

Title:

**Efficient Adaptive Designs Allowing Mid-Course Sample Size Adjustment in Clinical Trials**

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**Abstract:**

Whereas previous works on adaptive design of clinical trials and mid-course sample size re-estimation have focused on two-stage or group sequential designs and conditional power to determine either the second-stage sample size or adjustments to the prespecified group sizes, we consider here a new approach that involves four or fewer stages and a different criterion to determine the second-stage sample size. Not only does this approach maintain the prescribed type I error, but it also provides an asymptotically efficient sequential test whose finite-sample performance, measured in terms of the expected sample size and power, is shown to be superior to the existing two-stage or adaptive group sequential designs.