Biomedical TRANSLATION BRIDGE PROGRAM

Powered by MTPConnect
MedTech and Pharma Growth Centre

In partnership with

BioCurate UNIQUEST MEDICAL DEVICE PARTNERING PROGRAM

Biomedical Translation Bridge (BTB) Program

GUIDELINES | OCTOBER 2019

Australian Government
Department of Industry, Innovation and Science
Industry Growth Centres

Australian Government
Department of Health
Medical Research Future Fund

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GRANT OPPORTUNITY OVERVIEW AND OBJECTIVES

This grant opportunity is offered by the Commonwealth under the Biomedical Translation Bridge (BTB) program which forms part of the Medical Research Future Fund (the Fund). The BTB program can provide up to $1 million of funding over a maximum two-year year period to help eligible organisations fund and nurture early stage health and medical research to reach proof-of-concept stage with potential to attract further capital and support. Research ventures will be required to provide one to one matching funding in the form of cash to be eligible. MTPConnect will use its networks to facilitate applicants securing matching funding when needed.

ABOUT THE MEDICAL RESEARCH FUTURE FUND

As part of the 2014-15 Budget, the Australian Government announced the establishment of the $20 billion Fund to provide a sustainable source of funding for medical research over the medium to longer term. The Fund has been established through the Medical Research Future Fund Act 2015, with the objective to provide grants of financial assistance to support medical research and medical innovation to improve the health and wellbeing of Australians. The Fund complements existing health and medical research and innovation funding to improve health outcomes through new grant opportunities.

Grant funding targets identified national priorities (the Australian Medical Research and Innovation Priorities) determined by the independent Australian Medical Research Advisory Board consistent with the Medical Research Future Fund Act 2015. Grant opportunities disbursed from the Fund cover the entire research pipeline from basic to applied research with a focus on the translation and commercialisation of discoveries. The Medical Research Future Fund Funding Principles underpin the Fund and ensure it continues to support investments that are priority driven, strategic, collaborative, and contestable with a focus on maintaining research integrity.

The intended outcomes of the Fund are:

- Life changing discoveries such as new treatments, drugs and devices;
- Continuous improvement and innovation in the health system that benefits all Australians;
- Strengthening domestic research capacity through support, collaboration and the development of expert talent;
- Positioning Australia's health and medical research sector at the forefront of the innovation economy; and
- Improving Australia's reputation as a global leader in health and medical research.

ABOUT THE BIOMEDICAL TRANSLATION BRIDGE (BTB) PROGRAM

The BTB program supports the 'Translational Research Infrastructure' priority identified in the Australian Medical Research and Innovation Priorities 2018-2020.

The funding for the BTB program is drawn from the Fund, and MTP-IIGC LTD trading as MTPConnect, is delivering the program in partnership with BioCurate (University of Melbourne and Monash University), UniQuest (University of Queensland through its drug discovery initiative QEDDI), the Medical Device Partnering Program (MDPP, led by Flinders University) and the Bridge and BridgeTech program (through the Queensland University of Technology).

The BTB program aims to address key national gaps in Australia's research sector and support three goals:

- Increased commercialisation focus and expertise in early stage research and decision-making across Australia
- Accelerated development, and improved success, of early stage research that has commercial potential so that it can ultimately be commercialised into products and services that improve the health outcomes of Australians as well as contribute to the Australian economy
- Helping to identify existing and new sources of capital investment to bolster awareness and interest in early research investment opportunities.

The BTB will fund:

- Research and development projects to achieve proof-of-concept
- Development to progress novel therapeutics or medical devices. There must be a clear value proposition for the proposed drug candidate or medical device product and differentiating features from currently available solutions.

Beginning on 1 July 2019, MTPConnect will open a call for non-confidential Expressions of Interest (EOIs) to identify new therapies, technologies and medical devices.

EOI calls will be made twice yearly (January and July). Interested parties are encouraged to discuss potential applications with MTPConnect.

