# STRATEGIC EXAMINATION RESEARCH AND DEVELOPMENT SUBMISSION

April 2025

# **RESEARCH** AUSTRALIA

Championing Australian health & medical research & innovation

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What should an integrated, sustainable, dynamic and impactful Australian R&D system look like?	Given more than a quarter (26%) of Australia R&D is spent on health and medical research, there must be a dedicated focus in the Strategic Examination of R&D on health and medical research, development and innovation.	Page 11
system look like?	<ul> <li>Align the Strategic Examination of R&amp;D and the development of the National Health and Medical Research Strategy, especially during the development of recommendations and implementation. Jointly, they must have actions that:</li> <li>are developed by the sector for the sector;</li> <li>be led by a long-term vision and a theory of change;</li> <li>facilitate coordinated, sustainable investment in research;</li> <li>strengthen the connection between research, development and innovation and healthcare;</li> <li>enable emerging innovative health industries; and</li> <li>ensure accountability through embedding monitoring and evaluation of measures of success</li> </ul>	Page 11
	<ul> <li>An integrated, sustainable, dynamic and impactful Australian R&amp;D system looks like:</li> <li>A seamless pipeline from discovery science to health innovation, including translation and commercialisation;</li> <li>Longer and coordinated investment to enable sustainability;</li> <li>Health innovation prioritised as a critical sovereign capability;</li> <li>A whole of systems approach to ensure coordination and investment across all jurisdictions and portfolios towards a shared vision;</li> <li>Innovation embedded in the health system; and</li> <li>Workforce investments that ensure it meets the needs of a globally competitive future Australia</li> </ul>	Page 14

### Summary of recommendations

What do we need to build a	Australia needs to build a national culture of innovation excellence, especially focused on health and	Раде 17
	medical research development and innevation is the vision we need to achieve. It involves systemic	rage 17
	show and a second	
	changes across education, policy, media, investment, and both industry and public engagement. This	
public focus on success in health	includes:	
and medical R&D and		
innovation as a key national	• Building nearth innovation into the national identity	
priority	• Rewiring the education system to enable and empower innovators and critical thinkers	
	• Invest in a thriving health innovation ecosystem, through de-risking innovation in partnership, and	
	where appropriate, with industry, to accelerate bench to bedside and business	
	• Establishment of a governing body that is strategically appointed, and separate from existing funding	
	organisations, and tasked with monitoring and evaluation.	
	Industry partnerships	
	Engage the public (community and consumers) as stakeholders	
	Monitoring and Evaluation feedback loops	
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What types of funding sources,	The funding sources, models and/or infrastructure that are needed for Australian R&D include:	Page 18
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What changes are needed to enhance the role of research institutions and businesses (including startups, small businesses, medium businesses and large organisations) in Australia's R&D system?	<ul> <li>Australia needs to undertake both systemic and cultural reforms to enhance the role of research institutions and businesses in Australia's health and medical research, development and innovation system by incorporating the previous recommendations, as well as:</li> <li>Enabling collaboration across the pipeline and workforce through systems and cultural change; and</li> <li>Developing specific plans for health and medical research, development and innovation, such as a National Medical Products Industry Plan</li> </ul>	Page 22
How should Australia support basic or 'discovery' research?	<ul> <li>In order to support basic or 'discovery' research, Australia should increase</li> <li>funding for discovery science through the NHMRC and ARC;</li> <li>funding and ongoing commitment to National Collaborative Infrastructure Scheme (NCRIS); and</li> <li>investments and approaches that will enable Early and Mid Career Researchers to thrive</li> </ul>	Page 26
What should we do to attract, develop and retain an R&D workforce suitable for Australia's future needs?	In order to attract, develop and retain an R&D workforce suitable for Australia's future needs, Australia needs to develop a National Health and Medical Research, Development and Innovation Workforce Plan. The Plan should have a long-term vision with immediate incentives for boosting the current workforce. The actions need to be strategic, embed and leverage other workforce and employment strategies, such as gender responsive budgeting to address the gender disparity within the sector, especially in research leadership positions. Overall, the plan should:	Page 27
	<ul> <li>address the whole pipeline of skills required from initial discovery through to innovation, including translation, entrepreneurship, product development, commercialisation and manufacturing</li> <li>support a highly skilled and sustainable research workforce with circular mobility between academia, industry and other sectors across the pipeline</li> <li>align with changes required in our K-12 education curriculum and national plans to increase the development of skills needed for our future needs</li> <li>be aligned with key measures across other workforce strategies</li> <li>ensure universities (and other institutions across the ecosystem) are equipped to train the next generation of researchers</li> <li>retain Australian researchers and attracts the world's best talent</li> <li>prioritise marginalised workforces</li> </ul>	

	<ul> <li>Australia should respond to a gap in current workforce strategies and data about Early Mid Career</li> <li>Researchers by investing in a national Early-Mid Career Research Longitudinal Survey that</li> <li>builds on previous national EMCR surveys;</li> <li>provides the sector a regular environmental scan of key issues and monitor trends;</li> <li>engages directly with policy frameworks and institutions in identifying opportunities and systems changes; and</li> <li>identifies and recommends positive systems change across the health and medical research, development and innovation sectors in order to contribute to a sustainable future workforce</li> </ul>	
How can First Nations knowledge and leadership be elevated throughout Australia's R&D system?	First Nations knowledge and leadership be elevated throughout Australia's R&D system through identifying key actions in line with the Closing the Gap Priority Reforms.	Page 29
What incentives do business leaders need to recognise the value of R&D investment, and to build R&D activities in Australia?	<ul> <li>Incentives needed for business leaders to recognise the value of R&amp;D investment and to build R&amp;D activities in Australia should reduce risk, highlight potential returns, and align with broader national and business objectives. In addition to the existing recommendations they include:</li> <li>Financial incentives within funding programs to de-risk private investment in health innovation.</li> <li>Streamlined regulatory pathways, to accelerated approvals and support for clinical trials and innovative health technologies.; as well as align with international regulatory frameworks to support global market access.</li> <li>Intellectual Property support to assist in navigating and protecting IP rights</li> <li>Infrastructure and Ecosystem Support, for example subsidised access to biotech labs, clinical trial networks, AI health data platforms, and the investment of national networks for biobanking and genomics.</li> <li>Talent and workforce development, support for industry PhDs, postdocs, and internships in private companies.</li> <li>Innovation clusters and hubs such as investment in health innovation precincts, especially around universities and hospitals; and the co-location incentives for startups and corporates near research institutions.</li> <li>Market access and global opportunities, such as biobridges and strategic partnerships.</li> </ul>	Page 30

	• Investment promotion, for example, elevating Australia as a preferred destination for global pharma and medtech R&D and marketing Australia's strong clinical trials ecosystem and world-class research.	
What should be measured to	Given the contribution health and medical research, development and innovation contributes to our nation,	Page 32
assess the value and impact of	it is essential that we are able to specifically measure health and medical research, development and	
R&D investments?	innovation investments at a programmatic and systemic level, as well as including on impact on burden of	
	disease, productivity, economic and industry impact.	
	Australia should act on the Innovation Metrics Review; and restore funding to the Australian Bureau of	
	Statistics to improve the capture and analysis of data relating to R&D in Australia as first steps to developing	
	a proper framework for measuring the impact of Australian research and innovation.	

### Introduction

Research Australia, as the national alliance and peak of health and medical research, development and innovation, is pleased to have the opportunity to make this submission as part of the Strategic Examination Research & Development (SERD). This coming year offers a real opportunity to address the challenges identified in the Discussion Paper, through both the SERD and the Australian Government's development of the National Health and Medical Research Strategy, which Research Australia has advocated for since 2021. We have the unique opportunity to reform and reimagine a whole of R&D system that sets up a future Australia. One that is responsive, affordable, and sustainable. Given more than a quarter (26%) of Australia R&D is spent on health and medical research, there needs to be a dedicated focus in the Strategic Examination of R&D on health and medical research, development and innovation. We don't believe that these two initiatives should be seen or conducted as delinked.

