भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार
Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 27/05/2022

Expression of Interest (EOI) for Accelerating Medical Device & Diagnostics Product Development and Scale-up under "Product Ignition & Development Enabler (mPRiDE) Program" of Medical Device and Diagnostics Mission Secretariat, ICMR

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. ICMR has always attempted to address itself to the growing demands of scientific advances in biomedical research on the one hand and to the need of finding practical solutions to the health problems of the country, on the other.

The Indian Medical device market is currently valued at USD 11.2 billion and is experiencing a growth rate of 15% CAGR and is poised to be USD 50 billion by 2025. India is dependent on imports for its medical device needs with about 80% of medical devices being imported. In view of the huge import, dependency and long technology development cycle of medical devices, there is an urgent need for providing holistic support across the medical device development and commercialization cycle including R&D, scale-up, validation, regulatory compliance, market access etc.

To cater to the above challenges, ICMR has established Medical Device and Diagnostics Mission Secretariat (MDMS) at ICMR-Hqrs with a vision to support and catalyze research, development and indigenous manufacturing of cost-effective medical devices to strengthen health care sector in India and reduce import dependency through a Mission mode consortia approach. MDMS will incentivize and motivate local manufacturing in India and provide holistic support to the technologies/ products nearing commercialization.

Scope

ICMR invites Expression of Interest (EOI) from experienced Indian companies in joining hands with ICMR in accelerating development of medical device and diagnostic products and their scale-up, thus catalyzing their commercialization for public use. The priority medical device & diagnostic products significantly contributing to imports were identified by ICMR under the *P*Roduct *I*gnition and *D*evelopment *E*nabler (mPRiDE) program of MDMS. Companies which have extensive experience and demonstrated capabilities in developing products in the specified technology segment as given below are encouraged to put-up their application under this program. The medical device technologies at advanced stage of development will be supported through this Program. Subject to the terms and conditions of an agreement, ICMR-MDMS shall support indigenous development, scale-up and pilots of *Make-in-India* manufacturing of critical medical device and diagnostic products. Based on the recommendations of the Expert Committee the applications for manufacturing Make-In-India products in following areas will be duly considered for extending support:

- **Chronic Obstructive Pulmonary Disorders (COPD)**
- **Maternal, child healthcare and nutrition**
- **Remote Monitoring Devices**

Eligibility
The proposals can be submitted by:

a. Company (Start-up, Small, Medium or Large) incorporated under the Companies Act, 2013 having a minimum of 51% of the shares of the Company to be held by Indian Citizens (Indian passport holders).

b. Limited liability Partnership (LLP) incorporated under the Limited Liability Partnership Act, 2008 having a minimum half of the persons who have subscribed their names to the LLP document as its Partner should be Indian citizens (NOTE: The applicant Company/LLP should have adequate in-house facility to address the project implementation or should have suitable tie-ups for manufacturing of the product in a manufacturing facility compliant with current medical device regulations). The Company should have a DSIR certificate or should be incubated with any of the recognized incubation facility with suitable tie-ups for product manufacturing.

c. The applicant should have demonstrated capabilities of product development and scale-up.

d. The Company should have been in existence for the last 3 years working in the area of medical device or diagnostics product development and commercialization.

When and how to submit a proposal:

1. The "full length research (detailed) Ad-hoc proposal should be submitted through online mode only on **https://epms.icmr.org.in** and no proposal in physical/hard copy/email is to be submitted.

2. Detailed information, terms & conditions and guidelines for the mPRiDE Proposal are available on https://mdms.icmr.org.in/programs/mpride

Date of Submission of Proposal:

Start Date: 27/05 / 2022 **Time:** 05:00 PM
End Date: 17/06/ 2022 **Time:** 05:00 PM

In case of any query you may contact the following officials:

mPRiDE Program and EoI Related Queries	**e-PMS Related Queries**
Dr. Sarla Naglot, Scientist 'B' Medical Device and Diagnostics Mission Secretariat (MDMS) ICMR, New Delhi Email: naglot.s@icmr.gov.in, icmrmdmsoffice@gmail.com, Telephone No.: 91-11-26588895 Ext:337	**Dr. Lokesh Sharma,** Scientist 'E' Division of Biomedical Informatics, ICMR, New Delhi Email: po.epms@icmr.gov.in Telephone No.: 011-26589571

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Medical Device and Diagnostics Mission Secretariat (MDMS)

medtech -PRODUCT IGNITION AND DEVELOPMENT ENABLER(mPRiDE)

