# Medical Technologies and Pharmaceuticals

## A Roadmap for unlocking future growth opportunities for Australia

APRIL 2017

www.csiro.au

CSIRO

CSIRO FUTURES

CSIRO Futures is the strategic advisory and foresight arm of Australia's national science agency.

## CSIRO FUTURES

CSIRO Futures is the strategy and innovation advisory business of Australia's national science agency. We work with senior decision makers in Australia's largest companies – and government – to help them translate science into strategy and plan for an uncertain future. We build on CSIRO's deep research expertise to help our clients create sustainable growth and competitive advantage by harnessing science, technology and innovation.

## CSIRO MANUFACTURING

CSIRO Manufacturing plays a leading role as Australian manufacturing shifts focus from heavy industry to high tech products based on sustainable and advanced processes. We harnesses our science and engineering skills, equipment and international connections to keep Australian manufacturers globally competitive.

## CSIRO HEALTH AND BIOSECURITY

CSIRO Health and Biosecurity works together with government, industry and the community to provide leadership and deliver measurable improvement in Australia's one-Health system: enhancing health, social, environmental and economic wellbeing in the face of increased healthcare pressures and global biosecurity threats. Our science and technology innovations aim to address these challenges to ultimately enhance the nation's health system, ease the burden of disease and create new models of healthcare delivery across Australia.

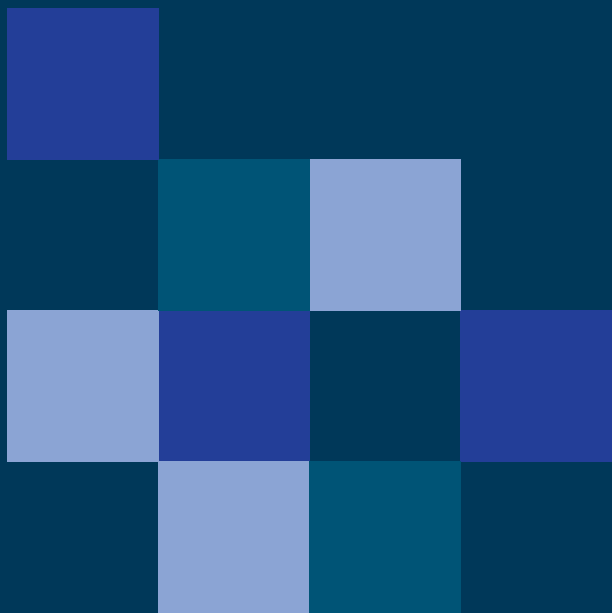
## MTPCONNECT

MTPConnect is an independent, not-for-profit organisation championing a sector-led approach to accelerating the growth of Australia's medical technology, biotechnology and pharmaceutical ecosystem to achieve greater commercialisation and establish Australia as an Asia-Pacific hub for MTP companies. It was formed in November 2015 as part of the Federal Government's $250 million Industry Growth Centres Initiative.


## ACKNOWLEDGEMENTS

We are grateful for the time and input of industry representatives consulted throughout this project and the many researchers who provided invaluable review and feedback on this report.



# CSIRO Foreword

The global medical technology and pharmaceutical sector is expected to undergo continued growth, driven by the universal challenge to improve human health and wellbeing. However, the sector faces unprecedented global changes, including shifting demographics, increasing healthcare burden, new disease pressures, digital disruption, and increasing societal expectations. In response to these profound changes, CSIRO's Strategy 2020 has accelerated the development of numerous medical technologies, including customised 3D implants, devices to alleviate chronic conditions, and new pharmaceutical agents for pain management and life-threatening diseases. These breakthrough innovations were driven by deep collaboration and partnership with the medical technologies and pharmaceuticals sector.

Our Strategy 2020 sets out a vision to be Australia's Innovation Catalyst, which will help CSIRO work closely with the sector to deliver significant growth by efficiently translating world-class science and research to improve the wellbeing of lives all over the world. 'Customer First' is the first pillar of our strategy, and we've prioritised the way we work side-by-side with our customers and partners to tackle the big challenges facing their industries. We're committed to responding with agility and creativity to find the right solutions for unique projects, and spending more time understanding the specific requirements of industries and businesses. This customer-centric approach doesn't just extend to how we work with our partners; it is also reflected in our broader research agenda.

CSIRO uses science to conceptualise, predict, and model the major trends shaping Australia's future, including the Australia 2030 Report, Our Future World: Global Megatrends report, and the Australian National Outlook. We believe the medical technologies and pharmaceuticals sector has a bright future in this country. This Industry Roadmap report identifies four opportunities that could secure the future competitiveness and success of medical technologies and pharmaceuticals in Australia. But building this future relies on a collaborative approach from the research, education, government, business and investor communities. CSIRO is committed to continuing to channel resources into this effort, including bringing our world class science and solutions to the table.

Responding to the disruption facing every part of the Australian landscape requires nothing short of deep collaboration. We are proud to stand shoulder to shoulder with the Industry Growth Centres as they further map out their roads to success. These industry roadmaps work inextricably with our science roadmaps to ensure alignment for national benefit. Together, we can apply world class scientific and technological expertise to our unique Australian challenges and chart a course for long term sustainable prosperity for our nation.

**Dr Larry Marshall**
CSIRO Chief Executive

# MTPConnect Foreword

I am delighted to introduce the CSIRO Medical Technologies and Pharmaceuticals Roadmap.

The vision and actions presented by the CSIRO offer medical technology and pharmaceutical (MTP) businesses and the broader sector with the direction to boost our vibrant ecosystem, highlighting the exciting, innovative and impactful future that we can achieve together.

MTPConnect is an independent, not-for-profit organisation championing a sector-led approach to accelerate the growth of Australia's MTP sector. Established in November 2015 as part of the Australian Government's $250 million Industry Growth Centres Initiative, our goal is to drive innovation, and promote greater collaboration, alignment and engagement to establish Australia as an Asia-Pacific hub for MTP companies.

In alignment with the Roadmap, MTPConnect's 10-Year Sector Competitiveness Plan outlines a vision and strategy to build on our internationally acclaimed sector to maximise competitiveness and productivity, address key barriers, and support rapid and sustained growth through the yearly, dollar-for-dollar matched MTPConnect Project Fund Program.

The Roadmap outlines four key opportunities for growth in the Australian MTP sector, leveraging our comparative advantages to provide impact 20 years into the future – and the work of MTPConnect will ensure the sector has a solid and flourishing foundation in order to successfully achieve this long-term vision to unlock future growth opportunities.

Collaboration is key to success, and the complementary programs presented by CSIRO and MTPConnect provide a unified approach to achieve our shared long-term vision. Together, we aim to attaining greater commercialisation success, overcoming barriers to develop more products that reach proof-of-concept and early stage commercialisation, and increase the number of medium to large companies with late-stage product successes.

Through our established relationship, MTPConnect and CSIRO have already begun having impact, collaborating in Project Fund Program consortiums to upgrade the CSIRO Clayton protein production platform, and establishing an Australian hub to support the development of foundational technologies to accelerate commercialisation of regenerative medicines.

The continued support of the CSIRO is critical to the success of the MTP ecosystem in Australia, and we look forward to continued collaboration to deliver on our joint programs ensuring sustainability, employment growth, and innovation of a sector that is securing the health and wellbeing of future generations.

**Sue MacLeman**
CEO MTPConnect

MTPConnect
MedTech and Pharma Growth Centre

# Executive Summary

# Executive Summary

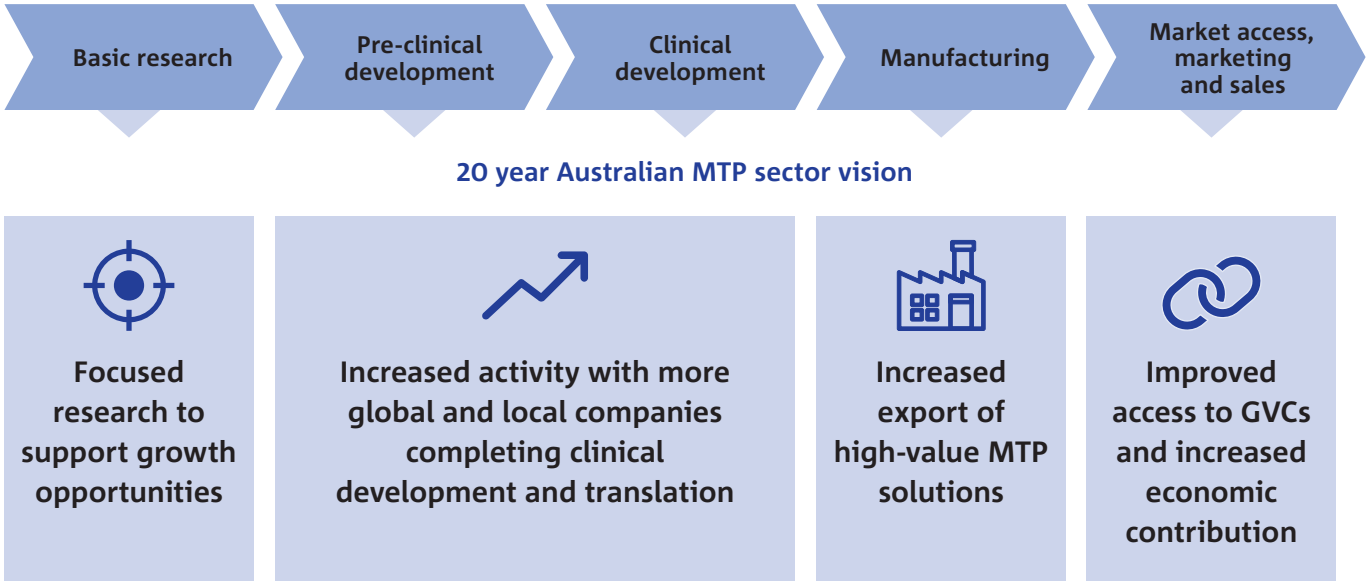
## Vision

**Over the next 20 years, Australia's medical technologies and pharmaceutical sector must capitalise on existing strengths to define a stronger global position, which will enhance the ability of the sector to translate basic research, and lead to an increased volume and value of IP, products and services for international markets.**

The Australian medical technologies and pharmaceutical (MTP) sector must endeavour to become more competitive, pushing forward the development of high-value and digitally enabled MTP solutions based on global market needs and trends. To realise growth, the Australian sector needs to focus on increasing its capacity and ability to translate basic research into commercially viable solutions for global markets, developing improved access to global value chains (GVCs) (Figure 1).

A supportive and efficient business environment is fundamental to increasing the competitiveness of the sector, promoting the success of start-ups and SMEs, and attracting and retaining companies of all sizes to complete on-shore development and manufacturing of high-value MTP solutions. Core to this is enhanced regulatory efficiency and a national approach to data and informatics. Under this vision, four growth opportunities and the relevant actions to enable their success have been identified.

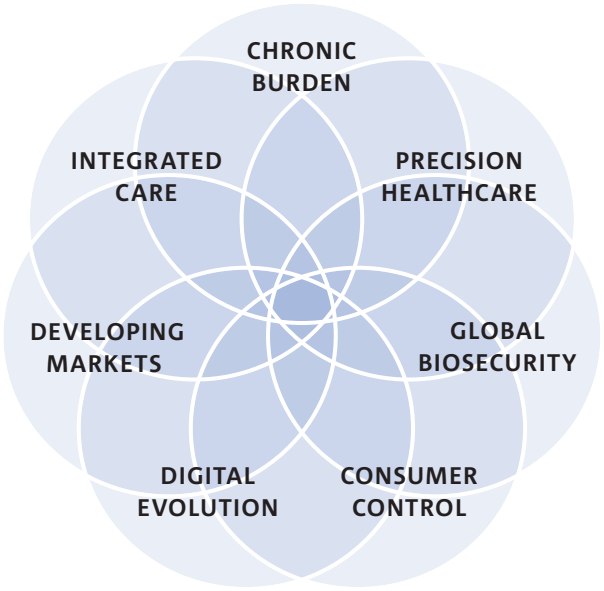
**FIGURE 1: MTP VALUE CHAIN AND ASSOCIATED 20 YEAR VISION CHARACTERISTICS**



# A changing global landscape

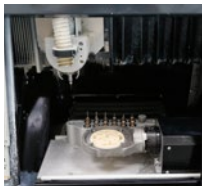
The global MTP sector is driven by various trends, ultimately underpinned by a universal desire for better health and wellbeing. The megatrends illustrated in Figure 2 represent seven significant trends in the global sector which are already disrupting commercial, societal and cultural approaches to the development of MTP solutions. Consideration of these trends is critical in order for stakeholders in the ecosystem to make strategic decisions that will successfully position the Australian sector for future success.

**FIGURE 2: GLOBAL MTP MEGATRENDS**




### 1. CHRONIC BURDEN

Modern MTP solutions allow patients to manage chronic disease and live longer than ever before, however, this comes at considerable cost to public health systems.



### 2. PRECISION HEALTHCARE

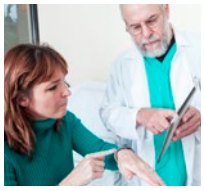
Advances in science and technology are enabling MTP solutions that are tuned to the specific needs of individuals. Targeted pharmaceuticals and bespoke technologies will be delivered that provide improved outcomes for individual patients.

### 3. GLOBAL BIOSECURITY

Recent pandemics highlight the globally transmissible nature of disease. When combined with increased treatment resistance this creates unpredictable threats that will require rapid technology responses.

### 4. CONSUMER CONTROL

Future patients will be educated and informed decision-makers, with more information available to them than ever before. Technology and information access are empowering patients to become more proactive in managing their healthcare.



### 5. DIGITAL EVOLUTION

With the massive amounts of data generated daily in the healthcare system, there will be significant shifts in how data is exchanged, processed and used.

### 6. DEVELOPING MARKETS

A rising middle class together with rapid growth in developing countries is creating increased demand for MTP solutions.

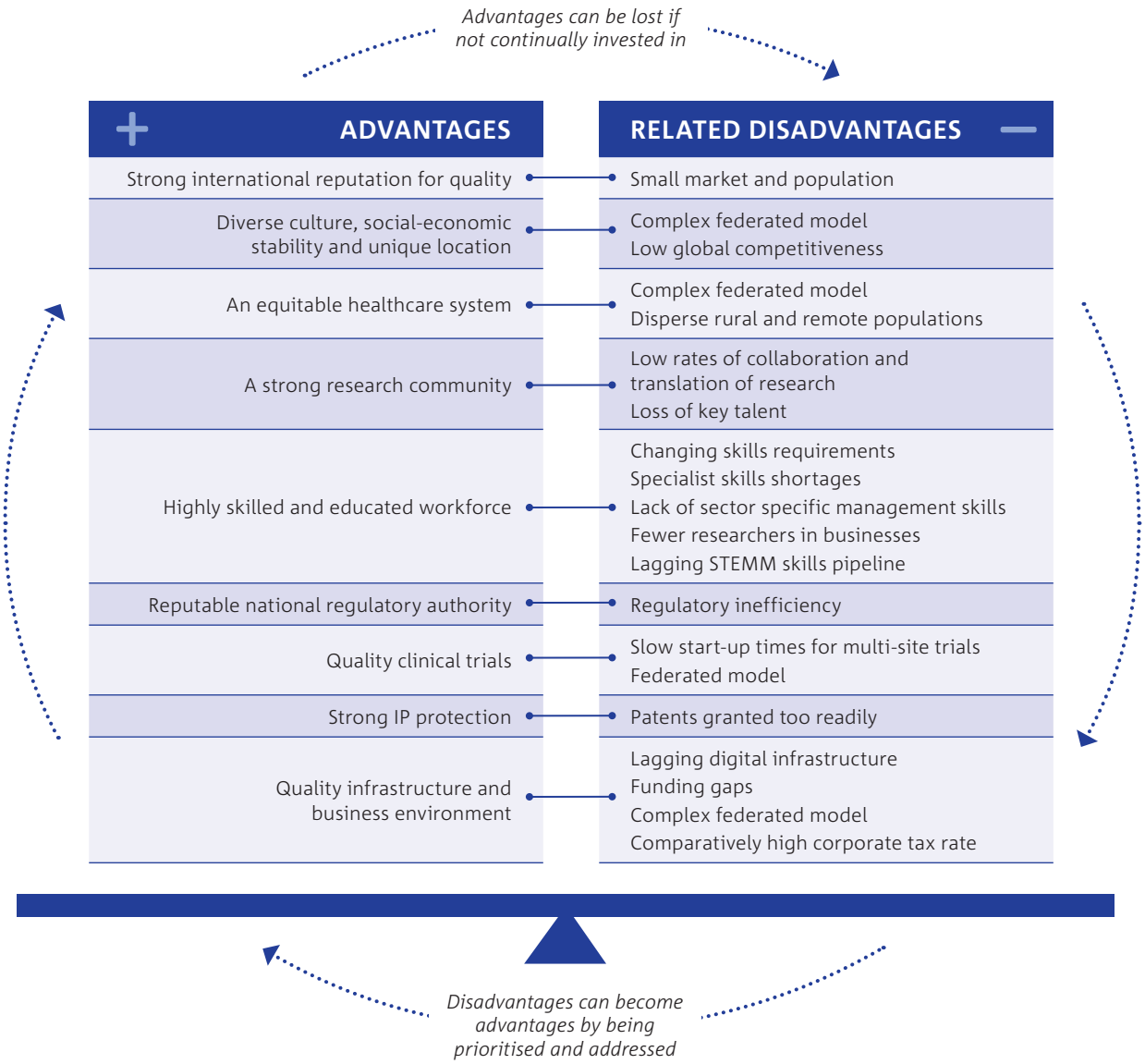
### 7. INTEGRATED CARE

Countries are shifting from highly fragmented healthcare systems to those based on end-to-end integration, driven by the need to meet the changing demands of patients and to improve efficiency.

## Australia's competitive landscape

There are numerous opportunities that can be pursued by the Australian sector in a global market. To understand which opportunities can be captured locally, the Australian sector must consider its comparative advantages and disadvantages. Advantages need to be leveraged, while disadvantages must be alleviated by specific actions from the ecosystem to provide a more sustainable base from which to build Australian growth.

**FIGURE 3: AUSTRALIA'S COMPARATIVE ADVANTAGES AND DISADVANTAGES RELATED TO THE MTP SECTOR**



## Opportunities for growth

Based on the global megatrends and Australia's competitive position, four growth opportunities have been identified. Each opportunity leverages existing research strengths, but requires considerable business and ecosystem actions to overcome challenges, as well as focused science and technology investment.

### Smart devices, implants and bionics

**VISION:** To significantly increase the number of MTP businesses designing, testing and manufacturing communicative and responsive devices, bionics and implants for global export. This opportunity would see improvements regarding the approach of the Australian regulatory system to personalised devices, and greater levels of digital integration between individuals, clinicians, researchers and developers, resulting in the development of expert systems.

**KEY OUTPUTS:** Examples include anatomically correct 3D printed implants; ingestible smart monitoring devices; integrated bionic limbs that are controlled by neural pathways; expert systems using data from biosensors.

### Manufacturing high-value pharmaceuticals

**VISION:** To focus Australian manufacturing efforts toward high-value and niche pharmaceutical products that create sustainable export revenue. Australia can leverage advantages around ingenuity, quality and reliability to attract businesses without the capacity to develop complex production processes in-house. This would see an increase in the number of local development teams required to manufacture products for direct export or clinical development.

**KEY OUTCOMES:** Development of novel drug delivery and manufacturing technologies; Australian based contract manufacturing and development of biologics, biosimilars and other complex products for global multinationals, with a focus on distribution into Asia.

### Accelerated pharmaceutical development

**VISION:** To cultivate a high-quality and efficient early-stage development environment for pharmaceutical products. This opportunity would result in an increasing number of businesses completing pharmaceutical development in Australia, improving activity in the high-value service sector and an increase in the rate of local research being pulled through to a higher value inflection point and ultimately exported to the global market in the form of IP.

**KEY OUTCOMES:** Improved reputation and benchmarks for Australian trials, increase in value and production of Australia's pre-clinical and clinical trials industry; increase in clinical products developed and commercialised in Australia.

### Diagnostic and informatics products and services

**VISION:** To develop a world-leading sector based on the development and integration of medical diagnostic and informatics platforms. Data security and interoperability is at the fore of this opportunity, and will underlie increased access to de-identified patient and population data. Information packages resulting from this data can be leveraged by local and international businesses for the development of diagnostic products, and preventative and precision MTP solutions.

**KEY OUTCOMES:** Robust prophylactic services ecosystem for patients receiving genome sequencing and analysis on predispositions; artificial intelligence enabled clinical decision support; population health analytics.

## Enabling Science and Technology

Foresight of the various technology innovations that will enable these opportunities over the next 20 years is impossible. However, by examining emerging technologies and the key technical challenges faced today, research priorities can be extrapolated to help provide a guide for MTP businesses on where to invest effort on research and development – either directly or by collaborating with publically funded research agencies or universities. The list below provides an overview of some of the enabling science and technology required to make these opportunities a reality.

**TABLE 1: ENABLING SCIENCE AND TECHNOLOGY – FUTURE RESEARCH PRIORITIES SUMMARY**

| Smart devices, implants and bionics | Accelerated pharmaceutical development | Manufacturing high-value pharmaceuticals | Diagnostics and informatics products and services |
|---|---|---|---|
| • Biocompatible materials<br>• Bionics and biosensors<br>• Bespoke and smart implants<br>• Data capture, analysis and communications | • Information and communications technologies<br>• Regulatory science<br>• Focused basic research | • Instrumentation and infrastructure<br>• Manufacturing and platform technologies | • Data analysis and digital integration<br>• Instrumentation and tools<br>• Focused clinical research |

## Enabling sector changes and the road forward

While the growth opportunities indicate a bright future, the sector must act quickly or risk losing its place in a competitive global market. Businesses cannot achieve this in isolation, with action requiring an integrated approach across the entire ecosystem.

Three enabling change themes were identified concerning approaches to digital infrastructure, regulation and market accessibility, and workforce skills, with actions summarised in Table 2.

**TABLE 2: ENABLING CHANGES SUMMARY**

| Digital infrastructure | Regulatory system and market access | Sector structure, skills and culture |
|---|---|---|
| **BUSINESS ACTIONS** | | |
| **Digital strategy** – assess business plans for inclusion of a digital strategy and consider data integration with the MTP ecosystem.<br><br>**Data collection** – design or retrofit products and services to collect valuable data that can be used to gain insights, improve products or provide a service of value.<br><br>**Infrastructure** – improve digital infrastructure within business, ensuring appropriate cybersecurity safeguards are in place. | **Regulatory knowledge –** employ staff with international regulatory know-how or engage regulatory consultants, early in the development process.<br><br>**International access** – connect with industry bodies to develop an understanding of the international market requirements. | **Invest in upskilling and management skills** – develop structured professional development programs to upskill staff in key required areas, and improve business operations by employing international experts.<br><br>**Graduate or intern programs** –provide clear pathways for the development, attraction and retention of graduates.<br><br>**Bring researchers into business** – employ researchers to improve transfer of knowledge outside universities. |
| **ECOSYSTEM ACTIONS** | | |
| **Health records** – improve the penetration, functionality and usability of national electronic health records.<br><br>**Standards and interoperability** – conduct an assessment to identify the requirements for standardising data collection, sharing and application.<br><br>**Infrastructure and cybersecurity** – improve internet speeds and capacity in Australia, and develop systems to prevent unintentional and intentional cybersecurity breaches. | **Regulatory agility** – address uncertainties regarding reimbursement of bespoke implants and bionics.<br><br>**Regulatory Sandbox** – assess the feasibility of a Regulatory Sandbox (see Section 5.2) for medical devices and digitally enabled MTP solutions.<br><br>**International branding and collaboration** – develop a unified international marketing message, and incentivise companies to establish an Australian presence. | **Skills development in tertiary education** – improve commercialisation, regulation and manufacturing skills for STEMM graduates.<br><br>**Workforce planning** – to ensure the skills required to efficiently translate MTP technology are being nurtured, and that they are in-line with global demands.<br><br>**Industry meets academia** – incentivise research institutes to employ a higher proportion of experienced industry professionals and provide mentorship programs. |

# Contents

# Introduction

# 1 Introduction

## Globally, the medical technologies and pharmaceuticals (MTP) sector is recognised as having the potential for significant growth.

The Australian MTP sector is small but productive, and with appropriate planning and action can increase in global competitiveness. Growth in the Australian sector will have economic benefits by creating new jobs and revenue, and societal benefits from improving the wellbeing of citizens.

To improve the sector's competitiveness, it is critical that the right kind of environment is supported to allow for the translation of inventive ideas into innovative solutions; one that encourages strategic and cross-disciplinary research, collaborative business partnerships, efficient development timeframes, agile and reputable regulatory frameworks, and appropriate investment incentives. While collaboration and cross-disciplinary research is applicable to many sectors, it is critical in the development of novel MTP solutions, as these are often underpinned by the convergence of disparate fields of science and technology.

While Australia holds a strong reputation regarding the discovery research that feeds the MTP sector due to high levels of public investment and existing incentives that encourage business spending, there are sub-optimal rates of translation of this research into commercial success. Failure to alter this and foster an environment that allows Australian research to be commercially developed will likely result in the Australian MTP sector reducing in global significance, leading to lost economic value and potential social impacts concerning availability to new MTP solutions.

This Roadmap has been developed by CSIRO through direct industry consultation. The Roadmap aims to complement the work of MTPConnect, the MedTech and Pharmaceutical Industry Growth Centre. MTPConnect have recently released the *Medical technology, Biotechnology and Pharmaceutical 10-year Sector Competitiveness Plan* (SCP),[1] which addresses growth priorities required to improve the sector's competitiveness and productivity. This Roadmap seeks to complement the SCP by assessing longer-term opportunities for growth, drawing upon the SCP to define enabling actions that will position the sector for sustainable and achievable growth.

### VISION

Over the next 20 years, Australia's medical technologies and pharmaceutical sector must capitalise on existing strengths to define a stronger global position, which will enhance the ability of the sector to translate basic research, and lead to an increased volume and value of IP, products and services for international markets.

1 L.E.K. Consulting Pty Ltd (2016). *Medical Technology, Biotechnology and Pharmaceutical Sector Competitiveness Plan*, MTPConnect, Clayton.

## 1.1 A vision for Australia's medical technologies and pharmaceuticals sector

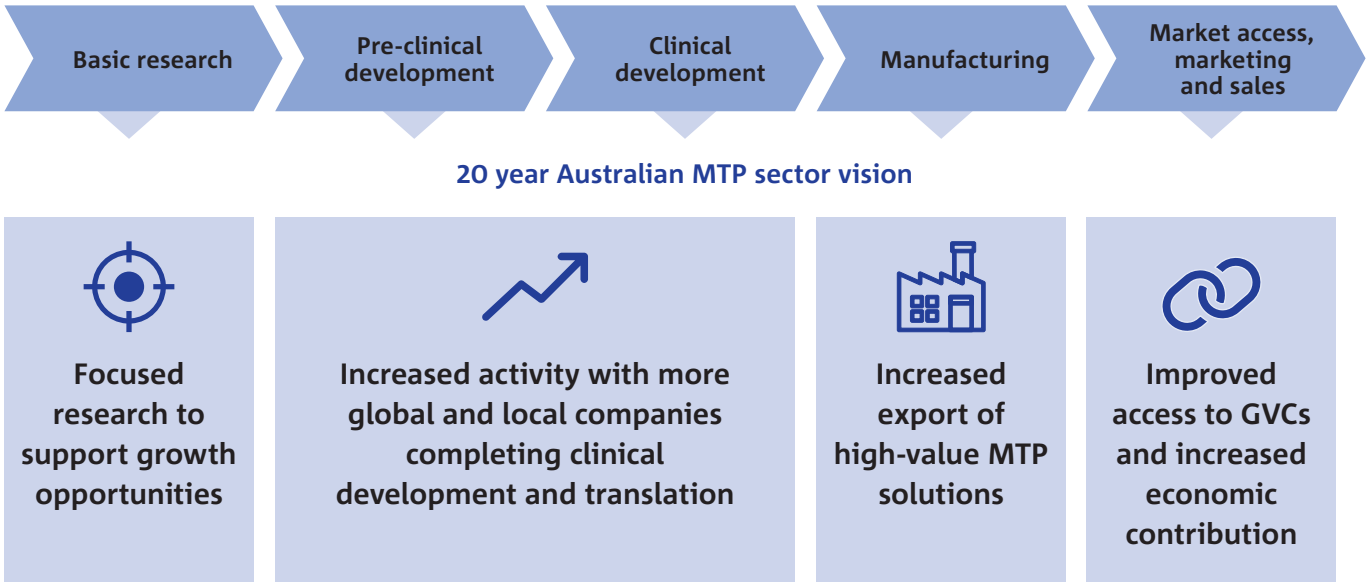
The Australian MTP sector must endeavour to become more competitive, pushing forward the development of high-value and digitally enabled MTP solutions based on global market needs and trends. To realise growth, the Australian sector needs to focus on increasing its capacity and ability to translate basic research into commercially viable solutions for global markets (Figure 4).

A supportive and efficient business environment is fundamental to increasing the competitiveness of the sector, promoting the success of start-ups and small to medium enterprises (SMEs), and attracting and retaining companies of all sizes to complete on-shore development and manufacturing of high-value MTP solutions. Core to this is enhanced regulatory efficiency and a national approach to data and informatics. Under this vision, four growth opportunities and the relevant actions to enable their success have been identified.

This vision can be considered discretely for each element of the MTP value chain:

- **Basic research**: maintain quality of research and focus efforts on subject areas that will enhance the competitiveness of each growth opportunity.
- **Pre-clinical development**: activity in pre-clinical development must be increased, ensuring that more Australian ideas are effectively translated from the laboratory to the clinic.
- **Clinical development**: skills and infrastructure must be enhanced to provide the capacity for more clinical development on-shore, increasing the value of MTP solutions in Australia.
- **Manufacturing**: efforts in manufacturing need to focus on an increased output of high-value and niche products that leverage Australia's comparative advantages.
- **Market access, marketing and sales**: ease of access to global value chains (GVCs) is critical for the longevity of smaller MTP businesses in Australia, and will increase export revenue.

**FIGURE 4: MTP VALUE CHAIN AND ASSOCIATED 20 YEAR VISION CHARACTERISTICS**



## 1.2 This report

The ultimate beneficiary of new MTP solutions is the patient, which is implicit to this Roadmap. However, in line with the objective of MTPConnect, the Roadmap is delivered through a lens which primarily considers the economic potential and competitive positioning of Australian MTP businesses.

