MTPConnect
MedTech and Pharma Growth Centre

Medical Technology, Biotechnology and Pharmaceutical Sector Competitiveness Plan

April 2022

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

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Note: The views and opinions expressed in this report are those of the authors and do not necessarily reflect those of the Australian Government or the Portfolio Ministers for the Department of Industry, Science, Energy and Resources.

Legal Information

MTPConnect
MedTech and Pharma Growth Centre

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Foreword from Chair and CEO

Sue MacLeman
Chair

Stuart Dignam
CEO

In November 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 10-year vision for growth developed following extensive consultation with hundreds of sector participants.

As well as examining the MTP sector's performance in 2020 and 2021, this SCP provides a progress report at the halfway point of our 10-year plan.

Between 2016 and 2021, Gross Value Added (GVA) has grown steadily at 2 per cent p.a., an additional 13,000 jobs have been created by the sector and the net number of MTP companies has increased by 100. As demonstrated by these metrics, the positive growth trajectory indicates the valuable contribution that the MTP sector makes to the Australian economy.

Across 2020 and 2021, the COVID-19 pandemic had marked impacts across all industries, including the MTP sector as outlined in our *COVID-19 Impact* report series.[1] However, the MTP sector has also been at the frontline of the national response to COVID-19 supporting the R&D of global vaccine candidates, pivoting local manufacturing capabilities to produce critical medical devices and personal protective equipment (PPE), and working with Federal and State governments to develop innovative policy solutions to supply chain disruptions.

Since our establishment, MTPConnect has played an invaluable role in boosting the sector's research commercialisation capabilities and outcomes. Our Growth Centre work is now complemented by five Medical Research Future Fund (MRFF) programs worth more than $166 million: BioMedTech Horizons (BMTH), Biomedical Translation Bridge (BTB), the Researcher Exchange and Development within Industry (REDI) Initiative, the Targeted Translation Research Accelerator (TTRA) and the Clinical Translation and Commercialisation Medtech (CTCM) Initiative. These initiatives combined allow us to support researchers along their commercialisation journeys and grow start-ups and SMEs into larger and more global players.

In addition, MTPConnect has worked with participants across the sector to identify and address key skills gaps to build an industry-ready workforce with the capability and capacity to generate continued growth for the sector.

As the pandemic continues to evolve with the emergence of new variants, there may well be additional economic shocks in the near term. It is critical to continue supporting the science, research, innovation and entrepreneurship that underpins Australia's medical products sector. We also need to build and enhance our supply chain resilience and sovereign manufacturing capabilities to boost preparedness for future pandemics.

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

[1] MTPConnect, COVID-19 Impact Report (June 2020) and COVID-19 Impact Report 2nd edition (October 2020)

Executive Summary

At the time of writing the last Sector Competitiveness Plan (SCP) in April 2020, the MTP sector had delivered robust and steady growth across many key metrics. However, the COVID-19 pandemic had just resulted in a nationwide lockdown and the economic and health outlook globally was uncertain. The last two years have been unprecedented in terms of the disruptions felt across all sectors of the economy.

During the pandemic, which continues to evolve, the MTP sector has played an influential role in driving the response to and subsequent recovery from COVID-19. It was an Australian scientist who released the sequence of SARS-CoV-2 to the world, opening the door for the rapid development of the COVID-19 vaccines. Subsequently, the sector responded in a number of critical ways including accelerating critical pre-clinical and clinical research and development of several COVID-19 vaccine candidates, establishing local manufacturing of essential PPE and medical devices (e.g. ventilators), and expediting the adoption of digital technologies such as tele-health to protect the health and wellbeing of Australians.

The sector contributed $5.3 and $5.5 billion in GVA to the Australian economy in 2020 and 2021, respectively. These figures represent an increase of $100 million and $300 million respectively when compared to the MTP sector GVA in 2019. The sector also added an additional 5,000 jobs during this two-year period. The market capitalisation of MTP companies continued to grow strongly at 20 per cent p.a. and MTP companies raised nearly $3.4 billion in capital through this period, as markets realised how resilient and vital the sector was to the broader economy. However, MTP sector manufacturing exports slipped, declining by 18 per cent p.a. across the two years, as MTP companies faced supply chain challenges that impacted their ability to get their products to overseas markets. Similar disruptions were experienced across a range of sectors.

These metrics and other sector highlights are explored in this 2022 SCP, a living document through which MTPConnect communicates the sector vision, priorities for growth and sector-wide progress against these priorities.

Despite the pandemic challenges, the MTP sector has made steady progress towards the 2025 sector aspiration set out in the 2016 SCP. The sector supported 73,000 jobs across industry and research in 2021. An addition of another 3,000 jobs over the next three years will see the sector achieve its 2025 sector aspiration. Similarly, the sector is more than halfway towards the target of 200 additional MTP companies compared to 2015, as an additional 116 companies were added to the sector from 2015-21.

Achieving the aspirational target of $7.6 billion in sector GVA will be more challenging as the sector will need to grow by an additional $2 billion by 2025. However, it takes time for sector investments to translate into GVA growth, particularly in the MTP sector with 10-15 year product development pathways. It is therefore critical that investments into the sector continue to be made in order to lock-in the benefits delivered so far and secure the foundations for future economic and jobs growth and improve the health and wellbeing of Australian and international consumers.

In addition, for a diverse sector like MTP, it is important that there is strong collaboration and coordinated actions across the sector in order to ensure sector investments deliver sustained growth. This is what MTPConnect has set out to do.

Since its inception late 2015, MTPConnect has worked collaboratively with all parts of the sector to improve collaboration and commercialisation of MTP innovation, improve management and workforce skills, optimise the regulatory and policy environment for growth and improve the capability of the sector to engage with international markets and access global supply chains.

Today, MTPConnect has $182 million in sector support funds under management, across six strategic funding initiatives. Combining the $225.9 million generated through MTPConnect's Growth Centre and MRFF granting programs to date, the additional flow-on external investment secured by those projects and investments secured by research institutes and SMEs assisted with industry-focused grant applications, MTPConnect has contributed to $967.8 million flowing into Australia's medical products sector.

MTPConnect has made notable progress against each of the four Growth Centre objectives as highlighted below:

Growth centre objective	Key achievements
Improve coordination and collaboration between research and industry to achieve stronger commercialisation outcomes	• Manages $182 million of funding across six programs that has resulted in six times additional flow-on investments, around 470 new patent and trademark applications and licenses and more than 1,500 new jobs created
Improve management and workforce skills	• Comprehensive set of skills gaps across the MTP sector identified via the REDI program • REDI funding supporting more than 30 training programs to build workforce skills
Optimise regulatory and policy environment	• Policy papers and thought leadership pieces developed around innovative growth areas such as regenerative medicine, antimicrobial resistance and clinical trials that identified key regulatory and policy reforms required in order to stimulate growth in those areas
Improve access to global supply chains and markets	• Worked with Austrade and key sector partners to promote Australian companies and capabilities on the global stage. Supported the pivot to virtual partnering and coordinated strong Australian presence at virtual conferences including MedTech Conference, BIO Digital 2021, BIO Korea and European Alliance for Personalised Medicine global conference

MTPConnect has also worked with sector stakeholders to define seven Sector Priorities, first identified in 2016 and refined in 2019, that remain relevant today to guide investment into the sector.

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 also provides an updated shortlist of Knowledge Priorities (KPs) that MTPConnect identified in 2020. These KPs are intended to provide strategic focus to the sector's activities. These KPs are based on a robust assessment framework 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. There were two additions to the KPs list in this SCP: ophthalmology and optometry and sterile/protective equipment. The diagnostic devices (point-of-care, lab and patients) KP has been broadened in scope to reflect the evolving market. One emerging KP, '*cardiovascular medicine and haematology*', was identified in this SCP due to further developments in Australia's competitive advantage in the area. This SCP also, for the first time, includes the skills and capability gaps analysis completed in the *REDI Skills Gap report* series.

Australia is well-positioned to sustain and grow the MTP sector by collectively focusing on continued investment into the Sector Priorities and KPs. This will, in turn, help boost the translation and commercialisation of medical products that are derived from our health and medical research and drive the creation of high-paying jobs, which will underpin economic growth, resiliency and future pandemic preparedness.

Document structure

1. Context

Context for this report

MTPConnect was formed as a not-for-profit company in 2015 to champion an industry-led approach to accelerating the growth of Australia's MTP sector. MTPConnect's 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.

This SCP update report presents a holistic view of the progress made across the MTP sector over the past five years as the sector is at the halfway mark of the 10-year vision set out by MTPConnect in 2016. The report also highlights the sector's performance and contributions over 2020 and 2021, a period defined by COVID-19 in which the MTP sector played a critical role in enabling Australia's response to the pandemic.

This document also summarises the key activities and outcomes achieved by MTPConnect over the past two years and since its inception.

2. Sector overview and performance

MTP sector definition and characteristics

The MTP value chain encompasses a vibrant sector with a diverse range of participants, each playing a central role in the sector's continued growth and success. The value chain comprises consumers and patients, universities, other research organisations, small and large local and multinational companies, investors, service providers, industry organisations, infrastructure providers, government, regulators, policymakers, funders, clinicians and others involved in healthcare delivery, such as state health departments and private medical practice. Example participants across the MTP sector are illustrated further in Appendix 2.

While the medical technology and pharmaceutical/biotechnology markets are similar in many aspects, it is important to note that there is one distinctive difference – the financial and time investment required to commercialise, and therefore, the extent to which globalisation becomes a necessity.

In the pharmaceutical/biotechnology market, the drug and biologics development pathways are long and expensive, but the value creation of a successful venture can be high. Typically, the pathway may require between 10 and 15 years to complete, and the risk-adjusted average cost of bringing a new medicine or vaccine to market has been decreasing over the years. In a 2020 study of approved FDA therapeutic drugs and biologic agents between 2009-2018, the estimated adjusted average cost of bringing a new drug to market was between US$985 million to US$1.3 billion.[2] 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 medical technology, this dynamic differs. The development timeframe is typically shorter – between four and 10 years – and the costs lower – between US$30 million and US$150 million.[3] 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 medical technology and digital health companies are more likely to be able to take a product all the way through to launch in Australia, with the need for global partners limited to suppliers. Nevertheless, as with the pharmaceutical/biotechnology subsectors, the full value is only likely to be realised if global markets are accessed and entered, either directly or via partnerships.

Digital health applications using mobile phone sensors, smartwatches, fitness trackers, apps and artificial intelligence were traditionally classified as medical technologies. Yet, digital health has emerged as a distinct subsector, with unique characteristics that differentiate it from medical technology (for example, the regulatory pathways to commercial and remuneration models differ). In digital health, the timeframes are typically even shorter and investment amounts smaller compared to medical technology.

As a consequence of the time and investment required in medical technology and pharmaceutical/biotechnology, 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 for digital health innovation, it may be possible to realise benefits in the short term.

[2] Wouters OJ, McKee M and Luyten J, 'Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018'. JAMA. Published: 2020

[3] 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 medical technology product development in the US. Costs may differ in other markets

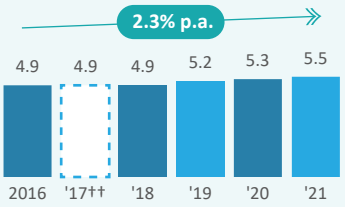
MTP sector performance

Since 2018, MTPConnect has invested in creating a consistent set of sector wide metrics to track and measure sector competitiveness and growth over the long term. These metrics have been regularly reviewed and methodologies updated to reflect the methodologies adopted by the Australian Bureau of Statistics (ABS) and other third-party data providers, in order to be consistent with the changing composition of economic activity in Australia. Prior to this MTPConnect initiative, a consistent and holistic set of metrics for the MTP sector did not exist.

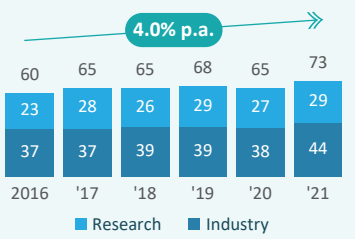
Overall, the MTP sector has made robust progress across all economic, commercial and R&D metrics from 2016-21 as illustrated by the figure on page 11.

ECONOMIC METRICS†

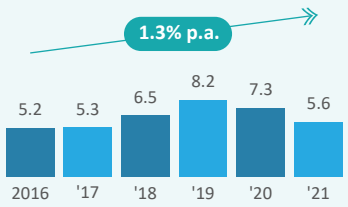
GROSS VALUE ADDED (PER ANNUM)
A$ billions



JOBS SUPPORTED – INDUSTRY* AND RESEARCH
Thousands of employees

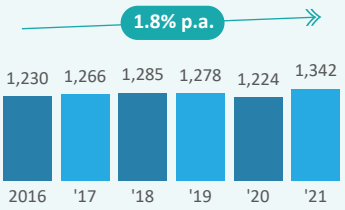


MTP MANUFACTURING EXPORTS
A$ billions

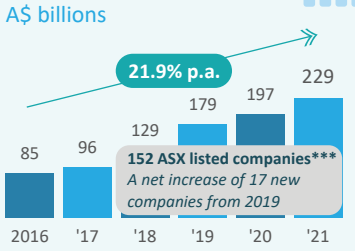


COMMERCIAL METRICS†

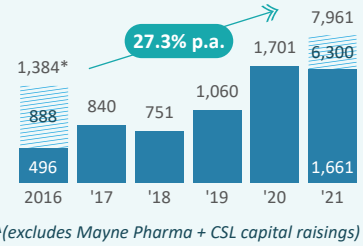
COMPANIES IN THE MTP INDUSTRY
No. of companies



MARKET CAPITALISATION OF MTP COMPANIES**
A$ billions

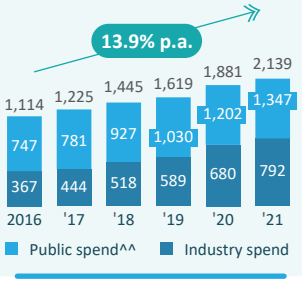


CAPITAL RAISED^
A$ millions

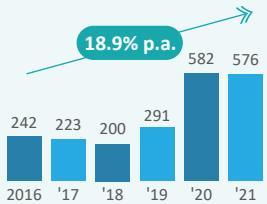


R&D METRICS†

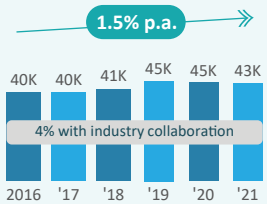
R&D INVESTMENT
A$ millions



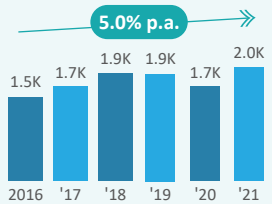
NUMBER OF COMPANIES PATENTING^^^



NUMBER OF PUBLICATIONS^^^



NUMBER OF CLINICAL TRIALS^^^^



Notes:

† All growth rates shown in the graphs below represent compound annual growth rates

†† GVA data shown here is as reported in the respective SCPs for consistency. 2017 GVA figure is interpolated using 2016 and 2018 data as GVA was only tracked as a sector metric annually from 2018 onwards

* Due to the volatile nature of quarterly employment metrics, the industry job porton 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 so ware / digital health companies whose products are not necessarily regulated by the TGA.

