User Manual
Online Clinical Trial Application & Monitoring System

URL: http://octams.gov.in/CT

For Scheme of Central Drugs Standard Control Organization (CDSCO)

Application Designed and Developed by NIC Department of Information Technology
Index

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Project Description

- Central Drugs Standard Control Organization (CDSCO), under Ministry of Health & Family Welfare proposes to create an IT enabled system for online submission of various information on clinical trials to streamline the process of approval, maintaining comprehensive database and monitoring of clinical trials for ensuring the protection of rights, safety and well beings of trial subjects and authenticity of the data generated.

- There should be complete transparency and accountability in functioning of CDSCO
Project Objectives

- Common Platform for online registration of Clinical Trials irrespective of any scheme.
- Facility to submit online application form for Central Drugs Standard Control Organization (CDSCO), under Ministry of Health & Family Welfare.
- Online submission of various information on clinical trials to streamline the process of approval.
- Maintaining comprehensive database and monitoring of clinical trials for ensuring the protection of rights, safety and well beings of trial subjects and authenticity of the data generated.
- Uploading the documents as prescribed in the respective scheme.
- On-line report generation of respective applicant.
- Work flow based application design as approved by Ministry.
- Online processing of the application by the role defined in the application.
- Complete transparent back office process to keep track of the application forms the stake holders.
- Proposals, Checklist and Inspection application.
Application Functionalities

Following functional requirement for project

- Registration by following Applicant
  - Sponsor
  - LR (Legal Representative)
  - Medical or Research Institute
  - Individual Researcher

- Access of the application by authorized Applicant Users.

- Proposal Entry on line, saving as Draft and Saving as Final.

- Uploading Documents as enclosure as per the CDSCO Division Requirement

- Taking Report of the final submission to CDSCO for checking/verification.
Application Stake Holders

✓ Central Drugs Standard Control Organization (CDSCO)
✓ Director General of Health Services
✓ Ministry of Health & Family Welfare
✓ Government of India
Application Covers

✓ Applicant Registration
✓ Authorization Letter Generation
✓ Application Submission
✓ Necessary Document Upload
✓ Application Status Check
✓ Report Generation
Application will be available on the address below

http://www.octams.gov.in/CT

Which can be accessed on the internet? After giving the above address in any web browser the user will get the following screen.
Getting Start as Applicant User

Go to tab Applicant Registration for Clinical Trials

Applicant Registration page will appear on the screen.
General Instructions

- New user is required to fill up the registration form along with the applicant-id and password in the registration form.

- User Can Register as
  - Sponsor
  - LR (Legal Representative)
  - Medical or Research Institute
  - Individual Researcher

- Duplicate values for following field that is not allowed to enter in to system.
  - Duplicate Organization Name
  - Duplicate Applicant ID
  - Duplicate Email Id
  - Duplicate Mobile Number

- Password must contain at least one special character from (#,@,*') with one capital alphabet & one number.
After successful registration following screen will appear with message.

You have registered successfully check mail, User activation message will be send by SMS

- Click on **Print Authorization Letter** button to get Authorization Letter for print.
- If user approved by admin then user will able to log in to the application for Clinical Trials.
Authorization Letter Format

- **Personal Details**
  - Organization Name: Trials
  - Contact Person Name: Chetan Mansing Pardeshi
  - Contact Address:
    - HIN.713, Shivkrupa Colony, Pune. 411017
    - Pune, Maharashtra, India
  - Contact Details:
    - Mobile No.: 919028641558
    - Email Id: chetanpardeshi@gmail.com

- **Identity Details**
  - PAN: BCUPP5032J

- **Registration Date**: 15-07-2015

- **General Instructions**
  - After registration site user should send details to CDSCO for authorization
  - After getting permission by CDSCO user will able to login
  - CDSCO will suggest this required document list to sent by Email/P.O.
User Login

Go to tab **User Login** for **Clinical Trials**

Login page will appear on the screen.

