MTPConnect
MedTech and Pharma Growth Centre

MEDTECH, BIOTECHNOLOGY AND PHARMACEUTICAL SECTOR COMPETITIVENESS PLAN

DECEMBER 2016

CONTACT DETAILS

HEAD OFFICE
New Horizons Building, Monash University,
20 Research Way, Clayton Vic 3168

NSW HUB
Level 5, J12 School of IT, University of Sydney,
1 Cleveland St, Darlington NSW 2006

SA HUB
Flinders University at Tonsley,
1284 South Road, Clovelly Park SA 5042

Email: info@mtpconnect.org.au
Website: www.mtpconnect.org.au

ABN 53 608 571 277

ACKNOWLEDGMENTS

The Sector Competitiveness Plan represents the combined input of hundreds of sector participants. MTPConnect would like to thank all those who gave their time to participate in consultations, roundtable discussions, online surveys and one-on-one meetings.

MTPConnect would particularly like to acknowledge the input it received from numerous sector participants in writing this report. Thanks to the CSIRO, particularly for work in relation to megatrends and manufacturing. Special thanks to those who provided early feedback and insights into the Sector Competitiveness Plan: AusBiotech, Association of Australian Medical Research Institutes, BioInnovation South Australia, Life Sciences Queensland, IMNIS, Medical Technology Association of Australia, Medicines Australia, and a number of Australian universities.

MTPConnect would like to thank the Department of Industry, Innovation and Science, the Department of Health, the Department of Education and Training, and each of the state and territory governments.

Thank you to MTPConnect's regulatory advisory committee for providing information about the regulatory environment and helping the team understand the complex issues. MTPConnect also thanks L.E.K. Consulting for its assistance in preparing this document.

MTPConnect
MedTech and Pharma Growth Centre

L.E.K.

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FOREWORD FROM THE CHAIR AND CEO

Dr. Bronwyn Evans
CHAIR

Sue MacLeman
CHIEF EXECUTIVE OFFICER AND MANAGING DIRECTOR

The growth of the Australian economy in the twenty-first century will depend on our ability to develop high-skill, value-adding industries that can compete in the global marketplace. Unless we translate our good ideas into marketable products, the living standards and well-being of all Australians will suffer.

The principal task of MTPConnect is ensuring we seize the opportunities created by our world-leading research into medical technologies, biotechnology and pharmaceuticals (**MTP**). MTPConnect is a new, not-for-profit, independent and industry-led organisation established as one of the Australian Government's Industry Growth Centres.

As set out in this Sector Competitiveness Plan (**SCP**), MTPConnect will work to ensure that Australian research, and the broader health and economic benefits that are generated by the associated clinical trials and commercialisation of that research, no longer slip through the fingers of the local sector.

MTPConnect sits at the nexus of the sector and will complement and work collaboratively with the existing industry associations, research bodies, investors and funders, and government agencies and departments in Australia. MTPConnect has an important role to play in bringing many sector stakeholders together to create a more unified approach to the development and promotion of Australia as an attractive clinical trial destination and research and development (**R&D**) hub.

By addressing the key issue of collaboration, along with well-known barriers—including skills, policy and regulatory impediments—that have limited the MTP sector's growth, MTPConnect will assist local industries to develop into global players and take our R&D output and services to the international market.

With the expanding middle classes of Asia on Australia's doorstep, there is no more exciting time for the MTP sector to capitalise on the full value of our country's research. In collaboration with the entire sector, MTPConnect will pursue its vision of transforming Australia into the Asia-Pacific medtech, biotech and pharmaceutical hub it has the potential to be.

Dr. Bronwyn Evans
CHAIR

Sue MacLeman
CHIEF EXECUTIVE OFFICER AND MANAGING DIRECTOR

EXECUTIVE SUMMARY

The medical technologies, biotechnology and pharmaceutical (**MTP**) sector in Australia has all the hallmarks of the high-skilled and innovation-based economy that Australia must develop to secure sustainable wealth and employment growth for its future.

Australia is an acknowledged world leader in the MTP sector due to its vibrant research environment. However, its poor record of commercialisation and tendency to see research drained offshore for development are also well known.

Extensive consultation with sector participants and previous reviews of the sector have uncovered six key barriers that limit the growth of the MTP sector:

- funding constraints and misalignment with commercial objectives
- lack of collaboration across the sector's various sub-segments, e.g. between industry and universities
- lack of commercialisation and business-management skills in specific areas of the value chain, including a deficient understanding of the pathway from research to market
- local policy instability and more favourable policies from competing nations in the areas of government program funding, intellectual property (**IP**) and reimbursement
- regulatory requirements that are not aligned to innovation cycles or to supporting small to medium-sized businesses
- the complexity and difficulty of accessing global markets

Removing the barriers that impede the translation of research into value-added products within Australia, through onshore commercialisation, is the key to growing the MTP sector and seizing global export opportunities.

Within this context, the Federal Government has acknowledged the sector's importance to Australia by nominating it as one of six Industry Growth Centres, each of which represents an area of strategic priority where Australian ingenuity could help local businesses lead the world. In total, $250 million of funding has been committed to supporting the initiative, and a portion of this will be available to fund the activities of MTPConnect. The Federal Government has also committed a further $250 million to the $500 million Biomedical Translation Fund (**BTF**) and established the $20 billion Medical Research Future Fund (**MRFF**), further highlighting the importance of the MTP sector to Australia's economic future.

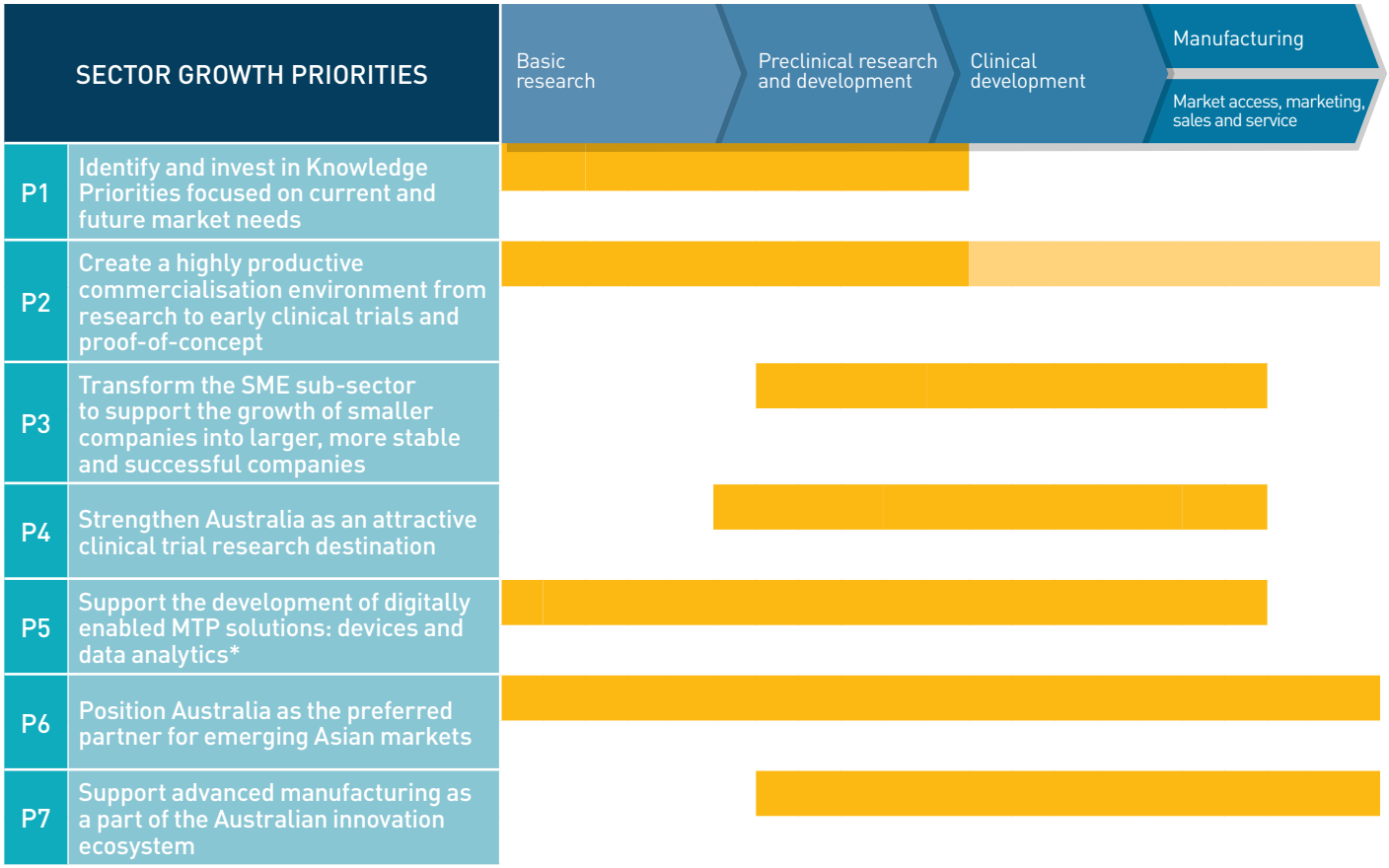
MTPConnect has been established as a not-for-profit organisation, distinct from government, to champion an industry-led approach to accelerating the MTP sector's rate of growth and establishing Australia as an Asia-Pacific hub for medical technology, biotechnology and pharmaceutical companies. This initiative will drive innovation, productivity and global competitiveness, with the ultimate goal of creating sustainable employment, growth and wealth for Australia through research, product development and a strong clinical trials sub-sector.

As an Industry Growth Centre, MTPConnect's mandate is to focus on four key objectives:

- improving coordination and collaboration across the sector—between research and industry, and within industry—to encourage commercialisation
- improving management and workforce skills necessary for growth
- identifying opportunities to address unnecessary or overly burdensome regulations that impede growth
- improving the sector's capability to engage with international markets and access global supply chains

This document sets out MTPConnect's 10-Year Sector Competitiveness Plan (**SCP**), which outlines a 10-year vision to maximise the sector's competitiveness and productivity, and to achieve more rapid and sustained growth. In doing so the plan also addresses three key areas that are vital to the sector's growth: (1) expected future challenges and opportunities; (2) identified areas for regulatory renewal; and (3) Knowledge Priorities (**KPs**), which set out the sector's research needs in a way that is tailored to market requirements and the goal of optimising commercialisation opportunities.

MTPConnect's vision is for Australia to retain all current and planned levels of research and development (**R&D**) expenditure while achieving greater commercialisation success, creating more products that reach proof-of-concept and early-stage commercialisation, increasing the number of medium-sized to large companies with late-stage product successes, maximising the value of any IP-monetisation events along the way, and increasing the scale and sophistication of the supporting R&D ecosystem such as clinical trials. The identification of Knowledge Priorities and engagement with key health care providers will help sector participants to engage in R&D that is driven by clinical and market needs and therefore more likely to achieve commercial success. Seven Sector Growth Priorities have been identified that underpin this vision, each addressing specific elements of the MTP value chain.



Note: * Some of the technologies and solutions within P5 do not fit the traditional MTP value chain and will have much shorter development and implementation pathways

The successful achievement of this vision will result in considerable benefits for Australia, through both improved healthcare and economic contributions. By reversing the sector's decline in recent years, an additional c.28,000 jobs and c.$18 billion of cumulative Gross Value Add (**GVA**) could be created by 2025.[1]

1 Refer to Appendix 5 for the calculation methodology that underpins the estimated sector growth potential and benefits

In delivering on its vision, MTPConnect will focus on three key types of activity.

1. Undertaking highly targeted actions to increase connectivity and collaboration

MTPConnect will act as a coordination point for all MTP-sector stakeholders by aggregating, analysing and disseminating knowledge. Australia has had numerous examples of success coming from collaboration, but in many cases, organisations in the MTP sector operate in silos, and there is inefficient and insufficient information exchange between them. More effective sharing of critical skills and knowledge, and greater awareness and sharing of resources, facilities and capabilities between pharmaceutical, biotech and medtech companies and universities, will be required to achieve greater success in commercialisation. MTPConnect will facilitate collaboration and connectivity by developing guidelines for allocating R&D grants and funding, working across the sector to articulate and implement the KPs identified for the industry, and identifying best practices to adapt and implement across Australia.

2. Providing an independent voice to shape policy and regulatory renewal, and to influence the direction of funding

The MTP sector's ability to achieve growth and add value is shaped by government regulation, public policy and funding programs. MTPConnect is unique in that its support for regulatory and program changes will provide a whole-of-sector perspective and an independent voice for the sector that is trusted by sector participants and government. MTPConnect will leverage its unique position to put forward changes that the sector needs and work with policy makers to enact sensible and sustainable policy that benefits the entire sector.

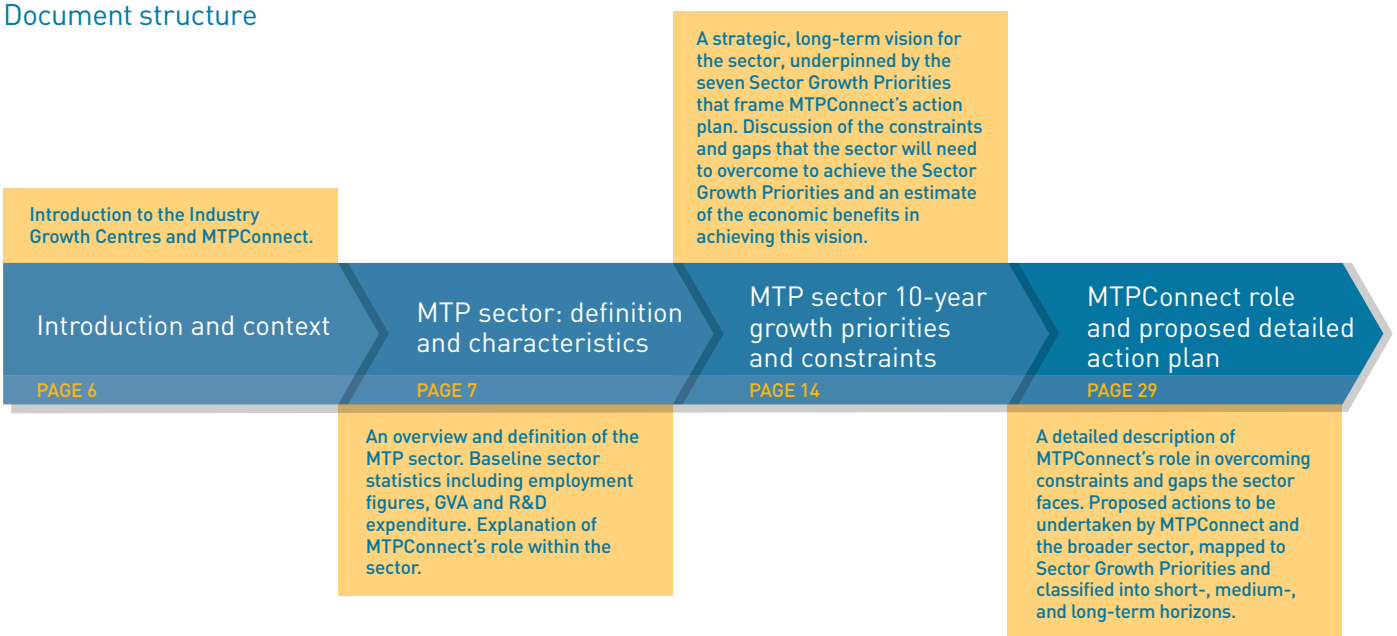
3. Providing funding for targeted, sector-led projects

MTPConnect has access to a dedicated funding pool for the sector, amounting to $15.6 million over four years. It will work with industry, research organisations and universities to jointly fund projects that align with the Sector Growth Priorities and drive greater commercialisation. Following the release of the Draft SCP in July 2016, MTPConnect's judging panel selected 14 initial projects to receive funding of $7.4 million over the next two years, with matched sector funding of c.$32 million. It is also launching a specific initiative to address the constraints and barriers in the clinical trials space, and provide momentum to clinical trials reforms.

MTPConnect's plan is to work with the sector and contribute to realising its potential by assisting and supporting all participants to address the constraints that restrict the sector's growth. Throughout the development of this plan MTPConnect has engaged in continuous dialogue with the sector to ensure it is relevant for all participants. This SCP is the result of consultation with over 600 sector participants.

This SCP is intended to be a living document that will be refined and revisited on at least an annual basis. Revisions will report on progress towards MTPConnect's objectives and capture insights to improve progress and outcomes.

Document structure



1. CONTEXT

The Medical Technologies and Pharmaceuticals Growth Centre, MTPConnect, was formed as a not-for-profit company in November 2015 as part of the Federal Government's $250 million Industry Growth Centres Initiative. The organisation was established to champion an industry-led approach to the development of the MTP sector and to drive innovation, productivity and competitiveness by focusing on areas of competitive strength and strategic priority.

To achieve this, MTPConnect has **four key objectives**:

This MTPConnect Sector Competitiveness Plan outlines a 10-year vision for the sector and focuses on the Sector Growth Priorities that will be necessary if sustainable growth and increased competitiveness are to be achieved over that period. It defines the constraints and gaps that currently limit value creation in the sector, the areas identified for regulatory renewal and the Knowledge Priorities. It also proposes clear actions that MTPConnect will undertake in response to the constraints and gaps.

It will be the roadmap by which MTPConnect will determine which actions to take and how it will direct its funding. MTPConnect will have $15.6 million over four years to support jointly funded projects, and a modest operating budget to undertake actions directly. MTPConnect itself is a lean organisation that aims to achieve the greatest impact possible with the funding available to it.

It has been informed by input from over 600 sector participants and stakeholders,[2] as well as an assessment of the many prior reviews of sector performance,[3] to create a holistic view of the MTP sector. This final SCP for 2016 is the result of revisions to the Draft SCP (released in July 2016) following sector feedback from 8 roundtables with 99 attendees, 54 completed survey responses, 11 detailed written submissions and over 50 meetings. It will be updated annually to reflect the changing environment, and to assess progress against targets and performance metrics.

2 Includes over 450 participants in initial industry consultations, and 150 individuals and companies who have provided input since the release of the Draft SCP in July 2016. Initial industry consultation included seven public forums, three focus groups, three webinars, an online survey and over 50 one-to-one meetings.

3 For example, Department of Health and Aging, *Strategic Review of Health & Medical Research In Australia*, Final Report, February 2013 (McKeon Review); Clinical Trials Action Group, *Clinically Competitive: Boosting the Business of Clinical Trials In Australia*, March 2011; and Lloyd Sansom, Will Delaat and John Horvath, *Review of Medicines and Medical Devices Regulation*, March 2015. See Appendix 7 for details of reviews consulted.

2. MTP SECTOR DEFINITION AND CHARACTERISTICS

MTP SECTOR DEFINITION

The purpose of the Federal Government's Industry Growth Centres Initiative is to drive innovation, productivity and competitiveness, generating local wealth and employment in Australia. Innovation is critical to the Australian economy, being the means by which organisations create competitive advantage and economic value. The MTP sector is among the most innovative in the global economy.[4] It is a major contributor to R&D both globally and within Australia. MTPConnect represents and supports all organisations directly involved in the research, development, manufacturing or market commercialisation of innovative products along the MTP value chain.

MTPConnect will focus its efforts primarily on innovative products which are regulated by the *Therapeutic Goods Act* and which make a therapeutic claim (see Appendix 1 for definitions of devices and product categories included in MTPConnect's purview). However, it is acknowledged that the sector definition should also include products that are highly innovative and play a critical role in healthcare delivery but do not require registration under the *Therapeutic Goods Act*, such as digital devices or software solutions that could be used for patient data collection, monitoring and care. MTPConnect is seeking to take a broad definition and will selectively engage with stakeholders that fall outside of the core definition of the MTP sector where a clear benefit to the Australian economy can be demonstrated.

The MTP value chain encompasses a vibrant sector with a diverse range of participants, each with a critical role to play in the sector's growth and success. This value chain comprises universities, other research organisations, small and large local and multinational companies, investors, service providers, industry organisations, regulators, policymakers, funders, and those involved in healthcare delivery such as state health departments and private medical practice. The development of MTP products underpins a strong clinical trial sub-sector that supports a range of jobs and adds significant value to the economy in Australia. The entire sector relies on a range of enabling research organisations, e.g. Contract Research Organisations (**CROs**), and infrastructure such as the ANSTO and NCRIS facilities that are vital to its ongoing success. Greater collaboration among all of these sector participants will be necessary to achieve the sector's growth goals.

4 Derwent World Patents Index, cited in Thomson Reuters 2015 State of Innovation Report

Sector participants (not exhaustive)	Basic research	Preclinical research and development	Clinical development	Manufacturing Market access, marketing, sales and service
Institutions	• Universities • MRIs • CSIRO • CRCs	• Universities • MRIs • CSIRO • Hospitals • CRCs • Incubators	• Universities • MRIs • CSIRO	
Private sector organisations	• Start-ups and SMEs • Large medtech and pharma companies	• Start-ups and SMEs • Large medtech and pharma companies	• Start-ups and SMEs • Large medtech and pharma companies	• Start-ups and SMEs • Large medtech and pharma companies
Industry organisations	• AAMRI • ASMR • AusBiotech	• AAMRI • AHMADA • ASMR • ATSE • AusBiotech • Medicines Australia • MTAA	• AAMRI • AHMADA • AMA • ATSE • AusBiotech • Medicines Australia • MTAA	• AusBiotech • Medicines Australia • MTAA
Service providers	• Research service providers • Clinical research organisations • Contract research organisations	• Research service providers • Clinical research organisations • Contract research organisations • Regulatory consultants	• Clinical research organisations • Contract research organisations • Regulatory consultants • Health economists • Professional advisers - Legal and IP - Financial - Regulatory	• Contract manufacturing organisations • Health economists • Professional advisers - Legal and IP - Financial - Regulatory
Funders	• Government (including NHMRC and ARC) • MNCs • MRFF • Philanthropic individuals and organisations • NGOs	• BTF • Government (including NHMRC and ARC) • MNCs • MRFF • Philanthropic individuals and organisations • NGOs	• BTF • Government • MNCs • Angel investors • Venture capital	• MNCs • ASX • Customers

MTPConnect's role in the sector

MTPConnect sits at the nexus between sector participants but is only one of many players driving the sector forward. MTPConnect is not intended to replace any existing industry associations, and will work with all sector participants and act as a connector between them, including:

- companies and industry organisations such as the Medical Technology Association of Australia (**MTAA**), Medicines Australia, the Association of Australian Medical Research Institutes (**AAMRI**) and AusBiotech;
- federal and state government agencies and departments, including Austrade, the Department of Industry, Innovation and Science, and the Departments of Health (federal and state levels);
- research organisations and academia, including universities and Medical Research Institutes (**MRIs**); and
- existing and potential funders and investors.

