MRC Hubs for Trial Methodology Research

North West Hub

Data and Safety Monitoring Board Workshop

A Workshop designed for people who serve on Data and Safety Monitoring Boards, people who organise them, and people involved in preparing adverse event and statistical reports for them

Location: **Sherrington Building, University of Liverpool**

Presenters: **John Whitehead and Anne Whitehead, Lancaster University**

Date: **Wednesday, 23 June 2010, 9.30 – 17.00**

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 focus of the day will be on definitive phase III trials.

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.

Programme

- Role and composition of a DSMB
- Confidentiality and blindness
- Presentation of safety reports
- Formal stopping rules for safety
- Interim efficacy analyses and sequential designs

Cost: £75, to include course materials, lunch and refreshments

Booking: Email: nwhtmr@liv.ac.uk

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