

TTRA

TARGETED TRANSLATION
RESEARCH ACCELERATOR
DIABETES + CARDIOVASCULAR DISEASE

Powered by **MTPConnect**

Targeted Translation Research Accelerator (TTRA) Program

PILLAR 1 RESEARCH CENTRE
FUNDING GUIDELINES |

JANUARY 2021

MTPConnect is calling for TTRA Research Centre applications to address priority areas for diabetes and cardiovascular disease. Expressions of Interest (EOI) applications are now open and will close on the 15 March 2021. Shortlisted EOI applications will be invited to submit a Full Proposal application.

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

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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). Expressions of Interest (EOIs) are now open to support the establishment of two Research Centres focused on addressing identified priority areas for disease-related complications associated with diabetes or cardiovascular disease, respectively.

Each Research Centre will be funded to a maximum of \$10 million over four years. Each Research Centre will comprise a *Research Portfolio* and a *Training Program* as well as a strategy for continued financial viability, ongoing clinical impact and talent management of the entity beyond the four years of TTRA funding.

Payments will be stage gated and provided upon receiving satisfactory biannual progress reports and achieving milestones in the proposed timeframe. Payment will be capped at a maximum of \$3 million per financial year for each funded Research Centre.

About the Targeted Translation Research Accelerator Program

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*; and
- 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.

About the Pillar 1 TTRA Research Centres

The TTRA Research Centres will accelerate therapies toward clinical practice for the prevention, diagnosis, treatment and management of disease related complications associated with diabetes or cardiovascular disease. In this context, 'therapies' are defined as behavioural interventions, therapeutic

pharmaceuticals, medical devices, diagnostic tools and digital health solutions. The Research Centres must also demonstrate how adoption and implementation of therapies will subsequently deliver health system outcomes, public health policy outcomes, consumer outcomes, commercial outcomes and reduce the burden of disease (QALY/DALY) and health inequalities in Australia.

The Research Centres will support translational research, development and implementation science activities (*Research Portfolio*), which may be commercial or non-commercial in nature and are encouraged to investigate diverse clinical and therapeutic treatment modalities to address the Priority Areas.

The Research Centre funding will not support basic discovery research, or the advancement of therapies or clinical outputs that do not address the identified Priority Areas.

Each Research Centre must focus on at least two of the identified Priority Areas, with favourable recognition given to proposals addressing all three Priority Areas. Priority numbering does not reflect weighting or preference, it simply provides a convenient reference link to the application form.

Priority Areas

The Diabetes Research Centre's translational research, development and implementation science activities within the *Research Portfolio* must address at least two of the following Priority Areas:

- Priority 1: Diabetic kidney disease;
- Priority 2: Peripheral neuropathy and diabetic foot syndrome;
- Priority 3: Short-term complications of hypoglycaemia and/or hyperglycaemic hyperosmolar syndrome (HHS) and ketoacidosis.

The Cardiovascular Research Centre's translational research, development and implementation science activities within the *Research Portfolio* must address at least two of the following Priority Areas:

- Priority 1: Coronary artery disease (including angina and MACE);
- Priority 2: Cardiomyopathy / heart failure;
- Priority 3: Transient ischaemic attack (TIA) /stroke (ischaemic and haemorrhagic).

Training Program

In addition to translational research, development and implementation science within the *Research Portfolio*, each Research Centre must include a training program as part of their activities. The *Training Program* should support postgraduate research students, early-to-mid-career researchers (EMCR) and/or clinicians in order to strengthen sustainable partnerships across research, clinical and industry for success in translation and commercialisation of health and medical research. The *Training Program* must include supervision of postgraduate students within the Research Centre, and may additionally include, for example, supervision of honours students, an industry internship/secondment, mentoring program, and/or implementation science or clinical method specialist training (health economy, biostatistics, health service research), commercialisation and/or regulatory framework training etc.

