

Expression of Interest

Indian Council of Medical Research, New Delhi

Invites EoI from ICMR-INTENT centres for

Collaboration in the design and conduct of Clinical Investigation studies

for Medical Devices and In-Vitro Diagnostics

Invitation of expression of Interest

The Indian Council of Medical Research (ICMR), New Delhi, is pleased to invite Expressions of Interest (EoI) from ICMR Indian Clinical Trial and Education Network (INTENT) centres for the purpose of design and conduct of clinical investigation of medical device ‘CerviScan’.

Schedule of EoI:

☐ Date of Publication: 08 July 2025

☐ Last Date of Submission: 31 July 2025

Interested applicants may submit required information through a Google form, the link for which is available at the end of this document. Please note that only shortlisted ICMR-INTENT centres will be contacted for the subsequent steps. ICMR reserves the right to cancel this EoI and/or reissue it with or without amendments, without incurring any liability or obligation. No reason may be provided for such decisions. Please be informed that the information provided at this stage is indicative. ICMR reserves the right to amend or add further details to the EoI as deemed necessary by the Competent Authority, which will be duly notified.

Background

The Indian Council of Medical Research (ICMR), in collaboration with the Central Drugs Standard Control Organization (CDSCO) and under the direction of NITI Aayog, Government of India, aims to support innovators of indigenous medical devices, in-vitro diagnostics (IVDs), therapeutics and vaccines by providing comprehensive handholding support for clinical evaluation, regulatory facilitation, and the uptake of new products through an initiative named 'MedTech Mitra'.

MedTech Mitra, as a platform, reflects our commitment to fostering scientific advancements by addressing the needs of emerging innovators. ICMR is dedicated to ensuring that innovative medical technologies are rigorously evaluated and successfully brought to market. Through MedTech Mitra, applications for support in clinical investigation of MedTech products have been received by ICMR from MedTech startups/companies.

In line with this mission, ICMR now invites EoIs from ICMR-INTENT sites to participate in the clinical investigation of such MedTech technologies. The goal of investigation is to assess the clinical effectiveness, safety, and usability of these technologies within a healthcare setting.

Purpose

The purpose of the EoI is to select ICMR-INTENT centres for the purpose of conducting clinical investigation to determine the efficacy and safety of the proposed medical device technology 'ÇerviScan' (details provided in table 1).

Table 1: Details of ‘CerviScan’

S.N.	Name of MedTech product	Name of Company/Start-up	Intended use	Brief description
1	CerviScan	Sascan Meditech Pvt Ltd	<ul style="list-style-type: none">• Detects cervical pre-malignancies non-invasively using Diffuse Reflectance and Fluorescence imaging.• Helps locate the most malignant site in an abnormal cervix for targeted biopsy.• Supports pathological confirmation of cervical disease.	<p>A non-invasive, handheld device designed for cervical imaging. Equipped with a 5-megapixel monochrome USB camera. Includes a zoom lens for enhanced visualization of the cervix. Emits light at four different wavelengths for tissue illumination and image capture. Connects to a Windows-based Tablet or PC.</p> <p>Uses proprietary software to:</p> <ul style="list-style-type: none">Control the camera.Manage LED operations.Process and display captured images for clinical interpretation.

Eligibility Criteria:

Institutes interested in submitting an Expression of Interest (EoI) for the clinical investigation of ‘CerviScan’ must meet the following eligibility criteria:

- 1. Proven Experience:** The applicant must have demonstrated experience in conducting clinical evaluations of medical technologies, such as medical devices and IVDs. This includes a history of successfully managing and executing such evaluations, with verifiable outcomes. Experience in conduct of regulation-compliant clinical studies is desirable.

2. **Access to Facilities and Resources:** The applicant must have access to the necessary facilities, equipment, and resources required to conduct comprehensive clinical evaluations. This includes laboratories, clinical trial sites, and any other infrastructure essential for the successful execution of the project.
3. **Access to adequate number of cases/ study participants:** The applicant should demonstrate capacity to enroll study participants from health facilities and community.

Applicants are required to submit required information in a Google form, the link for which is available at the end of this document. Only those entities that meet these eligibility criteria will be considered for the subsequent stages of the EoI evaluation process.

Important Points for Submitting the Expression of Interest (EoI): Your submission must thoroughly address each specific question outlined in the Google form. Provide clear, concise, and detailed responses that demonstrate your understanding and alignment with the EoI requirements.

Adherence to these points will be critical in the evaluation of your EoI. Please ensure that your submission is complete and aligned with the objectives of the MedTech Mitra initiative.

Review Process

The process for reviewing the Expression of Interest (EoI) submissions for the clinical investigation of 'CerviScan' will involve the following steps:

1. **Initial Screening by ICMR:** The EoI documents will be evaluated and shortlisted by a team at the Indian Council of Medical Research (ICMR). During this initial phase, the ICMR team will screen the applications for completeness and accuracy of information.

2. Short listing of Applicants: Applications that meet the eligibility criteria will be reviewed by independent experts based on the information submitted by applicants and shortlisted for further consideration by the Competent Authority of ICMR.

3. Further steps: Selected ICMR-INTENT centres will be informed about their selection and further procedures regarding clinical investigation study

Last Date of Submission: 31 July 2025

Link for Google application form: <https://forms.gle/4tcGF8AaXjL93KL67>

For any queries related to the call, please contact:

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