ABSTRACT

Debate and Round table discussions

- **D3-** Multicenter real world data studies, which impact can they generate?
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Evidence-Based medicine (EBM) is the gold standard in modern science, and high quality randomized clinical trial data are the highest expression of this EBM. However, data from clinical practice, or Real-World Evidence (RWE), is getting increasing interest for research purposes to complement data from clinical trials, in order to confirm the information obtained or to generate new hypotheses and evidence. Furthermore, from the perspective of regulatory agencies and health payers, also local decision makers, RWE can help improve the decision-making process. Health registries are of great value to analyze the variability and adequacy of clinical practice, as well as to measure the results obtained.

Drug use registries are extremely helpful, but are we ready for that paradigm shift? There are some limitations and challenges, but also many opportunities for improvement in this area. We will discuss about technologic and ethical issues, but also about the training and the capacity of health professionals to define and interpret new drug study designs, to ensure the quality of the data obtained and critically analize them, and about the collaboration between professional specialists to conduct multicenter studies.

We will try to address these issues with practical examples to show our local experience in cancer treatments.

Debate/Roundtable - Multicenter real world data studies, which impact can they generate?

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Due to their high prices, oncology drugs represent a huge burden on the health system and have a poorer safety profile compared to other groups of drugs. Therefore, it is extremely important that the data describing the clinically beneficial effect obtained from research (clinical studies) transfer this same effect to the real world. Overall survival is the most important parameter for measuring the effectiveness of treatment of a cancer patient with metastatic disease. It is also considered the gold standard for oncology drug approvals in a particular indication if the results are obtained from a satisfactorily designed study. Currently, there is a growing trend in the approval of oncology drugs by regulatory authorities based on surrogate markers of clinical benefit, due to faster results but also lower costs of such studies compared to studies aimed at examining the impact of the drug on overall survival. The aim of the debate is to try to critically make listeners aware of the results of clinical studies and to point out that sometimes even the strongest evidence of clinical benefit such as overall survival can be questioned regarding beneficial effect for patients and the health system as a whole. Special emphasis in debate will be put on importance of real world data studies.