Already registered user can log in to the application by entering their credentials

- Applicant ID and password will be allowed to user.
- Correct applicant-id and password will be required for online application of CDSCO proposal.
- User is required to fill up the login form along with the applicant-id, password and captcha code in the log in form

  - Captcha Code in login page is look likes following image.
Welcome to Clinical Trials

After successfully login welcome page will appear on the screen.

- **System Menu**

- **General Instructions**
  - **Application**
    Online submission of various information on clinical trials to streamline the process of approval.
  - **Update Profile**
    This section updates the Applicant Profile
  - **Report**
  - **Change Password**
    This section allow to change Applicant Password
Application Entry

Go to submenu Application Entry for Clinical Trials

Click on Application Entry following Status page will appear on the screen
General Instructions

- **Status**
  - Check status of your submitted application by following status

  ![Status](image)

  - APPLICATION SUBMITTED
  - IN PROCESS

  - To get sort records simply click on below table field,

  ![Table](image)

<table>
<thead>
<tr>
<th>Application ID</th>
<th>Trial Title</th>
<th>Application Date</th>
<th>Sponsor Name</th>
<th>Reference No</th>
<th>Status</th>
</tr>
</thead>
</table>

  - Search the result by entering keywords

  ![Search](image)
New Application Entry

Go to tab New Application Entry following page will appear on the screen.
General Instructions

- First A: Trial / Sponsor / LR / Applicant Identification form compulsory to filled then other tab will open.
- If user first try to fill up other form instead of “A: Trial / Sponsor / LR / Applicant Identification” then following message will appear on screen:
  
  Please Fill Trial Identification (A) and Save Initially

- Application ID is auto generated to each new application

  Application ID: 6

- Save as Draft

  Save as Draft

- The star (*) marked fields are compulsory
- Filled up all required field and Submit or save each form by simply click on Save as Draft button
- Following message will appear on every form after Save as Draft of each form

  Record Saved Successfully

- Application Status Bar

  Status
  - A
  - B
  - C
  - D
  - E
  - F
This status side bar shows the status of completion of form.
After Save as Draft of form the auto check display on each completion of form.

A:- Trial/Sponsor/LR Applicant Identification

General Instructions

- CDSCO Division list

- Status of Applicant

- Trial Title

- Enter upto 250 character to each row of trial title
- Special Characters [ Space, Comma (,), Dot (.), Underscore (_), & Dash (-) ] allowed with alphabets and numbers.
Go to tab **General Information** following page will appear on the screen.
**Disease Under Investigation**

- Select disease and click on add button it will listed in **Disease Description**.
- If select disease as **Other** option then enter disease name in textbox which is in front of **Other** option of disease.
- User can delete **Disease Description** by simply click on delete button.

**Scope / Objective of The Trial Like Is This**

- User can check multiple **Scope / Objective of the trial** by simply click on above option.
- If user checks **Other** option then **Other scope** text box option will open for edit.
 Trial Type and Phase

- Select **Trial Type and Phase** & click on **Add** button it will list in **Phase Description**.
- If select **Other** option then enter Trial Type and Phase name in textbox which is in front of **Other** option.
- User can delete **Phase Description** by simply click on **Delete** button.

 Design of Trial

- Select **Design of Trial** & click on **Add** button it will list in **Design Description**.
- If select **Other** option then enter Trial Type and Phase name in textbox which is in front of **Other** option.
- User can delete **Design Description** by simply click on **Delete** button.
Go to tab IP Details following page will appear on the screen

<table>
<thead>
<tr>
<th>Active Substances</th>
<th>Test / Reference Product</th>
<th>Active Substance</th>
<th>Origin</th>
<th>INN / Sponsor Code / CAS</th>
<th>INN Proposed / Brandname</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ref Product</td>
<td>Calcium</td>
<td>Chemical</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Details: Pharmaceutical Form</th>
<th>Other Details: Route Of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Form: tablet</td>
<td>Route Of Administration: Oral</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Details: Concentration / Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ref Product: Calcium</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Authorised site responsible for release of the Investigational Product (IP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsible For Release: Sponsor LR</td>
</tr>
<tr>
<td>Contact Address:</td>
</tr>
<tr>
<td>Building Name:</td>
</tr>
<tr>
<td>City:</td>
</tr>
<tr>
<td>Country:</td>
</tr>
<tr>
<td>Contact Details:</td>
</tr>
<tr>
<td>E-Mail:</td>
</tr>
<tr>
<td>Mobile No:</td>
</tr>
<tr>
<td>Web Site Of Sponsor / LR:</td>
</tr>
</tbody>
</table>

