A Report on Workshop

"Indian Good Clinical Practices (GCP)"
Organized by
R & D Cell, BLDE (DU) in collaboration with ISCR

Date: 14/7/2023 **Venue: Dept. of Medical Education.**

Participants: Academicians, Faculty, Research Scholars, PG Students from all disciplines.

Resource Person: Dr.Gaurav Mathur & Mr.Nanjaraje Urs, ISCR,Bangaluru.

Participants: Total 60 No's from all Departments' 1st year PG students, selected Faculties of the Ethical Committee.

The workshop began with the welcoming by Dr. Chndrika Doddihal, Dy.Director, R & D Cell and introducing the resource persons by Dr.M.M.Patil, Director, R & D Cell, BLDE (DU) and addressed few words about the important of **"Indian Good Clinical Practices (GCP)".**

Resource persons were honored with University gesture for the workshop by Hon'ble Vice Chancellor. Hon'ble Vice Chancellor briefed about, there is consistent demand on academicians to produce good quality research papers. With the help of some characteristic examples and activities, the workshop will serve as a practical guide to the art of writing papers. Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants.

Objectives of the workshop:

- To know the importance of GCP
- To know the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants.

GCP training ensures anyone involved in research knows how to perform specific tasks according to the highest scientific, practical, and ethical standards. GCP courses will empower learners to be more competent in their roles while preserving the rights, wellbeing, and safety of anyone involved in studies or research.

GCP guidelines ensure clinical data generated are verifiable, accurate and reproducible during a trial. Compliance with GCP is necessary for advancement in scientific knowledge and assurance of public well-being, safety and confidentiality.

All investigators and staff who are involved in the conduct, oversight or management of NIH funded clinical trials are required to complete training in Good Clinical Practice (GCP) and refresh this training every 3 years, consistent with principles of the International Conference on Harmonization (ICH) E6 (R2)

BLDE (DEEMED TO BE UNIVERSITY)
SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA
Research & Development Cell

Indian Society for Clinical Research ISCR Enhancing patient outcomes through clinical research

Workshop on Indian Good Clinical Practices (GCP)

Schedule

Time	Topic	ISCR Trainer
14.07.2023 (Friday)		
11.00 to 11.15	Welcome and Introduction	
11.15 to 12.00	Introduction to ISCR & GCP Workshop Highlights of NDCT Rules, 2019 Q&A session	Dr. Gaurav Mathur
12.00 to 12.45	ICG GCP R2 & Indian GCP. Q&A session	Nanjaraje Urs
12.45 to 13.30	Investigator and Clinical Research Coordinator Responsibilities Q&A session	Dr Gaurav Mathur
Lunch Break		
14.15 to 15.00	Sponsor Responsibilities Q&A session	Nanjaraje Urs
15.00 to 15.45	Safety Reporting and Compensation Q&A session	Dr Gaurav Mathur
15.45 to 16.30	National Ethical Guidelines for Biomedical Health Research -2017 Ethics Committee Responsibilities Q&A session	Nanjaraje Urs

Trainer:

GAURAV MATHUR, PH.D., MBA
SSENIOR DIRECTOR, REGULATORY AFFAIRS & REGIONAL HEAD REGULATORY OPERATIONS INDIA, PAREXEL INTERNATIONAL

NANJARAJE URS S.
MSC, MBA, PMP, (PHD)
FREELANCER CONSULTANT. FORMER DIRECTOR – QUALITY MANAGEMENT – INDIA & SRI LANKA, IQVIA

Medical Education Hall

Fri, 14th July, 2023

There are two chapters which are dedicated to EC. The new rules have separated the ethical governance system by having two different types of ECs with two authorities for their registration and monitoring

I. Introduction to ISCR & GCP Workshop highlights of NDCT Rules,2019 Q & A session:

The resource persons were focused on the New drugs and Clinical trials rules 2019 (New rules) was introduced on 19th March 2019 by Government of India. New rules have set specific requirements for ethics committee (EC). The EC is required to follow requirements set as per New rules and to forward their report to Central Licensing Authority (CLA). This document is divided into different sections like definitions and applicable chapter & schedules for EC; changes related to registration of clinical studies and biomedical and health research; changes related to constitution, functions, proceedings, responsibility of EC for clinical trial; maintenance of records by EC; suspension and cancellation of registration of EC, post-trial access of drugs, changes and clarity related to academic clinical trials and role of ECs in compensation and medical management process.

