Pipeline Accelerator 2021-2022 (Round 2) – Core Facilities Guidelines

## Facilitating Access to TIA Core Facilities[[1]](#footnote-2)

## Background

Therapeutic Innovation Australia (TIA), as an NCRIS entity, supports and facilitates researcher and SME access to a diverse range of Australian translational medical research capabilities. One specific mechanism, providing rapid, entry level access is via a voucher-style scheme - the **Pipeline Accelerator**.

The Pipeline Accelerator provides SMEs and researchers the access to one or more TIA core facilities to enable various therapeutic development projects, including (but not limited to):

* Supply of small molecule, biologics, cell or other compound libraries for hit, lead, or target discovery
* Assay development
* Drug optimisation and advice on development strategy
* Vaccine candidate development
* Process development for biologics
* TGA-licensed GMP testing to support production
* Pilot-scale GMP production
* TGA-licenced production of cell therapies for clinical trial and patient use
* Patient sample collection and apheresis
* Preclinical testing of small molecules, biologics and vaccine candidates
* Clinical trial support

In partnership with the [Australian Antimicrobial Resistance Network (AAMRNet),](https://www.mtpconnect.org.au/Category?Action=View&Category_id=266) Australia’s first industry-led and multi-stakeholder Antimicrobial Resistance Network, anadditional $200,000 will be allocated in this round to specifically support projects focused on developing novel treatments for drug-resistant infections. These applications will be assessed by a panel with expertise in antimicrobial resistance (AMR).

## Scheme Objectives and Key Features

TIA’s Pipeline Accelerator schemes are designed to respond quickly to the needs of researchers and industry by facilitating access to expertise in national research infrastructure. The scheme has three key participants, **Providers**, **Applicants** and **TIA**. For **Providers** (TIA-supported facilities), the general aims of the scheme common to all rounds are to:

* Enable and increase external business from academic research groups and SMEs (public and private sector researchers)
* Raise the profile, knowledge and use of the TIA facilities and their capabilities within the Australian research community
* Incentivise collaborative projects, leading to more effective use of research infrastructure.

For **Applicants** (public and private sector researchers) the aims of the scheme are to:

* Provide a mechanism for financially supporting and enabling hard-to-fund activities
* Lower the financial bar to access high quality translational research services.

To obtain a voucher, the project must require access to a TIA-supported facility (see **List of Providers** below). Applications must be made with the Providers involvement and agreement. Funding is via a fixed-value allocation of **either** $10,000/$20,000/$30,000/$40,000 **or** $50,000 ex GST. This funding will be provided directly to the service provider at project commencement, **allowing this cost saving to be passed on to the Applicant**. The voucher should **contribute** to the cost of accessing a facility but may not fully cover or exceed the entire cost.

For **TIA** the aims of the scheme are to:

* Support access to facilities, their capabilities and expertise
* Enable co-investment with NCRIS funding
* Increase external access to national research infrastructure enabling more collaborations
* Provide a means to identify and track progress of supported projects
* Provide case studies and exemplars for TIA reporting progress to government.

## Eligibility Criteria for 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 (MRIs)
* University or MRI’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](https://www.business.gov.au/assistance/research-and-development-tax-incentive).
* **Applications from international organisations may also be considered.**

In accordance with NCRIS principles around access to research infrastructure, applications that seek to access facilities external to their academic unit or host entity will generally be preferred.

