



Medical Research Commercialisation Landscape

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CONSULTING**



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The original artwork in our Acknowledgement of Country was produced by Emma Walke. Emma is a Bundjalung Aboriginal woman from northern NSW.

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GLOSSARY OF TERMS

Term	Description
Australian Investment Council (AVCAL)	AVCAL represents private capital investment in Australia.
Australian Research Council (ARC)	The ARC is an Australian Government entity that advises the Australian Government on research matters, administers the National Competitive Grants Program, and has responsibility for Excellence in Research for Australia.
Australian Stock Exchange (ASX)	The ASX is used by some early stage companies to fund both their commercialisation and growth aspirations.
BioMedTech Horizons (BMTH)	BMTH funds innovative and collaborative health to drive discoveries that address key health challenges towards proof of concept and commercialisation, maximising entrepreneurship, and idea potential.
Biomedical Translation Bridge (BTB)	The BTB funds and nurtures early-stage health and medical research to reach proof of concept with the potential to attract further capital and support.
Biomedical Translation Fund (BTF)	The BTF provides venture capital funding to medical research companies through licensed private sector fund managers.
Blue sky research	The term “blue sky research” refers to research that is driven by a desire to further our scientific understanding, without necessarily considering specific real-world applications. Blue sky research is also referred to as fundamental, discovery, or basic research.
Cooperative Research Centres (CRCs)	The CRC program is led by the Australian Department of Industry, Science, Energy and Resources. CRCs are collaborative bodies for scientific research which drive commercialisation.
Deductible Gift Recipient (DGR) status	A deductible gift recipient (DGR) is an entity or fund that can receive tax deductible gifts.
Health and Medical Research Office (HMRO)	The HMRO sits within the Department of Health. It is responsible for administering the Medical Research Commercialisation Initiative.
McKeon Review	Strategic Review of Health and Medical Research – Better Health through Research 2013.
Medical Research Future Fund (MRFF)	A \$20 billion long-term investment supporting Australian health and medical research. The MRFF aims to transform health and medical research and innovation to improve lives, build the economy and contribute to health system sustainability.
Medical Research Institute (MRI)	Australian MRIs that develop medtech, biotech, or pharmaceuticals.

Term	Description
MTPConnect	MTPConnect is a not-for-profit organisation aiming to accelerate the rate of growth of the medical technologies, biotechnologies and pharmaceuticals sector to increase commercialisation, collaboration and establish Australia as an Asia-Pacific hub for MTP companies. It was formed in December 2015 as part of the Australian Government's Industry Growth Centres Initiative. MTPConnect is the lead entity for the MRFF's BioMedTech Horizons and Biomedical Translation Bridge programs.
National Health and Medical Research Council (NHMRC)	NHMRC funds high quality health and medical research and builds research capability, supports the translation of research into better health outcomes, and promotes the highest ethical standards for health and medical research.
NHMRC Administering Institution (AI)	In order to be eligible to apply for and administer NHMRC funding, institutions are required to obtain the status of NHMRC AI.
Patient capital	"Patient capital" is a term that was frequently used by stakeholders, particularly those involved in financing commercialisation of medical research, and refers to capital that is invested for long periods of time.
Research pipeline	The journey of translating a discovery into improved health outcomes.
Research translation	The process whereby knowledge is passed anywhere along the translational pathway from basic science at one end to improved community-based health outcomes at the other and, of course, vice versa.
Researcher Exchange and Development within Industry (REDI)	REDI is an initiative of the MRFF that aims to bring universities and industries together. It provides researchers with industry placements, mentoring and exchange programs. The initiative was previously called Industry Researcher Exchange and Training.
Small and medium-sized enterprises (SMEs)	For Part 1 of this report, SMEs can refer to any enterprise. In the context of Part 2 of this report, SMEs are involved in medtech, biotech, pharmaceuticals or digital health.
Technology Transfer Office (TTO)	TTOs exist within a university and are responsible for technology transfer and other aspects of the commercialisation of research that takes place within a university.
The Venture Capital Limited Partnership (VCLP) and Early Stage Venture Capital Limited Partnership (ESVCLP)	The VCLP and ESVCLP programs are designed to increase venture capital investment in Australia by providing beneficial tax treatment to eligible local and foreign investors.
Therapeutic Goods Administration (TGA)	The TGA is the regulatory body for therapeutic goods in Australia. It is a Division of the Australian Department of Health established under the <i>Therapeutic Goods Act 1989</i> .

STRUCTURE OF THIS REPORT

This report is divided into the following sections:

Executive Summary:	An overview of the scope of the report and the approach. An overview of public and private funding of medical research development and commercialisation. An overview of the qualitative research and the key findings.
Introduction:	An overview of the research purpose and background.
Part 1:	Overview of public and private funding for medical research development and commercialisation.
Part 2:	Qualitative research, including an overview of the research questions, scope, and method and the key themes for each of the four research questions.
Appendices:	Quantitative data from the sector questionnaire.

EXECUTIVE SUMMARY

The Australian Government Department of Health (the department) commissioned *Allen + Clarke* to undertake qualitative research on the sector's views regarding the medical research commercialisation landscape since the *Strategic Review of Health and Medical Research – Better Health Through Research* 2013, also known as the McKeon Review¹.

This report includes an overview of public and private funding that supports the development and commercialisation of medical research in Australia, and qualitative research that sought to obtain responses to four research questions:

1. What are the sector's views regarding existing government funding support and gaps that remain unaddressed or are not sufficiently addressed, particularly in commercialisation and translation of research?
2. What are the sector's views regarding the impact of MRFF initiatives to improve the capability and capacity of the medical research and innovation sector to commercialise research outputs, and any perceived gaps?
3. How have institutions positioned themselves to maximise commercialisation opportunities?
4. What are the sector's views regarding other barriers to commercialisation of research outputs in Australia?

The findings presented in this report were prepared based on desktop research and document review, interviews with informants across the sector, and a sector questionnaire to broaden the perspectives gathered through the research.

The qualitative research is a representation of the views of people interviewed or surveyed as part of this process. The perspectives represent the views provided by people who participated in the process, and these views have not been validated for accuracy or correctness.

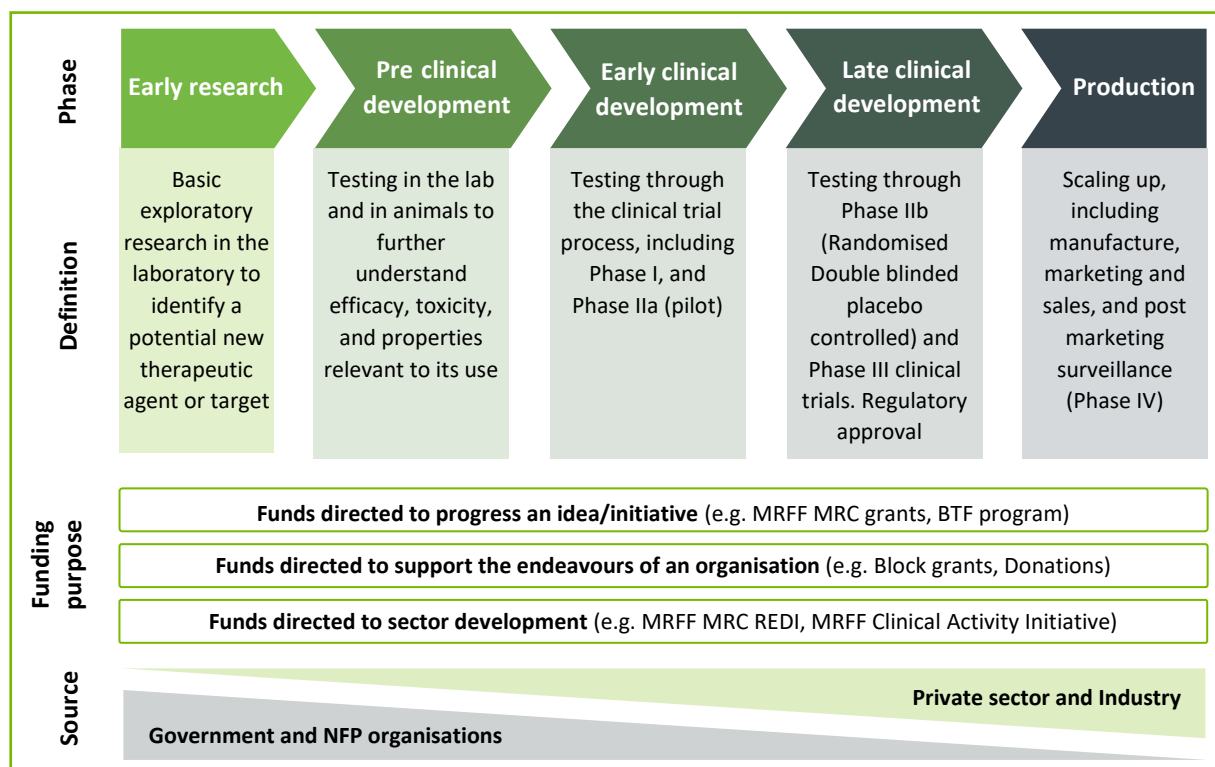
Overview of public and private funding

Funding for the development and commercialisation of medical research can come from many different sources, including public, private and non-government organisation (NGO) funding sources. Public funds tend to be used in the early stages of development (particularly for early research), and private sector funding tends to dominate the later stages of commercialisation.

Funding supports the development and commercialisation of medical research in different ways. For example, funds may be aimed at progressing a specific initiative or idea, they may provide support to an organisation in research and/or development activities, or funding may be directed to improving the capability and capacity within the system to support and facilitate the commercialisation and translation of research outputs. This range of approaches across the life cycle of medical research development and commercialisation is shown in Figure 1.

¹ McKeon, S *Strategic Review of Health and Medical Research: Final Report*. (Canberra, A.C.T.: Dept. of Health and Ageing, 2013)

Figure 1: Funding of medical research development and commercialisation



As well as providing funds, other support and resources are available to individuals and organisations developing and commercialising medical research. The provision of support and resources may be provided as part of a funding program – for example, mentoring is a feature of many government funding programs, such as the Accelerating Commercialisation program – or it can be provided independently of funding, such as the services and resources provided through TGA’s SME Assist.

Part 1 of the report further describes funding for the development and commercialisation of medical research, including funding from the Australian Government, state and territory government funding, non-government funding (including philanthropy, private sector investment, and self-financing), and government co-investment.

Qualitative research findings

Part 2 of the report presents the key themes for each research question. These key themes are based on the views of people interviewed or surveyed as part of this process.

In presenting the themes, there are some themes that are strongly held across the sector, while other themes that are of relevance to only specific groups, for example companies involved in the development of digital health innovations. Further, some stakeholders held different views to the themes presented in this report. These divergent views have been included in the report where relevant.

The themes presented in this report are not independent items. The development and commercialisation of medical research exists as part of a broader ecosystem, and responding to one theme without responding to others may impact the shape and integrity of this ecosystem.

A summary of the main points that were strongly held by stakeholders follows.

<i>The medical research commercialisation landscape has improved</i>	There is strong support from the sector (through the survey and the interviews) that the medical research commercialisation landscape has improved in the last five years.
<i>Government funding and industry growth has contributed to the improvement</i>	Stakeholders had mixed views on the factors that had contributed to the improvement. Government funding (including the MRFF) and the success of companies - such as CSL, ResMed and Cochlear - were seen as factors that had positively contributed to an improved medical research ecosystem.
<i>Funding for early stage medical research commercialisation has improved, but funding is regarded as insufficient and difficult to access</i>	There remain gaps in existing government support. Stakeholders stated there were now more funds available for medical research commercialisation than previously, but there are still insufficient funds available for the pre-clinical and early clinical stages of medical research development and commercialisation. Stakeholders also noted the difficulty in accessing funds during early stages of medical research commercialisation - with infrequent funding rounds for programs cited as an issue.
<i>The funding landscape is difficult to navigate</i>	Stakeholders raised concerns about the complexity of the funding landscape and that it was difficult for individuals and applicants to navigate the system to find and obtain funding.
<i>The MRFF is seen as having made a positive impact to the sector</i>	Stakeholders identified the MRFF as having a positive impact on sector capacity and capability through funding, facilitating and stimulating increased engagement between industry and researchers, and through improving clinical trial infrastructure.
<i>Government policy and funding could have a role in further addressing constraints in the commercialisation of medical research</i>	Stakeholders identified factors that constrain or are a burden to commercialisation. These include access to people with deep skills in commercialisation, access to research infrastructure and access to manufacturing capability. Further, there were systemic factors encumbering the commercialisation of medical research outputs that may be addressed through government policy and/or funding mechanisms, including systemic factors that discourage academic researcher engagement with industry and issues that increase the time and costs associated with the conduct of clinical trials.
<i>There are factors that affects the ability of technology transfer offices to position themselves to maximise commercialisation opportunities</i>	As well as specific initiatives undertaken by institutions themselves to maximise commercialisation opportunities, stakeholders pointed to factors that they believed underpinned a technology transfer office's (TTO) success. These factors include the commitment of the university to commercialisation, the TTO's access to adequate and consistent funding, the skills and experience of the commercialisation and legal officers in the TTO, and the ability of the TTO to cover the vast scope of research within the university.
<i>Clinical researchers face their own barriers in developing and commercialising research</i>	Stakeholders pointed to specific barriers and constraints for clinical researchers to develop and commercialise medical research, including demands of clinical work, access to research infrastructure and support, and access to support or arrangements for progressing the commercialisation of research.
<i>Distance to markets and suppliers places Australian organisations at a disadvantage in commercialising research</i>	Medical research commercialisation occurs within a global market. Stakeholders noted the impact of distance on commercialisation. The effect of distance is experienced most acutely by smaller universities and companies, and western states. The effect of distance is reported as placing Australian organisations at a disadvantage of accessing key industry players. Internet based communication and social media platforms (such as LinkedIn) and networking events and conferences have reduced the impact of this issue in recent years.

INTRODUCTION

Purpose

The Australian Government Department of Health (the department) commissioned *Allen + Clarke* to undertake qualitative research of sector views regarding the medical research commercialisation landscape since the *Strategic Review of Health and Medical Research – Better Health Through Research* 2013, also known as the McKeon Review².

This research report includes:

1. An overview of public and private funding programs that support the commercialisation of medical research in Australia.
2. A summary of interview responses from key stakeholders regarding existing government funding support, and perceived funding gaps, particularly in commercialisation and translation of research, that remain unaddressed or are not sufficiently addressed.
3. A summary of interview responses from key stakeholders regarding the impact of MRFF initiatives to improve capability and capacity in the medical research and innovation sector to commercialise research outputs and any perceived gaps.
4. A summary of institutional responses to commercialisation opportunities (e.g. establishment of technology transfer offices within tertiary institutions to support commercialisation endeavours).
5. A summary of views from key stakeholders on any other perceived barriers to commercialisation of research outputs in Australia.

The McKeon Review

The McKeon Review investigated the state of health and medical research in Australia and made recommendations about the strategic direction of the sector. The McKeon Review found that Australia was failing to extract the full benefits from its research outputs due to a lack of funding for early clinical projects and an underdeveloped culture for the commercialisation of innovation, with limited knowledge and skills among the research community. It also noted a lack of infrastructure to assist start-ups and an absence of funding to enable research commercialisation, which lead to the deficiency of a strong culture of innovation nationally.

The McKeon Review outlined 21 recommendations in relation to the future direction of health and medical research, including two recommendations in relation to supporting and enhancing the commercialisation environment. These recommendations have led to initiatives to address the shortfalls or inappropriately targeted funding in commercialising research and to improve commercialisation capability and culture.

² McKeon, S *Strategic Review of Health and Medical Research: Final Report*. (Canberra, A.C.T.: Dept. of Health and Ageing, 2013)

The Medical Research Future Fund

The Medical Research Future Fund (MRFF) is a \$20 billion long-term investment supporting Australian health and medical research. The MRFF aims to transform health and medical research and innovation to improve lives, build the economy and contribute to health system sustainability.

In July 2020, the MRFF grew to \$20 billion. The net interest from the fund pays for important health and medical research projects. From 2020/21, funding from the MRFF for medical research is expected to be more than \$500 million per annum.³

The Medical Research Commercialisation Initiative

The Medical Research Commercialisation (MRC) initiative sits within the MRFF. The MRC initiative aims to support opportunities for commercialisation by providing early-stage health and medical research and innovation through to proof of concept and beyond. It currently incorporates two programs:

1. BioMedTech Horizons (BMTH) which funds innovative and collaborative health research to drive discoveries that address key health challenges towards proof of concept and commercialisation, maximising entrepreneurship and idea potential.
2. Biomedical Translation Bridge (BTB) which funds and nurtures early-stage health and medical research to reach proof of concept with the potential to attract further capital and support.

The department's Health and Medical Research Office (HMRO) administers the MRC initiative, and MTPConnect delivers the BMTH and BTB programs. The MRC initiative will provide \$311.3 million in support over 10 years, of which \$67.3 million (for 2017–18 to 2021–22) has been committed, and \$254.0 million is not yet allocated.⁴

³ Source: Medical Research Future Fund 10 year investment plan

⁴ Medical Research Commercialisation Medical Research Future Fund Snapshot 2019–20 to 2020–21 available at https://www.health.gov.au/sites/default/files/documents/2020/01/mrff-snapshot-medical-research-commercialisation_0.pdf

PART 1 OVERVIEW OF PUBLIC AND PRIVATE FUNDING

1 OVERVIEW

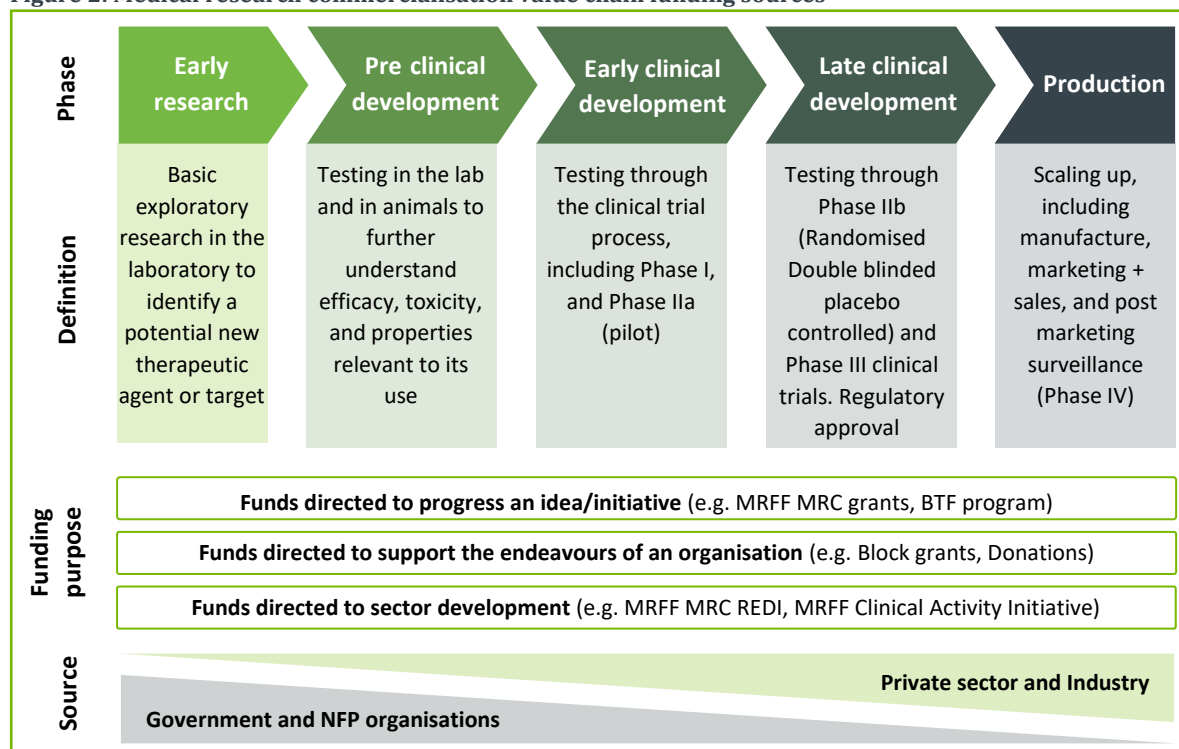
This section provides an overview of public and private funding programs that support medical research development and commercialisation in Australia. For completeness and context, the definition of funding programs has been expanded to include funding sources, and funding supporting translatable medical research.

A key feature of medical research commercialisation is that the time to development is long, and the costs over the life of the project are high.

Funding for medical research commercialisation comes from a number of sources, including public, private and NGO funding sources. Different sources of funds tend to dominate different stages of the life cycle, with public funds tending to be used in the early stages of development (particularly for early research), and private sector funding tending to dominate for later stages of commercialisation.

Funding is also targeted towards medical research in different ways. For example, funds may be targeted at progressing a specific initiative or idea, support a company in research and/or development activities, or it can also be used to improve the capability and capacity within the system to support and facilitate the commercialisation and translation of research outputs. The different approaches are depicted in the value chain shown in Figure 2.

Figure 2: Medical research commercialisation value chain funding sources



An overview of the funding programs described in this section is included in Table 1.

As well as funding support, there are products and services that provide advice and support to individuals and organisations developing and commercialising medical research. For example, TGA's SME Assist provides advice and resources to help SMEs, researchers, and start-ups to understand their regulatory and legislative obligations.