Sustainability

Each Research Centre will be funded a maximum of \$10 million over four years. It is expected that each Research Centre will have a strategy to become sustainable to ensure continued financial viability and talent management of the entity beyond the four years of TTRA funding. This *Sustainability Plan* should include a strategy for disseminating the outcomes of the proposed endeavours, including but not limited to, engagement with industry, clinicians, end users and the wider public, and academic outputs, conferences/workshops/symposia related to the *Research Portfolio*, during and beyond the funding-term. This *Sustainability Plan* may also support longer-term endeavours of the Research Centre that cannot be completed within the funding-term and must include a program logic or other mechanism to assess ongoing impact.

Partnering Summit

The funded Research Centres will co-host an annual two-day 'Partnering Summit' with MTPConnect. This will enable the TTRA Research Centres and recipients of TTRA *Research Project* funding to come together to access advice, assistance and training. In partnership with the TTRA Board, MTPConnect will explore the opportunity to invite relevant external researchers as well as industry and investors to increase potential for collaborative research and development and synergies in investment. The Research Centre will provide a venue for the Partnering Summit and budget \$30,000 annually to support relevant hosting costs which will be matched by MTPConnect.

Interested parties are encouraged to discuss potential applications with MTPConnect.

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

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.

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 36 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 deploys 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; and
- Researcher Exchange and Development within Industry: \$32 million program supporting 9 projects and further rollout underway

It was announced on the 13 July 2020 that MTPConnect will deliver the Targeted Translation Research Accelerator (TTRA) program.

Eligibility Criteria and Use of Funding

Encouraging partnerships

Partnerships and co-contributions are strongly encouraged in order to maximise impact of investment and to provide opportunities for translation, commercialisation and implementation of research outputs into clinical practices and outcomes. At a minimum, two independent organisations must be involved in the proposed Research Centre partnership. Partner organisations can include, but are not limited to: universities, medical research institutes, clinical organisations or health care providers, health systems, consumer groups, private research entities, commercial entities, not-for-profit organisations, and/or other end-users.

A strong application will include strategic partnerships with organisations that improve the health of Australians through influencing health policy and health care delivery.

Although the operating model for partnerships is not prescribed by the TTRA Research Centre Funding Guidelines, a 'Lead Applicant' must be identified for administrative purposes and to submit the application. A formal arrangement must be in place between all partners before funding can be awarded.

Lead applicant

Only the lead applicant can submit the application form and enter into the funding agreement with MTPConnect. MTPConnect is flexible as to who the lead applicant is, for example it could be one of the Research Centre partners or it could be a separate entity (such as a joint venture) formed for the purposes of the TTRA Research Centre application.

The application should identify all other members of the proposed partners and include a letter of support from each. Each letter of support should include:

- details of the Research Centre partner;
- an overview of how the Research Centre partner will work with the lead organisation and any other partners in the group to successfully establish and operate the Research Centre;
- an outline of the relevant experience and/or expertise the Research Centre partner will bring to the group;
- the roles/responsibilities the Research Centre partner will undertake, and the resources it will contribute (if any); and
- details of a nominated management level contact officer.

Research Centre eligibility

Applications must meet the following criteria to be eligible for TTRA Research Centre funding:

1. The application has been submitted on behalf of a group that has agreed to collaborate as part of a Research Centre;
2. Research Centre partners eligible to receive funding under the TTRA Program are defined in s20 and s24 of the [Medical Research Future Fund Act 2015](#) and include:
 - a medical research institute;
 - a university;
 - a state or territory government;
 - a corporate Commonwealth, state or territory government entity; and/or
 - a corporation;
3. International entities are eligible to be a Research Centre partner, but cannot receive TTRA funding;
4. Research Centre partners receiving TTRA funding must have an Australian Business Number (ABN);
5. Research Centre partners 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 Centre and to translate, implement or commercialise their product(s)/solution(s);
6. Applicants must meet any applicable timing, formatting, system or other similar administrative requirements from MTPConnect during the application process; and

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

An organisation may be involved in more than one Research Centre application.

