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Department of Health Research
Training NO. 1, Year 2025
Ensuring Integrity in Healthcare
Good Clinical Practice and Medical Ethics
Training Workshop held from 6th Jan to 7th Feb.

Inaugurated by: Dr. Kiran Katoch. Former Director,
National JALMA Institute of Leprosy and OMD.

FLOW of EVENTS

S.No	EVENT	TIMINGS
1.	Lamp Lighting and Ganesh Vandana	10:00- 10:05AM
2.	Welcome Address by Dr. Ashok Kumar Deorari, Principal, HIMS, SRHU	10:05- 10:10AM
3.	Induction to DHR Scheme by Dr. Bindu Dey, Director Research SRHU	10:10- 10:15AM
4.	Address by Dr. Vijendra Chauhan, Director General, Academic Development, SRHU	10:15- 10:25AM
5.	Address by Dr. Roli Mathur, Head, ICMR, Bioethics Unit, Bangalore	10:25- 10:35AM
6.	Address by Dr. Rajendra Dobhal, FNASc, Hon'ble Vice Chancellor, SRHU	10:35- 10:50AM
7.	Address by Chief Guest Dr. Kiran Katoch, Former Director, NJIL & OMD, Agra	10:50- 11:10AM
8.	Vote of Thanks by Dr. Ruchi Juyal, Co-Investigator, DHR Training Project	11:10- 11:15AM

Conducted By Department of Clinical Research, HIMS, SRHU.
Sponsored by Department of Health Research, ICMR MoHFW

Highlights of the Five-Week Training Program on Good Clinical Practice & Medical Ethics

Organized by:

Department of Clinical Research, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University (SRHU)

Sponsored by:

Department of Health Research, Ministry of Health and Family Welfare (MoHFW), Government of India

Duration:

January 6 – February 7, 2025

Introduction

The Department of Clinical Research at the Himalayan Institute of Medical Sciences (HIMS), Swami Rama Himalayan University (SRHU), successfully conducted a five-week training program from January 6 to February 7, 2025. Sponsored by the Department of Health Research, Ministry of Health and Family Welfare (MoHFW), this initiative was aimed at enhancing ethical competencies among faculty and Ethics Committees in Uttarakhand.

Training Workshop on Bioethics

As part of this initiative, a two-day workshop titled **"Training Workshop on Bioethics"** was held on January 6–7, 2025, in collaboration with the ICMR Bioethics Unit, Bengaluru. The workshop covered essential topics related to bioethics, emphasizing ethical considerations in clinical research and the role of Ethics Committees.

Overview of the Five-Week Training Program

Following the bioethics workshop, the five-week training program continued with a structured curriculum covering various aspects of **Good Clinical Practice (GCP)**. A total of **97 sessions** were conducted by distinguished faculty members and guest speakers, ensuring comprehensive coverage of relevant topics. **30 participants** actively engaged in the program, benefitting from expert knowledge and interactive discussions.

Speakers and Resource Persons

A total of **21 distinguished speakers** contributed to the training program, sharing their expertise on various topics related to bioethics, clinical research, and Good Clinical Practice. The list of speakers included:

1. **Prof. Yogendra Singh** – Chief Librarian, SRHU
2. **Dr. Amjad Hussain** – Director, HCIE
3. **Dr. Pradeep Varshney** – Director, IQAC
4. **Dr. Bindu Dey** – Former Secretary, TDB & Retd. Advisor, DBT Govt. of India; Director, Research, SRHU
5. **Dr. Nikku Yadav** – In-Charge, Department of Clinical Research, HIMS, SRHU
6. **Dr. D.C. Dhasmana** – Professor, Department of Pharmacology
7. **Dr. Ruchi Juyal** – Professor, Department of Community Medicine
8. **Dr. Suman Bal** – Professor & Head, Pharmacology, SGRR University
9. **Mr. Abhinav Bahuguna** – Lecturer, Department of Biostatistics
10. **Dr. Ashok Kumar Srivastava** – Professor & Head, Department of Community Medicine, SRHU
11. **Dr. Manisha Sharma** – Assistant Professor, Department of Clinical Research, SRHU
12. **Mrs. Akanksha Uniyal** – Lecturer, Department of Biostatistics, SRHU
13. **Mrs. Garima Kapoor** – Assistant Manager, C-PACE, SRHU
14. **Ms. Charu Paliwal** – Consultant, Quality Assurance, Bharat Biotech Pvt. Ltd.
15. **Mr. Ashish Gupta** – C-PACE, SRHU
16. **Mrs. Ekta Rao** – Assistant Professor, HSMS, SRHU
17. **Advocate Piyush Dhyani** – Assistant Registrar (Legal)
18. **Prof. Asha Chandola Saklani** – Professor, Department of Community Medicine, SRHU
19. **Dr. Somalata Jha** – Assistant Professor, HSYS, SRHU
20. **Dr. Neelam Bisht,** Incharge Ayurveda Centre, SRHU
21. **Dr. Bhavana Pal,** Scientific Officer, IPR Cell, SRHU

5 Week Schedule of the training program: Key Highlights

Week 1

Topic: Introduction to GCP and Ethics

Significance to Healthcare industry: An introduction to Good Clinical Practice (GCP) and ethics is essential to ensure the safety, rights, and well-being of research participants and to uphold the integrity of clinical research. It provides a framework for ethical decision-making and compliance with regulatory standards in clinical trials.

Week 2

Topic: Regulatory Compliance and Protocol Development

Regulatory compliance ensures that clinical research adheres to legal and ethical standards, safeguarding participant rights and data integrity. Protocol development is critical for structuring studies systematically, ensuring scientific validity, and aligning with regulatory and ethical guidelines.

Week 3

Topic: Conducting Clinical Trials

Conducting clinical trials is vital for evaluating the safety, efficacy, and quality of medical interventions, enabling evidence-based advancements in healthcare. It ensures that new treatments meet regulatory and ethical standards before becoming widely available to patients.

Week 4:

Topic: Ethical Issues and Professional Integrity

Addressing ethical issues and upholding professional integrity are crucial to maintaining trust, transparency, and fairness in clinical research. They ensure the protection of participant rights, the credibility of scientific findings, and adherence to moral and professional standards.

Week 5

Topic: Hands on Training and skill-based learning

Hands-on training and skill-based learning are essential for bridging the gap between theoretical knowledge and practical application. They enhance competency, confidence, and readiness to perform tasks effectively in real-world clinical research settings.

Conclusion

The five-week training program successfully provided faculty members and Ethics Committee members in Uttarakhand with valuable knowledge and insights into bioethics and Good Clinical

Practice. The diverse panel of speakers ensured a holistic learning experience, covering various critical aspects of clinical research ethics and regulatory frameworks.

The Department of Clinical Research at HIMS, SRHU, remains committed to fostering excellence in research and ethical clinical practices, with future initiatives aimed at further strengthening research ethics and governance in medical sciences.

"A group picture of students and faculty after successful completion on 5 weeks training"

"A group picture of students and faculty after successful completion on 5 weeks training"

SWAMI RAMA HIMALAYAN UNIVERSITY

Department of Clinical Research

Himalayan Institute of Medical Sciences

First two days training program conducted by ICMR Bioethics Unit, Bangalore

Program:6 Jan 2025-7 Jan 2025

Venue: B.C Roy

No of Participants: 122

Introduction: The Department of Clinical Research at the Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, launched a five-week training program from January 6 to January 7, 2025, sponsored by the Department of Health Research, Ministry of Health and Family Welfare (MoHFW). As part of this initiative, a two-day workshop titled "Training Workshop on Bioethics" was held on January 6–7, 2025, in collaboration with the ICMR Bioethics Unit, Bengaluru. This sensitization program was designed to enhance the ethical competencies of faculty and Ethics Committees in Uttarakhand. We invited ethical committee members of all medical college in Uttarakhand for participation. The workshop was inaugurated by distinguished dignitaries, including Dr. Kiran Katoch from NJILOMD, ICMR, as Chief Guest; Dr. Rajendra Dobal, Vice-Chancellor, SRHU; Dr. Vijendra Devisingh Chauhan, Director General (Academic & Development), SRHU; Dr. Ashok Kumar Deorari, Principal, HIMS, and Organizing Chairperson; Dr. Bindu Dey, Director of Research, SRHU, and Organizing Chairperson; Dr. Roli Mathur, Scientist G and Head, ICMR Bioethics Unit, Bengaluru; and Dr. Nikku Yadav, Organizing Secretary and Head, Department of Clinical Research, HIMS. The workshop focused on promoting adherence to ethical standards and Good Clinical Practices (GCP) in clinical research through expert-led sessions, interactive discussions, and practical exercises. Key topics included the principles of research ethics, roles and responsibilities of Ethics Committees, application of GCP guidelines, and strategies for addressing ethical dilemmas.

The event was attended by 100 participants, including faculty members and Ethics Committee representatives from five reputed medical colleges in Uttarakhand: AIIMS Rishikesh, Doon Medical College, Graphic Era Medical College, Government Medical College Haridwar, and Himalayan Institute of Medical Sciences.

This workshop served as a platform for capacity building and fostering collaboration among ethics oversight bodies in the region. By promoting a deeper understanding of ethical guidelines and cultivating a culture of responsible research, the program made a significant contribution to ensuring that clinical research in Uttarakhand adheres to national and international standards of integrity and compliance.

Geotag Photos:

“Lamp Lighting Ceremony: Honoring Dr. Kiran Katoch, Dr. Roli Mathur, Head of Bioethics Unit, ICMR Bangalore, Director General (Academic Development), SRHU & Principal, HIMS

Group Photo with Honourable Vice Chancellor Dr Rajendra Dobhal

"Dr Sunil Mishra, successfully completed the two-day workshop and receiving the Certificate"

Week 1; Day 3

Session 1

Title of Topic: National regulatory bodies and guideline

Date: 8/1/2025

Venue: Training and Development Cell, HIMS

No. of student: 27

Faculty Name: Dr Manisha Sharma

Objective: This report provides a brief overview of the CDSCO, DCGI, NDCT 2019, regulatory bodies, and the role of ,Ethics Committees in ensuring drug safety and ethical compliance in India.

Summary: The Central Drugs Standard Control Organization (CDSCO) is India's primary regulatory body responsible for overseeing the safety, efficacy, and quality of pharmaceuticals,

medical devices, and cosmetics. It functions under the Ministry of Health and Family Welfare, with the Drug Controller General of India (DCGI) at its helm. The DCGI plays a crucial role in approving new drugs, clinical trials, and ensuring that drugs meet regulatory standards.

The NDCT 2019 framework regulates the conduct of clinical trials in India, ensuring they adhere to strict ethical standards and prioritize participant safety. It aims to streamline the clinical trial process, promoting transparency and accountability. In addition to CDSCO, there are other bodies like the National Pharmaceutical Pricing Authority (NPPA), which manages the pricing of drugs, and various state-level regulatory authorities that ensure the legal compliance of pharmaceutical products. The Ethics Committees, meanwhile, play a critical role in ensuring that clinical trials are conducted ethically, safeguarding participants' rights and welfare. These regulatory bodies and committees collectively ensure that drug development and medical device approval processes in India maintain global standards while safeguarding public health.

Geotag Photos:

"India's regulatory framework for drug safety and clinical trials by Dr Manisha Sharma"

"India's regulatory framework for drug safety and clinical trials from Dr Manisha Sharma"

Session 2

Title of Topic: Future trends and challenges in regulatory guideline

Date: 8/1/2025

Venue: Training and development cell, HIMS

No. of student: 27

Faculty name: Dr. Nikku Yadav

Objective: This report provides a brief overview of the importance of clinical research, strategies for adherence to guidelines, audits and inspections, addressing non-compliance, and their significance in maintaining high standards in clinical trials and drug development.

Summary: Clinical research is essential for advancing medical knowledge, developing new treatments, and ensuring the safety and efficacy of drugs and medical devices. It involves systematic investigation to establish evidence that supports the use of new therapies and medical technologies. Adhering to established guidelines, such as those set by the Good Clinical Practice (GCP), ensures the integrity of clinical trials and protects the rights of participants. Strategies for adherence include regular staff training, maintaining clear documentation, and utilizing technology for monitoring compliance. Audits and inspections are critical components of clinical research, designed to ensure that trials follow regulatory standards and guidelines. These processes help identify areas for improvement, verify data integrity, and confirm the safety of participants. Addressing non-compliance involves timely corrective actions, conducting root cause analysis, and implementing robust corrective and preventive measures (CAPA) to avoid future issues. Regulatory bodies, such as the FDA and

EMA, conduct inspections to ensure that clinical trials comply with ethical and legal standards, thus maintaining public trust in clinical research. Overall, audits, adherence to guidelines, and proper handling of non-compliance are vital to the success of clinical trials and the development of safe, effective medical treatments.

Geotag Photos:

"Dr Nikku Yadav Taking session on Future trends and challenges in regulatory guideline "

"Interactive Session on Essentials of clinical research, ensuring safety, compliance, and innovation in medical trials by Dr Nikku Yadav

Session 3

Title of Topic: Icebreaker, share a fun fact and introduce a peer

Date: 8/1/2025

Venue: Training And Development Cell, HIMS

No. of student: 27

Faculty name: Ms Garima Kapoor

Objective: This report provides a brief overview of the icebreaker activity, where students share three fun facts with each other, and its role in fostering communication, building rapport, and promoting a positive atmosphere in group settings.

Summary: The icebreaker activity where students share three fun facts with each other is a simple yet effective way to break down social barriers and encourage interaction among participants. This activity helps create a relaxed and engaging environment, especially in new or unfamiliar settings. By sharing personal, fun, and unique facts, students learn more about their peers, which can promote understanding and strengthen group dynamics. The activity encourages communication, allowing students to express themselves in a lighthearted way, which helps reduce anxiety or nervousness in group interactions. It also fosters a sense of inclusivity, as everyone gets the opportunity to share something interesting or unexpected about themselves. This not only builds rapport but also cultivates a positive atmosphere where students feel more comfortable collaborating and engaging with one another. Overall, this icebreaker activity is a simple but impactful way to start any group activity or meeting, setting a friendly tone and promoting openness and trust among participants

Geotag Photos:

“Ms. Garima Mam taking session us the power of sharing fun facts to break the ice and build strong connections.”

Ms. Garima Explaining about how break the ice and build strong connections

Week 1 Day:4

Session 1

Title of Topic: Case Study – Informed Consent Challenges

Date: 9/1/2025

Venue: Training and Development Cell, HIMS

No. of Students: 30

Faculty Name: Dr. Nikku Yadav

Objective:

This report highlights the complexities of obtaining informed consent in clinical research, especially when dealing with vulnerable populations. It also examines cultural challenges and outlines key strategies to enhance participant protection while ensuring ethical compliance.

