

Current Regulatory Requirements for Conducting Clinical Trials in India for IND/New Drug Version 2.0

Dr. Vishnu Vardhan Rao
Department of Biotechnology
Indian Institute of Technology, Madras

Lecture – 27B **ONLINE SUBMISSION (CTRI)**

Welcome, all I am Dr. Vishnu Vardhana Rao director ICMR National Institute of Medical Statistics and Administrator to Clinical Trial Registry India. Today we are going to discuss about current regulatory requirements for conducting clinical trials in India. The this lecture is lecture number 23 myself and my colleagues are going to discuss about Online Submission of clinical trial registry India.

(Refer Slide Time: 00:39)



LEARNING OBJECTIVES



The faculty will cover the following in this lecture:

- Understand the relevance of CTRI.
- Learn how to search for a registered clinical study.
- Understand the importance of prospective registration.
- Understand the registration process.
- Learn how to update a clinical study.
- Understand post-registration requirements.



So, the objectives of this (Refer time: 00:40) lecture being understand the relevance of the CTRI, learn how to search for registered clinical studies, understand the importance of prospective registration, understand the registration process, learn how to update a clinical study, understand post registration requirements. These are all the things which we are going to we are going to talk and we are going to learn about this.

(Refer Slide Time: 01:08)



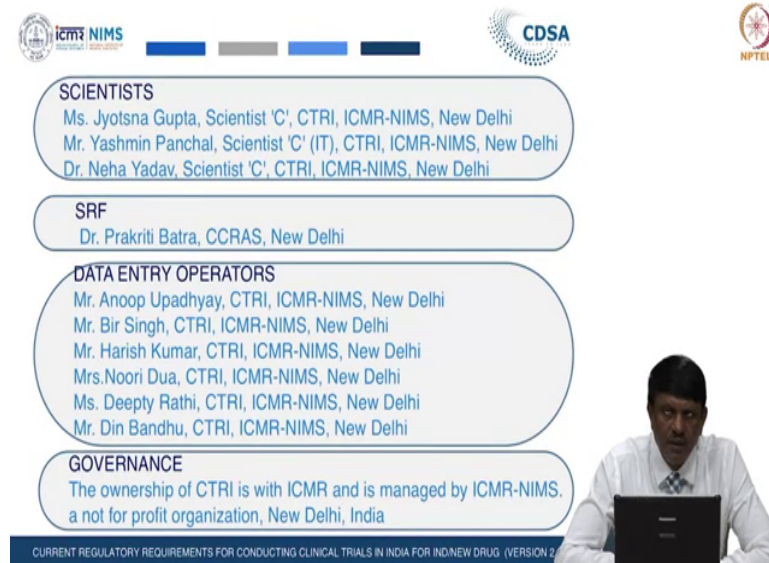
The slide displays the organizational structure of the Clinical Trials Registry of India (CTRI) Secretariat. At the top, logos for ICMR NIMS, CTRI SECRETARIAT, CDSA, and NPTEL are shown. The structure is as follows:

- CHAIRPERSON**
Prof. Balram Bhargava, Secretary, Department of Health Research & Director General-ICMR, New Delhi
- ADMINISTRATOR**
Dr. M. Vishnu Vardhana Rao, Scientist G & Director, ICMR-NIMS, New Delhi
- COORDINATORS**
Dr. Atul Juneja, Scientist 'E' ICMR-NIMS, New Delhi
Dr. Tulsi Adhikari, Scientist 'E', ICMR-NIMS, New Delhi
- MEMBER SECRETARY**
Dr. Saurabh Sharma, Scientist 'B', ICMR-NIMS, New Delhi
- CONSULTANTS**
Dr. Ashok Sehgal, Consultant-CTRI, THSTI, New Delhi
Dr. Mohua Maulik, Consultant-CTRI, ICMR-NIMS, New Delhi

At the bottom left, a footer reads: "CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG (VERSION 2)". On the right side of the slide, a man in a white shirt is seated at a desk with a laptop, looking at the screen.

So, CTRI has the secretariat of I mean NIMS and New Delhi ICMR, NIMS New Delhi. And the chain person being Professor Balram Bhargava secretary D HR and DG ICMR administrator being myself I am M Vishnu Vardhana Rao. I am Director of National Institute of Medical Statistics ICMR as well as administrative CTRI and have we have two coordinators and one member secretary and we have two consultants.

(Refer Slide Time: 01:39)



SCIENTISTS
Ms. Jyotsna Gupta, Scientist 'C', CTRI, ICMR-NIMS, New Delhi
Mr. Yashmin Panchal, Scientist 'C' (IT), CTRI, ICMR-NIMS, New Delhi
Dr. Neha Yadav, Scientist 'C', CTRI, ICMR-NIMS, New Delhi

SRF
Dr. Prakriti Batra, CCRAS, New Delhi

DATA ENTRY OPERATORS
Mr. Anoop Upadhyay, CTRI, ICMR-NIMS, New Delhi
Mr. Bir Singh, CTRI, ICMR-NIMS, New Delhi
Mr. Harish Kumar, CTRI, ICMR-NIMS, New Delhi
Mrs. Noori Dua, CTRI, ICMR-NIMS, New Delhi
Ms. Deepty Rath, CTRI, ICMR-NIMS, New Delhi
Mr. Din Bandhu, CTRI, ICMR-NIMS, New Delhi

GOVERNANCE
The ownership of CTRI is with ICMR and is managed by ICMR-NIMS, a not for profit organization, New Delhi, India

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG (VERSION 2)

There are three scientists which life science background where they screen the trials and has been followed by six data entry operators who does the registration. And we have one computer scientist where he looks after all the software and hardware requirements of the registry.

(Refer Slide Time: 02:01)



And this is the structure of the CTRI where you can see on the screen. And this is the website of the CTRI this is the homepage for that and you can see all the ingredients of the home site here homepage here. And the once you start opening the CTRI this is the homepage you will see and we can start entering your register trials.

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ICMR NIMS CDSA NPTEL

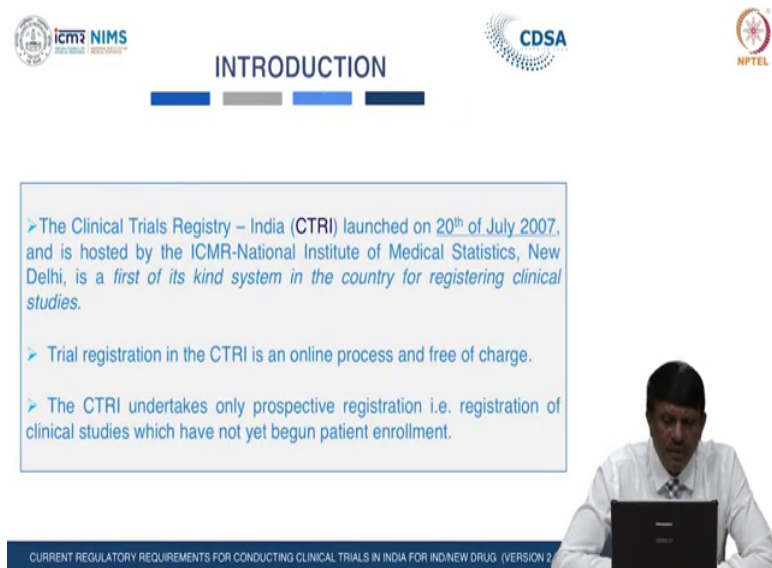
CLINICAL TRIAL REGISTRATION

- The registration of all interventional trials is a scientific, ethical and moral responsibility (WHO).
- Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject (*Declaration of Helsinki 2008*).
- When in doubt, register (WHO).

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG (VERSION 2.0)

The importance of the clinical trial registration is the registration of all interventional trials is a scientific, ethical and moral responsibility which is stated by WHO. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject that is the declaration of Helsinki 2008. When in doubt register WHO; that is the World Health Organization statement.

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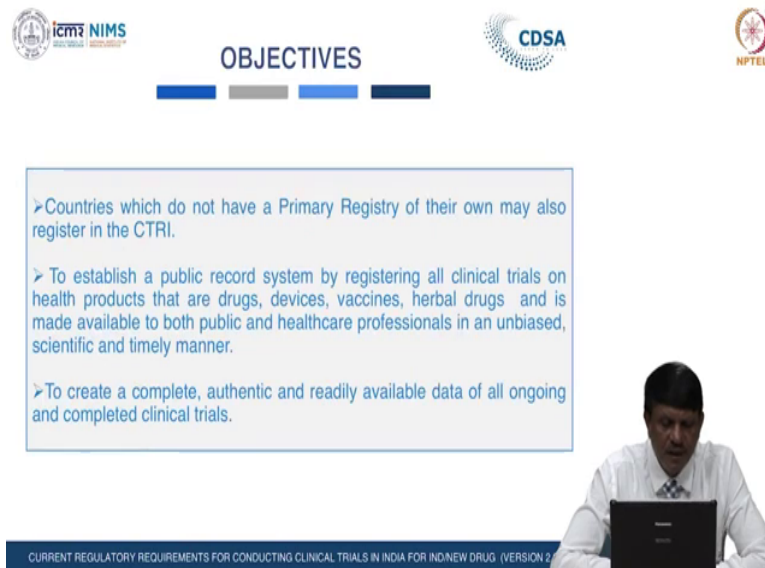
INTRODUCTION

- The Clinical Trials Registry – India (CTRI) launched on 20th of July 2007, and is hosted by the ICMR-National Institute of Medical Statistics, New Delhi, is a *first of its kind system in the country for registering clinical studies*.
- Trial registration in the CTRI is an online process and free of charge.
- The CTRI undertakes only prospective registration i.e. registration of clinical studies which have not yet begun patient enrollment.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG (VERSION 2)

About this CTRI the Clinical Trial Registry India CTRI launched in on 20th of July 2007, and hosted by the ICMR National Institute Medical Statistics New Delhi. It is a first of its kind system in the country for registering clinical studies, trial registration in the CTRI is an online process and free of charges. The CTRI undertakes only prospective registrations that is registration of the clinical trial studies which have not yet begun patient enrollment.

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OBJECTIVES

- Countries which do not have a Primary Registry of their own may also register in the 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.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG (VERSION 2)

Countries which do not have the Primary Registries of their own also can register in the clinical trial registry India. The objectives of the CTRI are as follows; the first objective being the 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 uncompleted clinical trials.

