CTCM

Clinical Translation & Commercialisation Medtech

Powered by MTPConnect

CLINICAL TRANSLATION AND COMMERCIALISATION – MEDTECH (CTCM) PROGRAM

ROUND 1

FUNDING GUIDELINES

DECEMBER 2021

Australian Government
Department of Industry, Science, Energy and Resources

Industry Growth Centres

CONTENTS

OPPORTUNITY OVERVIEW

MTPConnect's Clinical Translation and Commercialisation - Medtech (CTCM) program is a funding opportunity offered under the 2020 Early Stage Translation and Commercialisation Support Grant of the Medical Research Future Fund's Medical Research Commercialisation Initiative.

The CTCM program aims to support early clinical development of medical devices with commercial potential. While product development, manufacture and testing will be considered eligible activities, all projects must include clinical testing of devices. For applications relating to development of an in vitro diagnostic (IVD), the minimum requirement for eligibility under this program will be the conduct of a clinical performance study using biobank samples or samples from recruits into a study as part of the project plan.

MTPConnect is delivering the program in partnership with medical technology commercialisation, education and infrastructure partners: Medical Technology Association of Australia (MTAA), Medical Device Partnering Program (MDPP), Cicada Innovations (CI), the BridgeTech Program and Therapeutic Innovation Australia (TIA).

Through CTCM, funding of between $250,000 - $1,500,000 will be provided. The project term for funded CTCM projects is a maximum of 24-months. Applicants are required to provide a co-contribution to the value of 50 per cent of the CTCM funding request, with additional in-kind or cash contributions above this threshold viewed favourably.

ABOUT THE CTCM PROGRAM

The $19.75 million CTCM program is a four-year initiative which will identify and nurture high-quality medical device projects that have commercial potential and support their translation through early clinical trials.

The program takes a national and inclusive approach to working with clinicians, researchers, Aboriginal and Torres Strait Islander health groups and consumers.

By providing funding of between $250,000 and $1.5 million per project across two funding rounds (FY2022 and FY2023), CTCM will:

- deliver consultation and commercialisation programs to guide project development and assessment
- enable access to broader NCRIS and other critical engineering, fabrication and prototyping facilities to accelerate translation of early-stage discoveries
- emphasise collaboration, partnering and consultation to nurture the next generation of health and medical research innovators and provide ongoing SME education
- employ a process of continuous evaluation, based on established commercial principles, to optimise the potential for project success and maximise return on investment.

By supporting the development of innovative medical devices, the CTCM program aims to improve the health and wellbeing of Australians, while also helping projects to generate commercial returns and create high-paying jobs in the medical products sector.

ABOUT THE MEDICAL RESEARCH FUTURE FUND

As part of the 2014-15 Budget, the Australian Government announced the establishment of the MRFF, 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.

ABOUT MTPCONNECT

MTPConnect is Australia's Growth Centre for the medical technology, biotechnology and pharmaceutical sector. As an independent, not-for-profit organisation, MTPConnect works to forge stronger connections between research and industry and maximises opportunities for Australians to make scientific and technological breakthroughs that are successfully translated and commercialised.

In this way, MTPConnect is building a more resilient and competitive medical products sector.

As part of the Growth Centre Initiative, MTPConnect deploys funding for the Department of Industry, Science, Energy and Resources. It also operates five programs, including CTCM, for the Medical Research Future Fund:

- BioMedTech Horizons ($45 million)
- Biomedical Translation Bridge ($22.3 million)
- Researcher Exchange and Development within Industry ($32 million)
- Targeted Translation Research Accelerator ($47 million)
- Clinical Translation and Commercialisation – Medtech ($19.75 million)

ABOUT CTCM PROGRAM PARTNERS

Medical Technology Association of Australia

MTAA is the national association representing companies in the medical technology industry. Its members provide most non-pharmaceutical products used in the diagnosis, prevention, treatment and management of disease and disability in Australia. As the voice of the medical technology industry in Australia, MTAA works to ensure patient access to state-of-the-art technologies. By fostering collaborations between researchers, industry, end-users and government to develop novel medical devices with global market potential, MTAA forms an essential link between clinical need and knowledge with technical expertise and industry know how.

