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DHR Good Clinical Practice and Medical Ethics Training Workshop held from 4th July to 7th August 2025.

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

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:
4 July – 7 August 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 4 July to 7 August 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

The Department of Clinical Research at the Himalayan Institute of Medical Sciences (HIMS), Swami Rama Himalayan University (SRHU), in collaboration with the Department of Health Research, Ministry of Health and Family Welfare (MoHFW), launched a five-week training program on "Ensuring Integrity in Healthcare & Medical Ethics," beginning on July 4, 2025. As part of this initiative, a **two-day workshop on "Good Clinical Practice & Ethics"** was conducted from **July 4–5, 2025**, aiming to strengthen the ethical competence of faculty members and Research Ethics Committees across medical institutions in Uttarakhand. Research committee members from all medical colleges in the state were invited to participate in this sensitization program.

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 **76 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. **Dr. Bindu Dey** – Former Secretary, TDB & Retd. Advisor, DBT Govt. of India; Director, Research, SRHU
2. **Dr. Amjad Hussain** – Director, HCIE
3. **Dr. D.C. Dhasmana** – Professor, Department of Pharmacology
4. **Dr Priya Ranjan Avinash** Professor, Department of Phycology
5. **Dr. Ruchi Juyal** – Professor, Department of Community Medicine

6. **Dr. Abha Srivastava** – Professor & Head, Department of Physiology
7. **Dr. Nikku Yadav** – In-Charge, Department of Clinical Research, HIMS, SRHU
8. **Dr. Ashok Kumar Srivastava** – Professor & Head, Department of Community Medicine, SRHU
9. **Mr. Abhinav Bahuguna** – Lecturer, Department of Biostatistics
10. **Dr. Manisha Sharma** – Assistant Professor, Department of Clinical Research, SRHU
11. **Mrs. Akanksha Uniyal** – Lecturer, Department of Biostatistics, SRHU
12. **Mrs. Diksha** – Assistant Manager, C-PACE, SRHU
13. **Mrs Manju Nautiyal**-PDP trainer, 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. **Dr Vidisha Vallabh** – Associate Professor, Department of Community Medicine, SRHU
18. **Dr. Somlata Jha** – Assistant Professor, HSYS, SRHU
19. **Dr Neelam Bisht**- Incharge, Ayurveda Centre, SRHU
20. **Mr Ayushman Srivastava**- Assistant Registrar, Research and Development Cell
21. **Ms Pooja Kandari**- Office Assistant, Department of Clinical Research, HIMS, SRHU

Inaugural Session

The workshop was formally inaugurated by esteemed dignitaries:

- **Dr. Kiran Katoch**, NJILOMD, ICMR (Chief Guest)
- **Dr. Rajendra Dobhal**, Vice-Chancellor, SRHU
- **Dr. Vijendra D Chauhan**, Director General Academic Development, SRHU
- **Dr.Pradeep Varshney**, Director IQAC,SRHU
- **Dr. Yogender Singh**, other Principals and Departmental Heads of SRHU

The organizing team was led by:

- **Lt. Gen Dr. Daljit Singh**, Principal, HIMS (Organizing Chairperson)
- **Dr. Bindu Dey**, Director of Research, SRHU (Organizing Chairperson)
- **Dr. Nikku Yadav**, Head, Department of Clinical Research, HIMS (Organizing Secretary)
- Supporting organizers included: **Dr. Ruchi Juyal**, **Dr. Manisha Sharma**, **Mr. Abhinav**, **Ms. Akanksha**, **Ms. Jagriti**, and **Ms. Pooja**.

Distinguished Speakers

The workshop featured expert speakers from across India, including:

- **Dr. Vikas Dhiman** – Director, Regulatory Affairs, India Subcontinent, GSK Pvt. Ltd; Member, ISCR North Chapter
- **Dr. Abhishek Tyagi** – Senior Director, FSP Hub Lead – India & Philippines, PPD Clinical Research Services (Thermo Fisher Scientific)
- **Dr. Monika Bahl** – Founder Director, Shodh Clinicals
- **Dr. Puja Nagpal** – Consultant, Indian Spinal Injuries Centre

Workshop Highlights:

The sessions focused on fostering ethical conduct and adherence to Good Clinical Practice (GCP) guidelines in clinical research. Through expert-led presentations, interactive discussions, and practical exercises, the participants engaged with critical topics such as:

- Fundamental principles of research ethics
- Roles and responsibilities of Ethics Committees
- Implementation of GCP standards
- Ethical decision-making and management of dilemmas in clinical trials

The workshop was attended by **121 participants**, including faculty and research committee representatives from five prominent medical institutions in Uttarakhand:

- Doon Medical College, Dehradun
- Graphic Era Medical College, Dehradun
- Government Medical College, Haridwar
- Himalayan Institute of Medical Sciences, SRHU

Conclusion and Way Forward

This workshop served as a valuable platform for capacity building and inter-institutional collaboration among ethics oversight bodies within the region. By promoting a deeper understanding of ethical frameworks and cultivating a culture of research integrity, the program contributed significantly to enhancing the quality and compliance of clinical research in Uttarakhand

"A proud moment as all our esteemed guests unveil the event souvenir, marking the successful culmination of a memorable occasion. A token of gratitude, reflection, and celebration."

"Celebrating success together! Grateful for the hard work, dedication, and teamwork that made this event a big success. Here's to many more!"

5 Week Schedule of the training program: Key Highlights

Week 1

Topic **Ethics, Regulations, Stakeholders & Study Designs in Clinical Research: Global and Indian Perspectives**

Clinical research is the backbone of medical advancement and patient safety in the healthcare industry. Understanding the ethical principles, regulatory frameworks, key stakeholders, and study designs is crucial for ensuring that research is scientifically valid, ethically sound, and socially responsible.

Week 2

Clinical Trial Design and Execution: From Ethics to Data Integrity

In the healthcare industry, clinical trials are essential for evaluating the safety and efficacy of new treatments, devices, and interventions. A well-structured and ethically sound trial ensures scientific reliability, regulatory compliance, and most importantly, patient safety**.**

Week 3

Integrated Oversight in Clinical Trials: Safety, Product, Monitoring & Integrity

Integrated clinical trial oversight is essential for ensuring that every aspect of a clinical study—from product handling to patient safety and data accuracy—is conducted according to the highest standards. In the healthcare industry, where outcomes directly affect human lives, such oversight plays a pivotal role in the success, credibility, and ethical standing of clinical research.

Week 4

Research Excellence in Clinical Trials: Integrity, Compliance, Writing & Well-being

In the ever-evolving landscape of healthcare, comprehensive research excellence forms the foundation for advancing safe, effective, and ethical medical innovations. This theme emphasizes an integrated approach that not only strengthens scientific output but also promotes the well-being of the researchers themselves, creating a balanced ecosystem of innovation, compliance, and human-centered practice.

Week 5

Digital Tools for Research: Hands-On with MS Office, SPSS, Prism, Jamovi & Orange

In modern healthcare and clinical research, digital proficiency is no longer optional—it is essential. The ability to effectively use data and document tools like MS Office, SPSS, GraphPad Prism, Jamovi, and Orange empowers professionals to produce high-quality, evidence-based work that directly contributes to improved healthcare outcomes.

Day-3

Session 1

Topic: Overview of Clinical Research

Date: 7th July 2025

Venue: Training and development cell, Himalayan Institute of Medical Sciences

Organized by: Department of Clinical Research, Himalayan Institute of Medical Sciences, Swami Ram Himalayan University.

Speaker: Dr Nikku Yadav**,** In charge, Department of Clinical Research, HIMS, SRHU

Total Participants: 30

Objective of the Lecture:

- To provide an introduction to clinical research, emphasizing its significance and impact.
- To explain the drug development process, highlighting key stages.
- To introduce clinical trials and their role in advancing medical science.

Outcomes of the Lecture:

- Participants gained an understanding of the importance and outcomes of clinical research in healthcare.
- Clear insight was provided into the drug development process, from discovery to market approval.
- Participants were introduced to the fundamentals of clinical trials, including their phases and ethical considerations.
- The session fostered awareness of how clinical research contributes to evidence-based medicine and improved patient care.

Key Takeaways:

- Clinical research is vital for developing new, effective, and safe medical treatments.
- The drug development process is complex, involving multiple stages from discovery to approval.
- Clinical trials are essential to test the safety and efficacy of new drugs before they reach patients.
- Understanding clinical research empowers healthcare professionals to contribute to evidence-based medicine.
- Ethical considerations and participant safety are paramount throughout clinical trials.

Conclusion:

The session on the Overview of Clinical Research successfully highlighted the critical role that clinical research plays in advancing medical knowledge and patient care. Through a clear explanation of the drug development process and the fundamentals of clinical trials, participants gained valuable insights into how new treatments are developed and evaluated

for safety and efficacy. This foundational understanding is essential for anyone involved in healthcare, research, or related fields, fostering a greater appreciation of the rigorous efforts behind bringing new therapies to patients. The session set a strong base for further exploration of clinical research topics in subsequent sessions

Building future researchers—Dr. Nikku Yadav introduces clinical research concepts.

Dr. Nikku Yadav explaining the fundamentals of clinical research to attentive students.

Session 2

Topic: **Introduction to Ethical Principles**

Date: 7th July 2025
Venue: Training and development cell, Himalayan Institute of Medical Sciences
Organized by: Department of Clinical Research, Himalayan Institute of Medical Sciences, Swami Ram Himalayan University.
Speaker: Dr Manisha Sharma, Assistant Professor Department of Clinical Research
Total Participants: 30

Objective of the Lecture:

- To introduce the fundamental ethical principles guiding clinical research, including autonomy, beneficence, justice, and others.
- To provide historical context by discussing landmark documents such as the Nuremberg Code and the Declaration of Helsinki.
- To highlight the importance of ethics in protecting research participants and ensuring integrity in clinical trials.

Outcomes of the Lecture:

- Participants developed a solid understanding of core ethical principles that govern clinical research.
- The session emphasized the evolution of research ethics through historical milestones.
- Participants recognized the critical role of ethics in safeguarding participant rights and promoting fair and responsible research.
- Enhanced awareness of ethical obligations in designing and conducting clinical trials.

Key Takeaways:

- Ethical principles such as autonomy, beneficence, and justice form the foundation of ethical clinical research.
- The Nuremberg Code and Declaration of Helsinki have significantly shaped modern research ethics.
- Protecting participants' rights and welfare is a primary concern in all clinical studies.
- Adherence to ethical guidelines is essential to maintain public trust and scientific integrity.

Conclusion:

The session effectively underscored the importance of ethics in clinical research, providing participants with a clear understanding of fundamental principles and their historical development. By learning from past abuses and adhering to established ethical frameworks, researchers can ensure that clinical trials are conducted responsibly, respecting the dignity and rights of all participants. This ethical foundation is crucial for the advancement of trustworthy and impactful medical research.

Dr Manisha Sharma teaching students about Introduction to Ethical Principles

Dr. Manisha Sharma guiding students through the fundamentals of ethical principles in research.

Session 3

Topic: Importance of Ethics in Clinical Research
Date: 7th July 2025
Venue: Training and development cell, Himalayan Institute of Medical Sciences
Organized by: Department of Clinical Research, Himalayan Institute of Medical Sciences, Swami Ram Himalayan University.
Speaker: Dr Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
Total Participants: 30

Objective of the Lecture:

- To explain the evolution of ethics guidelines in clinical research.
- To highlight the importance of ethics by reviewing historical examples of unethical research practices.
- To reinforce the need for strict ethical standards to protect participants and maintain research integrity.

Outcomes of the Lecture:

- Participants gained insight into how ethical guidelines have developed over time in response to past abuses.
- The session provided a clear understanding of the consequences of unethical research through examples like the Plutonium Trials, Tuskegee Syphilis Study, Willowbrook Hepatitis Experiments, and MKULTRA.
- Emphasized the critical role of ethics in preventing harm and promoting respect for human dignity in clinical research.
- Participants recognized the importance of applying ethical principles to all stages of clinical research.

Key Takeaways:

- Ethics guidelines have evolved as a response to serious historical violations in research.
- Unethical research practices have led to significant harm, mistrust, and stricter regulations.
- Awareness and adherence to ethical principles are essential to protect research participants.
- Learning from past mistakes is vital to ensure ethical conduct in future clinical studies.

Conclusion:

The session successfully highlighted the crucial role of ethics in clinical research by examining the dark history of unethical studies. Understanding these past failures underscores the need for stringent ethical guidelines and vigilance in protecting participants' rights and welfare. This awareness empowers researchers and stakeholders to uphold the highest ethical standards, ensuring that clinical research contributes positively and responsibly to medical science.

Insightful session on Importance of Ethics in Clinical Research by Dr. Manisha Sharma.

Dr. Manisha Sharma sheds light on the importance of ethics in clinical research.

Session 4

Report on Ethics in India

Date: 7th July 2025
Venue: Training and development cell, Himalayan Institute of Medical Sciences
Organized by: Department of Clinical Research, Himalayan Institute of Medical Sciences, Swami Ram Himalayan University.
Speaker: Dr. DC Dhasmana, Professor, Department of Pharmacology, HIMS, SRHU
Total Participants: 30

Objective of the Lecture:

- To provide an overview of the ethical landscape specific to clinical research in India.
- To discuss notable case studies of unethical practices within the Indian context.
- To emphasize the need for strong ethical oversight in India's growing clinical research sector.

Outcomes of the Lecture:

- Participants gained an understanding of India's regulatory and ethical framework governing clinical research.
- The session highlighted real-life examples of unethical practices in India, fostering awareness of local challenges.
- Reinforced the importance of strict adherence to ethical guidelines to protect research participants and maintain trust.
- Participants became more informed about India-specific ethical issues and the evolving standards.

Key Takeaways:

- Ethics in clinical research must consider local cultural, social, and regulatory factors.
- India has faced ethical challenges in clinical research that necessitate vigilant regulation and enforcement.
- Case studies from India serve as important lessons to improve ethical practices.
- Commitment to ethical conduct is vital to sustain the credibility and growth of clinical research in India.

Conclusion:

This session effectively contextualized ethics in clinical research within the Indian framework, highlighting both progress and challenges. Through examining case studies of unethical practices, participants were reminded of the critical need for robust ethical standards and oversight. Strengthening ethical awareness and compliance will ensure that clinical research in India aligns with global best practices while respecting local values and protecting participants.

Dr. D.C. Dhasmana delivering an insightful lecture on ethics in the Indian context.

Dr. D.C. Dhasmana explores the ethical landscape of India with students.

Day-4

Session 1

Topic: National Regulatory Bodies and Guidelines

Date: 8th July 2025

Venue: Training and development cell, Himalayan Institute of Medical Sciences

Organized by: Department of Clinical Research, Himalayan Institute of Medical Sciences, Swami Ram Himalayan University.

Speaker: Dr Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS< SRHU

Total Participants: 30

Objective of the Lecture:

- To provide an overview of key national regulatory authorities involved in clinical research in India.
- To explain the structure and functions of the Central Drugs Standard Control Organization (CDSCO).
- To familiarize participants with national guidelines governing clinical trials and drug approvals in India.

Outcomes of the Lecture:

- Participants understood the role and responsibilities of national regulatory bodies in ensuring the safety and efficacy of drugs.
- The session clarified how CDSCO operates as the primary regulatory authority overseeing clinical trials and drug approvals.
- Participants gained knowledge of important national guidelines and regulatory frameworks applicable to clinical research.
- Enhanced awareness of compliance requirements and the regulatory process in India.

Key Takeaways:

- The CDSCO is the central regulatory authority responsible for the approval and regulation of clinical trials and drugs in India.
- National guidelines provide a structured framework to ensure ethical and scientific integrity in clinical research.
- Understanding regulatory processes is crucial for conducting compliant and successful clinical trials.
- Collaboration with regulatory bodies is essential for timely approvals and safeguarding public health.

Conclusion:

The session effectively introduced participants to the national regulatory landscape governing clinical research in India, with a detailed focus on the CDSCO and relevant guidelines. This foundational knowledge is vital for researchers and stakeholders to navigate regulatory requirements confidently and conduct clinical trials ethically and efficiently. Familiarity with these bodies and guidelines will contribute to enhancing the quality and credibility of clinical research in India.

Dr Manisha Taking session on National Regulatory Bodies and Guidelines

Session 2

Topic: IEC/IRB (Institutional Ethics Committee/Independent Review Board)
Date: 8th July 2025
Venue: Training and development cell, Himalayan Institute of Medical Sciences
Speaker: Dr Manisha Sharma
Total Participants: 30

Objective of the Lecture:

- To introduce the concept and role of Ethics Committees in clinical research.
- To explain different types of Ethics Committees.
- To outline the review process for clinical studies conducted by Ethics Committees.
- To discuss the registration and re-registration procedures for Ethics Committees.
- To highlight common violations of ethics approval rules and their implications.

Outcomes of the Lecture:

- Participants gained a clear understanding of the purpose and functions of Ethics Committees.
- The session clarified the types of Ethics Committees and their respective roles.
- Participants learned about the detailed review process that ensures ethical compliance of clinical studies.
- Awareness of the importance of registration and re-registration of Ethics Committees was established.
- The session underscored the consequences of violating ethics approval regulations and emphasized strict adherence.

Key Takeaways:

- Ethics Committees play a crucial role in safeguarding the rights and welfare of research participants.
- Proper registration and re-registration of Ethics Committees are mandatory for lawful oversight.
- A thorough review process by the Ethics Committee ensures that research meets ethical standards.
- Violations of ethics approval rules can lead to serious repercussions, including study suspension and legal actions.
- Understanding these processes is essential for conducting compliant and ethical clinical research.

Conclusion:

The session effectively detailed the vital role of Ethics Committees in clinical research, providing participants with a comprehensive understanding of their types, responsibilities, and procedural requirements. Emphasizing the review process and regulatory compliance, the lecture highlighted the necessity of ethical oversight to protect participants and maintain research integrity. This knowledge equips researchers and stakeholders to engage with Ethics Committees effectively and uphold ethical standards in clinical trials.

Students giving presentation on this topic

Session 3

Topic: International Regulatory Bodies and Their Guidelines

Date: 8th July 2025

Venue: Training and development cell, Himalayan Institute of Medical Sciences

Organized by: Department of Clinical Research, Himalayan Institute of Medical Sciences, Swami Ram Himalayan University.

Speaker: Dr Nikku Yadav, In charge & Associate Professor, Department of Clinical Research, HIMS< SRHU

Total Participants: 30

Objective of the Lecture:

- To provide an overview of major international regulatory bodies involved in drug evaluation and approval.
- To explain the regulations and approval pathways followed by FDA (USA), EMA (Europe), MHRA (UK), and TGA (Australia).
- To engage participants in understanding global regulatory frameworks through a Q&A session.

Outcomes of the Lecture:

- Participants acquired knowledge about the roles and responsibilities of key international regulatory agencies.

