International Conference on Advances in Interdisciplinary Statistics and Combinatorics, October 12–14, 2007, University of North Carolina at Greensboro, Greensboro, North Carolina, USA

Coauthors: Jose Pinheiro and Frank Bretz

SAMPLE SIZE CONSIDERATION AND MED PRECISION ESTIMATE IN DOSE-RESPONSE STUDIES

SHANHONG GUAN

Identifying and estimating target doses, such as the minimum effective dose (MED), is a key goal in the drug development. A unified approach, multiple comparison procedure and modeling (MCP-Mod), was proposed by Bretz, Pinheiro and Branson (2005) for designing and analyzing dose finding studies, including the estimation of the MED.

In this paper, we design and implement several bootstrap procedures for estimating the precision of the MED derived via MCP-Mod methodology, including the standard error and the 90% confidence interval. The results are further compared with the asymptotic standard errors and associated confidence intervals. Simulation studies are conducted to evaluate the performance of bootstrap methods and asymptotic variance formula. The methods are illustrated with an example from a Phase II dose finding study. In addition, sample size calculations taking into account the desired precision of the MED estimates are also discussed and illustrated.

Department of Statistics, Univeristy of Wisconsin, Madison, WI
E-mail address: shanhong@stat.wisc.edu