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

Prof. N.K. Ganguly, Director General, ICMR & Chairman, Clinical Trials Registry- India

Prof. Ganguly, Chairman of the ACHR, SEARO-WHO; Member of International Advisory Board of WHO International Clinical Trials Registry Platform; Member, Scientific Advisory Committee, Bill & Melinda Gates Foundation, initiated setting up of the Registry at NIMS with the support of DST and WHO, in April 2006.

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

1. Need for Registry of Clinical Trials

Clinical trials are a booming business today, and can cost up to US$180 million per trial in the US. Comparative costs in India are believed to be US$100 million. As a consequence, there has been a slow but steady rise in clinical trials being conducted in India, making our country a preferred clinical trial hub. According to estimates, in 2003, revenues were generated to the tune of $70 million, which is expected to increase to $200 million in 2007 and $1.5 billion by 2010.

However, as a series of incidences of unfortunate events associated with clinical trials came to light, there has been a growing call for transparency, accountability and accessibility of clinical trials and their results in order to re-establish public trust in clinical trial data.

All this appears to be possible only by mandatory registration of all clinical trial, with the ultimate goal of ensuring that all trial results, positive or negative, will be released to the public. Worldwide, this view has been accepted and set in motion through the commitment by the International Committee of Medical Journal Editors (ICMJE), who have made some minimum requirements for data to be included in such registries is a prerequisite for publication of trials in certain journals.

Several trial registries are already in place the world over, such as the ACTR, ClinicalTrials.gov, ISCRTN, etc. Furthermore, the WHO is promoting an international initiative to develop a meta-register of controlled trials that would offer a onestop search portal fed from existing registers and provide a unique identification number for clinical trials from certified registries that meet standard criteria for the exchange of essential trial data, such as disclosing 20 key details of the trial at or before the enrollment of the first patient (http://www.who.int/ictrp/en/).

Keeping with the times and its demands, a registry, Clinical Trials Registry-India (CTRI), funded jointly by the DST, WHO and ICMR has been initiated.

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 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.*

2. Clinical Trials Registry -India

In India, National Institute of Medical Statistics (NIMS), one of the institutions of Indian Council of Medical Research (ICMR), New Delhi has been identified as a neutral body for hosting the CTRI.

Setting up of the CTRI is a meaningful step toward greater transparency and accountability in clinical trials and their scientific process. With the proposal for declaration of trial results gaining ground, doctors and patients will in the very near future be assured of access to all scientifically sound information. Moreover, therapeutic strategies that are developed in the future will be based on all clinical trial data and not just the ones that get published.

CTRI will be used to provide a corrective system against "positive result bias" and "selective reporting" of research result to peer reviewed publication, to increase awareness and accountability of all the participants of the clinical trials and for public access, to promote training, assistance and advocacy for clinical trials by creating database and modules of study for various aspects of clinical trials and its registration.

To achieve these objectives, a number of internal and external meetings have been held. Once the Registry (www.ctri.in) is operational, anybody who wishes to conduct a clinical trial in the country would have to declare not only the twenty plus one items of the Trial Registration Data Set as required by the WHO's ICTRP, but also a few more data items relevant to the Indian scenario.

3. The Guiding Hand

The Registry is supported by Three Boards, namely the "Steering Committee", "Technical Working Group" and "Monitoring Committee" for smooth working of the Registry.

Steering Committee (SC)

The SC is composed of 15 members. The SC addresses issues related to strategies, policies and advocacy for clinical trials registration. The SC meets once a year for policy decisions and its first meeting was held on 15th February, 2007, in NIMS, ICMR under the chairmanship of Prof. NK Ganguly, Director General, ICMR.

Technical Working Group (TWG)

The TWG focuses primarily on the technical aspects of the software development and website related issues. TWG meetings were held on 3 rd, 11th and 16 th April to decide the various aspects of the software application to be hosted on the internet. Some examples include Trial Registration Data Set Items, Mandatory Items, Items of deduplication, Reference Numbering System, hardware requirements etc.

