September 2022

2022-23 PRE-BUDGET SUBMISSION

September 2022

for the October Budget



Executive Summary

A National Health and Medical Research Strategy

Approximately 0.4% of GDP is spent on HMR, yet there is little clarity about whether this investment is efficiently and effectively invested in areas of greatest health need or greatest economic opportunity. That is why Research Australia has led the call on behalf of the sector for the National Health and Medical Research Strategy. This national strategy is practically geared towards delivering better and more efficient health outcomes, a more effective health system and a stronger domestic health industry.

This Strategy, currently under development by the Department of Health, must be underpinned by:

A National Health and Medical Research Workforce Plan to enable the creation of new health industries, Australia needs to attract and support a highly skilled, sustainable health and medical research workforce with circular mobility between academia and industry; and

A National Stocktake of Health and Medical Research to better understand how much funding is available at each stage from pure basic research through to health system implementation and commercialisation. With this knowledge we can better connect the different funding programs, creating a more streamlined and efficient funding system that minimises funding duplication and gaps.

Invest in Innovation

The Government consider a substantially increased investment in national innovation and commit to increasing its spending on research and development to at least 0.75% of GDP annually over the forward estimates.

NHMRC and ARC Funding

Funding for the research programs of the National Health and Medical Research Council (NHMRC) and Australian Research Council (ARC) must be increased in real terms and in their own right, in the October Budget and over the forward estimates, if we as a nation are serious about innovation.

ABOUT RESEARCH AUSTRALIA

Our vision: Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Our mission: To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

Our role:

Engage	Connect	Influence		
Australia in a conversation	researchers, funders	government policies that		
about the health benefits	and consumers to	support effective health		
and economic value of its	increase investment	and medical research		
investment in health and	in health and medical	and its routine translation		
medical research.	research from all sources.	into evidence-based		
		practices and better		
		health outcomes.		

Established with the assistance of the Federal Government in 2002, Research Australia is the national alliance representing the entire health and medical research (HMR) pipeline, from the laboratory to the patient and the marketplace. Research Australia works to position Australian HMR as a significant driver of a healthy population and a healthy economy.

Nadia Levin

CEO & Managing Director

02 9295 8547

nadia.levin@researchaustralia.org

www.researchaustralia.org

384 Victoria Street Darlinghurst NSW 2010

This document and the ideas and concepts set out in this document are subject to copyright. No part of this document, ideas or concepts are to be reproduced or used either in identical or modified form, without the express written consent of Research Australia Limited ABN 28 095 324 379.

TABLE OF CONTENTS

Summary of recommendations	5
Introduction	7
Restoring the Health System	8
Reforming our economy and the role of HMR	9
The pipeline is changing, but to what end? Why we need a National Strategy	. 10
Ambition requires effort and investment	. 12
Funding to the ARC and NHMRC	.13
University Funding and Research Block Grants	.13
Medical Research Institutes	.14
National Critical Research Infrastructure Scheme	. 14
Government support for innovation	.16
Clear and ambitious targets needed	.16
Supporting the development of Medical Products Manufacturing	. 17
Using Government procurement to promote innovation	.19
Conclusion	. 22

Summary of recommendations

National Health and Medical Research Strategy	 A national health and medical research strategy which is geared towards delivering better and more efficient health outcomes, a more effective health system and a stronger domestic health industry. This requires a more comprehensive whole of government approach to health and medical research which: Streamlines existing funding across the pipeline for basic research to translation Ensures our research workforce is fit for purpose Reduces barriers to research in the health system and improves the focus of research and equips researchers with the skills and capability to better engage with the end users of research; and Focuses on the health industries and technologies of the future 					
	A national stocktake of health and medical research and development activity across Australia to understand:					
	 Who is funding HMR in Australia How much funding is available at each stage of the pipeline from pure basic research through to translation activity How we can better connect the different programs along the pipeline to create a more streamlined funding system, and avoid duplication and gaps. 					
Invest in Innovation	The Government should outline a substantially increased investment in national innovation and commit to increasing its spending on research and development to at least 0.75% of GDP annually over the forward estimates.					
	Australia needs to set some clear and ambitious goals if we are to position ourselves for the economic success the Prime Minister has stated as his Government's objective. For example, one such goal would be to become a net exporter of pharmaceuticals by 2035.					
NHMRC and ARC Funding	Funding for the research programs of the National Health and Medical Research Council (NHMRC) and Australian Research Council (ARC) must be increased in real terms and in their own right, in the October Budget and over the forward estimates.					
	Funding for these programs underpins the whole of Australia's research and innovation pipeline.					
	The Government must place a renewed emphasis on basic research in these research funding programs as an investment in Australia's future.					

