MTPConnect
MedTech and Pharma Growth Centre

MTPConnect REDI Initiative Skills Gap Analysis

Driving skills development and workforce training for the future MTP workforce

SECOND REPORT

MARCH 2021

MTPCONNECT.ORG.AU

REDI DEVELOPING AUSTRALIA'S MTP SECTOR WORKFORCE

Australian Government
Department of Industry, Science, Energy and Resources

Industry Growth Centres

Acknowledgments

MTPConnect would like to acknowledge the REDI Steering Committee, MTPConnect Board, AusBiotech, Medicines Australia, Medical Technology Association of Australia, and all sector stakeholders who provided their valuable inputs that have informed this report. A full list of stakeholders who contributed to the development of this report can be found in Appendix 1. MTPConnect also thanks SEEK for providing assistance with sector jobs analysis and L.E.K. Consulting for its assistance in preparing the document.

Funding declaration

The Researcher Exchange and Development within Industry (REDI) initiative is funded through the Australian Government's Medical Research Future Fund (MRFF).

Suggested citation

MTPConnect. (2021). *MTPConnect REDI Initiative Skills Gap Analysis Second Report*. mtpconnect.org.au

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

MTPConnect
MedTech and Pharma Growth Centre

Contents

Executive Summary

Australia's Medical Technology, biotechnology, and Pharmaceutical (MTP) sector has been among the most innovative contributors to the national economy. It contributed A$5.2 billion in Gross Value Added (GVA), A$8.2 billion worth of manufacturing exports and accounted for 68,000 jobs in 2019.

Australia competes in a global market and the upside growth potential is vast.

Innovations and technological advancements in areas such as precision medicine, digital health solutions and regenerative medicine supported by advanced manufacturing technologies present exciting growth opportunities.

The rate of adoption of innovation has been accelerated due to the COVID-19 pandemic, which has triggered widespread uptake in new products and services such as telehealth, remote monitoring products, e-prescriptions and genetic testing. In addition, the Australian Government's A$1.5 billion Modern Manufacturing Strategy (MMS), announced in the 2020–21 Budget, is aimed at developing and expanding onshore manufacturing capabilities to guard against trade, freight and supply chain disruptions associated with pandemics.

In order for Australia's MTP sector to continue its strong growth trajectory, the workforce will need to retain and evolve skills in current areas of competitive advantage, while also developing new skills that are aligned with these emerging areas.

The objective of the MTPConnect Researcher Exchange and Development within Industry (REDI) initiative is to ensure workforce skills are aligned to the current and future needs of the sector across the MTP sector value chain.

A comprehensive 'root and branch' analysis of the sector's workforce was carried out in the second half of 2020 to identify a broad set of skills gaps across the sector that need to be addressed to enable the Australian MTP sector to flourish.

The 20 priority skills gaps identified span seven key themes: advanced manufacturing and supply chain; business operations; clinical trials; health data and cybersecurity; health economics and regulatory affairs; product development and commercialisation; and specialist and technical skills.

The priority skills gaps identified are aligned with a number of key initiatives announced recently by the Australian Government such as the MMS, which has identified 'medical products' as a national manufacturing priority.

Summary of priority skills gaps

This report identifies three priority skills gaps within advanced manufacturing that are directly aligned to the MMS. Investment in these skills will help drive the growth of local advanced manufacturing capability and jobs within the MTP sector.

This report also identifies a balance of well-known priority skills gaps as well as emerging ones. Roughly half of the priority skills gaps are emerging and are driven by global megatrends shaping the sector, including precision medicine and digital health. Addressing well-known skills gaps, such as those identified in product development, commercialisation and clinical trials will allow Australia's MTP sector to realise immediate benefits while addressing emerging skills gaps that will position the sector to achieve future growth.

A number of the priority skills gaps identified are interlinked and co-dependent in nature. For example, addressing the shortage of experienced industry professionals with end-to-end commercialisation expertise (Skills gap #15) will help build capabilities in identifying unmet market needs (Skills gap #16) and securing funding, investment and/or industry collaboration. By addressing such priority skills gaps, the sector can expect an uplift of related skills, creating an amplified benefit.

Addressing these priority skills gaps is important to position Australia's MTP sector and its workforce for the next wave of innovation and growth. MTPConnect will be driving the development of bespoke solutions to address a range of priority skills gaps through the REDI initiative. However, broader stakeholder engagement, collaboration and action across the whole MTP sector value chain will be required to adequately address all the priority skills gaps identified. MTPConnect looks forward to working with the sector to guide the training and workforce development efforts in the coming years.

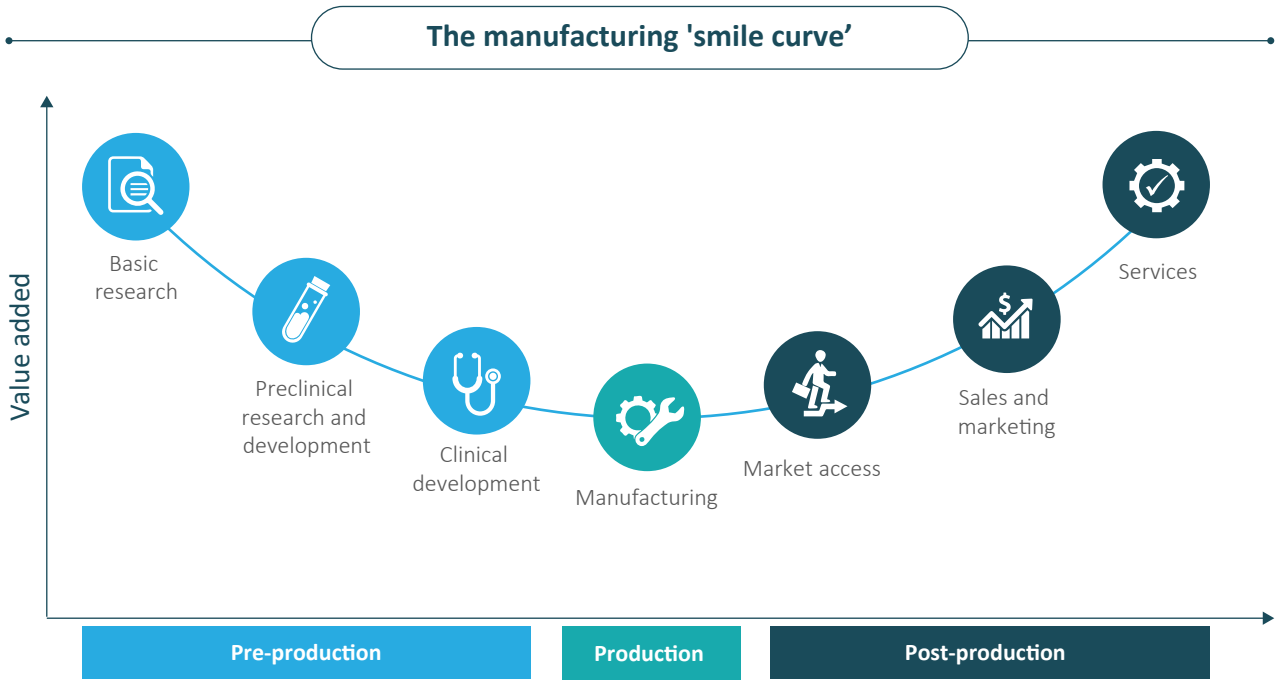
1. Introduction and Context

Context for this report

As Australia's growth centre for the MTP sector, MTPConnect is delivering the REDI initiative for the Medical Research Future Fund (MRFF).

The REDI initiative is focused on improving workforce skills and driving jobs growth across the MTP sector value chain, which includes research and development (R&D), preclinical and clinical development, production and manufacturing, logistics and distribution and product marketing, promotion and sales–all elements of the advanced medical products manufacturing ecosystem.

As shown in the 'manufacturing smiling curve' below[1], focusing on the two ends of the value chain–R&D/ design (left) and sales and marketing (right), as well as production–will deliver the biggest economic returns.



The REDI initiative's focus on developing an industry-ready MTP workforce across the pre-production, production and post-production phases of the advanced manufacturing cycle is underpinned by a thorough understanding of skills and workforce gaps.

REDI is delivering a 'root and branch' analysis of the sector's workforce; an essential step in preparing Australia's MTP workforce to meet future demands.

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

This is the second of three skills gap reports, with the first, an interim report, published in November 2020, identifying three skills gaps as near-term priorities for the sector, addressable within 12 to 18 months.[2]

- **Priority One:** Understanding of QMS and protocols
- **Priority Two:** Leadership awareness about the importance and best-practice management of cybersecurity
- **Priority Three:** Strategic design of clinical trials to meet regulatory and payer needs

This second report brings together findings from the interim report and identifies a broad set of skills gaps across the sector that need to be addressed to drive continued sector growth. These gaps are broader than what can be addressed through the REDI initiative directly and will help inform opportunities for other programs to be deployed.

In identifying the skills gaps, the report also considered additional elements: global megatrends that are shaping the sector over the long term, vision for the MTP sector and Sector Priorities, each of which are detailed in MTPConnect's 2020 Sector Competitiveness Plan.[3]

A third 'refresh' report will be delivered in late 2021.

Structure of the report

The findings of the skills gap analysis are structured around two main chapters in this report. Chapter 2 presents an overview of the methodology used to identify and prioritise the skills gaps across the sector, including key findings of the skills gaps review. Chapter 3 then provides a detailed characterisation of each of the priority skills gaps identified.

[2] MTPConnect, *REDI Program Skills Gap Analysis*, Interim Report, November 2020
[3] MTPConnect, Sector Competitiveness Plan, April 2020

2. Identification and Overview of the Skills Gaps

This chapter explores the skill themes, priority skills gaps, overarching findings of the skills gap analysis and the structural issues impacting the MTP sector skills gaps identified.

Overview of methodology

Skills gaps across the Australian MTP sector were identified through four main research activities, as illustrated in the figure below.

More than 200 MTP sector stakeholders spanning different segments of the MTP value chain were consulted through the project. The project also included an analysis of the workforce skills and capacity review undertaken by MTPConnect in July 2020, which surveyed 121 respondents with hiring responsibilities (such as managers and human resource personnel) from across the sector.[4]

In addition, an analysis of MTP sector jobs posted from 2017 to 2019 on the SEEK recruitment platform related to specific skills gaps has also been included in this report. The jobs posted data was kindly provided by SEEK for use in this report. SEEK's analysis was based on classifying job titles in advertisements from 2017 to 2019 according to relevant skills gap areas. Once classified, the growth in the number of job advertisements in each relevant skills gap area, the relative number of applications per role and relative growth in number of applications were also measured.[5]

Extensive desktop research was also conducted, including international case studies, where appropriate. The research and analysis tasks were completed over 16 weeks from August to December 2020. See Appendix 1 for details of the stakeholders consulted for this work.

Identifying skills themes across the sector

A total of 76 distinct skills gaps were identified across the sector and along the value chain through the methods described in the graphic above (see Appendix 2 for the complete list of skills gaps). These skills gaps were organised under seven themes: advanced manufacturing and supply chain; business operations; clinical trials; health data and cybersecurity; health economics and regulatory affairs;

[4] MTPConnect, *A Survey of Workforce Skills and Capacity in the MTP Sector*, October 2020

[5] This analysis was only performed for skills gap areas that had satisfactory data according to SEEK's internal data standards. The relative number of applications per MTP skills gap area was benchmarked against the overall average number of applications for all jobs (including those not specific to the MTP sector) on the SEEK platform

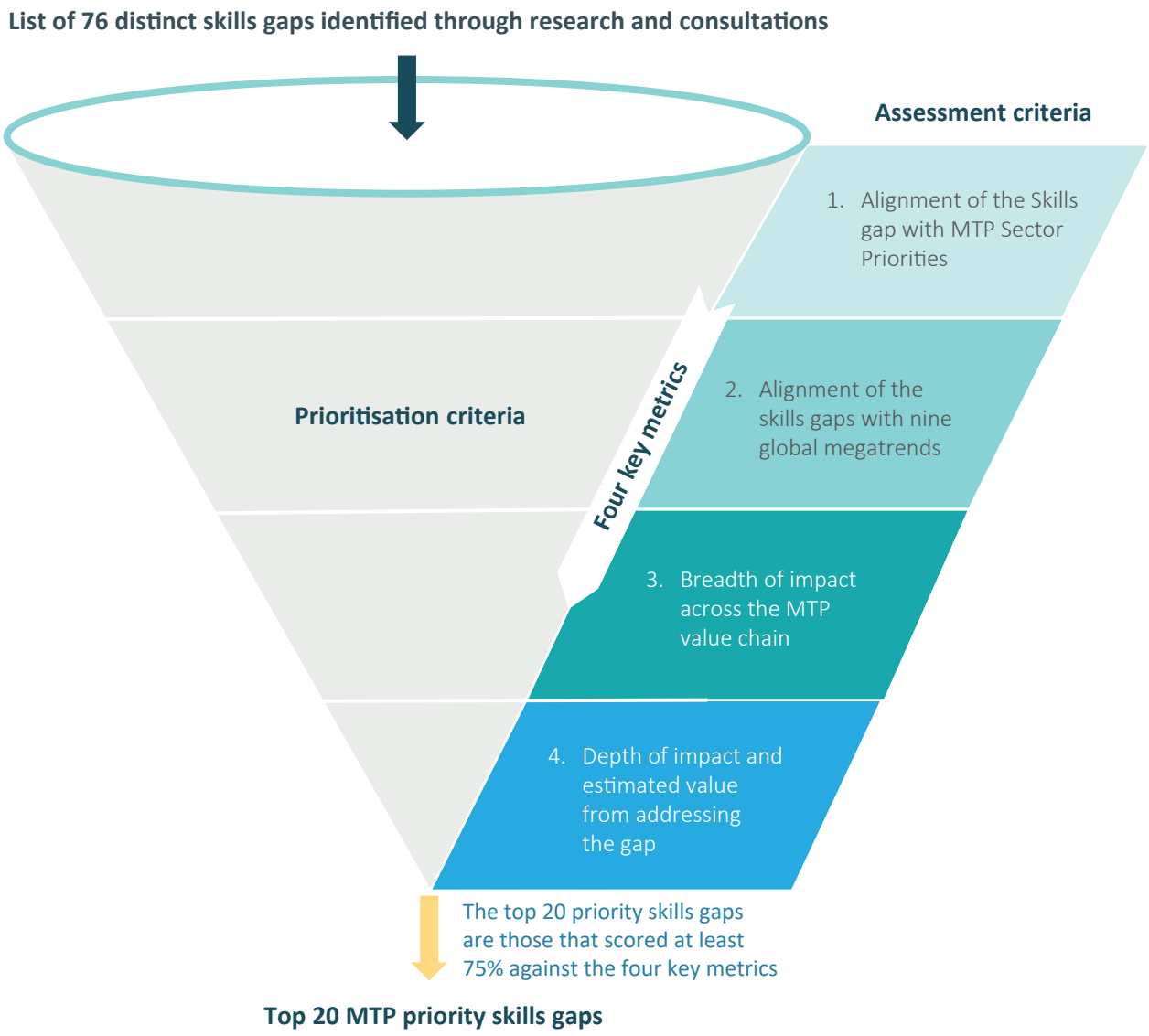
product development and commercialisation; and specialist and technical skills. These themes are described below:

Skill themes

Advanced manufacturing and supply chain	Skills in this area relate to the manufacturing, operations and logistics of MTP sector products such as high-value therapeutics, medical devices and digital health products. Examples of skills in this area include process engineering, expertise in developing and maintaining commercial scale cell lines and operating high-tech production equipment
Business operations	There are approximately 1,300 businesses within the sector. These businesses require a range of day-to-day business operations skills to support growth. Examples of skills in this area include project management, ability to write effective business plans and ability to comprehend financial statements
Clinical trials	Skills in this area relate to the creation and execution of clinical trials in Australia. Examples of skills in this area include ability to design clinical trials in line with regulatory and reimbursement requirements, ability to accurately collect trial data and communicate with investigators
Health data and cybersecurity	Skills in this area relate to the use of digital technologies and data to develop better medical devices, services and therapeutics for Australian consumers and patients. Examples of skills in this area include ability to design and use AI, expertise in big data and analytics and cybersecurity skills
Health economics and regulatory affairs	Skills in this area relate to a detailed understanding of regulatory and reimbursement processes required to bring a MTP product or service successfully to market. Examples of skills in this area include expertise in health economics modelling for reimbursement submissions and knowledge of regulatory requirements in Australia and key global markets such as the US
Product development and commercialisation	Skills required for successful product development and commercialisation are well-known to the sector. These include the ability to identify unmet market need, secure investment/funding from public and/or private funders and first-hand experience in taking MTP products and services from discovery to market
Specialist and technical skills	The MTP sector is highly specialised and is underpinned by a range of specialist and technical skills. Examples of skills in this area include expertise in medicinal chemistry, pharmacology and toxicology

Prioritising the 20 skills gaps

The list of priority skills gaps was identified by assessing each gap in the list (Appendix 2) against four key metrics outlined in the prioritisation framework below.



Further information on the scoring assessment can be found in Appendix 3.

Twenty skills gaps were identified as MTP priority skills gaps, i.e. they received a score greater than 75 percent when assessed against the four key metrics listed in the prioritisation framework. These priority skills gaps are outlined in the table below within each of the seven themes. Detailed descriptions of these priority skills gaps are provided in Chapter 3.

Description of priority skills gaps

Priority skills gaps

Advanced manufacturing and supply chain

1	Understanding of QMS and protocols	Capability gap in understanding and implementing quality assurance and control protocols, particularly relating to manufacturing of therapeutics and devices, including Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) guidelines and ISO standards. This also extends to quality control practices relating to data collection
2	Manufacturing expertise in high-tech and/or specialised medtech devices	Shortage of local expertise required for advanced medtech manufacturing (e.g. smart devices, implants and bionics), including process engineers, data and analytics experts and a GMP/GLP/GCP-certified workforce
3	Manufacturing expertise in high-value therapeutics at a commercial scale	Shortage of local expertise required for the manufacture of high-value pharmaceuticals (e.g. biologics and cell therapies) at a commercial scale. This includes a lack of process engineers and a GMP/GLP/GCP-certified workforce

Business operations

4	Shortage of MTP-specific project managers to support start-ups and spin-offs	Shortage of project management professionals who understand the product development pathway and are capable of managing new product development within early-stage MTP companies

Clinical trials

5	Strategic design of clinical trials to address regulatory and payer needs	Capability gap among SMEs in designing clinical trials for commercial success at the outset with understanding of regulatory and reimbursement approval requirements
6	Shortage of experienced Clinical Research Associates (CRAs)	Shortage of experienced CRAs, who are primarily responsible for monitoring clinical trials, including assuring compliance with protocol, documenting adverse events and protecting and verifying scientific integrity of data
7	Shortage of Clinical Trial Coordinators (CTCs)	Shortage of CTCs, who are responsible for day-to-day running of clinical trials at hospital sites, typically all the way from patient recruitment through to follow-up assessments

Priority skills gaps

Health data and cybersecurity

8	Leadership awareness about the value of best-practice management in cybersecurity	Capability gap among business leaders in MTP in understanding the importance of cybersecurity and best-practice management required to protect organisations from cyber attacks
9	Shortage of cybersecurity professionals and IT infrastructure resilience skills within MTP	Shortage of cybersecurity professionals who understand the tools, technologies, processes and practices that can be used to protect networks, computers and data across the MTP and healthcare sector from unauthorised access or attack
10	Understanding of and expertise in big data capture, management and analysis	Shortage of data scientists who can capture, curate and interpret large streams of (often unstructured) health data. This gap also extends to a lack of understanding among management around big data benefits and use cases, as well as a shortage of data 'influencers' who can demonstrate and communicate the value of analytics
11	Expertise in the design and use of AI within MTP	Capability gap in designing and using AI technologies for advanced MTP and healthcare applications (e.g. for diagnosis or decision-making). Skills gaps include understanding clinical workflow, complexities of working with healthcare data and associated regulations/legislations
12	Shortage of skills in health informatics	Shortage of health informatics specialists, whose field spans information systems, informatics and IT in the medical/healthcare system context. Gaps include understanding the complexities of working with healthcare data and creating real-time data registries. This gap also extends to a lack of awareness among management about the benefits and use cases of health informatics

Health economics and regulatory affairs

13	Awareness and understanding of regulatory requirements amongst start-ups and SMEs	Capability gap of start-ups and SMEs in understanding and integrating regulatory requirements early in the product development process
14	Shortage of experienced health economists	Shortage of health economists in Australia who have experience in successfully listing products on the MBS/PBS, as well as a shortage of skills in assessing emerging therapies (e.g. stem cell)

Priority skills gaps

Product development and commercialisation

15	Shortage of industry professionals with end-to-end translation and commercialisation experience	Shortage of experienced professionals who have practical commercialisation experience and can mentor researchers/start-ups through the research translational process. This includes early-phase drug development
16	Identifying unmet market need and understanding the clinical context	Capability gap in researchers/entrepreneurs in identifying and understanding an unmet need in the market, as well as understanding how the proposed solution would be used in the clinical environment
17	Ability to secure investment, funding and/or industry collaboration	Capability gap in entrepreneurs in pitching for funding, investment and collaboration from government and private organisations through clearly articulating unmet market need and commercial potential in proposals. This includes an understanding of how VC funds operate
18	Identification of the payer and understanding of reimbursement pathways and requirements	Capability gap in identifying who the end-product will be sold to and what pathways should be taken to obtain reimbursement (e.g. PBS vs state programs). Includes the ability to navigate the complex reimbursement processes and anticipate requirements (e.g. level and type of clinical evidence/validation, health economics input)

Specialist and technical skills

19	Shortage of skills in bioinformatics (particularly in genomics)	Shortage of capabilities in bioinformatics (the interdisciplinary field of biology, computer science and statistics). The gap is particularly significant in the ability to manage, analyse and interpret large biological (genomics and other '-omics') databanks
20	Shortage of pharmacologists and toxicologists with drug development expertise	Shortage of pharmacologists (who study drug interactions) and toxicologists (who study adverse effects) who understand and have expertise in the drug development pathway

Overarching findings of the skills gap review

There are five overarching findings that have emerged from the skills gap review as illustrated in the graphic below.

Finding	Description
Strong alignment to national strategic plans and initiatives	All priority skills gaps identified align with at least one key strategic plan such as the MMS set out by the Australian Government
Value chain breadth and stakeholders impacted	A higher prevalence of priority skills gaps exists after the discovery phase and in the pre-production phase on the MTP value chain. This tends to impact early-stage companies the most
Balance of well-known and emerging gaps	There is a good balance between well-known gaps that are consistently reported by the sector, and emerging gaps, which have been recently identified
Interlinked and co-dependent skills gaps	Some skills gaps are interlinked and co-dependent in their nature
Prevalence of experience gaps	At least one-third of the priority skills gaps require practical experience to address the gap

Strong alignment to national strategic plans and initiatives

The MTP priority skills gaps align with five key national strategic plans/initiatives of the Australian Government as illustrated in the graphic below. These include the MRFF, Encouraging More Clinical Trials in Australia (a Council of Australian Governments initiative), the MMS, Australia's Cyber Security Strategy and National Digital Health Strategy. These long-term strategic plans are reflective of the global megatrends and economic drivers shaping the sector, positioned to leverage the sector's demonstrated strengths.

Alignment of priority skills gaps with national strategic initiatives

	MRFF	Clinical Trials Initiative	MMS	Australia's Cyber Security Strategy	National Digital Health Strategy
1 Understanding of QMS and protocols	✓		✓	✓	✓
2 Manufacturing expertise in high-tech and/or specialised medtech devices			✓		✓
3 Manufacturing expertise in high-value therapeutics at a commercial scale			✓		
4 Shortage of MTP-specific project managers to support start-ups and early-stage spin-offs	✓	✓	✓	✓	✓
5 Strategic design of clinical trials to address regulatory and payer needs	✓	✓	✓		
6 Shortage of experienced CRAs	✓	✓	✓		
7 Shortage of CTCs	✓	✓	✓		
8 Leadership awareness about the value of best-practice management in cybersecurity			✓	✓	
9 Shortage of cybersecurity professionals and IT infrastructure resilience skills within MTP			✓	✓	✓
10 Understanding of and expertise in big data capture, management and analysis	✓		✓	✓	✓

	MRFF	Clinical Trials Initiative	MMS	Australia's Cyber Security Strategy	National Digital Health Strategy
11 Expertise in the design and use of AI within MTP	✓		✓	✓	
12 Shortage of skills in health informatics			✓	✓	✓
13 Awareness and understanding of regulatory requirements amongst start-ups and SMEs	✓		✓		
14 Shortage of experienced health economists	✓	✓	✓		
15 Shortage of industry professionals with end-to-end commercialisation experience	✓		✓		
16 Identifying unmet market need and understanding the clinical context	✓		✓		
17 Ability to secure investment, funding and/or industry collaboration	✓		✓		
18 Identification of the payer and understanding the reimbursement pathways and requirements	✓		✓		
19 Shortage of skills in bioinformatics (particularly in genomics)	✓	✓	✓		
20 Shortage of pharmacologists and toxicologists with drug development expertise	✓	✓	✓		

Medical Research Future Fund (MRFF)

The MRFF is a A$20 billion long-term investment supporting Australian health and medical research, strengthening the industry and reaffirming Australia's reputation as a world leader in medical research.[6] MTPConnect has been central to supporting the MRFF mission by delivering programs including REDI, the Targeted Translation Research Accelerator (TTRA) for diabetes and cardiovascular disease, Biomedical Translation Bridge (BTB) and BioMedTech Horizons (BMTH).[7]

More than half of the priority skills, specifically those that fall under the themes of clinical trials, product development, commercialisation and scientific and technical skills, are aligned with the MRFF strategic objectives. Addressing these skills gaps within the MTP workforce will be critical to maximising the impact of MRFF investments. For example:

- Addressing the shortage of bioinformaticians and big data and analytics experts (**Skills gap #10**) will be critical to drive development of cutting-edge digital health tools and support key MRFF research missions such as the Genomics Health Futures Mission.
- Addressing skills gaps relating to product development and commercialisation such as the ability to identify unmet market need (**Skills gap #16**) will enable researchers to identify and pursue more valuable commercialisation opportunities, resulting in greater translation of research into commercial products and services.
- Addressing the shortage of pharmacologists and toxicologists (**Skills gap #20**) will enable further expansion of the MRFF clinical trials initiative and grow Australia's world-class reputation in clinical trials further.

Encouraging more clinical trials in Australia

The Australian clinical trials capability is large and growing, with the potential to surpass A$2 billion of annual expenditure in the next 10 years.[8] The Australian Government has taken several steps to strengthen Australia's strong global reputation in clinical trials. Examples include establishing the Clinical Trials Project Reference Group (CTPRG) to drive the implementation of a streamlined and consistent national approach to clinical trials and providing A$7 million through the Encouraging More Clinical Trials in Australia initiative, assisting state and territory governments to centralise and streamline trial processes, reduce time to trial start-up and improve workforce capacity.[9]

In line with the government's appetite to develop Australia's clinical trials sector, this skills gaps review has highlighted three priority skills gaps in the clinical trials sector. These are:

- developing capabilities in strategic clinical trial design to meet regulatory and payer needs in order to optimise market access timelines (**Skills gap #5**)
- a shortage of experienced CRAs (**Skills gap #6**) and CTCs (**Skills gap #7**).

[6] Department of Health, Medical Research Future Fund 10-year plan, July 2020
[7] Department of Health, MRFF grants awarded as at November 2020
[8] MTPConnect, *Clinical Trials in Australia*, June 2017
[9] Department of Health, Clinical trials website, updated 7 August 2020

Addressing the shortages in experienced CRAs and CTCs will enhance Australia's ability to attract and conduct national and international clinical trials, driving job creation and eventually leading to better health outcomes for Australian patients.

Modern Manufacturing Strategy (MMS)

The MMS announced in the 2020–21 Budget is a A$1.5 billion strategy aimed at developing Australia's advanced manufacturing capability and driving the nation's economic recovery in response to the COVID-19 crisis. 'Medical products' has been identified as a national manufacturing priority within the MMS. As outlined in the *MTPConnect COVID-19 Impact Report 2nd Edition*, there is an opportunity to identify areas where Australia can build and sustain competitive advantage in advanced manufacturing, with a focus on the two ends of the value chain: basic research and sales/marketing, as well as production.[10] Stakeholder consultations have highlighted that this competitive advantage is likely to be in high-tech manufacturing of novel therapeutics, medical devices and services, rather than high-volume products where the low cost of labour is a major driver of competitiveness.[11]

This skills gaps review has identified three priority skills gaps within advanced manufacturing, each of which are important to address in line with key MMS initiatives. These include:

- understanding of quality management, protocols and systems (**Skills gap #1**)
- shortage of manufacturing expertise in high-tech and/or specialised medical devices (**Skills gap #2**)
- an undersupply of process engineers and other local expertise required for the manufacture of high-value pharmaceuticals at commercial scale (**Skills gap #3**).

Addressing these priority skills gaps will support Australia in further developing and expanding local advanced manufacturing capabilities. As an example, the A$800 million Seqirus influenza vaccine manufacturing facility planned to be built and operational by 2026 would require a domestic supply of skilled workers to support influenza vaccine supply to Australians and the rest of the world.[12]

Australia's Cyber Security Strategy

The Australian Cyber Security Strategy 2020 will invest A$1.7 billion over 10 years to achieve Australia's vision of creating a more secure online world for all Australians, including businesses and essential services. The strategy recognises that cybersecurity threats are increasing and that cyber criminals want to take advantage of more digitally connected Australians than ever before. With increasing numbers of digitally enabled products, platforms and databases, the MTP sector is a prime target. The health sector reported the largest proportion of data breaches comprising 22 percent of all breaches in the period from January to June 2020.[13] Therefore, it is important that the sector builds cyber resilience.

Two priority skills gaps identified leadership awareness about the value of best-practice management in cybersecurity (**Skills gap #8**) and shortage of skills in cybersecurity infrastructure and resilience (**Skills gap #9**). They align closely with this national strategy, especially the cyber skills agenda that focuses on growing a cyber-skilled workforce. The A$26.5 million Cyber Security Skills Partnership Innovation

[10] *MTPConnect COVID-19 Impact Report 2nd Edition*, October 2020
[11] Stakeholder consultations
[12] Seqirus, Seqirus Will Build World-class, Next-generation A$800m Influenza Vaccine Manufacturing Facility in Australia, 16 November 2020
[13] Office of the Australian Information Commissioner, *Notifiable Data Breaches Report: January–June 2020,* 31 July 2020

Fund is designed to encourage businesses and academia to work together to improve cybersecurity skills by supporting activities such as scholarships, apprenticeships, development and delivery of specialist cybersecurity courses for professionals.[14] The MTP sector is centrally placed to support existing initiatives such as this to address the priority skills gaps in cybersecurity.

