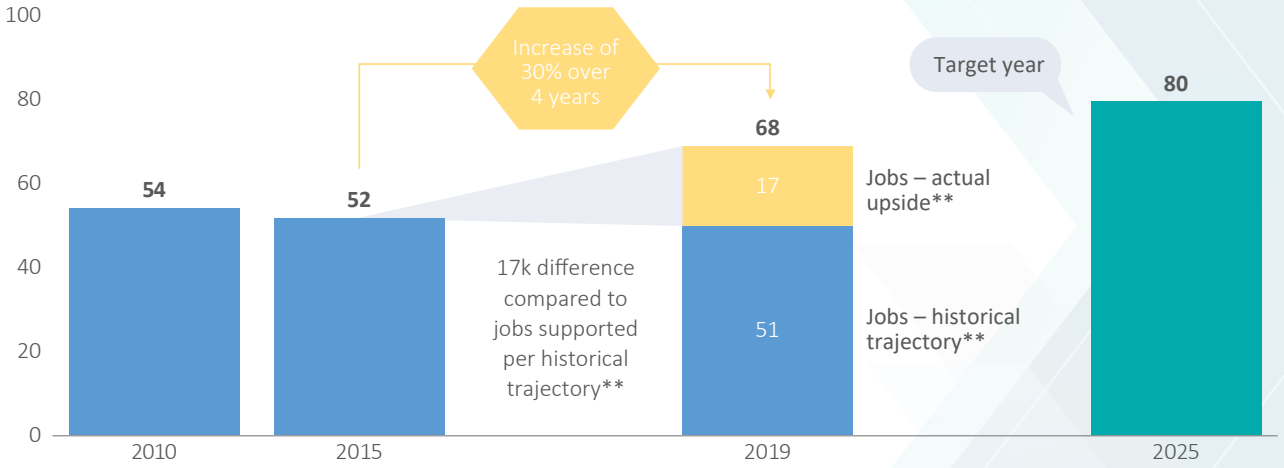


Note: * Historical trajectory GVA is calculated by extending the 2010-15 rate of decline to 2019; upside is calculated as the difference between this and the actual 2019 result

Source: ABS, AusTrade

The sector added 16,000 jobs between 2015 and 2019, an increase of 6.8% p.a. over the period. This growth was faster than the 20-year overall Australian employment growth rate of 2% and puts the sector on track to meet the growth target set in the 2016 SCP of 28,000 additional jobs by 2025. This performance is especially favourable for the sector given jobs growth in the MTP sector is typically a leading indicator of commercial activity and GVA growth given commercialisation time frames.

Jobs supported (research and industry)*
Thousands of persons employed



Note: * Due to the volatile nature of quarterly employment metrics, the industry job portion of the presented figures is calculated as a rolling 2-year average of the quarterly data. In the 2019 SCP, industry jobs was calculated as an annual average;

** Historical trajectory jobs supported metrics is calculated by extending the 2010-15 rate of decline to 2019; upside is calculated as the difference between this and the actual 2019 result

Source: ABS

However, it is worth noting that a better approach to estimate the total number of industry and research jobs supported by the MTP sector is required in the longer term. Whilst we have worked closely with the ABS to use the best available data source to estimate industry jobs, the ABS Labour Force Survey data is typically volatile, possibly due to the small underlying survey sample size used in the estimation. This year, the industry jobs figures presented are calculated as a rolling 2-year average of the quarterly data to account for this volatility. In comparison, the industry jobs figures in the 2019 SCP were calculated as an annual average. The research jobs figures presented are estimates currently based on reported employment and funding figures from the Association of Australian Medical Research Institutes (AAMRI) and the National Health and Medical Research Council (NHMRC). Next year, MTPConnect plans to revisit both the industry and research jobs methodologies to develop a more robust approach.

Finally, around 50 companies were added to the sector between 2015 and 2019, an increase of 4.2% or 1% p.a. This increase was a reversal of the decline between 2010 and 2015 (a decrease of 24 companies or 2%). If the MTP sector is to reach the upside growth potential of 200 additional companies outlined in the initial SCP, growth in the number of companies will need to lift to 1.8% p.a. between 2019 and 2025. As above, this should be possible given the investment undertaken over the 2015-19 period will take several years to be fully realised.

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. By nature, they are forward-looking and as a result the list of megatrends does not vary significantly from year to year; rather they evolve gradually. In the 2019 SCP, two additional megatrends (**healthy ageing** and **value-based healthcare**) were added to the original set of seven identified in 2016. **Mental health** and **wellbeing**, while not megatrends in their own right, were highlighted as underlying drivers in the **chronic burden** and **consumer control** megatrends respectively. **Digital evolution** continues to drive change and advancements across many aspects of healthcare and as a result is central as an enabler and disrupter for all other megatrends. And we have seen the dramatic impacts of **global biosecurity** threats with the COVID-19 pandemic.

It is acknowledged that, over time, the manifestations of climate variability (higher temperatures, altered rainfall patterns and more frequent or intense extreme events) will influence many of these megatrends, including global biosecurity, healthy ageing and wellbeing, developing markets and chronic burden and will need to be considered as part of strategic planning and operational activities.

Megatrend	Implications for the MTP sector
Digital evolution	
The digital world has, and will continue to have, a substantial impact on the healthcare landscape. Digital enablement is expected to drive advancement across many of the other megatrends, particularly precision healthcare, consumer control and integrated care models. This evolution will drive a significant shift in how we exchange and process data (enabling faster and more standardized exchange of data at scale), and the development of increasingly sophisticated tools to generate healthcare insights. The upside of this will be improved efficiency and effectiveness for everything from R&D to patient-care coordination. However, privacy and cybersecurity will also grow as concerns as more data is generated and 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. As a result, 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. 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 their healthcare decisions. Tomorrow's patients will be increasingly 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. In 2018, the WHO implemented an extension code for ageing-related diseases, an acknowledgement that ageing is a disease and hence can be treated. There is often an 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.[8]	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, representing a growing opportunity for researchers in areas not traditionally thought to support MTP to play a key role in driving sector growth.