Enabling Medical Device & Diagnostics Product Development and Scale-up

Scheme Guidelines
Version 1: February 2022

MEDICAL DEVICE & DIAGNOSTICS MISSION SECRETARIAT, ICMR
Nurturing Medtech Ecosystem

INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

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1. About the Medical Device and Diagnostics Mission Secretariat

The Indian Medical device market is currently valued at USD 11.2 billion and is experiencing a growth rate of 15% CAGR and is poised to be USD 50 billion by 2025. India is dependent on imports for its medical device needs with about 80% of medical devices being imported. In view of the huge import, dependency and long technology development cycle of medical devices, there is an urgent need for providing holistic support across the medical device development and commercialization cycle including R&D, scale-up, validation, regulatory compliance, market access etc.

To cater to the above challenges, ICMR has established Medical Device and Diagnostics Mission Secretariat (MDMS) at ICMR-Hqrs with a vision to support and catalyze research, development and indigenous manufacturing of cost-effective medical devices to strengthen health care sector in India and reduce import dependency through a Mission mode consortia approach. MDMS will incentivize and motivate local manufacturing in India and provide holistic support to the technologies/ products nearing commercialization.

The implementation of MDMS will involve comprehensive approaches including the following:

Bottom-up approach for supporting Product Development and Commercialization through the Product Ignition and Development Enabler Program (mPRiDE) and ICMR-DHR Centers of Excellence (CoE).

1.2 Top-down approach for supporting creation of Pipeline of Innovative Medical Device Technologies by Catalysing and Leveraging Innovation in Medtech Biodesign (CLiMB) Program.

About the Product Ignition and Development Enabler Program in Medtech Sector (mPRiDE):

This program aims to financially support and accelerate development of medical device products by catalyzing their commercialization for public use. This Program will accelerate medical device product development and commercialization through partners/companies which have extensive experience and demonstrated capabilities in developing similar products in the specified technology segment.

The medical device technologies at advanced stage of development will be supported through this Program.

Special calls will be announced under the Product Ignition and Development Enabler Scheme, under the ambitious Medical Device and Diagnostics Mission Secretariat to accelerate development, scale-up and pilots of critical medical device and diagnostic equipment's specified technology areas from time-to-time.

2. Processes and Terms related to mPRiDE Program

Key Features of the Program

(a) The theme of the current RFP is to promote development, scale-up and pilot batch manufacturing of Medical Device and Diagnostics products in any of the following categories:

- Chronic Obstructive Pulmonary Disorders (COPD)
- Maternal, child healthcare and nutrition
- Remote Monitoring Devices

(b) High impact products based on above categories that address medical device import dependency challenge shall be supported.

(c) Products at advanced stage of Technology Development/Commercialization and regulatory readiness shall be preferred for extending funding support. The Technology/ Products in the above product categories specified should be developed at fully functional clinical grade level with regulatory dossier for use on human subjects/patients wherein the Quality assurance certification (like CE)/DCGI approval is either applied for or granted. Manufacturing License for the product development should be either applied for or has been received from the CDSCO.

(d) The projects aimed at manufacturing and up-scaling high impact products in the area of medical device and diagnostics in the above priority areas shall be supported under this call.

Eligibility:

The proposals can be submitted by:

a. Company (Start-up, Small, Medium or Large) incorporated under the Companies Act, 2013 having a minimum of 51% of the shares of the Company to be held by Indian Citizens (Indian passport holders).

b. Limited liability Partnership (LLP) incorporated under the Limited Liability Partnership Act, 2008 having a minimum half of the persons who have subscribed their names to the LLP document as its Partner should be Indian citizens *(NOTE: The applicant Company/LLP should have adequate in-house facility to address the project implementation or should have suitable tie-ups for manufacturing of the product in a manufacturing facility compliant with current medical device regulations). The Company should have a DSIR certificate or shouldbe incubated with any of the recognized incubation facility with suitable tie-ups forproduct manufacturing.*

c. The applicant should have demonstrated capabilities of product development and scale-up.

d. The Company should have been in existence for the last 3 years working in the area of medical device or diagnostics product development and commercialization.

Duration of project

The funding is provided for a period of up to 18 months. The project will be implemented in a milestone based manner.

Extension: Extension of grant award duration is discouraged. Request for extension of milestone/project can be considered (without any additional financial implications) only in selected cases based on recommendation of the Review Committee conducted by ICMR. However, such request with proper justification must reach ICMR well before the scheduled date of completion of grant award period.

