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

NATIONAL INFORMATICS CENTRE

Index

Contents

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

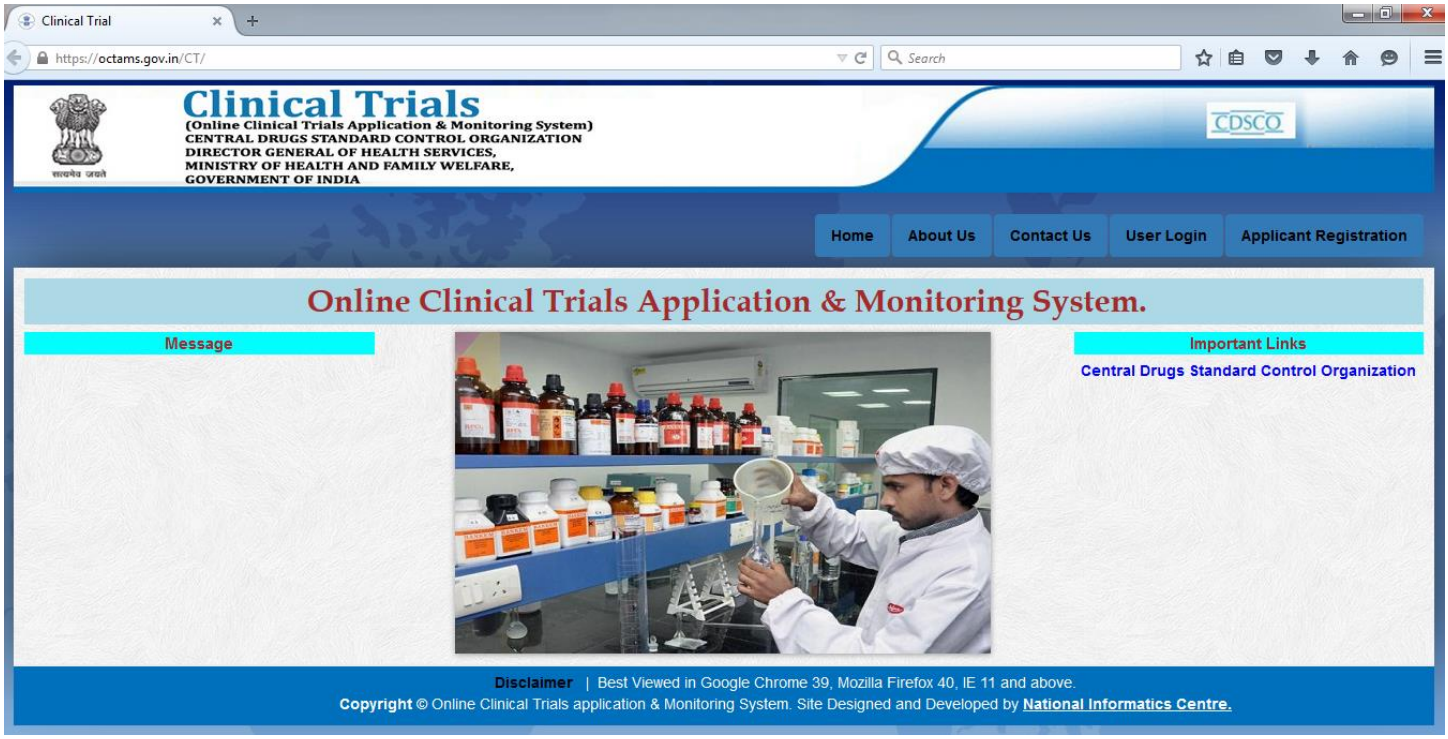
- ✓ Applicant Registration
- ✓ Authorization Letter Generation
- ✓ Application Submission
- ✓ Necessary Document Upload
- ✓ Application Status Check
- ✓ Report Generation

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.



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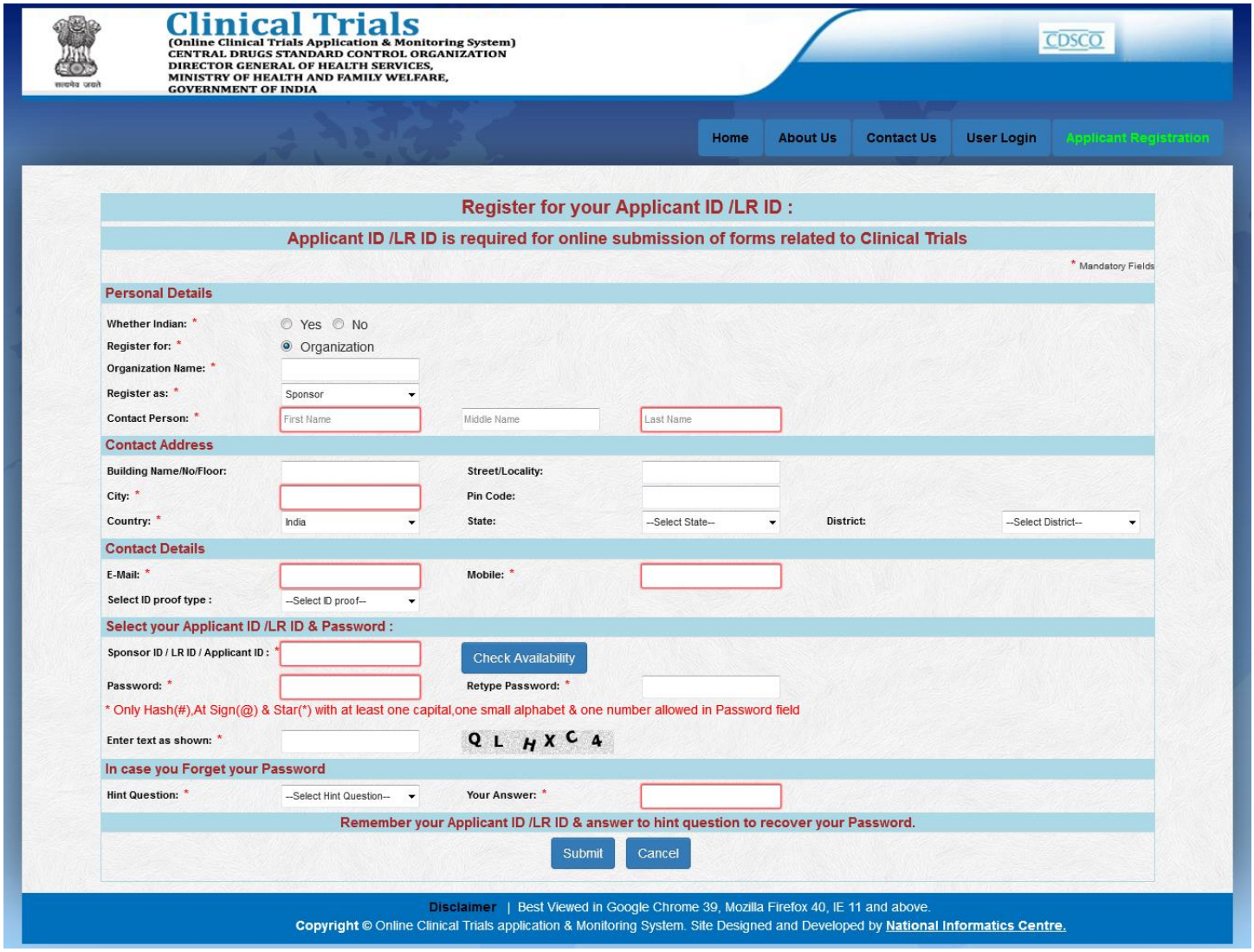
Getting Start as Applicant User