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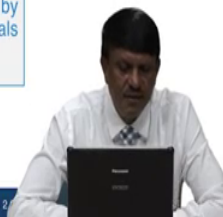


OBJECTIVES



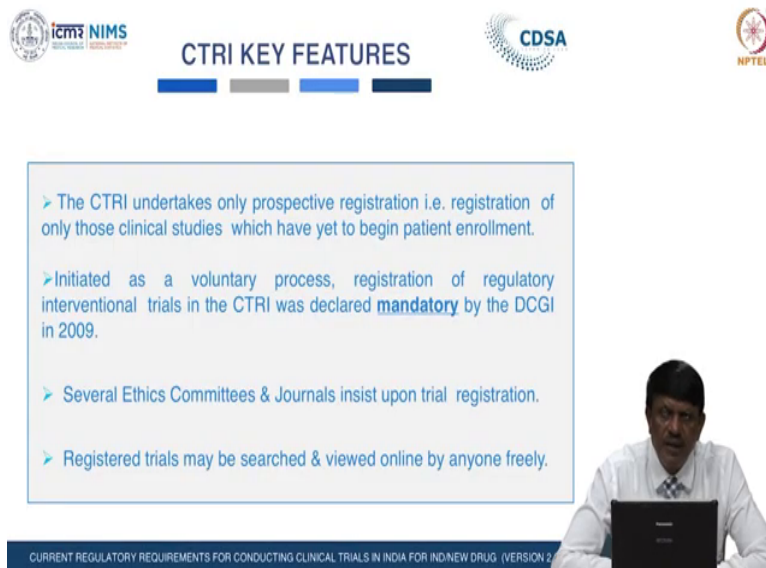
- To provide a corrective system against "positive results bias" and "selective reporting" of research results to peer review publication.
- To increase awareness and accountability of all the participants of the clinical trials and also for public access.
- To promote training, assistance and advocacy for clinical trials by creating database and modules of study for various aspects of clinical trials and its registration.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG (VERSION 2)



To provide a corrective system against positive results bias and selective reporting of research results to peer reviewed publications. To increase awareness and accountability of all patient participants of the clinical trials and also for public access, the process of training assistant and advocacy for clinical trials by creating database and modules of the study for various experts of clinical trials and its registration.

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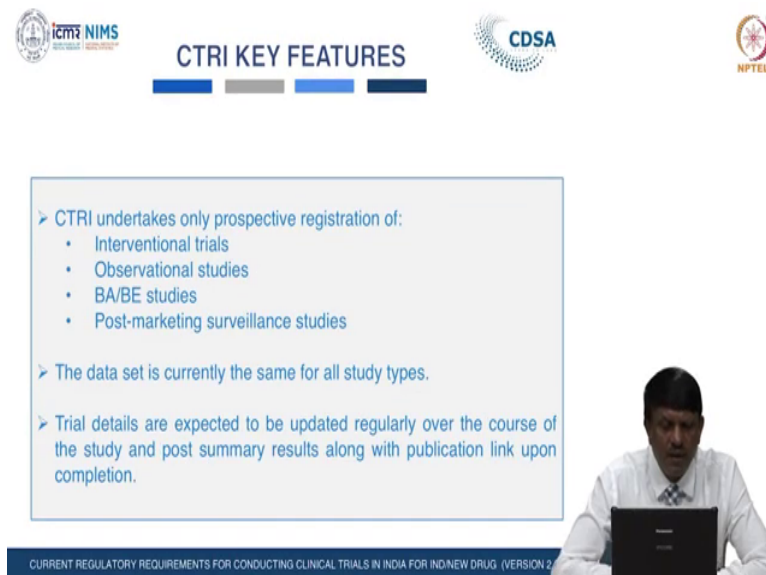
CTRI KEY FEATURES

- The CTRI undertakes only prospective registration i.e. registration of only those clinical studies which have yet to begin patient enrollment.
- Initiated as a voluntary process, registration of regulatory interventional trials in the CTRI was declared **mandatory** by the DCGI in 2009.
- Several Ethics Committees & Journals insist upon trial registration.
- Registered trials may be searched & viewed online by anyone freely.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG (VERSION 2)

The key features of the CTRI are the CTRI undertakes only prospective registration that is registration of the only those clinical studies which have yet to begin of the patient enrollment. Initiated as a voluntary process registration of interventional trials in the CTRI was declared mandatory by the DCGI in 2009, several ethical committees and journals insist upon trial registration. Registered trials may be searched and reviewed online by any of the any of the any person freely.

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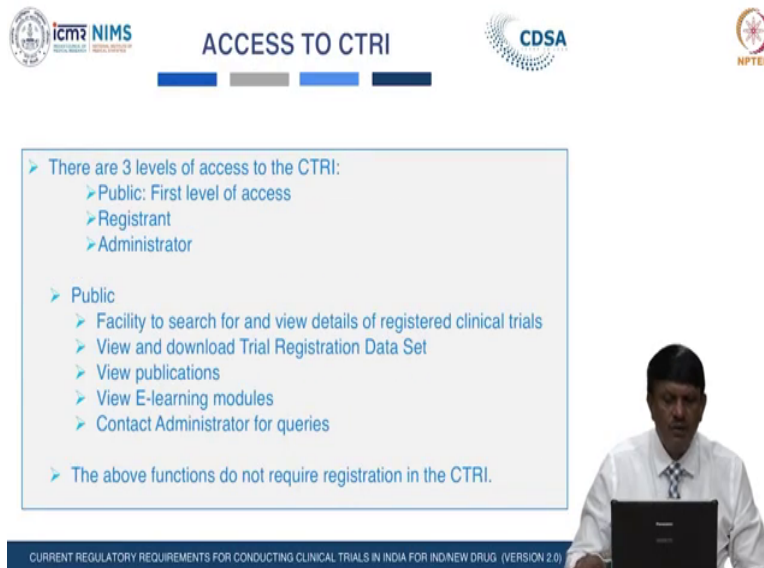
CTRI KEY FEATURES

- CTRI undertakes only prospective registration of:
 - Interventional trials
 - Observational studies
 - BA/BE studies
 - Post-marketing surveillance studies
- The data set is currently the same for all study types.
- Trial details are expected to be updated regularly over the course of the study and post summary results along with publication link upon completion.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG (VERSION 2)

The key features of the CTRI, CTRI undertakes only prospective registration that is interventions trials, observational trials, bioavailability and bioequivalent studies, post marketing, marketing surveillance studies. The data set is currently the same for all study types trial details are expected to be updated regularly over the course of study and post summary results along with the publication link upon completion of the trial.

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The slide is titled "ACCESS TO CTRI" and features logos for ICMR, NIMS, CDSA, and NPTEL. It lists three levels of access to the CTRI: Public, Registrant, and Administrator. The Public level includes facilities for searching and viewing clinical trial details, downloading registration data, viewing publications, viewing E-learning modules, and contacting administrators. A note states that these functions do not require registration in the CTRI.

- There are 3 levels of access to the CTRI:
 - Public: First level of access
 - Registrant
 - Administrator
- Public
 - Facility to search for and view details of registered clinical trials
 - View and download Trial Registration Data Set
 - View publications
 - View E-learning modules
 - Contact Administrator for queries
- The above functions do not require registration in the CTRI.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)

So, there are three levels of access in this. These will be taken up by my colleagues in subsequent lectures. And I also want to convey to you for the purpose of convenience during this presentation, clinical trial and clinical studies will be used interchangeably.

(Refer Slide Time: 06:33)

CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

PUBLIC ACCESS

NEW IN CTRI
Health Condition of trial participants is now coded as per ICD-10 classification and must be chosen from the drop down list provided up to a maximum of 4 levels to the nearest disease category possible.

E-Tutorial [click here](#)

Clinical trials hold enormous potential for benefiting patients, improving therapeutic regimens and ensuring advancement in medical practice that is evidence based. Unfortunately, the data and reports of various trials are often difficult to find and in some cases do not even exist as many trials abandoned or are not published due to "negative" or equivocal results. However, this tendency for availability of only selective information from the myriad clinical trials conducted is not commensurate with the practice of "evidence-based medicine". Today, world over, a need has been felt on the imperative for transparency, accountability and accessibility in order to establish public trust in clinical trials.

The Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (<http://nims-icmr.nic.in>), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (www.cdco.nic.in). Moreover, Editors of Biomedical Journals of 11 major journals of India declared that only registered trials would be considered for publication.^{1,2} Today, any researcher who plans to conduct a trial involving human participants of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials

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So, this we have to note down these two words we have been using that interchangeably. Welcome, back friends you just now heard Dr. Vishnu Vardhana Rao Administrator Clinical Trial Register India, who gave the overall background of the clinical trial registration and the objectives of the registration process. As you know that this is housed at National Institute of Medical Statistics ICMRs Institute at New Delhi, I will take you further on the levels of access.

I am Dr. Atul Juneja Coordinator at Clinical Trial Registry India. Let me tell you that the clinical trial registry has three levels of access; one is public followed by the registrant and administrator. The public access is important it does not require any registration or user id, any prospect resistant can have a look at this before going for any registration process.

It is possible to search and view already registered trials download the registration data set and the publications by CTRI can also be viewed on this access, one can also go to e module where the various process of registration is being explained. There is another section called frequently asked questions, it forms an important part of any system, so it is CTRI. Prospective registrant is advised to have a look at this section before proceeding for trial registration.

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VIEW FAQs

CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

Frequently Asked Questions:

- What is the Clinical Trials Registry - India?
- What is a Primary Registry?
- I am a patient of bronchial asthma and would like to participate in a clinical trial exploring new treatment options. How can I search for such a trial?
- Who is responsible for registering a trial?
- Why should trials be registered in the CTRI?
- My trial is already registered in another Primary Registry, then why do I need to register again with the CTRI?
- But if the same trial is registered in two or more registries won't it be counted as separate trials?
- Is it mandatory to register my purely observational study?
- What type of clinical studies are registered in the CTRI?
- What trial related information are collected in the CTRI?
- Is the trial registration dataset different for the different types of clinical studies?
- What documents, if any, are required to be submitted for study registration?
- Where do these documents have to be submitted?
- Are there any fees for registering a trial in the CTRI?
- How long does it take for a study to be registered?
- When should a clinical study be registered?
- I am doing a retrospective data collection study and I have begun the study. Can it still be registered?

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icmr NIMS
VIEW & DOWNLOAD TRDS
CDSA
NPTEL

CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

Home Page | Trial Search | Advanced Search | FAQ | Publications | News Editor | Feedback | Help/Contact | Site Map

Part One: A | A | A | A

Sign in to CTRI
Username:
Password:
Login

Forgot Password? New Applicant

Trial Registration Data Download (PDF)

Keyword Search:

News / Highlights


New in CTRI
Health Condition of trial participants is now coded as per ICD-10 classification and must be chosen from the drop down list provided up to a maximum of 4 levels to the nearest disease category possible.

E-Tutorial [click here](#)

The Clinical Trials Registry-India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (<http://nims-icmr.nic.in>), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (www.cdco.nic.in). Moreover, Editors of Biomedical Journals of 11 major journals of India declared that only registered trials would be considered for publication.^{1,2}





Today, any researcher who plans to conduct a trial involving human participants of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials


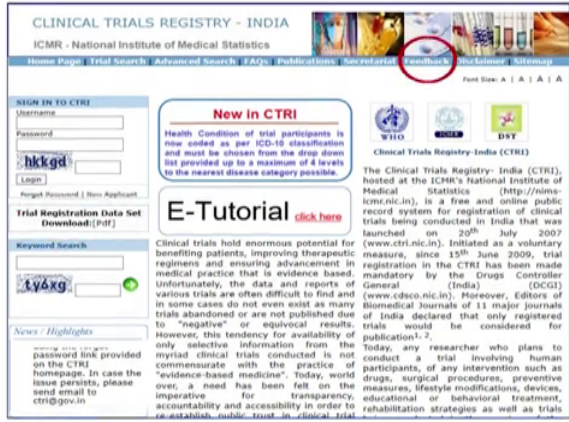
CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)



The trial registration data set can be downloaded which can be used for referencing and viewing, just remember it is used for referencing and viewing the registration process has to be done only online, I emphasize that it has to be done only online.