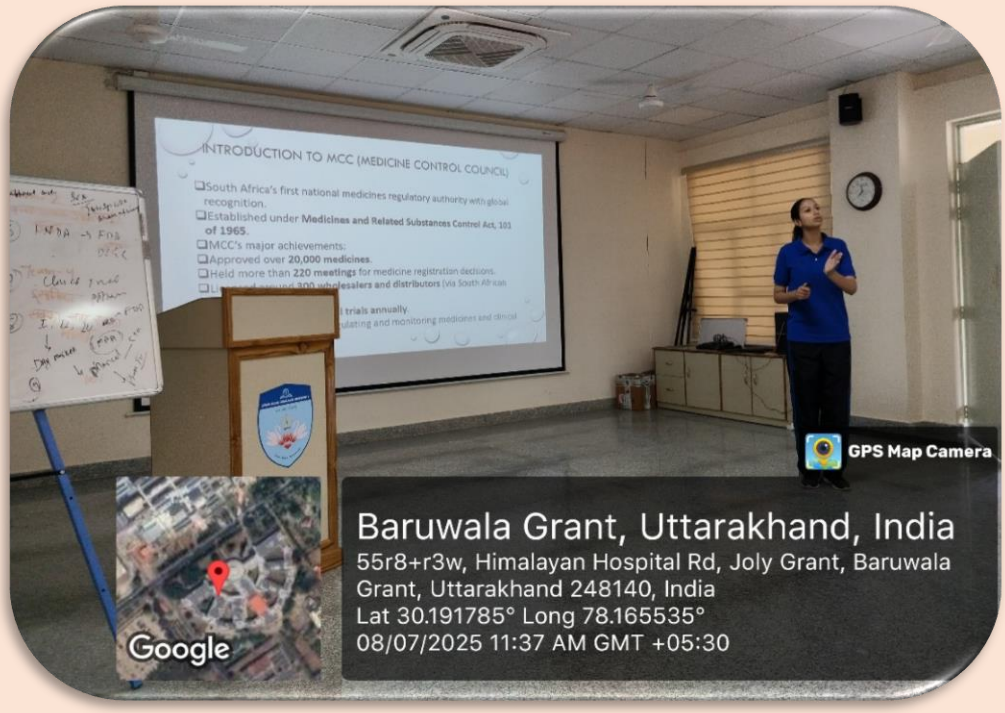
- The session clarified how each agency evaluates and approves drugs, highlighting similarities and differences.
- Participants gained insight into the global regulatory environment impacting clinical research and drug development.
- The Q&A segment helped address participant queries and deepened understanding of complex regulatory processes.

Key Takeaways:

- FDA, EMA, MHRA, and TGA are prominent regulatory authorities with distinct but aligned drug approval processes.
- Understanding international regulations is crucial for global clinical trials and drug marketing.
- Each agency's guidelines ensure safety, efficacy, and quality of medicines in their respective regions.
- Staying updated with these regulations is essential for compliance in multinational research.

Conclusion:

The session provided a comprehensive introduction to major international regulatory bodies and their drug approval pathways, enhancing participants' global perspective on clinical research governance. By comparing the approaches of FDA, EMA, MHRA, and TGA, the lecture equipped participants with essential knowledge to navigate regulatory requirements in different regions. The interactive Q&A further solidified their grasp of these important frameworks, preparing them for involvement in international clinical research initiatives.



Students Giving presentation on International Regulatory Bodies and Their Guidelines

Session 4

Report on The Power of First Impressions

Date: 8th July 2025
Venue: Training and development cell, Himalayan Institute of Medical Sciences
Organized by: Department of Clinical Research, Himalayan Institute of Medical Sciences, Swami Ram Himalayan University.
Speaker: Mr Ashish Gupta**,** C-PACE, SRHU
Total Participants: 30

Objective of the Lecture:

- To highlight the importance of first impressions in professional and interpersonal interactions.
- To engage participants in an interactive icebreaker activity to foster connection and communication skills.
- To encourage participants to practice positive self-presentation and peer introductions.

Outcomes of the Lecture:

- Participants actively engaged in the icebreaker activity, sharing fun facts and introducing peers.
- The session helped participants recognize how first impressions influence relationships and opportunities.
- Improved confidence and interpersonal communication among participants.
- Enhanced group cohesion and a comfortable environment for future sessions.

Key Takeaways:

- First impressions are powerful and can impact both professional and personal interactions.
- Effective introductions and positive self-presentation build trust and rapport.
- Icebreaker activities are valuable tools for creating an open and collaborative atmosphere.
- Developing awareness of first impressions helps improve communication skills.

Conclusion:

This session successfully demonstrated the significance of first impressions through an engaging icebreaker activity. Participants experienced first-hand the impact of introductions and learned practical tips for making positive initial connections. By fostering a supportive and interactive environment, the session laid a strong foundation for effective communication and teamwork throughout the program.

“Mr Ashish Gupta teaching students about The Power of First Impressions”

"Understanding the impact of first impressions with Mr. Ashish Gupta."

Day 5

Session 1
Topic: Role of Clinical Research Professionals
Date: 9th July 2025
Venue: Training and Development room, HIMS, SRHU

Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Nikku Yadav, In charge, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Introduction: The Department of Clinical Research organized a guest lecture on the topic **"Role of Clinical Research Professionals"** to provide students and faculty with insights into the dynamic and evolving landscape of clinical research and the critical role played by professionals in this field. The session aimed to bridge the gap between academic knowledge and industry expectations.

Objective of the Lecture:

The primary objective of the session was to:

- Highlight the career paths and core responsibilities of clinical research professionals.
- Emphasize ethical, regulatory, and operational aspects of clinical trials.
- Foster an understanding of the interdisciplinary nature of clinical research.
- Inspire students to pursue careers in the clinical research industry with clarity and confidence.

Key Highlights of the Session:

- Overview of the clinical research process: from protocol design to trial execution and post-marketing surveillance.
- Roles and responsibilities of various professionals such as Clinical Research Associates (CRAs), Clinical Trial Coordinators (CTCs), Data Managers, Regulatory Officers, and Medical Writers.
- Importance of Good Clinical Practice (GCP), ethics committees, and patient safety.
- Skills required to excel in the field—such as attention to detail, communication, documentation, and regulatory awareness.
- Current trends in the industry, including the rise of decentralized trials, digital health tools, and AI in clinical research.
- Career opportunities and growth trajectories within CROs, pharma companies, academic research centres, and regulatory bodies.

Interaction and Feedback:

The session concluded with an interactive Q&A round, where students eagerly clarified their doubts about internships, certifications, job roles, and global opportunities. The lecture was well-received and praised for its practical relevance and motivational tone.

Dr Nikku Yadav teaching them: Role of Clinical Research Professionals

Dr. Nikku Yadav explains the vital role of clinical research professionals in modern healthcare.

Session 2
Topic: Responsibilities of Sponsor and Investigators in Clinical Research
Date: 9th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Introduction:

The Department of Clinical Research conducted a guest lecture on the topic **"Responsibilities of Sponsor and Investigators in Clinical Research"** to enhance student understanding of the key roles and regulatory obligations involved in conducting ethical and scientifically sound clinical trials. The session aimed to bridge the gap between theoretical learning and practical implementation in clinical research.

Objective of the Lecture:

- To explain the distinct roles of **sponsors** and **investigators** in a clinical trial.
- To familiarize students with **ICH-GCP guidelines** and regulatory requirements.
- To highlight the importance of ethical conduct, safety monitoring, and accurate data management in clinical trials.

Session Highlights:

The speaker presented a detailed overview of the responsibilities of both sponsors and investigators as per **ICH-GCP guidelines**, focusing on the following areas:

◆ **Responsibilities of the Sponsor:**

- Designing and funding the trial
- Regulatory and ethics committee submissions
- Monitoring and auditing of trial sites

◆ **Responsibilities of the Investigator:**

- Conducting the trial as per protocol and GCP
- Ensuring informed consent from all participants
- Protecting the rights, safety, and well-being of participants

The speaker also discussed **real-world case studies** of protocol deviations and how roles and responsibilities were managed in such scenarios.

Interaction and Feedback:

The session concluded with an interactive Q&A round, where students asked insightful questions about sponsor-investigator relationships, clinical site challenges, and career paths in clinical operations and monitoring. The session received excellent feedback from participants for its clarity, relevance, and practical examples.

Dr Manisha teaching students about Responsibilities of Sponsor and Investigators in Clinical Research

"Guiding future professionals—Dr. Manisha Sharma discusses the vital roles of sponsors and investigators."

Session 3

Topic: **Drugs and Cosmetics Act, 1940**

Date: 9th July 2025

Venue: Training and Development room, HIMS, SRHU

Organized by: Department of Clinical Research, HIMS, SRHU

Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU

No. of Participants: 30

Introduction

The Department of Clinical Research organized a guest lecture on the topic "Drugs and Cosmetics Act, 1940", aimed at enhancing the understanding of the regulatory framework governing drugs and cosmetics in India. This session was part of the curriculum enrichment program to expose students and faculty to real-world applications of regulatory sciences.

Objectives of the Lecture

- To provide an overview of the Drugs and Cosmetics Act, 1940.
- To understand the legal framework for the manufacture, sale, import, and distribution of drugs and cosmetics.
- To explore the roles of regulatory authorities like CDSCO and State Drug Controllers.
- To discuss amendments and recent updates in the Act.
- To explain the compliance requirements for pharmaceutical and cosmetic companies

Lecture Highlights

Dr. Manisha began the lecture by outlining the historical background of the Act, explaining the need for a legal mechanism to control the quality of drugs in India. Key points covered during the session included:

- Structure of the Act: Chapters, schedules, and key provisions.
- Definition and classification of drugs and cosmetics.
- Licensing requirements for manufacturing and marketing.
- Labelling and packaging regulations.
- Provisions related to adulterated, misbranded, and spurious drugs.
- Role of Drug Inspectors and the process of enforcement.
- Overview of Schedules H, X, and M.
- Recent amendments and rules under the Act including medical devices regulation.
- Penalties and legal actions under non-compliance.

She also emphasized the **role of regulatory compliance** in ensuring public safety and discussed the interface between the Drugs and Cosmetics Act and other legislation like the **NDPS Act**, **Medical Devices Rules (2017)**, and **Clinical Trials Rules (2019)**.

Interaction and Q&A Session

The lecture concluded with an interactive Q&A session. Students asked insightful questions regarding career opportunities in regulatory affairs, challenges in drug regulation Enforcement, and recent controversies in drug recalls and bans. Dr. Manisha addressed all queries with real-time examples and case studies.

Dr Manisha Teaching students about: Drugs and Cosmetics Act, 1940

"Learning about the Drugs and Cosmetics Act, 1940 with Dr. Manisha Sharma."

Day 6

Session 1

Topic: "Stress Less, Live More: Strategies for Well-being"

Date: 10th July 2025
Venue: Training and development cell, Himalayan Institute of Medical Sciences
Guest Speaker: Dr. Priya Ranjan Avinash, Professor and Head, Department of Psychiatry
No. of Participants: 30

Objective of the Lecture: The session was organized with the purpose of equipping students and faculty with **practical techniques to manage stress**, enhance emotional resilience, and promote overall mental well-being, especially in high-pressure academic and professional environments.

Key points from the session included:

a. Understanding Stress
b. Common Triggers of Stress in Students and Professionals
c. Practical Strategies for Well-being

- Time Management Techniques – prioritization, Pomodoro method
- Mindfulness and Meditation – short breathing exercises practiced live
- Physical Activity – importance of movement and yoga
- Healthy Lifestyle Habits – sleep hygiene, balanced diet, digital detox
- Gratitude Journaling and Positive Self-Talk

d. Building Emotional Resilience
e. Institutional Support

The session was highly engaging, with live demonstrations of breathing techniques, mindfulness practices, and group sharing of stress-relief habits. The interactive nature helped attendees connect deeply with the topic.

Outcome of the Lecture:

- Participants became aware of **simple, science-backed strategies** to manage stress in their daily lives.
- The session fostered a **positive dialogue around mental health**, self-care, and proactive wellness.
- Students left with actionable techniques they could start implementing immediately.

Feedback:

The session received overwhelmingly positive feedback. Attendees found it to be relaxing, relatable, and energizing. Many expressed interests in having more such wellness-focused events.

Dr Priya Ranjan Avinash taking session on Stress Less, Live More: Strategies for Well-being

Dr. Priya Ranjan Avinash shares effective strategies for well-being in her session ‘Stress Less, Live More.’

Session 2

Topic: "Substance Abuse Awareness: Signs, Symptoms, and Support"

Date: 10th July 2025
Venue: Training and development cell, Himalayan Institute of Medical Sciences
Guest Speaker: Dr. Priya Ranjan Avinash, Head of the Department, Department of Psychiatry
No. of Participants: 30

Objective of the Lecture:
The session aimed to raise awareness among students and faculty about the growing concern of substance abuse among youth, to educate them on early signs and symptoms, and to inform them about support mechanisms, treatment, and rehabilitation options.

Key points discussed during the session included:

- Understanding Substance Abuse
- Warning Signs and Symptoms
- Physical and Psychological Impact
- Stigma and Barriers to Seeking Help
- Available Support Systems
- Role of Educational Institutions

The session concluded with real-life case studies and an interactive Q&A round, where students asked questions about dealing with peer pressure, identifying early signs in friends, and how to approach someone who might be struggling.

Outcome of the Lecture:

- Students became more aware of the **dangers of substance abuse**, its early indicators, and the importance of timely intervention.
- Faculty members appreciated the actionable strategies to **support students facing addiction-related issues.**
- The lecture promoted a **culture of empathy, awareness, and responsibility** within the institution.

Feedback: Participants described the session as highly educational, emotionally impactful, and practically useful. Many requested follow-up workshops on stress management and peer counselling.

"Dr. Priya Ranjan Avinash raises awareness on substance abuse: signs, symptoms, and support strategies."

"Educating students about substance abuse and support systems with Dr. Priya Ranjan Avinash."

Day 7

Session 1

Topic: **Formulation of a Research Question**
Date: 14th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Ruchi Juyal, Professor, Department of Community Medicine, HIMS, SRHU
No. of Participants: 30

Introduction:

The Department of Clinical Research conducted a guest lecture on the topic *"Formulation of a Research Question"*, a foundational element in the research process. The session was aimed at undergraduate and postgraduate students to strengthen their conceptual and practical understanding of research design and development.

Objectives of the Session:

- To understand the importance of a well-defined research question.
- To introduce different types of research questions: descriptive, analytical, comparative, etc.
- To apply structured frameworks like **PICO (Population, Intervention, Comparison, Outcome)** and **FINER (Feasible, Interesting, Novel, Ethical, Relevant)** for framing questions.
- To identify common pitfalls and challenges in question formulation.

Lecture Highlights:

Dr. Juyal started the session by emphasizing that **a well-formulated research question is the backbone of any successful study**. Key topics covered during the lecture included:

- The characteristics of a **good research question**.
- How research questions differ based on study design (qualitative vs. quantitative).
- Use of **clinical uncertainty or literature gap** to generate a question.
- Practical examples of transforming a general topic into a focused, researchable question.
- Tools and checklists to refine the research question.
- Examples using the **PICO model** (used in clinical trials and evidence-based practice).
- How the research question guides hypothesis formation, methodology, and data analysis.

Dr. Juyal also engaged students in a short activity where they were asked to develop a research question based on a public health topic of their interest, which was then discussed interactively.

Q&A and Interaction:

The session ended with a vibrant Q&A round where students inquired about how to align research questions with funding priorities, how to revise a question during the course of a study, and ways to validate the relevance of a research problem in clinical settings.

Dr Ruchi Juyal Taking session on Formulation of a Research Question

Dr Nikku Yadav offering the token of appreciation to Dr Ruchi Juyal

Session 2

Topic: **Leadership Among Students**
Date: 14th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mrs. Ekta Rao, Assistant Professor, School of Management Studies, HIMS, SRHU

No. of Participants: 30

Introduction

To promote holistic student development and instil leadership qualities, a guest lecture was organized on the topic **"Leadership Among Students"**. The session focused on inspiring students to take initiative, develop self-awareness, and build team skills essential for academic and professional success.

Objectives of the Session

- To understand the concept and traits of effective leadership.
- To explore the role of students as future leaders in society.
- To highlight real-life examples of youth leaders and changemakers.
- To provide tools and strategies for developing leadership skills in academic life.

Key Highlights of the Lecture

Mrs. Ekta opened the session by asking a thought-provoking question: *"Are leaders born, or made?"* She then proceeded to break myths around leadership and discussed the following:

- Definition and importance of leadership among students
- Qualities of a student leader: vision, communication, empathy, integrity, and accountability
- Differences between leadership and authority
- **Types of leadership styles** – democratic, transformational, servant leadership
- How to lead student clubs, projects, and community initiatives
- Balancing academics and leadership roles
- Overcoming self-doubt and stage fear
- Case studies of young leaders from India and around the world
- Simple exercises and daily habits to build leadership capacity

She also conducted an interactive **"Leadership Reflection Activity"** where students identified their core values and reflected on a time, they demonstrated leadership.

Q&A and Interaction

The session was followed by a lively interaction where students asked questions on managing leadership responsibilities with studies, building confidence, and handling peer pressure while leading teams. Mrs. Ekta offered personal anecdotes and practical tips to address each query.

Mrs Ekta Rao taking session on Leadership among Students

"A dynamic session on student leadership conducted by Mrs. Ekta Rao.

Session -3

Topic: **Communication Skills: The Key to Personal and Professional Success**
Date: 14th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mrs. Manju Nautiyal, PDP trainer, SRHU

No. of Participants: 30

Introduction
To enhance students' ability to express themselves clearly and confidently in academic, professional, and social settings, a guest lecture on "Communication Skills" was conducted. The aim was to help students understand the importance of effective communication and equip them with practical tools to improve verbal and non-verbal communication.

Guest Speaker Profile
The lecture was delivered by Ms. Priya Nair, a Corporate Trainer and Certified Soft Skills Coach with over 12 years of experience in training students and professionals. She is known for her engaging sessions on public speaking, interpersonal skills, and business communication.

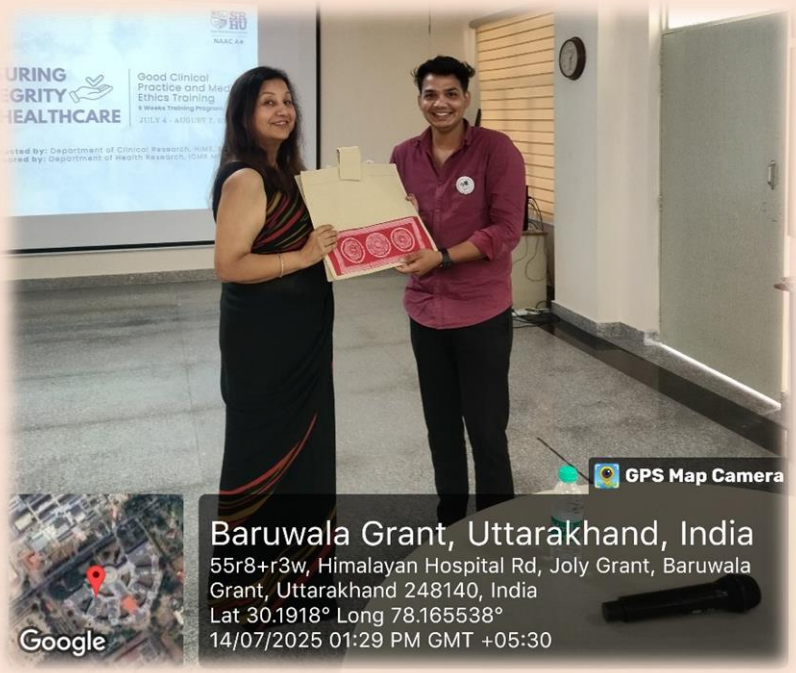
Objectives of the Session
- To understand the components of effective communication
- To improve verbal, non-verbal, and written communication skills
- To develop listening and interpersonal skills
- To overcome barriers in communication
- To boost confidence in public speaking and group discussions

Lecture Highlights
Ms. Nair began by defining communication and its types – verbal, non-verbal, written, and visual. She stressed that communication is more than just speaking fluently; it involves active listening, clarity of thought, empathy, and appropriate body language.

