ABSTRACT

Industry standards have evolved for data collection (CDASH), observed data (SDTM), and analysis datasets (AdAm). The next step is to develop standard tables and figures. The Development of Standard Scripts for Analysis and Programming Working Group is leading an effort to create several white papers providing recommended analyses and displays for common measurements, and has developed a Script Repository as a place to store shared code.

This poster will cover the recommended tables and figures associated with measures of central tendency (e.g., means and medians), as outlined in a final white paper titled "Analyses and Displays Associated with Central Tendency – Focus on Vital Sign, Electrocardiogram, and Laboratory Analyte Measurements in Phase 2-4 Clinical Trials and Integrated Submission Documents". This poster will also cover reasons for the recommendations and various alternatives that were considered. Developing shared code to create the displays in this white paper is planned for the Script Repository. Input for improving the analyses and displays will be welcome!

The Big Picture

Examples of Discussed Topics

- General Considerations
- Whether to report P-values and Confidence Intervals
- Handling of unplanned measurements
- Handling of measurements post drug exposure
- Laboratory Units and Transformations
- ECG Correction Factors

Recommended Tables and Figures

- Only has mean and SD - Lacks additional useful summary statistics
- Outliers not displayed
- Can be misleading when data are non-normal

Why Central Tendency?

For Labs, ECG and Vital Signs:

- The central tendency analysis generally compares mean or median changes from baseline across treatment groups, and the review should contain the results of these analyses for all laboratory measurements. Although marked outliers are typically of greatest interest from a safety standpoint, at times a potentially important effect may be revealed only in analyses looking at differences in mean change from baseline.

Our White Paper on Central Tendency

Provides the beginning of table and figure standardization
Provides guidance and foundation for the work in the Script Repository
Crowd-source a library of scripts/code
Feedback is welcome
Can be incorporated into a version 2.0

Appendix: Box Plot Interpretation

- Not ideal for central tendency – more suited for outliers and shifts
- Does not have summary statistics
- May be difficult to see treatment differences
- Only has mean and SD - Lacks additional useful summary statistics
- Outliers not displayed
- Can be misleading when data are non-normal