



UNIVERSITÀ
DEGLI STUDI DI MILANO-BICOCCA

SYLLABUS DEL CORSO

Study design: Ethics, Regulatory and Statistical Aspects

2405-1002-04

Aims

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.

Contents

Statistical Aspects

Design of RCTs – 6h Maria Grazia Valsecchi

Early phase study design – 4h Stefania Galimberti

Biomarker based designs – 4h Andrea Callegaro

Multiple testing – 2h Aldo Solari

Sample Size Calculation – 2h Davide Bernasconi

Adaptive designs – 4h Federico Rotolo

Estimands – 2h Stefano Vezzoli

Bayesian designs – 4h Paola Berchiolla

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

Criscuolo

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

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

Detailed program

Prerequisites

Teaching form

Textbook and teaching resource

Semester

Statistical Aspects

June 21st 17.00-19.00 Maria Grazia Valsecchi - PRE-RECORDED VIDEO

June 22nd 9.00-13.00 Maria Grazia Valsecchi - PRE-RECORDED VIDEO

June 26th 17.00-19.00 Andrea Callegaro - STREAMING

June 28th 17.00-19.00 Andrea Callegaro - STREAMING

June 29th 9.00-13.00 Stefania Galimberti - PRE-RECORDED VIDEO

July 1st 17.00-19.00 Aldo Solari - STREAMING

July 3rd 17.00-19.00 Davide Bernasconi - PRE-RECORDED VIDEO

July 5th 17.00-19.00 Stefano Vezzoli - STREAMING

July 6th 9.00-13.00 Federico Rotolo - PRE-RECORDED VIDEO

July 10th 17.00-19.00 Paola Berchialla - PRE-RECORDED VIDEO

July 12th 17.00-19.00 Paola Berchialla - PRE-RECORDED VIDEO

July 13th 9.00-13.00 Domenico Criscuolo - STREAMING

Research Ethics

July 15th 17.00-19.00 Luca Marelli - STREAMING

July 17th 17.00-19.00 Silvia Salardi - STREAMING

July 19th 17.00-19.00 Maddalena Lettino - STREAMING

Regulatory Aspects

July 22nd 17.00-19.00 Sandra Petraglia - STREAMING

July 24th 17.00-19.00 Silvia Mori - STREAMING

July 26th 17.00-19.00 Maria Elena Trovati - STREAMING
July 27th 10.00-12.00 Annabella Amatulli - STREAMING

Assessment method

Individual assignment - Multiple choice questions

Office hours

Sustainable Development Goals
