

Australian Government





Medical Research Future Fund

AUSTRALIAN MEDICAL RESEARCH AND INNOVATION STRATEGY 2016-2021

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LETTER FROM THE CHAIR

The Hon Sussan Ley MP Minister for Health and Aged Care

Dear Minister,

The Australian health system must be innovative and ready to respond to future challenges, including new health technologies, communicable diseases, and caring for an ageing population with complex and chronic health problems. Research is the best way to prepare for these challenges. Research can contribute to health system safety and quality, ensure effectiveness of health interventions, and enable Australia to develop better methods of preventing and treating disease.

Priority focussed research funded by the Medical Research Future Fund (MRFF) will complement largely investigator initiated research funded by the National Health and Medical Research Council (NHMRC). The MRFF will attract and retain excellent researchers, allow for the discovery and commercialisation of new medicines and technologies, and enable innovative treatments and cures. It will deliver improved health for all Australians, contribute to a sustainable health system, and provide significant economic benefits.

I am pleased to present this document, the *Australian Medical Research and Innovation Strategy 2016-2021* (the Strategy) and the accompanying inaugural two yearly set of *Australian Medical Research and Innovation Priorities 2016-2018* (the Priorities), prepared by the Australian Medical Research Advisory Board (Advisory Board) in accordance with the *Australian Medical Research Future Fund Act 2015*.

The Advisory Board has proposed a number of strategic research platforms to ensure that the Australian health system is ready for the future. This Strategy has been developed following extensive national consultation with consumers, researchers, healthcare providers and managers. The focus for this Strategy is on areas for investment that cut across the health system, with investment opportunities relevant to all health issues.

The Strategy does not identify specific health issues as targets for investment. Rather, the existing National Health Priority Areas¹ act as a reference. It is noted that over time and with new data these priority areas may be subject to change. The National Indigenous Reform Agreement (*Closing the Gap*)² also provides important context for the delivery of the Strategy and Priorities.

I would personally like to thank the members of the Advisory Board for their commitment. Collectively, the Advisory Board would like to acknowledge the goodwill of the health and research community and consumers for their engagement in the consultation. We also acknowledge, with gratitude, the considerable support of Department of Health staff in the preparation of this Strategy and the accompanying Priorities.

Yours sincerely,

Professor Ian Frazer AC Chair, Australian Medical Research Advisory Board

¹ Australian Institute of Health and Wellbeing, National Health Priority Areas, [website], 2016, http://www.aihw.gov.au/national-health-priority-areas/, (accessed 13 October 2016).

² Council of Australian Government, National Indigenous Reform Agreement (Closing the Gap), [website], http://www.federalfinancialrelations.gov.au/content/npa/health/_archive/indigenous-reform/nationalagreement_sept_12.pdf, (accessed 26 October 2016).

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THE STRATEGY

The Medical Research Future Fund (MRFF) is a \$20 billion vehicle for investment in health and medical research. It represents the single largest boost to research funding in Australia's history. The net earnings from the MRFF will serve as a permanent revenue stream, which when fully capitalised, is expected to disburse around \$1 billion annually, effectively doubling the Australian Government's direct investment in health and medical research and innovation.

This first five-year *Australian Medical Research and Innovation Strategy 2016-2021* (the Strategy) prepared by the Australian Medical Research Advisory Board (Advisory Board) sets out the vision, aims and objectives for the MRFF. It identifies a

Vision

A health system fully informed by quality health and medical research.

Aim

Through strategic investment, to transform health and medical research and innovation to improve lives, build the economy and contribute to health system sustainability.

Objectives

- Create health and economic benefits from research discoveries and innovations
- Embed research evidence in healthcare policy and in practice improvement
- Drive collaboration and innovation across the research pipeline and healthcare system
- Strengthen transdisciplinary research collaboration
- Provide better access to research infrastructure
- Maximise opportunities for research translation by engaging with consumers

series of strategic platforms that, if funded, have potential for greatest impact. These platforms will serve as a framework for the two-yearly identification of the *Australian Medical Research and Innovation Priorities* (the Priorities), the first of which accompany this Strategy.

