THERAPEUTIC INNOVATION AUSTRALIA

Strategic Plan

2023-28

NCRIS
National Research Infrastructure for Australia
An Australian Government Initiative

Vision

An Australian Research and Development ecosystem that effectively translates discoveries into improvements in human health through seamless access to a consortium of state-of-the-art infrastructure supported by a network of experts.

Mission

Enable and accelerate research translation along the therapeutic development pipeline by investing in research infrastructure that is coordinated, comprehensive, accessible and responsive to the needs of academic and industry researchers.

Why is national research infrastructure important?

Australia consistently demonstrates excellence in medical research discovery that belies the relatively small population and economy, but often falls short in transforming these discoveries into innovative medical products and treatments.

The Australian government has recognised this deficit and has identified **medical products** as a critical priority across a variety of policies and initiatives.

National research infrastructure (NRI) plays a critical role in overcoming some of the challenges in better realising the massive potential of Australia's medical research sector to create impact, both in commercial terms and health outcomes. The 2021 National Research Infrastructure Roadmap (the "2021 Roadmap") and a series of Research Infrastructure Investment Plans (the latest in 2020) clearly articulate the role of NRI in translation of research discoveries into health impact via commercial pathways.

What is NRI?

NRI comprises nationally significant assets, equipment, facilities, services and associated expertise to support leading-edge research and innovation. NRI is accessible to publicly and privately funded researchers in Australia and around the world.

What is TIA?

Established in 2011, Therapeutic Innovation Australia Ltd (TIA) is the lead agent for one of 24 investment projects under the **National Collaborative Research Infrastructure Strategy** (NCRIS) of the Australian Department of Education. TIA manages the **Therapeutic Innovation Australia** (previously named Translating Health Discoveries) project, which is focussed on improving access to research infrastructure to support therapeutic development. TIA executes this project by financially supporting selected service providers to enable researcher access to subsidised, seamless and value-adding expertise. Collectively, the TIA consortium provides a seamlessly connected pipeline that enables researchers and companies to develop innovative medical products in preparation for Phase I trials and beyond. In doing so, TIA supports retaining and attracting health innovation in Australia, along with the associated health and economic benefits.

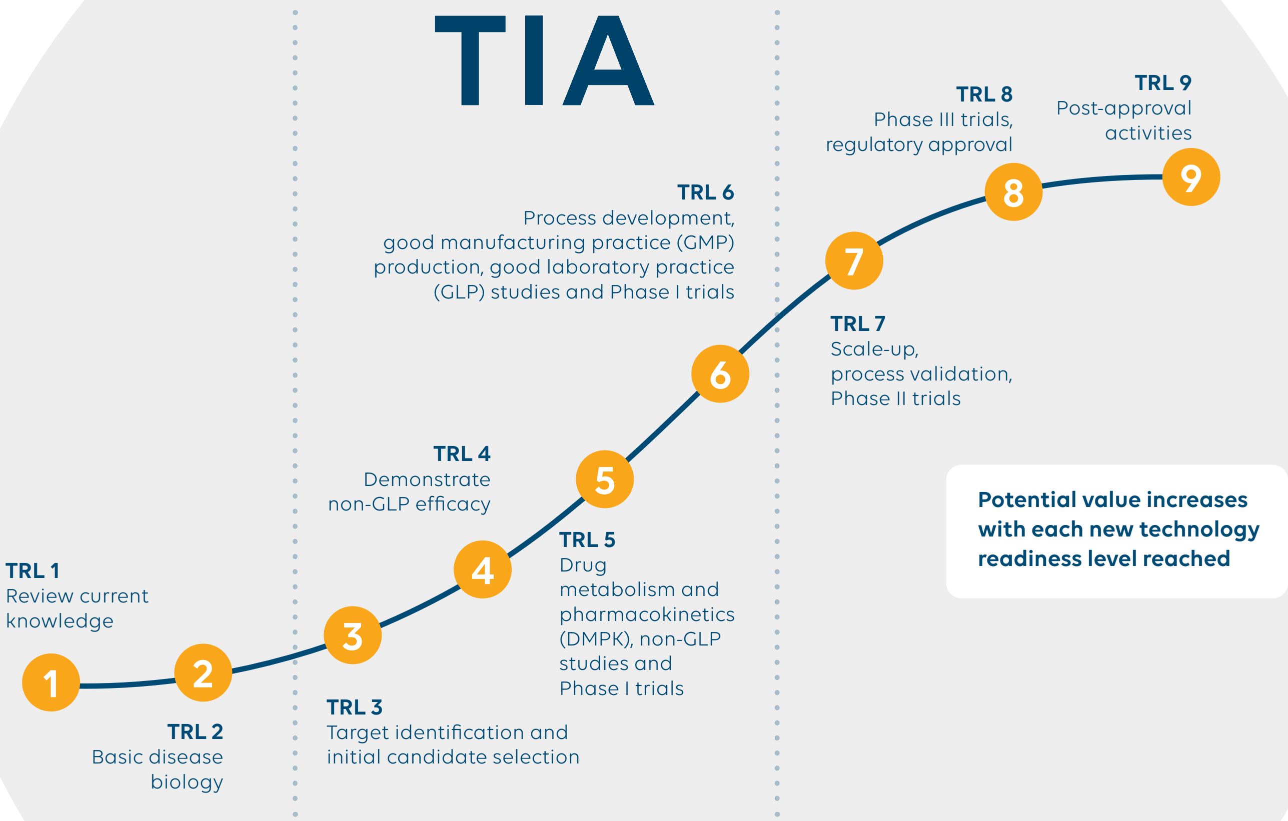
TIA's contribution to development of medical products