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

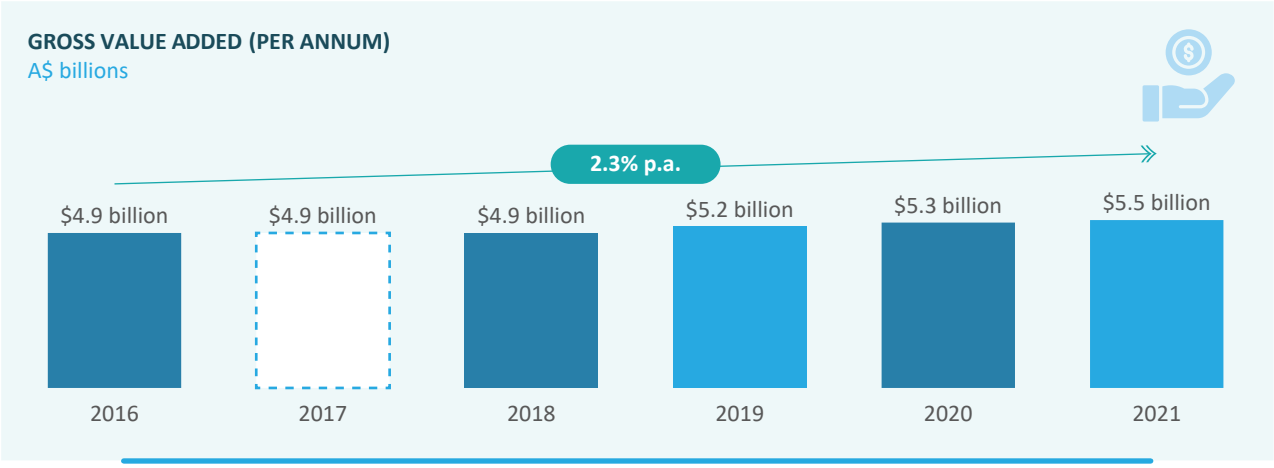
^^ Public spend analysis comprises grants made by ARC, NHMRC, BTF and MRFF; NHMRC and ARC (announced before August 2021) grant funding per year assumes grant funding distributed equally in each year of the grant; ARC funding estimates for grants announced after August 2021 assume a) the duration of each 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 2021, and b) grant funding is distributed equally across each year of the assumed grant duration; MRFF funding is based on committed funding announced by the MRFF; BTF funding is based on BTF grants awarded by year.

^^^ Data provided by Clarivate Analytics.

^^^^ Data provided by NHMRC CTC

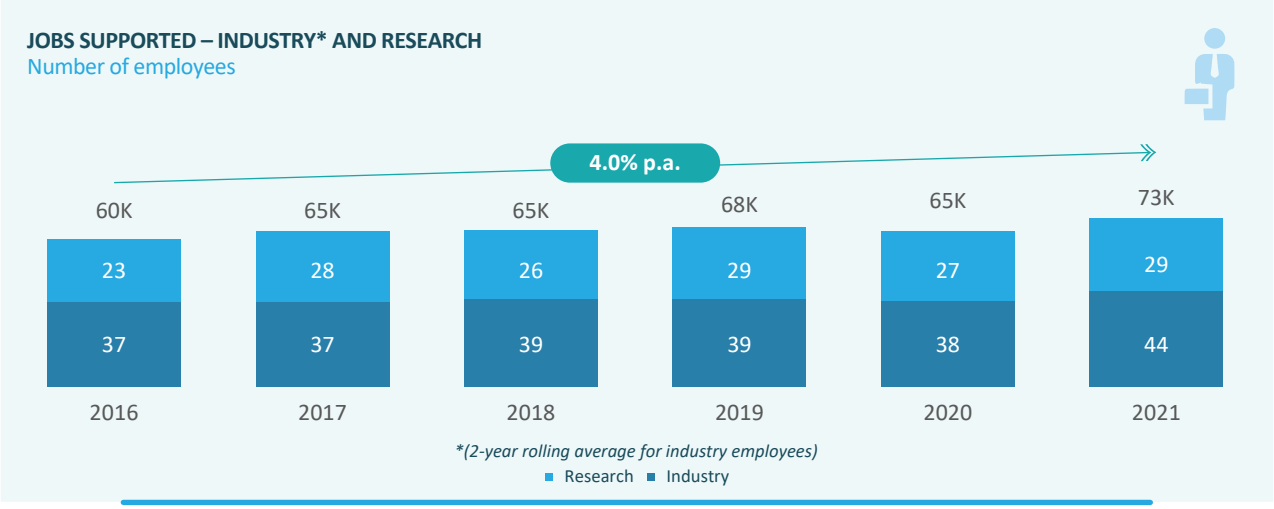
Economic metrics

Gross Value Added



The economic contribution of the MTP sector as measured by GVA has grown at a rate of 2.3 per cent per annum since 2016, adding a cumulative $21 billion in GVA to the Australian economy between 2018 and 2021 when GVA was tracked annually as part of MTP sector metrics. During 2020 and 2021, the MTP sector's GVA remained stable, adding $5.3 billion and $5.5 billion respectively. This illustrates the sector's resilience and its importance to the economy during COVID-19, as many other sector GVAs fell. For example, the construction sector's GVA declined by $12 billion in 2020 and $4 billion in 2021 (-4 per cent and -1 per cent respectively), while the transport, postal and warehousing sector's GVA declined by $10 billion and $14 billion (-5 per cent and -8 per cent respectively) over 2020 and 2021 respectively.[4]

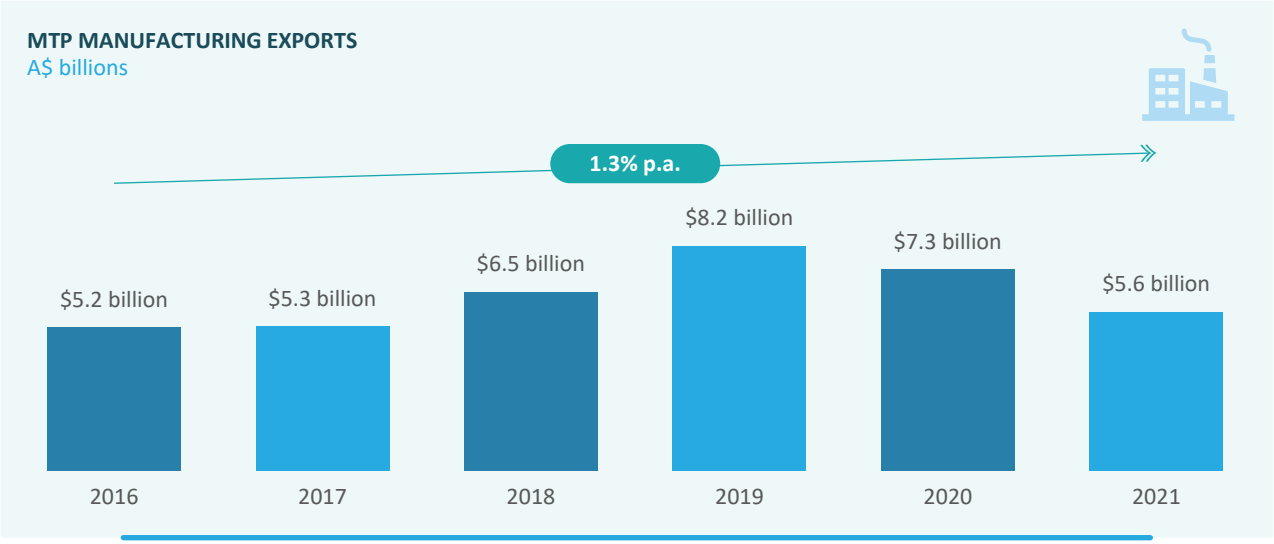
Job creation



[4] ABS, catalogue number 5204.0, October 2021. Note: data presented reflects financial years to June each year

A total of 13,000 jobs were added to the sector over the last six years. Approximately half of these jobs were industry jobs with the remaining half research jobs. The 4 per cent per annum growth rate for MTP sector jobs observed from 2016-21 was higher than overall jobs growth in Australia of 1.2 per cent per annum.[5] While jobs grew overall to 2021, jobs supported in the MTP sector declined by 3,000 in 2020 due to the impacts of COVID-19 restrictions. Approximately two-thirds of this decline came from research jobs. This is in line with modelling by the National Tertiary Education Union which indicated that 5,300 university research positions across all research areas were lost in 2020 as a result of COVID-19.[6] While research jobs appear to have bounced back to exceed pre-COVID-19 levels in 2021, it should be noted that the continued threat of the Omicron variant and other potential variants are not reflected in these figures. The sector supported an additional 6,000 industry jobs in 2021 with the largest contributor being the pharmaceutical and medicinal product manufacturing sub-sector. While this is potentially reflective of the significant investments in MTP manufacturing capabilities across Australia made by the likes of Seqirus and Cell Therapies, a longer time series is required to establish a trend for post-pandemic jobs growth.

Manufacturing exports

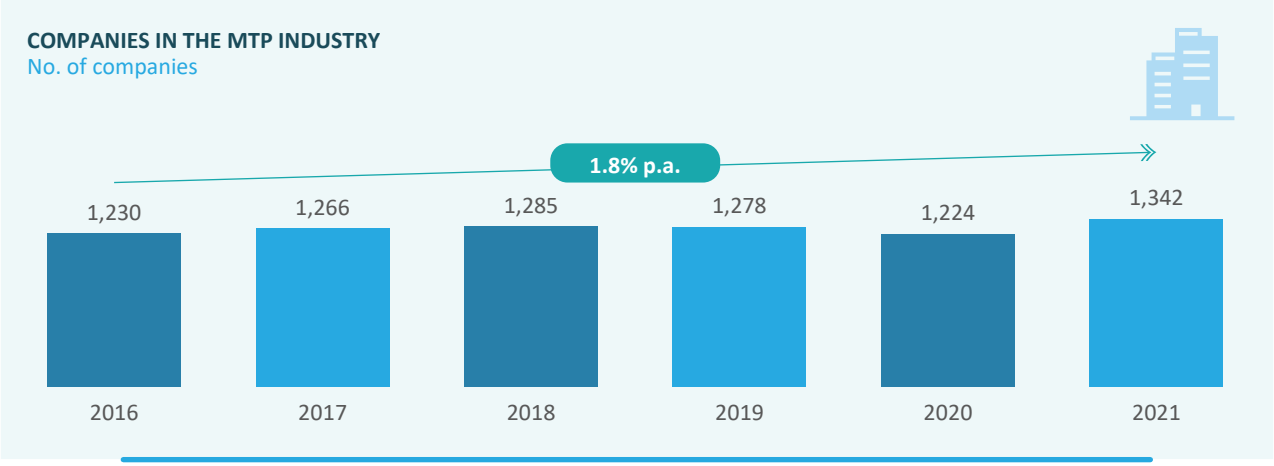


The MTP sector's manufacturing exports grew by 16 per cent p.a. from 2016 to 2019. It became the top exporter of non-primary goods in Australia and the 8th largest export sector in Australia at $8.2 billion in 2019. MTP exports continued to grow through the beginning of 2020, however, pandemic restrictions created headwinds with adverse trading, shipping and freight shortages and complexities. This led to a significant increase in the cost to export relative to pre COVID-19 levels, making Australia's products less price competitive globally. This is reflected in the metrics, with a 10 per cent decline of exports in 2020 and a further 24 per cent decline in 2021. This was in-line with the broader Australian export economy, which fell by 10 per cent in 2020 compared to 2019 and 20 per cent in 2021 compared to 2020.

[5] ABS, catalogue number 6202.0, January 2022. Note: the number based on average yearly employed people, seasonally adjusted
[6] Defined as 'continuing positions' within universities, inclusive of MTP and non-MTP related roles

Commercial activity metrics

MTP sector companies

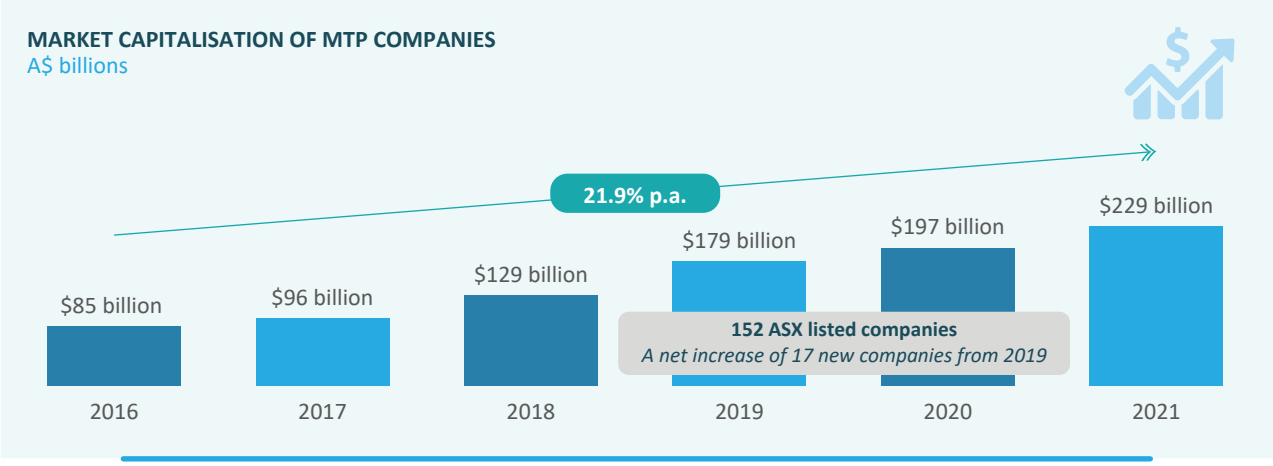


The total number of companies in the MTP sector grew by 112 over the last six years from 1,230 in 2016 to 1,342 in 2021. This represents a steady growth rate of 2 per cent p.a. which is slightly behind the overall company numbers, growing at 3 per cent p.a. during the same period.[7] In 2020, the number of total companies in the MTP sector declined by 54 companies (a 4 per cent decline) compared to 2019. This decline was slightly greater than the total number of companies in Australia, which declined by 1 per cent. Most of this decline was in small companies (defined as companies having one to 19 employees). As illustrated in MTPConnect's COVID-19 impact reports, smaller MTP companies were impacted more by COVID-19 than larger companies due to delays in public grants funding for existing and new research and development initiatives. These delays meant that smaller companies, that typically held less cash reserves than larger ones, were unable to weather the cash flow reduction. In addition, smaller companies, particularly start-ups and early-stage companies were further disadvantaged if they were pre-revenue as these organisations were not eligible for JobKeeper payments from the Federal Government.[8] The sector experienced the largest increase in company formations and the lowest rates of company dissolution in 2021, compared to the past five years, as the total number of MTP companies recovered to the five-year historical trend.

In line with the increase in the overall number of MTP companies, the number of MTP companies listed on the ASX grew by 15 in 2021 representing the largest annual increase over the last six years. The ASX, more broadly, had a strong year in terms of Initial Public Offerings (IPOs) in 2021. It ranked fourth by deal numbers among the top 12 stock exchanges globally.[9] Notable listings in 2021 included Clarity Pharmaceuticals, a clinical stage radiopharmaceutical company that raised $92 million in its IPO in August 2021, and Trajan Group, an analytical science and device company that raised $90 million in its IPO in June 2021. Overall, the number of MTP companies listed on the ASX grew from 84 in 2016 to 152 in 2021 at a rate of 13 per cent per year.

