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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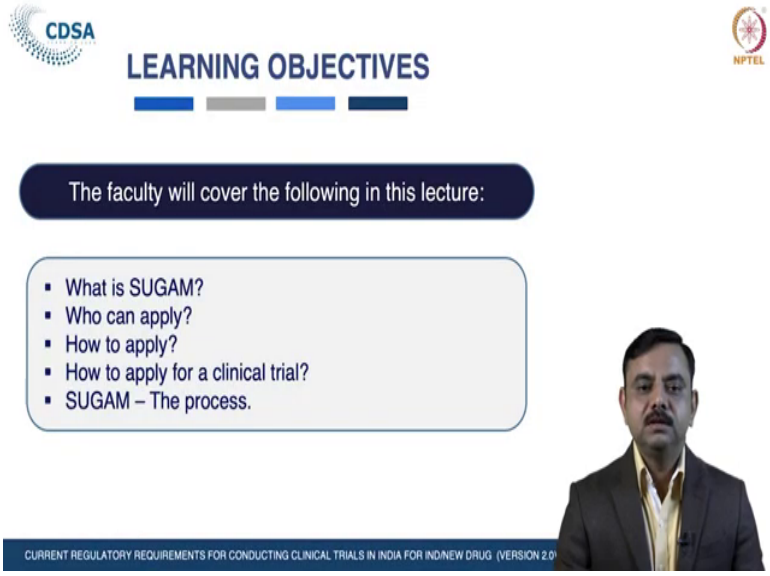

So, the learning objective from this lecture, we will see what is the objective of having the SUGAM. First, we will see what is the SUGAM, what is mean by SUGAM then what is its objective, why we have developed SUGAM, what are the benefit. And, the actual part that is online submission through this SUGAM.

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 mistakely 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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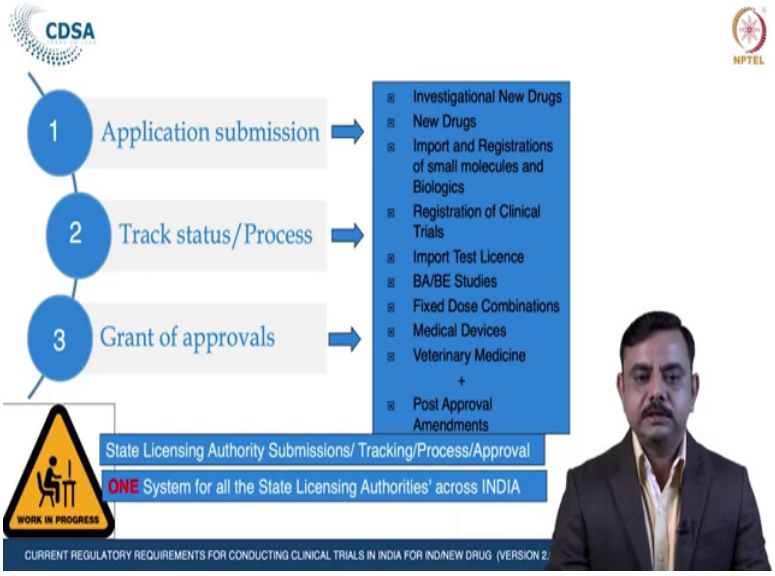

So, here you can submit your application you may be sitting in the US, UK or any part of the India you need not have come to the headquarter Delhi. So, it has reduced your travelling time, your submission time and the wastage of money also. So, you can submit your application from the corner of the country 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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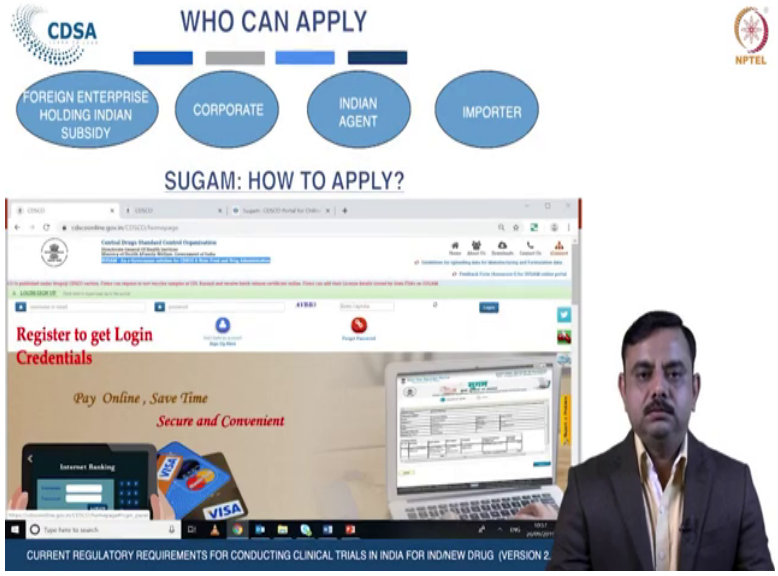

