NFMRI

National Foundation for Medical Research and Innovation

NFMRI: Strategy report card

2021

2013 - 2019

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National Foundation for Medical Research and Innovation



Preface



In 2013, the Board of the Foundation made the decision to focus on a specific strategy of assisting biomedical research to cross the 'valley

of death' and attract next-step partners. Reflecting that change of focus, the name of the Foundation was altered to include the word "innovation" after the reference to research.

This decision was based on an analysis of the medical research ecosystem and considered not only funding gaps in what was supported, but how to address cultural, policy and systems challenges. Funding alone was not seen to be a solution to the problem, and the strategy NFMRI introduced was intended to make a difference by doing things differently.

Introducing a new untested strategy was a bold decision that would enable the Foundation to test approaches that had the potential to benefit the Australian medical research sector, but more importantly the community. If this strategy proved successful, one project alone translating successfully from bench to bedside would be enough to make this decision worthwhile. However, we knew this would take time; research outcomes don't occur overnight and we needed to build evidence and test that the strategy achieved its primary goals and was reproducible, not just benefiting from a single lucky outcome. Along the way we persevered, stuck to the mandate and never looked back. We knew exactly what we were looking to achieve and the difference we were trying to make. This required educating the research community concerning the application process, the review criteria and the activities to which funds can be applied - all of which differ from the norm. Garnering support from our partners, supporters and mentors along the way, we progressed and scaled our efforts. Our collective efforts seemed to be making a difference.

Now eight years later, after supporting a significant number of projects across Australia addressing various diseases and conditions, it is time to take a step back and examine the effectiveness of the strategy. As stakeholders with a passion for real health outcomes, our Board, Research Advisory Committee and staff couldn't be prouder of what we have collectively achieved to date or more excited about the successes to come. On their behalf I thank everyone who has played a contributing role towards this accomplishment.

> Dr Rob Sauer Chairman

Summary

In 2013, the National Foundation for Medical Research (NFMRI) commenced the development and implementation of a <u>new</u> <u>strategy</u> to deliver its purpose.

The strategy focused on supporting biomedical research in Australian institutions to advance early innovations and enable them to attract next-step partners. NFMRI identified cultural, funding and support gaps along the innovation pathway that often left research floundering in what is referred to as the 'valley of death'.

NFMRI's strategy is to identify, review, select and support research in a way that bridges the gap and methodologies normally applied in academia and industry. Even the application form itself is designed to assist in moving research towards translation and commercialisation.

Although a number of research projects are ongoing and expected to succeed in attracting next-step partners, an analysis of projects commencing between 2013-2019 has yielded better than expected results.

Analysis of our strategic outcomes provides evidence that what NFMRI does is reproducible and effective, irrespective of indication, disease or innovation (medicine, vaccine, biological, device or diagnostic).

Strategic success measures	Strategic success outcomes
Attract next-step partners including industry and venture capital	Sixty-two percent of projects (16/26) achieved our primary measure of success in attaining next-step partners
Become clinical trial ready	Five innovations have commenced clinical trials and one innovation is approved, delivering benefits to cancer patients.
Leverage the funding, expertise and experience of next-step partners	Leveraged external funding of over \$10 for every dollar of grant funding - a total of \$45.3 million.

"SUCCESS REQUIRED MULTIPLE EXAMPLES OF THE MODEL WORKING, NOT ONE UNICORN"

Background

The NFMRI's purpose is "To advance innovations in medical research related to the nature, prevention, diagnosis, treatment and incidence of disease and other health problems that have a significant impact on the health of humans"

Following a comprehensive review of the medical research sector in Australia, NFMRI implemented a strategy to support the translation of early biomedical research. The primary goal of the strategy is to advance new potential biomedical innovations (e.g. medicines, vaccines, biologicals, diagnostics and devices) helping them attract next-step partners.

The challenge of attracting and attaining next-step partners is often referred to as the 'valley of death'. Crossing the 'valley of death' is a challenge for almost all research and is required to deliver the purpose of impacting human health.

