**Current Regulatory Requirements for Conducting Clinical Trials in India for IND/New Drug Version 2.0**
**Department of Biotechnology**
**Indian Institute of Technology, Madras**

**Lecture - 01**
**Courses Overview**

[FL] Welcome to the online course Current Regulatory Requirements for Conducting Clinical Trials in India for IND, Investigational New Drug and New Drug. I welcome you all to the joy of learning. This course is a new course. We have named it as Version 2 because the first online course which is current regulatory requirement for conducting clinical trials in India was launched in early 2019. Around 1047, 1047 people have registered for this course and around 222 participants have taken exams, 13 have fared well with gold, 90 have got silver and 75 have scored elite class. This course was passed by majority of people 217 and only 5 people had an unsuccessful attempts.

So, from this course 1, we had we have received several feedback and those feedbacks were studied in detail and we have planned for this course to be revised. But luckily in 19th March 2019, the new drugs and clinical trial rules was released by government of India and that gave us a more impetuous to have this new course which is the current regulatory requirements for conducting clinical trials in India for IND, that is Investigational New Drug and new drug.

We also have another course which is launched along with this course and that is on medical devices. That course is known as regulatory requirements from medical devices including IVD that is InVitro Diagnostics in India that is also a version 2 because the earlier course was launched in early 2019.

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Now, this course when we designed this course, we developed this course; we had several discussions and this course was its lot of effort by the many of the people. It is primarily developed by CDSA, Clinical Development Services Agency which is an extramural unit of Translational Health Science and Technology Institute, THSTI which is an, THSTI is an autonomous institute under Department of Biotechnology DBT and it comes under Ministry of Science and Technology, Government of India.

This course content were primarily developed by CDSA and CDSCO. So, the CDSCO plays a very critical role and a very strong role in this course. So, many of the course lectures were actually written by regulators, they have been reviewed by regulators and they have been recorded by regulators. We have majority of regulators taking up these lectures.

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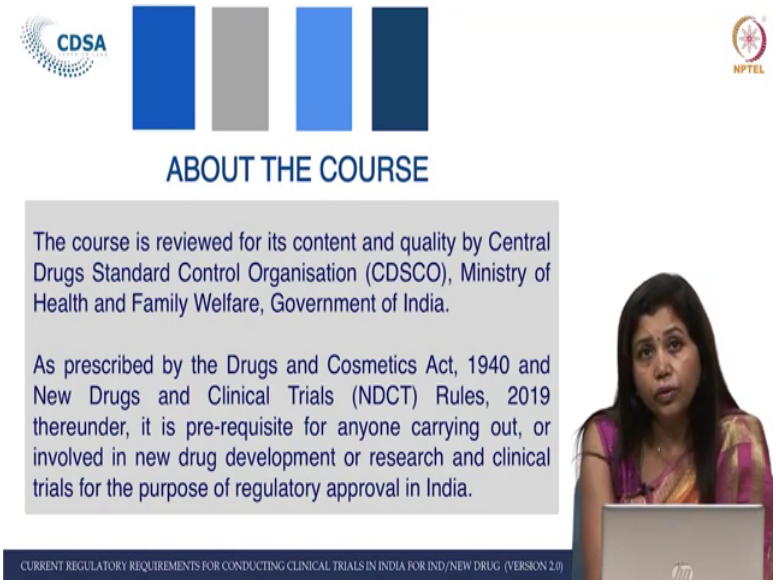


So, as I mentioned the course has reviewed for its content and quality by the Indian drug regulators CDSCO, Central Drugs Standard Control Organization which is under the Ministry of Health and Family Welfare, Government of India.

This course has several faculty, several faculty have taken lectures. There are around 24 lectures, it is a 8 week online course and we have a disclaimer for all the lectures because the information which is provided in this course and within this presentation is based on presentor's expertise and experience and represents the views of the presenter for the purpose of training. So, this course as I mentioned was why it started or why we had thought about it

We are actually contemplating about our revised version of the course and as I said earlier fortunately the new drugs and clinical trial rules was released on 19th March. So, as you know that as prescribed by the Drugs and Cosmetic Act 1940 and also the New Drugs and

Clinical Trial Rules, 2019 there under. It is a prerequisite for anyone who is involved in clinical trials new drug development to know this rules and regulations if they are planning to submit any document or seeking any regulatory approval in India.