Let us see who can apply on to the SUGAM online. So, corporate people they can apply then in case of the import the Indian agent, if he would like to apply he can apply then importer those who are importer they can also apply. And foreign enterprises holding Indian subsidy, they can also apply or anyone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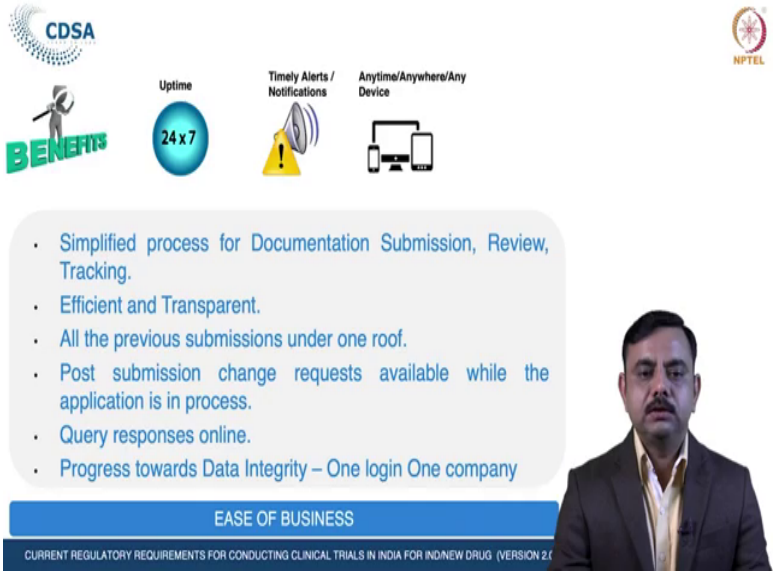

Let us see how to apply? This is the most important thing. So, as I have told if you open, if you put into the google also CDSCO online or SUGAM page will open. And on to this SUGAM page you have to first register to get login credential. So, once you get the login credential, then your name and your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

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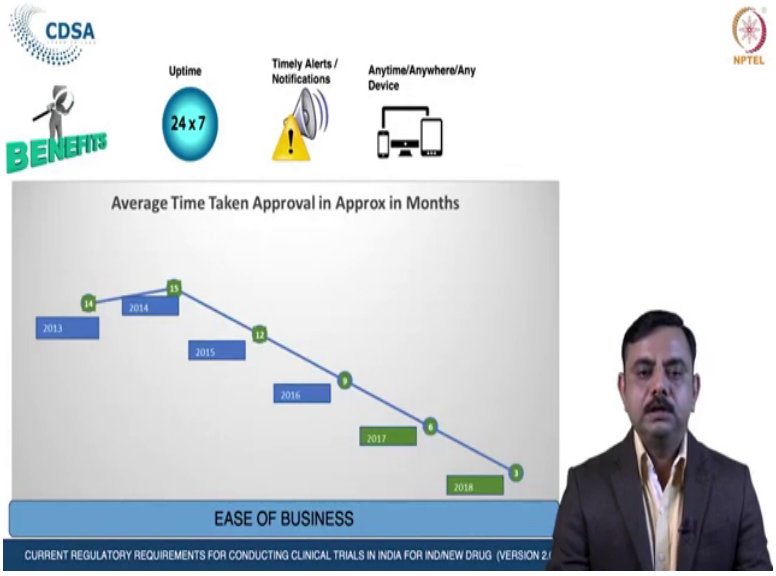

So, earlier we have seen the as I have mentioned there were lot of time and lot of pendency was with the CDSCO. And it was if we see in 2013 and 14; it would be taking 14 months 15 months or maybe the 2 years to get it the clearance with the SUGAM's. We have seen that in 2017 and the timeline was the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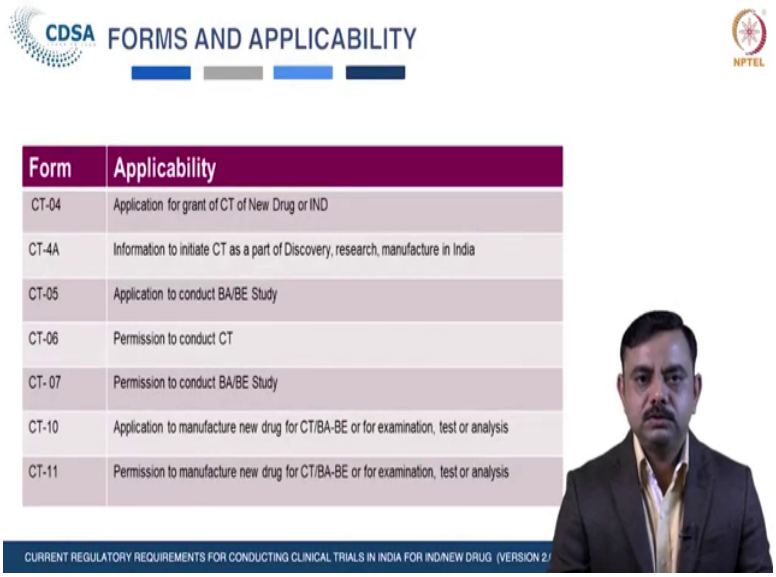