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

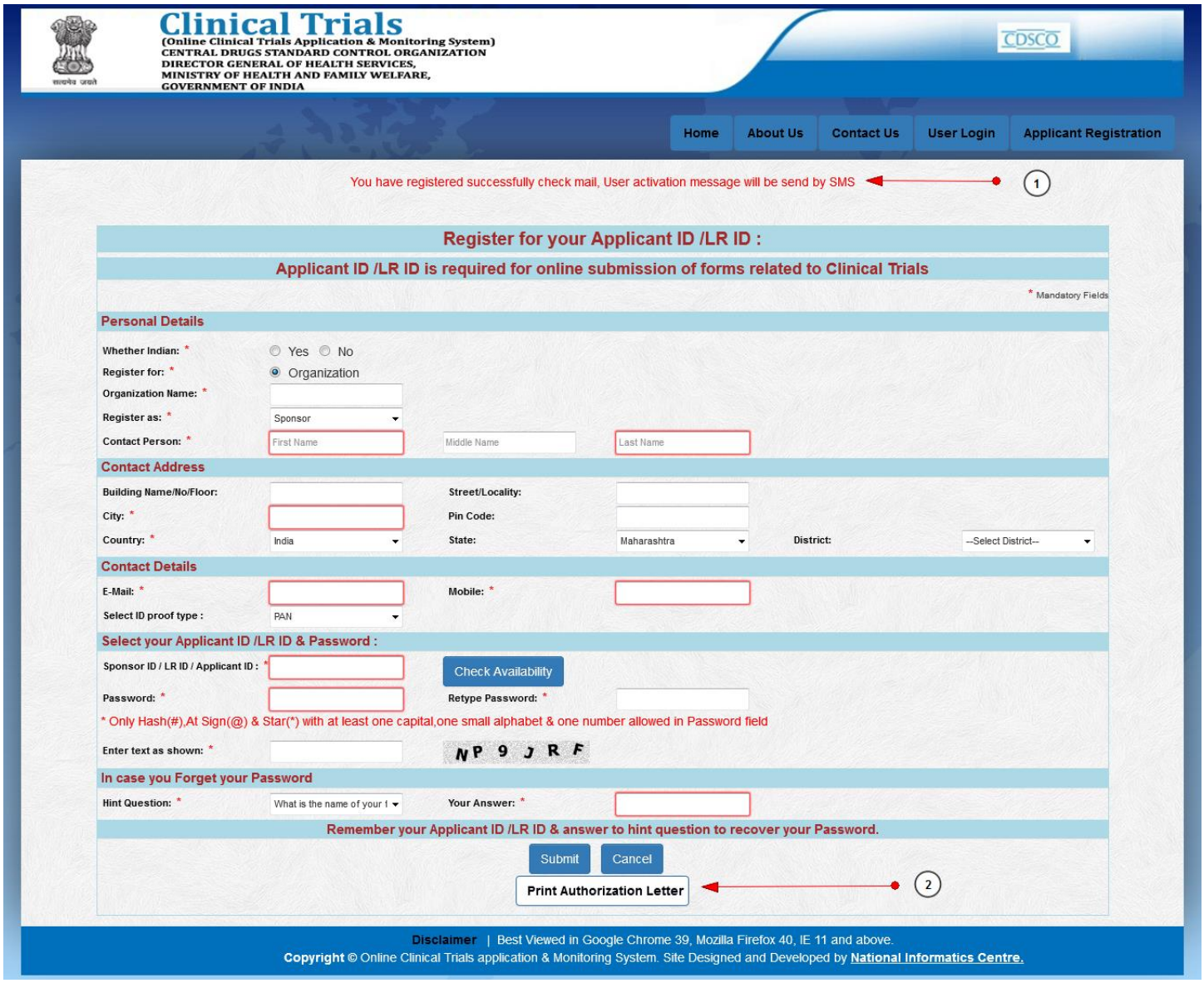
- Duplicate values for following field that is not allowed to enter in to system.

  - 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.

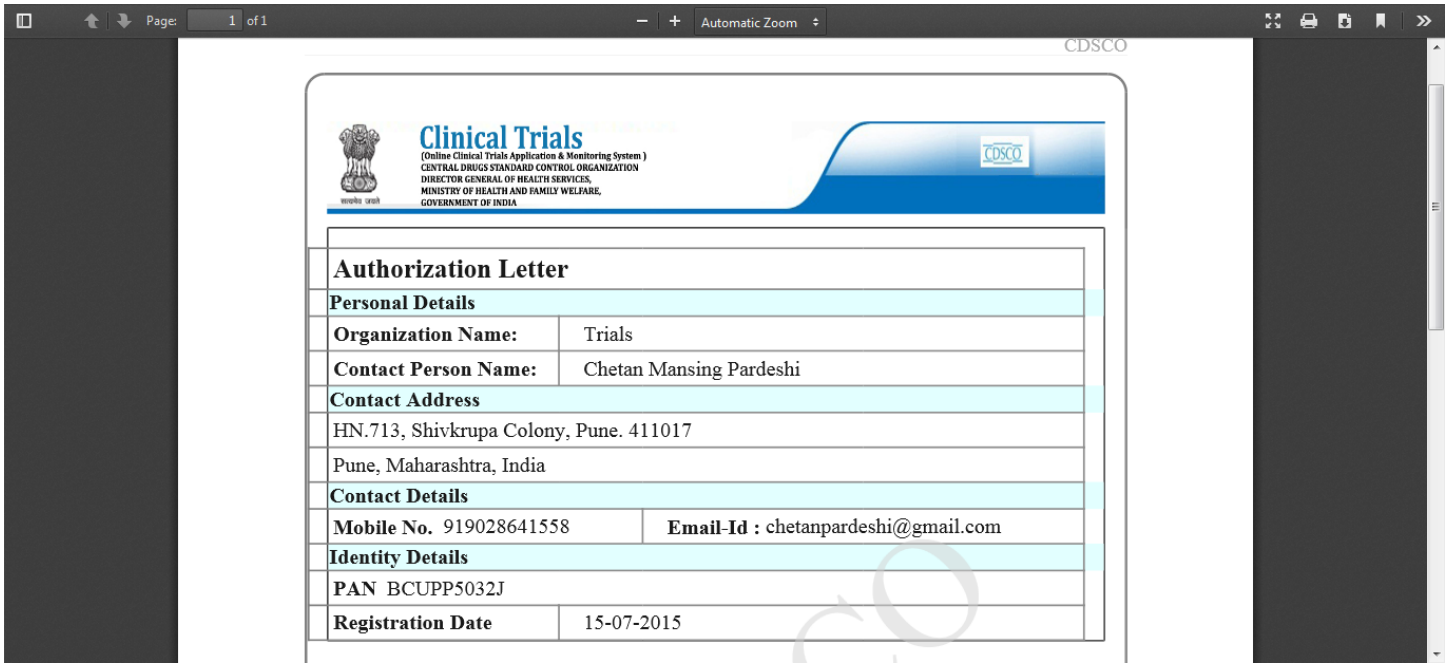
You have registered successfully check mail, User activation message will be send by SMS



➢ 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



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

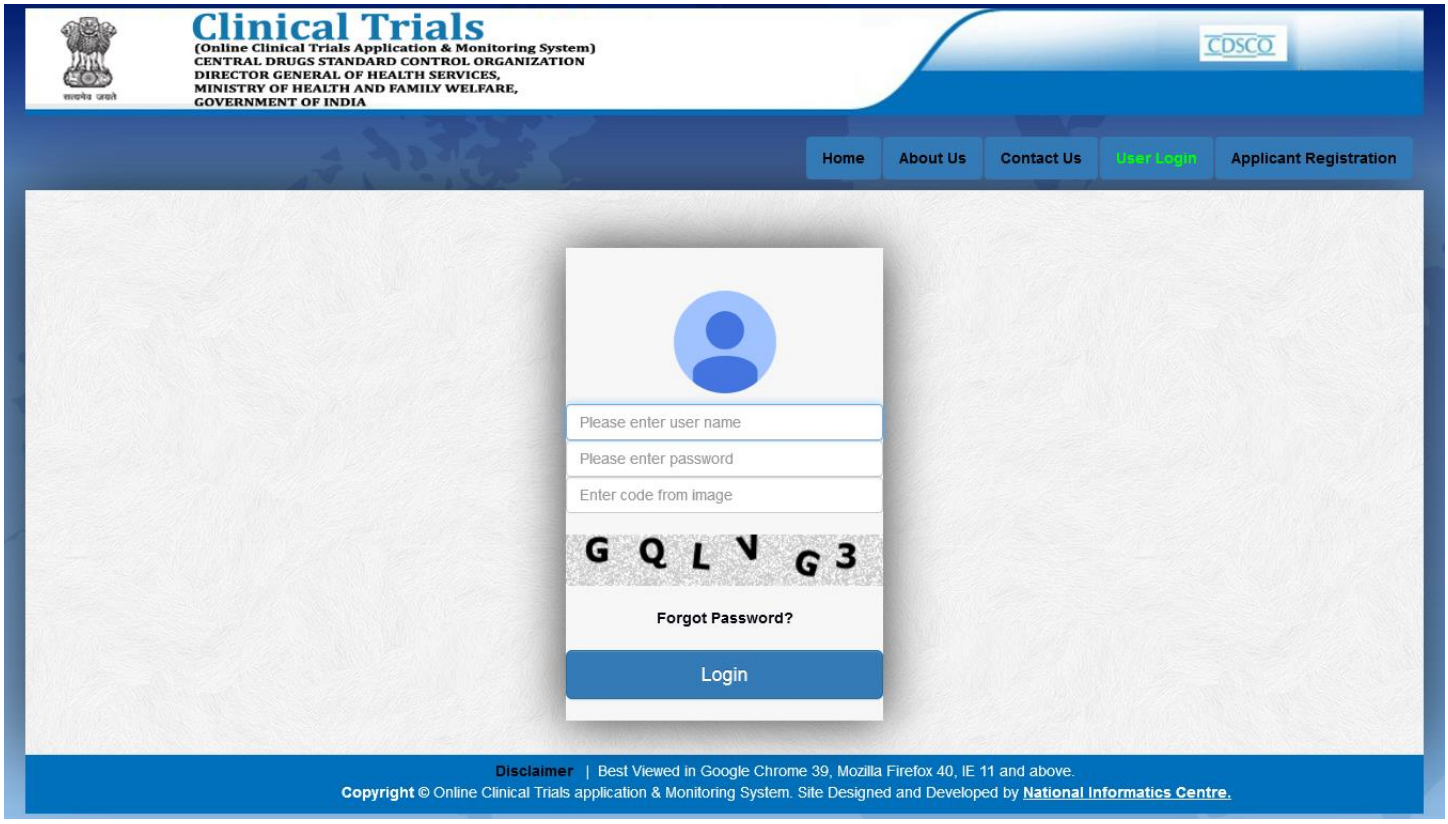
Authorization Letter	
Personal Details	
Organization Name:	Trials
Contact Person Name:	Chetan Mansing Pardeshi
Contact Address	
HN.713, Shivkrupa Colony, Pune. 411017	
Pune, Maharashtra, India	
Contact Details	
Mobile No. 919028641558	**Email-Id :** chetanpardeshi@gmail.com
Identity Details	
PAN BCUPP5032J	
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.

