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Primary outcome is not significant, now what?

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Randomized controlled trials provide a high level of evidence regarding the cause and effect relationship between intervention and a predefined primary outcome. Adequate well-controlled trials do not come with a low price tag. When the primary outcome show small non-significant positive trends, what can be done to salvage the trial? While these neutral trials fall short of providing convincing evidence of efficacy, sponsors are well served in mining the data for potential answers to the following: Are there any subgroups that may potentially benefit from the intervention?, and are there any posthoc analyses that may help elucidate the treatment effect? Posthoc analyses may help improve study design and in some cases establish care pathway. Subgroup analyses are a useful hypotheses generating activity for future trials. Preferably, they have been prespecified in the study protocol, based on the study primary outcome, found by tests for interactions and based on baseline risk categorization. We present examples based on the sponsor experience and from the literature.

Biography

Geraldine E Baggs has completed her PhD in Statistics from The Ohio State University. She is currently working as a Section Manager of the Statistical Sciences Department at Abbott Nutrition R&D. In this role, she provides statistical leadership in the design, monitoring, analysis, and interpretation of clinical trial data, contributes to regulatory submissions and registration efforts globally, assists legal, QA and food safety groups, and manages the strategic direction of the statistical sciences group.

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