In accordance with the *Medical Research Future Fund Act 2015* (the Act), the Australian Government must take into account the Priorities that are in force at the time of making disbursements from the MRFF. The Advisory Board has constructed the Priorities as a document that should be read and considered in conjunction with the Strategy as there is alignment with the strategic platforms.

- Position the research sector and health system to tackle future challenges
- Facilitate the commercialisation of great Australian research
- Demonstrate the value and impact of research investment

Strategic platforms

- Strategic and international horizons
- Data and infrastructure
- Health services and systems
- Capacity and collaboration
- Trials and translation
- Commercialisation

Impact measurement

- Better patient outcomes
- Beneficial change to health practices
- Evidence of increased efficiency in the health system
- Commercialisation of health research outcomes
- Community support for the use of and outcomes from funding

OPPORTUNITIES AND BENEFITS

Australian researchers have an excellent reputation and make a difference locally and globally. Our researchers have developed lifesaving discoveries, pioneered procedures, and been awarded Nobel Prizes for their extraordinary contributions to medicine. They continue to lead work in emerging fields of science, and champion the adoption of new technologies.

Health and medical research spans a pipeline from concept to laboratory through to translation, clinical application and community benefit. This research answers questions about causes, prevention, management and the impact of disease, and about how best practice healthcare and policy can be effectively implemented. It typically embraces a range of different disciplines, occurs in universities and hospitals, medical research institutes and companies, and in the community at large. It involves multiple professions, public and private entities and consumers.

Research is an essential part of the health system, sometimes visible to the larger community on the frontline of care, but often operating behind the scenes to make a difference in the type, quality and effectiveness of the care delivered.

Health and medical research results in healthier Australians and innovations that boost national wealth. It has a measureable impact on health system sustainability, productivity, and health outcomes. The 2013 *Strategic Review of Health and Medical Research*³ outlined a vision of better health through research and emphasised the importance of strong links between biomedical, clinical, public health, and health services research. The MRFF will build on this vision. The practical benefits of improved health have been supported and enabled by research, which has helped Australia become a leading economy of the 21st century. Between 1992-93 and 2004-05, the estimated expenditure on Australian research and development returned a net benefit of approximately \$29.5 billion.⁴ For every dollar invested in Australian research and development, an average of \$2.17 in health benefits is returned.⁵

An increase in wellbeing provides additional benefits to the economy and to society. It:

- enhances productivity gains by avoidance of premature mortality and morbidity;
- reduces care, carer and aids costs; and
- reduces loss associated with government transfers such as taxation revenue forgone and welfare and disability payments.⁶

In 2014, the National Commission of Audit raised concerns about the future cost of health, with expenditure on key health programs projected to continue to grow faster than Gross Domestic Product. Not all health expenditure is equally cost-effective.⁷ Cutting funding for health without transformational change can put health outcomes at risk. However, research accompanied by concerted efforts to translate findings into practice has the potential to reduce costs and improve health outcomes.

Strategic investment into health and medical research can serve to minimise the upward pressure on costs associated with new treatments, an ageing population and the

³ McKeon et al, Strategic Review of Health and Medical Research, Canberra, Department of Health and Ageing, 2013.

⁴ Lateral Economics, The Economic Value of Australia's Investment in Health and Medical Research: Reinforcing the Evidence for Exceptional Returns, Port Melbourne, Research Australia, 2010.

⁵ Access Economics, Exceptional Returns: The Value of Investing in Health R&D in Australia II, Canberra, Australian Society for Medical Research, 2008.

⁶ Access Economics, Returns on NHMRC funded Research and Development, Canberra, Australian Society for Medical Research, 2011.

⁷ National Commission of Audit, The Report of the National Commission of Audit - Volume 1, Canberra, Australian Government, 2014.

