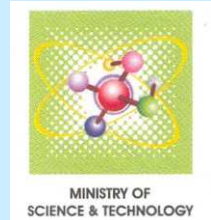




Clinical Trials Registry - India National Institute of Medical Statistics (ICMR)



CTRI Bulletin

www.ctri.nic.in

Vol.6 (6); Jan-June, 2010

In This Issue

- CTRI Highlights
- Points to Remember
- Registration Data Set of the CTRI
- Publications
- Dissemination Workshops
- Ethical Guidelines issued by ICMR
- Current Status of CTRI
- Contact Us

CTRI Highlights

- The CTRI is hosted on the Internet (www.ctri.nic.in) provides a platform for the free and online registration of clinical trials being conducted in India.
- Trials registered in the CTRI are freely searchable from the home page of the CTRI, and access to search facility does not require registration in the CTRI.
- Trial registration enhances transparency, accessibility and accountability of clinical trials and their results.
- Trial registration is also expected to reduce duplicate research while improving standard of research in the country.
- Till 30th June 2010, a total 1082 of trials have been registered in the CTRI

Breaking News



Please note that the URL for the CTRI site has changed to - www.ctri.nic.in

Clinical Trials in the Spotlight

Bhopal gas victims used as guinea pigs: NGO
Sushant Gupta, TNN, Jun 17, 2010, 02:42am IST

BHOPAL: A week after light punishment to six accused in Bhopal gas tragedy provoked nationwide outrage, an NGO dropped another bombshell on Wednesday saying the victims of the world's worst industrial disaster were used as guinea pigs in drug trials at a hospital set up for them.

Bhopal Gas Peedith Mahila Udyog Sangathan (BGPMS) claimed it had documents to prove that the trials were conducted without the patients' knowledge and some of them may have even died during the tests at Bhopal Memorial Hospital and Research Centre, which works under the Supreme Court's supervision.

The hospital director, Dr K K Mauder, washed his hands off the controversy, saying he had issued a circular ordering an end to the trials in August 2008. "The hospital hadn't issued orders for the trials, but individual faculty members get such assignments from pharmaceutical companies," he said, and claimed that proper protocol was followed. "The patients who underwent the trials had signed consent forms." Dr Mauder said pharmaceutical companies provide funds for such trials.

BGPMS convener, Abdul Jabbar, debunked the director's claim and alleged that the patients were duped into signing the consent papers. "Most victims couldn't read English and were asked to sign papers in the language," he said. "A copy of the consent statement should have been given to the patients, but that wasn't done. Victims were used as guinea pigs." Jabbar said the hospital was forced to issue the circular after similar trials allegedly killed 49 children at New Delhi's All India Institute of Medical Sciences in July 2008.

Ramodar Shrivastava, a victim, said a nurse asked him to sign the consent paper with explaining why he was doing so. "The nurse told me 'yahan dastakhat karo (sign here)'. After that, they gave me a few bottles of red-coloured capsules which I had to take twice daily. I was asked to return the empty bottles after I finish the dose," said Ramodar. "I had no clue that they were experimenting on me."

Activists have traced 160 patients and medicines used for the trials. The medicines tested included Fonda Parinox (for blood clog removal in the

Points to Remember

- Registration of clinical trials at www.ctri.nic.in is online and free.
- Registration of all clinical trials is mandatory as notified by Drugs Controller General (India) w.e.f.15th June 2009.
- All clinical trials including BA/BE, PMS, MD theses, AYUSH are being registered in the CTRI.
- Currently, ongoing and completed trials are also being registered.
- Trials should be registered either by Principal Investigator (PI) or the Primary Sponsor. Contract Research Organizations may also register a trial.
- For Multi-Centric and Multi-Sponsor Trials, the lead Sponsor should take responsibility for trial registration.
- In case of Multi-Country Trials, if trial is registered in another publically accessible registry, that number should be quoted in CTRI as Secondary ID.
- Submission of Ethics committee approval is required for registration of clinical trials.
- Submission of Drugs Controller General (India) approval, wherever applicable, is essential for registration of a trial.
- It is the responsibility of the Sponsor or the PI to ascertain whether or not DCGI approval is applicable or not for a particular trial.
- In case of PMS trials, DCGI notification is required.
- Central Council of Research in Ayurveda and Siddha (www.ccras.nic.in) should be contacted for further information on trials to be conducted in Ayurveda, Homeopathy, Siddha, Unani, Yoga and Naturopathy.
- Once a trial is registered, the trial is expected to be updated, at least once every 6 months.
- For any amendment in title of the clinical trial or in details of sites, etc. fresh ethics committee approval is required to be submitted with the specified amendments to register the trial.

