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

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Lecture - 13
Good Clinical Practice

Welcome to our online course, this is lecture-11; Good Clinical Practice.

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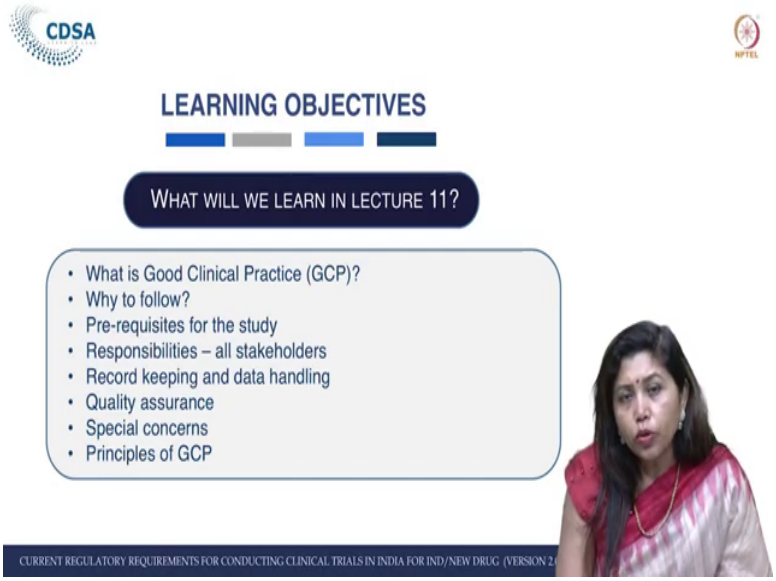

In this lecture, we will learn what is GCP that is good clinical practice, why we should follow GCP, what are the various pre-requisites for conducting a study, which has a compliance to GCP, what are the various responsibilities of stakeholders. The record keeping and data

handling, the quality assurance, the statistics, and also address special concerns. We will also briefly cover principles of GCP in this lecture.

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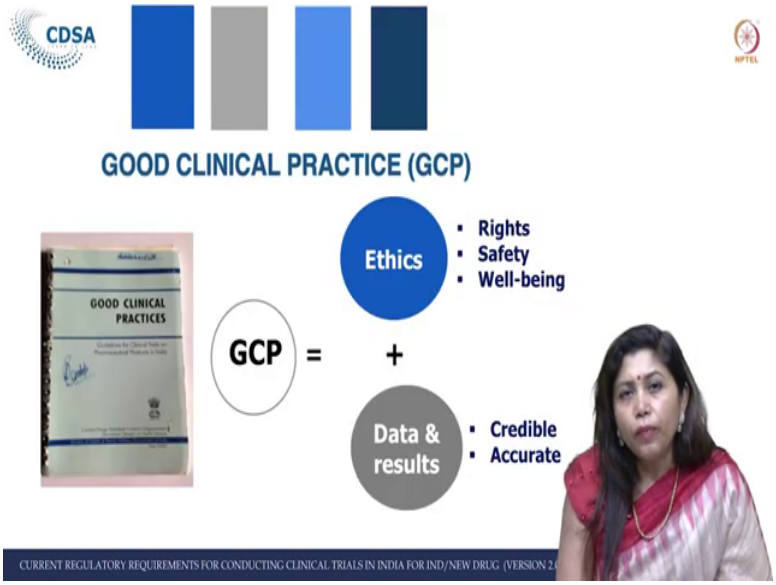

When we talk about GCP Good Clinical Practice, we may think that it is about the clinical practice. It is actually an international ethical and quality standard which is two focus areas; one is the ethics, where we talk about the right, safety and well-being of all the study participants. The other aspect is about the data and the results which should be credible and accurate.

So, if you see the GCP definition as per the Good Clinical Practice for clinical researchers in India, CDSCO launched in 2001 you will have the definitions described there and this course that this lecture-11 covers the GCP by CDSCO 2001.

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So, GCP in this CDSCO 2001 guideline defines as a standard, which is an international standard for quality as well as ethics for clinical studies or trials that encompasses various areas. What are those various areas? Design, conduct, monitoring of study, termination of the study, audit of the study, analysis, reporting and documentation of the studies. Whenever you conduct a study which is in compliance with GCP you give public in assurance.

This is the most critical an important part of GCP that any study, which is in compliance with GCP Good Clinical Practice assures 2 important factors; one, that the right, safety and well-being of subjects are well protected. I prefer to save participants not subjects because, I believe participants is a better term and subjects is like king and its subjects, that is why you will see that the ICMR ethical guideline released in 2017 refers them as participants. But the subjects are referred in the regulatory documents, hence it has been used as subjects.

So, what does the compliance to GCP ensure? It ensures it gives public assurance that the right, safety and well-being of all the study participants are well protected. And the data which are generated during a clinical trial or research are credible and accurate. GCP also ensures that the studies which are conducted using the IP that is the; Investigational Product or IMP that is the; Investigational Medicinal Product are scientifically authentic. They are produced in a GMP facility and all the details are properly documented.

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So, if you see the slide you will understand the GCP can be very easily remembered through this graph or the graphical representation which talks about how the study is designed. We say this design of the study is extremely important, because if there is a (Refer Time: 03:56) flaw in the design you may not be able to reach your possible outcome.

So, designing the study is critically important it is covered under the protocol. When the study is designed the protocol is reviewed and approved by the ethics come in ethical ethics committee as well as the regulators, then the study begins this conduct of the study is extremely important. And then when you conduct a study recording those data which are released or which are captured during the study is very very important.

During the entire conduct of the study, monitoring those for quality control is extremely important, when the data's are gathered analysis of all the data's are very important. Once the data's are analyzed reporting them which is a true representation of the data, which has been captured through source document is extremely important and that covers the entire cycle of GCP. GCP to easily remember to me is about rsw that is; right, safety and well-being of all the study participants to be well protected, and d q i that is; a data, quality and integrity.

So, GCP should be followed to ensure that the clinical trial as well as it can be clinical research is consistently performed to the highest ethical and scientific standards this is very very important. When we talk about GCP we come across various terms and understanding those terms and the definitions is extremely important.

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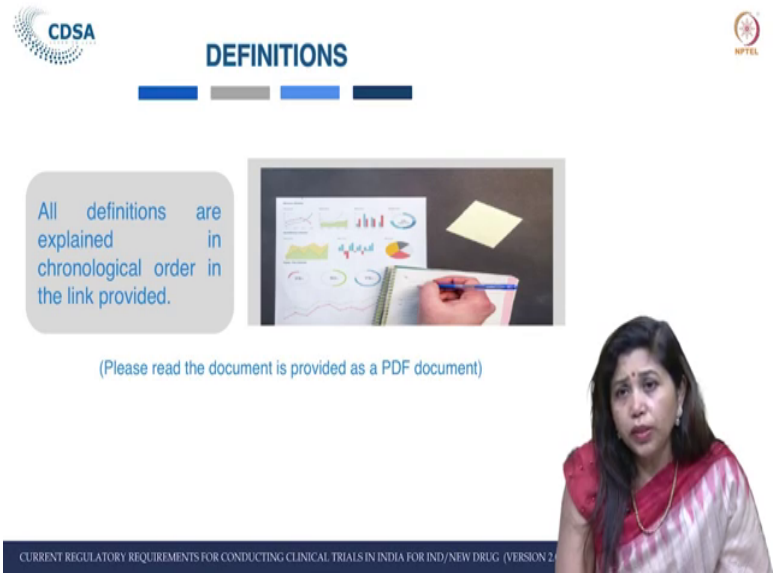

This presentation is extremely short. So, I where I'm not going to go deeper into the definitions, but there is a document attached with this lecture note. And this document will help you understand all the definitions which are explained in a chronological order. Please go through them carefully; this will help you to understand this lecture better.