CTRI Team

Chairperson
Prof. N.K. Ganguly, Director General, ICMR, New Delhi

Vice Chairperson
Prof. C. M. Gupta, Director, CDRI, Lucknow

Administrator
Prof. Arvind Pandey, Director, NIMS, ICMR, New Delhi

Advisor
Prof. S. D. Seth, Chair (Clin. Pharma.), ICMR, New Delhi

Coordinator
Dr. Abha Aggarwal, AD, NIMS, New Delhi

Technical Working Group
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Prof. Arvind Pandey, Director, NIMS, New Delhi
Dr. V. Muthuswamy, Sr. DDG, BMS, ICMR, New Delhi
Dr. P. Tharyan, Professor of Psychiatry, CMC, Vellore
Prof. C. M. Pandey, SGPGI, Lucknow
Dr. A. N. Kapoor, DDG (SG), ICMR, New Delhi
Dr. Abha Aggarwal, Coordinator CTRI, NIMS, New Delhi
DST Representative , New Delhi
WHO Representative to India, New Delhi

Scientists
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Dr. Mohua Maulik, Sr. Res. Sc., CTRI, NIMS, New Delhi
Dr. Rahmat Bano, Sr. Res. Sc., CTRI, NIMS, New Delhi
Ms. Anuradha Dubey, Scientist, CTRI, NIMS, New Delhi

Data Entry Operators
Mr. Lalit Parasher
Mr. Anoop Upadhyay
Ms. Noori Dua
Mr. Harish Kumar
Mr. Bir Singh

IT Development and Support
Govern-IT, Kerala

Pic. 1: Steering Committee Meeting

Pic. 2: Steering Committee Meeting

4. Advocacy & Consensus Building

ICMR-WHO Experts Group Meeting

The first Experts Group Meeting was conducted at ICMR on 28th October, 2006 under the chairmanship of Prof. N.K. Ganguly, Director General, ICMR, New Delhi. Experts from various fields from ICMR, WHO, DST, DBT, CSIR, CDRI, Pharma Industry, CROs, etc were invited for advocacy and consensus building regarding setting up of the clinical trials registry in India. The primary objective was to set up the CTRI with broad consultation that take into account the needs and available resources of all parties concerned.

Sensitization of the Pharma Industry

A Sensitization meeting with Pharmaceutical Industries was conducted on 27th April, 2007, under the Chairmanship of Prof. S.D. Seth in absence of Prof. N.K. Ganguly, Director General, ICMR. The industry, in general, welcomed the registry and offered a few suggestions relevant to their concerns.

5. Key Features of the CTRI

The Indian clinical trials registry is named the Clinical Trials Registry India. The acronym is CTRI and the domain name of the Registry is www.ctri.in. The CTRI is planned to be a freely available and searchable Primary register which will be linked to the WHO search portal, like other Primary Registers. As mentioned earlier, the WHO has identified 20 plus one points pertaining to clinical trials that need to be declared before enrolling the first patient in a clinical trial. In addition to the WHO items of the Registration Data Set, the CTRI also requires declaration of few additional items before the enrolment of the first patient. Thus to register a study, trialists will need to submit information as per the information required by the CTRI Registration Data Set. While registration is voluntary, some fields are mandatory for registration to proceed. Registration will not proceed if the fields marked with an asterisk are not filled. Some fields marked WHO also need to be filled if the trial is to receive a registration number and fulfill WHO/ICMJE requirements.

Incomplete entries will be given a provisional registration number that will not suffice for purposes of publication in journals that endorse the ICMJE recommendations for trial registration. If all the necessary fields are filled with valid and informative entries, the trial will be officially registered and allocated a unique registration number.

Trials which are not verifiable from relevant sources despite attempts to do so by the CTRI staff, but appear complete with respect to trial information is provided, the trial will be fully registered but a note will mention that it is "Not verified". CTRI will encourage registrants to include subsequent protocol amendments and give regular updates on the status of trial.

