



SUPPORTING TRANSLATION OF AUSTRALIAN MEDICAL TECHNOLOGY INNOVATION

BioMedTech Horizons 2.0

GUIDELINES | JUNE 2019



Australian Government
Department of Health
Medical Research Future Fund

Contents

BioMedTech Horizons 2.0	
1. GRANT OPPORTUNITY OVERVIEW AND OBJECTIVES	3
2. SELECTION PROCESS	5
2.1 Nine Clinical Challenges	5
3. ELIGIBILITY CRITERIA	6
4. THE SELECTION CRITERIA	7
5. USE OF FUNDING	8
6. HOW TO APPLY	9
7. NOTIFICATION OF APPLICATION OUTCOMES.....	9
7.1 The Grant Agreement & IP.....	10
7.2 Project specific legislation, policies and industry standards	10

1. GRANT OPPORTUNITY OVERVIEW AND OBJECTIVES

This grant opportunity is offered by the Commonwealth under the BioMedTech Horizons (BMTH) program which forms part of the Medical Research Future Fund (the Fund). BMTH2.0 is the latest round of funding to be offered under the BMTH Program. It can provide up to \$1 million of funding over a maximum two-year period to help eligible organisations progress medical technologies and devices through to Proof of Concept or beyond, the point where they are attractive to secure further venture capital or other funding. Please note that BMTH2.0 is a fully funded grant program that encourages, but does not require, matching funding be provided by the applicant.

1.1 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.

1.2 About the BioMedTech Horizons program

The funding for the BMTH program is drawn from the Fund and MTP-IIGC LTD, trading as MTPConnect, will deliver the program. The BMTH program is intended to address gaps in early biomedical and medical technology product development and increase the number of viable, new health technologies reaching proof-of-concept stages or beyond and that become attractive for private capital investment and commercialisation by:

- Expediting, through a competitive selection process, the identification of, investment in, and delivery of promising disruptive biomedical and medical technology innovation initiatives, for the benefit of the health and wellbeing of Australians; and
- Supporting industry access to expertise and infrastructure that will assist in accelerating rapid pre-clinical work and evaluation.

MTPConnect will deliver the BMTH program by:

- Identifying and selecting promising biological and medical technology innovation initiatives; and
- Partnering with other entities to deliver the initiatives, including supporting the selected initiatives through their formative stages in accordance with activity workplans approved by an oversight committee made up of representatives of the Department of Health, MTPConnect, AusBiotech and Medical Technology Association of Australia (MTAA).

Beginning on 15 June 2019, MTPConnect will open a call for non-confidential Expressions of Interest (EOI) to identify and select a number of biological and medical technology innovation initiatives that address one of the following four priority therapeutic areas:

- 1) Cardiovascular;
- 2) Orthopaedics;
- 3) Emergency medicine/trauma; or
- 4) Ophthalmology.

The BMTH2.0 program aims to:

- Develop new biomedical innovations and technologies in Australia to benefit Australians;
- Grow our biomedtech sector by ensuring that Australia's world-class research is translated into real treatments, drugs and devices; and
- Boost employment and grow businesses in Australia's biomedtech sector.

MTPConnect will operate the BMTH program in accord with the [Commonwealth Grants Rules and Guidelines \(CGRGs\)](#)¹.

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

2. SELECTION PROCESS

Application to BMTH2.0 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 based on the defined scoring criteria and generate a rank ordered list of applications that will progress to submit a complete Stage 2 application.

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”.

Stage 2 applications will be reviewed by an independent review panel, which will make recommendations for funding.

Award of BMTH 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.

Grant payments will be subject to MTPConnect’s receipt of the requisite funding amounts from the Commonwealth.

2.1 Nine Clinical Challenges

BMTH2.0 will support research and development of innovative medical technologies that address unmet clinical needs in four therapeutic areas including Orthopaedics, Ophthalmology, Cardiovascular and Emergency/Trauma Care. Extensive consultation with leading clinicians and industry thought-leaders has identified nine specific clinical challenges to be addressed within these four therapeutic areas.

Up to \$1 million of funding is offered for individual projects over a two-year period, that address one of more of the nine clinical challenges detailed in the next section.

Applications must address one of the following Clinical Challenges to be eligible.

Ophthalmology:

- 1) Image-based Artificial Intelligence (AI) systems, including those utilising AI for diagnosis of macular degeneration, glaucoma and/or diabetic retinopathy in the general population.
- 2) Drug delivery technologies for the treatment of eye disease (for example; drug-delivery systems to avoid intravitreal injections in patients with age-related macular degeneration or other conditions; or sustained drug delivery systems for the treatment of eye disease).

Cardiovascular

- 3) Global risk assessment tools for the prediction and early detection of atrial fibrillation, heart failure and coronary artery disease (for example, AI-based tools, genetic tools) and/or diagnostics/bedside diagnostics for screening for coronary/peripheral atherosclerosis, heart failure and risk of sudden death from acute myocardial infarction/arrhythmias in the general population.
- 4) Technological solutions for personalising advice and post-discharge monitoring in cardiovascular patients.

Orthopaedics

- 5) Enhanced 3-D imaging diagnostics, with or without virtual reality guidance (to provide anatomic, functional or other clinically relevant information), for personalised procedure planning in patients undergoing joint replacement and other orthopaedic procedures.
- 6) Medical devices and technologies for the prevention and/or management of infection in patients receiving orthopaedic implants.
- 7) New and more effective device-based technologies for the treatment of osteoarthritis.