[8] Australian Federal Government, Feb 2019, Healthy Ageing Summit – Report of Discussion and Outcomes

Megatrend	Implications for the MTP sector
The chronic burden	
Between 2015 and 2050, the proportion of the population aged 60 or over is projected to nearly double (from 12% to 22%).[9] 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. In recent years, mental health conditions such as depression and anxiety have become 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.[10] 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 through frugal innovation.[11] 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	
Technological advancement and growing demand are driving the rapid expansion of precision healthcare solutions worldwide. In 2018, 42% of FDA drug approvals were identified as medicines targeted for use in individual patients compared to 21% in 2014.[12] CAR-T therapies, for instance, have experienced an R&D boom with over 800 CAR-T clinical trials having commenced since Novartis obtained FDA approval for Kymriah in 2017. Other technologies advancing this trend include genomics, synthetic biology, gene-editing technologies, regenerative medicine, computational biology, medical imaging, 3D printing, data mining, and artificial intelligence,[13] Biosensors are also already providing clinicians and patients with real-time personalised data, regardless of location. In 2018, health monitoring (point-of-care and home diagnostic solutions) accounted for 66.6% of biosensor revenue globally.[14]	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 (e.g. adaptive clinical trial design, agile reimbursement structures) and the development of novel business models.[15]

9 World Health Organisation, Feb 2018, Ageing and Health Factsheet
10 https://www.beyondblue.org.au/media/statistics
11 MTPConnect, Dec 2019, Frugal Innovation in Medical Devices and Technology – The India Opportunity
12 Personalized Medicines Coalition (PMC), Personalized Medicine at FDA – A Progress & Outlook Report 2019
13 MTPConnect, Oct 2018, Regenerative Medicine – Opportunities for Australia
14 BIS Research, 2018, Global Biosensors Market Analysis and Forecast (2018–2027)
15 MTPConnect, Jun 2019, Precision Medicine Roundtable White Paper

Megatrend	Implications for the MTP sector
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 more than a decade.[16] 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 focused approach necessitated by value-based healthcare.
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 addresses patient as well as economic benefits to the healthcare system. Devices and digital technologies will also play a role in connecting and monitoring the patient between formal care episodes.
Global biosecurity	
Recent pandemics (e.g. Ebola, Coronavirus (COVID-19)) highlight the globally transmissible nature of diseases and the threat they can have on health. With more frequent travel, globalised trade and greater interconnectedness between countries, infectious disease outbreaks of international concern are becoming inevitable and unpredictable.[17] Anti-Microbial Resistance (AMR) is another complex global public health crisis that threatens the effective prevention and treatment of an ever-increasing range of infections.[18] The UK O'Neill Review estimated that drug-resistant infections could put up to 10 million lives and US$100 trillion at risk annually by 2050.[19] There has been a 'discovery void' since the 1980s, with a limited pipeline of new antibacterial drugs.[20]	As we have seen with COVID-19, 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.

[16] Porter, Jul 2009, New England Journal of Medicine, "A Strategy for Health Care Reform – Toward a Value-Based System"
[17] World Health Organisation, May 2018, Managing Epidemics
[18] World Health Organisation, Feb 2018, Antimicrobial Resistance Factsheet
[19] J. O'Neill, May 2016, Tackling Drug-Resistant Infections Globally: Final Report and Recommendations
[20] World Health Organization, Jan 2020, 2019 Antibacterial Agents in Clinical Development – An Analysis of the Antibacterial Clinical Development Pipeline

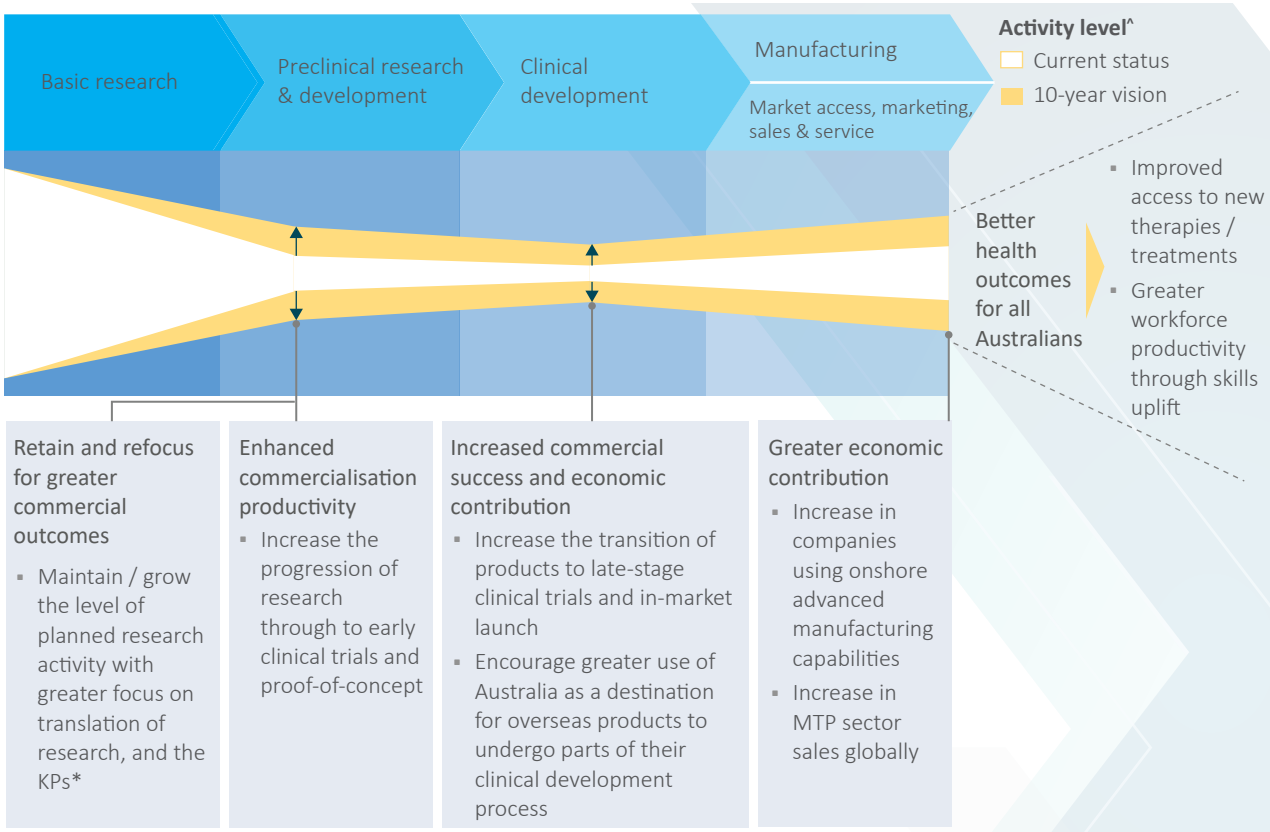
Megatrend	Implications for the MTP sector
Developing markets	
Demands for healthcare solutions are rising in developing countries. Today these markets are responsible for the majority of global sector growth (in percentage terms) and this trend will continue. However, it is important to note that the needs of these markets are at times distinct from developed economies. For example, Indian companies and foreign companies with operations in India are harnessing the country's expertise in frugal innovation to deliver healthcare products and solutions.[9]	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.

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.

MTPConnect's vision is to maintain and grow planned levels of R&D expenditure, achieve greater commercialisation success, create more products that reach proof-of-concept and early-stage commercialisation, increase the number of medium to large companies with late-stage product successes and maximise the value of any intellectual property (IP) monetisation events along the way. This vision was developed through a series of wide reaching sector consultations in 2016 and 2019 with over 600 sector participants and stakeholders.

