



Clinical Trials

(Online Clinical Trials Application & Monitoring System)
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
DIRECTOR GENERAL OF HEALTH SERVICES,
MINISTRY OF HEALTH AND FAMILY WELFARE,
GOVERNMENT OF INDIA

CDSCO

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



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CDSCO

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



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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.



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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.



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Application Stake Holders

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



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Application Covers

- ✓ Applicant Registration
- ✓ Authorization Letter Generation
- ✓ Application Submission
- ✓ Necessary Document Upload
- ✓ Application Status Check
- ✓ Report Generation



URL of the Application

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.

The screenshot shows a web browser window with the URL <https://octams.gov.in/CT/>. The page header includes the Government of India logo, the title "Clinical Trials (Online Clinical Trials Application & Monitoring System)", and the CDSCO logo. A navigation menu contains links for Home, About Us, Contact Us, User Login, and Applicant Registration. The main content area features the heading "Online Clinical Trials Application & Monitoring System." and a central image of a scientist in a lab coat working with glassware. To the left of the image is a "Message" section, and to the right is an "Important Links" section with a link to the Central Drugs Standard Control Organization. A footer contains a disclaimer and copyright information: "Copyright © Online Clinical Trials application & Monitoring System. Site Designed and Developed by National Informatics Centre."



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Getting Start as Applicant User

Go to tab **Applicant Registration** for Clinical Trials

Register for your Applicant ID /LR ID :

Applicant ID /LR ID is required for online submission of forms related to Clinical Trials

* Mandatory Fields

Personal Details

Whether Indian: * Yes No

Register for: * Organization

Organization Name: *

Register as: *

Contact Person: *

Contact Address

Building Name/No/Floor:

Street/Locality:

City: *

Pin Code:

Country: *

State:

District:

Contact Details

E-Mail: *

Mobile: *

Select ID proof type:

Select your Applicant ID /LR ID & Password :

Sponsor ID / LR ID / Applicant ID:

Password: *

Retype Password: *

* Only Hash(#),At Sign(@) & Star(*) with at least one capital,one small alphabet & one number allowed in Password field

Enter text as shown: *

In case you Forget your Password

Hint Question: *

Your Answer: *

Remember your Applicant ID /LR ID & answer to hint question to recover your Password.

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Applicant Registration page will appear on the screen.



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❖ 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

Register as: *
Sponsor
Sponsor
LR(Legal Representative)
Medical or Research Institute
Individual Researcher

- ✓ 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.



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- ❖ After successful registration following screen will appear with message.

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

Register for your Applicant ID /LR ID :

Applicant ID /LR ID is required for online submission of forms related to Clinical Trials

* Mandatory Fields

Personal Details

Whether Indian: * Yes No

Register for: * Organization

Organization Name: *

Register as: *

Contact Person: *

Contact Address

Building Name/No/Floor:

City: *

Country: *

Street/Locality:

Pin Code:

State:

District:

Contact Details

E-Mail: *

Mobile: *

Select ID proof type:

Select your Applicant ID /LR ID & Password :

Sponsor ID / LR ID / Applicant ID :

Password: * Retype Password: *

* Only Hash(#),At Sign(@) & Star(*) with at least one capital,one small alphabet & one number allowed in Password field

Enter text as shown: * NP 9 J R F

In case you Forget your Password

Hint Question: * Your Answer: *

Remember your Applicant ID /LR ID & answer to hint question to recover your Password.

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- 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

Authorization Letter	
Personal Details	
Organization Name:	Trials
Contact Person Name:	Chetan Mansing Pardeshi
Contact Address	
HN.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.



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User Login

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

Home About Us Contact Us **User Login** Applicant Registration

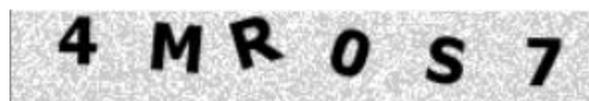
Please enter user name
Please enter password
Enter code from image
G Q L V G 3
Forgot Password?
Login

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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.