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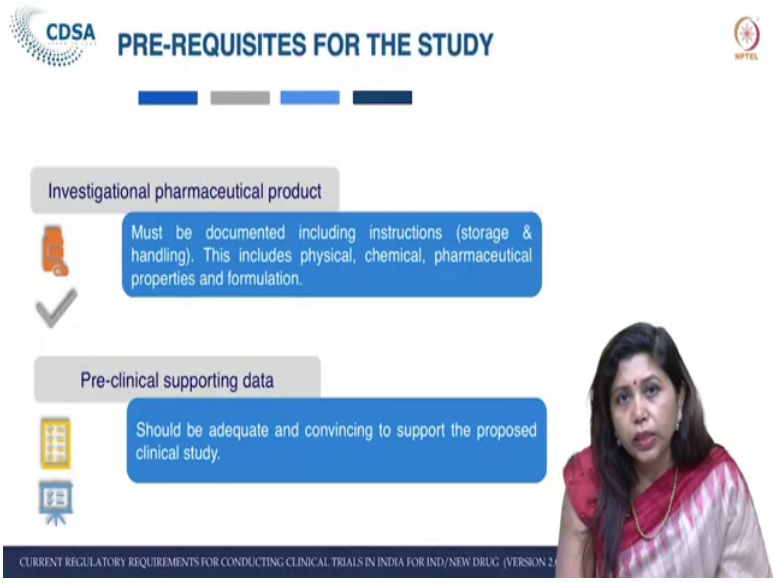

Once you have understood the definitions it is important for us to now move on and speak about the pre-requisites. What are the pre-requisites for conducting a clinical trial, which is in compliance with GCP? Let us understand about the first thing, which is required for a clinical trial. It is the IP that is; the investigational pharmaceutical product or investigational medicinal product or investigational product. This IP which we refer as must be documented properly; that means, the document should have the physical properties, the chemical properties, the pharmaceutical details the formulation.

But, apart from that the most important thing is about the storage and handling. How you are going to receive those? How you are going to keep it? How you are going to maintain the temperature, humidity this are extremely important. Second part is the pre-clinical supporting data; we have a separate lecture on pre-clinical requirements which is lecture L-4. You have

already undergone the L-4 because, this is the L-11 lecture and all the pre-clinical requirements are dealt in detail there.

You might have understood that, knowledge about the clinical about the animal pharmacology, the animal toxicology data, the safety pharmacology data are extremely important. Here, where you would like to understand that, what is the nature of the IP. So, this should be adequate and quite convincing to support the proposed clinical study.

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Then we move to the next part which is about the protocol. The protocol is dealt very in detail and if you read the new drugs and clinical trial tools, you will find all the details which are mentioned there.

So, the protocol should have all the elements required. We have a lecture which addresses this very critically. So, I will not go, I will not divulge more or discuss here in this lecture.

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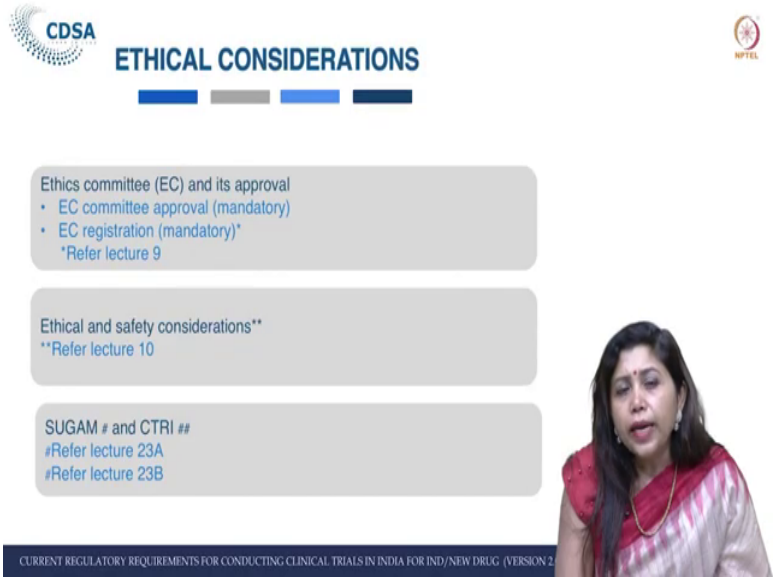

The second, the next part is about the ethics committee and its approval. We have a separate lecture which is about the ethics committee, it is called ethical consideration. This is the lecture L-10, which you have just now completed this lecture. And this describes about all the requirements which are necessary for conduct of any clinical trial.

We also have a separate lecture called L-9 which has already completed by you that is; about how to register your EC that is ethics committee, as well as a re registration. EC registration and re-registrations are mandatory for ethics committees, which you review studies which are for clinical trials.

We also have a separate lecture coming up, which is on SUGAM portal, how to use the SUGAM portal? And, also another lecture about CTRI registration Clinical Trial Registry of India. So, we will move now to the critical part of the GCP which is talks which where we discuss about the responsibilities.

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There are various stakeholders in a study in a clinical trial like sponsor, investigator, institution, ethics committees, monitor. We will try to deal them, deal with them one by one in very brief; first, let us begin with the sponsor. Sponsor as you know the name is the is an organization or it can be a person who initiates the study, who writes the protocol there can be an investigator who has written the protocol and is also initiating the study, that person can be sponsor investigator. Whereas, a person who has initiated a study may have taken a funding from another organization and that can be a funding agency.

So, there is distinguishing, you have to distinguish between sponsor and funding agency. Sponsor is most important, because sponsor owns the study. So, the sponsor is responsible for choosing the investigator and the institution, it is extremely important that he the sponsor or the organization chooses a right investigator and a good institution.

The sponsor has all the information about the IP its supply, how will get it, how its manufactured, how its stored, how its handled, how its returned back, how its destroyed. Sponsor is the owner of the protocol and ensures the compliance of protocol as per the good clinical practice as well as the, current regulatory requirements of clinical trial in India.

Sponsor is legally responsible for implementation of entire quality assurance system for the clinical trial. Monitoring and auditing is also a sponsor's responsibility. Monitoring is quality control whereas, auditing is quality assurance. We will deal with this in our subsequent slide, submission of the status report which is the update about the clinical trial happening is also a responsibility of sponsor.

Reporting all the adverse events which occur during the clinical trial conduct as well as serious adverse event is also the responsibility of sponsor. We have a special lecture which addresses these areas also the financial compensation in case of any injury and death this is also dealt in a specific lecture in this course.

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The responsibility of sponsor can be as can be said simply by one who selects protocol investigator and institution who pursues the regulatory authority that is; the central licensing authority, here it is CDSCO Central Drugs Standard Control Organization pursues ethics committee that is; IC or EC and the investigator.

Sponsor is one who organizes the logistics the trial logistics get gathers the funding, one who negotiates different contracts like tripartite agreements, budgets. Sponsors supports the investigator and the monitor so that, this conduct of the study is done in a very streamlined and in a good fashion.

Sponsor is responsible for operationalzing the quality systems of the entire clinical trial. Sponsor is also responsible for reporting all the safety issues that occur during the study

conduct and also to report to the regulatory authority, which is the central licensing authority here it is the CDSCO.

Sponsor selects the monitor; monitor is one who conducts monitoring visits from study start, till study end authorized by sponsor. Monitoring team is a team which works along with the team, along with the clinical trial team to find out if there has been any deviations or any non compliances, which has which is occurred during the trial conduct.

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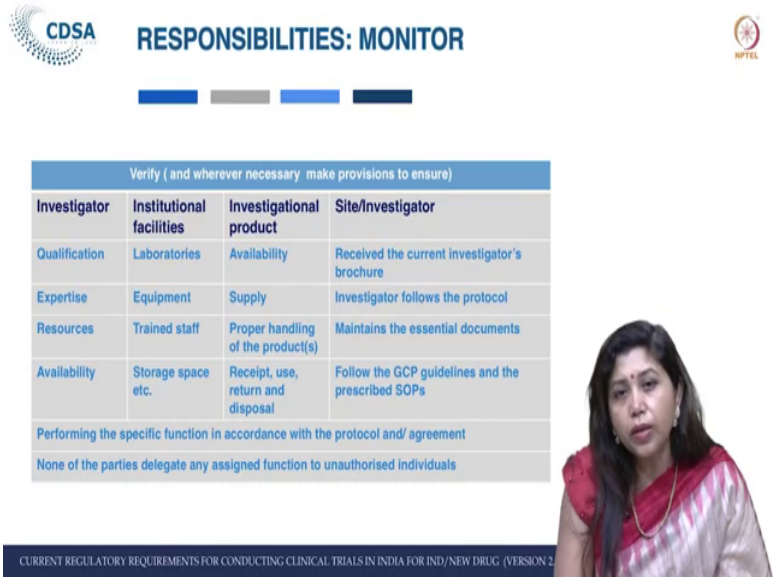

So, in brief if you want to like to know about this monitor is a person or a unit who will verify wherever, necessary and ensure. Ensure what? For example, we will ensure with the investigator who is involved in the studies, qualified, medically qualified has the required expertise, has all the resources this is very very critical that has all the resources in a ready

mode to conduct the study is available in terms of time as well as resources to ensure, that the studies conducted in a proper way.

