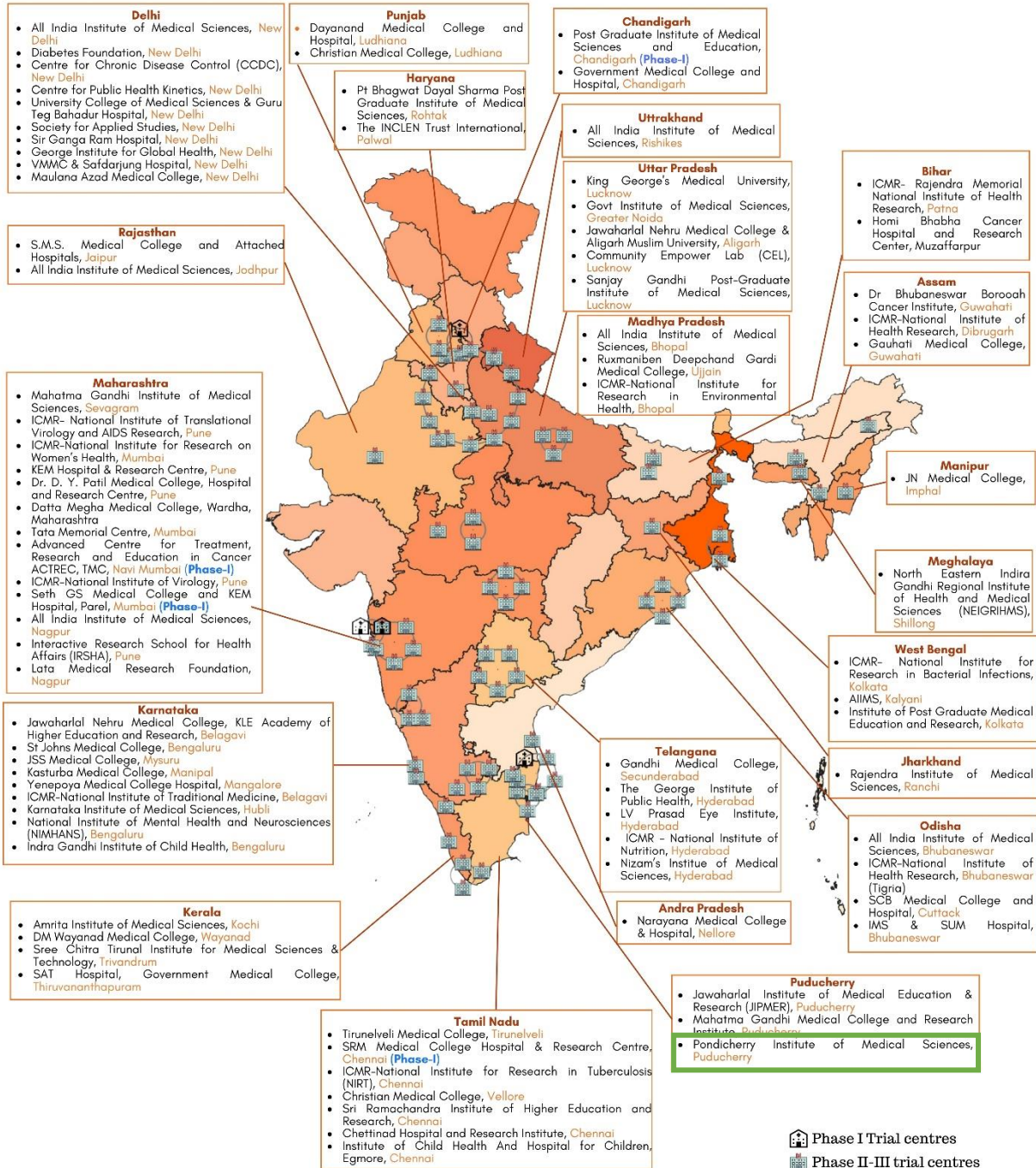


INTENT Centres



Indian Clinical Trial and Education Network (INTENT)

Indian Clinical Trial and Education Network (INTENT) is a flagship initiative by the Indian Council of Medical Research (ICMR), coordinated by the Clinical Studies & Trials Unit (CSTU) under the Division of Development Research at ICMR, New Delhi. The program aims to establish a robust ecosystem for clinical trials by integrating institutions, investigators, and resources across India to conduct high-quality, multicentric, regulatory-compliant trials.

INTENT is designed to:

- Foster collaboration among government agencies, academia, industry, and international organizations.
- Strengthen education and training to develop skilled clinical researchers and trial managers.
- Accelerate the development of new diagnostics, therapeutics, and preventive interventions tailored to India's diverse healthcare needs.

Currently, [\[81 Sites for Phase-II/III\]](#) clinical trials and [\[4 institutions for Phase-I\]](#) are part of the INTENT network, including public and private medical colleges, hospitals, research institutes, and ICMR institutions.

For more details on ICMR INTENT:

INTENT Phase II/ III Network Website: <https://intent.icmr.org.in/network-intent.html>

INTENT PIMS Website: https://intent.icmr.org.in/site_details.html?id=71

The following workshop has been conducted as a part of ICMR INTENT initiative

“Capacity Building Workshop on research Methodology, Clinical Trials, and Manuscript Writing”

Venue: Government Mohan Kumaramangalam Medical College (GMKMC), MEU, Salem

Date: 17th, 18th, 19th September 2025

Coordinators of South Zone: Medical Research Unit – MRU / Model Rural Research Health Unit – MRHU, from the Department of Health Research (MoHFW, GoI), New Delhi.

