





Pipeline Accelerator 2023-2024 (Round 2) Guidelines

Background

Through the National Collaborative Research Infrastructure Strategy (NCRIS) program, Therapeutic Innovation Australia, Phenomics Australia and ANSTO 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 competitive voucher-style scheme that can subsidise the cost of access to a full range of advanced capabilities. In this Pipeline Accelerator round, TIA is partnering with Phenomics Australia and ANSTO's National Deuteration Facility (NDF) 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 and enable seamless access to the NDF to enable various therapeutic development projects, including (but not limited to):

- Production and cryopreservation of bespoke in vivo models possessing targeted mutations of interest
- In vitro engineering and disease modelling system to include cell-, organoid- and iPSCs-based models, as well as 3D bioprinting
- Histopathological analysis of mouse tissue
- Assay development and high throughput screening of compounds, CRISPR, RNAi, or biologics libraries
- Hit-to-lead, lead optimisation and preclinical testing
- Synthesis of research and preclinical grade biologics (including process development)
- Synthesis of research-grade nucleic acids (e.g. mRNA, dsRNA and plasmid DNA)
- Pilot-scale GMP and TGA-licensed production of gene and cell therapies
- Production of bespoke deuterated and stable isotope labelled molecules and biomolecules (e.g., lipids, sterols, proteins and small organic molecules)*
- Multiple labelling of proteins (combinations of stable isotopes H-2, C-13 and N-15)*
- Deuterium labelling quantitative analysis (NMR, MS analysis)*
- * Services marked above are available from NDF in conjunction with applications to access other services.

CTRL-CLICK HERE FOR THE ONLINE FORM

New in this round

- Completion reports are now compulsory for a second voucher to support the same project.
- TIA will allocate dedicated funding for EMCRs.
- Applicants must acknowledge that successful applications will be sent directly to Facilities.
- Stable isotope labelling now offered by NDF for projects seeking to access another facility.
- Several new TIA facilities have been added to the scheme (see <u>Appendix</u> <u>1</u>).

The scheme has three key participants - **Providers**, **Applicants** and an **NCRIS** project (in this round, either **Therapeutic Innovation Australia** or **Phenomics Australia** or **NDF**). 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
- Raise the profile of NCRIS facilities and their range of accessible services
- Identify projects that can access more than one NCRIS facility to support the same project
- 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 <u>R&D Tax Incentive</u>.
- Applications from international organisations will also be considered to be eligible
- Early career researchers and/or female researchers are strongly encouraged to apply as the main applicants.
- Applications that seek to access facilities outside their academic unit or host entity will generally be favoured.

Eligibility of Providers

See <u>Appendix 1</u> 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 providers. This list may be amended for future rounds, subject to demand.

Access to the National Deuteration Facility *NEW*

In this round, the National Deuteration Facility (NDF) is accessible via applications to other NCRIS facilities that will also require NDF services. Select "Stable Isotope Labelling" box in the online application and provide a quote for services with supporting documentation. For example, if your project needs to access a deuterated molecule as part of a study on bioavailability of a lead candidate.

The applicant should contact NDF as soon as possible (ndf-enquiries@ansto.gov.au) for a feasibility assessment of their request. More information can be found on their website https://www.ansto.gov.au/facilities/national-deuteration-facility

This means that applications to access NDF <u>only</u> (i.e. with no other NCRIS facilities) will not be accepted in this call. This can be made directly through the NDF user program at https://www.ansto.gov.au/NDF/useraccess

Eligibility of Projects

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

- Indicate which Provider 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 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 outlicencing).
- Have obtained appropriate service quotes from the selected Provider facility(ies)
- Define an indicative desired timescale for the project
 - The timescale should align with the award and should not exceed 12 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 support from the Provider facility (see application form) that the project can commence within 6 months of award.
- Complete the application form with associated supporting documents (see below for details)

Notes:

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 include the completion report for the previous voucher (refer below Supporting

documents for details).

Supporting documents

- Upload a single A4 page of diagrams in JPG, PNG or PDF format
- O Upload as a single PDF of the following supporting documents:
 - NEW If applicable, please also include evidence of the source of matching funding if not from a grant (e.g. a letter from your host organization or funding body grant number).
 - Original quote or terms sheet for services (quote may be in email form).
 Multiple quotes can be submitted if multiple facilities are being accessed.
 - The quote amount must not take into account the requested voucher value but should align with any relevant Access and Pricing policy* including that of TIA.
 - 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 please upload the previously submitted completion report.

*Note:

TIA - Access and Pricing information is available here:

https://www.therapeuticinnovation.com.au/access-acknowledgement

Phenomics Australia - Contact Phenomics Australia provider for the relevant access and pricing information.

NDF – Contact NDF for the relevant access and pricing information.

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 access but cannot cover or exceed the entire cost.

Funding strategy

For this round, TIA will allocate a significant proportion of the funding pool to Early-Mid Career Researchers, that is, researchers up to 10 years from their PhD (excluding career breaks for illness, additional study or family responsibilities). Applications led by an EMCR will be preferentially funded from this EMCR pool.

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.

The voucher awarded will be exactly 50% of the total quote, up to \$50,000. Applicants are responsible for the remaining of the cost. The source of cash matching fund must be provided. If the matching

fund is from a grant, the **grant provider and identifier must be provided**. If it is not linked to a funded grant, an **evidence of funding source must be attached** to your application (e.g. a letter from your host organisation).

