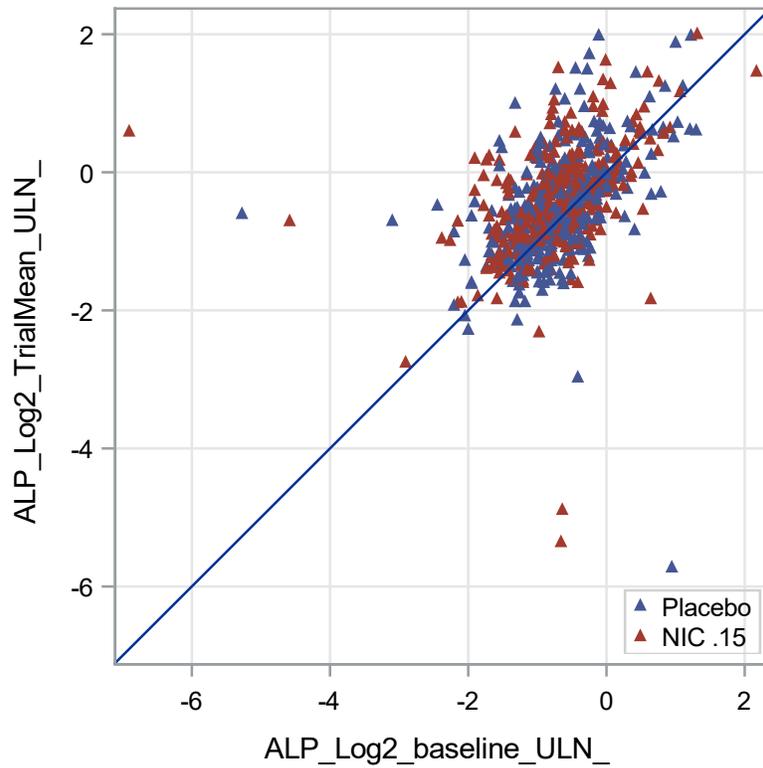


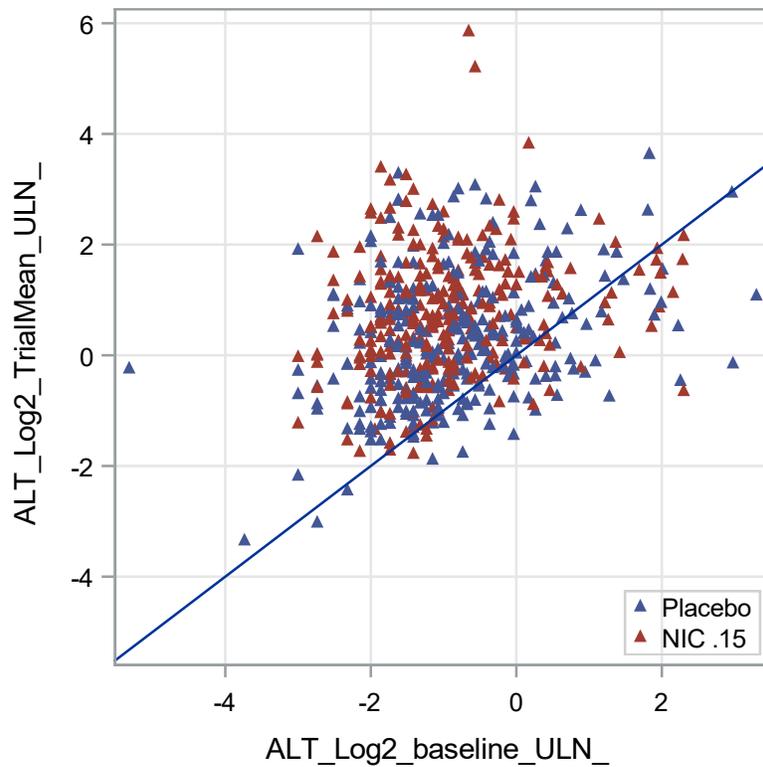
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

Trial Mean as finding measurements, ULN Normalization , log2 Transformation
ALP Shift Plots Trial Mean vs Baseline



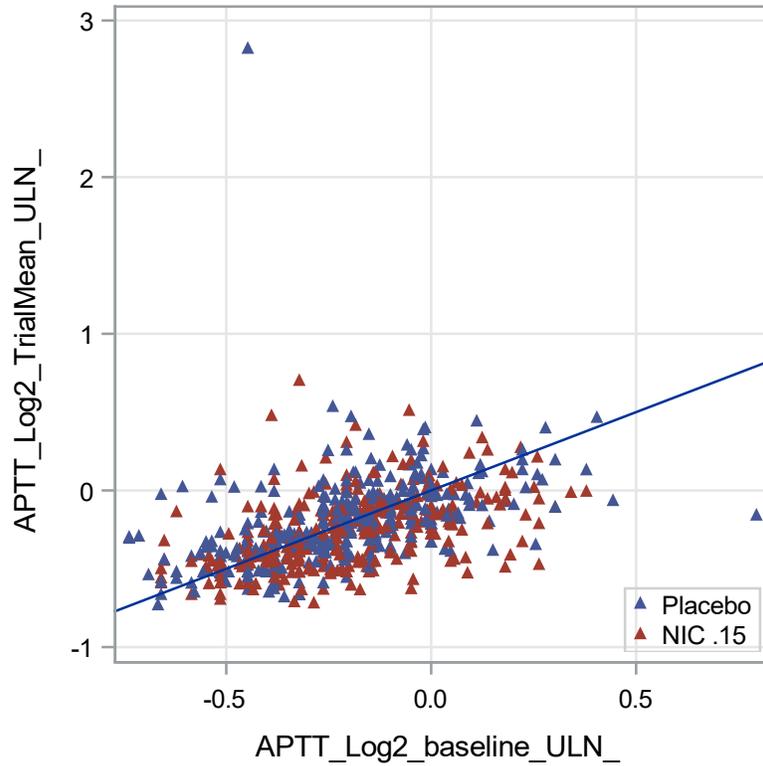
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

Trial Mean as finding measurements, ULN Normalization , log2 Transformation
ALT Shift Plots Trial Mean vs Baseline



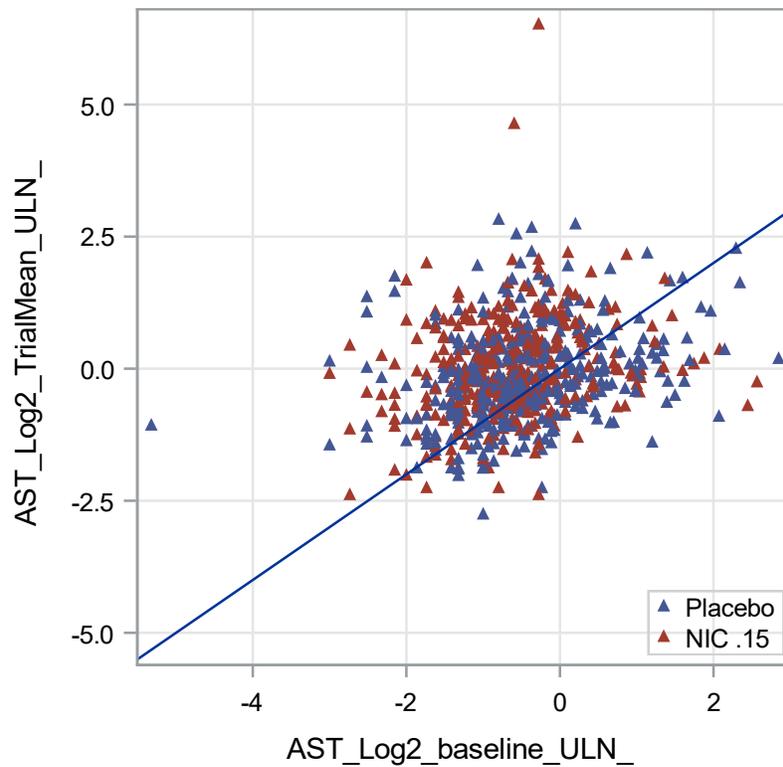
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
APTT Shift Plots Trial Mean vs Baseline**



