

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

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Lecture – 23A
Online Submission 23A: SUGAM

Hello friends, hope you are doing well and enjoyed most of the lectures. And, we are almost to finish the lectures and we are at the lecture of 23 and we are very near to our goal and objective. So, no need to tell you what is the course and what is its title its regarding the New Drug and Clinical Trial. So, this is a lecture number 23 actually, it has been divided in two part; part A and part B.

The part B it would be cover by my other colleagues and which would be for the CTRI, how to register on to the CTRI. And, this lecture is about lecture 23 A and it is related to the SUGAM online.

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LEARNING OBJECTIVES



The faculty will cover the following in this lecture:

- What is SUGAM?
- Who can apply?
- How to apply?
- How to apply for a clinical trial?
- SUGAM – The process.



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

So, the learning objective from this lecture, we will see what is the objective of having the SUGAM. First, we will see what is the SUGAM, what is mean by SUGAM then what is its objective, why we have developed SUGAM, what are the benefit. And, the actual part that is online submission through this SUGAM.

So, we will see in detail the process how to open the site and where to apply, what the documents to be applied and last we will have the quick summary of this lecture. So, without wasting the time let us start.

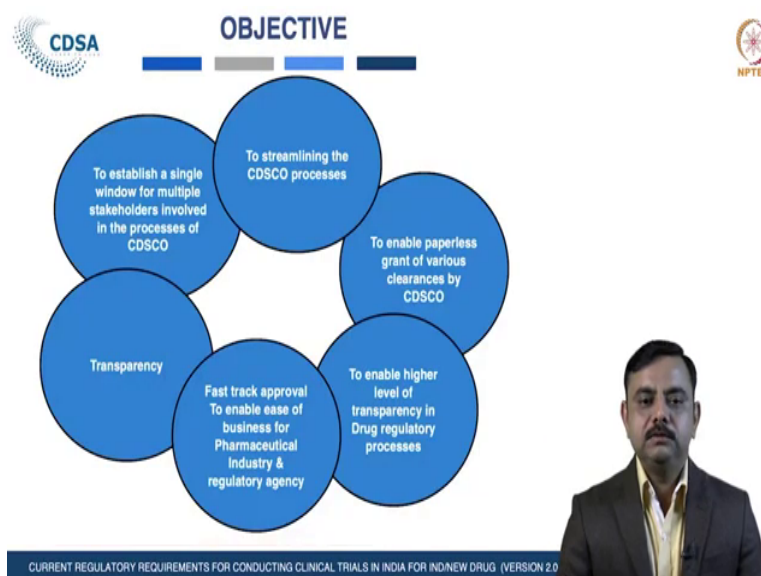
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So, you can see this is our site when you open this CDSCO online. It will appear like this wherein it is mentioned online licensing: application submission, track status, these are the different you know with the categories where you want to see.

So, the first I would like to share with you the SUGAM it is a Suraksha Gunvatta Avam Maanakta, many of the time we do not know in Hindi what is we called the safety quality and efficacy. So, it is an E governance solution for CDSCO and for the stakeholders and those who are applicants and also for the State Licensing Authority. So, this has been developed to reduce the timeline, to reduce the paperwork and to help the track of the system. This has started in the year 2016.

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Let us see what are the objective of having the SUGAM. The SUGAM has enable higher level of transparency in drug regulatory processes; earlier there were problem with the submission also. And, there were no transparency and the applicant could not track his applications where it whether it is lying with which officer and whether it is at what stage that, that was unable to see.

With this the level of transparency has been increase. And, it has also enabled the paperless grant of various clearances by the regulatory that is a CDSCO. Earlier the applicant required to submit very heavy and huge dose which consists of sometimes maybe 1000 pages, 2000, 10000 pages also and it was difficult also to archive this papers and archive all these files.

So, this problem has also been resolved by the SUGAM. Also it has streamlined the CDSCO processes; means once you open the SUGAM online and you are having the choice of

selecting the different options whether you want to apply for the GCT or new drug or SND. So, everything you will find in the SUGAM online and that application will go to the particular department

Otherwise previously the sometimes you know what happens the application is for the subsequent new drug. But, by mistake it goes to the GCT division then again it has to trace it and find out where the application is it takes lot of times. So, the SUGAM has streamlined this processes. The objective of SUGAM is to have the fast track approval also. So, once you are before your pc then you can at one go one go you can see all the application whether they have submitted the checklist, whether they have submitted the forms or not. So, it is completely organized one.

The SUGAM is also to establish a single window for multiple stakeholders involve in the process of CDSCO. So, these are few of the objective of the SUGAM online. Now, let us see what is the scope.

