

Graphical presentation of Clinical Trial Data and Results

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Agenda

01

The use of Graphs in Clinical trial reporting

02

Basic checks to be performed before starting programming of Graphs

03

Different type of Graphs we produce for CSR, DMC, IA and publications

04

How to review the Graphs before submitting to customer

05

Question and Answers

The use of Graphs in Clinical trial reporting

01 Graphical presentation of clinical trial data can quickly and effectively communicate the intended message

To communicate results, especially to non-statisticians and Management **04**

02 Emphasis on clear and transparent presentation of data for regulatory review and communications

To explore the data before deciding any exploratory or data driven analysis, to check statistical assumptions **05**

03 Graphs will help to get your audience's attention

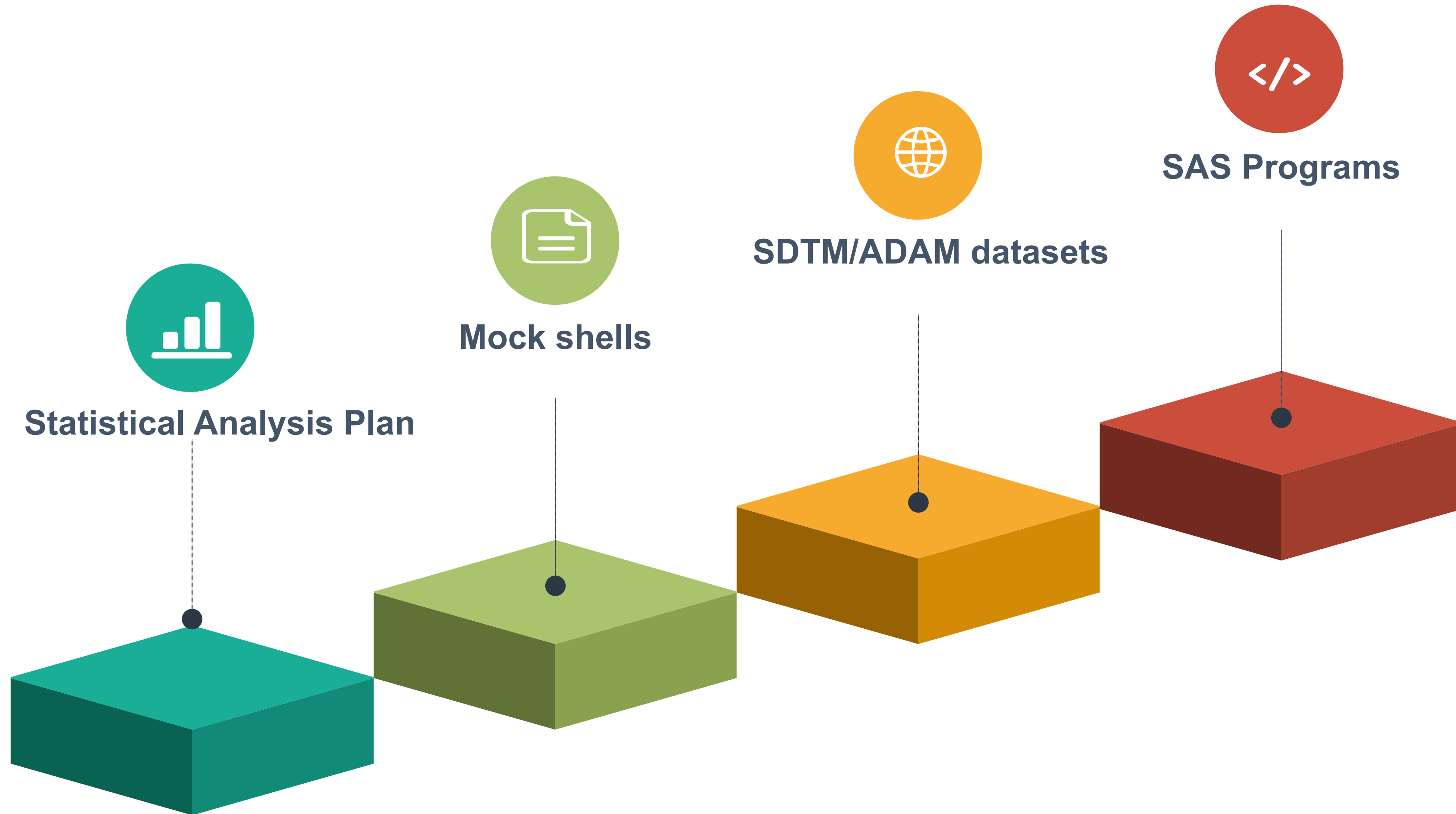
Easy to detect the outliers **06**

Basic checks before starting programming of Graphs

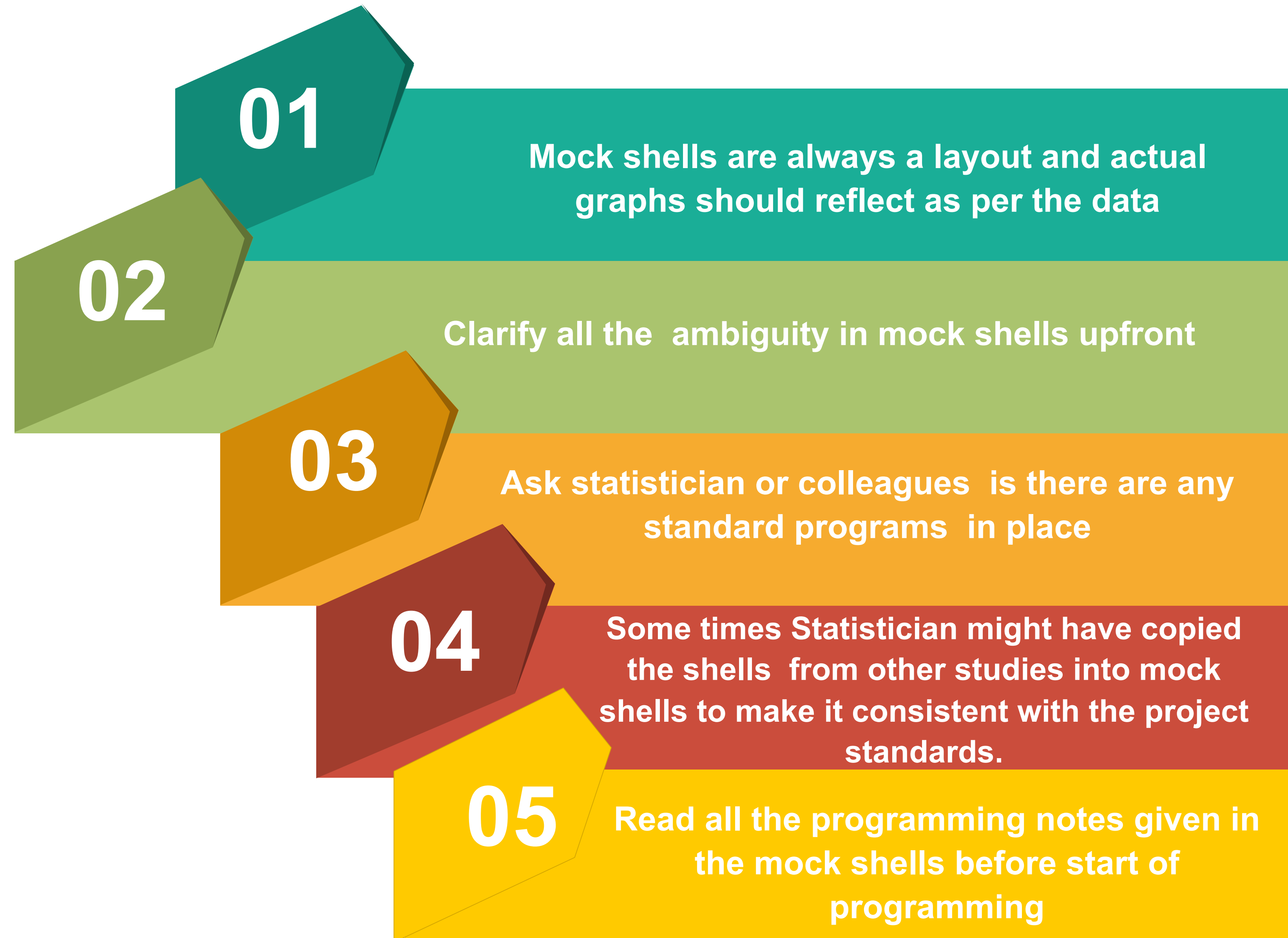
How many of us go through Statistical analysis Plan (SAP) and Mock shells before start of programming of datasets or TLF's?



Basic checks before starting programming of Graphs



Basic checks before starting programming of Graphs



Pros and cons

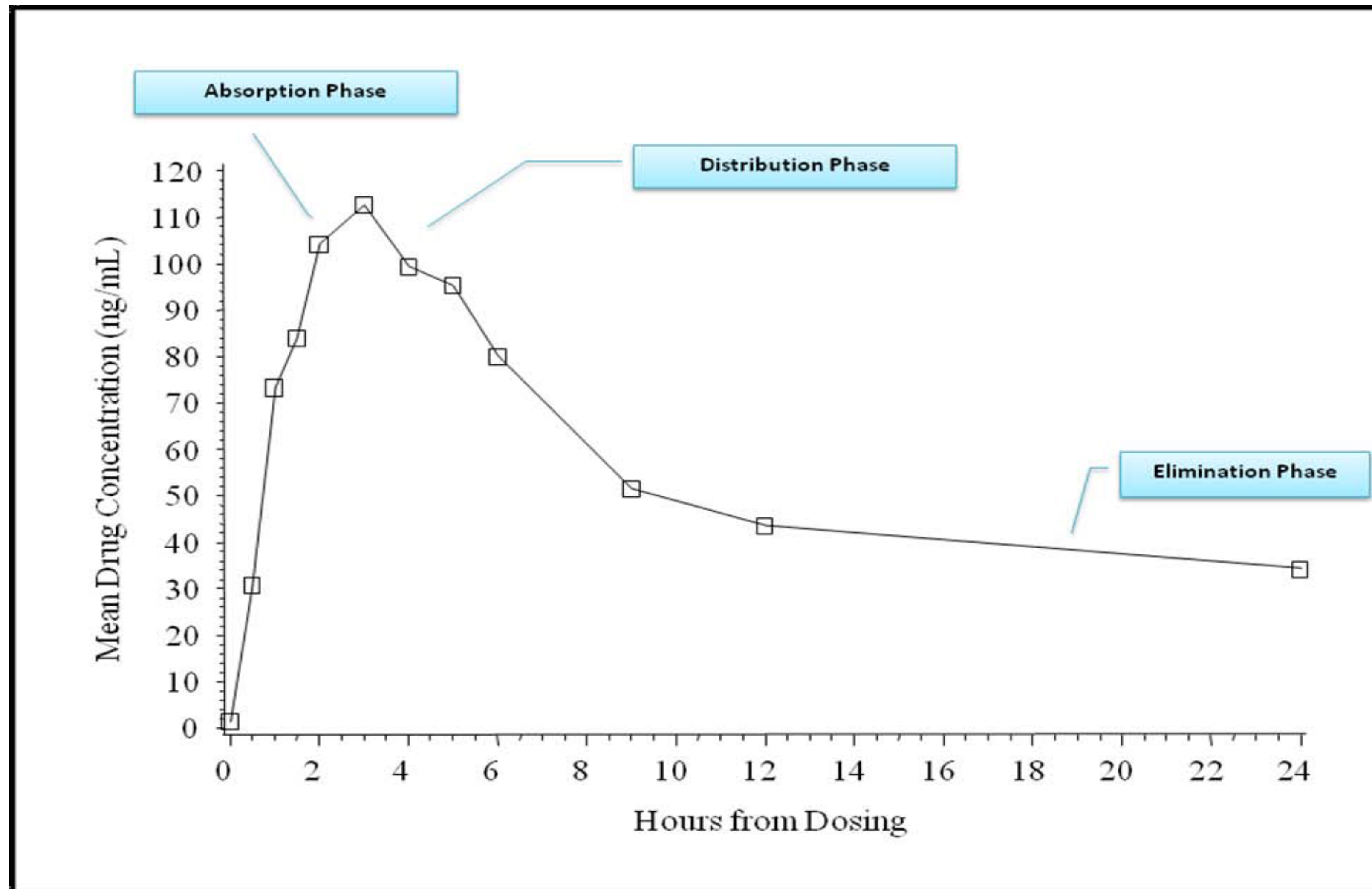
Graph	Table
Better in Presentations	Better in papers
Can only show summaries	Can often show all the data
Show only a few variables	Better for multiple variables
Trend better illustrated	Trend badly illustrated

