Trials Registry - India
ute of Medical Statistics (ICMR)

CTRI Bulletin

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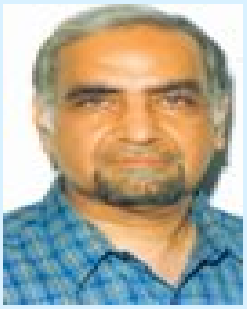

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Dr. Kant is Scientist ‘G’ and Head, Epidemiology & Communicable Diseases Division at ICMR.

Dr. Kant, an MD in Preventive & Social Medicine and Masters in Communicable Disease Epidemiology, from London School of Hygiene & Tropical Medicine, is a pivotal member of CTRI.

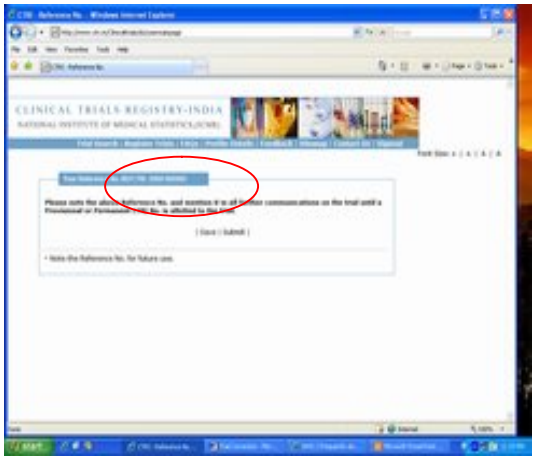
Welcome to the fifth Bulletin of the Clinical Trials Registry—India (CTRI). This newsletter provides a concise summary of recent and upcoming activities relevant to the

CTRI Highlights

- The CTRI, hosted on the Internet (www.ctri.in), provides a platform for the free and online registration of clinical trials being conducted in the country.
- Trials being conducted in neighboring countries, not having a Primary Registry of their own, are also being registered in the CTRI.
- Trials registered in the CTRI are freely searchable from the Home Page of the CTRI, and access to search facility does not require registration in the CTRI.
- Since 15th June 2009, trial registration in the CTRI, before the enrollment of the first patient, has been declared mandatory by the DCGI.
- Till 30th June 2009, a total of 320 trials were registered in the CTRI.
- Till 31st December 2009, a total of 694 trials were registered in the CTRI.

DCGI makes trial registration mandatory

Breaking News: *Trial registration declared mandatory by the DCGI with effect from 15th June 2009.*



- In case the number is not noted the first time, the number may be obtained by accessing the clinical trial and noting the number from the upper left panel of the trial registration Data Set form

Registration Data Set of the CTRI
(www.ctri.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 Investigatorôs 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

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

The REFCTRI is only a reference number and does not imply that the trial has been registered.

REFCTRI number should be quoted in all correspondence regarding the trial.

Whenever EC/DCGI approval documents are submitted, the REFCTRI number should be mentioned in the subject line

TEMP UTRN should not be quoted to refer to any trial submitted to the CTRI for registration

A Registered Trial will be assigned a CTRI number if all the WHO marked fields and site details are filled.

For trials where any of the WHO marked fields is not filled, a PROVCTRI number is assigned

However, this PROVCTRI number would not fulfill the WHO or ICJME criteria for trial registration/publication.

A trial may later acquire a full CTRI number by declaring earlier undisclosed fields for publishing purposes in future.

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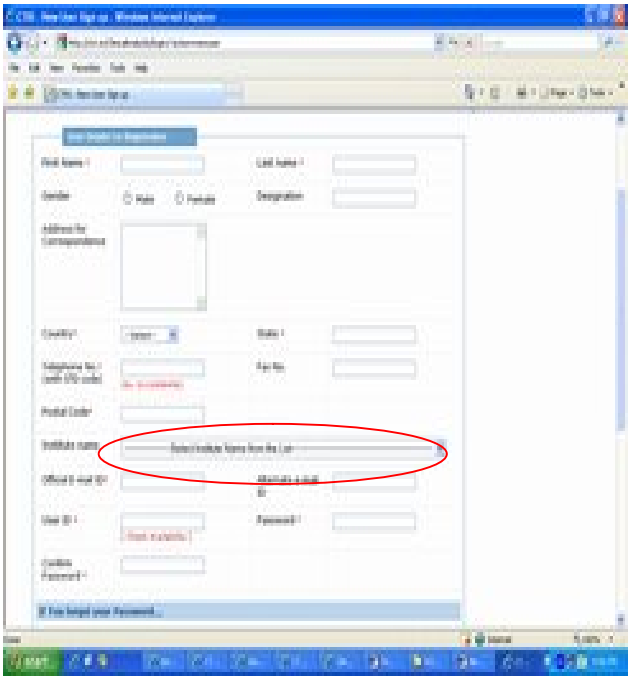
- The username and password may be obtained by accessing the Home Page of the CTRI (www.ctri.in) and clicking on NEW USER

- The form needs to be filled online and submitted online (click on SUBMIT button)
- Special care should be taken to ensure that the ñofficial email IDò provided is typographically correct and one which is regularly accessed.
- All fields marked with an asterisk are mandatory.