Application Process

The full length research (detailed) Ad-hoc proposal should be submitted through online mode only on **https://epms.icmr.org.in** and no proposal in physical/hard copy/email is to be submitted.

Month of Announcement: May, 2022

Call Duration: The call will be open for 20 days following Last date of Submission of Proposals by (5.00 pm), when open**.**

Selection Process

The applications received will be subjected to basic eligibility check. Stage wise screening of applications will be done by relevant Committees with domain experts.

a) Initial Stage: At this stage, proposals will be examined for preliminary technical strength and suitability of translational and scale-up potential by internal due – diligence.

b) Short listing Stage: This stage will have review of applications by a team of experts.

c) Recommendation Stage: At this stage, final shortlisted companies may be called for presentation via VC before an Expert Panel.

d) Financial Due-Diligence

Evaluation Criteria

The evaluation of proposals received will include following criteria at each step of selection:

1. Technical Rigor
2. National/Societal Impact
3. Frugality
4. Stage of product development
5. Experience and Track record of the Applicant
6. Readiness for Product Deployment at Scale

Funding Mechanism

1. The funding support under the present scheme is in the form of grant-in-aid.
2. Extent of funding is up to **INR 1.5 Crore**, based on merit.
3. The fund allocation is milestone based and shall be released in installments based on review of the milestones achieved.

Utilization of Grant Money

1. Development of Product (including outsourcing activity)-Up to 90%
2. Contingency: 10%

Signing of Agreement and Fund Disbursement

Agreement of funding

On announcement of Grant Awardees, an Agreement needs to be signed by the Fund Recipient and the ICMR-MDMS. Format of the Agreement shall be provided to the Grant Awardees by ICMR.

Other Requisites for Funds Disbursement

In addition to signing of the Agreement, the fund recipient needs to open up a No-Lien Account with a scheduled/nationalized Bank before release of first installment.

Mentoring, Monitoring and Review

1. ICMR-MDMS shall provide mentoring and monitor the progress of grant recipients periodically.
2. ICMR-MDMS shall organize and conduct:
    - Technical review of the Progress made by the Grant Recipients by ICMR-MDMS Review Committee
    - Site Visit, if required for review of projects by SITE Visit Committee
3. Final Review will be done by ICMR towards completion of the project

Transfer of Award Grant: The award grant is non-transferable.

Foreclosure and Termination

1. In case, during the Project Duration, if it is found that the Project or any Project component is not likely to lead to successful completion, ICMR may decide to foreclose the Project or a specific Project component as warranted. The decision of ICMR shall be final in all respects. If the Fund Recipient likes to continue the Project at its own cost, it would be able to do so without restrictions from ICMR after complying with these provisions.

2. The Fund Recipient may, before the completion of the Project, terminate the project by giving one month's notice in writing to ICMR. ICMR may also terminate the Agreement for Award of Grant by written notice in the event of "the Fund Recipient" committing breach of any term of the Grant and either not rectifying it to the satisfaction of ICMR or not satisfying ICMR about its inevitability within a specified period. In the event of termination of the Agreement for Award of Grant, no further disbursement shall be made by ICMR.

Acknowledgement of ICMR support

The fund recipient is obliged to acknowledge the assistance of ICMR while publishing, marketing the resultant Product or presenting in any manner the details of the Project, its progress or its success along with a "Disclaimer" that reference therein: to any specific commercial product, process, views or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or assuming liability of any sort by the ICMR. Use of ICMR logo is not permitted without written approval from ICMR.

Intellectual Property Ownership:

Intellectual Property, technology know-how generated during the present projects shall be owned by the award grantee.

Data Sharing with ICMR-MDMS Partner:

Information submitted by the applicants as part of the proposal under the mPRiDE Program may be shared with ICMR-MDMS partner. ICMR-MDMS partner will be an integral part of the Scheme implementation.

ICMR-MDMS Partner will execute a Confidentiality Agreement and No-Conflict-of-Interest document with reviewers before sharing any information provided in the current application.

Expected Deliverables:

The scheme's mandate is to promote and accelerate development, scale-up and pilot's production of critical medical device and diagnostic products required hugely contributing to imports. Suitable quantum of the Made-In-India products developed and ready for deployment shall be expected from the grant awardee. The quantum of products expected to be manufactured by the awardee shall vary with the product category. Failure to do so within 1.5 years from the project term, the grantee shall be requested to return the funds back to ICMR.

For any Queries, please contact ICMR for the Current Call:

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Medical Device and Diagnostics Mission Secretariat (MDMS)
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New Delhi - 110029, India
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