Different type of Graphs



Different type of Graphs

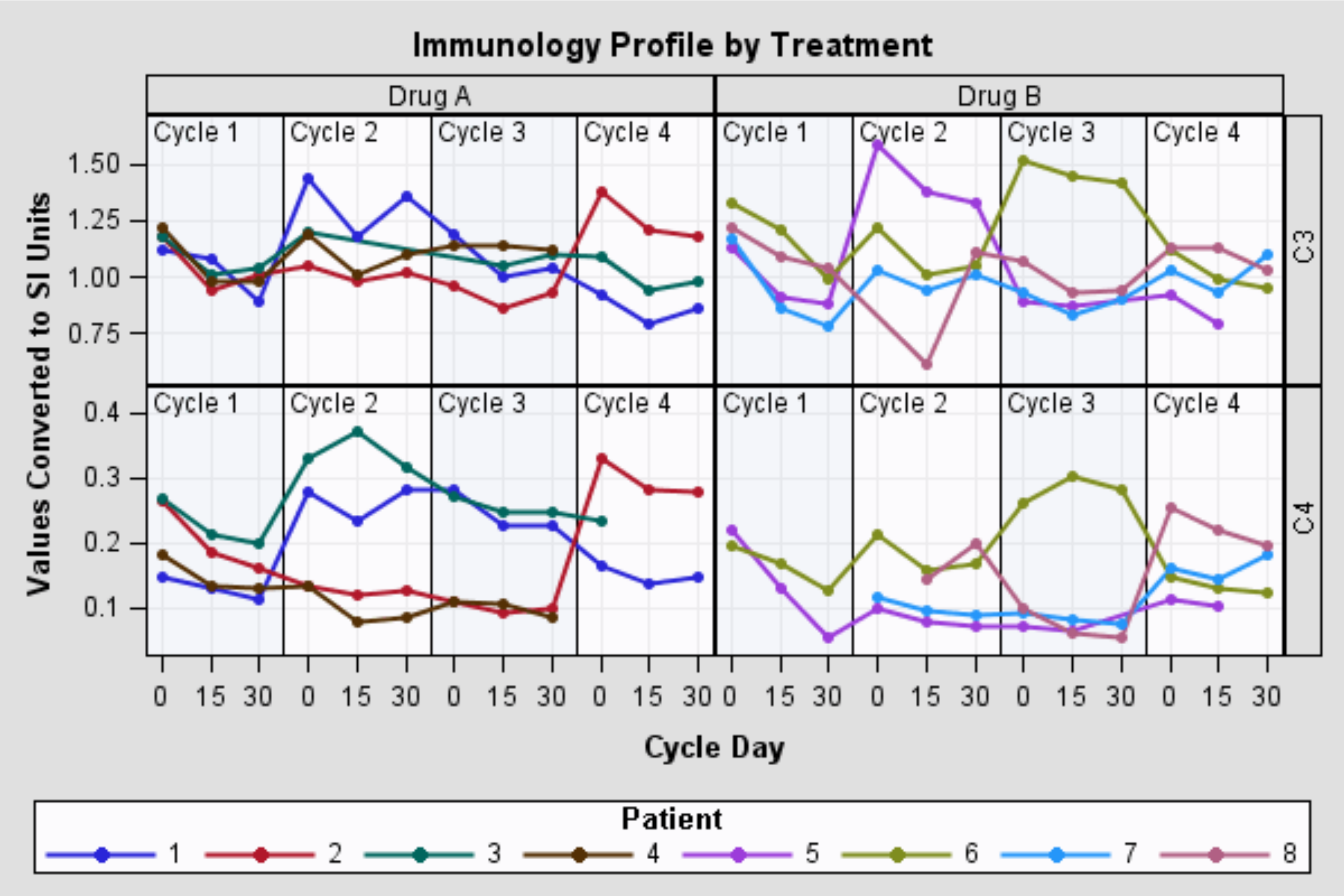
Figure 1 Mean plasma concentrations (unit) of Analyte X for Group A (PK analysis set)



Different type of Graphs

Figure 2

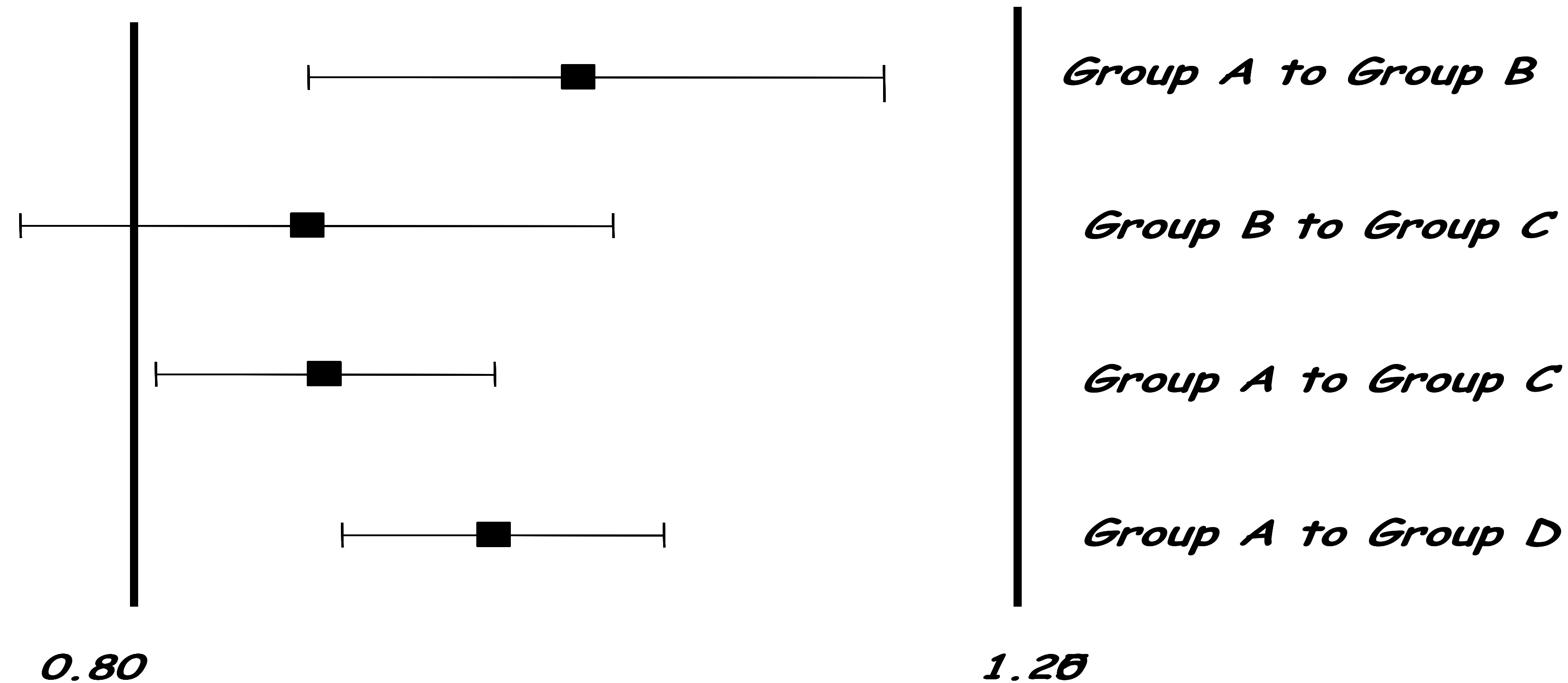
Individual immunology values for Treatment A (Full analysis set)



Different type of Graphs

Figure 3

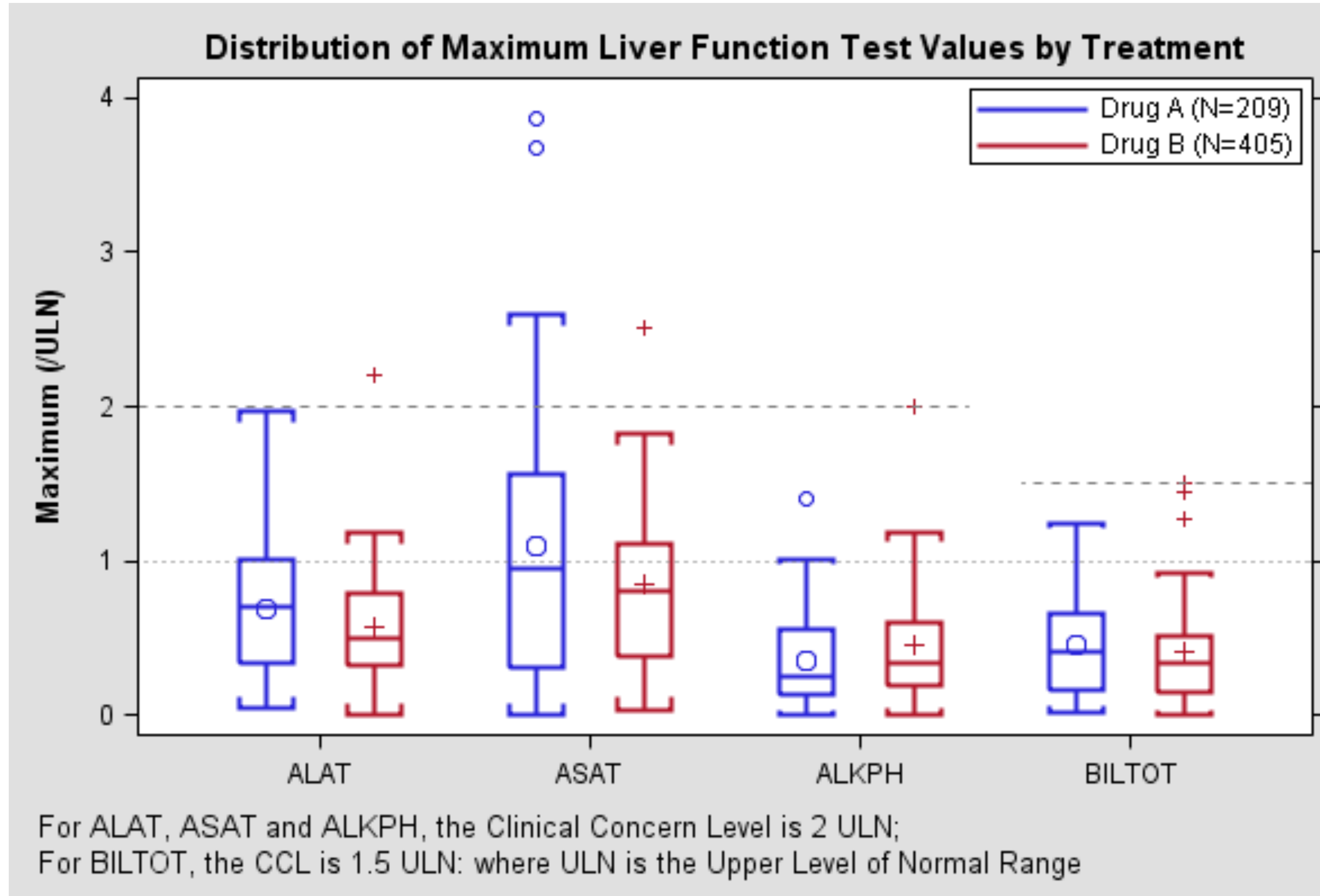
Geometric mean and 90% CI for ratio of pairs of Groups for parameter (PK analysis set)



