

EFFECTIVE GRAPHICAL DATA DISPLAYS TO FACILITATE EXPEDITED DSMB REVIEW OF CLINICAL TRIAL DATA

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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, to show the timing of important clinical events in relation to study intervention, to allow for comparison of clinical data from various data streams, and to 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.

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