NEELIMA INSTITUTE OF MEDICAL SCIENCES

NATIONAL WORKSHOP ON GOOD CLINICAL PRACTICE

ETHICS, SCIENCE, AND STANDARDS

(ONLINE MODE)

Event Report

- **INVITATION BROCHURE-**

Organized by;

Department of Pharmacology and Institutional Ethics Committee,

Neelima Institute of Medical Sciences

23rd August 2025 – 9.15am-1.45pm

The Department of Pharmacology and Institutional Ethics Committee, Neelima Institute of Medical Sciences, Anurag University, Venkatapur, Hyderabad successfully hosted the **National Workshop on Good Clinical Practice (GCP): Ethics, Science and Standards on 23rd August 2025** in online mode.

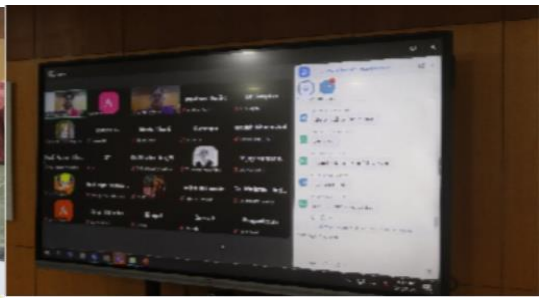
The event brought together distinguished faculty, postgraduate students, and researchers from across the country.

Organized under the **able leadership of Dr. B. Lakshmi Prasanna (Organizing Chairperson) and Dr. Vasavi Patra (Organizing Secretary), with dedicated support from the organizing committee (Dr. Venu Gopala Rao Konda, Dr. Mali Kalpana, Dr. Swati Negi, and Dr. Y. Venkata Ramana)**, the event was conducted seamlessly.

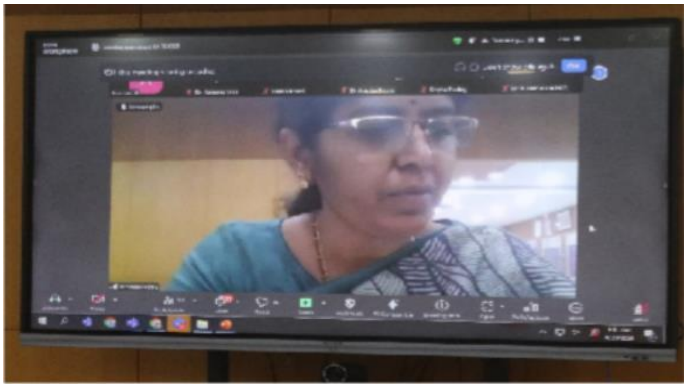
The workshop aimed to foster understanding of GCP guidelines, strengthen compliance with ethical standards in clinical research, and highlight evolving regulatory frameworks in India.

We had a tremendous response from all over the country with **392 registrations**, registration was free but mandatory, and the program carried **recognition with one CPD Credit Hour approved by TGMC**.

280 participants who completed **the pre- and post-test assessments** were awarded **e- Certificates** by the organizing team.

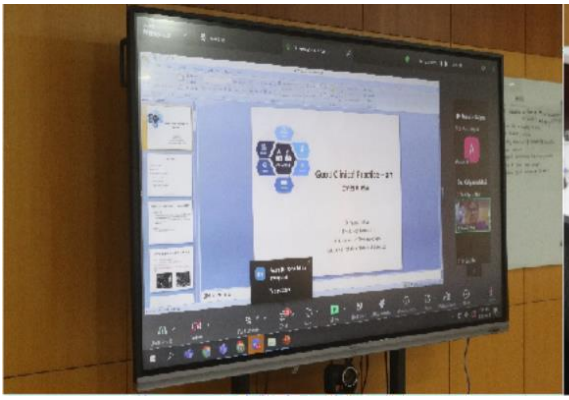
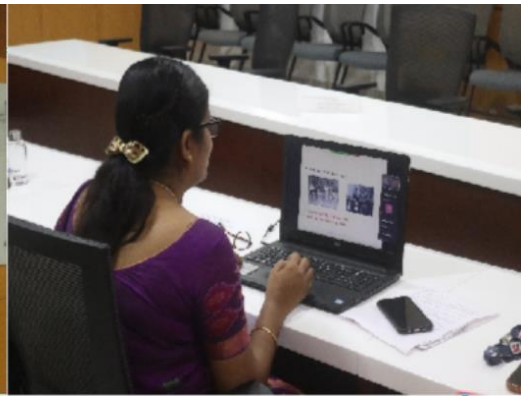



The inaugural session commenced at **09:15 am** on 23rd August 2025 with a welcome address by our Dean, Professor of Forensic Medicine **Dr. Lakshmi Prasanna madam** setting an academic and collegial tone for the day's scientific deliberation



The first lecture was delivered by **Dr. Vasavi Patra**, Professor and Head of the Department of Pharmacology, Neelima Institute of Medical Sciences, and Organizing Secretary of the workshop.

Dr. Patra gave an insightful overview of Good Clinical Practice (GCP), emphasizing the need for unified ethical and scientific quality standards in clinical research demarcating **how GCP functions as the backbone of credible data generation** and **safeguards the rights, safety, and well-being of research participants**.

Following this, **Dr. Madhavi Eerike**, Additional Professor, Department of Pharmacology, All India Institute of Medical Sciences (AIIMS) Bibinagar, addressed the critical theme of the **Informed Consent Process**.

Dr. Madhavi highlighted that informed consent is **not merely a signature on a form** but the embodiment of **respect for patient autonomy and voluntariness** in research **using several case-based examples** to illustrate ethical dilemmas encountered in practice, such as dealing with illiterate participants or vulnerable populations..

