Biomedical TRANSLATION BRIDGE PROGRAM

Powered by MTPConnect MedTech and Pharma Growth Centre

In partnership with

BioCurate UNIQUEST MEDICAL DEVICE PARTNERING PROGRAM BRIDGETECH PROGRAM BRIDGE PROGRAM

Biomedical Translation Bridge Program

EXPRESSION OF INTEREST

THERAPEUTIC PROJECTS

NON-CONFIDENTIAL

Biomedical Translation Bridge Program, Round 2 (R2)

- Expressions of Interest (EOIs) are now open for funding of projects **up to $1 million** to support development and commercialisation of health and medical research.
- This funding is being made available through the second round of the $22.3 million Biomedical Translation Bridge (BTB) Program, an initiative of the Medical Research Future Fund, operated by MTPConnect in partnership with BioCurate, Medical Device Partnering Program (MDPP), UniQuest and the Bridge and BridgeTech Programs administered by Queensland University of Technology (QUT).
- The BTB Program aims to nurture health and medical research ventures to reach commercial proof-of-concept with the potential to attract further capital and support.
- Activities supported will include hit-lead optimisation and validation studies (therapeutic focused projects), prototype development and product testing (medical device focused projects), as well as regulatory support, pre-clinical and clinical trial activity.
- Ideas and concepts, with no technical validation at the time of application, are out of scope for this program.
- This program **requires at least 1:1 matching cash contribution** provided by the applicant.

Before you begin

- This funding is available through a competitive process.
- **The project term for funded BTB R2 projects must end by 30 June 2022**.
- Applicants are encouraged to read the ***BTB Guidelines*** and ***FAQs*** carefully before commencing an application.
- To be eligible for consideration, applications must satisfy all the requirements set out in the ***BTB 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 Guidelines.
- Application to the BTB Program is a multi-step process:
    - All eligible projects are to be submitted as a **non-confidential** EOI. EOIs need to clearly articulate an unmet medical need, outline completed and/or planned scientific and commercial activities (substantiated with non-confidential data) and describe the strengths of the team.
    - EOIs will be evaluated by the BTB Selection Panel and shortlisted in three categories: a) Unsuccessful, b) Mentoring, c) Fast-Track.

Successful EOI applicants:

- **Mentoring:** EOI applications that align with the objectives and desired outcomes of the program but require further review will be invited to progress to the Mentoring Stage. Mentoring interactions will be held preferentially face-to-face (and/or videoconference as required) with the BTB Venture Partners - BioCurate, MDPP or UniQuest - and the outcome of this review will be assessed by the BTB Selection Panel. Mentored projects that strongly align with the objectives and desired outcomes of the BTB program will be invited to submit a Stage 2 Proposal with assistance from the matched BTB Venture Partner.
- **Fast-Track:** EOI applications strongly aligned with the objectives and desired outcomes of the program will be Fast Tracked and invited to proceed directly to a Stage 2 Proposal, prepared with assistance from the matched BTB Venture Partner.

Stage 2 Proposals:

- Stage 2 Proposals will include further detail on the project status and plans, a commercial strategy and detailed project milestones and budget. Invitation to a Stage 2 Proposal does not guarantee funding. All Stage 2 Proposals will be reviewed by the independent BTB Investment Panel which will make recommendations for funding.
- Applicants whose proposals are awarded funding will enter into a partnership with MTPConnect to receive up to $1 million over the defined project term to be paid in arrears upon milestone achievement and demonstrated matched cash expenditure. Projects will have a clear project plan which will include resourcing, timelines, milestones and go/no-go decision points. Awardees will have regular reporting and audit obligations to MTPConnect.

- At all stages of the BTB Program application process, unsuccessful applicants will be provided with feedback on their application.

EOI Closing Date

EOI submission closes on **Friday 6 March 2020 at 17:00 AEDT (Australian Eastern Day-light savings Time)**. Late applications will not be accepted.

Completing this EOI Form

- Please note that the email address used to create the SmartyGrants account to initiate the EOI will receive all correspondence throughout the BTB application process. Please check your Junk/Spam mailbox to confirm that correspondence has not been filtered incorrectly 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.
- Questions marked with an Asterix (*) are required. Please do not leave any answers blank. State for instance "not applicable" or "unknown at this stage".
- **Where the applicant entity is a public sector research organisation, this EOI form must be completed in conjunction with the institutional Business Development/Technology Transfer Office.**
- For assistance in completing the EOI, please contact:
    - MTPConnect via **BTB@mtpconnect.org.au**

Applicant Details

Organisation Details:

Organisation Name*

Organisation ABN*

Organisation Address*

Organisation Website*

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

Total number of staff based in Australia (if SME)

Project Lead Details:

Title, First Name, Last Name*

Position*

Role in Proposed Project*

Gender*

Phone number*

Primary email address*

Project Title*

Must be no more than 50 words

Public Summary of the Opportunity

Please provide a summary of your project for publicity purposes.

Must be no more than 150 words

Proposed Project Term

Please note, projects must end by 30 June 2022.

