



UNIVERSITÀ
DEGLI STUDI DI MILANO-BICOCCA

SYLLABUS DEL CORSO

Study design: Ethics, Regulatory and Statistical Aspects

2526-1002-04

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 Berchiulla

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

Statistical Aspects

June 20th 17.00-19.00 Maria Grazia Valsecchi - PRE-RECORDED VIDEO

June 21st 9.00-13.00 Maria Grazia Valsecchi - PRE-RECORDED VIDEO

June 25th 17.00-19.00 Andrea Callegaro - STREAMING

June 27th 17.00-19.00 Andrea Callegaro - STREAMING

June 28th 9.00-13.00 Stefania Galimberti - PRE-RECORDED VIDEO

June 30th 17.00-19.00 Davide Bernasconi - PRE-RECORDED VIDEO

July 2nd 17.00-19.00 Davide Bernasconi - STREAMING

July 4th 17.00-19.00 Stefano Vezzoli - STREAMING

July 5th 9.00-13.00 Domenico Criscuolo - STREAMING

July 9th 17.00-19.00 Paola Berchialla - PRE-RECORDED VIDEO

July 11th 17.00-19.00 Paola Berchialla - PRE-RECORDED VIDEO

July 12th 9.00-13.00 Federico Rotolo - PRE-RECORDED VIDEO

Research Ethics

July 14th 17.00-19.00 Luca Marelli - STREAMING
July 16th 17.00-19.00 Silvia Salardi - PRE-RECORDED VIDEO
July 18th 17.00-19.00 Maddalena Lettino - STREAMING

Regulatory Aspects

July 21st 17.00-19.00 Sandra Petraglia - STREAMING

September 3rd 17.00-19.00 Silvia Mori - STREAMING

July 25th 17.00-19.00 Maria Elena Trovati - STREAMING

July 28th 17.00-19.00 Annabella Amatulli - STREAMING

INDIVIDUAL COURSE EVALUATION: September 10th 17.00-19.00

Sustainable Development Goals