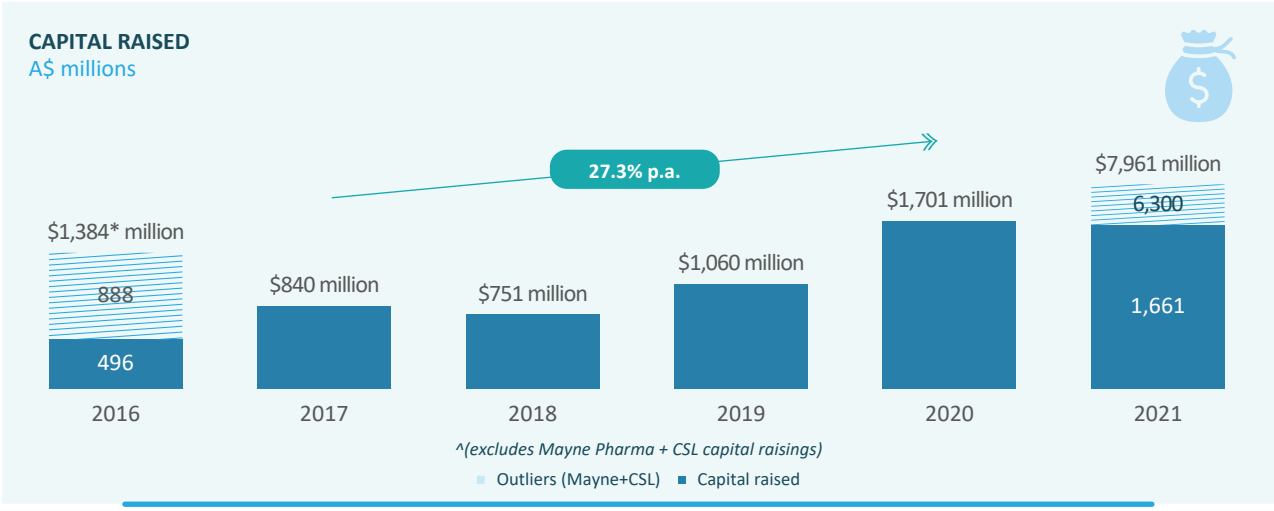
[7] ABS, catalogue number 8165.0, December 2021. Note: this counts of Australian Businesses, including entries and exits, June 2017 to June 2021
[8] MTPConnect, COVID-19 Impact Report, June 2020
[9] EY, Global IPO Trends reports, 2021

Market capitalisation of MTP companies



The market capitalisation of MTP companies listed on the ASX grew by a total of $144 billion since 2016, representing a 22 per cent p.a. growth rate over 2016-21. This aligns closely with the Biotech Daily's Top-40 Index (BDI-40) which grew by 23 per cent over the same period.[10] In comparison, the S&P/ASX 200 index grew by 9 per cent p.a. over the same period.[11] This positive story has been partly fuelled by positive investor sentiment, high global liquidity and strong pandemic tailwinds in specific MTP sub-sectors such as vaccines and diagnostics. CSL, Resmed and Cochlear remain the three largest publicly listed ASX companies in the sector. In 2016, these three companies represented 90 per cent of the market while over the last six years, the proportionate contribution of these three leaders has softened as a strong base of small, growing companies has emerged in the sector. In 2021, CSL, Resmed and Cochlear account for 85 per cent of MTP sector market capitalisation.

Capital raised

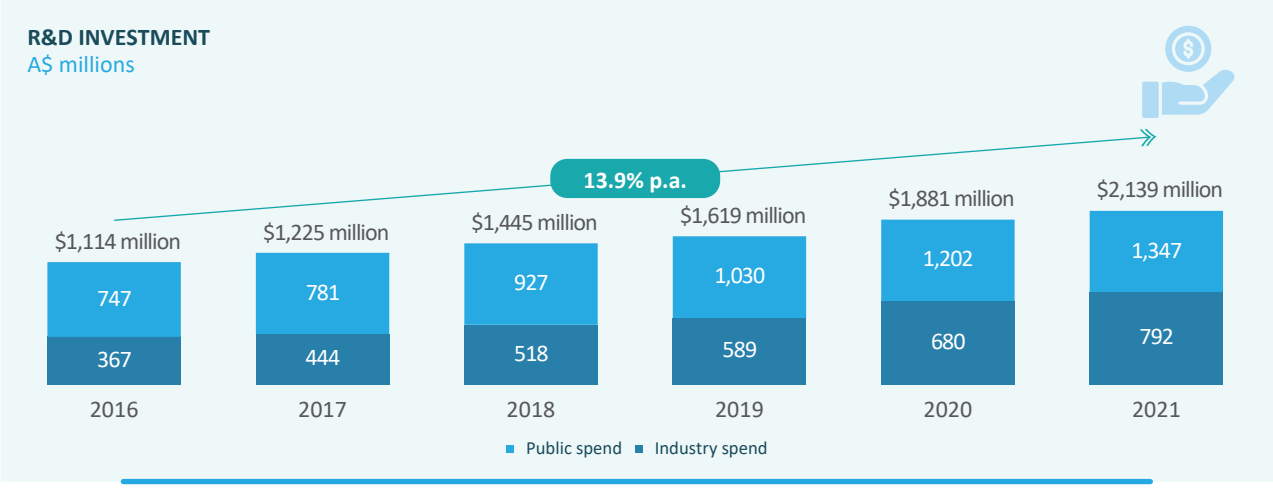


[10] Biotech Daily, January 2022. Note that the BDI-40 does not include CSL, Resmed or Cochlear stocks
[11] S&P Global, 2022

The value of capital raised by the MTP sector has grown four-fold from $496 million in 2016 to $1.7 billion in 2021. This excludes two significant capital raisings by Mayne Pharma ($888 million) in 2016 and CSL ($6.3 billion) in 2021. The value of capital raised by the MTP sector in a year grew from $1 billion in 2019 to $1.7 billion in 2020 and 2021 respectively as the onset of the pandemic created favourable conditions with historically low interest rates and an increased investor appetite for MTP related products.

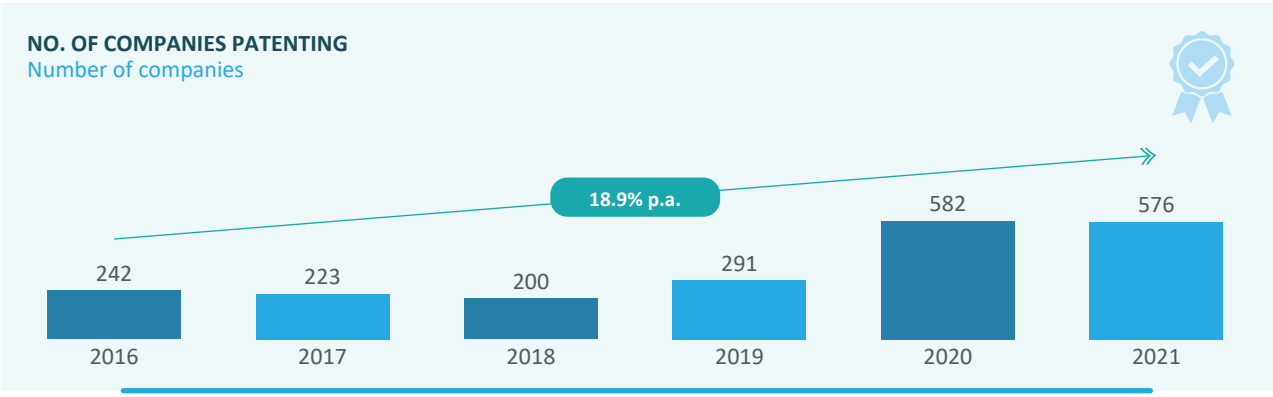
R&D activity metrics

R&D funding



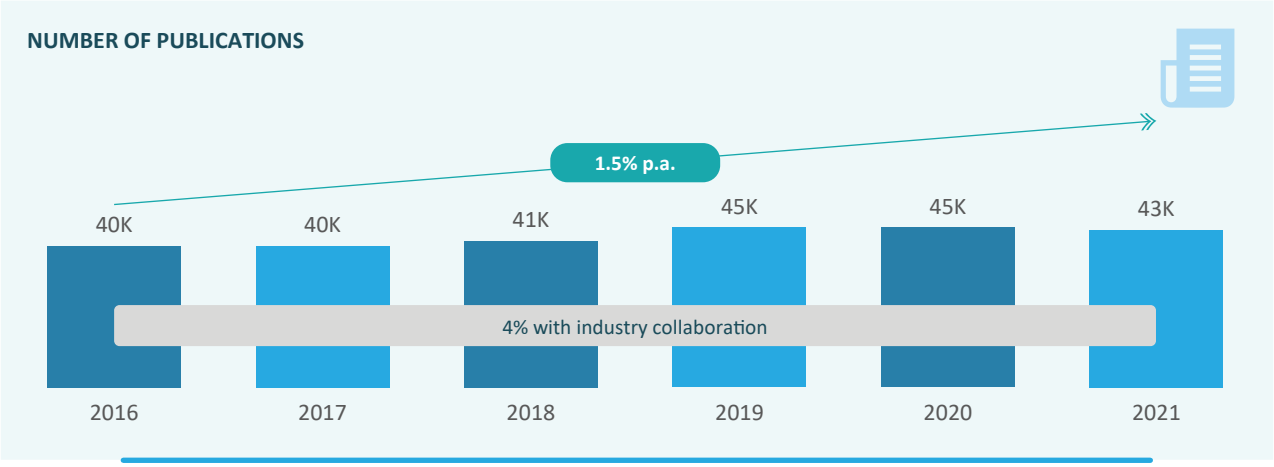
R&D activity has continued to grow steadily across the sector. R&D funding, as measured by the R&D investment made by both the public and private sector, has also grown by 14 per cent p.a. from $1.1 billion in 2016 to $2.1 billion in 2021. Public R&D spend has grown from $750 million in 2016 to $1.3 billion in 2021 driven primarily by the commitment of MRFF and BTF funding that has matured over this period. NHMRC and ARC funding for MTP sector R&D have remained broadly flat across the period. Industry R&D spend has increased by 17 per cent p.a. between 2016 to 2021, yet still represents a small portion.

Patenting activity



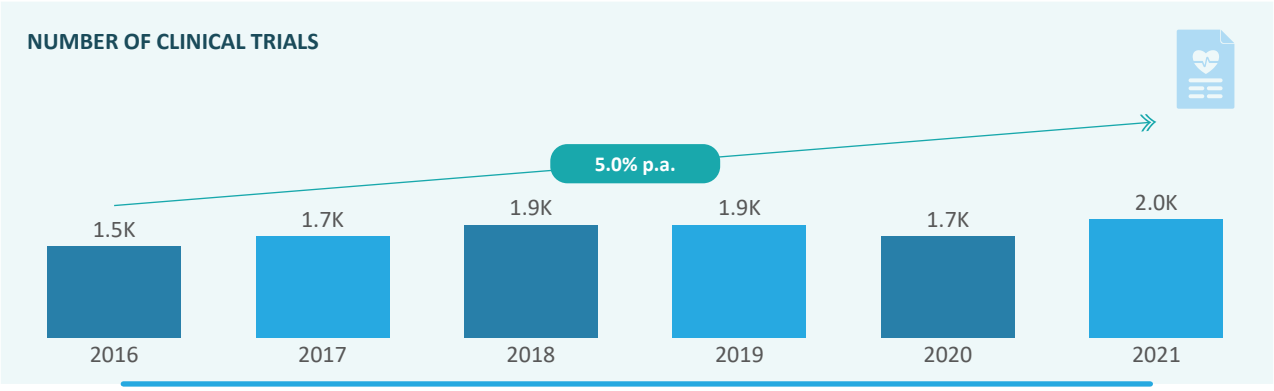
The number of companies undertaking patenting activities grew from 240 in 2016 to 580 in 2021, representing a 19 per cent annual growth rate. After a period of decline over 2016-18, the number of companies undertaking patenting has nearly tripled from 2018-21. This steep increase is supported by the fact that the total number of innovation patent applications filed in Australia in 2020 was approximately 2.5 times the 2019 level.[12] The top five patent technology classes included medical technology, biotechnolgy and pharmaceuticals.

Publications



Total publications have increased steadily at 1.5 per cent p.a. from around 40,000 publications in 2016 to 43,000 in 2021.[13] In 2021, there was a slight decline in the total number of publications due to COVID-19 as researchers were limited by lockdowns and social distancing requirements. The share of these publications involving industry collaborations has increased slightly over the last six years, from 3 per cent to 4 per cent indicating a slight increase in academic collaborations between industry and researchers.

Clinical trials



[12] The Australian Government, IP Australia, Australian Intellectual Property Report, 2021

[13] In the SCP 2022, the methodology used to calculate the absolute publication numbers differ compared to previous SCP reports. This is primarily due to a change in the classification of publications introduced by the ARC. In this report, MTPConnect used the Web of Science classification system to identify in scope publications. Refer to appendix for greater detail.

The total number of clinical trials in Australia grew from 1,545 in 2016 to 1,970 in 2021, an increase of 5 per cent p.a. over this period. Of those additional clinical trials, 225 or just over half the total increase, have come from industry-sponsored trials. There was an 11 per cent decline in 2020 in the number of clinical trials conducted in Australia compared to 2019, mainly driven by a decline in non-industry sponsored trials which were more impacted by suspensions and hospital capacity limitations during COVID-19. In 2021, the number of non-industry sponsored trials reverted to above 2019 levels as pandemic restrictions were eased in most of the country. The number of Phase I and II trials in Australia grew the fastest over the period 2016-21 at 10 and 11 per cent p.a. respectively. This reflects Australia's increasing reputation as an attractive destination for early-phase trials as noted in MTPConnect's Clinical Trials Report.[14] In comparison, the number of Phase III and IV trials were flat over the last six years.

Notable events and milestones

There have also been several notable events and milestones achieved within the MTP sector over the past 24 months, particularly in the areas of science including oncology and in diagnostic device areas. These 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:

- NSW-based molecular diagnostics company SpeeDX which commercialised an innovative approach to molecular diagnostics, while upscaling its manufacturing capabilities by 500 per cent to meet demand for its COVID-19 products. SpeeDx has been instrumental in rapid genomic sequencing of variants of concern during the pandemic.
- In 2020, Sydney-based company, Oncosil received FDA breakthrough designation status and full approval in the UK and EU for the use of its device in the treatment of pancreatic cancer.
- Pharmaxis' has successfully commercialised a portable inhaler Bronchitol, to assist in the treatment and symptom management of cystic fibrosis. Bronchitol has shown to significantly increase mucus clearance, improve lung function and overall quality of life for people living with cystic fibrosis. Pharmaxis has approval to market in the US, Australia, Russia and the EU.
- Melbourne-based, Telix Pharmaceuticals develops and produces targeted radiation products to diagnose and treat cancer. Their new prostate diagnostic imaging product Illuccix® has recently been FDA approved and will be able to service up to 85 per cent of prostate cancer patients in the US.
- Brisbane-based Ellume developed and produces the first FDA approved COVID-19 rapid self-test. Ellume exports predominately to the US as its product forms part of the US Government's pandemic response. Ellume has had notable success with its COVID-19 RATs and is expanding its diagnostics range into other infectious diseases such as tuberculosis.