Proposed Start Date *

Earliest Expected Start Date from 01 September 2020

Proposed End Date *

End Date must be no later than 30 June 2022

Eligibility Criteria

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

Yes ☐ No ☐

Will the required matched cash contribution be secured before the project start date? *

Yes ☐ No ☐

Please outline the source of the matched cash contribution, the stage of investment (e.g. secured, fundraising, discussions etc.) and any relevant key dates. *

Must be no more than 100 words

Supporting Information

In order to support your EOI, a 1-page document with no more than 6 legible figures (relevant tables, graphs, images, diagrams, designs and/or drawings) that are clearly labeled in a font size of no smaller than 12, can be uploaded below. All figures and/or pages over these specified limits will not be reviewed.

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

Attach a file:

Disease or Condition Background and Unmet Medical Need

For therapeutics, the FDA Guidance provides definitions of “serious condition” (page 2) and “unmet need” (page 4).

For medical devices, the TGA Priority Review Designation provides definitions of “serious condition” (page 5) and “unmet need” (page 6).

Summarise the primary disease indication or condition and its prevalence. Describe and provide evidence of the unmet need that will be addressed or met by your innovation. *

Must be no more than 200 words

How is this a serious condition, as defined by the FDA or TGA Guidelines? *

Must be no more than 100 words

How will your product differentiate from the solutions currently on the market or in clinical development, and why will your product be widely adopted in the long term? *

Must be no more than 200 words

Project Specific Questions

Therapeutic Projects

Stage of Development

Please select the stage of development that best describes the status of the therapeutic. *

- ◯ Target identification
- ◯ Target-to-hit
- ◯ Hit-to-lead
- ◯ Lead optimisation
- ◯ Preclinical
- ◯ Clinical

Please provide brief descriptions for each of the following questions.

Target Biology

Provide a description of the biological target and outline its role and attributes in the disease/indication of interest. * [tip: indicate if the target is known, its main functions, location (all parts of the body), intracellular vs cell surface expression; if it is overexpressed, dysregulated, mutated in the disease indication]

Must be no more than 200 words.

Briefly summarise the level of validation that the proposed therapeutic approach or target has in relation to human disease. * [tip: pharmacological (animal models, clinical trials), genetic (human genetics, animal genetics), human expression data, human tissue or cell data. Include comparators used where applicable]

Must be no more than 200 words.

List the biological assays and animal models required (as outlined in the example provided). * [tip: please distinguish between assays that currently exist and those that still need to be developed and 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.]

Assay/animal model	**Type**	**Assay/animal model established?** (yes, in development, to be developed)	**Location** (in-house or CRO/ partner)	**Throughput** (low, Medium, High)	**Comments**
Phosphodiesterase (PDE) inhibition	Selectivity assay	Yes	CRO (Eurofins)	medium	Compound X showed 500-fold selectivity for PDED2 in an assay assessing 11 PDEs.
+					

Indicate the most likely on-target and off-target safety effects associated with this mechanism and are there any mitigating factors? * [tip – for example, based on receptors with high homology or knock-out/knock-down data, differences from wild-type counterparts, off-target screening, toxicity]

Must be no more than 100 words.

Therapeutic approach and tractability

Indicate the proposed therapeutic approach:

Click here for Small Molecule

Click here for Peptide, Protein or Vaccine

Click here for Antibody

Click here for Cell or Gene Therapy

Small Molecule Therapeutics

Have any molecules been identified which show activity in modulating the intended target e.g. 'hit' or 'lead' compounds? *

Yes ☐ No ☐

If no, please indicate if there is a feasible approach to finding hits and provide details?

Must be no more than 100 words.

If yes, please indicate what stage the compounds are and if they are novel (from the applicant) or from the literature (reported in the literature or are the subject of a patent)

Must be no more than 100 words.

Has target-specificity been confirmed? If so, how were experiments performed? Indicate which experiments have been performed or planned. [tip: include IC50, EC50, KD and selectivity results over members of the same class if available and applicable (e.g. kinase panel)].

Must be no more than 200 words.

Peptide, Protein or Vaccine Therapeutics

Have any peptides, recombinant proteins or vaccines been tested against the target which show the desired mechanism of action (e.g. cell line assays, human/animal cells or tissues), and what were the outcomes? How are the peptides, recombinant proteins or vaccines currently produced and at what scale? *

Must be no more than 200 words.

Does your therapeutic cross-react with the target from different species? * [tip: If it does not cross-react with the target from other species, how has this impacted on the experiments undertaken to test your therapeutic against the target? What mitigation strategies have been implemented (e.g. producing a mouse and human therapeutic in parallel to enable pre-clinical testing)].

Must be no more than 100 words.

For protein therapeutics only:
Is the protein recombinant or naked? If the recombinant protein is fused with a Tag (e.g. His, FLAG, Strep, Fc), describe any impact on the protein function/folding ability and any positive benefits. If not, please state the reason why.

Must be no more than 100 words.