Also, summarizes major changes affecting ethics committee (EC) after coming into force of the New Drugs and Clinical Trials Rules 2019 (New rules), i.e. GSR 227 (E) by India's Ministry of Health and Family Welfare (MoHFW).

II. ICG GCP R2 & Indian GCP:

A. Clinical trial (CT), EC, constituted under Rule 7 and registered under Rule 8 of the New CT rules.
B. Biomedical and health research, EC, constituted under Rule 16 and registered under Rule 17 of the New CT rules.

Overview of ICH-GCP E6 (R2) & Indian GCP :The International Council for Harmonization (ICH) is committed to developing timely technical requirements for pharmaceuticals for human use in a manner that is responsive to the needs of the global community. ICH is committed to stakeholder engagement and transparency in the development of its guidelines. ICH E6 Good Clinical Practice (GCP) Guideline is widely used by clinical trial researchers beyond the membership and regional representation of ICH itself and has a significant impact on trial participants and patients. Acknowledging the wide and substantial impact of ICH E6, the ICH Management Committee is making available a draft, work-in-progress version of the updated principles that are currently under development by the ICH E6(R3) Expert Working Group (EWG). The principles are interdependent and should be considered in their totality to assure ethical trial conduct, participant safety, and reliable results of clinical trials.

The renovation of ICH E6 (R2) will set out principles which will be aligned with the principles in ICH E8(R1) Revision of General Considerations for Clinical Studies.

ICH E8 (R1) includes a framework for designing quality into clinical trials, stakeholder engagement, trial design, proportionate trial management and focus on factors critical to the quality of trials.

When complete, ICH E6 (R3) will be composed of an overarching principles document. The overarching principles document will replace the current ICH E6 (R2).

Although the EWG's work is continuing and the group is still progressing towards Step 2 of the ICH guidance development process, the ICH Management Committee decided that sharing the draft version of the principles would facilitate transparency and common understanding. Although public comments are not requested at this time, once the updated ICH E6 Guideline achieves Step 2 of the ICH guidance development process, public input will be invited and considered. Step 2 will involve simultaneous publication of both the draft principles and Annex 1, along with an introduction and a glossary. Public comment will be invited at that point since the principles need to be seen and commented on alongside the details in Annex 1. The ICH E6 (R3) EWG is organizing a web conference to present the current draft of the GCP principles as a work in progress. Additionally, the general ICH process will be presented with a focus on the ICH E6 (R3) development process.

The Principals of ICH GCP:

ICH GCP Principle 1 states that clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement.

13 Principles

 Ethics Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

 Trial risk vs trial benefit: Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

 Trial participants: The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

 Information on the Medicinal Product: The available non-clinical and clinical information on an Investigational Product should be adequate to support the proposed clinical trial.

 Good quality trials Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

 Compliance with the study protocol: A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.

 Medical decisions: The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

 Trial staff each: individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

 Informed consent: Freely given informed consent should be obtained from every subject prior to clinical trial participation.

 Clinical trial data: All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

 Confidentiality The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

 Good Manufacturing Practice Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.

 Quality assurance Systems with procedures that assure the quality of every aspect of the trial should be implemented.

III. ICH GCP E6(R2) Responsibilities of Investigator and Clinical Research Coordinator:

Investigator Responsibility:

4.1 Investigator's Qualifications and Agreements

4.1.1 The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority (ies).

4.1.2 The investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.

4.1.3 The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

4.1.4 The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).

4.1.5 The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

4.2 Adequate Resources

4.2.1 The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

4.2.2 The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.

4.2.3 The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

4.2.4 The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

4.2.5 The investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site.

4.2.6 If the investigator/institution retains the services of any individual or party to perform trial-related duties and functions, the investigator/institution should ensure this individual or party is qualified to perform those trial-related duties and functions and should implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

4.3 Medical Care of Trial Subjects

4.3.1 A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.

4.3.2 During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for inter current illness (es) of which the investigator becomes aware.
4.3.3 It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.
4.3.4 Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights.

