University of Basel

Faculty of Medicine

Ethical and Legal Aspects of Clinical Trials

Advanced Studies
Steinengraben 22
Basel, Switzerland
November 12–14, 2018

ECPM®
European Center of Pharmaceutical Medicine

ADVANCED STUDIES

Course Description

The implementation of clinical research projects requires conscientious review of research projects not only in terms of their scientific quality but also in regard to their ethical adequacy and appropriateness. How can we balance the risk benefit of our projects? Given the importance of ethics for the conduct of drug development and research, it should come as no surprise that many different professional associations, government agencies, and universities have adopted specific codes, rules, and policies relating to research ethics.

Each of these aspects will be carefully considered and discussed in the context of international and national principles and guidelines. These issues need to be carefully adhered to strengthen the health of the clinical trial enterprise to the benefit of patients and the overall health of the public. During our course, representatives from different institutions will introduce and discuss the most important concepts, tools, principles, and methods that can be useful in approaching and resolving ethical dilemmas. Realworld examples and case studies will be introduced and discussed.

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 the results obtained through the conduct of clinical trials
- Understand international and national principles and guidelines which have to be followed when performing clinical trials

Target Audience

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

Programme

Monday, November 12, 2018
The Evolution of Biomedical Research Ethics
Risk-Benefit Considerations of Research Interventions
Role of Ethics Committees
Successful Submission to an Ethics Committee
Role of Regulatory Authorities in Patient Protection
How to Design an Informed Consent
Ethical Review Systems in Europe and European Legal Framework
Ethics Committees' Role in Reviewing Safety Information

Tuesday, November 13, 2018
Equipoise
Transparency in Clinical Trials,
Common Technical Document
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)
Public Health Ethics (incl. biobanks)

Wednesday, November 14, 2018
Ethical Aspects of Clinical Research in Children
Informed Consent Process in Pedriatric Patients
Clinical Research in Vulnerable Populations
Misconduct and Fraud, Research Integrity
ICH E6 Regulation
Legal and Ethical Framework for Genetic Testing

Credits

2 ECTS

Organisation

ECPM
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E-mail ecpm@unibas.ch

Registration

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

Deadline for registration: October 19, 2018

Registration Fee

CHF 2000
CHF 1200 for university employees and nonprofit organisations
Fees include course material, coffee, and lunch

Cancellation

Refund of fee will be given if cancellation is received in writing before the deadline for registration, after this date no refund can be given.

Speakers are subject to change without notice.

Course Venue

Advanced Studies
Steinengraben 22
Basel, Switzerland

From Basel Bahnhof SBB / Swiss Railway Station:
Take bus no 30 (leaving in front of Confiserie Bachmann, direction Badischer Bahnhof) to „Steinenschanze“ (1 stop, 2 min).

From Basel Badischer Bahnhof / German Railway Station:
Take bus no 30 (direction Basel Bahnhof SBB) to „Steinenschanze“ (20 min).

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