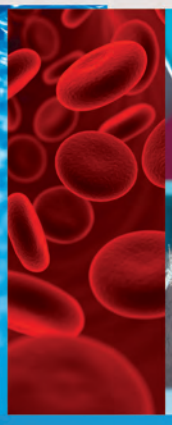
Annual report 2011 2012



THERAPEUTIC INNOVATION AUSTRALIA

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An Australian Government Initiative

Contents

Chairman & CEO's report 2011–12

All over the world, the translational medicine sector is gaining momentum. Countries have invested large sums of money to coordinate resources and expertise to speed up 'bench to bedside' research and outcomes. In 2012, the United States' National Institutes of Health established the National Center for Advancing Translational Science, which will receive more than $US500 million per year to 'reduce, remove or bypass costly and time-consuming bottlenecks in the translational research pipeline'. Europe has set up similar initiatives, such as the European Infrastructure for Translational Medicine and European Clinical Research Infrastructure Network.

Australia also recognises the importance of translational medicine, and how it can improve its global place in therapeutic development and, ultimately, health care outcomes. Specifically, Therapeutic Innovation Australia (TIA) provides access to capabilities, builds collaboration and encourages industry engagement. It also provides research and development, and project management expertise. These functions aim to support researchers in transitioning their ideas from the laboratory bench into proof-of-concept testing. We manage a national network of capabilities, which has a total investment of more than AU$350 million and requires nearly AU$50 million per year to support its operations. Our work and support enables the development of novel therapeutics in Australia, which underpins the National Health and Medical Research Council's and Australian Research Council's investments into the field.

In 'Our achievements to date', we show that—in a short time—we have achieved a great deal. We have had clinical trial success, with a $3 million investment enabling 24 clinical trials, implemented new ways to address common issues by providing free access to quality documents, developed new infrastructure ($100 million in development projects) and established six highly credentialed committees.

This reporting year, we have taken important steps towards achieving the vision first described in the Australian Government Department of Industry, Innovation, Science, Research and Tertiary Education's Translating Health Discovery into Clinical Application plan—that is, to improve the efficiency and effectiveness of translational health research activities in Australia. TIA supports this plan by developing functional linkages between academic and industry capability providers. This has been anchored by our advisory committees, which are composed of some of Australia's leading researchers and industry executives. The committees have guided our current infrastructure developments, reviewed research projects for commercial potential and have, more broadly, considered the current obstructions to development of therapeutics in Australia and how these might be best addressed.

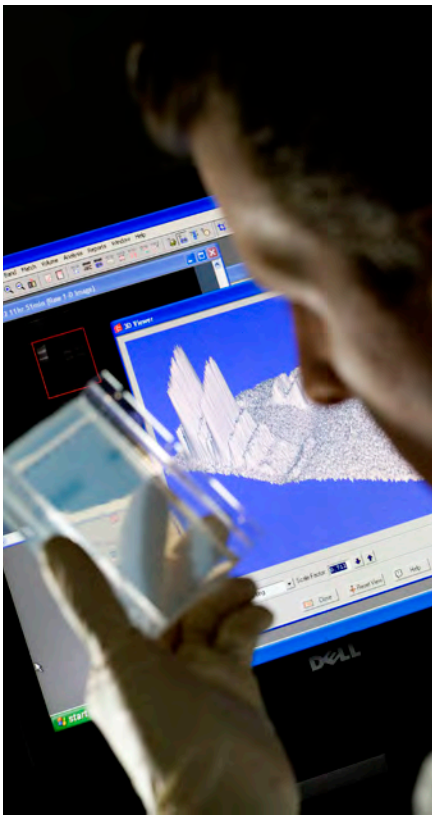
We have laid down these foundations to support translational medicine in Australia. Our challenge now lies in improving the outputs from the development pathway by providing world-class expertise and access to capabilities, developing our local skill base and adopting a holistic collaborative approach. We are proud of our achievements thus far, and look forward to improving Australia's standing in the global translational medicine sector.

Terry Slater
Chairman

Dr Stewart Hay
Chief Executive Officer

December 2012

Overview



Therapeutic Innovation Australia (TIA) supports Australian health researchers by providing access to world-class expertise for commercialising research, and state-of-the-art laboratories.

We are an Australian Government initiative established in 2010 by the Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education (DIICCSRTE).

TIA aims to improve the efficiency and effectiveness of Australian translational research by establishing clear innovation pathways.

Australia has a rich and distinguished history in basic science, particularly in the health sector. In contrast, the nation's ability to translate this knowledge into tangible commercial products has been poor. INSEAD data show that, although Australia ranks 13th in the world in innovation inputs, we rank 31st in innovation outputs. This places us a disappointing 107th on the global innovation efficiency index.

TIA aims to improve the efficiency and effectiveness of Australian translational research by establishing clear innovation pathways, such as:

- fostering linkages among translational health providers
- closing existing infrastructure gaps
- providing routes for researchers to move from the discovery phase to clinical translation
- facilitating access to expert panels to provide guidance on the best translational pathways and the design of research programs
- providing an expert focus for international engagement with key stakeholders in translational research.

We currently focuses our efforts in the areas of small molecule pharmaceuticals, biopharmaceuticals, cell-based therapies and biomarkers. We anticipate that future programs will see an expansion of our scope of activities to include medical devices, drug-delivery technologies and vaccines.

Our achievements to date

- Allocated $18.5 million to project participants.
- Leveraged Australian Government funds with co-investment contributions worth $45,694,556.
- Employed 243 people in the Translating Health Discovery (THD) Education Investment Fund and National Collaborative Research Infrastructure Strategy (NCRIS) consortiums, with 150 people employed through the THD2 project.
- Developed Australia's first translational health research capabilities map, which includes a database of more than 600 centres, and 5 preliminary supply-chain maps describing essential centres for production of novel therapeutics.
- Actively engaged with international organisations—including European Infrastructure for Translational Medicine, National Center for Advancing Translational Sciences, European Clinical Research Infrastructure Network, Centre for Drug Research and Development and Innovative Medicines Initiative—to facilitate increased collaboration between local and international researchers.
- Allocated more than $3 million to 24 clinical trials in Australia through the Researcher Access Scheme, many of which would not have otherwise proceeded. As a result, cofunding from industry and other stakeholders such as state governments and universities has been more than doubled.
- Expanded Australia's drug development capabilities from drug discovery through to Phase I/II clinical trials.
- Held a pilot Research Partnership Program, where TIA granted three recipient 'vouchers' to conduct required experiments at THD-funded facilities from 73 applications.
- Established links with 23 university technology-transfer offices (TTOs) across Australia, and identified 447 potential translational health research projects for development through THD-funded infrastructure.
- Convened Australia's first National Translational Research Capability workshop to facilitate interaction between researchers, government, industry, investor and consumer representatives, and to seek input into translational research priorities.
- Supported a total of 328 projects that have been active at THD facilities.

- Provided an 'honest broker' role in supporting innovation and collaboration in pharmaceutical development in Australia.
- Opened the TIA Queensland Node. A first for Australia, this node provides a facilitated product development pathway. Researchers have access to a suite of Queensland facilities, technical experts and a team of project managers.
- Established a National Regulatory Repository that stores documentation required to meet pharmaceutical production regulatory requirements. This initiative significantly limits the quantum of work an organisation would need to develop to satisfy the requirements of the regulator (e.g. the Therapeutic Goods Administration).
- Continued to support the consultancy services that help to implement or improve good manufacturing practice (GMP), and the ongoing development of quality assurance systems.
- Provided $1,050,000 for cell therapy facilities in several locations across Australia to maintain cGMP licences and enable access by external researchers.
- Conducted a pilot National Translational Research Survey of Australian translational health researchers to improve understanding of Australian translational health researchers and their ongoing requirements.
- Facilitated an inaugural strategic priority-setting exercise in translational health research. TIA's report to the Australian Government covered three proposed programs with overlapping strategies to improve the current system.
- Provided consultancy services that help to implement or improve GMP, and the ongoing development of quality assurance systems.
- Conducted a national Seminar Series on Smart Technologies that promoted collaboration between researchers in the cell therapy field, and in materials sciences and biomedical engineering.
- Implemented the Smart Surfaces Program, which provided education on pathways for developing smart technologies (e.g. medical devices).

