JOINT EVENT

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&
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Unbiased estimation following a phase II/III clinical trial

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Recently, seamless phase or combined phase clinical trials have become more popular for reducing the estimated time it takes to com-plete the development of drugs. A seamless phase II/III clinical trial's main purpose is to compare a number of drugs or doses in a single trial conducted in two stages. The firrst stage studies all of the experimental doses or drugs and selects the population with the largest sample mean. This selected treatment will continue to the second stage for further analysis. The problem is to obtain the best estimator of the mean of the selected population. In the analysis of two-stage trials, the issue of estimation bias introduced by treatment selection has long been known. The sample mean for the selected population and the maximum likelihood estimator (MLE) are biased estimators of the corresponding population mean, due to combining data from both stages. To correct for the bias efficiently, the uniformly minimum variance conditionally unbiased estimator (UMVCUE) has been derived for trial designs with normally distributed data and unequal stage one and stage two sample sizes. Moreover, formulae for the variances of the MLE and the UMVCUE have been obtained and are compared. Finally, simulation results for the bias of the MLE are presented.

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