# Expression of Interest (EoI) for Batch Manufacturing of Medical Devices & Diagnostics for Clinical Investigation

INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR)
Division of Development Research
New Delhi

## Background

The Indian Council of Medical Research (ICMR), under the Department of Health Research (DHR), is the apex body for biomedical research in India. In alignment with the vision of Viksit Bharat@2047, ICMR is committed to promote research & development of indigenous medical devices and diagnostics. Hence, it has launched several flagship initiatives—such as MedTech Mitra and Patent Mitra—to provide holistic support for healthcare technologies aligned with national health priorities, especially for infectious diseases and pandemic preparedness.

Test batch manufacturing is a critical step in the technology development pathway. It bridges the gap between prototype development and full-scale production by validating manufacturing processes, ensuring regulatory-compliant technology for preclinical/clinical evaluation, and mitigating risks before market launch. It helps refine quality, reduce scale-up issues, and accelerate time to market.

## Purpose

The purpose of this EOI is to invite applications from innovators requiring support for test batch manufacturing of medical devices and diagnostics including Software as Medial Device (SaMD).

Subsequently, ICMR will facilitate regulation-compliant preclinical and clinical evaluations of the test batches for selected devices/diagnostics, thereby accelerating their innovation journey and enabling timely market access.

## Scope

Applicants should meet the following requirements:
- Start-ups (DPIIT registered), MSMEs, DSIR recognized R&D, Deemed Universities, NGOs (registered with DSIR and NITI Aayog's NGO DARPAN) or Government Medical Colleges/Research Labs/ICMR Institutes.
- Possess MD-13 license for the proposed technology for test batch manufacturing or provides the same at the time of selection.

Applications for therapeutics & vaccine candidates will be excluded.

## Submission of EoI

All applications must be submitted through the ICMR e-PMS portal (https://epms.icmr.org.in/userLogin).

Steps for submission:

1. Log in to the ePMS portal.
2. Complete the PI profile and institutional details.
3. Navigate to: Proposal submission → EoI → **'Add new EoI proposal'**
4. Fill the EoI form step-by-step and upload all relevant documents.

## Review and Selection Criteria

A selection committee constituted by ICMR will evaluate the applications based on the following criteria:

1. Unmet Need
2. Novelty & Innovation of the product.
3. Alignment with National Health Priorities (especially for infectious diseases).
4. Readiness for Test License (MD-13).
5. Clinical Relevance and Potential Public Health Impact.
6. Techno-commercial evaluation – whether the candidate will have a reasonable marketable relevance.

Decisions of the committee and ICMR's competent authority will be final.

## Fund Release

50% fund release on project initiation followed by 50% fund release upon submission of successful analytical testing report of test batches of the selected technology.

## Deliverable/Output:

The selected applicant advances to regulation-compliant pre-clinical and/or clinical study evaluation stage.

## Expected Outcomes

1. Facilitation of batch manufacturing of indigenous medical devices & diagnostics.
2. Acceleration of preclinical and clinical evaluation by ICMR through MedTech Mitra Initiative.
3. Strengthening India's MedTech ecosystem toward self-reliance.

## Timelines

| Activity | Timeline |
|---|---|
| Release of Call | 01 September 2025 |
| Last Date of Submission | 21 September 2025, 17:30 hrs |
| Review and Selection | Oct 2025 |
| Proposal refinement& final submission of documents | Nov 2025 |
| Approval | December 2025 |

## Contact for Queries

| Concern | Email |
| --- | --- |
| Technical/Application Support | po.epms@icmr.gov.in |
| Scientific Queries | suchita.markan@icmr.gov.in |

**Annexure I - Format for EoI**

1) Details of investigator/ inventor (including name, designation and affiliation of researcher(s):
2) Contact details – phone & email
3) Summary of product (in less than 250 words)**:**
A structured summary should contain the following subheadings: Rationale/ gaps in existing knowledge, Novelty, Objectives, Methods, and Expected outcome.
4) Type of Technology: Medical Device/ *In-vitro* Diagnostics
5) Preliminary work done by the PI including the source of funding (up to 250 words): (Proof of concept as applicable)
6) MD-13 License Status: Issued / Applied
7) Technology Readiness Level (TRL):
8) Methodology: Include objective-wise work plan under the following sub-headings:

a) Number of units/test batch to be manufactured with justification
b) Bench-top Testing and/or Preclinical Study site
c) Project implementation plan (manufacturing and testing as applicable)

9) Inputs on each of the review criteria (upto 500 words each). Documentary evidence to be uploaded for each.

a. Need for the product
b. Novelty
c. Impact on the health condition
d. Techno-commercial evaluation
e. Readiness for Test License (MD-13)
f. Alignment with National Health Priorities

10) In case of EoI from academia/ NGO, please share details of potential technology transfer agreements being planned (in less than 100 words)
11) Describe the future plans for possible product development lifecycle/ clinical development plans (in less than 250 words)
12) Valid DSIR certificate available – Y/ N
13) Current & immediate intellectual property status (upto 250 words).