



UNIVERSITÀ
DEGLI STUDI DI MILANO-BICOCCA

SYLLABUS DEL CORSO

Study design: Ethics, Regulatory and Statistical Aspects

2627-1002-04

Title

Study design: Ethics, Regulatory and Statistical Aspects

Teacher(s)

Statistical Aspects

Design of RCTs – 6h Maria Grazia Valsecchi

Early phase study design – 4h Stefania Galimberti

Biomarker based designs – 4h Andrea Callegaro

Sample Size Calculation – 4h Davide Bernasconi

Study PASS (Post Authorization Safety Study) and PAES (Post Authorization Efficacy Study) – 4h Domenico Criscuolo

Estimands – 2h Stefano Vezzoli

Bayesian designs – 4h Paola Berchiolla

Adaptive designs – 4h Federico Rotolo

Research Ethics

Fundamental ethics principles in research; Data governance and regulatory landscape (GDPR); issues and models related to data access / data sharing – 2h Luca Marelli

The Ethics and Law of Experiments on Animals; End of life issues and the rights of terminally ill patients – 2h Silvia Salardi

The role of Ethical Committees – 2h Maddalena Lettino

Regulatory Aspects

Regulatory aspects & legislations: the view of AIFA – 2h Sandra Petraglia

Good clinical practices – 2h Silvia Mori

Regulatory aspects & legislations: the view of pharma – 2h Maria Elena Trovati

Language

English

Short description

Statistical Aspects

To understand the different types of studies in clinical research: a translational approach from pre-clinical to clinical research.

Research Ethics

To provide students with an overview of the main ethical and legal issues related to scientific research, access to data and data sharing. The Research Ethics course is designed in a highly innovative manner, with the goal of fostering an ethical attitude in the relationship with the patients and/or the lab animals (research ethics and animal ethics) and with the colleagues (research integrity).

Regulatory Aspects

Introduction to the key features relating to the regulatory legislation and the Good Clinical Practices (GCP) principles.

CFU / Hours

6 / 48

Teaching period

Sustainable Development Goals