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So, in past in recent years there have been many changes, lot of amendments have come in the field of clinical trial as well as new drug approval. And the regulations as you know are dynamic in nature they keep on changing. So, we have tried to address this to a great extent. This course will keep revising as and when new information comes in and your feedback as such is very important to make this more content based course. So, this course we have tried the most important thing is that I have always faced people telling that regulations are difficult to understand, it is tricky, it is not easily; it is easy to misinterpret or have confusion related to that.

So, we had tried our level best to make the language as simple as possible and make it as the examples or cases wherever possible, we have tried to do that. That is the reason, we have always taken help of the current regulators as well as formal regulators to take this lecture sessions and you will you can feel them that what is their perspective about that. So, when you hear that or you from them you will have I think you will have a better clarity to this.

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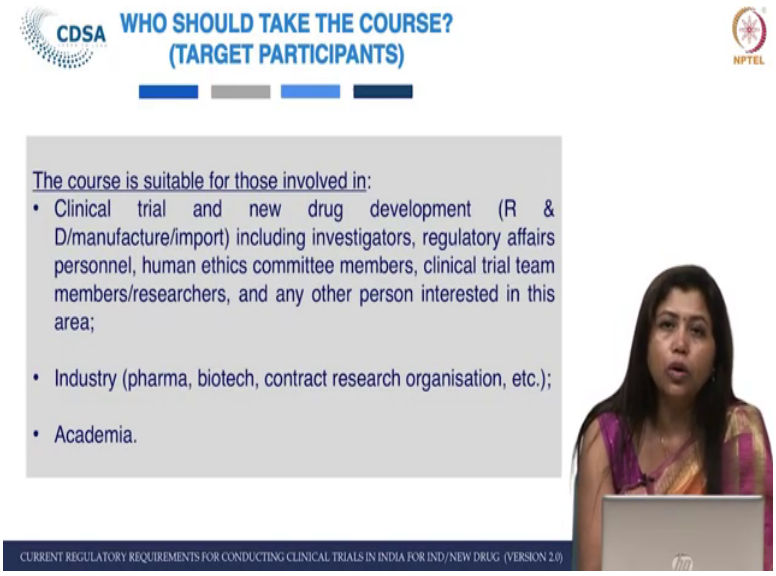


So, now the question who should take this course, who are the target participants. According to us, anybody can take this course, but this course might be more beneficial to people who are working in these areas, specially say clinical trial, new drug development maybe the person working in research and development, maybe manufacture maybe import including investigators, the clinicians, the regulatory affairs personnel's. The people who are the ethics committee members, human ethics committee members and many CRC like Clinical

Research Coordinator, CRA Clinical Research Associates any person who has working in this area can benefit from this course.

If you ask industry, I think Pharma pharmaceuticals bio biotechnological industry; the CR industry, the contract research organization. Over the past few years, we are seeing that many of the academia has getting interested in taking up this clinical trials and new drug approvals. And for them also, it is a unique thing for them to know about this through this course they can take this.

So, the earlier course which was launched in early 2019 was a 4 week course with the 12 lectures. This time the New Drugs and Clinical Trials rules is quite a big; it is a big course and even with 24 lectures, we felt that we could have done more. So, it is a 8 week course, so; that means, you will have 8 assignments, exam, if you are willing to take an exam, I will suggest you should take this exam because umm it will help you and maybe the certificate might be beneficial to you for your future and it is a unique experience. And I have spoken to many people who have taken the exam last year and if you have seen that many people out of 222 who took the exam last year, 217 have passed. So, for them I think so, it is a great journey and if you are not willing to take an exam, this course is free of free for you. So, you can just enjoy the course.

