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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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) 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).

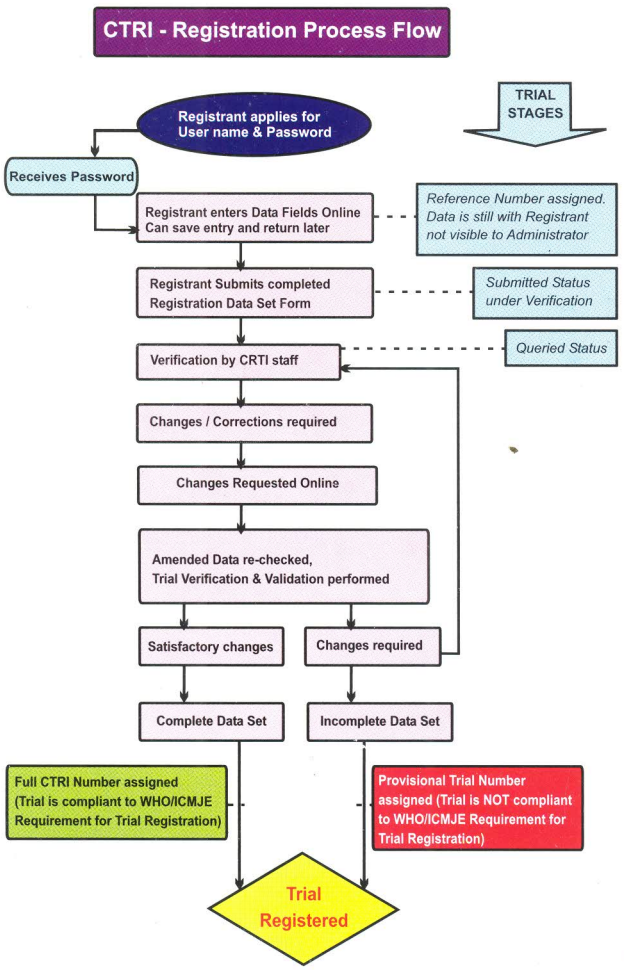

Table 1:

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).

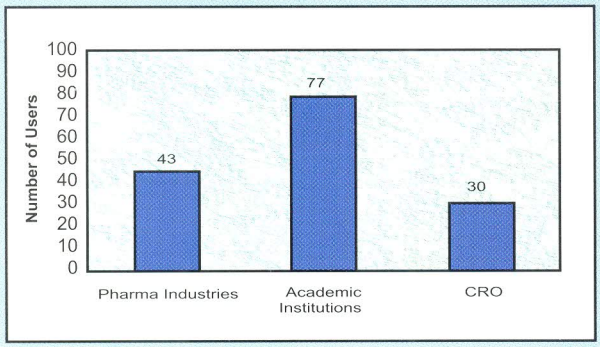

Fig -1: Category of Registered Users

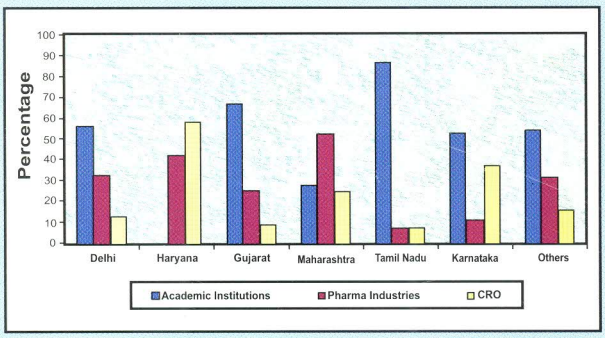

Fig -2: State-wise Breakup of Registered Users

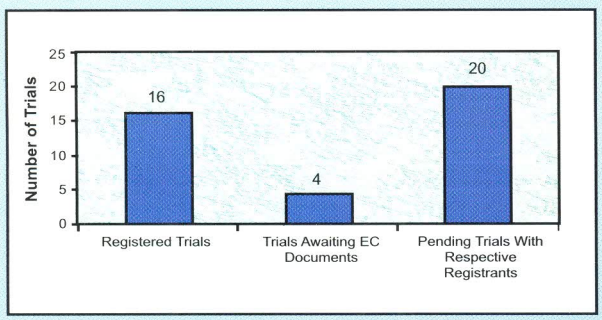

Fig-3: Details of Trials Submitted to CTRI

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

♦ **Diamond Jubilee Conference on Recent Advances in the Statistical Methods for Bioinformatics:** In the conference held on 14 November, 2007, at Chennai, Prof. S.D. Seth, CTRI was invited as Guest of Honor and he also chaired the CTRI session. He gave a brief introduction about the registry. He also clarified the doubts and queries related to registration of clinical trials in the CTRI. Dr. Rahmat Bano, CTRI, presented an overview of CTRI, while Dr. Mohua Maulik, CTRI, explained the process of trial registration in the CTRI.

Prof. Seth being felicitated by Mr. G. Viswanathan, Chancellor, Vellore Institute of Technology, Vellore

♦ **WHO Network Register Meeting, Geneva:** Dr. Ambujam N. Kapoor, ICMR attended the meeting during 29th, 30th November, 2007. She apprised the WHO Network Team about the current status of the CTRI and its future plans.

♦ **Silver Jubilee National Conference of Indian Society for Medical Statistics (ISMS) organized by Manipal University:** During the conference held between 30th November to 2nd December, 2007, Dr. Abha Rani Aggarwal, Coordinator, CTRI briefed the audience about the CTRI as well as the process of trial registration.

Common Bottlenecks to Trial Registration

Trials submitted to the CTRI undergo a series of validation and verification steps. Scrutiny of trials submitted to the CTRI since its launch has led to the identification of the following common hurdles to quick registration of trials :

- A submitted trial is not registered without receipt of **DCGI/EC** approval documents.
- Complete contact details, including email and telephone numbers of each contact person at each site is required for verification purposes.
- If a trial has not been registered in any other registry and the trial does not have any other **Secondary IDs**, registrant should fill in NIL. This is a WHO mandatory field and this would help the trial to be assigned a full CTRI number [this may be done by clicking on "click to add more"].
- However, if the trial has been registered in any other registry, such as the www.clinicaltrials.gov, that Registry's number should be quoted in the **Secondary ID** section of CTRI, and care should be taken to ensure the entered details are identical in both registers.
- If the trial does not have any **Secondary sponsor**, the registrant should fill in NIL. This is a WHO mandatory field and this would help the trial to be assigned a full CTRI number.
- In case of a multi-country trial, which has already been registered in another registry, the **Status of trial**, **Date of first enrolment**, **Target sample size** should be that of the parent trial and these details of the Indian arm are to be mentioned in the **Brief Summary** section.

WHO Network of Registers

Primary Registers

- Australian New Zealand Clinical Trials Registry (ANZCTR)
- Chinese Clinical Trial Registry (ChiCTR)
- Clinical Trials Registry - India (CTRI)
- ISRCTN.org

Although not a primary register, data from ClinicalTrials.gov is also included into WHO-ICTRP

www.who.int/ictrp/network/list_registers/en/index.html

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