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 EXPRESSION OF INTEREST (EOI) NON-CONFIDENTIAL

Australian Government
Department of Industry, Science, Energy and Resources
Industry Growth Centres

Australian Government
Department of Health
Medical Research Future Fund

1.0 TTRA APPLICATION INSTRUCTIONS

TARGETED TRANSLATION RESEARCH ACCELERATOR PROGRAM, ROUND 2 (R2)

Expressions of Interest (EOIs) are now open for funding of Research Projects between **$200,000 - $750,000** for up to 24 months, to develop innovative preventative, diagnostic, therapeutic and/or disease management products/solutions to address one of the following Priority Areas:

- 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 (T1D), type 2 diabetes (T2D), double diabetes and/or gestational diabetes mellitus (GDM).

Note: Behavioural interventions are **not** an eligible modality for Priority 5.

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

Research Projects funding is being made available through the second round of the $47 million Targeted Translation Research Accelerator (TTRA) program, an initiative of the Medical Research Future Fund, delivered by MTPConnect in partnership with ANDHealth, Medical Device Partnering Program (MDPP), and UniQuest.

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 Research Projects funding. Validation can include data from your own lab, a partner's lab and/or from published literature or a patent.

This program requires a co-contribution to be eligible. A co-contribution to the value of 50% of the TTRA funding request must be provided by the applicant and/or applicant partner. Additional in-kind or cash contributions above this threshold will be reviewed favourably.

BEFORE YOU BEGIN

This funding is available through a competitive process.

The project term for funded TTRA R2 Research Projects is a maximum of 24 months.

Applicants are encouraged to read the **TTRA Research Projects Funding Guidelines** carefully before commencing an application.

To be eligible for consideration, applications must satisfy all the requirements set out in the TTRA

Research Projects Funding Guidelines. An application may be considered ineligible and excluded from further consideration if it contravenes an eligibility rule or other requirement as set out in the TTRA Research Projects Funding Guidelines.

Application to the TTRA Research Projects program is a multi-step process:

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 the 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.

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 as required. Assignment will be based on partners' expertise.

The outcome of the consultation and further 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 / community and commercial experts, against the selection criteria articulated in the 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.

EOI PROPOSAL CLOSING DATE

EOI submission closes on **Thursday 25 November 2021 at 16:00 AEDT (Australian Eastern Daylight Time)**. Late applications will not be accepted.

COMPLETING THIS EOI FORM

Please note that the nominated project lead will receive all correspondence throughout the TTRA Research Projects funding application process. Please check your Junk/Spam mailbox to confirm that correspondence has not been incorrectly filtered out of your inbox.

Please do not use abbreviations unless fully explained.

Where any data are provided to support the EOI, please indicate if this is from your own research, or from another research group or from existing literature. Please provide clear in-text references to supporting data uploaded.

Any supporting documentation requested as an upload must be prepared in accordance with the instructions outlined in the application form. Any page over what is requested will not be reviewed.

Questions marked with an asterisk (*) are required. Please do not leave any answers blank. State for

instance "not applicable" or "unknown at this stage”.

For assistance in completing the EOI form, please contact:

- MTPConnect via ttra-dcvd@mtpconnect.org.au

For any technical enquiries, please contact the SmartyGrants Help Hub:

- +61 3 9320 6888
- service@smartygrants.com.au

2.0 APPLICATION SUMMARY

Have you submitted this project (or a variation of) for funding in TTRA Research Projects Round 1?

☐ Yes ☐ No

If yes, provide you previous TTRA reference number:

[e.g., TTRARP1XXX]

2.1 APPLICANT DETAILS

Organisation Name *

Organisation ABN *

Organisation Address *

SmartyGrants requires Address Line 1, Suburb/Town, State, Postcode and Country to be completed.

Organisation Website *

Total number of staff employed by your organisation (if SME)

Total number of staff based in Australia (if SME)

Project Lead *

Title	First Name	Last Name

Position *

Role in Proposed Project *

Must be no more than 10 words.

Gender of Project Lead *

☐ Male

☐ Female

☐ Diverse gender identity

☐ Prefer not to say

Phone number *

Must be an Australian phone number.

Primary email address *

Must be an email address.

2.2 PROJECT SUMMARY AND CONSENT

Please indicate which Priority Area your project is addressing. Priority numbering does not reflect weighting or preference, it simply provides a convenient reference link between the Funding Guidelines and application form. *

☐ 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 T1D, T2D, double diabetes and/or GDM

Project title *

Must be no more than 20 words.

Please provide a public summary of your project. *

Must be no more than 150 words.

Describe the specific objectives of the project. * [Tips: these could be listed as bullet points]

Must be no more than 125 words.