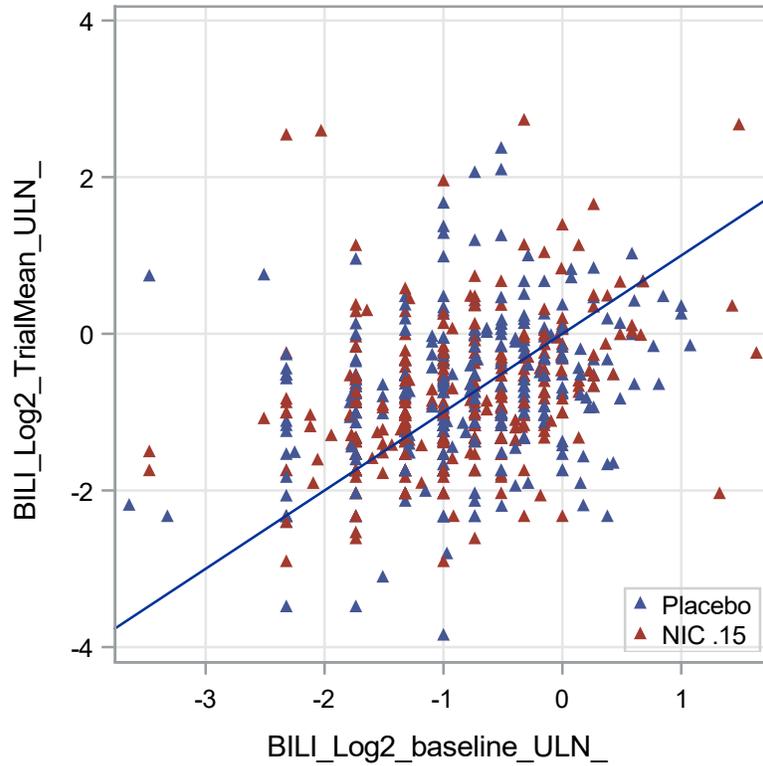
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
AST Shift Plots Trial Mean vs Baseline**



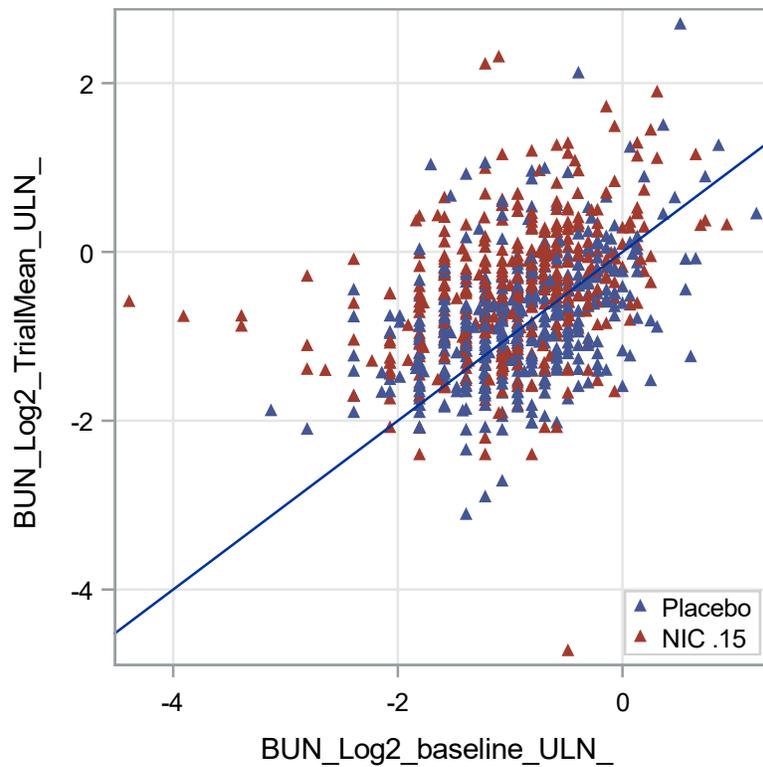
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
BILI Shift Plots Trial Mean vs Baseline**



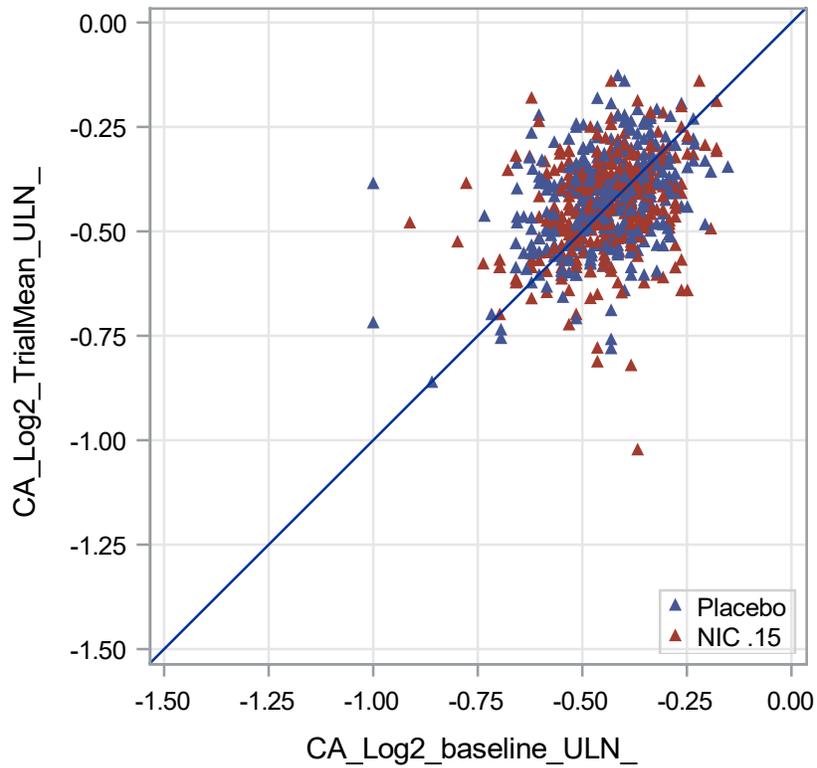
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
BUN Shift Plots Trial Mean vs Baseline**



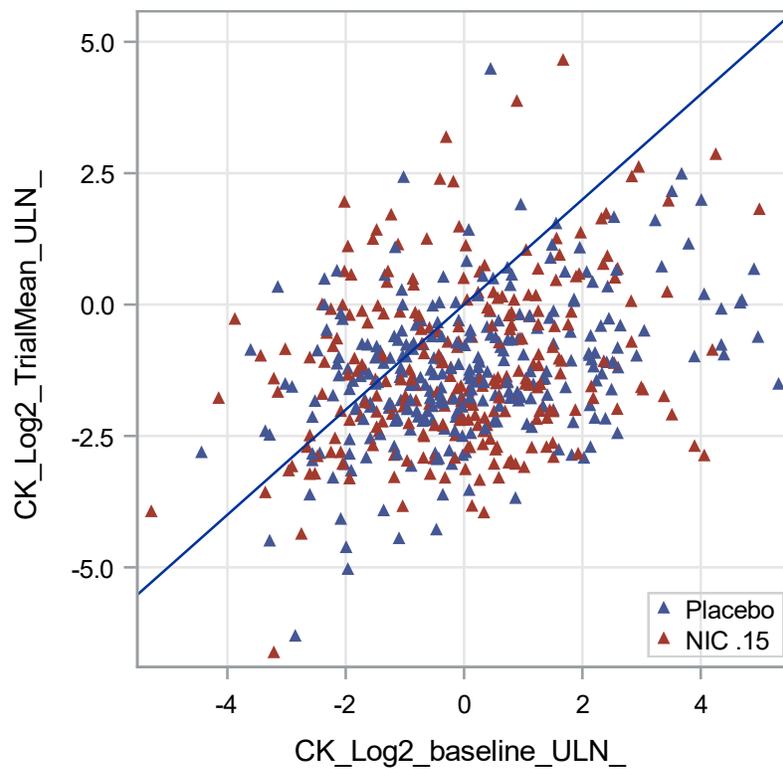
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
CA Shift Plots Trial Mean vs Baseline**



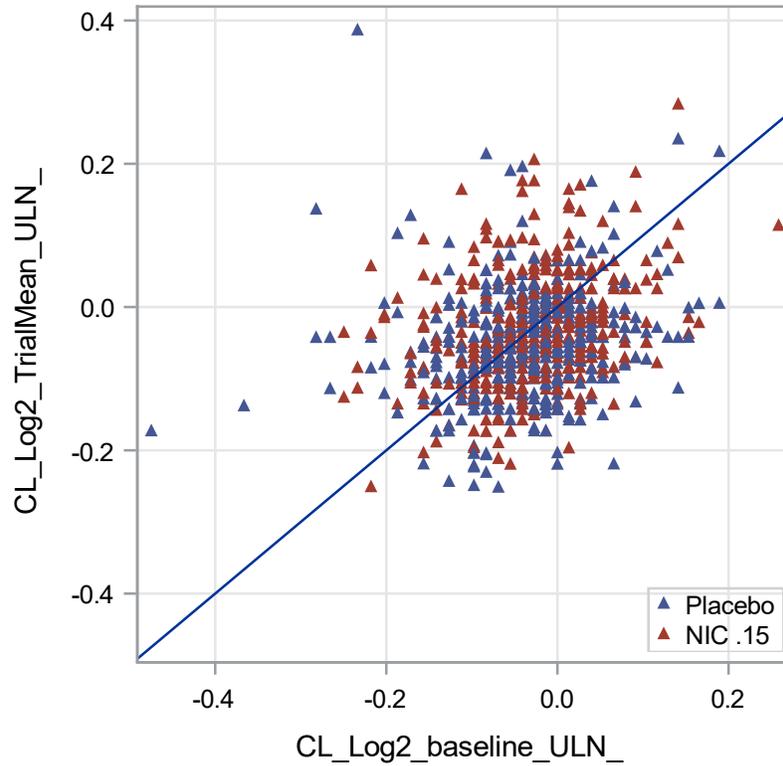
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
CK Shift Plots Trial Mean vs Baseline**