2025 is a real opportunity for advancing health and medical research, development and innovation in Australia being an election year as well as through reforms to emerge from the development of the National Health and Medical Research Strategy, the Strategic Examination into Research & Development. The National Health and Medical Research Strategy and SERD must be better aligned to enable the critical integration and elevation of health and medical research, development and innovation and as a key R&D sector; and the strengthening of the R&D sector to enable health innovation. The failure to recognise the importance of health and medical research, development and innovation as a priority and critical sector in its own right will risk unintended consequences for the sector and for economy. Health innovation and the potential industries it enables and creates offers an real opportunity for diversifying our economy.

Per capita, Australia is one of the wealthiest countries in the world. And while it is no longer true that Australia rides on the sheep's back, for a wealthy country our economy remains poorly diversified. This places Australia's long-term future at risk; a decline in the export value of just a few key commodities can jeopardise our whole economy and standard of living.

Covid exposed Australia's reliance on one major export partner, China, for three of our major exports: minerals, tourism and higher education. Such a concentrated reliance on one export partner and a few exports is unparalleled in the developed world, and it is a situation we need to change dramatically by creating a more innovative and diverse economy that exports a range of goods and services to the world.<sup>1</sup> The current rapidly changing, and unpredictable geopolitical environment again is requiring this even more than immediately after Covid.

This means supporting the companies in Australia, both small and large, that are engaging in research and development, creating new jobs and opportunities and diversifying our economy.

<sup>&</sup>lt;sup>1</sup> See for example, the *Atlas of Economic Complexity*, developed by Harvard University, which rates the complexity of Australia's economy as the 93<sup>rd</sup> most complex economy in the world, behind Morocco, Uganda and Senegal. *'Australia ranks as the 93<sup>rd</sup> most complex country in the Economic Complexity Index (ECI) ranking. Compared to a decade prior, Australia's economy has become less complex, worsening 22 positions in the ECI ranking. Australia's worsening complexity has been driven by a lack of diversification of exports... Australia is less complex than expected for its income level. As a result, its economy is projected to grow slowly.' Accessed on 26 February 2020 at http://atlas.cid.harvard.edu/countries/14* 

In general, the complexity of a country's economy, measured in terms of the diversity of its international trade, is a good measure of the economy's strength and resilience, and its capacity for continued innovation and growth. The *Atlas of Economic Complexity*, developed by Harvard University, rates the complexity of Australia's economy as the 99<sup>th</sup> most complex economy in the world, behind Morocco, Uganda and Senegal, and a decrease from 91<sup>st</sup> in 2022. As explained,

'Australia is a high-income country, ranking as the 9th richest economy per capita out of 145 studied. Its 27 million inhabitants have a GDP per capita of \$64,546 (\$67,900 PPP; 2023). GDP per capita growth has averaged 0.8% over the past five years, below regional averages.

Australia ranks as the 99<sup>th</sup> most complex country in the Economic Complexity Index (ECI) ranking. Compared to a decade prior, Australia's economy has become less complex, worsening 8 positions in the ECI ranking. Australia's worsening complexity has been driven by a lack of diversification of exports. Moving forward, Australia is positioned to take advantage of a moderate number of opportunities to diversify its production using its existing knowhow.

Australia is less complex than expected for its income level. As a result, its economy is projected to grow slowly. The Growth Lab's 2033 Growth Projections foresee growth in Australia of 1% annually over the coming decade, ranking in the bottom half of countries globally.<sup>2</sup>'

To summarise, the key to long term, sustainable prosperity is a more complex economy; greater complexity requires greater diversification of exports; existing knowhow provides a moderate number of opportunities to diversify our production; and the key to diversifying our exports and our economy is new knowledge creation and innovation, that includes smart manufacturing as an example.

A strong health and medical research, development and innovation sector enables greater outcomes and productivity through better health, drives efficiencies across Australia's health system and delivers new revenue opportunities through creating an Australian industry and the export of health innovations. We define health innovation as the development and implementation of new or improved health policies, practices, systems, products, technologies, services, and delivery methods that aim to improve healthcare efficiency, effectiveness, quality, sustainability, safety, and/or affordability. It includes both translation and / or commercialisation, including digital health, precision medicine, new models of care, improved infrastructure and service planning.

The investments we make during the next 18 months will be the difference between short term ad hoc investments or establishing a policy framework and infrastructure that will future proof the health and medical research, development and innovation sector, and Australia into the future. A cohesive, future-focused approach is essential for national health and economic prosperity. We have the potential to serve as a regional hub for world-class medical services and clinical trials, enhancing our global reputation as a leading health system and contributing to better health outcomes worldwide.

Research Australia's SERD Submission includes addressing all the consultation questions, as well as an upfront statement on the role of health and medical research, development and innovation to national productivity and the R&D landscape. It has been developed drawing on previous Research Australia

 $<sup>^2</sup>$  Harvard University Growth Lab, Centre for International Development, Atlas of Economic Complexity, Australia Profile, accessed on <u>15</u> April. 2025

submissions, the contribution of members and broader input. Research Australia undertakes a range of processes to develop evidence-informed positions.

### <u>Health and medical research, development and innovation's contribution to</u> <u>national productivity</u>

The priority for the Government's focus on increasing productivity, evident in the historic Statement of Expectations provided by the Treasurer to the Productivity Commission back in November 2023. It also highlights the critical role health and medical research can play in increasing national productivity, but the also the opportunity health and medical research holds for addressing wicked policy problems, as well as the risk in not investing<sup>3</sup>.

Specifically, the benefits of technological and digital transformation are nowhere more evident than in digitally and AI enabled healthcare, and Australia has world class research and innovation capabilities on this area. Climate change is driving the need for adaptation of our health systems and environment to protect human life. An ageing population is accompanied by increasing rates of chronic disease which are driving rising demand for care and support services; research can help reduce the incidence and burden of chronic disease and make our health system more effective and efficient. Geopolitical risk and fragmentation are driving increasing security concerns, in particular how to ensure greater self-reliance through the production of medicines and medical technologies. Australia's health and medical research, development and innovation sector can boost Australia's self-reliance in this critical area, including strengthening our knowledge economy.

Australia's health and medical research, development and innovation sector can fulfil its potential as a cornerstone of a more productive and prosperous post-carbon Australian economy, but we must have the vision, system-wide policies levers and enablers, smarter investment, industrial capacity, the manufacturing sector, and the workforce skills to make this happen. Given the rapidly changing geopolitics, we must mobilise the disparate parts of both the broad R&D pipeline and the health and medical research, development and innovation pipeline, activate policy implementation and remove barriers for the sector to thrive, and ignite the urgency of doing this now.

### The case for investing in health and medical research, development and innovation as a significant contributor to the Australian R&D landscape

Since the pandemic, Research Australia has closely examined how we tackle the challenges and opportunities of the health and medical research, development and innovation sector. There have been over 550 recommendations proposed by the 20 health and medical research reviews conducted nationally in the last 15 years. Some of these recommendations have been partially or fully

<sup>&</sup>lt;sup>3</sup> Australian Government, The Treasury, 2023, Statement of Expectations-Productivity Commission, November 2023

implemented, many have not. There seems to be little data on the impact of these recommendations. Consistent themes can be identified across these recommendations:

- Driving greater efficiencies and improvements in health and medical research funding;
- Developing a research informed health system;
- Improving the relationship between research and industry and increasing the capacity for research commercialisation; and
- Concerns about the research workforce<sup>4</sup>.

The most consistent recommendation across almost all the reviews has been to improve the funding structure of health and medical research. These recommendations do not just propose increasing funding but rather suggest improving the structure of health and medical research funding to be more streamlined and efficient. Over half of the 20 reviews also recommend establishing a national health and medical research strategy and governing body to help drive these efficiencies and improvements in funding.

In 2024, Research Australia undertook further consultation with its members and have identified the following key priority reforms for the sector across the pipeline or ecosystem.

- Whole of systems approach to health and medical research, development and innovation
- Smarter Investment in health and medical research, development and innovation
- A diverse and supported health and medical research, development and innovation Workforce
- Advancing Primary Prevention

The following section of the submission addresses the individual consultation questions.