So, which in for which forms you can apply on to the SUGAM and which are the portal presently functional onto the SUGAM; let us have a look for this. So, these are the forms. So, the CT 04 which is application for grant of clinical trial of new drug or IND. We have seen this all the forms CT 4A, CT 5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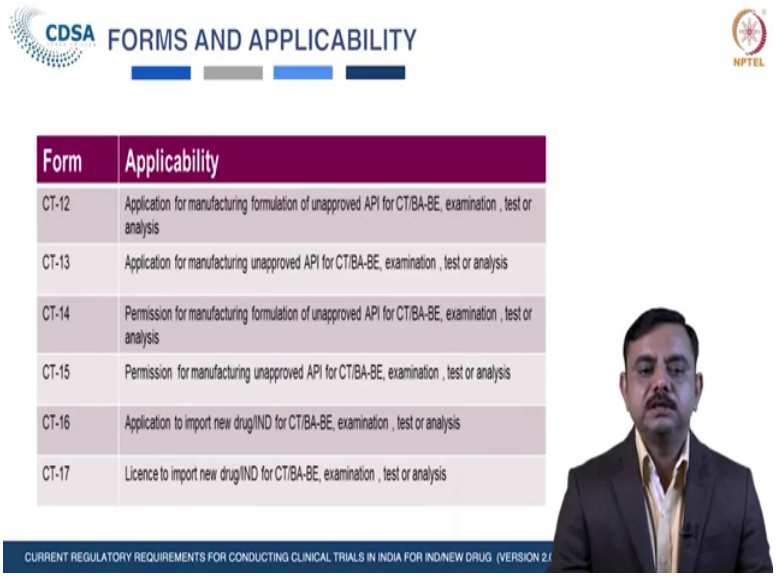

And these are the forms CT 12, 13, 14, 15, 16 and 17. So, these forms and these forms are now functional you can apply through the SUGAM online.

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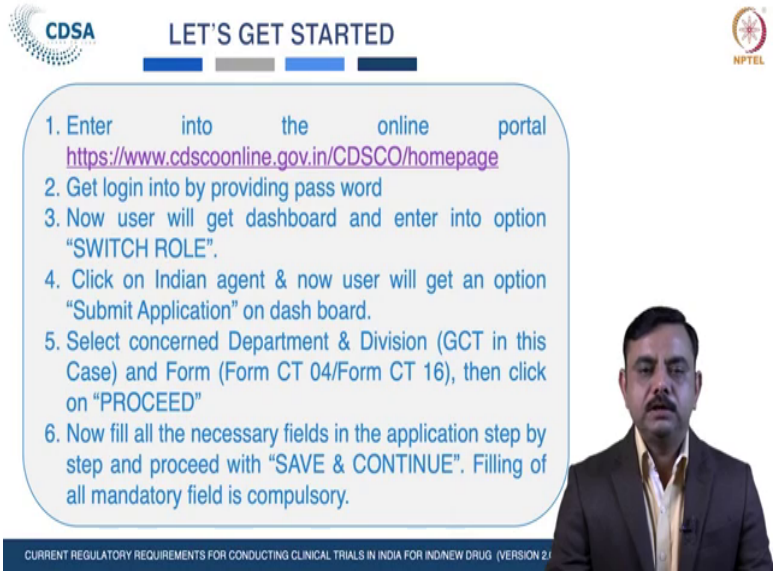

So, let us see the what is the actual process. As I have mentioned you have to enter into the online portal that is a CDSCO online dot gov dot in for the medical device it is a different it is the CDSCO md dot gov dot in. So, that might have been covered into our first course that is regulatory requirement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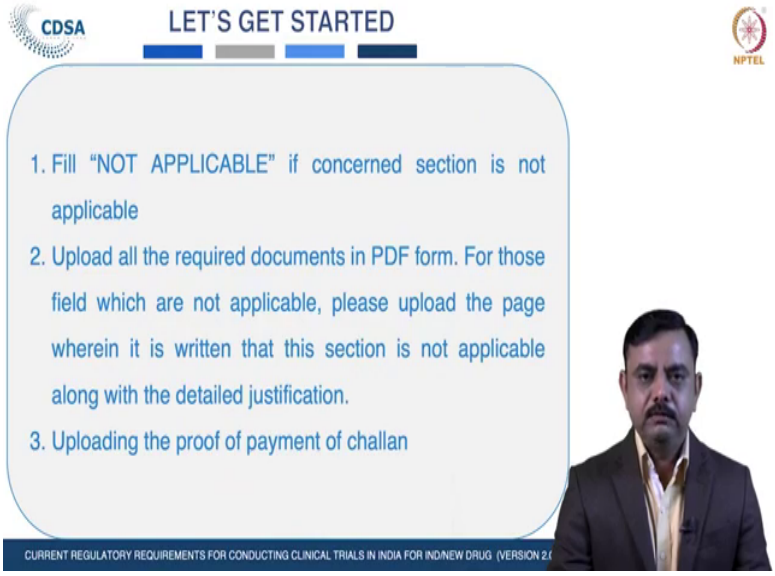

And wherever there is a no applicability for example, if it is given whether the CT whoever has been asked or not. And if you do not have the document that you should not have to blink you should not have to leave it to blank, you have to submit the document mentioning it is not applicable.

