○ Other:

Stage of Development

Referring to the Innovation Maturity Scale provided in the Guidelines **(link)** please indicate which of the following items you have completed. More detailed information is from CIMIT, available here.

Requirements at IML4

Business Requirements	**Regulatory Requirements**	**Technology Requirements**	**Clinical Requirements**
Check all that apply	Check all that apply	Check all that apply	Check all that apply
❑ Business advisory board established. ❑ Feedback from 5+ economic buyers. ❑ Key relationships identified. ❑ Preliminary business model. ❑ Development plan.	❑ Draft essential requirements checklist completed. ❑ Draft instructions for use. ❑ Draft product claims. ❑ Institutional approval request(s). ❑ Submission pathway defined.	❑ Product Requirement Document (PRD) completed. ❑ 'Works Like' and 'Looks Like' prototypes. ❑ Essential experiment results. ❑ Key in-sourcing plans. ❑ Manufacturing/ QMS plan. ❑ Provisional IP filing & initial FTO review.	❑ Feedback from clinical stakeholders in 20+ settings. ❑ Updated need statement and Use Case scenario/ workflow. ❑ Updated target outcomes.

Requirements at IML5

Business Requirements	**Regulatory Requirements**	**Technology Requirements**	**Clinical Requirement**
Check all that apply	Check all that apply	Check all that apply	Check all that apply
❑ Feedback from 20+ economic buyers. ❑ Incorporation & Founders Agreement in place ❑ Initial seed investment secured ❑ Investor ready business plan developed ❑ Key management team committed. ❑ Key relationships formalized.	❑ Application to regulatory authority submitted. ❑ Clinical Investigation approval(s). ❑ Essential requirements checklist developed	❑ 'Works Like, Looks Like' prototypes developed ❑ cGMP compliant pilot manufacturing process planned ❑ Essential technical experiments results. ❑ IP search report. ❑ Key in-sourcing requirements committed.	❑ Animal/first in/with man experiments. ❑ Clinical trial endpoints. ❑ Feedback from 100+ clinical stakeholders. ❑ Feedback from 5+ KOLs. ❑ Medical advisory board.

Requirements at IML6

Business Requirements	Regulatory Requirements	Technology Requirements	Clinical Requirement
Check all that apply	Check all that apply	Check all that apply	Check all that apply
❑ 1st Institutional Investment. ❑ Feedback from 50+ economic buyers. ❑ Value quantification.	❑ Data requirements confirmation. ❑ GDPR/HIPAA compliance. ❑ Pre-submission filed. ❑ Security and vulnerability certifications.	❑ All in-sourcing requirements achieved. ❑ cGMPs compliant manufacturing process. ❑ Full IP application. ❑ Updated specification & experimental validation.	❑ Demo feedback from 50+ clinical stakeholders. ❑ Endpoints achieved in pilot clinical trials. ❑ Peer reviewed publication(s) submitted.

Requirements at IML7

Business Requirements	Regulatory Requirements	Technology Requirements	Clinical Requirement
Check all that apply	Check all that apply	Check all that apply	Check all that apply
❑ 2nd round of institutional investment. ❑ Purchasing intent from 10+ buyers.	❑ Submission of Technical file to regulatory body.	❑ Quality assured process validation (cGMP). ❑ Updated specification & experimental validation.	❑ Endpoints achieved in pivotal clinical trials. ❑ Peer reviewed publication(s) accepted.

Stage of clinical trial planning (check all that apply): *
- ☐ In discussion with potential clinical trial sites
- ☐ Clinical trial sites confirmed
- ☐ Ethics application in development
- ☐ Ethics application submitted
- ☐ Ethics application reviewed
- ☐ Ethics application approved
- ☐ Clinical trial underway/completed
- ☐ N/A

Please describe this clinical trial activity. *

Word count:
Must be no more than 150 words.

Medical technology development progress (check all that apply): *
- ☐ Pre-clinical research prototype completed that demonstrates safety and efficacy
- ☐ The pathway to approval is known
- ☐ The device has been reviewed by a regulatory authority (e.g., TGA, FDA)
- ☐ Device design verification and validation underway
- ☐ Device design verification and validation completed
- ☐ N/A

Provide a summary of the aspects of the project that are (or will be) in place that will allow you to complete within the project timeframe. *

Word count:
Must be no more than 200 words.
[Tip: The timeframe for the BMTH4 activities will be approximately October 2021 through September 2022. This section should describe the critical activities underway now and up to September 2021.]

