Statistical Considerations on Complex Innovative Design in Clinical Trials

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Abstract

Clinical trials are an essential part of the drug development process. With the emergence of more complex therapies, such as immunotherapy and gene therapy, there is a need for more innovative and flexible clinical trial designs. These designs, known as Complex Innovative Designs (CIDs), allow for more efficient and informative clinical trials. CIDs can take many forms, including adaptive designs, umbrella designs, and platform trials. These designs often involve multiple stages, multiple treatments, and multiple endpoints. Therefore, one of the major challenges in CID is to determine an appropriate statistical framework for the design and analysis of trials. Many different statistical methods can be used, including Bayesian methods, frequentist methods, and hybrid approaches. Another challenge in CID is the need for flexible sample size calculations. CID often involve interim analyses that sample size calculations may be updated based on the information gained from interim analyses. Additionally, CID often involve multiple endpoints. In this presentation, I will introduce statistical considerations for the design of CID along these lines.

Keywords: Complex Innovative Designs; Bayesian methods; interim analyses.