Indirect Research Costs	Funding for the Research Support Program and the Research Training program must be increased in real terms in the October Budget.				
	In a similar manner, an additional stream of the IRIISS program needs to be funded by the Department of Health to cover the indirect costs associated with MRFF funding incurred by IMRIs.				
	This funding should be administered by the NHMRC.				
Research Infrastructure	The Government should adopt the recommendations made in the National Critical research Infrastructure Roadmap 2021 and provide the funding needed to fully implement the Roadmap.				
	Research Australia supports the view of the Expert Working Group that there is scope to involve existing service providers in industry to deliver research infrastructure, especially computing.				
Medical Products Manufacturing for clinical trials	The Commonwealth Government should further support the development of domestic manufacturing capability of medical products for clinical trials, including through the NCRIS Investment Plan and the National Reconstruction Fund. This includes funding a feasibility study into establishing one or more manufacturing facilities for clinical trial materials to capitalise on Australia's global competitive advantage in clinical trials. It should investigate the provision of facilities in partnership with the health and medical research and innovation sector and funding models involving consortia of government and private investors.				
	These facilities could provide a base for establishing full scale production capability for medical products in Australia, enabling new home-grown medical companies to manufacture here.				
Government Procurement to support medical product manufacturing	The Government should develop an Australian equivalent of the US Government's Biomedical Advanced Research and Development Authority (BARDA) and Centers for Innovation in Advanced Development and Manufacturing (CIADM), with the objective of supporting the development and domestic manufacture of new medical products needed to protect the health of the Australian population. As a major purchaser of healthcare products and services on behalf of the				
	Australian population, medical products provide an ideal opportunity for the Australian Government to use its role as customer to support Australian R&D and manufacturing.				

2022-23 PRE-BUDGET SUBMISSION

Introduction

Research Australia is pleased to have the opportunity to make this pre-Budget submission ahead of the Albanese Government's first Budget in October 2022.

We welcome the Government's emphasis on wellbeing beyond pure economic measures. As the national alliance representing the entire health and medical research (HMR) pipeline, from the laboratory to patient and the marketplace, Research Australia works to position Australian HMR as a significant driver of a healthy population and a healthy economy.

The ultimate goal of health and medical research is better health outcomes, and with it comes the opportunity for economic growth through commercialisation of our research; providing both health and prosperity.

Research Australia also welcomes a renewed focus on intergenerational effects of the Budget. While health and medical research that focuses on improving our health system can deliver returns in a short time frame, research to develop new medical products is necessarily a 'long game'- the benefits of research undertaken now may not be realised for many years, or even decades. In this way, health and medical research is an investment for future generations; a tangible way we can act now to improve future generations' health and prosperity.

Australia has world leading health and medical research but current investment is inadequate, poorly aligned and failing to deliver on the potential health and economic benefits.

In summary, we are recommending:

A Better integrated research strategy

Acceleration of current work on the development of an integrated national health and medical research strategy to achieve better alignment of current investments with national health and economic priorities for Australia

More investment in research and development

Substantially increased overall investment in national innovation, and a commitment to increasing Government spending on research and development to at least 0.75% of GDP annually, over the forward estimates.

Better research translation

Fundamental improvements in the coordination and management of Australia's research translation capabilities: ranging from better coordinated investments in the development, testing and manufacturing of pharmaceuticals and medical devices, through to mechanisms to support systematic implementation of evidence-based health care.

Restoring the Health System

Two and a half years after the advent of COVD-19, Australia's health system and health workforce remain under enormous stress. A research active health system delivers better outcomes more efficiently and research has a key role to play in helping address the stress Australia's health system and health workforce are under.

A better performing health system has personal, population and economy wide benefits:

- Better population health supports national productivity
- Improved patient experience leads to better wellbeing
- Better working environment for healthcare workers
- Improved equity across the Australian community
- More sustainable cost of health.

The greatest opportunities for improvement and innovation in our healthcare system lie in the systematic application of evidence-based healthcare, driven by the best research. We have seen this in Australia's response to COVID-19, which has been overwhelmingly evidence based, highlighting the vital link between research and good healthcare.

With Australian healthcare expenditure in 2019-20 estimated to be \$202.5 billion, even relatively small efficiency improvements can have significant economic benefits.¹ For example, adverse events in hospital are events that lead to harm to patients. Approximately 5% of patients experience an adverse event, and these 'can lead to increased length of stay and poorer patient outcomes, along with increased costs of treatment.'²

Research into better healthcare can lead to new interventions and models of care to reduce the incidence of adverse events, reducing the demand on hospital beds. More broadly, research can lead to shorter hospitals stays and more complete recoveries and avoided hospitalisations through early detection and prevention.

Many new interventions and treatments enter the health system after rigorous assessment, including through clinical trials. According to the Australian Commission on Safety and Quality in Healthcare, there is a \$5.80 return on each dollar invested in clinical trials conducted by Australian networks.³ For example, a clinical trial conducted in Australian intensive care units demonstrated that it was just as effective to treat patients with normal saline rather than the far more expensive human albumin solution. This discovery has led to a change in international guidelines and practice, saving hundreds of millions of dollars per year, not only in Australia but also worldwide.⁴

¹ Australian Institute of Health and Welfare (2021) Health Expenditure Australia 2019-20. Canberra: AIHW ² Australian Institute of Health and Welfare (2018) Australia's health 2018. Australia's health series no. 16. AUS 221. Canberra: AIHW. Chapter 7.9

³ https://www.safetyandguality.gov.au/our-work/clinical-trials/

⁴ See ACTA and NHMRC, 2015, Report on the Activities & Achievements of Clinical Trials Networks in Australia 2004 – 2014 for this and other examples

While undertaking the research to establish the best type of care to deliver is essential, it is not enough. We must redouble our efforts to ensure that this knowledge is communicated and implemented more quickly and consistently throughout our healthcare system and the broader community. This implementation includes the commercialisation of new medical products and technologies.