Summary: Informed consent is a critical ethical requirement in clinical trials, ensuring that participants voluntarily agree to take part after understanding all aspects of the study. However, challenges arise when working with vulnerable groups such as children, the elderly, economically disadvantaged individuals, and those with cognitive impairments. These populations may struggle with understanding complex medical terms or may be influenced by external pressures, raising ethical concerns.

Cultural factors also impact the informed consent process. Language barriers, traditional beliefs, and societal norms can affect participants' decision-making autonomy. In many communities, family or religious leaders play a significant role in healthcare decisions, requiring researchers to adopt culturally sensitive approaches.

To overcome these challenges, the following strategies can be implemented:

- **Simplified Communication:** Using clear, non-technical language, visual aids, and local dialects to explain study details.
- **Ethical Oversight:** Ethics Committees must assess risks and benefits carefully, particularly for vulnerable populations.
- **Third-Party Support:** Engaging independent advocates or legal representatives for those with limited decision-making capacity.
- **Voluntary Participation:** Ensuring that consent is free from coercion, undue influence, or misinformation.

  By addressing these challenges, researchers can improve ethical compliance, safeguard participant rights, and foster greater trust in clinical research.

Geotag Photo:

"Understanding Informed Consent: Navigating Ethical Challenges in Clinical Research by Dr. Nikku Yadav"

Case Study – Informed Consent Challenges by Dr Nikku Yadav

Week 1, Day 5

Session 2

Title of Topic: Session on Study Design and Randomization

Date: 10th January 2024

Venue: Training and development cell, HIMS

No. of Students:28

Faculty Name: Dr. Ruchi Juyal

Objective: The objective of the session was to introduce the fundamentals of **study design** and the importance of **randomization** in research. Participants were guided on how to structure research methodologies effectively and use randomization to ensure valid and reliable results.

Summary: On **10th January 2024**, **Dr. Ruchi Juyal** conducted an enlightening session on **Study Design and Randomization** for students at the **Department of Clinical Research**.

Dr. **Ruchi Juyal** explained various types of **study designs** and highlighted how each design method serves different research objectives. She emphasized the importance of choosing the right design based on the research question, available resources, and ethical considerations. Participants learned about:

- **Types of Study Designs:** Dr. Juyal discussed experimental designs (e.g., randomized controlled trials), observational designs (e.g., cohort, case-control studies), and descriptive designs (e.g., surveys, case reports).
- **Study Structure:** The session highlighted how to effectively structure a research study by having a clear introduction, methodological framework, and conclusion.
- **Role of Randomization:** Dr. Juyal introduced the concept of **randomization** as a critical step in ensuring unbiased allocation of participants to study groups. She discussed the types of randomization methods such as **simple randomization**, **block**

randomization, and **stratified randomization**, and their importance in eliminating bias and ensuring group comparability.

- **Ethical Considerations:** The session also covered the ethical aspects of designing a study, including ensuring participant consent, maintaining confidentiality, and considering the safety of participants in clinical trials.

Through **interactive discussions** and **real-life case studies**, participants gained practical insights into how study design and randomization contribute to the **validity** and **reliability** of research outcomes. Dr. Juyal provided guidance on how to address challenges such as non-randomization in non-clinical studies and the impact of **confounding variables**.

Conclusion: The **Study Design and Randomization** session, led by **Dr. Ruchi Juyal**, was highly effective in laying the foundation for research methodology. Participants walked away with a solid understanding of study designs, the necessity of randomization, and how both contribute to ensuring the credibility of research results. This session was essential for building the research skills of students and provided them with the knowledge to enhance the quality of their own studies.

Geotag photo:

"Fundamentals of Study Design & Randomization by Dr. Ruchi Juyal"

"Prof Ruchi Juyal asking questions on study Design and Randomization"

Session 2:

Title of Topic: Session on Statistical Analysis and Reporting

Date: 10th January 2024

Venue: Training and development cell, HIMS

No. of Students: 28

Faculty Name: Dr. A K Srivastava

Objective: The objective of the session was to provide participants with an understanding of **statistical analysis techniques** and how to effectively report research findings. The session aimed to enhance participants' ability to interpret data, apply appropriate statistical methods, and communicate their results clearly.

Summary: On **10th January 2024**, **Dr. A K Srivastava** conducted an insightful session on **Statistical Analysis and Reporting** for the students at the **Department of Clinical Research**.

Dr. A K Srivastava began by introducing the fundamentals of **statistical analysis** and its importance in research. Key areas covered included:

- **Types of Data and Statistical Methods:** Dr. Srivastava explained the difference between **qualitative** and **quantitative** data and how to choose the right statistical methods for each type. Students learned about techniques such as **descriptive statistics** (mean, median, mode), **inferential statistics** (t-tests, ANOVA, regression), and the importance of **hypothesis testing**.
- **Understanding Statistical Software:** Dr. Srivastava demonstrated the use of popular **statistical software** tools like SPSS, R, and Excel, which help researchers analyze complex datasets and perform various statistical tests. Students were shown practical examples of data analysis using these tools.
- **Interpreting Results:** The session emphasized how to interpret statistical results, including p-values, confidence intervals, and effect sizes. Dr. Srivastava discussed how to determine the significance of results and how to avoid common misinterpretations of statistical outcomes.
- **Common Mistakes in Statistical Reporting:** Dr. Srivastava highlighted common mistakes that researchers make when analyzing and reporting data, such as misusing statistical tests, over-interpreting results, and failing to account for confounding variables.

The session was highly interactive, with hands-on exercises where participants worked through data analysis problems and applied statistical methods to real datasets. Students received **constructive feedback** on their analysis and reporting techniques, helping them understand how to improve their future statistical work.

Conclusion: The **Statistical Analysis and Reporting** session conducted by Dr. **A K Srivastava** was invaluable in providing students with the tools and knowledge needed to analyze data effectively and communicate their findings accurately. The session helped students gain a deeper understanding of **statistical methods**, **data interpretation**, and **reporting standards**, all of which are crucial skills in clinical research and beyond. By the end of the session, students felt more confident in their ability to perform statistical analysis and present their research results with clarity and precision.

Geotag Photo:

"Mastering Statistical Analysis & Reporting with Dr. A K Srivastava at HIMS"

"Prof A.K Srivastava explain about Statistical Analysis and Reporting empowering future researchers with essential data skills"

Session 3

Title of Topic: Session on The Role of Meditation in Mental Health and Well-being

Date: 10th January 2024

Venue: Training and development cell, HIMS

No. of Students: 28

Faculty Name: Dr. Somlata Jha

Objective: To introduce students to the benefits of **meditation** for **mental health** and **well-being**, emphasizing its role in stress reduction, emotional balance, and cognitive enhancement.

Summary: On **10th January 2024**, Dr. **Somlata Jha** led a session on **Meditation's Role in Mental Health** for students at the **Department of Clinical Research**. The session focused on how meditation improves mental well-being, reduces stress, and enhances cognitive functions.

Types of Meditation (e.g., mindfulness, transcendental) and their benefits for emotional health, focus, and stress management.

Practical Techniques: Students learned simple exercises like **breathing** and **mindfulness meditation** to reduce stress and improve focus.

Conclusion: Dr. **Somlata Jha**'s session provided students with practical tools to integrate meditation into their daily routines. Students left with a deeper understanding of meditation's mental health benefits and how it can improve overall well-being.

Geotag Photos:

"Embracing the power of meditation for mental health and well-being with Dr. Somlata Jha at HSYS"

"Students understanding about Yoga and its benefit on human body"

Week 2, Day 6

Session 1

Title of Topic: Overview of Clinical Research and GCP Principles

Date: 13 January 2025

Venue: Training and Development Cell, HIMS

No. of Students: 26

Faculty Name: Dr. D.C. Dhasmana

Objective: The session aimed to introduce students to the field of clinical research and the fundamental principles of Good Clinical Practice (GCP). The focus was on providing students with a comprehensive understanding of clinical research methodologies, regulatory requirements, and ethical guidelines that ensure the credibility and safety of clinical trials.

Summary: The session, led by Dr. D.C. Dhasmana, provided an in-depth overview of clinical research, its significance, and the essential principles that guide clinical trials. Dr. Dhasmana began by defining clinical research as the process of investigating new medical treatments, devices, and therapies through well-structured studies. He

emphasized that clinical research is critical for advancing medical science and improving patient care by providing evidence-based outcomes. Dr. Dhasmana then shifted focus to the principles of Good Clinical Practice (GCP), a set of internationally recognized guidelines aimed at ensuring that clinical trials are conducted ethically, scientifically sound, and with patient safety as the priority. He explained the core aspects of GCP, which include:

- **Ethical Standards:** The importance of obtaining informed consent from participants and ensuring patient confidentiality and safety throughout the trial.
- **Protocol Adherence:** The necessity of following a detailed, pre-approved clinical trial protocol to maintain trial consistency and reliability.
- **Data Integrity:** Ensuring accurate, complete, and reliable data collection and reporting, which is critical for the validity of study results.
- **Regulatory Compliance:** Adhering to regulations and guidelines set by national and international regulatory bodies such as the FDA, EMA, and ICH GCP.

Dr. Dhasmana also discussed the roles of the various stakeholders involved in clinical research, including investigators, sponsors, ethics committees, and regulatory authorities. He highlighted the need for collaboration and transparent communication among all parties to ensure the success of a clinical trial.

Additionally, Dr. Dhasmana provided insights into the process of ethical review and approval by institutional review boards (IRBs) and ethics committees, which are crucial for ensuring that the rights, safety, and well-being of trial participants are protected.

By the end of the session, students had gained a clear understanding of the critical components of clinical research, the significance of GCP in maintaining ethical and scientific standards, and the importance of adhering to regulatory guidelines. This foundational knowledge will enable students to contribute effectively to clinical research activities and ensure the integrity and ethical conduct of future clinical trials.

Geotag Photos:

"Prof D.C. Dhasmana giving Overview of Clinical Research and GCP Principles"

"Students are attentively listening to the session and actively asking questions."

Session 2

Title of Topic: Responsibilities of Sponsor

Date: 13 January 2025

Venue: Training and Development Cell, HIMS

No. of Students: 26

Faculty Name: Dr. Manisha Sharma

Objective:

The session aimed to educate students about the critical responsibilities of the sponsor in clinical trials, highlighting their role in the design, conduct, and oversight of clinical research, ensuring the trials' compliance with regulatory standards, and safeguarding participants' welfare.

Summary:

The session, led by Dr. Manisha Sharma, focused on the fundamental responsibilities of the sponsor in clinical research, emphasizing their vital role in the successful execution of clinical

trials. Dr. Sharma began by explaining the term "sponsor" in the context of clinical trials as the individual or organization that initiates, manages, and finances a clinical study.

Dr. Sharma elaborated on the various responsibilities of the sponsor throughout the lifecycle of a clinical trial. These responsibilities are essential to ensure that clinical trials are conducted in compliance with ethical guidelines, regulatory requirements, and scientific standards. The key responsibilities discussed included:

- **Trial Design and Protocol Development:** Sponsors are responsible for designing the clinical trial and developing a comprehensive trial protocol that outlines the objectives, methodology, statistical analysis plan, and safety monitoring procedures. The protocol serves as a roadmap for the trial, ensuring consistency and standardization.

- **Regulatory Compliance:** The sponsor must ensure that the trial complies with all regulatory requirements set by national and international health authorities, including submission of necessary documents for approval by regulatory bodies such as the FDA, EMA, and other relevant agencies.
- **Ethical Oversight:** The sponsor is responsible for obtaining approval from an Institutional Review Board (IRB) or Ethics Committee (EC) to ensure that the study is ethical and that participant rights and safety are protected. This includes ensuring that informed consent is obtained from all participants.
- **Monitoring and Supervision:** Sponsors are tasked with monitoring the progress of the clinical trial, ensuring that it is being conducted according to the approved protocol. This includes overseeing the recruitment of participants, data collection, and the handling of adverse events.
- **Ensuring Adequate Resources:** The sponsor is responsible for providing the necessary resources, including funding, study materials, and training for investigators and site staff, to ensure the trial's successful conduct.
- **Data Integrity and Confidentiality:** Sponsors must ensure that all data collected during the trial is accurate, complete, and secure. They are also responsible for maintaining participant confidentiality and complying with data protection laws.
- **Adverse Event Reporting:** The sponsor has the responsibility to ensure that adverse events (AEs) and serious adverse events (SAEs) are properly monitored, reported, and managed in accordance with regulatory requirements.

Dr. Sharma also highlighted the sponsor's role in ensuring that the clinical trial is completed on time and within the budget while maintaining high-quality standards. She stressed that the sponsor must maintain effective communication with investigators, ethics committees, regulatory agencies, and other stakeholders to ensure smooth coordination throughout the trial. The session concluded with a discussion on the importance of transparency, accountability, and ethical conduct by the sponsor, which ultimately ensures the safety of participants and the validity of the clinical trial's results.

Geotag Photos:

"Dr Manisha Sharma taking session on Responsibilities of Sponsor "

"Students are fully attentive to the session and contributing by asking insightful questions."

Session 3

Title of Topic: Responsibilities of Investigator

Date: 13 January 2025

Venue: Training and Development Cell, HIMS

No. of Students: 26

Faculty Name: Ms Charu Paliwal

Objective:

The session aimed to provide students with an in-depth understanding of the roles and responsibilities of an investigator in clinical trials. The focus was on how investigators ensure the ethical, regulatory, and scientific integrity of the trial while safeguarding participants' rights and well-being.

Summary:

The session, conducted by Dr. Charu Paliwal, provided a comprehensive overview of the responsibilities of clinical trial investigators. Dr. Paliwal began by explaining the investigator's key role in clinical research as the person directly responsible for the conduct of the trial at a study site. She emphasized that investigators are essential in ensuring that trials are carried out in strict compliance with the approved protocol, regulatory standards, and ethical guidelines.

Dr. Paliwal outlined the primary responsibilities of the investigator during a clinical trial:

- **Protocol Compliance:** The investigator must ensure that the clinical trial is conducted according to the pre-approved protocol. This includes following all study procedures, ensuring eligibility criteria for participants, and making sure the trial is executed in a scientifically sound manner. Protocol deviations or violations must be documented and reported as required.
- **Participant Safety and Well-being:** The investigator is responsible for ensuring the safety of the trial participants. This includes providing appropriate care, managing any adverse events, and ensuring that participants fully understand the study and its potential risks through the informed consent process. The

investigator must ensure that participants' rights, health, and privacy are always protected.