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

1. Registration Number
2. Trial Registration Date
3. Public Title of Study
4. Scientific Title of Study, Acronym, if any
5. Secondary IDs, (UTN, Protocol No etc)
6. Principal Investigator's Name and Address
7. Contact Person (Scientific Query)
8. Contact Person (Public Query)
9. Source/s of Material or Monetary Support
10. Primary Sponsor
11. Secondary Sponsor
12. Countries of Recruitment
13. Site/s of study
14. Name of Ethics Committee and approval status
15. Regulatory Clearance obtained from DCGI
16. Health Condition/Problem studied
17. Study Type
18. Intervention and Comparator agent
19. Key inclusion/Exclusion Criteria
20. Method of generating randomization sequence
21. Method of allocation concealment
22. Blinding and masking
23. Primary Outcome/s
24. Secondary Outcome/s
25. Target sample size
26. Phase of Trial
27. Date of first enrollment
28. Estimated duration of trial
29. Status of Trial
30. Brief Summary

Underlined items are assigned by the CTRI software upon trial registration.

- For volunteer participation in any trial, if the volunteer/patient meets the inclusion/exclusion criteria and the trial is recruiting patients, the doctor nearest to you may be contacted for further information. The contact details are given on the site.
- For more information visit us at www.ctri.nic.in or email us at ctr.nims@gmail.com.

Publications

Pandey A, Aggarwal AR, Seth SD, Maulik, M. Clinical Trials Registry – India: Raising the veil. *Natl Med J India [Letter to Editor]2010; 23 (3):187 - 188.*

A Brief Summary

The Clinical Trials Registry – India (CTRI) is an online system for registration of all clinical trials being conducted in our country. This web based system (www.ctri.nic.in) is accessible through an internet with its headquarters at the National Institute of Medical Statistics (NIMS), Indian Council of Medical Research (ICMR). It serves as a platform for registering all clinical trials on health products including drugs, devices, vaccines, herbal drugs etc. The registration of trials in CTRI is free of cost and crucial information of these registered clinical trials is freely available. This article highlights the journey of CTRI and its role in enhancing transparency, accountability and accessibility of clinical trials being conducted in the country.

Dissemination Workshops

Northern Region



- CTRI workshop was held at Dayanand Medical College and Hospital (DMCH), Ludhiana on 27th February 2010. Prof. Arvind Pandey - Administrator CTRI briefed about the Genesis of CTRI



- The trial registration process in the CTRI was explained by Dr. Abha Aggarwal, Coordinator CTRI at DMCH.



- Diverse queries raised by the participants were answered by Prof. Arvind Pandey, Administrator CTRI, and Dr. Abha Aggarwal, Coordinator CTRI. Other members on the dais are Prof. Daljit Singh, Dept. Pediatrics Principal DMCH and Prof. Rajoo Singh (R), Dept. Gastroenterology and Dean Academy DMCH.

Western Region



- A workshop on CTRI was organized at Smt. NHL Municipal Medical College and Hospital, Ahmedabad on 25th June 2010, where Prof. Arvind Pandey, Administrator CTRI, Prof S.D. Seth, Advisor CTRI and Dr. Abha Aggarwal, Coordinator CTRI spoke on various aspects of the registry. Other member on the dais are Shri H G Koshia Commissioner, Food and Drug Control, Gujarat and Dr. Pankaj R. Patel (L), Dean, Smt. NHL Municipal Medical College, Ahmedabad



- The trial registration process in the CTRI was explained by Dr. Abha Aggarwal, Coordinator CTRI.



- Ms Anagha Khot, WHO representative highlighted the importance of trial registration.

Ethical Guidelines Issued by ICMR

ICMR issued the 'Ethical Guidelines for Biomedical Research on Human Participants provides that all clinical trials in India must be conducted in compliance with the below Guidelines.

(i) Principles of Essentiality: Research on human participants should be conducted only if it becomes absolutely essential and exhausting all other alternatives available.

(ii) Principles of Voluntariness, Informed Consent and Community Agreement: The research participants should be made aware of the research procedure, the risks involved and its impact on them.

