

PP18 Update to Recommended Analyses and Displays for Laboratory Data

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ABSTRACT

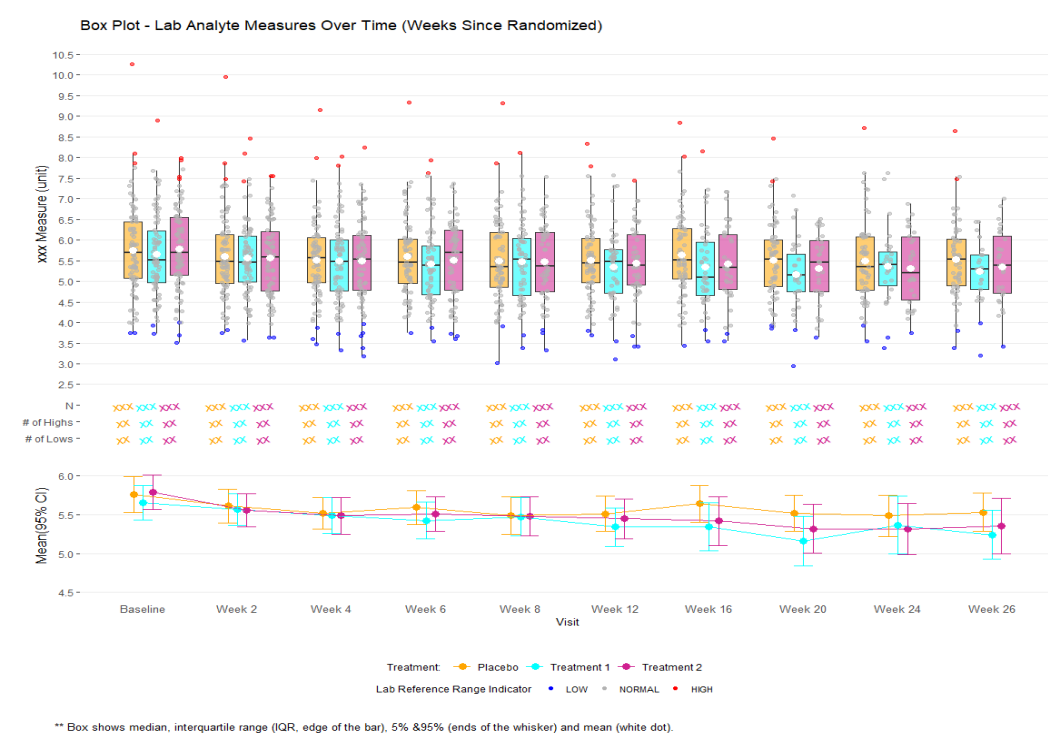
The PHUSE “Analysis and Display White Papers” project team developed recommendations for analyses of numerical safety data (vital signs, ECGs, laboratory data) with suggested tables, figures, and listings for the display of these analyses. The recommendations were provided in a 2013 white paper (central tendency) and a 2015 white paper (outliers/shifts).

The PHUSE “Analyses and Displays for Laboratory Data” project team has gathered shared learning and is providing an update to the recommendations for only laboratory data. The new PHUSE white paper covers both central tendency and outliers/shifts and, consistent with the 2013 and 2015 white papers, covers recommendations for individual studies and for integrated safety summaries. The poster presents the recommendations incorporated in this new PHUSE white paper. Recommendations are for screening all analytes. Screening can reveal analytes requiring additional analyses. Recommendations are for screening all analytes. Recommendations for additional analyses are planned for a future deliverable.