With that in mind, this Roadmap aims to support the development of Australia's MTP sector by identifying growth opportunities for the sector that are driven by current megatrends and that leverage the sector's comparative advantages. For each opportunity, the Roadmap provides key science and technology enablers, and identifies the business and ecosystem actions that need to be undertaken in order to realise the opportunity. The structure of the report is shown in Figure 5.

Throughout this report there will be reference to the ecosystem that supports Australia's MTP businesses, which includes research institutes (covering everything from basic science to clinical research), industry organisations, funders and regulatory bodies (Figure 6). When effective, this ecosystem should provide Australian MTP businesses with a global competitive advantage.

**FIGURE 5: STRUCTURE OF THIS REPORT**

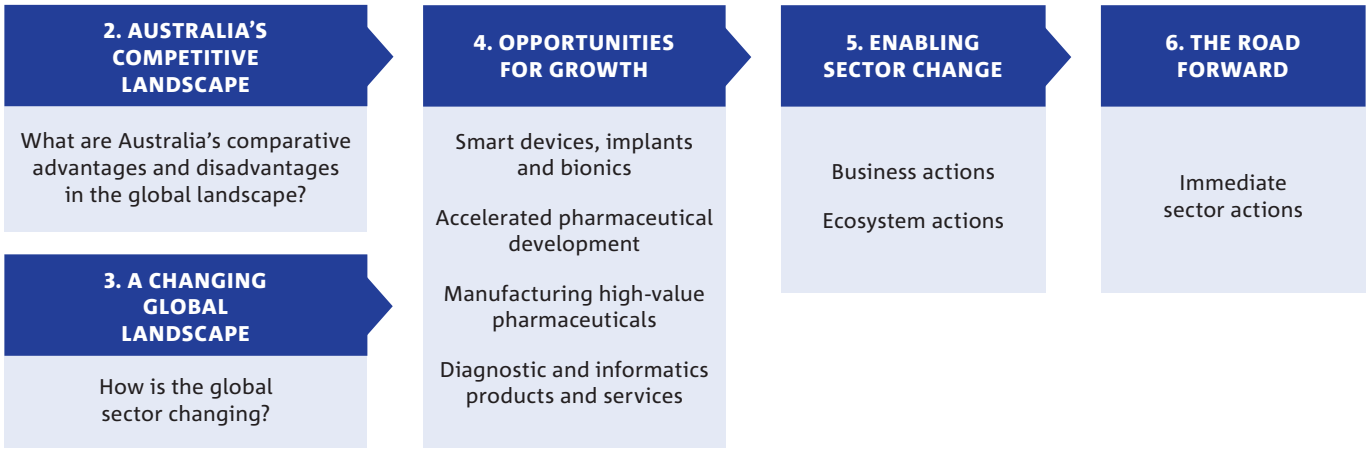
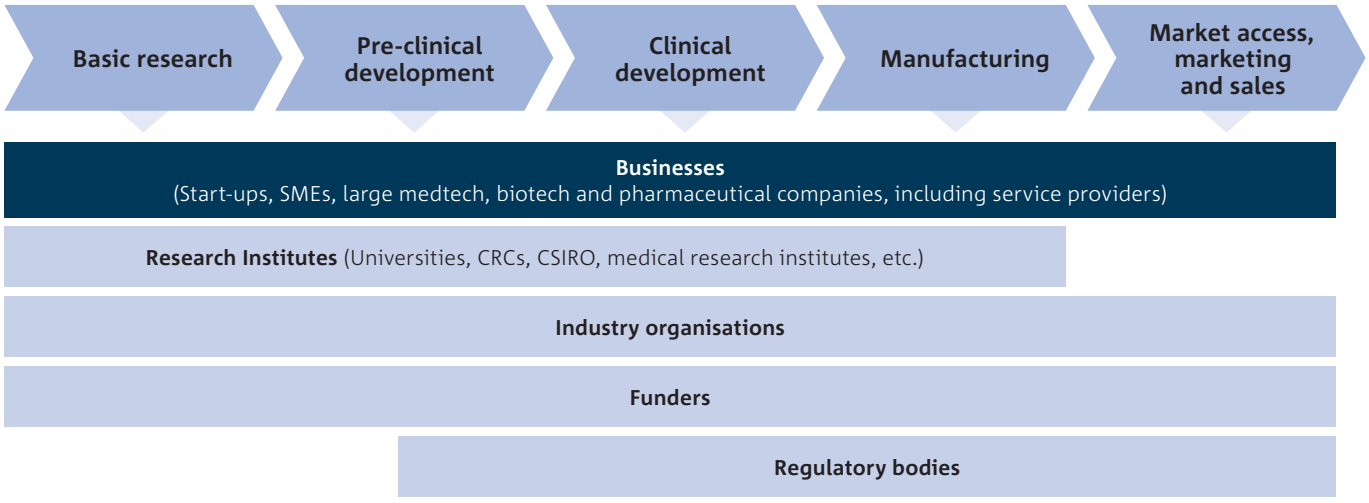



**FIGURE 6: MTP VALUE CHAIN AND ECOSYSTEM STAKEHOLDERS**




**It is important to note that this value chain may vary depending on the MTP solution being produced; pharmaceutical products currently take over a decade to develop and follow numerous sub-stages, devices and wearables generally avoid the need for toxicology and dose studies and have a significantly shorter path to market, and digital solutions require limited clinical development and avoid classic MTP manufacturing entirely.*

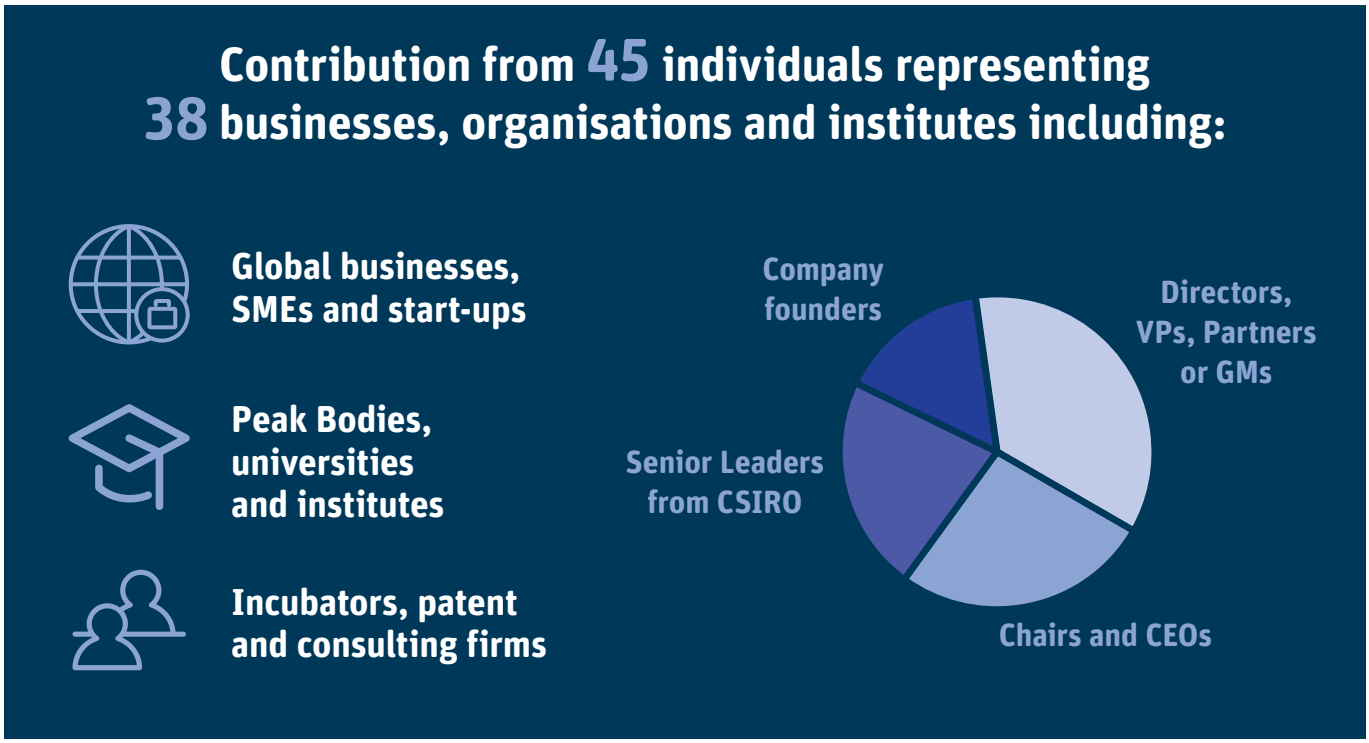
## 1.3 Sector consultation

The development of this Roadmap was industry-led with input provided by various leaders from across Australia's medical technology and pharmaceutical SMEs, large companies, academia and industry associations. This report was developed alongside the MTPConnect SCP, and leveraged information collected from MTPConnect sector consultations.

Directed consultation for this Roadmap took the form of structured interviews conducted by CSIRO consultants over two rounds. Early interviews focused on identifying key growth opportunities for the sector. The second cohort of interviews focused on refining the identified opportunities, as well as providing new perspectives.

Participants were asked to focus on opportunities that met the following criteria:

- **Disruptive and transformative** – significant shift from existing solutions that might require new business models, new healthcare models and societal/cultural adjustment.
- **Adds significant value** – creates a new industry, increases industry revenue, creates partnerships with the global community, enhances MTP sector competitiveness and sustainability.
- **Included in sector scope** – MTP solutions (intellectual property, platforms, diagnostics, products and/or services) that might require regulation for their application, either now or in the future.



# Australia's competitive landscape

# 2 Australia's competitive landscape

## 2.1 MTP in Australia

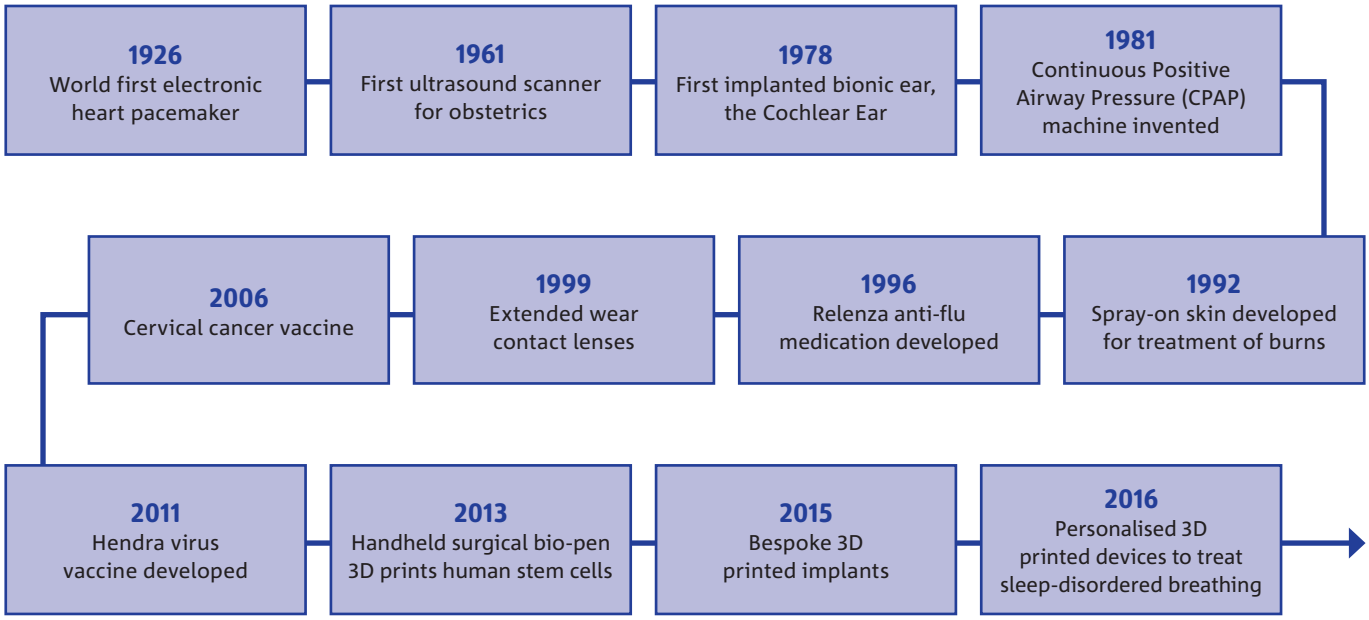
Although in decline, Australia's MTP sector remains a significant and important contributor to the Australian economy, providing a number of national benefits in the form of highly skilled cross-sector jobs and access to solutions that increase the efficiency of Australia's healthcare system and wellbeing of citizens. With Australia's spending on healthcare expected to increase from 9.8% of GDP in 2013–14[2] up to 15.7% in 2040,[3] focus on the successful translation of MTP solutions remains a national priority.

Historically, Australia's geographic isolation from other developed countries has created a need for a local MTP sector. Beyond meeting national needs, it has delivered numerous innovative MTP solutions with international success (Figure 7 provides a non-exhaustive snapshot). Currently, the MTP sector in Australia includes businesses of all sizes engaging in research, development, commercialisation, manufacturing and distribution of medical technologies, medical biotechnologies, and pharmaceuticals. The majority of businesses in the sector are SMEs, as highlighted by the medical technologies sub-sector, where it is estimated that over 54% of businesses are start-ups.[4]

**MTP SECTOR DEFINITION**

For this report, the MTP sector is considered to be the businesses and supporting ecosystem participants that are involved in the funding, research, development, clinical testing, regulation, commercialisation and distribution of products and services that make a therapeutic claim, and are therefore regulated by the Therapeutic Goods Act. However, CSIRO also recognises that many technologies that are currently unregulated, specifically numerous digital MTP solutions, are fundamental to the future success of the sector and as such are considered to be in scope.

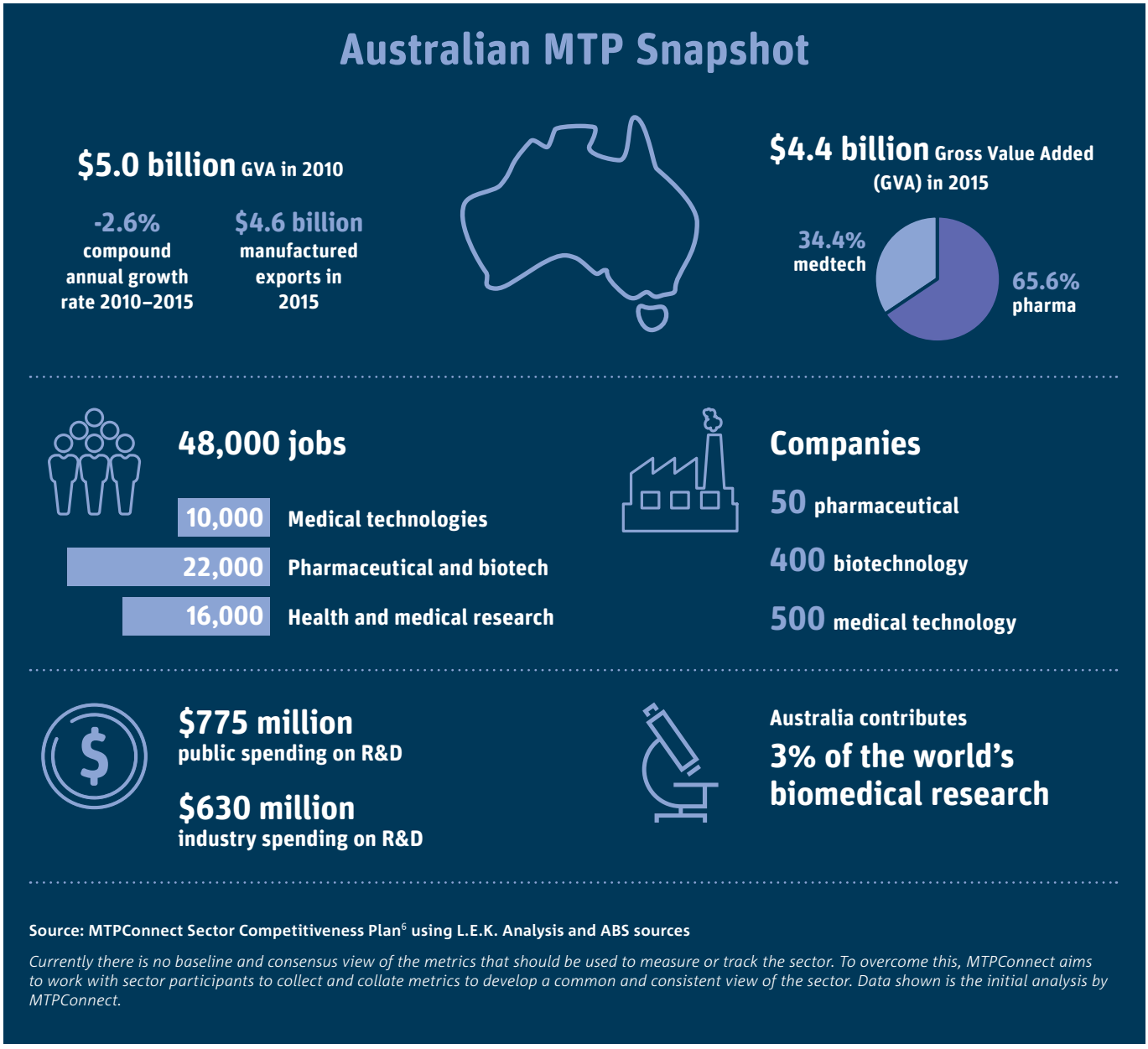
**FIGURE 7: SNAPSHOT OF AUSTRALIAN MTP INGENUITY**




Source: Adapted from Austrade[5]

2 Australian Institute of Health and Welfare (2014). *Health expenditure Australia 2013–14. Health and welfare expenditure series no. 54. Cat. no. HWE 63.* Canberra.
3 World Economic Forum (2013). *Sustainable Health Systems- Visions, Strategies, Critical Uncertainties and Scenarios,* Geneva.
4 Medical Technology Association of Australia Limited (2014). *Medical Technology in Australia: Key facts and figures 2014*, Occasional Paper Series, Sydney.
5 Australian Trade Commission (2016). *Medical devices and diagnostics,* Commonwealth of Australia.

FIGURE 8: AUSTRALIA'S MEDICAL TECHNOLOGIES AND PHARMACEUTICALS SECTOR



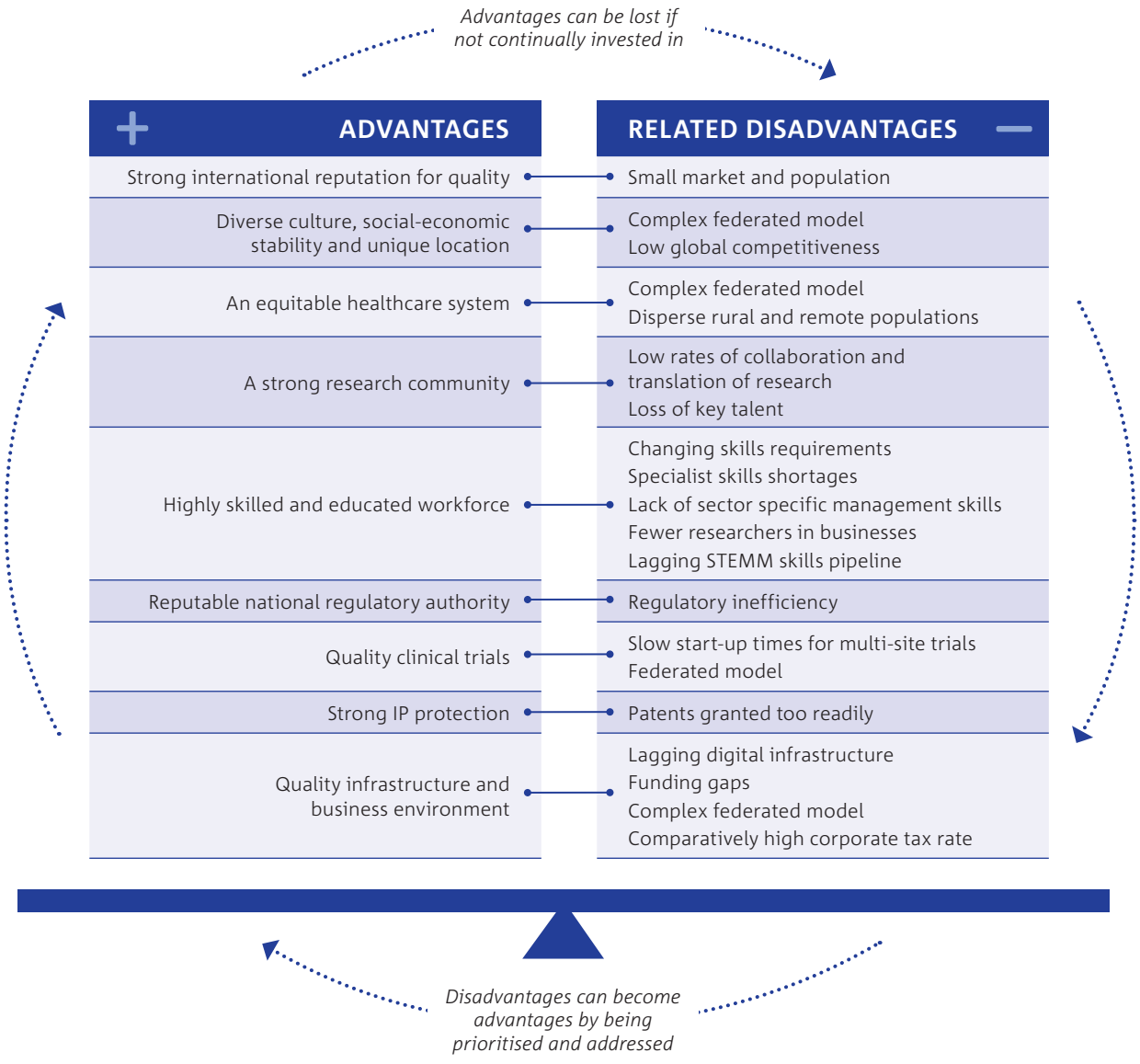

6 L.E.K. Consulting Pty Ltd (2016). *Medical Technology, Biotechnology and Pharmaceutical Sector Competitiveness Plan*, MTPConnect, Clayton.

## 2.2 Australian comparative advantages and disadvantages

The Australian MTP sector is underpinned by a number of comparative advantages that will drive opportunities for growth in the sector over the next 20 years. However, Australia's competitive position can be rapidly altered as a result of government policies, global disruptions and other significant events. Advantages can be lost if not continually nurtured and invested in, while disadvantages can often be turned to advantages if properly understood and addressed. In order to strengthen Australia's competitive position globally, businesses, governments and research organisations need to focus on addressing those comparative disadvantages that can be influenced.

Australia's comparative advantages and related comparative disadvantages are summarised in Figure 9. These advantages and disadvantages were identified through industry consultation and literature review, and are expanded upon in Appendix A.1. These advantages and disadvantages support the discussion of Australia's global positioning for each opportunity in Section 4.

**FIGURE 9: AUSTRALIA'S COMPARATIVE ADVANTAGES AND DISADVANTAGES RELATED TO THE MTP SECTOR**




**See Appendix A.1 for more information**

*There are a number of broad Australian comparative disadvantages such as high labour costs, a dispersed and geographically isolated market and small population which impact the MTP sector. These are unlikely to disappear in the next 20 years.

# A changing global landscape

# 3 A changing global landscape

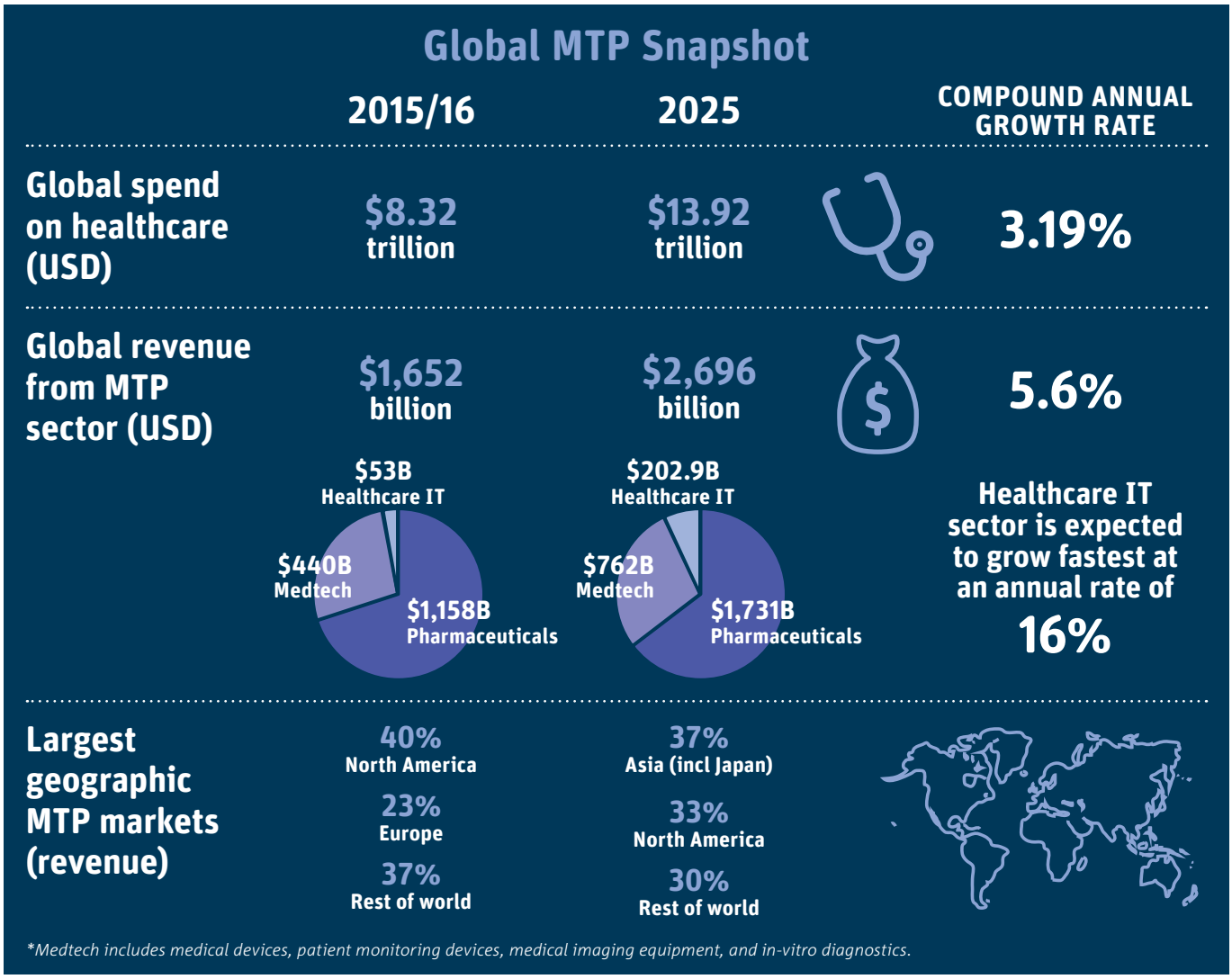
## 3.1 MTP globally

Healthcare spending is rising globally, driven by an increased demand for MTP solutions as economies develop and seek a longer and higher quality of life. This spending curve has created an appetite for novel solutions that can help cut costs while delivering a higher standard of care. Much of the innovation in healthcare will stem from the MTP sector, with data-driven insights providing platforms for novel and efficient MTP solutions, reducing the costs associated with their integration into the healthcare system.

North America and Europe are currently the most significant global MTP markets. This is changing, with the emerging BRICS (Brazil, Russia, India, China and South Africa) and ASEAN (Association of Southeast Asian Nations) markets rapidly increasing in buying power, and North America predicted to lose its 'largest healthcare market' tag to the Asia Pacific in the next decade.

Australia represents a very small market, with approximately 1% of global pharmaceutical and medical technology sales,[7] however, it is well placed to capitalise on the rapid growth of its densely populated neighbours.

FIGURE 10: THE GLOBAL MEDICAL TECHNOLOGIES AND PHARMACEUTICALS SECTOR[8]

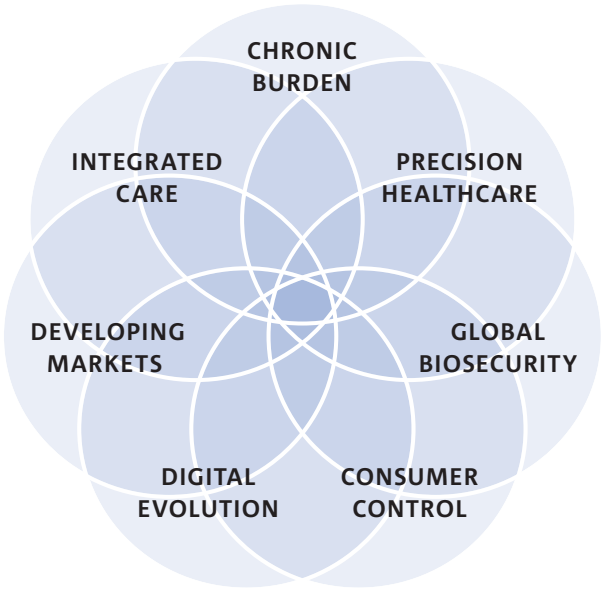



7 L.E.K. Consulting Pty Ltd (2016). *Medical Technology, Biotechnology and Pharmaceutical Sector Competitiveness Plan*, MTPConnect, Clayton.
8 Frost & Sullivan (2016). *Vision 2025 Future of healthcare,* Mountain View.

## 3.2 Global MTP megatrends

This Roadmap identifies seven megatrends relevant to the global medical technologies and pharmaceuticals sector that will have significant impact on the development of MTP solutions over the next 20 years.

A megatrend is defined as a substantial shift in social, economic, environmental, technological or geopolitical conditions that may reshape the way a sector operates in the long-run.[9] Megatrends occur at the intersection of many trends; they are not mutually exclusive and the trends that make up one megatrend can influence or contribute to another.




### 3.2.1 CHRONIC BURDEN

Modern MTP solutions allow patients to manage chronic disease and live longer than ever before, however, this comes at considerable cost to the public health systems. By 2040, it is expected that the average age dependency ratio across the OECD will nearly double, meaning that economies may shift from a ratio of four working-age people for every person aged over 65 years to roughly two working-age people.[10] As the elderly use the healthcare more and have a lower financial contribution, changes will be essential to adapt health systems to longer lifespans, maximising health and wellbeing at all ages.[11]

Along with an ageing population, the incidence of chronic disease is increasing globally, resulting in increased demand for healthcare.[12] The most common chronic disease groups include cardiovascular disease, cancer, chronic obstructive pulmonary disease and diabetes. Many factors are leading to the increasing incidence of chronic disease including increased life expectancy, changed diets, obesity rates and increasingly sedentary lifestyles.[13]

Between 2015 and 2030, the proportion of the global population aged 60+ is projected to **grow by 56%**.

