

2022-23 PRE-BUDGET SUBMISSION

December 2021

ABOUT RESEARCH AUSTRALIA

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

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

Our role:

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

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

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Summary of recommendations

Managing COVID-19 and preparing for the next pandemic	The Australian Government should initiate and lead a whole of governments review of pandemic preparedness and the development of a plan to mitigate the economic, societal and health impacts of the next pandemic.
RNA: seizing the initiative	The Government should establish a National RNA Technology Mission, building on the work the Commonwealth has already undertaken to establish an onshore mRNA manufacturing capability.
Invest in Innovation	The Government should outline a substantially increased investment in national innovation and commit to increasing its spending on research and development to at least 0.75% of GDP annually, over the forward estimates.
	Australia needs to set some clear and ambitious goals if we are to position ourselves for the economic success the Prime Minister has stated as his Government's objective. For example, one such goal would be to become a net exporter of pharmaceuticals by 2035.
Medical Products Manufacturing for clinical trials	Research Australia submits the Commonwealth Government should investigate how it can further support the development of domestic manufacturing capability of medical products for clinical trials. This includes funding a feasibility study into establishing one or more manufacturing facilities for clinical trial materials to capitalise on Australia's global competitive advantage in clinical trials. It should investigate the provision of facilities in partnership with the health and medical research and innovation sector and funding models involving consortia of government and private investors. These facilities could provide a base for establishing full scale production capability for medical products in Australia, enabling new home-grown medical companies to manufacture here.
Government Procurement to support medical product manufacturing	The Government should develop an Australian equivalent of the US Government's Biomedical Advanced Research and Development Authority (BARDA) and Centers for Innovation in Advanced Development and Manufacturing (CIADM), with the objective of supporting the development and domestic manufacture of new medical products needed to protect the health of the Australian population. As a major purchaser of healthcare products and services on behalf of the Australian population, medical products provide an ideal opportunity for

	the Australian Government to use its role as customer to support Australian R&D and manufacturing.
NHMRC and ARC Funding	Funding for the research programs of the National Health and Medical Research Council (NHMRC) and Australian Research Council (ARC) must be increased in real terms and in their own right, in the 2022-23 Budget and over the forward estimates. Funding for these programs underpins the whole of Australia's research and innovation pipeline.
Indirect Research Costs	Research Australia proposes the Chief Scientist lead a review of the funding of indirect research costs to establish a sustainable and equitable funding program. The cuts to the Research Block Grants outlined in the October 2020 Budget and retained in the May 2021 Budget must be reversed. Research Block Grants are essential to our universities' capacity to undertake research. The pool of funding for the Research Support Program and the Research Training Program needs to be increased in the 2022-23 Budget to reflect the inclusion of MRFF competitive grants in the Programs. In a similar manner, an additional stream of the IRIISS program needs to be funded by the Department of Health to cover the indirect costs associated with MRFF funding incurred by IMRIs. This funding should be administered by the NHMRC.
Patent Box	The Government should establish an expert working group with industry representation to support the design and implementation of the Patent Box.
Research Infrastructure	The Government should make a commitment in the 2022-23 Budget to expand the existing Government's \$1.9 billion, 12 year funding envelope for national research infrastructure in support of the 2021 National Research Infrastructure Roadmap. This increase is necessary to better support the 2021 National Research Infrastructure Roadmap.
Measuring Innovation Performance	Research Australia urges the Government to make provision in the 2022-23 Budget for the implementation of the Innovation Metrics Review's recommendations. 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.

Investing in Prevention	Research Australia urges the Government to use the Budget to make a significant multi-year commitment to fund implementation of the new National Preventive Health Strategy 2021-2030.
Government capacity to share and release data	The Government should make provision in the 2022-23 Budget for the infrastructure needed to support the new Data Availability and Transparency Bill in anticipation of its passage through the Parliament in 2022. Better use of Commonwealth Government data for research purposes will support better delivery of healthcare and innovation.
Utilising Health Data	Research Australia urges the Government to use the 2022-23 Budget to ensure the AIHW is adequately resourced to prepare for and undertake the significant new role of preparing and providing de-identified My Health Record data for research and public health purposes.

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Introduction

The COVID-19 pandemic has had an enormous toll on the Australian community and globally. The economic, social and health cost has been enormous.

The impact, could, of course, have been much greater. The Australian Government and the state and territory governments have responded rapidly and effectively with the support of the vast majority of the Australian people. Economic incentives and business subsidies have protected livelihoods, just as the public health measures have saved lives. The willingness of governments to act on scientific advice has been one of the hallmarks of Australia's response. As a consequence, the impact in Australia has been comparatively mild, and we have one of the highest vaccination rates in the world.

As the national peak body for Australian health and medical research, Research Australia has broad insight into the massive breadth and depth of the health and medical research and innovation sector's response to the COVID-19 pandemic. It is a response that has mobilised researchers and support staff from across universities, medical research institutes, pharmaceutical companies, public and private hospitals and not-for-profits.

Australia's response to COVID-19 has been so broad and deep because of previous investments in the nation's research and innovation capacity. This capacity, and the funding that underpins it, cannot be taken for granted. There is no guarantee that Australia's health and medical research and innovation community will be equally well placed to respond to a future pandemic.

The purpose of our submission is to make the case for why maintaining and expanding this existing capacity for health and medical research and innovation is in the national interest.

Much of what we have proposed is a natural pathway to a national health and medical research strategy that creates opportunities for medical innovation and exports. This national approach plays to Australia's strengths and will provide a framework for productive investment that can realise not only the obvious health benefits for the population but importantly create the industries and jobs of the future.

Research, innovation and the future

The last year has seen an increasing recognition of the importance of emerging technologies to the world's future. The pandemic, climate change and the increasing geopolitical tensions have all played a part in highlighting the importance of science and the new technologies it creates to Australia's future prosperity, our health, and increasingly, our national security.

The Australian Government's response to the pandemic is already addressing these issues. The Critical Technologies Blueprint and the accompanying Critical Technologies Action Plan are a recognition of both the promise and the threat that these technologies pose to Australia's future health and prosperity. The aim is to ensure that we continue to be a leader in developing and deploying new technologies in a manner that benefits Australia and the world.

The Modern Manufacturing Initiative, announced in the October 2020 Budget, is helping support new Australian initiatives that support our health, wealth and national security.

