

# Graphics for Clinical Trials

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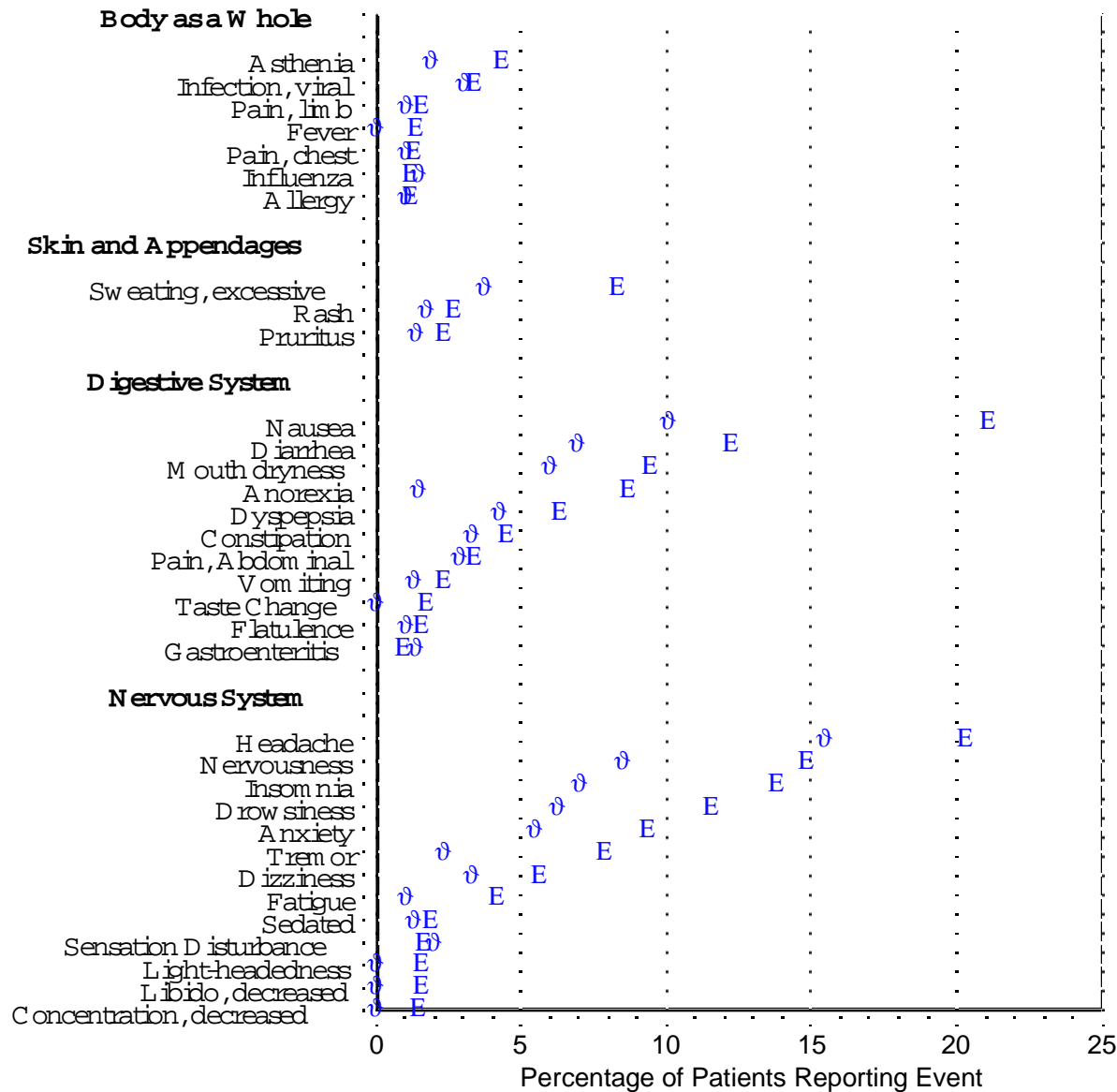
**[www.Lincolntechnologies.com](http://www.Lincolntechnologies.com)**

**[Jay.levine@lincolntechnologies.com](mailto:Jay.levine@lincolntechnologies.com)**

**The majority of the graphs in these slides were produced using either CrossGraphs ([www.belmont.com](http://www.belmont.com)) or S-PLUS. For more information on how they were constructed, please contact the author.**

# What were the adverse event rates?

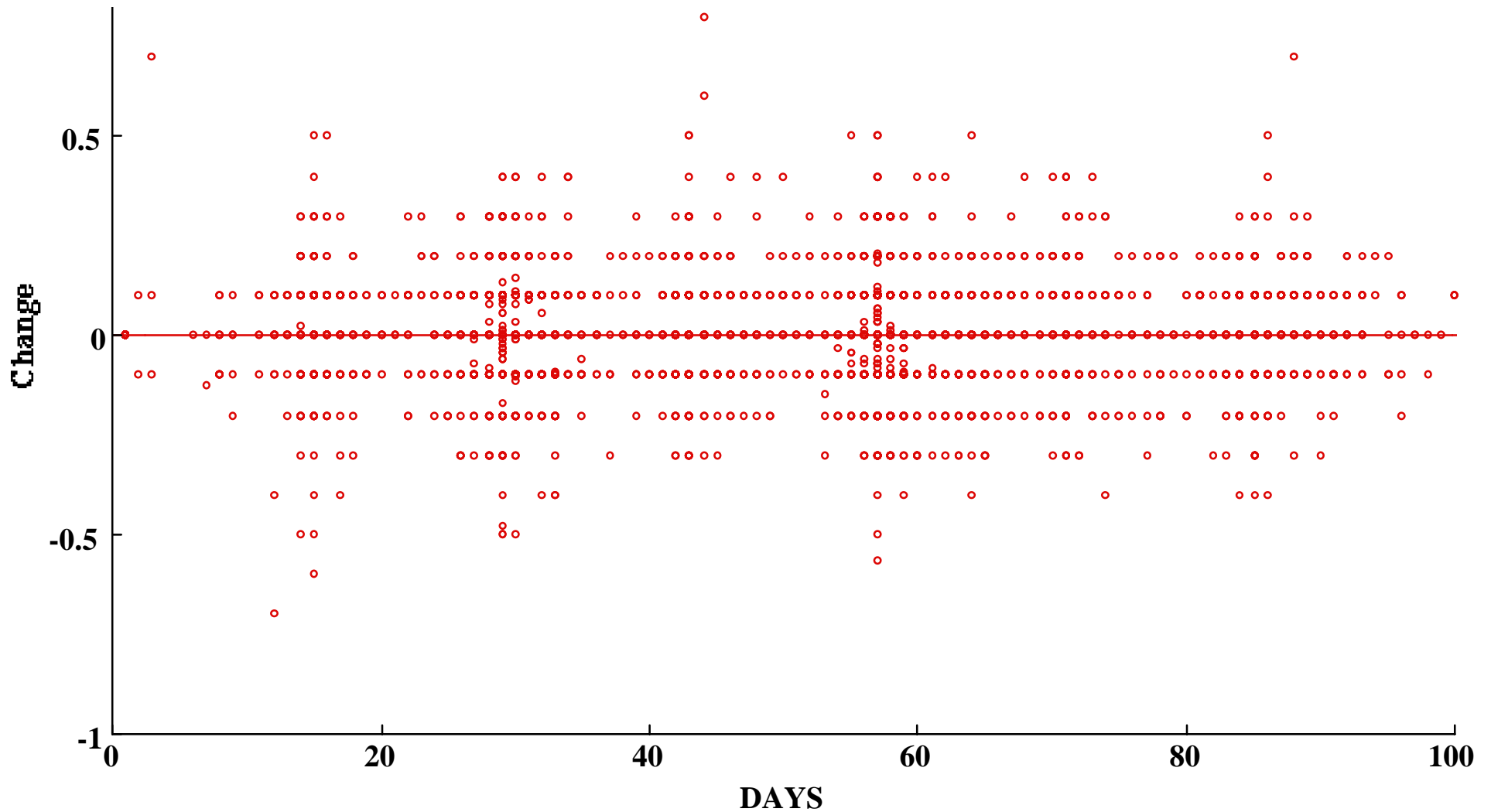
Adverse Events by Body System- Data From Placebo-Controlled Clinical Trials.



● Placebo, n=799    ■ Drug, n=1730

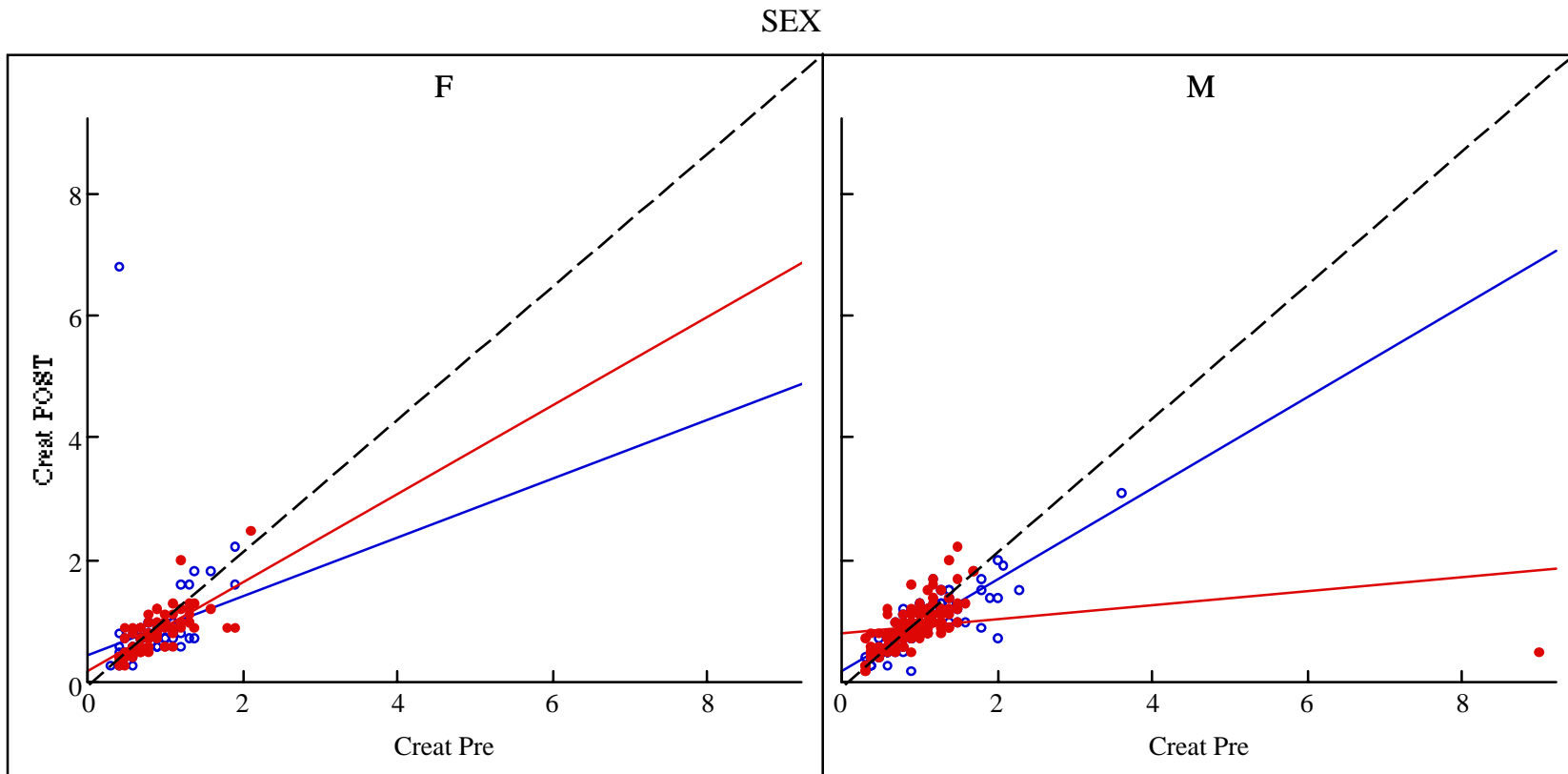
# Change From Baseline Over Time.

Red line is the regression line.

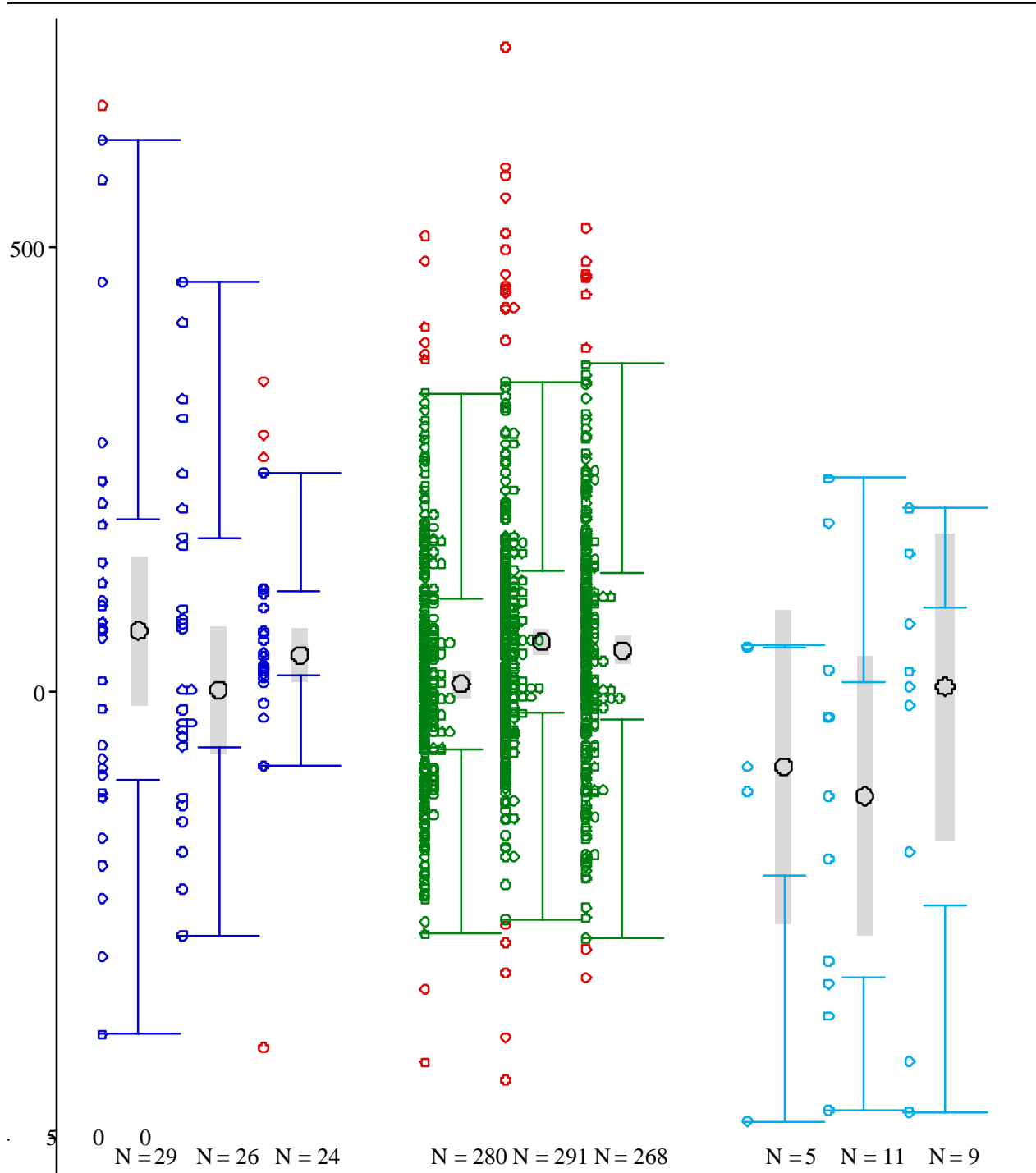


# Scatterplots and 45° lines

Scatter Plot: x=Creat Pre, y=Creat POST  
Inner Variable= TREATMNT Row Variable= SEX  
Data File: FDASmallobese.bin  
No filter is being used.