Medical Device Partnering Program

MDPP is an ideas incubator driving entrepreneurial culture within the medical technology sector. MDPP fosters collaborations between researchers, industry, end-users and government and develops novel medical devices with global market potential.

MDPP is a national initiative working closely with more than 30 partners across Australia. Since establishment, MDPP has assessed over 1,000 ideas for new medical and assistive technologies. The program has facilitated nearly 200 ideation workshops, completed more than 100 R&D projects for

medical technology companies and provided manufacturing, partnering and new long-term commercial opportunities to over 30 manufacturers.

Cicada Innovations

Cicada Innovations is the home of deep tech in Australia, with a twenty-year track record of developing deep tech ventures tackling some of the world's most pressing problems. Cicada Innovations support their deep tech ventures and innovators with cutting-edge labs, access to mentors and experts, commercialisation training, and a cohort of ambitious peers. By connecting a growing community of entrepreneurs, policymakers, researchers and the public, Cicada's mission is to make Australia a leader in deep technology. Since inception, they've seen an unprecedented $1.2bn in exits from six deep tech ventures in the last two decades. Cicada has helped over 300 companies to raise more than $900m in funding, twice been awarded 'Top Incubator in the World' by InBIA, and delivered commercialisation training to thousands working in science & technology.

The BridgeTech Program

The BridgeTech program, facilitated and hosted by Queensland University of Technology (QUT), is an industry-focussed nation-wide collaborative commercialisation training program for the medical technology-medical devices sector. Working in collaboration with 20 university and industry sector partners, the BridgeTech program selects up to 80 participants annually to focus on training for the medical technology, devices and diagnostic industries with a view to improving the skills and capabilities of Australia's life science entrepreneurs, researchers and scientists to improve the quality and quantity of commercial deals and deepen collaboration between Australian researchers and the relevant industry sectors.

Therapeutic Innovation Australia

Established in 2008, Therapeutic Innovation Australia (TIA) is the lead agent for the National Collaborative Research Infrastructure Strategy (NCRIS) "Therapeutic Innovation Australia" project funded by the Australian Department of Education, Skills and Employment. TIA supports national research infrastructure across three capabilities - Biologics & Vaccines, Cell & Gene Therapies, and Small Molecule Pharmaceuticals.

The TIA consortium helps researchers and industry to translate research findings down the development pipeline towards readiness for Phase I trials and beyond.

ROUND 1 CTCM FUNDING OPPORTUNITY

The CTCM program provides financial assistance, consultation, educational support and access to infrastructure to Australian SMEs developing clinical stage medical devices.

For the purposes of this grant opportunity, 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. You should refer to this definition for any regulatory purpose, including preparing your application. 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.

Funding will be deployed over two rounds (FY22 and FY23). Applications in each round will be assessed in a multi-step process:

- Phase I: non-confidential Expressions of Interest (EOI)
- Phase II: consultation interview via videoconference
- Phase III: Full Proposal

Activities supported will include, but are not limited to, product development and testing, clinical trial activity and regulatory support. Ideas and concepts, with no technical validation at the time of application, and preclinical studies, are out of scope for this funding. Projects to develop research tools (e.g., databases or animal models) in isolation are not eligible. Non-human health programs are not eligible. There must be evidence of experimental research that has been undertaken that validates the problem or the potential of the product/solution. The applicant must demonstrate understanding of the market/end-user. See below for further details on eligibility and application requirements.

Interested parties are encouraged to discuss plans for their applications with MTPConnect. Questions relating to eligibility should be directed to MTPConnect. The CTCM program is delivered in accordance with the Commonwealth Grants Rules and Guidelines (CGRGs).

