Herman E. Ray, J Biomet Biostat 2013, 4:4
http://dx.doi.org/10.4172/2155-6180.S1.019

OMICS Group Conferences
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2nd International Conference and Exhibition on
Biometrics & Biostatistics

June 10-12, 2013 Hilton Chicago/Northbrook, USA

Inference after a multistage single-arm trial incorporating multiple endpoints

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In the oncology setting, the phase II trial must monitor both efficacy and safety. There are designs which incorporate both response and toxicity into the sample size calculations. Often, the trial is designed with the primary endpoint of interest and it is augmented with monitoring rules for safety such as Continuous Toxicity Monitoring. The single-arm trials are designed to evaluate the response rate against a value derived from literature or experience that represents the response of the current treatment. After the conduct of the trial, an accurate estimate of the response rate is required. It is known that MLE is biased if we just consider response in the clinical trial design with multiple examinations, such as the Simon 2-Stage design. The MLE is also biased if the trial includes multiple endpoints that evaluate data in multiple stages during the conduct of the trial, even if the safety monitoring is constructed independently of the clinical trial design considering only response. We propose a Uniformly Minimum Variance Unbiased Estimator (UMVUE) for the efficacy response rate in multistage designs that include toxicity as well. The proposed estimator and the typical maximum likelihood estimator (MLE) are evaluated through simulation. We further modify our procedure when continuous toxicity monitoring is combined with a multistage design for response. The resulting modified estimator maintains low bias over the range of possible response values as well.

Biography

Herman Ray received his Ph.D. from the University of Louisville, where he conducted research at the JG Brown Cancer Center. He currently has several manuscript published considering multiple stage single-arm designs that consider multiple endpoints. He is now an Assistant Professor of Statistics at Kennesaw State University located in Kennesaw, GA.

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