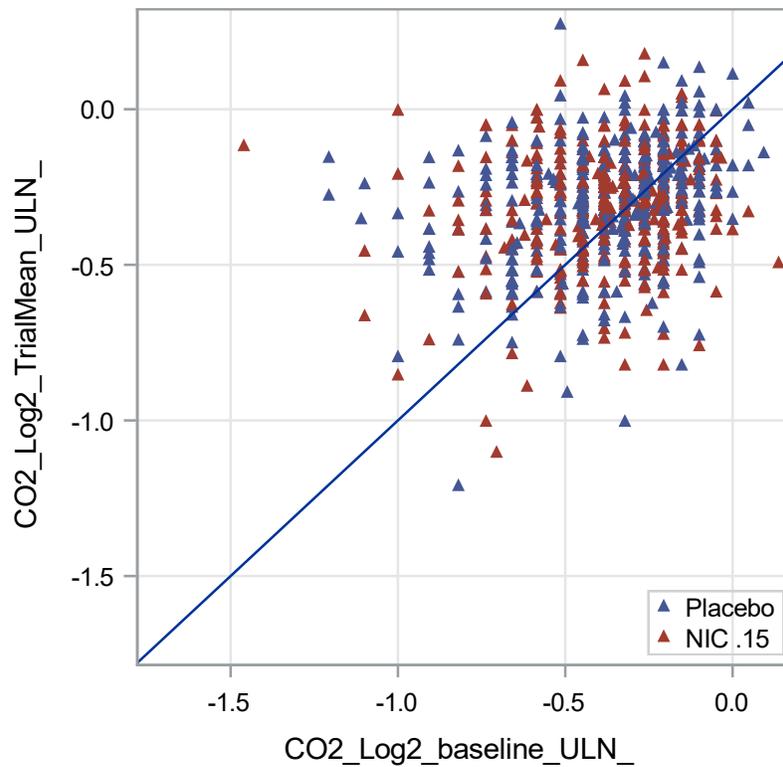
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
CL Shift Plots Trial Mean vs Baseline**



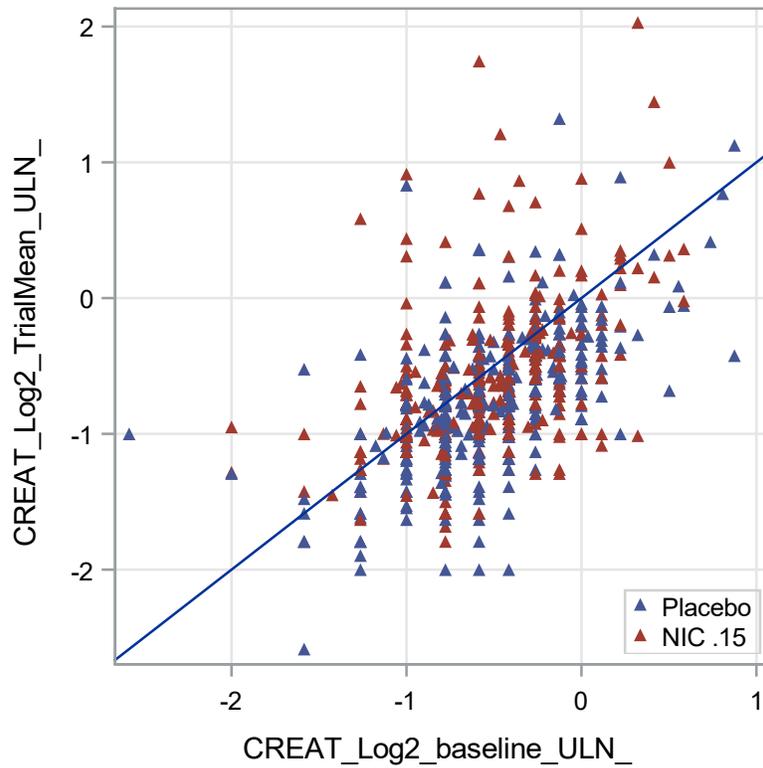
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
CO2 Shift Plots Trial Mean vs Baseline**



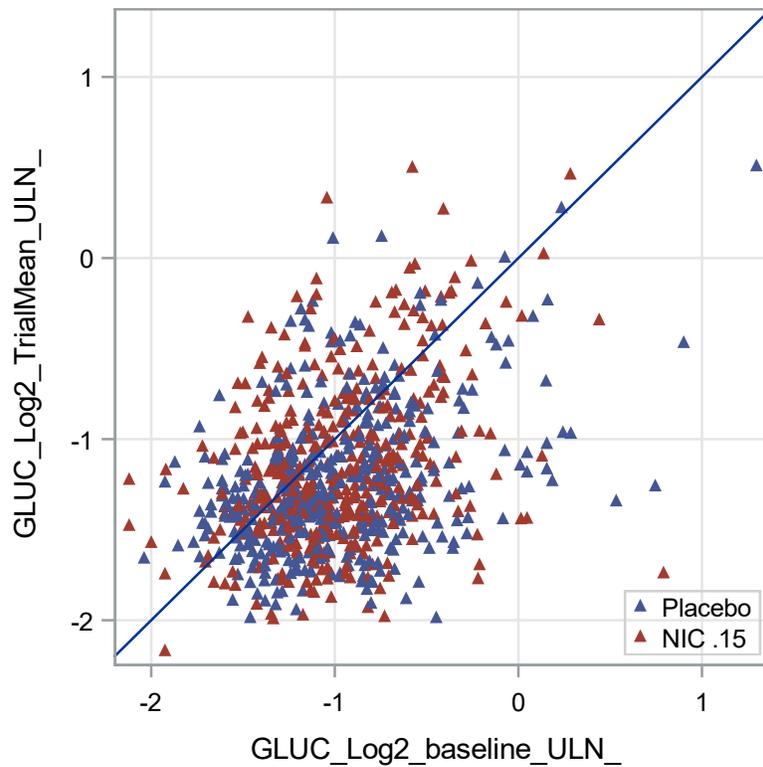
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

Trial Mean as finding measurements, ULN Normalization , log2 Transformation
CREAT Shift Plots Trial Mean vs Baseline



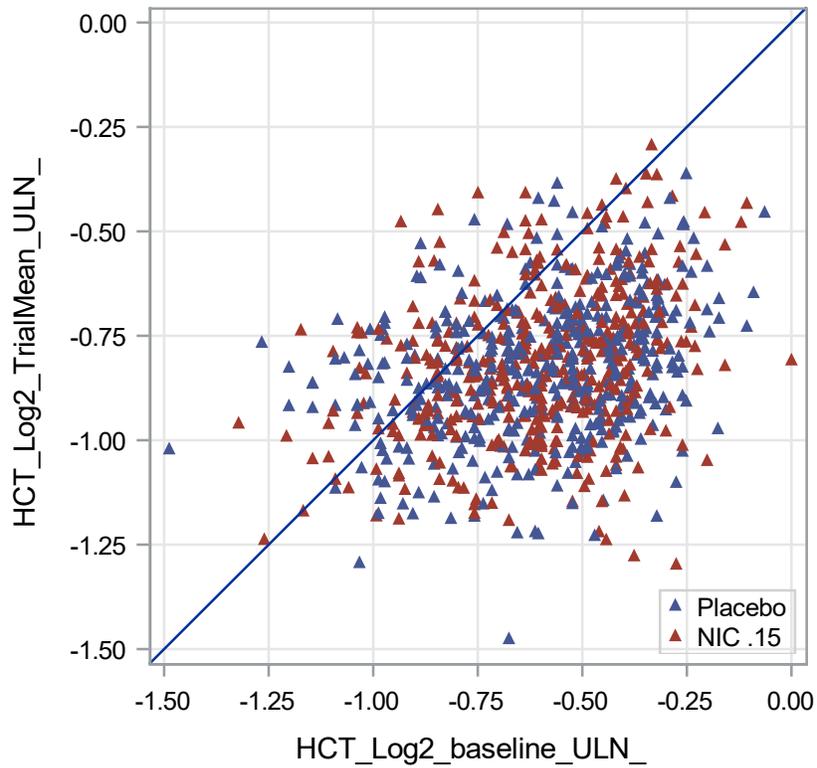
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

