BMTH BioMedTech Horizons PROGRAM

SUPPORTING TRANSLATION OF AUSTRALIAN MEDICAL TECHNOLOGY INNOVATION

BioMedTech Horizons Round Four Guidelines

March 2021

MTPConnect
MedTech and Pharma Growth Centre

Australian Government
Department of Health
Medical Research Future Fund

Contents

1. Funding Opportunity Overview and Objectives

This funding 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).

BMTH4 is the fourth competitive funding round to be offered under the BMTH Program.

Four funding opportunities of $800,000 each (excluding GST) will be available to help eligible organisations advance their medical device technology toward commercialisation by supporting Australian-based pre-commercial prototype development and testing.

BMTH4 will support the development of the Australian medical device sector by supporting critical research and create opportunities to locally manufacture pre-commercial prototypes of Australian based medical devices that are entering human clinical trials.

It is expected that medical device prototypes to be developed and tested will be at least entering Technology Readiness Level (TRL) 5 (prototype tested in intended environment) and mature one or two levels through the course of the project with a maximum term of 12-months. The expectation is that upon completion of the project activities, the prototype device will have been used in its intended environment. For BMTH4 the innovation maturity level (IML) to be used as a reference are developed by CIMIT[1] and are designed for medical technology innovations (Appendix A, below).

Lead applicants are required to provide a minimum of 1:1 matched cash co-contribution. BMTH funding will be used to support research, development and project costs in line with the eligible expenditures indicated in these Guidelines.

The nominal start date of project activities will be from 1 October 2021 and finish no later than 30 September 2022.

About the Medical Research Future Fund

As part of the 2014-15 Budget, the Australian Government announced the establishment of the MRFF, a A$20 billion fund to support medical research and medical innovation to improve the health and wellbeing of Australians. The MRFF was established through the *Medical Research Future Fund Act 2015*.

The intended outcomes of the MRFF 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.
- Improving Australia's reputation as a global leader in health and medical research.

[1] The Centre for Improving Medicine with Technology and Innovation, https://cimit.net/

About the BioMedTech Horizons Program

The BMTH program is drawn from the MRFF and administered by MTPConnect. 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.
- Supporting industry access to expertise and infrastructure that will assist in accelerating rapid pre-clinical work and evaluation.

The intended outcomes of the BMTH program are to:

- Develop new biomedical and medical innovation and technology in Australia to benefit Australians.
- Grow the Australian medical technology sector so that Australia's world-class research is developed into medical technologies.
- Boost employment and grow business in the medical technology sector.

MTPConnect will deliver the BMTH program by:

- Identifying and selecting promising biological and medical technology innovations.
- 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 and the Medical Technology Association of Australia (MTAA).

MTPConnect delivers the BMTH program in accordance with the Commonwealth Grants Rules and Guidelines (CGRGs).

2. Key Focus Area

Beginning on **24 March 2021**, MTPConnect will open a call for Expressions of Interest (EOI) to identify and select initiatives that meet all the following objectives:

- Research to achieve the goal of using the device in the intended environment in the project period.
- Sees the production of prototypes in Australia of a regulated medical device at a minimum classification of Class IIa as per TGA guidelines in any therapeutic area.

For the purposes of this funding opportunity a medical device is one that is used for humans and is intended to diagnose, prevent, monitor, treat or alleviate a disease or injury, or modify or monitor anatomy or physiological functions of the body, and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.

3. Application Process and Key Dates

Application to BMTH4 will be through a two-stage process; an EOI and a full application. EOIs will be reviewed by a panel of independent assessors and shortlisted applicants will be invited to submit a full application. More detail on the application process is included in Section 5 (The Selection Criteria and Process).

All EOIs and full applications will be treated as confidential except for your company name, project title, project lead applicant name and a non-confidential executive summary. This information will be used as described in Section 10 (Use of Your Information).

Key Dates

Activity Description	Due Date
MTPConnect portal opens for EOI submission	24 March 2021
MTPConnect portal closes for EOI submission	19 April 2021 at 5:00pm AEST
EOI assessment outcomes notified	14 May 2021
MTPConnect portal opens for Full Application submission	21 May 2021
MTPConnect portal closes for Full Application submission	2 July 2021 at 5:00pm AEST
Full Application assessment outcomes notified	6 August 2021
Latest date for contract execution	1 October 2021
Project Activities start	Upon contract execution
Project Activities finish (no later than)	30 September 2022

4. Eligibility Criteria

A strong proposal will:

- Demonstrate the potential to improve the health and wellbeing of Australians.
- Demonstrate how BMTH funds will accelerate the production and commercialisation of a medical device technology in Australia within a 12-month period.
- Demonstrate a commitment to Australian manufacturing of pre-commercial prototypes.
- Demonstrate the greatest potential to advance the medical technologies sector in Australia and economic and workforce development.
- Form partnerships or stimulate collaboration across disciplines and between the research, industry and technology sectors to maximise entrepreneurship.