Board members

The members of the TIA Board comprise five non-executive directors who have held leadership positions in the pharmaceutical and research sectors.

Mr Terry Slater

BSc BEc MPH FAIM MAICD

Chairman

Terry Slater is a former senior executive with the Australian Public Service including nine years as Chief Executive Officer of the Therapeutic Goods Administration (TGA). He also held senior executive level positions within the Health, and Housing and Construction departments, and the Australian Customs Service, and was Chief Executive Officer of the Australian Food Standards Authority. His most recent corporate role was as Chief Executive Officer of Australians Donate, a government-funded company established to oversee transition to new governance arrangements for organ donation and transplantation. Terry is also a board member of DrinkWise.

Prof Judith Whitworth AC

MBBS MD PhD DSc HonMD (Sydney) HonMD (UNSW) HonDSc (Glasgow) HonDLett (Charles Darwin) FTSE FRACP FAICD

Chair, TIA Clinical Trial Infrastructure Expert Advisory Committee

Judith Whitworth is an Emeritus Professor at the Australian National University and previous Director of the John Curtin Schools of Medical Research. She is a Fellow of the Australian Academy of Technological Sciences and Engineering, the Royal Australasian College of Physicians, and the Australian Institute of Company Directors. Professor Whitworth has chaired the Medical Research Committee of the National Health and Medical Research Council, is a Past-President of the Australian Society for Medical Research and the High Blood Pressure Research Council of Australia as well as an Honorary Life Member of the Australian and New Zealand Society of Nephrology.

Previous appointments include Chief Medical Officer of Australia, Chair of the World Health Organization Global Advisory Committee on Health Research, and Professor of Medicine at St George Hospital, University of New South Wales. Professor Whitworth was made a Companion in the Order of Australia in 2001.

Dr George Morstyn

MB BS B Med Sci PhD FRACP MAICD

Chair, TIA Virtual Pharma Advisory Committee

George Morstyn has longstanding experience and expertise in translational medicine in the interface between research and commercial practice, with outstanding background in preclinical and clinical development and regulatory affairs. He is a former Chief Medical Officer, Senior Vice President and Head of Development at Amgen and is currently on the boards of Proacta, Bio21 and CRC Cancer Therapeutics. He is Deputy Chairman of the Victorian Comprehensive Cancer Centre, a Director and Chairman of the scientific advisory board of SymBio, Japan, and Chair of GBS Venture Partners. Dr Morstyn's substantial clinical experience includes training in medical oncology at the National Cancer Institute in the US and being Head of the Clinical Program of the Ludwig Institute for Cancer Research in Melbourne.

Mr Rob Anderson

FCA FAICD

Company Secretary, Chairman of the Audit Committee

Rob Anderson was the Managing Director of Orthogen Australia, which operated in the field of cell therapies. He is a former Partner (Audit and Advisory) with Deloitte and has had extensive commercial and financial experience in a diverse range of industries and business structures, including consulting to government and industry. Rob is also principal of Anderson Business Consultants.

Ms Elizabeth Furler

BA (Social Work) MAICD

Director

Liz Furler is the Chief Executive Officer of Principals Australia, the peak professional association for principals from all schools sectors. She has previously held senior executive roles with the Australian Government Department of Health and Ageing and the Australian National Training Authority, as well as at state government level in both South Australia and Tasmania. She has also been Chief Executive Officer of the Royal Australian College of General Practitioners. She is a Member of the Public Health Association of Australia.

Brokering knowledge

Therapeutic Innovation Australia (TIA) has established a unique resource for government and researchers alike through its mapping and analysis of the field, and its highly credentialed committees. Table 1 outlines these committees, and the following sections illustrate how these committees interact to engage with researchers and provide strategic advice for government.

Table 1 Therapeutic Innovation Australia (TIA) committees and function

Committee	Chair and expertise	Function / speciality
National Translational Health Coordinating	Warwick Anderson Chief Executive Officer, National Health and Medical Research Council	Forum for coordination between committees, and engagement with other government agencies and industry associations
Virtual Pharma	George Morstyn Director, TIA, and former Chief Medical Officer, Amgen	Small molecule therapies and commercialisation
Queensland Node	Peter Andrews Former Chief Scientific Officer for Queensland	Product development, pathways for therapeutics
Clinical Trials	Judith Whitworth Director, TIA, and former Chief Medical Officer for Australia	Clinical trials
Biopharmaceutical, Biomaterial & Medical Device	Bryan Williams Director, Monash Medical Research Institute	Biopharmaceuticals, biomaterials and medical devices
Cell & Gene Therapy	Ian Gust Former Research & Development Director, CSL, and Chair, Victorian Biotechnology Advisory Council	Cell and gene therapy

National Translational Health Coordinating Committee

Warwick Anderson

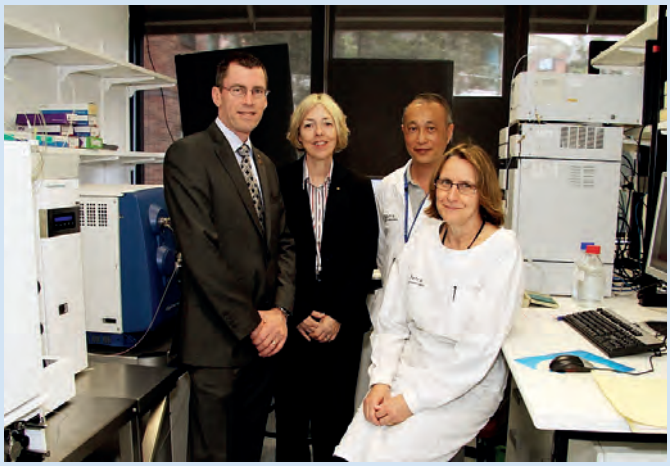
The National Translational Health Coordinating (NTHC) Committee facilitates interaction and coordination between the activities of our five advisory committees. The NTHC Committee brings together leaders in health science and policy from across industry, academia, and the federal, state and territory governments. It is the only committee of its type and enables a holistic collaborative response to the issues facing translation of health research.

Queensland Node committees

Peter Andrews

In July 2012, TIA launched the Queensland Node based at The University of Queensland. The node is designed to test a state-based model of accelerating the movement of inventions by Australian researchers from the laboratory through the various stages of development. It is then hoped that resulting 'reduced risk technologies' will attract investors to commercialise them into therapeutic products. The ultimate goal of the Queensland Facilitated Product Development Pathway is to implement this model on a national level.

Representatives from the TIA Qld Node Executive Committee together with Graham Perrett MP, Federal Member for Moreton (Australian Labor Party) (centre) and Mr Dale Shuttleworth MP, State Member for Ferny Grove (Liberal National Party) (second from left) at the TIA Qld Node opening in July 2012. (image courtesy of The University of Queensland)



(l-r) Mr Dale Shuttleworth MP, State Liberal National Party Member for Ferny Grove, Prof Maree Smith from The University of Queensland, Dr Jui Jiang and Ms Debra Siebert, at the University of Queensland Centre for Integrated Preclinical Drug Development / TetraQ (image courtesy of The University of Queensland)

Two committees are responsible for the TIA Queensland Node. The Executive Committee provides technical project management expertise. The Strategic Committee consides broader issues facing therapeutic development in Queensland.

The Qld Node model focuses on aggregating and leveraging existing infrastructure across Australia to reduce the constant reinvention of the wheel, improving access to researchers with appropriate skills and experience, and addressing gaps in existing infrastructure, rather than establishing a large number of new facilities.

The Queensland Node comprises five of the leading translational research centres based in South East Queensland.

The Queensland Node comprises five of the leading translational research centres based in South East Queensland: Centre for Integrated Preclinical Drug Development; Queensland Clinical Trials and Biostatistics Centre; Centre for Clinical Research and Diamantina Institute, which are based at The University of Queensland's Herston campus; and Griffith Health Institute based at Griffith University's Gold Coast campus.

Four exemplar projects have been selected to take part in fast tracking the translational process with the aim of producing tangible commercial returns in five years:

- a test aimed at protecting unborn babies who are at risk of premature birth
- a migraine prevention product
- a 'glucose alarm' software package to help people with conditions like diabetes to control their blood sugar levels
- an imaging technique to aid the development of treatments for bone disorders such as osteoporosis.

Virtual Pharma Expert Committee

One of the critical issues in Australia that has impacted our capacity to translate discoveries into clinical application has been the lack of high-quality industry/development expertise. The Virtual Pharma (VP)

committee has been established to address this issue. It brings together expertise from across the country to parallel that available in a fully integrated pharmaceutical company. When fully operational, the committee will be able to provide a free development advisory service to public sector researchers.

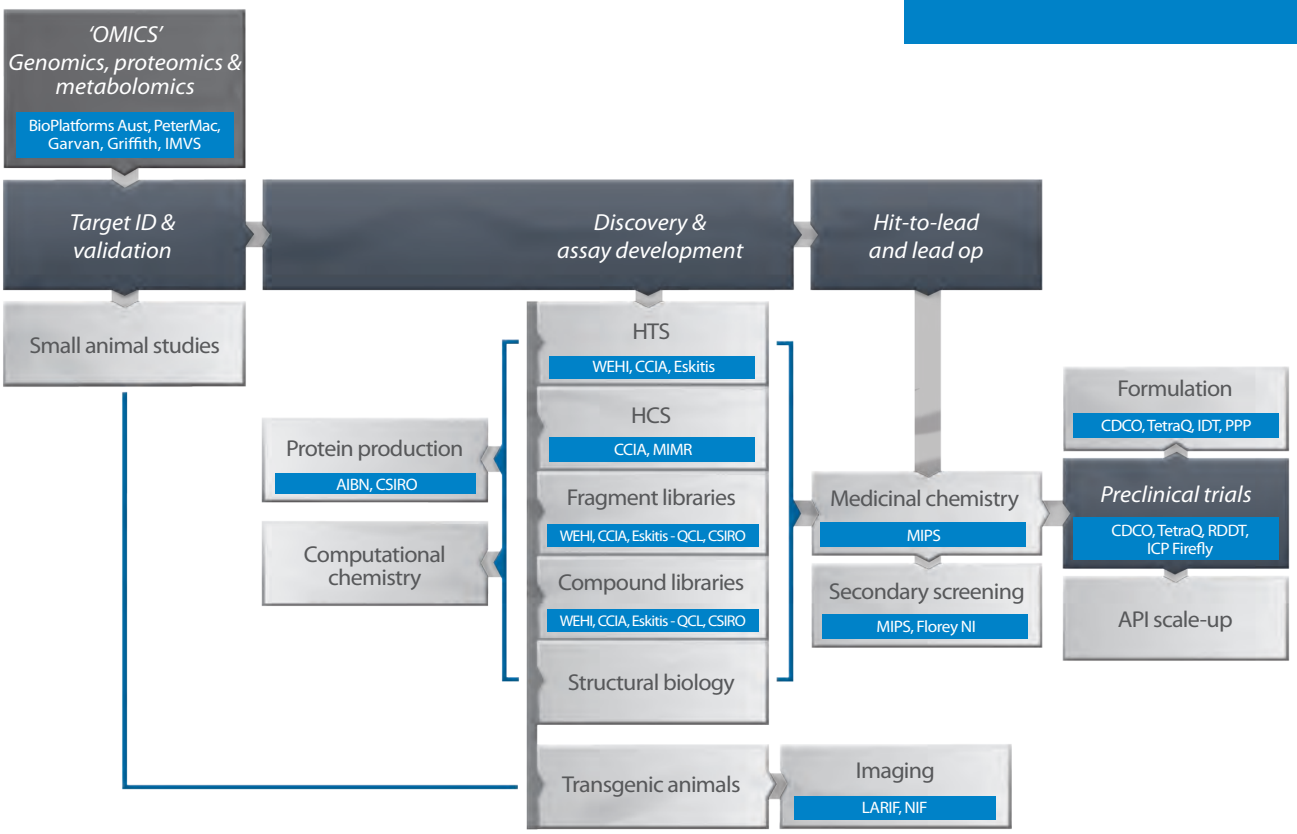
During 2011–12, the VP committee supported the development of a small molecule capability map representing the currently available translational health research infrastructure in Australia (see Figure 1). The map has assisted in identifying gaps in our translational infrastructure, and provides a focus to establish better systems for enabling research.

The VP committee was responsible for evaluating the applications received for TIA's highly successful Research Partnership Program, an extension of our Researcher Access Scheme, which proved extremely successful in stimulating clinical trial activity with 24 clinical trials funded from an investment of $3 million. A large number of applications were received from researchers working on novel small molecules, cell therapies, biopharmaceuticals and personalised medicine products.

Three applicants received 'vouchers' for conducting their experiments at THD-funded facilities:

- **Mark Smyth, Institute for Molecular Bioscience Queensland**, for 'The development of human haematopoietic prostaglandin D2 synthase inhibitors for allergic asthma'. Pharmacokinetic experiments are being undertaken at the Centre for Integrated Preclinical Drug Development/TetraQ and Centre for Drug Candidate Optimisation.
- **David Randerson, Transbio**, for 'Development of a monoclonal antibody targeting CD83 on dendritic cells as a treatment for GVHD'. Experiments are being done at the National Biologics Facility, Australian Institute for Bioengineering and Nanotechnology.
- **James Fraser and Avril Roberston, The University of Queensland**, for 'IMPDH as an antifungal drug target'. Drug screening is being conducted at the Walter and Eliza Hall Institute.

The Researcher Partnership Project is an extension of our Researcher Access Scheme, which proved extremely successful in stimulating clinical trial activity with 24 clincial trials funded from an investment of $3 million.



AIBN = Australian Institute for Bioengineering and Nanotechnology; CCIA = Children's Cancer Institute Australia; CDCO = Centre for Drug Candidate Optimisation; CSIRO = Commonwealth Scientific and Industrial Research Organisation; HCS = high-content screening; HTS = high-throughput screening; ID = identification; IMVS = Institute of Medical and Veterinary Sciences; LARIF = Large Animal Research and Imaging Facility; MIPS = Monash Institute of Pharmaceutical Sciences; NIF = National Imaging Facility; PPP = public–private partnership; QCL = Queensland Compound Library; WEHI = Walter and Eliza Hall Institute of Medical Research

Figure 1 Capability map of the small molecule pathway

Clinical Trials Infrastructure Committee

The Clinical Trials Infrastructure committee is chaired by TIA Board member and former Chief Medical Officer of Australia, Prof Judith Whitworth. The committee provides advice regarding implementation of clinical trial infrastructure including reference to one development recommended by the Australian Government Clinical Trials Action Group (CTAG).

This committee oversees projects such as the development of the Australia and New Zealand Clinical Trials Registry (a response to CTAG report, recommendation F) and a national harmonisation strategy on biobanking to enable development of a coherent biobanking system in Australia linked to clinical trials.

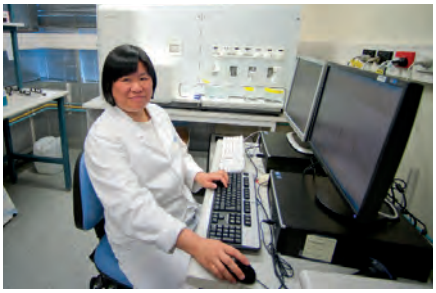
Cell and Gene Therapy Committee

Ian Gust

Cell therapy research has flourished in recent years with the notable success of Mesoblast and researchers funded through the National Collaborative Research Infrastructure Strategy program administered by TIA.

The Cell and Gene Therapy Committee committee has advised the TIA about the maturation of the emerging local industry. The field faces genuine issues regarding product approvals, and large-scale production and distribution. Opportunities exist locally for the development and validation of automated production technologies, which will facilitate industrial or health service delivery.

