
CME Webinar live

Real world data and shared decision making

Navigating the intersection of quality,
cost and survival

Webinar live

13 January 2025

SCIENTIFIC COORDINATORS

*Carmen Criscitiello
Massimo Di Maio*



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RATIONAL

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 routinely collected in the course of actual clinical practice.

Although RWE is not a substitute for RCTs, it is certainly a useful tool for supplementing 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 practice 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.



WEBINAR LIVE

13 January 2025

14:00 - 14:05 Introduction and Course Objectives

*M. Di Maio,
C. Criscitiello*

SESSION I: "Advancements in Real-World Evidence"

MODERATORS: *Giuseppe Curigliano and Mario Giuliano*

14:05 - 14:20 Exploring the Evolution of Real World Data (RWD) and Evidence (RWE); the AIOM point of view

F. Perrone

14:20 - 14:35 RWE Insights: A Statistical Analysis Perspective

A. Signori

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

A. 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

E. Bria

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

A. Botticelli

15:30 - 15:45 Data Sharing in the Modern Era: Case Studies and Models

C. 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

C. De Angelis

16:15 - 16:30 The Significance of Patient-Reported Outcomes in Healthcare

M. Di Maio

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

Patient Perspective
R. D'Antona

Physician Perspective
G. Arpino

Psychologist Perspective
G. Pravettoni

17:05 - 17:20 Q&A

17:20 - 17:30 Sum up e considerazioni conclusive

17:30 Webinar Closure

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Webinar live is included in the list of definitive CME events in the Provider's 2025 training programme

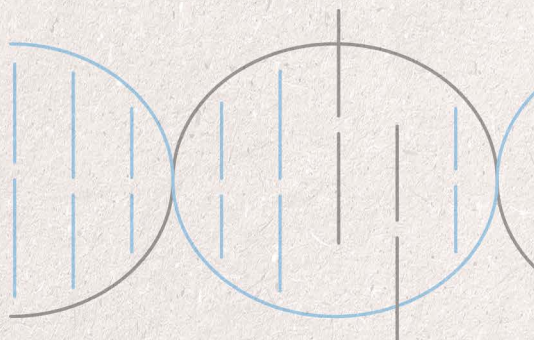
Upon passing the CME assessment test, **4.5 CME credits** will be awarded for the following professional figures: **Surgeon** (Disciplines: **Oncology, Pathological Anatomy**), **Biologist, Psychologist** (Disciplines: **Psychology**), **Biomedical Laboratory Health Technician**

HOW TO REGISTER

- Log on to **www.medicaecm.it**
- If accessing for the first time, click on **Register** in the bar at the top or bottom of the website homepage, and complete the registration form with your personal data.
- You will receive an automatic confirmation e-mail at the specified address.
- Log in/access the **www.medicaecm.it** platform with your personal data and register for the course '**Real-world data and shared decision making' How real-world data can help to solve the equation between quality, cost and survival**', which you will find in the list on the homepage. To complete your registration, please press send.
- This course will take place online on **13 January 2025**
- Once the event is over, the learner will have to fill in the questionnaires evaluation and quality questionnaires, necessary to obtain credits, within and no later than 3 days. Credits will be awarded upon actual attendance at attendance at least 90% of the total duration of the training activity and upon passing the learning test with at least 75% of the of the correct answers.
- For technical assistance, please write to **assistenza@medicaecm.it**.

Real world data and shared decision making

How real-world data can help to solve the equation between quality, cost and survival



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