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Welcome to Clinical Trials

Home Application Update Profile Report Change Password Logout

Welcome : Chetan

*Welcome to
Clinical Trials Application & Monitoring System.*

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After successfully login welcome page will appear on the screen.

➤ System Menu

Home Application Update Profile Report Change Password Logout

❖ 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



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Application Entry

Go to submenu **Application Entry** for Clinical Trials



Click on **Application Entry** following **Status** page will appear on the screen

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Welcome : nica

[Home](#)
[Application](#)
[Update Profile](#)
[Report](#)
[Change Password](#)
[Logout](#)

[Status](#)
[New Application Entry](#)
[Help](#)

Show 5 entries Search:

Select	Application ID	Trial Title	Application Date	Sponsor Name	Reference No	Status
Select	1	my new application for new drug	15-07-2015	nic1234	ref1234	APPLICATION SUBMITTED
Select	2	my application for GCT	15-07-2015	nic1234	12345	IN PROCESS
Select	4	A Multicentre, randomized, double-blind, double dummy study comparing the efficacy and safety of XYZ with ABC in patients with type 2 diabetes mellitus receiving background therapy with Metformin	16-07-2015	nic1234	4512	APPLICATION SUBMITTED
Select	5	A Phase IIIb, Multinational, Multicenter, Open-Label Extension Study Assessing the Long-Term Safety of PRN Intravitreal Injections of DE-109	16-07-2015	nic1234	1235	IN PROCESS

Showing 1 to 4 of 4 entries Previous **1** Next

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❖ General Instructions

Status

New Application Entry

➤ Status

- Check status of your submitted application by following status

Status
APPLICATION SUBMITTED
IN PROCESS

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

Application ID	Trial Title	Application Date	Sponsor Name	Reference No	Status
----------------	-------------	------------------	--------------	--------------	--------

- Search the result by entering keywords

Search:



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➤ New Application Entry

Go to tab **New Application Entry** following page will appear on the screen

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Welcome : User

Home
Application
Update Profile
Report
Change Password
Logout

Status
Help

A:- Trial/Sponsor/LR Applicant Identification
B:- General Information
C:- IP Details
D:- Population Subject
E:- Investigator
F:- Document Upload
Submit Application

A :- Trial / Sponsor / LR / Applicant Identification

Status
 A
 B
 C
 D
 E
 F

Application ID : 10

Application Id : *	<input type="text" value="10"/>	Application Type : *	<input type="text" value="Fresh"/>	Application Date : *	<input type="text" value="17-07-2015"/>
Name Of The Applicant : *	<input type="text" value="Trials"/>	Applicant Reference No :	<input type="text"/>	CDSCO Division : *	<input type="text" value="GCT"/>
Applicant Protocol : No :	<input type="text"/>	Version :	<input type="text"/>	Version Date :	<input type="text" value="17-07-2015"/>
Status Of Applicant : *	<input type="text" value="Pharmaceutical Firm"/>	Website URL : *	<input type="text"/>		
Trial Title : *	<input type="text"/>				

Applicant Address

Building Name :	<input type="text" value="HN,713"/>	Street / Locality :	<input type="text" value="Shivkrupa Colony"/>
City : *	<input type="text" value="Pune"/>	Pin Code :	<input type="text" value="411017"/>
Country : *	<input type="text" value="India"/>	State :	<input type="text" value="Maharashtra"/>
		District :	<input type="text" value="Pune"/>

Applicant Contact Details

Phone No :	<input type="text"/>	Mobile No : *	<input type="text" value="919028641558"/>	Fax No :	<input type="text"/>
E-Mail ID : *	<input type="text" value="chetanpardeshi@gmail.com"/>	Alternate E-Mail :	<input type="text"/>		

Legal Representative (LR)

