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Efficient adaptive designs with mid-course sample size adjustment in clinical trials

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Adaptive designs have been proposed for clinical trials in which the nuisance parameters or alternative of interest are unknown or likely to be misspecified before the trial. Whereas most previous works on adaptive designs and mid-course sample size re-estimation have focused on two-stage or group sequential designs in the normal case, we consider here a new approach that involves at most three stages and is developed in the general framework of multiparameter exponential families. Not only does this approach maintain the prescribed type I error probability, but it also provides a simple but asymptotically efficient sequential test whose finite-sample performance, measured in terms of the expected sample size and power functions, is shown to be comparable to the optimal sequential design, determined by dynamic programming, in the simplified normal mean case with known variance and prespecified alternative, and superior to the existing two-stage designs and also to adaptive group sequential designs when the alternative or nuisance parameters are unknown or misspecified.

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