



ICON Clinical Research

Graphs VS Reports - A Comparison Study

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The views expressed in this presentation are the views of the author and does not reflect the views or opinion of ICON Clinical Research.

- Usage of graphs and tabular data
- Comparison of graphical representation of data with tabular form of reports
- Importance of graphs
- Pros and cons of using tables and graphs



Agenda

- Why visualization is more important?
- Why graphs are used in general in any industry?
- Why Graphs are important in clinical trial data?
- Different kinds of graphs widely used in Clinical
- Common techniques used in the SAS
- Comparison of Graph vs. Report used in the clinical trial
- Pros & Cons
- Conclusion



Why visualization is more important than just presenting the data?

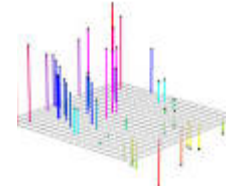
- Because of the way the human brain processes information
- Visualizations help people see things that were not obvious to them before such as patterns or trends of the data
- Visualizations convey information in a universal manner and make it simple, easy and quick to make decision
- Easy to compare many results



Universal

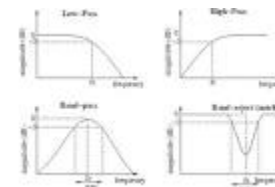
Why graphs are used in general in any industry?

- Visualize million of data points and compare their results
- Easier for decision makers across all organizations
- Identify areas that need attention or improvement
- Understand what factors influence our results
- Understand the pattern or trends of data
- Understand relationship and correlation of data points
- Easy to identify the outlier data points and maximize the ability to detect unusual features



Why Graphs are important in clinical trial data?

- Statistical graphics play an important role across various stages in clinical research
- Illustrate changes over time
- Illustrate differences in magnitude of response, particularly where more than two treatment groups are being compared
- Complex data analysis in graphical format for better representation



Different kinds of graphs widely used in Clinical trials

BAR GRAPH

DOT PLOT

MEAN PLOT

HISTOGRAMS

SCATTER PLOT

**CUMULATIVE
DISTRIBUTION**

**BUTTERFLY
PLOT**

BOX PLOT

SERIES PLOT

TRELLIS PLOT

FOREST PLOT

LINE PLOT

**SURVIVAL
CURVE**

**WATERFALL
PLOT**

**KAPLAN MEIER
PLOT**

Before
SAS 9.2

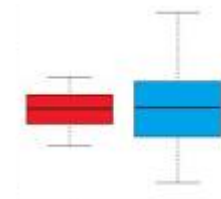
GPLOT,
LIFETEST,
GCHART,
GREPLAY,
GSLIDE etc.

SAS 9.2
Onwards

SGPLOT,
SGPANEL,
SGSCATTER,
SGRENDER,
SGDESIGN

- Generation of interactive graphs in SAS with help of JAVA scripts
- Graph annotation method to customize complex graph requirements