The monitor is also responsible for ensuring that the institutional facilities like the hospital or the nursing homes have the requisite requirements to ensure that; the study conduct has no gaps or does not have any non compliances; in terms of electricity or in terms of personnel, trained staff, storage space is sufficient all equipment are present the laboratories are well staffed and have all the requisites mandatory requirement for the conduct of the study.

Monitor also has an important role to monitor whether, the IP which is investigational product is available; available in proper quantity supplied through a proper system and the handling of this products have happened exactly the way it is written in the Standard Operating Procedure which is SOP. The monitor also ensures the entire chain like; cradle to grave of the receipt, use, return and disposal of the investigational product.

Monitor also has a very very critical role to ensure that the site that is the clinical trial site which can be a hospital or nursing home and the investigator that is a PI receives the current investigator investigation brochure which we call it IB. Because, this versions keep on changing having the latest version is extremely important.

It also checks whether the investigator follows the protocol this is extremely important because majority of the non compliances are because, of the protocol deviations and the serious ones are protocol violations. It is very important for us to know; what is deviation, what is amendment, what are violation. Protocol deviation is unplanned change you would like to do x and you do y is unplanned change that is; deviation.

Amendment is a planned change, where you plan to do something, you want to do something else you plan it and change it in an advance. Before the conduct of that exercise that plan changes amendment and violation is when we do not obey any of the protocol steps and you violate totally. Protocol violation is a serious has serious consequences.

Maintaining the essential documents; essential documents are extremely important. Essential documents is the name suggests are all the documents, which are essential for the conduct of the study. There available before the study conduct, during the study conduct and after the study conduct.

Some of the essential documents for examples are; protocol the investigation brochure, the case record form, the clinical study reports etcetera. Monitor also ensures that all the people are trained in the protocol and they follow the GCP guideline and all the prescribed standard operating procedures that are present in the study. The monitor also perform the specific functions, which are in accordance with the protocol or as per as the agreement that the clinical trial encompasses.

None of the parties can delegate any assigned functions to unauthorized individuals are also looked after by the monitor, ethics committee. The responsibility of ethics committee is extremely important they are the gatekeeper. And if you have heard the lecture L-10 which was just now we have which this is L th 11 so, you have you had an exposure to L-10 already.

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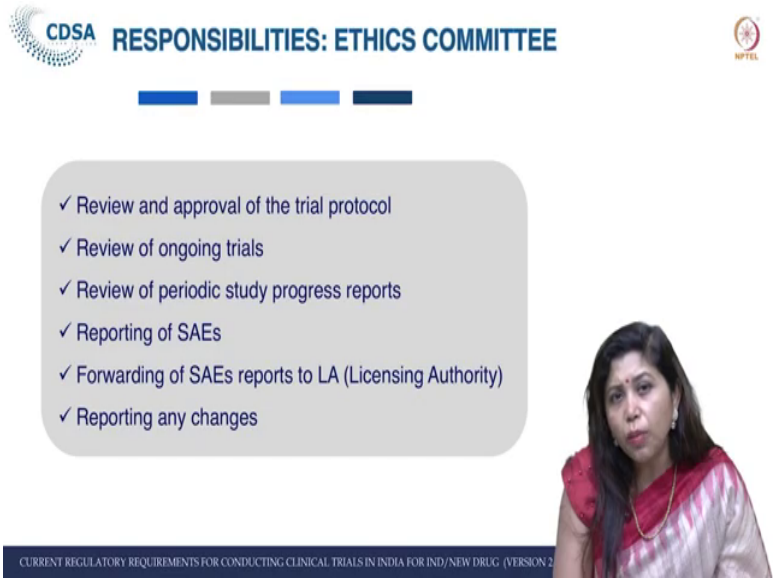

We have covered the ethical considerations especially the ethical guidelines by ICMR 2017 which speaks about all the areas. So, ethics committee are gatekeepers, they have a critical role of reviewing and approving a trial protocol they may review but, they may not approve. So, it reviewing as a separate thing and approving is a separate thing. They are supposed to review the ongoing trials on a continual basis also review the periodic study progress report.

Monitor the clinic the clinical trials for which they have already given approvals, they should be also vigilant about reporting the serious adverse events as per the timelines prescribed by the CLA that is; a Central Licensing Authority here it is the CDSCO and forward those essays as per those timelines.

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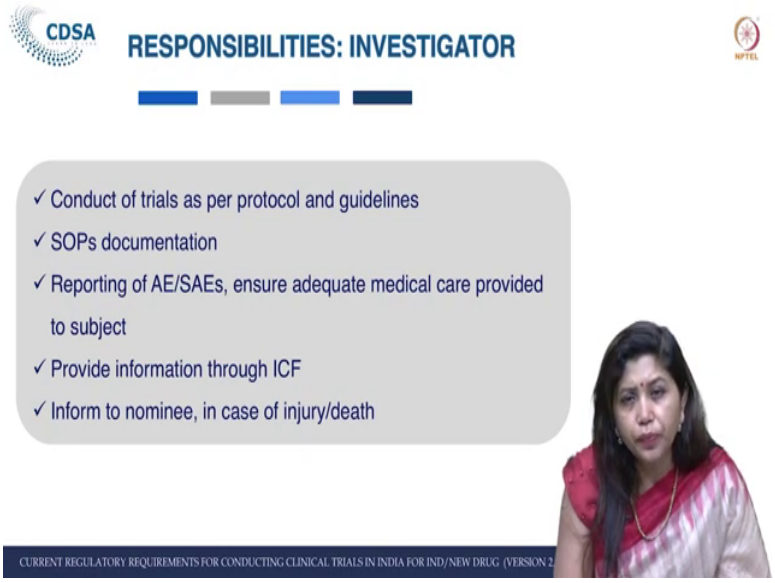

There are also supposed to report any changes that has occurred during the study they should inform that to the CLS. Responsibility of investigate; investigator is critical factor and is the most important stakeholder in any clinical trial. Investigator is a clinician he or she is responsible for conducting the clinical trial as per the protocol and guidelines.

So, it is extremely important that the investigator is medically qualified has enough experience and has already obtained a training on good clinical practice and is aware about the current regulatory requirements for conducting clinical trials in India.

The investigators should also be aware of the standard operating procedures, the documentations; the requirements of reporting of adverse events as well as, serious adverse

events ensure that, there is adequate medical care which is provided to the study participants or subject.

Investigator is responsible for providing all the information's during, the informed consent process and should participate actively during the entire process of taking seeking informed consent and also being responsible for all the medical care that the participant or the study subject deserves. The investigator should inform to the nominee in case of any injury or death.

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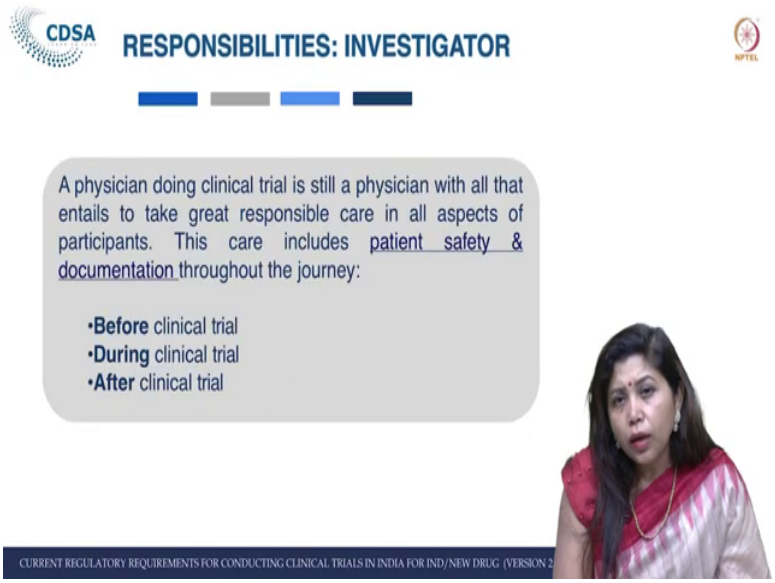

In clinical trial the investigator is a physician who is doing a clinical trial. So, investigator is a physician who takes a great responsibility in various aspects for ensuring that the study participant's medical care is not compromised. So, investigators care includes the patient safety which is foremost and sacrosanct in nature and the documentation which are very very critical during the journey of clinical trial.

So, the investigator is a personal who is involved with the clinical trial before it, during it, and after the clinical trial. Record keeping and data handling this is extremely important area and majority of the deficiencies that has been observed in clinical trial are actually, related to poor record keeping and data handling. The section covers about what is documentation, we see in clinical trial.