Trial Mean as finding measurements, ULN Normalization , log2 Transformation
GLUC Shift Plots Trial Mean vs Baseline



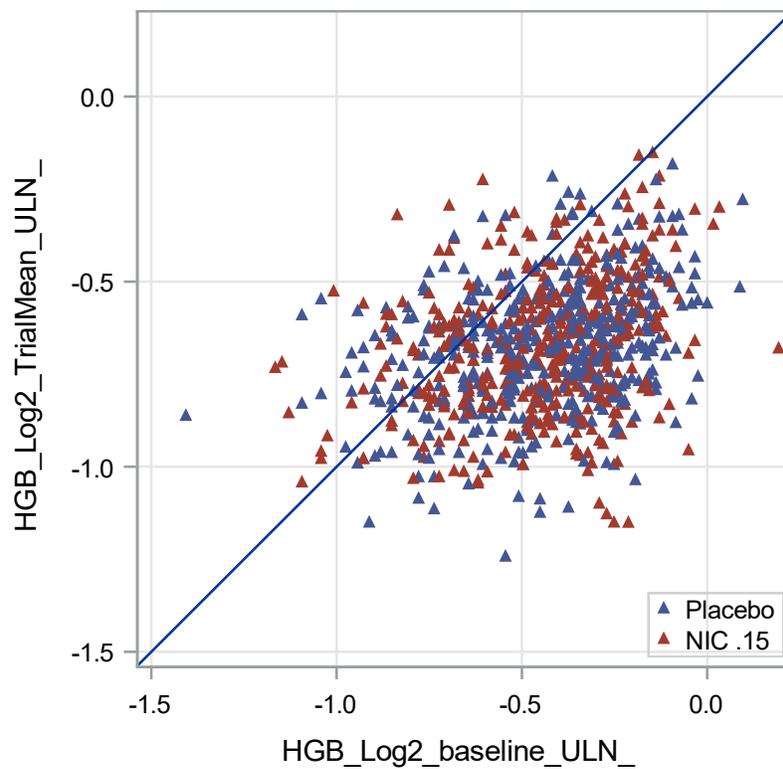
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
HCT Shift Plots Trial Mean vs Baseline**



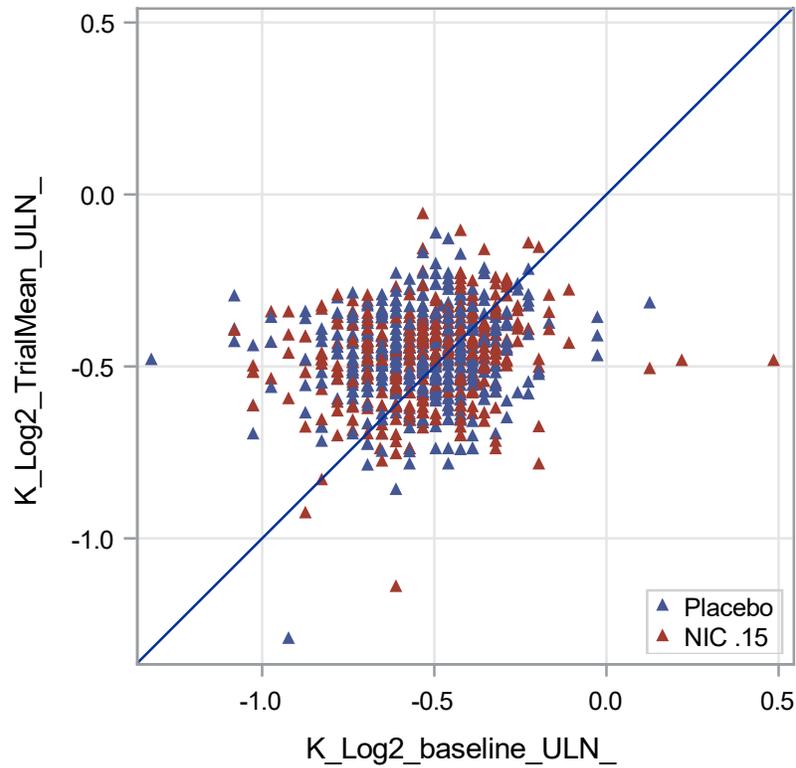
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
HGB Shift Plots Trial Mean vs Baseline**



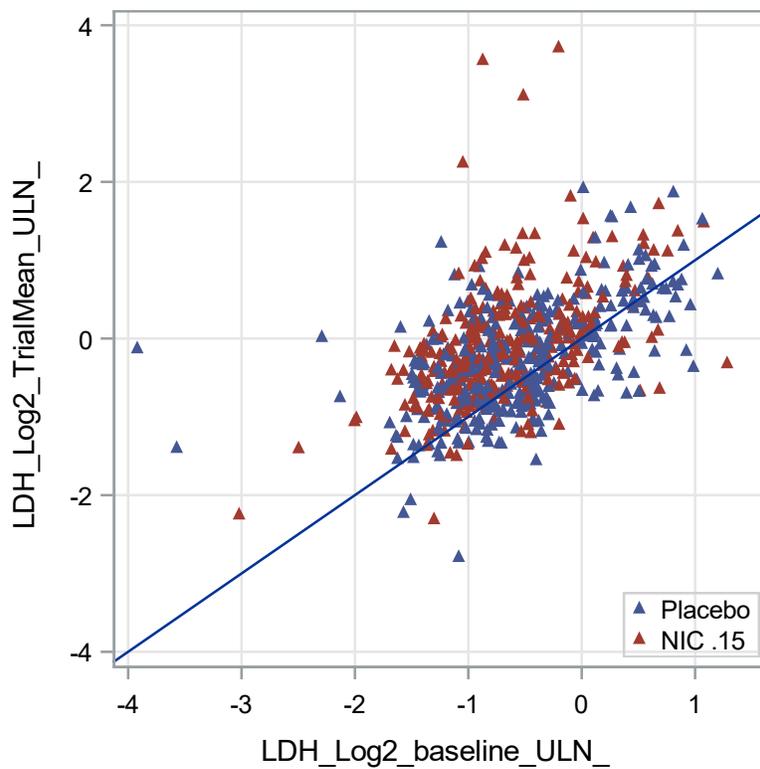
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
K Shift Plots Trial Mean vs Baseline**



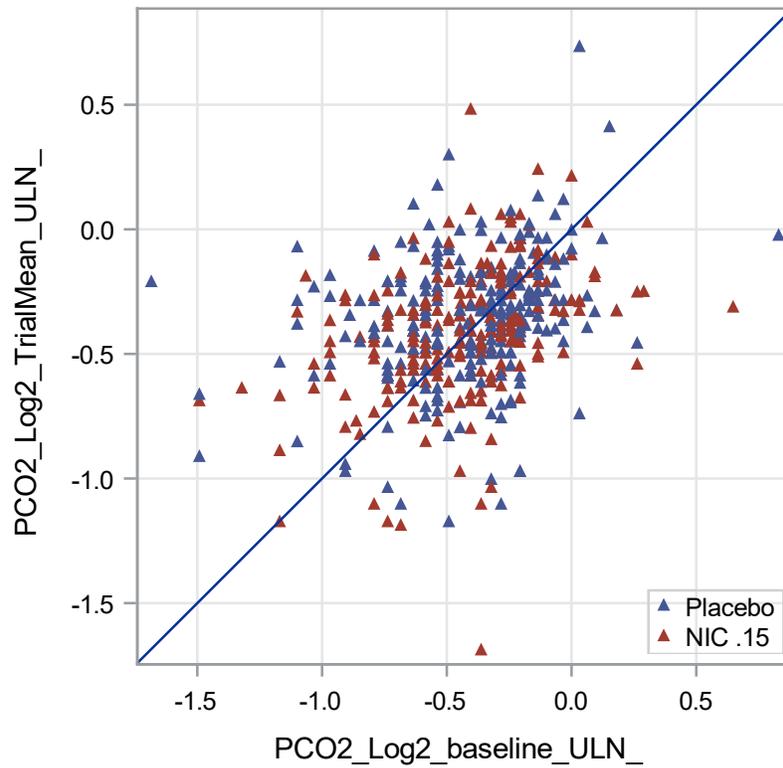
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
LDH Shift Plots Trial Mean vs Baseline**



