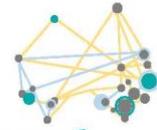




Biomedical
TRANSLATION BRIDGE
PROGRAM

Powered by



MTPConnect
MedTech and Pharma Growth Centre

In partnership with



Biomedical Translation Bridge (BTB) Program

GUIDELINES | APRIL 2020



Australian Government
Department of Industry, Science,
Energy and Resources

**Industry
Growth
Centres**



Australian Government
Department of Health
Medical Research Future Fund

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BTB 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). The BTB program can provide up to \$1 million of funding to help eligible organisations fund and nurture health and medical research to reach proof-of-concept with potential to attract further capital and support. Funded projects must have a completion date of no later than 30 June 2022. 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 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).

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 that improve the health outcomes of Australians as well as contribute to the Australian economy; and
- Helping to identify existing and new sources of capital investment to bolster awareness and interest in early research investment opportunities.

The BTB program 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.

MTPConnect will, in multiple funding rounds, open calls for non-confidential Expressions of Interest (EOIs) to identify new therapies, technologies and medical devices.

Interested parties are encouraged to discuss potential applications with MTPConnect and the BTB Venture Partners.

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

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

SELECTION PROCESS

Application to the BTB program will be conducted through a multi-stage process. During Stage 1, applicants will submit a non-confidential EOI through the [online application portal](#). Eligible EOIs will be reviewed by the BTB Selection Panel. The Selection Panel will evaluate the EOI applications, using an indicative list of selection criteria outlined further in this document, and rank applications into three categories.

The three categories are:

1. **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.
2. **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.
3. **Unsuccessful:** EOIs will receive feedback from MTPConnect on areas where the EOI was less competitive.

For the successful EOIs, Stage 2 Proposal applications will be prepared and submitted by the applicant with assistance provided by the matched BTB Venture Partner. At Stage 2, applicants may be required to disclose confidential information to MTPConnect and the Venture Partner. This will be done after entering into a Confidentiality Disclosure Agreement. 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. The applications will be reviewed against the selection criteria outlined later in these guidelines, which will then make recommendations for funding.

Award of BTB funding is subject to approval of 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.

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 novel product (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 commercialise 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 commercial proof-of-concept (i.e. establishing commercial viability of a new product, process etc.) within the funding period, and in any case by no later than 30 June 2022, positioning the product for future commercialisation via partnering/licensing or investment by the Biomedical Translation Fund (BTF) or other venture funding;
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.



THE SELECTION CRITERIA

Unmet Need (20%)

Criteria
Clear unmet need identified?
Serious condition?

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?
Evidence of end user demand or clinician support?
Strong safety profile and identification of class of device for regulatory approval?
Credible manufacturing strategy?

Scientific Criteria: Therapeutics (30%)

The scientific merit of applications seeking to develop therapeutics will be assessed based upon the strength of target validation and selection process and the nature of compound 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 Validation

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



Commercial Criteria (30%)

Intellectual property (IP) and freedom to operate

Criteria
Have any patent applications been filed? If so, will there be sufficient patent life once the product is on the market?
If IP has not been filed, is there a clear IP pathway and filing strategy?
Is there freedom to operate?
Does the IP have a clear chain of title? (Stage 2 Proposals only)

Feasibility of the clinical, regulatory and reimbursement path

Criteria
Is the proposed clinical development plan feasible?
Has the regulatory path been considered and is there a feasible plan?

Competitive positioning

Criteria
Is there evidence of differentiation from currently used solutions or other programs in development?
Is there a clear competitive advantage?

Commercialisation value and market positioning

Criteria
Is there a clear market/patient population for the eventual product now and in the future?
What is the potential reimbursement strategy? (Stage 2 Proposals only)
Is the proposed product attractive to VC firms or biotech/biopharma/medical device firms for potential licensing, partnering, acquisition, or spin-out opportunities?

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

Criteria
Has the team the requisite experience and demonstrated track record to achieve the milestones and commercial objectives of the project?
Does the team have access to the requisite infrastructure and matching funding to achieve the milestones?

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, as long as 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.

Stage 2 Proposals 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 name of the business, project title and description, 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 2020 KEY DATES – ROUNDS 2 AND 3

ACTIVITY	TIMEFRAME
R2 EOI Application	Mid-February – Early March
R2 EOI Outcomes	Mid-April
R2 Mentoring	Late-April – Mid-May
R2 Mentoring Outcomes	Late-May
R2 Stage 2 Proposal	Late-May – Late-June
R2 Stage 2 Outcomes	Late July
Contracting	August
R3 EOI Application	Early-June – Late-June
R3 EOI Outcomes	Late July
R3 Mentoring	Late-July – Late August
R3 Mentoring Outcomes	Early-September
R3 Stage 2 Proposal	Early-September – Late-September
R3 Stage 2 Outcomes	Late October
Contracting	November

Please note, Fast-Track projects will skip mentoring and be invited straight to Stage 2 Proposal. This will result in the following expected timeframes:

ACTIVITY	TIMEFRAME
R2 Stage 2 Proposal	Late-April – Late-May
R2 Stage 2 Outcomes	Early June
Contracting	June
R3 Stage 2 Proposal	Late-July – Late-August
R3 Stage 2 Outcomes	Early September
Contracting	September