



II LEVEL MASTER'S DEGREE IN METHODS AND DATA ANALYSIS IN BIOMEDICAL RESEARCH (MEDAL)

*Training the Next Generation of Data Scientists in
Biomedical Research*

3rd EDITION: 5th APRIL 2024 – 31st MARCH 2025

Department of Medicine & Surgery
University of Milano-Bicocca

Type of course: II LEVEL MASTER'S DEGREE WITH 60 CREDITS

Course Title: METHODS AND DATA ANALYSIS IN BIOMEDICAL RESEARCH (MEDAL in Biomedical Research)

	COURSES	CLASS HOURS	ECTS CREDITS
CORE COURSES & INTEGRATIONAL MODULES			
1.	Quantitative Approach to Biomedical Research	32	4
2.	Clinical Data Science: Advanced Statistics I	32	4
3.	Clinical Data Science: Advanced Statistics II – Summer School	40	5
4.	Study design: Ethics, Regulatory and Statistical Aspects	48	6
4.1	<i>Statistical Aspects</i>	32	4
4.2	<i>Research Ethics</i>	8	1
4.3	<i>Regulatory Aspects</i>	8	1
5.	Biostatistics for Epidemiological and Real World Studies – Winter School I	32	4
6.	Research in Practice	40	5
7.	Bioinformatics and Biostatistics for Big Data – Winter School II	24	3
8.	Research Grant writing	16	2
9.	Scientific Communication & Writing	16	2
	CLASS HOURS/CREDITS	280	35
	INTERNSHIP/DESIGN PROJECT	400	16
	FINAL EXAM		9
	TOTAL	680	60

COURSE: QUANTITATIVE APPROACH TO BIOMEDICAL RESEARCH	
SCIENTIFIC AREA: MED/01	
PROFESSOR INCHARGE:	Maria Grazia Valsecchi - grazia.valsecchi@unimib.it
FACULTY:	Maria Grazia Valsecchi - grazia.valsecchi@unimib.it (UNIMIB) Marika Vezzoli - marika.vezzoli@unibs.it (UNIBS) Davide Bernasconi - davide.bernasconi@unimib.it (UNIMIB) Laura Antolini - laura.antolini@unimib.it (UNIMIB) Alessandra Carobbio - acarobbio@fondazionefrom.it (FROM Fondazione per la Ricerca Ospedale di Bergamo) Stefania Galimberti - stefania.galimberti@unimib.it (UNIMIB)
COURSE HOURS:	32
COURSE CREDITS:	4 cfu

COURSE OBJECTIVES: To introduce the fundamental principles and approaches of statistics in biomedical research.

MAIN TOPICS:

Welcome and introduction – 2h Maria Grazia Valsecchi

Taxonomy of the studies – 2h Maria Grazia Valsecchi

Descriptive statistics – 6h Marika Vezzoli

Introduction to R – 4h Davide Bernasconi

Probability, sensitivity, specificity and ROC curve – 6h Laura Antolini

Statistical Distribution Functions – 4h Alessandra Carobbio

Inference: hypothesis testing & confidence interval – 4h Maria Grazia Valsecchi + 2h Marika Vezzoli

Variable transformation – 2h Stefania Galimberti

COURSE EVALUATION: Individual assignment 100%

COURSE MATERIAL: uploaded on the e-learning platform

COURSE SCHEDULE:

<i>Date</i>	<i>Faculty</i>
April 5 th 17.00-19.00	Maria Grazia Valsecchi
April 6 th 9.00-11.00	Maria Grazia Valsecchi
April 6 th 11.00-13.00	Marika Vezzoli
April 8 th 17.00-19.00	Marika Vezzoli
April 10 th 17.00-19.00	Marika Vezzoli
April 12 th 17.00-19.00	Davide Bernasconi
April 13 th 9.00-11.00	Davide Bernasconi
April 13 th 11.00-13.00	Laura Antolini
April 15 th 17.00-19.00	Laura Antolini
April 17 th 17.00-19.00	Laura Antolini
April 19 th 17.00-19.00	Alessandra Carobbio
April 20 th 9.00-11.00	Alessandra Carobbio
April 20 th 11.00-13.00	Marika Vezzoli
April 22 nd 17.00-19.00	Maria Grazia Valsecchi
April 24 th 17.00-19.00	Maria Grazia Valsecchi
May 3 rd 17.00-19.00	Stefania Galimberti
June 7th 17.00-19.00	Course evaluation

COURSE: CLINICAL DATA SCIENCE: ADVANCED STATISTICS I	
SCIENTIFIC AREA: MED/01	
PROFESSOR INCHARGE:	Laura Antolini – laura.antolini@unimib.it
FACULTY:	Laura Antolini - laura.antolini@unimib.it (UNIMIB) Paola Rancoita - rancoita.paolamaria@univr.it (Università Vita-Salute San Raffaele) Stefania Galimberti - stefania.galimberti@unimib.it (UNIMIB) Chiara Brombin - brombin.chiara@hsr.it (Università Vita-Salute San Raffaele) Federico Ambrogi - federico.ambrogi@unimi.it (UNIMI) Bernardo Nipoti - bernardo.nipoti@unimib.it (UNIMIB) Stefano Vezzoli - s.vezzoli@chiesi.com (Chiesi Farmaceutica)
COURSE HOURS:	32
COURSE CREDITS:	4 cfu

COURSE OBJECTIVES: To develop statistical skills and knowledge for the analysis and interpretation of studies through advanced statistical methods used in clinical trials and observational studies.

MAIN TOPICS:

Analysis of Variance (ANOVA) – 2h Laura Antolini

Principles of regression and models for continuous data – 6 h Paola Rancoita

Effect measures with binary endpoints – 2h Stefania Galimberti

Regression models for binary response – 6h Chiara Brombin

Variable selection – 2h Federico Ambrogi

Prediction models – 2h Federico Ambrogi

Bayesian Analysis – 8h Bernardo Nipoti

Missing data – 4h Stefano Vezzoli

COURSE EVALUATION: Individual assignment 100%

COURSE MATERIAL: uploaded on the e-learning platform

COURSE SCHEDULE:

<i>Date</i>	<i>Faculty</i>
May 4 th 9.00-11.00	Laura Antolini
May 4 th 11.00-13.00	Paola Rancoita
May 8 th 17.00-19.00	Paola Rancoita
May 10 th 17.00-19.00	Paola Rancoita
May 11 th 9.00-11.00	Stefania Galimberti
May 11 th 11.00-13.00	Chiara Brombin
May 15 th 17.00-19.00	Chiara Brombin
May 17 th 17.00-19.00	Chiara Brombin
May 18 th 9.00-13.00	Federico Ambrogi
May 22 nd 17.00-19.00	Bernardo Nipoti
May 24 th 17.00-19.00	Bernardo Nipoti
May 25 th 9.00-13.00	Bernardo Nipoti
May 29 th 17.00-19.00	Stefano Vezzoli
May 31 st 17.00-19.00	Stefano Vezzoli
June 7th 17.00-19.00	Course evaluation

COURSE: CLINICAL DATA SCIENCE: ADVANCED STATISTICS II – SUMMER SCHOOL	
SCIENTIFIC AREA: MED/01	
PROFESSOR INCHARGE:	Davide Bernasconi – davide.bernasconi@unimib.it
FACULTY:	Davide Bernasconi - davide.bernasconi@unimib.it (UNIMIB) Aldo Solari - aldo.solari@unimib.it (UNIMIB) Maria Grazia Valsecchi - grazia.valsecchi@unimib.it (UNIMIB) Paola Rebora - paola.rebora@unimib.it (UNIMIB) Elia Biganzoli - elia.biganzoli@unimi.it (Università degli Studi di Milano)
COURSE HOURS:	40
COURSE CREDITS:	5 cfu

COURSE OBJECTIVES: To advance the practice with R and to learn the methodology of survival data analysis.