Australian Vaccine technology supported by the MMI

Local manufacturer, Vaxxas, has received nearly \$5 million in funding from the Modern Manufacturing Initiative to enable the company to manufacture commercial quantities of its world-leading Micro Array Patch vaccination device.¹

The Micro Array Patch enables vaccines to be administered by a small patch applied to the skin, replacing a needle/syringe. It is smaller than a postage stamp and comprises thousands of micro-projections that are invisible to the naked eye. These micro-projections are coated with vaccine and can penetrate the outer layer of the skin to deliver the vaccine directly to dense populations of immune cells. The device is applied to the skin for just 10 seconds by using a disposable applicator. It has the potential to enable smaller vaccine doses to be used and for these to be provided in remote communities with less infrastructure than is required for current vaccines.

Funding from the MMI will support Vaxxas to develop a quality assured manufacturing line and process, employ and train skilled technical and engineering personnel and purchase key manufacturing equipment. Advanced automation, robotics and process control systems will establish the high standards required to supply regulated product for Phase 2 & 3 clinical trials and generate safety and efficacy data for vaccinations delivered on the device.

The project will transform the company from an Australian innovator to globally competitive manufacturer of sophisticated medical devices and technology for a rapidly growing vaccine market. This is the sort of innovation support on the ground that will set the pathway for others to follow thereby creating a future industry.

The core technology was developed at the University of Queensland and the company was founded with initial investments from Australian and US venture capital. It has also received financial support from the USA and Queensland governments.

¹ <https://www.grants.gov.au/Ga/Show/085eb78a-0848-4387-93f6-2eb38a854179>

While Australia has made a rapid start in responding to the economic and national security challenges that have arisen in the last two years, there is more that needs to be done to truly secure Australia's future.

Meeting the ongoing challenges of COVID-19 and preparing for the next pandemic

Australia has the opportunity and the research and industrial capacity to start preparing now for the next pandemic. Now is the time to take the lessons of the current pandemic and apply them to preparing our health systems, our research capability, our manufacturing industries and supplies lines and our community, for the next pandemic. This plan could build on programs already under way, such as the Modern Manufacturing Initiative and the University Research Commercialisation Program and the Critical Technologies Blueprint.

In September 2021, the US Government released a plan for a whole of government review of pandemic preparedness.² It will culminate in a decade long strategy to improve the USA's capability to deal with future pandemics and covers a range of areas where advances need to be made from more rapid development of vaccines to better and more comfortable PPE and education of the public.

'The work is organised across five pillars: 1) Transforming our Medical Defenses; 2) Ensuring situational awareness; strengthening public health systems; 4) Building core capabilities; and 5) Managing the Mission.

Achieving these capabilities will require a systematic effort and shared vision for biological preparedness across our Government akin to the Nation's Apollo Mission. The mission will require program management with the seriousness, commitment and accountability of the Apollo Program, overseen by a dedicated program office.'

The US has linked the Plan to its Jobs Plan, recognising that fulfilling its objectives will require the creation of new industries and expansion of existing industries, leading to new jobs. While recognising that such a program will be expensive, the cost is recognised as a sound investment in mitigating the health and economic costs of the next pandemic.

Even as we continue to deal with COVID-19, the next pandemic is a certainty; the only question is when.

An Australian pandemic preparedness plan would give these existing programs a pandemic overlay, a different and specific perspective on the national interest. It would identify where gaps remain; importantly it would take the focus beyond technologies to include our health system and communities. For example it will address how we ensure we have the infrastructure to rapidly deliver vaccines and provide effective quarantine facilities, and how we can better educate and inform our community to prepare for future pandemics and overcome misinformation.

² <https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf>

Research Australia proposes the Australian Government initiate and lead a whole of governments review of pandemic preparedness and the development of a plan to mitigate the economic, societal and health impacts of the next pandemic.

RNA: seizing the opportunity

The COVID pandemic has highlighted the enormous potential of mRNA technology, not just for the creation of vaccines to COVID-19 and other viruses, but for a range of diagnostic and therapeutic purposes. RNA technology more broadly, has the capacity to transform the life sciences and to lead to new technologies, across human and animal health and in agriculture.

BARD1 partners with Griffith University on RNA based cancer detection

BARD1 Life Sciences Ltd is an Australian diagnostics company with an innovative portfolio of diagnostic technologies and products. The Company is focused on developing and commercialising diagnostic solutions for healthcare professionals and patients.

BARD1 engaged Griffith University to support the development and evaluation of an exosome-based BARD1 RNA test for detection of ovarian and breast cancers.

The Mucosal Immunology Research Group (MIRG) at Griffith University that has significant expertise in RNA analysis and profiling infection and inflammatory/immune responses. The project aims to develop exosome-based RNA tests for earlier detection of breast and ovarian cancers by combining the Company's EXO-NET exosome capture and BARD1 biomarker technologies. CSO Dr Greg Rice said: "This project leverages the power of our EXO-NET technology to capture specific exosome populations and our BARD1 biomarker technology to enable the targeted profiling of exosomal RNAs thereby providing a more informative liquid biopsy for the presence of cancer."³

Australia is responding rapidly to the opportunities RNA technology (including mRNA) provide. The Commonwealth Government and several state governments have been quick to recognise the importance of having a domestic mRNA manufacturing capability as well as the capacity to develop new mRNA therapeutics and vaccines in Australia.

The Commonwealth Government is securing a population level mRNA manufacturing capability. Companies like IDT and BioCina are coming on board to deliver the materials required to support RNA research; the NSW and Victorian Governments are providing grants to support research and translation and to establish pilot facilities.

The first doses of an Australian mRNA based vaccine candidate for COVID-19 have now been produced, with Victorian Government support. It is being manufactured using new equipment at IDT Australia, based in the Melbourne suburb of Boronia, in preparation for clinical trials.⁴ In a separate announcement, BioCina has announced that it will have the capability to produce mRNA drug vaccine substances and encapsulation using lipid nanoparticles at its facility in Adelaide from mid 2022.⁵

³ <https://wcsecure.weblink.com.au/pdf/BD1/02459047.pdf>

⁴ <https://www.jaalapulford.com.au/media-centre/media-releases/>

⁵ <https://www.biocina.com/news-resources/biocina-expands-into-full-service-cdmo-with-full-control-of-pfizer-manufacturing-facility-in-adelaide-australia>

The NSW Government has committed \$96 million to a pilot facility established in partnership with all NSW universities to develop mRNA and RNA drugs and vaccines.⁶

