Data and Safety Monitoring Board Workshop

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Abstract

Data and Safety Monitoring Boards (DSMBs) are a common feature of long-term clinical studies in serious and life-threatening conditions. This Workshop describes the remit and composition of DSMBs, and how their work relates to other parties involved in the study, such as the sponsor, the study project team, the investigators, the Steering Committee and the data management centre. The importance of pre-trial preparation by the DSMB is stressed. Consideration is given to the nature and purpose of safety and efficacy data reports presented to the DSMB, and the balance between the timeliness and the accuracy of the data available is discussed. Statistical problems inherent in repeatedly making multiple treatment comparisons are highlighted, and formal stopping guidelines based on repeated safety analyses are presented. The role of the DSMB in trials with pre-specified interim efficacy analyses will be discussed.

The Workshop is structured around group discussions in which participants will play the roles of DSMB members and will discuss realistic trial reports of interim safety and efficacy.

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