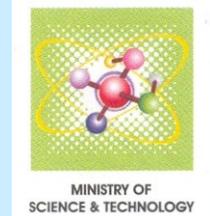




Clinical Trials Registry - India

National Institute of Medical Statistics (ICMR)



CTRI Bulletin

www.ctri.nic.in

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Objectives of CTRI

- To establish a public record system by registering all clinical trials on health products that are drugs, devices, vaccines, herbal drugs and is made available to both public and healthcare professionals in an unbiased, scientific and timely manner;
- To create a complete, authentic and readily available data of all ongoing and completed clinical trials;
- To provide a corrective system against “positive results bias” and “selective reporting” of research results to peer review publication;
- To increase awareness and accountability of all the participants of the clinical trials and also 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

CTRI Highlights

- The CTRI (www.ctri.nic.in) is a free and online system for registration of clinical trials
- Till 30th June 2013, 3790 trials have been registered in the CTRI.
- Prospective trial registration (i.e. before enrollment of first patient) is encouraged.
- The revised and upgraded version of the CTRI was launched on 15th March 2011
- All trials registered in the CTRI are expected to be updated as per revised format of the CTRI data set points.
- EC/DCGI approval documents are also to be uploaded on the site.

Independent Ethics Committee to approve BA/BE trials only

File No. ECR/Misc/Indt EC/007/2013
Directorate General of Health Services
O/o Drugs Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi - 110 002
Dated: 30 JUL 2013

NOTICE

Sub: Independent Ethics Committees in respect of periodic review of the ongoing clinical trials.

This office has registered the Independent Ethics Committees subject to the condition that “The Ethics Committees shall review and approve only the study protocols and relate documents of Bioavailability/Bioequivalence studies of the approved drug molecules and also carry ongoing review of such studies”.

It has been decided that Independent Ethics Committees which have been registered for conducting Bioavailability(BA)/Bioequivalence (BE) studies only can conduct periodic review of the ongoing clinical trials already approved by them. However, no new clinical trial shall be reviewed and approved by such independent Ethics Committees.

(Dr. G. N. Singh)
Drugs Controller General (I)

To,

1. All zonal and Subzonal offices of CDSCO
2. Web site of CDSCO

Breaking News:

Ethics committee must be registered with the DCGI office (www.cdsc0.nic.in)

Phases of Clinical Trials

All phases require approval from EC. The first three of the following four phases of clinical trials of drug require DCGI's clearance:

Phase I (Human Pharmacology) -

This is a non-therapeutic trial and the objective is to determine the safety of a new drug and determine the maximum tolerated dose as also to determine the nature of adverse reactions that can be expected. In healthy adults of both sexes. Healthy female volunteers could be included provided they have completed their family or do not intend to have a child in the future. These studies include both single and multiple dose administration and should ideally be carried out at a site that is adequately equipped.

Phase II (Therapeutic Exploratory Trials)

These are controlled studies conducted in a limited number of patients of either sex to determine therapeutic effects, effective dose range and further evaluation of safety and pharmacokinetics in patients. Generally due to selection of patients with narrow inclusion criteria to find effective dose the study population is more or less homogenous. The dose used is lesser than the highest dose used in phase I. Another objective of this Phase II is evaluation of potential study endpoints, therapeutic regimens including concomitant medications and target populations, and mild versus severe disease, for further studies in Phase II or III. These objectives may be served by exploratory analyses of subsets of data and by including multiple endpoints in trials. Normally 20 - 25 patients should be studied for assessment of each dosage. These studies are usually limited to 3 - 4 centres. It is advisable to include a clinical pharmacologist as a co-investigator in such studies

Phase III (Therapeutic Confirmatory Trials)