Consent

Do you provide consent for MTPConnect to use the public summary for publicity purposes if your project is awarded funding? *

☐ Yes ☐ No

Do you provide consent for MTPConnect to use the information contained in the non-confidential public summary as discussion points with industry who may have an interest in your research opportunity? *

☐ Yes ☐ No

Where the applicant entity is a public sector research organisation, has your innovation been disclosed to, and the EOI form been prepared in consultation with, your institutional Business Development/Technology Transfer Office. *

☐ Yes ☐ No ☐ N/A (SMEs)

If you selected 'No,' please provide justification for your answer. *

Must be no more than 100 words.

2.3 PROPOSED PROJECT TERM

Please note, projects must not be longer than 24 months.

Proposed Start Date *

Must be a date and between 1/7/2022 and 30/9/2022.

Proposed End Date *

End Date must be no later than 24 months after the Start Date.

Length of Project *

In months (must be equal or less than 24 months).

3.0 ELIGIBILITY CRITERIA AND FUNDING

Is the organisation applying an Australian enterprise and MRFF eligible organisation as defined by the Medical Research Future Fund Act 2015? *

☐ Yes ☐ No

State the funding amount requested through the TTRA program (all values must be in AUD and GST exclusive) *

$

Total amount must not exceed AUD $750,000.00.

Will the required 50% co-contribution be available from the start date? *

☐ Yes ☐ No

[Tips: 50% co-contribution can be cash or in-kind and should be a value of at least 50% of the TTRA funding requested. For example, if you are requesting $750,000 TTRA funding, the co-contribution should equal at least $375,000.]

Outline the source and amount of the required co-contribution to the project (all values must be in AUD and GST exclusive), any additional in-kind or cash co-contributions to the project and comment on the level of commitment (e.g., in-kind committed, cash investment secured, fundraising, discussions etc.) and any relevant key dates. *

Source of Contribution (Organisation)	In-kind	Cash	Comments
+			
Total	**$**	**$**	

Are the activities described in this project already fully or partially funded by another grant program or other investment? *

☐ Yes ☐ No

If yes, please outline which activities are supported and the source of this funding. *

Must be no more than 100 words.

If applicable, provide details of any pending applications that fully or partially fund the activities in this project.

Must be no more than 100 words.

Do you 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 the product(s)/solution(s)? * [Tips: if you select no or partially, please contact MTPConnect to discuss your eligibility.]

☐ Yes ☐ No ☐ Partially

If you selected 'No' or 'Partially', please provide justification for this selection. *

Must be no more than 100 words.

4.0 SUPPORTING INFORMATION

In order to support your EOI, a single document 1-page long may be uploaded below. This supporting information document is limited to data, figures and references, and any other text not directly referring to figures will not be assessed. Up to 6 legible figures (relevant tables, graphs, images, diagrams, designs and/or drawings) can be included that are clearly labeled in a font size of no smaller than 11 pt. All figures and/or pages over these specified limits will not be reviewed. Please note that EOIs are to be non-confidential.

In text responses should reference the relevant figure / table number.

Please attach the single document as a pdf with a file name in the following format: TTRARP2XXX_Organisation Name_Supporting Information

Attach a file:

5.0 CHALLENGE AND SOLUTION

Briefly describe your product/solution and how it aligns with the identified Priority Area. [Tips: reference supporting data / evidence as appropriate.] *

Must be no more than 200 words.

Outline, and quantify where possible, the value of your product/solution (i.e., your value proposition). * [Tips: depending on your modality consider value to relevant stakeholders – e.g., patients, clinicians, prospective partners, investors, health systems, users, payers etc. Depending on your modality you may include commercial and/or health economic benefits; include quantitative justification.]

Must be no more than 150 words.

Describe leading solutions currently on the market, implemented, and/or in clinical development, as well as emerging or indirect competitors, and your advantage over these competitors. How will your product/solution be differentiated? *

Must be no more than 150 words.

Describe how your product/solution will achieve and/or enhance equitable health service delivery and/or access. * [Tips: consider equitable delivery and/or access to regional, rural, remote, Aboriginal and Torres Strait Islander communities, and other underserved populations.]

Must be no more than 150 words.

6.0 TECHNICAL MERIT

Please select your project area.

If your project incorporates two or more modalities, please refer to the Modality section of the Funding Guidelines for guidance.

Digital Health

Medical Devices

Therapeutics

Behavioural Intervention

6.1 DIGITAL HEALTH PROJECTS

6.1.1 Stage of Development

Indicate the stage of development that best describes the status of the digital health solution, now and at the end of the proposed TTRA project. *

Now	Project End	Stage of Development
◯	◯	Proof of Principle, not yet tested with end-user or in clinical setting
◯	◯	Proof of Concept, proven with end-user or in clinical setting
◯	◯	Prototype, tested for a trial period with end-user or in clinical setting
◯	◯	Prototype, tested for a trial period with end-user or in clinical setting, clinical outcomes demonstrated
◯	◯	Prototype, tested for a trial period with end-user or in clinical setting, clinical outcomes demonstrated, economic outcomes demonstrated
◯	◯	Early product, in use with paying customers
◯	◯	Early product, in use with paying customers and demonstrating clinical outcomes
◯	◯	Final product on market
◯	◯	Final product in multiple markets

Please provide detailed descriptions for each of the following questions.