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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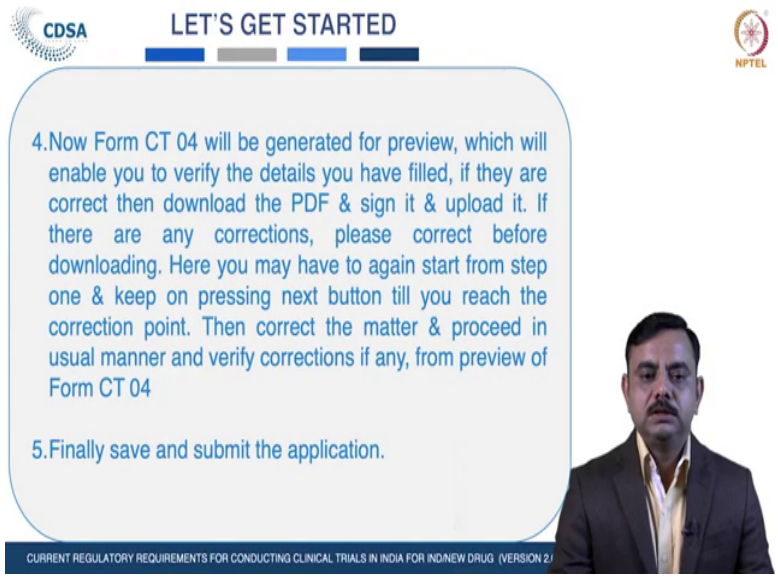

See if we take the example of form CT, then it will be generated for if once you have submitted the CT 4. It will be generated for the preview which will enable you to verify the details you have filled.

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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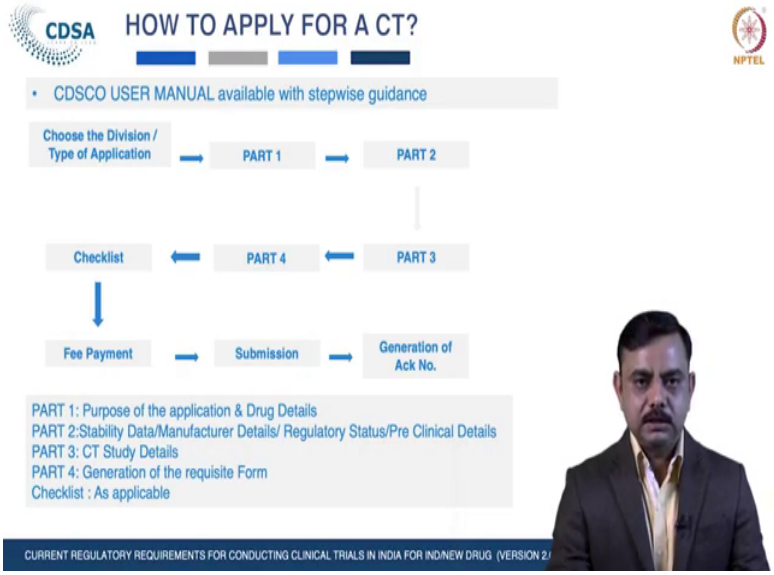

So, this is the pictorial diagram, what I have shown here, how to apply for the CT? So, you have to choose the division what I have mentioned then there are 4 parts part 1, part 2, part 3, part 4; part 4 is this all the information you are required to fill. Then there would appear a

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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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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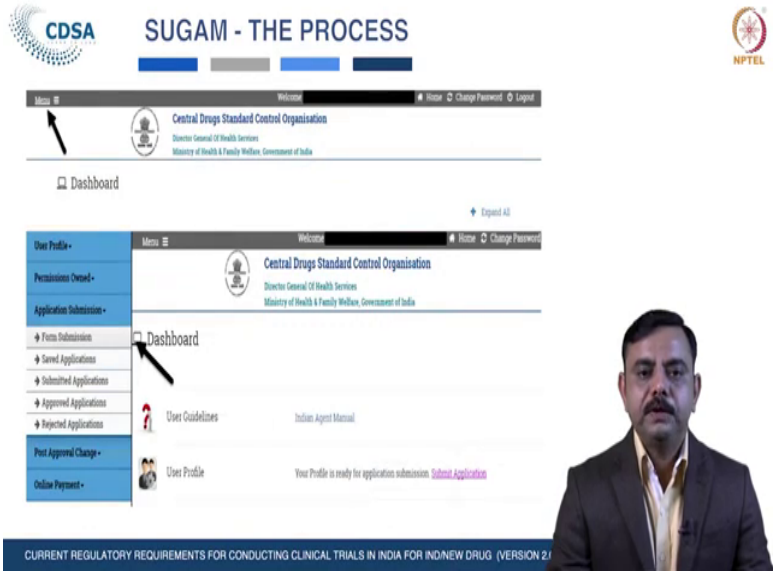

Then you have to select the menu and where it will appear the dashboard also, in that dashboard. There are various options are given for the form submission for the application you know for the track of the applications. If you would like to see the what are the approved application that also that are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