Researchers, government and academic institutions alone cannot drive research from the lab through to the community delivering new innovations. Next-step partners that bring knowledge, skills, capability and resources are required.



"<u>Impact giving: advancing medical</u> <u>innovations</u>" describes the strategy NFMRI implemented, our social investment portfolios and the gaps supported. For biomedical innovations, next-step partners such as pharmaceutical companies, venture capital investors and industry collaborators are crucial to navigating complex technical, product development, manufacturing, regulatory and distribution challenges required to deliver health benefits to the community.



Figure 1: NFMRI focuses not only on excellent science, but also on securing next-step partners

Beyond discovery, research needs to consider the pathway to maximise the potential for translation. Understanding community need, alternate innovations, a product profile and what makes your research and innovation attractive to those who can take it forward is critical in prioritising research activities.

Figure 1 outlines some of the considerations for building translational research plans, aligning research activities to demonstrate product utility, competitive advantage, safety, proof of concept, protecting intellectual property and allocating finite resources.

Key aspects of NFMRI's social investment portfolios two and three is enabling access to external capability to conduct research studies in the translational research plan by collaborating with experienced laboratories utilising quality systems.

Research translation requires looking beyond "what can I do in my lab" to "what does my innovation need to progress".

To achieve success, NFMRI developed a process and capability to identify, review, fund and support research for the specific purpose of advancing research and attracting next-step partners. Our process and support considers not only funding gaps, but culture and non-research activities.

NFMRI's focus on supporting research at the intersection of academia and attracting next-step partners that may not otherwise advance is built upon on the alignment of quality research, innovation push, partner pull and consumer need.

NFMRI looks to support specific research studies in funding gaps to enable activities

that would not otherwise occur and are required attract next-step partners and compete globally with other innovations.

The traditional academic research culture and ecosystem mean that these short and targeted studies that aim to de-risk research, enable clinical trials and meet the requirements of potential next-step partners are of lower interest as they generally occur in external, accredited facilities. They are often of lower interest to academia as the results are not of high interest to journals and funding for such studies generally is not spent inside the researcher's own labs - all factors that don't align with current reward metrics and KPIs inside academia.

Whilst NFMRI is supporting gaps in the innovation pathway, we also recognise that we are 'standing on the shoulders of others'. Without other organisations and institutions supporting basic blue sky and discovery research, capability and capacity building (including people support, infrastructure and equipment), and other aspects of research, there would be nothing for us to help progress.

Our impact

Spanning the 'valley of death'; analysing our strategic impact

NFMRI analysed the progress of 26 research projects from the introduction of the strategy in 2013 to projects commencing in 2019.

Highlights include:

- 62% of projects (16/26) supported by NFMRI attained next-step partners
- Five projects in active clinical trials and one project delivering community benefits

• Financial leverage is more than 10:1 for next-step funding (>\$45m:\$4.4m)

Some ongoing research during the transition period was not included as the research did not align with the strategy. Projects commencing after 2019 are too early to include them in this analysis.

Projects supported by NFMRI must be precommercial and the IP must be owned by the publicly funded research organisation. As our goal is to help early innovations cross the 'valley of death', applicants who already have investors and licensing in place are not eligible.

Dr Chris Nave, founding partner of Brandon Capital Partners and CEO of the Medical Research Commercialisation Fund, stated that "approximately 3.6% of opportunities they see progress to enter their pipeline."

We are already aware of projects that are included in this analysis where further positive outcomes are imminent. We have, however, only included data verified at the end of July 2021 in our progressive reporting system and with researchers.

Examples of research outcomes and impact can be found <u>here</u>.



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Next-step partners

62% of projects supported by NFMRI attained next-step partners



Next-step partners are critical in advancing innovations towards delivering community benefits. As community benefits for the type of research NFMRI supports are normally accessed through innovations such as new medicines, vaccines, diagnostics, devices and biologicals, it is not surprising that next-step partners are often industry and venture capital.