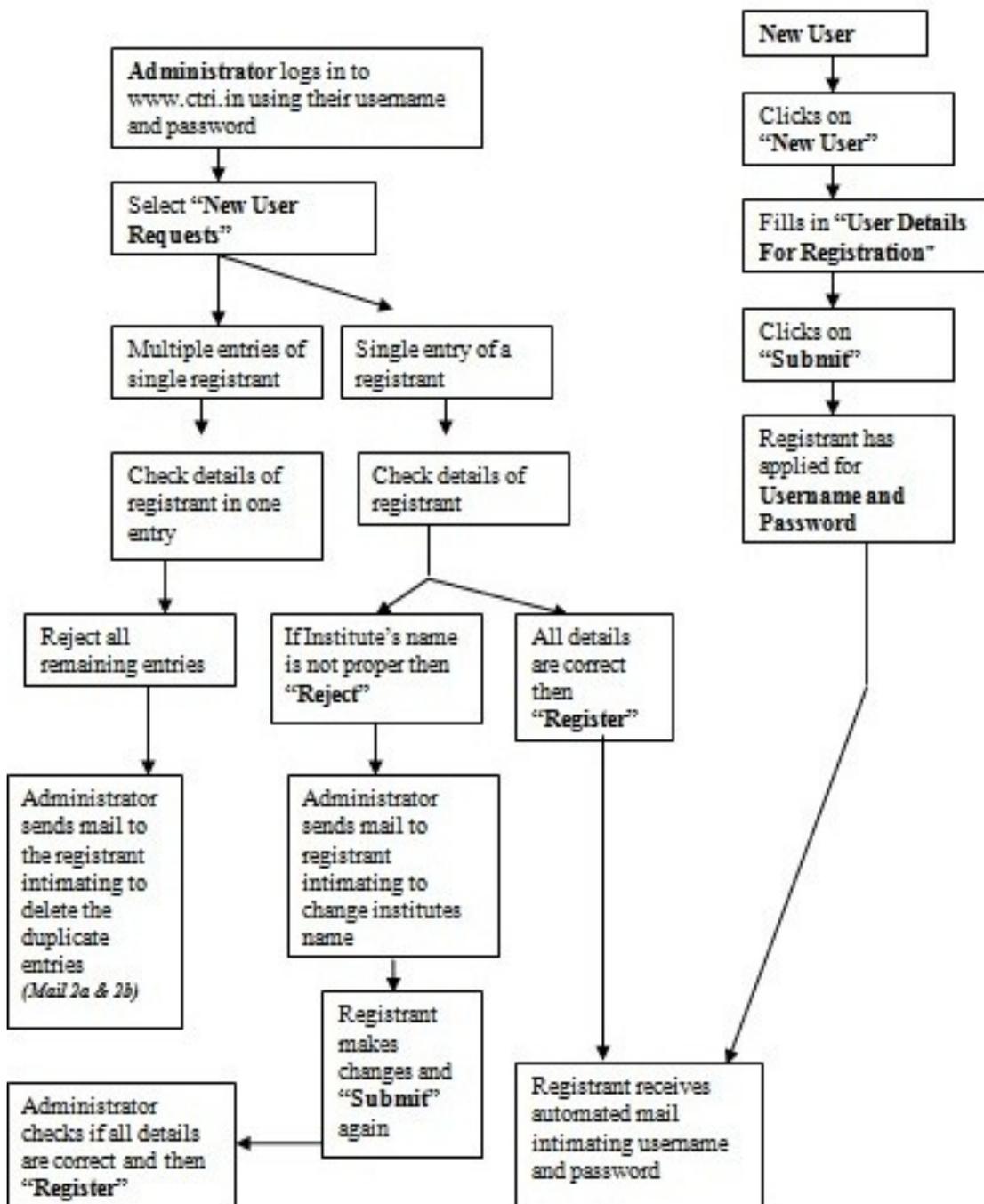
The purpose of these trials is to obtain adequate data about the efficacy and safety of drugs in a larger number of patients of either sex in multiple centres usually in comparison with a

standard drug and / or a placebo if a standard drug does not exist for the disease under study. This is to validate efficacy and safety found in Phase II. On successful completion of phase III trials permission is granted for marketing of the drug. Studies in Phase III may also further explore the dose-response relationship to drug concentration in blood and clinical response, use of the drug in wider populations, in different stage of disease, or the safety and efficacy of the drug in combination with other drug (s). For drugs intended to be administered for long periods, trial involving extended exposure to the drug are ordinarily conducted, although they may be initiated in Phase II. These studies carried out in Phase III complete the prescribing information needed to support adequate instructions for use of the drug

Phase IV

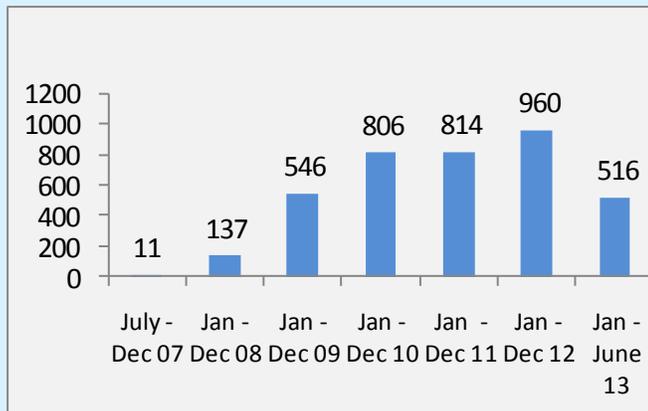
The Phase IV studies should have valid scientific objectives. After approval of the drug for marketing, phase IV studies or post marketing surveillance is undertaken to obtain additional information about the risks and benefits resulting from long term usage of drug. It is an important aspect of drug trial on the longterm effects of the drugs and the adverse reactions induced by drugs, if any, should be brought to the notice of the Ethics Committee There is a need to correlate the adverse events reported during Phase IV trials with the toxicity data generated in animals, to draw markers for future warnings of potential adverse events likely to occur with other drugs. These trials may not be necessary for approval of new drug for marketing but may be required by the Licensing Authority for optimizing its use. These studies also include those on specific pharmacologic effect, drug-interaction(s), dose-response studies, trials designed to support use under approved indication(s) e.g. mortality/morbidity studies, clinical trials in a patient population not adequately studied in the pre-marketing phase, e.g., children; and epidemiological studies etc. Bioequivalence and bioavailability study also falls under this category