Name of The LR / Applicant:	Delegation Of Authority to LR : * <input type="radio"/> Yes <input checked="" type="radio"/> No
-----------------------------	---

LR Address

Building Name :	Street / Locality :
City : *	Pin Code : *
Country : *	<input type="text" value="--select--"/>

LR Contact Details

Phone No :	<input type="text"/>	Mobile No : *	<input type="text"/>	Fax No :	<input type="text"/>
E-Mail ID : *	<input type="text"/>	Alternate E-Mail :	<input type="text"/>		

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Status Help

A:- Trial/Sponsor/LR Applicant Identification B:- General Information C:- IP Details D:- Population Subject E:- Investigator F:- Document Upload Submit Application

❖ 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	
<input checked="" type="checkbox"/>	A
<input type="checkbox"/>	B
<input type="checkbox"/>	C
<input type="checkbox"/>	D
<input type="checkbox"/>	E
<input type="checkbox"/>	F



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- 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

CDSCO Division : *

GCT	▼
GCT	
New Drugs	
SND	
FDC	
Medical Device	
Biological	

- Status of Applicant

Status Of Applicant : *

Pharmaceutical Firm	▼
Pharmaceutical Firm	
Research Organisation	
Govt Entity	
NGO	
Academic or Medical Institute	

- Trial Title

Trial Title : *

- Enter upto 250 character to each row of trial title
- Special Characters [Space, Comma (,), Dot (.), Underscore (_), & Dash (-)] allowed with alphabets and numbers.



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Go to tab **General Information** following page will appear on the screen



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Welcome : User

Home
Application
Update Profile
Report
Change Password
Logout

Status
Help

A:- Trial/Sponsor/LR Applicant Identification
B:- General Information
C:- IP Details
D:- Population Subject
E:- Investigator
F:- Document Upload
Submit Application

B :- General Information

Application ID: 8

Disease Under Investigation

Select: *

Is Rare Disease: *

Add

Disease Description

Is Rare Disease

Scope / Objective Of The Trial Like Is This

Scope / Objective Of The Trial : Diagnostic

Prophylaxis

Therapeutic

Trial Type And Phase

Select: *

Add

Phase Description

Design Of Trial

Trial Design : *

Add

Design Description

Proposed Study Period (In Weeks) *

Save as Draft

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B:- General Information

➤ Disease Under Investigation

Disease Under Investigation	
Select: *	Other <input type="text"/> Is Rare Disease: * No <input type="button" value="Add"/>
Disease Description	Is Rare Disease
Chronic Kidney Disease	N <input type="button" value="DELETE"/>

- 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

- Diagnostic
- Prophylaxis
- Therapeutic
- Safety
- Efficacy
- Pharmacokinetic
- Pharmacodynamics
- Bioequivalence
- Dose Response
- Pharmacogenomics
- Pharmacoeconomic
- Other

Other Scope

- 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.



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➤ Trial Type and Phase

Trial Type And Phase	
Select: *	Other
<input type="text"/>	Add
Phase Description	
Phase II-a	DELETE

- 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

Design Of Trial	
Trial Design: *	Other
<input type="text"/>	Add
Design Description	
Non-randomized, Placebo Controlled Trial	DELETE

- 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

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Welcome : User

Home
Application
Update Profile
Report
Change Password
Logout

Status
Help

A:- Trial/Sponsor/LR Applicant Identification
B:- General Information
C:- IP Details
D:- Population Subject
E:- Investigator
F:- Document Upload
Submit Application

C :- IP Details

Application ID: 8

*MA Authorisation other than India should upload document in Document Upload Statistics form.