<sup>&</sup>lt;sup>4</sup> Research Australia. <u>Consultation Paper Post pandemic opportunities for health medical research innovation</u> (2021)

### **Response to consultation questions:**

#### <u>1.What should an integrated, sustainable, dynamic and impactful Australian R&D</u> system look like?

An integrated, sustainable, dynamic, and impactful Australian R&D system should place health and medical research, development and innovation at its core, recognising that a healthy population is the foundation of a thriving, resilient society and economy. To achieve this, the system must be designed to:

- Seamless pipeline from discovery science to health innovation, including translation and commercialisation
- Ensure longer and coordinated investment to enable sustainability
- Prioritise health innovation as a critical sovereign capability
- Whole of systems approach to ensure coordination and investment across all jurisdictions and portfolios towards a shared vision
- Embed innovation in the health system
- Invest in the workforce to ensure it meets the needs of a globally competitive future Australia

### Foster a Seamless Pipeline from Discovery Science to Innovation

A globally competitive Australia must recognise and capitalise on the decades of investment into its research capabilities. The outcomes of this are evident in our excellence and standing as noted in the SERD discussion paper. A dynamic health and medical research, development and innovation system must support the entire research continuum—from basic discovery through to clinical trials, translation, and commercialisation. Integration across academia, healthcare, industry, and government should be actively facilitated to ensure research outcomes are rapidly transformed into improved diagnostics, treatments, and preventive strategies. This requires sustained and forecast investment.

### Ensure Long-term, Strategic Investment

Sustainability requires stable, long-term funding models that reward high-impact, collaborative, and translational research. This includes support for investigator-initiated discovery, mission-driven research programs, and infrastructure that enables open data sharing, biobanking, and advanced clinical trials. All of the aforementioned must also consider the active participation of industry led research, and partnerships to drive innovation in a shared model of both risk and reward. In addition, equity and addressing systemic discrimination and exclusion to equitable health outcomes and research priorities, must underpin the long-term, strategic investment. We welcome the review of the Government's current funding landscape of health and medical research funding, which we called for during the dissemination of our 2020-2021 national consultation report, however, await its findings.

### Prioritise Health Innovation as a sovereign capability

Health and medical research, development and innovation needs to be recognised as a critical sovereign capability—essential to economic productivity, social equity, and long-term national health and wellbeing, as well as contributor to the national economy through the creation of new industries and workforces, including manufacturing. Sustainable investment in this sector enables Australia to tackle pressing health challenges, reduce the burden of disease, be responsive to an ageing population, and respond rapidly to emerging health threats like pandemics or antimicrobial resistance. In order to achieve this SERD must not be separated from the development of the National Health and Medical Research Strategy.

### Whole of systems approach

Individual lives and health challenges are complex, expensive and intersect with many government policy silos – for example, social determinants of health, technology, disability, environment, and society. In 2020-21 Research Australia undertook national consultation on the needs of the sector, including a national strategy. We have consistently emphasised the need to facilitate coordinated, sustainable investment in research; strengthen the connection between research and healthcare; and strongly support emerging innovative health industries. This requires a whole of system and pipeline approach, across portfolios and jurisdictions. This can be achieved by putting research, development and innovation at the centre of all government policy. To enable a whole of systems approach, the R&D system needs to embed systemic levers for cross-sector and interdisciplinary research and collaboration.

### Embed Innovation into the Health System

To be truly impactful, the R&D system must enable health services to be active sites of innovation. This includes supporting clinician-led research, embedding real-world trials in clinical settings, and enabling the health system to adopt and scale innovations quickly—especially those that improve outcomes, reduce disparities, and enhance system sustainability. It also includes elevating the importance of consumers as active participants throughout the research pipeline and cycle – from bench to bedside, and from innovation to bedside.

### Invest in the HMR Workforce: Build Talent and Capacity for the Future

A future-focused system must invest in the people who drive health and medical research, development and innovation—training and retaining researchers, clinician-researchers, and innovation, including translation and commercialisation experts. It must also nurture emerging fields like precision medicine, medtech and digital health, and provide pathways for research careers that reflect the diversity of modern Australia. Importantly, Australia will be seeking the same critical skills in an increasingly competitive global environment. This becomes an important of sovereign capability.

## 2. What government, university and business policy settings inhibit R&D and innovation why?

There are a range of government, university and business policy settings that inhibit health and medical R&D and innovation, including:

- Fragmented and Short-Term Government Funding Model
- University Incentives Misaligned with Translation and Impact
- Limited Incentives and Pathways for Health System Innovation
- Lack of investment, capital incentives
- Risk-Averse Business and IP Settings
- Long waiting period between research and approvals
- Inadequate Support for Data Sharing and Collaboration
- Lack of monitoring and evaluation

### Fragmented and Short-Term Government Funding Model

We acknowledge there is considerable investment in the health and medical research, development and innovation sector (with an estimated annual expenditure of approximately \$10billion), however, policy frameworks and funding are not cohesive, there are duplications and gaps, we are reactive, focussing on the now, rather than preparing for the future and our evaluation is largely weak as a precursor to future targeted and larger investment. The health and medical research and innovation pipeline, including the policy and funding landscape, needs to be truly collaborative, transparent and competitive.

Uncoordinated funding sources for health and medical research leads to breaks in the pipeline, inefficiencies and exclusions. Health and medical research is funded and administered by several federal portfolios (Health, Education, Industry and Science, Social Services, Defence & Foreign Affairs). State and territory governments are also providing varying levels of funding, so too are non-government organisations across philanthropy, private healthcare and industry.

While each provides valuable funding, these sources have grown independently with little interscheme coordination, resulting in duplication of effort and inefficient allocation of funding in some places. Most importantly, running multiple, uncoordinated streams of research adds to the administration costs for funders. It is a disincentive for attracting funding from other sources, including private capital and philanthropy. Finally, the complexity of funding sources poses challenges in accurately quantifying the extent and distribution of funding within the health and medical research, development and innovation sector.

Australia needs smarter investment to remain globally competitive. Investing in Australia's health and medical research innovation industry is critical. It contributes to both a healthy nation and a healthy economy. This is not to say there is no investment. Recent initiatives include the National Reconstruction Fund, the Medical Sciences Co-Investment Plan and the Clinical Trials One Stop Shop to name but a few. Additionally, almost \$1.6 billion is dispersed through the National Health and Medical Research Council and the Medical Research Future Fund. Despite this and in addition to the ad hoc approach, 'health innovation' is fundamentally a policy, program and investment orphan – it is not considered the dedicated responsibility of any department or funding program.

### Lack of monitoring and evaluation of health and medical research, development and innovation

Australia's R&D system needs to have accountability, monitoring and evaluation embedded as a fundamental cornerstone of its implementation. Yet, we do not have effective methodology for monitoring and evaluating measures to support innovation, to enable us to understand what works and what doesn't<sup>5</sup>. As such investment in effective research evaluations need to be developed in order to monitor and evaluate all Government initiatives to support activity on the whole research and innovation pipeline and systems improvement. With innovation so central to Australia's future, it is

<sup>&</sup>lt;sup>5</sup> Industry Innovation and Science Australia, 2023, Barriers to collaboration and commercialisation, page 42.

essential that we are able to measure Australian Research and Development activity across the economy.

The Australian Bureau of Statistics undertakes two-yearly surveys of Research and Development activity in Government, Higher Education, Business and the Private Non-profit sectors. (It undertakes two surveys each year alternating between the sectors, so that each sector is measured every second year.) While the surveys are useful, the two-yearly 'staggered' nature of the data collection and analysis makes it difficult to capture an accurate snapshot of progress.

More significantly, the data are not reported in enough level of detail to enable an assessment of the performance of particular sectors, or the impact of particular Government programs. Data on Research and Development are reported by the Australian Bureau of Statistics using the Standard Research Classification Codes of Socioeconomic Objective (SEO) and Field of Research (FOR). These codes use a system whereby activity is initially grouped at a high level; for example, the broad activity of Manufacturing is assigned the Code 86. Specific industries within Manufacturing are assigned a specific code within this division; for example, Human Pharmaceutical products is 8608.