Individual Studies

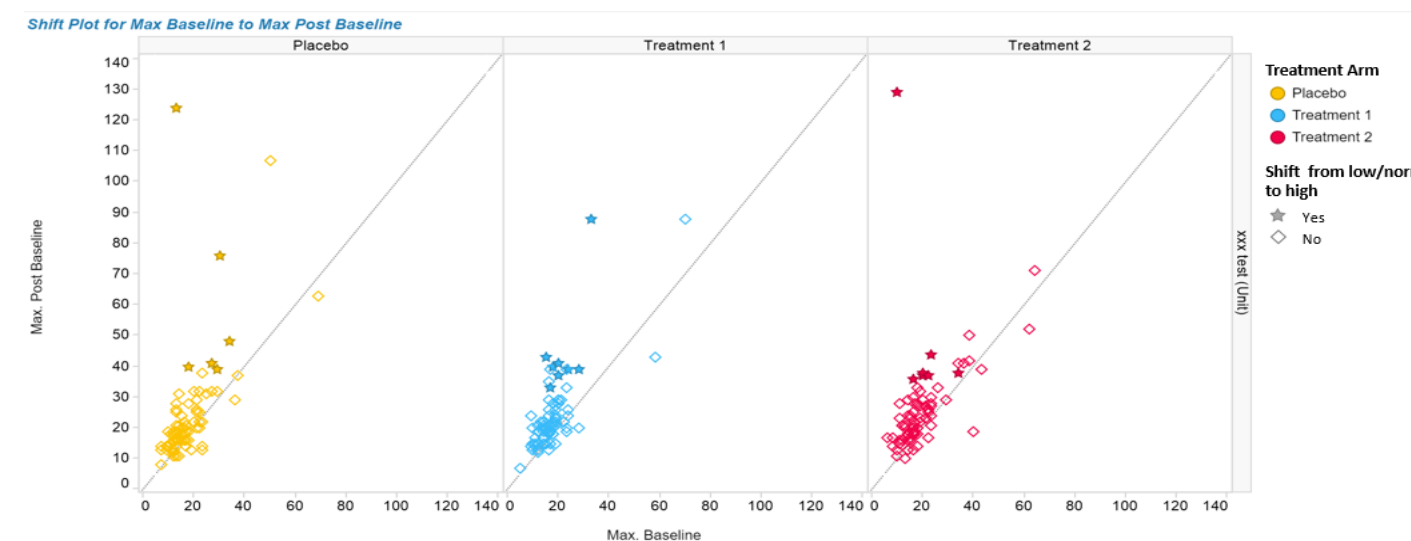
- Boxplot of Observed Values Over Time
- Boxplot of Changes from Baseline Over Time

Boxplot whiskers = 5th and 95th percentile, different than the typical default



- Scatterplot of Maximum Baseline versus Maximum Postbaseline
- Scatterplot of Minimum Baseline versus Minimum Postbaseline
- Shift to High/Low

Side-by-side scatterplots easier to read than a single scatterplot
For tables, group similar labs (metabolic labs shown as an example)



Metabolic labs:

Lab Analyte	Baseline	Post Baseline	T1 n, N (%)	T2 n, N (%)	PL n, N (%)	T1 & T2 n, N (%)	Comparison Metric ^a T1-PL (95% CI)	Comparison Metric ^a T2-PL (95% CI)	Comparison Metric ^a T1&T2-PL (95% CI)
Cholesterol	Low/Norm	High	xx, xxx (xx.x)	xx, xxx (xx.x)	xx,xxx (xx.x)	xx, xxx (xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	High/Norm	Low	xx, xxx (xx.x)	xx, xxx (xx.x)	xx,xxx (xx.x)	xx, xxx (xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
LDL	Low/Norm	High	xx, xxx (xx.x)	xx, xxx (xx.x)	xx, xxx (xx.x)	xx, xxx (xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

Renal labs:

Integrated Summaries

- Summary of Min, Max and Last Measures at Baseline and Post Baseline and the Changes
- Shift to High/Low

Metabolic labs:		PBO n, N (%)	TRT n, N (%)	PL n, N (%)
Lab Analyte		Mean (SD)	Mean (SD)	Mean Difference (95% CI)
Cholesterol (mmol/dl)	Max Baseline	xxx.x (xx.x)	xxx.x (xx.x)	
	Max Post Baseline	xxx.x (xx.x)	xxx.x (xx.x)	
	Change	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x, xxx.x)
	Min Baseline	xxx.x (xx.x)	xxx.x (xx.x)	
	Min Post Baseline	xxx.x (xx.x)	xxx.x (xx.x)	
	Change	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x, xxx.x)
	Last Baseline	xxx.x (xx.x)	xxx.x (xx.x)	
	Last Post Baseline	xxx.x (xx.x)	xxx.x (xx.x)	
	Change	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x, xxx.x)
LDL (mmol/dl)	Max Baseline	xxx.x (xx.x)	xxx.x (xx.x)	
	Max Post Baseline	xxx.x (xx.x)	xxx.x (xx.x)	
	Change	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x, xxx.x)
	Min Baseline	xxx.x (xx.x)	xxx.x (xx.x)	
	Min Post Baseline	xxx.x (xx.x)	xxx.x (xx.x)	
	Change	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x, xxx.x)

Metabolic labs:

Lab Analyte	Baseline	Post Baseline	TRT n, N (%)	PL n, N (%)	Comparison Metric ^a TRT-PL (95% CI)
Cholesterol	Low/Norm	High	xx, xxx (xx.x) [xx.x]	xx, xxx (xx.x) [xx.x]	xx.x (xx.x, xxx.x)
	High/Norm	Low	xx, xxx (xx.x) [xx.x]	xx, xxx (xx.x) [xx.x]	xx.x (xx.x, xxx.x)
LDL	Low/Norm	High	xx, xxx (xx.x) [xx.x]	xx, xxx (xx.x) [xx.x]	xx.x (xx.x, xxx.x)

Renal labs: