Speaker: Evan Kwiatkowski (University of Texas)

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Title: Incorporating External Data in Bayesian Clinical Trial Design Using Posterior Predictive Checks

Abstract:

Bayesian methods provide a natural approach for incorporating external data into the analysis of a clinical trial through an informative prior distribution. Prior-data conflict occurs when the prior primarily favors regions of the parameter space that are far from those supported by the likelihood for the current trial data. The predictive distribution based on the current trial data can be used to assess the compatibility or relevance of the external data (i.e., Box's p-value).

We determine the compatibility of a prior and the current trial data using posterior-predictive assessments and apply this to clinical trial designs for which pertinent preexisting data are available. In an application related to rare disease trials, we introduce an adaptive monitoring prior for efficacy evaluation that dynamically weighs skeptical and enthusiastic prior components based on the degree to which the trial data are consistent with a similar completed trial. In an application related to hybrid designs, we introduce a novel extension of the power prior where the discounting weights are computed separately for each external control based on compatibility with the randomized control data.