



28-30 April 2021
Milan, AIMS Academy

Coordinated by: Ing. Giacomo Pugliese

Faculty:

Prof. Abe Fingerhut, MD

Antonello Forgione, 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

28/04

12:45 – 12:55	Welcome	G. Pugliese
12:55 – 13:10	Introduction: Why do we need Clinical Research?	A. Forgione MD
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

29/04

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 ☕	2h Practice	
12:50 – 13:30	Lunch break	
13:30 – 15:00	Regulatory Issues	L. Mauro
15:00 – 18:50	Identification of a Good Clinical question 🇺🇸	Prof. A. Fingerhut Prof. V. Bagnardi A. Forgione MD G. Mari MD
16:00 coffee ☕	2.5 h Practice	

Module II
Practice &
Medical
Writing

30/04

08:00 – 12:00	Medical Writing - <i>part II</i> 🇺🇸	Prof. A. Fingerhut
10:00 coffee ☕	2h Practice	
12:00 – 12:20	Meet the sponsor: why is it important to support clinical research	
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



Antonello Forgione

MD, PhD MBA FACS FCBC (Hon) FRAES (Hon)

Scientific Director AIMS Academy,
General Oncologic Mininvasive Surgeon Niguarda Hospital



Luca Mauro

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

Expert in Clinical Data Management and Electronic Data Capture

VENUE: AIMS Academy

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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.