Table 1: Overview of medical research development and commercialisation funding

Funding source and programs	What it funds
Australian Government Funding	
NHMRC grants	<ul style="list-style-type: none"> Competitive grants for investigator-initiated research across every area of health and medical research, from discovery to clinical trials, population health interventions and health services research. A range of grant types to support people, teams and national networks, some targeted at specific initiatives. The Development Grant Scheme supports development of proof-of-concept data to support commercialisation of a product, process, procedure or process.
Medical Research Future Fund (MRFF)	<ul style="list-style-type: none"> The MRFF is aimed at supporting researchers and industry to tackle areas of unmet need, and to excel in collaborative and transformative research. A range of grants and initiatives that can be targeted at specific initiatives and directed at sector developments. The MRFF includes the Medical Research Commercialisation initiative which supports early stage health and medical research and innovation in Australia through to proof of concept and beyond. The initiative currently incorporates two programs: Biomedical Translation Bridge and BioMedTech Horizons.
Biomedical Translation Fund	<ul style="list-style-type: none"> An Australian Government initiative that co-invests with private sector capital to provide venture capital funding through a licensed private sector fund manager. The fund targets early to late clinical development of medical research initiatives.
Entrepreneurs' Programme	<ul style="list-style-type: none"> Initiatives aimed at supporting entrepreneurs, researchers and businesses to innovate, compete and grow by providing support, funding and incentives. The Entrepreneurs' Programme includes the Accelerating Commercialisation initiative. This initiative assists individuals and organisations to progress commercialisation of their novel product, process or service by means of funds and advice and guidance.
Tax incentive schemes	<ul style="list-style-type: none"> There are various tax incentive schemes that work to increase private sector investment in the development and commercialisation of medical research. The R&D Tax Incentive Scheme supports organisations by providing tax offsets (refundable and non-refundable) for research and development activities. Targeted at supporting organisations as they undertake research and development activities.
Higher Education Research block grants	<ul style="list-style-type: none"> Grants to support research and the training of researchers.
Cooperative Research Centre programs	<ul style="list-style-type: none"> Grants aimed at supporting industry partner with the research sector to solve industry-identified issues. Funding can be used to cover a range of costs, including research, proof of concept activities, and activities related to commercialisation of research outcomes.
National Collaborative Research Infrastructure Funding	<ul style="list-style-type: none"> Funds the establishment or upgrade of world class research infrastructure with the aim of supporting high quality research that will drive greater innovation in the Australian research sector and the economy more generally.

Funding source and programs	What it funds
State and Territory Government Funding	
Broad sector investment	<ul style="list-style-type: none"> State governments have made investments in their jurisdictions to develop the sector supporting the development and commercialisation of health and medical research, particularly in the investment of infrastructure.
Funding initiatives	<ul style="list-style-type: none"> Specific funding initiatives for medical research development and commercialisation initiatives varies by jurisdiction. Funding by states and territories may be targeted at programs specific to the development and commercialisation of health and medical research, innovation and business development programs, broader sector programs, and through contributions by governments to initiatives and institutions involved in progressing medical research initiatives.
Non-Government Funding	
Philanthropy <i>(including Donations and Bequests)</i>	<ul style="list-style-type: none"> Mostly targeted at organisations for a specific initiative, and tends to be used for research. Can sometimes be used in later stages (such as pre-clinical and early clinical development).
Private sector investment <i>Venture Capital; Angel and Seed Investment; Private Equity; Industry Funding; Equity/Debt Raising; Crowdsourced Equity Funding</i>	<ul style="list-style-type: none"> Mostly directed at specific initiatives and organisations. Mostly targeted at later stages of development, particularly late discovery and early clinical development. Angel investing and crowdsourced equity funding are more likely to be at early stages of development, such as pre-clinical development.
Self-financed	<ul style="list-style-type: none"> Individuals and organisations use their own funds, for example: personal funds and funds from friends and family; proceeds from the commercialisation of technology; subsidisation of medical research development and commercialisation/translation from other income.
Government Co-Investment	
Various <i>Government contributions to private/industry funds; Government contributions and collaborations with foundations; Industry matched funding as part of the application process; Tax incentives</i>	<ul style="list-style-type: none"> Governments co-invest in various ways to support and/or stimulate private sector investment in medical research, and in the translation and commercialisation of medical research.

2 AUSTRALIAN GOVERNMENT FUNDING

The Australian Government funds health and medical research through grants providing targeted assistance, direct support or assistance to organisations involved in research and in broader sector development. In addition, Australia's tax system provides incentives for private investment in the development and commercialisation of medical research, and the R&D Tax Incentive Scheme provides an income stream for organisations undertaking research and development activities.

The funding schemes discussed in this section are:

- NHMRC grants
- Medical Research Future Fund (including the Medical Research Commercialisation initiative)
- Entrepreneurs' Programme
- Biomedical Translation Fund
- Tax incentive schemes
- Higher education research block grants
- Cooperative Research Centre programs
- National Collaborative Research Infrastructure Strategy.

2.1 NHMRC Grants

The NHMRC funds health and medical research in Australia through competitive grant schemes. In 2019/20, \$1,259.6 million of new grants were awarded by the NHMRC through the medical research endowment account,⁵ including grants targeted at specific initiatives and grants aimed at improving sector capacity.

The majority of NHMRC's project related grants are for research that might lead to commercialisation. However, this is not the primary purpose of these grants. The exception is the Development Grants Scheme (\$14.6 million in 2019/20).⁶ This scheme exists to develop proof of concept data for research.

NHMRC's grant program from 2020 comprises of four funding streams,⁷ including:

- Investigator Grants: Fellowship and research support schemes (approximately 40% of fund allocation).
- Synergy Grants: \$5 million grants to multi-disciplinary research teams to work together to answer complex questions (approximately 5% of fund allocation).
- Ideas Grants: Support to researchers for innovative and creative research projects (approximately 25% of fund allocation).
- Strategic and Leveraging Grants: Support towards research that addresses identified national needs, such as clinical trials and cohort studies, and incorporates existing schemes, such as Development Grants (approximately 30% of fund allocation).

⁵ Source: NHMRC Annual Report 2019/20, p 11

⁶ Source: NHMRC Annual Report 2019/20, p 11

⁷ Source: <https://www.nhmrc.gov.au/funding/new-grant-program/overview> (viewed 9 September 2020)

To be eligible for grants through NHMRC, an organisation needs to obtain the status of NHMRC Administering Institution (AI). To be granted AI status, an organisation must engage in health and medical research as one of their main objectives, have a physical location in Australia where they conduct the research, have an independent governing board or council with scientific and administrative experience, skills and qualifications, have adequate facilities and equipment for research, and have the capacity to cover the indirect costs of research.⁸ Organisations with this status tend to be universities, larger health services or medical research institutes.⁹ Organisations that do not achieve this status, for example small biotech companies, need to partner with an organisation that has AI status.

2.2 Medical Research Future Fund

The Medical Research Future Fund (MRFF) was established in 2015 and is now a \$20 billion fund. The net interest from the fund pays for health and medical research projects. In 2018/19, the MRFF funded \$222.4 million into initiatives supporting Australian health and medical research.¹⁰ From 2020/21, funding from the MRFF for medical research is expected to be more than \$500 million per annum.¹¹

The MRFF is aimed at supporting researchers and industry to tackle areas of unmet need, and to excel in collaborative and transformative research. The MRFF has been organised into four funding themes,¹² including:

- **Patients**: Funding innovative treatments, supporting clinical trials, and delivering more advanced health care and medical technology to improve the health of all Australians (approximately 26% of funding allocation over 10 years).
- **Researchers**: Supporting researchers to make breakthrough discoveries, develop their skills and progress their careers in Australia (approximately 16% of funding allocation over 10 years).
- **Research missions**: Helping researchers think big to tackle significant health challenges through investment, leadership and collaboration (approximately 28% of funding allocation over 10 years).
- **Research translation**: Moving research ideas from the lab to the clinic, so that medical discoveries become part of clinical practice for GPs, specialists and hospitals (approximately 30% of funding allocation over 10 years).

⁸ Source: <https://www.nhmrc.gov.au/funding/manage-your-funding/nhmrcs-administering-institutions> (viewed 9 September 2020), and NHMRC Administering Institution Application Form, Section 4 (downloaded 9 September 2020)

⁹ Source: NHMRC Administering Institutions List 2020 (downloaded 9 September 2020)

¹⁰ Source: Medical Research Future Fund 10 year investment plan, Total for 2018/19 before adjusting for the balance over the forward estimates

¹¹ Source: Medical Research Future Fund 10 year investment plan

¹² Source: Medical Research Future Fund 10 year investment plan. Note, the 10 year funding period stated in the plan, commences 2018/19

2.2.1 Medical Research Commercialisation initiative

The Medical Research Commercialisation initiative is within the Medical Research Future Fund, coming under the Research Translation theme.

The Medical Research Commercialisation initiative exists to support early stage health and medical research and innovation in Australia through to proof of concept and beyond, providing increased opportunities to commercialise this research.¹³ There is \$311.3 million of funding being provided through this initiative over the next 10 years, commencing 2018-19.¹⁴

This initiative currently incorporates two programs:

- **Biomedical Translation Bridge:** Provides up to \$1 million matched funding for early stage therapies, technologies, and medical devices through to proof of concept stage.¹⁵
- **BioMedTech Horizons:** Provides funding of up to \$1 million for medical device projects that address unmet clinical need. The funding is focused on funding proof of concept to commercialisation of biomedical and medical technologies.¹⁶

2.3 Biomedical Translation Fund

The Biomedical Translation Fund (BTF) is an initiative of the National Innovation Science Agenda for the Australian Government to co-invest \$250 million with the private sector in order to increase the capital available for commercialising medical research in Australia.

The BTF was launched at the end of 2016. It provides venture capital funding through licensed private sector fund managers, including Brandon Capital Partners, One Ventures Managers and BioScience Managers.

The purpose of the BTF is to provide a vehicle for investment in promising biomedical discoveries and to assist in their commercialisation, as well as to encourage the development of companies commercialising biomedical discoveries by addressing capital and management constraints.

A total of \$501.25 million is available through the BTF. Of this, \$250 million is from Australian Government capital, and \$251.25 million is from private sector capital. The funds tend to be directed to initiatives that are in early and later stage clinical development. However, they could be available to earlier and later stage initiatives.

AusIndustry delivers the BTF on behalf of the Australian Department of Health. The BTF fund managers screen investment proposals and make venture capital investments.

To date, 16 biomedical companies have successfully received an investment commitment from the BTF, totalling \$188.33 million. The BTF has been credited for providing deeper funding pools of venture capital funding which has given biomedical companies improved access to capital for commercialisation, as well as providing Australian biomedical companies with sector commercialisation expertise and access to networks.

¹³ Source: <https://www.health.gov.au/initiatives-and-programs/medical-research-commercialisation-initiative> (last updated 4 September 2020, viewed 21 October 2020)

¹⁴ Source: Medical Research Future Fund 10 year investment plan

¹⁵ Source: <https://www.mtpconnect.org.au/projects/biomedicaltranslationbridgeprogram> (viewed 12 September 2020)

¹⁶ Source: <https://www.mtpconnect.org.au/biomedtechhorizons> (viewed 12 September 2020)

2.4 Entrepreneurs' Programme

The Australian Department of Industry, Science, Energy and Resources provides support to entrepreneurs, researchers and businesses to innovate, compete and grow by providing support, funding and incentives.¹⁷

The program provides support through four initiatives:

- **Accelerating Commercialisation:** Assists entrepreneurs, researchers, inventors, start-ups and SMEs who have a novel product, process or service they want to commercialise for trade in Australian and/or overseas markets. The program provides advice and guidance, and up to \$500,000 matched project funding for Research Commercialisation Entities and Eligible Partner Entities, or up to \$1 million matched program funding for all other eligible applicants. Unless the applicant is a Research Commercialisation Entity or an Eligible Partner Entity,¹⁸ they need to be incorporated in Australia and have a combined annual turnover of less than \$20 million for each of the prior 3 financial years.¹⁹
- **Business Growth Programs:** Various programs targeted at businesses specified growth sectors (including medical technologies and pharmaceuticals) to access a national network of business advisors to develop a growth plan to realise an Australian and/or overseas growth opportunity. Completion of the program may provide businesses with access to a growth grant of up to \$20,000.²⁰
- **Innovation Connections:** A program that assists businesses in an identified growth sector (which includes medical technologies and pharmaceuticals) to understand their research needs, connect with the research sector, and fund collaborative projects. Businesses can receive grants up to \$50,000 for research projects that are in collaboration with a Publicly Funded Research Organisation.²¹
- **Incubator Support Programs:** Provides new and existing incubators with funding to help start-ups develop the capabilities to succeed in international markets. It provides from \$13,000 to \$250,000 of funding for up to two years, covering up to 65% of eligible project value in regional areas or up to 50% in major cities.²² There is an additional program that provides between \$5,000 and \$100,000 in matched funding for one year to access an expert to work with an incubator's start-ups or to increase the capabilities of the incubator.²³

These programs were budgeted to expend \$419 million over four years commencing 2019/20, with \$69.5 million directed to the Accelerating Commercialisation program over this time.²⁴

¹⁷ Source: <https://www.business.gov.au/Grants-and-Programs/Entrepreneurs-Programme> (viewed 21 October 2020)

¹⁸ A Research Commercialising Entity and Eligible Partner Entity is a category of eligible entity and applies to researchers who want to apply for an Accelerating Commercialisation Grant without forming a company. This process is described in: <https://www.business.gov.au/grants-and-programs/accelerating-commercialisation/research-commercialisation-entities-and-eligible-partner-entities>

¹⁹ Source: <https://www.business.gov.au/Grants-and-Programs/Accelerating-Commercialisation> (last updated 21 August 2020, viewed 21 October 2020)

²⁰ Source: <https://www.business.gov.au/Grants-and-Programs/Entrepreneurs-Programme> (viewed 21 October 2020)

²¹ Source: <https://www.business.gov.au/grants-and-programs/innovation-connections> (last updated 21 August 2020, viewed 21 October 2020)

²² Source: <https://www.business.gov.au/grants-and-programs/incubator-support-new-and-existing-incubators> (last updated 21 August 2020, viewed 21 October 2020)

²³ Source: <https://www.business.gov.au/grants-and-programs/incubator-support-expert-in-residence> (last updated 21 August 2020, viewed 21 October 2020)

²⁴ Source: "2019-20 Science, Research and Innovation Budget Tables", Australian Department of Industry, Innovation and Science

2.5 Tax incentive schemes

Australia's tax system has a role in incentivising private investment into initiatives, including the development and commercialisation/translation of medical research. Examples are described below.

2.5.1 R&D Tax Incentive

While not a fund, the R&D Tax Incentive is the largest component of Australian government support for innovation. In 2018/19, the Australian Government's investment in R&D Tax Incentives (refundable and non-refundable) across all sectors and industries was \$2,059 billion.²⁵ The R&D Tax Incentive encourages industry, including medical research, to invest in R&D by offering tax offsets to organisations undertaking eligible activities.²⁶

The R&D Tax Incentive is a refundable tax offset for eligible entities whose aggregated turnover is less than \$20 million. It is a non-refundable tax offset for all other eligible entities.²⁷ An eligible entity is an R&D entity incorporated under Australian law, or incorporated under foreign law but an Australian resident for income tax purposes, or carrying on business as a resident of a country with which Australia has a double tax agreement.²⁸ It generally applies to R&D activities that occur in Australia.²⁹

This scheme is an example of government funding targeted to support the endeavours of an organisation by providing a revenue stream for supporting research and development activities – particularly for SMEs focused on research and development who have limited funding from other streams.

2.5.2 Tax incentives for donors

Donors are able to claim tax deductions for gifts to entities with a Deductible Gift Recipient (DGR) endorsement. This increases the attractiveness of organisations with DGR endorsement (e.g. medical research institutes, universities, hospitals) to attract donations which may then be used to fund health and medical research and commercialisation activities.

2.5.3 Tax incentives for early stage investors

The National Innovation and Science Agenda put forward measures to provide taxation incentives for early stage investors so that they receive concessional tax treatment for investments made in qualifying early stage innovation companies (ESICs), such as start-ups with high growth potential.

From 1 July 2016, sophisticated early stage investors (e.g. angel investors) could receive a 20% non-refundable carry forward tax offset (capped at \$200,000 per investor per year) of the total amount paid (including non-cash benefits) in return for qualifying shares. They could also receive a 10-year exemption on capital gains tax for investments held as shares in an ESIC for at least 12 months, provided the shares held do not constitute more than a 30% interest in the ESIC.

²⁵ Source: "2019-20 Science, Research and Innovation Budget Tables", Australian Department of Industry, Innovation and Science

²⁶ Source: <https://www.business.gov.au/Grants-and-Programs/Research-and-Development-Tax-Incentive/Help-guides-and-resources/Navigating-the-Tax-Incentive> (viewed 8 September 2020)

²⁷ Source: <https://www.ato.gov.au/business/research-and-development-tax-incentive/> (last updated 31 July 2020, viewed 21 October 2020)

²⁸ Source: <https://www.ato.gov.au/business/research-and-development-tax-incentive/eligibility/eligible-entities/> (last updated 26 June 2017, viewed 21 October 2020)

²⁹ Source: <https://www.ato.gov.au/business/research-and-development-tax-incentive/eligibility/eligible-activities/> (last updated 26 June 2017, viewed 21 October 2020)

The tax incentives are designed to promote this culture by connecting relevant start-up companies with investors that have both the requisite funds and business experience to assist entrepreneurs in developing successful innovative companies, particularly at the pre-commercialisation phase where a concept is in development, but the company requires additional investment to assist with commercialisation. To ensure the incentive was targeted as intended, the start-up must satisfy specific criteria.³⁰

2.5.4 Tax incentives for venture capital investment

The Venture Capital Limited Partnership (VCLP) and Early Stage Venture Capital Limited Partnership (ESVCLP) programs are designed to increase venture capital investment in Australia by providing beneficial tax treatment to eligible local and foreign investors.

The ESVCLP helps attract investors by providing flow-through tax treatment and a complete tax exemption for investors on their share of profits made by the ESVCLP on eligible investments. Investors also receive a 10% non-refundable tax offset on capital invested during the year.³¹

The VCLP provides flow-through tax treatment for investors, as well as a tax exemption for eligible foreign investors, on their share of profits made by the VCLP on eligible investments.³²

2.6 Higher education research block grants

Higher education institutions receive block grants from the Australian Department of Education and Training to support research (Research Support Program) and to support the training of researchers (Research Training Program).³³ In 2018, higher education institutions received \$1.9 billion from the government for these two programs.³⁴ The purpose of these programs is in sector development (through capacity building) and to support the research endeavours of universities by providing a flexible funding stream.

The 2020 Australian Government Budget announced an additional \$1 billion in research program funding in 2021 to alleviate the immediate financial pressures on universities caused by COVID-19. This funding will be delivered through the Research Support Program, taking the total funding delivered through the Research Support Program in 2021 to \$1.93 billion, and the Research Training Program to \$1.06 billion.³⁵

2.7 Cooperative Research Centre program

The Cooperative Research Centre (CRC) program is run by the Australian Department of Industry, Science, Energy and Resources. The program supports Australian industries' ability to compete and produce by helping industry partner with the research sector to solve industry-identified issues.

The program offers medium to long term grants for industry led research, and CRC Project Grants to support up to three years' worth of industry-led collaborative research. The funding can be used to cover costs related to new research, proof of concept activities, pre-commercialisation of

³⁰ Source: <https://treasury.gov.au/national-innovation-and-science-agenda/tax-incentives-for-early-stage-investors> (viewed 13 September 2020)

³¹ Source: <https://www.industry.gov.au/funding-and-incentives/venture-capital> (viewed 13 September 2020)

³² *ibid*

³³ Source: <https://www.education.gov.au/research-block-grants> (viewed 9 September 2020)

³⁴ Source: "Research Block Grant Series", Australian Department of Education <https://docs.education.gov.au/node/47846> (viewed 9 September 2020). Note, these funds are not confined to health and medical research.

research outcomes, industry focused education and training activities, conferences, workshops and symposia related to the joint research.

CRC grants support medium to long term, industry led collaborations, covering up to 50% of eligible grant project costs for up to 10 years. There is no prescribed limit on the size of grant, however, the number of CRC grants funded in each round will depend on the number of quality applications received, the relative merits of applications, the amount of available funding and the need to ensure funding is available for subsequent rounds. The Digital Health CRC receives \$55,000 over 7 years through the CRC program.

CRC Project grants support short term, industry led collaborations, for up to 3 years. These grants provide funding between \$100,000 and \$3 million. Examples of recent successful applications for CRC Project grants include \$2.4 million over 3 years for enhanced influenza vaccine production, and \$3 million over 3 years for a project that will develop an automated microscale bioreactor to manufacture genetically modified cells for use in human cell and gene therapy.

The Australian Government has committed a total of \$753 million over four years for the CRC program from 2019-20 to 2022-23.^{36,37}

2.8 National Collaborative Research Infrastructure Strategy

The Australian Government invests in national world-class research infrastructure projects that support high quality research that will drive greater innovation in the Australian research sector and the economy more generally through the National Collaborative Research Infrastructure Strategy (NCRIS).