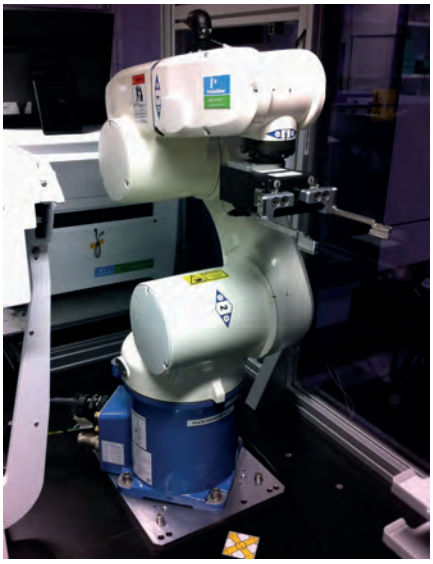
The committee has engaged with researchers, cell therapy researchers, capability providers, and small and large companies.

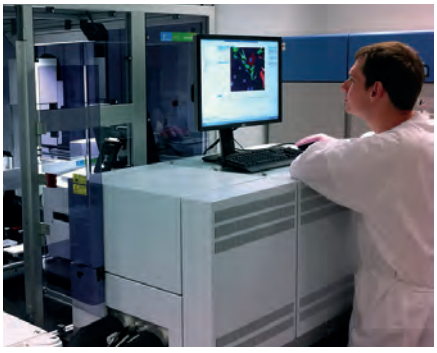


Biomaterials, Biopharmaceuticals and Medical Devices Committee

Bryan Williams

The Biomaterials, Biopharmaceuticals and Medical Devices Committee committee has the largest scope of specialist advisory functions of all our committees. The committee has identified several key findings from the Medical Device Partnering Program, coordinated by Flinders University, South Australia, to be used in a potential model for medical device commercialisation. Nationalisation of the model and integration as part of TIA's network is supported.





Translating Health Discovery into Clinical Application project

A key component of the Translating Health Discovery into Clinical Application (THD) project is to harness the local resources to facilitate first-class development programs. In Figure 2, we illustrate how the investments into research infrastructure are leveraged through inclusion in an innovation pathway.

The Virtual Pharma committee reviews projects for their commercial potential and acts as a gateway to subsidised access to facilities. Recommended projects are directed to capability providers through the THD consortium. In Queensland, through the Queensland Node, projects will be developed under the guidance of project managers. Linkages between the facilities enable local development of a research project from primary screening to proof of concept (see Figure 3).

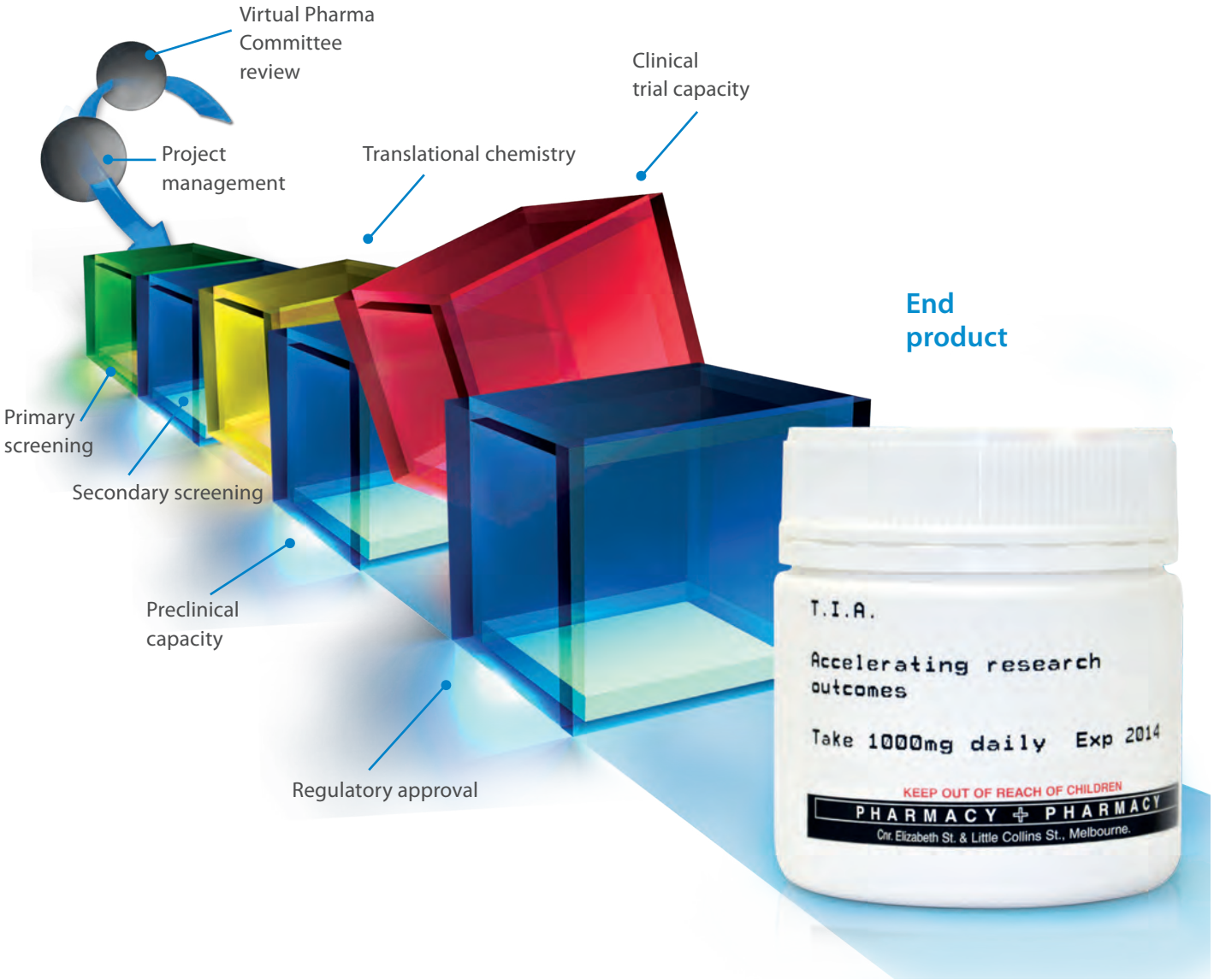
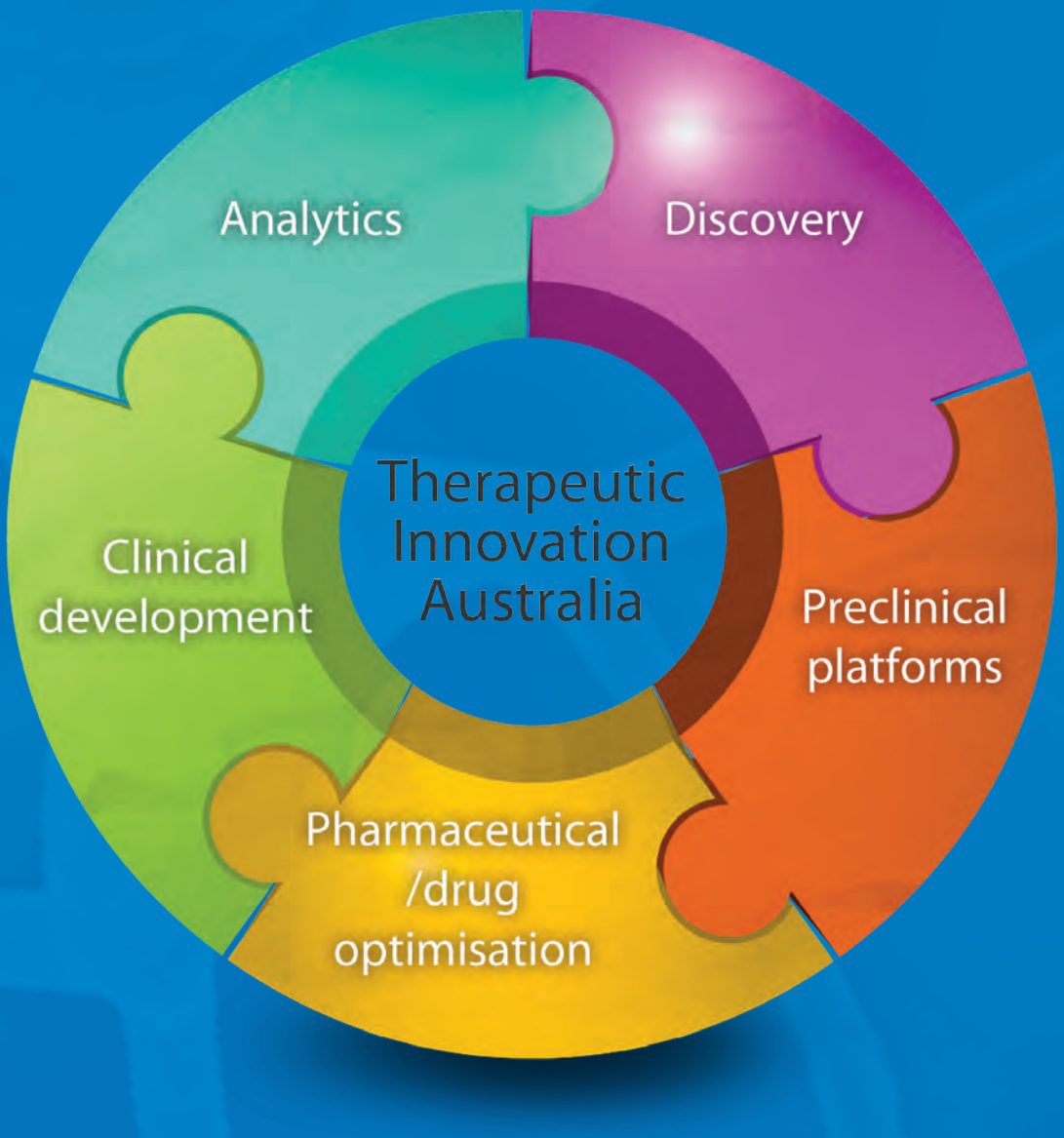


