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

CTRI Bulletin

www.ctri.nic.in

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Inside

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Dr. Rao, Scientist "G" and Director National Institute of Medical Statistics and Administrator CTRI is a trained mathematical statistician and data scientist. Apart from biostatistics, his areas of specialization include Big data Analytics & Bio-Informatics.

With over three decades of experience in planning, executing and analyzing data, he has been closely involved in several large scale community and clinical based research studies in the domain of nutrition and health. During his tenure at the ICMR-National Institute of Nutrition, Hyderabad, he played a pivotal role in establishing the Bio-informatics Centre at NIN which brought out the Nutrition Atlas which are online, virtual, interactive tools that draw from various datasets to provide an overview of nutrition and health scenario from macro to micro levels in India.

He is passionate about teaching and training and is a resource person and guest faculty with many Universities and Institutes across the country. He has several national and international publications to his credit and has guided several Ph.D. theses. He has served as an International consultant for UNICEF at Maldives, Ministry of Health to help and train officials on surveys and data analysis.

CTRI Highlights

- From **1st April 2018** the CTRI will *accept* submission of only those clinical studies where the first patient has not been enrolled.
- Trials should be submitted 15 -20 days before the date of first enrolment to CTRI to allow time for review, trial modification and receipt of email confirmation from trial contact persons.
- Not yet recruiting trials, i.e. where patient enrolment has not yet begun and ethics approval and DCGI approval (if applicable) have been uploaded are dealt on a priority basis as per proposed date of first enrolment.
- If there is no response to a submitted trial, new and modified trial, within 7-10 working days please follow up at ctri@gov.in regarding status of trial quoting the REF number of trial.
- Till 31st March 2018 ongoing, closed to recruitment and completed trials are also being accepted for registration.
- Follow up at ctri@gov.in for any pending ongoing/completed unregistered trials submitted to CTRI, which if not registered, will be deleted after 31st March 2018.

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Attention Clinical Researchers

Make sure to register your clinical study prospectively, i.e., before the enrolment of first patient.

From **1st April 2018** the Clinical Trials Registry – India (CTRI) will accept and register clinical studies only prospectively i.e. where the first patient has not yet been enrolled.

Moreover, reputed journals have made prospective registration of trials mandatory for consideration of publication

Please follow up at ctri@gov.in for any pending ongoing/completed unregistered trials submitted to CTRI, which if not registered, will be deleted after 31st March 2018.

Coming Soon: Structured format for summary results disclosure of interventional trials

Common Causes of Delay in Trial Registration

1. Trial data uploaded but trial not submitted.
   - If there is no acknowledgement number (REF number) assigned to trial, this indicates that trial has not yet been submitted to CTRI.
   - To submit trial to CTRI click on SUBMIT button in Part 8 of the trial registration form and an REF number will be instantly assigned to trial, if trial is successfully submitted.
   - Mere submission of trial does not mean trial is registered.

2. Ethics/DCGI approval is not uploaded.
   - Submission of Ethics approval (from at least one site) and DCGI approval (if applicable) is mandatory for trial registration.

3. Non-receipt of verification email.
   - Emails are sent to all trial contact persons (except for the trial registrant) for confirmation of participation in trial.
   - Delay in receipt of confirmation from contact person delays trial registration

4. Trial modifications
   - Once a trial is submitted to CTRI it is reviewed and sent back for modifications/clarifications.
   - Registrant often does not update trial records in a timely manner despite automated notification emails sent to registrant's email ID.
   - Occasionally Registrant updates trial records but does not click on Submit button.
   - Only once a trial is updated and resubmitted, the trial can be taken up for further processing.
   - A trial may undergo more than one round of clarification and the response time of registrant plays a critical role in the time taken to register a trial.
   - In case of any issue or perceived delay, registrant should follow up with REF number at ctri@gov.in

Ensure Trial is Prospectively Registered

Submit trial to CTRI at least 15 days before the anticipated date of first enrolment with status as Not Yet Recruiting.

Make sure all requested modifications are incorporated or appropriate clarifications provided.

Make sure ethics approval and DCGI approval (if applicable) is uploaded at the earliest.

Ensure trial contact persons have responded to verification email sent by CTRI.

Maintain regular contact with ctri@gov.in quoting REF number allotted to trial

Registration Data Set of the CTRI (www.ctri.nic.in)

1. Registration Number
2. Trial Registration Date
3. Public Title of Study *
4. Scientific Title of Study,* Acronym, if any
5. Secondary IDs, (UTN, Protocol No etc)
6. Principal Investigator's Name and Address
7. Contact Person (Scientific Query)*
8. Contact Person (Public Query)*
9. Source/s of Material or Monetary Support*
10. Primary Sponsor*
11. Secondary Sponsor*
12. Countries of Recruitment*
13. Site/s of study*
14. Name of Ethics Committee and approval status *
15. Regulatory Clearance obtained from DCGI*
16. Health Condition/Problem studied*
17. Study Type*
18. Intervention and Comparator agent*
19. Key inclusion/Exclusion Criteria*
20. Method of generating randomization sequence
21. Method of allocation concealment
22. Blinding and masking
23. Primary Outcome/s*
24. Secondary Outcome/s*
25. Target sample size*
26. Phase of Trial *
27. Date of first enrollment*
28. Estimated duration of trial
29. Status of Trial *
30. Brief Summary

New Data Set items * Once trial is Completed (last patient visit).