Coordination between all of these participants will be vital in ensuring the sector's growth and success. MTPConnect will focus on strengthening what already works in the sector, and at the same time will work with participants to remove barriers and improve innovation, unlocking the full potential of the sector for years to come.

Further detail on MTPConnect's role and the specific actions MTPConnect proposes to undertake are outlined in Section 4.

Sector characteristics and historical performance

Health is a major growth sector globally and Australia is no exception. Changing demographics, increasing disease burdens, and rising incomes and government health expenditure will continue to contribute to the sector's growth and to the need for continual innovation to address unmet needs and broader health-system constraints. The case for new innovations will become more powerful both in the context of patient benefit and whole-of-life costs.

The MTP sector is a significant contributor to the Australian economy, generating c.$4.4 billion in GVA (4.5% of Australia's total manufacturing GVA),[5] c.$4.6 billion in annual exports from manufacturing (10th largest export sector)[6] and employing c.48,000 people across medtech (c.10,000) biotechnology, and pharmaceuticals (c.22,000),[7] and health and medical research (c.16,000).[8] This gross value added figure is based on traditional industry output measures and includes only the economic output from the commercial activities that take place in the MTP sector (i.e. manufacturing and sales). As a result, it does not include the contribution from the proportion of MTP research activity which takes place outside of companies (e.g. in universities or MRIs), or the significant activity that occurs in the healthcare delivery sector (e.g. in public and private hospitals and other treatment settings) that is strongly supported by the MTP sector.

Sector GVA has declined slightly over the past five years across both medical devices and pharmaceuticals, primarily due to the withdrawal of MTP manufacturing activity from Australia. Despite this decline, MTP remains Australia's largest export sector for products that are not directly linked to primary industries such as mining and agriculture.

5 CY2015. Australian National Accounts – ABS 5206; ABS 8155 (for apportions) and ABS Census data (for apportions); L.E.K. analysis. Includes ANZSIC codes 1841, 2411 and 2412. The percentage has been calculated based on manufacturing as the ANZSIC codes for the MTP sector fall within the broader manufacturing sector of the economy

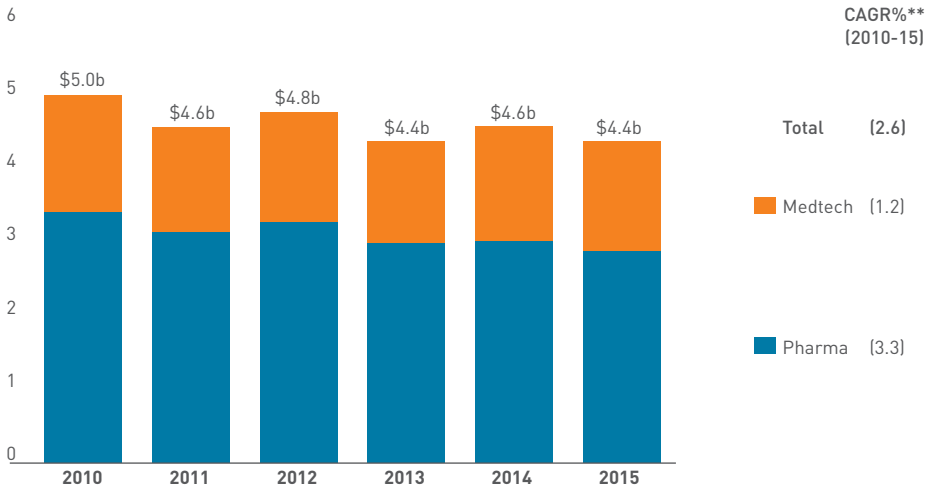
6 FY2016. ABS 5368; L.E.K. analysis. Includes Standard International Trade Codes 541, 542, 872 and 884

7 Department of Industry, Innovation and Science supplied ABS data; ABS census data; L.E.K. analysis. ANZSIC Codes 1841, 2411 and 2412 are included

8 c.8,000 in the university sector - NHMRC and Excellence in Research data, L.E.K. analysis; and c.8,000 working in medical research institutes (MRIs) and other medical research centres – AAMRI Enhancing the commercialisation outcomes of health & medical research, 2012

Medtech and Pharmaceutical Sector GVA – 2010-15

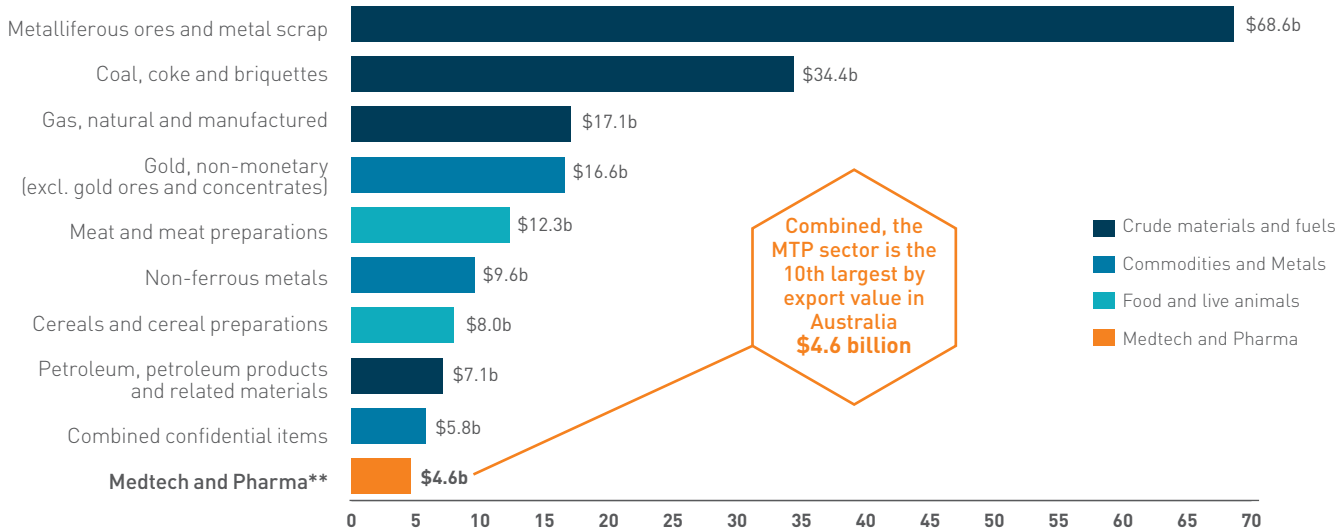
MTP Gross Value Added*
(2010-15)
$Billions



Notes: * Nominal; ** Compound Annual Growth Rate
Source: Australian National Accounts – ABS 5206; ABS 8155 (for apportions); ABS Census data (for apportions); L.E.K. analysis. ANZSIC Codes 1841, 2411 and 2412

Australian export value by trade classification

Export value, by trade classification*
(FY2016)
$Billions



Notes: * Based on 2 digit International Trade Classifications; ** Includes 2 digit category 54 - Medicinal and pharmaceutical products and 3 digit codes 872 - Instruments and appliances, for medical, surgical, dental or veterinary purposes and 884 – Optical goods (including contact lenses). Classification excludes other 3 digit categories within 2 digit codes 87 and 88 including photographic and film equipment, cinematographic film, optical instruments (e.g. microscopes), meters and counters, and measuring/checking instruments
Source: ABS 5368; L.E.K. analysis

The sector has a vibrant ecosystem of start-ups and established companies. MTAA notes that the Australian medical technology industry includes over 500 medical technology companies with products listed on the Australian Register of Therapeutic Goods (**ARTG**),[9] while Medicines Australia and AusBiotech note that there are approximately 50 multinational pharmaceutical companies and more than 400 locally-owned medical biotechnology companies operating in Australia.[10] Around one hundred medical technology, biotechnology and pharmaceutical companies are listed on the Australian Stock Exchange (**ASX**), with a combined market capitalisation of c.$85 billion.[11]

Australia also has a thriving research industry. The National Health and Medical Research Council (**NHMRC**) reports that Australia contributes c.3% of the world's published biomedical research.[12] Between 2001 and 2010, Australia ranked sixth in the world in terms of overall output of health and medical publications.[13] Australia ranked fifth in innovation in Scientific American Worldview 2016.[14]

Australia is well positioned to build a thriving MTP sector with R&D fundamental to both the public and private sub-sectors. Public grants awarded into the MTP sector from the NHMRC and Australian Research Council (**ARC**) are estimated at c.$775 million in 2015,[15] and industry R&D spend is estimated at c.$630 million per year.[16] The MTP sector receives c.45% of grants awarded by the NHMRC and ARC,[17] and accounts for c.14.0% of business expenditure on R&D within the manufacturing sector.[18] Business R&D in Australia has been largely supported by the R&D Tax Incentive program, which is the largest component of the Government's support for R&D.

The Federal Government is further backing Australia's research and commercialisation potential with the introduction of major funding initiatives like the $500 million BTF and the $20 billion MRFF.

Australia's MTP sector has produced numerous success stories over that past 20 years – companies that have commercialised ground-breaking research at a global level. With the right enablers in place and the barriers reduced, the sector can produce many more. However, shortfalls in funding at the pre-clinical and early stages of clinical development are common, and attracting private capital during these early stages is difficult. As a result, the pre-clinical and clinical stages of development have become known globally as the "twin valleys of death". In these "valleys", the cost of further translational research or early-stage clinical trials is substantial, but the risks are still too high to draw in sufficient funding from private investors alone. A proportion of potential MTP innovations never progress past these valleys due primarily to challenges in attracting funding, and these early exits from the innovation process are an impediment to fully maximising the outputs of the MTP sector. The BTF is one example of a national initiative aimed at overcoming these translational valleys.

A further distinguishing factor of the MTP sector relative to other Industry Growth Centre sectors is the high degree of local and international regulation and reliance on government policy, including reimbursement and procurement policy. Sector participants must consider innovations and investments in light of these

9 MTAA, Medical Technology in Australia: Key facts and figures 2014
10 Medicines Australia, Fact Book, 4th edition, 2015; AusBiotech website, *Biotherapeutics Fast Facts*
11 ASX; Thomas Reuters; L.E.K. analysis. As at June 2016.
12 NHMRC (2013), based on data 2005-2009
13 McKeon et al, Strategic Review of Health & Medical Research in Australia ("the McKeon Review"), 2013
14 Scientific American World View – A Global Biotechnology Perspective. Biotechnology Scorecard (June 2016)
15 CY2015. ARC Grants dataset; NHMRC Funding data; L.E.K. analysis
16 FY2012. ABS8104. Includes ANZSIC codes 1841, 2411 and 2412
17 CY2015. ARC Grants dataset; NHMRC Funding data; L.E.K analysis
18 FY2012. ABS 8104; L.E.K. analysis

regulatory hurdles. Similarly, government policies to do with reimbursement, tax and the strength of intellectual property laws can significantly affect innovation and investment within the sector. As a result, this SCP calls out opportunities for regulatory and policy renewal.

Australia's MTP sector is necessarily part of a global market. With a population of c.24 million,[19] the country does not have a large enough domestic market to support many MTP companies, and needs to be a competitive part of the global market to succeed.

Successfully increasing Australia's competitiveness and productivity in the MTP sector is not just important for a sustainable MTP sector; if Australia fails to be a competitive part of the global market, the impacts will be felt beyond direct MTP sector participants. Despite a rise in its position since 2009, Australia's ranking in Scientific American Worldview has slipped from fourth to fifth from 2015 to 2016.[20] Other countries are making significant investments in their MTP sectors. The recent Pugatch Consilium "Race for Biopharmaceutical Innovation" report places Australia 9th for overall biomedical investment attractiveness out of 10 mature markets assessed, with commentary suggesting Australia is lagging other countries.[21] If Australia does not maintain a similar focus it risks falling behind and becoming more heavily reliant on global organisations and less relevant to the global market. As a small market, Australia may find that product launches occur later and later, access to clinical trials becomes more difficult or Australians may miss out on new and innovative therapies altogether.

While these and other metrics and benchmarks exist that aim to measure Australia's standing in the global race for innovation, many are not focused on the MTP sector, use sources that are poor proxies for innovation and collaboration, or are limited by poor or inconsistent information capture across countries. As a result, MTPConnect will be developing its own baseline for the sector that will capture a range of metrics including employment, level of innovation and extent of collaboration, and will be specific enough to measure progress over time.

There are many similarities between the medtech and pharmaceuticals markets. Both markets are founded on innovation, require significant investment in R&D to remain competitive, are heavily regulated, and are shaped by government policy and healthcare funding. However, one distinct difference is the length and investment involved in the commercialisation pathway, and therefore the extent to which globalisation becomes a necessity.

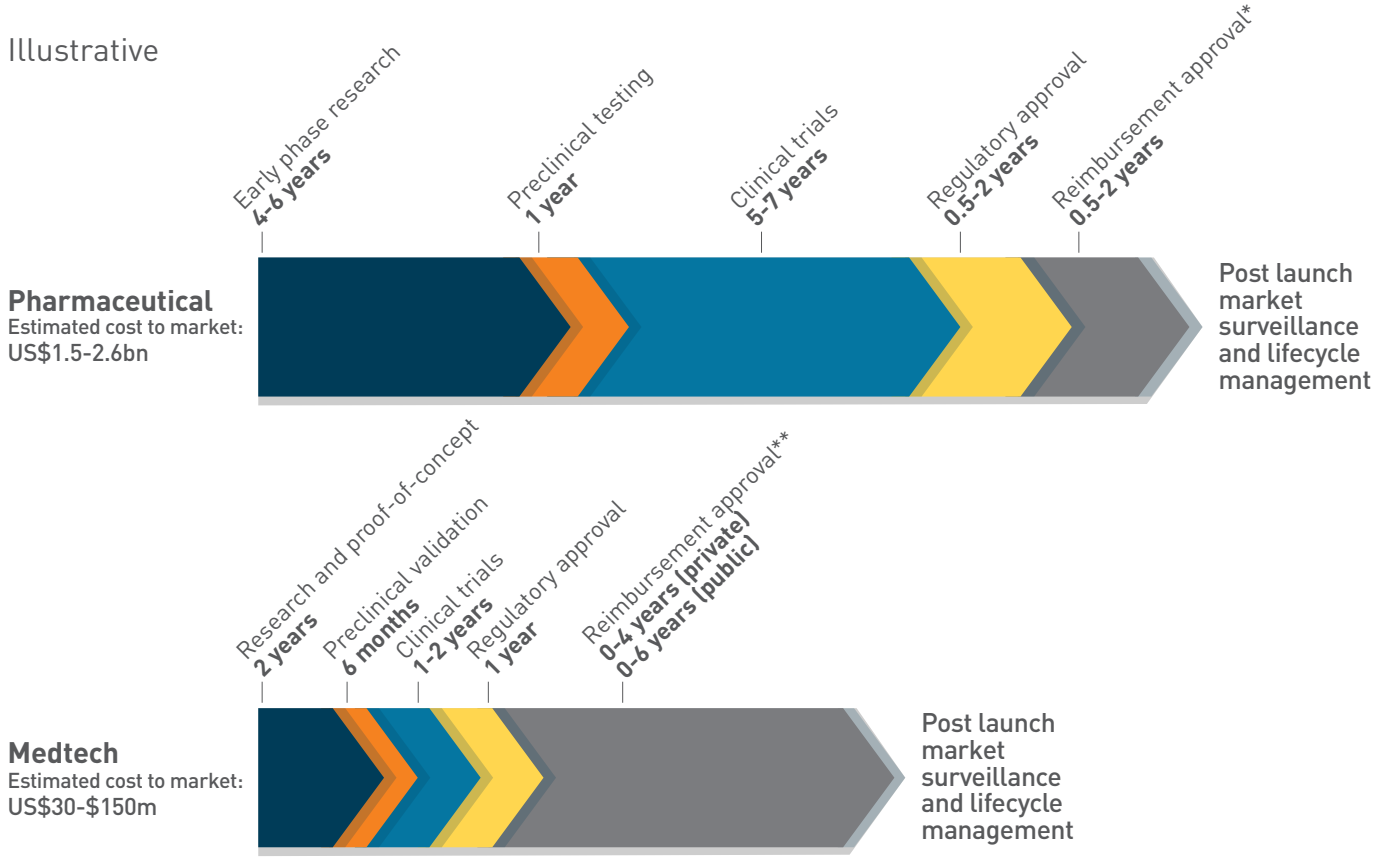
In pharmaceuticals and biotechnology, the drug and biologics development pathways are long and expensive. They may require between 10 and 15 years to complete, and the risk-adjusted average cost of bringing a new vaccine or medicine to market is cited as between US$1.5 billion[23] and US$2.6 billion.[24] Products must be commercialised at a global scale to deliver the required return on investment. As evidence of this, the large majority of pharmaceutical revenue in Australia is derived by a small number of multinational pharmaceutical companies that sell products developed for the global market. 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

19 Australian Bureau of Statistics – Population clock. Last accessed June 2016
20 Scientific American Worldview – A Global Perspective, Biotechnology Scorecard (2015, 2016)
21 Pugatch Consilium – The Race for Biopharmaceutical Innovation 2016
22 Espicom, World Medical Markets Factbook, 2015; Medicines Australia, Fact Book, 4th edition, 2015
23 In 2011 prices. Mestre-Ferrandiz, Sussex, Towse (December 2012) *The R&D cost of a new medicine*. Cited in Medicines Australia (23 January 2013) *Submission to the Pharmaceutical Patents Review*. Capitalised cost including failed drugs
24 In 2013 prices. DiMasi, Grabowski, Hansen (November 2014) *Innovation in the pharmaceutical industry: New estimates of R&D costs*. Capitalised cost including failed drugs

the development, regulatory, sales, marketing and distribution capabilities and resources to maximise its global reach and value as a product.

In medtech, the dynamic is often different. The development timeframe and cost for medtech products is typically shorter (between four and 10 years, and c.US$30 million–150 million in the United States),[25] and the product life cycle and investment return period are also shorter. As a result, small and mid-sized medtech companies are more likely to be able to take a product all the way through to an in-market launch in Australia, with the need for a global partners limited to suppliers. As with the pharmaceutical and biotech subsectors, full value is only likely to be realised if global markets are accessed, either directly or through partnerships.

High-level representation of pharmaceutical and medtech development pathways[26]



These pathways are illustrative only. Some products (e.g. digital solutions) will follow an iterative pathway with rapid development, prototyping and testing. Some participants may achieve faster development pathways if they can secure regulatory and reimbursement approval in parallel.

Notes: Time frames for each stage and cost estimates are indicative only and can vary for individual products. Regulatory and reimbursement timelines may occur in parallel in some cases.
* Reimbursement approval for PBS-funded or hospital-funded products.
** Time to reimbursement for medtech depends on care setting (public vs. private). For devices associated with existing procedures, no reimbursement approval is required. For devices requiring a new procedure or AR-DRG, approval may take 4-6 years.

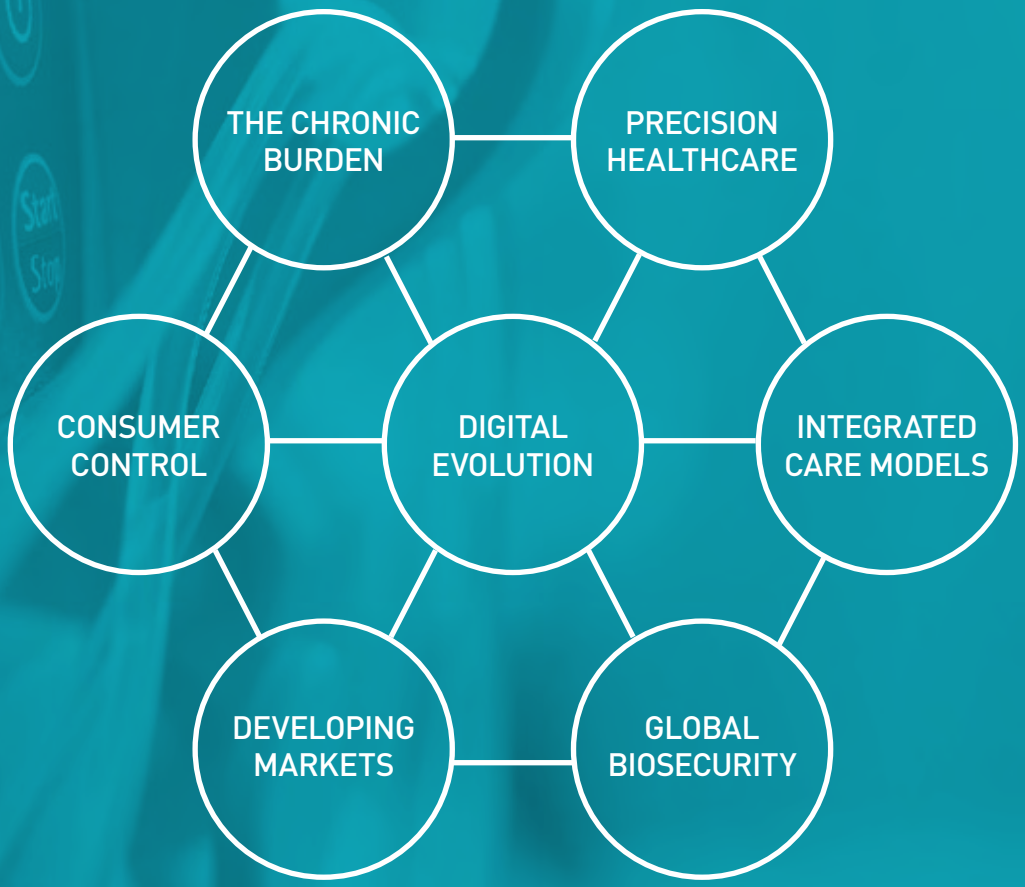
25 Medscape - FDA Approval Process for Medical Devices; Josh Makower, Aabed Meer and Lyn Denend, *FDA Impact on U.S. Medical Technology Innovation*, November 2010; and Wendy Lee, "Lean Times for Venture Capital", *Minneapolis Star Tribune*, 20 April 2012. Figures are for medtech product development in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

26 Medicines Australia; MTAA; ARCS Australia; Aaron V. Kaplan, et al, "Medical Device Development: From Prototype to Regulatory Approval", *Circulation 109* (2004): 3068–3072; Scott T. Ham, "Mapping the Medical Device Development Process", *Digital Commons* @ Cal Poly, June 2010; L.E.K. analysis

3. MTP SECTOR 10-YEAR GROWTH PRIORITIES AND CONSTRAINTS

MTP MEGATRENDS[27]

The priorities and actions of the MTP sector must be developed with the future in mind. Megatrends are the overarching social, economic, environmental, technological and geopolitical forces that will shape this future. These megatrends are often disruptive; they change existing business models and present opportunities and challenges for organisations. Seven megatrends have been identified that will significantly affect the Australian MTP and broader health care sector over the next 20 years.



