

BIOSTATISTICS SEMINAR



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Data Monitoring Committees: Deciding What's Out-of-Bounds For a Clinical Trial Sponsor

Data monitoring committees (DMCs) have a unique role in trial oversight, and while responsibilities may vary somewhat according to the clinical research setting, some fundamental principles apply broadly. DMCs are used to periodically review the accumulating unblinded safety and efficacy data by treatment arm, and advise the trial sponsor on whether to continue, modify, or terminate a trial based on a benefit–risk assessment. Statistical methods have been developed to control error associated with multiplicity when conducting interim analyses under fixed and adaptive designs. Plans for execution of interim analyses need to also safeguard against the potential of operational bias. Three scenarios where analysis plans, organization flow, and decision processes are critical to maintaining trial integrity are: (1) early termination in multi-arm studies, (2) adaptive sample size re-estimation, and (3) unplanned changes to the study design. Examples from NIH-sponsored and investigator-initiated trials are used to illustrate the complexity of these scenarios and the impact execution had on the trial.

Thursday September 26, 2019

3:30 pm - 4:30 pm

Blue Cross and Blue Shield of North Carolina Foundation Auditorium



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