Australia's National Digital Health Strategy

Australia's National Digital Health Strategy developed by the Australian Digital Health Agency (ADHA) proposes a set of strategic priority outcomes to be achieved by 2022. These include:

- **My Health Record** – Health information that is available whenever and wherever it is needed
- **Secure messaging** – Health information that can be exchanged securely
- **Interoperability and data quality** – High-quality data with a commonly understood meaning that can be used with confidence
- **Medicines safety** – Better availability and access to prescriptions and medicines information
- **Enhanced models of care** – Digitally enabled models of care that can improve accessibility, quality, safety and efficiency
- **Workforce and Education** – A workforce confidently using digital health technologies to deliver health and care
- **Driving innovation** – A thriving digital health industry delivering world-class innovation.

Addressing a number of MTP priority skills gaps would align with these outcomes, including 'secure messaging', which would benefit from addressing skills gaps in cybersecurity, and 'interoperability and data quality', which links to skills gaps in health informatics and big data management and analysis.[15]

Summary

Given the cross-sector nature of many of the priority skills gaps, there is an opportunity for MTPConnect and other industry groups such as the Advanced Manufacturing Growth Centre (AMGC), AustCyber and ADHA to work collaboratively in order to maximise the impact of addressing the skills gaps. Together, these organisations can enhance Australia's workforce strength in areas of national strategic priorities.

Value chain breadth and stakeholders impacted

Each part of the MTP value chain and its respective stakeholder groups plays a critical role in advancing the sector. Australia, irrespective of the area of science, ranks 10th globally in terms of the overall quality and quantity of its scientific publications, outperforming other countries in 20 out of the 22 fields of academic research.[16,17] These consistently high rankings have established Australia as a research excellence hub globally, indicating a strong performance in basic/discovery research on the value chain. However, despite efforts to improve Australia's R&D and commercialisation outcomes, Australia ranked

[14] Australian Government, Australia's Cyber Security Strategy 2020, August 2020
[15] Australian Digital Health Agency, Australia's National Digital Health Strategy, 2016
[16] Austrade, *Why Australia Benchmark Report 2020*
[17] World Economic Forum, *The Global Competitiveness Report 2019*

23rd on the 2020 Global Innovation Index, which takes into account a range of factors, including R&D, ICT and knowledge and technology outputs, and 31st on the Innovation Output Sub-Index.[18]

Consistent with this underperformance on commercialising products derived from this research, this review has uncovered that the majority of priority skills gaps are related to development and commercialisation of research (i.e. across the pre-production phase) as illustrated by the graphic below. Five skills gaps impact the entire value chain. Two of these skills gaps relate to cybersecurity, which is a broad, sector-wide concern. The other three key skills gaps – ability to identify unmet market need, securing funding/investment and/or industry collaboration and a shortage of professionals with end-to-end commercialisation experience – are crucial to address in the pre-production stages. Failure to do so will significantly impact the progress of projects to later parts of the value chain.

All of the priority skills gaps impact start-ups and SMEs, with some skills gaps having a greater impact than others. These early-stage companies are the engine room of innovation for the sector. For example, analysis by the Medical Technology Association of Australia in 2013 showed that the majority (54 percent) of Australian medical technology companies have grown from start-ups.[19] These are companies that are commercialising low Technology Readiness Level (TRL) technologies (therapeutics/ medical devices) through preclinical and clinical development and at times manufacturing. In these early stages, companies are most vulnerable to failure due to a range of reasons, including lack of and access to relevant skills. Skills gaps such as awareness and understanding of regulatory requirements at the outset of product development or shortage of skilled project managers to support spin-offs through their very early stages can be detrimental to the future success of these potentially value-adding companies. Supporting small companies by addressing the identified priority skills gaps is central to driving innovation and economic growth within the MTP sector and building an industry of the future (graphic below).

Therefore, in designing programs/initiatives to address the priority skills gaps, it is important that the most relevant stakeholder groups that need upskilling are mapped out by both the value chain and the size of the organisation.

[18] Global Innovation Index 2020, *Who Will Finance Innovation?* World Intellectual Property Organization 2020

[19] MTAA, *Medical Technology in Australia: Key facts and figures 2013*, Occasional Paper Series, 2013

			Pre-production			Production	Post-production		
			Basic research	Preclinical research and development	Clinical development	Manufacturing	Market access	Sales and marketing	Services
Advanced manufacturing and supply chain	1	Understanding of QMS and protocols		✓	✓	✓	✓	✓	✓
	2	Manufacturing expertise in high-tech and/or specialised medtech devices				✓	✓	✓	✓
	3	Manufacturing expertise in high-value therapeutics at a commercial scale				✓	✓	✓	✓
Business operations	4	Shortage of MTP-specific project managers to support start-ups and spin-offs		✓	✓	✓	✓	✓	✓
Clinical trials	5	Strategic design of clinical trials to address regulatory and payer needs		✓	✓	✓	✓	✓	✓
	6	Shortage of experienced CRAs			✓	✓	✓	✓	✓
	7	Shortage of CTCs			✓	✓	✓	✓	✓
Health data and cybersecurity	8	Leadership awareness about the value of best-practice management in cybersecurity		✓	✓	✓	✓	✓	✓
	9	Shortage of cybersecurity professionals and IT infrastructure resilience skills within MTP		✓	✓	✓	✓	✓	✓
	10	Understanding of and expertise in big data capture, management and analysis			✓	✓	✓	✓	✓
	11	Expertise in the design and use of AI within MTP	✓	✓	✓	✓	✓	✓	✓
	12	Shortage of skills in health informatics	✓	✓	✓	✓	✓	✓	✓

Key: Start-ups and SMEs | Companies of all sizes

Note: some gap names have been edited for length

		Pre-production			Production	Post-production		
		Basic research	Preclinical research and development	Clinical development	Manufacturing	Market access	Sales and marketing	Services
Health economics and regulatory affairs	13 Awareness and understanding of regulatory requirements amongst start-ups and SMEs		✓	✓	✓	✓	✓	✓
	14 Shortage of experienced health economists			✓	✓	✓	✓	✓
Product development and commercialisation	15 Shortage of industry professionals with end-to-end translation and commercialisation experience	✓	✓	✓	✓	✓	✓	✓
	16 Identifying unmet market need and understanding the clinical context	✓	✓	✓	✓	✓	✓	✓
	17 Ability to secure investment, funding and/or industry collaboration	✓	✓	✓	✓	✓	✓	✓
	18 Identification of the payer and understanding of reimbursement pathways and requirements		✓	✓	✓	✓	✓	✓
Specialist and technical skills	19 Shortage of skills in bioinformatics (particularly in genomics)		✓	✓				
	20 Shortage of pharmacologists and toxicologists with drug development expertise		✓	✓				

Key: Start-ups and SMEs | Companies of all sizes

Note: some gap names have been edited for length

Balance of well-known and emerging skills gaps

The identified priority skills gaps offer a balance between gaps that are well-known and broadly acknowledged, and others that are emerging as a critical future need that is not well-catered for. At the time of this review, just under half of the top 20 skills gaps have been identified as 'recently emerging' (see graphic below).

Emerging skills gaps are those that are primarily driven by global megatrends shaping the sector, particularly digital evolution and precision healthcare, as well as global biosecurity in light of COVID-19. These gaps range from a sector-wide capability gap in the design and use of AI to expertise in manufacturing high-value pharmaceuticals. Building a skilled workforce in these areas will be instrumental for the sector to continue to add value to the economy and remain globally competitive.

Well-known gaps are those that have been persistently identified as a gap within the sector for a long time. Many of these gaps relate to skills within product development and commercialisation, such as a shortage of professionals with end-to-end commercialisation experience.[20] The sector has already invested resources and continues to invest resources to address several of these gaps. Looking ahead, it will be important to ensure that the new initiatives build on learnings from past programs and that there is robust impact assessment put in place for future initiatives.

	Well-known gaps	Recently emerging gaps
Advanced manufacturing and supply chain		1. Understanding of QMS and protocols 2. Manufacturing expertise in high-tech and/or specialised medtech devices 3. Manufacturing expertise in high-value therapeutics at a commercial scale
Business operations	4. Shortage of MTP-specific project managers to support start-ups and spin-offs	
Clinical trials	5. Strategic design of clinical trials to address regulatory and payer needs 6. Shortage of experienced CRAs 7. Shortage of CTCs	
Health data and cybersecurity		8. Leadership awareness about the value of best-practice management in cybersecurity 9. Shortage of cybersecurity professionals and IT infrastructure resilience skills within MTP 10. Understanding of and expertise in big data capture, management and analysis 11. Expertise in the design and use of AI within MTP 12. Shortage of skills in health informatics
Health economics and regulatory affairs	13. Awareness and understanding of regulatory requirements amongst start-ups and SMEs	14. Shortage of experienced health economists
Product development and commercialisation	15. Shortage of industry professionals with end-to-end translation and commercialisation experience 16. Identifying unmet market need and understanding the clinical context 17. Ability to secure investment, funding and/or industry collaboration 18. Identification of the payer and understanding of reimbursement pathways and requirements	
Specialist and technical skills	20. Shortage of pharmacologists and toxicologists with drug development expertise	19. Shortage of skills in bioinformatics (particularly in genomics)

Note: some gap names have been edited for length

[20] Innovation and Science Australia, *Performance Review of the Australian Innovation, Science and Research System*, 2016

Interlinked and co-dependent skills gaps

While the priority skills gaps identified might fall under different parts of the value chain and different themes, some skills are interlinked and co-dependent in their nature. By addressing such priority skills gaps, the sector can expect an uplift of related skills in the overall workforce. Examples of interlinkages and co-dependencies include:

- Awareness and understanding of regulatory requirements (**Skills gap #5**), and understanding of the reimbursement pathways (**Skills gap #18**), are critical to strategically designing clinical trials to efficiently address key regulatory and/or reimbursement hurdles (**Skills gap #5**).
- Ability to identify an unmet market need (**Skills gap #16**) is an important pre-cursor skill that is critical to securing funding, investment and/or industry collaboration (**Skills gap #17**).
- Skills in big data capture, management and analysis (**Skills gap #10**) and the design and use of AI (**Skills gap #11**) are critical to developing strong health informatics and bioinformatics capabilities, as well as driving innovation in digital health products and services more broadly.
- Addressing the shortage of experienced industry professionals with end-to-end commercialisation expertise (**Skills gap #15**) will help build capabilities in other product development and commercialisation skills gaps, such as ability to identify an unmet market need (**Skills gap #16**) and ability to secure funding, investment and/or industry collaboration (**Skills gap #17**).

Prevalence of experience skills gaps

One-third of the priority skills gaps impacting the sector are experience gaps. These are gaps that require on-the-job training, experience and practical exposure in order to be addressed. The graphic below categorises gaps as either capability gaps, capacity gaps or experience gaps.

These experience gaps are typically challenging to address as the impact of not addressing these gaps is high, the need is often immediate and upskilling through experience takes time. Depending on the specific characteristic of the skills gap, the target stakeholder groups and the severity of the shortage, gaining 'experience' will likely require at least 12 months of on-the-job training.

Each skills gap has unique characteristics, and the sector can address these experience gaps in two ways (often concurrently), by building domestic experience and importing international experience. For example:

- Addressing the shortage in experienced CRAs can be addressed by expanding the domestic pool of junior CRAs through paid traineeship/internship programs and by providing training programs to senior CRAs to develop their coaching/mentoring skills.
- Similarly, the shortage of industry professionals with end-to-end translation experience is likely to be addressed by importing international experience, as it takes years to build such expertise. This may require expanding programs such as the veski innovation fellowships[21] to attract commercialisation professionals from a global talent pool, and leveraging the global talent visa program.

While there will always be some degree of on-the-job training required for most graduates as they enter the workforce, there is an opportunity for tertiary program providers in the sector to start making a shift towards industry-embedded modules where possible, to grow the talent pool at the graduate level. Companies and organisations would also need to continue to upskill their workforce to meet evolving needs.

[21] veski innovation fellowships website, accessed on 15 November 2020

Characterising the skills gaps

Capability Existing workforce requires upskilling or training	Experience Lack of experience in the existing workforce	Capacity Lack of supply of workforce in the sector
1. Understanding of QMS and protocols	2. Manufacturing expertise in high-tech and/or specialised medtech devices	7. Shortage of CTCs
4. Shortage of MTP-specific project managers to support start-ups and spin-offs	3. Manufacturing expertise in high-value therapeutics	9. Shortage of cybersecurity professionals and IT infrastructure resilience skills within MTP
5. Strategic design of clinical trials to address regulatory and payer needs	6. Shortage of experienced CRAs	12. Shortage of skills in health informatics
8. Leadership awareness about the value of best-practice management in cybersecurity	14. Shortage of experienced health economists	19. Shortage of skills in bioinformatics (particularly in genomics)
10. Understanding of and expertise in big data capture, management and analysis	15. Shortage of industry professionals with end-to-end translation and commercialisation experience	
11. Expertise in the design and use of AI within MTP	20. Shortage of pharmacologists and toxicologists with drug development expertise	
13. Awareness and understanding of regulatory requirements amongst start-ups and SMEs		
16. Identifying unmet market need and understanding the clinical context		
17. Ability to secure investment, funding and/or industry collaboration		
18. Identification of the payer and understanding of reimbursement pathways and requirements		

Note: some gap names have been edited for length

Structural issues impacting MTP sector skills gaps

Key system-level structural issues also need to be considered as these can exacerbate the skills gaps and/or limit the potential impact of programs and initiatives designed to address the gaps. These issues tend to be related to factors, including misaligned policy, underinvestment in key infrastructure, misaligned incentives between parts of the value chain, funding gaps and regulatory inefficiencies.

The importance of getting economic conditions right for business is acknowledged in the MMS. For medical products manufacturing, this requires a policy framework which creates an internationally competitive income tax regime, with specific policy settings designed to attract and retain both human and financial capital.

A focus on incentivising innovation investment will position Australia as a global competitor, help keep our Intellectual Property (IP) onshore for longer and support industry to develop high skill, high wage jobs in Australia.

Key policy initiatives identified by the MTP sector include the preservation of the R&D Tax Incentive program, which provides a refundable tax offset to eligible entities for eligible R&D activities. While

viewed as a key driver of growth in R&D and manufacturing, the program has been subjected to frequent change. The sector argues strongly against any future material adverse changes so industry has certainty regarding long-term investment in R&D.

Implementation of an IP tax incentive is favoured by many in the MTP sector to boost the international competitiveness of Australian companies. Such a program would incentivise the translation and commercialisation work of businesses which have significantly invested in the creation of patented IP by concessionally taxing any royalty income or capital gains arising from the licence or sale of related patented IP. It would help stop valuable IP from being lost overseas sooner than necessary and help build the pipeline of skilled MTP sector workers as these companies transform, grow and scale.

These 'patent box' incentive schemes have been implemented in China, the UK and several European countries including Ireland, France and the Netherlands. The UK scheme, introduced in 2013, reduces the tax rate to 10 percent for profits arising from IP, where 19 percent is the main rate of Corporation Tax.

Structural issues impacting specific priority skills gaps are discussed in Chapter 3.

The graphic below presents three major structural issues that have the broadest impact across the MTP value chain.

1 Lack of incentives and inconsistent support to commercialise research

Successful research commercialisation is a critical lever to drive growth within the MTP sector, delivering improved patient outcomes and economic growth.

Three main sub-issues have been highlighted through stakeholder consultations that have exacerbated skills gaps across the MTP sector:

- **Misalignment of expectations with academic incentives:** There is a misalignment from what the sector expectation is in terms of university research commercialisation and how the universities/MRIs recognise the success of their academic staff. In the current incentive structure, academics are promoted based on publications, research output and success with Category 1 research grants. There is little reward for commercially meaningful industry collaborations/commercialisation efforts.
- **Limited mobility between academia and industry:** Mobility between academic research/clinical work into industry/entrepreneurship and vice versa remains challenging. This restricted movement, and therefore flow of ideas, means that Australia is likely to continue trailing leading examples such as Boston.
- **Heterogeneity in the quality of commercialisation support services:** There is significant sector-wide heterogeneity in the quality of support services available to facilitate successful commercialisation in the university/MRI sector.

These challenges have been widely acknowledged for several years. For example, there was a parliamentary enquiry into the barriers to technology transfer looking for ways to ensure that Australia's tertiary system can meet the needs of a future labour force.[22] However, despite efforts, these challenges persist and need sustainable solutions. This review highlights at least two points that are actionable to unlock the commercialisation potential of the MTP sector:

- Build a skilled workforce with significant commercialisation experience (preferably international experience) in the support structure.
- Target workforce commercialisation-related training to early-stage spin-offs and start-ups that have a potential innovative technology but are most vulnerable to failure.

[22] Parliament of Australia, Inquiry into innovation and creativity: workforce for the new economy, 2017

2 Lack of sufficient scale in industry R&D

There has been a dearth of industry R&D activity in Australia's MTP sector as large MTP companies have typically only had a sales and marketing presence in Australia. Having sufficient scale in industry R&D presence in Australia is key to ensuring strong demand for innovation and to providing practical training in product development and commercialisation for the future workforce.

Key factors driving the lack of sufficient scale in industry R&D include the high cost of labour, competition from Australia's neighbours and less attractive R&D and investment schemes relative to other markets.[23,24]

A concerted effort from the government and industry is required to:

- identify strategic areas where Australia can build and sustain competitive advantage (e.g. novel therapeutics, advanced manufacturing)
- create an environment with the right policy settings and investments to build R&D infrastructure in the MTP sector.

Greater industry R&D would result in more early-stage companies completing their product development in Australia and an increase in the local research being pulled through to commercial products, ultimately with improved patient outcomes.

3 Lack of commercial-scale manufacturing

There is a lack of commercial-scale manufacturing in Australia's MTP sector. Similar to industry R&D, a key factor driving this is the high cost of labour and distance from the historical major sales markets in the northern hemisphere.[24,25] However, there is a unique opportunity for Australia to focus on developing manufacturing capabilities and processes for high-value and niche MTP products that are independent of labour costs.

The MMS is a welcome long-term strategy for the sector and will facilitate building essential manufacturing facilities. Ongoing concerted effort from the industry and the government will be required to establish a sustainable manufacturing hub for high-value MTP products to generate export revenue and build resilience in the MTP supply chain.

Doing so will result in greater demand for high-tech manufacturing skills and drive the upskilling of the MTP sector workforce. A greater number of job opportunities requiring manufacturing skills such as process engineering, for example, will encourage more training of graduates and retraining of experienced workers.

[23] Emma Koehn, *Sydney Morning Herald*, Biotechs call for more tax incentives to fund research, local production, June 2020

[24] Stakeholder consultations

[25] Australian Manufacturing Technology Institute Ltd., The decline of Australian manufacturing … and the impact of COVID-19, May 2020

3. Characterisation of Priority Skills Gaps

The following chapter provides a 'deep dive' for each of the 20 priority skills gaps across the MTP sector.

Each section details the skill and its context, a characterisation of the gap and why it exists. This is followed by commentary on how the gap impacts the sector, how it aligns with MTP Sector Priorities and megatrends and where relevant, other structural factors that are important to consider, such as policy and infrastructure.

Finally, potential solutions on how to address each skills gap are also presented for the short term (possible within two years), medium term (two to four) or long term (over four years).

The full list of skills gaps identified in this review can be found in Appendix 2.

Theme: Advanced manufacturing and supply chain

The MTP sector value chain includes R&D, preclinical and clinical development, production and manufacturing, logistics and distribution and product marketing, promotion and sales.

The sector is uniquely positioned to become a leader in advanced manufacturing by focusing on all elements of the medical products manufacturing ecosystem, including Industry 4.0 manufacturing technologies, high-value medical devices and therapeutics.[26] However, there are important skills gaps that exist in this area that are exacerbated by underlying structural challenges, as discussed in Chapter 2.

These skill gaps focus on the production phase of the value chain but have significant impacts across all elements of the pre-production and post-production phases as well.

Skills gap #1: Understanding of QMS and protocols

Overview of the skill

Products in the MTP sector are highly regulated. Manufacturers must meet relevant quality standards before they are eligible to seek approval from government regulators such as the Therapeutic Goods Administration (TGA) and the Food and Drug Administration (FDA) in the US. Applicable international quality standards for manufacturers of pharmaceutical/biotechnology and medical technology products include GMP, GLP and also ISO 9001, ISO 13485, ISO 17025 and ISO 27001.[27] ISO 27001 establishes requirements related to information security management systems, which is especially important for businesses that capture patient data. In addition, GCP is an international quality standard for conducting clinical trials that would apply to sponsors, service providers and hospitals running clinical trials.

Being accredited, or at least aligned with relevant industry standards, represents a mark of assurance regarding the competence of an organisation and the integrity, reliability and consistency of its products. As a result, it is important that researchers and companies in the sector understand the relevant accredited quality systems required for commercialisation. Participants need to understand the

[26] CSIRO, *Medical Technologies and Pharmaceuticals: A Roadmap for unlocking future growth opportunities for Australia*, April 2017

[27] ISO 9001: Quality management; ISO 13485: Medical devices; ISO 17025: Testing and calibration laboratories; ISO 27001: Information security management

steps required to implement QMS that meet the requirements for the appropriate certification, as well as learning appropriate documentation and audit processes.

Description of the skills gap

Stakeholder consultations have highlighted that universities, start-ups and SMEs within the MTP sector often lack an understanding of quality management.

These specific skills gaps include:

- understanding among business leaders about the importance of adopting and maintaining appropriate QMS
- lack of staff members with sufficient training in QMS to:
  - define best-practice quality management principles and protocols that are aligned to relevant industry standards
  - design and implement a path for achieving greater alignment to industry accreditation
  - maintain quality procedures and quality systems to ensure high-standard facilities.

Large pharmaceutical and medical technology companies tend to have sufficient in-house capabilities due to their scale and deep knowledge of the regulatory requirements of the sector. However, the skills gap is particularly evident within start-ups and SMEs across the sector. Emergence of digital health businesses has also brought to light the lack of understanding of ISO 27001 protocols, increasing exposure to potential data breaches.

There is also an observed heterogeneity in mandated training and adherence to quality systems across research institutions (such as universities, MRIs and public research organisations) where some research labs and institutions have more thorough training and protocols in place than others.[28] According to former Chief Scientist, Dr Alan Finkel AO, training in research institutions "varies widely in quality and is often seen as a pro forma exercise".

Impact of the gap

More widespread adoption of QMS and standards by start-ups and SMEs will drive greater commercialisation success as companies will be better positioned for investor/partnering discussions, regulatory submissions and obtaining preferred supplier status in a globally connected market.

Developing increased capabilities in quality management at the basic research level will also drive greater commercialisation outcomes in the long run. Researchers will gain greater credibility among big pharmaceutical and medical technology companies and the chances of out-licensing are likely to be higher if the asset and research data have been collated within an accredited quality framework from early in the development pathway. Stakeholder consultations highlighted that there were instances in which research had to be repeated and aligned under GLP processes, slowing commercialisation.

In addition, the current COVID-19 pandemic has stressed the value of appropriate quality accreditations

[28] Alan Finkel, *Nature*, To move research from quantity to quality, go beyond good intentions, February 2019

when responding to global supply chain disruptions. A number of domestic manufacturers were unable to effectively pivot their operations and contribute to the pandemic response by manufacturing medical products because they lacked ISO 13485 and/or GMP certification.[29]

Greater uptake of, and alignment with, QMS and standards will help Australia position itself as a home of advanced manufacturing. Meeting appropriate standards will unlock opportunities for Australian manufacturers to integrate further into global markets. Specifically, it will facilitate the expansion of Australia's manufacturing capacity and capability for novel therapy areas such as stem cell and gene therapies, intelligent medical devices and digital health technologies.

Alignment with Sector Priorities and Megatrends

The QMS and standards skills gap are aligned to three key MTP Sector Priorities. Demand will continue to be driven by four megatrends.

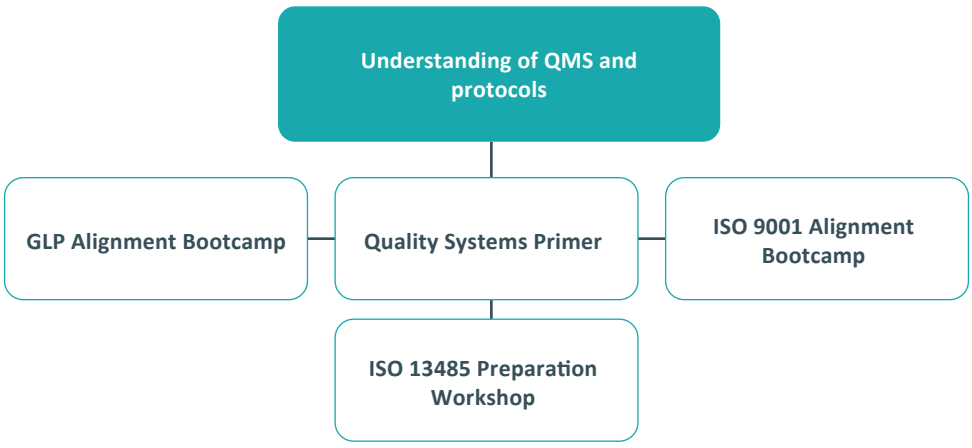
Sector Priority	Description
Priority 1: Align investment in Knowledge Priorities that meet current and future market needs	A highly productive commercialisation environment requires strong standards of quality assurance, data validity and testing replicability across the MTP sector
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Best-practice quality management and systems are hallmarks of large, professionally managed organisations and are essential capabilities for small enterprises looking to become larger, more stable and successful companies
Priority 7: Support advanced manufacturing as a part of the broader Australian innovation system	Australia's reputation in advanced manufacturing and its opportunities for integration with global markets will rely on industry-wide excellence in quality management

[29] *MTPConnect COVID-19 Impact Report 2nd Edition*, October 2020

Megatrend	Description
Precision healthcare	Meeting quality and manufacturing standards is increasingly important in the context of demand for precision medicine solutions and its evolving regulatory frameworks
Digital evolution	The increasing adoption of digital technology and patient data collection implores the understanding and use of certain protocols (e.g. ISO 27001) to safeguard systems against data breaches
Global biosecurity	Developing greater alignment to quality systems across the sector will also enable more effective pivoting of manufacturing efforts in response to pandemics as has been highlighted by COVID-19
Consumer control	As consumer-driven products and services such as wearable sensors and in-home monitoring devices continue to grow, quality standards will become increasingly important in winning consumer trust and confidence

Addressing the gap

The REDI initiative has already taken steps to address this skills gap. An RfP was released in November 2020 to seek proposals for four courses (see graphic to the right) that would reach a broad range of stakeholders and build an appropriate and relevant level of understanding.[30] The first program is a Quality Systems Primer course designed to educate participants on the benefits of having quality systems. The subsequent workshops are designed to enable participants to effectively implement QMS accredited to ISO 13485 (for medical technology companies), aligned to ISO 9001 (for medical technology and pharmaceutical companies) or GLP standards.



[30] MTPConnect, REDI Contestable Program Round 1 Guidelines, November 2020

Skills gap #2: Manufacturing expertise in high-tech and/or specialised medtech devices (e.g. smart devices, implants and bionics)

Overview of the skill

Medical devices are increasingly becoming part of a patient-driven, consumer-focused, digitally enabled ecosystem.[31] Examples of such innovative technologies include 3D printing of biocompatible and functional body parts and organs, integrated bionic limbs controlled by neural pathways, or ingestible smart devices that monitor disease.[32]

As mentioned in Chapter 2, Australia is well-placed to be a manufacturing hub for high-tech, specialised medical devices that require a highly skilled workforce. Some of the skills required to build a successful advanced medical technology manufacturing industry include:

- expertise in technologies such as additive manufacturing, including knowledge of advanced materials, biocompatible materials, precision tooling and niche machinery[33]
- development and integration of implantable bioelectronics, including microelectronics assembly
- a deep understanding of intelligent devices, including communication, connectivity and data interoperability
- highly skilled workers to operate and repair increasingly complex machinery
- best-practice processes to ensure predictable quality and performance of medical devices, including an understanding of quality standards such as GMP and ISO 13485.

Description of the skills gap

There is a shortage of local expertise for the manufacture of high-tech, specialised medical devices.

These specific skills include:

- a shortage of process engineers who can take a concept from R&D/prototyping to industrial-scale production of a specialised medical device
- a shortage of data and analytics experts who can design and drive the development of smart and connected devices (see **Skills gap #10: Understanding of and expertise in big data capture, management and analysis**)
- a capability and capacity gap in a specialist manufacturing workforce with GMP/GLP knowledge, quality control and general expertise for scale manufacturing of specialised/customised medical devices (see **Skills gap #1: Understanding of QMS and protocols**). This includes understanding how to ensure products meet standards in other markets.

Australia has sufficient supply of engineering graduates in applicable fields (e.g. biomedical engineering) whose skills could translate to becoming successful process engineers.[34] However, there is a lack of scale

[31] MTPConnect, Sector Competitiveness Plan, April 2020
[32] CSIRO, *Medical Technologies and Pharmaceuticals: A Roadmap for unlocking future growth opportunities for Australia*, April 2017
[33] Department of State Development, Queensland Advanced Manufacturing 10-Year Roadmap and Action Plan, 2nd ed. November 2018
[34] Socrates Dokos, IEEE, Biomedical Engineering Education "Down Under": the Australian Experience, April 2015

manufacturing in Australia to provide the corresponding demand for process engineers. Consequently, medical products manufacturing is viewed as a less attractive sector for engineers who instead pursue other avenues such as consulting, professional or financial services.[35]

As is the case in the pharmaceutical industry, most Australian manufacturing industries have declined due to the availability of lower cost labour in other parts of the world. As a result, there has been a decline in the pool of local manufacturing talent.[36] Consequently, Australia has only a small medical technology manufacturing footprint focused around companies such as Cochlear, Cook Medical and ResMed.

Impact of the gap

This gap in manufacturing expertise impacts medical technology companies of all sizes. Stakeholder consultations suggest that even large companies have struggled to adequately source expertise locally and often bring in talent from overseas hubs such as Ireland. A lack of this local expertise limits Australia's ability to become a leading global player in the manufacturing of high-tech and specialised medical devices.

Addressing this gap will enable medical technology start-ups to scale-up local production for clinical trials and commercial supply, keeping innovation, new jobs and economic growth onshore. For larger companies, access to a high-quality workforce is a critical drawcard for establishing a manufacturing facility. Australia also has the opportunity to become a regional training hub for developing process engineering talent for advanced manufacturing technologies given its strategic location and availability of a highly trained workforce. Overall, developing Australia's skills in advanced medical technology manufacturing will provide appreciable economic and clinical benefits.

