



**NSW Medical Devices Fund
Program Guidelines
2018-19
Round 6**

Office for Health and Medical Research

Overview

This document provides information on the requirements the submission procedure of the NSW Medical Devices Fund 2018-19

Application closing date

5pm 6 March 2018 (Late applications will not be accepted under any circumstances)

Indicative Program Timeline

Please note, dates are subject to change

Activity	Date
Call for Preliminary Applications	18 December 2017
Preliminary Applications close	6 March 2018
Medical Devices Expert Group meets	April 2018
Invitation to submit Full Application	April 2018
Full Applications close	May 2018
Medical Devices Expert Group meets	May/June 2018
Invitation to present to Expert Group	June/July 2018
Successful applicants announced	August 2018

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1 Introduction to the Medical Devices Fund

1.1 Background

The NSW Health and Medical Research Strategic Review recommended that NSW be enabled to contribute to the discovery and application of new treatments and diagnostic techniques and devices that will be major contributors to health reform into the future (*Recommendation 5.1*). The NSW Government established the Medical Devices Fund (MDF) to help encourage and support investment in the development and commercialisation of medical devices and related technologies in NSW.

The MDF is an \$8.2 million per annum, competitive technology development and commercialisation program funded by the NSW Government, through the NSW Ministry of Health. In the 2018-2019 financial year the Fund has over \$8 million available.

The key objective of the MDF is to promote new and innovative medical devices/technologies within NSW that may have a global benefit.

Broadly, the MDF aims to:

- provide support to individuals, companies, public and private hospitals, medical research institutes, universities, other public sector research organisations, and the medical devices industry, to take local innovation to market; and
- increase the uptake of NSW medical devices by the health system where they are cost effective and contribute to improved patient outcomes.

1.2 Principles

The following principles will apply to the MDF:

- The project must be capable of potentially:
 - improving patient care and/or health wellbeing;
 - generating, economic, social and/or environmental benefits to NSW
- Funding will be open, competitive and merit based, while maintaining commercial-in-confidence requirements
- Funding can be used for purposes including:
 - proof-of-concept, prototyping and piloting studies
 - manufacturing samples for product trials;
 - conducting market and product assessments;
 - engaging a consultant to locate other national and international trials and research relevant to the product under development; and
 - conducting clinical assessments.
 - The Fund will support a cross-section of products across a range of applications throughout the medical device product life-cycle (Technical Device concept demonstrated to marketing).
- The Fund will not support activities which are deemed to be research
- The MDF Expert Group will have sufficient flexibility to tailor funding support according to what it believes is required to assist the development and commercialisation of a medical device.

2 Medical Device Definition

The Medical Devices industry is defined as including those companies and organisations that develop, produce or supply devices or parts of devices that are regulated as medical devices by the TGA. The *Therapeutic Goods Act 1989*, as amended, defines a medical device as:

- (a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
- i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
 - iii. investigation, replacement or modification of the anatomy or of a physiological process; or
 - iv. control of conception, and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; or
- (b) an accessory to such an instrument, apparatus, appliance, material or other article.

For the purposes of the MDF, the definition of a medical device includes those technologies that have a patient application which will impact the health system that are not considered to be drugs. These include technologies such as ‘omics’ technologies, apps, virtual technologies, remote diagnostics and nanotechnologies.

2.1 Applicants

The MDF can be accessed by eligible NSW organisations with innovative medical devices/technologies supported by intellectual property. Eligible organisations include public and private hospitals, medical research institutes, universities, start-ups and established SMEs.

An applicant must be:

- A financially viable company or commercial enterprise based in NSW (e.g. location of manufacturing jobs, headquarters based in NSW, NSW investment,) and be able to provide evidence that the proposal connects and benefits NSW; have an Australian Business Number (ABN); typically with an annual turnover of less than \$25 million; and is a legal entity; or
- An individual who agrees to form such an entity so that NSW Government can enter into legally binding funding agreements; or
- A NSW public research organisation applying through its appropriate technology transfer office, or the CEO or equivalent of the research organisation

2.2 Projects

Projects throughout the medical device product life-cycle will be considered from a minimum Technology Readiness Level 3 (Technical proof of concept demonstration – see Appendix 1). A risk mitigation approach to funding will be undertaken as it is acknowledged that funding for a medical device at the technical proof of concept phase is a much higher risk from the point of view of return on investment than funding for market ready product.

