THERAPEUTIC INNOVATION AUSTRALIA

Address
Suite 6.05
365 Little Collins St
Melbourne, 3000
Phone
(03) 9670 7018
Email
stewart.hay@therapeuticinnovation.com.au
Website
www.therapeuticinnovation.com.au

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McKeon Review

Therapeutic Innovation Australia (TIA) is a not-for-profit company established by the Federal Government to invest in Australia's life science translational research capabilities. Our aim is to both accelerate and improve the effectiveness of translation. Our organisation currently manages $100M in translational research projects encompassing product optimisation, preclinical development and clinical trials. These areas are key elements in translating the outputs of life sciences discovery research into new products for improving human health and generating economic activity.

TIA currently supports researchers through both access to its facilitated product development pathway and experts who freely provide commercialisation support. Our program is similar to emerging collaborative initiatives from the US and Europe. The NIH's National Centre for Advancing Translational Sciences (NCATS) initiative works in partnership with the public and private sectors developing innovative ways to reduce, remove or bypass bottlenecks in translational research thereby accelerating the translation of basic discoveries to real world applications.

In this submission we outline opportunities for the Australian Government to similarly improve its capacity to deliver economic and public health outcomes through reforms to the health and medical research system. Five key areas we have identified for consideration include:

1. Operational support for a world class collaborative capability network,
2. Increased investment in translational research with special consideration given to address the paradigm shift in the R&D strategies of the pharmaceutical industry,
3. Greater efficiency be brought to current investments,
4. Greater support provided for development of medical technologies and
5. Provision of funding for a central organisation to enable researchers to access resources, identify relevant funding programs, and identify potential collaborators, both locally and internationally.

Why is it in Australia's interest to have a viable, internationally competitive health and medical research sector?
(Terms of Reference 1 and 6)

A viable, internationally competitive health and medical research sector should be supported because it leads to better health outcomes and increased economic activity. These outputs are reliant on a research sector that has the capacity to develop innovative improvements and solutions to existing health care technologies. To support world class biomedical research in Australia, it is imperative that improved mechanisms for funding its translation into new products are provided.

In addition to providing a platform for improved healthcare innovations, the health and medical research sector is an industry where Australia can compete on a global scale. In contrast it is becoming increasingly difficult for Australia to compete in manufacturing industries, given the low labour costs in Asia and other developing regions. Whilst the resource sector continues to perform, Australia must consider a future where it is not as reliant on its natural resources. For this innovation is fundamental.

Since the time of the Wills Review global pharmaceutical companies have increasingly outsourced development of new products and the scale of research undertaken internally by these companies has been significantly curtailed. The consequence of the ever growing outsourcing of R&D by large pharmaceutical companies is that it has never been more important for Australia to maintain and grow our capabilities in this field in order to compete as a source of viable, reputable research partners on the global scale. The potential economic impact of this shift in R&D investment by large pharmaceutical companies is significant as even in 2008 industry contributions to health research and development were reported to total approximately 26% (Access Economics. 2008. Exceptional Returns: The Value of Investing in Health R&D in Australia II).

The Australian government has invested large sums to support innovation through development of a world class research environment. This has been through contributions to the development of capabilities, through sustained funding of life sciences discovery projects and through programs encouraging secondary students to undertake tertiary studies in science. Failure to invest in strategies that build capacity and see research evolve to translatable outcomes would diminish the momentum that the Australian health and medical research sector has gained in the last few decades. Significantly, it would also lead to increasing underemployment of science graduates, loss of technical knowledge, and ultimately decreases in health and economic outputs due to a decline in the quality and capacity of Australia's skilled research workforce. According to data from Graduate Careers, there is currently a significant underemployment of science graduates.