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(Refer Slide Time: 08:20)

ICMR NIMS CONTACT INFO CDSA NPTEL


CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

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Font Size: A | A | A | A

FEEDBACK :

Administrator,
Clinical Trials Registry-India (CTRI),
ICMR National Institute of
Medical Statistics,
Anand Nagar,
New Delhi - 110029 - India
Ph: 91-11-26589435
Email: ctri[at]gov.in

Your Name:
E-Mail Address:
Type Of Feedback:
Your Feedback:
Security Code: 
[Submit]

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)

The contact section, in this section one can float any query to CTRI administrator and CTRI would be more than happy to answer you at the earliest.

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The screenshot displays the homepage of the Clinical Trials Registry - India (CTRI). At the top, there are logos for ICMR NIMS, SEARCH CTRI, CDSA, and NPTEL. Below these, a navigation bar contains links for Home, About, Basic Search, Advanced Search, E-Tutorial, Publications, News, Contact Us, and Help. The 'Basic Search' and 'Advanced Search' links are circled in red. The main content area includes a 'SIGN IN TO CTRI' section with fields for Username and Password, a 'Trial Registration Data Set Download [PDF]' link, and a search bar. The search bar contains the text 'hkggd' and 'Xq'. To the right of the search bar, there is a 'New in CTRI' section and an 'E-Tutorial' section. The 'E-Tutorial' section has a 'click here' link. The bottom of the page features a footer with the text 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND NEW DRUG. (VERSION 2.0)'.

Then is a search option, the search options are basic search and the advanced search, in the advanced search where trials can be searched more precisely.

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VIEW REGISTERED TRIALS

NPTEL

CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics



[Home Page](#) | [Trial Search](#) | [Advanced Search](#) | [FAQs](#) | [Publications](#) | [Secretariat](#) | [Feedback](#) | [Disclaimer](#) | [Sitemap](#)

Font Size: A | A | A | A

Search Result (Search Data can be sorted/rearrange by clicking on column headings)

Type of Trial=ALL Study Design=ALL Phase of Trial=ALL Primary Sponsor of Trial=ALL Recruitment Status of Trial(TOTAL)=ALL State where study is conducted=ALL Keyword=Vaccine

Total Records Found: 166

CTRI No.	Trial Title	Type of Trial	Recruitment Status	Health Condition	Intervention Name	Location	Details	Select
CTRI/2008/091/000100	A clinical study to assess protection against Rubella and also to assess the safety and immunogenicity of rubella vaccine in teenage girls in Maharashtra	Interventional	Total: Not Applicable Indian: Completed	Encounter for Immunization	Rubella Vaccine	12 districts of Maharashtra under KEM Hospital and Research Centre, MAHARASHTRA	View	<input type="checkbox"/>
CTRI/2008/091/000111	Cancer Vaccine Study for Unresectable Stage III Non-small Cell Lung Cancer	Interventional	Total: Not Applicable Indian: Not Applicable	Non-small cell lung cancer (NSCLC) subjects with unresectable stage III disease	Investigational arm: Pre-treatment: one intravenous infusion of cyclophosphamide infusion of 200 mg/m ² , determined by calculation of the subject's body surface area. A maximum dose of 600mg will be given. Primary treatment: weekly subcutaneous injections with Stimuvax. Intravenous injection of 1,000 µg for 8 consecutive weeks. Maintenance treatment	All India Institute of Medical Sciences (AIIMS), DELHI Apollo Speciality Hospitals, TAMIL NADU Christian Medical College & Hospital, TAMIL NADU Indo-American Cancer Institute & Research Centre, ANDHRA PRADESH Jaslok Hospital & Research Centre, MAHARASHTRA Nizam's Institute of Medical Sciences, ANDHRA PRADESH	View	<input type="checkbox"/>

This would provide all information on registered trials including in the PDF format. Then there is also possible to view the sequence of modifications done by the triallist to various data items such as change in sample size etcetera which is known as audit trail.

(Refer Slide Time: 08:43)



GENERATE TRIAL PDF




FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial									
CTRI Number	CTRI/2019/08/020939 (Registered on 26-Mar-2019) Trial Regd!								
Last Modified On:	26/08/2019								
Post Graduate Thesis	No								
Type of Trial	Interventional								
Type of Study	Vaccine								
Study Design	Randomized, Parallel Group, Active Controlled Trial								
Public Title of Study	Clinical study to show the effect and safety of Serum Institute of India Pneumococcal Vaccine in Indian children.								
Scientific Title of Study	A Phase 3, Randomized, Double-Blind Study to Evaluate the Immune Safety and Tolerability of Serum Institute of India's 10-valent Pneumococcal Conjugate Vaccine (PREUNOSIG) in Healthy Indian Infants								
Secondary IDs if Any	<table border="1"><tr><td>Secondary ID</td><td>Identify</td></tr><tr><td>PCV-10-004, version 1.0, Dated 29-Mar-2019</td><td>Protocol</td></tr></table>	Secondary ID	Identify	PCV-10-004, version 1.0, Dated 29-Mar-2019	Protocol				
Secondary ID	Identify								
PCV-10-004, version 1.0, Dated 29-Mar-2019	Protocol								
Details of Principal Investigator or overall Trial Coordinator (email center)	<table border="1"><tr><td>Name</td><td>Dr Ashish Ramesh Bardekar</td></tr><tr><td>Designation</td><td>Associate Professor</td></tr><tr><td>Affiliation</td><td>King Edward Memorial Hospital and Research Centre, Health Program, A/P, Vada Budruk, Taluka- Shirur, Dist- Pune MAHARASHTRA 412216 India</td></tr><tr><td>Address</td><td>Pune MAHARASHTRA 412216</td></tr></table>	Name	Dr Ashish Ramesh Bardekar	Designation	Associate Professor	Affiliation	King Edward Memorial Hospital and Research Centre, Health Program, A/P, Vada Budruk, Taluka- Shirur, Dist- Pune MAHARASHTRA 412216 India	Address	Pune MAHARASHTRA 412216
Name	Dr Ashish Ramesh Bardekar								
Designation	Associate Professor								
Affiliation	King Edward Memorial Hospital and Research Centre, Health Program, A/P, Vada Budruk, Taluka- Shirur, Dist- Pune MAHARASHTRA 412216 India								
Address	Pune MAHARASHTRA 412216								



View



(Refer Slide Time: 08:45)



AUDIT TRAIL





Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/E-mail
Dr Chandrakant Birkade	Government Medical college and hospital	HOD Room, Department of Paediatrics, 1st Floor Nagpur Nagar	9373115532 c.birkade77@gmail.com
Dr Sumanta Sankar	IPONER & SSKM Hospital	Department of Pediatrics, IPONER & SSKM Hospital, A.J.C. Bose Road, Kolkata	9433906390 drsumantasankar@gmail.com
Dr N. Ravi Kumar	Nalwar Hospital (Omania Medical College)	Research Room, First Floor, Nalwar Hospital (OPD Building), Jakhdiapal Hyderabad	9362393394 ravk1962@yahoo.com
Dr Kapil Garg	SMS Medical College	Professors chamber (Dr. Kapil Garg), 3rd Floor, Jay Jay Lam Hospital, Jaipur	01412610827 dkapilgarg@gmail.com

Details of Study Modification(s)




Name of Consultant	Approval Status
Ethics Committee, Omania Medical College, Koli, Hyderabad - 500038	Approved
Institutional Ethics Committee, Department of Pharmacology, Government Medical College, Nagpur - 440003, Maharashtra	Approved
IPONER & SSKM Research Oversight Committee, Institute of Post Graduate Medical Education and Research (IPONER & SSKM), 244, A.C. Bose Road, Kolkata-700029	Approved
The Ethics Committee, S.M.S. Medical College and Attached Hospitals, Jaipur First Floor, Dharamvati OPD Block, S.M.S. Hospital, T.L.R. Ward, Jaipur	Approved

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)



This is one of the important features of Clinical Trial Registry India.

(Refer Slide Time: 08:48)



HISTORY OF CHANGES

Investigator		Site		Contact Person	
Dr Chandrabati Bhakda	Government Medical college and hospital	HCD Room, Department of Paediatrics, 1st Floor Nagpur			9377111032 chboudh77@gmail.com
Dr Sumanta Sankar					
Dr N. Kavi Kumar					
Dr Kapil Gang					

Site of Study Modification(s)

Date of Change	Contact Person	Name of Site	Address	Phone/Fax/Email	Action Done
11/06/2017	Dr Sumanta Sankar	PONDER & SSGH Hospital, A.J.C. Bose Road, Kolkata WEST BENGAL		9338803060/drsumantasankar@gmail.com	Record Added

Details of Ethics Committee Modification(s)

Name of Committee	Address	Phone/Fax/Email	Action Done
Ethics Committee, Oranua me			Record Added
Institutional Ethics Committee			Record Added
SPICE & Research Oversight			Record Added
708025			Record Added
The Ethics Committee, S.M.S.			Record Added

Close

(Refer Slide Time: 08:50)



E-TUTORIAL



CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

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Font Size: A | A | A

SIGN IN TO CTRI

Username:

Password:

[Forgot Password](#) | [New Applicant](#)

Trial Registration Data Set Download (PDF)

[Download](#)

Keyword Search

News / Highlights

password link provided on the CTRI homepage. In case the link expires, please send email to ctri@gov.in

New in CTRI

Health Condition of trial participants is now coded as per ICD-10 classification and must be chosen from the drop down list provided up to a maximum of 4 levels to the nearest disease category possible.

E-Tutorial [click here](#)

Clinical trials hold enormous potential for benefiting patients, improving therapeutic regimens and ensuring advancement in medical practice that is evidence based. Unfortunately, the data and reports of various trials are often difficult to find and in some cases do not even exist as many trials abandoned or are not published due to "negative" or equivocal results. However, this tendency for availability of only selective information from the myriad clinical trials conducted is not commensurate with the practice of "evidence-based medicine". Today, world over, a need has been felt on the imperative for transparency, accountability and accessibility in order to establish public trust in clinical trials.