4.4 Communication with IRB/IEC

4.4.1 Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects.

4.4.2 As part of the investigator's/institution's written application to the IRB/IEC, the investigator/institution should provide the IRB/IEC with a current copy of the Investigator's Brochure. If the Investigator's Brochure is updated during the trial, the investigator/institution should supply a copy of the updated Investigator's Brochure to the IRB/IEC.

4.4.3 During the trial the investigator/institution should provide to the IRB/IEC all documents subject to review.

4.5 Compliance with Protocol

4.5.1 The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies) and which was given approval/favourable opinion by the IRB/IEC. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.

4.5.2 The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change in monitor(s), change of telephone number(s)).

4.5.3 The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.

4.5.4 The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/favorable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted:

(a) To the IRB/IEC for review and approval/favourable opinion,
(b) To the sponsor for agreement and, if required,
(c) To the regulatory authority(ies).

4.6 Investigational Product(s)

4.6.1 Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.

4.6.2 Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product(s) accountability at the trial site(s) to an

appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution.

4.6.3 The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, should maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product(s) received from the sponsor.

4.6.4 The investigational product(s) should be stored as specified by the sponsor and in accordance with applicable regulatory requirement(s).

4.6.5 The investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.

4.6.6 The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product(s) to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.

4.7 Randomization Procedures and Unblinding:

The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature Unblinding (e.g., accidental unblinding, Unblinding due to a serious adverse event) of the investigational product(s).

4.8 Informed Consent of Trial Subjects:

4.8.1 In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IRB/IEC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to subjects.

4.8.2 The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject’s consent. Any revised written informed consent form, and written information should receive the IRB/IEC's approval/favourable opinion in advance of use. The subject or the subject’s legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject’s willingness to continue participation in the trial. The communication of this information should be documented.

4.8.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.

4.8.4 None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

4.8.5 The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval/ favourable opinion by the IRB/IEC.

4.8.6 The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.

4.8.7 Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.

4.8.8 Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.

4.8.9 If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.

4.8.10 Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

a. That the trial involves research.
b. The purpose of the trial.
c. The trial treatment(s) and the probability for random assignment to each treatment.
d. The trial procedures to be followed, including all invasive procedures.
e. The subject's responsibilities.
f. Those aspects of the trial those are experimental.
g. The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.

h. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

i. The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.

j. The compensation and/or treatment available to the subject in the event of trial-related injury.

k. The anticipated prorated payment, if any, to the subject for participating in the trial.

l. The anticipated expenses, if any, to the subject for participating in the trial.

m. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

n. That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority (ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.

o. Those records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

p. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

q. The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.

r. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

s. The expected duration of the subject's participation in the trial.

t. The approximate number of subjects involved in the trial.

4.8.11 Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.

4.8.12 When a clinical trial (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.

4.8.13 Except as described in 4.8.14, a non-therapeutic trial (i.e. a trial in which there is no anticipated direct clinical benefit to the subject), should be conducted in subjects who personally give consent and who sign and date the written informed consent form.

4.8.14 Non-therapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:

(a) The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally.
(b) The foreseeable risks to the subjects are low.
(c) The negative impact on the subject's well-being is minimized and low.
(d) The trial is not prohibited by law.
(e) The approval/favorable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects, and the written approval/ favorable opinion covers this aspect.
Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

4.8.15 in emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative, if present, should be requested. When prior consent of the subject is not possible, and the subject's legally acceptable representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere, with documented approval/favorable opinion by the IRB/IEC, to protect the rights, safety and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate (see 4.8.10) should be requested.

4.9 Records and Reports

4.9.0 *The investigator/institution should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial subjects. Source data should be attributable, legible, contemporaneous, original, accurate, and complete. Changes to source data should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an audit trail).*

4.9.1 The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.

4.9.2 Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.

4.9.3 Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes or corrections (see 5.18.4 (n)). Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's

designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.