The global burden from non-communicable diseases is set to **rise from 68.4% in 2015** to **73.9% in 2030.**[14]

#### Implications for the Australian MTP sector

Significant pressure will be placed on the Australian sector as consumers demand new technologies and improved medicines, and governments and healthcare providers try to find ways to limit the economic burden associated with servicing these demands. The Australian MTP sector needs to work with governments and healthcare providers to ensure research priorities and new technologies will provide improved nation-wide healthcare outcomes at the same or reduced cost, turning care for chronic conditions into a long-term growth and commercialisation opportunities.

9 Hajkowicz, S. (2015). *Global Megatrends – Seven Patterns of Change Shaping Our Future,* CSIRO Publishing, Canberra.

10 Business Council of Australia (2015). *Overview of megatrends in health and their implications for Australia*, [Online] Available from: http://www.bca.com.au/docs/ab7e6d77-3b47-447a-a4c7-16f52df7221f/4_BCA%20Health%20megatrends%20document_Final.pdf Accessed 14/12/2016.

11 United Nations, Department of Economic and Social Affairs, Population Division (2015), *World Population Ageing 2015,* New York.

12 OECD (2015). *Health at a Glance 2015: OECD Indicators*, OECD Publishing, Paris.

13 EY (2015). *Health reimagined - Extract from Megatrends 2015, Making sense of a world in motion.*

14 World Health Organization (2013). *Global health estimates summary tables: projection of deaths by cause, age and sex,* Geneva, [Online] Available from: http://www.who.int/healthinfo/global_burden_disease/projections/en/ Accessed 14/12/2016.

### 3.2.2 PRECISION HEALTHCARE

Advances in science and technology are enabling MTP solutions that are tuned to the specific needs of the individual, accounting for genetic, environmental and lifestyle factors. Targeted pharmaceuticals and custom technologies will be delivered that provide improved outcomes for individual patients. The technology advances underpinning this include genomics, computational biology, medical imaging, biosensors and data mining. More recently in medical technology, 3D printing has accelerated interest in providing rapidly personalised medical technologies at a reduced cost. [15] [16]

> Targeted pharmaceuticals and custom technologies will be delivered that provide improved outcomes for individual patients.

Targeted therapies, together with genetic diagnostic tests will assist the selection of more precise treatments, avoiding costly trial-and-error prescribing.[17] By leveraging molecular knowledge (genomics, proteomics, metabolomics) it is possible to predict predisposition to disease, allowing early intervention on lifestyle choices, preventative actions, early diagnosis and monitoring of disease.[18] Future treatments will target the individual genes that cause disease.[19]

Biosensors are a key technology that will enable customised health outcomes, providing clinicians and patients with personalised data. Point-of-care and home diagnostics are two key markets driving revenues and development in the biosensor market. In 2014, health and wellness monitoring applications accounted for 66.3% of biosensor revenue globally, and show promise for applications in a regulated environment.[20]

#### Implications for the Australian MTP sector

Precision MTP 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 best-fit solutions, rather than single best-in-class products. Key implications for Australian developments is navigating the regulatory process in such a way that reimbursement for bespoke products is achieved.

### 3.2.3 GLOBAL BIOSECURITY

Recent pandemics highlight the globally transmissible nature of diseases and the threat these can have on human health and agricultural activity, in many cases exacerbated by geopolitical instability, changing climates and limited access to technology. With more frequent travel, globalised trade and greater interconnectedness between countries, infectious disease outbreaks of international concern are becoming inevitable and unpredictable.[21] When combined with increased treatment resistance, this creates dangerous situations that require rapid medical technology responses. Clinical leaders are important influencers for combating outbreaks, both by informing the responsible use of medicines to prolong effectiveness, and through development and release of accessible technologies and tools to combat pandemic outbreaks.

Antimicrobial resistance is another complex global public health crisis that threatens the effective prevention and treatment of an ever-increasing range of infections. Antimicrobial resistance will make the treatment of infections more difficult, costly, or even impossible.[22] For the pharmaceutical sector, medicines that are no longer effective lose their value. Since the 1980s, there has been a 'discovery void' with the pipeline for the development of new antibacterial drugs very limited.[23]

15 U.S. Food and Drug Administration (2013). *Paving the Way for Personalized Medicine: FDA's Role in a New Era of Medical Product Development.*

16 Frost & Sullivan (2016). *Advanced Manufacturing Technology--3D Printing in the Healthcare Industry,* Mountain View.

17 Deloitte (2016). *2016 Global health care outlook - Battling costs while improving care.*

18 Business Council of Australia (2015). *Overview of megatrends in health and their implications for Australia*, [Online] Available from: http://www.bca.com.au/docs/ab7e6d77-3b47-447a-a4c7-16f52df7221f/4_BCA%20Health%20megatrends%20document_Final.pdf Accessed 14/12/2016.

19 Ratnanesan A., Howarth, P., (2014). *Future Solutions in Australian Healthcare ~ White Paper*, Energesse.

20 Frost & Sullivan (2015). *Analysis of the Global Biosensors Market,* Mountain View.

21 World Health Organization Website (2016). *Emergencies preparedness response, Global strategy for R&D epidemic preparedness,* [Online] Available from: http://www.who.int/csr/research-and-development/strategy/en/ Accessed 14/12/2016.

22 World Health Organization (2014). *Antimicrobial resistance: global report on surveillance,* Geneva.

23 Silver, L. (2011). *Challenges of Antibacterial Discovery*, Clinical Microbiology Reviews, 24(1): 71–109.

The last completely **new classes of antibacterial drugs** were discovered during the 1980s.

### Implications for the Australian MTP sector

Growth will occur in markets where the primary customer will be governments concerned with the rapid implementation of biosecurity solutions and long-term risk mitigation. Continued development of technologies to combat global threats will require enabling government policy, access to agile research, clinical development and a capable 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.

## 3.2.4 CONSUMER CONTROL

Future patients will be educated and informed decision-makers, with more information available to them than ever before. Technology and information access are empowering patients to become more proactive in managing their healthcare. Examples of this include the informed selection of clinicians and treatment options; health status tracking via personal health records, wearable sensors and in-home monitors; and directly contributing to personal health data.[24] [25]

Technology and information access are empowering patients to become more proactive in managing their healthcare. 79% of Australians own a smartphone.[26]

As this trend accelerates, patients will demand prevention-based and patient-centric solutions with improved efficiency, cost and quality,[27] as well as access to tools and transparent information to help make informed and value-based decisions.[28] Current products and services, and their ecosystems, will need to evolve to meet consumer demands around self-management.

Additionally, patients are more connected than ever before, with over half of the world's population owning a mobile subscription.[29] Smart phones and tablets are enabling consumers to be more connected and informed, but also offer opportunities for MTP sector leaders to create products for a digitally enabled medical market.

### Implications for the Australian MTP sector

The historical model of healthcare provision based on consultation with medical specialists may change to one where medical technologies are part of a consumer-driven, consumer-focused, digitally enabled ecosystem. Opportunities exist for the Australian sector to build 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.

24 Business Council of Australia (2015). *Overview of megatrends in health and their implications for Australia*, [Online] Available from: http://www.bca.com.au/docs/ab7e6d77-3b47-447a-a4c7-16f52df7221f/4_BCA%20Health%20megatrends%20document_Final.pdf Accessed 14/12/2016.

25 Frost & Sullivan (2016). *Top Trends in Health IT from HIMSS16*, Mountain View.

26 Frost & Sullivan (2015). *Analysis of the Mobile Health (mHealth) Market in Australia*. Mountain View.

27 EY (2014). *Health Care Industry Report 2014, New horizons: voyage to value.*

28 GSMA (2016). *The Mobile Economy,* London.

29 Deloitte (2015). *Mobile Consumer Survey 2015 – The Australian Cut.*

### 3.2.5 DIGITAL EVOLUTION

With the massive amounts of data generated daily in the healthcare system, there will be significant shifts in how data is exchanged, processed and used. Standardisation of how data is shared across the industry will accelerate the development of new treatments, technologies and predictive systems, targeting both the individual and the wider health system.[30] The upside is improved efficiency from R&D through to patient care co-ordination; the downside is a growing cybersecurity risk as more data is exchanged.[31] Big Data from a variety of sources (medical diagnostic technologies, population health, clinical research, etc.) can be used to improve the efficiency and productivity of clinical trials, drug discovery, regulatory approval processes, basic research, and patient care co-ordination.[32]

Advances in technology and increased connectivity of patients, devices and equipment are shaping a digitally enabled and integrated health system (eHealth). This will foster growth in telehealth services, where remote monitoring, video conferencing and remote services allow patients to monitor their health at home, reducing the length of time in hospital. mHealth (mobile health) applications will also grow as the development of mobile applications and communication technologies help patients manage and monitor certain aspects of their healthcare, often leveraging wearable technology.[33]

#### Implications for the Australian MTP sector

Improvements to data standardisation, access, storage and security need to be central concerns for the sector if it is to take full advantage of the digital evolution. Agile countries will gain global advantage by setting and adopting global best practice standards around the rapid development and validation of digitally enabled technologies and by developing the practical use of de-identified patient datasets for not only healthcare research and practice, but also for the development of data-driven MTP solutions.

### 3.2.6 DEVELOPING MARKETS

Demand for healthcare solutions in developing countries is rising along with the growing middle class. Developing 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 such as generics and biosimilars, or diagnostics that can be implemented at the point-of-care.[34] Generic brands represent significant sales and volume in many emerging markets, accounting for 75% of the volume of prescriptions in China in 2015, and over 70% in India.[35]

Approximately US $70–$80 billion worth of biologics will lose exclusivity over the next five years, which will stimulate rapid growth in the market for biosimilars.[36] [37] Considerable market potential exists for biosimilars in emerging markets where patented biologics are currently deemed too expensive.[38]

In developing countries, various strategies are being employed to improve access to affordable medicines, where it is estimated that one-third of people are unable to receive or purchase essential medicines on a regular basis. Differential pricing (lower prices in developing countries) and compulsory licences (government authorised production of patented products without the consent of the patent owner) are two strategies that aim to increase access to affordable medicines in the developing world.[39]

By 2030, **China will have one billion people** with the purchasing power of an average Australian.[40]

30 The Australian E-Health Research Centre Website (2016). [Online] Available from: https://aehrc.com/ Accessed 14/12/2016.
31 Frost & Sullivan (2016). *Top Trends in Health IT from HIMSS16*, Mountain View.
32 EY (2015). *Health reimagined - Extract from Megatrends 2015, Making sense of a world in motion.*
33 Frost & Sullivan (2015). *Analysis of the Mobile Health (mHealth) Market in Australia*, Mountain View.
34 PWC Health Research Institute (2015). *Top health industry issues of 2016 - Thriving in the New Health Economy,* PWC.
35 Frost & Sullivan (2016). *Global Generic Pharmaceuticals Market*, Mountain View.
36 Frost & Sullivan (2016). *Global Generic Pharmaceuticals Market*, Mountain View.
37 PWC (2015). *Challenges and Change - A report on the Australian pharmaceutical industry.*
38 Jacoby, R., *et al* (2015). *Winning with biosimilars - Opportunities in global markets,* Deloitte.
39 World Trade Organization website (2006). *Compulsory licensing of pharmaceuticals and TRIPS*, [Online] Available from: https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm Accessed 14/12/2016.
40 Ernst & Young (2013). *Hitting the sweet spot, The growth of the middle class in emerging markets.*

### Implications for the Australian MTP sector

Developing countries will continue to be a growing market for and strong source of demand for MTP and healthcare solutions. Value can be created by partnering with businesses and governments in developing markets to understand their unique needs and providing know-how and tech-transfer to assist new product development, optimised manufacturing and distribution solutions for their local markets. Australia can leverage its high-quality production advantage in the short term, and collaborate over the longer term to develop solutions to deliver high quality and sophisticated technologies, products and healthcare to developing countries in a more cost-effective manner.

## 3.2.7 INTEGRATED CARE

Countries are shifting from highly fragmented healthcare systems to those based on end-to-end integration, driven by the need to meet the changing demands of patients and to improve the efficiency of healthcare delivery which is burdened by an ageing population and rising incidence of chronic disease. This model of care is centred on preventative actions for the individual, providing a continuum of care for both acute and chronic disease management.

A number of technologies, conditions and elements are enabling Integrated Healthcare models to emerge including: increased digitisation of healthcare, such as electronic health records; complex and high quality data collection; improved analytics and sharing of data; greater consumer engagement; education and empowerment to drive demand; multidisciplinary research teams, and individual care plans.[41]

A new integrated approach to 'owning the disease' is beginning to be adopted by advanced medical technology companies, changing from a business model that focuses on intervention to convergent care. Under this new model, companies look to create platforms that enable them to provide solutions along the continuum of care.[42]

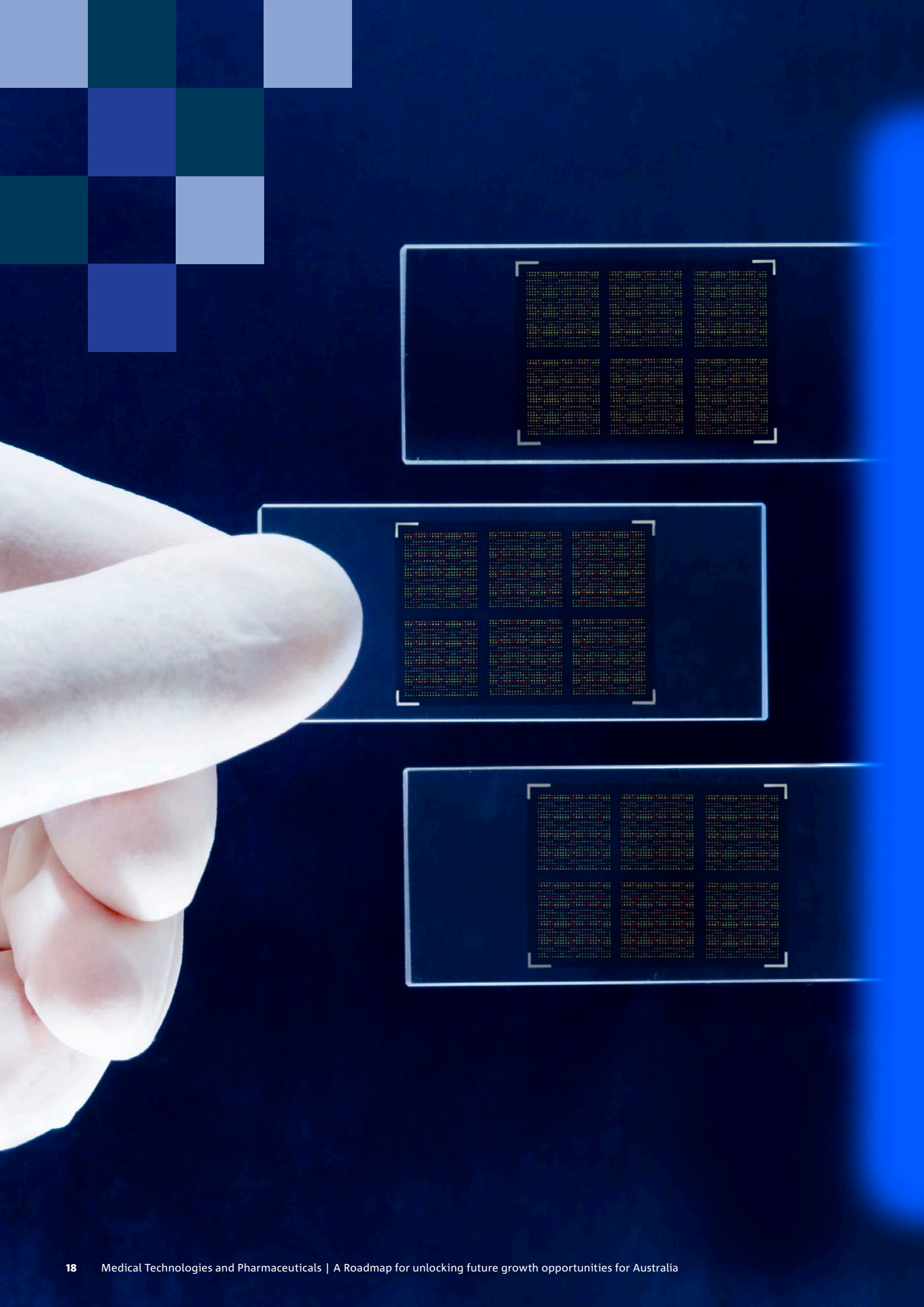
Integrated care programs are associated with a **19% reduction in hospital-admission rates,** compared with usual care.[43]

### Implications for the Australian MTP sector

As demand increases for Integrated Care models, products and devices that can coexist and communicate with other products and information sources will be required. Ongoing integrated patient management will require products that are packaged as part of a broader care proposition to the healthcare system.

As demand increases for Integrated Care models, products and devices that can coexist and communicate with other products and information sources will be required.

41 Retterath, M., et al (2013). *Opportunities in integrated care for pharma and medtech,* Bain & Company.
42 Frost & Sullivan (2015). *Analysis of the Mobile Health (mHealth) market in Australia*, Mountain View.
43 Dorling G., et al (2015). *The Evidence for Integrated Care*, McKinsey&Company.



# Opportunities for growth

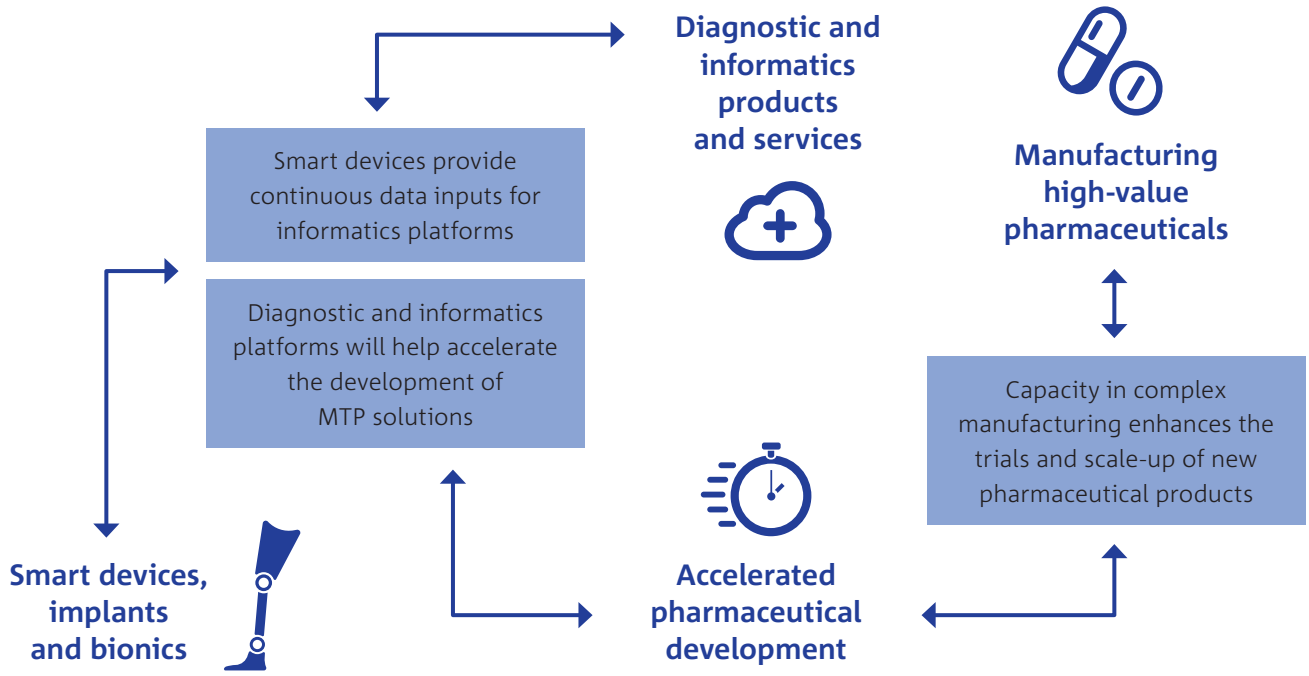
# 4 Opportunities for growth

## Four long term growth opportunities for the Australian MTP sector have been identified, driven by global megatrends and leveraging Australia's comparative advantages.

The opportunities are considered with a 20 year time to impact. Although described discretely throughout this chapter, the growth opportunities will exhibit a degree of convergence and interaction, as shown in Figure 11.

Each opportunity is described in detail over the following chapter, outlining the ecosystem changes required over the short, medium and long term. Importantly, research priorities from classic MTP fields and convergent technology areas are outlined that will enable the transformational shifts required for opportunity success.

**FIGURE 11: RELATIONSHIP AND INTERPLAY BETWEEN GROWTH OPPORTUNITIES**




**If realised concurrently, the opportunities have a synergistic relationship. Each opportunity provides reciprocal benefits, and will benefit from the shared cumulative knowledge that is developed in the pursuit of success. As the opportunity outcomes mature there will be the possibility to pursue new opportunities that leverage new sector know-how and enhanced sector characteristics.**

# Smart devices, implants and bionics

## VISION

To significantly increase the number of MTP businesses designing, testing and manufacturing communicative and responsive devices, bionics and implants for global export. This opportunity would see improvements regarding the approach of the Australian regulatory system to personalised devices, and greater levels of digital integration between individuals, clinicians, researchers and developers, resulting in the development of expert systems.

## DRIVING MEGATRENDS

**PRECISION HEALTHCARE** – accessibility of technology that allows highly customised implants and bionics is rapidly increasing, driven by long-term patient benefits and improved outcomes.

**DIGITAL EVOLUTION** – as connectivity and data interoperability challenges are overcome, rapid integration of communicative medical technology into consumer and clinical environments will occur.

**CONSUMER CONTROL** – early adopters are driving the demand for wearable and integrated technology, and will demonstrate the advantages associated with making data-driven medical decisions.

## 4.1 Smart devices, implants and bionics

### 4.1.1 THE OPPORTUNITY

Australia's MTP sector has the opportunity to become a leading global player in the research, development and manufacturing of smart and connected medical devices. Specifically, this includes personalised implants, bionics and monitoring devices, and the systems required to fully utilise the information captured by these devices (Figure 12).

An ageing global population combined with a rising middle class, will drive demand for the MTP solutions arising from this opportunity. In Australia alone there is a significant potential market for smarter and personalised medical technology; approximately 4.2 million Australians experience some form of physical disability, with over 30% experiencing profound or severe core activity limitation.[44] [45] Over 357,000 Australians are blind or have low vision; 30,000 have total hearing loss; 20,000 are amputees; and approximately 42,000 hip replacements and 53,000 knee replacements took place in 2013-14. [46] [47] [48]

Increasing Australia's focus on smart devices, implants and bionics will create skilled jobs and the development of agile medtech companies.

Increasing Australia's focus on smart devices, implants and bionics will create skilled jobs and the development of agile medtech companies. As the concentration of companies focusing on these technologies grows, international investors and global companies will be attracted to Australian shores. These, together with Australia's existing mature medical technology companies (see 'Many mature medtech companies call Australia home' case study), can be leveraged to access global value chains to export Australian ideas, building the industry brand in the process.

In Australia alone, there is a significant market for smarter and personalised medical technology.

Along with developing industry leadership in novel devices, Australia can also lead the development and implementation of innovative smart information ecosystems – creating an Internet of Medical Things (IoMT) model through the collection, de-identification (where necessary) and interpretation of data from integrated medical devices. This data will provide clinicians with valuable patient and population insights that can be used to help personalise treatments and predict the likelihood of disease, enabling preventative actions and treatments. Data from these devices can be a key input to the different types of diagnostic and informatics products discussed in Section 4.4.

44 ABS (2013). *4430.0 - Disability, Ageing and Carers, Australia: Summary of Findings, 2012,* Canberra.

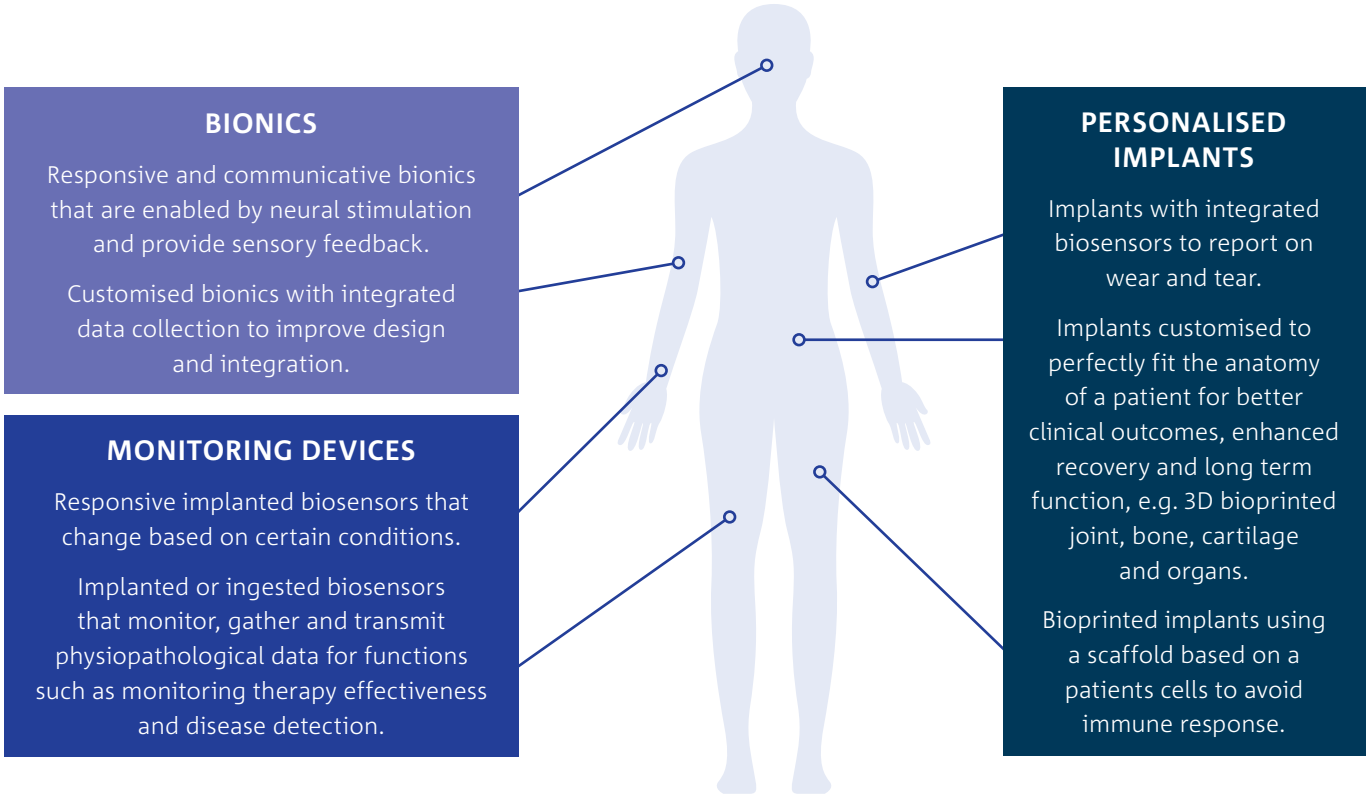
45 ABS (2013). *4430.0 - Disability, Ageing and Carers, Australia: Disability tables – Table 2,* Canberra.

46 Australian Network on Disability Website, *Stats and Facts,* [Online] Available from: http://www.and.org.au/pages/disability-statistics.html Accessed 19/12/2016.

47 Australian Orthotic Prosthetic Association (2010). *The Australian Orthotic Prosthetic Association Submission to The Productivity Commission: Disability Care and Support Review,* [Online] Available from: http://www.pc.gov.au/inquiries/completed/disability-support/submissions/sub0237.rtf

48 Australian Orthopaedic Association (2015). *Analysis of State & Territory Health Data All Arthroplasty – Supplementary Report 2015.*

FIGURE 12: OPPORTUNITY FOCUS AREAS




## ENABLING INFORMATION SYSTEMS

Data from implanted monitoring devices will enable clinicians to make decisions with near-instant optimisation
Secure sharing and interrogation of data used to make effective health decisions for the patient.
Data from monitoring devices used as an input in expert systems.

**Case study**

## Mature medtech companies call Australia home

Cochlear, Cook Medical Australia and ResMed are major medical technology companies with international operating models and major manufacturing centres in Australia. Together these companies are responsible for over 20% of the total inventions in the medical devices field in Australia (based on IP registration).[49] As mature international companies, these firms have the ability to set up manufacturing centres in any location, but choose to manufacture products for the Asia-Pacific region and beyond from facilities in Australia.