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So, here you can submit your application you may be sitting in the US, UK or any part of the India you need not have come to the headquarter Delhi. So, it has reduced your travelling time, your submission time and the wastage of money also. So, you can submit your application from the corner of the country sitting in one place. Then further after submission of the application, you need not have to worry or to you know frequently call to the CDSCO office and to ask where is our application and what is going with our applications.

So, you can track the status of your application online; sitting at your home also you can see the status of your application. Then in case of query you will get the queries through your email it there is a provision in the SUGAM, once the query has been generated it will directly come to your profile that is to the your email. Then the grant of approval is also through the online.

So, earlier it was you know offline and sometimes the receiver or applicant they may not receive the applications grant. And sometimes there is a misplace of the grant of permission which has been issued by the licensing authority. So, that problem has been resolved with this online SUGAM. The grant of approval you will get it in the soft copy and it would be there with the digital signature of the licensing authority.

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The image displays the SUGAM (Software User Grant Application Management) system interface. At the top, the CDSA (Central Drugs Standard Control Organisation) logo is shown alongside the text "WHO CAN APPLY". Below this, four categories are listed in blue ovals: "FOREIGN ENTERPRISE HOLDING INDIAN SUBSIDY", "CORPORATE", "INDIAN AGENT", and "IMPORTER". The text "SUGAM: HOW TO APPLY?" is prominently displayed. Below this, a screenshot of the SUGAM website is shown, featuring a registration banner that reads "Register to get Login Credentials" and "Pay Online, Save Time Secure and Convenient". The banner also includes an image of a laptop and a credit card. The NPTEL logo is visible in the top right corner. A man in a suit is positioned in the bottom right corner of the image, likely the presenter.

Let us see who can apply on to the SUGAM online. So, corporate people they can apply then in case of the import the Indian agent, if he would like to apply he can apply then importer those who are importer they can also apply. And foreign enterprises holding Indian subsidy, they can also apply or anyone who is desirous to apply for the application for the clinical trial for input or for the test licence, they can apply on to the SUGAM.

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CDSA

BENEFITS

Uptime
24x7

Timely Alerts / Notifications

Anytime/Anywhere/Any Device

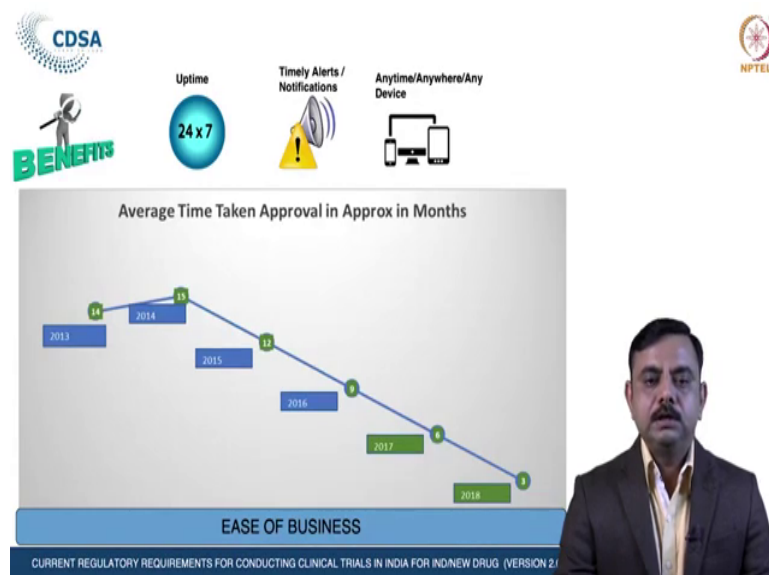
- Simplified process for Documentation Submission, Review, Tracking.
- Efficient and Transparent.
- All the previous submissions under one roof.
- Post submission change requests available while the application is in process.
- Query responses online.
- Progress towards Data Integrity – One login One company

EASE OF BUSINESS

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

Let us see how to apply? This is the most important thing. So, as I have told if you open, if you put into the google also CDSCO online or SUGAM page will open. And on to this SUGAM page you have to first register to get login credential. So, once you get the login credential, then your name and your company name that that would be registered with the SUGAM and it would remain with the licensing authority.

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So, earlier we have seen the as I have mentioned there were lot of time and lot of pendency was with the CDSCO. And it was if we see in 2013 and 14; it would be taking 14 months 15 months or maybe the 2 years to get it the clearance with the SUGAM's. We have seen that in 2017 and the timeline was the 6 month and now we have again devise a timeline with the in 2018 to dispose of the application in 3 months.