ROUND 1 KEY DATES

Application Process	Start Date	End Date
EOI Application	17 December 21	11 March 22
EOI Outcomes	Mid May 22	-
Consultation	Mid May 22	Mid June 22
Consultation Outcomes	Late June 22	-
Full Proposal Application	Late June 22	Late July 22
Full Proposal Outcomes	Early September 22	-
Contracting	Early September 22	Late October 22
Funding Term	On contract execution	24 months

APPLICANT AND PROJECT ELIGIBILITY AND USE OF FUNDING

A strong proposal will:

- Demonstrate the potential to improve the health and wellbeing of Australians
- Demonstrate how CTCM funds will accelerate the production and commercialisation of a medical device technology in Australia within a 24-month period
- Demonstrate a commitment to Australian manufacturing
- Demonstrate the 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.

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.

APPLICANT AND PROJECT ELIGIBILITY

For a proposal to be deemed eligible for CTCM Project Funding it must meet the following criteria:

1. The lead applicant must:
    a. be a registered Australian based business
    b. be incorporated in Australia
    c. have an Australian Business Number (ABN).
    d. have less than 200 employees.

2. Demonstrated capacity to match the co-contribution requirement.

3. The applicant's project must involve the development of a medical device.

4. The applicant must provide evidence of technical and/or commercial feasibility of their product.

5. The applicant must 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 Research Project and to translate, implement or commercialise their product(s)/solution(s).

6. Applicants must meet any applicable timing, formatting, system or other similar administrative requirements from MTPConnect during the application process.

EOIs and Full Proposals must be received on or before their respective closing dates. Late or incomplete submissions will not be accepted.

Funding recipients must adhere to the terms and conditions of funding set out in a funding agreement as determined by MTPConnect.

PARTNER ELIGIBILITY

It is understood that the lead applicant may not be the group manufacturing the device prototypes or final product design. 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 registered business
- be incorporated in Australia
- have an ABN
- establish and operate the manufacturing facility in Australia
- be ISO13485 accredited, achieve accreditation within the project activity period, or operate a quality management system aligned to ISO13485.

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
- 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.

INTELLECTUAL PROPERTY ELIGIBILITY

Applicants are encouraged to use the following flow chart (Figure 1) to self-assess the IP status of their project to determine if the application meets the IP eligibility requirements to apply for CTCM funding.

