

F: Mean Daily Insulin Use Over Time (Study 1022)

Table 5.10.1.1.2
 Inhaled Human Insulin Protocol 1022IA
 Summary of Average Total Daily Insulin Dose, Full Analysis Set (HbA1c)
 Interim Analysis

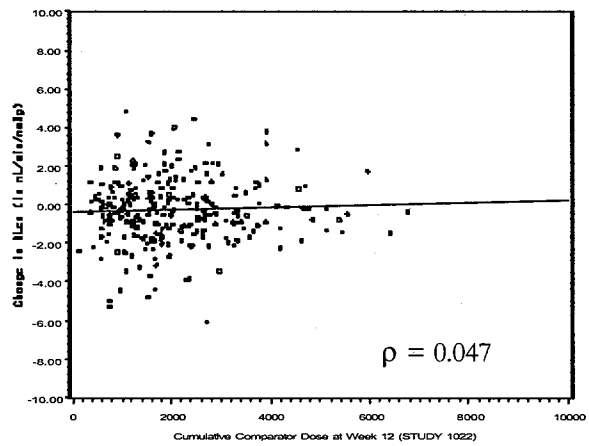
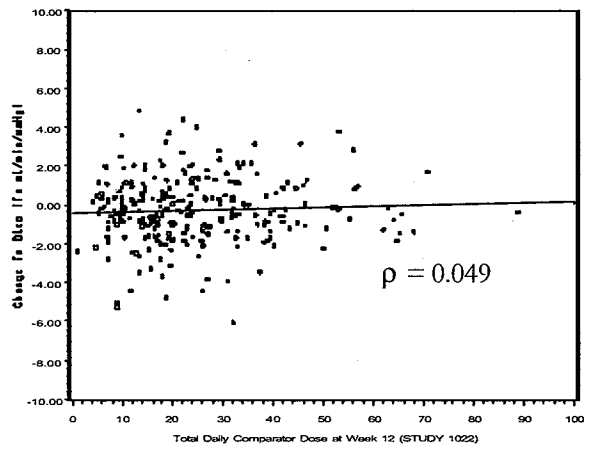
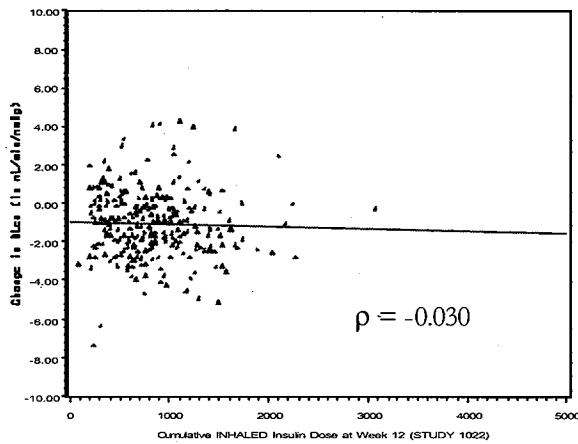
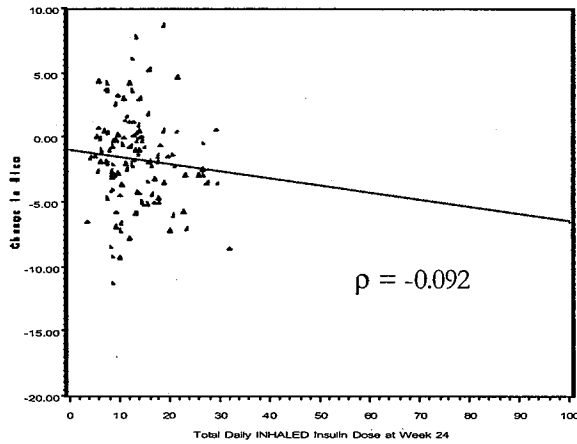
	Inhaled Insulin						Subcutaneous Insulin																	
	Long Acting (units)			Short Acting (units)			Long Acting (units)			Short Acting (units)														
	N	Mean	Median	SD	Min	Max	N	Mean	Median	SD	Min	Max												
Baseline	288	30.69	29.65	13.49	5.50	84.00	297	22.59	21.00	13.25	0.20	100.0	285	32.94	30.00	16.05	1.60	88.00	286	23.91	21.04	14.38	1.10	77.00
Month 3	280	30.48	28.36	16.04	3.00	96.00	280	10.46	9.50	5.70	2.50	38.00	285	34.98	32.00	17.37	6.70	94.00	285	25.09	22.10	14.70	1.00	88.80
Month 6	271	30.58	28.00	16.48	1.30	94.00	271	11.51	10.30	6.71	2.40	44.10	278	35.40	32.60	17.75	7.00	98.00	279	25.08	22.30	14.71	2.00	88.00
Month 9	254	31.02	28.20	16.52	0.80	90.00	256	12.00	10.55	6.79	1.00	45.00	266	35.39	33.00	17.85	4.06	94.00	267	24.92	22.10	14.60	2.78	78.30
Month 12	243	30.66	27.40	17.30	1.00	96.16	243	12.68	11.50	6.94	1.00	37.30	258	35.69	33.20	18.08	0.40	97.70	262	25.37	22.50	14.45	3.30	81.30