To be eligible for consideration, applications must satisfy all the requirements set out in this Guidelines document. An application may be ineligible and excluded from further consideration if it contravenes an eligibility rule or other requirement set out in this Guidelines document or does not fulfill each of the Key Focus Areas requirements (above).

Throughout the application and selection process, an applicant must advise of any changes that may affect the proposal and the intended outcomes. Failure to do so may result in applications being withdrawn from consideration.

Proposals that deliver outcomes aligned with other national initiatives such as the Modern Manufacturing Initiative and the Medical Products Roadmap are encouraged.

General Eligibility

The medical device to be developed is a physical device that is a smart monitoring device, diagnostic, personalised implant or a bionics device. The medical device prototype to be developed must be at least entering a maturity level consistent with IML5/TRL5 (Appendix A, below) and achieve the objectives of the round as set in the Key Focus Area (above). The facility building the device prototypes for use will therefore be appropriately accredited or the accreditation will be achieved within the project activity period allowing endpoints to be achieved. Evidence and justifications will be sought throughout the application process.

Lead Applicant Eligibility

For a proposal to be eligible the following requirements for the lead applicant must be met:

1. The lead applicant must be an:
    - Australian based business registered before 1 January 2021
    - be incorporated in Australia
    - have an ABN
    - have fewer than 200 staff
    - have group sales of less than $50M in the last fiscal year
    - the Lead Applicant cannot be a University or Medical Research Institute.
2. The lead applicant will be a medical device company developing a device and must control or have the legal right to access and use the patent(s), trademarks or other IP that will be necessary to undertake the proposed activities and to translate, implement or commercialise their product(s)/solution(s).
3. Meet the requirements demonstrating cash co-contribution outlined in Matched Funding Eligibility (below).
4. Meet any applicable application deadlines, timing, formatting, system or other similar administrative requirements imposed by MTPConnect.

Partner Eligibility

It is understood that the lead applicant may not be the group manufacturing the device prototypes. To accommodate this scenario, partnerships and collaborations with Australian medical device manufacturers are allowed. A partner is not a mandatory requirement and is not considered an advantage or a disadvantage.

If a manufacturing partner is named that partner must satisfy the following eligibility criteria. The partner must:

- be an Australian business registered before 1 January 2021
- be incorporated in Australia
- have an ABN
- establish and operate the manufacturing facility in Australia
- be ISO14385 accredited or achieve accreditation within the project activity period.

Other partner organisations can include, but are not limited to:

- universities

- medical research institutes
- clinical organisations or health care providers
- health systems
- consumer groups
- private research entities
- commercial entities
- not-for-profit organisations
- and/or other end-users.

A partner or collaborator is not required to provide an additional matched cash co-contribution; however, any cash or in-kind co-contribution will be considered favourably. Cash co-contributions from partners or collaborators will meet the requirements outlined in Matched Funding Eligibility (below).

A formal arrangement must be in place between all partners before funding can be awarded. This arrangement must be detailed in the EOI, and evidence will be required at the time of submission of the Full Application.

Matched Funding Eligibility

Matched funding is required in BMTH4 to demonstrate current and ongoing commitment by the business to the proposed project and its outcomes.

Matched funding must be provided as a cash co-contribution, be at least equivalent to the amount requested from the BMTH4 program and fulfil the requirements set out below. Additional cash or in-kind contributions will be considered favourably. Cash contributions from non-government sources are considered most favourably.

Evidence of the at least 1:1 matched funding cash co-contribution must be provided at the EOI stage. Evidence will include letter(s) of support that provides assurance that matched funding is available. Letter(s) of support must outline what is being contributed (cash and in-kind), be on the organisation's letterhead and be signed by an authorised individual.

Matched funding can be derived from multiple sources. Matched funding eligibility:

- Matched funding cannot be from any other Australian Government program.
- All non-Australian Government sources of matching cash are acceptable.
- Grants or capital from international sources are acceptable.
- Universities, Medical Research Institutes (MRIs) and foundations may contribute matching funding from non-Australian Government sources of revenue.