- **Ethical Conduct and Informed Consent:** The investigator must ensure that participants provide voluntary informed consent before enrolling in the trial. They must communicate the study's purpose, risks, benefits, and alternative treatment options clearly and comprehensively. Informed consent must be documented and revisited as necessary, especially in the case of any changes in the study or new risks identified.
- **Data Integrity and Accuracy:** The investigator is responsible for ensuring that all data collected during the trial is accurate, complete, and properly recorded. This includes maintaining case report forms (CRFs) and ensuring that all clinical data is verifiable against source documents. They must also ensure proper data management and ensure that all records are securely stored and maintained.

Dr. Paliwal also emphasized the importance of continuous communication and collaboration with other stakeholders involved in clinical research, such as the sponsor, ethics committees, and regulatory bodies. This ensures alignment with trial objectives, regulatory requirements, and ethical standards

The session concluded with a discussion on the challenges investigators may face during clinical trials, including managing participant recruitment, addressing unforeseen risks, and maintaining protocol adherence. Dr. Paliwal stressed the importance of adaptability, critical thinking, and ethical responsibility in overcoming these challenges. By the end of the session, students had gained a clear understanding of the investigator's key responsibilities in clinical research. This knowledge will prepare them to contribute effectively to the planning, execution, and oversight of clinical trials in the future while ensuring the highest standards of ethical conduct and participant safety.

Geotag Photos

"Ms. Charu Paliwal taking session on Responsibilities of Investigator"

"Ms. Charu Paliwal is receiving presentations from the students"

Session 4

Title of Topic: Role of Clinical Research Personnel

Date: 13 January 2025

Venue: Training and Development Cell, HIMS

No. of Students: 26

Faculty Name: Ms Charu Paliwal

Objective:

The session aimed to introduce students to the various roles and responsibilities of clinical research personnel involved in clinical trials. The focus was on the importance of teamwork and the individual responsibilities of each role in ensuring the success of a clinical trial while maintaining the highest ethical and scientific standards.

Summary:

The session, led by Dr. Charu Paliwal, provided an insightful overview of the roles of various personnel involved in clinical research. Dr. Paliwal emphasized that clinical trials are complex endeavors that require collaboration among multiple professionals, each contributing to different aspects of the trial to ensure its success and compliance with regulatory and ethical guidelines.

Dr. Paliwal explained that the role of clinical research personnel varies depending on the type of clinical trial and the specific responsibilities of each individual within the research team. The key roles discussed included:

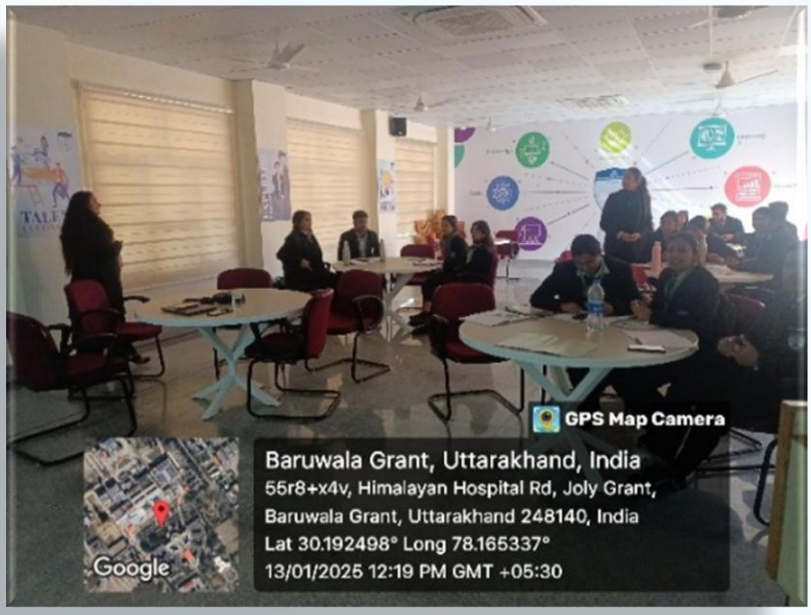
- **Principal Investigator (PI):** The Principal Investigator is the leader of the clinical research team and is responsible for the overall conduct of the trial at the study site. The PI ensures the trial follows the approved protocol, maintains participant safety, and ensures compliance with regulatory requirements. The PI also supervises other study personnel and communicates with the sponsor and regulatory bodies.
- **Sub-investigators (Co-Investigators):** Sub-investigators support the Principal Investigator by assisting in the implementation of the trial at the study site. They

may have specialized roles, such as medical or scientific oversight, and are responsible for specific aspects of the trial. They must ensure the trial's ethical conduct and support the PI in patient care and data collection.

- **Clinical Research Coordinators (CRCs):** Clinical Research Coordinators play a vital role in the day-to-day management of the clinical trial. They are responsible for participant recruitment, obtaining informed consent, ensuring protocol adherence, managing case report forms (CRFs), and coordinating data collection. CRCs also serve as the point of contact between the study site and the sponsor or regulatory authorities.
- **Clinical Research Associates (CRAs):** CRAs are responsible for monitoring the progress of the clinical trial at the site level. They ensure that the trial is being conducted according to the protocol, GCP guidelines, and regulatory requirements. CRAs also perform site visits, verify data accuracy, and ensure that adverse events are reported promptly. Their role is crucial in maintaining data integrity and compliance throughout the trial.

Dr. Paliwal also emphasized the importance of effective communication, collaboration, and teamwork among these various roles to ensure the trial runs smoothly and is conducted in compliance with ethical and regulatory standards. Each member of the clinical research team has a unique responsibility, and their contributions are crucial to the success of the trial and the safety of participants.

Geotag Photos:



"Ms Charu Paliwal Teaching students about role of Clinical Research Personnel "

"Students are actively listening to their peers' presentations."

Session 5

Title of Topic: Data Collection

Date: 13 January 2025

Venue: Training and Development Cell, HIMS

No. of Students:26

Faculty Name: Dr. Ruchi Juyal

Objective:

The session aimed to provide students with a clear understanding of the data collection process in clinical research. The focus was on the importance of accurate, reliable, and ethical data collection methods to ensure the integrity and validity of clinical trial results.

Summary:

The session, led by Dr. Ruchi Juyal, provided an insightful overview of the critical process of data collection in clinical trials. Dr. Juyal began by emphasizing that data collection is a fundamental aspect of clinical research, as it forms the basis for evaluating the safety and efficacy of the investigational product. Accurate and ethical data collection ensures that the conclusions drawn from the study are valid and reliable.

Dr. Juyal discussed the key components involved in data collection and highlighted the importance of following strict protocols and guidelines throughout the process. The main points covered included:

- **Protocol Adherence:** Data collection begins with strict adherence to the clinical trial protocol. The protocol outlines the study design, objectives, and data collection methods. Ensuring that data is collected in line with the protocol is essential for maintaining consistency and ensuring the study's validity.
- **Source Data:** Dr. Juyal explained the importance of source data, which refers to the original records or documents from which clinical trial data is derived. Source data includes patient medical records, laboratory results, diagnostic images, and

other primary documentation. Ensuring that source data is accurate, complete, and traceable is essential for maintaining the integrity of the trial.

- **Case Report Forms (CRFs):** Case Report Forms are the primary tool for recording data during the trial. Dr. Juyal explained that CRFs should be completed accurately and consistently, ensuring that all required data fields are filled in properly. She emphasized the importance of timely submission and the need to correct any discrepancies or missing data to maintain data quality.
- **Data Integrity:** Dr. Juyal discussed the importance of ensuring data integrity, meaning the data should be accurate, complete, and consistent. She explained that any errors or inconsistencies in the data should be addressed promptly through data cleaning procedures. Data integrity is crucial to maintaining the credibility of the trial results.
- **Data Management Systems:** Dr. Juyal introduced various data management systems that are used in clinical trials to store and analyze data. These systems help in organizing large volumes of data, ensuring that it is easily accessible, secure, and compliant with regulatory requirements. The use of electronic data capture (EDC) systems was highlighted as an essential tool for streamlining the data collection process and ensuring accuracy.
- **Blinding and Randomization:** Dr. Juyal explained the concepts of blinding and randomization in clinical trials and how they play a role in the data collection process. Blinding helps eliminate bias by ensuring that neither the participants nor the researchers know which treatment the participant is receiving, while randomization ensures that the treatment allocation is done in a way that is not influenced by external factors.

"Students are actively engaged, listening to the session and inquiring with thoughtful questions."

“Prof Ruchi Juyal is reviewing the presentations given by students.”

Week 2, Day 7

Session 1

Title of Topic: Session on Understanding Ethics Committees as per ICH & Indian GCP.

Date:14 January 2025

Venue: Training and Development Cell HIMS

No. of Students:25

- **Objective**: The objective of this report is to provide a comprehensive understanding of Ethics Committees (ECs) as per the International Council for Harmonisation (ICH-GCP) and Indian Good Clinical Practice (GCP) guidelines.

- **Summary** :

In this session, Ethics Committees (ECs) are discussed as responsible entities for safeguarding the rights, safety, and well-being of study participants while ensuring that clinical trials adhere to ethical and scientific standards. The guidelines governing ECs are established by the International Council for Harmonisation (ICH-GCP) and Indian Good Clinical Pract20ice (GCP). The **ICH-GCP (E6 R2)** outlines the structure, responsibilities, and functioning of Ethics Committees to ensure the safety and well-being of study participants. An EC must have a minimum of five members with diverse

qualifications, including medical, scientific, and non-scientific members. At least one member should be independent of the institution conducting the research, and a layperson should be included to represent community interests. Their responsibilities include reviewing and approving the clinical trial protocol and informed consent documents, ensuring that the risk-to-benefit ratio is acceptable, and conducting periodic reviews of ongoing studies.

The **Indian GCP Guidelines**, issued by the **Central Drugs Standard Control Organization (CDSCO)** and **Indian Council of Medical Research (ICMR)**, align with international standards while incorporating region-specific ethical considerations. Indian ECs must have a minimum of seven members, including

experts in medical science, law, ethics, and social sciences. At least one layperson and one legal expert

must be included, with an emphasis on gender representation and independence from the sponsor/investigator.

Ethics Committees in India must be registered with CDSCO, and they are subject to regular audits and re-registration to ensure compliance. Their responsibilities include protecting the rights and welfare of study participants, ensuring adherence to ethical principles, reviewing informed consent documents for language clarity and cultural appropriateness, monitoring ongoing trials, and reporting adverse events.

- **Conclusion**

  In this session, the role of Ethics Committees in clinical research has been thoroughly examined. These committees serve as a cornerstone of clinical research by ensuring ethical and scientific rigor. Adherence to both ICH-GCP and Indian GCP guidelines is essential for maintaining public trust and ensuring ethical clinical trials in India and globally.

  Geo Tag Photo

"Ms Charu Paliwal Taking session on on Understanding Ethics Committees as per ICH & Indian GCP"

"Ms. Charu is clarifying students' queries."

Session 2

Title of Topic: Session on Principles of Informed Consent.

Date:14 January 2025

Venue: Training and Development Cell HIMS

No. of Students:25

Objective: The session on *Principles of Informed Consent* was conducted to educate participants on the ethical, legal, and practical aspects of obtaining informed consent in clinical and research settings.

Summary: The session focused on the key principles of informed consent, including voluntariness, full disclosure, comprehension, competence, proper documentation, and the right to withdraw. Ethical considerations, such as autonomy, beneficence, and non-maleficence, were discussed alongside regulatory guidelines like the Declaration of Helsinki and Good Clinical Practice (GCP). Challenges in obtaining informed consent, including language barriers and cultural differences, were highlighted. Case studies

illustrated the consequences of inadequate consent processes. Participants appreciated the session's insights and recommended incorporating interactive elements like role-playing. Future sessions will emphasize practical applications to enhance informed consent procedures.

Voluntariness: Informed consent must be given without coercion, undue influence, or pressure. Participants should make their decision freely. **Disclosure of Information**: Essential details regarding the procedure, risks, benefits, and alternatives must be provided clearly to the participant. **Comprehension**: The subject must fully understand the provided information. This involves using layman's terms and assessing understanding. **Competence**: The individual providing consent must be legally and mentally capable of making an informed decision. **Consent Documentation**: Written consent forms should be clear, concise, and include all necessary details regarding the procedure or research study. **Right to Withdraw**: Participants should be made aware that they can withdraw consent at any time without facing consequence.

Geotag Photos:

"Ms Charu Paliwal is doing discussion on Principles of Informed Consent"

"Students are also presenting PowerPoint presentations on various topics assigned by Ms Charu."

- **Title of Topic**: Session on Body Language and Non-Verbal Cues
- **Date**:14 January 2025
- **Venue**: Training and Development Cell HIMS
- **No. of Students**:25
- **Objective**: The objective of this session is to understand the importance of body language and non-verbal cues in effective communication.
- **Summary**: In this session, the significance of body language and non-verbal cues is explored, emphasizing their role in communication. Body language includes facial expressions, gestures, posture, eye contact, and other physical behaviors that

complement verbal communication. Understanding these cues helps in interpreting hidden emotions, detecting deception, and strengthening interpersonal interactions. Effective use of non-verbal communication is essential in fields such as business, healthcare, leadership, and daily conversations.

Key non-verbal cues include **facial expressions**, which reflect emotions like happiness, anger, or sadness; **gestures**, such as hand movements that emphasize speech; **posture**, indicating confidence or nervousness; **eye contact**, which conveys attentiveness and trust; and **tone of voice**, which adds depth to verbal messages. Misinterpretation of non-verbal signals can lead to misunderstandings, making it essential to be aware of cultural differences and contextual factors.

The session also included some fun activities where different groups of students took part. activity included some fun and mind games that the groups had to solve and complete in a given period of time. The session became very interactive and full of fun.

- **Conclusion**

  Understanding body language and non-verbal cues is essential for effective communication. This session provides insights into interpreting and using non-verbal signals to enhance interactions in personal and professional settings. By practicing awareness and mindfulness of these cues, individuals can improve their communication skills and build stronger relationships.

Geotag Photos:

"Mr Ashish Gupta conducting lecture on Body Language and Non-Verbal Cues"

"Explaining to students how they can interpret body language and non-verbal cues."

Session 3

Title of Topic: Session on Best Practices in Informed Consent Documentation.