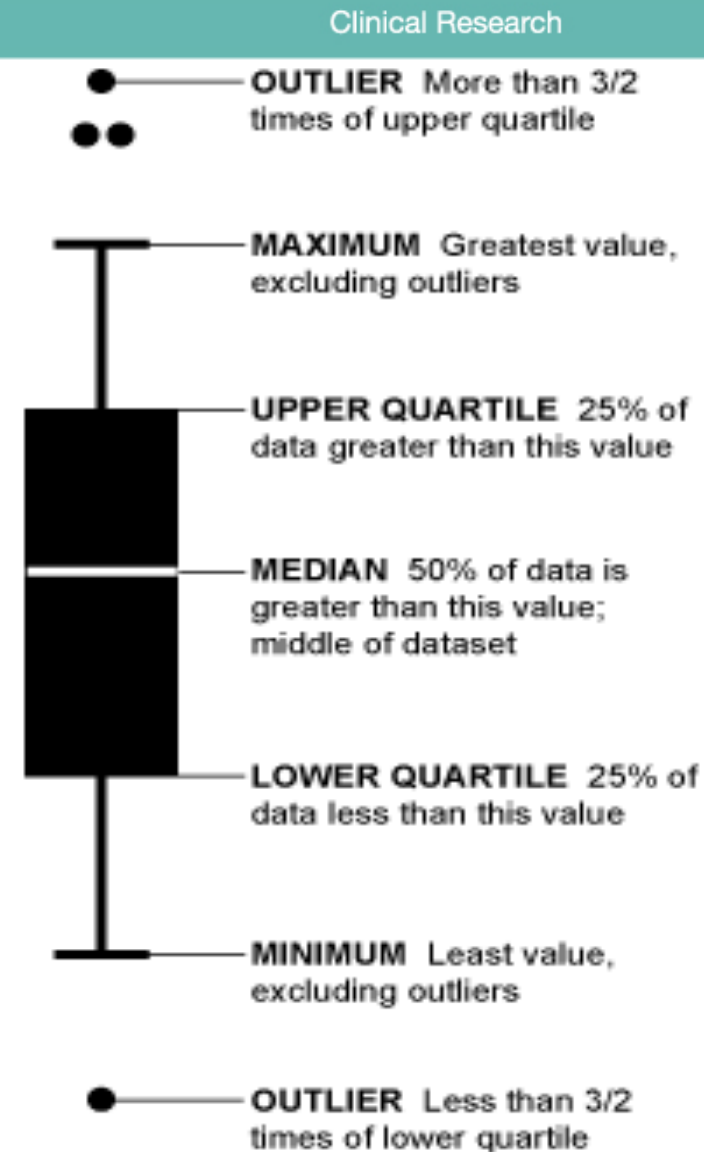
Comparison of Graph with Reports



Example Study Design

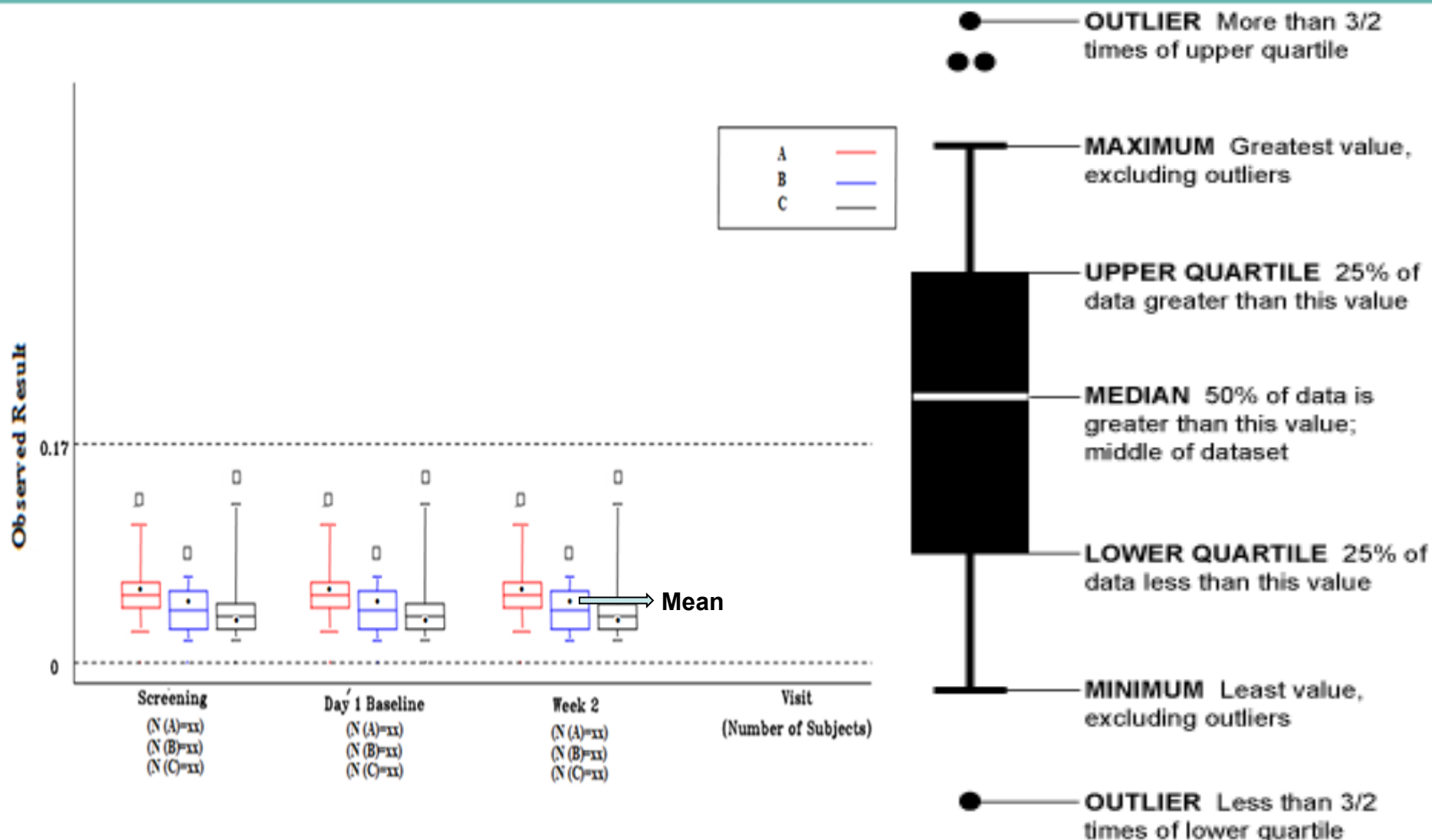
Box plots reveal the main features of a batch of data, i.e. how the data are spread out. A box plot displays summary statistics for the distribution of values for a variable.