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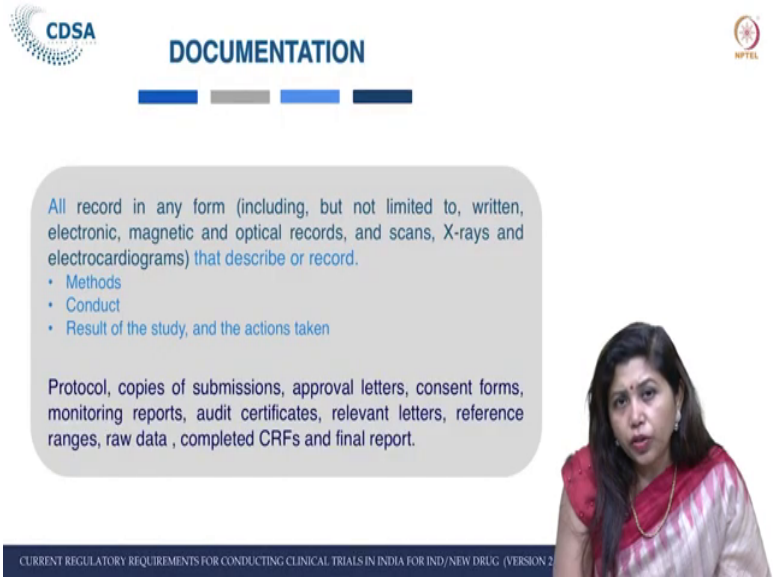

If it is not documented, it is not done it is equally important to document what was not done because, you if you try to capture what was done there might be things which you have not done it and it will be too late to recollect those and write it. So, the suggestion is also always to write what was done and also to capture all that was not done this will help you in later on in the clinical trial phase.

What are records, which should be documented? All records, in all forms whether, it can be written it can be electronic, it can be magnetic, it can be optical, it can be scan, it can be X rays, it can be ECGs. All the methods, all the conduct process, all the results, all the action taken this all should be recorded.

So, the records for examples like; protocols, the copies of various submissions, the approval letters, that you get from ethics committee or the regulators. The consent forms that you take, the re-consent forms, the monitoring reports, the audit certificates, the relevant letters that you receive from various agencies during the conduct of the study, the reference ranges that you receive from the laboratories, the raw data and the completed case record forms and final reports are to be documented.

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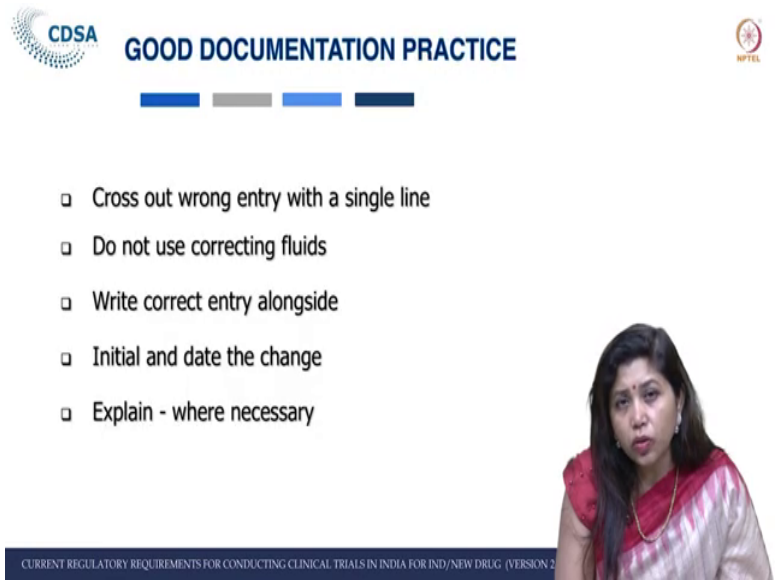

Corrections; extremely important to know that in clinical trial whenever, you write in a document you have to remember that writing a document in clinical trial is as good as signing a cheque. So, when you write a wrong thing in a cheque, how do you cancel it? You exactly follow the same procedures when you undertake any clinical trial and do the documentation; that means, whenever you make any corrections you are not suppose to use any white marker or any whiteout or a post it.

You have to use a pen, which is black or blue in color and obscure the should mark in such a way the corrections should be made in such a way that it should not obscure the original entry. The correct data should be written with a reason for why you are writing those data and the reason and it should be signed, dated with initials and it should be one of the authorized person who has been delegated by the investigator.

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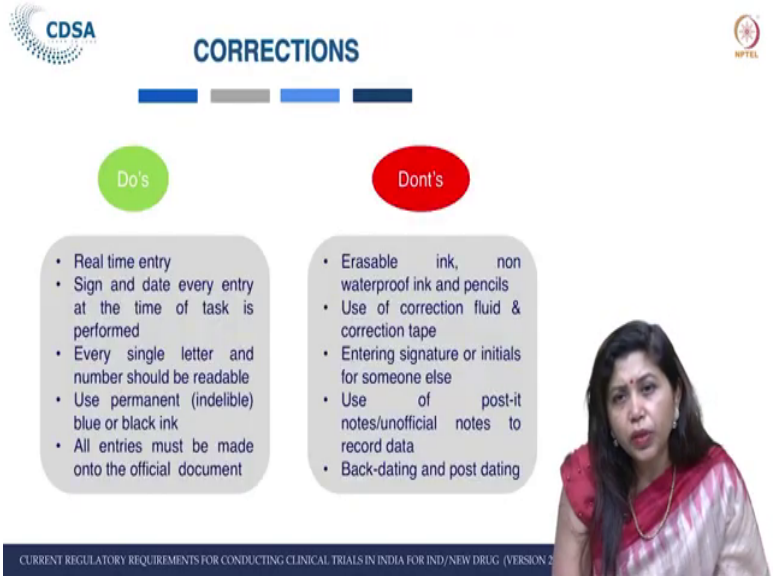

It is extremely important to know about good documentation practice. So, some of the do’s and dont's are like, what you should do? You should always do real time entry, never bagged it, never ever play with the dates because, you will land in problem. Sign and date every entry at the time of the task is done if there is any blank area please delete those areas please mark it that it is blank.

Because, it can be misused later on every single letter that you write and every number that you write in a clinical trial should be readable. Please use permanent ink which is indelible you can use black or blue all entries which are made into an official document must be preserved properly.

What are dont's? Never use anything which is erasable non waterproof ink and pencils, use of correction fluid and correction tapes are banned in clinical trial. Entering signature or initials of someone else can be very risky. Use of post it notes, unofficial notes to record data can land into problem, back dating and post dating are equally dangerous.

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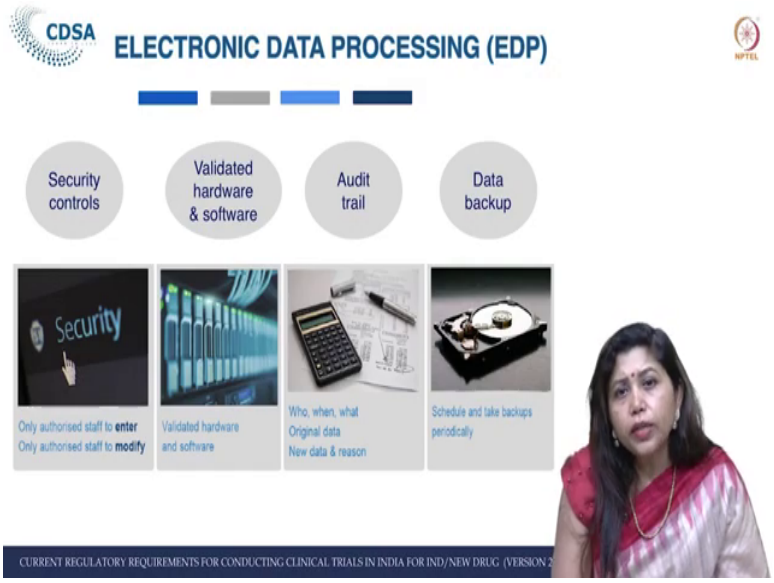

EDP; Electronic Data Processing. What is electronic data processing? You should have few of the elements for electronic data processing as you know that we are in the era of electronic data. We cannot avoid having data's or information's in electronic forms but, it is extremely important that we should have few of the important things which are like security controls, validation, validated hardware and software, the audit trail and the data backup.

So, what is security control? Whenever, you have any electronic data which is about clinical trial you must have a authorized staff who can enter the data. You should also have an authorized staff who can modify the person who enters the data should not have the right to modify the hardware and the software that you use should be validated.

I will invite you or request you to study about 21 CFR, part 11 to understand this area better. Audit trail it is very important when you see any data whether electronic data or non electronic

data, any data should be able to answer five w and one h. Who, when, where, what, why and how.

