NATIONAL RECONSTRUCTION FUND

Response to Consultation Paper on Implementation

February 2023

RESEARCH AUSTRALIA

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Introduction

Research Australia welcomes the opportunity to make this submission in response to the NRF Implementation Consultation.

As the peak body for Australian health and medical research and innovation, the focus of our submission is the priority are of medical products. Relative to other products, the process from initial research discovery to a new drug, therapy or technology is a long one, commencing upstream with research that leads to a new discovery and flowing downstream through various stages of testing, refinement and regulatory approval to the realisation of a new product which can be manufactured and sold to a customer. Investment in medical products can be costly and challenging, but commensurately rewarding.

It is also a sector in which Australia has historically had world leading research and in which significant advances in developing a more mature domestic industry have been made recently. In the last two years:

- The federal and state (Victorian) governments have partnered to bring Moderna to Australia's shores to manufacture mRNA vaccines and therapeutics.[1]
- Australia's CSL has continued to invest in Australia with the recent opening of a new plasma fractionation plant, and a start-up incubator due to open in its new Melbourne headquarters in 2023.[2]
- The Queensland Government has announced an mRNA partnership with Sanofi.[3]
- BioNTech have chosen Victoria to establish their Asia-Pacific mRNA clinical research and development centre.[4]
- NSW is establishing a first-of-its-kind pilot facility to develop mRNA and RNA drugs and vaccines in partnership with all NSW universities.[5]

This is the environment in which the National Reconstruction Fund is being proposed, and Research Australia believes it has a vital role to play in creating a mature and vibrant domestic medical products industry as a cornerstone of a post-carbon Australian economy.

We have made four recommendations:

- **The Ministers should obtain the advice of a future CDC about medical products for which there is a critical unmet need for domestic manufacturing. This should be a consideration in how funds are subsequently allocated by the NRF, although not to the exclusion of the need to generate a return on the investment.**

[1] https://www.austrade.gov.au/international/invest/investor-updates/moderna-to-build-mrna-vaccine-manufacturing-facility-in-australia
2https://www.google.com/search?q=CSL+manufacturing+in+austrlia&rlz=1C5CHFA_enAU930AU930&oq=CSL+manufacturing+in+austrlia&aqs=chrome..69i57.5914j0j15&sourceid=chrome&ie=UTF-8
3 https://statements.qld.gov.au/statements/96732
4 https://www.premier.vic.gov.au/biontech-coup-more-mrna-manufacturing-research-melbourne
5 https://www.nsw.gov.au/media-releases/new-96-million-rna-pilot-manufacturing-facility-for-nsw

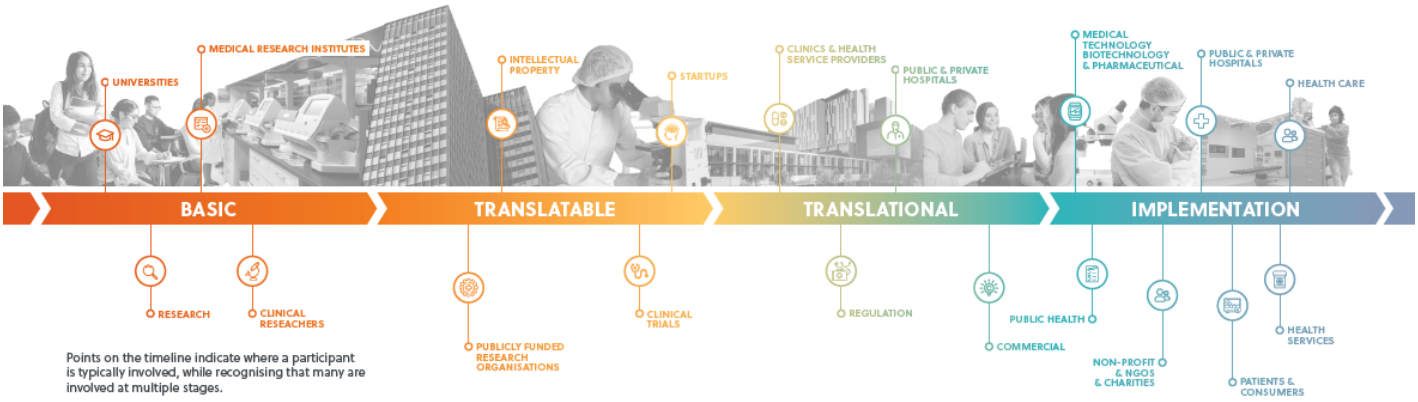
- **Development of the investment mandate for the priority area of medical products should include identification of areas with the potential for profitable domestic manufacturing. This should be a consideration in how funds are subsequently allocated by the NRF, although not to the exclusion of the need to generate a return on the investment.**