Research Australia has proposed a national health and medical research strategy which is geared towards delivering better and more efficient health outcomes, a more effective health system and a stronger domestic health industry. This requires a more comprehensive whole of government approach to health and medical research which:

- Streamlines existing funding across the pipeline for basic research to translation
- Ensures our research workforce is fit for purpose
- Reduces barriers to research in the health system and improves the focus of researchers on problems identified by the health system
- Puts patients at the centre of research and equips researchers with the skills and capability to better engage with the end users of research; and
- Focuses on the health industries and technologies of the future

Reforming our economy and the role of HMR

One of the Government's signature policy initiatives is the \$15 billion National Reconstruction Fund, and the \$1.5 billion Medical Products sub fund. Research Australia congratulates the Government on this initiative. It is recognition that Australia's future lies in advanced manufacturing and that we need to better commercialise our own research to secure Australia's economic future by creating jobs and a viable and sustainable economy.

The process from initial research discovery to a new drug, therapy or technology is a long one, often characterised as a pipeline; commencing upstream with research that leads to a new discovery and flowing downstream through various stages of testing, refinement and development to the realisation of a new product which can be manufactured and sold to a customer. (Alternatively, it might be a solution with a non-commercial product, such as a new model of care. The pipeline analogy remains.)

The Medical Products sub fund will operate at the downstream end of the R&D pipeline, helping Australian companies exploit Australian intellectual property by manufacturing new medical products in Australia.

At the upstream end of the pipeline lies the Australian Government's investment in basic research, primarily through the National Health and Medical Research Council's (NHMRC) Medical Research Endowment Account and the Discovery Program of the Australian Research Council (ARC).

In between there is a range of different programs and initiatives intended to support research and development at different stages. At the Commonwealth level the main programs include aspects of the ARC's Linkage program, some of the more translationally oriented NHMRC funding programs, the Medical Research Future Fund, the CRC Program, the Biomedical Translation Fund, and the Entrepreneur's Program. In the last two years new programs have been added with the Trailblazer Universities Program, and the Modern Manufacturing Initiative.

Some of these programs specifically target medical research and others support different aspects of R&D more broadly. Some are grant programs, while others are investment support

(e.g. the Biomedical Translation Fund) or are tax subsidies (the R&D tax Incentive). The Research Block Grants support universities to meet the indirect costs of research. The National Critical Research Infrastructure Scheme provides vital research infrastructure.

There are also programs in other portfolios with specific objectives- e.g. medical countermeasures (Defence) and health and medical research as foreign aid (Foreign Affairs). State and Territory governments are also funders of health and medical research and innovation.

While often characterised as a pipeline, the reality is a system that does not 'flow' smoothly from research discovery to new product. Funding and incentives are available for some stages, but the connections between these different stages are tenuous, or don't exist. With total annual expenditure from all sources on health and medical research in Australia equivalent to around 0.4% of GDP, better coordination of funding can deliver significant benefit to the Australian economy and community.⁵

We need to take this current collection of miscellaneous programs with different objectives and requirements and turn it into a true pipeline, where the ultimate objective of developing a new product or intervention is considered appropriately at the outset, and where progress towards this objective is better planned for and evaluated at each stage, with progress to the next stage assured if the appropriate requirements (scientific and commercial) have been met. Turning the current collection of different programs into a true research and development pipeline requires a new mindset, with changes to what is funded, the selection criteria, and when and how support is provided.

The pipeline is changing, but to what end? Why we need a National Strategy

The most significant change in funding for health and medical research in the last decade has been the creation of the Medical Research Future Fund. The Medical Research Future Fund is primarily targeted towards more applied and translational research. Since its inception in 2015 to January 2022, it has provided research funding of \$1948.6 million.⁶

In the last decade, there has also been a drive to increase research engagement between industry and universities. The latest available data suggests this is working; between 2018 and 2020, research expenditure at universities increased by 15.5% to \$603 million. Like the research funded by the MRFF, industry funded research is typically more applied and translational in nature.

There is also evidence of increased commercial activity; Ausbiotech has reported that ASXlisted biotech companies now represent a market capitalisation of approximately \$233 billion as

⁵ Research Australia, Funding health and medical research in Australia, *https://researchaustralia.org/category/hmr-facts/*

⁶ Australian Government Department of Health, Since inception of the MRFF in 2015, all grants announced, committed or paid as at 21 January 2022, <u>https://www.health.gov.au/summary-of-mrff-grant-recipients</u>

at March 2020 compared to around \$170 billion in 2019, demonstrating a substantive 27 per cent increase in value.⁷

As noted earlier, while basic research is not all that they fund, the main Government funders of basic research are the NHMRC and ARC. The NHMRC funding predominantly goes to universities and ARC funding is only for universities. Between 2018 and 2020, **pure basic research conducted by universities declined by \$314 million (11%)**.⁸ The same decline is not evident in research at medical research institutes, where expenditure on pure basic research increased by around \$19 million between 2018-19 and 2020-21. Nonetheless, the net overall decline in pure basic research of around \$300 million is significant.

Reduced expenditure in basic research disadvantages future generations. The basic research conducted now and the new knowledge it generates will fuel the new applications of research and development in future decades. By reducing our investment in basic research today, we are reducing the opportunity for future generations to secure the health and economic benefits of applying that research in the years to come.

While these high-level trends of a decline in basic research and increases in applied and translational research are evident, we know little about how much research is being conducted at the different research stages in different disciplines, or what the balance should be.

The previous Government committed to establishing a National Health and Medical Research Strategy. The Department of Health has been charged with its development, and an expert steering committee has been appointed. Development of a National HMR Strategy provides a valuable opportunity to address many of these issues but only if the Terms of Reference are sufficiently broad. The Terms of Reference need to consider:

- How programs and initiatives from across the Australian Government relate to and can better complement each other (the Medical Products sub fund of the NRF is just the latest example)
- The contributions being made by state governments, the private sector and philanthropy to the funding of research, research infrastructure and translation, and how these contributions can be better integrated into a national strategy
- The research needs of our health system and how these can best be addressed
- Developing the health and medical research workforce for the future.
- How we better put the patient (and consumer) at the centre of research and development.