Describe the environment your device will be used in and an outline your customer/stakeholder engagements to date? *

Word count:
Must be no more than 150 words.

Proposed Activities

Outline the proposed BMTH4 project plan, describing key activities and their timing, deliverables, outcomes and measures of success. *

Word count:
Must be no more than 400 words.
[Tip: refer to the Innovation Maturity Levels and indicate the deliverables that are part of this project. The timeframe for the BMTH4 activities will be approximately October 2021 through September 2022]

UPLOAD GANTT CHART *
Attach a file:

A maximum of 1 file may be attached.
[Tip: Your Gantt chart should include the main deliverables of the project referenced above and indicate the interim critical milestones to be achieved. You Gantt chart should be legible in a single A4 page with minimum font size of 8pt and provided in a pdf file format.]

Describe how you will achieve production of your prototype medical device within Australia. *

Word count:
Must be no more than 300 words.
[Tip: Demonstrate your readiness to make the required prototype(s). For example, are facilities currently available or are you/partners establishing new facilities, include details and status of any accreditations required to manufacture for use in the intended environment. Described the role of any partners and collaborators in the research and prototype manufacture.]

Indicate the major risks associated with the project, their likelihood, rating and strategies to manage or mitigate the risks. *

Word count:
Must be no more than 300 words.

Benefits and Commercial Opportunity

* indicates a required field

Disease Burden and Health Benefit

The purpose of this question is to align your EOI proposal with the The Australian Burden of Disease Study 2015.

Select the primary disease burden area your device will address. *
- ○ Blood and metabolic disorders
- ○ Cancer
- ○ Cardiovascular diseases
- ○ Endocrine disorders
- ○ Gastrointestinal disorders
- ○ Hearing and vision disorders
- ○ Infant and congenital conditions
- ○ Infectious diseases
- ○ Injury (external cause)
- ○ Kidney and urinary diseases
- ○ Mental and substance use disorders
- ○ Musculoskeletal disorders
- ○ Neurological conditions
- ○ Oral disorders
- ○ Reproductive and maternal conditions
- ○ Respiratory diseases
- ○ Skin disorders
- ○ Other:

Within this disease group, select the specific disease cause(s) your device will address. *
- ☐ Iron-deficiency anaemia
- ☐ Other blood and metabolic disorders

Within this disease group, select the specific disease cause(s) your device will address. *
- ☐ Bowel cancer
- ☐ Brain and CNS cancer
- ☐ Breast cancer
- ☐ Liver cancer

- ☐ Lung cancer
- ☐ Melanoma of the skin
- ☐ Non-Hodgkin lymphoma
- ☐ Oesophageal cancer
- ☐ Ovarian cancer
- ☐ Pancreatic cancer
- ☐ Prostate cancer
- ☐ Stomach cancer
- ☐ Unknown primary
- ☐ Other cancers

Within this disease group, select the specific disease cause(s) your device will address. *
- ☐ Aortic aneurysm
- ☐ Atrial fibrillation and flutter
- ☐ Cardiomyopathy
- ☐ Coronary heart disease
- ☐ Non-rheumatic valvular disease
- ☐ Stroke
- ☐ Other cardiovascular diseases

Within this disease group, select the specific disease cause(s) your device will address. *
- ☐ Type 2 diabetes
- ☐ Other endocrine disorders

Within this disease group, select the specific disease cause(s) your device will address. *
- ☐ Chronic liver disease
- ☐ Functional gastrointestinal disorders (FGID)
- ☐ Inflammatory bowel disease (IBD)
- ☐ Other gastrointestinal disorders

Within this disease group, select the specific disease cause(s) your device will address. *
- ☐ Hearing loss
- ☐ Other hearing and vision disorders

Within this disease group, select the specific disease cause(s) your device will address. *
- ☐ Birth trauma and asphyxia
- ☐ Pre-term birth and low birth weight complications
- ☐ Other infant and congenital conditions

Within this disease group, select the specific disease cause(s) your device will address. *

☐ Lower respiratory infections
☐ Other infectious diseases

Within this disease group, select the specific disease cause(s) your device will address. *
☐ Falls
☐ Homicide and violence
☐ Poisoning
☐ RTI - motor vehicle occupants
☐ Suicide and self-inflicted injuries
☐ Other unintentional injuries