Marketing Authorization (MA) in India : * Yes No

Product Information:

Orphan Product in India : * Yes No Not Known

Orphan Product Outside India : * Yes No Not Known

Product Name / Device Name : Product Code : *

Active Substances

Test / Reference Product	Active Substance	Origin	INN / Sponsor Code / CAS :	INN Proposed / Brandname :	
<input type="text"/>	Calcium	Chemical	<input type="text"/>	<input type="text"/>	
Add					
Test/Reference Product	Active Substance	Chemical Origin	INN/Sponsor code/CAS	INN Proposed/Brand name	Delete
Ref Product	Calcium	Chemical	Code	BrandName	DELETE

Other Details:- Pharmaceutical Form

Pharmaceutical Form : * [Add](#)

Pharmaceutical Form	Delete
<input type="text"/>	Delete

Other Details:- Route Of Administration

Route Of Administration : [Add](#)

Route Of Administration	Delete
<input type="text"/>	Delete

Other Details:- Concentration / Strength

Test/Reference Product	Name of Active Substance	Dosage Form	Concentration/Strength	Unit
Ref Product	Calcium	<input type="text" value="Tablet"/>	<input type="text"/>	<input type="text" value="lu"/>

Is This

Select Is This : *

Cell Therapy Medicinal Product

Gene Therapy Product

Radiopharmaceutical Product

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

Responsible For Release : * Sponsor LR

Organization Name : *

Contact Address

Building Name : Street / Locality :

City : * Pin Code : *

Country : *

Contact Details

E-Mail : * Alternate E-Mail : * FAX : *

Mobile No : * Phone No : *

Web Site Of Sponsor / LR: Identify The Products Released:

(Under Whose guidance / instruction the IP will be released in India for CT purpose.)

[Save as Draft](#)

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C:- IP Details

➤ **Marketing Authorization (MA)**

Marketing Authorization (MA) in India : * Yes No

If Marketing Authorization (MA) Not in India

MA Country Names : *

Country Name	Delete
United States	<input type="button" value="DELETE"/>

- 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**

Orphan Product In India : * Yes No Not Known

- 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**

Active Substances

Test / Reference Product :*	Active Substance :*	Substance Name :*	Origin :*	INN / Sponsor Code / CAS :	INN Proposed / Brandname :
<input type="text" value="Ref Product"/>	<input type="text" value="Other"/>	<input type="text" value="Subs Name"/>	<input type="text" value="Chemical"/>	<input type="text" value="Code"/>	<input type="text" value="BrandName"/>
<input type="button" value="Add"/>					
Test/Reference Product	Active Substance	Chemical Origin	INN/Sponsor code/CAS	INN Proposed/Brand name	Delete
Ref Product	Calcium	Chemical	Code	BrandName	<input type="button" value="DELETE"/>

- 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.



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➤ Concentration / Strength

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

Other Details:- Concentration / Strength

Test/Reference Product	Name of Active Substance	Dosage Form	Concentration/Strength	Unit
Ref Product	Calcium	Tablet	50	MG

- 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 Orgnaisms
- 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**



Clinical Trials

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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
DIRECTOR GENERAL OF HEALTH SERVICES,
MINISTRY OF HEALTH AND FAMILY WELFARE,
GOVERNMENT OF INDIA



Go to tab **Population Subject** following page will appear on the screen

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Welcome : User

Home
Application
Update Profile
Report
Change Password
Logout

Status Help

A:- Trial/Sponsor/LR Applicant Identification
B:- General Information
C:- IP Details
D:- Population Subject
E:- Investigator
F:- Document Upload
Submit Application

D :- Population Subject

Status

A

B

C

D

E

F

Application ID: 8

Select Age Group : * Male Female Both

Age Group Gender

Population of Trial Subjects

No of Healthy Volunteers : <input type="text"/>	No of Patients : <input type="text"/>	No of Women of Child Bearing : <input type="text"/>	
No of Pregnant Women : <input type="text"/>	No of Nursing Women : <input type="text"/>	Subjects Incapable of Giving Consent Personally : <input type="text"/>	
Planned No. of Subjects To Be Included In India : *	Emergency Situation : * <input type="radio"/> Yes <input type="radio"/> No		

Is Global Clinical Trial : * Yes No (If Global Clinical Trial then participating country name selection will be displayed.)

