Current Regularoty Requirements for Conducting Clinical Trials in India

Dr. S. Eshwara Reddy
Dr. K. Bangarurajan
Dr. Dhananjay K. Sable
Prof. A. B. Ramteke
Prof. Gagandeep Kang
Prof. Usha Menon
Prof. Nitya Wadhwa
Prof. Y. K. Gupta
Prof. Vandana Chawla
Drugs Controller General, CDSCO
Joint Drugs Controller, CDSCO
Assistant Drugs Controller, CDSCO
Former Joint Controller, CDSCO
Executive Director, THSTI
Strategy Lead, CDSCO
Assistant Professor, THSTI
Chairman, Training Advisory Committee, CDSCO
Training Manager, CDSCO

Lecture - 02
C1 Introduction Assorted Interviews

As you know medicine plays very important role in the public healthcare system. Indian medicines have been recognized globally because of its quality and because of its affordability to all needy patients. The clinical trials are regulated under the provisions of drugs and cosmetic act and drugs and cosmetic rules. These rules clearly specify various regulatory requirements to conduct clinical trials in India and also to grant marketing authorization of new drugs in India.

The Central Drug Standard Control Organization in association with CDSCO has already conducted various training programs to all stakeholders including sponsors, principle investigators, ethics committees and also drug regulators, but this classroom training program we are not able to reach to all needy stakeholders.

In order to reach the maximum number of stakeholders the Central Drug Standard Control Organization, CDSA, THSTI and DBT has developed this online course on current regulatory requirements for conducting the clinical trials in India. This training this online training program is well designed and also this is a very user-friendly mechanism. I am sure that all viewers will benefit from this online course. As you know many innovators they are not aware about the regulator requirements to commercialize

their new products that has been developed in their institute to market the that particular product into the market.

This online course program will help them and will also assist them to understand the regulatory requirements to commercialize their products. I am sure that this online training program will not only as encourage the innovation in India; this course will also further develop and ensure the accessibility affordability of the drugs to all the needy patients. This online course is very well designed and it is very user-friendly and this course you can learn from anywhere and at any time as per your convenience.

The Government of India is also come up with new draft clinical trial regulations and also for approval of new drugs which will encourage us the ethical and scientific clinical research in India. I appeal all the viewers please provide feedback so that we get better and better in future I wish you all a happy learning; thank you.

Greetings from Central Drugs Standard Control Organization CDSCO course 1; Current Regulatory Requirements for Conducting Clinical Trials in India is a topic which had been a matter of discussion since long as there were many amendments in 2013 till date. This topic was in fact, suggested by me to CDSA because we felt that CDSCO can help in resolving any confusion through this online course. I am happy that today this program is taking shape. I and my team had been involved in reviewing and approving the online course for it quality and content.

So, that only correct information reaches you. Anything first is tough and at CDSCO we have huge workload; yet me and my team have supported this initiative by CDSA. Please share your feedback with us and we would certainly like to undertake changes once we know what you would like to know more or in different areas. If you have missed addressing those I and my team at CDSCO wish you a happy learning. [FL]

Hello everyone watching this video I am Dr. Dhananjay Sable; Assistant Drugs Controller of India CDSCO DGHS Ministry of Health and Family Welfare Government of India. At the very outsight I would like to congratulate CDSA for developing such a wonderful online course. I also would like to express my sincere thanks to CDSA for giving me an opportunity to say something about this online course.

Dear friends, I take this privilege to welcome all of you to join this online clinical trial course. The online course that is current regulatory requirement for clinical trial has been developed by CDSA THSTI which is a government body under Ministry of Science and Technology and it has been supported and reviewed by CDSCO which is another top most central government agency under Ministry of Health and Family Welfare for giving approval to clinical trial in India.

Friends, I have been reviewing clinical trial application for its approval for about last 10 years. I have observed that the delay in getting the clinical trial permission is because of lack of course, understanding of rules and regulation pertains to clinical trial. CDSA has organized many workshops and seminar to make the people aware about this rules and regulation not only to get the permission with in time, but also to have an ethical conduct of trials in India.

In order to set back the rights and will be nest of subjects. As per my knowledge since 2013 there have been lot of changes in these rules and regulation and is now the right time we should have a reliable and updated course to check and upgrade our understanding regarding clinical trial in India.

For the long time CDSA is working hard to come up with this course. I can say CDSA particularly Dr. Sucheta and her team are literally smitten with the course to make it best possible. I have also gone through the course rather I would say I have reviewed each and every slide for its correctness in compliance to current regulatory requirement that is as per drug and cosmetic act and rules there under. The design of the course is (Refer Time: 08:008) and it has made it fascinating for the learners. I am sure the learners will definitely get benefited by this course and they will enjoy the course as well.

The course is compressive one and it has tried to cover from its all rudimentary aspect to its contemporary and all latest amendment till date. As I have mentioned the course has been made very interesting by incorporating various pictures, images at appropriate places. The examples given will keep you awake and alert all the time you study the course. The questionnaire given are like puzzles which will keep challenging your knowledge and interest. Dear friend, the course is best suitable for those who would like to make career in CROs or in pharma field for those medical and paramedical fraternities

who are directly or indirectly involved in conduct of clinical trial new drug R and D approval etcetera.