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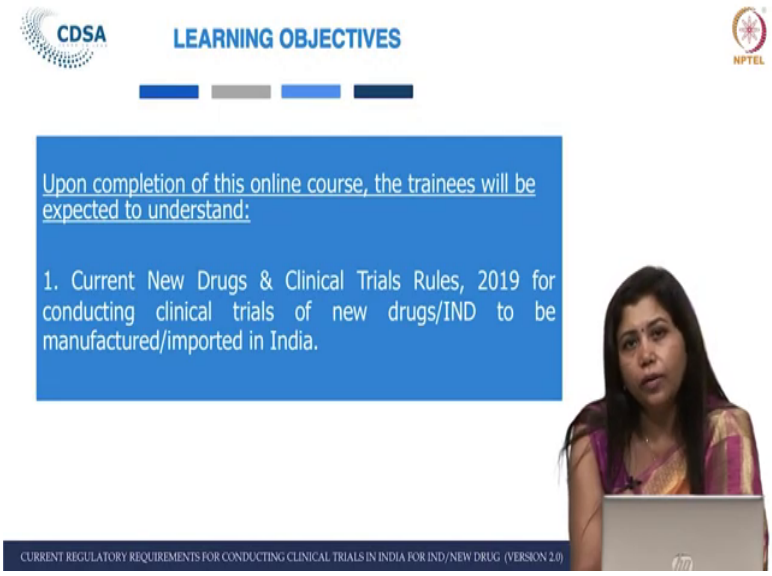


So, what will you learn after 8 weeks is that we have tried carefully to keep the lectures in a chronological order based and then interest of you. So, you will learn about the New Drugs and Clinical Trial Rules in a better way. You will understand how the things are done when you manufacture it when you import it.

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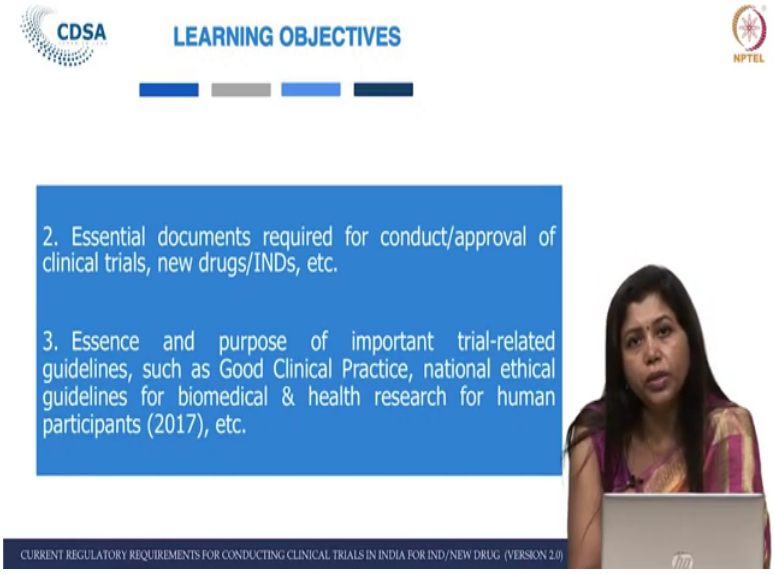


You will also know about various essential documents which are required by the regulators when you want to say take any approval for clinical trial from the CDSCO who is who are the Indian drug regulators. You can also know how to conduct trials specially, new drugs IND investigation and new drugs. You also have chance to undergo something like the good clinical practice, very important lecture in this course. You also have a chance to understand the ethics guidelines. ICMR has two ethics guidelines which are national ethical guidelines for biomedical research biomedical and health research for human participants in 2017.

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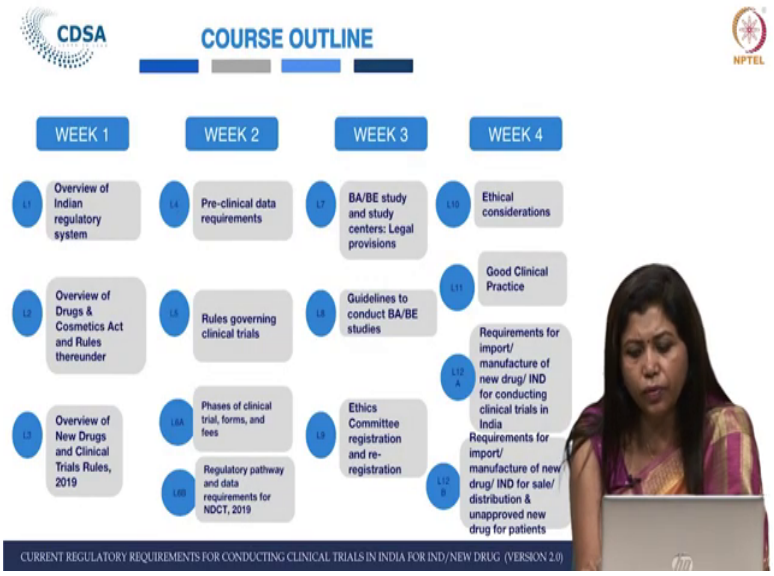