As in the case of **Skills gap #3: Manufacturing expertise in high-value therapeutics at a commercial scale**, the COVID-19 pandemic has highlighted the importance of having onshore manufacturing capabilities and reducing Australia's reliance on global supply chains. The central role played by the Australian medical technology sector during the pandemic, as detailed in the 2020 MTPConnect report, 'Collaborating in the Public Interest: How Australia's Medical Technology Sector joined with Government to fight COVID-19', demonstrates the economic and public health benefits of having access to these capabilities.

Alignment with Sector Priorities and Megatrends

Building capabilities in advanced manufacturing for high-value medical products is aligned to all seven Sector Priorities. Demand for this skill will continue to be driven by four primary megatrends. Addressing this skills gap is also aligned with the Australian Government's 2020–21 announcement of the MMS, as indicated in Chapter 2.[37]

[35] Stakeholder consultations

[36] Gareth Hutchens, *The Guardian*, Census 2016: manufacturing jobs in Australia drop 24% in five years, October 2017

[37] Australian Government, Modern Manufacturing Strategy, October 2020

Sector Priority	Description
Priority 1: Align investment in Knowledge Priorities (KPs) that meet current and future market needs	Building local advanced manufacturing capabilities will help strengthen Australia's competitive advantage in relevant KPs, particularly in the science and therapeutic areas
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	Advanced manufacturing capabilities will foster an ecosystem that spans the entire value chain. This will support end-to-end translation of medical devices
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Keeping manufacturing facilities onshore will support small medical technology companies, in particular, in becoming larger and more successful companies
Priority 4: Strengthen Australia as an attractive clinical trial research destination	Local manufacturing 'hubs' (e.g. in close proximity to hospitals and clinical trial sites) will support the efficiency and cost effectiveness of Australia's high-quality clinical trial sector, particularly in the case of customised bionics and other bespoke devices
Priority 5: Support the development of digital healthcare solutions: devices and data analytics	Onshore advanced manufacturing capabilities and expertise will enable Australia to become a leader in the development and manufacturing of smart and connected medical devices
Priority 6: Position Australia as a preferred partner for international markets	Australia can capitalise on its strong reputation for high quality and use its niche manufacturing capabilities to position Australia as a desirable supplier of specialised medical technology for the global market
Priority 7: Support advanced manufacturing as a part of the broader Australian innovation system	Establishing these capabilities will increase the value of the advanced manufacturing sector, provide unique job opportunities in the industry and strengthen the MTP innovation ecosystem

Megatrend	Description
Digital evolution	The adoption of connected and integrated medical technology is increasing. As challenges (e.g. data interoperability) are overcome, this megatrend will drive the rapid integration of communicative medical technology into patient and clinical environments
Precision healthcare	The technology advancements underpinning the development and manufacture of highly customised implants and bionics is rapidly increasing, making these personalised devices more accessible to patients
Global biosecurity	COVID-19 has highlighted the risk of not having a sovereign manufacturing industry. With an increasingly complex global supply chain, it would be prudent for Australia to have strong medical technology manufacturing capabilities onshore that can pivot to produce lifesaving equipment if required
Consumer control	The demand for wearable and integrated technology continues to grow, alongside the advantages of using consumer-collected data in clinician decision-making

Other considerations

Several of the world leaders in advanced medical products manufacturing operate in localised 'hubs' or 'clusters', which are typically integrated with research and clinical institutes.[38] This collaborative, at-scale, patient-centric ecosystem is largely missing in Australia, which limits its ability to produce such specialised medical technologies.

Addressing the gap

In the short term:

- Graduate programs for engineering students to work in medical technology manufacturing would be valuable to develop a pipeline of people with specialised, high-end manufacturing skills (e.g. additive manufacturing). Similar programs have been successfully demonstrated in Singapore and are considered a government priority.[39]
- Supporting cross-skilling programs for highly skilled process engineers from other high-tech industries, such as the automotive industry, to transition into the MTP sector would also be valuable in helping maximise the available pool of talent in Australia.

In the long term, there are a number of opportunities for the industry to address the gap in the workforce. However, these strategies should be considered in parallel with addressing the broader structural issues impacting the growth outlook.

[38] Medical Device and Diagnostic Industry, The Seven Most Important Medtech Clusters in Europe, May 2017
[39] Ministry of Manpower, Jobs Situation Report, August 2020

Structurally, forming more public-private partnerships could accelerate the growth of the sector. Examples include:

- Government/industry investment to develop new purpose-built facilities to meet the manufacturing infrastructure gap (e.g. Brisbane's new facility to manufacture start-up Vaxxas' needle-free vaccinations is supported by MTPConnect, the Queensland Government and the Translational Research Institute).
- Government collaboration with Multinational Enterprises (MNEs) to establish new companies dedicated to manufacturing high-quality and intelligent medical technology. For example:
    - 61medical, a subsidiary of 41medical, has been established in partnership with Queensland Government to set up a contract medical device development and advanced manufacturing business, bringing international expertise to Australia.
    - Stryker's R&D and Advanced Manufacturing Hub is a collaboration between Stryker, academia and government to commercialise medical technology research in Australia.

In the short term, greater promotion of career pathways in medical technology manufacturing to science and engineering students/graduates will also be required to raise awareness of the opportunities available within the medical technology sector.

Longer-term workforce development opportunities include:

- Building on existing higher education manufacturing qualifications (e.g. NSW's new Diploma of Applied Technologies) to establish medical technology-specific modules/certificates that would give graduates a baseline level of understanding of how to operate within the industry (e.g. manufacturing regulations, automation techniques, micro/nano-fabrication technologies).
- Further, Australia could follow Ireland's example of a Master of Engineering in Digitalisation of Manufacturing. Developed in conjunction with an industry expert working group, this is a practice-based professional award for experienced employees in advanced manufacturing facilities.

International case study: medtech manufacturing in Ireland

- Ireland's medical technology sector is relatively large for a population of five million.
  - It employs 38,000 people across 450 companies.
  - The sector is expected to continue to grow at 3.7 percent p.a. between 2020 and 2024, despite the economic impact of COVID-19.[40]
  - Irish medical technology exports, which does not include pharmaceuticals and biotechnology, are estimated to be worth A$20 billion annually, representing 10 percent of all Irish exports. In comparison, the value of Australian MTP manufacturing exports, which includes pharmaceuticals and biotechnology, was estimated at A$8 billion in 2019.[41,42,43]
  - Eighteen of the world's top 25 medical technology companies are headquartered in Ireland, attracted by a low corporate tax rate of 12.5 percent and significant tax breaks (e.g. a 25 percent R&D tax credit) as well as other supportive government programs for the advanced manufacturing sector.
- A key piece of government support is the BioExel Medtech Accelerator, a partnership with private enterprise and the National University of Ireland (NUI). The program provides significant support to the sector by assisting the most attractive start-up ventures through commercialisation to manufacturing, providing A$150,000 in seed funding and access to experts.[44]
  - The physical hub is located in Galway and houses advanced manufacturing plants of global players including Medtronic, Boston Scientific, Johnson & Johnson, Abbott and Stryker, as well as NUI, which is well-equipped for clinical trials.[45]
- More widely across Ireland, a combination of a highly trained labour force, large numbers of graduates in science and technology, several higher-education institutes that are well-equipped for clinical trials and a culture of close relationships between academia and industry creates an environment conducive to a successful advanced medical products manufacturing sector.[46]

Skills gap #3: Manufacturing expertise in high-value therapeutics at a commercial scale

Overview of the skill

High-value therapeutics such as novel biologics, gene and stem cell therapies are growing, as these technologies offer more targeted treatment for many diseases.[47] As discussed in **Chapter 2**, the Australian MTP sector has an opportunity to capture value from developing, manufacturing and supplying international markets with niche, high-value pharmaceuticals such as biologics, novel therapies and high-value medicines to help manage public health and sovereign risks.

[40] Fitch Solutions, *Ireland Medical Devices Report Q3 2020*
[41] *Irish Medtech Association Statement of Strategy 2016-2020*
[42] *A Plan for Budget 2020 from the Irish Medtech Association*
[43] MTPConnect, Sector Competitiveness Plan, April 2020
[44] BioExel website, accessed on 1 November 2020
[45] *The Irish Times,* Ireland second only to Germany for medical device exports, 25 November 2018
[46] Irish Medtech Association (IMA), Priorities for the next government, 2020
[47] EvaluatePharma®, *World Preview 2019, Outlook to 2024*, 12th ed. June 2019

Some of the skills required to build commercial-scale pharmaceutical/biotechnology manufacturing of high-value therapeutics include:

- expertise in developing and maintaining cell lines (e.g. mammalian, viral, bacterial)
- expertise in formulation, protein chemistry and purification
- expertise in quality control and assurance
- GMP-certified manufacturing workforce
- highly skilled technicians to install, operate and maintain production equipment.

Description of the skills gap

There is a shortage of skills in the manufacture of high-value pharmaceuticals and novel therapies at a commercial scale.

These specific skills gaps include a shortage of:

- skills in commercial-scale development and analysis of biologics and novel therapies (e.g. nanobodies, antibody drug conjugates)
- production technicians/operators who have GMP training and certification (see **Skills gap #1: Understanding of QMS and protocols**)
- quality control and assurance professionals in pharmaceutical/biotechnology manufacturing
- process engineers, particularly in processing chemistry and formulation.

As is the case in the medical technology industry, most Australian manufacturing industries have declined due to the availability of lower cost labour in other parts of the world. As a result, the pool of local manufacturing talent across the country has declined and Australia has only a small pharmaceutical manufacturing footprint concentrated in the facilities of companies such as CSL and AstraZeneca. The lack of local scale manufacturing means less demand for these jobs and therefore development of these skillsets has not been a priority.

In the emerging biologics and novel therapies sector (e.g. viral vectors), a dearth of commercial-scale expertise is seen globally.[48] The experts that do exist tend to move between companies, with companies prioritising hiring rather than aiming to build talent organically. Australia's industry is nascent but developing, although stakeholders still report a lack of training and higher education opportunities to develop people to work in the industry. This is exacerbated by lack of awareness of advanced manufacturing opportunities in established degree programs such as pharmacy and chemistry.

Impact of the skills gap

The global market for novel therapeutics such as cell therapies and immunotherapies is worth an estimated US$17 billion and is forecast to grow at 23.2 percent p.a. to reach US$54.9 billion by 2024.[49] Building the manufacturing capabilities for niche and high-value pharmaceuticals would contribute significantly to Australia's revenue and create an influx of high-skilled, high-paying jobs in the sector.[50]

[48] *Pharma in Focus*, Talent shortage stunts pharma, 30 October 2020

[49] Market Data Forecast, Regenerative Medicines Market Size to Grow USD 54.88 Bn by 2024, January 2020

[50] Department of Industry and Science, Australian Pharmaceuticals Industry Data Card, 2014

This skill gap impacts pharmaceutical and biotechnology companies, though smaller companies are more affected due to lack of access to global manufacturing infrastructure and talent pools.

One specific example is facilitating the production of drugs for smaller biotechnology companies that conduct clinical trials in Australia. Currently, companies tend to head overseas to manufacture their potentially lifesaving drugs for use in clinical trials back in Australia.[51] This is associated with high costs and long wait times, which prevents these smaller companies from taking their new therapies beyond the laboratory. Addressing this gap would give biotechnology companies lower cost and more timely access to clinical-grade therapies appropriate to their phase of clinical development, ultimately extending to commercial supply. With Australia's strong basic research capabilities in biotechnology, this presents an opportunity to capitalise on its competitive advantage going forward. Australia could also use this opportunity to extend its strong domestic value chain from research and clinical trials to build a vertically integrated high-value pharmaceutical and biotechnology industry. This would give Australia more resilient supply chains as well as providing efficient access to global markets.

Finally, as brought out by the COVID-19 pandemic, establishing strong onshore advanced manufacturing capabilities is critical to increase Australia's resilience and preparedness for future biosecurity threats. Australia is often at the end of long and complex global supply chains, making it vulnerable to disruptions and mandating pre-emptive stockpiling.[52] Of particular concern is that according to a report by the Institute for Integrated Economic Research, Australia has little capacity to produce any of the active pharmaceutical ingredients listed on the World Health Organization's List of Essential Medicines.[53] While a completely self-reliant pharmaceutical manufacturing industry would be unrealistic for Australia, efforts to develop resilience through some level of sovereign capabilities to safeguard supply of critical medicines is possible.[54]

This has been recently acknowledged with a deal between Seqirus (a subsidiary of CSL) and the Victorian and Australian governments to construct a A$1.8 billion vaccine manufacturing plant – the largest influenza vaccine manufacturing plant in the Southern Hemisphere.[55] This facility is expected to provide an important sovereign vaccine manufacturing capability for the next 20 years.

[51] CSIRO, Building Australia's new Advanced Biologics Manufacturing Facility, May 2020

[52] The Institute for Integrated Economic Research – Australia, *The Implications of the COVID-19 pandemic for Australia's Foreign Affairs, Defence and Trade*, 2020

[53] The Institute for Integrated Economic Research – Australia, *Australia's medicine supply; is our health a national security/resilience issue?*, February 2020

[54] Phillip Coorey, *Australian Financial Review*, Australia looks to boost drug manufacturing, April 2020

[55] *ABC News*, Melbourne vaccine manufacturing facility announced as hope for coronavirus vaccine continues, 16 November 2020

Alignment with Sector Priorities and Megatrends

The skills gap in advanced manufacturing of high-value pharmaceuticals is aligned to six MTP Sector Priorities. Demand for this skill will continue to be driven by five megatrends.

Sector Priority	Description
Priority 1: Align investment in KPs that meet current and future market needs	Building local advanced manufacturing capabilities will help strengthen Australia's competitive advantage in relevant KPs, particularly in the science and therapeutic areas
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	Advanced manufacturing capabilities will foster an ecosystem that spans the entire value chain. This will support end-to-end translation of pharmaceuticals and novel therapies
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Keeping manufacturing facilities onshore will support small biotechnology companies, in particular, in becoming larger and more successful companies
Priority 4: Strengthen Australia as an attractive clinical trial research destination	Local manufacturing capabilities, particularly of novel therapies (e.g. regenerative medicines), will support the efficiency and cost-effectiveness of Australia's high-quality clinical trial sector
Priority 6: Position Australia as a preferred partner for international markets	Australia can capitalise on its strong reputation for high quality and use its niche manufacturing capabilities to position Australia as a desirable supplier of high-value therapies for the global market
Priority 7: Support advanced manufacturing as a part of the broader Australian innovation system	Establishing these capabilities will increase the value of the advanced manufacturing sector, provide unique job opportunities in the industry and strengthen the MTP innovation ecosystem

Megatrend	Description
The chronic burden	The pressure of the chronic burden is driving the rise of high-value pharmaceuticals and novel therapies as a preventative force going forward. Australia can focus on high-value rather than high-volume medicines
Precision healthcare	As precision healthcare continues to boom, Australia can establish its position in manufacturing novel therapies at a commercial scale and supply the global market
Global biosecurity	COVID-19 has highlighted the risk of not having a sovereign manufacturing industry. With an increasingly complex global supply chain, it would be prudent for Australia to have its own pharmaceutical manufacturing capabilities to reduce its dependence on the stability of the global market
Developing markets	Australia can leverage its high-quality facilities and production advantage to deliver sophisticated products to its densely populated neighbours and capitalise on their rapid growth
Healthy ageing	Solutions for healthy ageing will focus on preventing diseases which is likely to include novel therapies such as stem cell therapies. This presents a unique opportunity for the manufacturing sector to take the lead and support this increasingly important area

Other considerations

As discussed in **Chapter 1**, manufacturing of pharmaceuticals/biologics in Australia has historically been restricted by the high cost of labour, particularly when compared to the rest of Asia-Pacific[56].

This gap is compounded by the absence of financial and fiscal incentives offered by other countries (e.g. Ireland and Singapore) to attract manufacturing, in addition to structural factors such as price regulation on the PBS that have forced non-generics manufacturing offshore.[57,58] Significant government prioritisation and investment will be required before Australia's MTP sector can become a leader in manufacturing of next-generation therapies.

Addressing the gap

While addressing the structural issues will take a coordinated response from government and industry, there are some short-term opportunities that could develop the capabilities required.

[56] Stakeholder consultations

[57] The Productivity Commission, *Evaluation of the Pharmaceuticals Industry Investment Program: The Victorian Government Policy Contribution*, October 2002

[58] Ewen Levick, *Australian Defence Magazine*, Does Australia have a medicine supply problem?, 21 February 2020

Short-term opportunities could include:

- Graduate programs for students in relevant disciplines (e.g. medicinal chemistry) to work in pharmaceutical/biotechnology manufacturing would be valuable to develop a pipeline of people with niche, high-end manufacturing skills. Similar programs have been successfully demonstrated in Singapore and are considered a government priority.[59]
- Companies could work with the TAFE system and educational providers that have hands-on laboratory technology courses to implement modules that would prepare students for the workforce (e.g. to achieve GMP certification). These education providers could also support the establishment of traineeships/apprenticeships within these organisations.
- Within existing postgraduate courses, industry partners could sponsor students to work in an organisation as part of their degree, giving students a real-life understanding of process development alongside the research component.
- Greater focus on building the industry's profile among university students who may have a transferable skillset, such as pharmacy or chemistry. This could include offering short courses or manufacturing site visits to demonstrate the opportunities in the pharmaceutical/biotechnology sector.

Longer-term workforce development opportunities include:

- Forming a partnership between the AMGC and/or MTPConnect and education providers to develop recognised tertiary qualifications for advanced complex pharmaceutical manufacturing (e.g. Trinity College Dublin's Master of Science/Postgraduate Diploma in Pharmaceutical Manufacturing Technology).
- Coordinating placements in companies overseas to learn best-practice high-value pharmaceuticals manufacturing capabilities (e.g. Singapore). This could extend to a two-way system, where Australia supports the placement of overseas professionals into local companies to train and upskill the workforce.
- Leveraging the global visa talent program to recruit a highly skilled pharmaceutical manufacturing workforce from overseas. These professionals could then train and upskill the local workforce.

[59] Ministry of Manpower, Jobs Situation Report, August 2020

Theme: Business operations

This report identified a number of skills gaps under the theme of business operations, ranging from stakeholder management skills to the ability to think strategically and make long-term financial and commercial plans. However, only one skills gap was prioritised and is interlinked to product development and commercialisation.

Skills gap #4: Shortage of MTP-specific project managers to support start-ups and spin-offs

Overview of the skill

Effective project management practices are vital for the successful development and commercialisation of products, particularly in early stages of business operations. Start-ups/spin-offs, generally those that are led by clinicians or researchers, require project managers who effectively act as 'business operators' during the early stages of the business.

A project management professional operating in the MTP sector is generally required to have a broader skillset than a traditional project manager, requiring both rigorous technical and commercial knowledge. The project manager is typically appointed by the business/venture capital (VC) fund and is involved in managing the day-to-day operations of the business, which can range from coordinating high-level processes and inputs along the product commercialisation pathway to negotiating agreements with customers and manufacturers.

Description of the skills gap

There is a shortage of project management professionals who can oversee an early-stage MTP company and have a holistic understanding of the MTP sector and the product development pathway.

These specific skills include:

- strong technical/medical science background with operational skills such as, but not limited to:
  - awareness of regulatory and reimbursement requirements as relevant to the product
  - ability to identify and apply for grant applications to support R&D
  - navigate agreements with multiple parties (e.g. inter-institute grants, commercial R&D co-development)
  - ability to manage a budget/P&L
  - ability to identify manufacturing partners where relevant.
- ability to identify processes that can and need to be done in parallel, as well as anticipating when and from whom to seek advice or expert input
- a very strong understanding of the commercial environment that the business operates in
- ability to manage multiple stakeholders and sensitive intellectual property portfolios.

It can be difficult for people in early-stage businesses to acquire the necessary 'on-the-job' project management skills. Further, project managers who prefer to work in multi-asset businesses with a pipeline of opportunities are not typically attracted to these early-stage businesses because they tend to be built around a single asset (e.g. single molecule/device) and are inherently riskier.

Australia's nascent entrepreneurial ecosystem means that there is a shortage of professionals with this specific skillset. This contributes to a lack of coherent talent development in that space and therefore a thin pipeline for future project managers.

Impact of the gap

This gap primarily impacts start-ups/spin-offs and therefore in many cases the VC funds that capitalise and manage these early-stage companies.

This role is critical for efficient and effective business operations, fundamentally for the very early-stage companies that are most vulnerable to failure. Absence of a project manager for an MTP company creates inefficiencies across the value chain and longer to-market timelines as a result. In addition to delaying patient access to therapies and devices, long development processes (e.g. in early-phase drug development) means that any misstep in timing or management of rate limiting activities can have a significant financial cost.

Companies with this gap tend to manage by placing an academic in the role and using the investment manager to provide the business acumen, but this is not a sustainable or effective solution in the long-term. When an investment manager assumes the role and/or carries out training for a new project manager, this is attached to the significant opportunity cost of seeking new deals.

Alignment with Sector Priorities and Megatrends

Although this skills gap is not directly aligned with specific megatrends due to its general nature, it is an important one that underpins four MTP Sector Priorities.

Sector Priority	Description
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	Expertise in project management can improve commercialisation outcomes as effective project management practices are critical to taking a product through the product development pathway successfully
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Developing project management expertise is critical in early-stage MTP companies and SMEs to foster effective and efficient business operations, particularly through a strong, holistic understanding of the commercial environment
Priority 5: Support the development of digital healthcare solutions – devices and data analytics	As the industry moves towards digital healthcare solutions, future development in this space can be assisted through having a strong project manager that has up-to-date experience in digital product development pathways
Priority 7: Support advanced manufacturing as a part of the broader Australian innovation system	Developing strong project management skills that can progress a product from concept to manufacturing will contribute to increasing the value of the advanced manufacturing sector

Addressing the gap

In the short term, the sector could benefit from leveraging existing, or implementing new, project management courses specifically tailored to the MTP sector. Content in such courses could give an overview of the product life cycle and expected timelines, validation and feasibility studies, regulatory strategy, clinical evaluation, risk management, and documentation and records management.

In the longer term:

- Traineeships, graduate programs or Qualified Professionals Programs could be offered in VC firms or top-tier Technology Transfer Offices (TTOs), for participants to gain exposure to the role and skills required. These participants could include appropriate clinicians/early-career researchers, MBA graduates with a science/technical background. The traineeships would be designed such that they give the participants the opportunity to learn these project management skills in a safe, low-risk environment so they can come out as skilled project managers to contribute to the MTP ecosystem.[60]
- The sector could leverage and expand existing programs to cover relevant project management content, such as the steps required to manage medical device project cycles (e.g. regulatory strategy, risk management, clinical evaluation).
- The global visa talent program could be leveraged to recruit highly skilled project managers from overseas. These professionals could then train and upskill the local workforce.

[60] Stakeholder consultations

Theme: Clinical trials

Australia is globally regarded as an attractive destination for clinical trials.[61] The research environment is underpinned by high-quality scientists, physicians and healthcare professionals, world-class clinical trial research infrastructure and globally competitive R&D tax incentives.[62]

Addressing priority skills gaps in this theme will strengthen Australia's workforce in the clinical trials sector and enhance its reputation as an attractive clinical trial destination.

Skills gap #5: Strategic design of clinical trials to meet regulatory and payer needs

Overview of the skill

It is critical that MTP investigators and companies have the capabilities to design clinical trials with the end goal of regulatory and payer approval considered from the earliest stages of product development.

These capabilities include ensuring that clinical trials are designed to meet regulatory guidelines and frameworks. In the likely scenario that businesses seek approval outside of Australia (e.g. FDA and European Medicines Agency (EMA)/CE Mark approval), these overseas requirements must also be considered and incorporated into the clinical trial design. This skill also extends to a deep understanding of the level and type of clinical evidence needed to satisfy relevant reimbursement criteria.

Description of the skills gap

Despite excellence in the clinical research environment, there is a notable skills gap in clinical trial design for optimising market access and beneficial commercial outcomes amongst investigators – within research institutes as well as amongst MTP start-ups/SMEs.

These specific skills gaps include:

- inadequate expertise in strategically designing clinical trials that consider the downstream requirements for regulatory and reimbursement approvals from an early stage
- lack of understanding of the level and type of clinical evidence required by regulatory and reimbursement agencies to demonstrate efficacy and 'cost-effectiveness' of the intervention.

Stakeholder consultations have indicated that start-ups and SMEs tend to focus heavily on product design and prototype development in the first instance and regulatory affairs requirements are, at best, a secondary consideration. The path to late-stage clinical trials and regulatory approval is complex and expensive and SMEs tend to lack the expertise – or access to such expertise – to appropriately anticipate regulatory and payer requirements when designing their clinical trial programs. This skills gap is further observed in companies undertaking innovative clinical trials (e.g. complex first-time-in-human trials) as well as for novel therapies and digital health applications where regulatory requirements are less understood.

[61] MTPConnect, *Clinical Trials in Australia*, June 2017

[62] Austrade, *Clinical Trials Capability Report*, January 2018

Impact of the gap

Large pharmaceutical and medical technology companies are typically experienced at strategically designing clinical trials and can leverage global networks and expertise when required. However, the skills gap relating to strategic design of clinical trials is particularly evident amongst research institute-based investigators and within start-ups and SMEs across the MTP sector. With clinical trials currently contributing over A$1 billion to the Australian economy, improving the quality and efficiency of these clinical trials through more strategic early-stage design will further increase the value to the economy.[63]

If the results from a clinical trial prove to be insufficient for regulatory approval, this results in wasted time, effort and resources. Stakeholder consultations have emphasised that many SMEs and start-ups often have to conduct additional work after receiving feedback from regulatory bodies such as the TGA/FDA or potential licensing partners in order to collate the necessary clinical evidence required for approval. Furthermore, a significant amount of patent life (sometimes up to three years) may be wasted if clinical studies are conducted without proper consideration of regulatory requirements. It is also important that businesses strategically design their trials to align to regulatory and reimbursement requirements simultaneously.

Improved capabilities in strategic clinical trial design by start-ups and SMEs across the sector will drive faster and more effective commercialisation of therapeutics and medical devices. Sophisticated clinical trial designs that incorporate regulatory and reimbursement needs for both domestic and international markets are also likely to facilitate earlier market access to potentially lifesaving therapies and devices and earlier revenue generation.

[63] MTPConnect, *Clinical Trials in Australia,* June 2017

Alignment with Sector Priorities and Megatrends

The ability to strategically design clinical trials is aligned with three Sector Priorities and two megatrends.

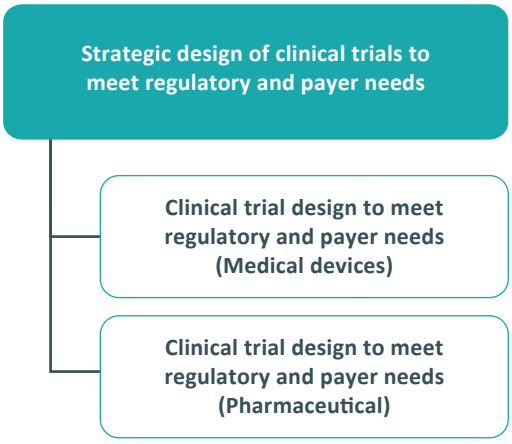
Sector Priority	Description
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	Clinical trials that are strategically designed to meet regulatory and reimbursement requirements will increase commercialisation outcomes throughout the ecosystem
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Strategically designed clinical trials will enable the SME sub-sector to increase their chances of commercialising their products
Priority 4: Strengthen Australia as an attractive clinical trial research destination	More efficient design of clinical trials will enable greater throughput and strengthen Australia's reputation as an attractive clinical trial destination

Megatrend	Description
Digital evolution	As the sector moves towards a digital era and regulations evolve alongside it, keeping abreast of regulatory requirements to inform clinical trial design will become increasingly important
Precision healthcare	The emergence of precision medicine is driving demand for novel and patient-centric therapies, for which clinical trials will need to be carefully designed to maximise regulatory and reimbursement outcomes

Addressing the gap

The REDI initiative has already taken steps to address this skills gap. An RfP was released in November 2020 to seek proposals for two courses: one specific to the pharmaceutical industry and the other specific to medical devices.[64]

These programs will be targeted at educating relevant stakeholders including start-ups, SMEs (particularly leaders with responsibilities for appointing clinical trial partners or strategy development), commercialisation executives, clinicians and researchers.



[64] MTPConnect, REDI Contestable Program Round 1 Guidelines, November 2020

Skills gap #6: Shortage of experienced clinical research associates (CRAs)

Overview of the skill

Clinical research associates (CRAs) are primarily employed by Contract Research Organisations (CROs) and pharmaceutical companies and serve as a liaison between the study's sponsor and the sites where the studies are conducted. CRAs have several responsibilities, such as ensuring trial sites are set up and staff are trained appropriately to conduct the trial, verifying compliance with clinical trial protocol, ensuring accurate data collection and communicating with investigators, clinical research coordinators and clinical trial staff.

In order to succeed in their roles, CRAs require a unique skillset that combines a scientific background with strong stakeholder management skills to engage with industry and clinical staff and excellent project management skills. Junior CRAs are typically more involved with verifying data and collating documentation while senior CRAs will often manage multiple trials, keep investigative reports and provide project communications to other stakeholders, as well as mentoring and training junior staff.

Description of the skills gap

There is a significant shortage of experienced CRAs, particularly at the senior level, in the Australian clinical trials ecosystem.[65] Stakeholder consultations have highlighted that this shortage stems from two key factors: it takes a lot of time and effort to develop experienced CRAs and there is a high turnover rate among CRAs.

- Time and effort taken to develop CRAs: Australia has a sufficient and growing supply of graduates with relevant science degrees that can provide a source for entry-level CRA roles. A typical CRA job posting may attract 200 to 300 applicants, most of whom would only have minimal or no prior experience in clinical trials. Stakeholder consultations have indicated that training entry-level CRAs can take anywhere between six months and two years before they gain sufficient experience to be able to manage a variety of different trials.
    - Many pharmaceutical companies and CROs have consequently developed internal training programs to provide on-the-job training. For example, Pharmaceutical Product Development (PPD), a world-leading CRO, is widely acknowledged as having one of the top CRA training programs in the industry.[66,67] PPD puts its entry-level CRAs through an internal seven-week CRA Academy that covers comprehensive theoretical knowledge as well as hands-on activities and scenarios to simulate the tasks required on the job. The award-winning competency-based program has produced 1,000 graduates around the world since its inception in 2013.[68] However, developing and running such training programs is expensive and often beyond the reach of smaller local CROs.