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Form	Applicability
CT-04	Application for grant of CT of New Drug or IND
CT-4A	Information to initiate CT as a part of Discovery, research, manufacture in India
CT-05	Application to conduct BA/BE Study
CT-06	Permission to conduct CT
CT-07	Permission to conduct BA/BE Study
CT-10	Application to manufacture new drug for CT/BA-BE or for examination, test or analysis
CT-11	Permission to manufacture new drug for CT/BA-BE or for examination, test or analysis




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


So, which in for which forms you can apply on to the SUGAM and which are the portal presently functional onto the SUGAM; let us have a look for this. So, these are the forms. So, the CT 04 which is application for grant of clinical trial of new drug or IND. We have seen this all the forms CT 4A, CT 5 application to conduct the BA BE study then clinical trial, form 6 permission to conduct CT, CT 7, CT 10, 11.

Further the other forms which are required to get a test license or permission to manufacture or import small quantities of the drug, which are not approved into the country for this there is a provision to apply online.


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**CDSA**

FORMS AND APPLICABILITY



Form	Applicability
CT-12	Application for manufacturing formulation of unapproved API for CT/BA-BE, examination , test or analysis
CT-13	Application for manufacturing unapproved API for CT/BA-BE, examination , test or analysis
CT-14	Permission for manufacturing formulation of unapproved API for CT/BA-BE, examination , test or analysis
CT-15	Permission for manufacturing unapproved API for CT/BA-BE, examination , test or analysis
CT-16	Application to import new drug/IND for CT/BA-BE, examination , test or analysis
CT-17	Licence to import new drug/IND for CT/BA-BE, examination , test or analysis



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And these are the forms CT 12, 13, 14, 15, 16 and 17. So, these forms and these forms are now functional you can apply through the SUGAM online.

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CDSA **LET'S GET STARTED** **NPTEL**

1. Enter into the online portal <https://www.cdsoonline.gov.in/CDSCO/homepage>
2. Get login into by providing pass word
3. Now user will get dashboard and enter into option "SWITCH ROLE".
4. Click on Indian agent & now user will get an option "Submit Application" on dash board.
5. Select concerned Department & Division (GCT in this Case) and Form (Form CT 04/Form CT 16), then click on "PROCEED"
6. Now fill all the necessary fields in the application step by step and proceed with "SAVE & CONTINUE". Filling of all mandatory field is compulsory.

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So, let us see the what is the actual process. As I have mentioned you have to enter into the online portal that is a CDSCO online dot gov dot in for the medical device it is a different it is the CDSCO md dot gov dot in. So, that might have been covered into our first course that is regulatory requirement for the medical devices. So, first get login into by providing your passwords.

So, you have to first as we know that you have to give your username, then the password, then the whatever the capture that has to be covered into that then you will get your credential. After this user will get dashboard and you have to enter into the option that is a switch role. So, once you have to apply it the dashboard will appear and then you have to switch the role.

Further next to this click on Indian agent and now user will get an option to submit an application. So, after having submitted all this document and the information the final will come that submit application on dashboard. For this you have to select the concern department and the division. So, once you entered then the all the divisions which are functional online that will appear.

For example: if your application is for the fees those combination or for the subsequent new drug IND or global clinical trial. So, that division will appear. So, and you have to select a particular type of application, after that you have to fill the necessary field in the application step by step. So, there are 4 steps has been given whereby you have to select one by one and you have to fill up the form. You have to save it and you have to continue it. So, this is very important unless and until you save it will not remain.

So, kindly save it to avoid the rework and you have to fill all the field which are mandatory, otherwise it will not accept your form.

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CDSA **LET'S GET STARTED** **NPTEL**

1. Fill "NOT APPLICABLE" if concerned section is not applicable
2. Upload all the required documents in PDF form. For those field which are not applicable, please upload the page wherein it is written that this section is not applicable along with the detailed justification.
3. Uploading the proof of payment of challan

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And wherever there is a no applicability for example, if it is given whether the CT whoever has been asked or not. And if you do not have the document that you should not have to blank you should not have to leave it to blank, you have to submit the document mentioning it is not applicable.

So, you cannot leave it unattended, otherwise it will not accept your application and it will show the incomplete applications. You required to upload all the required documents in the PDF format. So, first you have to convert all the document into the PDF format and then so, that nobody can change your documents or the data what you have submitted. So, you have to submit it into the PDF form for those fields which are not applicable. As I mentioned you have to upload the page in the written that is not that is not applicable.

Then, with respect to the fees you need not have to directly pay the cash, you have to have the challan through the Bharatkosh. And the copy of that challan you are required to submit onto the or we can say you have to upload on to the SUGAM online.