Baseline dosing was with subcutaneous insulin in both treatment groups.
 Long acting includes Insulin NPH, Ultralente, and Insulin Glargine for both groups.
 Short Acting (unit) includes Insulin Lispro, Insulin Aspart, and Regular Insulin. short Acting (mg) is Inhaled Insulin.
 Doses at each scheduled visit are collected as average daily doses between the day of the previous visit and the day before the present visit.
 Source Data: Section 13, Table 2.8 Date of Data Extraction: 30MAR2004 Date of Table Generation: 11OCT2004 (10:11)

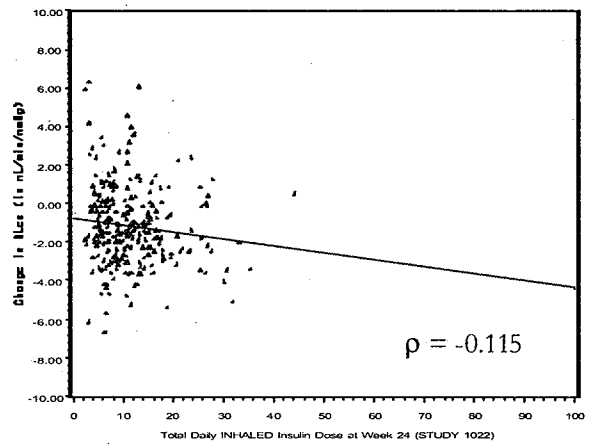
Source: Study Report A2171022 (One-Year Interim Report)

G: Mean Change in DLco by Average and Cumulative
Daily Insulin Dose at Week 12 (Study 1022)

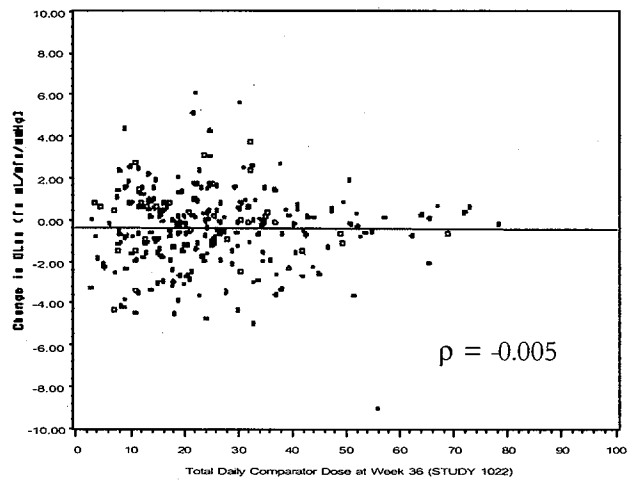
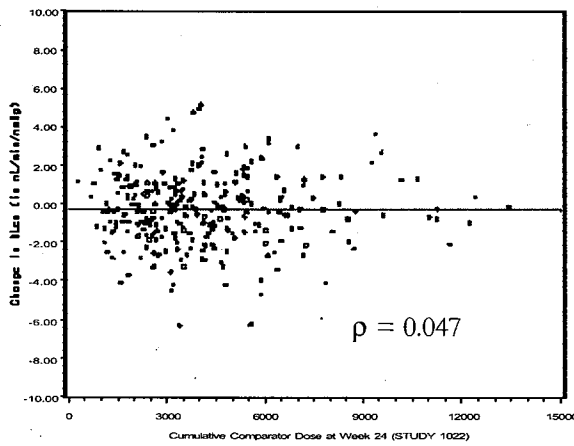
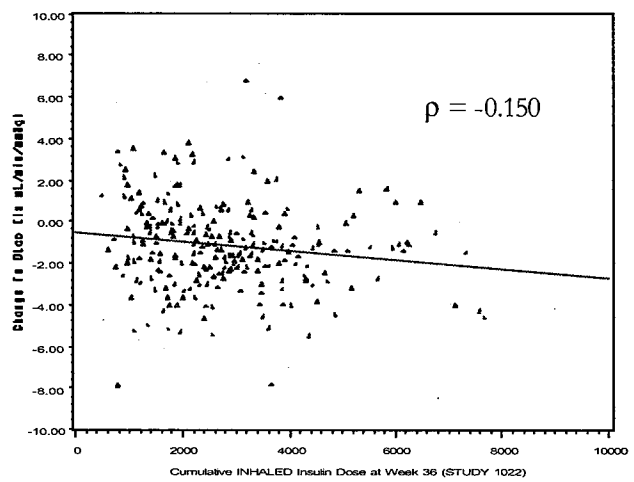
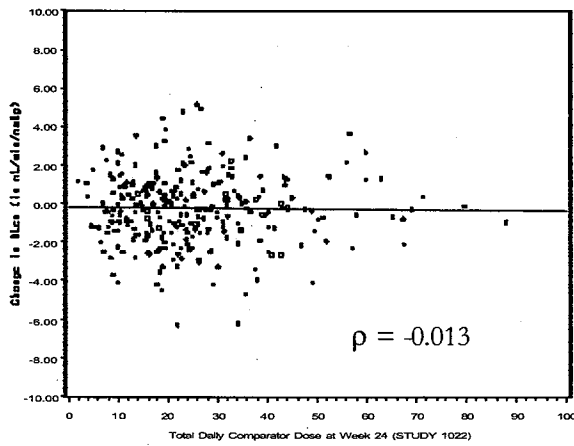
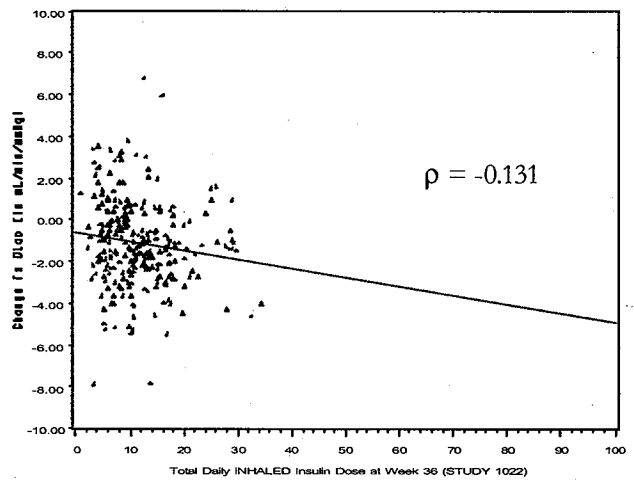
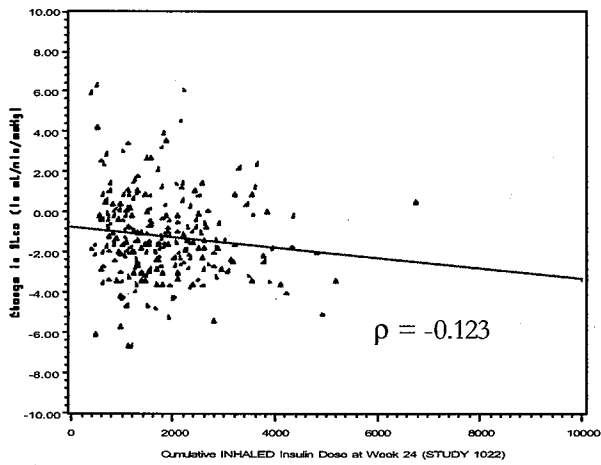
Red: Inhaled Insulin Group
Blue: Comparator Group

