

GENERAL INFORMATION

The event takes place in Rome, at the Conference Centre "Roma Eventi - Fontana di Trevi" (Piazza della Pilotta 4, Rome).
The staff is available from 8.00 am on March 20th and for the entire duration of the event.

By attending the event you will be entitled to have all the congress materials and the certificate of attendance. Coffee break and lunch for both days and deluxe aperitif on Friday evening are included.



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CLINICAL RESEARCH COURSE

4th
edition



Conference Centre "Roma Eventi - Fontana di Trevi"
ROME - March 20-21, 2026

PROGRAM

DAY 1
MARCH 20TH,
2026

8.45am **WELCOME AND INTRODUCTION**

AIOM – M. Di Maio (Turin)
*ASCO – E. A. Mittendorf (Boston, USA)**
Fondazione AIOM – F. Perrone (Naples)
FICOG – G. Procopio (Milan)
AIOM Sezione Lazio – E. Bria (Rome)



SESSION I: OVERVIEW OF CLINICAL RESEARCH
Chair: M. Di Maio (Turin), F. Perrone (Naples)

9.00 am	How to develop a protocol? From the hypothesis to study design <i>G. Daniele (Rome)</i>
9.20 am	Questions & Answers
9.35 am	Good Clinical Practice: basic principles and Roles & Responsibilities of the Research Team <i>M. Piccirillo (Naples)</i>
9.55 am	Questions & Answers

10.10 am COFFEE BREAK

10.45 am	Predictive and prognostic biomarkers <i>N. Normanno* (Meldola, FC)</i>
11.05 am	Questions & Answers
11.20 am	Early Drug development & Phase I trials <i>G. Curigliano* (Milan)</i>
11.40 am	Questions & Answers
11.55 am	De-escalation trials in oncology <i>B. Gyawali (Kingston)</i>
12.15 pm	Questions & Answers



12.30 pm LIGHT LUNCH

**Via pre-recorded video*

SESSION II: PHASE II AND PHASE III TRIALS <i>Chairs: B. Gyawali (Kingston), M. Di Maio (Turin)</i>	
1.45 pm	Phase II trials: basic principles, basket & umbrella trial design <i>I. Tannock (Toronto)</i>
2.05 pm	Questions & Answers
2.10 pm	Statistical principles in early trials <i>A. Signori (Genoa)</i>
2.30 pm	Questions & Answers
2.45 pm	Phase III trials: basic principles <i>F. Perrone (Naples)</i>
3.05 pm	Questions & Answers
3.20 pm	Statistical principles in Phase III; Analysis of survival curves <i>P. Chiodini (Naples)</i>
3.40 pm	Questions & Answers
3.55pm	How to distinguish between statistical and clinical significance? <i>B. Gyawali (Kingston)</i>
4.15 pm	Questions & Answers



4.30 pm GROUP SESSION I
Workshops – critical review of concepts and/or reports of clinical trials
Practice groups, around 10 participants, each with two or three facilitators (oncologist + biostatistician).
Members of the faculty will act as facilitators:
R. Berardi, P. Chiodini, G. Curigliano, G. Daniele, M. Di Maio, L. Guizzaro, B. Gyawali, F. Perrone, M. Piccirillo, A. Signori, I. Tannock, D. Trapani
In addition, a further group of facilitators will be present and distributed among groups:
• Oncologists: *A. Brunello (Padova), L. Formisano (Naples), N. Silvestris (Bari)*
• Statisticians: *L. Arenare (Naples), L. Carmisciano (Genoa), M. Fordellone (Napoli), G. Maglietta (Parma), R. Miceli (Milan), E. Rulli (Milan), S. Signoriello (Naples)*

6.30 pm End of Session and deluxe aperitif

SESSION I: CLINICAL TRIAL DESIGN AND METHODOLOGY II
Chairs: R. Berardi (Ancona), F. Perrone (Naples)

DAY 2
MARCH 21ST,
2026

8.30 am	Observational studies <i>I. Tannock (Toronto)</i>
8.50 am	Real World Evidence <i>F. Perrone (Naples)</i>
9.10 am	Questions & Answers
9.20 am	Patient-reported outcomes <i>M. Di Maio (Turin)</i>
9.40 am	Questions & Answers
9.50 am	Meta-analyses <i>P. Chiodini (Naples)</i>
10.05 am	Questions & Answers
10.10 am	The role of EMA and the future of clinical trials in the EU <i>L. Guizzaro (Amsterdam)</i>
10.25 am	Questions & Answers



10.30 am COFFEE BREAK

SESSION II: CLINICAL TRIAL DESIGN AND METHODOLOGY III
Chairs: M. Di Maio (Turin), F. Perrone (Naples)

11.00 am	Ethical aspects in research <i>D. Trapani (Milan)</i>
11.20 am	Questions & Answers
11.30 am	Common causes for bias in trials and how to avoid them <i>I. Tannock (Toronto)</i>
12.00 pm	Questions & Answers
12.10 pm	The Common sense in oncology initiative <i>B. Gyawali (Kingston)</i>
12.30 pm	Questions & Answers

12.40 pm LIGHT LUNCH

1.30 pm GROUP SESSION II
Workshops – Critical review of concepts and/or reports of clinical trials
Same as day 1

3.30 pm	Final test and review
3.45 pm	Closing, certification and evaluation