

Unlocking the Puzzle of Borrowing Adult Data for Designing Hybrid Pediatric Clinical Trials

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Abstract : A challenging aspect of any clinical trial is to carefully plan the study design to meet the study objective in optimum way and to validate the assumptions made during protocol designing. And when it is a pediatric study, there is the added challenge of stringent guidelines and difficulty in recruiting the necessary subjects. Unlike adult trials, there is not much historical data available for pediatrics, which is required to validate assumptions for planning pediatric trials. Typically, pediatric studies are initiated as soon as approval is obtained for a drug to be marketed for adults, so with the adult study historical information and with the available pediatric pilot study data or simulated pediatric data, the pediatric study can be well planned. Generalizing the historical adult study for new pediatric study is a tedious task; however, it is possible by integrating various statistical techniques and utilizing the advantage of hybrid study design, which will help to achieve the study objective in a smoother way even with the presence of many constraints. This research paper will explain how well the hybrid study design can be planned along with integrated technique (SEV) to plan the pediatric study; In brief the SEV technique (Simulation, Estimation (using borrowed adult data and applying Bayesian methods)) incorporates the use of simulating the planned study data and getting the desired estimates to Validate the assumptions. This method of validation can be used to improve the accuracy of data analysis, ensuring that results are as valid and reliable as possible, which allow us to make informed decisions well ahead of study initiation. With professional precision, this technique based on the collected data allows to gain insight into best practices when using data from historical study and simulated data alike.

Keywords : adaptive design, simulation, borrowing data, bayesian model

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