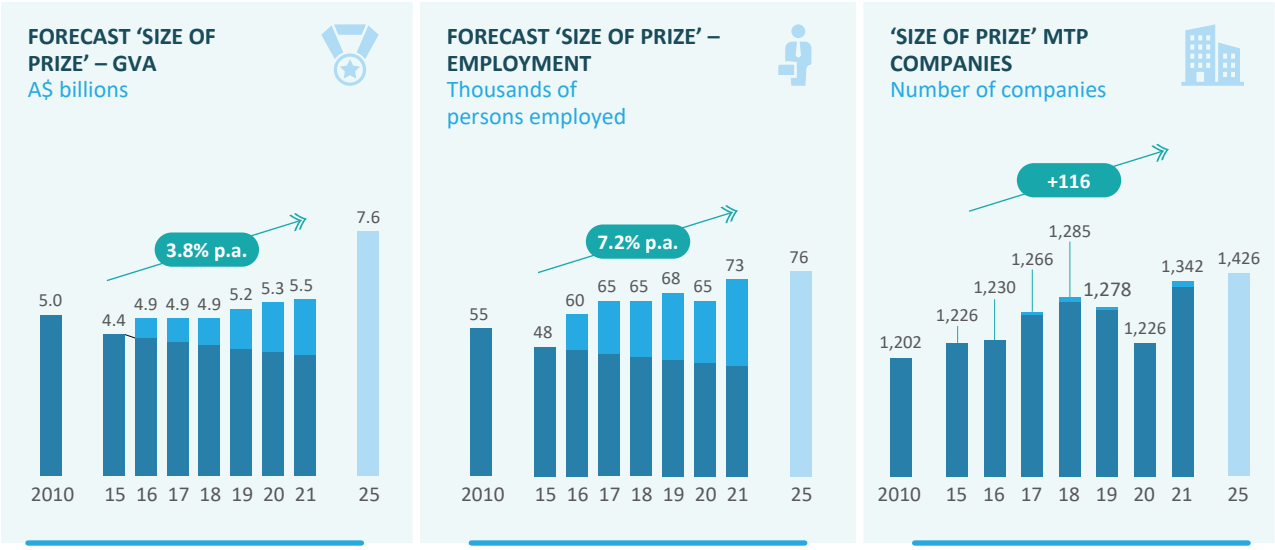
[14] MTPConnect, Australia's Clinical Trials Sector, 2021

Progress against 2025 goals

The MTP sector's progress over the last six years has been encouraging, with particular strength in job creation. In the 2016 SCP, MTPConnect outlined an aspirational scenario that aimed to reverse the decline in GVA and jobs experienced from 2010-15 within five years, and to continue this growth at an equivalent rate out to 2025.

The interim five-year goal of reversing the decline in GVA and jobs has been met as illustrated below.

PROGRESS AGAINST 10-YEAR PLAN



The MTP sector GVA has grown by 2.3 per cent from 2016-21, slightly above the GVA growth rate for the Australian economy overall (1 per cent p.a.).[15] In the 2016 SCP, the GVA forecast target for 2021 was estimated as $5 billion, so the sector has outperformed this initial target. The 2016 SCP also forecast a 'stretch' goal of $7.6 billion for the MTP sector GVA in 2025. To achieve this 'stretch' goal, MTP sector GVA growth would need to lift to 6.7 per cent p.a. Given the length of commercialisation timeframes in the MTP sector, the payoff in investments made by the Australian Government will likely take several years to be fully realised. Hence, it is possible for the sector to achieve its 'stretch' goal, although continued focus and investments will be required to ensure the MTP sector remains on-track in the face of global headwinds as the world recovers from COVID-19.

For jobs growth, the MTP sector has surpassed the 2016 SCP estimate of reaching 2010 levels by 2021. The sector has added an additional 18,000 jobs compared to 2010 levels. In fact, the sector is already close to meeting its 2025 target of supporting 76,000 jobs, with only another 3,000 new jobs needed over the next four years to achieve that target.

[15] ABS, October 2021, Catalogue number 5204.0. In line with the ABS methodology, Australian economy GVA is calculated using ANZSIC division of A to N, R and S

Furthermore, 116 companies were added to the sector between 2015 and 2021, an increase of 9 per cent or 2 per cent p.a. In comparison, only 24 companies were added to the sector between 2010 to 2015. To meet the upside growth potential of 200 additional companies by 2025, growth in the number of companies will need to lift to 1 per cent p.a. between 2021 and 2025. Given the investment undertaken over the 2015-21 period, the MTP sector is well positioned to achieve this goal as investment returns typically 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 over the next 10-20 years. These megatrends are often disruptive, altering existing business models and presenting opportunities and challenges for organisations. By nature, they are forward looking and as a result do not vary significantly from year to year; rather they evolve gradually. As a result of the dramatic global impacts of COVID-19, two additional megatrends – sovereign capability and supply chain resilience – have been added to the set of nine megatrends identified in the 2020 SCP report. The disruptions to global supply chains during the COVID-19 pandemic has led to businesses and governments around the world actively pursuing initiatives to critically review and strengthen supply chains. Governments are also building sovereign capability in key areas such as manufacturing of critical medical products and vaccines, and equipment such as masks and ventilators.

It is acknowledged that the continued evolution of COVID-19 and future global pandemics will influence many of these megatrends, including global biosecurity, digital evolution and chronic burden. These impacts will need to be considered as part of strategic planning, policy development and operational activities for MTP businesses and governments alike.

Megatrend	Implication for the MTP sector
Digital evolution	
Digital evolution has and will continue to have a substantial impact on the healthcare landscape. Digital enablement is expected to drive continued advancement across many of the other megatrends, particularly precision healthcare, modern manufacturing, consumer control and integrated care models. The COVID-19 pandemic has accelerated the pace of adoption of digital innovations across the healthcare landscape globally. Technology has enabled remote consultations to occur more effectively than ever before, with patients and physicians becoming more accepting of such innovations as a result of their experiences during COVID-19 lockdowns.[16] While the use of some digital solutions may decline as COVID-19 vaccinations and boosters enable greater in-person interactions, digital-enabled activity is likely to remain high in areas for which the pandemic has acted as a catalyst, including telework, e-health and e-commerce.[17] Digital evolution will also drive a significant shift in how we exchange and process data (enabling faster and more standardised exchange of data at scale) and the development of increasingly sophisticated analytical tools to generate healthcare insights. The last two years has seen momentum build in the industry, with personalised smart healthcare services using information communication technology becoming widely available and adopted across the global healthcare industry. In the US, the use of telehealth during 2020 increased by 154 per cent, compared with the same period in 2019.[18] During June-November 2020, 30 per cent of weekly health centre visits occurred via telehealth.[19] In Australia, overall use of telehealth since the start of the pandemic has increased significantly, with 97 per cent of GPs providing care via either phone (96 per cent) or video (30 per cent), compared to just 15 per cent prior to the pandemic.[20] More than 89,000 providers have used telehealth services, which have been delivered to 16.1 million patients.[21] The upside of this will be improved efficiency and effectiveness across the value chain, from R&D to patient-care coordination.	The digital evolution is central to the MTP sector, allowing for the rapid exchange of health-related information, enabling advances in genomic sequencing, facilitating the collection and analysis of big data to support precision medicine and revolutionising healthcare models with AI and robotics. 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. That said, data standardisation and cybersecurity need to be central concerns and focus areas for the MTP sector, if it is to unleash the full potential of the digital world.

[16] Sang M. Lee and DonHee Lee, Opportunities and challenges for contactless healthcare services in the post-COVID-19 Era, Technological Forecasting and Social Change, published in ScienceDirect, 2021, Volume 167

[17] OECD (2020), Digital Transformation in the Age of COVID-19: Building Resilience and Bridging Divides, Digital Economy Outlook 2020 Supplement, OECD

[18] Koonin LM, Hoots B, Tsang CA, et al. Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic – United States, January. March 2020. MMWR Morb Mortal Weekly Report 2020

[19] Demeke HB, Merali S, Marks S, et al. Trends in Use of Telehealth Among Health Centers During the COVID-19 Pandemic – United States, June 26 – November 6, 2020. MMWR Morb Mortal Weekly Report 2021

[20] The Royal Australian College of General Practitioners, General Practice: Health of the Nation 2020. East Melbourne, Vic: RACGP, 2020

[21] Australian Government, Department of Health, Permanent telehealth to strengthen universal Medicare, December 2021

Megatrend	Implication for the MTP sector
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. Globally, consumer awareness of health issues has grown rapidly during COVID-19 as consumers have become more aware about clinical trials, infectious diseases and making decisions about elective surgeries more actively. 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 technology and in-home monitors, gathering information and data that enables patients to make better, more informed, healthcare decisions. Tomorrow's patients will be increasingly educated and informed decision-makers who take more responsibility and control for their own wellbeing.	Increasing consumer control will see a paradigm shift in the model of healthcare provision, from a model where healthcare was delivered based on consultation with medical specialists to one which is more consumer-driven. 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 technologies, 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.[22]	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.

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

Megatrend	Implication for the MTP sector
The chronic burden	
Between 2015 and 2050, the proportion of the world's population over 60 years will nearly double from 12 per cent to 22 per cent.[23] 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 are becoming increasingly prevalent. The emergence of the COVID-19 pandemic in 2020 had direct psychological effects and long-term economic and social consequences.[24] The mental health of the population was affected by the restrictions, lockdowns, business impacts, loss of income, decrease in economic activity and shifting government priorities to control COVID-19 outbreaks. It was estimated there were an additional 53.2 million cases of major depressive disorder globally (a 27.6 per cent increase), during the COVID-19 pandemic.[25] Locally, 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.[26] Globally, the management of mental health will require a consumer-centric approach and a focus on prevention as well as treatment.	This trend places significant pressure on the MTP sector. The public may demand new technologies, but access will be determined by governments' and healthcare providers' judgements about the economic sustainability of those technologies. Sector participants need to work with governments and healthcare providers to make sure research priorities and new technologies improve population health outcomes in a more cost-effective manner.[27] 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.

[23] World Health Organisation, Ageing and Health Factsheet, October 2021
[24] Kola L, Kohrt BA, Hanlon C et al., COVID-19 mental health impact and responses in low-income and middle-income countries: reimagining global mental health. Lancet Psychiatry. 2021; 8: 535-550
[25] The Lancet, 2021, ISSN: 0140-6736, Vol: 398, Issue: 10312, Page: 1700-1712
[26] https://www.beyondblue.org.au/media/statistic
[27] MTPConnect, Frugal Innovation in Medical Devices and Technology – The India Opportunity, December 2019

Megatrend	Implication for the MTP sector
Precision healthcare	
Advances in science and technology are enabling more precise and effective healthcare solutions for patients. Worldwide, patients are receiving better outcomes via targeted pharmaceuticals, biologicals and personalised medical technologies. In oncology, for example, rationally designed targeted therapies and immunotherapies are expected to comprise 80 per cent of the overall global oncology market by 2022, up from 70 per cent in 2016. Other technologies advancing this trend include genomics, synthetic biology, gene-editing technologies, cell therapies, computational biology, medical imaging, 3D printing, data mining and artificial intelligence.[28] 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 67 per cent of biosensor revenue globally.[29]	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.[30]
Value-based healthcare	
The concept of value-based healthcare, where patients' health outcomes drive the choice, delivery and reimbursement of therapies, has been around for almost a decade.[31] The rise of precision medicine combined with the rising cost of traditional fee-for-service approach to healthcare is driving a paradigm shift towards this new patient-centric model.	This megatrend has enormous implications across multiple parts of the healthcare value chain. For example, the regulatory process for approving and reimbursing drugs and devices will need to adapt from the current volume-based approach to an outcome-based approach. There will need to be greater coordination among sector participants in the delivery of care and more efficient capturing of value delivered. MTP companies will need to rethink their operating models to cater for the more customer (and value) focused approach necessitated by value-based healthcare.
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.

[28] MTPConnect, Regenerative Medicine – Opportunities for Australia, October 2018
[29] BIS Research, Global Biosensors Market Analysis and Forecast (2018–2027), 2018
[30] MTPConnect, Precision Medicine Roundtable White Paper, June 2019
[31] M.E. Porter, New England Journal of Medicine, 'A Strategy for Health Care Reform – Toward a Value-Based System', July 2009

Megatrend	Implication for the MTP sector
Global biosecurity	
COVID-19 and other recent pandemics such as Ebola highlight the globally transmissible nature of diseases and the threat they can have on health, the standard of living and the economy. With more frequent travel, globalised trade and greater interconnectedness between countries, infectious disease outbreaks of international concern are becoming inevitable and unpredictable.[32] Antimicrobial Resistance (AMR) is another complex global public health crisis that threatens the effective prevention and treatment of an ever-increasing range of infections.[33] Known as the 'silent pandemic', 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.[34] There has been a 'discovery void' since the 1980s, with a limited pipeline of new antibacterial drugs.[35] MTPConnect has established the Australian Antimicrobial Resistance Network (AAMRNet) to bring together industry and research to combat the impacts of AMR on human health.	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.
Resilient supply chain	
COVID-19 has highlighted the risk of the interconnected nature of global supply chains and created a need to better secure supply chains against external shocks. Global supply chains are vulnerable to disruption from political instability, natural disasters, trade disputes and manufacturing issues. In Australia, approximately 68 per cent of medical supply imports come from the US and Europe.[36] During the COVID-19 pandemic, disruption in the supply chains of essential goods and medical products, e.g. the lack of PPE supply, highlighted the need for greater sovereign manufacturing and more resilient supply chains.	Suring-up critical supply chains in Australia to ensure there is access to critical products is crucial to reducing the dependence on foreign supply chains. For the sector, the greatest opportunities to build a more resilient supply chain is in building greater domestic manufacturing and workforce capabilities across the value chain. For those products that are predominantly manufactured overseas such as medicines, creating security of supply measures in the form of minimum stock holdings is a complementary approach

[32] World Health Organisation, Managing Epidemics, May 2018
[33] World Health Organisation, Antimicrobial Resistance Factsheet, February 2018
[34] J. O'Neill, Tackling Drug-Resistant Infections Globally: Final Report and Recommendations
[35] World Health Organization, January 2020, Antibacterial Agents in Clinical Development – An Analysis of the Antibacterial Clinical Development Pipeline
[36] Department of Foreign Affairs and Trade, Composition of Trade Australia 2018-19 - includes import of 'Pharm products (excl. medicaments), 'Medicaments (incl veterinary)', 'Medical electrodiagnostic apparatus' and 'Medical instruments (incl. veterinary)'

Megatrend	Implication for the MTP sector
Sovereign capability	
Globalisation over the last few decades has created connected global value chains (GVCs). COVID-19 has highlighted the need for on-shore manufacturing capabilities as it has exposed the dependency of nations on others. This has created a need to secure supply chains via sovereign capabilities and resources, thereby reversing globalisation progress. In 2020, it was found that Australia now ranks last on the OECD rankings for manufacturing self-sufficiency – making us the most underdeveloped manufacturing sector of any industrial country in the world.[37]	Front of mind today is building and maintaining strong on-shore advanced manufacturing and research capabilities for biosecurity products, that will help enable Australia to retain access to the products and know-how required to combat risks.
Developing markets	
The growth in the developing countries demands for better health services is accelerating. Today these markets are responsible for the majority of global sector growth (in percentage terms) and this trend is expected to 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.[38]	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.

[37] Grant Thornton, Federal Budget: a 10-year retrospective, November 2020
[38] World Health Organisation, Ageing and Health Factsheet, February 2018

Sector vision

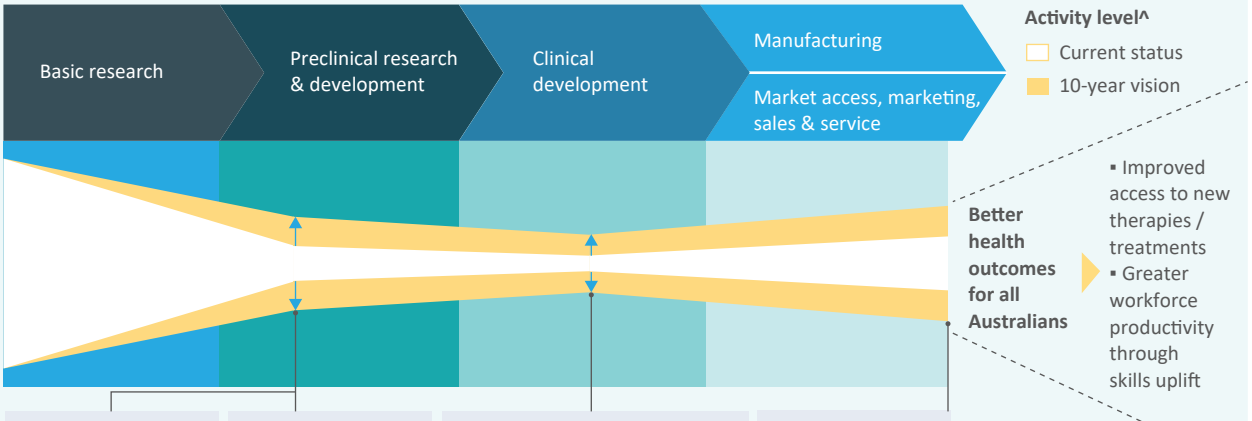
The Australian MTP sector has the potential to be a significant contributor to improving patient outcomes and driving economic and jobs growth over the next 10-20 years. The central role played by the sector during the nation's response to the COVID-19 pandemic has highlighted the strength and capabilities within the sector.