In some cases, however, next-step partners can also be very large, sophisticated international Foundations with the experience, resources, capability and capacity to move innovations towards and/or through clinical trials and regulatory approval.

In our analysis, projects must have been financially supported by next-step partners who have the ability to also assist in advancing the innovation in order to be included.

To date, we have verified that sixteen of the twenty six projects had attained next-step partners resulting in the completion of four licensing agreements and four spin-off companies. Other projects include financially supported collaborations that may include other rights and options.

Next-step partners

62%

Leveraging support

Financial leveraging is more than 10:1 for next-step funding

Analysing the disclosed leveraged next-step funding from commercialisation and major grants such as NHMRC development grants and MRFF has resulted in more than \$45 million in additional funding.

In some cases, the commercial arrangements and financial contributions are not public and we have only included the verified funding associated with next-step partners. We have not included downstream investments such as series B investments, or potential milestones and royalty returns to the institutions.



Clinical trials and beyond

Five projects in active clinical trials One project approved delivering benefits to cancer patients

NFMRI supports preclinical research, but the pathway to deliver community benefits is long and expensive. Enabling research to be clinical trial ready is a key component of what NFMRI hopes to achieve.

Clinical trials are different to clinical studies. We consider clinical trials to be those conducted under quality systems, where the data can be used to meet regulatory approval requirements.

The preclinical research activities we support similarly need to meet the standards required to allow clinical trials to proceed and help attract next-step partners who will support the ongoing research and clinical stages of development.

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Clinical trials Approved 5

Doing things differently to make a difference

NFMRI's methodology

NFMRI's Research Advisory Committee (RAC) is built around what we call 'four lenses'.

Our members have skills, backgrounds and expertise including roles as:

- traditional academic scientists,
- scientists with experience of commercialising their discoveries from within academia,
- commercial scientists with experience in industry R&D and commercialising academic research, and
- clinician researchers.

Each individual brings a unique set of skills, experience and knowledge that in aggregate allows for the identification of opportunities and challenges from bench to bedside. The RAC also plays an import role in monitoring and assisting research projects as they progress.

Our methodology focusses on the innovation and how NFMRI can contribute towards translational outcomes aligning with our strategic objectives.

We look at more than past research performance and traditional measures to consider: unmet need, competitive advantage, intellectual property, access to external capability and capacity, data utility and usability, the need for funding and the strategic priority of the specific studies being requested.

"NFMRI has had incredible success in progressing biomedical innovation, proving the value of their multi-faceted approach. More will succeed as a result, which will eventually change more lives for the better." Mike Wilson, CEO, Juvenile Diabetes Research Foundation (JDRF)

Successfully being awarded a grant is just the start of our methodology (Figure 2).

Monitor and liais Recognising that NFMRI is only one element in successfully achieving a common goal, we look to partner with and support researchers and institutions during, as well as beyond the grant period. Review Select Support Attract

Figure 2: NFMRI's process includes a feedback loop to better support our projects

The translation of research takes time and requires research and non-research activities to achieve success. Focussing on research only can negatively impact outcomes throughout the process.

Many of the researchers we support stay in touch after they have completed their grant to not only let us know how they are progressing, but to also ask questions and seek in-kind support.

Researchers can also apply for subsequent research support as innovations progress. This helps manage risk and to address the needs of next-step partners as they arise.

Deal flow: attracting relevant proposals

With the adoption of the strategy to support research advancing innovations, NFMRI also expanded its reach beyond NSW to support publicly funded research organisations (e.g. universities, hospitals and medical research institutes) throughout Australia.

Working with researchers, institutions, other funders, technology transfer offices and downstream partners was essential. We worked diligently to educate potential applicants about research translation, our strategy and how they could be competitive. This entailed the delivery of targeted presentations at institutions throughout Australia, the implementation of our translation conference and also working with next-step partners directly to help grow awareness.