[65] Stakeholder consultations
[66] Brandon Hall, Winners of the 2020 Brandon Hall Group Excellence in Learning Awards, 2020
[67] BioSpace, PPD Clinical Research Associates Honored for Excellence in Global Competitions, May 2019
[68] PPD, CRA Academy celebrates 1,000 graduates, October 2020

- High turnover rate among experienced CRAs: This occurs because (a) the CRA role is demanding in terms of travel requirements and intensity of work leading to a desire for a more sustainable role for some employees, and (b) the skills acquired and the intensive hands-on experience gained in their first few years results in employees being able to progress to more senior roles (e.g. project management) or to other roles within industry. CRAs typically find that their skillset is valuable and can attract higher compensation elsewhere after three to five years' experience in the role.[69] Additionally, the turnover of CRAs is a global issue, with CROs experiencing an average turnover rate of 16 percent.

Impact of the skills gap

As the predominant employer of CRAs, pharmaceutical companies and CROs are impacted by the shortage of experienced CRAs in three ways:

- A lack of experienced CRAs limits the number of clinical trials that organisations can effectively support, which carries the risk of constraining growth in Australia's clinical trial sector.
- The extensive on-the-job training programs for entry-level CRAs to provide them with necessary experience is a significant cost to the business (including the resource allocated to train the entry-level CRAs), where the return on training investment is compromised by high turnover rates of experienced CRAs.
- The pervasive shortage of CRAs means that the loss of a CRA can disrupt clinical trials, as well as damage the reputation of a CRO and relationship with the trial sponsor and sites.

Between 2016 and 2019, the number of clinical trials in Australia grew by five percent p.a. to a total of 1,820 trials. As the sector continues to expand, CRAs will be required to support this growth. A shortage of experienced CRAs in the sector limits Australia's ability to expand the number of clinical trials carried out locally, consequently constraining the economic and health benefits that flow to Australians.

Historically, some pharmaceutical companies and CROs have recruited CRAs from overseas markets in order to overcome the shortage in local talent. However, recruitment of overseas talent has been severely constrained by the international travel restrictions in place as a result of the COVID-19 pandemic. The sector is unlikely to be able to rely on overseas talent for the near future as international travel is not expected to return to pre-pandemic levels until 2024 at the earliest.[70] Therefore, to maintain or increase the sector's strong growth trajectory it is imperative to develop and retain experienced CRAs locally.

[69] BDO, *2019/2020 Insights Report: CRO Industry*, 2020

[70] IATA, Recovery Delayed as International Travel Remains Locked Down, 28 July 2020

Alignment with Sector Priorities and Megatrends

This skills gap underpins three MTP Sector Priorities as outlined below:

Sector Priority	Description
Priority 1: Align investment in KPs that meet current and future market needs	For Australia to successfully pursue a globally competitive position in its KP areas, it requires robust clinical trial capabilities, which includes a strong CRA workforce
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	High-quality, efficient, and on-time clinical trials is an essential capability for small enterprises seeking approval for their therapies and to grow into a large, successful company
Priority 4: Strengthen Australia as an attractive clinical trial research destination	Without a strong and stable workforce of highly skilled CRAs, Australia risks damaging its reputation as an attractive clinical trials destination and will lose out to better-equipped countries

In addition, clinical trials are a critical step in the advancement of R&D to the clinic and a key component of the pre-production phase of the MTP sector value chain. Establishing a strong supply of CRAs is important to ensure there is sufficient workforce capacity to conduct clinical trials that will eventually lead to commercialisation of new products.

Addressing the gap

In the short to medium term:

- This skills gap can be addressed by expanding the pool of junior CRAs and providing subsidised training for them. Doing so will allow for a larger cohort of senior CRAs to be developed over the next two to three years. This could be achieved through paid traineeship/internship programs that last one to two years. Such programs would help reduce the cost of training these junior CRAs for CROs and pharmaceutical companies. The use of an external standardised training program would alleviate costs and resources otherwise required by CROs and companies to develop these materials.
- There may be an opportunity for the sector to deliver training programs to senior CRAs that develop their coaching/mentoring skills to allow them to train their junior colleagues more efficiently. These training programs could potentially leverage digital technologies/platforms to drive further efficiency in the training of junior CRAs.

In the longer term:

- An accredited training qualification would help alleviate organisations from having to resource training individually and provide greater consistency in training CRAs across the sector. Such a

training program could leverage global knowledge and resources through, for example, the Institute of Clinical Research and ARCS Australia.[71]

- These training programs will need to be endorsed by, and developed in consultation with, industry to ensure that the training is targeted, consistent and effective. The training should also provide on-the-job experience through placements/internships at CROs and/or pharmaceutical companies so that trainees develop real-world experience that will enable them to be more effective in their jobs.

Skills gap #7: Shortage of clinical trial coordinators (CTCs)

Overview of the skill

Clinical trial coordinators (CTCs) are responsible for the day-to-day running of clinical trials at sites and predominantly involves liaising with and monitoring patients. CTCs are the primary contact point during a trial and are involved from setting up the trial, to recruitment of patients, all the way through to follow-up assessments. CTCs need to be able to navigate the hospital system, understand the patient flow and be able to communicate with a range of stakeholders including patients, clinicians, other hospital staff, ethics committees and sponsors.

Other responsibilities include coordinating, managing and implementing activities for trial planning, recruiting and enrolling eligible participants and collecting and documenting patient data as required. CTCs require a strong, functional understanding of GCP principles and protocols.

Description of the skills gap

There is a shortage of CTCs in the Australian clinical trial ecosystem that can perform the diverse range of tasks required to enable successful clinical trial operations at the trial site.

This shortage stems from four primary factors:

- lack of awareness regarding the CTC role and career pathways in clinical research
- lack of clear education/training program dedicated to developing CTCs
- competition with industry (CROs and pharmaceutical companies) for trained CTCs
- difficulty in attracting talented individuals due to the short-term, per-trial nature of employment contracts.

Most CTCs come from a life sciences or healthcare background. Attracting graduates to apply for the role can be challenging as most undergraduate degrees give students little exposure to the clinical trial industry. Stakeholder consultations suggest that this lack of awareness extends until a graduate has spent significant time in a hospital environment.

Even professional programs such as nursing or pharmacy fail to adequately introduce career opportunities within clinical trials. Graduates also seldom have a fundamental grounding in GCP protocols, which can make it more challenging to transition into a CTC role.

[71] The Institute of Clinical Research website, accessed on 15 October 2020

Once they are in the CTC position, there is a lack of a clear career pathway within the hospital setting through the clinical trial sector. This means that hospitals tend to lose CTCs to industry, typically after they have reached the natural 'ceiling' after around five years in the CTC role.[72]

This shortage is mainly evident in small-to-mid tier sites. While most large hospitals can offer attractive incentives to attract and retain CTCs, this shortage means smaller clinical trial sites may be more likely to be limited in their ability to conduct clinical trials.[73]

Other considerations

Stakeholder consultations highlight that there are major structural issues in hiring CTCs as permanent employees, and instead they are commonly engaged as shorter-term contract positions. One reason is because clinical trial staff are budgeted for on a per-trial basis; another is because the variability of the clinical trial pipeline means a long-term contract at a clinical trial site cannot be confirmed.

Impact of the gap

With CTCs playing such a critical role in clinical trial operations, a shortage of CTCs is a major impediment to the volume and quality of trials that can be performed. Further, the shortage is cited as a common reason that clinical trials are not commenced at sites, with smaller sites most affected.[74] This shortage seriously impacts the success of Australia's A$1.1 billion clinical trial industry, as well as the associated economic and clinical benefits.[75] It is important to address this shortage in order to maintain and further enhance Australia's excellent reputation in clinical trials.

It is also important to note that the training offered for CTCs in Australia is consistent with the training needs for trial sites across the Asia-Pacific region. This means there is a potential for Australia to establish a CTC training hub that would attract talent from across the region as well as connect local talent with international opportunities. Australia could become a regional leader in developing high-quality CTCs, creating an opportunity to impact the sector beyond Australia.

Alignment with Sector Priorities and Megatrends

As in the case of **Skills gap #6: Shortage of experienced CRAs**, this skills gap underpins three MTP Sector Priorities.

[72] Stakeholder consultations
[73] Stakeholder consultations
[74] Stakeholder consultations
[75] MTPConnect, *Clinical Trials in Australia*, June 2017

Sector Priority	Description
Priority 1: Align investment in KPs that meet current and future market needs	For Australia to successfully pursue a globally competitive position in its KP areas, it requires robust clinical trial capabilities, which includes a strong supply of CTCs
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	A strong supply of CTCs is important in enabling high-quality, efficient, and on-time clinical trials. This is therefore an enabling capability for smaller enterprises to run successful clinical trials and obtain approval for their novel devices/therapies
Priority 4: Strengthen Australia as an attractive clinical trial research destination	Without a strong and stable workforce of highly skilled CTCs, Australia risks damaging its reputation as an attractive clinical trials destination and will lose out to better-equipped countries

Addressing the gap

In the short term:

- The industry should work to raise the profile of the clinical trial sector, the role and the career pathways. The lack of awareness of the CTC position reportedly begins at the undergraduate level and extends through to the level of practicing nurses and similar roles in hospitals.
- There is an opportunity for feeder programs (such as nursing) to provide education/awareness around different roles in the clinical trial industry and potential career paths that they could pursue, including as a coordinator.

In the medium term:

- The industry could also look to fund traineeships to encourage science and nursing graduates in particular to take up CTC roles within hospitals. To ensure the appropriate base level of knowledge, potential trainees could be required to complete a GCP course endorsed by a global training framework (e.g. TransCelerate).
- Accelerating the development of potential CTCs (e.g. aspiring nurses and clinical staff) could be achieved by subsidising on-the-job training to encourage a smoother transition to the role and minimising disruption to their clinical practice and incomes.

In the longer term, there is an opportunity to develop a national competency framework that standardises the training and development of CTCs.

Theme: Health data and cybersecurity

The skills gaps in this theme are strongly driven by global megatrends such as digital evolution, precision healthcare and consumer control. The MTP sector workforce of the future requires skills at the nexus of the technical data-facing world and the MTP/healthcare context to build clinician- and patient-centric solutions (e.g. the ability to design and use AI within MTP).

The skills gaps identified here (e.g. cybersecurity professionals) are also in high demand across other industry sectors such as financial services and retail. This means Australia must find ways to attract talent as well as provide continued learning opportunities to the existing workforce.

Skills gap #8: Leadership awareness of best-practice management in cybersecurity

Overview of the skill

The digital evolution of the healthcare system is delivering products and services tailored to individuals and certain groups of consumers with seamless digital connectivity and integration. As more of the sector becomes connected and more reliant on digital solutions, the greater the importance of cybersecurity management to protect private, highly personal and confidential research and product data captured and stored on digital systems.

Australia's Cyber Security Strategy, published in August 2020, noted that after government, the health sector recorded the second highest number of cyber incidents in the period July 2019 to June 2020.[76] In 2018, Australia implemented a new data breach notification law requiring companies to notify any individuals affected by a data breach, as well as reporting it to the Office of the Australian Information Commissioner. Since the start of this scheme, the broad health sector (including the MTP sector) has consistently reported the highest number of data breaches compared to any other industry.[77] A survey following the introduction of the law showed that nearly half of all Australian SMEs, including those from the MTP sector, did not consider themselves prepared for the new laws, further emphasising the scale of lack of leadership awareness on cybersecurity as a skills gap.[78]

It is critical for MTP sector organisations to understand the risks that cyber attacks can pose to their products and services (e.g. loss of sensitive IP, patient/consumer health information) and consequently, ensure their products and services are sufficiently protected from cyber attacks, and continue to align with evolving data protection and privacy regulations.

Description of the skills gap

Business leaders in the MTP sector tend to lack awareness about the importance, value and best-practice management of cybersecurity. Consequently, the implementation of measures to protect the rapidly growing amount of digital information across the MTP sector tends to be highly variable.

[76] Department of Home Affairs, Australia's Cyber Security Strategy 2020, 2018
[77] Office of the Australian Information Commissioner, *Notifiable Data Breaches Report: January–June 2020,* 31 July 2020
[78] ACA Research, *HP Australia IT Security Study,* 2018

These specific skills gaps include:

- a lack of awareness about the importance and value of cybersecurity amongst senior managers, executives and board members across the MTP sector
- skills required in adequate planning and management of cybersecurity risks, from clinical trial data, to formulations and chemical structures of medicines, to vulnerable medical devices (e.g. connected devices), to electronic medical results.

The skills gap relating to cybersecurity leadership awareness and management impacts the entire MTP sector but is most readily observed in the clinical and market segments of the value chain where research, intellectual property and patient data is most exposed. Senior managers, executives and company directors amongst start-ups and SMEs have been identified as key stakeholders where more work is required to raise awareness and experience in implementing best-practice management protocols to protect data and devices. This gap exists because leaders tend not to understand the tangible impact of cyber attacks unless they have experienced one themselves.

By contrast, large MTP companies, healthcare providers and government organisations tend to display better cyber maturity and more readily employ cybersecurity best practices. That said, these established companies and institutions are equally or at a greater risk of cyber attack as they often carry greater volumes of sensitive data. Those entities that have outdated, legacy IT systems are particularly vulnerable to malicious attacks.

Impact of the gap

The threat of cyber attacks on organisations, which impact patient safety, privacy and care delivery, has never been higher. In the past year, researchers working on COVID-19 vaccines, hospitals, laboratory testing companies and even government departments have all been targeted, resulting in several data breaches that exposed Australians' sensitive health data.[79] A 2017 study by Accenture found 16 percent of consumers surveyed had experienced a breach of their healthcare data, indicating the vulnerability of the sector and the urgency of a cybersecurity leadership problem.[80] The cost of failing to promptly address this skills gap can be severe. Cyber attacks on MTP companies can threaten consumer/end-user trust, erode the value of sensitive IP and cause significant financial losses and disruptions for companies.

The COVID-19 pandemic has further accelerated the world's transition to digital platforms and is changing how the public accesses healthcare, from digital prescriptions, to telehealth consultations and remote monitoring of patients in clinical trials. The sector is becoming increasingly reliant on digital tools and with that comes greater exposure to cyber risk. For customers to trust these new digital health services, companies need to ensure they have a greater focus on prevention and management of cybersecurity threats.

In addition, there is growing digital interconnectedness between medical records, prescriptions and consumer data from digitally enabled medical devices and wearables. It is vital for MTP sector organisations to collaborate with public and private healthcare providers and government in mitigating cybersecurity risks.

[79] Webber Insurance Services, The Complete List of Data Breaches in Australia, 2020
[80] Accenture Consulting, Consumer Survey on Healthcare Cybersecurity and Digital Trust, 2017

Alignment with Sector Priorities and Megatrends

Leadership awareness of cybersecurity directly affects three Sector Priorities and will continue to be driven by three primary megatrends going forward.

Sector Priority	Description
Priority 1: Align investment in KPs that meet current and future market needs	Robust and reliable cybersecurity practices are essential to strengthening Australia's capability in data science, which is a current MTP KP and a national priority
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Building awareness of cybersecurity among SME business leaders will enable them to embed cybersecurity principles and best practices within their business processes and products from an early stage
Priority 5: Support the development of digital healthcare solutions – devices and data analytics	Reliable cybersecurity protocols are critical for creating society-wide trust in digital healthcare solutions and are critical for broad-scale adoption

Megatrend	Description
Digital evolution	The ongoing development of digital health solutions comes with inherent risk, which must be carefully balanced to protect patient data and ensure patient safety
Precision healthcare	The growing demand for precision healthcare solutions involves the collection, storage, and analysis of patients' genetic data which is at high risk of malicious attack, emphasising the need for cybersecurity leadership, awareness and management protocols
Consumer control	Growing adoption of personal health technology (e.g. in-home sensors, wearables) increases personal data capture that demands best-practice security and safeguarding

Other considerations

Australia has taken substantial steps to provide standardised regulatory guidance on cybersecurity for medical devices and products. Publications by the TGA have included cybersecurity guidance for medical device manufacturers, consumers, health professionals and small and large businesses and have been broadly welcomed by the sector.[81]

[81] Therapeutic Goods Administration website, accessed on 5 February 2020

However, more work is needed to ensure stringent cyber-related regulations are in place. To support the continuing evolution of a robust regulatory framework, Australia could look to examples like the US National Cybersecurity Center, which has developed special publications that provide detailed 'how-to' guidance to help companies improve cybersecurity principles in the design of their products and platforms (e.g. wireless infusion pumps).

Addressing the gap

In the short term, there is an opportunity for MTPConnect to collaborate with AustCyber, the Australian Cyber Security Growth Network, to address this skills gap. There is a need to identify the key cybersecurity/resilience risks faced by Australian MTP companies to provide the basis for a targeted, integrated program to promote awareness of these risks within the broader sector through targeted forums and workshops that illustrate the reality and potential impact of cyber attacks on businesses.

Over the medium term, such a program would also support direct actions (bespoke cyber training programs and SME-level remediation initiatives) that will remediate the identified key risks and build cyber best-practice capabilities across Australia's MTP sector.

Skills gap #9: Shortage of cybersecurity professionals and IT infrastructure resilience skills within MTP

Overview of the skill

Cybersecurity and IT infrastructure resilience describes the tools, technologies, processes and practices that can be used to protect networks, equipment and data across the healthcare sector from unauthorised access or malicious attack.

The cybersecurity sector has a diverse range of technical and non-technical roles. The more common technical roles relate to building, operating, testing and maintaining secure IT systems. Newer, non-technical roles (such as risk management officers and government liaison officers) are more multidisciplinary and incorporate elements of law, risk, communications and psychology. A skilled cybersecurity professional may work across several of these different functional areas.

A nuanced understanding of the MTP sector is required to design, implement and test security protocols. For example, in the case of pharma, there is a need to understand the medicine supply chain to identify where there are vulnerabilities to malicious attack, between design of the drug and its delivery to patients. In the case of medical technology, there is a need to understand the interaction between legacy operational technology (OT) and new IT systems in hospitals and identify where an attacker could exploit a gap in a medical device connected to these systems.

Description of the skills gap

There is a capacity gap of cybersecurity professionals, especially those with knowledge of the MTP/healthcare sector.

These specific skills gaps include:

- supply of cybersecurity professionals that understand the unique context of MTP/healthcare systems and data

- ability to 'think like a hacker' and design and test appropriate precautions to safeguard systems, IP and patient data
- in the case of product development, the ability for these professionals to design and integrate cybersecurity safeguards at the beginning of a project, and continuously testing vulnerability throughout the process
- the awareness of and ability to adhere to cybersecurity regulations and legislation (both general and MTP/healthcare-specific) when developing products.

One factor contributing to the gap is that the pace of medical technology development and adoption of digital health initiatives has overtaken the content of traditional and training education courses. Alongside this, 'malicious actors' are becoming more sophisticated and creative at targeting the MTP/healthcare sector. This adds additional challenges to the already rapidly evolving sector.

Relative to other sectors, healthcare is considered to be average in terms of cyber maturity, but lags behind exemplar industries such as telecommunications.[82] Historically, the healthcare sector in Australia has been shown to invest 40 percent less in cybersecurity compared to the global average.[83] This is also reflected in **Skills gap #8: Leadership awareness about best-practice management in cybersecurity**. As a result, investment in creating a specialised MTP/healthcare cybersecurity workforce has not been a priority.

This gap affects discovery-phase clinicians/researchers, companies of all sizes across the sector, as well as healthcare organisations and government bodies. This gap puts Australian MTP companies, healthcare organisations and end-user privacy at risk from cyber attacks.

Impact of the gap

As the world becomes increasingly connected, demand for cybersecurity professionals continues to increase and now far exceeds supply. In Australia, there is a severe shortage of job-ready cybersecurity workers, with an estimated additional 17,000 workers needed by 2026 across all sectors.[83] All job market indicators demonstrate that cybersecurity is facing major labour constraints, presenting a particularly challenging issue for the MTP sector, which is contending with skills gaps in leadership awareness of cybersecurity. For example, analysis of SEEK jobs data showed that while the number of cybersecurity job advertisements placed grew by 38 percent from 2017 to 2019, the number of job applications for cybersecurity jobs only grew by 10 percent in the same period.

As identified in **Skills gap #8: Leadership awareness about best-practice management in cybersecurity**, insufficient cybersecurity protocols can lead to exposure of patient data, exploitation of vulnerable medical devices, significant financial and productivity losses and threaten consumer and end-user trust. The healthcare sector will always be a target, so it is critical to address this gap and increase the resilience of the sector.

This gap has a tangible economic impact. In 2017, it was estimated that the workforce shortfall in the domestic cybersecurity sector may have forfeited up to A$405 million in revenue. Going forward, the cybersecurity sector has the potential to triple in size to A$6 billion of revenue and employ up to 32,000 people by 2026.[83]

[82] Stakeholder consultations

[83] AustCyber, Australia's Cyber Security Sector Competitiveness Plan, 2019

Alignment with Sector Priorities and Megatrends

The shortage of cybersecurity professionals in the MTP/healthcare space impacts three Sector Priorities and will continue to be driven by three primary megatrends going forward.

Sector Priority	Description
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	A supply of MTP/healthcare-specific cybersecurity professionals that can assist SMEs in implementing specific protocols is important to strengthening their resilience to cyber threats and protecting valuable data and information
Priority 5: Support the development of digital healthcare solutions – devices and data analytics	Reliable cybersecurity protocols are critical for creating society-wide trust in digital healthcare solutions and are crucial for wide-scale adoption. An MTP-literate cyber workforce is key to achieving this
Priority 7: Support advanced manufacturing as a part of the broader Australian innovation system	As devices become more technologically sophisticated and increasingly connected, Australia needs a stable supply of skilled cybersecurity professionals that can ensure the appropriate protocols and safeguards are embedded during the manufacturing process of these devices

Megatrend	Description
Digital evolution	The ongoing development of digital health solutions comes with inherent risk. This risk must be proactively identified by product developers and mitigated to protect patient data and ensure patient safety
Precision healthcare	The growing demand for precision healthcare solutions involves the collection, storage, and analysis of patients' genetic data which is at high risk of malicious attack, emphasising the need for implementing robust cybersecurity safeguards into databases and related tools
Consumer control	The growing adoption of personal health technology (e.g. in-home sensors, wearables) increases personal data capture that demands embedding top-quality data security protocols into the design of such products

Other considerations

This area has been historically overlooked in terms of investment priority. The Australian Government's 2020 National Strategic Priority for cybersecurity is a positive start and identifies the urgent need to address cybercrime. However, there needs to be a greater focus and investment to specifically build these capabilities in the MTP workforce.

Addressing the gap

In the short term:

- Increasing awareness among university students could be done in conjunction with sponsoring internships or traineeships within MTP companies for graduates or final-year students. Less than half of IT students in Australian universities have the opportunity to do an industry placement, which hinders students in being 'job-ready' upon graduation.[84] Supporting higher education providers to place students in the MTP sector during their study would provide a long-term benefit to the sector.

In the medium term:

- The sector could work to attract people with transferable skills (e.g. IT) to transition into MTP cybersecurity roles. This could be achieved by partnering with AustCyber to run an upskilling program to give them a systems-level overview of the sector and prepare them for work in this specialisation.
- AustCyber has coordinated the establishment of several cyber-specific degrees, certificates and diploma-level courses to boost the number of graduates in the sector. The MTP sector should work with experts such as AustCyber to incorporate MTP-specific teaching modules into cybersecurity programs so students have an understanding of the sector before they enter the workforce. These programs could integrate the aforementioned professional cybersecurity internships or placements within industry (e.g. in a hospital or medical technology company).

Skills gap #10: Understanding of and expertise in big data capture, management and analysis

Overview of the skill

'Big data' is an overarching term that describes a voluminous amount of data that can be mined for information, characterised by the 'three Vs': high volume, high velocity and high variety. The MTP sector has the potential to capitalise on the reams of data generated across a variety of different settings; from patients' comprehensive genetic profiles to modelling of clinical trials data to develop adaptive trials for novel therapies to self-generated consumer/patient data from wearable devices. This data can then be used in myriad ways to aid rapid product development; prevent, treat and cure disease; as well as drive healthcare policy decisions.

Effective capture, management and analysis of big data requires a collection of interdisciplinary skills including data science, systems and data architecture, data security and governance, data visualisation and communication skills. In the MTP sector, analysts need to understand the whole life cycle of the data, from acquisition to application, as well as the clinical or biological context in which they operate, in order to draw coherent and meaningful insights. Analysts also need to be able to handle and de-identify sensitive data and adhere to data governance frameworks.

[84] AustCyber, Australia's Cyber Security Sector Competitiveness Plan, 2019

Description of the skills gap

While demand for data analysts and data scientists is high across all sectors, there is a shortage of analytics skills specific to the healthcare/MTP sector. Further to this, there is a general lack of understanding by other stakeholders in the value chain regarding the numerous applications of data and analytics.

These specific skills gaps include:

- A lack of awareness and understanding in a) middle management up to board-level executives and b) clinicians, of the importance, value and possible use cases of data and analytics in their organisations. This extends to identifying the need to build up data analytics capabilities among their respective workforces.
- A shortage of data 'influencers' who can demonstrate and communicate the value of these analytics, in order to build buy-in for more sophisticated data capabilities within these organisations. This requires a unique mix of technical, clinical and commercial acumen in order to translate technical findings into clinically relevant and commercially feasible outcomes.
- A shortage of data scientists, analysts and systems architects that can perform big data integration, visualisation and interpretation in the MTP context:
    - These roles are complex and require an understanding of the challenges of biological and clinical data, as well as the healthcare context and how to deploy these skills in the required setting (e.g. understanding the role of data in adaptive clinical trials).
    - This requires an understanding of data governance, privacy and de-identification and applicable state and federal legislation when working with the data.
    - Further, they require the ability to work in interdisciplinary teams and communicate to a range of stakeholders, including understanding the priorities and needs of clinicians.

Globally, demand for data scientists has skyrocketed and is one of the fastest-growing jobs in the world.[85] Analysis of SEEK data from 2017 to 2019 supported this trend as data scientist job advertisements rose by 36 percent during this period. While some education providers have adapted and introduced more courses, the traditional tertiary education model cannot produce sufficient graduates to meet the demand.

There are a wide variety of job opportunities available to individuals with skills in data science and analytics. The most popular industries include technology, finance and retail, where data science capabilities are commonly used to understand customers, increase sales and optimise supply chains. In the world of data analytics these dynamic and fast-paced sectors are viewed as attractive to people with data science skills, further exacerbating workforce shortages for companies in the MTP sector.

In contrast to these consumer-facing sectors, the healthcare sector has been slower to adopt digital innovations. Consequently, MTP innovation suffers from slow adoption and utilisation of data analytics which, in turn, compounds the shortage of data skills within the MTP sector.

[85] Deloitte Access Economics, *The future of work: Occupational and education trends in data science in Australia*, February 2018

Impact of the gap

The global market for data analytics in healthcare is expected to grow at 14 percent p.a. between 2019 and 2025 to reach a value of US$39 billion. Prioritising the local development of these skills could realise a significant economic opportunity for Australia.[86]

This skills gap impacts companies and organisations of all sizes across the MTP sector. It is most evident within medical technology and digital health companies that are building smart devices, as well as patient-/consumer-facing organisations such as hospitals and CROs. While start-ups and SMEs might be more agile in how they recruit data analysts, they are still sourcing data science talent from the same pool as large MTP MNEs and are equally affected by the skills shortage. Training an established data scientist to understand the nature and nuances of healthcare data can take 12 to 18 months, which requires a considerable investment of resources.[87]

The opportunity cost of limited data and analytics expertise in the Australian MTP/healthcare sector is significant. The application is broad, touching upon all aspects of the value chain and sub-sectors and across a range of stakeholders.

A few examples of the benefits of this skillset include:

- From a public health perspective, analysts during COVID-19 developed complex epidemiological models to guide the government's public health response.[88] These capabilities are critical to maintain and develop in order to analyse disease patterns and predict outbreaks in the future.
- In the clinical setting, the use of data can also help the medical community prioritise high-value interventions (e.g. certain medicines, diagnostic tests) and identify low-value care, which can assist clinicians with their choice of intervention.
- Analysis of rich patient phenotype data can improve pharmaceutical R&D, accelerating market access for new treatments. Examples of potential benefits in clinical trials include improving patient selection, analysing patient records in near real-time and enabling high-resolution observational cohort studies.[89]
- On a population level, the large-scale deployment of data analytics can translate into actions and services that could improve population health management (especially chronic disease management).
- From an economic perspective, the analysis of real-world evidence could help ensure the highest-value treatments are appropriately funded through the MBS and PBS. With fewer than five percent of MBS items assessed for safety and cost-effectiveness against contemporary evidence, big data analytics could be used to review the system and ensure high-value items are funded and obsolete items are deprioritised.[90]

[86] Valuates Reports, *Global Healthcare Big Data Analytics Market Size, Status and Forecast 2018–2025*, April 2020
[87] Stakeholder consultations
[88] Steve Singer, Government News, How big data is powering Australia's COVID-19 response, 27 April 2020
[89] The McKell Institute, *Big Data, Big Possibilities: How Australia can use big data for better healthcare*, 2016
[90] Australian Government, Senate Select Committee on Health, Sixth Interim Report, *Big Health Data: Australia's big potential*, May 2016

Alignment with Sector Priorities and Megatrends

This skills gap is closely coupled with **Skills gap #9: Expertise in the design and use of artificial intelligence**. Addressing these skills gaps would set the sector up for success in the following five Sector Priorities. Furthermore, demand for capabilities in AI and big data capabilities will be driven by the six megatrends below.

Sector Priority	Description
Priority 1: Align investment in KPs that meet current and future market needs	AI and big data can be deployed in a plethora of ways to help Australia succeed in its KP areas, from accelerating drug discovery to turning patients' smartphones into POC diagnostic tools
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	As seen in large-scale enterprises, SMEs could implement AI technologies and data analytics to streamline their business operations and improve their performance
Priority 4: Strengthen Australia as an attractive clinical trial research destination	The adoption of AI technologies and data analytics in clinical trials could inform intelligent trial design, improve patient selection and compliance, and increase trial effectiveness, all of which strengthen Australia's position as an attractive clinical trial destination
Priority 5: Support the development of digital healthcare solutions – devices and data analytics	The development of digital devices and data analytics capabilities can be greatly enhanced by incorporating and leveraging AI technology to better understand biological and patient data
Priority 7: Support advanced manufacturing as a part of the broader Australian innovation system	Integrating AI technologies and data analytics into Australia's MTP manufacturing sector will bolster the manufacturing ecosystem, maximise efficiencies and expand the value and capabilities of the sector

Megatrend	Description
Digital evolution	The digital enablement of the healthcare landscape is driving the use of AI and big data analytics. It is changing everything from the way healthcare data is exchanged and processed, to the development of increasingly sophisticated tools to generate healthcare insights
Precision healthcare	The computational power of AI and data analytics can be used as a tool to analyse and interpret complex medical data in order to predict patient treatment outcomes and disease risks
Integrated care models	Implementation of AI and data analytics technologies can support a connected healthcare ecosystem that will help shift the emphasis from individual care episodes to ongoing patient management
Value-based healthcare	AI and data analytics techniques can be used to drive value-based healthcare by using analytical insights from patients, populations, and the healthcare ecosystem
Global biosecurity	AI and data analytics have played a pivotal role during the COVID-19 pandemic, being used for a range of applications such as informing governments' public health responses, accelerating analysis of genomic data and supporting clinicians' diagnoses from CT scans
Consumer control	The shift to consumer-centric care – from Electronic Health Records (EHRs) to wearables – is generating reams of big data that can be harnessed to offer personalised care and improve individual health outcomes

Other considerations

Australia's healthcare system is a large, fragmented and complex network with information captured and held by a range of public and private stakeholders. One of the biggest barriers that Australia faces in building its data and analytics capabilities is access to these established data sets. There are several pieces of legislation, such as the *National Health Act 1953* and the My Health Records Act 2012, that impact the utilisation of existing data.