The Victorian Government has announced programs specifically to fund a) early-stage RNA-based therapeutic research projects, and b) RNA-based therapeutics projects that can demonstrate a clear pathway to translation and secure development and commercialisation opportunities. It has also forecast funding for RNA enabling technology, such as novel nanoparticle encapsulation technology or novel modified nucleotides.⁷

The University of Queensland in partnership with Therapeutic Innovation Australia have established “BASE” as an enabling facility to produce high quality RNA for the research community under the NCRIS access model.⁸ This facility is co-located with the National Biologics Facility and the Protein Expression facility at the Australian Institute for Bioengineering and Nanotechnology. They have begun production and recently announced their first commercial contract with New Zealand’s CVC Limited.⁹

Australia has the opportunity to become a world leader in using mRNA and RNA technologies to revolutionise our own health and the food systems we rely on. We have the research expertise and we are rapidly developing the supporting infrastructure and manufacturing capability. Development of domestic RNA R&D and manufacturing capability is something Research Australia has been calling for, and we are delighted to see this now progressing to reality.

What is lacking is national coordination, to ensure that all the pieces are in place, from basic research to manufacture. This is a role that only the Australian Government can play.

Research Australia submits the Government should establish a National RNA Technology Mission, building on the work the Commonwealth has already undertaken to establish an onshore mRNA manufacturing capability.

The Mission would ensure Australia has a world leading position in the research, commercialisation, manufacture and adoption of RNA technology, including mRNA technology. Its objective would be to utilise RNA technology to provide better health outcomes and support Australian agriculture, making Australia more self sufficient in these critical domains. In doing so, it will create jobs and a new, high value export oriented industry for Australia.

The RNA Mission would provide a roadmap for how we utilise existing infrastructure and research expertise to establish an end-to-end mRNA research, development and manufacturing capability. It would identify and fill existing gaps in capabilities. It would ensure for example, that researchers across Australia have the funding to access and utilise the new facilities that are being developed, fostering national collaboration; and that we train the scientific, technical and engineering workforce we will need in our laboratories, clinics and manufacturing facilities.

It would include the initiatives of the State and Territory Governments, and by aligning the efforts of governments and industry, it would support greater private sector investment.

⁶ <https://www.nsw.gov.au/media-releases/new-96-million-rna-pilot-manufacturing-facility-for-nsw>

⁷ <https://djpr.vic.gov.au/medical-research/initiatives/mrna-victoria/mrna-victoria-research-acceleration-fund>

⁸ <https://stories.uq.edu.au/news/2021/australia-first-facility-to-produce-revolutionary-mrna-therapies/index.html>

⁹ https://www.cvc.nz/News/16_sep_2021.html

If we are to seize this opportunity, while the field is still relatively new, we need an Australian Government led National RNA Technology Mission now. This will enable an Australian capability onshore that can also be fed into our neighbouring region, which meets our objectives on the international stage. Importantly, it establishes a local capability with revenue opportunities realised mostly onshore.

Why invest in innovation?

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; as recent developments in our relationship with China have demonstrated, a decline in the export value of just a few key commodities can jeopardise our whole economy and our standard of living. COVID-19 has exposed just how vulnerable Australia is because of our relatively small and narrow manufacturing base.

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 86 out of 133.¹⁰

Australia is a high-income country, ranking as the 8th richest economy per capita out of 133 studied. Its 25.4 million inhabitants have a GDP per capita of \$55,05 (\$52,203 PPP; 2019). GDP per capita growth has averaged 0.9% over the past five years, in line with regional averages.

Australia ranks as the 86th most complex country in the Economic Complexity Index (ECI) ranking. Compared to a decade prior, Australia's economy has become less complex, worsening 6 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 2029 Growth Projections foresee growth in Australia of 2.5% annually over the coming decade, ranking in the bottom half of countries globally.¹¹

The risk of this lack of diversity was exposed by the COVID-19 pandemic in our inability to produce basic medical supplies and medicines. At a more sophisticated level, a lack of manufacturing capability for some types of vaccines leaves Australians exposed in the event of vaccines being developed and manufactured overseas.

¹⁰ <https://atlas.cid.harvard.edu/rankings>, accessed 23 November 2021

¹¹ <https://atlas.cid.harvard.edu/countries/14>

The Australian Government has recognised these deficiencies in relation to COVID and has responded in ways which seek to reduce our vulnerability and will also help our economic complexity. But the response to COVID-19 needs to be just the start, and we need a sustained effort over decades if we are to achieve lasting and significant change.

To summarise:

- **The key to long term, sustainable prosperity is a more complex economy.**
- **Greater complexity requires greater diversification of exports.**
- **Existing knowhow provides some opportunities to diversify our production.**
- **The key to diversifying our exports and our economy is new knowledge creation and innovation that enables domestic advanced manufacturing.**
- **The response to COVID-19 is a step in the right direction.**
- **We need a sustained effort over decades if we are to achieve lasting and significant change in the complexity of Australia's economy**

Australian R&D has declined, but not evenly

In a little more than a decade from 2008-09 to 2019-20, Australia's Gross Expenditure on Research and Development (GERD) declined as a percentage of GDP from 2.25% to 1.79% ¹²¹³

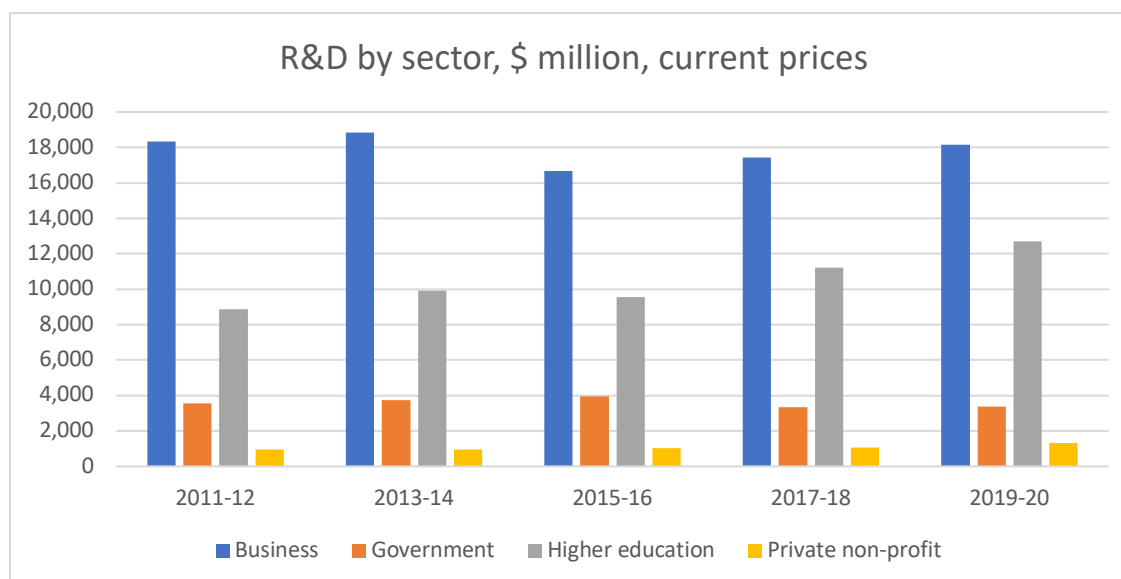
2008-09	2010-11	2011-12	2013-14	2015-16	2017-18	2019-20
2.25%	2.18%	2.11%	2.09%	1.88%	1.79%	1.79%