TIA's investments and initiatives focus on the so-called Valley of Death, which represents the relative lack of funding and support that researchers must navigate to successfully translate their discoveries into meaningful health and commercial impacts.

TIA helps medical product development projects by addressing identified **capacity and capability gaps** in the research translation pipeline and maintaining a forward-looking view of future requirements. By providing a connected pipeline of capabilities at this precarious stage of development, TIA supports researchers and companies through key value inflection points to be ready to engage with development partners and to progress their products to commercial endpoints and health impacts.

The Valley of Death can be expressed in several ways, but we articulate the gap in terms of **Technology Readiness Levels** (Figure 1), where our facilities offer capability from TRLs 3 through to 6. This encompasses the earliest stage of post-discovery translation of research findings into potential products (TRL 3), through to preparation of data and materials to enable Phase I clinical trials (TRL 6). Certain TIA facilities also support manufacturing for Phase II and III trials (TRLs 7 and 8).

Figure 1. Technology readiness levels as applied to therapeutic development and TIA's area of focus



Source for Technology Readiness levels: DMTC

TIA's contribution to national priorities

The 2021 Research Infrastructure Roadmap highlighted the development of **Medical Products** as one of eight key priorities. TIA's objectives are in lockstep with this priority, as well as numerous other government priorities and initiatives, including (but not limited to):

POLICY/INITIATIVE	TIA CONTRIBUTION (examples)
2021 Research Infrastructure Roadmap	Management of NCRIS investment in key priority areas. Promotion of facilities. Enabling seamless access to translational research infrastructure
National Health and Medical Research Council	Provide accessible state-of-the-art research infrastructure to support medical R&D
Australian Research Council	
Medical Research Future Fund	As above, plus partnerships on key funding schemes that support critical research infrastructure
National Reconstruction Fund	Provide proof of concept and scale-up facilities to prepare products for large-scale manufacturing
Science and Research Priorities	Support research that aligns with the **Advanced Manufacturing** and **Health** priorities
Australian Medical Research and Innovation Priorities	Support research that aligns with most listed priorities, with a particular focus on **Translational Research Infrastructure, Drug Repurposing, Global Health and Health Security** and **Antimicrobial Resistance**
National Climate Resilience and Adaptation Strategy	Support development of novel products to improve public health
Blueprint for Critical Technologies	Contribute to supply chain protection, commercialisation and sovereign capability.

