Medical Device Commercialisation Program

Application Guidelines

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1.1. MEDICAL DEVICE COMMERCIALISATION PROGRAM

The Medical Device Commercialisation Program (MDCP) is a $500,000 per annum, competitive commercialisation program funded by the South Australian Government, through the Department of Trade and Economic Development (DTED).

1.2. OBJECTIVES

The objective of the MDCP is to:

• support technically viable products with a compelling value proposition through the early stages of commercialisation;
• promote innovation in the medical and assistive devices sector; and
• stimulate economic development in South Australia.

02 Definition

Consistent with the Therapeutic Goods Administration, the MDCP defines medical devices as any technology, including devices, software or diagnostic, intended to be used by human beings for the prevention, monitoring or treatment of disease, injury or physiological process, excluding devices that act biologically or on biological agents. The commercialisation program will also include assistive devices, or devices intended to support aged care.

03 Delivery Model

Applicants will have the choice of applying for a Medical Device Research Grant (MDRG) or a Medical Device Commercialisation Grant (MDCG) through two delivery streams depending on the level of assistance required.

Applicants will note that they are responsible for all negotiations involving their intellectual property.

3.1. STREAM 1

Stream 1 is for applicants who wish to apply for a MDCP grant with the assistance and support of the Medical Device Partnering Program* (MDPP) co-ordinated by Flinders University, which will:

• undertake a preliminary technical assessment of the applicant’s project;
• identify the appropriate research team to add value to the project;
• include a preliminary commercial assessment by Flinders Partners;
• provide applicants with a project scoping document and market assessment document that can be used to support a MDCP grant application;
• complete the MDCP grant application in conjunction with the applicant; and
• where the grant is successful, the MDPP, through Flinders University, will receive the funding and co-ordinate expenditure on behalf of the applicant.

* Information about the MDPP is available at www.mdpp.org.au.

3.2 STREAM 2
Stream 2 is for applicants that wish to apply directly for a MDCP grant without participating in the MDPP. Stream 2 applicants are also eligible to receive preliminary commercial assessment assistance from Flinders Partners when applying for a MDRG.

04 Grants

4.1. MEDICAL DEVICE RESEARCH GRANT
The MDRG awards recipients up to $15,000 (Ex GST) on a 3:1 funding basis (ie a recipient co-contribution of $5,000 (Ex GST) is required to receive the maximum grant), for recipients to engage a research organisation to validate their product’s technical viability. In addition to the grant, recipients will be eligible to receive commercial evaluation assistance from Flinders Partners, Flinders University’s commercialisation company.

4.2. MEDICAL DEVICE COMMERCIALISATION GRANT
The MDCG awards recipients up to $40,000 (Ex GST) on a 1:1 funding basis (ie a recipient co-contribution of $40,000 (Ex GST) is required to receive the maximum grant), to:
• support recipients develop a proof of concept and commercialisation strategy;
• demonstrate that technical and commercial risks have been identified and mitigated; and
• enable applicants to attract Australian Government and/or private sector funding to bring new products to market.
Applicants will note that:
1. There is a finite pool of grant funding available each financial year.
2. Time restrictions may apply to the funding, such that it must be expended within a specified time.

The Minister reserves the right not to award any grants.

05 Application, Assessment and Approval Process

The process consists of the following stages:
1. Applicants apply for the MDCP on-line at www.mdpp.org.au. There will be a minimum of two funding rounds per financial year subject to available funding.
2. The MDPP, led by Flinders University, will evaluate each application in terms of its eligibility. If eligible, the MDPP will work with the applicant to determine which stream is appropriate.
3. Applicants:
   a. will work with the MDPP to develop a preliminary technical and commercial assessment and application for a MDRG; or
   b. will work with Flinders Partners to develop a preliminary commercial assessment for a MDRG provided they have conducted their own technical assessments; or
   c. can choose to have their applications sent directly to the MDCP Assessment Panel provide that they have conducted their own technical and commercial assessments sufficient to meet the eligibility criteria for a MDRG or MDCG.

4. DTED will evaluate each application to assess financial situation.

5. After reviewing applications against the eligibility and selection criteria the MDCP Assessment Panel will make one of four decisions:
   a. application recommended;
   b. application recommended subject to clarification of issues;
   c. application deferred – further information required; or
   d. application not recommended.

