

Data Visualization for Data Monitoring Committees for Clinical Trials

**Adam Hamm
PhUSE Connect
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Overview

- Background
- Overview of DMCs
 - Membership, roles, and responsibilities
- Communication of results to DMCs (Focus on Closed Sessions)
 - Tabular representations
 - Executive summaries (reports)
 - Current practices
- Alternative graphical presentations
 - Enrollment and disposition
 - Adverse events
 - Lab data
- References
- Questions/Discussion

Background

- **Clinical Trials Transformation Initiative**
 - **Provide recommendations for DMCs**
 - **Conduct**
 - **Communication practices**
 - **Member Preparation/Training**
 - **Link to information**

<https://www.ctti-clinicaltrials.org/projects/data-monitoring-committees-dmcs>

Overview of DMCs

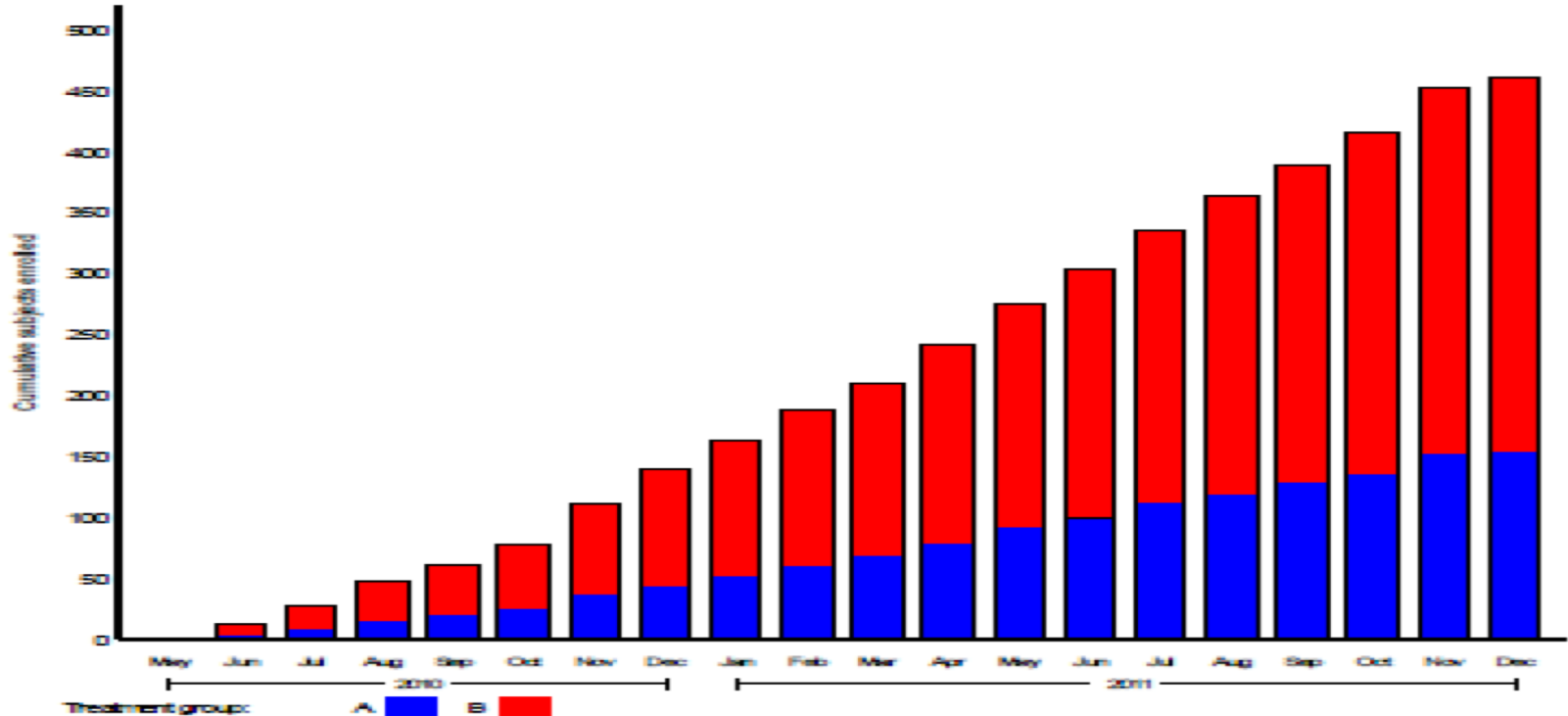
- **Membership and Roles**
 - **Clinical experts in the therapeutic area**
 - **Statisticians well versed in the therapeutic area and/or analyses being performed**
- **Responsibilities**
 - **Meet regularly to review safety data**
 - **Make sound decisions for the study based on unblinded results provided by an independent statistical center (ISC)**

