SOUTH AFRICAN MEDICAL RESEARCH COUNCIL & TECHNOLOGY INNOVATION AGENCY JOINT MEDICAL DEVICES & DIAGNOSTICS SEED FUND PROGRAM

Under the auspices of

MEDICAL DEVICE AND DIAGNOSTIC INNOVATION CLUSTER

Request for Applications (RFA):

SAMRC-RFA-GIPD-02-2022

Release Date: 7 November 2022

Closing Date: 28 November 2022

1. Introduction

The mission of the South African Medical Research Council (SAMRC) is to improve the nation's health and quality of life by conducting and funding relevant and responsive health research, development, innovation and research translation. The SAMRC is the largest local funder of health research in Southern Africa and supports high quality research, innovation and capacity development through a variety of grant programs and strategic partnerships.

The Technology Innovation Agency (TIA) is a national public entity that serves as the key institutional intervention to bridge the innovation chasm between research and development, and commercialization. TIA achieves this through facilitating the translation of South Africa's knowledge resources into sustainable socio-economic opportunities that improve the quality of lives for all South Africans.

The Medical Device and Diagnostic Innovation Cluster (MeDDIC), hosted by the SAMRC under the Global Health Innovation Accelerator (GHIA) program, is a national initiative created to exploit a high concentration of skills, expertise, infrastructure and companies across South Africa within the medical devices field. The initiative, supported by TIA and the Department of Science and Innovation (DSI), is aimed at stimulating and intensifying technology innovation within the sector as well as encouraging an integrated ecosystem in support of increasing the competitiveness of the industry.

Medical devices and diagnostics are at the core of public health interventions and play an essential role in meeting the needs of patients and providers in delivering quality outcomes. According to the WHO, high-quality, safe and appropriate priority medical devices are essential tools for the prevention of death or disability, and for managing the diseases of poverty. The use of medical devices impacts on the continuum of care under the universal health coverage strategy. Their role is not restricted to diagnosis and treatment but is also required in the constant management and monitoring of on-going health.

Currently South Africa imports more than 90% of medical devices by market value, which negatively impacts on the country's trade balance. A landscape analysis of the medical devices sector undertaken by the SAMRC (www.samrc.ac.za/reports/samrc-medical-devices-landscape-report) revealed that 77% of respondents from the medical devices manufacturing sector were active in research and development and around 48% had collaborated with science and technology institutions either locally or abroad. Similarly, 60% of the universities and science councils surveyed indicated that they engage in collaborative partnerships with medical device companies on their medical device projects, with half of them having local partners, 30% international partners, and 20% both local and international partners. Despite this, only 11 medical device manufacturers (17% of respondents) indicated that they had co-developed products with or licensed products from research institutions. Substantial interest was expressed by respondents from both the manufacturing and academic sectors in increasing collaboration between the sectors.

MeDDIC aims to increase the level of successful innovation within the medical devices and diagnostics sector leading to novel high quality medical device and diagnostic products that address local health priorities and simultaneously build the local manufacturing industry. Through the current call for applications, MeDDIC strives to increase collaboration between academia and industry for the development of new or improved products, facilitate the development of medical devices and diagnostics of particular relevance to South Africa and other low- and middle-income countries, and increase local manufacture in the sector to stimulate job creation and economic development.

2. Funding Opportunity Description

MeDDIC is seeking to fund late-stage product development projects with the following key attributes:

1. Aimed at developing a new or improved **medical device or diagnostic** that addresses a **global health priority**. Specifically, the new innovation should address a key health need / priority in South Africa and other low- and middle-income countries (LMICs) and should have:
    - relevance to the disease burden in LMICs;
    - relevance to the context (health systems and resource availability) in LMICs;
    - the potential to significantly impact on health outcomes; and
    - the potential to reduce the costs of healthcare.
2. Involves a collaboration between academia (university or science council) and industry (preferably a small, micro or medium enterprise), with the academic institution as the lead applicant.
3. Has already achieved proof of concept (Technology Readiness Level 3 or above).
4. Brings together all the required expertise and capability to develop, test, register and commercialize the new or improved medical device or diagnostic.
5. Aims to deliver a product ready for commercialization within a maximum of 12-18 months.
6. Will result in a product that is competitively priced and rapidly scalable in terms of manufacture and deployment.

