



SAMPLE SIZE RE-ESTIMATION FOR ADAPTIVE SEQUENTIAL DESIGN IN CLINICAL TRIALS

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Abstract

There is considerable interest in methods that use accumulated data to modify trial sample size. However, sample size re-estimation in group sequential designs has been controversial. We describe a method for sample size re-estimation at the penultimate stage of a group sequential design that achieves specified power against an alternative hypothesis corresponding to the current point estimate of the treatment effect.

Key Words: Adaptive design; Brownian motion; Conditional power; Markov process; Sample size, re-estimation; Sequential design; Transition function

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