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.

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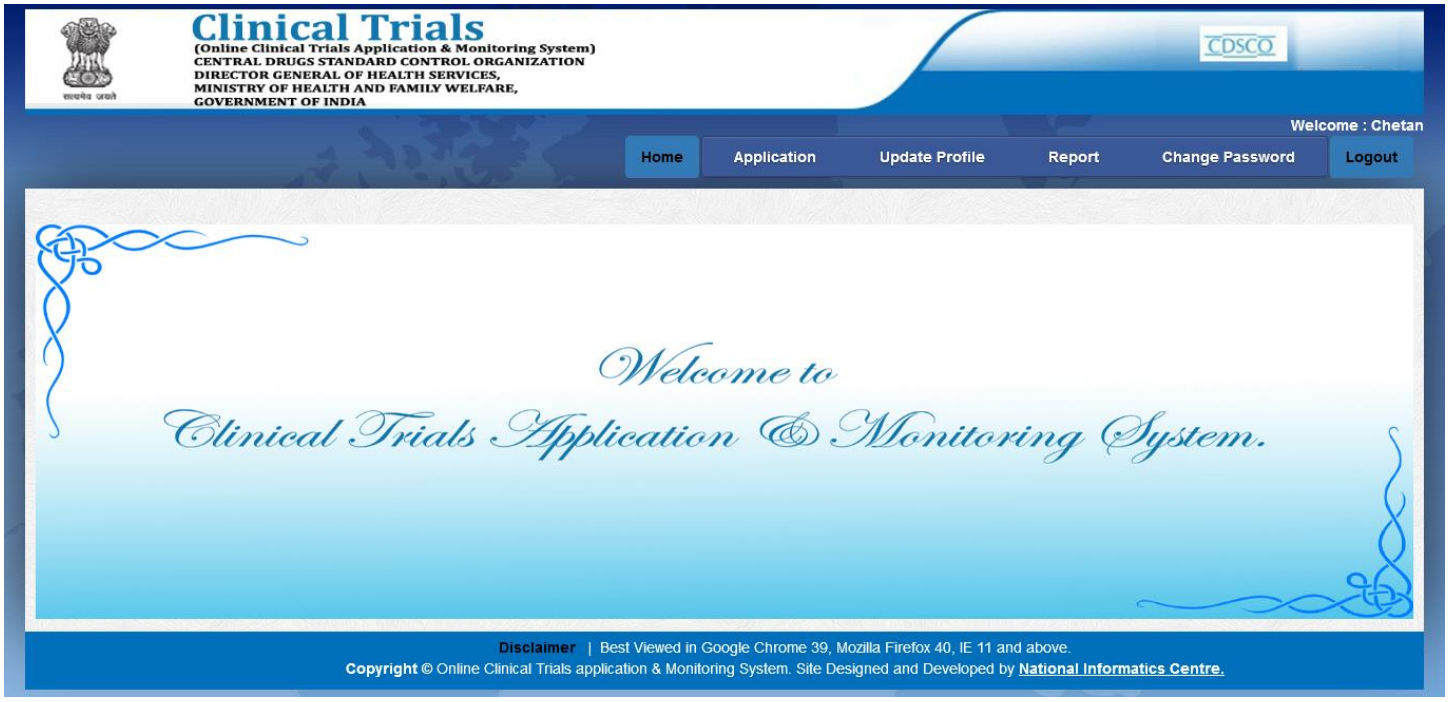
Welcome to Clinical Trials



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

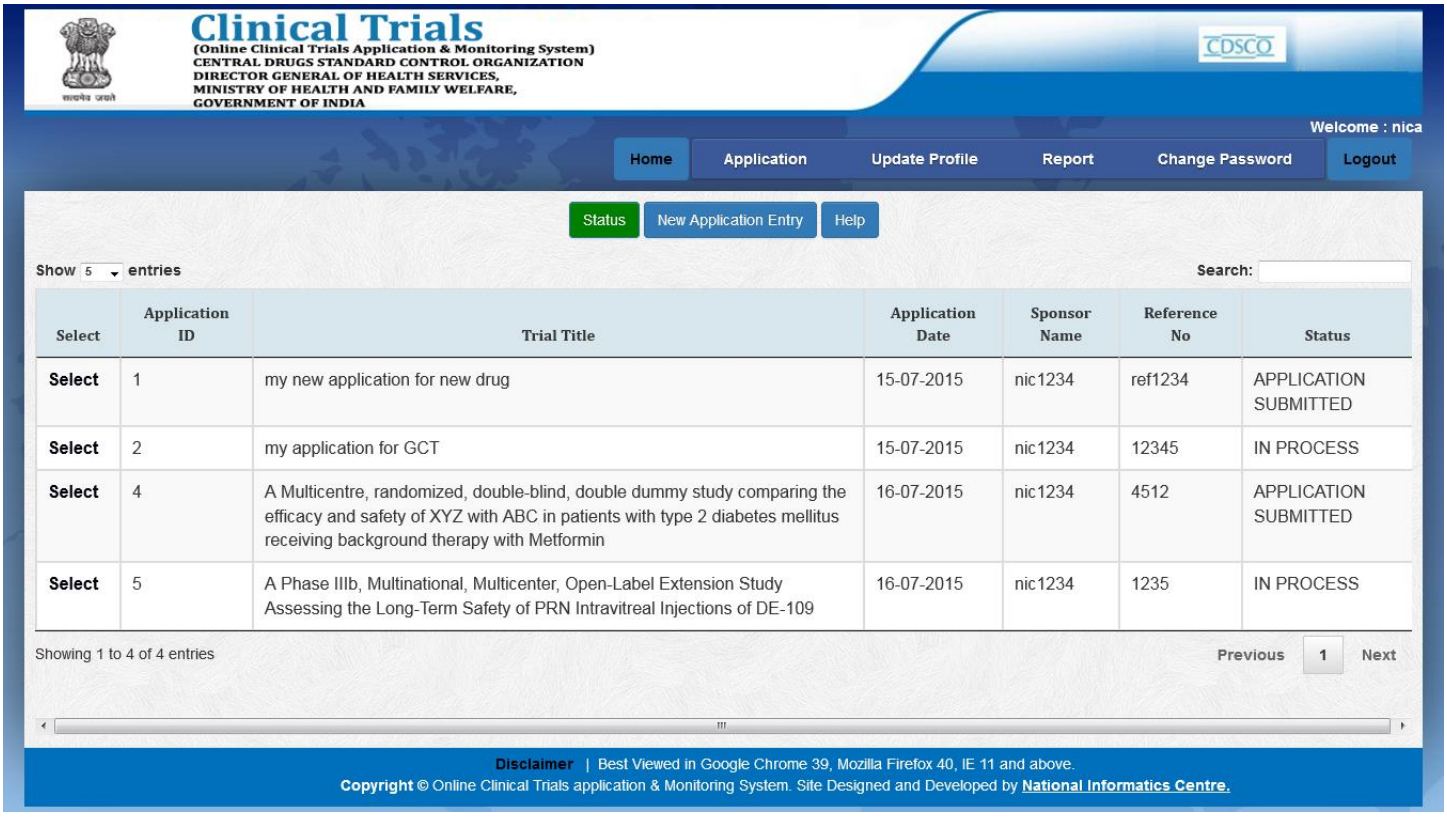
- **Report**

- **Change Password**
  This section allow to change Applicant Password

Application Entry

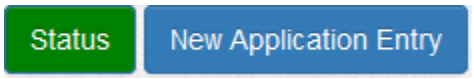
Go to submenu **Application Entry** for **Clinical Trials**

