



**University
of Basel**

Faculty of
Medicine



Ethical and Legal Aspects of Clinical Trials

University of Basel
Basel, Switzerland
November 16–18, 2020



European Center of Pharmaceutical Medicine

ADVANCED STUDIES

Course Description

The implementation of clinical research projects requires a thorough review of both scientific quality and ethical adequacy. The importance of ethics for research and overall drug development is reflected in institutional, national, and international principles and guidelines.

During our course, representatives from various institutions will explain the main concepts and methods to address ethical issues. Real-world examples and case studies support the understanding and transfer of theoretical concepts into the clinical research environment.

Learning Outcomes

By the end of the course, students will be able to:

- Name key principles of ethical considerations during clinical research and development
- Discuss ethical concerns for designing, conducting and reporting of clinical trials
- Understand international and national principles and guidelines as basis to perform clinical trials

Target Audience

All pharmaceutical and health care professionals who are interested in getting a deeper understanding of ethical and legal aspects in medicines development.

Program

Monday, November 16, 2020

- The Evolution of Biomedical Research Ethics
- Risk-Benefit Considerations of Research Interventions
- Role of Ethics Committees
- Successful Submission to an Ethics Committee
- Coordinating Human Research in Switzerland
- How to Design an Informed Consent
- Ethical Review Systems in Europe and European Legislation
- Ethics Committees' Role in Reviewing Safety Information

Tuesday, November 17, 2020

- Equipoise
- Ethical Issues in Big Data Research
- ICH E6 Regulation
- Confidentiality and Intellectual Property
- Personal Data Protection
- Inducement in Clinical Research – from Recruitment
- Advertisement to Subject Compensation
- Role of Patient Organisations in Clinical Trials (EUPATI)
- Legal and Ethical Framework for Genetic Testing

Wednesday, November 18, 2020

- Ethical Aspects of Clinical Research in Children
- Informed Consent Process in Pediatric Patients
- Clinical Research in Vulnerable Populations
- Misconduct and Fraud, Research Integrity
- Ethical Issues in Big Data Research
- Legal and Ethical Framework for Genetic Testing
- Public Health Aspects of Genetic Testing and Biobanks
- Swiss Personalised Health Network

Credits

2 ECTS

Organization

ECPM

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Registration

www.ecpm.ch or www.ecpm.ch/ethical/

Deadline for registration: October 15, 2020

Registration Fee

CHF 2000; for academia and NGOs a reduced fee is applied

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