- **The Australian Government should create a National Medical Products Industry Plan to accompany the introduction of the National Reconstruction Fund to make the most of all the Government's investments throughout the health and medical research and development pipeline .**

- **The Australian Government should develop a medical products research, development and manufacturing workforce plan to determine where the gaps in existing skills are and to address them.**

Research Australia's submission addresses most of the questions posed in the consultation paper.

The Health and Medical Research and Innovation pipeline



Target Investment levels

1. What types of projects or investments should the Government direct the NRF to focus on, or not invest in, within each of the seven priority areas to achieve the NRF's purpose?

To respond to this question it is important to understand what the relevant priority area is. Under Clause 6 of the Bill, each priority area will be defined by the Ministers, and how the Ministers define the priority area will be critical. The Consultation paper variously refers to:

1. The Priority area of Medical science: '**Medical science**: Leverage Australia's world-leading research to provide essential supplies such as medical devices, personal protective equipment, medicines and vaccines.' (page 2) and
2. The target investment of '**$1.5 billion** for medical manufacturing.' (page 3)

Research Australia has used the term 'medical products' throughout this submission to describe this priority area.

Research Australia accepts that the priority area of medical products should include medical devices, personal protective equipment, medicines and vaccines as outlined in the Consultation paper. Research Australia submits the priority area should also include medical equipment, diagnostics and reagents used in pathology testing and medical research. (See the box below for further information on reagents.) It should also include medical software ('apps'). Examples of Australian companies in some of these areas at different stages of maturity are EmVision (imaging), SpeedX (diagnostics) and Vaxxas (vaccine delivery technology).[6]

Medical Products should include reagents

As with many products, there have been 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, the reagents required for pathology tests was another area where Australia experienced significant extra demand due to the COVID pandemic and difficulty with accessing the required reagents, which were in high demand globally. ABS import data using customs declarations valued imports of reagents into Australia at $569 million in 2019, $774 million in 2020 and $1074 million in 2021, with the sharp increase presumably reflecting demand for reagents for COVID-19 testing.[7]] Despite this increase in imports, there was evidence of a shortage of reagents restricting Australian COVID testing.[8] While widespread testing has been critical to Australia's response to the COVID-19 pandemic, reagents are not currently included in the National Medicines Stockpile.

[6] EmVision has been supported by the MRFF Frontiers Program https://emvision.com.au/ SpeedX https://plexpcr.com/ Vaxxas has received Australian Government support and is establishing a new manufacturing facility in Queensland. https://www.vaxxas.com/

[7] Australian Government, Australian Bureau of Statistics, Cat. No. 5368 last updated May 2022, Pivot Table for item 382200 Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents, whether or not on a backing and certified reference material (excl. those of HS 2843 to 2846, 2852, 3002, 3006, 3204 and 3821)

[8] 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

The Explanatory Memorandum refers to the following in the Outline of the Bill:

> '…better positioning industry to be … more resilient against supply chain vulnerabilities. …making it easier for industry to commercialise innovation and technology, supporting the development of our national sovereign capabilities … providing finance for projects that add value, improve productivity and support transformation, rather than enabling expansion of business as usual. Investment in these activities will help create secure, high value jobs for Australians and strengthen our future prosperity.'

There are different and potentially competing priorities for investment expressed here.

Supply chain vulnerabilities and sovereign manufacturing capability are particularly important in the Medical Science and Manufacturing priority area.

As with many products, there have been significant shortages of some medicines during the COVID-19 pandemic. In addition to medicines and the reagents referred to above, these shortages extended to other supplies required by our hospitals and health services. Supply chain vulnerabilities leading to shortages in critical medicines pose a real threat to the Australian population.