Date:14 January 2025

Venue: Training and Development Cell HIMS

No. of Students:25

Objective: The objective of this report is to provide a comprehensive understanding of the principles of informed consent in clinical research

Summary: In this session, best practices for informed consent documentation are explored, focusing on accuracy, completeness, and compliance with regulatory guidelines. Proper documentation ensures that participants' rights and autonomy are protected and that the consent process is ethically sound. It is crucial that all consent forms are written in clear and comprehensible language, reviewed by an Ethics Committee (EC), and stored securely for future reference.

Best practices in informed consent documentation include ensuring that consent forms contain all essential elements such as study purpose, procedures, risks, benefits, voluntary participation, and confidentiality. The consent form should be signed and dated by both the participant and the investigator, with an impartial witness present when necessary. Additionally, it is essential to document any additional consent obtained due to protocol amendments, ongoing risks, or changes in study procedures.

Regulatory guidelines, including **ICH-GCP and Indian GCP**, require that informed consent forms be regularly updated to reflect any changes in study information. Proper documentation also includes maintaining accurate records of all consent-related discussions, participant questions, and any instances where re-consent is obtained. Electronic consent (e-consent) is becoming increasingly popular and must follow the same ethical and regulatory principles to ensure validity.

Common challenges in informed consent documentation include incomplete forms, missing signatures, failure to document ongoing consent discussions, and non-

compliance with language requirements. Addressing these challenges requires proper training for
investigators, routine audits, and continuous monitoring of consent documentation practices.

Conclusion: Proper documentation ensures that participants' rights and autonomy are protected and that the consent process is ethically sound. It is crucial that all consent forms are written in clear and comprehensible language, reviewed by an Ethics Committee (EC), and stored securely for future reference.

Geotag Photos:

"Ms Charu taking presentation from students on given topic."

"Students are delivering PPT presentations on different topics given by Ms Charu."

Week 2, Day 8

Session 1

Title of Topic: Introduction to Clinical Trial Protocol

Date: 15 January 2025

Venue: Training and development cell, HIMS

No. of Students: 29

Faculty Name: Ms. Charu Paliwal

Objective:

The session aimed to introduce students to clinical trial protocols, providing foundational knowledge on their development, key components, and the regulatory and ethical guidelines that govern them.

Summary:

The session, led by Ms. Charu Paliwal, provided a comprehensive understanding of clinical trial protocols and their critical role in ensuring the successful and ethical conduct of trials. Ms. Paliwal began by explaining the protocol as an essential document that outlines the objectives, design, methodology, and statistical considerations for a clinical trial. It serves as a blueprint to ensure that trials are conducted in a systematic and consistent manner. The session covered the key components of a protocol, such as trial objectives, design and methodology, inclusion and exclusion criteria, monitoring and reporting of adverse events, statistical analysis, data management, and ethical considerations.

Ms. Paliwal also emphasized the importance of adhering to regulatory and ethical guidelines during protocol development. She discussed compliance with major regulatory bodies like the FDA, EMA, and ICH GCP, and highlighted the ethical considerations that must be taken into account, including informed consent, patient safety, and confidentiality. The importance of a well-structured protocol in maintaining the integrity and quality of clinical trials was stressed, as it serves as a reference for investigators, sponsors, and regulatory bodies to ensure ethical and consistent trial conduct. By the end of the session, students had gained a solid understanding of the structure, purpose, and ethical requirements involved in clinical trial protocol

development, equipping them with the knowledge to contribute to protocol development in the future.

Ms. Paliwal also highlighted the role of collaboration and communication among all parties involved in the clinical trial process, including investigators, sponsors, ethics committees, and regulatory authorities. She explained how clear and transparent communication ensures that

all stakeholders are aligned with the trial's objectives and ethical standards, ultimately enhancing the trial's credibility and success. Additionally, she discussed the importance of updating and revising the protocol when necessary to reflect new scientific findings or regulatory changes. By maintaining flexibility within the protocol while upholding core ethical principles, clinical trials can adapt to evolving circumstances, ensuring Participant safety and the validity of the results throughout the trial's duration.

Geotag Photos:

"Students are fully attentive to the session and contributing by asking insightful questions."

"Ms. Charu Paliwal leading an insightful group discussion with students during the 'Introduction to Clinical Trial Protocol' session."

Session 2

Title of Topic: Ethical Considerations in Protocol Design

Date: 15 January 2025

Venue: Training and development cell, HIMS

No. of Students: 29

Faculty Name: Dr. D.C.Dhasmana

Objective:

The session aimed to introduce students to clinical trial protocols, providing foundational knowledge on their development, key components, and the regulatory and ethical guidelines that govern them.

Summary:

The session on "Ethical Considerations in Protocol Design," led by Mr. D.C. Dhasmana, focused on the fundamental ethical principles that guide the development and implementation of clinical trial protocols. The session explored how these ethical considerations ensure that clinical trials are conducted with the utmost respect for participant well-being, transparency, and fairness.

Mr. Dhasmana began by explaining the core ethical principles in clinical trials: **respect for persons**, **beneficence**, and **justice**. He highlighted that these principles should be integrated into every stage of trial protocol design, ensuring that participants are treated with dignity and their rights are protected. **Informed consent**, a critical element in clinical trials, was emphasized as an essential process where participants are fully informed of the risks, benefits, and objectives of the trial, as well as their right to withdraw at any time without penalty.The discussion then turned to the ethical considerations in the creation of inclusion and exclusion criteria. Mr. Dhasmana stressed the importance of developing criteria that are fair and reasonable, ensuring that participants are not unnecessarily excluded or exposed to undue risk. He discussed the delicate balance between ensuring the safety of participants and achieving scientifically valid results, explaining that every effort should be made to minimize harm while maximizing potential benefit.

The session also delved into the importance of monitoring and ongoing oversight throughout the clinical trial process. Mr. Dhasmana emphasized that ethical considerations must extend beyond the design phase and into the execution of the trial. This includes continuous assessment of participant safety, adherence to ethical guidelines, and the integrity of data collection. Regular reviews by ethics committees and institutional review boards (IRBs) are crucial to ensure that the trial remains in compliance with ethical standards and that any emerging concerns are addressed promptly. Additionally, transparency in reporting trial results, including negative or inconclusive outcomes, was underscored as a key element in maintaining public trust and advancing scientific knowledge in a responsible manner.

Geotag Photos:

Prof. D.C.Dhasmana delivering a valuable session on 'Ethical Considerations in Protocol Design' at the Training and Development Cell, HIMS."

"Prof. D.C.Dhasmana delivering a valuable session on 'Ethical Considerations in Protocol Design' at the Training and Development Cell, HIMS."

Session 3

Date: 15 January 2025

Venue: Lab [Department of Clinical Research]

Number of Students: 29

Faculty Name: Mr. Abhinav Bahuguna

Objective:

The session aimed to provide students with a thorough understanding of the importance of scientific rigor and statistical considerations in clinical research, highlighting how these principles ensure the reliability, validity, and integrity of study results.

Summary:

The session on "Scientific Rigor and Statistical Considerations," led by Mr. Abhinav Bahuguna, focused on the critical components that ensure the integrity and reliability of clinical research. Mr. Bahuguna began by defining scientific rigor as the careful application of the scientific method to design, conduct, and analyze research studies in a way that ensures accurate and reliable results. He emphasized that scientific rigor forms the foundation for drawing valid conclusions in clinical trials and other scientific investigations.

The session delved into the concept of statistical considerations, particularly in clinical trials, explaining how statistical techniques help researchers make informed decisions based on data. Mr. Bahuguna explained the key aspects of statistical analysis, including hypothesis testing, p-values, confidence intervals, and sample size calculations.

He clarified how these elements are crucial for determining whether the results of a clinical trial are statistically significant and whether the findings can be generalized to a larger population.Additionally, Mr. Bahuguna highlighted the importance of randomization, blinding, and control groups in clinical trial designs. These measures, he noted, help eliminate bias and ensure that the results of a study are attributable to the intervention being tested rather than to extraneous factors.

The session also covered the potential pitfalls in statistical analysis, such as overfitting, underpowered studies, and data manipulation. Mr. Bahuguna stressed the need for careful data management, proper analysis techniques, and transparency to maintain scientific rigor and avoid misleading conclusions.

Geotag Photos:

"Mr. Abhinav Bahuguna delivering a session on 'Scientific Rigor and Statistical Considerations,' providing a detailed demonstration through a presentation."

“Mr. Abhinav Bahuguna is explaining 'Scientific Rigor and Statistical Considerations' in a session, using a detailed presentation for demonstration”

Session 4

Title of Topic: Risk-Benefit Assessment and Monitoring Plans

Date: 15 January 2025

Venue: Training and development cell, HIMS

No. of Students: 29

Faculty Name: Ms. Charu Paliwal

Objective:

The session aimed to provide students with an understanding of risk-benefit assessment and the development of monitoring plans in clinical trials, emphasizing the importance of balancing risks and benefits to ensure participant safety and trial success.

Summary:

The session on **Risk-Benefit Assessment and Monitoring Plans**, led by Ms. Charu Paliwal, focused on the essential aspects of evaluating the risks and benefits associated with clinical trials and how to establish effective monitoring strategies to ensure participant safety and trial integrity.

Ms. Paliwal began by explaining the concept of **risk-benefit assessment**, which involves evaluating the potential risks to participants and weighing them against the expected benefits of the trial. She highlighted that this process is critical for ensuring that the potential benefits of a clinical trial justify the risks, particularly when it comes to participant health and safety. Ms. Paliwal emphasized that this assessment must be done at every stage of the trial, from the planning phase to the trial's completion.

The session also covered the importance of **monitoring plans** in clinical trials, which are designed to track participant safety and ensure that any adverse events or issues are identified and addressed promptly. Ms. Paliwal outlined the key elements of an effective monitoring plan, including adverse event reporting, data collection procedures, and regular reviews of the trial's progress. She stressed the need for continuous oversight to detect any issues that may arise during the trial and to ensure that appropriate actions are taken to mitigate risks.

Ms. Paliwal further emphasized the significance of adaptive risk management strategies, where the monitoring plan allows for flexibility and modification in response to emerging data or

unforeseen challenges. She discussed how ongoing data analysis and risk assessments during the trial can help identify trends or safety concerns early on, enabling timely adjustments to the trial protocol. Additionally, she highlighted the importance of collaboration among the trial's medical, scientific, and ethical teams, ensuring that all stakeholders are aligned in their approach to risk management and participant safety. This proactive, dynamic approach to monitoring not only safeguards participant health but also contributes to the overall integrity and validity of the trial results

Geotag Photos

"Enlightening session on Risk-Benefit Assessment and Monitoring Plan by Ms. Charu Paliwal, enhancing our understanding of balancing patient safety with clinical efficacy in research."

"Students are fully attentive to the session and contributing by asking insightful questions."

Session 5

Title of Topic: Visit to Ayurveda Centre

Date: 15 January 2025

Venue: Ayurveda centre

No. of Students: 29

Faculty Name: Dr Neel

Objective:

The objective of the visit was to introduce students to Ayurvedic practices and therapies, providing a practical understanding of traditional healing methods and their integration with modern clinical approaches.

Summary:

On 15 January 2025, students from the Department of Clinical Research visited an **Ayurveda Centre** under the guidance of **Dr. Manisha Sharma**. The visit provided valuable insights into Ayurvedic medicine, focusing on its holistic approach to health and healing. Dr. Sharma explained the foundational principles of Ayurveda, which include the balance of the body's three doshas (Vata, Pitta, and Kapha) and the use of natural remedies such as herbs, diet, and lifestyle modifications.

During the visit, students observed various **Ayurvedic treatments** and therapies, such as **massage therapies**, **herbal concoctions**, and **detoxification processes**. Dr. Sharma discussed how Ayurveda emphasizes prevention and personalized care, aiming to maintain overall well-being and balance within the body.

Students also had the opportunity to interact with practitioners at the centre, who demonstrated the use of Ayurvedic treatments and shared their knowledge about integrating Ayurvedic principles with modern healthcare practices. The visit highlighted the growing interest in combining traditional healing systems with contemporary medicine, providing a more holistic approach to patient care.

Geotag Photos:

"Students of M.Sc. Clinical Research during an educational visit to the Ayurveda Centre, the teacher from the Ayurveda Centre is explaining traditional therapies practiced in Ayurveda to students and faculty members."

"During an educational visit to the Ayurveda Centre, M.Sc. Clinical Research students are receiving an explanation of traditional Ayurvedic therapies from an Ayurveda Centre instructor"

Week 2, Day 9

Session 1

Title of Topic: Introduction to Investigational Product

Date: 16 January 2024

Venue: Training and Development Cell HIMS

No. of Students : 27

Faculty Name: Dr Manisha Sharma

Objective : To define investigational products (IP) in clinical trials, explain their types, outline the regulatory requirements, and clarify the responsibilities of the sponsor, investigator, and clinical trial sites.

Faculty N: Dr Manisha Sharma

Summary:

In this session, we defined the concept of an Investigational Product (IP) in clinical trials, which includes any drug, device, biologic, or placebo being tested for safety and efficacy. We

explored the different types of IPs, such as investigational drugs, devices, and combination products. Additionally, we discussed the regulatory requirements that govern clinical trials, such as adherence to Good Clinical Practice (GCP) guidelines, ensuring ethics committee approvals, and maintaining proper documentation to meet the standards of health authorities like the FDA and EMA.

We also highlighted the key responsibilities of the sponsor, investigator, and clinical trial site. The sponsor is responsible for initiating, managing, and funding the trial, ensuring compliance with regulations, and providing the necessary IP. The investigator oversees the conduct of the trial at the site, ensuring participant safety and accurate data collection. The clinical trial site ensures that the trial protocol is implemented correctly, manages participant recruitment, and ensures the trial runs smoothly. These roles, along with regulatory adherence, ensure that clinical trials are conducted ethically, safely, and in a scientifically rigorous manner.

Geotag Photos

"Dr Manisha Conducting Lecture on Introduction to Investigational Product"

"Students are listening intently to the session and actively participating through questions."

Session 2

Title of Topic: Administration of Investigational Product

Date: 16 January 2024

Venue: Training and Development Cell HIMS

No. of Students : 27

Faculty Name: Dr. Manisha Sharma

Objective : To explore the methods of **IP administration, dosing regimens**, monitoring of **adverse reactions,** and managing **side effects** and **accountability** in clinical trials.

Summary:

In this session, we discussed the different methods of Investigational Product (IP) administration, which includes oral, intravenous, subcutaneous, or topical methods, each chosen based on the optimal way to deliver the treatment. We also focused on the significance of protocol-specific dosing regimens, which are carefully designed to maintain consistency across participants, ensuring that each receives the correct dose to assess the product's safety and effectiveness.

Additionally, we highlighted the process of monitoring adverse reactions, where participants are regularly assessed to identify any negative effects that might arise from the IP. This includes timely reporting and proper documentation of any side effects. The handling of side effects was emphasized, including procedures for intervention, adjustment of dosage, or discontinuation if necessary. Lastly, we discussed the accountability of the investigational product, which involves rigorous tracking of its use and effects during the trial, ensuring compliance with regulatory standards and safeguarding participant health throughout the study.

Geotag Photos

“Students asking question from Dr Mnaisha on Administration of Investigational Product”

"Dr. Mnaisha is explaining the administration of an investigational product to the students."

Session 3

Title of Topic: Engaging Presentations

Date: 16 January 2025

Venue: Training and Development Cell HIMS

No. of Students:27

Objective: Equip individuals with the skills and techniques needed to create engaging and impactful presentations.

Faculty Name: Mr Ashish Gupta

Summary: In this session, we had focused on crafting engaging presentations to ensure effective communication. We started by emphasizing the importance of understanding the audience's interests, knowledge level, and expectations. Presenters were advised to tailor their content to meet these needs, making the information relevant and interesting. We had also discussed the significance of structuring presentations with a clear introduction, main points, and conclusion. This helped the audience follow along and retain the information presented.

Visual aids, such as slides, videos, and infographics, were used to enhance the audience's understanding and retention of the content. Props were incorporated to make the presentations more interactive and memorable.

Storytelling played a key role in engaging the audience emotionally and illustrating key points. We had also included interactive elements like quizzes, polls, and Q&A sessions to encourage active participation and provide feedback.

Effective body language and vocal delivery, such as eye contact, gestures, and voice modulation, helped establish a connection with the audience. Presenters were advised to practice and prepare thoroughly to ensure a confident and smooth delivery.

By the end of the session, participants had gained valuable strategies to captivate their audience, convey information clearly, and leave a lasting impact.

Geotag Photos

"Ms Ashish Gupta teaching student how to give Engaging Presentations"

"Students are engaged in a group discussion how they can give Engaging Presentation"

Week 2, Day 10

Session 1

Title of Topic: Introduction to descriptive statistics & Fundamentals of Inferential statistics.

Date: 17 August 2024

Venue: TRAINING AND DEVELOPMENT CELL HIMS

No. of Students:25

Faculty Name: Prof. A.K Srivastava

Objective: Learn how to organize and summarize large amounts of data into simple, understandable forms (e.g., tables, graphs).

Summary Descriptive statistics help summarize and organize data to make it easier to understand. It includes calculating averages (mean, median, mode), measuring data spread (range, variance, standard deviation), and using graphs to visualize data patterns. Inferential statistics allows us to make predictions and conclusions about a larger population based on a sample. It involves sampling techniques, hypothesis testing (to check assumptions), confidence intervals (to estimate values), and p-values (to assess significance). Additionally, inferential statistics helps distinguish between correlation (relationship) and causation (cause and effect). Together, they guide decision-making using data.

By the end of the session, they had acquired practical tips and built confidence to improve their presentation skills.

Geotag Photos

"Prof A K Srivastava explain students Introduction to descriptive statistics & Fundamentals of Inrential statistics and solving their doubt."

"Students are engaging by asking questions on the topic."

Session 2

Title of Topic :

-Defining Clinical Relevance.

-How to Interpret Statistical Significance in the Context of Clinical Practice

-Examples from Recent Clinical Trials

Date: 17 Jan 2025

Venue: Training and Development Cell HIMS

No. of Students:25

Faculty Name: Dr Ruchi Juyal

Objective: Understand what statistical significance means in clinical research .Learn how to interpret p-values in clinical studies. Recognize the difference between statistical significance and clinical relevance. Apply statistical findings to real-world patient care.Understand when statistical significance does not always mean clinical importance.

Summary: In clinical practice, **statistical significance** helps determine whether the results of a study are likely due to chance, often measured with a p-value of less than 0.05. This suggests that the observed effect in a study is probably real rather than a random occurrence. However, **statistical significance** alone doesn't guarantee that the results are meaningful in real-world clinical settings. It's possible for a treatment to show statistical significance but have a small effect that doesn't significantly impact patient health or outcomes. This is where **clinical relevance** becomes important.

Clinical relevance refers to whether the treatment or intervention produces an effect that is meaningful for patients' health or quality of life. For example, a drug might significantly lower cholesterol (statistical significance), but if the reduction is minimal and doesn't prevent heart attacks or strokes, it may not be clinically relevant for most patients.When interpreting research results in clinical practice, healthcare providers must consider both statistical significance and clinical relevance. A treatment could be statistically significant but offer only a small benefit that does not justify its use in practice. By the end of the session, they had acquired practical tips and built confidence to improve their presentation skills.

Geotag Photos

“Dr Ruchi Juyal explaining the importance of Statistical Significance in the Context of Clinical Practice,”

"Dr. Ruchi is also asking students questions related to the topic, and they are responding with their answers."

Session 3

Title of Topic:

Interpreting P-values, Confidence Intervals, and Effect Sizes

-Understanding Subgroup Analysis

-Assessing Bias and Confounding Factors

Date: 17 January 2025

Venue: Training and Development Cell HIMS

No. of Students:25

Faculty Name: Mr. Abhinav Bahuguna

Objective: Understand the meaning and significance of **p-values** in determining whether research results are statistically significant. Learn how to interpret **confidence intervals** and understand their role in assessing the precision and reliability of study estimates.
Understand the concept of **effect sizes** and how they measure the magnitude of the difference or treatment effect between groups.
Comprehend the importance of **subgroup analysis** and how it helps identify specific populations that may respond differently to treatments or interventions.

Summary Interpreting p-values, confidence intervals, and effect sizes is crucial in understanding the results of clinical studies. **P-values** help determine the statistical significance of findings, typically with values below 0.05 suggesting that results are unlikely due to chance. However, p-values alone do not provide information about the size or practical importance of an effect. This is where **confidence intervals** come in, providing a range of values within which the true effect is likely to lie, offering more insight into the precision of the results. **Effect sizes** measure the magnitude of the difference between groups, helping to determine if a treatment or intervention has a meaningful impact.

Subgroup analysis is also essential in identifying specific groups of patients who may benefit differently from a treatment. It helps pinpoint whether the results of a study apply equally across various populations or if certain subgroups show a different response.

Additionally, assessing **bias** and **confounding factors** is crucial for valid study interpretations. **Bias** (e.g., selection or reporting bias) can distort results, while

confounding factors are variables that can affect both the independent and dependent variables, leading to misleading conclusions. Understanding and controlling for these factors ensures the accuracy and reliability of study findings in clinical practice.

By the end of the session, they had acquired practical tips and built confidence to improve their presentation skills

Geotag:

"An interactive session on P-values, Confidence Intervals, and Effect Sizes by Mr. Abhinav Bahuguna.

"Mr. Abhinav Bahuguna conducted an interactive session on Understanding Subgroup Analysis"

Session 4

Title of Topic:

-Case Study: Interpreting Study Results.

-Group Activity: Analyzing and Interpreting Clinical Trial Data using SW SPSS/Graph pad Prism

Date: 17 January 2025

Venue: Training and Development Cell HIMS

No. of Students:25

Faculty Name: Mr. Abhinav Bahuguna

Objective:Learn how to analyse and interpret key findings from clinical study results, including statistical significance, effect size, and clinical relevance.

- **Apply Critical Thinking**: Develop skills in critically evaluating study designs, methodologies, and results to identify strengths and weaknesses in clinical research.

- **Use SPSS/GraphPad Prism**: Gain hands-on experience using SPSS or GraphPad Prism software to analyze and interpret clinical trial data.
- **Understand Statistical Analysis**: Learn how to run basic statistical tests (e.g., t-tests, ANOVA) in SPSS/GraphPad Prism and interpret the outcomes.
- **Visualize Data**: Develop the ability to create and interpret graphical representations of clinical trial data (e.g., bar charts, scatter plots).

Summary: The topic **"Case Study: Interpreting Study Results & Group Activity: Analyzing and Interpreting Clinical Trial Data using SPSS/GraphPad Prism"** focuses on developing the skills to interpret clinical research findings and analyze data using statistical software. In the **case study**, participants will learn how to critically evaluate clinical study results, focusing on key concepts such as statistical significance, effect size, and clinical relevance. Understanding how to apply these concepts ensures that clinical results are not just statistically significant but also meaningful in a healthcare context.

The **group activity** involves using **SPSS or GraphPad Prism** to analyze and interpret real clinical trial data. This hands-on experience helps participants learn to run statistical tests (e.g., t-tests, ANOVA) and understand their outcomes. Additionally, participants will gain skills in data visualization, creating graphs like bar charts or scatter plots, which are crucial for presenting results clearly.

Working in groups allows for collaboration in analyzing data and interpreting the results, ensuring that different perspectives are considered. The activity also emphasizes effective presentation skills, enabling participants to clearly communicate their findings. Finally, understanding the **clinical implications** of the data is a key outcome, as participants will discuss how the results can impact patient care and treatment decisions in real-world scenarios. This combined approach of theoretical learning and practical application ensures a comprehensive understanding of clinical trial data analysis.

By the end of the session, they had acquired practical tips and built confidence to improve their presentation skills.

Geotag Photo:

"Group Activity on Analyzing and Interpreting Clinical Trial Data using SW SPSS/Graph pad Prism."

"Mr. Abhinav Bahuguna is teaching students about SW SPSS."

Week 3, Day 11

Session 1

Topic: Addressing compliance issues and Non-compliance, Corrective Action & Preventive Action

Date: January 20, 2025

Time: 12:00 PM – 01:30 PM

Venue: Training and Development Cell, HIMS

Faculty Name: Dr. Manoj Karwa, Head of Clinical Trials and Pharmacovigilance at Auriga Research Pvt. Ltd.

No. of Students:28

Introduction

On January 20, 2025, the Department of Clinical Research at HIMS organized a guest lecture on "Addressing compliance issues and Non-compliance". The session was conducted by Dr. Manoj Karwa, who currently serves as the Head of Clinical Trials and Pharmacovigilance at Auriga Research. The lecture aimed to provide students with insights into the fundamentals of compliance, and consequences of non-compliance.

Key Points Discussed

1. **Strategies for addressing protocol deviations:** Dr. Manoj began the session by addressing protocol deviations involves identifying and categorizing them based on their impact, analyzing root causes, and implementing corrective actions to resolve issues. Preventive measures, such as protocol revisions and staff training, are essential to avoid future occurrences. Effective communication with stakeholders and continuous monitoring through audits ensure compliance and maintain study integrity.
2. **Managing noncompliance:** Managing non-compliance in clinical research involves identifying and documenting issues, analyzing root causes, implementing corrective and preventive actions, and maintaining transparent communication with stakeholders. Regular monitoring, follow-up, and

continuous staff training ensure adherence to protocols and regulatory requirements.

3. **Corrective and Preventive actions (CAPA):** Corrective and Preventive Actions (CAPA) in clinical trials focus on identifying, addressing, and preventing issues to maintain compliance and data integrity. Corrective actions resolve immediate problems, while preventive measures address root causes to avoid recurrence. CAPA involves thorough root cause analysis, implementing targeted solutions, documenting actions taken, and continuously monitoring processes to ensure effectiveness and adherence to regulatory standards.
4. **Interactive Session:** Participants actively engaged in the Q&A session.

Key Takeaways

1. **Proactive Identification:** Early detection and accurate documentation of compliance issues are essential for effective resolution.
2. **Root Cause Analysis:** Understanding the underlying causes helps in developing targeted solutions to address and prevent issues.
3. **Corrective and Preventive Actions (CAPA):** Implement corrective measures for immediate problems and preventive actions to minimize recurrence.
4. **Stakeholder Communication:** Transparent and timely communication with regulatory bodies, ethics committees, and other stakeholders is critical.
5. **Training and Awareness:** Continuous education for staff ensures awareness of protocols, regulations, and best practices.
6. **Monitoring and Follow-Up:** Regular audits and follow-up processes ensure compliance and the sustainability of corrective measures.
7. **Ethical and Regulatory Adherence:** Addressing non-compliance maintains participant safety, data integrity, and trust in the research process.

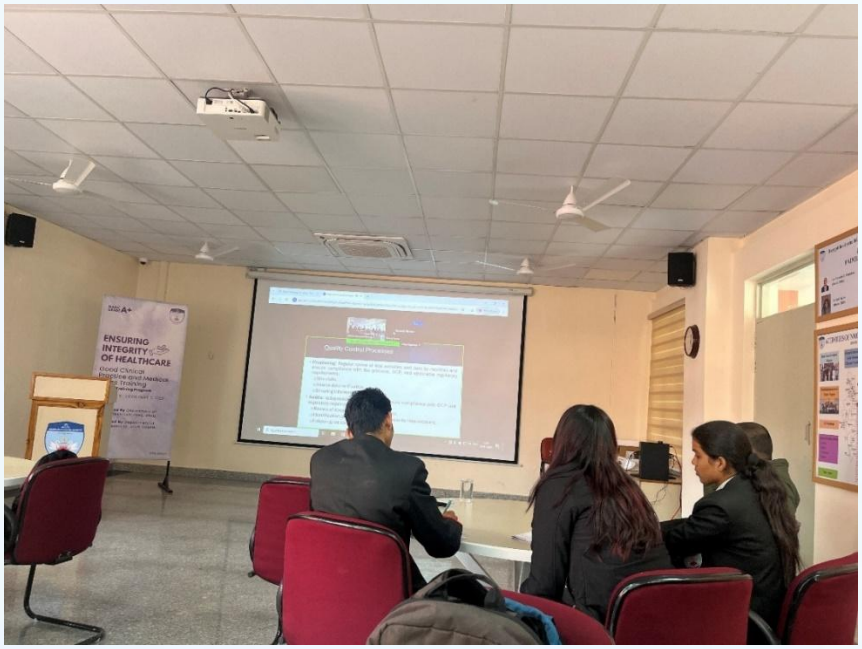
Feedback and Conclusion

The lecture received overwhelmingly positive feedback from participants, who appreciated Dr. Manoj's ability to simplify complex topics and provide practical insights. The session concluded with a vote of thanks delivered by Dr. Nikku Yadav, Incharge,

Department of Clinical Research, expressing gratitude to Dr. Manoj for his valuable time and expertise.

Geotag Photo:

"Dr. Manoj Karwa taking online session on Addressing compliance issues and Non-compliance, Corrective Action & Preventive Action"



"Dr. Manoj Karwa is leading an online session on compliance issues, and CAPA."

