AI in Clinical Trials

SCIENTIFIC DIRECTORS

Arsela Prelaj, Andrea Botticelli

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AIOM ASSOCIAZIONE ITALIANA ONCOLOGIA MEDICA

OVERVIEW

Artificial Intelligence (AI) is rapidly changing Medicine, especially oncology. It offers groundbreaking tools to optimize clinical trial design, improve patient selection, accelerate fact collection from real-world data, increase clinical experimentation efficiency, and maximize the use of innovative pharmacological treatments, such as immunotherapy and targeted therapy. The event promises to explore the potential of AI in oncological clinical research with a multidisciplinary and clinical-praxis-oriented approach.

THE FOLLOWING SPECIFIC OBJECTIVES WILL BE DISCUSSED:

- ***Innovative clinical trial design***
  New experimental models will be explained, including adaptive studies, "umbrella" and "basket trials", as well as the use of synthetic arms and RWD (real-world data) data, to make studies more agile, efficient, and less costly.

- ***Clinical Trial Matching boosted by AI***
  AI can automatically select patients eligible for studies. Therefore, AI can enhance equity in accessing and efficiency in recruiting, even in complex, personalized trials.

- ***AI-driven biomarkers and validation***
  The integration of AI-based predictive biomarkers derived from genomic, clinical, and radiomic data will be discussed, focusing on the level of validation required for their adoption in regulatory and clinical settings.

- ***Ethics, biases, and legal framework in AI***
  A proper use of AI requires great attention to algorithmic biases, discrepancies in its access, and ethical responsibilities. European regulatory principles and implications for AI-assisted trials will be presented.

- ***From validation to clinical implementation***
  Lastly, strategies to efficiently validate and integrate AI models in therapeutic planning and in everyday oncological praxis will be examined.

SCIENTIFIC DIRECTORS

Arsela Prelaj, *Esac President, MD, PhD, Medical Oncologist, Thoracic Oncology Unit, Department of Medical Oncology, Fondazione IRCCS Istituto Nazionale Tumori, Head Of Artificial Intelligence for Oncology Lab, Milano, Italy*

Andrea Botticelli, *Associate Professor, Università La Sapienza, Roma, Breast Unit Coordinator, Policlinico Umberto I, Roma*

CME CREDITS

CME accreditation (valid for Italian participants only) for: Medical Doctor, Pharmacist, Biologist, Nurse, Physicist, Chemist, Biomedical Laboratory Technician, Medical Radiation Technologist
RES ID CME 459606 CME credits RES: 6
FAD ID CME 459613 CME credits RES: 9
Educational objective: 29 - Technological innovation: assessment, process improvement in the management of biomedical, chemical, physical technologies and of medical devices. Health Technology Assessment.
Italian CME credits will be granted to those participants who attend at least 90% of scientific works, fill in the questionnaire assessment of perceived quality and duly fill in the evaluation questionnaires answering correctly 75% of the questions.

REGISTRATION

Registration is free of charge. You may register for:
IN-PERSON OR ONLINE-ONLY ACCESS
www.events-communication.com/event/aiinclinicaltrials/
For information: **segreteria@events-communication.com**

CONGRESS VENUE

Università La Sapienza
Scuola Superiore di Studi Avanzati (SSAS) Aula 201,
Edificio D, 2 ° piano
Viale Regina Elena 295, 00161 - Roma

SCIENTIFIC PROGRAM

09.30 Registration

09.50 Welcome and overview
Arsela Prelaj, Andrea Botticelli,

Filippo de Braud, *Director, Dpt. Oncology&Hemato-Oncology, Fondazione IRCCS INT , Milano*

Paolo Marchetti, *Full Professor of Medical Oncology, Università La Sapienza, Roma*

Paolo Foggi, *Head, Innovation and Pharmaceutical Strategy Dpt. , AIFA, Roma*

INNOVATIVE TRIALS AND MOLECULAR TUMOR BOARDS

Chairs: **Filippo De Braud**
Paolo Marchetti
Claudio Vernieri

10.00 ***TALK:***
Innovative clinical trial design in immunotherapy and targeted therapies
Andrea Botticelli

10.20 Discussion

10.30 ***SPECIAL TALK:***
Molecular Tumor Boards in Real World Data, how we candidate patients in Real World Data to new drugs
Andrea Vingiani

