# Central Tendency White Paper Requirements Specification

## Scripts for Figure 7.3 Box Plot – Observed Values and Change in xxx Over Time

Figure 7.3 combines Figures 7.1 and 7.2 onto a single page, side-by -side. The processing and analyses are the same, the layout is compressed to a single page.

The plot is intended to describe a baseline measurement with a single post-baseline measurement.

### 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)
* ***See Fig. 7.1 specifications for the left-hand plot (Observed values)***
* ***See Fig. 7.2 specifications for the right-hand plot (Change from baseline)***
* ***Changes to Fig. 7.1 and 7.2 specifications:***
* **Default setting** for reference ranges is **NARROW** rather than UNIFORM
* ***Additions to Fig. 7.1 and 7.2 specifications:***
* 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. Red dots indicate measures outside the normal reference range. *[ Red lines indicate any upper and low limits of normal range, and only the most conservative values if they differ by gender, age, etc..]* P-value is for the treatment comparison from ANCOVA model Change = Baseline + Treatment.
* The statement about *Red lines ... limits of normal range* should only appear if one or more lines does appear on the left-hand (absolute value) plot.

#### 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, AVAL, 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: ???

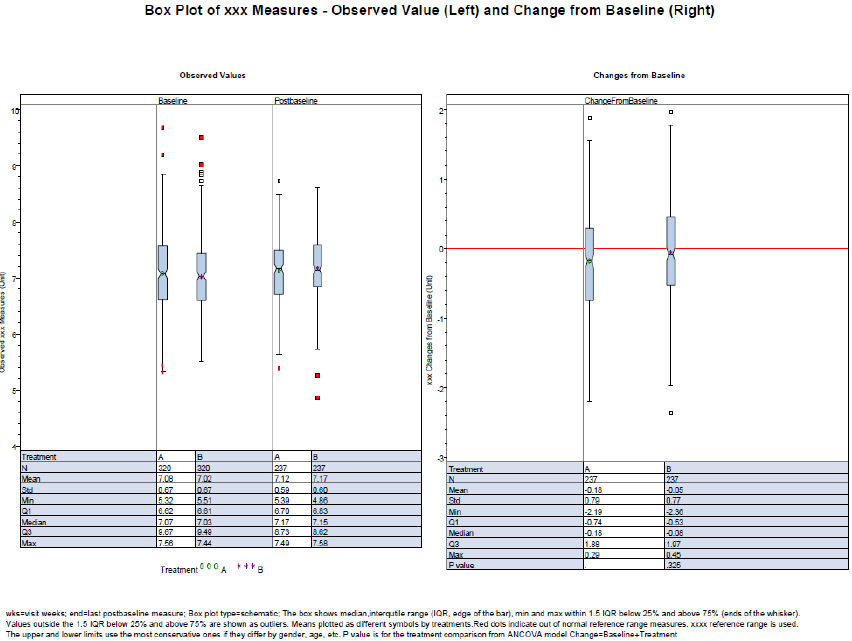
#### Macros

* 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>