**Cochlear Ltd** is an Australian company with global operations. The company's global headquarters is located on campus at Macquarie University in Sydney, however, Cochlear has direct operations in 20 countries and exports to over 100 countries. For over three decades, Cochlear has been developing and manufacturing a range of implants, investing more than $100 million each year in research and development, with the majority of these R&D activities taking place in Australia. Most of Cochlear's manufacturing takes place in Australia and Sweden, with smaller sites in Belgium and the USA. In 2016, Cochlear's Asia Pacific (APAC) sales totalled over $210 million (18% of total sales) while the major markets of Europe, the Middle East and Africa (EMEA) and the Americas totalled over $427 and $519 million respectively.[50]

**William A. Cook Australia Pty Ltd** manufactures two key product ranges specialising in IVF and endovascular repair, and exports over 92% to 135 countries at a value exceeding US$100 million. The products are manufactured in the company's Brisbane facility, which employs over 500 staff. The Australian operations also double as the headquarters for the APAC region. In 2015, Cook achieved an annual sales figure of US $408 million for the APAC region, which is their 33rd year of consecutive growth.[51]

**ResMed Ltd** was established in Australia in 1989 to commercialise a device to treat and manage obstructive sleep apnoea. Since then, ResMed has grown dramatically to become an international company, active in more than 100 countries through direct offices and distribution networks, and employing over 5,000 people. ResMed has six manufacturing facilities across the globe, with its largest facility located in Sydney, Australia. This Australian facility manufactures ResMed's full product range and employs 1,360 staff. Approximately 95% of the company's products manufactured in Australia are exported to other countries. ResMed's global R&D spend is approximately $163 million, of which $100 million is expended in Australia.[52]

49 IP Australia (2014). *Australian Medical Devices: A Patent Analytics Report*, Commonwealth of Australia, Canberra.

50 Cochlear Limited (2016). *2016 Cochlear Annual Report – Innovation for life*.

51 O'Connell, E. (Personal communication, 23/12/2016).

52 Sandercock, B., Price, A., (2016). *Feedback on the Review of the R&D Tax Incentive report ResMed Ltd*, Department of Industry, Innovation and Science [Online] Available from: https://www.business.gov.au/~/media/Business/RDTI/Review/Research-and-development-tax-incentive-review-submission-ResMed-Ltd-PDF.ashx?la=en Accessed 04/01/2017

### 4.1.2 AUSTRALIA'S GLOBAL POSITIONING

#### Why Australia?

- **Strong international reputation for quality** – Australia's medical technology sector comprises over 500 companies and has established a global reputation and track record for being inventive in the areas of bionics and implants, with device companies such as Cochlear Ltd, Cook Medical Australia and ResMed (see Case Study) providing industry leadership.[53] Sector maturity makes it easier for start-ups and SMEs to gain access to the knowledge, value chains and infrastructure needed to succeed.
- **A strong research community** – Australia's strongest categories of published research include engineering, materials science, clinical medicine, molecular biology and genetics, fields required in the development of this opportunity.[54] Australia is home to world leading research programs that feed this opportunity, such as the translation of neuroscience research into new devices,[55] development of next generation implants and devices,[56] and the 3D bioprinting of replacement body parts.[57]
- **Diverse culture, social-economic stability, and unique location** – Australians have a reputation for being early adopters of innovations and new technologies, with already high adoption rates for wearable technologies.[58] By 2025, it is expected that virtual consults will surpass face-to-face patient consultations in rural regions.[59] Australia's many rural and remote communities provide a great test bed for telehealth service innovation, aided by smart monitoring from wearable devices and communicative implants. In addition, Australia has a rich mineral wealth, currently supplying 51% of the world's titanium ore, which is a key material used for the production of some medical devices.[60]
- **Reputable national regulatory authority** – Australia has a robust regulatory environment that allows rapid development, improvement and refinement cycles, making it an ideal market for prototyping and testing new medical technologies.[61]

#### Competitors

Australia faces competition scientifically, commercially and politically from a number of countries that are building capability across relevant technical areas and are establishing attractive economic environments as a method to attract international business investment for the development of growth industries.[62] Strong competition in the field of bionics comes from US, Canada, and Germany,[63] while competition for customised medical implants is predominantly from the US.[64] The US Government has invested heavily in bionics and implantable device research through various projects at the Defense Advanced Research Projects Agency (DARPA). Australia needs to ensure continued investment in these areas to maintain the development of relevant businesses on-shore (see SmartStent case study).

Australia's MTP sector also faces competition from a number of non-traditional companies. For example, the collection and interpretation of medical data sees strong competition from a range of consumer driven companies, such as Alphabet (Google's parent company that acquired the artificial intelligence company, Deepmind, in 2014) and Apple (medical data integration into an application ecosystem driven by developer packages such as CareKit and ResearchKit). These companies have total R&D expenditure that rivals entire developed countries, with Alphabet spending USD $12.3 billion in 2015.[65]

53 Australian Trade Commission (2016). *Medical devices and diagnostics,* Commonwealth of Australia.
54 Australian Trade Commission (2016). *Why Australia Benchmark Report 2016,* Commonwealth of Australia.
55 Australian Government Factsheet: *Research Strengths & Capabilities*, [Online] Available from: http://www.industry.gov.au/science/SKAandAstronomy/Documents/AustraliaResearchStrengthsandCapabilitiesFactSheet.pdf Accessed 19/12/2016.
56 CSIRO Website, *Surgical implants and medical devices,* [Online] Available from: http://www.csiro.au/en/Research/MF/Areas/Biomedical/Implants Accessed 19/12/2016.
57 Queensland Government, The Queensland Cabinet and Ministerial Directory (2016). *Media Statements,* [Online] Available from: http://statements.qld.gov.au/Statement/2016/11/21/queensland-to-revolutionise-modern-medicine-with-new-biofabrication-institute Accessed 19/12/2016.
58 Drumm J., and Swiegers M., (2015). *Mobile Consumer Survey 2015 – The Australian Cut,* Deloitte.
59 Frost & Sullivan (2016). *Vision 2025 – The Future of Healthcare,* Mountain View.
60 Frost & Sullivan (2016). *Strategic Analysis of the Additive Manufacturing Market in Australia,* Mountain View.
61 Australian Trade Commission (2016). *Medical devices and diagnostics,* Commonwealth of Australia.
62 Schwab, K., (2016). *The Global Competitiveness Report 2016–2017,* World Economic Forum, Geneva.
63 Frost & Sullivan (2014). *Innovations in Bionics (Technical Insights)*, Mountain View.
64 Frost & Sullivan (2016). *Advanced Manufacturing Technology (TechVision) – 3D Printed Medical Implants and Organs*, Mountain View.
65 United States Securities and Exchange Commission (2015). *Form 10-K Alphabet Inc. and Google Inc.* [Online] Available from: https://abc.xyz/investor/pdf/20151231_alphabet_10K.pdf Accessed 22/12/2016.

## Partners and buyers

Important partnerships required for realising this opportunity include collaborations between researchers, clinicians, funding bodies and commercialisation professionals to ensure products are developed along appropriate pathways through evidence-based research. SMEs are likely to develop solutions that capture this opportunity, with the quickest path to market being partnerships with global companies that provide ready access to global value chains.

**Case study**

### SmartStent[66]

SmartStent is an Australian start-up developing an endovascular electrode array, a sensor for minimally invasive acquisition of brain signals. The technology offers a means for acquiring, translating and transmitting brain signals to robotic devices to aid movement in patients suffering from paralysis or injury.

Funded through grants from the US Defense Advanced Research Projects Agency (DARPA), the NHMRC and the Australian Research Council, the technology has been developed in Melbourne with a pool of expertise largely accumulated through the bionic ear and bionic eye research programs, as well as medical research at Royal Melbourne Hospital, Florey Institute of Neuroscience and Mental Health and University of Melbourne.

The company has recently being transferred to the US through establishment of a parent company based in Silicon Valley, Synchron Inc, with the appointment of an experienced medical technology CEO.

Under current modes of healthcare reimbursement, the primary buyers should ultimately be governments and insurance companies. However, the benefits provided by these technologies may encourage some patients and certain companies to source the technologies without subsidy. With early adopters demonstrating the success and cost benefits associated with these types of innovations, governments and insurance companies may be more likely to introduce subsidy programs for the wider population. Examples of key markets that could become early adopters thanks to the benefits from these smart technologies include:

- **Defence technologies** – bionics for rapid recovery and rehabilitation from injuries. Research entities such as DARPA in the United States are investigating the use of bionic technologies to assist soldiers with war related physical disabilities. Over 50,000 people were wounded in action in the US military between 2001 and 2015.[67]
- **Elderly healthcare** – devices for improved quality of life. Devices that monitor and communicate between clinicians and patients will enable the reduction of significant adverse health events, helping to decrease the cost associated with delivering aged care while improving outcomes. Research is underway to develop bionics to help return movement function to patients after significant events such as stroke, where patients may incur neurological deficits or paralysis.
- **High health-risk industries** – monitoring devices for workers in mines, fatigue prone occupations or other high-risk environments. For example, commercial trucking is the focus of many communicative devices to help monitor stress, fatigue, and illness common in the profession. In Australia, around 42% of truck crashes are due to fatigue. Monitoring devices for heart rate, blood pressure, breathing rate and glucose level monitoring are expected to become commonplace to measure and improve the productivity and health of truck drivers.[68]

66 Smartstent website, *About Us,* [Online] Available from: http://smartstent.com.au/about-us/ Accessed 20/12/2016.

67 Fischer, H., (2015). *A Guide to U.S. Military Casualty Statistics: Operation Freedom's Sentinel, Operation Inherent Resolve, Operation New Dawn, Operation Iraqi Freedom, and Operation Enduring Freedom,* Congressional Research Service.

68 Frost & Sullivan (2016). *Growth Opportunity Analysis of Health, Wellness, and Wellbeing Technologies in Commercial Trucking*, Mountain View.

### Opportunity threats

Societal and cultural acceptance (social licence to operate) is required for smart implants that monitor, respond and transmit data, as well as for bionic devices that can be visually confronting. Western cultures, for example, are culturally less accepting of devices that make humans appear robotic, which could hinder early uptake in countries such as Australia.[69] In a similar cultural context, there is an underlying apprehension toward devices that collect personal information, based on the potential inappropriate use of data. Cybersecurity risks will need to be mitigated and communicated.

Failing to achieve growth and support research translation will result in Australian patients having to import or travel overseas to access cutting edge medical devices and implants, with the Australian sector losing the value, exports and jobs that may be created.

## 4.1.3 PLANNING FOR THE FUTURE

Growth of the sector that includes smart and personalised medical implants and bionics requires significant change in the MTP ecosystem, as well as continued strategic investment in key research. Translation of technology will be jeopardised if appropriate focus is not placed on ensuring an attractive business ecosystem and regulatory systems for product development, testing, commercialisation, and export.

### Australia's smart devices, implants and bionics in the 2030s

- Global reputation for excellence in customisation, design and integration of smart medical technologies and associated data capture systems.
- Specialists in the development of high-value biomaterials and manufacturing processes for personalised devices.
- Leadership in the development and use of implant enabled health data capture (biosensors) used to improve clinical outcomes.
- Home to manufacturing hubs integrated with research and clinical institutes, providing valuable services for patient centric medical technology.

### Ecosystem changes

Currently, lack of reimbursement for smart and personalised implants and bionics is restraining growth associated with this opportunity, not only in Australia but across the globe. Access to customised devices is challenging, as many are excluded from the Australian Register of Therapeutic Goods, making reimbursement impossible. Local growth will require a regulatory environment that is responsive to these technologies and can accommodate the clinical sample size of n=1 that is characteristic of bespoke devices. High levels of customisation not only challenge the regulatory system, but disrupts the existing supply chain, requiring new skills, an accepting culture, and an agile industry structure.

- **Regulatory environment and market access** – Australia's regulatory body, the Therapeutic Goods Administration (TGA), does not currently have the ability to provide rapid and binding feedback for pre-submission, something that competing countries offer.[70] Existing frameworks have incorporated some flexibility for customised devices, but reimbursement can be limited, assessed on a case-by-case basis. More value will be captured by the Australian industry if next generation devices are readily accessible through public healthcare and private health insurance. Any efficiencies that Australia may achieve in the regulatory environment will provide a significant sectoral advantage.
- **Skills, culture and industry development** – Accessible and localised manufacturing hubs will become critical for the design and refinement of customised implants to occur in tight collaboration with the clinician, the patient, and multidisciplinary experts. Skills development, patient and community acceptance, as well as funder and investor education will be important for the growth of this opportunity.
- **Technology outputs** – Tight integration between MTP businesses, clinicians and the research community is needed to advance technologies and services, moving beyond isolated wearables towards customised and communicative implants, and bionics that are controlled by neural stimulation.

69 Ross, A., (2016). *The Industries of the Future*, Simon & Schuster.
70 Medicines Australia (2015). *Submission to the Expert Review of Medicines and Medical Devices Regulation.*

**FIGURE 13: MTP ECOSYSTEM ACTIONS FOR SMART DEVICES, IMPLANTS AND BIONICS INDUSTRY**

| SHORT TERM (0-3 YEARS) | MEDIUM TERM (3-10 YEARS) | LONG TERM (10+ YEARS) |
|---|---|---|
| **REGULATORY ENVIRONMENT AND MARKET ACCESS** | | |
| **From 20th century models ...** | | **... to embracing personalised devices** |
| • Clearly address uncertainties regarding reimbursement of bespoke implants and bionics.<br>• Improve access to pre-clinical models for continued development of bionics and implants.<br>• Introduce regulatory efficiencies suggested in various reviews (e.g. Medicines Australia) that make it more efficient for start-ups and SMEs to navigate the correct regulatory pathway.<br>• Use focused marketing to improve Australia's international reputation as a safe and efficient destination for pre-clinical research and clinical trials.<br>• Assess feasibility of a 'Regulatory Sandbox' to address complexity of regulatory approvals (see Section 5.2). | • Access to global value chains enabled via increased national trade agreements.<br>• Introduce incentives to encourage global MTP companies to establish Australian presence, for example strategic tax concessions or government supported asset and infrastructure hubs.<br>• Development of data sharing framework and privacy policies to enable suitable communication and access to devices and data.<br>• Nimble regulatory pathways for continuous improvement of customised implants and bionics. | • Review Australia's competitive position and address regulatory hurdles. |
| **SKILLS, CULTURE AND INDUSTRY DEVELOPMENT** | | |
| **From disconnection and silos ...** | | **... to truly multidisciplinary medtech experts** |
| • Develop short courses on clinical trials and medical technology regulations.<br>• Develop short courses for researchers on intellectual property protection and commercialisation methods for medical technologies.<br>• Redesign academic incentives to encourage commercialisation and establishment of start-ups (i.e. KPIs aligned to translation of research rather than publications).<br>• Build societal acceptance of bionics, robotically augmented humans and implanted monitoring devices to ensure market pull for these technologies.<br>• Educate patients/public on the benefits of data collection (identifiable and de-identified).<br>• Develop best practice guidelines for maintaining social licence in the collection and use of data.<br>• Establish multidisciplinary research/ commercialisation teams (engineers, eHealth, software engineers, clinicians, biologists, surgeons, business, marketing etc.). | • Improve workforce skills required for advanced manufacturing, automation techniques and customised design.<br>• Initiate cultural shift in MTP investment community to have more realistic expectations regarding timeframes for commercial development of devices.<br>• Develop local manufacturing hubs for personalised implants – near or within hospitals. | • Established and recognised STEMM courses that include innovation components, allowing graduate to better understand how research can be translated into industry.<br>• Industry development activities to increase locally produced and refined biomaterials for Australian manufacturing. |

Timeframes should be viewed as a guide only.

**FIGURE 14: TECHNOLOGY OUTPUTS OF AUSTRALIA'S SMART DEVICES, IMPLANTS AND BIONICS INDUSTRY**

| SHORT TERM (0-3 YEARS) | MEDIUM TERM (3-10 YEARS) | LONG TERM (10+ YEARS) |
|---|---|---|
| **TECHNOLOGY OUTPUTS** | | |
| **From isolated wearables ...** | | **... to personalised implants and bionics that predict your behaviours** |
| • Wearable devices for high risk industries (e.g. truck drivers and mine workers to monitor fatigue).<br>• Anatomically correct 3D printed orthopaedic implants.<br>• Advanced analytical platforms to capture data from wearable devices.<br>• Patients able to track their own health metrics using sensors and smartphones.<br>• Neuro-stimulated robotics such as exoskeletons which create mechanical enhancements for certain tasks.<br>• Telehealth models enabling remote monitoring, video conferencing and remote services reducing hospitalisation with Australian rural community test beds for novel remote monitoring technologies. | • Integration of data from wearable devices into clinical decision making.<br>• Minimally invasive electrodes for implantable devices.<br>• 3D printing of functional body parts, such as ears.<br>• Ingestible smart devices that monitor disease.<br>• Bionic heart and bionic eye.<br>• Internally powered and wirelessly communicative biosensors for continuous monitoring.<br>• Data from implantable monitors integrated into clinical decision making.<br>• Analytics to provide population insights from de-identified wearable device data. | • Bionics that mimic the aesthetics and responsiveness of natural body parts.<br>• Integrated bionic limbs that are controlled by neural pathways.<br>• 3D printed biocompatible functioning organs.<br>• Implantable biosensors contributing data to expert systems to offer insights and diagnoses through predictive analytics.<br>• Bionics that enhance memory and regeneration for treatment of neurological conditions. |

Timeframes should be viewed as a guide only.

**Case study**

## Anatomics[71]

Demonstrating the growing importance of customisation in medical technologies is Anatomics Pty Ltd, a Melbourne based medical device company that specialises in the manufacture of patient-specific implants. Operating since 1996, Anatomics has pioneered the use of medical imaging to develop personalised surgical implants that utilise innovative advanced manufacturing techniques such as 3D printing, saving time in the operating theatre and enabling better patient outcomes. The range of customised implants Anatomics designs and manufactures allow surgeons to consider a whole new suite of operations that were once impossible. Implants are manufactured from a range of materials including acrylic, titanium and porous polyethylene.

Anatomics has helped over 4,000 patients with its customised implants. In a world first surgery, one patient received a 3D printed titanium rib and sternum implant after suffering from a chest wall sarcoma that resulted in a large portion of the rib and sternum being removed. The 3D printed implant closely mimics the original bone that had to be removed.

In another world-first, Anatomics recently designed and manufactured a 3D printed vertebrae to replace two cancerous vertebrae from a patient's neck, allowing anatomically correct replacement for better outcomes.

71 Anatomics website, *Company*, [Online] Available from: http://www.anatomics.com/company/ Accessed 19/12/2016.

### Enabling science and technology

Technology and research priorities to further enable the development of smart devices, implants and bionics will need to focus on materials and communications. New advanced materials are needed for implants to ensure true imitation, strength and biocompatibility, likewise for bionics, advanced materials will allow for a better product. Overcoming issues around data collection and usage will also be important to the development of this opportunity. The list below provides an overview of some of the enabling science and technology required to make this opportunity a reality. See Appendix A.2.1 for an expanded list.

New advanced materials are needed for implants to ensure true imitation, strength and biocompatibility, likewise for bionics, advanced materials will allow for a better product.

## FUTURE RESEARCH PRIORITIES

### Biocompatible materials

- Advanced, responsive materials that truly replicate inherent biological strength and form, e.g. implants for bone replacement constructed from material that truly replicates porous 3D microstructures.

### Biosensors and bionics

- Improved biosensors with better durability, reaction times, specificity and sensitivity, alongside development of new biosensors for novel targets.
- Advanced bionics through clever algorithms, improved software and hardware and advanced materials, allowing greater flexibility in bionic product design.[72] Development and incorporation of real-time sensors to increase bionic functionality.

### Bespoke and smart implants

- Additive manufacturing technology to enable printing of integrated dissimilar materials, and process improvement for metallic additive manufacturing to ensure predictable quality, consistency and performance of printed implants.
- Smart, communicative implants with enhanced wireless communications, controls and encapsulation technologies for implantable bioelectronics.

### Data capture, analysis and communications

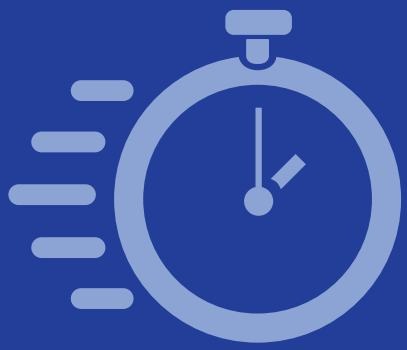
- Improved platforms to capture and analyse data from wearable and implantable devices. Advanced cybersecurity solutions for connected medical devices and implants. Improvements in bioinformatics to enable tools allowing clinicians to effectively use collected data.

72 Frost & Sullivan (2014). *Innovations in Bionics (Technical Insights)*, Mountain View.

# Accelerated pharmaceutical development

## VISION

To cultivate a high-quality and efficient early-stage development environment for pharmaceutical products. This opportunity would result in an increasing number of businesses completing pharmaceutical development in Australia, improving activity in the high-value service sector and an increase in the rate of local research being pulled through to a higher value inflection point and ultimately exported to the global market in the form of IP.



## DRIVING MEGATRENDS

**CHRONIC BURDEN** – increasing chronic disease will drive the demand for more effective pharmaceutical solutions, ideally curbing the cost associated with maintaining a high quality of population health.

**DEVELOPING MARKETS** – as countries' build a better understanding of region specific health and medical challenges there will be increased demand for clinical development of pharmaceutical products.

**GLOBAL BIOSECURITY** – developed and developing countries are placing more importance on biosecurity medical counter measures; rapid and agile clinical development is critical to meet the demands associated with combating emerging infectious diseases and microbial pandemics.

## 4.2 Accelerated pharmaceutical development

### 4.2.1 THE OPPORTUNITY

Australia's MTP sector has the opportunity to cultivate a globally competitive pharmaceutical development environment, taking targeted local and international drug candidates/discoveries and accelerating them through to first-in-human phase 1 clinical trials (Figure 15). Successfully reaching phase 1 is a significant milestone in the pharmaceutical development pathway, leading to a major increase in the value of the drug candidate in development.

Accelerated pharmaceutical development involves connecting competitive clinical trials, services in pre-clinical research and development, and efficient ethics and regulatory processes.

Annually, the Australian clinical trials industry is estimated to be worth $1 billion to the economy.[73] Putting concentrated effort into becoming a global hub for efficient, high quality, early stage, pre-clinical and clinical research will have many positive economic and social benefits for Australia, including:

- Growth in the pipeline of pre-clinical and phase 1 products being developed and trialled in Australia, from both local and international research.
- Attraction of large global companies to Australia to both conduct their own trials and to scout for acquisitions targets with high potential value.
- Sector growth through the development of clinical trials expertise and associated infrastructure.
- Improved local access to cutting edge medicines (and devices).

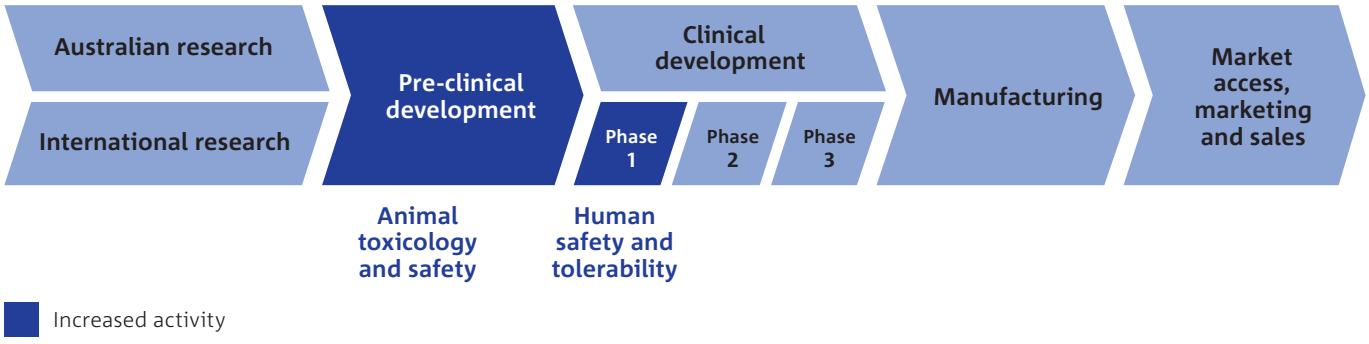
**Medical Technologies**

While the focus of this opportunity is on pharmaceutical products, the pathway is similar, though shorter, for medical technologies/devices. A demonstrated ability to increase the speed at which pharmaceuticals can enter first-in-human trials should benefit development time-frames for medical technologies in Australia.

Increasing Australian activity in pre-clinical and phase 1 trials will help the MTP sector extract more value from Australia's globally competitive medical and biotechnology research investments, leading to more therapies progressing further along the development pathway. Companies that utilise Australia for clinical trials are more likely to pursue market access in Australia, improving access to innovative pharmaceuticals. This opportunity will ultimately enable faster and more efficient translation of therapies and medicines to meet unmet medical needs, while creating value for the Australian MTP sector.

There are multiple research areas where Australia has respectable international standing, such as oncology and cardiovascular disease, and these should be used as inputs to develop critical mass for this opportunity. Areas of national and regional importance, such as emerging infectious disease, can also supply significant pipelines for rapid development to first-in-human trials.

**FIGURE 15: AUSTRALIAN CLINICAL DEVELOPMENT PATHWAY (PHARMACEUTICALS)**




73 Australian Government, Department of Health website (2016). *Clinical Trials*, [Online] Available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials Accessed 19/12/2016.

**Case Study**

## d3 Medicine

d3 Medicine (d3M) is a strategic advisory company specialising in pharmaceutical development and commercialisation. The company has deep expertise in pharmacology and the pharmaceutical commercialisation process, including clinical trials, drug development and optimisation, regulatory liaison and licensing/M&A plans.[74]

d3M provides services ranging from strategic advice to active assistance in the drug development. d3M has been engaged by various biotechnology, not-for-profit, larger corporate and life-science investment clients to evaluate, troubleshoot and help overcome various developmental roadblocks to help clients achieve regulatory approval. d3M also helps larger corporate, global not-for-profits and government clients on broader strategic programs, including changing drug development paradigms for large corporates, developing new tools to accelerate medicine development in global health, and advising on R&D ecosystems to address emerging infectious diseases and bioterrorism threats to national interests. In one example, d3M was engaged to lead a national review of capability across areas of antimicrobial resistance, point-of-care diagnostics and advanced/innovative development expertise and manufacturing to influence policy and medical countermeasures preparedness.

d3M has recently become part of Certara, a US company that includes Certara Strategic Consulting (CSC), one of the world's largest specialised consulting companies for pharmaceutical commercialisation. Certara has assisted in bringing more than 80 drugs to market, and Certara clients accounted for 90% of all FDA approved drugs in 2015.[75]

74 D3 Medicine Website (2014). *Introduction,* [Online] Available from: http://www.d3medicine.com/what-we-do/introduction Accessed 19/12/2016.

75 Business Wire website (2016). *Certara Acquired d3 Medicine,* online http://www.businesswire.com/news/home/20160907005021/en/Certara-Acquires-d3-Medicine Accessed 19/12/2016.

### 4.2.2 AUSTRALIA'S GLOBAL POSITIONING

#### Why Australia

Australia is well regarded globally as a clinical development destination based on a number of comparative advantages: [76] [77]

- Internationally-recognised world-class medical research infrastructure
- Highly skilled researchers and key opinion leaders producing impactful scientific research
- A strong network of universities, medical research institutes and hospitals
- A fast and pragmatic regulatory system that allows flexibility without compromising quality
- Strong intellectual property protection
- Attractive R&D tax incentives
- Compliance with international clinical data standards
- Mandatory good clinical practice (GCP) standards for all Australian clinical trials
- Experienced Contract Research Organisations (CROs)
- Ethnically diverse, English-speaking patient population
- Easy access to single-site phase 1 trials with a small number of healthy volunteers.

Australia's perceived advantages for clinical trials often vary depending on the perspective of the company looking to conduct these trials. For example, Chinese companies often look to Australia for transparent approval processes that produce clinical results that are acceptable by the US Food and Drug Administration (FDA), while US companies look to Australia for cost efficiency and approval timeliness.[78]

Australia ranks first in the APAC region for scientific research productivity and impact, which assists Australia in standing out from the rest of the region.[79]

#### Competitors

For clinical trials, the key competition Australia faces comes from the greater APAC region. Between 2007 and 2013, the number of new clinical trials in Australia declined due to increasing competition from Asia and other regions. However, this decline has been moderated with growth in numbers over more recent years.[80] Despite this recent growth, the proportion of phase 1 first-in-human trials in Australia is still low, representing 17% of all trials initiated in Australia in 2015.[81]

#### Partners and buyers

The main partner and buyer for this opportunity are large global pharmaceutical companies that license or acquire target therapies once success in pre-clinical and phase 1 trials is achieved. Building a sustainable and significant pipeline of drug candidates reaching these milestones may attract companies to Australia that require portfolio expansion or are driven by an acquisition strategy. In the event that Australia can become an attractive destination for large companies looking to conduct early clinical trials, it will be able to capture part of a global market expected to exceed $56 billion by 2020.[82] Once present, many global companies may choose to progress drug candidates through phase 2 and phase 3 trials in Australia as well.

Other significant partners could include defence agencies and consortia, such as the Medical Counter Measures (MCM) Consortium, involving Australia, Canada, the UK and the US, where the ability to rapidly develop and test MCM solutions will be highly valued.[83]

Key regions that represent lucrative partners and buyers of pharmaceuticals developed in Australia include those with rapidly changing demographics, such as members of BRICS and ASEAN economies, who have increasing demands for pharmaceutical solutions and are geographically or politically aligned to Australia.

76 Australian Trade Commission (2015). *Clinical Trials,* Commonwealth of Australia.
77 Frost & Sullivan (2016). *Australia: Preferred Destination for Early Phase Clinical Trials.*
78 Frost & Sullivan (2016). *Australia: Preferred Destination for Early Phase Clinical Trials.*
79 Frost & Sullivan (2016). *Australia: Preferred Destination for Early Phase Clinical Trials.*
80 L.E.K. Consulting Pty Ltd (2016). *Medical Technology, Biotechnology and Pharmaceutical Sector Competitiveness Plan*, MTPConnect, Clayton.
81 Analysis from: TGA (2015). *Half Yearly Performance Report Snapshot – July to December 2015,* AND *Half yearly performance report – January to June 2015,* Commonwealth of Australia.
82 Frost & Sullivan (2016). *Australia: Preferred Destination for Early Phase Clinical Trials.*
83 Defence Science and Technology (DST) Group, [Online] Available from: http://www.dst.defence.gov.au/partnership/medical-countermeasures-consortium Accessed 13/01/2017.

**Case study**

## Novotech

Headquartered in Sydney, Novotech is internationally recognised in the industry as a leading regional full-service contract research organisation (CRO). Focused on conducting clinical monitoring in the Asia Pacific region, Novotech has been instrumental in the success of hundreds of phase 1 to 4 clinical trials in Australia and more broadly. Novotech provides clinical development services across all clinical trial phases and therapeutic areas including: feasibility assessments, ethics committee and regulatory submissions, data management, statistical analysis, medical monitoring, safety services, central lab services, report write-up to ICH requirements, project and vendor management.[84]

One company assisted by Novotech is US-based cancer therapeutics pharmaceutical company. This company conducted three phase 1 oncology studies in patients with three types of cancers in Australia. Novotech recruited seven patients from six sites for a metastatic colorectal cancer study, 46 patients from seven sites for a non-small cell lung cancer study, and 56 patients from six sites for a pancreatic cancer study.

The flexibility of the Australian clinical trial process benefitted the US pharmaceutical company, allowing it to adapt and revise the dosing schedule over the duration of the trial. Novotech helped accommodate adaptions by implementing protocol changes and ensuring appropriate training for investigators and site staff on the amended protocol.[85]

### Opportunity threats

Globally, the APAC region is an attractive destination for clinical research, with over 50% of international clinical trials in 2014 having sites in the region, driven by its low cost advantage and patient access. The cost of conducting clinical trials in countries such as China, India, and Indonesia is generally between 25-40% lower than that in Western countries.[86] With China expected to experience rapid growth in clinical trials over the short term, the Australian industry needs to remain competitive by focusing on quality factors as a differentiator.