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



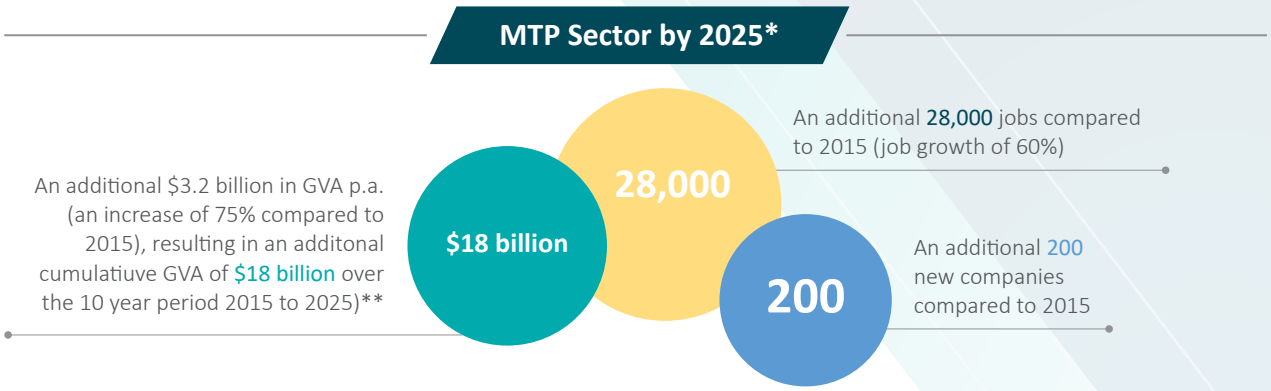
Note: * These are areas of high unmet need and in which a sizeable commercial opportunity exists, where Australia can develop world class research excellence. The list of current KPs can be found on page 39 of this report;
^ Activity level includes all forms of activity and economic value creation in Australia regardless of whether it originates from Australia or overseas. Diagram is intended to be illustrative only and is not to scale

It is also important to note that while the 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 from 2010-15, the following growth potential could be achieved by 2025:

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

The MTP sector has made steady progress towards these targets as illustrated in the previous chapter. Further details of MTPConnect's sector growth potential and benefits estimates are available in the 2016 SCP.



Notes: * The 2025 estimates developed by MTPConnect in 2016 assume that the decline in GVA, employment and companies over the 2010-2015 period can be reversed, with the industry returning to 2010 levels by 2020 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

Seven Sector Priorities underpin the achievement of the vision for enhanced healthcare and economic outcomes for Australia. As with the sector vision these priorities were developed in consultation with the sector in 2016 and 2019 and remain relevant today. The Sector Priorities are summarized on the following pages. At the end of the section, a table demonstrates the alignment of these priorities with the four Growth Centre objectives. More information about these Sector Priorities, and their origins, can be found in the 2019 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 with a strategic approach that focuses on areas with strong market need and commercial potential that also draw on Australia's unique competitive advantages. Aligning strategically around key KPs will enable Australia to build long term world-class positions in targeted areas of research and commercialisation.

In 2019, MTPConnect completed a robust, independent assessment to define KPs tailored to market needs and Australia's research strengths. These KPs and the methodology applied to identify them are described in Section 5.

Description / purpose of this priority	▪ To align R&D investment in the KPs identified to optimise commercialisation potential ▪ To ensure a sufficient percentage of R&D spending (not 100%) is allocated and targeted to these KP areas
Current constraints & gaps	▪ There have been few sector-wide initiatives (e.g. MRFF) focused on concentrating research investment in areas with a strong likelihood of commercial outcomes. However, grant funding and application criteria can be better aligned with prioritisation of commercially focused research ▪ Lack of collaboration between researchers, industry and clinicians, small-scale collaboration hubs and a lack of focus on the commercialisation potential of research activities ▪ Difficulty in attracting and retaining talented researchers due to lack of certainty over long-term funding ▪ Lack of awareness of appropriate IP and other relevant regulations among researchers
Outcomes	▪ Increased strategic allocation of public R&D funding channelled towards identified KP areas ▪ A greater number of successful commercialisation opportunities arising from research to drive better patient outcomes, sector GVA and employment

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[21]. Australia must become more effective in translating research to commercial outcomes that benefit patients. 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.

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 ▪ 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 ▪ 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
Current constraints & gaps	▪ Need to optimise and leverage funding available for advancing innovations from discovery to proof-of-concept phase ▪ Australia's researchers and clinicians are not sufficiently incentivised to focus on commercialisation / translation ▪ Lack of knowledge regarding regulatory and clinical pathways to market, and lack of skills in crucial areas of research support ▪ TGA is not resourced / required to provide pre-submission support to SMEs in navigating regulatory hurdles
Outcomes	▪ Significant economic benefits, including high-value jobs and inflows of royalties and returns to investors ▪ Better health outcomes for patients ▪ Incentives and rewards for researchers and clinicians

[21] 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 longer 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.

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

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. 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.

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

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

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.

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).

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 ▪ **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
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 ▪ 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 ▪ Shortage of biomedical engineering, bioinformatics, health informatics and data analytics skills ▪ 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
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 ▪ 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

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. 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.

Description / purpose of this priority	▪ To develop partnerships with key overseas investors, companies, industry bodies, universities and institutes ▪ 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) ▪ To develop systems and tools that can help local companies better understand and navigate overseas markets and regulatory processes
Current constraints & gaps	▪ Need for stronger links with research, trade and investment partners globally with a focus on the US, Europe and Asia ▪ Current instability of policy and need to ensure ongoing international competitiveness of IP laws ▪ 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 ▪ Lack of knowledge and understanding of commercial and regulatory processes in international markets
Outcomes	▪ For researchers, start-ups and SMEs, increased cross-border collaborations will improve prospects of uncovering new insights and tapping international funding pools ▪ 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 ▪ Overall outcomes will be increased funding, research collaboration and value of exports

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". Expanding Australia's advanced manufacturing capabilities within the MTP sector and the broader innovation ecosystem will further strengthen Australia's reputation and open up additional opportunities for integrating with global markets up and down the manufacturing value chain.

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 ▪ 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
Current constraints & gaps	▪ Lack of targeted R&D funding that is market-led and considers commercial potential of projects ▪ 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 ▪ Shortage of advanced manufacturing skills specific to the MTP sector ▪ Australian production costs are often uncompetitive for lower-skilled and well-established manufacturing processes
Outcomes	▪ Increase the value of advanced manufacturing in the MTP sector, supporting the next generation of Australia's evolved manufacturing economy ▪ Provide an opportunity for the re-skilling and redeployment of Australia's existing manufacturing workforce into highly-skilled jobs along the value chain

These Sector Priorities are strongly aligned with the four Growth Centre objectives and each Sector Priority will benefit from actions from under more than one Objective, as shown in the table below.

