

## DIA 2013 49<sup>th</sup> Annual Meeting "Advancing Therapeutic Innovation and Regulatory Science" June 23 – 27, 2013 Boston Convention and Exhibition Center Boston, MA

## Session 143- Key Multiplicity Issues in Clinical Trials

Multiple-outcome testing within a clinical trial can increase the probability of a false positive study or a family wide error rate (FWER). Therefore, controlling this probability in a clinical trial at a desired nominal significance level is a major area of concern. This challenging issue and statistical methods to address it were discussed in the *Key Multiplicity Issues in Clinical Trials* (Session 143).

Mohammad Huque, PhD (FDA), began the session by summarizing the draft guidance "Multiple Endpoints in Clinical Trials" from a regulatory perspective. Dr. Huque identified important concepts and considerations throughout the 5 sections of the draft, which encompasses multiplicity topics and issues arising in adequate and well-controlled studies. According to Dr. Huque, the guidance is "intended for a broad audience" and allows for "clinical and statistical ideas to flow together."

Ralph B. D'Agostino, SR PhD, MA, a chair in the academics department at Boston University, presented *Key Multiplicity Issues in Clinical Drug Development*. Here, Dr. D'Agostino pointed out various methods to control FWER with multiple endpoints using examples of "the good, the bad, and the ugly" that he has witnessed in academia.

Alex Dmitrienko, PhD (Quintiles Inc.), served as the session chair and concluded the forum with an *Analysis of Clinical Trials with Multiple Objectives*. In his presentation, Dr. Dmitrienko described the requirements and history of gatekeeping procedures used in clinical trials for multiple families of null hypotheses. He then elaborated on their applications and statistical considerations through case studies.

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