The Australian Government is currently developing a Centre for Disease Control and one of its key areas of focus will be to review and manage the National Medicines Stockpile, with the objective of ensuring Australia's access to vital medicines and other medical products in a health emergency. Research Australia has proposed that the CDC's responsibilities should extend to identifying for which Stockpile items Australia should have domestic manufacturing capability.

Research Australia submits the Ministers should obtain the advice of a future CDC about medical products for which there is a critical unmet need for domestic manufacturing. This should be a consideration in how funds are subsequently allocated by the NRF, although not to the exclusion of the need to generate a return on the investment.

The emphasis on **secure, high value jobs and future prosperity** suggests that a 'standard' Venture Capital model of supporting products to commercialisation, at which point they might be licensed to an overseas company, is not good enough. This NRF must be about retaining IP in Australian hands and manufacturing here to address supply chain vulnerabilities and create jobs. The NRF must be prepared to invest for the long term, through product development and on to manufacturing rather than developing investment strategies which plan an exit via licensing or acquisition of IP by a multinational.

Research Australia submits development of the investment mandate for the priority area of medical products should include identification of areas with the potential for profitable domestic manufacturing. This should be a consideration in how funds are subsequently allocated by the NRF, although not to the exclusion of the need to generate a return on the investment.

2. How should industry 'transformation' and 'diversification' be defined and measured for each of the seven priority areas?

Transformation of Australia's existing medical products industry could be measured in terms of:

- increased capacity across the sector at all stages from research through to manufacturing
- greater complexity of products developed
- increased export revenue and import replacement
- reduced reliance on overseas suppliers for essential medical products
- greater engagement of researchers in higher education and medical research institutes with industry through placements, fellowships and greater workforce mobility between industry, academia and medical research institutes
- a stronger domestic medical products investment community.

Diversification could be measured in terms of:

- the number of medical products being developed and/or manufactured in Australia
- the range of medical products being developed and/or manufactured in Australia
- the number of companies engaged in the development and/or manufacture of medical products in Australia
- more domestic investors in medical products

3. How should 'value add' be defined and measured in relation to relevant priority areas?

Medical products provide better health outcomes in addition to economic benefits. The domestic development of medical products provides greater opportunities for Australians to access innovative new treatments earlier through clinical trials.

There is also significant potential for spillover benefits to the broader economy. Medical products require multidisciplinary teams for research development and manufacture, with skills and capabilities developed for medical products also being useful in other industry sectors.

Domestic manufacture of medical products reduces supply chain vulnerability, particularly in time of global health emergencies. Over time, the NRF could lead to greater availability of domestically manufactured items on the National Medical Stockpile and a reduction in listings on the PBS Scare and Substitutable medicines list. These outcomes enhance the health and security of the Australian population during global health emergencies.

4. How much detail should be provided on each of the priority areas? How should greater detail and the need for flexibility be balanced?

The priority areas are established by the Ministers under declarations made under the Act; priority areas can be updated as required, ensuring a degree of flexibility over time. The rules should establish the boundaries of the definition of medical products, and provide any specific directions from the Ministers about areas considered to be of special importance or in the national interest. Beyond this, the NRF should be able to invest as per the investment mandate where the best economic opportunities exist.

Investment needs and opportunities

5. What are the opportunities for value-add, growth and diversification in each of the priority areas?

Medical products is a large and ever evolving category, in which research is driving rapid evolution and creating new opportunities for different types of products and technologies. The global market is enormous; the market for medical devices alone is estimated to be nearly USD 500 billion in 2023.[9]

Even within Australia, the opportunity for export replacement is significant. In 2019, global exports of pharmaceutical products accounted for USD582 billion. Twenty of the world's nations accounted for 92% of this total, valued at USD534 billion. The world's Number 1 exporter of pharmaceutical products was Germany at USD89.4 billion, with 15.3% of global pharmaceutical exports. Number 23 was Australia, with exports of USD3.2 billion, or 0.55% of global exports.[10]

In the same year (2019), Australia imported pharmaceutical products valued at $USD7.38 billion, or 1.27% of global pharmaceutical imports.[11]

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.