Failing to position Australia's early stage clinical trials industry for global recognition and growth could leave patients in Australia with limited access to early new treatments, and reduce the link between basic and clinical research, making development of new therapies more difficult. The ultimate consequence of non-activity is that the Australian sector will have little relevance to global pharmaceutical companies, and with a small domestic market, many will not pursue market access for their products in Australia.

With China expected to experience rapid growth in clinical trials over the short term, the Australian industry needs to remain competitive by focusing on quality factors as a differentiator.

84 Novotech website, [Online] Available from: http://www.novotech-cro.com/ Accessed 19/12/2016.
85 Frost & Sullivan (2016). *Australia: Preferred Destination for Early Phase Clinical Trials.*
86 Frost & Sullivan (2015). *APAC Contract Research Organisation (CRO) Market,* Mountain View.

### 4.2.3 PLANNING FOR THE FUTURE

Developing and nurturing Australia's early stage clinical trials industry to become globally competitive will require a coordinated effort from government, regulators, industry and research. To capture this opportunity a focus should be to increase the number and proportion of early-stage trials completed in Australia. In time, Australia should focus on increasing its capacity to operate phase 2 multi-site trials to complement enhanced competitiveness in early-stage trials.

**Accelerated pharmaceutical development in the 2030s**

- Australian trials are quick to start-up and reach recruitment targets, producing valuable high quality data.
- Australia is known for its safe and efficient regulatory environment and streamlined ethical approval processes.
- Australia is a recognised destination for challenging early stage clinical trials.
- Australia has a strong research focus on the rapid development of solutions for infectious diseases, biosecurity risks and novel approaches to treatments for existing acute and chronic diseases.
- Australia has witnessed a noticeable increase in the rate of discovery research being pulled through to a global market, either taken through to market access by an Australian company, or by global licensing deals.

#### Ecosystem changes

A number of recent Australian reviews have highlighted the importance of this opportunity to the Australian MTP sector and the need for broader ecosystem changes to capture it: the Clinical Trials Action Group (CTAG), established in 2009 put forward 11 recommendations to secure Australia's competitiveness in the clinical trials sector,[87] and the 2013 Strategic Review of Health and Medical Research in Australia: Summary Report (the McKeon Review) made recommendations that reinforced those of the CTAG, listing them as an urgent national priority.[88] Furthermore, the National Health and Medical Research Council (NHMRC) is working with States, Territories, clinical trials sites, sponsors and researchers to improve clinical trials in Australia in response to the CTAG and McKeon recommendations by achieving: [89]

- timely and more efficient research governance authorisation
- efficient ethics approval
- Increased site readiness and transparency
- better training of staff
- increased recruitment and awareness.

While a number of these recommendations have now been fully or partially implemented, more work needs to be done to ensure long term growth.

87 Commonwealth of Australia (2011). *Clinically competitive: Boosting the business of clinical trials in Australia - Clinical Trials Action Group Report.*

88 Australian Government, Department of Health and Ageing (2013). *Strategic Review of Health and Medical Research in Australia – Better Health Through Research*, Commonwealth of Australia, Canberra.

89 NHMRC website (2016). *Clinical Trials*, [Online] Available from: https://www.nhmrc.gov.au/research/clinical-trials Accessed 19/12/2016.

**FIGURE 16: MTP ECOSYSTEM ACTIONS FOR ACCELERATED PHARMACEUTICAL DEVELOPMENT**

| SHORT TERM (0-3 YEARS) | MEDIUM TERM (3-10 YEARS) | LONG TERM (10+ YEARS) |
|---|---|---|
| **INFRASTRUCTURE AND INDUSTRY DEVELOPMENT**<br>**From limited infrastructure and a small industry ...** | | **... to a globally recognised hub for pre-clinical and early stage trials** |
| • Improve access to animal models for Australian based toxicology studies.<br>• Expand Compounds Australia (Australia's dedicated compound management facility) and the support it provides.<br>• Support development of robust and comprehensive pre-clinical services industry.<br>• Educate the broader Australian investor community on the long-term reward profile of the MTP sector.<br>• Branding and PR activity to improve awareness and build support for Australia's clinical research, highlighting benefits to the sector, individuals and clinicians.<br>• Implement appropriate technology for traceable, sharable, ethical, trackable and secure electronic health records for all Australians that can be used to help select candidates for clinical trials.<br>• Improved electronic health systems to support trial feasibility assessments and improve patient recruitment processes.<br>• Improved clinical research infrastructure at both major and rural hospitals to enable rural patient recruitment. | • Improve SME access to key infrastructure such as imaging tools, PET scanners, biobanks and high throughput screening.<br>• Develop and support industry scale in Australia's clinical trials service industry (CROs, biostatistics, data management, pharmacovigilance, bioanalytics etc.).<br>• Improve incentives to attract large pharmaceutical companies to establish or grow their presence in Australia.<br>• Improve benchmarks for Australian trials to reduce costs and improve reputation; in particular study initiation durations (protocol approved to first patient screened) and Last Patient Last Visit through to report.<br>• Improved clinical research infrastructure to support the development of hubs with focus area specialisation. | • Incentivise interactions between investors, R&D, pre-clinical and clinical environments to develop a work-force with skills that extend along the value chain.<br>• Build capacity to participate in or lead phase 2 and phase 3 Australian based multi-national trials. |
| **SKILLS**<br>**From limited awareness ...** | | **... to a skilled industry** |
| • Improve industry awareness of clinical trials requirements, both in Australia and internationally.<br>• Continued education and training for primary investigators, clinicians and site study coordinators.<br>• Increase number of physician-scientists in Australia through mentorship and support. | • Increase number of skilled clinical trials professionals in Australia through mentorship and support.<br>• Structured professional development, education and training for members of HREC. | • Improve training to enable Australian investigators to lead Australian based multinational trials and foreign based trials (e.g. Asian based trials) from Australia. |

**FIGURE 16: CONTINUED**

| SHORT TERM (0-3 YEARS) | MEDIUM TERM (3-10 YEARS) | LONG TERM (10+ YEARS) |
|---|---|---|
| **APPROVAL PROCESS AND MARKET ACCESS** | | |
| **From inconsistency ...** | | **... to a nationally consistent approach** |
| • Implement a national clinical trials liability insurance scheme (a key recommendation from the McKeon Review).<br>• Address multi-site issues such as ensuring consistent processes and national approach.<br>• Improve timeliness of HREC meetings.<br>• Streamline HREC approvals processes with a national approach and consistency in requirements; this includes streamlining and improving the actions of the CTAG and the state-based National Mutual Acceptance Scheme by consolidation to a national clinical trials office to drive reforms (a key recommendation from the McKeon Review). | • Introduce regulatory frameworks to help SMEs understand correct regulatory pathway.<br>• Establish 8–10 national ethics committees to replace the proliferation of local committees (200 HREC in Australia in 2016[90]) (a key recommendation from the McKeon Review).<br>• Develop clear incentives for a site to become the lead for ethics submissions to counter the additional administrative responsibilities associated with this role.[91] | • Access to global value chains enabled via trade agreements. |

**FIGURE 17: OUTCOMES FOR ACCELERATED PHARMACEUTICAL DEVELOPMENT**

| SHORT TERM (0-3 YEARS) | MEDIUM TERM (3-10 YEARS) | LONG TERM (10+ YEARS) |
|---|---|---|
| **OUTCOMES** | | |
| **From a nascent industry ...** | | **... a robust and productive ecosystem** |
| • Improved reputation and benchmarks for Australian trials.<br>• Increase in the number of early-stage clinical trials being completed by in Australia with strategic partners. | • Increase in value and production of Australia's pre-clinical and clinical trials industry.<br>• Increase in Australian intellectual property developed through to early-stage clinical testing.<br>• Increased number of services providers, such as clinical research organisations and prototype manufacturing organisations. | • Increase in clinical products and associated diagnostics developed and commercialised in Australia (significant increase in both early and late stage clinical trials).<br>• Significantly increased clinical trials skill profile, skills transfer and associated job creation. |

Timeframes should be viewed as a guide only.

90 NHMRC website (2016). *Human Research Ethics Committees (HRECs)*, [Online] Available from: https://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs Accessed 19/12/2016.

91 Health Outcomes International (2015). *Australian Government Department of Health Analysis of recently conducted clinical trials,* Australian Government, Department of Health.

## Enabling science and technology

The future vision of an ecosystem conducive to accelerated therapy development, through early-stage clinical trials will be supported by a number of technical developments. Research priorities to enable these technical developments are detailed below.

## FUTURE RESEARCH PRIORITIES

### ICT

- Model, study and implement appropriate technology for traceable, sharable, ethical, trackable and secure electronic health records for all Australians to enhance clinical trials data.
- Develop systems and platforms for eClinical trial solutions to help standardise and manage processes and enable virtual ethics reviews.
- Seamless connection of national research, trials and care based information systems, enabling easier collaboration.

### Regulatory Science

- Improved models and protocols for Australian pre-clinical toxicology studies and drug candidate optimisation, including: absorption, distribution, metabolism, and excretion studies (ADME bioanalysis), drug metabolism and pharmacokinetic (DMPK) studies.
- Focus on demonstrating safety using new approaches to data-science and statistical modelling.

### Focused basic research

- Biologics – improve understanding on the development and manufacture of complex biologics.
- Diseases that threaten the biosecurity of Australia and neighbouring regions.
- Emerging infectious diseases that are of potential significant global impact.
- The clinical translation of emerging therapeutic focus areas such as gene therapy, and technology areas of heightened complexity such as stem-cell therapies.
- Regulatory science for clinical focus areas where Australia has an existing strength, such as chronic diseases (diabetes, cardiovascular), neuro-degenerative disorders, oncology, otolaryngology, ophthalmology, and tropical medicine.

# Manufacturing high-value pharmaceuticals

## VISION

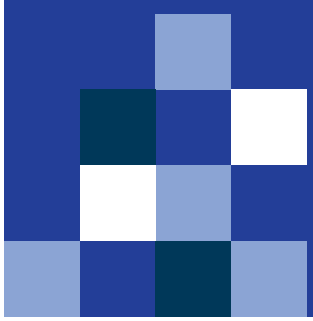
To focus Australian manufacturing efforts toward high-value and niche pharmaceutical products that create sustainable export revenue. Australia can leverage advantages around ingenuity, quality and reliability to attract businesses without the capacity to develop complex production processes in-house. This would see an increase in the number of local development teams required to manufacture products for direct export or clinical development.

## DRIVING MEGATRENDS

**CHRONIC BURDEN** – increasing incidence of chronic diseases has created an increase in demand for pharmaceuticals, many of which are complex to manufacture and require reliable and efficient production environments.

**DEVELOPING MARKETS** – developing economies represent significant markets for all pharmaceutical products, in particular, complex high-quality generics and biosimilars.

**GLOBAL BIOSECURITY** – developed economies like Australia, with an educated and skilled workforce, access to key infrastructure, and stable supply-chains, will be critical for manufacturing therapies needed in markets which endure less stable environments.



## 4.3 Manufacturing high-value pharmaceuticals

### 4.3.1 THE OPPORTUNITY

Driven by an increased global demand for MTP solutions,[92] the Australian MTP sector has an opportunity to create value by developing, manufacturing and supplying international markets with niche high-value pharmaceutical products. Products could include novel biologics, biosimilars, and a range of small molecules from synthetic active pharmaceutical ingredients (APIs) to naturally derived compounds. The commonality between these products is that they require complex manufacturing processes to reach and maintain the required level of quality. Importantly, these products have a high cost per unit weight, which mitigates numerous Australian comparative disadvantages.

Biologics and biosimilars requiring a high degree of manufacturing complexity are of particular significance for the Australian sector with these products exhibiting significant capacity for growth.[93] As a class of products, they have gained rapid market share and are expected to comprise over 27% of the global pharmaceutical market by 2020.[94] Of the 20 top-selling global pharmaceuticals, eight are biologics set to lose patent protection by 2020.[95] As these patents expire, the market for biosimilars will witness rapid growth, especially in developing markets. By 2020, the global market for biologics and biosimilars is expected to generate revenues of over US $290 billion, and US $25 billion respectively.[96] Biologics manufacturing has historically been restricted due to several factors including the complex manufacturing processes and high skill sets requirements.[97]

Beyond biologics, it is anticipated that all categories across the pharmaceutical sector will exhibit growth as economies develop and increase their demand for medical solutions. This will cover everything from patented small-molecules through to over-the-counter drugs and high-value complementary medicines. To capture value, Australia must define which of these are going to benefit most from innovations in manufacturing and production processes, and which markets are going to put most value on quality, reliability and provenance. For manufacturing (contract and in-house) in particular, there must be a level of technological complexity or value-add for Australia to compete with low cost markets.

#### What is a biologic?

Biological medicines or biopharmaceuticals (biologics) are defined by the TGA as therapeutic goods that are derived from biological sources and are regulated as registered medicines. They include proteins and polysaccharides such as:

- vaccines
- products of the fermentation of recombinant cell-lines
- medicines derived from the fluids and tissue of humans and animals
- bacterially-derived proteins
- animal-derived polysaccharides such as heparin.

Biologics do not include antibiotics and small peptides or molecules <2500 Da.

#### What is a biosimilar?

A biosimilar is a version of an already registered biologic that has a demonstrable similarity in physicochemical, biological and immunological characteristics, efficacy and safety, based on comprehensive comparability studies.

*Source: TGA website (2015). Acronyms and glossary.*

92 OECD (2015). *Health at a Glance 2015: OECD Indicators*, OECD Publishing, Paris.
93 Frost & Sullivan (2014). *Analysis of the Global Biosimilars Market*, Mountain View.
94 Jacoby, R., et al (2015). *Winning with biosimilars - Opportunities in global markets,* Deloitte.
95 Frost & Sullivan (2014). *Analysis of the Global Biosimilars Market*, Mountain View.
96 Jacoby, R., et al (2015). *Winning with biosimilars - Opportunities in global markets,* Deloitte.
97 Frost & Sullivan (2016). *Global Pharmaceutical Contract Manufacturing Organization (CMO) Market,* Mountain View.

**Case study**

## IDT Australia

IDT Australia is an Australian listed company, headquartered in Melbourne with a minority interest in a clinical trials facility in Adelaide. IDT offers a full range of contract pharmaceutical product development and manufacturing services, from API development through to commercial finished dose manufacturing, specialising in difficult to manufacture drugs.

Traditionally IDT has sold API's and provided contract manufacturing, drug development and R&D services, however, recently the company has gained approval to market its first proprietary generic drug product, the oral chemotherapy drug temozolomide. In pursuing this opportunity, IDT aims to increase the company's share of the wholesale price and capture additional value by undertaking the registration and sale of its own drug product portfolio.[98] To support the sale of temozolomide and 24 other drugs in development in their pipeline, IDT has established international sales channels through relationships with Mayne Pharma and ANI Pharmaceuticals in the USA and is actively exploring opportunities in other geographical markets.[99]

### 4.3.2 AUSTRALIA'S GLOBAL POSITIONING

#### Why Australia

- **Strong international reputation for quality –** Australia's national manufacturing brand in this sector is based on high-quality production processes, safety, reliability and ingenuity. This brand is especially strong in the Asian region.
- **Highly skilled and educated workforce –** Australia's highly educated graduates and quality workforce skills enable the industry to find and protect answers to complex challenges inherent in manufacturing biologics and other complicated products. Ensuring Australia has a skilled workforce, particularly in STEMM fields is crucial to capturing this opportunity.
- **A strong research community** – Australia has numerous research programs focused on complex pharmaceuticals, providing the sector with know-how to remain competitive. CSIRO has research programs that focus on biomedical manufacturing and Australia's Monash University is ranked number four in the world in pharmacy and pharmacology, according to the 2016 QS World University Rankings.[100]
- **Reputable national regulatory system** – Australian manufacturers have a quality advantage over companies in Asian countries due to Australia's stringent regulatory system, skilled workforce and track record of high-quality, clean and safe manufacturing. This reputation has been developed by a cultural attitude that embraces a strong regulatory approach to any products and services that may compromise the safety of an individual, and while it may hinder agility in the development of new products and services, it creates output of a highly reliable and safe nature, which are highly appealing product attributes for this market segment.
- **Diverse culture, social-economic stability, and unique location** – Australia's geographic and social proximity to economies undergoing healthcare transformation provides a valuable advantage over other countries. As does Australia's supply chain security and stability of inputs required to enable the production of complex pharmaceutical products, such as the quality of tap water through to the inherent stability of the workforce.

98 IDT Australia Limited (2013). *AGM Presentation, November 2013,* [Online] Available from: http://idt.live.irmau.com/irm/PDF/1127/ManagingDirectorsAGMpresentation Accessed 21/12/2016

99 IDT Australia (2016). *Investor Presentation,* [Online] Available from: http://idt.live.irmau.com/irm/PDF/1528_0/InvestorPresentation Accessed 21/12/2016

100 Top Universities website (2016). *QS World University Rankings by Subject 2016 - Pharmacy & Pharmacology*, [Online] Available from: http://www.topuniversities.com/university-rankings/university-subject-rankings/2016/pharmacy-pharmacology Accessed 19/12/2016.

## Competitors

Australia faces competition from global contract manufacturers that are rapidly enhancing their portfolios to become commercial development and manufacturing organisations, with up to 40% of global contract manufacturing organisations (CMOs) expected to move to this model over the next few years.[101] Further, some CMOs are expanding to focus on pre-clinical development services. There are a growing number of CMOs in emerging markets, particularly in the BRICS economies, however, these competitors may inadvertently strengthen Australia's global position as a high quality manufacturer of high quality complex pharmaceuticals due to the problems they face with manufacturing, delivery, service and product quality.[102]

However, the changing operating models of global CMOs does highlight that Australian industry must ensure competitiveness by offering commercial development services alongside the manufacture of complex pharmaceuticals.

## Partners and buyers

Key buyers include global companies looking to leverage Australia's location, brand and quality to access Asia, as well as companies looking to manufacture product for clinical trials. Small and medium pharmaceutical companies represent key buyers, as they outsource between 60-70% of manufacturing, due to lack of manufacturing infrastructure and skills. It is estimated that big pharmaceutical companies outsource only 20-25% of biologic manufacturing with the remainder kept in-house due to intellectual property concerns.[103]

Small and medium pharmaceutical companies represent key buyers, as they outsource between 60-70% of manufacturing, due to lack of manufacturing infrastructure and skills.

**Case study**

### GlaxoSmithKline (GSK) Australia[104]

In 2009, GSK Australia and the Monash Institute for Pharmaceutical Science (MIPS) collaborated to establish the MIPS-GSK Australian Centre of Innovation and Industrialisation (MIPS-GSK Centre). The centre draws upon Australian pharmaceutical research and manufacturing expertise, combining skills and ideas to develop next-generation formulations and platform technologies. Initially established with $3.3 million of funding from the Victorian Science Agenda Investment Fund and GSK, GSK has since invested over $100 million to expand its manufacturing presence in Victoria.

In October 2016, building on the success of GSK's collaboration with MIPS, the company announced support for Australia's manufacturing industry as a founding partner for the Victorian Medicine Manufacturing Innovation Centre (MMIC). The MMIC will provide medicine manufacturers with access to specialist scientific capabilities to solve technical challenges as well as encouraging investment in research and development, high-tech manufacturing, skills development and collaboration.

The success of GSK's collaborations have played a key role in the decision by GSK to remain in Australia and invest an additional $7.7 million in its 'blow-fill-seal' advanced manufacturing capability located in Melbourne, a decision that will create almost 60 new highly-skilled jobs. GSK exports approximately 75% of the medicines manufactured in Australia to 58 countries across Europe, the Middle East and Asia.

101 Frost & Sullivan (2016). *Analysis of the Global Biologics API Market,* Mountain View.
102 Frost & Sullivan (2016). *Global Pharmaceutical Contract Manufacturing Organization (CMO) Market,* Mountain View.
103 Frost & Sullivan (2016). *Analysis of the Global Biologics API Market,* Mountain View.
104 GSK website (2016). *GSK founding partner for Victorian Medicines Manufacturing Innovation Centre,* [Online] Available from: https://au.gsk.com/en-au/media/press-releases/2016/gsk-founding-partner-for-victorian-medicines-manufacturing-innovation-centre/ Accessed 19/12/2016

With the development pipelines of big pharmaceutical companies increasingly focused on large molecule drugs such as biologics, Australia can ensure it is an attractive destination and partnership proposition by demonstrating capacity and capability in complex manufacturing needed for traditional and developing markets, as well as continuing to ensure strong IP protection. While Australia's limited market size is indicated to be one of the unavoidable disadvantages, the purchasing power of the Pharmaceutical Benefits Scheme (PBS) provides single point negotiations with annual expenditure of over $10.8 billion, a lucrative buyer for any pharmaceutical manufacturer.[105]

Other buyers will be those countries and companies that lack the ability or scale to manufacture highly complex pharmaceutical products, and are willing to develop long-term relationships with Australian manufacturers to do so on their behalf. For example, international governments looking to strengthen their biosecurity preparedness might value access to Australian manufacturers that are able to rapidly produce niche products. In this context, remaining a partner and enabler of this opportunity for its own biosecurity measures is an important consideration for the Australian Government. Buyers with a purely cost-focused outcome are not a desirable target.

Partners for businesses looking to capitalise on this opportunity could be research organisations that can help streamline and overcome complex manufacturing problems, and marketing and distribution partners to provide efficient access to high-value markets.

### Opportunity threats

Failing to support growth in complex pharmaceutical manufacturing will result in lower contributions from high-value manufacturing to Australia's GDP. Australia will instead be an importer of these products from other regions, missing out on employment and economic growth as well as access to high quality pharmaceuticals. Australia is dependent on international manufacturers for products required to combat biosecurity threats and needs to pre-emptively stock-pile. If stock-piling falls short, Australia is dependent on the good-will of allies for continued access to complex pharmaceutical products.

## 4.3.3 PLANNING FOR THE FUTURE

Transitioning Australia into a hub for manufacturing and export of complex pharmaceuticals requires coordination of skills and training, infrastructure and incentives, and needs to be supported by cutting-edge process technologies and research platforms.

### Ecosystem changes

There are a number of possible roadblocks that can inhibit the success of Australia's complex pharmaceutical manufacturing sector; as such, it is critical that businesses align efforts to realise this opportunity.

- **Skills and infrastructure** – Competitive advantage will be gained through the creation, development and support of state-of-the-art manufacturing infrastructure that supports commercial scale-up and incorporates novel emerging technologies, a skilled and agile workforce, and an intellectual property system that provides global companies with peace of mind.
- **Market access and sales** – A fundamental enabler for this opportunity is access to global markets for new entrants in Australia. An excellent demonstration of this is the cohorts of industry groups that undertake international trade missions to promote Australian capabilities, and this should be continued and encouraged at a much larger scale. There is an opportunity for the Australian Government to support the sector in this regard through the diplomatic relationships it can develop with neighbouring countries, particularly for international matters related to biosecurity and medical counter measures.
- **Outcomes** – The MTP sector will need to work with the research community to overcome complex manufacturing problems and develop world-class manufacturing facilities to build Australia's reputation as a trusted complex manufacturing hub.

105 Thomas, G., Marlton, P., (2016). *Expenditure and Prescriptions Twelve Months to 30 June 2016,* PBS Information Management Section, Pharmaceutical Policy Branch.

## High-value pharmaceutical manufacturing in the 2030s

- Australia will be home to numerous companies specialising in the development and production of complex high-value products that require complicated processes, monitoring and analytics, for a global market.
- Companies will specialise in development of novel and cost-efficient drug delivery and synthesis systems.
- International companies will look to Australia to meet manufacturing requirements to supply clinical trials and global markets.

**FIGURE 18: MTP ECOSYSTEM ACTIONS FOR COMPLEX PHARMACEUTICAL MANUFACTURING**

| SHORT TERM (0-3 YEARS) | MEDIUM TERM (3-10 YEARS) | LONG TERM (10+ YEARS) |
|---|---|---|
| **SKILLS & INFRASTRUCTURE** | | |
| **From limited infrastructure ...** | | **... to a skilled, well-resourced export hub** |
| • Develop industry think-tanks to combat complex pilot scale and scale-up manufacturing problems.<br>• Enable industry access to state-of-the-art screening facilities and equipment such as liquid chromatograph-mass spectrometers, and other facilities.<br>• Nurture an Australian skilled workforce capable of complex trouble-shooting for pharmaceutical manufacturing and on-the-run adaptation.<br>• Develop specialised workforce skills and expertise to produce sophisticated high potency active pharmaceutical ingredients (APIs). | • Develop incentives to support large commercial scale, adaptable and modularised manufacturing facilities that enable quick scale up for manufacturing of biologics.<br>• Development of skills and novel infrastructure for emerging technologies such as nanobodies, bi-specific antibodies, and antibody drug conjugates.[106]<br>• Develop tertiary qualifications for advanced complex pharmaceutical manufacturing.<br>• Develop stronger relationships with R&D teams from local and international businesses to develop a strong product pipeline and pre-empt manufacturing challenges. | • Improve agile manufacturing infrastructure. |
| **MARKET ACCESS & SALES** | | |
| **From several independent companies ...** | | **... to a globally focused national industry** |
| • International branding of Australian industry capabilities and facilities.<br>• Strengthened cooperative national alliance of high-value pharmaceutical manufacturers.<br>• Development of a consistent dialogue regarding Australia's competitive positioning for niche high-value pharmaceutical manufacturing.<br>• Government-derived relationships for the manufacturing of products for international biosecurity markets. | • Increase volume of international contracts with small and medium pharmaceutical companies.<br>• Development of pilot-scale manufacturing contracts for large pharmaceutical companies.<br>• Ensure export facilities enable Australian participation in global value chains. | • Ensure Australia's intellectual property system remains robust and valuable. |

Timeframes should be viewed as a guide only.

106 Frost & Sullivan (2016). *Analysis of the Global Biologics API Market,* Mountain View.

**FIGURE 19: OUTCOMES FOR COMPLEX PHARMACEUTICAL MANUFACTURING**

| SHORT TERM (0-3 YEARS) | MEDIUM TERM (3-10 YEARS) | LONG TERM (10+ YEARS) |
|---|---|---|
| **OUTCOMES** | | |
| **From small scale contract manufacturing ...** | | **... to a trusted and innovative manufacturing hub** |
| • Greater local capability for contract manufacturing of complex pharmaceutical agents and APIs for Australian clinical trials.<br>• Development of focused Australian manufacturing strengths in monoclonal antibodies and recombinant proteins (fastest growing biologics).[107]<br>• Clinical development and manufacture of products in clinical areas that Australia has strengths (e.g. cancer, immunotherapies and neurological diseases). | • Development and commercialisation of innovative processes for efficient pharmaceutical synthesis.<br>• Development of new methods for efficient manufacturing scale up.<br>• Australian manufacturing hub for complex pharmaceuticals for export to developing Asian countries and globally.<br>• Growth in Australian biologics start-up community supported by local state-of-the-art manufacturers. | • Australian based contract manufacturing and development of biologics, biosimilars and other complex products for global multinationals, with a focus on distribution into Asia.<br>• Niche and high-value pharmaceuticals contributing significantly more to Australian export revenue.<br>• A significant increase in the number of IP claims for novel processes and methods to manufacture complex pharmaceutical products.<br>• Development of novel drug delivery and manufacturing technologies such as 3D printed bio-macromolecules and targeted oral drug delivery through smart pills. |

Timeframes should be viewed as a guide only.

107 Frost & Sullivan (2016). *Analysis of the Global Biologics API Market,* Mountain View.

### Enabling science and technology

Technology developments aim to allow for higher production flexibility, lower input costs and increased yields. These developments might be enabled by improved quality control, fast changeover, greener production lines, and minimised contamination risks.[108] Adoption and development of world-class technologies and analytical instruments will help keep Australian industry globally competitive. The list below provides an overview of some of the enabling science and technology required to make this opportunity a reality. See Appendix A.2.2 for an expanded list.

Adoption and development of world-class technologies and analytical instruments will help keep Australian industry globally competitive.

## FUTURE RESEARCH PRIORITIES

### Instrumentation and infrastructure

- Development of advanced and sophisticated infrastructure and analytical instruments, such as mass spectrometers with increased sensitivity,[109] advanced high performance liquid chromatography (HPLC) and size exclusion column chromatography (SEC) for improved characterisation.
- Improved in-line data capture and analytics to allow for continuous improvement in manufacturing processes.

### Manufacturing and platform technologies[110]

- Development of improved platforms to manufacture complex products in liquid and semi-solid dose formulations (nasal, nebulised, ophthalmic, otic, and topical), liquid formulations (vaccines and cytotoxics) and solid formulations (tablets and capsules) including sterile and non-sterile preparations.[111]
- Development of continuous manufacturing systems for biologics.

108 Frost & Sullivan (2016*). Potential and Impact of Single-Use Pumps on the Biopharmaceuticals Industry.*
109 Frost & Sullivan (2016). *Biopharmaceuticals Analytical Instrumentation Market.*
110 Frost & Sullivan (2016). *Analysis of the Global Biologics API Market,* Mountain View.
111 Frost & Sullivan (2016). *Global Pharmaceutical Contract Manufacturing Organization (CMO) Market,* Mountain View.

# Diagnostic and informatics products and services

## VISION

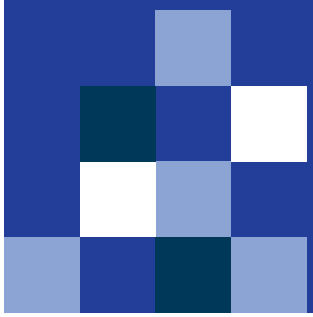
To develop a world-leading sector based on the development and integration of medical diagnostic and informatics platforms. Data security and interoperability is at the fore of this opportunity, and will underlie increased access to de-identified patient and population data. Information packages resulting from this data can be leveraged by local and international businesses for the development of diagnostic products, and preventative and precision MTP solutions.

## DRIVING MEGATRENDS

**PRECISION HEALTHCARE** – the ability to better understand the needs of a patient based on how their profile compares to population data will drive the development of MTP solutions that are more precise and effective.

**DIGITAL EVOLUTION** – as data generation continues at an increasing rate, complex informatics platforms will allow for data to be leveraged for the development of novel MTP solutions, both traditional and digital.

**INTEGRATED CARE** – the integration of diagnostic and informatics platforms into models of care will enable a lower cost and more effective, patient-centric health services model.