## List of Providers

**Only** the following facilities 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.

| Capability | Facility Name (click name for website) | Contact(s) | Email |
| --- | --- | --- | --- |
| Biologics & Vaccines | [**BASE Facility**](https://basefacility.org.au/) **/** [**Protein Expression Facility (PEF)**](https://pef.facility.uq.edu.au/) | Balaji SomasundaramRomain Tropee | PEF: pef@uq.edu.auBASE: base@uq.edu.au |
| [**National Biologics Facility – QLD Node (UQ)**](http://www.nationalbiologicsfacility.com/) | Trent MunroMartina Jones | t.munro@uq.edu.aumartina.jones@uq.edu.au |
| [**National Biologics Facility – VIC Node (CSIRO)**](http://www.nationalbiologicsfacility.com/) | Susie Nilsson | Susie.Nilsson@csiro.au |
| [**National Biologics Facility – NSW Node (UTS)**](http://uts.edu.au/bif) | Jeff Welch Andrew Groth |  jeffrey.welch@uts.edu.auandrew.groth@uts.edu.au |
| Cell & Gene Therapies | **[Cell & Tissue Therapies WA](https://rph.health.wa.gov.au/Our-services/Cell-and-Tissue-Therapy)** **[(Royal Perth Hospital)](https://rph.health.wa.gov.au/Our-services/Cell-and-Tissue-Therapy)** | Leon Brownrigg Zlatibor Velickovic | leon.brownrigg@health.wa.gov.auzlatibor.velickovic@health.wa.gov.au |
| **[Q-Gen Cell Therapeutics](http://www.q-gencell.com/)****[(QIMR Berghofer)](http://www.q-gencell.com/)** | Leon Scott | Leon.Scott@qimrberghofer.edu.au |
| [**Sydney Cell & Gene Therapies (Westmead Precinct)**](http://www.scgt.org.au/) | Mark OrnatowskiMargot Latham | mark.ornatowski@health.nsw.gov.aumargot.latham@health.nsw.gov.au |
| [**Cell & Molecular Therapies (Royal Prince Alfred Hospital)**](https://www.slhd.nsw.gov.au/research/department_details.html?research=cmt) | Sharon Sagnella | sharon.sagnella@health.nsw.gov.au |
| [**Vector and Genome Engineering Facility (CMRI)**](https://www.cmrijeansforgenes.org.au/research/research-facilities/vector-and-genome-engineering-facility) | Leszek Lisowski | llisowski@cmri.org.au |
| [**Centre of Excellence in Cellular Immunotherapy (Peter Mac)**](https://www.petermac.org/centreofexcellence) | Nathan SmithJennifer Hollands | nathansmith@celltherapies.com.aujenniferhollands@celltherapies.com.au |
| Small Molecule | [**Australian Translational Medicinal Chemistry Facility (ATMCF; Monash)**](https://www.monash.edu/atmcf) | Jonathan BaellLeanne Hawkey | jonathan.baell@monash.eduleanne.hawkey@monash.edu |
| [**Centre for Drug Candidate Optimisation (Monash)**](https://platforms.monash.edu/cdco) | Susan CharmanAndrew Powell | susan.charman@monash.eduandrew.powell@monash.edu |
| [**Centre for Integrated Preclinical Drug Development (UQ)**](https://biomedical-sciences.uq.edu.au/cipdd) | Maree SmithAndy Kuo | maree.smith@uq.edu.aua.kuo1@uq.edu.au |
| [**Compounds Australia (Griffith)**](http://www.compoundsaustralia.com/) | Moana SimpsonKatherine Andrews | m.simpson@griffith.edu.auk.andrews@griffith.edu.au |

For projects seeking to access High Throughput Screening (HTS) facilities, please refer to the **Pipeline Accelerator 2021-2022 (Round 2 - Screening)** guidelines on the Pipeline Accelerator webpage.

## Eligibility of Projects

To achieve support, the Project application must:

* Indicate which core facility will be accessed
* Briefly articulate the current state of research relating to the chosen therapeutic modality in terms of biochemical 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 combination for an existing or new market
		- 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 an assessment committee with external members appointed by TIA
* Demonstrate a plan for the next steps in therapeutic development as they relate to the project, in the context of the project’s potential to lead to new therapeutic product or product/service for an existing or new market (including via out-licencing)
* Have obtained appropriate service quotes from the selected Provider
* Define an indicative desired timescale for the project
	+ The timescale should align with the award value and would ordinarily not exceed **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
* Define an endpoint for the supported Project activity (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 and complete **within 18 months of commencement**
* Applicants seeking to access facilities within their own academic units or host entities (that is, “Internal” projects) will be required to clearly articulate why voucher funding is necessary to specifically access an internal facility
* Submit all the required documents – Application form, quotes from Providers, letter/email of support from Providers. Incomplete applications will be automatically rejected

## Funding Level

Five levels of funding are offered:

* Increments starting from $10,000 ex GST;
	+ i.e., $10,000/$20,000/$30,000/$40,000 or $50,000 ex GST

Applications should specify the level of funding applied for. Applicants will **not** be offered a **different** level of funding than was applied for.

**PLEASE NOTE the following:**

* Multiple facilities may be accessed using a single voucher.
* An applicant may apply to multiple facilities to support **different aspects** of the same project, although the maximum voucher benefit will be $50,000 per project.

## Co-investment Expectations

Co-investment 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, **TIA expects a minimum level of cash co-investment of 50%**. Applicants are required to select a voucher value based on the provided quote (according to TIA access and pricing policies).

Some example scenarios are below.

