**Clinical Trial Unit - Formazione**

# Ethical Issues in Biomedical Research

**Monday, November 28th, 2022**
Room A1.03 Campus EST USI
From 08:30 AM to 16:00 PM

## Teachers:

PD Dr. Marta **Fadda**, Lecturer of Bioethics, Faculty of Biomedical Sciences, Università della Svizzera italiana, Lugano
Dr. Pietro **Gervasoni**, Managing Director of Swissethics, Bern
Prof. Silvio **Garattini**, President and Founder of Mario Negri Institute, Milan
Tamara **Kohler**, Swiss Clinical Trial Organization
Dr. Valter **Torri**, Head of Laboratory, Mario Negri Institute, Milan
Dr. Rita **Banzi,** Center for Health Regulatory Policies, Mario Negri Institute, Milan

## Objectives:

The increasing knowledge in molecular biology and the development of the techniques for the evaluation of the biological processes and of their interaction have brought about, in preclinical and clinical research, what is called precision medicine, to select the treatment that works best for an individual.
The development of new therapeutic approaches raises many ethical issues, of which investigators' also and in particular at the preclinical level, should be aware of and take into consideration in their decisions and activities.
The objectives of this course are to increase this awareness of the ethical issues and of their potential impact in the selection and preclinical evaluation of new molecules, in the decision making process, in the care of patients and in the social environment.
In particular,

- in the active involvement of patients already at the beginning of the clinical project;
- in the planning and modalities of activation of clinical studies;
- in the selection of treatment, relationship and care of patients;
- in the collection of data and biological tissues;
- in the analysis, report, publication and sharing of data and results;
- in the registration, selling and marketing of therapeutic compounds in Europe;
- in the new aspects of biomedical research involving tissue cultures and human embryos.

## ETHICAL ISSUES PROGRAM – November 28th, 2022

| TIME | TITLE | CONTENT | TEACHER |
|---|---|---|---|
| **8h30-8h45**<br>15' | **Welcome and Introduction** | | *Prof. Dr. med. Dr phil. med. Alain Kaelin* |
| **8h45-9h30**<br>45' | **Introduction to biomedical research ethics** | 1. The core ethical principles of biomedical research<br>2. A preliminary understanding of the ethical and social justice issues in various aspects of biomedical research<br>3. A structured/systematic ethical analysis to real-world challenges in research | *PD Dr. Marta Fadda* |
| **9h30-10h15**<br>45' | **Ethics in human research** | 1. Basic:<br>• Ethics and law<br>• Ethical committees<br>• Ethical requirements<br>2. Consent:<br>• Informed consent<br>• General consent<br>• Comprehensibility<br>• Biobanks<br>3. Current challenges<br>• Data sharing<br>• Digitalisation<br>• Genetics<br>• Personalised medicine<br>• Artificial intelligence | *Dr. Pietro Gervasoni* |
| **10h15-10h30** | | | |
| **10h30-11h15**<br>90' | **Clinical research is not scientific if it is not ethical** | 1. Preclinical research<br>2. Clinical research<br>• Controlled clinical trials | *Prof. Silvio Garattini* |
| **12h00-13h00** | **LUNCH BREAK** | | |
| **13h00-13h45**<br>45' | **The ethics of patient and public involvement (PPI) in academic clinical research** | 1. The concept of PPI<br>2. Ethical considerations why patients and the public should be involved in academic clinical research.<br>3. Ethical principles in the performance of PPI | *Mrs. Tamara Kohler* |
| **13h45-14h30**<br>45' | **Ethical issues in the statistical analysis of clinical trials** | Ethical implications of statistical planning and analysis in clinical experimentation, focus on:<br>1. Key statistical aspects of design (randomization, choice of control group, use of placebo, type of comparison);<br>2. Statistical analysis (interim analysis, multiple tests, reporting of results). | *Dr. Valter Torri* |
| **14h30-14h45** | **BREAK** | | |
| **14h45-15h30**<br>45' | **Ethical issues in drug approval and marketing at the European level** | 1. Overview of the role and responsibilities of the European Medicines Agency<br>2. Ethical aspects in drug development and assessment (i.e., issues in pivotal trials and evaluation criteria)<br>3. Ethical issues and accountability (i.e., financing, transparency and data sharing, communication and engagement with the public) | *Dr. Rita Banzi* |
| **15h30-16h00**<br>30' | **General discussion with all participants** | | *All* |
| **16h00-16h30**<br>30' | **Summary** | | *All* |