#### Overview

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 for 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<sup>®</sup> system software version 9.1 (or higher). Many of these figures could be utilized for clinical trials across therapeutic areas to facilitate DSMB review.



## **Cumulative Enrollment**

This enrollment figure accounts for varying enrollment rates at each site as well as the staggered activation of sites throughout the enrollment period. This gives a more accurate depiction of where the trial is in terms of meeting the enrollment goals and would help a reviewer identify high enrolling sites and sites that may be experiencing enrollment issues.



# Effective Graphical Data Displays to Facilitate Expedited DSMB Review of Clinical Trial Data

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This disposition summary figure allows DSMB members to quickly see the current disposition of subjects in the study compared to what is expected and what is needed to reach total target. This figure could be applied to other parameters such a visits, mechanistic samples, or other assessments to show compliance or progress.

## Subject Status



This figure gives an overall view of each subject's status in the trial. The colored lines can be used to depict various periods of a trial and symbols can be used to show important milestones or events of interest from various data streams.



e: Extreme values indicated by \*: 921.05 on Day 85 for ALT, 391.30 on Day 85 for GGT, 308.70 on Day 319 for GGT, 319.57 on Day 893 for GGT. Alkaline Phosphatase: Baseline value= 301 (U/L), Maximum observed post-baseline value = 425 (U/L). ALT: Baseline value= 38 (U/L), Maximum observed post-baseline value = 388 (U/L). GGT: Baseline value= 46 (U/L), Maximum observed post-baseline value = 226 (U/L).

This figure allows reviewers to see a complete picture of an individual subject in a trial. A reviewer can compare important lab results, dosing information, and events of interest to fully understand what was occurring at specific time points in the trial.



### **Summary of Laboratory Results**

OTE: Blue and green bars represent 25th percentile, median, and 75th percentile for Treatment Groups A and B respectively. Dotted lines display results from subjects with values outside their site's normal range. Bold dots signify values outside the site normal range.

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.



### Frequency of AEs by Preferred Term and Treatment Group

Note: Only preferred terms that are serious or have more than fifteen occurrences are included.

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.

#### Summary

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.