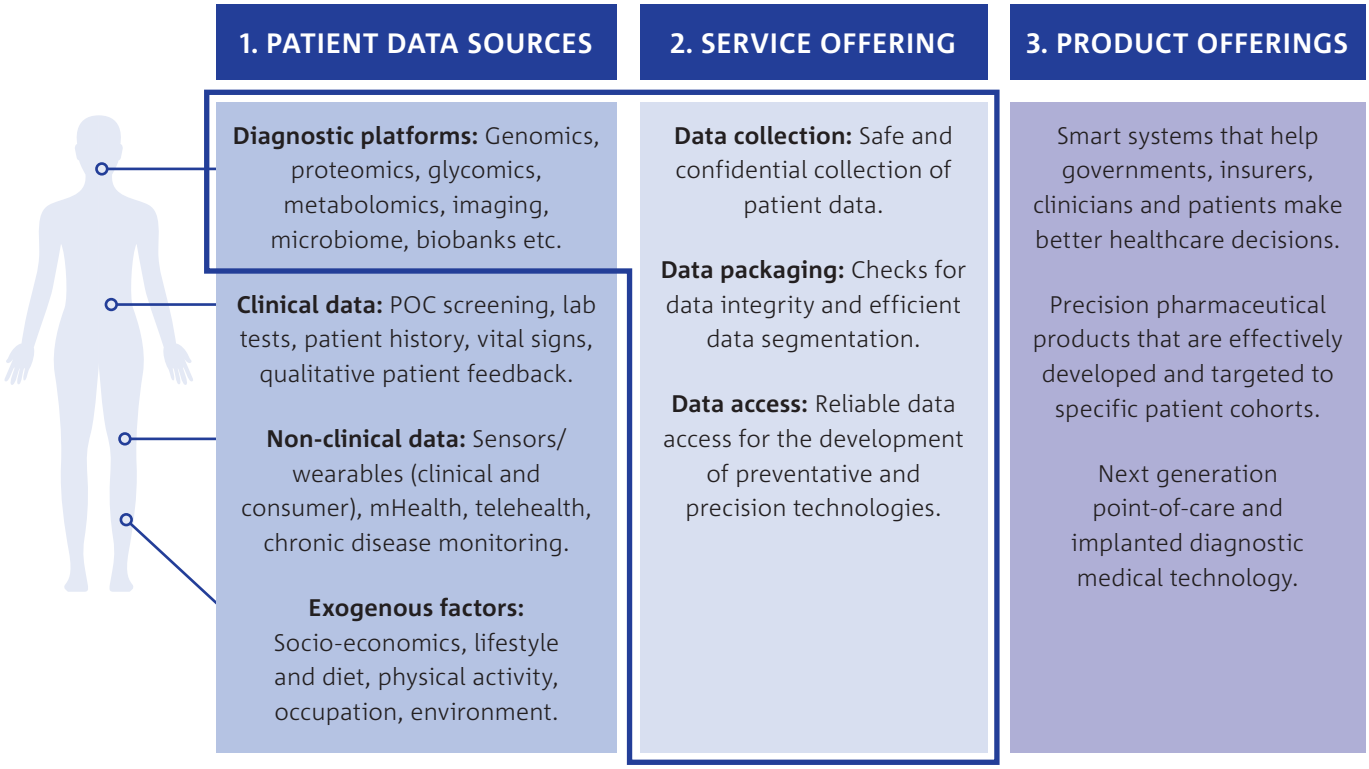
## 4.4 Diagnostic and informatics products and services

### 4.4.1 THE OPPORTUNITY

The Australian MTP sector has an opportunity to develop novel business and service models around the collection, interrogation, interpretation and packaging of medical and population data which is needed for the development of diagnostic products and platforms, and preventative and precision medicine solutions. This opportunity is driven by a need to develop efficiency in healthcare delivery, and will help establish strong growth in the MTP sector via novel data services.

In the past decade there has been an explosion in the variety and volume of health data collected. Patient data sources span research and clinical study data generated from genomics, epigenomics and proteomics, data from traditional clinical diagnostics such as imaging and pathology, through to the numerous options for patients to collect their own physiological data on a daily basis via wearables (see *Section 4.1 –Smart devices, implants and bionics).* Figure 20 highlights some of the ways value can be captured from the use of de-identified or confidential patient data. So far, patient data has not been effectively utilised as its value can only be realised when integrated with a broader set of patient and population information – a challenge that has nuanced quality, security and integration requirements.

**FIGURE 20: CAPTURING VALUE FROM HEALTH, MEDICAL AND POPULATION DATA**




**As outlined in the figure, Australia can create a strong competitive advantage by focusing on the development of diagnostic platforms that will generate complex patient data, concurrently developing services around data collection, data packaging and data access. These services will also work with existing data sources. The ultimate outcomes are next generation MTP solutions, driven by complex data.**

Beyond the technical challenges, new service and business models will need to address cultural challenges as part of their development process. For example, cultural acceptance of the use of confidential or de-identified patient data can be increased by communicating how preventative and precision products will improve patient wellbeing.

New business models and services will need to be developed in a way that takes advantage of existing infrastructure, and can be scaled up as reliability and performance success is demonstrated. If successful in capturing value from patient data, the Australian sector will gain a strong global advantage in the development of data driven diagnostic and informatics products. A data driven MTP environment in Australia will cultivate the testing and development of truly preventative and precision MTP solutions.

If successful in capturing value from patient data, the Australian sector will gain a strong global advantage in the development of data driven diagnostic and informatics products.

**Casy study**

## Complex Data Integration

A number of alliances have been established with the goal of integrating genomics data into the broader Australian health and medical ecosystem. A fundamental driver behind these alliances is the need to standardise access to information to develop effective preventative and precision solutions. The Australian Genomics Health Alliance (AGHA) is a network of 47 partner organisations including research institutes, hospitals and universities. It aims to enable Australia to become a global leader in the translation of genomics data for cancer and rare diseases into preventative solutions for the Australian healthcare system.[112] Queensland[113] and Victoria have similar state based alliances, with the Melbourne Genomics Health Alliance demonstrating that patients get a faster and more accurate diagnosis when genomic sequencing is efficiently utilised, resulting in patients requiring fewer tests as the data can be stored and analysed multiple times.[114] These alliances indicate that with limited investment Australia has been able to link together platforms that deal with significant volumes of complex data.

112 Australian Genomics Health Alliance website, *Our Approach,* [Online] Available from: https://www.australiangenomics.org.au/about-us/our-approach/ Accessed 19/12/2016.

113 Queensland Genomics Health Alliance website, *About Us,* [Online] Available from: http://www.qgha.org/about/ Accessed 19/12/2016.

114 Melbourne Genomics Health Alliance website (2016). *Our results demonstrate genomic medicine's success,* [Online] Available from: http://www.melbournegenomics.org.au/news/our-results-demonstrate-genomic-medicines-success, Accessed 19/12/2016.

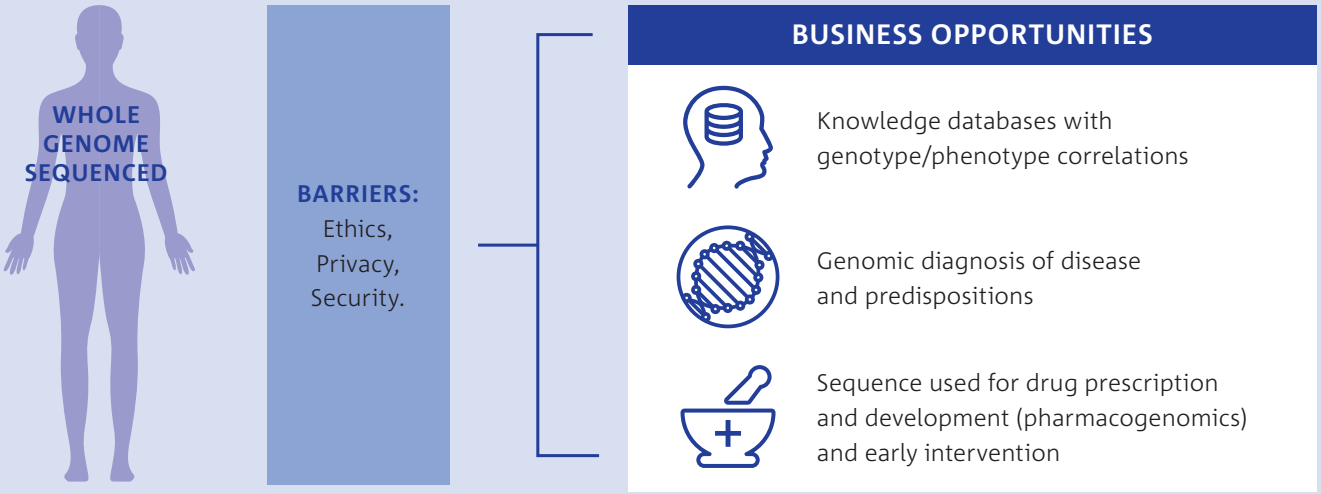
## Potential service models

An example of an MTP service model that could be assessed is diagnostic platforms for analysis on an isolated genome sequence. This model relies on a patient's genomic data being collected and stored securely to be drawn upon as needed. If a diagnostic test is prescribed by a clinician, diagnostic service providers are granted restricted access to a particular gene sequence or section relevant to the syndrome being considered. This prevents the inadvertent risk of making other genetic discoveries or findings for which informed consent has not being given, where results could have significant impacts on patients' lives.

As well as providing a diagnosis, service providers may, upon receiving consent, indicate a patient's predisposition to certain conditions, allowing a clinician to prescribe preventative medical services focused on patient wellness. Genomics will also allow clinicians to prescribe tailored treatment plans that will best work for an individual based on their specific characteristics.

Other possible services include examination and analysis of environmental data alongside genome sequencing to make phenotypic projections and pharmacogenomics analysis to understand personalised drug dosages for a patient. When effectively de-identified, this data can be packaged for the development of new technologies.

**FIGURE 21: POTENTIAL SERVICES**



Case study

## ASPREE Large Cohort Clinical Trial

ASPREE (ASPirin in Reducing Events in the Elderly) is an international clinical trial that aims to determine whether daily, low-dose aspirin improves quality of life for older people around the world. Specifically, the study aims to assess the ability of low dose aspirin to prevent or delay the onset of age-related illness such as cardiovascular disease (heart attack and stroke), dementia, depression and certain cancers and if the benefits outweigh the risks, such as bleeding and haemorrhagic stroke.

As the largest primary prevention aspirin study ever undertaken in healthy older people (70+ years), the trial has over 19,100 participants across Australia and the US (87% from Australia, 13% from the US). The trial is a randomised, double blind, placebo-controlled study, with participants taking a randomised placebo or low dose aspirin for an average of 5 years. In Australia, the trial is led by Monash University, with the first results expected to emerge in 2018.

The ASPREE trial has created a valuable and rich dataset and biobank with a depth and breadth unparalleled in Australia. Although established primarily to study low dose aspirin, ASPREE has become an important vehicle to study many other aspects of the health of older Australians, with a number of sub-studies investigating the effects of aspirin on specific diseases.[115]

### 4.4.2 AUSTRALIA'S GLOBAL POSITIONING

#### Why Australia

- **An equitable healthcare system** – The provision of healthcare in Australia is among the best in the world, with high levels of baseline coverage and incentives to access private health insurance. This is one less variable that may inhibit the development of data based resources collected from patients. A 2016 analysis ranked Australia in the top five countries based on perceived readiness to realise the benefits of integration and connected care in the healthcare system.[116]
- **Diverse culture, social-economic stability, and unique location** – Australia's population diversity when combined with excellent levels of baseline healthcare access, makes Australian patients a statistically interesting pool from which information can be collected to provide data sets needed for the development of preventative and precision MTP products. Also, compared to other countries, patients and healthcare professionals in Australia generally feel comfortable sharing their data; a recent survey shows that 91% of Australians would be willing to share their de-identified medical data if it went towards research purposes.[117]
- **Quality infrastructure and business environment** – Australia has been an early investor in the infrastructure required to drive down the cost of obtaining various forms of complex health data. Using genome sequencing as an example, it is estimated that there are approximately 85 next-generation sequencers in Australia.[118] The Garvan Institute's Genome.One is an example of a state-of-the-art Australian platform that can generate the high-value data needed to explore this opportunity.
- **A strong research community** – Australia has demonstrated success in leading significant data analytics projects that draw on a variety of patient inputs. For example, the Australian eHealth Research Centre has successfully taken data from multiple sources and packaged it in ways found to be useful for the development of MTP products and services.

115 Aspree website (2015). *About the Aspree Study,* [Online] Available from: http://www.aspree.org/aus/about-us/the-aspree-study/ Accessed 22/12/2016
116 Institute for the Future (IFTF) (2016). *Future health index 2016,* Philips.
117 Research Australia website (2016). *New Poll: Australian's will share their personal health data if privacy protected,* [Online] Available from: http://researchaustralia.org/new-poll-australians-will-share-personal-health-data-privacy-protected/ Accessed 19/12/2016.
118 Frost & Sullivan (2015). *Global Clinical Next-generation Sequencing Market,* Mountain View.

## Partners and buyers

When pursuing this opportunity, emerging Australian MTP sector participants should consider partnering early with global companies that are driven to develop precision and preventative products. The ultimate buyers will include insurers and governments in search of solutions to change the profile of healthcare spending to one that increases overall wellness and enhances productivity. Consequently, these stakeholders should also be considered in the partnership process.

Insurance companies may wish to leverage medical data services in the development of new products and services to help their customers understand disease profiles and the subsequent preventative measures that can be taken to increase wellness. This is an area that pro-active patients are already showing an interest in. Similarly, insurers have a financial interest in understanding how to deliver precision healthcare, reducing the current trial and error prescription method, and more prosaically reducing *Never Events* associated with incorrect dosing, therapy contradictions or therapy timing.

As genomics and other complex diagnostics become commonplace into the future, multi-stakeholder partnerships will be required to develop an integrated system that provides easy access to the platforms that will generate the data and insights needed to develop preventative and precision MTP solutions.

Global companies such as Google, Apple, Samsung and IBM, driven by their investments into decision making tools in the health and medical space, will also be searching for well packaged and robust data sets needed for machine learning. The connection between the data and these companies can be developed by Australian based MTP service providers that meet health specific quality and regulatory requirements, and understand how to securely collect and package health data.

## Competitors

Globally, coordinated national efforts are underway to understand the best way to integrate complex patient and cohort information into healthcare systems, as such, the Australian MTP sector faces significant competition for this opportunity. It is likely that countries with more advanced, digitally integrated health systems, such as Denmark and the Netherlands, will provide an environment conducive to the development of the products and services outlined.

**Case study**

### LifeCourse

The Melbourne Children's LifeCourse Initiative aims to maximise the value of the extensive population and clinical studies performed at and in collaboration with the Melbourne Children's to inform better outcomes for children and adolescents across the continuum of care. LifeCourse brings together resources and data to aid new research questions that cannot be addressed using lone studies. LifeCourse includes over 20 separate population-based longitudinal studies, spanning 0-35 years (including two intergenerational studies), involving over 70,000 participants, 1 million data points and over 250,000 aliquots of biological specimens across 10 tissue types.

The initiative aims to lead the national integration of early data to create an unparalleled resource for informing practice and policy. The data can be used to inform best timing and targeting of interventions that prevent disease and disorder, enhance treatment and promote wellbeing. LifeCourse data is available for researchers, service providers, policy makers and industry from across the world to propose questions to be answered using the LifeCourse cohorts.[119]

119 LifeCourse website, *LifeCourse - The Melbourne Children's LifeCourse Initiative,* [Online] Available from: http://lifecourse.melbournechildrens.com/ Accessed 19/12/2016.

Emerging markets, which under the right conditions should be buyers of the technology, have the potential to leapfrog Australia in the adoption of fully integrated digital health models and develop their own health data services.[120] Similarly, the patient inputs that make this opportunity viable in Australia face competition from other countries. The Precision Medicine Initiative in the US is an effort to build a national, data-driven research enterprise with over one million volunteers to extend precision medicine to all diseases.[121]

### Opportunity threats

Keeping up with or ahead of competitors is a necessity, with Australia facing the reality of being left behind if a concentrated effort is not put into pursuing information integration, and the business models that will underpin the exchange and application of this data. Failure to consider this means that MTP businesses will have little incentive to develop precision or preventative health solutions in Australia.

Currently, access to new information generating technologies such as genome sequencing is limited to those willing to pay for it out of pocket.[122]

Lagging reimbursement standards could present a threat to the significant collection and analysis of patient data. Similarly, Australia's slow adoption of electronic health records could threaten development of novel diagnostic and informatics products.

Further, it is important that businesses maintain a social licence for the collection and use of patient data. Failure to build safeguards, transparency and effective management of risk for the use of data will result in loss of community trust and acceptance.[123]

> It is important that businesses maintain a social licence for the collection and use of patient data.

### 4.4.3 PLANNING FOR THE FUTURE

Perhaps the most important action required to realise this opportunity is collaboration, as SMEs, the research community, service provides, regulators and clinicians will be required to work together to develop a digitally connected and integrated MTP and health ecosystem. Service models must be considered in the context of clinical trials regulation, reinforcing Australia's position as an attractive destination to complete the clinical development of next generation precision and preventative MTP products.

#### Australia's diagnostic and informatics products and services in the 2030s

- The Australian MTP sector has developed a new service industry that collects, de-identifies, packages and delivers data for the development of precision and preventative medical products and services.
- Australian clinicians have access to cutting edge precision medical products and services.
- Australian based services have been deployed into developing countries, helping improve the development of digitally enabled healthcare systems.
- Australia is known for its large cohort studies that have been used to create reliable and informative databases, accessible to MTP product developers, accelerating the production of preventative and precision products and services for patients.

The Australian Government is committed to building a nationwide approach to medical data management through the Australian Government's Australian Digital Health Agency, which commenced operations on 1 July 2016. The Agency is tasked with improving health outcomes for Australians through the delivery of digital healthcare systems and the national digital health strategy for Australia.

120 McKeering, D., Norton, C., Gulati A., (2016). *The Digital Healthcare Leap*, PWC.
121 U.S. Department of Health & human Services, National Institutes of Health website. *About the Precision Medicine Initiative,* [Online] Available from: https://www.nih.gov/precision-medicine-initiative-cohort-program Accessed 19/12/2016.
122 Genome.One Pty Ltd (2016). *A patient's guide to Whole Genome Sequencing*, Garvan Institute of Medical Research, Darlinghurst.
123 Productivity Commission (2016). *Data Availability and Use, Draft Report,* Commonwealth of Australia, Canberra.

In 2016, the Productivity Commission undertook an inquiry into the benefits and costs of options for increasing availability of and improving the use of public and private sector data by individuals and organisations. The Government seeks to increase availability and use of data to boost innovation and competition in Australia.[124]

### Ecosystem changes

A number of ecosystem challenges currently limit the implementation of patient data collection and distribution in Australia, including issues around ethics, privacy and data sharing, regulations and reimbursements. It is critical that MTP businesses consider a digital integration strategy, and develop shared industry data standards.

- **Critical skills and infrastructure** – In capturing this opportunity, key skills will need to be developed in the Australian medical workforce, including a deeper understanding of genomics and broader digital literacy. Enabling infrastructure includes the widespread national adoption of electronic health records and frameworks to allow industry to have access to de-identified data.
- **Industry development** – Development of recognised standards in the short term is imperative, as in the absence of these robust standards, companies will adopt their own guidelines. Currently in Australia there are a number of initiatives that are investigating the integration of complex patient data into Australia's healthcare system, which will help establish the parameters for safe and efficient data handling.
- **Outcomes** – Successful development of this opportunity will see the industry evolve from one with limited data integration to a system with patient-centric precision and preventative MTP products, serviced by a vibrant Australian industry.

**Case study**

## Mission Massimo

In 2010, Stephen and Sally Damiani utilised genomic sequencing to isolate the rare and complex disease that threatened the life of their son, Massimo. Massimo was one of the first 20 individuals in the world to have a clinical whole genome sequenced. After searching worldwide, the Damiani's found Ryan Taft (at the time a research scientist in the University of Queensland, currently Senior Director of scientific research at Illumina), who drove forward the complex project of aligning the three Damiani genomes to identify a unique variation in Massimo that might explain his symptoms.[125] By exploring imaging biobanks in the US and EU, nine children with similar symptoms were identified, and were subsequently shown to have mutations in the same gene; this led to the identification of a new disease known as Hypomyelination with Brain stem and Spinal cord involvement and Leg spasticity (HBSL), a subset of a group of genetic disorders termed Leukoencephalopathies. By understanding the mutation and how it causes the body to react, the Damiani family and their clinicians have been able to potentially slow the advancement of the disease in Massimo.

Driven by this success and with significant knowledge behind them, the Damiani family has embarked on a research program to define a therapy that will halt progression of the disease. The program involves a team of international scientists, including members of the University of Queensland, University of New South Wales and Walter and Eliza Hall Institute of Medical Research. This case exemplifies the power of genomic data and the potential it has for rapid identification of rare diseases. In terms of developing MTP solutions, this case exemplifies early success in Australia regarding the process required to leverage medical imaging and genomic data for the identification of diseases that do not currently have an associated pharmaceutical therapy.

124 Productivity Commission (2016). *Data Availability and Use, Draft Report,* Commonwealth of Australia, Canberra.
125 Kaminsky, L., Damiani, S., Damiani, S., (2015). *Cracking the Code*, Penguin Books.

**FIGURE 22: MTP ECOSYSTEM ACTIONS FOR DIAGNOSTIC AND INFORMATICS PRODUCTS AND SERVICES**

| SHORT TERM (0-3 YEARS) | MEDIUM TERM (3-10 YEARS) | LONG TERM (10+ YEARS) |
|---|---|---|
| **CRITICAL SKILLS AND INFRASTRUCTURE** | | |
| **From limited integration ...** | | **...to data driven clinicians** |
| • Improve digital and genomic literacy in the MTP and health system workforce.<br>• Encourage state governments to work together on a unified national approach to medical and health data.<br>• Efficient use of research infrastructure and resources through data and informatics infrastructure networks.<br>• Develop best practice for disaster recovery/business continuance for secure information storage.<br>• Continue investment in and development of advanced sequencing and imaging infrastructure. | • Introduce data sharing service platforms and systems to allow diagnostic service providers to have access to relevant data to run diagnostic analysis.<br>• Introduce specialised clinicians trained in the multidisciplinary field of clinical genomics.<br>• Standard analytic tools and procedures for large sets of population health data, to improve precision of care delivery.[126]<br>• Continue investment in and development of advanced high performance computing clusters. | • Integration of diverse data management platforms and protocols. |
| **INDUSTRY DEVELOPMENT** | | |
| **From recognised potential ...** | | **... to an integrated digital health system** |
| • Development of communication programs that provide patients with information and education on the process of collecting and using health data for product development.<br>• National standards for gaining informed consent, quality control and accreditation for genome sequencing and diagnostics.<br>• Development of national ethical guidelines for clinical genomic testing.<br>• Framework for secure, ethical and legal data sharing.<br>• Develop best practice guidelines for maintaining social licence in the collection and use of data.<br>• Define interoperability standards for health and medical data. | • Improved collaborative working relationships with specialists across diverse disciplines (e.g., clinicians, researchers, experimental scientists, bioinformaticians).<br>• Ensure equity of access to high-content diagnostic platforms (imaging and sequencing).<br>• Reimbursement of clinically indicated genomic sequencing.<br>• National standards and quality control for phenotype data collection.<br>• Economic analysis to show cost benefit of precision and preventative MTP products enabled by accessing complex patient data. | • Digitally enabled health system allows data collected from cohorts to inform individual patient care. |

Timeframes should be viewed as a guide only.

126 Frost & Sullivan (2016). *Hospitals of the Future – Creating an Era of Personalized Medicine (TechVision)*, Mountain View.

**FIGURE 23: OUTCOMES FOR DIAGNOSTIC AND INFORMATICS PRODUCTS AND SERVICES**

| SHORT TERM (0-3 YEARS) | MEDIUM TERM (3-10 YEARS) | LONG TERM (10+ YEARS) |
|---|---|---|
| **OUTCOMES** | | |
| **From limited data integration ...** | | **... to patient-centric precision and preventative MTP products** |
| • Initiation of companies that provide services aligned with collecting and de-identifying data for use in developing preventative MTP solutions.<br>• Accessible diagnostic platforms that are designed to upload complex information directly to a National eHealth platform.<br>• Point-of-care and personal devices and diagnostics that collect simple patient information in a sharable format.<br>• Population health analytics. | • Accessible genomic sequencing and imaging services for healthy individuals with available infrastructure to store results securely.<br>• Accessible genomic diagnostics services.<br>• Novel diagnostic service providers enabled by integration of all patient data.<br>• Integration of personal genomic data with electronic medical records.<br>• Service platforms for data warehousing.<br>• Large anonymous cohort knowledge datasets that can be interrogated to answer research questions.<br>• Development of novel companion diagnostic products.<br>• Development of scalable and portable genomic sequence analysis tools. | • Robust prophylactic services ecosystem for patients receiving genome sequencing and analysis on predispositions.<br>• Pharmacogenomic prescription of precision therapies enabled by point-of-care testing platforms.<br>• Artificial intelligence enabled clinical decision support and expert systems.<br>• Majority of the population subject to genome sequencing at birth. |

Timeframes should be viewed as a guide only.

### Enabling science and technology

Data aggregation, storage, handling, security and analytics present key technical challenges that need to be addressed to enable this opportunity. The computing resources and data storage required just to handle complex data will be enormous, and increase significantly when accessibility to the diagnostic platforms that generate the data is increased. For example, the data-storage demands for a single genome is 30 times larger than the size of the genome itself, accounting for errors incurred during sequencing and preliminary analysis.[127] The information systems needed to effectively integrate health data from MTP ecosystem via novel service models also need to overcome a number of technical barriers, not least of which is cybersecurity and assurance of patient anonymity through the process.

The computing resources and data storage required just to handle complex data will be enormous, and increase significantly when accessibility to the diagnostic platforms that generate the data is increased.

The list below provides an overview of some of the enabling science and technology required to make this opportunity a reality. See Appendix A.2.3 for an expanded list.

## FUTURE RESEARCH PRIORITIES

### Data analysis and digital integration

- Solutions for secure electronic health records and knowledge datasets enabled by dynamic de-identification systems, cybersecurity and data interoperability solutions.
- Development of improved high performance computing technology to enable smarter bioinformatics tools, allowing clinicians to effectively use collected data and develop actionable insights to improve the outcomes, efficiency and cost-effectiveness of healthcare processes.

### Instrumentation and tools

- Development and improvement of point-of-care testing platforms, biomarkers for companion diagnostics, improved medical imaging technologies, and bioinformatics platforms.

### Focused clinical research

- Rare and complex diseases, degenerative and age related disorders, and areas of high-public interest, such as emerging infectious diseases, anti-microbial resistance and potential pandemic outbreaks.

127 Hayden, E.C., (2015). *Genome researchers raise alarm over big data,* Nature News.

# Enabling
## sector change

# 5 Enabling sector change

## The growth opportunities discussed in this report indicate a bright future for the Australian MTP sector, however, the sector must act quickly or risk losing its place in the global market.

By leveraging Australia's comparative advantages, businesses will be able to unlock growth opportunities and position the Australian MTP sector for growth over the coming decades. However, businesses cannot achieve this in isolation and will require support from the entire ecosystem.

This chapter discusses common change themes that appear across each opportunity, and suggested short-term actions required to enable change. Actions have been separated into business actions (those which businesses in the MTP industry should proactively lead) and ecosystem actions (those to be led by industry bodies, research, education, investors and governments, in consultation with businesses). The industry growth centre, MTPConnect, has identified seven growth priorities that will underpin short and medium term ecosystem changes to maximise the sector's competitiveness and long-term sustainability; short-term sector sustainability is critical for capturing the longer-term opportunities outlined in this Roadmap. Taking direct action in-line with these priorities, MTPConnect have established a project fund program. In late 2016, 14 projects were supported covering everything from skills gaps to infrastructure development. Table 3 demonstrates the strong alignment between each MTPConnect growth priority and the four industry opportunities.

**TABLE 3: MTPCONNECT SECTOR GROWTH PRIORITIES ALIGNMENT MATRIX**

| MTPCONNECT SECTOR GROWTH PRIORITIES (MTPConnect MedTech and Pharma Growth Centre) | INDUSTRY OPPORTUNITIES FOR GROWTH | | | |
|---|---|---|---|---|
| | Smart devices, implants and bionics | Accelerated pharmaceutical development | Manufacturing high-value pharmaceuticals | Diagnostics and informatics products and services |
| 1 – Identify and invest in Knowledge Priorities focused on current and future market needs | ✓ | ✓ | ✓ | ✓ |
| 2 – Create a highly productive commercialisation environment from research to early clinical trials and proof-of-concept | ✓ | ✓ | | |
| 3 – Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies | ✓ | | ✓ | ✓ |
| 4 – Strengthen Australia as an attractive clinical trial research destination | | ✓ | | |
| 5 – Support the development of digitally enabled MTP solutions: devices and data analytics | ✓ | | | ✓ |
| 6 – Position Australia as the preferred partner for emerging Asian markets | ✓ | ✓ | ✓ | ✓ |
| 7 – Support advanced manufacturing as a part of the Australian innovation ecosystem | ✓ | | ✓ | |

## 5.1 Digital infrastructure

A significant enabler for each sector opportunity is the improvement of Australia's digital infrastructure. Sector growth necessitates a coordinated effort in connecting, securing, storing and standardising medical research and patient data to transform Australia's MTP sector. Improved infrastructure will facilitate the development, testing, and commercialisation of digitally enabled MTP solutions.

Recognising the crucial need for improved digital health infrastructure, the Australian Government's Australian Digital Health Agency (the Agency) commenced operations in 2016, tasked with improving health outcomes through the delivery of digital healthcare systems and the national digital health strategy.[128]

A key piece of digital health infrastructure that will have a profound effect on this industry is a national electronic health records system. The My Health Record system is a core component of the national digital health system, with over 4.2 million Australians registered for a My Health Record.[129] The My Health Record contain the following types of information: health summaries, event and discharge summaries, medication records, eReferrals and specialist letters.[130]

Sector growth necessitates a coordinated effort in connecting, securing, storing and standardising medical research and patient data to transform Australia's MTP sector.

Importantly, infrastructure needs to be put into place around these electronic records to enable de-identified data to be used to inform medical research, derive efficiency insights, and foster industry growth, in addition to improving patient care. This will require sector strategies that consider privacy-preserving analytics, advanced cybersecurity solutions and best practice management of social licence in the collection and use of data. As patient data becomes available from varied sources, electronic health records will need to accommodate increasingly larger data sets, especially genomic data.