31. Date of actual study completion
32. Final enrolment number achieved

Underlined items are assigned by the CTRI software upon trial registration.

** Items that are in Blue are WHO Data Set items.*

** While the ones in Green are additional requirements of the CTRI.*

** Items that are in Red are New Data Set Items for Completed trials*

*Items are marked with an * have to be filled for the Data Set form to be submitted successfully.*

All Stem cell trials must be Registered

In 2017, the National Guidelines for Stem Cell Research was released and the section pertaining to mandatory approvals from ICSCR, IEC, CDSCO and trial registration in CTRI before enrolling participants for clinical trials is given below**:**

11.2.4.1 All clinical trials using stem cells shall be registered with the CTRI

11.2.4.2 Only those institutions that have their IC-SCR and IEC registered with the NAC-SCRT and CDSCO respectively are permitted to conduct clinical trials.

11.2.4.3 Clinical trials using minimally manipulated autologous SSCs (i.e. HSCs and MSCs) for homologous use for indications other than those listed in Annexure III or for non-homologous use for any indication should be approved by IC-SCR, IEC and CDSCO.

11.2.4.4 Clinical trials using stem cells with substantial manipulation should have prior approval of IC-SCR, IEC and CDSCO.

"As per the National Guidelines for Stem Cell Research - 2017, at present, there are no approved indications for stem cell therapy other than Haematopoietic Stem Cell Transplantation (HSCT) for haematological disorders. Accordingly, all stem cell therapies other than the above shall be treated as investigational and may be conducted only in the form of clinical trials after obtaining necessary regulatory approvals. Use of stem cells for any other purpose outside the domain of clinical trials will be considered unethical and hence not permissible."

http://bic.icmr.org.in/nacscrt/

11.2.4.5 Clinical trials using allogeneic SSCs (with any degree of manipulation) and those using autologous SSCs with more than minimal and major manipulation should have prior approval of IC-SCR, IEC and CDSCO.

11.2.4.6 Clinical trials using human pluripotent stem cells (hESCs or iPSCs) or their derivatives should have prior IC-SCR, IEC and CDSCO and in combination is needed from CDSCO after clearance from IC-SCR and IEC.

11.2.4.7 Any stem cell based product already approved and marketed outside India (or for concurrent clinical trial in India) will require approval of CDSCO after clearance from IC-SCR and IEC.

11.2.4.8 Any clinical trial with a product intended to be licensed and marketed shall have prior approval of CDSCO after clearance from IC-SCR and IEC.

http://icmr.nic.in/guidelines/Guidelines_for_stem_cell_research_2017.pdf

SOP for Updating Registered Trials

For site addition/deletion: Please upload EC/DCGI approval of additional site or site deletion under Ethics Approval– this field is permanently unlocked and revert by mail for site unlocking. Please also mention the list of new site PIs in the mail. For those sites which have not received EC approval, please mark a copy of the mail to the PIs requesting a confirmation email to ctri@gov.in regarding their participation in trial.

For new contact person (Overall trial PI/ Scientific/public query): Please indicate new person, mark a copy of the mail to concerned person and request mail confirmation of responsibility

For Intervention/comparator agent/ inclusion & exclusion criteria, sample size, scientific title primary and secondary outcome: Please specify changes (in a tabular format) and confirm if EC approval has been received for the same and upload the same.

Moving towards Results Disclosure

As per the Joint Statement of the WHO released in 2017 and endorsed by ICMR, all interventional trials would have to declare summary results within one year of trial completion (http://www.alltrials.net/wp-content/uploads/2017/05/18-May-2017-joint-statement.pdf) CTRI is in the process of implementing results disclosure in a structured manner for interventional trials.

The following information is expected to be declared in summary results of interventional trials

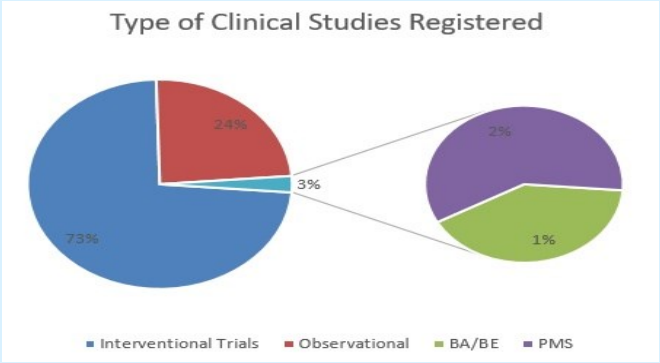
Participant flow - A tabular summary of the progress of participants through each stage of a study, by study arm or comparison group.

