



UNIVERSITÀ  
DEGLI STUDI DI MILANO-BICOCCA

## SYLLABUS DEL CORSO

### Study design: Ethics, Regulatory and Statistical Aspects

2627-1002-04

---

#### **Titolo**

Study design: Ethics, Regulatory and Statistical Aspects

#### **Docente(i)**

##### *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

## Lingua

English

## Breve descrizione

### *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 / Ore

6 / 48

## Periodo di erogazione

### *Statistical Aspects*

June 15th 17.00-19.00 Stefania Galimberti - PRE-RECORDED VIDEO

June 17th 17.00-19.00 Stefania Galimberti - PRE-RECORDED VIDEO

June 19th 17.00-19.00 Maria Grazia Valsecchi - PRE-RECORDED VIDEO

June 20th 9.00-13.00 Maria Grazia Valsecchi - PRE-RECORDED VIDEO

**June 22th 17.00-19.00 Stefano Vezzoli - STREAMING**

June 24th 17.00-19.00 Davide Bernasconi - PRE-RECORDED VIDEO

**June 26th 17.00-19.00 Davide Bernasconi - STREAMING**

**June 27th 9.00-13.00 Domenico Criscuolo - STREAMING**

June 29th 17.00-19.00 Andrea Callegaro - ??

July 1st 17.00-19.00 Andrea Callegaro - ??

July 4th 9.00-13.00 Federico Rotolo - PRE-RECORDED VIDEO

July 6th 17.00-19.00 Paola Berchialla - PRE-RECORDED VIDEO

July 8th 17.00-19.00 Paola Berchialla - PRE-RECORDED VIDEO

*Research Ethics*

**July 13th 17.00-19.00 Luca Marelli - STREAMING**

July 15th 17.00-19.00 Silvia Salardi - PRE-RECORDED VIDEO

**July 17th 17.00-19.00 Maddalena Lettino - STREAMING**

*Regulatory Aspects*

**July 20th 17.00-19.00 Sandra Petraglia - STREAMING**

**July 20nd 17.00-19.00 Silvia Mori - STREAMING**

**July 24th 17.00-19.00 Annabella Amatulli - STREAMING**

**July 27th 17.00-19.00 Maria Elena Trovati - STREAMING**

**INDIVIDUAL COURSE EVALUATION:** September 4th 17.00-19.00

## **Sustainable Development Goals**

---