Data backup, it is extremely important that you backup your data in various forms like; back up 1, back up 2 and also do go and check up and retrieve document that whether it is possible to retrieve them and keep a proper documentation. The backup can be off site backup and or can be on site backup. You should have a standard operating procedures for this in this area.

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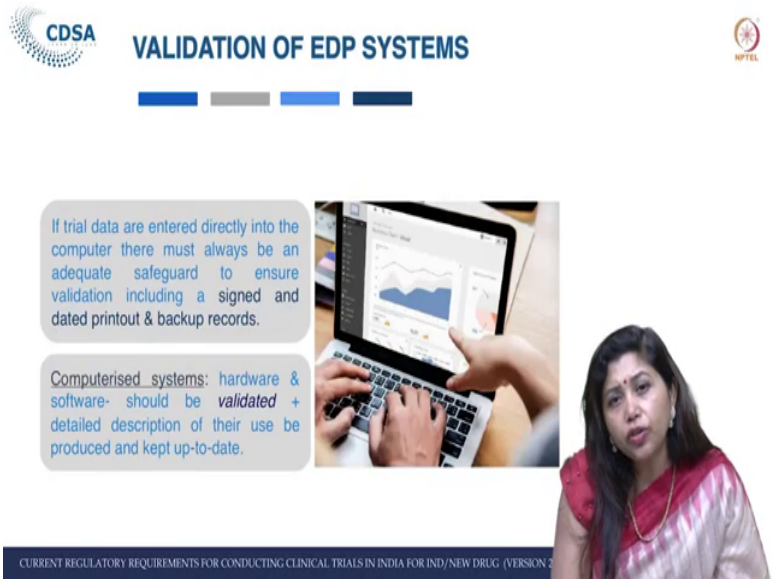

Validation of the EDP system; if any trial data are entered directly in the computer there must always be an adequate safeguard to ensure that the validation is done; that means, you sign it and date it the printout and have a backup of the records. Whenever I spoke about that computerized systems, I spoke about hardware and software and I spoke about how you

should validate it and should have a detailed description when it was validated and if the validations has to be kept up to date.

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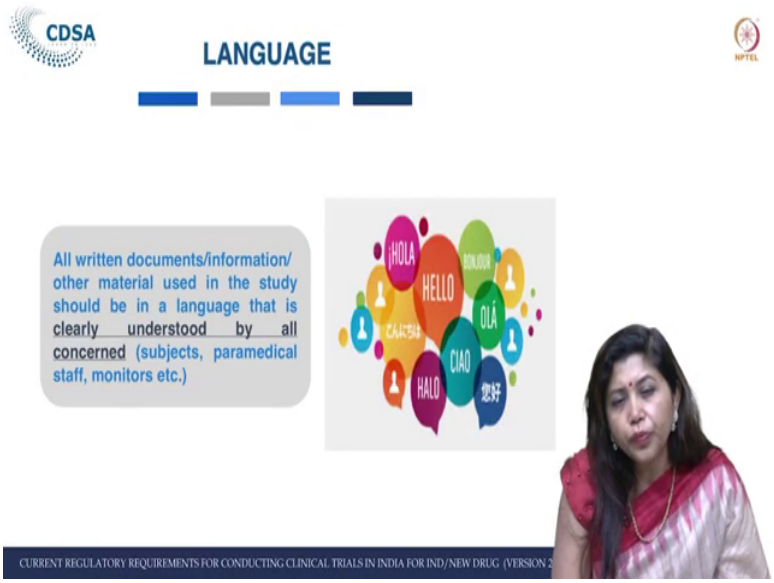

Language: What should be the language for any documents that you write during clinical trial? It should be in a language that is; clearly understood by all the concerned stakeholders. For example the participants or subjects, the paramedical staffs and monitors it should be simple to be better understood

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Quality assurance: this is extremely important because at the end of the study you give public in assurance the right, safety, and well-being of all the study participants are well protected. You can only do it when you have a very strong quality assurance system. Quality is the legal responsibility of sponsor.

So, sponsor is sponsor ensures that the quality system is placed throughout monitoring as well as quality assurance that is; audit. But is the sponsor alone responsible? All the stakeholders are equally responsible to ensure that the study conduct is done as per all the compliance or all the requirements.

So, the sponsors responsibility is to ensure first, that the studies performed, if perform the data is generated, if the data is generated they are recorded. If they recorded their report and all this that happen, happen in compliance with the protocol, which is the mother document as

well as the good clinical practice guidelines and all the applicable regulatory requirements at that scenario; that means, all the current regulatory requirements.

So, having a documented Standard Operating Procedures or SOPs are a pre-requisite for an effective quality assurance. All the observations which happened during the clinical trial conduct should be verifiable. What is verifiable? That means, you should be able to give credibility of the data that is generated and assured. Assured, what is assured? The conclusions are correctly derived from the raw data. This is extremely important because this ensures that the verification process is specified and justified.

Acceptable method of data verification is extremely important; that means, you should have a statistical control sampling you should do data QC and this data QC should be applied at every stage of the data handling because, there are good chances that you make mistakes and you take some data which is a wrong data so, to ensure that all data that are captured are reliable and have been processed correctly, it is mandatory to undergo or undertake data QC.

Sponsors audit are conducted by whom? The sponsors audits are conducted by persons who are independent of all the responsible in the study why? Because, then they will have no bias and will have no conflictive interest. Investigational sites facilities all data's and documentation should be covered when we talk about quality assurance about this. And they should be available at the site or the clinical trial site and sponsors auditor as well as other people should have an access to that.

So, if we speak about three levels of checking; the first level, can be the monitoring which is the quality control. The second level can be the audit which is quality assurance and the third level can be inspection, if it happens inspection is always by the regulatory authority or the central licensing authority.

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Who is responsible for quality as we discussed legally it is the sponsors responsibility, but if you see each and every stakeholder involved in the clinical trial is responsible for the total quality we say totality of responsibility. So, the investigator who is involved in the study the study co-coordinator the CRA, CRCs the ethics committee or the gatekeepers of that the laboratory, who is who has generated all the data's. The monitors who were involved in monitoring the study and if you are very lucky or otherwise the auditor and the regulators are also responsible.

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So, 3.1.17 speaks about that the sponsor we transfer any or all of the responsibilities, but still it is the responsibility of the sponsor to ensure that the quality and integrity of the study data always remain with them.

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Statistics: this is the area which is which is quite interesting and important. The role of biostatistician should be defined they should be involved in the planning as well as throughout the study conduct, they should be qualified and experienced. And they should have a statistical model, which should be incorporated in the protocol there is a number of subjects or the sample size should be designed in advance.

Study design; study design is extremely important because it determines the scientific integrity and credibility of the report. The study design should has specify the rationally; that means, why the target difference between the treatment that the study is designed to detect. The study design should also be able to have the power to detect. The difference the clinical significance of the statistical difference, the measures which are taken to avoid bias that is how you address randomization and blinding.

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Statistical analysis they should be planned in advance all the types should be clearly identified, what forms the basis of the statistical model should be addressed.

It should describe and justify in the final report and all the subsequent deviations. It is that there is a need and extent of an interim analysis in if it is there is a need then you should specify that in the protocol well in advance. All the missing data, unused data's spurious data should be accounted all emissions must be document. And the results which are presented to facilitate interpretations which are like clinical importance also should be consider. These are all very important areas of statistical analysis.

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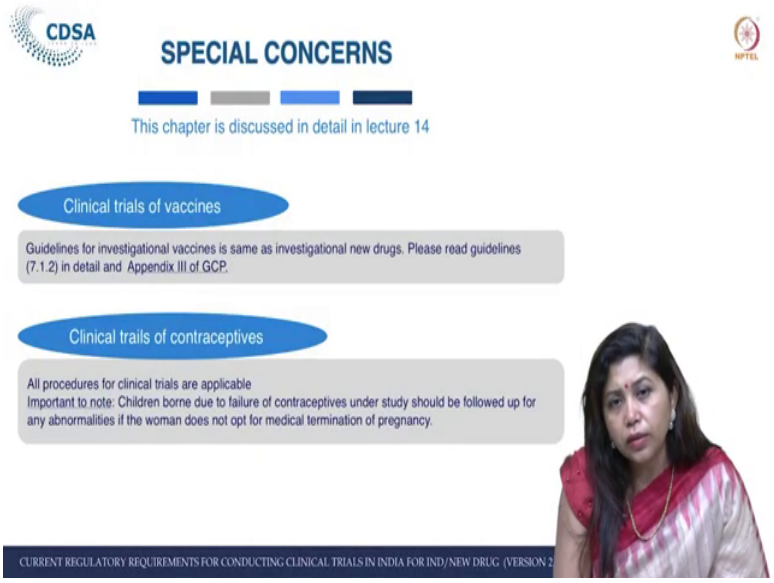

We have a special chapter or lecture on special concerns that is why, I will not go deep into that and that lecture will address all the areas whether it is vaccines, or contraceptives, or surgical procedures, or medical devices diagnostic agents like; radioactive materials and X rays, phi two pharmaceuticals all etcetera.