MTPConnect's vision is to strengthen and grow Australia's MTP sector further by:

- maintaining or growing planned levels of R&D expenditure
- creating more products that reach proof-of-concept stage and achieving greater commercialisation success
- increasing the number of companies with late-stage product successes and maximising the value of Intellectual Property monetisation events along the way.

This vision was developed through a series of wide-reaching sector consultations in 2016 and 2019 with over 600 participants and stakeholders.

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



Retain and refocus for greater commercial outcomes

- Maintain / grow the level of planned research activity with greater focus on translation of research, and the KPs*

Enhanced commercialisation productivity

- Increase the progression of research through to early clinical trials and proof-of-concept

Increased commercial success and economic contribution

- Increase the transition of products to late-stage clinical trials and in-market launch
- Encourage greater use of Australia as a destination for overseas products to undergo parts of their clinical development process

Greater economic contribution

- Increase in companies using onshore advanced manufacturing capabilities
- Increase in MTP sector sales globally

Notes: * 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 45 of this report

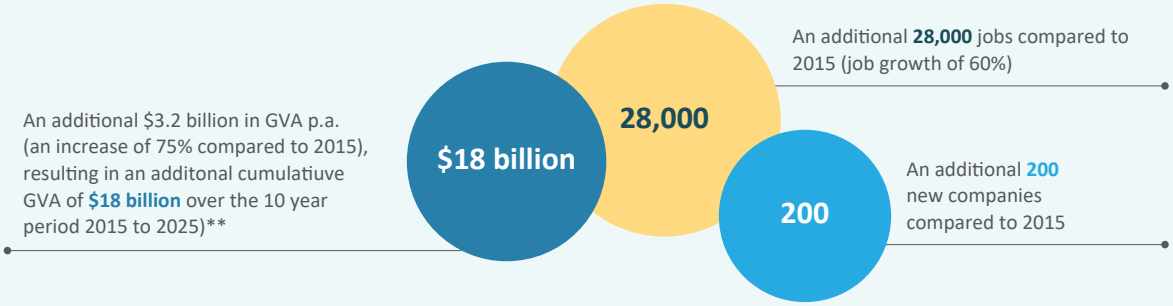
It is also important to note that while the value chain for MTP innovation – stretching from basic science to manufacturing and market launch – remains the core pathway for the development of MTP products, there are increasing examples of innovations that require alternative development models. In particular, 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 per cent).
- an additional $3.2 billion in GVA per annum (an increase of 75 per cent compared to 2015), resulting in an additional cumulative GVA of approximately $18 billion over the 10-year period 2015 to 2025.
- an additional 200 MTP companies in the sector.

The MTP sector has made consistently positive progress towards these targets as illustrated in the previous chapter.

MTP Sector by 2025*



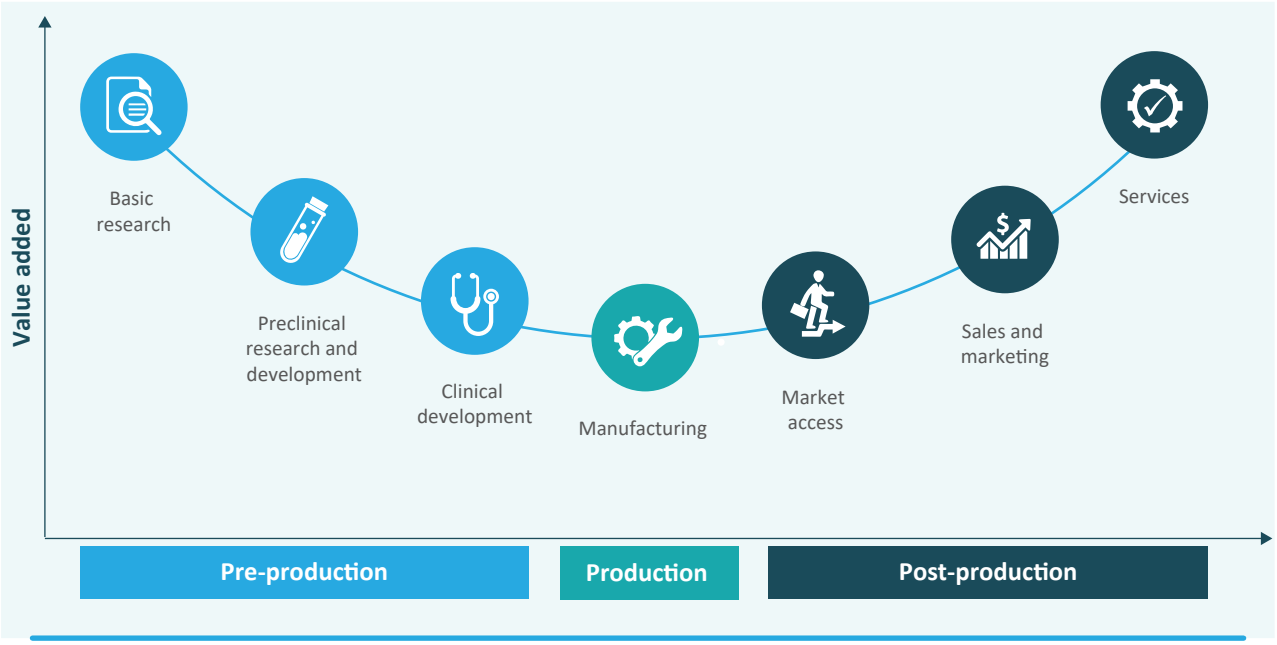
Notes: * The 2025 estimates developed by MTPConnect in 2016 assume that the decline in GVA, employment and companies over the 2010-2015 period can be reversed, with the industry returning to 2010 levels by 2020 and then continuing to grow at an equivalent rate out to 2025. This scenario reflects the 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

The Australian Government's Modern Manufacturing Strategy (MMS), particularly the supporting Medical Products National Manufacturing Priority road map, emphasises that value can be achieved across the full ecosystem by building strength across all phases of the manufacturing 'smile curve' illustrated below.[39]

In line with this, MTPConnect has identified seven Sector Priorities that will build strength across all phases of the manufacturing 'smile curve' and will underpin the achievement of the sector vision articulated in the previous section. As identified in the Medical Research Future Fund Australian Medical Research and Innovation Priorities 2021-2026 report, manufacturing capabilities are seen as a critical enabler.

The manufacturing 'smile curve'



While the seven Sector Priorities from the 2019 SCP remain relevant today, they have been updated to reflect the lessons from COVID-19 over the past two years. The Sector Priorities are summarised on the following pages.

[39] Adapted from Australian Government, Make it Happen, The Australian Government's Modern Manufacturing Strategy, October 2020

Sector Priority	Description	Summary of priorities
Priority 1	Align investment in Knowledge Priorities to 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.
Priority 2	Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	• 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.
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 medical technology firms with products in early-stage development. As a result there is a need to create access to sufficient long-term funding and to appropriate skills, resources and experts. • Transforming the medical technology and digital health SME sector will have more immediate impact in terms of new product launches and local companies compared to the pharma/biotech SME sector due to the shorter development timeline.
Priority 4	Strengthen Australia as an attractive clinical trial research destination	• Australia's clinical trial industry contributes c.$1.4 billion to Australia's economy annually and is recognised as a globally competitive destination for clinical trials, in particular early phase trials. • International peers are increasing their competitiveness in this space, offering access to larger patient populations. To improve Australia's position, regulatory bodies will need to ensure they create an attractive and workable environment for both local and international trials.
Priority 5	Support the development of digital healthcare solutions, devices and data analytics	• The COVID-19 pandemic drove a surge in the adoption of digital healthcare solutions to improve patient outcomes. The industry is poised for future growth and Australia has an opportunity to be a leader. • The focus should be on the development of digital devices and datasets to enable new software solutions and healthcare platforms to change how healthcare providers diagnose and administer health solutions and how consumers choose to be treated.
Priority 6	Position Australia as the preferred partner for international markets	• Foreign markets present a number of unique opportunities for Australian researchers and developers, yet due to cultural, regulatory, demographic and resourcing differences, healthcare markets require tailored needs. • Australia can address these needs by understanding these differences and tailoring R&D and product development to meet them, unlocking licensing and distribution deals as well as opening partnership opportunities.

Sector Priority	Description	Summary of priorities
Priority 7	Support advanced manufacturing as part of the broader Australian innovation ecosystem	• Expanding Australia's advanced manufacturing capabilities, within the MTP sector and the broader innovation ecosystem, will further strengthen Australia's reputation and create opportunities for integrating with global markets across the value chain. • Recent focus has been in building capabilities in mRNA advanced manufacturing, offering the opportunity for Australia to be a global and regional centre of research and manufacturing.

For greater detail on sector priorities, including the purpose, current constraints and gaps and desired outcomes, refer to the Appendix 4.

4. MTPConnect progress

Role of MTPConnect as a growth centre

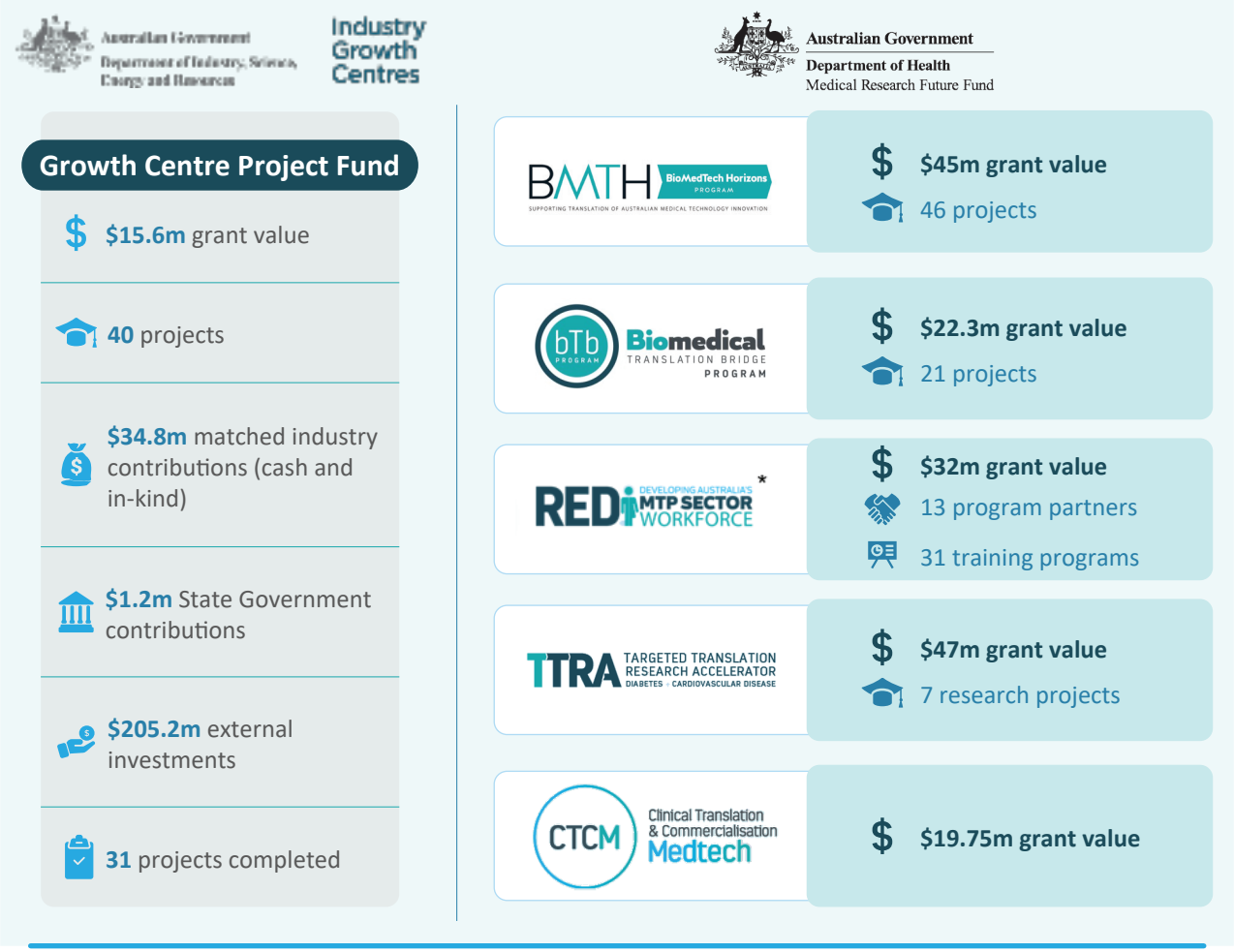
The Industry Growth Centre (IGC) Initiative, administered by the Australian Government Department of Industry, Science, Energy and Resources (DISER), aims to drive innovation, productivity and competitiveness, generating local wealth and employment in Australia.

Focusing on the four objectives of the IGC initiative – increasing Collaboration and Commercialisation, improving Management and Workforce Skills, optimising the Regulatory and Policy Environment and improving access to Global Supply Chains and Markets – MTPConnect works to enhance outcomes from the pre-production, production and post-production phases of the medical products development and manufacturing cycle.

In this way, MTPConnect is building a more resilient and competitive medical products manufacturing sector.

Overview of MTPConnect's progress

MTPConnect has $182 million in sector support funds under management, across six strategic funding initiatives.



Across MTPConnect's six strategic funding programs, a total of $94.9 million has so far been committed since 2016 to support 145 projects, with more funding to be deployed in the coming years. With its focus on increasing collaboration and commercialisation, MTPConnect has been able to draw on multiple industry partners and substantial flow-on industry investment into projects to support them through the early stages of clinical development and maximise the chances for commercialisation success. These include:

- 40 Growth Centre projects – $15.6 million investment has leveraged $36 million in matching industry and other contributions and generated a further $205 million in third-party, external investment.
- 105 MRFF projects – $79.3 million investment (so far) has leveraged $95 million in matching industry contributions and generated a further $230 million in flow-on external investment, including capital raises and other funding support.

Across all programs, MTPConnect's $95 million in strategic funding investments has gone into the sector to date. This has funded 145 projects and yielded $566 million in additional industry contributions and flow-on external investment (representing almost six times the MTPConnect funding investment). Combining the investment made by MTPConnect's Growth Centre project fund and MRFF program, work with the additional industry contributions has seen a total of $661 million flow into Australia's MTP sector.

MTPConnect assists research institutes and SMEs with pre-submission review of their translational and industry-focused product development competitive grant applications. Over the last six years, this has included:

- 173 consortia advised/mentored prior to their application submission
- reviews of 359 MMI, ARC, CRC, CRC-P and GIL grant applications

This value-add activity has seen grants worth $306.8 million awarded to 64 MTPConnect-supported projects (not including matching industry funding).