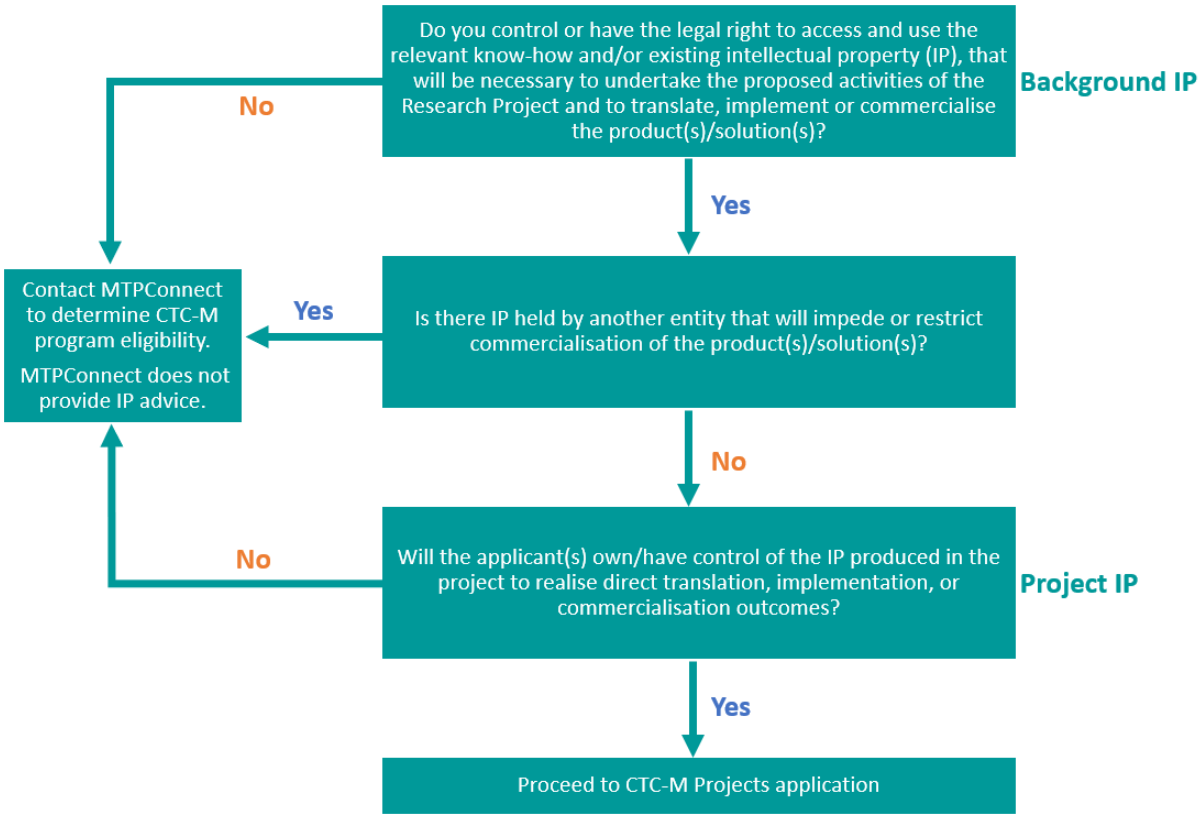

Figure 1. Intellectual Property eligibility flow chart.

USE OF FUNDING

Projects awarded funding under the CTCM program following the Full Proposal will enter into a funding agreement with MTPConnect and receive up to $1,500,000 over the agreed term. Commonwealth funding provided through the CTCM program can only be spent on eligible expenditures incurred on eligible activities during the term of the project and in accordance with the terms of the funding agreement with MTPConnect and the Commonwealth Terms & Conditions for Standard Funding Agreement (Dec 2018).

Examples of *eligible expenditure* include, but are not limited to:

- project consumables directly attributable to the delivery of project outcomes
- salaries (whole FTEs or fractional) directly attributable to the delivery of project outcomes. The maximum salary claimable per person, including packaged components (superannuation) is limited to $175,000 per financial year. On a case-by-case basis, where it can be adequately justified, CTCM funding may support salaries greater than $175,000 per financial year
- Commonwealth funded positions can be considered eligible to count towards an in-kind contribution. However, the Commonwealth funded position cannot also draw a salary from funds awarded through this grant opportunity for the same activity
- labour expenditure for leadership staff (e.g., founder, CEO, CSO, CMO) is considered eligible, provided there are direct, demonstrated and monitored links to project objectives and outcomes. Salaries for leadership staff will be limited to 10 per cent of the total amount of eligible labour expenditure claimable per person (i.e., maximum $17,500). On a case-by-case

basis, where it can be adequately justified, CTCM funding may support leadership salaries greater than $17,500 per financial year
- labour on-costs are eligible. Examples of labour on-costs are employer paid superannuation, payroll tax, workers compensation insurance and leave entitlements (including paid maternity leave, sick leave, long service leave and recreation leave). These costs must be reasonable, appropriate and separately identified in the project budget
- accessing specialist professional services including regulatory consultants, manufacturing and product development firms, clinical research organisations, technology evaluation, process evaluation, key opinion leaders or strategic stakeholders
- accessing IP expertise as a service, freedom to operate search costs and provisional and PCT drafting and filing costs (or costs associated with comparable stages of IP protection e.g., trade marks, designs, copyright circuits etc.)
- access to specialist equipment, hardware and software essential to the research
- purchase of equipment that is essential to research capped at $80,000 in total. Justification for purchase and why the applicant(s) cannot support the expense must be provided
- prototyping and development of a Minimum Viable Product
- market research/testing and engaging with major customers and end-users including clinical trials
- data procurement and efforts to obtain regulatory approval
- international activity expenditure where it can be justified that this work cannot otherwise be performed in Australia and is critical to the success of the project. If proposed international activities and expenditure exceeds 10 per cent of the total CTCM project funding (grant funding plus co-contribution), the Department of Health must provide its approval (which will be managed by MTPConnect)
- essential travel within Australia directly related to project activities
- essential travel overseas on a case-by-case basis directly related to project activities.

