TTRA

TARGETED TRANSLATION RESEARCH ACCELERATOR
DIABETES + CARDIOVASCULAR DISEASE

Powered by MTPConnect

ANDHealth | MEDICAL DEVICE PARTNERING PROGRAM | UNIQUEST

# Targeted Translation Research Accelerator (TTRA) Program

## PILLAR 2 RESEARCH PROJECTS FUNDING GUIDELINES |

ROUND 2 | OCTOBER 2021

MTPConnect is calling for Round 2 of TTRA Research Projects applications to address Priority Areas for diabetes and cardiovascular disease.
Expressions of Interest (EOI) applications are now open and will close on the 25 November 2021 (deadline extended).

For more information, contact ttra-dcvd@mtpconnect.org.au

MTPConnect | Championing a sector-led approach to accelerating the growth of the medical technology, biotechnology and pharmaceutical ecosystem in Australia

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# Opportunity Overview

This opportunity is offered by the Commonwealth under the Targeted Translation Research Accelerator (TTRA) Program which forms part of the Medical Research Future Fund (MRFF). The TTRA Research Projects funding can provide between $200,000 - $750,000 to help eligible organisations develop innovative preventative, diagnostic, therapeutic and disease management products/solutions for diabetes and cardiovascular disease. The project term for funded TTRA Research Projects is a maximum of 24 months. Applicants will be required to provide a co-contribution to the value of 50% of the TTRA funding request to be eligible. Additional in-kind or cash contributions above this threshold will be viewed favourably.

# About the Targeted Translation Research Accelerator Program

## Medical Research Future Fund

The MRFF, established under the Medical Research Future Fund Act 2015 (MRFF Act), provides grants of financial assistance to support health and medical research and innovation to improve the health and wellbeing of Australians. It operates as an endowment fund with $20 billion of capital preserved in perpetuity. The MRFF provides a long-term sustainable source of funding for endeavours that aim to improve health outcomes, quality of life and health system sustainability.

In the 2019-20 Budget, the Government announced its continued commitment to supporting lifesaving medical research with a $5 billion 10-year investment plan for the MRFF. It will place Australia at the leading edge of research in areas like genomics and will support the search for cures and treatments, including for rare cancers. The plan is underpinned by four key themes – patients, researchers, translation and missions.

This MRFF investment is also guided by the Australian Medical Research and Innovation Strategy 2016–2021 and related set of Australian Medical Research and Innovation Priorities 2020–2022, developed by the independent and expert Australian Medical Research Advisory Board following extensive national public consultation.

## Targeted Translation Research Accelerator (TTRA)

The $47 million Targeted Translation Research Accelerator (TTRA) program is a four-year initiative of the Medical Research Future Fund being delivered by MTPConnect.

The TTRA for Diabetes and Cardiovascular Disease (D&CVD) will provide a new, integrated research program to improve the prevention, diagnosis, treatment and management of D&CVD and their associated complications in Australia. The TTRA will:

- Under Pillar 1, establish two new Research Centres in Australia, one for diabetes related complications and one for cardiovascular disease related complications.
- Under Pillar 2, establish a contestable funding program to support discrete D&CVD Research Projects.

- Promote the clinical and commercial translation of innovative digital health technologies, medical devices, therapeutics or behavioural interventions, for D&CVD.

The TTRA will take a national and inclusive approach to working with clinicians, researchers, health administrators, Aboriginal and Torres Strait Islander health groups, regional, rural and remote Australians and consumers. It will be delivered in collaboration with an independent Board of experts.

## MTPConnect

MTPConnect is the Industry Growth Centre for the medical technology, biotechnology and pharmaceutical sector. As an independent, not-for-profit organisation MTPConnect champions a sector-led approach to accelerating the growth of Australia's MTP sector.

Since establishment in November 2015, MTPConnect has significantly impacted the MTP sector by delivering Strategic Funding to key initiatives, undertaking Direct Action and being the trusted and Independent Voice to inform government on key issues, challenges and opportunities.

Through the Department of Industry, Science, Energy and Resources' Growth Centre Project Fund, MTPConnect has committed $15.6 million across 40 collaborative projects, leveraging $35.8 million of matching industry and other contributions and generated a further $103.5 million in third party, external investment. In addition to the TTRA program, MTPConnect also operates three additional and complementary funding programs through the Medical Research Future Fund (MRFF), including:

- BioMedTech Horizons: $45 million program supporting 41 projects
- Biomedical Translation Bridge: $22.3 million program supporting 21 projects
- Researcher Exchange and Development within Industry: $32 million program supporting 13 projects and further rollout underway

## ANDHealth

ANDHealth is Australia's only organisation which designs and delivers specialised technology identification, screening and commercialisation programs proven to accelerate the scale up and commercial growth of digital health companies. Our mission is to strengthen the Australian digital health ecosystem and support Australian digital health companies to prepare for institutional investment and international market entry.

ANDHealth's non-equity-taking, industry-led programs actively de-risk digital health innovations across key areas of clinical and commercial validation, providing hands-on support, access to clinical and industry experts, and to global networks. ANDHealth's ANDHealth+ cohort companies have so far created (across the 10 companies who participated in the pilot): 296 jobs; 44 clinical trials; 887 commercial pilots; 21 international market launches; generated $28.4 million in revenue, raised $47.2 million in dilutive and nondilutive funding, and have impacted 203,363 patients.

## MDPP

The Medical Device Partnering Program (MDPP) is an ideas incubator driving entrepreneurial culture within the medtech sector. MDPP fosters collaborations between researchers, industry, end-users and government and develops novel medical devices with global market potential.

MDPP forms the essential links between clinical need and knowledge with technical expertise and industry know how. As such, the program is a key enabler for the sector, building the bridge to connect bench to bedside and supporting ideas to the proof-of-concept and prototypes that are required to drive engagement with industry and end users.

