Current Regulatory Requirements for Conducting Clinical Trials in India

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Lecture - 01
C1L00

[FL]. Greetings from CDSA; Clinical Development Services Agency an extramural unit of THSTI; Translational Health Science and Technology Institute; an extramural unit of Department of Biotechnology, Ministry of Science and Technology Government of India. It gives me great pleasure to welcome you onboard to our online course called Current Regulatory Requirements for Conducting Clinical Trials in India.

This course is our very attempt to initiate the line of online courses from CDSA. Regulatory requirements for conducting clinical trials in India has been a topic of great concern and we receive lot of queries across the nation because there are a lot of questions which create lot of confusions among the investigators ethics committees where they feel that there is no clarity on some of the areas. This course makes an attempt to address those.

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This course is developed by CDSA with and its reviewed and recorded by CDSCO; the Indian drug regulators; Central Drugs Standard Control Organization; the CDSCO and I

am really thankful to all the people at CDSCO team led by Dr. Eswara S Reddy the drugs controller general of India, Dr. K Bangarurajan JDCI, Dr. D K Sable EDCI and entire team of CDSCO to support us in making this course possible. In spite of their hectic schedule and number of commitments they have worked day and night with us so that only the correct information reaches you.

They have in fact, vetted each and every slide and the presentations so that there is no chance of any confusion or lack of clarity in the information that reaches to you.

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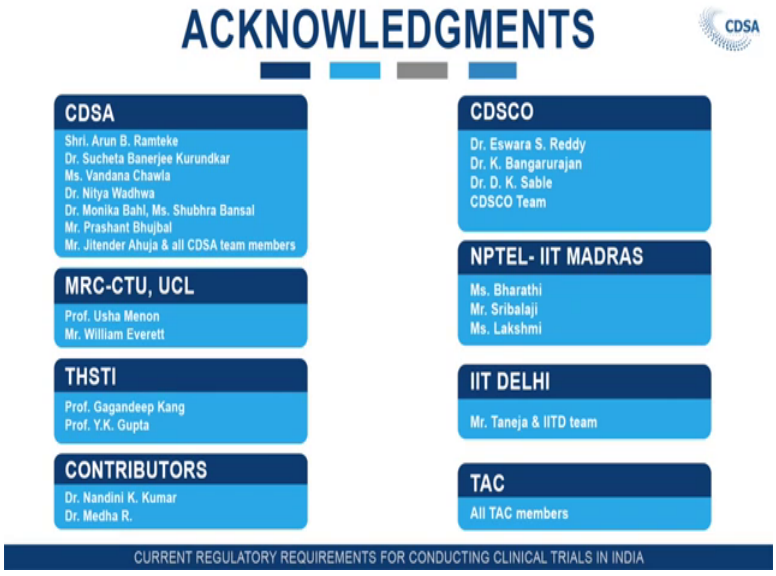

I must thank my CDSA team to make this possible. This course was not possible without the initial development by Shri. A B. Ramteke [FL] who is the former join drugs controller at CDSCO and my team from my team Vandana Chawla, Dr. Nitya Wadhwa and Prashant Bhujbal. The MRC-CTU at the University College of London, Professor Usha Menon and Mr. William Everett has supported us in understanding and making the content more user-friendly.

The THSTI administration has been very supportive of this and I thank Professor Gagandeep Kang and in all members of TAC which is training advisory committee. In fact, this course current regulatory requirements for conducting clinical trials in India was suggested by the Indian drug regulators; the CDSCO as I mentioned earlier the CDSCO stand for Central Drugs Standard Control Organization.

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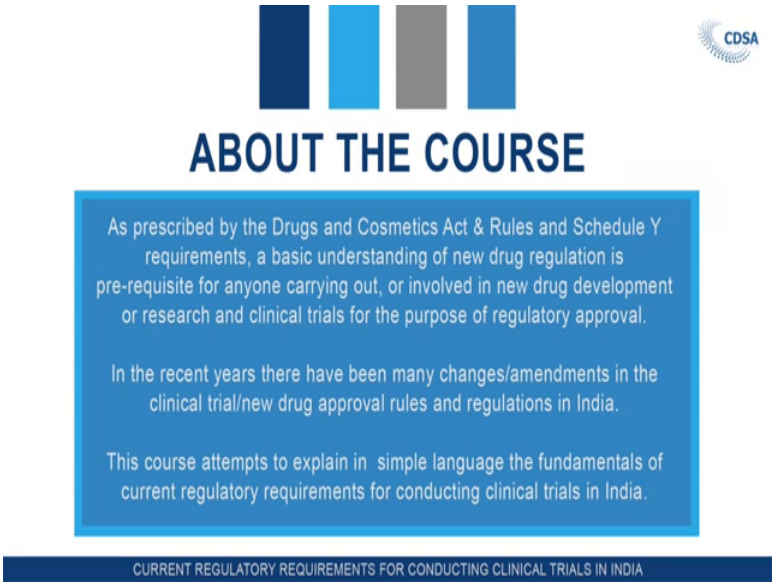