Clinical Trials Registry-India (CTRI)

The Clinical Trials Registry-India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (<http://nims-icmr.nic.in>), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (www.cdco.nic.in). Moreover, Editors of Biomedical Journals of 11 major journals of India declared that only registered trials would be considered for publication^{1,2}. Today, any researcher who plans to conduct a trial involving human participants of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)



(Refer Slide Time: 08:52)



Then coming on to e module further by clicking on e module section, the registrant is taken to presentation with audio, which describes the detail process of trial registration this video audio video is about for 2 hours thank you so much. And to take you further on the registrant access I will request my colleague to explain further thank you.

(Refer Slide Time: 09:13)






ACCESS TO CTRI

- There are 3 levels of access to the CTRI:
 - Public
 - **Registrant: Second level of access**
 - Administrator
- **Registrant**
 - Authorized to register clinical trials
 - Registration in the CTRI is needed to gain access to this facility

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)

Welcome, Dr. Atul Juneja just described the public access to the CTRI, I am Dr. Mohua Maulik consultant with the CTRI and I will be discussing the second level of access to the CTRI that is of the registrant. A registrant is one who is authorized to register clinical trials, although anyone may be a registrant the it is the responsibility of the principal investigator and the primary sponsor to ensure that a clinical trial is registered in the CTRI. Registration in the CTRI is needed to gain access to this facility, the on the homepage of the CTRI you may register as a new applicant by clicking the new applicant button.

(Refer Slide Time: 09:53)



USER REGISTRATION

CLINICAL TRIALS REGISTRY - INDIA

ICMR - National Institute of Medical Statistics

Home Page | Trial Search | Advanced Search | FAQ | Publications | Newsletters | Conditions | About Us | Helpdesk

Print View: A | A | A

SIGN IN TO CTRI

Username:

Password:

Trial Registration Data and Download (PDF)

Keyword Search:

News / Highlights

password link provided on the CTRI homepage. In case the link persists, please send email to ctri@gov.in

New in CTRI

Health Condition of trial participants is now coded as per ICD-10 classification and must be chosen from the drop down list provided up to a maximum of 4 levels to the nearest disease category possible.

E-Tutorial [click here](#)

Clinical trials hold enormous potential for benefiting patients, improving therapeutic regimen and ensuring advancement in medical practice that is evidence based. Unfortunately, the data and reports of various trials are often difficult to find and in some cases do not even exist as many trials abandoned or are not published due to "negative" or equivocal results. However, this tendency for availability of only selective information from the myriad clinical trials conducted is not commensurate with the practice of "evidence-based medicine". Today, world over, a need has been felt on the imperative for transparency, accountability and accessibility in order to establish public trust in clinical trials.

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Today, any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)



(Refer Slide Time: 09:58)

NEW APPLICANT FORM

Please Provide the Following Details

Notes for New Applicants

- New Applicant request is liable to be rejected if, Official address details are not provided.
- New Applicant request is liable to be rejected if, verifier details (including email and name) is same as that of New Applicant.
- New Applicant request is liable to be rejected if, Official email ID of applicants from private organizations, is not provided.
- New Applicant request is liable to be rejected if, full details of new Organization/Company, including Company/Organization Type is not provided (only where Organization name is not present in drop-down list).
- Certain characters (" ' , < > , / , \ , ~ , & , + , %) are not allowed to be used in the CTRI but there is no restriction of the use of @ symbol at email id column.

First Name *

Last Name *

Login ID *

Security Question *

Answer *

Gender *

Official Address with Name of Organization *

Only Ten Digit Mobile No (Please do not include 0 before number) *

Email *

Designation *

Company/Organization *

Register New Company/Organization: In case Company not Available in the list

Address & Other Details: In case Company not Available in the list

Company/Organization Type: In case Company not Available in the list

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND-NEW DRUG. (VERSION 2.0)

This will take you to the new applicant form, instructions to fill the new applicant form and likely issues to be faced are listed right on top, take a few moments to read these before proceeding to fill the form online.

(Refer Slide Time: 10:20)

ICMR NIMS ONLINE SUBMISSION CDSA NPTEL

Company/Organization: *

Register New Company/Organization
(In case Company not Available in the list)

Address & Other Details:

Country:

State:

District:

Pincode:

Office Address with Name of Organization: *

User Details:

User Name:

User Password:

User Email:




Security Code:

Your registration request has been successfully submitted to the CTRE and message sent to the provided email ID. Registration process would be complete after review by CTRE Administrator.
If no communication is received from CTRE within 5 working days, please send a mail to ctreg@icmr.in.
[Please click here to go home page](#)

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND-NEW DRUG. (VERSION 2.0)

Once all the details have been filled click on the submit button, if the form is submitted successfully login credentials such as the username and password will be mailed to the provided email id, subsequently a second confirmatory mail will activate these username and password. In case, of failure to receive email from the CTRE please check junk or spam mail before contacting CTRE, in case an incorrect email id is provided there will be failure to receive these emails.

(Refer Slide Time: 11:57)



USER LOGIN

CLINICAL TRIALS REGISTRY - INDIA

ICMR - National Institute of Medical Statistics

Home | Search | Trial Search | Advanced Search | E-AT | Publications | News & Events | Contact Us | Site Map | Help

Print View: A | A | A | A

NEW IN CTRI

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E-Tutorial [click here](#)

Clinical trials hold enormous potential for benefiting patients, improving therapeutic regimens and ensuring advancement in medical practice that is evidence based. Unfortunately, the data and reports of various trials are often difficult to find and in some cases do not even exist as many trials abandoned or are not published due to "negative" or equivocal results. However, this tendency for availability of only selective information from the myriad clinical trials conducted is not commensurate with the practice of "evidence-based medicine". Today, world over, a need has been felt on the imperative for transparency, accountability and accessibility in order to establish public trust in clinical trials.

Log In To CTRI

Username:

Password:

[Forgot Password](#) | [New Applicant](#)

Trial Registration Data Set Download [\[PDF\]](#)

Keyword Search

News / Highlights

[New link provided on the CTRI homepage. In case the link persists, please send email to \[ctri@gov.in\]\(mailto:ctri@gov.in\)](#)

The Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (<http://nims-icmr.nic.in>), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (www.cdco.nic.in). Moreover, Editors of Biomedical Journals of 11 major journals of India declared that only registered trials would be considered for publication^{1,2}. Today, any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)

Once your credentials are activated you may login to your account in the CTRI.

(Refer Slide Time: 11:04)

WELCOME PAGE

Clinical Trials Registry - India (ICMR NIMS)

Welcome: Sanku Sharma (Trial ID: 1234567890) | 01/08/2024 | Main Page | Change Password | Update Profile | Logout

Total Trials: 0
Under Review Stage: 0
Registered Trials: 0
Terminated/Suspended Trials: 0

[Click here to update trial's sent back after review by CTRI](#)

[Click here to Add New Trial](#)

S.No.	REF Number	CTRI No.	Scientific Title	Study Under Entry / Review	Secondary ID	View Details	Select
-------	------------	----------	------------------	----------------------------	--------------	--------------	--------

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)

This is your personal welcome page on the CTRI, where several facilities and options are available such as viewing registered trials, editing your profile all at all profile features may be edited such as email id, name etcetera, password may also be changed. To upload your new clinical trial data click on the add new button.

(Refer Slide Time: 11:32)

The screenshot displays the 'CREATE TRIAL' web interface. At the top, logos for ICMR NIMS, CDSA, and NPTEL are visible. The main heading is 'CREATE TRIAL'. Below it, a section titled 'Add New Trial' contains instructions: 'Note: While typing, please pay attention to spellings, capitalise first letter of each new sentence and use proper upper and lower case alphabets, with proper spacing. Please note that once a trial is: A. Submitted - All fields become locked for editing B. Registered - All information is viewable globally much like any publication.' The form has three input fields: 'Public Title: +', 'Scientific Title: +', and 'Acronym:'. A 'Proceed' button is located below the 'Acronym' field. To the right of the input fields, a text box provides detailed guidelines: 'Title intended for the lay public in easily understood language. Technical terminologies should be avoided wherever feasible.' (circled in red), 'Scientific title of the study as cleared by the Ethics review Committee, should be mentioned. In case of multi-centric trials, all Ethics approvals should carry the same title and discrepancies, if any should be checked before submission of approval document. Please include trial acronym, if available. Example: A randomized double-blind placebo controlled crossover clinical trial to compare the safety and efficacy of...'. A red 'Alert! Critical Information' banner at the bottom states: 'At the time of publication, many journals insist upon Prospective Registration of trial'. A presenter is visible in the bottom right corner of the slide.

ICMR NIMS

CREATE TRIAL

CDSA

NPTEL

Add New Trial

Note: While typing, please pay attention to spellings, capitalise first letter of each new sentence and use proper upper and lower case alphabets, with proper spacing. Please note that once a trial is:
A. Submitted - All fields become locked for editing
B. Registered - All information is viewable globally much like any publication.

Public Title: +

Scientific Title: +

Acronym:

Proceed

Alert! Critical Information
At the time of publication, many journals insist upon Prospective Registration of trial

Title intended for the lay public in easily understood language. Technical terminologies should be avoided wherever feasible.

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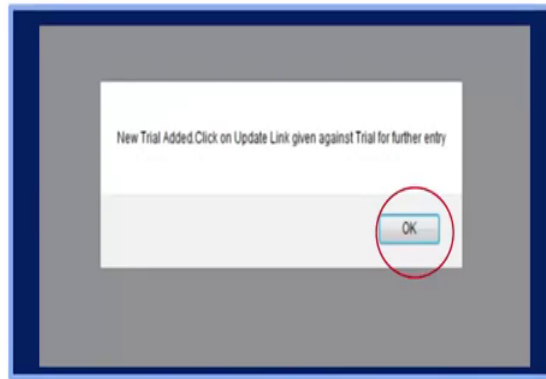
CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND NEW DRUG. (VERSION 2.0)

First the trial has to be created, for creation of trial the public title and the scientific title have to be provided. Acronym is an optional field, information or description of what is to be provided in each of the fields is present under this icon. Once the appropriate and necessary information has been filled click on the proceed button this would save your changes and create your trial.

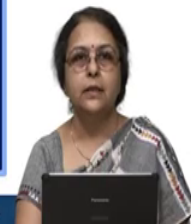
(Refer Slide Time: 11:58)



NEW TRIAL ADDED



CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)



(Refer Slide Time: 12:02)

The screenshot shows the 'Clinical Trials Registry - India (ICMR NIMS)' website. At the top, there are logos for ICMR NIMS, CDSA, and NPTEL. The main heading is 'TRIAL CREATED'. Below this, there is a summary of trial counts:

Clinical Trials Registry - India (ICMR NIMS)	
Total Trials	1
Under Entry Stage	1
Under Review Stage	0
Registered Trials	0
Terminated/Suspended Trials	0

Below the summary, there is a link: [Click here to update trial's went back after review by CTRI](#).


At the bottom, there is a table with the following columns: S.No., Ref Number, CTRI No., Scientific Title, Trial Acronym, Secondary ID, View Details, and Action. The first row shows a trial with 'Pending' status in both 'Ref Number' and 'CTRI No.' columns, and 'Creating a new trial' in the 'Scientific Title' column. The 'Action' column has a red circle around the 'Update' button.