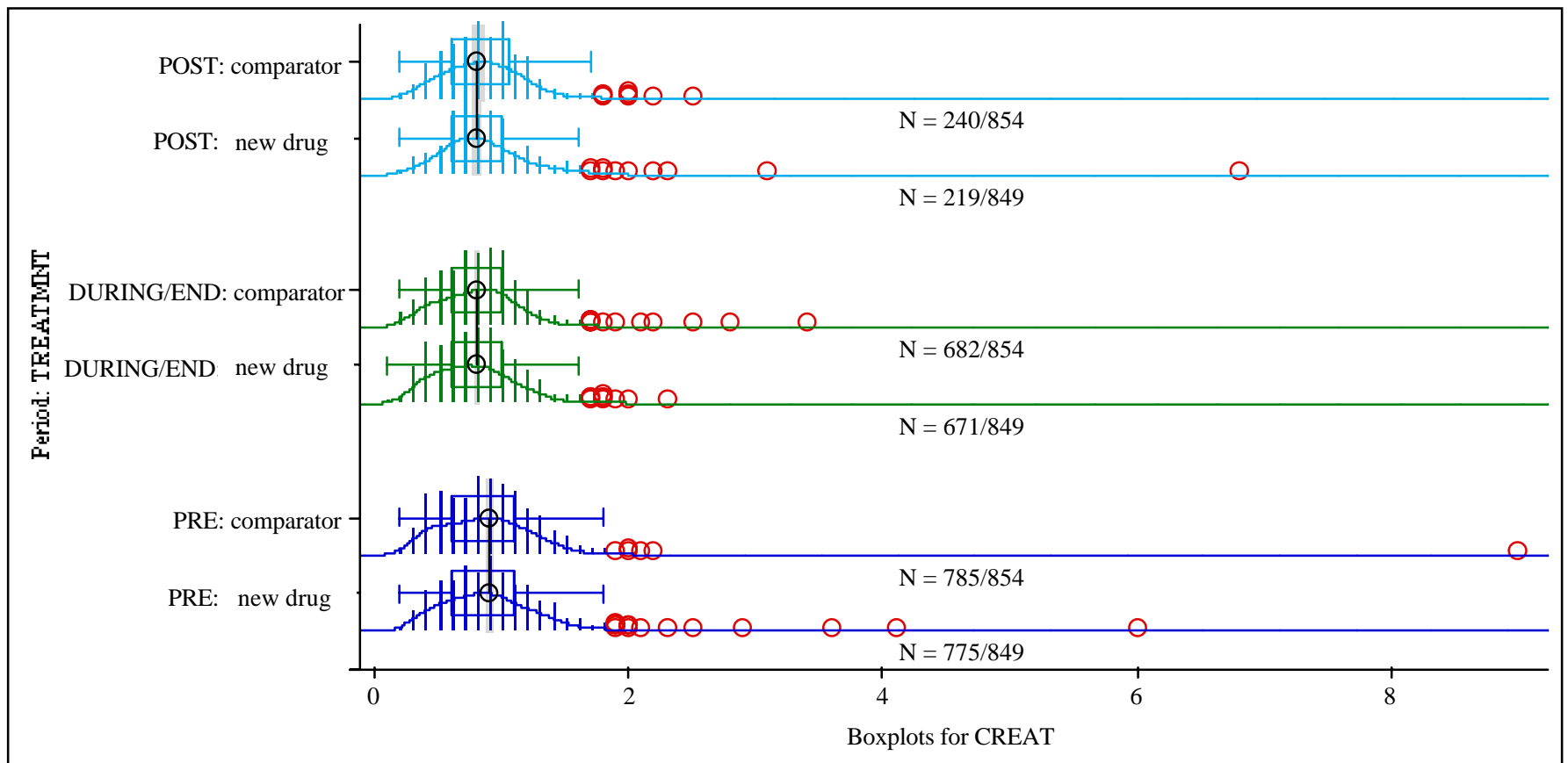


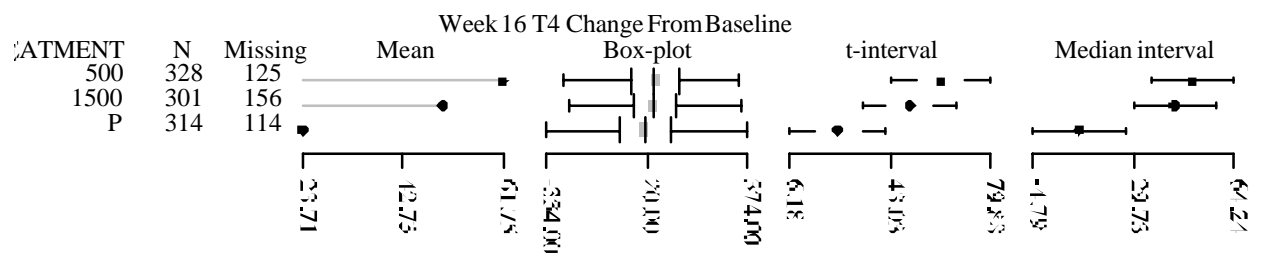
TREATMNT:  
—○— new drug  
—●— comparator



