ICMR

Clinical Trials Registry - India

National Institute of Medical Statistics (ICMR)

CTRI Bulletin

www.ctri.nic.in

Vol.8 July-Dec. 2011 &
Vol.9 Jan-June. 2012

In This Issue

- CTRI Highlights
- Trial Details in Public Domain
- How to Modify/Clarify Trials
- Revised Data Set fields of CTRI
- Dissemination Workshops of CTRI
- PG Thesis Registration
- Current Status
- Publications

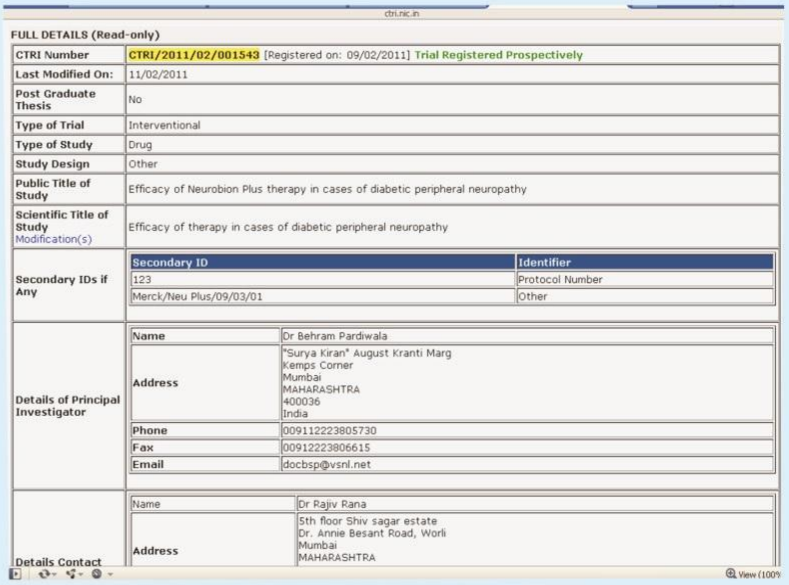
Objectives of CTRI

- 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 2012, 2749 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 fields.
- EC/DCGI approval documents are also to be uploaded on the site.

Trials Details in Public Domain



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FULL DETAILS (Read-only)

CTRI Number	CTRI/2011/02/001543 [Registered on: 09/02/2011] Trial Registered Prospectively
Last Modified On:	11/02/2011
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Other
Public Title of Study	Efficacy of Neurobion Plus therapy in cases of diabetic peripheral neuropathy
Scientific Title of Study Modification(s)	Efficacy of therapy in cases of diabetic peripheral neuropathy
Secondary IDs if Any	Secondary ID: 123 — Identifier: Protocol Number Merck/Neu Plus/09/03/01 — Other
Details of Principal Investigator	Name: Dr Behram Pardiwala Address: "Surya Kiran" August Kranti Marg, Kemps Corner, Mumbai, MAHARASHTRA, 400036, India Phone: 009112223805730 Fax: 00912223806615 Email: docbsp@vsnl.net
Details Contact	Name: Dr Rajiv Rana Address: 5th floor Shiv sagar estate, Dr. Annie Besant Road, Worli, Mumbai, MAHARASHTRA

View (100%)

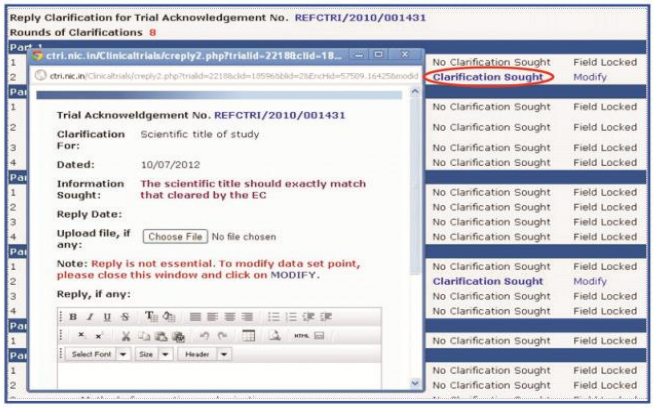
Breaking News

All Registrants are requested to update their trials regularly. PDF files can be generated for all trials.