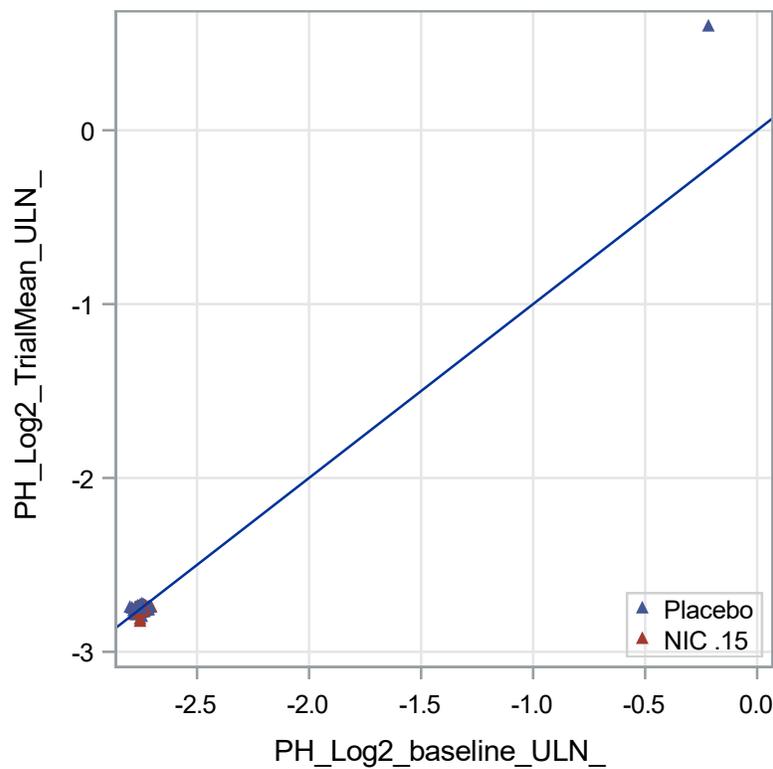
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
PCO2 Shift Plots Trial Mean vs Baseline**



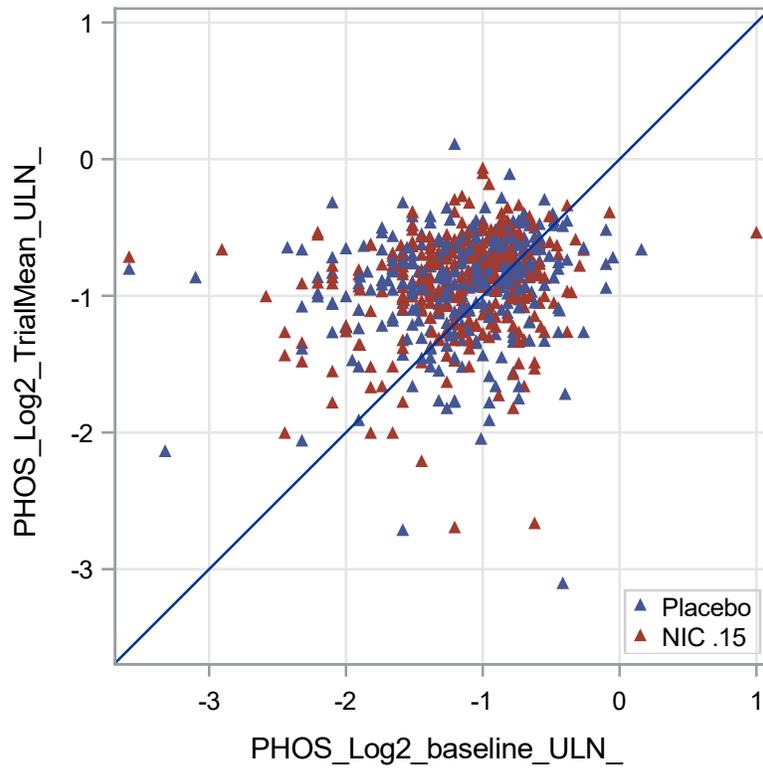
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
PH Shift Plots Trial Mean vs Baseline**



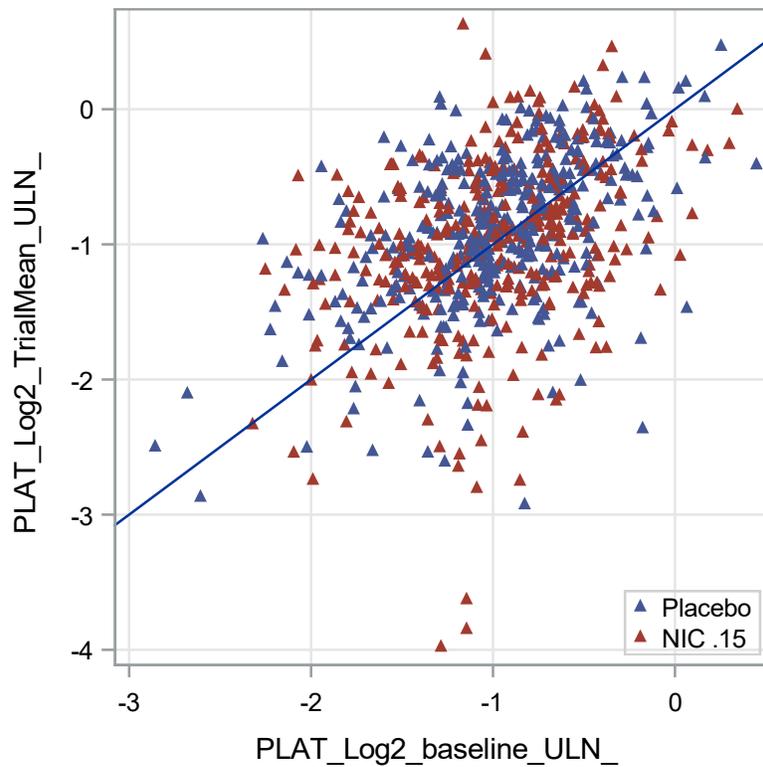
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

Trial Mean as finding measurements, ULN Normalization , log2 Transformation
PHOS Shift Plots Trial Mean vs Baseline



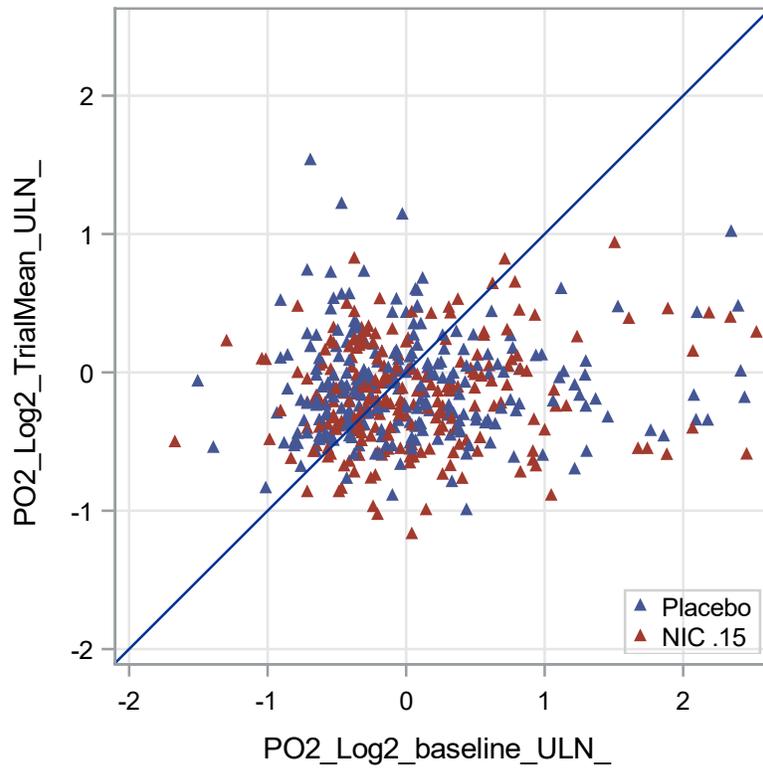
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

Trial Mean as finding measurements, ULN Normalization , log2 Transformation
PLAT Shift Plots Trial Mean vs Baseline



