Community Healthcare System

The Review

Community Healthcare System Central IRB (CHS CIRB)
Website: www.drcomhs.org

Volume 2 No. 4 *April 2019*

Data Safety Monitoring Board (DSMB)

What is a DSMB?

A DSMB is a multidisciplinary group that is usually composed of three to six experts in at least two areas: 1) medical issues; the disease, drug, device, procedure, or outcome measures and 2) research methodology; clinical trials design, data management, and statistical analysis. For some studies, expertise in research and biomedical ethics is also required. The criterion for serving on a DSMB is a lack of ties, affiliations, or interests that might create bias when evaluating data or making recommendations. The independence of the DSMB requires that its members have no professional or financial interest in the outcome of the studies it monitors.

What if the function of a DSMB?

The boards usually review data at predetermined intervals during the study, operating under protocol specified rules for considering whether or not the study should continue. They can monitor the timeliness of accrual, the quality of data collection and management, and the accumulating outcomes to assure the safety of the subjects and the scientific integrity of the study.

The DSMBs meet with investigators to discuss issues of data quality, accrual rates, outcomes and adverse events. Following an open meeting, a closed session is conducted to review the issues. The discussion may result in recommendations to continue the study as planned, modify or stop the study entirely.

The DSMB may conclude that a study should be stopped for several reasons.

- Efficacy – With high certainty, the study question has been answered
- Futility – The study question will not be answered when the study is completed
- Safety – The risks to subjects are too high

Their decisions are rendered as suggestions to the sponsors or investigators and are subject to review and negotiation before their implementation.

DSMBs and the IRB

IRBs are inundated with massive amounts of adverse event reports that have not been organized into a format conducive to meaningful review. DSMBs can assist IRBs in their oversight of studies because they have greater access to the accumulating data than IRBs and can unblind the treatment assignments of either individuals or groups of participants. Review of unblinded data by a DSMB can detect excess morbidity or mortality in one arm of a large trial that is not apparent to the IRB or investigators. This unique insight of the DSMB contributes to safety because it minimizes the exposure of subjects to more risky or less effective therapies.

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