ECM Fad Sincrona

Real world data and shared decision making: Navigating the intersection of quality, cost and survival

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Scientific Rationale

Scientific research in oncology has led to very significant changes, particularly in the area of breast cancer, in terms of response to treatment and improved clinical outcomes for patients.

Although randomised controlled trials (RCTs) remain the research modality most relied on by regulatory authorities to establish the safety and clinical efficacy of drugs, evidence from the so-called 'real world' of clinical practice outside trials (real world evidence - RWE) is currently playing an increasingly important role as a valuable component for the evaluation, theoretically both 'pre' and 'post' regulatory approval.

RWD refers to analysis derived from prospective and/or retrospective data rou- tinely collected in the course of actual clinical practice.

Although RWE is not a substitute for RCTs, it is certainly a useful tool for supple- menting efficacy and safety data from registration studies. Therefore, important resources must be used to standardise the quality of RWE and validate its use, so that it can be integrated with RCTs to provide unique insights into patients, treatments and outcomes in routine oncology practice.

RWD could play an instrumental role in what is called Shared Decision Making (SDM), i.e. decision-making that actively involves patients in treatment choices, making them aware of different options and the evidence supporting them.

SDM and RWE would, therefore, be tools that contribute to enrich clinical prac- tice and improve patients' care pathways.

Genomic tests represent a key advancement in the personalization of oncology treatments, particularly in breast cancer, by enabling clinicians to tailor therapies based on individual tumor profiles. RWD studies provide critical insights into the adaptability and effectiveness of these tests outside the controlled environment of clinical trials, enhancing their potential to impact patient care within routine practice. By understanding how genomic tests influence treatment choices and patient outcomes in diverse real-world settings, we can further solidify their role in precision medicine.

The course will provide an overview of RWD and SDM, particularly in the context of breast cancer.

PROGRAM

Introduction and Course Objectives – C. Criscitiello, M. Di Maio

Session I: Advancements in Real-World Evidence

Moderators: Giuseppe Curigliano and Mario Giuliano

14:00 – 14:20 Exploring the Evolution of Real World Data (RWD) and Evidence (RWE); the AIOM point of view – Francesco Perrone

14:20 – 14:35 RWE Insights: A Statistical Analysis Perspective – Alessio Signori

14:35 – 14:50 The value of RWD for scientific societies and regulators: are the rules changing? – Antonis Valachis

14:50 – 15:00 Discussion

Session II: Innovations and Future Outlook in Real-World Studies

Moderators: Massimo Di Maio and Giampaolo Bianchini

15:00 – 15:15 Implementing Next-Generation Real-World Studies – Emilio Bria

15:15 - 15:30 Impact of RWD on Clinical Practices: A Case Study in Metastatic Breast Cancer – Andrea Botticelli

15:30 – 15:45 Data Sharing in the Modern Era: Case Studies and Models – Claudio Vernieri

15:45 – 16:00 Discussion

Session III: Enhancing Patient Care through Shared Decision Making

Moderators: Carmen Criscitiello and Grazia Arpino

16:00 – 16:15 Quality of Life and Oncology: Measuring the Impact of New Therapies – Carmine De Angelis

16:15 – 16:30 The Significance of Patient-Reported Outcomes in Healthcare – Massimo Di Maio

16:30 – 17:05 Round Table: Optimizing the Shared Decision-Making Process in Patient Care

Patient Perspective - Rosanna D'Antona
Physician Perspective – Grazia Arpino
Psychologist Perspective - Gabriella Pravettoni

17:05 – 17:20 Q&A

17:20 – 17:30 Summary and Concluding Remarks by Scientific Directors

17:30 - Webinar Closure

RESPONSABILI SCIENTIFICI

Carmen Criscitiello, Divisione Sviluppo di Nuovi Farmaci per Terapie, Innovative. IEO Istituto Europeo di Oncologia IRCCS di Milano, Professore Associato di Oncologia Medica, Dipartimento di Oncologia ed Emato-Oncologia dell'Università degli Studi di Milano
Massimo Di Maio, Professore Ordinario presso Dipartimento di *Oncologia*, Università di Torino

FACULTY

Grazia Arpino, Dipartimento *di* Medicina clinica e Chirurgia, Università Federico II di Napoli
Andrea Botticelli, Policlinico Umberto I, Dipartimento di Scienze Radiologiche, Oncologiche, Anatomopatologiche Università di Roma La Sapienza
Giampaolo Bianchini, IRCCS Ospedale San Raffaele, Milano
Emilio Bria, U.O.S.D. Oncologia Toraco-Polmonare, Fondazione Policlinico Universitario 'A. Gemelli' IRCCS, Università Cattolica del Sacro Cuore, Roma.
Giuseppe Curigliano, Divisione di Sviluppo di Nuovi Farmaci per Terapie Innovative
Rosanna d'Antona, Presidente di Europa Donna Italia
Carmine De Angelis, Oncologia Medica, Università degli studi di Napoli Federico II
Mario Giuliano, Oncologia Medica presso A.O.U. Federico II di Napoli
Francesco Perrone, Struttura Complessa Sperimentazioni Cliniche dell'Istituto Tumori Pascale di Napoli
Antonis Valachis, Department of Oncology Örebro University Hospital Sweden
Gabriella Pravettoni, Professore Ordinario di Psicologia delle Decisioni presso l'Università degli Studi di Milano
Alessio Signori, Dipartimento di Scienze della Salute, Università di Genova.

Segreteria Scientifica: Beatrice Taurelli Salimbeni

Richiesta Patrocinio in corso:
AIOM

CREDITI ECM E DESTINATARI

Il numero di crediti formativi riconosciuti sarà di XX.
L'evento sarà accreditato per un massimo di 500 partecipanti.
La partecipazione al corso è riservata alle professioni di Medico Chirurgo (Discipline: Anatomia patologica, Oncologia), Biologo, Tecnico Sanitario di Laboratorio Biomedico.