27 These Megatrends were developed in collaboration with CSIRO Futures. We thank the CSIRO for its input.

Megatrend	Implications for the MTP sector
The chronic burden Modern medical and pharmaceutical technology allows us to manage chronic disease and live longer than ever before, but comes at considerable cost to the public health system. Between 2015 and 2030, the proportion of the population aged 60 or over is projected to grow by 56%.[28] Globally, changes will be essential to adapt health systems to longer lifespans and maximise health and well-being at all ages.	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' judgments 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.
Precision healthcare Advances in science and technology are enabling more precise healthcare solutions. Targeted pharmaceuticals and personalised medical technologies will be delivered that provide improved outcomes for cohorts of patients. The technology advancing this trend includes genomics, computational biology, medical imaging, 3D printing and data mining.[29, 30] Biosensors are already providing clinicians and patients with real-time personalised data regardless of location. In 2014, health wellness monitoring applications accounted for 66.3% of biosensor revenue globally.[31]	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.
Consumer control Technology and information access are empowering patients to manage their healthcare more actively. In the future, patients will be able to track their health status via personal health records, wearable sensors and in-home monitors, gathering information that allows them to contribute more actively to healthcare decisions that concern them. Tomorrow's patients will be educated and informed decision-makers.	This trend will see a change from the historical model of healthcare provision, based on consultation with medical specialists, to one where medical technologies are part of a consumer-driven, consumer-focused, digitally enabled ecosystem. Opportunities exist for Australia to build advanced clinical product development systems that support consumer-driven decisions and consumer-responsive products and services. Australia could become a preferred region for developing and testing this next generation of medical technology, with corresponding economic benefits.
Digital evolution There will be a significant shift in how we exchange and process the massive amounts of data generated daily. Standardisation of data sharing will accelerate the development of new technologies and treatments that target individuals and the wider health system. The upside will be improved efficiency for everything from R&D to patient-care coordination. The downside is that cybersecurity risks will grow as more data is exchanged.	Data standardisation and security need to be central concerns for the MTP sector if it is to take full advantage of the digital world. There is an opportunity for agile countries to gain global advantage by setting and adopting global best practice standards around the rapid development and validation of digitally enabled health technologies and by developing the use of de-identified health datasets in healthcare research and practice. Fully integrated systems will allow continuous improvement in the MTP sector and in healthcare services more broadly and ensure Australia keeps pace with the global digital frontier.

28 United Nations, Dept. of Economic and Social Affairs Report "World Population Aging 2015"
29 http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM372421.pdf
30 Frost & Sullivan, Feb 2016, 3D Printing in the Healthcare Industry
31 Frost & Sullivan, May 2015, Analysis of the Global Biosensors Market

Megatrend	Implications for the MTP sector
Integrated care models Models for the delivery of healthcare are evolving to better address the context and specific needs of the patient. These integrated models reflect the whole of a patient's care needs, from prevention through to the end of life, across both physical and mental health, and in partnership with the patient, their carers and family.	Demand will increase for products and devices that are suited to integrated care models. Products will be required that can coexist and communicate with other products and information sources as part of an ongoing, continuous care ecosystem. As emphasis shifts from individual care episodes to ongoing patient management, products and devices will increasingly need to be packaged as part of a broader care proposition that attaches patient as well as economic benefits to the healthcare system. Devices will also play a role in connecting and monitoring the patient between formal care episodes.
Developing markets Demands for healthcare solutions are rising in developing countries. Today these markets are responsible for the majority of global sector growth (in percentage terms) and this trend will continue. However, it is important to note that the needs of these markets are at times distinct from developed economies. For example there is demand for lower-cost solutions, or solutions delivered in different settings such as point of care versus laboratory.	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 production advantage in the short term and to collaborate over the longer term to develop innovative solutions that deliver high quality and sophisticated technologies, products and healthcare to developing countries in a cost-effective manner.
Global biosecurity Recent pandemics highlight the globally transmissible nature of diseases and the threat these can have on human health and agricultural activity. 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 is another complex global public health crisis that threatens the effective prevention and treatment of an ever-increasing range of infections.[33] There has been a 'discovery void' since the 1980s, with a limited pipeline of new antibacterial drugs.[34]	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 access to an agile research, clinical development and manufacturing industry. Maintaining strong on-shore advanced manufacturing and research capabilities for biosecurity products will enable Australia to retain access to the products and know-how required to combat such risks.

32 http://www.who.int/csr/research-and-development/strategy/en/
33 http://apps.who.int/iris/bitstream/10665/112642/1/9789241564748_eng.pdf
34 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3021209/

MTP SECTOR GROWTH PRIORITIES

THE VISION FOR THE FUTURE

The MTP sector has many strengths, but if it is to remain sustainable and increase its economic and health contributions to the Australian economy there are important growth priorities that cannot be ignored.

While Australia has a vibrant research sector, its commercialisation productivity is behind that of other leading research countries and Australia's position in the Global Innovation Index 2015 reflects this. Australia ranked 10th in innovation input but 24th in innovation output, (a decrease from 22nd in 2014).[35]

MTPConnect's vision is for Australia to retain all current and planned levels of R&D expenditure[36] while achieving greater commercialisation success, creating more products that reach proof-of-concept and early-stage commercialisation, increasing the number of medium to large companies with late-stage product successes, and maximising the value of any IP monetisation events along the way. The overall effect would be greater employment and wealth creation for Australia.

The Knowledge Priorities and megatrends are fundamental to achieving this vision, as they help guide the sector towards areas of greater market need and hence commercialisation potential. Engagement with state health departments and end product users will ensure that MTPConnect is supporting innovations that align with market needs and possess commercial potential.

Australia has created some successful MTP companies, such as Cochlear, CSL, Mesoblast, Nanosonics and ResMed. However, they are too few and the vision is to create more success stories. Australia has a pool of start-ups with an inventive and entrepreneurial mindset. It is important to not only foster this culture to continue to drive innovation, but to also provide more support to translate start-ups into successful SMEs.

The development of more MTP companies within Australia will also encourage growth of the R&D services sector. As more products are developed locally, there will be a greater demand for service providers such as CROs that are fundamental to product development in Australia.

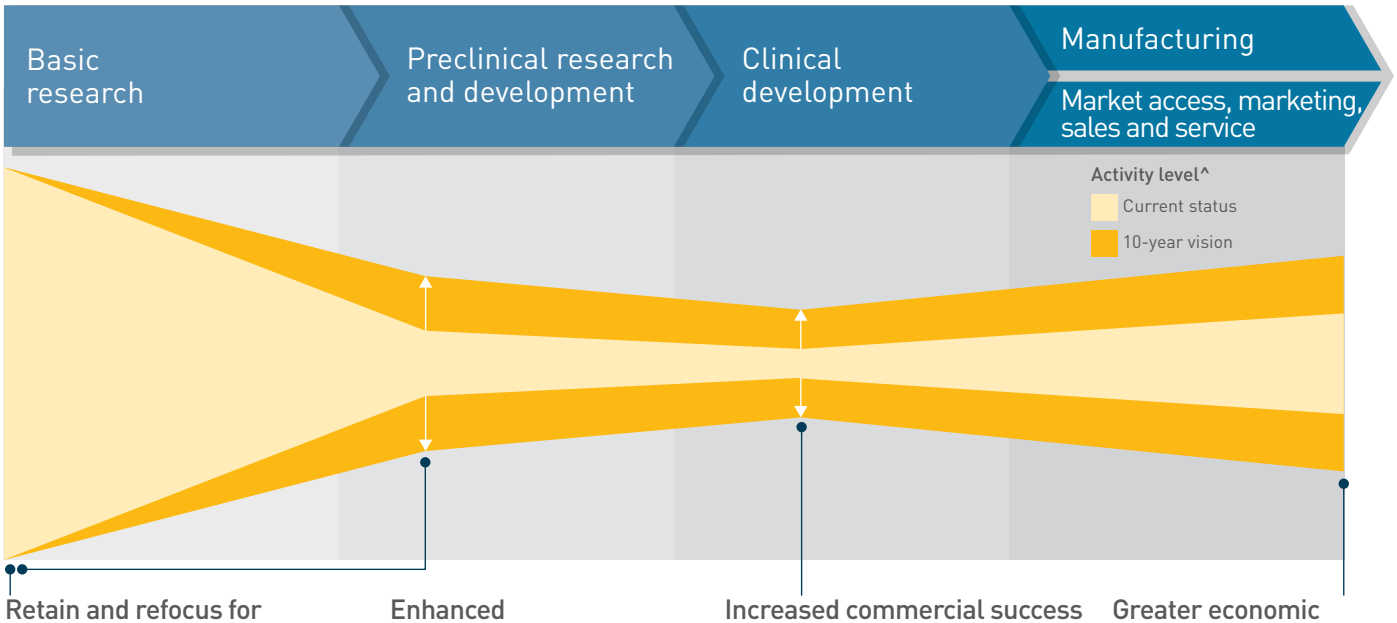
Success for the sector does not require that commercialised products remain entirely in the hands of Australian-owned companies. In some cases, an appropriate commercialisation pathway will be out-licensing or divestment to a larger, global company that can provide the resources and capabilities to maximise an innovation's value. Acquisitions such as that of Spinifex by Novartis and Fibrotech by Shire, or licensing deals such as those of Hatchtech and Acrux, provide examples of successful pathways in the MTP sector and assist to return funds to Australia for further investment. But, it is critical that Australia generates more products that reach clinical development and proof-of-concept, commanding stronger commercial terms from global partners. By doing this, a sustainable sector will be assured with jobs and capabilities developed for future national prosperity.

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

35 Cornell University, INSEAD, and WIPO, "The Global Innovation Index 2015: Effective Innovation Policies for Development", September 2015; Cornell University, INSEAD, and WIPO, "The Global Innovation Index 2014: The Human Factor in Innovation", 2014

36 This includes new funding initiatives such as the BTF and the MRFF

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



Retain and refocus for greater commercial outcomes

- Maintain the same level of planned research activity with greater focus on translation of research, and the Knowledge Priorities*

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

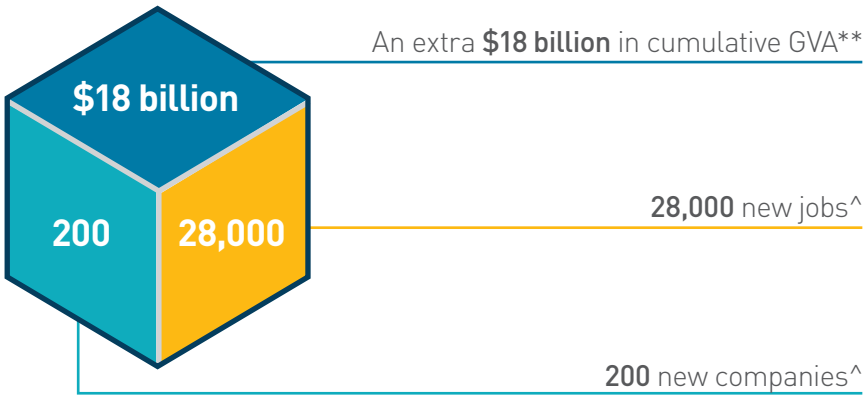
Note: * These are areas of high unmet need and in which a sizeable commercial opportunity exists, and where Australia can develop world class research excellence; ^ Activity level includes all forms of activity and economic value creation in Australia regardless of whether it originates from Australia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

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

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

Further details of MTPConnect's sector growth potential and benefits estimates are available in Appendix 5.

MTP sector by 2025*



Notes: * Estimated additional GVA, employment and companies assumes the decline from over the past five years can be reversed, with the industry returning to 2010 levels within 5 years and then continuing to grow at an equivalent rate out to 2025. This scenario reflects the full potential of the government's incremental investment in the sector including MTPConnect, the BTF and the MRFF; ** Compared to the baseline forecast; ^ Compared to 2015

Source: Office of the Chief Economist – MTP Employment 2015 analysis; Australian Bureau of Statistics – Census Data; NHMRC; AAMRI; L.E.K. analysis; Medicines Australia; AusBiotech; MTAA; AAMRI

MTPConnect has identified seven priorities that will need to be focused on if the Australian MTP sector is to achieve this vision of success. These seven priorities are introduced below. The actions required to achieve these priorities are detailed in Section 4 of this plan.

PRIORITY 1:
IDENTIFY AND PROMOTE KNOWLEDGE PRIORITIES FOCUSED ON CURRENT AND FUTURE MARKET NEEDS

THE OUTCOME of addressing this priority will be a more strategic allocation of public R&D funding channelled towards the identified Knowledge Priority areas, and a greater number of successful commercialisation opportunities arising from that research, driving sector GVA and employment.

Public research in the MTP sector in Australia tends to be investigator-led and lacks sufficient focus on market needs and commercial potential. While priority frameworks such as the National Health Priority Areas exist, they focus on optimising health outcomes with little regard for commercialisation outcomes.

Australia can maximise the commercial results of its existing public R&D investment by complementing investigator-led research with a top-down, strategic approach to research that focuses on areas with strong market need and commercial potential, and draws on Australia's competitive advantages. MTPConnect has worked with stakeholders from across the broad MTP sector to develop a set of Knowledge Priorities, tailored to market needs and research strengths, that will optimise the commercialisation potential of research. The Knowledge Priorities are intended to focus research and product development on the needs of the market – diverging from the traditional basic research approach. Placing more emphasis on these Knowledge Priorities will ensure that Australian MTP innovation is focused on emerging opportunities in-line with the megatrends highlighted above.

With these initial Knowledge Priorities identified, it is important to ensure that a sufficient percentage of all R&D spending is allocated and targeted in a coordinated fashion to them. It is not prudent to allocate all R&D expenditure to these areas, as there is still an important role for exploratory research, and serendipitous discovery. New funding over and above existing levels and announced programmes (including the BTF and the MRFF) is not anticipated. Instead, existing and planned funds should be aligned to these Knowledge Priorities and a full ecosystem of research, skills and industry links should be developed to support them. This ecosystem will be the platform needed to create an attractive investment climate for global pharmaceutical companies to undertake more R&D in Australia.

Defining these Knowledge Priorities and disseminating them throughout the MTP community is an important activity for MTPConnect, which it has commenced already in consultation with sector participants (including clinicians and healthcare providers). The Knowledge Priorities intentionally have a commercial or clinical practice focus, and MTPConnect acknowledges that many of them are underpinned by skills and knowledge in the fundamentals of science, technology, engineering and mathematics (**STEM**). The key attributes of Knowledge Priorities include:

- **an area of significant market need and in which a sizable commercial opportunity exists**, such as a specific therapy area, e.g. oncology, or a broader area of science, e.g. genomics, or technology, e.g. device. The megatrends identified earlier in this report are important drivers of those areas of future market need
- **areas where Australia is or can be world class**, including emerging areas where there is no clearly defined global leader

MTPConnect has developed its initial list of Knowledge Priorities based on existing research productivity, commercialisation success, future potential and sector consultation. These are laid out in Appendix 3.

PRIORITY 2:
CREATE A HIGHLY PRODUCTIVE COMMERCIALISATION ENVIRONMENT FROM RESEARCH TO EARLY CLINICAL TRIALS AND PROOF-OF-CONCEPT

THE OUTCOME of addressing this priority will be significant economic benefits, including high-value jobs and inflows of royalties and returns to Australian investors, along with incentives and rewards for researchers and clinicians.[37] CSL notes that "being able to progress translational research through even just one more stage of development can lead to a doubling or tripling of returns for Australia."[38]

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 early-stage commercialisation often finds it difficult to cross the first "valley of death". Australia must become more effective in translating research ideas and products to commercial outcomes if it is to benefit from enhanced and sustainable economic growth in the MTP sector. Achieving this outcome requires not only effective research and start-up sub-sectors, but a healthy, full value-chain ecosystem from research through to commercial marketing and sales of products. Collaboration and sharing of skills between industry, support services and research is critical to commercialisation success. To be successful at the global level, ideas will also need to come from a combination of industry innovation, new technologies and global thought leadership. There are a number of important foundations that must be in place to support this priority, including aligned and available funding (the BTF will be significant in addressing this), a strong intellectual property regime, and a local ecosystem of drug development and commercialisation service providers, e.g. regulatory advisors, CROs, formulation companies. These requirements are outlined in greater detail in Section 4.

The necessary focus on providing a clear value proposition to funders and investors, together with a lower risk path to translation and commercialisation, will accelerate existing and create new product development opportunities. This, in combination with a greater focus on market needs through the megatrends and Knowledge Priorities, will result in more products overcoming the first "valley of death" and moving through Phase I trials to proof-of-concept and into later-stage trials. In particular, there are opportunities to focus Australia's early stage innovation on those needs that are being shaped by the megatrends such as addressing the chronic disease burden, delivering precision healthcare, supporting integrated care models, delivering consumers greater control over their care, and increasing the use of digital healthcare solutions. Increasing Australia's success in translating research to early-stage development will also lead to a greater appreciation of issues to be addressed and choices to be made in basic science.

37 McKeon et al, Strategic Review of Health & Medical Research in Australia ("the McKeon Review"), 2013
38 CSL, Submission to the McKeon Strategic Review of Health and Medical Research (2012).

PRIORITY 3:
TRANSFORM THE SME SUB-SECTOR TO SUPPORT THE GROWTH OF SMALLER COMPANIES INTO LARGER, MORE STABLE AND SUCCESSFUL COMPANIES

THE OUTCOME of addressing this priority will be an increase in private investment in the sector, a larger, high-skilled workforce, and an increase in the number of products that are brought to Phase II and III clinical trials by Australian pharmaceutical companies, and in the case of medtech, more product launches by Australian companies. The direct economic benefit will be greater MTP sector employment and GVA.

The majority of companies in Australia's MTP sector are start-ups and small biotechnology and medtech firms with products in early-stage development. These companies often struggle to access sufficient long-term funding to commercialise their products, leading to the second "valley of death", 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. Smaller companies can fail simply due to limited engagement with customers and healthcare providers who play a valuable role in shaping the product as it's developed. Start-ups and small companies, in particular, often fall short in skills for areas such as navigating taxation, clinical and regulation hurdles. Consequently, the company may realise suboptimal value from its innovation and/or delays to market launch. For instance, regulatory requirements must be factored in very early in the R&D process, well before clinical trials commence, and years in advance of a formal submission to the regulator. Failure to get this right can result in the collection of incomplete data, or significant delays due to the need to revisit previous stages. For those small companies that do out-license or sell to a large partner, valuations may not be maximised due to a lack of skills and capabilities in negotiating IP-monetisation deals.

Increasing the number of mid-sized companies will stabilise the sector and create opportunities to develop additional products per company. 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. A more vibrant and successful mid-sized sector also provides a hub of skills and commercialisation 'know-how' that can link with universities, research centres and start-ups, helping to bring their ideas and products to market.

The nature of late-stage opportunities in medtech differs from that of those in biotechnology and pharmaceuticals. As described previously, the lengthier and more costly pharmaceutical and biologics development pathway requires a global commercialisation approach to deliver a return on investment in line with the risk undertaken and the sums invested. As such, a realistic goal in pharmaceuticals would be to increase the number of products that reach Phase II and III clinical trials before partnering with or out-licensing to a global organisation.

Conversely, there are aspects of medtech, particularly those involved in some Class I and Class II TGA-regulated[39] products, that can be developed quickly and at a feasible cost for smaller businesses. It is possible that such products could be commercialised in Australia first, before businesses access global markets in a phased manner. As such, it is a realistic goal to increase the number of medtech companies (such as Cochlear and ResMed) that achieve successful in-market launches in Australia, and then go on to produce further innovations and global success.

39 Note: TGA refers to the Therapeutic Goods Administration

Nanosonics, an Australian success story:[40]

Founded in 2001, Nanosonics is now among the largest medical technology companies in Australia by market capitalisation. The company's flagship device, the Trophon EPR, is a high-level disinfection system which has seen global adoption in recent years. Nanosonics financed its development through government grants, capital raisings and an eventual listing on the ASX in 2007. The company had its first sales of the Trophon EPR in Australia and New Zealand in early 2009 following TGA approval, with a European launch following later in the same year. A significant partnership was formed with GE Healthcare in 2012 when the US company purchased a $7.5 million off-market equity stake in Nanosonics. This additional capital enabled further product development and production facility improvements, and the collaboration with GE allowed Nanosonics to penetrate the North American market by leveraging GE's existing marketing and distribution network. Coinciding with the GE deal, sales revenue for FY2012 increased to $12.3 million from $2.2 million (FY2011), and is now $42.8 million (FY2016). Nanosonics remains headquartered in Sydney, with offices in the US and Europe.

PRIORITY 4:
STRENGTHEN AUSTRALIA AS AN ATTRACTIVE CLINICAL TRIAL RESEARCH DESTINATION

THE OUTCOME of addressing this priority will be a robust clinical trial industry which confers many benefits. It provides Australians participating in local trials with early, free access to new healthcare technologies, it creates skilled employment and transfers knowledge to the health sector on new trends in medicine and devices, improves the profile of Australia as a destination for international medical research and assists in the development of an internationally competitive MTP ecosystem.[42]

Historically, Australia's well-structured health sector, strong research competence, diverse demographics and competitive completion times have made it an attractive clinical trial destination. However, the country's clinical trial industry is now facing competition from more populous regions such as Asia. Data from the TGA on new clinical trial notifications shows a decline in the volume of new clinical trials from a peak in 2007, and more recently the volume trend has been flat. This is despite data from international sources that global clinical trial volumes have been steadily rising, suggesting that Australia's market share of global clinical trial volumes is in decline, and we are at risk of losing our position in the global marketplace.[41]

The 2009 Clinical Trials Action Group (**CTAG**) review called for change in eleven areas to strengthen clinical trials in Australia, including timely ethics and governance review, improved patient recruitment, greater use of e-health to facilitate efficiency and improved access to information, measurement and monitoring of clinical trials activity and performance in Australia. Considerable progress has been made on the changes recommended by CTAG, and MTPConnect acknowledges and supports the coordinated work being undertaken by the Federal and State Departments of Health. However, there is broad consensus that more needs to be done and rapidly, and there is not yet a clear plan of action across the whole sector detailing the steps needed to fully achieve these changes.

Despite the shift to Asia, opportunities remain for Australia to increase the number of medicine clinical trials being undertaken locally. Australia can differentiate itself as a highly skilled, cost-effective and efficient clinical trial destination, targeting companies seeking certainty around cost and time, and as a location that provides scale and a vibrant environment for local innovators. Australia can establish itself as

40 Nanosonics website & ASX releases *"Nanosonics receives additional AusIndustry Grant funding for its Ultrasound Probe Disinfector"*; *"New NHS Scotland decontamination guidelines support high level disinfection of ultrasound probes"*; Nanosonics Annual Report 2006; Nanosonics ASX Announcement for TGA Approval, 2009; Nanosonics Investor Briefing 2010; Associate Professor Steen, J, *Productivity, exporting and innovation in Australian SMEs: Evidence from a longitudinal dataset*, University of Queensland, 2013

41 Based on a comparison of both TGA data and clinicaltrials.gov data on Australian trials with the global clinical trials dataset held by clinicaltrials.gov

42 McKeon et al, Strategic Review of Health & Medical Research in Australia ("the McKeon Review"), 2013

a specialist provider with skills and expertise in certain areas such as adaptive trial design, efficient patient recruitment and complex trials that require access to world class imaging, pathology and clinical practices. The underlying service sub-sector and research infrastructure that support clinical trials, including CROs, research institutes, hospitals and facilities, can become a thriving MTP export in their own right. Within this context, clinical trials in Australia can become a valuable source of revenue, growth and innovation for the sector.

Sensible, efficient and effective governance and regulation is crucial to the success of clinical trials within Australia. 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.

PRIORITY 5:
SUPPORT THE DEVELOPMENT OF DIGITALLY ENABLED MTP SOLUTIONS: DEVICES AND DATA ANALYTICS

THE OUTCOME of addressing this priority will be a 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 in turn will benefit patients while enhancing Australia's relevance in a fast growing area of the global economy.

The digital world has, and will continue to have, a substantial impact on the healthcare landscape. **Digital devices** and **data analytics** will affect how healthcare providers diagnose and administer health solutions and how consumers choose to be treated.

Digital Devices

Medical devices in the digital age are characterised by rapid design, development and prototyping, and often have short but highly effective product lifetimes. Australia can play a significant role in developing these advanced devices, diagnosis equipment and technology platforms. These would aid in the fast and accurate diagnosis of patient conditions and allow prescribers to more closely tailor treatments to individual needs. Given Australia's geography and familiarity with remote-care scenarios, it is also well positioned to become a world leader in remote care practices which are likely to be enhanced by digital devices and platforms.

Data Analytics

Australia holds a latent competitive advantage in the area of health data as a result of the scale, scope and quality of the existing data sets held in certain parts of the sector. Australia's unique position combines comprehensive nation-wide medical services and pharmaceutical data sets (Medicare, PBS), broad coverage of private health insurance claims data, a number of high quality patient registries, and an emerging comprehensive e-health record system. If these datasets can be streamlined and opened up to the sector for analysis and use in product development, Australia will have a significant advantage across the entire value chain, and will be much more attractive to international talent, collaboration and investment. As these datasets become deeper and richer, there will be a greater need to ensure their integrity and security against both local and international threats. MTPConnect will work with the Cyber Security Industry Growth Centre and the Commonwealth Scientific and Industrial Research Organisation's (**CSIRO's**) Data61 to ensure the use of these datasets is in line with best practice.

Together, these new digital devices and datasets will enable new software solutions and healthcare platforms that will allow consumers to have greater control over their own healthcare. They are the crucial elements needed as the sector moves towards greater adoption of precision healthcare. The success of these new solutions also relies on education of end users such as state health departments and public and private healthcare providers on the potential of digital innovations. If there is no desire to implement and integrate digital solutions within existing healthcare systems, these innovations will fall flat, and Australia may fail to provide efficient, cost-effective and world-leading healthcare.

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).

PRIORITY 6:
POSITION AUSTRALIA AS THE PREFERRED PARTNER FOR EMERGING ASIAN MARKETS

CLOSER ALIGNMENT with Asia has the potential to drive benefits across the MTP value chain. For researchers, start-ups and SMEs, increased cross-border collaborations will improve the prospects of uncovering new insights and tapping international funding pools. SMEs and established companies will gain accelerated access to export markets that are aligned to the fastest growing region for healthcare demand. The overall outcomes will be increased funding, research collaboration and value of exports.

With over 60% of the world's population,[43] the Asia-Pacific region presents a large and rapidly growing opportunity.[44] The Asia-Pacific was the fastest growing market for medical devices from 2008 to 2014, with an estimated total medtech market size of c.US$65 billion in 2015.[45] The Asia-Pacific market for pharmaceuticals reached c.US$261 billion in 2014, with growth of c.9% p.a. between 2010-14.[46] This makes Asia the most significant cluster of developing markets that are highlighted in the megatrends above. The speed and extent of Asia-Pacific's development presents a number of unique opportunities for Australian researchers and developers. In addition, the increasing integration of many developing Asian markets into the global economy introduces new global biosecurity threats which Australia is well positioned to play a role in managing. Success in Asia 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.

The Asia-Pacific market has 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 therapy 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.

However, reaching a fragmented set of culturally diverse Asia-Pacific markets presents a challenge. Success will require strong overseas linkages to Asian markets to facilitate streamlined access and expansion pathways. Establishing such connections has already commenced. For example, several research organisations have already established strategic research relationships throughout Asia, and AusBiotech has launched the Australian Medical Devices & Diagnostics

43 United Nations, World Population Prospects, 2015 revision
44 MTAA, Submission to Senate Economics References Committee Inquiry into Australia's Innovation System, 2014
45 Espicom, World Medical Markets Factbook 2015 and 2012
46 MarketLine, Pharmaceuticals in Asia Pacific, Dec 2015

to China project. Additionally, Australia can use its expertise to provide institutional strengthening and capability building within these emerging countries and economies, for example, in the areas of regulatory standards and trade processes. These approaches are well established in other sectors of the economy and lead to greater market access and market opportunities.

Signostics going to Asia and beyond[47]

Formed in South Australia in 2005, Signostics developed the world's smallest portable ultrasound system. Originally developed for local doctors with limited access to conventional ultrasound equipment, such as those operating in rural areas, the products are now exported to numerous overseas markets.

Signostics devices have had success in countries with a strong demand for in-home care, where doctors and nurses require portable diagnostic devices that are simple to use. Through a distribution partnership with Konica Minolta, Signostics has sustained strong sales in Asian countries, where an ageing population is driving increased demand for in-home care.

Aside from being additional markets in which to sell Australian goods, developed Asian countries also offer considerable partnership opportunities throughout the value chain. As noted by McKeon, Australian researchers may be able to leverage expertise in Asian countries to fast-track ideas or develop new research insights,[48] and small and medium-sized enterprises (**SMEs**) could secure new sources of funding through Asian investors.

PRIORITY 7:
SUPPORT ADVANCED MANUFACTURING AS A PART OF THE BROADER AUSTRALIAN INNOVATION ECOSYSTEM

THE OUTCOME of addressing this priority will be an increase in the value of advanced manufacturing in the MTP sector, supporting the next generation of Australia's evolved manufacturing economy. This will provide an opportunity for the re-skilling and redeployment of Australia's existing manufacturing workforce into highly-skilled jobs along the value chain.

The Advanced Manufacturing Growth Centre (**AMGC**) defines advanced manufacturing as "the application of leading-edge technical knowledge and expertise to the creation of products, production processes and associated services for the purpose of sustaining high growth and profitability". In practice, this means an advanced manufacturer can be considered best in class, rather than purely high-tech. Pursuit of advanced manufacturing can involve numerous elements of best practice across cost reduction, value differentiation and market focus.

While Australia is unlikely to be able to compete strongly with low-cost, high-volume manufacturers, it is well positioned to compete in manufacturing that requires deep technical expertise, innovative processes and high market responsiveness. Some of Australia's MTP companies already exhibit numerous characteristics of advanced manufacturing such as a higher proportion of highly skilled workers and after-sales service offerings.[49]

47 Sydney Morning Herald, *From zero to $6m in two years for SignosRT*, 2015; http://www.signosticsmedical.com/ Last accessed June 2016; Department of Industry, *Medical Technology Innovators: Signostics*; Pacific Bridge Medical, The Expanding Home Healthcare Market in Asia, 2014;
The Advertiser, *Signostics launches pocket-ultrasound device in Europe*, 2010
48 McKeon et al, Strategic Review of Health & Medical Research in Australia ("the McKeon Review"), 2013
49 Advanced Manufacturing Growth Centre, Sector Competitiveness Plan, 2016

Some medical technologies and new pharmaceutical products (e.g. biologics, cell therapies, assistive technologies) require highly specialised manufacturing that is well suited to those countries with a reputation for clean, safe and high quality manufacturing. Australia's reputation for high-quality manufacturing has resulted in a growing demand from Asia for Australian-manufactured products, including pharmaceuticals.[50] Given Australia is already positioned as a high-value, lower-volume manufacturer, there is an opportunity to leverage this expertise and expand the country's advanced manufacturing capabilities within the MTP sector and the broader innovation ecosystem.

Production is only one component of the manufacturing value chain. Australian companies can also extend operations up and down the value chain to provide a full service offering, widening their market focus. Local manufacturers can 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. They can also become more involved in sales and after-sales service, strengthening their relationships with end-users of their products, and integrate more fully with global markets up and down the manufacturing value chain.

ResMed, advancing its manufacturing[51]

ResMed is one of Australia's largest manufacturers of medical devices, but it is also quickly developing into one of Australia's leading advanced manufacturers. Building on its success in manufacturing devices to treat sleep apnoea, ResMed has carved out positions up and down the value chain by developing a range of additional services and tools to aid in the diagnosis and post-acute treatment and monitoring of patients, for example ApneaLink Air™ and myAir™ collect data to help doctors and patients track the progress of sleep problems. Through its acquisition of Brightree (a leading provider of cloud-based business management and clinical software) in 2016, ResMed intends to become even more involved in service delivery across the continuum of care, and be a world leader in integrated care models for patients.

50 State of Victoria, Medical Technologies and Pharmaceuticals: Sector Strategy, March 2016
51 ResMed website, annual reports and investor presentations

CONSTRAINTS

There are a number of constraints and gaps that must be overcome to achieve the Sector Growth Priorities. Through a combination of industry consultation and extensive reviews of existing reports on the MTP sector, MTPConnect has detailed the constraints and gaps below.[52]

Policy

MTP products have high development costs and failure rates, requiring long payback periods to recoup costs through product sales.

An internationally aligned and stable intellectual property regime is fundamental to keeping innovations in Australia.

Frequent changes to grant and funding initiatives, product reimbursement policies, tax incentives or IP laws stifle investment in Australia's MTP sector or drive innovation offshore to countries with greater policy stability.

Funding and focus

Lack of both private and public funding contributes to the "twin valleys of death" at the preclinical or clinical stages.

Funding is often misaligned with capital requirements, either in amount or duration. Private funding is mostly directed to later-stage products that have passed proof-of-concept, placing a heavy reliance on limited government funding for research and early development.

There is insufficient funding targeting priority research areas with proven commercial viability. Grants that target commercial outcomes often fail to close the loop on whether these outcomes are achieved.

Regulation

The complexity, cost and time of navigating the regulatory pathway are a constraint, particularly for SMEs with limited resources.

The majority of Australian MTP businesses will require an international launch to be viable, and differences in regulatory and reimbursement environments can create issues if not explored early.

The regulation associated with capital raising for small companies impedes efforts to finance product development through private investors.

Global supply chain

The MTP market is a global one, and Australian companies need to develop their products with international markets in mind. Linkages to global markets are necessary to understand international needs, regulatory environments, market conditions and differing clinical practices.

Access to relevant market information and market opportunities for local companies developing business plans and international strategies is needed.

Commercialisation and collaboration

A commercialisation culture is missing from many research facilities. Incentive structures for researchers and clinicians are geared towards publication output or patient throughput instead of commercial innovation. In many cases, the motivations and attitudes of researchers do not align with a commercialisation agenda.

Australia does not have close links between practicing clinicians, industry and researchers, leading to outputs that are not always focused on practical health applications or needs, and often have little commercial viability.

Existing collaboration hubs are often sub-scale and lack strategic direction, limiting their effectiveness.

Skills

Attracting and retaining talented researchers can be difficult due to career uncertainty and the availability of more competitive international opportunities.

Researchers and researcher-founded start-ups often lack the business acumen and experience to assess the commercial potential of their research, translate it into commercial products, or develop regulatory strategies.

In early-stage clinical development, SMEs often struggle to fund, attract or engage strong managerial talent, staff with business development skills, or skilled advisors.

The sector faces a shortage of skills in enabling disciplines such as bioinformatics, health economics, regulatory affairs, and data analytics.

52 See Appendix 7 for a full list of reviews consulted

RELATIONSHIPS BETWEEN CONSTRAINTS AND SECTOR GROWTH PRIORITIES

All of these constraints affect multiple Sector Growth Priorities, and as a result, it is important to keep the linkages between those priorities in mind as the actions to overcome them are identified and implemented.

PRIORITY		MAJOR CONSTRAINTS AND GAPS: Funding and focus	Commercialisation and collaboration	Skills	Policy	Regulation	Global supply chain
P1	Identify and invest in Knowledge Priorities focused on current and future market needs						
P2	Create a highly productive commercialisation environment from research to early clinical trials and proof-of-concept						
P3	Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies						
P4	Strengthen Australia as an attractive clinical trial research destination						
P5	Support the development of digitally enabled MTP solutions: devices and data analytics						
P6	Position Australia as the preferred partner for emerging Asian markets						
P7	Support advanced manufacturing as a part of the Australian innovation ecosystem						

Following sector reviews and consultations, initiatives have been launched to address these constraints and gaps. However, many still remain to be addressed. The next section of this report outlines MTPConnect's role and proposed action plan to address these constraints and gaps.

4. MTPCONNECT ROLE AND PROPOSED DETAILED ACTION PLAN

MTPCONNECT'S ROLE IN ACHIEVING THE SECTOR GROWTH PRIORITIES

MTPConnect will play an integrating role across the sector, driving regulatory and policy change, coordinating activities between sector participants, facilitating deeper collaboration between research organisations, healthcare service providers and industry, and accelerating the development and progress of innovative companies. Importantly, MTPConnect will not duplicate actions that are already being undertaken by industry associations, and government departments and agencies unless there is agreed benefit in supplementing them further. MTPConnect will champion a unified national approach, encouraging collaboration across both state and company borders, with success of the overall sector preferred above any one state or company. There are three ways in which MTPConnect will create change: by taking direct action, as an independent voice, and by funding specific projects.

Taking action

Industry Growth Centres are not expected to amass significant program delivery capability in their own right, and the MTPConnect operating budget is modest. As a result, the programs MTPConnect deploys in its own right will be:

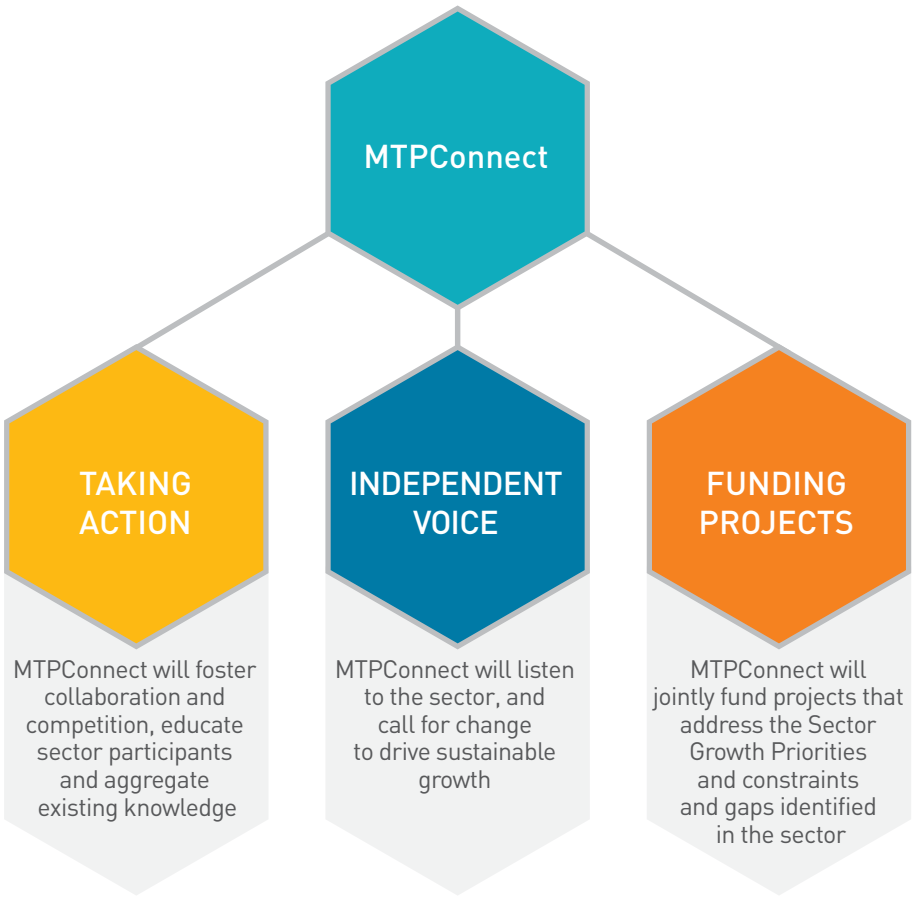
- **highly focused**, involving a few targeted and impactful actions designed to deliver benefits for participants at an efficient cost
- **targeted** to areas aligned to the Sector Competitiveness Plan and the Industry Growth Centre objectives
- **addressed to a genuine need** that is not being sufficiently met by existing programs or organisations

MTPConnect's role in taking direct action is best suited to those Sector Growth Priorities where the constraints are related to skills, investment and collaboration in areas where there is a substantial role for a connecting organisation. MTPConnect will direct the majority of its efforts to Sector Growth Priorities 1, 2, 3 and 4 which have a strong commercialisation focus.

The sector is highly disaggregated and in many cases operates in silos with inefficient information exchange. These barriers must be broken down to allow more effective sharing of critical skills and knowledge from one part of the sector to another, e.g. commercialisation skills from medtech and pharmaceutical companies into universities. Australia has excellent localised examples of best practice, which ought to be scaled nationally. MTPConnect will also play a key role in identifying international best practice and adapting it for Australia, so local organisations and researchers can stay at the forefront internationally. MTPConnect will undertake actions to increase connectivity, collaboration and commercialisation success across the MTP sector.

This will have multiple dimensions, including:

- **facilitating collaboration by being a central coordination point for all MTP sector stakeholders.** MTPConnect will foster collaboration both within the sector and outside it, with a view to ultimately increasing the success of Australian research commercialisation and the monetisation of Australian intellectual property. MTPConnect will bring participants together to share knowledge and best practice, and facilitate deeper connections between industry and research



- **aggregating and disseminating knowledge to give organisations the best chance of commercialisation success**. Information about opportunities, resources and initiatives in the sector is available, but it can be difficult to locate, or is available from disparate sources. MTPConnect will play a role in aggregating and curating critical information, and in helping stakeholders and participants to navigate the information to connect with the opportunities, resources and initiatives available within the sector. MTPConnect will sit with industry and academia to ensure that universities and research institutes are providing students and researchers with the skills necessary for commercial success. MTPConnect will also support the education of those who are less familiar with the sector, such as potential new investors, to enable them to participate more fully
- **developing guidelines for the allocation of research grants and funding to significantly improve commercial outcomes**. MTPConnect will work with public funding organisations such as the NHMRC, the MRFF and the BTF to establish appropriate criteria and encourage funding of research with commercialisation potential in line with the Knowledge Priorities. It will provide input into other government funding programs such as CRC, CRC-P and ARC funding to ensure these are aligned to market needs. MTPConnect will work to change the established incentive structure within academia to overcome the culture of "publish or perish"

MTPConnect has already taken significant actions in the sector since the release of its Draft SCP. Examples include hosting "Collaborate-to-Innovate" events that were attended by over 600 sector participants, working with Austrade to showcase Australia's MTP sector at international events and conferences in Seoul, Berlin and San Francisco, supporting the education of investors on the opportunities in the Australian MTP sector, and attending/convening workshops and roundtables to identify and plan for future workforce needs. MTPConnect consulted on the guiding principles of the MRFF and BTF, and how funding should be applied to

support translation and overcome the "valleys of death" to deliver commercialisation outcomes. MTPConnect is also in the process of preparing a whitepaper on funding sustainability options for its ongoing operations in the sector.

Independent voice

MTPConnect is not a paid membership organisation, which distinguishes it from established industry associations. As such, it is an independent body, but one attuned to the needs of industry, research organisations, universities, investors and policymakers, and can influence change across the entire sector.

The MTP sector is heavily shaped by government regulation, public policy and funding, and changes in these areas are necessary to allow the sector to generate significant economic growth and value-add. On behalf of the sector, MTPConnect will call for stable, long-term policies that encourage both local and international investment in R&D, educating the government and regulatory bodies of their importance to the success of the sector. MTPConnect will not be lobbying or advocating in a traditional sense, instead it will leverage its unique position to put forward changes that the sector needs and work with policy makers to enact sensible policy that benefits the entire sector. MTPConnect will work with state and federal governments to achieve policy alignment.

MTPConnect has commenced a process of regulatory renewal with numerous stakeholders from government and industry. The Government has also released its response to the Sansom Review of Medicines and Medical Devices Regulation (Sansom Review), in which it supports 56 of the 58 recommendations made. MTPConnect will work with stakeholders and sector participants to support the implementation of these recommendations. Appendix 6 contains the full list of focus areas MTPConnect has identified for regulatory renewal.

MTPConnect will influence how funding is directed via the Knowledge Priorities, ensuring that commercial potential and demonstrated market need are key criteria in the awarding of funds. By using its existing relationships with major funding bodies and research hubs such as the NHMRC, ARC, Cooperative Research Centres (**CRCs**), the BTF, the MRFF, the CSIRO and various universities, MTPConnect aims to guide the entire sector towards tangible healthcare outcomes and commercial successes.

