UNIVERSITÀ
DEGLI STUDI DI MILANO-BICOCCA

COURSE SYLLABUS

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 Berchialla
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

Regulatory aspects & legislations in the area of rare-diseases – 2h Annabella Amatulli

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