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

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Lecture – 17
Content of a Clinical Trial Report

Hello friends, you are once again welcome to the course Current Regulatory Requirement for Conducting Clinical Trial in India for New Drug and investigational new drug. This is our lecture 17. In our previous lecture, we have seen how to propose a clinical trial protocol. And in this lecture, we are going to see after completion of the clinical trial study, how to report that study that is the content of clinical trial report.

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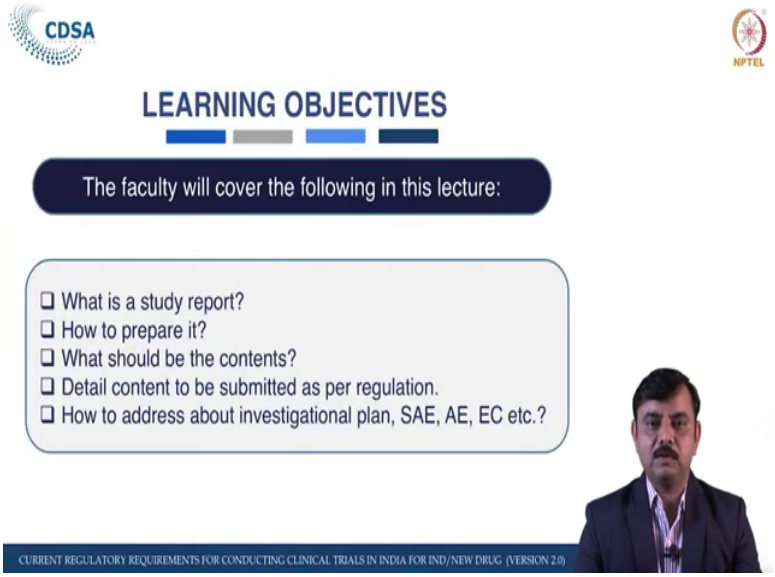

So, after completion of the lecture the learners will come to know, what is means by study report? How to prepare it? What should be the content? The detail content to be submitted as per the regulation that is what the regulatory authority expect to submit. How to address about the investigational product investigational plan? How to report the SAE adverse event? How to write about the ethics committee and the other things?

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So, let us move to our report. The clinical study report described here is an “integrated” full report of an individual study of any therapeutic, prophylactic or diagnostic agent conducted in patients, in which the clinical and statistical description, presentation and analysis are integrated into a single report incorporating tables and the figures.

The appendices containing the protocol, sample, case report forms, investigator related information, information related to the test drug, investigational plan, then the investigational product and the other things.

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The full integrated report of the individual study should include the most detailed discussion of individual adverse events or laboratory abnormalities. But these should usually be reexamined as part of an overall safety analysis of all available data in any application.

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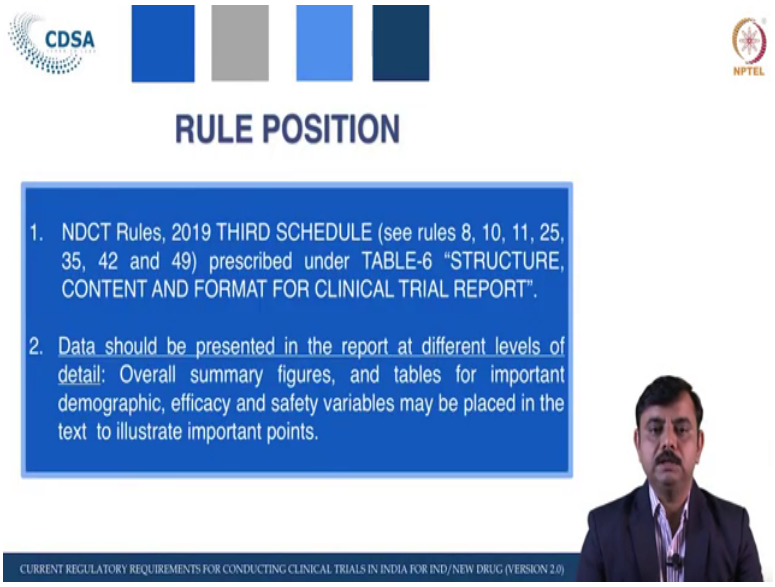

Let us see what is the rule position and where it has been given in our New Drug Clinical Trial Rules 2019. So, it is given in the Third Schedule of New Drug and Clinical Trial Rule. If you would like, you can refer the rules 8 rule, 10, 11, 25, 35, 42 and 49.

In the third schedule that TABLE-6 it mentions the "structure content and format for clinical trial report". So, the data should be presented in the report at different level of details: The overall summary figures, and tables for important demographic, efficacy and safety variables maybe placed in the text to illustrate important points.