To inform the development of the National HMR Strategy, Research Australia proposes a national stocktake of health and medical research and development activity across Australia to understand:

• Who is funding HMR in Australia

⁷ Ausbiotech, 2022, Australia's Life Sciences Sector Snapshot 2022, page 16

⁸ Australian Government, Australian Bureau of Statistics, Higher Ed Expenditure on R&D 2020 <u>https://www.abs.gov.au/statistics/industry/technology-and-innovation/research-and-experimental-development-higher-education-organisations-australia/latest-release#data-download</u>

- How much funding is available at each stage of the pipeline from pure basic research through to translation activity
- How we can better connect the different programs along the pipeline to create a more streamlined funding system, and avoid duplication and gaps.

Ambition requires effort and investment

Innovation and Science Australia developed a plan for innovation, which was delivered in 2017.⁹ *Australia 2030: Prosperity through Innovation* outlined how the Australian Government could drive innovation and productivity across the whole economy through investment in research and development (R&D) at the medium-term average level of 0.63% of GDP.

While Research Australia contends that this level of Government investment in R&D is too low, even this modest target has not been achieved to date, with the previous Government's expenditure on R&D across all areas having fallen to around half of one percent of GDP.

Financial Year						Forecast						
10- 11	11- 12	12- 13	13- 14	14- 15	15- 16	16- 17	17- 18	18- 19	19- 20	20- 21	21- 22	Average
0.63	0.67	0.64	0.62	0.60	0.58	0.54	0.55	0.51	0.52	0.58*	0.56	0.61

Australian Government investment in R&D as a percentage of Gross Domestic Product¹⁰

*includes one off additional \$1 billion increase in Research Support Program. Data is not yet available for the 2022-23 financial year.

Without further sustained investment, Australia will be condemned to a low growth future, and remain highly dependent on just a few key exports. It is essential that we act now, while we still have relatively high levels of wealth, to invest in developing the export industries that can sustain our wealth in the future.

This decline in spending on R&D is not consistent with the Albanese Government's recognition of the need to increase local manufacturing and jobs, which requires a renewed and sustained focus on R&D by all sectors of the economy.

The National Reconstruction Fund and the Medical Products sub fund are clear evidence of a willingness to develop new export industries, but without adequate support at earlier stages of the innovation cycle to help progress new research towards new products, the NRF risks having too few promising companies to invest in.

⁹ Innovation and Science Australia 2017, *Australia 2030: prosperity through innovation*, Australian Government, Canberra.

¹⁰Australian Government, Science, Research and Innovation (SRI) Budget Tables, 2021-22, Australian Government investment in R&D by sector and sub-sector, and other analyses Table 6, Australian Government investment in R&D as a percentage of Gross Domestic Product.

Research Australia submits the Government should outline a substantially increased investment in national innovation and commit to increasing its spending on research and development to at least 0.75% of GDP annually over the forward estimates.

This new investment should be directed to new programs and to increased support for existing programs. In the remainder of this submission, Research Australia provides several proposals for how this additional investment should be utilised in health and medical research and innovation, and more broadly across Australia's world leading research and innovation. We start at the upstream end of the pipeline with basic research and work progressively towards translation into new medical products, interventions and policy.

These proposals are consistent with the ambition the Albanese Government has outlined for Australia's future economy, with manufacturing based on our research expertise in areas of competitive advantage. They are about building new industries and increasing wellbeing in Australia not just for the next decade but for future generations.

Funding to the ARC and NHMRC

Funding to the NHMRC's Medical Research Endowment Account and to the ARC's research programs have declined in real terms over the last decade, with increases in funding consistently lower than inflation over that period.

This trend cannot continue if Australia is to develop the more diversified and knowledge driven economy that we need to secure our future. In particular, we need to reverse the decline in pure basic research conducted at our universities; the NHMRC and ARC are the primary funders of pure basic research at universities, which declined by \$314 million between 2018 and 2020.¹¹

Research Australia submits that funding for the research programs of the NHMRC and ARC must be increased in real terms and in their own right, in the October Budget and over the forward estimates.

Research Australia submits the Government must place a renewed emphasis on basic research in these research funding programs as an investment in Australia's future.

University Funding and Research Block Grants

Research Block Grants (RBG) help support the costs of conducting research in universities. The Research Training Program pays stipends for Higher Degree by Research (HDR) students, and helps universities meet the costs associated with their research. The Research Support Program is intended to support the indirect costs of research at universities that are not funded by direct research revenue, such as libraries, laboratories consumables and support staff.

Universities' direct research income has increased by 66.3% between 2010 and 2020, from \$3.1 billion to \$5.1 billion.¹² HDR completions also increased by 40.3% over this period, from

¹¹ Australian Government, Australian Bureau of Statistics, Higher Ed Expenditure on R&D 2020 https://www.abs.gov.au/statistics/industry/technology-and-innovation/research-and-experimentaldevelopment-higher-education-organisations-australia/latest-release#data-download

¹² Australian Government, Department of Education, Skills and Employment, HERDC time series 2020 v.2, last modified 8 April 2022, accessed 24 May 2022 at <u>https://www.dese.gov.au/research-block-grants/resources/research-income-time-series</u>

7390 to 10,372.¹³ By contrast, RBG funding to universities only increased by 37% over the same period, from \$1.4 billion to \$2 billion.¹⁴

To look at this another way, in 2010 the ratio of all RBG funding to direct research income was 46.4%. By 2020, this ratio had fallen to 38.3%.

