

Biomarker-Based Clinical Trial Designs in Oncology

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Opinion

In the precision medicine era, especially in the oncology area, there have been explosions in knowledge of the molecular profile of disease. With cost for the genomic sequencing are also decreasing and becoming more affordable, a large number of tumors are now be able to be classified from molecular biology perspective, with different treatment options and tailored strategies for patients based on their tumor biomarker status. Under the drug development setting, there are new generation trials emerged and targeted to patients selection within any given tumor type based on specific underlying molecular and biologic characteristics. In the early phase drug development of targeted therapies, 'Basket trials' usually are focused only on specific molecular aberrations, in several tumor types (Figure 1). On the other hand, 'Umbrella trials' focus on drug development targeting several molecular subtypes in one tumor type (Figure 2). These innovative approaches to clinical drug development have resulted in rapidly revolutionized methodologies, including adaptive randomization [1], to conduct clinical trials in the setting of biomarkers and targeted therapies, where the traditional paradigm of treating very large number of unselected patients is increasingly less efficient, lack of cost effectiveness and ethically challenging.

In the past few years, there have been a variety of thought-provoking next generation biomarker-based clinical trials conducted multi-institutionally in oncology: specific recognized examples include I-SPY2, BATTLE, NCI MATCH, LUNG-MAP, ALCHEMIST and FOCUS4. Changing the traditional clinical trial design paradigms, biostatisticians are fully integrated in these clinical trials partnering with clinicians, and make critical contribution for advancing therapeutic development in this era of molecular medicine. Meanwhile, the new development of immunotherapeutic agents and implementation of next-generation sequencing (NGS) also brings many new and exciting opportunities in the biomarker driven trials design. From clinical trial operational perspective, they are some logistical challenges to implementing these innovative designs, e.g. central assay testing, drug supply, multiple institutional collaboration, real time data collection and integrations. However, these additional efforts are all worthwhile given the substantial improvement of efficient medicine development, and most importantly, the benefit of the patients.

References

1. Lin, J, Lin L, Sankoh S (2016) A general overview of adaptive randomization design for clinical trials. J Biom Biostat 7: 294.
2. Menis J, Hasan B, Besse B (2014) New clinical research strategies in thoracic oncology: clinical trial design, adaptive, basket and umbrella trials, new end-points and new evaluations of response. Eur Respir Rev 23: 367-378.

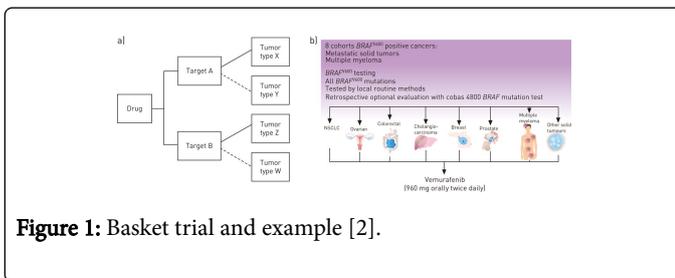


Figure 1: Basket trial and example [2].

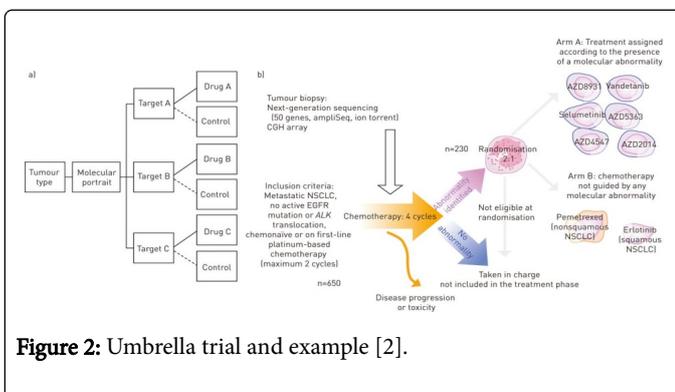


Figure 2: Umbrella trial and example [2].