Within this disease group, select the specific disease cause(s) your device will address. *
☐ Chronic kidney disease
☐ Other kidney and urinary diseases

Within this disease group, select the specific disease cause(s) your device will address. *
☐ Alcohol use disorders
☐ Anxiety disorders
☐ Autism spectrum disorders
☐ Bipolar affective disorder
☐ Depressive disorders
☐ Drug use disorders (excluding alcohol)
☐ Eating disorders
☐ Schizophrenia
☐ Other mental and substance use disorders

Within this disease group, select the specific disease cause(s) your device will address. *
☐ Back pain and problems
☐ Osteoarthritis
☐ Rheumatoid arthritis
☐ Other musculoskeletal disorders

Within this disease group, select the specific disease cause(s) your device will address. *
☐ Dementia
☐ Epilepsy
☐ Migraine
☐ Other neurological conditions
☐ Parkinson disease

Within this disease group, select the specific disease cause(s) your device will address. *

☐ Dental caries
☐ Periodontal disease
☐ Severe tooth loss
☐ Other oral disorders

Within this disease group, select the specific disease cause(s) your device will address. *
☐ Genital prolapse
☐ Polycystic ovarian syndrome
☐ Other reproductive and maternal conditions

Within this disease group, select the specific disease cause(s) your device will address. *
☐ Asthma
☐ COPD
☐ Upper respiratory conditions
☐ Other respiratory diseases

Within this disease group, select the specific disease cause(s) your device will address. *
☐ Dermatitis and eczema
☐ Other skin disorders

Select the age group(s) of patients who would benefit from your intervention/ device. *
☐ 0-4
☐ 5-14
☐ 15-24
☐ 25-44
☐ 45-64
☐ 65-74
☐ 75-84
☐ 85-94
☐ 95+

Select the sex(es) of patients relevant to your treatment/intervention/device. *
☐ Female
☐ Male

MTPConnect recognises and respects diversity of gender identity and expression. The purpose of this question is to align with the The Australian Burden of Disease Study 2015, which classifies based on a male/female binary.

Describe how the product will improve the health and wellbeing of Australians, how the disease burden will be improved, the estimated impact on the health economics (if investigated). *

Word count:

Must be no more than 200 words.

Market and Commercial Potential

Describe the market for your medical device. *

Word count:
Must be no more than 200 words.
[Tip: Should include total and addressable market, information on the likely payers and any known reimbursement paths]

Described any predicate devices, the current gold standard for treatment and how your device will be differentiated. *

Word count:
Must be no more than 200 words.

Provide a justification for manufacturing the device in Australia. *

Word count:
Must be no more than 200 words.

Please describe how your project aligns with the Modern Manufacturing Strategy and the Medical Products Roadmap.

[Links: Modern Manufacturing Strategy, Medical Products Roadmap]

Word count:
Must be no more than 200 words.

Describe other anticipated economic benefit of the project, including jobs creation opportunities and any other longer-term benefits. *

Word count:
Must be no more than 100 words.

Development and Regulatory

Describe the regulatory pathway for your product/solution and any plans already in place. *

Word count:
Must be no more than 100 words.
[Tips: For example, if you or a partner will be responsible for regulatory filing, completed or intended interactions with regulatory authorities, supporting studies to ISO/GLP standards.]

Explain your clinical development plan for your product/solution. *

Word count:
Must be no more than 100 words.
[Tips: For example, include endpoints and clinical outcome claims, associated timeframes, cost per phase.]

Intellectual Property (IP) Strategy

Key elements of your IP protection strategy? (check all that apply) *
☐ Patents
☐ Trade secret
☐ Trademark
☐ Copyright
☐ Know how
☐ Other:

[Tip: Should include protections relating to both the device and any specific manufacturing technologies]

Please comment on the status of your current portfolio and future patent strategy and, if applicable, describe the IP strategy to protect your medical device(s) and prototype manufacturing technologies and proprietary knowledge and information other than patents. *

Word count:
Must be no more than 200 words.
[Tips: Geographic coverage, breadth of claims, freedom to operate, findings of International Search Reports (ISR). Other forms of IP include know-how, copyrights, trade secrets, trademarks, designs, circuit layouts, software and databases.]