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 service) 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, Phenomics Australia and NDF 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 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, Phenomics Australia or NDF websites at the following URLs:

TIA – https://www.therapeuticinnovation.com.au/pipeline-accelerator

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

NDF- https://www.ansto.gov.au/facilities/national-deuteration-facility#content-more-information

Detailed instructions are included on the Application form template.

Applicant submits application via <u>online application form</u> 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 or 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 (<u>NOT</u> 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 (<u>TIA</u> or
 <u>Phenomics Australia</u>).
- 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 (<u>TIA</u> or <u>Phenomics Australia</u>).

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 (<u>NOT</u> 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 <u>6 months</u> 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 service provided. This template includes instructions for a brief
completion report.

6. Acknowledgement of NCRIS facilities and NCRIS support

Applicants and/or Providers are expected to acknowledge TIA, Phenomics Australia, or NDF 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 /NDF, 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/

NDF - https://www.ansto.gov.au/NDF/useraccess

Scheme timelines

Approximate timeline (subject to change)	Timeframe
Scheme opens for applications	4 March 2024
Scheme closes for applications	26 April 2024, 5pm (AEST)
Applications assessed	May 2024
Awards made	June 2024
Projects commence	Strictly within 6 months of award*
Projects complete	Within 12 months of commencement

^{*}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 websites (<u>TIA or Phenomics Australia</u>).

- Pipeline Accelerator Guidelines 2023-24 Round 2 (this document)
- Letter of Commencement template to accompany initial invoice
- Letter of Completion template to inform TIA/Phenomics Australia of project completion

Appendix 1

Capability grouping	Provider (click name for website)	Contact(s)
Biologics and vaccines	CSIRO Biomanufacturing	Charlotte Williams
Diologico ana vaccines		John Power
		<u>Judy Scoble</u>
		Susie Nilsson
	National Biologics Facility (UQ)	Ben Hughes
		Martina Jones
	Biologics Innovation Facility (UTS)	<u>David Rickards</u>
	Protein Expression Facility (PEF)	<u>David Owen</u>
	Recombinant Products Facility (UNSW RPF)	Helene Lebhar Christopher Marquis
Cell & Gene Therapies	Cell & Tissue Therapies WA (Royal Perth Hospital)	Zlatibor Velickovic
	Cell & Molecular Therapies (Royal Prince Alfred Hospital)	Sharon Sagnella
	Centre of Excellence in Cellular Immunotherapy (Peter Mac)	Jennifer Hollands
	Q-Gen Cell Therapeutics (QIMR Berghofer)	Andrew Masel
	Sydney Cell and Gene Therapy (Westmead Precinct)	Leighton Clancy
	Vector and Genome Engineering Facility (CMRI)	Betty Kao
	Viral Vector Manufacturing Facility (Westmead)	Michael Shum
RNA Products	Australian Centre for RNA Therapeutics in Cancer (UWA)	Archa Fox
	BASE Facility (UQ)	Tim Mercer
	mRNA CORE (Monash)	Colin Pouton
	RNA Institute (UNSW)	Palli Thordarson
		Joshua Peterson
Small Molecule	Australian Translational Medicinal Chemistry Facility (Monash	Paul Stupple
Therapeutics	<u>University</u>)	<u>Leanne Hawkey</u>
	Centre for Drug Candidate Optimisation (Monash University)	Susan Charman
		Alex Stupple
	Centre for Integrated Preclinical Drug Development (UQ)	Maree Smith
		Andy Kuo
	Compounds Australia (Griffith University)	Rebecca Lang Nyssa Drinkwater
	Qld Emory Drug Discovery Initiative (UQ)	Andrew Harvey
	CSIRO Biomanufacturing	Mark York
High throughput	ACRF Drug Discovery Centre for Childhood Cancer (Children's	Greg Arndt
screening	Cancer Institute)	<u>Tim Failes</u>
	ANU Centre for Therapeutic Discovery (ANU)*	Amee George
	Cell Function & Screening Facility (VCCRI Innovation Centre)	Jacek Kolanowski
	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
		Jeff Mitchell
	National Drug Discovery Centre (WEHI)	Kym Lowes
	Stem Cell Disease Modelling & Drug Screening Facility (MCRI)	Alejandro Hidalgo
		<u>Gonzalez</u>
	Victorian Centre for Functional Genomics (Peter Mac)*	Kaylene Simpson
In vitro genome	Induced Pluripotent Stem Cell Derivation & CRISPR Gene	Sara Howden
engineering and	Editing Facility (MCRI)	
disease modelling **	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)	Jacek Kolanowski
	<u>Translational Cancer Research Program (Harry Perkins Institute</u> of Medical Research)	Louise Winteringham
	Monash Organoid Program (Monash University)	Helen Abud
Biobanking and in vivo 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
	Australian Transgenic Drosophila Facility	<u>Kieran Harvey</u>
Pathology **	Histopathology and Digital Slide Service (Uni of Melbourne)	Janet Keast
Stable Isotope	National Deuteration Facility	Tamim Darwish
Labelling		Karyn Wilde

^{*} Supported by TIA and Phenomics Australia

^{**} Supported by Phenomics Australia only