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CDSA **LET'S GET STARTED** **NPTEL**

4. Now Form CT 04 will be generated for preview, which will enable you to verify the details you have filled, if they are correct then download the PDF & sign it & upload it. If there are any corrections, please correct before downloading. Here you may have to again start from step one & keep on pressing next button till you reach the correction point. Then correct the matter & proceed in usual manner and verify corrections if any, from preview of Form CT 04

5. Finally save and submit the application.

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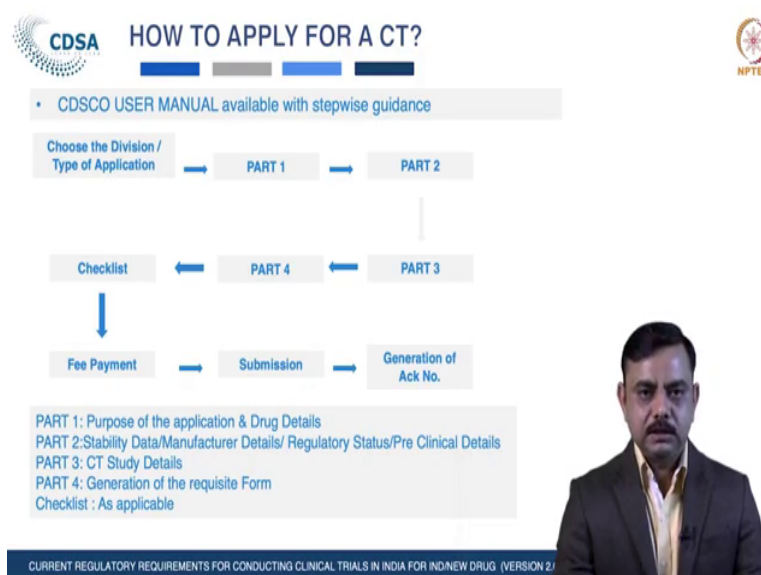
See if we take the example of form CT, then it will be generated for if once you have submitted the CT 4. It will be generated for the preview which will enable you to verify the details you have filled.

So, once you have fill the application, then it will show you the preview option whereby you can see whatever the information you have filled. If they are correct then you have to download the pdf and sign it and upload it. If there are some correction or you feel that some

of the information what you have submitted that is not correct, then please correct that before the downloading, once it is downloaded then it will not be corrected.

So, before downloading you have to correct it. Here you can have to again you may have to again start from step 4 and keep on pressing the next button till you reach the correction point. Then correct the matter and proceed in user manner and verify the corrections if any from the preview of whatever the application. For example, CT 4 or any other application you have filled. Finally, you required to say all this information and data what you have submitted and the last stage you have to submit the applications.

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So, this is the pictorial diagram, what I have shown here, how to apply for the CT? So, you have to choose the division what I have mentioned then there are 4 parts part 1, part 2, part 3, part 4; part 4 is this all the information you are required to fill. Then there would appear a

checklist that checklist you have to fill, then the receipt of the fee payment that you have to upload and finally, you have to submit that application then it will generate a acknowledgement number.

So, from that you can trace and track your application. This part 1, part 2, part 3 and part 4 it is a part is purpose of the application and the drug details. The part 2 is the details about the drug manufacturer details then the regulatory status, that you have to fill into the part 2. In the part 3, you have to upload you have to fill the details about the clinical trials whether it is phase 1, phase 2, phase 3 or phase 4.

Whatever the details available with you and the purpose for which you have applied that details you have to fill in the part 3. Part 4 is the generation of the requisite form. So, here the legal forms you have to generate, then after that there is a checklist and the remaining procedure you can see here.

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CDSA **SUGAM - THE PROCESS**

LOG IN DETAILS

Central Drugs Standard Control Organisation
Director General Of Health Services
Ministry of Health & Family Welfare, Government of India
Online Application Submission System For Licensing

Online GCT & BA/BE processes are now available

Apply Online for Global Clinical Trial

Sign In **Forgot Password?**

username or email
Username/email is required and cannot be empty

password

WVIR 5

Login

Don't have an account? Sign Up Here

Monitoring

ONLINE SERVICES

What does it offer?

Online Submission

- Applicant can apply for permission under the Clinical Trials Act, 1931
- Track the status of submitted application.
- Answer Back to the Raised Queries
- Applicant can also upload essential documents

For Patients
Learn about drug/device approvals

For Industry
Guidance, Regulations

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

Let us see actually what appears. So, this these are some screenshots of our SUGAM online. As I have mentioned first you have to create your login details by filling the user name password and the capture here given then you can log in through it.

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The image shows a screenshot of the SUGAM (SUGAM - THE PROCESS) portal. At the top, there is a header with the CDSA logo and the title "SUGAM - THE PROCESS". Below this, a navigation bar includes links for "Home", "History", "Change Password", and "Logout". The main content area displays the "Central Drugs Standard Control Organisation" logo and name, along with the text "Director General of Health Services" and "Ministry of Health & Family Welfare, Government of India". A "Dashboard" link is visible in the left sidebar. The main content area shows a "Dashboard" section with a "User Profile" card and a "User Guidelines" link. A presenter, a man in a suit, is overlaid on the right side of the screen. At the bottom, a blue banner reads "CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR INDNEW DRUG (VERSION 2)".