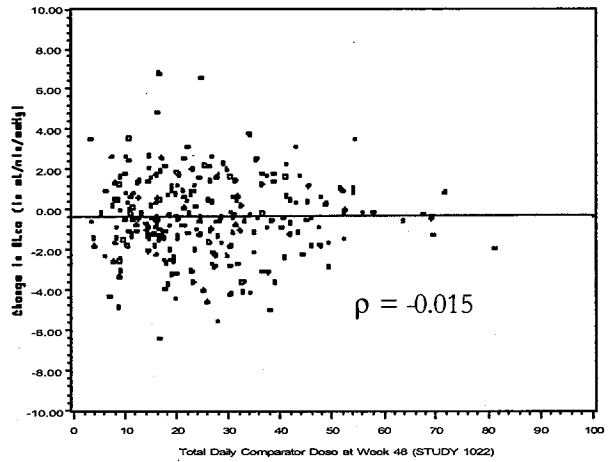
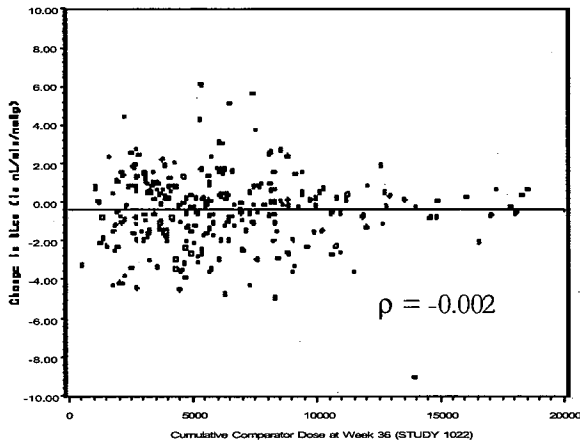


I: Mean Change in DLco by Average and Cumulative
Daily Insulin Dose at Week 24 (Study 1022)

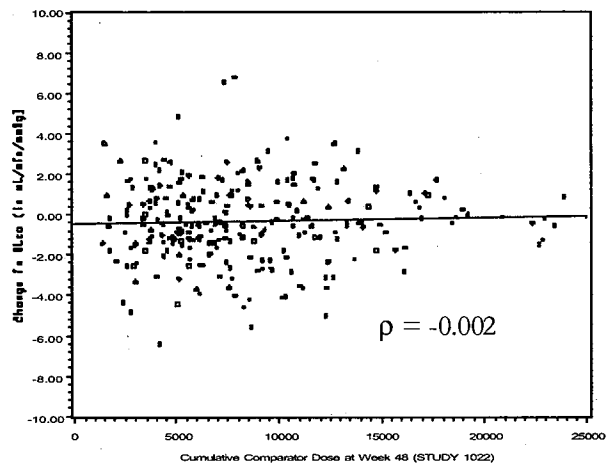
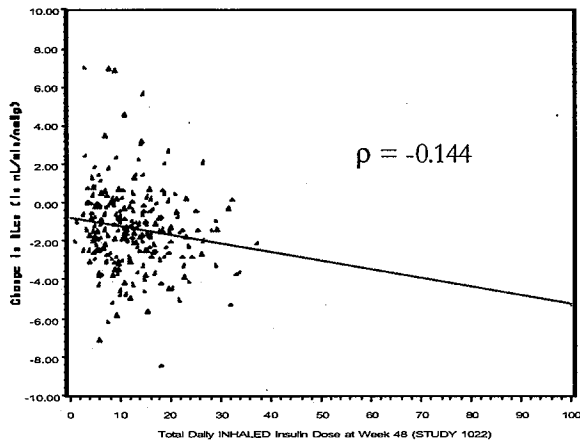


