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Bayesian Decision-Optimal Interval (BOIN) designs for Phase I clinical trials

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Interval designs are a class of phase I trial designs for which the decision of dose assignment is determined by comparing the observed toxicity rate at the current dose with a pre-specified (toxicity tolerance) interval. If the observed toxicity rate is located within the interval, we retain the current dose. If the observed toxicity rate is greater than the upper boundary of the interval, we deescalate the dose. If the observed toxicity rate is smaller than the lower boundary of the interval, we escalate the dose. The most critical issue for the interval design is choosing an appropriate interval so that the design has good operating characteristics. By casting dose finding as a Bayesian decision-making problem, we propose new flexible methods to select the interval boundaries so as to minimize the probability of inappropriate dose assignment for patients. We show, both theoretically and numerically, that the resulting optimal interval designs not only have desirable finite- and large-sample properties, but also are particularly easy to implement in practice. Compared to existing designs, the proposed (local) optimal design has comparable average performance, but a lower risk of yielding a poorly performing clinical trial.

Biography

Suyu Liu is an Assistant Professor at the University of Texas MD Anderson Cancer Center, USA. Her current research focuses on the development of novel adaptive designs for clinical trials. Examples include phase I trial designs to find the maximum tolerated dose (MTD), Phase I/II designs to find the recommended dose accounting for both toxicity and efficacy, dose-finding designs that accommodate late-onset toxicities and biomarker-based adaptive designs for targeted therapy development. She has published more than 30 papers in reputed statistical journals and medical journals.

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