Then you have to select the menu and where it will appear the dashboard also, in that dashboard. There are various options are given for the form submission for the application you know for the track of the applications. If you would like to see the what are the approved application that also that are also there. If your previous application has got rejected that also you can see here.

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CDSA SUGAM - THE PROCESS NPTEL

LOG IN DETAILS
Online Forms Submission

Select Department: GCT Division

Select Form: Select
Import & Registration of drugs
Medical Devices & Diagnostic
BA/BE for Export
GCT Division
Test License



☐ I agree that I will provide accurate information and I will be solely responsible for the information provided to the division.

Proceed

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So, after having this then you have to select the division. So, many of the divisions will appear here like a BA BE division medical devices though it has been separated now. The import and registration division or the test license division. So, you have to select that division and again you have to click the button that is a proceed.

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 **SUGAM - THE PROCESS** 



OPTION A: IF "FORM CT 04" IS SELECTED:


Online Forms Submission

Select Department: GCT Division


Select Form: (Select Form)
(Select Form)
Form44

☐ I agree that I will provide accurate information and I will be solely responsible for the information provided to the division.



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Then its time to submit the form. Once you have selected the type of application, accordingly you have to select the form for the clinical trial you know earlier it was a form 44. So, now, it is a form CT. So, wherever it is showing that form 44 you have to upload the form CT 04; because it has now not it has not been revised and there was delay for making this. And the applicants were waiting to submit the application for applications for that we have ask them to submit your form CT 04, wherever it is showing the form 44.

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The slide is titled "SUGAM - THE PROCESS" and features the CDSA and NPTEL logos. It explains Option B: If "Form CT 16 is linked with Form CT 04" is selected. When this option is selected, Form CT 16 application is opened. Once all the steps of filling in Form CT 16 are completed & submitted on SUGAM, a reference no. is generated. This reference no. should be used to link the Form CT 16 application to the main Form CT 04 application shown above.

The screenshot shows the "Online Forms Submission" interface. It includes a "Select Department" dropdown menu set to "CCT Division". Below it, a "Select Form" dropdown menu is open, showing options: "Select Form", "Form04", and "Form04 to be linked with Form04". A checkbox is checked, indicating agreement to provide accurate information. A "Proceed" button is visible. The footer of the screenshot reads: "CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA FOR INDNEW DRUG (VERSION 2)".

So, if for the test license as we know earlier it was different form now it is a different form. And, if form CT 16 is which is related to the test licence if it is linked with the form CT 04 it has to be selected, when this option is selected from then form CT 16 application is open. When once you open this all these steps of filling in forms CT 16 are required to be completed and submitted on to the SUGAM.

Or reference number will be generated once you fill this form 16 and this reference number should be used to link the form CT 16; application to the main form CT 04 application as we have seen in our previous slides. So, this is the information we required to give into the form CT 16. So, at present it would it would show the form twelve which was the old form.

So, wherever it is showing, you can consider this is a application for the test license and you have to upload and you have to fill the information as this expected from the form 16.

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CDSA **SUGAM - THE PROCESS** **NPTEL**

1. FORM CT 16:
Form 12
(Per Rule 16)
Application for license to import drugs for purposes of investigation, test or analysis

Application Details

Purpose of Application
Place Name where application is being made

Residential Address Details
Note: Please enter your residential address.

Address Line 1
Address Line 2

Country **State** **District**
City **Pincode**



Test or Analysis Site Address
Site Name
Address Line 1
Address Line 2

Country **State** **District**
City **Pincode**

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So, we can see these are the steps and this is the process this will appear, when you open this form 16.

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SUGAM - THE PROCESS

1. FORM CT 16:

Import Address

Note: Please enter the address from where drug needs to be imported. It is mandatory to mention Country of Import.

Country:

Address Line 1: Address Line 2:

Country/Region: City: Zip/Postal code:

Latitude No. (Please include Country Code - State Code - Location Number): Pin No. (Please include Country Code - State Code - Pin Number):

Multiple Countries/Regions can be added with separate registration. Multiple Pin Numbers can be added with separate registration.

Product Details

Form 12
(New Form 12)

Application for license to import drugs for purposes of experimental, test or research

Product Details

Product Name

Place of Origin: ☒ ☐ ☐


Place of Manufacture: ☒ ☐ ☐

Place of Sale: ☒ ☐ ☐

Place of Storage: ☒ ☐ ☐

Place of Distribution: ☒ ☐ ☐



Place of Use: ☒ ☐ ☐



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As I have mentioned the steps, we will see it in brief. The step 1, you have to fill the form.