J: Mean Change in DLco by Average and Cumulative Daily Insulin Dose at Week 36 (Study 1022)

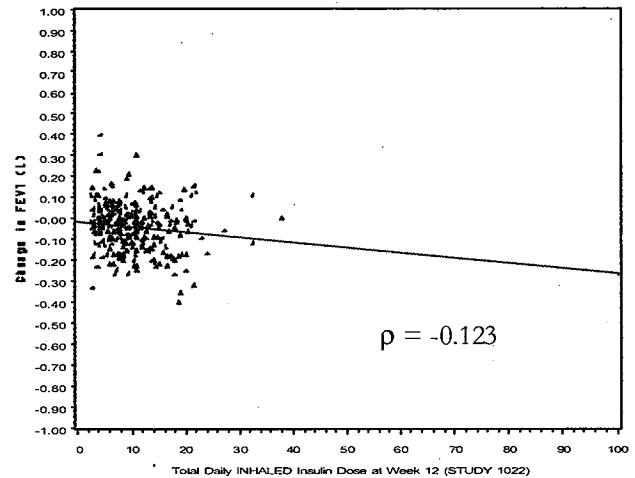
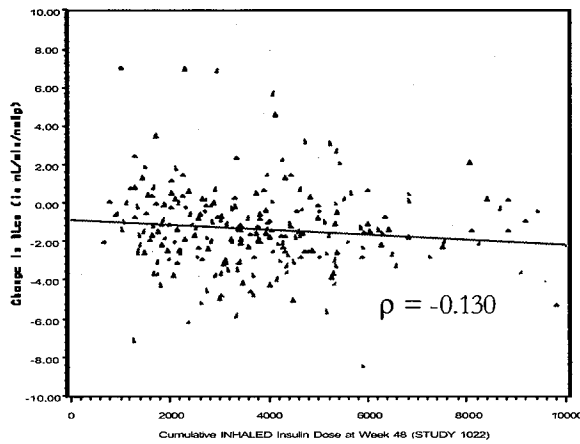




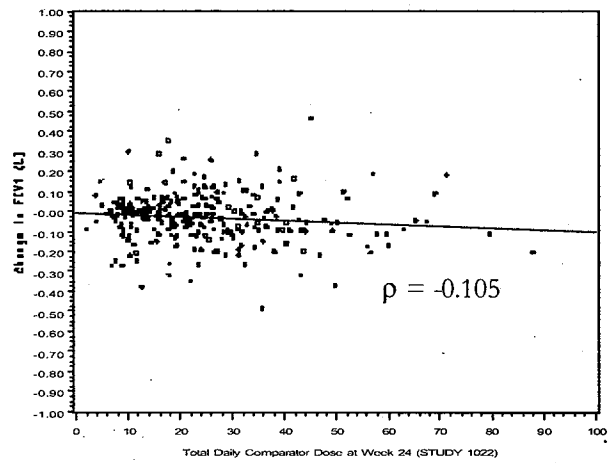
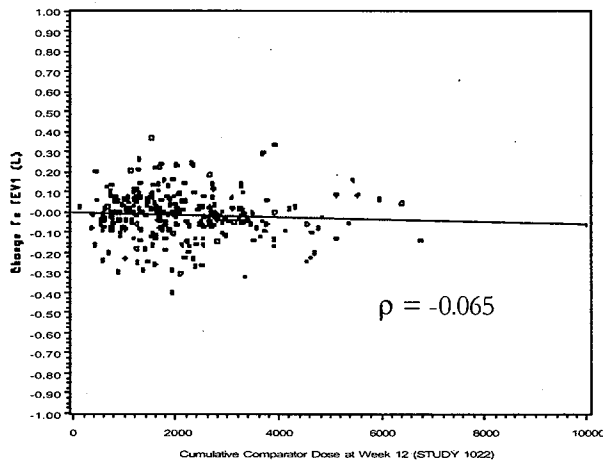
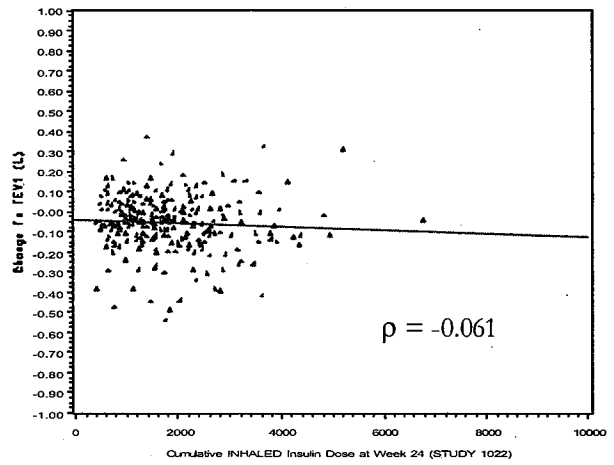
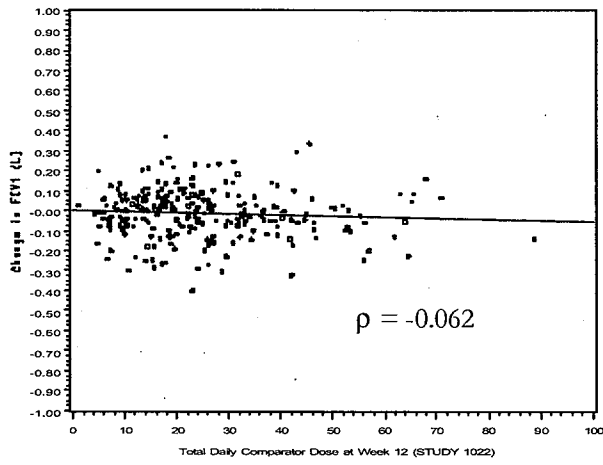
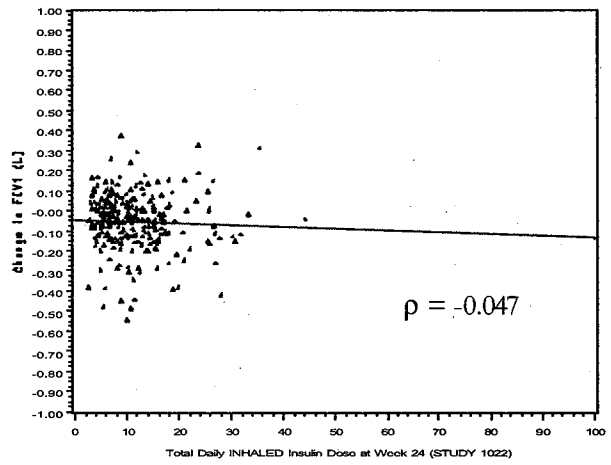
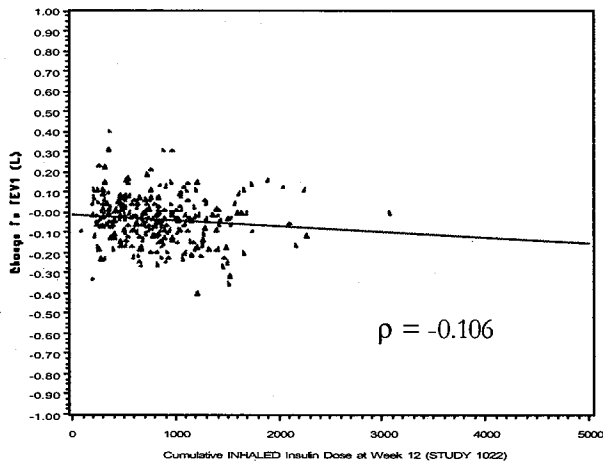
K: Mean Change in DLco by Average and Cumulative Daily Insulin Dose at Week 48 (Study 1022)

