Welcome to the third Bulletin of the Clinical Trials Registry - India. This newsletter provides a concise summary of recent and upcoming activities relevant to the CTRI.

**CTRI Highlights**
- The CTRI (www.ctri.in) was formally launched on 20th July, 2007.
- Registration of trials is online, free and voluntary.
- Presentations have been made at various conferences to enhance awareness.
- The CTRI site has received more than 8500 hits.
- 62 trials have been registered in the CTRI till June 2008.
- Regional Workshop was conducted at Kidwai Memorial Institute of Oncology (KMICIO), Bangalore. More than 100 participants attended the workshop.
- Several queries have been answered through email and telephonically. Of these, about 60 queries were directly related to the trial registration process in the CTRI.
- For more information visit us at www.ctri.in.

**Statement in Indian Biomedical Journals**

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On behalf of all biomedical journals published from India, we urge all those who are either conducting or planning to conduct clinical trials involving human subjects, to register their trials in CTRI and any primary clinical trial registry. From January 2009 onwards, we will consider publication of a trial only if it has been registered prospectively if started in or after Jan 2008. Trials undertaken before June 2008 need to be registered retrospectively.

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**References**


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**Indian J Med Res. 2008 (Feb), 127:104-105**

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**In brief:** The Clinical Trials Registry-India (CTRI) has been set up at NIMS, ICMR, New Delhi to provide a platform for registration of all clinical trials. Primary objectives are to establish a public record system by registering all prospective clinical trials (before recruitment of first patient) conducted in India on health products including drugs, devices, and vaccines, herbal drugs, which will be made publicly available on the internet at no cost. At present, ongoing and completed clinical trials are also being registered in the CTRI.
2 The New Indian Express

‘Creating national registry can help control cancer’

Express News Service

Mumbai, March 24

Through the recently established registry of a national cancer registry of a cancer study, more than 1,000 patients were registered in the country. This information is being kept in a national database. The database is being updated regularly. This information will benefit the patients and doctors in India. It will also help in creating new strategies for cancer management.

Dr. Rohit Agarwal, director of the National Cancer Registry of India said: ‘The database is being updated regularly. This information will benefit the patients and doctors in India. It will also help in creating new strategies for cancer management.’

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Registration Data Set of the CTRI

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 enrollment
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 are mandatory for registration
Advocacy & Dissemination of CTRI

- National Conference on Recent Statistical Techniques in Biostatistics, Management Sciences and Related Areas (14th – 16th Feb, 2008), Dr. Abha Rani Aggarwal, was deputed to present the overview of CTRI.

- 18th ICON Meet (Indian Co-operative Oncology Network) 21st-23rd March, 2008, held at Swasti Plaza, Bhubaneswar. Prof. Arvind Pandey Dr. Abha Rani Aggarwal and Dr. Juneja attended the Workshop and disseminated the information regarding CTRI.

![Image of Workshop]

Prof. Arvind Pandey, Director, NIMS, Administrator, CTRI; Dr. Abha Rani Aggarwal, Scientist E & Co-ordinator, CTRI and Dr. Atul Juneja, Scientist B, NIMS on the dais.

- NIMS was invited to attend the Global Registration Session in 2nd South Asian Symposium on Evidence Informed Health Care at CMC, Vellore on 9th April, 2008, where a session was organized on the CTRI. The session was attended by Dr. Abha Rani Aggarwal, Co-ordinator, CTRI, disseminated the registration process in the Registry.

- Meeting with Ms. Davina Gherti (Co-ordinator ICTR, WHO), Dr. Ambujam N. Kapoor (ICMR), Dr. Abha Rani Aggarwal (NIMS) and Dr. Pratap Tharyan (CMC) attended the meeting on 9th April, 2008, at CMC, Vellore, to discuss to trial registration in respect of CTRI as a Primary Register.

- A Student Forum of AIIMS, New Delhi, invited Prof. Arvind Pandey to disseminate the information about the CTRI on 30th April, 2008 at AIIMS, New Delhi. Prof. Pandey discussed the genesis of CTRI and Dr. Abha Rani Aggarwal presented the process flow of the CTRI.

Monitoring Committee Meeting

The first Monitoring Committee Meeting of CTRI was held on 16th June 2008, at NIMS, CMR, New Delhi under the Chairmanship of Dr. P.S.S. Sundar Rao. The progress of the CTRI was presented before the committee. The work done till date was appreciated by the committee members.

![Image of Committee Meeting]

From Left: Prof. Arvind Pandey; Dr. Lakshman Prasad, DST; Dr. P.S.S. Sundar Rao, Chairman; Prof. S.D. Seth, Adviser, CTRI; Dr. G.J. Sanathanam, DST.

![Image of Committee Meeting 2]

From Left — Ms. Anagha Khot, WHO, New Delhi; Dr. Abha Rani Aggarwal, Prof. Arvind Pandey, Dr. Lakshman Prasad.

![Image of Workshop]

Participants in CTRI Dissemination workshop.
Regional Workshop

- Dissemination workshop on CTRI was organized at KMIO, Bangalore on 20th June, 2008, where the members of the CTRI team spoke on various aspects of the registry, including global scenario, its genesis as well as trial registration process. Moreover, diverse queries raised by the participants were also answered by the CTRI team.

Prof. Arvind Pandey, Dr. Ambujam N. Kapoor, Ms. Anagha Khot, Dr. Abha Rani Aggarwal, Prof. S.D. Sethi, Sri M.P. George, Drug Controller, Kerala, Dr. B.R. Jaga Shetti, Drug Controller, Karnataka

Prof. S.D. Seth discussing the queries raised by participants. Also seen, Dr. Ambujam N. Kapoor, Prof. Arvind Pandey, Dr. Abha Rani Aggarwal.

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
- Sri Lanka Clinical Trials Registry (SLCTR)

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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