Use of Bayesian approach to design and evaluation of bridging studies

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Abstract

To accelerate the drug development process and shorten approval time, the design of multi-regional clinical trials (MRCTs) incorporates subjects from many countries/ regions 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. In this paper, we focus on a specific region and establish a statistical criterion to assess the consistency between the specific region and overall results in a MRCT. More specifically, we treat each region in a MRCT as an independent clinical trial, and each perhaps has different treatment effect. We then construct the empirical prior information for the treatment effect for the specific region on the basis of all of the observed data from other regions. We will conclude similarity between the specific region and all regions if the posterior probability of deriving a positive treatment effect in the specific region is large, say 80%. Numerical examples illustrate applications of the proposed approach in different scenarios.

Keywords: consistency trend, empirical Bayes, multiregional clinical trials