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



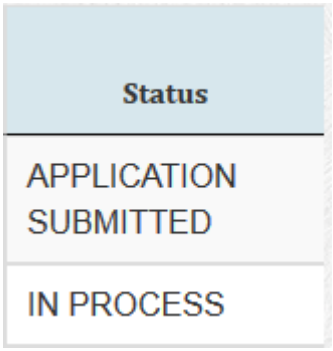
NATIONAL INFORMATICS CENTRE

❖ General Instructions



➢ Status

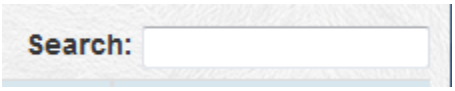
- Check status of your submitted application by following status



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

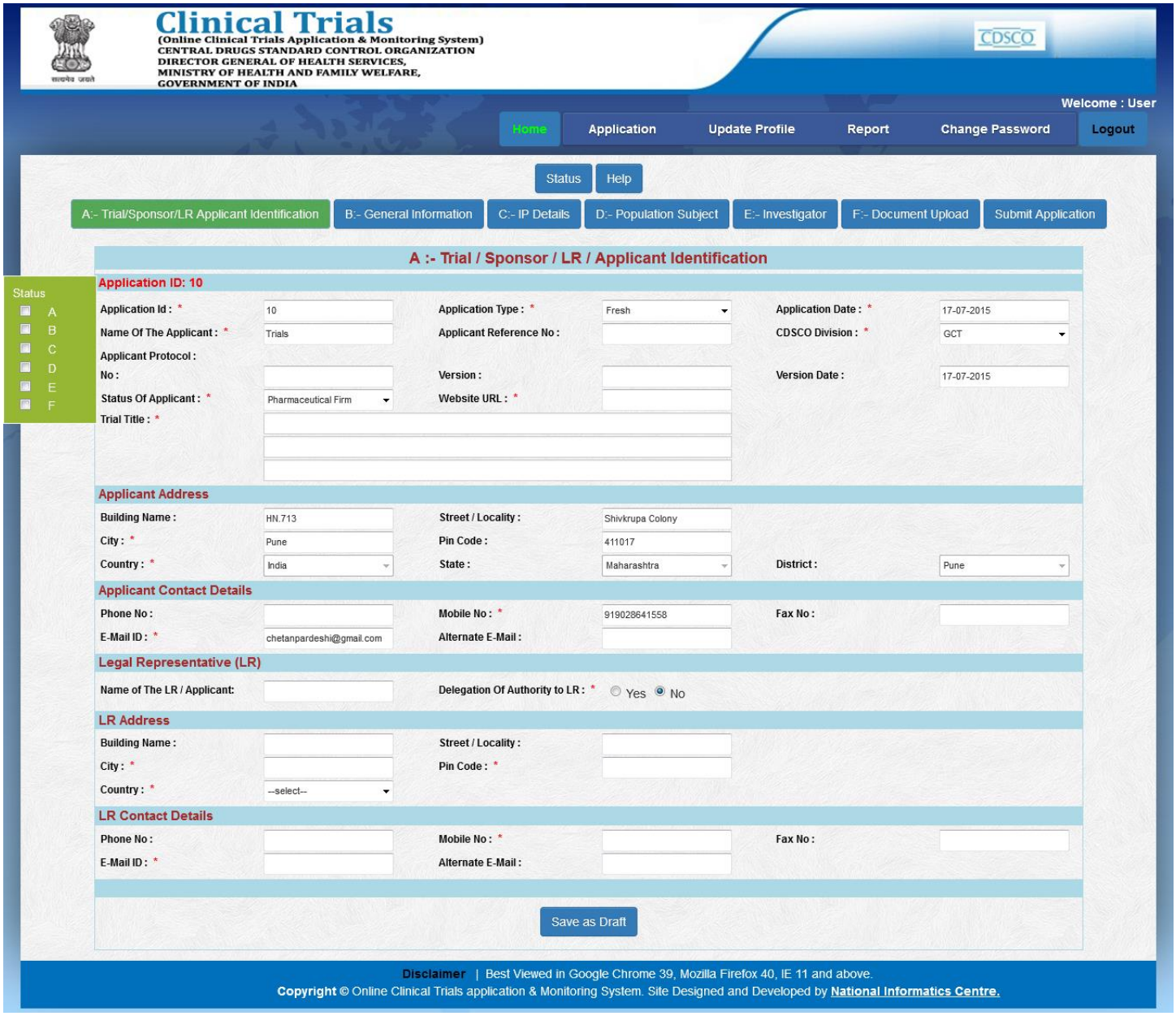
Application ID	Trial Title	Application Date	Sponsor Name	Reference No	Status

- Search the result by entering keywords



- **New Application Entry**

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

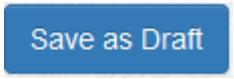


❖ General Instructions

- 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.

- Application ID is auto generated to each new application

- **Save as Draft**



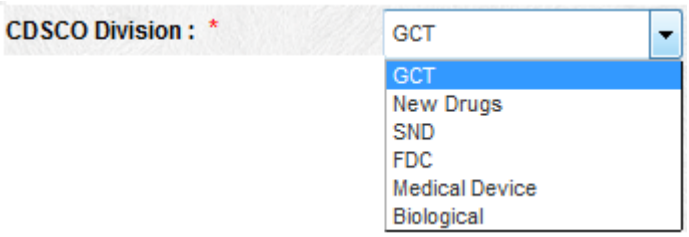
- The star (*) marked fields are compulsory
- Filled up all required field and Submit or save each form by simply click on Save as Draft button
- Following message will appear on every form after **Save as Draft** of each form

- **Application Status Bar**

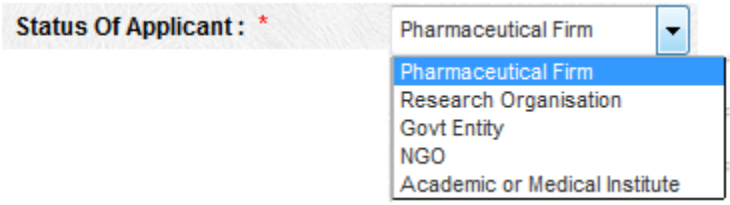
- This status side bar shows the status of completion of form.
- After Save as Draft of form the auto check display on each completion of form.