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

Use of funding

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

- Consumables directly attributable to the delivery of Research Centre outcomes;
- Salaries (whole FTEs or fractional) directly attributable to the delivery of Research Centre outcomes. The maximum salary claimable per person, including packaged components, 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;
- Student scholarships (Honours, Masters and PhD) up to the value of an Australian Government Research Training Program International Fee Offset Scholarship;
- Lead and/or partner organisations may claim up to 10% of the eligible labour expenditure (i.e. \$17,500 per financial year) to support labour costs for leadership staff (e.g. Founder, CEO, CSO, CMO, CTO, Head of Department/School etc) who support the entities participation in the Research Centres but do not directly undertake activities in the Research Centre. 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%. Examples of labour on-costs are employer paid superannuation, payroll tax, workers compensation insurance. These costs must be reasonable, appropriate, and separately identified in the Research Centre budget;
- Accessing specialist professional services/advice including regulatory consultants, manufacturing and product development firms, technology evaluation, process evaluation, training professionals, key opinion leaders or strategic stakeholders;
- Accessing intellectual property (IP) expertise as a service, freedom to operate search costs, and provisional and PCT 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 must be provided and why the lead and/or partner organisations cannot support the expense;
- 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 Research Centre funding, the Department of Health must provide its approval (which will be managed by MTPConnect);
- Essential travel within Australia directly related to Research Centre activities; and

- Essential travel overseas on a case by case basis directly related to Research Centre 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 within the Research Centre, including interest on loans, job advertising and recruitment, and contract negotiations;
- Costs related to preparing the grant application, preparing any funding reports and preparing any funding variation requests;
- Conference attendance, and associated travel (except in pre-approved circumstances where the research outputs of Research Centre activities 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; and
- 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 Centre or that they are contrary to the objectives of the TTRA program.

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

Applicants requiring further assistance around eligibility and use of funding should contact MTPConnect at ttra-dcvd@mtpconnect.org.au.

TTRA Program Modalities

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.

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 Program 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.

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 Centre 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 Centre, 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 attachments must be uploaded as a single document where requested. Please ensure that all data, figures, tables, diagrams, designs, drawings are legible and clearly labelled in size 12 font.

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 application form. You should only attach requested documents. Information in attachments that was not requested will not be considered.

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 Centre program will be conducted through a two-stage process (see Figure 1. flow chart):

Phase I Expression of Interest:

applicants will submit a non-confidential EOI through the SmartyGrants online application portal. Eligible EOIs will be reviewed and evaluated by the TTRA Assessment Panel – an independent, national and international panel of clinical, research, industry, and advocacy/health administration experts, using the selection criteria outlined below.

Phase II Full Proposal and Interview:

the most meritorious EOIs, as determined by the TTRA Assessment Panel, will be invited to submit a Full Proposal. The merits of an application are based on how well it meets the selection criteria and how it compares to other eligible applications. The Full Proposal will

expand on the EOI application to provide a more comprehensive outline of the Research Centre’s *Research Portfolio, Training Program, Sustainability Plan, Risk Management Strategy and Team*. The applications will be reviewed against the selection criteria and following a meeting of TTRA Assessment Panel members to discuss all Full Proposals, written feedback will be provided to each applicant. Applicants will be invited to an interview where they will be provided the opportunity to address the TTRA Assessment Panel’s feedback and clarify or elaborate on complex, technical or commercial aspects of their proposal for the panel’s benefit.

The interviews will be held for 45 minutes with the TTRA Assessment Panel. Three to five team members may participate in the interview. As a career development opportunity, it is encouraged that an early career researcher / professional in the applicant team attend the interview as an observer.