Communication of Results

- **Unblinded results (Closed Session)**
- **Usually communicated by lead from ISC**
 - **Executive summary (report)**
 - **Tabular Summaries**
 - **Key listings of interest**
 - **Graphical summaries**

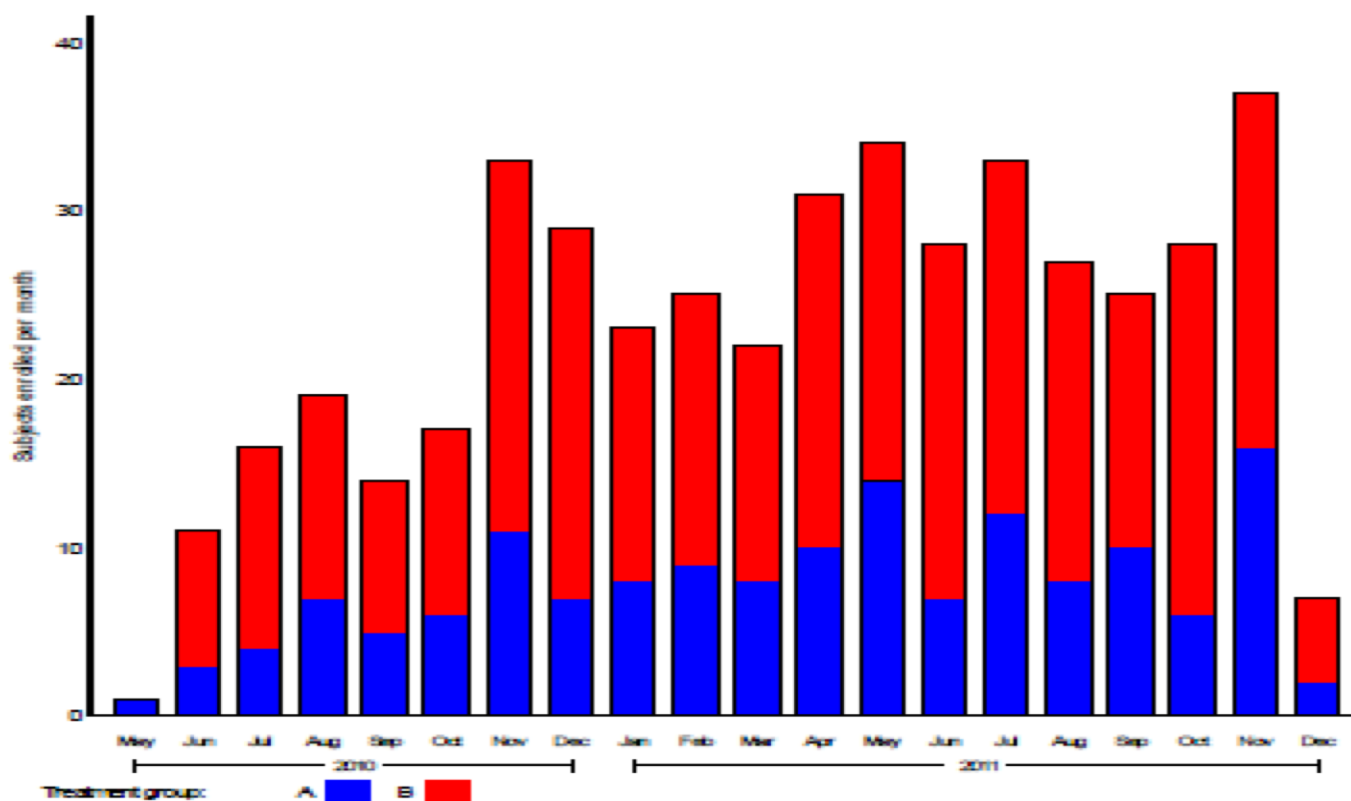
Data Visualization - Enrollment

- Cumulative enrollment by month and treatment group

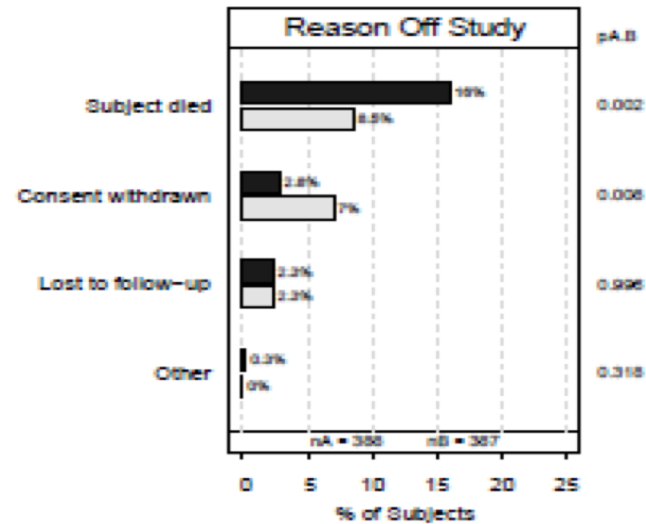
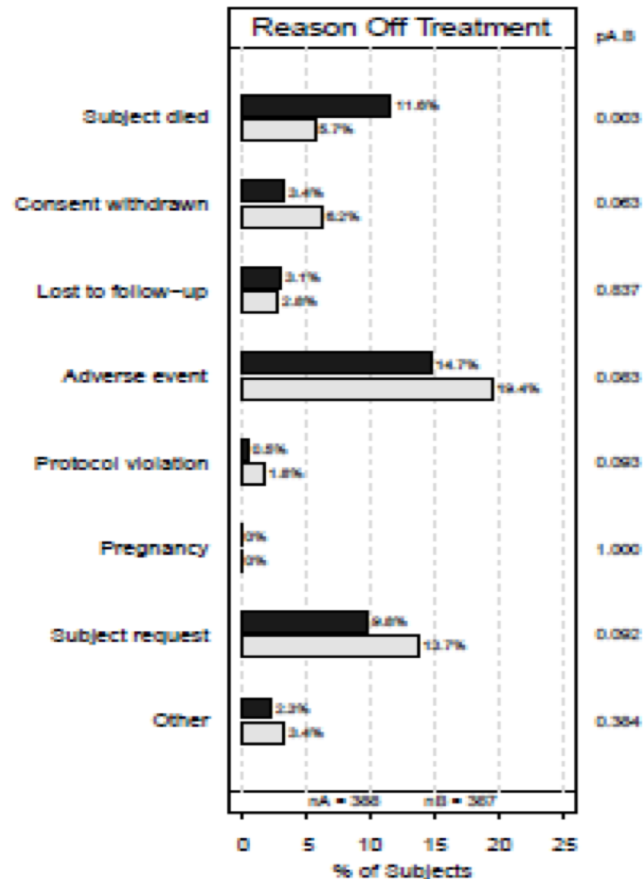