MDPP is a national initiative working closely with more than 30 partners across Australia. Since commencing operations MDPP has assessed over 720 ideas for new medical and assistive technologies. The program has facilitated 182 ideation workshops, completed 103 R&D projects for medtech companies, and provided manufacturing, partnering and new long-term commercial opportunities to over 30 manufacturers. MDPP has also provided a stream of new clients and work to 15 service providers (intellectual property, industrial design, product development, finance and regulatory). The overwhelming response to the MDPP, and results to date, are evidence that the Program continues to break new ground and revolutionise industry-institutional engagement.

## UniQuest and QEDDI

UniQuest is a leading university-based commercialisation company, managing the intellectual property of The University of Queensland. Since 1984, it has created more than 100 start-ups based on UQ research. These companies have gone on to raise more than $812 million to take UQ technologies to market. UniQuest manages an extensive intellectual property portfolio, including the HPV vaccine Gardasil®. Gross sales of products licensed by UniQuest have surpassed $US41 billion. More than $855 million in revenue has been returned to UQ.

The Queensland Emory Drug Discovery Initiative (QEDDI), a division of UniQuest, is a small molecule drug discovery and development capability translating academic biomedical research into new medicines to deliver faster health benefits. Using and industry experienced team, QEDDI will translate drug target biology or small molecule hits/leads into lead molecules/drug candidates using medicinal chemistry with the ultimate aim of a commercial partnership. By advancing academic research to novel molecules, it is expected to increase the probability of the translation of the research creating new treatments and therapeutics for unmet diseases for Australians.

## About the Pillar 2 TTRA Research Projects

To inform the Priority Areas that Research Projects must address for call in Round 2, a sector wide needs assessment was conducted focusing on unmet medical or health-related needs in diabetes and cardiovascular disease. 180 individuals were surveyed in total resulting in over 500 priority responses identified for Research Projects funding. Following deduplication, 53 unique priorities were discussed with a representative group of research, clinical and industry experts, health administrators, consumers and investors to determine the highest priorities to be addressed in Round 2.

Through Pillar 2 Research Projects funding, the Research Projects must develop innovative preventative, diagnostic, therapeutic and/or disease management products/solutions to address one of the following Priority Areas employing one of the eligible modalities:

| | **Eligible modalities** | | | |
|---|---|---|---|---|
| | Digital Health | Medical Device | Therapeutic | Behavioural intervention |
| **Priority 1: Atherosclerosis, including cerebrovascular disease** | ✓ | ✓ | ✓ | ✓ |
| **Priority 2: Cardiomyopathy and heart failure** | ✓ | ✓ | ✓ | ✓ |
| **Priority 3: Obesity as it relates to diabetes** | ✓ | ✓ | ✓ | ✓ |
| **Priority 4: Mental health as it relates to diabetes** | ✓ | ✓ | ✓ | ✓ |
| **Priority 5: Glucose control in type 1 diabetes, type 2 diabetes, double diabetes and/or gestational diabetes mellitus** | ✓ | ✓ | ✓ | ✗ |

Priority numbering does not reflect weighting or preference, it simply provides a convenient reference link to the application form.

The TTRA Research Projects funding aims to nurture these health and medical research projects to reach commercial proof-of-concept or deliver health economic benefits with the potential to attract further capital and support.

Activities supported will include, but are not limited to, prototype development and product testing (digital health and medical device focused projects), lead generation and optimisation (therapeutic focused projects), observational studies (behavioural intervention focused projects), as well as pre-clinical studies, clinical trial activity and regulatory support.

Ideas and concepts with no technical validation at the time of application are out of scope for TTRA Research Projects funding. Validation can include data from your own lab, a partner's lab and/or from published literature or a patent.

Projects to develop research tools (e.g., databases or animal models) in isolation are not eligible. Non-human health programs are not eligible. There must be evidence of experimental research that has

been undertaken that validates the problem or the potential of the product/solution. The applicant must demonstrate understanding of the market/end-user.

Opportunities will only be considered when a viable intellectual property (IP) and commercialisation plan can be demonstrated or there is a demonstrated economic health benefit from translation and implementation of the solution. Applicants seeking support for repurposing are encouraged to contact MTPConnect before completing an application. If you are performing contract research, please speak to MTPConnect to determine eligibility.

Interested parties are encouraged to discuss plans for application with MTPConnect, ANDHealth, MDPP or UniQuest at any time throughout the year. MTPConnect and the Partners can provide general advice on the TTRA Program, including the application process and the most appropriate modality (digital health, medical devices, therapeutics or behavioural intervention) for your project should you wish to apply. In addition, applications from researchers within universities/medical research institutes should be discussed with the relevant technology transfer office/business development group of the applicant prior to submission.

MTPConnect delivers the TTRA program in accordance with the **Commonwealth Grants Rules and Guidelines** (CGRGs).

## Round 2 expected key dates

| Research Projects Application | Start Date | End Date |
|---|---|---|
| EOI Application | 27 Sep 21 | 25 Nov 21 |
| EOI Outcomes | Mid Feb 22 | - |
| Consultation | Mid Feb 22 | Mid Mar 22 |
| Consultation Outcomes | Mid Mar 22 | |
| Full Proposal Application | Mid Mar 22 | Late Apr 22 |
| Full Proposal Outcomes | Early Jun 22 | - |
| Contracting | Early Jun 22 | Late Jun 22 |
| Funding Term | 1 Jul 22 | 30 Jun 24 |

Note, these expected key dates are current as at 28 October 2021.

# Applicant and Project Eligibility and Use of Funding

## Applicant and project eligibility

For a proposal to be deemed eligible for TTRA Research Project Funding it must meet the following criteria:

1. Entities eligible for funding under the TTRA Program are defined in s24 of the Medical Research Future Fund Act 2015 and include:

    - a medical research institute
    - a university
    - a corporate Commonwealth, state or territory government entity
    - a corporation.

