Andrew M Hartley, Clinic Pharmacol Biopharm 2014, 3:2
http://dx.doi.org/10.4172/2167-065X.S1.006

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Summit on
Clinical Pharmacy
December 02-03, 2014 DoubleTree by Hilton Hotel San Francisco Airport, USA

Bayesian adaptive blinded sample size adjustment for comparing two normal means

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Adaptive sample size adjustment (SSA) for clinical trials consists of examining early subsets of on-trial data, so as to adjust prior estimates of statistical parameters and sample size requirements. Blinded SSA, in particular, while in use already, seems poised to proliferate even further, due to recent draft guidance from the U.S. Food and Drug Administration. On the other hand, current blinded SSA methods offer little to no new information about the treatment effect (TE); the obvious resulting problem is that the TE estimate scientists might simply "plug in" to the SS formulae could be severely wrong. This presentation describes a blinded SSA method which formally synthesizes sample data with prior knowledge about the TE and the variance. It evaluates the method in terms of the average absolute deviation from the targeted statistical power, the type 1 error rate, the bias of the estimated TE and other measures. Under the conditions considered, the method reduces that average absolute deviation by roughly 15% to 25%, relative to another, established method. Simulations show the method to induce minimal bias and negligible to no increase to the type 1 error rate.

Biography

Andrew Hartley, PhD, is an Associate Statistical Science Director in PPD's Wilmington, North Carolina office and has over 8 years of experience as lead statistician and senior reviewer, on clinical trials in anti-infectives, oncology, neuroscience and metabolic disorders. He earned his PhD in Statistics at Old Dominion University in 1997, and has a total of 14 years of experience in clinical trials, with particular focus in longitudinal analysis, Bayesian inference, and decision analysis.

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