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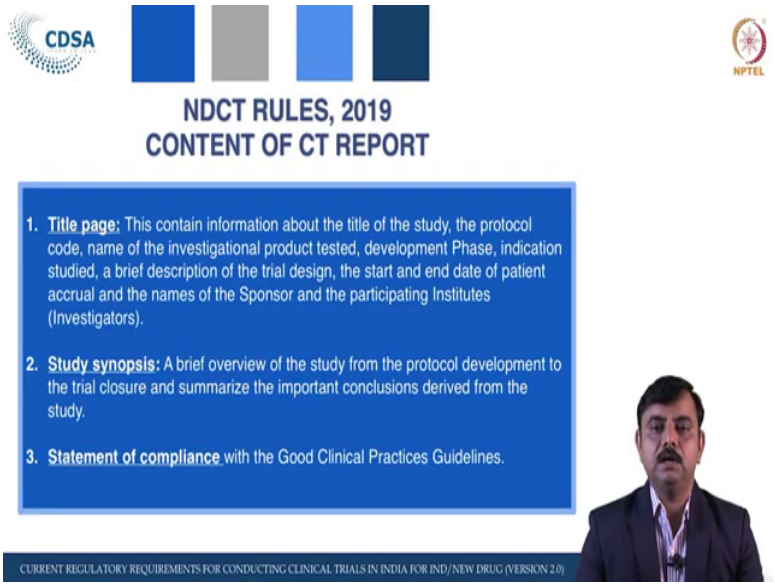

Let us move towards the actual content of the clinical trial report and how it should be.

The first what we have seen in our previous lecture in that propose clinical trial report also that was the title page. Here also it is a title page and this title page this should contain information about the title of the study, whether it is double blended, single blended. Then the protocol code, name of the investigational product tested, the product which is use here during that clinical trial then indication, for which it has been study, a brief description of the trial design the start and end date of patient accrual and the names of the sponsor and participating institutes that is the investigators.

The study synopsis, it should be in a brief that is 1-2 page. A brief overview of the study from the protocol development to the trial closure and it should summarize the important conclusion derived from the study. Then the statement of compliance require to be given that

whatever the study the sponsor investigator they have performed that was as per the good clinical practices guideline and norms; that statement of compliance required to be submitted.

Then list of abbreviation and definition. For example, IP it is Investigational Product, AE Adverse Event. So, all the abbreviations use and it is definition that has to be given, then table of content required to be given.

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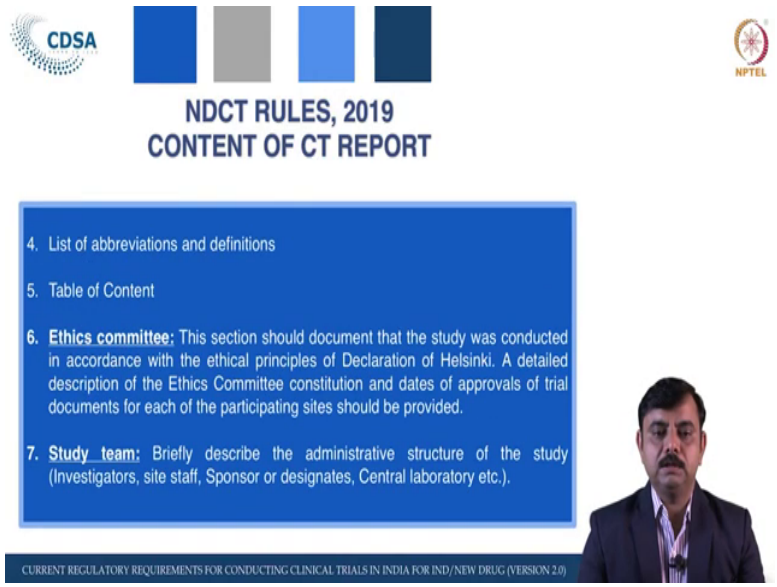

Next to this the detail of the ethics committee which has accorded the approval and this section should document that the study was conducted in accordance with the ethical principles of given in the declaration of Helsinki. Then a detailed description of the ethics committee constitution and dates of approval of trial document for each of the participating sites should be provided.

A declaration it should state that ethics committee notification as per good clinical practice guideline, ethical guideline for biomedical research and human subject we should by ICMR have been followed. So, in case of it is a; if it is a research for the biomedical and health, then the respective ethics committee approval should be there. And in case of the chemical trial the ethics can be registration from the central licensing authority we have seen in our previous lecture. Then regarding the study team, briefly required to describe the administrative structure of the study including investigators involved the site staff, then sponsor or his designates and the central laboratory which are involved.