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 **SUGAM - THE PROCESS** 

1. FORM CT 16:

Applicant Details

Product Details

Product Details

Search:

Name of Drug/Formulation #	Class of Drug #	Drug Strength #	Quantity #	Pack Size #	Type of Drug #	Edit #	Delete #
ABC	XYZ	200 milligrams (mg)	14 Tablets	14 tablets per strip	Foosbed Formosidone		

Continue

Form 12

Application for the purpose of submission, test or analysis

I/We, _____, residing at _____, do hereby apply for a license to import the drug specified below for the purpose of submission, test or analysis. I undertake to comply with the conditions applicable to the license.

S.No. #	Name of Drug & Brand Name #	Class of Drug #	Strength #	Quantity which may be imported #
1	ABC (Drug)	XYZ	200 milligrams (mg)	14 Tablets (14 tablets per strip)

PLACE: Mumbai

DATE: 10 Nov 2015

Signature: _____

Designation: _____

Submit Form Preview Form Cancel

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Then the step 2, you have to preview it whether you have correctly filled or not. Then it will appear the checklist then you have to fill all the checklists mentioning that you have submitted the documents or not. Then you have to submit the challan of the requisite fee what you have paid through the Bharatkosh or the Bank of Baroda. Then you can you can have full preview of all whatever the documents you have submitted and upload submitted.

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CDSA **SUGAM- THE PROCESS** **NPTEL**

1. FORM CT 16:

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

Fill Form Preview Checklist Payment Full Preview Submit Form

Upload Essential Documents For Form 12

Note:

1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 10 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/review under the Saved Application link available on the Dashboard.



0 1. Justification of Quantity

Submit

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And in the last stage you have to click the submit form option also. Otherwise once you have filled all the information and if you have not submitted, you will it will not reach to the licensing authority. So, the final is the submit button.

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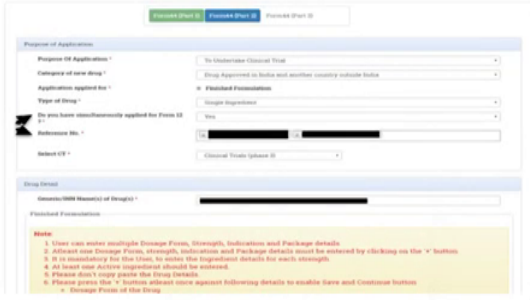


SUGAM - THE PROCESS

1. FORM CT 04: Part 1

The question: "Have you simultaneously applied for Form 12?" should be answered "Yes". The reference no. of the Form 12 application can be then selected from a drop down list.



Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.



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As I have mentioned there are 4 parts. So, this type of part will appear for the form CT 04; the part first you can see this this information you required to fill for part 1.

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SUGAM - THE PROCESS

1. FORM CT 04: Part 2

Study Details

Manufacturer of Study Product

Study Product

Product Details in India

Regulatory Status of the Investigational Product in other countries, as applicable

Assess Toxicology Studies

Item No.	Item	Status
1	Single dose Toxicity Studies	Ready for Request
2	Repeated dose Toxicity Studies	Ready for Request
3	Male Fertility Study	Ready for Request
4	Female Reproductive and Developmental Toxicity Studies	Ready for Request
5	Local Irritation	Ready for Request
6	Allogeneicity/Hypersensitivity	Ready for Request
7	Genotoxicity	Ready for Request
8	Carcinogenicity	Ready for Request

Assess Pharmacokinetic Studies


Item No.	Item	Status
1	Single Pharmacokinetic Studies	Ready for Request
2	Repeated Pharmacokinetic Studies	Ready for Request
3	Follow up and Reproductive Safety Pharmacokinetic Studies	Ready for Request
4	Conditions under which Safety Pharmacokinetic Studies are not necessary	Ready for Request
5	Timing of Safety Pharmacokinetic Studies in relation to Clinical Pharmacokinetic	Ready for Request
6	Appropriateness of Study Laboratory Procedures (GLP)	Ready for Request

Go Back and Continue

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Then this is for the part 2. So, all these details whatever applicable you required to fill the part 2.

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SUGAM - THE PROCESS

1. FORM CT 04: Part 3



CT Study Details

Whether Global Clinical Trial

Scope/Objective of Trial *

Study Design *

Is it a Global Clinical Trial? *

☒ Yes ☐ No

Select Name of Participating Countries *

Planned No. of Subjects Globally *

Planned No. of Subjects in India *


Sponsor Details

Sponsor *

☒ Self Sponsored ☐ Sponsored by Others

Comparator Drug Details (Optional)

S.No.	Comparator Drug Name	Dosage Form	Route of Administration	Name of Company	Name of Country	Delete
1	<input data-bbox="496 824 592 840" type="text" value="Paracetamol"/>	<input data-bbox="592 824 639 840" type="text" value="Tablet"/>	<input data-bbox="639 824 687 840" type="text" value="Oral"/>	<input data-bbox="687 824 772 840" type="text" value="Cipla"/>	<input data-bbox="772 824 857 840" type="text" value="India"/>	<input data-bbox="911 824 938 840" type="button" value="X"/>



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Then the part 3, this type of you know format will appear.