Budgets submitted in response to this RFA should not exceed R1,000,000 (excluding VAT) over 12-18 months. Given the limited funds available for this RFA, it is expected that the budgets in the applications will be substantially subsidized through co-funding, contributions from the applicant organization(s) and/or leveraging / repurposing of existing resources, i.e., the projects will not be funded at full cost.

The following are eligible activities that may be included in the applications:

- development / improvement of a prototype
- product/design refinement
- development of a comprehensive technology package
- product testing (clinical testing and/or testing of product characteristics)
- user testing
- production of testing and/or market samples
- piloting and technology scale-up
- preparation of technical and manufacturing documentation
- certification or regulatory registration
- techno-economic evaluation studies

Proposals must, however, outline all necessary steps towards development, testing, and commercialization of the product.

The following are <u>non-fundable activities / non-eligible costs:</u>

- early-stage research projects
- salary contributions to the applicant's staff members who are working on the project and/or who form part of the general operating budget staff
- equipment, except for essential specialized equipment that is within the budget constraints and required to enable qualifying activities
- working capital
- operational costs such as rent, administration, grant management, etc.
- overheads

The focus will be on funding direct development costs and budgets should not include any major infrastructure costs. Value added tax (VAT) will be applicable to the grant totals and all expenses must be budgeted exclusive of VAT.

2.1 Important Considerations

- Projects must meet at least criteria 1- 3 stipulated above to be considered for funding.
- Preference will be given to projects that also meet criteria 4 - 6 above.
- Preference will be given to projects led by historically disadvantaged individuals and/or institutions.
- Projects will be supported for a maximum period of 18 months and should be budgeted accordingly.
- Projects will be prioritized for funding based on technical and commercial merit and relevance to the objectives of the call.
- Funding levels must be commensurate with the proposed work and timeline.
- Funding will be provided by way of grants, however, the SAMRC and TIA reserve the right to share in benefits from the commercialization of the funded product for reinvestment in public research and innovation in proportion to their contribution.
- The SAMRC and TIA reserve the first right of refusal to fund further development of the outputs of the project.
- Recipients must undertake to ensure access of the resulting products to those most in need in developing countries and to use all reasonable efforts to manufacture locally.

3. Eligibility

This is an open call for proposals from innovators at South African universities, science councils (including the SAMRC) and other similar research/ public organisations, including any institution approved by the Minister of Higher Education Science and Technology for NRF funding, that are collaborating with South African private/ for-profit small, micro and medium enterprises to develop and commercialize a new or improved medical device or diagnostic. The academic institution must be the lead applicant.

Entities that have not previously received grant funding from the SAMRC will be subject to due diligence before the award of funds.

Foreign entities are not eligible to apply for funding through this RFA but may be included as collaborators if they provide a service, technology or capability that is not available among the project partners or among other eligible organizations.

In addition to the above, the project leads must be South African citizens or permanent residence holders. While there is no limit to the number of applications submitted per organization, any individual may only be the project lead on one application.

4. Application Process and Timeline

It is critical that applicants follow the instructions in this RFA. **Applications will not be processed further or considered for funding if they:**

- Are deemed non-responsive to the parameters of, and/or do not meet the criteria specified in this RFA
- Are received after the deadline for submission
- Are incomplete, i.e., do not have **all** sections of the proposal and budget templates completed and all requested supporting documents attached
- Are from non-eligible organizations or individuals

All applications must be submitted using the MeDDIC Proposal and Budget templates available on the SAMRC website. The length of the application should not exceed 15 single-spaced A4 pages, excluding annexures, using Arial 11 font. The submission must include the following:

- The fully completed Proposal Template signed by the relevant authority at the organization and the Project Lead – the proposal may be submitted as a Word document with a separate scanned pdf with signatures or a converted pdf document with signatures. Signed documents submitted after the closing date and time will not be accepted.
- The fully completed Budget Template in Excel
- CVs of the Project Leads from the applicant and co-applicant

The full set of application documents must be emailed to meddic@mrc.ac.za by 6 pm SA time on 28 November 2022. Any applications received after this date and time will not be accepted.

The timelines for the application process are shown in Table 1.

Table 1 Application timelines:

RFA Release Date	**7 November 2022**
Application Due Date	**28 November 2022, 6pm SAST**
Peer Review of Applications	**December – January 2023**
Internal Approvals	**February 2023**
Notification of Awards	**March 2023**

For more information on this Seed Fund Program please go to *General Guidelines for the SAMRC-TIA Joint Medical Devices and Diagnostics Seed Fund Program* and on the SAMRC's General Terms and Conditions of Funding please go to https://www.samrc.ac.za/funding/samrcfunding.