Combining the $225.9 million generated through MTPConnect's Growth Centre and MRFF granting programs to date, the additional flow-on external investment secured by those projects of $435.1 million and the $306.8 million from grant reviews, MTPConnect has contributed to $967.8 million flowing into Australia's medical products sector.

The overall economic impact of MTPConnect's activities, calculated by applying a benefit-cost ratio of $3.901 to reflect the wider economic benefits of medical research, shows a total attributable return of around $3.8 billion.

These real-world outcomes clearly demonstrate not only MTPConnect's impacts but also the effectiveness of the Growth Centre Initiative in supporting the growth of Australia's medical products sector. More information about MTPConnect programs and outcomes can be found in the FY2021 Annual Report.[40]

[40] MTPConnect, Annual Report FY2021, October 2021

Improving commercialisation spotlight: The development of regenerative medicine report and creation of the catalyst body (2017/18)

Regenerative medicine (RM) holds the promise of curative healthcare. Unlike traditional medicines and devices, it harnesses cells and tissues, often in combination with gene therapy and devices, to enable the body to regenerate and, in effect, heal itself. Global investment in RM has escalated over the last five to seven years and 37 therapies have been approved and marketed for clinical use. A wave of new therapies is expected in the next four years and beyond, particularly in immunotherapy and cell therapy.

In 2017-18, MTPConnect worked in collaboration with the AusBiotech Regenerative Medicine Advisory Group and other key stakeholders including the Centre for Commercialization of Regenerative Medicine (CCRM) Australia, to produce a growth roadmap for RM in Australia.[41] The report 'Regenerative Medicine: Opportunities for Australia', was a landmark report for the industry.

The report provided a vision to create an end-to-end world leading value chain (from discovery to delivery) that grants Australian patients access to world-class RM therapies, creates jobs and enables the export of Australian therapies to the world.

The Report's five-point plan is to:

- Prioritise skills development by attracting, building and retaining world-class talent
- Improve collaboration across the value chain to accelerate commercialisation
- Secure long-term investment by expanding the diversity of the pool of funders and venture capitalists
- Create a clear market access pathway through regulatory reform and alignment with key global markets
- Enhance manufacturing capacity and capability to support commercial-scale manufacturing

This report catalysed a lot of stem cells mission investment that subsequently deployed in Australia. In 2020, MTPConnect funded the founding of the Regenerative Medicine Catalyst Project which has a mandate to address priority action areas including: workforce capabilities, collaboration, funding, regulation and policy infrastructure and Australian manufacturing capability. The Catalyst Consortium and the subsequent Catalyst Body aim to support the Australian RM industry to see it thrive and drive benefits to the health of its people and Australia's economy.

More than 60 companies in Australia are developing RM products and there are more than 130 clinical trials in progress.[42] In 2021, a total of $394.1 million was invested across gene-based therapies, cell therapy, tissue engineering and cell-based IO initiatives, compared with $184.7m in 2019. This is a 113 per cent increase in funding.[43] As a result of these initiatives, Australia now accounts for 1.5 per cent of global investment (AU$26.3 billion in 2020).[44]

41 Regenerative Medicine Catalyst Project, Regenerative Medicine: Opportunities for Australia, 2021
42 Regenerative Medicine Catalyst Project, Australia's Regenerative Medicine Clinical Trials Database, 2021
43 Regenerative Medicine Catalyst Project, Australian RM Investments Database, 2021
44 2020: Growth & Resilience in Regenerative Medicine, Annual Report Cell & Gene State of the Industry Briefing, Alliance for Regenerative Medicine, 2021

Collaboration spotlight: AAMRNet Tackling antimicrobial resistance

Antimicrobial resistance (AMR) is on track to claim 10 million lives per year globally and put at risk a cumulative US$100 trillion of economic output if no action is taken by 2050. To successfully combat AMR, collaboration across a wide range of stakeholders including industry, clinicians, government and researchers is crucial.

The Australian Antimicrobial Resistance Network – AAMRNet – is an Australian-first network bringing together key stakeholders to address the impact of AMR on human health. AAMRNet, operated by MTPConnect, is an industry-led, inclusive collaboration of stakeholders ensuring cross-sector input, investment and support. Formed in September 2020, the network has 15 consortium members and has recently presented to the parliamentary inquiry into approval processes for new drugs and medical technologies in Australia.

Industry contributions were provided and partnerships were formed with local and global MTP sector players. These include, but are not limited to:

CONTRIBUTORS

CSIRO
Pfizer
botanix
SpeeDx
Biointelect
gsk
Medicines Australia
MSD
MONASH University

PARTNERS

DMTC
AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION
menzies school of health research
GARDP
Global Antibiotic Research & Development Partnership
MONASH University
MONASH BIOMEDICINE DISCOVERY INSTITUTE
results
BiomeBank
epichem
Roche Diagnostics
FORMulytica®
CO-ADD Community for Open Antimicrobial Drug Discovery

AAMRNet is well-placed to work closely with the Australian Government to deliver progress on its commitment to combat AMR and is currently working on an accelerator program to enhance the commercialisation of technologies to combat AMR, as well as a report to estimate the real human health impacts of AMR in Australia.

Workforce skills Spotlight: REDI skills gap analysis and assessment

In 2020, MTPConnect was selected by the Government to deliver the Researcher Exchange and Development within Industry (REDI) initiative: a $32 million program supported by the Medical Research Future Fund (MRFF). The REDI initiative is focused on improving workforce skills and driving jobs growth across the medical technology, biotechnology and pharmaceutical sector value chain, including all elements of the advanced medical products manufacturing ecosystem, such as R&D; preclinical and clinical development; production and manufacturing; logistics and distribution; and marketing, promotion and sales activities.

To date, REDI has produced three skills gaps assessments and reports, the findings of which have formed the foundation of targeted investments in skills gap training programs. The three reports identified a total of 81 skills gaps, with detailed analysis provided on 24 of these.

A total of 76 distinct skills gaps were identified over six key themes, including: advanced manufacturing and supply chain; business operations; clinical trials; health economics and regulatory affairs; product development and commercialisation; health data and cyber security and specialist and technical skills.

Twenty skills gaps were identified as MTP priority skills gaps, both emerging and well-known gaps

These skills gaps will need to be addressed for Australia to build an MTP sector workforce that can deliver desired health outcomes for the community and, more broadly, support an economy that is more resilient to diseases and future biosecurity threats.

MTPConnect is taking a leading role in closing the skills gap in Australia, funding several programs that target the gaps identified. REDI now has 13 industry partners, delivering 31 training programs with over 2,215 targeted recipients in 2021.

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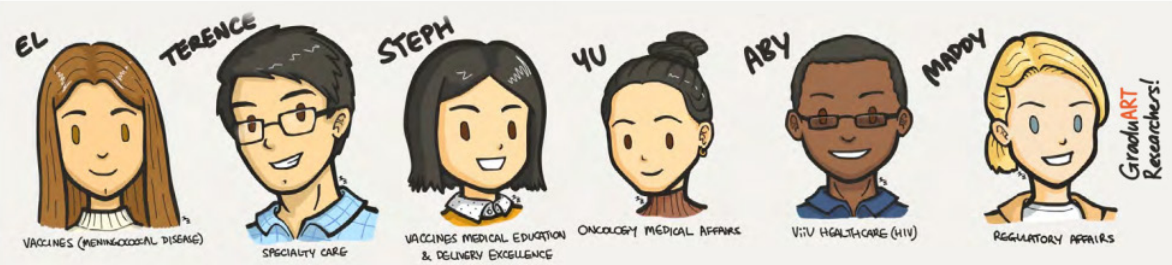
Workforce skills Spotlight: REDI skills gap analysis and assessment (continued)

Summary of priority skills gaps

Workforce skills Spotlight: GSK Graduate Researcher Program



Pictured: caricature of the six GSK graduate researchers. Image reproduced with kind permission from Dr Stephanie Yee.

Graduate Researcher ProgramGSK Australia is helping to bridge the skills gap between academia and the pharmaceutical industry, through its new three-year program for PhD graduates supported by MTPConnect's REDI initiative.

The GSK Australia Graduate Researcher Program, was launched in March 2021 and is the organisation's first program to offer PhD graduates hands-on experience in the medicines and vaccines industry.

Over the course of a 12-month placement, six PhD graduates will make meaningful contributions to key GSK business units, including regulatory and medical affairs in oncology, respiratory, vaccines and more. Six places will be available each year, over a three-year timeframe.

GSK Australia's program has been developed in partnership with MTPConnect's $32 million REDI initiative – funded through the MRFF and designed to facilitate the cross pollination of scientific, academic research expertise with that of the pharmaceutical industry.

Dr Stephanie Yee, a graduate researcher participating in the 2021 GSK program is confident that the program will continue to be instrumental in broadening her professional portfolio and building meaningful connections in the pharmaceutical industry.

"The GSK Graduate Researcher Program has been an eye-opening experience. I've really enjoyed exploring different areas of the business and seeing how researchers can make an impact in industry. Working alongside industry experts here at GSK has also given me an opportunity to broaden my skillset, and I'm incredibly thankful for the support and mentorship that I've received along the way," Dr Yee said.

GSK is committed to working closely with leading local researchers and clinicians to ensure that Australian patients can access the latest global innovations. The contributions of this cohort of graduate researchers to its projects and operations will be important in driving innovation for Australian patients. Recruitment for the 2022 intake of the GSK Australia Graduate Researcher Program opened in October 2021.

For more information, visit www.au.gsk.com/en-au/home/

Optimising Regulatory and Policy Environment spotlight: Clinical trials

Clinical trials, an important part of the commercialisation pathway for medical products, were a major focus for MTPConnect over the last two years. MTPConnect released a major new report, Australia's Clinical Trials Sector: Advancing innovative healthcare and powering economic growth, which reveals the size and scope of Australia's clinical trials sector and opportunities for future growth.

Key findings from the report, which serves as an important resource for the sector, include:

- $1.4 billion contributed to the Australian economy in 2019
- Employs more than 8,000 Australians
- 95,000 Australians participated in clinical trials in 201

Launched in May 2021, the report involved extensive and whole-of-sector stakeholder engagement, including an advisory group convened to guide the scope of the report, as well as AusBiotech, Medicines Australia, MTAA and the R&D Task Force.

Importantly, the report identified aspects of the regulatory and policy environment that were driving Australia's competitive advantage in clinical trials, as well as those presenting barriers to further growth in clinical trials activity in Australia.

The table below summarising the key regulatory and policy drivers of competitive advantage and impediments respectively.

Drivers of competitive advantage	Impediments
Convenience and speed of the TGA CTN and ethics approval	Lengthy and highly variable site governance approval process
R&D Tax Incentives (R&D TI)	

The report highlights that clinical trials are an essential part of health and medical research and can lead to better health outcomes for patients. It identifies four emerging opportunities to capture a greater share of global clinical trials over the next 10-years. These relate to building our capability in precision healthcare in trials and undertaking innovative clinical trial design, applying digital health innovations to enhance patient recruitment and achieve efficiencies, and an increased focus on patient awareness and engagement to increase recruitment.

The findings of the report have since been useful in galvanising cross-sector support for key initiatives and programs that can help maintain the drivers of competitive advantage identified (e.g. R&D TI), as well as address the impediments (e.g. continued focus on streamlining ethics and governance processes).

Improving Access to Global Supply Chains and Markets Spotlight: MTPConnect COVID-19 reports

The MTP sector has been on the frontline for research, diagnosis, management, prevention and treatment of infectious diseases in the COVID-19 pandemic.

Over two reports, launched in June and October 2020, MTPConnect interviewed senior sector leaders to understand the burden of the pandemic and lockdown restrictions. The reports were developed with input from senior sector executives, through an online survey and targeted stakeholder consultations.

Across these reports, MTPConnect highlighted a number of impacts felt by businesses due to COVID-19, including:

- An inability to conduct existing clinical trials and source participants for new trials, with up to 90 per cent of clinical trials put on hold[45]
- Delays to/lack of funding for new and on-going R&D efforts (typically smaller biotech organisations rather than large pharma) with some funding organisations, such as the NHMRC, having to delay or cancel certain grant funding rounds due to pandemic impacts on clinical trials and research[46]
- Supply chain challenges in sourcing critical input materials and facilities for R&D, as well as commercial operations with air freight costs, have increased between three to 10 fold during the pandemic compared to the typical pre-COVID costs[47]
- Changes in demand for end-user products with the pivot to digital/virtual healthcare delivery
- a reduction in operating cash flow, impacting the business sustainability for companies servicing elective surgery patients.

With the global experiences of COVID-19, it is also widely accepted that an opportunity exists to learn from this experience and undertake actions to be better prepared for future pandemics. Through MTPConnect's research and consultations, three key actions have been identified for federal, state and territory governments and MTP sector organisations to embrace relating to improving global supply chain resilience. These include:

- Enhance sovereign supply/manufacturing capabilities: COVID-19 has highlighted that it is important for Australia to retain sovereign capability in the manufacture of essential medical equipment and supplies that are critical to Australians in times of crisis. In order to better prepare for future pandemics, there are three key steps that should be undertaken: (1) Identify areas where sovereign capability is required, (2) Identify key gaps in existing infrastructure and capabilities, (3) Invest and build infrastructure and capabilities in key gap areas
- Enhance advanced manufacturing capability to enable more effective pivoting of production during pandemics: There is an opportunity for Australia to improve the quality standards of the manufacturing capability that exists in and around the MTP sector. Doing so would enable a greater proportion of Australian manufacturers to contribute to pandemic response efforts when required in the future, and help strengthen supply chain resilience within Australia. Australia should enhance its advanced manufacturing capabilities in areas such as production of novel therapeutics/vaccines, development of medical devices for diagnostic testing and digital technologies that can enable a more effective pandemic response.
- Diversify MTP sector supply chains: As a result of COVID-19, organisations have experienced significant disruptions to their global supply chains and logistics operations. With 90 per cent of air freight carried in passenger planes prior to COVID-19, the reliance on air freight, in particular, has had a significant impact on companies as the volume and frequency of global air traffic has dramatically reduced during the pandemic.

[45] MTPConnect, COVID-19 Impact Report, June 2020
[46] NHRMC, Update – Changes to NHMRC 2020 funding schemes, March 2020
[47] MTPConnect, COVID-19 Impact Report, June 2020

Improving Access to Global Supply Chains and Markets Spotlight: SpeeDx and SynGenis

Pictured: SpeedDx and SynGenis teams meet in Perth to discuss oligonucleotides supply.

A new partnership between Perth-based oligonucleotides manufacturer SynGenis and Sydney-based diagnostic company SpeeDx has led to an investment and ongoing collaboration between the two companies.

SpeeDx is a privately owned company that specialises in innovative multiplex real-time quantitative polymerase chain reaction (qPCR) solutions for clinical diagnostics. The Sydney-based organisation has a portfolio of kits for detection of infectious disease pathogens and antimicrobial resistance markers, including COVID-19.

In the wake of the pandemic, demand rose for diagnostics along the supply chain, but SpeeDx faced constrained supply of oligonucleotides (oligo) which are a critical component of its diagnostic kits. Oligonucleotides are molecules, oligomers, that have a wide range of applications in genetic testing, research and forensics. When Australia's last oligo manufacturer closed its doors in late 2019, the company was forced to look to overseas manufacturing facilities for supply.

"[We were] totally reliant on overseas production suppliers, and suppliers that the rest of the world were reliant on. It seems that everyone was scaling up at the exact same time," SpeeDx CEO, Colin Denver said.

"Oligo lead times from the overseas suppliers were up to a year for more complex molecules. A typical lead time before COVID was a month," SpeeDx Director of Operations, Tom Lin added.