But it hasn't declined evenly across all sectors. The decline has been due to reduced investment in R&D by governments and the private sector. The Medical Research Future Fund is an exception in terms of government investment and will provide around \$650 million per annum in additional expenditure over the next 10 years. This is not enough, however, to offset the overall decline in government investment in R&D. The only significant increase in investment across R&D nationally has been by the Higher Education sector, largely funded by international student revenue, as illustrated in the following table. ¹⁴

¹² Australian Bureau of Statistics, 8104.0 - Research and Experimental Development, Businesses, Australia, 2017-18, Gross Expenditure on R&D,

¹³ Australian Bureau of Statistics, Research and Experimental Development, Businesses, Australia Expenditure and human resources devoted to Research and Experimental Development (R&D) carried out by businesses in Australia Reference period 2019-20 Financial year, Released 3 September 2021

¹⁴ Ibid, ABS, Research and Experimental Development, Businesses Australia, 2019-20, Released 03/09/2021 <https://www.abs.gov.au/statistics/industry/technology-and-innovation/research-and-experimental-development-businesses-australia/latest-release#methodology>



Notes (ABS):

- Higher education estimates have been modelled in 2011-12.
- From 2013-14 Gov't, Private non-profit and Higher education estimates have been modelled.

In 2011-12, 28% of total Australian R&D was undertaken in universities. By 2019-20 this had risen to 36%. Of course, the capacity of the higher education sector to sustain this investment has been badly affected by the COVID-19 pandemic.

But who funds research in universities?

Research undertaken in higher education is funded from a range of different sources, including from business and governments, so it is also important to look at the source of funds expended on research by universities.

Between 2008 and 2018 (the latest year for which statistics are available) total Higher Education expenditure on R&D increased by 78% in current prices from \$6.8 billion to \$12.1 billion.¹⁵ (In **real terms**, adjusted for inflation total Higher Education expenditure on R&D increased by 37.5% over this period.)¹⁶

The combined contribution from Australian Government funding (Commonwealth competitive schemes and Other Commonwealth Government grants) increased by 68%, (mostly in Research Support Program and Research Training Program), while the contribution from business increased by 54%.

¹⁵ Australian Bureau of Statistics, 8111.0 - Research and Experimental Development, Higher Education, Australia, 2018, current prices

¹⁶ Australian Bureau of Statistics, 8111.0 - Research and Experimental Development, Higher Education, Australia, 2018 chain volume measures, reference year 2018.

The contribution from 'General university funds' (including international teaching revenue) rose by 88%. The biggest percentage increase in that period (from a much smaller base) is funding from 'Donations, bequests and foundations' which increased by 213% to \$300 million (but only represents 2.5% of all funding).¹⁷

R&D Higher Education by source of funds \$'000 (current prices)

	2008	2018	% difference 2008 to 2018
General university funds	3,620,624	6,822,562	88%
Australian competitive funds			
Commonwealth schemes	1,142,870	1,700,454	49%
Other schemes	61,926	73,656	19%
<i>Total</i>	<i>1,204,796</i>	<i>1,774,110</i>	<i>47%</i>
Other Commonwealth government	1,001,321	1,891,230	89%
State and local government	402,989	457,013	13%
Business	338,156	521,889	54%
Donations, bequests and foundations	95,902	300,531	213%
Other Australian	41,004	96	-98%
Overseas	138,736	390,396	181%
Total	6,843,526	12,157,826	78%

In summary, between 2008 and 2018, **the proportion of Australian R&D undertaken in higher education has increased, and a greater proportion of it is funded from universities' own funds.**

It is clear that reform is needed. Ultimately, research is valued because it leads to outcomes that benefit the economy and society. This requires the 'D' in R&D, and that needs greater participation in R&D from industry and from governments.

This is the conclusion reached by the IMF in a recent report. While expecting economic growth to experience a post pandemic boost, in the medium term it expects GDP growth to be low; and both labour productivity growth and total factor productivity growth are expected to be below the OECD median. The remedy it proposes is an increase in R&D spending by governments and business.¹⁸

¹⁷ Australian Bureau of Statistics, 8111.0 - Research and Experimental Development, Higher Education, Australia, 2014, 2016, 2018 (2014 has historical data for 2008 and 2010), current prices

¹⁸ International Monetary Fund, December 2021, Country Report 21/256, Australia, Selected Issues

Ambition requires effort and investment

The Government commissioned Innovation and Science Australia to develop a plan for innovation, which was delivered to the Government in 2017.¹⁹ *Australia 2030: Prosperity through Innovation* outlined a plan for how the Australian Government could drive innovation across the whole economy through investment at the medium-term average level of 0.63%.

While Research Australia contends that this level of Government investment in R&D is too low, even this modest target has not been achieved, with the **Government's expenditure on R&D across all areas having fallen to around half of one percent of GDP**. The increase in 2020-21 is due to the additional \$1 billion provided to the higher education sector through the Research Support Program as a one year COVID-19 response.

Australian Government investment in R&D as a percentage of Gross Domestic Product²⁰

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

*includes one off additional \$1 billion increase in Research Support Program

It is clear from the October 2020 and May 2021 Budgets that the Government understands the need to increase its investment. New programs such as the Modern Manufacturing Initiative and the Strategic University Research Fund are designed to provide jobs and growth in areas where Australia has been identified as having strategic advantages. Research Australia supports this approach, but we need to do more.

