ICMR

Clinical Trials Registry - India

National Institute of Medical Statistics (ICMR)

DST

CTRI Bulletin

www.ctri.nic.in

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In This Issue

CTRI Highlights

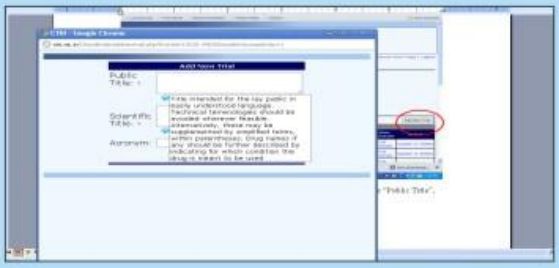
- The CTRI (www.ctri.nic.in) provides a platform for the free and online registration of clinical trials being conducted in the country
- Till 30th June 2011, 1852 trials have been registered in the CTRI
- The revised and upgraded version of the CTRI was launched on 15th March 2011
- The data set points remain much the same as before, although a few additional sub-points have been added to ease data collection, analysis and improve search facility.
- All registered in the CTRI are expected to be updated as per revised format of the CTRI data set points.
- To update registered trials, registrants should click on "Registered trials" and then clicking on Modify against each data set point
- Following update, the field will become "locked" for further editing, and may be unlocked by sending in a request to CTRI.
- All Modification made to registered trials are visible in the public domain (Audit Trail)
- Dissemination/advocacy workshops were held at Sharda University, Noida, NIOH, Ahmedabad and IGMC&RI, Puducherry.

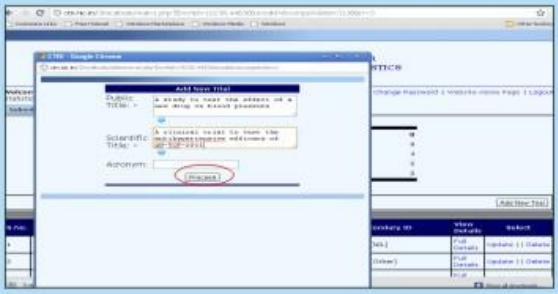
CTRI Software Application Upgraded

Login page of registrants

Note : ***Please note that the CTRI software application has been revised and upgraded. All registrants are requested to login and update all data set points of trials (including registered trials) as per revised data set format of the CTRI to enable correct representation of their trial data in the public view.***

How to add a Add New Trial





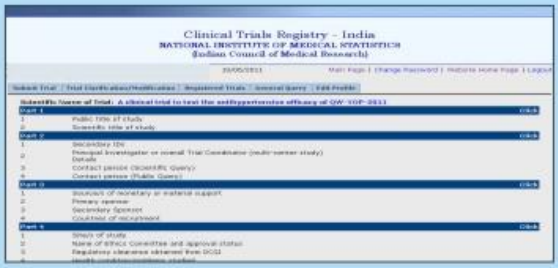
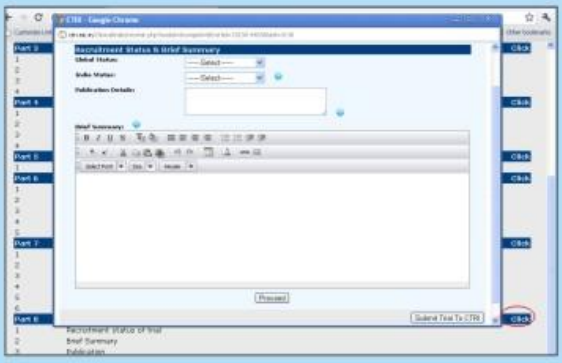


Table 1 Revised Data set points of the CTRI

CTRI data set points are divided into 8 parts (Table 1). 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	
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	
4	Phase of trial	
5	Date of first enrollment	
6	Estimated duration of trial	
Part 8		**Click**
1	Recruitment status of trial	
2	Brief Summary	
3	Publication	

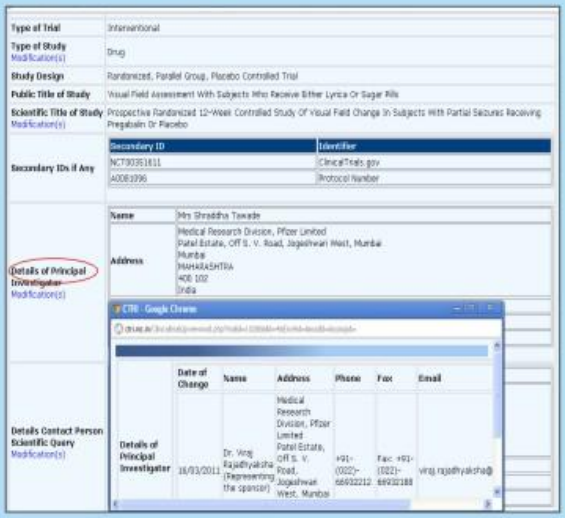
To submit trial, click on Part 8 and click on "Submit Trial To CTRI" button



New features of the upgraded version

Audit trail

All updates incorporated in a registered trial are visible in the public domain under "Modifications"

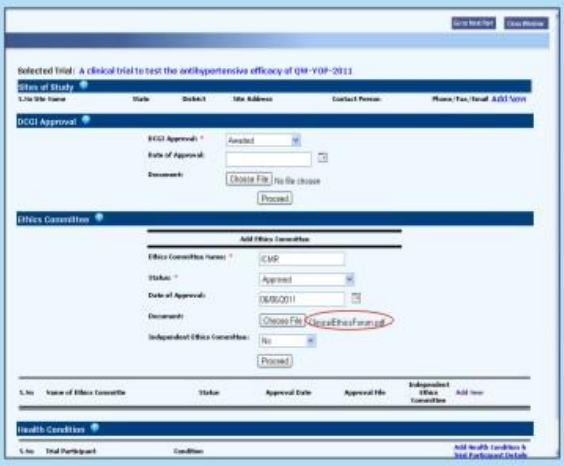


Trial Transfer

It is now feasible to transfer a trial from one Registrant to another, within a company or between companies.