Disclaimer: Best Viewed in Google Chrome 39, Mozilla Firefox 40, IE 11 and above.
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Marketing Authorization (MA)

- If Marketing Authorization (MA) in India is Yes then under Document Upload section, document related to Marketing Authority in India should only be mandatory.
- If Marketing Authorization (MA) in India is selected as No then user can select country names and add it by simply click on Add button.
- User can delete country name by simply click on Delete Button.

Orphan Product

- If Orphan product in India is selected as Yes then under Document Upload section, document related to orphan product in India should only be mandatory.

Active Substances

- User can add Active Substances by simply click on Add button it will listed in table format.
- If select Other option from Active Substances then enter Substance Name textbox which is in front of Active Substances.
- User can delete Active Substances by simply click on Delete button.
➢ Concentration / Strength

- If active substances added then it will also added in section of **Concentration / Strength**

<table>
<thead>
<tr>
<th>Test/Reference Product</th>
<th>Name of Active Substance</th>
<th>Dosage Form</th>
<th>Concentration/Strength</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ref Product</td>
<td>Calcium</td>
<td>Tablet</td>
<td>50</td>
<td>MG</td>
</tr>
</tbody>
</table>

- Add **Concentration / Strength** and **Unit to Active Substance**

➢ Is This

- **Select Is This:**
  - ☐ Cell Therapy Medicinal Product
  - ☐ Gene Therapy Product
  - ☐ Radiopharmaceutical Product
  - ☐ Immunological Product (such as Vaccine, allergen, immune Serum)
  - ☐ Herbal Medicinal Product
  - ☐ Homeopathic Product
  - ☐ Medical Product Containing Genetically Modified Organisms
  - ☑ Other Medicinal Product To Be Used
  - ☐ Placebo Used
  - ☐ Medical Device
  - ☐ Chemically Synthetic Drugs

➢ Responsible For Release

- **Authorised site responsible for release of the Investigational Product (IP)**

  Responsible For Release: ☐ Sponsor ☑ LR

- Select Responsible For Release option **Sponsor** or **LR**
Go to tab **Population Subject** following page will appear on the screen.
Age Group

- User can add **Age Group** by simply click on **Add** button it will listed in **table format**.
- If select **Other** option from **Age Group** then enter **Age** in textbox which is in front of Other option.
- User can delete **Age Group** by simply click on **Delete** button.

**Global Clinical Trial**
- If **Global Clinical Trial** is selected as **Yes** then following section will appear on the screen.
  - User can add **Select Name of Participating Countries** by simply click on **Add** button it will listed in **table**.
  - User can add **Select Countries Where The Protocol Is Already Approved** simply click on **Add** button it will listed in **table**.
  - User can delete **Country** by simply click on **Delete** button.
Go to tab **Investigator** following page will appear on the screen.

![Clinical Trials Form](image_url)

**E. Investigator**

**Application ID:**

**Select Investigator Status**

- Investigator ID
- Investigator Name
- Designation
- Name of Site

- You can add multiple investigators by selecting New Investigator option

- New investigator
- Existing

**Clinical Trial Site Address**

- Building Name:
- Street / Locality:
- State:
- District:

**Clinical Trial Site Contact Details**

- Phone No.:
- Mobile No.:
- Fax No.:

**Details Of Laboratory / Bioanalytical Facility** (Multiple Labs can be added using 'Save Lab' button)

**EC Registration No.**

**Name of Ethics Committee:**

- Accreditation:
- YES
- NO

**EC Members Secretary**

- Name:
- Experience:
- Qualification:

**Contact Details**

- Phone No.:
- Mobile No.:
- Fax No.:

**Other Info**

- No of Meetings of the Committee For Trial:
- CDSCO Last Inspection Date:
- Date Of Opinion:
- Options: Favorable / Non-Favorable

Financial support / amount of fees / Honorarium / payment in kind per Investigator by Sponsor / LR:

[Save as Draft]
- User can add multiple investigator by selecting New Investigator option

> You can add multiple investigator by selecting New Investigator option

- **New investigator**  
- **Existing**

- Details of Investigator

- Details of Laboratory
- Investigator should be added with Lab details.
- Investigator can add multiple labs as per the requirement.
- Fill up the Details of Laboratory form and by simply clicking on Save Lab, it will list in the table.
- Details of Laboratory save by Save Lab button.

> Details of Ethics Committee

<table>
<thead>
<tr>
<th>Ethics Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC Registration No.:</td>
</tr>
<tr>
<td>Name of Ethics Committee:</td>
</tr>
<tr>
<td>Accreditation: Yes/No</td>
</tr>
<tr>
<td>Name Of Site/Hospital:</td>
</tr>
<tr>
<td>EC Type: Institutional</td>
</tr>
<tr>
<td>EC Members Secretary</td>
</tr>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Building Name:</td>
</tr>
<tr>
<td>City:</td>
</tr>
<tr>
<td>Country: India</td>
</tr>
<tr>
<td>State:</td>
</tr>
<tr>
<td>District:</td>
</tr>
<tr>
<td>Contact Details</td>
</tr>
<tr>
<td>Phone No.:</td>
</tr>
<tr>
<td>Mobile No.:</td>
</tr>
<tr>
<td>E-Mail ID:</td>
</tr>
<tr>
<td>Alternate E-mail ID:</td>
</tr>
<tr>
<td>Other Info</td>
</tr>
<tr>
<td>No of Meetings of the Committee for Trial:</td>
</tr>
<tr>
<td>CDSCO Last Inspection Date:</td>
</tr>
<tr>
<td>Date Of Opinion:</td>
</tr>
<tr>
<td>Opinion: Favorable/Non-Favorable</td>
</tr>
<tr>
<td>Financial support/amount of fees/Honorarium/payment in kind per Investigator by Sponsor/IR:</td>
</tr>
</tbody>
</table>

> Existing Investigator

- Once new investigator is Save as Draft then it will listed in Investigator Status section.
- User can select Existing Investigator from Investigator Status section by simply clicking on Select label.

<table>
<thead>
<tr>
<th>Select</th>
<th>Investigator ID</th>
<th>Investigator Name</th>
<th>Designation</th>
<th>Name of Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select</td>
<td>1033</td>
<td>INV Investigator</td>
<td>Scientist</td>
<td><a href="http://www.inv.com">www.inv.com</a></td>
</tr>
</tbody>
</table>

- If user clicks on Select which is shown in above fig, then all details of investigator will be listed in every field of investigator tab.
Go to tab **Document Upload** following page will appear on the screen.