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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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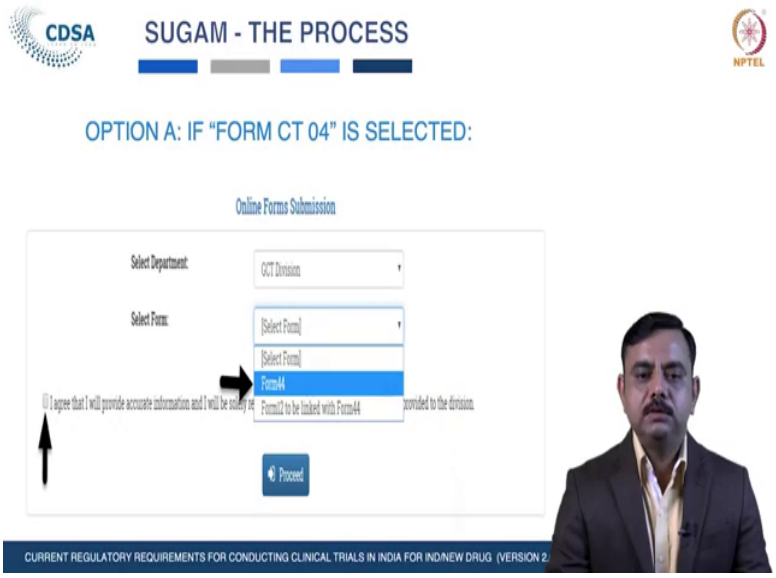

Then its time to submit the form. Once you have selected the type of application, accordingly you have to select the form for the clinical trial you know earlier it was a form 44. So, now, it is a form CT. So, wherever it is showing that form 44 you have to upload the form CT 04; because it has now not 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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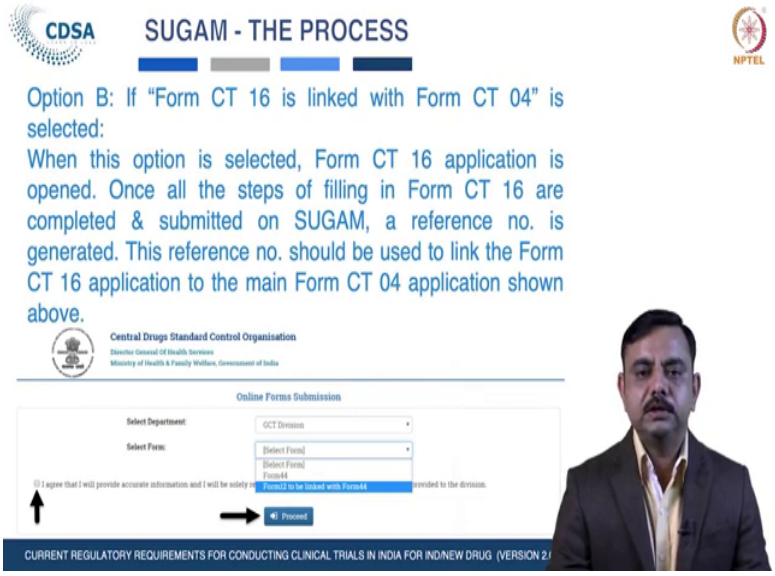

So, if for the test license as we know earlier it was different form now it is a different form. And, if form CT 16 is which is related to the test licence if it is linked with the form CT 04 it has to be selected, when this option is selected from then form CT 16 application is open. When once you open 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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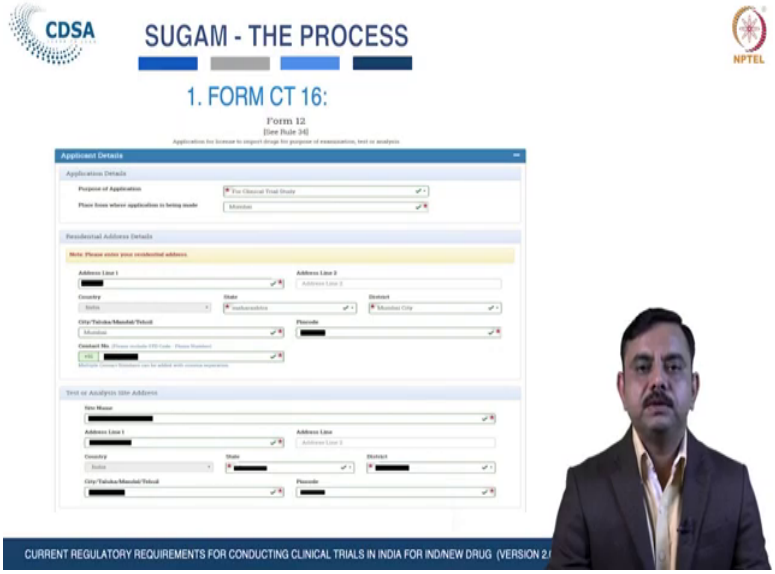

So, we can see these are the steps and this is the process this will appear, when you open this form 16.