How might health and medical research be best managed and funded in Australia?
(Terms of Reference 2, 3 and 7)

TIA sees support for translational research as the best way to generate health and economic benefits for Australia through investment into health and medical research. TIA makes five main recommendations to improve the management and funding of health and medical research for translation:

1. Operational support for a world class collaborative capability network,

Initiatives such as the National Collaborative Research Infrastructure Strategy (NCRIS) and Super Science have provided valuable funding for development of capabilities. These investments have enabled NH&MRC and ARC funded researchers to undertake important investigations into discovery and development of therapeutics.

High-end hard infrastructure is important but the critically under resourced component of the system is the scientific expertise at the centres (including medicinal chemists and pharmacologists). A world class research pipeline requires substantial investment to support the attraction and importantly the retention of world class specialists. An investment here would be a foundation for effective and efficient development of products.

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Short term programs with limited or no funding for personnel severely restricts our capacity to deliver products to the health system and our international competitiveness. Career paths need to be developed so that we can leverage the abilities of our best scientists.

We note that the combination of core facility funding for staff with an activity based voucher (as delivered through a program such as our Researcher Access Program) would alleviate some pressure.

To further develop an internationally competitive product development pathway sustained investment is required to build cohesion between translational research providers. These cohesive pathways are necessary to maximise the use of funds through leveraging existing expertise and knowledge and decreasing redundancy in infrastructure investment.

2. Increased investment in translational research with special consideration given to address the paradigm shift in the R&D strategies of the pharmaceutical industry

The argument for greater investment for translational research lies with its close connection to both health and economic outcomes. Novel therapeutics have received significant investment by the time they reach this maturity so a failure to support the critical evaluation of the therapeutic potential reduces the impact of prior investments.

Special consideration must be given to address the paradigm shift in the R&D strategies of the pharmaceutical industry. Australia could bridge the gap and leverage its exceptional research and product development capabilities into a virtual pharmaceutical company partially funded by private investors. Research projects could be critically reviewed by industry professionals to assess the commercial prospects and development pathway and projects could then be undertaken in high quality Australian facilities rather than being performed sent internationally or in undertaken an ad hoc setting.

An opportunity for development of novel public-private partnerships (PPP) which involve large pharmaceutical and medical device companies

There is also an opportunity for development of novel public-private partnerships (PPP) which involve large pharmaceutical and medical device companies. This type of collaborative exercise has the capacity to bring further investment into Australia. A PPP would also foster a research culture in which innovators are more aware of the key drivers that make projects attractive to industry. We recommend that the government provide a mechanism for supporting development of these initiatives which in themselves offer an opportunity for leveraging of funds and access to further critical expertise.

3. Greater efficiency be brought to current investments

This can be achieved through increased oversight over projects. For instance a mechanism to apply “Go / No-go” decision points to grant funded projects (such as through the NHMRC Development Grants program) would ensure that the limited funding currently available for Development Grants (1.3% of the NHMRC budget) is more efficiently used. Projects that fail critical, predetermined experiments would not be further funded and unused funds could then be returned and reallocated. Many NHMRC Development grants provide up to 3 years of funding support. Given the real world failure rate in the early stages of drug development, it could be expected that at least half of these should be terminated before all of the funding has been spent. Furthermore, many NHMRC Development Grant applications are written by researchers and the research goals are often not the most appropriate for increasing the commercial potential of the project. Expert commercialisation advice will further optimize the use of Development Grant funds.

Additionally, access to expert intellectual property and commercialisation reviews for earlier stage projects would also better enable development of a compelling value proposition for investors and thereby support progress through the cash intensive clinical trials process.

4. Greater support provided for development of medical technologies.

Medical device technologies have not received government support comparable to biomedical research yet the area is represented by an equal number of Australian-based companies. We note the competitiveness of this field in both the time taken to get to market and the favourable risk profile.

5. Provision of funding for a central organisation to enable researchers to access resources, identify relevant funding programs, and identify potential collaborators, both locally and internationally.

Australia has had many successes in medical research however our capacity to translate discoveries into clinical practice has been limited. However, this problem is not unique to Australia. As mentioned in the introduction Europe and the US are developing agencies to

respond to the issues around translational research through a central agency. Here we suggest that a similar focused approach to translational research is required in Australia.