# Enhanced boxplots.

Boxplot and density estimate for CREAT  
Inner variable= Period

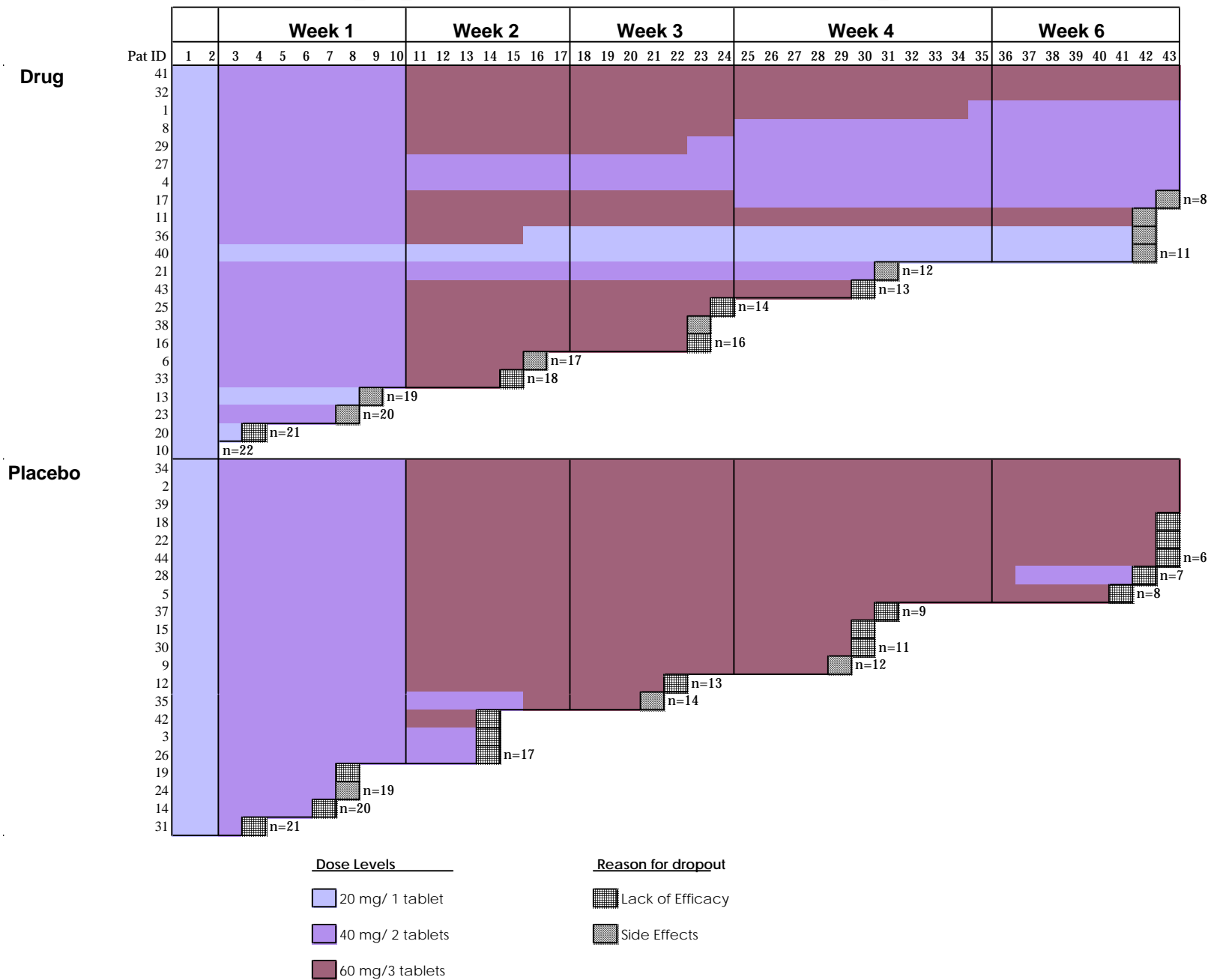




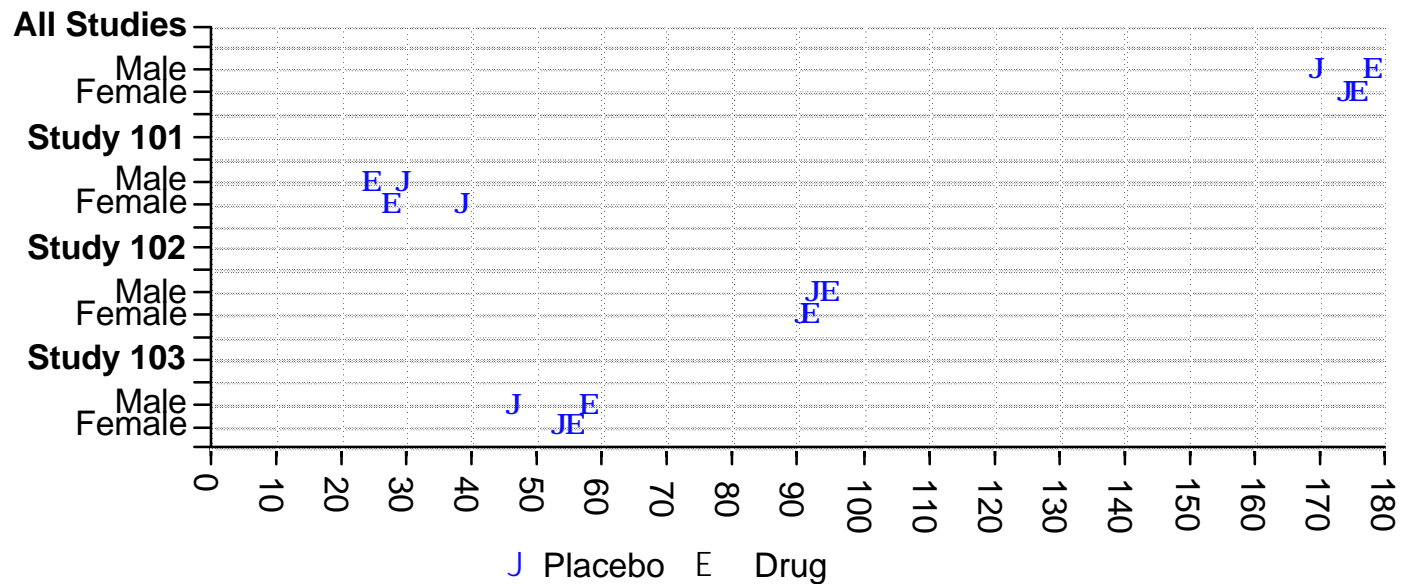
# Tables and graphs can be combined.

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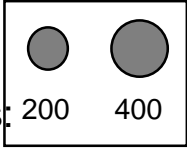
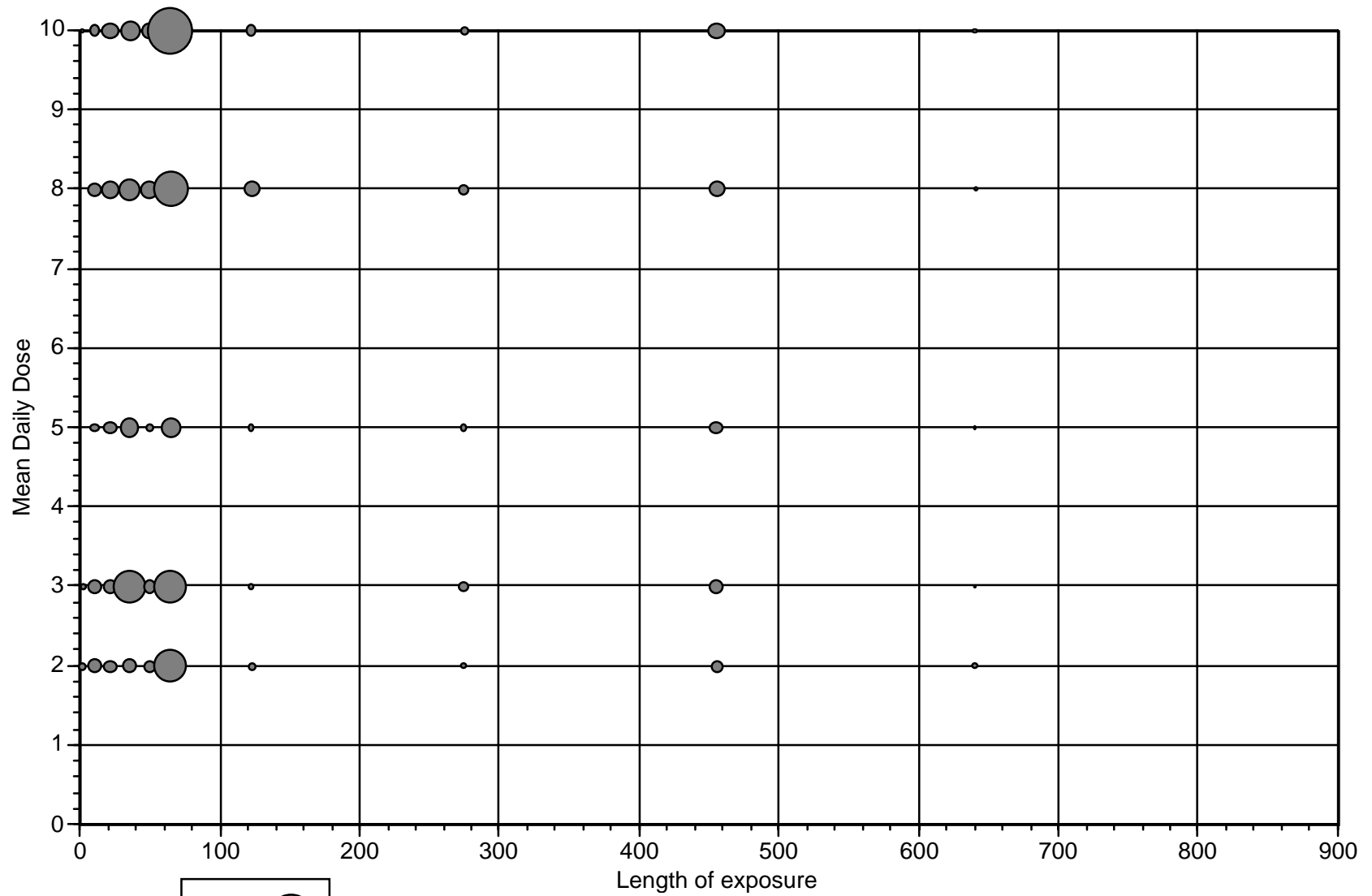
# What happened to the patients?