		Growth Centre objectives:			
Sector Priorities		**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 KPs 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

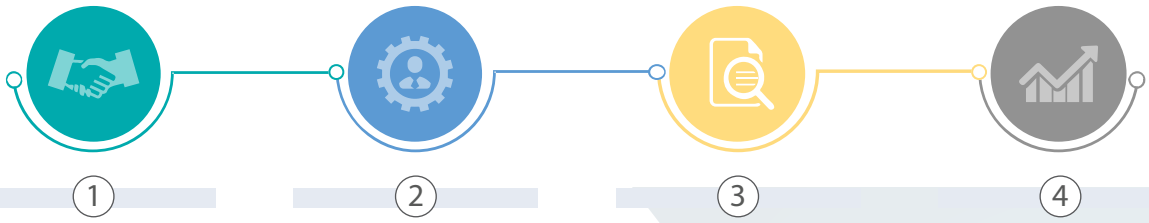
Role of MTPConnect as a Growth Centre

The Industry Growth Centre Initiative, administered by the Australian Government Department of Industry, Science, Energy and Resources (DISER), 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. This will maximise opportunities for Australians to not only make scientific and technological breakthroughs to improve the health of Australians, but also see them developed through the proof-of-concept stage and successfully translated and commercialised. 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. MTPConnect has provided a strategic lens for the sector's activities by generating thought leadership around global trends such as anti-microbial resistance and regenerative medicine, knowledge priority areas for Australia, and metrics to understand the contribution of the MTP sector to the Australian economy.

MTPConnect's Board and executive team were honoured to host the Hon. Karen Andrews MP, the Minister for Industry, Science and Technology, at Brisbane's Translational Research Institute in October 2019 to brief her on MTPConnect's achievements and provide her with an opportunity to engage directly with leading MTP sector participants. As discussed with the Minister and senior representatives from DISER, 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



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

Overview of MTPConnect's progress

MTPConnect has delivered concrete and measurable outcomes against each of the four growth centre objectives over the past four years. MTPConnect has achieved this through three themes:

1. **Deploying strategic initiative funding.** MTPConnect now delivers almost $115 million in strategic initiatives through Commonwealth and State funding programs focused on translating and commercialising Australian MTP innovation and the development of workforce skills.
2. **Providing industry thought leadership through an independent voice.** MTPConnect works with sector participants across the MTP value chain to identify policy and regulatory barriers and provide independent advice and recommendations to government.
3. **Taking direct action focused on the four Growth Centre objectives.** MTPConnect has achieved this in numerous ways including, delivering education events to build greater collaboration and commercialisation expertise and outcomes, facilitation of national and international connections and collaborations for Australian researchers and companies.

Growth Centre objective 1: Improving coordination and collaboration

170 **New technologies** invented or progressed

125 **New patent** and **trademark applications** and **licenses**

74 **New products** launched

54 **New start-up** companies formed

344 **New jobs** (direct and indirect) created in **project companies**

$31M **Investment** in incubator companies

Growth Centre objective 2: Improving management and workforce skills

2,230 Individuals received workforce skills / commercialisation training

12,926 People attended **896** training events and seminars

13,746 People attended **242** collaboration events

$32M Funding secured to deliver MTP REDI program

Growth Centre objective 3: Identifying opportunities to address regulations

Ongoing development of other reports:

- Adaptive Regulation for Digital Health
- Antimicrobial resistance
- Drug repurposing

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

International market access

Direct MTPConnect support

23 **Trade** missions

850 Companies participating in trade mission

MTPConnect project support

119 number of inbound and outbound missions supported by projects

A key achievement by MTPConnect over the past four years has been the successful delivery of impactful funding programs that enable the translation and commercialisation of Australian MTP innovation. MTPConnect has secured almost $100 million in funding to deliver various programs including the BMTH ($45 million), BTB ($22.3 million) and most recently, REDI ($32 million) programs. These programs complement the $15.6 million in funding that MTPConnect has committed as part of its Growth Centre activities. Together, these programs enable MTPConnect to foster commercialisation and collaboration and address the skill gaps and the key constraints identified across the sector.

Strategic funding programs

Industry Growth Centres	BMTH BioMedTech Horizons Program	Biomedical Translation Bridge Program	REDI Developing Australia's MTP Sector Workforce *
Department of Industry, Science, Energy and Resources	Department of Health Medical Research Future Fund	Department of Health Medical Research Future Fund	Department of Health Medical Research Future Fund
$15.6M	**$45M**	**$22.3M**	**$32M**
$15.6M committed	$18.9M committed	$5.9M committed	9 partners
$26M matching	18 projects	8 projects	Building the MTP workforce
36 projects: 15 university-led 22 industry-led	Round 3 EOIs currently being assessed	Round 2 open	Addressing skills gaps
			Enhancing entrepreneurial ecosystem

Note: * MTPconnect was selected to manage the REDI program in early 2020

More information about MTPConnect programs and outcomes can be found in the **FY19 Annual Report**.

MTPConnect priority actions

MTPConnect's priority actions will build on its achievements since inception and continue addressing the key challenges of the sector and align with the four key objectives of the Growth Centre Initiative.

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.

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 DISER, BMTH and BTB funding Secure and deliver additional non-GC sourced funding to key initiatives in the sector Help ensure high quality MTP projects are funded by assisting entities with CRC, CRC-P, ARC ITRP and Global Innovations Linkage program pre-submission review and mentoring and providing post-submission	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 Continue to refine KPs in light of market pull or science push Continue to monitor, assess and promote international best practice approaches to funding SMEs Review and revise "The Economic Benefits of Clinical Trials to Australia" report following sector consultation	Develop programs that link large research-intensive Multinational Companies to Australia's researchers / SMEs Expand activity in existing state-based Hubs (WA, NSW, VIC, QLD) and explore additional activities in new Hubs (SA) Expand communications and engagement with the general public, including patients Enhance effectiveness of technology transfer offices by sharing best practices Collate and report on a consistent set of sector metrics on behalf of the sector Deploy Guidance and Impact Tracking System (GAITS) software through BMTH / BTB program participants	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 Continue working with accelerators, including ANDHealth and the MedTech 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. With the newly established MTP REDI program, MTPConnect will continue to support skills development across the sector, bringing together researchers, clinicians, industry and the entrepreneurial ecosystem to deploy the integrated workforce training plan. 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