So, basically we will cover this. So, out of the 24 lectures that you see here, we have as I mentioned that we have kept it quite chronological to see but there are good chances that some of the informations might be redundant in nature repeated. So, it is purposefully being made redundant. So, that you remember things better and it is not just because of out of sight. So, we have carefully reviewed, but if you feel that something is could have been add something are missed out, please let us know.

So, we will begin with the first week, all the week we have three lectures. So, first week we have the course 1 begins with the lecture 1, Ll we call it. We take you through the Indian the regulatory system mainly how a regulatory system, how do Indian regulators work. So, it is an introduction to the Indian regulatory system. Then many people have heard about Drugs and Cosmetic Rules and Act. So, we will first take you to Drugs and Cosmetics Act and then we will take you to the rules and there under all the things which comes under DNC Act Rules.

Then we have an overview type of lecture which is brief about the New Drugs and Clinical Trials Rules, 2019 very brief overview. So, that you know what you are going to study in detail.

Then second week, start with pre clinical data requirements. We talk about animal pharmacology, animal toxicology. The lecture 5, we talk about various rules. There are several rules which govern clinical trials in India as well as globally. The lecture 6 is divided in two points; 6 A, 6 B we call it, phases of clinical trials the all the phases and all about the different regulatory requirements for each phase like phase 1, 2, 3 and also we talk about data requirements which are necessary for clinical trials.

Now week 4; week 3rd. So, last year course, we did not address the bio availability and bio prevalence area altogether. So, this time we have two dedicated lectures for this, the people who are working in BA BE area. I think so it is a good news for them because they got to hear from the regulators, what are their perspectives regulators perspectives about BA BE study and the study centers which will really benefit you and lectures 8 teaches about the BA BE guidelines. It this also is going to be helpful for people who are working in the area of BA BE let us say, bio availability and bio prevalence.

Lecture 9 which is L 9, talks about Ethics Committee registration. This Ethics Committee is about human ethics committee also it talks about re-registration, this was apparently covered in last lecture. This time I think so we have done some improved details how data has been added. Lecture 10 is an interesting lecture, it is about ethical consideration.

So, here we discuss about the ICMR guidelines which I just now mentioned earlier 2017 two guidelines were released, they have briefly discussed here and I am sure all the ethics committee members will appreciate this lecture very much. Lecture 11 is about Good Clinical Practice like I was mentioning you, these two are some added things which are in L10 and L 11. And this here we speak about the GCP guidelines by CDSC 2001. We also take you little bit overview about the ICGCP.

The lecture 12 which is the last lecture of fourth week is about the Requirements of Import, Manufacture of new drug and IND which is investigational new drug.

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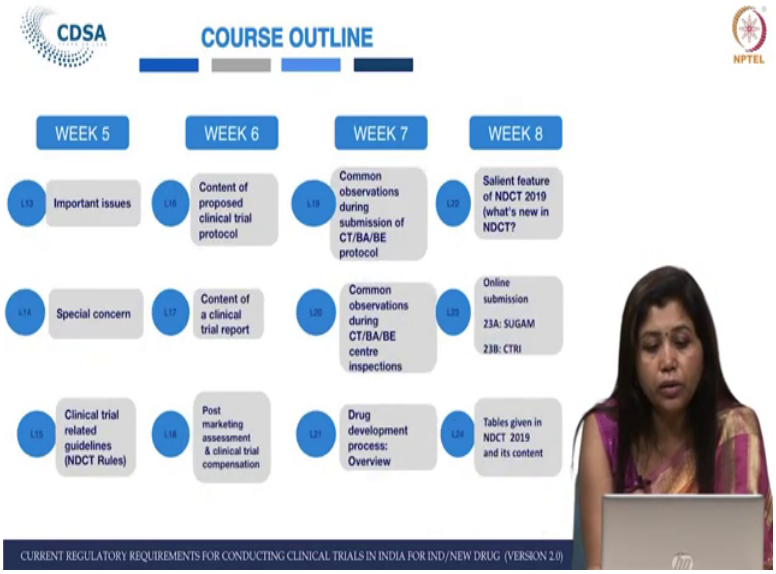