So, it is very very important that as you know that as per the Drug and Cosmetic Act and the schedule Y; the requirements are a pre-requisite for any investigator or ethics committee member or any personnel who are involved in clinical trials to have a thorough knowledge of what it takes to begin or conduct a clinical trial in India; mainly because you involve human being as patients or volunteers.

Especially in the new drug development areas the things are more difficult because they are very challenging. Since 2013; if you know the regulators have been coming up with various guidelines, amendments, gazette notifications so that things become better and better as we move. This course makes a sincere attempt in making this learnings come to you in a simple language and lucid illustrations so that you are aware about the fundamentals or the basics of the current regulatory requirements for conducting clinical trials in India. This course will help you to understand few of the areas which are our core learning objectives.

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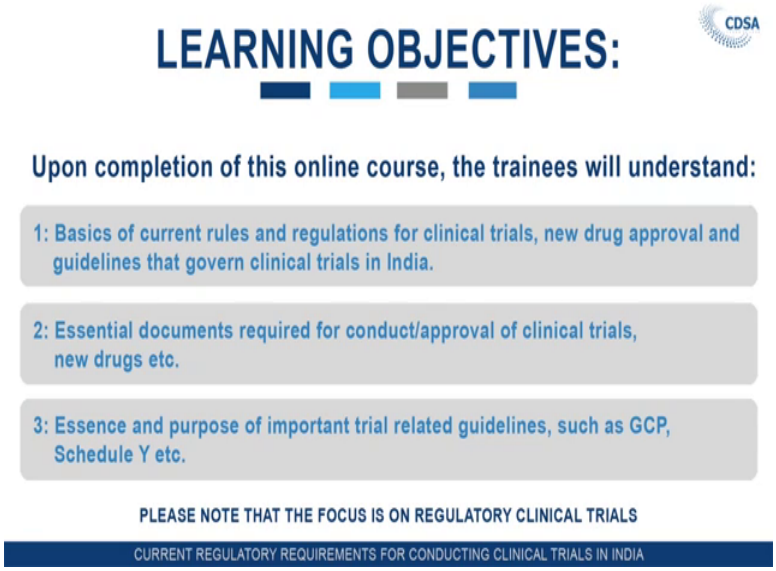

The basics of the current rules, regulations, act, schedule Y which are all related to clinical trials; new drug approvals various guidelines that govern clinical trial in India.

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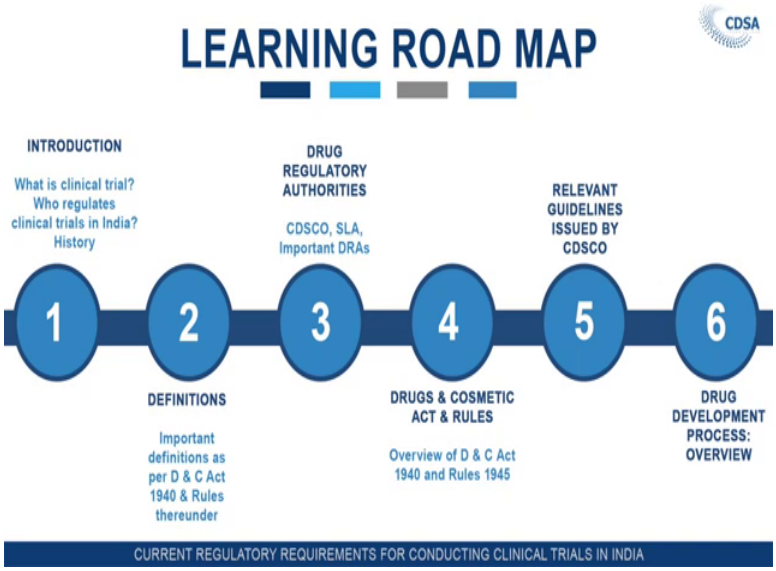

One will also understand all the essential documents which are involved in the conduct of clinical trial. This course also provides you with an essence and purpose to understand the important trial related documents and files.