4.9.4 The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial (see 8.) and as required by the applicable regulatory requirement(s). The investigator/institution should take measures to prevent accidental or premature destruction of these documents.

4.9.5 Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained (see 5.5.12).

4.9.6 The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

4.9.7 Upon request of the monitor, auditor, IRB/IEC, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.

4.10 Progress Reports

4.10.1 The investigator should submit written summaries of the trial status to the IRB/IEC annually, or more frequently, if requested by the IRB/IEC.

4.10.2 The investigator should promptly provide written reports to the sponsor, the IRB/IEC (see 3.3.8) and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.

4.11 Safety Reporting

4.11.1 All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(ies) and the IRB/IEC.

4.11.2 Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

4.11.3 For reported deaths, the investigator should supply the sponsor and the IRB/IEC with any additional requested information (e.g., autopsy reports and terminal medical reports).

4.12 Premature Termination or Suspension of a Trial

If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority(ies). In addition:

4.12.1 If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution where applicable, and the investigator/institution should promptly inform the sponsor and the IRB/IEC, and should provide the sponsor and the IRB/IEC a detailed written explanation of the termination or suspension.

4.12.2 If the sponsor terminates or suspends a trial (see 5.21), the investigator should promptly inform the institution where applicable and the investigator/institution should promptly inform the IRB/IEC and provide the IRB/IEC a detailed written explanation of the termination or suspension.

4.12.3 If the IRB/IEC terminates or suspends its approval/favourable opinion of a trial (see 3.1.2 and 3.3.9), the investigator should inform the institution where applicable and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

4.13 Final Report(s) by Investigator

Upon completion of the trial, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB/IEC with a summary of the trial's outcome, and the regulatory authority(ies) with any reports required.

New Drugs and Clinical Trials Rules, 2019:

Why Regulatory Changes:

1. Consolidation of existing regulations.
2. Harmonization of regulations
3. R & D –New Technologies
4. New Therapies and products
5. Legalized
6. FAQ documents
7.

Structure: Chapters and Schedules

1. Drugs and cosmetic at 1940
2. New drugs and clinical trials rules,2019
3. Chapter (13)/schedule (8).

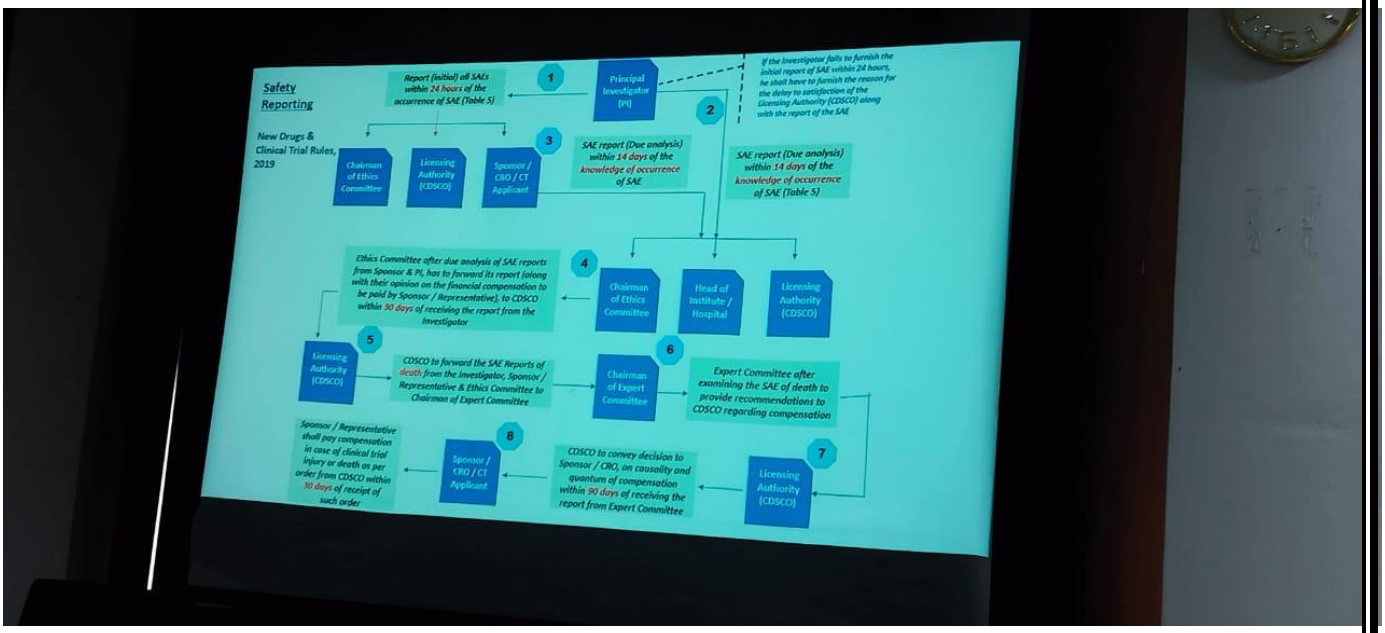
IV.Sponsor Responsibilities:

The sponsor is responsible for supplying the investigator(s)/institution(s) with the investigational product(s).

The sponsor should not supply an investigator/institution with the investigational product(s) until the sponsor obtains all required documentation (e.g., approval/favorable opinion from IRB/IEC and regulatory authority (ies)).

The sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of investigational product(s) for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and return of unused investigational product(s) to the sponsor (or alternative disposition if authorized by the sponsor and in compliance with the applicable regulatory requirement(s)).

The sponsor should:



(a) Ensure timely delivery of investigational product(s) to the investigator(s).

(b) Maintain records that document shipment, receipt, disposition, return, and destruction of the investigational product(s) (see 8. Essential Documents for the Conduct of a Clinical Trial). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice 28

(c) Maintain a system for retrieving investigational products and documenting this retrieval (e.g., for deficient product recall, reclaim after trial completion, expired product reclaim).

(d) Maintain a system for the disposition of unused investigational product(s) and for the documentation of this disposition.

The sponsor should:

(a) Take steps to ensure that the investigational product(s) are stable over the period of use.

(b) Maintain sufficient quantities of the investigational product(s) used in the trials to reconfirm specifications, should this become necessary, and maintain records of batch sample analyses and

characteristics. To the extent stability permits, samples should be retained either until the analyses of the trial data are complete or as required by the applicable regulatory requirement(s), whichever represents the longer retention period.

Adverse Drug Reaction Reporting:

The sponsor should expedite the reporting to all concerned investigator(s)/institutions(s), to the IRB(s)/IEC(s), where required, and to the regulatory authority (ies) of all adverse drug reactions (ADRs) that are both serious and unexpected.

2 Such expedited reports should comply with the applicable regulatory requirement(s) and with the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

The sponsor should submit to the regulatory authority (ies) all safety updates and periodic reports, as required by applicable regulatory requirement(s).

Clinical trial documents also **demonstrate the degree of compliance of the investigator(s), sponsor and monitors with applicable regulations and GCP guidelines**. They are usually audited by the Sponsor and inspected by the regulatory authorities to confirm data validity and integrity.

IV. Ethics Committee Responsibilities, safety reporting and compensation:

The Institutional Ethics Committees play the vital role of guiding researchers in the ethical issues associated with their research. FUNCTIONS: The major responsibility of IECs is to protect the rights, safety and well-being of the research participants.

The IECs conducts regular meetings for reviewing the research proposals and give suggestions to the investigators to make their research ethical before approving them. All research projects in humans should get the approval of any one of the IECs before starting their study.

Clinical trial related injury and serious adverse events (SAE) are a major area of concern. In all such scenarios the investigator is responsible for medical care of the trial participant and also ethically bound to report the event to all the stakeholders of the clinical trial. The trial sponsor is responsible for ongoing safety evaluation of the investigational product, reporting and compensating the participant in case of any SAE. The Ethics Committee and regulatory body of the country are to uphold the ethical principles of beneficence, justice, non-maleficence in such cases. Any unwanted and noxious effect of a drug when used in recommended doses is an adverse drug reaction (ADR) whereas if causal association is not yet established it is termed adverse event (AE). An AE or ADR that is associated