The NRF could support a focus on the Australian manufacture of new, high value medical products in Australia. It would significantly boost our terms of trade in a key world market and create high value jobs, as well as enable Australia to play a larger geopolitical role within our region and provide further export opportunities. It would also create an ecosystem which would further support new research and commercialisation of new products.

Pharmaceutical products is the case study used here, but similar opportunities exist with other types of medical products, including diagnostics and medical devices.

[9] https://www.statista.com/outlook/hmo/medical-technology/worldwide#:~:text=Revenue%20in%20the%20Medical%20Technology,US%24701.90bn%20by%202027.

[10] Sourced 7 July 2022 from https://atlas.cid.harvard.edu/explore?country=undefined&product=129&year=2019&productClass=HS&target=Product&partner=undefined&startYear=undefined

[11] Sourced 7 July 2022 from https://atlas.cid.harvard.edu/explore?country=undefined&product=129&year=2019&tradeDirection=import&productClass=HS&target=Product&partner=undefined&startYear=undefined

6. What are the manufacturing capabilities needed to support each priority area?

For medicines and vaccines, manufacturing capabilities are required to support the scaling of manufacture from the experimental GLP (Good laboratory Practice) to small scale GMP (Good Manufacturing Practice) required to develop sufficient materials for clinical trials. Equivalent requirements for the scalable manufacture of prototypes exist for medical devices and equipment.

Commercial manufacturing requires scale sufficient to make the manufacture profitable; this will typically require manufacture for both domestic and export markets.

7. What are other capabilities needed to support each priority area?

Other capabilities required are in commercialisation- skills in evaluation of investment opportunities, development of IP strategies, planning pathways to market and reimbursement. See the response at Question 9 below for more detail.

8. What are the strategic priorities for supply chains/enabling inputs in each priority area?

The strategic priorities are meeting the national interests in critical areas by securing domestic manufacture, and ensuring the manufacturing can be done profitably. In most cases this will mean manufacturing for both domestic and export markets, requiring careful evaluation of the global market opportunity and competitors. Australia is unlikely to be able to complete in low value add high volume commodities.

9. What are the gaps in or barriers to private sector investment in each of the priority areas?

The most significant gaps to private sector investment are the long lead times to revenue generation and the expertise required to evaluate investment opportunities for medical products. Medical products are held to higher regulatory standards than most consumer or industrial products. The requirements to demonstrate safety and efficacy are demanding, meaning it takes longer, and requires more money, to get to market. Consequently, medical products require patient capital, willing to invest early and support a product through the decade or more it can take to reach the market.

The opportunities for failing to reach the market are also greater than for most products, increasing the investment risk. Evaluation of an investment opportunity requires an understanding of the science, the IP strategy, the market, the regulatory process and the opportunities for reimbursement. This requires specialist expertise which can be difficult to acquire and can be in short supply in Australia. However, there are pockets of expertise and there are existing organisations and individuals in Australia with this expertise. Expertise in developing medical products manufacturing is also in relatively short supply in Australia although there is an opportunity to draw on capabilities in other industries and on existing medial products manufacturing capabilities.

Research Australia submits the Government should develop a medical products research, development and manufacturing workforce plan to determine where the gaps in existing skills are and to address them. In doing so, the Government can build on the MTPConnect REDI Skills Gaps Analysis Reports and the REDI program more generally, and the ARC Industrial

Transformation Training Centres.[12]

10. How can the NRF help build or encourage stronger pathways for Australian developed innovation and research, and encourage additional private investment in priority areas?

The existing funding environment for research within and beyond our universities is complicated and disjointed, with many gaps and duplication. This leads to lack of continuity of funding, with each grant progressing a research project only to a certain point before further funding has to be sought, often leading to a 'pause' in the research, or to the research stalling altogether. Multiple funding schemes operating independently of each other but funding the same types of research h can also lead to a situation where separate teams are funded by different funding schemes to undertake the same or similar research, leading to duplication of effort.

A more strategic and streamlined approach to funding health and medical research in Australia will lead to greater efficiency and improve the capacity of our research to progress beyond discoveries to new products and therapies.