2. Demonstrated capacity to match the co-contribution requirement.

3. Applicants must have an Australian Business Number (ABN).

4. Corporations must have less than 200 employees.

5. The applicant's Research Project must address one of the identified Priority Areas.

6. The applicant's Research Project must involve the translation of a product/solution (to treat, diagnose, cure, mitigate and/ or prevent disease) that has potential markets beyond Australia.

7. The applicant must control or have the legal right to access and use the relevant know-how and/or existing and/or potential intellectual property (IP), that will be necessary to undertake the proposed activities of the Research Project and to translate, implement or commercialise their product(s)/solution(s).

8. Applicants must meet any applicable timing, formatting, system or other similar administrative requirements from MTPConnect during the application process.

Where applicable (public research organisations), applications must be prepared in consultation with the Institutional Business Development/Technology Transfer Office.

EOIs and Full Proposals must be received on or before their respective closing dates. Late or incomplete submissions will not be accepted.

Funding recipients must adhere to the terms and conditions of funding set out in a funding agreement as determined by MTPConnect.

## Intellectual property eligibility

Applicants are encouraged to use the following flow chart (Figure 1) to self-assess the IP status of their Research Project to determine if the application meets the IP eligibility requirements to apply for the TTRA Research Projects funding.

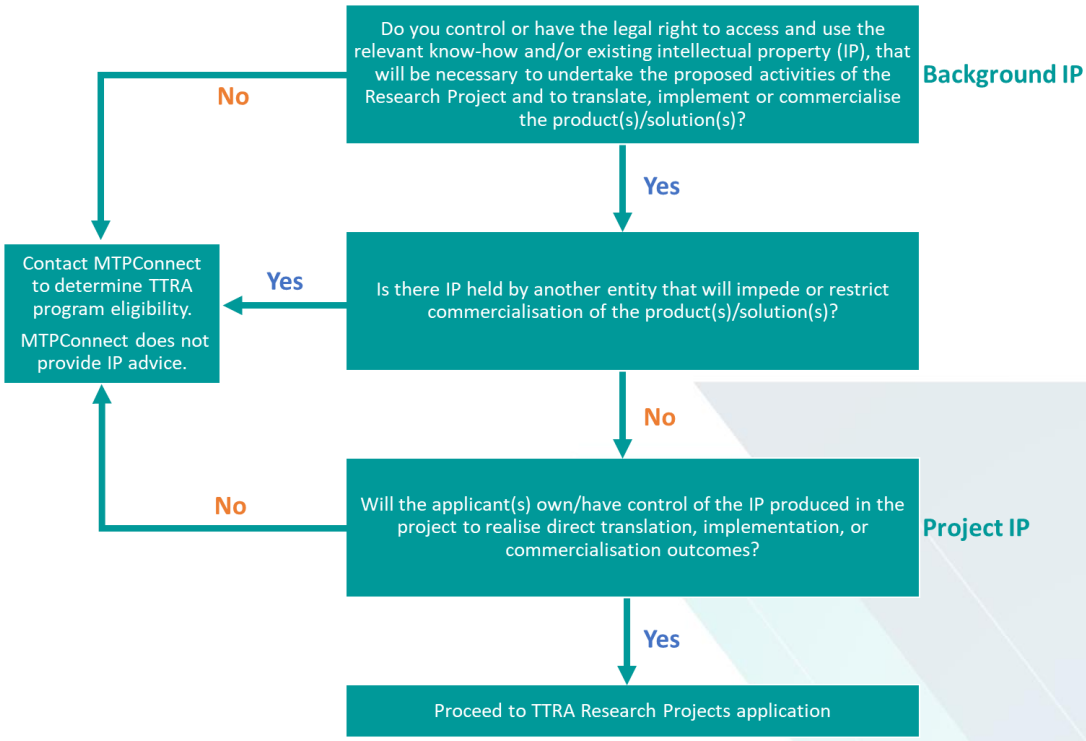


**Figure 1.** Intellectual Property eligibility flow chart.

## Use of funding

TTRA Research Projects that are successful for funding under the TTRA Program following the Full Proposal will enter into a funding agreement with MTPConnect and receive up to $750,000 over the agreed term. Commonwealth Funding provided through the TTRA program can only be spent on eligible expenditures incurred on eligible activities during the term of the project and in accordance with the terms of the funding agreement with MTPConnect and the **Commonwealth Terms & Conditions for Standard Funding Agreement** (Dec 2018).

Examples of *eligible expenditure* include, but are not limited to:

- project consumables directly attributable to the delivery of project outcomes
- salaries (whole FTEs or fractional) directly attributable to the delivery of project outcomes. The maximum salary claimable per person, including packaged components (superannuation) is limited to $175,000 per financial year. On a case-by-case basis, whereby it can be adequately justified, TTRA funding may support salaries greater than $175,000 per financial year