Different type of Graphs

Figure 4

Box plot by Treatment group (Full analysis set)

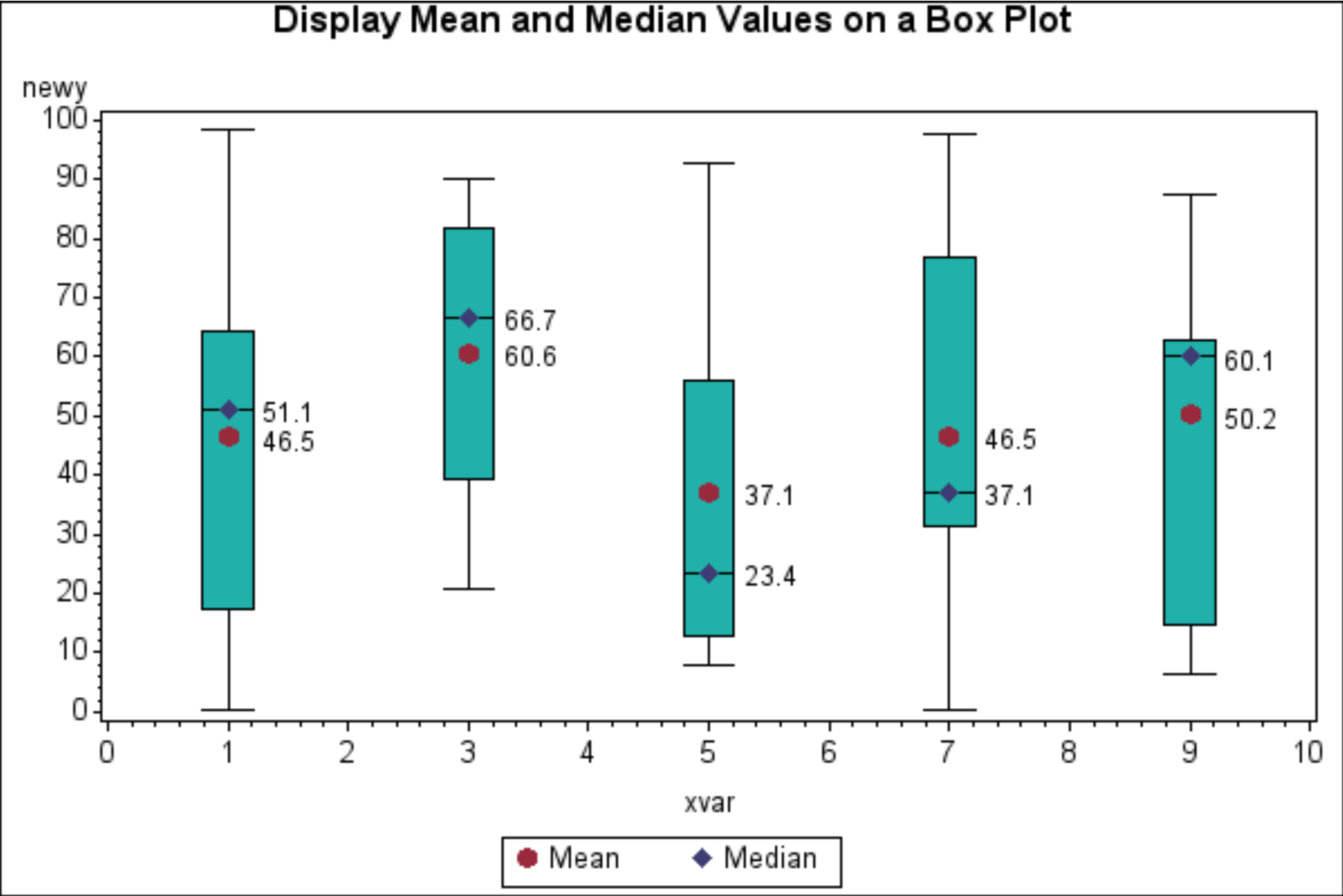


- A mild outlier is any observation lying between the inner and outer fences on either side, while a serious outlier is an observation that lies beyond the outer fences on either side
- Some definitions:
 - Interquartile Range (IQR)= $Q3 - Q1$
 - Inner Fences: $Q1 - 1.5 \times IQR$; $Q3 + 1.5 \times IQR$
 - Outer Fences: $Q1 - 3 \times IQR$; $Q3 + 3 \times IQR$

Different type of Graphs

Figure 5

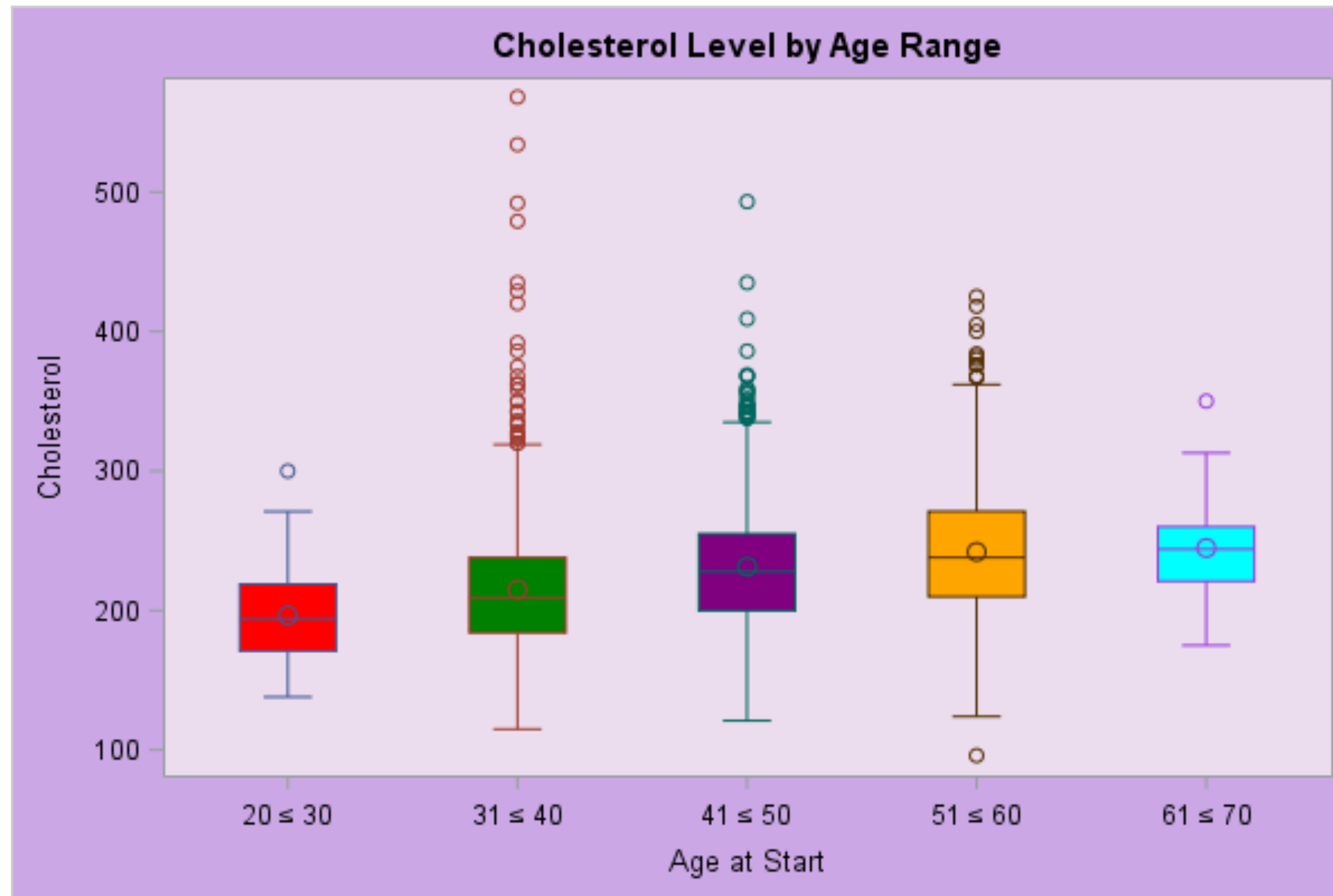
Box plot with mean and median (Full analysis set)



Different type of Graphs

Figure 6

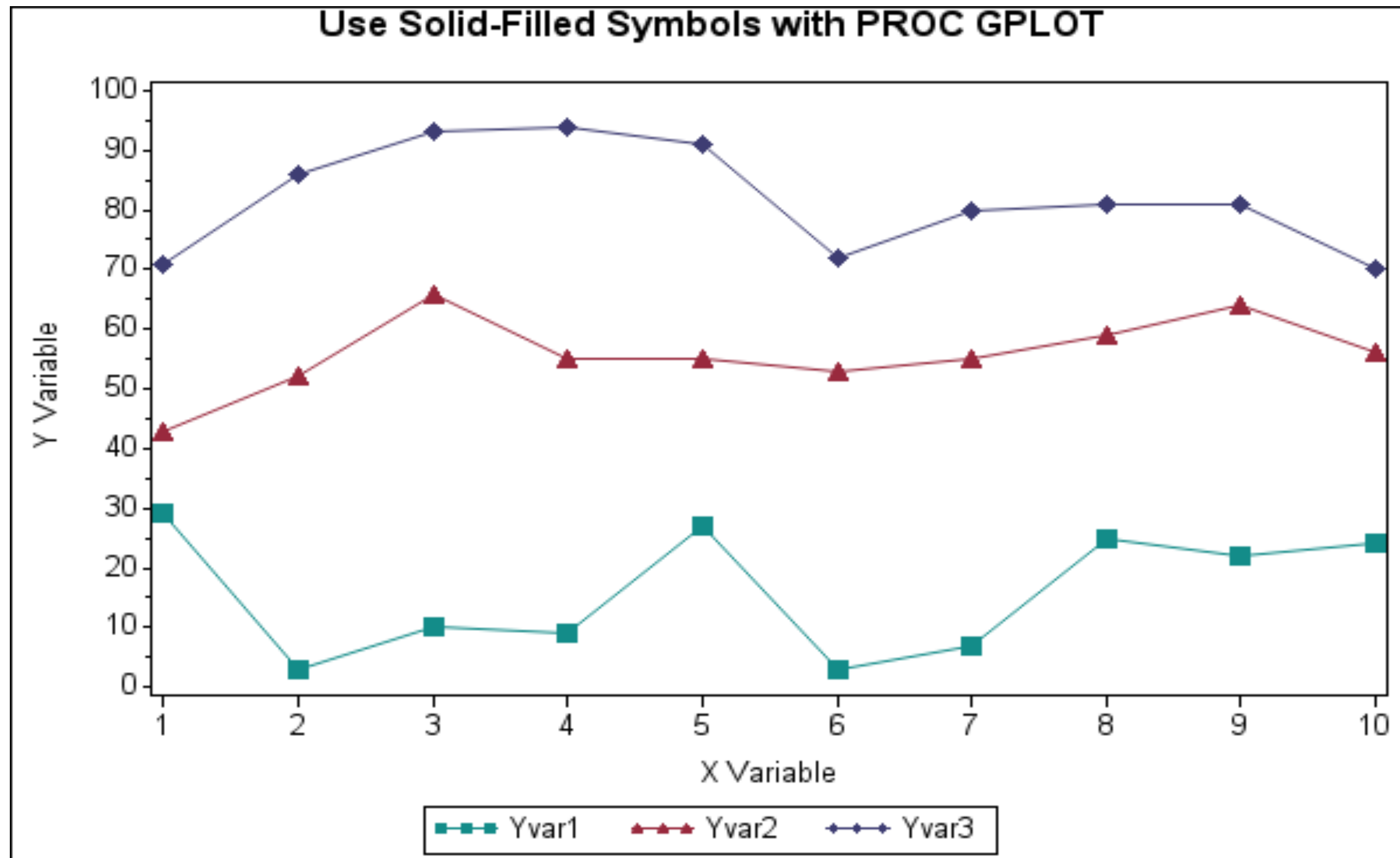
Box plot for two variables (Full analysis set)



