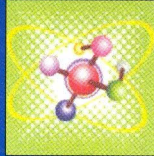




ICMR



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# Clinical Trials Registry - India

## National Institute of Medical Statistics (ICMR)



WHO

# CTRI Bulletin

www.ctri.in

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Director

National Institute of Medical Statistics (NIMS), Fellow of the Royal Statistical Society (FRSS), Chairman of Taskforce in Statistics, ICMR and NFHS-3, MOHFW, GOI; and Member of various National & International Bodies such as WHO, NACO, UNAIDS, International Biometric Society; IUSSP etc. is the **Administrator** of the Clinical Trials Registry - India, NIMS, ICMR, New Delhi.

## About CTRI

The Clinical Trials Registry - India (CTRI) has been set up at the National Institute of Medical Statistics (NIMS), ICMR, New Delhi to provide a platform for the online registration of all clinical trials conducted in the country. The primary objective of the CTRI is to establish a more authentic and complete public record system by registering all clinical trials on health products that are drugs, devices, vaccines, herbal drugs with a minimum set of data before the enrolment of the first patient, and this information will be made freely available to the public.

## CTRI Highlights

- The CTRI ([www.ctri.in](http://www.ctri.in)) was launched on the 20<sup>th</sup> of July 2007.
- Registration of trials is online, free and voluntary.
- A meeting with editors of Indian Biomedical Journals was held to garner their support for the CTRI.
- A Regional Workshop was organized at NIRRH, Mumbai for various stakeholders.
- Presentations were made at various conferences to enhance awareness.
- Till 31st January 2008, more than 150 users from all over the country had registered in the CTRI.
- The CTRI site has received more than 4500 hits.
- Several queries have been answered through email and telephonically. Of these, one third of queries were directly related to the trial registration process in the CTRI.
- For more information visit us at [www.ctri.in](http://www.ctri.in)

CLINICAL TRIALS REGISTRY-INDIA  
NATIONAL INSTITUTE OF MEDICAL STATISTICS, (ICMR)



Home | Trial Search | Register Trials | FAQs | Feedback | Contact Us | Sitemap  
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**SIGN IN TO CTRI**

Username

Password

[Forgot Password](#) | [New User](#)

**Trial Registration Set Download:** [Word][Pdf]

**SEARCH FOR TRIALS**

[Advanced Search]

### News & Events

**Launch of Clinical Trials Registry-India (CTRI)**  
CTRI has been successfully launched on 20th July 2007 by Prof. N.K. Ganguly, DG, ICMR at National Institute of Medical Statistics (ICMR)

The Clinical Trials Registry - India (CTRI) has been set up by the ICMR's National Institute of Medical Statistics (NIMS) and is funded by the Department of Science and Technology (DST) through the Indian Council of Medical Research (ICMR). It also receives financial and technical support through the WHO, WHO-SEARO, and the WHO India Country office. [Read more...]

### Mission

The mission of the Clinical Trials Registry-India (CTRI) is to encourage all clinical trials conducted in India to be prospectively registered before the enrollment of the first participant and to disclose details of the 20 mandatory items of the WHO International Clinical Trials Registry Platform (ICTRP) dataset. [Read more...]

### Vision

The vision of the CTRI is to ensure that every clinical trial conducted in the region is prospectively registered with full disclosure of the 20-item WHO ICTRP dataset, as well as all items of the CTRI dataset, in order to 1) improve transparency and accountability, 2) improve the internal validity (details of the methods of the trial that produce reliable results primarily the method of random



