

Title: **Real world data in the new era of clinical research**

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The clinical research has been marked by significant events that have revolutionized the way to do research. Although the Randomized Clinical Trial (RCT) is the gold standard for establishing the effectiveness of a treatment, it is however well known that it is characterized by a series of important limitations. Due to the ethical and scientific criteria and rigorous methodological that characterize them, the RCTs usually experience a single pharmacological therapy in a highly selected group of patients. For these reasons, it is quite rare that in the course of the RCTs there may be identified beneficial effects on outcomes not foreseen by the study protocol, phenomena of drug interactions as well as rare adverse events or appearing as a result of long-term therapies. For these characteristics, the RCTs lack the so-called external validity. Today begins a new era of clinical research, based on the use of Real World Data (RWD) on the efficacy and safety of pharmacological. Based on these assumptions, the need for RWDs is founded, as a tool to implement knowledge on health services, to generate new evidence, respond to unresolved clinical questions and to promote the development of personalized medicine. The analysis and interpretation of the RWD, or that data collected in the absence of a predetermined question will produce real scientific evidence, better defined as Real-World Evidence.

(Up to 250 words)

**Biography**
Acctually clinical research unit director at the Maria Cecilia Hospital, she worked for several years as a clinical project manager at the Hematology Institute of University of Bologna. She has gained experience in oncology and hematology research. She has taught as an assistant and master professor at the University of Bologna; speaker at national and international conferences. Associate Editor for the journal Hematology Reports, member of the Editorial Board of the Italian Society of Hospital Pharmacy.

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Session name/ number: Challenges in clinical trials- data collection and sharing/ track 7

Category: (Oral presentation/ Poster presentation)

Poster presentation