(Refer Slide Time: 22:15)

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1. FORM CT 04: Part 4

Part 3

Documents to be uploaded in the checklist

Note: You will be required to upload below listed documents in the checklist section for successful submission of application.

- **1. Test specifications:**
 - Active ingredients
 - Excipients
- **2. Preclinical data to market a new drug:**
 - Chemical and Pharmacological data
 - Marketing information
 - Proposed product monograph
 - Details of label and packaging
 - Application for test license
- **Subsequent approval/permissions for manufacture of already approved new drug:**
 - Formulation
 - Bio-availability/bio-equivalence protocol
 - Name of the investigator/institute
 - Source of raw material (bulk drug substances) and stability study data
 - Raw material (bulk drug substances)
 - Manufacturing method
 - Quality control parameters and to analytical specifications, stability report
 - Animal toxicity data
- **Approval/permissions for fixed dose combinations:**
 - Therapeutic justification (scientific literature in favor/relevant preclinical/clinical trials)
 - Data on pharmacokinetics/pharmacodynamics combinations
 - Any other data generated by the applicant on the safety and efficacy of the combination
- **Subsequent approval or approval for new indication, new dosage form:**



➡ If I hereby declare that I will upload the above listed documents in the Checklist and I will be solely responsible for any false or inaccurate document provided to the authority.

Continue

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In the last that is a part 4, which is related to the documents to be uploaded into the checklist. So, with respect to you to your application the checklist will appear and you will be asked you will be requested to upload the document given in the checklist. Again you have to continue it, till you get the final submission of it.

(Refer Slide Time: 22:44)



SUGAM - THE PROCESS

1. CHECKLIST

7. Module VI TRIAL RELATED DOCUMENTS

- ☐ 7.1 Study Protocol (state the Version No. and Date)
- ☐ 7.2 Inclusion/Exclusion criteria as per the protocol, whether the subjects will receive the Standard of Care
- ☐ 7.3 Patient Information Sheet (PIS) and informed consent form (ICF) as per Annex A of Schedule Y including the following clauses
 - ☐ 7.3.1 Understanding by the Sponsor/Investigator representative to the Licensing Authority to provide medical management and compensation in case of clinical trial-related injury or death for which insurance or medical compensation or required under rule 12(1)(a) of
 - ☐ 7.3.2 Declaration regarding financial status of the applicant for a medical management and compensation to be paid to the trial participants in case of injury or death or clinical trial
 - ☐ 7.3.3 Insurance of the CDF to be used
 - ☐ 7.3.4 Investigator's Bioethics
 - ☐ 7.3.5 Affidavit declaring that the information about study drug as mentioned in Investigator's Bioethics is correct and based on available facts
 - ☐ 7.3.6 List of Participating Sites, along with name and contact details of the Principal Investigators and C1 Details
 - ☐ 7.3.7 Details of the contract entered by the sponsor with the investigator/investigators with regard to financial support, amount of fees, honorarium, payments to staff etc. and for the investigator to enter the contract fee and fees related with the investigator's functions, plan the financial support, fees, honorarium and payments to staff etc. to be paid to the investigator
 - ☐ 7.3.8 Undertaking by the investigator as per Appendix VI of Schedule Y including List of Investigator with qualification along with C1 and SMC
 - ☐ 7.3.9 Clinical committee approval if any
 - ☐ 7.3.10 Proposed Draft of IMP Label
 - ☐ 7.3.11 Copy of the Investigator Certificate of Goodwill (ICG)
 - ☐ 7.3.12 Assessment of risk versus benefit to the patient (for this proposal)
 - ☐ 7.3.13 Investigator's existing therapeutic opinion (if it is this proposal)
 - ☐ 7.3.14 (Document required used in the receipt of IMP from parent)
 - ☐ 7.3.15 Any particular literature on the development of the IMP

7.4 Post Marketing Phase (PMP) Studies

- ☐ 7.4.1 Marketing Approval status of the drug under study
- ☐ 7.4.2 Product patentability information
- ☐ 7.4.3 Summary of phase I, phase II & Phase III studies
- ☐ 7.4.4 Any other information (if any)

Step 1: Fill Form

Step 2: Review

Step 3: Checklist


Step 4: Payment

Step 5: Full Preview

Step 6: Submit Form

Note:- Once the checklist is completed, the payment challans need to be uploaded. Finally, a preview of Form-44 is shown which needs to be downloaded & signed. The signed Form 44 has to be uploaded & then the application can be submitted and a reference no. is assigned to it.