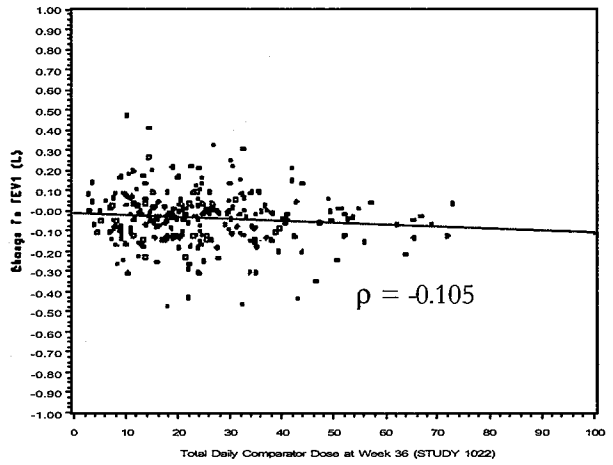
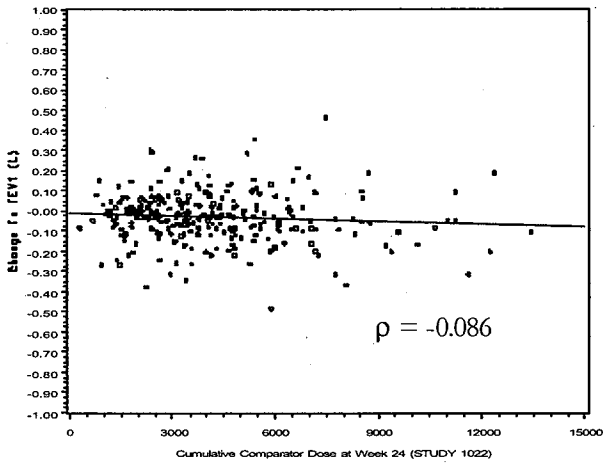


L: Mean Change in FEV1 by Average and Cumulative Daily Insulin Dose at Week 12 (Study 1022)

