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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: 22/09/2021

Expression of Interest (EOI) for Participation in “Indian Clinical Trial & Education Network (INTENT)”

The Indian Council of Medical Research (ICMR) under the Department of Health Research (DHR), Ministry of Health & Family Welfare, Government of India, is the apex biomedical research body in the country for formulation, co-ordination, and promotion of medical research. The overall goal of ICMR-DHR is to generate evidence to inform policy, program and practices pertaining to health care in India.

Clinical Studies, Trials and Projection Unit (CSTPU), Indian Council of Medical Research (ICMR), Department of Health Research (DHR) proposes to launch the **Indian Clinical Trial & Education Network (INTENT)**, which will serve as a pan-India network of institutes with proven excellence in clinical research. The network, thus established, will conduct large scale, multi-centric clinical trials in a timely and well-regulated manner.

Why clinical trial network

INTENT envisages to provide evidence-based, cost effective, scientifically sound, and culturally appropriate solutions to diseases and health issues of national and/or regional importance. It will provide a single platform to conduct a range of randomized clinical trials (RCT), that will enable harmonization of trial methods, pooling of results and timely completion of the projects, along with an inclusive representation of the diverse Indian communities. Additionally, this network will be at the forefront for capacity building of a pool of health researchers across the country. The trainees will acquire requisite skills to plan and conduct RCTs and to analyse and disseminate the results that could inform policy and practice.

Structure of INTENT

INTENT will work on a hub and spoke model with a co-ordinating centre located at ICMR-DHR. Hubs will be distributed over the six regions of the country (North, South, East, West, Central and North-east) and will function as nodal point for RCTs in that region. These **Advanced Centres for Clinical Trials (ACCT)** will include Institutes/Medical Colleges/Hospitals of repute with rich experience and expertise related to RCTs. They will have functional linkages with Multi-disciplinary Research Unit (MRU) and/or Model Rural Health Research Unit (MRHRU) under the aegis of ICMR-DHR in the region.

Each regional hub, thus identified, will act as the mentoring body for a region, with the responsibilities of supportive supervision and troubleshooting as required. They will have an inclusive expansion plan so that the newly identified potential partnering agency/institutes/organizations are inducted in the regional network. The identified MRU/MRHRU will act as a **Regional Clinical Trial Unit (RCTU)**, responsible for daily functioning and monitoring of the trials. Each regional hub will select their study sites (spokes) as per the research question to be answered. Funding for human resource, as well as for the mentoring activities at each of these hubs will be provided by ICMR-DHR (Figure 1). The number of regional hubs will be scaled up in a phased manner.

Disease-oriented domain specific networks within INTENT will be recognised according to the domain expertise and subject specific clinical requirements.

Who can apply for Advanced Centre for Clinical Trial?

1. Govt. Medical Colleges/Institutes
2. Private Medical Colleges/Institutes
3. Hospitals with experience of conducting RCTs
4. ICMR Institutes

Investigators motivated to lead the regional hubs can apply with institutional approval.

Criteria for selection

Investigator

- a. Endorsed by the Head of the Institute/College
- b. Experience of initiating/participating in multi-centric RCT
- c. Good quality publications on RCTs
- d. Subject specialization
- e. Preferably a multi-disciplinary team of investigators to be involved, with at least 2 of the team members being mid-level faculty (associate or additional professor, or equivalent experience)

Institute

- a. Community outreach programme
- b. Access to potential trial participants, both in-patient and outpatients
- c. History of collaboration with other institutes/medical colleges/community-based organizations
- d. Catchment area catering to various geographical and population groups
- e. Presence of requisite infrastructure and space

Trials to be conducted via INTENT

Research priorities of INTENT will reflect the national and/or health priorities of urgent and important nature. Among others, the areas which will be covered by INTENT are reproductive, maternal, neonatal, child and adolescent health (RMNCHA), communicable and non-communicable diseases, nutrition, mental health, environmental health, health system research, healthcare financing, digital health, occupational health, vulnerable people's health and oral health.

The clinical trials to be conducted by INTENT partners can be grouped as short, intermediate, and long-term projects. To begin with, the focus of the network will be on short-term projects, where questions relevant to national health needs can be answered within 1-2 years. The projects will be primarily funded by ICMR.

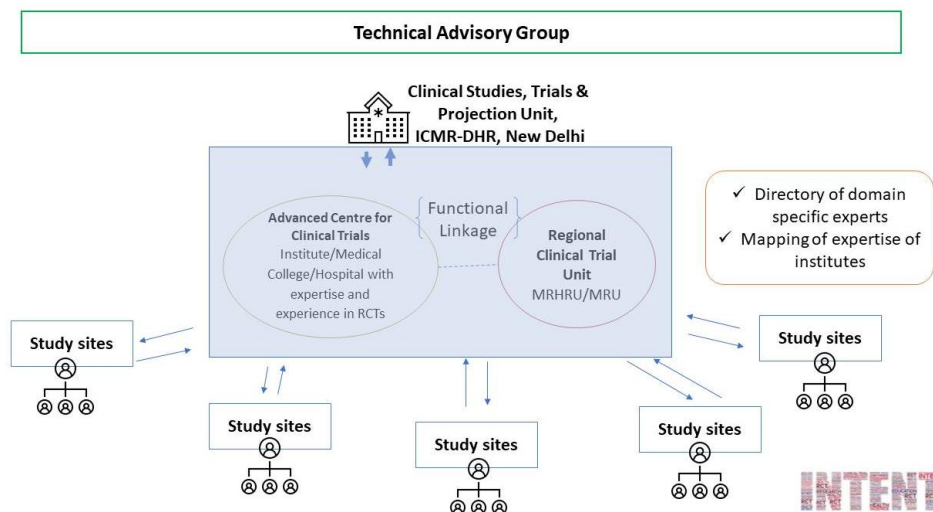


Figure 1: Structure for INTENT

Interested parties should fill the Google form at the following link:

https://docs.google.com/forms/d/e/1FAIpQLSf6yt0HbP0vfjswup8q8nHRt5b1omYX8iQNWtGEN8aSd3VjaA/viewform?usp=sf_link

The last date of receiving application: 15th October 2021

For further information, please contact:

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