Within the public system alone, hospitals are not required to release their data to their state authority. At the next level, datasets captured by states and territories are not linked to national datasets. Further, national databases (e.g. the MBS and PBS databases) are not linked with each other.

Addressing the gap

In the short term, in order for the MTP/healthcare sector to move forward in the field of data and analytics, there is a need to address the lack of awareness across the different stakeholder groups.

- At the leadership level of companies and healthcare providers, short courses or workshops are needed to educate them around the potential societal and commercial value of data and analytics for their organisations.
- For clinicians, there is a need to increase awareness of what data science and analytics can bring to their research and practice. This could include demonstrations of available technologies.
- For university students in relevant programs such as IT and computer sciences, the MTP sector should work to increase the profile of employment and career opportunities in the industry.

In the medium term:

- Sponsoring internships or graduate programs within MTP companies for graduates or final-year students would help increase awareness of opportunities in the MTP sector.
- In partnership with education providers, the MTP industry could help their existing workforce upskill by offering access to training such as micro-credentials in data and analytics (e.g. Torrens University Australia has partnered with IBM to deliver degree programs and micro-credentials in cloud computing and AI).
- For people outside the MTP sector who have an active interest in health and medical research and technology, these programs could be tailored to offer MTP-specific modules (e.g. case studies to analyse available EHR data, genomics databases) to give people exposure to the healthcare context.
- On the clinician side, there is the potential to embed data or digital fellowships within clinician training. This concept has been successfully demonstrated in the US (Stanford) and in the UK (through the National Health Service (NHS) and the Topol Programme) to accelerate knowledge transfer between disciplines.[91]

In the longer term:

- Education providers could develop postgraduate programs in health data science to build the hybrid skillset and produce job-ready graduates for the MTP workforce.

Skills gap #11: Expertise in the design and use of artificial intelligence within MTP

Overview of the skill

Artificial intelligence (AI) describes a collection of technologies that aim to mimic human cognitive functions. These technologies include, but are not limited to, natural language processing, machine learning, data-based diagnostic tools and speech recognition. The use of AI and deep learning offer a range of potential benefits, from improved diagnosis to enhanced clinical workflow management.[92] There is an early focus on specialty areas such as clinical radiology, which presents significant opportunities in areas of radiation oncology and metabolic imaging.

[91] Stakeholder consultations

[92] The Royal Australian and New Zealand College of Radiologists, *Artificial Intelligence in Radiology and Radiation Oncology: The State of Play 2019*

A successful AI project within the MTP/healthcare setting requires a combination of technical expertise, an understanding of the underlying biology and a deep understanding of the end use-case clinical application. This skillset incorporates:

- the underpinning skills in software engineering and machine learning
- working knowledge of the digital health regulatory frameworks and guidelines (domestic and international)
- a nuanced understanding of clinical workflow where applicable.

Description of the skills gap

There is a capability gap in the design and use of AI specifically for the MTP and adjacent healthcare sector.

These specific skills gaps include:

- AI engineers tend to lack a deep understanding of clinical workflow and an understanding of the nuances and complexity of working with healthcare data (e.g. data management, privacy issues, differences due to population, modality, disease indication) – related to **Skills gap #10: Understanding of and expertise in big data capture, management and analysis**.
- AI engineers also lack sufficient understanding of MTP/healthcare regulatory frameworks relating to application of AI and ability to design and implement technical solutions efficiently (e.g. ensuring platforms meet ISO standards; demonstrating data generalisability to local and international regulatory agencies) – related to **Skills gap #13: Awareness and understanding of regulatory requirements among start-ups and SMEs**.
- Stakeholders have also highlighted that MTP organisations struggle to effectively bring together interdisciplinary teams of clinicians, engineers and commercial experts as there is a lack of urgency among senior leadership to prioritise AI capability development. Only 23 percent of Australian health executives reported being focused or highly focused on AI (the lowest rate among OECD countries).[93]
- Lack of awareness at the clinician level (as primary users of the technology) for its potential applications.

This gap is widely acknowledged. A 2018 global Deloitte survey identified that 72 percent of executives in Australia's overall AI sector (not just limited to MTP) believe there is a moderate-to-extreme skills gap in AI, higher than the global average of 68 percent.[94]

Stakeholder consultations have highlighted that while there are several high-quality software engineers with skills in machine learning and AI, there is a significant capacity gap in the workforce of people who can develop and implement custom AI solutions for the MTP sector. One reason for this is that the technical expertise largely resides in universities with minimal exposure to the MTP context. As a

[93] Accenture Consulting, *Injecting intelligence into healthcare – Accenture Executive Survey on AI in healthcare Australia*, 2018

[94] Jeff Loucks, Susanne Hupfer, David Jarvis and Timothy Murphy, *Future in the balance? How countries are pursuing an AI advantage: Insights from Deloitte's State of AI in the Enterprise*, 2nd Edition survey, 1 May 2019

result, research projects tend to be more of an academic exercise rather than focusing on a clinically implementable end-product. Therefore, for PhDs and postdoctoral researchers to be considered 'job-ready' – when they transition into industry from an academic path – they require upskilling in both commercial and clinical aspects of technology deployment.

Those who possess AI skills are typically attracted into sectors that aggressively pursue AI capabilities, like financial technology. Compared to such industries, healthcare is viewed as less attractive due to the specialised clinical knowledge required and perceived regulatory constraints surrounding data use.

The talent pool is much smaller for medically trained professionals who are skilled in building and implementing AI technologies. This coveted hybrid skillset is not currently part of any formal clinical training program in Australia. Additionally, this cohort may not be aware of alternative career paths that involve AI in MTP/healthcare.

This capacity gap impacts companies of all sizes across the MTP sector, as well as research-led healthcare providers that are driving the deployment and commercialisation of AI. For example, several large pharmaceutical companies are investing heavily in internal, AI-based R&D projects, with companies like Novartis establishing their own in-house AI Innovation Lab.[95] Larger companies are able to source this talent from the global market; however, a deep talent shortage is evident in the local start-up and SME ecosystem that is developing tailored algorithms and tools for the Australian MTP/healthcare sector (e.g. Harrison.ai).

Impact of the gap

The global AI health market is growing at 45 percent p.a. and is estimated to reach US$45.2 billion by 2026, which represents a significant commercial opportunity for Australia.[96]

This capacity gap means Australian clinicians, patients and hospitals are missing out on benefits that could be realised from advances in AI and deep learning. While the industry is very nascent in Australia, there are a few local examples that illustrate such benefits. One example includes an MRFF-funded A$2.3 million research study led by St Vincent's Hospital and St Vincent's Institute of Medical Research, which is using AI to help improve and transform current methods in breast screening, benefiting thousands of Australian women.[97] Another example of AI use is the Queensland Government's use of CSIRO's Patient Admission Prediction Tool to forecast demand on hospital resources with a view to cutting patient waiting times. It has been estimated that this could deliver efficiencies worth A$23 million per year if implemented across the Australian healthcare system.[98]

If implemented and embraced to its full potential, AI can be deployed to increase diagnostic accuracy, design intelligent drugs and power surgical robots. In clinical trials, AI can be used to better understand the factors that drive and predict patients' response to treatments. Within healthcare delivery, there is potential for lower-order tasks to be automated to increase healthcare providers' productivity and time for patient care. The COVID-19 pandemic has accelerated adoption of AI in Australia's healthcare system, as seen in the adaptation and large-scale deployment of The University of Sydney-affiliated start-up

[95] Alex Zhavoronkov, *Forbes*, Deep Dive Into Big Pharma AI Productivity: One Study Shaking The Pharmaceutical Industry, 15 July 2020
[96] Markets and Markets, Artificial Intelligence in Healthcare Market, 2020
[97] St Vincent's Health Australia, Beating breast cancer with Artificial Intelligence, July 2020
[98] PwC, Adopting AI in healthcare: Why change?, 2019

DetectED-X that can detect COVID-19 in lung CT scans.[99] The myriad examples of AI's application within healthtech and healthcare demonstrate that building capacity and capabilities would be highly valuable to the sector.

Alignment with Sector Priorities and Megatrends

This skills gap is in alignment to the Sector Priorities and megatrends listed in **Skills gap #10: Understanding of and expertise in big data capture, management and analysis**.

Other considerations

Four system-level issues should be considered, as they exacerbate this skills gap.

First, there is limited funding for AI in MTP research, including from the Australian Research Council (ARC) and National Health and Medical Research Council (NHMRC). The 2018–19 Australian Federal Budget earmarked A$30 million over four years to enhance Australia's efforts in AI and machine learning, which is significantly less than comparable countries like Singapore, which invested A$155 million over the same time period.[100] However, grant opportunities such as the 2020 MRFF's A$19 million for Applied Artificial Intelligence Research in Health are a step in the right direction and demonstrate that these technologies are becoming a higher priority for policy makers.

Second, a lack of public trust in AI capabilities is a barrier to adoption among both clinicians and patients. However, a 2017 survey conducted by HCF revealed that 80 percent of Australians would be comfortable with AI being used to diagnose common medical problems and interpret test results.[101] This suggests that the public sentiment towards AI is warming and there will be a need to build these capabilities for the future.

Third, as discussed in **Skills gap #10: Understanding of and expertise in big data capture, management and analysis**, there is also the issue of poor data infrastructure. The most successful AI tools are those built on large centralised 'lakes' of data, but a significant barrier to AI development is obtaining access to public databases. Further, decentralised data collection systems and scepticism around sharing healthcare data across organisations makes it difficult for AI coders to access sufficient data with which to train their algorithms.

Finally, there is the ongoing challenge of managing issues in AI safety, quality and ethics. There is currently no robust regulatory framework to ensure the safety of AI technologies, nor are there local or international guidelines for clinical development, testing and certification of AI.[102] This is further compounded by the fact that despite several parties with a stake in this (e.g. ADHA, the Australian Commission on Safety and Quality in Health Care), there is no overarching coordination of AI research and policy development across Australia. There is also no harmonised ethics framework in Australia that will underpin the safe and appropriate use of AI.[103] Companies in the AI space have to keep abreast of changes and navigate this uncertainty, which adds another layer of difficulty to understanding and working in the sector.

[99] Sophie Scott, *ABC News*, Australian-designed artificial intelligence set to aid diagnosis of coronavirus, 30 March 2020
[100] Bo Seo, *Australian Financial Review*, Fears Australia will be left behind with minimal AI spending, 28 January 2019
[101] HCF, Aussies ready to embrace artificial intelligence in healthcare, 10 January 2017
[102] Nicole Mackee, *InSight+*, AI in health care: Australia in danger of lagging behind, 7 September 2020
[103] Australian Digital Health Agency, Workforce and Education Roadmap, 2020

Addressing the gap

In the short term, similar to what is required in other skills gaps within the theme of health data and cybersecurity, the first step is to raise awareness around the use and potential of AI within the sector (extending the value chain to healthcare provision).

- At the leadership and decision-maker level of key deployment companies and organisations (e.g. healthcare providers), this program could encourage them to invest in developing AI capabilities. One example of a program addressing this gap is MIT Sloan's six-week Artificial Intelligence in Health Care program, which aims to equip healthcare leaders with an understanding of the potential for AI innovations in the industry.
- For practicing clinicians and AI/machine learning engineers that are embedded within a research environment, an awareness program could drive them to seek opportunities in the industry AI workforce.

In the medium term:

- An approach to stimulate interest among computer scientists and prepare them for an AI role in the field could include an introductory course with an integrated internship that provides practical experience with AI in the MTP/healthcare industry. These internships should give its participants an opportunity to 'observe and learn' onsite (e.g. at a radiology clinic) to understand how their technologies might be used outside of the research environment.
- Introductory courses could be offered to clinicians who are interested in pursuing AI. These courses could be targeted at key specialties where AI is utilised, such as radiology and pathology.

Longer term, Australia could follow examples like the US and set up postgraduate programs that allow students to be dual trained in AI and healthcare. One example of this is Johns Hopkins University's Master of Science and Engineering (Biomedical engineering) program, which has a dedicated focus area of AI in Medicine, offered to medical students, residents and clinical fellows.

From a structural perspective, developing a successful local AI industry could be supported by driving collaboration and public-private partnerships between public health systems and private companies. This has been demonstrated successfully within the NHS – they grant companies access to datasets in exchange for free use of a successful product developed using those data.[104]

Skills gap #12: Shortage of skills in health informatics

Overview of the skill

Health informatics describes the interdisciplinary study of the design, development, adoption and application of IT-based innovations in healthcare services delivery, management and planning.[105]

Health informatics professionals require an understanding of how data and digital information are generated and managed for clinical care, biomedical research, public health and health policy.

[104] Julia Kollewe, *The Guardian*, NHS data is worth billions – but who should have access to it?, 10 Jun 2019
[105] As defined by the US National Library of Medicine

Examples of health informatics applications include:

- driving the adoption, utilisation and analysis of EHRs
- developing software and IT support to enhance clinical efficiencies, e.g. using health informatics to optimise scheduling protocols and staffing choices
- identifying and managing rising-risk patients through the collection and analysis of real-world of evidence (RWE) of patient journeys and outcomes
- enhancing R&D of new therapeutics and medical devices through the collection and analysis of real-time data from clinical trials and RWE.

Description of the skills gap

There is a shortage of health informatics specialists that understand information systems, informatics and IT in the medical/healthcare system context. This shortage extends all the way from clinical analyst to health information manager/director/CIO.

These specific skills gaps include:

- A lack of awareness amongst middle and senior management about the importance, value and possible use cases of health informatics in their MTP/healthcare organisations. This extends to identifying the need to build up health informatics capabilities among the workforce.
- An understanding of the nature for health data collection, processing and use. A distinctively evident gap is in the creation and use of live data registries to support real-time decisions (see **Skills gap #10: Understanding of and expertise in big data management and analysis**).
- An understanding of data governance, privacy and de-identification and applicable state and federal legislation when working with data.

As the digital landscape for healthcare continues to evolve, the need for health informatics skills becomes more pressing, but it is difficult to fill positions with skilled health informatics specialists.[106] Two primary factors contribute to this: first, the education system has been slow to adapt (as in the case of big data and cybersecurity) and cannot readily supply the workforce required. Second, this job requires candidates to have both medical and IT expertise, which is a difficult combination to source.

Australia offers very few opportunities for undergraduate and postgraduate education in health informatics. This is coupled with low awareness of the field and its opportunities. The lack of entry options is also reflected in the existing health informatics workforce, which is largely from other disciplines (e.g. software engineering, IT) who have an interest in healthcare.[107] The other part of the health informatics discipline is housed in academia, wherein researchers (typically academic clinicians and epidemiologists) are focused on using health informatics methods to produce publications rather than translating these techniques to the clinical/public health setting.

[106] Stakeholder consultations
[107] Stakeholder consultations

An alternative, much smaller talent pool is found in medically trained professionals who are skilled in health informatics. This coveted hybrid skillset is not currently part of any formal clinical training program. Similar to **Skills gap #11: Expertise in the design and use of AI in MTP**, these clinicians may not be aware of alternative career paths in industry that involve health informatics.

Finally, it has been noted that attrition for current health informatics professionals may be partly attributed to the lack of structured career paths and options for personal development. The same issue has been noted in the UK and Canada, which have both since established a matrix to provide more structured pathways for careers in health informatics.[108]

Impact of the gap

This skills gap impacts companies and organisations of all sizes across the MTP sector. It is most pressing in digital health/technology companies, e.g. those working with computerised medical records. Employers are struggling to recruit staff: for example, analysis from the US showed that new and emerging health informatics positions stay open twice as long as the ones they are replacing (e.g. hiring clinical analyst to replace a medical records clerk).[109]

However, Australia lags behind comparable regions such as the US and the EU in its utilisation of health informatics techniques, which means missing out on significant value. For example, Australia's Digital Health CRC is working with Texas-based healthcare technology company, HMS, which coordinates benefits for the US Medicaid program. HMS can analyse Medicaid data in near real-time and use this to identify and notify at-risk patients. This both improves patients' health outcomes and reduces costs for the government and insurance companies. This skills shortage limits Australia's ability to improve patient care and gain the numerous health and financial benefits that can be drawn from this discipline.

Similar to **Skills gap #10: Understanding of and expertise in big data capture, management and analysis**, this multidisciplinary skillset is difficult to find and therefore requires significant upskilling before these professionals have sufficient knowledge and understanding of the healthcare context. Training an established IT/software professional to understand the nature and nuances of healthcare data can take 12 to 18 months, which requires considerable investment.[110]

Alignment with Sector Priorities and Megatrends

The use of health informatics underpins three Sector Priorities. Demand for this skillset will continue to be driven by six megatrends in the future.

[108] See the UK's Health Informatics Career Pathways Project and Canada's Health Informatics Professional Career Matrix
[109] Burning Glass Careers in Focus, *Missed Opportunities? The Labor Market in Health Informatics 2014*, December 2014
[110] Stakeholder consultations

Sector Priority	Description
Priority 1: Align investment in KPs that meet current and future market needs	Using health informatics methods will put Australia in a better position to understand and maximise the health benefits of the KPs, particularly in priority therapeutic areas
Priority 4: Strengthen Australia as an attractive clinical trial research destination	The use of real-world evidence in clinical trials can bolster the sector's understanding of a therapy in the 'real world' (e.g. studying effects of therapies in patients with co-morbidities, who otherwise would not be included in the clinical trial)
Priority 5: Support the development of digital healthcare solutions – devices and data analytics	Developing high-quality health informatics capabilities will strengthen Australia's digital healthcare sector (e.g. designing new software solutions and healthcare platforms to optimise the capture and processing of data)

Megatrend	Description
The chronic burden	As the chronic burden continues to put pressure on the MTP sector and healthcare providers, health informatics can be used to identify and proactively manage rising-risk patients in the healthcare system
Digital evolution	Health informatics plays a critical enabling role in the digital transformation of the healthcare system, so a supply of highly skilled specialists is required
Integrated care models	Harnessing the power of health informatics can support a connected healthcare ecosystem that will help shift the emphasis from individual care episodes to ongoing patient management
Value-based healthcare	The shift toward value-based care is gaining momentum with the utilisation of health informatics techniques, e.g. by supporting clinical decision-making and incorporating patient-reported outcomes
Consumer control	The emerging sub-speciality of consumer health informatics is growing as patients seek a greater role in decision-making regarding their health
Healthy ageing	The ageing population offers numerous opportunities in health informatics, e.g. providing efficiencies and a higher quality of care from the use of EHRs in aged care

Other considerations

See **Skills gap #10: Understanding of and expertise in big data capture**, management and analysis for further details on structural issues around the use of health data.

Addressing the gap

In the short term, similar to what is required in other skills gaps within the theme of health data and cybersecurity, the first step is to raise awareness around the use and potential of health informatics within the sector (extending the value chain to healthcare provision).

- At the leadership level of companies, healthcare providers and government organisations, a short course or workshop could be run to educate these stakeholders around the potential societal and commercial value of health informatics for their organisations.
- For practicing clinicians with a penchant for data analytics, an awareness program could drive them to seek opportunities within the health informatics workforce.
- Increasing awareness among university students could be done in conjunction with sponsoring internships or traineeships within MTP companies for graduates or final-year students.

In the medium term:

- For professionals who enter the discipline laterally, the industry and organisations such as the ADHA could provide additional opportunities for personal development in the workforce. For example, this could include providing accreditation for completing health data and informatics modules.
- A group of peak Australian health informatics bodies have noted the need to develop a national capability framework to 'professionalise' the discipline.[111] The MTP sector could support this by detailing the health information competencies required for their companies and how this could translate into a clear career pathway.

In the longer term:

- The industry should work with education providers to help develop undergraduate and postgraduate programs in health informatics to build the hybrid skillset and produce job-ready graduates for the MTP workforce (e.g. Tallinn University of Technology's Master of Health Care Technology).
- On the clinician side, there is the potential to develop and embed health informatics fellowships within their practice. For example, NYU Langone Health offers a multidisciplinary Clinical Informatics Fellowship to medical professionals that covers several informatics rotations over the course of two years.

[111] nab website, Workforce shortages loom as eHealth threat, accessed on 13 November 2020

Theme: Health economics and regulatory affairs

Obtaining both regulatory approval and national reimbursement is a significantly involved process, requiring a highly skilled and knowledgeable workforce to rigorously demonstrate safety, efficacy and economic benefits to the appropriate bodies.

The skills gaps in this theme significantly impact the ability of Australian innovators and entrepreneurs to commercialise their discoveries. There is a need for the sector to grow the pool of young talented professionals, invest in retaining top talent in Australia and facilitate access to this talent for start-ups and SMEs where the skills gaps tend to be most evident.

Skills gap #13: Awareness and understanding of regulatory requirements amongst start-ups and SMEs

Overview of the skill

The MTP sector is strictly governed by regulatory bodies in domestic and international markets (e.g. the TGA in Australia, FDA in the US). MTP companies are required to go through a rigorous process and submit comprehensive data on the safety and efficacy of each product before it can be made broadly available for use.

This requires MTP companies to have a proficient understanding of the regulatory requirements (domestic and international) as it applies to their medical device or therapeutic. In order to maximise the potential for a product to be approved by the regulatory bodies, regulatory requirements need to be considered and appropriately incorporated from the very first stages of the product development process through to manufacturing. It is also important to note that these regulatory requirements can be expected to increase in complexity as more novel therapies and software-based devices enter the market.

Description of the skills gap

Stakeholder consultations have highlighted that MTP start-ups (particularly university spin-offs) and SMEs tend to lack awareness and understanding of regulatory requirements at the right stage of the product development process.

These specific skills gaps include:

- awareness of regulatory requirements and knowledge to incorporate relevant planning and design early on in the product development and commercialisation process
- an understanding of and an ability to navigate the complex regulatory process to gain approval for use in patients. This requires an understanding of TGA and overseas approval processes in key markets, e.g. FDA, EMA. This also includes an understanding of the required level and forms of evidence required for clinical trials and manufacturing requirements (e.g. cleanroom, documentation processes and standards)
- lack of expertise in novel, emerging areas such as digital health or stem cell therapies.

The gap exists because founders (e.g. researchers, clinicians) are typically interested in the technology and its capabilities in the first instance rather than regulatory requirements. Founders often lack the understanding that regulatory requirements are imperative to the product development process and cannot be 'tacked-on' at the end. Stakeholder consultations suggest that these start-ups typically only become aware of this issue once they have progressed down the product development pathway and have funding applications declined due to lack of a robust regulatory strategy.

For companies that can afford to hire an in-house regulatory affairs officer, they often struggle to find appropriate local candidates, especially those with international regulatory knowledge. Analysis of MTP sector jobs on the SEEK recruitment platform supported this insight. In 2019, the number of job applications received via SEEK for regulatory affairs job advertisements ranked in the bottom 20 percent when compared to all other jobs posted across all sectors. Stakeholder consultations have indicated that these skills are even harder to source in the context of novel therapies and digital health. Small companies tend to outsource these skills to regulatory consultants, often at great expense.[112]

Impact of the gap

Failing to incorporate these regulatory requirements early in the product development process leads to repeating studies that were not appropriately designed to deliver the regulatory needs. This might include once-off toxicity studies or redesign of a preclinical study or clinical trial (see **Skills gap #5: Strategic design of clinical trials to meet regulatory and payer needs**). This consequently leads to delays to market and patient access to therapies. A lack of regulatory strategy also hinders companies from securing investment, which also has a significant impact on a start-up's ability to take a product to market in a timely manner.

Similarly, companies that do not take a strategic view of regulatory requirements across all their potential key end markets, and instead focus on one specific jurisdiction typically must repeat studies, resulting in lost time and resources.

Alignment with Sector Priorities and Megatrends

This skills gap has a broad impact, directly affecting five Sector Priorities. It will also continue to become increasingly important as the aligned megatrends continue to evolve.

[112] Deloitte Access Economics, *Medical technology industry workforce and skills review*, 2015

Sector Priority	Description
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	An understanding of regulatory requirements early in the product development process is critical to creating a highly productive commercialisation environment as it maximises efficiencies in approval
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	A strong regulatory strategy is a hallmark of large, professionally managed companies and is an essential capability for start-ups/SMEs to become successful companies
Priority 4: Strengthen Australia as an attractive clinical trial research destination	The ability to incorporate regulatory requirements for different jurisdictions into clinical trial operations makes Australia an attractive destination for clinical trials
Priority 5: Support the development of digital healthcare solutions – devices and data analytics	Understanding how to get digital health innovations approved by the appropriate regulatory bodies is critical to developing this sector
Priority 6: Position Australia as a preferred partner for international markets	A strong understanding of international regulatory requirements makes the Australian MTP sector attractive because investors can also have confidence the products will efficiently gain approval in all key commercial markets

Megatrend	Description
Digital evolution	SMEs and start-ups must maintain an up-to-date understanding of regulatory requirements to ensure they can efficiently take their digital health innovations to market
Precision healthcare	As demand for precision medicine solutions increases, it is critical that researchers and companies stay up to date on evolving regulatory frameworks
Consumer control	As the adoption of consumer-driven products and services continues to grow, adhering to regulatory frameworks will be increasingly important in winning consumer trust and confidence

Addressing the gap

In the short term,

- The REDI initiative could run a short training course on regulatory strategy for start-ups (particularly university biotechnology/medical technology spin-offs that are at very early stages of development) and SMEs (particularly those that are focussed on commercialising novel therapies and devices). This could take the form of a primer course that demonstrates the importance of having a holistic and international regulatory strategy. This course could also provide guidance on where to go for a detailed understanding of regulations, relevant to their specific product or technology.
- The short training course could be complemented by a deeper training course (e.g. a three-day course), covering first principles of regulatory requirements in Australia and key international markets. This would include case study-based immersive learning experiences where the participants take a product to Australia and international markets by applying learnings from the beginning of the course. The course could be delivered in partnership with the TGA and/or regulatory affairs service providers. It will be important for the course to be tailored to the right audience, i.e. medical technology and pharmaceuticals to be two separate courses. Delivering such a course that brings together founding researchers/clinicians from spin-offs and SMEs and large medical technology and pharmaceutical companies into the same space would also encourage peer-to-peer learning.
- Select early-stage spin-offs could also be offered subsidies to access regulatory advice or consulting services at appropriate points in their product development journey.

In the longer term,

- FDA/EMA/ISO experts could be brought over to train and upskill Australia's current regulatory affairs officers on international frameworks. As an example, Cochlear along with other large Australian medical technology companies have collaborated to bring US experts to Australia. The collaboration intended to educate Australian staff on FDA regulatory requirements to address the gap in FDA regulatory experience in Australia. This form of upskilling for regulatory capabilities is cost-effective mainly because costs are shared between all companies involved and travel expenses are for a small cohort of trainers, as opposed to a large group of staff.

Skills gap #14: Shortage of experienced health economists

Overview of the skill

The role of a health economist is to analyse clinical and economic evidence to demonstrate value of an intervention and then communicate this information to the relevant payers in order to enable market access for products and services.[113] Every application submitted to the Pharmaceutical Benefits Advisory Committee (PBAC) or the Medical Services Advisory Committee (MSAC) requires a comprehensive health economic assessment. This assessment includes modelling population-based outcomes, impacts and cost-effectiveness of healthcare-related interventions.

[113] N.B. This skills gap focuses on domestic market access. Skills Gap #13 and #18 specifically pertain to international market access

The role requires a unique set of experience and knowledge. From a technical perspective, the role requires analytical skills, an economics background and a deep understanding of the healthcare system, its policies, pricing and reimbursement processes. A successful health economist also needs strong stakeholder relationship and management skills including excellent communication and negotiation skills.

Description of the skills gap

Stakeholder consultations have indicated that specific skills gaps include:

- lack of awareness amongst heath economics graduates of jobs in MTP companies
- a shortage of experienced health economists who have successfully supported the listing of product(s) listed on the PBS and/or MBS. These professionals will need to have strong quantitative skills, a comprehensive understanding of domestic reimbursement processes as well as an understanding of market access requirements in Australia and key international markets (e.g. US, Europe)
- a shortage of skills in evaluating and assessing the health economics of new and emerging products and therapies (e.g. 3D-printed implants and gene and stem cell therapies).

There are several undergraduate-level health economics programs at universities and a wide range of career opportunities for graduates spanning government, non-government organisations and private MTP sector companies. However, these courses tend to have a public health focus rather than a perspective on industry needs, which limits MTP company training skills.

Further, postgraduate courses and opportunities for continued education are reportedly limited, making it difficult for people to enter health economics from other backgrounds. Companies have typically sought to address this shortage by transferring people from other business units into a market access team and training them in-house.

It takes three to five years for health economics expertise to be developed, completing the full process from initial submission to the PBAC/MSAC through to eventual listing of the product on the PBS/MBS.[114] For health economics graduates that go straight into an MTP company, there is a very steep learning curve and wealth of expertise that needs to be developed, covering everything from performing budget impact analyses of healthcare interventions to developing reimbursement strategies. Those who achieve success in getting products listed on the PBS/MBS tend to move into more lucrative regional or global market access roles, further compounding the shortage of experienced health economists in Australia.

There is also a shortage of health economists with expertise in emerging products and therapies such as 3D-printed implants and gene and stem cell therapies. Regulators and payers are currently grappling with these new technologies as they typically do not fit within the traditional reimbursement frameworks.[115] Consequently, the complexity of PBAC/MSAC submission increases for these emerging products and there is a need for sophisticated stakeholder management and negotiation skills.