(iii) Principles of Non-Exploitation :All research participants should be paid for their participation in the research irrespective of their socio-economic background, educational level etc.

(iv) Principles of Privacy and Confidentiality: Identity and records of participants should be kept confidential and no details should be disclosed without a valid scientific reason and without the consent of the participant.

(v) Principles of Precaution and Risk Management: Due care and caution should be taken that the research participants and those affected by it are subjected to minimum risk and suffer no irreversible adverse effect.

(vi) Principles of Professional Competence : Research must be conducted by qualified persons who are impartial, have been trained and are aware of all the ethical guidelines required to be followed.

(vii) Principles of Accountability and Transparency: The research should be conducted in a fair, honest, impartial and transparent manner and only after full disclosure of the procedure and risks

(viii) Principles of Maximization of Public Interest and of Distributive Justice : The research and its application must benefit all human beings irrespective of their socio-economic, educational and cultural background.

(ix) Principles of Institutional Arrangement : It is the duty of all persons connected with the research to ensure that all procedures are made in a bonafide and transparent manner.

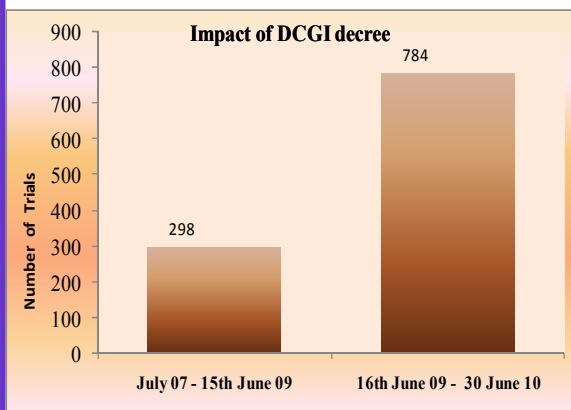
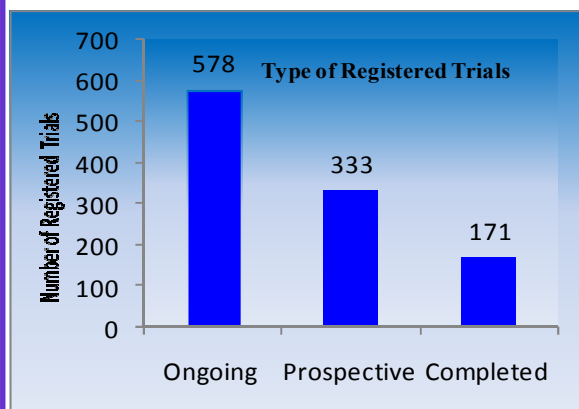
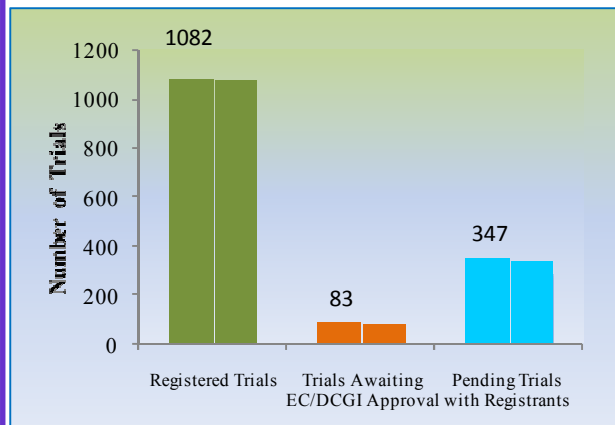
(x) Principles of Public Domain: The research should be made public through scientific and other publications subject to such rights which are available to the researchers under the law in force.

(xi) Principles of Totality of Responsibility :Professional and moral responsibility for observance of all principles, guidelines lies on all those who are directly or indirectly connected with such research

(xii) Principles of Compliance : There is a general duty on all persons conducting, associated or connected with any research to ensure that all guidelines are complied with.

Source: http://www.icmr.nic.in/ethical_guidelines.pdf

Current Status of CTRI till 30th June 2010.



Contact us

Administrator

Clinical Trials Registry-India,

National Institute of Medical Statistics

Indian Council of Medical Research

Ansari Nagar, New Delhi – 110029

Tel: 91-11-26588725, 91-11-26588803

Fax: 91-11-26589635

Email: ctr.nims@gmail.com

For more information visit us at www.ctri.nic.in