

Call for funding Clinical Trials by functional Clinical Trial Units under ICMR-Intramural Research Program

Background:

ICMR promotes to conduct academic or non-regulatory clinical trials in ICMR-institutes and intends to support ambitious, rigorously designed, well-powered Randomized Clinical Trials (RCTs) that aim to redefine or improve standard-of-care protocols for various disease conditions. Under its intramural research program ICMR-institutions are encouraged to demonstrate their ability to seamlessly integrate clinical expertise and robust data acquisition, expertise in data analysis and interpretation of results and overall research governance such that the results of the clinical trials will contribute to guidelines developed by the Department of Health Research, Ministry of Health and Family Welfare.

Scope:

The primary goal is to support high-impact, academic or non-regulatory RCTs to achieve statistical significance and generalizability to address any priority health conditions preferably as per the mandate of the respective ICMR-institute.

The research proposals from any medical discipline to evaluate:

1. Medical or surgical treatment options
2. Digital health integrations to improve clinical care
3. Lifestyle, Dietary or Behavioural Interventions

The objectives of proposed clinical trials may be one or more of the following:

- i. Reduce adverse effects
- ii. Increase efficacy
- iii. Reduce costs
- iv. Increase acceptability
- v. Increase feasibility
- vi. Newer indications for an existing medicine
- vii. Precision and stratified medicine

Additional considerations

- **Newer designs:** In addition to classical individually RCTs, investigators are encouraged to use of Bayesian or Adaptive designs that allow for modifications like sample size re-estimation or dropping ineffective arms based on interim results, if these designs are appropriate to answer the research question.
- **Capacity Building:** A key objective is to strengthen the clinical research infrastructure of participating research team from ICMR-institutions.
- **Data acquisition and sharing:** Standardized data collection protocols to collect data using Electronic Case Report Forms (eCRFs) and concurrent transfer of data from all

participating sites to a central data management facility, as well as regular transfer to the ICMR National Research Data Repository is mandatory.

- **Policy Transformation:** The ultimate goal is to generate high-quality evidence that can be directly translated into National Clinical Practice Guidelines by DHR.
- **Cost-Effectiveness Analysis:** We encourage inclusion of a secondary objective to evaluate the economic impact of the intervention to determine if the new treatment is not only better but also affordable for the public health system.
- **Patient-Reported Outcome Measures:** We encourage inclusion of patient-centric outcomes, such as quality of life, functional recovery, and treatment satisfaction.
- **Mechanistic sub-studies:** We encourage mechanistic sub-studies to explain the results of the trial, where possible.

Eligibility Criteria

- **Investigators:** Each proposal must have one Principal Investigator preferably a medical scientist to lead a clinical trial (PI) and one Co-PI from same ICMR institution. Multicentre clinical trials are also encouraged under the scheme.
- **Team:** Scientists (Medical/ Non-medical) preferably from clinical subjects, epidemiologists, laboratory scientists, basic scientists etc. should be part of team. The Technical staff are also encouraged to be part in the PI lead research team.
- **Intrinsic capacity:** Each participating site should have intrinsic capacity to conduct an RCT because no funds will be provided for Contract Research Organizations.

The Two-Stage Application Process

Stage 1: Expression of Interest (EOI)

- **Duration:** 4 weeks.
- **Requirements:** An expression of interest with maximum 4 pages (minimum 12 font) with a brief description of Rationale, Objectives, Design, Population, Intervention, Comparator, Outcomes, Sample Size, Study Implementation Strategy, Budget outline

Stage 2: Full Proposal (Only for selected EOI)

- **Duration:** 4 weeks.
- **Requirements:** Full study protocol, with detailed Rationale, Objectives, Design, Population, Intervention, Comparator, Outcomes, Sample Size, Study Implementation Strategy, Statistical Analysis Plan, Data Management Plan, Ethics Committee approval, and a detailed budget.

5. Funding Framework

- **Grant Ceiling:** Funds will be allocated from research funds allocated to ICMR-institute. Each trial can be proposed up to INR 8 crores. In case of a clinical trial > 8 Cr competent authority of ICMR will take a final decision for funding support if proposal gets shortlisted based on merit. Budget can be proposed as per routine headings of ICMR proposals.
- **Duration:** maximum 4 years (with milestone-based fund release).
- **Allowable Costs:** In addition to costs allowed as per ICMR guidelines, intervention costs and trial insurance costs may also be included.
- The institute are expected to create functional CTUs in institute premises with allocated research grants.
- ICMR institutes may partner with medical colleges or hospitals for patient recruitment if required, and will be allowed to give subgrants to these institutions within the allocated total budget of the trials

Evaluation Criteria

Proposals will be scored by project selection committee using the following criteria:

Criterion	Weightage	Description
Clinical Impact	30%	Will the results of research have a major impact on clinical care? Are they likely to have a large impact on Disability-Adjusted Life Years?
Study Design	30%	Is the proposed methodology and statistical power robust?
Feasibility	20%	Can the sites realistically recruit the required number of participants and collect the required data with high quality?
Collaborative Strength	20%	Multidisciplinary expertise and experience of the PI and the investigators of the multi-centre network.

Timeline for the Call

1. **Launch Date:** February 6, 2026.
2. **EOI Submission Deadline:** March 9, 2026, 17:00hrs.

Steps for the submission of the EoI:

1. After completing mandatory section of PI profile on i-ePMS portal (<https://i-epms.icmr.org.in>), click on “Proposal Submission” → Click on EOI → Click on the green tab “Call for funding Clinical Trials by functional Clinical Trial Units under ICMR Intramural Research Program” to apply for new proposal → Fill the form step by step.
2. Kindly ensure that all sections are adequately filled with the necessary details.
3. PI’s are advised to submit proposals well ahead of the last date, since servers may be overloaded and slow to respond on the last day of submission.