Data Visualization - Enrollment

- Enrollment by Month

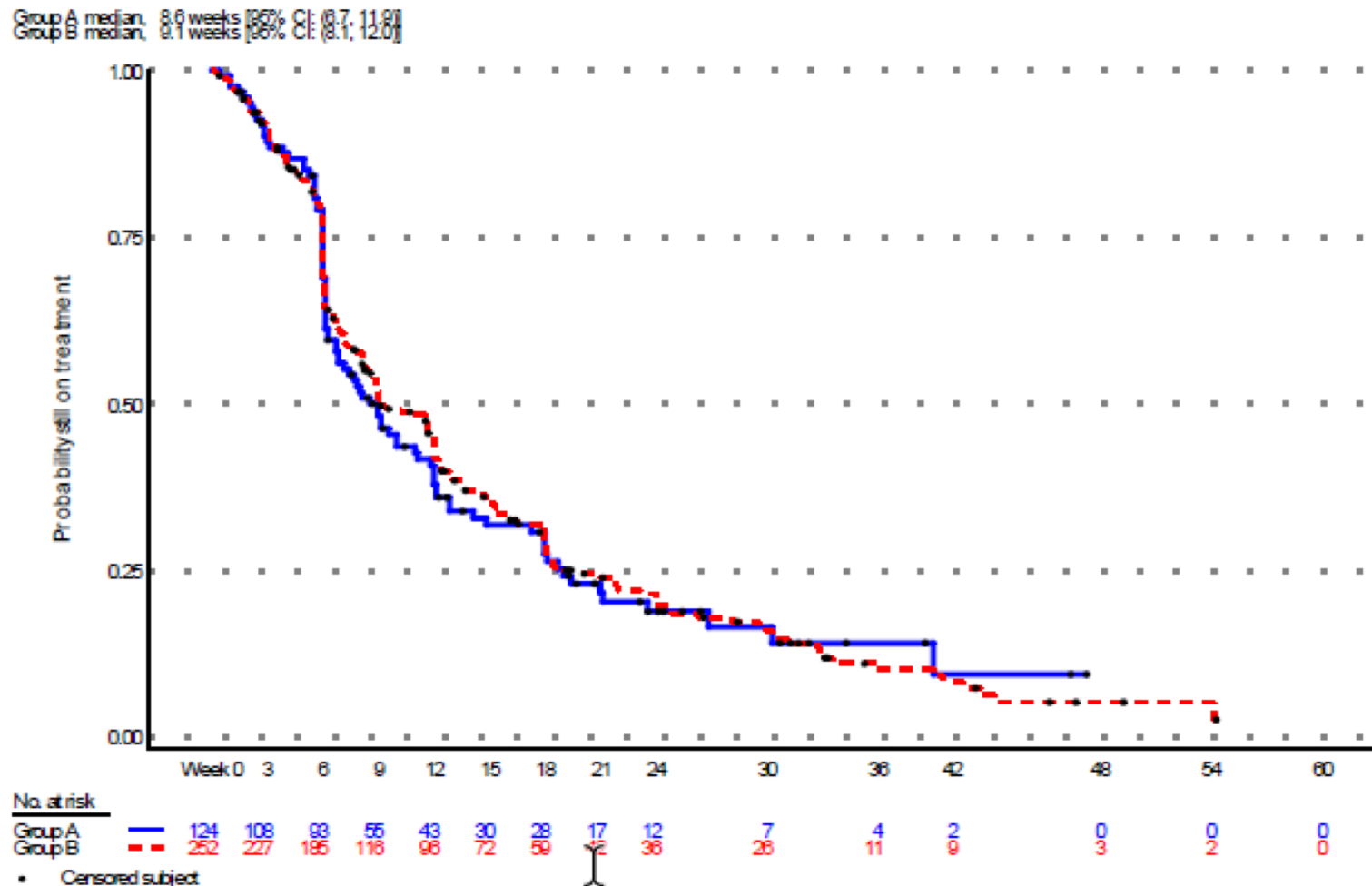


Data Visualization - Disposition



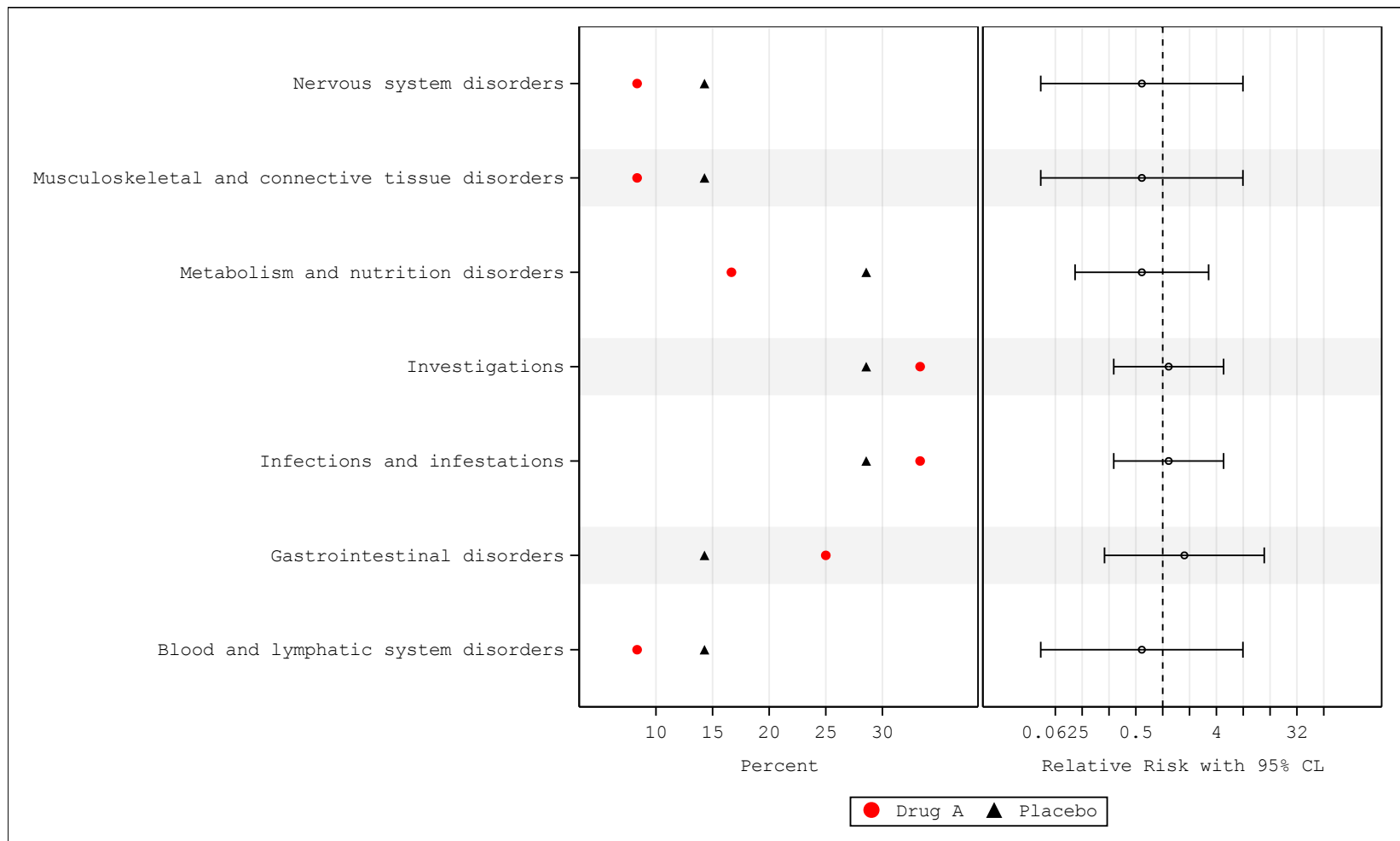
Data Visualization - Disposition

Time to Discontinuation from Study



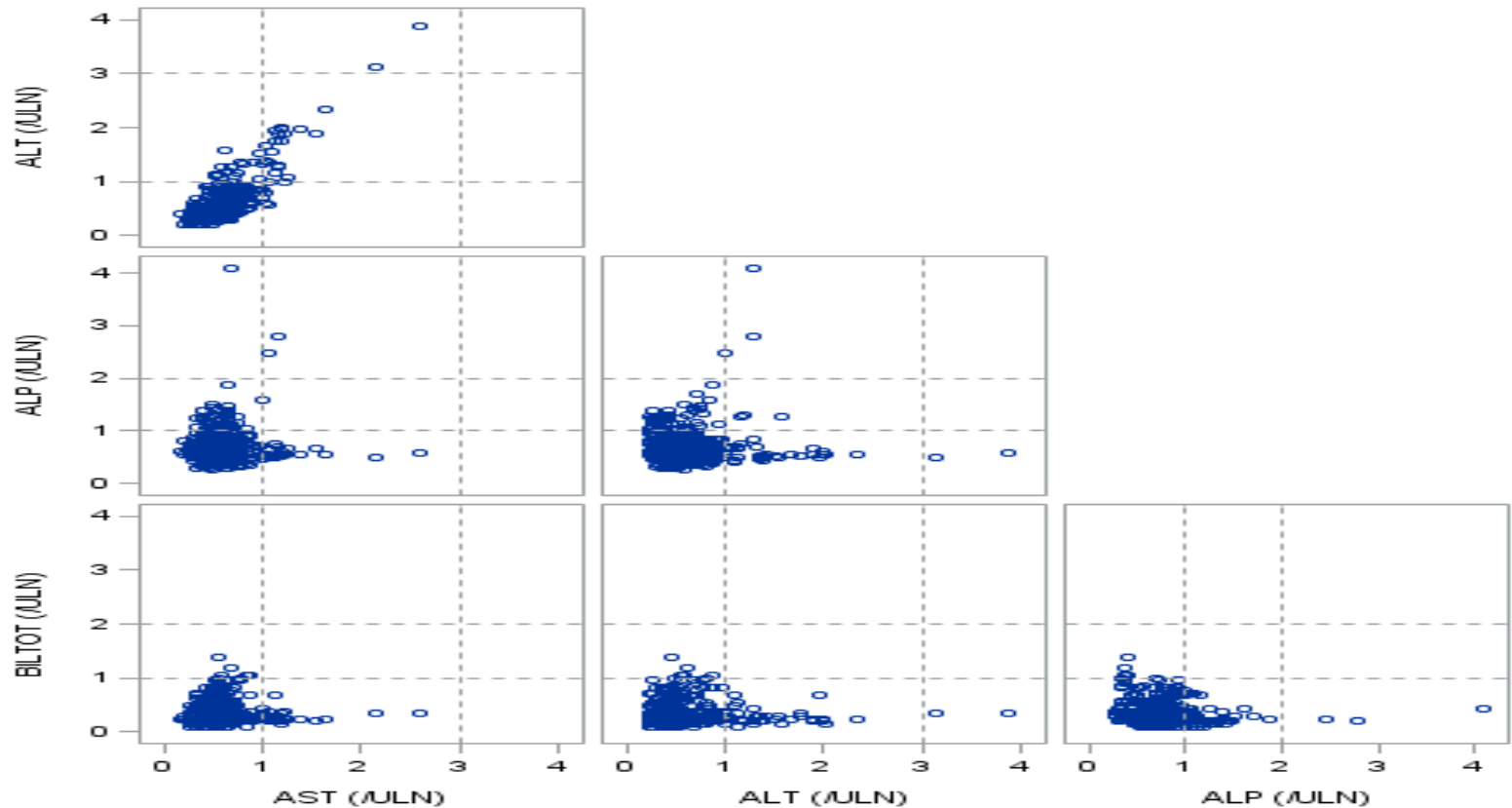
Data Visualization – Adverse Events

Incidence Rates for SOC AEs by Treatment Group and Summary Statistics for Relative Risk



Data Visualization – Laboratory Data

Liver Function Tests – Baseline Values vs. Worst Post-Treatment Value (Normalized)



Summary/Comments