❖ General Instructions

- CDSCO Division list



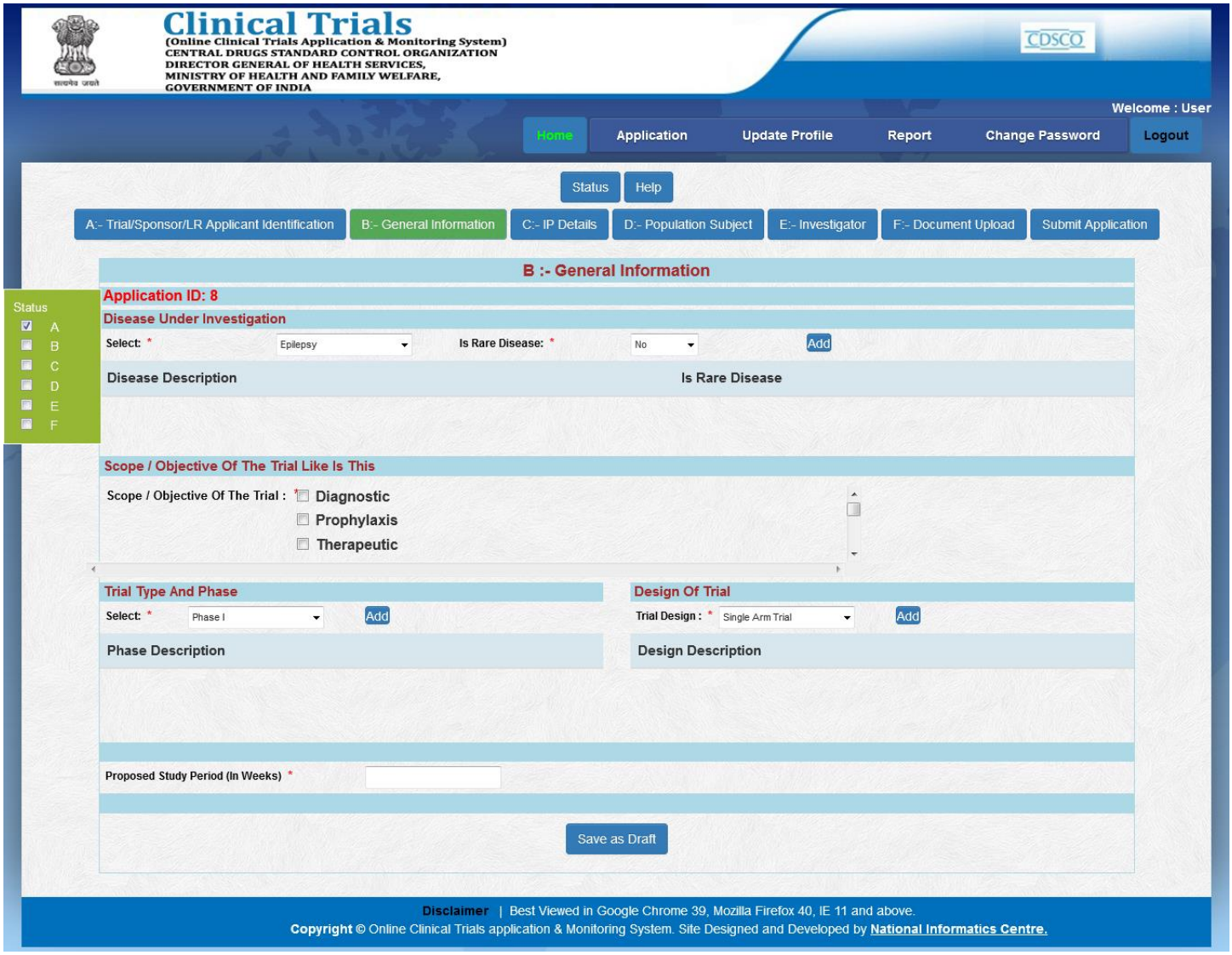
- Status of Applicant



- Trial Title

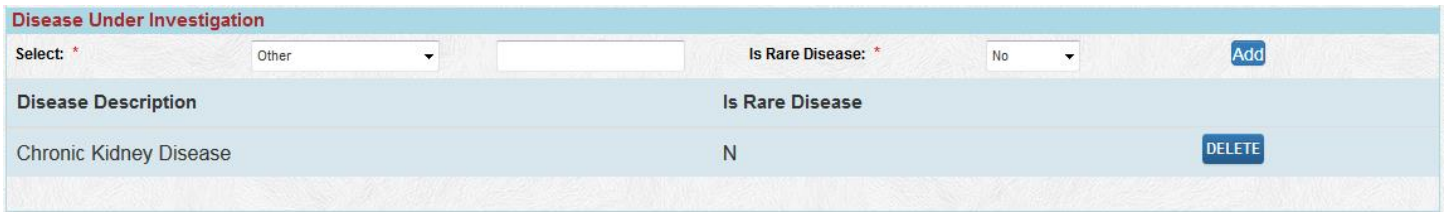
- Enter upto 250 character to each row of trial title
- Special Characters [Space, Comma (,), Dot (.), Underscore (_), & Dash (-)] allowed with alphabets and numbers.

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



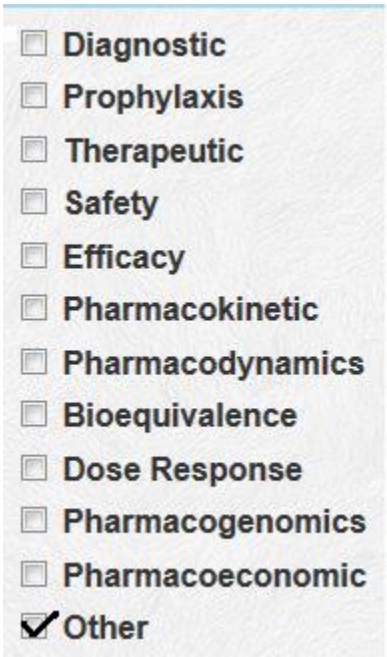
B:- General Information

- **Disease Under Investigation**



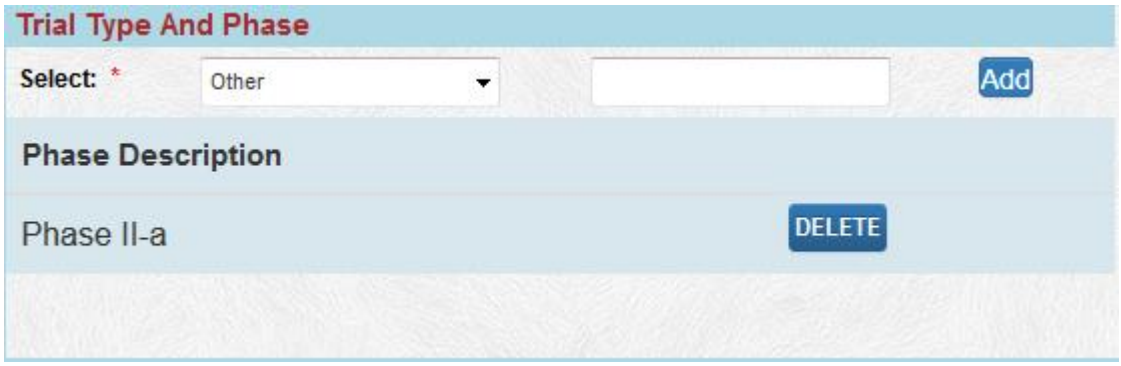
- Select disease and click on add button it will listed in D**isease Description**.
- If select disease as **Other** option then enter disease name in textbox which is in front of **Other** option of disease.
- User can delete **Disease Description** by simply click on delete button.

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



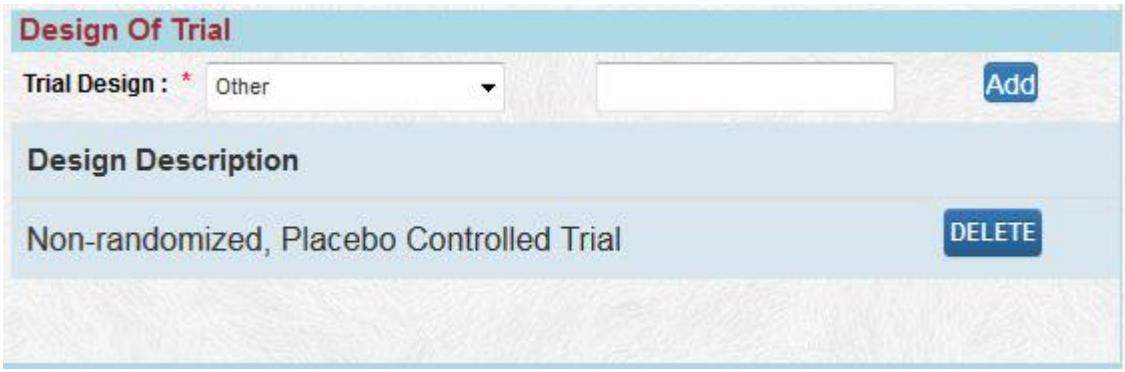
- User can check multiple **Scope / Objective of the trial** by simply click on above option.
- If user checks **Other** option then **Other scope** text box option will open for edit.

- **Trial Type and Phase**



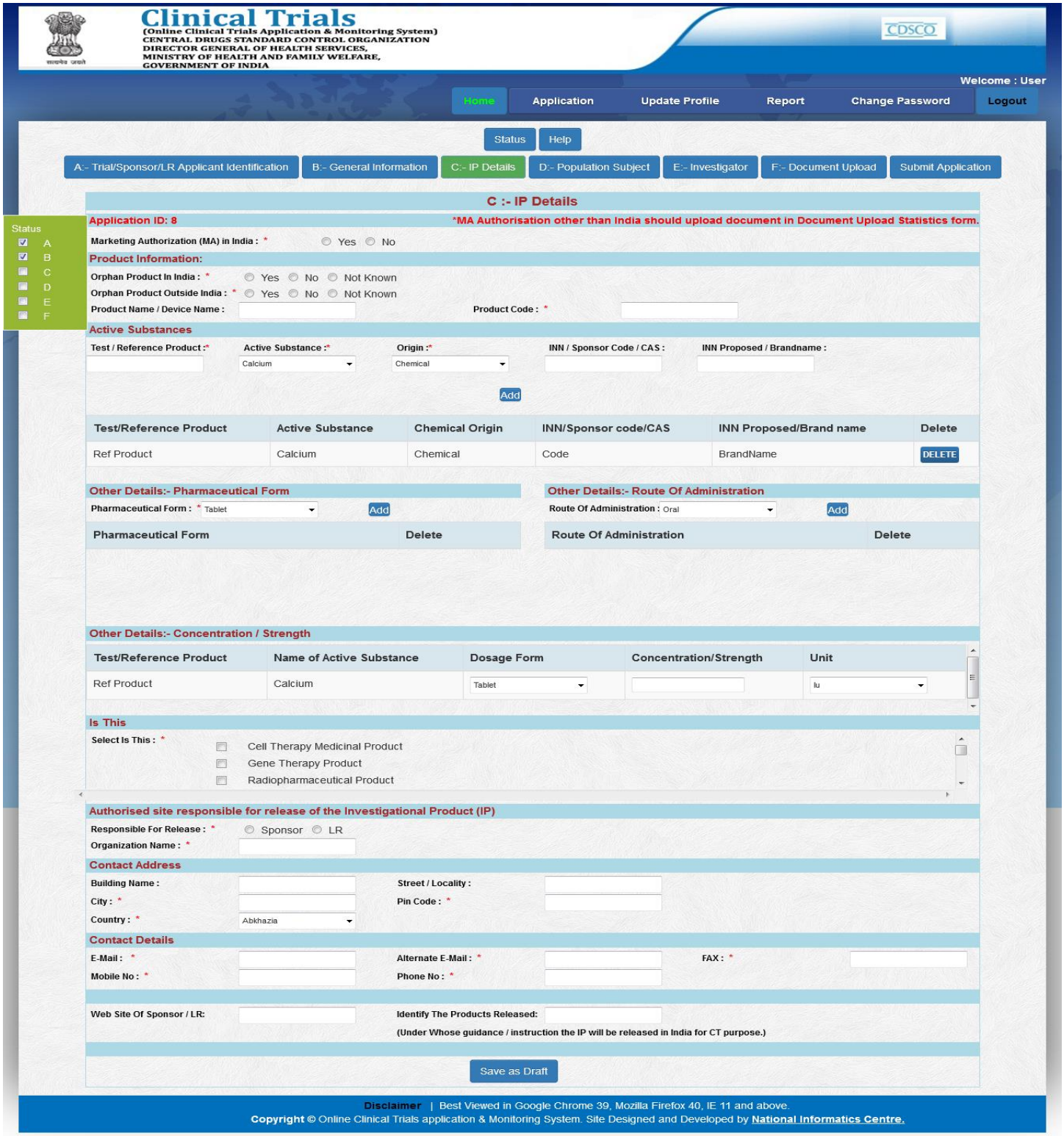
- Select **Trial Type and Phase** & click on **Add** button it will list in **Phase Description**.
- If select **Other** option then enter Trial Type and Phase name in textbox which is in front of **Other** option.
- User can delete **Phase Description** by simply click on **Delete** button.