Where matched funding is provided through a grant from another government, foundation or agency, MTPConnect will seek evidence that activities do not overlap.

Applicants are required to disclose other sources of State/Territory or Australian Government funding that has been received that have supported the development of the proposed project to date.

5. The Selection Criteria and Process

Projects with more validation and a clear development path to defined commercial inflection point will be ranked higher and will be more likely to receive funding.

The Assessment Panel

EOIs and full applications will be reviewed by an assessment panel comprised of MTPConnect, research, industry, and investment experts.

MTPConnect will manage a conflict-of-interest process (Section 10) and ensure all reviewers have signed a Confidentiality Agreement. Members of the assessment panel who declare a conflict of interest will not be involved in any element of the review or recommendation process for that application.

The Approval Processes

The assessment panel will recommend to the BMTH oversight committee which project(s) are to be supported. The BMTH oversight committee will review the recommendations, make the final decision and notify the Department of Health and the lead applicant of the funding outcome. Provision of funding is contingent upon successful execution of a Funding Agreement.

The decision of the BMTH oversight committee is final in all matters.

EOI Application Selection Criteria

The EOI must contain information addressing the following points:

- Project title.
- Company information and contact person of the lead applicant and partner(s) (if any).
- Non-confidential executive summary which should include the purpose of the activity, major milestones and commercial outcome.
- A concise work plan including major milestones across each term (below), deliverables and measures of success.
- Economic justification, the business case and benefit to the sector.
- Budget by categories as specified in the EOI form.
- The project delivery team, roles and contribution by partner(s) (if any)

The most meritorious EOIs will be invited to submit a full application.

EOI Selection Criteria - EOIs are scored and rated as per Appendix B and Appendix C.	
Section 1:	**Eligibility and Collaborators.** This section includes questions addressing the eligibility of the lead applicant and partners and/or collaborators including information on planned co-contributions. Letters of support will be required where appropriate.

EOI Selection Criteria - EOIs are scored and rated as per Appendix B and Appendix C.	
Section 2:	**Project Details.** This section will include the non-confidential executive summary. The proposal will be evaluated based on: a. Alignment with BMTH Objectives and the Key Focus Area. b. Alignment with the target IML/TRL as described in Appendix A. c. Scope of activities proposed including: ▪ What medical device products will be produced including evidence of the maturity of these products. ▪ Major milestones to be achieved, deliverables and measures of success. d. Major risks and mitigation strategies.
Section 3:	**Benefits and Commercial Opportunity.** The proposal should outline how the health and wellbeing of Australians will be improved, how the project achieves the intended outcomes of the BMTH program and provide a clear commercial and market justification of the project. This section will detail the high-level business plan of the lead applicant and any named partner and/or collaborators. The proposal will be evaluated based on: a. The disease burden and the Target Product Profile of the medical device prototype to be developed. b. Market need, including providing a business justification for manufacturing the device in Australia. c. What is the commercial advantage of your approach, how it is differentiated? d. Evidence of ownership of IP forming the basis of the medical device(s) to be made. e. Evidence of ownership of IP relating to the prototype manufacturing technologies (if any). f. Partners and their contributions to the outcome. g. Overall economic benefit, including jobs creation opportunity. h. How the project achieves the intended outcomes of the BMTH program and improves the health and wellbeing of Australians. i. Anticipated longer term benefits relating to the outcomes of the project.

EOI Selection Criteria - EOIs are scored and rated as per Appendix B and Appendix C.	
Section 4:	**Team Capability and Track Record.** The proposal will be evaluated based on: a. Governance structure to lead and support the delivery of the objectives. b. Team leadership, project management and commercialization skills available, including addressing gender balance. c. The applicant's track record of delivering successful commercial outcomes; and Additional merit will be considered for applicants that: a. Demonstrate how their project or business will advance gender and/or social inclusion activities. b. Deliver environmental and sustainability outcomes. c. Align with other national initiatives such as the Modern Manufacturing Initiative. Evidence will be sought through the application stages to validate these additional merit criteria.
Section 5:	**Budget.** The budget in the EOI must give an indication of expenditures against the proposed activities for both the BMTH4 and the co-contribution components. Any in-kind contributions and corresponding activities should be indicated.