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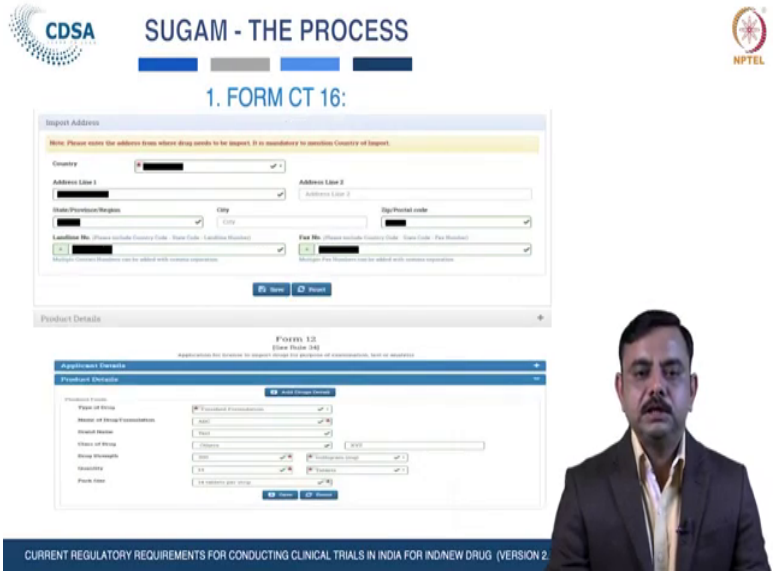

As I have mentioned the steps, we will see it in brief. The step 1, you have to fill the form.

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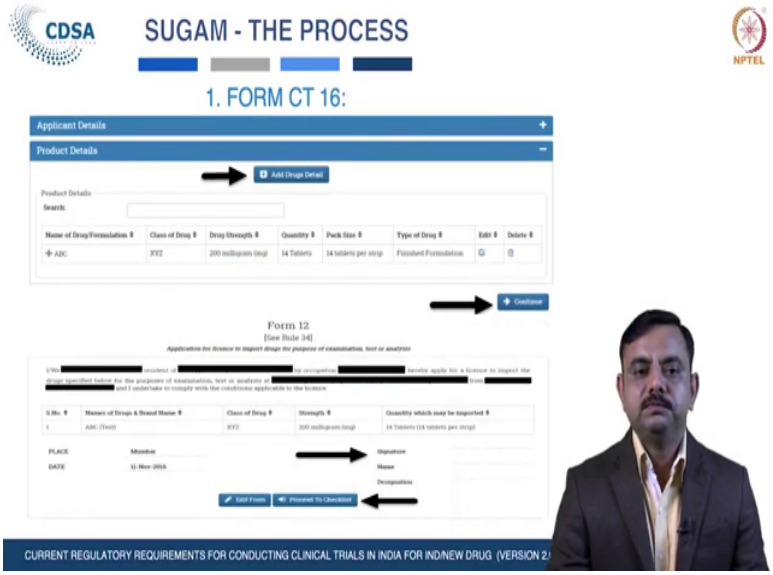

Then the step 2, you have to preview it whether you have correctly filled or not. Then it will appear the checklist then you have to fill all the checklists mentioning that you have submitted the documents or not. Then you have to submit the challan of the requisite fee what you have paid through the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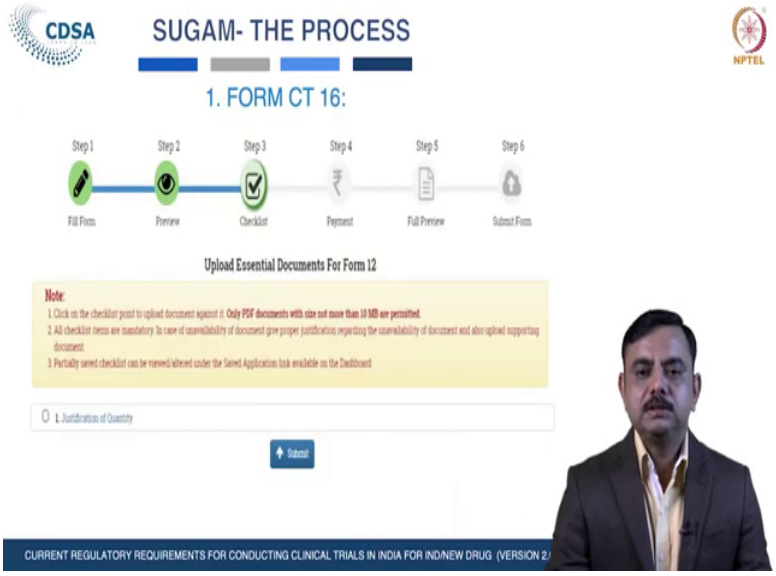

And in the last stage you have to click the submit form option also. Otherwise once you have filled all the information and if you have not submitted, you will it will not reach to the licensing authority. So, the final is the submit button.

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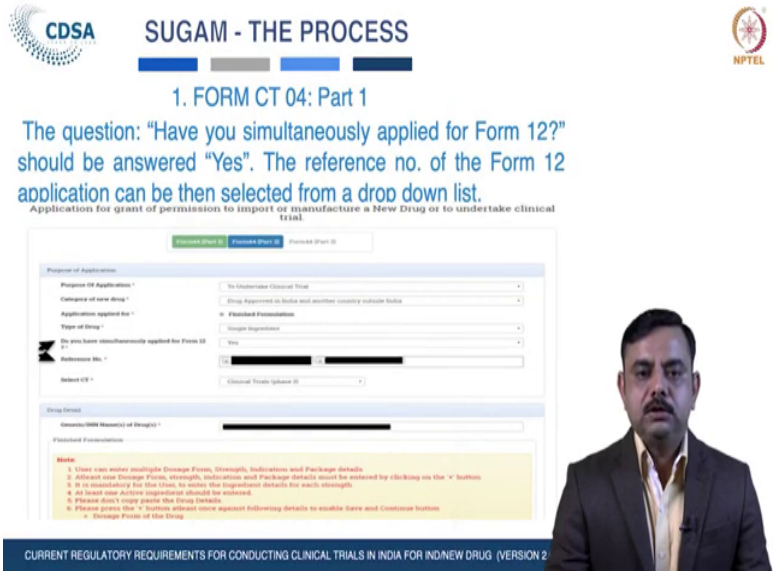

As I have mentioned there are 4 parts. So, this type of part will appear for the form CT 04; the part first you can see this this information you required to fill for part 1.