Key points covered included:
- The **7 Cs of communication**: Clear, Concise, Concrete, Correct, Coherent, Complete, Courteous
- **Importance of tone, posture, and eye contact**
- Techniques for improving **listening skills**
- **Common communication barriers** and how to overcome them
- Tips for **email etiquette** and professional writing
- How to give and receive feedback effectively
- **Role-playing exercises** to practice conversations and interviews

Students participated in **interactive activities** such as impromptu speaking, mock interviews, and team communication games, making the session lively and engaging.

Q&A and Interaction
During the Q&A round, students asked questions about improving confidence in public speaking, dealing with language barriers, and managing communication anxiety in group settings. The speaker offered personalized advice and encouraged regular practice and exposure.



"Manju Nautiyal receiving token of appreciation from a student of Gurukul Kangdi."

Mrs Nautiyal teachings students about Communication Skills: The Key to Personal and Professional Success

Session -4

Topic: **Exploring Innovation: A Visit to the Entrepreneurship Bootcamp at the Innovation Centre**
Date: 14th July 2025
Venue: Skill and Innovation centre, Himalayan Centre of Innovation and Entrepreneurship, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Amjad Hussain, Director, Himalayan Centre of Innovation and Entrepreneurship, SRHU
No. of Participants: 30

Introduction
As part of our efforts to foster entrepreneurial thinking and exposure to real-world innovation ecosystems, students visited the Entrepreneurship Bootcamp organized at the Skill and Innovation centre, Himalayan Centre of Innovation and Entrepreneurship. This visit was aimed at igniting interest in start-ups, creativity, and design thinking among young minds.

Objective of the Visit
- To expose students to the startup ecosystem and innovation practices
- To understand how business ideas are developed, pitched, and incubated
- To encourage critical thinking, collaboration, and leadership through real-time case studies
- To interact with startup founders, mentors, and innovation coaches

Key Highlights of the Visit
- Design Thinking Workshop: A hands-on session on identifying user needs and prototyping solutions
- Idea Validation Clinic: How early-stage ideas are tested for feasibility and market fit
- Pitching 101: A mock pitch event where start-ups presented their ideas and received feedback from mentors
- Panel Discussion: Featuring young entrepreneurs who shared their startup journey, challenges, and lessons learned

Student Interaction and Feedback
Students engaged in group discussions and interacted with innovators and incubator managers. They gained insights into:
- Steps to launch a startup
- Role of incubators and seed funding
- Importance of teamwork, resilience, and innovation

Outcomes of the Visit

- Improved understanding of entrepreneurial thinking and problem-solving
- Motivation among students to participate in future innovation programs and competitions

Student visit to Entrepreneurship Bootcamp at the Innovation Centre

Dr. Amjad Hussain explaining students about the Innovation Centre

Day 8
Session 1
Topic: **Ethics Committee Approval Process**
Date: 15th July 2025
Venue: Training and Development room, HIMS, SRHU

Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. DC Dhasmana, Professor, Department of Pharmacology, HIMS, SRHU
No. of Participants: 30

Introduction:
The Department of Clinical Research organized a lecture on the topic "Ethics Committee Approval Process" to educate students and researchers about the ethical review framework that governs biomedical and clinical research. The session aimed to guide participants through the essential steps and documentation required for obtaining Ethics Committee (EC) approval, ensuring research is ethically sound and compliant with national and international standards.

Key Highlights of the Lecture:
The speaker presented a structured overview of the Ethics Committee Approval Process, covering the following major points:

- Purpose of Ethics Committee Review
- Composition of the Ethics Committee
- Steps in the Approval Process:
- ✓ Preparation of the Research Proposal
- ✓ Submission to IEC with required documents
- ✓ Review Type
- ✓ Deliberation and Decision
- ✓ Communication of Decision to PI
- ✓ Post-approval Monitoring and Amendments
- Ethical Principles Followed
- Common Reasons for Delay or Rejection

The speaker also discussed **important guidelines and frameworks**, including:

- ICMR National Ethical Guidelines
- Schedule Y
- Good Clinical Practice (GCP)
- Declaration of Helsinki

Interactive Session:
The lecture was followed by an interactive session where participants posed questions related to:

- Timeline for ethics approval
- Differences between IEC, IRB, and Ethics Sub-Committee
- Protocol amendments and re-submissions
- Handling vulnerable populations in research

Dr. Dhasmana addressed all queries with practical insights, offering real-world examples from committee deliberations

Outcome and Feedback:
Participants appreciated the clarity and depth of the session. It demystified the approval process and emphasized the importance of thorough documentation, ethical sensitivity, and regulatory compliance in research planning. The session proved especially beneficial for students preparing to initiate their thesis or independent research projects.

Dr DC Dhasmana teaching students about *Ethics Committee Approval Process*

"Dr. D.C. Dhasmana explains the Ethics Committee Approval Process to students.

Session 2

Topic: **Introduction to Ethics Committee and Its Review Process in Research**
Date: 15th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU

Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Introduction:
The Department of Clinical Research organized a lecture on "Introduction to Ethics Committee and Its Review Process in Research" to enhance awareness among students and research scholars about the ethical frameworks that govern clinical and biomedical research. The lecture aimed to emphasize the role of Institutional Ethics Committees (IECs) in safeguarding participants' rights, safety, and well-being.

Key Highlights of the Lecture:
The session provided a comprehensive overview of the following:

- **Definition and Importance of Ethics Committees**
  → Ensuring that research is conducted in an ethical, scientific, and legally acceptable manner
- **Composition of an Ethics Committee**
  → As per ICMR guidelines: medical, non-medical, legal, lay person, etc.
- **Steps in Ethical Review Process:**
  - Submission of research proposal with documents
  - Initial screening for completeness
  - Allocation of reviewers
  - Discussion during IEC meeting
  - Decision: approval, modification, or rejection
- **Role of the Ethics Committee in:**
  - Informed consent documentation
  - Participant safety
  - Confidentiality of data
  - Monitoring ongoing studies

The speaker also emphasized **national and international guidelines** like ICMR 2017, Declaration of Helsinki, CIOMS, and Good Clinical Practice (GCP) standards.

Interactive Session:
An interactive discussion followed, where students raised questions on real-world challenges in ethics approvals, re-submissions after queries, timelines involved, and the role of Data Safety Monitoring Boards (DSMBs). The speaker responded with practical insights and examples from institutional review experiences.

Outcome and Feedback:
Participants found the session to be extremely informative, especially those involved in thesis projects or clinical trials. It clarified many ambiguities regarding ethical submissions and prepared students for ethical compliance in research.

Dr Manisha Teaching students about *Introduction to Ethics Committee and Its Review Process in Research*

"Understanding the Ethics Committee and review procedures with Dr. Manisha Sharma."

Session -3

Topic: **Body Language and nonverbal cues**
Date: 15th July 2025
Venue: Training and Development room, HIMS, SRHU

Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mrs Diksha, C-PACE, SRHU
No. of Participants: 30

Introduction:

The Department of Clinical Research organized a lecture on **"Body Language and Non-Verbal Cues"** to enhance students' understanding of effective interpersonal communication beyond spoken words. The session aimed to introduce the concept of non-verbal communication and highlight its importance in professional, academic, and personal interactions.

Key Highlights of the Lecture:

The lecture provided a deep dive into the world of **non-verbal communication**, covering various forms of body language and how they influence perception. Key topics included:

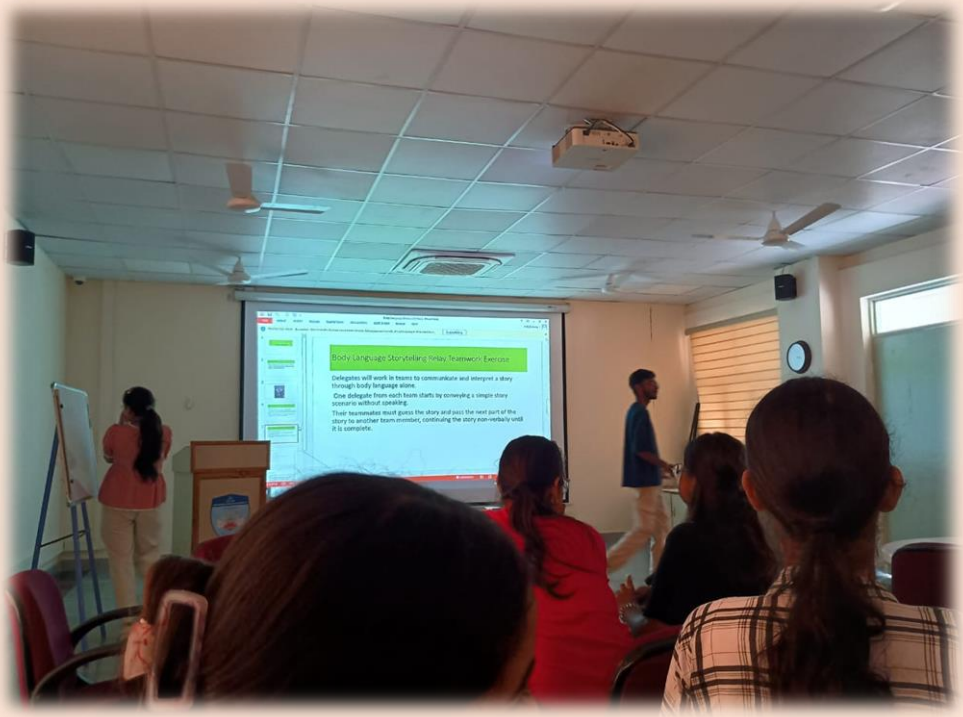
- **Definition of Non-Verbal Communication**
  → Communication through facial expressions, gestures, posture, eye contact, tone of voice, and physical space.
- **Types of Non-Verbal Cues:**
  - **Facial expressions** – conveying emotions
  - **Gestures** – supporting or contradicting verbal messages
  - **Posture** – confidence, openness, or defensiveness
  - **Eye Contact** – building trust and engagement
  - **Paralanguage** – tone, pitch, and pace of speech
  - **Proxemics** – use of personal space
- **Interpreting Body Language Accurately**
- **Cultural Variations in Non-Verbal Cues**
- **Importance in Professional Settings**
  - Interviews
  - Public speaking
  - Doctor-patient communication
  - Workplace collaboration

Interactive Session:

Participants enthusiastically engaged in role-plays and practical exercises designed to help identify positive and negative non-verbal signals. The Q&A session allowed students to ask about posture improvement, nervous habits, and the influence of non-verbal cues in digital communication.

Outcome and Feedback:

The session was **highly appreciated** by students and faculty alike. Attendees gained valuable insights into how to present themselves effectively, how to "read the room", and how to develop more mindful communication habits. The practical approach and engaging style of the speaker made the session memorable and impactful.



Mrs Diksha teaching students about: *Body Language and nonverbal cues*

"An engaging session on interpreting body language and nonverbal cues by Mrs. Diksha."

Day – 9

Session1
Topic: **Data collection and management workflow**
Date: 16th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Ruchi Juyal, Professor, Department of Community Medicine, HIMS, SRHU
No. of Participants: 30

Introduction:

The Department of Clinical Research organized a lecture on the topic **"Data Collection and Management Workflow"** aimed at enhancing the understanding of effective data practices in research. The session was attended by faculty, postgraduate students, and research scholars.

Key Highlights of the Lecture:

Dr. Juyal provided a comprehensive overview of the **data lifecycle in research**, highlighting the critical stages of:

- Planning the data collection process
- Designing data collection tools (e.g., CRFs, eCRFs, questionnaires)
- Standard Operating Procedures (SOPs) for data management
- Data entry methods (manual, electronic, and automated)
- Data validation and cleaning procedures
- Data storage, security, and backup protocols
- Maintaining data integrity and audit trails
- Compliance with Good Clinical Practice (GCP) and regulatory requirements

The speaker also demonstrated how modern **Electronic Data Capture (EDC)** systems have streamlined the data collection process and emphasized the importance of **data quality assurance** and **real-time monitoring**.

Interactive Session:

The session concluded with an engaging **Q&A segment**, where participants raised practical concerns regarding data errors, handling missing data, and maintaining confidentiality. Dr. Juyal addressed these queries with clarity and provided useful tips based on real-world experiences.

Outcome and Feedback:

Participants found the session **highly informative** and appreciated the practical insights into efficient data management workflows. The lecture successfully bridged the gap between theoretical understanding and real-world application, making it especially beneficial for early-career researchers and students.

Dr Juyal taking session on *Data collection and management workflow*

"Understanding efficient data workflows in research with Dr. Juyal."

Session 2

Topic: **Study Startup**
Date: 16th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU

Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Introduction:

The Department of Clinical Research organized a lecture on **"Study Startup in Clinical Research"**, focusing on the foundational processes involved in initiating a clinical study. The session was designed to provide students, researchers, and faculty members with a practical understanding of regulatory, ethical, and operational aspects of study startup. The event was well attended by postgraduate students, faculty, and clinical research professionals.

Key Highlights of the Lecture:

The speaker outlined the **phases of study startup**, emphasizing the critical steps that ensure the successful initiation of clinical trials. Key points discussed included:

- Site Selection and Feasibility Assessment
- Regulatory Document Preparation and Submission
- Ethics Committee/IRB Approval Processes
- Budget Finalization and Contract Negotiation
- Investigator Meeting and Site Initiation Visit (SIV)
- Essential Document Collection (per ICH-GCP)
- Timelines and Common Challenges in Startup Phase

The lecture also addressed the importance of collaboration among sponsors, CROs, and site teams during the startup phase, and how efficient project management can significantly reduce delays in trial activation.

Interactive Session:

Following the lecture, a **Q&A session** was conducted, where attendees asked insightful questions on site qualification requirements, regulatory bottlenecks, and the role of technology in accelerating the startup process. The speaker answered all queries with practical examples and industry perspectives.

Outcome and Feedback:

The session was highly appreciated by participants, especially those pursuing careers in clinical operations and regulatory affairs. It provided a **practical framework** for understanding the complexities and importance of the study startup phase, which is often underestimated but crucial for the overall success of a clinical trial.

Dr Manisha taking session on *Study Startup*

Understanding the essentials of Study Start-up with Dr. Manisha.

Session 3

Institution Visited: Himalayan School of Yoga Sciences (HSYS), SRHU

Date of Visit: 16th July 2025
Organized by: Department of Clinical Research
Theme of the Visit:
1. The Role of Meditation in Mental Health and Well-being
2. Yoga Asanas: An Overview of Their Benefits and Importance

Introduction:
A group of students and faculty from [Department Name] visited the Himalayan School of Yoga Sciences (HSYS), Swami Rama Himalayan University (SRHU), with the objective of understanding the practical and theoretical aspects of meditation and yoga asanas, and their relevance in promoting mental health, physical well-being, and holistic living.

Purpose of the Visit:
The visit was aimed at:

- Gaining insights into traditional and scientific perspectives on meditation.
- Learning about various yoga asanas and their physiological and psychological benefits.
- Understanding the integration of yoga and meditation into daily life as preventive and therapeutic tools.

Session 1: Meditation and Mental Health
The first session, led by faculty members of HSYS, focused on the importance of meditation in maintaining and improving mental health.
The following key points were covered:

- Introduction to **meditative practices** rooted in yogic philosophy.
- Evidence-based benefits of meditation including:
- ✓ Reduction in stress, anxiety, and depression
- ✓ Improved emotional regulation and focus
- ✓ Enhancement of self-awareness and resilience
- Guided session on **mindfulness-based meditation**, allowing participants to experience calmness and clarity.

Session 2: Yoga Asanas – Benefits and Importance
The second session involved a practical demonstration and discussion on yoga asanas.
Topics included:

- ✓ Classification of asanas (standing, seated, prone, supine, and balancing postures)
- ✓ Physiological benefits such as improved flexibility, strength, circulation, and digestion
- ✓ Mental benefits including enhanced mood, reduced fatigue, and better sleep
- ✓ The role of yoga in preventive healthcare and rehabilitation
- ✓ Emphasis on asana alignment, breath awareness, and contraindications

Interactive Discussion and Feedback:

An interactive Q&A session followed, where participants asked questions about incorporating yoga and meditation into busy routines, contraindications for certain conditions, and how these practices could complement conventional therapies. The faculty provided insightful and practical responses.

Feedback from students indicated that the sessions were enlightening, therapeutic, and deeply engaging. Many expressed a renewed interest in adopting yoga and meditation as part of their lifestyle.

Dr Somlata Jha Teaching students about The Role of Meditation in Mental Health and Well-being

Yoga Asanas: An Overview of Their Benefits and Importance by Dr Somlata Jha

Session 4

Topic: **Business Simulation Activity – Strategic Thinking Through Group Simulation**
Date: 16th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mrs. Ekta Rao, Assistant Professor, School of Management Studies, HIMS, SRHU
No. of Participants: 30

Objective of the Activity:
To engage students in hands-on learning through simulated business scenarios that foster teamwork, strategic planning, problem-solving, and decision-making.

Structure of the Activity:

- Total Participants: 30 students
- Number of Groups: 4 (8 students in two groups and 7 students in the other two groups)
- Simulation Topic: *"Start-Up Strategy Challenge"*

Each group was tasked with **setting up a virtual startup**. They had to choose a business domain (tech, retail, food, education, or healthcare) and develop a comprehensive business plan. The simulation was divided into three rounds:

- Round 1: Ideation and Planning (30 minutes)
- Round 2: Budget Allocation and Risk Management (30 minutes)
- Round 3: Presentation and Review (30 minutes)

Outcome of the Activity:

- Students displayed excellent team coordination and creative thinking
- Common challenges included budget mismanagement and crisis response delays, offering rich learning opportunities
- Three groups were shortlisted for best performance:

1. **Team Bloom** – Tech-based education solution for rural students
2. **Team Blasters** – Sustainable packaging startup
3. **Team Purple** – Cloud kitchen model targeting working professionals

Student Feedback:
The activity was well-received. Students mentioned they learned:

- How to apply classroom concepts to real-world-like challenges
- The importance of team dynamics under pressure
- Financial discipline and adaptability in business planning

Mrs Ekta Rao taking session on Business Simulation Activity – Strategic Thinking Through Group Simulation

Developing strategic thinking skills through group simulation with Mrs. Ekta Rao.

Day -10

Session 1:

Topic: **Best Practices for Data Security and Privacy**
Date: 17th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mr. Abhinav Bahuguna, Lecturer, Department of Biostatistics, HIMS, SRHU
No. of Participants: 30

Objective of the Lecture: To create awareness among students and faculty members about the importance of **data security and privacy**, and to educate them on **current threats**, **legal frameworks**, and **best practices** for protecting digital information.