Full Application Selection Criteria

Full Application Selection Criteria - The weighting of each section is indicated. - Detailed criteria will be provided to applicants invited to submit a Full Application. - Character/word limits will apply to each question.	**Weighting**
Section 1: Potential to impact healthcare outcomes while addressing Key Focus Area.	15 %
Section 2: Uniqueness of solution and level of competition in current market.	10 %
Section 3: Commercial opportunity.	25 %
Section 4: Technical feasibility.	15 %
Section 5: Team capability and track record.	15 %

Section 6: Project plan including milestones, risk mitigation, defined go/no go decisions and budget.	20 %

6. Eligible Activities/Use of Funding

Commonwealth Funding provided through the BMTH program can only be spent on eligible expenditures incurred on eligible activities during the project period and be in accordance with the Commonwealth Terms & Conditions for Standard Funding Agreement (March 2015);

Eligible Expenditure

Not all expenditure on your project will be eligible for support under this funding opportunity. The program delegate makes the final decision on what expenditures may be eligible and may give additional guidance on eligible expenditure if required.

To be eligible, expenditure must be:

- incurred by you within the project period
- a direct cost consistent with the agreed activity workplan
- incurred by you to undertake required project audit activities.

Eligible expenditure items can include:

- Direct labour costs: Employees you directly employ on the core elements of the project for the fraction of time spent on the project. A person is an employee when you pay them a regular salary or wage, out of which you make regular tax instalment deductions.
- Labour on-costs and administrative overheads: You may increase eligible salary costs by an additional 30% allowance to cover on-costs such as employer paid superannuation, payroll tax, workers compensation insurance, and overheads such as office rent and the provision of computers.
- Contract expenditure: The cost of any agreed project activities that you do or contract to others, including external advice on IP, market, business planning, financial audit, technical and/or competitive analysis to support the commercial potential of the opportunity.
- Travel: Domestic travel limited to the reasonable cost of accommodation and transportation required to conduct agreed project activities in Australia, including the domestic travel of persons associated with a selected eligible entity where this travel is aligned with the activity workplans of the initiative.
- Staff training that directly supports the achievement of project outcomes
- Other eligible expenditure as approved by MTPConnect in advance.

The budget and expenditure categories used for BMTH4 provide indication of eligible project expenses and are:

- Consultants
- Consumable supplies & materials
- Faculty & staff salaries
- Other operating costs

- Services
- Space rental fees
- Subcontracts
- Travel

If your proposal is successful, we will ask you to verify the project budget that you provided in your proposal when we negotiate your Agreement. You may need to provide evidence, including quotes for major costs.

The Agreement will include details of the evidence you will need to provide when you achieve certain milestones in your project.

You must keep payment records of all eligible expenditure and be able to explain how the costs relate to the agreed project activities. At any time, we may ask you to provide records of the expenditure you have paid. If you do not provide these records when requested, the expense may not qualify as eligible expenditure.

At the end of the project, you will be required to provide an independent audit report of all eligible expenditure from the project. The cost of the financial audit is an eligible expense.

Funding from the BMTH Program should be spent in Australia. However, limited overseas expenditures may be approved where applicants can clearly demonstrate that the specific expertise or activity required to progress a project cannot be accessed or completed from an Australian company.

Ineligible Expenditure

Examples of ineligible expenditure include:

- Expenses associated with business-as-usual activities not related to the project.
- 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.
- Purchase of equipment for general usage.
- Manufacturing costs that are not directly related to the precommercial prototype.
- Construction of buildings.
- Financing costs, including debt financing and interest.
- Costs involved in the purchase or upgrade/hire of software (including user licences) and ICT hardware (unless it directly relates to the project).
- Non-project-related staff training and development costs.
- Costs related to obtaining resources used on the project, including interest on loans, job advertising and recruiting, and contract negotiations.
- Costs related to preparing the proposal, preparing any project reports (except costs of independent audit reports) and preparing any project variation requests.

Capital expenditures/infrastructure or manufacturing infrastructure may, on a case-by-case basis be deemed an eligible expenditure, but **they must be paid for from the matched funding co-contribution budget and not the BMTH4 funding.**

This list is not exhaustive and applies only to the expenditure of the BMTH4 funds. Other costs may be ineligible where we decide that they do not directly support the achievement of the planned outcomes for the project or that they are contrary to the objective of the project.

You must ensure you have adequate funds to meet the costs of any expenditure items that are not eligible to be paid from BMTH funds.

7. How to Apply

EOI and full applications must be completed through the MTPConnect online application portal. The dates for various stages of application will be as set out in Section 3 (Key Dates).

All sections that require free text are character limited. Additional characters beyond the specified limit of each section will preclude submission.

Attachments to the application must be submitted in line with the instructions provided within the form. You should only attach requested documents. Additional material will not be considered.

