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# Clinical Trials Registry - India

## National Institute of Medical Statistics (ICMR)



WHO

# CTRI Bulletin

www.ctri.in

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## In This Issue

- CTRI Highlights
- CTRI Registration Process
- CTRI Registration Dataset
- News Clippings
- Advocacy & Dissemination of CTRI
- Monitoring Committee Meeting
- Regional Workshop
- Current Status
- WHO Network of Registers



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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 20<sup>th</sup> 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 (KMIO), 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.

## Statement in Indian Biomedical Journals

STATEMENT ON PUBLISHING CLINICAL TRIALS IN INDIAN BIOMEDICAL JOURNALS

105

On behalf of all biomedical journals published from India, we urge to all those who are either conducting and/or planning to conduct clinical trials involving human subjects, to register their trials in CTRI or in any primary clinical trial register. From January 2010 onwards, we will consider publication of a trial only if it has been registered prospectively if started in or after June 2008; trials undertaken before June 2008 need to be registered retrospectively.

1. **K. Satyanarayana, Anju Sharma**  
*Indian Journal of Medical Research*
2. **Purvish Parikh**  
*Indian Journal of Cancer*
3. **V. K. Vijayan**  
*Indian Journal of Chest Diseases and Allied Sciences*
4. **D. K. Sahu**  
*Indian Journal of Medical Sciences*
5. **Barun K. Nayak**  
*Indian Journal of Ophthalmology*
6. **R. K. Gulati**  
*Indian Journal of Pediatrics*
7. **Mahendra N. Parikh**  
*Journal of Obstetrics and Gynecology of India*
8. **Prati Pal Singh**  
*Journal of Parasitic Diseases*
9. **S.B. Bavdekar**  
*Journal of Postgraduate Medicine*
10. **U. Sreehari**  
*Journal of Vector Borne Diseases*

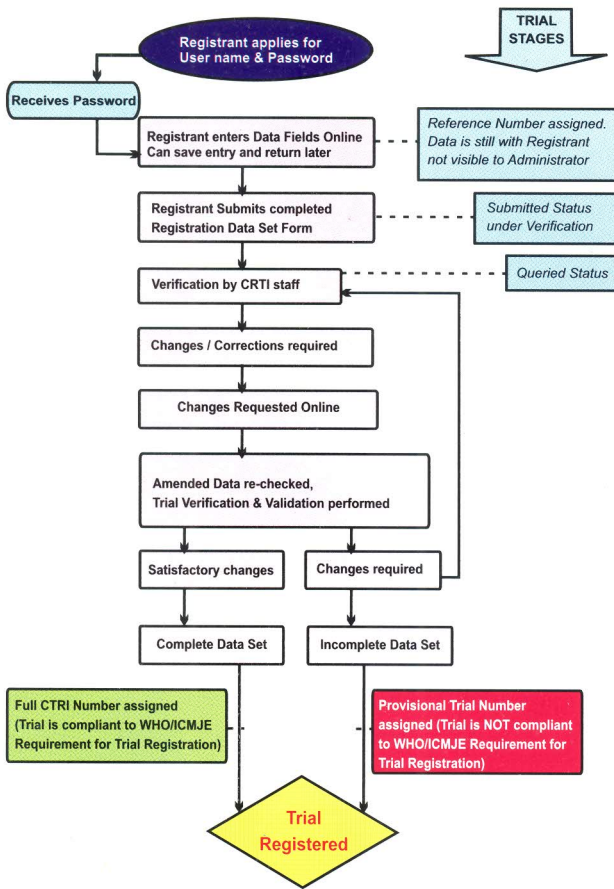
**Peush Sahn**  
*National Medical Journal of India*  
For Correspondence  
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2. Clinical Trials Registry - India, National Institute of Medical Statistics (ICMR). Available at [http://www.ctri.in/Clinicaltrials/trials\\_jsp/index.jsp](http://www.ctri.in/Clinicaltrials/trials_jsp/index.jsp)
3. Laine C, Horton R, De Angelis CD, Drazen JM, Frizelle FA, Godlee F, et al. Clinical trial registration: looking back and moving ahead. Available at [http://www.icmje.org/clin\\_trial07.pdf](http://www.icmje.org/clin_trial07.pdf).
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5. De Angelis C D, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration. A statement from the International Committee of Medical Journal Editors. *JAMA* 2004; 292: 1363-4.
6. De Angelis C D, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. International Committee of Medical Journal Editors (ICMJE). Is this clinical trial fully registered? A statement from the International Committee of Medical Journal Editors. Available at [http://www.icmje.org/clin\\_trialup.htm](http://www.icmje.org/clin_trialup.htm).
7. Dickersin K, Rennie D. Registering clinical trials. *JAMA* 2003; 290: 516-23.
8. Mudur G. India plans to audit clinical trials. *BMJ* 2005; 331: 1044.  
*Indian J Med Res, 2008 (Feb); 127:104-105*

**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.

## CTRI - Registration Process Flow



## 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 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 in Blue—WHO Data Set.

\* Items are mandatory for registration

## 'Creating national registry can help control cancer'

EXPRESS NEWS SERVICE

Bhubaneswar, March 24: Though the country is witnessing over a lakh new cancer cases a year, many more go unregistered. Though there are some hospital specific and population specific registries, the process is still in its nascent stage and needs proper planning in future.

Calling for adequate funds, experts at the concluding session of 18th Indian Cooperative Oncology Network (ICON) said keeping a proper registry would certainly help in mitigating the spread of cancer and creating new modules for awareness generation.