Key Topics Covered:

1. Understanding Data Security vs. Data Privacy
2. Common Threats to Data
3. Best Practices for Data Security
4. Best Practices for Data Privacy
5. Legal and Regulatory Frameworks
6. Case Studies

Interactive Session: Students actively participated in the Q&A session. Topics such as securing personal devices, career paths in cybersecurity, and ethical hacking were discussed. Mr. Batra also shared free resources and certification courses on data security.

"An important session on data security and privacy best practices by Mr. Abhinav Bahuguna."

"Building awareness around data privacy and security best practices with Mr. Abhinav Bahuguna."

Session 2:

Topic: **Medical Writing: Scope, Structure, and Standards**
Date: 17th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objective of the Lecture:

To provide students with a foundational understanding of **medical writing**, its various types, regulatory importance, career scope, and essential skills required for success in this specialized field.

Lecture Summary:

Dr. Sharma began her lecture by explaining the **definition and significance of medical writing** in the pharmaceutical and clinical research industries. She emphasized how medical writing plays a critical role in **documenting clinical trials, communicating scientific results**, and ensuring regulatory compliance.

Key Topics Covered:

1. What is Medical Writing?
2. **Types of Medical Writing**
    - Regulatory Writing
    - Scientific Writing
    - Medical Communication
    - Publication Planning and Medical Journalism
3. Role of a Medical Writer
4. Essential Skills for Medical Writers
5. Ethical and Regulatory Considerations
6. Career Pathways and Opportunities

Interactive Session:

The session concluded with an engaging Q&A round. Students asked questions about career opportunities, internship options, and certification courses in medical writing. Dr. Nair also provided valuable guidance on resume building and freelancing in the field.

Dr Manisha Sharma teaching students about Medical Writing: Scope, Structure, and Standards

"An in-depth session on medical writing essentials by Dr. Manisha Sharma."

Session 3:

Topic: **Activity on Empathy and communication**
Date: 17th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Vidisha Vallabh, Associate Professor, Department of Community Medicine, HIMS, SRHU
No. of Participants: 30

Objective:

The activity was designed to help students:

- Understand the importance of empathy in effective communication
- Learn and practice empathetic listening skills
- Recognize barriers to empathy and how to overcome them
- Apply empathetic communication in real-life scenarios

Structure of the Activity:

Part 1: Introduction (30 minutes)

- The session began with a short presentation on the definitions and differences between *empathy* and *sympathy*.

- Key concepts like *active listening*, *non-verbal communication*, and *emotional intelligence* were explained.
- A brief video was shown to illustrate how empathy changes the quality of interactions.

Part 2: Interactive Activity (40 minutes)

- **Activity 1: "Empathy Walk"** – Students were paired and given identity cards with different life situations (e.g., a refugee, a single mother, a bullied teenager). Each student shared how their character might feel in a given situation while the partner practiced empathetic listening without interrupting.
- **Activity 2: "Two Truths and a Feeling"** – Each participant shared two true statements and one emotional statement. Group members identified and responded empathetically to the emotional content.
- Debriefing was conducted after each activity to reflect on what made them feel heard and understood.

Part 3: Reflection and Feedback (20 minutes)

- An open discussion was held on how communication changes when empathy is present.
- Students shared their experiences and challenges during the activities.
- A feedback form was distributed to evaluate the effectiveness of the session.

Outcomes:

- Participants showed increased awareness of the role of empathy in communication.
- Many students reported realizing that simply "listening to understand" can reduce conflict and build trust.
- The interactive nature of the activities encouraged self-reflection and improvement in interpersonal communication.

Dr Vidisha Vallabh conducting an activity on Empathy and communication

"Building compassionate communication skills—activity led by Dr. Vidisha Vallabh."

Session 4:

Topic: **HIPAA Guidelines: Safeguarding Patient Privacy and Data Security**
Date: 17th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objective of the Lecture:

To educate students on the key components of the **Health Insurance Portability and Accountability Act (HIPAA)**, including the **Privacy Rule**, **Security Rule**, **Breach Notification Rule**, and **Enforcement Rule**, and to explain their significance in protecting patient information.

Key Points Covered:

1. Introduction to HIPAA

2. The Four Major Rules under HIPAA

- **Privacy Rule**: Protects all forms of PHI (oral, paper, electronic); governs the use/disclosure of personal health data
- **Security Rule**: Focuses on safeguarding **electronic PHI (ePHI)** through administrative, physical, and technical safeguards
- **Breach Notification Rule**: Requires timely notification to patients and regulatory bodies in case of data breaches
- **Enforcement Rule**: Outlines penalties for violations—civil and criminal

3. Who Must Comply with HIPAA?
4. Best Practices for Compliance
5. Case Studies

Interactive Session:

Students asked questions about the **application of HIPAA in India**, how it compares with **India's Digital Personal Data Protection Act (DPDP) 2023**, and the role of **data protection officers** in clinical trials. Dr. Sharma encouraged students to stay updated with evolving global data protection standards.

Dr Manisha teaching students about *HIPAA Guidelines: Safeguarding Patient Privacy and Data Security*

"An insightful session on HIPAA and patient data protection led by Dr. Manisha Sharma."

Day 11
Session 1:

Topic: **Quality Control in Data Management**
Date: 18th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mrs. Akanksha Uniyal, Lecturer, Department of Biostatistics, HIMS, SRHU
No. of Participants: 30

Objective of the Lecture:

The aim of the lecture was to enhance participants' understanding of quality control (QC) principles and practices in data management, especially in the context of clinical research and healthcare datasets

Key Points Covered in the Lecture:

1. Introduction to Data Quality
2. Quality Control vs Quality Assurance
3. QC Activities in Data Management
4. Tools and Technologies Used
5. Regulatory and Industry Guidelines
6. Real-life Examples and Case Studies

Interactive Session:
A short Q&A followed the lecture, where students inquired about:

- How to set up QC plans in small-scale studies
- Balancing automation with manual review
- Common challenges in maintaining data integrity

"Understanding the importance of data accuracy and consistency—session by Mrs. Akanksha Sharma."

"Mrs. Akanksha Sharma teaches best practices in data quality management.

Session 2:

Topic: **Quality Control and Error Prevention in Data Entry**
Date: 18th July 2025
Venue: Computer Lab, Department of Clinical Research, HIMS, SRHU

Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mr. Abhinav Bahuguna, Lecturer, Department of Biostatistics, HIMS, SRHU
No. of Participants: 30

Objective of the Lecture:

The lecture aimed to educate participants on best practices for quality control and methods for preventing errors during data entry in research and administrative settings. Emphasis was placed on ensuring data accuracy, completeness, and compliance with regulatory and institutional standards.

Session Highlights:

1. Introduction to Data Entry and Its Importance
2. Common Data Entry Errors
3. Error Prevention Strategies
4. Quality Control Measures
5. Tools and Technologies

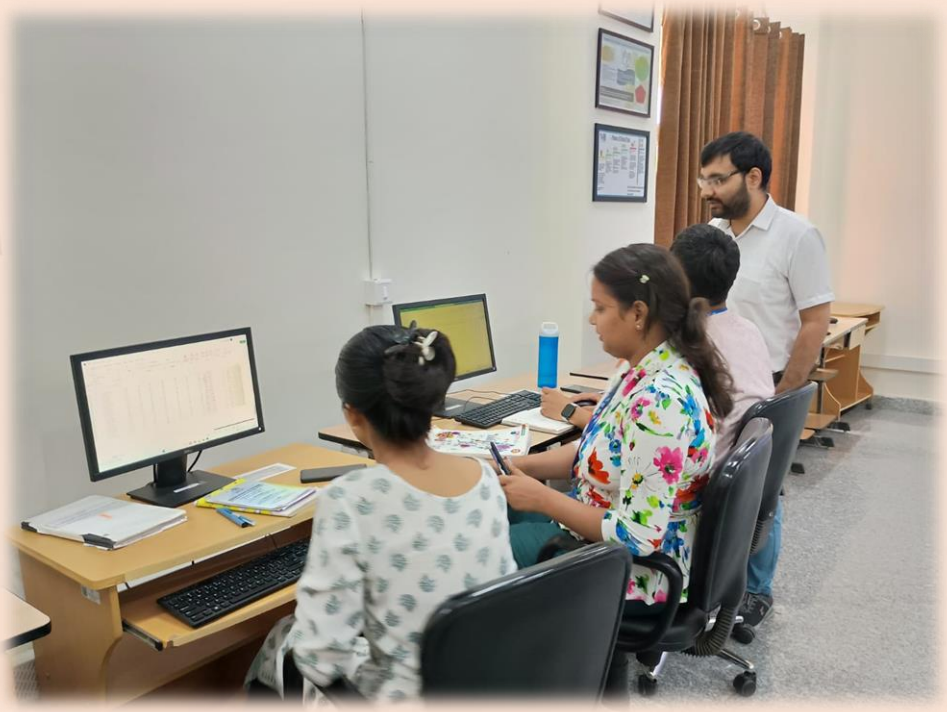
Interactive Component:

Participants engaged in a hands-on activity where they entered a mock dataset with built-in error traps. Teams were asked to identify and correct errors using provided checklists and validation rules. This helped reinforce theoretical concepts through practical application.

Outcomes and Learnings:

- Participants gained practical skills in identifying and preventing data entry errors
- Enhanced understanding of the role of QC in maintaining data accuracy
- Encouragement to implement SOPs and periodic audits in their respective institutions

Mr Abhinav teaching students about Quality Control and Error Prevention in Data Entry



"Ensuring data accuracy: Mr. Abhinav teaches students key strategies for quality control and error prevention."

Session 3

Topic: **Overview of Clinical Data Management**
Date: 18th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objectives of the Lecture

- To introduce the concept and significance of Clinical Data Management (CDM)
- To discuss the workflow of data collection, validation, and reporting
- To understand regulatory requirements and tools used in CDM
- To highlight the challenges and career opportunities in the field

Key Points Discussed

a. Definition and Importance of CDM
b. CDM Workflow
The speaker explained the CDM process in a stepwise manner:

- **Study Start-up Activities:** CRF/eCRF design, Data Management Plan (DMP), database setup
- **Data Collection:** Paper-based or electronic capture
- **Data Validation:** Query generation, discrepancy management, data cleaning
- **Database Lock and Archival**

c. Tools and Systems Used

d. Regulatory Guidelines and Standards

- ICH-GCP (International Conference on Harmonisation – Good Clinical Practice)
- 21 CFR Part 11 compliance (FDA)
- CDISC standards (CDASH, SDTM)

e. Challenges in CDM
She spoke about common challenges such as:

- Data inconsistency
- Protocol amendments
- Managing multi-site trials
- Ensuring timely database lock

f. Career Pathways

The lecture concluded with a discussion on career roles in CDM such as:

- Data Coordinator
- Clinical Data Associate
- Database Programmer
- CDM Lead/Manager

Interactive Session

The last 20 minutes were dedicated to Q&A. Students asked insightful questions related to eCRF design, audit trails, and differences between EDC and CTMS (Clinical Trial Management System). Dr. Sharma patiently addressed all queries with practical examples.

Dr Manisha teaching students about Overview of Clinical Data Management

A comprehensive overview of clinical data management led by Dr. Manisha Sharma.

Session 4:

Topic: **Understanding Key Statistical Outputs in Clinical Trials**
Date: 18th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. AK Srivastava, Professor, Department of Community Medicine, HIMS, SRHU
No. of Participants: 30

Objective of the Session:

To familiarize participants with the fundamental statistical outputs generated during clinical trials, their interpretations, and their importance in evaluating the efficacy and safety of investigational products.

Overview of the Session:

1. Introduction to Clinical Trial Statistics
2. Key Statistical Outputs Discussed
a. Descriptive Statistics
b. Confidence Intervals (CI)
c. P-values and Hypothesis Testing
d. Kaplan-Meier Curves and Survival Analysis
e. Adverse Event Summary Tables
f. Forest Plots
g. Interim Analysis and Data Monitoring

Interactive Session Highlights:

- Participants were shown anonymized statistical outputs from real clinical trials

- A short quiz was conducted to test participants' understanding of p-values and CI
- Open Q&A session allowed attendees to clarify doubts on statistical terminology

Outcomes and Learning Points:

- Participants gained a clear understanding of essential statistical terms and outputs
- Emphasis was placed on the appropriate interpretation and communication of results
- Importance of collaboration between statisticians and clinical teams was highlighted

Dr AK Srivastava teaching students about Understanding Key Statistical Outputs in Clinical Trials

Understanding statistical findings in clinical research—Dr. A.K. Srivastava's expert session

Day 12

Session 1:

Topic: **Debate on the Use of Artificial Intelligence**
Date: 21st July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty Coordinator: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objective of the Activity

The debate aimed to:

- Encourage critical thinking on the benefits and challenges of Artificial Intelligence (AI).
- Develop students' communication, argumentation, and public speaking skills.
- Provide a platform to express diverse perspectives on the impact of AI in different sectors.

Format of the Debate

- The debate followed a **team-based format** with two teams: **For the Motion** and **Against the Motion**.
- Topic: *"Artificial Intelligence is a Boon to Humanity."*

- Each team consisted of **four members**.
- Each speaker was given **3 minutes** to present their views, followed by a rebuttal round.

Highlights of the Debate

- **Team For the Motion** highlighted the following:
  - AI enhances productivity and efficiency in healthcare, education, transportation, and manufacturing.
  - Smart assistants, language models, and automation improve quality of life.
  - AI contributes to scientific innovation and data-driven decision-making.
- **Team Against the Motion** argued:
  - Overreliance on AI threatens employment and privacy.
  - Ethical concerns, such as bias in algorithms and lack of accountability, were emphasized.
  - Human intelligence and emotional reasoning cannot be replaced.
- The **audience participated actively** in the Q&A session and raised thoughtful questions on data privacy, ethical AI, and future implications.

Outcome

The debate was an engaging and thought-provoking session that provided students with a deeper understanding of the implications of Artificial Intelligence. It fostered awareness about the opportunities and risks associated with AI and encouraged balanced, ethical perspectives.

Debate session on the Use of Artificial Intelligence

"A thought-provoking debate session on the use of Artificial Intelligence in modern society."

Session 2:

Topic: **Safety Monitoring and Data Collection**
Date: 21st July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. DC Dhasmana, Professor, Department of Pharmacology, HIMS, SRHU
No. of Participants: 30

Introduction
A lecture on "**Safety Monitoring and Data Collection**" was conducted to provide students with in-depth knowledge on how patient safety is ensured during clinical trials and the critical role of accurate data collection in regulatory compliance. The session focused on methods used to monitor adverse events and the importance of maintaining data integrity throughout a clinical study.

Objectives of the Lecture

- To understand the principles and procedures of safety monitoring in clinical research.
- To learn about adverse event (AE) and serious adverse event (SAE) reporting.
- To explore methods and tools for effective data collection.
- To understand the regulatory importance of safety data.

Key Points Discussed
a. Safety Monitoring in Clinical Trials

- Definition and goals of safety monitoring.
- Roles of the sponsor, investigator, and ethics committee in safety oversight.

b. Adverse Event Reporting

- Classification of AEs: mild, moderate, severe.

- Differentiating between AE, SAE, and SUSAR (Suspected Unexpected Serious Adverse Reaction).

c. Data Collection Methods

- Importance of accurate and timely data collection.
- Use of **Case Report Forms (CRFs)** and **Electronic Data Capture (EDC)** systems.

d. Regulatory and Ethical Considerations

- Guidelines under **ICH-GCP**, **Schedule Y**, and **21 CFR Part 11**.
- Informed consent and participant protection in safety reporting.

Student Interaction and Engagement

The session was interactive, with students asking questions about:
How to identify and grade an AE.
Practical challenges in rural clinical sites.
Case examples of regulatory action based on poor safety reporting.Dr. Dhasmana also shared real-world case studies and emphasized the importance of a safety-first approach in clinical practice and trials.

Dr D C Dhasmana teaching students about Safety Monitoring and Data Collection

Dr. Dhasmana shares key insights on clinical safety and data tracking

Session 3

Topic: **Visit to the Ayurveda Centre**
Date: 21st July 2025
Venue: Ayurveda School, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty accompanied: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Introduction

A visit to the Ayurveda Centre, Swami Rama Himalayan University was organized for the students to enhance their understanding of traditional Indian systems of medicine. The purpose of the visit was to provide students with first-hand exposure to the principles and practices of **Ayurveda**, and how they are integrated into modern wellness approaches.

Objective of the Visit

- To understand the fundamental concepts of Ayurveda.
- To observe the preparation and application of Ayurvedic medicines.
- To learn about various Ayurvedic therapies like Panchakarma.
- To interact with practitioners and gain insight into Ayurvedic diagnosis and treatment.

Activities During the Visit

- **Welcome and Orientation:** The students were welcomed by Dr. Rohit Bhatt, gave a brief overview of the centre's mission and services.
- **Tour of the Facility:** Students were taken around the therapy rooms, herbal garden, and pharmacy unit where Ayurvedic medicines were being prepared from raw herbs.
- **Demonstration of Therapies:** Live demonstrations of **Abhyanga (oil massage)** and **Shirodhara (oil pouring therapy)** were conducted, with explanations on their therapeutic benefits.

Key Learnings

- Ayurveda emphasizes **holistic well-being** by balancing the body, mind, and spirit.
- Diet, daily routines, seasonal regimens, and natural remedies form the core of Ayurvedic practice.
- The integration of Ayurveda with modern health approaches offers a complementary path to patient care.
- Panchakarma therapies are unique detoxification methods that play a central role in Ayurvedic treatment.

Feedback from Students

Students found the visit highly informative and enriching. It deepened their appreciation of India's traditional medical knowledge and inspired many to explore how Ayurvedic principles can be integrated into modern healthcare.

"A deep dive into holistic wellness—students visit the Ayurveda Centre to learn about ancient medicinal systems."

"Exploring traditional healing practices during our visit to the Ayurveda Centre."

Day 13

Session 1:

Topic: **Clinical Data Management: Concepts and Scope**
Date: 22nd July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty Coordinator: Mrs. Akanksha Uniyal, Lecturer, Department of Biostatistics, HIMS, SRHU
No. of Participants: 30

Objectives of the Lecture

- To define and explain the concept of Clinical Data Management.
- To describe the core components and workflow in CDM.
- To highlight the importance of data quality, integrity, and compliance.

Session Highlights

Mrs. Akanksha began the session by defining Clinical Data Management as a critical process in clinical research focused on the collection, cleaning, and management of data generated during clinical trials. She emphasized that CDM ensures high-quality, reliable, and statistically sound data for regulatory submissions.
The lecture covered the following key points:

1. **CDM Lifecycle Overview**:
    - Protocol review
    - Case Report Form (CRF) design
    - Data entry and validation
2. **Concepts in CDM**:

- Data accuracy, consistency, and completeness
- Source Data Verification (SDV)
- Edit checks and validation rules

3. **Scope of CDM in Clinical Trials**:
    - Importance of Good Clinical Practice (GCP) compliance
    - CDM's role in regulatory submissions (e.g., to DCGI, USFDA)
    - Integration with EDC (Electronic Data Capture) systems
4. **Emerging Trends in CDM**:
    - Use of Artificial Intelligence and automation
    - Real-world data and decentralized trials
    - Integration of wearable devices and ePRO (electronic patient-reported outcomes)

Interactive Session

The lecture was followed by a Q&A session where students inquired about career opportunities in CDM, challenges in data reconciliation, and how data privacy is maintained during trials. Mrs. Uniyal shared practical insights from her industry experience and encouraged students to gain hands-on exposure to CDM tools like Medidata Rave and Oracle Clinical.