- **Design of Trial**



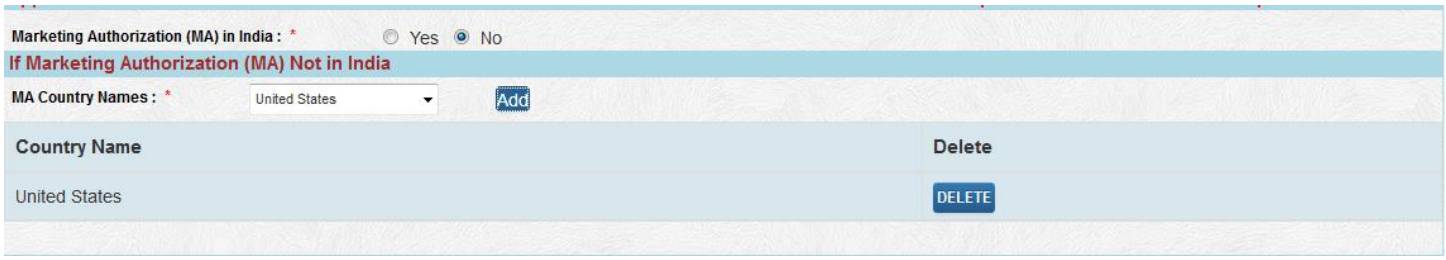
- Select **Design of Trial** & click on **Add** button it will list in **Design Description**.
- If select **Other** option then enter Trial Type and Phase name in textbox which is in front of **Other** option.
- User can delete **Design Description** by simply click on **Delete** button.

Go to tab **IP Details** following page will appear on the screen



C:- IP Details

- **Marketing Authorization (MA)**

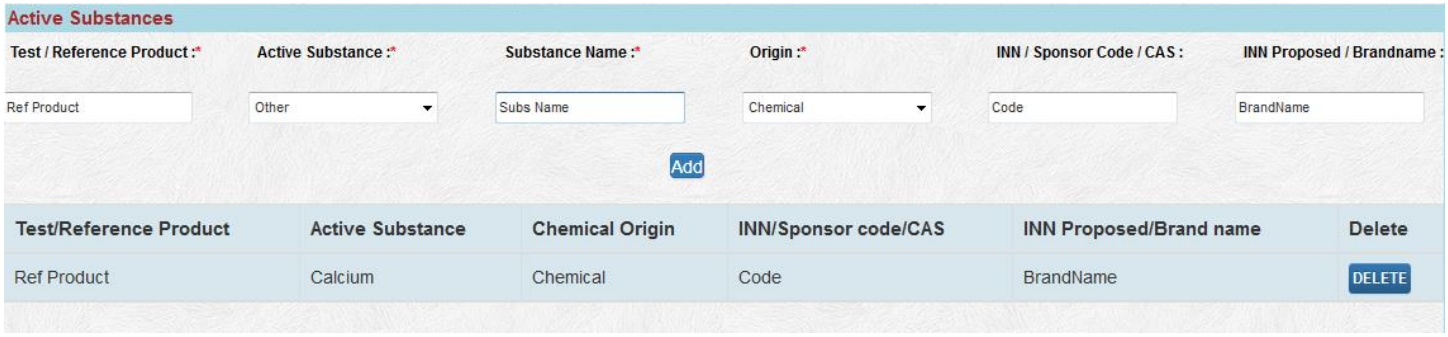


- If **Marketing Authorization (MA) in India** is **Yes** then under Document Upload section, document related to Marketing Authority in India should only be mandatory.
- If **Marketing Authorization (MA) in India** is selected as **No** then user can select country names and add it by simply click on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

- **Orphan Product**

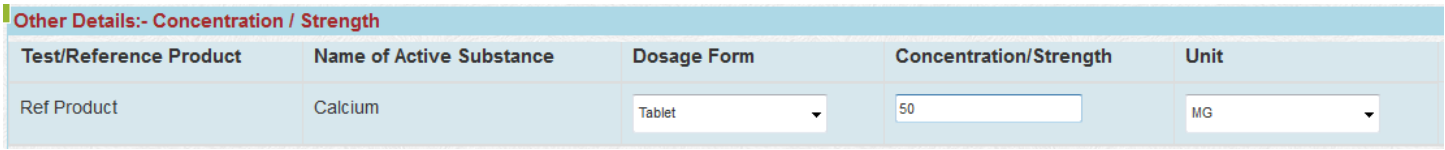
- If **Orphan product in India** is selected as **Yes** then under Document Upload section, document related to orphan product in India should only be mandatory.

- **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**



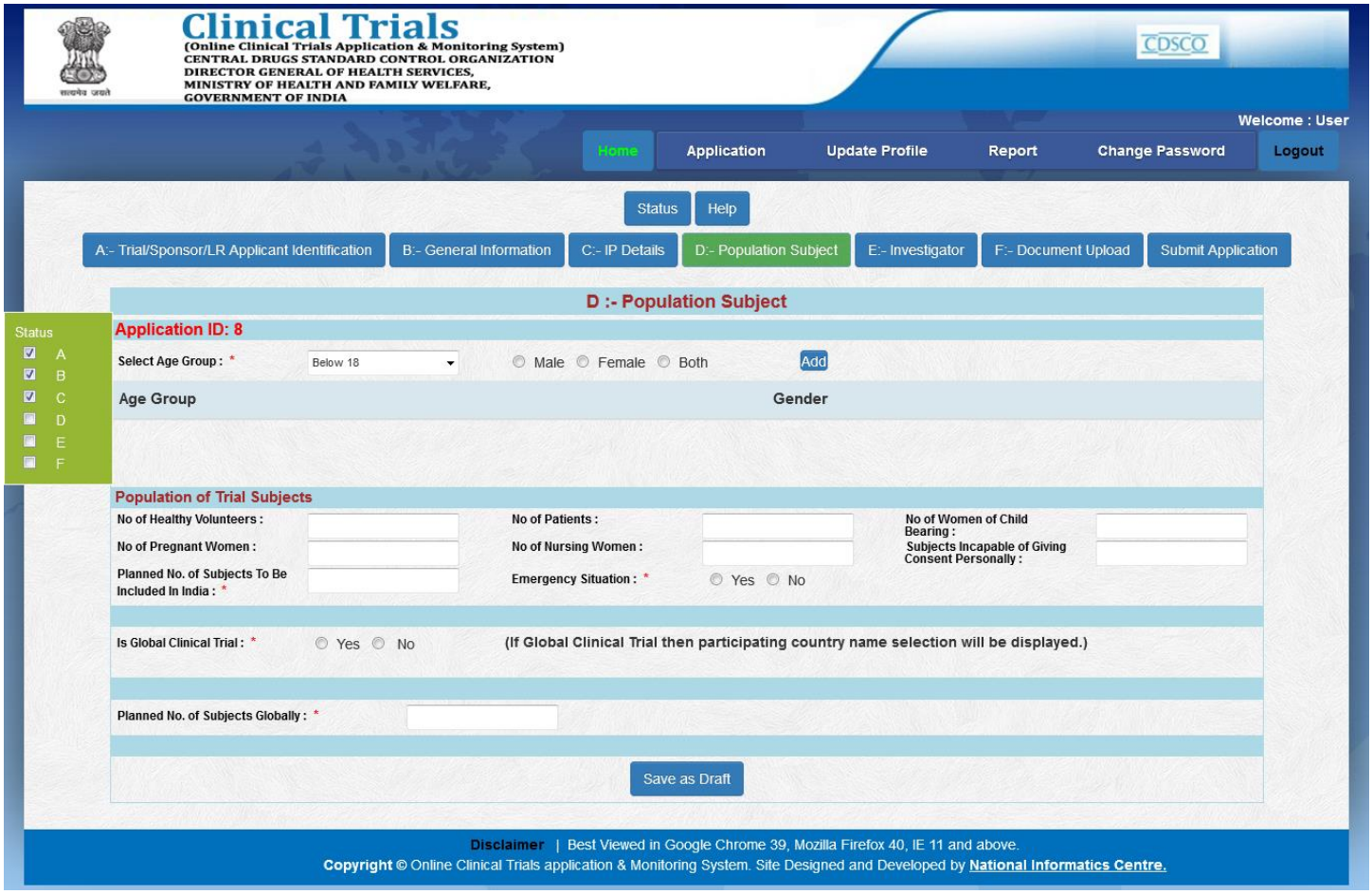
  - Add **Concentration / Strength** and **Unit to Active Substance**