- labour expenditure for leadership staff (e.g., Founder, CEO, CSO, CMO) is considered eligible, provided there are direct, demonstrated and monitored links to project objectives and outcomes. Salaries for leadership staff will be limited to 10% of the total amount of eligible labour expenditure claimable per person (i.e., maximum $17,500). On a case-by-case basis, whereby it can be adequately justified, TTRA funding may support leadership salaries greater than $17,500 per financial year
- labour on-costs are eligible with an allowance of up to 30% on top of eligible salary amounts. Examples of labour on-costs are payroll tax, workers compensation insurance. These costs must be reasonable, appropriate, and separately identified in the project budget
- accessing specialist professional services including regulatory consultants, manufacturing and product development firms, technology evaluation, process evaluation, key opinion leaders or strategic stakeholders
- accessing intellectual property (IP) expertise as a service, freedom to operate search costs, and provisional and PCT drafting and filing costs (or costs associated with comparable stages of IP protection e.g., trade marks, designs, copyright, circuits etc.)
- access to specialist equipment, hardware and software essential to the research
- purchase of equipment that is essential to research capped at $80,000 in total. Justification for purchase of equipment, and why the applicant institution(s) cannot support the expense, must be provided
- prototyping and development of a Minimum Viable Product
- market research/testing and engaging with major customers, and end-users including clinical trials
- Data procurement and efforts to obtain regulatory approval
- International activity expenditure where it can be justified that this work cannot otherwise be performed in Australia and is critical to the success of the project. If proposed international activities and expenditure exceeds 10% of the total TTRA Research Projects funding, the Department of Health must provide its approval (which will be managed by MTPConnect)
- Essential travel within Australia directly related to project activities
- Essential travel overseas on a case-by-case basis directly related to project activities.

Examples of *ineligible expenditure* include but are not limited to:

- rent or other property fees
- major or minor capital works projects
- salaries, activities, equipment or supplies that are already being supported through any other source of funding
- service or repair costs for eligible equipment purchases made with TTRA funding
- purchase of computers, except where these are an integral component of a piece of laboratory equipment or are of a nature essential for work in the research field, for example, a computer which is dedicated to data collection from a mass spectrometer, or used for the manipulation of extensively large datasets (i.e., requiring special hardware)
- reimbursement of activities that have occurred prior to the execution of a Funding Agreement
- financing costs, including interest
- debt financing

- costs related to obtaining resources used on the project, including interest on loans, job advertising and recruitment, and contract negotiations
- costs related to preparing the funding application, preparing any project reports and preparing any project variation requests
- conference attendance, and associated travel (except in pre-approved circumstances where the research outputs of the Research Project are to be presented)
- health insurance, travel insurance, foreign currency, airport and related travel taxes, passports and visas
- entertainment and hospitality costs
- personal subscriptions (e.g., personal journal subscriptions)
- personal membership of professional organisations and groups
- airline club membership
- communications costs (mobiles, telephone calls)
- institutional overheads and administrative costs
- basic office supplies and equipment
- any other activities that are the usual requirement of business.

The above list is not exhaustive. Other costs may be ineligible where it is determined that they do not directly support the achievements of the planned outcomes for the Research Project or that they are contrary to the objectives of the TTRA program. Enquiries about expenditure eligibility can be directed to MTPConnect at ttra-dcvd@mtpconnect.org.au.

The applicant must ensure it has adequate funds to meet the costs of any ineligible expenditure associated with the Research Project. This will be provided through a declaration at the end of the application form, and in any required Letters of Support.

The TTRA Program will accept applications for Research Projects that have already been submitted to other funding sources. However, the TTRA Program will not fund research activities that are already funded by an alternative source. Should your application to an alternative funding source be successful it may impact on the eligibility of your TTRA application /funding.

# TTRA Program Modalities

## Which modality is my product/solution?

Questions asked on the EOI and application forms have been tailored, where appropriate, to be specific to each modality and to allow each modality to address their strengths. As outlined in these Funding Guidelines, the Selection Criteria are also specific to each modality where appropriate. The key to deciding which modality to apply through is to examine "Where does the project's ***novelty and core differentiation*** lie?"

Is it:

- in the way behaviour is influenced (patient or clinician) to generate clinical outcomes, where successful translation is measured by sustainable implementation resulting in a public health and/or economic benefit? > **apply for Behavioural Intervention**
- in the software component, where the software facilitates prevention, diagnosis, treatment or management of a disease or disorder, where successful commercialisation is measured by commercial outcomes and/or health economic impact? For example, for a connected device, if the core innovation to be developed during the TTRA Program is in the software, apply to the digital health stream (e.g., novel algorithm which collects data through off the shelf hardware). > **apply for Digital Health**
- in the medical device, instrument, apparatus, appliance, material, where successful commercialisation is measured by commercial outcomes and/or health economic impact. For example, for a connected device, if the core innovation to be developed during the TTRA Program, is the device itself then apply to the medical device stream (e.g., pump mechanics, sensor, hardware design). > **apply for Medical Device**
- in a therapeutic product, including but not limited to small molecules and biologics (such as vaccines, proteins, peptides, antibodies and cell/gene therapies), where successful commercialisation is measured by commercial outcomes including partnerships, licensing, investment or new company formation etc.? > **apply for Therapeutic**

If you are still unsure or feel you're a combination of two modalities, contact MTPConnect at ttra-dcvd@mtpconnect.org.au.

## Digital Health

The TTRA Program accepts applications across the broad scope of digital health solutions that meet the definition of the US Food and Drug Administration (FDA), including: mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalised medicine. These technologies can empower consumers to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life-threatening diseases, and management of chronic conditions outside of traditional care settings.

The TTRA Program is seeking digital health solutions related to the Priority Areas that benefit or solve pain points experienced by patients or clinicians, giving preference to those with evidence of clinical outcomes data.

## Medical Device

As defined by the Therapeutic Goods Act 1989, a medical device is any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception
- and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.

## Therapeutics

The TTRA Program will accept applications for the development of innovative therapeutics. Therapeutic classes within the scope of TTRA include but are not limited to small molecules and biologicals such as vaccines, proteins, peptides, antibodies and cell/gene therapies. Constructs comprising one or more of these classes are also eligible.

Does your TTRA Project involve repurposing a drug? Get in contact with MTPConnect at ttra-dcvd@mtpconnect.org.au.

## Behavioural Interventions

Behavioural interventions are interventions or lifestyle changes designed to affect the actions that individuals take with regard to their health in order to improve outcomes with respect to prevention, treatment or management. The TTRA Program will support behavioural intervention projects delivering biomedical and psychosocial benefits with a feasible path to sustainable implementation resulting in a public health and/or economic benefit.

