Introduction:

Industry standards have evolved over time for data collection (CDASH), observed data (SDTM), and analysis datasets (ADaM). There is now recognition that the next step would be to develop standard tables and figures for common measurements across clinical trials and across therapeutic areas. 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.

Last year we presented a poster on the first draft of the white paper titled "Analyses and Displays Associated with Outliers or Shifts from Normal to Abnormal – Focus on Vital Sign, Electrocardiogram, and Laboratory Analyte Measurements in Phase 2-4 Clinical Trials and Integrated Submission Documents". Since then, we have made a lot of improvements to this paper based on the all the great comments we received during the review process. This poster will provide an update on the improvements.

Since March, 2014, we have ...

- Received reviews across industry colleagues in various organizations
- Added more details and clarity on various discussion topics
- Improved the TFL display
- Separated the 3-panel display to 2 pages with graph in one page and summary table in second page
- Less crowded report
- Add Weighted (study size adjusted) percentage for integrated result

Examples of Discussed Topics

- General Considerations
  - Whether to report P-values and Confidence Intervals
  - Handle of
    - Measures collected in reflex manner, repeated measures, unplanned measures, measurements post drug exposure
    - Baseline definition Multi-phase Clinical Trials
    - Measurements After Stopping Study Medication
    - Measurements at a Discontinuation Visit
- Laboratory Analyte Measurements
  - Handling of central versus local laboratories
  - Choices of lab reference limits

Summary

- We are finalizing the version 1 of the white paper.
- Please continue providing us your review comments and recommendations.
- You can access the draft white paper in PhUSE wiki.