Since 2004, the Australian Government has invested nearly \$3.3 billion in research infrastructure, and this has attracted more than \$1 billion in co-investment from state and territory governments, universities, research facilities and industry.³⁸ In December 2015, as part of the National Innovation and Science Agenda, the government announced \$150 million per year (ongoing, indexed from 1 July 2017) to support the operations of NCRIS projects.³⁹ A further \$1.9 billion in funding for NCRIS projects over 12 years was announced as part of the government's response to the 2016 National Research Infrastructure Roadmap.⁴⁰

The types of health and medical research infrastructure projects funded through the NCRIS include upgrades to physical containment facilities at CSIRO's Australian Centre for Disease Preparedness, the establishment of the Australian National Fabrication Facility, the establishment of Bioplatforms Australia, and the establishment of the National Imaging Facility.⁴¹

The 2020 investment plan provides funding of \$157 million from 2020/21 to 2022/23 to fund existing and new national research infrastructure projects.⁴²

³⁶ Source: "Cooperative Research Centres Program Round 22 Grant Opportunity Guidelines", Australian Department of Industry, Science, Energy and Resources, April 2020

³⁷ Source: "2019-20 Science, Research and Innovation Budget Tables", Australian Department of Industry, Innovation and Science

³⁸ Source: <https://www.education.gov.au/national-collaborative-research-infrastructure-strategy-ncris> (last updated 7 October 2020, viewed 21 October 2020)

³⁹ Source: <https://www.education.gov.au/national-collaborative-research-infrastructure-strategy-ncris> (last updated 7 October 2020, viewed 21 October 2020)

⁴⁰ Source: <https://www.education.gov.au/national-collaborative-research-infrastructure-strategy-ncris> (last updated 7 October 2020, viewed 21 October 2020)

⁴¹ Source: <https://www.education.gov.au/funded-research-infrastructure-projects> (last updated 6 October 2020, viewed 21 October 2020)

⁴² Source: <https://www.education.gov.au/2020-21-budget-research-package> (last updated 7 October 2020, viewed 21 October 2020)

3 STATE/TERRITORY GOVERNMENT FUNDING

Funding for medical research by states and territories varies according to jurisdiction, and approaches to the development of sector and individual participants. Investment by individual jurisdictions also varies over time. Typically, the states and territories fund research undertaken within state and territory hospital systems, and provide support to medical research institutes for the indirect costs of research, as well as funding other programs that support start-ups and research and development (a portion of which funds health and medical research and commercialisation/translation). State and territory governments also provide capital funding for stand-alone research institutions (e.g. the South Australian Health and Medical Research Institute), for research infrastructure (e.g. the establishment of the Australian Synchrotron), and for organisations that combine research with health care delivery (e.g. the Victorian Comprehensive Cancer Centre).⁴³

3.1 Broader sector investment by jurisdictions

A number of jurisdictions have made substantial investment into health and medical research within their regions. The Victorian government has invested approximately \$4 billion in the last 20 years in infrastructure and capability building in science, technology, innovation and medical research, infrastructure support, and in post-doctoral research fellowships,⁴⁴ of which a significant proportion of these funds was directed to the development of health and medical research. There have been substantial investments made by the Queensland Government in developing their health and medical research sector.⁴⁵ The New South Wales Government has invested in medical research largely through the medical research support program and medical device funds,⁴⁶ and the South Australian and Western Australian governments have contributed capital funds to the development of their medical research centres as well as operational and research funding.⁴⁷

3.2 State and territory funding for the development and commercialisation/translation of health and medical research

Current funding of medical research development and commercialisation varies by jurisdiction and is usually aligned to economic development within the region for jurisdiction identified priority sectors. Funding programs may be targeted at progressing an initiative, or for the development of capacity and capability within the sector. In many instances, funding programs require matched funding. In most instances, these programs are independent of Commonwealth program funding, however, in some cases they may augment funds an organisation receives from the Australian Government, such as the Queensland Government's Research Infrastructure Co-investment Fund.⁴⁸

⁴³ Source: "Health and Medical Research Facts", Research Australia, <https://researchaustralia.org/category/hmr-facts/> (viewed 10 September 2020)

⁴⁴ Source: "Inquiry into Health and Medical Research in Australia Issues Paper", South Australia Productivity Commission, 13 March 2020, p 16

⁴⁵ Source: "Bio-Savvy: How Australia can build a stronger biotechnology industry", The McKell Institute, October 2016, p 42

⁴⁶ Source: "Inquiry into Health and Medical Research in Australia Issues Paper", South Australia Productivity Commission, 13 March 2020, pp 16, 46

⁴⁷ Source: "Inquiry into Health and Medical Research in Australia Issues Paper", South Australia Productivity Commission, 13 March 2020, p 16

⁴⁸ Source: "Inquiry into Health and Medical Research in Australia Issues Paper", South Australia Productivity Commission, 13 March 2020, pp 16, 46

Most jurisdictions also have programs to support innovation. This can include SMEs undertaking health and medical research commercialisation activities. In addition, states and territories provide funds that may be used for the development and commercialisation/translation of medical research.

Examples of funding by states and territories for the development and commercialisation/translation of health and medical research, and/or to support the sector are shown in the Table 2.

Table 2: Examples of state and territory funding to support medical research development and commercialisation⁴⁹

Jurisdiction	Program	Description
Australian Capital Territory	ANU Connect Ventures ⁵⁰	<p>ANU Connect Ventures invests in early stage commercialisation opportunities in the Canberra region. The fund offers initial investments of up to \$500,000 and follow on investment.</p> <p>The \$27 million Seed Investment Fund was established with the support of the ACT Government to invest in promising commercial opportunities arising from Australian National University research, other ACT based research institutions and local R&D companies.</p> <p>Funds are invested in any industry, including but not limited to life sciences, biotech and health care, ICT, advanced materials, space, defence and energy sectors.</p>
New South Wales	Medical Devices Fund ⁵¹	<p>The Medical Devices Fund is an \$8.2 million per annum, competitive technology development and commercialisation program funded by the NSW Government.</p> <p>The Fund provides support to NSW based individuals, companies, public and private hospitals, medical research institutes, universities and the medical devices industry for developing and commercialising an innovative medical device/technology.</p> <p>The program offers funding in the range of \$500,000 to \$5 million, depending on the product's stage of development, over a period of one to three years. The NSW Government requires repayment of the grant once the recipient earns a profit through commercialisation of the device.</p>
New South Wales	Medical Research Support Program (MRSP) ⁵²	<p>The MRSP provides research infrastructure support to independent medical research institutes located in NSW. The purpose of the program is to develop state-wide capacity to deliver world class health and medical research through the provision of this funding.</p>

⁴⁹ Note: This table is a sample of funding for different jurisdictions. Its purpose is to demonstrate different ways medical research development and commercialisation is funded, and it is not representative of all funding provided by the jurisdiction. The information is sourced from desktop research, and the research was undertaken at a time when the support for medical research commercialisation and industry support is rapidly evolving

⁵⁰ Source: <http://www.anuconnectventures.com.au/> (viewed 21 October 2020)

⁵¹ Source: "Medical Devices Fund Round 8 Guidelines", NSW Ministry of Health, 2019

⁵² Source: "Medical Research Support Program Application Guidelines & Program Details 2020 - 2024", NSW Ministry of Health, 2020

Jurisdiction	Program	Description
		<p>To be eligible for funding, the medical research institute needs to be receiving an average annual income from eligible competitive grants⁵³ of at least \$3 million over the three previous years.</p> <p>The fixed pool of funding will be shared between eligible applicants based on their average annual NHMRC income in the preceding three years. This was expected to be in the range of 25 to 45 cents per NHMRC grant dollar.</p>
Northern Territory	Business Innovation Program ⁵⁴	<p>The Business Innovation Program is an example of a state/jurisdiction program that provides support for innovation and could include SMEs undertaking health and medical research commercialisation activities.</p> <p>The Business Innovation Program supports planning, development, and commercialisation activities. The program provides professional mentoring and funding of up to \$30,000 on a dollar-for-dollar matched funding basis.</p>
Queensland	Business Development Fund ⁵⁵	<p>Co-investment by the Queensland Government to commercialise research (including medical research), an innovative idea, or an innovative product or service.</p> <p>It is targeted at Australian companies with the majority of its businesses located in Queensland. It provides seed, early stage and follow-on investment funding.</p> <p>The Queensland Government will co-invest between \$250,000 and \$2.5 million through the fund, and it must be at least matched by a private sector co-investor.</p>
Queensland	Research Infrastructure Co-investment Fund (RICF) ⁵⁶	<p>The RICF is a Queensland Government program that provides co-investment in research infrastructure capabilities for existing or planned Queensland operations.</p> <p>Funding is open to organisations (universities, research agencies, and limited companies) with committed National Collaborative Research Infrastructure Strategy (NCRIS) funding and aligns with the Queensland's Advance Queensland Industry Roadmap and Priorities.</p> <p>The total fund size in a single round is \$25 million, with no stated cap on an individual grant.</p>

⁵³ Includes: Australian Research Council, Cancer Australia, Medical Research Future Fund, and National Health Medical Research Council

⁵⁴ Source: <https://nt.gov.au/industry/start-run-and-grow-a-business/grow-your-business/business-grants-and-funding/business-innovation-program> (last updated 9 September 2020, viewed 20 October 2020)

⁵⁵ Source: <https://advance.qld.gov.au/entrepreneurs-and-startups-industry-investors-small-business/business-development-fund> and <https://www.bulletpoint.com.au/business-development-fund/> (viewed 20 October 2020)

⁵⁶ Source: <https://science.des.qld.gov.au/funding/ricf> (viewed 20 October 2020)

Jurisdiction	Program	Description
South Australia	Research and Commercialisation Start Up Fund ⁵⁷	<p>The Research and Commercialisation Start Up Fund provides funding to South Australian based businesses, universities, and research institutes to undertake:</p> <ul style="list-style-type: none"> • Initiatives that provide innovative solutions or translate research into commercial outcomes that address economy-wide challenges for South Australia. • Initiatives that increase the level of national funding for South Australian research and research infrastructure. • Research collaborations that result in new financial services technologies or products. • Initiatives that support the establishment and growth of start-ups to scale-ups. • Initiatives that encourage and promote investment into South Australia's start-up and entrepreneurship ecosystem. <p>There are three funding streams: strategic research initiatives; start-up and early stage business incentives; and entrepreneurship and innovation ecosystem initiatives.</p> <p>Funding varies according to the stream. The funding for Stream 2 (Start-up and early stage business incentives) is between \$20,000 and \$1 million depending on the pathway the proposal falls within and there is a requirement for matched funding.</p> <p>Grants greater than \$100,000 in value are contingently repayable by way of a royalty.</p>
Tasmania	Grant funding to Menzies Institute for Medical Research	<p>The Tasmanian Government provides grant funding to the Menzies Institute for Medical Research. In 2018, the Menzies Institute for Medical Research received \$1.76 million of grant funding.⁵⁸</p>
Victoria	Victorian Medical Research Acceleration Fund ⁵⁹	<p>The Victorian Medical Research Acceleration Fund supports early stage research that is predominantly conducted in Victoria. This includes discovery research, clinical research and health practice. It is a competitive program designed to leverage funding from philanthropic, industry and international sources, and also to facilitate the development of collaborative partnerships between health services, industry, and medical institutes.</p> <p>The fund provides up to \$3 million in research grants per round to help address current market research gaps. Early stage research proposals receive up to \$100,000. Proposals to 'fast track'</p>

⁵⁷ Source: "Research, Commercialisation and Startup Fund Guidelines" South Australia Department of Innovation and Skills, May 2020

⁵⁸ Source: "Menzies Institute for Medical Research Annual Report 2018", p 33

⁵⁹ Source: "Victorian Medical Research Application Fund: Round 4 Application Guidelines", Victorian Government, February 2020

Jurisdiction	Program	Description
		translation into health or clinical practice receive up to \$500,000. Matched funding is a requirement for all proposals.
Victoria	Future Industries Fund	<p>In 2016, the Victorian Government established a \$200 million Victorian Future Industries Fund. This fund is focused on industry sectors that have the potential to drive significant jobs growth and attract investment into the future. The medical technologies and pharmaceuticals sector is one of the identified industry sectors supported by this fund.⁶⁰</p> <p>The fund provides investment facilitation, grants and other programs, targeted infrastructure improvements, programs to build workforce skills, and collaborative initiatives to support the adoption of global best practices⁶¹.</p> <p>The scope of application of these funds is broad. As an example, the Victoria Future Industries Fund was used to support the establishment of BioCurate and the Medicines Manufacturing Innovation Centre to accelerate the development and commercialisation of new medicines, and further boost Victoria's pharmaceutical manufacturing capability.⁶²</p>
Western Australia	Future Health Research and Innovation Fund (FHRI)	<p>The FHRI provides grants supporting health and medical research, innovation and commercialisation that can contribute to improving the health of individuals and the wider population, and to help the health system to be more effective and efficient while creating jobs and new industries and bringing broader economic benefits to Western Australia.⁶³</p> <p>In 2020, the FHRI invited proposals from Western Australian institutions requiring grants for research, innovation or infrastructure projects that had a COVID-19 focus.⁶⁴ This included:</p> <ul style="list-style-type: none"> • Research grants of up to \$250,000 over 2 years for research projects that will generate knowledge and have the potential to be translated into improved policy and/or practice. • Innovation grants of up to \$50,000 over 1 year for innovation projects that will develop new ideas, research and/or technology to create new processes, products and/or services. • Infrastructure grants of up to \$ 1 million over 2 years for essential infrastructure that supports research and innovation.

⁶⁰ Source: <https://sites.research.unimelb.edu.au/research-funding/mi/victorian-future-industries-fund> (viewed 10 September 2020)

⁶¹ Source: <https://www.business.vic.gov.au/support-for-your-business/grants-and-assistance/future-industries> (viewed 20 October 2020)

⁶² Source: https://www.business.vic.gov.au/_data/assets/pdf_file/0009/1506348/Future-Industries-Factsheet.pdf (viewed 20 October 2020)

⁶³ Source: <https://fhrifund.health.wa.gov.au/Funding> (last updated 25 September 2020, viewed 20 October 2020)

⁶⁴ Source: "FHRI Focus Grants: Covid-19 Guidelines and Conditions", Government of Western Australia Department of Health, 2020

4 NON-GOVERNMENT FUNDING

There are sources of funding outside of government, including philanthropy, private sector investment, and self-financing. These are described in further detail below.

4.1 Philanthropy

Philanthropy for health and medical research and commercialisation/translation can come from a number of sources and be used for different purposes.

4.1.1 Charitable organisations and foundations

Many charitable organisations and foundations exist for a specific purpose, for example to support research or to raise awareness about a particular disease (e.g. the Heart Foundation) or to support the endeavours of an organisation that includes research and commercialisation/translation (e.g. the Epworth Medical Foundation). Other charitable organisations fund medical research and/or commercialisation/translation as part of their portfolio (e.g. the Ian Potter Foundation).

These foundations tend to fund earlier stage research, although there are examples of foundations funding later stage development and commercialisation/translation (e.g. National Foundation for Medical Research and Innovation). In most cases, recipients of the funds need to have Deductible Gift Recipient (DGR) status. This requirement acts to exclude most private sector organisations, such as biotech companies.

4.1.2 Corporate philanthropy

Corporate philanthropy can be another potential source of funds for health and medical research and/or commercialisation/translation. The funds are typically directed to a specific initiative, or for development within the sector.

For the last eight years, the QBE Foundation has provided support to the Kids Cancer Foundation for research to find better treatments for children diagnosed with diffuse intrinsic pontine glioma, and to gather the necessary preclinical data required to progress to human trials.^{65,66}

The BUPA Foundation has invested more than \$35 million in partnerships across Australia in the last 10 years. The majority of these initiatives have been in projects aimed at improving the evidence base within the health system and/or initiatives enabling people to live longer, healthier and happier lives. However, one stream of funding is targeted towards capacity building by developing skills and networks of health and medical researchers. For example, in 2018, BUPA awarded a total of \$49,000 distributed across nine researchers, with one early career medical researcher receiving \$25,000.⁶⁷

4.1.3 Overseas philanthropy

Large trusts and foundations, such as the Bill and Melinda Gates Foundation and the Wellcome Trust, have been funding medical research, translation and product development in Australia. For example, in November 2019 the Bill and Melinda Gates Foundation funded the QIMR Berghofer Medical Research Institute \$2.7 million to establish dose/concentration-response of single doses

⁶⁵ Source: Kids Cancer Project 2019 Annual Report

⁶⁶ Source: "Corporate Giving and Innovative Research Have the Greatest Impact", Research Australia, 13 October 2017

⁶⁷ Source: "Longer, healthier, happier lives Highlights Report 2018", BUPA Health Foundation

of tafenoquine in induced blood-stage malaria infections.⁶⁸ Additionally, there are overseas grant agencies that provide grants to medical research include European Union grants, and the United States National Science Foundation, National Institutes of Health, Centres for Disease Control and Prevention, and Department of Defense. These grants are targeted at research and translation and can be very large.

4.1.4 Donations and bequests

Donations and bequests can be received by an organisation (usually an organisation with DGR status, such as a medical research institute, hospital, or university) to support the organisation's endeavours, including medical research and/or commercialisation/translation. The donations and bequests can be made to a foundation associated with an organisation, for example the RMH Neurosciences Foundation, or directly to the organisation, such as the University of Melbourne.

Donations and bequests can be a significant source of revenue for some research organisations. Some examples are shown in Table 3.

Table 3: Donations and bequests to selected MRIs and Universities 2018/19⁶⁹

Organisation name	Organisation type	Donations & bequests	% of total income
Walter and Eliza Hall Institute (2019)	Medical research institute	\$16.74 million	9.9%
Murdoch Children's Research Institute (2018)	Medical research institute	\$16.05 million	10.7%
Garvan Institute of Medical Research (2019)	Medical research institute	\$54.62 million	48.8%
Telethon Kids Institute (2019)	Medical research institute	\$25.15 million	27.9%
University of Melbourne (2019)	University	\$22.77 million (philanthropic endowments)	0.8%
Curtin University (2019)	University	\$3.26 million	0.34%

⁶⁸ Source: <https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2019/11/INV-001965> (viewed 10 September 2020)

⁶⁹ Source: Annual reports

4.2 Private sector investment

There are many sources and avenues of private sector investment. Most of these funding sources are targeted towards the mid to later stages of development and commercialisation. However, angel investment, seed funding and crowd funding are employed at earlier stages of health medical research development.

4.2.1 Venture Capital

The Australian Investment Council (AVCAL) defines venture capital as investment in early stage companies that are developing new and innovative technologies, therapies, systems and processes, which typically have higher risk/return profiles. These investors provide capital and commercialisation skills and hold equity in the companies they invest in.⁷⁰

While all venture capital is focused on early stage, high growth firms, it can take different forms,⁷¹ including:

- Institutional venture capital: Venture capital investment takes place under the stewardship of a fund manager whose role is to raise funds (e.g. from high net worth individuals and superannuation funds), and to invest in a diverse portfolio of companies, often with an industry focus (e.g. life sciences). The funds invested aim to deliver a high financial return to investors, usually within an average ten-year timeframe. Brandon Capital Partners and One Ventures Pty Ltd are examples of venture capital firms in this category.
- Corporate venture capital: An established corporation making investments in early stage companies, through either an independent arm of its business or a dedicated corporate division. Companies make these investments in order to gain exposure and technological insights and/or to supplement in-house research and development.
- University venture capital: Assists with taking research generated through the university to market. For example, Uniseed operates at the Universities of Melbourne, Queensland, Sydney and NSW, and the CSIRO. The Uniseed fund (currently \$50 million) invests capital, provides commercial expertise, and networks to research partner intellectual property. This can be from early stage development through to commercialisation (through subsequent funding rounds).⁷² University venture capital firms such as Uniseed will typically invest at an earlier stage than institutional venture capital.
- Government funds: Australian governments have created dedicated venture capital funds which invest in both commercial and public interest objectives. For example, CSIRO's \$240 million Innovation Fund invests in start-up and spin off companies, and small and medium-sized enterprises (SMEs) engaged in the translation of research generated in the Australian publicly funded research sector.⁷³

In the 2019 calendar year, venture capital deals in the Australian healthcare sector were valued at \$228.34 million and totalled \$572.66 million for the years 2015 to 2019.⁷⁴

⁷⁰ Source: "The Venture Capital Effect: A Report on the Industry's Impact on the Australian Economy", Australian Private Equity & Venture Capital Association Limited, June 2017, p 11

⁷¹ Source: "The Venture Capital Effect: A Report on the Industry's Impact on the Australian Economy", Australian Private Equity & Venture Capital Association Limited, June 2017, p 17

⁷² Source: Uniseed Overview and Investments (presentation from their website), August 2020.