Number of inventive claims that are recognised to date directly related to this project. *

Must be a number.
[Tip: Inventive claims is referring to patents only.]

Provide details of filed patents in the table below.

[Tips: Provide the PATENTSCOPE reference for PCT applications, or national patent office references for non-PCT applications]

Patent ID	Priority Date	Status	Type	Ownership	Reference
	Must be a date.				Must be a URL.

Team Capability and Track Record

* indicates a required field

List the entire team required to deliver your proposed BMTH4 project.

[Tips: For example, researchers, partners, collaborators, consultants, IP owners, manufacturers, contractors (e.g. CROs), distributors, designers etc. If the resource is yet to be identified, indicate with 'to be determined (TBD)' or similar. As a guide to completing FTEs, an individual working full-time on the project will represent 1.0 in the FTE column.]

Name	Position	Organisation	Role in project	FTE on this project	LinkedIn profile
					Must be a URL.
		Organisation Name			
		Organisation Name			

Please outline any relevant background experiences of the project lead and the lead at any named partner organisations/collaborations. *

Word count:
Must be no more than 150 words.

Describe the diversity of your team with respect to, but not limited to, gender, career stage and/or different cultural backgrounds. Describe what your team's diversity brings to the project. Outline your plan for addressing diversity and inclusion into the future. *

Word count:
Must be no more than 200 words.
[Tip: diversity includes gender, cultural and expertise.]

Please outline key governance structures and key accountable people. *

Word count:
Must be no more than 50 words.

Please list any corporate social responsibility programs in place at the lead applicant organisation.

[Tip: For example, gender and/or social inclusion activities, environmental and sustainability outcomes]

Budget

* indicates a required field

Budget

Activity	BMTH funding	Lead applicant cash co-contribution	Other cash contribution	In-kind contribution
[Tip: Enter activities that align with items in the GANTT chart and other key deliverables]	(excl. GST) Must be a dollar amount.	(excl. GST) Must be a dollar amount.	(excl. GST) Must be a dollar amount.	(excl. GST) Must be a dollar amount.
	$	$	$	$

Total BMTH funding

$

This number/amount is calculated.

Total lead applicant cash co-contribution

$

This number/amount is calculated.

Total other cash contribution

$

This number/amount is calculated.

Total in-kind contribution

$

This number/amount is calculated.

Are the activities described in this project already fully or partially funded by another grant program or other investment? *

- ○ Yes
- ○ No

If yes, please outline which activities are supported and the source of this funding. *

Word count:
Must be no more than 100 words.

Have you received State/Territory or Australian Government funding that has supported the development of the proposed project in the last 5 years? *

- ○ Yes
- ○ No

Source of funding	Program name	Amount	What activities did this fund?
			Must be no more than 100 words.
		$	

Total previous funding amount

$

This number/amount is calculate

Acknowledgement and Authorisation

* indicates a required field

Conflict of Interest

Does the project lead, any other investigators and/or key individuals in the applicant organisation (CEO, CSO/CTO, Board) have any conflict of interest with regard to the BMTH Program, MTPConnect, and/or the MRFF Program? *

- ○ Yes
- ○ No

If yes, please detail any perceived or actual conflict of interest. *

Word count:

Must be no more than 200 words.

Disclaimer/Declaration

I am authorised on behalf of the applicant to submit this application and I certify that the information in this application and attachments is, to the best of my knowledge, true and correct. I will notify MTPConnect of any changes to this information and any circumstances that may affect this application.

I acknowledge that MTPConnect may refer this application to external parties for assessment, reporting, advice, comment or for discussions regarding alternative or collaborative funding or partnering opportunities.

Unless specifically indicated, I acknowledge and agree that this application does not contain confidential information and will not be treated as confidential by MTPConnect. I confirm that consent has been granted for MTPConnect to use and disclose any personal information contained herein. Accordingly, MTPConnect may publish, use and disclose the contents of this application.

I understand that this is an expression of interest only and will not result in funding approval. Following evaluation, applicants may be invited to the next stage of the BMTH Program. Shortlisted applications will require further submission and review.

Any funding offers will be subject to MTPConnect's receipt of funding from the Commonwealth and the terms of MTPConnect's standard funding agreement with awardees.

I have read and agree to the above *

- ○ Yes
- ○ No

Authorised representative

Title | First Name | Last Name

Organisation

Organisation Name

Position

Email

Must be an email address.