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

Downstream from this basic research there is a range of different programs and initiatives intended to support research and development at different stages. At the Commonwealth level the main grant programs include aspects of the ARC's Linkage program, some of the more translationally oriented NHMRC funding programs, the Medical Research Future Fund (including Cureator and the Frontiers Program), the CRC Program, and the Entrepreneur's Program. In the last two years the Trailblazer Universities Program has been added to the mix. The Australia's Economic Accelerator is to be introduced in 2023, providing grant funding to support Proof of Concept experiments and activities where a university has an industry partner.

In terms of government investment rather than grants, the Biomedical Translation Fund (The BTF) is a fund created by the Australian Government in 2016 to co-invest with the private sector in medical technologies. The BTF has some similarities with the NRF. The original programme guidelines for the BTF state:

> 'The BTF Programme policy objectives are:
> - to invest in promising biomedical discoveries and assist in their commercialisation.
> - by addressing capital and management constraints, to encourage the development of companies which are commercialising biomedical discoveries.'[13]

While the BTF has a focus on encouraging the development of companies there is not an emphasis on Australian manufacturing; evidence of how the priorities have changed since 2016.

[12] https://www.mtpconnect.org.au/programs/REDI ; https://www.arc.gov.au/funding-research/funding-schemes/linkage-program/industrial-transformation-research-program/industrial-transformation-training-centres

[13] Australian Government, Department of Industry Innovation and Science, Department of Health Programme Guidelines Biomedical Translation Fund 3 August 2016, page 3

The challenge for the Government and the NRF is to identify how the NRF can draw on all these 'upstream' Government activities in a way that helps provide a more streamlined and coherent approach to supporting research, innovation and manufacturing in Australia. Please also see our response to Question 18 about actions the Government could take.

11. How could the NRF consider Government policy priorities in performing its investment function?

The NRF Bill provides for the Ministers to provide instructions to the NRF.

As outlined in our response to Question 1, supply chain vulnerabilities and sovereign manufacturing capability are particularly important in the Medical Science and Manufacturing priority area; addressing these is a strategic priority for the Government.

The Australian Government is currently developing a Centre for Disease Control and one of its key areas of focus will be to review and manage the National Medicines Stockpile, with the objective of ensuring Australia's access to vital medicines and other medical products in a health emergency. Research Australia has proposed that the CDC's responsibilities should extend to identifying for which Stockpile items Australia should have domestic manufacturing capability.

Research Australia submits the Ministers should obtain the advice of a future CDC about medical products for which there is a critical unmet need for domestic manufacturing. This advice could inform the Ministers' instructions to the NRF about priorities for funding allocation by the NRF, although not to the exclusion of the need to generate a return on the investment.

The emphasis on **secure, high value jobs and future prosperity** suggests the NRF must be about retaining IP in Australian hands and manufacturing here to address supply chain vulnerabilities and create jobs.

Research Australia submits the Minister should direct the NRF to invest in projects with the greatest potential for profitable domestic manufacturing. This can include investment in early-stage technologies and IP but with the objective of retaining IP in Australia and establishing domestic manufacturing. The NRF must be prepared to invest for the long term, through product development and on to manufacturing rather than developing investment strategies which plan an exit via licensing or acquisition of IP by a multinational.

Research Australia submits development of the investment mandate for the priority area of medical products should include identification of areas with the potential for profitable domestic manufacturing. This should be a consideration in how funds are subsequently allocated by the NRF, although not to the exclusion of the need to generate a return on the investment.

Returns, financial instruments and working with other investors

12. What factors and considerations should inform the portfolio rate of return for the NRF?

No response provided to this question.

13. What factors and considerations should inform the setting of acceptable but not excessive level of risk? Should the acceptable level of risk differ between priority areas?

No response provided to this question.

14. What types of concessional offerings would be preferred if these were offered (for example, lower interest rates) and why?

No response provided to this question.

15. What factors drive or constrain co-investment (for example, by industry, financial sector or domestic or offshore investors) and how should these be taken into account?

