Blinded and Unblinded Sample-size Recalculation under Parametric Models

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# Introduction

We use design re-sampling framework, previously proposed in [1], for approximating distributions of estimates of population parameters in the presence of nuisance parameters in pre-planned adaptive designs. We apply this re-sampling to likelihood ratio tests in Linear, Logistic and Poisson multiple regression models with sample size re-estimation (SSR). We consider estimation of nuisance parameter in blinded and unblinded manner. At the interim analysis, the sample size recalculation procedure resamples the whole study design to find a total sample size and a new critical value. As shown in our Monte-Carlo simulation studies this re-sampling method shows more accurate control of type I error and power when compared with naive sample size recalculation. This resampling procedure for SSR allows researchers to spend less resources than the naive SSR while it asymptotically secures the pre-determined type I error and power against a local alternative.

**References**

[1] Tarima S., He P., Wang T., and Szabo A. An Interim Sample Size Recalculation for Observational Studies / Observational Studies, 2, p. 65-85, 2016.

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