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

WHO

CTRI Bulletin

www.ctri.in

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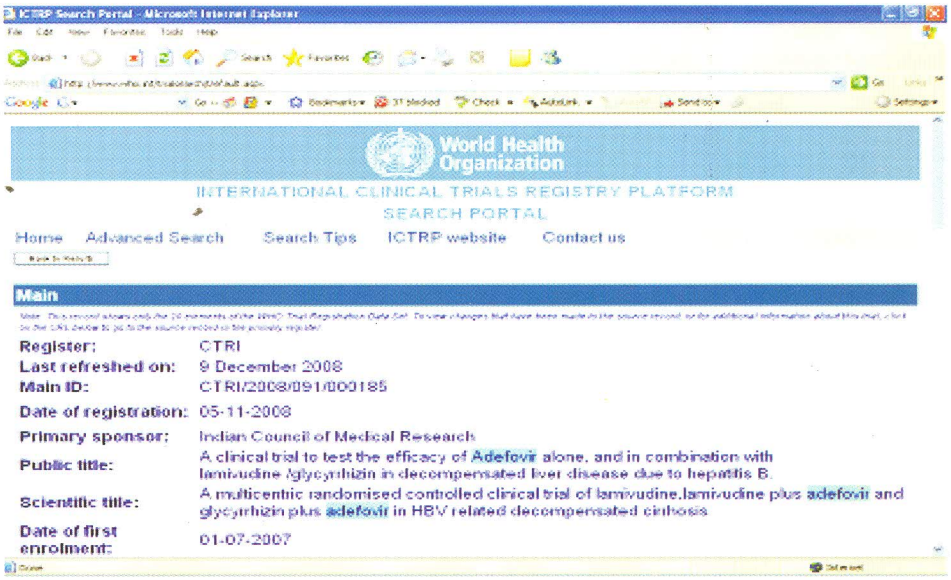
Developed modern methods of rapid diagnosis of TB, leprosy, DNA chips, DNA fingerprinting methods. Published more than 245 papers in National & International Journals. Recipient of several National & International Awards. Membership of National agencies like DBT, DST, CSIR, ICMR, DRDO & International agencies like WHO/ The Leprosy Mission International (TLM).

Welcome to the fourth Bulletin of Clinical Trials Registry—India (CTRI). This newsletter provides a concise summary of recent and upcoming activities relevant to the CTRI.

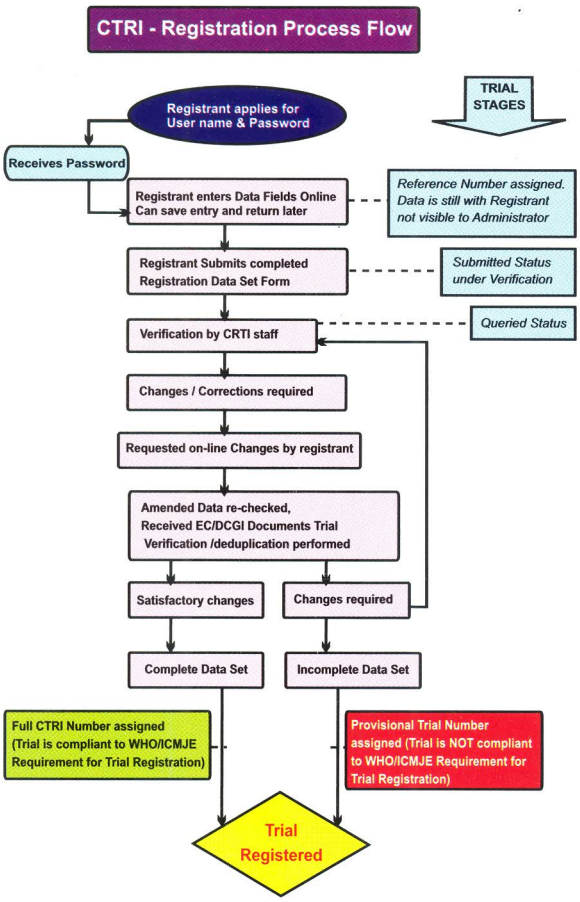
CTRI Highlights

- Since 9th December 2008, trials registered in the CTRI (www.ctri.in), are also searchable from the WHO's International Clinical Trials Registry Platform.
- Since November 2008, registration of trials in CTRI is advised and recommended by the DCGI.
- In addition, Ethics Committee of prestigious Institutions have also started recommending trial registration in CTRI.
- Presentations have been made at various conferences to enhance awareness.
- The CTRI site has received more than 16000 hits.
- 148 trials had been registered till 31st Dec. 2008.
- A Regional Workshop of CTRI was conducted at the National Institute of Cholera & Enteric Diseases, Kolkata. More than 70 participants from various Institutions from Eastern Zone attended the workshop.
- For more information visit us at www.ctri.in



Breaking News

UTRN which will help in Unique Trial Identification as well as avoid duplicate trial registration, has been developed by WHO and is ready for Pilot Testing. CTRI will be the part of UTRN Pilot Testing.