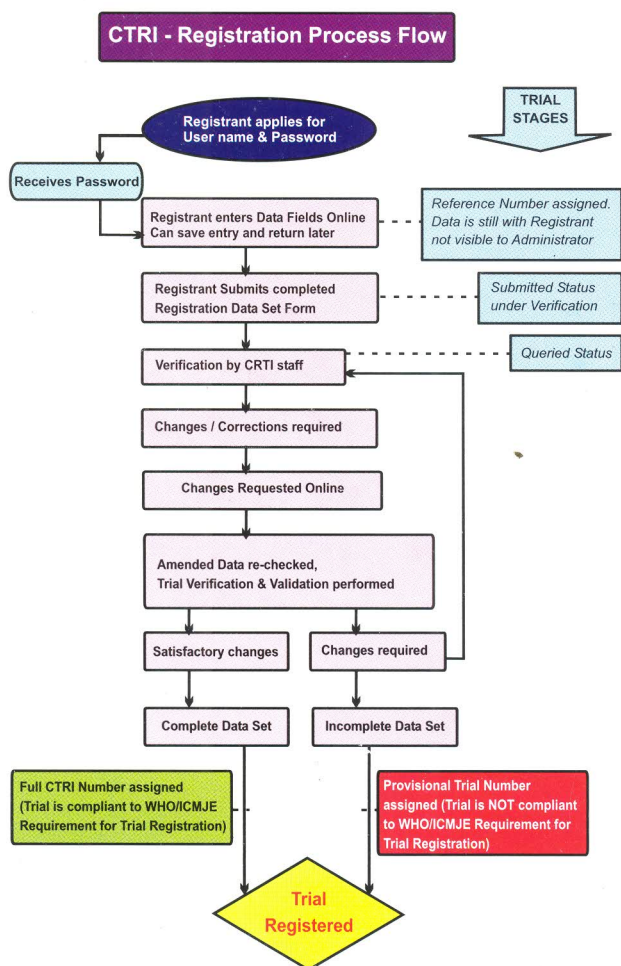
Clinical Trials Registry-India (CTRI)

The CTRI is an online register of clinical trials being conducted in India. Any researcher who plans to conduct a trial involving human participants, of any intervention (drug, surgical procedure, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies and complementary therapies) are expected to register the trial in CTRI before enrollment of the first participant. Registration is voluntary but some fields marked\* are mandatory for registration to proceed. Some fields marked WHO also need to be filled if the trial is to receive a registration number and fulfill WHO/ICMDE requirements. Incomplete entries will be given a provisional registration number that will not suffice for purposes of publication in journals that endorse the ICMDE recommendations for trial registration. Registration of trials in the CTRI is free. All registered trials will be made publicly available. The CTRI will be searchable by anyone free of charge. The Clinical Trials Registry - India (CTRI) has



## Clinical Trials Registry - India

All clinical trials being conducted in India are expected to be registered through an online process in the CTRI. A trialist first needs to register as a user in the CTRI. Subsequently, on receipt of **Username** and **Password**, trialists are required to submit details of the trial as per the trial registration data set (Table 1). Registrants have the facility to fill up the data set in parts or full according to their individual convenience by clicking on the **save** button and a **Reference Number** is assigned (REFCTRI), which is used in all future correspondence regarding the trial. Once the trial is **Submitted**, the details of the trial are validated. In case, of any ambiguity, the trial details are sent back to the trialist for further modifications/clarifications. After completion of these formalities and receipt of DCGI/EC documents, the trial is registered and assigned a registration number. If all the WHO fields are filled, a full CTRI **Registration Number** (CTRI) that fulfills WHO/ICMJE requirements is assigned. However, incomplete entries are assigned a **Provisional Registration Number** (PROVCTRI), which is not sufficient for journals that endorse the ICMJE recommendations (also see the chart below).



**Table 1:**

### Registration Data Set of the CTRI ([www.ctri.in](http://www.ctri.in))

- Public Title of Study \*
- Scientific Title of Study \*, and Trial Acronym, if any.
- Secondary IDs, if any
- Principal Investigator's Name and Address
- Contact Person (Scientific Query)
- Contact Person (Public Query)
- Funding Source/s
- Primary Sponsor
- Secondary Sponsor
- Name of Ethics Committee and approval status \*
- Regulatory Clearance obtained from DCGI \*
- Date of first enrolment
- Estimated duration of trial
- Target sample size
- Health Condition/Problem studied
- Intervention and Comparator agent
- Key inclusion/Exclusion Criteria
- Primary Outcome/s
- Secondary Outcome/s
- Countries of Recruitment
- Site/s of study
- Status of Trial \*
- Phase of Trial \*
- Study Type
- Brief Summary
- Method of generating randomization sequence
- Method of allocation concealment
- Blinding and masking

*Items in Blue are the WHO Data Set.*

*Items in Green are additional dataset of CTRI.*

*Mandatory items are marked with an \**

*For more information visit us on [www.ctri.in](http://www.ctri.in)*

Although trials are expected to be registered before the enrolment of the first patient, currently, ongoing trials are also being registered in CTRI.