- Importance of box plot as well as tabular data
- Pros and cons of using them



Box Plot

Clinical Research



- A rectangular box representing middle half of all scores (between Q1 and Q3)
 - Any boxplot is a graph of the five-number summary:
 - MINIMUM
 - 1ST QUARTILE
 - MEDIAN
 - 3RD QUARTILE
 - MAXIMUM
- with suspected outliers plotted individually
- Lines called whiskers extend from the box out to the minimum and maximum scores that are not possible outliers

Comparison of Graph vs. Report

Clinical Research

Lab Parameter (SI unit) Study Visit (a)	10 mg BID (N=251)		Placebo (N=67)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Neutrophils/Leukocytes (%)				
Baseline Value				
n	250		67	
Mean	67.39		67.59	
Median	67.30		68.60	
SD	11.653		13.496	
Q1	60.60		59.10	
Q3	75.50		75.50	
Min	37.4		33.3	
Max	96.0		94.0	
Visit 3 / Week 2				
n	227	227	64	64
Mean	68.01	0.70	66.05	-1.05
BL Mean	67.31		67.10	
Median	68.80	0.70	66.80	1.00
SD	12.752	10.881	13.705	12.598
Q1	59.80	-5.20	55.65	-9.20
Q3	77.60	7.10	74.55	7.00
Min	34.6	-34.7	31.9	-30.7
Max	93.5	40.6	91.7	37.0
Visit 4 / Week 4				
n	228	228	60	60
Mean	66.36	-0.90	64.09	-3.68
BL Mean	67.25		67.77	
Median	67.50	-1.30	64.90	-2.15
SD	12.439	11.535	14.048	14.662
Q1	57.50	-7.55	53.10	-15.05
Q3	75.80	5.80	75.55	8.05
Min	29.7	-44.5	35.4	-50.2
Max	93.2	38.3	92.4	27.7

Note: BL Mean is the baseline mean for subjects with nonmissing results at the specified visit. Unscheduled assessments are not included in table reporting.

(a) The baseline value is defined as the last observation prior to or on the date of the first dose of study drug.

Comparison of Graph vs. Report

Clinical Research

Lab Parameter (SI unit) Study Visit (a)	10 mg BID (N=251)		Placebo (N=67)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Visit 5 / Week 8 / ET				
n	219	219	57	57
Mean	67.95	0.89	66.43	-1.42
BL Mean	67.06		67.85	
Median	68.50	2.30	64.30	-2.60
SD	10.966	12.537	11.638	13.352
Q1	60.40	-6.70	59.60	-7.60
Q3	75.70	9.40	73.40	8.30
Min	33.7	-43.1	37.1	-37.8
Max	92.5	48.8	93.8	26.7
Visit 7 / Week 13 / Follow-up / EOS				
n	13	13	3	3
Mean	67.33	-5.30	75.87	5.97
BL Mean	72.63		69.90	
Median	68.80	-0.90	72.50	1.40
SD	13.159	10.412	15.919	15.464
Q1	54.40	-10.70	61.90	-6.70
Q3	76.20	1.30	93.20	23.20
Min	46.8	-29.2	61.9	-6.7
Max	86.7	5.1	93.2	23.2

Note: BL Mean is the baseline mean for subjects with nonmissing results at the specified visit. Unscheduled assessments are not included in table reporting.