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increasing burden and complexity of disease. This is where the MRFF can have an impact.

THE FUND

The MRFF was established as an endowment fund to be preserved in perpetuity, to provide a secure additional revenue stream for health and medical research and innovation. Under the Act, the independent Advisory Board is responsible, following consultation, for developing the Strategy, which spans five years, and a two yearly set of Priorities for Government investment consideration.

In accordance with the Act, once made, the Strategy and accompanying Priorities are lodged with the Federal Register of Legislative Instruments to enable the documents to be tabled in Parliament. The Health Minister is required under the legislation to consider the Priorities when putting forward proposals to Government for MRFF funding distribution.

The Act provides flexibility on how MRFF funds can be distributed by Government. This can occur via an approach to market, by an independent expert selection process, or by direct funding to any eligible organisation. Alternatively, funds may flow through a corporate Commonwealth entity, or under an agreement with states and territories. Ultimately, decisions about disbursements are made by the Government.

The MRFF is managed by the Future Fund Board of Guardians, which invests the assets of the Fund. The Board of Guardians is required to maintain the nominal value of the credits made to the MRFF in order to enable a predictable and secure ongoing flow of funding for health and medical research and innovation.

ALIGNMENT AND COMPLEMENTARITY

It is critical that funding from the MRFF and other sources is complementary to, and does not duplicate, the work of the National Health and Medical Research Council (NHMRC), the emerging National Science and Innovation Agenda (NISA), and other interests including state and territory governments and the private and not-for-profit sectors.

National Health and Medical Research Council

The NHMRC is Australia's leading body for supporting health and medical research and has been operating since 1937. Australia's excellent research reputation has been nurtured and built by NHMRC's commitment to sponsoring quality research administered through nationally competitive grant programs.

Australia's research system is mature enough to run distinct and parallel funding streams, like many other nations. The MRFF will neither replicate the role of, nor operate in competition with the NHMRC. Rather, it will enable Government to provide targeted funding guided by the Advisory Boarddetermined Strategy and Priorities.

The relationship between the MRFF and NHMRC will evolve through collaboration, facilitated by the welcome inclusion of the NHMRC Chief Executive Officer on the Advisory Board.

There are opportunities for collaboration between the MRFF and NHMRC, based on the flexibility permitted in the Act. The Government can decide, with reference to the Strategy and the Priorities, to administer disbursements using the NHMRC's peer review processes, or collaborate on joint targeted calls for research. The MRFF can also be used to top up one or more existing NHMRC programs to maximise impact.

Both the NHMRC and the Advisory Board are committed to working together to ensure complementarity of funding is maintained through collaboration, governance, and shared administration where appropriate.

Innovation and Science

The NISA recognises that the next wave of economic prosperity for Australia depends on

building domestic science and innovation capabilities. Governance of the NISA is facilitated by Innovation and Science Australia, an independent statutory board, with responsibility for providing strategic whole-of-government advice to the Government on all science, research and innovation matters. Innovation and Science Australia complements the Commonwealth Science Council, which continues to advise the Government on high level science challenges facing Australia.

Innovation and Science Australia will develop a whole-of-government 15-year plan for innovation, science and research for Government consideration at the end of 2017, and this will likely have relevance to advancing health and medical research capacity. It is important for the MRFF to be connected with the NISA to ensure complementarity of activities, and to maximise opportunities for health and medical research advancement.

A key initiative under the NISA is the Biomedical Translation Fund. This fund seeks to open up the research pipeline by investing in the commercialisation of the outcomes of health and medical research. The Biomedical Translation Fund operates as a for-profit co-investment venture capital fund under which licensed fund managers secure at least matched private capital to the Australian Government contribution of \$250 million. Together, the Biomedical Translation Fund and the MRFF provide a real opportunity to address the twin 'valleys of death' commonly referred to along the research pipeline where the translation and commercialisation of research can be put in jeopardy.