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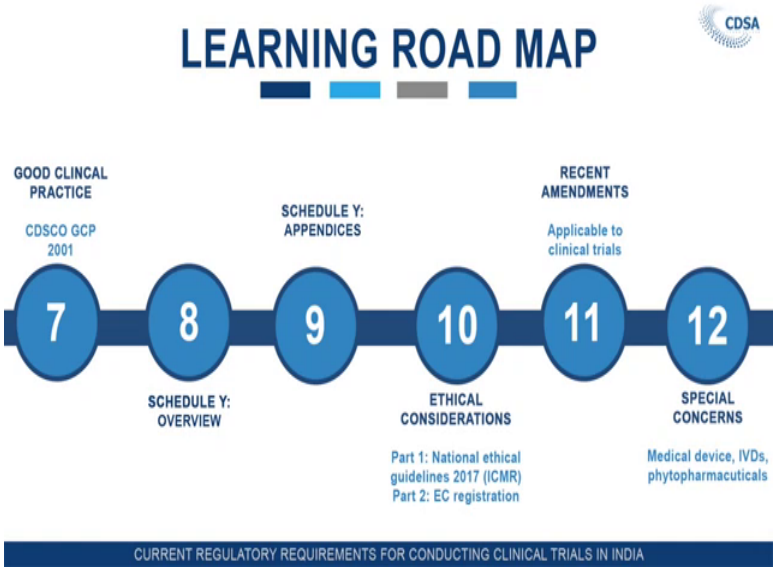

This course give you a very very brief overview with various examples, pictographical representations, question answers in between and puzzles to make you an attempt to make this course an interactive learning; who should take this course?

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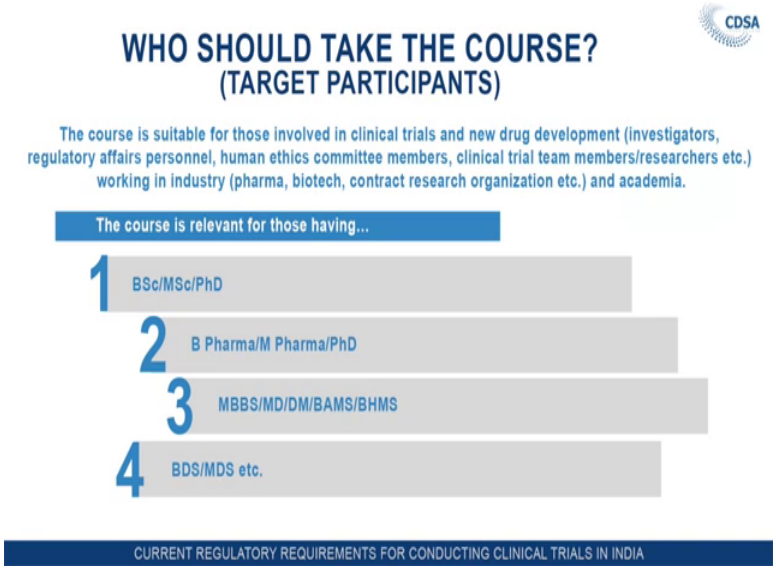

I feel anybody who is interested to pursue in the field of clinical trials, any ethics committee members, any investigators, any clinicians, any scientist, any SME Small and Medium Enterprise, any industry personnel, any academia, any member who will

become a part of the clinical trial team and would like to work in India for current regulatory requirements of clinical trial in India.

They can be from various background; a medico with an MBBS, MD, DM, MCH background, anybody from the basic sciences BSC, M.SC, PhD, anybody from pharmaceuticals B.Pharm, M.Pharm, PhD, anybody from the dental faculty BDS, MDS, anyone who is interested can take this course. This course has been offered free of cost as you know because like NPTEL we also at CDSA believe that knowledge is free and should not be restricted. You should be able to learn anywhere, anytime. If you wish to take a certificate you will have to give an exam which is a proctored exam by NPTEL and if you qualify the certificate is yours.

We feel that this course is only successful if we are able to address all the areas which you felt are necessary for us to do. We tried, we made an attempt to have 12 beautiful lectures in very simple languages took in this course.

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It begins with an introduction, the lecture 2 talks about the definition, the lecture 3 talks about the drug regulatory authorities. The lecture 4 talks about the D and C Act and Rules which is Drugs and Cosmetic Act and Rules, the lecture 4 speaks about the various relevant guidelines that have been issued by the CDSCO from time to time.