As improved digital infrastructure is developed, digital literacy and specialised skills will become increasingly important to ensure the sector is prepared to adopt and realise benefits from emerging technologies. A number of Australian entities are investigating how to implement digital strategies required to leverage medical research and patient data for the development of digital MTP solutions, including Data61, the Australian e-Health Research Centre, AusBiotech via the Digital Health Advisory Group, and the Murdoch Children's Research Institute via the National Digital Health Initiative.

128 Australian Government, Australian Digital Health Agency website, *About the Agency,* [Online] Available from: https://www.digitalhealth.gov.au/about-the-agency Accessed 19/12/2016.

129 Australian Government, Australian Digital Health Agency (2016). *Your health. Your say. Shaping the future of health and care together. Discussion Paper.*

130 Australian Government, Australian Digital Health Agency website, *My Health Record system and Healthcare Identifiers (HI),* [Online] Available from: https://www.digitalhealth.gov.au/get-started-with-digital-health/what-is-digital-health/features-of-the-my-health-record-system/my-health-record-system-healthcare-identifiers Accessed 19/12/2016.

TABLE 4: BUSINESS AND ECOSYSTEM ACTIONS – DIGITAL INFRASTRUCTURE

| BUSINESS ACTIONS | ECOSYSTEM ACTIONS |
|---|---|
| **Digital strategy** – assess business plans for the inclusion of a digital strategy and consider data integration with the MTP ecosystem.<br><br>**Social licence** – maintain social licence through enhancement of data safeguards, transparency and effective management of risk.<br><br>**Data collection** – design or retrofit products and services to collect valuable data that can be used to gain insights, improve products or provide a service of value.<br><br>**Digital literacy** – actively improve digital literacy skills in business workforce.<br><br>**Infrastructure** – improve digital infrastructure within business, ensuring appropriate cybersecurity safeguards are in place. | **Health records** – improve the penetration, functionality and usability of national electronic health records.<br><br>**Infrastructure** – improve internet speeds and capacity in Australia, especially rural areas.<br><br>**Standards and interoperability** – conduct an assessment to identify the requirements for standardising data collection (ensuring informed consent and quality control), sharing (ensuring it is secure, ethical, traceable, private and legal), and data use (ensuring privacy and integrity).<br><br>**Cybersecurity** – develop systems to prevent unintentional and intentional cybersecurity breaches such as malicious attack, information leakages and accidental data manipulation (i.e. adding, modifying or deleting information). |

**Aligned MTPConnect Growth Priorities**

- Identify and invest in (*digital*) Knowledge Priorities focused on current and future market needs.
- Support the development of digitally enabled MTP solutions: devices and data analytics.

## 5.2 Regulatory system and market access

While medical technology and pharmaceutical regulation in Australia is responsible for maintaining high standards, it can also be confusing, slow and costly for companies to navigate and can limit new technologies access to markets. Developments in personalised medical technology and digitally driven MTP solutions are at risk of being lost to countries with more agile systems. Modernisation in Australia's regulatory practices will facilitate competitive growth of opportunities outlined in this Roadmap, and catalyse the creation of ancillary services such as electronic health knowledge sharing and new digital applications.

Sector consultations raised the proposition for an Australian-based assessment of a new regulatory model based on emerging trends in the global financial technology industry. This trend involves creating a regulatory sandbox (see case study), a basic regulatory system that mirrors the essential features of the operational regulatory environment without the complexity, formality and cost. The development of a regulatory sandbox or similar reform of regulatory processes to address the complexity of regulatory approvals would serve to place the Australian MTP sector in a globally competitive position to exploit emerging opportunities, however, would obviously require limitations in scope.

Tightly linked to international regulatory approval is access to global value chains and international markets; an important factor for the success of Australia's MTP sector. Increased global confidence in Australia's MTP solutions will be developed through continual demonstration of the safety, quality and agility of Australia's regulatory system, and its close alignment with the essential requirements of critical international regulatory bodies.

Access to international markets will be driven by companies banding together to form collaborative cohorts and leveraging established Australian companies, or partnering and licensing with international firms. Either approach is strengthened by collaboration with complementary businesses, and by leveraging trade and brand initiatives already in place by organisations such as Austrade, AusBiotech and MTPConnect.

**TABLE 5: BUSINESS AND ECOSYSTEM ACTIONS – REGULATORY SYSTEM AND MARKET ACCESS**

| BUSINESS ACTIONS | ECOSYSTEM ACTIONS |
|---|---|
| **Regulatory intermediaries** – engage consultants to help navigate the regulatory pathway if required.<br><br>**Build experienced teams** – integrate staff with international regulatory know-how early in the development process.<br><br>**International access** – connect with industry bodies to develop an understanding of the international market requirements and how to effectively leverage existing programs.<br><br>**Collaborative research** – utilise existing funding schemes to access basic research and early development (refer to Appendix A3). | **Regulatory agility –** address uncertainties regarding reimbursement of bespoke implants and bionics.<br><br>**Regulatory Sandbox** – assess the feasibility of a Regulatory Sandbox for medical devices and digitally enabled MTP solutions.<br><br>**Enable collaboration with global companies** – create incentives to encourage global companies to establish an Australian presence.<br><br>**Strengthen brand Australia** – develop a unified marketing message for international leaders concerning Australia's strengths and ambition. |

**Aligned MTPConnect Growth Priorities**

- Strengthen Australia as an attractive clinical trial research destination.
- Position Australia as the preferred partner for emerging Asian markets.

**Case Study**

## ASIC Regulatory sandbox

In the financial technologies (FinTech) industry, a number of regulators globally are proposing to establish 'regulatory sandboxes' to help enable innovation, including the UK, Singapore, Hong Kong, Malaysia, Indonesia, Thailand and Australia.[131] While there are significant differences between the FinTech and MTP sectors, there are numerous similarities; of particular relevance are the social expectations regarding customer/patient privacy which underpin cross-sector goals concerning data security, integrity and interoperability.

To enable innovation, the sandbox model provides a faster path to market for inventive companies (especially start-ups) by allowing them to test and develop products in a restricted environment, lowering the risk of failure that can be caused by complex regulatory frameworks during the product development phase. Australia seeks to be a leader in FinTech and is currently building on existing initiatives from the Australian Securities and Investments Commission to implement a limited industry-wide licensing exemption to allow start-ups to test certain financial services for six months, provided they comply with a limited range of requirements (the 'regulatory sandbox' exemption).[132]

In the context of MTP solutions, the goal of a sandbox is to allow developers to test and optimise digitally driven products and services before embarking on the more complex, time-consuming and expensive regulatory approvals process. It is recognised that this is an unrealistic model for pharmaceutical products where extensive safety studies must be completed prior to efficacy studies, but if structured correctly it may provide the correct framework to allow for rapid development cycles of solutions that are inherently safe, such as data capturing devices. Many of these types of technologies currently fall in a grey area for regulation and are sold direct to the consumer without any efficacy requirements; demonstrating how to efficiently move these products and services to a regulated environment could help establish Australia as a preferred development destination.

131 Gnirch, M., (2016). *Asian Fintech Sandboxes -- Can They Work And Do We Need Them?* Forbes, [Online] Available from: http://www.forbes.com/sites/gnirckmarkus/2016/09/27/asian-fintech-sandboxes-can-they-work-and-do-we-need-them/#56bb3b472e32 Accessed 19/12/2016.

132 ASIC website (2016). *16-185MR ASIC consults on a regulatory sandbox licensing exemption,* [Online] Available from: http://asic.gov.au/about-asic/media-centre/find-a-media-release/2016-releases/16-185mr-asic-consults-on-a-regulatory-sandbox-licensing-exemption/ Accessed 19/12/2016.

## 5.3 Sector structure, skills and culture

Each opportunity detailed in this report requires the dedicated development of specific skills in the workforce. The MTP sector relies on strong research skills across the STEMM fields, and draws upon skills from a variety of other disciplines, including business and commerce, law, nursing and industrial design. Future workforce planning and skilling will also need to consider the effects of digital technologies on the workforce, as well as skills for key service industries to the MTP sector, such as clinical trials, contract research organisations, and pre-clinical services. MTPConnect has identified a number of skills gaps in the sector including:[133]

- Enabling disciplines such as bioinformatics, biomedical engineering, health economics, regulatory affairs, and data analytics.
- Advanced manufacturing specific to the MTP sector (re-skilling and redeploy Australia's existing underutilised manufacturing workforce is an opportunity).
- Business acumen and commercialisation skills (particularly in researcher-founded start-ups).

Developing, attracting and retaining STEMM research talent is critical to success in this sector, as it provides the ideas pipeline of inventive concepts that can be translated into valuable MTP solutions. Given the importance of researchers in the pipeline of the MTP sector, the decline in the number of full-time researchers in Australia since 2012 has raised concerns over the erosion of Australia's health and medical research workforce.[134]

Collaboration, both research-to-industry and business-to-business, is recognised as an important factor for innovation, especially in the MTP sector where SMEs are often spun out from universities or other public sector research organisations. With Australia's level of research collaboration between research sector and industry amongst the lowest in the OECD,[135] collaboration is recognised as a key weakness of the Australian innovation system.

A key cause is the lack of understanding that business and research have of each other; businesses lack understanding on how to effectively engage with researchers, and researchers lack business exposure and appreciation/understanding of industry timeframes and commercial imperatives.[136] Networking and industry clusters are two mechanisms that can help improve both culture and collaboration in the MTP industry.

In combination with weak collaboration, Australia has historically lacked funding and investor interest for the translation of MTP solutions. Recent developments such as the $500 million Biomedical Translation Fund (BTF), the $200 million CSIRO Innovation Fund and the $20 billion Medical Research Future Fund (MRFF) include success metrics designed to overcome this problem.[137] [138] [139]

In combination with weak collaboration, Australia has historically lacked funding and investor interest for the translation of MTP solutions.

In addition, there is a responsibility for the MTP community to educate and show the value to the Australian investment community of investment in MTP product and service development. Australia is home to one of the largest stock markets in the world by market capitalisation, however there is poor representation of MTP companies in the ASX200; excluding CSL, less than 2% is derived from MTP businesses.[140] The innovation and translation funds must be complemented by investor activity to see real growth in the sector. There has been as increase in the number of incubators and investors, with companies such as Bluechilli or Cicada Innovations providing access to funding as well as product development expertise, and advice and support, to build a sustainable business. These incubators offer increased access to funding for the sector.

133 L.E.K. Consulting Pty Ltd (2016). *Medical Technology, Biotechnology and Pharmaceutical Sector Competitiveness Plan*, MTPConnect, Clayton.
134 Deloitte Access Economics (2016). *Australia's health and medical research workforce: Expert people providing exceptional*, Deloitte, Canberra.
135 Joint Select Committee on Trade and Investment Growth (2016). *Inquiry into Australia's Future in Research and Innovation 2016,* Commonwealth of Australia, Canberra.
136 NSW Business Chamber (2014). *Industry Research Collaboration - Discussion Paper,* North Sydney.
137 Australian Government (2016). *Australian Medical Research and Innovation Strategy 2016-2021.*
138 Australian Government, National Innovation & Science Agenda website (2016). *Biomedical Translation Fund to commercialise promising discoveries*, [Online] Available from: http://www.innovation.gov.au/page/biomedical-translation-fund Accessed 19/12/2016.
139 Australian Government, National Innovation & Science Agenda website (2016). *CSIRO Innovation Fund to commercialise early stage innovations*, [Online] Available from: http://www.innovation.gov.au/page/csiro-innovation-fund Accessed 19/12/2016.
140 *ASX 200 List* (June 2016). [Online] Available from: http://www.asx200list.com/ Accessed 19/12/2016.

TABLE 6: BUSINESS AND ECOSYSTEM ACTIONS – INDUSTRY WORKFORCE AND SKILLS

| BUSINESS ACTIONS | ECOSYSTEM ACTIONS |
|---|---|
| **Invest in upskilling** – develop structured professional development programs to upskill staff in key required areas.<br><br>**Graduate or intern programs** – help provide clear pathways for the attraction and retention of graduates.<br><br>**Digital literacy** – improve digital literacy skills to enhance absorptive capacity of business.<br><br>**Management skills –** improve business acumen, including negotiation skills, commercial assessment, and investor pitching.<br><br>**Attend networking events** – networking events provide exposure to potential collaborators, novel ideas, and new information.<br><br>**Bring researchers into business** – bring researchers into businesses to improve transfer of knowledge outside universities.<br><br>**Funding access** – explore and understand the various opportunities that support and accelerate product development. | **Skills development in tertiary education** – improve tertiary STEMM graduates skills in/knowledge of: commercialisation, regulation and advanced manufacturing (including pharmaceuticals).<br><br>**New skills for healthcare workforce** – foster improved digital and genomic literacy in healthcare workforce.<br><br>**Workforce planning** – to ensure the right skills are being nurtured now to support the growth of a competitive industry.<br><br>**Develop industry clusters** – support the co-location of businesses, research institutes and education providers.<br><br>**Industry meets academia** – incentivise research institutes to employ a higher proportion of experienced industry professionals and provide mentorships.<br><br>**Investor education** – encourage interest from the Australian investment community into the MTP sector, marketing the incentives in place to assist research translation. |

**Aligned MTPConnect Growth Priorities**

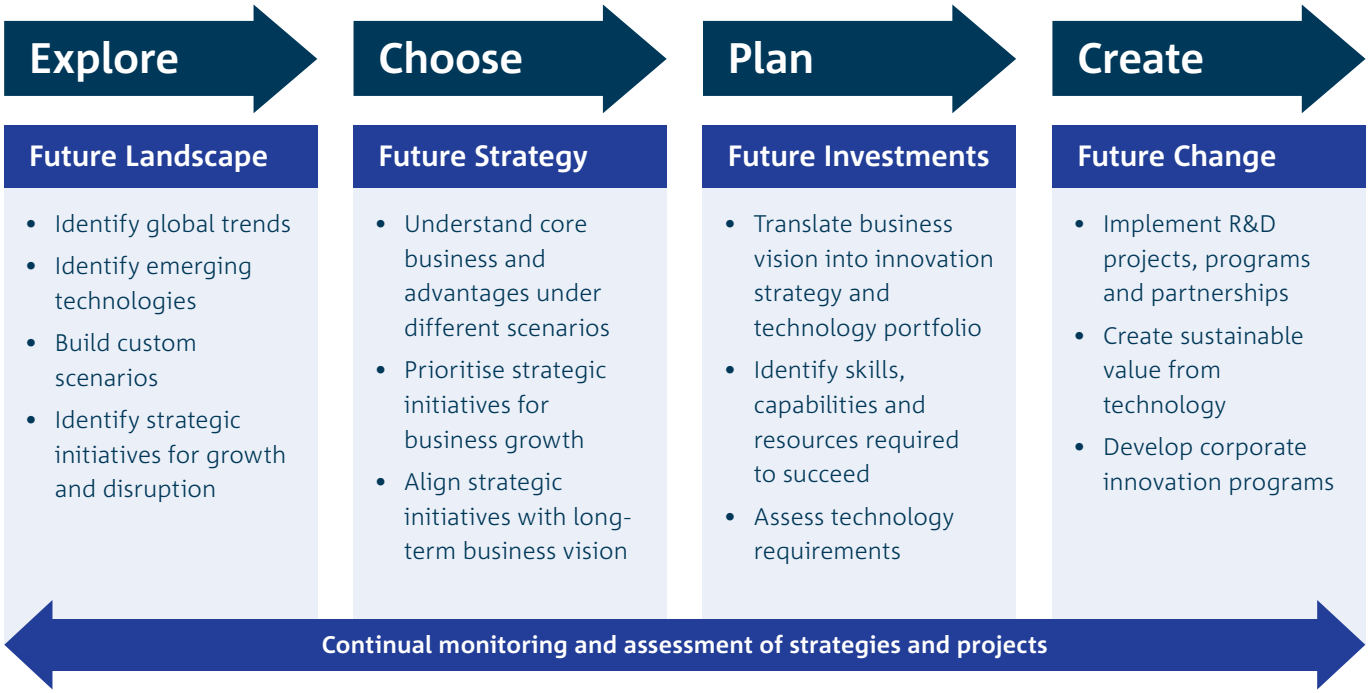
- Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies.
- Create a highly productive commercialisation environment from research to early clinical trials and proof-of-concept.
- Support advanced manufacturing as a part of the Australian innovation ecosystem.

## 5.4 Strategic planning

To realise growth opportunities, the enabling business actions and changes discussed in this chapter need to be key components of individual business strategies. Navigating long-term change requires MTP businesses to constantly assess the way they run their businesses – ensuring that scarce resources are appropriately allocated and that business decisions are underpinned with strong underlying market and technology assumptions.

This roadmap can be used as a tool to inform strategic decision making within MTP businesses. Global megatrends, opportunities for growth, and enabling science, technology and business changes can be tailored for specific business needs using the Explore, Choose and Plan steps of the framework depicted in Figure 24. Scenario planning and input for the Create step have been excluded from this report as application is highly company specific, however additional information can be found in CSIRO's Australia 2030 report.

**FIGURE 24: CSIRO FUTURES STRATEGIC PLANNING FRAMEWORK**




PERK
01
02
03
04
05
06
07
08
09
10

# The road forward

# 6 The road forward

## A number of changes are needed to help transform Australia's MTP sector to achieve the vision for the future and pursue the opportunites for sector growth.

For Australia's MTP sector to be globally competitive, it is critical that the right kind of environment is supported to allow for the translation of inventive MTP ideas into innovative solutions; one that encourages strategic and cross-disciplinary research, collaborative business partnerships, efficient development timeframes, agile and reputable regulatory frameworks, and appropriate investment incentives.

Building on these enabling sector changes, the four long term growth opportunities highlighted in this report aim to improve Australia's competitiveness within the global MTP sector. The road forward to capitalising on these opportunities and realising industry growth begins with the common change themes discussed in this chapter. The following table summarises the key themes to help enable MTP sector change.

**TABLE 7: ENABLING CHANGES SUMMARY**

| Digital infrastructure | Regulatory system and market access | Sector structure, skills and culture |
|---|---|---|
| **BUSINESS ACTIONS** | | |
| **Digital strategy** – assess business plans for inclusion of a digital strategy and consider data integration with the MTP ecosystem.<br><br>**Data collection** – design or retrofit products and services to collect valuable data that can be used to gain insights, improve products or provide a service of value.<br><br>**Infrastructure** – improve digital infrastructure within business, ensuring appropriate cybersecurity safeguards are in place. | **Regulatory knowledge –** employ staff with international regulatory know-how or engage regulatory consultants, early in the development process.<br><br>**International access** – connect with industry bodies to develop an understanding of the international market requirements. | **Invest in upskilling and management skills** – develop structured professional development programs to upskill staff in key required areas, and improve business operations by employing international experts.<br><br>**Graduate or intern programs** –provide clear pathways for the development, attraction and retention of graduates.<br><br>**Bring researchers into business** – employ researchers to improve transfer of knowledge outside universities. |
| **ECOSYSTEM ACTIONS** | | |
| **Health records** – improve the penetration, functionality and usability of national electronic health records.<br><br>**Standards and interoperability** – conduct an assessment to identify the requirements for standardising data collection, sharing and application.<br><br>**Infrastructure and cybersecurity** – improve internet speeds and capacity in Australia, and develop systems to prevent unintentional and intentional cybersecurity breaches. | **Regulatory agility** – address uncertainties regarding reimbursement of bespoke implants and bionics.<br><br>**Regulatory Sandbox** – assess the feasibility of a Regulatory Sandbox (see Section 5.2) for medical devices and digitally enabled MTP solutions.<br><br>**International branding and collaboration** – develop a unified international marketing message, and incentivise companies to establish an Australian presence. | **Skills development in tertiary education** – improve commercialisation, regulation and manufacturing skills for STEMM graduates.<br><br>**Workforce planning** – to ensure the skills required to efficiently translate MTP technology are being nurtured, and that they are in-line with global demands.<br><br>**Industry meets academia** – incentivise research institutes to employ a higher proportion of experienced industry professionals and provide mentorship programs. |

Developments in enabling science and technology will be pivotal to growth in this sector. Perhaps more than any sector, novel solutions to global MTP demands are underpinned by convergence of disparate fields of science and technology. Convergence of technologies through innovative combinations will transform the sector and create new challenges for researchers, businesses and regulators. The key themes of these enabling technologies across the four growth opportunities are summarised in Table 8.

Convergence of technologies through innovative combinations will transform the sector and create new challenges for researchers, businesses and regulators.

**TABLE 8: ENABLING SCIENCE AND TECHNOLOGY – FUTURE RESEARCH PRIORITIES SUMMARY**

| Smart devices, implants and bionics | Accelerated pharmaceutical development | Manufacturing high-value pharmaceuticals | Diagnostics and informatics products and services |
|---|---|---|---|
| • Biocompatible materials<br>• Bionics and biosensors<br>• Bespoke and smart implants<br>• Data capture, analysis and communications | • Information and communications technologies<br>• Regulatory science<br>• Focused basic research | • Instrumentation and infrastructure<br>• Manufacturing and platform technologies | • Data analysis and digital integration<br>• Instrumentation and tools<br>• Focused clinical research |

# Appendix

# 7 Appendix

## A.1 Australia's competitive landscape

The Australian MTP sector is underpinned by a number of comparative advantages that will drive opportunities for growth in the sector over the next 20 years. These advantages and related disadvantages are detailed below.

### A.1.1 STRONG INTERNATIONAL REPUTATION FOR QUALITY

Australia has built a strong international reputation for its stringent regulatory systems, quality management and standards, helping to differentiate Australian research, services and manufactured products in a global marketplace. Globally, Australia was rated as the fourth most reputable country in the Reputation Institute's 2016 rankings, behind Sweden, Canada and Switzerland.[141]

In Australia, companies are required to gain approval from the TGA to manufacture and sell pharmaceutical agents and must adhere to Good Manufacturing Practice among other quality assurance frameworks. This has built a reputation for high quality, clean and safe production processes resulting in growing demand from Asia for Australian manufactured products, including pharmaceuticals.[142]

#### Related disadvantage

- **Small market and population** – While the output from Australia is highly rated, it is limited in quantity. In a sector as tightly regulated as MTP, any dip in the quality of output will rapidly harm the reputation of all Australian outputs. Australian quality standards across all industries within the sector must be upheld to the highest standards.

### A.1.2 DIVERSE CULTURE, SOCIAL-ECONOMIC STABILITY, AND UNIQUE LOCATION

Australia's social-economic stability and resilience, demonstrated by 25 years of uninterrupted annual growth, together with its well-regulated business environments and comparatively high access to resources provides beneficial supply chain security and a safe, low-risk environment for investment.[143] Australia's high living standards, culture, climate and lifestyle act as significant drawcards in attracting skilled people to Australia, with Melbourne named as the most liveable location in a 2015 survey of 140 global cities.[144]

With 28.2% of Australia's resident population born overseas,[145] Australia's MTP sector has access to a predominantly English speaking, ethnically diverse population – a valuable advantage for Australian clinical trials and the development of health and medical data sets. Similarly, the large proportion of Australian residents that have emigrated from Asia provides cultural familiarity for Australian market access into this region, adding to Australia's proximity advantage.

The MTP sector can uniquely leverage Australia's proximity to Asia to form partnerships with global companies. As many companies investigate market access into the region, Australia's location and its many existing cultural, business and academic links make it a great base and partner for development activities.

#### Related disadvantages

- **Complex federated model** – Australia's federated approach leads to different state policies and inter-state transactions that can promote competitive rather than collaborative behaviours, resulting in duplication of effort and spending.
- **Low global competitiveness** – Australia's highly stable environment may have cumulated in an inability to be agile, leading to uncompetitive international ranks for factors such as business sophistication, innovation, goods and labour market efficiency.[146]

141 Reputation Institute (2016). *2016 Country RepTrak – the most reputable countries in the world.*

142 Victorian Government, Department of Economic Development, Jobs, Transport & Resources (2016). *Medical Technologies and Pharmaceuticals Sector Strategy*, State of Victoria.

143 Australian Trade Commission (2016). *Why Australia Benchmark Report 2016,* Commonwealth of Australia.

144 The Economist Intelligence Unit Limited (2015). *A Summary of the Liveability Ranking and Overview.*

145 ABS Website (2016). *3412.0 - Migration, Australia, 2014-15*, [Online] Available from: http://www.abs.gov.au/AUSSTATS/abs@.nsf/allprimarymainfeatures/66CDB63F615CF0A2CA257C4400190026?opendocument Accessed 14/12/2016.

146 Schwab, K., (2016). *The Global Competitiveness Report 2016–2017,* World Economic Forum, Geneva.

### A.1.3 AN EQUITABLE HEALTHCARE SYSTEM

Australia's stability has led to high levels of healthcare accessibility for citizens through a well-developed national healthcare system (Medicare), providing high levels of baseline care. Private health insurance remains fair and ethical due to the guidelines established by the Private Healthcare Insurance Act,[147] resulting in 55% of Australian's covered by private insurance in 2012-13.[148] Access to prescription medicine is subsidised by the Pharmaceutical Benefits Scheme (PBS). The PBS decides which products will be reimbursed to the public.

This structure enables Australia's healthcare system to perform well on a global scale, ranked as the 6th most efficient healthcare system internationally in 2014 (based on life expectancy and cost of health care), above the UK, Canada and the US, with average life expectancy exceeding the OECD average by two years.[149] [150]
Much like Australia's broader stability, this helps to remove a variable when conducting clinical trials or collecting population data.

#### Related disadvantages

- **Complex federated model** – Australia's state based healthcare approach makes it difficult to create a cohesive national based cost containment strategy and integrated healthcare models.
- **Disperse rural and remote populations** – health statistics for Australia's remote and rural populations are less impressive than for urban dwellers, due in part to limited access to healthcare infrastructure. While this is an undesirable situation, these populations provide an ideal test-bed for remote MTP solutions.

### A.1.4 A STRONG RESEARCH COMMUNITY

Australia has a rich history in strong scientific research, home to a network of globally influential research organisations, universities and medical research institutes that are prolific in the production of high impact research.

**Australia produces approximately 3.8% of the world's medical research outputs (publications)[151] from an estimated 1.1% of global health research dollars.[152]**

**Australia's MTP research community is supported by $775 million in public spending on R&D, and $630 million of industry R&D spend.[153]**

**Medical Research Future Fund (MRFF) is a $20 billion vehicle for investment in health and medical research.[154]**

**Translation of MTP research is a key priority for 2017, supported by the launch of the $500 million biomedical translation fund (BTF).[155]**

147 Australian Government (2007). *Private Health Insurance Act 2007*, [Online] Available from: https://www.legislation.gov.au/Details/C2016C00911.
148 Australian Institute of Health and Welfare (2014). *Australia's health 2014 – Australia's health system.* [Online] Available from: http://www.aihw.gov.au/australias-health/2014/health-system Accessed 14/12/2016.
149 Bloomberg (2014). *Most Efficient Health Care 2014: Countries,* [Online] Available from: http://www.bloomberg.com/graphics/best-and-worst/#most-efficient-health-care-2014-countries Accessed 19/12/2016.
150 OECD (2016). *OECD Better Life Index, Australia,* [Online] Available from: http://www.oecdbetterlifeindex.org/countries/australia/ Accessed 19/12/2016.
151 Deloitte Access Economics (2016). *Australia's health and medical research workforce: Expert people providing exceptional*, Deloitte, Canberra.
152 Access Economics (2008). *Exceptional Returns The Value of Investing in Health R&D in Australia II,* Australian Society for Medical Research, Canberra.
153 L.E.K. Consulting Pty Ltd (2016). *Medical Technology, Biotechnology and Pharmaceutical Sector Competitiveness Plan*, MTPConnect, Clayton.
154 Australian Government (2016). *Australian Medical Research and Innovation Strategy 2016-2021.*
155 Australian Government, National Innovation & Science Agenda website (2016). *Biomedical Translation Fund to commercialise promising discoveries*, [Online] Available from: http://www.innovation.gov.au/page/biomedical-translation-fund Accessed 19/12/2016.

Analysis shows that of Australia's most influential research institutions, half of the top 22 organisations have concentrations in the categories of health and medicine, with the most notably recurrent areas in terms of impact being oncology, cardiovascular and diabetes research.[156]

Australia has demonstrated success across a number of research fields. An assessment of Australia's publication output indicates that Australian research ranks amongst the top 10 in the world for basic research in the following health and medical areas:[157]

- Human movement and sports science
- Ophthalmology and optometry
- Public health and health services
- Evolutionary biology
- Psychology
- Physiology
- Cognitive science
- Genetics
- Clinical sciences
- Medical microbiology
- Neurosciences
- Paediatrics and reproductive medicine
- Medical physiology
- Microbiology
- Medical biochemistry and metabolomics
- Cardiovascular medicine and haematology
- Immunology
- Nutrition and dietetics
- Oncology and carcinogenesis

Australia has demonstrated success across a number of research fields.

### Related disadvantages

- **Low rates of collaboration and translation of research** – Australia's industry is often disconnected, leading to low levels of collaboration between research organisations and industry.[158] This manifests itself in Australia's poor ability to translate world class research into innovative commercial outcomes despite its strong research community, with developing products often obtaining funding from international investors, resulting in lost value from the Australian sector. This is exacerbated by limited access to and interest from the Australian investment community.
- **Loss of key talent** – The total NHMRC workforce has decreased 16% over the three years to 2016,[159] and NHMRC success rates for medical research grants are declining, with only 13.73% of 2015 grant applications successful in getting funding.[160] This is creating career uncertainty that leads to Australian researchers leaving the research field or leaving Australia to seek a stable future.[161]

156 Thomson Reuters (2015). *Australian Research & Innovation, A whitepaper*.
157 Custom analysis from InCites Analytics by Thomson Reuters (2016).
158 Australian Government, Department of Education, Department of Industry (2014). *Boosting the commercial returns from research*.
159 Deloitte Access Economics (2016). *Australia's health and medical research workforce: Expert people providing exceptional*, Deloitte, Canberra.
160 NHMRC (2015). *2015 NHMRC Project Grant Outcomes Explanatory Guide,* [Online] Available from: https://www.nhmrc.gov.au/_files_nhmrc/file/grants/fellows/funded/attachment_3_2015_nhmrc_project_grant_outcomes_explanatory_guide_v3.pdf Accessed 19/12/2016.
161 ATSE (2014). *Research alliance calls for long-term vision to lock in prosperity*, [Online] Available from: http://www.atse.org.au/Documents/media-release/research-alliance-mr-23042014.pdf Accessed 19/12/2016.