Research infrastructure is a crucial enabler of research. Under NISA a new National Research Infrastructure Roadmap (the Roadmap) is also being developed by Australia's Chief Scientist, which will inform future consideration of national research assets for public and private collaborative benefit over the next decade. Infrastructure for health and medical science is being considered in the Roadmap. There are a broad range of Australian Government activities that contribute to the research infrastructure landscape in Australia, including the NISA and the National Collaborative Research Infrastructure Strategy. This highlights the need for an ongoing coordinated and integrated approach across Government, industry and health, especially as research increasingly crosses disciplinary boundaries.

The MRFF cannot operate in isolation from broader research infrastructure considerations under the Roadmap and National Collaborative Research Infrastructure Strategy, but it also cannot fund all needs. As the MRFF is still maturing, the best immediate use of funds will be through measures that harness existing infrastructure and human capital.

Other governments and non-government interests

State and territory governments have a strong history of funding research and, as health system managers, are critical to implementing on-the-ground projects. The MRFF has legislative flexibility to participate in unique co-funding opportunities in collaboration with states and territories to maximise research translation. The MRFF could amplify investment by working closely with all levels of government.

High-end philanthropy is still relatively underdeveloped in Australia. This is in contrast to the increasing global trend exemplified by organisations such as the Wellcome Trust in the United Kingdom and the Bill and Melinda Gates Foundation in the United States. The Australian philanthropic sector is currently characterised by a large number of small charitable organisations that mostly raise funds for disease-specific research. The potential for co-investment by the MRFF along shared national research agendas as articulated in the Priorities is significant.

Leading nations support research from multiple sources, including government,

industry and philanthropy. There is an opportunity through the MRFF national priority setting exercise to leverage non-government funding to maximise strategic investment. Once harnessed, these co-funding relationships from domestic and international sources can address national and regional health security and build health system capacity in our region.

International alignment

Health and medical research is ultimately an international effort. Australia is a significant collaborator with researchers from other countries, and it is important to look for strategic input and insight. Several recently published international research strategies complement the intention of this Strategy.

The Canadian Institutes of Health Research five-year strategic plan (2014-15 to 2018-19)⁸ discusses the importance of achieving a broader disciplinary mix of researchers across the health fields, and embracing the data revolution.

In the United Kingdom, the Academy of Medical Sciences' recent publication *Improving the health of the public by 2040*⁹ calls for encouraged transdisciplinary research, to develop innovative and ethical means to utilise data, and unite public health, health and medical research and clinical practice for the purpose of translation and universal improvement.

The US Academy of Medicine recently published *Advancing the Science to Improve Population Health*,¹⁰ which explores the basic and translational research needs for

population health science, and discusses specific research priorities and actions to foster population health improvement.

The importance of engaging with consumers is emphasised across all of these agendas.

CHALLENGES AND CULTURE

Health and medicine is one of Australia's strongest fields of research and Australia ranks highly against a range of international benchmarks.^{11,12} There are, however, a number of challenges facing the health and medical research sector in Australia that need to be addressed to lift and accelerate the health and economic gains to be made from research.

The research pipeline

From the consultation process to develop this Strategy, the Advisory Board has identified that the level of research and development supporting the health system is insufficient and the research pipeline itself needs to be strengthened.

The pipeline is often characterised as having two 'valleys of death'. Typically these occur at (1) the pre-clinical phase, where a lack of funding inhibits the progression of discoveries to early proof-of-concept, and (2) the post proof-of-concept commercialisation stage; where funds are required for advanced pre-clinical work and early phase clinical trials. It is important that the MRFF is used to address not only these two valleys, but to reinforce the pipeline along its entire continuum. Discovery, development, and commercialisation cannot occur without appropriate workforce capacity, effective implementation and a means to evaluate the

⁸ Canadian Institutes of Health Research, Health Research Roadmap II: Capturing Innovation to Produce Better Health and Health Care for Canadians Strategic Plan 2014-15 – 2018-19, Ottawa, 2015.