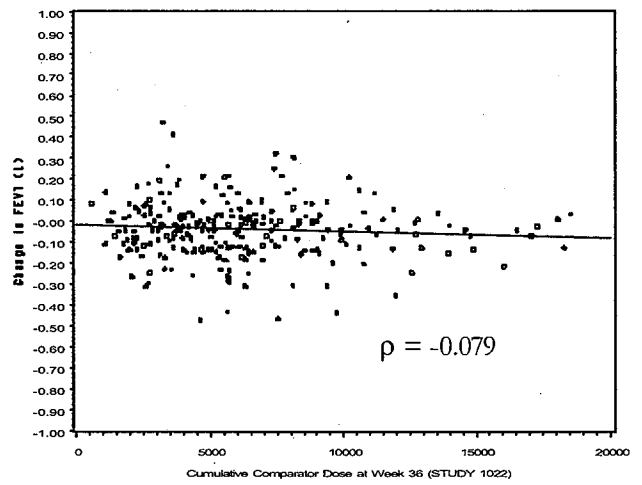
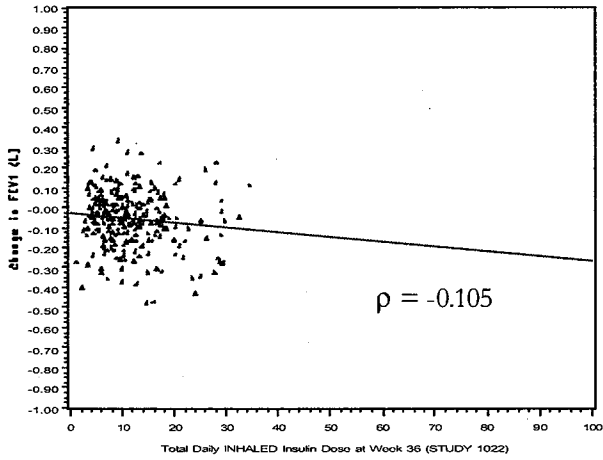


M: Mean Change in FEV1 by Average and Cumulative Daily Insulin Dose at Week 24 (Study 1022)

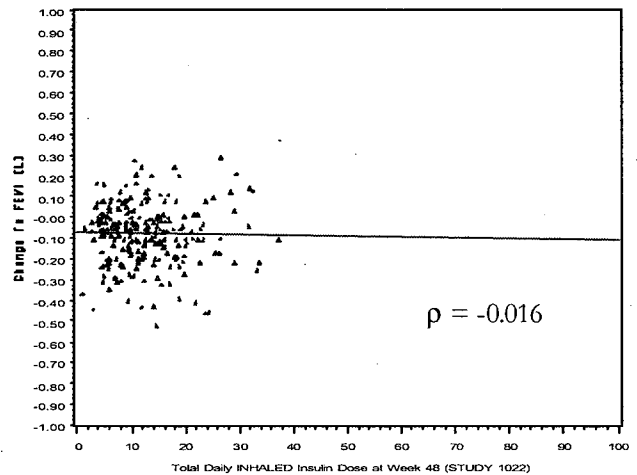
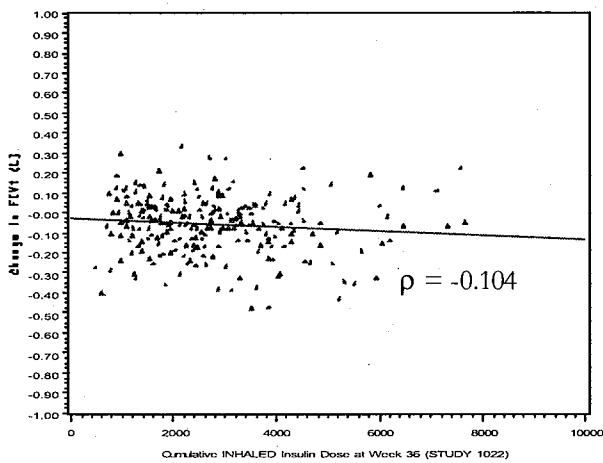