The additional funding committed in the last two Budgets is not, by itself, enough to drive the profound change that is required in Australia's economy to capture the full benefits of our world class science and research.

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

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

This new investment should be directed to new programs and to increased support for existing programs. In the remainder of this submission, Research Australia provides a number of

¹⁹ Innovation and Science Australia 2017, *Australia 2030: prosperity through innovation*, Australian Government, Canberra.

²⁰ Australian Government, Science, Research and Innovation (SRI) Budget Tables, 2021-22, Australian Government investment in R&D by sector and sub-sector, and other analyses Table 6, Australian Government investment in R&D as a percentage of Gross Domestic Product.

proposals for how this additional investment should be utilised in health and medical research and innovation, and more broadly across Australia's world leading research and innovation.

These proposals are consistent with the ambition the Prime Minister has outlined for Australia's post COVID recovery, with manufacturing based on our research expertise in areas of competitive advantage.

Clear and ambitious targets needed

Government spending on R&D of 0.75% of GDP is a clear and ambitious target, but we also need others.

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

In 2019, global exports of pharmaceutical products accounted for USD582 billion. 20 of the world's nations accounted for 92% of this total, valued at USD534 billion. The world's Number One exporter of pharmaceutical products was Germany at USD89.4 billion, with 15.3% of global pharmaceutical exports. Number 23 was Australia, with exports of USD3.2 billion, or 0.55% of global exports.²¹

In the same year (2019), Australia imported pharmaceutical products valued at \$USD7.38 billion, or 1.27% of global pharmaceutical imports.²²

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. As noted above, we have the potential to be a world leader in RNA technologies.

Research Australia submits Australia needs to set some clear and ambitious goals if we are to position ourselves for the economic success the Prime Minister has stated as his Government's objective. 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.

²¹ Sourced 23 November 2021 from

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

²² Sourced 23 November 2021 from

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

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

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

Supporting the development of Medical Products

Manufacturing

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

Australia already has many processes and programs to support the development and commercialisation of medical products, and many of these components are now working well. The Research and Development Tax Incentive is one such example.

Australia has existing advanced manufacturing capability in key areas, including medical devices.

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

Having more of this manufacturing capacity in Australia would:

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

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

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

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

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

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

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

Research Australia submits the Commonwealth Government should investigate how it can further support the development of domestic manufacturing capability of medical products for clinical trials. This includes funding a feasibility study into establishing one or more manufacturing facilities for clinical trial materials to capitalise on Australia's global competitive advantage in clinical trials. It should investigate the provision of facilities in partnership with the health and medical research and innovation sector and funding models involving consortia of government and private investors.

Pharmaceuticals- supported by the MMI

Once again, the Modern Manufacturing Initiative is demonstrating how it can help drive change and create jobs, including in pharmaceuticals.

Noumed Pharmaceuticals, part of UK company Noumed Life Sciences, will build a pharmaceutical manufacturing facility in northern Adelaide after receiving \$20 million in funding through the latest round of the federal government's Modern Manufacturing Initiative.

Noumed has revealed plans to build an \$85 million facility at Salisbury South, allowing it to locally manufacture around 40 million units of tablets, creams and liquids when the facility opens in 2025.

The Noumed facility will have a strong focus on research and development, in addition to manufacturing. This will create job opportunities for scientists, pharmacy graduates, logistics experts and engineers. There will also be collaboration opportunities with local research institutions.

The company currently manufactures its products offshore Initiative (MMI) will see the new facility built in Australia and create an expected 180 ongoing jobs.²³²⁴

Using Government procurement to promote innovation

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

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

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

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

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

²³ <https://www.grants.gov.au/Ga/Show/6a01dab9-90ce-4cc0-ac27-4e5dbf2724ce>

²⁴ <https://www.austrade.gov.au/international/invest/investor-updates/2021/uk-pharmaceutical-firm-to-build-a-85m-manufacturing-facility-in-australia>

*Research Initiative was established in 2001 to improve the number of small R&D-based businesses winning contracts from government.*²⁵

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

A suitable overseas model exists with the U.S. Government's Biomedical Advanced Research and Development Authority (BARDA). While similar to the US Small Business innovation Research Program referred to in the ISA report, it has a more specific and strategic focus.

BARDA

Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response, was established to aid in securing the nation from chemical, biological, radiological, and nuclear (CBRN) threats, as well as from pandemic influenza (PI) and emerging infectious diseases (EID). BARDA supports the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development towards consideration for approval by the FDA and inclusion into the Strategic National Stockpile.

BARDA's support includes funding, technical assistance and core services, ranging from a clinical research organization network to Centers for Innovation in Advanced Development and Manufacturing, and a fill-finish manufacturing network. BARDA supports a diverse portfolio of medical countermeasures and these products have received a total of 55 FDA approvals, licensures, or clearances.

Their mission is accomplished through successful public-private partnerships with industry to share risk, improve efficiency and accelerate development all while sustaining a marketplace that guarantees continued access to countermeasures vital to US national security.²⁶

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

²⁵ Innovation and Science Australia (2016) Performance Review of the Australian Innovation, Science and Research System 2016. Commonwealth of Australia. Canberra. Page 29

²⁶ <https://www.phe.gov/about/barda/Pages/default.aspx>

Centers for Innovation in Advanced Development and Manufacturing

These three centres develop and manufacture medical countermeasures, such as vaccines and therapeutics used to protect health in emergencies, which can transition quickly and cost effectively between products.

They provide a significant domestic infrastructure in the United States capable of producing medical countermeasures to protect Americans from the health impacts of bioterrorism as well as pandemic influenza and other disease in response to public health emergencies.

They bring together the innovative ideas of small biotech firms, the training expertise of academic institutions, and the development and manufacturing experience of large pharmaceutical companies. This helps to ensure a sustainable domestic medical countermeasure infrastructure with unprecedented ability to accelerate development and manufacture medical countermeasures in time of need.

These Centers will also be used to explore emerging and innovative technologies that could be applied to current or future medical countermeasure development efforts to reduce risk, increase yield, and ultimately to reduce total life-cycle costs through flexible manufacturing, consolidating other costly product development expenditures, or any other economy-of-scale opportunities.²⁷

BARDA and the CIADM have been critical components of the US Government's vaccine development response to the COVID-19 pandemic.²⁸²⁹³⁰

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

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

The Australian equivalent of the BARDA and CIADM could be a key component of the Government's implementation of the plan Research Australia has proposed to prepare for the next pandemic. It would provide a mechanism by which the Government could source the new products it identifies as necessary to mitigate the economic, societal and health impacts of the next pandemic.