At the very bottom, there is a footer: 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)'.


Clicking on the button will take you back to your welcome page, as you can see now your trial has been created and available under review stage. In this stage both the CTRI and the ref numbers are pending. CTRI number will be assigned only once your trial is registered, ref number will be assigned when the trial is submitted to the CTRI. Hence, at this stage the trial is not submitted to the CTRI, and hence not available to the CTRI for review or processing.


To submit your trial to the CTRI click on the update button this will display the CTRI dataset form there are eight parts to the CTRI dataset form each part may be filled individually and in any sequence.

(Refer Slide Time: 12:52)




8 PARTS OF CTRI FORM





Part 1		ChA
1	Public title of study	
2	Scientific title of study	
Part 2		ChA
1	Sponsor/Co-sponsor	
2	Principal Investigator or overall Trial Coordinator (multi-center study) Details	
3	Contact person (Scientific Query)	
4	Contact person (Public Query)	
Part 3		ChA
1	Source(s) of monetary or material support	
2	Primary sponsor	
3	Secondary sponsor	
4	Countries of recruitment	
Part 4		ChA
1	Object of study	
2	Name of Ethics Committee and approval status	
3	Regulatory clearance obtained from DCGI	
4	Health care/healthcare provider studied	
Part 5		ChA
1	Study Type	
Part 6		ChA
1	Intervention and comparison agent	
2	Inclusion & Exclusion Criteria	
3	Method of generating randomization sequence	
4	Method of allocation concealment	
5	Blinding/masking	
Part 7		ChA
1	Primary outcomes	
2	Secondary outcomes	
3	Target sample size	
4	Phase of trial	
5	Date of first enrollment	
6	Estimated duration of trial	

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)



It is advisable to keep a copy of your protocol handy while filling this form. Submission of ethics approval is mandatory for registration of any clinical study in the CTRI; in addition regulatory trials must submit DCGI approval.

Since, the CTRI undertakes only prospective clinical trial registration that is the registration of clinical trials before the enrollment of the first patient it is advisable to submit your trial to the CTRI, well in advance of the anticipated date of first patient enrollment. To facilitate the registrant in this the CTRI encourages registrants to submit their trial for registration before receipt of ethics or DCGI approval.

(Refer Slide Time: 14:01)

The screenshot displays the 'TRIAL SUBMISSION LINK' interface. At the top, logos for ICMR NIMS, CDSA, and NPTEL are visible. The main content area is divided into two parts: Part 7 and Part 8. Part 7 includes fields for Primary outcome(s), Secondary outcome(s), Target sample size, Phase of trial, Date of first enrollment, and Estimated duration of trial. Part 8, titled '(Includes Trial Submission link)', includes fields for Recruitment status of trial, Brief Summary, and Publication. Below these fields, there is a section titled 'DISPATCH: REF and CTX numbers' which explains the significance of the REF number (acknowledgement number) and the CTX number (trial registration number). It states that if a trial has not been assigned a REF number, it has not been submitted to the CTX and cannot be reviewed or registered. It also mentions that upon successful submission, the trial will be instantly assigned an REF number. A footer note states: 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)'.

Part 7

- 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 (Includes Trial Submission link)

- 1 Recruitment status of trial
- 2 Brief Summary
- 3 Publication

DISPATCH: REF and CTX numbers

REF number is the acknowledgement number while CTX number is the trial registration number

Please note that if a trial has **not been assigned** an REF number (acknowledgement number) this means that the trial has not been submitted to the CTX and hence cannot be reviewed or registered.

To submit trial to CTX and acquire REF number go to PART 8 and click on **SUBMIT TRIAL TO CTX** button.

Upon successful trial submission, the trial will be **instantly** assigned an REF number which is to be quoted in all trial related queries sent to cdg@pqi.in

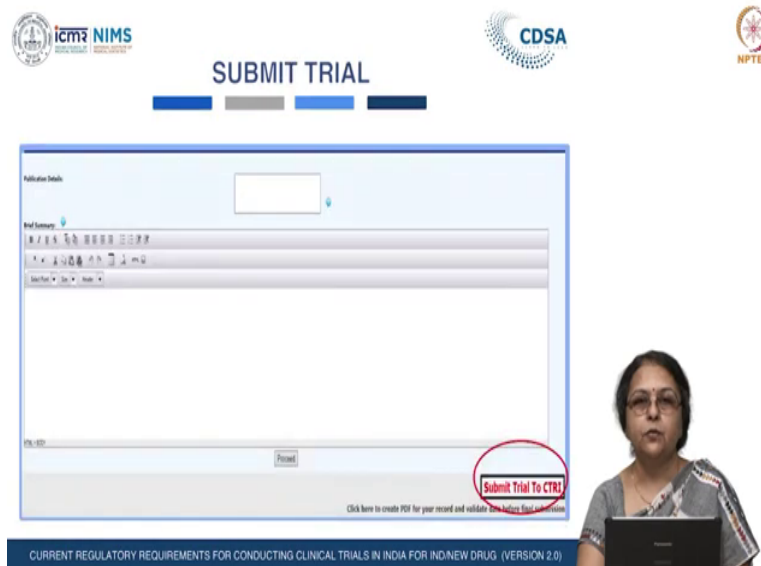
If REF number is assigned but CTX (trial registration) number is pending this means that the trial has been submitted to CTX but **not registered**. Hence the trial should not begin enrolling patients until CTX number has also been assigned.

Please note to follow up at cdg@pqi.in if there is no response within 7 days of trial submission or resubmission

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)




Once all the fields have been appropriately populated the trial must be submitted to the CTX. The trial submission link is available in part eight, fill the section and click on the submit button.

(Refer Slide Time: 14:21)



If all the fields the mandatory if all the mandatory fields have not been filled the trial will not be submitted, a cross mark will highlight the fields which need further attention. Click on the link to go back to that field and updated as applicable and try for trial resubmission submission again.

(Refer Slide Time: 14:41)



SUBMISSION CHECKLIST

Selected Trial: A randomized controlled trial to describe the process of trial registration in the CTRI (ICMR)

Regulatory Parameters	Status
Public Title	✓
Scientific Title	✓
Contact Person (Scientific Query) (Scientific query contact person name is not provided)	X
Contact Person (Public Query) (Public query contact person name is not provided)	X
Source of Monetary/Material Support	X
Primary Sponsor (Primary sponsor name is not provided)	X
Secondary Sponsor	✓
Countries of Recruitment	X
IRB/Committee	X
GDSP	X
Health Conditions/Problems Studied	X
Study Type, Including Study Design	X
Intervention and Comparison Agent (Please provide the details of Intervention)	X
Primary Outcome	X
Secondary Outcome	X
Target Sample Size (Please check the sample size.)	X
Phase of Trial	X
Date of First Enrollment	X
Recruitment Status of Trial	X
Inclusion Criteria Details	X




Trial Submission Failed!

Item(s) that are mandatory for submission of trial have either been omitted or are not proper. You are requested to kindly check the marked items and then RESUBMIT the trial again.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)

If all the fields have been filled the trial will be successfully submitted and an ref number assigned.

(Refer Slide Time: 14:50)



SUCCESSFUL SUBMISSION


Selected Trial: CLINICAL EVALUATION OF CHIRNA IN THE MANAGEMENT GASTROENTERITIS

Mandatory Parameters	Status
Public Title	✓
Scientific Title	✓
Contact Person (Scientific Query)	✓
Contact Person (Public Query)	✓
Source of Monetary/Material Support	✓
Primary Sponsor	✓
Secondary Sponsor	✓
Countries of Recruitment	✓
Ethics Committee	✓
COCI	✓
Health Condition/Problems Studied	✓
Study Type, including Study Design	✓
Intervention and Comparator Agent	✓
Primary Outcome	✓
Secondary Outcome	✓

Your Trial Has Been Successfully Submitted to CTRI for Review...




Your Trial Acknowledgment Number is: REF/2019/06/020411

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)



This ref number must be quoted in all trial related queries and correspondence, once a trial has been assigned a ref number it is picked up for review by the CTRI within 7 to 10 working days.

(Refer Slide Time: 15:06)



TRIAL SENT BACK

Clinical Trials Registry - India (ICMR-NIMS)

Welcome: Yash Sharma (National Institute of Medical Statistics (NIMS)) 01/10/2019 [Main Page](#) [Change Password](#) [Website Home Page](#) [Logout](#)

[Trial Certification/Modification](#) [Registered Trials](#) [Second Query](#) [LDR Profile](#)

Total Trials1

Under Entry Stage1

Under Review Stage0

Registered Trials0


Terminated/Suppressed Trials0

[Click here to update trial's sent back after review by CTRI](#)

[Click here to Add New Trial](#)




S.No.	REF Number	CTRI No.	Scientific Title	Trial Acronym	Secondary ID	View Details	Select
1	Pending	Pending	Creating a demo trial			Full Details	Update CT Details

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)



Usually the trial is sent back for modifications and clarifications and is available on the welcome page under the encircled link; in addition an automated email alert is sent to the registrant regarding the need for action on the trial.

(Refer Slide Time: 15:30)



MODIFICATION PAGE

Reply Clarification for Trial Acknowledgment No. 807/2018/04/020411

Reads of Clarifications - 1 (Please click [CLASSIFICATION SOUGHT](#) to view the query raised by CTRE admin then click to [MODIFY](#) link for modification. Please click [SUBMIT](#) link only after ensuring that ALL requested [MODIFICATIONS](#) have been appropriately addressed.)

Part 1			
1	Public title of study	No Clarification Sought	Field Locked
2	Scientific title of study	Clarification Sought	Modify (Click to update data)

Part 2

1	Secondary IDs	No Clarification Sought	Field Locked
2	Principal Investigator or overall Trial Coordinator (multi-center study) Details	No Clarification Sought	Field Locked
3	Contact person (Scientific Query)	No Clarification Sought	Field Locked
4	Contact person (Public Query)	No Clarification Sought	Field Locked

Part 3

1	Sources of monetary or material support	No Clarification Sought	Field Locked
2	Primary sponsor	No Clarification Sought	Field Locked
3	Secondary sponsor	No Clarification Sought	Field Locked
4	Quantities of recruitment	No Clarification Sought	Field Locked

Part 4

1	Object of study	No Clarification Sought	Field Locked
2	Name of Ethics Committee and approval status	Clarification Sought	Modify (Click to update data)
3	Regulatory clearance obtained from DCGI	No Clarification Sought	Field Locked
4	Health conditions/problems studied	No Clarification Sought	Field Locked

Part 5

1	Study Type	No Clarification Sought	Field Locked
---	------------	-------------------------	--------------




Part 6

1	Intervention and comparator agent	No Clarification Sought	Field Locked
2	Inclusion & Exclusion Criteria	No Clarification Sought	Field Locked
3	Method of generating randomization sequence	No Clarification Sought	Field Locked
4	Method of allocation concealment	No Clarification Sought	Field Locked

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)

Clicking on the link will take you to the modification page, once a trial is submitted to the CTRE all fields become locked automatically only the fields which require further modifications or clarifications are unlocked.

