A Data Monitoring Committee (DMC) is responsible for the monitoring of patient safety and treatment efficacy of ongoing clinical trials. Interim DMC reports provide analyses in the form of tables and graphics that are frequently aggregated by treatment group.

The Statistical Data Analysis Center (SDAC) at the University of Wisconsin-Madison specializes in producing interim reports and analyses for DMCs. Our reports are graphically based, allowing DMC members to easily identify differences between treatment groups or changes over time, and to review a large amount of information in a short amount of time.

DMCs may also require subject-level presentation of data in order to look more closely at particular cases of concern. For example, an aggregate graphical view of laboratory data such as box plots may reveal outliers suggesting hepatotoxicity but provide no additional information. Plots displaying multiple types of data over time, such as laboratory results, adverse events, and dosing, for individual subjects, may provide additional insight into the possible underlying pathology. Concurrent elevated liver enzymes could indicate drug induced liver injury; however, elevated liver enzymes could also occur in the presence of viral hepatitis. These patterns, lost in aggregate analysis of a single parameter, are revealed in the subject-level graphical presentation.

Here we present examples of graphics for individual subject data with features that we have found useful for DMC reports. Types of data displayed may include demographics, subject disposition (on treatment, discontinued treatment, completed study, death), dosing, event data (adverse events, positive antibody test results), and continuous measures (laboratory test results, bone density). Relevant text, such as a list of adverse events, may be presented adjacent to the graphic panel.

For more information about SDAC, including a link to a sample DMC report, please visit our web site: https://www.biostat.wisc.edu/content/clinical-trials-statistical-data-analysis-center-sdac