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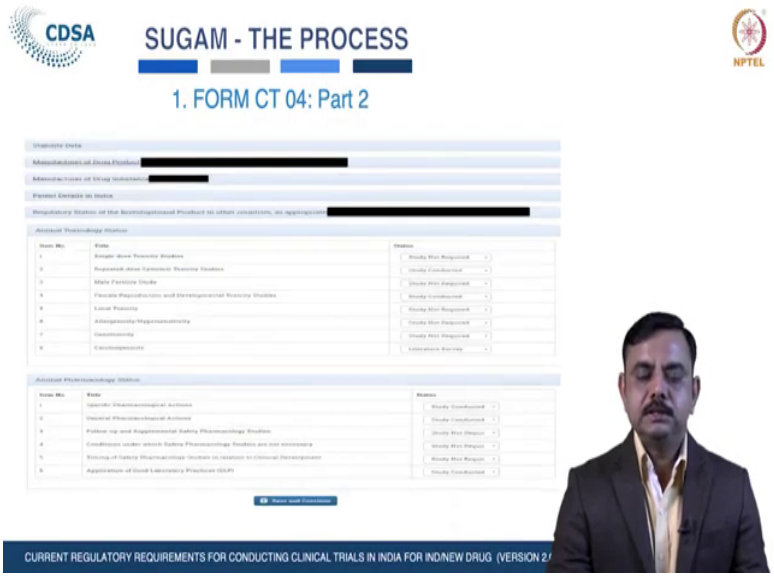

Then this is for the part 2. So, all these details whatever applicable you required to fill the part 2.

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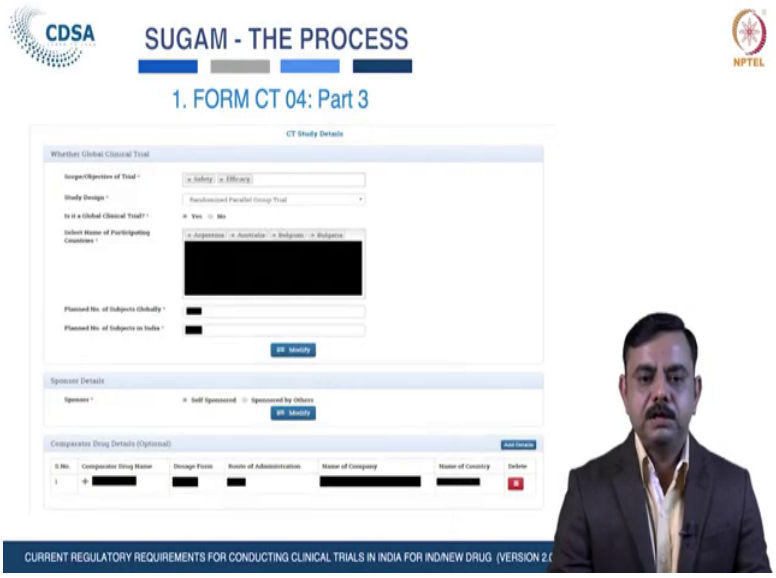

Then the part 3, this type of you know format will appear.

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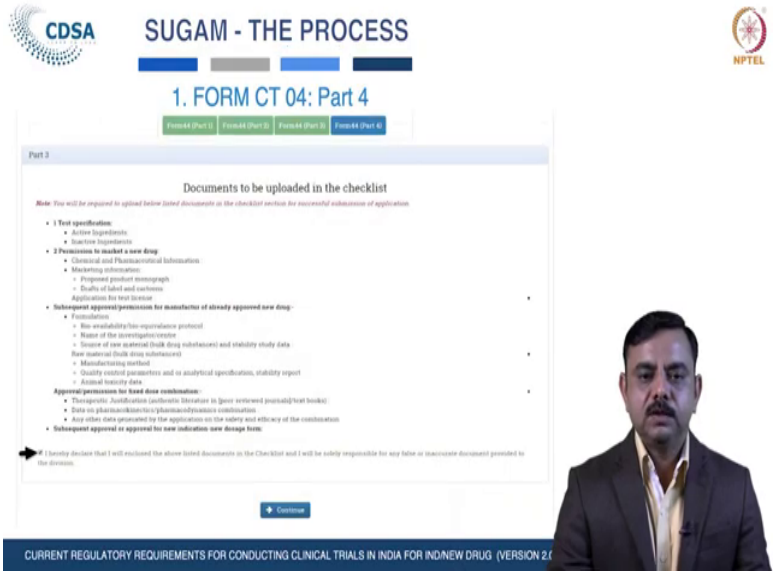

In the last that is a part 4, which is related to the documents to be uploaded into the checklist. So, with respect to you to your application the checklist will appear and you will be asked you will be requested to upload the document given in the checklist. Again you have to continue it, till you get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

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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.