Human Pharmaceuticals manufacturing is a strategic target of the Australian Government's investment in innovation, however the ABS does not provide data on R&D at the four-digit code of 8608. Data is only available at the level of Manufacturing, making it impossible to distinguish expenditure on pharmaceuticals from any of the other 18 categories in the Division. A similar issue arises with Fields of Research, with data on research and development only reported at the two-digit code level. It is not possible, for example to distinguish expenditure on biochemistry and cell biology from expenditure on genetics, physiology, plant biology or zoology. All are simply reported in the ABS statistics as expenditure on '06 Biological Sciences'. This issue was identified in Australia 2030: Prosperity through Innovation, and the Government acted on the report's recommendation to commission a review of how innovation is measured. The Innovation Metrics Review, originally due to publish its report in December 2019, finally reported in 2022.

### University Incentives Misalign with Translation and Impact

It is well known academic metrics still overwhelmingly prioritise publications and citations over translational outcomes or partnerships with health systems and industry. Commercialisation, patient impact, and interdisciplinary collaboration are often undervalued in career progression and research performance metrics. This discourages researchers from pursuing innovation pathways, engaging in collaborative research, or moving into translational roles. This ties into our earlier comments regarding the need for whole of systems reform to achieve the desired future focused outcomes.

"Researchers are not paid enough. They have to fight for funding, meet stringent 'publish or perish' guidelines while also doing the actual research to find the answers to the problems the medical professionals need us to find." (Research Australia Member)

"[An R&D system is] one where academic researchers intersect with industry and that that traditional academic metrics of publications are no longer a benchmark of performance or a metric for performance assessment." (Research Australia member)

### Limited Incentives and Pathways for Health System Innovation

Policy and funding mechanisms do not adequately support clinician-researchers or health services to participate in R&D. Health settings often lack the time, funding, and support to run clinical trials, adopt new technologies, or lead research initiatives. This leads to missed opportunities to embed innovation in care delivery, adapt implementation and evaluate outcomes in real-world settings, and scale proven innovations across the health system. It is also seen as adjunct to core business of

Research Australia

delivering health services for which our state run systems are incentivised and run.

### **Risk-Averse Business and IP Settings**

Australian businesses often lack incentives to invest in early-stage health innovation due to high regulatory barriers, long development timelines, and uncertain returns. University IP policies are frequently complex and rigid, discouraging industry partnerships and slowing commercialisation. This contributes to the "valley of death" in health innovation—where discoveries fail to progress due to lack of industry uptake or capital support. As a result, Australian health and medical innovations are often commercialised overseas or not at all. This must be assessed against realistic expectations of Australia's market size and for us to then find the niche value that we can offer domestically and internationally.

### Long period from research discovery to approvals

The long wait between research discovery and Health Technology Assessment (HTA) or Pharmaceutical Benefits Advisory Committee (PBAC) approvals in Australia is an ongoing challenge for the health and medical research, development and innovation sector, including patients and consumers. Barriers include a combination of structural, regulatory, and systemic factors that can slow the pathway from innovation to patient access. Research Australia supports the full implementation of the recent HTA Review, which should be incorporated into SERD. For further information, see <u>Research Australia's Submission into The Health Technology Assessment Policy and Methods Review</u>.

Omjjara (momelotinib), discovered by Melbourne scientists Professor Andrew Wilks and Dr Chris Burns in 2005, became available on the Pharmaceutical Benefits Scheme (PBS) on 1 April 2025 to treat the rare bone marrow cancer myelofibrosis. The PBS listing marked the culmination of 20-year journey from initial discovery to finally reaching Australian patients. However, the journey to PBS listing was not straightforward, involving multiple acquisitions, unsuccessful clinical trials and millions of dollars in R&D investment. This case study demonstrates the challenges in commercialising biomedical discoveries in Australia and the role of global biopharmaceutical companies in navigating regulatory hurdles, facilitating extensive clinical trials and ensuring patient outcomes are improved. (GSK Case Study)

### Inadequate Support for Data Sharing

There is limited infrastructure and policy support for data integration, open science, and cross-sector collaboration. Privacy and governance frameworks, while essential, are often inconsistently applied and not designed with research and innovation in mind. Health research relies on access to linked, high-quality data and collaboration across institutions. Without nationally consistent data-sharing frameworks and collaborative funding structures, Australia lags behind in areas like AI in healthcare, precision medicine, and real-world evidence generation.

### Inadequate Support for Collaboration

With regards to the need for collaboration across the R&D system and in particular the health and medical research, development and innovation pipeline, challenges in achieving better collaboration between government funding bodies, academia, the private and public health sectors, health charities and industry to achieve health and economic outcomes continue to persist.

These challenges can be viewed at an individual and systemic level and can be explored at multiple levels: leadership and values; governance, policies and systems; workforce; and health and medical

research policies, programs and practice across the pipeline. We need clearly articulated measures of success and impact of collaboration to be developed.

In a recent Research Australia survey of members across the health and medical research, development and innovation pipeline, 43% acknowledged there was little or no collaborative practice across the sector that is working well. The five top factors that were identified were: needing resources specifically allocated to collaborative activities; trust in other organisations; agreed approaches to intellectual property; shared vision and values; and workforce capacity.

# <u>3. What do we need to do to build a national culture of innovation excellence, and engage the public focus on success in R&D and innovation as a key national priority?</u>

Building a national culture of innovation excellence, especially focused on health and medical research, development and innovation, is the vision we need to achieve. It involves systemic changes across education, policy, media, investment, and both industry and public engagement. This includes:

- Building health innovation into the national identity through embedding it in SERD
- Rewiring the education system to enable and empower innovators and critical thinkers
- Invest in a thriving health innovation ecosystem, through de-risking innovation in partnership, and where appropriate, with industry, to accelerate bench to bedside and business
- A governing that body that is strategically appointed, and separate from existing funding organisations, and tasked with monitoring and evaluation.
- Industry partnership
- Engage the Public (community and consumers) as Stakeholders
- Monitoring and Evaluation feedback loops

# Building on the value the public places on health and medical research, development and innovation

At a time when the Australian Government is focused on building Australia's advanced manufacturing capability, Research Australia's 2024 Poll shows the public believe a strong health and medical research industry is critical to Australia's future. And of all the ways governments can support our sector, the most popular is by using their procurement power in healthcare to 'Buy Australian', especially for new and innovative products that solve existing problems.

The COVID pandemic highlighted how vulnerable the globalisation of manufacturing has made every country. With global borders closed, the breakdown in global supply chains led to shortages of essential goods, including medicines and medical equipment. This has led to a belated recognition by policy makers that making things in Australia is important, and a renewed emphasis on domestic manufacturing for essential goods and services.

Public support is critical to health and medical research and innovation and takes many forms. It includes willingness to participate in clinical trials, to allow personal health data to be used for research, donating money, and supporting taxpayer funding for research.

Research Australia has been undertaking annual opinion polling since 2003, gauging the Australian public's perceptions, priorities and expectations on a wide range of issues in health and medical research and innovation.<sup>6</sup> Our most recent poll, conducted in 2024, confirms the importance the public places on government funding for health and medical research and explores what motivates Australians to reach into their own pockets to support research. In every poll since 2003, more funding for health and medical research has been a top 10 priority for Australian Government funding.

There is overwhelming support by the public for local industries and the manufacturing of medical products in Australia with 41.7% of respondents identifying it as Extremely Important and 41.4% identifying it as Very Important. This is likely to increase given the recent changes to geopolitics and trade, and the need to increase Australia's sovereign capabilities.

# <u>4. What types of funding sources, models and/or infrastructure are currently missing or should be expanded for Australian R&D?</u>

As described in Question 2, the landscape for Australian health and medical R&D and innovation is strong in many respects, however, there are some notable gaps and areas where expansion or reform could accelerate impact and global competitiveness. Uncoordinated funding sources for health and medical research, development and innovation leads to breaks in the pipeline, inefficiencies and exclusions.

Health and medical research, development and innovation is funded and administered by several federal portfolios (Health, Education, Industry and Science, Social Services, Defence & Foreign Affairs). State and territory governments are also providing varying levels of funding, so too are non-government organisations across philanthropy, private healthcare and industry. While each provides valuable funding, these sources have grown independently with little inter-scheme coordination, resulting in duplication of effort and inefficient allocation of funding in some places.