ICON convener Dr Purvish Parikh of Tata Memorial Hospital, Mumbai, said apart from hospital-based registry, population-based registries are maintained at Mumbai, Delhi and Barsi and the one at Mumbai alone costs Rs 22 lakh a year to maintain.

There is also a registry maintained by

'Cancer Atlas Project' of the Indian Council of Medical Research (ICMR), he pointed out.

Earlier during a technical session, Director, Clinical Trial Registry of India, Dr Arvind Pandey and deputy director Dr Abha Agarwal also called for creation of at least hospital specific registries to know the spread of cancer and its control.

On controlling head and neck cancer, tobacco habits in case of young adults between 10 and 15 years need a re-look and specially in Orissa with its peculiar 'pan chewing habit and intake of black tobacco' the awareness programmes should be implemented strictly, he said.

Chief guest and most senior oncologist of the State Prof. U.N. Panda said since seventies there was a sea change in the availability of medicines and procedures.

On alternative therapies, Dr Parikh said ICON would be taking up research projects in ayurveda and homeopathy in treating cancer.



- No proper registry for cancer figure in the country
- Hospital specific registries should be maintained
- Awareness drives on 'pan chewing habit and intake of black tobacco' should get priority in Orissa

सिंह आवस का परमिट पेश करना होगा।

में मंगलूर स्थित नरी के फेज तीन के तहत

## क्लिनिकल ट्रायल के आउटसोर्सिंग बाजार के रूप में उभर रहा है भारत

नई दिल्ली, 5 जून (भास)। दुनिया में क्लिनिकल ट्रायल सबसे तेजी से उभर रहे उद्योगों में एक बन गया है और भारत विश्व के कुछ सतों से पचासों और उपचार विधियों के क्लिनिकल ट्रायल के आउटसोर्सिंग बाजार के रूप में तेजी से उभर कर सामने आया है। 2005 में तेजी से उभर कर सामने आया है। 2005 में तेजी से उभर कर सामने आया है। 2005 में तेजी से उभर कर सामने आया है।

भारतीय चिकित्सा अनुसंधान परिषद के सहायक अध्यक्ष राष्ट्रीय चिकित्सीय सॉल्यूशंस संस्थान को 'क्लिनिकल ट्रायल रजिस्ट्री-इंडिया' की प्रगति रिपोर्ट के मुताबिक दुनिया भर में भारत क्लिनिकल ट्रायल का केंद्र बिंदु बनता आ रहा है। इसका सबसे बड़ा कारण यह है कि परिचय देती के मुकामले यहां इलाज

करने की कुल लागत बहुत कम बैठती है। क्लिनिकल ट्रायल रजिस्ट्री-इंडिया के निदेशक प्रो. अश्विनी पंडे और संयोजक डाक्टर आभा कुंजी आवाला के मुताबिक वर्तमान में करीब 80 संस्थाएँ और निजी स्वामित्व वाले भारतीय अस्पताल वैश्विक एवं स्थानीय क्लिनिकल ट्रायल में व्यस्त हैं। इसके अलावा कई भारतीय फार्मास्यूटिकल कंपनियाँ और प्रोसेसर सीआरएडो भी क्लिनिकल ट्रायल कर रहे हैं।

भारतीय चिकित्सा अनुसंधान परिषद (आईसीएमएआर) के पूर्व महादेशिक डा एनके गांगुली ने बताया कि आने वाले सालों में भारत क्लिनिकल ट्रायल उद्योग में बहुत तेजी से आगे बढ़ सकता है क्योंकि यहां पर वे सभी सुविधाएँ आसानी से उपलब्ध हैं जिनका किसी भी क्लिनिकल ट्रायल के लिए होना बहुत जरूरी है।

उन्होंने बताया कि भारत में क्लिनिकल परीक्षण पंजीकरण सुविधा शुरू हो जाने से इस क्षेत्र में निश्चित रूप से तेजी आएगी। इससे डाक्टरों और रोगियों की पंजीकरण करने से कई लाभ मिलेंगे। उनके शोध पर सरकार को नजर रखे और वे नीतिकता के सभी पहलुओं के बारे में जानकारी से सचेत और चतुर्धन से किसी कानूनी पंचद में नहीं फंसेंगे। उनको अपने शोध दुनिया की जाने माने जनरली में प्रकाशित करने में काफी आसानी होगी क्योंकि वे जनस किराी मान्यता प्राप्त संस्थान से पंजीकरण योग्य हैं।

रिपोर्ट में कहा गया है कि भारत में घरेलू रोगियों की संख्या काफी ज्यादा है। सर्वोच्च विशेषज्ञता प्राप्त अस्पताल आसानी से उपलब्ध हैं और अंग्रेजी भाषी कर्मचारियों की संख्या काफी बनी जा रही है।

## **Advocacy & Dissemination of CTRI**

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

- **18<sup>th</sup> ICON Meet (Indian Co-operative Oncology Network) 21<sup>st</sup>-23<sup>rd</sup> 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.



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 2<sup>nd</sup> South Asian Symposium on Evidence Informed Health Care** at CMC, Vellore on 9<sup>th</sup> 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 Gheri (Co-ordinator ICTRP, WHO)**, Dr. Ambujam N. Kapoor (ICMR), Dr. Abha Rani Aggarwal (NIMS) and Dr. Pratap Tharyan (CMC) attended the meeting on 9<sup>th</sup> 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 30<sup>th</sup> 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 16<sup>th</sup> 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.



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. Samathanam, DST.



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



Participants in CTRI Dissemination workshop.

