

Pipeline Accelerator 2022-2023 (Round 2)

Guidelines

Background

Through the National Collaborative Research Infrastructure Strategy (NCRIS) program, Therapeutic Innovation Australia (TIA) and Phenomics Australia support a network of national research infrastructure to address the medical products challenge in the [2021 National Research Infrastructure \(NRI\) Roadmap](#). We collectively offer academic researchers and SMEs access to a diverse range of Australian translational medical research capabilities, from the molecular basis of health and disease through to clinical trials.

To encourage access to these capabilities, TIA has developed the Pipeline Accelerator, a voucher-style scheme that can subsidised the cost of access to a full range of advanced capabilities. In this Pipeline Accelerator round, we are partnering with Phenomics Australia to expand the list of translation expertise necessary for the discovery and translation of medical research.

The Pipeline Accelerator aims to further reduce the cost of access to TIA and Phenomics Australia facilities to enable various therapeutic development projects, including (but not limited to):

- Production of organoids from tumour-derived samples or iPSCs
- Production end genome engineering of organoids and iPSCs from patient-derived samples
- Reanimation, redistribution or importation of mouse strains
- Gene targeting in mouse embryonic stem cells
- Production of CRISPR/Cas9-edited mice, transgenic mice, rats and other species
- DNA construct design and production
- Histopathological analysis of human and mice tissue
- Characterisation of tumour-derived cell lines or organoids in high throughput
- Synthesis of research-grade nucleic acids (e.g. mRNA, dsRNA and plasmid DNA)
- Assay development and screening of compounds, CRISPR, RNAi, or biologics libraries
- Data curation and analysis
- Consultation on experimental design for grant and ethics applications
- Hit-to-lead and medicinal chemistry
- Drug optimisation and advice on development strategy
- Vaccine candidate development
- Process development for biologics and advanced therapy medicinal products
- Preclinical testing of small molecules, biologics and vaccine candidates
- Pilot-scale GMP production
- TGA-licenced production of gene and cell therapies for clinical trials and patient use
- Patient sample collection and apheresis
- Clinical trial support

The scheme has three key participants - **Providers**, **Applicants** and an **NCRIS project**. For **Providers**, the general aims of the scheme are to:

- Provide a mechanism for financially supporting and enabling hard-to-fund activities
- Enable and increase external business from publicly funded research groups and SMEs
- Lowering barriers to entry and helping develop new research and industry user communities
- Create an ecosystem of seamless services for researchers and SMEs, leading to more effective use of national research infrastructure

- Bridging innovation gaps with translation NRI to drive increased industry investment

The scheme can be a great way to develop track record in translational research for therapeutic discovery and development, particularly for early-career researchers (ECRs).

Eligibility of Applicants

The Pipeline Accelerator scheme is open to applications from the following organisations:

- University-based researchers and research groups
- Research groups within Publicly Funded Research Organisations, including Medical Research Institutes
- University or Medical Research Institute’s technology transfer offices or organisations, and university/MRI spin-outs
- Commercial entities that meet the general eligibility criteria for the [R&D Tax Incentive](#).
- **Applications from international organisations will also be considered to be eligible**

Applications that seek to access facilities **outside their academic unit or host entity will generally be favoured.**

Early career researchers and/or female researchers are strongly encouraged to apply as the main applicants.

Eligibility of Providers

See [Appendix 1](#) for facilities that are eligible for voucher support from this round of the scheme (“Providers”). Multiple Providers may be named on a single application if the project makes use of capabilities at several different facilities. This list of providers may be amended for future rounds, subject to demand.

Eligibility of Projects

To be eligible for the voucher, the Project application **MUST**:

- Indicate which facility(-ies) will be accessed
- An applicant may apply to multiple facilities to support **different aspects** of the **same project**, although the maximum voucher benefit to a facility is \$50,000 per project.
- Applications that seek to access a combination of TIA and Phenomics Australia facilities to support the same projects are strongly encouraged
- Briefly articulate the current state of research understanding, as relating to the chosen therapeutic or disease modality in terms of biochemical/phenotypic characterisation, mechanism of action, target validation, etc.
 - Articulate the potential short- and long-term outcomes including (for example):
 - a new therapeutic product or product/service/healthcare outcome combination for an existing or new market
 - a new understanding of disease to benefit human health
 - an increase in health service cost effectiveness or a global health outcome through a new practice or product
 - a new patent or patentable IP, and/or license
- Be regarded as scientifically meritorious by assessment committees, which may have external members, appointed by TIA and Phenomics Australia.
- Demonstrate a plan for the next steps in development as they relate to the project, in the context of the project’s potential to lead to new therapeutic product or product/service/healthcare outcome for an existing or new market (including via out-licencing).
- Have obtained appropriate service quotes from the selected Provider(s)
- Define an indicative desired timescale for the project