A PDF copy of the application EOI and full application forms will be available on the MTPConnect webpage when applications opens.

All 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.

8. Announcements

We will publish non-confidential details of successful projects. We are required to do this by the *Commonwealth Grants Rules and Guidelines* unless otherwise prohibited by law. This information may include:

- Name of your organisation
- Title of the project
- Description of the project and its aims (non-confidential executive summary)
- Amount of funding awarded and partnership duration
- Australian Business Number
- Business location
- Your organisation's industry sector.

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.

Notification of Application Outcomes

Applicants will be contacted about the outcome of their application in a timely manner. The email address registered as the account owner within the online application portal will receive all correspondence. Applicants are advised to check inbox filters if notifications are not received by the expected dates.

Unsuccessful applicants at either EOI or full application stage will be provided with any feedback offered from the external assessment panel.

If you are successful, MTPConnect will advise you of any specific conditions attached to the funding, including embargo conditions and the timing of any public communications you make regarding being awarded funding.

9. Funding Recipients

The funding recipient will be required to provide regular project and financial reports and annual independent audits to MTPConnect to demonstrate the delivery of activities, achievement of milestones, financial acquittal and compliance with the Agreement. MTPConnect will make payments in accordance with the agreed schedule set out in the Agreement. Payments will be stage gated and provided upon receiving satisfactory quarterly progress reports and achieving milestones in the proposed timeframe.

Keeping Us Informed

MTPConnect must be notified if anything is likely to affect your Project and/or its activities. If a funding recipient becomes aware of a breach of terms and conditions under the Agreement, MTPConnect must be contacted immediately.

MTPConnect must be notified of any events relating to your Project and its activities and provide an opportunity for the Minister for Health or their representative to attend.

Funding Agreement

The successful applicant must enter into a legally binding Agreement with MTPConnect. The Agreement will be provided for consideration after the applicant is notified of their success in the application. Standard terms and conditions will apply and cannot be changed.

MTPConnect will enter an Agreement with the lead applicant only.

The Agreement must be fully executed before any payments can be made. MTPConnect is not responsible for any expenditure incurred by the applicant until an Agreement is executed. MTPConnect will not reimburse the applicant for any activities that have occurred prior to execution of an Agreement.

The approval of Project funding may have specific conditions determined during the assessment process or other considerations made by the BMTH Steering Committee or the Department of Health Program Delegate. These will be identified in the offer of Project funding.

MTPConnect may recover BMTH funds if there is a breach of the Agreement.

The offer of funding may lapse if both parties do not sign the Agreement within the timeframe outlined in key dates. Under certain circumstances, MTPConnect may extend this period. MTPConnect bases the approval of BMTH Project funding on the information provided in the application. MTPConnect will review any required changes to these details to ensure they do not impact the project as approved by the BMTH Steering Committee, MTPConnect and the Department of Health Program Delegate.

The 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.

Payments

The Agreement will state the:

- maximum amount MTPConnect will pay.
- proportion of eligible expenditure covered by the BMTH program.
- any in-kind contribution the funding recipient or partners will make.
- any cash contributions provided by the funding recipient or partners.

MTPConnect will not exceed the maximum funding amount under any circumstances. If the funding recipient incurs additional costs, these must be met by the funding recipient.

The first payment from MTPConnect will normally be made upon contract execution and subsequent payments are made according to an agreed schedule set out in the Agreement and subject to satisfactory milestone-progress on the project. Ten per cent of the total funded amount will be withheld until acceptance of the final report.

Any Agreements with other named entities including any partner must be in place before MTPConnect will pay the first instalment from the BMTH fund.

Any named entity providing cash co-contribution will be required to demonstrate they have matching funding in a cost-centre specific to the project before MTPConnect will pay the first instalment from the BMTH fund.

If the funding recipient is registered for the Goods and Services Tax (GST), where applicable MTPConnect will add GST to payments. MTPConnect must be notified if GST registration status changes during the project period.

BMTH funding may be assessable income for taxation purposes, unless exempted by a taxation law. MTPConnect recommends the successful funding recipient seek independent professional advice on taxation obligations or seek assistance from the Australian Taxation Office. MTPConnect does not provide advice on tax.

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

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

Agreement. MTPConnect will monitor and report progress of successful applicants to the Commonwealth.

Applicants will be required to submit quarterly reports in line with the 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.

An independent audit will be required at the end of the project to verify expenditure in accordance with the Agreement. Expenditures that do not align with the Agreement or are otherwise ineligible will be clawed back.

Project activity and progress reports will be on the following schedule.