Mrs Akanksha taking lecture on Clinical Data Management: Concepts and Scope

Mrs. Akanksha explains the key concepts of clinical data management."

Session 2:

Topic: **Scientific Rigor and Statistical Considerations**
Date: 22nd July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty Coordinator: Mr. Abhinav Bahuguna, Lecturer, Department of Biostatistics, HIMS, SRHU
No. of Participants: 30

Objectives of the Lecture

- To explain the concept of scientific rigor and its importance in clinical research.
- To discuss appropriate statistical methods for research design and analysis.
- To identify common pitfalls in data interpretation and reporting.

Session Highlights

Dr. Anil Kumar opened the session by defining **scientific rigor** as the strict application of scientific methods to ensure robust, unbiased, and reproducible results. He stressed that without rigor, even statistically significant outcomes can be misleading.
The major points discussed were:

1. **Scientific Rigor Defined**:
    - Importance of hypothesis-driven research
    - Clear research objectives and standardized procedures
    - Protocol adherence and data fidelity
2. **Statistical Considerations in Clinical Research**:
    - Study design types: observational vs. interventional
    - Sample size calculation and power analysis
    - Appropriate use of randomization and blinding

3. **Avoiding Bias and Misinterpretation**:
    - Types of bias: selection bias, measurement bias, publication bias
    - The role of confidence intervals and p-values
    - Common errors in data handling and reporting
4. **Reproducibility and Transparency**:
    - Importance of data sharing and clear documentation
    - Pre-registration of trials and open-access results
    - Use of CONSORT guidelines for transparent reporting
5. **Ethical Considerations in Statistical Practice**:
    - Avoiding data manipulation or selective reporting
    - Justifying statistical choices in research publications
    - Ensuring data privacy and compliance with regulatory standards

Interactive Discussion

During the Q&A session, students asked about the differences between statistical significance and clinical significance, and how to ensure adequate sample size with limited resources. Dr. Kumar emphasized planning and collaboration with statisticians during the study design phase.

Mr Abhinav teaching students about Scientific Rigor and Statistical Considerations

Learning scientific rigor and statistics with Mr. Abhinav Bahuguna.

Session 3:

Topic: **Building Trust in Teams**
Date: 22nd July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty Coordinator: Mr. Ashish Gupta, C-PACE, SRHU
No. of Participants: 30

Objectives of the Lecture

- To define and explain the concept of trust in professional settings
- To identify the key elements that foster trust within teams
- To understand the consequences of trust breakdown

Session Highlights

Mr. Ashish began the session with a thought-provoking question: *"Can a team function without trust?"* This led to an engaging discussion about the role of trust as the foundation of every high-performing team.

Key topics covered included:

1. **Understanding Trust**:
    - Definition of trust in team dynamics

- Types of trust: interpersonal trust, organizational trust
- Trust vs. compliance in workplace behaviour

2. **Pillars of Trust-Building**:
    - Transparency
    - Integrity
    - Accountability
3. **Barriers to Trust**:
    - Poor communication
    - Unclear roles and expectations
    - Micromanagement and lack of autonomy
4. **Strategies for Building Trust**:
    - Active listening and honest feedback
    - Encouraging shared goals and team values
    - Conflict resolution with empathy
5. **Restoring Broken Trust**:
    - Owning up to mistakes
    - Rebuilding through consistent actions over time
    - Offering apologies and making amends

Interactive Activities

The session included a short role-play where participants acted out scenarios of broken and rebuilt trust in a team setting. This helped them better understand the emotional and behavioural aspects of trust.

Ashish Gupta taking session Building Trust in Teams

An engaging session on the foundation of successful teams—trust, led by Mr. Ashish Gupta.

Day 14

Session 1:

Topic: **Sample Size Calculation and Risk Analysis**
Date: 23rd July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty Coordinator: Mrs. Akanksha Uniyal, Lecturer, Department of Biostatistics, HIMS, SRHU
No. of Participants: 30

Objectives:

A lecture on "Sample Size Calculation and Risk Analysis" was organized to provide students with foundational knowledge on designing statistically sound clinical studies and identifying potential risks that may impact trial outcomes. The lecture aimed to bridge theoretical biostatistics with practical research application.

Key Highlights of the Lecture:

1. **Sample Size Calculation:**
    - Importance of determining the appropriate sample size in research.Key components influencing sample size: effect size, power, significance level (alpha), and variability.

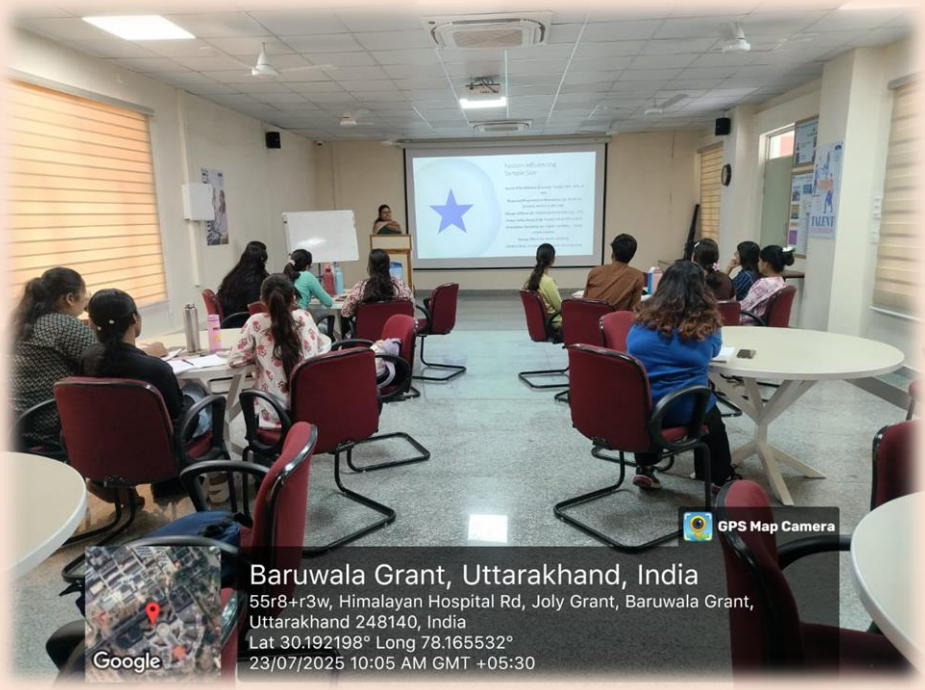
- Types of study designs (e.g., parallel, crossover, case-control) and how they affect sample size.
- Tools and software for sample size estimation (e.g., G*Power, nQuery).
- Real-life examples showing the impact of underpowered and overpowered studies.

2. **Risk Analysis in Clinical Trials:**
   - Definition of risk in the context of clinical research.
   - Risk identification, assessment, and prioritization (e.g., risk matrix method).
   - Use of Risk-Based Monitoring (RBM) strategies to optimize resources and safety.
   - Regulatory perspectives (ICH E6 R2) on risk-based approaches.
   - Case scenarios illustrating typical risks (e.g., patient dropouts, protocol deviations, data integrity issues) and mitigation plans.
3. **Integration of Both Topics:**
   - How risk considerations may influence sample size (e.g., accounting for attrition rate).
   - Importance of early planning and collaboration between statisticians and clinical operations teams.

Interactive Session: The session concluded with an engaging discussion where participants asked questions such as:

- How to estimate dropout-adjusted sample size?
- What are acceptable thresholds for risk in multicentric trials?
- Can risk analysis be integrated with feasibility assessments?

Mrs Akanksha taking session on Sample Size Calculation and Risk Analysis



Mastering sample size and risk analysis with Mrs. Akanksha Sharma.

Session 2:

Topic: **Trial Management and Quality Assurance**
Date: 23rd July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty Coordinator: Mrs. Charu Paliwal, Lecturer, Consultant Quality Assurance, Bharat Biotech Pvt Ltd.
No. of Participants: 30
Objectives:

A lecture on "Trial Management and Quality Assurance" was organized to provide students and professionals with a detailed understanding of how clinical trials are effectively managed while ensuring the highest standards of quality and regulatory compliance.

Key Highlights of the Lecture:

1. **Introduction to Clinical Trial Management:**
    - Definition and objectives of trial management.
    - Phases of clinical trial planning and execution.
    - Roles and responsibilities of the Trial Management Team (e.g., Sponsor, Investigator, Clinical Research Coordinator).
2. **Project Planning and Site Management:**
    - Study start-up activities including site selection and investigator training.
    - Timeline management, patient recruitment strategies, and budget control.
    - Tools and technologies used for trial tracking and communication.
3. **Quality Assurance (QA) in Clinical Trials:**

- Importance of QA in maintaining data integrity and participant safety.
- Difference between QA and Quality Control (QC).
- Regulatory guidelines (e.g., ICH-GCP, ISO 14155) that govern quality practices.

4. **Auditing and Monitoring:**
    - Types of audits: internal, sponsor, and regulatory.
    - Monitoring visits and Corrective and Preventive Actions (CAPA).
    - Documentation practices to support quality.
5. **Common Challenges and Mitigation Strategies:**
    - Addressing protocol deviations, data discrepancies, and delayed timelines.
    - Role of risk-based monitoring and electronic data capture systems (EDC).

Interactive Session:

The session included a Q&A segment where attendees asked questions about:

- How to handle protocol amendments during an ongoing trial.
- Risk management planning in multicentric studies.
- Preparing for regulatory inspections.

Charu Paliwal taking session on Trial Management and Quality Assurance

Charu Paliwal explains the essentials of managing trials and ensuring quality.

Session 3:

Topic: Exercise on Mock Boardroom
Date: 23rd July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty Coordinator: Mrs. Ekta Rao, Assistant Professor, School of Management Sciences
No. of Participants: 30

Objective of the Activity:

The main objective of the mock boardroom exercise was to simulate a professional corporate board meeting environment, helping students understand real-world decision-making, business communication, leadership dynamics, and team collaboration.

Description of the Activity:

Students were divided into teams representing different roles typically seen in a boardroom setting—such as CEO, CFO, COO, Marketing Head, HR Head, Legal Advisor, and Board Members. Each group was given a business scenario to discuss, analyze, and take strategic decisions on.

Scenario for the Exercise:
1. Data Sharing with Tech Companies

Case Brief: A tech company offers a lucrative partnership to use anonymized patient data to develop AI diagnostics. Privacy advocates raise concerns.

Roles: Hospital Director, Chief Information Officer, Chief Privacy Officer, Legal Advisor, Patient Rights Representative, Tech Company Liaison

Ethical Dilemma: Is it ethical to share patient data—even anonymized—for commercial development?

Discussion Points:

- Can data truly be anonymized?
- Should patients be asked for consent?
- Who profits from this partnership?

Learning Objective: Understand health data ethics, informed consent, and commercialization.

2. **Medical Error Disclosure**

Case Brief: A surgical team made an error that led to a patient's severe complication. The family is unaware. Risk of legal action is high.

Roles: Chief of Surgery, Legal Advisor, Ethics Committee Member, Hospital PR Manager, Patient Safety Officer, Nursing Director

Ethical Dilemma: Should the board enforce full disclosure, even with legal risk?

Discussion Points:

- What's the moral duty of disclosure?
- How do you rebuild patient trust?
- Should apology policies be formalized?

Learning Objective: Promote transparency, ethical disclosure, and risk management.

3. **Resource Allocation During a Pandemic**

Case Brief: The hospital is overwhelmed during a viral outbreak. ICU beds and ventilators are in short supply. The board must decide on triage policies.

Roles: Hospital Director (Chair), Chief Medical Officer, Ethics Committee Head, Nursing Director, Public Health Representative, Legal Advisor

Ethical Dilemma: Who gets care when resources are limited—first-come-first-served, youngest first, highest survival chance?

Discussion Points:

- What ethical framework will guide your policy?
- Should non-COVID services be suspended?
- How will transparency with the public be maintained?

Learning Objective: Analyze ethical triage principles, fairness, and public communication.

Structure of the Exercise:

- **Preparation Phase (30 mins):**
  Teams studied the case, discussed roles, and prepared presentations/arguments.
- **Boardroom Simulation (60 mins):**
  A mock meeting was held where participants discussed agendas such as budget approval, market entry strategy, risk assessment, and compliance issues. Each student spoke from the perspective of their designated role.
- **Debrief and Feedback (30 mins):**
  The faculty moderator provided feedback on presentation skills, business analysis, clarity of thought, and teamwork. Students also reflected on their experiences.

Learning Outcomes:

- Developed decision-making and problem-solving abilities.
- Improved communication, negotiation, and leadership skills.
- Gained hands-on experience in handling business issues under pressure.
- Understood the structure, function, and flow of a corporate boardroom meeting.

"Interactive mock boardroom session—where students turn theory into practice."

Experiential learning in action—students participate in a mock boardroom exercise to simulate real-world corporate scenarios."

Day 15
Session 1:

Topic: **Introduction to Investigational Product**
Date: 24th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty Coordinator: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objectives:
A lecture on "Introduction to the Investigational Product (IP)" was conducted to familiarize students with the fundamental concepts, regulatory requirements, and operational aspects related to the handling and management of investigational products in clinical trials.

Key Highlights of the Lecture:

1. **Definition and Importance of Investigational Product:**
    - An **Investigational Product** is a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial.
    - Importance in the context of drug development and ethical clinical research.
2. **Types of Investigational Products:**

- New Chemical Entities (NCEs), biological products, medical devices, vaccines, and placebos.
- Distinction between **test product**, **comparator**, and **placebo**.

3. **IP Management in Clinical Trials:**
   - Processes involved in **receipt, storage, labeling, blinding, dispensing, and accountability**.
   - Role of site staff, sponsor, and monitor in ensuring IP compliance.
4. **Good Manufacturing Practices (GMP) and IP:**
   - GMP requirements for production and packaging.
   - Importance of maintaining product quality, safety, and traceability.
5. **IP Documentation and Accountability:**
   - Importance of IP logs, accountability forms, temperature logs, and storage conditions.
   - Role of **Standard Operating Procedures (SOPs)** in IP handling.
6. **Regulatory Guidelines:**
   - Overview of ICH-GCP, Schedule Y (India), and relevant DCGI requirements.
   - Storage and destruction of expired/unused IP.

Interactive Session:
Participants engaged in a lively discussion on:

- Challenges in blinding and unblinding procedures.
- Handling deviations in IP accountability.
- Role of pharmacists and CRCs in IP management.

Dr Manisha taking session on Introduction to Investigational Product

"Understanding the role and handling of investigational products—session led by Dr. Manisha Sharma."

Session 2:

Topic: **Investigational Product (IP) Storage Requirements and Guidelines**
Date: 24th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty Coordinator: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objectives:
A lecture on "Investigational Product (IP) Storage Requirements and Guidelines" was organized to educate students and clinical research professionals on the critical principles of proper IP storage. The session focused on maintaining product integrity, ensuring regulatory compliance, and minimizing risks during clinical trial conduct.
Key Highlights of the Lecture:

1. **Importance of IP Storage:**
    - Ensures the **safety, stability, and efficacy** of the investigational product.
    - Prevents degradation or contamination due to improper storage conditions.
    - Supports compliance with **ICH-GCP**, **Schedule Y**, and **sponsor protocols**.
2. **Temperature and Environmental Requirements:**

- Common IP storage conditions
- Use of **calibrated temperature monitoring devices** and **alarms**.
- Monitoring for **temperature excursions** and maintenance of daily logs.

3. **Storage Area Requirements:**
   - Designated, **restricted-access** areas for IP storage.
   - **Separation of investigational and non-investigational products**.
   - Clearly labelled containers and secure, locked storage units.
4. **Documentation and Accountability:**
   - Maintaining **temperature logs, inventory records, receipt logs**, and **return/destruction records**.
   - Proper documentation of any **temperature excursions or deviations**.
5. **Compliance and Audits:**
   - Importance of being inspection-ready at all times.
   - GCP inspectors or sponsors may verify storage practices during audits.
   - Examples were shared where improper storage led to data invalidation.

Interactive Session:
The Q&A session focused on practical challenges such as:

- What to do during a power failure?
- How to manage IP at satellite sites?
- Best practices for managing short-dated IPs.

Session 3:

Topic: **Monitoring Activities in Clinical Trials**
Date: 24th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty Coordinator: Mrs. Charu Paliwal, Lecturer, Consultant Quality Assurance, Bharat Biotech Pvt Ltd.
No. of Participants: 30

Objectives:
The lecture on "Monitoring Activities in Clinical Trials" was conducted to provide students and research staff with a comprehensive understanding of the role and responsibilities of clinical trial monitors, also known as Clinical Research Associates (CRAs). The session emphasized the importance of monitoring in ensuring data integrity, participant safety, and compliance with Good Clinical Practice (GCP).
Key Highlights of the Lecture:

1. **Introduction to Monitoring:**
   - Definition of monitoring in the context of clinical trials.

- Purpose: to oversee the progress of a clinical trial and ensure it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and regulatory requirements.

2. **Types of Monitoring Visits:**
    - **Site Qualification Visit (SQV):** Assessing the site's capabilities before trial initiation.
    - **Site Initiation Visit (SIV):** Training site staff and reviewing trial procedures.
    - **Interim Monitoring Visits (IMVs):** Ongoing review of data and processes during the trial.
3. **Monitoring Activities:**
    - **Source Data Verification (SDV):** Comparing case report forms (CRFs) with source documents.
    - Ensuring **informed consent** has been properly obtained and documented.
    - **Investigational Product (IP) accountability.**
4. **Monitoring Tools and Reporting:**
    - Use of **monitoring checklists** and **report templates**.
    - Remote monitoring and risk-based monitoring strategies.
    - Documentation of findings and communication with the sponsor.

Interactive Session:

During the Q&A, students raised questions such as:

- How are monitoring findings categorized and reported?
- What are the key challenges faced during remote monitoring?
- How should CRAs handle repeated protocol deviations?

Mrs Charu Paliwal Taking session on Investigational Product (IP) Storage Requirements and Guideline

Understanding the safe handling and storage of Investigational Products—an informative session by Mrs. Charu Paliwal

Day 16

Session 1:

Topic: **Different Dosage Forms in Pharmaceutics**
Date: 25th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30
Objective of the Lecture:
To provide a comprehensive understanding of the various dosage forms used in the formulation of pharmaceutical products, their classifications, purposes, and selection criteria in drug delivery systems.

Key Highlights of the Lecture:

1. **Introduction to Dosage Forms:**
    - Definition: A dosage form is the physical form in which a drug is produced and dispensed.
    - Importance: Determines the route of administration, absorption rate, stability, patient compliance, and therapeutic efficacy.
2. **Classification of Dosage Forms:**

A. Based on Physical Form:

- **Solid Dosage Forms:**
  - Tablets, Capsules, Powders, Granules, Lozenges
- **Liquid Dosage Forms:**
  - Solutions, Emulsions, Suspensions, Syrups, Elixirs
- **Semi-solid Dosage Forms:**
  - Ointments, Creams, Gels, Pastes, Suppositories
- **Gaseous Dosage Forms:**
  - Inhalers, Aerosols, Nebulizers

B. Based on Route of Administration:

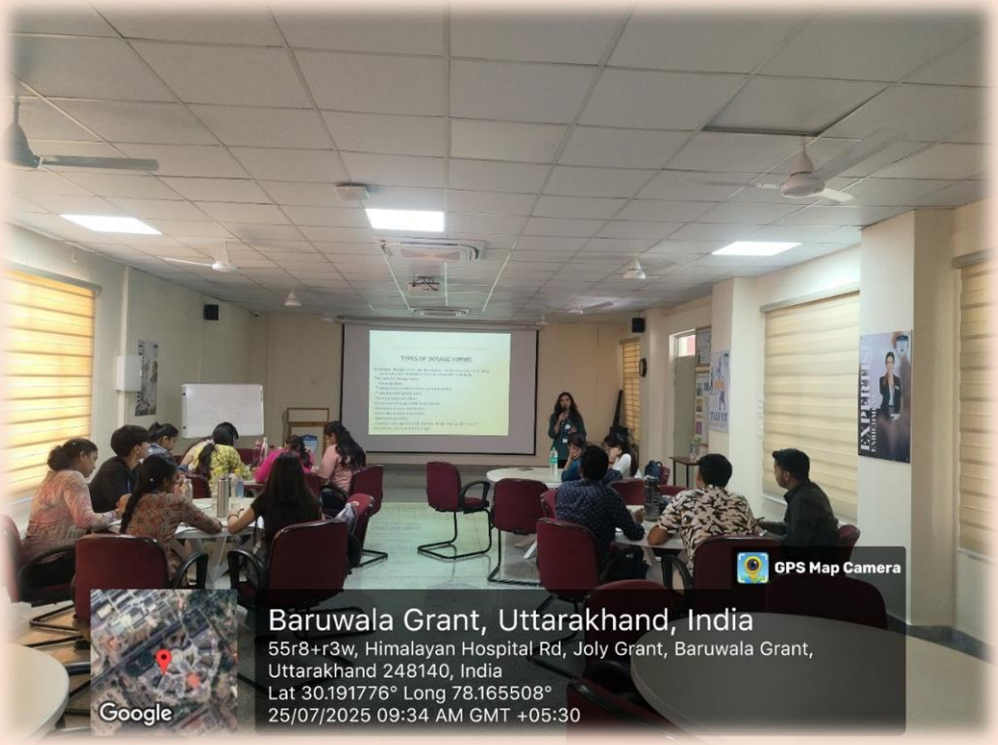
- Oral, Topical, Parenteral, Rectal, Nasal, Ophthalmic, Vaginal, Pulmonary

3. Criteria for Selecting a Dosage Form
4. Recent Advances

Interactive Session:

Students actively participated in the Q&A session. Questions about the difference between dosage forms and drug delivery systems and the suitability of specific forms in chronic conditions were addressed.

Dr Manisha Sharma taking session on Different Dosage Forms in Pharmaceutics



"Learning about pharmaceutical dosage forms with Dr. Manisha Sharma."

Session 2:

Topic: **Different Routes of Drug Administration**
Date: 25th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objective of the Lecture:
To educate students on the various routes through which drugs can be administered into the human body, with emphasis on their advantages**,** limitations**,** suitability, and clinical significance in different therapeutic conditions.

Key Highlights of the Lecture:

Introduction to Drug Administration:

- Definition: The process by which a drug is brought into contact with the body.

- Purpose: To deliver drugs at the desired site of action, at the appropriate time, in the right concentration.

Classification of Routes:

A. Enteral Routes:

- **Oral (PO):** Most common, convenient, economical.
- **Sublingual/Buccal:** Rapid absorption, bypasses first-pass metabolism (e.g., nitro-glycerine).
- **Rectal:** Useful in unconscious patients, partial first-pass avoidance.

B. Parenteral Routes:

- **Intravenous (IV):** Fastest onset, 100% bioavailability.
- **Intramuscular (IM):** Sustained effect, painful.
- **Subcutaneous (SC):** Self-administration possible (e.g., insulin).
- **Intradermal (ID):** Mainly for sensitivity tests.

C. Topical Routes:

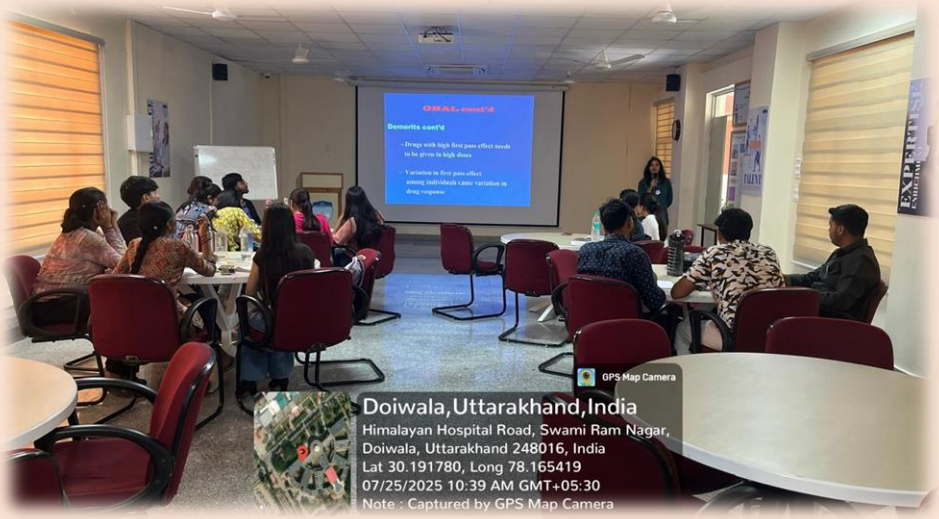
- **Skin (dermal):** Local effect (e.g., antifungal creams).
- **Eye (ocular), Ear (otic), Nose (nasal):** Local use in ENT and ophthalmology.

D. Inhalation Route

E. Transdermal Route

Interactive Session:

- Students asked questions about oral vs. IV delivery for antibiotics.
- Discussion on why some drugs cannot be given orally due to first-pass metabolism.



Dr Manisha Sharma taking session on Different Routes of Drug Administration

"Understanding how medicines reach the body—Dr. Manisha Sharma teaches different drug administration routes."

Session 3:

Topic: Case Studies on Real-World Adverse Event Reporting
Date: 25th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. DC Dhasmana, Professor, Department of Pharmacology, HIMS, SRHU
No. of Participants: 30

Objective of the Lecture:
To provide students with practical insight into adverse event (AE) reporting using real-world case studies. The session aimed to enhance understanding of pharmacovigilance practices**,** data interpretation, and regulatory reporting standards**.**

Key Highlights of the Lecture:

1. **Introduction to Adverse Events (AEs):**
    - Definition: Any untoward medical occurrence in a patient administered a pharmaceutical product, not necessarily causally related.
    - Difference between Adverse Event (AE) and Adverse Drug Reaction (ADR)
    - Importance of AE reporting in ensuring drug safety post-marketing.

2. **Importance of Real-World AE Reporting:**

- Detects rare and long-term side effects
- Helps update drug safety labels
- Supports regulatory decisions like black-box warnings, market withdrawal
- Encourages healthcare professional and patient participation

3. **Case Studies Presented:**
    - Case 1: Rofecoxib (Vioxx) Withdrawal
    - Case 2: Thalidomide Tragedy
    - Case 3: Signal Detection – Pioglitazone and Bladder Cancer
    - Case 4: COVID-19 Vaccine – Mild to Severe AEs
4. **Reporting Systems Discussed**
5. **Challenges in Real-World AE Reporting**

Interactive Segment:
Dr. Dhasmana also shared tips on what makes a high-quality AE report and discussed how students can contribute to AE reporting as future healthcare professionals.

Dr DC Dhasmana taking session on Case Studies on Real-World Adverse Event Reporting

"Case study session on adverse events led by Dr. Dhasmana to improve reporting accuracy."

Session 4:
Topic: **A visit to the Skills and Simulation Centre, Swami Ram Himalayan University**
Date: 25th July 2025
Venue: Skills and Simulation Centre, Swami Ram Himalayan University
Organized by: Department of Clinical Research, HIMS, SRHU
Accompanying faculty: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objective of the Visit:
Mr. Suresh Chandra and Ms. Sapna Semwal provided students with hands-on exposure to clinical and procedural skills using simulation-based learning techniques and to understand the role of simulation in clinical education and patient safety.

About the Skills and Simulation Centre:
The Skills and Simulation Centre at Swami Ram Himalayan University is a state-of-the-art training facility designed to replicate real-life clinical environments. It includes various high-fidelity mannequins, task trainers, simulation labs, operating room setups, emergency response modules, and audio-visual debriefing systems.

Activities Conducted During the Visit:

1. **Orientation Session:**
   - A brief introduction to the concept and objectives of simulation-based learning.
   - Safety protocols and ethical considerations in simulation.
2. **Tour of the Simulation Labs:**

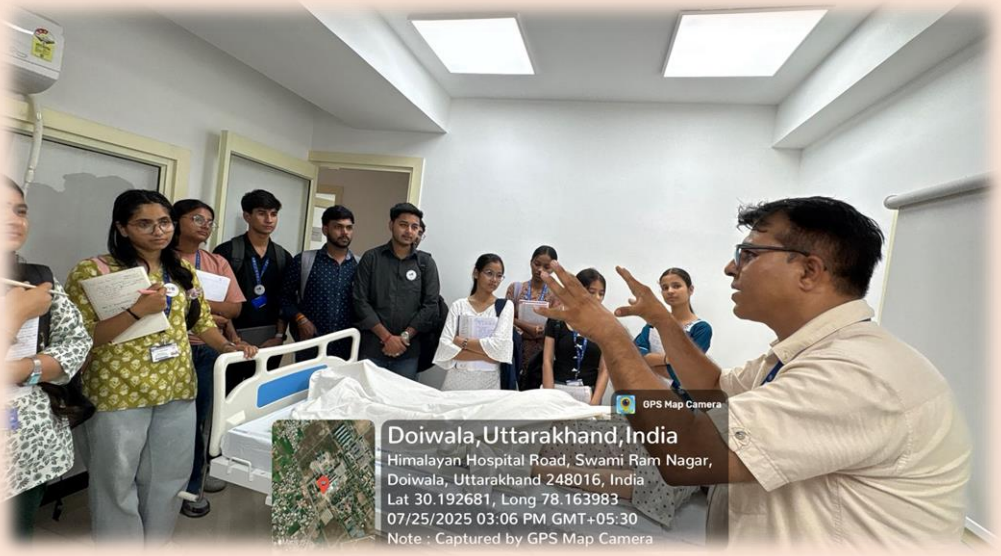
- **Basic Skills Lab:** Students were shown stations for IV insertion, suturing, catheterization, and airway management.
- **Advanced Simulation Lab:** Demonstration of high-fidelity mannequins used for CPR, emergency resuscitation, and trauma response.
- **Operation Theatre Simulation:** Exposure to the surgical simulation setup for team-based learning.
- **Labour and Delivery Suite:** Overview of obstetric mannequins simulating normal and complicated deliveries.

3. **Live Demonstration:**
   - Faculty and simulation technicians conducted a simulated **cardiac arrest scenario** using a high-fidelity mannequin.
   - Emphasis on the ABC (Airway, Breathing, Circulation) approach, CPR technique, and teamwork.

Key Learnings:
Simulation effectively bridges the gap between theory and real-life practice, allowing learners to build confidence through safe error correction. It also emphasizes teamwork, communication, and supports ongoing professional development and clinical assessment.

Feedback from Students:
The visit was found to be highly informative and engaging, offering valuable hands-on learning opportunities. Students expressed interest in more frequent simulation sessions to enhance their clinical confidence.

A visit to the Skills and Simulation Centre, Swami Ram Himalayan University



"Exploring hands-on training opportunities during our visit to the Skills and Simulation Centre."

Day 17

Session 1:

Topic: **Introduction to Conflict of Interest in Research**
Date: 28th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objectives:

The lecture on **"Introduction to Conflict of Interest (COI) in Research"** provided an insightful exploration of the ethical challenges that can arise when personal, professional, or financial interests compromise—or appear to compromise—the integrity of research. The session emphasized the importance of transparency, disclosure, and institutional oversight in upholding public trust and scientific credibility.

Key Points Covered:

1. **Definition and Types of Conflict of Interest:**
   - **Conflict of Interest (COI)** occurs when an individual's personal interests interfere with their professional responsibilities.
   - Types of COI discussed:
     - Financial COI
     - Non-financial COI
     - Institutional COI
2. **Real-World Examples:**

- Case studies were shared, including instances where undisclosed financial ties influenced the direction and publication of clinical trial results.
- Ethical concerns raised when supervisors promote products from companies they are affiliated with.

3. **Consequences of COI:**
   - Loss of public trust.
   - Retraction of published articles.
   - Damage to the credibility of researchers and institutions.
   - Legal and professional repercussions.
4. **Strategies for Management and Disclosure:**
   - Importance of full disclosure to institutional review boards (IRBs), sponsors, and journals.
   - Use of COI declarations in manuscripts and grant applications.
   - Establishment of COI policies by academic and research institutions.

Interactive Session:

The lecture concluded with a Q&A segment, where participants raised concerns about navigating potential COIs in student-supervisor relationships, industry-sponsored research, and collaborative multi-center trials. Dr. Manisha emphasized the need for early dialogue and institutional support in managing these situations ethically

Dr Manisha taking session on: Introduction to Conflict of Interest in Research

A foundational lecture by Dr. Manisha on recognizing and managing conflicts of interest in research.

Session 2:

Topic: **Real World Case Studies on Conflict of Interest**

Date: 28th July 2025

Venue: Training and Development room, HIMS, SRHU

Organized by: Department of Clinical Research, HIMS, SRHU

Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU

No. of Participants: 30

Objectives:

The lecture Topicd "Real World Case Studies on Conflict of Interest" aimed to illustrate how conflicts of interest (COI) manifest in various research and clinical settings. Through detailed case studies, the session emphasized the ethical dilemmas faced by researchers and healthcare professionals and highlighted strategies for ethical decision-making and institutional accountability.

Case Studies Discussed:

1. **Case Study 1: Financial Ties in Drug Trials**
   - A well-known pharmaceutical company sponsored a clinical trial for a new diabetes drug.
   - The lead investigator held stock in the company and failed to disclose this to the institution or in publications.
   - The results of the trial were later questioned for bias after adverse effects were underreported.

- **Key Lesson:** Importance of transparent financial disclosure and independent data monitoring.

2. **Case Study 2: Ghost-writing in Medical Journals**
   - A pharmaceutical company paid for scientific articles promoting its drug but used academics as nominal authors.
   - The ghost-writers were not disclosed, and the articles appeared in peer-reviewed journals.
   - This misled the medical community and patients, resulting in regulatory scrutiny.
   - **Key Lesson:** Authorship must reflect actual contributions; ghost-writing breaches academic integrity.
3. **Case Study 3: Institutional COI in Research Funding**
   - A university received a large endowment from a company whose product was being evaluated in a university-sponsored study.
   - The ethical committee approved the study without sufficient scrutiny of the funding source.
   - After the product failed in the market, the neutrality of the study was called into question.
   - **Key Lesson:** Institutions, like individuals, must actively manage and disclose conflicts.

Discussion Highlights:

- Participants discussed how early-career researchers are especially vulnerable to COI due to power imbalances with mentors or sponsors.
- Students raised concerns about navigating industry collaborations, and Dr. Manisha stressed the importance of written agreements and institutional support.+

Dr Manisha Sharma taking session on Real World Case Studies on Conflict of Interest

A deep dive into ethical dilemmas: Dr. Manisha discusses real-world conflict of interest cases.

Session 3:

Topic: **Research Misconduct and Fraud**
Date: 28th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Nikku Yadav, Associate Professor and In charge, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objective:
The lecture on **"Research Misconduct and Fraud"** addressed the growing concerns surrounding unethical practices in scientific research. The session provided a comprehensive overview of what constitutes research misconduct, its impact on the scientific community and public trust, and mechanisms in place to detect and prevent it.
Key Concepts Covered:

1. **Definition of Research Misconduct:**
   - As per international guidelines (e.g., U.S. ORI, ICMJE), research misconduct is defined as:
     - **Fabrication:** Making up data or results.
     - **Falsification:** Manipulating data, processes, or results to misrepresent findings.

        - **Plagiarism:** Using others' work or ideas without proper credit.
    - Honest errors or differences of opinion do not constitute misconduct.
2. **Types and Examples:**
    - Fabrication Example
    - Falsification Example
    - Plagiarism Example
3. **Notable Real-World Cases:**
    - Case of Dr. Hwang Woo-suk, who fabricated stem cell research data.
    - Example of Diederik Stapel, a social psychologist who falsified numerous datasets.
    - Misuse of image manipulation in biomedical journals.
4. **Consequences of Research Fraud:**
    - Retraction of publications.
    - Damage to reputation and academic career.
    - Loss of funding and institutional credibility.
5. **Detection and Reporting Mechanisms:**
    - Role of peer review and editorial scrutiny.
    - Use of plagiarism detection software (e.g., Turnitin, iThenticate).
    - Importance of whistle-blower policies and institutional inquiry committees.
6. **Prevention Strategies:**
    - Ethics training and mentoring for young researchers.
    - Promoting a culture of research integrity and open data.

Interactive Session:

- The Q&A session allowed students to ask about grey areas, such as self-plagiarism and salami slicing (publishing the same research in multiple papers).
- Dr. Nikku emphasized the value of ethical authorship, proper supervision, and institutional accountability.

Dr Nikku Yadav taking session on Research Misconduct and Fraud

"Learning about research misconduct and fraud with Dr. Nikku Yadav."

Session 4:

Topic: **Basics of MS Excel**
Date: 28th July 2025
Venue: Computer Laboratory, Department fo Clinical Research, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Ms. Pooja Kandari, Office Assistant, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objectives:
The lecture Topicd **"Basics of MS Excel"** provided an introductory yet practical understanding of Microsoft Excel, one of the most widely used spreadsheet programs. The session aimed to equip students with foundational skills needed to organize, analyse, and present data efficiently using Excel.

Key Topics Covered:

1. **Introduction to Excel Interface:**
   - Ribbon, Tabs, and Groups
   - Workbook vs Worksheet
   - Rows, Columns, and Cells
   - Quick Access Toolbar and File Menu
2. **Data Entry and Formatting:**
   - Entering and editing data (text, numbers, dates)
   - Formatting cells (font, alignment, number formats)
   - Merging cells, adjusting column width and row height
   - Use of "Format Painter" and "Clear Formatting" features

3. **Basic Formulas and Functions:**
   - Introduction to formulas (e.g., `=A1+B1`)
   - Common functions:
     - **SUM ()** – Adds a range of cells
     - **AVERAGE ()** – Calculates mean
     - **MIN (), MAX ()** – Finds smallest and largest values
     - **COUNT (), COUNTA ()** – Counts cells with numbers or any data
   - Use of AutoFill and relative vs absolute cell referencing (`$A$1`)
4. **Working with Tables and Data Management:**
   - Creating and formatting tables
   - Sorting and filtering data
   - Freezing panes and using split view
5. **Hands-on Demonstration:**
   - Real-time creation of a student marksheet
   - Calculating total, average, highest, and lowest marks
   - Generating a bar chart to visualize performance

Interactive Session:

- Students actively participated in solving practical exercises.
- Questions were raised about shortcut keys, creating templates, and exporting Excel data to other formats like PDF.
- Ms. Pooja emphasized the real-world applications of Excel in data analysis, budgeting, inventory tracking, and academic research.

