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The Optimal Design of Clinical Trials with Potential Biomarker Effects, A Novel Computational Approach

As a future trend of healthcare, personalized medicine tailors medical treatments to individual patients. It requires to identify a subset of patients with the best response to treatment. The subset can be defined by a biomarker (e.g. expression of a gene) and its cutoff value. Topics on subset identification have received massive attention. There are over 2 million hits by keyword searches on Google Scholar. However, designing clinical trials that utilize the discovered uncertain subsets/biomarkers is not trivial and rarely discussed in the literature. This leads to a gap between research results and real-world drug development.

To fill in this gap, we formulate the problem of clinical trial design into an optimization problem involving high-dimensional integration, and propose a novel computational solution based on Monte-Carlo and smoothing methods. Our method utilizes the modern techniques of General-Purpose computing on Graphics Processing Units for large-scale parallel computing. Compared to a published method in three-dimensional problems, our approach is more accurate and 133 times faster. This advantage increases when dimensionality increases. Our method is scalable to higher-dimensional problems since the precision bound of our estimated study power is a finite number not affected by dimensionality.