TITLE: Bayesian hierarchical model for subgroup analysis

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ABSTRACT:
In conventional subgroup analyses, only data within the subgroup are used to estimate that subgroup's treatment effect. Subgroup treatment effects estimated this way tend to lead to a collection of estimates more variable than the underlying subgroup treatment effects. A Bayesian hierarchical model (BHM), starting with exchangeability in treatment effect across subgroups, after adjusting for effect modifiers and other relevant covariates, can be used to derive more precise, and less heterogenous estimates of subgroup treatment effects. The collection of the underlying subgroup treatment effects will tend to be closer to these "shrinkage" estimates than the conventional estimates. In this presentation, we will discuss the technical details for applying one-way, and multi-way BHM using summary-level statistics, and patient-level data for subgroup analysis. Case studies based on new drug applications are used to illustrate the application of these models in subgroup analyses for continuous, dichotomous, time-to-event, and count endpoints.