Ms Pooja Kandari taking session on Basics of MS Excel

Ms. Pooja Kandari introduces students to the fundamentals of MS Excel for effective data management.

Day-18

Session 1:

Topic: **Basics of SPSS software**
Date: 29th July 2025
Venue: Computer Laboratory, Department of Clinical Research, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mr. Abhinav Bahuguna, Lecturer, Department of Biostatistics, HIMS, SRHU
No. of Participants: 30

Objectives of the Lecture
To understand the interface and functionality of SPSS.
To learn the steps involved in data entry and data management.
To perform basic descriptive and inferential statistical analysis.
To interpret SPSS output and generate meaningful reports.

Topics Covered

1. **Introduction to SPSS**
    - History and evolution of SPSS
    - Applications in social sciences, health, education, and business research
    - Overview of the SPSS interface: Data View and Variable View
2. **Data Entry and Management**
    - Defining variables: Name, type, width, decimals, labels, values, missing values
    - Entering and editing data in SPSS

3. **Descriptive Statistics**
    - Frequency distributions
    - Measures of central tendency (mean, median, mode)
    - Measures of dispersion (range, standard deviation, variance)
4. **Graphical Representation**
    - Creating charts: bar charts, pie charts, histograms, boxplots
    - Customizing graphs for presentation and publication
5. **Basic Inferential Statistics**
    - Independent sample t-test
    - Paired sample t-test
    - Chi-square test
6. **Data Transformation and Cleaning**
    - Recode variables
    - Compute new variables
    - Detecting and handling missing data and outliers
7. **Interpreting Output**
    - Understanding SPSS output windows
    - Interpreting tables and statistical results
    - Exporting results to Word and Excel

Interactive Session

The session also included a hands-on practice component where participants analysed a sample dataset under the guidance of the instructor. Real-time queries were addressed, and the importance of choosing the correct statistical test was emphasized.

Mr Abhinav Bahuguna teaching students Basics of SPSS software

Mr. Abhinav Bahuguna introduces students to the basics of SPSS software for statistical analysis."

Session 2:

Topic: **Understanding Data Falsification and Fabrication and the Role of GDP (Good Documentation Practices)**
Date: 29th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objectives of the Lecture

- To define and differentiate data falsification and fabrication in research.
- To understand real-world implications and consequences of research misconduct.
- To introduce and elaborate on Good Documentation Practices (GDP).
- To highlight the preventive role of GDP in ensuring data integrity and compliance.

Key Topics Covered

1. Understanding Research Misconduct

- Definition of Data Falsification
- Definition of Data Fabrication
- Examples of both

2. Consequences of Misconduct

- Ethical violations and loss of public trust.
- Retraction of publications.
- Legal and regulatory actions (e.g., disqualification, fines).
- Damage to professional reputation and career setbacks.

3. Introduction to Good Documentation Practices (GDP)

- GDP refers to systematic procedures and standards to ensure proper, complete, and accurate documentation in research and clinical trials.

- **Key Principles of GDP:**
    - **ALCOA+:** Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available.
    - Use of permanent ink, proper date/time formats.
    - Avoiding backdating or overwriting.

4. Role of GDP in Preventing Misconduct

- GDP enforces **accountability and traceability** of data.
- Enables **audit readiness** and verification during inspections.

5. Case Studies and Real-Life Examples

- Review of high-profile cases involving falsification and fabrication.
- Discussion on institutional responses, retractions, and policy changes.

Interactive Component

Participants were presented with sample scenarios and asked to evaluate whether proper GDP was followed and whether the data presented might be falsified or fabricated. This stimulated critical thinking and real-world application of the concepts learned.

Dr Manisha Sharma taking session on Understanding Data Falsification and Fabrication and the Role of GDP (Good Documentation Practices

A critical session on research integrity: data falsification, fabrication, and GDP by Dr. Manisha Sharma.

Session 3:

Topic: **Basics of MS Word**
Date: 29th July 2025
Venue: Computer Laboratory, Department of Clinical Research, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Ms. Pooja Kandari, Office Assistant, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objectives of the Lecture

The lecture on *"Basics of MS Word"* aimed to introduce participants to Microsoft Word, one of the most commonly used word processing software applications. The session was designed for beginners and focused on the fundamental tools, interface, and basic functions of the software to help users create, edit, and format professional documents.

Key Points Covered:

1. Introduction to MS Word
2. User Interface Overview
    - Components of the MS Word window:
    - Topic bar
    - Ribbon and Tabs (Home, Insert, Design, Layout, etc.)
    - Quick Access Toolbar

- Status bar
- Document area

3. Creating and Managing Documents
4. Basic Text Formatting
5. Page Layout and Design
6. Inserting Elements
7. Proofing and Editing Tools
8. Printing and Sharing Documents
9. Templates and Styles
10. Basic Shortcuts and Tips

Demonstration and Hands-on Session:

The instructor provided a live demonstration of MS Word functionalities, allowing participants to follow along on their own systems. Tasks included formatting a sample document, inserting images and tables, and saving a file in multiple formats

Interactive Q&A Session:

Participants asked questions about layout customization, inserting citation references, and document security features. The speaker addressed all queries with practical examples.

"Students deepen their MS Word skills and clarify doubts in an interactive session with Ms. Pooja."

"Interactive session with Ms. Pooja where students learn and explore MS Word features."

Session 4:
Topic: **ICH-GCP Guidelines (International Council for Harmonisation – Good Clinical Practice)**
Date: 29th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Bindu Dey, Director Research, Swami Ram Himalayan University
No. of Participants: 30

Objectives of the Lecture:

- To provide an overview of the ICH and GCP framework.
- To explain the core principles of ICH-GCP.
- To discuss the roles and responsibilities of key stakeholders in clinical research.
- To highlight the importance of compliance with regulatory and ethical standards.

Key Topics Covered:

1. Introduction to ICH and GCP
2. Historical Background
3. Scope of ICH-GCP
4. Key Principles of ICH-GCP:
    - **Ethical Conduct**: Trials must adhere to ethical standards and Declaration of Helsinki.
    - **Risk-Benefit Assessment**: Clinical trials should have a favourable risk-benefit ratio.

- **Informed Consent**: Voluntary and documented consent is essential.
- **Confidentiality**: Participant data must be protected.
- **Scientific Soundness**: Studies should be based on sound scientific principles.
- **Protocol Adherence**: Trials must be conducted according to a predefined protocol.
- **Responsibilities**: Clearly defined responsibilities for sponsors, investigators, and monitors.
- **Quality Assurance**: Implementation of systems for data integrity and safety.

5. Roles and Responsibilities
6. Essential Documents:
    - Investigator's Brochure (IB)
    - Clinical Trial Protocol
    - Informed Consent Form (ICF)
    - Case Report Forms (CRFs)
    - Trial Master File (TMF)
7. ICH-GCP E6 (R2) Update Highlights

Interactive Session Highlights:

The session included case scenarios and MCQs to test the understanding of ICH-GCP principles. Participants actively engaged with questions related to consent documentation, adverse event reporting, and protocol deviations.

Dr Bindu Dey Taking session on ICH-GCP Guidelines (International Council for Harmonisation – Good Clinical Practice

"Dr. Bindu Dey empowers students to uphold international standards in clinical trials through ICH-GCP training."

Day-19

Session 1:

Topic: **Indian Perspective of Clinical Research**
Date: 30th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30
Objective of the lecture:
The lecture on "Indian Perspective of Clinical Research" provided a comprehensive overview of how clinical research is evolving in India. The speaker emphasized the increasing global interest in India as a hub for clinical trials due to its diverse population, skilled medical professionals, and cost-effectiveness. The session highlighted historical milestones, current trends, regulatory frameworks, ethical concerns, and future directions of clinical research in the Indian context.

Key Points Discussed
1. Historical Background

- Clinical research in India has its roots in traditional systems of medicine (Ayurveda, Unani).

- The modern framework started gaining traction post-2005 with India's acceptance of ICH-GCP guidelines.

2. Current Landscape

- Approximately 1000+ trials are registered yearly with the Clinical Trials Registry - India (CTRI).

3. Regulatory Framework

- *Key regulatory bodies:*
  - Drugs Controller General of India (DCGI)
  - Indian Council of Medical Research (ICMR)
  - Central Drugs Standard Control Organization (CDSCO)
- Ethics Committees are mandatory and must be registered.
- New Drugs and Clinical Trials Rules, 2019, improved transparency, subject safety, and ethical standards.

4. Ethical Considerations
5. Challenges in Indian Clinical Research
6. Opportunities and Strengths
7. Future Outlook

Feedback from Participants

- Participants appreciated the detailed and structured overview of the Indian clinical research environment.
- The real-life examples and case studies shared by the speaker made the session engaging.

Dr Manisha Sharma taking session on Indian Perspective of Clinical Research

"A detailed lecture on the nuances of clinical research in India by Dr. Manisha Sharma."

Session 2:

Topic: **Basics of MS PowerPoint Presentation**
Date: 30th July 2025
Venue: Computer Laboratory, Department of Clinical Research, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Ms. Pooja Kandari, Office Assistant, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objectives of the Lecture:
The lecture on "Basics of MS PowerPoint Presentation" aimed to introduce participants to the fundamental concepts and functionalities of Microsoft PowerPoint. The session focused on enabling students and professionals to create impactful and well-structured presentations for academic, research, and professional purposes.

Key Points Covered
1. Introduction to Microsoft PowerPoint
2. User Interface Overview
    - Ribbon Interface: Home, Insert, Design, Transitions, Animations, Slide Show, Review, View.
    - Slide Pane: Shows the currently selected slide.
    - Notes Section: For speaker notes.
    - Slides Tab: Displays thumbnail versions of all slides.
3. Creating a Presentation
4. Working with Text and Images
5. Slide Design and Themes

6. Transitions and Animations
7. Inserting Multimedia
8. Running the Slide Show
9. Saving and Sharing

Tips for Effective Presentations

- Keep slides simple and uncluttered.
- Use bullet points instead of long paragraphs.
- Choose appropriate font sizes and colors for readability.
- Avoid overusing animations and transitions.
- Practice and rehearse the presentation before delivering.

Feedback and Outcomes

- Participants found the session highly informative and interactive.
- Hands-on demonstration helped in better understanding of concepts.
- Requested follow-up workshops on advanced PowerPoint techniques including data visualization and infographic design.

Ms Pooja teach students about Basics of MS PowerPoint Presentation

"Ms. Pooja introduces students to the fundamentals of creating effective MS PowerPoint presentations."

Session 3:

Topic: **Understanding Plagiarism in Research and Hands-on Turnitin Software**
Date: 30th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. AK Srivastava, Professor, Department of Community Medicine, HIMS, SRHU
No. of Participants: 30

Introduction
This lecture session was conducted to provide participants with an in-depth understanding of plagiarism in research and hands-on experience with Turnitin software, a widely used tool for plagiarism detection. The objective was to promote academic integrity, responsible writing, and ethical publishing practices among researchers and students.

Part 1: Understanding Plagiarism in Research
1. Definition and Concept
2. Types of Plagiarism
    - Direct plagiarism – Copying text word-for-word without citation.
    - Self-plagiarism – Republishing one's own work without acknowledgment.
    - Mosaic plagiarism – Mixing copied phrases from various sources.
    - Accidental plagiarism – Due to improper citation or lack of paraphrasing skills.
3. Consequences of Plagiarism
4. UGC and Institutional Policies
5. Avoiding Plagiarism

Part 2: Hands-on Training on Turnitin Software

1. Introduction to Turnitin
2. Key Features Demonstrated
3. Live Demonstration
4. Tips for Effective Use

Participant Feedback

- Participants found the session highly interactive and insightful.
- The Turnitin demonstration clarified several doubts about interpreting the similarity index.
- Attendees suggested including sessions on reference management tools such as Zotero or Mendeley as a follow-up.

Dr AK Srivastava taking session on Understanding Plagiarism in Research and Hands-on Turnitin Software

"Dr. AK Srivastava guides students on avoiding plagiarism and ensuring research authenticity."

Session 4:

Topic: **Effective Team Meetings**
Date: 30th July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mrs Diksha, C-PACE, SRHU
No. of Participants: 30

Introduction

The lecture on *Effective Team Meetings* aimed to provide practical strategies for planning, conducting, and following up on meetings in team-based environments. The session highlighted the importance of communication, collaboration, and clarity in ensuring productive and goal-oriented meetings, especially in academic, healthcare, corporate, and research settings.

Key Points Discussed

1. Importance of Effective Team Meetings

- Ensures alignment of goals and responsibilities among team members.
- Facilitates open communication and idea exchange.

- Promotes accountability, transparency, and timely decision-making.
- Reduces confusion and improves overall productivity.

2. Planning the Meeting

- Define clear objectives: What do you want to accomplish?
- Create an agenda: Prioritize key topics and allocate time slots.
- Invite the right participants: Involve stakeholders who can contribute meaningfully.
- Distribute materials in advance: Helps attendees come prepared.

3. Conducting the Meeting

- Start and end on time: Respect participants' schedules.
- Appoint a moderator/facilitator: Keeps the discussion focused.
- Encourage participation: Give every member a chance to voice opinions.

4. Post-Meeting Activities

- Circulate minutes: Include key discussions, decisions, and responsibilities.
- Follow-up on action items: Monitor progress and hold members accountable.
- Seek feedback: Ask for suggestions to improve future meetings.

Interactive Segment

- Participants were divided into small groups and conducted a mock team meeting on a selected project topic.
- Each group practiced:
  - Setting an agenda
  - Assigning roles (leader, timekeeper, note-taker)
  - Discussing goals and tasks
  - Groups reflected on what went well and what could be improved.

Mrs Diksha Teach student about Effective Team Meetings

"Group photo celebrating the successful completion of today’s insightful session."

Day-20

Session 1:

Topic: **Proceeding a Manuscript**
Date: 31st July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Abha Srivastava, Professor and Head, Department of Physiology, HIMS, SRHU
No. of Participants: 30

Objective of the lecture:
The lecture on "Proceeding a Manuscript" aimed to guide students and researchers through the step-by-step process involved in preparing and submitting a scientific manuscript for publication. The session was tailored to enhance participants' understanding of manuscript structure, formatting requirements, journal selection, submission processes, and post-submission communication with editors and reviewers.

Key Points Covered:
1. Understanding the purpose of a manuscript
2. Preparing the Manuscript:

- **Topic:** Should be concise, informative, and reflect the core idea of the paper.
- **Abstract:** A brief summary of the objective, methods, results, and conclusions.

- **Keywords:** Select 4–6 keywords for indexing and discoverability.
- **Introduction:** Provides context, identifies gaps, and states the study objective.
- **Materials and Methods:** Details study design, data collection, and analysis to ensure reproducibility.
- **Results:** Presents findings with appropriate tables and figures.
- **Discussion:** Interprets results, compares with previous studies, and states limitations.
- **Conclusion:** Summarizes the key findings and implications.
- **References:** Citing sources as per the journal's formatting style (e.g., Vancouver, APA).

3. Selecting a Target Journal
4. Manuscript Submission Process
5. Peer Review and Revision
6. Ethical Considerations

Interactive Session:

The session concluded with a Q&A round where participants raised practical queries regarding journal selection, handling rejections, plagiarism checking tools (like Turnitin), and predatory journals. Live examples and templates for cover letters and response to reviewers were demonstrated.

"Dr. Nikku Yadav presents a token of appreciation to Dr. Abha Srivastava in recognition of her valuable contributions."

Dr Abha taking session on Proceeding a Manuscript

Session 2:

Topic: **Understanding Literature Review**
Date: 31st July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Yogindra Singh, Professor and Head, Central Library, HIMS, SRHU
No. of Participants: 30

Objectives of the lecture:
The lecture on "Understanding Literature Review" aimed to provide students, early-career researchers, and academicians with a clear understanding of what a literature review is, its importance in the research process, and how to effectively conduct and write one. The session emphasized both theoretical concepts and practical strategies.

Key Points Covered:
1. Definition and Purpose of a Literature Review
2. Types of Literature Reviews:
    - **Narrative Review:** Qualitative summary without a systematic approach.
    - **Systematic Review:** Structured method for identifying, evaluating, and synthesizing all relevant studies.
    - **Scoping Review:** Explores the breadth of literature without assessing the quality.
    - **Meta-analysis:** Quantitative synthesis of results from multiple studies.
3. Key Functions of a Literature Review
4. Steps in Conducting a Literature Review:

- Define the Research Question or Topic.
- Identify Keywords and Search Terms.
- Search Academic Databases (e.g., PubMed, Scopus, Google Scholar, JSTOR).
- Select Relevant Literature based on inclusion/exclusion criteria.

5. Tools and Resources:
   - **Reference managers**: Zotero, Mendeley, EndNote.
   - **Plagiarism checkers**: Turnitin, Grammarly.
   - **Note-taking tools**: Notion, OneNote, Research Rabbit.
6. Writing the Literature Review:
   - **Introduction:** Explain the scope and purpose.
   - **Main Body:** Group studies by theme, methodology, or chronology.
   - **Conclusion:** Highlight gaps, contradictions, and research opportunities.
7. Common Mistakes to Avoid

Interactive Segment:

Participants were guided through a live demonstration of conducting a basic literature search using PubMed and Google Scholar. The speaker also provided templates for organizing literature and example excerpts from well-written reviews. Questions about review length, language clarity, and inclusion of grey literature were addressed.

Prof Yogindra Singh taking session on: Understanding Literature Review

"Building research foundations: Prof. Yogindra Singh's session on understanding literature reviews."

Session 3:

Topic: **Women in Indian Society**
Date: 31st July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mrs. Manju Nautiyal, PDP trainer, SRHU
No. of Participants: 30
Introduction:
The lecture on "Women in Indian Society" offered an insightful exploration of the evolving role, status, contributions, and challenges faced by women in India. The speaker discussed the subject from historical, cultural, socio-economic, and legal perspectives, emphasizing both progress and persisting gender disparities.

Key Points Covered:
1. Historical Perspective:
- In ancient India, women were respected and enjoyed considerable freedom in Vedic society.
- The medieval period witnessed the emergence of regressive practices like purdah, child marriage, and Sati.

2. Role of Women in Modern India:
- With the rise of reform movements in the 19th and 20th centuries (e.g., by Raja Ram Mohan Roy, Ishwar Chandra Vidyasagar), there was renewed advocacy for women's education and rights.
- Women played vital roles during the freedom struggle (e.g., Rani Lakshmi Bai, Sarojini Naidu, Kasturba Gandhi).

3. Current Status and Achievements:
    - Legal safeguards such as:
    - The Hindu Succession Act (2005 Amendment) for property rights.
    - Beti Bachao, Beti Padhao campaign.
4. Persistent Challenges:
    - Gender-based violence (domestic violence, dowry, sexual harassment).
    - Gender discrimination in wages, promotions, and employment opportunities.
5. Role of Education and Awareness:
    - Education as a tool of empowerment and self-reliance.
    - Importance of gender sensitization in schools and media.