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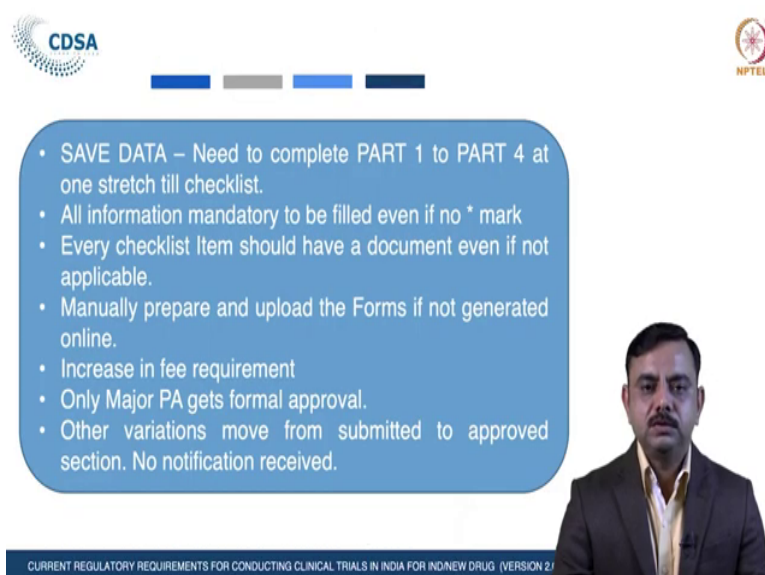


This is what about the checklist, you can see here there is a checklist and these are the elements we have taken the example of global clinical trial here. So, you can you can have the view of all these applications like IND and new drug. So, this is exclusive example for the GCT division.

Once the checklist is completed, the payment challan need to be uploaded finally, as I have mentioned. So, after the submit button, this will reach to The Licensing Authority. And we know the next procedure, The Licensing Authority can review your application and can give the query if it is not you know adequate in all the manners and if it is complete in all respect then you may get the permission.

So, while filling this form you require to take some precaution. So, that it would be completely filled and it would be completely submitted to the licensing authority.

(Refer Slide Time: 23:59)



The slide features the CDSA logo on the top left and the NPTEL logo on the top right. Below the logos is a horizontal bar with four colored segments: blue, grey, blue, and dark blue. A large blue rounded rectangle contains a list of bullet points. To the right of this rectangle is a video feed of a man in a suit. At the bottom of the slide, a dark blue bar contains white text.

- SAVE DATA – Need to complete PART 1 to PART 4 at one stretch till checklist.
- All information mandatory to be filled even if no * mark
- Every checklist Item should have a document even if not applicable.
- Manually prepare and upload the Forms if not generated online.
- Increase in fee requirement
- Only Major PA gets formal approval.
- Other variations move from submitted to approved section. No notification received.

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So, whenever you are filling these applications, you required to save all these data like we have seen part 1 to part 4 is there and again there is a checklist. So, so as I and when you are filling this part 1, part 2, part 3, every time you required to save it otherwise if you do not save it then there will be a rework for you.

Wherever there is a stretch has been given, you know that it is a mandatory and you have to fill all these mandatory documents and the information. Every checklist item should have a document even if it is not applicable; what I have mentioned in previous slide if it is not

pertains to your applications still you how to upload a document of not applicable then only it will accept. So, you have to keep in mind all this precautions.

So, best is that you manually prepare and upload the form, if its it is not generated online. If it is not there then you have to manually prepare and upload the line that is also acceptable. Then only major PA gets the formal approval other variations move from submitted to approved section then no notification received.

So, these are the precautions and one thing I would like to mention before submission as I have mentioned, there are the two times there is a preview. So, you can before submission you can have the preview of your application; first after submission and then final submission there are two options given for the full preview and the part preview.

So, you go through it and have the full preview and if you are satisfactory then only submit it. So, this is what about the SUGAM online and how to fill the applications. So, that it would be reach in a complete manner to the licensing authority. And there would be no delay there would be no unnecessary query for you. So, you have to keep in mind all these things. So, this is what about the SUGAM online.

(Refer Slide Time: 26:30)



SUMMARY

In Lecture 23A (L23A), we briefly learnt about:




- What is SUGAM?
- Who can apply?
- How to apply?
- How to apply for a clinical trial?
- SUGAM – The process.



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I hope that you have understood all this. And now to this lecture 23, I know that you become a more intelligent. And, I think there is no need of asking you the question and checking your memory even though we will continue it in our 24th lecture.

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DISCLAIMER
The information within this presentation is based on the presenter's expertise and experience and represents the views of the presenter for the purpose of training.

■ ■ ■ ■

END OF LECTURE L23A: ONLINE SUBMISSION (SUGAM).
THANK YOU.



So, we will meet in our next lecture that is a in lecture 24, till then you take care and bye, bye.

Thank you.