MAIN TOPICS:

R software – 6h Davide Bernasconi

Multiple testing – 2h Aldo Solari

Survival Analysis – 4 days Maria Grazia Valsecchi, Paola Rebora, Davide Bernasconi, Elia Biganzoli (2h)

COURSE EVALUATION: Group assignment 100%

COURSE MATERIAL: uploaded on the e-learning platform

COURSE SCHEDULE:

<i>Date</i>	<i>Faculty</i>
June 10 th 9.00-18.00	Summer School in presence
June 11 th 9.00-18.00	Summer School in presence
June 12 th 9.00-18.00	Summer School in presence
June 13 th 9.00-18.00	Summer School in presence
June 14 th 9.00-16.00	Summer School in presence
June 14th 16.00-18.00	Course evaluation

COURSE: STUDY DESIGN: ETHICS, REGULATORY AND STATISTICAL ASPECTS	
SCIENTIFIC AREA: MED/01	
PROFESSOR INCHARGE:	Stefania Galimberti – stefania.galimberti@unimib.it
COURSE HOURS:	48
COURSE CREDITS:	6 cfu

COURSE EVALUATION: Individual assignment 100%

COURSE MATERIAL: uploaded on the e-learning platform

MODULE: STATISTICAL ASPECTS	
PROFESSOR INCHARGE:	Stefania Galimberti – stefania.galimberti@unimib.it
FACULTY:	Maria Grazia Valsecchi - grazia.valsecchi@unimib.it (UNIMIB) Stefania Galimberti - stefania.galimberti@unimib.it (UNIMIB) Andrea Callegaro - andrea.x.callegaro@gsk.com (GSK) Davide Bernasconi - davide.bernasconi@unimib.it (UNIMIB) Federico Rotolo - federico.rotolo@sanofi.com (Sanofi) Stefano Vezzoli - s.vezzoli@chiesi.com (Chiesi Farmaceutica) Paola Berchialla - paola.berchialla@unito.it (UNITO) Domenico Criscuolo - dcriscuolo@genovax.it (consultant)
MODULE HOURS:	32
MODULE CREDITS:	4 cfu

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

MAIN TOPICS:

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

Adaptive designs – 4h Federico Rotolo

Estimands – 2h Stefano Vezzoli

Bayesian designs – 4h Paola Berchialla

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

Domenico Criscuolo

MODULE SCHEDULE:

<i>Date</i>	<i>Faculty</i>
June 21 st 17.00-19.00	Maria Grazia Valsecchi
June 22 nd 9.00-13.00	Maria Grazia Valsecchi
June 26 th 17.00-19.00	Andrea Callegaro
June 28 th 17.00-19.00	Andrea Callegaro
June 29 th 9.00-13.00	Stefania Galimberti
July 1 st 17.00-19.00	Davide Bernasconi
July 3 rd 17.00-19.00	Davide Bernasconi
July 5 th 17.00-19.00	Stefano Vezzoli
July 6 th 9.00-13.00	Federico Rotolo
July 10 th 17.00-19.00	Paola Berchialla
July 12 th 17.00-19.00	Paola Berchialla
July 13 th 9.00-13.00	Domenico Criscuolo
September 11th 17.00-19.00	Course evaluation

MODULE: RESEARCH ETHICS	
PROFESSOR INCHARGE:	Maria Grazia Valsecchi – grazia.valsecchi@unimib.it
FACULTY:	Luca Marelli - luca.marelli@unimi.it (UNIMI) Silvia Salardi - silvia.salardi@unimib.it (UNIMIB) Maddalena Lettino - maddalena.lettino@irccs-sangerardo.it (ASST Monza, Presidente Comitato Etico Area 3-MI)
MODULE HOURS:	8
MODULE CREDITS:	1 cfu

MODULE OBJECTIVES: 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).

MAIN TOPICS:

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

MODULE SCHEDULE:

<i>Date</i>	<i>Faculty</i>
July 15 th 17.00-19.00	Luca Marelli
July 17 th 17.00-19.00	Silvia Salardi
July 19 th 17.00-19.00	Maddalena Lettino
September 11th 17.00-19.00	Course evaluation

MODULE: REGULATORY ASPECTS	
PROFESSOR INCHARGE:	Silvia Mori – silvia.mori@unimib.it
FACULTY:	Sandra Petraglia - s.petraglia@aifa.gov.it (AIFA) Silvia Mori - silvia.mori@unimib.it (UNIMIB) Maria Elena Trovati - etrovati@amgen.com (AMGEN) Annabella Amatulli - annabella.amatulli@gmail.com (Chief Regulatory Officer presso Napo Therapeutics SpA / President #HBAMilan)
MODULE HOURS:	8
MODULE CREDITS:	1 cfu

MODULE OBJECTIVES: Introduction to the key features relating to the regulatory legislation and the Good Clinical Practices (GCP) principles.

MAIN TOPICS:

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

MODULE SCHEDULE:

<i>Date</i>	<i>Faculty</i>
July 22 nd 17.00-19.00	Sandra Petraglia
July 24 th 17.00-19.00	Silvia Mori
July 26 th 17.00-19.00	Maria Elena Trovati
July 29 th 17.00-19.00	Annabella Amatulli
September 11th 17.00-19.00	Course evaluation

COURSE: BIOSTATISTICS FOR EPIDEMIOLOGICAL AND REAL WORLD STUDIES (WINTER SCHOOL I)	
SCIENTIFIC AREA: MED/01	
PROFESSOR INCHARGE:	Paola Rebora - paola.rebora@unimib.it (UNIMIB)
FACULTY:	Paola Rebora - paola.rebora@unimib.it (UNIMIB) Anita Andreano - aandreano@ats-milano.it (ATS Città Metropolitana MI) Marco Villa - marco.villa@ats-valpadana.it (ATS Val Padana) Carlo Alberto Scirè - carlo.scire@unimib.it (UNIMIB) Davide Bernasconi - davide.bernasconi@unimib.it (UNIMIB) Francesca Mastromauro - francesca.mastromauro@astrazeneca.com (Astrazeneca) Francesca Graziano - francesca.graziano@unimib.it (UNIMIB)
COURSE HOURS:	32
COURSE CREDITS:	4 cfu

COURSE OBJECTIVES: To understand the different types of studies in epidemiological research and real world studies.

MAIN TOPICS (TO BE BETTER DEFINED):

Real world (pharmaceutical)

Epidemiological designs

Epidemiological designs

Introduction to Real World Data, Geo-spatial analysis

Real world study

Introduction to causal models

COURSE EVALUATION: Group assignment 100%

COURSE MATERIAL: uploaded on the e-learning platform

COURSE SCHEDULE:

<i>Date</i>	<i>Faculty</i>
September 13 th 17.00-19.00	
September 14 th 9.00-13.00	
September 16 th 17.00-19.00	
September 19 th 9.00-18.00	Winter School in presence
September 20 th 9.00-18.00	Winter School in presence
September 21 st 9.00-13.00	Winter School in presence
September 28th 9.00-13.00	Course evaluation