10.45 ***TALK:***
Integration of digital pharmacology into Molecular Tumor Boards
Romano Danesi

11.05 Discussion

MAXIMIZING SUCCESSFUL AI CLINICAL TRIAL DESIGNS WITH AI

Chairs: **Claudia Proto**
Loic Verlingue

11.15 ***TALK:***
Clinical Trial Matching, useful tools how we can incorporate these agents in clinic?
Loic Verlingue

11.35 Discussion

11.45 ***TALK:***
How AI can be useful to design innovative clinical trials
Leonardo Provenzano

12.05 ***TALK:***
Synthetic arms vs Real World Data arms in clinical trials
Saverio D'Amico

12.25 Discussion

12.35 *Lunch*

13.25 Welcome address
Massimo Di Maio,
President-elect of AIOM

TRASTWORTHY CLINICAL TRIALS WITH AI

Chairs: **Giuseppe Lo Russo**
Vanja Miskovic

13.30 ***TALK:***
Biases, disparites and fairness in AI clinical trials
Vanja Miskovic

13.50 ***SPECIAL TALK:***
Ethics in AI-based trials, regulations
Carlo Rossi Chauvenet

14.10 Discussion

AI BIOMARKERS AND REAL WORLD DATA

Chairs: **Luca Boldrini**
Arsela Prelaj

14.25 ***KENOTE LECTURE 1:***
The value of the Real World Data in pragmatic clinical trials
Miriam Koopman

14.50 Discussion

15.00 ***KEYNOTE LECTURE 2:***
The validation process and value of AI biomarkers in clinical trials
Mireia Crispin-Ortuzar

15.25 Discussion

15.35 ***FINAL SPECIAL LECTURE:***
A fingerprint drug for patients: what next with AI discovery?
Marina Chiara Garassino

16.00 Discussion

16.10 *Break*

16.30 ***WORKSHOP:***
AI in clinical trials
Federica Corso, Saverio D'Amico, Alberto Ferrarin, Narmin Ghaffari Laleh, Leonardo Provenzano, Giovanni Scoazec, Giuseppe Viscardi

17.30 ***RECAP***
Arsela Prelaj, Andrea Botticelli

FACULTY

Luca Boldrini, Fondazione Policlinico Universitario A. Gemelli IRCCS, Roma

Andrea Botticelli, Università La Sapienza, Roma, Breast Unit, Policlinico Umberto I, Roma

Federica Corso, Fondazione IRCCS Istituto Nazionale dei Tumori, Milano

Mireia Crispin-Ortuzar, University of Cambridge

Saverio D'Amico, AI Center Humanitas Research Hospital, Milano

Romano Danesi, Università degli Studi di Milano, ASST Grande Ospedale Metropolitano Niguarda, Milano

Filippo De Braud, Fondazione IRCCS Istituto Nazionale dei Tumori, Milano

Alberto Ferrarin, Fondazione IRCCS Istituto Nazionale dei Tumori, Milano

Marina Chiara Garassino, University of Chicago

Narmin Ghaffari Laleh, TU Dresden & University Hospital of Heidelberg

Miriam Koopman, Utrecht University, The Netherlands

Giuseppe Lo Russo, Fondazione IRCCS Istituto Nazionale dei Tumori, Milano

Paolo Marchetti, IDI-IRCCS, Università La Sapienza, Roma

Vanja Miskovic, Fondazione IRCCS Istituto Nazionale dei Tumori and Politecnico di Milano DEIB, Milano

Arsela Prelaj, Fondazione IRCCS Istituto Nazionale dei Tumori, Milano

Claudia Proto, Fondazione IRCCS Istituto Nazionale dei Tumori, Milano

Leonardo Provenzano, Fondazione IRCCS Istituto Nazionale dei Tumori, Milano

Carlo Rossi Chauvenet, SDA Bocconi School of Management, Milano

Giovanni Scoazec, ESAC – European Interdisciplinary Society for AI in Cancer Research, Milano

Loic Verlingue, Centre Léon Berard, Lyon

Claudio Vernieri , Fondazione IRCCS Istituto Nazionale dei Tumori, Milano

Andrea Vingiani, Fondazione IRCCS Istituto Nazionale dei Tumori, Milano

Giuseppe Viscardi, Azienda Ospedaliera Monaldi Cotugno CTO, Università degli Studi della Campania Luigi Vanvitelli, Napoli

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