5. Review and Evaluation of Proposals

There will be a two-step review and evaluation process:

1. Internal SAMRC screening for responsiveness to all the specified criteria, administrative and procedural requirements in the RFA.
2. Independent peer review to assess the relevance, technical and commercial merit (and other review criteria as specified below) of applications found to be responsive to the RFA.

5.1 Internal screening

All applications will be screened by the SAMRC for completeness and responsiveness to the RFA and its administrative requirements/provisions. If the application is found to be incomplete or unresponsive to the provisions and criteria described in the RFA, or was submitted after the deadline, the application will not be processed further.

5.2 Peer review

Each responsive and complete application received by the due date will be reviewed by independent reviewers, taking into account at least the following criteria:

- Relevance and potential impact of the product
- Technical feasibility and likelihood of success
- Timeframe to completion of market-ready product

- Compatibility with existing infrastructure and capabilities for development and manufacture
- Scalability, portability, cost /competitiveness and commercial feasibility
- Track record of the organization/team
- Demographics of the team, with preference for teams led by individuals from previously disadvantaged backgrounds and/or institutions
- Budget

6. Selection of Awardees

The award of grants emanating from this call will be determined by a committee convened by the SAMRC and TIA and the respective Executive Management Committees from the 2 organizations, taking into account the recommendations of the peer reviewers. Additional factors, such as geographical and institutional diversity and transformation / BBBEE may be considered in making a final determination on funding awards. Based on the merit of the applications and/or budget limitations, the SAMRC may award fewer or more grants than expected and may elect not to allocate all of the available funds to awards from this RFA.

7. Important Information

- The SAMRC may seek to verify any information provided by applicants through independent research or by third parties approved by the SAMRC.
- The SAMRC assumes no responsibility for costs incurred in responding to this RFA or any further invitations or communications.
- The SAMRC reserves the right to amend or withdraw the RFA at any time.
- Successful awards may be subject to addressing reviewer comments and/or negotiation of project plans and budget.
- Grants will be paid to the institution/organization where the project lead is employed, as set out in a funding agreement to be concluded between the parties.
- The SAMRC reserves the right to withhold grant funds until proof of the necessary ethics and regulatory approvals for the project have been provided to the SAMRC, where relevant. Should the investigators fail to obtain the necessary approvals within a reasonable time period, the SAMRC reserves the right to withdraw the award.
- The SAMRC may use text, video or other visual representation submitted by successful applicants on the SAMRC website or on SAMRC materials for publicity and/or public awareness.

8. Compliance with POPIA

As of the 1st of July 2021, the new Protection of Personal Information Act (POPIA) came into full effect. The law is designed to protect how all juristic persons use, store and process data. You can read the full details on the act here: https://popia.co.za/.

The SAMRC as a responsible statutory science council complies with POPIA. The SAMRC will receive personal information through the proposals/applications submitted to the SAMRC in response to this RFA. The personal information requested on the proposal template is necessary for the SAMRC to fully evaluate the proposal for funding. This information will be shared with external reviewers, as well as the SAMRC management for the purposes of processing the project proposals. The SAMRC will process this personal information strictly in accordance with POPIA. The SAMRC undertakes specifically to process the personal information on the basis that (a) it was provided voluntarily and (b) the information will be processed only as far may be necessary and within the limitation and ambit of the purpose of evaluating the proposal/application for funding *(i.e., the purpose with which the personal information was received)*. The SAMRC confirms that it is lawfully processing the information since the purpose of processing is to seek

quality proposals for funding which the SAMRC is mandated to do in terms of Section 4 of the SAMRC Act 58 of 1991, thus the SAMRC is fulfilling its legislated and lawful mandate, and strategic objectives as provided for in the SAMRC Act.

By submitting your project proposal to the SAMRC you acknowledge and agree to the use of your personal information as outlined above. Should you not approve of such use of your personal information then please refrain from submitting an application.

9. Contact Details

Please direct any requests for information and questions/queries on this RFA **by email** to:

Ms Grace Baloyi
Grants Innovation and Product Development (GIPD)
email: grace.baloyi@samrc.ac.za