6.1.2 Solution and Use case

Indicate the proposed digital health approach: *

☐ Health Information technology (IT)

☐ Mobile health (mHealth)

☐ Personalised medicine

☐ Telehealth/telemedicine

☐ Wearable devices

☐ Other

Describe your product/solution and how it works. Outline how your product/solution fits into current clinical workflows and/or patient journeys. Describe who interacts with your product/solution and how. * [Tips: if applicable add details of inputs to algorithms used when describing a digital health solution. Identify and differentiate between the end-user, payer and/or beneficiary. Consider including a use case example.]

Must be no more than 200 words.

6.1.3 Clinical Outcomes

Outline the unmet need and how your product/solution benefits or solves pain points experienced by patients or clinicians (i.e., the clinical impact). Include data demonstrating efficacy of the product/system and provide a summary of any clinical outcomes data that you have. * [Tips: where possible, use quantitative information/data.]

Must be no more than 200 words.

6.1.4 Technical Viability

Provide evidence that your product/solution has met the stage of development indicated above. * [Tips: describe results and data from testing in clinical settings or with end-users. If a user experience study has been conducted, explain how the results have been incorporated into your solution.]

Must be no more than 200 words.

6.1.5 Stakeholder Engagement

Provide details and summarise feedback from stakeholders (especially users) who have been consulted on the development of the product. If available, present evidence of demand from

stakeholders over existing solutions. * [Tips: stakeholders may include but are not limited to end-users, patients, advocacy groups, hospitals, local health authorities, funders, payers, manufacturers, supply chain partners.]

Must be no more than 200 words.

6.1.6 Scalability

Describe the elements of your product/solution that make it scalable. How will it be scaled commercially to meet the demands of the addressable market. * [Tips: scalability should consider integration with any necessary digital infrastructure such as Electronic Medical Records, app interfaces, cloud servers, connected medical devices, or connected medical equipment, etc.]

Must be no more than 150 words.

Describe barriers to implementation and/or adoption and how you will address and overcome these. *

Must be no more than 150 words.

Detail how you collect and store data, and outline how access rights or ownership of this data will be secured as you go to market. Describe the approach to data security and patient/user privacy for your product/solution. List any standards you plan to comply with. *

Must be no more than 150 words.

6.2 MEDICAL DEVICE PROJECTS

6.2.1 Stage of Development

Indicate the Technology Readiness Level (TRL) that best describes the status of the medical device, now and at the end of the proposed TTRA project. *

Now	Project End	TRL
○	○	TRL 1 - Scientific literature reviews and initial market surveys are initiated and assessed. Potential scientific application to defined problems is articulated.
○	○	TRL 2 - Hypothesis generated. Research plans and/or protocols are developed.
○	○	TRL 3 - Initial technical proof-of-concept for device candidates is demonstrated in a limited number of laboratory models.
○	○	TRL 4 – Technical proof-of-concept and safety of candidate devices/systems demonstrated in defined laboratory/animal models.
○	○	TRL 5 - Devices compared to existing modalities and indications for use and equivalency demonstrated in model systems.
○	○	TRL 6 - Safety in humans demonstrated in clinical trial in small number of patients.
○	○	TRL 7 - Clinical safety and effectiveness trials conducted in an operational environment.
○	○	TRL 8 - Application for use has been approved, limited adoption of device in market.
○	○	TRL 9 - Device is fully approved and in market worldwide.

Please provide detailed descriptions for each of the following questions.

6.2.2 Product Description

Indicate the proposed medical device approach: *

☐ Assessment/monitoring device

☐ Drug delivery device

☐ In vitro diagnostic

☐ Medical Imaging

☐ Software

☐ Therapeutic device

☐ Other

Describe your device, including the key design features and how the technology works. Provide details of the prototype device, including in the attachment a drawing or photograph, if available. * [Tips: for drug delivery devices please include details about the drug(s) utilized in the device i.e., are they a small molecule, peptide etc., whether an NCE or naturally occurring biologic.]

Must be no more than 250 words.

6.2.3 Technical Validation

Describe the current stage of development of the device. Summarise evidence from key technical testing supporting medical use. Include data demonstrating efficacy of the device. * [Tips: results and data from benchtop testing, simulation, in tissue or organ models, or animal models. For diagnostic devices include evidence of diagnostic accuracy (e.g., sensitivity, specificity, ROC curve).]

Must be no more than 200 words.