How to Modify/Clarify Trials

1. Click to view clarification on registrant's home page

2. Click to view 'Clarification sought' by CTRI Administrator.



3. Click on 'Modify' to access data set field.

4 Step 3 provides access to original data set field for editing purposes.

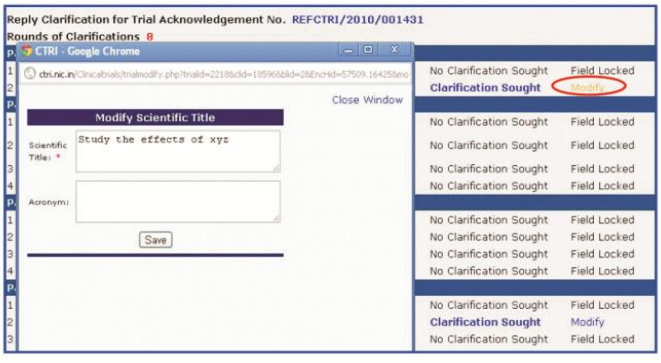
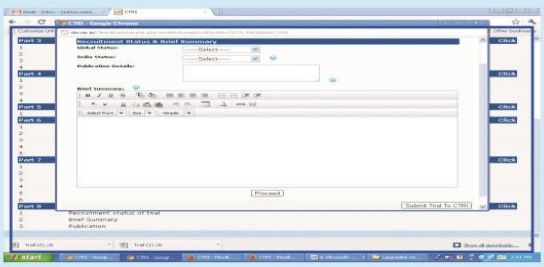


Table 1 Revised Data set fields of the CTRI

CTRI data set fields are divided into 8 parts. After filling part 1, any of the parts may be filled up at the convenience of the registrant .

Part 1		**Click**
1	Public title of study	
2	Scientific title of study	
Part 2		**Click**
1	Secondary IDs	
2	Principal Investigator or overall Trial Coordinator (multi-center study) Details	
3	Contact person (Scientific Query)	
4	Contact person (Public Query)	
Part 3		**Click**
1	Source/s of monetary or material support	
2	Primary sponsor	
3	Secondary Sponsor	
4	Countries of recruitment	
Part 4		**Click**
1	Site/s of study	
2	Name of Ethics Committee and approval status	
3	Regulatory clearance obtained from DCGI	
4	Health condition/problems studied	
Part 5		**Click**
1	Study Type	
2	Postgraduate Thesis	
3	Type of Trial	
4	Study Design	
Part 6		**Click**
1.	Intervention and comparator agent	
2	Inclusion & Exclusion Criteria	
3	Method of generating randomization sequence	
4	Method of allocation concealment	
5	Blinding/masking	
Part 7		**Click**
1.	Primary outcome/s	
2.	Secondary outcome/s	
3.	Target sample size • Total • India	
4.	Phase of trial	
5.	Date of first enrollment • India • Global	
6.	Estimated duration of trial	
Part 8		**Click**
1.	Recruitment status of trial • Global Status • India Status	
2.	Brief Summary	
3.	Publication	

To submit trial, click on Part 8 and click on "Submit Trial To CTRI" button



Dissemination workshops of CTRI

In order to ensure smooth trial registration as well as to enhance awareness regarding the importance of trial registration, several regional workshops were conducted in North and South zones.

Northern Region:

PGIMER, Chandigarh 21 July 2011

A dissemination workshop of CTRI was held on 21st July 2011 at PGI, Chandigarh to disseminate information among clinical researchers from various regions of North India regarding registration of clinical trials being conducted in India.

SGPGI Lucknow 19th August 2011

A dissemination workshop of CTRI was held on 19th August 2011 at SGPGI, Lucknow to enhance awareness regarding trial registration among trialists in the region

Southern region:

SCTIMST Trivandrum 28th Aug 2011

A CTRI workshop was organized at Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST), Trivandrum 28th Aug 2011. More than 100 participants attended this workshop aimed at generating awareness regarding trial registration and clarifying issues related to the trial registration process.

Ethics Committee Meeting 26th Sept. 2011

A dissemination workshop for the members of the ethics committee from different parts of the country including Delhi based medical institutions was organized at Delhi on 26th September 2011. This workshop was attended by more than 70 participants representing different parts of the country including Delhi. The purpose of the workshop was to create awareness amongst members of Ethics Committees and garner their support in recommending registration of clinical trials.

Advocacy meetings of CTRI

5th Annual Clinical Trial Disclosure Conference (DIA), USA 13-14th September 2011

Prof Arvind Pandey delivered a talk on CTRI in the 5th Annual Clinical Trial Disclosure Conference of the Drug Information Association (DIA) during 13-14th September 2011 of USA. The policy of collecting all PI and site details was particularly appreciated and deliberations were held at the DIA meeting to discuss how these could be included in the other registries.