The success of the MTP sector also relies on sector participants having support and a 'licence to operate' from the general public. Healthcare affects all Australians and it is important that sector participants articulate the health and economic benefits of a vibrant MTP sector for the Australian community. Thus, in addition to being a voice to government, MTPConnect will work with all sector participants to tell the positive story of the MTP sector's contribution to Australia.

MTPConnect's role as an independent voice and trusted advisor is best suited to priorities where the constraints and gaps identified have a significant policy, regulatory or government-funding dimension. This includes Sector Growth Priority 1 (government funding), Priority 2 (policy), and Priorities 4 and 5 (policy and regulatory burden).

MTPConnect has already been highly active as an independent voice for the sector since the release of the Draft SCP. Examples include reviewing ARC, CRC and CRC-P grant applications, providing input into the Office of Innovation and Science Australia's review of the innovation system, working with the TGA on implementing the recommendations from the Sansom Review, working with the TGA on other reforms such as legislation for medicinal cannabis, working with the Departments of Health and Border Security on placebo import guidelines and convening roundtables on the development of clinical trials in Australia.

Funding projects

MTPConnect will deploy a pool of $15.6 million over four years to fund projects to be led and undertaken by sector participants that address the Sector Growth Priorities. Funding deployed by MTPConnect will require matching funding from sector participants of at least 50%, and will be deployed via a competitive, merit based process towards any project that addresses the Sector Growth Priorities.

In July 2016, MTPConnect invited expressions of interest for its first round of matched funding. As part of its role MTPConnect worked with a number of sector stakeholders to shape and scope initiatives ranging from e-health to addressing skill gaps to reforming clinical trials, and connected stakeholders with other potential consortium members from across the sector. It received a large number of applications from the sector, 38 in total, with total funds requested of $51 million and matched funding up to $90 million. The judging panel ultimately selected 14 initial projects to receive funding of $7.4 million over the next two years, with matched sector funding of c.$32 million. These 14 projects were chosen because they align with one or more of the Sector Growth Priorities and aim to help sector participants overcome some of the constraints and gaps detailed later in this plan. The range of projects includes an initiative to shape the national digital and e-health landscape in Australia, industry/research training programs including Industry Mentoring Network in STEM and The Bridge Program, and an investor training program. A full list of the funding recipients and descriptions of their projects is provided in Appendix 2.

ALIGNMENT OF MTPCONNECT'S ROLE TO SECTOR GROWTH PRIORITIES

PRIORITY		MTPCONNECT ROLE: Taking action	MTPCONNECT ROLE: Independent voice	MTPCONNECT ROLE: Funding projects
P1	Identify and invest in Knowledge Priorities focused on current and future market needs	✓	✓	✓
P2	Create a highly productive commercialisation environment from research to early clinical trials and proof-of-concept	✓	✓	✓
P3	Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	✓	✓	✓
P4	Strengthen Australia as an attractive clinical trial research destination	✓	✓	✓
P5	Support the development of digitally enabled MTP solutions: devices and data analytics	✓	✓	✓
P6	Position Australia as the preferred partner for emerging Asian markets	✓	✓	✓
P7	Support advanced manufacturing as a part of the Australian innovation ecosystem	✓	✓	✓

Key: ✓ = MTPConnect strong focus ✓ = MTPConnect partial focus

MTPConnect's goals will evolve over three time horizons:

YEAR 1
(2016/17)

Define the Knowledge Priorities and deliver rapid impacts

- First SCP and 10-year vision in place
- Commence programs with a rapid impact (eg. clinical trials improvements, implementation of the Sansom review, investor education events, showcasing Australia at international events)
- Create MTP sector fact base and identify sector Knowledge Priorities
- Determine opportunities for sustainable funding of MTPConnect (whitepaper commenced)

YEARS 2–3
(2017/18–2018/19)

Build the connections for long-term sector success

- Facilitate collaboration
- Education and knowledge dissemination
- Encourage the removal of unnecessary regulatory barriers
- Review and refine actions

YEARS 4–10+

Strengthen and expand the connections for long-term sector success

- Refine and expand impact
- Review progress and outcomes
- Redefine and execute next phase of programs

MTPCONNECT'S ROLE IN DEVELOPMENT OF AN MTP SECTOR FACT BASE

In addition to the specific actions MTPConnect will take to support the Sector Growth Priorities, MTPConnect will also work with other sector participants to develop a sector-wide fact base. Currently there is no baseline and consensus view of the metrics that should be used to measure or track the sector. Data is often siloed, focused on a specific area rather than being sector-wide, or the relevant data does not exist. This hinders the ability of sector participants to obtain a strong understanding of the current state of the MTP sector or to track its progress.

To overcome this, MTPConnect will work with sector participants (including government) to determine the types of data and metrics that should be collected and collated and the organisations that will be involved in developing a common and consistent view of each of the metrics. Once created and compiled, the metrics will form the baseline that will be used to robustly measure the impact of MTPConnect's and the sector's actions.

MTPConnect has identified six broad outcome metrics that define the success of the sector:

- Increasing the number of products reaching each phase of development and clinical trials
- Increasing sector employment
- Increasing the number of Australian MTP companies
- Increasing sector GVA
- Increasing the number and size of clinical trials conducted in Australia
- Increasing MTP exports (particularly to Asia)

These are long-term sector objectives that will take some time to be delivered. MTPConnect will also track short-term input and output metrics for its activities as outlined in Section 4.

CONSTRAINTS, SECTOR ACTIONS AND MTPCONNECT ACTIONS

This section describes, for each of the seven Sector Growth Priorities, the specific constraints and gaps the sector faces, recommended actions for the MTP sector as a whole, and proposed actions that MTPConnect could take. The proposed actions for MTPConnect have been developed with input from a range of sector participants, and the aim is for MTPConnect to continue refining them, ensuring they remain relevant, are not duplicative, and are focused on the areas where MTPConnect can have the greatest impact given funding and reach.

As mentioned above, MTPConnect cannot act in isolation. It must be attuned to, and aligned with the various sector initiatives already underway. This section focuses predominantly on the MTPConnect proposed actions, however, a thorough review of broader sector actions and recommended initiatives has been considered in developing the MTPConnect proposed actions. The consolidated list of sector actions and recommended initiatives are outlined in Appendix 4 by Sector Growth Priority and constraint area.

PRIORITY 1:
IDENTIFY AND PROMOTE KNOWLEDGE PRIORITIES FOCUSED ON CURRENT AND FUTURE MARKET NEEDS

CONSTRAINTS, GAPS AND SECTOR ACTIONS

Funding and focus

While there is a broad range of funding sources available for R&D, there is little strategic focus on investing in research that has a strong likelihood of commercial outcomes. Grant funding and application criteria do not currently strongly align to or support prioritisation of commercially-focused research.

Consultation with sector stakeholders by MTPConnect and previous reviews of the sector (McKeon 2013, NSW Health and Medical Research [HMR] Strategic Review 2012) have identified recommendations to address this, including:

- Allocating public research funds to top-down strategic priorities (i.e. Knowledge Priorities). These will be dependent on the development of a fact base and will need to be cascaded through major research funding vehicles and institutions, for example, the CSIRO and NHMRC. The recently announced BTF and MRFF will also help to relieve some funding pressures and provide a greater commercial focus on grants within the sector
- Revising funding and application criteria to support prioritisation of commercially driven research. The Federal Government has recently announced its support for recommendations arising from the Watt Review in 2015, which include additional funding to support collaboration and increased weighting of commercialisation criteria in grant funding, some of which will flow to the MTP sector[53]

Commercialisation and collaboration

Commercially-focused research is currently constrained in multiple ways:

- Despite some examples of collaboration successes, there is not a strong culture of collaboration between researchers and universities, industry and clinicians. This is primarily due to misaligned incentive structures, pressure on physicians to treat rather than research and poor communication between medical practitioners and researchers/developers
- Australian collaboration hubs are often small-scale, and have less industry involvement than those of international peers
- There is a lack of focus on the commercialisation potential of research activities

Ensuring a focus on current and future market needs also requires strong links between those conducting research and product development, and the end users of those products and services. Researchers and MTP innovators often have insufficient access to clinicians and to policymakers and the administrators of public and private healthcare service providers. Actions to address this include creating stronger links between these various groups, and creating forums in which they can come together to uncover and articulate end user needs.

In addition, there are limited metrics available that accurately capture the level of commercially-driven research or collaboration between research institutes, industry and clinical practice. This makes it difficult to assess or recognise progress that is being made.

53 Department of Education and Training. Response to the Watt Review of Research Policy and Funding Arrangements 6 May 2016

MTPConnect's consultations, as well as a number of recent reviews in the research sector (e.g. by McKeon), have recommended actions to address collaboration and commercialisation constraints and gaps. These include adding commercialisation criteria to assessments for researcher reward and recognition, and supporting integrated health research centres that bring together hospitals, universities, MRIs and industry (McKeon 2013, NSW HMR Strategic Review 2012). More generally, the Federal Government has committed funds to improving collaboration between businesses, end users and university researchers, and sought to prioritise research involving a business partner.[54] The recently released independent review into the R&D tax incentive has also recommended that a collaboration premium of up to 20% be introduced to further encourage collaboration in R&D.[55]

Skills

Attracting and retaining talented researchers can be difficult due to factors such as career uncertainty arising from short-term funding and policy changes and the availability of more competitive international opportunities. To develop a globally competitive MTP sector, Australia needs to ensure it is developing and retaining top-tier research talent, as well as attracting additional talent from overseas. An additional skill gap is a lack of awareness of appropriate IP regulations among researchers which can impede commercially-focused research. This includes uncertainty around IP legislation in collaborative situations, and poor knowledge of IP protection practices, leading researchers to either over-patent or to publish without appropriate protections in place.

Focusing research funding on commercially prospective areas (as noted above) will create greater funding stability and help to attract researchers to those areas. Encouraging researchers to consider the pathway to commercialisation will provide clearer career trajectories and will clarify when IP protection is required (McKeon 2013).

54 Department of Education and Training. Response to the Watt Review of Research Policy and Funding Arrangements 6 May 2016

55 Review of the R&D Tax Incentive, April 2016

PROPOSED MTPCONNECT ACTIONS

MTPConnect sees its greatest area for action in defining the Knowledge Priorities (KPs), aggregating and distributing valuable information and education resources to support researchers to develop an understanding of commercial requirements, while acting as a catalyst for more commercial focus in research funding.

PRIORITY 1: IDENTIFY AND PROMOTE KNOWLEDGE PRIORITIES FOCUSED ON CURRENT AND FUTURE MARKET NEEDS

	Year 1	Years 2–3	Years 4-10+
MTPConnect taking action	• Gather the necessary fact base to establish where Australia currently is, or could be, a leader in research • Engage with stakeholders to develop a comprehensive list of KPs to be adopted • Develop a portal to educate the sector regarding product development, commercialisation progress and resources available to address the continuum of innovation, including key regulatory, IP, legal, quality and manufacturing questions	• Develop cost / benefit models to assess the effectiveness of various grant programs against commercialisation objectives • Develop case studies highlighting successful translation of focused research into commercial outcomes and showcase them nationally • Fund specific projects that align with the KPs and reward success	• Continue to refine commercial KPs in light of market pull (shifting clinical needs) or science push (scientific breakthroughs and emerging research fields)
MTPConnect independent voice	• Encourage the inclusion of commercialisation factors in sector rankings, grant-assessment criteria, and increases to translation and commercialisation-focused grant programs	• Encourage greater focus of research spending on KP areas by developing a document recommending focus areas and links to commercialisation outcomes	• Continue to encourage greater focus on KP areas and the establishment of collaboration hubs focused on these areas • Develop frameworks for sharing of infrastructure and free movement of researchers between institutions to complete research projects
Success metrics	• Commercialisation factors included in sector rankings and grant assessments • Portal generated	• Increasing % of R&D spend in KP areas	• Increasing % of R&D spend in KP areas

PRIORITY 2:
CREATE A HIGHLY PRODUCTIVE COMMERCIALISATION ENVIRONMENT FROM RESEARCH TO EARLY CLINICAL TRIALS AND PROOF-OF-CONCEPT

CONSTRAINTS, GAPS AND SECTOR ACTIONS

Funding and focus

Historically there has been little funding available for advancing MTP innovations from discovery to the proof-of-concept phase. Private investment is typically not available at this earlier stage of development. The grant funding that is available does not adequately focus on areas of commercial potential or industry need, and there is little funding for supporting infrastructure or research-support services such as bioinformatics, data analytics, or early-stage commercial advice. Industry consultations have also indicated that there is no incentive for business-to-business collaboration as the majority of grant funding is for projects involving research organisations.

The recently announced BTF and MRFF will provide funding directly targeted at overcoming these constraints, and MTPConnect will help sector participants to access these funds. Multiple industry reviews and organisations have recommended other actions to address funding constraints (AAMRI 2012, NSW HMR Strategic Review 2012, McKeon 2013). These include revising grant criteria to focus on successful translation of research and commercialisation metrics, working to attract private funding (local and offshore) by engaging and educating investors, and linking early stage start-ups with industry experts. Actions related to infrastructure gaps include creating dedicated infrastructure-funding vehicles.

Commercialisation and collaboration

In general, Australia's researchers and clinicians are not given incentives to focus on commercialisation. Research incentive and reward structures are focused on publications, citations and grant funding secured. For clinicians, funding constraints and focus on patient throughput have diminished the research culture and skills of hospitals and clinicians. Some states have introduced new metrics reporting for clinical trials which may help to rebuild this research culture (see Priority 4 for further details).

There is considerable overlap in the actions recommended to address funding (see above), skills (see below), and commercialisation and collaboration constraints in early stages. Opportunities exist to draw on international and local best practice examples for national roll out. Examples include the SPARK program, which other organisations (e.g. MTAA) are exploring developing in Australia, and the IMNIS mentoring program (which MTPConnect has recently funded to assist with a national rollout).

Skills

The importance of human capital (i.e. experienced and capable staff) is often not realised within the sector, but is crucial for the development of new and innovative products. Many researchers lack the awareness of commercial imperatives and drivers and the business acumen necessary to encourage and enable the translation of research into commercially viable products. In particular, there is a lack of knowledge regarding the regulatory and clinical pathways to get to market, as well as skills shortages in crucial areas of research support (regulatory advice, market access, target product profile development, bioinformatics, data analysis and clinical trial design). Limited career pathways between research and industry make it difficult for researchers to acquire these skills.

Actions to raise the level of commercialisation skills have also been addressed in recent industry reviews and by industry associations. Key recommended actions include broadening internship and mentoring programs (McKeon 2013), establishing research and advisory services and biotech incubator or accelerator programs (NSW HMR Strategic Review 2012), educating the academic and research sector regarding commercial skills (AAMRI 2012), and ensuring awareness of the need for regulatory understanding is raised early in the commercialisation process. A number of programs to overcome these gaps exist in the form of incubators or university TTOs, which MTPConnect will not aim to replicate. Rather, it will work with them and facilitate connections to existing companies in the sector. Support for industry exchange fellowships was also recently named as a priority area for the MRFF.

Policy

Stability of government incentives, IP laws and reimbursement policy is required to encourage investment. Past reviews have highlighted the need for government and industry to commit to ongoing stability of R&D tax incentives, clinical trial regulation (CTN/CTX), grant schemes, and policies relating to reimbursement and IP protection. A strong intellectual property regime is particularly important in this priority, and failure to secure this poses the risks that Australian innovators will choose to commercialise their IP elsewhere and Australians will have access to fewer innovative products. The recently announced recommendations from the independent review into the R&D Tax Incentive in Australia will likely impact the sector. MTPConnect supports a long term sustainable R&D Tax Incentive policy that is globally competitive and drives the intended outcome of truly innovative MTP research and commercialisation.

Regulation

The TGA differs from regulators in a number of other markets (e.g. the FDA) in that it operates on a full cost recovery model and does not receive government funding for 'public good' activities. As a result, the TGA is not resourced or required to provide pre-submission consultations or to support SMEs (in particular) in navigating regulatory hurdles. Actions to address this would include encouraging both the TGA and the Federal Government to consider a new role for the regulatory body, and funding the TGA to adopt a more partnership-based approach for working with industry by providing consultation and support services.

PROPOSED MTPCONNECT ACTIONS

MTPConnect envisages its focus areas for action under this priority to be improving access for start-ups to the skills, information and expert advice they need to progress from discovery to proof-of-concept. MTPConnect will also take a role in stimulating the national roll out of existing, best practice local and global initiatives identified.

PRIORITY 2: CREATE A HIGHLY PRODUCTIVE COMMERCIALISATION ENVIRONMENT FROM RESEARCH TO EARLY CLINICAL TRIALS AND PROOF-OF-CONCEPT

	Year 1	Years 2–3	Years 4-10+
MTPConnect taking action	• Create databases and decision frameworks to assist start-ups in need of funding to navigate the range of options available (e.g. crowd-funding, seed funding, VC etc.) • Expand existing and successful state mentoring programs nationally (e.g. Industry Mentoring Network in STEM [IMNIS], Molecules to Medicines) • Establish a best practice internship program between researchers and industry to encourage exchange of information and skills • Develop a commercialisation roadmap of what needs to be considered in each stage of the commercialisation pathway, including major regulatory considerations and requirements for different types of funding • Support the introduction of the BTF and the MRFF, and provide assistance to sector participants seeking their funds	• Provide education and advice to potential funding partners (philanthropists and investors) seeking to engage in the sector • Identify both local and international best practice, tailor it to the needs of the sector, and distribute it through case studies, seminars and/or programs • Promote programs to support the early stages of start-up and company formation (e.g. super mentors, professors of practice and entrepreneurs in residence) • Support a regulatory internship program for employees of SMEs and large pharma and medtech companies allowing them to spend a period of time working within the TGA to increase industry awareness of regulator perspectives • Establish a research and advisory service to assist with market research, value proposition definition, market potential definitions, and biostatistics and health-economics consulting services to start-ups (modelled on the Market Intelligence service provided by MaRS in Toronto)	• Enhance the effectiveness of TTOs by sharing best practices from successful entities, encouraging collaboration to support sub-scale TTOs, and supporting TTO skill development under a PraxisUnico-style model.[56] MTPConnect will also facilitate connections between TTOs/ incubators and established companies within the sector • Create new and raise awareness of existing publicly available presentations and information talks and videos on commercialisation, clinical trials and regulations
MTPConnect independent voice	• Encourage government to take a long-term view of regulation and policy impacting upon the industry, particularly in relation to IP laws and tax and reimbursement policies • Encourage the inclusion of commercialisation factors in sector rankings, grant-assessment criteria, and increases to translation- and commercialisation-focused grant programs • Provide advice to government to grow grant funding or target existing funding • Support the Government's implementation of the recommendations from the Sansom Review	• Work with SMEs to identify the missing skills needed for successful commercialisation (e.g. regulatory affairs, industrial engineering etc.). Promote these to the university sector and work to incorporate them into relevant courses and disciplines • Continue to support the Government's implementation of the recommendations from the Sansom Review	• Continue to support the Government's implementation of the recommendations from the Sansom Review
Success metrics	• Commercialisation factors included in sector rankings and grant assessments	• Increase in commercialisation grants • Increase in (commercially valuable) patent output • Higher rate of industry co-authorship of publications • Increase in quality internship programs • Databases and decision frameworks established	• Increase in commercialisation grants • Increased (commercially valuable) patent output • Higher rate of industry co-authorship of publications • Increase in the number of products reaching proof-of-concept or Phase I

56 https://www.praxisunico.org.uk/. Last accessed June 2016

PRIORITY 3:
TRANSFORM THE SME SUB-SECTOR TO SUPPORT THE GROWTH OF SMALLER COMPANIES INTO LARGER, MORE STABLE AND SUCCESSFUL COMPANIES

CONSTRAINTS, GAPS AND SECTOR ACTIONS

Funding and focus

Funding of later stage clinical development is often insufficient to meet the high cost of clinical trials and gaining market access. Companies struggle to attract private investment or achieve sustainable cash flow. Actions proposed in MTPConnect's sector consultations have been focused on creating an ecosystem that attracts private investors and potential partners to the Australian MTP sector, and facilitates companies' identification and maximisation of existing funding sources.

Skills

Many of the skill gaps identified above in relation to Priority 2 persist in Priority 3. More relevant to the growth of SMEs, however, is a lack of business management skills related to product commercialisation and monetisation. Also, SMEs often lack the necessary skills to negotiate attractive commercial terms during out-licensing or divestment. Actions to address these gaps are generally focused on skills-transfer programs aimed at filling key skills gaps in SMEs and larger companies. The focus should be on developing an understanding of industry, commercial acumen, and the knowledge to seek out and maximise negotiated outcomes in funding, out-licensing or divestment deals. An additional action would be to ensure a proportion of investment from major funders (BTF, MMRF, CSIRO) flows to areas where skill and capability gaps are greatest. Consultations have also noted the declining availability of clinicians who are willing and available to get involved in clinical trial design and execution.

Policy

International competitiveness and stability of policy and IP laws is required to encourage investment. Sector consultations have identified areas where greater policy stability, predictability or international alignment, are essential to the long-term health of the sector, including intellectual property protections, reimbursement policies (of the Pharmaceutical Benefits Advisory Committee [**PBAC**], Medical Services Advisory Committee [**MSAC**] and Prostheses List), and tax and other funding related policy (specifically the R&D Tax Incentive). In particular, the progress on regulatory renewal as represented by the Sansom Review needs to be continued through a review of reimbursement policy and the overall time to bring a product to market.

Regulation

Regulatory constraints exist across clinical trials, and the regulatory approval process. Processes related to clinical trials and regulatory approvals are complex and present challenges, especially for SMEs that lack resources and are navigating these processes for the first time. Lack of understanding of regulatory requirements can add significant delay, cost and failure in the commercialisation process, e.g. unintentional collection of incomplete data for a TGA submission can result in years of delay and in some cases, a decision by the sponsor to halt development if trials must be re-run.

For clinical trials, the approval process suffers from duplication and differing requirements between the various states and institutions. For regulatory approvals, SMEs are generally navigating a sequence of regulatory approvals simultaneously (in Australia and overseas) and TGA processes that are opaque for some medicines and medical devices (e.g. Class III) act as a barrier to launching products in Australia. SMEs would benefit if the TGA were to adopt a more partnership-driven approach and provide pre-submission consultation as a 'public good' service.