This reduction in the relative value of RBG funding to research expenditure is placing real capacity constraints on the ability of universities to undertake research.

Research Australia submits that funding for the Research Support Program and the Research Training program must be increased in real terms in the October Budget.

Medical Research Institutes

While their circumstances and sources of funding for indirect costs are different, the situation is at least as difficult for Independent Medical Research Institutes (IMRIs), those not affiliated with a university. IMRIs are ineligible to participate in the RSP or to receive funding from the ARC. IMRIs receive funding to partially subsidise indirect research costs from the NHMRC through the Independent Research Institute Infrastructure Support Scheme (IRIISS). IRIISS provides funding to IMRIs to assist with indirect research costs, at a rate of up to 20% of the value of NHMRC grants awarded to IMRIs. No funding support for indirect research costs associated with MRFF grants is available to IMRIs.

Research Australia submits an additional stream of the IRIISS program needs to be funded by the Department of Health to cover the indirect costs associated with MRFF funding incurred by IMRIs. This funding should be administered by the NHMRC.

National Critical Research Infrastructure Scheme

'National Research Infrastructure (NRI) comprises a range of nationally significant assets, facilities and services that support leading-edge research and innovation. It is more than instruments and devices: a highly skilled workforce supports both the equipment and the researchers that use it. Australia's NRI network has been built over decades and successfully underpins fundamental and applied research across many disciplines.'¹⁵

The expert committee that undertook the most recent five yearly review of Australia's national critical research infrastructure has concluded that the current portfolio of infrastructure assets has served Australia well. It has recommended new and/or renewed investments in a range of areas, several of which have applications to health and medical research, including:

- Biobanks (national collections);
- Synthetic Biology;
- Digital research infrastructure; and
- Translational research infrastructure

¹⁵ Australian Government, 2021, National Research Infrastructure Roadmap 2021, page 1

¹³ Australian Government, Department of Education, Skills and Employment, HDR Completions by time series 2020, last modified 8 April 2022, accessed 25 May 2022 at https://www.dese.gov.au/research-block-grants/resources/hdr-completions-time-series

¹⁴ Australian Government, Department of Education, Skills and Employment, RBG time series 2001-2022 v.6, last modified 19 April 2022, accessed 24 May 2022 at <u>https://www.dese.gov.au/research-block-grants/resources/rbg-allocations-time-series</u>

Digital Research Infrastructure is a pressing need across all areas of research, with existing infrastructure operating at capacity. Access to greater and faster computing capability can accelerate research, leading to greater impact and/or earlier commercialisation. It is also an area where there is existing domestic capability in specific areas which could be utilised either directly or through existing infrastructure providers.

DUG Technology Australia (DUG)

DUG Technology is an ASX-listed technology company headquartered in Australia, specialising in reliable, green high-performance computing (HPC).¹⁶ Built on a strong foundation of applied science and a history of converting research into practical, real-world solutions, DUG supports and enables its clients to leverage big data and solve complex problems. It is proud to design, own, and operate a network of some of the largest and greenest supercomputing installations on Earth.

Utilising its patented immersion-cooling technology, DUG offers green, cost-effective compute to its clients. Coupled with a focus on data sovereignty and security, a dedicated Australian-based HPC support team and domain-specific expertise, DUG empowers its clients to focus 100% on what matters most to them, helping them accelerate the translation of their research and data sets and commercialisation of their intellectual property assets.

A constant focus on research and development combined with a wealth of industry experience has equipped DUG with the technical excellence to support a diverse industrial client-base that includes life sciences, healthcare, biotech, and medtech, as well as the resources, government and education sectors. DUG continues to invest and innovate at the forefront of HPC, working towards a climate-positive future.

Expanding data research infrastructure by utilising existing industry providers like DUG can be a cost effective and flexible way of meeting research infrastructure needs. One option would be to fund access to infrastructure on merit using dedicated grants (a voucher system) similar to those which currently operates for the Pawsey Supercomputing Research Centre and the NCI.

Research Australia submits the Government should adopt the recommendations made in the National Critical research Infrastructure Roadmap 2021 and provide the funding needed to fully implement the Roadmap.

Research Australia supports the view of the Expert Working Group that there is scope to involve existing service providers in industry to deliver research infrastructure, especially computing.

¹⁶ https://dug.com/

Government support for innovation

As noted earlier, there are many Australian Government programs that seek to bridge the divide between research discovery and translation, either as new product (commercialisation) or as a new intervention or change in policy or practice.

The variety and number of these programs is not of itself a problem. However the lack of an overall strategy to guide and inform these programs, and a clear understanding of how and where the programs complement each other and where they duplicate effort is a missed opportunity to improve the effectiveness of the Government support along the pipeline. While the national HMR Strategy is an opportunity to address this for the health sector, there is also scope for a broader strategy across all Australian R&D. The National HMR Strategy complements the proposals in Industry, Innovation and Science Australia's 2021 report, *Driving effective Government investment in innovation, science and research*, recognising the need for whole of government priorities to support innovation, science and research. This report and its recommendations received no formal response from the previous Government.

Research Australia submits the Government should act on the recommendations of the IISA in its 2021 report, *Driving effective Government investment in innovation, science and research.*

Clear and ambitious targets needed

A commitment to increase Government spending on R&D to 0.75% of GDP would set a clear and ambitious target, but we also need others.