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In the introduction part, a brief description of the product development rationale should be given. Then the study objective in this regard a statement describing the overall purpose of the study and the primary and secondary objective to be achieve should be mentioned. Under the investigational plan, this section should describe the overall trial design, in the subject selection

criteria, the treatment procedure followed blinding or randomization techniques if employed any and the efficacy and safety criteria assessed, the data quality assurance procedure and the statistical method plan for the analysis of the data obtained.

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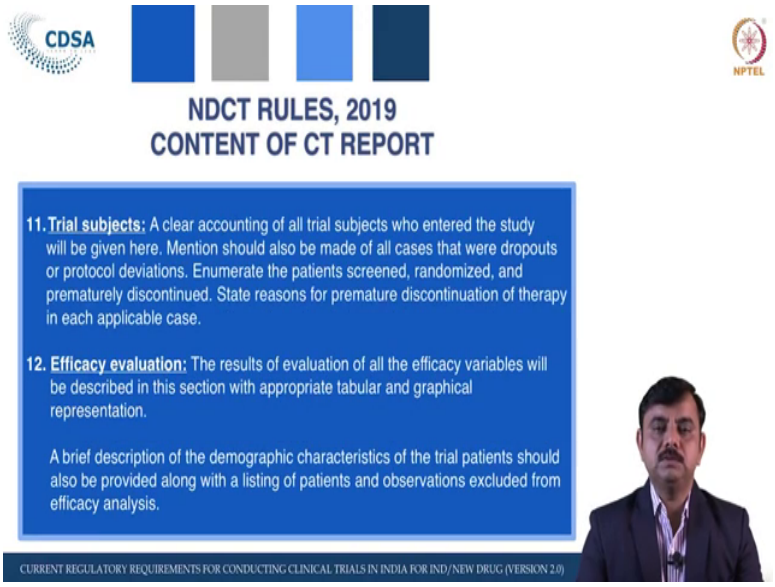

With respect to that trial subject, a clear accounting of all trial subjects who entered the study will have to be given and there should be a mention also to be made of all cases that were dropout or protocol deviations. Then enumerate the patients screened, randomize, and prematurely discontinued. State the reason for premature discontinuation of therapy in each applicable case.

Under the efficacy evaluation, the result of evaluation of all the efficacy variables will be described in this sections with appropriate tabular and graphical representation. A brief

description of the demographic characteristic of the trial patients should also be provided along with a listing of patient and observation excluded from efficacy analysis.

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Then with respect to the safety evaluation, this section should include the complete list of; all SAEs whether expected or unexpected that should be included.

Unexpected AEs that is adverse event whether serious or not that also required to be noted down. The comparison of adverse event across study groups may be presented in a tabular or graphical form. Then the discussion and overall conclusion in this section the: discussion of the important conclusion derive from the trial and scope for further development required to be give. Then for the study whatever the list of references, which they have preferred and they have used during the study that list trial of the references required to be given.

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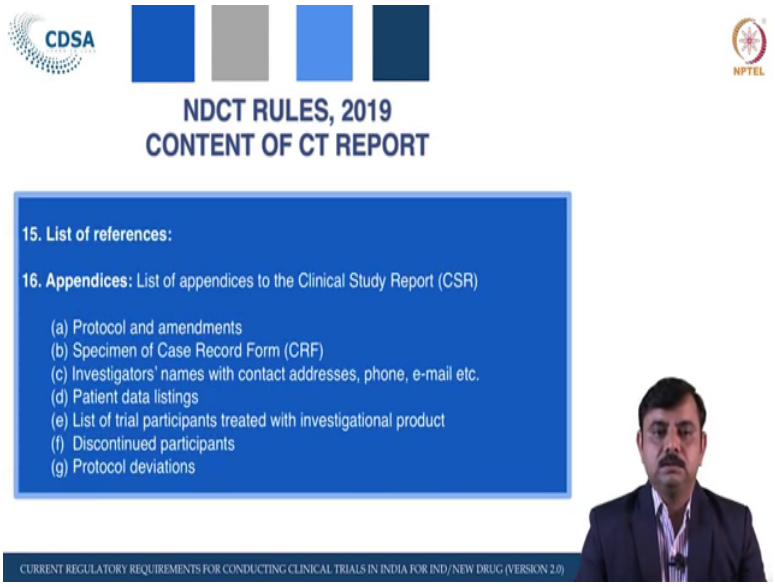

The next part is the appendices. In this section, the list of appendices to the clinical study report like a protocol and amendments, specimen of the Case Record Form, investigator name with contact address, phone, e-mail and the details of the investigator, then the patient data listing, the list of trial participant treated with investigational product that list has to be submitted. Also the participants those you have discontinue withdrawn that require to be given. If there are any protocol deviation that is also, required to be submitted.