Now, we have the four more week left remaining. So, every week we have assignments. The assignments are based on 3 lectures which are taught during those during that week. So, week 5 we talk about some important issues which we felt were missed last time.

Lecture 14 talks about we talk about discuss about the special concern and this was earlier there in the earlier course. We have tried and see what can be the best done. The lecture 15, we talk about the various guidelines which are related to clinical trial like earlier lecture, we had spoken about all the rules which are related to clinical trial. Here we are talking about all the guidelines that are related to clinical trial.

Now comes the week 6, we discuss about the protocol. So, we discuss how what should be the content of the proposed protocol which is very important when you conduct clinical trial. And then we talk about the next lectures; lecture 17, we talk about what are the content of the clinical trial report that is also extremely important. The CSR, the clinical study report is the report which you submit to the regulator after the trial is over and it is very important to understand the regulators perspective of what they expect from both protocol as well as report.

I am sure that these two lectures, L 16 and L 17 is going to help many of the people who are looking in this area. Lecture 18, Post marketing assessment; post market assessment has been addressed in the new drugs and clinical trial rules quite briefly and we will cover them.

We also discuss about the clinical trial compensation in detail. Then we have last two weeks remaining, week 7 and week 8. Week 7, we have a very interesting lecture which is L19. We talk about all the common observations during the submission of clinical trial protocol which is pretty interesting one because it will help you to find out what regulators feel at their end when they when you accept protocol and what are the things you should do and you should not do and this lecture is definitely going to help many human ethics committee members, investigators, pharma, biotech or even industry academia a lot.

Similarly, sites for hospitals and various ECS, it is a very interesting one. The L 20, the lecture 20 talks about the common observations and during the clinical trial or ethics committee site. There is an inspection what the regulative find out what is the most common thing what they see whether it is the protocol divisions or documentation lacking at there you know they all are discussed there. Lecture 21 is about new drug development and discovery. We felt that this can be adequately addressed here. Lecture 22 is like we started with lecture L3, let us talk about the important points. Here we speak about what is new.

So, we cover what was not existing at all and what are the things which the new drugs and clinical trial rules have addressed. So, it is a very pretty interesting lecture, lecture L 22 and online submission we have SUGAM online submission and which is 23A and we have

another online submission which is CTRI, Clinical Trial Registry of India. And that is pretty interesting you know lecture. So, you will surely enjoy these lectures.

Lecture 24 is a last lecture of this entire course and it talks about all the tables that you see in the new drugs and clinical trial rules. The contents are described in little detail. So, that you understand the tables better.

This course has many people many faculty was spoken like Professor Y.K Gupta, he has spoken; he has taken lecture 22 and Dr. Nandini Kumar, she has taken lecture 10 and 10. The entire CTRI team, Clinical Trial and Registry of India the entire team, Dr. Vishnu Rao, Dr. Mohua, Dr. Atul, Dr. Tulsi, they have taken the CTRI lecture. So, you hear from horse's mouth all the CTRI people tell you how to work with the CTRI submissions.

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So, as you know this course or any course the matter is a matter of team effort, it is not possible to do that alone and maybe a small team of ours. So, the CDSA training team only has 3 people including me. So, it is very tough for us it is only possible because few people have really worked hard along with us and made it possible.

