



Biomedical
TRANSLATION BRIDGE
PROGRAM

Powered by



MTPConnect
MedTech and Pharma Growth Centre

In partnership with



Biomedical Translation Bridge (BTB) Program

GUIDELINES - COVID-19 CALL |
MAY 2020



Australian Government
Department of Health
Medical Research Future Fund

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BTB ROUND 3 COVID-19 OPPORTUNITY OVERVIEW AND OBJECTIVES

This opportunity is offered by the Commonwealth under the Biomedical Translation Bridge (BTB) program which forms part of the Medical Research Future Fund (the Fund). In this specific COVID-19 call, the BTB Program can provide up to \$1 million to support eligible organisations develop medical devices, diagnostics, prophylactic or therapeutic approaches that will achieve an impact on the global response to the pandemic in less than 12-months. Funded projects must have a completion date of no later than 31 August 2021. Applicants will be required to provide one-to-one matching funding in the form of cash to be eligible.

This BTB program call will fund COVID-19 projects with:

- A clear value proposition for the proposed medical device product or prophylactic or therapeutic approach;
- Differentiating features from currently available solutions or those in clinical development nationally and on the global market; and
- Delivery of impact in the current pandemic in less than 12-months.

Interested parties are encouraged to discuss potential applications with MTPConnect and the BTB Venture Partners (BioCurate, the Medical Device Partnering Program and UniQuest).

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 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 opportunities.

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. 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 the BTB Venture Partners – BioCurate (The 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 programs (through the Queensland University of Technology).

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

SELECTION PROCESS

Application to this BTB Program call will be conducted through a two-stage process. During Stage 1, applicants will submit a non-confidential EOI through SmartyGrants, the BTB [online application portal](#). Eligible EOIs will be reviewed by the BTB Selection Panel against an indicative list of selection criteria outlined further in this document. EOI applications strongly aligned with the objectives and desired outcomes of the Program will be invited to proceed to a Stage 2 Proposal. Unsuccessful EOIs will receive feedback from MTPConnect on areas where the EOI was less competitive.

Stage 2 Proposal applications will be prepared and submitted by the applicant with assistance provided by the matched BTB Venture Partner (BioCurate, MDPP or UniQuest). At Stage 2, applicants may be required to disclose confidential information to MTPConnect and the BTB Venture Partner. This will be done after entering into a Confidential Disclosure Agreement. Standard terms and conditions will apply and cannot be changed. All confidential information disclosed in Stage 2 must be clearly identified as “Confidential”.

Stage 2 Proposal applications will be reviewed by the BTB Investment Panel - an independent, national and international panel of research, industry and investment experts - against the selection criteria outlined later in these guidelines. The Investment Panel will make recommendations for funding.

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

- The approval of the project;
- The funding amount to be awarded; and
- The terms and conditions of the Funding Agreement.

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

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 it:

- Does not meet the objectives of the BTB Program; or
- Does not meet 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. Demonstrated capacity to match the funding (cash) requested;
3. Applicants must have an Australian Business Number (ABN);
4. The applicant's project must involve the development of a product (prophylactic, therapeutic or medical device) that has potential markets beyond Australia;
5. The applicant must provide evidence of technical and/or commercial feasibility of their product;
6. The applicant must demonstrate access to the relevant know how and/or existing and/or potential intellectual property (IP) that will be necessary to progress their product;
7. 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;
8. Projects need to demonstrate their ability to achieve impact in the current pandemic (i.e. establishing commercial viability of a new product, process etc.) in less than 12 months, and in any case by no later than 31 August 2021.
9. Applicants must meet any applicable timing, formatting, system or other similar administrative requirements from MTPConnect; and
10. Funding recipients must adhere to the terms and conditions of funding set out in a Funding Agreement (see later) as determined by MTPConnect.

EOIs and Stage 2 Proposals must be received on or before their respective closing dates. Late submissions will not be accepted. Where applicable (public research organisations), applications should be approved by the relevant technology transfer/business development office prior to submission.

SELECTION CRITERIA

Unmet Medical Need (20%)

Differentiation from solutions in clinical development or available on the national and/or global market(s).