# What types of patients are in the different studies?



Number of patients

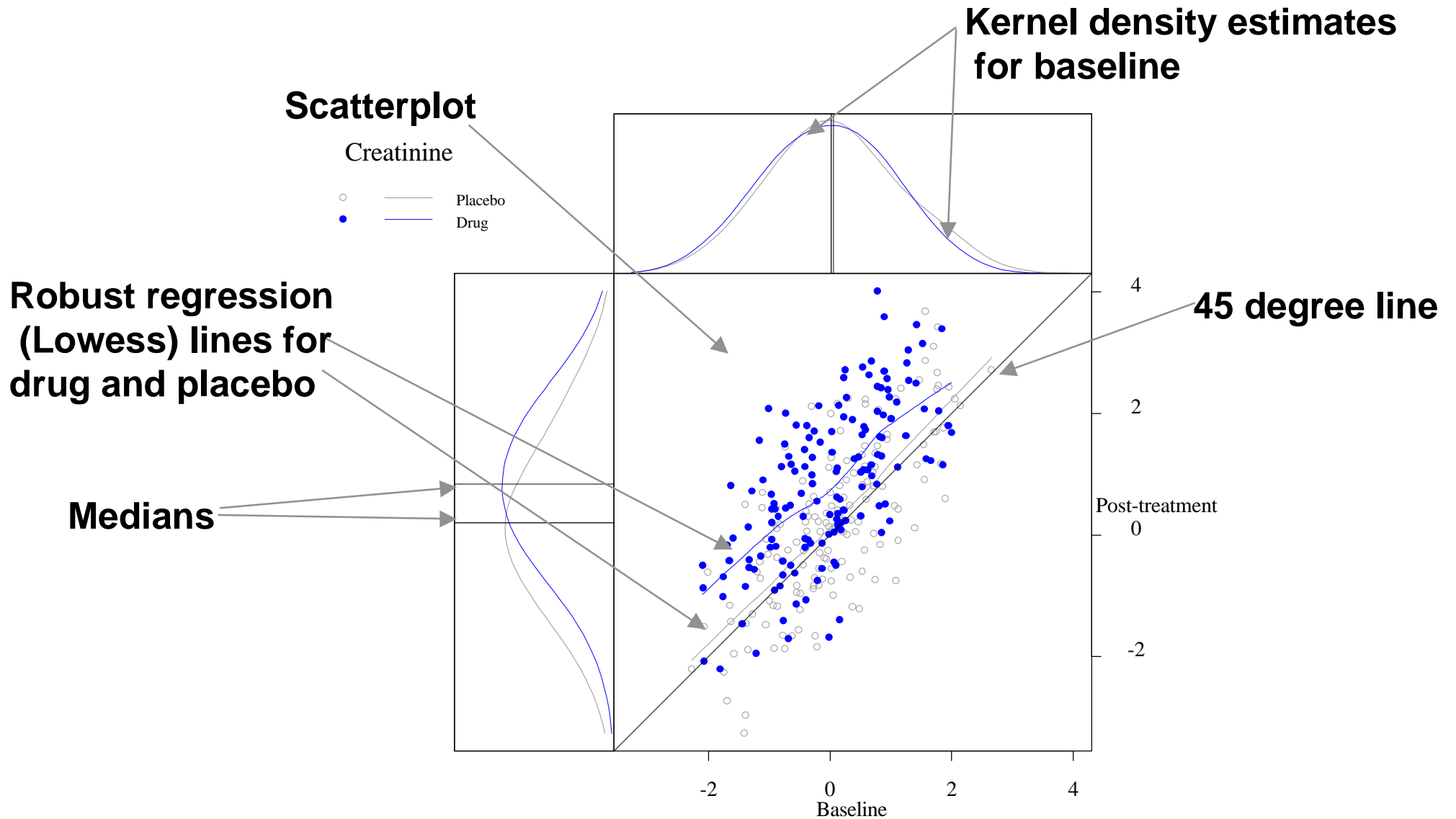


Number of patients:

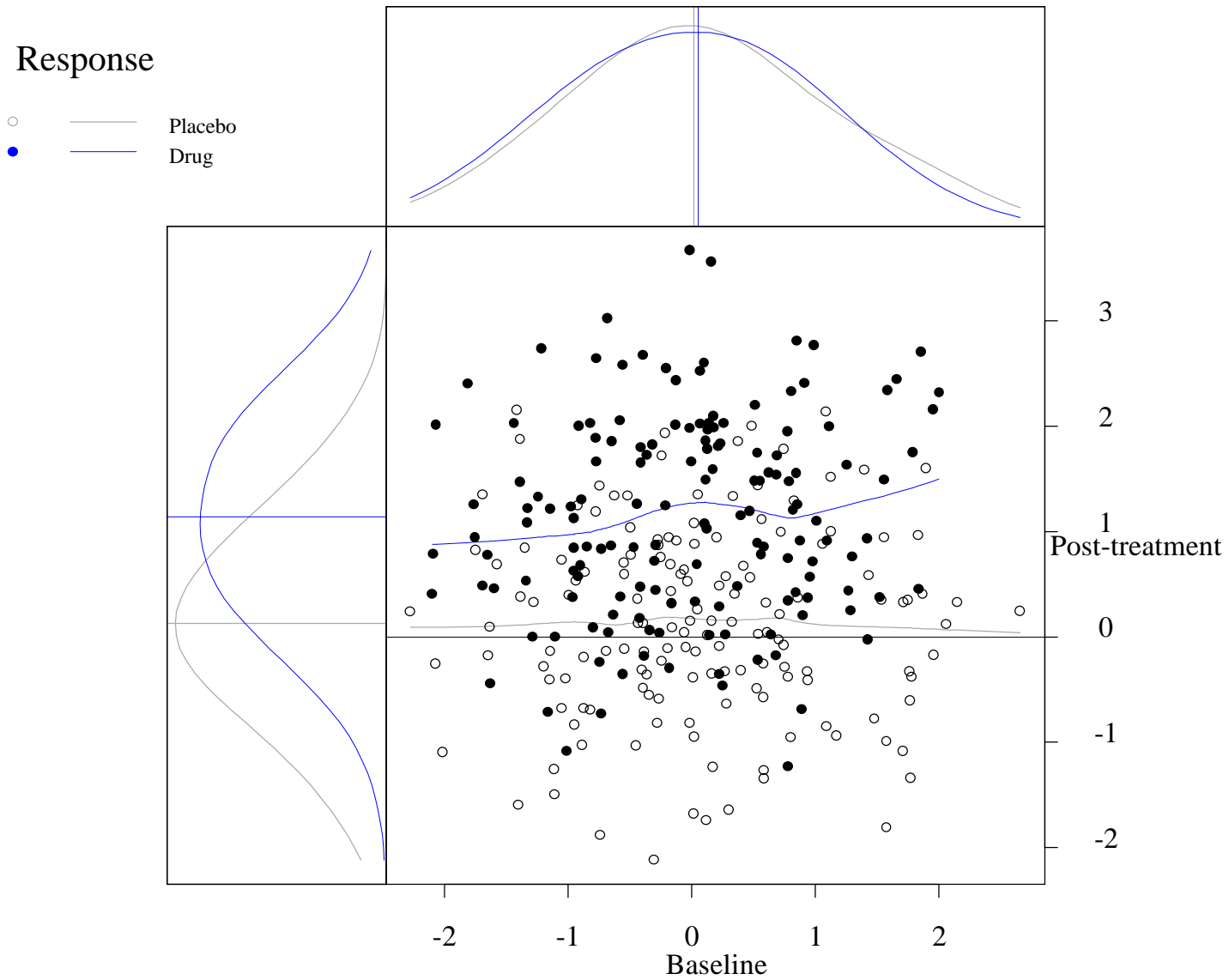
200

400

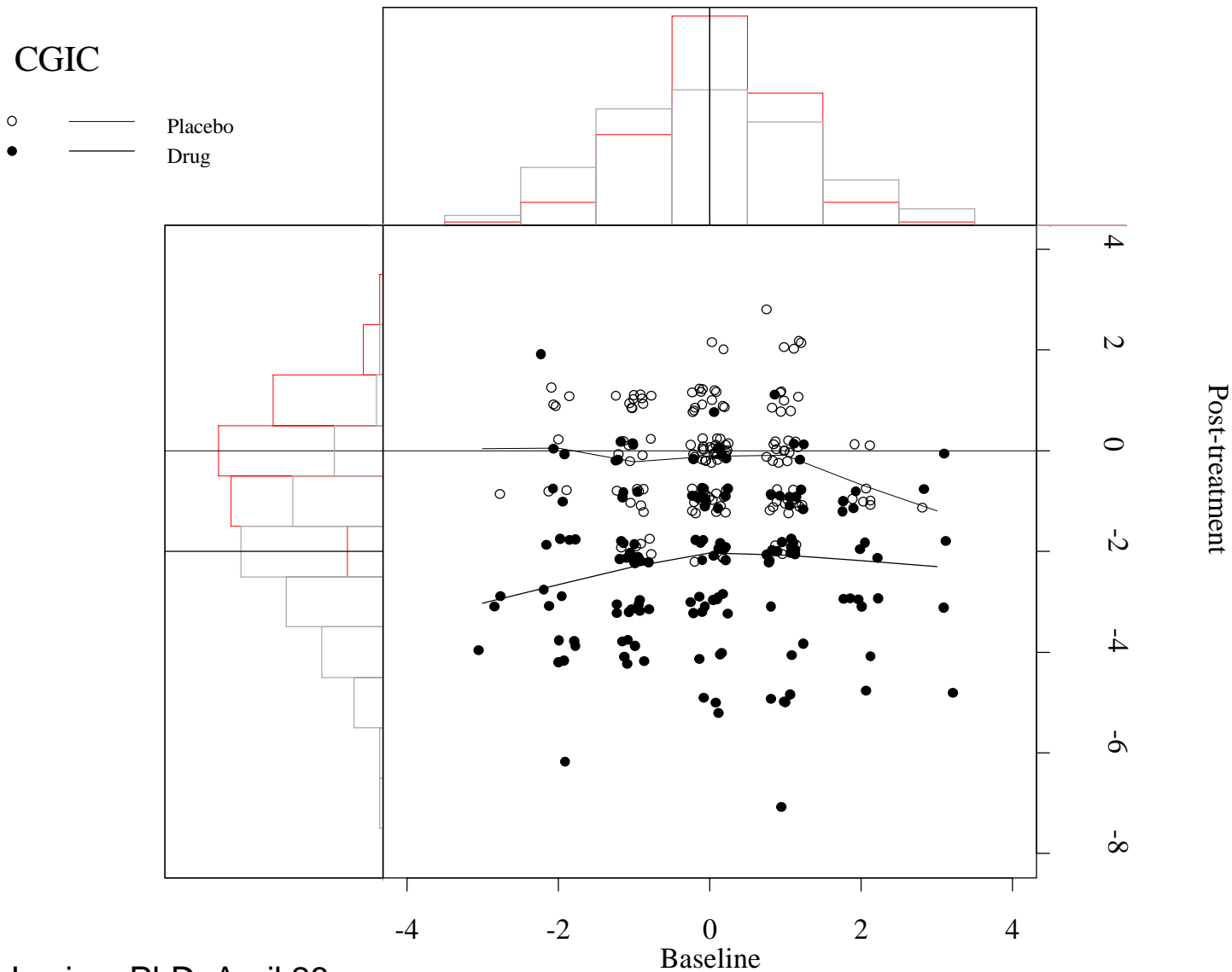
# Scatterplots with lowess lines and marginal density estimates.



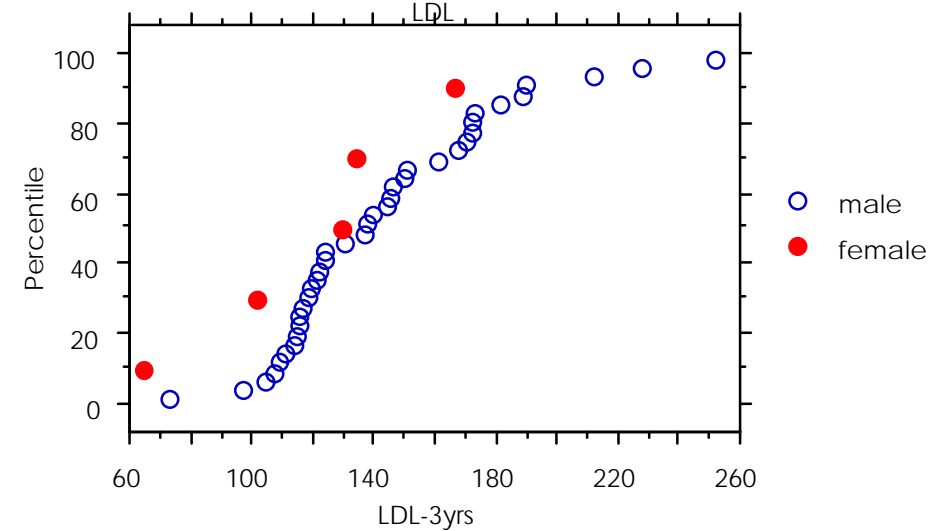
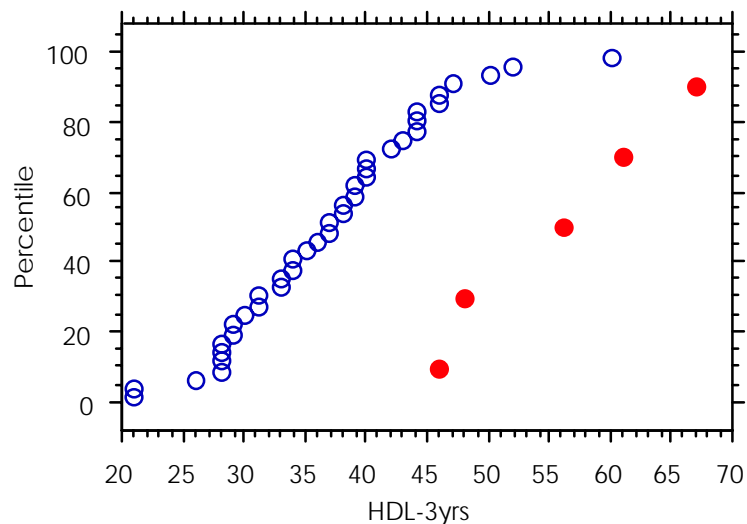
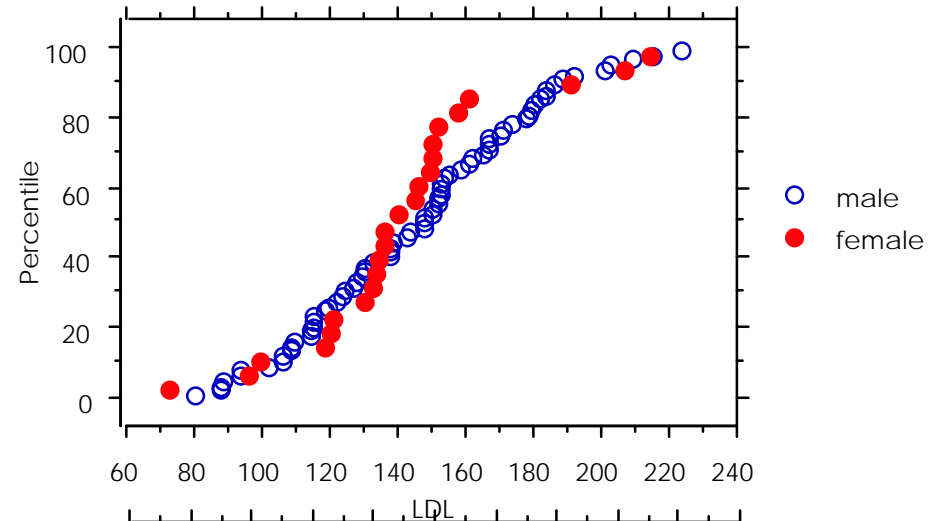
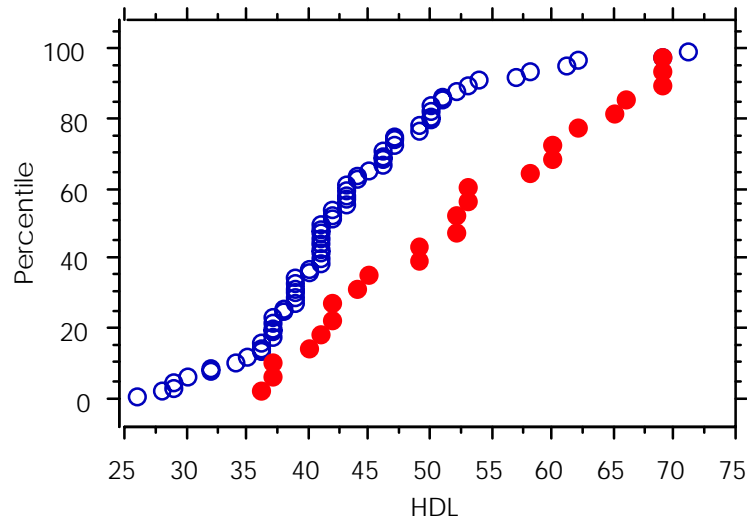
# Is There a Between Treatment Difference?