⁹ The Academy of Medical Sciences, Improving the Health of the Public by 2040, London, 2016. ¹⁰ National Academies of Sciences, Engineering, and Medicine, Advancing the Science to Improve Population Health: Proceedings of a Workshop, Washington, DC, National Academies Press, 2016.

¹¹ Butler 'Impacts of Performance-based Research Funding Systems: A Review of the Concerns and the Evidence', Performance-based Funding for Public Research in Tertiary Education Institutions: Workshop Proceedings, Paris, OECD Publishing, 2010.

¹² Australian Research Council, Excellence in Research for Australia National Report 2012, Canberra, 2012.

impact this work has on quality of life for consumers and patients.

The current level of expenditure on health and medical research is disproportionately small when compared to the size of the sector. The MRFF has the potential to meet a need for investment in proof-of-concept, preclinical, clinical and health services research, to facilitate translation and the pathway to market, and to build the capacity of the sector to pursue these activities. Such investment would help improve the reproducibility and reliability, and therefore the impact, of biomedical and technological research.¹³

Consumer engagement and collaboration

There is a limited degree of consumer engagement and collaboration across the research pipeline, which impacts on the success of research outcome translation into clinical practice. Consumers and their families are the ultimate funders, users and beneficiaries of health and medical research. Healthcare is a significant social, economic and political issue and there is evidence in Australia that consumers are willing and wanting to be more engaged.¹⁴

Australians appreciate the connection between evidence-based healthcare and health outcomes. However, often consumers are not engaged early in research discovery work, particularly in applied research. Codesign and creation present an opportunity to think about the end product or therapy and its user, its degree of direct benefit and adoptability. In the future, consumers will drive their own healthcare in partnership with clinicians, and it is therefore important to start working together earlier in the research pipeline.¹⁵ Collaborations between researchers, those involved in health service delivery (public and private) and industry must improve. Cultural and institutional issues have historically constrained these connections and have limited the flexibility of career pathways for researchers with an interest in applying or commercialising their research. Many universities have commercialisation or translation offices that help researchers bring their discoveries to market and there are noticeable improvements in this space. However, university rankings and income remain largely driven by academic excellence, including indicators such as publications and student intake. These can discourage efforts in translation and commercialisation.

Industry experience, past success in solving industry problems, and non-academic translation are not generally part of the metrics of academic excellence. The 2015 *Review of Research Policy and Funding Arrangements*¹⁶ has recommended a shift (consistent with the NISA) in policy settings for higher education to maximise innovation performance, including the provision of incentives to increase university (and other research organisation) engagement and collaboration with business and other end users.

Research in practice

There are barriers and disincentives that impede research within the healthcare sector itself. Historically, teaching, training and research resources have been block funded, with their utility neither measured nor fully appreciated. Research is frequently viewed as an 'added cost' easily redirected towards

¹³ Academy of Medical Sciences, Reproducibility and Reliability of Biomedical Research: Improving Research Practice, London, 2015.

¹⁴ Research Australia, Australia Speaks! 2016 Opinion Poll, Darlinghurst, 2016.

¹⁵ Topol E., , The Patient Will See You Now, New York, Basic Books, 2015.

Transdisciplinary and industry cooperation

¹⁶ Watt et al, Report of the Review of Research Policy and Funding Arrangements, Canberra, Australian Government, 2015.

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urgent activity demands.¹⁷ Often, ability and reputation of an institution to undertake world-class research depend on the administration appreciating the benefits for patients, for staff recruitment and retention, and for health outcomes more broadly. Similar experience is evident in the primary care sector, where private business models based on care transactions have limited capacity to embed research in practice. These pressures must be addressed so that the potential for research translation is realised.

Full cost of research

The full cost of research includes indirect costs that cannot easily be attributed to a single research program or grant. These include the cost of research administration, research infrastructure, and research support services. Approaches to equitably funding these costs across the research sector and by different funding agencies have met with little success. Currently, direct research costs can be paid by one agency and the indirect research costs by another, based on fragile and administratively complex and expensive arrangements.

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 wholeof-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.

FIVE YEAR STRATEGIC PLATFORMS

The Advisory Board has consulted widely across the sector and broader community. Feedback received has been used to develop six strategic platforms that underpin this Strategy. The platforms recognise the challenges and cultural issues outlined, and the inherent need to maintain and support basic research into disease causation that underpins all health research, translation and delivery.

The platforms capture and group together themes and provide a framework for the Priorities to improve research capacity and capabilities in the research sector. Through targeted funding from the MRFF, these platforms will advance health and medical research and innovation over the next five years and help Australia meet its future healthcare challenges.

Strategic and international horizons

Health services in Australia can benefit from strategic and focused international research efforts, with funding models that are agile in the face of disruptive health challenges and new technologies. The health problems of today and tomorrow are complex and will require large scale, globally collaborative and long-term research efforts.

Many countries are currently investing heavily in international consortia to address a range of research issues, including the impact of new technologies such as genomics, synthetic biology, epigenetics, microbiomics, the challenge of antimicrobial resistance and the emergence of new pathogenic viruses.

Australia stands to benefit from being a leader rather than a follower in international collaborative research. The MRFF should provide support for Australian consortia to participate in and lead international research projects focusing on major global health challenges and threats, and these should be complementary to the international

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¹⁷ McKeon et al, Strategic Review of Health and Medical Research, Canberra, Department of Health and Ageing, 2013.

collaborative research activities of the NHMRC. MRFF funding can enable Australia to reap local, regional and global economic benefits and further raise Australia's reputation as a health research powerhouse that 'punches above its weight'.

Data and infrastructure

Emerging fields such as bioinformatics, computational biology, metagenomics, artificial intelligence and new diagnostics depend on data assets. An integrated national health data framework that supports healthcare delivery, service improvement and best practice adoption is essential, and the MRFF should fund research that enables the planning and implementation of this initiative.

National datasets currently have limited utility without linkage with clinical software and the use of common data dictionaries. MRFF funding can facilitate research on the interoperability of existing and future datasets for basic science and health services research.

Providing access to health data facilitates evidence-based care and drives efficient use of resources. This applies to cliniciancaptured data, surveillance information, clinical quality registries, biobanks, and the wealth of data related to the new 'omics' technologies. These datasets and the means to analyse them will be the basis of the future health system architecture and will drive new advances in healthcare.

The collection, curation, linkage and application of health data across the health system must be nurtured, and where possible integrated with the digital health agenda via My Health Record. Custodianship and governance should be clear, systems must be interoperable, privacy must be protected, and data assets must be made appropriately available to drive research, industry and service delivery.

Physical infrastructure requirements for health and medical research are another key part of any capacity building exercise. Maintaining internationally competitive technology and supporting talent to operate it is demanding because equipment costs continue to increase, while their length of time as 'state of the art' items contracts. The MRFF, noting the National Research Infrastructure Roadmap, must help build research infrastructure capacity, specifically as it relates to health and medicine. This can be best realised by sharing new and existing infrastructure, and by enhancing user expertise.

Health services and systems

Much of the health and medical research conducted in Australia is product and drug focussed, and research on health interventions is dominated by the acute care experience. The MRFF can play a significant role in bolstering Australia's capacity in health services and systems research. For example, MRFF investment activities can work with the Medicare Benefits Schedule Review Taskforce and new policy and program agendas, such as the Australian Government's Health Care Homes trial.

Health services and systems research seeks more affordable models of healthcare and innovative evidence-based approaches to treatment, prevention, diagnosis and the management of disease. It combines clinical, public and population health disciplines with economics, and behavioural and implementation science. This form of research is often embedded in healthcare delivery to maximise translation by engaging actual clinicians.

The efficiency and cost-effectiveness of many routinely used health interventions are not known and/or not proven. Healthcare professionals continue to undertake activities that are suspected to be of little benefit in place of, or alongside, proven effective interventions. Research delivering new methods that avoid wasteful interventions, adopt best practice and foster information exchange will allow clinicians to benchmark with peers and lead to continuous quality improvement. Equally important is an appreciation of the impact of location (urban, regional and remote), culture, and socio-economics on healthcare access and outcomes. Close collaboration is also required with Aboriginal and Torres Strait Islander Australian health stakeholders, including the community controlled sector, to ensure Indigenous Australians are engaged in research process and design, and that research is utilised to *Close the Gap*.

Adequate numbers of healthcare professionals with training in clinical research are critical to ensuring meaningful service and system performance and the MRFF can make a significant contribution in building this capacity.

Capacity and collaboration

The MRFF can encourage increased interchange between academia, service delivery and industry with research practice and solutions in mind.

Health and medical research depends largely on workforce talent. Research training should be integral to the education of all health service providers, and be one of the key performance indicators for the health services and their senior management. Insufficient attention to developing the skills of our scientists and healthcare professionals will sell Australia short in the health and medical research arena.

Researchers in more diverse, yet relevant disciplines (e.g., social sciences, behavioural sciences, economics, chemistry, engineering, and mathematics) equally need to be offered opportunities to participate in health sciences research to harness innovation.

Collaboration across research disciplines with the intent of innovation and productivity is crucial – the same is true between sectors.¹⁸ The MRFF can work to enhance research collaboration on a national scale by investing in multi-disciplinary, institute and sector teams. The funding itself can be collaborative by leveraging co-investment from other governments, private and philanthropic interests.

Through collaboration, researchers can be encouraged to adopt entrepreneurial approaches, test implementation science applications, and look for opportunities to traverse academic, health service and industry work.¹⁹

Trials and translation

Clinical trials guide the development of new drugs and devices, new models of care, and improved clinical practice. Australia has an excellent reputation for delivering clinical trials, and significant efforts have been made by all levels of government to streamline ethics and governance arrangements. This work needs to continue, to lift Australia's reputation as a preferred location for clinical trials.

The MRFF has an important role to play in facilitating non-commercial clinical trials of potential significance. MRFF support of clinical trial networking infrastructure can also serve to enhance the efficient conduct of multicentre trials, with both public and commercial impact.

Clinical trial networks are groups of active clinician researchers who come together to design research questions and implement multi-site and multi-sector trials that solve real time practice problems. Networks are not confined geographically, and work horizontally across the care continuum, providing on-site training and mentoring, multi-site recruitment and collective peersupport. The researchers that perform clinical trials and the networks themselves must incorporate all relevant professions, including general medical, nursing, and allied health. There are a number of clinical trial networks

¹⁸ Bell et al, The Role of Science, Research and Technology in Lifting Australia's Productivity, Australian Council of Learned Academies, Melbourne, 2014.

¹⁹ The Academy of Medical Sciences, Improving Recognition of Team Science Contributions in Biomedical Research Careers, London, 2016.

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across Australia and some have international connections. The MRFF is in a unique position to galvanise the potential of these networks.

The main way that health research is measured as having impact is by research findings being translated into both clinical practice and behavioural change. Recent accreditation of Advanced Health Research and Translation Centres (AHRTCs) by the NHMRC has identified world-class clinical facilities ready to embrace and facilitate translation. AHRTCs are leading centres of collaboration with a focus on practical translation, education and training, and outstanding healthcare. They foster research across boundaries between general and hospital practice, geographical regions, and health service disciplines. The NHMRC is looking to accredit further AHRTCs and potentially broaden the scope into regional areas.

The MRFF is well placed to support these AHRTCs to conduct targeted collaborative and transformative research. Cooperation between the MRFF as funder and the NHMRC as accreditor is an excellent demonstration of complementary practice, and shared purpose.