Delays in research funding results in teams being dispersed and research, valuable time, investment, and knowledge is then lost. Running multiple, uncoordinated streams of research adds to the administration costs for funders. It is a disincentive for attracting funding from other sources, including private capital and philanthropy. Finally, the complexity of funding sources poses challenges in accurately quantifying the extent and distribution of funding within the health and medical research, development and innovation sector.

<sup>&</sup>lt;sup>6</sup> https://researchaustralia.org/reports/public-opinion-polling-2/

Fundamentally, Australia needs to ensure it:

- Establishes a measurable path to R & D investment of 3% GDP
- Better coordinates funding
- Defines a pathway to fund the full cost of research, in a rational and sustainable way, including infrastructure
- Bridges translational funding gaps
- Expands long-term funding models
- Activates government procurement powers
- Boosts investment in research infrastructure, including the Centre for Disease Control, clinical trials one stop shop, and data and digital health infrastructure
- Grows venture capital and commercialisation pipelines
- Increase philanthropically-based health and medical research, development and innovation
- Diversifying International funding streams, such as Horizons Europe

#### Establish a measurable path to R & D investment of 3% GDP

While the Government is increasingly filling the gaps in Australia's pipeline for R&D, the level of investment in R&D by both Governments and the private sector is still well below the levels required to achieve the Government's ambitions for a prosperous and productive nation. The Strategic Examination of R&D Discussion paper highlights the historic decline in R&D as a proportion of GDP and that we are well below the OECD average expenditure.

The Government must significantly increase investment in R&D throughout the pipeline, from discovery science to commercialisation. We are hopeful the Strategic Examination into R&D will elevate the critical need for increased investment in R&D, with a clear pathway to R&D investment of at least 3% of GDP. Given more than a quarter (26%) of Australia R&D is spent on health and medical research, there needs to be a dedicated focus in the Strategic Examination of R&D on HMR.

### Better MREA and MRFF Coordination

The Government's review into better coordination of NHMRC's Medical Research Endowment Account and the Medical Research Future Fund will provide opportunities for smarter investment, enhancing Australian R&D. This review, including revisiting the proposed legislative amendments to the MRFF's investment mandate to improve the returns available as research funding, provides the opportunity to improve the overall operations of the MRFF and MREA.

#### Defining a pathway to fund the full cost of research, including infrastructure

Affordable and consistent funding streams are the anchor points for research and development including in health. Funding the full cost of research is essential for advancing health and medical research and the development and innovation that follows. By fully funding research, governments, institutions, and private sectors can foster an environment where health and medical researchers have the resources needed to safeguarding public health and driving economic growth through medical innovation. A definitive pathway to reaching full cost of research needs to be developed acknowledging what's working well and what the country has defined as necessary to its innovation economy of the future.

### Bridge translational funding gaps

As noted in the SERD discussion paper, there's often a "valley of death" between early-stage research (well-supported by NHMRC, MRFF) and late-stage private investment.

Australia needs targeted health innovation funds that include Translational and Commercialisation funds to support pilot trials, scale-up studies, or tech validation. The Government should monitor the demand for new programs (Australia's Economic Accelerator, Start Up Year, the Industry Growth Program) and increase the level of funding where warranted.

Another approach could be to explore a similar model to the UK's Biomedical Catalyst. The Biomedical Catalyst is an ongoing scheme that assists small and medium-sized businesses test and develop innovative health and care solutions across life sciences, including therapeutics, medical devices, and digital health.

### Expand long-term funding models

One suggestion for increasing long-term investigator-initiated grants linked to national priorities could include expanding MRFF Frontier Health and Medical Research program into a recurrent programme. Frontiers is an economies-of-scale approach that takes in both public and privately funded collaborative research in a medium to higher risk environment. The opportunity for private companies to have government support for projects that are at a slightly more advanced stage or pre-market stage not only derisks (to some extent) but contributes to an environment of translation be it commercial or clinical.

Another example could be the dedicated creation of national or regional bio-medical and bio-tech innovation hubs that unite hospitals, biotech, and startups. Similar to the Gold Coast Health and Knowledge Precinct. These sorts of hubs enable collaboration and initiatives across pipelines and the ecosystem, strengthening understanding and workforce capabilities, and creating opportunities for health innovation to thrive directly across bench to bedside and business.

### Government procurement powers to activate Australian innovation

Building on 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 and activate innovation, Australia develop a similar model to the US Government's Biomedical Advanced Research and Development Authority (BARDA). Through establishing our own BARDA system, the Australian Government could use its role as customer to purchase medical products to support Australian R&D and manufacturing, while also protecting Australia's population and ensuring supply of essential medical products, including in emergencies. This could be directly aligned to the streamlined funding off innovation across the pipeline, whereby BARDA would indicate interest in an area of exploration or product, that could be supported by Frontiers or another accelerator stream of funding.

BARDA would also provide the infrastructure to enable the collaboration between private companies, pharmaceuticals, therapeutics and medical devices.<sup>7</sup> Australia has a similar model in defence, with the Advanced Strategic Capabilities Accelerator.<sup>8</sup>

Case Study: Using an Australian BARDA to increase health innovation in rural, regional and remote Australia

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.<sup>1</sup> 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.

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. This is just one example of how such a program could be used to further the Government's objective of more equitable access to healthcare for marginalised and systemic disadvantaged communities.

Boost investment in national infrastructure such as the Centre for Disease Control, clinical trials National One Stop Shop, and data and digital health infrastructure The Australian Centre for Disease Control (CDC), with its extensive data gathering and analysis capabilities and its responsibility for assessing and mediating the risks of future health emergencies, will be ideally placed to undertake the function of coordinating the application of research, development and innovation in both prevention and control of disease, communicable and noncommunicable. The Australian CDC could also play a role in identifying promising interventions (e.g. from clinical trials) with the potential to help address a disease and support the activities needed to help implement and test the intervention in a pilot program and its subsequent scaling up into routine care. Research Australia encourages the expansion of the recommendations to include direction of emergency funding and a wider remit in supporting the alignment of Australian research and innovation with unmet health needs.

The implementation and ongoing sustainability of the Clinical Trials Reforms Agenda, including the National One Stop Shop (NOSS) should be monitored and evaluated, to ensure that it meets its purpose of streamlining health and medical research through a single, national approvals and data system for clinical trials. The NOSS, and associated reforms related to Clinical Trials have the potential to

<sup>&</sup>lt;sup>7</sup> https://www.vaxxas.com/

<sup>&</sup>lt;sup>8</sup> https://www.asca.gov.au/

strengthen Australia as a preferred destination for clinical trials. Improving the environment for clinical trials enables Australian patients to benefit from the latest medicines and technologies developed both in Australia and overseas. It also helps Australian health and medical research, development and innovation to flourish in a competitive and lucrative world market.

Another key infrastructure investment must be on unlocking Australia's healthcare data, as noted in the Digital Health CRC SERD submission. This can be prioritised *by standardising and uniting the secure data environment infrastructure, data governance and access protocols to data for both public and private authenticated researchers. R&D has a key role to play in demonstrating and supporting adoption of the data standards and data governance frameworks required to establishing a network of healthcare data that can be the foundation for health and medical research and innovation over successive quintennial phases of activity.* 

### Venture Capital & Angel Investment in health and medical research, development and innovation

Australia has limited biotech-focused venture capital compared to the US and Europe. Incentivise private investment through co-investment schemes (like BioBridge or Catalyst Funds) and offer increased tax incentives for health-tech/medtech angels.

For example, Bio-bridges enable key connections between clinicians, researchers, and industry within the health innovation ecosystems. As mentioned earlier, Frontiers or the Biomedical Translation Fund (BTF) which aims to invest in promising biomedical discoveries and assist in their commercialisation and encourage the development of companies commercialising biomedical discoveries by addressing capital and management constraints would be an ideal starting point. However, with the lack of alignment across the health and medical research, development and innovation pipeline, these individual programs are not cohesive, joined up and achieving their full potential.

<u>Philanthropy-backed health and medical research, development and innovation</u> Philanthropic funding for medical research, development and innovation is not as structurally integrated or incentivised as it is in other countries. We need better frameworks to leverage philanthropic investment and foster long-term partnerships between donors and research institutions.