Week 3, Day 12

Session 1

Topic: Definition and Classification of Adverse event, Safety monitoring and Data Collection

Time: 9.30 AM – 04:30 PM

Date :21-01-2025

Venue: Training and Development Cell, HIMS

Faculty Name: Dr. Suman Bala, Professor and Head of Pharmacology, Shri Guru Ram Rai University

Participants:

The event was attended by 35 participants, including undergraduate and postgraduate students, faculty members, and researchers.

Introduction

On January 21, 2025, the Department of Clinical Research at HIMS organized a guest lecture on "Definition and Classification of Adverse event, Safety monitoring and Data Collection". The session was conducted by Dr. Suman Bala, who currently serves as the Head of Department of Pharmacology in Shri Guru Ram Rai University.

Key Points Discussed

1. **Definition and Classification of adverse events:**
   Dr. Suman began the session by defining an adverse event (AE) which is any unfavorable medical occurrence in a patient or clinical trial participant after receiving a medical intervention (e.g., drug, vaccine, or therapy). It may not necessarily be caused by the intervention. Adverse events can vary from mild to severe and include unintended signs, symptoms, or diseases.
2. **Safety monitoring and Data Collection**: Safety monitoring and data collection in clinical trials are essential processes to ensure participant safety, evaluate the risks and benefits of interventions, and comply with regulatory requirements.
3. **Ethics in patient recruitment:**
   Dr. Suman discussed the Ethical Issues in using incentives, addressing

vulnerable populations, ensuring respect and autonomy in recruitment and retention.

4. **Access to Clinical Trials:** Barriers and Solutions: Dr. Suman explained how barriers to accessing clinical trials can prevent certain populations from participating, which may impact the generalizability of trial results and how addressing these barriers is crucial for improving trial inclusivity
5. **Interactive Session:**
   Participants actively engaged in the Q&A session, seeking clarification on topics like ethical dilemmas in patient recruitment, adverse events, and the safety data collection strategies.

Key Takeaways:

- Understanding the classification of adverse events helps in monitoring safety, assessing risks, and improving medical treatments or interventions.
- Effective safety monitoring and data collection safeguard participants, maintain the trial's integrity, and ensure the reliability of the results.
- Ethical patient recruitment ensures respect for participants' rights, promotes fairness, and upholds the integrity of clinical trials, fostering trust and reliability in research.
- By tackling the barriers, clinical trials can become more inclusive, ensuring broader participation and improving the generalizability of trial outcomes.

Feedback and Conclusion

The lecture received overwhelmingly positive feedback from participants, who appreciated Dr. Suman's ability to simplify complex topics and provide practical insights. The session concluded with a vote of thanks delivered by Dr. Nikku Yadav, Incharge, Department of Clinical Research, expressing gratitude to Dr. Suman Bala for her valuable time and expertise.

Geotag Photos:

"Dr Suman Bala taking session on Definition and Classification of Adverse event, Safety monitoring and Data Collection"

"Dr Suman Bala also solving the doubt of students"

Week 3, Day 13

Session 1

Title of Topic: Legal perspective into Clinical Research

Date: 22 January 2025

Venue: Development and Training Centre ,HIMS

No. of Students:29

Faculty Name : Mr Piyush Dhyani

Objective: To understand medico-legal concepts, intellectual property and legal issues, liability and risk management strategies, and dispute resolution methods in clinical research for effective navigation of the legal landscape in healthcare and clinical research.

Summary: In this session, we were introduced to medico-legal concepts, examining how legal principles apply to healthcare practices. We explored the intersection of law and medicine, gaining insights into patient consent, confidentiality, and professional accountability. These foundational concepts are essential for ensuring compliance with legal standards and protecting patient rights.

The session also covered intellectual property and legal issues, emphasizing the importance of protecting medical innovations. We learned about patents, trademarks, and copyrights, and how these can safeguard new treatments and medical devices. The discussion highlighted the challenges of navigating the legal landscape of intellectual property and the strategies necessary to address these challenges.

Additionally, the session addressed liability and risk management, focusing on strategies to mitigate risks and manage potential liabilities. We examined professional and product liability, as well as malpractice, and discussed proactive measures to minimize legal risks. Lastly, the session covered dispute resolution and legal action in clinical research, offering insights into negotiation, mediation, arbitration, and legal processes involved in addressing disputes. This comprehensive overview equipped us with the essential knowledge to navigate the complex legal landscape in healthcare and clinical research.

Geotag Photos:

"Mr Piyush Dhyani explaining participants about Legal perspective into Clinical Research"

"Mr. Piyush Dhyani is providing insights into the legal aspects of clinical research for the participants."

Session 2

Title of Topic: Entrepreneurship bootcamp at the Innovation Centre.

Date: 22 January 2025

Venue: HCIE

No. of Students:29

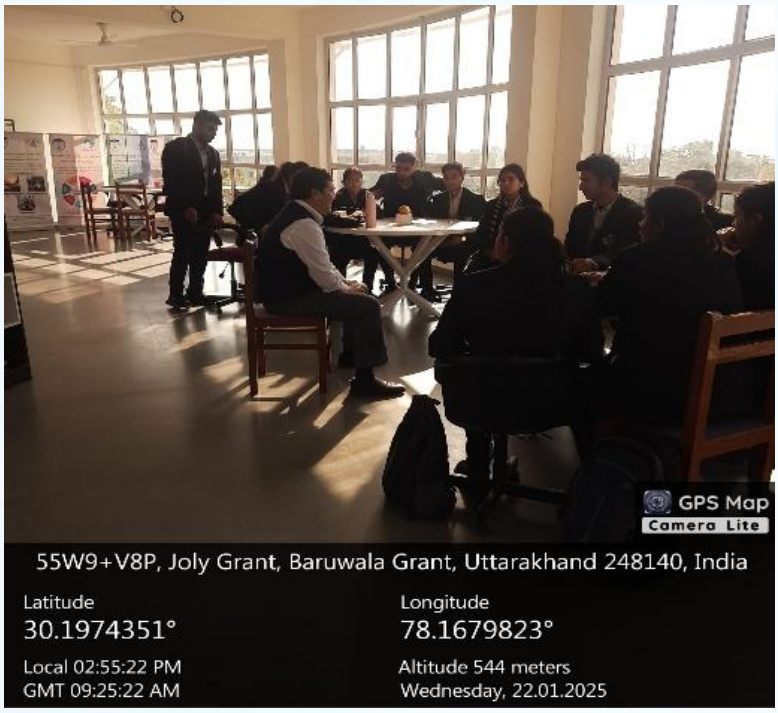
Objective: Poster creativity, practical skills and strategic thinking.

Faculty Name: Dr Amjad Hussain.

Summary A visit to the Entrepreneurship Bootcamp at the Innovation Centre is a transformative experience focused on fostering creativity, enhancing practical skills, and developing strategic thinking. Participants engage in brainstorming sessions and design thinking workshops to cultivate innovative solutions to real-world problems. Hands-on activities teach essential entrepreneurial skills such as business planning, financial management, marketing strategies, and product development. Through case studies, mentorship sessions, and strategic planning activities, participants learn to identify opportunities, assess risks, and develop long-term plans. By the end of the bootcamp, they gain a clearer understanding of the entrepreneurial process and are equipped with the tools and mindset needed to start and grow their ventures. In addition to practical skills, the bootcamp focuses on strategic thinking. Participants engage in case studies and receive mentorship from experienced entrepreneurs, allowing them to learn from real-world examples and gain valuable insights. Strategic planning activities help participants identify opportunities, assess risks, and develop comprehensive plans to achieve their goals. By learning to think critically and make informed decisions, participants are better equipped to navigate the complexities of the entrepreneurial landscape.

Overall, the bootcamp provides a holistic experience that combines creativity, practical skills, and strategic thinking. By the end of the program, participants have a clearer understanding of the entrepreneurial process, along with the tools, knowledge, and mindset needed to start and grow their venture.

Geo Tag Photo



“Dr Amjad Hussain explaining participants about innovative solutions to real-world problems.”

"Dr. Amjad Hussain is guiding participants on innovative approaches to solving real-world challenges."

Week 3, Day 14

Session 1

Title of Topic: Role of Clinical Monitor During Site Visits& Preparing for the visit

Date: 24 January 2025

Venue: TRAINING AND DEVELOPMENT CELL, HIMS

No. of Students: 29

Faculty Name: Dr. Nikku Yadav

Objective: overview of site monitoring activities and understanding the protocol and data management assessing site compliance with GCP and regulatory requirements

Summary: In the session on Clinical monitoring ensures compliance with protocols, regulations, and Good Clinical Practice (GCP) throughout a clinical trial. During site visits, monitors verify data accuracy, patient safety, protocol adherence, and regulatory compliance while identifying and resolving issues. Preparation for a study includes site selection, investigator training, document verification, and ensuring site readiness. Site monitoring involves initiation, routine, and close-out visits, focusing on informed consent, source data validation, investigational product accountability, and protocol deviations. Effective monitoring maintains trial integrity, ensures data reliability, and safeguards patient welfare.

"Dr. Nikku Yadav conducting lecture on Role of Clinical Monitor During Site Visits& Preparing for the visit"

Session 2

Title of Topic: Assess to clinical trial: barrier and solution

Date: 24 January 2025

Venue: Training And Development Cell,HIMS

No. of Students: 29

Faculty Name: Dr. Suman Bala

Objective: identify to barrier to assess geography and financial, cultural and social overcoming the barrier to enhance participants in clinical trial an ethics consideration in recruitment and retention

Summary: In the session on assessing geographical, financial, cultural, and social barriers is essential for enhancing participant recruitment and retention in clinical trials. **Geographical barriers** such as the distance between participants and trial sites can prevent access to trials, particularly for individuals in remote areas. To overcome this, virtual trials or decentralized models, where participants can engage from their location, can be implemented. **Financial barriers**, like the cost of travel, time off work, or lack of insurance coverage, can also discourage participation. Offering travel reimbursement, compensation for time, or adjusting the trial's financial requirements can help mitigate these issues. **Cultural and social barriers** arise when participants' backgrounds, beliefs, or values conflict with the trial process. Cultural sensitivity training for staff, multilingual materials, and addressing specific concerns about trial procedures can help increase inclusivity and comfort for diverse populations.

Ethics considerations in recruitment and retention involve ensuring **informed consent**, **non-coercion**, and **privacy**. Participants should fully understand the trial's risks and benefits, without undue pressure to join or stay in the study. Furthermore, respecting **confidentiality** and ensuring that personal information is protected is crucial. Additionally, ongoing support and clear communication with participants help maintain trust and encourage retention throughout the trial. By addressing these barriers with ethical practices and tailored strategies, clinical trials can become more inclusive, leading to a diverse participant pool that enhances the validity and generalizability of study results

“Dr. Suman Bala conducting lecture on Assess to clinical trial: barrier and solution”

“A group picture with Dr. Suman Bala after the completion of her lecture."

Session 3

Title of Topic: Mock the site visit: observation exercise and report writing

Date: 24 January 2025

Venue: Training And Development Cell Hims

No. of Students: 29

Faculty Name: CTC Team and Dr. Nikku Yadav

Objective: role play of site visit monitoring and Interaction with staff and conduct assessment Assessing participants recruitment, informed consent, and data documentation Identifying Protocol deviation

Summary During a site visit monitoring, the Clinical Research Associate (CRA) interacts closely with the site staff to assess how well they are conducting the trial. The CRA begins by reviewing the **site's overall compliance**, ensuring that all staff members are trained and that they are adhering to the protocol. They will meet with the Principal Investigator (PI) and other key personnel to understand the processes in place for **participant recruitment** and **informed consent**. This includes checking if the recruitment targets are being met, whether recruitment practices are ethically sound, and confirming that participants are provided with clear, comprehensive information before consenting to participate.

The CRA will also **assess data documentation** during the visit by comparing the source documents with the data entered in the clinical trial database or Electronic Data Capture (EDC) system. They verify the accuracy, consistency, and completeness of the data to ensure that no discrepancies or errors exist. If any issues arise, the CRA works with the site staff to rectify the documentation promptly.

An essential aspect of monitoring is identifying **protocol deviations**. The CRA closely reviews any discrepancies between the actual study conduct and the study protocol, including recruitment methods, participant eligibility, or procedural timing. Any deviations are documented and assessed for their potential impact on the trial's integrity. The CRA ensures corrective actions are taken to prevent further issues,

emphasizing the importance of adherence to the protocol to maintain regulatory compliance and data quality.

By conducting these assessments, the CRA ensures that the trial runs smoothly, ethically, and in full compliance with GCP guidelines.

“Students discuss about exercise and report writing”

“Students are discussing exercise and the process of writing reports."

Session 4

Title of Topic: Effective team meeting

Date: 24 January 2025

Venue: TRAINING AND DEVELOPMENT CELL HIMS

No. of Students: 29

Faculty Name Ms Garima Kapoor & Mr Ashish Gupta

Objective:: mock meeting to solve a hypothetical Problem and requirements meeting agenda

Summary In a session focused on a **Mock Meeting Agenda for Problem-Solving & Requirements Discussion**, the goal is to simulate a structured approach to addressing challenges and defining necessary actions for a specific project or initiative. The meeting typically begins with a **clear identification of the problem or issue** that needs resolution, ensuring all participants understand the context. Following that, key stakeholders or team members present their perspectives, concerns, and data relevant to the problem. This open exchange allows for a comprehensive understanding of the situation, which is crucial for effective problem-solving.

The discussion then moves to the **requirements phase,** where participants collaboratively outline the necessary actions, resources, and timelines needed to resolve the problem. This includes identifying key deliverables, prioritizing tasks, and assigning responsibilities to appropriate individuals or teams. During this phase, it is essential to ensure that all requirements are feasible, well-defined, and aligned with broader project or organizational goals.

The meeting also incorporates **problem-solving techniques,** such as brainstorming, root cause analysis, or SWOT analysis, to generate potential solutions. The facilitator ensures that the conversation stays on track and that all voices are heard, encouraging collaboration and creative thinking.

"Ms Garima teaching students about Effective team meeting"

"Mr Ashish Gupta is instructing students on effective team meeting strategies."

Week 4, Day 15

Session 1

Title of Topic: Vulnerable Population in Clinical Research

Date: 27 January 2025

Venue: TRAINING AND DEVELOPMENT CELL HIMS

No. of Students: 28

Faculty Name Dr. Bindu Ray

Objective: Defining Vulnerable population children elderly, prisoners, economically, disadvantaged, Ethics considerations for research involving vulnerable group, special protections and regulation.