6. The MDCP Assessment Panel will be advised of all applications received.

7. The MDCP Assessment Panel will make recommendations to the Minister for Industry and Trade on which projects to be funded and the level of funding.

8. Final decisions on project funding will rest with the Minister for Industry and Trade.

9. Successful applicants will be required to enter into a Funding Agreement with the Minister for Industry and Trade. Key components will include: the purpose of the funding, eligible expenditure, expenditure sunset time frames, evidence of eligible expenditure, payment milestones and outcome reporting back to DTED.

10. Monitoring of the Funding Agreement contractual obligations will be undertaken by DTED.

06 Eligibility

6.1. APPLICANTS

An applicant must be:

- a financially viable company or commercial enterprise with a current or proposed connection in SA; have an Australian Business Number (ABN); with an annual turnover of less than $25 million; and is a legal entity; or an individual who agrees to form such an entity i.e. with whom the South Australian Government can enter into legally binding funding agreements.
- a South Australian public research organisation applying through their appropriate technology transfer office, or the CEO or equivalent of the research organisation.

An applicant must also own the right to use any intellectual property necessary to commercialise the project, be able to demonstrate that they can provide their required MDRG or MDCG co-funding contribution and willing to enter into a Funding Agreement.
6.2 PROJECTS
A project needs to meet the following criteria:
- the project must satisfy the definition of a medical or assistive device;
- the project must seek to commercialise a medical or assistive device that clearly exhibits commercial potential in response to a defined market opportunity; and
- the project must exhibit the potential to provide favourable economic outcomes for South Australia.

6.3 EXPENDITURE
- The grant funding supports expenditure incurred directly on the agreed project, within the agreed project period, details of which must be clearly provided in the application and will be detailed in the Funding Agreement.
- For the MDRG (Stream 1), eligible expenditure includes the cost of engaging the MDPP to evaluate a product’s technical viability.
- For the MDRG (Stream 2) eligible expenditure includes the cost of engaging a research organisation to evaluate a product’s technical viability.
- For the MDCG, eligible expenditure includes:
  - Engaging research organisations or additional internal expertise to assist with technical research to develop a proof of concept or prototype, including clinical evaluation;
  - engaging specialist technical, regulatory or commercial advice to develop a commercialisation strategy;
  - approved expenses associated with the project;
  - leveraging of third party funding in support of the above activities.
- The applicant will need to provide a statutory declaration detailing expenditure incurred to support all expenditure claims made on the project.

07 Selection Criteria

The MDCP Assessment Panel will evaluate grant applications against information and evidence provided in support of the following selection criteria.

7.1. SELECTION CRITERIA FOR A MEDICAL DEVICE RESEARCH GRANT
- Compelling commercial value proposition ie why will your product be purchased, what problem does it solve?
- Applicant understanding of how, when and where the customer would use the product.
- Technology benefits compared to current market solutions.
- Commercial experience and skills of the applicant.
- Need for financial assistance.
- Extent to which the project will provide economic benefits to South Australia.
7.2. SELECTION CRITERIA FOR A MEDICAL DEVICE COMMERCIALISATION GRANT

In addition to the above, applications for a MDCG must address:

- technical viability of a project including manufacturing options, and scalability;
- evidence of an addressable market opportunity;
- route to market options;
- financial model and funding options to commercialise the project; and
- regulatory compliance plan.

08 Post Approval Administration and Evaluation

- Successful applicants will be required to report on the outcomes of the project in accordance with the Funding Agreement.
- Failure to comply with the terms of the Funding Agreement may result in the applicant being required to refund some or the entire grant.
- For the purpose of promoting the MDCP, DTED may publicly release broad project information such as name of successful applicants, the amount of grant funding and a brief project description.

09 Confidentiality and Conflicts of Interest

Protecting applicants’ confidential information is important to DTED. Information provided by applicants will be considered confidential and treated as such by DTED, Flinders University, Flinders Partners, MDPP Partners, MDCP Assessment Panel members, and any third parties from whom advice is sought. Confidential information will only be released with the applicant’s agreement or when required by law.

All DTED, Flinders University, Flinders Partners, MDPP Partners, MDCP Assessment Panel members, and any third parties from whom advice is sought regarding applications, will be required to declare any conflict of interest before having access to confidential information.
Contact us

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