⁷³ Source: <https://www.bulletpoint.com.au/csiro-innovation-fund/> (viewed 12 September 2020), and "Australian Private Capital Market Overview: A Preqin and Australian Investment Council Yearbook 2020", Australian Investment Council, p 15

⁷⁴ Source: Derived from "Australian Private Capital Market Overview: A Preqin and Australian Investment Council Yearbook 2020 - Data Pack", Australian Investment Council

Australia is increasingly becoming attractive to international venture capital, with several examples of Australian organisations attracting capital from international venture capital groups.⁷⁵

4.2.2 Private equity

Private equity is provided by organisations with money committed by pension funds, other institutional investors and high net worth individuals. When compared to venture capital and angel investors, private equity will typically have a lower risk profile and a preference of investing to secure a majority stake in mature businesses, while venture capital tends to invest minority stakes in high risk growth companies. The average deal size for private equity is \$150 million. The median venture capital deal size for an early stage investment is \$3.03 million.⁷⁶

4.2.3 Angel investment and seed funding

An angel investor is one who invests their personal capital in early stage, potentially high-growth companies, usually in exchange for convertible debt or ownership equity. Angels play an important role in the early stage funding space, providing funds (between \$100,000 and \$1 million), mentorship, networks and connection, and advice on establishing businesses.⁷⁷ Angel investors may exist as angel groups (e.g. Melbourne Angels) or as an individual angel investor.

Angel investing in Australia reached \$280 million in 2016/17, and \$90 million in 2017/18.⁷⁸ This reduction in angel investment between these two years occurred at the time of increased venture capital investment.⁷⁹

In 2016/17, the median investment by an angel investor was \$250,000, and \$100,000 by a seed investor.⁸⁰

4.2.4 Industry funding

Funding can come from the industry itself, particularly global pharmaceutical companies. The reason these companies engage in this funding is usually to develop the relationships and profile to access intellectual property, or to access intellectual property itself.

Most industry funding occurs at later stage commercialisation by means of buying a company or the technology and/or licensing the technology. For example, in 2015 Novartis bought Spinifex Pharmaceuticals for an upfront cash consideration of \$283.25 million plus clinical development and regulatory milestone payments of up to \$708.11 million. The acquisition was centred on Spinifex's EMA401, a new drug that provided relief for people suffering from chronic neuropathic pain.^{81,82} These funds provide the life science company and earlier stage investors with an exit and a return on their investments, which they can then invest in further research and development.

⁷⁵ Source: "IP Group plc - Commits A\$200 million in landmark deal with nine leading universities in Australia and New Zealand", 30 May 2017

⁷⁶ Source: "Productivity is not an accident: The economics and impact of Victoria's startup ecosystem", Deloitte Access Economics, June 2020

⁷⁷ Source: "Best Practices for Angel Networks", LaunchVic, 2019

⁷⁸ Source: "Angel Investors on the Wane in Australia", AFR, 25 September 2019

⁷⁹ Source: "Angel Investors on the Wane in Australia", AFR, 25 September 2019

⁸⁰ Source: "Victorian Startup Investment Snapshot", LaunchVic, November 2017

⁸¹ Source: "Spinifex Pharmaceuticals to be Acquired by Novartis", PR Newswire, 29 June 2015. Note, currency was expressed in \$US and has been converted to Australian currency at the RBA rate as at 25 September 2020, 0.7061

⁸² Source: "The Venture Capital Effect: A Report on the Industry's Impact on the Australian Economy", Australian Private Equity & Venture Capital Association Limited, June 2017, p 18. Note, currency was expressed in \$US and has been converted to Australian currency at the RBA rate as at 25 September 2020, 0.7061

4.2.5 Equity/debt raising

Larger established companies involved in commercialising medical research can access the traditional debt and equity markets for funding the commercialisation of medical research, which are not as readily accessible for smaller companies.⁸³ Many of the impediments to smaller companies accessing capital in this way relate to imbalances between lenders and borrowers, and barriers to market-based funding.⁸⁴

Listing on the Australian Stock Exchange (ASX) through an Initial Public Offering is also used by larger and smaller companies as a capital raising venue for early stage companies (typically Phase 2 clinical trials or later) to fund both their commercialisation and growth aspirations.⁸⁵ The company needs to have significant profit or assets, for example \$4 million net tangible assets, in order to be eligible for listing on the ASX.⁸⁶

4.2.6 Crowdsourced equity funding

Crowdsourced funding is a form of finance that enables start-ups and early stage companies to raise funds, generally from a large number of investors that invest small amounts of money. Crowdsourced equity funding is when the investors take an equity stake in the company.

The *Corporations Amendment (Crowd-sourced Funding) Act 2017 (Cth)* allows eligible companies to raise up to \$5 million per year, with any single investor investing a maximum of \$10,000 in a year.

There are some examples of crowdsourced funding being used by Australian medtech and life science companies, for example, Magnetica (an Australian biomedical engineering and technology company) raised \$1.1 million in 2016.⁸⁷ As this method of financing is relatively new, it is expected this could be a source of finance for further early stage companies seeking to develop and commercialise medical research in the future.

4.3 Self-financed

Organisations also use their own funds to develop and commercialise medical research – particularly earlier stage research and development. Examples of self-financing include:

- Personal funds and funds from friends and family, particularly in earlier stage development.
- Proceeds from the commercialisation of technology. For example, the University of Queensland has reinvested a portion of the proceeds from the commercialisation of Spinifex into the Queensland Emory Drug Discovery Initiative. This initiative was established for the purpose of translating university research into new medicines.⁸⁸
- Subsidisation of medical research development and commercialisation/translation from other income. For example, according to the Australian Bureau of Statistics, universities

⁸³ Source: "Non-government funding for Victorian health and medical research", Research Australia, December 2018

⁸⁴ Source: "Financial System Inquiry – Final Report", The Australian Government the Treasury, November 2014

⁸⁵ Source: "Roadmap to a successful IPO for life sciences companies", AusBiotech, August 2017

⁸⁶ Source: "Roadmap to a successful IPO for life sciences companies", AusBiotech, August 2017

⁸⁷ Source: <https://equitise.com/blog/magnetica-successful-crowdfund> (viewed 13 September 2020)

⁸⁸ Source: The University of Queensland Annual Report 2015

fund approximately half of their research and development activities from general university funds.⁸⁹

5 GOVERNMENT CO-INVESTMENT

There are numerous examples of where public funding has been used to support and/or stimulate private sector investment in medical research, and in the translation and commercialisation of medical research. This funding is targeted at different stages of the process of research and translation/commercialisation. However, it is typically targeted at the research, pre-clinical and early clinical development stages.

The following sections describe the types of public and private collaborations and provides illustrative examples of each.

5.1 Government contributions to private/industry funds

There are several examples of the Australian Government and state/territory governments providing contributions to private sector and industry funds that fund the development and commercialisation of medical research.

The Australian Government established the Biomedical Translation Fund (BTF) to increase the capital available for commercialising medical research in Australia. The program provides venture capital through licensed private sector fund managers. The Australian Government contributes \$250 million to the fund, and \$251.25 million is from private sector capital contributions. AusIndustry delivers the BTF on behalf of the Australian Department of Health. The BTF fund managers screen investment proposals and make venture capital investments.

Contributions by government to private/industry funds can be made in other ways. For example, the ACT Government contributed to ANU Connect Ventures for early stage funding. Australian governments have contributed to the Medical Research Commercialisation Fund, which is managed by Brandon Capital Partners, but receives contributions from Australian and New Zealand governments, industry and Australian superannuation funds.

5.2 Government contributions and collaborations with foundations

Governments have contributed funds and collaborated with foundations to support medical research development and commercialisation.

An example is the contributions that the Australian Government has made through the Medical Research Future Fund and philanthropic organisations to establish a mission to support research into brain cancer treatments.

⁸⁹ Source: "8111.0 - Research and Experimental Development, Higher Education Organisations, Australia, 2018", Australian Bureau of Statistics, 20 May 2020

Note, "General university funds" as a source of R&D funding is defined as funds from: a) the Australian Government (other than targeted research funding), including the portion of other revenue sourced from the Australian Government spent on R&D but not identified as 'Competitive Research Grants' or 'Other Australian Government'; and b) fees and charges, income relating to Higher Education Contribution Scheme liabilities, income from non-research specific donations, bequests and foundations, investment income, reversions from provisions accounts, loans drawn down, income from the institutions commercial operations and from sale of products or assets. [Source: ABS]

The Australian Brain Cancer Mission is a \$133 million fund that supports research into brain cancer treatments⁹⁰. It aims to double the survival rate of Australians living with brain cancer over the next 10 years. Funding for the Australian Brain Cancer Mission comes from the Australian Government's Medical Research Future Fund (\$60.26 million over 10 years), philanthropic contributions (\$59.3 million), and state and territory governments (\$13.45 million).⁹¹

The Cure Brain Cancer Foundation and the Eliminate Cancer Initiative are contributing \$20 million and \$10 million respectively over a period of 10 years. Prior to the establishment of the Australian Brain Cancer Mission, the Cure Brain Cancer Foundation had been a strong advocate for making brain cancer a national priority.⁹²

Funds from the Australian Brain Cancer Mission are directed towards research, clinical trials (including joining international trials), and a review of whether existing brain cancer research platforms and technologies are meeting researchers' needs.⁹³

5.3 Matched funding as part of the application process

Many Australian government programs (including state and territory programs) require matched funding as part of the application process. This requirement facilitates leveraging of government supplied funds, commitment from the applicant, and industry participation.

There are several examples of matched funding programs discussed in this report. Examples of Australian Government programs include the CRC program, the MRFF's Biomedical Translation Bridge program and the Accelerating Commercialisation program. Examples of state and territory government funded programs include the Queensland Government's Business Development Fund, the South Australian Government's Research and Commercialisation Start Up Fund, and the Victorian Government's Medical Research Acceleration Fund.

5.4 Tax incentives

Australia's tax system also has a role in incentivising private investment into initiatives, including the development and commercialisation/translation of medical research. Section 2.5 of this report discusses tax incentive schemes, including tax incentives for donors (through tax deductions donors can receive for gifts to entities with Deductible Gift Recipient endorsement), tax incentives for early stage investors (through concessional tax treatment for investments made in qualifying early stage innovation companies), and tax incentives for venture capital investment (through programs that provide beneficial tax treatment to eligible local and foreign investors).

The R&D Tax Incentive Scheme (discussed in section 2.5.1) is also relevant, although the main beneficiary of this Scheme are the organisations undertaking R&D activities by means of the revenue stream eligible organisations receive through the tax offset.

⁹⁰ Source: <https://www.health.gov.au/initiatives-and-programs/australian-brain-cancer-mission> (last updated 4 November 2020, viewed 24 November 2020)

⁹¹ Source: <https://www.canceraustralia.gov.au/research-data/research/australian-brain-cancer-mission> (viewed 24 November 2020)

⁹² Source: <https://www.curebraincancer.org.au/page/268/australian-brain-cancer-mission> (viewed 13 September 2020)

⁹³ Source: <https://www.health.gov.au/initiatives-and-programs/australian-brain-cancer-mission> (viewed 13 September 2020)

PART 2 QUALITATIVE RESEARCH

1 METHOD

The research questions and research scope for the qualitative research collection and analysis are described below.

1.1 Research questions

The key research questions the qualitative research sought to answer are:

1. What are the sector's views regarding existing government funding support and gaps that remain unaddressed or are not sufficiently addressed, particularly in commercialisation and translation of research?
2. What are the sector's views regarding the impact of MRFF initiatives to improve the capability and capacity of the medical research and innovation sector to commercialise research outputs, and any perceived gaps?
3. How have institutions positioned themselves to maximise commercialisation opportunities?
4. What are the sector's views regarding other barriers to commercialisation of research outputs in Australia?

1.2 Research scope

The scope for this research is outlined below. While a wide range of insights were provided by stakeholders during the data collection process, only findings that are within the scope of this research have been presented in this report.

1.2.1 In scope

- Australian Government and state/territory government initiatives that support commercialisation of medical research and medical innovation in Australia.
- Academic and industry initiatives that seek to enhance capacity and capability to commercialise medical research and innovation outputs in Australia.
- Perceptions and views of individuals and organisations in the medical research and commercialisation sector regarding the medical research commercialisation landscape.
- Perceptions and views from the public sector, academia, medical research institutes and private enterprise.

1.2.2 Out of scope

- Determining the impact, value or effectiveness of initiatives to improve commercialisation of medical research.
- Determining the impact, value or effectiveness of research or projects funded under initiatives to improve commercialisation of medical research.

1.3 Research methods

The research methods used for the review of key documents, key stakeholder and sector expert interviews, and sector questionnaire are described below.

1.3.1 Review of key documents

Allen + Clarke undertook an initial review of key documents that focus on current initiatives that aim to improve commercialisation culture and capability within Australia. Documents included funding and/or grant guidelines, documents relating to other available funding, and key documents provided by the department.

1.3.2 Sector interviews

As part of the qualitative research, *Allen + Clarke* engaged with 53 key informants through sector interviews.⁹⁴ Table 4 provides an overview of informants by cohort.

Table 4: Informants by cohort

Cohort	Number interviewed
Australian Government	11
Industry peak bodies + accelerators	11
Technology transfer offices	9
Venture capital / investment firm	7
State + territory government portfolio holders	6
Biotech, medtech + pharmaceutical companies	5
Research institutions / researchers	3
Philanthropic	1
TOTAL	53

1.3.3 Sector questionnaire

A sector questionnaire was undertaken to broaden the perspectives gathered through the research. Information obtained through the key stakeholder and sector expert interviews was used to design the questionnaire. The questionnaire was targeted towards people who are or have been involved in:

- the research and development of medical innovations, for example as an academic, researcher or inventor
- the spin out/creation of a medical commercialisation company
- small-medium medtech, biotech or pharmaceutical companies that undertake commercialisation of medical innovations.

There were 274 responses to the questionnaire with a completion rate of 64% (the percentage that completed the entire questionnaire. Some respondents only answered some of the questions.)

The largest cohort of respondents are primarily based in medtech, biotech or pharmaceutical companies (28.3% in small-medium and 3.6% in large); followed by universities (23.6%) and

⁹⁴ Participants in the interviews were identified through discussion with the department

medical research institutes (13%) with a further 1.8% in technology transfer offices. The spread of response across the cohorts is outlined in Table 5 below.

Table 5: Sector questionnaire respondents

Cohort	% responders
Small to medium medtech, biotech or pharmaceutical company	28.3%
University	23.6%
Medical research institute	13.0%
Hospital/health care provider	4.7%
Digital health company	4.3%
Government	4.0%
Consultant	4.0%
Large medtech, biotech or pharmaceutical company	3.6%
Venture capital or investment firm	2.9%
Industry body or peak	2.2%
Technology Transfer Office	1.8%
Philanthropic funder	0.7%
Other	6.9%

Respondents demonstrated a deep experience of the sector, with more than two thirds having experience in the research and development of medical innovations and ideas (67.8%), almost half being involved in the spin out/creation of a medical commercialisation company (for example as a researcher, inventor, executive or director) (47.6%) and almost half having experience at a medtech, biotech or pharmaceutical company that undertakes commercialisation of medical innovations and ideas (48%). This is shown in Table 6.

Table 6: Sector experience of questionnaire respondents

I am or have been involved in...	% responders
the research and development of medical innovations and ideas	67.8%
the spin out/creation of a medical commercialisation company	47.6%
a medtech, biotech or pharmaceutical company that undertakes commercialisation of medical innovations and ideas	48.0%
the identification, support and mentoring of promising medical innovations and ideas	39.2%
the provision of capital/investment for medical innovations and ideas	21.6%
clinical practice and application of medical technologies, biotechnologies and/or pharmaceuticals	21.6%
a digital health company that undertakes commercialisation of medical innovations and ideas	15.8%

I am or have been involved in...	% responders
policy development in regard to medical research and/or medical research commercialisation	13.9%
the provision of philanthropic funding of medical innovations and ideas	7.3%

Quantitative data from the questionnaire is presented in Appendix One.

1.3.4 Approach to data analysis

A thematic analysis of the interviews and questionnaire results was undertaken using NVivo Pro. A coding template was developed and applied to the data from the interviews and questionnaire to undertake attribution to the key research questions. This method enabled identification of themes and sub-themes relevant to each of the research questions, and the categorisation of perceptions held by different stakeholder groups.

1.3.5 Limitations

This report contains a representation of the views of people interviewed or surveyed as part of this process. There may be some people in the sector that hold different views to those captured as part of this process. The perspectives have not been validated for accuracy or correctness.

In some cases, a theme emerged that is relevant to only a small number of stakeholders. This theme was prompted by the questions in the interviews and/or the survey, however, there was not a specific question about this theme. In these cases, we are unable to state whether this theme is widely held across sector cohorts, or whether there were stakeholders who held a different view. We have highlighted this situation where it is relevant in the body of the report.

2 KEY THEMES BY RESEARCH QUESTION

2.1 Research Question 1 – Gaps in existing government funding support

What are the sector's views regarding existing government funding support and gaps that remain unaddressed or are not sufficiently addressed, particularly in commercialisation and translation of research?

An overview of the key themes representing the sector's views as they relate to this research question is provided in Table 7. The themes are further described in the subsequent sections.

Table 7: Research Question 1 - Key themes

<p>Research Question 1: What are the sector's views regarding existing government funding support and gaps that remain unaddressed or are not sufficiently addressed, particularly in commercialisation and translation of research?</p>
<p>Contextual factors relevant to funding for the commercialisation and translation of medical research</p> <ul style="list-style-type: none"> A. The funding landscape is complex and changing. B. Funding medical research requires “patient capital”.
<p>Expectations of stakeholders regarding government funding for commercialisation and translational research</p> <ul style="list-style-type: none"> A. Government has a role in “de-risking” research so that it can progress to translation and commercialisation. B. There remains the need for “blue sky research” funding.
<p>Gaps regarding existing government support</p> <ul style="list-style-type: none"> A. While improved, there is still insufficient funding, particularly at the pre-clinical and early clinical stages. B. Availability and accessibility of funding at the points where it is needed. C. Equitable access to funding for medical research and early stage development. D. Eligibility and application criteria for medical research commercialisation grants are inadvertently excluding some digital health applications. E. Funding for indirect costs is fragmented and insufficient. F. Funding needs to recognise that some costs are by necessity incurred outside Australia.
<p>Other identified issues regarding existing government support</p> <ul style="list-style-type: none"> A. The complexity of the grant landscape. B. Changes in funding programs creates uncertainty. C. MRFF funding needs to be deeper and more targeted. D. Funding criteria needs to focus more on factors that are directly related to the probable success of the application for commercialisation. E. Insufficient industry representation on expert advisory and selection panels. F. Government may be inadvertently funding initiatives that will never succeed. G. It is perceived that there is a lack of transparency in health and medical research funding in Australia.

2.1.1 Contextual factors relevant to funding for the commercialisation and translation of medical research

A - The funding landscape is complex and changing

The main points emphasised by stakeholders during the research are:

- i. There have been a number of changes to the funding landscape in recent years, including the introduction of the Biomedical Translation Fund in 2016, the Medical Research Future Fund, and the introduction and changes to taxation incentives, including tax incentives for early stage investors, and changes to the R&D tax incentive. These changes have injected further funds into the system and have been behind increased private sector capital (particularly venture capital) directed to medical research commercialisation investment.
- ii. Universities and medical research institutes have been looking towards commercialisation revenue to fund activities related to further research and commercialisation. However, this revenue stream takes time, and is likely to make up a relatively small percentage of a university's income stream. Therefore, their focus is likely to remain on obtaining research grants.

B - Funding medical research commercialisation requires “patient capital”

Stakeholders repeatedly emphasised that:

- i. The sheer cost and the time to commercialise medical research requires capital that is invested for long periods.

2.1.2 Expectations of stakeholders regarding government funding for commercialisation and translational research

A – Government has a role in “de-risking” research so that it can progress to translation and commercialisation

Most stakeholders across the sectors stated:

- i. The need for government funding for early stage research and development, as the risk profile of initiatives were less attractive to private sector investment.
- ii. Government funding is seen as required to sufficiently “de-risk” medical research so it can attract private sector investment to progress commercialisation.
- iii. There is an expectation that government funding is required for pre-clinical development, and in some cases early clinical development.

B – There remains the need for “blue sky research” funding

Some stakeholders stated:

- i. There remains a need for “blue sky research” funding, however, translational research needs to be aligned to unmet medical need and requires industry engagement. Some stakeholders suggested that funding tied to shorter term commercial outcomes is prioritised over larger scale, innovative, and higher risk research.

2.1.3 Gaps regarding existing government support

A - While improved, there is still insufficient funding, particularly at the pre-clinical and early clinical stages

Stakeholders across the sectors said:

- i. There are more funds available for medical research commercialisation than there were previously, however, there is still insufficient funds available for pre-clinical and early clinical stages.
- ii. Early seed funding is required to build the pre-clinical dataset in medical research (e.g. early animal studies and toxicology studies). This acts to “de-risk” the medical research so it becomes more attractive to private investment.
- iii. There are few early seed funders in Australia. Universities may have some funds established for pre-seed funding. However, these are typically small and are insufficient to make an impact on life science innovations.
- iv. There are programs aimed at providing funding to medical research at the pre-clinical stage, including the MRFF’s MRC initiative. While these are well received, some stakeholders stated this is not enough to meet demand, and that the requirements of matched funding for the Biomedical Translation Bridge are difficult to attain for smaller universities and medical research institutes.

Divergent views

There is a view by some stakeholders (a minority, and mostly views by stakeholders who have visibility of applications receiving funding), that the funding exists for early stage development, but it needs to be more targeted, and potentially a larger quantity of funds made available to the successful applicant. This is because there are “clear winners” and resources should be devoted to progressing these initiatives, rather than distributing the funds more broadly. This is discussed further in section 2.1.4.

A few stakeholders (primarily smaller biotech and pharmaceutical businesses) said that government funding was required at later stages of clinical development and commercialisation for the commercialisation of drugs and medtech.

