Pipeline Accelerator 2020-21 (Round 1)

Guidelines

## Facilitating access to all TIA-supported facilities

## Background

Therapeutic Innovation Australia (TIA), as a major NCRIS project, 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**.

In the past, access to core capabilities and high throughput screening (HTS) centres has been in separate rounds. For the first time, this round of the Pipeline Accelerator provides SMEs and researchers the access to one or more facilities associated with TIA, including **the core capabilities and HTS.**  TIA facilities enable various therapeutic development projects, including (but not limited to):

* Supply and screening of small molecule, biologics, cell or other compound libraries for hit, lead, tool or target discovery
* Assay development, library screening and/or hit validation
* 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 and toxicological testing of small molecules, biologics and vaccine candidates
* Clinical trial support

## 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 SMEs and publicly-funded research groups
* Raise the profile 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 **Eligibility of Providers** below). Applications must be made with the Providers involvement and agreement. Funding is via a fixed-value allocation of **either** multiples of $5,000 + GST (capped at $20,000 + GST) **or** $50,000 + GST, 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.

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

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

## 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](https://www.business.gov.au/assistance/research-and-development-tax-incentive).
* **Applications from international organisations will also be considered.**

## Eligibility of Providers

The following facilities are eligible for voucher support from this round of the scheme (“Providers”). Multiple Providers can 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  | [**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) | Edwin HuangAndrew Groth | edwin.huang@uts.edu.auandrew.groth@uts.edu.au |
| Cell & Gene Therapies | [**Cell & Tissue Therapies WA (Royal Perth Hospital)**](https://rph.health.wa.gov.au/Our-services/Cell-and-Tissue-Therapy) | Marian Sturm | marian.sturm@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) | Zlatibor Velickovic  | Zlatibor.Velickovic@health.nsw.gov.au |
| [**Centre of Excellence in Cellular Immunotherapy (Peter Mac)**](https://www.petermac.org/centreofexcellence) | Nathan Smith | nathansmith@celltherapies.com.au |
| Small Molecule | [**Australian Translational Medicinal Chemistry Facility (ATMCF; Monash)**](https://www.monash.edu/atmcf) | Jonathan BaellBernard Flynn | 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 SimpsonWilma James | m.simpson@griffith.edu.auwilma.james@griffith.edu.au |
| [**TetraQ (UQ)**](https://www.tetraq.com.au/) | Peter Tapley | p.tapley@tetraq.com.au |
| High Throughput Screening\* | [**ACRF Drug Discovery Centre for Childhood Cancer (Children's Cancer Institute)**](https://www.ccia.org.au/our-services/drug-discovery-centre/) | Greg ArndtAndrew StoneTim Failes | garndt@ccia.org.auAStone@ccia.org.autfailes@ccia.org.au |
| [**ANU Centre for Therapeutic Discovery (ANU)**](https://jcsmr.anu.edu.au/services/high-throughput-screening) | Amee George | amee.george@anu.edu.au |
| [**Cell Screen SA (Flinders)**](https://www.flinders.edu.au/research/facilities/cell-screen-sa-facility) | Amanda Aloia | amanda.aloia@flinders.edu.au |
| [**Community for Open Antimicrobial Drug Discovery (UQ)**](http://www.co-add.org/) | Johannes Zuegg Mark Blaskovich | j.zuegg@imb.uq.edu.au, m.blaskovich@imb.uq.edu.au |
| [**Griffith Discovery Biology (Griffith)**](http://www.discoverybiology.org/) | Vicky Avery | v.avery@griffith.edu.au |
| [**GRIDD Mass Spectrometry Screening (Griffith)**](https://www.griffith.edu.au/institute-drug-discovery/unique-resources/mass-spectrometry-screening) | Wendy LoaRaya Monteiro | w.loa@griffith.edu.au, r.monteiro@griffith.edu.au |
| [**Monash Fragment Platform (Monash)**](https://www.monash.edu/researchinfrastructure/mfp) | Martin Scanlon Bradley Doak | martin.scanlon@monash.edubradley.doak@monash.edu |
| [**National Drug Discovery Centre** \*\* **(WEHI)**](https://www.wehi.edu.au/about-business-development/partnering-opportunities/opportunities-platform-technologies) | Jeff MitchellKym Lowes | mitchell.j@wehi.edu.aulowes@wehi.edu.au |
| [**Victorian Centre for Functional Genomics (Peter Mac)**](https://www.petermac.org/research/core-facilities/victorian-centre-functional-genomics) | Kaylene Simpson | kaylene.simpson@petermac.org |
| [**Victor Chang Cardiac Research Institute Innovation Centre**](https://www.victorchang.edu.au/innovation-centre) | Jeffrey McArthurJohanna Barclay | j.mcarthur@victorchang.edu.auj.barclay@victorchang.edu.au |

