



SUPPORTING TRANSLATION OF AUSTRALIAN MEDICAL TECHNOLOGY INNOVATION

BioMedTech Horizons 3.0

GUIDELINES | OCTOBER 2019



Australian Government
Department of Health
Medical Research Future Fund

Contents

BioMedTech Horizons 3.0	
1. PARTNERSHIP OPPORTUNITY OVERVIEW AND OBJECTIVES	3
2. KEY FOCUS/THERAPEUTIC AREA	4
3. SELECTION PROCESS	5
4. ELIGIBILITY CRITERIA	5
5. THE SELECTION CRITERIA	6
6. USE OF FUNDING	7
7. HOW TO APPLY	8
8. NOTIFICATION OF APPLICATION OUTCOMES.....	9
8.1 THE PARTNERSHIP AGREEMENT & IP	9
8.2 PROJECT SPECIFIC LEGISLATION, POLICIES & INDUSTRY STANDARDS	9
8.3 FUNDING ACQUITTAL & REPORTING	10

1. PARTNERSHIP OPPORTUNITY OVERVIEW AND OBJECTIVES

This partnership opportunity is made possible by the Commonwealth under the BioMedTech Horizons (BMTH) program which is an initiative of the Medical Research Future Fund (the Fund). BMTH3.0 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 BMTH3.0 is a funded partnership opportunity 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.

MRFF 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*. Investments made 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, is delivering 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).

2. KEY FOCUS/THERAPEUTIC AREA

Beginning on **15 October 2019**, MTPConnect will open a call for non-confidential Expressions of Interest (EOI) to identify and select a few innovative solutions to address unmet clinical needs in three key Focus/Therapeutic Areas:

1. Digitally enabled medical devices in mobile health, health information technology, wearable devices, telehealth and telemedicine, and digitally enabled personalised medicine;
2. Digitally enabled implantable medical devices addressing unmet needs in any therapeutic area; and
3. General medical devices in the areas of regenerative medicine, women's health, cardiovascular, orthopaedics, neuroscience, general surgery and oncology.

The BMTH3.0 program aims to support projects that:

- 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.

3. SELECTION PROCESS

Application to BMTH3.0 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. 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 to MTPConnect for funding.

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

4. ELIGIBILITY CRITERIA

To be eligible for consideration, applications must satisfy all the requirements set out in this Guidelines document.

For a proposal to be deemed eligible for BMTH3.0 funding, it must:

1. Identify novel biomedical and biotechnology initiatives that are likely to impact healthcare outcomes while targeting one of the Focus / Therapeutic Areas listed above in the Guidelines. Clinical needs will be taken into consideration during the Stage 2 review of applications to ensure that clinical relevance is maintained;
2. Come from an Australia based SME (firms which employ up to 200 staff and have an ABN number). Eligible companies must be at a stage of development equivalent to Level 3 or beyond on the Technology Readiness Level Scale and will have preliminary data demonstrating Technical Proof of Concept. Companies must hold rights to the patent(s) or other IP related to the technology being developed;
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 organisation/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. Have a developmental plan demonstrating how the BMTH funds would help accelerate development and/or commercialisation of the technology within a two-year period.

- This may include an ability to achieve or exceed 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 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 partnership agreement as determined by MTPConnect.
 8. EOI applications must be received on or before the closing date. Late or incomplete applications will not be accepted.
 9. An application may be considered ineligible and excluded from further consideration if it:
 - a. Does not meet the objectives of the program;
 - b. Fails to address one of the identified Focus / Therapeutic Areas;
 - c. Contravenes an eligibility rule or other requirement as set out in this Guidelines document.

5. 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 Key Focus/Therapeutic Area; 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 Key Focus/Therapeutic Area</u> (Weighting 25%; word limit 1,500)
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 1,500)
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 1000)
Section 6:	<u>Project plan: milestones, risk mitigation and defined go/no go decisions:</u> (Weighting 10%; word limit 1,000)

6. 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 partnership agreement 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.

7. HOW TO APPLY

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

EOI applications will open on **Tuesday, 15 October 2019**.

EOI applications received after **17.00hrs (AEDT) on Monday, 16 December 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, Director BioMedTech Horizons on +61 3 9905 1754 or BioMedTechHorizons3.0@mtpconnect.org.au.

8. NOTIFICATION OF APPLICATION OUTCOMES

Application to the BMTH3.0 will be conducted through a two-stage process. Applicants will be notified of the outcomes of their EOI by 13 March 2020 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.

8.1 THE PARTNERSHIP AGREEMENT & IP

The successful applicant must enter into a legally binding partnership agreement with MTPConnect in the form of the MTPConnect Partnership Agreement. The Partnership 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 Partnership 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 partnership agreement with the applicant before any payments can be made. Applicants must not start any project activities until a partnership agreement is executed.

8.2 PROJECT SPECIFIC LEGISLATION, POLICIES & INDUSTRY STANDARDS

Applicants are required to be compliant with all relevant laws and regulations, including those specified in the Commonwealth Grant Agreement between the Commonwealth and MTPConnect.

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' partnership 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.

8.3 FUNDING ACQUITTAL & 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 partnership 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 partnership agreement. Payments are subject to satisfactory milestone-progress on the project. Applicants will be required to submit reports in line with the partnership 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.