²⁷ <https://medicalcountermeasures.gov/barda/core-services/ciadm.aspx>

²⁸ <https://www.hhs.gov/about/news/2020/07/27/hhs-reserves-and-rapidly-expands-manufacturing-capacity-for-covid-19-vaccines-at-texas-center.html>

²⁹ <https://www.tamug.edu/update-on-production-of-covid-19-vaccine-candidates-by-texas-am-system-subcontractor/>

³⁰ <https://www.medicalcountermeasures.gov/newsroom/2020/emergent-plasma/>

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

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

This investment decision follows the agreement with the Australian Government for the supply over 10 years of influenza pandemic protection for the Australian population, anti-venoms for Australian snakes, spiders and marine creatures and Q-Fever vaccine.’
16 November 2020³¹³²

Point of Care Diagnostics

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.³³

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.

NHMRC and ARC funding

Australia’s universities and medical research institutes are the foundation on which Australian health and medical research and innovation is built, and the Commonwealth Governments’ premier funding bodies for the research they undertake are the National Health and Medical Research Council (NHMRC) and the Australian Research Council (ARC).

The NHMRC’s funding programs are clearly aligned with health and medical research; the importance of the Australian Research Council’s own programs to health and medical research is less obvious but just as real. While the ARC does not fund ‘medical and dental research’, it funds basic life sciences research. It also funds the application of research in a range of disciplines, including biochemistry, engineering, computing and the social sciences, which directly and indirectly support health and medical research and its application.

³¹ <https://wcsecure.weblink.com.au/pdf/CSL/02309014.pdf>

³² <https://www.seqirus.com.au/news/seqirus-will-build-world-class-vaccine-manufacturing-facility>

³³ <https://www1.racgp.org.au/newsgp/clinical/are-we-about-to-see-a-new-dawn-for-point-of-care-t>

In a period when the Australian Government is focusing on innovation, new technology and reinventing Australian manufacturing, the continued neglect of the funding of basic and applied research through the NHMRC and ARC is counterproductive.

NHMRC Programs

The 2021/22 Budget revealed funding for the NHMRC's programs continuing to grow very slightly. The increase in this financial year is 1.1%, with annual increases of around 1% thereafter. This is lower than the forecast CPI of 3.5% for 2020-21 and CPI of between 1.75% and 2.5% expected in subsequent years. In effect, NHMRC funding continues to decline in real terms, as it has done for many years now. Research Australia remains concerned about this deficit because research and its outcomes is a long-term commitment.

NHMRC MREA Funding 2021 Budget

\$m.	20-21	21-22	22-23	23-24	24-25
Funding to MREA	853,864	863,266	875,362	887,588	899,124
2021 Budget					

ARC Programs

The Australian Research Council's Funding Programs are critical to Australian publicly funded research including to the life sciences and medical technologies.

Over the forward estimates, the funding to the ARC for the Discovery Program increases slightly each financial year and while higher than in last year's Budget, the funding is at significantly lower levels than forecast in the 2019 Budget. In real terms funding to the Discovery Program declines over the forward estimates. Again, a cause for concern.

\$m.	20-21	21-22	22-23	23-24	24-25
Discovery 2021 Budget	483,272	489,188	494,922	501,162	509,432

The ARC Linkage Program has been singled out by the Government as an important component of Australia's innovation system, and it was announced that from 1 July 2016 the Program would be open to continuous applications and decision making would be fast tracked.

Funding over the forward estimates is higher than forecast in last year's budget, but future years fail to keep pace with inflation.

\$m.	20-21	21-22	22-23	23-24	24-25
Linkage 2021 Budget	323.166	325.454	329.948	334.109	339.622

While not funding ‘medical and dental research’, the ARC Linkage program remains important to the health and medical research and innovation sectors for the reasons outlined earlier.

The trend of funding NHMRC and ARC research program increases at less than inflation cannot continue if Australia is to develop the more diversified and knowledge driven economy that we need to secure our future. We are currently missing a real opportunity to capitalise on the sector’s expertise to make technological advances and address current and emerging issues, such as our ageing population. We are also at risk of jeopardising the ‘golden opportunity to become a leader in future medical research and clinical trials, bringing not only new medicines but new jobs to the country’, outlined by Health Minister Greg Hunt in July 2020.³⁴

We also know that COVID-19 is continuing to create a range of issues for our community, directly through the impact of the virus but also through the economic disruption it is causing. These include the long-term effects of COVID-19 post recovery and evaluating the impact of new innovations such as telehealth. All of these are areas that could benefit from new research, and additional funding.

And if the MRFF is to achieve its full potential it is essential that the financial assistance it provides ‘complements and enhances’ existing government funding sources, as specified in the MRFF’s enabling legislation. It was not designed to be, and nor should it be seen as, the panacea to existing funding challenges. Sustainable and consistent funding at the basic end of the pipeline must occur if there is to be research for translation at the other end, including via the MRFF.

Research Australia submits that funding for the research programs of the NHMRC and ARC must be increased in real terms and in their own right, in the 2021-22 Budget and over the forward estimates.

Indirect research costs

The funding from the ARC, NHMRC and MRFF meet only part of the costs of the research to which they are directed. They are a contribution to the direct costs of research, such as paying researchers’ salaries and purchasing necessary equipment and experimental materials. They do not cover the cost of ‘keeping the lights on’, quite literally and metaphorically: paying utility bills, administrative staff, maintenance on buildings and facilities.

Securing appropriate levels of funding for the indirect costs of research conducted in Australia’s higher education institutions and medical research institutes is a longstanding problem and far from international best practice. It has been exacerbated by recent developments, including an emphasis on universities partnering with industry on research projects and reductions in the revenue of higher education institutions. It is widely recognised that teaching revenues from domestic and international students subsidise research expenditure, including covering indirect costs. The reduction in universities’ international teaching revenues caused by COVID-19 has further limited the ability of universities to contribute to meeting indirect research costs.

³⁴ <https://www.abc.net.au/news/2020-06-14/coronavirus-opportunity-australia-medical-research-global-leader/12353754>

Universities

Currently, universities receive funding from the Department of Education and Training's Research Support Program (RSP). The RSP distributes a pool of money to universities in proportion to the research income each university received in the reporting period.

In the October 2020 Budget, the Government used the Research Support Program to provide a vital injection of \$1 billion into higher education research in the 2020-21 financial year. No further injection was provided in the 2021 Budget and the funding provided was actually lower than was forecast in the 2019 Budget.

