Estimation in classic and adaptive group sequential trials

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Abstract. We present a R-package for estimation in classic and adaptive group sequential trials. We will give an overview of classic and adaptive group sequential designs and will present two methods for the calculation of p-values and confidence intervals. The first method is based the repeated approach of Jennison and Turnbull (1984), which was extended by Mehta, Bauer, Posch and Brannath (2006) to the adaptive setting. The second method is based on the stage-wise ordering of Tsiatis, Rosner and Mehta (1989), which was extended by Brannath, Mehta and Posch (2008) to the adaptive setting. The key idea of both methods, based on the method of Müller and Schäfer (2001), is to preserve the overall type I error rate after a possible design adaptation, by preserving the null conditional rejection probability of the remainder of the trial at each time of an adaptive change. The implementation and the application of these methods in R (available in package AGSDest) will be illustrated.

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Keywords

ADAPTIVE GSD, CONFIDENCE INTERVALS, POINT ESTIMATES