Monitoring Adverse Events using an Interactive Web-Based Tool

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More than 8,000 adverse events (AEs) have been reported in studies funded by the Immune Tolerance Network (ITN) – a large, NIH-funded, clinical research network. Frequent and careful monitoring of AEs is one of the most important responsibilities of clinical trial investigators, medical monitors and members of the DSMB. With data of this magnitude, innovative approaches are needed to monitor the data, both on a study- and participant-level, in order to safeguard participant safety.

Traditional reporting methods require combing through scores of static listings and summary tables. This method is inefficient and poses the risk that clinically-relevant signals will be obscured by the sheer volume of events.

We created an interactive, web-based AE Explorer tool to aid ITN medical monitors and DSMB members. Using responsive design elements common in website development (e.g., metadata, filterable results, nested displays, searchable fields), our AE Explorer allows them to interact with AE data in a dynamic manner.

The default Explorer view is a single-screen display of AEs grouped by the MedDRA System Organ Class. Dot plots portray the incidence in the different treatment groups. However, users can interact with the display in real time to: view confidence intervals for between-group differences, expand the dataset to show preferred terms, drill down to participant-specific data, search by term of interest, filter according to causality and severity, and select events based on a minimum incidence threshold (e.g., 5%).

In this presentation, we describe the salient features of this approach. In addition, we present a live demonstration of the Explorer using data from a recently completed ITN study. Our experience shows that using available web-based technology can dramatically improve the way AEs are reported and monitored in clinical trials.