DMC/KLR/CTC/ 18 / 2025 **Date: 24/05/2025**

Event Report

Name of the Event: "CME -Good Clinical Practice"

Level: Local

Department: Clinical Trial Centre (Division of Research & Development Cell), SDUAHER

Venue: Dr. B C Roy Seminar Hall 1st floor, ULLRC, SDUAHER.

Date: 20-05-2025

Sl. No.	Particulars
1.	**Introduction**: Good Clinical Practice (GCP) represents a globally accepted framework of ethical and scientific quality standards for designing, conducting, recording, and reporting clinical trials involving human participants. These standards are defined by the International Council for Harmonisation (ICH) under the ICH E6 (R2) guideline. By adhering to GCP, researchers ensure that the rights, safety, and well-being of trial participants are protected, and that the data generated are credible and accurate, fostering both innovation in medical treatments and public confidence in clinical research. Recognizing the importance of GCP in modern clinical research, the **Clinical Trial Centre** (a unit under the Division of Research & Development Cell), **Sri Devaraj Urs Academy of Higher Education and Research** in collaboration with the **Department of Pharmacology** and **Indian Society for Clinical Research (ISCR), Academic Consortium for Clinical Research in India (ACCRI), South Chapter,** organized CME on Good Clinical Practice. This collaborative initiative aimed to promote high standards of clinical research through knowledge sharing and skill development among researchers and healthcare professionals. The event also was organised to commemorate the celebration of International Clinical Trials Day on 20th May.
2.	**Proceedings:** **Inauguration**: The event commenced on **20th May 2025 at 9:40 AM** with a soulful invocation rendered by **Mrs. Suma**. The proceedings were gracefully compered by **Dr. Bhargavi S**, Deputy Coordinator, Clinical Trial Centre. The inauguration ceremony was marked by a symbolic gesture of **watering the plant** by all the dignitaries and resource persons, signifying growth and sustainability in clinical research.

Welcome Address:
Dr. Kalyani R, Director of the Research & Development Cell, SDUAHER, extended a warm welcome to the dignitaries of the institution, esteemed speakers, and all participants. With great pleasure, she welcomed everyone to the CME on **Good Clinical Practice (GCP)**, emphasizing that the active participation of all attendees which will reflect a shared commitment to maintaining the highest standards in scientific research and clinical excellence.

Opening Remarks:
Dr. B Vengamma, Hon'ble Vice Chancellor, SDUAHER , highlighted the need and importance of Good Clinical Practice in the context of Clinical trials and advised all the participants to make use of the new knowledge generated from the workshop.

Dr. S. R. Prasad, provided the insight about the safety and ethical aspects in the conduct of clinical trials and wished all the participants to have a fruitful experience from the talks of the resource persons and utilize them in clinical practice.

Speaker 1
A video presentation by **Dr. Ananya Chakraborty**, Chair of ISCR ACCRI, was played, offering insights into the Indian Society for Clinical Research (ISCR) and importance of International Clinical Trials Day (ICTD). The video provided an overview of clinical trials and emphasized the critical need for such trials in the Indian context.

Speaker 2
Dr. Bhuvana K : Professor of Pharmacology, Sri Devaraj Urs Medical College, Kolar. Delivered detailed talk on topic titled **GCP Guidelines- An overview** provided a comprehensive introduction to the principles of Good Clinical Practice, focusing on ethical and scientific standards in clinical research. It emphasized the importance of safeguarding the rights, safety, and well-being of trial participants while ensuring the credibility of clinical trial data.

Speaker 3
Dr Sunil Kumar D, Professor and Head, Community Medicine, JSS Medical College, JSSAHER, Mysuru. Delivered detailed talk on topic titled **ICMR National Ethical Guidelines for Biomedical and Health Research involving human participants 2017 – An overview** and offered valuable insights into the ethical framework governing biomedical research in India. The speaker elaborated on the core principles such as respect for persons, beneficence, and justice, which guide ethical research conduct. The importance of informed consent, risk minimization, and the role of ethics committees in safeguarding participant rights were emphasized. This session helped participants understand their responsibilities in upholding ethical standards while conducting human research.

Speaker 4

Dr. Niveditha, Director, Professor and Head, Pharmacology, ESIC Medical College & PGIMSR, Bangalore. Delivered detailed talk on topic titled **Clinical Trial Protocol, Essential Documents, New Drugs and Clinical Trials Rules, 2019** and provided an in-depth understanding of the regulatory framework governing clinical trials in India. The speaker outlined the critical components of a clinical trial protocol and highlighted the importance of proper documentation for regulatory compliance and transparency. Key provisions of the NDCT Rules, 2019, were discussed, including streamlined approval processes, safety reporting, and ethical obligation.