To be considered for the MDF, the project:

- Must satisfy the definition of a medical device
- Must seek to progress a medical device along the commercialisation pathway
- Must be innovative (i.e. new to market, or new to world)
- Should have the potential to assist health delivery in NSW
- Must have been developed in NSW and derive health, economic, social and/or environmental benefit to NSW

3 Application Process

Applications are called for once a year, and there is a three stage application process:

- a) **Mandatory Self-Assessment** – this is an online form that acts as an early filtering process before the preliminary application is submitted. This process will explicitly define what is required of the applicants to be competitive and measure the technology readiness level of their device. A short summary of all assessments will be provided to the MDF Expert Group. This assessment will provide applicants an early indication of what the MDF Expert Group will be reviewing in terms of the strengths and weaknesses of a proposal. It is strongly recommended that applicants consider the results of this stage before submitting a preliminary application.

The mandatory self-assessment must be submitted with the preliminary application.

Preliminary Application – this is an early screening document of no more than 4 pages that allows the MDF Expert Group to determine eligibility, review the opportunity and assess the quality of the application.

- b) **Full Application** – the MDF Expert Group will determine if a Preliminary Application will proceed to a Full Application. This is a more detailed document of 10-20 pages that covers all aspects of the opportunity. Applicants may be required to present the proposal or be interviewed. This stage is by invitation only.

To be eligible to be invited to submit a Full Application, applicants must submit the mandatory self-assessment and a preliminary application.

The application forms are available online from the Office for Health and Medical Research website: <http://www.health.nsw.gov.au/ohmr/mdf/Pages/mdf-applications-for-funding.aspx>.

Submission of Applications

Applicants must submit one electronic copy of their application and 13 hard copies of the application in the requested format for each stage.

Hardcopies (and attachments) must be double-sided, hole punched, clipped but NOT stapled or bound.

The Office for Health and Medical Research requires all hard copies to be formally lodged (i.e. in person, signed courier or registered post).

Hard copies should be sent:

By mail to:

Ms Anne O'Neill
Director
Office for Health and Medical Research
NSW Ministry of Health
LMB 961
NORTH SYDNEY NSW 2059

OR

In person or by courier to:

Ms Anne O'Neill
Director
Office for Health and Medical Research
NSW Ministry of Health
73 Miller St
NORTH SYDNEY NSW 2060

The electronic copy should be emailed to: medicaldevicesfund@doh.health.nsw.gov.au

Enquiries may be directed to:
Office for Health and Medical Research
Tel. (02) 9424 5911

Both electronic and hard copy Online Self-Assessments and Preliminary Applications must be received by COB (5.00pm) on the due date.

4 Assessment Process

The MDF sub-group, which supports the MDF Expert Group, will conduct an initial review of the Mandatory Self-Assessments and Preliminary Applications and will provide the Expert Group with advice regarding the eligibility and quality of the applications against the agreed criteria.

The MDF Expert Group will take this advice into consideration when reviewing the applications and determine which applications will proceed to Full Application. The MDF Expert Group reserves the right to refer proposals to the Secretariat for further discussion and development with applicants. It will convene at most three times a round depending on suitable applications to review.

All applications and supporting material will be treated commercial-in-confidence. If applications progress to Full Application an independent clinical expert review will be undertaken. An independent financial review will also be undertaken. Advice will also be sought from other relevant commercialisation experts, science and technical experts as required. All parties will be required to agree to the same confidentiality undertaking when reviewing applications.

The Office for Health and Medical Research will provide the secretariat for the MDF sub-group and MDF Expert Group.