Applicants are strongly encouraged to consider combining their behavioural intervention with an appropriate technological application to allow implementation and adoption by end-users.

## Application Process

Before applying, you should read and understand these guidelines and the sample EOI application form published on the MTPConnect **TTRA webpage**.

### SmartyGrants platform

EOI applications and Full Proposals for TTRA Research Projects funding must be completed online in SmartyGrants, the TTRA **online application portal.**

Late applications will not be considered. Any additional attachments over what is permissible, or repeated submissions for the same Research Project, will not be accepted.

All sections that require free text are word count-limited and clearly outlined. Additional words beyond the specified limit of each section will prevent submission of the application.

All relevant supporting data must be uploaded as a single pdf under the Supporting Information section:

- **1 page** of supporting data, with no more than 6 figures/tables, is allowed for EOI applications.
- **6 pages** of supporting data are permitted for Full Proposals.

Please ensure that all data, figures, tables, diagrams, designs, drawings are legible and clearly labelled in size 11 font.

Please ensure data supplied in supporting documentation is referenced appropriately (relevant figure/table number and, for Full Proposals, the page number of the supporting data document) within the EOI application/Full Proposal.

You need to allow enough time for each file to upload before trying to attach another file. Files can be up to 25MB each; however, we do recommend trying to keep files to a maximum of 5MB – the larger the file, the longer the upload time.

Attachments to the application must be submitted in line with the instructions provided within the form. You should only attach requested documents. Information in attachments that was not requested will not be considered.

The EOI application is non-confidential and therefore should not contain any sensitive or enabling information or data.

Full Proposals must upload Letter(s) of Support to provide an assurance from the organisation that the required co-contribution and any additional in-kind or cash contributions are available. The Letter(s) of Support should outline what is being contributed and if this is cash or in-kind, be on the organisation's letterhead, and signed by an appropriately authorised individual (i.e., Head of School or Institute/Dean/Provost/CEO/Chair). If in-kind support or cash is being provided from multiple organisations, separate Letters of Support from each organisation must be uploaded.

All applications received will be acknowledged automatically upon submission. Following an EOI submission, applicants will be provided with a Reference Number to be used in all future communications in relation to the application.

Applicants requiring further assistance should contact MTPConnect at ttra-dcvd@mtpconnect.org.au.

## Application and selection process

Application to the TTRA Research Projects program is a multi-step process (see Figure 2. flow chart):

**Phase I Expression of Interest (EOI):** All eligible projects are to be submitted as a non-confidential EOI. EOIs need to clearly articulate the challenge and solution, outline completed and/or planned technical, commercial and implementation activities (substantiated with non-confidential data) and describe the strengths of the project team. EOIs will be evaluated by the TTRA Selection Panel using selection criteria published in these TTRA Research Projects Funding Guidelines.

The most meritorious EOIs, as determined by the TTRA Selection Panel, will be invited to progress to Phase II. The merits of an application are based on how well it meets the selection criteria and how it compares to other eligible applications.

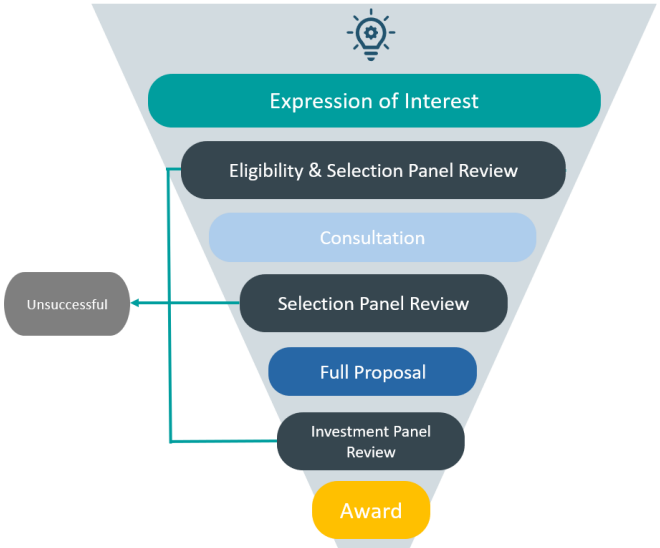


**Figure 2**. TTRA Pillar 2 Research Projects application and selection process

**Phase II Consultation:** Applicants who reach Phase II will be assigned a TTRA Partner – ANDHealth, MDPP or UniQuest – for consultations which will be held via videoconference. Assignment will be based on expertise.

Confidential Disclosure Agreements will be entered into with applicants whose projects move beyond the EOI stage to allow for a complete review and assessment of your project.

Consultations will provide an opportunity for applicants to address Selection Panel feedback on their EOI, have a two-way due diligence conversation with the assigned TTRA Partner on the technical aspects of the project and its commercial potential or translatability, and allow for financial vetting with respect to co-contributions. Time will be provided for the applicant to ask general questions on commercialisation as well.

The outcome of the consultation and due diligence evaluation will be assessed by the TTRA Selection Panel.

The most meritorious applications, as determined by the TTRA Selection Panel post Phase II consultation, will be invited to progress to Phase III and submit a Full Proposal.

**Phase III Full Proposal:** Full Proposal applications will expand on the EOI application to provide a more

comprehensive outline of the project.

Full Proposal applications will be reviewed by the TTRA Investment Panel, an independent, national and international panel of clinical, research, consumer and commercial experts, against the selection criteria articulated in these TTRA Research Projects Funding Guidelines. The TTRA Investment Panel will make recommendations for funding award to the most meritorious Full Proposals. Funding recommendations must be approved by the TTRA Expert Advisory Board.