Examples of *ineligible expenditure* include but are not limited to:

- rent or other property fees
- salaries, activities, equipment or supplies that are already being supported through any other source of funding
- service or repair costs for eligible equipment purchases made with CTCM funding
- purchase of computers, except where these are an integral component of a piece of laboratory equipment or are of a nature essential for work in the research field, for example, a computer which is dedicated to data collection from a mass spectrometer, or used for the manipulation of extensively large datasets (i.e., requiring special hardware)
- reimbursement of activities that have occurred prior to the execution of a Funding Agreement
- financing costs, including interest
- debt financing
- costs related to obtaining resources used on the project, including interest on loans, job advertising and recruitment, and contract negotiations
- costs related to preparing the funding application, preparing any project reports and preparing any project variation requests
- conference attendance and associated travel (except in pre-approved circumstances where the research outputs of the project are to be presented)
- health insurance, travel insurance, foreign currency, airport and related travel taxes, passports and visas
- entertainment and hospitality costs

- personal subscriptions (e.g., personal journal subscriptions)
- personal membership of professional organisations and groups
- airline club membership
- communications costs (mobiles, telephone calls)
- institutional overheads and administrative costs
- basic office supplies and equipment
- any other activities that are the usual requirement of business.

The above list is not exhaustive. Other costs may be ineligible where it is determined that they do not directly support the achievements of the planned outcomes for the project or that they are contrary to the objectives of the CTCM program. Enquiries about expenditure eligibility can be directed to MTPConnect at ctcm@mtpconnect.org.au.

The applicant must ensure it has adequate funds to meet the costs of any ineligible expenditure associated with the project. This will be provided through a declaration at the end of the application form and in any required Letters of Support.

The CTCM program will accept applications for projects that have already been submitted to other funding sources. However, the CTCM program will not fund research activities that are already funded by an alternative source. Should your application to an alternative funding source be successful it may impact on the eligibility of your CTCM application/funding.

APPLICATION PROCESS

Before applying, you should read and understand these guidelines and the sample EOI application form published on the MTPConnect CTCM program webpage.

SMARTYGRANTS PLATFORM

EOI applications and Full Proposals for CTCM projects funding must be completed online in SmartyGrants, the CTCM online application portal.

Late applications will not be considered. Any additional attachments over what is permissible, or repeated submissions for the same project will not be accepted.

All sections that require free text are word count-limited and clearly outlined. Additional words beyond the specified limit of each section will prevent submission of the application.

All relevant supporting data must be uploaded as a single pdf under the Supporting Information section:

- **1 page** of supporting data, with no more than 6 figures/tables, is allowed for EOI applications.
- **6 page** of supporting data, including up to 1 page for references is allowed for Full Proposals.

Please ensure that all data, figures, tables, diagrams, designs, drawings are legible and clearly labelled in size 11 Calibri font.

Please ensure data supplied in supporting documentation is referenced appropriately (relevant figure/table number and, for Full Proposals, the page number of the supporting data document) within the EOI application/Full Proposal.

You need to allow enough time for each file to upload before trying to attach another file. Files can be up to 25MB each; however, we recommend trying to keep files to a maximum of 5MB – the larger the file, the longer the upload time.

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

The EOI application is non-confidential and therefore should not contain any sensitive or enabling information or data.

Full Proposals must upload Letter(s) of Support to provide an assurance from the organisation that any co-contribution and additional in-kind or cash contributions are available. The Letter(s) of Support should outline what is being contributed and if this is cash or in-kind, be on the organisation's letterhead and signed by an appropriately authorised individual (i.e., CEO/chair). If in-kind support or cash is being provided from multiple organisations, separate Letters of Support from each organisation must be uploaded.