6.2.4 Safety

Provide evidence that the device is safe (safety studies completed to date, predicate devices or other publicly available data). Identify any further safety considerations and outline how they will be addressed. Cite the intended **TGA classification** of the device. *

Must be no more than 150 words.

6.2.5 Clinical Use

Explain and provide evidence of how feedback from clinicians and/or payers has informed the design and development of the device. Describe existing clinical workflows and articulate how the device will be incorporated into clinical practice. * [Tips: this could include clinical survey or pilot trial results.]

Must be no more than 150 words.

6.2.6 Stakeholder Engagement

Provide details and summarise feedback from other stakeholders who have been consulted on usability, acceptability and likely uptake of the device. Present evidence of demand from stakeholders over existing solutions. * [Tips: stakeholders may include but are not limited to end-users, patients, advocacy groups, hospitals, local health authorities, funders, payers, manufacturers, supply chain partners.]

Must be no more than 200 words.

6.2.7 Scalability

Detail production costs, intended manufacturing plans and/or partners or other factors that will enable the implementation of your device at scale. * [Tips: other factors may include supply chain, distribution, shelf life.]

Must be no more than 150 words.

Describe barriers to implementation and/or adoption and how you will address and overcome these. *

Must be no more than 150 words.

6.3 THERAPEUTIC PROJECTS

6.3.1 Stage of Development

Please select the stage of development that best describes the status of the therapeutic now and at the end of the proposed TTRA project. *

Now	Project End	Status
◯	◯	Target identification
◯	◯	Target-to-hit
◯	◯	Hit-to-lead
◯	◯	Lead optimisation / candidate selection
◯	◯	Pre-clinical (i.e., preclinical candidate has been selected)
◯	◯	Clinical (i.e., developed product entering clinical trials)

Indicate the proposed therapeutic approach: *

☐ Small Molecule

☐ Antibody

☐ Peptide

☐ Protein

☐ Cell

☐ Gene Therapy

Please provide detailed descriptions for each of the following questions.

Describe your proposed therapeutic product. * [Tips: specify therapeutic class e.g., peptide, its target/mechanism, how the target is reached, administration route, patient group to be treated and their characteristics, and intended duration of treatment.]

Must be no more than 50 words.

6.3.2 Target Biology & Safety

Describe the biological target and outline its role in addressing the disease (identified Priority Area). Summarise the level of validation that the proposed therapeutic approach or target has in relation to the identified Priority Area. * [Tips: draw from project and literature data (please distinguish) to describe the following: Identification: indicate if the target is known, its main functions, location (tissue distribution), intracellular vs cell surface expression. Validation: pharmacological (animal models, clinical trials), genetic (human genetics, animal genetics), human expression data, human tissue or cell data. Druggabilty: precedent (known drugs), nature of the target modulation e.g., disrupt a protein-protein interaction, activate a receptor, etc. For all data, indicate comparators / controls used where applicable.]

Must be no more than 250 words.

Indicate the most likely on-target and off-target safety effects associated with the mechanism and if there are any mitigating factors. Discuss preclinical and clinical impact of any safety concerns. * [Tips: include as many of the following as possible: target knock-out/knock-down data, differences from wild-type counterparts, receptors with high homology, off-target screening data, toxicity data.]

Must be no more than 100 words.

Describe the assays / models conducted-to-date and required for your TTRA project. * [Tips: use bullet points for brevity. Please distinguish between assays that currently exist and those that still need to be developed, indicate the validation methods used. For example: no assays, primary assay (on-target biochemical or cellular), selectivity assays, functional assay (cellular or tissue), in vivo model etc. Identify location of the assay/model (in-house or CRO / partner), throughput (Low, Medium, High), relevant controls (positive and negative). Include N numbers, statistical methods etc., where appropriate and indicate whether models/assays are industry standard.]

Must be no more than 300 words.

6.3.3 Therapeutic Approach and Tractability

6.3.3.1 Small Molecule Therapeutics

Provide an overview of the data for the most advanced compound(s) to convey the stage of development in your project, and if they are novel (from the applicant) or from the public domain. * [Tips: provide data on potency, selectivity, basic drug-like properties (logD, solubility, metabolic stability, permeability etc.), pharmacokinetics, safety pharmacology. For selectivity include IC_{50}, EC_{50}, KD and selectivity. Beyond the lead compound(s), convey the numbers of compounds showing the desired mechanism of action.]

Must be no more than 200 words.

Summarise your *in vitro* and *in vivo*/pre-clinical data supporting the therapeutic concept. * [Tips: data can be for your lead or tool compounds or through genetic techniques. Experiments performed demonstrating the desired mechanism of action. *In vitro* data: functional data in disease-relevant cell types (species, cell lines or primary cells), include IC_{50}, EC_{50}, N numbers, controls. *In vivo* data: describe your model(s) and highlight translatability into the clinical setting; (hint: robust, reproducible, standardised, including controls and benchmarks, PKPD, N numbers, appropriate statistical methods).]