Planned No. of Subjects Globally : *

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D:- Population Subject

➤ **Age Group**

Select Age Group : * Male Female Both

Age Group	Gender	
Below 18	M	<input type="button" value="DELETE"/>

- 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.

Is Global Clinical Trial : * Yes No (If Global Clinical Trial then participating country name selection will be displayed.)

Select Name Of Participating Countries : *

Select Countries Where The Protocol Is Already Approved : *

Country Name	
United States	<input type="button" value="DELETE"/>

Country Name	
Faroe Islands	<input type="button" value="DELETE"/>

- 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.



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Go to tab **Investigator** following page will appear on the screen

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Welcome : User

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Application
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Status Help

A- Trial/Sponsor/LR Applicant Identification
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C- IP Details
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E- Investigator
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Submit Application

Status
 A
 B
 C
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 E
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E :- Investigator

Application ID: 8 *To update existing investigator info select from investigator status table.

Investigator Status

Select	Investigator ID	Investigator Name	Designation	Name of Site								
*You can add multiple investigator by selecting New Investigator option												
<input checked="" type="radio"/> New Investigator <input type="radio"/> Existing												
Name of Investigator : *		Designation : *	Name of site : *									
City : *		Qualification : *	<input style="width: 100%;" type="text"/>									
Medical Council Registration No.:		Specialization : *	<input style="width: 100%;" type="text"/>									
No of CT Completed : *		Nature of Hospital : *	<input style="width: 100%;" type="text"/>									
No of Bed's : *		Category of Hospital : *	<input style="width: 100%;" type="text"/>									
GCP Trained : *		Is Emergency Facility Available? <input type="radio"/> Yes <input type="radio"/> No										
Clinical Trial Site Address												
Building Name :		Street / Locality :										
City : *		Pincode : *										
Country : *		State : *										
<input style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>										
<input style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>										
<input style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>										
Clinical Trial Site Contact Details												
Phone No. : *		Mobile No. : *		Fax No. : *								
E-Mail ID : *		Alternate E-mail Id : *		<input style="width: 100%;" type="text"/>								
Details Of Laboratory / Bioanalytical Facility (Multiple Labs can be added using Save Lab button)												
Name Of Lab : *		Building Name :		Street / Locality :								
City : *		Pincode : *		<input style="width: 100%;" type="text"/>								
Country : *		State : *		District : *								
<input style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>								
<input style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>								
<input style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>								
GLP /ISO / NABL /Other Certified : * <input type="radio"/> Yes <input type="radio"/> No												
<input type="button" value="Save Lab"/>												
Name of lab	Building	Street	City	Pincode	Country	State	District	Email Id	Phone No	Mobile No	Fax No	GLP Certified
Ethics Committee												
EC Registration No. : *		Accreditation : *			<input type="radio"/> Yes <input type="radio"/> No		EC Type : *					
Name of Ethics Committee : *		Name Of Site / Hospital : *			<input style="width: 100%;" type="text"/>							
EC Members Secretary												
Name :		Experience :		Qualification :			<input style="width: 100%;" type="text"/>					
Building Name :		Street / Locality :			<input style="width: 100%;" type="text"/>							
City :		Pincode :			<input style="width: 100%;" type="text"/>							
Country :		State :			<input style="width: 100%;" type="text"/>							
<input style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>			<input style="width: 100%;" type="text"/>							
Contact Details												
Phone No. :		Mobile No. :			Fax No. :							
E-Mail ID :		Alternate E-mail Id :			<input style="width: 100%;" type="text"/>							
Other Info												
No of Meetings of The Committee For Trial :		CDSCO Last Inspection Date :			<input style="width: 100%;" type="text"/>							
Date Of Opinion :		Opinion : (Favorable / Non-Favorable)			<input style="width: 100%;" type="text"/>							
Financial support / amount of fees / Honorarium / payment in kind per Investigator by Sponsor / LR :		<input style="width: 100%;" type="text"/>										
<input type="button" value="Save as Draft"/>												