Proposed actions to address regulatory complexity are well documented (e.g. McKeon 2013, Sansom 2015, AusBiotech 2014, MTAA 2015) and aimed at harmonising and streamlining clinical trial procedures, aligning TGA processes and evidence requirements with those of international regulators, and better recognising existing international regulatory approvals. The Federal Government has recently announced that it will support 56 of the 58 recommendations from the Sansom Review, including an accelerated assessment pathway for medical devices, with implementation to occur over the next three years. Additional actions are to provide education or advisory programs to help researchers and SMEs navigate the regulations and to assist with regulatory strategy. Industry organisations such as MTAA and AusBiotech are already active in helping sector participants to navigate the regulatory requirements.

Global supply chain

Often, Australian MTP businesses must launch their products globally to achieve the scale required for sustainability and profitability. This necessitates adherence to international regulations, which are difficult to navigate and time consuming. Australian researchers and SMEs typically do not have the knowledge or skills to navigate these processes. Better overseas linkages are needed to assist commercialisation and collaboration.

MTPConnect's consultations have indicated that the actions to address this involve developing connections and tools to help companies access international sector participants (including researchers, investors, established industry players, regulators, and IP and market access experts).

PROPOSED MTPCONNECT ACTIONS

MTPConnect's proposed role in relation to this priority is as an aggregator of information, a facilitator to support connectivity and collaboration between small and large sector participants and experts, and an advisor to SMEs in the sector. The goal is for SMEs to be better prepared to attract investment, develop regulatory strategy and navigate market approvals and access. MTPConnect will also take a role in stimulating the national roll out of existing, best practice initiatives identified at a state and international level.

PRIORITY 3: TRANSFORM THE SME SUB-SECTOR TO SUPPORT THE GROWTH OF SMALLER COMPANIES INTO LARGER, MORE STABLE AND SUCCESSFUL COMPANIES

	Year 1	Years 2–3	Years 4-10+
MTPConnect taking action	• Develop a portal to alert participants to potential funding opportunities • In consultation with Austrade, develop an "international readiness" checklist specific for the MTP sector to allow SMEs to assess what skills, actions and connections they need to develop to allow them to successfully engage in the global supply chain	• Identify potential investors and develop education materials about the risk-return profile of MTP investments and an industry data book to promote Australia's value proposition and MTP investment potential • Identify both local and international best practice, tailor it to the needs of the sector, and distribute it through case studies, seminars and/or programs • Provide direction and advice to funding partners on areas of focus for investment and to companies that have the greatest potential to benefit from targeted funding • Design and develop checklists and assistance for businesses to use to determine if they are investment- or export-ready • Develop opportunities for SMEs and start-ups to meet with investors to showcase their developments • Set up a program to attract world-regarded successful MTP entrepreneurs/ investors to set up in Australia as Australia's Entrepreneur in Residence	• Develop a comprehensive program to advise start-ups on how to conduct product design and development phases to produce technical and trial outcomes which support regulatory and reimbursement approvals (modelled on the MaRS EXCITE program)
MTPConnect independent voice	• Support the implementation of key changes (aligned with CTAC[57] and HoMER[58]) to streamline and accelerate the clinical trial process • Encourage government to take a long-term view of regulation and policy impacting upon the industry, particularly in relation to IP laws and tax and reimbursement policies • Support the Government's implementation of the recommendations from the Sansom Review	• Continue to encourage government to take a long-term view of regulation and policy impacting upon the industry, particularly in relation to IP laws and tax and reimbursement policies • Continue to support the Government's implementation of the recommendations from the Sansom Review	• Continue to encourage government to take a long-term view of regulation and policy impacting upon the industry, particularly in relation to IP laws and tax and reimbursement policies • Continue to support the Government's implementation of the recommendations from the Sansom Review
Success metrics		• Higher rate of company formation • Increase in the number of mid-sized companies • Increase in sector investment and VC deal flow • Increase in the number of Phase II and III trials by local companies	• Higher rate of company formation • Increase in the number of mid-sized companies • Increase in sector investment and VC deal flow • Increase in the number of Phase II and III trials by local companies • Increase in the number of companies reaching launch

57 https://www.australianclinicaltrials.gov.au/australian-government-clinical-trials-initiatives. Last accessed June 2016

58 http://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review. Last accessed June 2016

PRIORITY 4:
STRENGTHEN AUSTRALIA AS AN ATTRACTIVE CLINICAL TRIAL RESEARCH DESTINATION

CONSTRAINTS, GAPS AND SECTOR ACTIONS

Commercialisation and collaboration

The availability of longitudinal patient datasets and patient registries could greatly improve the effectiveness and speed of clinical trials in Australia. However, datasets are currently fractured across multiple collecting agencies and in some instances are proprietary. E-health records are underdeveloped and clinician-focused, offering little benefit to researchers.

Reviews and consultations have identified that access to unified, national datasets would enhance the efficiency and cost-effectiveness of Australia as a clinical trial destination. The sector could focus on developing a de-identified dataset of health records that is available to and meets the needs of researchers, clinical trial sponsors and healthcare providers to support research and assist in identifying health trends. The use of patient databases, registries and biobank hubs as enabling infrastructure for the industry could be encouraged.

As noted in Priority 2, the sector faces some challenges to a diminished research culture within hospitals. The NSW Office for Health and Medical Research has recently introduced initiatives to increase the number of ethics and governance metrics collected within NSW hospitals, to provide greater insight into the clinical trial approval and enrolment processes.[59] The requirement to report these metrics may increase hospital managements' focus on clinical trials and improve clinicians' willingness to conduct them within the hospital. Such initiatives could be rolled out at a national level to help rebuild the research culture within hospitals.

Regulation

The current regulatory framework for clinical trials in Australia is complex, with state and local health networks having duplicated and differing governance and ethics requirements.

A number of opportunities to renew clinical trial sector regulation have already been suggested by past reviews (e.g. McKeon 2013, Clinical Trials Action Group [CTAG, now CTAC], NSW HMR Strategic Review). Several of these changes have already been implemented, however, the sector needs to continue to call for the timely implementation of further key changes to streamline and accelerate the clinical trial process, including all CTAC and HoMER recommendations.[60] Sector participants have indicated that a risk-based approach to ethics approval applications will help to alleviate some of the delays and frustrations caused by nuanced administrative requirements. MTPConnect will also push for greater consistency in regulation and processes across states to improve the efficiency of clinical trials across Australia. Dedicated structures to provide guidance and support to those seeking to navigate the clinical trial process would be beneficial.

Other

Other issues hinder progress in relation to this Sector Growth Priority. These include a lack of cost competitiveness compared with other jurisdictions and Australia's geographically dispersed and comparatively small patient base, which increases the difficulty of recruiting sufficient patients for trials. Australia does have strengths, for example its multi-ethnic population which allows trials to be conducted in Australia with multi-ethnic sub-populations.

MTPConnect consultations suggest that these constraints may also create opportunities for trials that could use Australia's unique characteristics to its advantage, conducting ethnicity-specific studies facilitated by our diverse population or exploring healthcare delivery in rural and remote areas. Cost-effective access to trials for SMEs could also be provided by aggregating local demand across different SMEs for similar patient sets.

59 NSW Office for Health and Medical Research - NSW Metrics for Health and Medical Research, including Clinical Trials, 2016

60 https://www.australianclinicaltrials.gov.au/australian-government-clinical-trials-initiatives. Last accessed June 2016. http://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review. Last accessed June 2016.

PROPOSED MTPCONNECT ACTIONS

MTPConnect's role in relation to this priority will largely involve encouraging and assisting with the implementation of reforms to streamline the clinical trial process.

PRIORITY 4: STRENGTHEN AUSTRALIA AS AN ATTRACTIVE CLINICAL TRIAL RESEARCH DESTINATION			
	Year 1	**Years 2–3**	**Years 4-10+**
MTPConnect taking action	• Convene roundtables to identify priority actions and projects for the next wave of clinical trial reform • Work with the Commonwealth Department of Health and/or the Clinical Trials Jurisdictional Working Group (or equivalent) to develop clinical trials metrics that can be used to promote Australia as a preferred clinical trials destination	• Promote Australia's unique strengths as a clinical trial destination (in conjunction with Austrade) to international organisations (such as MNCs and research institutes) that may consider conducting clinical trials in Australia • Work with local SMEs to aggregate demand for similar trials and patient populations	• Continue to promote Australia as a specialist clinical trial destination. Develop case studies of local trials that showcase Australia's expertise and niche experience
MTPConnect independent voice	• Support regulatory renewal to streamline and accelerate the clinical trial process, including all CTAC[61] and HoMER[62] recommendations • Support the introduction of an advisory service(s) to assist sector participants looking to conduct clinical trials in Australia • Develop a fact-based report that provides a comprehensive view of reform progress to date, and quantification of the economic and health value to Australia of a harmonised, more robust, and competitive clinical trials sector • Support the Government's implementation of the recommendations from the Sansom Review	• Work with the Australian Digital Health Agency to ensure the clinical-research system is appropriately considered when designing or changing the standards, systems and programs supporting e-health records in Australia • Continue to support the Government's implementation of the recommendations from the Sansom Review	
Success metrics		• An increase in the number of clinical trials conducted in Australia	• An increase in the number of clinical trials conducted in Australia

61 https://www.australianclinicaltrials.gov.au/australian-government-clinical-trials-initiatives. Last accessed June 2016

62 http://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review. Last accessed June 2016

PRIORITY 5:
SUPPORT THE DEVELOPMENT OF DIGITALLY ENABLED MTP SOLUTIONS: DEVICES AND DATA ANALYTICS

CONSTRAINTS, GAPS AND SECTOR ACTIONS

Funding and focus

There is a lack of funding for research support services such as bioinformatics, computational biology and data analytics to meet the next wave of health innovation. As noted in Priority 3 above, this will involve ensuring that a proportion of investment from major funders (e.g. BTF, MMRF and CSIRO) flows to areas where skill and capability gaps are greatest.

Commercialisation and collaboration

Australia holds a latent competitive advantage in the area of health data which could be used for product development, clinical trials and evidence of product efficacy. However, at present these data sets are underutilised due to inaccessibility, lack of IT investment, lack of linkages between them, and policy restrictions regarding the use of records.

Actions to address this constraint focus on investing in and developing a de-identified dataset of health records that is available to and meets the needs of researchers, clinical trial sponsors and healthcare providers, to assist in identifying health trends and to support research.

Digital products also face a unique adoption challenge in that their benefits often flow to different parties than those who pay to use or implement them and they are often disruptive to the status quo. Without a collaborative approach between public and private healthcare providers, and state and federal governments, these products will continue to struggle for adoption within the Australian healthcare system. Actions to address this include holding "Futures Forums" to explore new digital innovations, and providing resources to educate end users on the implications of digital healthcare innovations.

Skills

Market leadership in digitally enabled products and discovery methods requires a highly skilled workforce with an understanding of medical sciences and data analysis or digital technologies. At present, there is a shortage of biomedical engineering, bioinformatics, health informatics, and data analytics skills, in universities, research institutes and industry.

Past reviews and sector consultations have recommended engaging with sector participants to highlight skills shortages and develop skills programs that strongly align with industry needs.

Regulation

The Australian regulatory system is designed to take a risk-based approach to regulation of medicines and medical devices that have a clear therapeutic claim. The wave of new digital device, 'app' and algorithm development in recent years has led to uncertainty amongst new sector participants about the appropriate risk level for their products, or a perception that even low risk devices will face onerous regulatory pathways. As a result, developers often elect not to make therapeutic claims, or develop a regulatory strategy too late in the development process. The Australian reimbursement framework also creates challenges for digital developers as it does not support many innovative data-enabled applications such as those for remote monitoring and predictive or responsive analytics. There are also challenges for highly sophisticated but non-implantable devices that can struggle to be reimbursed under the current funding model.

MTPConnect's sector consultations have identified a variety of sector actions to adapt Australia's regulatory framework and capabilities to respond to the growth of fast-moving digital health innovations. These include educating developers on regulatory pathways, encouraging early access to and use of low-cost regulatory advice (including from the TGA itself). The Federal Government has recently announced the introduction of an accelerated assessment pathways for medical devices. Implementing these may require deepening the assessment skill set for digital technologies within the TGA.

PROPOSED MTPCONNECT ACTIONS

MTPConnect will focus on helping those within and outside the industry understand the particular opportunities available in digital technology and the skills and regulatory stance that are required to respond to them.

PRIORITY 5: SUPPORT THE DEVELOPMENT OF DIGITALLY ENABLED MTP SOLUTIONS: DEVICES AND DATA ANALYTICS

	Year 1	Years 2–3	Years 4-10+
MTPConnect taking action	• Host "Futures Forums" to predict future trends and emerging scientific breakthroughs (e.g. precision and digital medicine) and to help government develop appropriate responses and identify opportunities for regulatory renewal • Support and fund a national digital health initiative to create an integrated ecosystem for the development and commercialisation of evidence-based digital health products	• Engage with sector participants, funding bodies and universities to highlight the need to focus training and development in priority skill areas • Engage with end customers to raise awareness of digital product and service innovations and their role in healthcare service delivery	• To be determined
MTPConnect independent voice	• Provide SMEs developing digitally enabled devices and algorithms with educational resources and connections to regulatory advisors, to raise awareness of the regulatory strategy and pathways for these products • Encourage better data linkages across public and private data sets, and development of Australian e-health clearing houses to develop Australia's data assets into a platform for commercial success • Support broader access to e-health databases for clinical trials and innovation and commercialisation applications • Support the Government's implementation of the recommendations from the Sansom Review	• Continue to encourage better data linkages across public and private data sets, and development of Australian e-health clearing houses to develop Australia's data assets into a platform for commercial success • Continue to support broader access to e-health databases for clinical trials and innovation and commercialisation applications. This includes supporting the recently funded Digital Health Initiative project • Continue to support the Government's implementation of the recommendations from the Sansom Review	• To be determined
Success metrics		• Increase in output of patented digital products	• Increase in output of patented digital products • Increase in the number of TGA registered Class I and Class IIa/b digital devices

PRIORITY 6:
POSITION AUSTRALIA AS THE PREFERRED PARTNER FOR EMERGING ASIAN MARKETS

CONSTRAINTS, GAPS AND SECTOR ACTIONS

Commercialisation and collaboration

Strong links need to be established with research, trade and investment partners in the emerging Asian economies. Actions arising from MTPConnect's sector consultations include forging offshore partnerships in the Asian region to position Australia strongly as a regional hub for exports, providing platforms and roadshows to engage Asian investors, and developing partnerships with key Asian universities and research institutes that allow collaboration on meeting the needs of markets in the Asia-Pacific, e.g. low-cost healthcare delivery solutions and treatments for tropical diseases. The capabilities and knowledge of organisations such as Austrade will be of use in this effort.

Policy

A strong and sustained policy commitment is required to give international businesses, funders and research organisations sufficient confidence to invest in the infrastructure, knowledge and supply chains needed to collaborate across borders. To support this, the sector and MTPConnect will need to continue to call for a stable policy environment and IP protections that are consistent with international best practice.

Regulation

Home market approval for medical devices is mandatory prior to market access being granted in a large number of Asian countries. This reinforces the need for the TGA to provide efficient approvals and support for Australian SMEs. In recent years the full cost recovery model has caused the TGA to play less of a role in leading and influencing the development of regulatory capabilty across Asian markets. This erodes the strong position that Australian products have when entering Asian markets, since the more influential the TGA the greater significance TGA approval has with Asian regulators. The provision of funding to support 'public good' activities, as discussed in Priority 3, would support the TGA in playing this role in the region.

Global supply chain

Lack of knowledge and understanding of commercial and regulatory processes in international markets is a barrier to success in relation to this Sector Growth Priority. Without such knowledge, it is difficult for local products and ideas to find an expanded, international market. To overcome this problem, the sector can develop systems and tools that can help companies understand overseas markets and regulatory processes so they can collaborate or export overseas. A key part of this involves engaging more closely with alumni of Australian academic institutions who are working in Asian markets. Links with Austrade will play an important role in providing access to information on Asian markets, sector participants, and clinical practices, however, further action is required to bolster this understanding and fill gaps.

PROPOSED MTPCONNECT ACTIONS

MTPConnect can play a pivotal role in helping to forge connections between Australia and other MTP participants in the Asian region.

PRIORITY 6: POSITION AUSTRALIA AS THE PREFERRED PARTNER FOR EMERGING ASIAN MARKETS

	Year 1	Years 2–3	Years 4-10+
MTPConnect taking action	• Coordinate with Austrade to develop a consolidated calendar to market and promote the sector to the global market and Asia in particular • Organise a "whole-of-Australia" presentation at events and conferences, rather than the current state-based presentations	• Provide advice, guidance and connections to international market experts to help prepare Australian companies for international expansion • Forge offshore partnerships in the Asian region to strongly position Australia as a hub for exports	
MTPConnect independent voice	• Promote case studies of collaboration between Australia and Asian markets that have led to commercial success, providing guidance and inspiration to other sector participants	• Encourage government to take a long-term view of regulation and policy impacting upon this priority, in particular trade policy and IP laws • Promote a role for Australian regulators to provide regulatory best practice for South East Asian countries, allowing Australia to take the lead in harmonising regulatory regimes and providing an advantage for Australian exporters looking to access these markets • Work with the relevant Australian government agencies to embark on institutional strengthening and capability building missions in key emerging markets in South East Asia to ensure that their regulators are able to effectively manage regulatory processes	• Continue to encourage government to take a long-term view of regulation and policy • Continue to promote a role for Australian regulators to provide regulatory best practice for South East Asian countries • Continue working with the relevant Australian government agencies to embark on institutional strengthening and capability building missions
Success metrics		• Increase in R&D collaborations with Asia	• Increase in R&D collaborations with Asia • Increase in MTP exports to Asia

PRIORITY 7:
SUPPORT ADVANCED MANUFACTURING AS A PART OF THE BROADER AUSTRALIAN INNOVATION ECOSYSTEM

The Advanced Manufacturing Growth Centre (AMGC) is a 'horizontal' growth centre which spans across a number of industry verticals, including MTP. As such, many of the constraints, gaps and actions listed below leverage the analysis in the AMGC Sector Competitiveness Plan.

CONSTRAINTS, GAPS AND SECTOR ACTIONS

Funding and Focus

The AMGC Sector Competitiveness Plan calls for a shift towards R&D funding that is direct and targeted at commercial purposes. This is consistent with the findings earlier in this SCP that research and development in the MTP sector needs to be more market-led and that commercial potential should be explicitly considered in the allocation of public research funding. Actions to address this include the focus on Knowledge Priorities noted under Priority 1.

Collaboration & Commercialisation

Australia is a small market and it can be challenging for local companies to achieve the scale and cost advantages of international competitors. As the AMGC notes, a part of the solution is for Australian manufacturers to focus on high value, high quality and niche areas as a means of differentiating based on value rather than cost. However, there are also opportunities for Australian MTP manufacturers to collaborate with other firms to 'play bigger' to improve capital efficiency and reduce cost. Collaborations between universities, SMEs and larger international manufacturing companies will also be important to provide access to innovative advanced manufacturing processes, e.g. in the form of a technology partnership or licensing agreement.

Skills

There is a large and skilled product development and manufacturing workforce in Australia. However, there is a shortage of advanced manufacturing skills specific to the MTP sector. Australia is cost competitive relative to the US economy in the area of highly skilled labour.[63] Given this, it is imperative that Australia builds on this advantage and invests in advanced manufacturing that is heavily dependent on high skilled labour, not low skilled labour.

Industry bodies have suggested developing and promoting Australia as an advanced manufacturing hub for the MTP sector as part of a broader innovation ecosystem. Suggested actions include introducing funding for and promoting advanced manufacturing, and in parallel implementing long-term workforce planning coupled with tax and policy incentives for companies to upskill their employees, targeting students with information about careers in the MTP sector and high-value manufacturing, and promoting case studies of manufacturing successes in Australia.

Policy

Current R&D tax structures favour research over manufacturing capability. Industry associations call for an advanced manufacturing and innovation tax incentive to encourage the development of IP in Australia.

63 Advanced Manufacturing Growth Centre, Sector Competitiveness Plan, 2016

Global supply chain

Australian production costs are often uncompetitive for lower-skilled and well-established manufacturing processes. To create a competitive advantage, industry associations suggest the development of capability in niche industry sectors where fast prototyping, highly customised products, or high-quality products support high-value or high-margin manufacturing processes.[64] Examples from the MTP sector include high-end medical technologies, implants, and biological products such as stem cells and vaccines. Targeting these areas will mean focusing on manufacturing business models that align to upstream value-adding activities such as product development, or downstream service bundling.

PROPOSED MTPCONNECT ACTIONS

PRIORITY 7: SUPPORT ADVANCED MANUFACTURING AS A PART OF THE BROADER AUSTRALIAN INNOVATION ECOSYSTEM

The AMGC has developed its Sector Competitiveness Plan in parallel with MTPConnect, and has identified medtech as an immediate focus area. To ensure the two industry growth centres are aligned and not duplicating efforts, MTPConnect will sign a memorandum of understanding with the AMGC to foster collaboration between the two growth centres and sector participants.

There are a number of proposed AMGC actions that MTPConnect plans to actively engage in and support, including:

- development of industry Knowledge Priorities, particularly technology priorities in areas of competitive advantage that relate to the MTP sector
- increasing management awareness of international best practices in advanced manufacturing processes to improve productivity and reduce costs
- encouraging greater introduction of complementary services by manufacturers and showcasing examples of firms that have successfully expanded up the value chain into services in MTP
- identifying opportunities for firms to collaborate on R&D pooling and shared resources
- working with Austrade to identify underserved markets and communicate these markets to MTP manufacturers[65]

In addition, MTPConnect will support and encourage the TGA to develop stronger capabilities in supporting and evaluating advanced manufacturing processes (or overseeing the assessment of these processes by third party assessment bodies).