Points to Remember

All trialists are requested to keep the following points in mind when registering as Users or registering a trial:

- Once a User form or trials is submitted to the CTRI, trialists should regularly check their email ID for further communication from ctr.nims@gmail.com
- If no communication is received within 7 working days, registrants should send an email quoting REFCTRI number.
- The REFCTRI number is just an acknowledgement number for easy tracking of trials and does not indicate registration of trial. This number should be quoted in all future correspondence regarding the trial.
- While submitting User registration forms, registrants should take care to check the given email ID as all communications from the CTRI will be made to this email ID.
- On the personal page of the registrant, while a trial is in the SAVED/MODIFIED panel, the trial is not visible to the Administrator at CTRI.
- When a trial is submitted, the trial appears in the PENDING REGISTRATION panel and is not editable in this stage but visible to the Administrator.

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
30. Blinding and masking

Items in Blue are WHO Data Set items.

** Items are mandatory for trial registration to proceed.*

Items in Green are additional Indian Data Set items.

- If subsequently, a registrant finds that a trial has reverted back to the SAVED/MODIFIED panel, the registrant should check his/her email for further information on desired modifications and then resend the trial by clicking on the SUBMIT button.
- While the email ID is displayed in the public domain upon trial registration, phone numbers do not appear in the public domain. Hence, registrants are requested to provide personal phone numbers rather than board numbers to enable quick clarification in case of need.
- In order to expedite trial registration, registrants should simultaneously forward EC/DCGI approval documents either by post or through email.
- In the near future, registrants may have to obtain UTRN from WHO—ICTRP search portal.

CTRI in the News

Publications

- Clinical Trials Registry—India: Redefining the conduct of clinical trials. *Pandey A, Aggarwal A R, Seth S D et al, Maulik M, Bano R, Juneja A; Indian Journal of Cancer; July-September 2008, 45 (3), 79-81.*

- Statement on Publishing Clinical Trials in Indian Biomedical Journals. *Satyanarayan K, Sharma A, Indian Journal Medical Research 127, February 2008, 194-105.*

- Planning a Clinical Trial! Please Register Before Enrolling. *Lalit Kant, Indian Journal of Tuberculosis 2008;55:42-44.*

Declaration of Helsinki Revised Oct. 2008

The World Medical Association, in its latest revision of the Declaration of Helsinki (Oct 2008) among other modifications, specifies that ***"Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject."***

In addition, it also declares, *"Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication."*

The new version replaces all previous versions.

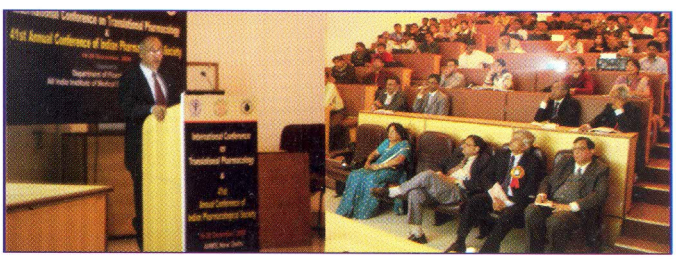
http://www.wma.net/e/policy/b3.htm

Advocacy & Dissemination of CTRI

Workshop on "How to conduct a randomized Clinical Trial" was conducted by Pediatric Hematology Oncology of Indian Academy of Pediatrics on 7 Nov. 2008 at Sir Ganga Ram Hospital, New Delhi. Prof. S.D. Seth (Advisor, CTRI) gave brief introduction about the registry and clarified the doubts related to the registration of clinical trials. Dr. Mohua Maulik explained the process of trial registration.

Best Practices Group of ICTRP on 29th - 30th Sept 2008, WHO HQ, Geneva, was attended by Dr. Ambujam N. Kapoor, Scientist F, ICMR, New Delhi. The objective of the meeting was to arrive at a consensus on Minimum Standards, Data Standards, Unique Trial Identification Number for primary and partner registries of ICTRP.

International Conference on Translational Pharmacology & 41st Annual Conference of Indian Pharmacological Society, was organized on December 18-20, 2008, at the All India Institute of Medical Sciences, New Delhi. Prof. S.D. Seth, Chaired the session. Prof. Arvind Pandey Administrator, CTRI explained the need of the Registry in India and various primary registries linked with WHO. Dr. Abha Rani Aggarwal Co-ordinator, CTRI, explained the process of clinical trial registration. The session was interactive and fruitful discussion was held on certain issues on trial registration and Ethics etc.



Prof. Arvind Pandey, Prof. S.D.Seth and Dr. Abha Aggarwal addressing the delegates about CTRI at the IPS Conference at AIIMS, New Delhi