ICMR DST

Clinical Trials Registry - India

National Institute of Medical Statistics (ICMR)

WHO

CTRI Bulletin

www.ctri.in

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In This Issue

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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) was launched on the 20th 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

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).

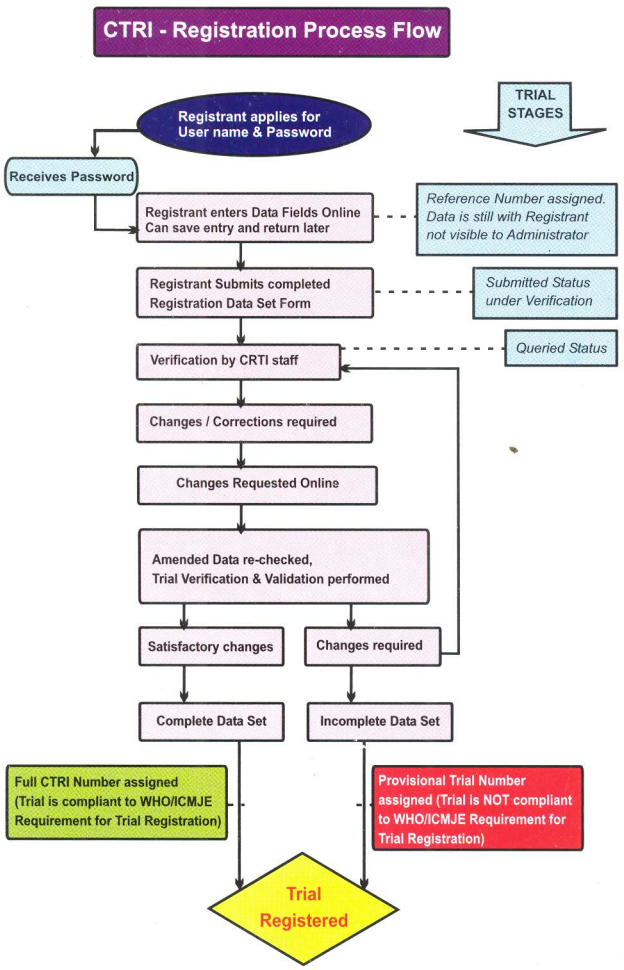

Table 1:

Registration Data Set of the CTRI (www.ctri.in)

1. Public Title of Study *
2. Scientific Title of Study *, and Trial Acronym, if any.
3. Secondary IDs, if any
4. Principal Investigator's Name and Address
5. Contact Person (Scientific Query)
6. Contact Person (Public Query)
7. Funding Source/s
8. Primary Sponsor
9. Secondary Sponsor
10. Name of Ethics Committee and approval status *
11. Regulatory Clearance obtained from DCGI *
12. Date of first enrolment
13. Estimated duration of trial
14. Target sample size
15. Health Condition/Problem studied
16. Intervention and Comparator agent
17. Key inclusion/Exclusion Criteria
18. Primary Outcome/s
19. Secondary Outcome/s
20. Countries of Recruitment
21. Site/s of study
22. Status of Trial *
23. Phase of Trial *
24. Study Type
25. Brief Summary
26. Method of generating randomization sequence
27. Method of allocation concealment
28. 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 **

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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 31st 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).

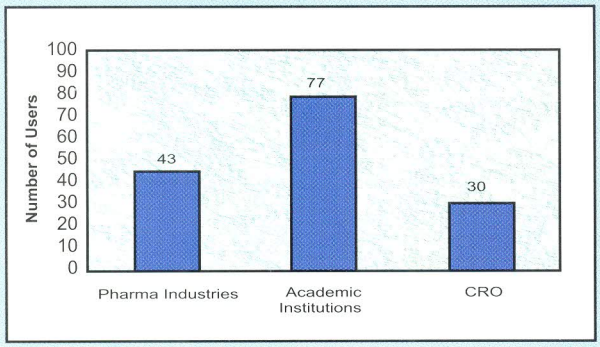

Fig -1: Category of Registered Users

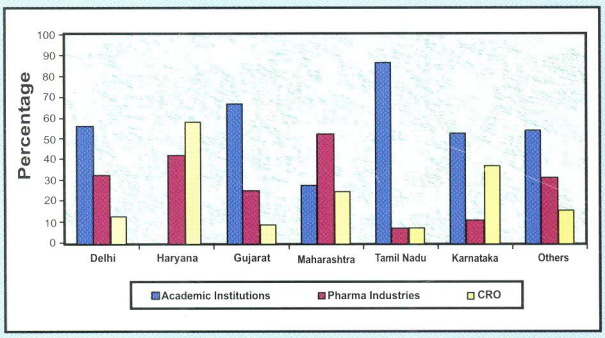

Fig -2: State-wise Breakup of Registered Users

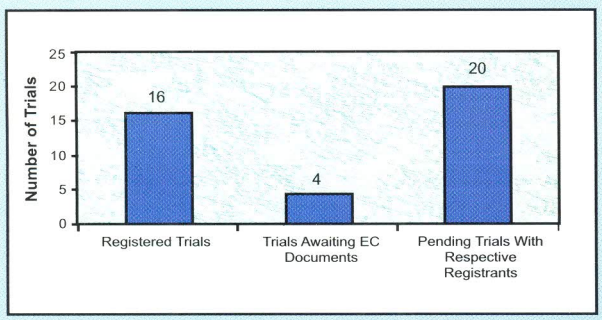

Fig-3: Details of Trials Submitted to CTRI

Advocacy & Dissemination of CTRI

♦ **Meeting of Indian Biomedical Journal Editors:** Journal editors from all over the country met on 9th 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