PP06 Analyses and Displays for Elevated or Low Laboratory Measurements

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Background

The Analyses and Displays for Laboratory Data project team from the PHUSE Safety Analytics Working Group has developed a set of analyses and displays for elevated or low laboratory measurement data meeting specific levels. These analyses and displays were developed to

1) inform the CDISC ADaM sub-team to provide recommendations on how ADaM can be structured to facilitate implementation of lab-related analyses and displays
2) inform sponsors as they build their standards library of lab-related data.

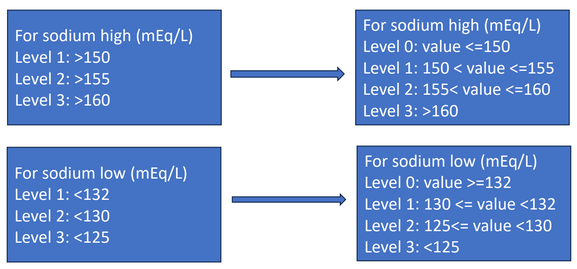
These analyses and displays focus on phase 2-4 clinical trials and integrated summary documents,

- Includes the September 2022 FDA standard safety tables plus expected additional tables and figures.

Notes and Recommendations

Applicable when multiple levels of elevated and low are used. Recommend to define to have mutually exclusive groups. Examples include

- Levels informed by Tables 59 and 60 from FDA's September 2022 FDA standard safety tables and figures document. Redefine to have mutually exclusive groups:



- Levels informed by CTCAE grade definitions (referred to as "Grades" instead of "Levels")
- Levels informed by the 2007 FDA guidance titled "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials" (referred to as "Grades" instead of "Levels")

Tables and Figures

- Displays show examples with 2 dose levels, low dose and high dose, and a placebo arm, and can be modified as needed.
- The displays show examples in which categories are defined using 3 levels, and can be modified as needed
- The displays are shown as static displays, and can be modified as needed if included in an interactive display/package

Main Display

Participants with elevated or low values meeting specified levels

	PBO (N=xxx) NAR n (%)	TRT Low Dose (N=xxx) NAR n (%)	TRT High Dose (N=xxx) NAR n (%)	TRT Low Dose vs PBO Risk Difference (95% CI)	TRT Low Dose vs PBO Risk Difference (95% CI)	TRT Low Dose vs PBO Risk Difference (95% CI)
[Analyte 1], low	xxx	xxx	xxx			
Level >=1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
Level >=2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
Level 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
[Analyte 1], high	xxx	xxx	xxx			
Level >=1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
Level >=2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
Level 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)

Abbreviations:
n = number of participants in the specified category; NAR=number of participants at risk;
N = number of participants in the analysis population in the specified treatment group
Percentages are calculated with NAR as the denominator

Likely Display

Shift Matrix of Maxiumum Baseline versus Maximum Postbaseline by Treatment

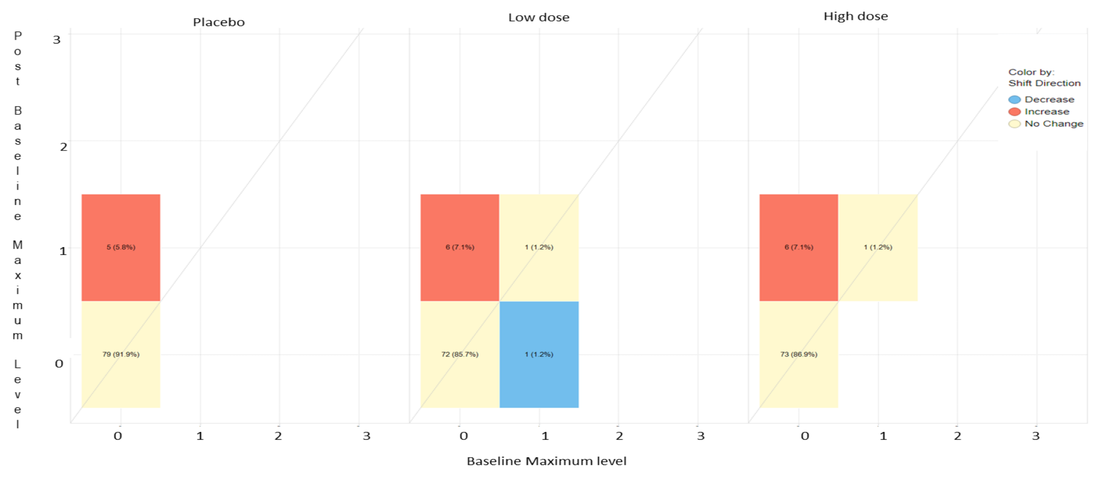
[Analyte 1]

