Title: Protect clinical trial integrity by reducing the allocation predictability of subject randomization algorithm

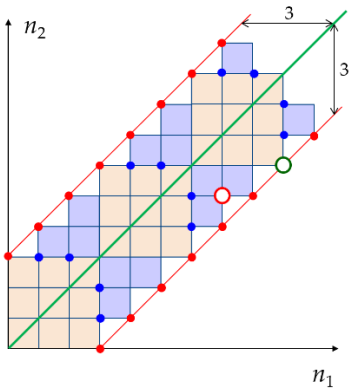
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I. Abstract

Well-blinded randomized controlled trials are often considered the gold standard for assessing the efficacy of clinical treatments. In practice, complete random treatment allocation has rarely been used. Permuted block design and minimization are the two most commonly used methods for treatment allocation, in order to control treatment imbalance as well as baseline covariate imbalances. The cost of using the restricted and dynamic randomization methods is the increase of allocation predictability, which is the primary risk factor for selection bias in clinical trials. Better alternatives to the permuted block design and the minimization method have been proposed in recent years. The block urn design releases the permuted block design's enforced block-end perfect balance, while keep the same maximum tolerated imbalance. It significantly reduces the proportion of deterministic assignments, and therefore, the allocation predictability. The mass-weighted urn design is capable to accurately target any unequal allocation ratios, in the format of rational or irrational numbers. It is especially valuable in Bayesian adaptive trials where the target allocation is updated based on accrued response data in the study. Unlike the minimization method, which uses a zero-tolerance rule toward baseline covariate imbalance, the minimal sufficient balance strategy prevents serious imbalances only. Therefore, it can handle a large number of baseline covariates while keeping a high level of allocation randomness. These three new methods have been published and used in many large multicenter clinical trials. This talk presents the design concepts and the implementation procedure of these advance randomization methods.

II. Image:



III. Biography (Up to 100 words)

Wenle Zhao is a professor of biostatistics in the Department of Public Health Sciences at the Medical University of South Carolina (MUSC), USA. He obtained his PhD in biostatistics from MUSC and worked on clinical trial design and operation management for more than 20 years. He is the associate direct of the Data Coordination Unit at MUSC, and has published more than 60 papers and given more than 40 invited talks in the field of clinical trials.

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