COURSE: RESEARCH IN PRACTICE	
SCIENTIFIC AREA: MED/01	
PROFESSOR INCHARGE:	Maria Grazia Valsecchi – grazia.valsecchi@unimib.it (UNIMIB)
FACULTY:	Maria Grazia Valsecchi - grazia.valsecchi@unimib.it (UNIMIB) Silvia Mori - silvia.mori@unimib.it (UNIMIB) Stefania Galimberti - stefania.galimberti@unimib.it (UNIMIB) Giulia Capitoli - giulia.capitoli@unimib.it (UNIMIB) Davide Gaudesi - davide.gaudesi@gmail.com (Advice Pharma Group S.R.L.) Elena Tassistro - elena.tassistro@unimib.it (UNIMIB) Matteo Petrosino - matteo.petrosino@unimib.it (UNIMIB) Emanuela Rossi - emanuela.rossi@unimib.it (UNIMIB) Francesca Graziano - francesca.graziano@unimib.it (UNIMIB) Valeria Edefonti - valeria.edefonti@unimi.it (UNIMI) Anita Andreano - aandreano@ats-milano.it (ATS Città Metropolitana MI)
COURSE HOURS:	40
COURSE CREDITS:	5 cfu

COURSE OBJECTIVES: To cover the key steps of the entire life cycle of a clinical trial from inception to dissemination.

MAIN TOPICS:

Protocol development – 2h Maria Grazia Valsecchi + 2h Silvia Mori

End Point – 2h Stefania Galimberti

End point Surrogate – 2h Giulia Capitoli

Organizing Data & Data Management, Case Report Form & ECRF – 6h Davide Gaudesi

Safety issues – 1h Silvia Mori

Safety data analysis – 3h Elena Tassistro

Analysis of longitudinal data – 4h Matteo Petrosino

Practical Review (Def. of a protocol) – 10h Emanuela Rossi

Reporting results – 2h Francesca Graziano

Reproducibility – 2h Valeria Edefonti

Meta-analysis – 4h Anita Andreano

COURSE EVALUATION: Class discussion 100%

COURSE MATERIAL: uploaded on the e-learning platform

COURSE SCHEDULE:

<i>Date</i>	<i>Faculty</i>
October 2 nd 17.00-19.00	Maria Grazia Valsecchi
October 4 th 17.00-19.00	Silvia Mori
October 5 th 9.00-11.00	Stefania Galimberti
October 5 th 11.00-13.00	Giulia Capitoli
October 9 th 17.00-19.00	Davide Gaudesi
October 11 th 17.00-19.00	Davide Gaudesi
October 12 th 9.00-11.00	Davide Gaudesi
October 12 th 11.00-12.00	Silvia Mori
October 12 th 12.00-13.00	Elena Tassistro
October 16 th 17.00-19.00	Elena Tassistro
October 18 th 17.00-19.00	Matteo Petrosino
October 19 th 9.00-11.00	Matteo Petrosino
October 19 th 11.00-13.00	Francesca Graziano
October 23 rd 17.00-19.00	Emanuela Rossi
October 25 th 17.00-19.00	Emanuela Rossi
October 26 th 9.00-13.00	Emanuela Rossi
October 30 th 17.00-19.00	Valeria Edefonti
November 6 th 17.00-19.00	Anita Andreano
November 8 th 17.00-19.00	Anita Andreano
November 9th 10.00-12.00	Course evaluation (Emanuela Rossi)

COURSE: BIOINFORMATICS AND BIOSTATISTICS FOR BIG DATA – WINTER SCHOOL II	
SCIENTIFIC AREA: MED/01	
PROFESSOR INCHARGE:	Daniela Besozzi - daniela.besozzi@unimib.it (UNIMIB)
FACULTY:	Daniela Besozzi - daniela.besozzi@unimib.it (UNIMIB) Daniele Papetti - daniele.papetti@unimib.it (UNIMIB) Marco S. Nobile - marco.nobile@unive.it (Università Ca' Foscari Venezia) Fabio Stella - fabio.stella@unimib.it (UNIMIB)
COURSE HOURS:	24
COURSE CREDITS:	3 cfu

COURSE OBJECTIVES: To understand the different applications of bioinformatics on big data in medical research.