- Visual representation is almost always more appealing to reviewers than bulky tables
 - Tabular summaries are fine to accompany informative plots
- Clinicians may be able to better understand statistics being presented graphically
- Are graphic summaries commonplace for DMC meetings?
 - Budget considerations
 - Consistency with final analyses

References

1. CALIS KA, ARCHDEACON P, BAIN R, DEMETS D, DONOHUE M, ELZARRAD MK, FORREST A, MCEACHERN J, PENCINA MJ, PERLMUTTER J, AND LEWIS RJ. "RECOMMENDATIONS FOR DATA MONITORING COMMITTEES FROM THE CLINICAL TRIALS TRANSFORMATION INITIATIVE". CLINICAL TRIALS. 2017: 14(4): 342-248.
2. MATANGE, SANJAY. "CLINICAL GRAPHS USING ODS GRAPHICS." *PROCEEDINGS OF THE 2010 WESTERN USERS OF SAS SOFTWARE CONFERENCE*.
3. AMIT O, HEIBERGER RM, AND LANE PW. "GRAPHICAL APPROACHES TO THE ANALYSIS OF SAFETY DATA FROM CLINICAL TRIALS."
4. SAMPLE CLOSED SESSION DM REPORT FROM UW-MADISON SDAC. [HTTPS://WWW.BIOSTAT.WISC.EDU/SITES/DEFAULT/FILES/SAMPLE_REPORT_CLOSED_20160920.PDF](https://www.biostat.wisc.edu/sites/default/files/sample_report_closed_20160920.pdf)

Questions?