Different type of Graphs

Figure 7

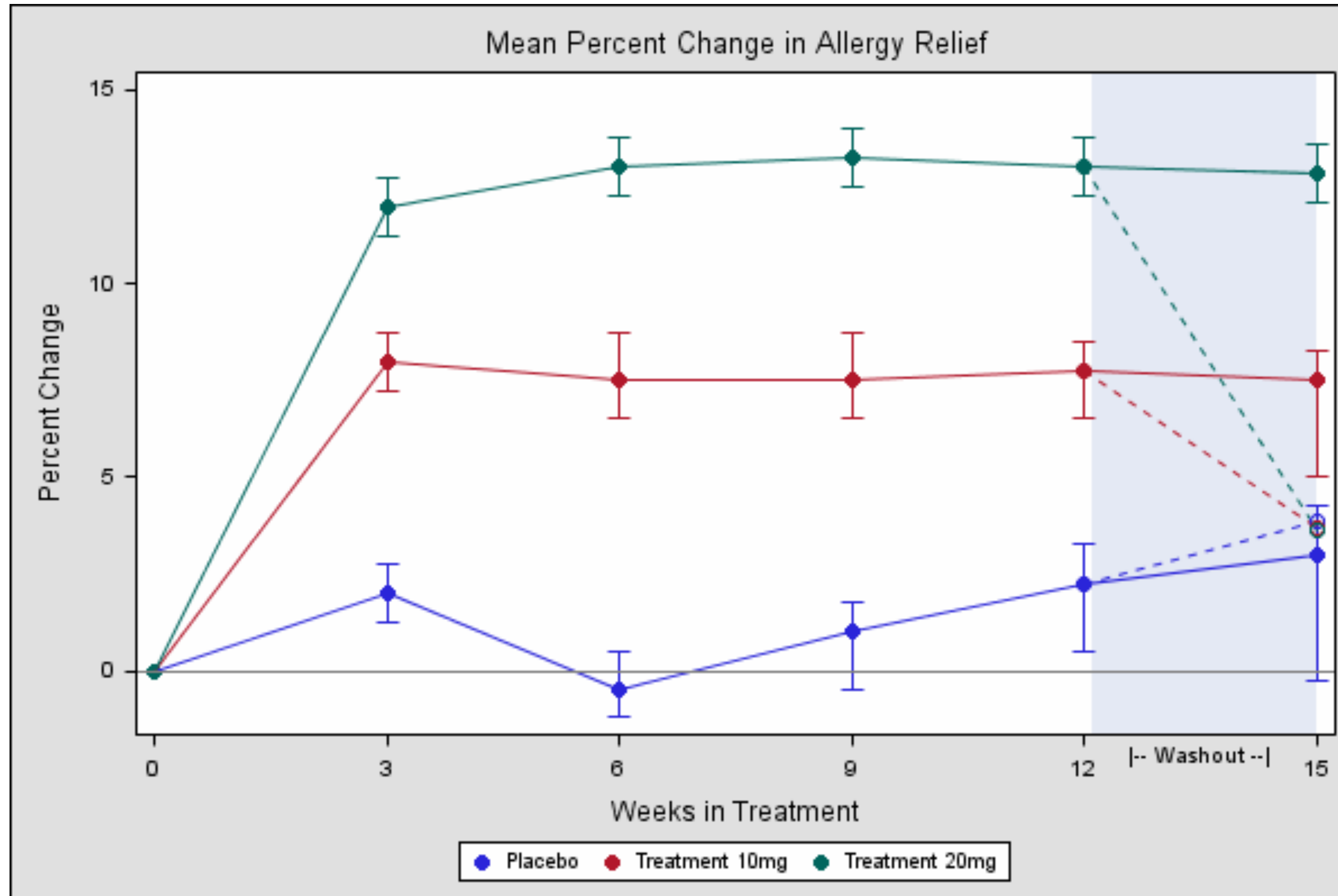
Mean change from baseline score over time by treatment (Full analysis set)



Different type of Graphs

Figure 8

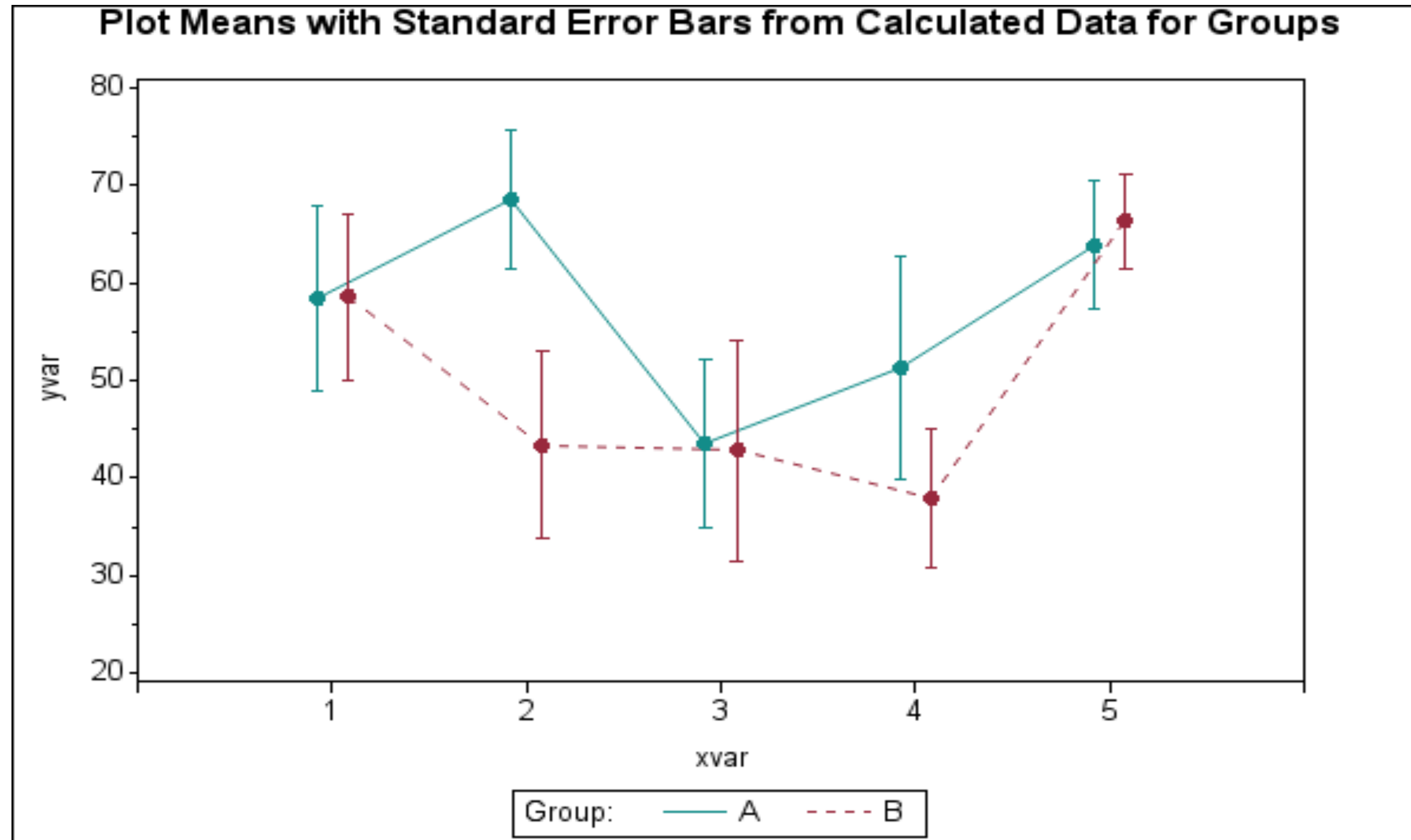
% Mean change ($\pm$ SD) from baseline score over time by treatment (FAS)



Different type of Graphs

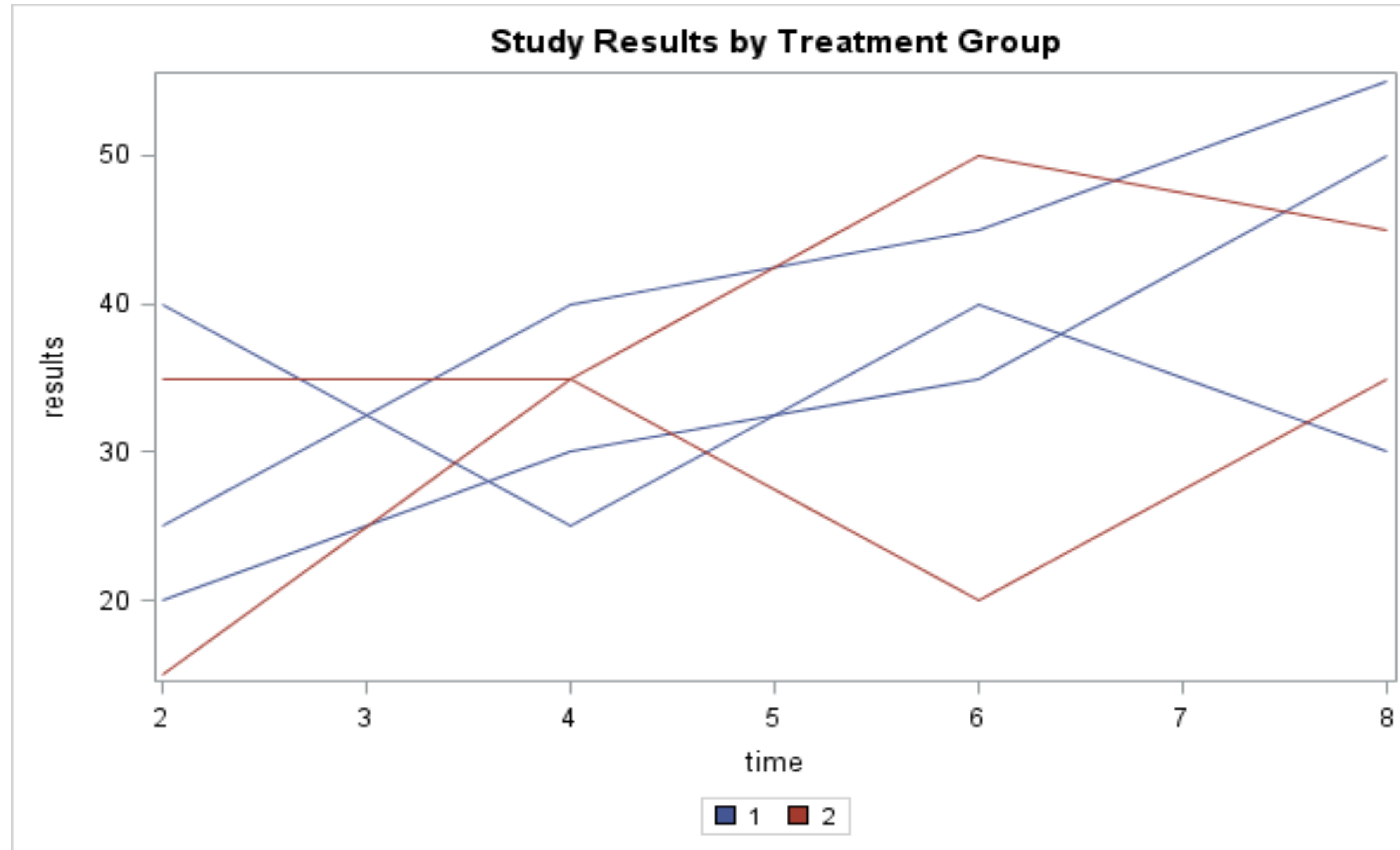
Figure 9

Mean ($\pm$ SE) on Variable X (Full analysis set)