- **Term 1:** From contract execution to 31 December 2021. Activity and expenditure report due in January 2022.
- **Term 2:** 1 January to 31 March 2022. Activity and expenditure report due in April 2022
- **Term 3:** 1 April 2022 to 30 June 2022. Activity and expenditure report due in July 2022
- **Term 4:** 1 July to 31 Sept 2022. Activity and expenditure report and draft final report due in October 2022.
- Final report including independent audit of expenditure due in November 2022.

Independent Audits

Funding recipients will be required to provide an annual independent audit report. An audit report will verify the funding recipient spent BMTH funding in accordance with the Agreement. The audit report requires the funding recipient to prepare a statement of funding income and expenditure. A report template will be provided.

Compliance Visits

MTPConnect and/or the Department of Health delegate may visit the funding recipient during or at completion of the BMTH funding term, to review compliance with the Agreement. Inspection of any records the funding recipient is required to keep under the Agreement may be made. MTPConnect and/or the Department of Health will provide the funding recipient with reasonable notice of any compliance visit.

Funding Agreement Variations

We recognise that unexpected events may affect project progress. In these circumstances, you can request a variation to your Agreement to change your:

- project milestones
- project activities
- project budget

The program does not allow for an increase of funds. Variations must be proposed in writing and developed using provided templates.

Funding Acknowledgement

Successful funding recipients must not make any public announcement, including by social media, in connection with the awarding of their Project until the Minister for Health has publicly announced the outcome, or as otherwise instructed by MTPConnect.

If the funding recipient makes a public statement about project activities, including in a media release, brochure, publication, website or by social media, funding must be acknowledged by using the following: 'This project received MRFF funding from the Australian Government's BMTH program, delivered by MTPConnect.'

10. Probity

Conflict of Interest

A conflict of interest may affect the performance of the funding opportunity or program. A conflict of interest may arise when an individual prioritises, or gives equal weight to, a secondary interest over a primary interest. Where a conflict of interest exists, or is perceived to exist, it undermines the credibility, reputation and efforts of the BMTH Program, its governance and its administrator.

There may be a conflict of interest, or perceived conflict of interest, if project personnel have a professional, commercial or personal relationship with a party who is able to influence the application selection process, such as an Australian Government officer, member of the BMTH steering committee, selection or investment panels, MTPConnect or BMTH partners.

As part of the application, the applicant must declare any perceived or existing conflict of interest or confirm that, to the best of their knowledge, there is no conflict of interest.

If the applicant later identifies an actual, apparent, or perceived conflict of interest, they must inform MTPConnect in writing immediately.

Use of Your Information

MTPConnect may use and refer applications and the information contained therein to external experts or government departments for assessment of the application and MTPConnect's programs, reporting, advice, comment or for discussions regarding alternative or collaborative funding opportunities. Any information which is identified as and is confidential by nature will be appropriately treated as such by MTPConnect.

The applicant should minimise any personal information contained in the application to that required by MTPConnect for assessment and contact purposes. MTPConnect will treat personal information according to the Australian Privacy Principles (APPs) and the *Privacy Act 1988* (Cth) as specified in its Privacy Policy.

Freedom of Information

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.

Intellectual Property Management

EOIs should not contain any enabling data or material. Confidential Disclosure Agreements may be entered into with applicants whose projects move beyond the EOI stage to allow for a complete review and assessment of the opportunity.

All intellectual property related to the project defined in the EOI and full proposal is owned by the applicant, subject to any arrangements it has with third parties. If MTPConnect or its partners creates intellectual property as part of the consultation or full application, the intellectual property will be owned by the applicant. Inventorship will be determined based on standard protocols.

MTPConnect does not require a return on investment.

Legislation, Policies and Industry Standards

MTPConnect will ensure that the funding opportunity process is fair, according to the published guidelines, incorporates appropriate safeguards against fraud, unlawful activities and other inappropriate conduct and is consistent with the CGRGs. .

Funding recipients are required to be compliant with all relevant laws and regulations, including those specified in the Commonwealth Terms & Conditions for Standard Funding Agreement and principles of ethical conduct in research published in the National Health and Medical Research Council website.

To the extent that research involves the use of animals, the applicant will be required to comply with the Australian Code for the Care and Use of Animals for Scientific Purposes which promotes the ethical, humane and responsible care and use of animals used for scientific purposes.

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 including the National Principles for Child Safe Organisations.

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 funding recipients' Agreement with MTPConnect.