[114] Stakeholder consultations

[115] MTAA, MTAA Pre-Budget Submission FY2020/21, September 2020

Impact of the gap

The shortage of expertise impacts companies across the entire MTP sector, as preparation for a major submission to the PBAC and/or MSAC is a time- and resource-intensive affair that can cost a company over A$300,000.[116] An experienced health economist is critical to minimising the number of submissions and time required to obtain a positive recommendation from the PBAC and/or MSAC. Each additional submission can result in a six to 12-month delay in getting to market, potentially costing the organisation millions in lost revenue and delaying patient access to critical new products/therapies.[117]

The shortage of experienced health economists impacts companies of all sizes; however, the degree of shortage tends to be less severe for large pharmaceutical and medical technology companies due to their access to global talent, collective knowledge and comprehensive training schemes. Small businesses tend to outsource their skills/services at significant cost. Increasing the local pool would make it easier for smaller companies to access these critical skills.

For emerging products and therapies, health economics expertise that can understand and communicate the value of these technologies to payers and government bodies will be critical in establishing these technologies as standard of care in the future. This expertise will also be critical in establishing innovative reimbursement frameworks that will expedite patient access to these potentially life-changing products and therapies while maintaining cost-effectiveness for the payer.

Alignment with Sector Priorities and Megatrends

A secure supply of experienced health economists underpins three Sector Priorities. Demand for this skillset will continue to be driven by three megatrends.

Sector Priority	Description
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	A supply of experienced health economists that can develop a robust assessment to demonstrate clinical and economic benefits to the overall health system is critical to commercialisation and market access
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Successfully obtaining government reimbursement for a therapy and maximising patient access is a critical feature in becoming a larger, successful company
Priority 5: Support the development of digital healthcare solutions – devices and data analytics	In order to support a successful digital healthcare sector, there needs to be an adequate supply of health economists who can drive successful reimbursement outcomes for these interventions to maximise patient access

[116] Medicines Australia, Submission into the House of Representatives Standing Committee on Health, Aged Care and Sport inquiry into approval processes for new drugs and novel medical technologies in Australia, November 2020

[117] The Senate, Community Affairs References Committee: *Availability of new, innovative and specialist cancer drugs in Australia*, September 2015

Megatrend	Description
Digital evolution	As the sector continues to adopt digital health and intelligent/connected devices, this will drive demand for health economists with expertise in obtaining reimbursement for innovative digital health initiatives. Ever-growing datasets sets from the digital evolution of the MTP sector will also require health economists to be able to manipulate these datasets and clearly demonstrate the value of new products for reimbursement
Precision healthcare	In a growing area where outcomes are focused on individuals rather than populations, there is a need for highly skilled health economists who can demonstrate this value to support reimbursement outcomes
Value-based healthcare	As the healthcare model slowly shifts towards this paradigm, health economists will become increasingly important to guide reimbursement decisions on an outcomes-based approach rather than a volumes-based decision

Other considerations

It is widely acknowledged that current Health Technology Assessment (HTA) and PBAC/MSAC assessment processes are complex, and non-traditional therapies and technologies face additional issues. Even for large pharmaceutical companies, submitting a new cancer medicine typically takes at least two submissions (equating to approximately three years) before obtaining a positive recommendation from the PBAC.[118] The complexity surrounding these processes can lead to delays to the point where companies decide to no longer seek reimbursement and therefore forfeit widespread patient access.[119]

Addressing the gap

In the short-term,

- The sector should work to provide industry placements/traineeships to expose undergraduate and/or graduate health economics students to the MTP sector. These traineeships would give students a practical understanding of the process flow of reimbursement submissions. This could include expanding on existing programs such as the Higher Degree Research (HDR) scholarships offered by the Macquarie University Centre for the Health Economy (MUCHE) in partnership with five pharmaceutical companies.
- To supplement the current health economics degrees that tend to have a public health focus, the sector should work with education providers to implement industry-focused courses or modules that introduce and prepare students for a career in MTP. These modules could introduce the concepts of economic evaluation for pharmaceuticals and medical technologies and how these translate into preparing PBAC/MSAC submissions. This, combined with the industry placements mentioned above, would help raise the profile of the sector.
- There is an opportunity for the industry to provide continuing education to current health economists. One area of focus could be to accelerate their understanding of the guiding principles of assessing emerging therapies and digital health in the context of Australia's reimbursement frameworks. Course content could involve working through hypothetical case studies to prepare successful economic evaluations for the PBAC/MSAC. This could be facilitated by the Australian Health Economics Society and/or their partner organisations.

[118] The Senate, Community Affairs References Committee: *Availability of new, innovative and specialist cancer drugs in Australia*, September 2015

[119] Roche, Submission to the Senate Community Affairs References Committee: *Availability of new, innovative and specialist cancer drugs in Australia*, February 2015

Theme: Product development and commercialisation

Driving greater commercialisation productivity and outcomes is a central part of MTPConnect's vision for the sector.

The skills gaps in this theme are pivotal to enabling this sector vision to be realised. Several of the skills gaps identified are well-known to the sector. Although there have been many attempts to address many of these gaps, they continue to persist. While there are some structural challenges to be considered (as described in **Chapter 2**), there is an opportunity to expand existing successful programs and deliver new programs that target specific skills gaps identified in this review.

Skills gap #15: Shortage of industry professionals with end-to-end translation and commercialisation experience

Overview of the skill

Australia has excellent capabilities in basic research and clinical trials and is home to several world-leading universities and research institutions. While there are some examples of successful research translation and commercialisation within the MTP sector (e.g. Elastagen, Gardasil, Hatchtech, Spinifex and Fibrotech), Australia ranks poorly amongst comparable OECD countries for commercialising its research.[120] The MTP sector is no exception, particularly in metrics relating to IP generation and collaboration between industry and researchers.[121,122]

The commercialisation pathways for medical technology, pharmaceutical and digital health are long, complex and unique. Taking any product to market involves a series of common steps but the road is by no means linear. Successfully translating and commercialising a promising piece of research means navigating regulatory bodies, reimbursement agencies, clinical trials and validation studies, as well as simultaneously engaging with a diverse set of stakeholders across the sector. Further complexity is added when considering market access overseas.

Description of the skills gap

One of the key factors hindering commercialisation success in Australia is a shortage of people who possess first-hand experience in end-to-end research translation and commercialisation.

Key aspects of this longstanding experience skills gap include:

- the ability to build in translation/commercial considerations early in the basic research or development phase
- an understanding of the steps required to efficiently take a concept through the entire development pathway to a viable and commercially successful product. This includes an understanding of the technical, commercial and regulatory aspects

[120] Australian Technology Network of Universities, *Innovate and Prosper: Ensuring Australia's Future Competitiveness through University-Industry Collaboration*, 2014
[121] Australian Academy of Technology & Engineering, *A new prescription: Preparing for a healthcare transformation*, April 2020
[122] AVCAL, *The Venture Capital Effect: A Report on the Industry's Impact on the Australian Economy*, 2017

- knowledge of when and where to seek expert advice on specific matters to expedite successful outcomes (e.g. regulatory requirements in overseas markets)
- an understanding of the industry and how to communicate with its different stakeholders. For example, this could include understanding how to appeal to and alleviate concerns of, investors when pitching for investment (e.g. in early-phase drug development – see **Skills gap #17: Ability to secure investment, funding and/or industry collaboration** for more detail).

Talented commercialisation professionals are often attracted by better opportunities overseas. This means that there are very few people locally that have gone through the whole MTP product life cycle. This is partly a function of Australia's small MTP end-to-end ecosystem (outside the likes of CSL, Cochlear and ResMed) that limits the ability for the next generation of commercialisation experts to build these skills. Furthermore, for the global companies that have a presence in Australia, the people in these roles (typically executives) sit overseas. The lack of cross-pollination between global organisations and their Australian counterparts is a key barrier to knowledge-sharing and developing more people with this skillset.

Impact of the skills gap

This shortage has a substantial impact on the commercialisation culture and ecosystem in Australia. Successful new ventures and those who lead them become the exemplars for the next generation of entrepreneurs. A strong presence and network of entrepreneurs will foster and encourage a culture of innovation and entrepreneurship and is likely to alleviate Australia's noted 'fear of failure'.[123] As success begets success, creating and celebrating local entrepreneurial activity will encourage researchers to take the leap to commercialise their work, rather than focusing solely on producing publications.

As highlighted in the structural issues section in **Chapter 2**, academic incentives and promotions at research institutions are focused on publications rather than commercialisation outcomes. This encourages talented researchers to focus on their academic pursuits rather than entrepreneurial opportunities.

The lack of access to experienced advisors tends to lead to inefficient and poorly managed translation pathways by innovators. The associated rework and inefficiencies result in either delayed (and overpriced) or failed commercialisation efforts. Addressing this gap will give researchers, entrepreneurs and start-ups exposure to the end-to-end process and guidance on how to strategically navigate it. This will set them up with a greater chance of successfully taking their products to market and eventually reaching patients.

Addressing this skills gap will also realise economic benefits. Across the entire Australian economy, start-ups (defined as businesses less than two years old) were the largest contributor to job creation from 2004 to 2011.[125] During this period, start-ups created more than 1.2 million jobs and contributed A$164 billion to the Australia economy.[124] In the MTP context, two recent highlights include Spinifex, which was one of the most successful exits in the history of Australian VC with an upfront payment of US$200 million, with Hatchtech close behind. Successfully commercialising Australia's top-quality research would contribute to the country's economic growth and strengthen its position on the global stage.

[123] Don Scott-Kemmis and Claire McFarland, United States Studies Centre, *Entrepreneurship in Australia and the United States: Contrasts in attitudes and perceptions, and insights from successful Australian ventures*, April 2020

[124] Department of Industry, Innovation and Science, *Australian Innovation System Report 2017*

Alignment with Sector Priorities and Megatrends

This skills gap underpins several MTP Sector Priorities as outlined below.

Sector Priority	Description
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	Professionals with translational and commercialisation experience can mentor and guide researchers and SMEs through the commercialisation pathway and help them navigate complex regulatory approval processes
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Experienced professionals can support SMEs in advancing their products in early-stage development through to market and support their growth into larger, more successful companies
Priority 4: Strengthen Australia as an attractive clinical trial research destination	Professionals with deep translational expertise in drug development will help drive more effective clinical trial design and operations
Priority 5: Support the development of digital healthcare solutions – devices and data analytics	As this is an emerging area, guidance from a professional with translational expertise and experience will help support successful commercial outcomes for digital health and device companies
Priority 6: Position Australia as a preferred partner for international markets	Professionals with deep translational experience, particularly those with international relationships and networks, are viewed as desirable partners and could attract foreign investment

The skills involved are critical to success in each and every one of the megatrend areas. Without commercialisation experience and efficiency, the innovations in the megatrend areas will take longer to reach the market – if they are commercialised at all – and hold back Australia in adapting to and capitalising on these megatrends.

Other considerations

It is important to note that there are some deep-rooted key structural and cultural issues that inhibit Australia's ability to readily and consistently develop and retain such talent.

In Australia there is a shortage of 'serial entrepreneurs' who have tried, failed and eventually succeeded. This shortage primarily stems from a lack of skills and lack of opportunity; there are fewer commercialisation opportunities for serial entrepreneurs relative to other markets and these opportunities remain small because there are not enough entrepreneurs in the market who can take managed risks and innovate.[123,125]

Addressing the gap

In the short term:

- An approach to address this skills gap could be to leverage the Global Talent Visa Program to attract professionals from overseas. Another potential mechanism to tap into this global talent pool of executives – from MTP sector organisations who have extensive commercialisation experience – is to provide funding or incentives to encourage them to engage in a mentoring role to budding Australian entrepreneurs. The COVID-19 pandemic has made it easier than ever to work remotely and collaborate across time zones. This new 'way of working' can be leveraged to help Australian entrepreneurs access a broader pool of expert advisors.

In the medium term:

- Another possible mechanism is to develop incentives or expand existing programs (e.g. the veski innovation fellowships) to attract Australian expatriates with deep MTP commercialisation expertise back to Australia. This program may be difficult to establish until the COVID-19 pandemic abates and international borders are fully reopened.

Over the longer term:

- It will be important to develop a local pool of commercialisation experts. Whilst there are a number of accelerator and incubator programs to provide mentoring and support to Australian entrepreneurs, they generally lack sufficient scale and expertise to have broad impact nationally.
- The UK NHS Clinical Entrepreneur training program could be an exemplar for Australia. Focused on clinicians only, the program is the largest entrepreneurial workforce development program of its kind. The program offers expert mentoring, exclusive networking and bespoke training to clinicians to develop their innovative ideas into products and businesses that benefit NHS patients. The curriculum covers all aspects of setting up and running a small business, including attracting investors, applying for funding and ensuring appropriate corporate governance. The program intends to enable entrepreneurs to pursue their innovation without having to leave their clinical career, which is currently seen as a barrier to entrepreneurship. Over 500 clinical staff have been part of the program since its inception in 2016.[126]

In the long-term, building a thriving research translation and commercialisation ecosystem will need to address the key underlying cultural and structural issues, including reform to academics'/clinicians' incentive structure and employment conditions. Investment in building commercial-scale R&D, product development and manufacturing capabilities in Australia will also be needed. Lastly, a more

[125] Stakeholder consultations

[126] NHS, Clinical Entrepreneur training program, 2020

collaborative approach to commercialisation across government, industry and academia will also be required (see international case study below).

International case study: Building a commercialisation ecosystem in Israel

- Israel is a country with just eight million people, but it has built a successful commercial ecosystem:
  - Tel Aviv is the second-largest start-up ecosystem in the world next to Silicon Valley.
  - Israel is home to a similar number of life science companies as Australia, despite being only one-third of Australia's population.[127,128]
  - Over 300 multinationals have set up an R&D centre in Israel, with MTP companies including Merck Group, Johnson & Johnson, GE Medical Systems and Teva Pharmaceutical Industries.
  - In 2017, Israel spent c.4.4 percent of its GDP on R&D vs. the OECD average of 2.4 percent. Australia spent c.1.8 percent.[129]
- Israel has a strong 'pay it forward culture', where serial entrepreneurs are passionate about mentoring others and believe that their efforts get multiplied when their mentees do the same in the future.[130]
- The government's Technological Innovation Incubators Program targets disruptive, early-stage ideas that are 'too risky' for private investors:
  - The government backs them during their most vulnerable stage of growth until they can scale up to receive private sector capital.
  - Forty percent of the companies that have made it through this program are still in operation.[130]
  - A combination of entrenched supporting and mentoring systems, plus a government-backed system that lowers the risk of entrepreneurs, creates an environment conducive to commercialisation.
  - As a result, there is a strong supply of industry professionals with end-to-end translational expertise that are well equipped to mentor and support the country's budding entrepreneurs.

Skills gap #16: Identifying unmet market need and understanding the clinical context

Overview of the skill

Identifying unmet market need is the first step towards realising successful clinical and commercial outcomes of an MTP solution. Developing medical technology, pharmaceutical and digital health products can take a long time to reach the market from the initial phases of R&D and therefore it is important that the unmet market needs are identified at the outset and continually evaluated throughout the development process.

This requires skills ranging from developing a deep understanding of pain-points from the perspective of the end-user, e.g. patient, clinicians and other MTP participants, to understanding how the solution would be used in practice.

[127] Israel Advanced Technology Industries, *Israel's Life Sciences Industry IATI Report*, 2019
[128] MTPConnect, Sector Competitiveness Plan, April 2020
[129] OECD, Gross domestic spending on R&D, November 2020
[130] David Yin, *Forbes*, What Makes Israel's Innovation Ecosystem So Successful, 9 January 2017

Description of the skills gap

Stakeholder consultations have highlighted that there is a capability gap in identifying an unmet market need and understanding the clinical context surrounding that need.

These specific skills gaps include the ability to:

- identify an unmet market need by involving the end-user (e.g. patients, clinicians) early in the R&D phase
- assess the scale of the market need by performing in-depth market research, assessing the competitive landscape of both existing and in-development products and understanding where the product fits into the market
- characterise existing solutions and why they are not sufficient (i.e. recognising that the need is truly unmet)
- understand standard treatment pathways, existing clinical guidelines and current treatment paradigms
- understand how the proposed solution could be practically applied to the clinical environment.

This gap exists because researchers/entrepreneurs typically do not engage with the end-user (patient or clinician) early in the development of a device or digital intervention. In the case of therapeutics, this gap typically arises when researchers/entrepreneurs do not understand the existing treatment pathways and clinical practices.

Taking digital health as an example, one of the key challenges faced by Australian innovators is difficulty in accessing frontline healthcare providers to identify problems (unmet market needs) and test digital health solution concepts early.[131] Researchers/entrepreneurs tend to struggle to access expertise from other professionals or clinicians who could advise on how to identify a market need and understand the clinical drivers. This is partly a function of the absence of collaborative ecosystems (e.g. integrated hubs with universities, hospitals and manufacturing companies) and interdisciplinary networking opportunities.

Impact of the gap

This gap impacts researchers, start-ups and spin-offs, across the MTP sector. The inability to identify unmet market need and understand the clinical context leads to wasted resources and at times, failed businesses. This gap is not uncommon – stakeholder consultations suggest that some VC firms reject up to 30 percent of investment proposals because they do not identify an unmet market need.[132]

For products that do make it to market, some are misaligned with the end-user needs and do not integrate smoothly with the existing clinical workflow. This limits the extent of clinical uptake and therefore the extent of positive patient outcomes that can be achieved.

[131] ANDHealth, *Digital Health: Creating a new growth industry for Australia,* 2018
[132] Stakeholder consultations

Alignment with Sector Priorities and Megatrends

This skills gap is general in nature and is aligned with a number of megatrends. It is also important in underpinning three MTP Sector Priorities.

Sector Priority	Description
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	Identifying unmet market needs at the outset of product development will increase the likelihood of successful commercialisation outcomes, and will ensure that products reaching market are aligned with existing gaps and clinical needs
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	A better understanding of the clinical context and ability to find gaps in the market for new products can strengthen SMEs, as they can develop targeted solutions for the market
Priority 5: Support the development of digital healthcare solutions – devices and data analytics	The sector is placing increasing value on digital technologies not only for achieving operational efficiencies but for use in improving clinical outcomes, diagnosis and treatment. The future of digital healthcare will be underpinned by a better understanding of unmet patient needs

Addressing the gap

In the short term:

- A standalone short course (based on the expansion of existing commercialisation and accelerator courses) that develops skills and knowledge to perform in-depth market research, developing product profiles and understanding where the product fits into the market.
- Encourage greater collaboration and networking between researchers/spin-offs and clinicians through a range of options. This could involve hosting interdisciplinary product design workshops that invite clinicians, researchers, aspiring and current MTP entrepreneurs to encourage knowledge-sharing and collaboration. In the case of therapeutics, this could involve hosting workshops to educate researchers/entrepreneurs on how to perform a market assessment (e.g. market size, competitive landscape, current standard of care).
- Expand on existing commercialisation and accelerator programs that are specifically designed to enhance collaboration to develop clinically relevant medical devices.

In the medium to long term:

- There is an opportunity for the sector to develop a standardised curriculum of education programs that provide training for potential entrepreneurs on assessing unmet market needs and understanding the clinical context in different settings. The Clinical Educator Programme in the UK is an example of such an education framework in South-East Scotland.[133] The initiative has been developed by The University of Edinburgh and University of St Andrews in partnership with the NHS.

[133] Clinical Educator Programme website, accessed on 15 February 2021

Skills gap #17: Ability to secure investment, funding and/or industry collaboration

Overview of the skill

A critical step in taking a product to market is attracting and securing investment, non-dilutive grants, funding and/or key industry collaborations. Many early-stage spin-offs falter in progressing from discovery to development because they cannot secure sufficient funding and the right collaborations required to advance to the next stage.

Successful commercialisation typically has an underlying long-term strategy and business development plan in place, rather than just trying to fill a funding gap through every stage of product development. This requires the ability to:

- identify and pursue long-term relationships with appropriate investment partners
- effectively communicate their research/start-up, both written (e.g. business plans, key grant applications) and orally. This includes articulating their clearly identified unmet market need, value proposition, market access, reimbursement and regulatory approval strategies where relevant
- adapt this communication to the audience based on an understanding of the perspective and motivations of the audience, whether it is a government non-dilutive grant, a VC firm or a corporate investor.

Description of the skills gap

There is a lack of capability in researchers, clinicians and entrepreneurs to identify investment sources, pitch their research and secure funding from commercially focused government grants/VC funds/ commercial partners to advance their research and produce commercially relevant outcomes.

These specific skills gaps include the ability to:

- strategically network to identify the appropriate potential partners and develop a long-term relationship
- understand the motivations and perspectives of investors
- communicate at the right level of scientific depth with the skill to adapt their style to the audience; someone who understands science but can also sell the clinical and commercial relevance of their idea
- pitch for funding, investment and collaboration from government and private organisations through clearly articulating unmet market need and commercial potential in proposals, business plans and presentations
- successfully tap into international markets by attracting overseas investors and developing globally relevant business plans.

This gap affects founding scientists and first-time entrepreneurs more than anyone else. Of the sub-sectors, biotechnology and pharmaceutical start-ups typically have a harder time securing funding because of the long return on investment (ROI).

Market uncertainty and the shift to virtual interactions due to COVID-19 have exacerbated this situation. Stakeholder consultations suggest that international investors in particular have been very selective in deploying capital and are reluctant to invest in start-up opportunities where they are unable to meet founders face to face. Despite this, ASX-listed companies reported a record trading period and raising of capital.[134] This suggests that there might be sufficient capital available in the sector, but entrepreneurs have to work to put forward more compelling cases for funding.

It is important to note that this skills gap builds on other priority gaps identified in this report. Specifically, these include understanding regulatory requirements (**Skills gap #13**), identifying an unmet market need (Skills gap #16) and understanding of the payer and reimbursement models (**Skills gap #18**).

Impact of the gap

Researchers and companies that lack the skills to effectively target and secure funding, investment or industry support will struggle to reach successful commercialisation outcomes. This means they cannot get their product to market and therefore will not reach patients, which translates to a loss of clinical and commercial benefits. Instead, time and resources may be misdirected towards progressing research ideas that are not likely to yield 'investable' outcomes.

Alignment with Sector Priorities and Megatrends

This skills gap underpins three MTP Sector Priorities as outlined below.

Sector Priority	Description
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	Developing capabilities in seeking partnerships and developing and communicating business plans will improve commercialisation outcomes for Australia's entrepreneurs
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Strengthening the skills to seek and secure funding, investment and collaboration will set up SMEs to become larger and more successful companies going forward
Priority 6: Position Australia as a preferred partner for international markets	Enabling Australia's entrepreneurs to communicate globally relevant business plans will attract overseas investors to the sector

[134] Asha Barbaschow, *ZDNet*, A$498m profit for ASX in record trading period boosted by COVID-19, 20 August 2020

While this skills gap is not aligned to specific megatrends, the skills are critical to success in realising the potential benefits from each megatrend. Without the ability to secure investment, the innovations enabled by the underlying megatrends will take longer, or fail, to reach the market and hold back Australia in adapting to and capitalising on these megatrends.

Other considerations

Compared to global comparators, Australia is considered to have a nascent entrepreneurial ecosystem to provide a rich training ground for such skills. Entrepreneurs in world-leading ecosystems such as Boston have greater exposure to the VC community and typically have a network of highly experienced advisors before they do their first pitches.

These advisors are typically those who have successfully raised significant amounts of funding and are available to support, mentor and train upcoming entrepreneurs and set them up for success. Such an ecosystem is still developing in Australia.

Addressing the gap

In the short term, there are opportunities to:

- Provide a short one-day course/workshop to guide select aspiring researchers/clinicians and supporting TTO technology managers on how to 'pitch' for funding to a range of stakeholder groups (e.g. for industry partnerships, VC firms or for government grants).
- Invest in new programs, or expand existing successful programs, that provide focused support and advisory services to start-ups/entrepreneurs, including how to procure investment. These programs will also need to provide networking opportunities for the participant to build familiarity with the VC community, which is an important aspect of being able to secure funding.
- In parallel with the short-term opportunities, a new workshop could be established to educate the Australian investment community regarding timelines and what is a typical ROI for the sector, especially with pharmaceutical and biotechnology. Over time, this could include attracting expertise from world-class innovation ecosystems (e.g. Boston) to support investors' development.

In the medium to long term, there is an opportunity to develop a standardised curriculum of education programs that provides training for potential entrepreneurs (similar to **Skills gap #16: Ability to identify unmet market need and understand the clinical context**).

Skills gap #18: Identification of the payer and understanding of reimbursement pathways and requirements

Overview of the skill

The payer and end-user of MTP sector products and services are often distinct in the Australian healthcare system and in many international markets. Potential payers can include hospital procurement teams, private health insurers, the Australian Government (e.g. when listed on PBS/MBS), or consumers/patients themselves (e.g. patients in the private system who pay for out-of-pocket products).

Entrepreneurs and innovators need to be able to identify who the likely payer(s) will be at the onset of product development. They will also need to understand what requirements and evidence the likely payer(s) will expect in order to accept/approve reimbursement. This may include:

- designing clinical trials to ensure the correct level and type of clinical evidence is captured to satisfy the reimbursement agency (see **Skills gap #5: Strategic design of clinical trials to meet regulatory and payer needs**)
- demonstrating cost-effectiveness of the new product/service through detailed modelling by an experienced health economist.

Description of the skills gap

There is a capability gap in identifying the payer and understanding the requirements for public reimbursement in domestic and international markets.

These specific skills gaps include the ability to:

- develop a reimbursement/funding strategy in the early phases of product development. This requires an understanding of the key payment drivers of the MTP market players (patient, payer or provider) in both domestic and international markets to assess the best commercialisation/monetisation model
- navigate complex domestic (national and state) and international reimbursement processes and anticipate their requirements (e.g. level and type of clinical evidence, validation, Key Opinion Leader (KOL) input, health economics input).

Similar to **Skills gap #13: Awareness and understanding of regulatory requirements among start-ups and SMEs**, there is an awareness gap around the importance of having a clear reimbursement strategy at the earliest stages of development among entrepreneurs and innovators. Most founders typically do not think beyond the end-user of the product and tend to only give attention to payers and reimbursement pathways near the end of the product development process.

This gap is exacerbated in the case of novel therapies, where the pathways to public reimbursement are less clear. Stakeholder consultations suggest that assessment pathways for novel pharmaceutical/biotechnology therapies tend to be inconsistent and uncertain, making it difficult to navigate the reimbursement submission process in these areas with confidence.[135,136]

[135] Medicines Australia, Submission into the House of Representatives Standing Committee on Health, Aged Care and Sport inquiry into approval processes for new drugs and novel medical technologies in Australia, November 2020

[136] Roche, Submission to the Senate Community Affairs References Committee: *Availability of new, innovative and specialist cancer drugs in Australia*, February 2015

Unlike in medical technology and pharmaceutical, where the business model is generally dichotomous (either a government-pays or patient-pays model), digital health companies have diverse expectations about who will ultimately pay for their technologies.[137] This wider range of options in digital health means it can therefore be more difficult to identify the payer and the appropriate business model. ANDHealth notes that 38 percent of digital health companies said seeking reimbursement was part of their business model, and only one-third of digital health companies said they were confident dealing with reimbursement in Australia.[137]

Impact of the gap

This gap impacts start-ups and spin-offs (particularly those led by researchers and clinicians) across all sub-sectors. In the case of start-ups, the lack of ability to identify the payer and develop a monetisation model/reimbursement strategy is a major barrier to market access. The need for this strategy applies all the way from seeking early-stage investment to clinical trials. Inability to develop and implement such a strategy can result in significant cost and re-work (see **Skills gap #13: Awareness and understanding of regulatory requirements among start-ups and SMEs**), or in the worst case, failure of the enterprise.

In areas like companion diagnostics, digital health and novel therapies, the gap in understanding reimbursement pathways can extend to SMEs and large pharmaceutical and medical technology companies.[138] In the case of large companies, a lack of clear understanding of reimbursement pathways for novel therapies (e.g. gene therapies) leads to submission 'churn' and process inefficiencies.[139]

In all cases, the product faces a delayed path to market and significant costs to the company for resubmission. As discussed in **Skills gap #14: Shortage of experienced health economists, Australia's submission processes are costly**, complex and resource-intensive and the inability to navigate them effectively can result in products never reaching the market.[136] If the product does make it to market without reimbursement and patients are forced to pay out of pocket, the product will be far less accessible and adoption will be limited.[140]

[137] ANDHealth, *Digital Health: The sleeping giant of Australia's heath technology industry*, August 2020

[138] AusBiotech, Submission in response to the *Inquiry into approval processes for new drugs and novel medical technologies in Australia*, 16 October 2020

[139] Medicines Australia, Submission into the House of Representatives Standing Committee on Health, Aged Care and Sport inquiry into approval processes for new drugs and novel medical technologies in Australia, November 2020

[140] Roche, Submission to the Senate Community Affairs References Committee: Availability of new, innovative and specialist cancer drugs in Australia, February 2015

Alignment with Sector Priorities and Megatrends

The ability to identify and understand the payer and reimbursement pathways underpins three Sector Priorities. Demand for this skill will continue to grow in line with three primary megatrends.

Sector Priority	Description
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	Identifying and understanding the payer and any requirements early in the product development process is critical to getting a product to market
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Executing a successful reimbursement strategy for a therapy and maximising patient access in local and international markets is a critical feature in becoming a larger, successful company
Priority 5: Support the development of digital healthcare solutions – devices and data analytics	In order to grow a successful digital healthcare sector, there is a need for companies of all sizes to understand the payers and reimbursement processes

Megatrend	Description
Digital evolution	As guidelines evolve, companies must maintain a current understanding of reimbursement requirements to ensure they can efficiently take their digital health innovations to market
Precision healthcare	Increased demand for precision medicine solutions means that it is critical for companies to stay up-to-date on its evolving reimbursement frameworks
Value-based healthcare	The shift towards value-based healthcare may mean that companies have to adapt their reimbursement submissions to capture outcomes-based evidence (rather than volume-based)

Addressing the gap

Similar to **Skills gap #13: Awareness and understanding of regulatory requirements among start-ups and SMEs**, a number of courses could be developed and delivered to start-ups, SMEs and large companies.

In the short term, there is an opportunity to:

- Expand on existing introductory courses run by accelerator programs around the country for start-ups (particularly early-stage university biotechnology/medical technology spin-offs) and SMEs

(particularly those focused on commercialising novel therapies and digital health) that focuses on the importance of developing a reimbursement/payer strategy and the flow-on benefits of doing so early in the development process would be valuable.

- Leverage existing longer training courses to build a deeper understanding, covering first principles of reimbursement and funding in Australia and key international markets. This would include a case study-based immersive learning experience where the participants take a product to Australia and international markets (in theory) by applying learnings from the beginning of the course. The course could be delivered in partnership with expert consultants in this area. It will be important for the course to be tailored to the right audience, i.e. medical technology, pharmaceutical and digital health should be separate courses.
- Select early-stage start-ups and spin-offs could also be offered subsidies to access reimbursement advice or consulting services at appropriate time points of their product development journey.