Pic 3: Sensitization Meeting with Pharma Ind.

CTRI Registration Data Set

1. UTRN *(to be assigned by WHO)* * WHO
2. Registration Number *(to be assigned by CTRI)* WHO
3. Trial Registration Date *(to be assigned by CTRI)* WHO
4. Public Title of study (meant for the lay public) * WHO
5. Scientific Title of Study, * WHO
6. Secondary IDs, if any WHO
7. Principal Investigator's Name and Address
8. Contact Person (Scientific Query) WHO
9. Contact Person (Public Query) WHO
10. Funding Source/s WHO
11. Primary Sponsor WHO
12. Secondary Sponsor
13. Name of Ethics Committee and approval status *
14. Regulatory Clearance obtained from DCGI *
15. Date of first enrollment WHO
16. Estimated duration of trial
17. Target sample size WHO
18. Health Condition/Problem studied WHO
19. Intervention and Comparator agent WHO
20. Key inclusion/Exclusion Criteria WHO
21. Primary Outcome/s WHO
22. Secondary Outcome/s WHO
23. Countries of Recruitment WHO
24. Site/s of study
25. Status of Trial * WHO
26. Phase of Trial *
27. Study Type WHO
28. Brief Summary
29. Method of generating randomization sequence
30. Method of allocation concealment
31. Blinding and masking

Highlighted items are those which are additional to the WHO's Data Set . Fields marked with are mandatory for registration.*

For more details please visit www.ctri.in

6. Presentations

(i) A presentation was made by Prof. Arvind Pandey, Director, NIMS (ICMR), New Delhi, being conducted to the Steering Committee on the development of the work done in the registry so far. He brought forward the various issues that needed to be decided by the Steering Committee.

(ii) A presentation was made by Prof. Arvind Pandey, Director, NIMS (ICMR), New Delhi to sensitize the Pharma Industry members to the CTRI.

(iii) A presentation was made by Dr. Abha Aggrawal, Project Coordinator, CTRI to the Pharma Industry members to familiarize them with the process flow of the trial version of the software application of the Registry.

7. Contact Us

We welcome your questions, comments and suggestions on any of the topics presented in this Bulletin and on our project in general. Please send your email to: ctr.nims@gmail.com

To subscribe/unsubscribe to the Clinical Trials Registry India, Newsletter, please send an email to: ctr.nims@gmail.com with the word "Subscribe" or "Unsubscribe" in the subject line.

WHO Network of Registries

Primary

- Australian Clinical Trials Registry
- ClinicalTrials.gov
- ISRCTN

Potential Contributing Registers

- Clinical Trial Database of the University Hospital Freiburg
- Clinical Trials Registry - India (in development: not yet open to registrants)
- Latin American Clinical Trials Register (LatinRec)

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

News & Events

Society for Clinical Trials invited Dr. Ambujam Nair Kapoor, DDG (SG), ICMR and Dr. Abha Aggrawal, Coordinator, CTRI to present the features of the Indian Registry at the meeting held on 20th- 23 rd May 2007 at Montreal, Canada. A special interaction session was organized with Ms Davina Ghersi, Coordinator ICTRP.

News You Can Use

- **Cochrane Library** ICMR has ensured that all residents of India can access the full contents of *The Cochrane Library* for free. (http://www.cochrane.org)
- **Diabetes Registry** ICMR has initiated diabetic registry in September 2006 at 5 centers of the country to record the data pertaining to young diabetic patients. More information is available at ECD Division of ICMR, New Delhi
- **Cancer Registry** ICMR has opened the cancer registry by keeping the objectives in mind - To obtain an overview of patterns of cancer in different parts of the country; and to calculate estimates of cancer incidence wherever feasible. You can access the register on the website: http://www.canceratlasindia.org

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Address

Postage