All applications received will be acknowledged automatically upon submission. Following an EOI submission, applicants will be provided with a Reference Number to be used in all future communications in relation to the application.

APPLICATION AND SELECTION PROCESS

Application to the CTCM program is a multi-step process (see Figure 2. flow chart):

Phase I 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, commercial and implementation 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 this guidelines document.

The most meritorious EOIs, as determined by the 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.

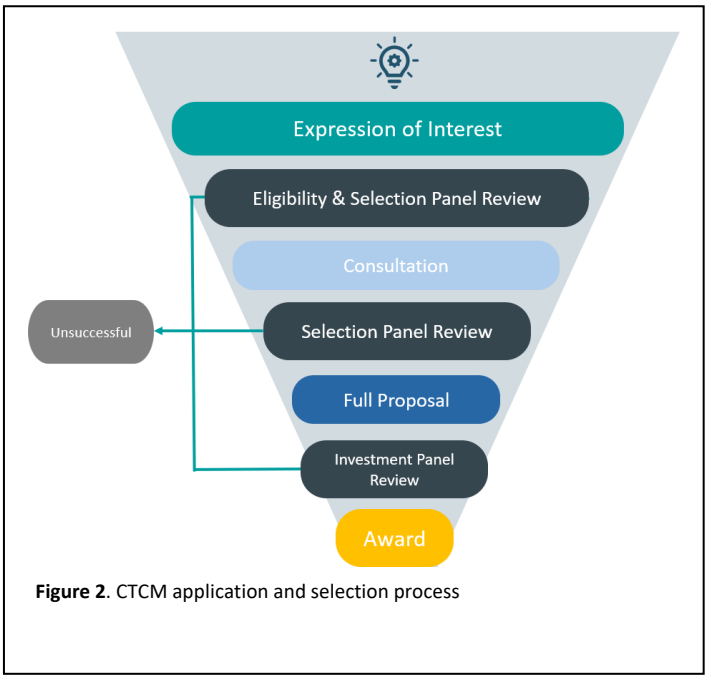

Figure 2. CTCM application and selection process

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

Confidential Disclosure Agreements will be entered into with applicants whose projects move beyond the EOI stage to allow for a complete review and assessment of your project.

Consultations will provide an opportunity for applicants to address Selection Panel feedback on their EOI, have a two-way due diligence conversation with the assigned CTCM partner on the technical aspects of the project and its commercial potential or translatability and allow for financial vetting with respect to any co-contributions. Time will be provided for the applicant to ask general questions on commercialisation as well. The outcome of the consultation and due diligence 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 and submit a Full Proposal.

Phase III Full Proposal: Full Proposal applications will expand on the EOI application to provide a more comprehensive outline of the project.

Full Proposal applications will be reviewed by the CTCM Investment Panel; an independent, national and international panel of research, industry and investment experts, against the selection criteria articulated in this guidelines document. The CTCM Investment Panel will make recommendations for funding award 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 $1,500,000 over the defined project term to be paid in accordance with the agreed budget and a quarterly payment schedule. Payments are paid in advance and are subject to satisfactory progress on the project plan and achieving agreed milestones.

The funding agreement will have a clear project plan which will include resourcing, timelines, milestones, go/no-go decision points and a risk register. Funding recipients will have regular reporting and audited financial obligations to MTPConnect.

At all stages of the CTCM application process, unsuccessful applicants will be provided with feedback on their bid.

SELECTION CRITERIA

You must address all selection criteria in your application. Your application will be assessed based on the weighting given to each criterion.

CHALLENGE AND SOLUTION (20%)

All applications will be assessed on how their product/solution addresses an unmet or underserved need and how their approach will have a competitive advantage.

a. clear articulation of how the proposed product/solution addresses an unmet or underserved need

b. applicant clearly describes the value proposition of their product/solution and its intended impact

c. there is a clear competitive advantage over, or differentiation from, the current standard of care or products/solutions available or in clinical development.