Submission of EC/DCGI approval documents

EC/DCGI approval documents may now be uploaded from the CTRI site itself. The uploaded documents are not visible in the public domain

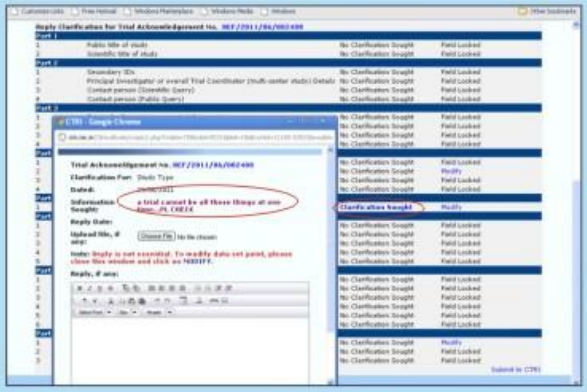


Points to be noted:

- Name of Ethics Committee to be mentioned
- Status of approval, i.e. Submitted/under review; Approved, No Objection Certificate, Not Applicable to be selected
- If Independent Ethics Committee, YES should be selected
- Name of the city from where the Independent Ethics Committee functions should be mentioned
- EC approvals to be uploaded after selecting Status as APPROVED and selecting date of approval from calendar provided.
- Only MS-WORD or PDF format should be uploaded
- File names should not contain blank spaces or dots eg EC APPROVAL.1, please change this file name to EC_APPROVAL1 or ECapproval1
- Uploaded files should not be more than 1 MB.
- After uploading file, it the uploaded file should be viewed to confirm that it is viewable.

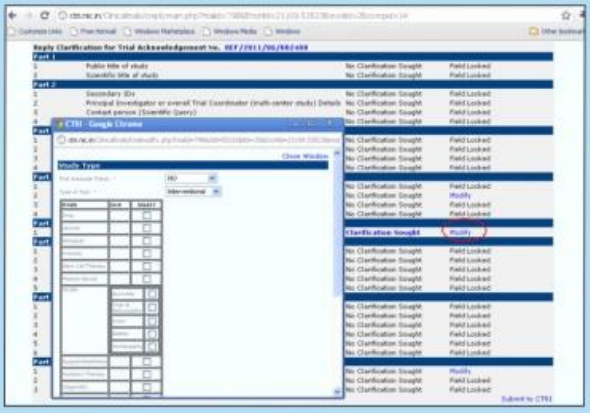
How to update a registered trial

After a trial has been reviewed, the trial will be available in the second panel [Trials sent back after review by CTRI]



All fields which are satisfactory would be "Locked", while fields requiring clarification would be labeled "Clarification Sought" and specifies the clarification or modification desired. Any reply sent is meant for only communication with the CTRI and any data uploaded in the REPLY panel is not reflected in the data set.

To incorporate changes in the data set click on MODIFY, which provides access to the relevant data set point (see below).



Note: Data set points "Name of Ethics Committee and approval status" and Recruitment status of trial" remains "unlocked" to enable registrant to freely update status and upload of EC approval (for multi-centre trials) as and when available.

Current Status of CTRI (till 30 June 2011)

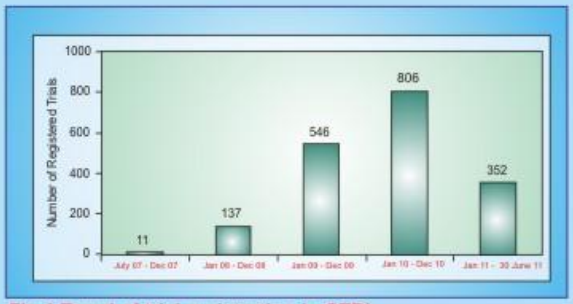


Fig 1 Trend of trial registration in CTRI

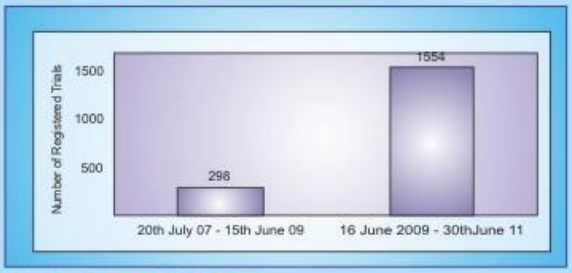


Fig 2 Impact of DCGI decree

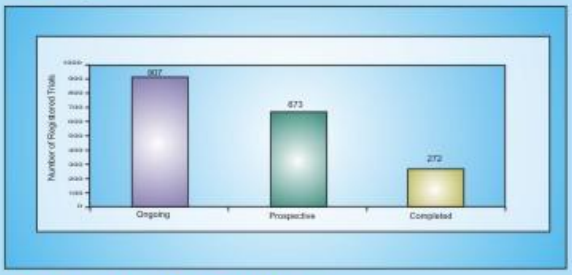


Fig 3 Break up of registered trials

Publications

1. 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.
2. 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.
3. Pandey A, Aggarwal AR, Maulik M, Seth SD. Clinical trial registration gains momentum in India. Indian J Med Res. [Letter to Editor] 2009; 130: 85-86.
4. Pandey A, Aggarwal AR, Seth SD, Maulik M, Bano R, Juneja A. Clinical Trials Registry – India: Redefining the conduct of clinical trials. Indian J Cancer. 2008; 45 (3): 79-82.

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