### A.1.5 HIGHLY SKILLED AND EDUCATED WORKFORCE

The development of MTP solutions depends on a diverse, skilled and educated workforce. Australia is recognised globally for its highly educated workforce, which has been a traditional source of advantage to the sector. Australian tertiary level education rates have grown each year since 2001 and are now well above the OECD average.[162]

In the global landscape, Australia has competitive strengths in the access to and quality of its education system, ranked 9th globally for higher education and training.[163] As Australia moves to a knowledge-driven economy and as new technological advancements are realised in the MTP sector, jobs will change, becoming reliant on highly skilled employees with a significant focus on digital literacy.

In 2016, nearly **30% of Australians aged 20–64 held a bachelor degree or higher.**[164]

Australian tertiary level education rates have grown each year since 2001 and are now well above the OECD average.

#### Related disadvantages

- **Changing skills requirements –** In the healthcare system and the MTP industry, changing requirements for workforce skills will place pressure on tertiary education institutions into the future. For example, Australia's aged care system is experiencing rapid growth due to an ageing population, with demand for skilled aged care staff expected to quadruple by 2050.[165]
- **Specialist skills shortages –** a 2012 study identified that Australia will face a shortage of 3,800 GPs, 366 radiologists, 142 obstetricians and gynaecologists, and 182 ophthalmologists by 2025,[166] which would reduce Australia's capacity to develop clinically driven MTP solutions and conduct clinical trials.
- **Lack of sector specific management skills –** Professionals with the appropriate mix of commercial acumen and MTP product development experience are lacking in Australia, resulting in a shortfall of local candidates with the know-how to successfully create new ventures. Over half of the CEOs from the top 200 companies in the Australian Securities Exchange were born overseas.[167] While this indicates that there may be a lack of talent in Australia, it also emphasises the comparative advantage of Australia being an attractive destination based on lifestyle and stability.
- **Fewer researchers in businesses –** Compared to other similarly developed countries, Australia has fewer PhDs working in industry, with less than one in three Australian researchers working in private industry – the OECD average is 60%.[168] This leads to a lack of researchers with important business skills.
- **Lagging STEMM skills pipeline –** the pipeline of STEMM skills into the national workforce is low compared to similar economies, with a declining rate of STEMM-related course completions.[169] This lowers the availability of suitably skilled workforce for the MTP sector.

162 OECD (2016). *Education at a Glance 2016: OECD Indicators*, OECD Publishing, Paris.
163 Schwab, K., (2016). *The Global Competitiveness Report 2016–2017,* World Economic Forum, Geneva.
164 ABS (2016). *6227.0 - Education and Work, Table 27*, Canberra.
165 Arico, S., & Srinivasan, V., (2014). *Enabling Australia's Digital Future: cyber security trends and implications,* CSIRO Futures, Canberra.
166 Australian Medical Association website (2012). *Severe shortage of GPs and other specialists looms*, [Online] Available from: https://ama.com.au/ausmed/severe-shortage-gps-and-other-specialists-looms Accessed 20/12/2016.
167 Market Index website, [Online] Available from: http://www.marketindex.com.au/asx200 Accessed 19/12/2016.
168 NHMRC website (2015). *Health and medical researchers for the future - what does Australia need?* [Online] Available from: https://www.nhmrc.gov.au/media/newsletters/ceo/2015/health-and-medical-researchers-future-what-does-australia-need Accessed 19/12/2016.
169 The Australian Industry Group (2015). *Progressing STEM Skills in Australia.*

### A.1.6 REPUTABLE NATIONAL REGULATORY AUTHORITY

Australia's National Regulatory Authority (NRA), the Therapeutic Goods Administration (TGA) is responsible for regulation of all therapeutic goods that are supplied in Australia, including medical devices and medicines. The TGA plays a critical role in protecting the Australian community by managing the registration of products for which therapeutic claims are made on the Australian Register of Therapeutic Goods (ARTG). The TGA has an excellent reputation both internationally and domestically and is widely respected for its work in ensuring the availability of high quality, safe and efficacious therapeutic products on the Australian market. Compared to NRAs in other countries, the TGA performs well in its regulation of medicines, however, performance in the regulation of devices is less notable, lacking timeliness and predictability.[170]

Recognised as a critical enabler for Australian clinical trials, the TGA offers a comparatively simple process for trial commencement which reduces the regulatory burden on clinical trial sponsors (see section A.1.7).[171]

#### Related disadvantages

- **Regulatory inefficiency** – a 2015 independent review of medicines and medical device regulation in Australia provided recommendations to improve the TGA, aiming to remove or streamline areas of unnecessary, duplicative or ineffective regulation, without undermining the safety or quality of therapeutic goods available in Australia.[172] Of the Review's 58 recommendations, 56 are supported by the Government and will be implemented in a staged approach over the next four years, supported by a $20 million reform fund. As reforms are implemented, Australia will stabilise its place a global leader for the development of regulatory efficiency.[173]

### A.1.7 QUALITY CLINICAL TRIALS

Australia has a strong ability to complete high quality clinical trials across numerous therapeutic areas (Figure 25), with particular strengths in oncology and cardiovascular disorders. Australia also has a strong and growing service industry for clinical trials with reputable contract research organisations helping differentiate Australia as a global destination for early stage trials. Australia's reputation for these early stage clinical trials is based on comparably high cost efficiency, regulatory speed, flexibility and quality,[174] as well as being the home to world leading key opinion leaders. As addressed in Section A.1.2, Australia also has comparative advantages in its access to an ethnically diverse, English speaking patient population; this is leveraged by operating many single-site trials using healthy and diverse volunteers, creating a key advantage. Seasonal differences between the Northern and Southern hemisphere allow trials dependent on seasonal factors to continue in Australia.

Australia is generally recognised as an expensive destination for trials, however this is balanced by other factors including data quality, timeliness of start-up and capacity to recruit.[175] However, while expensive compared to low cost economies – Australia is 28% cheaper before tax incentives and 60% cheaper after R&D tax incentives compared to US trials.[176]

Australia also has comparative advantages in its access to an ethnically diverse, English speaking patient population.

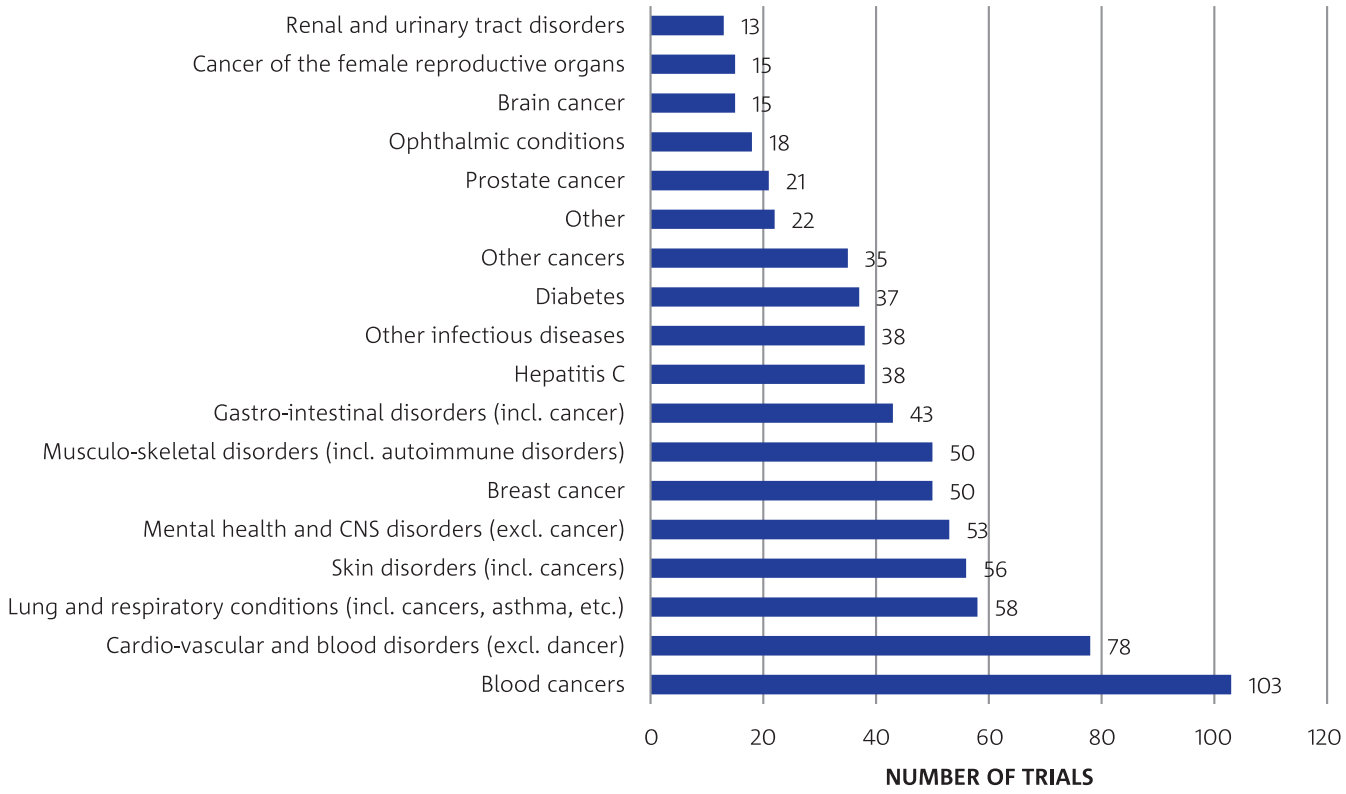
170 Sansom L., et al (2015). *Expert Panel Review of Medicines and Medical Devices Regulation.*
171 Frost & Sullivan (2016). *Australia: Preferred Destination for Early Phase Clinical Trials.*
172 Sansom L., et al (2015). *Expert Panel Review of Medicines and Medical Devices Regulation.*
173 Australian Government, Department of Health (2016). *Australian Government Response to the Review of Medicines and Medical Devices Regulation*, Commonwealth of Australia, Canberra.
174 Frost & Sullivan (2016). *Australia: Preferred Destination for Early Phase Clinical Trials.*
175 Health Outcomes International (2015). *Australian Government Department of Health Analysis of recently conducted clinical trials,* Australian Government, Department of Health.
176 Frost & Sullivan (2016). *Australia: Preferred Destination for Early Phase Clinical Trials.*

Australia's regulatory system has also been recognised as a key international drawcard for clinical trials, allowing flexibility without compromising quality. Clinical trials in Australia operate through either the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes. The CTX scheme is an approval process through the TGA, while the CTN scheme designates responsibility for trial approval to Human Research Ethics Committees (HREC), with the TGA simply notified. While the TGA has the authority to audit the management of a clinical trial, the CTN process eliminates duplications and avoids costly preparation of extensive regulatory applications, allowing clinical research to start much sooner, saving time and money. [177] [178]

## Related disadvantages

- **Slow start-up times for multi-site trials** – governance and ethics approvals specific to each site can be a lengthy and inconsistent process. Reviews show this requires multiple ethics submissions without a consistent framework, difficulties sourcing a lead site and in the worst case the exclusion of a site from the trial.[179]
- **Federated model** – many clinical trials will involve sites across different Australian cities, and will navigate state based hospital frameworks. On an international scale, attracting partners requires seamless collaboration. Internal complexities create unnecessary inefficiencies that hinder collaboration. In an effort to decrease clinical trial complexities, the Australian Government has recently invested $20 million in the improvement of the clinical trial environment, including multi-site trials.

**FIGURE 25: ACTIVE CLINICAL TRIALS/STUDIES IN AUSTRALIA, JULY 2014**




Active = Not Yet Recruiting + Recruiting + Recruiting By Invitation + Active, Not Recruiting
**Source: Medicines Australia**[180]

177 Frost & Sullivan (2016). *Australia: Preferred Destination for Early Phase Clinical Trials.*

178 Australian Government, Australian Clinical Trials Website, *Why conduct a clinical trial in Australia,* [Online] Available from: https://www.australianclinicaltrials.gov.au/why-conduct-clinical-trial-australia Accessed 04/10/2016.

179 Medicines Australia (2015). *Medicines Australia Facts Book, 4th Edition*, Canberra.

180 Health Outcomes International (2015). *Australian Government Department of Health Analysis of recently conducted clinical trials,* Australian Government, Department of Health.

### A.1.8 STRONG INTELLECTUAL PROPERTY (IP) PROTECTION

Australia's IP system is competitive, ranked 18th globally by the World Economic Forum in 2016 based on its capacity to protect inventions developed.[181] Companies commercialising medical technologies and pharmaceuticals rely on strong IP protection to recoup the expenses of development. Australian IP law is designed to encourage innovation and protect companies that develop original IP, providing them with a competitive advantage. The pharmaceutical sector benefits from other specific IP arrangements such as an extension of term, where further to the 20-year term applying to the majority of patents, pharmaceutical patents can qualify for an additional five years of protection.

#### Related disadvantages

- **Patents granted too readily** – While Australia's system is comparatively strong, a key issue is that Australia's patent system often grants exclusivity too easily, resulting in a proliferation of low-quality patents which can reduce follow-on innovations.[182] Australia can gain a comparative advantage by aligning its IP systems with areas of strategic importance, and by continuing to implement and review the IP Laws Amendment (Raising the Bar) Act.

### A.1.9 QUALITY INFRASTRUCTURE AND BUSINESS ENVIRONMENT

Australia has a transparent and well-regulated business environment. Businesses are incentivised to engage in Australian research and development through R&D tax incentives; these incentives are currently under review.[183] In a broader context, Australia has held AAA sovereign debt rating for over a decade and is one of the 20 largest stock exchanges in the world, which indicates a culturally pragmatic approach to economics that should be leveraged by the MTP sector.[184] [185]

Australia's research community and MTP industry is supported by internationally competitive scientific facilities, ranked 12th in the world for quality.[186] Research clusters, such as the Parkville precinct in Melbourne, encourage and enable development of the MTP sector. Initiatives under the Australian Government's National Innovation and Science Agenda are mapping the long term research infrastructure needs for Australia, ensuring Australia's research community will be continually advantaged through access to advanced infrastructure that assist in the translation of inventive MTP solutions. The 2016 National Research Infrastructure Roadmap (draft) identifies nine focus areas, a number of which align with the needs of the MTP sector, including: digital data and eResearch platforms; characterisation; advanced fabrication and manufacturing; biosecurity; complex biology; and therapeutic development.[187]

181 Schwab, K., (2016). *The Global Competitiveness Report 2016–2017,* World Economic Forum, Geneva.

182 Productivity Commission (2016). *Intellectual Property Arrangements, Inquiry Report No. 78*, Commonwealth of Australia, Canberra.

183 Ferris, B., Finkel, A., Fraser, J., (2016). *Review of the R&D Tax Incentive.*

184 Trading Economics website, [Online] Available from: http://www.tradingeconomics.com/australia/rating Accessed 19/12/2016.

185 The World Bank, Market capitalization of listed domestic companies (current US$), [Online] Available from: http://data.worldbank.org/indicator/CM.MKT.LCAP.CD?year_high_desc=true Accessed 19/12/2016.

186 World Economic Forum Website, *Competitiveness Rankings, 12.02 Quality of scientific research institutions,* [Online] Available from: http://reports.weforum.org/global-competitiveness-index/competitiveness-rankings/#series=EOSQ071 Accessed 19/12/2016.

187 Australian Government (2016). *Draft 2016 National Research Infrastructure Roadmap,* Canberra.

## Related disadvantages

- **Lagging digital infrastructure** –Australia lags behind global leaders such as Finland and Singapore in its overall environment for digital technology.[188] Progress to introduce national electronic health records has been slow[189] and digital infrastructure has significant differences between rural and urban areas, with some Australian communities digitally excluded and a large number of small, rural hospitals with no or minimal investment in IT. Australia's global ranking for internet speed (average peak connection speed) dropped from 30th to 56th between September 2013 and July 2016.[190] [191]
- **Funding gaps** – traditionally, there has been a lack of investor driven funding to bridge the gap between discovery research and clinical development, which results in poor translation of ideas to market (lack of incentives and funding for start-ups). Initiatives such as the new Biomedical Translation Fund aim to address this.[192] Assessment of ASX200 businesses show that by market capitalisation 5.4% relates to MTP, and removing CSL reduces this to less than 2%.[193]
- **Complex federated model** – competition between state based research groups often leads to duplication of research infrastructure that is not fully utilised, with limited coordination between funding bodies (national grant systems, philanthropic, state governments).
- **Comparatively high corporate tax rate** – countries such as Ireland and Singapore offer more attractive tax structures for large companies, which makes it financially disadvantageous for companies to expand operations in Australia.

188 Baller, S., Dutta, S., Lanvin, B., (2016). *The Global Information Technology Report 2016,* World Economic Forum and INSEAD, Geneva.
189 Productivity Commission (2015). *Efficiency in Health, Commission Research Paper*, Commonwealth of Australia, Canberra.
190 Akamai (2013). *Volume 6, Number 3 – The State of the Internet 3*rd *Quarter, 2013 Report,* Cambridge.
191 Akamai (2016). *Volume 9, Number 2* – Akamai's *State of the Internet Q2 2016 Report,* Cambridge.
192 Australian Government, National Innovation & Science Agenda website (2016). *Biomedical Translation Fund to commercialise promising discoveries*, [Online] Available from: http://www.innovation.gov.au/page/biomedical-translation-fund Accessed 19/12/2016.
193 *ASX 200 List* (June 2016). [Online] Available from: http://www.asx200list.com/ Accessed 19/12/2016.

# A.2 Future research priorities for industry growth opportunities

## A.2.1 FUTURE RESEARCH PRIORITIES – SMART DEVICES, IMPLANTS AND BIONICS

### Biocompatible materials

- Advanced, responsive materials that truly replicate inherent biological strength and form (e.g. implants for bone replacement should be constructed from material that truly replicates the 3D porous microstructure).
- Improved metallic biomaterials, such as porous metals and shape-memory alloys.
- Advanced polymers such as bioresorbable, biodegradable and responsive polymers.
- Advanced bioceramics that are bioinert, bioactive or biodegradable.
- Advances in biological stem-cell based biomaterials.
- Development of synthetic materials that mimic biological cells.
- Advanced materials for implantable batteries, including biodegradable batteries and materials that harness in situ materials (e.g. glucose) for power.
- Advanced combination materials that exhibit the desirable traits of many biocompatible materials.

### Biosensors

- Improved reaction times, sensitivity and accuracy.
- Improved life span, durability and long term stability.
- Miniaturisation of biosensors for increased ability to embed within larger implants.
- New targets and improved parameters for biosensors.
- Convergence of biosensors with advanced materials will enable developments such as self-healing sensors and bioresorbable sensors.

### Bionics

- Advanced algorithms and software to allow greater flexibility in product design.
- Improved implantable and miniaturised wireless communication tools.
- Development and incorporation of real-time sensors to increase bionic functionality.
- Bionics that mimic the aesthetics of soft natural body parts.
- Development of effective energy harvesting technologies, battery minimisation and power improvement.
- Development of personalised neural electronics for bionics.
- Improved neuro-electronic interfacing to avoid neural degeneration and other biological stimulation constraints.
- Advances in methods and technologies used for body and electronic interfaces to stop neural degeneration.

### Bespoke implants

- Process improvement for metallic additive manufacturing to ensure predictable quality, consistency and performance of printed implants.
- Sterile additive manufacturing techniques.
- Additive manufacturing process improvements to enable printing of integrated dissimilar materials.
- Process improvements to enable/improve 3D bioprinting of organs, tissue and cartilage.

### Smart implants

- Enhanced wireless communications, controls and encapsulation technologies for implantable bioelectronics.
- Development of effective energy harvesting technologies for implants.
- Development of novel controllable, drug eluting implants.
- Integration of patient data with other ‘omics’ data to draw more informed insights.

### Data analysis and communications

- Improved platforms to capture data and develop insights from wearable and implantable devices.
- Tools to enable patients to track their own physiological responses using implanted sensors connected to personal devices.
- Advanced cybersecurity solutions for connected medical devices and implants.
- A secure national technology system for electronic health records.
- Depersonalisation of data and privacy preserving analytics for expert systems.
- Improvements in bioinformatics to enable tools allowing clinicians to effectively use collected data.
- Development of application program interfaces to allow systems to interact efficiently.

## A.2.2 FUTURE RESEARCH PRIORITIES – MANUFACTURING HIGH-VALUE PHARMACEUTICALS

### Instrumentation and infrastructure

- Development of advanced sophisticated analytical instruments, such as mass spectrometers with increased sensitivity, advanced high performance liquid chromatography (HPLC) and size exclusion column chromatography (SEC) for improved characterisation.
- Clever transport solutions to ensure stability and preserve products from reduction in potency. Examples include advances in lyophilisation – the process by which perishable materials such an active pharmaceutical ingredients, can be preserved by freeze drying.[194]
- Improved sterilisation techniques that preserve product properties, such as gamma sterilisation.

### Manufacturing and platform technologies[195]

- Improvements to usability and availability of platforms for QMS (Quality Management Systems, e.g. ISO13485) and GMP (Good Manufacturing Practice).
- Improved platforms to manufacture complex products in liquid and semi-solid dose formulations (nasal, nebulized, ophthalmic, otic, and topical), liquid formulations (vaccines and cytotoxics) and solid formulations (tablets and capsules) including sterile and non-sterile preparations.
- Development of process analytical technology (PAT) methods used to monitor and analyse the manufacturing and design process, ensuring quality.
- Development of novel antibody-drug conjugates (ADCs) or immunoconjugates, a combination of small molecules and biologics that supports efficient targeting of cancer cells.
- Novel antibodies for treatments, including nanobodies (single domain antibodies derived from camelids), chimeric antibodies (antibodies with a combination of mouse and human components), and bi-specific antibodies (two antibodies targeting different antigens).
- Introduction and refinement of green chemistry practices such as the use of natural enzymes and bio-based renewable chemicals.
- Development of continuous manufacturing systems for biologics.
- Improvement of mammalian cell culture platforms.

194 Frost & Sullivan (2016). *Global Pharmaceutical Contract Manufacturing Organization (CMO) Market,* Mountain View.
195 Frost & Sullivan (2016). *Analysis of the Global Biologics API Market,* Mountain View.

## A.2.3 FUTURE RESEARCH PRIORITIES – DIAGNOSTIC AND INFORMATICS PRODUCTS AND SERVICES

### Data analysis and digital integration

- Develop solutions for data interoperability.
- Model, study and implement appropriate technology for traceable, sharable, ethical and secure electronic health records for all Australians. Electronic records to facilitate integration of genomic and medical information for clinical and research applications.
- Advanced cybersecurity solutions for all data collection.
- Secure creation of knowledge datasets and databases that contain known genotype/phenotype correlations and genomic and clinical associations from large populations of individuals.[196]
- Dynamic de-identification systems and privacy preserving analysis for data, enabling development of expert systems that provide intelligence on clinical operations, disease and demographic relations, procedure outcomes, patient interaction, etc.[197]
- Development of bioinformatics tools allowing clinicians to effectively use collected data.
- Development of novel means to store data, helping address predicted data storage issues inherent with the large amounts of big data generated through genomic analysis.
- Adapt and optimise analysis algorithms to obtain intelligent and actionable insights to improve the outcomes, efficiency and cost-effectiveness of healthcare processes.
- Establish national and international knowledge sharing platforms using a standardised approach for recording, sharing and interrogating fully integrated clinical data, enabling deeper understanding of disease, precision therapeutic targeting and gene causality studies.[198] [199]
- Improve high performance computing technology output and tolerance.

### Instrumentation and tools

- Improve variability and reliability in sequencing and analysis interpretation.[200]
- Development of advanced proteomic technologies such as protein biochip arrays, antibody engineering systems, reverse phase protein microarrays and multiplex Enzyme Linked Immunosorbent Assay (ELISA).[201]
- Development and improvement of point-of-care testing platforms and biomarkers for companion diagnostics. E.g. platforms for genome sequencing and analysis allowing clinicians to have access to genotype information relevant to drug metabolism at the time of prescribing.
- Improved medical and diagnostic imaging technologies.
- Development of tools for bioinformatics and proteoinformatics, and improved transcriptome profiling and epigenome profiling.

### Clinical focus areas

- Rare and complex diseases that when solved will provide compelling case studies for how new diagnostic technologies and informatics platforms can provide novel MTP solutions.
- Areas of high-public interest, such as emerging infectious diseases, anti-microbial resistance and potential pandemic outbreaks, which provide platforms for public engagement.
- Degenerative and age related disorders where MTP solutions using diagnostic and informatics will have the most economic impact.

196 Mattick J., et al. (2014). *The impact of genomics on the future of medicine and health,* Medical Journal of Australia.
197 Frost & Sullivan (2015). *Management of health information - Trends and Innovation*, Mountain View.
198 Mattick J., et al. (2014). *The impact of genomics on the future of medicine and health,* Medical Journal of Australia.
199 Ashley, E.A., (2016). *Towards Precision Medicine,* Nature Reviews Genetics.
200 Frost & Sullivan (2015). *Global Clinical Next-generation Sequencing Market,* Mountain View.
201 Frost & Sullivan (2016). *Innovations in Global Proteomics Technologies Market,* Mountain View.

# A.3 Co-contributing funding schemes for Australian SMEs and start-ups

Many of the activities recommended in this report require investment in R&D. In addition to the R&D tax incentives available, the table below lists national and state-based funding schemes available to Australian SMEs and start-ups that support innovation and commercialisation.[202] A complete list of Federal grants is available on the Federal Government Business website.[203]

**TABLE 9: CO-CONTRIBUTING FUNDING SCHEMES FOR AUSTRALIAN SMES AND START-UPS**

| PROGRAM | | PROJECT | | |
|---|---|---|---|---|
| NAME | STATE | VALUE | SME CONTRIBUTION | ELIGIBILITY / NOTES |
| Innovation Connections | All | < $50k | 1:1 cash | $1.5m - $100m turnover, 3+ years in business. Grants available for researcher, business researcher and graduate placements. |
| CSIRO SIEF STEM+ Business | All | < $105k p.a. | 1:1 cash | $1m - $100m turnover. Projects delivered by early-career researchers. |
| Accelerating Commercialisation | All | < $1 mil | 1:1 | < $20m turnover. Funds commercialisation, not research and development. |
| ICon Proof of Technology grant | ACT | $5k-30k | 1:1 cash and/or in-kind | < $2m turnover. |
| ICon Accelerating Innovation grant | ACT | $5k-10k | 1:1 cash and/or in-kind | < $2m turnover. |
| TechVouchers | NSW | < $15k | 1:1 cash | < $30m turnover, < 20 employees, 1+ years in business. Preference for companies not previously engaged in research. |
| BISI Innovation Voucher | NT | < $25k | 40% | < 100 employees. |
| Knowledge Transfer Partnerships | QLD | < $50k | 1/3 cash | < 200 employees, 2+ years in business. Research performed by KTP eligible graduates. |
| Innovation Voucher program | SA | $10k -$50k | 1:2 or 1:1 | < $200m turnover, 1+ years in business. Contribution 1:2 for SMEs below $5m. |
| Business Transformation Voucher | SA | < $50k | 1:1 cash | 1+ years in business. Can include developing new business models or R&D. |
| BioSA Industry Development program | SA | $50k-250k repayable | | Early-stage/start-ups. Bioscience and related industry sectors. |
| SBDF Start-up business grant | SA | < $20k | 1:1 cash | To contribute to starting a new business or buying a business. |
| SBDF Business Expansion grant | SA | $10k-100k | 1:1 cash | < 20 employees, 1+ years in business. |
| Innovation Vouchers | WA | < $20k | At least 20% | < $500k turnover, < 200 employees. |
| Defence Materials Technology Centre – Medical Countermeasures Program | All | Variable | > 1:1 | Projects must be translational and in alignment with a Medical Countermeasures priority. Contribution from project participants must exceed DMTC funding. |
| MTPConnect – Project Fund Program | All | 100K-3M | 1:1 | Matched funding from a non-government consortium required. For example, if MTPConnect funds $600k and CSIRO $300k, the consortium must contribute $900k. There must be at least two businesses in each consortium. |

202 For more information on the funding schemes available to Australian SMEs and start-ups see CSIRO's SME Connect Program http://www.csiro.au/SMEConnect
203 For more information on Federal funding mechanisms see https://www.business.gov.au/assistance

## A.4 Further reading

The following reports provide deeper insights into some of the specific trends and concepts covered in this Roadmap:


1. Australian Government, Department of Health and Ageing (2013). *Strategic Review of Health and Medical Research in Australia – Better Health Through Research,* Commonwealth of Australia, Canberra.
2. Sansom L., et al (2015). *Expert Panel Review of Medicines and Medical Devices Regulation.*
3. AusBiotech (2016). *Biotechnology - Industry Position Survey 2016,* Melbourne.
4. Australian Trade Commission (2015). *Clinical Trials,* Commonwealth of Australia.
5. Jacoby R., et al (2016). *Winning with biosimilars: Opportunities in global markets*, Deloitte.
6. Productivity Commission (2016). *Data Availability and Use, Draft Report*, Commonwealth of Australia, Canberra.


### OTHER ROADMAPS IN THE CSIRO SERIES

This report is the second of a series of roadmaps being developed by CSIRO.

1. Advanced Manufacturing – A Roadmap for unlocking future growth opportunities for Australia.
2. Mining Equipment, Technology and Services – A Roadmap for unlocking future growth opportunities for Australia. *(In development)*
3. Food and Agribusiness – A Roadmap for unlocking future growth opportunities for Australia. *(In development)*
4. Oil and Gas – A Roadmap for unlocking future growth opportunities for Australia. *(In development)*

**CONTACT US**
**t** 1300 363 400
+61 3 9545 2176
**e** csiroenquiries@csiro.au
**w** www.csiro.au

**WE DO THE EXTRAORDINARY EVERY DAY**

We innovate for tomorrow and help improve today – for our customers, all Australians and the world.

Our innovations contribute billions of dollars to the Australian economy every year. As the largest patent holder in the nation, our vast wealth of intellectual property has led to more than 150 spin-off companies.

With more than 5,000 experts and a burning desire to get things done, we are Australia's catalyst for innovation.

**WE IMAGINE**
**WE COLLABORATE**
**WE INNOVATE**

**FOR FURTHER INFORMATION**

**Dr Keith McLean**
Director, CSIRO Manufacturing
**t** +61 3 9545 2599
**w** www.csiro.au/en/Research/MF

**Dr Rob Grenfell**
Director, CSIRO Health and Biosecurity
**t** +61 3 9662 7322
**w** www.csiro.au/en/Research/BF

**James Deverell**
Director, CSIRO Futures
**t** +61 2 9490 8456
**e** futures@csiro.au
**w** www.csiro.au/futures

**Simon Hanson**
Director, SME Connect
**t** +61 3 9545 2752
**w** www.csiro.au/SMEConnect

B&M | 16-00727