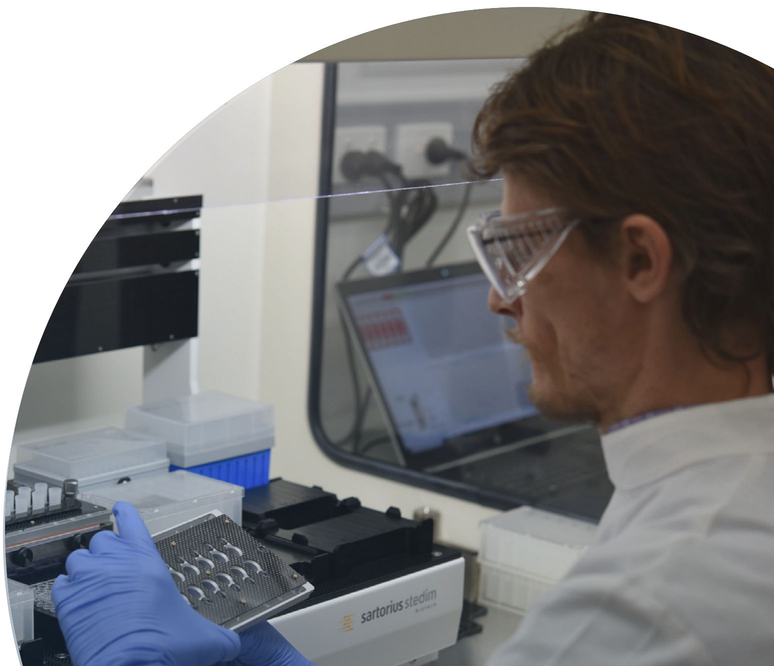
TIA's structure and investment plan

Product-focussed structure

TIA will retain the successful product focussed capability structure implemented under our previous Strategic Plan 2018-23 (rows 1-3 in Table 1), which strongly contributes to the **Medical Products** priority of the 2021 Research Infrastructure Roadmap. With COVID-19 vaccines based on mRNA technology having significantly impacted therapeutic innovation, TIA is establishing a fourth capability supporting development of **RNA Products** (row 4 in Table 1).

TIA'S CAPABILITIES TO ENCOMPASS MAJOR AND EMERGING THERAPEUTIC MODALITIES IN WHICH AUSTRALIA HAS PROVEN RESEARCH STRENGTH	
National Biologics Facility	Access to expertise and services in biologics discovery, development and GMP manufacture to support early-stage clinical trials. Therapeutic products include recombinant proteins, antibodies and other macromolecules produced in mammalian and microbial systems.
Small Molecule Therapeutics	A comprehensive and seamless pipeline of capabilities encompassing compound library logistics and supply, hit compound discovery (including high-throughput screening of libraries), medicinal chemistry, lead optimisation and industry-standard, quality-accredited efficacy testing.
Cell & Gene Therapies	A clinically focussed network of TGA-licenced facilities for development and production of advanced therapeutic products for early to late-stage clinical trials and patient use.
RNA Products (New)	A complementary network of facilities that supports Australian excellence in RNA science and development of novel therapeutics through access to rapid synthesis and formulation of a variety of high-quality RNA products.

Table 1. TIA Capabilities are organised around product types



TIA investment strategy

TIA's investments are managed by a team of operational and outreach staff headed by a CEO and including expert brokers/facilitators. Strategic and audit oversight is provided by a skills-based Board. Investments are organised across five key components (Table 2), enabling effective prioritisation of investment as well as accurate and timely reporting. TIA ensures that all investments are in alignment with NCRIS investment principles as endorsed in the 2021 National Research Infrastructure Roadmap.

TIA INVESTMENT STRATEGY	
People	• Support for key technical and operational salaries across all TIA capabilities • Support for broker/facilitator roles • Training and workforce development
Equipment	• Maintaining state-of-the-art equipment and quality outcomes
Pipeline Accelerator	• Enabling project access to facilities and expertise • Targeted support for specific projects using a voucher mechanism
Opportunities	• Rapid response to opportunities
Administration	• Governance • Investment management • Outreach

Table 2 TIA Investment Strategy

A fourth TIA capability

mRNA technology has changed the world

The success of the Pfizer-BioNTech and Moderna vaccines for COVID-19 has thrust mRNA into the global spotlight and the public conversation. But mRNA is only one of a family of potentially game-changing therapies, including siRNA, gRNA, miRNA, antisense RNA.

In response, TIA is establishing a fourth capability supporting development of **RNA Products.**

The new capability will capitalise on recent regulatory approvals for mRNA vaccines and realise the massive potential for RNA-based therapeutics. Australia already has a strong reputation in RNA biology, a position that must be preserved. The new capability will maintain this momentum and support the exciting RNA-based therapeutics that will flow from Australian research, while seamlessly complementing our existing three capabilities as well as other NCRIS capabilities.