At the last I would like to say improvement and success of anything is continuous process which cannot be completed without your valuable feedback. So, do not forget to give your valuable feedback for further improvement of the course. Enjoy the course and update your knowledge, thanks and all the best.

Hello everybody, my name is Arun Kumar Ramteke. I am a retired Joint Drugs Controller CDSCO. I retired in 2011 and since then I am working as a consultant at Clinical Development Services Agency which is the department of biotechnology and we have developed this course online course for the stakeholders mostly and the regulatory requirement for conducting the clinical trial in India. So, hope you will learn something from this course and we will help in the learning.

Clinical research is absolutely essential if we are to develop new products or processes for improving health in India. This is something that everyone is aware of, but frequently faces challenges and not quite understanding what the path ways are from research to actually developing products and then introducing them to the market. The Clinical Development Service Agency of the translational Health Ccience and Technology Institute has developed material for an online course that covers the current regulatory requirements for clinical trials in India. The content of this course has been provided by experts and has been reviewed by the staff of the CDSCO which is the regulatory authority in India.

We worked together very closely to bring this content to you and we hope that you will enjoy the experience of learning what is required to take products forward. This is very important, but its also a dynamic process. So, we would welcome hearing from you about what your learning experience has been as well as if you identify gaps or see ways of improving what has been structured here. I hope that you will all enjoy the experience and will provide feedback to us.

Clinical trials are crucial to improving healthcare; however, unlike other research they involve patients and healthy volunteers. So, safety and the quality of the data generated is paramount governments all over the world have therefore, created rules and regulations to stringently oversee conduct of clinical trials. The MRC-CTU is at the

forefront of design and conduct of such clinical trials and I have been privileged to be able to spend some time away from CTU at CDSCO in THSTI working with the training team to develop this course.

The course has been developed by Dr. Sucheta Banerjee, Mister Ramteke and Miss Vandana Chawla. We are hugely indebted to their senior officials at CSDCO for betting the course and ensuring that everything that you see is correct. I have learnt a lot from working with the team to develop this course. I hope you will enjoy it and you will find it useful and interesting best wishes.

Greetings from Clinical Development Services Agency at THSTI. Welcome to this online course on current regulatory requirements for conducting clinical trials in India. As a founder member of the human ethics committee at THSTI way back in 2010; I realize that not only investigators, but even ethics committee members have many queries and unsure of answers on current regulatory requirements for doing chemical trials in the country.

This is merely because there is no information available in the public domain especially something vetted or endorsed by the Indian drug regulators at CDSCO. Today I am happy that Clinical Development Services Agency has worked coherently with CDSCO to come out with this course on current regulatory requirements for conducting clinical trials in India. The course can be undertaken by investigators, ethics committee members, clinical research organisations and anyone who is interested.

There is no fee to undertake the course, but if one wishes to apply for certification a proctored online examination has to be taken by the candidate. When you undergo this course you may have some unanswered questions; some areas where you feel you need more clarification or information. Please do write to us we would appreciate a feedback to help us improve the course. Good luck and hope you enjoy while learning.

I am Professor Y. K. Gupta in the capacity of Training Advisory Committee, Chairman of CDSCO which is Clinical Development Services Agency of THSTI which is an extramural institution of department of biotechnology. I am giving this introductory remark about the online course which CDSA and CDSCO that is a regulator of the country is making jointly for the purpose of creating awareness, clarity among the

researchers who are doing clinical trials, clinical research and are involved or contemplating any drug development process and finally, testing that in humans.

In India the clinical research or clinical trials have been much more in practice. In last couple of last 10 years or 15 years because of lot of favorable conditions including good infrastructure, patient navy treatment navy patients; the good laboratory and good GCP practices training. Each clinician or each person involve in clinical research clinical trial has to be fully aware of the current regulatory status, current regulatory practices, current guidelines of the country related to clinical trials.

There is lot of confusion and we get lot of queries from across the world, across the country and across the state about what is the rule about, who can do trial, which site can do trial, how many times a person can do, what happens if the person gets clinical trial related injury, what happens if the SAE is not reported in time, how much compensation a person may get, who will pay the compensation, how the compensation is paid and what happens if the investigator does some negligence, what happens if the sponsor runs away and does not pay compensation and so on and so forth?

And there are clinical trial courses run across the country by various organization. We attempt that through this workshop we provide an absolutely correct information which is authenticated and this information will directly come from the regulator with examples and our experts will also give some narration of the situations which you my face time to time.

I am sure that after going through this module of 10 lectures on current clinical trial regulatory practices; you will get to know the games rule of the games of clinical trial and it will improve the status, the recognition and the correctness of the clinical trial in India. I wish you a very happy and good learning process and I wish my team of regulators and my team of CDSA a great success; thank you very much.

[FL]. Greetings from CDSA and welcome to the joy of learning. It gives me great pleasure to welcome you onboard to our online course current regulatory requirements for conducting clinical trials in India. We hope you have a good experience that exceeds your expectation and enjoy the whole course. Your interactions and feedback in this course is extremely important to us. It would help us to improve and fill the gaps if any.

This course is developed only for you and if it is not useful to you we will not certainly be happy. Our team has worked hard to make this course possible for you; with your inputs we will be able to make it still better. We are always available to help you in all aspects of learning, follow up, portal support, examination. So, please do not hesitate to contact us; we will be happy to help you.

Thank you.