# Baseline versus Change From Baseline for Discrete Data. Plotted Points are Jittered.



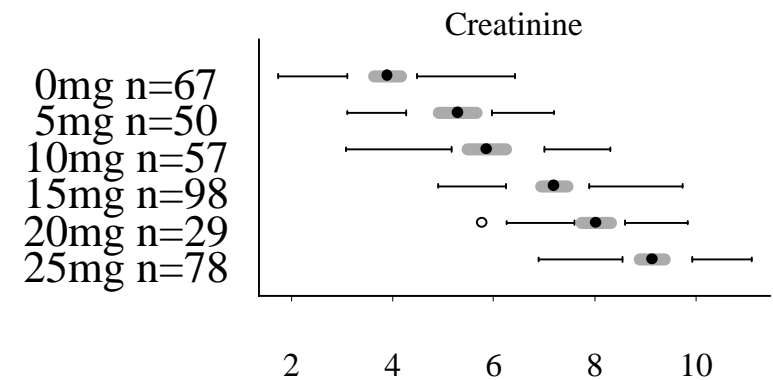
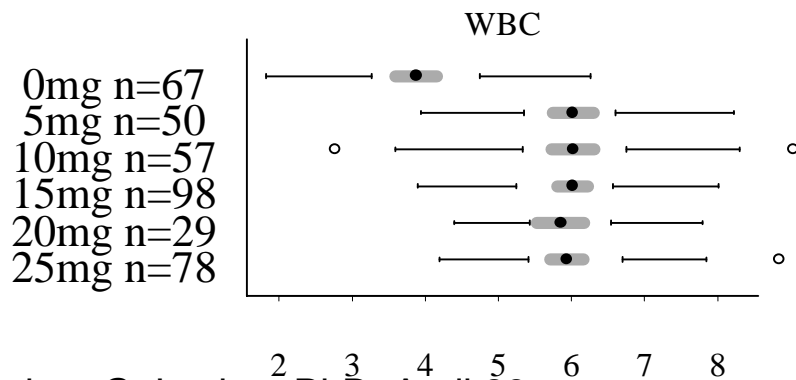
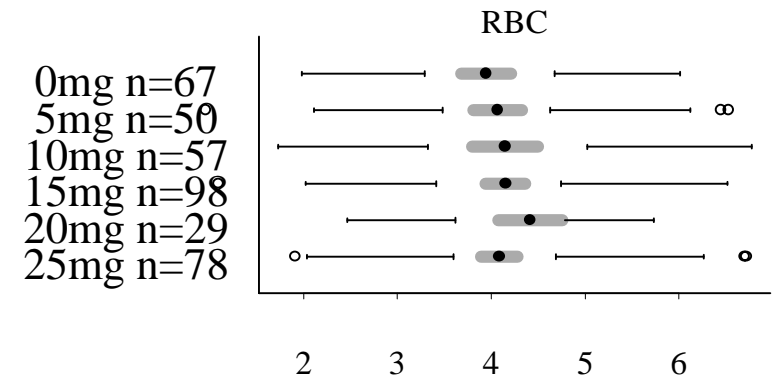
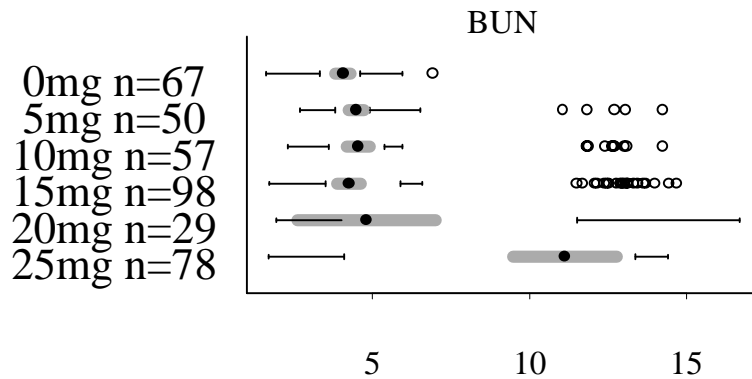
# Are the distributions of subgroup responses the same?



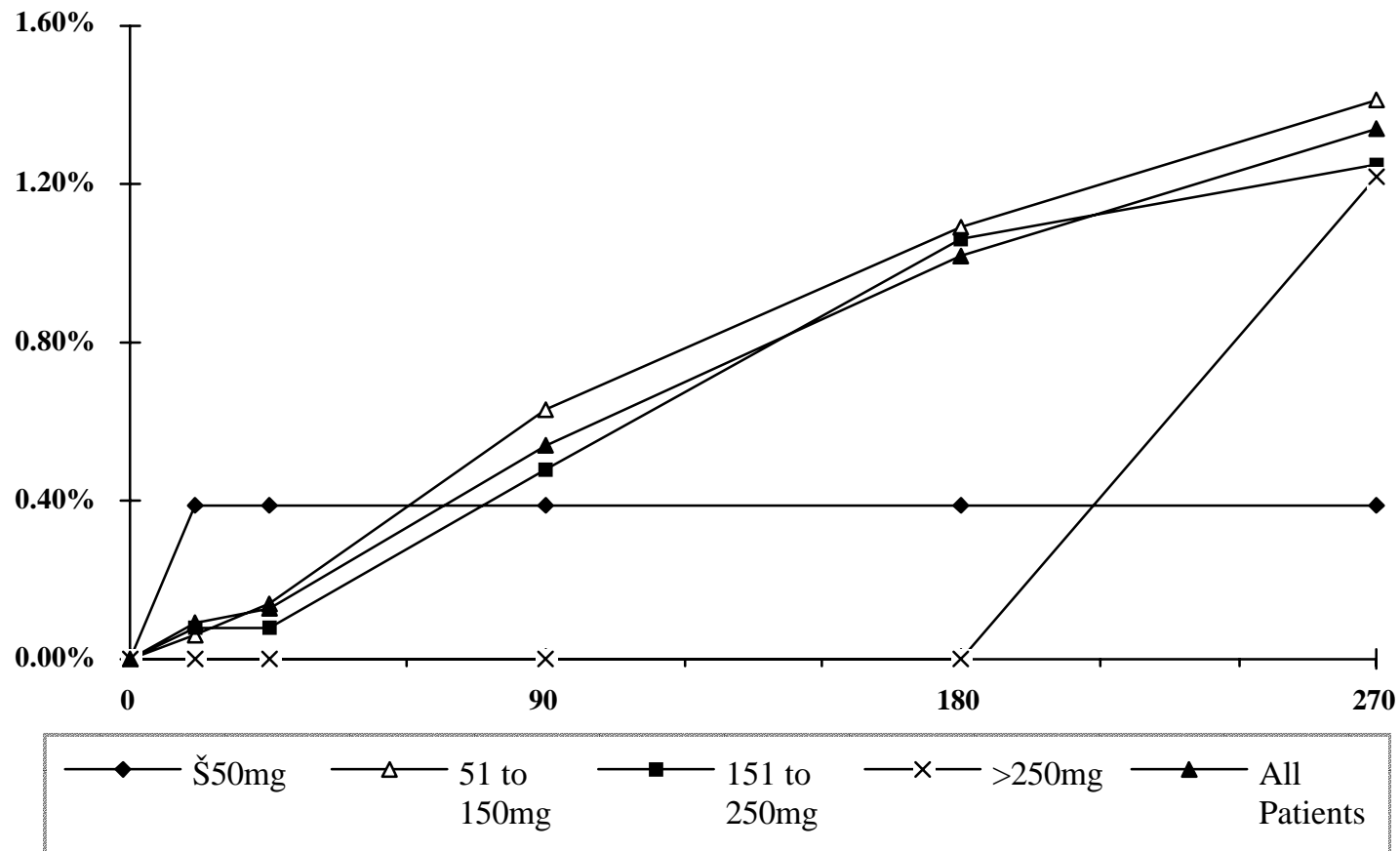
# What was Measured?

