

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 7.30am on April 12th 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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ASCO-AIOM CLINICAL RESEARCH COURSE

Second
edition



Conference Centre "Roma Eventi - Fontana di Trevi"
Piazza della Pilotta 4

ROME - April 12 -13, 2024

PROGRAM

DAY 1
APRIL 12TH,
2024

8.30am

WELCOME AND INTRODUCTION

AIOM – F. Perrone (Naples)
 ASCO – Lynn Mara Schuchter (Pennsylvania)
 ASCO – I. Tannock (Toronto)
 FONDAZIONE AIOM – S. Cinieri (Brindisi)
 FICOG – E. Maiello (S. Giovanni Rotondo)



SESSION I: OVERVIEW OF CLINICAL RESEARCH

8.45am

Good Clinical Practice: basic principles
 M. Piccirillo (Naples)

9.15am

Questions & Answers

9.30am

Roles & Responsibilities of the Research Team
 G. Daniele (Rome) – PI perspective
 J. Bryce (Tulsa) – Research nurse perspective

10.15am

Questions & Answers

10.30am

How to develop a protocol?
 From the hypothesis to study design
 P. Bruzzi (Genoa)

11.00am

Questions & Answers



11.10am – 11.40am COFFEE BREAK

11.40am

Predictive and prognostic biomarkers
 N. Normanno (Naples)

12.10pm

Questions & Answers

12.20pm

Early Drug development & Phase I trials:
 importance of PD assays
 G. Curigliano (Milan)

12:50pm

Questions & Answers

13.00pm – 2.00pm LIGHT LUNCH

2.00pm

Phase II trials: basic principles, basket & umbrella trial design
 I. Tannock (Toronto)

2.30pm

Questions & Answers

2.40pm

Statistical principles in early trials
 M. Sydes (London)

3.10pm

Questions & Answers

3.20pm

Phase III trials: basic principles
 F. Perrone (Naples)

3.50pm

Questions & Answers

4.00pm

Statistical principles in Phase III;
 Analysis of survival curves
 M. Sydes (London)

4.30pm

Questions & Answers



4.40pm – 6.30pm GROUP SESSION I

Workshops – Critical review of concepts and/or reports of clinical trials

Practice groups, around 10 participants, each with two facilitators (oncologist + biostatistician).

Members of the faculty (P. Bruzzi, J. Bryce, G. Curigliano, M. Di Maio, G. Daniele, N. Normanno, F. Perrone, M. Piccirillo, M. Sydes, I. Tannock, D. Trapani) will act as facilitators.

In addition, a further group of facilitators will be present and distributed among groups:

- **Oncologists:** R. Berardi (Ancona), N. La Verde (Milan), F. Nichetti (Milan).
- **Statisticians:** E. Blondeaux (Genoa), L. Boni (Genoa), P. Chiodini (Naples), M. Fordellone (Naples), G. Maglietta (Parma), R. Miceli (Milan), E. Rulli (Milan), S. Signoriello (Naples), V. Simeon (Naples).

6.30pm

End of Session

SESSION I: CLINICAL TRIAL DESIGN AND METHODOLOGY II

DAY 2
APRIL 13TH,
2024

8.30am

Observational studies, real world data
 I. Tannock (Toronto)

9.00am

Questions & Answers

9.10am

Patient-reported outcomes
 M. Di Maio (Turin)

9.40am

Questions & Answers

9.50am

The roles of EMA and the future of clinical trials in the EU
 L. Guizzaro (Amsterdam)

10.20am

Questions & Answers

10.30am – 11.00am COFFEE BREAK

11.00am

Ethical aspects in research
 D. Trapani (Milan)

11.30am

Questions & Answers

11.40am

Common causes for bias in trials and how to avoid them
 I. Tannock (Toronto)

12.10pm

Questions & Answers



12.20pm – 1.30pm LIGHT LUNCH

GROUP SESSION II

1.30pm – 4.00pm

Workshops – Critical review of concepts and/or reports of clinical trials
 Same as day 1

4.00pm

Final test and review

5.15pm

Closing, certification and evaluation