Once all interviews are completed, the TTRA Assessment Panel will make a final recommendation of funding award to the most meritorious Full Proposal. Funding recommendations must be approved by the TTRA Expert Advisory Board and then by the Commonwealth Minister for Health.

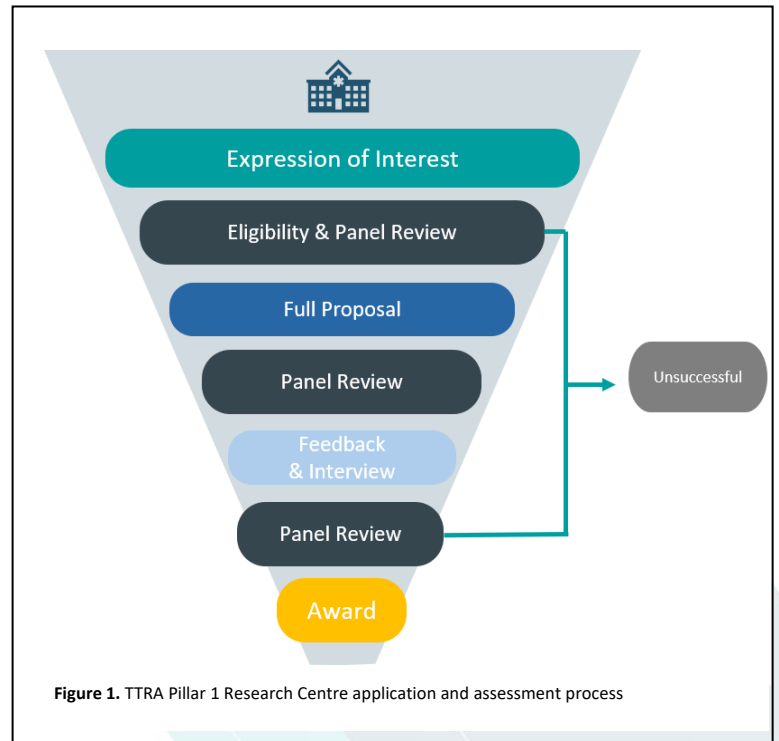


Figure 1. TTRA Pillar 1 Research Centre application and assessment process

Selection Criteria

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

The application form requests information that directly relates to the selection criteria below. The amount of detail and supporting evidence you provide in your application should be relative to the Research Centre size, complexity and grant amount requested. You should provide evidence to support your responses. Word limits, page limits and file size limits apply and are articulated in the application form.

MTPConnect reserves the right to invite competing EOIs, where synergies are observed, to submit a Full Proposal together.

To inform the priority areas that each Research Centre must focus on, a sector wide needs assessment was conducted. 318 individuals were surveyed resulting in over 650 priority responses submitted. Following deduplication, 43 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 by each Research Centre.

Each Research Centre must focus on at least two of the identified Priority Areas, with favourable recognition given to proposals addressing all three Priority Areas. Priority numbering does not reflect weighting or preference, it simply provides a convenient reference link to the application form.

Priority Areas

The Diabetes Research Centre's translational research, development and implementation science activities within the *Research Portfolio* must address at least two of the following Priority Areas:

- Priority 1: Diabetic kidney disease;
- Priority 2: Peripheral neuropathy and diabetic foot syndrome;
- Priority 3: Short-term complications of hypoglycaemia and/or hyperglycaemic hyperosmolar syndrome (HHS) and ketoacidosis.

The Cardiovascular Research Centre's translational research, development and implementation science activities within the *Research Portfolio* must address at least two of the following Priority Areas:

- Priority 1: Coronary artery disease (including angina and MACE);
- Priority 2: Cardiomyopathy / heart failure;
- Priority 3: Transient ischaemic attack (TIA) / stroke (ischaemic and haemorrhagic).

Selection Criterion 1 – Research & Clinical Impact (30% weighting)

Applications must demonstrate how they will achieve research and clinical impact by providing details of:

- a. how the identified Priority Areas will be addressed by the Research Centre's translational *Research Portfolio* and progress therapies towards clinical practice for the prevention, diagnosis, treatment and management of the prioritised disease related complications associated with diabetes or cardiovascular disease;
- b. the value proposition of the *Research Portfolio* and how the approaches will be differentiated from current solutions on market/in clinical practice or in clinical development, to address the unmet needs of consumers;
- c. the economic analysis of benefits related to the *Research Portfolio*, where relevant, including strategies for intellectual property, clinical development, regulatory pathways, commercialisation and reimbursement as well as health outcomes;
- d. the capacity of the *Research Portfolio* to deliver health system outcomes, public health policy outcomes, consumer outcomes, commercial outcomes, health economic benefits and reduce the burden of disease (QALY/DALY); and
- e. the capacity of the outcomes of the *Research Portfolio* to have national reach, reduce inequalities and health disparities, and meet the needs of high risk and underserved populations.

Selection Criterion 2 – Sustainability (30% weighting)

Application must demonstrate how the Research Centre will be sustainable beyond the term of funding committed by the TTRA by providing details of:

- a. a *Sustainability Plan* (including feasibility assessment) that will support the Research Centre's long-term outcomes beyond the four years of funding provided by the TTRA program with respect to:
 - i. business model, commercialisation strategy and funding source for maintaining financial viability of the Research Centre;
 - ii. on-going knowledge translation of the Research Centre's research and clinical activities and strategy for disseminating the outcomes of the Research Centre; and
 - iii. on-going assessment of impact derived from TTRA funding.
- b. a *Training Program* that supports opportunities for postgraduate students, early- and mid-career researchers (EMCR) and/or clinicians to build capability and capacity both within the Research Centre, and in the industry, clinical and research sectors during the TTRA funding term.

Selection Criterion 3 – Capacity, Capability and Resources (30% weighting)

Application must demonstrate how the Research Centre will leverage and access appropriate capacity, capability and resources to deliver the proposed activities by providing details of:

- a. at least two independent partner organisations who will participate in the Research Centre and the business/partnership model proposed for the Research Centre, including the proposed governance structure and operations strategy linking the applicant partners;
- b. how the Research Centre partnership will lead to collaborative gain to successfully deliver the *Research Portfolio, Sustainability Plan and Training Program*;
- c. access to, and/or a feasible plan to recruit, an appropriate, multi-disciplinary, and diverse (including, but not limited to, gender, career stage and/or different cultural backgrounds) team, with a track record in undertaking translationally-focused research and commercialisation matched with the scientific expertise across relevant disciplines. This includes identifying:
 - i. proposed key Research Centre personnel, their skills and experience clearly articulated, along with explanations of how their skills (project/commercialisation/intellectual property management) and experiences (qualifications and achievements) are important to the success of the Research Centre objectives;
 - ii. a strategy to identify and engage input from strategic experts, end-users and consumers (including rural, remote and Aboriginal and Torres Strait Islander communities) to support the expected outcomes from the *Research Portfolio*.
- d. track record in developing, implementing and delivering similar research projects towards clinical development and/or clinical impact;
- e. access to requisite infrastructure and patient populations and relevant co-contributions (both cash and in-kind) to achieve the milestones; and
- f. any additional resources that can be leveraged to support the Research Centres' undertakings.

Selection Criterion 4 – Overall Value & Risk (10% weighting)

Application must demonstrate the overall value the Research Centre will bring to Australia and include robust risk identification and management processes by providing details of:

- a. a proposed budget and budget justification to complete all Research Centre activities (abridged for EOI, detailed for Full Proposal);
- b. any other funding sources received/committed to the proposed Research Centre activities; and
- c. a summary of the key risks and mitigation strategies for the Research Centre and its undertakings (EOI) and, a complete risk management plan (Full Proposal).

