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Study Designs Reducing Placebo Response

Yun Chon, PhD

Director of Biostatistics

AMGEN Inc

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3:30pm - 4:30pm, CHS 33-105A

Refreshments served at 3:00 PM in room 51-254 CHS

ABSTRACT: Placebo response in clinical trials has been a problem especially in the drug development of neuroscience area. Not only trials of new drug that are unable to beat the sugar pills, some products that have been on the market are faltering in more recent follow-up study (Silberman 2009). Some literature mentioned percent of total randomized subject to placebo, placebo lead in, number of countries, sites and visit in the study and central rating as factors related to placebo response. In this talk, we will discuss some design factors that have been used in neuroscience clinical trials to reduce the placebo response and will introduce a novel design to reduce placebo response, Sequential Parallel Comparison Design (SPCD). An SPCD trial involves two double blind phases of treatment where the randomization in 2nd phase is performed within each response status of the first phase results. This design enriches study population by randomizing the placebo non-responder into placebo vs. treatment group. The treatment inferences are based on a combined analysis of both the initial and second phases of the study.