- If the desired organizationôs name does not appear under the head ñInstitute Nameò, none should be selected

UTN

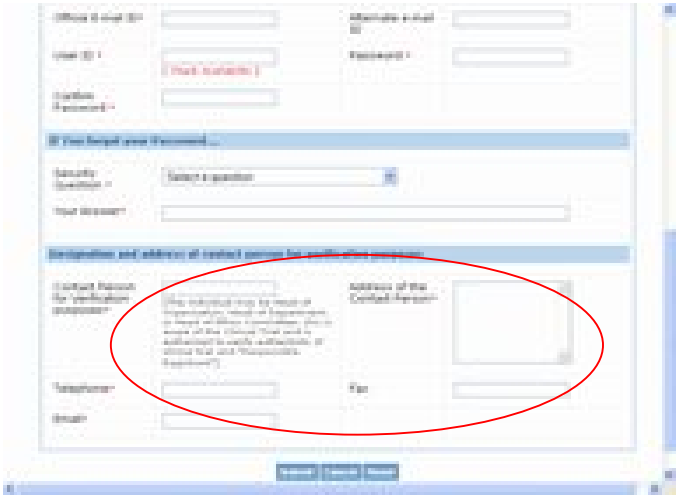
- Universal Trial Number or (UTN) (earlier known as Universal Trial Reference Number or UTRN) is now functional at WHO and may be obtained from http://apps.who.int/trailsearch/utn.aspx

- The purpose of the UTN is to facilitate the unambiguous identification of clinical trials.

- The UTN is **not** a registration number.

- The obtained UTN number may be quoted under SECONDARY ID in CTRI
- Currently, obtaining the UTN is not mandatory.

- Technical errors may occur when forms are submitted without "user verification detailsò.



- After submitting a New User form, registrant should regularly check their email ID as mentioned in the form (including Junk/spam mail) for further communication regarding confirmation of username and password.

- If no communication is received within 4 working days, registrants should send an email to ctr.nims@gmail.com to follow up for the same.

Dissemination workshops

- A CTRI session was organized at the ISMS conference held at BHU, Varanasi 27th ï 29th Nov. 2009.

- A CTRI session was organized at the IPS conference held in Kolkata 10th-12th Dec. 2009

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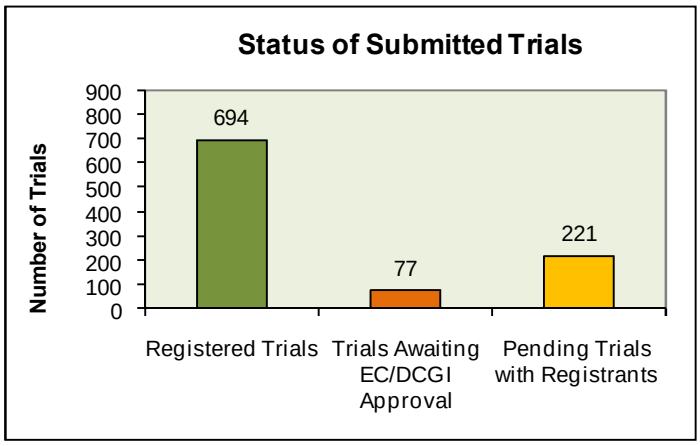
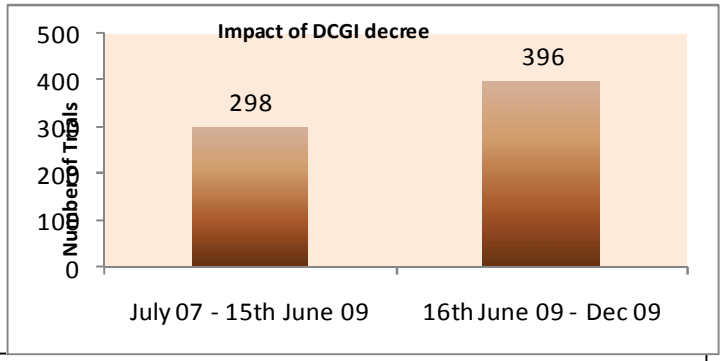
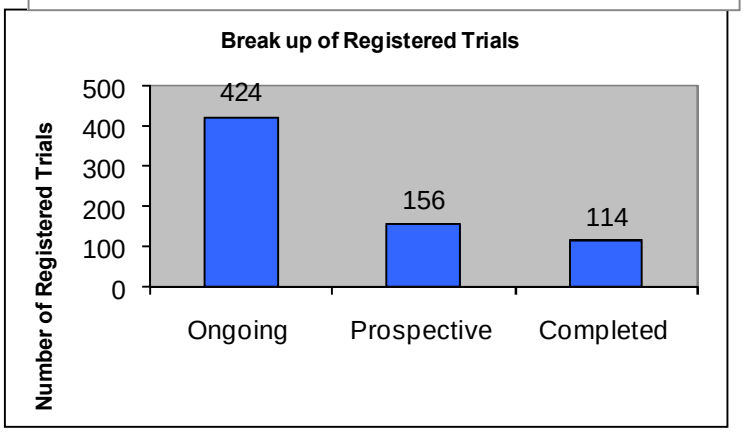
- Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
- The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
- The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
- Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
- A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/ favourable opinion.
- The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
- Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
- Freely given informed consent should be obtained from every subject prior to clinical trial participation.
- All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
- The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
- Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
- Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Source: ICH GCP Guidelines 2006

Current Status of CTRI (till 31st Dec 2009)







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