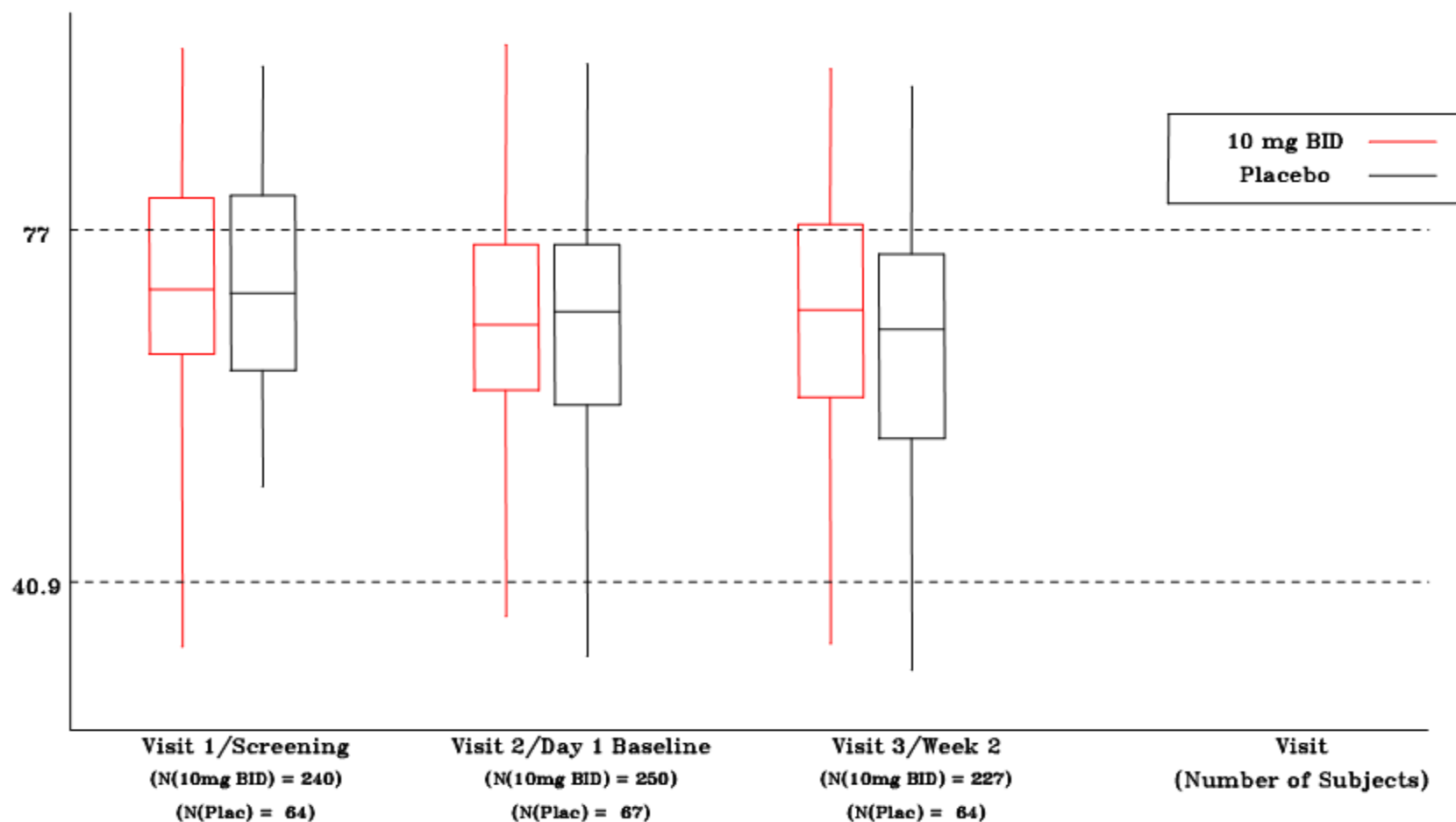
(a) The baseline value is defined as the last observation prior to or on the date of the first dose of study drug.

Example code to generate the BOX PLOT for PH value in Lab data

```
proc boxplot data = adlb ;  
    plot Aval * Visitnum=trt01an / vaxis = axis2  
    cboxfill=white cboxes=black  
    haxis = axis1  
    boxstyle = schematic noframe nohlabel symbollegend = legend1;  
run;
```