Relevance to the MRFF

The MRC initiative’s programs (Biomedical Translation Bridge and BioMedTech Horizons) are generally well received. However, there may be opportunities for reviewing or addressing any shortcomings that may exist with these programs, and/or ways they may be complemented.

Suggestions from the sector

A few stakeholders (mostly involved in financing or commercialising medical research) suggested approaches for addressing the points described above:

- i. Scope for government funding for establishing a BTF type program (i.e. assessed by a venture partner and matched funding) for earlier stage development (e.g. at early proof of concept stage).
- ii. Dedicated funding schemes for each stage of drug discovery – awarded to research on the basis of scientific and commercial potential. Wellcome (UK)’s international seeding drug discovery initiative was suggested as an example.
- iii. The establishment of “a pool of public sector investment funding” for later stage medtech and pharmaceutical commercialisation – similar to models in Singapore and Norway.

B – Availability and accessibility of funding at the points where it is needed

Many stakeholders across the sectors believed it was important that earlier stage companies could access funds and support in small amounts as they needed it, so that they can progress their research to the next stage. Specific points raised include:

- i. The stop/start nature of applying and accessing funds at set funding rounds slows the process and adds cost and uncertainty to medical research commercialisation. Smaller organisations are more acutely impacted by this.
- ii. Faster access to funds for earlier stage commercialisation (e.g. to proof of concept) is important. One company said frequent funding rounds occurring every 8 weeks is important for earlier stage companies.
- iii. There is a need for shorter, sharper programs, with easier access to smaller amounts of funds (e.g. \$40,000 - \$50,000) to help the innovation to progress to the next stage (e.g. proof of concept). If it works, the organisation may then apply for further funding through the Biomedical Translation Bridge program.
- iv. Support can come in many forms, for example technical support, marketing insight, and direct funding. It is important that the right type of support is available at the right time.

Divergent views

Several stakeholders, particularly those leading or working within biotechnology companies, emphasised that commercialising medical research is a long-term proposition, and requires more patience, sophistication and nurturing. Some stated that government needs to be thoughtful about where money is spent in the early stages.

Relevance to the MRFF

The MRC initiative's programs (Biomedical Translation Bridge and BioMedTech Horizons) were identified as meeting a key need in terms of funds and support for early stage commercialisation. However, there is a call for either these programs to be more flexible, or for the availability of further flexible funding streams to assist with early stage commercialisation.

Suggestions from the sector

A couple of stakeholders suggested the establishment of a funding program that is similar to the program provided by the Commercialisation Partner Network in New Zealand. In this program, qualified partners work with researchers, and where necessary, grant a small amount of funds to support the researcher to progress the research to the next stage. The funds are issued as they are required, rather than as part of a formal funding round.

C – Equitable access to funding for medical research and early stage development

Many stakeholders pointed to the fact that some features of government funding of medical research and commercialisation are inadvertently causing inequities in access to funds at different stages of the pipeline. This is ultimately affecting the supply of quality research that is commercialised. Specific points raised include:

- i. In Australia, the majority of the research for commercialisation comes from universities and medical research institutes. This is different compared to overseas (e.g. United Kingdom) and is potentially limiting the production of research that is more likely to be successfully commercialised.
- ii. Academic inclined funding requirements – such as publication records, matched funding/investment requirements, academic principal investigator stipulations, patent applications – can rule out potential applicants (e.g. SMEs, smaller universities and institutes) from eligibility, unless they partner.
- iii. Most medical technology innovation occurs in companies, and this is an area where funding needs to be bolstered.

Divergent views

There were no specific divergent views raised about this point.

Relevance to the MRFF

These points are more relevant to funds coming through the ARC and NHMRC. These points may be relevant to MRFF initiatives that are directed through the NHMRC, and early stage commercialisation programs (such as Biomedical Translation Bridge) where matched funding is required.

D – Eligibility and application criteria for medical research commercialisation grants are inadvertently excluding some digital health applications

A small number of stakeholders (mostly involved in digital health research and commercialisation) stated that digital health applications (that are not a connected device) are being inadvertently excluded from funding to support commercialisation, and that this may result in a lost opportunity in terms of the benefits to public health and in terms of flow on benefits to industry. Specific points raised include:

- i. Digital health is being increasingly used to improve the processes in which diagnosis, monitoring and treatment are performed in clinical settings. However, it is difficult to access grants for digital health research.
- ii. Digital health (except for connected devices) is largely excluded from the MRFF medical research commercialisation funds. For example, the BioMedTech Horizons program invites digital health projects to apply, however, the application requires evidence of intellectual property – this is reportedly not appropriate for digital innovations as the software code is protected by copyright. Further, other criteria, such as technical readiness levels, may not be appropriate for digital health applications, and as a result may be acting to inadvertently exclude digital health applications from funding.
- iii. There is potential value that is lost from inadvertently excluding digital health applications that are not connected to a device.

Divergent views

No divergent views were provided by stakeholders.⁹⁵

Relevance to the MRFF

The MRFF MRC initiative's programs may be inadvertently excluding otherwise eligible applications for program funding based on application assessment criteria. Referring to the application process for BioMedTech Horizons program, informants have said that providing evidence of intellectual property and stating the Technical Readiness Level are not applicable to digital health. Informants have stated they are concerned their applications for digital health solutions are overlooked, as they are unable to respond satisfactorily to these questions on the application.

E – Funding for indirect costs is fragmented and insufficient

Several stakeholders across the sectors stated that Australian Government funding programs do not cover indirect costs associated with research and development, and access to these funds is fragmented and changing. Specific points raised include:

⁹⁵ Note, that these points were only brought up by a small number of stakeholders and were not discussed or explored in interviews or the survey. Therefore, we are unable to state whether this point is widely held across sector cohorts, or whether there were other stakeholders with different views.

- i. Usually organisations are funded for the cost of the researcher and possibly a research assistant and are not funded for the indirect costs of research. For instance, organisations may not receive funding for salaries of group leaders, electricity, administration, animal care, and legal advice. This results in a “cottage industry” where organisations, and medical research institutes in particular, need to cobble together funds from multiple channels.
- ii. State/territory governments, industry and philanthropy have in some cases funded the indirect costs associated with research and development. However, this is usually based on the desire of the funder to support the organisation – for example, for the generation of jobs. As a consequence, there is not an efficient or even approach across the country.

Divergent views

There were no specific divergent views raised about this point.

Relevance to the MRFF

The discussion for funding indirect costs was mostly directed at research activities, however, it also applies to pre-clinical and clinical development of research. For example, eligible expenditures funded by the MRFF MRC initiative’s programs are for direct costs related to early stage development, not business costs and activities related to the usual requirement for a business.

F - Funding needs to recognise that some costs are by necessity incurred outside Australia

A few stakeholders (mostly in research and industry sectors) identified limitations associated with funds being limited to expenditure in Australia. A specific point raised was:

- i. MRFF funds do not allow for expenditure outside of Australia. For example, if, as part of clinical development, an aspect of the product needs to be manufactured or trialled overseas, the funds cannot be used for this.⁹⁶

Divergent views

No divergent views were provided by stakeholders.⁹⁷

Relevance to the MRFF

This point refers to the MRFF. As a specific example, a stakeholder said that only a small fraction of MRFF money can be spent overseas. This precludes MRFF funding of some research that may be useful to Australia. As an example, a COVID-19 study is likely to be performed overseas as there are insufficient patients here. Similarly, some specialised manufacturing is only available overseas. MRFF funds could not be used in these two examples.

2.1.4 Other identified issues regarding existing government support

A – The complexity of the grant landscape

Many stakeholders pointed to the number and the complexity of programs. Specifically:

⁹⁶ Note, this is the reported perception. The expectation of the MRFF is that most of the research activities and funding expenditure will occur in Australia. However, there is provision in the MRFF to allow a component of the research to be undertaken overseas if the equipment/resources required for that component are not available in Australia, and the component is critical to the successful completion of the research project.

⁹⁷ Note, that these points were only brought up by a small number of stakeholders and were not discussed or explored in interviews or the survey. Therefore, we are unable to state whether this point is widely held across sector cohorts, or whether there were other stakeholders with different views.

- i. The grants landscape is very complex – there are too many programs, and this is too difficult to engage with.
- ii. It is difficult to understand where to obtain funds, and navigation of the grants landscape is an additional cost in research development and commercialisation.

Divergent views

There were no specific divergent views raised about this point.

Relevance to the MRFF

While stakeholders discussed the medical research development and commercialisation grant landscape in broad terms, the MRFF (and the MRFF initiatives) is a funding scheme that fits within the landscape of grants available for research and commercialisation.

Suggestions from the sector

As a way of streamlining programs and increasing cohesiveness between the Australian Government's and state/territory governments' funding streams, a stakeholder pointed to Australia's Renewable Energy Target scheme as a way for providing an overarching framework for funding renewable energy projects by allowing organisations and funders to align themselves along the value chain to reaching the target.

The Australian Renewable Energy Agency (ARENA) was noted as a mechanism for states and territories to invest in progressing projects that fall within the Scheme but are relevant to the priorities of their jurisdiction. It was suggested that elements of this Scheme could be relevant to providing a more coherent funding framework for the development and commercialisation of medical research in Australia.

A SME suggested that all grants across all levels of government should be centralised in order to remove the need for monitoring multiple websites.

B - Changes in funding programs creates uncertainty

Stakeholders across the sectors pointed to instability and uncertainty resulting from changes to funding programs. Specifically:

- i. Due to the long time it takes to develop and commercialise medical research, it is important for that organisations have predictable support, understanding its availability and nature.
- ii. Stopping, starting and changing programs creates uncertainty in the revenue streams of organisations involved in the development and commercialisation of medical research.
- iii. Government cuts and changes, including R&D Tax Incentive changes, were identified as creating uncertainty and placing fiscal pressure on medical research development and commercialisation.

Divergent views

There were no specific divergent views raised about this point.

Relevance to the MRFF

The stakeholders were referring to a number of programs, and particularly to changes to the R&D Tax Incentive. However, their commentary also referred to the MRFF, particularly changes to initiatives over time. In terms of the MRFF MRC initiative's programs, it was pointed out that the communication and transparency of these initiatives – i.e. who was awarded funding, the status of funding rounds and money available - was welcome.

C – MRFF funding needs to be deeper and more targeted

There were many stakeholders, particularly those with more of an industry focus, who believed that in order to maximise the outcomes achieved, then funding needed to be deeper and more targeted. Specifically:

- i. Funding is spread very thin. There are small amounts of funding across too many initiatives.
- ii. There are many MRFF programs. Within some MRFF programs, there are ideas/research being funded that should not be funded (as it is likely to eventually fail). Rather than meeting a quota of funding x programs for \$1 million, it may be better to identify the "winners", and then to fund these with \$2 million to \$3 million if funds permit.
- iii. The areas of medical research being considered as part of the MRFF is too broad.
- iv. In order to have a real impact, investment should be made in specific areas where Australia is strong, rather than taking a scatter gun approach – i.e. there needs to be larger amounts of money for a smaller number of projects.

Divergent views

Some stakeholders (particularly those closer to research) believed that funding is already too targeted and is potentially providing unnecessary constraints on the research that is developed and commercialised. Specifically, they emphasised:

- i. Funding is already too targeted and is potentially limiting access to opportunities that could reap the greatest reward.
- ii. The big opportunities on the horizon are interdisciplinary and broad and would not fit into a targeted funding approach.

Relevance to the MRFF

There is significant division in these views. All stakeholders shared the view that the MRFF funds need to be used in a way that results in the best outcome. However, opinions on how this is achieved varied enormously by stakeholder.

D - Funding criteria needs to focus more on factors that are directly related to the probable success of the application for commercialisation

There were several stakeholders (mostly industry based) who believed that the funding criteria needs to focus more tightly on factors directly related to the probable success of the application for commercialisation. Specific points raised include:

- i. Criteria for funding of medical research needs to be based on medical need and evidence, and the ability of the researcher to take the research to the next step.
- ii. Other factors – such as gender and geography – come into play when funding the commercialisation of medical research.

Divergent views

There were some stakeholders (industry and private investor based) who agreed that funding for medical research commercialisation needs to be directed to good science where there was unmet medical need. However, they also believed that government funding could support factors that were within the public interest, such as gender diversity.

Relevance to the MRFF

While some of the stakeholders referred to medical research and commercialisation funding programs generally, most of their commentary was referring to MRFF funding programs, including MRC initiative programs.

E - Insufficient industry representation on expert advisory and selection panels

There were many stakeholders (mostly industry based) who believed that there was insufficient industry representation on expert advisory and selection panels, and that this was potentially biasing funding priorities and decisions. Specific points raised include:

- i. MRFF expert advisory panels consist mostly of academics. This is perceived as biasing funding priorities.
- ii. Panels for evaluating grants are mostly comprised of academics with limited input from industry, therefore funding decisions are potentially biased towards academics.
- iii. MRFF Mission Expert Advisory Committees often have a single industry representative. This lone voice is seen as insufficient for effective industry engagement of the Mission at the outset.

Divergent views

No divergent views were provided by stakeholders.⁹⁸

Relevance to the MRFF

While some of the commentary referred to medical research and commercialisation expert advisory and selection panels generally, most of the commentary was referring to the MRFF expert advisory committees, MRFF funding selection panels, and the MRFF Australian Medical Research Advisory Board itself.

F –Government may be inadvertently funding initiatives that will never succeed

Some stakeholders (mostly government and industry) pointed to the fact that government may be funding research that will never succeed, and that funding programs often provide a disincentive to researchers to do the “killer experiment.” A specific point raised was:

- i. The structure of research grant programs and the size of funds are a disincentive to a “fast fail.” There is no incentive for researchers to ascertain quickly that their research does not work/has no future, which is key to successful commercialisation.

Divergent views

This stakeholder view was referring to translational research. Most stakeholders (including stakeholders involved in industry, government and research) acknowledged the need for blue sky research. While there were no views raised that disagreed with this statement, there are likely to be some stakeholders (particularly stakeholders that are more involved in research) who would provide a different emphasis on this statement.

Relevance to the MRFF

This stakeholder view is directed more to government funding for research, which includes MRFF programs. It has some, but relatively low, relevance to MRFF MRC initiative programs.

⁹⁸ Note, that these points were raised by a number of mostly industry-based stakeholders. The point was not expressly discussed or explored in interviews or the survey. Therefore, we are unable to state whether this point is widely held across sector cohorts, or whether there were other stakeholders with different views.

G – It is perceived that there is a lack of transparency in health and medical research funding in Australia

Many stakeholders from industry and research commercialisation stated the distribution of funding for medical research was not transparent and noted receiving insufficient and unclear feedback on the reasons for not receiving funding for a particular grant. Specific points raised include:

- i. Industry needs to understand decisions, so they can learn how to do better applications. The reasons for not receiving funding are not always clear.
- ii. Funding directions and decisions are not transparent.

Divergent views

Stakeholders that were involved in these programs, for example were on a selection panel or an expert advisory committee, were less likely to state there was a lack of transparency in the funding process, and in most cases would disagree this is the case.

Relevance to the MRFF

This stakeholder view is directed to government funding programs generally, and to the MRFF. Some stakeholders noted that the MRFF MRC initiative's programs do provide clear feedback to applicants.

2.2 Research Question 2 – Impact of MRFF initiatives

What are the sector's views regarding the impact of MRFF initiatives to improve the capability and capacity of the medical research and innovation sector to commercialise research outputs, and any perceived gaps?

An overview of the key themes representing the sector's views as they relate to this research question is provided in Table 8. The themes are further described in the subsequent sections.

Table 8: Research Question 2 - Key themes

Research Question 2: What are the sector's views regarding the impact of MRFF initiatives to improve the capability and capacity of the medical research and innovation sector to commercialise research outputs, and any perceived gaps?
Contextual factors relevant to the impact of MRFF initiatives to improving the capability and capacity of the medical research and innovation sector to commercialise research outputs
A. The medical research commercialisation ecosystem has improved in the last 5 - 10 years, and government initiatives have contributed to this.
The impact of MRFF initiatives on capacity and capability of the medical research sector to commercialise research outputs
A. There are more funds in the system to support commercialisation.
B. There is increased engagement between industry and researchers.
C. Actual programs and initiatives themselves are seen as positive and are filling a needed gap, particularly the Biomedical Translation Bridge and BioMedTech Horizons programs and also more recently the REDI program.
D. There have been improvements in clinical trial infrastructure.
Perceived gaps that could potentially increase the impact of MRFF initiatives on capacity and capability
A. Education / awareness amongst researchers of commercialisation.
B. Deep commercialisation expertise is still limited.
C. There are limitations with clinical development and trial capability to be overcome.
D. There are limitations with access to research infrastructure.
E. There is a need for more local manufacturing capability.
Broader systemic factors that impact the capacity and capability of the medical research sector to commercialise research outputs
A. Perverse incentives affecting academic researchers to engage with industry and to seek to commercialise / translate research.

2.2.1 Contextual factors relevant to the impact of MRFF initiatives

A – The medical research commercialisation ecosystem has improved in the last 5 - 10 years, and government initiatives have contributed to this

Most stakeholders agreed that the medical research commercialisation ecosystem had improved over the last 5 to 10 years. Specific points raised include:

- i. The medical research commercialisation ecosystem has been improving over the last 5 to 10 years.
- ii. The system was improving anyway – particularly on the back of investment by state/territory governments, earlier Australian Government initiatives and the success of companies such as CSL, ResMed and Cochlear. However, government initiatives (including the MRFF) have contributed to this.
- iii. Improvements in the ecosystem vary across the country, with the ecosystems in the Eastern states (particularly Victoria and Queensland) seen as more active, while other parts of the country reported they felt their ecosystems were behind the “A game”.
- iv. The participants within the ecosystem have become more mature and sophisticated.
- v. There is access to capability that was previously hard to access (e.g. access to clinical trial capability).
- vi. Broader technological change was also noted as contributing to changes in the ecosystem. For example, social media has allowed the community to gain visibility and to look for opportunities to expand professional networks and potential development partners.

Divergent views

There were a small number of stakeholders (mostly from within industry) who agreed that the ecosystem had improved but not significantly, or that the ecosystem had improved but government initiatives were not a major contributor.

Some stakeholders, especially from industry (including SMEs), said that there has been no improvement in the medical research commercialisation ecosystem, and there was a failure to deliver real commercial outcomes and that there was less appetite for risk.

Relevance to the MRFF

This stakeholder view is directed to government funding programs generally, which includes the MRFF.

2.2.2 Impact of MRFF initiatives on capacity and capability of the medical research sector to commercialise research outputs

A – There are more funds in the system to support commercialisation

Most stakeholders stated there are more funds in the system now to support commercialisation than was the case in the past. It was also noted that there has been an increased appreciation for medical research in recent years. Specific points raised include:

- i. There are more funds for medical research commercialisation now than there has been in the past.
- ii. The emphasis of government funding in recent years has shifted from research to more support for translation and commercialisation.
- iii. In the last 5 to 8 years, there has been an increased appreciation for medical research.

- iv. The MRFF is seen as a major contributor of funds to support commercialisation in the last few years. Increased funding from state governments, university seed funds and venture capital (including the MRCF) were also noted.

Divergent views

There were no specific divergent views raised about this point.

Relevance to the MRFF

This statement is directed to funding in general, but the MRFF was widely acknowledged as injecting further funding for the purposes of medical research commercialisation.

B – There is increased engagement between industry and researchers

Most stakeholders acknowledged that there has been increasing engagement between industry and researchers in recent years, and that government funding and programs (particularly the MRFF) have contributed to this change. Specific points raised include:

- i. There is increased engagement between medical research institutes and universities with industry.
- ii. The MRFF has stimulated TTOs and venture funds to engage more with researchers to seek research to commercialise. This has contributed to raising interest, understanding and engagement in translation and commercialisation.
- iii. While new, the MRFF REDI program is widely seen as potentially having some impact in addressing this issue. However, it has been noted that it can be difficult to implement these programs effectively on scale.

Divergent views

While most stakeholders acknowledged there was increased engagement between industry and researchers. Both industry and university stakeholders described their counterparts as being reluctant to collaborate. SMEs described the challenges recruiting academics for their projects and one university explained that there are no incentives for industry to collaborate.

Suggestions from the sector

Stakeholders (usually those involved in a particular initiative or a program) have identified specific programs and initiatives (outside the MRFF) that have contributed to increased engagement between industry and researchers and have pointed to these examples of programs that work to increase engagement between researchers and industry. These programs include:

- i. Other programs run from universities, such as the Queensland University of Technology's Bridge Program and Curtin University's Ignition Program, better equip researchers to engage more effectively with industry.
- ii. Collaborative grant requirements, such as those in Cooperative Research Centres grants, which bring research into industry.
- iii. Industry peak bodies have been active in initiatives for improving networking, including conferences.
- iv. Colocation of medical research institutes with major teaching hospitals and the establishment of precincts improve engagement between researchers and industry and are important for progressing the translation and commercialisation of medical research.

A medical research institute suggested there is a need for start-up environments to be collocated with health precincts.

Relevance to the MRFF

Stakeholders have acknowledged the way that the MRFF has contributed to increased engagement between research and industry.