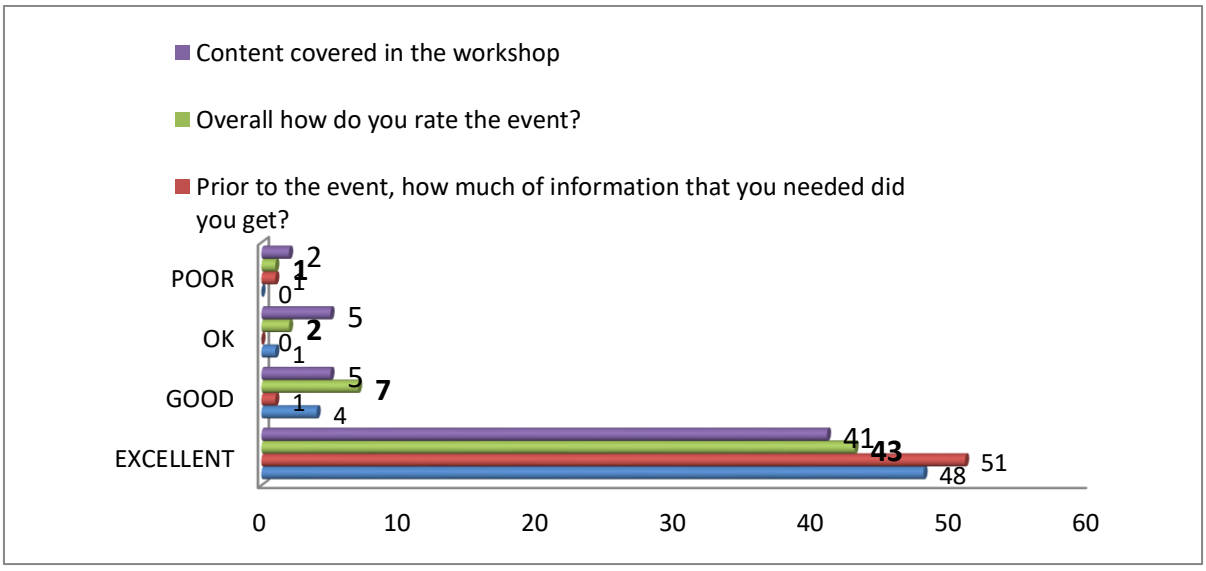
with death, in-patient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, a congenital anomaly, or is otherwise life threatening is termed as an SAE. The principal investigator reports the event to the licensing authority (DCGI), sponsor and Chairperson of the Ethics Committee (EC) within 24 hours of occurrence of the SAE. This report is furthered by a detailed report by both the investigator and the EC and given to the DCGI who then gives a final decision on the amount of compensation to be given by the sponsor or the sponsor's representative to the grieving party.

As a Clinical Research Associate (CRA) you have to understand it is not your responsibility to report anything. All you are doing is making sure that the Principal Investigator (PI) and whoever they put on the delegation of duties log, usually it is the study coordinators, are reporting adverse events on the source documents. Also, they are to report serious adverse events, many of which require hospitalization, to the IRB and to the sponsor. Adverse events do not need to be reported to the sponsor; they just need to be written down in the adverse event log and then put in the EDC. However, serious adverse events must be submitted to the IRB. You, as a CRA, have to make sure that the events that they are putting as adverse events are not actually serious adverse events. Your job as a CRA is to make sure these events are being documented properly. If you go to a high-enrolling site doing a long-term study and there are no reported adverse events, that is highly improbable, and you should bring that up to the PI. An adverse event can be someone who has had a headache or stomach ache or a cough or sneeze. I have heard monitors say that they have gone to research clinics where they enrolled thirty patients in a year-long study and nobody had any adverse events. Obviously someone was not reporting adverse events. Now, most sites won't have that issue. They will have adverse events up for every patient.

V. **National Ethical Guidelines for Biomedical Health Research-2017:**

https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf

Session concluded with the feedback:



The session summarizes with the few points by Dr.Akram A.Naikwadi, Former Dean R & D & Member secretary of IEC & Dr.M.M.Patil, Director R & D Cell with vote of thanks to all the dignitaries, Resource persons, Students & Staffs.

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