

Title:

**A Combined Superiority and Non-Inferiority Approach to Multiple Endpoints in Clinical Trials**

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**Abstract:**

Treatment comparisons in clinical trials often involve multiple endpoints. By making use of bootstrap tests, we develop a new nonparametric approach to multiple-endpoint testing that can be used to demonstrate non-inferiority of a new treatment for all endpoints and superiority for some endpoint when it is compared to an active control. It is shown that this approach does not incur a large multiplicity cost in sample size to achieve reasonable power and that it can incorporate complex dependencies in the multivariate distributions of all outcome variables for the two treatments via bootstrap resampling.

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