C – Actual programs and initiatives themselves are seen as positive and are filling a needed gap, particularly the Biomedical Translation Bridge and BioMedTech Horizons programs and also more recently the REDI program

There was broad support for the MRFF MRC initiative programs and stakeholders said they have been well targeted to provide funds and support for early stage commercialisation of medical research. Specific points raised include:

- i. The programs have been instrumental in providing needed funds at the early stages of commercialisation.
- ii. The building of knowledge of commercialisation and the development of networks is important.
- iii. Mentoring is an important part of this process and it also provides commercialisation advice and experience that the grant recipient may otherwise not easily access.
- iv. These programs provide an important step to obtaining privately invested funds.
- v. Awareness of the programs, and the process of applying for these programs, is beneficial for developing an understanding and awareness of commercialising medical research.
- vi. The programs are well targeted. For example, it was noted that the BioMedTech Horizons program is more targeted at medtech and pharma enterprises and that it is a more streamlined and less onerous process compared to research grants.

Divergent views

While most stakeholders agreed on the need for these programs and initiatives, some stakeholders (usually those who would apply for these programs or government portfolio holders) noted there were some aspects of the programs that affected their overall impact. These include:

- i. The matched funding requirements of the Biomedical Translation Bridge program may be inadvertently excluding some applicants, for instance smaller universities that may not have access to funds to meet this requirement.
- ii. The awareness of these programs may still be low, particularly amongst SMEs. Some SMEs said that they have missed funding rounds because they were not aware of them.
- iii. The application processes involve an onerous level of paperwork and this is off-putting for some applicants.
- iv. There is a large gap before these initiatives are in the pipeline where no investors will provide funding, as the research is too high risk.
- v. Funding decisions are biased towards the most de-risked projects.
- vi. A couple of stakeholders (involved in investment and commercialisation) raised concerns that public companies are receiving funding for the Biomedical Translation Bridge program.

Relevance to the MRFF

These statements refer to MRFF programs, specifically the MRFF MRC initiative's programs.

D – There have been improvements in clinical trial infrastructure

It is broadly acknowledged that there have been significant improvements in clinical trial infrastructure in Australia, particularly Phase I and to a lesser extent Phase II, and that government investment (including the MRFF) has contributed to this. Specific points raised include:

- i. Phase I, and to a lesser extent Phase II, clinical trial capability in Australia is now world class.
- ii. The attractiveness of the Australian environment for conducting clinical trials is evidenced by the extent that Australian clinical trials are sponsored by international funding.

Divergent views

While most stakeholders agreed with this statement, there were views from stakeholders (mostly those involved in the development and commercialisation of medical research) about running clinical trials that impacts time and costs associated with the conduct of the trials. These are described in further detail in section 2.2.3.

Relevance to the MRFF

These statements refer to the improved clinical trial capability in Australia, and the role of government investment (including MRFF investment) in this improved capability. There are opportunities to further build capability and streamline clinical trials (see section 2.2.3) which may be of relevance to the MRFF.

2.2.3 Perceived gaps that could potentially increase the impact of MRFF initiatives on capacity and capability

A – Education / awareness amongst researchers of commercialisation

Stakeholders across the board said that while the understanding of commercialisation by medical researchers had improved, further improving researcher awareness, interest and understanding in commercialisation could result in less cost and unproductive time in progressing a medical research initiative. There are some programs aimed at addressing this issue. However, they are either limited in terms of who can access these programs, or they are seen as missing the mark. Specific points raised include:

- i. While improving, there is still a lack of awareness, engagement and contribution of academic researchers in medical research development and commercialisation.
- ii. There is a lack of education/awareness amongst researchers of the requirements for private sector funding (e.g. proof of concept data set requirements), and also where to find assistance (e.g. assistance in developing a prototype, or with conducting a safety study). This delays development and makes it more expensive.
- iii. There are mixed views as to whether education and acceleration programs for researchers hit the mark. For example, the experience of some medical research institutes is that these programs are working. However, other stakeholders said that they are improving their ability to pitch, but not skilling researchers to work with industry and develop research informed by industry's needs.
- iv. Most universities have entrepreneurship type courses as part of their programs. These are of value to understanding the mechanics of assembling a business plan and pitching a business idea but they fall short in developing the know-how of commercialisation.

- v. There are programs offered by universities to develop commercialisation skills and networks. While there is some success in these programs, they can be limited, particularly if the researcher, or supervisors of a post-graduate fails to see the value of participating in these programs.
- vi. Large medtechs and SMEs noted that there is a lack of access to information and professional advice on the TGA and medical device regulations and processes.
- vii. Some SMEs noted that they find it difficult to find suitable training for commercialisation locally, and have been seeking this training outside Australia.
- viii. Some stakeholders identified a need for more regionally delivered programs.
- ix. Some digital health SMEs have stated the need more specific support for digital health commercialisation, as they have their own unique challenges and opportunities.

Divergent views

A couple of stakeholders (researchers and a peak body) held a different view. Specifically:

- i. The extent to which researchers needed to have commercialisation expertise. Specifically, some stakeholders argued that researchers did not need to have commercialisation expertise as this was the role of TTOs.

Suggestions from the sector

A digital health SME suggested that Australia needs more opportunities for young professionals who have been trained in commercialisation, including support for hands-on training at global R&D hotspots overseas that can be applied in Australia.

Relevance to the MRFF

While these statements do not describe shortcomings of MRFF initiatives, they do provide information relevant to work by the MRFF to improve sector capacity and capability.

B – Deep commercialisation expertise is still limited

Many stakeholders across the sectors stated there were not enough people with deep commercialisation expertise for the number of companies commercialising medical research and that this was impacting time, cost and the outcomes associated with commercialising medical research. Specific points raised include:

- i. There is a very small number of people who have successfully commercialised medical research in Australia and even fewer who have done this more than once. This lack of experience (and lack of access to this experience) slows down and increases the cost of commercialisation.
- ii. There have not been enough successes in Australia, with some stakeholders stating, “Success breeds further success.”
- iii. People go overseas, and there is often little incentive for them to come back (e.g. they earn more money and have better access to opportunities overseas).
- iv. Distance adds to the problem. In particular, it is a global sector (with large pharma etc.), and it is difficult to form relationships and access the right people. This issue is felt very strongly in states such as Western Australia.
- v. We need big companies to stay here, and/or set up to create the skills in this country (e.g. Cochlear through its size and presence has played a huge role in developing skills in bionics in the sector).

Divergent views

No divergent views were provided by stakeholders.

Relevance to the MRFF

These statements do not refer directly to programs or initiatives funded by the MRFF; however, they are relevant to the capacity and capability of the sector to commercialise medical research outputs.

Suggestions from the sector

Some stakeholders (particularly those in biotech companies and investors) suggested that there was a need to have financial incentives to bring people with deep medical research commercialisation experience to Australia.

C – There are limitations with clinical development and trial capability to be overcome

While most stakeholders agreed with the statement that clinical development and trial capability has improved in Australia (see section 2.2.2), there were concerns from stakeholders (mostly those involved in the development and commercialisation of medical research) in relation to running clinical trials, especially the impacts of time and costs associated with the conduct of the trials. The main points raised were:

- i. There are problems with harmonisation of ethics approvals across states. This is time consuming and adds to costs, and delays in commencing clinical trials (particularly phase II and III).
- ii. There are problems with negotiating costs and processes with individual hospitals. They are all different and need to be negotiated with independently. This is time consuming, and adds to costs (including cost uncertainty, and delays clinical trials).
- iii. There is a lack of access to medically trained people in early clinical development, particularly people to translate late stage pharmacology and toxicity findings from late stage Phase I to Phase II.

Divergent views

No divergent views were provided by stakeholders.

Relevance to the MRFF

There are opportunities to further build capability and streamline clinical trials, which may be of relevance to the MRFF.

D – There are limitations with access to research infrastructure

Many stakeholders across the sectors, including researchers, government and industry, identified the need to access infrastructure for research and early development, with some industry stakeholders saying access to research infrastructure is very limited. Medical research institutes and medtech, biotech and pharmaceutical companies were particularly vocal about accessing research infrastructure. Specific points raised were:

- i. Investment in fundamental research infrastructure is extremely important, as is investment to keep this infrastructure up to date and leading edge, and the coordination of, and access to, this infrastructure. Examples of research infrastructure are genomic infrastructure, biobanking, and high-performance computing facilities.

- ii. Research infrastructure in Australia is fragmented and duplicated in institutional silos. Access to research infrastructure can be restricted. For example, researchers may not be able to access state funded infrastructure that exists in another state.
- iii. There may be funding to establish research infrastructure, but there may not be funding to maintain it.

Divergent views

One stakeholder from a larger biotech company said that the infrastructure for supporting medical research commercialisation is good. The stakeholder said that infrastructure was adequate for preclinical development, undertaking early stage clinical studies, and doing later stage clinical studies if part of a larger program.

Relevance to the MRFF

These points are about broader access to specialised infrastructure to support research and early stage development. They are not directly related to the MRFF, particularly the MRC initiative's programs. However, access to infrastructure does impact the development of translatable research for commercialisation.

Suggestions from the sector

One stakeholder noted that in times of economic contraction, Australia could be looking at innovative ways of better using already established infrastructure and investing in cutting edge whole-of-nation platforms under the National Collaborative Research Infrastructure Strategy (NCRIS). This stakeholder cautioned that the role of MRFF funding in the development and establishment of infrastructure needs to be coordinated with the NCRIS otherwise infrastructure will become even more fragmented.

E – There is a need for more local manufacturing capability

Most stakeholders across the sectors highlighted access to local manufacturing capability as a key gap that affects costs and the time to commercialise medical research. Some stakeholders also said that poor access to manufacturing is causing technology to move offshore at an earlier stage than it needs to. Specific points raised were:

- i. There is a lack of onshore manufacturing capability. As a result, companies need to go offshore in order to manufacture their product (whether it is a biological or new chemical entity, and in some cases for devices).
- ii. The market is very thin in Australia. Therefore, where there is manufacturing capability here, the costs of using it are very high, compared to other countries (such as the United States), or they have an academic focus and don't support the development of technologies to commercial requirements on a commercial timescale.

Divergent views

There were no specific divergent views raised about this point.

Relevance to the MRFF

These points are about broader access to infrastructure and support to develop and commercialise medical research. They are not directly related to the MRFF. However, they do have an impact on the commercialisation of medical research, and potentially to the broader objectives of the MRFF, which includes building the economy.

2.2.4 Broader systemic factors that impact the capacity and capability of the medical research sector to commercialise research outputs

A – Perverse incentives affecting academic researchers to engage with industry and to seek to commercialise / translate research

Most stakeholders across the sectors stated that incentives within the university system act to discourage researchers to actively engage with industry and to commercialise/translate medical research. Specific points raised were:

- i. Academic incentives (and government funding) do not drive good medical research that can be translated/commercialised. Researchers in a university environment are rewarded based on factors such as their publication record, rather than track record in commercialisation. It is suggested this is slowly changing.
- ii. Research funding goes to researchers with a research track record, including publishing their research. (Note, NHMRC is now considering an applicant's research impact to date when awarding funding for some of their programs).
- iii. In Australia, it is very difficult to move between academia and industry, and to bring commercial experience back into the university system.

Divergent views

Most stakeholders were in broad agreement that this situation exists. There were minor differences in view (particularly by those more involved in universities) as to the extent that researchers need to understand and engage in industry, and the extent to which this situation impacts the commercialisation of medical research.

Relevance to the MRFF

These points refer to broader systemic issues that are contextually relevant to the MRFF's objectives in respect to the commercialisation of medical research.

2.3 Research Question 3 – Positioning of institutions to maximise opportunities

What are the sector's views regarding how institutions have positioned themselves to maximise commercialisation opportunities?

An overview of the key themes representing the sector's views as they relate to this research question is provided in Table 9. The themes are further described in the subsequent sections.

Table 9: Research Question 3 - Key themes

Research Question 3: How have institutions positioned themselves to maximise commercialisation opportunities?
The steps institutions have taken to position themselves to maximise commercialisation opportunities
<p>A. Institutions have taken steps to position themselves to maximise commercialisation opportunities.</p> <ul style="list-style-type: none">i. Actively creating partnerships with industry and clinicians, and COVID-19 has accelerated this.ii. Established a drug discovery unit to facilitate the translation of small molecules into commercial products.iii. Creating forums between industry and researchers.iv. Establishment of university seed funds to develop early stage medical research.v. Shifting focus to fund researchers to focus on IP commercialisation.
Factors contributing to the success of a technology transfer office (TTO)
<p>A. The ability of a TTO to be successful is affected by a number of factors.</p> <ul style="list-style-type: none">i. The commitment of the university to commercialisation.ii. Access to adequate and consistent funding.iii. The skills and experience of commercialisation and legal officers in the TTOs.iv. The attractiveness of the commercialisation position within a TTO.v. Ability of the TTO to cover the vast scope of research within a university.
Initiatives underway to improve the capacity and capability of TTOs
<p>A. There are initiatives underway to improve the capacity and capability of TTOs.</p> <ul style="list-style-type: none">i. Governance.ii. Control over budgets.iii. Improving the skills and capabilities of commercialisation officers in the TTOs.

2.3.1 Steps institutions have taken to position themselves to maximise commercialisation opportunities

A – Institutions have taken steps to position themselves to maximise commercialisation opportunities

Stakeholders (particularly TTOs) reported that they were taking steps to position themselves to maximise commercialisation opportunities. However, the extent they do this can be affected by individuals within the organisation, external factors, and financial resources. Examples are as follows:

- i. Actively creating partnerships with industry and clinicians, and COVID-19 has accelerated this.
- ii. Establishment of a drug discovery unit to facilitate the translation of small molecules into commercial products.
- iii. Creating forums between industry and researchers.
- iv. Establishment of university seed funds to develop early stage medical research.
- v. Shifting focus to fund researchers to focus on IP commercialisation.

Divergent views

Not applicable.

Relevance to the MRFF

These examples are initiatives that are independent of the MRFF.

2.3.2 Factors contributing to the success of a technology transfer office (TTO)

A – The ability of a TTO to be successful is affected by a number of factors

Stakeholders (both within and external to TTOs) reported a number of factors that affected the relative performance of a TTO in commercialising medical research. The points raised are as follows:

- i. The commitment of the university to commercialisation: Stakeholders reported that a university's commitment to commercialisation can vary and be changeable, both in terms of resourcing and the place of technology transfer within the organisation. Commitment to technology transfer is often dependent on the priorities of the Vice Chancellor at the time.
- ii. Access to adequate and consistent funding: Development of relationships and putting in place plans and programs requires a commitment to resourcing over time. The effectiveness of TTOs is greatly enhanced with adequate funding and resourcing.
- iii. The skills and experience of commercialisation and legal officers in the TTOs: Most stakeholders said that the skills and experience of the commercialisation officers within the TTOs was a significant factor contributing to the success of the TTO. However, apart from some notable exceptions, staff in many TTOs lacked commercialisation experience and skills relevant to commercialising medical research. It was also noted that legal departments within universities were often not equipped with the skills and experience for commercialising medical research.
- iv. The attractiveness of the commercialisation officer position within a TTO: Some stakeholders said TTOs are generally under-resourced and the officers are underpaid. As

an example, a stakeholder noted that a job for 10 people will have 2 people doing the work. Commercialisation officers in a TTO are reportedly paid less than industry peers. Stakeholders noted many TTOs experienced a high turnover of staff.

- v. Ability of the TTO to cover the vast scope of research within a university: A key challenge for a TTO is its ability to cover the vast scope of research within a university, particularly when the TTO is very small. A larger TTO is at an advantage of being able to engage with researchers and their research. However, there are some smaller TTOs that have developed approaches to overcome shortcomings associated with their size, including building capability and empowering researchers, so that researchers can more effectively articulate commercial opportunities for their research.

Divergent views

Most stakeholders would support the above points, with most seeing the skills and experience of the people in the TTOs being a critical success factor. Stakeholders may have slightly different views on the extent that the above points affects the relative success of a TTO, and this is largely dependent on whether the stakeholder has worked in a TTO and the size of the TTO they worked within.

Relevance to the MRFF

These points refer to broader factors that are contextually relevant to the MRFF's objectives in respect to the commercialisation of medical research.

Suggestions from the sector

Some stakeholders have suggested the government can have a role in providing funding for TTOs. They pointed to the United Kingdom as an example where the government directly funds commercialisation and translation activities based on performance metrics.

2.3.3 Initiatives underway to improve the capacity and capability of TTOs

A – There are initiatives underway to improve the capacity and capability of TTOs

Stakeholders (largely those who work within TTOs or are a professional body) describe actions they have taken (or are taking) to improve the capacity and capability of TTOs. Specifically:

- i. Governance: TTOs discussed the need for stability within the structure of the university and the need for oversight from a board or a committee with an understanding of commercialisation and early stage tech ventures. One university appointed a Commercialisation Advisory Board. This board provides high level strategic advice on the university's technology commercialisation program and makes recommendations on investments from the university's pre-seed and follow-on funds. The Board includes external expertise in areas such as commercialisation and early stage tech ventures, so members bring specific experience and capabilities in these areas to the decision making. The Finance Committee continues to have responsibility and oversight in monitoring the university's activities with respect to the commercialisation of its intellectual property. However, through the establishment of a Commercialisation Advisory Board, it has provided the university with the processes and expertise that enables the Finance Committee and the Council with a level of comfort that there is governance in place, while at the same time providing the TTO with the space and stability to work effectively within the university and provides them with access to specialised expertise and experience.
- ii. Control over budgets: A couple of TTOs discussed the importance of accessing funding and having control over their budgets in order to fulfil their role. One TTO described a situation

where their commercialisation staff were partly funded by the university's faculties, and then a decision was made that staff would be fully funded by the TTO. They described that this change enabled them having the freedom to commercialise the best research rather than being encumbered with specific interests of faculties.

- iii. Improving the skills and capabilities of commercialisation officers in the TTOs: There are a number of initiatives underway within the sector to improve the skills and capabilities of commercialisation officers through activities such as networking, skill building, training, and through developing credentials for commercialisation officers through professional certification. The intent is for this skill building and accreditation to raise the capability standard of all professionals, but also to provide a career path and raise respect in the profession.

Divergent views

Not applicable

Relevance to the MRFF

These points are outside the scope of the MRFF at this time; however, are contextually relevant to the MRFF's objectives in respect to the commercialisation of medical research.

2.4 Research Question 4 – Other barriers to commercialisation of research outputs

What are the sector's views regarding other barriers to commercialisation of research outputs in Australia?

An overview of the key themes representing the sector's views as they relate to this research question is provided in Table 10. The themes are further described in the subsequent sections.

Table 10: Research Question 4 - Key themes

Research Question 4: What are the sector's views regarding other barriers to commercialisation of research outputs in Australia?
Other contextual factors relating to commercialisation of research outputs in Australia
A. Australia is commercialising research within a global market.
Other barriers relevant to the commercialisation of research outputs in Australia
A. Distance to markets and suppliers.
B. Arrangements that enable a clinical researcher to research and to translate/commercialise research outputs.
C. The proliferation of forms, tools and processes associated with commercialisation.
D. Lack of diverse role models and success stories.
E. There are some broader systemic issues that may be hampering the conduct of research and the clinical development of medical research in Australia.
Other issues affecting the commercialisation of research outputs in Australia
A. Early patenting of intellectual property in Australia.
B. Tightening university budgets may reduce their expenditure on commercialisation and/or development of research.
C. The need for a coherent vision for medical research in Australia.

2.4.1 Other contextual factors relating to commercialisation of research outputs in Australia

A – Australia is commercialising research within a global market

Many stakeholders (particularly those in government and involved in commercialisation of medical research) noted:

- i. Australia is commercialising research within a global market. This means competing with products internationally for market, funds, and resources, and also access to resources on the international stage.

Divergent views

One state government representative noted that recent developments with COVID-19 may have some effect on increasing the emphasis on further development of our local environment.

Relevance to the MRFF

This point is contextually relevant to the MRFF.

2.4.2 Other barriers relevant to the commercialisation of research outputs in Australia

A – Distance to markets and suppliers

Many stakeholders (particularly those in states not on the Eastern seaboard, and some peak bodies) noted the impact of distance on commercialisation. Specific points raised were:

- i. Medical research commercialisation occurs within a global market. However, Australia is somewhat disadvantaged as key industry players (such as pharmaceutical companies) are on the other side of the world, and there are very limited opportunities to “rub shoulders” and develop a relationship with them.
- ii. The effect of distance is experienced most acutely by smaller universities and companies in states such as Western Australia, who can feel particularly isolated compared with counterparts on the Eastern seaboard.
- iii. Internet based communication and social media platforms (such as LinkedIn), and networking events (such as those provided by AusBiotech) have been instrumental in addressing some of the effects experienced and networking technologies have been instrumental in recent years in reducing the impact of distance.

Divergent views

There were no specific divergent views raised about this point.

Relevance to the MRFF

This point is largely contextually relevant to the MRFF in its objective to translate and commercialise medical research outputs. However, it was noted that some jurisdictions have poorer access to MRFF programs, including the medical research commercialisation initiatives. For example, some people noted that MTPConnect has only recently had a representative in Western Australia.