The Albanese Government has identified Medical Products as a priority area, and indicated that \$1.5 billion of the National Reconstruction Fund will be committed to Medical Products

A broad category, this includes, for example, pharmaceutical products. Australia already has world class research to support the development of new medicines and pharmaceuticals. We also have expertise in the manufacturing and supply chain for pharmaceuticals. The same is true of many other categories within medical products, and we congratulate the Australian Government on playing to our strengths.

In 2019, global exports of pharmaceutical products accounted for USD582 billion. Twenty of the world's nations accounted for 92% of this total, valued at USD534 billion. The world's Number 1 exporter of pharmaceutical products was Germany at USD89.4 billion, with 15.3% of global pharmaceutical exports. Number 23 was Australia, with exports of USD3.2 billion, or 0.55% of global exports.¹⁷

In the same year (2019), Australia imported pharmaceutical products valued at \$USD7.38 billion, or 1.27% of global pharmaceutical imports.¹⁸

¹⁷Sourced 7 July 2022 from

https://atlas.cid.harvard.edu/explore?country=undefined&product=129&year=2019&productClass=HS&ta rget=Product&partner=undefined&startYear=undefined

¹⁸Sourced 7 July 2022 from

https://atlas.cid.harvard.edu/explore?country=undefined&product=129&year=2019&tradeDirection=impor t&productClass=HS&target=Product&partner=undefined&startYear=undefined

Pharmaceutical manufacturing, including vaccines and serums, is a sensible area for Australia to seek to expand its capability. It is an area where security of supply is paramount; it is also an area where we have existing expertise in manufacturing and world leading expertise in life sciences that we can leverage. It is a growing market, and one where capability is relatively well dispersed around the developed world.

Research Australia submits Australia needs to set some clear and ambitious goals if we are to position ourselves for economic success. One such goal would be to become a net exporter of pharmaceuticals by 2035.

Achieving such a target will involve a focus on the Australian manufacture of new, high value pharmaceutical products in Australia. It would significantly boost our terms of trade in a key world market and create high value jobs. It would also create an ecosystem which would further support new research and commercialisation of new products.

Pharmaceutical products is the case study used here, but similar opportunities exist with other types of medical products, including diagnostics and medical devices. There is increasing evidence we can develop new products in Australia, capitalising on our world class research.

The Medical Research Commercialisation Fund, started in 2007, has an increasing suite of products under development at advanced stages. While there was a tendency even five years ago to license promising new products to international pharmaceutical companies to complete their commercialisation, we have a growing capability to undertake the later stage commercialisation of these products in Australia. The Government's Biomedical Translation Fund is following a similar trajectory, investing in the commercialisation of promising Australian research.

Research Australia looks forward to the National Reconstruction Fund providing further impetus to this endeavour.

Supporting the development of Medical Products Manufacturing

The development of medical products, including pharmaceuticals, therapeutics, diagnostics and medical devices is a long and expensive process, typically taking more than a decade. However the rewards for successful products, and the companies and countries that manufacture them, can be substantial.

As noted above, Australia already has many processes and programs to support the development and commercialisation of medical products, and Australia has existing advanced manufacturing capability in key areas, including medical devices, but there is plenty of potential for further growth.

The transition from product development to the manufacture of medical products provides both a particular challenge and an opportunity for Australia. Clinical trials are an essential part of the process of bringing a medical product to market. The conduct of clinical trials requires having thousands (or tens of thousands) of the product being tested available for use with patients. The manufacture of the product for clinical trials requires facilities that are flexible enough to produce batches of products to the required standard for use in clinical trials but at a scale that is beyond research facilities.

Having more of this manufacturing capacity in Australia would:

- help support Australia as a destination for clinical trials,
- build Australian expertise in manufacturing for the latest types of devices, diagnostics, medicines and drugs; and
- support Australian research which is reliant on access to clinical trial materials to be able to continue research into promising new therapies.

This manufacturing capacity would provide direct economic benefits. It is also a good starting point from which to scale up to the manufacture of a range of new medical products on a fully commercial scale for products that prove to be viable.

If the initial manufacturing for clinical trials has been undertaken in Australia, it provides Australia with a natural advantage. It can be easier and quicker to expand the manufacturing capability here, drawing on the skills and expertise developed in the clinical trial production phase, rather than start the whole process from the beginning in another country. This natural advantage does not exist where the manufacturing for the clinical trials has been undertaken overseas.

There are currently very few facilities in Australia with the capacity to produce the volumes of materials required for later stage clinical trials. In part this is because there has been a tendency in the past for Australian entrepreneurs to license promising products at an early stage of development to a foreign multinational company, which results in the further product development and manufacturing occurring overseas.

With an increasing trend towards developing products locally to a later stage, there is a need for greater local manufacturing capability. Australian medical product start-ups are typically still 'pre revenue' at this stage of their development and are not in a position to invest the capital needed to establish a new manufacturing facility. We need alternative solutions.

Readier access to manufacturing facilities to produce medical products for clinical trials could be key to keeping the further development of new medical products in Australia; and it could provide a base for establishing the full-scale manufacturing capability for medical products in Australia when the product is in the market and generating revenue.

The provision of manufacturing facilities for clinical trials would contribute to the development of new home-grown medical product companies undertaking full scale manufacturing in Australia and contribute to the goal proposed earlier to make Australia a net exporter of pharmaceuticals by 2035.