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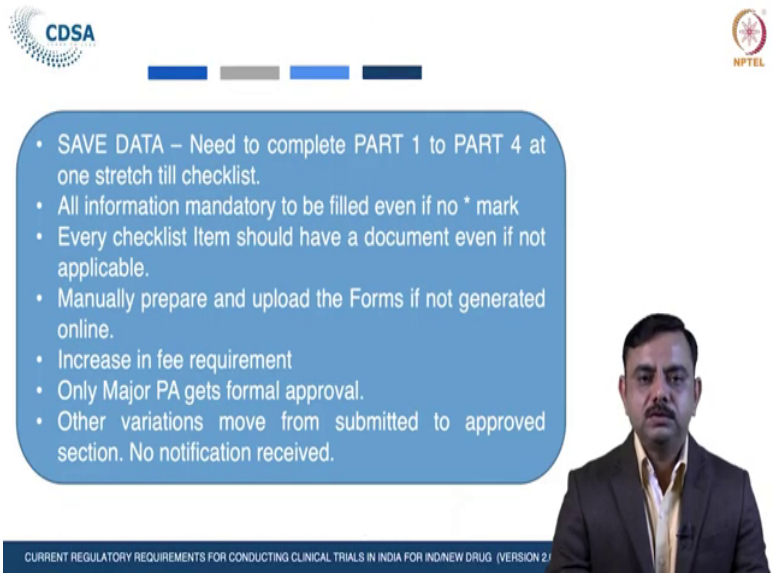

So, whenever you are filling these applications, you required to save all these data like we have seen part 1 to part 4 is there and again there is a checklist. So, so as I and when you are filling this part 1, part 2, part 3, every time you required to save it otherwise if you do not save it then there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

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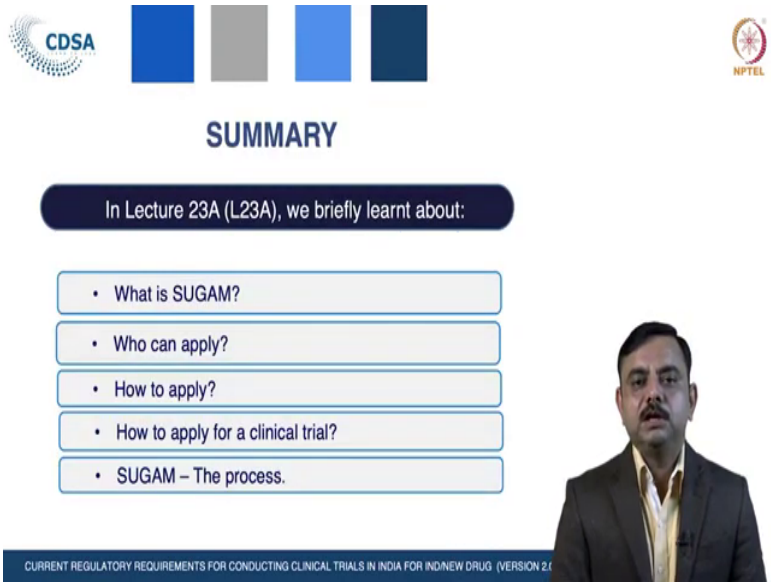

I hope that you have understood all this. And now to this lecture 23, I know that you become a more intelligent. And, I think there is no need of asking you the question and checking your memory even though we will continue it in our 24th lecture.

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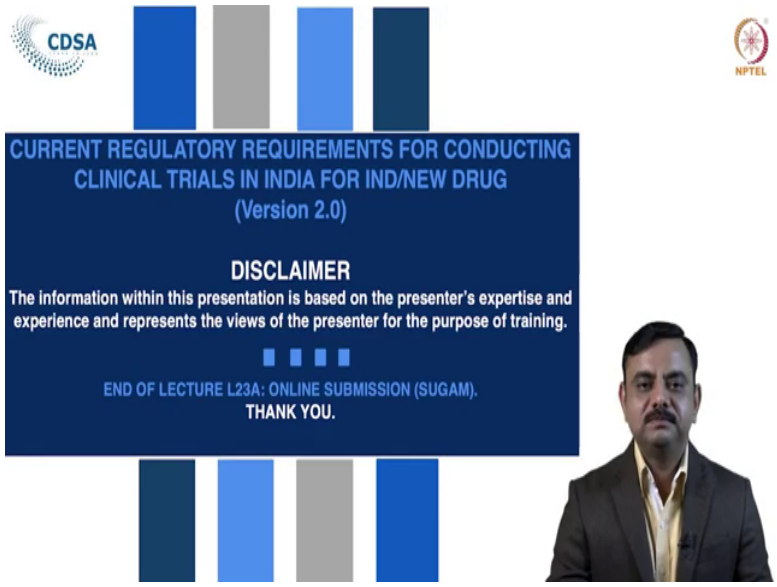

So, we will meet in our next lecture that is a in lecture 24, till then you take care and bye, bye.

Thank you.