Summary : The session on Vulnerable populations in research include individuals who may have limited ability to protect their own interests or make fully informed decisions. This group includes **children**, **elderly individuals**, **prisoners**, and those who are **economically disadvantaged**. **Children** lack legal capacity to consent and need surrogate consent from parents or guardians. **Elderly individuals** may face challenges due to cognitive decline or physical limitations, which can impact their ability to participate in research. **Prisoners** may face coercion or undue influence due to their confinement, requiring careful consideration of their consent. **Economically disadvantaged individuals** might participate out of financial necessity, which could compromise their voluntary participation. Ethical considerations for research involving vulnerable groups emphasize **informed consent**, **voluntariness**, and **minimizing harm**. Special protections, such as requiring independent oversight or an additional layer of consent (e.g., guardian or legal representative), help safeguard these groups. Regulations like the **Belmont Report** and **Federal Regulations (45 CFR 46)** in the U.S. require extra protections for these populations, including Institutional Review Board (IRB) review and justification of the research's risks and benefits

“Participants taking session from Dr. Bindu Ray on Vulnerable Population in Clinical Research”

"Participants are attending a session by Dr. Bindu Ray on Vulnerable Populations in Clinical Research asking questions."

Session 2

Title of Topic: Decentralised Clinical Trials

Date: 27 January 2025

Venue: TRAINING AND DEVELOPMENT CELL HIMS

No. of Students: 28

Faculty Name Dr. Manisha Sharma

Objective: Using Real World Technology ethics opportunities & challenges

Summary The session on Real-world technology presents both **opportunities** and **challenges** when applied to ethics in various sectors. On the one hand, **advancements** such as artificial intelligence, machine learning, and data analytics offer significant opportunities for improving efficiency, healthcare, education, and accessibility. These technologies can enhance decision-making, streamline processes, and provide personalized solutions for individuals. However, these advancements also pose **ethical challenges**, including issues around **data privacy**, **bias**, and **accountability**. The widespread use of personal data can lead to breaches of privacy and unintended exploitation. Additionally, algorithms may inherit or amplify biases, leading to discriminatory outcomes in areas like hiring or law enforcement. There's also a challenge in ensuring that these technologies are used responsibly, with transparent decision-making processes and mechanisms for accountability.

Geotag Photos

“Real-world technology offers benefits but also raises ethical concerns about privacy, bias, and accountability.”

"Although real-world technology enhances various aspects of life, it raises ethical issues such as privacy, bias, and accountability."

Session 3

Title of Topic: The Power of emotional intelligence enhancing Personal and Professional Growth

Date: 27 January 2025

Venue: Training And Development Cell Hims

No. of Students: 28

Faculty Name Dr. Ekta Rao

Objective: Emotional intelligence is crucial for building strong relation, improving communication, and managing stress, thereby enhancing there by changing both personal wellbeing and Professional Effectiveness

Summary The session on Emotional intelligence (EI) plays a vital role in both personal well-being and professional effectiveness. It involves the ability to recognize, understand, and manage one's emotions, as well as the emotions of others. High EI fosters strong relationships by improving communication, allowing individuals to empathize with others, resolve conflicts, and build trust. It also helps in managing stress, as emotionally intelligent individuals can cope with challenges more effectively and remain calm under pressure. In the workplace, EI enhances professional effectiveness by promoting collaboration, leadership, and adaptability. Leaders with high EI inspire and motivate teams, fostering a positive work environment. It also aids in decision-making and problem-solving, as emotionally intelligent individuals can assess situations more thoughtfully and consider the emotional impact of their choices. Ultimately, developing EI leads to better interpersonal interactions, improved mental health, and a more productive and harmonious professional life.

Geotag Photos:

“Emotional intelligence enhances personal well-being, professional effectiveness, and fosters strong relationships through empathy, communication, and stress management.”

"By fostering empathy, communication, and stress management, emotional intelligence enhances personal well-being, professional success, and meaningful relationships."

Week 4, Day 16

Session 1

Title of Topic: Introduction to literature search.

Date: 28 January 2025

Venue: Training and Development Cell HIMS

No. of Students: 30

Faculty Name: Professor Yogendra Singh

Objective:

The session aimed to introduce students to web page optimization methods and literature search and reference management.

Summary:

The session, led by prof. Yogendra Singh provided a comprehensive understanding of Google scholar and web page optimization methods and literature search.

Google Scholar is a powerful academic search engine that provides access to scholarly articles, books, and conference papers, allowing users to track citations and set alerts for new research. Effective literature search strategies involve using Boolean operators, advanced filters, and reliable databases like PubMed, IEEE Explore, and Scopus to find relevant sources. Web page optimization, including SEO techniques like keyword optimization, mobile responsiveness, and technical improvements, enhances website visibility and performance. Combining these skills—efficient literature search and web optimization—can improve academic research and digital presence, ensuring accessibility and credibility in both domains.

Geotag Photos:

"Introduction to Literature Search: An Overview of Research Techniques and Best Practices for Identifying Relevant Clinical Data."

"Students are actively engaged, listening to the session and inquiring with thoughtful questions."

Session 2

Title of Topic: Mock networking event with role play introductions.

Date: 28 January 2025

Venue: Training and Development Cell HIMS

No. of Students: 30

Faculty Name: Mr. Ashish and Mrs Garima Kapoor.

Objective:

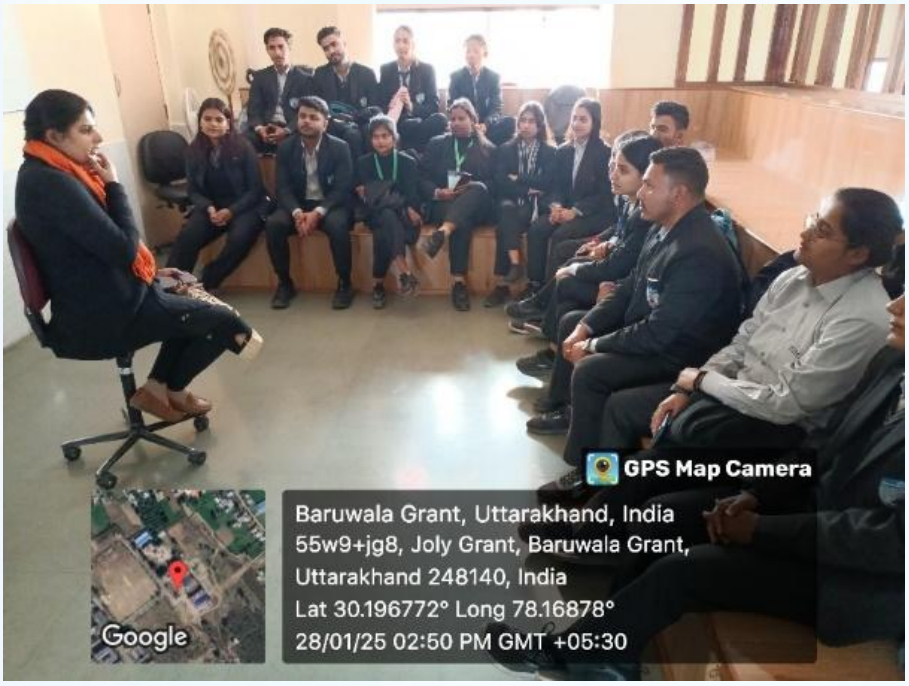
The session aimed to introduce students to network for personal and professional growth and role play introductions.

Summary:

The session, led by Mrs Garima Kapoor provided a comprehensive understanding mock networking event and role introduction for professional and personal growth.

A mock networking event is a simulated professional gathering designed to help individuals practice and refine their networking skills for both professional and personal growth. Participants take on roles such as job seekers, entrepreneurs, recruiters, or industry experts, engaging in structured conversations to enhance communication, confidence, and relationship-building. The event typically includes icebreakers, one-on-one networking, group discussions, and feedback sessions, allowing participants to develop their elevator pitches, improve adaptability, and strengthen their personal brand. By practicing in a low-pressure environment, attendees gain valuable experience in initiating conversations, making meaningful connections, and following up effectively, ultimately preparing them for real-world networking success.

Geotag Photos:



"Mock Networking Event: Role Play Session for Practicing Professional Introductions and Networking Skills."

"Simulated Networking Event: Role Play for Enhancing Professional Introductions and Networking Abilities."

Week 4, Day 17

Session 1

Title of Topic: Role play Activities

Date: 29 January 2025

Venue: Cancer research institute (CRI)

No. of Students: 30

Faculty Name: Dr.Nikku yadav

Objective:

The activity or role play ethics committee review meeting on multiple myeloma new diagnosed patient.

Summary:

The session, led by Dr.Nikku yadav provided a comprehensive understanding of Ethics committee review meeting in multiple myeloma new diagnosed patients.

An Ethics Committee Review Meeting for newly diagnosed multiple myeloma (NDMM) patients is a critical step in ensuring that clinical research is conducted ethically, prioritizing patient safety, scientific validity, and regulatory compliance. The committee evaluates the study's risk-benefit balance, ensuring that potential benefits outweigh risks and that patients are not exposed to unnecessary harm. A key focus is on the informed consent process, ensuring patients fully understand the study, its risks, and their rights. The review includes documents such as the study protocol, investigator's brochure, informed consent form (ICF), and risk management plan. The committee then decides whether to approve, request modifications, or reject the study. If approved, ongoing monitoring of patient safety, adverse events, and protocol compliance is mandatory.

An Ethics Committee Review Meeting for newly diagnosed multiple myeloma (NDMM) patients ensures the study is ethical, safe, and regulatory-compliant. The committee evaluates:

Patient Safety: Ensuring risks are minimized.

Scientific Justification: Validating study design and potential benefits.

Informed Consent: Clear communication of risks and procedures to patients.

Regulatory Compliance: Adhering to ICH-GCP and local guidelines.

Key documents reviewed include the study protocol, investigator's brochure, informed consent form, and risk management plan. The committee may approve, request modifications, or reject the study based on risk-benefit analysis. Post-approval, ongoing monitoring and safety reporting are required.

Geotag photos:

"Role Play Activity: Simulating a Site Initiation Visit to Ensure Readiness and Protocol Understanding for Clinical Trial Implementation."

"Training Simulation: Role-Playing a Site Initiation Visit to Ensure Compliance and Preparedness for Clinical Trials."

Week 4, Day 18

Session 1

Title of Topic: Introduction to prism

Date: 30 January 2025

Venue: Computer Lab

No. of Students: 28

Faculty Name: Dr.Nikku Yadav

Objective: The objective of the session was to familiarize participants with the PRISM interface's functionalities, features, and its potential applications in improving data management and operational efficiency.

Summary: Dr. Nikku Yadav conducted a session providing an **overview of PRISM interface projects** and highlighted their key features. The session focused on the PRISM interface, a platform designed to streamline and enhance the management of data and processes in various sectors. Dr. Yadav explained how PRISM interfaces with different systems to facilitate seamless data integration and improve operational efficiency. She also emphasized the versatility of the platform, showcasing its adaptability across various industries such as healthcare, research, and data management. The key features of PRISM, such as its user-friendly interface, real-time data tracking, and robust analytics capabilities, were discussed in detail. Dr. Yadav further explained how these features contribute to optimizing workflows, improving decision-making, and ensuring accurate data handling in complex projects. Overall, the session provided valuable insights into how PRISM interface projects are revolutionizing the way data is managed and utilized across different fields.

Geotag Photos:

“Mastering Data Visualization And Analysis With Prism Graphpad : Dr Nikku Yadav”

"Dr. Nikku Yadav is instructing students on how to effectively use GraphPad software."

Session 2

Title of Topic: Deliver a 60 second elevator pitch

Date: 30January 2025

Venue: YOUNITE

No. of Students: 28

Faculty Name: Mr.Ashish Gupta

Objective:

The objective of the session was to equip participants with the skills and strategies needed to craft a compelling elevator pitch that communicates their ideas effectively, makes a strong impression, and maximizes opportunities in professional scenarios.

Summary:

Mr. Ashish conducted an insightful session on **crafting an effective elevator pitch**, focusing on the art of delivering a concise, impactful message within a short amount of time. The session began with Mr. Ashish explaining the importance of an elevator pitch, particularly in professional settings where first impressions matter. He outlined the essential elements of an elevator pitch, emphasizing the need to clearly communicate the value proposition, capture the audience's attention, and leave a lasting impression, all within a brief time frame—typically 30 to 60 seconds. Mr. Ashish also provided practical tips on structuring an elevator pitch, such as starting with a hook, highlighting key benefits or outcomes, and ending with a call to action. Throughout the session, he encouraged participants to tailor their pitch to different audiences, practice delivering it confidently, and focus on clarity and engagement. The session included real-world examples to demonstrate how an effective elevator pitch can open doors to opportunities, whether in networking events, job interviews, or business meetings.

Geotag Photos:

"Mr. Ashish Gupta is taking lecture on Building Your Personal Brand"

"Mr. Ashish Gupta is teaching a session on strategies for Building Your Personal Brand."

Week 4, Day 19

Session 1

Title of Topic: Introduction to Informed Consent Process

Date: 31 January 2025

Venue: Training and Development Cell HIMS

No. of Students: 28

Faculty Name: Dr. Manisha Sharma

Objective:

The session aimed to introduce students to informed consent process, providing foundational knowledge on the key components, and the regulatory and ethical guidelines that govern them.

Summary:

Dr. Manisha Sharma's session on "Introduction to Informed Consent" emphasized its ethical and legal importance in medical treatments and research. She explained that informed consent is a process, not just a form to sign, requiring clear communication between healthcare providers or researchers and participants. Key components include explaining the procedure or study, its risks, benefits, and ensuring participants understand the information provided. Consent must be voluntary, free from coercion, and individuals should know they can withdraw at any time without consequence. Dr. Sharma highlighted that the information should be presented in a way that the participant can easily understand, considering language and literacy differences. Confidentiality of personal information is also crucial to maintain trust. Finally, documentation, in the form of a signed consent form, is necessary to confirm that the individual was properly informed. The session stressed that informed consent protects autonomy and ensures ethical practices in healthcare and research.

Geotag Photos:

“Dr Manisha Sharma conducting session on Information On Informed Consent Process”

"Students are fully attentive to the session and contributing by asking insightful questions."

Session 2

Title of Topic: Introduction to IPR

Date: 31 January 2025

Venue: Training and Development Cell HIMS

No. of Students: 28

Faculty Name: Dr. Bhawana Pal

Objective:

The session aimed to introduce students to Intellectual Property Right, providing foundational knowledge on the key components, and the regulatory and ethical guidelines that govern them.