The need for this type of manufacturing facility has been identified as a priority in the 2021 NCRIS Roadmap, and there is scope to use funding through the next NCRIS Investment Plan to deliver this.¹⁹ There is also scope for the National Reconstruction Fund to play a role.

Research Australia submits the Commonwealth Government should further support the development of domestic manufacturing capability of medical products for clinical trials, including through the NCRIS Investment Plan and the National Reconstruction Fund. This includes funding a feasibility study into establishing one or more manufacturing facilities for clinical trial materials to capitalise on Australia's global competitive advantage in

¹⁹ Australian Government, 2022, 2021 National Research Infrastructure Roadmap, page 56

clinical trials. It should investigate the provision of facilities in partnership with the health and medical research and innovation sector and funding models involving consortia of government and private investors.

Using Government procurement to promote innovation

Research Australia welcomes the Government's recognition of the importance of its role as a purchaser of products and services and the capacity for better government procurement policy to support Australian businesses. What is perhaps not so well recognised is the scope for this policy to support innovation and the development of new products and services.

In 2016, Innovation and Science Australia undertook a review of the performance of Australia's innovation performance. One of the ways it identified the Australia Government could better support Australian innovation was through its procurement processes.

'Relative to other countries, government procurement could do more to foster innovation.

The majority of OECD countries use procurement approaches 'not only to foster value for money but also to pursue other policy objectives'.137 Australia ranks 63rd out of 138 countries for the extent to which government purchasing decisions foster innovation.138

Australia's relatively poor performance on this measure may be related to the emphasis government procurement guidelines place on value for money. This could discourage domestic innovation and investment in innovation.

Conversely, overseas examples highlight the potential for governments to use procurement as a direct mechanism to increase the incentives for innovation. For example, the government-wide US Small Business Innovation Research (SBIR) programme was established in 1982 to encourage small businesses to participate in US Government R&D and potentially commercialise their outputs. The programme requires government departments spending more than \$100 million on extramural R&D to set aside a portion of this spend for small businesses. Similarly, the UK Small Business Research Initiative was established in 2001 to improve the number of small R&D-based businesses winning contracts from government.²⁰

Medical products provide an ideal opportunity for the Australian Government to use its role as customer to support Australian R&D and manufacturing. This is because the Australian Government is a major purchaser of healthcare products and services on behalf of the Australian population.

While Innovation and Science Australia cited the SBIR program as an example, the US Government's Biomedical Advanced Research and Development Authority (BARDA) and Centers for Innovation in Advanced Development and Manufacturing (CIADM) provide a closer model for how this could work in Australia for health and medical research.

²⁰ Innovation and Science Australia (2016) Performance Review of the Australian Innovation, Science and Research System 2016. Commonwealth of Australia. Canberra. Page 29

BARDA

Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response, was established to aid in securing our nation from chemical, biological, radiological, and nuclear (CBRN) threats, as well as from pandemic influenza (PI) and emerging infectious diseases (EID). BARDA supports the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development towards consideration for approval by the FDA and inclusion into the Strategic National Stockpile. BARDA's support includes funding, technical assistance and core services, ranging from a clinical research organization network to Centers for Innovation in Advanced Development and Manufacturing, and a fill-finish manufacturing network. BARDA supports a diverse portfolio of medical countermeasures and these products have received a total of 55 FDA approvals, licensures, or clearances.

Our mission is accomplished through successful public-private partnerships with industry to share risk, improve efficiency and accelerate development all while sustaining a marketplace that guarantees continued access to countermeasures vital to our national security.²¹

The focus is on products the US Government needs to protect its population and BARDA provides financial and other support from later stage research through to manufacture of the product and then acts as a cornerstone purchaser. The manufacturing capability is delivered through three BARDA sponsored Centers for Innovation in Advanced Development and Manufacturing (CIADM).

Centers for Innovation in Advanced Development and Manufacturing

The CIADMs were created through a public-private partnership model, bringing together the innovative ideas of small biotech firms, the training expertise of academic institutions, and the development and manufacturing experience of large pharmaceutical companies. This helps to ensure a sustainable domestic medical countermeasure infrastructure with unprecedented ability to accelerate development and manufacture medical countermeasures in time of need.²²

BARDA and the CIADM have been critical components of the US Government's vaccine development response to the COVID-19 pandemic.²³²⁴²⁵

Medical products provide an opportunity for the Australian Government to use its role as customer to support Australian R&D and manufacturing, while also protecting Australia's population and ensuring supply of essential medical products, including in emergencies. The Government could support the development of products in areas where it thinks the product will be useful and it will be a potential purchaser- this includes pharmaceuticals, therapeutics and medical devices, as well as drug delivery mechanisms like Vaxxas.²⁶

²² https://www.medicalcountermeasures.gov/barda/core-services

²¹ https://www.phe.gov/about/barda/Pages/default.aspx

²³https://www.hhs.gov/about/news/2020/07/27/hhs-reserves-and-rapidly-expands-manufacturing-capacity-for-covid-19-vaccines-at-texas-center.html

²⁴https://www.tamus.edu/update-on-production-of-covid-19-vaccine-candidates-by-texas-am-system-subcontractor/

²⁵ https://www.medicalcountermeasures.gov/newsroom/2020/emergent-plasma/

²⁶ https://www.vaxxas.com/

The Australian Government already provides some of this support on an adhoc basis. An example is the 2020 agreement reached with CSL in which the Government supported the development of a new manufacturing facility here and has committed to buying vaccines.