B – Arrangements that enable a clinical researcher to research and to translate/commercialise research outputs

Some stakeholders (particularly those who work closely with researchers and those involved in commercialising research) noted barriers associated with development of research in the clinical environment and the translation and commercialisation of this research. Specific points raised were:

- i. Clinical research is important to the MRFF's objectives, as clinicians are in a strong position to identify where there is unmet clinical need and to develop and translate research so that it improves lives and contributes to health system sustainability.
- ii. Demands by hospitals for clinical researchers to do clinical work often outweighs the time they can devote to research.
- iii. There were several examples raised of how co-locating medical research institutes with major teaching hospitals, and funding clinician time through the medical research institute has in some cases supported clinical researchers to spend time on research, and provided a research infrastructure to support the clinical researcher.
- iv. Hospitals often don't have a TTO or other arrangements for progressing the commercialising of the research, therefore, this research is often not commercialised.
- v. There can be a lack of clarity around intellectual property ownership for joint appointments – i.e. clinician researchers who work for both a university or medical research institute, and a hospital.

Divergent views

No divergent views raised as part of this process.

Relevance to the MRFF

This point is contextually relevant to the MRFF in its objective to translate and commercialise medical research outputs.

C – The proliferation of forms, tools and processes associated with commercialisation

Some stakeholders (particularly those involved in medical research commercialisation) noted there was significant effort in “reinventing the wheel” in terms of using forms, undertaking processes etc. They believed there was an opportunity for standardised templates, and possibly centralised coordinated resources around commercialisation. Specific points raised include:

- i. The creation of standardised fit for purpose templates for non-disclosure agreements etc.
- ii. There is a need for a centralised, coordinated effort around commercialisation in order to improve overall capability.

Divergent views

No specific divergent views raised as part of this process.

Relevance to the MRFF

This point is contextually relevant to the MRFF in its objective to translate and commercialise medical research outputs.

D – Lack of diverse role models and success stories

While there are some strong stories and role models related to the commercialisation of medical research in Australia, a couple of stakeholders (mostly those closely involved in research and early stage commercialisation) noted:

- i. There is a need to promote further role models in order to inspire medical researchers to engage with industry and commercialise research outputs.

Divergent views

There were no specific divergent views raised about this point.

Relevance to the MRFF

This point is contextually relevant to the MRFF in its objective to translate and commercialise medical research outputs.

E – There are some broader systemic issues that may be hampering the conduct of research and the clinical development of medical research in Australia

One stakeholder (a university) described a broader systemic issue affecting the conduct and commercialisation of medical research in Australia. While this was the only example, it has been included to illustrate there may be some broader systemic issues that may be hampering the conduct of research and/or the clinical development of medical research in Australia. The example provided was:

- i. Accreditation from National Association of Testing Authorities for research labs is becoming tighter, and it is difficult to access the expertise for accrediting specialised labs.

Divergent views

No specific divergent views raised as part of this process.

Relevance to the MRFF

This point is contextually relevant to the MRFF in its objective to translate and commercialise medical research outputs.

2.4.3 Other issues affecting the commercialisation of research outputs in Australia

A – Early patenting of intellectual property in Australia

Some stakeholders (mostly involved in commercialisation of medical research) held the view that the patenting of intellectual property is undertaken too early in Australia. Specific points raised were:

- i. Researchers and TTOs in universities are under pressure to patent early in order to publish research findings, or because of KPIs.
- ii. By patenting early, the potential value of the intellectual property is eroded, as the “clock has started ticking” and there has been insufficient clinical development to demonstrate the effectiveness and value of the research.
- iii. Some grant applications, such as those for the MRFF Biomedical Translation Bridge, were noted for having a check box as to whether a patent has been filed.
- iv. A couple of stakeholders noted that this factor contributes to selling intellectual property overseas too early, and therefore losing the benefits from later development of the intellectual property.

Divergent views

There were no specific divergent views raised about this point.

Relevance to the MRFF

This point is contextually relevant to the MRFF in terms of supporting the sector to obtain value in commercialisation of medical research outputs. It may also have relevance to MRFF medical research commercialisation initiative criteria and grant applications.

B – Tightening university budgets may reduce their expenditure on commercialisation and/or development of research

A couple of stakeholders (mostly involved in the investment and commercialisation of medical research) noted:

- i. Tightening university budgets from reduced student revenue may result in some universities shutting down their commercialisation and/or reduced research capacity.

Divergent views

There were no specific divergent views raised about this point.

Relevance to the MRFF

This point is contextually relevant to the MRFF in its objective to translate and commercialise medical research outputs.

C – The need for a coherent vision for medical research in Australia

Several stakeholders across the sector noted that the vision for medical research was not as coherent as it could be, and that it will be important for the MRFF to be able to demonstrate tangible outcomes in order to continue to have broader support to operate. Specific points raised were:

- i. Innovation (and medical research) was a key priority for the Australian Government a few years ago, but the momentum seems to be lost.
- ii. There is a lack of coherence and coordination between the Australian Government and states/territories regarding medical research policy. Policies seem to compete, duplicate and sometimes undermine one another.
- iii. Both an Australian Government and state policy review is required, so that there is a united and cohesive approach to commercialisation (rather than undermining each other). There are a large number of programs with different focuses, and the Australian Government and states and territories are not aligned.
- iv. There is a need to ensure policies and programs have some continuity, i.e. 15 to 20 year development timeframe, and that there is no chopping and changing between programs.
- v. National direction and competitiveness between states is leading to duplication and issues with coordination. The impact this has on industry (including SMEs) in particular is that the funding landscape appears piecemeal and disaggregated, and there are different funding opportunities with different rules and people. One industry stakeholder said that different governments may be funding different parts of similar research but none of it appears to fit together.
- vi. There have been concerns raised that down the track, unless the MRFF actually demonstrates tangible outcomes that show its investment in medical research has resulted in impacts people expect to see, then it may lose its social licence/support.

Divergent views

Several stakeholders (mostly involved in the MRFF as a board or advisory committee member) believed the vision for medical research was coherent and clear.

Relevance to the MRFF

This point is contextually relevant to the MRFF in its objective to translate and commercialise medical research outputs, and the buy in and support of the broader community as the MRFF works towards this objective.

APPENDICES

Appendix One: Sector questionnaire quantitative data

The following pages present the quantitative findings collected through the sector questionnaire.

The questionnaire was targeted towards people who are or have been involved in:

- the research and development of medical innovations, for example as an academic, researcher or inventor
- the spin out/creation of a medical research commercialisation company
- small-medium medtech, biotech or pharmaceutical companies that undertake commercialisation of medical innovations.

There were 274 responses to the questionnaire with a completion rate of 64%.

Types of organisations that respondents are primarily based in

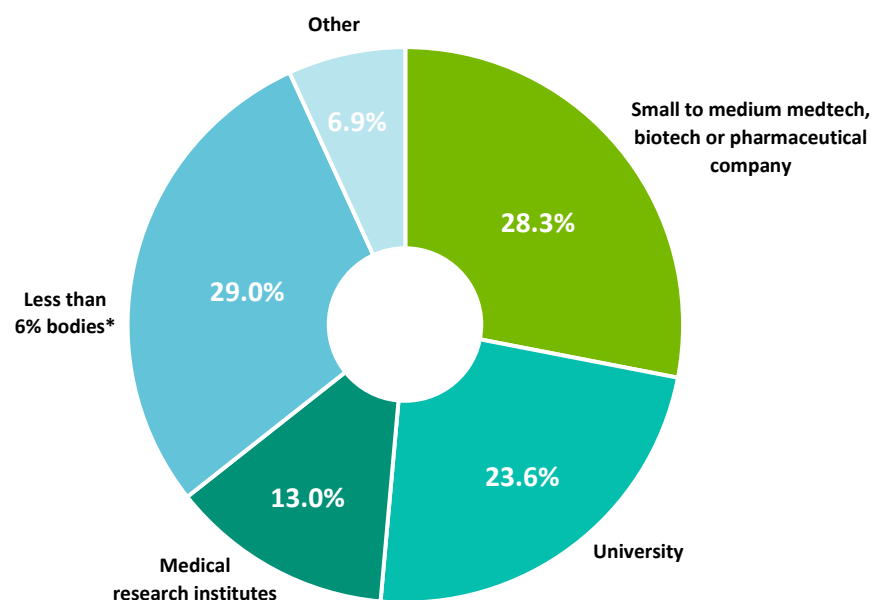
Respondents self-identified their sector in the questionnaire. 65% of the responses were from three sectors, including:

- small-medium medtech, biotech or pharmaceutical companies (28%)
- universities (24%)
- medical research institutes (13%).

The following sectors each represented less than 6% of the responses: Hospital/health care provider; Digital health company; Government; Consultant; Large medtech, biotech, or pharmaceutical company; Venture capital or investment firm; Industry peak body; Technology transfer office; Philanthropic funder.

7% of respondents identified their sector as: Other.

The following pages will present findings of all respondents, and cohort analysis for the small-medium companies, universities and medical research institutes only⁹⁹.



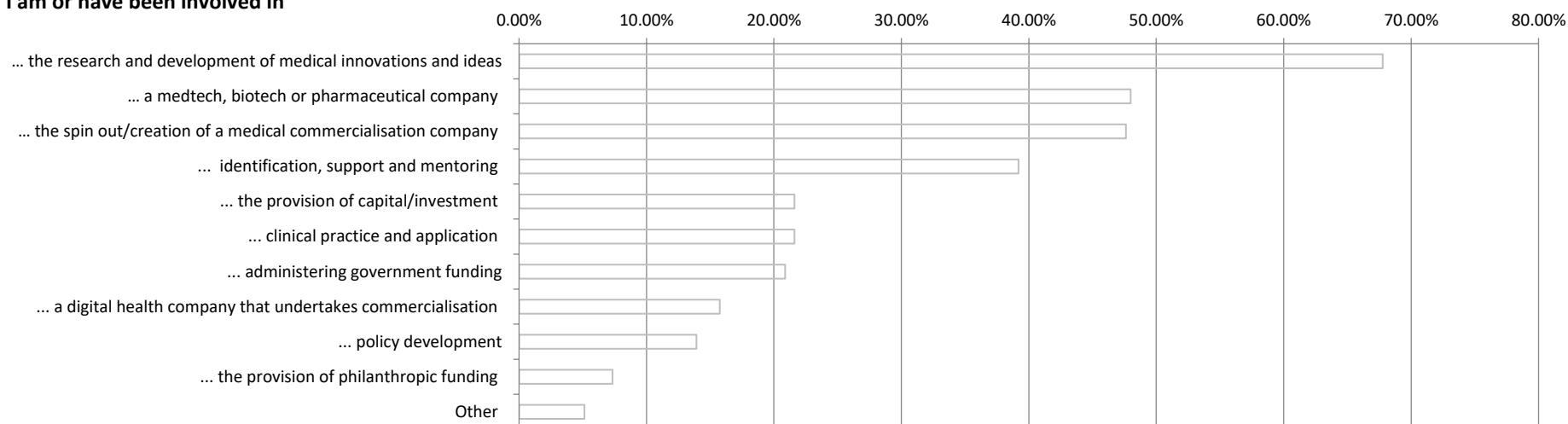
* Organisation types with responses of less than 6%

⁹⁹ There is very low representation of respondents of cohorts outside these three cohorts and are more likely to represent the views of individuals rather than the views of the respondent from that organisation type.

Experience in medical research commercialisation

Key message: The responses in the questionnaire are representative of respondents who have had experience in the research and development of medical innovations and ideas, had worked for a medtech, biotech or pharmaceutical company, and/or had experience in the spin out or creation of a medical commercialisation company.

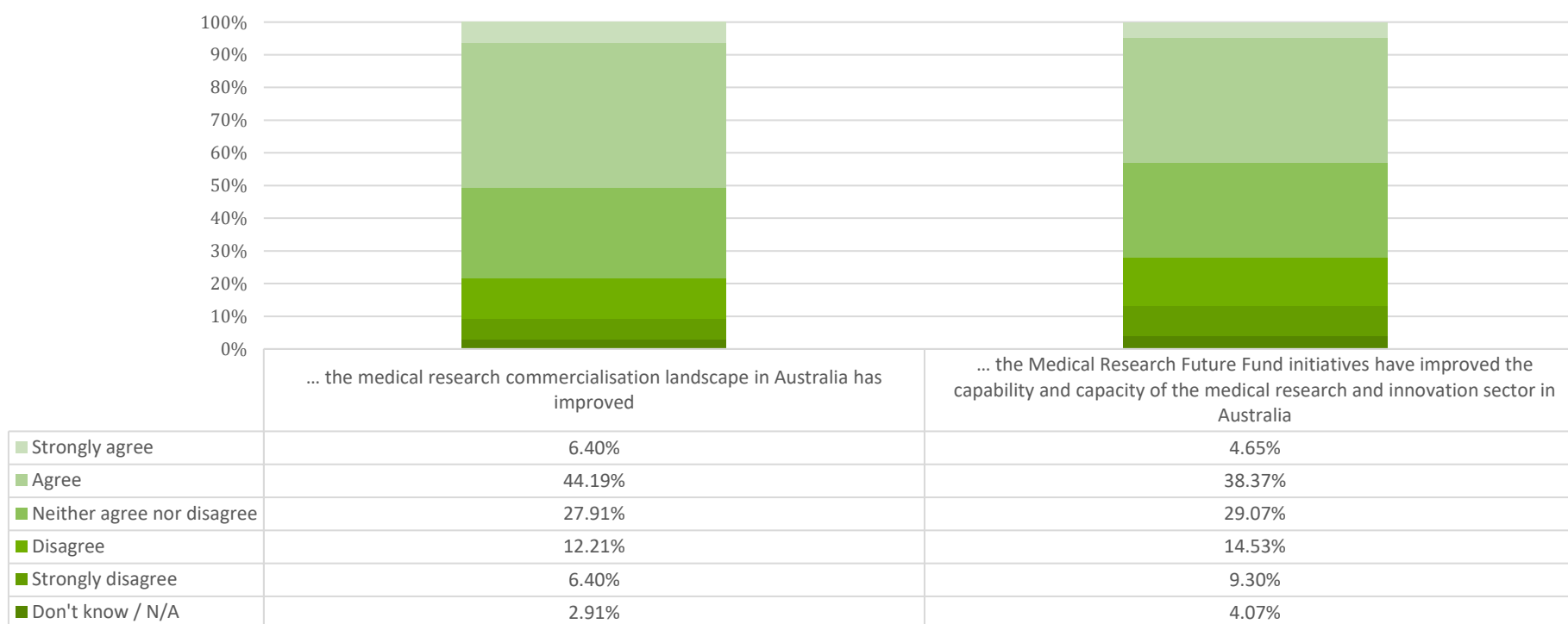
I am or have been involved in



Sector views of the medical research commercialisation landscape and the impact of the MRFF

Key message: Approximately half of the respondents believed that the medical research commercialisation landscape had improved in Australia in the five years (44.19% agree, 6.4% strongly agree), and that the MRFF had improved the capability and capacity of the medical research and innovation sector in Australia (38.37% agree, 4.65% strongly agree).

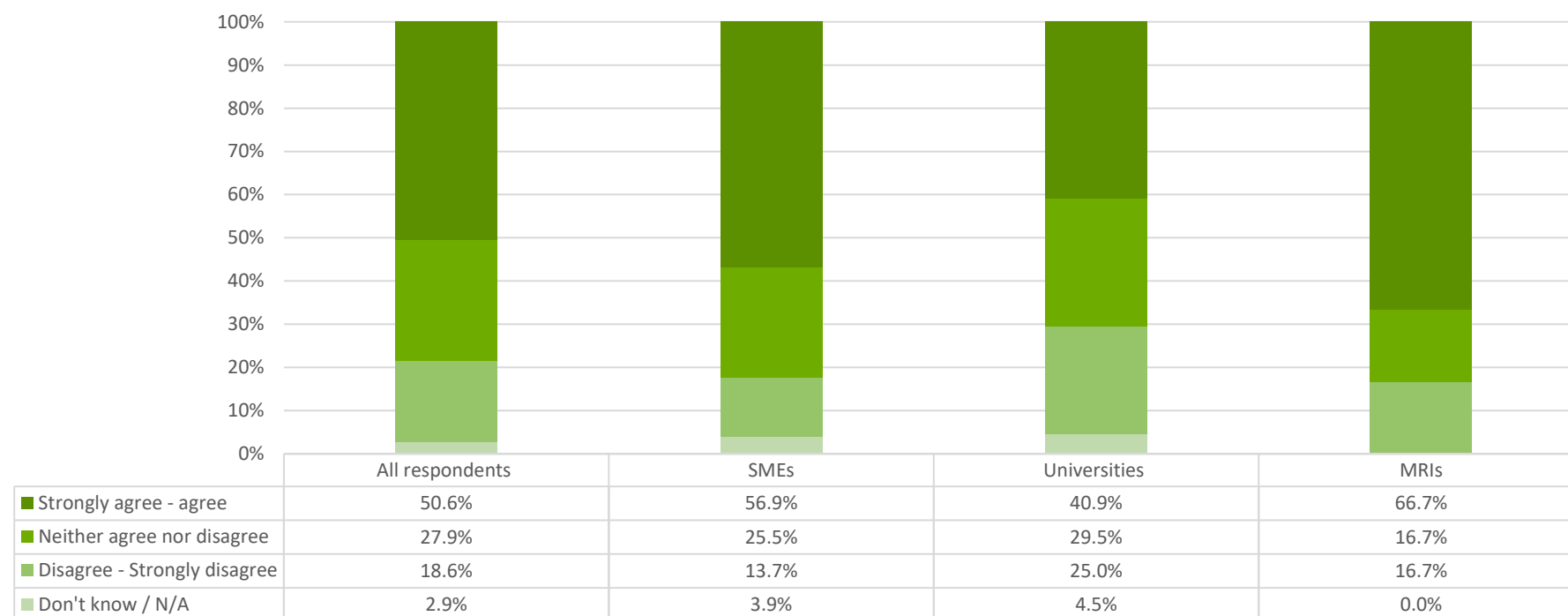
In the last five years



Cohort views of the medical research commercialisation landscape

Key message: Respondents from the medical research institute and SME cohorts were relatively more positive in their perception on improvements of the medical research commercialisation landscape. Respondents from the university cohort were relatively less positive on their perception on improvements in the landscape.

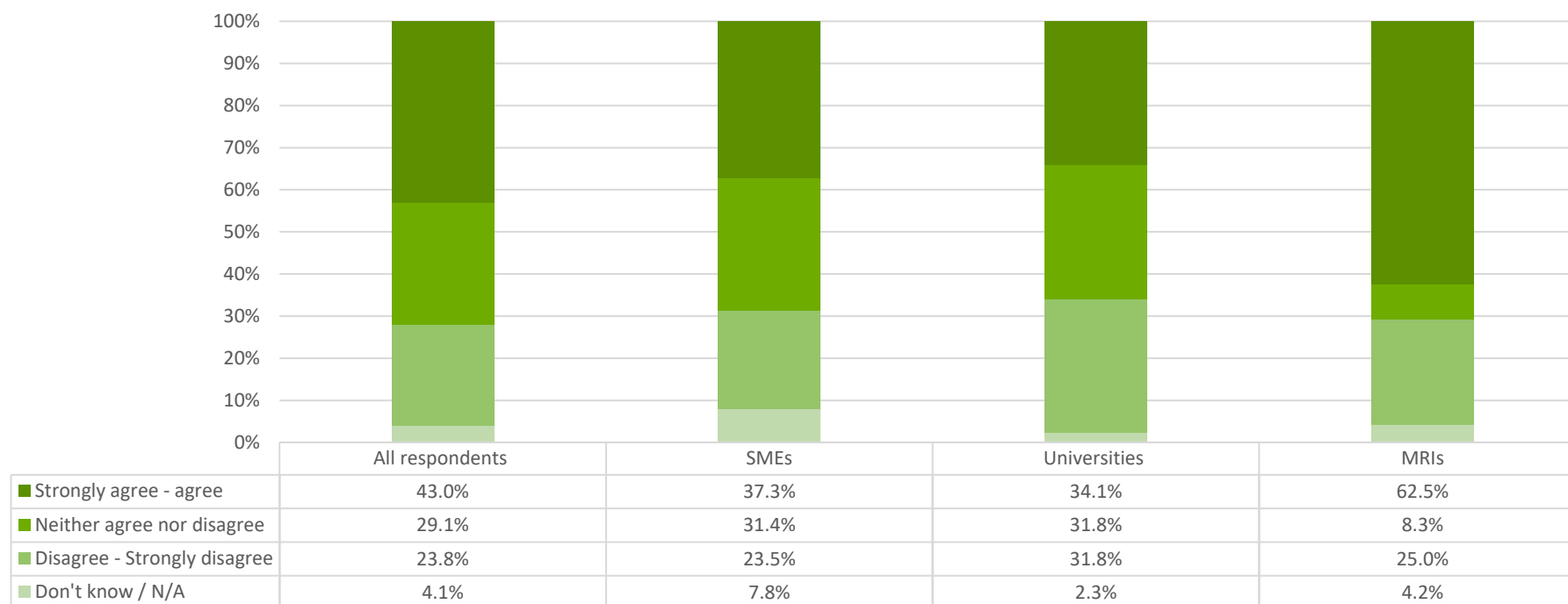
In the last five years the medical research commercialisation landscape in Australia has improved



Cohort views of the impact of the MRFF

Key message: Respondents from the medical research institute cohort were relatively more positive in their perception on the impact of the MRFF to the sector. Respondents from the university cohort were relatively less positive on their perception on the impact of the MRFF. Respondents from the SME cohort had mixed views.