I just would like to tell you about something like; all vaccines are new drugs, all monoclonal antibodies are new drugs. So, we should understand what are new drugs, where clinical trial is applied also we should know about the medical device.

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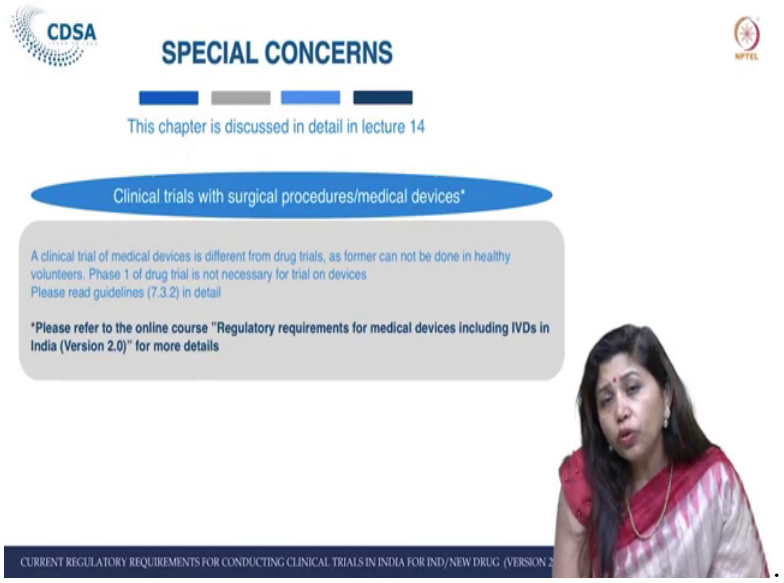

We have another online course, which is running parallel with this, which is on medical devices and in vitro diagnostics. The clinical trial of medical device and in vitro diagnostics are different they are done in a way which we call it clinical investigation plan.

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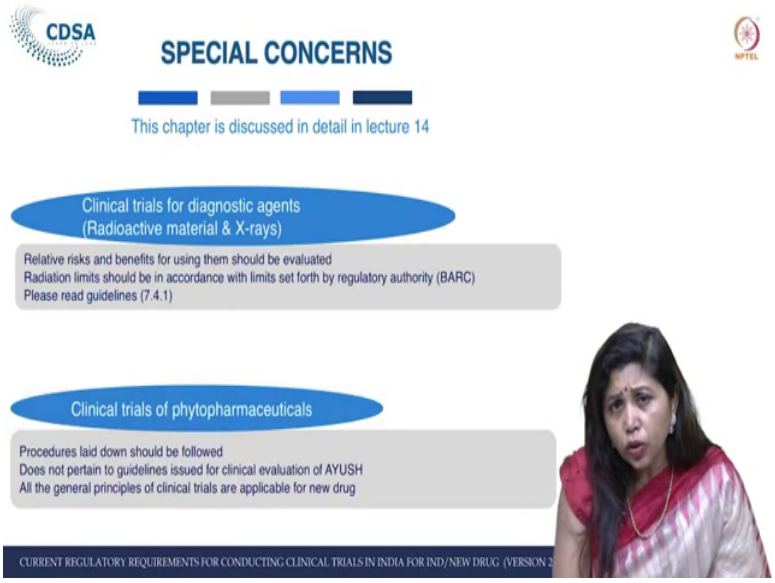

So, that is what we had studied about all the chapters where the end.

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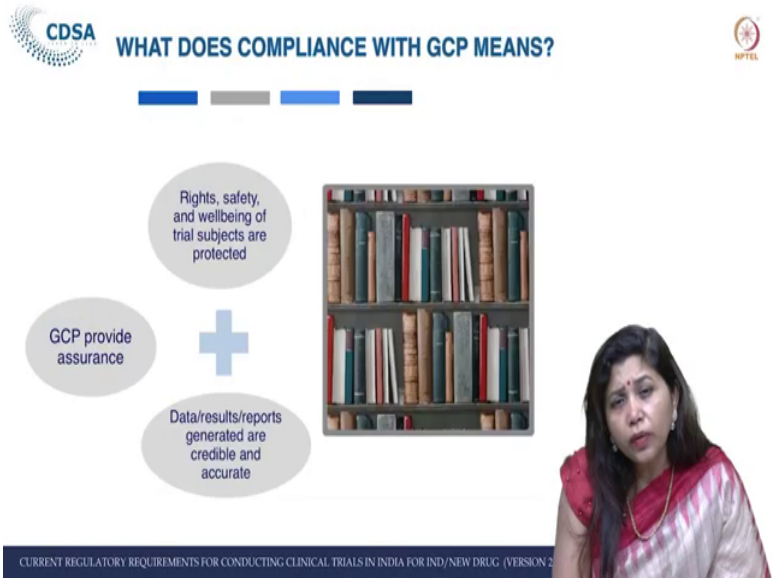

If somebody asks you, what does the compliance with GCP mean to you? It is same what we addressed when we started this session we spoke the GCP means that you give public an assurance about rsw tableau that is; the right safety and right, safety and well-being of all the study participants are well protected during the conduct of the study and d q i that is; the data, quality and integrity are assured; that means, the data credible and accurate.

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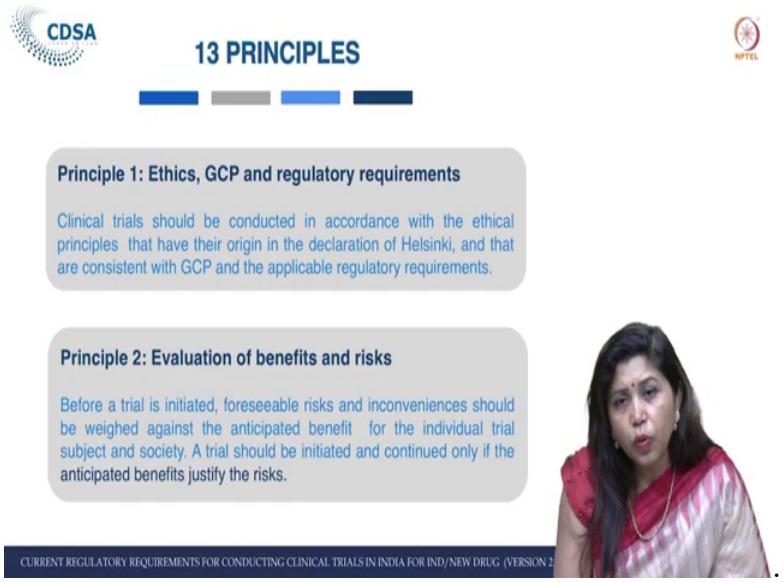

So, the CDSCO or the Indian GCP does not address the 13 principles, but it is important for us to know all the 13 principles will briefly cover all of them. The 1st principle, begins with ethics, GCP and regulatory requirements. It talks about the first most important crucial element of any clinical trial conduct is about ethics we say a bad science, is bad ethics and vice versa.

So, the all the clinical trials that should be conducted should be conducted in accordance to the ethical principles that is in India, it is a ethical lyceum and national ethical guidelines 2017, there is another one for pediatric children that is also 2017. Al these have their origin on the declaration of Helsinki, and all the clinical trial that you conduct should be in consistent with the good clinical practice in India it is a CDSCO 2001. And the all applicable regulatory requirements which are present here in India it is the new drugs and clinical trial rules 2019.

The 2nd principle talks about benefit and risk, whenever you conduct a study or when a whenever the study is being reviewed before a trial is initiated, it is very important to see the foreseeable risk and the inconveniences. And this should be weighed against the anticipated benefits of the individuals or the trial subjects or the participants and the society. A trial, a clinical trial should only be initiated and continued where, once its anticipated benefits justify the risk; that means, your benefit should always be more than.