**\*** **For projects accessing HTS services**, TIA also offers to arrange access to a new service that provides guidance on compound selection and triaging for further development via medicinal chemistry. This service is offered by ATMCF and is known as APHID (Action Plan for Hit Identification). The APHID service will perform relevant electronic structure-activity relationship (e-SAR) studies and assess the feasibility of sourcing the follow-up sets of molecules/compounds of interest, including library searches for additional potential compounds of interest. [Click here for more information on APHID](https://www.therapeuticinnovation.com.au/aphid). This service will be offered to relevant voucher holders at no additional cost

**\*\*** **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 [NDCC’s ongoing process to identify and support large scale high throughput screens](https://www.wehi.edu.au/research/research-technologies/drug-discovery/apply). Pipeline Accelerator applications may describe a subsequent application to NDCC as part of a development plan, and external projects emerging from NDCC may apply to the Pipeline Accelerator scheme for support for hit validation.

## Eligibility of Projects

* Projects accessing facilities in the **Biologics**, **Small Molecules** or **Cell & Gene Therapies** capabilities as defined above must seek to access a core capability of that facility.
* Projects accessing **HTS facilities** must align with at least one of the following activities:
	+ Development of a novel assay into a format suitable for compound library screening
	+ Screening of compound libraries against a target with a suitable assay
	+ Post-screening hit validation prior to entry into medicinal chemistry
* All applications must address the following criteria:
	+ Clearly articulate the current state of research relating to the chosen therapeutic modality in terms of biochemical characterisation, mechanism of action, proof of concept *in vitro,* 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

Projects may seek to access multiple facilities, including both Core and HTS facilities, in a single application. However, only one voucher will be issued per application.

To achieve support, the Project application must:

* Briefly articulate the current state of research relating to the chosen therapeutic modality in terms of biochemical characterisation, mechanism of action, target validation*,* etc.
* Be regarded as scientifically meritorious by an assessment committee appointed by TIA.
* Demonstrate significant cash co-investment, with a preferred minimum level of 50% of the requested award. This component may include competitive grant funding specifically awarded to support the project.
* 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 and would ordinarily 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.
* Define an endpoint for the supported Project (as noted above, not necessarily for the entire development project).

## Funding level

Two levels of funding are offered:

* $5,000 (multiples) up to a total value of $20,000
* $50,000

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

## Application and funding process

1. ***Prior to Applications opening***

TIA informs Providers that a call for applications will be forthcoming and shares this guidelines document.

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.

Applicant writes brief application for support, using the template provided, and requests either $5-20,000 or $50,000.

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: <http://www.therapeuticinnovation.com.au/accelerator>. Detailed instructions are included on the Application form template.

Applicant submits application package to TIA 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. Letter includes:

Obligations of TIA, Applicant and Provider as follows:

**TIA must:**

* pay invoices submitted by the named Provider totalling either $5-20,000 + GST or $50,000 + GST (depending on the voucher value) 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.therapeuticinovation.com.au/accelerator).
* provide brief (<1 page) reports on project progress according to a reporting schedule agreed with TIA.
* 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 [webpage](https://www.therapeuticinovation.com.au/accelerator).

**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.
* Ordinarily, TIA would expect the project to commence within 3 months of award of the voucher. Because of the nature of this scheme, ***offers may be withdrawn if projects do not commence within three 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 commences***

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 + 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:

* 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 on request.
* TIA may request brief informal updates (~½ page) on project progress.
* In the event of early termination, 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 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 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.
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 |
| Guidelines and documentation circulated to Providers | Late August |
| Scheme opens for applications on the TIA website | Early September |
| Scheme closes for applications | 5pm, 31st October |
| Applications assessed | Early November |
| Awards made | Late November |
| Projects commence | **Strictly** within 3 months of award\* |
| Projects complete | Within 12 months of award |

\*Offers may be withdrawn if projects have not commenced within three 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).

1. **Pipeline Accelerator 2020-21 (Round 1) Guidelines document (this document)**
2. **Pipeline Accelerator 2020-21 (Round 1) Application form**
3. **Letter of Commencement template from Provider and Applicant** to accompany initial invoice
4. **Letter of Completion template from Provider and Applicant** to inform TIA of project completion