In the long term:

- Market experts from comparable overseas regulators such as the FDA could be brought over to train and upskill Australia's current reimbursement officers/consultants in international frameworks to improve success of overseas submissions. A focus on digital health and novel therapies would be highly valuable.
- For novel therapies/digital health start-ups, subsidies or grants could be offered to these early-stage companies to enable them to seek the latest and most relevant advice from consultants/reimbursement bodies regarding reimbursement.

Theme: Specialist and technical skills

The MTP sector is underpinned by a range of specialist and technical skills. These skills span a range of disciplines, including biological, chemical, physiological and data sciences.

Several of the identified gaps in this theme are highly specialised and only impact a niche part of the sector (see Appendix 2 for the complete list). Others are 'enabling' skills that have a broader and deeper impact (e.g. bioinformatics). These gaps are required to support Australia in its KP areas. The identified priority gaps are relevant for emerging therapeutics and therefore align with a higher number of Sector Priorities and megatrends.

In general, the sector does not recognise a gap in the quality of this workforce; rather, there is a shortage of people with these skills in the workforce. Within industry, some shortages in specialist and technical skills are exacerbated by a highly specialised workforce (e.g. postgraduates) being 'locked in' the academic research setting, with limited mobility to industry.

Skills gap #19: Shortage of skills in bioinformatics (particularly in genomics)

Overview of the skill

Bioinformatics is an interdisciplinary field of science, combining biology, computer science, information technology and statistics to manage, analyse and interpret biological data. Bioinformatics is a critical enabling discipline for life sciences and its applications promise tremendous benefits in health. The most recognised application of bioinformatics has been the mapping of the human genome.

In the MTP industry, pharmaceutical companies may employ bioinformaticians for a range of activities, such as modelling protein structures or molecular interactions, discovering potential new drugs using computational methods, or processing and analysing DNA sequencing data. Bioinformaticians may also write computer programs, design databases, or perform statistical analysis on genome-sized datasets.

Description of the skills gap

There is both a capability and a capacity gap in bioinformatics skills in Australia. This is particularly noted in the fields of genomics, proteomics and metabolomics.

These specific skills gaps include:

- Bioinformatics capabilities in a commercial/clinical trial setting. This includes skills in data stewardship (management, storage, integration and sharing), as well as data analysis (visualisation and interpretation)
- Ability to interpret clinical/biological data in context, synthesise results and communicate technical findings to scientists, clinicians and commercial stakeholders.

Demand for bioinformatics and genomics skills is greater than the supply of graduates. This is a longstanding skills gap, which Australia has recognised and has made some efforts in recent years to

build research capabilities in academia (e.g. with the Australian Genomics Health Alliance), but a gap still exists in the commercial setting. Analysis of MTP sector jobs on the SEEK recruitment platform showed that the number of bioinformatics job applications grew by only 5 percent from 2017 to 2019 even though the number of advertisements placed doubled in the same period. It has been acknowledged that it will take time to develop a sufficient workforce supply that matches the high growth rate of the industry.[141,142]

Further, it has been noted that students with highly applicable skillsets such as computer science and statistics are often drawn to other higher-profile disciplines, such as software engineering or computer science.[143] This means that MTP companies are competing with other industries for this talent pool, further exacerbating the shortage.

Impact of the gap

The global market for bioinformatics is valued at c.US$7 billion and is expected grow at c.14 percent p.a. to reach c.US$20.5 billion by 2025.[141] There is an opportunity to capture part of this market and capitalise on the clinical, technological and commercial value offered by bioinformatics, by leveraging Australia's strong research capabilities and infrastructure in life sciences.

The shortage of skilled bioinformaticians impacts biotechnology, pharmaceutical and biological/health software companies. This has been noted as a global issue and can even be a bottleneck for big pharmaceuticals that are pioneering precision therapeutics.[144] The shortage slows the pace of drug discovery, particularly those based on large-scale genome sequencing projects. It also results in reduced efficiencies around data management and integration, which is an additional pain point for these companies.

Australia's life sciences companies have previously coped by importing talent, but this is unsustainable and forfeits Australia's opportunity to build a homegrown bioinformatics workforce.[143] By failing to prioritise the development of this workforce, Australia runs the risk of becoming reliant on the global marketplace for these capabilities and stifling the growth of local biotechnology and pharmaceutical companies.

There is also a significant economic opportunity associated with addressing this gap. For example, estimates suggest that the Human Genome Project delivered US$178 to the US economy for every public dollar spent on the original sequencing.[145] Developing national capabilities in bioinformatics and establishing an onshore industry will strengthen local biotechnology and pharmaceutical companies, retain IP and expertise within Australia and grow the international perception of Australia as a bioinformatics hub.

[141] *Medgadget*, Bioinformatics Market Size, Growth and Industry Report 2020-2025 | CAGR of 13.80%, July 2020
[142] Stakeholder consultations
[143] Australian Bioinformatics Network, Senate Inquiry into Australia's Innovation System: Submission 91, 2015
[144] *Genestack*, Is a shortage of bioinformaticians holding back adoption of precision medicine?, 28 July 2017
[145] United for Medical Research, *The Impact of Genomics on the U.S. Economy*, June 2013

Alignment with Sector Priorities and Megatrends

Skills in bioinformatics underpin three Sector Priorities. Demand for these skills will continue to grow in line with four megatrends, with precision medicine being one of the primary drivers.

Sector Priority	Description
Priority 1: Align investment in KPs that meet current and future market needs	Using bioinformatics methods will put Australia in a better position to understand and maximise the insights from the KPs, particularly in areas of science
Priority 4: Strengthen Australia as an attractive clinical trial research destination	Growth of clinical trials in areas like precision medicine require a strong bioinformatics workforce, particularly those with an understanding of genomics data banks and repositories
Priority 5: Support the development of digital healthcare solutions – devices and data analytics	Developing a strong workforce of high-quality bioinformaticians will strengthen Australia's capabilities in data analytics and interpretation of complex biological processes

Megatrend	Description
Digital evolution	The rapid growth of biological databases (e.g. for genomic data) requires highly skilled bioinformaticians to capture, manage and analyse these large biological data banks
Precision healthcare	Bioinformatics is a key enabler for the burgeoning field of precision medicine and its clinical applications. It is important to build local capacity and capabilities in this area to maximise the clinical, technological and commercial benefits
Global biosecurity	Bioinformatics and genomic sequencing have been critical to tracking, studying and understanding the COVID-19 pandemic. Strengthening these capabilities will continue to be critical to Australia's public health responses
Consumer control	Greater accessibility to genomic analysis will drive demand for skilled bioinformaticians as patients seek to be more informed for clinical, wellness or lifestyle reasons

Other considerations

As discussed in **Skills gap #10: Understanding of and expertise in big data capture, management and analysis**, there are several structural issues that hinder research and commercial access to health and biological data, including legislation and the fragmented data infrastructure.

Bioinformatics relies on investment from life science industries and government funding, but its 'behind-the-scenes' nature has meant that it has not been an area of priority in Australia. The top countries in bioinformatics and genomics have invested heavily into the infrastructure, capabilities and capacity to drive and support growth of the sector. For example, following the successful conclusion of its '100,000 Genomes Project' in 2018, the UK has committed to a £200 million Whole Genome Sequencing Project that involves the government, charities and four big pharmaceutical companies.

The Australian Academy of Technology & Engineering suggested that to establish a world-leading precision medicine industry in Australia, there would need to be significant infrastructure investment, such as the UK's Cell and Gene Therapy Catapult that supports researchers and companies in cell and gene therapies from research through to manufacturing, regulatory approval and market access.[146] Certain states have made their own investments; however, a coordinated strategy and investment plan from the Australian Government may be necessary for the country to achieve its full potential. The latest partnership between Bioplatforms Australia and the Australian Research Data Commons to make large-scale investments in digital infrastructure for biosciences is demonstration of progress in this area.[147]

Addressing the gap

In the medium term:

- Industry bodies and education and training providers could develop short courses (e.g. online modules or face-to-face workshops) to enable the workforce to acquire new skills in bioinformatics (e.g. next-generation sequencing data analysis) and data stewardship.
- Industry bodies and education and training providers could develop traineeship programs or degree apprenticeships to build highly skilled, job-ready graduates. This has been demonstrated in the UK, with bioinformatics-specific degree apprenticeships offered by Anglia Ruskin University and the Wellcome Sanger Institute. This has been supported by global companies involved in genetics and computation biology, such as GSK.[148]
- To accelerate the pipeline of bioinformatics graduates, education providers could look at expanding existing programs, e.g. Master of Bioinformatics, to reach a wider cohort of students from engineering and nursing backgrounds. There is also an opportunity to integrate bioinformatics techniques into life science undergraduate degree programs, so that these skills are instilled in students earlier in their career.[149]

Skills gap #20: Shortage of pharmacologists and toxicologists with drug development expertise

Overview of the skill

Pharmacologists study and predict how drugs interact with the human body. Toxicologists predict and study the adverse effects of medicines.[150] Both specialists play an integral role in drug discovery

[146] Australian Academy of Technology & Engineering, A *new prescription: Preparing for a healthcare transformation*, April 2020

[147] Australian Research Data Commons, Strategic partnership between the Australian Research Data Commons and Bioplatforms Australia provides a solution to the bioinformatics challenge, 25 February 2020

[148] *Education Technology*, Apprenticeships to address bioinformatics skills shortage, November 2017

[149] T. K. Attwood et al. A global perspective on evolving bioinformatics and data science training needs, *Briefings in Bioinformatics*, 29 August 2017

[150] In Australia, a 'clinical toxicologist' refers specifically to a qualified doctor with a specialisation in toxicology. This skills gap refers only to toxicology practitioners with a science degree with a relevant major

and development and ultimately determine the success (or failure) of a new drug candidate during preclinical and early clinical testing.

Pharmacologists can provide specialist support ranging from preclinical discovery of new target molecules through to analysing the effects of drugs in different populations. Similarly, toxicologists are responsible for evaluating the safety of potential drug candidates to support first-in-human studies, through to providing risk profiles for registration of a product. Both specialist skills are critical to the design, oversight and review of clinical trials to ensure that all the pharmacological and toxicology studies have been completed with the appropriate level of evidence required by the regulatory bodies. These skills are important across most of the MTP sector value chain from research institutes to CROs, pharmaceutical and biotechnology companies and even the TGA.

Both roles require a strong scientific/medical background with in-depth expertise in drug properties, excellent analytical and communication skills and an understanding of effective clinical trial design.

Description of the skills gap

Australia has a significant shortage of pharmacologists and toxicologists that have expertise in drug development, predominantly early-phase clinical trials.

These specific skills gaps include a shortage of pharmacologists and toxicologists with the following expertise:

- Practical understanding of the drug development pathway. This includes experience in the design, oversight and review of clinical trials
- Understanding of regulatory frameworks, both in Australia and with key markets like the US and EU.

Several of Australia's leading universities offer undergraduate degrees majoring in pharmacology, although there are far fewer available in toxicology. These degrees primarily focus on the fundamental scientific knowledge required to understand the fields of pharmacology and toxicology from a technical perspective rather than a clinical one. There are few opportunities to learn about preclinical and clinical drug development, including the planning and executing of clinical trials and regulatory applications. As a result, there is an insufficient number of graduates coming out of undergraduate programs with a functional understanding of the drug development pathway or practical clinical skills associated with it.

Stakeholder consultations also suggest that undergraduate students with degrees in pharmacology and toxicology are not aware of potential career pathways in drug development. Very few programs incorporate an industry placement, further limiting students' exposure to the field of drug development. People with degrees in pharmacology have several career options, namely: joining pharmaceutical companies across a variety of roles (e.g. sales and marketing, quality assurance [QA]), product formulation in adjacent industries (e.g. food sciences, cosmetics), or continuing in academia.

In short, there are limited options to work in drug development and anecdotally, due to Australia's limited onshore drug development opportunities, graduates wanting to pursue this area seek jobs overseas. This further exacerbates the shortage of local graduates with this knowledge.

Australia has adequate supply of toxicologists across other higher-profile industries (e.g. agriculture, poisons and overdose), but the shortage distinctly lies in toxicologists with expertise in drug development. While there is the prospect of transferable skills across industries, e.g. from agricultural toxicology to drug development toxicology, stakeholder feedback suggests that there is a cultural aversion to changing industries. Australia's toxicologists tend to have a siloed mindset regarding their specialisation and therefore it is unlikely that they could be diverted from other industries towards MTP.

This shortage is leading CROs and pharmaceutical companies to hire doctors and train them in these skills, or recruit from overseas. This approach is both difficult and expensive and is unsustainable for the sector in the long term.

Impact of the skills gap

The shortage of pharmacologists and toxicologists, with drug development expertise, affects Australia's ability to develop and commercialise new therapeutics. Roughly $600 million p.a., or c.35–40 percent of total clinical trial expenditure, is spent on early-phase trials.[151] A shortage of on-the-ground, high-quality pharmacologists and toxicologists with early-phase drug development expertise limits Australia's ability to attract and conduct early-phase clinical trials. Addressing this skills gap can also potentially have flow-on impacts on the number of later-stage trials conducted in Australia, as trial sponsors who have a good experience in Phase I/II are more likely to continue with Phase III/IV in Australia.[152]

As the industry moves towards precision medicine and smart medical devices, pharmacologists and toxicologists will become increasingly important to ascertain the safety and efficacy of these new therapeutics. They will also play an important role in developing effective regulatory frameworks that enable these novel technologies to thrive whilst maintaining high safety and quality standards for patients and consumers.

The COVID-19 pandemic has highlighted the importance of Australia having local capabilities to develop vaccines and therapeutics to combat new diseases. Developing a greater pool of pharmacologists and toxicologists will play an important role in enabling development of vaccines and other therapeutics for biodefence, as highlighted by a 2017 audit by the Department of Defence.[153] While Australian organisations such as CSIRO, The University of Queensland (UQ) and Nucleus Network have all played world-leading roles in developing potential vaccine candidates for COVID-19, there is room for Australia to do even more in preclinical and clinical R&D by addressing this skills gap.

[151] Based on 2015 proportions of clinical trial expenditure from industry. See MTPConnect, *Clinical Trials in Australia,* June 2017

[152] Stakeholder consultations

[153] Department of Defence, Certara, *Medical Countermeasures Initiative: National Capability Audit 2017 Summary*, 2018

Alignment with Sector Priorities and Megatrends

Although this skills gap is not directly aligned with specific megatrends due to its broad nature, it is important as it underpins MTP Sector Priorities. The shortage of pharmacologists and toxicologists directly affects four Sector Priorities.

Sector Priority	Description
Priority 1: Align investment in KPs that meet current and future market needs	A supply of skilled pharmacologists and toxicologists with drug development expertise is necessary for Australia to succeed in pursuing world-class positions in its identified KP areas, particularly in the identified therapeutic areas
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	Pharmacologists and toxicologists play a significant role in drug development and translational medicine. This shortage affects the translation of drug candidates to early-phase clinical trials and subsequent commercialisation
Priority 4: Strengthen Australia as an attractive clinical trial research destination	Clinical trials require clinical pharmacologists and toxicologists to assess the safety and efficacy of the drug. This shortage limits Australia's attractiveness as a clinical trial destination.
Priority 7: Support advanced manufacturing as a part of the broader Australian innovation system	An onshore supply of pharmacologists and toxicologists with experience in drug development will support advanced manufacturing of high-value pharmaceuticals as part of the broader Australian innovation ecosystem

Other considerations

Australia's sub-scale pharmaceutical and biotechnology R&D industry is a barrier to developing and retaining talented pharmacologists and toxicologists, with the required expertise. Without an at-scale industry, career pathways within Australia are limited and therefore many of these practitioners tend to seek opportunities offshore. The Australian Government's recent announcements around developing modern manufacturing capabilities in Australia could help develop a stronger pharmaceutical/biotechnology R&D industry.[154] However, these efforts will take several years to have a meaningful impact.

Addressing the gap

In the short term:

- There is a need for the sector to raise awareness of the field and possible career pathways to undergraduate students. This could involve engaging pharmacology and toxicology students at career events, or through short courses to give students first-hand exposure to the drug development applications of their studies.

[154] The Hon Karen Andrews MP, 2020–21 Budget – Manufacturing Australia's future, 6 October 2020

- Alongside this is an opportunity to provide undergraduates and postgraduates with internships or graduate programs in pharmacology or toxicology, in drug development. These traineeships could teach participants how to design, analyse, interpret and report drug development research and clinical trials across academia, industry and CROs.

In the medium term:

- Expand on existing programs to prepare the next generation of industry-experienced pharmacologists and/or toxicologists. For example, Certara and Monash University developed the Certara-Monash University Industry Fellowship Program – a program supported by MTPConnect (April 2019–October 2021). It is the country's only fellowship program designed to prepare the next generation of industry-experienced pharmacologists that will support drug development in Australia. Going forward, these courses could be expanded and offered to a wider cohort of postdoctoral fellows.
- To support this training, incentives could be provided to attract skilled pharmacologists and toxicologists from overseas to Australia and share their drug development expertise with the next generation of scientists. However, limitations imposed by COVID-19 travel restrictions would need to be considered.

In the longer term:

- There is a need for the existing programs in pharmacology and toxicology to carry a greater focus on industry-relevant material. This should include content on drug development and practical skills such as designing robust clinical trials to gather evidence on safety and efficacy.
- Australian education providers should look to establish postgraduate courses that build on undergraduate courses and offer training and placements within industry. There are very few postgraduate courses available for students that want to further their theoretical and practical knowledge of pharmacology and toxicology. .

4. Conclusion and Next Steps

A comprehensive 'root and branch' analysis of current and future skills gaps across the MTP sector has been carried out with the input of more than 200 individuals spanning different segments of the value chain, extensive desktop research including international case studies where appropriate and an analysis of MTP sector jobs posted on the SEEK recruitment platform over the past three years.

Through this research and analysis, a total of 76 unique skills gaps were identified across seven themes. The seven themes are advanced manufacturing and supply chain, business operations, clinical trials, health data and cybersecurity, health economics and regulatory affairs, product development and commercialisation, and specialist and technical skills.

These gaps were assessed through a prioritisation framework and deep dives were conducted for the 20 priority skills gaps. These gaps were characterised as gaps in capability, capacity or experience. Of the 20 priority gaps, half are considered 'well-known' to the sector; the other half were identified as 'recently emerging' as summarised in the graphic below. Additionally, the priority skills gaps identified have a strong alignment with five key national strategic plans/initiatives of the Australian Government, especially with the Modern Manufacturing Strategy.


Summary of priority skills gaps
Advanced manufacturing and supply chain
1 Understanding of Quality Management Systems (QMS) and protocols
2 Manufacturing expertise in high-tech and/or specialised medtech devices
3 Manufacturing expertise in high-value therapeutics at a commercial scale
Clinical trials
5 Strategic design of clinical trials to address regulatory and payer needs
6 Shortage of experienced Clinical Research Associates (CRAs)
7 Shortage of Clinical Trial Coordinators (CTCs)
Health economics and regulatory affairs
13 Awareness and understanding of regulatory requirements amongst start-ups and SMEs
14 Shortage of experienced health economists
Specialist and technical skills
19 Shortage of skills in bioinformatics (particularly in genomics)
20 Shortage of pharmacologists and toxicologists with drug development expertise
Business operations
4 Shortage of MTP-specific project managers to support start-ups and spin-offs
Health data and cybersecurity
8 Leadership awareness about the value of best-practice management in cybersecurity
9 Shortage of cybersecurity professionals and IT infrastructure resilience skills within MTP
10 Understanding of and expertise in big data capture, management and analysis
11 Expertise in the design and use of artificial intelligence (AI) within MTP
12 Shortage of skills in health informatics
Product development and commercialisation
15 Shortage of industry professionals with end-to-end translation and commercialisation experience
16 Ability to identify unmet market need and understand the clinical context
17 Ability to secure investment, funding and/or industry collaboration
18 Identification of the payer and understanding of reimbursement pathways and requirements
Key : Recently emerging gap
Well-known gap
Capacity
Capability
Experience

Addressing these priority skills gaps will be essential to developing the MTP sector workforce of the future and consequently unlocking significant value for the MTP sector that can continue to enhance Australia's reputation globally.

MTPConnect will be driving the development of bespoke solutions to address some of these priority skills gaps through the REDI initiative. RfPs for solutions addressing two priority skills gaps – understanding of QMS and strategic clinical trial design to meet regulatory requirements and payer needs – were announced in November 2020. To address the other priority skills gaps, a second round of RfPs will open in March 2021, with programs expected to begin mid-2021.

Given the cross-sector nature of many of the priority skills gaps, MTPConnect will continue to collaborate with all interested stakeholders across the sector to develop appropriate solutions that can help address these skills gaps and enable Australia to prepare and develop a well-equipped MTP sector workforce across the industry value chain for the future.

Appendices

Appendix 1: List of senior sector stakeholders consulted

This MTP sector skills gap assessment report was developed with input from over 100 senior sector executives, through targeted stakeholder consultations. The perspectives shared by these senior stakeholders from industry associations, companies, regulatory bodies, research organisations, government representatives and funders have informed key insights, themes, stories and recommendations within this report. MTPConnect would like to thank all those who shared their time and insights through these stakeholder consultations. The list of stakeholders is shown in the table below.

Name	Organisation	Name	Organisation
Dr Peter Thomas	AAMRI	Nick Northcott	Chrysalis Advisory
Ailsa Surman	Amgen	Sally-Ann Williams	Cicada Innovations
Bronwyn Le Grice	ANDHealth	Dr Michael Bettess	Cincera/Brandon Capital Partners
Dr Shanny Dyer	ARCS	Jane Kelly	CMAX
Dr Ashley Bates	AusIndustry	Dr Leszek Lisowski	CMRI
Michelle Price	AustCyber	Marni Leffler	Cochlear
Julie Constantin	Austin Health	Nicole Bisschop	Cochlear
Tiffany Boughtwood	Australian Genomics Health Alliance	Brooke O'Rourke	Cochlear
Renan Bac	Bayer	Maria Dionyssopoulos	Commercial Eyes
Mary Flannery	Bayer	Andrew Carter	Commercial Eyes
Kylie Sproston	Bellberry Ltd	Dr Rob Grenfell	CSIRO
Dr Glenn Begley	BioCurate	Dr Geoff Dumsday	CSIRO
Jenny Herz	Biointelect	Dr Andrew Nash	CSL
Peter Gover	Bionics Institute	Anna Schulze	CSL
Michael Reynolds	BIOTRONIK	Dirk Beelen	Department for Trade and Investment, SA
Adam Waters	BIOTRONIK	Professor Tim Shaw	Digital Health CRC
Stephen Thompson	Brandon Capital Partners	Dr Bronwyn Evans	Engineers Australia
Grant Bennett	Brandwood CKC	Dr Andrew Milligan	Flinders University
Yvette Waddell	Brien Holden Vision Institute	Dr Melissa Ryan	Flinders University
Kirpal Kaur	Bristol Myers Squibb	David Barva	Garvan Institute of Medical Research
Jeremy Wurm	Brooker Consulting	Dr Parisa Glass	George Institute for Global Health
Professor Enrico Coiera	Centre for Health Informatics	Carolyn Tucek-Szabo	GlaxoSmithKline
Professor Caroline McMillen	Chief Scientist of SA	Carrie Bloomfield	GlaxoSmithKline
Professor Peter Klinken	Chief Scientist of WA	Mark Flynn	Global Edge Medtech Consulting

Name	Organisation	Name	Organisation
Professor Peter Leedman	Harry Perkins Institute of Medical Research	Catherine O'Mahony	On Q Recruitment
Kevin Wightman	Illingworth Research	Dr Megan Baldwin	Opthea
Jason Coonan	IMCRC	Professor Andrew Wilson	PBAC
Dr Marguerite Evans-Galea	IMNIS	Professor Grant McArthur	Peter MacCallum Cancer Centre (PMCC)
Megan Ford	Ingham Institute for Applied Medical Research	Associate Professor Dominic Wall	PMCC
Thomas Bryant	IQVIA	Brian Hewitt	Pfizer
Kathy Connell	J&J Innovation	Dr Bill Lam	Pfizer
Elizabeth de Somer	Medicines Australia	Dr Paul MacLeman	Pharmaceutical Manufacturing Industry Reference Committee
Peter Komocki	Medicines Australia	Sam Lanyon	Planet Innovation
Sara Pantzer	Medicines Australia	Angela Masterton	PPD
Mark Sullivan	Medicines Development for Global Health	Professor Fabienne Mackay	QIMR Berghofer
Dr Pinky Dharmshaktu	Merck	Leanne Kemp	Queensland Chief Entrepreneur
Stefan Czyniewski	Mobius Medical	Crystal Howell	Randstad Sourceright
Professor Peter Currie	Monash University	Greg Mullins	Research Australia
Ian Burgess	MTAA	Alan Lipman	Romar Engineering
Lee Grow	MTAA	Professor Steve Wesselingh	SAHMRI
Dr Nicholas Cerneaz	MTPConnect Board	Helen Critchley	Sanofi
Alex Fowkes	MTPConnect Board	Lisa Nelson	Scientia Clinical Research
Hamish George	MTPConnect Board	Dr David Lloyd	Southern Star Research
Sue MacLeman	MTPConnect Board	Dr Megan Robertson	St Vincent's Hospital Melbourne
Julie Phillips	MTPConnect Board	Robert Kent	St Vincent's Hospital Sydney
Dr Douglas Robertson	MTPConnect Board	Katrina Kunicki	St Vincent's Institute of Medical Research
Dr Tina Soulis	Neuroscience Trials Australia	Rob Wood	Stryker
George Lillis	Novartis	Mathew Palmer	Syneos Health
Eleanor Clifford	Novo Nordisk	Evan Watson	Teleflex
Dr Daniela Caiazza	Novotech	Adjunct Professor Paul Watt	Telethon Kids Institute
Dr Antonio Penna	NSW Health	Professor Kevin Pfleger	The University of Western Australia
Cameron Johnson	Nucleus Network	Dr Anthony Doyle	Teva Pharmaceuticals

Name	Organisation	Name	Organisation
Professor Sir John Savill	The University of Melbourne	Chris Packer	VCCC
John Kurek	Uniseed	Michelle Barrett	VCCC
Dr Stephen Palmer	UNSW	Anthony Green	Vifor Pharma
Dr Zoe Terpening	UNSW	Professor Doug Hilton	Walter & Eliza Hall Institute of Medical Research
Emeritus Professor Maree Smith	The University of Queensland	Professor Mark Kendall	WearOptimo
Dr Mark Buzza	Victorian Comprehensive Cancer Centre (VCCC)		

Appendix 2: Complete list of identified skills gaps

Theme	Skills gap	Description of the gap	Final score[155]
Advanced manufacturing and supply chain	Understanding of QMS and protocols	Understanding and implementation of quality assurance and control protocols, particularly relating to manufacturing of therapeutics and devices (including GLP, GCP, GMP guidelines and ISO standards). This also extends to quality control practices relating to data collection	9
	Manufacturing expertise for high-tech and/or specialised medtech devices	Shortage of local expertise required for advanced medical technology manufacturing (e.g. smart devices, implants and bionics), including process engineers, data and analytics experts and a GMP/GLP/GCP-certified workforce	9
	Manufacturing expertise for high-value therapeutics at a commercial scale	Shortage of local expertise required for the manufacture of high-value pharmaceuticals (e.g. biologics and cell therapies) at a commercial scale. This includes a lack of process engineers and a GMP/GLP/GCP-certified workforce	9
	Shortage of senior operations management talent in medical technology manufacturing	Capacity gap of experienced professionals with leading and managing operations relating to medical technology manufacturing	6
	Shortage of skilled robotics engineers	Shortage of robotics engineers, skilled in design of intelligent, IoT-enabled, customised medical technology devices	6
	Shortage of experienced service engineers particularly for medical technologies	Shortage of experienced service engineers with knowledge on service, preventative maintenance and repairs of high-tech equipment particularly in manufacturing of medical technologies	6
	Supply chain expertise, e.g. for emerging therapies	Lack of experts with knowledge of supply chain management for cell therapies, including distribution logistics, packaging and temperature control	6
	Expertise in product sterilisation	Shortage of expertise in good-quality product sterilisation that meets compliance standards and is appropriate for the product (in terms of choosing the technology). This is somewhat further limited by access to sufficient product sterilisation facilities	5
	Expertise in stock inventory management	Capabilities in understanding how much inventory to hold on to; volume of safety stock; expiry and obsolescence across MTP companies	5
	Shortage of experts in 3D printing of biocompatible materials	Shortage of experts who can generate 3D solid biocompatible prototypes/products from a digital model	*NR*[156]

Keys REDI focus areas identified in Phase 1 REDI focus areas identified in Phase 2

[155] Based on prioritisation framework (see Appendix 3 for scoring methodology). Scores denoted 'n/a' indicate that the gap was not run through the prioritisation framework

[156] NR means not rated. Skills gaps identified by less than half of eligible survey respondents to the MTPConnect workforce survey conducted in July 2020 were not rated as they were deemed to be low priority

Theme	Skills gap	Description of the gap	Final score[155]
Business operations	Shortage of MTP-specific project managers to support start-ups and spin-offs	Shortage of project management professionals who understand the product development pathway and are capable of managing new product development within early-stage MTP companies	10
	Soft skills required for medical science liaisons and market access roles	Lack of negotiation, influencing and communication skills among medical science liaisons and market access professionals who typically have strong technical backgrounds	8
	Stakeholder management skills, particularly for middle-to-senior managers	Lack of ability for middle-senior managers to appropriately engage and manage stakeholders, including investors and government representatives	8
	Business risk assessment and decision-making skills	Lack of ability to be objective and make commercially minded decisions (avoiding 'founder syndrome'). This includes the ability to assess and mitigate investment risks, deployment of capital and other business strategies	7
	Shortage of experienced CEOs for spin-offs/start-ups	Shortage of CEOs who have operational experience in successfully running MTP spin-offs/start-ups locally and/or overseas	7
	Understanding of the MTP sector and returns possible among investors	Lack of understanding of MTP development pathways, timelines and returns on investment among investors	7
	Change management skills	Lack of ability to adopt and promote innovation, and drive a change in culture towards greater entrepreneurialism for leaders in the MTP sector across the value chain	6
	Effective communication skills among business leaders	Lack of ability among business leaders in early-stage MTP companies to lead successful negotiations and/or communicate scientific and commercial ideas persuasively to different stakeholder groups (e.g. industry, government)	6
	Leadership skills with ability to think strategically, financial and commercial planning with a long-term view	Lack of ability to think and plan strategically with a long-term view. Leaders, particularly of start-ups, can tend to have a myopic focus on the product at hand and not necessarily think how it will fit into their larger business strategy. This also extends to long-term financial and commercial planning	6
	Shortage of experienced government affairs and relations professionals	Shortage of professionals that have experience engaging with government departments and personnel and are skilled at navigating and understanding the policy environment	6
	Understanding of corporate governance	Lack of ability for business leaders to understand the importance of corporate governance standards and how to proactively ensure the company is fully compliant	6

