Data Monitoring Committees

About Data Monitoring Committees

A Data Monitoring Committee (DMC), also known as a Data Safety Monitoring Board (DSMB), is an independent group of expert clinicians and statisticians that monitors patient safety and treatment efficacy data throughout a clinical study. It is a sensitive process as the DMC deliberates over unblinded data in order to provide recommendations to the sponsor as to whether a trial be continued, modified, or stopped due safety concerns, overwhelming benefit or treatment futility. DMC oversight of a clinical trial, can be helpful to keep trials on track, catch any safety issues early on and reduce risk.

WCG's Data Monitoring Services

As an industry leader in DMC management, WCG brings clients the largest committee dedicated staff in the industry, our own global network of more than 950 vetted medical experts who can serve as committee members or expert advisors to clients, and a proprietary technology platform that provides user-friendly data packages and streamlined operations for effective decision-making.

WCG's executive leadership remains deeply involved in public-private thought leadership efforts that focus on shaping DMC best practices. We work with clinical trial sponsors, academic experts and regulatory agencies to focus on providing the best independent committee solutions on the market to enhance trial integrity by providing independent, unbiased recommendations to our sponsors.

The use of Data Monitoring Committees is thought to be especially helpful in the following situations:

- Studies with highly favorable or unfavorable endpoint results
- Studies in which there is a prior reason for a particular safety concern (e.g., an invasive procedure)
- Studies where there is prior information suggesting the possibility of serious toxicity with the study treatment
- Studies being performed in a potentially fragile population, such as children, pregnant women, the elderly, or those who are terminally ill or of diminished mental capacity
- Studies being performed in a population at elevated risk of death or other serious outcomes
- Studies with high enrollment or long duration across multiple sites

Data Monitoring Best Practices and Thought Leadership

WCG's Data Monitoring solutions are largely focused on the proper establishment of the process. In order to provide consistent and efficient services, we have created detailed "Best Practice Guides" to help clients navigate through the critical decisions that should be made upfront in the design of the process. Additionally, WCG structures our processes around current regulatory thinking. WCG's Chief Scientific Officer, Dr. Jonathan Seltzer, serves on Clinical Trial Transformation Initiative's (CTTI) Steering Committee and is heavily involved in their DMCs project which is working to propose solutions to several emerging issues in the conduct of DMCs and guide the revision of the 2006 FDA Guidance on the Establishment and Operation of Data Monitoring Committees.