KEM Hospital, Mumbai 5-6th November 2011

Dr. Abha Aggarwal, Coordinator, CTRI presented as a faculty the CTRI at the 1st FERCI National Conference on Research Ethics on 5-6th November 2011

Medanta, Gurgaon 14-15th December 2011

Dr. Abha Aggarwal, Coordinator, CTRI presented the process of registration of clinical trials during the training programme on Clinical Research Ethics Workshop at Medanta, Gurgaon on 15th December 2011

St. John's Medical Collage Bangalore, 20-24th February 2012

Dr. Abha Aggarwal, Coordinator, CTRI, as a faculty made a presentation CTRI in a Training Programme on PG Diploma in Bioethics at St. John's National Academy of Health Sciences, Bangalore on 24th February 2012

PGI Chandigarh 25th February 2012

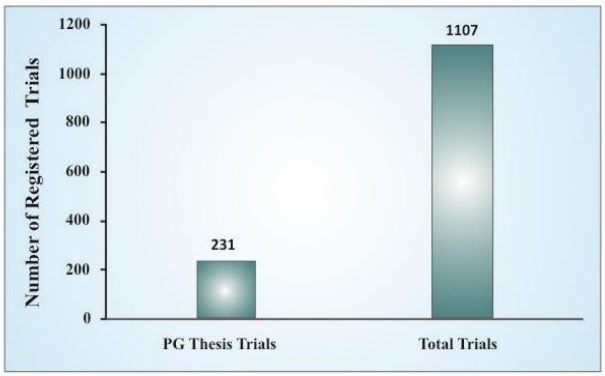
Prof. Arvind Pandey, Administrator, CTRI, as Guest of Honour, in a training workshop on Advances in Pharmacology at Department of Pharmacology, PGI Chandigarh and Dr. Atul Juneja as a resource person presented the process of registration.

PG Thesis registration

Trials being conducted as part of post-graduation thesis are also expected to be registered in the CTRI. The advantages and purpose of registering such trials are several:

- It will help researchers avoid unnecessary duplication of effort (which is distinct from appropriate replication). If a study has already been conducted and has conclusively shown positive or negative results, then it is unethical, wasteful and in some cases dangerous to repeat it.
- This will also serve as a valuable source of information for researchers as they initiate and design their studies and it is a valuable source of information as it is now mandatory to include the personal information like name of student doing the research and the details of the guide under whose guidance the research is being conducted etc.
- Registration of thesis might also reveal areas of fruitful future investigation. For example, if few studies have been conducted in certain disease areas or for certain drugs or combinations of drugs, and then investigators and funding organizations might consider these as important opportunities for future research.
- The information will serve as an unbiased source of data for researchers who are conducting meta-analyses of trial results to create systematic reviews of the literature on treatments for a particular disease.
- It would help to overcome publication bias that exists because of the tendency of researchers to publish only "positive" results" and "selective reporting" of research results to peer review publication.

Fig 1 PG theses registered between 15th March 2011 - 15th June 2012



Current Status of CTRI (till 30 June 2012)

Fig 2 Trend of trial registration in CTRI

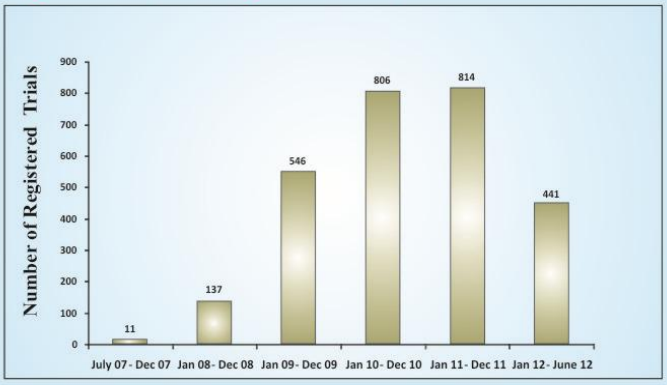
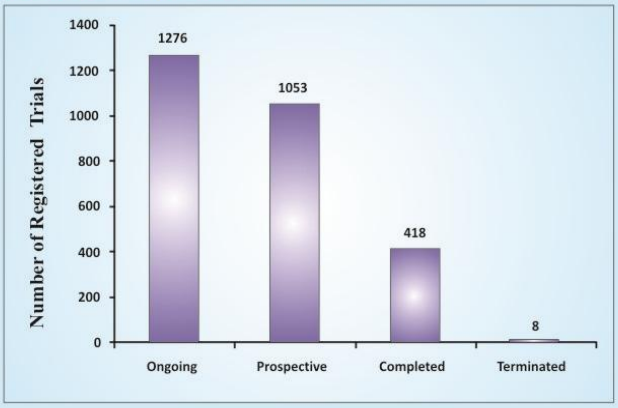


Fig 3. Break up of registered trials



Publications

1. 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.
2. Pandey A, Aggarwal AR, Seth SD, Maulik M, Juneja A. Strengthening ethics in clinical research. *Indian J Med Res.* [Letter to Editor] 2011; 133:339-340.
3. 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.
4. Pandey A, Aggarwal AR, Maulik M,Seth SD. Clinical trials registration gains momentum in India. *J Med Res.* (Letter to Editor) 2009;130:85-86.
5. 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

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