Must be no more than 250 words.

If relevant to project stage (i.e., at drug candidate selection) comment on the amenability of the synthetic route for scale and any manufacturing (Chemistry, Manufacturing and Controls) considerations. * [Tips: including formulation plan, salts etc. Discuss any regulatory requirements for manufacture.]

Must be no more than 100 words.

6.3.3.1 Antibody, Peptide, or Protein Therapeutics

Provide an overview of the data for the most advanced biologic(s) to convey the stage of development in your project. * [Tips: provide data on potency, selectivity and pharmacokinetics. For selectivity include IC_{50}, EC_{50}, KD and selectivity. For antibodies include; basic drug-like properties (e.g., SEC, AC-SINS etc.) and how antibodies were generated. For peptide or proteins include properties such as specificity, include properties such as logD, solubility, metabolic stability, permeability etc. Beyond the lead biologic(s), convey the breadth of biologics showing desired mechanism of action in the project.]

Must be no more than 200 words.

Summarise your *in vitro* and *in vivo*/pre-clinical functional data generated to date supporting the therapeutic concept. * [Tips: data can be for your lead biologic, a tool biologic or through genetic techniques, include experiments performed demonstrating the desired mechanism of action. *In vitro*: functional data in disease-relevant cell types (species, cell lines or primary cells), include IC_{50}, EC_{50}, N numbers, controls. *In vivo*: describe your model(s) and highlight translatability into the clinical setting; (hint: robust, reproducible, standardised, including controls, standard of care, N numbers, appropriate statistical methods).]

Must be no more than 250 words.

If relevant to project stage (i.e., at candidate selection) comment on the amenability for scale and any manufacturing (Chemistry, Manufacturing and Controls) considerations. * [Tips: describe the production method. Are there any major issues associated with production (e.g., solubility, aggregation, stability)? discuss relevant regulatory requirements for manufacture.]

Must be no more than 100 words.

6.3.3.1 Cell and Gene Therapies

Provide an overview of the data for the most advanced lead(s) to convey the stage of development in your project. * [Tips: e.g., where relevant provide data on potency, selectivity, pharmacokinetics, safety pharmacology, nature of the cell or gene therapy (e.g., over-expression or knock-down of genes, adoptive transfer of cells). Indicate if the cells to be adoptively transferred have been manipulated (e.g., peptide pulsed, transduced with CAR-T or other constructions, cytokine activated).] Beyond the lead(s), convey the breadth of the project (e.g., number of CGT prototypes you have generated which show the desired mechanism-of-action.]

Must be no more than 200 words.

Summarise your *in vitro* functional and *in vivo*/pre-clinical data generated to date supporting the therapeutic concept. * [Tips: experiments demonstrating mechanism of action. *In vitro*: functional data in disease-relevant cell types (species, cell lines or primary cells), include IC_{50}, EC_{50}, N numbers, controls). *In vivo*: describe your model(s) and highlight translatability into the clinical setting; demonstrating mechanism of action; any lineage tracing; (hint: robust, reproducible, standardised, including controls, standard of care, N numbers, appropriate statistical methods).]

Must be no more than 250 words.

As relevant to project stage describe the technology and/or Chemistry, Manufacturing and Controls (CMC) pathway (e.g., shRNA, siRNA, CRISPR, type of virus), characterisation, amenability to scale. * [Tips: method of procurement and manufacture (e.g., sourcing, isolation/purification), manipulation (e.g., transfection, differentiation etc.), expansion (media, growth factors and excipients), banking, storage, thawing, reformulation, stability studies, release criteria, scale that the cell/gene therapy has currently been generated, discuss relevant regulatory requirements for manufacture.]

Must be no more than 100 words.

6.4 BEHAVIOURAL INTERVENTION PROJECTS

6.4.1 Stage of Development

Indicate the stage of development that best describes the status of the behavioural intervention, now and at the end of the proposed TTRA project. *

Now	Project End	Stage of Development
◯	◯	Stage 0 – Basic science
◯	◯	Stage I – Intervention generation, refinement, modification, and adaptation and pilot testing
◯	◯	Stage II – Traditional efficacy testing
◯	◯	Stage III – Efficacy testing with real-world providers
◯	◯	Stage IV – Intervention design and evaluation plan
◯	◯	Stage V – Translation into practice and dissemination

Please provide detailed descriptions for each of the following questions.

6.4.2 Solution Description

Indicate the proposed behavioural intervention approach: * [Tips: The following sub-categorisation of behavioural interventions used the COM-B model, refer https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3096582/, for definitions of these interventions.]