Deploy strategic initiative funding	Provide industry thought leadership through an independent voice	Taking direct action – Provide specialist skills / services
Deploy REDI funding to expand training programs with proven partners (e.g. The MedTech Actuator, IMNIS, MDPP, ANDHealth) Deploy REDI funding to support new programs to fill emerging skills gaps across the industry value chain (selection through contestable RFP process)	Conduct a comprehensive 'root and branch' skills gap analysis for the MTP sector Conduct an assessment of MTP sector's digital cyber capabilities 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 industry placement, internship and fellowship programs that link researchers and industry Promote an SME education program to maximise negotiated funding outcomes, out-licensing arrangements or divestment Explore opportunities for provision of coordinated professional development programs for TTOs Conduct a 2-day national MTP workshop that brings recipients of GC Project Funding, BMTH funding and BTB funding together with key industry, VC and Government leaders Launch Growth Centre Project cohort network and Alumni Event to promote knowledge sharing and provide specific training for project leads

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 and optimise policy frameworks within the MTP sector. It will continue to drive progress against this objective by focusing on generating independent insights regarding emerging areas such as AMR, adaptive regulation for digital health, clinical trials, drug repurposing 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	Hold roundtables and 'future forums', and deliver white papers on future trends and significant growth areas including digital health, precision medicine, 3D printing, and clinical trials to help government develop appropriate responses and identify areas for regulatory renewal Continue to deliver white papers on emerging sectoral issues and megatrends to inform policy development (e.g. AMR, adaptive regulation for digital health, and drug repurposing) Continue to work with relevant government bodies such as TGA on streamlining and harmonising the regulatory regime for clinical trials Continue to engage with CSIRO on sector specific initiatives such as the Adaptive Regulatory Project and roadmap projects including Future of Health report With increasing risk of infectious disease outbreaks such as Coronavirus (COVID-19), we will build on our work with the CSIRO's Health and Biosecurity Advisory Committee and the Medical Countermeasures Strategic Advisory Committee of DMTC/Department of Defence aimed at development of technologies to combat global threats and maintaining strong on-shore advanced manufacturing and research capabilities for biosecurity products to enable Australia to retain access to the products and know-how required to combat such risks Identify and establish a national Regenerative Medicine sector 'catalyst' collaboration body to advance the development of Australia's RM sector

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

Provide industry thought leadership through an independent voice	Taking direct action – Promote and connect Australia globally
Continue to work with Asialink to deliver white papers on emerging trends and opportunities for Australian developers and producers (e.g. Frugal Innovation in Medical Devices and Technologies—The India Opportunity)	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 Continue to leverage our biosecurity and medical countermeasures networks to maintain strong on-shore advanced manufacturing and robust supply chains to provide biosecurity products required to combat infectious disease outbreaks

5. Sector Knowledge Priorities

Introduction

KPs 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 realising greater commercialisation outcomes; and
- Other existing national priorities

The categorisation of priorities into these five 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

In 2019, MTPConnect carried out a robust, independent assessment of KPs and tested these with key stakeholders across the broad MTP sector. This assessment methodology remains relevant this year and has been retained. The data for this assessment has been refreshed to account for advances in the sector over the last twelve months. The universe of potential KPs have been considered against a framework including:

- 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

The prioritised KPs are then segmented into:

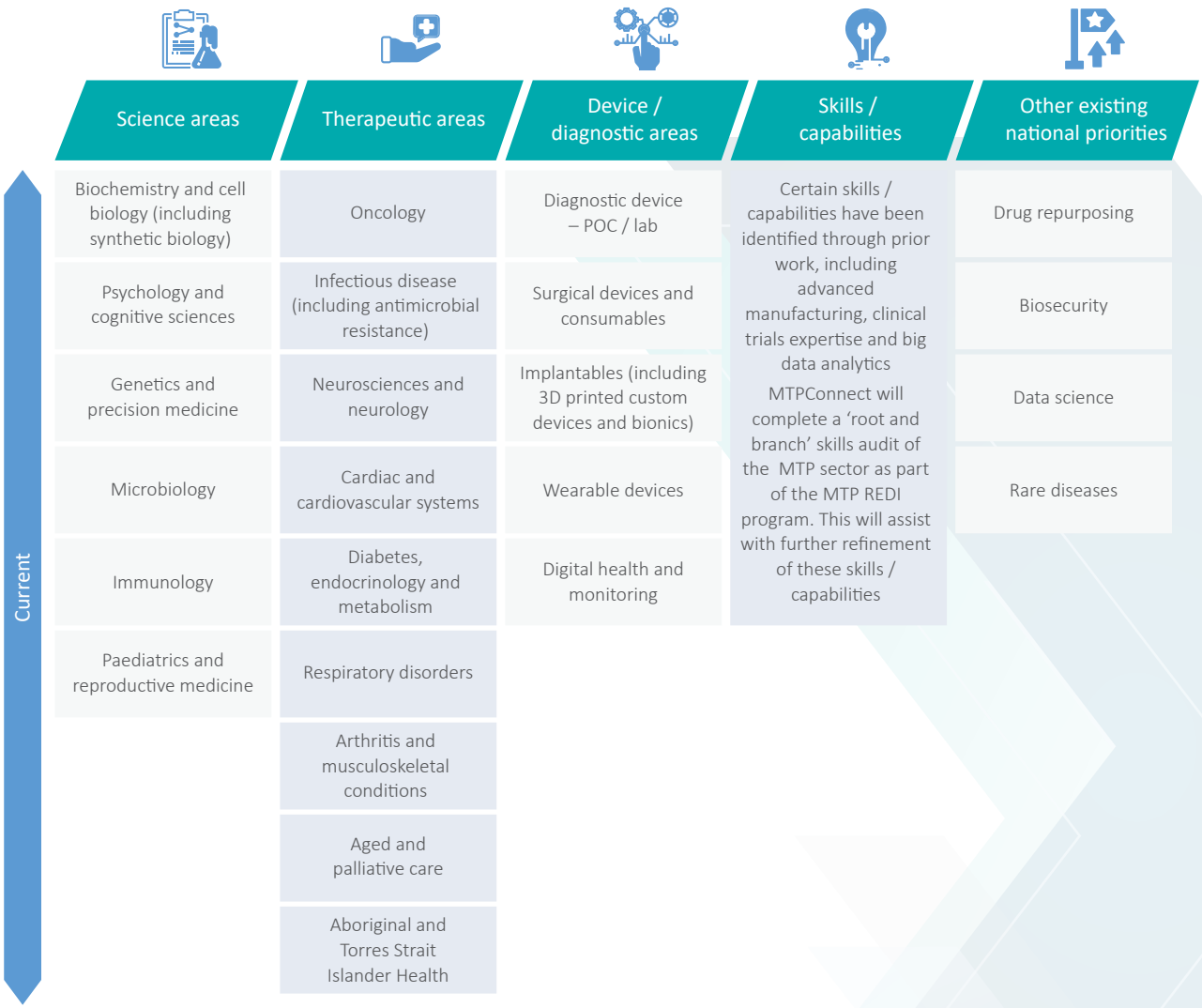
- **Current KPs:** KPs that reflect current areas of unmet market need and / or competitive strength for Australia; and
- **Emerging KPs:** KPs that reflect areas with future commercial potential and / or potential for Australia to build competitive strength

These KPs are not intended to be final, and will be revisited and updated as they evolve over time. The detailed methodology and data used to identify KPs are laid out in Appendix 2.