Summary:

Dr. Bhawana Pal's session on "Introduction to IPRT" provided a comprehensive overview of Intellectual Property Rights (IPR) and their importance in protecting innovations. She began by defining IPR as legal rights granted to individuals or organizations for their inventions, creative works, or distinctive marks. Dr. Pal emphasized the role of IPR in encouraging creativity, innovation, and economic growth by providing legal protection to creators and inventors, thereby allowing them to benefit financially from their work. The session covered various types of IPR, including patents, trademarks, copyrights, and trade secrets. Dr. Pal explained how patents protect inventions, trademarks safeguard brand identities, copyrights cover creative works like literature and art, and trade secrets protect business-related information. She highlighted the procedures for acquiring these rights, as well as the duration of protection, which varies depending on the type of IPR. Dr. Pal also discussed the challenges of enforcing IPR and the importance of awareness in preventing infringement. The session emphasized that understanding and utilizing IPR is crucial for creators, businesses, and researchers to safeguard their innovations and maintain a competitive edge in the global market. Ultimately, IPR plays a pivotal role in fostering creativity and promoting economic development.

Geotag Photo

“Dr. Bhavna Pal is is conducting lecture on Introduction To IPR “

"Dr. Bhavna Pal is presenting a session on Introduction to Intellectual Property Rights (IPR)."

Week 5, Day 20

Session 1

Title of Topic: Introduction to SPSS and data entry and management

Date: 03 February 2025

Venue: Computer lab

No. of Students: 28

Faculty Name: Mr. Abhinav Bahuguna

Objective:

Introduce SPSS interface and basic functionalities. Teach data management, cleaning ,and manipulation techniques, develop statistical analysis skills using SPSS, enhance understanding of visual data presentation .

Summary: This report provides a brief overview of SPSS (Statistical Package for the Social Sciences), focusing on its introduction, data entry, and data management processes.

SPSS is a powerful software used for statistical analysis across various fields such as social sciences, business, and healthcare. It features a user-friendly interface, consisting of **Data View** (for entering and viewing data), **Variable View** (for defining variables like data type and measurement scales), and **Output Viewer** (for displaying results).

Effective **data entry and management** in SPSS are essential for accurate analysis. Data can be entered manually in the **Data View**, where each column represents a variable, and each row an observation. The **Variable View** allows users to define variable properties, such as data types (numeric, string) and measurement levels (nominal, ordinal, scale). SPSS also supports importing data from formats like Excel or CSV.

Data management includes techniques such as **data cleaning** (handling missing values, correcting outliers), and **data manipulation** (recoding variables, creating new ones, and merging datasets). These functions ensure that data is properly structured for statistical analysis.

Geotag Photos:

“Mr. Abhinav Bahuguna is conducting session on Introduction to SPSS and data entry and management”

"Mr. Abhinav Bahuguna is facilitating a session on SPSS, explaining data entry and management techniques."

Session 2

Title of Topic: Descriptive statistics and introduction to graphs

Date: 03 February 2025

Venue: Biostatistics lab

No. of Students: 28

Faculty Name: Mr. Abhinav Bahuguna

Objective:

The objective is to understand and apply **descriptive statistics** (mean, median, mode, etc.) and create various **graphs** (bar charts, histograms, etc.) using SPSS to summarize and visually present data effectively.

Summary:

Descriptive statistics involve summarizing and interpreting data using key measures like **mean**, **median**, **mode**, **range**, **variance**, and **standard deviation**. These measures help to describe the central tendency and spread of data. Descriptive statistics provide a quick overview of a dataset, allowing researchers to identify patterns and make informed decisions.

In addition to numerical summaries, graphical representations are essential for visualizing data. Common types of graphs include **bar charts**, **histograms**, **pie charts**, and **box plots**, each serving a different purpose based on the nature of the data. For instance, bar charts and histograms display frequencies or distributions, while pie charts represent proportions, and box plots highlight data distribution and outliers.

In SPSS, users can easily calculate descriptive statistics and generate these graphs, helping to present data findings clearly. Using graphs and descriptive statistics together allows researchers to communicate complex data insights in a simple and understandable manner. This combination is foundational for effective data analysis and reporting.

Geotag Photos:

“Mr Abhinav Bahuguna giving introduction on software named SPSS”

"Mr. Abhinav Bahuguna is demonstrating the use of SPSS software in research."

Week 5, Day 22

Session 1

Title of Topic: Conducting High-Impact Research for Societal Change

Date: 04 February 2025

Venue: Training and Development Cell HIMS

No. of Students: 30

Faculty Name: Dr. Pradeep K. Varshney

Objective:

The objective is to explore how **academic research** and **innovation** can drive societal change, focusing on methods to create impactful solutions that address pressing issues and contribute to sustainable development.

Summary:

As taught by **Dr. Pradeep K. Varshney**, academic research and innovation are crucial for societal development. The **Global Innovation Index** emphasizes India's growing role in fostering innovation, with advancements in technology, healthcare, and education. Dr. Varshney highlighted how these innovations contribute significantly to global progress.

By aligning research with the **17 Sustainable Development Goals (SDGs)**, we can address critical global issues such as poverty, climate change, and clean energy. Dr. Varshney explained the importance of both **basic** and **applied research**—where basic research expands theoretical knowledge, while applied research focuses on practical solutions for real-world challenges.

Dr. Varshney also emphasized the significance of maintaining **ethical standards** in research. Ethical considerations ensure transparency, integrity, and respect for participants, which is essential for the credibility and social impact of research.

The ultimate impact of quality research, as explained by Dr. Varshney, lies in its ability to influence policy, improve societal well-being, and contribute to sustainable development, driving progress toward a better global future.

Geotag Photos:

"Dr Pradeep Varshney enlightens about the topic quality research."

"Dr. Pradeep Varshney shares his expertise on quality research."

Session 2

Title of Topic: Basic statistical tests (t test, Chi-Square, ANOVA and case study)

Date: 04 February 2025

Venue: Computer lab

No. of Students: 30

Faculty Name: Mr. Abhinav Bahuguna

Objective:

The objective is to understand and apply basic statistical tests, including **t-tests**, **Chi-Square**, and **ANOVA**, to analyse data, interpret results, and conduct case studies for practical decision-making.

Summary:

Basic statistical tests are essential tools in data analysis, allowing researchers to make informed decisions based on data. As taught by **Mr. Abhinav Bahuguna**, the **t-test** is used to compare the means of two groups, determining whether any significant differences exist. This test is commonly used in experiments to test hypotheses related to group differences. The **Chi-Square test**, another fundamental tool, is employed to assess the relationship between categorical variables by comparing observed frequencies to expected frequencies, often used in survey or categorical data analysis.

ANOVA (Analysis of Variance) is a statistical method used to compare means across multiple groups, identifying whether there are significant differences between them. It is widely applicable in experiments with more than two groups.

A **case study**, as explained by Mr. Bahuguna, involves applying these tests to real-world data, helping to illustrate their practical applications and their role in guiding decision-making and drawing actionable insights from data.

Geotag Photos:

“Mr. Abhinav Bahuguna teaching students about graphical representation on SPSS.”

"Mr. Abhinav Bahuguna is demonstrating graphical representation techniques in SPSS to students."

Week 5, Day 23

Session 1

Title of Topic: Introduction to protocol writing

Date: 5th February 2025

Venue: Department of Clinical Research

No. of Students: 29

Faculty Name: Dr. Nikku Yadav

Objective: Introduction to protocol which includes the objectives, methodologies, budget, timeline, evaluation, conclusion and reference of the innovative idea on healthcare problems.

Summary:

Dr. Nikku Yadav enlightens us about the Protocol writing which is the process of creating a detailed plan for a research study or clinical trial, outlining key elements like objectives, methodologies, budget, timeline, and evaluation criteria. It ensures clarity and structure by defining the research goals, the methods to achieve them, and the resources required. The protocol also sets expectations for assessing the study's success and includes a conclusion summarizing the outcomes. References to relevant literature support the methodology. Overall, protocol writing serves to guide the research process, ensuring a well-organized and scientifically sound approach to the study.

This topic involves the methodology section describes the research design, techniques, and tools that will be used to gather and analyse data. The budget estimates the financial resources needed, while the timeline establishes milestones and deadlines for each phase of the project. The evaluation section defines how the success and outcomes of the study will be measured. Finally, the conclusion provides a summary of the anticipated findings and their potential implications. The references section acknowledges the research and sources used in shaping the protocol. The goal of protocol writing is to ensure that the study is well-organized, reproducible, and adheres to ethical and regulatory standards, facilitating efficient and transparent research processes

“Dr Nikku Yadav explaning students how to write and present proposal writing”

"Dr. Nikku Yadav is teaching students the process of writing and presenting proposals."

Session 2

Title of Topic: Introduction to ethical guidelines which includes ICH, GCP, GLP, GMP, CSCO,DCGI and EU.

Date: 5th February 2025

Venue: Department of Clinical Research

No. of Students: 29

Faculty Name: Dr. Bindu Dey

Objective: The objective of **ICH** is to harmonize global pharmaceutical standards for consistent safety, efficacy, and quality. **GCP** aims to protect human participants in clinical trials while ensuring reliable and credible trial results. **GLP** ensures the quality and consistency of non-clinical laboratory studies and safety testing. **GMP** focuses on maintaining high standards in clinical trials.

Summary:

Dr. Bindu Dey gives a concept of ICH (International Council for Harmonisation) works to harmonize global standards for pharmaceuticals, ensuring consistency in safety, efficacy, and quality. GCP (Good Clinical Practice) sets ethical and scientific standards for clinical trials involving humans, ensuring participant safety and reliable results. GLP (Good Laboratory Practice) ensures the quality and consistency of laboratory studies, particularly non-clinical safety testing. GMP (Good Manufacturing Practice) focuses on maintaining high standards in the production of pharmaceuticals and other products, ensuring they are safe, effective, and consistently meet quality standards. Together, these guidelines ensure the safety and quality of pharmaceutical and medical products across all stages of development and production.

Bindu Dey enlightens us with the **CFR** (Code of Federal Regulations) concept which is a comprehensive collection of rules and regulations published by the U.S. federal government, organized into 50 titles that cover a wide range of administrative and regulatory topics. It serves as a legal framework for various industries and sectors, including pharmaceuticals, healthcare, food, and manufacturing.

Geotag Photos:

“Dr Bindu Dey giving session on Introduction to ethical guidelines which includes ICH, GCP, GLP , GMP, CSC

"Dr. Bindu Dey is providing an introduction to ethical guidelines and EU frameworks."

Week 5, Day 24

Session 1

Title of Topic: Introduction to

Date: 6th FebruarY 2025

Venue: Training and Development Cell HIMS

No. of Students: 28

Faculty Name: Dr. Nikku Yadav

Objective: Introduction to NIDA GCP (**National Institute on Drug Abuse Good Clinical Practice)**

Summary:

Dr. Nikku Yadav enlightens us about **NIDA GCP (National Institute on Drug Abuse Good Clinical Practice)** is to ensure the safety, well-being, and rights of participants in clinical trials, particularly those related to drug abuse and addiction research. It aims to establish rigorous ethical and scientific standards for conducting clinical trials, ensuring that they are designed, monitored, and reported with integrity. NIDA GCP guidelines promote consistency in clinical research, ensuring compliance with regulatory requirements, proper documentation, and the credibility of trial data, ultimately contributing to the development of safe and effective treatments.

Preparing a certificate on **NIDA GCP** involves documenting the successful completion of training in Good Clinical Practice standards set by the National Institute on Drug Abuse. The certificate confirms that individuals have gained knowledge on ethical conduct, participant safety, data integrity, and regulatory compliance in clinical trials related to drug abuse research. It ensures the individual is trained to adhere to the standards for designing, conducting, and monitoring clinical trials, and can ensure the quality and credibility of research data. This certificate is essential for researchers, investigators, and clinical trial staff involved in NIDA-funded studies.

Geo Tag Photos

"Dr. Nikku Yadav highlights the importance of NIDA GCP in ensuring participant safety, ethical standards, and data integrity in drug abuse research."

"Students are gathering more details about NIDA GCP."

Week 5, Day 25

Session 1

Title of Topic: COMPREHENSIVE QUIZ OR PRACTICAL EXERCISE TO EVALUATE LEARNING

Date: 07 FEBRUARY 2025

Venue: Biostatistics lab

No. of Students: 29

Faculty Name: Dr . Manisha Sharma

Objective:

The objective of the comprehensive quiz was to evaluate the effectiveness of the learning session conducted by Dr. Manisha and Dr. Nikku. It aimed to assess participants' understanding of the key concepts presented, measure their ability to retain and apply the learned material, and identify areas that may require further clarification or focus in future sessions. The quiz sought to provide both instructors and participants with a clear indication of the learning outcomes achieved during the session.

Summary:

The quiz was structured to cover key topics presented during the session, with a focus on both theoretical knowledge and practical application. A variety of question formats, including multiple-choice, short-answer, and case-based questions, were used to test different levels of cognitive engagement. This approach allowed for a well-rounded evaluation of the participants' grasp of the material.

The results of the quiz provided valuable insights into areas where participants excelled and areas requiring further attention. It also highlighted the strengths of the teaching methods employed by Dr. Manisha and Dr. Nikku, as well as pinpointing aspects that could be enhanced in future sessions. Overall, the quiz served as a critical tool in evaluating the effectiveness of the learning session and guiding future improvements in teaching strategies.

Geotag Photos:

"**Students performing** comprehensive quiz or practical exercise to evaluate learning"

Title of Topic: Certificate Distribution

Date: 07 February 2025

Venue: sushurta lecture hall

No. of Students: 29

Objective: The objective of the certificate distribution ceremony was to formally recognize and celebrate the successful completion of the training program by the participants. It aimed to acknowledge their hard work and dedication, while also motivating them to apply the knowledge gained in their future endeavours. The event served as a symbol of achievement and an encouragement for continuous learning and growth.

Summary: The certificate distribution ceremony on the final day of the training program was held in a grand manner, marking the successful completion of the course. The event was graced by the presence of our esteemed Principal Sir, who played a pivotal role in the ceremony.

The training program had been an enriching experience for all participants, and the certificate distribution served as a formal recognition of the hard work and dedication shown by the attendees throughout the course. Honourable Principal Sir addressed the gathering with an inspiring speech, congratulating the participants for their commitment to learning and growth. He emphasized the importance of continuous learning and encouraged the participants to apply the knowledge gained during the program to further their personal and professional endeavours.

The certificates were then presented to the participants, acknowledging their successful completion of the program. Each certificate was handed over with a sense of pride and accomplishment, marking the participants' achievement in completing the comprehensive training.

Geotag Photos:

"Successful completeion of 5week training Principal addressing the students and Teachers."

"Completion of training marked by students receiving their certificates.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