So, I think a big applaud should go to Dr. D. K. Sable, Dr. Dhananjay Kumar Sable who is an assistant Drugs Controller at CDSCO headquarter in New Delhi who had been working for past 1 year with us earlier course as well as this course to make it possible. It was really lot of effort by him and I should never forget Shri Arun B. Ramteke who is a former Joint Drugs Controller of India CDSCO headquarter and he is a consultant regulatory affairs at CDSA and he has been a backbone with both the courses. He had started with the initial drafting of the lecture which is the which is a crucial or a cornerstone for this development. So, these two people have really contributed and I must not forget my team members Ms. Vandana Chawla who is a training manager at CDSA, Jitender Ahuja who is our training coordinator. They both have really put in lot of efforts to see what you see today, so its lot of effort by team.

I also thank Professor Usha Menon who is a mentor and strategy leader at CDSA because she has been constantly working with us and mentoring those what she feels from a perspective of a user or a participant and had been a strong support behind us.

I also thank Dr. Nitya Wadhwa, Assistant Professor at THSTI and faculty in charge at CDSA. She had been also very supportive to make this possible, clear all the hurdles that we face because of them I think so it is possible. Anyhow any such course requires a huge commitment from the management and I am really thankful to Professor Gagandeep Kang who is the executive director of THSTI.

She had been a very strong support and it was her vision to take this forward for this first course launch as well as the subsequent launch of version 2. So, they are really have contributed in building up this course and we have many more thinking about many more such courses in the way forward. There are various contributors as I said Dr. Nandini Kumar

who is a former DDG and senior grade at ICMR Indian Council of Medical Research who has taken this lecture L 10 on ethical considerations.

Professor Y. K. Gupta, he was he is the advisor project advisor at THSTI and CDSA and had been the former dean of All India institute of Medical Sciences, New Delhi and was heading the Pharmacology Department at All India Institute of Medical Sciences New Delhi for long time.

So, he has been a great support towards this and Dr. Vishnu Rao and the entire CTRI team as I mentioned they took lecture 23 B which is which includes Dr. Mohua, Dr. Atul and Dr. Tulsi. This course is on regulations and we are talking about current regulatory requirements. I doubt whether this course would have been successful without a current regulator. So, I think so the current regulators contribution to this course should be applauded.

They are terribly busy, they have huge commitments and they have really no time. In spite of that I think so, everybody, in spite of the hectic schedule, they had worked with me over a period of say 1 year to few months and recorded this lectures on Saturdays, Sundays, holidays just to make it possible. So, I really salute to their commitment because, they believed along with us that knowledge is for sharing and if they share their perspective as a regulator I think so, the nation will benefit from it.

So, I must thank the leader Dr. V.G. Somani who is the drugs controller general of India for allowing us, supporting us and strongly promoting this online course. So, it reaches you. So, thank you Dr. Somani. Dr. K. Bangarurajan, I cannot forget the first support which I derived from him. So, when we started this course way back in 2018 planning to roll it out in 2019, it was the first time and we had several hurdles. We did not know how to do a course we literally learned from scratches and it was a strong support of Dr. K. Bangarurajan to hold our hand and make it possible. It was not possible without him.

If he had backed out even for a single day, I think so, we would have crumbled down. I also thank Dr. Vishwaraj Reddy who has who is the joint drugs controller presently and that time in the course 1, he was the DCGI that time. He has been a strong support in the earlier course

as well as this I thank them. Of course, I mentioned that this course has got lot of contribution and efforts from Dr. Dhananjay Kumar Sable who is assistant drugs controller at CDSCO headquarter And he has literally worked day and night changed many slides and have taken lot of pain and efforts along with his entire CDSCO team at CDSCO headquarters to refine them and so that we can ensure that only correct information reaches you.

I also thank Dr. Rubina Bose who is the deputy drugs controller west zone at Mumbai of CDSCO. She is very busy person, but in spite of her busy hectic schedule, she took her weekends off, holidays off to record for this course. I cannot thank her enough because when you have very less time and you try to do it out of lot of efforts personally, it really makes lot of difference to the team spirit.

I also thank all the CDSCO team members who had contributed and I really feel proud that we are all been able to make this together for a greater public good. This course was first conceived and delivered during our first early session with NPTEL, and IIT, Madras. Since 2018 that we have been working with Ms. Bharati from IIT, Madras the entire NPTEL team, they have been a very strong support, very prompt, very positive, very supportive. I have never heard them saying no for last 2 years and unbelievably they are effective and prompt. So, thank you Bharathi.