Knowledge Priorities identified

Current Knowledge Priorities

Overall, six areas of science, nine therapeutic areas, five device / diagnostic areas and four other existing national priorities were identified as Current KPs in 2019. These Current KPs remain relevant today and there have been no changes to this list in 2020.



Science areas

The six science areas identified reflect areas where Australia is among the top ten in high-quality research publications internationally and areas that are in the top ten in terms of national competitive grant funding attracted over the past four 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.

Therapeutic areas

The nine therapeutic areas have been identified as Current KPs. Oncology, infectious diseases (including AMR), 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.

Device / diagnostic areas

Five device / diagnostic areas have been identified as Current KPs. Diagnostic devices (POC / lab) which refers to technologies / devices that are used to diagnose specific medical conditions and are typically used at the point-of-care or in laboratory settings. 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. Finally, digital health / monitoring, which includes 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 key focus areas across the MTP value chain where there is a need for Australia to develop greater skills / capabilities. These include commercialisation expertise, advanced manufacturing skills and capabilities (e.g. cell and tissue manufacturing, 3D printing), clinical trials expertise (particularly in early stage biopharma trials that may involve novel trial designs) and big data analytics capability.

Commercialisation expertise is particularly important and includes 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.

As part of the MTP REDI program, MTPConnect will complete a 'root and branch' skills audit of the MTP sector that will identify areas of shortage, strength and competitive advantage and will subsequently assist with refining these skills / capabilities KPs.

Other existing national priorities

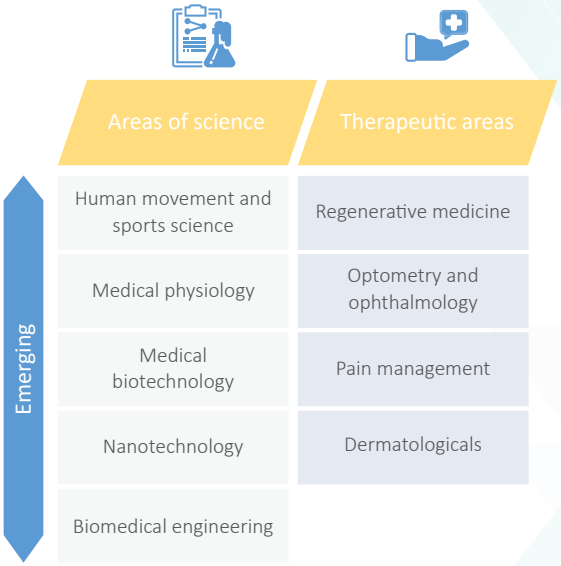
Four other KPs were identified - drug repurposing, biosecurity, data science and rare diseases. These areas were shortlisted as they were identified as national priorities by the MRFF and do not fit into any of the three areas above. These areas remain national priorities for the MRFF and thus remain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

- Drug repurposing - the identification of new uses for approved or investigational drugs that are outside the scope of the original medical indication;
- Biosecurity - 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 - the use of scientific methods, processes, algorithms and systems to extract knowledge and insights from data; and
- Rare diseases - R&D related 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.

Emerging Knowledge Priorities

Seven Emerging KPs were identified in 2019 and these remain relevant this year. These are regenerative medicine, human movement and sports science, medical physiology, medical biotechnology, nanotechnology, pain management, optometry and ophthalmology.

Two additional Emerging KPs have also been identified - biomedical engineering and dermatologicals.



Areas of science

Human movement and sports science, medical physiology, medical biotechnology, biomedical engineering and nanotechnology are classified Emerging KPs as Australia has a strong presence in terms of high-quality publications in these areas (4th, 6th, 7th, 8th and 9th in the world respectively) but they have not attracted much national competitive grant funding in recent years. These Emerging KPs should be considered candidates for additional funding.

The addition of biomedical engineering as an Emerging KP alongside nanotechnology and medical biotechnology highlights the importance of advanced manufacturing as an area of emerging competitive advantage for Australia, requiring continued support and investment. Advanced manufacturing is a critical part of the broader Australian innovation ecosystem and supporting it remains a key sector priority.

Therapeutic areas

Optometry and ophthalmology, pain management and regenerative medicine remain Emerging KPs this year as Australia continues to build capability and reputation in these areas in terms of research capability, clinical trials and commercial success. Dermatologicals has also been added to the list of Emerging KPs, with a strong global sales forecast for 2025 ($36 billion) and 5 dermatologicals-focused companies listed on the ASX, including Melbourne-based Polynovo, which has demonstrated considerable commercial success over the past year. Of these Emerging KPs, regenerative medicine in particular represents significant commercial potential, estimated to be a $120 billion global market in 2035, and is an area where Australia has competitive strengths in R&D.

Appendices

Appendix 1: Glossary of terms

AAMRI	Association of Australian Medical Research Institutes
ABS	Australian Bureau of Statistics
ACOLA	Australian Council of Learned Academies
ACTA	Australian Clinical Trials Alliance
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
AMR	Anti-Microbial Resistance
ARCS	Association of Regulatory and Clinical Scientists
ASMR	Australian Society for Medical Research
ASX	Australian Securities Exchange
ATSE	Australian Academy of Technological Sciences and Engineering
BMTH	BioMedTech Horizons
BTB	Biomedical Translation Bridge
BTF	Biomedical Translation Fund
CERI	Centre for Entrepreneurial Research and Innovation
COSA	Clinical Oncology Society of Australia
CRC	Cooperative Research Centre
CRO	Contract Research Organisation
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DISER	Department of Industry, Science, Energy and Resources
DMTC	Defence Materials Technology Centre
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

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
PTA	Pathology Technology Australia
QUT	Queensland University of Technology
RACS	Royal Australasian College of Surgeons
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 four 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 four 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, NHMRC and MRFF competitive grants either announced or dispensed over the last four years. This total includes funding announced prior to 2016 but dispensed from 2016 onwards and funding for future years that were announced in 2019 or earlier.