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E:- Investigator

- 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

Name of Investigator : *	<input type="text"/>	Designation : *	<input type="text"/>	Name of site : *	<input type="text"/>
City : *	<input type="text"/>	Qualification : *	Select <input type="text"/>		
Medical Council Registration No.:	<input type="text"/>	Specialization : *	Test <input type="text"/>		
No of CT Completed : *	<input type="text"/>	Nature of Hospital : *	Govt <input type="text"/>		
No of Bed's : *	<input type="text"/>	Category of Hospital : *	General <input type="text"/>		
GCP Trained : *	<input type="radio"/> Yes <input type="radio"/> No	Is Emergency Facility Available?	<input type="radio"/> Yes <input type="radio"/> No		
Clinical Trial Site Address					
Building Name :	<input type="text"/>	Street / Locality :	<input type="text"/>		
City : *	<input type="text"/>	Pincode : *	<input type="text"/>		
Country : *	India <input type="text"/>	State : *	--select-- <input type="text"/>	District : *	--select-- <input type="text"/>
Clinical Trial Site Contact Details					
Phone No. : *	<input type="text"/>	Mobile No. : *	<input type="text"/>	Fax No. : *	<input type="text"/>
E-Mail ID : *	<input type="text"/>	Alternate E-mail Id : *	<input type="text"/>		

➤ Details of Laboratory

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

Name Of Lab : *	Lab1 <input type="text"/>	Building Name :	Lab Building <input type="text"/>	Street / Locality :	Lab Street <input type="text"/>
City : *	Pune <input type="text"/>	Pincode : *	456465 <input type="text"/>	District : *	Dadra and Nagar Haveli <input type="text"/>
Country : *	India <input type="text"/>	State : *	Dadra and Nagar Haveli <input type="text"/>	Fax No. : *	5879132 <input type="text"/>
Phone No. : *	456546 <input type="text"/>	Mobile No. : *	5646546541 <input type="text"/>		
E-Mail ID : *	lab1@gmail.com <input type="text"/>				
GLP / ISO / NABL /Other Certified : *	<input checked="" type="radio"/> Yes <input type="radio"/> No				

Name of lab	Building	Street	City	Pincode	Country	State	District	Email Id	Phone No	Mobile No	Fax No	GLP Certified	
Lab1	Lab Building	Lab Street	Pune	456465	India	Dadra and Nagar	Dadra and Nagar Haveli	lab1@gmail.com	456546	5646546541	5879132	Y	<input type="button" value="DELETE"/>



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

➤ Details of Ethics Committee

Ethics Committee			
EC Registration No. : *	<input type="text"/>	Accreditation : *	<input type="radio"/> Yes <input type="radio"/> No
Name of Ethics Committee : *	<input type="text"/>	Name Of Site / Hospital : *	<input type="text"/>
		EC Type : *	Institutional <input type="text"/>
EC Members Secretary			
Name :	<input type="text"/>	Experience :	<input type="text"/>
Building Name :	<input type="text"/>	Street / Locality :	<input type="text"/>
City :	<input type="text"/>	Pincode :	<input type="text"/>
Country :	India <input type="text"/>	State :	--select-- <input type="text"/>
		District :	--select-- <input type="text"/>
Contact Details			
Phone No. :	<input type="text"/>	Mobile No. :	<input type="text"/>
E-Mail ID :	<input type="text"/>	Alternate E-mail Id :	<input type="text"/>
		Fax No. :	<input type="text"/>
Other Info			
No of Meetings of The Committee For Trial :	<input type="text"/>	CDSCO Last Inspection Date :	<input type="text"/>
Date Of Opinion :	<input type="text"/>	Opinion : (Favorable / Non-Favorable)	<input type="text"/>
		Financial support / amount of fees / Honorarium / payment in kind per Investigator by Sponsor / LR :	<input type="text"/>

➤ Existing Investigator

New investigator Existing

- 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 click on **Select** label

Select	Investigator ID	Investigator Name	Designation	Name of Site
Select	1033	INV Investigator	Scientist	www.inv.com

- If user click on **Select** which is show in above fig. then all details of investigator will listed in every field of investigator tab.