64 For examples, see the Advanced Manufacturing Industry Growth Centre website. Last accessed 16 June 2016

65 Advanced Manufacturing Growth Centre, Sector Competitiveness Plan, 2016

GLOSSARY OF TERMS

AAMRI	Association of Australian Medical Research Institutes
AMA	Australian Medical Association
ARC	Australian Research Council
AMGC	Advanced Manufacturing Growth Centre
ARTG	Australian Register of Therapeutic Goods
ASMR	Australian Society for Medical Research
ASX	Australian Securities Exchange
BTF	Biomedical Translation Fund
CRC	Cooperative Research Centre
CRO	Contract Research Organisation
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DIIS	Department of Industry, Innovation and Science
HMR	Health and Medical Research
IMNIS	Industry Mentoring Network in STEM
IP	Intellectual property
KPs	Knowledge Priorities
MA	Medicines Australia
MNC	Multinational corporation
MRFF	Medical Research Future Fund
MRI	Medical Research Institute
MSAC	Medical Services Advisory Committee
MTAA	Medical Technology Association of Australia
MTP	Medical technology, biotechnology and pharmaceutical
NGO	Non-government organisation
NHMRC	National Health and Medical Research Council
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
R&D	Research and development
SME	Small and medium-sized enterprises
STEM	Science, Technology, Engineering and Mathematics
TGA	Therapeutic Goods Administration
TTO	Technology Transfer Office
VC	Venture capital

APPENDIX 1: DEFINITION OF PRODUCT FOCUS

MTPConnect is focused on the development of innovative medical technology and pharmaceutical products, and primarily focuses on products that make a therapeutic claim regulated by the TGA. However, MTPConnect is seeking to take a broad definition of innovation and will selectively engage with stakeholders that fall outside of the core definition of the MTP sector where a clear benefit to the Australian economy can be demonstrated.

In the following illustration, product categories that will be the focus of MTPConnect are indicated.

			Example	MTPConnect Focus
Medicines →	Registered (higher risk)	All prescription	• Cancer drugs	✓
		Some OTCs	• OTC pain medication	✓
		Some complementary	• Some dietary supplements	✓
	Listed (lower risk)	Some OTCs	• Vitamins	✗
		Some complementary	• Sunscreens	✗
Medical devices →	Medical Devices excluding IVD	Class I	• Diagnostic devices for thermography	✓
		Class II a & b	• Hearing aid, surgical lasers	✓
		Class III	• Prosthetic heart valves	✓
		AIMD	• Pace makers	✓
	IVD devices	Class 1 IVD	• Microscope counting chambers	✓
		Class 2 IVD	• Urine testing kits	✓
		Class 3 IVD	• STD tests	✓
		Class 4 IVD	• Red Cross blood tests	✓
Biologicals →	Regulated as a biological (neither a medicine nor exempt)	Class 1	• Currently none	✓
		Class 2	• Frozen bone, heart valves	✓
		Class 3	• Demineralised bone	✓
		Class 4	• Genetically modified cells	✓
Other therapeutic goods →	Disinfectants and sterilants, Tampons and menstrual cups	Class IIb	• Medical device cleaners	✓
		Class I	• Instrument grade disinfectants	✗
		Registered	• Hospital or household cleaners making claims	✗
		Listed	• Tampons, cups	✗

APPENDIX 2: MTPCONNECT FUNDED PROJECTS

Consortium members	Brief description of project	Proposed partner contribution	Length of project	Proposed MTPConnect Grant
ATSE, AusBiotech Ltd.	Aiming to narrow the cultural gap that exists in Australia between business and academia through the Industry Mentoring Network in STEM (IMNIS) program, that will develop a national mentoring program linking PhD students with qualified industry mentors.	$200,000	24 months	$200,000
STC Australia, Artesian Venture Partners as well as MoUs with 16 other organisations	A National MedTech Accelerator to create a dedicated commercialisation infrastructure to leverage Australia's existing industry and research capabilities in the acceleration of new high-value, niche advanced manufacturing and medical device technology development opportunities through a focused, 15-month program.	$10,000,000	24 months	$1,100,000
Monash University, CSIRO, with letters of support from additional 8 organisations.	Aiming to upgrade the CSIRO (Clayton) protein production platform to human GMP capability for pilot-scale (<=200L) for a variety of expression systems (mammalian/yeast/ bacterial) as well as scale-up of cells.	$3,300,000	24 months	$1,100,000
St Vincent's Hospital Limited, University of Melbourne, University of Wollongong, Swinburne University of Technology, RMIT University, Stryker.	Support for BioFab3D@ACMD, a robotics and biomedical engineering centre, embedded within a hospital. Researchers, clinicians, engineers and industry partners will work alongside each other with a vision to build biological structures such as organs, bones, brain, muscle, nerves and glands.	$3,250,000	24 months	$1,100,000

Consortium members	Brief description of project	Proposed partner contribution	Length of project	Proposed MTPConnect Grant
Murdoch Children's Research Institute, Fidere Group, AusBiotech Ltd, Planet Innovation, Novartis Pharmaceuticals, Konica Minolta, Curve Tomorrow, RMIT, GP2U, Royal Children's Hospital, HealthXL, Bright Arena	A National Digital Health Initiative to create an integrated ecosystem for the development and commercialisation of evidence-based digital health products.	$1,800,000	24 months	$900,000
AusBiotech Ltd, ASX, Dibbs Barker, WEBuchan, KPMG	Development of a comprehensive global investment education program for the Australian life science sector - companies, investors and researchers.	$400,000	24 months	$400,000
Monash University, CSIRO, CCRM, Cell Therapies, St Vincent's Institute of Medical Research, AusBiotech Ltd	CCRM Australia, an Australian hub of Canada's Commercialisation Centre for Regenerative Medicine (CCRM) will support the development of foundational technologies to accelerate the commercialization of regenerative medicine products and therapies.	$350,000	24 months	$200,000
Cancer Therapeutics CRC Pty Ltd, Compounds Australia, UniQuest, Queensland Emory Drug Discovery Initiative (QEDDI), Monash Institute of Pharmaceutical Sciences (MIPS), Walter and Eliza Hall Institute (WEHI), Children's Cancer Institute (CCI).	Build on a national framework to provide Australian drug discovery organisations access to a comprehensive Hit ID platform that includes: a fit for purpose drug discovery library (up to 450,000 compounds); an ultra-high throughput screening facility; fragment based drug design capability; and a state of the art software platform for in silico drug discovery.	$5,568,500	24 months	$1,100,000
Clinical Oncology Society of Australia (COSA), Rare Cancers Australia, Cancer Voices Australia, Australian Institute of Tropical Health and Medicine (AITHM), The Garvan Institute of Medical Research, The Walter and Eliza Hall Institute of Medical Research (WEHI), Icon Group, c/-Icon Consolidated Holdings, St John of God Hospital, Medicines Australia, AbbVie, Janssen, Novartis Pharmaceuticals Australia, Pfizer Australia	The Clinical Oncology Society of Australia has developed a national guide for implementation of the Australasian Tele-Trial Model in consultation with clinical trial sponsors, clinicians, health administrators and regulatory bodies. This project will implement a feasible and effective tele-health strategy to increase access to clinical trials closer to the participant's homes, while at the same time ensuring the proper conduct of cancer clinical trials.	$115,000	24 months	$115,000

Consortium members	Brief description of project	Proposed partner contribution	Length of project	Proposed MTPConnect Grant
Flinders University of South Australia, Medical Technology Industry, and co-fund projects within the Program.	Initial scoping of the roll out of a National Medical Device Partnering Program (NMDPP) to bring together research, clinical and industry partners in a streamlined process for collaboration and product development.	$2,415,000	24 months	$150,000
Vaxine Pty Ltd, Morningside Ventures Australia, Mylexa, Australian Respiratory and Sleep Medicine Institute, Flinders University, University Of Adelaide, University of Queensland, University of South Australia, Institute Of Health and Biomedical Innovation, Queensland University Of Technology, Kollings Institute, Royal North Shore Hospital, University of Sydney, Australian Institute Of Tropical Health and Medicine James Cook University, Translational Research Institute, University of Queensland.	Project to assist in landscaping Australia's vaccine research capabilities and relevant services for the use by the whole MTP sector.	$1,725,000	24 months	$250,000
Abbvie, Amgen, Australian Private Equity & Venture Capital Association Limited, BMS, Boehringer Ingelheim, CSL Limited, Deputy Vice Chancellors Research Group (tbc), Johnson & Johnson Family of Companies in Australia, Macquarie University, Medical Research Commercialisation Fund, Medicines Australia, MSD Australia, Mundipharma, Novartis, Queensland University of Technology	A consortium of 14 companies, universities and industry associations that aims to transfer practical skills on pharmaceutical commercialisation through online and residential training in drug discovery and development, and direct exposure to industry practitioners in the scientific, legal, financial, clinical, regulatory and reimbursement disciplines that contribute to the commercialising of medicines.	$540,000	24 months	$540,000

Consortium members	Brief description of project	Proposed partner contribution	Length of project	Proposed MTPConnect Grant
Centre for Entrepreneurial Research and Innovation (CERI), The University of Western Australia, Monash University, University of Sydney, SPARK Co-Lab Ltd, University of Technology Sydney, Proteomics International Limited, Orthocell Ltd, St John of God Healthcare, Avita Medical, Adelaide University, Murdoch University, Curtin University, Edith Cowan University, Harry Perkins Institute of Medical Research, Telethon Kids Institute, Lion's Eye Institute, Ear Science Institute of Australia, WA Neuroscience Research Institute	Support for a national consortium for translational medical technology and pharmaceuticals research and training.	$2,445,000	24 months	$150,000
Queensland University of Technology, Hear and Say, Advanced Manufacturing Growth Centre, Innovative Manufacturing CRC	Support for a biofabrication research centre located on a hospital campus utilising 3D digital scanning, modelling and advanced manufacturing technologies.	$300,000	24 months	$100,000
MTPConnect has also set funds aside to create a specific clinical trial initiative which will be further scoped with the sector in late 2016.				
Total		**$32,408,500**		**$7,405,000**

APPENDIX 3: SECTOR KNOWLEDGE PRIORITIES

Knowledge Priorities (**KPs**) are intended to reflect:

- significant areas of unmet clinical need, and
- areas where Australian researchers or developers have a competitive advantage relative to their global peers. They also reflect areas where Australia does not currently have a competitive advantage, but could feasibly develop one

In practice, these priorities reflect areas with significant local and international commercial potential and should help to guide industry focus and funding towards areas of clinical need. The Knowledge Priorities intentionally have a commercial/clinical practice focus, and MTPConnect acknowledges that many of them are underpinned by skills and knowledge in the fundamentals of science, technology, engineering and mathematics (**STEM**). These enabling skills have not been listed as there are many, and it would not be practical to list them all.

A range of factors were considered to develop MTPConnect's Knowledge Priorities including:

- international research publication analysis
- Excellence in Research for Australia rankings
- NHMRC and MRFF priority research areas
- Medical Research Institute specialties
- existing commercial successes (e.g. industry success stories or large ASX listed companies)
- sector megatrends

MTPConnect also engaged widely with sector stakeholders to seek input and feedback on a draft set of KPs, and the list below reflects that feedback.

The KPs below are by no means final, and they will evolve over time. Future revisions will make use of robust industry baseline statistics, continued analysis of research publications, ERA rankings, commercial successes, and a review of successful and unsuccessful grant applications through the NHMRC, ARC, MRFF, BTF and MTPConnect. These will ultimately be used to narrow down a clear set of success criteria for MTP sector innovations.

Despite MTPConnect's classification of the priorities into three categories, their categorisation is somewhat fluid and success may actually come from a combination of Knowledge Priorities. For example, success in rural and remote care most likely relies on the development of new and innovative devices and diagnostic tools.

Potential Knowledge Priorities: Clinical speciality / therapy areas

- Arthritis and musculoskeletal
- Cardiac and cardiovascular
- Diabetes, endocrinology and metabolism
- Geriatrics and gerontology
- Haematology
- Inflammatory diseases
- Immunology
- Infectious disease (including tropical disease, vaccinations and medical countermeasures)
- Neurosciences and neurology
- Oncology
- Ophthalmology and optometry
- Otorhinolaryngology (including sleeping and hearing devices)
- Paediatrics
- Pain management
- Precision medicine and personalised care
- Reproductive endocrinology
- Respiratory
- Rural and remote care
- Sleep

Potential Knowledge Priorities: Areas of science

- Antimicrobial resistance
- Biochemistry, cell biology and metabolomics
- Biologics discovery
- Biomedical engineering
- Genetics and heredity
- Materials science and manufacturing
- Mathematical and computational biology
- Medical informatics (including data science, medical statistics and e-health)
- Molecular biotechnology
- Pharmacology and pharmaceutical science
- Regenerative medicine

Potential Knowledge Priorities: Devices and diagnostics

- Bionics
- Custom 3D printing and advanced prosthetics (including robotics)
- Diagnostic imaging
- Drug delivery
- Genomics
- Implantables
- Patient monitoring and clinical devices
- Point of care diagnostics
- Sterile and protective equipment
- Surgical devices, instruments and consumables
- Wearable devices

APPENDIX 4: SECTOR ACTIONS

This section lays out possible sector actions against each of the constraints and gaps within each Sector Growth Priority. These have been compiled based on past major reviews of the MTP sector, industry association policy papers and submissions to reviews, government and sector participant whitepapers, and the extensive program of consultations conducted by MTPConnect during 2015. These are not necessarily actions for MTPConnect – instead they provide a cumulative summary of the reform actions proposed up to now. The source for each possible action has been noted below.

PRIORITY 1:
IDENTIFY AND PROMOTE KNOWLEDGE PRIORITIES FOCUSED ON CURRENT AND FUTURE MARKET NEEDS

Funding and focus

- Develop a sector Knowledge Priorities document that identifies priority research areas and links to commercialisation opportunities (Source: MTPConnect)
- Develop cost / benefit models to assess the effectiveness of various grant programs against commercialisation objectives (MTPConnect)
- Support the introduction of the BTF and the MRFF (MTPConnect)
- Implement recommendations from recent reviews, in particular:
  - allocate and align a portion of the NHMRC medical research endowment account budget and other existing funding schemes to high-priority, strategic research. Establish a panel of experts to set the research agenda and evaluate outcomes (McKeon 2013)
  - ensure appropriate criteria for setting priorities within HMR funding organisations (NHMRC, Australian Research Council [**ARC**]) that include assessment of the commercialisation potential of proposed research (NSW HMR Strategic Review 2012)
  - increase the number of Marshall and Warren awards to 10 per year to fund a greater volume of high-risk, high-reward research (McKeon 2013)

Commercialisation and collaboration

A number of recent reviews, e.g. McKeon 2013, have recommended actions to address constraints and gaps in this area. MTPConnect supports action in these areas, in particular:

- Include commercialisation factors in sector rankings and implement awards and events for commercialisation success (McKeon 2013)
- Embed research into health-professional training and accreditation, support dual research-practitioner education pathways and streamline medical-practitioner accreditation processes for leading overseas research professionals (McKeon 2013)
- National rollout of a Clinician Scientist Program to support excellence in clinician research and fund protected time for research (similar to Western Australian Clinician Research fellowships) (NSW HMR Strategic Review 2012)
- Build a dynamic and supportive research culture within Local Health Networks (LHNs) by introducing strategic leadership and governance (NSW HMR Strategic Review 2012). Establish integrated health research centres and industry hubs that combine hospital and community-care networks, MRIs, research organisations and universities and encourage collaboration (McKeon 2013, MTAA 2014)

Skills

- Strengthen Australia's IP system and harmonise it with international best practice (McKeon 2013)
- Encourage researchers to consult business development offices, TTOs and other resources to assess commercial potential before filing patents (McKeon 2013)
- Develop a commercialisation roadmap to educate the sector on key regulatory and IP milestones (MTPConnect)

Other sector actions

- Open ARC Linkage Projects to include medical research (including in hospitals and MRIs) (AAMRI 2012)
- Develop social infrastructure to support collaboration, including physical clustering of organisations and development of incubators (MTAA Response to Innovation Inquiry 2014)

PRIORITY 2:
CREATE A HIGHLY PRODUCTIVE COMMERCIALISATION ENVIRONMENT FROM RESEARCH TO EARLY CLINICAL TRIALS AND PROOF-OF-CONCEPT

Funding and focus

- Support the introduction of the BTF and the MRFF (MTPConnect)
- Continue to embed appropriate commercialisation metrics (for example, the Research Engagement for Australia [**REA**] metrics from the Australian Academy of Technological Sciences and Engineering [**ATSE**]) into the major grant and fellowship schemes (i.e. NHMRC and ARC) (AAMRI 2012; MTPConnect)
- Set up pre-commercial proof-of-concept funds that dedicate resources to health-research precincts. Funds should be specifically for the proof-of-concept phase and IP protection. The case study is that of the Walter and Eliza Hall Institute Business Development Catalyst Fund (AAMRI 2012)
- Create databases and decision frameworks to assist start-ups in need of funding to navigate the range of options available, with profiles and case studies of successful applicants (MTPConnect)
- Provide education and advice to potential funding partners (philanthropists and investors) seeking to engage in the sector (NSW HMR Strategic Review 2012; McKeon 2013; MTPConnect)
- Implement an infrastructure funding vehicle that provides substantial funding for major projects and directs investment to priority areas. Ensure that health research centres and other organisations have sufficient access to existing and new infrastructure (similar to the VTPN Facility Directory in Victoria) (NSW HMR Strategic Review 2012; McKeon 2013)
- Develop an infrastructure register and require organisations that hold publicly funded infrastructure assets to make them available to other sector participants (NSW HMR Strategic Review 2012)
- Rationalise indirect funding for competitive grants and ensure that all qualified HMR institutions receive at least 60% indirect cost funding for nationally competitive grants (McKeon 2013)

- Develop additional specialist seed funds, with the Federal Government funding the administration and operation of these funds (AAMRI, Submission to Enhancing Commercialisation 2012)
- Develop and support non-grant funding sources including philanthropic funding (with government matching) or alternative funding sources such as government future health bonds or social bonds (McKeon 2013)

Commercialisation and collaboration

- Include commercialisation factors in sector rankings and implement awards and events for commercialisation success (McKeon 2013)
- National rollout of a grant funding scheme that is only for priority-driven, clinician-initiated research. The grants should only be awarded to research that has demonstrated potential for translation into clinical practice (similar to the NSW Translational Research Grants scheme) (NSW HMR Strategic Review 2012)
- Identify both local and international best practice and distribute it to sector participants through case studies and/or seminars (MTPConnect)

Skills

- Establish a national internship program between researchers and industry to encourage exchange of information (McKeon 2013; MTPConnect)
- Promote programs to support the early stages of start-up and company formation (e.g. super mentors, professors of practice, and entrepreneurs in residence). Expand the IMNIS mentoring program nationally (MTPConnect – now underway)
- Develop (and leverage existing) industry experience programs for STEM students and PhD candidates (MTPConnect)
- Establish a research and advisory service to provide market research, value-proposition definition, market-potential definitions, and biostatistics and health-economics consulting services to start-ups (MTPConnect)
- Nationally roll out successful state- or territory-based biotech incubator and accelerator programs (e.g. Victoria's "Medtech's Got Talent") (MTPConnect)
- Partner with appropriate providers to educate the academic and research sector on commercial skills, the commercialisation process and the capabilities required for successful entrepreneurship. Agitate to ensure training in these skills is a mandatory component of PhD programs (AAMRI 2012; MTPConnect)
- Enhance the effectiveness of University Technology Transfer Offices (TTOs) by sharing best practices from successful entities (UniQuest, UNSW Innovations), encouraging collaboration to support sub-scale TTOs, and supporting TTO skill development under a PraxisUnico-style model (AAMRI 2012; NSW HMR Strategic Review 2012; MTPConnect)
- Develop NHMRC support schemes, and coordinate efforts with the tertiary information sector, to meet capacity requirements in enabling technologies and support services (McKeon 2013)
- Support and encourage the national roll out of transitional research support programs (for example, SPARK Sydney) (MTAA)

Policy

- Strengthen Australia's IP system and harmonise with international best practice (McKeon 2013)
- Ensure government commitment to the ongoing stability of funding and related policies for medtech and pharmaceuticals (MTPConnect)
- Support the Government's implementation of the recommendations from the Sansom Review (MTPConnect)

Other sector actions

- Support sector participants in engaging the general public to tell the positive story of the MTP sector's contribution (MTPConnect sector roundtables)

PRIORITY 3:
TRANSFORM THE SME SUB-SECTOR TO SUPPORT THE GROWTH OF SMALLER COMPANIES INTO LARGER, MORE STABLE AND SUCCESSFUL COMPANIES

Funding and focus

- Design and develop checklists and assistance for businesses to determine if they are investment- or export-ready (MTPConnect)
- Develop a portal to alert participants to the funding opportunities in their area and the application guidelines for them (MTPConnect)
- Expand opportunities for SMEs and start-ups to meet with investors and showcase their developments (MTPConnect)
- Identify potential investors and develop educational materials about the risk-return profile of MTP investments and an industry data book to promote Australia's value proposition and MTP investment potential (MTPConnect)
- Provide direction and advice to investors on areas of focus for investment and companies that have the greatest potential to benefit from targeted funding (MTPConnect)

Skills

- Establish a clear view of the entire HMR workforce within Australia (a "single source of truth") (McKeon 2013)
- Develop a program linking existing health and biotech incubators to share best practices and develop skills and programs (MTPConnect)
- Develop a program to educate SMEs on approaches to maximise negotiated outcomes when seeking funding, out-licensing arrangements or divestment (MTPConnect sector roundtables)
- Develop NHMRC support schemes to meet capacity requirements in enabling technologies and support services, and coordinate efforts to achieve these requirements with the tertiary-information sector (McKeon 2013)
- Identify both local and international best practice and distribute it to sector participants through case studies and/or seminars (MTPConnect)

Policy

- Maintain the current Innovation Patent system by implementing some of the Advisory Council on Intellectual Property's recommendations (Medicines Australia response to Advisory Council on Intellectual Property's report, 2015)
- Commit to a predictable PBS reimbursement policy that acknowledges innovation, as well as an efficient PBS listing process (Medicines Australia 2014)
- Restore the R&D tax incentive to its pre-FY15 budget form (Medicines Australia 2014)

Regulation

Provide regulatory guidance:

- Develop a comprehensive program to advise start-ups on how to conduct product design and development phases to produce technical and trial outcomes which support regulatory and reimbursement approvals (modelled on the MaRS EXCITE program) (MTPConnect)

Agitate for harmonisation of clinical trial regulations:

- Support regulatory renewal to streamline and accelerate the clinical trial process, including the full set of CTAC and HoMER recommendations (MTPConnect)
- Agitate to harmonise animal regulation – bring together state managers to work through inconsistencies (MTPConnect)

Refine TGA processes for more streamlined approvals:

- Introduce an accelerated approval program for areas of unmet need and serious or life-threatening illness. The process should offer multiple paths for approval, and there should be very clear guidelines published by the TGA (AusBiotech 2015 – now underway for medical devices)
- Encourage the TGA to cease conducting conformity assessment reviews for medical devices and instead become a designating authority of third party assessments. The TGA could audit existing assessment bodies and, once satisfied with their processes, allow them to conduct conformity assessments without further TGA review. The TGA could then refocus resources to post-market tasks of monitoring and compliance (MTAA, Improvements to Regulation of Medical Devices, 2014)
- Agitate for variations for low-risk medicines and low-risk variations to moderate risk devices to have a correspondingly lower fee and processing time (AusBiotech 2015)
- Agitate for the TGA to review its advice services and strengthen them by providing pre-submission advice to sponsors on submission requirements, a schedule of costs and timelines and support programs to assist SMEs with the process (AusBiotech 2015)
- Encourage the TGA to place greater emphasis on post-market data, and streamline pre-market assessment as much as possible. Harmonise pre-market assessment with other regulatory agencies (AusBiotech 2015)

Global supply chain

- Develop a checklist for companies to use to determine if they are investment- or export-ready (MTPConnect)
- Coordinate with Austrade to provide resources and connections between companies and overseas regulators (MTPConnect)
- Link Australian companies with international research agencies for collaboration of ideas (MTAA 2014)

PRIORITY 4:
STRENGTHEN AUSTRALIA AS AN ATTRACTIVE CLINICAL TRIAL RESEARCH DESTINATION

Commercialisation and collaboration

- Work with the Australian Digital Health Agency to ensure the clinical-research system is appropriately considered when designing or changing the standards, systems and programs supporting e-health records in Australia (NSW HMR Strategic Review 2012)
- Encourage the use of patient databases, registries and biobank hubs as enabling infrastructure for the industry (MTAA Response to Innovation Inquiry 2014)

Regulation

- Convene roundtables to identify priority actions and projects for the next wave of clinical trial reform (MTPConnect)
- Develop a fact-based report that provides a comprehensive view of reform progress to date, and quantification of the economic and health value to Australia of a larger, more robust, and competitive clinical trials sector (MTPConnect)
- Support regulatory renewal to streamline and accelerate the clinical trial process, including the full set of CTAC and HoMER recommendations (MTPConnect)
- Establish a Clinical Trial Support Team for Medical Research. The support team would be a point of contact for participants looking to conduct trials, develop policies to improve research ethics and governance processes, investigate ways to improve patient recruitment and monitor and report on clinical trial activity (NSW HMR Strategic Review 2012)

Other

- Create a system to aggregate local demand for pre-clinical and clinical trials, to encourage service providers, create greater certainty of scale for trials and decrease costs (MTPConnect)
- Continue to promote Australia as a specialist clinical trial destination. Develop case studies of local trials that showcase Australia's expertise and niche experience (MTPConnect)

PRIORITY 5:
SUPPORT THE DEVELOPMENT OF DIGITALLY ENABLED MTP SOLUTIONS: DEVICES AND DATA ANALYTICS

Funding and focus

- Develop NHMRC support schemes to meet capacity requirements in enabling technologies and support services, and coordinate efforts to meet these requirements with the tertiary information sector (McKeon 2013)

Commercialisation and collaboration

- Support broader access to e-health databases for clinical trials and innovation and commercialisation applications (MTPConnect)
- Work with the Australian Digital Health Agency to ensure the clinical research system is appropriately considered when designing or changing the standards, systems and programs supporting e-health records in Australia (NSW HMR Strategic Review 2012)
- Conduct a public education campaign to highlight the importance of e-health patient records and convert the current system to opt-out rather than opt-in. Accelerate efforts to integrate existing datasets (McKeon 2013)
- Engage with end customers to raise awareness of digital product and service innovations and their role in healthcare service delivery (MTPConnect)

Skills

- Engage with CRCs and universities to highlight the need to focus training and development in priority skill areas (MTPConnect)

Regulation

- Agitate for the development of a fast-track system for regulatory approval of particular devices and medicines, including digital technologies, which could be funded by applicant processing fees. The fast-track system could require different skill sets to be brought into the TGA, and encouragement may be needed to spur the TGA to develop appropriate capabilities. (AusBiotech 2015; MTP Connect)
- Bring sector participants together to predict trends (e.g. precision and digital medicine) and help government develop appropriate responses (MTPConnect)
- Support the Government's implementation of the recommendations from the Sansom Review (MTPConnect)

PRIORITY 6:
POSITION AUSTRALIA AS THE PREFERRED PARTNER FOR EMERGING ASIAN MARKETS

Commercialisation and collaboration

- Forge offshore partnerships in the Asian region to firmly position Australia as a regional hub for exports (MTPConnect)
- Coordinate with Austrade to develop a consolidated calendar for promoting the MTP sector to the Asian market (MTPConnect)
- Forge partnerships with key Asian universities and research institutes to collaborate to meet the needs of Asia-Pacific markets, e.g. for tropical-disease treatments and low-cost healthcare delivery solutions (MTPConnect)

Policy

- Maintain the current Innovative Patent system by implementing some of the Advisory Council on Intellectual Property's recommendations (Medicines Australia Response to Advisory Council on Intellectual Property's Report 2015)
- Strengthen Australia's IP system and harmonise with international best practice (McKeon 2013)

Global supply chain

- Provide advice, guidance and connections to international market experts to help prepare Australian companies for international expansion (MTPConnect)

PRIORITY 7: SUPPORT ADVANCED MANUFACTURING AS A PART OF THE BROADER AUSTRALIAN INNOVATION ECOSYSTEM

Skills

- Implement long-term workforce planning coupled with tax and policy incentives for companies to upskill their employees in knowledge-intensive industries (Medicines Australia 2014; MTAA 2014)
- Target students with information about careers in the medtech sector and high-value manufacturing (MTAA 2014)
- Continue to develop and promote case studies of manufacturing successes in Australia (MTPConnect)

Policy

- Introduce a tax incentive for advanced manufacturing and innovation to encourage the development of IP in Australia (MTAA 2014)

Global supply chain

- Encourage the development of capability in niche industry sectors where fast prototyping or highly customised products support high-value, high-margin manufacturing processes in collaboration with the Advanced Manufacturing Industry Growth Centre (MTPConnect)

Other sector actions

- Encourage greater introduction of complementary services by manufacturers and showcase examples of firms that have successfully expanded up the value chain into services in MTP (AMGC)

APPENDIX 5: ESTIMATED SECTOR GROWTH POTENTIAL AND BENEFITS

The Federal Government has committed to a range of funding mechanisms for the MTP sector including MTPConnect (c.$30 million), the BTF (c.$250 million, with another $250 million from industry) and the MRFF (c.$1 billion per annum at maturity). This funding and activity is intended to drive a step change in the economic contribution of the sector. To understand the impact this will have MTPConnect has developed an estimate of the growth potential "size of the prize" for the MTP Sector.

The primary metric for these estimates is **sector Gross Value Added (GVA)**, a measure of the economic contribution of the sector to the Australian economy. MTPConnect also estimated the change in the **number of jobs** and **number of active companies** in the MTP Sector. These were calculated based on the historical trends in these metrics and their relationship to the level of GVA for the sector (i.e. as GVA grows the number of jobs and companies also grows).

GVA has declined in both real and nominal terms in the MTP Sector over the past 5 years. This decline is well-documented, and is largely attributed to the decline in onshore manufacturing of medical devices and pharmaceuticals. This in turn has led to a decline in the level of employment in the sector, although the decline has been somewhat cushioned by employment in universities and research institutes which has remained relatively stable due to a stable level of research funding. The number of companies in the sector has also remained broadly flat during this period – while many companies no longer manufacture in Australia they have retained a presence here as Australia remains a relatively important sales and distribution market.

Two forecasts were developed that reflect possible scenarios for the sector over the next 10 years:

1. **Baseline** – this scenario continues the historical downward trend for the sector. This is the "do nothing" scenario that assumes none of the investments (MTPConnect, MRFF, BTF) occur
2. **Outperform Australian industry growth** – this scenario assumes the decline over the past five years can be reversed, with the industry returning to 2010 levels within 5 years and then continuing to grow at an equivalent rate out to 2025. The 10 year growth rate for the MTP sector would outperform the recent historical average growth rate of all Australian industries. This scenario reflects the full potential of the Government's incremental investment in the sector

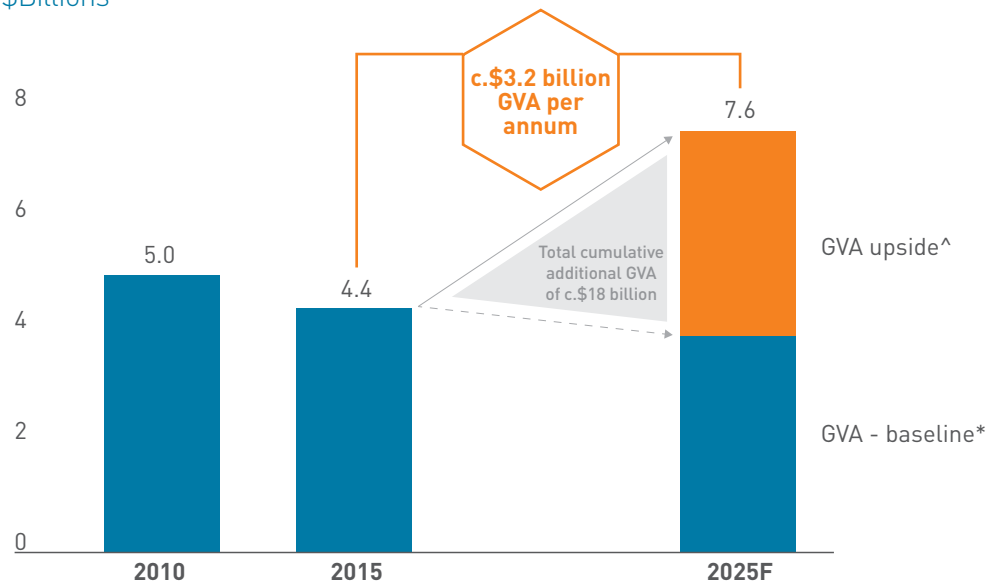
Scenario 1, the Baseline results in a reduction in nominal GVA of $0.7 billion per annum compared to 2015 (15% decrease) over the forecast period. Declines in employment and the number of companies also occur, although at a reduced rate of decline than the rate of decline in GVA. This is due to the stable nature of research sector employment (assuming no significant reductions to R&D funding), and the fact that reductions in sector output are not expected to translate directly to company exits (as historical trends have demonstrated).

Scenario 2, Outperform Australian industry growth adds c.$3.2 billion in nominal GVA compared to 2015 (74% increase) and c.28,000 new jobs to the sector in 2025 relative to 2015 (58% increase). c.14,000 of these jobs are in universities and MRIs, which reflects the substantial increase in research funding being delivered by the MRFF. The cumulative additional nominal GVA generated from 2015 to 2025 compared to the baseline is estimated to be c.$18 billion.

When compared to the investments committed by the government through MTPConnect, the BTF and the MRFF, the outcomes are significant. It is also important to note that the return time horizon on these investments must be long term. The nature of R&D and the significant time frame required to take a product from research concept through to a commercially successful product makes it only appropriate that the success of the investments is tracked on a long term time frame that exceeds ten years. The returns generated by these government investments will extend and continue to grow well beyond the 2025 time frame.

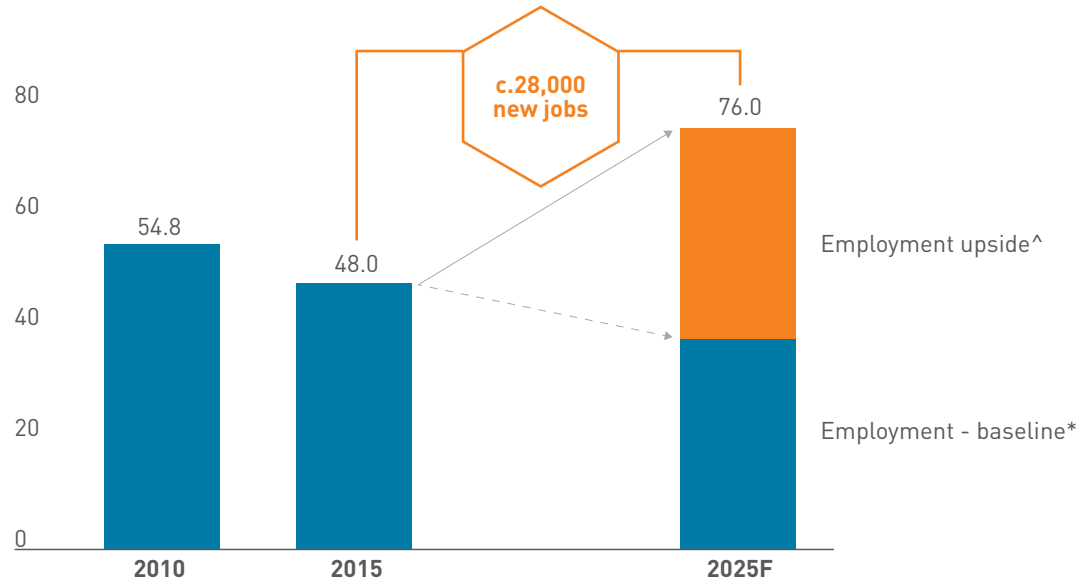
Forecast "size of prize" – Gross Value Added (nominal) (2010-2025F)

$Billions



Forecast "size of prize" – Employment (2010-2025F)

Thousands of persons employed



Notes: * Baseline assumes the historical downward trend for the sector. This is the "do nothing" scenario that assumes none of the investments (MTPConnect, MRFF, BTF) occur; ^ Estimated additional GVA/employment assumes the decline from over the past five years can be reversed, with the industry returning to 2010 levels within 5 years and then continuing to grow at an equivalent rate out to 2025. This scenario reflects the full potential of the government's incremental investment in the sector

Source: Office of the Chief Economist – MTP Employment 2015 analysis; Australian Bureau of Statistics – Census Data; NHMRC; AAMRI; L.E.K. analysis; Medicines Australia; AusBiotech; MTAA; AAMRI

APPENDIX 6: SUMMARY OF REGULATORY RENEWAL OPPORTUNITIES

Identifying opportunities to streamline unnecessary regulation is one of four MTPConnect mandates. Regulation plays a particularly important role in the MTP sector, encompassing almost all aspects of R&D and stages of the product lifecycle. Regulation includes clinical trial governance and ethics reviews, TGA registration and post marketing monitoring, reimbursement frameworks and rules, sales and marketing regulations, Industry Codes of Conduct, patent laws etc. Ultimately, regulation seeks to ensure safe treatment and ethical outcomes for patients and consumers, while balancing the need for new innovative treatments to be made available quickly, without excessive regulatory burden and cost for organisations.

In determining the scope for regulatory renewal, MTPConnect has considered

a) the recommendations from formal reviews in the sector, e.g. the Sansom Review and the CTAG recommendations;

b) ideas that emerged from consultation with the sector, and detailed discussions with MTPConnect's panel of regulatory experts.

MTPConnect has developed an initial shortlist of regulatory renewal opportunity areas for further discussion and evaluation with regulators, government and sector participants. These opportunities have been included where appropriate throughout the report, and a brief summary is provided below, organised by Sector Growth Priority. As detailed throughout the SCP, regulation is only one of the six key barriers impeding the potential growth of the MTP sector. MTPConnect will work with the sector, government agencies and regulation experts over the coming months to further assess these from a cost benefit perspective, and to develop more detailed recommendations.

MTPConnect also supports the recently released Government response to the Sansom Review of Medicines and Medical Devices Regulation, in which it supports 56 of the 58 recommendations made. MTPConnect supports these recommendations and will work with stakeholders and sector participants to achieve the regulatory renewal implied by their implementation.

PRIORITY 2:
CREATE A HIGHLY PRODUCTIVE COMMERCIALISATION ENVIRONMENT FROM RESEARCH TO EARLY CLINICAL TRIALS AND PROOF-OF-CONCEPT

Context

- Start-ups and small companies often fall short in the skills needed to navigate regulation hurdles. The need for regulatory planning is often realised too late in the development process. Lack of understanding of regulatory requirements can add significant delay, cost and failure in the commercialisation process e.g. unintentional collection of incomplete data for a TGA submission can result in years of delay and in some cases, a decision by the sponsor to halt development if trials must be re-run
- The TGA differs from regulators in a number of other markets (e.g. the FDA) in that it operates on a full cost recovery model and does not receive government funding for 'public good' activities. As a result, the TGA is not resourced or required to provide pre-submission consultations or to support SMEs (in particular) in navigating regulatory hurdles

Action

- There is an opportunity for both the TGA and the Federal Government to consider a new role for the regulatory body, and to fund the TGA to adopt a more partnership-based approach for working with industry by providing consultation and support services

PRIORITY 3:
TRANSFORM THE SME SUB-SECTOR TO SUPPORT THE GROWTH OF SMALLER COMPANIES INTO LARGER, MORE STABLE AND SUCCESSFUL COMPANIES

Context

- As mentioned under Priority 2, start-ups and small companies often do not have the skills or experience to navigate regulatory requirements in an optimised way. Additionally, SME companies seeking to bring products to market are generally navigating a sequence of regulatory approvals simultaneously (in Australia and overseas) and TGA processes that are opaque for some medicines and medical devices (e.g. Class III) act as a barrier to launching products in Australia. TGA processes are not the only hurdle to product approval (products also need a strong evidence base of safety and efficacy), however, more streamlined, harmonised and transparent processes would reduce the burden on product approval
- Australia lacks an expedited approval path for highly innovative products with significant potential to positively impact patients (either breakthrough medicines or devices). Recommendations from the Sansom Review would address this to some extent

Action

- MTPConnect supports the recommendations to address regulatory complexity in prior reviews, including McKeon 2013, Sansom 2015, AusBiotech 2014, MTAA 2015. Recommendations supported by MTPConnect include:
  - harmonising and streamlining clinical trial procedures
  - aligning TGA processes and evidence requirements with those of international regulators
  - better recognising existing international regulatory approvals, e.g. Europe
  - introducing an accelerated assessment pathway for innovative products that address areas of high unmet need or where the product delivers a significant improvement over and above the existing treatments available on the market
- MTPConnect also supports a continuation of the regulatory renewal process through an examination of reimbursement policies (PBAC, MSAC and the Prostheses List), including opportunities to streamline these processes and to do more in parallel with regulatory approval. MTPConnect acknowledges and supports the work already being undertaken by the Federal Department of Health and will work closely with the Department to provide it with guidance from the sector

PRIORITY 4:
STRENGTHEN AUSTRALIA AS AN ATTRACTIVE CLINICAL TRIAL RESEARCH DESTINATION

Context

- The 2009 CTAG review called for change in eleven areas to address the decline in Australia's clinical trial competitiveness, including timely ethics and governance review, improved patient recruitment, greater use of e-health to facilitate efficiency and improved access to information, measurement and monitoring of clinical trials activity and performance in Australia. Progress has been made in these areas, and while there is broad consensus that more needs to be done and rapidly, there is not consensus on the exact steps to be taken to achieve the outcomes the sector desires. As global competition for clinical trials increases, regulatory bodies at the Federal, State and local hospital level will need to ensure they create an attractive and workable environment for both local and international trials

Action

- MTPConnect is developing a fact-based report that provides a comprehensive view of reform progress to date, and quantification of the economic and health value to Australia of a larger, more robust, and competitive clinical trials sector. This document will be used to guide further reforms to the clinical trials regulatory environment

PRIORITY 5: SUPPORT THE DEVELOPMENT OF DIGITALLY ENABLED MTP SOLUTIONS: DEVICES AND DATA ANALYTICS

DEVICES

Context

- The wave of new digital device, 'app' and algorithm development in recent years has led to uncertainty amongst new sector participants about the appropriate risk level for their products, or a perception that even low risk devices will face onerous regulatory pathways

Action

- There is an opportunity to educate developers on regulatory pathways, and encourage early access to low-cost regulatory advice. As part of this, consideration should be given to shifting the role of the TGA to create a greater focus on pre-submission consultation and providing support services to local applicants
- The Federal Government has recently announced the introduction of an accelerated assessment pathways for medical devices as part of its response to the Sansom Review. Implementing these may require deepening the assessment skill set for digital technologies within the TGA

Context

- The Australian reimbursement framework creates challenges for digital developers as it does not currently support many innovative data-enabled applications such as those for remote monitoring and predictive or responsive analytics. The current funding model also does not support reimbursement of non-implantable devices, even when they deliver significant cost savings to the health system or patient

Action

- MTPConnect supports a revision of the funding framework such that it supports the reimbursement of new therapies that deliver genuine patient and health system benefits and/or cost savings

DATA ANALYTICS

Context

- Unlocking the potential of Australia's e-health data assets also requires regulatory renewal. The current approach to managing these assets, which is based on heavy restrictions on access to national datasets and registries, limits the potential for this data to be used in the development of innovative products and treatments that can deliver improved health outcomes, and for post-market monitoring and proof of efficacy

Action

- MTPConnect will also support broader access to e-health databases for clinical trials, innovation and commercialisation applications, and post-market monitoring and proof of efficacy

PRIORITY 6:
POSITION AUSTRALIA AS THE PREFERRED PARTNER FOR EMERGING ASIAN MARKETS

Context

- Home market approval for medical devices is mandatory prior to market access being granted in a large number of Asian countries. This reinforces the need for the TGA to provide efficient approvals and support for Australian SMEs. In recent years the full cost recovery model has caused the TGA to play less of a role in leading and influencing the development of regulatory capability across Asian markets. This erodes the strong position that Australian products have when entering Asian markets, since the more influential the TGA the greater significance TGA approval has with Asian regulators

Action

- There is an opportunity for broad-based renewal of the role that the TGA plays in supporting Australia's standing in Asia. The provision of funding to support 'public good' activities, as discussed in Priority 3 in the body of the document, would support the TGA in playing this role in the region

APPENDIX 7: REFERENCES

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

MTPConnect
MedTech and Pharma Growth Centre

MEDICAL TECHNOLOGIES AND PHARMACEUTICALS INDUSTRY INNOVATION GROWTH CENTRE

CONTACT US FOR FURTHER INFORMATION

HEAD OFFICE
New Horizons Building, Monash University,
20 Research Way, Clayton Vic 3168

NSW HUB
Level 5, J12, School of IT, University of Sydney,
1 Cleveland St, Darlington NSW 2006

SA HUB
Flinders University at Tonsley, 1284 South Road,
Clovelly Park SA 5042

E info@mtpconnect.org.au
W www.mtpconnect.org.au

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