The agenda then moved to **Adverse Event Reporting and Documentation**, a session delivered by **Dr. Gerard Marshall Raj**, Associate Professor, Department of Pharmacology, AIIMS Bibinagar.

Dr. Gerard underscored how **adverse event monitoring is central to both participant safety and the credibility of any clinical research program.** His talk carefully **differentiated between adverse events and adverse reactions**, **explained the timelines and levels of seriousness**, and shared insights into regulatory reporting requirements.

Post the short break,

Dr. A. Maduram, Professor and Head, Department of Pharmacology, Sri Satya Sai Medical College & Research Institute, Chennai, presented on **Roles and Responsibilities of Ethics Committees, Sponsors, and Investigators**.

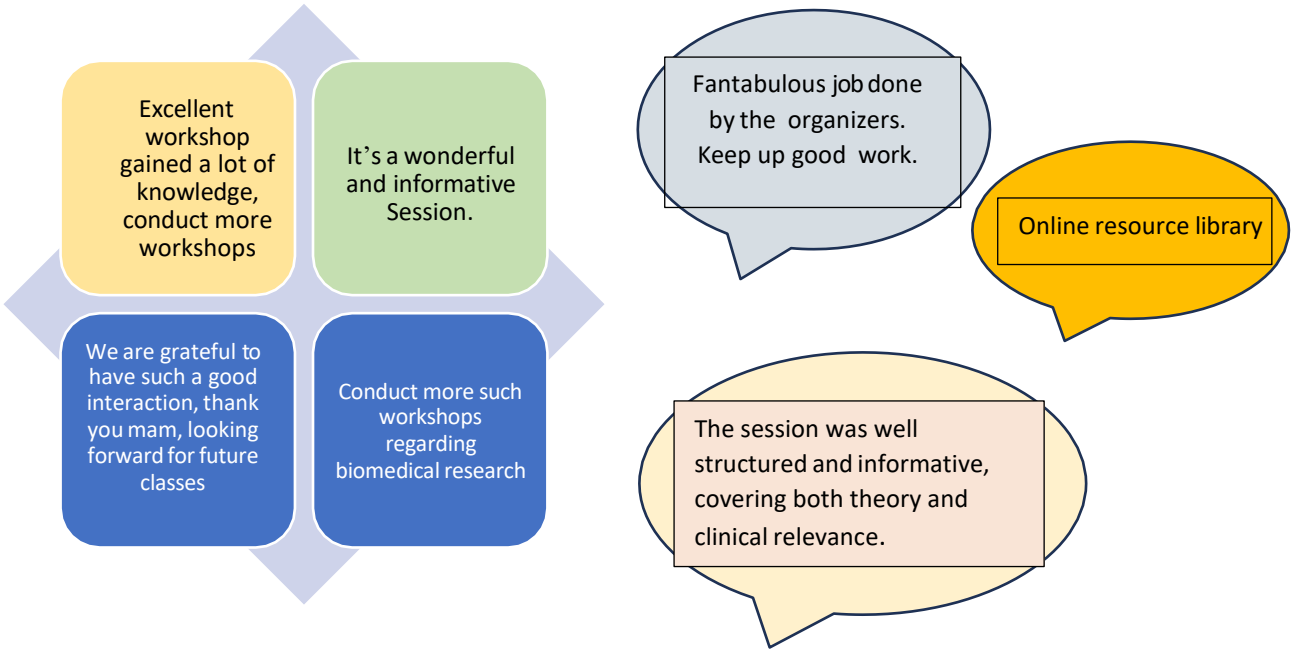
Dr. Maduram shed light on the **crucial balance of responsibilities in ethical oversight, financial sponsorship, and investigator conduct.** She spoke about the expectations of **transparency, accountability, and adherence to protocol** modifications.

The final scientific session of the workshop was conducted by **Dr. D. Shailendra**, Professor and Head, Department of Pharmacology, MediCiti Institute of Medical Sciences, Hyderabad, who delivered a comprehensive and engaging lecture on **NDCT Rules 2019 – An Overview**.

His session stood out for its clarity, depth, and practical relevance. Dr. Shailendra **traced the evolution of India's regulatory landscape**, situating the New Drugs and Clinical Trials (NDCT) Rules 2019 within the broader framework of clinical research governance. He provided a lucid explanation of key changes introduced under the rules, such as **accelerated approvals, compensation frameworks, and strengthened ethics committee functions**. Dr. Shailendra's session particularly engaging was his interactive style inviting questions from participants, **shared real-world case experiences from recent clinical investigations, and contextualized the rules in scenarios** that many postgraduate students and investigators could directly relate to.

The workshop concluded with a discussion and feedback session, where participants reflected on the rich knowledge gained throughout the morning.

Feedback from participants:



The well-structured scientific program ensured that each dimension of GCP—principles, informed consent, safety monitoring, ethical oversight, and regulatory law—was comprehensively addressed by experts in the field.

ACKNOWLEDGEMENTS-

We are immensely thankful to the management of Anurag University and our beloved Dean Dr. B. Lakshmi Prasanna madam for their unwavering support

Their meticulous coordination contributed to the success of the workshop, which was widely appreciated by participants nationwide.

CONCLUSION-

In summary, the National Workshop on Good Clinical Practice 2025 proved to be a highly enriching program that successfully met its objectives. Each speaker contributed substantive expertise to their respective domains.

The workshop reaffirmed the importance of ethics and standards in clinical research and inspired participants to adopt practices aligned with both national regulations and international excellence.