This process has enabled the submission of high-quality projects annually and the ability for NFMRI to successfully run special purpose rounds with our funding partners.

Reviewing and selecting for success

Our project selection process is unique. Whilst quality research is a prerequisite, we look beyond the research and focus on the potential for translation. We have briefly outlined some of the important factors we consider below:

Strategic fit

Does the application align with our strategic intent?

Identifying what translation looks like and the innovation (eg therapeutic, vaccine, diagnostic, device, biological, tool) is critical in answering this question.

NFMRI has three social investment (grant) portfolios supporting research early in the innovation pathway. We recognise that research doesn't deliver community impact directly from the lab and that next-step partners are required. Our portfolios are focused on supporting research to not only attract next-step partners, but develop data packages that are competitive and support the due-diligence requirement of potential partners.

Unmet need

NFMRI's purpose is about delivering better health outcomes for communities. Understanding the needs of those communities, what current interventions are available and the pathway to deliver benefits is critical.

Of course, research takes time so it is not only what is currently available, but what is in development and what may be the future needs of the communities.

Clearly identifying the problem the research is seeking to solve and what success looks like helps identify the innovation, as well as potential competitive advantages for communities. It also helps identify whether or not the innovation has any chance of success, if there are many existing alternatives or if there is limited potential health or socioeconomic impact.

Weakest link

NFMRI utilises an EOI and an invited application process that not only includes research/innovation questions, but also explores potential barriers such as intellectual property, support for translation, the utility of the innovation and other potential partnership considerations.

Our initial process entails culling EOIs that don't align with our strategy or have weak links, making them unlikely to attain a partner, and then selecting competitive projects for progression.

Research considerations

Quality of research is critical and the data supporting the innovation and potential competitive advantages completed or underway is the foundation of our support. We look to support key research questions that are important to attracting and securing next-step partners that are not normally funded by traditional grants.

Whilst we recognise the role of publications, some research activities required to achieve this goal are less interesting to publications and may often be better performed by external collaborators.

A significant consideration is supporting access to external capability, capacity, experience and expertise to answer these questions. Our support often supplements traditional grants that fund research activities in the chief investigator's own lab.

We also consider carefully the usability and utility of both the data and the innovation, the need for quality systems and both the 'will it work' and 'will it fail' questions. Enabling external research, including access to established preclinical models, manufacturing, pharmacology and toxicology studies to advance research can help advance research and attract partners.

Budget

NFMRI does not stipulate minimum or maximum funding amounts. Instead, we ask researchers to tell us exactly what they need to complete a specific study and then ascertain if the ask is reasonable. Asking too little or too much can influence decisions.

NFMRI does not partially fund research. If applicants are successful they normally receive the full amount of eligible and justifiable costs. If applicants ask for part funding, they need to clearly demonstrate where the other funding is coming from.

NFMRI is only able to financially support research activities. This means that the institutions need to support other aspects of the innovation and translation. We look for evidence that this support is available and ongoing.

Supporting research

A key aspect of NFMRI has been its ability to be highly flexible and supportive. We maintain strong, ongoing communication introductions to key contacts or potential next-step partners.

We wish to value-add to the grants we make

"The gap between basic research and commercial support for the discovery and development of new therapies, the so called "valley-of-death", is not just a funding gap but it is also a skills gap. Notwithstanding its notable 62% success rate in helping researchers bring their programs to next-step partners, NFMRI funding is 100% successful in helping train the next generation of Australian innovators and industry-ready researchers and leaders. The impact of this output is immeasurable." Associate Professor Bernard Flynn, Monash University

with every researcher we fund, providing tailored support based on the needs of the researcher and the innovation.

We provide individual, in-kind support to many of our researchers utilising our in-house capability and that of our networks. In some instances, NFMRI provides advice or mentorship, and where appropriate makes and help researchers connect with each other to share information and learn. Providing this extra support enables the innovation to advance with the best chances possible.