- The timescale should align with the award and should not exceed 12-18 months from commencement. Note: this timescale applies to the supported activities only, and **not** the full completion of the project or development of a potential therapeutic or healthcare outcome.
- Define an endpoint for the supported Project (as noted above, not necessarily for the entire development project).
- Provide some level of assurance **in the indication of facility support** (see application form) that the project can commence **within 6 months** of award.
- Applicants seeking to access facilities within their own academic units or host entities (that is, “Internal” projects) will be required to briefly articulate why voucher funding is necessary to access an internal facility.
- **You may apply for voucher to support a project that has previously been supported under this scheme. However, you must either include the completion report for the previous voucher or articulate significant progress to date (refer below *Supporting documents* for details). This progress can be described in the required email.**
- Supporting documents (see below for details)
 - **Upload** a single A4 page of diagrams in JPG, PNG or PDF format
 - **Upload** as a single PDF of the original quote or terms sheet for services (quote may be in email form)
 - The quote amount must not take into account the requested voucher value.
 - The quote must specify the appropriate level of GST to be applied.
 - A brief indication of Provider support for the application (an email is acceptable) stating that:
 - The quote provided is priced in accordance with TIA’s Access and Pricing Policy
 - The quote is valid for at least 3 months.
 - The Provider consents to being named in the Application
 - The Project will be able to commence within 6 months of award
 - **If the project has previously been awarded a voucher**, include a brief (~½ page) update on the progress of that Project to date **or** upload the previously submitted completion report.

Funding level and Co-investment expectations

Funding level

The voucher awarded will be **50% of the total cost (ex-GST)** up to a **maximum award of \$50,000**, and will be provided directly to the service provider at project commencement, **allowing this cost saving to be passed to the Applicant.**

The voucher may contribute to the cost of accessing a facility but cannot cover or exceed the entire cost.

Co-investment expectations

Co-investment/matching fund is an important aspect of this scheme, as applicants must have some “skin in the game” and must have access to sufficient resources to complete the proposed work. **Vouchers are not intended to fully-fund projects.** Applications must therefore demonstrate significant **cash co-investment** to confirm that, should the voucher be awarded, the proposed work is fully supported. In this round, the voucher awarded will be exactly 50% of the total quote, up to \$50,000. Applicants are responsible for the remaining of the cost.

Application and funding process

1. Applications open

A call for applications will be published through a variety of channels.

Applicants approach Providers with a project (i.e., request to access a specific translational research capability) and request a quote for services. The level of detail of the quotes will vary between facilities.

Applications proposing to access multiple facilities (such as a combination of TIA and Phenomics Australia services) should request separate quotes from each service Provider.

Applicant writes brief application for support using the template provided.

IMPORTANT: It is strongly encouraged that Providers to work closely with Applicants on the application and provide necessary advice and guidance to maximise the chance of project success.

You can access the Application package on either TIA or Phenomics Australia websites at the following URLs:

TIA – <https://www.therapeuticinnovation.com.au/voucher-documents>

Phenomics Australia - <https://phenomicsaustralia.org.au/voucher-scheme/>

Detailed instructions are included on the Application form template.

Applicant submits application via [online application form](#) before the closing date, which will be advised on the scheme's webpage and on the application form.

2. Applications close

3. Project selection

A panel, including independent external experts, assesses applications and decide on awards. The assessment process may be staged, depending on the number of applications received.

All outcomes will be notified via email, including unsuccessful applications. For successful applications, a **Letter of Offer** will be sent to the Applicants, cc: the specified Provider(s). This letter includes the obligations of TIA/Phenomics Australia, Applicant and Provider as follows:

TIA /Phenomics Australia must:

- pay invoices submitted by the named Provider totalling the amount awarded ex GST once the Applicant and Provider meet certain obligations to the satisfaction of TIA/Phenomics Australia (see below).