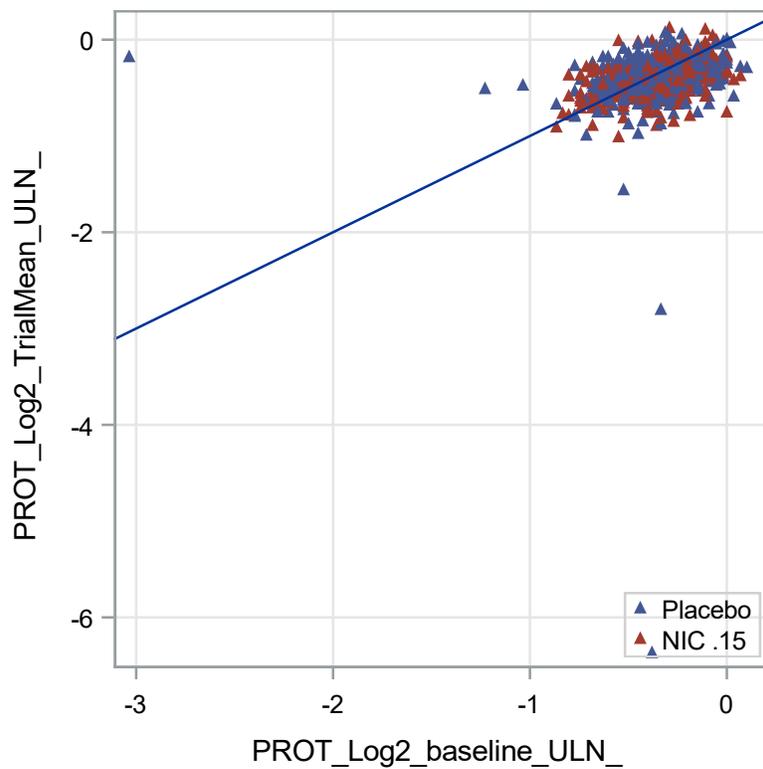
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

Trial Mean as finding measurements, ULN Normalization , log2 Transformation
PO2 Shift Plots Trial Mean vs Baseline



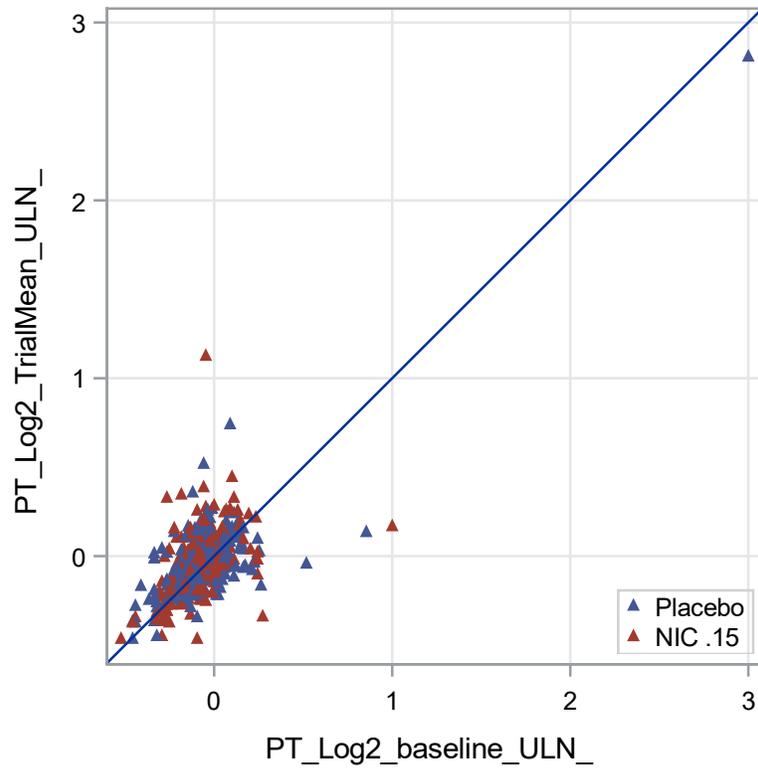
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

Trial Mean as finding measurements, ULN Normalization , log2 Transformation
PROT Shift Plots Trial Mean vs Baseline



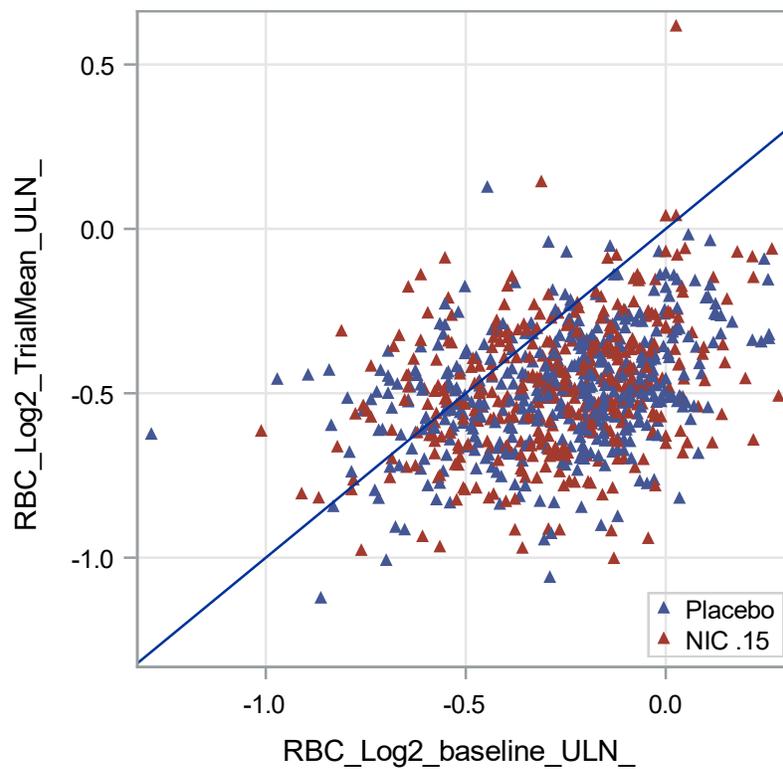
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
PT Shift Plots Trial Mean vs Baseline**



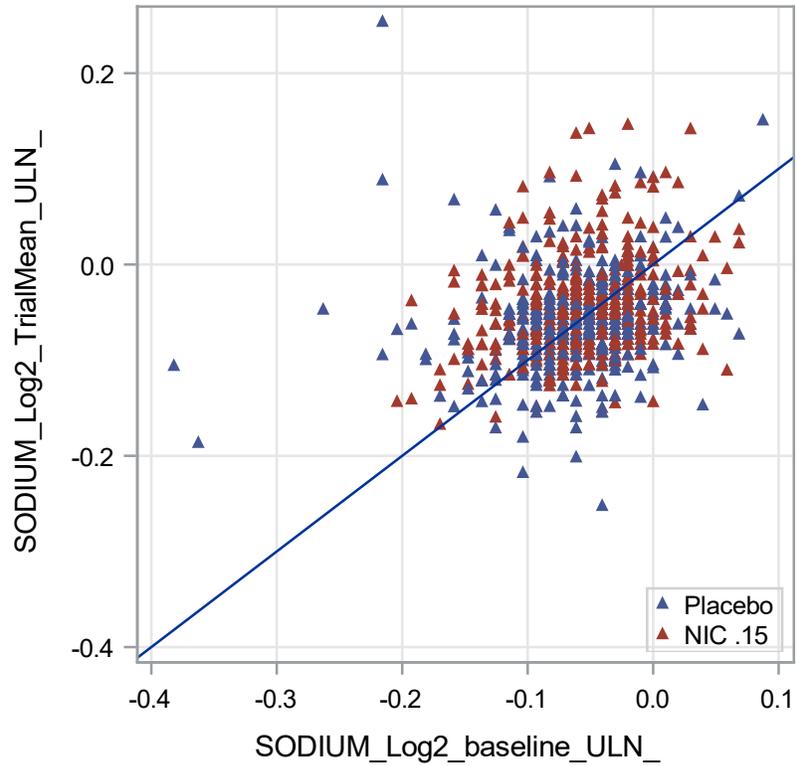
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
RBC Shift Plots Trial Mean vs Baseline**



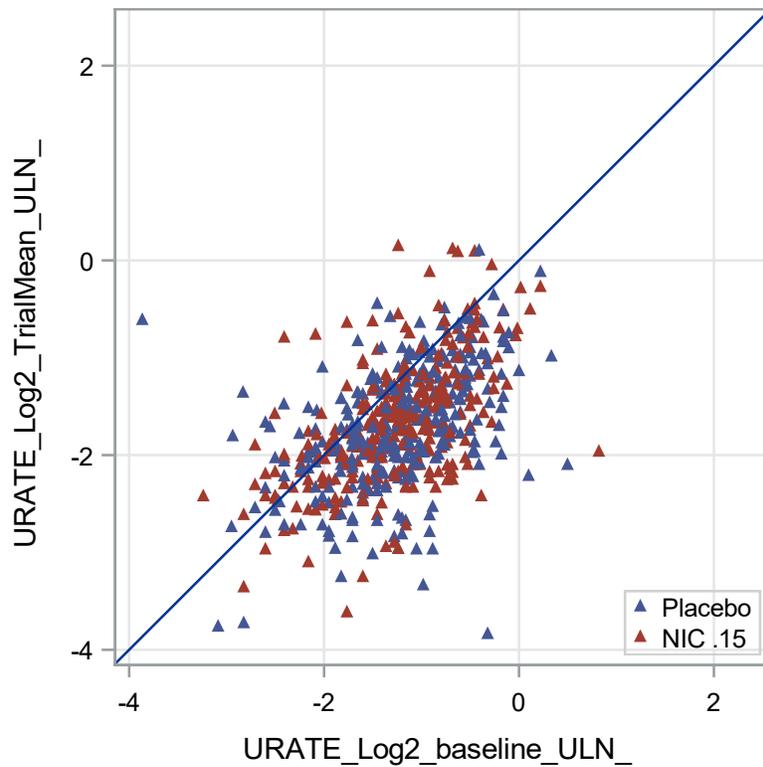
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
SODIUM Shift Plots Trial Mean vs Baseline**