Based on the location of the target indicate any delivery/drug administration considerations. * [tip: route of administration, experiments testing the route of administration and/or desired mechanism of action]

Must be no more than 100 words.

Has specificity of the peptide, recombinant protein or vaccine been validated? If yes, briefly describe experiments performed or planned and panels used. If specificity has not been validated, outline the proposed plan to evaluate specificity. *

Must be no more than 100 words.

Antibody Therapeutics

Is the proposed therapeutic a naked antibody, ADC, probody, nanobody etc? How was the antibody identified?

Must be no more than 100 words.

What was the source of these antibodies and how were they generated (e.g. hybridoma, phage display, yeast display, mammalian production, bacterial production)? Has the specificity of these antibodies been validated *(*e.g. ELISA, immunofluorescence, immunohistochemistry, western blot and SPR techniques if available)? *

Must be no more than 100 words.

Have any antibodies been generated against the target which show the desired mechanism-of-action (e.g. receptor-ligand blockade, agonism, inhibition of dimerization, ADCC/P)? *

Yes ☐ (describe and complete the next question) No ☐ (skip the next question)

Must be no more than 100 words.

If answered Yes to the above question, please provide details of the *in vitro* and *in vivo* experiments that demonstrate the antibody's desired mechanism of action and specificity. [tip: include relevant details on concentrations/doses used, the dynamic range of the assay, the specific controls used, any protein quality control data (e.g. endotoxin, SDS-PAGE, SEC, DLS, HIC, DSF etc)].

Must be no more than 200 words.

Does your therapeutic cross-react with the target from different species? * [tip: If it does not cross-react with the target from other species, how has this impacted on the experiments undertaken to test your therapeutic against the target? What mitigation strategies have been implemented (e.g. producing a mouse and human therapeutic in parallel to enable pre-clinical testing)].

Must be no more than 100 words.

Cell and Gene Therapies

What is the nature of the cell or gene therapy (e.g. over-expression or knock-down of genes, adoptive transfer of cells)? Have the cells to be adoptively transferred, been manipulated (peptide pulsed, transduced with CAR-T or other constructs, cytokine activated)? *

Must be no more than 200 words.

Describe the technology/manufacturing process used to produce the cell/gene therapy (e.g. shRNA, siRNA, CRISPR, what type of virus)? Do you or your collaborators require/have any licences to use the technology to produce the cell/gene therapy? *

Must be no more than 100 words.

Are there any technical or developmental difficulties, encountered or anticipated, which may affect translation of the product? * [tip: specificity of gRNA, efficiency of knock-down scale up manufacturing, safety concerns in clinical trials etc.]

Must be no more than 100 words.

For CAR-T, how was the ScFv region identified? Has the specificity been validated?

Must be no more than 100 words.

Commercial Potential

IP Strategy

What IP protection exists or is pending (indicate any filed patents, their priority dates and stage, and your rights status)? If you do not hold a patent or intend to file during the project term, what is your IP strategy? Are you aware of any patents or patent applications that this technology may be at risk of infringing? *

Must be no more than 200 words.

Development/Regulatory Strategy

Explain the development, clinical and regulatory requirements for the project and any plans already in place. *

For therapeutic projects, indicate if there is a possibility for patient selection via the use of biomarkers.

Must be no more than 200 words.

Target Market & Size

Which markets will be targeted globally, and how large are the end-user groups? What is the expected time to market? If available, provide a forecast of sales. Who are the direct purchasers of the product, and is there evidence of willingness to pay? *

Must be no more than 200 words.

Commercialisation Strategy

What is your commercialisation strategy after completion of the BTB project (e.g. establish a company, commercial licence, partnership, investment round etc.)? *

Must be no more than 200 words.

BTB Proposed Project

Proposed Project

Provide details of your proposed project, key objectives, timeline and the rationale. *

Must be no more than 200 words.

What are the expected results, deliverables, major risks and go/no-go decision points? *

Must be no more than 200 words.

Team

Project Team Composition

Describe the team (including researchers, partners, collaborators, consultants, IP owners, manufacturers, contractors, distributors, designers). *

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

Project Team Experience

What evidence of requisite experience or track record does the team have to achieve the proposed research and commercial objectives of the project? *

Must be no more than 200 words.

Budget

Indicative Budget

Funding Request from BTB (all values must be in AUD and GST exclusive) *

$

Total amount must not exceed AUD $1,000,000.00

Contributions

Identify the cash and in-kind contributions provided*

Organisation	Cash	In-Kind
+		
Total	**$**	**$**

Acknowledgement and Authorisation

Conflict of Interest*

Does the project lead, any other investigators and/or key individuals in the applicant organisation (CEO, CSO, Board) have any conflicts of interest with regard to the BTB Program, it's administrator and partners and/or the MRFF Program?

Yes ☐ No ☐

Please detail any perceived or actual conflicts of interest that may impact project assessment, selection, management and/or the partnering/exit process?

Must be no more than 200 words

Disclaimer/Declaration

I am authorised on behalf of the applicant to submit this application 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 BTB 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

Position

Email

APPLICATION END