The Applicant must:

- co-sign with the Provider the received letter of offer and return to indicate agreement with the terms
- enter into a legally binding agreement with the Provider (**NOT** with TIA/Phenomics Australia) to provide payment for access to capabilities specified in the Application (*note: TIA and Phenomics Australia do not require sight of the contract, but requires written confirmation that such a contract exists in the Letter of Commencement*)
- co-sign a **Letter of Commencement** with the Provider, confirming that work has commenced. A template Letter of Commencement is available for download on the scheme's webpages ([TIA](#) or [Phenomics Australia](#)).

- provide brief (<1 page) reports on project progress according to a reporting schedule agreed with TIA/Phenomics Australia.
- provide a **Letter of Completion** including a brief final report that describes the overall outcomes. A template Letter of Completion is available for download on the scheme's webpages ([TIA](#) or [Phenomics Australia](#)).

The Provider must:

- co-sign with the Applicant the received letter of offer and return to indicate agreement with the terms.
- enter into a legally binding agreement with the Applicant (**NOT** with TIA/Phenomics Australia) to provide specific capabilities in exchange for payment. The final quoted cost should include subsidy from the awarded voucher.
- co-sign a **Letter of Commencement** and a **Letter of Completion** with the Applicant, as described above.
- Ordinarily, we expect the project to commence within 6 months of award of the voucher. Because of the nature of this scheme, ***offers may be withdrawn if projects do not commence within six months of award without a reasonable explanation.***
- submit an invoice to TIA/Phenomics Australia for part-reimbursement for the services as described in the quotation to the value of the awarded voucher.
- provide the services as described in the quotation within an agreed time window.

4. Project commences

Once the Project has commenced, the Provider is directly reimbursed by TIA/Phenomics Australia according to the following conditions:

- The Provider has sent to TIA/Phenomics Australia a copy of a proper invoice for the awarded voucher value ex GST, that references the Project and the Applicant.
- The Invoice must have extended payment terms (60 days) to allow TIA/Phenomics Australia to assess whether payment conditions have been met.
- The Invoice accompanies **written notice** that the services have commenced. This proof shall be via the provided template **Letter of Commencement** from the Applicant (counter-signed by the Provider) stating that the services have begun, and briefly outlining the capabilities being provided.

Note:

- The voucher awarded is **not transferable** to another project.
- TIA/Phenomics Australia **does not** need to see the agreement between Provider and Applicant.
- TIA/Phenomics Australia **does not** seek any ownership or beneficial interest in supported projects but reserves the right to receive brief project updates (~1/2 page) on request.
- In the event of early termination, the Provider must notify TIA/Phenomics Australia in writing at the earliest possible opportunity. Depending on the scenario, TIA/Phenomics Australia will advise the Provider on the next steps.

5. Project complete

Once the work of the Provider is complete, Provider and Applicant must meet the following conditions:

- The Applicant and Provider have provided **written proof** that the services have completed. This proof shall be the provided template **Letter of Completion** from the Applicant

(counter-signed by the Provider) describing the capability provided. This template includes instructions for a brief completion report.

6. Acknowledgement of TIA/Phenomics Australia/NCRIS

Applicants and/or Providers are expected to acknowledge TIA or Phenomics Australia and NCRIS in all publications associated with this work and send publication details to TIA/Phenomics Australia via the following online form:

TIA - <http://bit.ly/TIA-pubs>

Phenomics Australia - <https://phenomicsaustralia.org.au/news-media/>

Guidance for acknowledging TIA/ Phenomics Australia /NCRIS, including use of logos, is available at the following URL:

TIA - <https://www.therapeuticinnovation.com.au/access-acknowledgement>

Phenomics Australia - <https://phenomicsaustralia.org.au/acknowledge-us/>

Scheme timelines

Approximate timeline (subject to change)	Timeframe
Scheme opens for applications	6 th March 2023
Scheme closes for applications	28 th April 2023, 5pm (AEST)
Applications assessed	Early May 2023
Awards made	Late June 2023
Projects commence	Strictly within 6 months of award*
Projects complete	Within 12 months of award

*Offers may be withdrawn if projects have not commenced within six months without an explanation satisfactory to TIA/Phenomics Australia.

Scheme documents

These documents make up the Application and reporting package for the **Pipeline Accelerator** scheme. All documents are available for download on the scheme's ([TIA](#) or [Phenomics Australia](#)).