'Global biotechnology leader CSL Limited (ASX:CSL; USOTC:CSLLY) today announced that Seqirus, a wholly owned subsidiary of CSL, plans to invest more than AUD\$800 million in the construction of a new biotech manufacturing facility in Melbourne to supply influenza vaccines to Australia and the rest of the world.

This investment decision follows the agreement with the Australian Government for the supply over 10 years of influenza pandemic protection for the Australian population, anti-venoms for Australian snakes, spiders and marine creatures and Q-Fever vaccine.' 16 November 2020²⁷

Better diagnosis and support for mental illness in rural, regional and remote Australia

Demand for mental health services has increased across Australia, including in regional and rural areas, where access to a diagnosis, let alone treatment, remains a particular problem.

The Australian Government could call for the development of technologies and programs to support the diagnosis and treatment of people experiencing mental illness in rural regional and remote Australia to support the delivery of better mental health care by existing health services.

Specific patient-reported outcome measures can be used to discern 'stress' from 'depression' and from 'anxiety'. Psychologists at the Mater Hospital Brisbane use the *Depression, Anxiety and Stress Scale 21* (DASS-21) in this way to aid diagnosis and track the progress of patients.

DASS 21 could form the basis of a simple app that rural and remote health workers could use to more accurately identify and triage people with stress, anxiety and depression, and help make referrals to appropriate telehealth and other specialist services. It could also help support local health workers to deliver mental health services and monitor patients' progress.

Point of Care diagnostics (POCDs) enable conditions to be diagnosed in the GP clinic without the need to send samples to an external laboratory. While centralised pathology laboratories work well in our capital cities, this model can mean patients in remote communities wait days to get vital results, and the cost of transporting samples is much greater.²⁸

In addition to delaying the commencement of treatment, pathology lab testing requires follow up appointments to act on the results when received. All this can lead to additional workload for practitioners, poorer treatment and greater inconvenience for patients, and extra costs to the Australian Government.

²⁷ <u>https://wcsecure.weblink.com.au/pdf/CSL/02309014.pdf</u>

²⁸ https://www1.racgp.org.au/newsgp/clinical/are-we-about-to-see-a-new-dawn-for-point-of-care-t

Supporting the development and production of accurate and cost-effective POCDs could provide benefits to the Australian Government, the population and our medical products industry. POCDs could be a good target area for an Australian BARDA style program.

Research Australia submits the Government should develop an Australian equivalent of the US Government's Biomedical Advanced Research and Development Authority (BARDA) and Centers for Innovation in Advanced Development and Manufacturing (CIADM), with the objective of supporting the development and domestic manufacture of new medical products needed to protect the health of the Australian population.

Conclusion

The COVID-19 pandemic has highlighted the world leading health and medical research being undertaken in Australia and the critical role research and innovation has played in helping us navigate this health crisis.

At the same time, it has highlighted successive Australian Governments' historic under investment in health and medical research, leading to an over reliance on the capacity of universities to generate international student revenue and direct it to funding research, and on philanthropy to fill the gaps. It has also highlighted some points in which our systems are still not strongly enough connected, including the interface between researchers and the health system.

The Albanese Government has already taken important steps to address the impact of COVID-19 on our health system and economy. In the longer term, economic recovery from the pandemic creates an opportunity for a healthier and more prosperous Australia, which this Government is determined to seize upon.

All Australians benefit from strong investment in health and medical research and innovation. The opportunity provided through the health, medical research and innovation sector is immense for both the health and wealth of our nation. From a national security perspective, a strategic investment in enhanced medical production and preparation for the next pandemic can help ensure Australians have access to vital medical products at future times of crisis. While welcome steps have already been taken in this regard, it is worthwhile looking at other models and adapting them in the Australian context and the USA provides a useful model for what more can be done and achieved.

Improving the health of the Australian population is central to improving national productivity. Australian health and medical research leads to new medicines, technologies and treatments that cure us when we are ill or injured. It plays a significant role in disease prevention through the development of vaccines, as well as technologies for early disease diagnosis. More immediately, health and medical research in Australia continues to tackle how to best deliver healthcare, providing critical evidence that addresses clinically important unanswered questions.

The October Budget provides the opportunity for the Australian Government to improve the health and wellbeing of the Australian population and to reposition Australia as a modern and innovative nation with a knowledge-based economy. However, this requires a renewed commitment to significant investment in innovation to reverse the declines in recent years that are evident when investment in R&D is considered as a proportion of GDP.

In addition to raising national prosperity and diversifying our economy, smarter investment in health and medical research and innovation can improve the effectiveness and productivity of our health system, constraining the rise in health costs that accompany an ageing population. It can also provide a sustainable pathway to addressing modern lifestyle factors such as obesity. Smarter investment also drives skilled employment in vibrant new pharmaceutical, medical device and biotechnology industries.

An overarching national health and medical research strategy which ensures smarter, coordinated, strategic public investment in all stages of research would maximise impact on national priorities such as burden of disease, the stronger translation of evidence-based research into healthcare delivery, and exploit areas of international competitive advantage. Imagining and preparing for the Australia we want in 50 years' time has to start today.

Research Australia is pleased to have had the opportunity to make this submission on behalf of our broad membership which is drawn from across the health and medical research pipeline. We are also willing to provide further information and/or contribute further to support all efforts in ensuring health and medical research can play a leading role in supporting productivity gains, both health and financial in securing Australia's healthy future.

RESEARCH AUSTRALIA LIMITED

384 Victoria Street, Darlinghurst NSW 2010

P +61 2 9295 8546 ABN 28 095 324 379

www.researchaustralia.org