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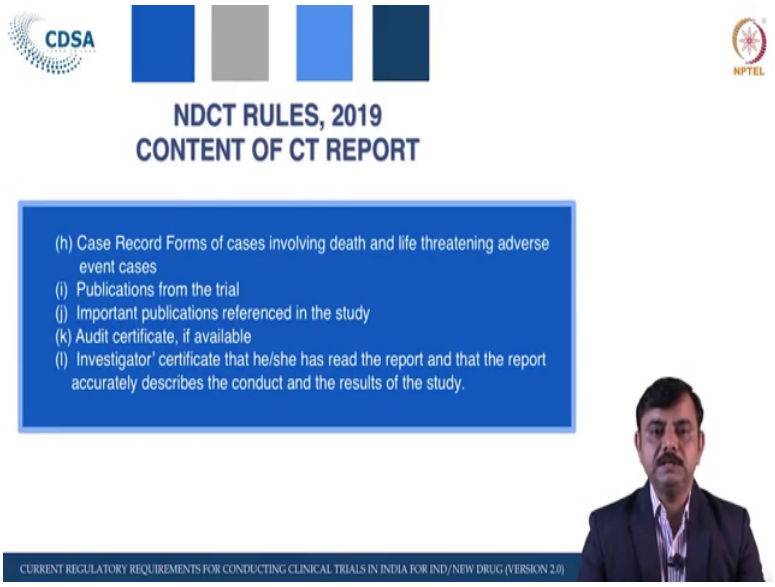

In the case require form of cases involving death and life threatening adverse event cases that is required to be given. Then publication from the trial if after the trial any publication has been made that is a required to be submit important publication reference in the study if the data regarding the trial subject, or the design, or the product that has been sited from the references, then the important publication that should be given.

Audit certificate if available; if any authority has audited the site and if any audit certificate is available, then that is also required to be attach with the report. Investigators certificate that he or she has read the report and that the report accurately describe the conduct and the results of the certificate. So, this certificate has to be attached with that that the investigator that he has read all the reports and it is a correct to his or her knowledge.

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So, this is about the lecture let us have the summary for this lecture.

So, in this lecture we have seen, what is the study report? How to prepared the clinical trial study report? What should be the data element? The what is the position of this content of the report in drug and cosmetic and new drug and clinical trial rule regulation. We have seen about the data management and the other things.

Let us have the quick recap.

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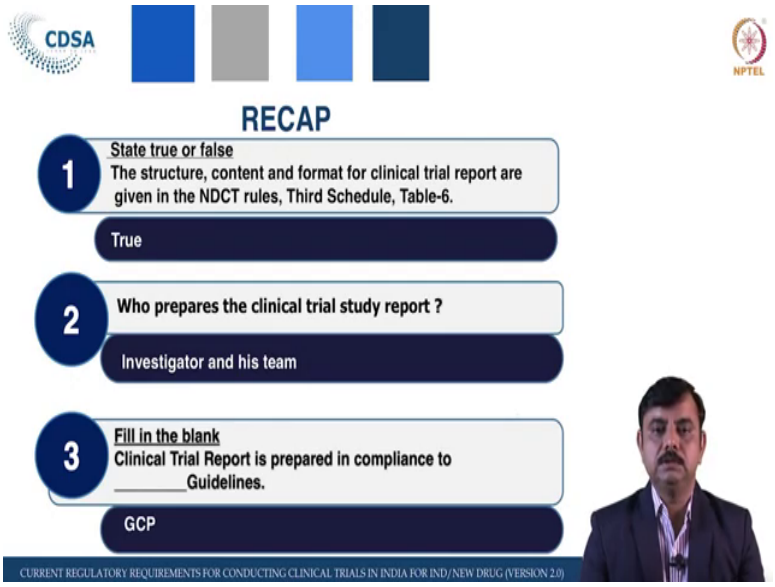

The question for you is the structure and content and format for clinical trial report are in NDCT rules. So, you have to tell whether it is true or false, whether the structure content and format for clinical trial report are given in NDCT rules So, this is true, the structure content and format given in the NDCT rule we have seen it is in the Third Schedule.

The next question who prepares clinical trial study report? So, it is the responsibility of investigator and his team who prepare the clinical trial study report. Clinical trial report compliance as per the which guideline it has to be; so it is as per the good clinical practices guideline and as per the NDCT rule 2019.

So, this is all about the clinical trial report. In previous lecture we have seen content of propose report. Now, I hope you are capable of proposing clinical trial in proper format, with a proper content and was this study completed, you would be able to report it to the licensing

authority. So, we will see some next other things in our next lecture. Till then thank you for watching the video. Bye, bye and take care.