MTPConnect operates the BTB program in accordance with the Commonwealth Grants Rules and Guidelines (CGRGs).[1]

SELECTION PROCESS

Application to the BTB program will be conducted through a two-stage process. During Stage 1, applicants will submit a non-confidential EOI through the online application portal. Eligible EOIs will be reviewed by an independent selection panel of research, industry and investment experts. The selection panel will evaluate the EOI proposals using the comprehensive Selection Criteria outlined further in this document and rank proposals into 3 categories. The EOI should provide enough details to assess the category of the application (i.e. particularly relevant for fast-track pathway).

The three categories are:

1. Mentorship pathway: EOIs that are successful in passing through the selection panel will be matched with one of our three Venture Partners to provide mentorship/guidance in the development of a full proposal for stage two;
2. Fast Track Pathway: Compelling EOIs may progress immediately to full application submission to the Stage 2 selection panel;
3. Unsuccessful EOIs will receive guidance and advice from our Venture Partners on identified shortcomings of their EOI.

Stage 2 applications may require applicants to disclose confidential information to MTPConnect.

This will be done after entering into a Confidentiality Disclosure Agreement. All confidential information disclosed in Stage 2 must be clearly identified as "Confidential".

[1] https://www.finance.gov.au/sites/default/files/commonwealth-grants-rules-and-guidelines.pdf

Stage 2 applications will be reviewed by an independent selection panel, against the selection criteria outlined, and will make recommendations for funding.

Award of BTB grants is subject to approval of the Commonwealth Department of Health. The Commonwealth's decision is final in all matters, including:

- The approval of the grant;
- The grant funding amount to be awarded; and
- The terms and conditions of the grant.

ELIGIBILITY CRITERIA

To be eligible for consideration, applications must satisfy all the requirements set out in this Guidelines document. An application may be considered ineligible and excluded from further consideration if:

- Does not meet the objectives of the grant opportunity;
- Contravenes an eligibility rule or other requirement as set out in this Guidelines document.

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

1. Entities eligible for funding under the BTB Program are defined in s24 of the Medical Research Future Fund Act 2015 and include:
    a. a medical research institute;
    b. a university;
    c. a corporate Commonwealth entity;
    d. a corporation.
2. Financially viable company or commercial enterprise in Australia;
3. Demonstrated capacity to match funding (cash);
4. Applicants must have an Australian Business Number (ABN);
5. The applicant's project must involve the development of a novel product (therapeutic or medical device) that has potential markets beyond Australia;
6. The applicant must provide evidence of technical and/or commercial feasibility of their product;
7. The applicant must demonstrate access to the relevant know how and/or existing and/or potential intellectual property (IP) that will be necessary for their proposal;
8. Applications must relate to research or related activities which are to be undertaken in Australia unless otherwise approved by MTPConnect. Activities that are critical to the success of the project that cannot be undertaken in Australia will be considered for eligibility on a case by case basis;
9. Projects need to demonstrate their ability to achieve commercial proof-of-concept (i.e. establishing commercial viability of a new product, process etc.) within a two-year period, positioning the product for future investment by the Biomedical Translation Fund (BTF) or other venture funding;
10. Meet any applicable timing, formatting, system or other similar administrative requirements imposed by MTPConnect; and
11. Advise that the proposed funding recipient will adhere to the terms and conditions of funding set out in a Collaborative Agreement (see later) as determined by the MTPConnect.

Applications must be received on or before the closing date. Late or incomplete applications will not be accepted. Where applicable, applications should be approved by the relevant technology transfer/business development group prior to submission.

THE SELECTION CRITERIA

Unmet Need (20%)

Criteria
Clear unmet need identified?
Serious condition?