Emergency Medicine/Trauma

- 8) Wearable sensors and integrated data analysis/display to achieve vital sign monitoring in acutely injured patients.
- 9) Advanced bedside imaging to diagnose and monitor critically-ill patients who can't easily be moved.

3. 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 grant opportunity;
- Fails to address one of the identified Clinical Challenges;
- Contravenes an eligibility rule or other requirement as set out in this Guidelines document.

For a proposal to be deemed eligible for BMTH2.0 funding, it must:

1. Identify novel biomedical and biotechnology initiatives that are likely to impact healthcare outcomes while targeting one of the Clinical Challenges and Therapeutic Areas listed in the Guidelines;
2. Come from an Australia based SME (firms or industry which employ up to 200 staff) including start-up companies
3. Stimulate collaboration across disciplines and between the research, industry, and technology sectors to maximise entrepreneurship. Applicants are encouraged to form strategic partnerships. Applicant's research collaborator must be an Australian research organization/institute/university;
4. Support 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;

5. Demonstrate an 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 program for future investment by the Biomedical Translation Fund (BTF) or other venture funding;
6. Meet any applicable timing, formatting, system or other similar administrative requirements imposed by MTPConnect; and
7. Advise that the proposed funding recipient will adhere to the terms and conditions of funding set out in a collaborative agreement as determined by the MTPConnect.

EOI applications must be received on or before the closing date. Late or incomplete applications will not be accepted.

4. THE SELECTION CRITERIA

The following selection criteria will be used to assess EOI and Stage 2 applications.

EOI Selection Criteria (note all section are equally weighted in the EOI application).	
Section 1:	<p><u>Project description</u> (Word limit 500)</p> <p>The proposal will be evaluated based on:</p> <ol style="list-style-type: none"> a. Alignment with BMTH Objectives and Clinical Challenges; b. Scope of activities proposed; c. Novelty of scientific/technological approach; d. Major milestones to be achieved; and e. Major risks and mitigation strategies.
Section 2:	<p><u>Commercial Potential</u> (Word limit 500)</p> <p>The proposal will be evaluated based on:</p> <ol style="list-style-type: none"> a. Technical feasibility; b. Market potential and value proposition; c. Intellectual property position, including freedom to operate; and d. Clinical/regulatory requirements/pathways.
Section 3:	<p><u>Team capability and track record</u> (Word limit 500)</p> <p>The proposal will be evaluated based on:</p> <ol style="list-style-type: none"> a) Governance structure will lead and support the delivery of the objectives; b) Team leadership, project management and commercialization skills available; c) The applicant's reputation and track record of delivering successful commercial outcomes; and d) Access to the facilities, infrastructure and networks needed to effectively and efficiently deliver the project.

Stage 2 Application Selection Criteria (note independent weighting of each section). Detailed selection criteria to be provided to Stage 2 applicants.	
Section 1:	<u>Potential to impact healthcare outcomes while addressing one of the defined Clinical Challenges</u> (Weighting 25%; word limit 1,000)
Section 2:	<u>Uniqueness of solution and level of competition in current market</u> (Weighting 12.5%; word limit 1,000)
Section 3:	<u>Commercial opportunity</u> (Weighting 25%; word limit 1,000)
Section 4:	<u>Technical feasibility</u> (Weighting 12.5%; word limit 1,000)
Section 5:	<u>Team capability and track record:</u> (Weighting 15%, word limit 500)
Section 6:	<u>Project plan: milestones, risk mitigation and defined go/no go decisions:</u> (Weighting 10%; word limit 1,000)

5. USE OF FUNDING

Commonwealth Funding provided through the BMTH 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:

- Prototype development and/or validation;
- In-vivo proof-of-concept studies in relevant disease models for therapeutic opportunities;
- Software coding and documentation to enable field trials or alpha/beta testing;
- External advice on IP, market, business planning, technical and/or competitive analysis to support the commercial potential of the opportunity;
- Labour: Contract staff employed for specific project purposes; and
- Direct research costs specific to the project receiving funding.

Examples of ineligible expenditure include but are not limited to:

- Staff payments that would otherwise have been paid by your organisation;
- Patent application or prosecution expenditures;
- Marketing or promotion;
- Conference participation;
- Non-economy domestic travel;
- International travel; and
- Purchase of equipment for general usage.

6. HOW TO APPLY

EOI applications must be completed online on the MTPConnect [online application portal](#).

EOI applications will open on **15 June 2019**.

EOI applications received after **17.00hrs (AEST) on 15 July 2019** 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 Dr Vishal Srivastava, BMTH Project Manager, on +61 3 9905 1754 or BioMedTechHorizons2.0@mtpconnect.org.au.

7. NOTIFICATION OF APPLICATION OUTCOMES

Application to the BMTH2.0 will be conducted through a two-stage process. Applicants will be notified of the outcomes of their EOI by 30 September 2019 and those successful will be invited to submit a complete Stage 2 application. MTPConnect will engage directly with successful EOI applicants to progress a Stage 2 application.

Successful Stage 2 applicants will receive a written offer which will include specific conditions attached to the grant.

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 Department of Health's websites.

7.1 The Grant Agreement & IP

The successful applicant must enter into a legally binding grant agreement with MTPConnect in the form of the MTPConnect Standard Grant 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.

7.2 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 a request is made, MTPConnect will consult with the applicant before any decision is made to release the application or supporting documentation.

7.3 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.