# Central Tendency White Paper Requirements Specification

## Scripts for Figure 7.2 Box Plot – Change in 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***
* Schematic or Tukey notched box plots, as described in [SAS/STAT 9.4 Graph Template Language: Reference (Boxplot Statement)](http://support.sas.com/documentation/cdl/en/grstatgraph/67882/HTML/default/p0vuh82v39fsasn1vqhzmhdl8y16.htm#n0g9wrnpg9zsryn1dk5csdrdfnqy)
* analyze by treatment
* group the boxes by time point, and label each time point clearly
* outliers:
* **IQR outliers** as box outlines, and
* Zero reference line
* ***methodology***
* Change-from-baseline to Endpoint includes all subjects with both a baseline and post-baseline measurement
* P-value comparing Active Treatment with Comparator, using ANCOVA containing terms for treatment and the continuous covariate of baseline measurement
* ***User variability***
* library and name of each input data sets
* output location (user-specified path)
* option to suppress the p-value for Endpoint treatment comparison
* parameterize core variables required for analysis & display:
* "Treatment name" which could be planned or actual
* "Treatment number" used for display order of Treatment Names
* CHG variable (change-from-baseline outcome)
* "Baseline" visit number for ANOVA comparison & p-value (e.g., an AVISITN value)
* "Endpoint" visit number for ANOVA comparison & p-value (e.g., an AVISITN value)
* SAFFL variable (population flag)
* ANL01FL variable (analysis flag)
* ANCOVA p-value option: Leave these value blank to omit Endpoint ANCOVA p-values
* "Baseline" measurement variable , such as BASE
* "Reference" treatment number, such as a TRTPN value like zero (0)
* ***basic readability features***
* maximum number of boxes to display on a page (basic paging control)
* Restrictions
* Footnote:
* Box plot type is schematic: the box shows median and interquartile range (IQR, the box height); the whiskers extend to the minimum and maximum data points within 1.5 IQR of the lower and upper quartiles, respectively. Values outside the whiskers are shown as outliers. Means are marked with a different symbol for each treatment. P-value is for the treatment comparison from ANCOVA model Change = Baseline + Treatment.

#### General Output and Formatting Requirements

See the specification document **CS\_GeneralOutputandFormattingRequirements.docx**.

### Usage Requirements

#### Required Input

##### Vital Signs Domain

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

##### Laboratory Domain

* Dataset: 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: ???
* Variables: ???
* Record selection: ???

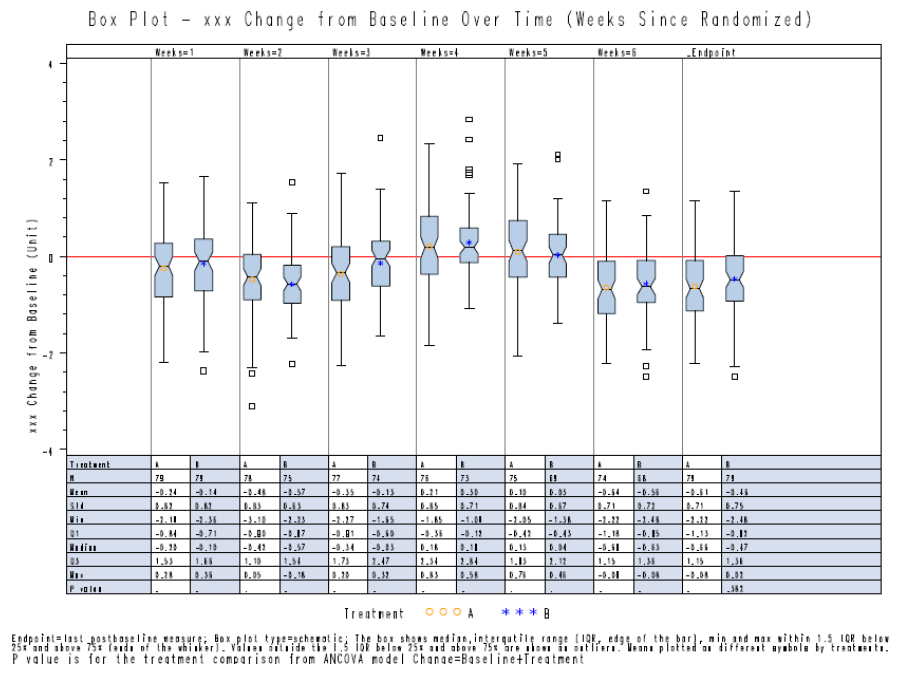
#### Macros

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

### Test Data

* Data sets from <https://github.com/phuse-org/phuse-scripts/tree/master/data/adam/cdisc>
* 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>