INTENT Sites:

1. Pondicherry Institute of Medical Sciences , Puducherry
2. Mahatma Gandhi Medical College & Research Institute (MGMC&RI), Puducherry

Participating Sites:

Host MRU - GMKMC, Salem; MRU – Madras Medical College, Chennai; Madurai Medical College & MRHRU, Madurai and Thanjavur Medical College, Thanjavur.



WORKSHOP BROCHURE



Capacity Building Workshop on Research Methodology, Clinical Trials, and Manuscript Writing

Venue: Government Mohan Kumarmangalam Medical College [GMKMC], MEU, Salem

Date: 17th, 18th & 19th September 2025

Time: 9:00 AM – 5:00 PM

Co-ordinators of South Zone (Medical Research Unit- MRU/ Model Rural Research Health Unit- MRHU), from the Department of Health Research (MoHFW, GoI), New Delhi

INTENT Sites: Pondicherry Institute of Medical Sciences [PIMS], Puducherry & Mahatma Gandhi Medical College & Research Institute [MGMC&RI], Puducherry

Participating Sites: Host MRU- GMKMC, Salem; MRUs- Madras Medical College, Chennai; Madurai Medical College & MRHRU, Madurai and Thanjavur Medical College

Day 1: Foundation of Clinical Research and Methodology

Time	Session Title	Speaker/Expert
9:00 – 9:30 AM	Inauguration & Welcome Address	Host MRU- GMKMC & Team
9:30 – 10:30 AM	Overview of Clinical Research and its Importance in Modern Medicine	Dr. P Sumathi Professor & HOD Department of General Surgery, GMKMC.
10:30 – 11:00 AM	Tea Break	
11:00 – 12:00 PM	Research Questions and Hypothesis Development in Clinical Trials	Prof. (Dr.) Dr. Anil J. Purty Professor & HoD Department of Community Medicine, PIMS
12:00 – 1:00 PM	Types and Designs of Clinical Trials: RCTs, Cross-Over, Adaptive Designs	Dr. Rajesh Kumar Konduru, Professor of Community Medicine, PIMS
1:00 – 2:00 PM	Lunch Break	
2:00 – 3:00 PM	Inclusion/Exclusion Criteria, Endpoints and Randomization Methods	Dr. Prem Kumar Assistant Professor Department of Community Medicine, MGMCRI
3:00 – 4:00 PM	Sample Size Calculation & Statistical Considerations in Clinical Trials Use of AI Tools for Literature Review, Data Analysis, and Research Planning	Dr. Manikandan M Professor cum Statistician Community Medicine, PIMS
4:00 – 5:00 PM	Hands-on: Protocol Drafting – Part I (Title, Objectives, Design)	All Resource Faculty

Day 2: Conduct, Regulation & Ethics in Clinical Trials

Time	Session Title	Speaker/Expert
9:00 – 10:00 AM	Clinical Trial Regulations in India: CDSCO, CTRI, ICMR Guidelines	Dr. Tanu Anand Scientist -E South Zone Co-ordinator ICMR
10:00 – 11:00 AM	Good Clinical Practice (GCP): Principles and Compliance	Dr.R.Subashri Assistant Professor & Head i/c Clinical Trial & Training Centre, MGMCRI
11:00 – 11:30 AM	Tea Break	
11:30 – 12:30 PM	Informed Consent Process: Challenges and Best Practices	Dr.R.Subashri Assistant Professor & Head i/c Clinical Trial & Training Centre, MGMCRI
12:30 – 1:30 PM	Legal Issues in Research Collaborations: Drafting MOUs, Data Sharing Agreements, and IP Clauses	Dr. R Arunachalam Professor Department of Anaesthesia, GMKMC
1:30 – 2:30 PM	Lunch Break	
2:30 – 3:30 PM	Trial Monitoring, Adverse Event Reporting, and Quality Assurance	Prof (Dr.) Manikandan M Professor cum Statistician Community Medicine, PIMS
3:30 – 4:30 PM	Hands-on: Protocol Drafting – Part II (Ethics, Consent, Monitoring Plan)	All Resource Faculty
4:30 – 5:00 PM	Mock IEC Review of a Clinical Trial Proposal	All Resource Faculty

Day 3: Publication, Funding & Trial Management

Time	Session Title	Speaker/Expert
9:00 – 10:00 AM	Budgeting and Funding Clinical Trials: ICMR, DBT, Pharma Collaborations	Prof. (Dr.) Dr. Anil J. Purty Professor & HoD Department of Community Medicine, PIMS
10:00 – 11:00 AM	Trial Registration and Result Dissemination (CTRI & WHO ICTRP)	Prof (Dr.) Rajesh Kumar Konduru Professor Department of Community Medicine, PIMS
11:00 – 11:30 AM	Tea Break	
11:30 – 12:30 PM	Converting Research Results into Patents: Process, Criteria, and Support Mechanisms	Dr. Senthil.M, Professor & HOD in Deputy Director SBV Innovation Eco System MGM Bioincubator Sri Balaji Vidyapeeth Puducherry
12:30 – 1:30 PM	Manuscript Writing for Clinical Trials (CONSORT Guidelines)	Dr. Prem Kumar Assistant Professor Department of Community Medicine, MGMCRI
1:30 – 2:30 PM	Lunch Break	
2:30 – 3:30 PM	Group Exercise: Drafting an Abstract from a Clinical Trial Protocol	All Resource Faculty
3:30 – 4:30 PM	Panel Discussion: From Idea to Impact – Success Stories in Clinical Trials	All Resource Faculty
4:30 – 5:00 PM	Feedback, Certificate Distribution & Valedictory	Organizing Committee

PIMS INTENT faculties facilitating sessions in “Capacity Building Workshop on research Methodology, Clinical Trials, and Manuscript Writing” workshop