TECHNICAL MERIT (20%)

Merit of applications will be assessed based upon the technical and stakeholder validation of the product, including current evidence for proof-of-concept, efficacy and safety. Key data should be robust and reproducible, with appropriate controls, and include a comparator to the gold standard or standard of care where possible. Projects should not be based purely on others' published and non-validated data. Consideration will be given to:

a. innovative design features and evidence provided of prototype

b. evidence of applicant's preclinical benchtop and/or animal and/or clinical studies data validating the technology (including measures of diagnostic accuracy (e.g., sensitivity, specificity, ROC curve) for diagnostic devices)

c. the safety profile of the device, taking into consideration the class of the device. Where applicable, evidence of safety (applicant's own safety study data or publicly available evidence) is provided

d. feedback from clinicians and/or payers has informed the design and development of the device. There is consideration of how the product will be incorporated into clinical practice

e. evidence of stakeholder engagement and that proposed benefits are highly desired over existing solutions

f. scalability of the device, including production, costs and barriers to adoption.

PROJECT PLAN (20%)

All applications will be assessed on their proposed CTCM project plan and its implementation:

a. proposed project is supported and justified by clear activities, deliverables and outcomes

b. proposed activities are on the critical path towards commercial proof-of-concept or other important translation milestones

c. proposed project is focused, well defined and allows appropriate timeframes for completing activities

d. key risks are identified, and management/mitigation strategies outlined

e. indicative budget is appropriate for the proposed project plan and project term.

TRANSLATION AND COMMERCIALISATION (20%)

Applications will be assessed on their product/solution's potential across IP, development and regulatory strategy, commercialisation opportunity and strategy and sustainable implementation/adoption strategy, as applicable to their modality.

a. applicant has secured appropriate IP protection or has adequately described a robust IP strategy (e.g., patent, trade secret, database, copyright, trademark, know-how etc.)

b. IP status/strategy is favourable with respect to patentability, freedom to operate, period of exclusivity (as applicable)

c. proposed clinical development plan is appropriate and feasible

d. credible regulatory pathway articulated

e. clear, quantified and justified relevant market segment or end-user for the product or market-ready solution

f. feasible business model and commercialisation strategy clearly outlined

g. the proposed solution is attractive to investors or medical device firms for potential licensing, partnering, acquisition or spin-out opportunities

h. the applicant's product/solution can reach the intended target markets/end-users, with evidence of willingness to pay or market demand by defined paying customer(s).

TEAM AND CAPABILITIES (20%)

All applications will be assessed on their CTCM project team's composition, experience, diversity and access to requisite infrastructure.

a. the team outlined has the requisite experience and demonstrated track record to achieve the milestones and translational objectives of the proposed project

b. the team outlined is diverse (including, but not limited to, gender, career stage and/or different cultural backgrounds) and will provide expertise, build capacity and foster collaborative gain for the proposed project. If the team is not yet diverse, a feasible strategy for increasing diversity which will provide expertise, build capacity and foster collaborative gain has been articulated

c. the team has access to the requisite infrastructure and relevant co-contributions to achieve the milestones.

APPLICATION OUTCOMES

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 and the identified project lead will receive all correspondence. At all stages of the application process, unsuccessful applicants will be provided with feedback by MTPConnect in partnership with the CTCM program partners.

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.

FUNDING AGREEMENT

Successful applicants must enter into a legally binding funding agreement with MTPConnect.

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

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

MTPConnect may recover CTCM funds if there is a breach of the funding agreement.

The offer of funding may lapse if both parties do not sign the funding agreement within the timeframe outlined in key dates. Under certain circumstances, MTPConnect may extend this period. MTPConnect bases the approval of CTCM 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 CTCM Steering Committee, MTPConnect and the Department of Health Program Delegate.

