

Use of Hierarchical Bayesian Methods to Evaluation of Multiregional Trials

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Abstract

In recent years, global collaboration has become a conventional strategy for new drug development. To accelerate the development process and shorten approval time, the design of multi-regional trials incorporates subjects from many countries around the world under the same protocol. After showing the overall efficacy of a drug in all global regions, one can also simultaneously evaluate the possibility of applying the overall trial results to all regions and subsequently support drug registration in each of them. Several statistical methods have been purposed for the design and evaluation of multi-regional trials. However, in most of recent approaches, two methods provided by the Japanese MHLW are often used to establish consistency in treatment effect between the specific region and the entire group. In this paper, a hierarchical Bayes method is applied to assess the consistency between the region of interest and overall results in a multi-regional trial. Method for sample size determination for the bridging study is also proposed. Numerical examples illustrate applications of the proposed approaches in different scenarios.