Application Outcomes

Expected Key dates

Research Centre Application	Start Date	End Date
EOI Application	12 Jan 21	15 Mar 21
EOI Outcomes	Mid May 21	-
Full Proposal Application	Mid May 21	Mid Jun 21
Interview	Mid Aug 21	-
Awardee Approval	Mid Aug 21	Late Aug 21
Full Proposal Outcomes	Late Aug 21	-
Contracting	1 Sep 21	30 Sep 21
Funding Term	1 Oct 21	30 Sep 25

Notification of application outcomes

MTPConnect will advise you of the outcome of your EOI and Full Proposal (if applicable) in writing through the SmartyGrants platform. 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 lead applicant from the successful Research Centre 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 Research Centre until a funding agreement is executed. MTPConnect will not reimburse the Research Centre for any activities that have occurred prior to execution of a funding agreement.

The approval of Research Centre 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 Centre 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 Centre funding on the information provided in the application. MTPConnect will review any required changes to these details to ensure they do not impact the Research Centre as approved by MTPConnect and the Department of Health Program Delegate.

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 Research Centre partners will make; and
- any cash contributions provided by Research Centre partners or a third party.

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

MTPConnect will make payments according to an agreed schedule set out in the funding agreement. Payments are subject to the Research Centre making satisfactory progress on the *Research Portfolio* and achieving agreed milestones.

If the Research Centre/administering organisation 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 funding period.

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

Announcement

MTPConnect will publish non-sensitive details of successful applications on the MTPConnect website. This information may include:

- name of all organisations in the partnership and their locations;
- name of the TTRA Research Centre;
- public summary of the *Research Portfolio* and its aims;
- amount of funding awarded and funding term; and
- amount of any co-contributions.

Funding Recipients

The funding recipient will be required to provide regular Research Centre activities and financial reports and annual independent audits to MTPConnect to demonstrate the Research Centre's 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.

Keeping us informed

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

If a Research Centre becomes aware of a breach of terms and conditions under the funding agreement, MTPConnect must be notified immediately.

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

Reporting

The Research Centre must provide reports to MTPConnect at the times and with details specified in the funding agreement. Progress reports will be required biannually, 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 Research Centre to report:

- progress against agreed milestones;
- activity expenditure, including expenditure of TTRA funds; and
- Research Centre partner contributions.

We may ask the Research Centre 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

The Research Centre will be required to provide an annual independent audit report. An audit report will verify the Research Centre partners spent TTRA funding in accordance with the funding agreement. The audit report requires the Research Centre 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 Research Centre and/or its partners during or at completion of the TTRA funding term, to review compliance with the funding agreement. Inspection of any records the Research Centre and/or its partners are required to keep under the funding agreement may be made. MTPConnect and/or the Department of Health will provide the Research Centre and/or its partners with reasonable notice of any compliance visit.

Funding agreement variations

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

- changing project milestones;
- changes to Research Centre partners; and
- changing Research Centre activities.

Note the program does not allow for:

- an increase of TTRA funds; nor
- extending the funding term.

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

Funding acknowledgement

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

If the Research Centre or its partners make a public statement about Research Centre activities, including in a media release, brochure, publication 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 Centre 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, Assessment Panel, or MTPConnect.

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 applications move beyond the EOI stage to allow for a complete review and assessment of Full Proposals.

All intellectual property related to the Research Centre activities defined in the EOI and Full Proposal is owned by the Research Centre partners, subject to any arrangements it has with third parties. All intellectual property in the EOI and Full Proposal and that is created by the applicant in the conduct of the Research Centre activities is retained by the Research Centre partners pursuant to their partner arrangements.

MTPConnect does not require any ownership rights to Research Centre intellectual property or any returns arising from use or commercialisation thereof.

Legislation, policies and industry standards

MTPConnect will ensure that the funding 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 the Research Centre 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 Research Centre 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

Email ttra-dc vd@mtpconnect.org.au

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