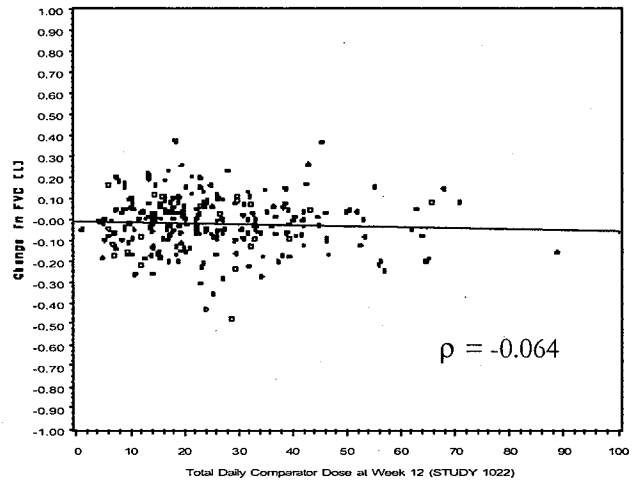
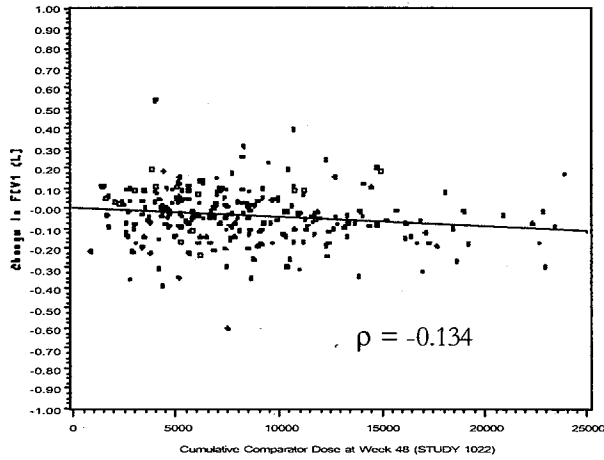
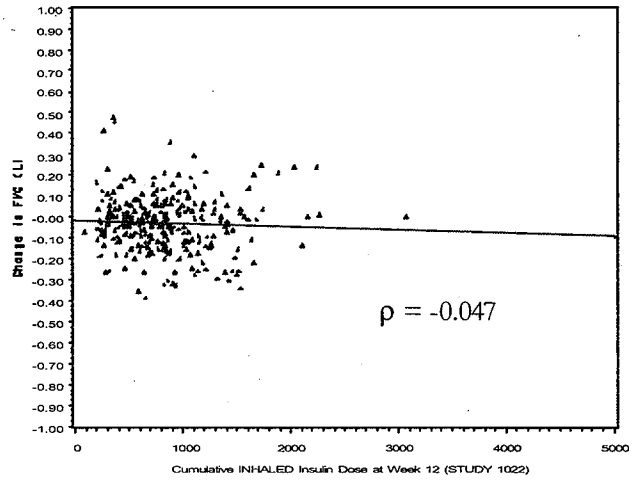
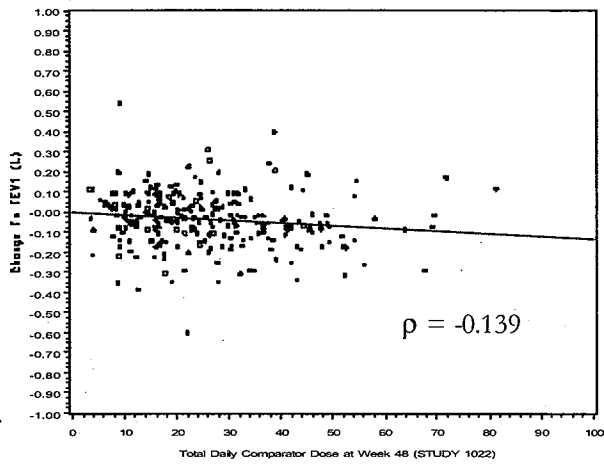
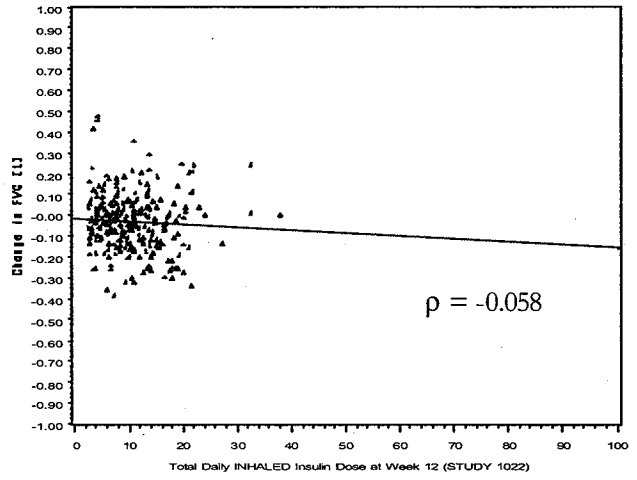
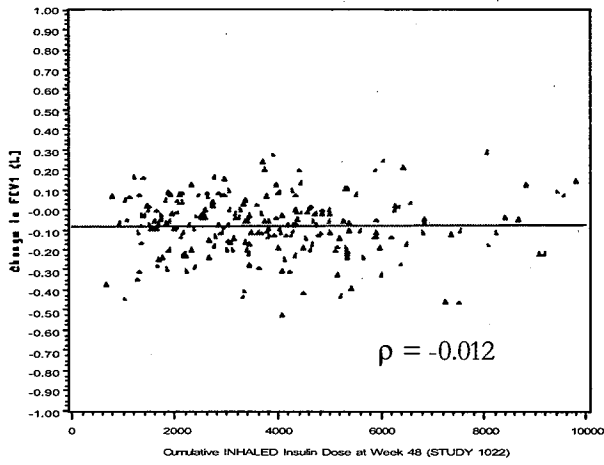
N: Mean Change in FEV1 by Average and Cumulative Daily Insulin Dose at Week 36 (Study 1022)

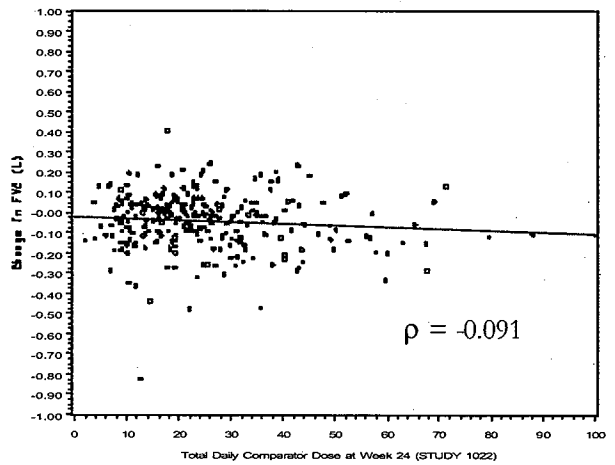
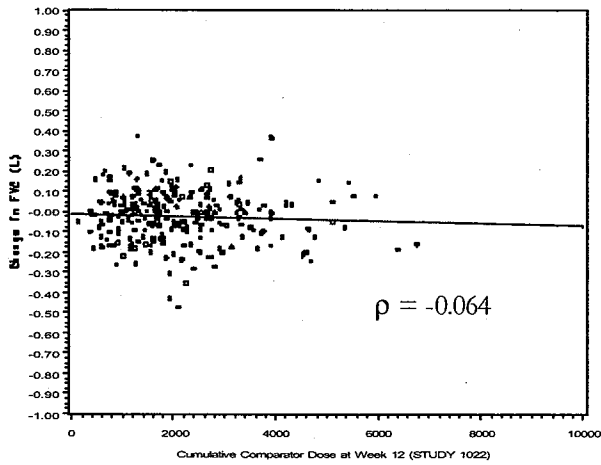