Additionally, it is critical to recognise the important role charities/not-for-profit organisations play in both undertaking research, development and innovation and funding it. Notably, around 87% of all R&D undertaken in the not-for-profit sector occurs in health. For further information, see Research Australia's report <u>here</u>. In developing the SERD, recognition of this crucial role most be acknowledged.

<u>Diversifying International funding streams and relations, such as Horizons Europe</u> As noted previously, Australia needs to diversify its International relations and funding streams. The current rapidly changing, and unpredictable geopolitical environment is requiring this even more than immediately after Covid. It is critical to diversify sources of funding so that Australia does not become vulnerable when the major source of funding potentially leaves the scene.

Australia should seek associate country status in Horizon Europe, which would provide a greater level of access to EU research and innovation funding for Australian researchers and industry. Joining the

EU's Horizon poses several benefits/opportunities for the Australian researchers and organisations, including:

- Providing access to the world's largest research fund, partnerships with world leaders (from EU and EU partners) on major global challenges, access to leading scientists and industry opportunities; and
- Open more opportunities for greater international collaboration.

# <u>5. What changes are needed to enhance the role of research institutions and businesses (including startups, small businesses, medium businesses and large organisations) in Australia's R&D system?</u>

In addition to the response provided in Questions 3 and 4, there are a range of systemic and cultural reforms needed to enhance the role of research institutions and businesses in Australia's health and medical research, development and innovation system. As mentioned throughout the submission, the SERD and the current development of the National Health and Medical Research Strategy cannot affort to be undertaken in isolation of each other. This will enable critically needed integration and elevation of health and medical research, development and innovation as a fundamental sector of the broader R&D sector. These include:

- Enabling collaboration across the pipeline and workforce through systems and cultural change; and
- Specific plans for health and medical research, development and innovation, such as a National Medical Products Industry Plan

### Enabling Collaboration

Health and medical research, development and innovation occurs in a range of settings (universities, medical research institutes, healthcare settings, industry) and requires collaboration across the pipeline. There are many ways this can be enhanced across the pipeline, mentioned previously, and include:

- Incentivising collaboration, through structuring funding opportunities to require collaboration
- Shared infrastructure and spaces, such as innovation precincts
- Increase entrepreneurial culture in research through embedding as a post-graduate attribute.
- Incentivise multi-disciplinary teams to combine research, tech, business and clinical skills.
- Increase research mobility between sectors, eg the REDI initiative

MTP Connect has delivered many programs for the Australian Government including the \$32 million Researcher Exchange and Development within Industry (REDI) initiative funded through the MRFF. Launched in 2020, the four-year REDI initiative aimed to build the MTP workforce, address skills gaps and enhance the entrepreneurial ecosystem to improve Australia's Medical Technology and Pharmaceuticals workforce. It started with a comprehensive skills gap analysis and has subsequently developed and implemented a range of training and placement programs to target the identified gaps.<sup>9</sup> The program has now ceased due to a lack of funding, despite strong support from industry and academic partners. This, and other similar programs should be reinstated.

#### National Medical Products Industry Plan

Research Australia recommends Australia should establish national plans for health and medical research, development and innovation as a key industry with the potential for future growth and in areas of critical national security and sovereign capability. Research Australia has called for several years for Australia to set a goal of becoming a net exporter of medical products. Medical products include medicines and vaccines, diagnostic tests, medical devices, technology and equipment. To enable this, we recommend a National Medical Products Industry Plan, covering the whole pipeline from research through to product development, commercialisation and domestic manufacturing, with the objective of making Australia a net exporter of medical products, and securing domestic supply of critical products. This would complement the existing National Health and Medical Research Strategy and assist the whole pipeline of health and medical research, development and innovation, including manufacturing with a clear direction.

The COVID-19 pandemic revealed how exposed Australia's supply chain is for essential medical products, with significant shortages of some medicines during the COVID-19 pandemic. In addition to medicines these shortages extended to other supplies required by our hospitals and health services. While PPE was a well-publicised identified shortage, there were many other areas where supplies were in short supply, such as reagents required for COVID testing.<sup>10</sup> In October 2024, the government announced that it it will finalise the establishment of the much-anticipated Australian Centre for Disease Control (CDC) in response to the independent inquiry into Australia's response to the COVID-19 pandemic.

The Australian Government is currently implementing an Australian Centre for Disease Control, which has assumed responsibility for Australia's National Medical Stockpile. While warehousing products in a National Medical Stockpile is one solution to supply chain risks, expanded domestic manufacturing is another approach which can further secure Australia's supplies, particularly in the face of an extended medical emergency, or when novel products are required. With its extensive data gathering and analysis capabilities and its responsibility for assessing and mediating the risks of future health emergencies, the CDC would be ideally placed to provide input to a National Medical Products Industry Plan to prioritise manufacturing for medical products where domestic manufacturing capability is considered essential to Australia's national security.

One of the objectives of the \$15 billion National Reconstruction Fund is to address supply chain vulnerabilities. In the case of the \$1.5 billion allocated for medical products, the aim is to 'Leverage Australia's world-leading research to provide essential supplies such as medical devices, personal

<sup>&</sup>lt;sup>9</sup> https://www.mtpconnect.org.au/programs/REDI

<sup>&</sup>lt;sup>10</sup> See for example, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7833915/ and https://www.theguardian.com/australia-news/2022/jan/14/pressure-grows-on-australias-pcr-testing-amid-supply-chain-issues-and-omicron-case-surge

protective equipment, medicines and vaccines.<sup>11</sup> The scope for the NRF and the CDC to work together to support the supply chain for critical medicines in Australia is one example of why a whole of government approach to the CDC is critical, and the role a National Medical Products Industry Plan can play. A National Medical Products Industry Plan would complement and coordinate the work of the CDC in identifying essential medical products and the role of the NRF in supporting the manufacture of essential supplies.

This could also be aligned to the Clinical Trials Reform Agenda, including the National One Stop Shop. 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 available for use with trial participants. 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. Achieving regulatory approval for a product requires having an existing manufacturing capability that meets the necessary standards- this requires an investment up front as part of securing regulatory approval, before a business can move to manufacture and commercialise the product.

Having more of this clinical (small) scale 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.
- Provide jobs and expertise to support these activities Plant management, validation experts, process engineers, regulatory advisors, quality professionals, process equipment vendors, transport and logistics etc.

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

<sup>&</sup>lt;sup>11</sup> Australian Government Department of Industry Science and Resources, 2022, National Reconstruction Fund Consultation Paper, page 2

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. 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. The need for this type of manufacturing facility was identified as a priority in the 2021 NCRIS Roadmap, currently under review, and there is scope to use funding

through the next NCRIS Investment Plan to deliver this.<sup>12</sup> There is also scope for the National Reconstruction Fund to play a role.

In addition to the national security benefits, the economic benefit from taking a strategic approach to the medical products industry. 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 health innovation.

#### Pharmaceutical Manufacturing as a case study

In 2023, global exports of pharmaceutical products accounted for USD747 billion. Australia had exports of USD2.39 billion, or 0.32% of global exports.<sup>1</sup>

In the same year (2023), Australia imported pharmaceutical products valued at \$USD9.68 billion, or 1.29% of global pharmaceutical imports.<sup>1</sup> Exports to the USA have received intense focus recently; while the focus has been on beef, pharmaceuticals and medical instruments are Australia's third and fourth largest exports to the USA, behind meat and gold.<sup>1</sup>

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.

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.

<sup>&</sup>lt;sup>12</sup> Australian Government, 2022, 2021 National Collaborative Research Infrastructure Roadmap, page 56

### 6. How should Australia support basic or 'discovery' research?

It is fundamental that the any Government supports basic or discovery science. Any examination of direct or indirect R&D should be inclusive of discovery science. It should not be a question of if, but rather how, as this question poses.

Discovery science is the precursor to any further research activity within the ecosystem. It must have equal weight when considering what to fund in the national interests and should be ring fenced and have sustainable investment in line with inflation to ensure not only the research is undertaken, but to recognise that it is the global academic evaluation metric that ranks Australia as knowledge intensive and academically rigorous, which then provides the backdrop for translation and subsequent investment.