Scientific Criteria: Medical Devices (30%)

Stage of development, product description, technical validation, safety, manufacturing. Proposed project objectives, timeline, rationale, deliverables, risks, and go/no-go decision points.

Scientific Criteria: Therapeutics (30%)

Stage of development, target biology and compound/biologic validation. Proposed project objectives, timeline, rationale, deliverables, risks, and go/no-go decision points.

Development Strategy (30%)

Intellectual property and freedom to operate, development and regulatory strategy, patients and end-users, implementation strategy.

Team (20%)

Composition, FTE commitment, experience, and infrastructure access.

USE OF FUNDING

Research ventures that are successful for funding under the BTB Program following the Stage 2 Proposal will enter into a partnership with MTPConnect and receive up to \$1 million over the agreed term. Commonwealth Funding provided through the BTB program can only be spent on eligible expenditures incurred on eligible activities during the term of the project and in accordance with the terms of the Funding Agreement with MTPConnect and the [Commonwealth Terms & Conditions for Standard Funding Agreement](#) (Dec 2018);

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

- Salaries (whole FTEs or fractional) and consumables, if they are directly attributed to the delivery of the project outcomes, if not, they will be deemed in-kind contributions
- 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 (no more than 15% of total budget)
- 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
- Essential travel within Australia

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
- Funding application or administration costs
- University administration/infrastructure levies
- Any other activities that are the usual requirement of business.

HOW TO APPLY

EOI applications and Stage 2 Proposals must be completed online in SmartyGrants, the BTB [online application portal](#).

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

All sections that require free text are word count-limited and clearly outlined. Additional words beyond the specified limit of each section will not be accepted by the online application portal.

All relevant supporting data must be uploaded as a single document under the Supporting Information section. Please ensure that all data, figures, tables, diagrams, designs, drawings are legible and clearly labelled in size 12 font. Within comment boxes, responses should reference both the relevant figure / table number and the page number of the data document (Stage 2 Proposals only).

A single page of supporting data is allowed for EOI applications, with no more than 6 clearly labelled and legible figures / tables.

For Stage 2 Proposals, 6 pages of supporting data is permitted. All figures / tables must be clearly labelled and legible.

Additional pages submitted above the page limit for supporting data will not be reviewed by the Panel.

EOI applications must upload Financial Letter(s) of Support 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 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 BTB@mtpconnect.org.au.

NOTIFICATION OF APPLICATION OUTCOMES

You will be contacted about the outcome of your application in a timely manner. The email address registered as the account owner within the online application portal will receive all correspondence. At all stages of the BTB Program application process, unsuccessful applicants will be provided with feedback on their application by MTPConnect in partnership with the BTB Venture Partners.

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

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

THE FUNDING AGREEMENT

The successful applicant must enter into a legally binding Funding Agreement with MTPConnect. Standard terms and conditions will apply and cannot be changed.

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

MTPConnect must execute a Funding Agreement with the applicant before any payments can be made. Applicants will not be reimbursed for any project activities conducted before execution of the Funding Agreement.

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 funding that all applicants meet these requirements and these requirements will be set out in applicants' funding agreements with MTPConnect.

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.

FINANCIAL ACQUITTAL AND REPORTING

The applicant will be required to provide regular project and financial reports and independent audits to MTPConnect to demonstrate its delivery of the project, financial acquittal and compliance with the funding agreement. MTPConnect will make payments in accordance with the agreed

schedule set out in the Funding Agreement. These payments are made in arrears after successful achievement of milestones and demonstration of matched cash contributions expensed. MTPConnect will report progress of successful applicants to the Commonwealth.

EXPECTED KEY DATES – ROUND 3 COVID-19 CALL

ACTIVITY	TIMEFRAME
R3 EOI Application	18 May – 1 June 2020
R3 EOI Outcomes	Late-June 2020
R3 Stage 2 Proposal	Late-June – Mid-July 2020
R3 Stage 2 Outcomes	Late July 2020
Contracting	August 2020
Project Start Date	From 1 September 2020
Project End Date	By 31 August 2021