TIA strategic goals

To deliver on our mission, we will pursue four crucial strategic goals during 2023-28. We will provide **seamless access**, form **strategic partnerships**, help to build a **quality workforce** and remain **future focussed**.

While these goals represent the guiding parameters for TIA's decision making and investment strategy, we will periodically revisit and continuously improve this strategic plan as required to ensure that we continue to deliver upon our vision.

SEAMLESS ACCESS

Regardless of location and organisation, Australian researchers enjoy seamless access to the quality research infrastructure and expertise critical for translating discoveries into medical products.

We will maximise access by seeking to expand the scope and size of the established Pipeline Accelerator voucher scheme and continue with our model of appointing brokers/facilitators to raise their profile and drive access to facilities, particularly in relation to engaging with industry.

TIA will also put in place materials and initiatives to ensure that researchers accessing TIA facilities are sufficiently informed, prepared and supported to embark on the long, risky and expensive journey to translate research discoveries.

To maximise return on investment in research infrastructure and reduce duplication, TIA will continue to invest in people and equipment at the appropriate facilities to enable access by academic and industry researchers. We will demonstrate a strong return on investment by seeking co-contributions from state governments and other funding bodies, and by collecting and communicating the outcomes of researcher access.

Quality systems and, where appropriate, formal accreditation remain crucial aspects of therapeutic development. Facilities require an appropriate quality system to ensure that projects are "investor-ready" and suitable for regulatory applications. TIA will support the strategic deployment of quality systems at facilities.

STRATEGIC PARTNERSHIPS

TIA forms and maintains partnerships that add value to research infrastructure and drive industry engagement

TIA plays a convening role in the therapeutic development ecosystem by bringing together key research infrastructure to provide a seamless experience for the researcher. We also play a key connecting role to related organisations that support translation of research discoveries. We will seek to form new joint initiatives that add value to research infrastructure, including supporting our facilities in their efforts to form partnerships that extend and enhance their capacity and capability. We will maintain existing partnerships such as those with MTPConnect, MRFF, the global Translation Together consortium and related NCRIS projects.

QUALITY WORKFORCE

TIA facilities can recruit and retain the staff they require, provide appropriate skills and development, and acknowledge their important contributions to research.

TIA believes that people represent the most valuable investment in research infrastructure, as without a skilled core of staff, even the most advanced equipment is of very little utility. The 2021 Roadmap also highlights the critical importance of people in research infrastructure projects. TIA will continue to support and encourage a strong "customer service" culture in facilities.

TIA will foster a collaborative, equitable and inclusive culture in partnership with facilities, while we monitor emerging workforce needs and take appropriate action as needed. TIA will provide mechanisms to support external training and career development for supported staff.

FUTURE-FOCUSSED

TIA has an informed and current view of the "state of the art" to ensure that Australian translational research infrastructure can respond to future requirements.

Research methods, technologies and paradigms evolve quickly, with a recent example being the rapid emergence of mRNA. To ensure that TIA's investments remain current and fit for purpose into the future, TIA will establish a Scientific Advisory Committee as a sub-committee of the TIA Board, with responsibility for horizon scanning. This committee will be independent and inclusive and will advise TIA on emerging trends and technologies.

TIA will retain resources and operational flexibility to enable rapid response to opportunities, such as partnerships or large-scale funding opportunities with direct relevance to research infrastructure.

TIA and TIA-supported research infrastructure have an evidence-based strategy in place to reduce carbon emissions

TIA accepts the international scientific consensus on climate change, one of the most significant issues impacting society, where the health R&D sector will have a significant role to play. Australia has legislated targets to reduce carbon emissions. In joining this effort, TIA will take action at Board and company level and will work with TIA-supported facilities and researchers to develop and implement a plan for carbon emission reduction which sets out the actions we will take between 2023-2028.

TIA invests in research infrastructure to enable seamless access to expertise and services vital to translate Australian research discoveries into improvements in human health. We develop strategic partnerships that are informed by a strong focus on future needs, while working to build a quality workforce – all in support of a vibrant and productive Australian Research and Development ecosystem.

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