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कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 06/08/2020

Invitation for submitting Letter of Intent for Participation in National Clinical Registry of COVID-19

There is a pressing need for collection of systematic data on clinical signs & symptoms, laboratory investigations, management protocols, clinical course of COVID-19 disease, disease spectrum and outcomes of patients. Such data will serve as an invaluable tool for formulating appropriate patient management strategies, predicting disease severity, patient outcomes etc. In view of this, Ministry of Health & Family Welfare (MoH & FW), Indian Council of Medical Research (ICMR), New Delhi and All India Institute of Medical Sciences (AIIMS) New Delhi have proposed to launch a National Clinical Registry for COVID-19 (NCRC). The NCRC will aim at collecting good quality real time clinical data to inform evidence-based clinical practice, research, formulating guidelines and policy making.

In view of this, ICMR invites a letter of intent from institutions/hospitals identified as dedicated COVID Hospitals or dedicated COVID Health Centres under the project to establish “**National Clinical Registry of COVID-19**”.

Objectives of the project are as follows -

Primary

1. To develop a National Clinical COVID-19 registry to collect data regarding clinical and laboratory features, treatments, and outcomes of hospitalized COVID-19 patients in India.
2. To study the frequency, clinical and laboratory features, treatments, and outcomes of COVID-19 related multisystem inflammatory disorder in children and adolescents by analyzing the national COVID-19 registry.

Secondary

1. To utilize data to answer research questions on COVID -19 including -
 - Natural Course of Disease
 - Disease Spectrum
 - Prognostic Factors
 - Risk Factors
 - Outcomes Data - Medications, health systems.
 - Context specific questions - Like COVID in Tuberculosis, Malnutrition etc.
2. To serve as a platform for additional clinical research studies in selected sites.
3. To collect follow-up data of discharged COVID 19 patients, if possible.

Methodology-

A COVID-19 clinical registry with prospective data collection from 100 hospitals across the country is proposed to be established. The duration of the study will be 1 year. Any COVID-19 lab confirmed and hospitalized patient of any age and meeting the inclusion criteria for the study will be enrolled. Data entry of clinical and laboratory parameters as well as patient management/ outcomes will be filled in a predesigned structured proforma on an electronic platform by participating sites across the country (Maximum number =100). Data will be stored in-central server/ NIC cloud and analysis will be done centrally by a team of scientists at ICMR. The data will be used to generate hypotheses for various parameters of the COVID-19 disease and the registry platform will be utilized in the future for interventional studies. The data entered by individual sites will be accessible to them on the central server. Analyzed data will be shared periodically with all sites.

Expected outcomes -

The expected output of developing and maintaining a NCRC are:

1. To generate weekly reports - epidemiological and clinical reports from the registry data will be published on ICMR/MOHFW website.
2. To formulate patient management protocols and develop policy guidelines for decision making.
3. To understand the predictors of disease severity and optimize patient management protocols accordingly.
4. To understand variations (if any) in clinical signs & symptoms and spectrum of disease in India as compared to other affected countries.
5. To generate context specific (TB survivors, malnourished) research answers for India.
6. To publish data periodically in peer reviewed journals.
7. To make evidence-based decisions on implementing various interventions in COVID-19 patients.

Dedicated COVID -19 hospitals and dedicated COVID-19 health centers will serve as primary sites for data collection. These sites will be trained, mentored and supervised by 15 Medical Institutes of repute across the country. (Annexure 1)

Funding – All the Institutions involved in the study will be funded by the Indian Council of Medical Research (ICMR), New Delhi. A uniform budget will be prepared for the sites (COVID-19 hospitals) and the mentor institutes.

More details will be shared once the sites have been finalized as collaborating centers.

Please fill the google form on the link - <https://forms.gle/APQdyf5cMji9AezW7> if your institution is interested in participating in this project. The necessary approvals for the project are being obtained. Once all the approvals are in place, we will get back to you regarding further paperwork and site-specific approvals. The matrix for site selection is mentioned in Annexure 2. Kindly ensure that you fulfil the criteria laid down in the attached matrix before you apply to ICMR.

For any questions/ queries, please contact on the email - covidclinical.registry@gmail.com



Annexure 1

Sl No.	Name of the Mentor Institute	Allocated States & UTs
1.	Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh	Jammu & Kashmir, Ladakh, Punjab, Haryana, Chandigarh, Uttarakhand
2.	All India Institute of Medical Sciences, Delhi	Delhi, Bihar
3.	All India Institute of Medical Sciences, Jodhpur	Rajasthan
4.	Smt. Nathiba Hargovandas Lakhmichand (NHL) Municipal Medical College (NHLMMC), Ahmedabad	Gujarat, Daman & Diu
5.	Armed Forces Medical College, Pune	Maharashtra, Goa, Dadra & Nagar Haveli
6.	Institute of Post Graduate Medical Education and Research, Kolkata, West Bengal	West Bengal
7.	National Institute of Mental Health and Neurosciences, Bengaluru	Karnataka
8.	Shri Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvnathapuram	Kerala, Andaman & Nicobar Islands, Lakshwadeep
9.	Jawaharlal Institute of Postgraduate of Medical Education and Research, Puducherry	Tamil Nadu, Andhra Pradesh, Puducherry
10.	All India Institute of Medical Sciences, Bhubaneswar	Odisha
11.	King George Medical University, Lucknow	Uttar Pradesh
12.	All India Institute of Medical Sciences, Bhopal	Madhya Pradesh
13.	All India Institute of Medical Sciences, Raipur	Chhattisgarh, Jharkhand
14.	North-Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong	Assam, Meghalaya, Sikkim, Tripura, Manipur, Mizoram, Arunachal Pradesh, Nagaland
15.	Nizam's Institute of Medical Sciences, Hyderabad	Telangana



Satellite sites will be selected based on following criteria:-

1-Site Location

- Sites/Institutes/Hospitals will be selected from each zones of India (north east, east, west, north, south, central) to ensure adequate representation of all the zones.
- Site selection methodology will ensure diversity and adequate representation of all States and Union Territories as well as the hotspot areas.

2-Site Infrastructure

- Institutes with higher inpatient COVID -19 admission will be preferred (admission rate should be a minimum of 100/month for consideration; region-wise decision regarding the number of patients admitted can be taken).
- Sites with in-house pathology and microbiology units will be prioritized.
- Sites with COVID -19 follow up clinic will be prioritized.

3-Previous track record of biomedical research

- Institutes with experience in COVID -19 research will be prioritized.
- Institutes with experience in research will be prioritized.

4-Human resource engagement

- Sites capable of recruiting a dedicated project medical officer on an expedited basis will be preferred.

5-Investigators experience

- Clinicians directly involved in COVID-19 patient care management.
- Investigators with publications in peer reviewed journals will be accorded preference.

6- Institutes expressing their interest earlier will be prioritized.