CTCM

Clinical Translation & Commercialisation Medtech

Powered by MTPConnect

CLINICAL TRANSLATION AND COMMERCIALISATION MEDTECH (CTCM) PROGRAM

EXPRESSION OF INTEREST (EOI) SAMPLE FORM

Non-confidential

Note: Please use this document as a guide only. All applications must be completed online in SmartyGrants, which opens Friday 9 September 2022.

Australian Government
Department of Industry, Science and Resources

Industry Growth Centres

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1.0 CLINICAL TRANSLATION AND COMMERCIALISATION MEDTECH PROGRAM, ROUND 2 CALL

- Expressions of interest (EOI) are now open for funding of between $250,000 and $1.5 million to support early clinical development of medical devices with commercial potential.
- This funding is being made available through the first round of the $19.75 million Clinical Translation and Commercialisation MedTech (CTCM) program, an initiative of the Medical Research Future Fund.
- The CTCM program is operated by MTPConnect in partnership with Medical Technology Association of Australia (MTAA), Medical Device Partnering Program (MDPP), Cicada Innovations (CI), the BridgeTech Program and Therapeutic Innovation Australia.
- For the purposes of this call, medical devices are defined by section 41BD of the *Therapeutic Goods Act 1989* and further informed by the Therapeutic Goods (Articles that are Medical Devices) Specification 2014. In summary, medical devices:
    - Are used for humans
    - Are intended to diagnose, prevent, monitor, treat or alleviate a disease or injury, or modify or monitor anatomy or physiological functions of the body
    - Generally achieve their purpose by a physical, mechanical or chemical action.
- Activities supported will include, but are not limited to, product development and product testing, clinical trial activity and regulatory support.

1.1 BEFORE YOU BEGIN

This funding is available through a competitive process.

The project term for funded CTCM Round 2 projects is a maximum of 24-months.

Applicants are encouraged to read the CTCM funding Guidelines carefully before commencing an application.

To be eligible for consideration, applications must satisfy all the requirements set out in the CTCM funding Guidelines. An application may be considered ineligible and excluded from further consideration if it contravenes an eligibility rule or other requirement as set out in the Guidelines.

Application to the CTCM program is a multi-step process:

Phase I Expression of Interest (EOI): All eligible projects are to be submitted as a non-confidential EOI. EOIs need to clearly articulate the challenge and solution, outline completed and/or planned technical and commercial activities (substantiated with non-confidential data) and describe the strengths of the project team. EOIs will be evaluated by the CTCM Selection Panel using selection criteria published in the CTCM funding Guidelines.

The most meritorious EOIs, as determined by the CTCM Selection Panel, will be invited to progress to Phase II. The merits of an application are based on how well it meets the selection criteria and how it compares to other eligible applications.

Phase II Consultation: Applicants who reach Phase II will be assigned a CTCM program partner – MTAA, MDPP or CI – for consultations which will be held via videoconference as required.

The outcome of the consultation and further evaluation will be assessed by the CTCM Selection Panel. The most meritorious applications, as determined by the CTCM Selection Panel, post-Phase II consultation, will be invited to progress to Phase III.

Phase III Full Proposal: Full Proposal applications will expand on the EOI application to more comprehensively address the selection criteria.

Full Proposal applications will be reviewed by the CTCM Investment Panel, an independent, national and international panel of clinical, research, consumer/community and commercial experts, against the selection

criteria articulated in the CTCM project funding Guidelines. The CTCM Investment Panel will make recommendations for funding awards to the most meritorious Full Proposals. Funding recommendations must be approved by the CTCM Steering Committee.

Funding Award: Applicants whose proposals are awarded funding will enter into a funding agreement with MTPConnect to receive up to $1.5 million over the defined project term to be paid in accordance with the agreed budget and a quarterly payment schedule.

1.2 EOI PROPOSAL CLOSING DATE

EOI submission closes on **Friday 7 October 2022 at 16:00 AEDT (Australian Eastern Daylight Time)**. Late applications will not be accepted.

1.3 COMPLETING THIS EOI FORM

Please note that the nominated project lead will receive all correspondence throughout the CTCM projects funding application process. Please check your junk/spam mailbox to confirm that correspondence has not been incorrectly filtered out of your inbox.

Please do not use abbreviations unless fully explained.

Where any data are provided to support the EOI, please indicate if this is from your own research, or from another research group or from existing literature. Please provide clear in-text references to supporting data uploaded.

Any supporting documentation requested as an upload must be prepared in accordance with the instructions outlined in the application form. Any page over what is requested will not be reviewed.

Questions marked with an asterisk (*) are required. Please do not leave any answers blank. State for instance "not applicable" or "unknown at this stage".