**Funding Award:** Applicants whose proposals are awarded funding will enter into a funding agreement with MTPConnect to receive up to $750,000 over the defined project term to be paid in accordance with the agreed budget and a quarterly payment schedule. Payments are paid in advance and are subject to satisfactory progress on the project plan and achieving agreed milestones.

The funding agreement will have a clear project plan which will include resourcing, timelines, milestones, go/no-go decision points and a risk register. Funding recipients will have regular reporting and audited financial obligations to MTPConnect.

At all stages of the TTRA Research Projects application process, unsuccessful applicants will be provided with feedback on their bid.

## Selection Criteria

You must address all selection criteria in your application. Your application will be assessed based on the weighting given to each criterion.

### Challenge and Solution (20%)

All applications will be assessed on how their product/solution meets the research or clinical priority called for, and how their approach will have a competitive advantage.

a. Clear articulation of how the proposed product/solution will address the identified Priority Areas.

b. Applicant clearly describes the value proposition of their product/solution and its intended impact.

c. There is a clear competitive advantage over, or differentiation from, the current standard of care or products/solutions available or in clinical development.

d. Consideration has been given to achieve and/or enhance equitable health service delivery and/or access.

### Technical Merit (20%)

Applications will be assessed across technical aspects of their product/solution as it relates to their modality - Digital Health, Medical Device, Therapeutic or Behavioural Intervention.

#### *Digital Health*

Merit of applications seeking to develop digital health solutions will be assessed based upon the technical viability, interoperability and usability of the product. Consideration will be given to:

a. extent to which the applicant's solution delivers clinical value for the benefit of the patient

b. applicant differentiates between the end-user, payer and/or beneficiary

c. description of how the solution fits within clinical workflows and/or typical patient journeys. The applicant describes how healthcare professionals and/or patients interact with the solution. Evidence of end user demand or clinician support

d. evidence of technology prototype or proof of principle use in the clinical or market setting is detailed

e. where applicable, the applicant describes access rights and/or ownership of clinical/user data and how this be secured as the solution is upscaled in the market. Strategy for patient data privacy and security is outlined

f. consideration has been given to scalability of the solution, including implementation into current health systems, and costs and barriers of adoption. Where applicable, describe integration into IT infrastructure, whether connected medical devices, equipment, or Electronic Medical Records.

### *Medical Devices*

Merit of applications seeking to develop medical devices will be assessed based upon the technical and stakeholder validation of the product, including current evidence for proof-of-concept, efficacy and safety. Key data should be robust and reproducible, with appropriate controls, and include a comparator to the gold standard or standard of care where possible. Projects should not be based purely on others' published and non-validated data. Consideration will be given to:

a. innovative design features and evidence provided of prototype

b. evidence of applicant's preclinical benchtop and/or animal and/or clinical studies data validating the technology (including measures of diagnostic accuracy (e.g., sensitivity, specificity, ROC curve) for diagnostic devices)

c. no serious safety concerns anticipated. The correct class of device for regulatory approval has been determined. Where applicable, evidence of safety (applicant's own safety study data or publicly available evidence) is provided

d. feedback from clinicians and /or payers has informed the design and development of the device. There is consideration of how the product will be incorporated into clinical practice

e. evidence of stakeholder engagement and that proposed benefits are highly desired over existing solutions

f. consideration has been given to scalability of the device, including production, costs and barriers to adoption.

### *Therapeutics*

Merit of applications seeking to develop innovative therapeutics will be assessed based upon the strength of target biology and therapeutic approach and tractability. Expectations in relation to experimental data include ideally randomised, blinded and controlled (positive, negative) with standard of care comparator where possible. Key data are reproducible either within your own group with appropriate design and control measures, or ideally at an independent site. Projects should not be based purely on others published, non-validated data. Consideration will be given to:

a. target identified, druggable, linked to disease and sufficiently validated for the therapeutic approach to address the identified Priority Areas

b. assays used to-date and proposed are appropriate, robust, controlled and standardised

c. on/off-target safety effects have been considered and any mitigating factors have been articulated

d. The therapeutic lead has been sufficiently validated (e.g., specificity, selectivity, potency, cross-reactivity, structure, sequence)

e. existing in vitro and in vivo/pre-clinical data support the therapeutic concept and are appropriate, robust, controlled and standardised

f. where applicable, production method and scale have been articulated.

### *Behavioural Intervention*

Merit of applications seeking to translate a behavioural intervention will be assessed upon the evidence based biomedical and psychosocial benefits that can be implemented or adopted by end-users, public and community. Consideration will be given to:

a. extent to which the applicant's intervention/solution delivers clinical value for the benefit of end-users

b. extent to which the applicant's intervention/solution will deliver health economic benefits

c. description of how the solution fits within clinical workflows and/or typical patient journeys. The applicant describes how patients, healthcare professionals and/or health systems will engage with the intervention/solution. Evidence of end-user demand or clinical support is provided

d. evidence of proof of principle use in the clinical or market setting is detailed

e. evidence of stakeholder engagement and that proposed benefits are highly desired over existing solutions

f. consideration has been given to intervention/solution uptake and implementation along with costs and barriers for adoption.

## Project Plan (20%)

All applications will be assessed on their proposed TTRA project plan and its implementation:

a. Proposed project is supported and justified by clear activities, deliverables and outcomes.

b. Proposed activities are on the critical path towards commercial proof-of-concept or other important translation / implementation milestones.

c. Proposed project is focused, well defined and allows appropriate timeframes for completing activities.

d. Key risks are identified, and management/mitigation strategies outlined.

e. Indicative budget is appropriate for the proposed project plan and project term.