For medical products, a shortage of expertise in evaluating the investment opportunity and the cost of undertaking the evaluation can be a significant factor. (There are specialist fund managers in this area, for example Brandon Capital.[14]) If the costs of evaluating investment targets are borne by the NRF, and the NRF's evaluation provided to other potential co-investors, this could help encourage co-investment.

There is an existing investor base for medical products, established initially by the Medical Research Commercialisation Fund and subsequently expanded for the Biomedical Translation Fund. The BTF could leverage this base when seeking co-investment.

16. What are the mechanisms and types of finance which will best attract co-investment from the private sector? How can the NRF best crowd-in investment?

No response provided to this question.

[14] https://brandoncapital.vc/who-we-are/

Complementary reforms

17. What are the non-financial barriers preventing businesses from making the most of opportunities for value-add, growth and diversification in the priority areas?

Probably the biggest non-financial barrier in Australia is the relatively small size of our innovation ecosystem. This can only be overcome by growing the sector, as the NRF is seeking to do.

A lack of mobility of researchers from universities and medical research institutes into industry, and vice versa, is another factor. While partly a consequence of the relatively small and immature medical products industry in Australia, it is also influenced by the practices and culture of universities and medical research institutes and how researcher identity is perceived in Australia. Measures to increase mobility between industry, academia and medical research institutes will be critical to the long-term success of the NRF in medical products. This requires communication, collaboration and cooperation. across industry and science, higher education and health portfolios.

18. Are there non-financial mechanisms that could support priority areas and the objectives of the NRF?

Research Australia submits the Australian Government should create a National Medical Products Industry Plan to accompany the introduction of the National Reconstruction Fund.

A National Medical Products Industry Plan would bring a new and clear focus to the disparate policy initiatives, funding programs and actions being taken by Commonwealth, State and Territory Governments that support health and medical research, innovation and commercialisation (detailed in our response to Question 10). It would consider how we can better address the unique challenges to commercialising medical products. It would look to the strengths and opportunities of our existing manufacturing capability, and how these can be supported and expanded. It would take a workforce lens to the entire pipeline from research through to manufacturing, to ensure we have the skills and capabilities necessary to deliver the vision. It would help ensure Australia's national security by prioritising manufacturing and skills development in areas essential to our national security.

As we have demonstrated above, many of the components are already here. A National Medical Products Industry Plan would help better coordinate these existing components, including the National Reconstruction Fund, and identify gaps and emerging opportunities. It would provide a clear focus and goals for Australia's research and innovations sectors and help develop a clear pathway to domestic manufacturing of new and existing medical products. It would help align Australia's national security with the substantial economic benefits of developing a significant, vibrant and innovative medical products manufacturing industry in Australia.

19. How could the NRF work alongside other complementary reforms to best deliver on the Government's policy priorities?

Please see our response to Question 18.

20. To what extent are other levers required to support the objectives of the NRF (for example, skills, trade, supply chains)?

As outlined in our response to Question 9, addressing workforce shortages will be critical to the success of the NRF.

Research Australia submits the Government should develop a medical products research, development and manufacturing workforce plan to determine where the gaps in existing skills are and to address them. In doing so, the Government can build on the MTPConnect REDI Skills Gaps Analysis Reports and the REDI program more generally, and the ARC Industrial Transformation Training Centres.[15]

21. How does the NRF, with other private and Government settings, drive the right ecosystems for sustainable industry growth?

Please see our response to Question 18.

Conclusion

Research Australia believes the National Reconstruction Fund provides the opportunity to better leverage Australia's world leading health and medical research and create a vibrant and successful medical products industry which propels Australia forward to become a net exporter of medical products. Doing so would provide significant benefits for Australians with more secure access to medical products, better health outcomes and the creation of well-paying jobs and new businesses in a sector that has enormous scope for ongoing global growth.

Our submission seeks to ensure that the NRF is given the opportunity to be as effective as possible in meeting these objectives.

If you have any questions regarding this submission or require further information, please contact Greg Mullins, Head of Policy, at greg.mullins@researchaustralia.org

[15] https://www.mtpconnect.org.au/programs/REDI ; https://www.arc.gov.au/funding-research/funding-schemes/linkage-program/industrial-transformation-research-program/industrial-transformation-training-centres

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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