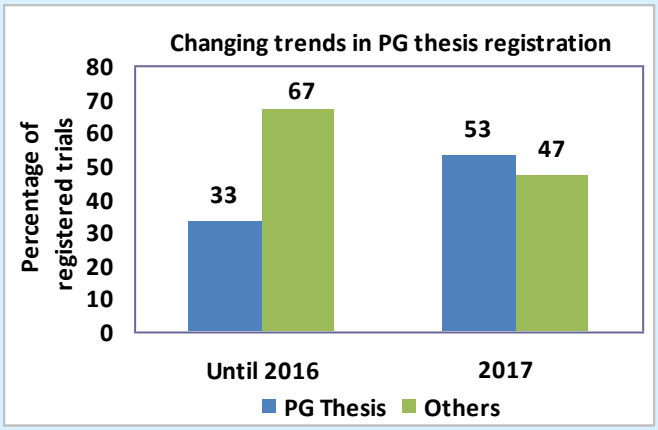
Baseline characteristics - A tabular summary of the data (including demographics and study-specific measures) collected at the beginning of a study for all participants

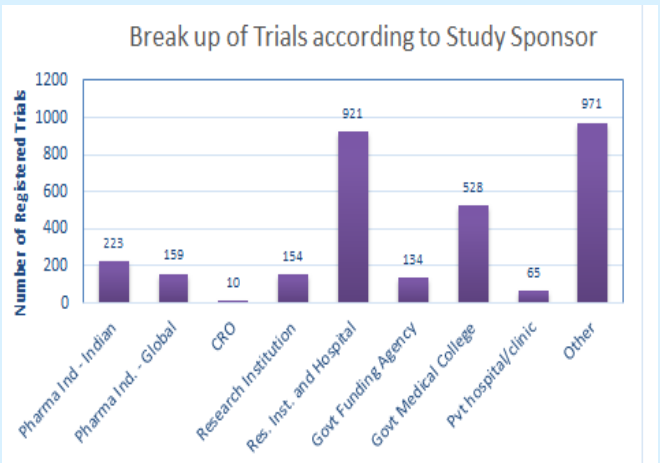
Outcome Measures and Statistical Analyses - A tabular summary for each pre-specified Primary Outcome and Secondary Outcome and may also include other pre-specified outcomes, and any appropriate statistical analyses.

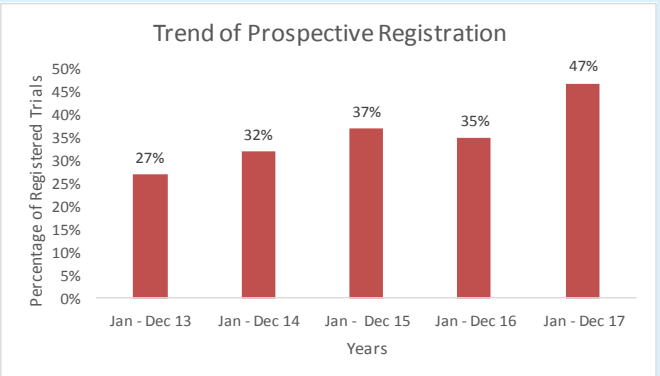
Adverse Events - A tabular summary of all SAEs and other AEs exceeding a specific frequency threshold. For each, the summary includes the adverse event term, affected organ system, number of participants at risk, and number of participants affected, by study arm or comparison group.

CTRI Facts and Figures
(Data of 3433 trials registered in 2017)

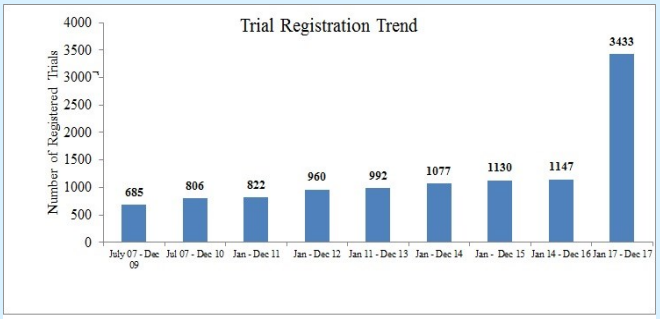






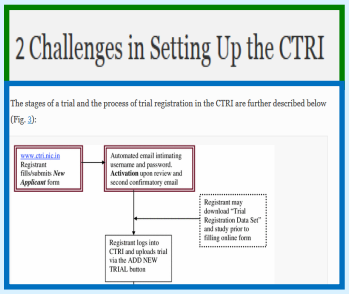


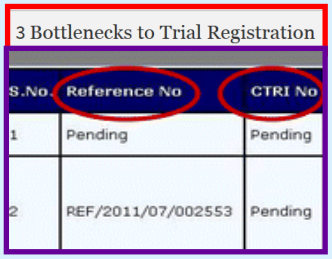
(Data of 11,052 Registered Trials in CTRI since inception)



Publications

Challenges in Administering a Clinical Trials Registry: Lessons from the Clinical Trials Registry-India





For more details, follow this link: https://link.springer.com/article/10.1007/s40290-013-0009-3

[Links to all articles & news bulletins are available under Publication button at www.ctri.nic.in]

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Registrants may take the help of e-tutorials http://10.1.75.7:8079/ctri