Flowchart 1: New User registration by registrant/ CTRI



Current Status of CTRI (till 31st Dec.2012)

Fig 1: Trend of trial registration in CTRI



Current Status of CTRI (till 30th June 2013)

Fig 3: Trend of trial registration in CTRI

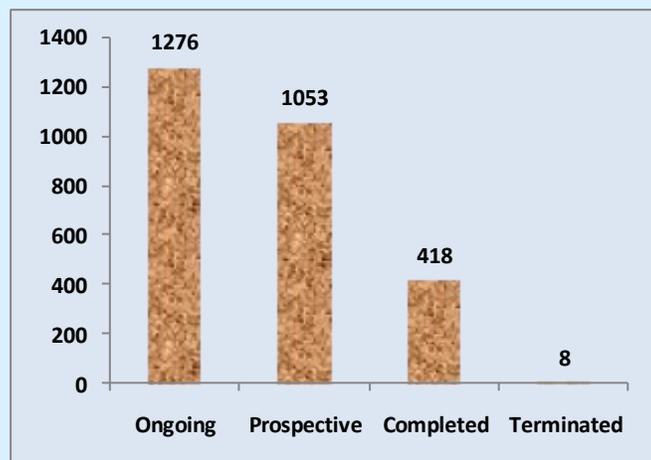
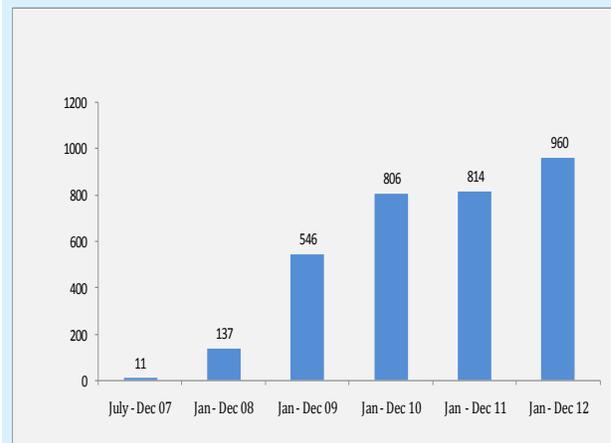
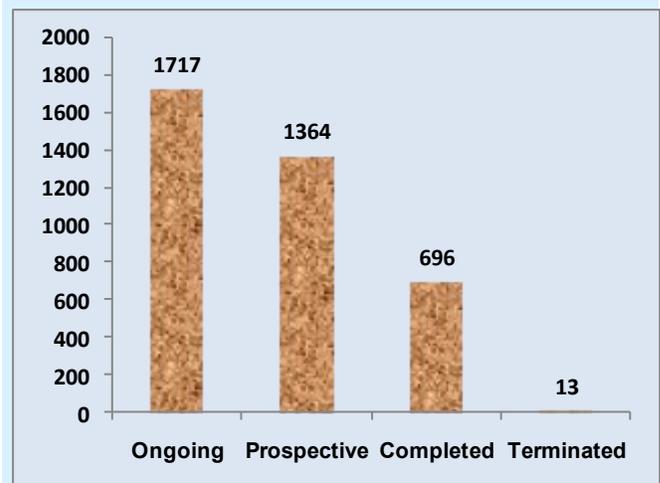


Fig 4. Break up of registered trials



Publications

- Pandey A, Aggarwal AR, Maulik M, Gupta J, Juneja A. Challenges in Administering a Clinical Trials Registry: Lessons from the Clinical Trials Registry-India
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- Pandey A, Aggarwal AR, Seth SD, Maulik M, Clinical Trials Registry – India: Raising the veil. Nati Med J India. [Letter to Editor] 2010;23(3):187-188.
- Pandey A, Aggarwal AR, Moulik M, Seth SD, clinical trials registration gains momentum in India: J Med res. (Letter to Editor) 2009;130:85-86.
- Pandey A, Aggarwal AR, Seth SD, Maulik M, Bano R, Juneja A, Clinical Trials Registry-India: Redefining the conduct of clinical trails. Indian J Cancer.2008;45(3):79-82
- Pandey A, Aggarwal AR, Maulik M, Gupta J, Juneja A, Seth SD. The upgraded Clinical Trials Registry India: a summary of changes. Indian Journal of Medical Ethics. 2011; VIII(3):186.

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