11. Enquiries and Feedback

Applicants requiring further assistance should contact Dr Gerard Gibbs, Senior Director BioMedTech Horizons on 0455 032 540 or BMTH4@mtpconnect.org.au.

12. Appendix A: Innovation Maturity Level: MedTech Solution – *CIMIT*

The grey shaded columns are the focus area for the BMTH4 round.

The CIMIT Innovation Maturity Level (IML) aligns with the Technology Readiness Level originally defined by NASA (next page).

IML	IML 1	IML 2	IML 3	IML 4	IML 5	IML 6	IML 7	IML 8	IML 9	IML 10
Stage	**Need**	**Idea**	**Proof of Concept (PoC)**	**Proof of Feasibility (PoF)**	**Proof of Value (PoV)**	**Initial Clinical Trials (ICT)**	**Validation of Solution (VoS)**	**Approval & Launch (A&L)**	**Clinical Use (Use)**	**Standard of Care (SoC)**
Definition	**Insights into unmet medical needs and available solutions**	**Potential solution to unmet need described, evaluated, and selected**	**Key component concepts validated in models and value proposition tested**	**Feasibility of whole solution demonstrated in models and in feedback from stakeholders**	**The potential of the solution to work and create value for all stakeholders is demonstrated**	**Regulated production of prototypes and collection of clinical and economic data**	**The solution is shown to be effective and its value to all stakeholders is validated**	**Institutional and regulatory approval received and sales launch**	**The solution is used successfully in day-to-day clinical practice**	**The solution is recognised as the standard of care**
Business requirements	Needs screening & selection. Existing solutions characterization.	Competitive landscape. Envisioned Value Proposition. Reimbursement familiarization. Key stakeholders identified.	Competing solutions characterization. Preliminary value proposition. Path-to-Payment plan. Stakeholder map. Business protection model.	Business advisory board. Feedback from 5+ economic buyers. Key relationships identified. Preliminary business model. Development plan.	Feedback from 20+ economic buyers. Incorporation & Founders Agreement. Initial seed investment. Investor ready business plan. Key management team committed. Key relationships formalized.	1st Institutional Investment. Feedback from 50+ economic buyers. Value quantification.	2nd round of institutional investment. Purchasing intent from 10+ buyers.	Initial sales. Regionalization plans.	New markets launched. Profitable sales.	Dominant market share. Health economics study.
Regulatory requirements	Regulatory familiarization.	Comparables identified. Medical device determination.	Preliminary regulatory classification. Preliminary regulatory pathway. Preliminary indications for use. Preliminary risk and hazard analysis.	Draft essential requirements checklist. Draft instructions for use. Draft product claims. Institutional approval request(s). Submission pathway defined.	Application to regulatory authority submitted. Clinical Investigation approval(s). Essential requirements checklist.	Data requirements confirmation. GDPR/HIPAA compliance. Pre-submission filed. Security and vulnerability certifications.	Submission of Technical file to regulatory body.	CMS/Public Coverage and CPT/DRG code determination. Registration and listing.	Monitoring/ inspections.	Product Obsolescence Plan.
Technology requirements	State-of-the-Art Summary.	Idea screening and selection. Paper prototype. Hypothesis and experimental design. Institutional IP disclosure.	Demonstration results. Preliminary Freedom to Operate (FTO) Assessment. Key component PoC prototypes. Key in-sourcing requirements. Updated institutional IP disclosure.	Product Requirement Document (PRD). “Works Like” and “Looks Like” prototypes. Essential experiment results. Key in-sourcing plans. Manufacturing/QMS plan. Provisional IP filing & initial FTO review.	"Works Like, Looks Like” prototypes. cGMP compliant pilot manufacturing process. Essential technical experiments results. IP search report. Key in-sourcing requirements committed.	All in-sourcing requirements achieved. cGMPs compliant manufacturing process. Full IP application. Updated specification & experimental validation.	Quality assured process validation (cGMP). Updated specification & experimental validation.	Finalized cGMP manufacturing process. IP for improvements filed.	Improvement plan. Patents issued.	Component Obsolescence Plan.

