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ADeS: A Flexible Adaptive Design Strategy for Ethical and Covariate-Balanced Clinical Trials

Adaptive randomization in clinical trials often requires balancing competing goals: improving patient benefit, preserving statistical efficiency, and maintaining adequate randomness in treatment assignment. We propose the Adaptive Design Strategy (ADeS), a flexible group-sequential framework that unifies covariate-adaptive (CA), response-adaptive (RA), covariate-adjusted response-adaptive (CARA), and hybrid RA+CA/CARA+CA designs within a single objective-based formulation. At each interim step, ADeS selects treatment allocations for the incoming patient group by minimizing a composite criterion that combines ethical or response-adaptive targets with covariate balance. The optimization is performed through a simulated annealing engine, while an acceptance-randomization step preserves a controlled level of randomness in the implemented assignments.

The framework accommodates multiple treatments, different outcome types, and arbitrary baseline covariates. In particular, predictive components can be specified through either parametric or nonparametric models; in our implementation, Bayesian Additive Regression Trees are used to capture complex treatment-covariate interactions. For finite stratified covariates, we establish strong consistency of the resulting stratified estimators. Extensive simulation studies with homogeneous and heterogeneous treatment effects show that ADeS achieves a favorable trade-off between ethical allocation and inferential performance, while remaining more flexible than existing adaptive procedures.

Special/ Invited session

Statistics and data science in the technological field: current issues and new proposals

Classification

Mainly methodology

Keywords

Biomarkers; Covariate-Adaptive procedures; Covariate-Adjusted Response-Adaptive designs; Inferential efficiency; Precision medicine; Treatment by covariate interactions

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