



**27-29 April 2022**  
**Milan, AIMS Academy**

**Coordinated by:** Ing. Giacomo Pugliese

## Faculty:

Prof. Abe Fingerhut, MD

Prof. Vincenzo Bagnardi, Biostatistician

Luca Mauro, Clinical Study Coordinator



### **Clinicians and residents**

Willing to improve their skills  
in research design, methodology  
and biostatistics

### Main topics:

#### Principles of Clinical Research

- Identification of a good clinical question
- Research Study Design
- Understanding treatment effects

#### Practice of Clinical Research

- Planning and conducting a research study
- Medical Writing
- Clinical Data management

# PRINCIPLES

## Understanding Research Study Design

- The Clinical Case Series
- The Case-Control Study
- The Prospective Cohort Study
- The Randomized Trial
- Meta-Analysis

## Understanding Treatment Effects

- Common ways to present treatment effects
- The confidence interval defined
- The P value defined
- Errors in hypothesis testing
- Clinical versus statistical significance

## Sum-up

- Synoptic view of various research design classifications
- Hierarchy of research studies: from case series to meta-analyses

# PRACTICE

## Planning and conducting a Research Study

- The identification of a good research question: attitude, elements of a good idea (PICO), refining a research question
- How to conduct a comprehensive literature search
- Critical appraisal of proposed hypothesis
- Regulatory issues and Ethical Committee

## Medical Writing

- Learn the rules of medical writing style, adapted to the type of study and conclusion
- Compose a surgical scientific manuscript, prepare it for publication
- Choose the right Journal for submission

## Clinical Data Management

- Introduction to Clinical Data Management System (CDMS)
- eCRF development (electronic Case Report Forms)
- Create your own e-CRF on REDCap

# PROGRAM

27/04

12:45 – 12:55	Welcome	G. Pugliese
12:55 – 13:10	Introduction: Why do we need Clinical Research?	Prof. A. Fingerhut
13:10 – 16:10	Understanding Research Study Design	Prof. V. Bagnardi
16:10 coffee ☕	Q&A, exercises and sum up	
16:30 – 19:10	Understanding Treatment Effects	Prof. V. Bagnardi
	Q&A, exercises and sum up	

Module I  
Principles

28/04

08:00 – 08:30	Principles of Clinical Research - Sum up	G. Pugliese
08:30 – 12:50	Medical Writing - <i>part I</i> 🇺🇸	Prof. A. Fingerhut
10:30 coffee ☕	Theory	
12:50 – 13:30	Lunch break	
13:30 – 15:00	Regulatory Issues	L Mauro
15:00 – 18:50	Medical Writing - <i>part I</i> 🇺🇸	Prof. A. Fingerhut
16:00 coffee ☕	Practice	

Module II  
Practice &  
Medical  
Writing

29/04

08:00 – 12:45	Medical Writing - <i>part II</i> 🇺🇸	Prof. A. Fingerhut
10:00 coffee ☕	2h Theory & 2h Practice	
12:45 – 13:45	Lunch break	
13:45 – 16:45	Clinical Data Management and REDCap Practice	L Mauro

Module III  
REDCap



# FACULTY:



## Abe Fingerhut

MD, FACS (hon), FRCS (hon), FRCPS (g), FRCS (Ed) (hon), FASCRS (hon)

Co-Editor-in-Chief of Annals of Laparoscopic and Endoscopic Surgery (ALES)



## Vincenzo Bagnardi

PhD, Associate Professor of Medical Statistics

Director of the Master program in Data Management for Clinical Research, Department of Statistics and Quantitative Methods, University of Milan-Bicocca



## Luca Mauro

Clinical Study Coordinator in NEMO Centre (NEuroMuscular Omnicentre), Milan

Expert in Clinical Data Management and Electronic Data Capture



### VENUE: AIMS Academy

Piazza Ospedale Maggiore 3 - 20162 Milan (Niguarda Ca' Granda Hospital)

[www.aimsacademy.org](http://www.aimsacademy.org)



[segreteria@aimsacademy.org](mailto:segreteria@aimsacademy.org)

+ 39 02 6444 7600

### COURSE LANGUAGE:

English and Italian

### REGISTRATION FEES:

Module I: 245 € (200 € + 22% IVA)

Module II: 450 € (370 € + 22% IVA)

Module III: 185 € (150 € + 22% IVA)

Module I+II+III: 730€ (600€ + 22% IVA)

Registration fee includes lunches and coffee breaks.