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SÉMINAIRE

Comment évaluer la médecine personnalisée en cancérologie : Des études rétrospectives aux essais randomisés

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Personalized medicine is defined by the National Cancer Institute as "a form of medicine that uses information about a person's genes, proteins, and environment to prevent, diagnose, and treat disease." In oncology, the term "personalized medicine" arose with the emergence of molecularly targeted agents. The prescription of approved molecularly targeted agents to cancer patients currently relies on the primary tumor location and histological subtype. Predictive biomarkers of efficacy of these modern agents have been exclusively validated in specific tumor types. A major concern today is to determine whether the prescription of molecularly targeted therapies based on tumor molecular abnormalities, independently of primary tumor location and histology, would improve the outcome of cancer patients. This new paradigm requires prospective validation before being implemented in clinical practice. In this communication, we will first review different designs, including observational cohorts, as well as nonrandomized and randomized clinical trials, that have been recently implemented to evaluate the relevance of this approach. We then focus on the SHIVA trial, a randomized proof-of-concept phase II trial comparing therapy based on tumor molecular profiling versus conventional therapy in patients with refractory cancer. We will present various aspects of implementation, underlying statistical and design questions, limits and strengths and review the results using this prism.