The lecture 6 talks about the drug development process; how a medicine is discovered and how it comes from bench to bedside. It gives you an brief overview; when the medicine comes to the clinical phase the lecture 7 talks about GCP; the Good Clinical Practice. The lecture 7 covers a brief overview of schedule Y as well as its appendices. The lecture 10 is extremely important because it talks about the ethical considerations; the ethical considerations cover two parts; the guidelines which was issued by IC mod in 2017 and also what it takes to register your ethics committee with CDSCO.

The lecture 11 talks about all the recent amendments that the regulators have come recently in this area. The lecture 12 is the last lecture and it speaks about the special concerns in different areas when you want to conduct clinical trials. This program or this online course was a distant dream to us until NPTEL was there with us holding our hand in every respect to make this possible.

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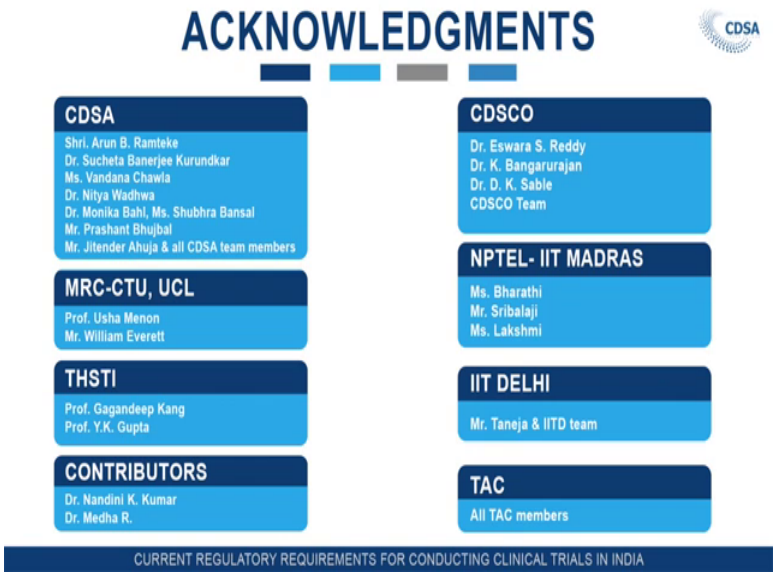

I immensely thank NPTEL and their team both from IIT Madras as well as IIT Delhi to make this possible. From IIT Madras it is Bharthi, Sribalaji and Lakshmi and in IIT Delhi we have Taneja [FL] helping us. Anything which is first is very difficult. It is challenging and we are learning like you. This course can only be successful if you feel this course has made a difference to you.

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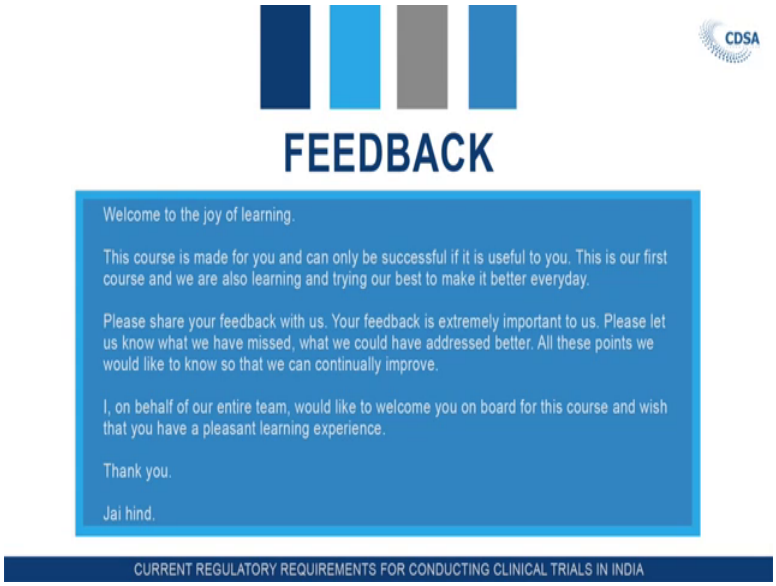

So, ladies and gentlemen, my dear colleagues please feel free to write to us what you felt was lacking, what we could have done better, how we could have addressed, which example was missing, how it was still not clarified to you. Your feedback will help us to continually strive and be better and better. So, enjoy this course and enjoy the joy of learning.

And thank you so much to this course and [FL].