UNIVERSITÀ
DEGLI STUDI DI MILANO-BICOCCA

SYLLABUS DEL CORSO

Study design: Ethics, Regulatory and Statistical Aspects

2526-1002-04

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 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

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 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