TIA's aim is to both accelerate and increase the efficiency of Australian translational health research by establishing clear innovation pathways. TIA provides central linkage of capabilities to benefit Australian researchers and industry. It is anticipated that the aggregating capacity of TIA will help harness Australia's outstanding basic science discoveries, generating health gains for consumers and added value for the biotechnology and pharmaceutical sectors (Figure 1).

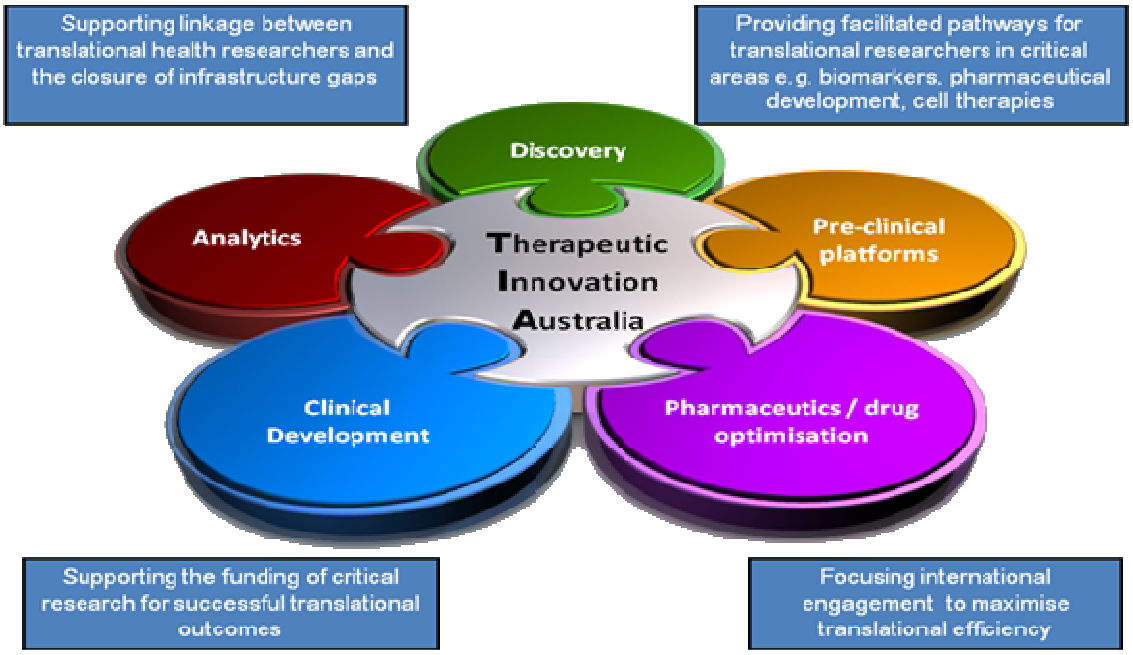

Figure 1: Illustration of the role of TIA

One role for a central agency could be though provision of targeted funding. For example, the value of providing funding to facilities for researchers to undertake product development activities was demonstrated to TIA through the success of its Researcher Access Program. This program provided access for cell therapy researchers to cGMP compliant manufacturing facilities. Interest in the program grew several-fold and as a result TIA provided further funding to cater for the increase in demand. This program supported development of translational expertise and rewarded active centres. An extension of this program to include translational research centres of excellence would provide a mechanism for facilitating development of novel therapeutics.

A single agency could also be used to create uniform Material Transfer Agreements which could be used between academic and industry researchers and service providers. This

would improve access, coordination and better enable Australia to engage with international companies.

An improved network of both research and commercial expertise will also accelerate the transition of discovery projects to a stage where non-government support can be leveraged. Therefore better central management of the network of infrastructure and expertise available domestically as proposed by the TIA will improve research outcomes and progression of discoveries nationally.