Different type of Graphs

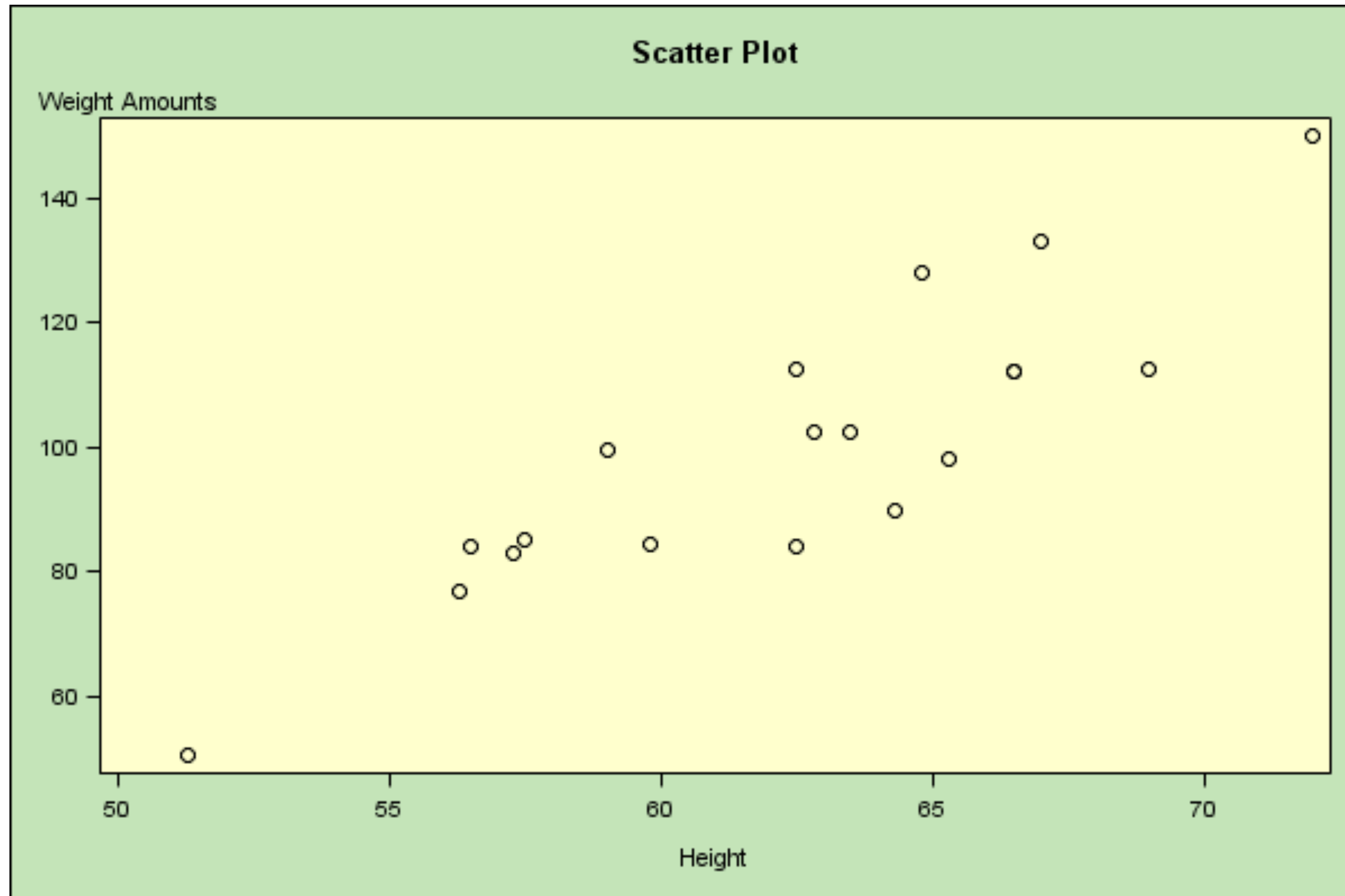
Figure 10 Response rates for all treatment on Variable X (Full analysis set)



Different type of Graphs

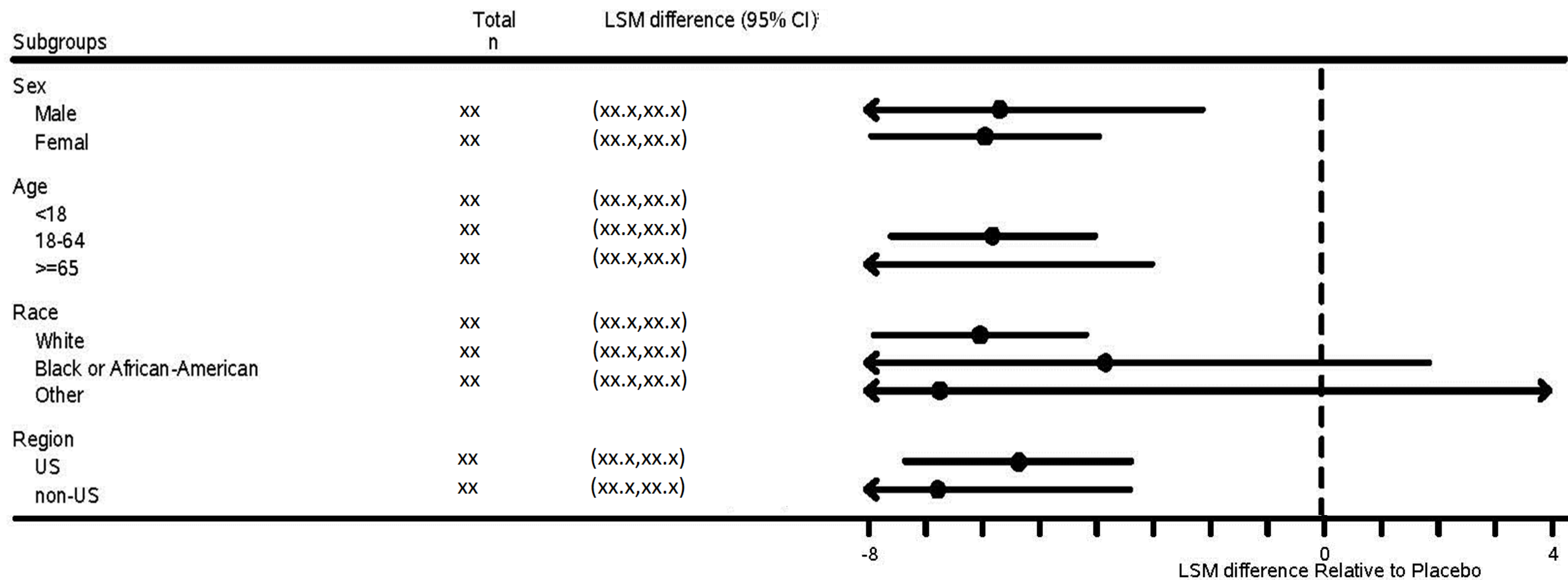
Figure 11

Scatter plot of Variable X and Y (Full analysis set)



Different type of Graphs

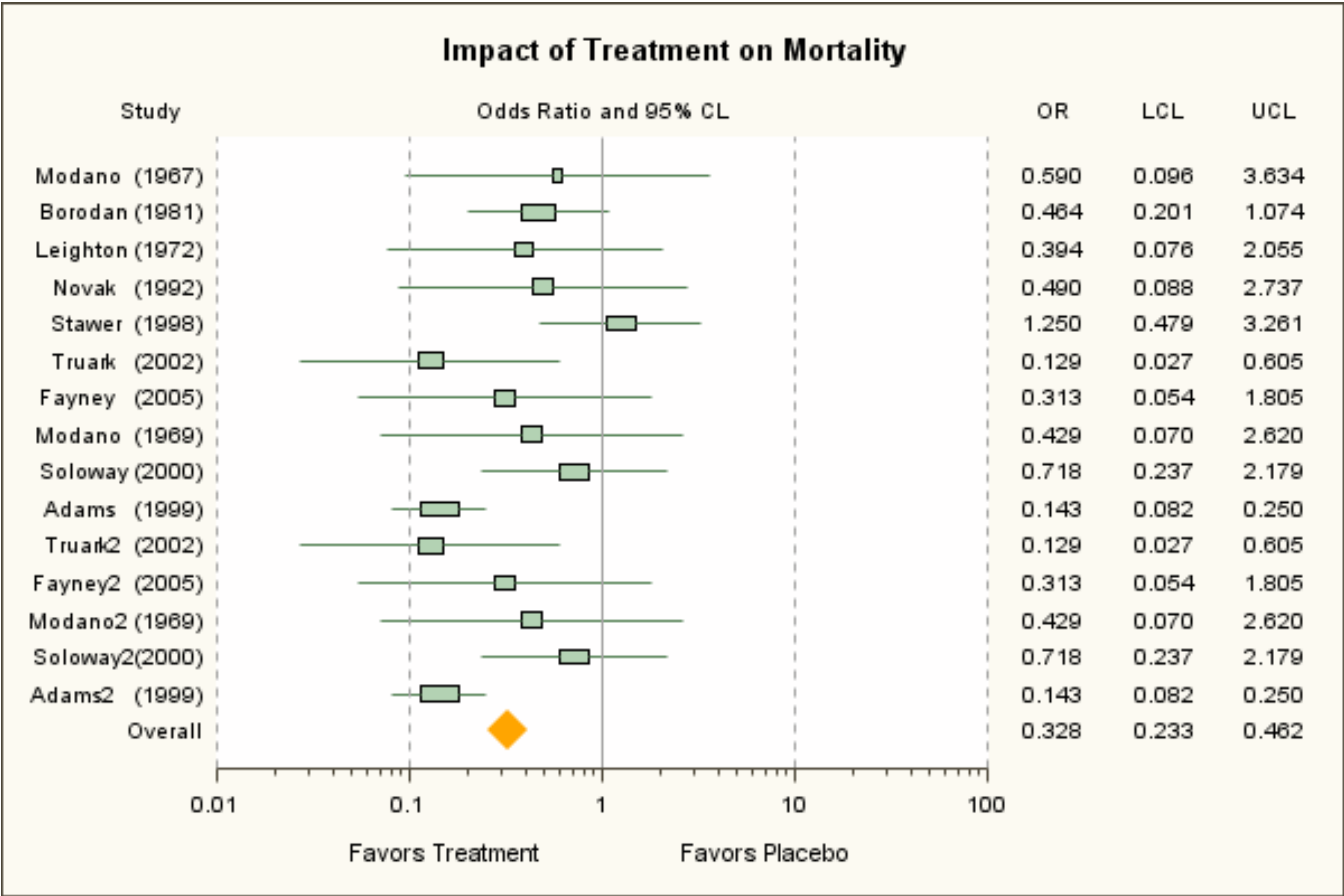
Figure 12 Statistical analysis of change from baseline score by sub group (Full analysis set)