Perth start-up SynGenis was established in late 2020 by Associate Professor Rakesh Veedu, who had run the oligonucleotide synthesis service out of the Murdoch University campus in Western Australia. The company operates a large facility in Technology Park Bentley to manufacture high quality oligonucleotides for the Australian and New Zealand market, and international customers.

In early 2021, MTPConnect Directors of Stakeholder Engagement (for Western Australia and New South Wales, respectively), Dr Tracey Wilkinson and Dr Duncan Macinnis, organised an introduction between the two organisations, having recognised synergies in their activities.

"When I heard about SynGenis, it seemed like a great fit for SpeeDx – their values and commercial needs aligned," Dr Macinnis said. "The success of their collaboration is indicative of the many opportunities that the MTP sector has to connect stakeholders across all geographical and interest areas, building our industries' expertise and capability as 'Team Australia'."

Within five days of MTPConnect setting up the first introductory meeting, SynGenis had sent SpeeDx a shipment of oligos for a supplier assessment – a record supply time! This initial partnership allowed SpeeDx to meet an obligation to a large overseas customer and set the foundation for a longer-term collaboration.

Dr Wilkinson believes that the pandemic has reaffirmed the importance and value of MTPConnect's nation-wide team in assisting collaboration and commercialisation efforts across the sector, regardless of geographic distance.

...continued

Improving Access to Global Supply Chains and Markets Spotlight: SpeeDx and SynGenis (continued)

"This successful partnership is a great illustration of how combining our on-the-ground awareness and local knowledge of the sector within MTPConnect's national team can identify opportunities for collaboration. Without strong communication and strategic connections across the country, the sector risks missing opportunities like this – opportunities that then head overseas, which is not ideal for suppliers, customers, patients, or the economy and jobs," Dr Wilkinson said.

The ability to solve domestic challenges with domestic solutions has proven to be an effective way to combat supply resilience issues and enable potential expansion in domestic and international markets in the future. SynGenis and SpeeDx are both excited to see where those future opportunities take them, after SpeeDx announced an investment in SynGenis in October.

What started as an exploratory introduction between two companies has led to a financial investment that will support the expansion of SynGenis to provide reliable, high quality large-scale oligos and bolster the capacity of SpeeDx to support large-scale increases in manufacturing.

"Moving forward, it's exciting to be increasing local capacity at a time when we really had no local options. Having our two companies aligned means we can better respond to Australian and international commercial demands," Mr Lin said.

"It is an absolute pleasure that we have this partnership now, which is based in Australia, and manufactured in Australia, and supplied in Australia," said SynGenis Founder and Managing Director, Associate Professor Veedu.

MTPConnect's matchmaking means SpeeDx and Syngenis can now develop and expand the sovereign capacity of important raw materials used in molecular diagnostics and also expand efforts in the global diagnostic market.

NB: SpeeDx is also a BTB program Round 1 recipient, seeking to commercialise its ResistancePlus® MABSC/MAC test – a rapid in vitro diagnostic tool to accurately and quickly identify bacterial infections related to cystic fibrosis, while using gene markers to predict antibiotic susceptibility or resistance.

For more information: www.plexpcr.com and www.syngenis.com

5. Sector Knowledge Priorities

Introduction

Knowledge Priorities (KPs) are meant to provide guidance for sector investment and activities towards areas where patient outcomes can be realised and opportunities exist for strong returns. KPs represent areas where there is a high level of unmet need globally and where Australia is, or has the potential to be, a leading contributor.

They are categorised into the following five 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/capability areas** – 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 five areas. As a recent example, success in developing vaccines will rely on focusing on microbiology (area of science) and infectious disease (therapeutic area).

Methodology

In 2019, MTPConnect first established a robust, independent assessment of KPs and tested these with stakeholders across the 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 two years (2020 and 2021). The universe of potential KPs have been identified using a framework that considers:

- 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
- skills and capability gaps within the current workforce and the future need of such skills
- 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.
- **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 should continue be revisited and updated as they evolve over time. The detailed methodology and data used to identify KPs are laid out in Appendix 4.

Knowledge Priorities identified

Current Knowledge Priorities

Overall, six areas of science, 10 therapeutic areas, six device/diagnostic areas, 20 skills/capability areas and four other existing national priorities were identified as Current KPs in 2022. There were two new additions to the current KPs list and one current KP that was broadened in scope, as highlighted in the table below. These new additions are discussed in more detail later in this section.

LIST OF CURRENT KPs (BOLD = NEW)	
AREAS OF SCIENCE	Biochemistry and cell biology (including synthetic biology) Psychology and cognitive sciences Genetics and precision medicine Microbiology Immunology Paediatrics and reproductive medicine
THERAPEUTIC AREAS	Cardiac and Cardiovascular systems **Ophthalmology and Optometry** Diabetes, endocrinology and metabolism Respiratory disorders (asthma) Aged and palliative care Arthritis and musculoskeletal conditions Neurosciences and Neurology Infectious disease (including tropical disease and medical countermeasures) Oncology Aboriginal and Torres Strait Islander Health
DEVICE/ DIAGNOSTIC AREAS	Wearable device **Diagnostic device (point of care (POC), lab and patient)*** Implantables and bionics Surgical devices and consumables Digital health/monitoring **Sterile/protective equipment**

...continued

LIST OF CURRENT KPs (BOLD = NEW)

OTHER EXISTING NATIONAL PRIORITIES

Drug repurposing
Biosecurity
Data science
Rare diseases

SKILLS/ CAPABILITIES

Advanced manufacturing and supply chain

Understanding of Quality Management Systems (QMS) and protocols

Manufacturing expertise in high-tech and/or specialised medtech devices

Manufacturing expertise in high-value therapeutics at a commercial scale

Business operations

Shortage of MTP-specific project managers to support start-ups and spin-offs

Clinical trials

Strategic design of clinical trials to address regulatory and payer needs

Shortage of experienced Clinical Research Associates (CRAs)

Shortage of Clinical Trial Coordinators (CTCs)

Health data and cybersecurity

Leadership awareness about the value of best-practice management in cybersecurity

Shortage of cybersecurity professionals and IT infrastructure resilience skills within MTP

Understanding of and expertise in big data capture, management and analysis

Expertise in the design and use of artificial intelligence (AI) within MTP

Shortage in skills in health informatics

Health economics and regulatory affairs

Awareness and understanding of regulatory requirements amongst start-ups and SMEs

Shortage of experienced health economists

Product development and commercialisation

Shortage of industry professionals with end-to-end translation and commercialisation experience

Ability to identify unmet market need and understand the clinical context

Ability to secure investment, funding and/or industry collaboration

Identification of the payer and understanding of reimbursement pathways and requirements

Specialist and technical skills

Shortage of skills in bioinformatics (particularly in genomics)

Notes: * In 2021, diagnostic devices (POC/lab) KP was broadened to explicitly include consumer-focused diagnostic devices which have become increasingly inter-related with POC/laboratory. Together, diagnostic devices (POC, lab and patients) has been elevated as a Current KP devices

Areas of science

The six science areas identified in 2020 remain relevant today. This reflects areas where Australia is among the top 10 in high-quality research publications internationally, and areas that are in the top 10 in terms of national competitive grant funding attracted over the past four years. Many of these areas are fundamental research priorities that underpin biological discovery and are the basis for generating commercialisation opportunities in relevant therapeutic and device/diagnostic areas.

Therapeutic areas

Ten therapeutic areas have been identified as Current KPs, with one new addition this year. Oncology, infectious diseases (including AMR), neurosciences, cardiovascular disease, diabetes, endocrinology and metabolism, respiratory disorders and arthritis and musculoskeletal conditions are all diseases that are among the most prevalent globally and have the most impact on healthcare systems. In addition, a continued focus on aged and palliative care as a KP is relevant in the context of an ageing population. Aboriginal and Torres Strait Islander Health also remains a current KP, consistent with the national priorities laid out by the NHMRC and the MRFF.

Ophthalmology and optometry has been elevated from an emerging KP to a current KP this year, reflecting Australia's strengthening capability, the strong global sales forecast for 2025 ($36 billion) and recent commercial success over the last 24-months. In this area alone, 14 additional clinical trials commenced in 2020-2021.

Device/diagnostic areas

One additional device/diagnostic KP, sterile/protective equipment, was added this year to the five device/diagnostic areas identified in the 2020 report. COVID-19 highlighted the importance of having sovereign manufacturing capability for critical sterile/protective equipment such as face masks, hand sanitisers, etc. The elevation of this KP reflects the government's growing focus on encouraging domestic capabilities in areas such as PPE manufacturing to help strengthen Australia's resistance to threats and emergencies. This is consistent with the NHMRC's new health priority introduced in its 2021-22 Corporate Plan of 'strengthening resilience to emerging health threats and emergencies, including environmental change, pandemics and antimicrobial resistance'.[48]

In addition, the diagnostic devices (POC/lab) KP was broadened to explicitly include consumer-focused diagnostic devices, which have become increasingly inter-related with POC/laboratory devices. The broadened KP, diagnostic devices (POC, lab and patients) is relevant as a Current KP due to new ASX listings, success stories and heightened interest due to COVID-19. Over 2020-21, six new ASX listings were recorded which included Atomo, known for rapid antigen tests (RATs), and Truscreen Group, known for cervical cancer devices, as were five success stories in areas ranging from cardio to gut health testing and two notable licencing deals with Telix Pharma and SpeeDx.

Four other current KPs remain relevant from 2019. They are:

- Wearable sensors include portable devices such as blood pressure sensors, hearing and sleeping aids
- Implantables include custom-made 3D printed implants and bionics, that are used as prosthetics in surgical environments
- 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
- Digital health/monitoring refers to big data analytics, portable devices and smartphone apps that provide consumers and healthcare professionals with instantaneous access to patient's health status, including smart inhalers, diabetes management apps and mental health management apps.

[48] National Health and Medical Research Council, NHMRC Corporate Plan 2021–22 Canberra: National Health and Medical Research Council, 2021

Skills and capabilities

In 2020, MTPConnect completed the first comprehensive 'root and branch' skills audit of the MTP sector in Australia. Over a series of three reports published in 2020 and 2021, MTPConnect conducted a review of current and future skills gaps in the MTP sector to help identify skills gaps not currently addressed by the sector. The skills gaps identified must be addressed to enable the Australian MTP sector to continue to flourish and become a leader in the global MTP arena.

In the *REDI Initiative Skills Gap Analysis Second Report*, a total of 76 distinct skills gaps were identified across the Australian MTP sector and along the global value chain.[49] Of the 76 gaps identified, 20 were categorised as priority across seven themes including:

- Advanced manufacturing (e.g. cell and tissue manufacturing, 3D printing) and supply chain
- Business operations
- Clinical trials
- Health data and cybersecurity
- Health economics and regulatory affairs
- Product development and commercialisation
- Specialist and technical skills.

Other existing national priorities

Four other KPs were included on the basis that they are national priorities as identified by the MRFF, but do not fit into any of the four areas above. These KPs are:

- 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.
- Data science – the use of scientific methods, processes, algorithms and systems to extract knowledge and insights from data which has also been captured as a priority skills gap.
- 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

Nine emerging KPs have been identified in 2022. Eight of these were all identified in 2019 and continue to remain relevant today. They include: human movement and sports science, medical physiology, medical biotechnology, nanotechnology, biomedical engineering, pain management, dermatologicals and regenerative medicine. One new emerging KP – cardiovascular medicine and haematology – has

[49] MTPConnect, REDI Initiative Skills Gap Analysis Second Report, 2020

been identified. It should be noted that optometry and ophthalmology was changed from an emerging KP to a current KP in the SCP2022 as noted earlier.

SCIENCE AREAS	THERAPEUTIC AREAS
Cardiovascular medicine and haematology	Regenerative medicine
Human movement and sports science	Pain management
Medical physiology	Dermatologicals
Medical biotechnology	
Biomedical engineering	
Nanotechnology	

Areas of science

Cardiovascular medicine and haematology has emerged as a KP over the past two years. Australia has maintained its global position in terms of high-quality publications (10th in the world) and grown funding for this sector. Research funding has been aided by the establishment of the MRFF's Cardiovascular Health Mission, which aims to invest $220 million in research over 10 years.[50]

Therapeutic areas

Regenerative medicine, pain management and dermatologicals 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. 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. In 2020-21, Australia has taken significant steps to improve its regenerative medicine capability through the establishment of the Regenerative Medicine Catalyst Body in September 2020, to boost research and commercial opportunities in Australia. The Catalyst Body will further strengthen Australia's regenerative medicine ecosystem, which comprised of more than 60 companies developing products and more than 130 clinical trials being conducted in 2021.[51] Australia now accounts for 11 per cent of ongoing clinical trials investigating regenerative medicine.[52]

[50] MRFF Cardiovascular Health Mission website, accessed on 3 February 2021
[51] Australia's Regenerative Medicine Clinical Trials Database. Regenerative Medicine Catalyst Project, 2021
[52] A total of 1,220 clinical trials were ongoing in 2021. Alliance For Regenerative Medicine, State of the Industry Briefing 2021. alliancerm.org

Appendices

Appendix 1: Glossary of terms

AAMRI	Association of Australian Medical Research Institutes
ACOLA	Australian Council of Learned Academies
AHMADA	Australian Health Manufacturers and Development Association
AHRTC	Advanced Health Research and Translation Centre
AI	Artificial Intelligence
AMA	Australian Medical Association
ARC	Australian Research Council
AMGC	Advanced Manufacturing Growth Centre
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
COVID-19	Coronavirus Disease
CRC	Cooperative Research Centre
CRO	Contract Research Organisation
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DISER	Department of Industry, Science, Energy and Resources
GVA	Gross Value Added
GVC	Global Value Chain
HMR	Health and Medical Research
IMNIS	Industry Mentoring Network in STEM
IGC	Industry Growth Centre
IP	Intellectual Property

...continued

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
PPE	Personal protective equipment
QUT	Queensland University of Technology
REDI	Research Exchange and Development with Industry Initiative
R&D	Research and Development
RM	Regenerative Medicine
SCP	Sector Competitiveness Plan
SME	Small and Medium-sized Enterprises
STEM	Science, Technology, Engineering and Mathematics
TGA	Therapeutic Goods Administration
TI	Tax Incentive
TTO	Technology Transfer Office
VC	Venture Capital

Appendix 2: Summary of example participants across the MTP sector

Example participants across the MTP sector are included below.

	Example participants	
Private sector organisations	• SMEs and start-ups • Large medical technology and pharmaceutical companies • CROs	
Institutions	• Universities • Medical Research Institutes • Government (departments and 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)
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)	

Appendix 3: Detailed summary of MTP sector priorities

Priority 1: Align investment in Knowledge Priorities to 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 2022, MTPConnect refreshed its assessment of KPs based on 2020-21 data accounting for the impact of COVID-19 on KPs. These KPs and the methodology applied to identify them are described in Section 5.

Description/ purpose of priority	• To align R&D investment in the KPs identified to optimise commercialisation potential for current and future areas of need • To ensure a sufficient percentage of R&D spending (not 100 per cent) is allocated and targeted to these KP areas
Current constraints and 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, increased grant funding and targeted application criteria can better align to 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 talent due to long-term funding uncertainty • 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.[53] For example, the 2021 INSEAD Global Innovation Index ranks Australia 15th in terms of innovation input and 33rd in innovation output, but when these figures are converted to innovation efficiency ratio, Australia ranks 25th out of 132 countries assessed.[54] 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.