## Commercialisation/Implementation (20%)

Applications will be assessed on their product/solution's potential across IP, development and regulatory strategy, commercialisation opportunity and strategy, and sustainable implementation/adoption strategy, as applicable to their modality.

a. Applicant has secured appropriate IP protection or has adequately described a robust IP strategy (e.g., patent, trade secret, database, copyright, trademark, know-how etc.).

b. IP status / strategy is favourable with respect to patentability, freedom to operate, period of exclusivity (as applicable).

c. Proposed clinical development plan is appropriate and feasible.

d. Credible regulatory pathway articulated.

e. Clear, quantified and justified relevant market segment or end-user for the product or market-ready solution.

f. Feasible business model and commercialisation strategy clearly outlined.

g. Feasible implementation/adoption strategy clearly outlined.

h. The proposed solution is attractive to venture capital firms or biotech/biopharma/medical device firms for potential licensing, partnering, acquisition, or spin-out opportunities.

i. The applicant's product/solution can reach the intended target markets/end-users, with evidence of willingness to pay or market demand by defined paying customer(s).

## Team and Capabilities (20%)

All applications will be assessed on their TTRA project team's composition, experience, diversity and access to requisite infrastructure.

a. The team outlined has the requisite experience and demonstrated track record to achieve the milestones and translational objectives of the proposed project.

b. The team outlined is diverse (including, but not limited to, gender, career stage and/or different cultural backgrounds) and will provide expertise, build capacity and foster collaborative gain for the proposed Research Project. If the team is not yet diverse, a feasible strategy for increasing diversity which will provide expertise, build capacity and foster collaborative gain has been articulated.

c. The team has access to the requisite infrastructure and relevant co-contributions to achieve the milestones.

# Application Outcomes

## Notification of application outcomes

Applicants will be contacted about the outcome of their application in a timely manner. The email address registered as the account owner within the online application portal and the identified project lead will receive all correspondence. At all stages of the TTRA Research Projects application process, unsuccessful applicants will be provided with feedback on their application by MTPConnect in partnership with the TTRA Partners.

If you are successful, MTPConnect will advise you of any specific conditions attached to the funding, including embargo conditions and the timing of any public communications you make regarding being awarded funding.

## Funding agreement

The successful applicant must enter into a legally binding funding agreement with MTPConnect.

The funding agreement must be fully executed before any payments can be made. MTPConnect is not responsible for any expenditure incurred by the applicant until a funding agreement is executed. MTPConnect will not reimburse the applicant for any activities that have occurred prior to execution of a funding agreement.

The approval of Research Project funding may have specific conditions determined during the assessment process or other considerations made by the TTRA Expert Advisory Board or the Department of Health Program Delegate. These will be identified in the offer of Research Project funding.

MTPConnect may recover TTRA funds if there is a breach of the funding agreement.

The offer of funding may lapse if both parties do not sign the funding agreement within the timeframe outlined in key dates. Under certain circumstances, MTPConnect may extend this period. MTPConnect bases the approval of TTRA Research Project funding on the information provided in the application. MTPConnect will review any required changes to these details to ensure they do not impact the project as approved by the TTRA Expert Advisory Board, MTPConnect and the Department of Health Program Delegate.

The funding agreement will adopt a simple applicant-friendly intellectual property (IP) model whereby IP ownership will reside with the applicant. Any reports and materials delivered to MTPConnect will be subject to a non-exclusive use licence to MTPConnect and the Commonwealth for their purposes.

## Payments

The funding agreement will state the:

- maximum amount MTPConnect will pay
- proportion of eligible expenditure covered by the TTRA program
- any in-kind contribution the funding recipient or partners will make
- any cash contributions provided by the funding recipient or partners.

MTPConnect will not exceed the maximum funding amount under any circumstances. If the funding recipient incurs additional costs, these must be met by the funding recipient.

MTPConnect will make payments according to an agreed schedule set out in the funding agreement. Payments are subject to the funding recipient making satisfactory progress on the research plan and achieving agreed milestones.

If the funding recipient is registered for the Goods and Services Tax (GST), where applicable MTPConnect will add GST to payments. MTPConnect must be notified if GST registration status changes during the project period.

TTRA funding may be assessable income for taxation purposes, unless exempted by a taxation law. MTPConnect recommends the successful funding recipient seek independent professional advice on taxation obligations or seek assistance from the Australian Taxation Office. MTPConnect does not provide advice on tax.

### Announcement

The Commonwealth Minister for Health may publicly announce successful applicants and may include the name of the business, project title and non-confidential project summary (provided by the applicant), and amount of funding awarded.

Details of successful applicants and projects may also be published on MTPConnect and the Department's websites.

## Funding Recipients

Ongoing project management, guidance and support will be provided by both MTPConnect and the assigned TTRA Partner for the duration of the TTRA funding term.

The funding recipient will be required to provide regular project and financial reports and annual independent audits to MTPConnect to demonstrate the delivery of activities, achievement of milestones, financial acquittal and compliance with the funding agreement. MTPConnect will make payments in accordance with the agreed schedule set out in the funding agreement. Payments will be stage gated and provided upon receiving satisfactory quarterly progress reports and achieving milestones in the proposed timeframe.

### Keeping us informed

MTPConnect must be notified if anything is likely to affect your Research Project and/or its activities.

If a funding recipient becomes aware of a breach of terms and conditions under the funding agreement, MTPConnect must be contacted immediately.

MTPConnect must be notified of any events relating to your Research Project and its activities and provide an opportunity for the Minister for Health or their representative to attend.

## Reporting

Funding recipients must provide reports to MTPConnect at the times and with details specified in the funding agreement. Progress reports will be required quarterly, and a final report will be required at the TTRA funding-term end. Sample templates will be provided for these reports.

We will expect the report to cover:

- progress against agreed milestones
- activity expenditure, including expenditure of TTRA funds
- additional funding recipient or partner contributions.

We may ask the funding recipient for ad-hoc reports on activities. This may be to provide an update on progress, or any significant delays or difficulties in completing milestones and/or projects, or about any post TTRA funding plans.

