The Statistical and Data Coordinating Center (SDCC) at Rho is responsible for creating materials for Data and Safety Monitoring Board (DSMB) review for many studies in the Immune Tolerance Network (ITN) project. Fifteen studies in this network are reviewed by four different DSMBs based on therapeutic category: autoimmunity, type 1 diabetes, asthma/allergy, and solid organ transplant.

Since the primary purpose of the DSMB is to ensure the safety of the subjects in the trial, it is important to create materials containing a large amount of information in a way that facilitates expedited review. In order to gain a clear understanding of the study data and have minimal displays, Rho creates graphical displays whenever possible. Supporting tables and listings are included with the DSMB materials to provide additional details; however, we have found that these tables and listings are seldom utilized when informative graphical displays are provided.

Several graphical displays have been developed to illustrate subject visit status, show the timing of important clinical events in relation to study intervention, allow for comparison of clinical data from various data streams, and summarize trends while showing troublesome outlying data. Examples of graphical displays will be shown and described on the poster. These figures were created using the SAS® system software version 9.1 (or higher). Many of these figures could be utilized for clinical trials across therapeutic areas to facilitate DSMB review.

The figures included in this poster are examples of tools to allow DSMB members to more efficiently review a clinical trial. Overall trends, group comparisons, and problems are easier to observe in a figure than listings of data or summary tables. Figures permit review of multiple parameters at once and are easier for reviewing temporal relationships. Coloring in figures also allows the creator to highlight key findings for the DSMB members to review. Overall, a one page figure is more efficient and effective at giving the reviewer a thorough understanding of the trial data than reading through pages of data listings.

In contrast to summarizing the number of adverse events in a table, including a figure of frequencies by preferred term permits efficient review. A reviewer is quickly able to see any imbalances in treatment groups and alarming frequencies of events. Coloring serious adverse events or other key outcomes points out important information for the DSMB’s review.

This laboratory figure shows summary statistics across all subjects while presenting results for subjects with extreme values. Figures for each laboratory test are much easier to review than hundreds of pages of laboratory listings. It is difficult to observe overall trends in spaghetti plots with values for all subjects included. Note that this figure cannot be used when the number of subjects with abnormal values is large.