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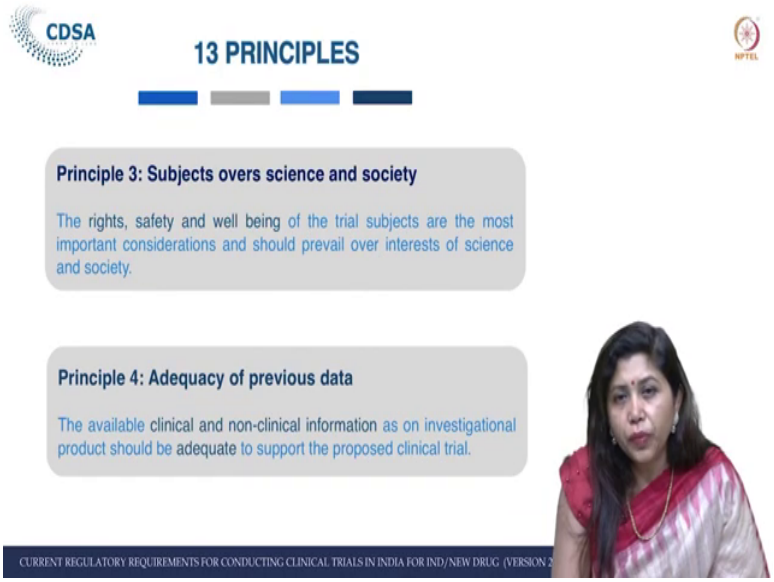

3rd subject over science and society: There is a discussion about good science and bad science that I spoke just now at any moment at any given time of during the conduct of the study this the subjects should be of more subjects should be important. And the right, safety and their well-being are the most important considerations and should prevail over the interest of science and society at any given time and every time.

Adequacy of previous data; it is extremely important we have a special lecture on, lecture L-4 which is about the previous data which is pre-clinical requirements, where we have discussed about all the non clinical and the clinical information that the product should have and what are the different requirements. for example, the animal pharmacology, the toxicology, the safety pharmacology data these all information's should be adequate to support the proposed clinical trial.

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5th Scientifically sound protocol; protocol is the most important document in a clinical trial. Any areas where you face queries or have any confusion I think so, protocol should be able to answer those. So, a clinical trial should have a scientifically sound protocol, which should have a clear and a detailed description of all the steps that the study intends to address.

Independent review principle 6th, extremely important the review which is done by the ethics committee should be independent in nature. How do you ensure that? The ethics committee should have people who are outside the institution and also the chairman of the ethics committee should be from the other than the should be from outside. So, we had a detailed discussion about this in our lecture L-10 which is ethical consideration.

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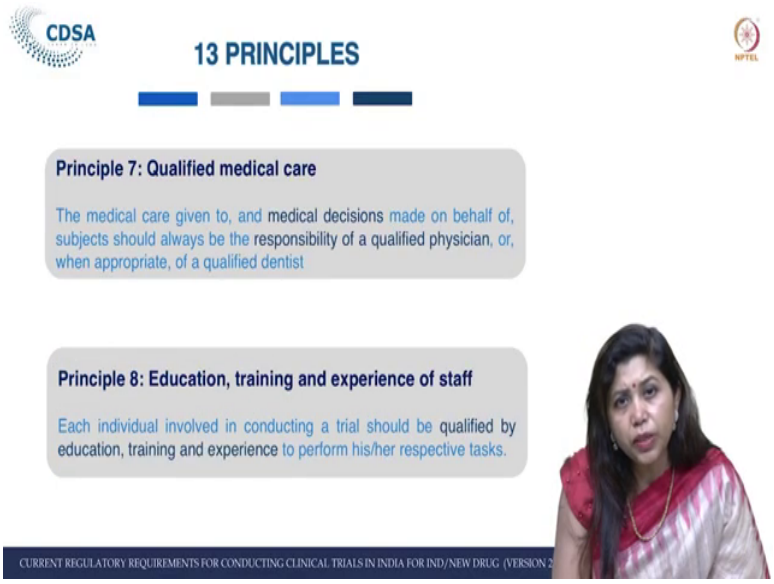

Principle 7: Qualified medical care; what does this mean? The people who are involved the clinicians should be qualified; that means, they should have a degree which is recognized by MCI, if it is a dental study it should be a dentist.

Principle 8; it is about education training and experience we all know that the people who are engaged in clinical trial the clinicians are of course, qualified by education they can an be MBBS, MD or MCh or DM degrees. And they can have several years of experience, but they

are training on GCP, and the current regulatory requirements, and current ethical requirements for conducting clinical trials in India is extremely important and this training should not be initial it should be ongoing.

So, initial as well as ongoing and their curriculum vitae and their details should be updated and kept. It is extremely important to fulfill the three requirements about education, experience and training.

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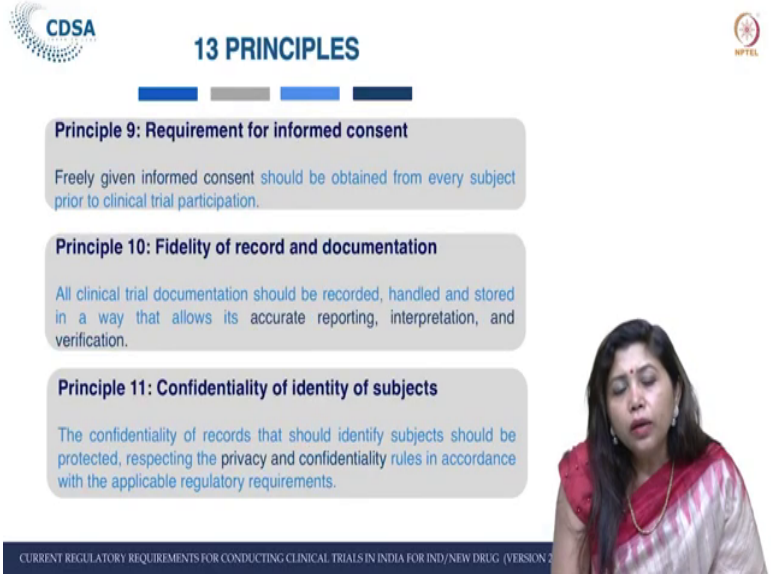

Principle 9: requirement of informed consent; informed consent is the weakest link in clinical trial we call it [FL]. The way the informed consent is taken, the way the informed consent documentation is kept is extremely important to understand how the clinical trial is conducted at that site.

The informed consent should be given freely; that means, the people should have autonomy to withdraw from the study, without hampering their medical care and should be obtained from each and every participant prior to their participation in the clinical trial.

Principles 10: fidelity of record and documentation when the GCP was revised by the ICH in 2016. The 10th principle was the only principle which was revised; that means, we definitely have some lacunae in how you record and document when we conduct a clinical trial. It is extremely important to understand the power of good record keeping and documentation.

We say that clinical trial is all about documents, documents and documents and how you keep them is extremely important. So, all clinical trial all the information that you gather from source data till clinical study report should be recorded properly, should handle properly, should be stored with several backups what we discussed so, that it allows an accurate reporting interpretation and verification

Principle 11; confidentiality of the subject, the identity of subjects should not be revealed they should be protected thus respecting the privacy and confidentiality. The privacy and the confidentiality we have discussed how we differentiate between them in our earlier lecture L10.

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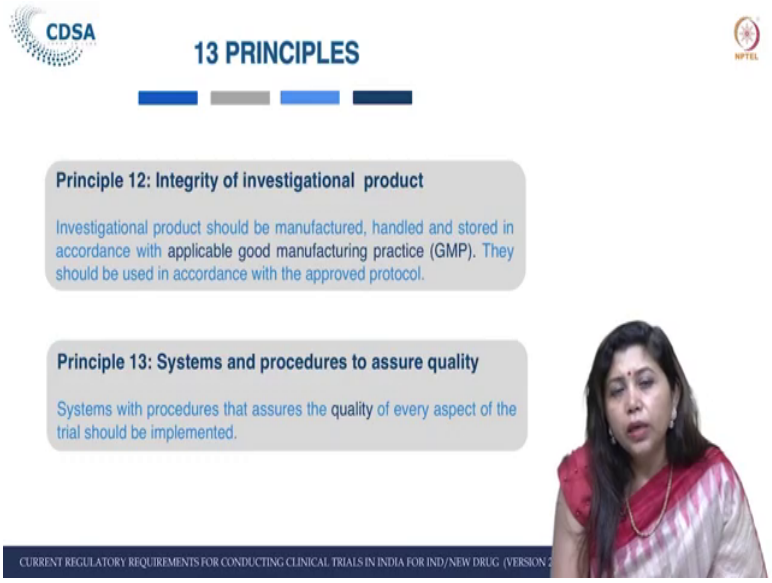

So, that is the reason all the participants or the study subjects involved in the study are referred as a number like; subject id or participant id.