Interactive Session:

The session concluded with an engaging Q&A. Students raised questions about the implementation of women's safety laws, the gender pay gap, and the importance of women's voices in rural governance. The speaker emphasized collective responsibility and encouraged youth to be change-makers in their communities.

Mrs Manju Nautiyal Taking session on Women in Indian Society

"An insightful session on women's contributions and challenges in India by Mrs. Manju Nautiyal."

Session 4:

Topic: **Good Laboratory Practices**
Date: 31st July 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Introduction:
The lecture on Good Laboratory Practices (GLP) provided an in-depth understanding of standardized principles that govern non-clinical laboratory studies to ensure the generation of reliable, high-quality, and reproducible data. The focus was on maintaining integrity, accountability, and traceability in laboratory environments—critical for research, testing, and regulatory submissions.

Key Points Covered:

1. Definition and Origin of GLP:
2. Objectives of GLP:
    - To promote standardization of processes across laboratories.
    - To ensure accurate documentation, reporting, and reproducibility.
    - To meet regulatory requirements for preclinical safety studies of drugs, chemicals, and cosmetics.
4. Fundamental Principles of GLP:

- Organization and Personnel: Clear roles, responsibilities, and training for all laboratory staff.
- Standard Operating Procedures (SOPs): Detailed written instructions for consistent execution of all procedures.
- Study Protocols: Well-defined study plans, approved before initiation.
- functioning correctly.
- Sample and Test Item Management: Proper labelling, storage, and tracking to maintain integrity.

4. Importance of GLP in Research and Industry
5. GLP vs GCP vs GMP
6. GLP in the Indian Context

Interactive Session:

The session involved case examples of GLP non-compliance and how they led to regulatory delays or rejections. Students were asked to identify errors in mock lab reports and suggest GLP-compliant practices. The speaker encouraged discussion on the ethical implications of non-compliance.

Dr Manisha Sharma taking session on Good Laboratory Practices

"Ensuring quality and compliance—Dr. Manisha Sharma's session on Good Laboratory Practices

Session 5:

Topic: **Graphical Representation using MS Excel**
Date: 31st July 2025
Venue: Computer Laboratory, Department of Clinical Research, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Faculty coordinator: Mrs. Akanksha Uniyal, Lecturer, Department of Biostatistics, HIMS, SRHU and Mrs Pooja Kandari, Office Assistant, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objectives of the Activity:
The objective of this hands-on activity was to provide participants with practical knowledge and skills for creating and interpreting various types of graphical representations using Microsoft Excel. The session aimed to enhance data visualization abilities for academic, research, and professional applications.

Activity Summary:
1. Introduction to Graphical Representation
2. Overview of MS Excel Features:
    - Introduction to Excel interface: Ribbon, Chart Tools, Insert Tab.
    - Quick tips on formatting cells, entering data, and organizing datasets.
3. Types of Graphs Created:

Participants practiced creating the following graphs using sample datasets:

- Bar Chart: Used to compare categories (e.g., sales by region).

- Column Chart: For displaying data in vertical bars.
- Line Graph: Ideal for showing trends over time.
- Pie Chart: Representing proportions or percentages of a whole.
- Scatter Plot: To show relationships between two variables.
- Histogram: For frequency distribution of continuous data.

4. Step-by-Step Demonstration:

- Entering and organizing data in rows and columns.
- Selecting the appropriate chart type from the Insert tab.
- Customizing chart elements

Learning Outcomes:

By the end of the activity, participants were able to:

- Choose the appropriate chart type based on data characteristics.
- Create and customize various charts in MS Excel.

Feedback from Participants:

- Majority found the session highly interactive and informative.
- Requested more sessions on advanced Excel functions like conditional formatting, dashboards, and statistical tools.
- Appreciated the real-time practice with sample datasets.

Mrs Akanksha and Ms Pooja taking session on Graphical Representation using MS Excel

"A collaborative session on creating impactful graphs in MS Excel led by Mrs. Akanksha and Ms. Pooja."

Day – 21

Session 1:

Topic: **Introduction and Hands on Jamovi software**
Date: 1 Aug 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. AK Srivastava, Professor, Department of Community Medicine, HIMS, SRHU
No. of Participants: 30

Objectives of the Session

- To introduce the core features and interface of Jamovi software
- To demonstrate basic statistical procedures using Jamovi
- To enable participants to perform data analysis through hands-on practice
- To foster an understanding of interpreting outputs and generating reports

Topics Covered

a. Introduction to Jamovi
b. Data Management in Jamovi
c. Descriptive Statistics
d. Inferential Statistics
e. Regression Analysis
f. Exporting Results

Hands-on Activities

Participants were guided through a live demonstration using a sample dataset. Key activities included:

- Importing data and recoding variables
- Running descriptive analyses and interpreting tables
- Conducting a paired t-test to compare pre- and post-intervention scores
- Creating publication-ready graphs

Participants practiced each activity on their own systems with support from the instructor and assistants.

Interactive Q&A and Discussion

The session concluded with an interactive Q&A segment where participants clarified doubts related to:

- Using Jamovi for thesis or dissertation data
- Limitations compared to SPSS or R

Feedback and Takeaway

Participants expressed appreciation for the clear, hands-on teaching approach. Many found Jamovi to be a practical and accessible alternative to proprietary statistical software. The session encouraged attendees to further explore Jamovi's advanced modules like mediation analysis, factor analysis, and reliability testing.

Dr Nikku offering the token of appreciation to Dr AK Srivastava

Dr AK Srivastava taking session on Introduction and Hands on Jamovi software

Session 2:

Topic: **Understanding Plagiarism and Hands-on Experience with Turnitin Software**
Date: 1st August 2025
Venue: Training and Development room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mr. Ayushman Srivastav, Assistant Registrar, Research and Development cell, HIMS, SRHU
No. of Participants: 30

Objectives of the Session

- To define and explain plagiarism and its types
- To educate on ethical writing and citation practices
- To introduce Turnitin software as a plagiarism detection tool
- To provide hands-on training in using Turnitin for checking similarity reports
- To interpret Turnitin results and improve academic writing

Key Topics Covered

a. Understanding Plagiarism
b. Avoiding Plagiarism
c. Introduction to Turnitin Software

Hands-on Experience with Turnitin

Participants were guided through a live demonstration of Turnitin:

- Logging into the Turnitin portal
- Uploading a document for similarity check
- Understanding the Turnitin dashboard
- Interpreting the Similarity Index (percentage and colour codes)
- Reviewing matched sources and flagged content
- Downloading and saving the similarity report

Interactive Discussion and FAQs

Key questions addressed:

- What percentage of similarity is considered acceptable?
- Can Turnitin detect translated or paraphrased plagiarism?
- How to reduce similarity without altering the meaning?

Differences between Turnitin and free online plagiarism checkers

Feedback and Takeaways

Participants appreciated the interactive and practical approach of the session. They expressed increased awareness of ethical research practices and gained confidence in using Turnitin effectively. The session served to dispel myths about plagiarism and promoted responsible academic writing.

Dr Nikku Yadav offering the token of appreciation to Mr Ayushman Srivastav

Mr Ayushman taking session on Understanding Plagiarism and Hands-on Experience with Turnitin Software

DAY-22

Session 1:

Topic: **Clinical Trial Centre, Swami Rama Himalayan University**
Date: 1st August 2025
Venue: Clinical Trial Centre, Cancer Research Institute, Swami Rama Himalayan University
Organized by: Department of Clinical Research, HIMS, SRHU
Accompanying Faculty: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objective of the Visit
The main objective of the educational visit was to familiarize students with the real-world functioning of a Clinical Trial Centre and to provide practical exposure to key software platforms used in clinical research, including:

- **IMPALA** (Integrated Management Platform for Academic and Laboratory Activities)
- **IWRS** (Interactive Web Response System)
- **Sand Dunes** (Clinical Data Management Software)

Demonstration of Software Tools

a. IMPALA

- IMPALA was introduced as a platform used for clinical documentation, data capture, and workflow management.

- The speaker demonstrated how researchers can create case report forms (CRFs), enter subject data, and track visit schedules.

b. IWRS (Interactive Web Response System)

- IWRS was explained as a randomization and trial supply management tool used in multicentric trials.
- The instructor demonstrated how subjects are enrolled and randomized to different study arms.

c. Sand Dunes

- This software was showcased as a clinical data management system (CDMS).
- Key features like query management, discrepancy resolution, data cleaning, and locking were covered.

Interactive Session

Students were encouraged to ask questions during and after the demonstration. Discussions included:

- Role of software in minimizing human error
- How data security and confidentiality are maintained

Feedback and Suggestions

- Students appreciated the structured demonstrations and clarity of explanations.
- Many expressed interest's in future hands-on workshops on these platforms.

A Visit to Clinical Trial Centre, Swami Rama Himalayan University

Students learn there about different software

Day -23

Session 1:

Topic: **Introduction and Hands-on Training on SPSS Software Version 30**
Date: 4th August 2025
Venue: Computer Lab, Department of Clinical Research, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mr. Abhinav Bahuguna, Lecturer, Department of Biostatistics, HIMS, SRHU
No. of Participants: 30

Objectives of the Session

- To introduce the basic features and interface of SPSS v30
- To provide training on data entry, management, and basic statistical analysis
- To develop skills in interpreting outputs and generating charts
- To promote data-driven thinking and analytical capabilities in research

Lecture Highlights

a. Introduction to SPSS

- Overview of SPSS and its applications in various fields
- What's new in SPSS version 30 (updated UI, syntax enhancements, new analytical procedures)
- Key windows: Data View, Variable View, Output Viewer, Syntax Editor

b. Data Handling

- Creating a new dataset: defining variables, value labels, and measurement scales
- Importing data from Excel and CSV formats

- Managing missing values and recoding variable.

c. Descriptive Statistics

- Running frequency tables, mean, median, mode, standard deviation
- Cross-tabulation and graphical summaries: pie charts, histograms, boxplots

d. Inferential Statistics

- Conducting t-tests (One-sample, Independent, Paired)
- Chi-square tests for categorical data
- Correlation and bivariate analysis
- One-way ANOVA with post hoc tests

e. Report Generation

- Customizing tables and exporting to Word/PDF
- Creating graphs suitable for publication
- Introduction to syntax for reproducibility

Hands-on Activity

After the theoretical session, students participated in a structured hands-on exercise using SPSS Version 30 in the computer lab. Activities included:

- **Task 1:** Creating a sample dataset (10 variables, 20 entries)
- **Task 2:** Running descriptive statistics and interpreting the output
- **Task 3:** Performing an independent samples t-test
- **Task 4:** Generating a correlation matrix and scatter plot
- **Task 5:** Exporting the output to a formatted report

Students worked in pairs and received individual assistance as needed. Sample data related to public health and education were used to simulate real-world scenarios.

Outcomes and Observations

- Students demonstrated improved understanding of statistical concepts through application.
- They gained practical skills in data entry, manipulation, and analysis using SPSS.
- Participants learned to interpret tables, charts, and p-values effectively.
- The interactive structure of the workshop promoted collaborative learning and problem-solving.

Feedback

- Students appreciated the clarity of explanation and simplicity of software interface.
- Many requested follow-up sessions on advanced techniques like regression, factor analysis, and non-parametric tests.
- Participants expressed interest in using SPSS for their thesis and project work.

Conclusion

The session on **SPSS Software Version 30** was a successful blend of theory and practice. It enabled students to explore one of the most important statistical tools used in research, enhancing both their analytical and technical competencies. This training contributes meaningfully to academic excellence and research preparedness.

Mr Abhinav Bahuguna taking session on Introduction and Hands-on Training on SPSS Software Version 30.

"Building data analysis skills with practical SPSS training by Mr. Abhinav Bahuguna."

Day- 24

Session 1:

Topic: **Introduction and Hands-on Training on GraphPad Software**
Date: 5th August 2025
Venue: Computer Lab, Department of Clinical Research, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Mrs. Akanksha Uniyal, Lecturer, Department of Biostatistics, HIMS, SRHU
No. of Participants: 30

Objectives

- To introduce the features and applications of GraphPad software in research.
- To demonstrate the process of data entry, analysis, and result interpretation.
- To train participants in generating publication-quality graphs.
- To enhance skills in statistical test selection and execution using the software.

Session Highlights

1. Introduction to GraphPad Prism

The resource person provided an overview of the software's capabilities, including:

- Data organization in table formats.
- Built-in statistical analyses (t-tests, ANOVA, regression, non-parametric tests, etc.).
- Customizable graphing options for scientific publications.

- Integration of results and graphs into reports.

2. Navigating the Interface

Participants were introduced to the dashboard, menu options, and the workflow from data entry to output. The speaker demonstrated how to select the appropriate data table format depending on the type of experiment (e.g., XY, Column, Grouped, Contingency).

3. Statistical Analysis

The trainer explained:

- Selection of the correct statistical test based on study design.
- Setting significance levels and interpreting p-values.
- Understanding confidence intervals and error bars.

4. Graph Creation and Customization

Participants learned to:

- Create bar charts, scatter plots, line graphs, and survival curves.
- Customize axis labels, legends, and colour schemes.
- Export graphs in high-resolution formats for publications and presentations.

5. Hands-on Training

The session included practical exercises where participants:

- Entered sample datasets into GraphPad.
- Performed descriptive and inferential statistics.
- Generated and edited graphs to represent their results effectively.

6. Troubleshooting and Tips

The resource person shared common mistakes to avoid, keyboard shortcuts, and tips for efficient workflow.

Outcome of the Session

By the end of the session, participants were able to:

- Confidently navigate the GraphPad interface.
- Choose and execute appropriate statistical tests.
- Interpret the statistical output correctly.
- Create high-quality, publication-ready graphs.

Feedback

Participants appreciated the balance between theory and practice. Many noted that the hands-on component significantly improved their understanding of the software's application in their ongoing research projects.

Mrs Akanksha teaching students about Introduction and Hands-on Training on GraphPad Software

"Mrs. Akanksha leads an introductory and hands-on training session on GraphPad software.

Day -26

Session 1:

Topic: **Introduction and Hands-on Training on GraphPad Software**
Date: 6th August 2025
Venue: Training and Development Room, HIMS, SRHU
Organized by: Department of Clinical Research, HIMS, SRHU
Speaker: Dr. Nikku Yadav, Associate Professor, Department of Clinical Research, HIMS, SRHU
No. of Participants: 30

Objectives

- To introduce the features and applications of orange software in data analysis.
- To demonstrate the workflow creation process for data exploration and modelling.
- To train participants in visualizing datasets and interpreting analytical results.
- To provide hands-on experience in using Orange for machine learning tasks.

Session Highlights

1. Overview of Orange Software

The resource person began with a presentation on:

- The history and development of Orange.
- Key features such as visual programming, widget-based workflows, and machine learning integration.
- Areas of application in research, healthcare analytics, and education.

2. Navigating the Interface

Participants were introduced to the orange canvas, widget toolbox, and workflow editor. The trainer explained the different categories of widgets, including:

- Data (loading, saving, and editing datasets).
- Visualize (scatter plot, box plot, heatmap, etc.).
- Model (classification, regression, clustering).
- Evaluate (model comparison and performance metrics).

3. Data Analysis Workflow

The session covered:

- Importing datasets from local files and online repositories.
- Data pre-processing (filtering, feature selection, normalization).
- Visual data exploration techniques.

4. Machine Learning Models

Participants learned to:

- Apply classification algorithms (Decision Trees, Naïve Bayes, Logistic Regression).
- Perform clustering using k-means and hierarchical clustering.
- Evaluate models using confusion matrices, ROC curves, and accuracy metrics.

5. Hands-on Exercises

Practical exercises included:

- Building a workflow for data cleaning and visualization.
- Training and testing models on a sample dataset.
- Comparing model performances to select the best approach.

5. **Tips and Best Practices**

   The trainer shared recommendations for workflow optimization, proper dataset preparation, and result interpretation.

Outcome of the Session

By the end of the training, participants were able to:

- Navigate the Orange interface with ease.
- Build complete data analysis workflows using drag-and-drop widgets.
- Visualize datasets and apply machine learning models.
- Interpret model outputs and performance metrics.

Feedback

Participants expressed enthusiasm about the simplicity and flexibility of Orange. They appreciated the visual approach to data analysis, which made understanding machine learning concepts easier.

Dr Nikku Yadav taking session on Introduction and Hands-on Training on GraphPad Software

"Dr. Nikku Yadav teaches practical skills on GraphPad software to students."

Day - 27

Valedictory Ceremony of the 5-Week Training Program on "Ensuring Integrity in Healthcare: Good Clinical Practice and Medical Ethics"

Date: 7th August 2025

Venue: Sushruta Lecture Theatre-1

Participants: 47 Students & Faculty 25

Organized by: Department of Clinical Research, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University.

The Department of Clinical Research, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, successfully concluded its 5-week training program Topic **"Ensuring Integrity in Healthcare: Good Clinical Practice and Medical Ethics."** The program was generously sponsored by the **Department of Health Research, Ministry of Health and Family Welfare, Government of India.**

The **Valedictory Ceremony**, held with great enthusiasm and reverence, marked the culmination of an intensive and enriching learning journey. The event was graced by the presence of distinguished dignitaries, faculty members, and enthusiastic participants.

This comprehensive training program offered a total of **43 insightful lectures** spanning over **92 hours**, delivered by more than twenty-five esteemed experts from the fields of clinical research, bioethics, regulatory affairs, biostatistics, and medical sciences. In addition to theoretical learning, the program emphasized practical skill development through **23 hands-on activities** totalling **46 hours**.

A unique highlight of the program was the **12-hour hands-on demonstration experience** conducted across some of the university's most prestigious departments and centres. These included the **School of Yoga Sciences, Ayurveda Centre, Clinical Trial Centre, Himalayan Hospital, the Himalayan Centre for Innovation and Entrepreneurship,** and the **Skills and Simulation Centre.** These sessions provided participants with an immersive understanding of ethical and good clinical practices in real-world healthcare and research settings.

The ceremony featured an inspiring **address by Dr. Bindu Dey**, Director of Research, SRHU, and heartfelt **blessings by Lt. Gen. Dr. Daljit Singh**, Dean cum Principal of the Himalayan Institute of Medical Sciences. Their words motivated participants to carry forward the values of integrity and ethics in their professional journeys.

The event also included certificate distribution to all participants and acknowledgment of the resource faculty for their valuable contributions. In addition, awards were presented to students who excelled in the **Treasure Hunt** and **Business Idea activity**, recognizing their creativity, teamwork, and problem-solving skills.

A special video presentation showcased the journey of the participants throughout the five weeks, capturing their learning moments, collaborative efforts, and feedback.

The event concluded on a patriotic and celebratory note with the chanting of the National Anthem, followed by a group photograph and a warm high tea, marking the end of a successful and impactful training program.

Dr. Bindu Dey addressing the audience

Lt. Gen Dr. Daljeet Singh blessing the audience

Students collecting their Certificates

A group photograph of all the resource persons

Group photograph featuring all the participants, resource faculties and dignitaries involved in the successful completion of the 5-week training program

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