Keys REDI focus areas identified in Phase 1 REDI focus areas identified in Phase 2

Theme	Skills gap	Description of the gap	Final score[155]
Business operations	Understanding of sales and marketing communications	Lack of capable sales and marketing professionals who can effectively target the right markets with the right strategies and have the appropriate technical, commercial, and market knowledge to manage a variety of stakeholders. This includes building business development plans	5
Clinical trials	Strategic clinical trial design to address regulatory and payer needs	Capability gap among SMEs in designing clinical trials for commercial success at the outset with understanding of regulatory and reimbursement approval requirements	10
	Shortage of experienced CRAs	Shortage of experienced CRAs, who are primarily responsible for monitoring clinical trials, including assuring compliance with protocol, documenting adverse events and protecting and verifying scientific integrity of data	9
	Shortage of CTCs	Shortage of CTCs, who are responsible for day-to-day running of clinical trials at hospital sites, typically all the way from patient recruitment through to follow-up assessments	9
	Consistency in implementation of clinical trial governance frameworks	Shortage of clinical trial governance experts who have expertise in implementation of clinical trial governance frameworks	8
	Expertise in capturing, managing and analysing RWE, patient-reported outcomes	Lack of RWE expertise to capture, manage and analyse data (e.g. from clinical trials, access schemes) and communicate findings from RWE in a compelling fashion to business leaders	7
	Shortage of expertise in design and operation of investigator-initiated trials (IIT)	Shortage of expertise among academic and clinician researchers in designing and operating efficient IITs	7
	Expertise in the use of digital technologies to facilitate virtual clinical trials (including tele-trials, remote monitoring)	Lack of expertise among study managers/directors in effectively incorporating digital technologies for clinical trials, such as digital recruitment, remote monitoring and digital data collection	7
Health data and cybersecurity	Leadership awareness about the value of best-practice management of cybersecurity	Capability gap among business leaders in MTP in understanding the importance of cybersecurity and best-practice management required to protect organisations from cyber attacks	9
	Shortage of cybersecurity professionals and IT infrastructure resilience skills within MTP	Shortage of cybersecurity professionals who understand the tools, technologies, processes and practices that can be used to protect networks, computers and data across the MTP and healthcare sector from unauthorised access or attack	10

Keys REDI focus areas identified in Phase 1 REDI focus areas identified in Phase 2

Theme	Skills gap	Description of the gap	Final score[155]
Health data and cybersecurity	Understanding of and expertise in big data capture, management and analysis	Shortage of data scientists who can capture, curate and interpret large streams of (often unstructured) health data. This gap also extends to a lack of understanding among management around big data benefits and use cases, as well as a shortage of data 'influencers' who can demonstrate and communicate the value of analytics	12
	Expertise in the design and use of AI within MTP	Capability gap in designing and using AI technologies for advanced MTP and healthcare applications (e.g. for diagnosis or decision-making). Skills gaps include understanding clinical workflow, complexities of working with healthcare data and associated regulations/legislation	12
	Shortage of skills in health informatics	Shortage of health informatics specialists, whose field spans information systems, informatics and IT in the medical/healthcare system context. Gaps include understanding the complexities of working with healthcare data and creating real-time data registries. This gap also extends to a lack of awareness among management about the benefits and use cases of health informatics	10
	Ability to effectively develop, manage and curate patient registries	Capability gap in establishing data registries with the right types of data and understanding of what is required from a medical or market access perspective	8
Health economics and regulatory affairs	Awareness and understanding of regulatory requirements amongst start-ups and SMEs	Capability gap of start-ups and SMEs in understanding and integrating regulatory requirements early in the product development process	11
	Shortage of experienced health economists	Shortage of health economists in Australia who have experience in successfully listing products on the MBS/PBS, as well as a shortage of skills in assessing emerging therapies (e.g. stem cell)	9
	Legal expertise in emerging MTP areas such as digital health and personalised medicine	Lack of legal experts with expertise in regulatory affairs in emerging areas such as digital health and personalised medicine	8
	Ability to align HTA with emerging therapies and devices	Shortage of HTA experts who can provide advice, particularly to emerging therapies and devices such as stem cell therapies based on clinical effectiveness, cost-effectiveness, as well as safety, social, ethical and legal aspects. This is important to developing high quality and efficient reimbursement strategies for these new and emerging products	7
	Skills in designing flexible regulatory frameworks for innovative areas, e.g. digital health	Lack of expertise in developing agile regulatory guidelines that keep pace with the level of innovation in the MTP sector	7

Keys REDI focus areas identified in Phase 1 REDI focus areas identified in Phase 2

Theme	Skills gap	Description of the gap	Final score[155]
Health economics and regulatory affairs	Shortage of pharmacovigilance experts	Shortage of experts who can collect, monitor, assess and evaluate adverse event information for medicines from healthcare providers and patients	6
	Significant shortage of skills in medical device safety monitoring	Shortage of experts in medical device monitoring (similar to the above for medicines). This role involves evaluating reported adverse events, disseminating information that could be used to prevent or minimise the consequences of adverse events and suggest modifications to the medical device if required	5
	Understanding market access requirements for overseas jurisdictions	Capability gap in understanding the complexity of accessing overseas markets, including government negotiations, supply chains, regulatory requirements, reimbursement processes and healthcare systems. Particularly applicable to start-ups and SMEs	6
Product development and commercialisation	Shortage of industry professionals with end-to-end commercialisation experience	Shortage of experienced professionals who have practical commercialisation experience and can mentor researchers/start-ups through the research translational process. This includes early-phase drug development	11
	Ability to identify unmet market need and understand the clinical context	Capability gap in researchers/entrepreneurs in identifying and understanding an unmet need in the market, as well as understanding how the proposed solution would be used in the clinical environment	10
	Ability to secure investment, funding and/or industry collaboration	Capability gap in entrepreneurs in pitching for funding, investment and collaboration from government and private organisations through clearly articulating unmet market need and commercial potential in proposals. This includes an understanding of how VC funds operate	10
	Identification of the payer and understanding of reimbursement pathways and requirements	Capability gap in identifying who the end-product will be sold to and what pathways should be taken to obtain reimbursement (e.g. PBS vs state programs). Includes the ability to navigate the complex reimbursement processes and anticipate requirements (e.g. level and type of clinical evidence/ validation, health economics input)	9
	Ability to network and build relationships across the sector (locally and internationally)	Lack of ability of start-ups/SMEs to seek and form commercial relationships. This may include building international trade and investment networks, connecting with potential overseas manufacturers or suppliers, or networking with clinician groups and associations	8
	Expertise in IP strategy and pathways	Lack of ability in early-stage MTP companies to develop an appropriate IP strategy that optimises the value and go-to-market of their product	8

Keys REDI focus areas identified in Phase 1 REDI focus areas identified in Phase 2

Theme	Skills gap	Description of the gap	Final score[155]
Product development and commercialisation	Expertise in product design, including understanding of the end-user	Lack of design capability to take a research concept and design a product that will meet the needs of the end-user. This requires an understanding of the context in which a product will be used, e.g. knowing the patient and/or clinician workflow. Primarily observed in early-stage medical technology and digital health companies	8
	Ability to communicate across the sector	Lack of ability of researchers/SMEs to effectively communicate their ideas/products to different stakeholder groups with different backgrounds (e.g. clinicians, government bodies, larger companies)	7
	Business acumen among researchers and entrepreneurs	Capability gap among researchers and entrepreneurs in recognising commercial opportunities, identifying ways to monetise technology, and understanding the current landscape (e.g. market research skills). This also requires understanding and developing budgets and/or financial models	7
	Collaboration mindset and ability to work in multidisciplinary teams	Absence of collaborative mindset among researchers/ start-ups/SMEs often results in relevant expertise from across different disciplines not being brought in to develop new products and solutions	7
	Entrepreneurial mindset and risk tolerance	Lack of willingness of researchers/entrepreneurs to take risks and pursue entrepreneurial pathways with a willingness to fail	7
	Strategic marketing capabilities for new product launches, particularly in medical technology and digital health	Capability gap particularly among smaller medical technology and digital health companies to develop, implement and evaluate marketing strategies for market entry and to secure a competitive advantage	6
	Ability to build effective business plans, particularly for early-stage companies	Capability gap among start-ups to develop comprehensive business plans that communicate their proposed business model, financials, sources of funding, market assessment and reimbursement strategy	5
Specialist and technical skills	Significant shortage of skills in bioinformatics (particularly in genomics)	Shortage of capabilities in bioinformatics (the interdisciplinary field of biology, computer science and statistics). The gap is particularly significant in the ability to manage, analyse and interpret large biological (genomics and other '-omics') databanks	10
	Shortage of pharmacologists and toxicologists with drug development expertise	Shortage of pharmacologists (who study drug interactions) and toxicologists (who study adverse effects) who understand and have expertise in the drug development pathway	10
	Shortage of medicinal chemists, particularly those with industry experience	Shortage of medicinal chemists (involved in the design of compounds and modelling of their activity and safety properties) that have worked in pharmaceutical companies	7

Keys REDI focus areas identified in Phase 1 REDI focus areas identified in Phase 2

Theme	Skills gap	Description of the gap	Final score[155]
Specialist and technical skills	Significant shortage of skills in epidemiology and biostatistics	Shortage of skills in epidemiology, the study of health and disease conditions in a defined population to identify patterns, using statistical methods. This extends to pharmacoepidemiology, which uses these techniques to study the uses and effects of medicines in large populations	7
	Shortage of skills in Phase II/III clinical trials for emerging areas (e.g. regenerative medicine, stem cell therapies)	Shortage of specialist skillset in conducting Phase II/III clinical trials in regenerative medicine/stem cell therapies, with research involving replacing, engineering, or regenerating human or animal cells, tissues or organs, to restore or establish normal function	6
	Shortage of skills in computational modelling and simulation related to synthetic biology	Lack of capacity and capabilities in application of computational modelling and simulation in areas of synthetic biology. More generally, there is a shortage of professionals who possess interdisciplinary skills spanning across molecular biology, engineering and systems biology	6
	Shortage of chemical biologists	Shortage of skills in chemical biology, the science of using chemical techniques and tools and compounds synthesised by chemists, to understand the biological processes that cause disease	5
	Shortage of expertise in drug metabolism and ADME	Shortage of scientists with expertise in drug metabolism and ADME, the study of how the drug affects the body following its administration, through the rate and extent of absorption, distribution, metabolism and excretion (ADME)	5
	Shortage of scientists with expertise in pharmacokinetic/pharmacodynamic modelling	Significant shortage of scientists with expertise in pharmacokinetics (PK) and pharmacodynamics (PD). These disciplines are a critical part of drug development; PK and PD analyses are used to characterise drug exposure, determine dosing thresholds, and understand concentration-effect relationships	5
	Shortage of experienced biochemists	Shortage of experienced biochemists, who study chemical processes in living organisms, looking at the structure and function of biomolecules (e.g. proteins, DNA)	*NR*[158]
	Shortage of experienced material scientists, including nanotechnologists	Shortage of experienced material scientists, an interdisciplinary field which deals with the discovery and design of new biocompatible materials and devices. This includes nanotechnology	*NR*
	Shortage of experienced laboratory technicians	Shortage of experienced laboratory technicians who possess deep operational knowledge of specialist scientific equipment such as cryo-electron microscopy	*NR*

Keys REDI focus areas identified in Phase 1 REDI focus areas identified in Phase 2

[158] NR means not rated. Skills gaps identified by less than half of eligible survey respondents to the MTPConnect workforce survey conducted in July 2020 were not rated as they were deemed to be low priority

Theme	Skills gap	Description of the gap	Final score[155]
Specialist and technical skills	Shortage of scientific expertise in immunology	Lack of expertise in immunology, which is a critical scientific area underpinning basic research and development within the MTP sector	*NR*
	Shortage of scientific expertise in microbiology	Lack of expertise in microbiology, the study of microscopic organisms. This specialty includes the sub-disciplines of virology, mycology, parasitology, and bacteriology	*NR*
	Lack of expertise in histology	Capability gap in histology, the study of microscopic anatomy. Histology techniques and procedures are performed for the benefit of a range of disciplines across the sector	*NR*
	Lack of scientific expertise in molecular biology	Lack of scientific expertise in molecular biology, the study of biology at a molecular level, which is a critical scientific area underpinning basic research and development within the MTP sector	*NR*
	Shortage of protein and peptide chemists	Shortage of protein and peptide chemists, who typically work in multidisciplinary groups to develop and execute analytical methods alongside characterisation of techniques such as expression of recombinant proteins and peptides for both research and commercial purposes	*NR*
	Shortage of expertise in biotechnology	Lack of capabilities and capacity in biotechnology, the combined discipline of biological sciences, microbiological sciences and protein engineering to discover and optimise biologic drug candidates to be medicines, or to use biological molecules to perform specific processes to enable their discovery. This also includes the use of stem cell biology tools and technologies to assemble biologically relevant, predictive assays and cell models, with the end-goal of bringing cell therapy tools and technologies into clinical practice	*NR*
	Shortage of skills in analytical chemistry and biochemistry	Lack of capabilities in analytical chemists/ biochemists, who work at every stage of development of a medicine, from confirming the structure of a compound that has been made for the first time, to checking the purity of a batch of medicine that is about to be released for sale. Analytical chemists/ biochemists may be involved in investigating biological targets, using biophysical techniques to screen and validate targets and studying how molecular properties affect biological activity	*NR*
	Shortage of skills in biomedical imaging	Shortage of biomedical imaging professionals, who use imaging technologies as a non-invasive technique during preclinical and clinical studies, as well as providing data on biomarkers of disease	*NR*

Keys REDI focus areas identified in Phase 1 REDI focus areas identified in Phase 2

Appendix 3: Scoring matrix

Overview of skills gaps prioritisation framework				
	Description	Scoring matrix		
		1	2	3
Alignment with Sector Priorities	Alignment of the skills gap with the identified Sector Priorities (see SCP 2020 for more detail)	Gap impacts one to two of the Sector Priorities	Gap impacts three to four of the Sector Priorities	Gap impacts five to seven of the Sector Priorities
Alignment with megatrends	Alignment of the skills gap with the nine global megatrends that are expected to have a significant impact on sector growth and innovation (see SCP 2020 for more detail)	Gap directly relates to one to two of the megatrends	Gap directly relates to three to five of the megatrends; or A gap cannot be assessed against megatrends*	Gap directly relates to six to nine of the megatrends
Breadth of impact of the skills gap	The extent of impact of skills gaps across different parts of the MTP value chain and sub-sectors	Gap is experienced only in one segment of the value chain	Gap is experienced across two segments of the value chain	Gap is experienced in three or four segments of the value chain
Depth of impact of the skills gap	The value that can be achieved by addressing the skills gap (e.g. in regards to economic benefits, social benefits, or health outcomes)	• Gap has low likelihood of causing value loss or time delays, or • Carries a limited opportunity cost of not addressing, or • Has few jobs and public health implications	• Gap has medium likelihood of causing value loss or time delays, or • Carries some opportunity cost of not addressing, or • Has moderate jobs and public health implications	• Gap has high likelihood of causing value loss or time delays, or • Carries considerable opportunity cost of not addressing, or • Has major jobs and public health implications

Note: *a score of 2 is given to skills gaps that cannot be assessed against a megatrend due to the general nature of the gap. This methodology ensures that a particular skills gap is not disadvantaged in scores

Appendix 4: Scoring breakdown for priority skills gaps

	Sector priority alignment	Megatrend alignment	Value chain breadth of impact	Depth of impact (value of impact)	Final score
Expertise in the design and use of AI within MTP	3	3	3	3	12
Understanding of and expertise in big data capture, management and analysis	3	3	3	3	12
Awareness and understanding of regulatory requirements among start-ups and SMEs	3	2	3	3	11
Shortage of industry professionals with end-to-end commercialisation experience	3	2*	3	3	11
Identifying unmet market need and understanding the clinical context	2	2*	3	3	10
Securing investment, funding and/or industry collaboration	2	2*	3	3	10
Shortage of cybersecurity professionals and IT infrastructure resilience skills within MTP	2	2	3	3	10
Shortage of MTP-specific project managers to support start-ups and spin-offs	2	2*	3	3	10
Shortage of skills in health informatics	2	3	2	3	10
Shortage of skills in bioinformatics (particularly in genomics)	2	2	3	3	10
Shortage of pharmacologists and toxicologists with drug development expertise	2	2*	3	3	10
Strategic clinical trial design to address regulatory and payer needs	2	2	3	3	10
Understanding of quality management, protocols and systems	2	2	3	2	9
Leadership awareness about the value of best-practice management of cybersecurity	2	2	2	3	9
Manufacturing expertise for high-tech and/or specialised medtech devices	3	2	1	3	9
Manufacturing expertise for high-value therapeutics at a commercial scale	3	2	1	3	9
Shortage of clinical trials coordinators	2	2*	2	3	9
Shortage of experienced clinical research associates	2	2*	2	3	9
Shortage of experienced health economists	2	2	2	3	9
Identification of the payer and understanding of reimbursement pathways and requirements	2	2	3	2	9

Note: * Megatrends are not applicable due to the general nature of the skill gap. Such gaps have been given a score of '2' so as not to disadvantage them with respect to other gaps

Appendix 5: References

Author(s), Organisation	Title	Year
ABC News	Melbourne vaccine manufacturing facility announced as hope for coronavirus vaccine continues	2020
ACA Research	Australia IT Security Study	2018
Accenture Consulting	Injecting intelligence into healthcare – Accenture Executive Survey on AI in healthcare Australia	2019
Accenture Consulting	Consumer Survey on Healthcare Cybersecurity and Digital Trust	2017
Alan Finkel, Nature	To move research from quantity to quality, go beyond good intentions	2019
Alex Zhavoronkov, Forbes	Deep Dive into Big Pharma AI Productivity: One Study Shaking the Pharmaceutical Industry	2020
ANDHealth	Digital Health: The sleeping giant of Australia's heath technology industry	2020
ANDHealth	Digital Health: Creating a new growth industry for Australia	2018
Asha Barbaschow, ZDNet	A$498m profit for ASX in record trading period boosted by COVID-19	2020
ATSE	A new prescription: Preparing for a healthcare transformation	2020
AusBiotech	Submission in response to the Inquiry into approval processes for new drugs and novel medical technologies in Australia	2020
AustCyber	Australia's Cyber Security Sector Competitiveness Plan	2019
Austrade	Why Australia Benchmark Report 2020	2020
Austrade	Clinical Trials Capability Report	2018
Australian Bioinformatics Network	Senate Inquiry into Australia's Innovation System: Submission 91	2015
Australian Digital Health Agency	Australia's National Digital Health Strategy	2016
Australian Digital Health Agency	Workforce and Education Roadmap	2020
Australian Government	Australia's Cyber Security Strategy 2020	2020
Australian Government	Modern Manufacturing Strategy	2020
Australian Government	Senate Select Committee on Health, Sixth Interim Report, Big Health Data: Australia's big potential	2016
Australian Research Data Commons	Strategic partnership between the Australian Research Data Commons and Bioplatforms Australia provides a solution to the bioinformatics challenge	2020
Australian Technology Network of Universities	Innovate and Prosper: Ensuring Australia's Future Competitiveness through University-Industry Collaboration	2014
AVCAL	The Venture Capital Effect: A Report on the Industry's Impact on the Australian Economy	2017
BDO	2019/2020 Insights Report: CRO Industry	2020
BioExel	BioExel Medtech Accelerator webpage	2020

Author(s), Organisation	Title	Year
BioSpace	PPD Clinical Research Associates Honored for Excellence in Global Competitions	2019
Bo Seo, Australian Financial Review	Fears Australia will be left behind with minimal AI spending	2019
Brandon Hall	Winners of the 2020 Brandon Hall Group Excellence in Learning Awards	2020
Burning Glass Careers in Focus	Missed Opportunities? The Labor Market in Health Informatics 2014	2014
CSIRO	Medical Technologies and Pharmaceuticals: A Roadmap for unlocking future growth opportunities for Australia	2017
CSIRO	Building Australia's new Advanced Biologics Manufacturing Facility	2020
David Yin, Forbes	What Makes Israel's Innovation Ecosystem So Successful	2017
Deloitte Access Economics	The future of work: Occupational and education trends in data science in Australia	2018
Deloitte Access Economics	Medical technology industry workforce and skills review	2015
Department of Defence, Certara	Medical Countermeasures Initiative: National Capability Audit 2017 Summary	2018
Department of Health	Clinical trials website	2020
Department of Health	Medical Research Future Fund 10-year plan	2020
Department of Health	MRFF grants awarded as at Nov 2020	2020
Department of Industry and Science	Australian Pharmaceuticals Industry Data Card	2014
Department of Industry, Innovation and Science	Australian Innovation System Report 2017	2017
Don Scott-Kemmis and Claire McFarland, United States Studies Centre	Entrepreneurship in Australia and the United States: Contrasts in attitudes and perceptions, and insights from successful Australian ventures	2020
Education Technology	Apprenticeships to address bioinformatics skills shortage	2017
Emma Koehn, Sydney Morning Herald	Biotechs call for more tax incentives to fund research, local production	2020
EvaluatePharma®	World Preview 2019, Outlook to 2024, 12th edition	2019
Ewen Levick, Australian Defence Magazine	Does Australia have a medicine supply problem?	2020
Fitch Solutions	Ireland Medical Devices Report Q3 2020	2020
Gareth Hutchens, The Guardian	Census 2016: manufacturing jobs in Australia drop 24% in five years	2017
Genestack	Is a shortage of bioinformaticians holding back adoption of precision medicine?	2017
HCF	Aussies ready to embrace artificial intelligence in healthcare	2017
IATA	Recovery Delayed as International Travel Remains Locked Down	2020

Author(s), Organisation	Title	Year
Innovation and Science Australia	Performance Review of the Australian Innovation, Science and Research System	2016
Irish Medtech Association	Irish Medtech Association Statement of Strategy 2016–2020	2016
Irish Medtech Association	A Plan for Budget 2020 from the Irish Medtech Association	2020
Irish Medtech Association	Priorities for the next government	2020
Israel Advanced Technology Industries	Israel's Life Sciences Industry IATI Report	2019
Jeff Loucks, Susanne Hupfer, David Jarvis and Timothy Murphy, Deloitte	Future in the balance? How countries are pursuing an AI advantage: Insights from Deloitte's State of AI in the Enterprise, 2nd edition survey	2019
Julia Kollewe, The Guardian	NHS data is worth billions – but who should have access to it?	2019
Market Data Forecast	Regenerative Medicines Market Size to Grow USD 54.88 Bn by 2024	2020
Markets and Markets	Artificial Intelligence in Healthcare Market	2020
Medgaget Market Research	Bioinformatics Market Size, Growth and Industry Report 2020–2025 | CAGR of 13.80%	2020
Medical Device and Diagnostic Industry	The Seven Most Important Medtech Clusters in Europe	2017
Medicines Australia	Submission into the House of Representatives Standing Committee on Health, Aged Care and Sport inquiry into approval processes for new drugs and novel medical technologies in Australia	2020
Medicines Australia	House of Representatives Standing Committee on Health, Aged Care and Sport inquiry into approval processes for new drugs and novel medical technologies in Australia	2020
Ministry of Manpower	Jobs Situation Report	2020
MTAA	MTAA Pre-Budget Submission FY2020/21	2020
MTAA, Occasional Paper Series	Medical Technology in Australia: Key facts and figures 2013	2013
MTPConnect	A Survey of Workforce Skills and Capacity in the MTP Sector	2020
MTPConnect	Clinical Trials in Australia: The economic profile and competitive advantage of the sector	2017
MTPConnect	Collaborating in the Public Interest: How Australia's Medical Technology Sector joined with government to fight COVID-19	2020
MTPConnect	COVID-19 Impact Report 2nd Edition: Sector impacts, the road to recovery and future pandemic preparedness	2020
MTPConnect	REDI Program Skills Gap Analysis, Interim Report	2020
MTPConnect	Sector Competitiveness Plan 2020	2020
nab	Workforce shortages loom as eHealth threat	2020
NHS	Clinical Entrepreneur training program	2020
Nicole Mackee, InSight+	AI in health care: Australia in danger of lagging behind	2020

Author(s), Organisation	Title	Year
Office of the Australian Information Commissioner	Notifiable Data Breaches Report: January–June 2020	2020
Parliament of Australia	Inquiry into innovation and creativity: workforce for the new economy	2017
Pharma in Focus	Talent shortage stunts pharma	2020
Phillip Coorey, AFR	Australia looks to boost drug manufacturing	2020
PPD	CRA Academy celebrates 1,000 graduates	2020
PwC	Adopting AI in healthcare: Why change?	2019
Roche	Submission to the Senate Community Affairs References Committee: Availability of new, innovative and specialist cancer drugs in Australia	2015
Seqirus	Seqirus Will Build World-class, Next-generation A$800m Influenza Vaccine Manufacturing Facility in Australia	2020
Socrates Dokos, IEEE	Biomedical Engineering Education "Down Under": the Australian Experience	2015
Sophie Scott, ABC News	Australian-designed artificial intelligence set to aid diagnosis of coronavirus	2020
Steve Singer, Government News	How big data is powering Australia's COVID-19 response	2020
St Vincent's Health Australia	Beating breast cancer with Artificial Intelligence	2020
T. K. Attwood et al., Briefings in Bioinformatics	A global perspective on evolving bioinformatics and data science training needs	2017
The Hon Karen Andrews MP	2020–21 Budget – Manufacturing Australia's future	2020
The Institute for Integrated Economic Research	The Implications of the COVID-19 pandemic for Australia's Foreign Affairs, Defence and Trade	2020
The Institute of Clinical Research	The Institute of Clinical Research website	2020
The Irish Times	Ireland second only to Germany for medical device exports	2018
The McKell Institute	Big Data, Big Possibilities: How Australia can use big data for better healthcare	2016
The Productivity Commission	Evaluation of the Pharmaceuticals Industry Investment Program: The Victorian Government Policy Contribution	2002
The Royal Australian and New Zealand College of Radiologists	Artificial Intelligence in Radiology and Radiation Oncology: The State of Play 2019	2019
United for Medical Research	The Impact of Genomics on the U.S. Economy	2013
Valuates Reports	Global Healthcare Big Data Analytics Market Size, Status and Forecast 2018–25	2020
Veski	Innovation fellowships webpage	2020

Author(s), Organisation	Title	Year
Webber Insurance Services	The Complete List of Data Breaches in Australia	2020
World Economic Forum	Global Competitiveness Report 2019	2019
World Intellectual Property Organization	Global Innovation Index 2020: Who Will Finance Innovation?	2020

Appendix 6: Glossary of terms

ADHA	Australian Digital Health Agency	IP	Intellectual Property
AGHA	Australian Genomics Health Alliance	ISO	International Organization for Standardization
AI	Artificial intelligence	KOL	Key Opinion Leader
AMGC	Advanced Manufacturing Growth Centre	MBA	Master of Business Administration
ARC	Australian Research Council	MBS	Medicare Benefits Schedule
ARCS	ARCS Australia	MMS	Modern Manufacturing Strategy
ASX	Australian Securities Exchange	MNE	Multinational enterprise
ATSE	Australian Academy of Technology & Engineering	MRFF	Medical Research Future Fund
CE Mark	Conformité Européenne (CE) Mark	MRI	Medical Research Institute
CEO	Chief Executive Officer	MSAC	Medical Services Advisory Committee
CIO	Chief Information Officer	MTAA	Medical Technology Association of Australia
COAG	Council of Australian Governments	MTP	Medical technology, biotechnology and pharmaceutical
CRA	Clinical Research Associate	NGO	Non-government organisation
CRO	Contract Research Organisation	NHMRC	National Health and Medical Research Council
CSIRO	Commonwealth Scientific and Industrial Research Organisation	NHS	UK National Health Service
CTC	Clinical Trial Coordinator	OECD	Organisation for Economic Co-operation and Development
CTPRG	Clinical Trials Project Reference Group	OT	Operational technology
EHR	Electronic Health Record	P&L	Profit & loss (statement)
EMA	European Medicines Agency	PBAC	Pharmaceutical Benefits Advisory Committee
FDA	U.S. Food and Drug Administration	PBS	Pharmaceutical Benefits Scheme
GCP	Good Clinical Practice	PK/PD	Pharmacokinetics/Pharmacodynamics
GDP	Gross Domestic Product	PPD	Pharmaceutical Products Development (company)
GLP	Good Laboratory Practice	QA	Quality assurance
GMP	Good Manufacturing Practice	QMS	Quality management system
GVA	Gross Value Added	R&D	Research and Development
HCP	Healthcare professional	REDI	Researcher Exchange and Development within Industry initiative
HTA	Health Technology Assessment	RfP	Request for Proposal
IIT	Investigator-initiated trial	ROI	Return on investment

RWE	Real-world evidence	TRL	Technology Readiness Level
SCP	Sector Competitiveness Plan	TTO	Technology Transfer Office
SME	Small and medium-sized enterprise	VC	Venture capital
TAFE	Technical and Further Education	WHO	World Health Organization
TGA	Therapeutic Goods Administration		

MTPConnect
MedTech and Pharma Growth Centre

Contact us for further
Information

PHONE +61 3 9070 8298

EMAIL info@mtpconnect.org.au

GET SOCIAL

Join the conversation:
@MTPConnect_AUS
#MTPConnect #AusInnovation

Follow MTPConnect
@MTPConnect

Subscribe on:
Apple Podcasts

Head Office
Ground floor
Suite 2
155 Cremorne Street
Cremorne
VIC 3121
Australia

NSW Sydney Hub
Level 5
J12 School of IT
The University of Sydney
1 Cleveland Street
Darlington
NSW 2006
Australia

QLD Brisbane Hub
Translational Research Institute
Level 7
37 Kent Street
Woolloongabba
QLD 4102
Australia

VIC Melbourne Hub
Monash University
Clayton
VIC 3168
Australia

WA Perth Hub
The University of Western Australia
Harry Perkins Institute of Medical Research Building
QEII Medical Centre
6 Verdun Street
Nedlands WA 6009
Australia

MTPCONNECT.ORG.AU

Australian Government
Department of Industry, Science, Energy and Resources

Industry Growth Centres

Further information about the Industry Growth Centres Initiative is available at www.business.gov.au/industrygrowthcentres