(Refer Slide Time: 15:48)



HOW TO UPDATE

Reply Clarification for Trial Acknowledgment No. **NEI/2018/06/020411**

Records of Clarifications: 1 (Please click CLASSIFICATION SOUGHT to view the query raised by CTRI when then click to MODIFY link for modification. Please click **REVERT** link only after ensuring that all requested MODIFICATIONS have been appropriately addressed.)

Part 1	Public title of study	Scientific title of study	Classification	Field Locked
1	Public title of study	Scientific title of study	Classification sought	Field Locked
2	Scientific title of study	Scientific title of study	Classification sought	Field Locked
3	Principal Investigator or co	Principal Investigator or co	No Clarification Sought	Field Locked
4	Contact person (Scientific)	Contact person (Scientific)	No Clarification Sought	Field Locked
5	Contact person (Public Qn	Contact person (Public Qn	No Clarification Sought	Field Locked
6	Sources of monetary or	Sources of monetary or	No Clarification Sought	Field Locked
7	Primary sponsor	Primary sponsor	No Clarification Sought	Field Locked
8	Secondary Sponsor	Secondary Sponsor	No Clarification Sought	Field Locked
9	Countries of recruitment	Countries of recruitment	No Clarification Sought	Field Locked
10	Site/s of study	Site/s of study	No Clarification Sought	Field Locked
11	Name of Ethics Committee	Name of Ethics Committee	No Clarification Sought	Field Locked
12	Regulatory clearance status	Regulatory clearance status	No Clarification Sought	Field Locked
13	Health condition/condition	Health condition/condition	No Clarification Sought	Field Locked
14	Study Type	Study Type	No Clarification Sought	Field Locked
15	Intervention and compar	Intervention and compar	No Clarification Sought	Field Locked
16	Inclusion & Exclusion Crite	Inclusion & Exclusion Crite	No Clarification Sought	Field Locked
17	Method of generating rand	Method of generating rand	No Clarification Sought	Field Locked
18	Method of allocation con	Method of allocation con	No Clarification Sought	Field Locked

Part 2

Trial Acknowledgment No. NEI/2018/06/020411

Classification Scientific title of study

Field: Scientific title of study

Detail: 06/09/2019

Information Sought: The scientific title should exactly match that claimed by the EC

Reply Date:

Upload file, if any:

Note: Reply is not essential. To modify data set point, please close this window and click on **MODIFY**.

Reply, if any:

Part 3

Study Type

Part 4

Intervention and compar

Part 5


Inclusion & Exclusion Crite

Part 6

Method of generating rand

Part 7




Method of allocation con



CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR INDNEW DRUG. (VERSION 2.0)

To know what clarifications are sought click on the clarification sort link this will open another window. In this case the query raised by CTRI is that the scientific title must exactly match that in the ethics approval.

(Refer Slide Time: 16:04)



MODIFY TITLE




Reply Clarification for Trial Acknowledgement No. 837/2018/04/02/0151

Ready for Clarifications: 1 (Please click **CLARIFICATION SOUGHT** to view the query raised by CTRI admin then click to **MODIFY** link for modification. Please click **REVERT** link only after ensuring that ALL requested **MODIFICATIONS** have been appropriately addressed.)

Part	Field	Status	Action
Part 1	Public title of study	No Clarification Sought	Field Locked
	Scientific title of study	Clarification Sought	Modify (click to update data)
	Principal Investigator ID	No Clarification Sought	Field Locked
	Contact person (Scientist)	No Clarification Sought	Field Locked
Part 2	Contact person (Public)	No Clarification Sought	Field Locked
	Sources of monetary or non-monetary benefit	No Clarification Sought	Field Locked
	Primary sponsor	No Clarification Sought	Field Locked
	Secondary Sponsor	No Clarification Sought	Field Locked
Part 3	Country of recruitment	No Clarification Sought	Field Locked
	Ethics of study	No Clarification Sought	Field Locked
	Name of Ethics Committee	No Clarification Sought	Field Locked
	Regulatory clearance at health commission	No Clarification Sought	Field Locked
Part 4	Study Type	No Clarification Sought	Field Locked
	Intervention and comparison	No Clarification Sought	Field Locked
	Inclusion & Exclusion Criteria	No Clarification Sought	Field Locked
	Method of generating randomization	No Clarification Sought	Field Locked
Part 5	Method of allocation concealment	No Clarification Sought	Field Locked
	Blinding	No Clarification Sought	Field Locked
	Statistical analysis	No Clarification Sought	Field Locked
	Other	No Clarification Sought	Field Locked


In case, your ethics committee has approved a change in title you may mention the same in the reply box below and upload the relevant document in the ethics approval section. If not close this window and click on the modify link to gain access to the originally uploaded data save it and exit the field.

(Refer Slide Time: 16:28)




DEFAULT UNLOCKED FIELDS

Part 4			
1	Steps of study	No Clarification Sought	Field Locked
2	Name of Ethics Committee and approval status	No Clarification Sought	Field Locked
3	Regulatory clearance obtained from DCGI	No Clarification Sought	Field Locked
4	Health condition/problems studied	No Clarification Sought	Field Locked
Part 5			
1	Study Type	No Clarification Sought	Field Locked
Part 6			
1	Intervention and comparator agent	No Clarification Sought	Field Locked
2	Inclusion & Exclusion Criteria	No Clarification Sought	Field Locked
3	Method of generating randomization sequence	No Clarification Sought	Field Locked
4	Method of allocation concealment	No Clarification Sought	Field Locked
5	Blinding/masking	No Clarification Sought	Field Locked
Part 7			
1	Primary outcome/s	No Clarification Sought	Field Locked
2	Secondary outcome/s	No Clarification Sought	Field Locked
3	Target sample size	No Clarification Sought	Field Locked
4	Phase of trial	No Clarification Sought	Field Locked
5	Date of first enrollment	No Clarification Sought	Field Locked
6	Estimated duration of trial	No Clarification Sought	Field Locked
Part 8			
1	Recruitment status of trial	No Clarification Sought	Field Locked
2	Final Summary	No Clarification Sought	Field Locked
3	Publication	No Clarification Sought	Field Locked



It may be noted that while all fields become unlocked upon submission and registration two fields that is ethics approval section and recruitment status of trial are permanently unlocked by default this is to enable regular update of the trial even upon registration. If no clarification is sought for these sections there is no need for any modifications in these fields.

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TRIAL RESUBMISSION

Part 6			
1	Intervention and comparator agent	No Clarification Sought	Field Locked
2	Inclusion & Exclusion Criteria	No Clarification Sought	Field Locked
3	Method of generating randomization sequence	No Clarification Sought	Field Locked
4	Method of allocation concealment	No Clarification Sought	Field Locked
5	Blinding/masking	No Clarification Sought	Field Locked
Part 7			
1	Primary outcome(s)	No Clarification Sought	Field Locked
2	Secondary outcome(s)	No Clarification Sought	Field Locked
3	Target sample size	No Clarification Sought	Field Locked
4	Phase of trial	No Clarification Sought	Field Locked
5	Date of first enrollment	Clarification Sought	Modify (click to update data)
6	Estimated duration of trial	No Clarification Sought	Field Locked
Part 8			
1	Recruitment status of trial	No Clarification Sought	Modify (default selected field)
2	Brief Summary	No Clarification Sought	Field Locked
3	Publication	No Clarification Sought	Field Locked

[Click here to re-Submit to CTRI](#)

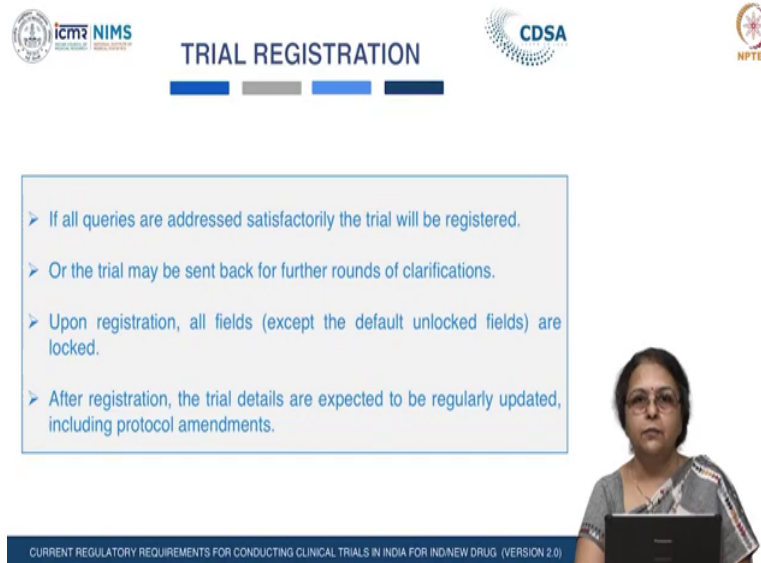
Please note that trial verification (confirmatory email reply from trial contact person such as CDRs, trial PI etc.) is mandatory for trial resubmission. Please follow up with contact person

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Once all the clarification sort links have been similarly addressed, make sure to submit the trial back to CTRI without this action the CTRI is not alerted on the need for action on this particular trial.

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TRIAL REGISTRATION

- If all queries are addressed satisfactorily the trial will be registered.
- Or the trial may be sent back for further rounds of clarifications.
- Upon registration, all fields (except the default unlocked fields) are locked.
- After registration, the trial details are expected to be regularly updated, including protocol amendments.

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If all queries are satisfactorily addressed the trial will be registered, if not the trial will be sent back for further rounds of clarification and modification. Once registered all fields except for the default unlock fields will become locked. And after registration all trial details are expected to be regularly updated including with protocol amendments as and when applicable.

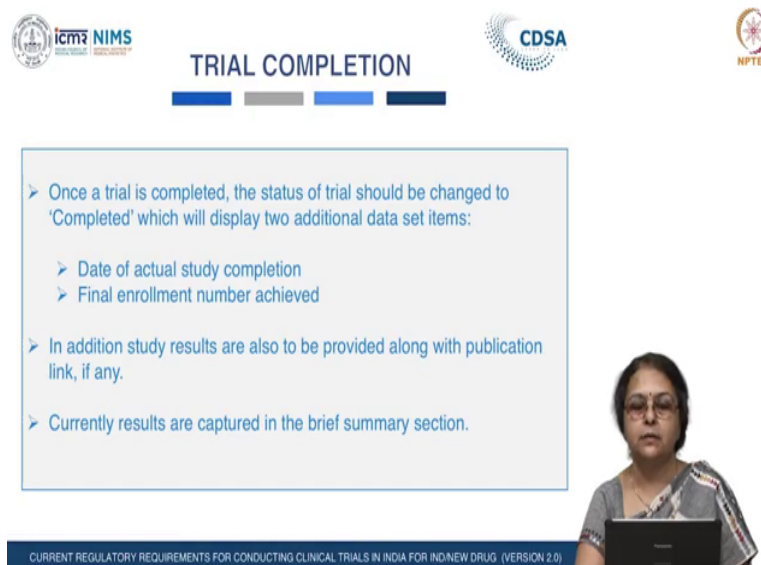
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The screenshot displays the Clinical Trials Registry - India (ICTR-NIMS) website. At the top, there are logos for ICTR-NIMS, CDSA, and NPTEL. The main heading is "SOP FOR FIELD UNLOCKING". Below this, the website interface shows a navigation bar with links: "Total Certifications/Modifications", "Registered Trials", "General Query", and "Edit Profile". The "Registered Trials" link is highlighted with a red circle. Below the navigation bar, a red oval highlights the text "SOP to be followed for field unlocking in registered trials". The page also contains instructions for site addition/deletion, new contact person, and intervention/comparator agent. At the bottom, there is a table with columns: "Pending", "Pending", "Creating a dummy trial", "Trial Details", and "Update () Details".

