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 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 15th 17.00-19.00 Stefania Galimberti - PRE-RECORDED VIDEO
June 17th 17.00-19.00 Stefania Galimberti - PRE-RECORDED VIDEO
June19th 17.00-19.00 Maria Grazia Valsecchi - PRE-RECORDED VIDEO
June20th 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