Figure 2 **Illustration of the nationally coordinated drug development**

1 Supporting the funding of critical research for successful translational outcomes.

2 Supporting the funding of critical research for successful translational outcomes.



3 Focusing international engagement to maximise translational efficiency.

4 Providing facilitated pathways for translational researchers in critical areas—for example, biomarkers, pharmaceutical development, cell therapies.

Figure 3 The model underpinning the Translating Health Discovery into Clinical Application project

Strategic investment priorities

Since its establishment, Therapeutic Innovation Australia (TIA) has consulted widely with stakeholders and drawn in experts in the therapeutics innovation sector in Australia. As a result of this consultation, we have developed three strategic priorities that we regard as being pivotal for translating basic science discoveries into clinical application.

Investment in projects that adhere to these priorities would see Australia maintain its capacity to:

- produce the materials required for translating research
- perform the most appropriate tests to assess a drug's prospects in preclinical and clinical settings
- better engage with industry.

Australia's historical lack of engagement with industry can be viewed as a key shortcoming, and would be addressed through the development of a partnership model to achieve cultural change.

The Research Infrastructure priority aims to:

- provide hard infrastructure capabilities that are necessary for developing therapeutic and device technologies
- provide soft infrastructure capabilities that are critical for developing therapeutic and device technologies
- ensure access and pricing policies are in place to enable external research activity
- coordinate a national product development pathway by providing a network of project managers.

The National Accelerator priority aims to:

- enable researchers to perform critical translational experimentation, including preclinical testing and Phase I clinical trials
- provide commercialisation expertise
- support university- and hospital-based technology-transfer offices in the development of new therapeutics and devices.

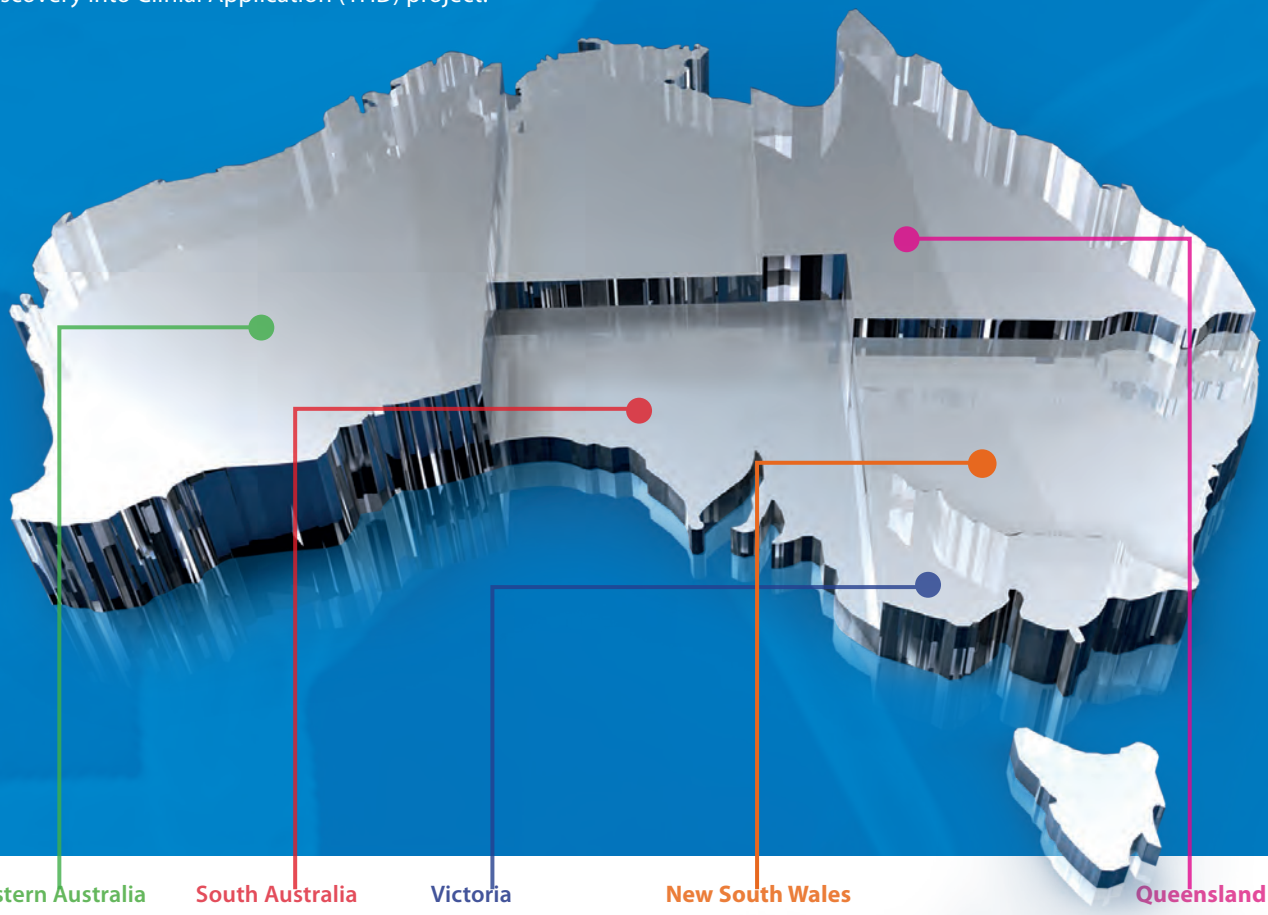
The Public–Private Partnership priority aims to:

- foster a holistic collaborative initiative between industry, government and, potentially, philanthropic sources
- provide researcher access to commercialisation, regulatory, scientific and intellectual property expertise
- fund the development of therapeutics into Phase II studies
- provide a forum for industry and government agencies to evaluate the process and challenges of therapeutic innovation in Australia.

Education Infrastructure Fund

The Education Infrastructure Fund (EIF) allows TIA to support the ongoing development of infrastructure that is vital to the continuing delivery of education services in the Australian health sector. Students and teachers need access to the best and latest equipment, both for conducting research and to gain experience on that equipment before entering the workforce.

TIA will provide funding for infrastructure development at 18 institutions across the three years of the Translating Health Discovery into Clinial Application (THD) project.