- **Is This**

- Responsible For Release

  - Select Responsible For Release option **Sponsor** or **LR**

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



D:- Population Subject

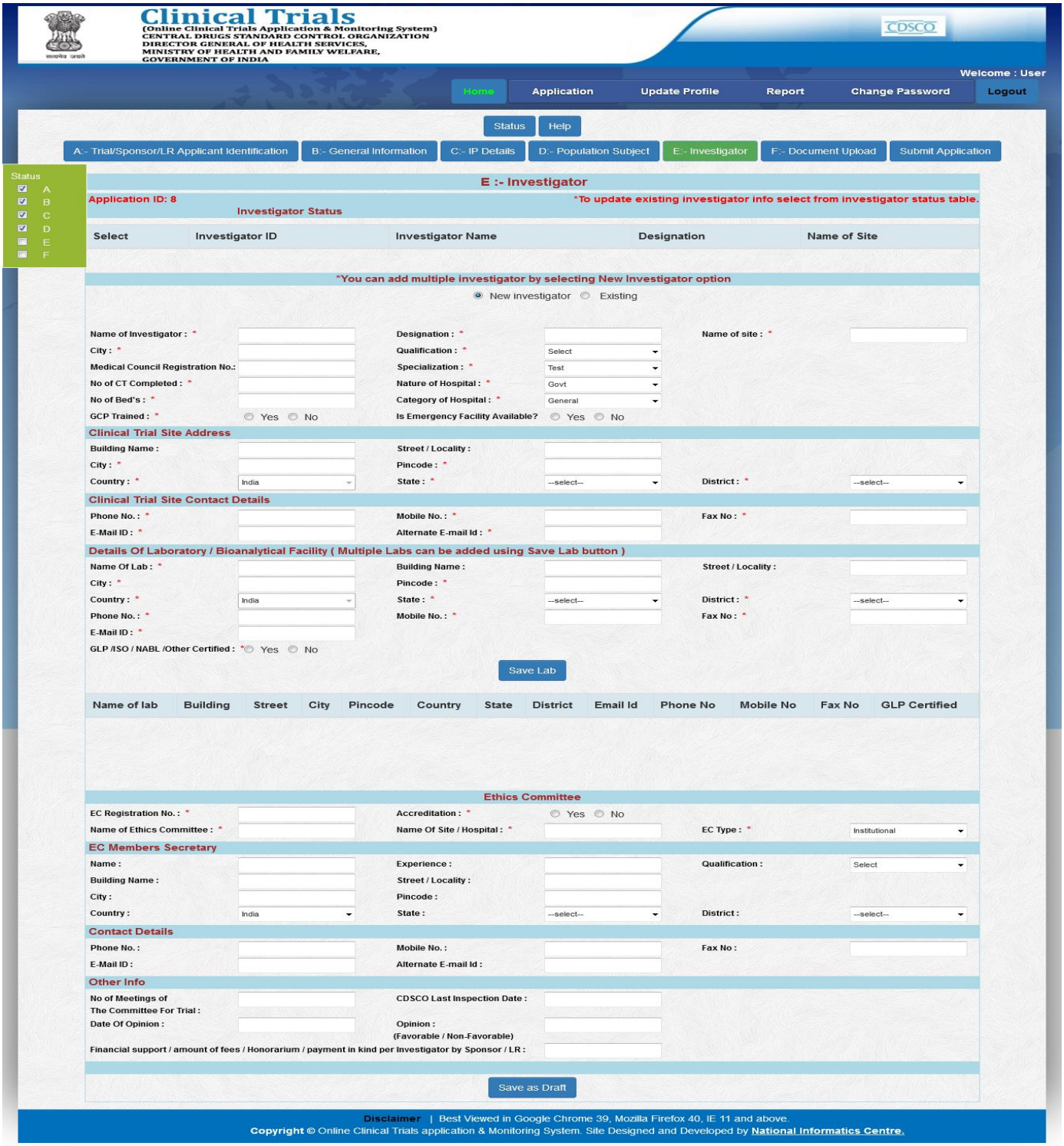
- **Age Group**

- 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.

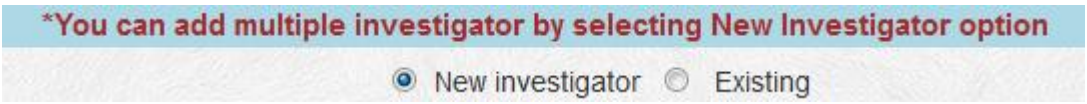
- User can add **Select Name of Participating Countries by** simply click on **Add** button it will listed in **table.**
- User can add **Select Countries Where The Protocol Is Already Approved** simply click on **Add** button it will listed in **table.**
- User can delete **Country** by simply click on **Delete** button.