MAIN TOPICS (TO BE BETTER DEFINED):

Introduction to machine learning

Unsupervised learning

Neural networks and deep learning

From data to models in pandemics

Interpretable and explainable artificial intelligence

Computational intelligence for biomedicine and healthcare

Bayesian and causal networks - part I

Bayesian and causal networks - part II

COURSE EVALUATION: Group assignment 100%

COURSE MATERIAL: uploaded on the e-learning platform

COURSE SCHEDULE:

<i>Date</i>	<i>Faculty</i>
November 14 th 9.00-18.00	Winter School in presence
November 15 th 9.00-18.00	Winter School in presence
November 16 th 9.00-13.00	Winter School in presence
November 30th 9.00-13.00	Course evaluation

COURSE: RESEARCH GRANT WRITING	
COURSE CODE:	
SCIENTIFIC AREA: MED/01	
PROFESSOR INCHARGE:	Maria Grazia Valsecchi – grazia.valsecchi@unimib.it
FACULTY:	Myriam Alcalay – myriam.alcalay@ieo.it (Università degli Studi di Milano, Istituto Europeo di Oncologia)
COURSE HOURS:	16
COURSE CREDITS:	2 cfu

COURSE OBJECTIVES: High quality scientific writing is essential to communicate research findings in a clear and concise manner. Scientists need to develop the ability to write well-structured manuscripts to communicate their research results and findings with other scientists or experts. The course has been designed to help students understand the steps in scientific writing, using practical examples and exercises.

MAIN TOPICS: Funding opportunities for Young Investigators in Italy and Europe; Understanding the review process: writing for success; How to develop an Irresistible idea; The writing schedule; Background and Review of Literature; Hypothesis, Aim of the study, Preliminary Results; Experimental design & methods; Time & deliverables; Pitfalls; Expected outcome; Dissemination; Future directions.

COURSE EVALUATION: Class participation & group assignment 100%

COURSE MATERIAL: uploaded on the e-learning platform.

COURSE SCHEDULE:

<i>Date</i>	<i>Faculty</i>
November 22 nd 17.00-19.00	Myriam Alcalay
November 25 th 17.00-19.00	Myriam Alcalay
November 27 th 17.00-19.00	Myriam Alcalay
December 4 th 17.00-19.00	Myriam Alcalay
December 6 th 17.00-19.00	Myriam Alcalay
December 9 th 17.00-19.00	Myriam Alcalay
December 14th 9.00-13.00	Course evaluation

COURSE: SCIENTIFIC COMMUNICATION & WRITING	
SCIENTIFIC AREA: MED/01	
PROFESSOR INCHARGE:	Maria Grazia Valsecchi – grazia.valsecchi@unimib.it
FACULTY:	Chiara Gabbi – chiara917@gmail.com (Freelance)
COURSE HOURS:	16
COURSE CREDITS:	2 cfu

COURSE OBJECTIVES: How to write and communicate Science "is a scientific writing and communication course that provides the knowledge and skills of writing various forms of scientific publication (research paper, review, case report, etc.), along with the skills on how to present at congresses (oral communication, poster presentation, etc.) and communicating through social media."

MAIN TOPICS: Basic principles of scientific writing; How to write a scientific paper; How to write a Review; Case report; letter to the editor; Authorship; Cover letter; Peer review and manuscript evaluation; Communicating science; writing an effective abstract; poster and oral presentation; Communicating science to general public; Social Media Communication.

COURSE EVALUATION: Class discussion & group assignment 100%

COURSE MATERIAL: uploaded on the e-learning platform

COURSE SCHEDULE:

<i>Date</i>	<i>Faculty</i>
January 8 th 17.00-19.00	Chiara Gabbi
January 10 th 17.00-19.00	Chiara Gabbi
January 11 th 9.00-13.00	Chiara Gabbi
January 15 th 17.00-19.00	Chiara Gabbi
January 17 th 17.00-19.00	Chiara Gabbi
January 18th 9.00-13.00	Course evaluation