Research Support Program

\$m.	20-21	21-22	22-23	23-24	24-25
2021 Budget	1918.298	930.659	942.775	958.326	974.143
2020 Budget	1918.298	926.490	929.270	938.107	N/A
2019 Budget	920.573	941.748	962.455	N/A	N/A

Funding for the indirect costs of research funded by the MRFF is now provided from the Research Support Program. With the MRFF providing hundreds of millions of dollars in funding to universities over the next few years, a substantial increase in the Research Support Program is needed just to maintain the levels of research support funding for research projects at their current already inadequate level. The cuts to the Research Support Program beyond the one-off boost in 2020-21 represent a real and continued threat to the capacity of our universities to undertake vital health and medical research.

The issue of indirect research costs remains unresolved for the whole health and medical research sector and indeed publicly funded research more broadly. Research Australia continues to call for a whole of government approach to the issue of funding indirect research costs.

Research Australia proposes that the Chief Scientist lead a review of the funding of indirect research costs to establish a sustainable and equitable funding program. In the short term, the pool of funding for the Research Support Program must be increased substantially.

Similar issues arise with the Research Training Program (RTP), used to fund the training of Higher Degree by Research students. More than half of research in universities is undertaken by PhD students, and more grants from the MRFF is creating greater demand for PhD students to undertake the research.

The RTP is also falling in real terms over the course of the forward estimates and like the RSP the level of funding is lower than forecast in the 2019 Budget. These cuts further undermine the ability of universities to undertake research, and they increase the component of indirect research costs which is unfunded.

Research Training Program

\$m.	20-21	21-22	22-23	23-24	24-25
2021 Budget	1054.981	1069.182	1083.160	1100.967	1119.137
2020 Budget	1054.981	1064.392	1067.585	1077.738	N/A
2019 Budget	1057.595	1081.921	1105.710	N/A	N/A

Medical Research Institutes

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

Funding for indirect research costs was raised as an issue during the public consultation on the inaugural five-year strategy and two-year priorities for the MRFF conducted by the MRFF Advisory Board in 2016. While the MRFF Advisory Board subsequently drew attention to the issue of funding for indirect research costs, it did not offer a solution:

A whole-of-government approach is needed to address the issue of research costing to ensure the research sector can continue to thrive. MRFF funding cannot in isolation solve the conundrum that surrounds indirect costs and may with the injection of new funds increase the need for a solution. The Advisory Board, while advocating for a whole-of-government and research sector agreed solution, must therefore abstain from implementing yet another funding model. In the short term MRFF program investment should adhere to existing costing approaches. Collaboration between Government and funded bodies to identify an equitable solution should be prioritised.³⁵

Indirect research costs were also examined by the House Standing Committee on Education, Employment and Training at the request of the Minister for Education. The Committee's report, tabled on 26 November 2018, recommended that 'the administration of research block grants be reviewed to provide more timely and adequate support for the indirect costs of research.'

The following four recommendations reiterate Research Australia's position outlined in our Pre-Budget submissions every year since 2016. They remain valid.

The cuts to the Research Block grants outlined in the October 2020 Budget and retained in the 2021 Budget must be reversed.

³⁵ Australian Government, MRFF Advisory Board, 2016, Australian Medical Research and Innovation Strategy 2016-2021, p.7

The pool of funding for the Research Support Program and the Research Training Program needs to be increased in the 2022-23 Budget to reflect the inclusion of MRFF competitive grants in the Programs.

In a similar manner, an additional stream of the IRISS program needs to be funded by the Department of Health to cover the indirect costs associated with MRFF funding incurred by IMRIs. This funding should be administered by the NHMRC.

Building on current initiatives

The Patent Box

Research Australia welcomed the announcement by the Government in the last Budget of its plans to introduce a patent box, a tax concession that provides a lower tax rate for income derived from certain forms of intellectual property (IP), typically patents. The policy goal of patent boxes is to promote R&D and the commercialisation of IP, objectives which are strongly supported by Research Australia.

With the right policy settings, a Patent Box will ensure Australian discoveries in health are developed here, ensuring Australia captures the opportunity for new industries and jobs in health innovation. Research Australia has responded to the Treasury's subsequent Discussion Paper, and we look forward to working with Treasury to ensure the design of the patent box adequately incentivises Australian health innovators to develop and manufacture their ideas onshore.

Research Australia acknowledges the need for the design of the Patent Box to be consistent with the OECD's Base Erosion and Profit Sharing (BEPS) Action 5 Minimum Standard. **We recommend the Government establish an expert working group with industry representation to support the design and implementation of the Patent Box.**

Funding for research infrastructure

In the October 2020 Budget, the Government announced several new funding initiatives as part of the 2020 NCRIS Investment plan, including the BioFoundry, and committed funding to several scoping studies for new infrastructure, such as biobanking.

The 2021 National Research Infrastructure Roadmap is currently being finalised. It will outline the national research infrastructure required over the coming decade so that Australia's research system continues to improve productivity, create jobs, enhance national security, lift economic growth and support a healthy environment.

It provides an opportunity to consider Australia's future research infrastructure needs in the context of the Government's current strategy to increase the commercialisation of research, and Research Australia's call for a substantially increased investment by the Government in R&D.

Research Australia submits the Government should make a commitment in the 2022-23 Budget to expand the existing Government's \$1.9 billion, 12 year funding envelope for national research infrastructure in support of the 2021 National Research Infrastructure Roadmap.

Measuring Innovation performance

With innovation so central to Australia's future, it is 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, is expected to make recommendations for improved collection of data around Australian 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. Research Australia urges the Government to make provision in the 2022-23 Budget for the implementation of the Innovation Metrics Review's recommendations.

Investing in Prevention

One of the most cost-effective ways of improving Australians' health outcomes is through investment in prevention.

Research Australia congratulates the Health Minister and the Government on the recently developed 10 Year National Health Prevention Strategy, launched on 13 December. This strategy will bring together existing initiatives as well as lead to new programs, and preparatory workshops have already identified areas where new resources will be required; for example in better data collection to ensure that we can effectively monitor and evaluate new programs.

While there are many elements to a Health Prevention Strategy, changing Australians' behaviour is key. And while we know this is difficult, we also know that we have been successful in doing so in the past, for example with reducing smoking rates, and with Sun Smart campaigns to reduce the risk of melanoma.