Areas of science were shortlisted if ranked in the top 10 for both of the above metrics. In 2019, this shortlist was combined with stakeholder consultation to arrive at the final list of Current KPs (highlighted in blue below). This list of Current KPs will be revisited regularly, and additions may be made in line with refreshed data. Those areas not shortlisted, but identified with strong potential for future growth, have been classified as Emerging KPs – 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 (2016-19)	Competitive grants (2016-19)	
		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	2	Yes
	Genetics	7	5	Yes
	Microbiology (3)	7	16	No
Chemical Sciences	Medicinal and biomolecular chemistry	13	11	No
Engineering	Biomedical engineering	8	14	Yes (emerging)

Areas of science		Australia's capability		Shortlisted as KP?
Relevant MTP ARC 2-digit codes	Relevant MTP ARC 4-digit codes	Academic strength (2016-19)	Competitive grants (2016-19)	
		Aus global ranking in each area of science (1)	Total funding ranking – NHMRC + ARC (2)	
Medical and Health Sciences	Cardiovascular medicine and haematology	10	9	No
	Clinical sciences	10	1	Yes (4)
	Dentistry	13	22	No
	Human movement and sports science	4	21	Yes (emerging)
	Immunology (5)	12	6	Yes
	Medical biochemistry and metabolomics	11	20	No
	Medical microbiology (3)	7	7	Yes
	Medical physiology	6	18	Yes (emerging)
	Neurosciences (6)	10	3	Yes
	Oncology and carcinogenesis	12	4	No
	Optometry and ophthalmology	6	17	Yes (emerging) (7)
	Paediatrics and reproductive medicine	7	8	Yes
	Pharmacology and pharmaceutical sciences	11	12	No
Psychology and Cognitive Sciences	Cognitive science (6)	7	19	No
	Other psychology and cognitive sciences (6)	5	23	No
	Psychology (6)	5	10	Yes
Technology	Industrial biotechnology	17	24	No
	Medical biotechnology	7	13	Yes (emerging)
	Nanotechnology	9	15	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 four 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. Microbiology and Medical Microbiology have been combined into one category, namely: Microbiology;
4. The ARC 6-digit codes within Clinical Sciences predominantly relate to therapeutic areas which have already been considered in the therapeutic area analysis below;
5. 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;
6. Neurosciences, Cognitive science, Other psychology and cognitive sciences and Psychology have been combined into one category, namely: Psychology and Cognitive Sciences;
7. Optometry and ophthalmology has been excluded from the list of emerging areas of science due to its overlap with the equivalent therapeutic area. Optometry and ophthalmology has been included in the list of emerging 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 2025 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' 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; and
    e. number of global 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 2019-20)

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 2025 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		Shortlisted as KP?
		Global Sales 2025 ($b)	Global Sales CAGR (%)	# ASX companies	Success Stories	Licensing deals	# MRIs researching	# Clinical trials (% of global trials)	MRFF	NHMRC	
Cardiac and cardiovascular system	SCP '16	91	1.0%	8	3	0	20	28 (22%)	1	0	Yes
Diabetes, endocrinology & metabolism		59	2.9%	3	2	1	16	19 (17%)	1	0	Yes
Immunology (1)		58	12.9%	6	0	0	24	N/A	0	0	Yes
Neurosciences & neurology		36	3.5%	15	2	0	24	62 (28%)	1	0	Yes
Obesity		18	13.4%	1	0	0	4	N/A	0	0	No
Oncology		264	11.4%	21	8	3	27	338 (43%)	1	0	Yes
Ophthalmology and optometry		32	6.3%	4	0	0	8	8 (29%)	0	0	Yes (emerging)
Pain management		83	4.0%	16	1	2	3	N/A	0	0	Yes (emerging)
Respiratory disorders (asthma)		45	4.2%	9	0	0	9	55 (36%)	0	0	Yes
Sleep		3	5.3%	5	0	1	4	N/A	0	0	No
Arthritis & musculoskeletal conditions		75	(1.1%)	6	0	0	9	22 (24%)	0	0	Yes
Haematology		66	3.2%	3	0	0	3	N/A	0	0	No
Infectious disease (inc. antimicrobial resistance)		91	3.8%	9	3	1	16	49 (35%)	1	0	Yes
Otorhinolaryngology		12	3.2%	2	0	0	1	N/A	0	0	No
Paediatrics and reproductive medicine (1)		152	3.5%	5	0	0	11	N/A	0	0	Yes
Reproductive endocrinology		23	9.3%	0	0	0	0	N/A	0	0	No
Surgery		23	5.7%	1	0	0	0	N/A	0	0	No

Therapeutic areas	Source	Global trends		Australia's capability					Existing priorities		Shortlisted as KP?
		Global Sales 2025 ($b)	Global Sales CAGR (%)	# ASX companies	Success Stories	Licensing deals	# MRIs researching	# Clinical trials (% of global trials)	MRFF	NHMRC	
Regenerative medicine	New	120 (2)	N/A	6	1	1	2	0 (0%)	0	0	Yes (emerging)
Dermatologicals	Evaluate Pharma	36	12.5%	9	2	0	1	N/A	0	0	Yes (emerging)
Nephrology	Evaluate MedTech	16 (3)	4.2%	3	1	0	4	10 (43%)	0	0	No
Aboriginal and Torres Strait Islander Health	MRFF; NHMRC	7 (4)	3.4%	0	0	0	5	N/A	1	1	Yes
Aged, supportive and palliative care	MRFF; NHMRC	1,091	7.3%	0	1	0	6	N/A	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. Refers to 2024 forecast from Evaluate MedTech, extrapolated to 2025.
4. Using health expenditure, by Indigenous status in 2010-11. This has been forecasted using the CAGR for Indigenous population growth between 2011-16.
5. Global clinical trials data only analysed for a subset of therapeutic areas. Therapeutic areas for which clinical trials data is not analysed are labelled 'N/A'

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 2025 from relevant market research reports
2. Australia's capability
   a. number of ASX companies in each device / diagnostic area; and
   b. number of companies identified as commercialisation 'success stories' 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); and
    b. NHMRC priorities (listed in the NHMRC Corporate Plan 2019-20)

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 2025 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 2025 ($bn)	Global Sales CAGR (%)	# ASX companies	Success stories	MRFF	NHMRC	
Wearable device	SCP '16	77	15.5%	14	4	0	0	Yes
Diagnostic device – patient	SCP '16	5	6.2%	3	2	0	0	No
Diagnostic device – POC / lab	SCP '16	84	6.1%	24	5	0	0	Yes
Drug delivery	SCP '16	26	4.6%	7	1	0	0	No
Sterile / protective equipment	SCP '16	12	7.0%	2	1	0	0	No
Implantables and bionics	SCP '16	126	6.2%	7	5	0	0	Yes
Surgical devices and consumables	SCP '16	107	7.5%	12	3	0	0	Yes
Digital health / monitoring	MRFF; NHMRC	505	19.4%	19	2	1	1	Yes
Dental	Evaluate MedTech	23	6.5%	1	1	0	0	No