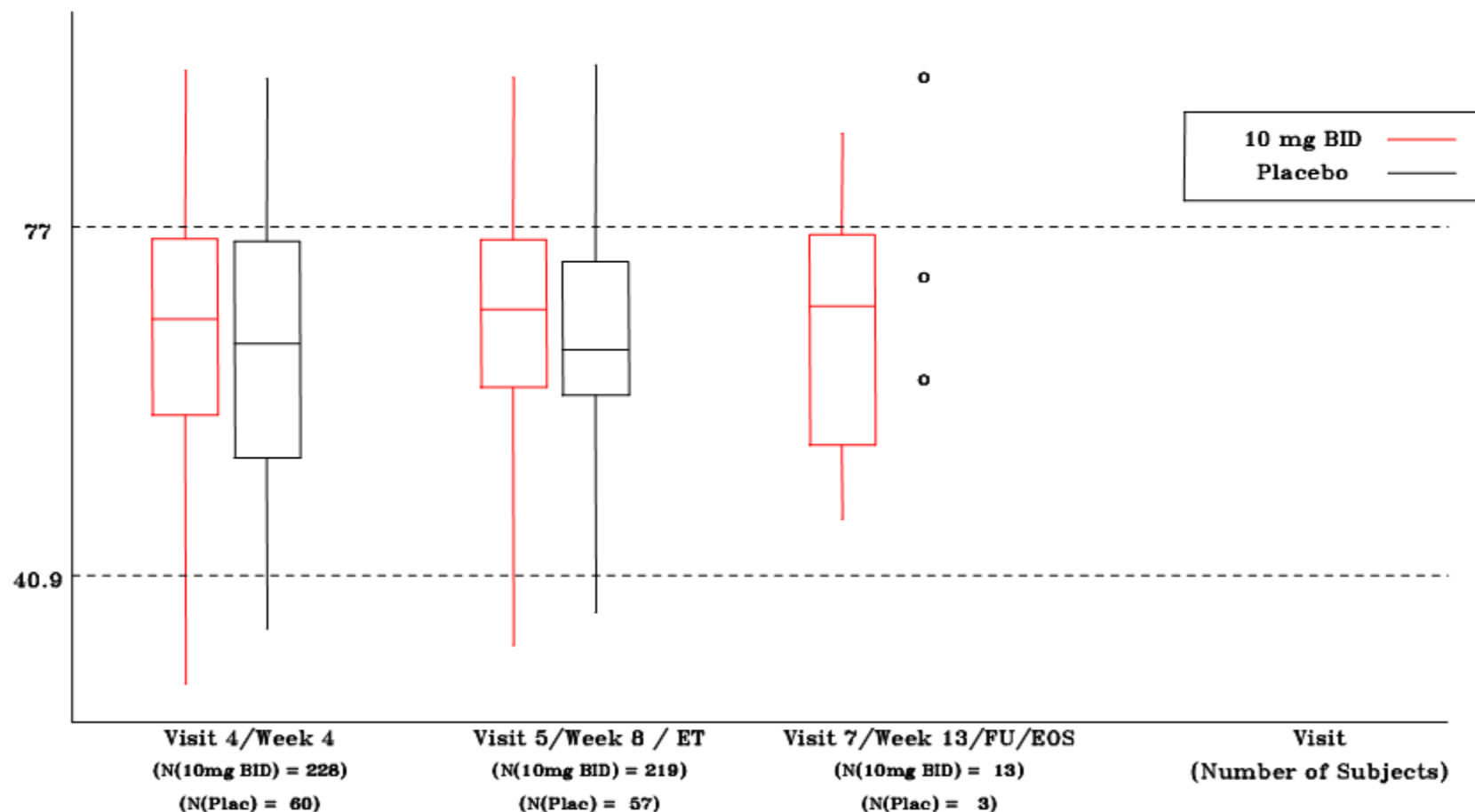
Comparison of Graph vs. Report

Neutrophils/Leukocytes



Comparison of Graph vs. Report

Neutrophils/Leukocytes





Tabular report gives accurate number for N, Median, Mean, Min, Max

In tabular report it is not easy to understand patterns.

In tabular report it is not easy to understand outliers.

whereas Graphical representation it is very hard to read based on axis

The graphs provide an overview of result by comparing all the visits and comparative drugs. Also pattern of the data can be visualized.

Graphical representation help to identify the outliers in the data with comparative drug.

- The Graphs and Tabular Reports have their own pros and cons when comes to representation of data for the end users.
- We should be utilizing the Graphs and Tabular Reports based on the requirement of the clinical trials and make best use of them.



A person wearing a dark blue suit, light blue shirt, and dark tie is holding a large white rectangular sign with both hands. The sign contains handwritten text in black ink. The background is a solid light grey.

Thank you for your attention !

Questions ?