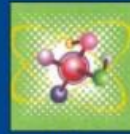




ICMR

Clinical Trials Registry - India

National Institute of Medical Statistics (ICMR)



DST

CTRI Bulletin

www.ctri.nic.in

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CTRI Highlights

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

CTRI Software Application Upgraded

The screenshot shows the CTRI software application interface. At the top, it says "CLINICAL TRIALS REGISTRY - INDIA" and "NATIONAL INSTITUTE OF MEDICAL STATISTICS (INDIAN COUNCIL OF MEDICAL RESEARCH)". Below this, there are navigation links: "Home", "About Us", "Advanced Search", "Register Trial", "FAQ", "Publications", "Registered Trials", "News".

The main content area is divided into two columns. The left column contains a "Login" form with fields for "Username" and "Password", and a "Login" button. Below the login form is a "Forgot Password" link and a "Trial Registration Set Download" link. The right column contains a "News" section with a heading "Clinical trials have 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 are not even available to many who are interested in them. To address this, the Indian Council of Medical Research (ICMR) has launched the Clinical Trials Registry - India (CTRI). The CTRI is a free and online public record system for registration of clinical trials being conducted in India commensurate with the practice of evidence-based medicine. Today, with a need has been felt on the part of the regulatory authorities to ensure transparency, accountability and accessibility in order to make the clinical trials conducted in India more credible and trustworthy. The registration of clinical trials will ensure transparency, accountability and accessibility of clinical trials. The mission of the Clinical Trials Registry - India (CTRI) is to encourage all clinical trials conducted in India to be registered in the CTRI before the start of the trial." Below the news section, there is a "View: English" dropdown menu and a "Home" link.

Login page of registrants

The screenshot shows the CTRI login page for registrants. At the top, it says "Clinical Trials Registry - India" and "NATIONAL INSTITUTE OF MEDICAL STATISTICS (Indian Council of Medical Research)". Below this, there is a date "11/03/2011" and navigation links: "Main Page", "Change Password", "Website Home Page", "Logout".

The main content area is divided into two sections. The top section is a dashboard with a table showing trial statistics:

Total Trials	8
Under Entry Stage	4
Under Review Stage	3
Registered Trials	1
Terminated/Suspended Trials	0

Below the dashboard is an "Add New Trial" button.

The bottom section is a table listing registered trials:

S.No.	Reference No	CTRI No	Scientific Title	Acronym	Secondary ID	View Details	Select
1	REF-2010-10-000003	CTRI-2010-11-000001	Test to Trial	NT10111	1001[ClinicalTrials.gov] 1002[EudraCT]	Full Details	Submitted to CTRI on 29/10/2010 Last Submitted On: 30/11/2010
2	REF-2010-11-000006	Pending	A large, simple multicentre, international randomized placebo-controlled trial utilizing a 2 x 2 factorial design and...	HOPE-3 (Heart Outcomes)	MOH_22_11_10(Protocol Number)EC-12-NEW-	Full Details	Submitted to CTRI on 23/11/2010 Link Submitted

Note :

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

New features of the upgraded version

Audit trail

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

Type of Trial	International
Type of Study	Drug
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Visual Field Assessment With Subjects Who Receive Either Lyrica Or Sugar Pills
Scientific Title of Study	Prospective Randomized 12-Week Controlled Study Of Visual Field Change In Subjects With Partial Seizures Receiving Pregabalin Or Placebo
Secondary ID	Identifier
NCT03316111	ClinicalTrials.gov
A0081996	Protocol Number
Details of Principal Investigator	<p>Name: Mrs Sheelika Taxwale</p> <p>Medical Research Division, Pfizer Limited Patel Estate, Off S. V. Road, Jogeshwari West, Mumbai</p> <p>Address: Mumbai MUMBAI,INDIA 408 102 India</p>
Details Contact Person	<p>Dr. Vinod Rajadhyaksha Representing Jogeshwari West, Mumbai</p> <p>16/03/2011</p>

Trial Transfer

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

Submission of EC/DCGI approval documents

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

Clinical Trials Registry - India NATIONAL INSTITUTE OF MEDICAL STATISTICS (Indian Council of Medical Research)	
16/09/2011	Main Page Change Password Website Home Page Logout
Submit Trial	Trial Classification/Modifications Registered Trials General Query SSB Profile
Scientific Name of Trial: A clinical trial to test the antihypertensive efficacy of QW-YDP-2011	
Part 1	Public title of study
2	Scientific title of study
Part 2	Secondary ID
1	Principal Investigator or overall Trial Coordinator (multi-center study)
2	Contact person (Scientific Query)
3	Contact person (Public Query)
Part 3	Sources of monetary or material support
1	Primary sponsor
2	Secondary sponsor
3	Countries of recruitment
Part 4	Status of study
1	Name of Ethics Committee and approval status
2	Regulatory clearance obtained from DCGI
3	Health conditions/health status

Selected Trial: A clinical trial to test the antihypertensive efficacy of QW-YDP-2011					
Line No	Name	Status	Approval Date	Approval File	Independent Ethics Committee
DCGI Approval					
DCGI Approval: <input type="text" value="--Select--"/>					
Date of Approval: <input type="text" value=""/>					
Documents: <input type="button" value="Choose File"/> No file chosen					
<input type="button" value="Proceed"/>					
Ethics Committee					
Line No	Name of Ethics Committee	Status	Approval Date	Approval File	Independent Ethics Committee
Health Conditions					
Line No	Trial Participant	Condition	Add health conditions & Trial Participant Details		

Selected Trial: A clinical trial to test the antihypertensive efficacy of QW-YDP-2011					
Line No	Name	Status	Approval Date	Approval File	Independent Ethics Committee
DCGI Approval					
DCGI Approval: <input type="text" value="Awaited"/>					
Date of Approval: <input type="text" value=""/>					
Documents: <input type="button" value="Choose File"/> No file chosen					
<input type="button" value="Proceed"/>					
Ethics Committee					
Add Ethics Committee					
Ethics Committee Name: <input type="text" value="CNSP"/>					
Status: <input type="text" value="Approved"/>					
Date of Approval: <input type="text" value="08/03/2011"/>					
Documents: <input type="button" value="Choose File"/> Choose Ethics Form.pdf					
Independent Ethics Committee: <input type="text" value="No"/>					
<input type="button" value="Proceed"/>					
Line No	Name of Ethics Committee	Status	Approval Date	Approval File	Independent Ethics Committee
Health Conditions					
Line No	Trial Participant	Condition	Add health conditions & Trial Participant Details		

Points to be noted:

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