Western Australia

- Cell & Tissue Therapies, Royal Perth Hospital

South Australia

- South Australia Pathology, trading as the Institute of Medical and Veterinary Science
- University of South Australia

Victoria

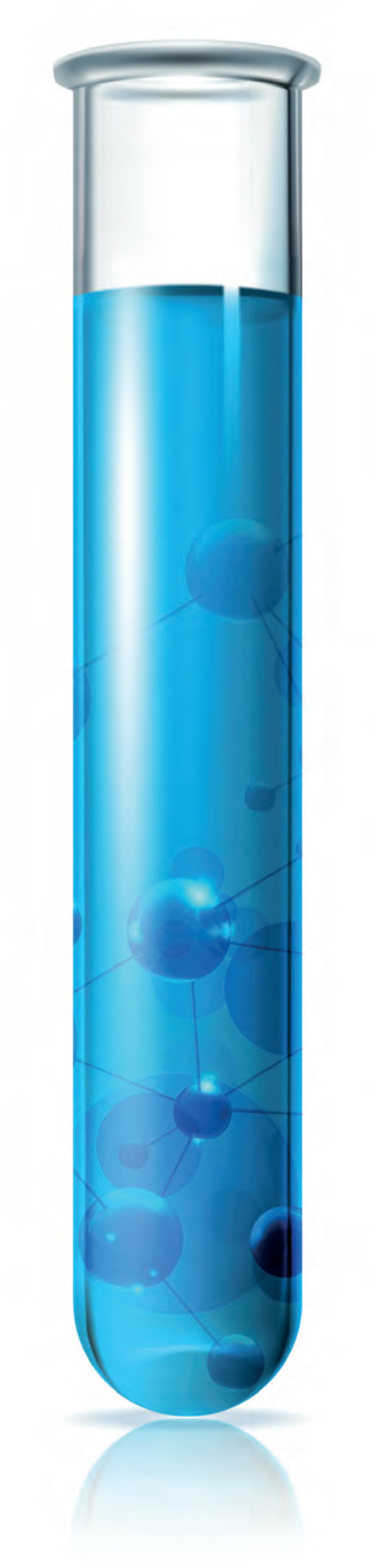
- Walter and Eliza Hall Institute of Medical Research
- The University of Melbourne
- Children's Cancer Institute Australia for Medical Research
- Monash Institute of Medical Research
- Peter MacCallum Cancer Centre

New South Wales

- Kids Research Institute, The Children's Hospital at Westmead
- NHMRC Clinical Trials Centre, The University of Sydney
- University of New South Wales
- Sydney Centre for Cell and Gene Therapy, Westmead Research Hub
- Cell and Molecular Therapies, Royal Prince Alfred Hospital, Sydney South West Area Health Service
- Garvan Institute of Medical Research

Queensland

- The University of Queensland
- Griffith Health Institute, Griffith University
- Eskitis Institute for Cell and Molecular Therapies, Griffith University
- Australian Institute for Bioengineering and Nanotechnology



In the first two years of EIF funding, 13 organisations have received an allocation of funds totalling $18.5 million. Additional co-investment of more than $30 million in 2011–12 has been targeted to supporting clinical research.

	Total investment in THD project ($)	
	2010–11	2011–12
EIF cash contribution	8,500,000	10,000,000
Cash co-investment	4,241,640	34,494,997
In-kind co-investment	648,000	6,309,919
Total resources applied to project	**13,389,640**	**50,804,916**

EIF = Education Infrastructure Fund; THD = Translating Health Discovery into Clinical Application

THD funding has helped to broaden the scope and range of projects being undertaken in Australia in TIA's designated fields for investment.

Financial report

for the financial year ended 30 June 2012

Directors' report

The directors of Therapeutic Innovation Australia Limited (TIA) submit herewith the financial report of the company for the financial year ended 30 June 2012. In order to comply with the provisions of the *Corporations Act 2001*, the directors report as follows.

The names and particulars of the directors of the company during or since the end of the financial year are shown to the right.

Name	Title	Date of Appointment	Qualification
Elizabeth Furler	Director	11/12/2007	BA(Social Work), MAICD
George Morstyn	Chair, Virtual Pharma Committee, and Board Member	11/12/2007	MB BS, BMedSci, PhD, FRACP, MAICD
Terry Slater	Chairman	16/08/2007	BSc, BEc, MPH, FAIM, MAICD
Rob Anderson	Secretary, and Chairman, Audit Committee	16/08/2007	FCA, FAICD
Judith Whitworth AC	Chair, Clinical Trials Infrastructure Committee, and Board Member	10/08/2011	MBBS MD, PhD, DSc, FTSE, FRACP, FAICD

Note: The above named directors held office during and since the end of the financial year unless otherwise stated.

Company secretary

Mr Rob Anderson (FCA, FAICD)—appointed as at 16 August 2007.

Principal activities

TIA is an Australian not-for-profit company formed to promote investment in research infrastructure in the field of human cell and cellular based products for transplantation.

In the previous year TIA was awarded the distribution of a 3-year Superscience Grant program from the Department of Innovation, Industry, Science and Research (DIISR). The program is aimed at investment in hard research infrastructure in the field of translational research and development.

No significant change in the nature of these activities occurred during the year.

Review of operations

The surplus of the company for the financial year amounted to $464,845 (2011: $121,438 surplus).

Changes in state of affairs

No significant changes in the company's state of affairs occurred during the financial year other than the expansion of service provided by the DIISR Superscience grant distribution program.

Subsequent events

There has not been any matter or circumstance occurring subsequent to the end of the financial year that has significantly affected, or may significantly affect, the operations of the company, the results of those operations, or the state of affairs of the company in future financial years.

Future developments

Disclosures of information regarding likely developments in the operations of the company in future financial years and the expected results of those operations is likely to result in unreasonable prejudice to the company. Accordingly, this information has not been disclosed in this report.

Environmental regulations

The company's operations are not regulated by any significant environmental regulation under a law of the Commonwealth or of any state or territory.

Dividends

Under the company's constitution there are no dividends payable.

Indemnification of officers and auditors

No indemnities have been given or insurance premiums paid, during or since the end of the financial year, for any person who is or has been an officer or auditor of the company, except that a premium has been paid to obtain insurance for directors and officers of the company. The amount of the premium paid can not be disclosed as a condition of the insurance contract.

Directors' meetings

The number of meetings of the company's directors whilst the director was in office held during the financial year ended 30 June 2012 and the number of meetings attended by each director were:

Director	Available for	Attended
George Morstyn	8	7
Liz Furler	8	8
Terry Slater	8	8
Rob Anderson	8	8
Judith Whitworth	7	7

Proceedings on behalf of the company

No person has applied for leave of Court to bring proceedings on behalf of the company or intervene in any proceedings to which the company is a party for the purpose of taking responsibility on behalf of the company for all or any part of those proceedings.

The company was not a party to any such proceedings during the year.

The company's objective

The company engages with the translational health research sector and supports the translation of research through the distribution of grants from the Australian Government.

Members funds and guarantee

The company is a company limited by guarantee. If the company is wound up the Constitution states that the liability of the company is limited to $10 towards meeting any outstanding obligation of the company. There are 4 members of the company at 30 June 2012 (2011: 4 members) and the total liabilities from the members are limited to $40 if the Company is wound up.

Auditor's independence declaration

The auditor's independence declaration is included on page 5 of the financial report.

Signed in accordance with a resolution of directors made pursuant to s. 298(2) of the *Corporations Act 2001*.

On behalf of the Directors

Robert Bruce Anderson
Director

Melbourne, 27 September 2012

Deloitte Touche Tohmatsu
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The Board of Directors
Therapeutic Innovation Australia Limited
Suite 5, Level 6, 365 Little Collins Street,
MELBOURNE, VIC 3001

27th September 2012

Dear Board Members,

Therapeutic Innovation Australia Limited

In accordance with section 307C of the *Corporations Act 2001*, I am pleased to provide the following declaration of independence to the directors of Therapeutic Innovation Australia Limited.