The funding agreement will adopt a simple, applicant-friendly 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 funding agreement will state the:

- maximum amount MTPConnect will pay
- proportion of eligible expenditure covered by the CTCM 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.

MTPConnect will make payments according to an agreed schedule set out in the funding agreement. Payments are subject to the funding recipient making satisfactory progress on the project plan and achieving agreed milestones.

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.

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

ANNOUNCEMENT

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

The Minister for Health's announcement may include the name of the business, project title and non-confidential project summary (provided by the applicant) and amount of funding awarded.

MTPConnect 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 project duration
- Australian Business Number
- Business location
- Your organisation's industry sector.

Details of successful applicants and projects may also be published on MTPConnect and Department of Health websites.

FUNDING ACKNOWLEDGEMENT

Once announced, subsequent public statements by the funding recipient about the project, including in a media release, brochure, publication, website or by social media, must acknowledge the support of the CTCM program by using the following: 'This project received Medical Research Future Fund support through the CTCM program, delivered by MTPConnect.'

FUNDING RECIPIENTS

Ongoing project management, guidance and support will be provided by both MTPConnect and the assigned CTCM program partner for the duration of the funding term.

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 funding agreement. 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 funding 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.

REPORTING

Funding recipients must provide reports to MTPConnect at the times and with details specified in the funding agreement. Progress reports will be required quarterly and a final report will be required at the CTCM funding-term end. Sample templates will be provided for these reports, which will cover:

- progress against agreed milestones
- activity expenditure, including expenditure of CTCM funds
- additional funding recipient or partner contributions.

We may ask the funding recipient for ad-hoc reports on activities. This may be to provide an update on progress, or any significant delays or difficulties in completing milestones and/or projects or about any post CTCM funding plans.

INDEPENDENT AUDITS

Funding recipients will be required to provide independent financial audit reports on an annual basis and at project completion. An audit report will verify the funding recipient spent CTCM funding in accordance with the funding 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 CTCM funding term to review compliance with the funding agreement. Inspection of any records the funding recipient is required to keep under the funding 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

MTPConnect recognises unexpected events may affect project progress. In these circumstances, the funding recipient can request a variation to the funding agreement, including:

- changing project milestones
- changes to project partners
- changing project activities

- extension of timeframe for completing the project.

Note the program does not allow for an increase of CTCM funds.

Funding agreement variations need to be proposed in writing. A template will be provided.

You should not assume a variation request will be successful. MTPConnect will consider your request based on factors such as:

- how it affects the Research Project outcomes
- consistency with the CTCM Research Project Funding Guidelines and any relevant policies of the Department of Health
- changes to the timing of funding payments

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 CTCM 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 CTCM Selection or Investment Panels, MTPConnect or CTCM partners.

As part of the application, the applicant must declare any perceived or existing conflicts 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 contacting 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 are disclosed on a non-confidential basis and 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 created by the applicant in the project is owned by the applicant, subject to any arrangements it has with third parties.

MTPConnect and CTCM program partners do not require a return on investment. CTCM partner involvement in the CTCM mechanism is on a service basis. If a CTCM partner and applicant enter into a commercial arrangement at the end of a CTCM funded project, any requirement for return on subsequent investment after the end of the funding period will be negotiated outside of the CTCM mechanism.

LEGISLATION, POLICIES AND INDUSTRY STANDARDS

MTPConnect will ensure that the grant 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 Commonwealth Grants Rules and Guidelines (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 (NHMRC) 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 funding that all applicants meet these requirements and these requirements will be set out in funding recipients' funding agreements with MTPConnect.

ENQUIRIES AND FEEDBACK

For further information or clarification, contact the MTPConnect CTCM team by email at ctcm@mptconnect.org.au.

Danielle Shand, Director CTCM Program, can also be contacted on +61 427 197 448

MTPConnect
MedTech and Pharma Growth Centre

CONTACT US FOR FURTHER

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Further information about the Industry Growth Centres Initiative is available at www.business.gov.au/industrygrowthcentres