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name Of The File's</th>
<th>Upload Status</th>
<th>View</th>
<th>Choose File</th>
<th>Upload/Update</th>
<th>Multiple File</th>
<th>No. Of Parts</th>
<th>Sample Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts*</td>
<td>Yes</td>
<td>Browse</td>
<td>No file selected.</td>
<td>Upload/Update</td>
<td>Y</td>
<td>N</td>
<td>Add</td>
</tr>
<tr>
<td>2.1</td>
<td>CASE REPORT FORMAT CRF*</td>
<td>Yes</td>
<td>Browse</td>
<td>No file selected.</td>
<td>Upload/Update</td>
<td>Y</td>
<td>N</td>
<td>Add</td>
</tr>
<tr>
<td>3.1</td>
<td>Declaration about the number of clinical trial being undertaken by each of the investigator if available*</td>
<td>Yes</td>
<td>Browse</td>
<td>No file selected.</td>
<td>Upload/Update</td>
<td>Y</td>
<td>N</td>
<td>Add</td>
</tr>
<tr>
<td>4.1</td>
<td>Declaration from Sponsor that protocol subjects will receive standard of care if applicable*</td>
<td>Yes</td>
<td>Browse</td>
<td>No file selected.</td>
<td>Upload/Update</td>
<td>Y</td>
<td>N</td>
<td>Add</td>
</tr>
<tr>
<td>5.1</td>
<td>Duty filled and signed Form 44*</td>
<td>Yes</td>
<td>Browse</td>
<td>No file selected.</td>
<td>Upload/Update</td>
<td>Y</td>
<td>N</td>
<td>Add</td>
</tr>
<tr>
<td>6.1</td>
<td>Ethic Committee Registration Certification*</td>
<td>Yes</td>
<td>Browse</td>
<td>No file selected.</td>
<td>Upload/Update</td>
<td>Y</td>
<td>N</td>
<td>Add</td>
</tr>
<tr>
<td>7.1</td>
<td>Executive Summary Annex ES*</td>
<td>Yes</td>
<td>Browse</td>
<td>No file selected.</td>
<td>Upload/Update</td>
<td>Y</td>
<td>N</td>
<td>Add</td>
</tr>
<tr>
<td>8.1</td>
<td>Financial Aspects of the trial. Details of the contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator. *</td>
<td>Yes</td>
<td>Browse</td>
<td>No file selected.</td>
<td>Upload/Update</td>
<td>Y</td>
<td>N</td>
<td>Add</td>
</tr>
<tr>
<td>9.1</td>
<td>Financial Status of the Applicant LR Upload declaration on firm letter head duly signed sealed*</td>
<td>Yes</td>
<td>Browse</td>
<td>No file selected.</td>
<td>Upload/Update</td>
<td>Y</td>
<td>N</td>
<td>Add</td>
</tr>
<tr>
<td>10.1</td>
<td>Form 12 Duty filled and signed for the import of Investigational Products IP*</td>
<td>Yes</td>
<td>Browse</td>
<td>No file selected.</td>
<td>Upload/Update</td>
<td>Y</td>
<td>N</td>
<td>Add</td>
</tr>
</tbody>
</table>
General Instructions

- Only Alphabets, Numbers, Underscore and Space are allowed in file name.
- File type: Only pdf, doc and docx allowed.
- More than 20 MB not allowed for upload
- More than 5 file cannot be split
- On each split file user can upload 20 MB file. So user can upload (5 X 20) 100 MB file in split.
- User should upload all mandatory file which are mention in document upload section
- User can download Sample Format of file by simply click on download link from Sample Format section.
- User can download uploaded file by simply click on Download link from View section
- User can able to Add / Update uploaded file by simply Browse new file and click on Upload/Update button.

Procedure to upload multiple file to one file

- For Upload multiple file select as Y and enter less than 6 No. of Parts
- And by simply click on Add button 5 files will be added and screen will display like following.
<table>
<thead>
<tr>
<th>SL. No.</th>
<th>Name Of The File's</th>
<th>Upload Status</th>
<th>View</th>
<th>Choose File</th>
<th>Upload/Update</th>
<th>Multiple File</th>
<th>No. Of Parts</th>
<th>Sample Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_1</td>
<td></td>
<td></td>
<td>Browse</td>
<td>No file selected</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_2</td>
<td></td>
<td></td>
<td>Browse</td>
<td>No file selected</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_3</td>
<td></td>
<td></td>
<td>Browse</td>
<td>No file selected</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td>AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_4</td>
<td></td>
<td></td>
<td>Browse</td>
<td>No file selected</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5</td>
<td>AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_5</td>
<td></td>
<td></td>
<td>Browse</td>
<td>No file selected</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Go to tab **Submit Application** following page will appear on the screen

- **General Instructions**
  - Check whether compulsory documents & following multiple documents are uploaded with related information (eg. If Pathology Lab document is compulsory check at least one pathology lab is added.)
Make sure your status bar show all check to each form then you can go for Submit Application

Submit your application by simply click on Submit Application button.

After successfully application is submitted then check the status of application in Status page.