Fundamentally, Australia should support basic or 'discovery' research by ensuring it has a consistent, predictable funding mechanism that ensures we have a solid discovery foundation that not only supports the building of new ideas, but also that we are developing and delivering on research and knowledge excellence. This can be achieved by increasing government funding for discovery science through the NHMRC and ARC is critical.

In addition it is critical that the research infrastructure then supports discovery research. For example, the Government should use the National Collaborative Infrastructure Scheme (NCRIS) Roadmap Advisory Group's recommendations to commit new funding to NCRIS beyond the funding already allocated in the Budget forward estimates of at least a further \$100 million per annum. The Advisory Group's recommendations will enable this additional investment to be made effectively, in a manner which supports valuable research infrastructure and the expected recommendations of the Universities Accord Expert Panel.

As will be detailed in Question 7, in order to strengthen basic or discovery science, we also need to increase invest in enabling Early and Mid Career Researchers.

### 7. What should we do to attract, develop and retain an R&D workforce suitable for Australia's future needs?

Retain: Sustained/long-term contracts; it's hard to be a worker with a kid and a mortgage when you're not sure if you'll have a job next year. Politicians get four year terms; why should a researcher have any less. Develop: Allow for failure and risk. The current performance system still promotes papers and grants as the metrics of success. Why don't we hire and promote those with a serendipitous and unplanned discovery, an open access database, and those special connectors who enable collaboration without ever being senior author? (Research Australia Member)

Being a specialist consultant in a health service lacks career progression opportunities without research or leadership aspects. Genuine quarantined time for - and value attributed to -leadership and research service would incentivise retention. Under the current model, people who do research just work harder than others - while those who don't get to go home on time. (Research Australia Member)

Australia needs to activate a responsive, supported and diverse health and medical research, development and innovation workforce. The health and medical research and innovation sector workforce is located in a range of settings (universities, medical research institutes, healthcare settings, industry), requires a variety of different techniques and approaches, constantly evolving, and requires adaptive skills. Understanding not just the skills and roles required today but those we will need in ten years' time and beyond is critical to our future success in undertaking research, commercialising the outcomes and building the manufacturing industries that will enable us to capitalise on our discoveries. Health and medical research, development and innovation, like many sectors have skills shortages in particular areas and oversupply in others. In addition, Australia will be seeking the same critical skills in an increasingly competitive global environment. This becomes an important sovereign capability.

There remain particular gaps in workforce investment, such as Clinician Researchers, Early-Mid Career Researchers, and lived-experience researchers<sup>13</sup>. Clinician researchers are health practitioners including medical, nursing and midwifery, allied health or other health professions, active in research. Effectively, clinician researchers hold two roles – being clinicians or health care practitioners and conducting research. By being truly embedded in Australia's health system, clinician researchers play an important bridging role between the research world and the health system, delivering better care and health outcomes for Australians. However, the decline in the clinician researcher workforce is a problem affecting both the traditional research side of the health and medical research pipeline – universities and medical research institutes – and the health system end of the pipeline – local health districts, primary health networks and public and private hospitals. Prioritising clinician researchers and new workforce models across the entire health and medical research, development and innovation ecosystem will strengthen the workforce and a research active health system.

Workforce development for priority groups needs to include strategies for creating and maintaining organisational environments that enable health and medical researchers to thrive. For example insufficient priority and under resourcing are currently preventing the sector wide, comprehensive and routine adoption of measures for Early and Mid-Career Researchers to thrive. Individual institutions are implementing their own approaches, resulting in isolated improvements and islands of excellence, rather than system wide improvement, and nationwide growth of investing in the future the workforce<sup>14</sup>.

Greater clarity of career pathways is essential to enable individuals to have mobility across the pipeline. For example, in a knowledge intensive industry like medical products, better defined pathways between academia and industry must be established, encouraged and incentivised to build new industries and foster true innovation. The private sector research, development and innovation workforce is a critical component of this mix, but a relatively small component in the Australian context. Increasing employment in private sector research organisations and increasing private sector R&D are critical to the long-term future of our entire research and innovation workforce and our capacity to increase advanced manufacturing<sup>15</sup>.

<sup>14</sup> Research Australia. <u>Measures to Support Early and Mid Career Researchers</u>. (2024)

<sup>&</sup>lt;sup>13</sup> Research Australia. <u>Research Australia Submission MRFF Priorities and MRFF Act Review</u>. (2024)

<sup>&</sup>lt;sup>15</sup> Research Australia. <u>Developing Advanced Manufacturing in Australia</u>. (2023)

Furthermore, due to the siloed approach to health and medical research, development and innovation, current policies are working in contradiction with each other. For example, there is recognition of the importance of Australia's EMCRs and clinician researchers, however, policy decisions in other portfolios are reducing funding to universities.

As in all the priorities there is a need to increase diversity within the workforce, such as the participation and retention of women into research leadership positions, as critical for both economic participation, improved health and wellbeing of marginalised groups, likelihood of increased focus in health and medical research in research that impacts on marginalised groups.

In response to the lack of investment in workforce, there is a need to develop a National Health and Medical Research, Development and Innovation Workforce plan. The Plan should have a long-term vision with immediate incentives for boosting the current workforce. The actions need to be strategic, embed and leverage other workforce and employment strategies, such as gender responsive budgeting to address the gender disparity within the sector, especially in research leadership positions. Overall, the plan should:

- address the whole pipeline of skills required from initial discovery through to innovation, including translation, entrepreneurship, product development, commercialisation and manufacturing
- support a highly skilled and sustainable research workforce with circular mobility between academia, industry and other sectors across the pipeline
- align with changes required in our K-12 education curriculum and national plans to increase science
- be aligned with key measures across other workforce strategies
- ensure universities (and others) are equipped to train the next generation of researchers
- retains Australian researchers and attracts the world's best talent
- prioritise marginalised workforces

### <u>A focus on Early – Mid Career Researchers</u>

To support the gap in longitudinal data for priority workforces, the development of a national longitudinal survey of EMCRs is required. This survey would build on a previous survey, supported by Research Australia, with a purpose to provide the sector a regular environmental scan of key issues and monitor trends; respond to a gap in current workforce strategies and data, provide a national picture; engage directly with policy frameworks and institutions in identifying opportunities and systems changes; and identify and recommend positive systems change in across health and medical research, development and innovation sectors in order to develop a sustainable future workforce.

The survey will provide the sector a regular environmental scan of key issues and monitor trends; should engage directly with policy frameworks and institutions in identifying opportunities and systems changes; and identifies and recommend positive systems change across health and medical research, development and innovation sectors in order for a sustainable future workforce.

# <u>8. How can First Nations knowledge and leadership be elevated throughout Australia's R&D system?</u>

The SERD should identify key actions in line with the Closing the Gap Priority Reforms. This includes through developing partnerships; dedicating a focus on strengthening the community-controlled sector, as well as Aboriginal and Torres Strait Islander researchers, developers and innovators; addressing systemic racism underpinning the privileging of western research, development and innovation frameworks; and ensuring that data is aligned with emerging fields embedded within Indigenous data sovereignty.

Research Australia recognises the strengths of the Aboriginal and Torres Strait Islander research, development and innovation sector and the Community Controlled Health Sector, and the need for continued investment to elevate the application of such expertise and frameworks across the health and medical research, development and innovation sector, not only for First Nations peoples and communities, but also for Australia more broadly.

## <u>9. What incentives do business leaders need to recognise the value of R&D investment, and to build R&D activities in Australia?</u>

The leading role industry plays in health and medical research, development and innovation is clear. Analysis undertaken by Research Australia shows that 31% of all health and medical research expenditure is in the private sector. If we have a look at the overarching view, Australia is home to over 1,200 biotech companies. There are 178 life sciences companies listed on the ASX representing a market capitalisation of \$255 billion.

We are ranked 5<sup>th</sup> in the World Index of Healthcare Innovation. This is only set to increase. It's a solid baseline from which we are operating. Since 2018, the sector has been expected to significantly increase its contribution to our society and economy, with:

- \$8 billion in Gross Value Added
- 80,000 jobs supported
- 12 billion dollars in manufacturing exports<sup>16</sup>

Clearly supporting our healthcare innovation industry is crucial to Australia's economy.