Further opportunities for a central translational research agency are described under “How can we optimise translation of health and medical research into better health and wellbeing?” To summarise, these include:

- Single entry point to government programs (State and Federal),
- A central database which logs researchers, projects and infrastructure to foster collaboration and reduce duplication and
- Integration of this and other information to provide a policy knowledge base to support ongoing management and development of funding programs and future system reviews.

What are the health and medical research strategic directions and priorities and how might we meet them?
(Terms of Reference 5, 12 and 13)

Setting strategic directions and priorities, particularly in the area of translational research, may unnecessarily limit our capacity to respond to the rapidly changing environment of health and medical research commercialisation. Government is a clearly critical component in a nexus which involves pharmaceutical and medical device companies, venture capitalists, clinicians and other health specialists. However, for a functional integrated system an ongoing opportunity for meaningful communication is required.

A responsive investment model would allow strategic directions to be determined in an evolving sense. This could involve assessment of applications against their capacity to deliver health and economic gain. Setting priorities for addressing the issues of an aging population for example presupposes that this will generate outcomes against the criteria mentioned. It could be argued that an aging population will have a greater impact on the economy rather than on the health system due to compression of time spent in ill health.

The investment model should foster development of products beyond that normally supported through biomedical research (e.g. medical device technology).

How can we optimise translation of health and medical research into better health and wellbeing?
(Terms of Reference 4, 8, 9, 10 and 11)

TIA recommends a number of reforms that will optimize translation of health and medical research into better health and wellbeing.

Firstly, as mentioned previously, greater efficiencies could be delivered through provision of early advice regarding the commercial potential of prospective products. Additionally critical experiments could be identified which would provide an opportunity to cull following failure (particularly in relation to NHMRC Development Grants). In this scenario the remaining funding could be reapplied to other prospective projects. Increasing funding for meritorious projects entering the pre-clinical phase would help offset the high attrition of projects at this point and further clarify the value proposition for investors.

To improve the likelihood of bringing forward a new generation of products for the health system we should strengthen our handling of intellectual property and regulatory compliance as we should improve our engagement with the purchasers of the technology – not presuming that we can anticipate their needs but relying on continued broad engagement to inform funding agencies.

The number of programs and agencies involved in supporting research and innovation both at a Federal and State level represents an impediment in itself due a) to the lack of awareness of these programs and agencies, b) the turnover in programs and c) the number of times in which a researcher must apply. There is an opportunity for a whole of government approach which integrates all funding programs and services through a central resource.

Researchers could be listed on a central database and subsequently informed of all government-based funding opportunities. Central online lodgement of all government based applications and increased harmonisation of these application processes would deliver greater efficiency to the system by the reducing time spent in applying. We note that this is consistent with the findings of the Cutler Review (2008).

We also suggest that funding should be available to support development of a policy knowledge base which can integrate data and identify the strengths and weaknesses of past funding initiatives across governments and agencies. This could see tracking of projects so that unnecessary duplication of research is avoided. An internationally based approach here would not only further minimise redundancy but also increase the rewards for Australian researchers.

Opportunities also exist for better utilisation of data in including post-market surveillance information. This data in conjunction with information on the e-Health system would provide an excellent service for the Australian population and would better enable related agencies to deliver therapeutic benefits. Provision of research staff to collate and analyse this data could lead to improvements in therapeutic interventions. An opt in system would mitigate issues of confidentiality and personal choice.

Significant opportunities also exist for preventative health measures. Clearly the benefits to the economy in reducing the incidence of smoking for example are widely acknowledged. Similar efforts could be fostered through use of epidemiological data and post-market surveillance data as discussed above.

Conclusion

This review has the opportunity to play a significant role in shaping what Australia might become over the next decade. The image and prospects of Australians has changed significantly over the last twenty years and our hope is that this vision would continue to mature with a sustained effort to support development of an innovation based economy. For this concept to take hold outcomes will need to be shown. In this proposal we describe several ways in which both health and economic outcomes may be readily delivered.

Stewart Hay PhD

Chief Executive Officer
Therapeutic Innovation Australia
www.therapeuticinnovation.com.au