EXAMPLE 1: A facility provides a quote of $60,000 (ex-GST). The \*maximum\* voucher to select is $30,000, based on a cash co-investment equal to the minimum ratio of 50:50.

EXAMPLE 2: A facility provides a quote of $120,000 (ex-GST). The most appropriate voucher to select is the maximum value of $50,000 with a cash co-investment of $70,000.

## Application and Funding Process

1. ***Applications open***

TIA publishes a call for applications 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.

Applicant writes brief application for support, using the template provided, and requests either of the five levels of funding mentioned above.

***IMPORTANT: It will be assumed that Providers will have worked closely with Applicants on the application and will have provided the necessary advice and guidance to maximise the chance of project success.***

The Application package will be hosted on the TIA website at the following URL: <https://www.therapeuticinnovation.com.au/accelerator-documents>. Detailed instructions are included on the Application form template.

Applicant submits application package to TIA via [online application form](https://app.smartsheet.com/b/form/93ea045ad338411d83469f2af5899d03) before the closing date, which will be advised on the scheme’s webpage and on the application form.

1. ***Applications close***
2. ***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.

TIA sends unsuccessful applicants a letter with, if available, feedback on the application.

TIA sends successful Applicants a **Letter of Offer**, cc: the specified Provider. This letter includes the obligations of TIA, Applicant and Provider as follows:

**TIA must:**

* pay invoices submitted by the named Provider totalling the amount awarded, plus GST, once the Applicant and Provider meet certain obligations to the satisfaction of TIA (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) to provide payment for access to capabilities specified in the Application (*note*: TIA does 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 [webpage](https://www.therapeuticinnovation.com.au/accelerator-documents).
* provide brief (<1 page) reports on project progress on request (TIA will provide a reasonable timeframe for project updates and will make frequent and unreasonable requests).
* within **18 months** of the date of the **Letter of Commencement**, provide a **Letter of Completion**, co-signed by the Provider, including a brief final report that describes the overall outcomes. A template Letter of Completion is available for download on the scheme’s [webpage](https://www.therapeuticinnovation.com.au/accelerator-documents). Non-submission of a brief final report may preclude the applicant from any future voucher applications.

**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) 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
* A **Letter of Completion** must be provided once the project has ended, ordinarily within **18 months** of the date of the **Letter of Commencement**
	+ **NOTE:** Brief final project reports are the key deliverable to TIA from this scheme. Timely submission of a **Letter of Completion** is required to ensure ongoing eligibility as a Provider
* Ordinarily, TIA would 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 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.
1. ***Project commencement***

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

* The Provider has sent to TIA 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 to assess whether payment conditions have been met
* The Invoice accompanies **written notice** that the services have commenced. This proof shall be via a TIA-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 **does not** need to see the agreement between Provider and Applicant.
* TIA **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 and/or significant project scope change, the Provider must notify TIA in writing at the earliest possible opportunity. Depending on the scenario, TIA will advise the Provider on the next steps.
1. ***Project completion***

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 a TIA-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.
* As noted above, submission of a Letter of Completion is required to ensure ongoing eligibility of Providers.
1. ***Acknowledgement of TIA/NCRIS***

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

[**http://bit.ly/ATRAX-DOI**](http://bit.ly/ATRAX-DOI)

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

[**http://www.therapeuticinnovation.com.au/acknowledging-tia**](http://www.therapeuticinnovation.com.au/acknowledging-tia)

## Scheme timelines

The scheme’s approximate timelines, which will remain subject to change, are listed below:

|  |  |
| --- | --- |
| Stage | Timeframe |
| Scheme opens for applications on the TIA website | 17th February 2022 |
| Scheme closes for applications | 29th April 2022, 5pm |
| Applications assessed | Early May 2022  |
| Awards made | Early July 2022 |
| Projects commence | **Strictly** within 6 months of award\* |
| Projects complete | Within 18 months of commencement |

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

## 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 [webpage](https://www.therapeuticinnovation.com.au/accelerator-documents).

1. Pipeline Accelerator Guidelines 2021-22 Round 2.docx **(this document)**
2. Letter of Commencement template 2021-2022 Round 2.docx **to accompany initial invoice**
3. Letter of Completion template 2021-2022 Round 2.docx **to inform TIA of project completion.**
1. For access to High Throughput Screening facilities, please refer to **Pipeline Accelerator 2021-2022 (Round 2- Screening) guidelines** on the Pipeline Accelerator webpage. [↑](#footnote-ref-2)