For assistance in completing the EOI form, please contact:

- MTPConnect via ctcm@mtpconnect.org.au

For any technical enquiries, please contact the SmartyGrants Help Hub:

- +61 3 9320 6888
- service@smartygrants.com.au

2.0 APPLICATION SUMMARY

2.1 APPLICANT DETAILS

Organisation Name *

Organisation ABN *

Organisation Address *

SmartyGrants requires Address Line 1, Suburb/Town, State, Postcode and Country to be completed.

Organisation Website *

Total number of staff employed by your organisation *

Total number of staff based in Australia *

Project Lead *

Title	First Name	Last Name

Position *

Role in Proposed Project *

Must be no more than 10 words.

Gender of Project Lead *

☐ Male

☐ Female

☐ Diverse gender identity

☐ Prefer not to say

Contact mobile number *

Must be an Australian mobile number.

Primary email address *

Must be an email address.

2.2 PARTNERS

Does this project involve partner/s? *

Yes ☐ No ☐

If yes:

Partner/s:

Organisation Name	ABN	Address	Website

2.2 PROJECT SUMMARY AND CONSENT

Project title *

Must be no more than 20 words.

Please provide a public summary of your project. *

Must be no more than 150 words.

Describe the specific objectives of the project. * [Tips: these may be listed as bullet points]

Must be no more than 125 words.

2.3 PROPOSED PROJECT TERM

Please note, projects must not extend beyond 24 months.

Proposed Start Date *

Proposed End Date *

End Date must be no later than 24 months after the Start Date.

Length of Project *

In months (must be equal or less than 24 months).

3.0 ELIGIBILITY CRITERIA AND FUNDING

Is the organisation applying an Australian enterprise and a MRFF eligible organisation as defined by the Medical Research Future Fund Act 2015, sub-section 24? *

☐ Yes ☐ No

State the funding amount requested through the CTCM program (all values must be in AUD and GST exclusive) *

$

Total amount must be between AUD $250,000 and $1,500,000.00.

Will the required co-contributions be available from the start date? *

[Tips: Co-contribution is based on the total funding requested as stated in the CTCM R2 Funding Guidelines. E.g., if the funding request is between $250,000-$500,000, the expected co-contribution is 1:4. If the funding request is between $500,001 - $1,000,000, then the expected co-contribution is 1:2. Any funding request made at $1,000,001 and above will require matched contributions at 1:1.]

☐ Yes ☐ No

Outline the source and amount of the co-contribution to the project (all values must be in AUD and GST exclusive), any additional in-kind or cash co-contributions to the project and comment on the level of commitment (e.g., in-kind committed, cash investment secured, fundraising, discussions etc.) and any relevant key dates. Please include all partner organisations, even where they aren't making an in-kind or cash contribution.*

Source of Contribution (Organisation)	In-kind	Cash	Comments
+			
Total	$	$	

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. *

Must be no more than 100 words.

If applicable, provide details of any pending applications that may fully or partially fund the activities in this project.

Must be no more than 100 words.

Do you control or have the legal right to access and use the relevant know-how and/or existing and/or potential intellectual property (IP), that will be necessary to undertake the proposed activities of the project and to translate or commercialise the product(s)/solution(s)? * [Tips: if you select no or partially, please contact MTPConnect to discuss your eligibility.]

☐ Yes ☐ No ☐ Partially

If you selected 'No' or 'Partially', please explain how you will obtain the rights or why you will not need them. *

Must be no more than 100 words.

4.0 SUPPORTING INFORMATION

In order to support your EOI, a single, one-page document may be uploaded below. This supporting information document is limited to data, figures and references and any other text not directly referring to figures will not be assessed. Up to six legible figures (relevant tables, graphs, images, diagrams, designs and/or drawings) can be included that are clearly labeled in Calibri font of size no smaller than 11 pt. All figures and/or pages over these specified limits will not be reviewed. Please note that EOIs are to be non-confidential.

In-text responses should reference the relevant figure/table number.

Please attach the single document as a pdf and use the following file naming convention:

CTCMR2XXX_Organisation Name_Supporting Information

Attach a file:

5.0 CHALLENGE AND SOLUTION

Describe and provide evidence of the unmet medical need (including prevalence, mortality and quality of life impacts, health economic factors etc). [Tips: reference supporting data/evidence as appropriate.] *

Must be no more than 200 words.

Briefly describe your product/solution. Outline, and quantify where possible, your value proposition. * [Tips: e.g. efficacy, safety, accessibility, cost, ease-of-use. Consider value to relevant stakeholders – e.g., patients, clinicians, prospective partners, investors, health systems, users, payers etc. You may include commercial and/or health economic benefits.]

Must be no more than 200 words.

Describe leading solutions currently on the market, and/or in clinical development, as well as emerging or indirect competitors, and your advantages over these competitors. How will your product/solution be differentiated? *

Must be no more than 150 words.