Different type of Graphs

Figure 13

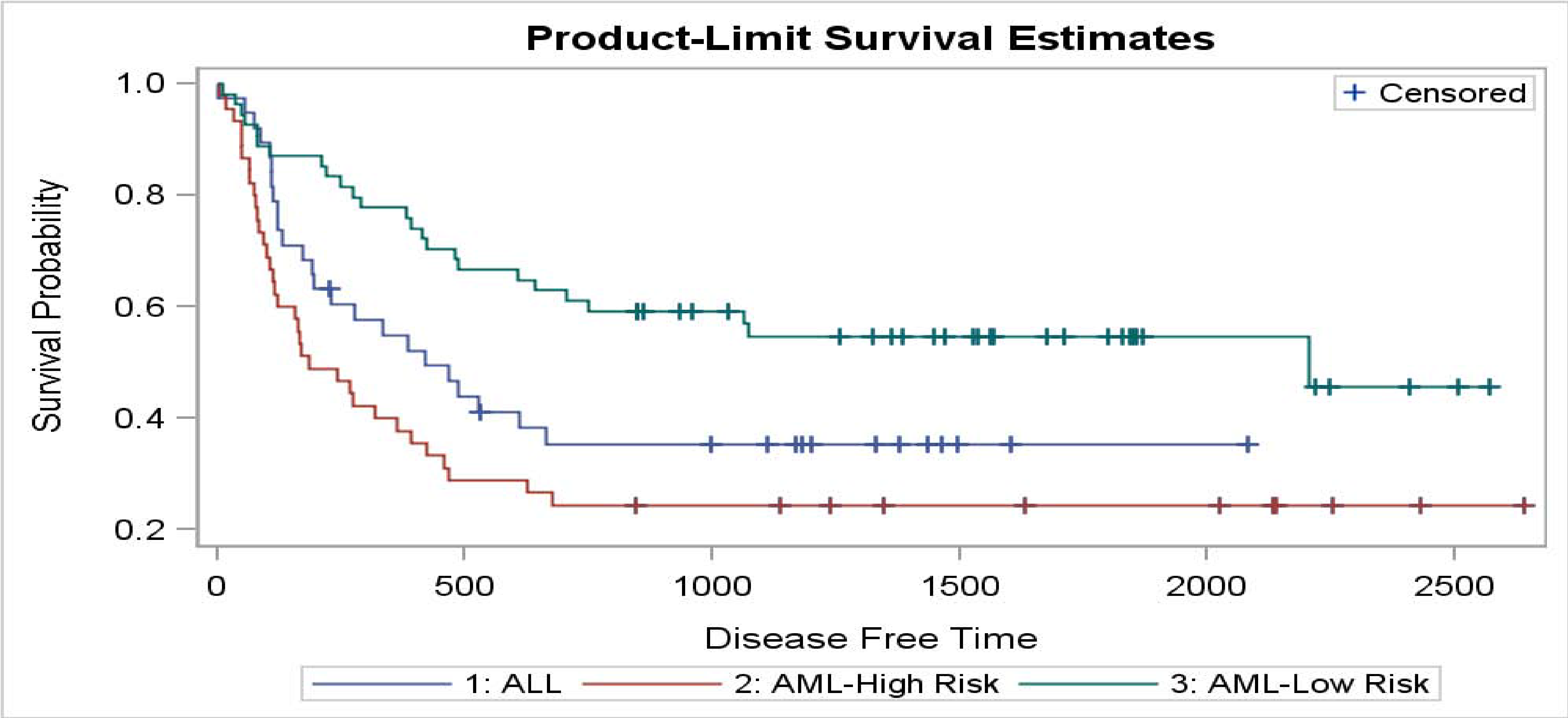
Forest plot (Full analysis set)



Different type of Graphs

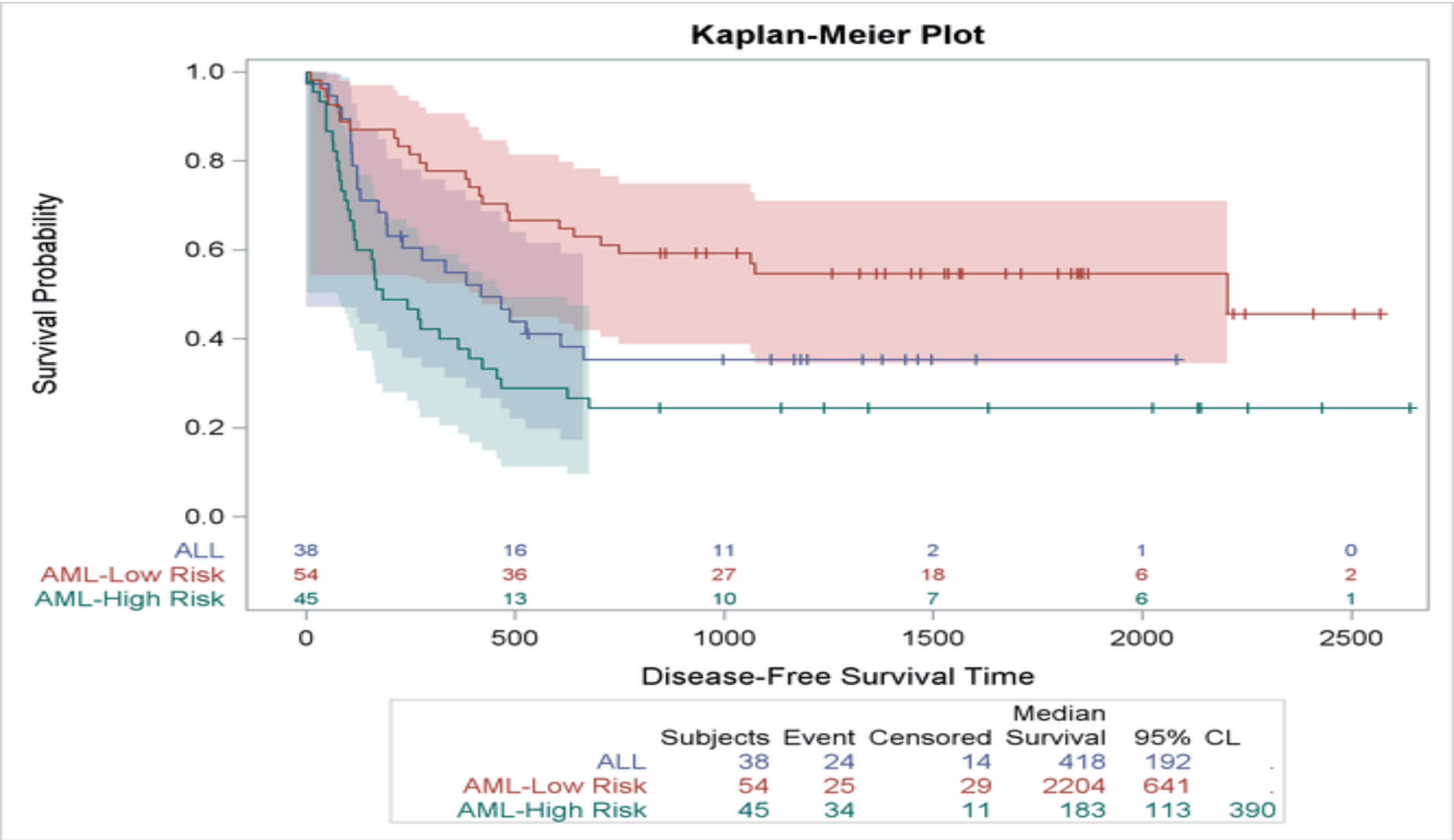
Figure 14

Kaplan-Meier comparison of variable tested between Group A and Group B (FAS set)



Different type of Graphs

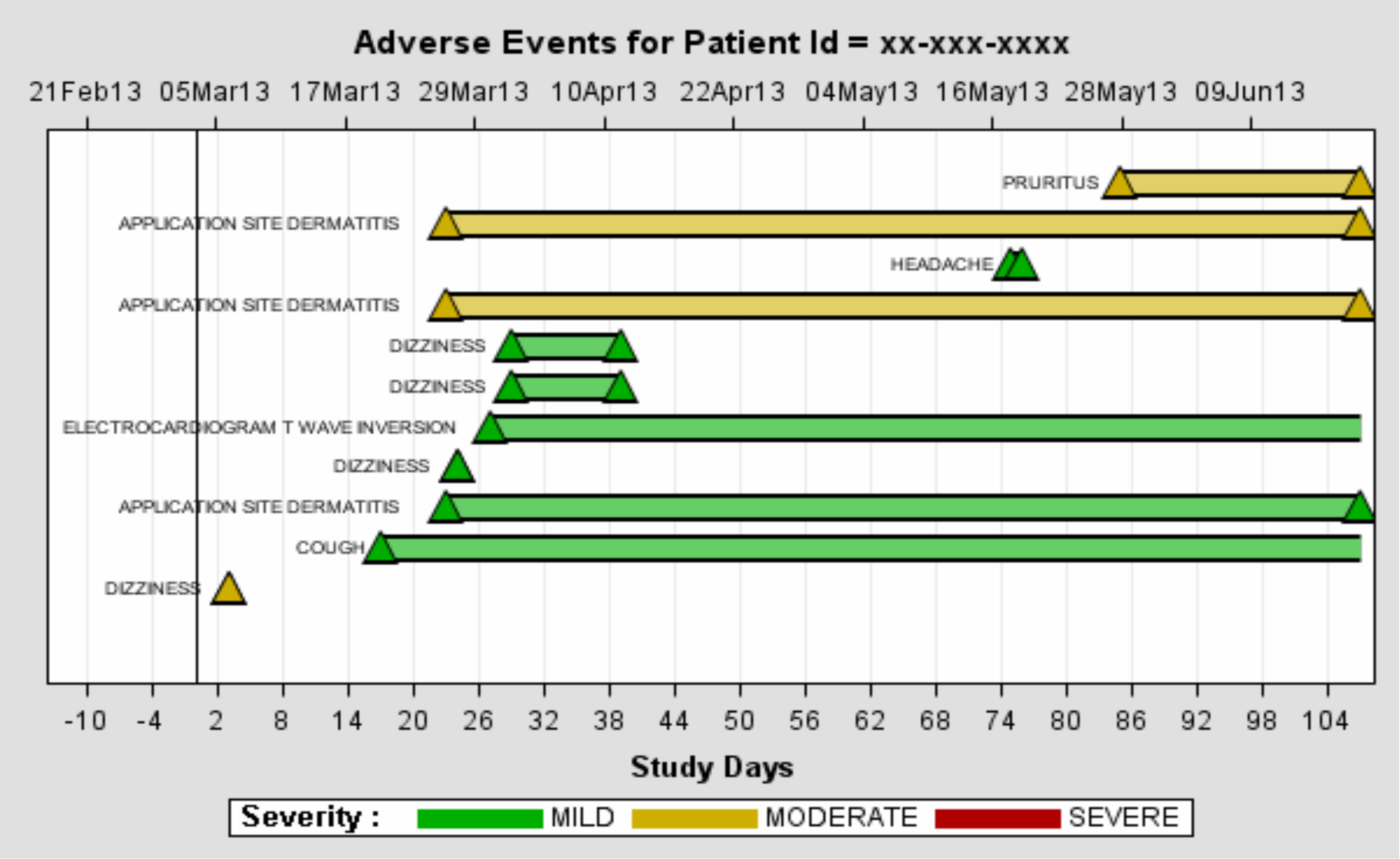
Figure 15 Kaplan-Meier comparison of variable tested between Group A and Group B - (FAS set)