IML	IML 1	IML 2	IML 3	IML 4	IML 5	IML 6	IML 7	IML 8	IML 9	IML 10
Clinical requirements	Unmet need statement. Disease state characterization.	Workflow scenario. Updated need statement. Envisioned benefit statement. Feedback from 5+ clinical stakeholders.	Feedback from clinical stakeholders in 5+ settings. Target outcomes. Updated need statement and workflow scenario.	Feedback from clinical stakeholders in 20+ settings. Updated need statement and Use Case scenario/ workflow. Updated target outcomes.	Animal/first in/with man experiments. Clinical trial endpoints. Feedback from 100+ clinical stakeholders. Feedback from 5+ KOLs. Medical advisory board.	Demo feedback from 50+ clinical stakeholders. Endpoints achieved in pilot clinical trials. Peer reviewed publication(s) submitted.	Endpoints achieved in pivotal clinical trials. Peer reviewed publication(s) accepted.	Specialty medical groups review in place. Training materials & Support established.	Included in local practice guidelines. Peer reviewed publications.	Recommended practice by medical specialty.
Complementary Technology Readiness Level (TRL)	**TRL 1**	**TRL 2**	**TRL 3**	**TRL 4**	**TRL 5**	**TRL 6**	**TRL 7**	**TRL 8**	**TRL 9**	
	Basic research. Principles postulated and observed but no experimental proof available.	Technology formulation. Concept and application have been formulated.	Applied research. First laboratory tests completed; proof of concept.	Small scale prototype build in laboratory environment ("rough and ready" prototype).	Large scale prototype tested in intended environment.	Prototype system tested in intended environment close to expected performance.	Demonstrated system operating in operational environment at pre-commercial scale.	First of a kind commercial system. Manufacturing issues solved.	Full commercial application, technology available for consumers.	

13. Appendix B: Assessment Scoring Scale

When assessing the merits of your application against the assessment criteria, the Assessment Panel will use the following ten-point scale (10 highest, 1 lowest).

Score	Rating Scale
10	Excellent Quality – response to this criterion significantly exceeds expectations. Evidence confirms consistent superior performance against this criterion in all areas. Claims are fully substantiated.
9	Outstanding Quality - response to this criterion exceeds expectations in most key areas and addressed to a very high standard in others. Most Claims are fully substantiated with others very well substantiated.
8	Very Good Quality - response to this criterion meets expectations to a very high standard in all areas. All claims are well substantiated.
7	Good Quality – response to this criterion meets expectations to a high standard in all areas. Claims are well substantiated in key areas.
6	Fair Quality – response to this criterion addresses all areas well. Claims are well substantiated in most areas. Some minor shortcomings.
5	Acceptable Quality – response addresses most key areas to a consistent acceptable standard with no major shortcomings. Most claims are adequately substantiated. Some proposals may be questionable.
4	Marginal Quality – response is marginal and does not fully meet expectations. Some claims unsubstantiated; others only adequately substantiated or lack sufficient detail. Some proposals may be unworkable.
3	Poor Quality – response poorly addresses some areas or fails to address some areas. Claims largely unsubstantiated. A number of proposals may be unworkable.
2	Very Poor Quality – response inadequately deals with most or all areas. Claims almost totally unsubstantiated. A number of proposals may be unworkable.
1	Unacceptable Quality – response does not meet expectations. Criteria not addressed or insufficient or no information to assess the criterion. Claims unsubstantiated, no evidence and unworkable.

14. Appendix C: Rating Scale for Assessment Overall Value and Risk

Rating	Descriptor
Excellent	▪ The application provides excellent overall value. ▪ The proposed budget is detailed, aligns very well with the scope and scale of the proposed project, and is sufficient to undertake all components of work. ▪ The applicants risk management plan is well considered and appropriate to the project. ▪ The stated approach to the management, monitoring and reporting of risks is clearly articulated within their application. ▪ Any risks arising through the assessment are tolerable and well mitigated, and not likely to adversely impact on the achievement of stated objectives of the project.
Good	▪ The application provides good overall value. ▪ The proposed budget, with some minor shortcomings, is substantiated and will meet the scope and scale of the proposed project. ▪ The applicants risk management plan is appropriate to the project, with some minor shortcomings. ▪ The stated approach to the management, monitoring and reporting of risk is articulated within their application, with claims supported across key areas. ▪ Any risks arising through the assessment are tolerable and unlikely to adversely impact on the achievement of stated objectives of the project, although some risks may require additional mitigations and/or monitoring to ensure the delivery of project outcomes.
Marginal	▪ The application provides marginal overall value. ▪ The proposed budget is higher than expected for a project of the same scale and scope, with some line items questionable. ▪ The applicant's risk management plan lacks detail in some areas, there are some gaps in risk identification or analysis or some mitigation and management strategies appear questionable. ▪ Some risks arising through the assessment may require additional mitigation and/or monitoring to ensure that they are managed in a way that doesn't impact on the delivery of some project outcomes.