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 March 31st 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 are included.

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Thanks also to

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ASCO AIOM CLINICAL RESEARCH COURSE

ROME, Italy

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

March 31 - April 1, 2023

Program

FRIDAY, MARCH 31, 2023

WELCOME AND INTRODUCTION

8.30am	AIOM - *S. Cinieri (Brindisi)* ASCO - *E. Winer (New Haven)* ASCO - *I. Tannock (Toronto)* FICOG - *C. Pinto (Reggio Emilia)*

SESSION I: OVERVIEW OF CLINICAL RESEARCH

8.45am	Good Clinical Practice: basic principles *F. De Braud (Milan)*
9.15am	Questions & Answers
9.30am	Roles & Responsibilities of the Research Team PI perspective - *L. Licitra (Milan)* Research nurse perspective - *J. Bryce (Tulsa)*
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
1.00pm - 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)*
3.05pm	Questions & Answers
3.15pm	Phase III trials: basic principles *F. Perrone (Naples)*
3.45pm	Questions & Answers
3.55pm	Statistical principles in Phase III; Analysis of survival curves *M. Sydes (London)*
4.30pm	Questions & Answers

GROUP SESSION I

4.40pm - 6.30pm	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, F. De Braud, M. Di Maio, L. Licitra, N. Normanno, F. Perrone, M. Sydes, I. Tannock, D. Trapani, G. Viale)* will act as facilitators.

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

- Oncologists: *R. Berardi (Ancona), G. Daniele (Rome), C. De Angelis (Naples), M. C. Piccirillo (Naples), F. Pietrantonio (Milan)*
- Statisticians: *L. Arenare (Naples), L. Boni (Genoa), P. Chiodini (Naples), G. Maglietta (Parma), R. Miceli (Milan), A. Signori (Genoa), S. Signoriello (Naples), V. Simeon (Naples)*

6.30pm	End of Session

SATURDAY, APRIL 1, 2023

SESSION I: CLINICAL TRIAL DESIGN AND METHODOLOGY II

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 role of the pathologist and the central lab in clinical research *G. Viale (Milan)*
10.20am	Questions & Answers
10.30am - 11.00am	*COFFEE BREAK*

SESSION II: CLINICAL TRIAL DESIGN AND METHODOLOGY III

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