Describe how your project can align with the Modern Manufacturing Strategy and the National Manufacturing Priority Road Map for Medical Products. **(As of 28/09/2022, the MMS guidelines and the NMP Roadmap have been archived. Responses to this question will not be considered for assessment.)**

Entry not required.

Describe anticipated economic benefits of the project, including local manufacturing activity, job creation opportunities, sovereign supply chain development and any other longer-term benefits. * [Tips: consider also how the project is translating Australian research, integrating into local and international supply chains, establishing collaborative ecosystems and improving international competitiveness.]

Must be no more than 250 words.

Please describe how your project aims to demonstrate sustainable practices in the product design, production, packaging, and marketing. *

Must be no more than 200 words

6.0 TECHNICAL MERIT

6.1 STAGE OF DEVELOPMENT

Indicate the Technology Readiness Level (TRL) that best describes the status of the medical device, now and at the end of the proposed CTCM project. Please note, projects need to enter between TRL4 – TRL6. Projects that are not at this level are outside of scope for this program.*

Now	Project End	TRL
○	○	TRL 4 – Technical proof-of-concept and safety of candidate devices/systems demonstrated in defined laboratory/animal models.
○	○	TRL 5 – Devices compared to existing modalities and indications for use and equivalency demonstrated in model systems.
○	○	TRL 6 – Safety in humans demonstrated in clinical trial in small number of patients.
	○	TRL 7 – Clinical safety and effectiveness trials conducted in an operational environment.
	○	TRL 8 – Application for use has been approved, limited adoption of device in market.
	○	TRL 9 – Device is fully approved and in market worldwide.

Please provide detailed descriptions for each of the following questions.

6.2 PRODUCT DESCRIPTION

Indicate the proposed medical device approach: *

☐ Assessment/monitoring device

☐ General surgery or dental device

☐ In vitro diagnostic

☐ Medical Imaging

☐ Therapeutic device

☐ Other

Describe your device, including the key design features and how the technology works. Include justification for why your device is “clinical stage”. Provide details of the prototype device, including in the attachment a drawing or photograph, if available.*

Must be no more than 250 words.

6.3 TECHNICAL VALIDATION

Describe the current stage of development of the device. Summarise evidence from key technical testing supporting medical use. Include data demonstrating efficacy of the device. * [Tips: results and data from benchtop testing, simulation, in tissue or organ models, animal models or human subjects. For diagnostic devices include evidence of diagnostic accuracy (e.g., sensitivity, specificity, ROC curve).]

Must be no more than 200 words.

6.4 SAFETY

Provide evidence that the device is safe (safety studies completed to date, predicate devices or other publicly available data). Identify any further safety considerations and outline how they will be addressed. Cite the intended **TGA classification** of the device. *

Must be no more than 150 words.

6.5 CLINICAL USE

Explain and provide evidence of how feedback from end-users, clinicians and/or payers has informed the design and development of the device. Describe existing clinical workflows and articulate how the device will be incorporated into clinical practice. * [Tips: this could include clinical survey or pilot trial results.]

Must be no more than 150 words.

6.6 STAKEHOLDER ENGAGEMENT

Provide details and summarise feedback from other stakeholders who have been consulted on usability, acceptability and likely uptake of the device. Present evidence of demand from stakeholders over existing solutions. * [Tips: stakeholders may include but are not limited to end-users, patients, advocacy groups, hospitals, local health authorities, funders, payers, manufacturers, supply chain partners.]

Must be no more than 200 words.

6.7 SCALABILITY

Provide estimated production costs, and outline intended manufacturing plans and/or partners or other factors that will enable the implementation of your device at scale. * [Tips: other factors may include supply chain, distribution, shelf life.]

Must be no more than 150 words.

Describe barriers to implementation and/or adoption and how you will address and overcome these. *

Must be no more than 150 words.

7.0 PROJECT PLAN

7.1 PROJECT PLAN

Outline and briefly justify the proposed project plan, list milestones/key activities, timings and key deliverables and outcomes. *

Must be no more than 300 words.

Describe how your project will achieve commercial proof-of-concept or reach other important translation/commercialisation milestones by the completion of the funding period. * [Tips: include any activities that a potential partner or investor or end-user has indicated would support the achievement of commercial proof-of-concept.]

Must be no more than 200 words.

7.2 PROJECT RISKS

Indicate the major risks associated with the project and strategies to manage or mitigate the risks. * [Tips: types of risk to consider including stage of development, safety, regulatory, technical, implementation, commercialisation, key personnel, infrastructure, COVID-19 impacts etc.]

Must be no more than 150 words.