Current Regulatory Requirements for Conducting Clinical Trials in India for IND/NEW DRUG (VERSION 2.0)

Registered trials may be viewed under this link where in case any field is required to be unlocked for updation the SOP for field unlocking is mentioned. Please, follow the same while sending along with sending a mail to the CTRI quoting the CTRI number in this subject line.

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TRIAL COMPLETION

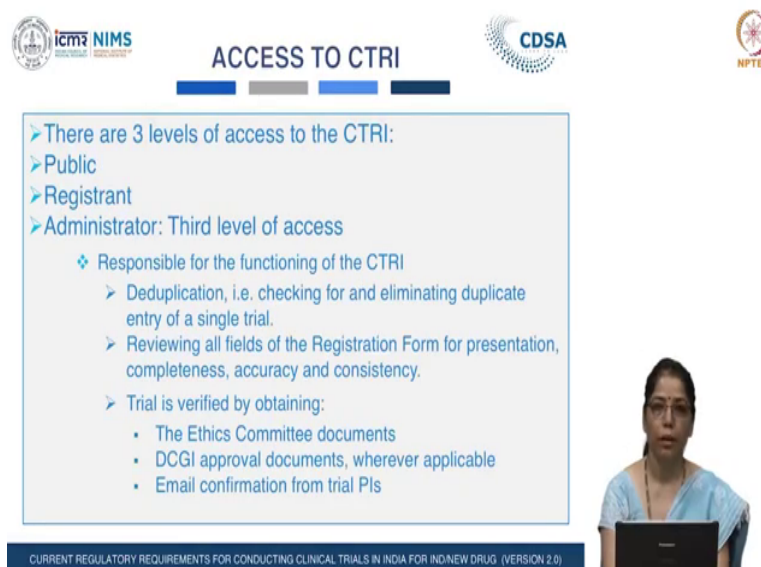
- Once a trial is completed, the status of trial should be changed to 'Completed' which will display two additional data set items:
 - Date of actual study completion
 - Final enrollment number achieved
- In addition study results are also to be provided along with publication link, if any.
- Currently results are captured in the brief summary section.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)

Once the trial is completed the status of trial should be changed to completed which will display two additional data set items that is data of actual study completion and final enrollment numbers achieved. In addition study results are also to be provided along with publication link if any; currently results are captured in the brief summary section.

However in the near future some structured summary results will be have to be posted in the result disclosure section which is currently being tested. In the next section Dr. Tulsi Adhikari will discuss the third and final level of CTRI access that is of the administrator, thank you.

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ACCESS TO CTRI




- There are 3 levels of access to the CTRI:
 - Public
 - Registrant
 - Administrator: Third level of access
 - ❖ Responsible for the functioning of the CTRI
 - Deduplication, i.e. checking for and eliminating duplicate entry of a single trial.
 - Reviewing all fields of the Registration Form for presentation, completeness, accuracy and consistency.
 - Trial is verified by obtaining:
 - The Ethics Committee documents
 - DCGI approval documents, wherever applicable
 - Email confirmation from trial PIs

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)

Welcome, friends I am Dr. Tulsi Adhikari and I am one of the Coordinator of CTRI and I am working as scientist e under ICMR NIMS. As my colleagues have talked about various types of accesses under the CTRI and the first one is the public access, the second one is the registrant access and the third one is the administrative access that I am talking about. So, an administrator is the identity who can make changes on the system that will affect the registering as well as the public.


And under CTRI the administrator is responsible for the duplication that is checking for an eliminating duplicate entries of a single trial also reviewing all the fields of the registration form for the trials for completeness, accuracy and consistency. And verification of the trial by obtaining; The Ethics Committee documents for that particular trial DCGI approval documents wherever applicable and email confirmation from trial principal investigators.

(Refer Slide Time: 20:03)



UPON SUBMISSION

- Once a trial is submitted to CTRI, all data fields become locked for editing as they are scrutinized and reviewed by CTRI scientists.
- Subsequently, only fields requiring modifications and/or clarifications are unlocked and trial sent back to Registrant for editing with the necessary request for modification or clarification specified under the link "Clarification sought"
- Hence only those fields which require modifications/clarifications will be unlocked for editing when the trial is sent back to the Registrant.
- The exceptions to this include the *Recruitment status of trial* and the *Name of Ethics Committee and approval status*, which remain permanently unlocked, even upon trial registration.

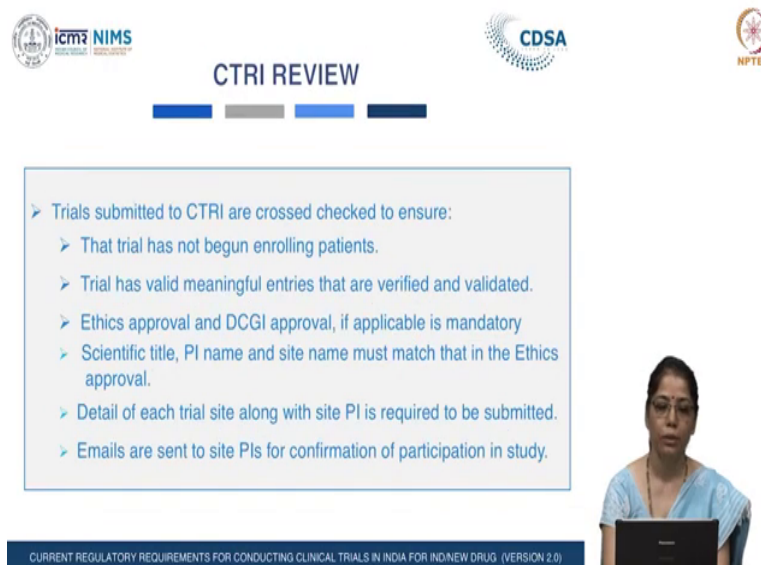


CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG (VERSION 2.0)

Once a trial is submitted to CTRI all data fields become unlocked for editing as they are scrutinized and reviewed by the CTRI scientist. Subsequently only fields requiring modifications and or clarifications are unlocked and the trial is sent back to the registrant for editing with the necessary request for modification or clarification specified under the link clarification sought.

Hence, only those fields which require modifications or clarifications will be unlocked for editing when the trial is sent back to the registrant. The recruitment status of the trial and Name of the Ethics Committee and approval status remains permanently unlocked even after the registration of the trial.

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CTRI REVIEW

- Trials submitted to CTRI are cross checked to ensure:
 - That trial has not begun enrolling patients.
 - Trial has valid meaningful entries that are verified and validated.
 - Ethics approval and DCGI approval, if applicable is mandatory
 - Scientific title, PI name and site name must match that in the Ethics approval.
 - Detail of each trial site along with site PI is required to be submitted.
 - Emails are sent to site PIs for confirmation of participation in study.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG (VERSION 2.0)

So, CTRI reviews all the trials submitted and trial submitted to CTRI are cross checked to ensure that trial has not begun enrolling patient that is prospective registration only. Trial has valid meaningful entries that are verified and validated ethics approval and DCGI approval if applicable is mandatory and CTRI ensures that these approvals are uploaded on the system.

Scientific title, PI name and the site name must match with that with the Ethics Committee document. Detail of each site along with the site PI is required to be submitted and emails are sent to the side PI for confirmation of participation in the study.

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SITE DETAILS



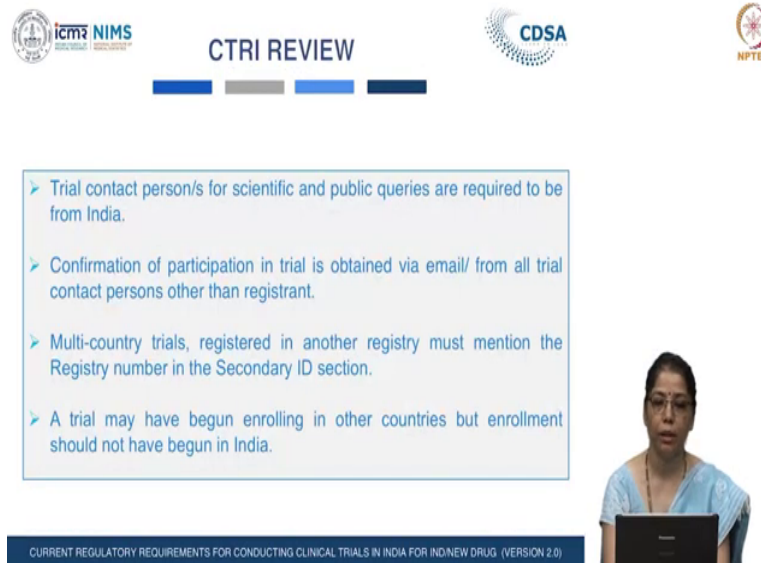
Contact Person	Name of Site	Site Address	Phone/Fax/Email
Dr Puneet Agrawal	Chopra Super specialty Hospital	Dr Chopra Super Specialty Hospital, Department of General Surgery, Gurukulam Road, Sector, Agrawal, UTTAR PRADESH	91-9837444287 91-9862-222879 Puneet255@shoo.com
Dr Mohd Yunus Salarshah	Crescent Hospital & Heart Centre	Crescent Hospital & Heart Centre, Department of General surgery, Behind must camel school, Near Lokmat Square, Dhantoli, Nagpur-440011, Maharashtra, India	91-9890318105 91-712-2426168 dryunus29@rediffmail.com
Dr Manjuresh Talure Ramachandra	K.R. Hospital	K.R. Hospital, Department of General Surgery, NO.979,25th Main Road, Banasani 1st Stage Opp PES college Manamathanagar Bangalore-560050 Karnataka, India	91-9845009494 91-89-23407614 banthemen@rediffmail.com
Dr Sanjay C Desai	M. S. Ramiah Medical College and Hospitals	M. S. Ramiah Medical College and Hospitals, Department of Vascular and Endovascular Surgery, OPD No. 9, New BEL road, MSRIT Bangalore Karnataka India	91-9848290876 91-80-40522402 indesa@rediffmail.com
Dr Vinod Kumar Singh	Pandit J.N.M Medical College and B.R. Ambedkar Memorial Hospital	Pandit J.N.M Medical College and B.R. Ambedkar Memorial Hospital, Department of Surgery, Room No. 127, First Floor, Nagpur-440001, Chhattisgarh-India	91-9926131309 91-771-4267789 singh.vinod@rediffmail.com
Dr Prashant Rahate	Rahate Surgical Hospital & ICU	Rahate Surgical Hospital & ICU 117, Department of General surgery, Killa Swami square, Central Avenue, Nagpur -08	91-9822444068 91-712-4536680 prashantrahate@yahoo.co
Dr Ajay Yadav	Sir Ganga Ram Hospital	Sir Ganga Ram Hospital, Department of Vascular and Endovascular Surgery, First Floor, Room No.1110, Old Rajendra Nagar, New Delhi-110060 Central Delhi	91-9717183395 91-11-29461002 yadav.vascular@gmail.com
Dr Snehal Pundarik	Smt. Karthika Nayale General Hospital	Smt Karthika Nayale General Hospital, Department of Clinical research, First Floor, 45/2, Off Western Express Highway, Nanhe (Ambegani) Pune-411041, India	91-9822061991 91-20-24792111 sn92331@rediffmail.com

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND NEW DRUG. (VERSION 2.0)



So, now I am going to give you a sample of site details what we are cover, what we all cover under the site details, the contact person name, name of the site, site address and phone number, fax and email of the contact person.