## Independent audits

Funding recipients will be required to provide an annual independent audit report. An audit report will verify the funding recipient spent TTRA funding in accordance with the funding agreement. The audit report requires the funding recipient to prepare a statement of funding income and expenditure. A report template will be provided.

## Compliance visits

MTPConnect and/or the Department of Health delegate may visit the funding recipient during or at completion of the TTRA funding term, to review compliance with the funding agreement. Inspection of any records the funding recipient is required to keep under the funding agreement may be made. MTPConnect and/or the Department of Health will provide the funding recipient with reasonable notice of any compliance visit.

## Funding agreement variations

MTPConnect recognises unexpected events may affect project progress. In these circumstances, the funding recipient can request a variation to the funding agreement, including:

- changing project milestones
- changes to project partners
- changing project activities
- extension of timeframe for completing the project.

Note the program does not allow for an increase of TTRA funds.

Funding agreement variations need to be proposed in writing, a template will be provided.

You should not assume a variation request will be successful. MTPConnect will consider your request based on factors such as:

- how it affects the Research Project outcomes

- consistency with the TTRA Research Project Funding Guidelines and any relevant policies of the Department of Health
- changes to the timing of funding payments
- availability of TTRA program funds.

### Funding acknowledgement

Successful funding recipients must not make any public announcement, including by social media, in connection with the awarding of their Research Project until the Minister for Health has publicly announced the outcome, or as otherwise instructed by MTPConnect.

If the funding recipient makes a public statement about Research Project activities, including in a media release, brochure, publication, website or by social media, funding must be acknowledged by using the following: 'This project received MRFF funding from the Australian Government's TTRA program, delivered by MTPConnect.'

## Probity

### Conflict of interest

A conflict of interest may affect the performance of the funding opportunity or program. A conflict of interest may arise when an individual prioritises, or gives equal weight to, a secondary interest over a primary interest. Where a conflict of interest exists, or is perceived to exist, it undermines the credibility, reputation and efforts of the TTRA Program, its governance and its administrator.

There may be a conflict of interest, or perceived conflict of interest, if Research Project personnel have a professional, commercial or personal relationship with a party who is able to influence the application selection process, such as an Australian Government officer, member of the TTRA Expert Advisory Board, Selection or Investment Panels, MTPConnect or TTRA Partners.

As part of the application, the applicant must declare any perceived or existing conflict of interest or confirm that, to the best of their knowledge, there is no conflict of interest.

If the applicant later identifies an actual, apparent, or perceived conflict of interest, they must inform MTPConnect in writing immediately.

### Use of your information

MTPConnect may use and refer applications and the information contained therein to external experts or Government Departments for assessment of the application and MTPConnect's programs, reporting, advice, comment or for discussions regarding alternative or collaborative funding opportunities. Any information which is identified as and is confidential by nature will be appropriately treated as such by MTPConnect.

The applicant should minimise any personal information contained in the application to that required by MTPConnect for assessment and contact purposes. MTPConnect will treat personal information

according to the Australian Privacy Principles (APPs) and the *Privacy Act 1988* (Cth) as specified in its Privacy Policy.

## Freedom of information

MTPConnect may be subject to Freedom of Information (FOI) requests and, if such a request is made, MTPConnect will consult with the applicant before any decision is made to release the application or supporting documentation.

## Intellectual property management

EOIs are disclosed on a non-confidential basis and should not contain any enabling data or material. Confidential Disclosure Agreements may be entered into with applicants whose projects move beyond the EOI stage to allow for a complete review and assessment of the opportunity.

All intellectual property related to the project defined in the EOI and Full Proposal is owned by the applicant, subject to any arrangements it has with third parties. If MTPConnect or its Partners creates intellectual property as part of the consultation, Full Proposal or funding recipient mentoring, the intellectual property will be owned by the applicant. Inventorship will be determined based on standard protocols.

MTPConnect and the TTRA Partners do not require a return on investment. TTRA Partner involvement in the TTRA mechanism is on a service basis. If a TTRA Partner and applicant enter into a commercial arrangement at the end of a TTRA funded project, then any requirement for return on subsequent investment after the end of the funding period will be negotiated outside of the TTRA mechanism.

## Legislation, policies and industry standards

MTPConnect will ensure that the grant opportunity process is fair, according to the published guidelines, incorporates appropriate safeguards against fraud, unlawful activities and other inappropriate conduct and is consistent with the **Commonwealth Grants Rules and Guidelines** (CGRGs).

Funding recipients are required to be compliant with all relevant laws and regulations, including those specified in the Commonwealth Terms & Conditions for Standard Funding Agreement and principles of ethical conduct in research published in the National Health and Medical Research Council (NHMRC) website.

To the extent that research involves the use of animals, the applicant will be required to comply with the Australian Code for the Care and Use of Animals for Scientific Purposes which promotes the ethical, humane and responsible care and use of animals used for scientific purposes.

To the extent that a project involves work with children or vulnerable people, the applicant will be required to undertake clearance checks to demonstrate and ensure that its personnel are in compliance with legislative requirements including the National Principles for Child Safe Organisations. To the extent that the project involves collecting and using personal information, the applicant will be required to comply with privacy requirements; including obtaining appropriate consents for the collection, storage and use of personal information. It is a condition of the funding that all applicants

meet these requirements and these requirements will be set out in funding recipients' funding agreements with MTPConnect.

## Enquiries and Feedback

For further information or clarification, contact the MTPConnect TTRA team by email at ttra-dcvd@mtpconnect.org.au

Lauren Kelly, Senior Director TTRA Program, can also be contacted on +61 411 063 303

MTPConnect
MedTech and Pharma Growth Centre

## CONTACT US FOR FURTHER
# INFORMATION


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Further information about the Industry Growth Centres Initiative is available at www.business.gov.au/industrygrowthcentres