

Statistics and Data Science Seminar

Enhanced Understanding of MCPMod in Dose-ranging Studies

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Abstract: In dose ranging clinical trials, it is critical to investigate the dose-response profile and to identify a minimum effective dose (MED) to guide the dose selection for phase 3 confirmatory trials. Traditional dose ranging trials focus on pairwise comparisons between placebo and each investigational dose, while in recent years MCP-Mod (Multiple Comparison Procedures & Modeling) arose and gained popularity in the design and analysis of dose ranging trials. Comprehensive comparison between MCP-Mod and other methods have been made on continuous variables assuming a normal distribution. We extend the comparison to binary/binomial response variables. Via simulation, the rate of correct and incorrect MED identification are compared for Dunnett's test, trend test and MCP-Mod for a variety of underlying dose response profiles including both monotone and non-monotone dose responses and are compared under a large number of trial design settings. The precision of MED estimation using MCP-Mod is also evaluated comparing the design options of more dose levels and smaller sample size per dose versus fewer dose levels and larger sample size per dose

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