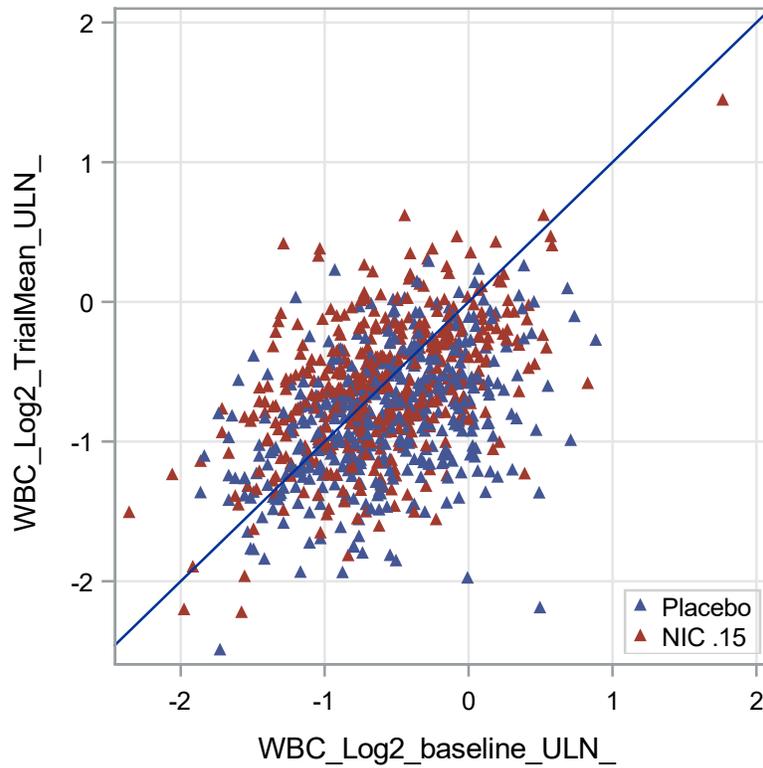
FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
URATE Shift Plots Trial Mean vs Baseline**



FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program

**Trial Mean as finding measurements, ULN Normalization , log2 Transformation
WBC Shift Plots Trial Mean vs Baseline**



The FREQ Procedure

Lab Test or Examination Short Name=ALP

**Frequency
Percent**

Table of Trial_Elevation by Baseline_Elevation				
Trial_Elevation	Baseline_Elevation			Total
	Less than 2x ULN	2x and 5x ULN	Missing	
Less than 2x ULN	653 72.48	3 0.33	89 9.88	745 82.69
2x and 5x ULN	19 2.11	6 0.67	0 0.00	25 2.77
Missing	99 10.99	0 0.00	32 3.55	131 14.54
Total	771 85.57	9 1.00	121 13.43	901 100.00

**FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program
Trial Mean as finding measurements, ULN Normalization , log2 Transformation**

The FREQ Procedure

Lab Test or Examination Short Name=ALT

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation						
	Trial_Elevation	Baseline_Elevation				Missing	Total
		Less than 2x ULN	2x and 5x ULN	5x and 10x ULN			
	Less than 2x ULN	371 41.18	13 1.44	1 0.11	62 6.88	447 49.61	
	2x and 5x ULN	132 14.65	15 1.66	1 0.11	23 2.55	171 18.98	
	5x and 10x ULN	31 3.44	2 0.22	1 0.11	6 0.67	40 4.44	
	10x and 20x ULN	2 0.22	1 0.11	0 0.00	1 0.11	4 0.44	
	20x ULN or Greater	2 0.22	0 0.00	0 0.00	0 0.00	2 0.22	
	Missing	84 9.32	4 0.44	1 0.11	148 16.43	237 26.30	
	Total	622 69.03	35 3.88	4 0.44	240 26.64	901 100.00	

The FREQ Procedure

Lab Test or Examination Short Name=APTT

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		Total
		Less than 2x ULN	Missing	
	Less than 2x ULN	663 73.58	28 3.11	691 76.69
	5x and 10x ULN	1 0.11	0 0.00	1 0.11
	Missing	167 18.53	42 4.66	209 23.20
	Total	831 92.23	70 7.77	901 100.00

**FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program
Trial Mean as finding measurements, ULN Normalization , log2 Transformation**

The FREQ Procedure

Lab Test or Examination Short Name=AST

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation					
	Baseline_Elevation					
	Trial_Elevation	Less than 2x ULN	2x and 5x ULN	5x and 10x ULN	Missing	Total
	Less than 2x ULN	563 62.49	33 3.66	3 0.33	71 7.88	670 74.36
	2x and 5x ULN	75 8.32	8 0.89	1 0.11	10 1.11	94 10.43
	5x and 10x ULN	4 0.44	0 0.00	0 0.00	1 0.11	5 0.55
	20x ULN or Greater	2 0.22	0 0.00	0 0.00	0 0.00	2 0.22
	Missing	88 9.77	9 1.00	0 0.00	33 3.66	130 14.43
	Total	732 81.24	50 5.55	4 0.44	115 12.76	901 100.00

The FREQ Procedure

Lab Test or Examination Short Name=BILI

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation				
	Baseline_Elevation				
	Trial_Elevation	Less than 2x ULN	2x and 5x ULN	Missing	Total
	Less than 2x ULN	657 72.92	6 0.67	88 9.77	751 83.35
	2x and 5x ULN	16 1.78	0 0.00	2 0.22	18 2.00
	5x and 10x ULN	4 0.44	1 0.11	0 0.00	5 0.55
	10x and 20x ULN	0 0.00	0 0.00	1 0.11	1 0.11
	Missing	98 10.88	1 0.11	27 3.00	126 13.98
	Total	775 86.02	8 0.89	118 13.10	901 100.00

FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program
 Trial Mean as finding measurements, ULN Normalization , log2 Transformation

The FREQ Procedure

Lab Test or Examination Short Name=BUN

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation				
	Trial_Elevation	Baseline_Elevation			Total
		Less than 2x ULN	2x and 5x ULN	Missing	
	Less than 2x ULN	830 92.12	1 0.11	7 0.78	838 93.01
	2x and 5x ULN	24 2.66	0 0.00	0 0.00	24 2.66
	5x and 10x ULN	1 0.11	0 0.00	0 0.00	1 0.11
	Missing	36 4.00	0 0.00	2 0.22	38 4.22
	Total	891 98.89	1 0.11	9 1.00	901 100.00

The FREQ Procedure

Lab Test or Examination Short Name=CA

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		Total
		Less than 2x ULN	Missing	
	Less than 2x ULN	694 77.03	84 9.32	778 86.35
	Missing	85 9.43	38 4.22	123 13.65
	Total	779 86.46	122 13.54	901 100.00

The FREQ Procedure

Lab Test or Examination Short Name=CK

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation								
	Trial_Elevation	Baseline_Elevation						Missing	Total
		Less than 2x ULN	2x and 5x ULN	5x and 10x ULN	10x and 20x ULN	20x ULN or Greater			
	Less than 2x ULN	366 40.62	81 8.99	25 2.77	9 1.00	8 0.89	122 13.54	611 67.81	
	2x and 5x ULN	12 1.33	6 0.67	4 0.44	4 0.44	1 0.11	8 0.89	35 3.88	
	5x and 10x ULN	4 0.44	0 0.00	2 0.22	2 0.22	0 0.00	1 0.11	9 1.00	
	10x and 20x ULN	1 0.11	0 0.00	0 0.00	0 0.00	0 0.00	0 0.00	1 0.11	
	20x ULN or Greater	1 0.11	1 0.11	0 0.00	0 0.00	0 0.00	0 0.00	2 0.22	

FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program
 Trial Mean as finding measurements, ULN Normalization , log2 Transformation