Different type of Graphs

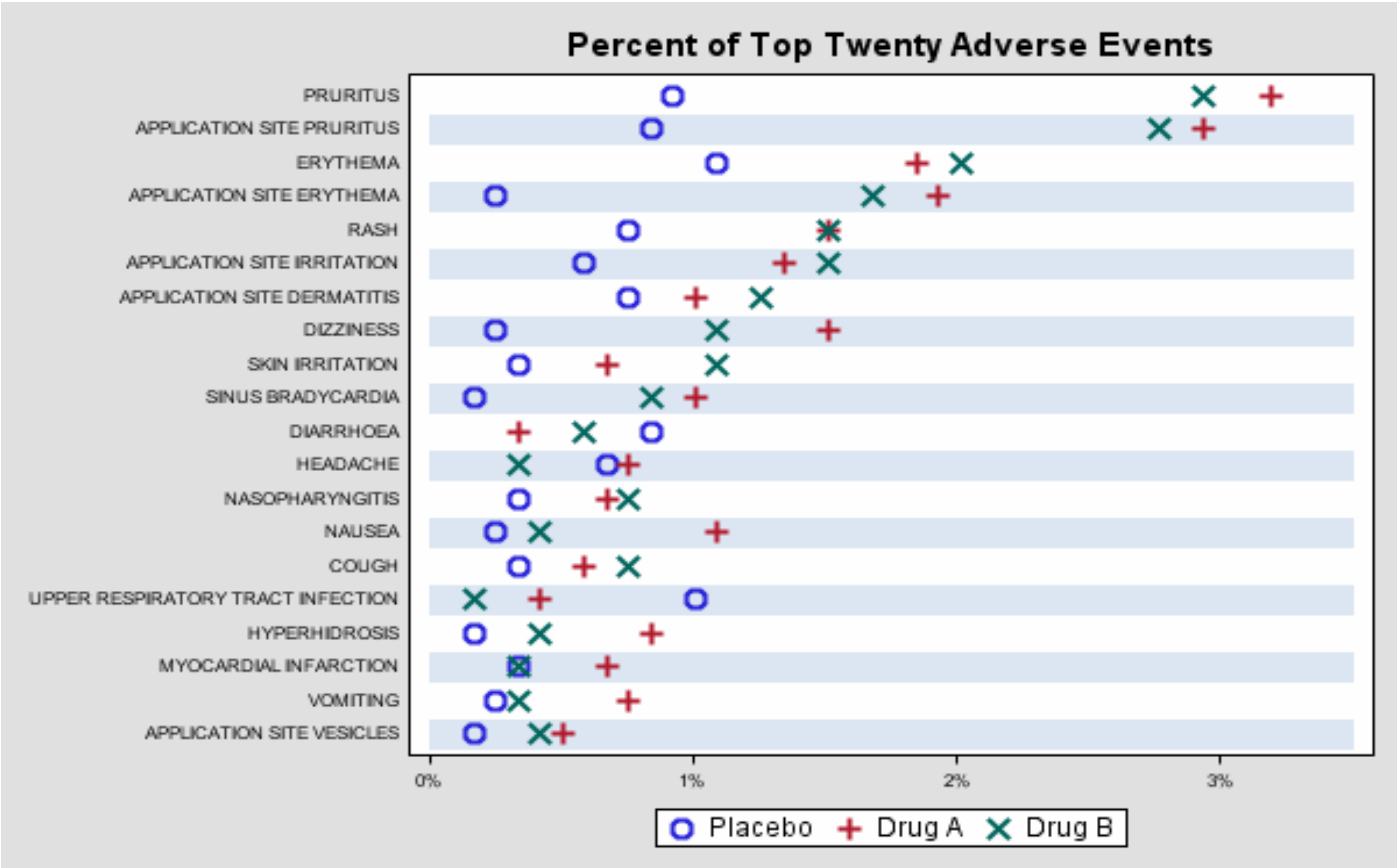
Figure 16

AEs for particular patient (Safety analysis set)



Different type of Graphs

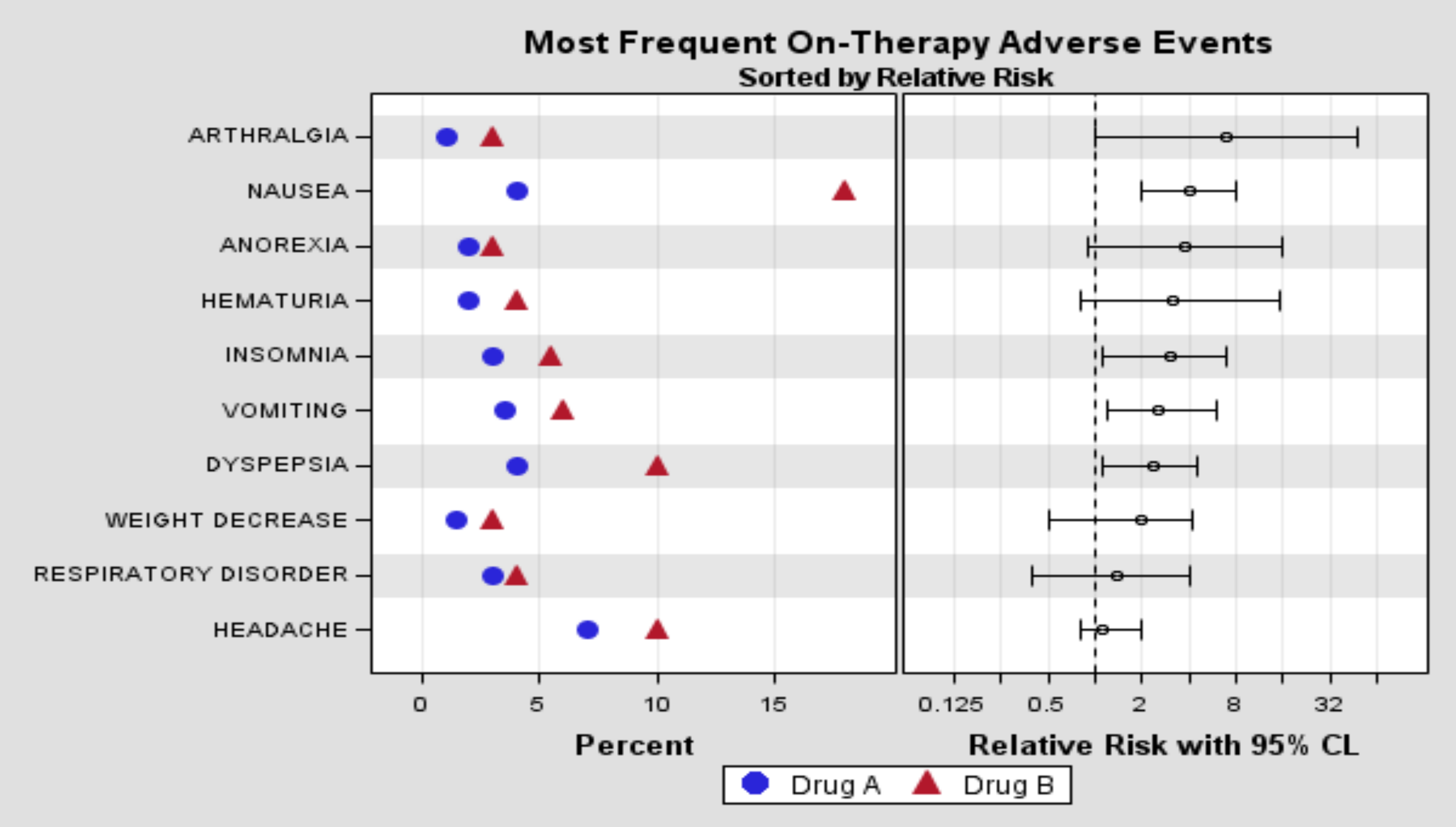
Figure 17 Number (%) of top 20 AE by preferred term (Safety analysis set)



Different type of Graphs

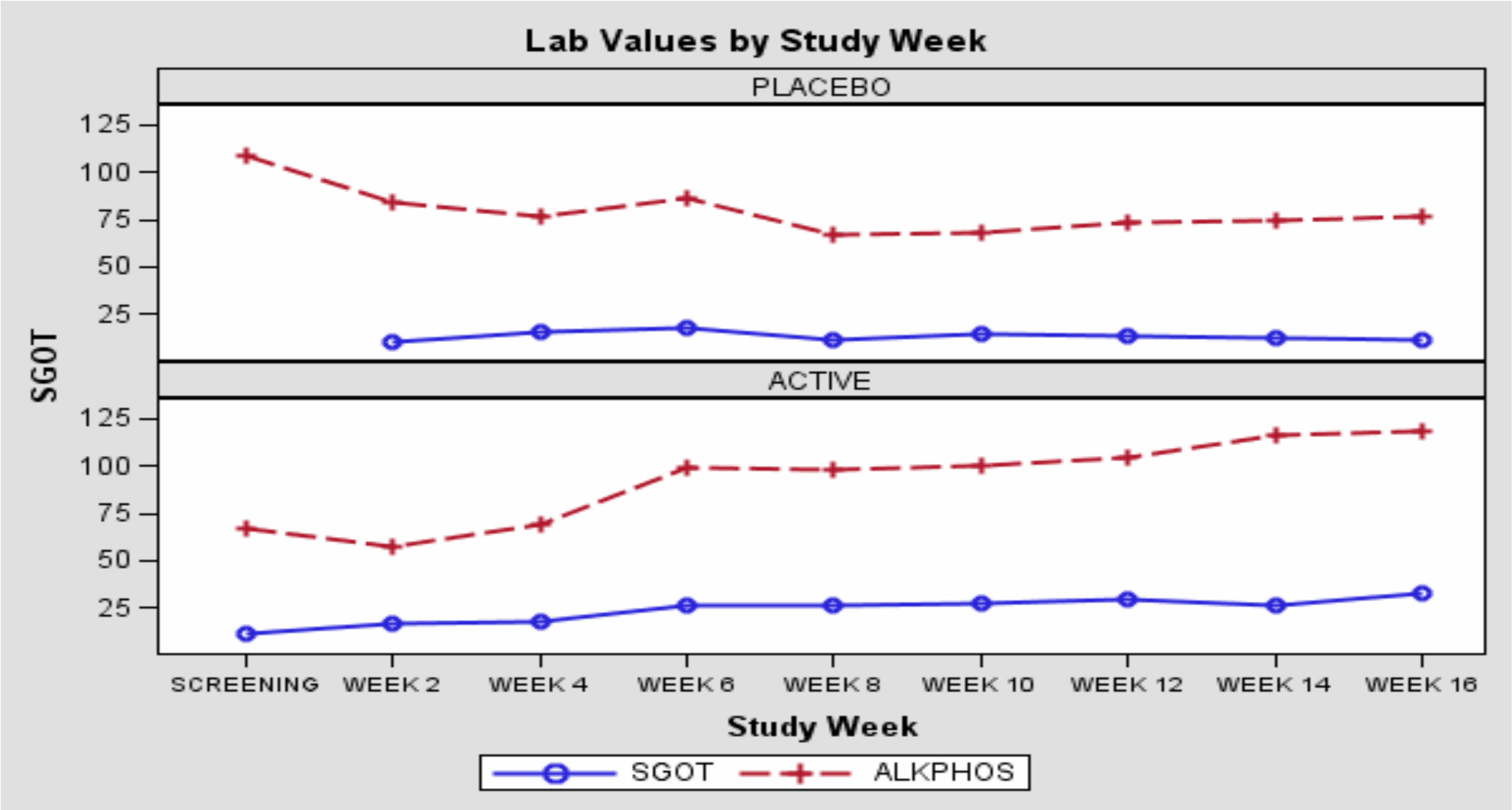
Figure 18

Number (%) of patients reporting AE and SAEs by SOC (Safety analysis set)