12th principle: Integrity of the investigational product this is of utmost important because, the entire clinical trial is based on the investigational product. And if the investigational product integrity is doubtful the entire study will be null and void.

So, how the investigational product is manufactured, whether its manufactured as for the GMP that is good manufacturing practice is important how it is handled, how its stored how it is used is extremely important. All this will be mentioned in your study protocol, which will be approved protocol from the ethics committee as well as from the central licensing authority that is CDSCO.

The last principle: Principle 13 which talks about systems and procedures to assure and quality. So, what is system and what is procedure and how will they ensure quality? Systems with procedure means standard operating procedures; that means, to ensure quality you have to assure that all the steps which are written in the protocol are by abided and there is no non compliance.

How you can do that? you can you can start by begin writing SOP, the first SOP should be your SOP of SOP and then all the standard operating procedure should be aligned to the protocol. So, that you have very minimal or no non compliances.

Every standard operating procedure should have a template, checklist, forms so, that you ensure by filling of this form that you are compliance to SOP. Once your compliance to SOP you are very close to compliance to the protocol and you should do for each and every aspect of the trial so, that you can assure by ensuring those

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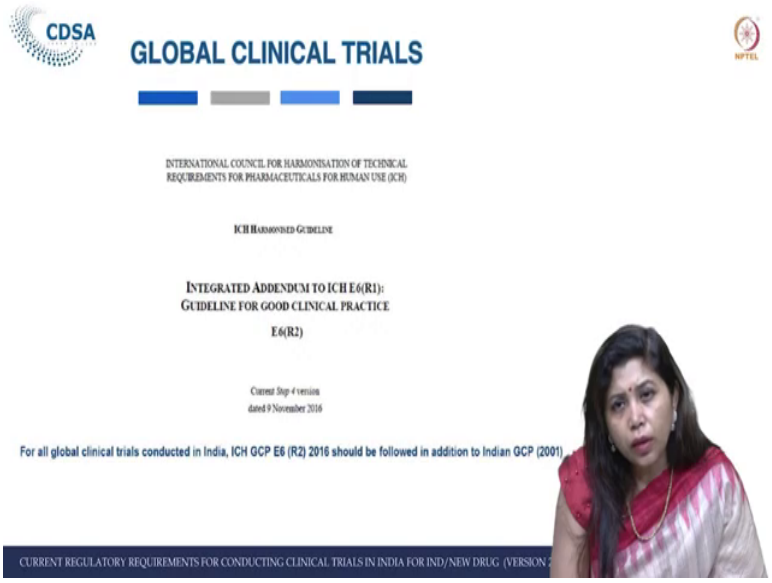

ICH-GCP guideline; this lecture covers the GCP guideline by CDSCO 2001 and we are not covering 2016 ICH GCP E 6 R 2. But, for all global clinical trials which are conducted in India ICH GCP E 6 R 2 which was released in 2016 should be followed in addition to the Indian GCP or the CDS co GCP 2001.

I request all of you to go through this guideline of E 6 R 2 the link is provided here along with this please go through it and read the both the guidelines.

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Just briefly, what is ICH? ICH is the International Council for Harmonization of technical requirements for pharmaceutical for human use, it was first, initiated in 1996 by European Union, US Japan. And the main purpose of this was to standardize the conduct of the study and all the requirements among all the countries so, that the study which is conducted in say India should not be repeated in x or y countries. So, repeating in individual countries will be reduced by following a standardized guideline and that is; how ICH GCP was there.

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ICH GCP got revised from 1996 to 2016. The WHO GCP was released in 2002, it has 14 principles which are almost the similar principles that we covered just now.

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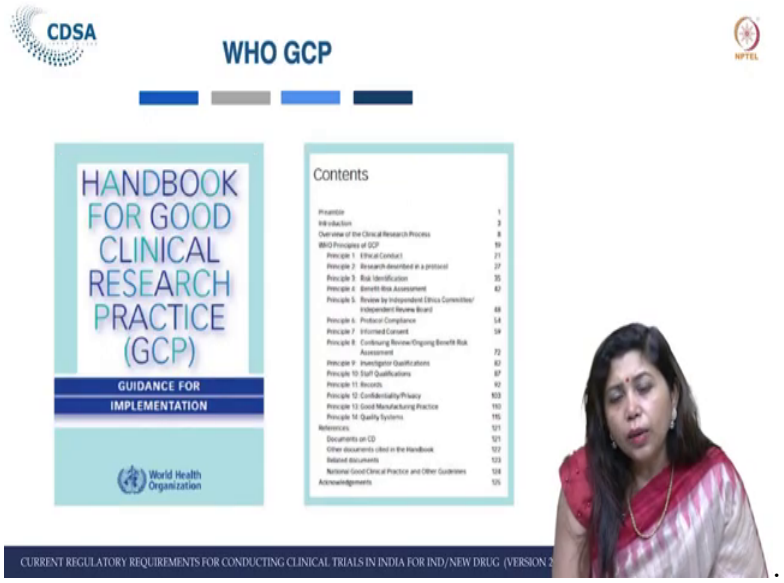

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They were from the ICH GCP, and that is it ladies and gentlemen this is a very short course on GCP actually, GCP is a very big lecture in general when we are planning to come up with only a course which is on good clinical practice. So, that is we are upcoming online course on good clinical practice please keep watching us maybe you will have a link when we will release this course on good clinical practice. Let us do a quick recap to understand whether you have understood this better.

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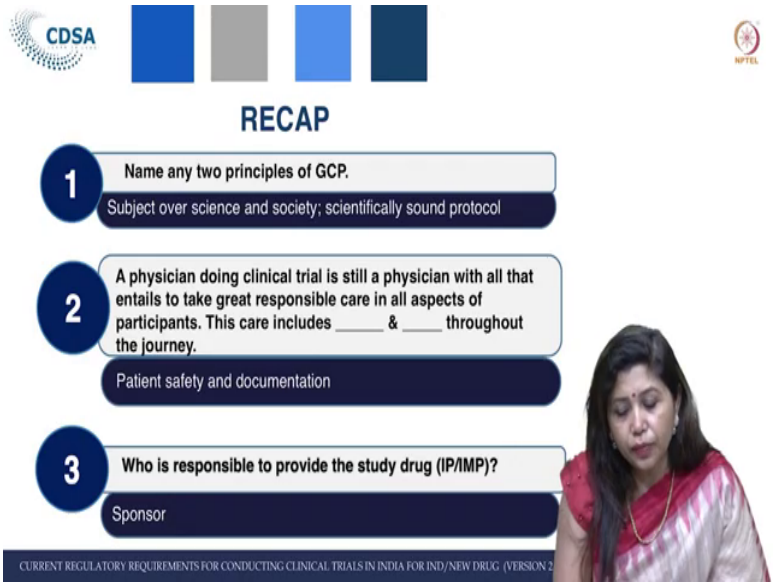

So, can you please name any of the 2 principles that we discussed about a GCP any 2 we had 13 principles, yes anything else? Yes you can remember science over society. So, subject over science and society that you can remember and say as s 3 so, this is one of the principle. Principle 3rd I think so, scientifically sound protocol can be 1. You can name any of the 2 from the 30.

Now, can you fill in the blank and you say what were there what is there in the fill in the blanks? The fill in the blanks read as a physician doing clinical trial is still a physician with all that entails to take great responsible care in all aspects of study participant. This care includes dash and dash throughout the journey.

Do you remember the responsibilities of investigator? Yes, yes please try, no; no the answer is wrong. It is about patient safety which is of paramount importance as well as the

documentation. So, the physician is responsible for patient safety as well as the documentation. Can you tick up this question, who is responsible to provide the study drug that is investigational product? Yes, please try.

Student: (Refer Time: 43:26)

Yes you are right. It is a responsibility of sponsor to provide the study drug to the investigator.

So, let us do a quick summary recap about this is that what did we study today we studied about what is GCP good clinical practice, we actually touched upon the Indian GCP that is the CDCSO guideline as per released in 2001. We also went through the prerequisites of the study for definitions I had given a link please go through the definitions carefully it is a long list we are unable to cover in the short course. And we spoke about all the rules and responsibilities very brief all the stakeholders like; the sponsor, the monitor, the investigator, the ethics committees all. We discussed about the record keeping and data handling which is extremely important.

We also touched upon the quality assurance and the statistics. We also briefly covered about the vaccines and medical devices, but we have a special lecture on special concerns that is why; we have not touched upon this. So, that is it ladies and gentlemen I hope you had a; you had a brief idea about good clinical practice in lecture 11 and best wishes to all of you and [FL] and [FL].