We have this time Mr. Mahesh who has been helping us with all the recordings, editing, post editing. We have Lakshmi who is helping us with all our teaching assistants and assignments, I am really thankful to them. Majority of the lectures were recorded at IIT, Delhi and IIT Delhi's entire team is very supportive, we had huge issues of getting time of the regulators, working on a weekends; they have really spent blood and sweat with us in getting time from people. So, I thank Mr. Taneja and his IIT Delhi team. Mr. Sanjay, Mr. Mahendra, they have really contributed. So, without that it is not possible.

This time we had IIT, Mumbai also. So, IIT, Bombay we had Ms. Bharati, Mr. Tushar and Mr. Amin. So, they have also contributed in making this because we are not physically present, but they have managed it wonderfully well. I personally feel that their quality of recording that they do and the support they provide is outstanding. I am also thankful to all

the TAC which is Training Advisory Committee members of CDSA who have contributed to this, specially Prof. Y.K. Gupta, Prof. Sanjay Bhatnagar, Prof. Devender Kang, Dr. Vishnu Rao.

Earlier we had Dr. Jain from ICMR, then we have Dr. (Refer Time: 25:10) from SAAS, Prof. J.P. Muliyil who is the former principal of CMC, Vellore. All the TAC members have been really supportive and have understood all the efforts and have reviewed and guided us from time to time. So, any course is a matter of huge efforts from our end once the course is delivered, it is totally to you.

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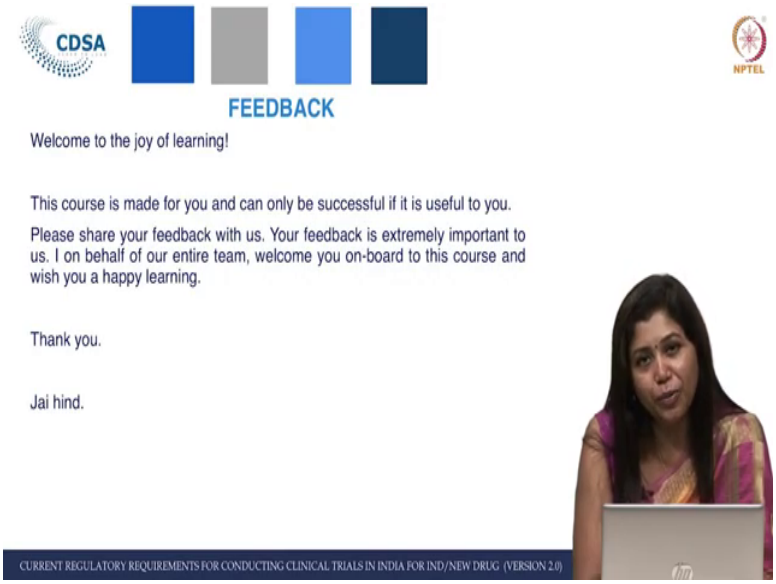


So, I personally feel that once you go through this course, please do not think any of the feedback as a small feedback or a big feedback or a bad feedback or a good feedback every feedback matters to us.

We had I think so, more than 400 feedbacks in the earlier course. We have read each and every feedback with utmost sincerity and we have implemented majority of them in version 2. So, when you write to us please be ensured that we will definitely go through your feedback and we will try our level best to address those. So; that means, your this course matters a lot to us and your feedback matters a lot to us. So, because this course is made for you and it can only be successful if it is useful to you; if it does not make any sense to you, all our efforts will be null and void.

We have learned a lot while designing the first course. It was not a cup of tea; we are still learning even today we feel that we could have done better. So, in the version 3 or in new course which is launched by us, I am sure we will be able to do better. So, please remember, please share your feedback with us. Your feedback is extremely important to us, we would like to know what we have missed, what we should have done better like I thought that we should do more examples, we should do more case studies, maybe some more videos, maybe some areas are left; please write to us.

When we hear same topic from many people may be it is a time for us to add on those topics. So, that is it. All of you I on behalf of the entire team, welcome you onboard to this course and wish you all a happy learning.

Thank you [FL] and [FL].