5 Selection Criteria

The MDF Expert Group will evaluate grant applications against information and evidence provided in relation to the following selection criteria. The application will be assessed against the extent to which it meets the Selection Criteria below.

5.1 Applicant

1. A NSW-based organisation supportive of the technology applying for funding
2. The organisation's interest/involvement in the opportunity must have initially been derived from the activities of their researcher(s)/employee(s)
3. The organisation must benefit from the MDF investing in the opportunity. However, the benefit need not be financial
4. The organisation researcher(s)/employee(s) to have some ongoing role in the development of the technology
5. The organisation will derive financial benefit if the technology is commercialised
6. The organisation receiving some of the funding to complete project activities
7. The organisation will gain recognition/kudos if the technology is commercialised and will benefit from publications relating to the work to be funded

5.2 Project

1. Demonstrate the potential state, national and/or international significance of the medical device and show how it will improve people's health and well-being
2. Demonstrate how the medical device will potentially deliver economic, social and/or environmental benefits for NSW

3. Demonstrate how the medical device will result in:
 - a. Improved clinical outcomes
 - b. Improved practice efficiency or effectiveness
 - c. Improved ease of use
 - d. Improved quality
 - e. Improved safety

All submissions will be assessed against the Australian regulatory requirements for medical devices (TGA).

Sufficient information and evidence must be provided by the applicants to enable the MDF Expert Group to undertake a diligent review of the applications without the need to source significant further data/information to evaluate the submission.

6 Duration, Size and Payment of Grants

6.1 Grant duration and size

Funding will be in the range of \$200,000 to \$5 million, depending on the product's stage of development, over a period of one to three years.

Depending on the value of the grant provided through the Fund, the Ministry of Health may elect, through the individual agreements with grantees, to either require repayment of a proportion of the grant provided once the recipient earns a profit through the commercialisation of the device. The specific terms of this repayment/payment, such as time period, percentage of either grant, interest and other factors would be agreed on as part of the contract negotiations.

6.2 Payment of Grants

Payment of grants awarded under the MDF will be made directly to the applicant's organisation.

7 Reporting and Accountability Requirements

Successful applicants will be required to sign a Funding Agreement that outlines the State's obligations in relation to the flow of funds and the grant recipient's obligations in relation to reporting and accountability.

All information provided in support of MDF applications may be subject to external audit under the Funding Agreement.

Organisations will be awarded funding for one term at a time. The organisation must fulfil its obligations as set out in the Funding Agreement to receive funds for subsequent years within the funding period.

An authorised signatory from research organisations awarded grants under the MDF will be required to sign the Funding Agreement with the State before funds are made available.

8 Appendix 1 – Technology Readiness Level Scale

TRL	TRL Description	Evidence of Achievement
1	Basic principles observed and reported	Published research that identifies the principles that underlie this technology
2	Technical Device concept formulated	Practical applications (e.g. devices) of the basic principles are invented
3	Technical proof of concept demonstration	The basic performance of the invention is demonstrated in a laboratory setting
4	Alpha prototype validation in laboratory environment	A simple prototype is developed and its performance is demonstrated in a laboratory environment. The performance indicates its potential for solving a clinical need
5	Beta prototype validation in clinical environment	A more advanced prototype is developed and its performance is demonstrated in a clinical environment and further clinical feedback is gained for the final design phase
6	Final Device design validation with clinical pilot study	The design of the device is frozen and a small number of devices are manufactured and a clinical pilot study is conducted by a key opinion leader. A pilot study report is prepared showing the results of the study
7	Device from pilot manufacturing line is being clinically trialed in multiple geographical locations	A larger sample of devices are manufactured and sent to multiple clinical sites in different geographical locations for clinical trials. The reports from these trials will be used for submissions to regulatory authorities (e.g. TGA, CE, FDA)
8	Device is partially approved and in clinical use	The device has been approved in limited geographical regions and is in clinical use in those regions
9	Device is fully approved and in clinical use worldwide	The device is approved for use worldwide and is in clinical use worldwide