- Pipeline Accelerator Guidelines 2022-23 Round 2.docx (**this document**)
- Letter of Commencement template 2022-23 Round 2.docx **to accompany initial invoice**
- Letter of Completion template 2022-23 Round 2.docx **to inform TIA/Phenomics Australia of project completion**

Appendix 1

Capability	Provider (click name for website)	Contact(s)
Biologics	BASE Facility (UQ)	Tim Mercer
	National Biologics Facility – Vic Node (CSIRO)	Susie Nilsson John Power
	National Biologics Facility – Qld Node (UQ)	Ben Hughes Martina Jones
	National Biologics Facility – NSW Node (UTS)	David Rickards
	Protein Expression Facility (PEF)	David Owen
	Recombinant Products Facility (UNSW RPF)	Helene Lebhar Christopher Marquis
	UNSW RNA Institute (UNSW)	Palli Thordarson Joshua Peterson
Cell & Gene Therapies	Cell & Tissue Therapies WA (Royal Perth Hospital)	Zlatibor Velickovic
	Q-Gen Cell Therapeutics (QIMR Berghofer)	Andrew Masel
	Gene Therapy Research Unit (Westmead Precinct)	Margot Latham
	Sydney Cell and Gene Therapy (Westmead Precinct)	Leighton Clancy
	Cell & Molecular Therapies (Royal Prince Alfred Hospital)	Sharon Sagnella
	Vector and Genome Engineering Facility (CMRI)	Leszek Lisowski
	Centre of Excellence in Cellular Immunotherapy (Peter Mac)	Jennifer Hollands
Small Molecule Therapeutics	Australian Translational Medicinal Chemistry Facility (Monash University)	Paul Stuppel Leanne Hawkey
	Centre for Drug Candidate Optimisation (Monash University)	Susan Charman
	Centre for Integrated Preclinical Drug Development (UQ)	Maree Smith Andy Kuo
	Compounds Australia (Griffith University)	Rebecca Lang Sally-Ann Poulsen
High throughput screening	ACRF Drug Discovery Centre for Childhood Cancer (Children's Cancer Institute)	Greg Arndt Andrew Stone Tim Failes
	ANU Centre for Therapeutic Discovery (ANU)*	Amee George
	Cell Function & Screening Facility (VCCRI Innovation Centre)	Jeffrey McArthur
	Community for Open Antimicrobial Drug Discovery (UQ)	Johannes Zuegg Mark Blaskovich
	Functional Genomics South Australia (Uni of Adelaide) **	Simon Barry
	Griffith Discovery Biology (Griffith University)	Vicky Avery
	GRIDD Mass Spectrometry Screening (Griffith University)	Wendy Loa
	Monash Fragment Platform (Monash University)	Martin Scanlon
	Monash Functional Genomics Platform (Monash University) **	Sefi Rosenbluh
	National Drug Discovery Centre *** (WEHI)	Jeff Mitchell Kym Lowes
	Stem Cell Disease Modelling & Drug Screening Facility (MCRI)	Alejandro Hidalgo Gonzalez
	Victorian Centre for Functional Genomics (Peter Mac)*	Kaylene Simpson
<i>In vitro</i> genome engineering and disease modelling **	Induced Pluripotent Stem Cell Derivation & CRISPR Gene Editing Facility (MCRI)	Sara Howden
	Stem Cell Disease Modelling Laboratory (Uni of Melbourne)	Alice Pébay
	Genome Engineering and Disease Modelling Service (UQ)	Ernst Wolvetang
	Stem Cell Production Facility (VCCRI Innovation Centre)	Jeffrey McArthur
	Translational Cancer Research Program (Harry Perkins Institute of Medical Research)	Louise Winteringham
	Monash Organoid Program (Monash University)	Helen Abud

Biobanking and <i>in vivo</i> genome engineering and disease modelling**	Monash Genome Modification Platform (Monash University)	Alexander Combes
	The Australian Phenomics Facility (ANU)	Dominik Spensberger
	Melbourne Advanced Genome Editing Centre (WEHI)	Marco Herold
	South Australia Genome Editing Facility (Uni of Adelaide)	Paul Thomas
Pathology **	Histopathology and Digital Slide Service (Uni of Melbourne)	Janet Keast

* Supported by TIA and Phenomics Australia

** Supported by Phenomics Australia only

*** **National Drug Discovery Centre:** Applications to the Pipeline Accelerator scheme may seek to access capacity and capability at the National Drug Discovery Centre, if the project is outside the [NDDC's ongoing process to identify and support large scale high throughput screens](#). Pipeline Accelerator applications may describe a subsequent application to NDDC as part of a development plan, and external projects emerging from NDDC may apply to the Pipeline Accelerator scheme for support for hit validation.