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

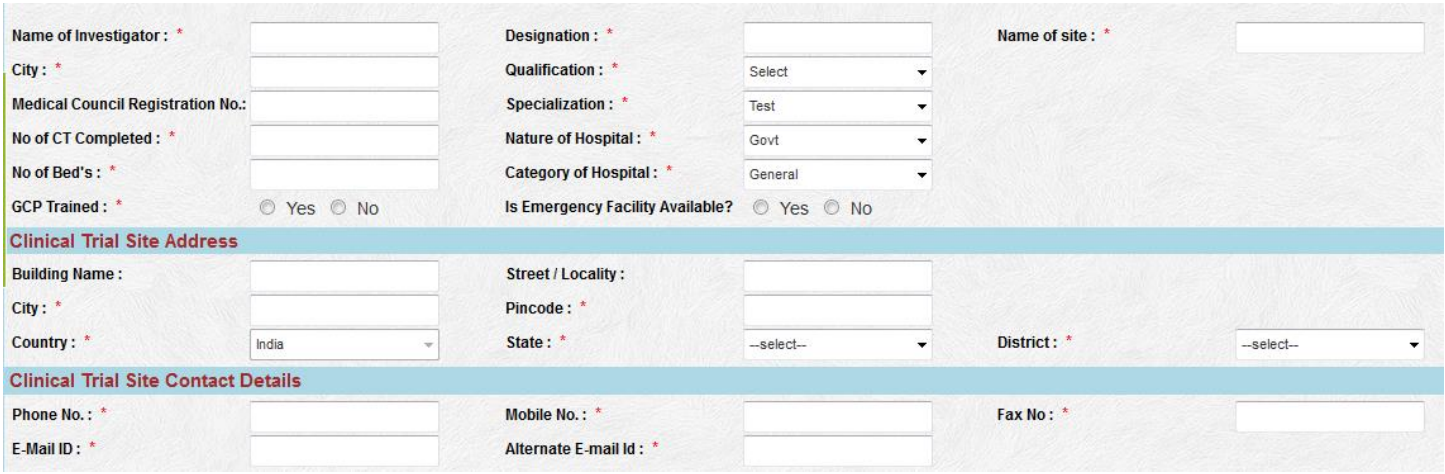


E:- Investigator

- User can add multiple investigator by selecting New Investigator option



- **Details of Investigator**



- **Details of Laboratory**

- 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**

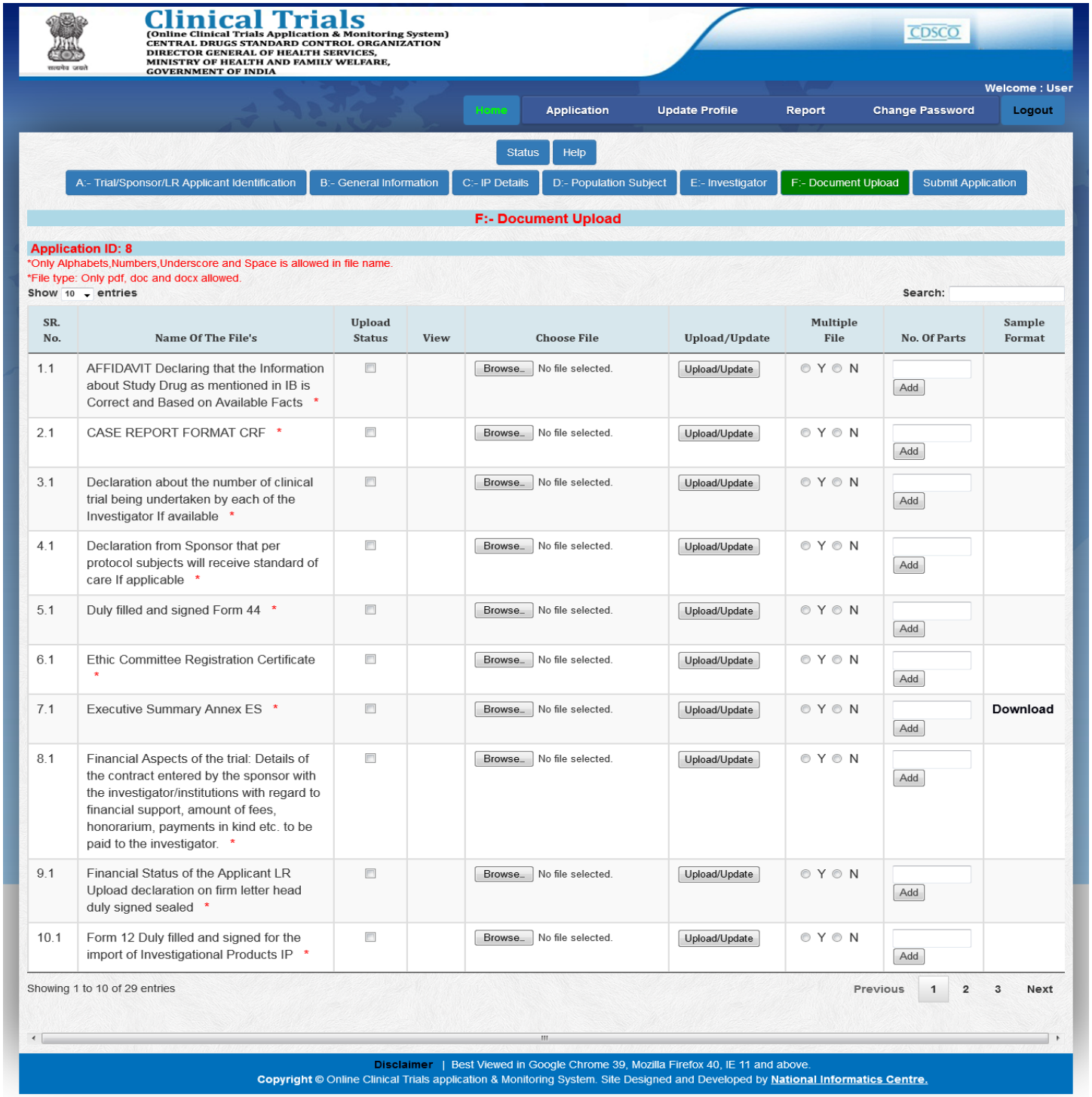
➢ **Existing Investigator**

- 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 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.

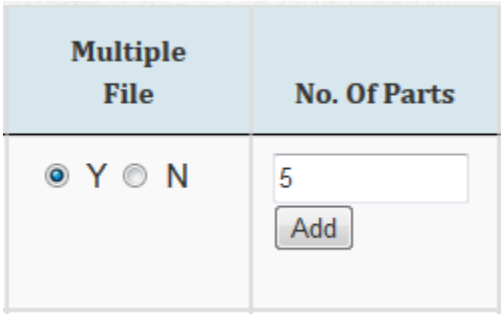
Go to tab **Document Upload** following page will appear on the screen



❖ 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.

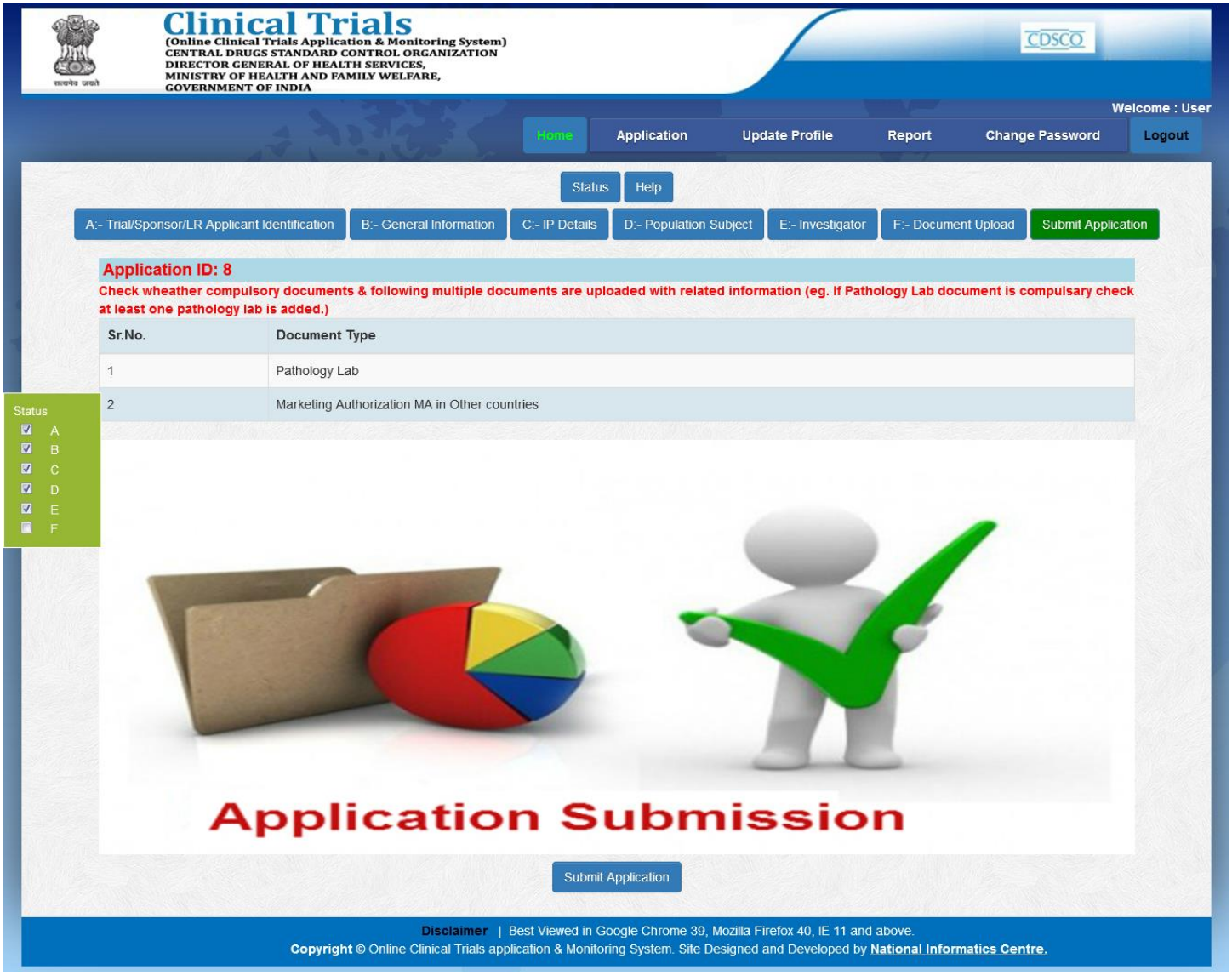
➢ Procedure to upload multiple file to one file



- 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.

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 *	☐		Browse... No file selected.	Upload/Update	Y N	Add	
1.2	AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_2 *	☐		Browse... No file selected.	Upload/Update			
1.3	AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_3 *	☐		Browse... No file selected.	Upload/Update			
1.4	AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_4 *	☐		Browse... No file selected.	Upload/Update			
1.5	AFFIDAVIT Declaring that the Information about Study Drug as mentioned in IB is Correct and Based on Available Facts_5 *	☐		Browse... No file selected.	Upload/Update			

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



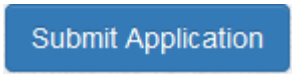
❖ General Instructions

- 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.)

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

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



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