		Study Day								
		25mg Rx bid								
		12.5mg Rx bid								
		6.5mg Rx bid								
		P bid								
		Screen	.....							
		-7	0	7	14	21	28	35	42	Poststudy
Medical and Psychiatric History		•								
Patient Orientation		•								
Recording of Concomitant Medications			•	•	•	•	•		•	•
Completion of Dosage Record			•	•	•	•	•		•	•
<b>Efficacy Determinations</b>										
		-7	0	7	14	21	28	35	42	Poststudy
Ham-D		•	•	•	•	•	•		•	
MADRS		•	•	•	•	•	•		•	
CGI		•	•	•	•	•	•		•	
SCL-61			•			•			•	
Quality of Life Questionnaire			•						•	
Investigator's Subjective Rating									•	
Patient's Subjective Rating									•	
<b>Safety Determinations</b>										
		-7	0	7	14	21	28	35	42	Poststudy
Supine Pulse		•	•	•	•	•	•		•	•
Supine and Standing Blood Pressure		•	•	•	•	•	•		•	•
Weight		•	•	•	•	•	•		•	•
Hematology		•							•	•
Blood Chemistry		•							•	•
Urinalysis		•							•	•
Free Thyroxine Index		•								
Urine Drug Test		•								
Urine Pregnancy Test		•								
ECG		•							•	
Recording of Study Events			•	•	•	•	•		•	•

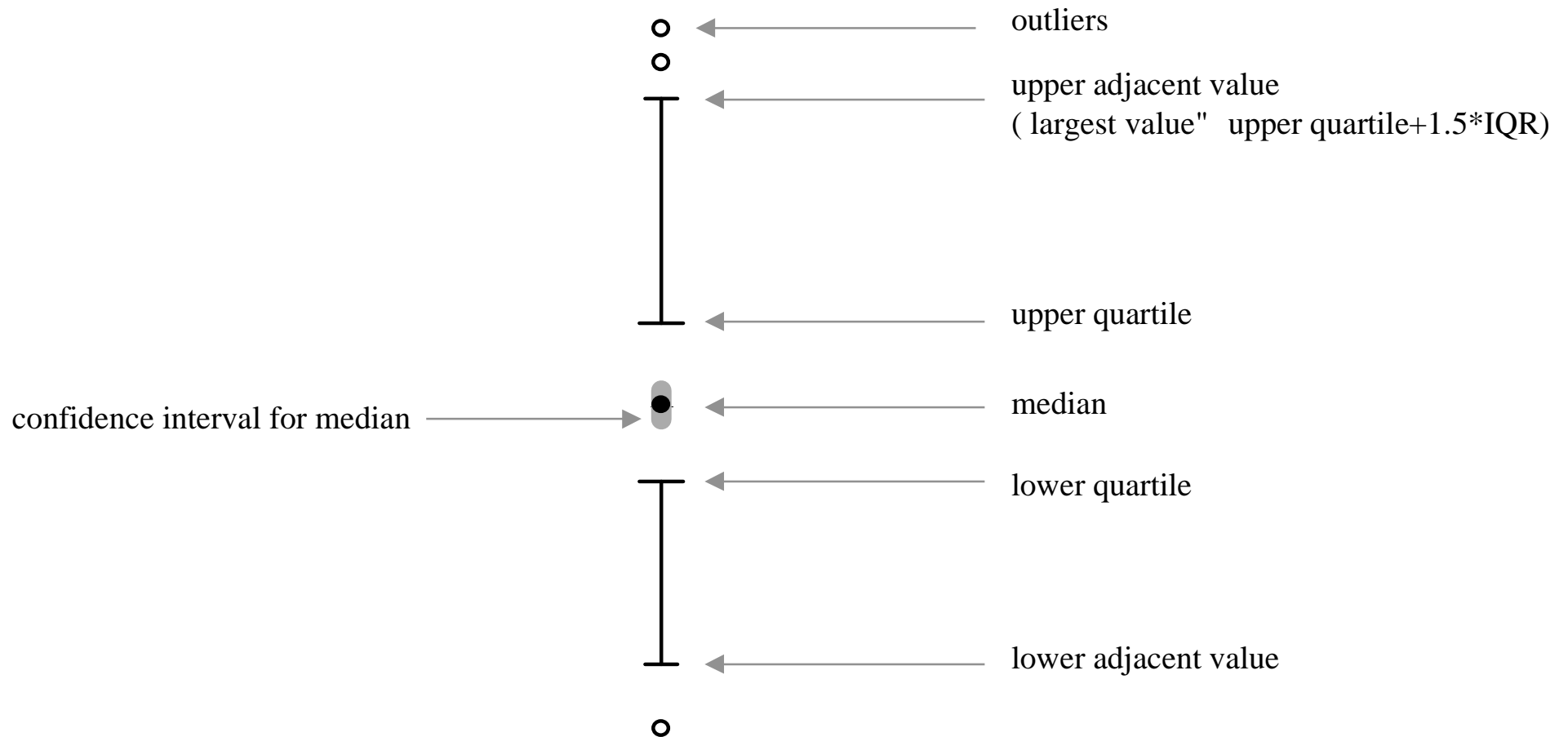
# Are the Values Comparable In the Dose Groups?



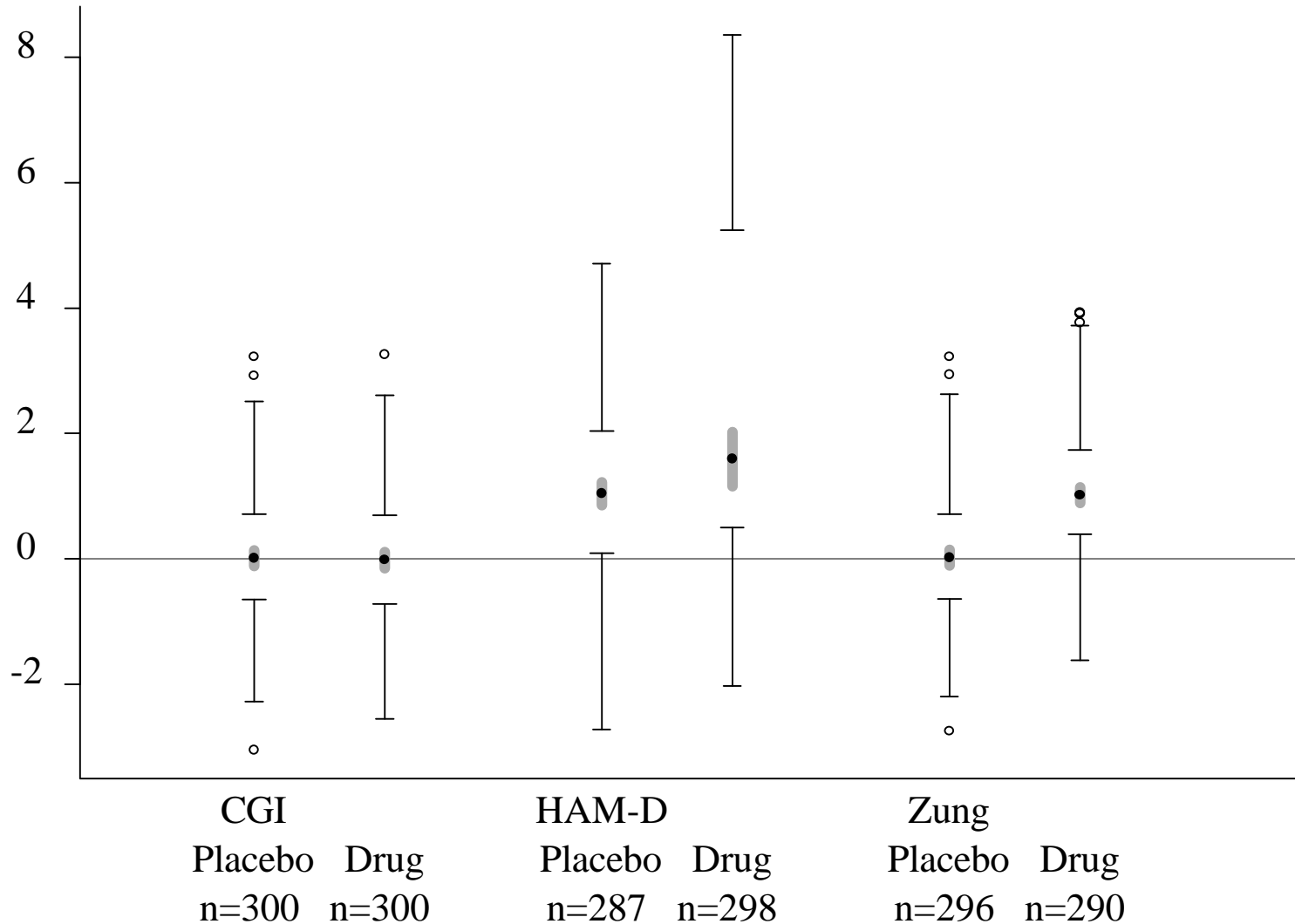
# Are the crude adverse event rates different from the life table rates?



# Boxplot (Tukey, 1977, Revised by Levine)



# Comparing Drug and Placebo for Several Variables.



# Comparing Subgroup Differences.

Gaps represent standard errors.