Speaker 5

Dr. Praveen Kumar B.A. Professor of Community Medicine, PESIMSR, Kuppam, Andra Pradesh, delivered an insightful session providing an overview of the Ethics Committee (EC), its constitution, and the applicable regulatory frameworks, particularly those outlined by the Indian Council of Medical Research (ICMR) and Good Clinical Practice (GCP) guidelines. He emphasized the critical role of the EC in the scientific and ethical review of research protocols, aimed at safeguarding the rights, safety, and well-being of research participants. The session underscored the necessity for diverse representation within the EC, comprising clinicians, legal experts, social scientists, and laypersons, to ensure balanced and informed decision-making. A detailed explanation of the informed consent process was provided, covering its essential components, the need for participant comprehension, and proper documentation practices. Dr. Praveen also highlighted the ongoing ethical responsibilities of the EC, including the review of protocol amendments and the monitoring of adverse events throughout the study. The importance of maintaining transparency, confidentiality, and impartiality in all EC activities was strongly reinforced, reflecting the foundational principles of ethical conduct of clinical research.

Speaker 6

Mr. Madhusudhan B Acharya, Associate Director Clinical Safety, Adjudication, Fortrea, Bangalore, presented a comprehensive session on adverse events (AEs) and serious adverse events (SAEs) in clinical research, highlighting their significance in ensuring the safety of study participants and adherence to regulatory standards. He stressed the critical importance of timely and accurate documentation of AEs to facilitate prompt intervention and maintain compliance with both national and international guidelines. The session provided an overview of key concepts such as causality assessment, expectedness, and severity classification, which are essential for evaluating the relationship between investigational products and reported events. Mr. Acharya also discussed the regulatory requirements set forth by agencies such as the Drug Controller General of India (DCGI), International Council for Harmonization - Good Clinical Practice (ICH-GCP), and the Central Drugs Standard Control Organization (CDSCO). He elaborated on best practices in case narrative writing, follow-up reporting, and data reconciliation to ensure comprehensive and coherent safety reporting. He also explained the process of data monitoring by the Clinical Research Associate and sponsor on a regular basis. The presentation concluded by emphasizing the vital roles of clinical investigators and pharmacovigilance teams in upholding data integrity and

	protecting patient safety throughout the course of a clinical trial.
3.	**Panel Discussion:** The panel discussion was effectively led by Dr. Ravi M, Professor of Anesthesiology, who facilitated an engaging and insightful exchange among the distinguished panel members—Dr. Vengamma B, Dr. Niveditha, Dr. Praveen Kumar B.A., and Mr. Madhusudhan B Acharya. The discussion revolved around key ethical and safety considerations in clinical research, with each expert contributing their unique perspectives based on their professional expertise. Dr. Vengamma B and Dr. Niveditha emphasized the institutional challenges and strategies for strengthening ethics committee operations and participant protection. Dr. Praveen Kumar elaborated on the practical implementation of informed consent and the need for continuous ethics training among committee members. Mr. Madhusudhan B Acharya provided critical insights into current trends in pharmacovigilance, regulatory expectations, and the integration of digital tools for adverse event tracking. The session encouraged active audience participation, and the panelists addressed various questions, reinforcing the importance of multidisciplinary collaboration in upholding Good Clinical Practice (GCP) standards.
4.	**Concluding remarks**: The GCP workshop successfully achieved its objective of educating participants on the ethical and regulatory requirements of clinical research. It equipped attendees with essential knowledge and skills to ensure compliance with GCP guidelines, thereby promoting the conduct of ethical and scientifically rigorous clinical trials.
5.	**Participants & delegates:** A total of 75 members participated in the event
6.	**Certificate Distribution**: Distributed to all the participants
7.	**Valedictory Ceremony**: Vote of thanks was proposed by Dr. Sathishbabu P, Organizing Secretary, CME GCP


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1st floor, ULLRC
Clinical Trial Centre
UAHER


LLRC, SDUAHER

Organizing Chairman 1

24/05/2025

Dr. Bhuvana K
Chief Co-Ordinating Officer
CTC, SDUAHER

Dr. Bhuvana. K.
Chief Co-Ordinating Officer
Clinical Trial Centre
SDUAHER, Kolar

Organizing Chairman 2

26/05/25

Dr. Kalyani R
Director
R&D Cell

Prof. Dr. Kalyani . R.
MD (Path), Ph.D FAMS, FICP, FIAMS, FIMSA, FKSTA
Director
Research and Development Cell, SDUAHER
Professor & Former Head
Dept. of Pathology, SDUMC