Exploring Clinical Research: Foundations and Practical Applications

Wednesday, 25 June 2025 - Wednesday, 25 June 2025

Scientific Programme

Exploring Clinical Research: Foundations and Practical Applications

As the landscape of healthcare continuously evolves, the demand for awareness about the importance of clinical research in society is more essential than ever. This workshop aims to provide university students with a comprehensive understanding of the clinical research process, from drug development to the regulatory framework guiding clinical trials. It is designed to offer a structured and educational opportunity, bringing together key concepts and practical insights that will enhance students academic and professional journeys.

Format:
• Duration: 1 full day (3-4 hours per module)
• Methodology: Interactive sessions combining lectures, group discussions, case studies, and hands-on activities to encourage student engagement and practical understanding.
• Target Audience: University students in health sciences, pharmacy, biomedical engineering, and related fields.

Module 1: The Drug Development Process and Study Design

Learning Outcomes:
Participants will be able to:
• Outline and critically appraise the different phases and landmarks in drug development from target identification to market license.
• Explain the general purpose and concept of each phase in clinical development.
• Critically appraise different types of study designs and assess their pros and cons.
Topics Covered:
1. The Drug Development Process
o Overview and significance of drug development
2. Drug Discovery
o Mechanisms and methodologies in discovering new drugs
3. Manufacturing Issues
o Challenges in drug production and quality control
4. Pre-clinical Studies
o Importance of safety and efficacy testing before clinical trials
5. Phases of Clinical Development
o Detailed exploration of Phase I-IV studies
6. Study Types and Designs
Comparative analysis of study designs: RCTs, cohort studies, case-control studies, etc.

Module 2: Ethics, Regulations, and Practical Aspects of Clinical Studies

Learning Outcomes:
Participants will be able to:
• Outline the structure and contents of the Good Clinical Practice guideline (ICH-GCP) (specifically, the Human Research Act (HRA) and related ordinances).

• Appraise the roles and responsibilities of different parties involved in the planning and conduct of clinical studies.
• Demonstrate knowledge of the requirements for the structure and content of a study protocol and appraise its importance in a clinical study.
• Explain the requirements for clinical study documentation according to regulations and guidelines.
• Define and appraise the principles of the informed consent process.
• Outline the content of a Quality Management System in a clinical study.
• Understand the basic principles of effective planning of a clinical study.

Topics Covered:

1. Ethics, Laws, and Regulations
o Overview of ICH-GCP guidelines
2. Roles and Responsibilities
o Identifying key stakeholders in clinical research and their duties
3. The Study Protocol
o Requirements and importance of a well-structured study protocol
4. Study Documentation
o Compliance with documentation standards and best practices
5. Informed Consent
o Overview of the informed consent process and ethical considerations
6. Quality Management
o Elements of a Quality Management System in clinical studies
7. Getting Ready
o Strategies for effective planning and execution of clinical studies