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Go to tab **Document Upload** following page will appear on the screen

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Welcome : User

Home
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Update Profile
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Change Password
Logout

Status Help

A:- Trial/Sponsor/LR Applicant Identification
B:- General Information
C:- IP Details
D:- Population Subject
E:- Investigator
F:- Document Upload
Submit Application

F:- Document Upload

Application ID: 8

*Only Alphabets,Numbers,Underscore and Space is allowed in file name.
*File type: Only pdf, doc and docx allowed.

Show 10 entries Search:

SR. No.	Name Of The File's	Upload Status	View	Choose File	Upload/Update	Multiple File	No. Of Parts	Sample Format
1.1	AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text" value=""/> <input type="button" value="Add"/>	
2.1	CASE REPORT FORMAT CRF *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text" value=""/> <input type="button" value="Add"/>	
3.1	Declaration about the number of clinical trial being undertaken by each of the Investigator If available *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text" value=""/> <input type="button" value="Add"/>	
4.1	Declaration from Sponsor that per protocol subjects will receive standard of care If applicable *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text" value=""/> <input type="button" value="Add"/>	
5.1	Duly filled and signed Form 44 *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text" value=""/> <input type="button" value="Add"/>	
6.1	Ethic Committee Registration Certificate *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text" value=""/> <input type="button" value="Add"/>	
7.1	Executive Summary Annex ES *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text" value=""/> <input type="button" value="Add"/>	Download
8.1	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. *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text" value=""/> <input type="button" value="Add"/>	
9.1	Financial Status of the Applicant LR Upload declaration on firm letter head duly signed sealed *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text" value=""/> <input type="button" value="Add"/>	
10.1	Form 12 Duly filled and signed for the import of Investigational Products IP *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>	<input type="radio"/> Y <input type="radio"/> N	<input type="text" value=""/> <input type="button" value="Add"/>	

Showing 1 to 10 of 29 entries Previous 1 2 3 Next

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❖ 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

Multiple File	No. Of Parts
<input checked="" type="radio"/> Y <input type="radio"/> N	<input type="text" value="5"/> <input type="button" value="Add"/>

- 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.



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SR. No.	Name Of The File's	Upload Status	View	Choose File	Upload/Update	Multiple File	No. Of Parts	Sample Format
1.1	AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_1 *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>	<input type="radio"/> Y <input checked="" type="radio"/> N	<input type="text"/> <input type="button" value="Add"/>	
1.2	AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_2 *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>			
1.3	AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_3 *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>			
1.4	AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_4 *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>			
1.5	AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_5 *	<input type="checkbox"/>		<input type="button" value="Browse..."/> No file selected.	<input type="button" value="Upload/Update"/>			



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Go to tab **Submit Application** following page will appear on the screen

Application ID: 8
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.)

Sr.No.	Document Type
1	Pathology Lab
2	Marketing Authorization MA in Other countries

Application Submission

Submit Application

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❖ 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.)



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Sr.No.	Document Type
1	Pathology Lab
2	Marketing Authorization MA in Other countries

- Make sure your status bar show all check to each form then you can go for Submit Application

Status

A

B

C

D

E

F

- Submit your application by simply click on **Submit Application** button.

[Submit Application](#)

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

[Status](#) [New Application Entry](#) [Help](#)

Show 5 entries Search:

Select	Application ID	Trial Title	Application Date	Sponsor Name	Reference No	Status
Select	8	Trial on Testing	17-07-2015	Trials	REF789	APPLICATION SUBMITTED

Showing 1 to 1 of 1 entries Previous **1** Next