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

Appendix 3: References

Author(s)	Title	Year
ACOLA	The Future of Precision Medicine in Australia	2018
ACOLA	Synthetic Biology in Australia: an outlook to 2030	2018
Advanced Manufacturing Growth Centre	Advanced Manufacturing: A new definition for a new era	2018
Advanced Manufacturing Growth Centre	Advanced Manufacturing Growth Centre: Sector Competitiveness Plan 2017	2017
ANDHealth	Digital Health: Creating a new growth industry for Australia	2018
Association of Australian Medical Research Institutes	Annual Report – FY18	2018
ASX	ASX listed company database	2019
AusBiotech	AusBiotech 30 success stories, published on the AusBiotech website	2018
Australian Bureau of Statistics	ABS6291.0.55.003- EQ06 – Employed persons by Industry group of main job (ANZSIC), Sex, State and Territory	2019
Australian Bureau of Statistics	ABS5368, tables 12A & B: International Trade in Goods and Services, Australia, Dec 2018	2019
Australian Bureau of Statistics	8104.0- Research and Experimental Development, Businesses, Australia, 2017-18	2019
Australian Bureau of Statistics	ABS8165.0 – Counts of Australian Businesses, including Entries and Exits, Jun 2013 to Jun 2017	2018
Australian Bureau of Statistics	Census data: INDP – number of employees, by INDP 4 digit level	2016
Australian Institute of Health and Welfare	Expenditure on health for Aboriginal and Torres Strait Islander people, 2010-11	2013
Australian New Zealand Clinical Trials Registry	Database for clinical trials started in Australia	2019
Australian Research Council	National Competitive Grants Program Dataset – NCGP Projects Field of Research Collection (New & Ongoing Projects)	2019
Australian Research Council	National Competitive Grants Program Dataset – NCGP Project and Fellowship Collection (New & Ongoing)	2019
Australian Research Council	National Competitive Grants Program Dataset – NCGP Project Field of Research Collection (Completed Projects)	2019
Australian Research Council	National Competitive Grants Program Dataset – NCGP Project and Fellowship Collection (Completed)	2019
Biomedical Translation Fund	Biomedical Translation Fund Factsheet	2016
Bioshares	Bioshares quarterly reviews newsletter	2016-19
BIS Research	Global Biosensors Market Analysis and Forecast (2018–2027)	2018
Clarivate Analytics	The State of Innovation Report 2017: The relentless desire to advance	2017
Clinicaltrials.gov	Clinical trials database	2019
Coherent Market Insights	ENT disorder treatment market, by treatment type, organ type, end user and region – global trends and forecast to 2025	2018
CSIRO Futures	Future of Health: Shifting Australia's focus from illness treatment to health and wellbeing management	2018
CSIRO Futures	Medical Technologies and Pharmaceuticals: A Roadmap for unlocking future growth opportunities for Australia	2017

Author(s)	Title	Year
EvaluateMedTech	World Preview 2018, Outlook to 2024	2018
EvaluatePharma	World Preview 2019, Outlook to 2024	2019
Federal Government	Healthy Ageing Summit – Report of Discussion and Outcomes	2019
FIAL	Sector Competitiveness Plan 2019	2019
GlobalData	General surgery market 2017 global overview, GlobalData Healthcare Intelligence Centre	2018
Global Info Research	Global pediatric healthcare market report	2019
Grand View Research	Obesity treatment market size and forecast, by drugs, surgery and devices, and trend analysis to 2024	2016
IHS Global Insight	World Industry Service database, accessed 17 July 2017	2017
InCites	InCites Datasets for research areas, by location. This includes Web of Science content indexed through	2019
Innovation and Science Australia	Australia 2030: Prosperity through innovation – a plan for Australia to thrive in the global innovation race	2017
Innovation and Science Australia	Performance Review of the Australian Innovation, Science and Research System	2016
JAMA Internal Medicine	Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval	2017
Jim O'Neil	Tackling Drug-Resistant Infections Globally: Final Report and Recommendations	2016
Journal of Health Economics	Innovation in the pharmaceutical industry: New estimates of R&D costs	2016
KPMG	Economic Impact of Medicinal Research in Australia	2018
Market Research Engine	Wearable devices market by product analysis, application analysis and regional analysis – global forecast by 2018-2024	2018
McKeon, S., et al.	Strategic Review of Health and Medical Research in Australia ("McKeon Review")	2013
Medical Research Future Fund	2018-20 Priorities Consultation Discussion Paper	2018
Medical Research Future Fund	Australian Medical Research and Innovation Priorities 2018-20	2018
Medical Technology Association of Australia	Strategic Plan 2017-20	2017
Medscape	FDA Approval Process for Medical Devices	2013
National Health and Medical Research Council	Corporate Plan 2019-20	2019
National Health and Medical Research Council	National Health and Medical Research Council grant announcements	2016-19
National Health and Medical Research Council	Research Funding Facts Book 2014	2016
Nature International Journal of Science	Australia makes its mark in biotechnology	2018
NERA	Sector Competitiveness Plan: Update 2019	2019
Personalized Medicines Coalition	Personalized Medicine at FDA – A Progress & Outlook Report 2019	2019
Queensland Health	Queensland Advancing Health Research 2026 – Healthier Queenslanders through research-informed healthcare	2017
Report Buyer	IVF services market, by cycle type, thawed IVF cycles, donor egg IVF and end user – Global opportunity analysis and industry forecast, 2019-2026	2019

Author(s)	Title	Year
Report Linker	Global respiratory drugs market to 2023 – a changing therapeutic landscape as key patents expire and biologics, targeted therapies and CFTR Modulators for Asthma and Cystic Fibrosis treatment emerge as market growth drivers	2017
Research and Markets	The global Ophthalmic drugs market	2018
Research and Markets	Insomnia therapeutics market analysis by treatment type, sales channel and segment forecasts, 2014-2025	2017
Research and Markets	Global geriatric medicine market, by therapeutic category, condition, region – market size, demand forecasts, company profiles, industry trends and updates (2017-23)	2018
Research and Markets	Global point-of-care testing market – focus on application, market share, product mapping and country – analysis and forecast (2017-2026)	2018
Research and Markets	Sterilization equipment market by product and service, consumables, services – global forecast to 2023	2018
TEConomy / BIO	Investment, Innovation and Job Creation in a Growing U.S. Bioscience Industry	2018
The New England Journal of Medicine	A Strategy for Health Care Reform – Toward a Value-Based System	2009
Transparency Market Research	Cardiovascular drugs market – global industry analysis, size, share, growth, trends and forecast 2017-2025	2018
World Health Organisation	Ageing and Health Factsheet	2018
World Health Organisation	Antibacterial Agents in Clinical Development – An Analysis of the Antibacterial Clinical Development Pipeline	2020
World Health Organisation	Antimicrobial Resistance Factsheet	2018
World Health Organisation	Managing Epidemics	2018
Zion Market Research	Pain management therapeutics market, by drug class, indication and distribution channel: Global industry perspective, comprehensive analysis and forecast, 2017 – 2024	2018
Zion Market Research	Neuroscience market by component and by end-user – global industry analysis, size, share, growth, trends, and forecast 2016-2024	2018
Zion Market Research	Digital Health Market by Product Type – Comprehensive Analysis and Forecast, 2017-2024	2018

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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