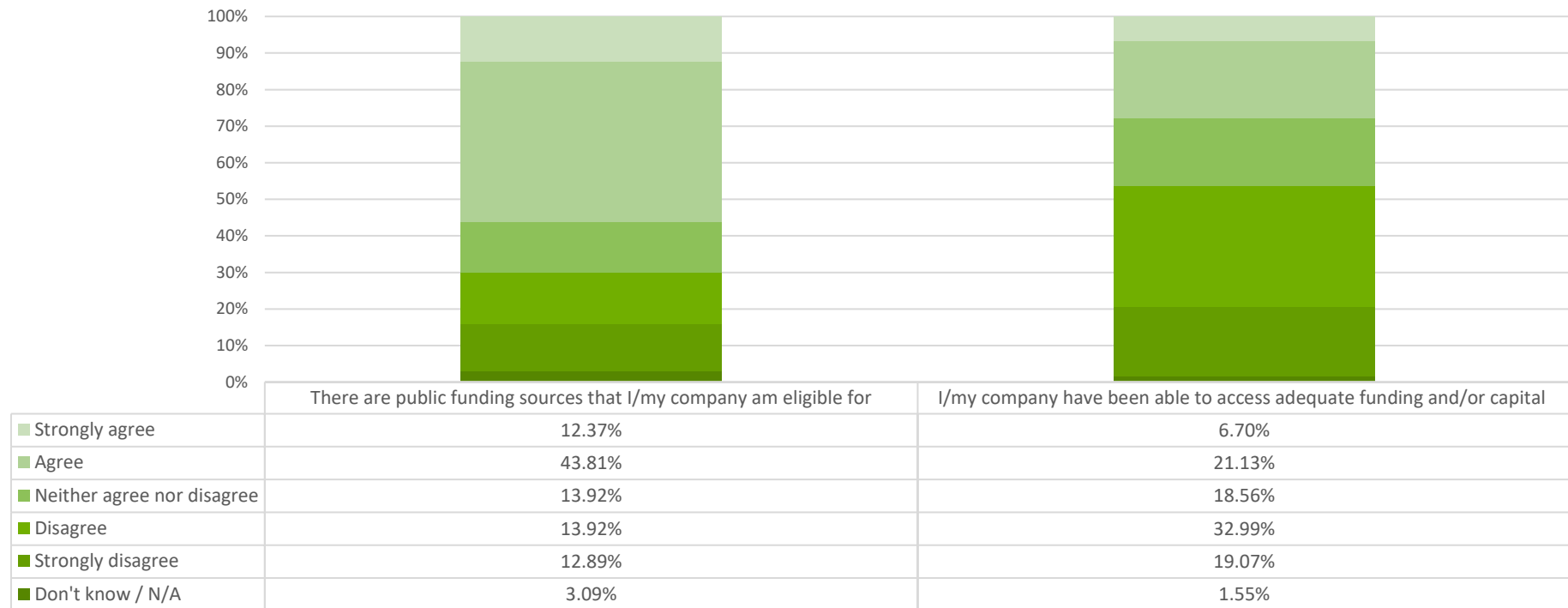
In the last five years the Medical Research Future Fund initiatives have improved the capability and capacity of the medical research and innovation sector in Australia



Access to funding and capital

Key message: The majority of respondents believed there are public funding sources that they are eligible for, however, more than half of the respondents stated they have not been able to access adequate funding and/or capital.

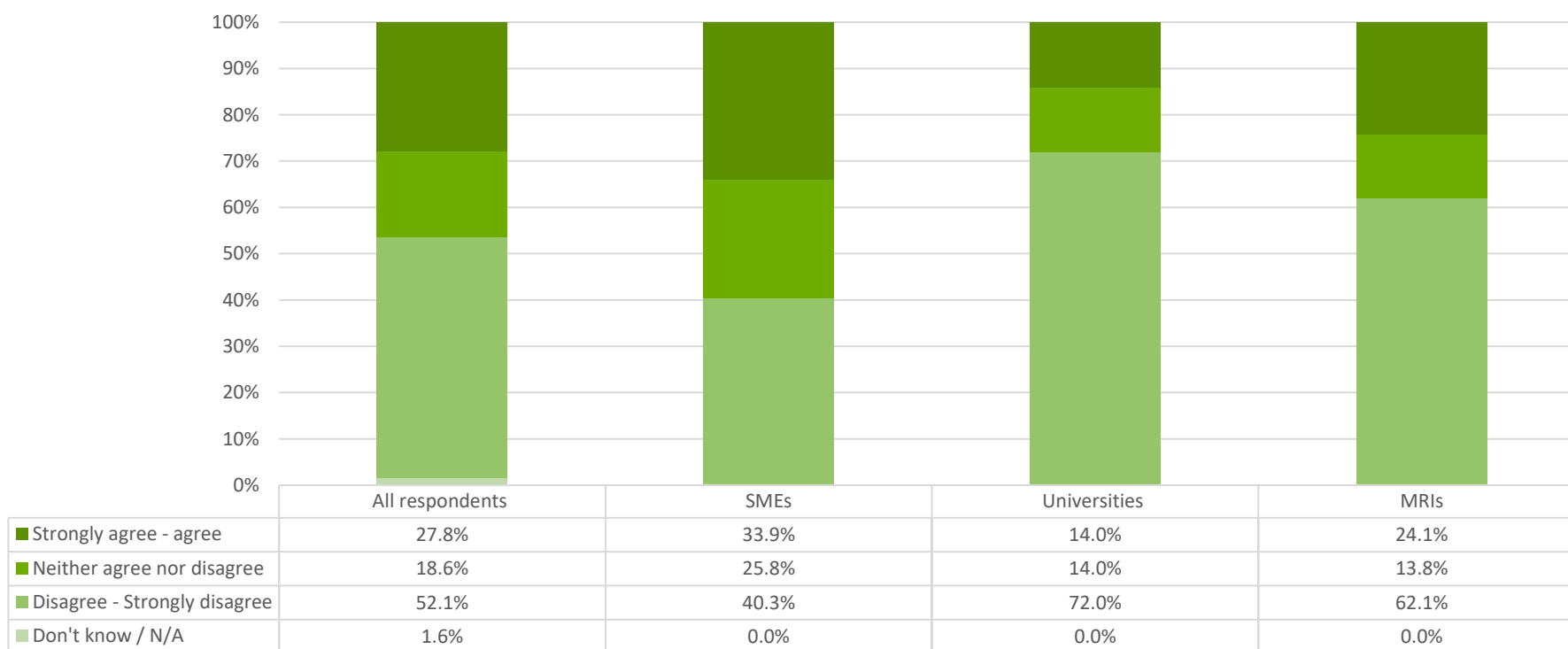
Access to funding and capital



Cohort views of access to funding and capital

Key message: Compared to responses from all respondents, respondents from the university and medical research cohorts disagreed or strongly disagreed that they had been able to access adequate funding and/or capital.

I/my company have been able to access adequate funding and/or capital



Awareness of funding initiatives

Key message: Most respondents were aware of the MRFF MRC initiative's programs and the Biomedical Translation Fund.

Awareness of funding initiatives

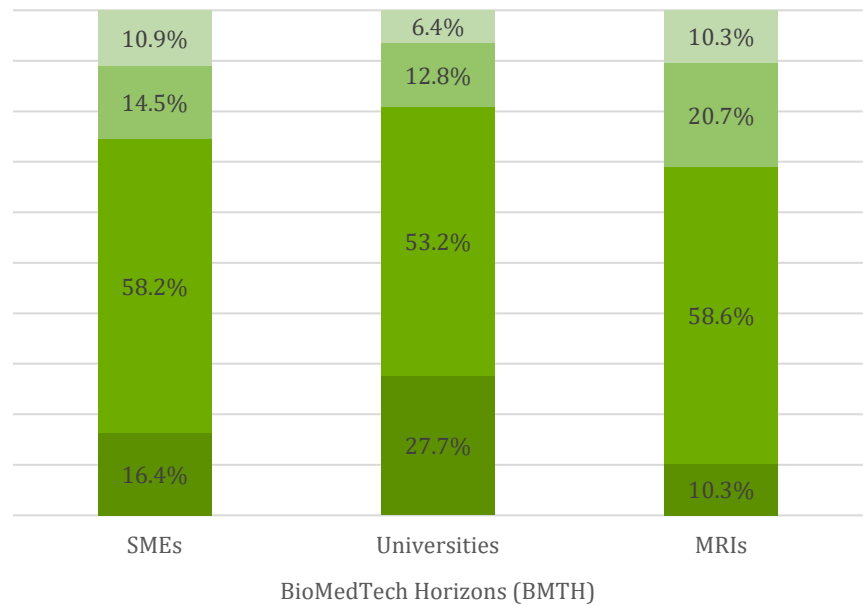


	BioMedTech Horizons (BMTH)	Biomedical Translation Bridge (BTB)	Biomedical Translation Fund (BTF)
Have applied for and were successful	7.49%	8.11%	4.30%
Have applied for but was not successful	12.83%	18.92%	8.06%
Am aware of but not applied to	59.36%	56.22%	69.35%
Am not aware	20.32%	16.76%	18.28%

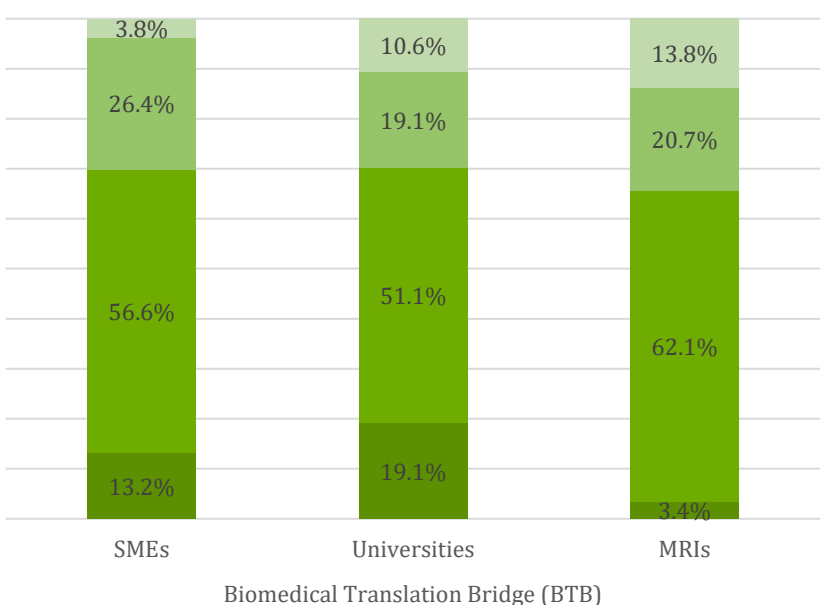
Awareness of funding initiatives by cohort

Key message: Respondents from the university cohort are relatively less aware of the BioMedTech Horizons program compared to all respondents.

BioMedTech Horizons



Biomedical Translation Bridge



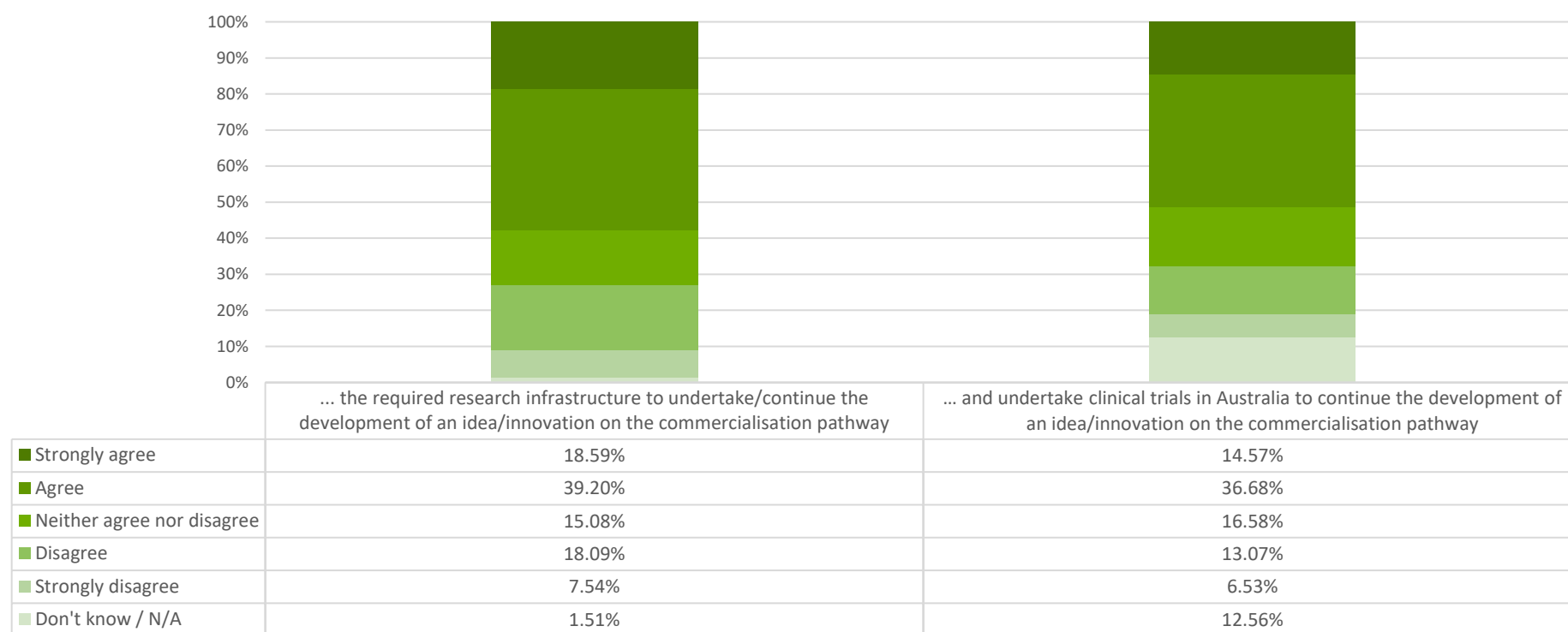
Have applied for and were successful Have applied for but was not successful
Am aware of but not applied to Am not aware

Have applied for and were successful Have applied for but was not successful
Am aware of but not applied to Am not aware

Access to research infrastructure and clinical trials

Key message: The majority of respondents (57.79%) agreed that they have been able to access the required research infrastructure to undertake/continue the development of an idea/innovation on the commercialisation pathway, and to undertake clinical trials (51.25%).

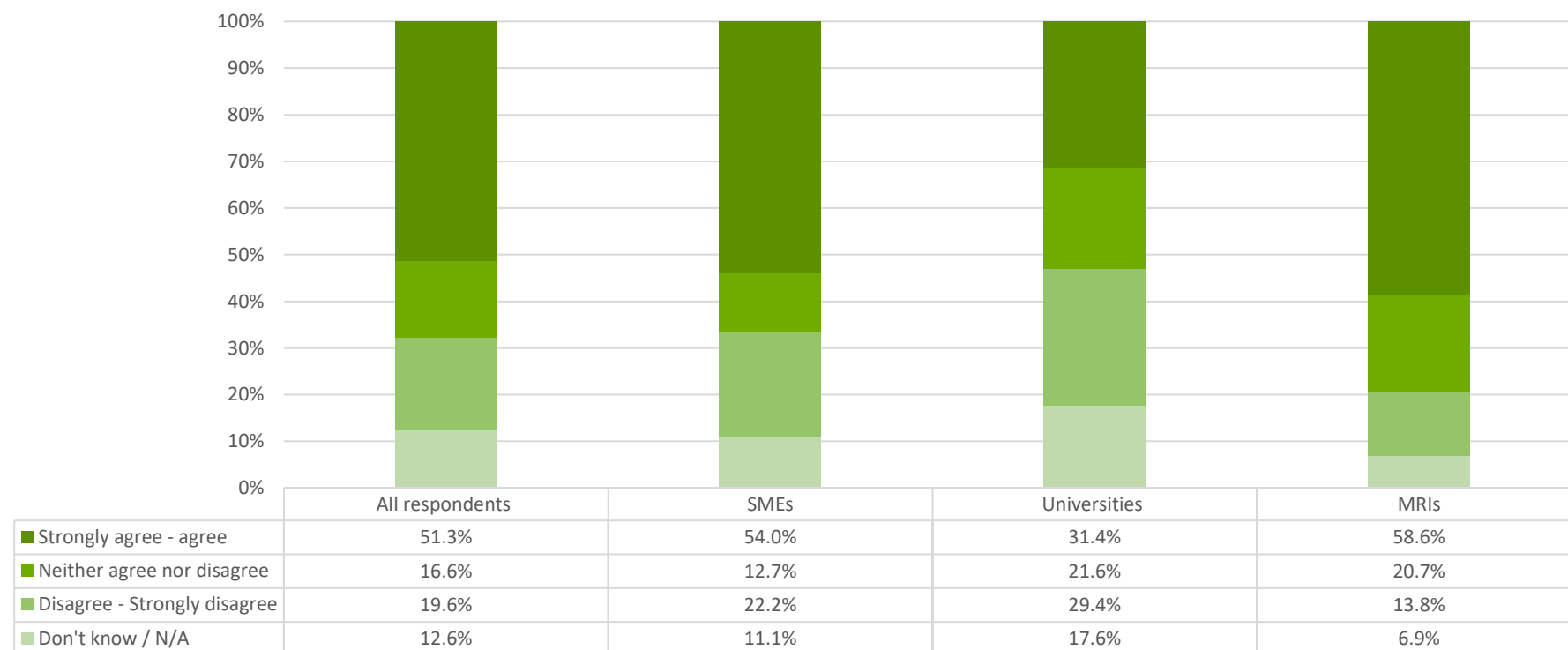
I/my company have been able to access...



Cohort views of access to clinical trials to progress medical research

Key message: Respondents from the university cohort state they are less able to access and undertake clinical trials to progress the commercialisation of medical research, compared to the responses from respondents across the sector.

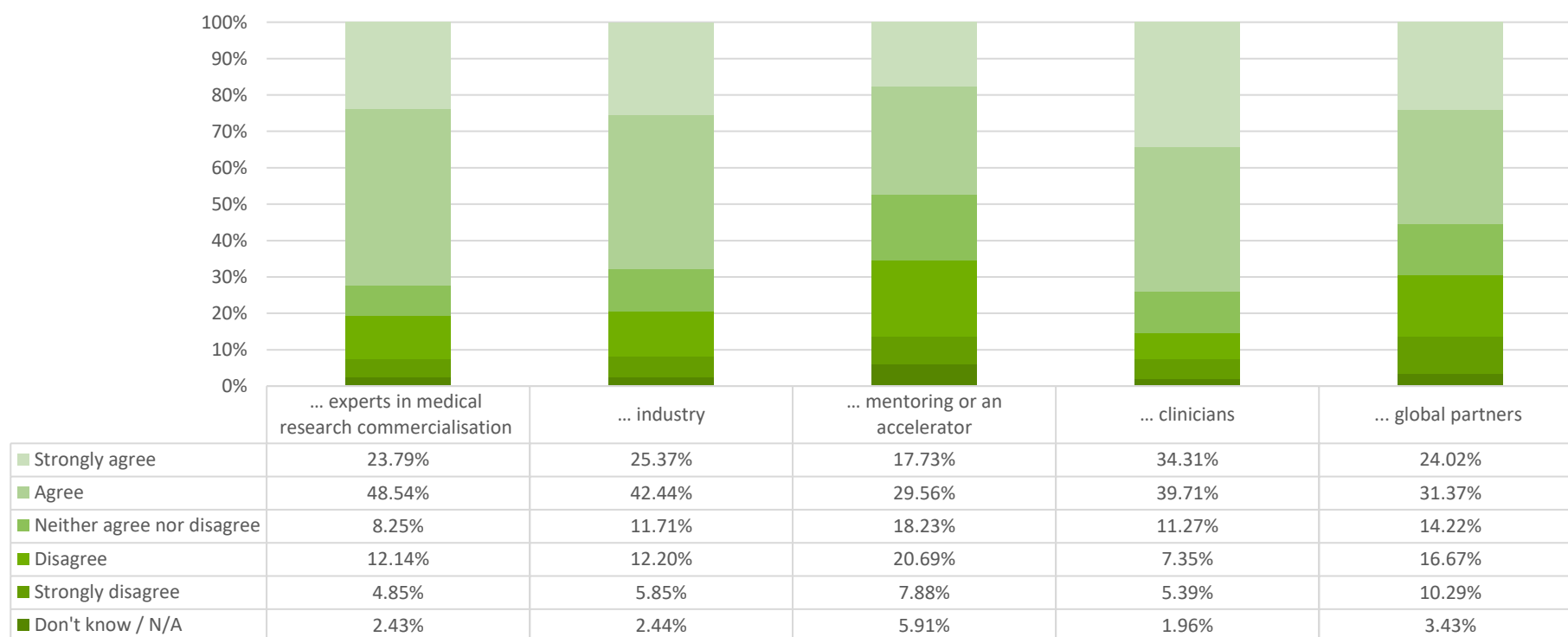
I/my company have been able to access and undertake clinical trials in Australia to continue the development of an idea/innovation on the commercialisation pathway



Collaboration and engagement

Key message: Most respondents agreed that they had opportunities to connect and collaborate with experts, industry, and clinicians.

I/my company have had opportunities to connect and collaborate with...



Impact of COVID-19

Key message: For most respondents, their ability to undertake/continue the development of an idea/innovation has been negatively impacted by COVID-19.

Impact of COVID-19