Scientific Criteria: Therapeutics (30%)

The scientific merit of applications seeking to develop therapeutics will be assessed based upon the strength of target identification and selection process and the nature of compound/reagent validation undertaken. Consideration will be given to:

Target Identification and Selection

Criteria
Has the biological/protein target been identified?
Can a drug be developed against the target?
Is the target validated for a specific disease?
Is the data package robust? For example, are the experiments blinded, include appropriate controls, repeated, significantly powered, performed in multiple models, independently confirmed?

Compound/Reagent Validation

Criteria
Have the compounds/reagents used for pharmacologic/therapeutic intervention been sufficiently validated (e.g. specificity, potency, cross-reactivity, structure, sequence)?
Are the assays used for compound/reagent validation robust, controlled, and standardized?
Are the compounds/reagents drug-like? Are there validated tool compounds against the target?

Scientific Criteria: Medical Devices (30%)

The scientific merit of applications seeking to develop medical devices will be assessed based upon the technical viability of the program. Consideration will be given to:

Technical Viability

Criteria
Strong scientific and clinical evidence of problem and/or technological solution?
Preclinical benchtop and or animal studies data validating the technology?
Identification of relevant international standards for regulatory approvals?
Design for manufacturing strategy?

Commercial Criteria (30%)

Intellectual property (IP). Freedom to operate for strong IP position.

Criteria
Has the work been published or publicly disclosed?
If IP has not been filed, is there freedom to operate (FTO) and a clear IP pathway?
In case where no IP has been filed is there a clear plan and strategy to file strong IP?

Competitive positioning

Criteria
Is there evidence of differentiation from standard of care or other programs in development?
Have competing drugs / technologies been validated in any publications or patents?
Is there evidence of competing products or organisations?

Feasibility of the clinical, regulatory and reimbursement path

Criteria
Is the proposed clinical development and regulatory path feasible?
What is the potential reimbursement strategy?

Commercialisation Value and Market Positioning

Criteria
Is there a clear market/patient population for the eventual product?
Clear competitive advantage?
Is the proposed product attractive to VC firms or biotech/biopharma firms for potential licensing, partnering, acquisition, or spin-out opportunities?
Is the potential market/patient population anticipated to decrease due to development of other products in the indication of interest (e.g. Hepatitis C population being cured)?
If there are already competing drugs or devices in development, is there scope/precedent to make a more potent, safe, and/or selective product? What will be the point of differentiation?

Team (Composition, Experience and Infrastructure) Criteria (20%)

Criteria
Has the team the requisite experience and track record to achieve the milestones?
Does the team have access to the requisite infrastructure and matching funding to achieve milestones?

USE OF FUNDING

Research ventures that are successful for funding under the BTB Program will enter into a partnership with MTPConnect and receive up to $1 million over a period of up to two years. Research ventures will be required to provide one-to-one matching funding (cash) to be eligible. Commonwealth Funding provided through the BTB program can only be spent on eligible expenditures incurred on eligible activities during the term of the grant and in accordance with the Commonwealth Terms & Conditions for Standard Funding Agreement (March 2015);

Examples of the eligible expenditures include, but are not limited to:

- Salaries and consumables are considered in-kind contributions unless salaries and consumables directly attributed to the delivery of the project outcomes
- Accessing specialist professional services including IP attorney firms, regulatory consultants, manufacturing and product development firms
- Access to and acquisition of specialist equipment, hardware and software
- Accessing or protecting intellectual property rights
- 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.

Examples of ineligible expenditure include but are not limited to:

- Rent or other property fees
- Salaries for business founders unless these are essential to the execution of the project (i.e. unique technical skills/knowledge)
- Recruitment and procurement fees
- Basic office supplies and equipment
- Grant application or administration costs
- University administration/infrastructure levies
- Any other activities that are the usual requirement of business.

HOW TO APPLY - EOI STAGE

EOI applications must be completed online on the MTPConnect online application portal.

EOI applications will open on **1 July 2019**.

EOI applications received after **16 August 2019 at 5:00PM** (AEST) will not be considered. Any additional attachments or repeated submissions for the same project will not be accepted.