To encourage business leaders to recognise the value of health and medical research and development, and innovation, and to invest and build R&D activities in Australia, a combination of financial, strategic, and systemic incentives is needed. These should all be included in the National Health and

<sup>&</sup>lt;sup>16</sup> Projections based on targets set by the 2018 Health and Medical Research Industry Growth Plan, and growth trajectory over 2016-2019 as reported by the MTPConnect 2020 Sector Competiveness Plan as cited in Biotechnology in Australia - strategic plan for health and medicine

Medical Research Strategy, and supported by a clear vision, funding commitments, alignment of research priorities with national priorities and health challenges and commercial opportunities.

However, as mentioned in Question 2, we need to build a national culture of innovation excellence, especially focused on health and medical research, development and innovation to create a culture of recognising the value of health and medical research, development and innovation investments, and to build activity in Australia. These incentives should reduce risk, highlight potential returns, and align with broader national and business objectives. Some examples include:

- Financial incentives within funding programs to de-risk private investment in clinical trials, digital health, or biotechnology.
- Streamlined regulatory pathways, to accelerated approvals and support for clinical trials and innovative health technologies.; as well as align with international regulatory frameworks to support global market access.
- Intellectual Property (IP) support to assist in navigating and protecting IP rights
- Infrastructure and ecosystem support, for example subsidised access to biotech labs, clinical trial networks, AI health data platforms, and the investment of national networks for biobanking, genomics, and proteomics research.
- Talent and workforce development, support for industry PhDs, postdocs, and internships in private companies.
- Innovation clusters and hubs such as investment in health innovation precincts, especially around universities and hospitals; and the co-location incentives for startups and corporates near research institutions.
- Market access and global opportunities, such as biobridges and strategic partnerships.
- Investment Promotion, for example, elevating Australia as a preferred destination for global pharma and medtech R&D and marketing Australia's strong clinical trials ecosystem and world-class research.

### Government procurement powers to activate Australian innovation

As mentioned in Question 4, specifically, one incentive could build on 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 and activate innovation, Australia could develop a similar model to the US Government's Biomedical Advanced Research and Development Authority (BARDA). Through establishing our own BARDA system, the Australian Government could use its role as customer to purchase medical products to support Australian R&D and manufacturing, while also protecting Australia's population and ensuring supply of essential medical products, including in emergencies. Knowing that there is a 'cornerstone' buyer for a product if the development is successful can help de-risk the R&D and commercialisation process and make it easier for a business to attract finance. Australia has a similar model in defence, with the Advanced Strategic Capabilities Accelerator.<sup>17</sup>

<sup>&</sup>lt;sup>17</sup> https://www.asca.gov.au/

In Research Australia's 2024 Opinion Poll the Australian public supported a strong health and medical research industry as critical to Australia's future. And of all the ways governments can support our sector, the most popular is by using their procurement power in healthcare to 'Buy Australian', especially for new and innovative products that solve existing problems.<sup>18</sup>

### <u>10. What should be measured to assess the value and impact of R&D</u> investments?

Measuring the value and impact of health and medical research, development and innovation investments requires a blend of economic, health, scientific, innovation, policy and societal indicators. Accountability, monitoring and evaluation must be embedded as a fundamental cornerstone of Australia's R&D system. Given the contribution health and medical research, development and innovation contributes to our nation, it is essential that we are able to specifically measure health and medical research, development and innovation investments at a programmatic and systemic level, as well as including on impact on burden of disease, productivity, economic and industry impact.

As highlighted throughout the Submission, any value and impact measurements must be directly aligned to the National Health and Medical Research Strategy, currently in development. The National Strategy should have a long term vision, supported by a Theory of Change, monitoring and evaluation Framework (M&E Framework). The M&E Framework should identify gaps in available R&D data and implement strategies to address such gaps. For example, Australia does not have effective methodology for monitoring and evaluating measures to support innovation, to enable us to understand what works and what doesn't (Industry Innovation and Science Australia, 2023, Barriers to collaboration and commercialisation, p 42). As such, the SERD and National Strategy and its M&E Framework should then identify investments that not only will provide the data for the monitoring and evaluation of the Strategy or implementation of recommendations, but will also contribute to the whole R&D ecosystem and systems improvement through improving data collection.

As noted in Question 2, there are specific examples of the gap in measuring health and medical research, development and innovation as a priority in R&D. For example, despite Human Pharmaceuticals manufacturing being a strategic target of the Australian Government's investment in innovation, the ABS does not provide data on R&D detailing Human Pharmaceuticals. Data is only available at the level of Manufacturing, making it impossible to distinguish expenditure on pharmaceuticals from any of the other 18 categories in the Division. A similar issue arises with Fields of Research, with data on research and development only reported at the two-digit code level. It is not possible, for example to distinguish expenditure on biochemistry and cell biology from expenditure on genetics, physiology, plant biology or zoology. All are simply reported in the ABS statistics as expenditure on '06 Biological Sciences'. As a starting point, Australia should act on the Innovation Metrics Review; and restore funding to the Australian Bureau of Statistics to improve the capture and

<sup>&</sup>lt;sup>18</sup> https://researchaustralia.org/reports/public-opinion-polling-2/

analysis of data relating to R&D in Australia as first steps to developing a proper framework for measuring the impact of Australian research and innovation.

It is vital that we are able to appropriately measure and evaluate the performance of innovation in Australia and the effectiveness of Government programs to ensure transparent and efficient use of public funds with the highest possible positive impact and outcomes.

### Conclusion

Positioning Australia as a nation with a strong advanced health and medical manufacturing base and a diversified economy 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 GDPImproving the health of the Australian population is central to improving national productivity. Australian health and medical research, development and innovation leads to new industries, including in medicine, technologies and treatments.

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, development and innovation in Australia continues to tackle how to best deliver healthcare, providing critical evidence that addresses clinically important unanswered questions. This includes from a national security perspective, where a strategic investment in enhanced medical production and preparation for the next pandemic can assist Australians in access to vital medical products at future times of crisis.

In addition to raising national prosperity and diversifying our economy, smarter investment in health and medical research, development 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, as well as industries we are yet to imagine.

The SERD and the National Health and Medical Research Strategy provides a real opportunity for the Australian Government to consolidate the steps it has already taken 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. Much of this is about utilising the various reviews and initiatives (including beyond the SERD and National Strategy, such as the HTA Review and Implementation Plan) that are currently in development or recently completed to coordinate and then significantly scale up the Government's investment in health and medical research, development and innovation.

All Australians benefit from strong investment in health and medical research, development and innovation. The opportunity provided through the sector is immense for both the health and wealth of our nation.

Research Australia

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, development and innovation can play a leading role in supporting productivity gains, both health and financial in securing Australia's healthy future, .

### About Research Australia

Research Australia is the national alliance and peak body representing the entire Australian health and medical research and innovation pipeline. Our membership is drawn from the whole pipeline of health and medical research and innovation, from universities and medical research institutes to charities and patient groups, and health care providers and companies commercialising new health technologies.

Research Australia was established in December 2000 from the recommendations of the Australian Government's Strategic Review into Health and Medical Research. Peter Wills AC led this strategic review and was instrumental in Research Australia being established. Our former Chair and Patron, Emeritus Professor Christine Bennett AO, was Chair of the Rudd Government's National Health and Hospitals Reform Commission. Research Australia's current Chair, Mr Martin Bowles AO PSM is a former Secretary of the Department of Health and the Department of Immigration and is national CEO of Calvary Health Care.

We have 20 years of demonstrated policy expertise for health and medical research, development and innovation, including providing credible, politically neutral, policy advice to governments and our members. Health and medical research, development and innovation is a complex ecosystem sustained by many participants and multiple funding streams. We have been instrumental in policy development to support the sector over the past 20 years, not least working with the then government to double funding for the NHMRC and through the McKeon Review to establish the Medical Research Future Fund.

Research Australia is in the unique and privileged position of having visibility over the breadth of medical research, development and innovation undertaken in Australia and the public, commercial and philanthropic funding that drives it. We see the policy levers and barriers differently – we understand, and we reflect collaboration across the pipelines. This includes the policy levers and barriers that sit across the health and medical research, development and innovation policy ecosystem – industry, health, education, science, digital, social policy, environment, defence to name a few.

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