[53] McKeon Review, 2013, Chapter 6
[54] WIPO (2021). Global Innovation Index 2021: Tracking Innovation through the COVID-19 Crisis. Geneva: World Intellectual Property Organization

Description/ purpose of 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 and 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 national 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

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 medical technology 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 medical technology and digital health development pathways are usually shorter and more likely to be commercialised locally. Therefore, transforming the medical technology 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 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 and 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 medical technology 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 contributes c.$1.4 billion to Australia's economy annually, generating more export revenue than construction, intellectual property charges and government services.[55] It has a global reputation for clinical trials excellence, which has made Australia a go-to destination for companies wanting to conduct clinical trials and seen the clinical trials sector develop into one of the country's most important and valuable services exports. Clinical trials are a critical step in the research and development process for new drugs, vaccines, medical devices and diagnostics. Australia's clinical trial industry is facing competition from Europe, South America and Asia that can offer access to large patient populations. COVID-19 has driven further recognition of Australia's strengths in clinical trials, where Australia's effective pandemic response with many COVID-19 restrictions eased, saw a rebound of trials and relative to peers.[56]

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.

For further reading on the clinical trials sector in Australia, refer to the MTPConnect 2021 report, Australia's Clinical Trials Sector.

[55] Department of Foreign Affairs and Trade, Trade and Investment at a Glance, 2020
[56] MTPConnect. (2021). Australia's Clinical Trials Sector. mtpconnect.org.au

Description/ purpose of 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 and 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 COVID-19 pandemic drove a surge in the global adoption of digital healthcare solutions to improve patient outcomes. This area of the sector is poised for future growth as the development of digital devices and datasets enables new software solutions and healthcare platforms, to 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 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 keep patient information records safe
Current constraints and 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 the 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 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 and 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.

COVID-19 has highlighted the importance of development of advanced manufacturing capabilities as a key national priority. The Australian government recognised the benefit of nurturing advanced manufacturing and has been optimising policies to incentivise growth in this area. The focus has been on building mRNA manufacturing capabilities, with the Australian Government, along with the Victorian Government recently reaching an in-principle agreement with global pharmaceutical company

Moderna, to establish mRNA respiratory vaccine manufacturing in Australia. This will be the first onshore manufacturing of mRNA vaccines for Australia and will provide capacity to create up to 100 million vaccine doses a year.[57] This offers the opportunity for Australia to be a global and regional centre of research and manufacturing.

Description/ purpose of 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 and 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

[57] The Australian Government, Health Minister Update, December 2021

Appendix 4: 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 six years. This is calculated by multiplying the total number of published documents by the percentage of publications that placed in the top 10 per cent based on citations by category, year and document type. Australia's global ranking in each area of science is shown in the data table on page 60. 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 six 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. 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 near the top 10 for academic strength, but are yet to receive significant grant funding (highlighted in yellow on page 60).

It should be noted that the ARC is currently in the process of transitioning to a new Fields of Research (FoR) classification system. This transition is expected to be completed by mid-2022. In this SCP, where publications data was available in the new FoR classification system, this has been mapped back onto the existing FoR classification for consistency with prior data. However, the FoR codes reported below may need to change in future updates after 2022.

Table 1: Analysis of areas of science KPs

Areas of Science		**AUS capability**		
Relevant MTP ARC 2-digit codes **Area of science**	*Relevant MTP ARC – 4 digit codes*	**Academic strength (2016-21)** *Aus global ranking in each area of science*[1]	**Competitive grants (2016-21)** *Total funding ranking – NHMRC + ARC*[2]	**Shortlisted as KP?**
Medical and Health Sciences	Medicinal and biomolecular chemistry	15	14	No
	Biochemistry and cell biology[5]	11	2	Yes
	Genetics	8	4	Yes
	Microbiology[3]	7	16	No
	Biomedical engineering	8	13	Yes (emerging)
	Industrial biotechnology	8	24	Yes (emerging)
	Medical biotechnology	11	11	Yes (emerging)
	Nanotechnology	6	15	Yes (emerging)
	Medical biochemistry and metabolomics	11	20	No
	Cardiovascular medicine and haematology	10	7	Yes (emerging)
	Clinical sciences	9	1	Yes[4]
	Dentistry	11	23	No
	Human movement and sports science	3	22	Yes (emerging)
	Immunology	6	6	Yes
	Medical microbiology[3]	8	8	Yes
	Neurosciences	10	3	No[6]
	Oncology and carcinogenesis	12	5	No
	Optometry and ophthalmology	6	17	Yes[7]
	Paediatrics and reproductive medicine	8	9	Yes
	Medical physiology	7	19	Yes (emerging)
	Pharmacology and pharmaceutical sciences	11	12	No
Psychology and Cognitive Sciences	Psychology	7	10	Yes[6]
	Cognitive science	6	21	No[6]
	Other psychology and cognitive sciences	3	25	No[6]
	Indigenous peoples	4	18	Yes (TA)[8]

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

Notes for Table 1: Analysis of areas of science Knowledge Priorities:

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 per cent 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. Biochemistry and cell biology has been included despite being ranked outside of the top 10 for Academic Strength, given its particular relevance in the MTP sector. It should be noted that the number of publications included in the top 10 increased since 2019 as did the number of quality publications. This has been left as a KP
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 current areas of science due to its overlap with the equivalent therapeutic area. Optometry and ophthalmology has been included in the list of current KP in the therapeutic areas
8. Indigenous peoples has been excluded from the list of emerging areas of science, due to its overlap with the equivalent therapeutic area. Indigenous peoples has been included in the list of current 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 2022-24 report and on the MRFF website)
    b. NHMRC priorities (listed in the NHMRC Corporate Plan 2021-22)

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 projected 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		AUS capability						Existing priorities		Shortlisted as KP?
		Global sales 2025 ($b)	Global sales forecast CAGR (%)	# of ASX companies	Success Stories	Licensing Deals	# MRIs researching	# Clinical trials[5]	% global trials[5]	MRFF	NHMRC	
Cardiac and Cardiovascular sys	SCP '16	91	1.0%	11	3	1	20	57	27%	1	0	Yes
Diabetes, endocrinology & metabolism		59	2.9%	2	3	1	15	31	17%	1	0	Yes
Immunology		58	12.9%	6	1	2	24	N/A	N/A	0	1	Yes[6]
Neurosciences & Neurology		36	3.5%	16	2	0	29	123	29%	1	0	Yes
Obesity		18	13.4%	0	0	0	4	N/A	N/A	0	0	No
Oncology		264	11.4%	25	13	10	29	710	45%	1	0	Yes
Ophthalmology and Optometry		32	6.3%	4	0	0	9	22	37%	0	0	Yes[7]
Pain management		83	4.0%	17	1	2	3	N/A	N/A	0	0	Yes (emerging)
Respiratory disorders (asthma)		45	4.2%	10	2	0	11	119	40%	0	0	Yes
Sleep		3	5.3%	5	0	1	5	N/A	N/A	0	0	No
Arthritis & musculoskeletal conditions		75	(1.1%)	5	0	1	9	44	29%	0	0	Yes
Haemotology		66	3.2%	3	0	1	3	N/A	N/A	0	0	No
Infectious disease (including tropical disease and medical countermeasures)		91	3.8%	10	8	4	18	80	30%	1	1	Yes
Otorhinolaryngology		12	3.2%	2	0	0	2	N/A	N/A	0	0	No

...continued

Therapeutic Areas	Source	Global trends		AUS capability						Existing priorities		Shortlisted as KP?
		Global sales 2025 ($b)	Global sales forecast CAGR (%)	# of ASX companies	Success Stories	Licensing Deals	# MRIs researching	# Clinical trials[5]	% global trials[5]	MRFF	NHMRC	
Paediatrics and Reproductive Medicine[1]	SCP '16	152	3.5%	4	0	0	12	N/A	N/A	0	0	Yes
Reproductive Endocrinology		23	9.3%	0	0	0	0	N/A	N/A	0	0	No
Surgery		23	5.7%	4	0	0	0	N/A	N/A	0	0	No
Regenerative medicine	SCP '20	120	N/A	6	1	2	1	0	-	0	0	Yes (emerging)
Dermatologicals	Evaluate Pharma	36	12.5%	8	2	0	2	N/A	N/A	0	0	Yes (emerging)
Nephrology	Evaluate MedTech	16	4.2%	3	1	1	5	29	48%	0	0	No
Aborginal and Torres Straight Islander Health	MRFF, NHMRC	7	3.4%	0	0	0	5	N/A	N/A	1	1	Yes
Aged and palliative care		1,091	7.3%	2	1	0	7	N/A	N/A	1	0	Yes

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

Notes:

1. 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'
6. Immunology has already been included as a KP in the areas of science
7. Ophthalmology and optometry has been elevated from an emerging KP to a current KP this year, reflecting Australia's strengthening capability, the strong global sales forecast for 2025 ($36 billion) and recent commercial success over the last 24-months. In this area alone, 14 additional clinical trials commenced in 2020-2021

Device/diagnostic areas

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

As on page 63 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 2022-24 report and on the MRFF website), and
    b. NHMRC priorities (listed in the NHMRC Corporate Plan 2021-22)

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 projected 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/Diagnostic areas	Source	Global trends	Global trends	AUS capability			Existing priorities		Shortlisted as KP?
		Global sales forecast 2025	Global sales forecast CAGR	ASX	Success Story	Licensing Deals	MRFF priorities	NHMRC Priorities	
Wearable device	SCP '16	77	15.5%	14	4	0	0	0	Yes
Diagnostic device-patient and POC/lab	New[1]	90	6.2%	33	14	4	0	0	Yes
Drug delivery	SCP '16	26	4.6%	7	1	1	0	0	No
Sterile/protective equipment	SCP '16	12	7.0%	1	1	0	0	0	No
Implantables and bionics	SCP '16	126	6.2%	7	5	0	0	0	Yes
Surgical devices and consumables	SCP '16	107	7.5%	9	3	0	0	0	Yes
Digital health/ monitoring	MRFF, NHMRC	505	19.4%	22	3	0	1	0	Yes
Dental	Evaluate MedTech	23	6.5%	1	1	0	0	0	No

Keys Current device/diagnostic area

Notes:

1. In this SCP, Diagnostic devices (POC/lab) KP was broadened to explicitly include consumer-focused diagnostic devices, which have become increasingly inter-related with POC/laboratory. Together, diagnostic devices (POC, lab and patients) has been elevated as a Current KP devices

Skills/capabilities areas

For more detail, refer to *REDI Skills Gap Analysis Reports*

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 four areas above.

Table 4: Analysis of broader landscape area KPs

Broader landscape areas	Source	Existing priorities		KP Shortlist
		MRFF	NHRMC	
Drug repurposing	MRFF	Yes	No	Yes
Biosecurity	MRFF	Yes	No	Yes
Data science	MRFF	Yes	No	Yes
Rare diseases	MRFF	Yes	No	Yes

Appendix 5: References

Author(s)	Title	Year
Alliance for Regenerative Medicine	2020: Growth & Resilience in Regenerative Medicine, Annual Report Cell & Gene State of the Industry Briefing	2021
Alliance for Regenerative Medicine	State of the Industry Briefing 2021	2021
ASX	ASX listed company database	2021
Australian Bureau of Statistics	ABS6291.0.55.003- EQ06 – Employed persons by Industry group of main job (ANZSIC), Sex, State and Territory	2021
Australian Bureau of Statistics	ABS5368, tables 12A & B: International Trade in Goods and Services, Australia, Dec 2018- 2022	2021
Australian Bureau of Statistics	8104.0- Research and Experimental Development, Businesses, Australia, 2017-2020	2021
Australian Bureau of Statistics	6202.0 – Australian Labour Force	2021
Australian Bureau of Statistics	5204.0 – Australian System of National Accounts for financial year 2020-21	2021
Australian Bureau of Statistics	ABS8165.0 – Counts of Australian Businesses, including Entries and Exits, Jun 2013 to Jun 2021	2021
Australian Federal Government	Healthy Ageing Summit – Report of Discussion and Outcomes	2019
Australian Government	The Australian Government's Modern Manufacturing Strategy	2020
Australian New Zealand Clinical Trials Registry	Database for clinical trials started in Australia	2021
Australian Research Council	National Competitive Grants Program Dataset – NCGP Projects Field of Research Collection (New & Ongoing Projects)	2021
Australian Research Council	National Competitive Grants Program Dataset – NCGP Project and Fellowship Collection (New & Ongoing)	2021
Australian Research Council	National Competitive Grants Program Dataset – NCGP Project Field of Research Collection (Completed Projects)	2021
Australian Research Council	National Competitive Grants Program Dataset – NCGP Project and Fellowship Collection (Completed)	2021
Biomedical Translation Fund	Biomedical Translation Fund Factsheet	2016
Bioshares	Bioshares quarterly reviews newsletter	2016-21
BIS Research	Global Biosensors Market Analysis and Forecast (2018–2027)	2018
Clinicaltrials.gov	Clinical trials database	2021
Department of Foreign Affairs and Trade	Composition of Trade Australia 2018-19	2020
Ernst Young	Global IPO Trends reports	2021

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Author(s)	Title	Year
EvaluateMedTech	World Preview 2018, Outlook to 2024	2018
EvaluatePharma	World Preview 2019, Outlook to 2024	2019
Grant Thornton	Federal Budget: a 10-year retrospective	2020
Hanna Demeke, Sharifa Merali, Suzanne Marks	Trends in Use of Telehealth Among Health Centres During the COVID-19 Pandemic	2021
InCites	InCites Datasets for research areas, by location. This includes Web of Science content indexed throughout	2019
Jim O'Neil	Tackling Drug-Resistant Infections Globally: Final Report and Recommendations	2016
Lisa Koonin, Brooke Hoots, Clarisse Tsang	Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic	2020
Lola Kola, Brandon Kohrt, Charlotte Hanlon	COVID-19 mental health impact and responses in low-income and middle-income countries: reimagining global mental health	2021
Medical Research Future Fund	2021-22 Priorities Consultation Discussion Paper	2021
Medscape	FDA Approval Process for Medical Devices	2013
Michael E. Porter	A Strategy for Health Care Reform – Toward a Value-Based System	2009
National Health and Medical Research Council	Update – Changes to NHMRC 2020 funding schemes	2021
National Health and Medical Research Council	NHMRC Corporate Plan 2021–22	2021
National Health and Medical Research Council	National Health and Medical Research Council grant announcements	2016-21
Oliver Wouters, Martin McKee and Jeroen Luyten	Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018'	2020
Organisation for Economic Co-operation and Development (OECD)	Digital Transformation in the Age of COVID-19: Building Resilience and Bridging Divides, Digital Economy Outlook 2020 Supplement	2020
Regenerative Medicine Catalyst Project	Regenerative Medicine: Opportunities for Australia	2021
Regenerative Medicine Catalyst Project	Australia's Regenerative Medicine Clinical Trials Database	2021
Regenerative Medicine Catalyst Project	Australian RM Investments Database	2021
S&P Global	Performance on ASX 200 companies, 2016- 2021	2021
Sang M. Lee and DonHee Lee	Opportunities and challenges for contactless healthcare services in the post-COVID-19 Era, Technological Forecasting and Social Change	2021

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Author(s)	Title	Year
The Federal Government, IP Australia	Australian Intellectual Property Report	2021
The Royal Australian College of General Practitioners	General Practice: Health of the Nation 2020	2020
World Health Organisation	Ageing and Health Factsheet	2018, 2021
World Health Organisation	Managing Epidemics	2018
World Health Organisation	Antimicrobial Resistance Factsheet	2018
World Health Organisation	Antibacterial Agents in Clinical Development – An Analysis of the Antibacterial Clinical Development Pipeline	2020

Note: In addition to these sources, MTPConnect has drawn on a number of internal documents that have not been released publicly.

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