Treatment	Maximum Baseline	Maximum Postbaseline: Missing n (%)	Level 0 n (%)	Level 1 n (%)	Level 2 n (%)	Level 3 n (%)	Any level n (%)	Total n (%)
PBO (N=xxx)	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Any level	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TRT Low Dose (N=xxx)	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Any level	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TRT High Dose (N=xxx)	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Level 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Any level	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

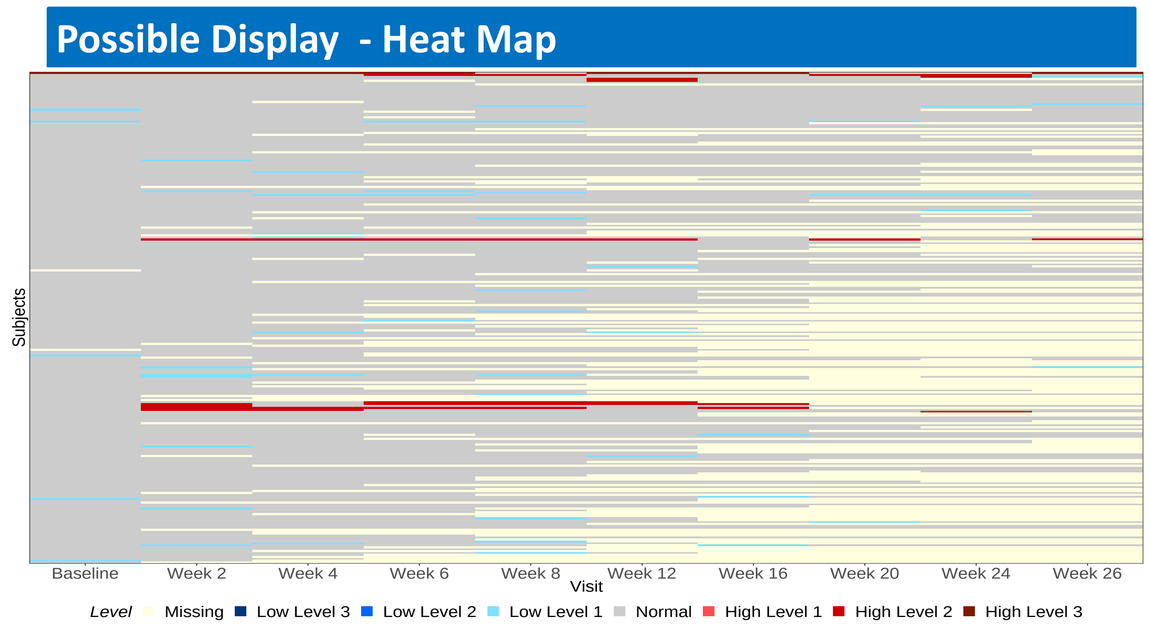
Abbreviations:
n = number of participants in the specified category;
N = number of participants in the analysis population in the specified treatment group;
Percentages in the total rows and total columns are based on the total number of participants; otherwise, percentages are based on row totals.

Similar table can be generated for minimum values

Lab Level Shift Plot



Possible Display - Heat Map



For more information or join PHUSE Safety Analytics Working Group? Scan the QR code!