☐ Enablement (information technology)

☐ Environmental restructuring

☐ Education

☐ Persuasion

☐ Incentivisation

☐ Coercion

☐ Training

☐ Restriction

☐ Modelling

☐ Other

Describe your behavioural intervention and how the solution works at a high level. Outline how your solution fits into current clinical workflows and/or clinical trial participant or patient journeys. Describe who interacts with your solution and how. * [Tips: indicate primary and secondary target groups where relevant. If you have a digital component to your solution, add details of inputs to algorithms used, if applicable. Clearly differentiate between the end-user, payer and/or beneficiary, as applicable.]

Must be no more than 200 words.

6.4.3 Clinical Value and Impact

Outline how it provides clinical value (i.e., benefits or solves pain points experienced by patients or clinicians). *

Must be no more than 150 words.

Outline and provide a justification for the potential health economic benefits provided by your solution. * [Tips: this may reference current cost inefficiencies experienced by use of inferior solutions/work-arounds. Include quantitative justification. Health economic benefits should align with target markets.]

Must be no more than 150 words.

6.4.4 Technical Viability

Provide evidence that your solution has met the stage of development indicated above. * [Tips: describe results and data on biomedical and psychosocial benefits in clinical settings or with end-users. If a user experience study has been conducted, explain how the results have been incorporated into your solution.]

Must be no more than 150 words.

6.4.5 Stakeholder Engagement

Provide details and summarise feedback from stakeholders (especially users) who have been consulted on the development of the solution. If available, present evidence of demand from stakeholders over existing solutions. * [Tips: stakeholders may include but are not limited to end-users, patients, advocacy groups, hospitals, local health authorities, funders, payers, manufacturers, supply chain partners.]

Must be no more than 150 words.

6.4.6 Scalability

Describe how your solution is scalable to meet the needs of the target group(s). * [Tips: scalability of the solution should consider including implementation into current health systems and costs of adoption.]

Must be no more than 125 words.

Describe barriers to implementation and/or adoption and how you will address and overcome these. *

Must be no more than 125 words.

7.0 PROJECT PLAN

7.1 PROJECT PLAN

Outline and briefly justify the proposed TTRA project plan, list milestones/key activities, timings, and key deliverables and outcomes. *

Must be no more than 300 words.

Describe how your TTRA project will achieve commercial proof of concept or reach other important translation/commercialisation/implementation milestones by the completion of the funding period. *
[Tips: include any activities that a potential partner or investor or end-user has indicated would support the achievement of commercial proof-of-concept or sustainable implementation respectively.]

Must be no more than 200 words.

7.2 PROJECT RISKS

Indicate the major risks associated with the TTRA project and strategies to manage or mitigate the risks. * [Tips: types of risk to consider including stage of development, safety, regulatory, technical, implementation, commercialisation, key personnel, infrastructure, COVID-19 impacts etc.]

Must be no more than 150 words.

8.0 COMMERCIALISATION / IMPLEMENTATION

8.1 INTELLECTUAL PROPERTY (IP) STRATEGY

Has the innovation been disclosed? *

☐ Yes ☐ No

If yes, tick all that apply: *

◯ Academic Technology Transfer Office (if applicable, describe outcomes below)

◯ Conference

◯ Publication

◯ Patent

◯ Other (please describe)

Provide details of the disclosure. *

Must be no more than 100 words.

Is patent filing part of your IP protection strategy? *

☐ Yes ☐ No ☐ Unsure

If patent filing is part of your IP protection strategy, have any patent applications already been filed? *

☐ Yes ☐ No

If patent/s have been filed, provide details in the table below. * [Tips: provide the PATENTSCOPE reference for PCT applications, or national patent office references for non-PCT applications.]

Patent ID	Priority Date	Status (Provisional, PCT, National Phase, Granted)	Type (method of use, method of manufacture, composition of matter, device, system, software, other)	Ownership	Reference (URL)
+					

Please comment on the status of your current portfolio and future patent strategy and, if applicable, describe the IP strategy to protect your innovations and proprietary knowledge and information other than patents. * [Tips: geographic coverage, breadth of claims, freedom to operate, findings of **International Search Reports (ISR).** Other forms of IP include know-how, copyrights, trade secrets, trademarks, designs, plant breeder's rights and circuit layouts.]

Must be no more than 100 words.

If a patent has not, or will not, be filed, describe the IP strategy to protect your innovation and proprietary knowledge and information. * [Tips: other forms of IP include know-how, copyright, trade secrets, designs, plant breeder's rights and circuit layouts.]

Must be no more than 100 words.

Please comment on the ownership and/or the legal right to access and use the relevant background and project IP for the Research Project. * [Tips: IP ownership and legal arrangement may be detailed in staff contracts and agreements e.g., Inter-Institutional Agreement, Collaboration Agreement, Patent Exploitation Agreement, Material Transfer Agreement. For Digital health consider how access to essential source/key data will be secured to enable operation.]

Must be no more than 100 words.

8.2 DIGITAL HEALTH PROJECTS

8.2.1 CLINICAL DEVELOPMENT AND REGULATORY STRATEGY

Outline your intended clinical product claims and describe how you will gather the clinical evidence required to substantiate these claims for the launch of your commercial product. * [Tips: state the clinical claims for your commercial product. Clarify what data you have to justify those claims now, and how you plan to gather the data to justify them in the future both within this project and beyond.]

Must be no more than 100 words.

Describe the regulatory pathway for your product/solution and any plans already in place. Cite the intended **TGA classification** of the device and classifications in any other target jurisdictions. * [Tips: for example, state if you or a partner will be responsible for regulatory filing, outline any completed or intended interactions with regulatory authorities, and any standards you currently or plan to comply with e.g., ISO standards. Justify that your clinical plan will support your regulatory filing.]

Must be no more than 100 words.

8.2.2 OPPORTUNITY AND STRATEGY

Identify the customer segments/types that will be paying for your product/solution. Describe who will pay for the product/solution and why they will pay. Provide any evidence that your identified payer(s) are willing to pay for your product/solution or products/solutions like yours. * [Tips: for business models taking a product/solution to market, provide evidence of willingness to pay, which may be demonstrated by e.g., voice of customer studies, surveys or adoption of similar solutions. Detail any contacts, leads or preliminary conversations you have had with customer segments or payers.]

Must be no more than 100 words.

Justify the size and value of this customer type/ market segment in the markets of interest (e.g., Australia, USA and/or other major markets). * [Tips: provide justification for your estimates. Include the total available market, the serviceable addressable market and the serviceable obtainable market.]

Must be no more than 100 words.

Describe your business model and the commercialisation strategy you will implement upon the completion of the TTRA funded project. * [Tips: commercialisation strategy could involve partnerships, license or sale of IP, organic growth, or an alternative go-to-market/exit strategy. If aligned with your strategy, outline why the product/solution will be attractive to venture capital firms or other investors. Provide any evidence that you have gathered to date, to de-risk your commercialisation strategy- e.g., interest from investors or partners, comparable successful businesses. Detail any contacts, leads or preliminary conversations you have had. If you anticipate taking a product to market, describe your proposed revenue model/pricing strategy. If this includes reimbursement, list the amounts/codes expected to be used.]

Must be no more than 200 words.

8.2 MEDICAL DEVICE PROJECTS

8.2.1 CLINICAL DEVELOPMENT AND REGULATORY STRATEGY

Detail the clinical development plan for your device. * [Tips: for example, include endpoints and clinical outcome claims, associated timeframes, cost per phase.]

Must be no more than 100 words.

Describe the regulatory pathway for your device and any plans already in place. * [Tips: for example, if you or a partner will be responsible for regulatory filing, completed or intended interactions with regulatory authorities, safety and other supporting studies to ISO/GLP standards.]

Must be no more than 100 words.

8.2.2 OPPORTUNITY AND STRATEGY

Describe which markets will be targeted for your device. Indicate the size and value of the markets of interest in detail (e.g., Australia, USA and/or other major markets). * [Tips: provide justification for your estimates. Include the total available market, the serviceable addressable market and the serviceable obtainable market.]

Must be no more than 100 words.

Describe your business model and the commercialisation strategy you will implement upon the completion of the TTRA funded project. Describe who will pay for the device and how they will pay. * [Tips: commercialisation strategy could involve partnerships, license or sale of IP, organic growth, or an alternative go-to-market/exit strategy. If aligned with your strategy, outline why the product/solution will be attractive to venture capital firms or other investors. For business models taking a product/solution to market, provide evidence of willingness to pay, which may be demonstrated by e.g., voice of customer studies or adoption of similar solutions.]

Must be no more than 300 words.

8.2 THERAPEUTIC PROJECTS

8.2.1 CLINICAL DEVELOPMENT AND REGULATORY STRATEGY

Outline the clinical development plan for your product. * [Tips: for example, Phase 1 (brief summary incl. size, participants and endpoints) Phase 2 and/or Phase 3 include endpoints, indicative size for POC or registration trial and associated timeframes and costs per phase).]

Must be no more than 100 words.

Outline the regulatory pathway for your product. * [Tips: for example, any completed or upcoming interactions with regulatory authorities, any opportunities for expedited review.]

Must be no more than 100 words.

8.2.2 OPPORTUNITY AND STRATEGY

Describe which markets (based on specific target patient population) will be targeted by your therapeutic product. Indicate their size, value in the commercial markets of interest (e.g., USA and/or other major markets) now and predicted for the future. * [Tips: provide justification for your estimates compared to SoC/emerging products. Reference the total available market in relation to your target market, and whether there are additional patient groups/markets that could be targeted.]

Must be no more than 100 words.

Describe how the TTRA funded project fits into your commercialisation strategy, including how you will achieve commercial proof-of-concept following TTRA and subsequent commercial events. * [Tips: commercialisation strategy could involve partnerships, license or sale of IP, venture capital investment or newco formation. If aligned with your strategy, provide evidence from prospective partners why the product would be attractive for them to invest. Mention any relevant benchmark deals.]

Must be no more than 300 words.

8.2 BEHAVIOURAL INTERVENTION PROJECTS

8.2.1 CLINICAL DEVELOPMENT AND REGULATORY STRATEGY

Describe the clinical development plan for your solution. * [Tips: for example, include endpoints and clinical outcome claims, associated timeframes, cost per phase.]

Must be no more than 100 words.

Describe the regulatory pathway for your solution, if applicable. * [Tips: for example, if you or a partner will be responsible for regulatory filing, completed or intended interactions with regulatory authorities, safety and other supporting studies. If not applicable to your solution, respond N.A.]

Must be no more than 100 words.

8.2.2 OPPORTUNITY AND STRATEGY

Describe which markets will be targeted for your solution. Indicate the size and value of the markets of interest in detail (e.g., Australia, USA and/or other major markets). * [Tips: provide justification for your estimates. Include the total available market, the serviceable addressable market and the serviceable obtainable market.]

Must be no more than 100 words.

Describe the implementation/adoption strategy to the targeted markets and/or end-users after the completion of the TTRA funded project. Describe if there will be a payer for the solution and if not how the solution will be sustainable. * [Tips: implementation/adoption strategy could involve partnerships, license or sale of solution or IP. If there will be a payer for your solution, provide evidence of willingness to pay, which may be demonstrated by e.g., voice of customer studies or adoption of similar solutions.]

Must be no more than 300 words.

9.0 TEAM AND CAPABILITIES

9.1 PROJECT TEAM COMPOSITION

List the entire team required to deliver your proposed TTRA project. * [Tips: for example, researchers, partners, collaborators, consultants, IP owners, manufacturers, contractors (e.g., CROs), distributors, designers etc. If the resource is yet to be identified, indicate with 'to be determined (TBD)' or similar. As a guide to completing FTEs, an individual working full-time on the project will represent 1.0 in the FTE column.]

Name and Position	Organisation	Role within Project	FTE on TTRA project
+			

9.2 PROJECT TEAM EXPERIENCE

Describe the requisite experience or track record of the team to achieve the proposed research and translational/commercial objectives of the project. * [Tips: refer to the experience and track record of the entire team, not just the project lead.]

Must be no more than 200 words.

9.3 PROJECT TEAM DIVERSITY

Describe the diversity of your team with respect to, but not limited to, gender, career stage and/or different cultural backgrounds. Describe what your team's diversity brings to the project. Outline your plan for addressing diversity and inclusion into the future. * [Tips: outline any programs operating within your institution/organisation which promote and encourage diversity, and any specific involvement team members have in such programs.]

Must be no more than 100 words.

9.4 RESOURCES AND INFRASTRUCTURE

What resources and infrastructure do you have access to in order to achieve the objectives of your proposed project? * [Tips: describe capacity, capabilities, major equipment required, laboratory set-ups, animal models, data sets etc., and align with your project plan.]

Must be no more than 100 words.

10.0 ACKNOWLEDGEMENT AND AUTHORISATION

10.1 CONFLICT OF INTEREST

Does the project lead, any other investigators and/or key individuals in the applicant organisation (CEO, CSO, Board) have any conflict of interest with regard to the TTRA Program, MTPConnect, TTRA Expert Advisory Board, TTRA Partners and/or the MRFF Program? *

☐ Yes ☐ No

If yes, please detail any perceived or actual conflict of interest. *

Must be no more than 200 words.

10.2 SUBMISSION TERMS/DECLARATION

I am authorised on behalf of the applicant to submit this TTRA Research Projects EOI and I certify that the information in this application and attachments is, to the best of my knowledge, true and correct. I will notify MTPConnect of any changes to this information and any circumstances that may affect this application.

I acknowledge that MTPConnect may refer this application to external parties for assessment, reporting, advice, comment or for discussions regarding alternative or collaborative funding or partnering opportunities.

I acknowledge and agree that this application does not contain confidential information and will not be treated as confidential by MTPConnect. I confirm that consent has been granted for MTPConnect to use and disclose any personal information contained herein. Accordingly, MTPConnect may publish, use and disclose the contents of this application.

I understand that this is an expression of interest only and will not result in funding approval. Following evaluation, applicants may be invited to the next stage of the TTRA Program. Shortlisted applications will require further submission and review.

Any funding offers will be subject to MTPConnect's receipt of funding from the Commonwealth and the terms of MTPConnect's standard funding agreement with awardees.

I have read and agree to the above *

☐ Yes ☐ No

Authorised representative

Title	First Name	Last Name
Organisation		
Position		

Email

APPLICATION END