8.0 TRANSLATION AND COMMERCIALISATION

8.1 INTELLECTUAL PROPERTY (IP) STRATEGY

Has the innovation been disclosed? *

☐ Yes ☐ No

If yes, tick all that apply: *

◯ Academic Technology Transfer Office (if applicable, describe outcomes below)

◯ Conference

◯ Publication

◯ Patent

◯ Other (please describe)

Provide details of the disclosure. *

Must be no more than 100 words.

Is patent filing part of your IP protection strategy? *

☐ Yes ☐ No ☐ Unsure

If patent filing is part of your IP protection strategy, have any patent applications already been filed? *

☐ Yes ☐ No

If patent/s have been filed, provide details 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 (Provisional, PCT, National Phase, Granted)	Type (device, system, method of use, method of manufacture, software, other)	Ownership	Reference (URL)
+					

Please comment on the status of your current portfolio and future patent strategy and, if applicable, describe

the IP strategy to protect your innovations and proprietary knowledge and information other than patents. * [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, and circuit layouts.]

Must be no more than 150 words.

If a patent has not, or will not, be filed, describe the IP strategy to protect your innovation and proprietary knowledge and information. * [Tips: other forms of IP include know-how, copyright, trade secrets, designs, and circuit layouts.]

Must be no more than 150 words.

Please comment on the ownership and/or the legal right to access and use the relevant background and project IP for research purposes and for commercial exploitation of your product/solution. * [Tips: IP ownership and legal arrangement may be detailed in staff contracts and agreements e.g., Inter-Institutional Agreement, Collaboration Agreement, Patent Exploitation Agreement, Material Transfer Agreement.]

Must be no more than 150 words.

8.2 CLINICAL DEVELOPMENT AND REGULATORY STRATEGY

Detail the clinical development plan for your device. * [Tips: for example, include endpoints and clinical outcome claims, associated timeframes, cost per phase.]

Must be no more than 150 words.

Describe the regulatory pathway for your device and any plans already in place. * [Tips: for example, if you or a partner will be responsible for regulatory filing, completed or intended interactions with regulatory authorities, predicate devices, safety and other supporting studies to ISO/GLP standards.]

Must be no more than 150 words.

8.3 OPPORTUNITY AND STRATEGY

Describe which markets will be targeted for your device. Indicate the size and value of the markets of interest in detail (e.g., Australia, USA and/or other major markets). * [Tips: provide justification for your estimates. Include the total available market, the serviceable addressable market and the serviceable obtainable market.]

Must be no more than 150 words.

Describe your business model and the commercialisation strategy you will implement upon the completion of the CTCM funded project. Describe who will pay for the device, how they will pay and how you will access customers. * [Tips: commercialisation strategy could involve partnerships, license or sale of IP, organic growth, or an alternative go-to-market/exit strategy. If aligned with your strategy, outline why the product/solution will be attractive to venture capital firms or other investors. For business models taking a product/solution to market, provide evidence of willingness to pay, which may be demonstrated by e.g., voice of customer studies or adoption of similar solutions.]

Must be no more than 300 words.

9.0 TEAM AND CAPABILITIES

9.1 PROJECT TEAM COMPOSITION

List the entire team required to deliver your proposed CTCM 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 and Position	Organisation	Role within Project	FTE on CTCM project
+			

9.2 PROJECT TEAM EXPERIENCE

Describe the requisite experience or track record of the team to achieve the proposed research and translational/commercial objectives of the project. * [Tips: refer to the experience and track record of the entire team, not just the project lead.]

Must be no more than 250 words.

9.3 PROJECT TEAM DIVERSITY

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. Summarise your diversity statement. Outline your plan for addressing diversity and inclusion into the future. * [Tips: outline any programs operating within your institution/organisation which promote and encourage diversity, and any specific involvement team members have in such programs.]

Must be no more than 100 words.

9.4 RESOURCES AND INFRASTRUCTURE

What resources and infrastructure do you have access to in order to achieve the objectives of your proposed project? * [Tips: describe capacity, capabilities, major equipment required, laboratory set-ups, animal models, data sets etc., and align with your project plan.]

Must be no more than 200 words.

10.0 ACKNOWLEDGEMENT AND AUTHORISATION

10.1 CONFLICT OF INTEREST

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

☐ Yes ☐ No

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

Must be no more than 200 words.

10.2 SUBMISSION TERMS/DECLARATION

I am authorised on behalf of the applicant to submit this CTCM EOI 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.

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 CTCM 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		
Position		
Email		

APPLICATION END

MTPConnect
MedTech and Pharma Growth Centre

CONTACT US FOR FURTHER

INFORMATION

PHONE	+61 3 9070 8298
CTCM PROGRAM	ctcm@mtpconnect.org.au
GENERAL INFO	info@mtpconnect.org.au
HEAD OFFICE	Level 1, Suite 1.01 250 Bay Street Brighton VIC 3186 Australia

See our website for other locations

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