As lead audit partner for the audit of the financial statements of Therapeutic Innovation Australia Limited for the financial year ended 30 June 2012, I declare to the best of my knowledge and belief, there have been no contraventions of:

(i) the auditor independence requirements of the *Corporations Act 2001* in relation to the audit; and

(ii) any applicable code of professional conduct in relation to the audit.

Yours sincerely

DELOITTE TOUCHE TOHMATSU

Robert D D Collie
Partner
Chartered Accountants

Independent auditor's report to the members of Therapeutic Innovation Australia Limited

We have audited the accompanying financial report, being a special purpose financial report, of Therapeutic Innovation Australia Limited, which comprises the statement of financial position as at 30 June 2012, the statement of comprehensive income, the statement of cash flows and the statement of changes in equity for the year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration as set out on pages
8 to 18.

Directors' Responsibility for the Financial Report

The directors of the company are responsible for the preparation of the financial report that gives a true and fair view and have determined that the basis of preparation described in Note 3 to the financial report is appropriate to meet the requirements of the *Corporations Act 2001* and is appropriate to meet the needs of the members. The directors' responsibility also includes such internal control as the directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on the financial report based on our audit. We have conducted our audit in accordance with Australian Auditing Standards. Those standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance whether the financial report is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation of the financial report that gives a true and fair view, in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the financial report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Auditor's Independence Declaration

In conducting our audit, we have complied with the independence requirements of the *Corporations Act 2001*. We confirm that the independence declaration required by the *Corporations Act 2001*, which has been given to the directors of Therapeutic Innovation Australia Limited would be in the same terms if given to the directors as at the time of this auditor's report.

Opinion

In our opinion, the financial report of Therapeutic Innovation Australia Limited is in accordance with the *Corporations Act 2001*, including:

- (a) giving a true and fair view of the Therapeutic Innovation Australia Limited's financial position as at 30 June 2012 and of their performance for the year ended on that date; and
- (b) complying with Australian Accounting Standards to the extent described in Note 3, and the *Corporations Regulations 2001*.

Basis of Accounting

Without modifying our opinion, we draw attention to Note 3 to the financial report, which describes the basis of accounting. The financial report has been prepared for the purpose of fulfilling the directors' financial reporting responsibilities under the *Corporations Act 2001*. As a result, the financial report may not be suitable for another purpose.

DELOITTE TOUCHE TOHMATSU

Robert D D Collie
Partner
Chartered Accountants
Melbourne, 27th September 2012

Deloitte.

Directors' declaration

As detailed in Note 3 to the financial statements, the company is not a reporting entity because in the opinion of the directors there are unlikely to exist users of the financial statements who are unable to command the preparation of reports tailored so as to satisfy specifically all of their information needs. Accordingly, these special purpose financial statements have been prepared to satisfy the directors' reporting requirements under the *Corporations Act 2001*.

The directors declare that:

- (a) in the directors' opinion, there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable; and

- (b) in the directors' opinion, the attached financial statements and notes thereto are in accordance with the *Corporations Act 2001*, including compliance with accounting standards and giving a true and fair view of the financial position and performance of the company.

Signed in accordance with a resolution of the directors made pursuant to s. 295(5) of the *Corporations Act 2001*.

On behalf of the Directors

Robert Bruce Anderson
Director

Melbourne, 27 September 2012

Statement of comprehensive income

for the year ended 30 June 2012

	Note	2012 ($)	2011 ($)
Continuing operations			
Revenue	4	10,718,572	10,184,488
Distribution of funds		(9,475,500)	(9,546,147)
Consultancy fees	5	(410,599)	(256,185)
Directors fees	5	(130,208)	(87,010)
Hosting fees—Australian Red Cross Blood Service		(10,001)	(72,000)
Audit fees	5	(10,718)	(10,450)
Other administration expenses		(216,701)	(91,258)
Surplus before tax	5	464,845	121,438
Income tax expense	3(a)	–	–
Surplus for the year		**464,845**	**121,438**
Other comprehensive income		–	–
Total comprehensive income for the year		**464,845**	**121,438**

Notes to the financial statements are included on pages 24–28.

Statement of financial position
at 30 June 2012

	Note	2012 ($)	2011 ($)
Current assets			
Cash and cash equivalents	8(a)	1,534,756	11,095,147
Trade and other receivables	6	25,743	44,359
Total current assets		**1,560,499**	**11,139,506**
Total assets		**1,560,499**	**11,139,506**
Current liabilities			
Trade and other payables	7	964,463	11,008,315
Total current liabilities		**964,463**	**11,008,315**
Total liabilities		**964,463**	**11,008,315**
Net assets		**596,036**	**131,191**
Equity			
Retained earnings		596,036	131,191
Total equity		**596,036**	**131,191**

Notes to the financial statements are included on pages 24–28.

Statement of changes in equity
for the year ended 30 June 2012

	Retained earnings ($)	Total ($)
Balance at 1 July 2010	9,753	9,753
Surplus for the year	121,438	121,438
Other comprehensive income	–	–
Total comprehensive income for the year	**121,438**	**121,438**
Balance at 30 June 2011	**131,191**	**131,191**
Surplus for the year	464,845	464,845
Other comprehensive income	–	–
Total comprehensive income for the year	**464,845**	**464,845**
Balance at 30 June 2012	**596,036**	**596,036**

Notes to the financial statements are included on pages 24–28.

Statement of cash flows
for the year ended 30 June 2012

	Note	2012 ($)	2011 ($)
Cash flows from operating activities			
Receipts from Commonwealth Government		11,415,600	11,051,700
Payments to suppliers, fees and grants paid		(21,318,563)	(1,126,059)
Interest received		322,572	137,488
Net cash (used in)/ generated by operating activities	8(b)	(9,560,391)	10,063,129
Net (decrease)/increase in cash and cash equivalents		**(9,560,391)**	**10,063,129**
Cash and cash equivalents at the beginning of the year		**11,095,147**	**1,032,018**
Cash and cash equivalents at the end of the year	**8(a)**	**1,534,756**	**11,095,147**

Notes to the financial statements are included on pages 24–28.

Notes to the financial statements

1. General information

Therapeutic Innovation Australia Limited (formerly known as Research Infrastructure Support Services Limited) is a public company limited by guarantee, incorporated and domiciled in Australia.

The address of its registered office and principal place of business is:

Suite 5, Level 6, 365 Little Collins Street,
MELBOURNE VIC 3001

2. Adoption of new and revised Accounting Standards

2.1 Standards and Interpretations affecting amounts reported in the current period (and/or prior periods)

The following new and revised Standards and Interpretations have been adopted in the current year and have affected the amounts reported in these financial statements. Details of other Standards and Interpretations adopted in these financial statements but that have had no effect on the amounts reported are set out in section 2.2.

Standards affecting presentation and disclosure

Amendments to AASB 101 'Presentation of Financial Statements'

The amendments (part of AASB 2010-4 'Further Amendments to Australian Accounting Standards arising from the Annual Improvements Project') clarify that an entity may choose to present the required analysis of items of other comprehensive income either in the statement of changes in equity or in the notes to the financial statements.

AASB 1054 'Australian Additional Disclosures' and AASB 2011-1 'Amendments to Australian Accounting Standards arising from Trans-Tasman Convergence Project' adopted in IFRSs.

AASB 1054 sets out the Australian-specific disclosures for entities that have adopted Australian Accounting Standards. This Standard contains disclosure requirements that are in addition to IFRSs in areas such as compliance with Australian Accounting Standards, the nature of financial statements (general purpose or special purpose), audit fees, and the reconciliation of net operating cash flow to profit (loss).

AASB 2011-1 makes amendments to a range of Australian Accounting Standards and Interpretations for the purpose of closer alignment to IFRSs and harmonisation between Australian and New Zealand Standards. The Standard deletes various Australian-specific guidance and disclosures from other Standards (Australian-specific disclosures retained are now contained in AASB 1054), and aligns the wording used to that adopted in IFRSs.

The application of AASB 1054 and AASB 2011-1 in the current year has resulted in the simplification of disclosures in regards to audit fees, franking credits and capital and other expenditure commitments as well as an additional disclosure on whether the company is a for-profit or not-for-profit entity.

