# Central Tendency White Paper Requirements Specification

## Scripts for Output defined in: Figure 7.1 Box Plot – Observed Values of xxx Over Time

### Script Specification

#### Specific Output Requirements

* Generates a box plot of AVAL by AVISITN and TRTPN. See domain variations in Usage Requirements, below
* Basic script functionality (user options)
* ***data display features***
* notched box plot as described in [SAS/STAT 9.2 User's Guide – Styles of Box Plots](http://support.sas.com/documentation/cdl/en/statug/63033/HTML/default/statug_boxplot_sect017.htm)
* analyze by treatment
* group boxes by time point, and label clearly
* outliers:
* **IQR outliers** as box outlines, and
* **reference range outliers** as red dots
* reference ranges - options to draw reference lines for various scenarios (based on values found in data)
* **uniform:** If all reference range values are uniform for a set of measures, draw those uniform low/high reference range line.
* **narrow:** If reference range values are NOT uniform for a set of measures, draw the only the *narrow* reference range lines (highest of the lows, lowest of the highs)
* **all:** Discouraged by white paper authors – draw all reference lines relevant to the set of measures.
* **none**
* **numeric value(s):** draw exactly these specific reference lines (e.g., a zero (0) line for change from baseline boxplots.
* ***User variability***
* location and name of each input data sets
* output location (user-specified path)
* parameterize core variables required for analysis & display:
* AVAL (measured outcome)
* ANRLO (lower limit of reference range)
* ANRHI (upper limit of reference range)
* SAFFL (population flag)
* ANL01FL (analysis flag)
* ***basic readability features***
* maximum number of boxes to display on a page (basic paging control)
* on/off jitter option (to reduce overlap of reference range outliers)
* Restrictions
* Footnote:
* Box plot type is schematic: the box shows median and interquartile range (IQR, the box edges); the whiskers extend to the minimum and maximum data points within 1.5 IQR below 25% and above 75%, respectively. Values outside the whiskers are shown as outliers. Means are marked with a different symbol for each treatment. Red dots indicate measures outside the normal reference range.

#### General Output and Formatting Requirements

NOTE: These might or might not apply to the specific output or feature of the script.

***[DDT] Suggestion:***

* **Move all general requirements to a "CSS Standard Analyses General Output and Formatting Requirements" document.** [**This looks like a good starting point.**](http://www.phusewiki.org/wiki/index.php?title=Scriptathon_targets_as_of_January_4_2015)
* **Move all "Central Tendency" requirements to a "Output and Formatting Requirements" section of the CT white paper**
* **Keep only target-specific requirements in this document**
* *Move to new Project 8 doc at same level as the white papers:* ***"CSS Standard Analyses General Output and Formatting Requirements"***
* The page margins used in this document mirror the margins required for US regulatory submissions. TFL fits within 9.25” x 6” common text area.
* This document contains generic titles and footnotes to aid review.
* Titles must be centered.
* Footnotes must be left justified
* Placeholders for the program, output, date generated, and source data footnotes do not need to be displayed for each shell but will be produced for each TFL consistent with the standard macro output.
* P-values should follow the formats below (these guidelines align with medical journal requirements):
* For p > 0.1, report the p-value to 2 decimal places
* For 0.1 > p > 0.001, report the p-value to 3 decimal places
* For p < 0.001, report p < 0.001.
* Decimal places for continuous data summaries should follow these guidelines:
* mean and estimates of precision (e.g., variance, SD, SE, Confidence Intervals) have 1 more decimal place than the collected data
* distributional parameters (eg, Q1, Q3) also have 1 more decimal place than the collected data
* present Minimum and Maximum to the same decimal places as collected
* percentages have at least one decimal place
* All tables summarizing baseline data must include a “total” column for studies with more than 1 arm.

### Usage Requirements

#### Required Input

* Dataset-1: ADSL
* Variables: STUDYID, USUBJID, SAFFL, TRT01P, TRT01PN

##### Vital Signs Domain

* Dataset-2: ADVS
* Variables: STUDYID, USUBJID, SAFFL, ANL01FL, TRTP, TRTPN, PARAM, PARAMCD, AVAL, ANRLO, ANRHI, AVISIT, AVISITN, ATPT, ATPTN
* Record selection: SAFFL='Y' and ANL01FL='Y'

##### Laboratory Domain

* Dataset-2: ADLBC or ADLBH or ADLBHY?
* Variables: STUDYID, USUBJID, SAFFL, ANL01FL, TRTP, TRTPN, PARAM, PARAMCD, AVAL, A1LO, A1HI, AVISIT, AVISITN~~, ATPT, ATPTN~~
* Record selection: SAFFL='Y' and ANL01FL='Y'

##### ECG Domain

* Dataset-2: ???
* Variables: ???
* Record selection: ???

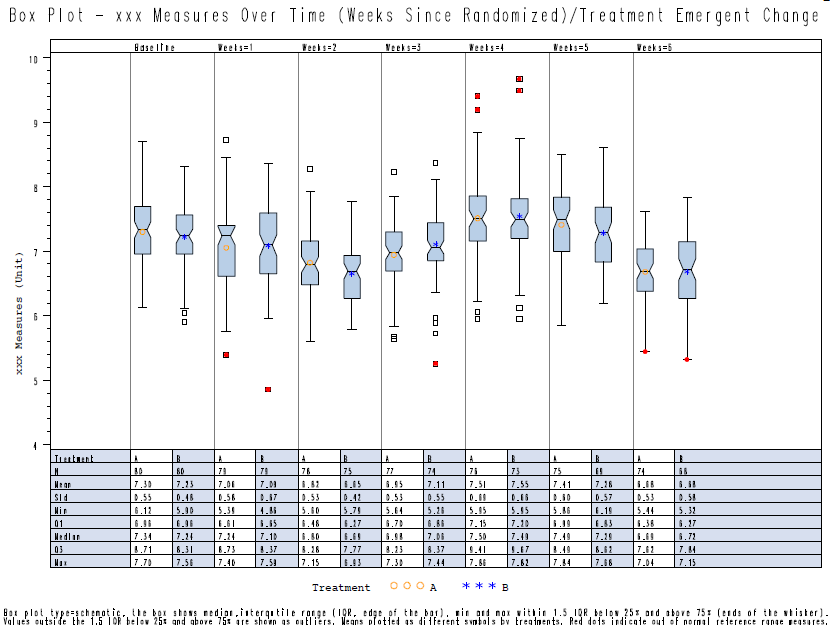
#### Macros

* Requires the PhUSE/CSS macro library:   
   <https://github.com/phuse-org/phuse-scripts/tree/master/whitepapers/utilities>
* User must ensure that SAS can find PhUSE/CSS macros in the SASAUTOS path

### Test Data

* Data sets from <https://github.com/phuse-org/phuse-scripts/tree/master/scriptathon2014/data>
* ADSL – Subject-level data
* Domain data
  + Vital Signs Domain
  + ADVS – Vital signs
  + ADLBC, ADLBH, ADLBHY – Laboratory measures
  + ??? – ECG measures

### Sample Output



### Reference Documents:

White paper: <http://www.phusewiki.org/wiki/images/4/48/CSS_WhitePaper_CentralTendency_v1.0.pdf>

Programming Guidelines: <http://www.phusewiki.org/wiki/index.php?title=WG5_P02_Programming_Guidelines>