Different type of Graphs

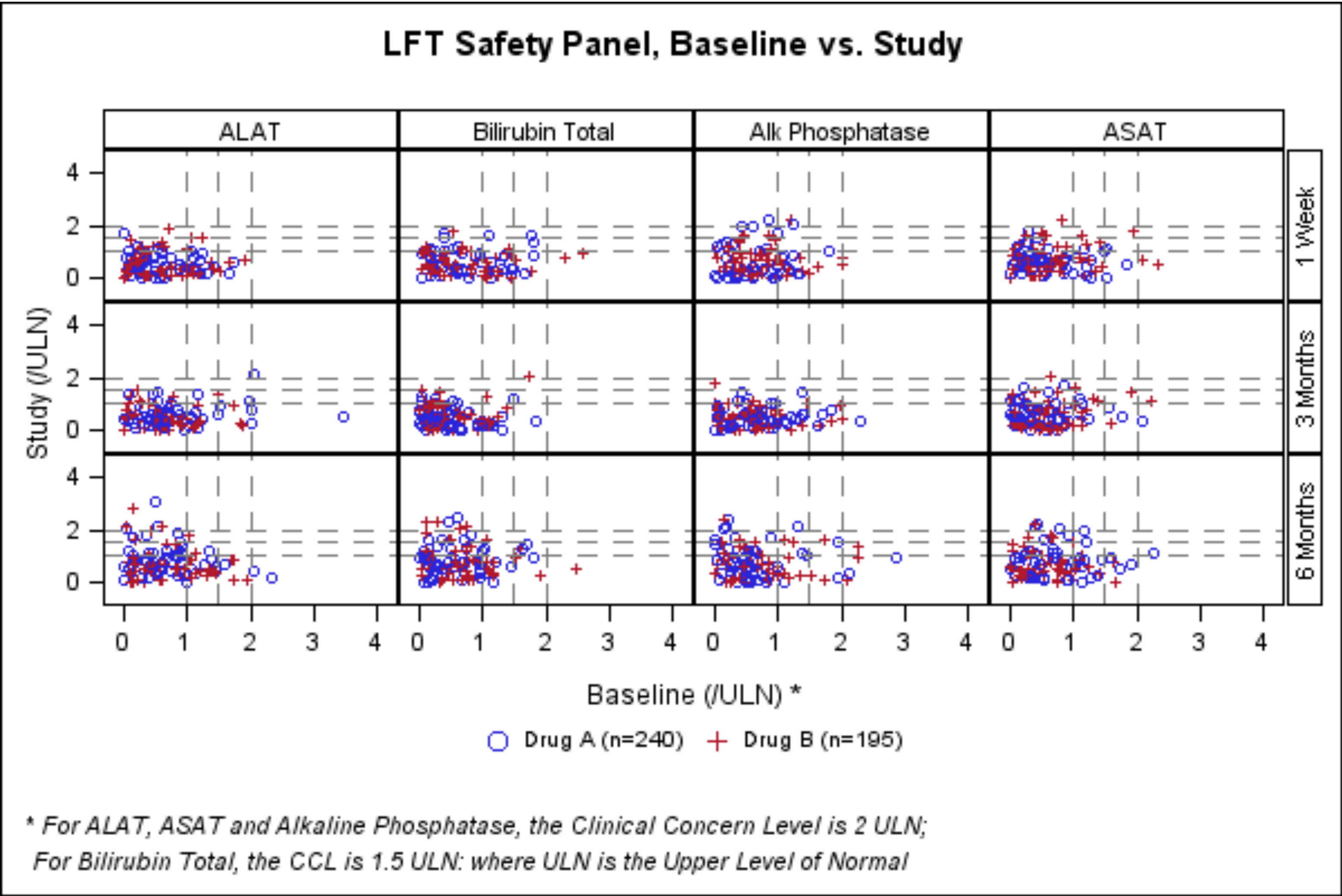
Figure 19 Mean laboratory values over time for laboratory safety variable A (Safety analysis set)



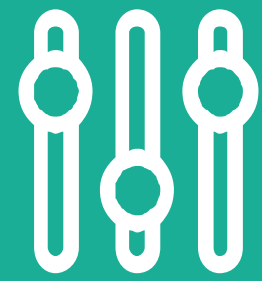
Different type of Graphs

Figure 20

Shift plot comparing baseline to different time points on treatment, for laboratory variables (Safety analysis set)



How to review the Graphs before submitting to customer



Make sure the colors and symbols are clear in Graphs, Maintain consistency of color, Scale and symbol for same treatment across graphs

01

Consistency



Cross check the value, mean, SE, percentage with corresponding table

02

Compare



Provide a reference table or listing for each graph as a footnote.

03

Reference

Question and Answers



KEEP CHALLENGING™

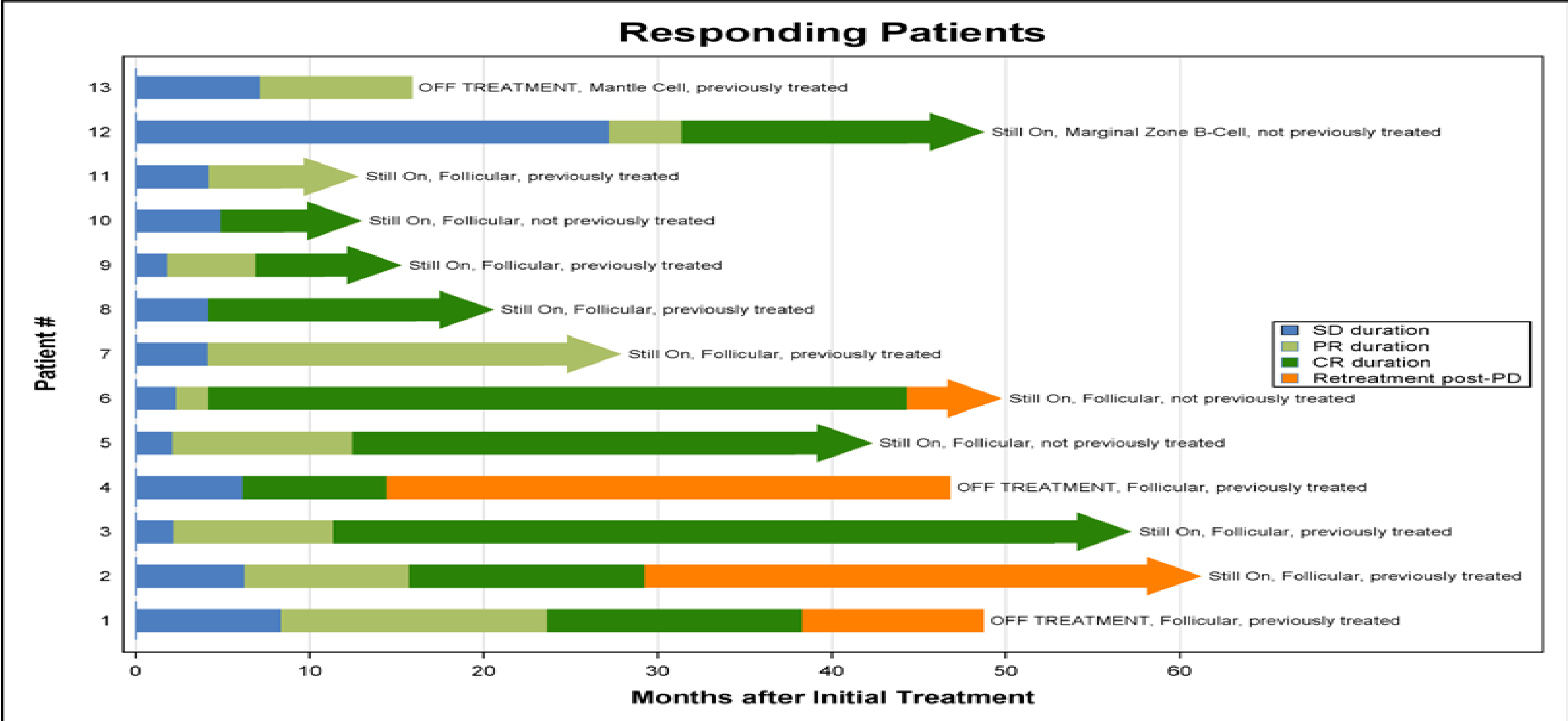
Thank You

Looking forward to work with you!



Annexure

Different type of Graphs

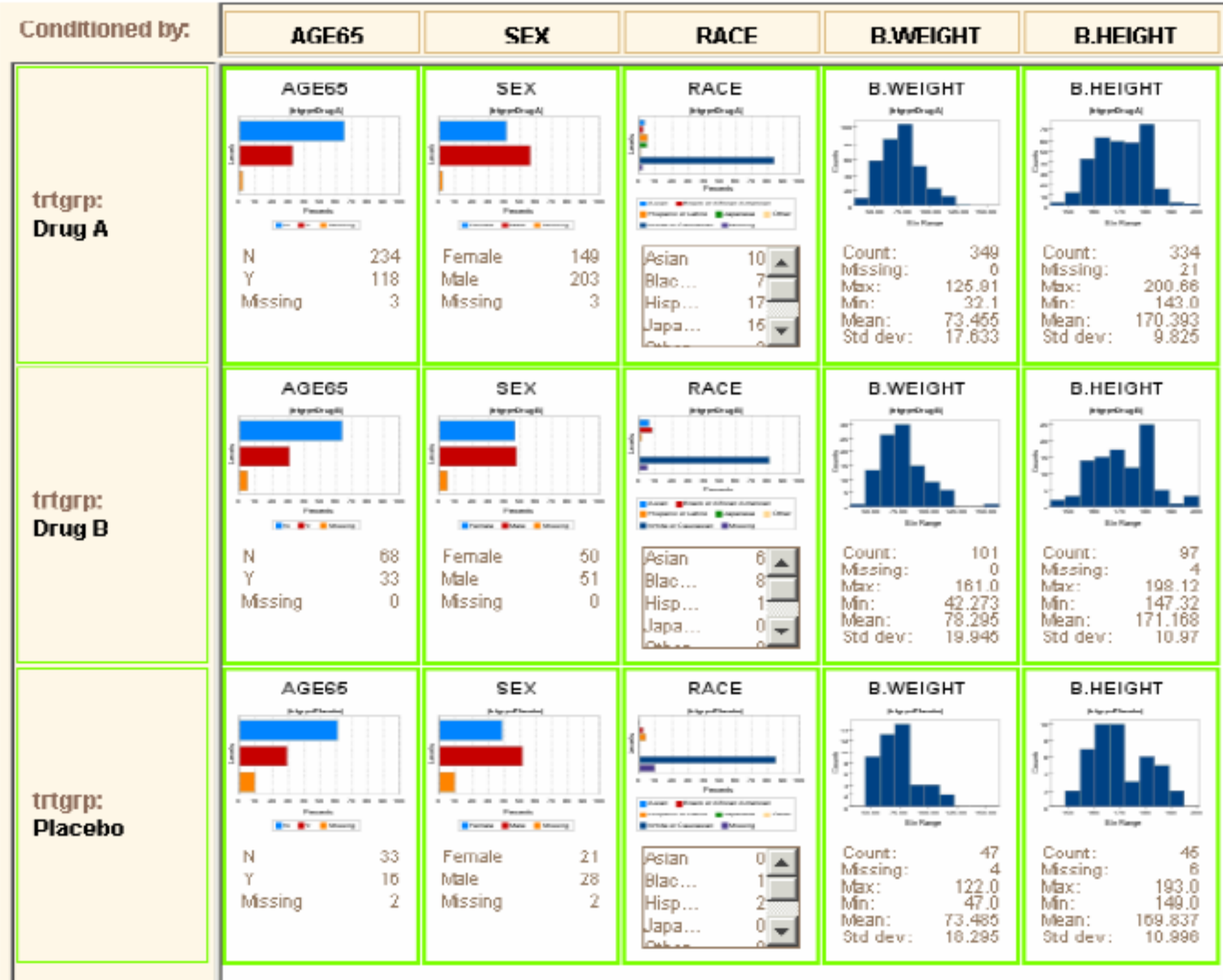


Different type of Graphs

Table 2.1. Baseline Demographics
(Subjects Exposed to Study Drug)

	Study XXXX		
	Placebo (N=165)	Drug A (N=164)	Total (N=329)
Sex - n(%)			
Female	65 (39.4)	64 (39.0)	129 (39.2)
Male	100 (60.6)	100 (61.0)	200 (60.8)
Race - n(%)			
Caucasian	136 (82)	135 (82)	271 (82)
African American	6 (4)	8 (5)	14 (4)
Hispanic	13 (8)	10 (6)	23 (7)
Asian	6 (4)	7 (4)	13 (4)
Japanese	2 (1)	2 (1)	4 (1)
American Indian	0 (0)	1 (1)	1 (0)
Native Hawaiian	0 (0)	0 (0)	0 (0)
Other	2 (1)	1 (1)	3 (1)

Baseline Demographics



Different type of Graphs