Commercialisation

The MRFF cannot overlook the commercialisation end of the research pipeline, where discoveries become every day realities. Through commercialisation, consumers are given access to innovations. Despite occasional commercial success stories, Australia has a relatively underdeveloped culture for biomedical and biotechnology commercialisation, resulting in limited knowledge and skills among the broader research community.

Challenges to the commercialisation of research discoveries in Australia include lack of funding for proof-of-concept and early stage clinical research, which discourages start-up companies and provides infertile ground for would-be entrepreneurs within the research workforce. Under ordinary circumstances the MRFF should not replace industry and venture capital funding, but there is capacity for the MRFF to support the progression of some projects to a stage more attractive for private sector investment, as per the MRFF aligned Biomedical Translation Fund. Translational research with limited potential for profit – but with significant public benefit – should also be considered for MRFF support.

Aside from the challenge of attracting venture capital, many researchers lack awareness of entrepreneurial options and/or confidence in their own abilities. Commercially-focused research is sometimes viewed as incompatible with unrestricted sharing of research results. Researchers largely remain focussed on academic metrics rather than application. Although barriers are more perceived than real, researchers may not pursue commercialisation because they regard other aspects of research activity as more important. Often, commercial efforts reduce the time available for researchers to pursue activities necessary to maintain their current academic employment. A cultural and systems change is required.

To overcome barriers to research commercialisation, the MRFF can support the creation and brokering of linkages between researchers and industry that are transdisciplinary in nature. A two-way exchange of knowledge and expertise in research, and its translation into clinical practice is needed. This would result in researchers increasingly looking to industry as a pathway for career advancement. There is also a need to better encourage adoption of the requirements for successful commercialisation in both the academic and business environment.

MEASUREMENT, MONITORING AND EVALUATION

For the MRFF to be successful it requires an architecture that can support both the Advisory Board and Government into the future. The following tasks will be first year priorities for the MRFF Advisory Board:

- determine ways to effectively engage consumers and define priorities;
- determine a durable methodology for future MRFF priority setting; and
- establish a measurement framework to support ongoing monitoring of return on investment.

MRFF investments will occur within a complex landscape of modern health and medical research, where the pace of change and interactions among stakeholders make it critical to measure the return on investment.

The Advisory Board has proposed the following initial key indicators for the MRFF:

- better patient outcomes;
- beneficial change to health practices;
- evidence of increased efficiency in the health system;
- commercialisation of health research outcomes; and
- community support for the use of and outcome from funding.

A more comprehensive evaluation framework and defined measurement methodology will be critical to determine the difference the MRFF has made. Such a framework will need to be practical, durable and sensitive enough to capture social and economic benefits as well as health outcomes. Many of these impacts will not be immediately evident as MRFF investments will span the medium- to long-term, with far-reaching and diffused direct and indirect effects. Further consultation with stakeholders will inform this framework and other foundational architecture for the MRFF.

NEXT STEPS

Through this Strategy the Advisory Board is confident that the purpose and scope of the MRFF encompasses support for not only laboratory based and pre-clinical research, but also clinical and applied research in hospitals, primary care and other health settings. This direction affords unprecedented opportunities to address existing and emerging national health priorities.

This Strategy and the related Priorities serve as a guide for the Australian Government to ensure that funding from the MRFF has a strong evidence base. Program level disbursement decisions will be made through Government Budget processes and will be reported in Budget papers. The decisions on funding will be accountable to Parliament in biennial reports from the Health Minister, which must describe how financial assistance provided for health and medical research and innovation is consistent with the Strategy and Priorities; and how the spending profile for the MRFF complements and builds on existing Australian Government funding.

The MRFF represents a significant opportunity for Australia to improve the effectiveness, efficiency, quality and safety of clinical service delivery to yield substantial benefits for consumers, the community and the health system - one from which future generations will benefit.



