A Statistician’s Guide to DMC – Overview, Standards, and Best Practice

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PDMCs (Data Monitoring Committees) are an important component of the clinical trial process. They are charged with reviewing interim data and making recommendations to protect the safety of trial participants and ensure the scientific integrity of the study. We will cover beginning, intermediate, and advanced topics regarding the DMC process and how all statisticians – the DMC member, the sponsor, and the SDAC (Statistical Data Analysis Center) supporting the DMC - can better work together.

Specific topics to be discussed will include the history of DMCs and current guidance documents; the organizational flow of the DMC process and the responsibilities of those involved; DMC meeting structure, timing, and purpose; logistics of DMC membership including assessment of conflict of interest; DMC review of study conduct, safety, efficacy (possibly with formal boundaries); closed session interaction between the SDAC and DMC; hallmarks of a good SDAC; DMC recommendations including considerations for recommending premature termination of the study or alternatives; and examples of “tricky situations” sometimes faced by the DMC and the SDAC and how to deal with them.

Finally, we will review the latest draft FDA guidance on DMCs and the implications for all parties.