All sections in the EOI application that require free text are character-limited. Additional characters beyond the specified limit of each section will not be accepted.

All EOI applications received will be acknowledged automatically upon submission and applicants will be provided with an Identification Number to be referenced in all future communications in relation to the application.

Applicants requiring further assistance should contact BTB@mtpconnect.org.au.

HOW TO APPLY - STAGE 2 PROPOSAL

Stage 2 Proposals must be completed online on the MTPConnect online application portal.

Proposals received after **1 November 2019 at 5:00PM** (AEDT) will not be considered. Any additional attachments or repeated submissions for the same project will not be accepted.

All sections within the portal must be completed, these comprise of:

- General
- Team composition, experience and infrastructure
- Unmet need
- Project Status (select the appropriate option(s) for your project to enable all relevant questions)
  - Medical Devices OR Therapeutic (for combination projects, select both)
  - For Therapeutics, please select the appropriate classification (modality and stage of development)
- Commercial Criteria
- Proposed Project Plan
- Project Budget
- Project Milestones
- Acknowledgement

All sections in the Proposal that require free text are character-limited and outlined.

All relevant supporting data must be uploaded as a single document under the Project Status section. Please ensure that all data, figures, tables, diagrams, designs, drawings are legible and clearly labelled. In text responses should reference both the page number of the data document and the relevant figure / table number.

Total page limits for the supporting data document are:

- 6 pages for Medical devices
- 6 pages for Therapeutics (excluding Cell & Gene Therapies)
- 3 pages for Cell & Gene Therapies
- For combination projects, the page limits are additory

Financial Letter(s) of Support must be uploaded to provide an assurance from the organisation that matched funding is available. The Letter(s) of Support should outline what is being contributed and if this is cash or in-kind, be on the organisations' letterhead, and signed by an appropriately authorised individual (i.e. Head of School or Institute / Dean / Provost / CEO / Chair). If matched funding is being obtained from multiple organisations, separate Letters of Support must be uploaded for each.

All Stage 2 Proposals received will be acknowledged automatically upon submission.

Applicants requiring further assistance should contact BTB@mtpconnect.org.au.

NOTIFICATION OF APPLICATION OUTCOMES

You will be contacted about the outcome of your application. Advice will be provided to all applications by MTPConnect in partnership with our Venture Partners.

The Federal Minister for Health may publicly announce successful applicants and may include name of the business, project title and description, amount of funding awarded.

Details of successful applicants may also be published on the MTPConnect and Departments' websites.

THE GRANT AGREEMENT

The successful applicant must enter into a legally binding Collaborative Agreement with MTPConnect in the form of the MTPConnect Standard Collaborative Agreement. The Standard Grant Agreement will be provided for consideration as part of the Stage Two application process. Standard terms and conditions will apply and cannot be changed.

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

MTPConnect must execute a grant agreement with the applicant before any payments can be made. Applicants must not start any project activities until a grant agreement is executed.

PROJECT SPECIFIC LEGISLATION, POLICIES AND INDUSTRY STANDARDS

Applicants are required to be compliant with all relevant laws and regulations, including those specified in the Commonwealth Terms & Conditions for Standard Funding Agreement.

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

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

GRANT ACQUITTAL AND REPORTING

The applicant will be required to provide regular project and financial reports and audits to MTPConnect to demonstrate its delivery of the project, financial acquittal and compliance with the grant agreement.

MTPConnect will monitor and report progress of successful applicants to the Commonwealth. Funding will be tied to reporting obligations. MTPConnect will make payments according to an agreed schedule set out in the grant agreement. Payments are subject to satisfactory milestone-progress on the project. Applicants will be required to submit reports in line with the grant agreement. MTPConnect will provide sample templates for these reports. MTPConnect will monitor the progress of applicants' project and may conduct site visits or request information or records to confirm details of applicants' reports as necessary.