The FREQ Procedure

Lab Test or Examination Short Name=CK

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation								
	Trial_Elevation	Baseline_Elevation						Missing	Total
		Less than 2x ULN	2x and 5x ULN	5x and 10x ULN	10x and 20x ULN	20x ULN or Greater			
Missing	75 8.32	22 2.44	3 0.33	3 0.33	0 0.00	140 15.54	243 26.97		
Total	459 50.94	110 12.21	34 3.77	18 2.00	9 1.00	271 30.08	901 100.00		

The FREQ Procedure

Lab Test or Examination Short Name=CL

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		
		Less than 2x ULN	Missing	Total
Less than 2x ULN	859 95.34	5 0.55	864 95.89	
Missing	36 4.00	1 0.11	37 4.11	
Total	895 99.33	6 0.67	901 100.00	

The FREQ Procedure

Lab Test or Examination Short Name=CO2

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		
		Less than 2x ULN	Missing	Total
Less than 2x ULN	855 94.89	8 0.89	863 95.78	
Missing	36 4.00	2 0.22	38 4.22	
Total	891 98.89	10 1.11	901 100.00	

**FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program
Trial Mean as finding measurements, ULN Normalization , log2 Transformation**

The FREQ Procedure

Lab Test or Examination Short Name=CREAT

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		
		Less than 2x ULN	Missing	Total
Less than 2x ULN	851 94.45	5 0.55	856 95.01	
2x and 5x ULN	7 0.78	0 0.00	7 0.78	
Missing	34 3.77	4 0.44	38 4.22	
Total	892 99.00	9 1.00	901 100.00	

The FREQ Procedure

Lab Test or Examination Short Name=GLUC

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation				
	Trial_Elevation	Baseline_Elevation			Total
		Less than 2x ULN	2x and 5x ULN	Missing	
Less than 2x ULN	846 93.90	1 0.11	8 0.89	855 94.89	
Missing	46 5.11	0 0.00	0 0.00	46 5.11	
Total	892 99.00	1 0.11	8 0.89	901 100.00	

The FREQ Procedure

Lab Test or Examination Short Name=HCT

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		
		Less than 2x ULN	Missing	Total
Less than 2x ULN	860 95.45	6 0.67	866 96.12	
Missing	35 3.88	0 0.00	35 3.88	
Total	895 99.33	6 0.67	901 100.00	

**FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program
 Trial Mean as finding measurements, ULN Normalization , log2 Transformation**

The FREQ Procedure

Lab Test or Examination Short Name=HGB

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		
		Less than 2x ULN	Missing	Total
Less than 2x ULN	857 95.12	8 0.89	865 96.00	
Missing	35 3.88	1 0.11	36 4.00	
Total	892 99.00	9 1.00	901 100.00	

The FREQ Procedure

Lab Test or Examination Short Name=K

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		
		Less than 2x ULN	Missing	Total
Less than 2x ULN	863 95.78	4 0.44	867 96.23	
Missing	34 3.77	0 0.00	34 3.77	
Total	897 99.56	4 0.44	901 100.00	

The FREQ Procedure

Lab Test or Examination Short Name=LDH

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation				
	Trial_Elevation	Baseline_Elevation			Total
		Less than 2x ULN	2x and 5x ULN	Missing	
Less than 2x ULN	609 67.59	2 0.22	82 9.10	693 76.91	
2x and 5x ULN	32 3.55	2 0.22	4 0.44	38 4.22	
5x and 10x ULN	1 0.11	0 0.00	1 0.11	2 0.22	
10x and 20x ULN	2 0.22	0 0.00	0 0.00	2 0.22	
Missing	90 9.99	4 0.44	72 7.99	166 18.42	
Total	734 81.47	8 0.89	159 17.65	901 100.00	

**FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program
Trial Mean as finding measurements, ULN Normalization , log2 Transformation**

The FREQ Procedure

Lab Test or Examination Short Name=PCO2

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		
		Less than 2x ULN	Missing	Total
Less than 2x ULN	470 52.16	101 11.21	571 63.37	
Missing	182 20.20	148 16.43	330 36.63	
Total	652 72.36	249 27.64	901 100.00	

The FREQ Procedure

Lab Test or Examination Short Name=PH

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		
		Less than 2x ULN	Missing	Total
Less than 2x ULN	470 52.16	100 11.10	570 63.26	
Missing	181 20.09	150 16.65	331 36.74	
Total	651 72.25	250 27.75	901 100.00	

The FREQ Procedure

Lab Test or Examination Short Name=PHOS

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation				
	Trial_Elevation	Baseline_Elevation			Total
		Less than 2x ULN	2x and 5x ULN	Missing	
Less than 2x ULN	652 72.36	1 0.11	95 10.54	748 83.02	
Missing	86 9.54	0 0.00	67 7.44	153 16.98	
Total	738 81.91	1 0.11	162 17.98	901 100.00	

**FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program
Trial Mean as finding measurements, ULN Normalization , log2 Transformation**

The FREQ Procedure

Lab Test or Examination Short Name=PLAT

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		
		Less than 2x ULN	Missing	Total
Less than 2x ULN	723 80.24	43 4.77	766 85.02	
Missing	83 9.21	52 5.77	135 14.98	
Total	806 89.46	95 10.54	901 100.00	

The FREQ Procedure

Lab Test or Examination Short Name=PO2

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation					
	Trial_Elevation	Baseline_Elevation				Total
		Less than 2x ULN	2x and 5x ULN	5x and 10x ULN	Missing	
Less than 2x ULN	424 47.06	35 3.88	6 0.67	100 11.10	565 62.71	
2x and 5x ULN	3 0.33	0 0.00	1 0.11	2 0.22	6 0.67	
Missing	165 18.31	16 1.78	1 0.11	148 16.43	330 36.63	
Total	592 65.70	51 5.66	8 0.89	250 27.75	901 100.00	

The FREQ Procedure

Lab Test or Examination Short Name=PROT

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		
		Less than 2x ULN	Missing	Total
Less than 2x ULN	660 73.25	96 10.65	756 83.91	
Missing	98 10.88	47 5.22	145 16.09	
Total	758 84.13	143 15.87	901 100.00	

FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program
 Trial Mean as finding measurements, ULN Normalization , log2 Transformation

The FREQ Procedure

Lab Test or Examination Short Name=PT

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation					
	Trial_Elevation	Baseline_Elevation				Total
		Less than 2x ULN	2x and 5x ULN	5x and 10x ULN	Missing	
	Less than 2x ULN	667 74.03	1 0.11	0 0.00	27 3.00	695 77.14
	2x and 5x ULN	1 0.11	0 0.00	0 0.00	0 0.00	1 0.11
	5x and 10x ULN	0 0.00	0 0.00	1 0.11	0 0.00	1 0.11
	Missing	165 18.31	0 0.00	0 0.00	39 4.33	204 22.64
	Total	833 92.45	1 0.11	1 0.11	66 7.33	901 100.00

The FREQ Procedure

Lab Test or Examination Short Name=RBC

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		Total
		Less than 2x ULN	Missing	
	Less than 2x ULN	847 94.01	15 1.66	862 95.67
	Missing	38 4.22	1 0.11	39 4.33
	Total	885 98.22	16 1.78	901 100.00

The FREQ Procedure

Lab Test or Examination Short Name=SODIUM

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation			
	Trial_Elevation	Baseline_Elevation		Total
		Less than 2x ULN	Missing	
	Less than 2x ULN	863 95.78	4 0.44	867 96.23
	Missing	34 3.77	0 0.00	34 3.77
	Total	897 99.56	4 0.44	901 100.00

**FindingsShiftPlots_LB001.sas: Laboratory Test Results Shift Plots Validation Program
 Trial Mean as finding measurements, ULN Normalization , log2 Transformation**

The FREQ Procedure

Lab Test or Examination Short Name=URATE

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation				
	Trial_Elevation	Baseline_Elevation			Total
		Less than 2x ULN	5x and 10x ULN	Missing	
Less than 2x ULN	578 64.15	0 0.00	109 12.10	687 76.25	
Missing	95 10.54	1 0.11	118 13.10	214 23.75	
Total	673 74.69	1 0.11	227 25.19	901 100.00	

The FREQ Procedure

Lab Test or Examination Short Name=WBC

Frequency Percent	Table of Trial_Elevation by Baseline_Elevation				
	Trial_Elevation	Baseline_Elevation			Total
		Less than 2x ULN	2x and 5x ULN	Missing	
Less than 2x ULN	856 95.01	0 0.00	8 0.89	864 95.89	
2x and 5x ULN	0 0.00	1 0.11	0 0.00	1 0.11	
Missing	36 4.00	0 0.00	0 0.00	36 4.00	
Total	892 99.00	1 0.11	8 0.89	901 100.00	