UNIVERSITÀ
DEGLI STUDI DI MILANO-BICOCCA

COURSE SYLLABUS

Study design: Ethics, Regulatory and Statistical Aspects

2324-1002-04

Title

Study design: Ethics, Regulatory and Statistical Aspects

Teacher(s)

- Luca Marelli
- Silvia Salardi
- Maddalena Lettino
- Sandra Petraglia
- Silvia Mori
- Maria Elena Trovati
- Annabella Amatulli
- Maria Grazia Valsecchi
- Luca Porcu
- Stefania Galimberti
- Andrea Callegaro
- Davide Bernasconi
- Stefano Calza
- Federico Rotolo
- Stefano Vezzoli
- Francesca Mastromauro
- Paola Berchialla
- Domenico Criscuolo

Language

English

Short description

COURSE OBJECTIVES

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.

Statistical Aspects

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

TOPICS

Research Ethics

Fundamental ethics principles in research; Data governance and regulatory landscape (GDPR); issues and models related to data access / data sharing – 4h 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

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

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

Good clinical practices – 2h Silvia Mori

Statistical Aspects

Design of RCTs – 4h Maria Grazia Valsecchi

Pre-clinical study design – 4h Luca Porcu

Early phase study design – 4h Stefania Galimberti

Biomarker based designs – 4h Andrea Callegaro

Sample Size Calculation – 4h Davide Bernasconi

Omics designs – 4h Stefano Calza

Adaptive designs – 4h Federico Rotolo

Estimands – 2h Stefano Vezzoli

Real world (pharmaceutical) – 2h Francesca Mastromauro

Bayesian designs – 4h Paola Berchialla

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

CFU / Hours

7 / 56

Teaching period

Research Ethics
July 7th 17.00-19.00 Luca Marelli - STREAMING
July 8th 9.00-11.00 Luca Marelli - PRE-RECORDED VIDEO
July 15th 9.00-11.00 Silvia Salardi - PRE-RECORDED VIDEO
July 15th 11.00-13.00 Maddalena Lettino - STREAMING

Regulatory Aspects
July 19th 17.00-19.00 Sandra Petraglia - STREAMING
July 20th 17.00-19.00 Silvia Mori - STREAMING
July 22nd 9.00-11.00 Maria Elena Trovati - STREAMING
July 22nd 11.00-13.00 Annabella Amatulli - STREAMING

Statistical Aspects
September 4th 17.00-19.00 Maria Grazia Valsecchi - PRE-RECORDED VIDEO
September 6th 17.00-19.00 Maria Grazia Valsecchi - STREAMING
September 8th 17.00-19.00 Luca Porcu - PRE-RECORDED VIDEO
September 9th 9.00-11.00 Luca Porcu - PRE-RECORDED VIDEO
September 9th 11.00-13.00 Stefania Galimberti - PRE-RECORDED VIDEO
September 11th 17.00-19.00 Stefania Galimberti - PRE-RECORDED VIDEO
September 13th 17.00-19.00 Andrea Callegaro - STREAMING
September 15th 17.00-19.00 Andrea Callegaro - STREAMING
September 16th 9.00-13.00 Davide Bernasconi - PRE-RECORDED VIDEO
September 20th 17.00-19.00 Stefano Calza - PRE-RECORDED VIDEO
September 22nd 17.00-19.00 Stefano Calza - PRE-RECORDED VIDEO
September 23rd 9.00-13.00 Federico Rotolo - PRE-RECORDED VIDEO
September 27th 17.00-19.00 Stefano Vezzoli - STREAMING
September 29th 17.00-19.00 Francesca Mastromauro - STREAMING
September 30th 9.00-13.00 Paola Berchialla - PRE-RECORDED VIDEO
October 7th 9.00-13.00 Domenico Criscuolo - STREAMING

COURSE EVALUATION: October 11th 18.00-19.00

Sustainable Development Goals