Research Australia conducts annual polling of the Australian public on matters relating to health and medical research. In our 2020 Poll we asked people about managing their own health. A large majority of Australians would welcome practical for maintain their own health, with a greater emphasis on mental health (70.9%) than physical health (62.8%).³⁶

There is clearly a role for more health prevention measures as part of a new National Health Prevention Strategy, and while cost effective in the long term, effective national prevention programs need to be adequately funded. We also need to ensure we have the resources in place to develop effective programs and to monitor and evaluate the outcomes.

Research Australia urges the Government to use the Budget to make a significant multi-year commitment to fund implementation of the new National Preventive Health Strategy 2021-2030.

Data for better health and prosperity

The experience with the COVID pandemic has clearly illustrated the benefits of the digital capture, communication and display of health information, including vaccination status.

The potential value of publicly held data has been recognised by the Australian Government and action is being taken to improve the value Australia derives from this data.

Initiatives in this area include the Department of Prime Minister and Cabinet's work on the Public Sector Data Management Strategy, the creation of the Australian Government Public Data Policy Statement, and the Government's response to the Productivity Commission Inquiry into the Availability and Use of Public Data. Most recently, the Government has released the Australian Data Strategy and accompanying Action Plan, with a 'vision to create a national ecosystem of data that is accessible, reliable and relevant and easily used to power our national endeavour and become a modern data-driven society by 2030.'³⁷ We welcome the Government's commitment in the new Australian Data Strategy to continue to invest in capacity building in Commonwealth departments to enhance data maturity, skills and capability within the APS.

Research Australia has been actively involved in the consultations to develop the new Data Availability and Transparency Bill, which is currently before the Parliament. In addition to supporting Government departments and agencies to share and release data, it will implement a process for accrediting researchers and research institutions as 'trusted users' of data.

Research Australia submits the Government should make provision in the 2022-23 Budget for the infrastructure needed to support the new Data Availability and Transparency Bill in anticipation of its passage through the Parliament in 2022.

³⁶ Research Australia, 2020, *Public Opinion Poll on Health and Medical Research*, p.18, available at <http://researchaustralia.org/reports/public-opinion-polling/>

³⁷ <https://ausdatastrategy.pmc.gov.au/australian-data-strategy/executive-summary/our-vision>

This funding will complement the legislative steps being taken with the Data Availability and Transparency Bill and build on the investment the Government has already made in modernising Government Departments through the Data Integration Project for Australia (DIPA), which concluded on 30 June 2020.³⁸

Utilising Health Data

The Government has made a significant commitment over many years to the development and implementation of the My Health Record. This is an important initiative with the potential to save lives, improve the delivery of healthcare, and increase the health system's efficiency and productivity.

The report of the Productivity Commission Inquiry into Data Availability and Use has highlighted the significant social and economic benefits to be derived from making public data more available. The relative importance of health data was highlighted by the Commission's Report.³⁹ It concluded that across all of Government, some of the greatest gains could be made through making health data more available.⁴⁰ Many of these recommendations relate to better access to data for researchers and innovators.

An earlier report of the Productivity Commission looking at the opportunities for productivity improvements in health highlighted the role of data in this regard:

*'More generally, administrative data — including performance data, patient health records and government-held datasets on patients' use of medications or procedures — can support development of a more rigorous evidence base on the clinical and cost effectiveness of health interventions. Among other things, these data (subject to appropriate privacy safeguards) enable researchers to investigate the burden of disease, access to health care across the community, and the effectiveness of specific health interventions. This can help health care providers to choose the best treatments for individual patients. It also helps governments and insurers to make better overall funding decisions by directing funding to where the greatest health benefits can be achieved (including to preventive health measures), and away from interventions with low or no clinical value.'*⁴¹

Some of the greatest opportunities for better health outcomes lie in preventive health measures and public interventions. The burden of non-communicable disease has increased rapidly in the last two decades, linked to obesity and population wide changes in daily activity. Health data can be used to monitor changes in populations and sub-populations, and to identify emerging issues and solutions.

Access to reliable and current health data makes public health interventions both more effective and more cost effective, making it possible to respond more quickly to emerging issues. In addition to making the data available, it requires a commitment to use this data and a meaningful commitment by governments to evidence-based policy development and implementation.

³⁸ <https://www.pmc.gov.au/public-data/data-integration-partnership-australia>

³⁹ Productivity Commission 2017, *Data Availability and Use*, Report No. 82, Canberra Pp. 509

⁴⁰ Productivity Commission 2017, *Data Availability and Use*, Report No. 82, Canberra Pp. 5-6

⁴¹ Productivity Commission 2015, *Efficiency in Health*, Commission Research Paper, Canberra. p.75

The secondary use of My Health Record data for research and public health purposes is central to achieving this ambition and is supported by the Australian public. In public polling undertaken on behalf of Research Australia in mid 2018, ninety percent of respondents supported the use of patients' medical records for research purposes.⁴²

The Australian Institute for Health and Welfare (AIHW) has been appointed to manage and release datasets for the My Health Record secondary use of data. The first data releases was expected to occur in 2020, but has been delayed.

Research Australia urges the Government to use the 2022-23 Budget to ensure the AIHW is adequately resourced to prepare for and undertake the significant new role of preparing and providing de-identified My Health Record data for research and public health purposes.

⁴² Research Australia, 2018, *Australia Speaks! 2018 Opinion Polling for Health and Medical Research*, available at <http://researchaustralia.org/reports/public-opinion-polling/>

Conclusion

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

At the same time, it has highlighted successive Australian Governments' historic under investment in health and medical research, leading to an over reliance on the capacity of universities to generate international student revenue and direct it to funding research, and on philanthropy to fill the gaps.

It has also highlighted some points in which our systems are still not strongly enough connected, including the interface between researchers and the health system.

In the longer term, economic recovery from the pandemic creates an opportunity for a healthier and more prosperous Australia.

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

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

The 2022-23 Budget provides the opportunity for the Australian Government to consolidate the reviews and policy changes it has initiated in the last few years to improve the health and wellbeing of the Australian population and to reposition Australia as a modern and innovative nation with a knowledge-based economy. However, this requires a renewed commitment to significant investment in innovation to reverse the declines in recent years that are evident when investment in R&D is considered as a proportion of GDP.

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

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

Research Australia is pleased to have had the opportunity to make this submission on behalf of our broad membership which is drawn from across the health and medical research pipeline. We are also willing to provide further information and/or contribute further.

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