Academic Webinar Series

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Nov 8th, Wednesday
9-10 am EST

For more information regarding upcoming webinar schedule, please contact: medecc.us@boehringer-ingelheim.com

Title

Blinded Ongoing Aggregate Safety Evaluation (Blinded-OASE)

Abstract

In order to identify potential safety issues earlier in the development process, more interest and attention have been paid to Ongoing Aggregate Safety Evaluation (OASE). The FDA IND Safety Reporting Final Rule requires a safety report whenever aggregate analysis indicates that events occur more frequently in the drug treatment group than in a concurrent or historic control group. We have designed Blinded-OASE using a Bayesian method with a dynamic, cross-disciplinary process that allows for continual safety monitoring with blinded data and that is ideal for learning and making decisions. At any time during the study, we can make easily interpretable posterior probability statements about arm-specific rates of specified events using the observed pooled numbers of events and patients (or exposure times). Simulation studies of our approach demonstrate good operating characteristics when some relevant prior information is available. We have evaluated this procedure in a pilot project and are currently working to implement it in several Phase 3 clinical trial programs.

Professional Biography

Dr. Greg Ball's current research on blinded safety monitoring procedures emerged from his early work at academic medical centers and CROs, developed into his college dissertation and continues to be developed in collaboration with statistical and clinical scientists from several pharmaceutical companies. He is a co-lead for the ASA Safety Monitoring working group, focusing on safety regulations and cross-disciplinary scientific engagement.

Dr. William Wang is an executive director, clinical safety Statistics, at Merck. He has supported regulatory filings in multiple therapeutic areas and established the biostatistics Asia Pacific operation. He serves on DIA's China Regional Advisory Board and Global Community Leadership Council (CLC), chairs an ASA safety monitoring working group, and is a deputy topics-leader in the ICH E17 working group on multi-regional clinical trials.

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