(Refer Slide Time: 21:55)



The slide is titled "CTRI REVIEW" and features logos for ICMR NIMS, CDSA, and NPTEL. It contains four bullet points regarding clinical trial regulations in India. A presenter is visible in the bottom right corner.

- Trial contact person/s for scientific and public queries are required to be from India.
- Confirmation of participation in trial is obtained via email/ from all trial contact persons other than registrant.
- Multi-country trials, registered in another registry must mention the Registry number in the Secondary ID section.
- A trial may have begun enrolling in other countries but enrollment should not have begun in India.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)

Under CTRI review the trial contact person for scientific and public queries are required to be from India only. And confirmation of participation in trial is obtained by a email from all the trial contact person other than the registering. If a trial is multi country and is registered in another registry, then the other registry number must be mentioned in secondary ID section of the CTRI form. A trial may have begun enrolling in other countries, but enrollment should not have begun in India.

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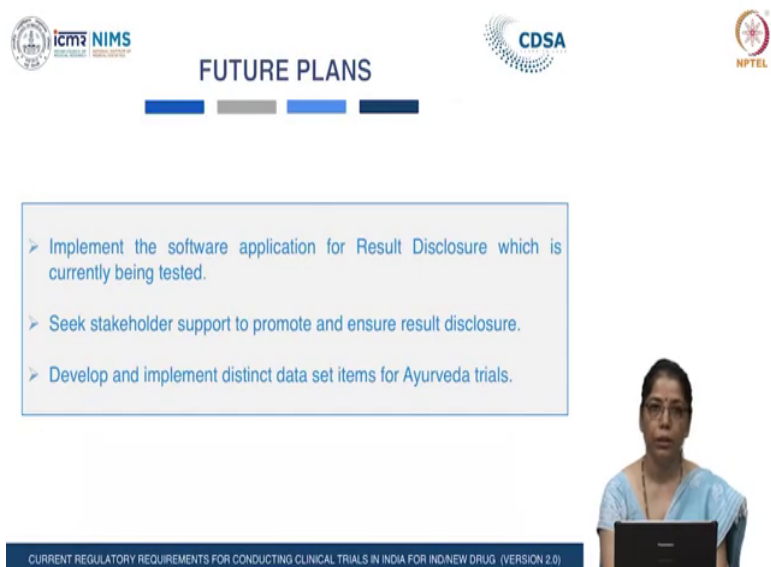
The slide features logos for ICMR, NIMS, CDSA, and NPTEL at the top. The title 'UPDATES IN REGISTERED TRIALS' is centered. Below it, a list of five bullet points provides details on trial updates. A woman is visible in the bottom right corner, and a footer at the bottom reads 'CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)'.

- Registered trials are expected to be updated regularly over the course of the study.
- All fields are locked upon registration, except status and ethics approval sections.
- For any changes in the scientific title, intervention, outcomes, sample size etc, ethics approval is mandatory.
- For change in contact persons, email confirmation from the concerned individual is mandatory.
- SOP is to be followed for field unlocking in detailed under the [Registered Trials](#) button on registrant's Welcome Page.

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And we keep on updating the registered trials and the registered trials are expected to be updated regularly over the course of the study. All fields are logged upon registration except status and ethics approval section, for any changes in this scientific title intervention, outcome, sample size etcetera, ethics approval is mandatory. For change in contact persons email confirmation from the concerned individual is mandatory. And SOP as mentioned by Dr. Mohua is to be followed for field unlocking in detail under the registered trial button on the registrants welcome page.

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FUTURE PLANS

- Implement the software application for Result Disclosure which is currently being tested.
- Seek stakeholder support to promote and ensure result disclosure.
- Develop and implement distinct data set items for Ayurveda trials.

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That was what we are already doing in CTRI and we have plans for CTRI. So, we keep on updating the CTRI also the future plans are implement the software application for result disclosure which is currently being tested. So, we are developing the research, we are also developing the result disclosure the beta version is ready and it is being tested.

So, very soon you will see the result disclosure portal under CTRI also and we seek these stakeholder support to promote and ensure the result disclosure also. And the second future plan is develop and implement distinct data set items for Ayurveda studies also that also we have already started. So, very soon we will have a different data set items for the Ayurveda study, Ayurveda studies.

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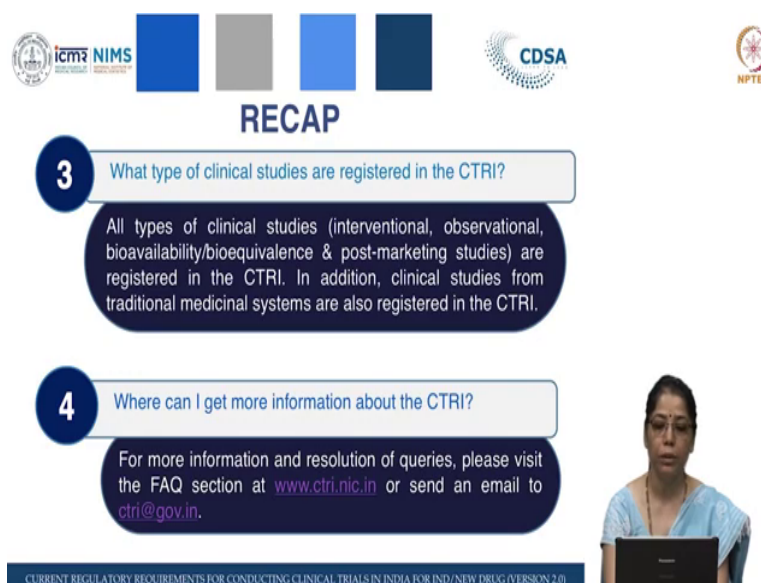
RECAP

- 1** Why should trials be registered in the CTRI?
Registration of all regulatory trials is mandatory as per the licensing authority in India. In addition, several journal editors, ethics committees and medical colleges make it mandatory to register clinical studies in the CTRI.
- 2** When should a clinical study be registered?
A clinical study should be registered prospectively i.e. before the enrolment of the first patient into the study.

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Now, let us take a quick recap what we have seen, so if we ask why should trial be registered in CTRI? The answer to this question will be registration of all regulatory trial is mandatory as per the licensing authority in India that is DCGI. In addition several journal, editors ethics committees and medical colleges make it mandatory to register clinical studies in the CTRI, when should a clinical study be registered? So, the answer to this question is a clinical study should be registered prospectively that is before the enrollment of the first patient into the study.

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RECAP

3 What type of clinical studies are registered in the CTRI?

All types of clinical studies (interventional, observational, bioavailability/bioequivalence & post-marketing studies) are registered in the CTRI. In addition, clinical studies from traditional medicinal systems are also registered in the CTRI.

4 Where can I get more information about the CTRI?

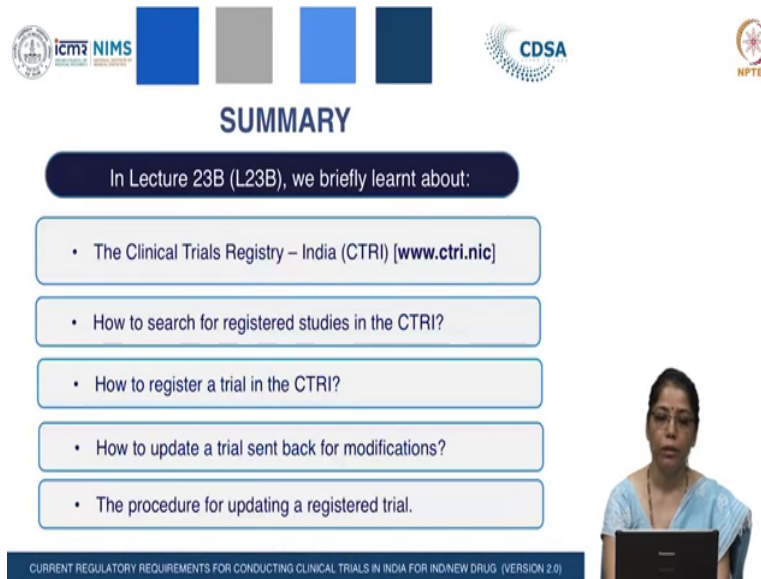
For more information and resolution of queries, please visit the FAQ section at www.ctri.nic.in or send an email to ctri@gov.in.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG (VERSION 2.0)

What types of clinical studies are registered in CTRI? The answer is all types of clinical studies including interventional studies, observational studies, bioavailability, bioequivalence and post marketing studies are registered in CTRI. And in addition clinical studies from the traditional system of medicines are also registered under CTRI.

And at present we have already and at present we have around 2000 Ayurveda and the and at present we have around 2000 clinical studies from the traditional system of medicine under CTRI. Where can I get more information about CTRI? So, you can have more information about CTRI under the FAQ section of CTRI and also you can send email to CTRI at this address ctri@gov.in.

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SUMMARY

In Lecture 23B (L23B), we briefly learnt about:

- The Clinical Trials Registry – India (CTRI) [www.ctri.nic]
- How to search for registered studies in the CTRI?
- How to register a trial in the CTRI?
- How to update a trial sent back for modifications?
- The procedure for updating a registered trial.

CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR IND/NEW DRUG. (VERSION 2.0)

So, let us see briefly what we have learned in this lecture, the Clinical Trial Registry India is available at [www dot ctri dot nic dot in](http://www.ctri.nic.in). How to search for registered studies in CTRI that we have learnt? How to register a trial in CTRI? How to update a trial sent back for modification and the procedure for updating a registered trial, so all this we have learned in this lecture.

Thank you.