## Current Status

Awareness regarding the CTRI has gained momentum as evidenced by the hits numbering more than 4500 at the CTRI site. Further, since the launch of the CTRI till 31<sup>st</sup> January, 2008, a total of 150 users had been registered. Of these, 77 are from the Academia (Institutions and Hospitals) and 43 are from the Pharmaceutical Industry while 30 are from CROs (Fig 1 and 2). Further, 16 trials have been fully registered, 20 trials are pending with the respective registrants for various modifications/clarifications, while 4 trials are pending with the Administrator, awaiting EC/DCGI approval documents (Fig 3).

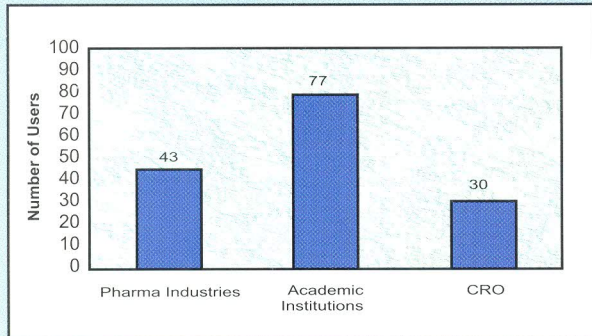


Fig -1: Category of Registered Users

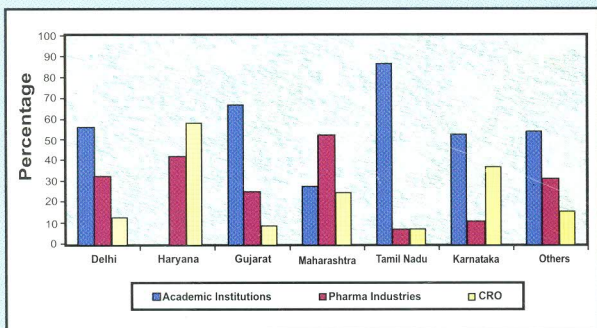


Fig -2: State-wise Breakup of Registered Users

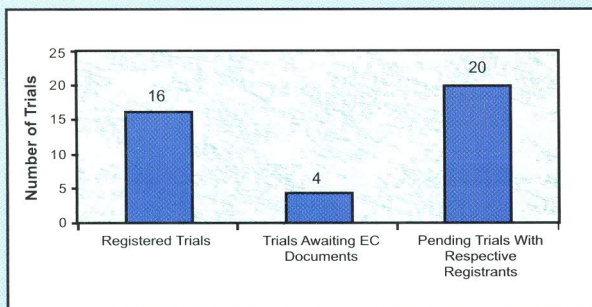


Fig-3: Details of Trials Submitted to CTRI

## Advocacy & Dissemination of CTRI

◆ **Meeting of Indian Biomedical Journal Editors:** Journal editors from all over the country met on 9<sup>th</sup> October, 2007, at ICMR, New Delhi to generate awareness regarding trial registration in the CTRI and garner their support for the venture. Prof. Prathap Tharyan, CMC Vellore and Dr. Abha Rani Aggarwal, Coordinator CTRI, New Delhi made presentations to sensitize the invited editors. It was proposed that a tentative time limit up to January, 2009 could be set as the deadline beyond which only registered trials would be published by biomedical journals of India.



Biomedical Journal Editors Meeting in ICMR, New Delhi

◆ **Regional Meeting:** In order to promote trial registration in the CTRI as well as clarify doubts and queries regarding the functioning of the CTRI software application and trial registration process, a meeting was held for various stakeholders at NIRRH, Mumbai on 12 September 2007. Prof. S.D. Seth, CTRI, chaired the meeting and Prof Arvind Pandey, Director NIMS and Administrator, CTRI gave an introduction of the CTRI and emphasized the national importance of such a registry. Dr. Atul Juneja, NIMS, presented an overview of the CTRI, while Dr. Abha Rani Aggarwal, Coordinator, CTRI, presented the process of trial registration.



Regional Workshop of CTRI in NIRRH, Mumbai