Our online progressive reporting system (Figure 3) and ongoing communication means that researchers and key stake holders feel we are here to help. They are comfortable to

> speak to us so that together we can work to find solutions and maximise the potential for innovations to progress.

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Figure 3: NFMRI's progressive reporting system helps us help researchers

CEO's commentary



Seeing good potential medical innovations wither on the vine is heart breaking. Most will not succeed, but they should have the opportunity to stand on their own two feet and be tested.

There are many, many reasons why innovations won't succeed, some of them are research related.

Traditionally, researchers normally apply for grants to carry out research activities in their own labs, with their own teams. Drivers of success are also often based upon a foundation of academic metrics, where the research activities undertaken focus on the interests of high impact journals that in turn attract traditional grants.

I have seen numerous opportunities over the years where discoveries and early innovations had potential, but they needed to attract commercial partners to advance and be tested. This is not an easy task, it is highly competitive and my experience is that historically less than 2% of opportunities that industry sees enter their pipeline. This is daunting when multinational companies receive more than 10,000 unsolicited opportunities globally per year.

When specific studies were suggested to researchers that were of less interest to journals, outsourced or needed quality systems to help make the innovation attractive for industry partnerships. Funding, cultural and institutional barriers were easily identifiable. These often prevented the opportunities from progressing further.

Building better translational outcomes upon the foundation of research excellence, fundamental basic science and discovery research can be achieved. However, it does require a shift of thinking. Key to achieving success is a shift when applying for funding on "not what can I do" but what "needs to be done". This is not only at the researcher level, but at the institutional level.

NFMRI took a leading position, recognising the need for innovations to attract next-step partners if they were to provide future community benefits. NFMRI implemented a strategy taking a middle ground approach between academia and industry when identifying, reviewing and supporting research.

Our approach to supporting research is more than just about funding. It is also about how we can motivate and assist researchers to undertake priority research activities that are often outsourced and of lower academic value with the primary goal of securing next-step partners. It is working with and around other sources of support to help our academic discoveries become commercialisation ready.

When the Board approved that strategy in 2013, I never expected that at this stage we would see more than 60% of our projects securing next-step partners and leveraging more than \$10 for each dollar provided by NFMRI and our funding partners.

Pleasingly I often recall an early conversation I had with Mike Wilson (CEO, JDRF) where I said that success needed to be more than a one-off lucky outcome but something that could be reproduced and potentially impact the medical research ecosystem more widely.

I hope that the evidence we are building encourages other funders to identify what success looks like to them and that together we can get the funding balance right.

About NFMRI

The National Foundation for Medical Research and Innovation is a not-for-profit organisation that is entirely independent. It is not affiliated with any university, hospital, government or state body. The Foundation provides financial support to research projects, whilst conserving and building its capital base.

The National Foundation for Medical Research and Innovation was incorporated on 3 November 1977, originally as the Sydney Hospital Foundation for Research.

The Foundation has DGR and TCC status.

In 2013, the Foundation undertook a strategic review of its activities and funding in the Australian medical research sector. This review identified opportunities for the Foundation to increase its impact by refocussing and supporting research to advance medical innovations and form collaborations.

As part of the review, the Foundation also decided to increase its support

nationally and to change its name to the National Foundation for Medical Research and Innovation.

Our Mission

"To advance innovations in medical research related to the nature, prevention, diagnosis, treatment and incidence of disease and other health problems that have a significant impact on the health of humans"

The Foundation is looking to increase its impact by partnering with other Trusts and Foundations, Private Ancillary Funds (PAFs) and corporate donors. We are also happy to receive donations and bequests. Through our activities utilising our expertise and experience in research and innovation, the Foundation is looking to become the partner of choice and a national ambassador for medical research innovation.

With best practice governance systems and continual improvement processes in place, supported by an enthusiastic and highly qualified Board, Research A d v i s o r y C o m m i t t e e a n d management, the Foundation is well positioned to stay at the forefront of impact giving. We have developed portfolios focused on impact to support medical innovation.



National Foundation for Medical Research and Innovation

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