2.2 Standards and Interpretations adopted with no effect on financial statements

The following new and revised Standards and Interpretations have also been adopted in these financial statements. Their adoption has not had any significant impact on the amounts reported in these financial statements but may affect the accounting for future transactions or arrangements.

AASB 2009-12 'Amendments to Australian Accounting Standards

The Standard also makes numerous editorial amendments to a range of Australian Accounting Standards and Interpretations, which includes AASB 108. The application of AASB 2009-12 has not had any material effect on amounts reported in the financial statements.

AASB 2010-5 'Amendments to Australian Accounting Standards'

The Standard makes numerous editorial amendments to a range of Australian Accounting Standards and Interpretations, which includes AASB 101 and AASB 107. The application of AASB 2010-5 has not had any material effect on amounts reported in the financial statements.

AASB 1048 'Interpretation of Standards' (revised)

AASB 1048 identifies the Australian Interpretations and classifies them into two groups: those that correspond to an IASB Interpretation and those that do not. Entities are required to apply each relevant Australian Interpretation in preparing financial statements that are within the scope of the Standard. The revised version of AASB 1048 updates the lists of Interpretations for new and amended Interpretations issued since the June 2010 version of AASB 1048.

2.3 Standards and Interpretations in issue not yet adopted

At the date of authorisation of the financial statements, the Standards and Interpretations listed below were in issue but not yet effective.

Standard/Interpretation	Effective for annual reporting periods beginning on or after	Expected to be initially applied in the financial year ending
AASB 9 'Financial Instruments', AASB 2009-11 'Amendments to Australian Accounting Standards arising from AASB 9' and AASB 2010-7 'Amendments to Australian Accounting Standards arising from AASB 9 (December 2010)'	1 January 2013	30 June 2014
AASB 119 'Employee Benefits' (2011) and AASB 2011-10 'Amendments to Australian Accounting Standards arising from AASB 119 (2011)'	1 January 2013	30 June 2014
AASB 2011-4 'Amendments to Australian Accounting Standards to Remove Individual Key Management Personnel Disclosure Requirements'	1 July 2013	30 June 2014
AASB 2011-9 'Amendments to Australian Accounting Standards—Presentation of Items of Other Comprehensive Income'	1 July 2012	30 June 2013
Offsetting Financial Assets and Financial Liabilities (Amendments to IAS 32)	1 January 2014	30 June 2015
Disclosures—Offsetting Financial Assets and Financial Liabilities (Amendments to IFRS 7)	1 January 2013	30 June 2014

3. Significant accounting policies

Financial reporting framework

The company is not a reporting entity because in the opinion of the directors there are unlikely to exist users of the financial statements who are unable to command the preparation of reports tailored so as to satisfy specifically all of their information needs. Accordingly, these special purpose financial statements have been prepared to satisfy the directors' reporting requirements under the *Corporations Act 2001*.

Statement of compliance

The financial statements have been prepared in accordance with the *Corporations Act 2001*, the recognition and measurement requirements specified by all Australian Accounting Standards and Interpretations, and the disclosure requirements of Accounting Standards AASB 101 'Presentation of Financial Statements', AASB 107 'Cash Flow Statements', AASB 108 'Accounting Policies, Changes in Accounting Estimates and Errors' and AASB 1054 Australian Additional Disclosures.

Basis of preparation

The financial statements have been prepared on the basis of historical cost, except for the revaluation of certain non-current assets and financial instruments. Cost is based on the fair values of the consideration given in exchange for assets. All amounts are presented in Australian dollars, unless otherwise noted.

Going concern

The financial report has been prepared on the basis that the company is a going concern which assumes the continuity of normal business activities and the realisation of assets and the settlement of liabilities in the ordinary course of business.

The company operates under a three-year funding agreement with the Department of Innovation, Industry, Science & Research (DIISR) which is due to end in 2014.

Critical accounting judgements and key sources of estimation uncertainty

In the application of the company's accounting policies, which are described below, the directors are required to make judgements, estimates and assumptions about carrying values of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

The following significant accounting policies have been adopted in the preparation and presentation of the financial statements:

(a) Income tax

The company is exempt from income tax under subdivision 50-B of the *Income Tax Assessment Act 1997*.

(b) Cash and cash equivalents

Cash comprises cash on hand and demand deposits. Cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

(c) Comparative amounts

Comparative figures have been adjusted to conform to changes in presentation for the current financial year where required by accounting standards or as a result of changes in accounting policy.

(d) Revenue

TIA is a not-for-profit company and receives a principal part of its income from government grants as cash. Amounts granted can be recognised only as revenue when the company gains control, the economic benefits are probable and the amount of the contribution can be reliably measured.

Revenue is measured at the fair value of the consideration received or receivable.

Interest revenue is accrued on a time basis, by reference to the principal outstanding and at the effective interest rate applicable, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to that asset's net carrying amount.

(e) Goods and Services Tax (GST)

Revenues, expenses and assets are recognised net of the amount of goods and services tax (GST), except:

i. where the amount of GST incurred is not recoverable from the taxation authority, it is recognised as part of the cost of acquisition of an asset or as part of an item of expense;

or

ii. for receivables and payables which are recognised inclusive of GST.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables.

Cash flows are included in the statement of cash flows on a gross basis. The GST component of cash flows arising from investing and financing activities which is recoverable from, or payable to, the taxation authority is classified as operating cash flows.

(f) Trade and other payables

Trade payables and other accounts payable are recognised when the company becomes obliged to make future payments resulting from the purchase of goods and services. They are recognised initially at their fair value and subsequently measured at amortised cost using the effective interest method.

4. Revenue

An analysis of the company's revenue for the year, from continuing operations is as follows:

	2012 ($)	2011 ($)
Continuing operations		
Grant revenue	9,550,000	9,546,147
Other operating revenue	846,000	500,853
Interest revenue	322,572	137,488
	10,718,572	**10,184,488**

5. Surplus for the year

Surplus for the year has been arrived at after charging the following items of expense:

	2012 ($)	2011 ($)
Continuing operations		
Consultancy fees	(410,599)	(256,185)
Directors fees	(130,208)	(87,010)
Audit of the financial report (i)	(10,718)	(10,450)

(i) The auditor of the financial report is Deloitte Touche Tohmatsu Limited

6. Trade and other receivables

	2012 ($)	2011 ($)
Prepaid expenses	25,743	44,359
	25,743	44,359

7. Trade and other payables

An analysis of the company's revenue for the year, from continuing operations is as follows:

	2012 ($)	2011 ($)
Trade payables	–	55,520
Accrued expenses	170,010	1,043,474
Unearned grant income	330,000	9,115,547
Income in advance	**435,660**	**777,660**
GST payable	**21,265**	**10,352**
Other payables	**7,528**	**5,762**
	964,463	**11,008,315**

8. Cash and cash equivalents

a) Reconciliation of cash and cash equivalents

For the purposes of the statement of cash flows, cash and cash equivalents includes cash on hand and in banks and investments in money market instruments, net of outstanding bank overdrafts. Cash and cash equivalents at the end of the year as shown in the statement of cash flows can be reconciled to the related items in the statement of financial position as follows:

	2012 ($)	2011 ($)
Cash and cash equivalents	1,534,756	11,095,147

b) Reconciliation of (deficit)/surplus for the year to net cash flows from operating activities

	2012 ($)	2011 ($)
Surplus for the year	464,845	121,438
Movement in working capital		
(Increase)/decrease in assets:		
Trade and other receivables	18,616	(33,745)
Increase in liabilities:		
Trade and other payables	(10,043,852)	9,975,436
Net cash (used in)/from operating activities	(9,560,391)	10,063,129

9. Commitments for expenditure

	2012 ($)	2011 ($)
Operating lease commitments		
Not longer than 1 year	15,910	19,092
Between 1 to 2 years	–	15,910
	15,910	35,002

10. Subsequent events

There has not been any matter or circumstance occurring subsequent to the end of the period that has significantly affected, or may significantly affect, the operations of the company, the results of those operations, or the state of affairs of the company in future financial years.

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