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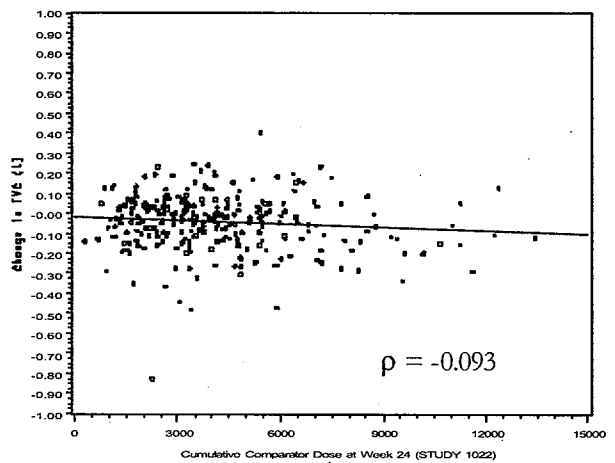
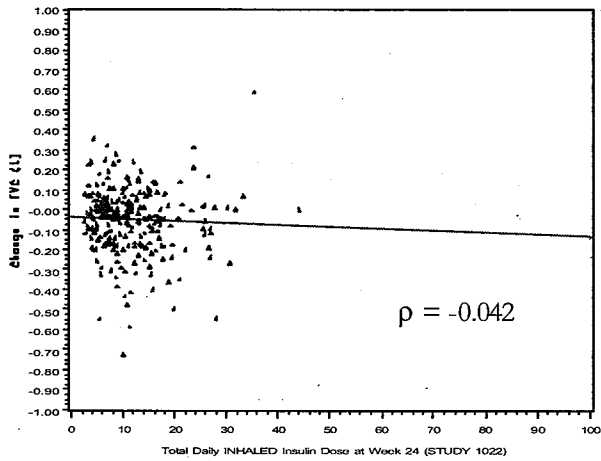


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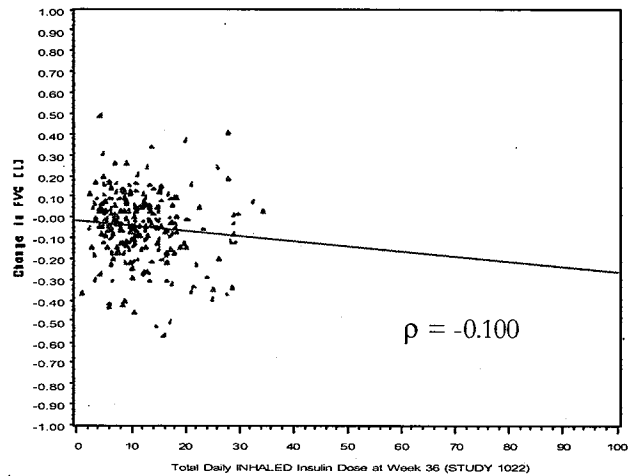
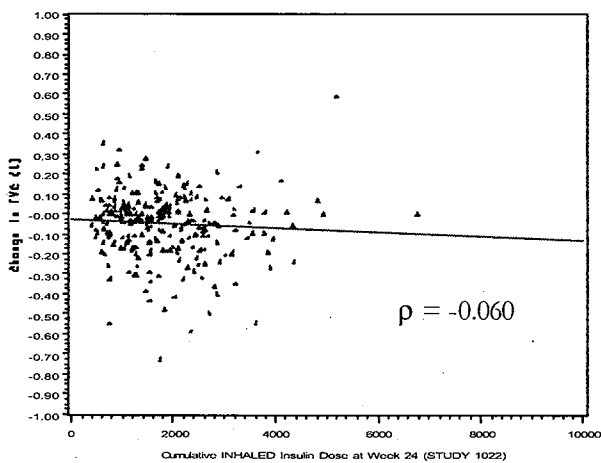




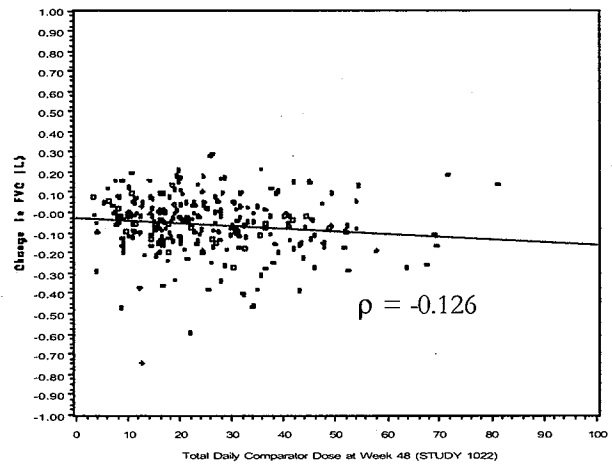
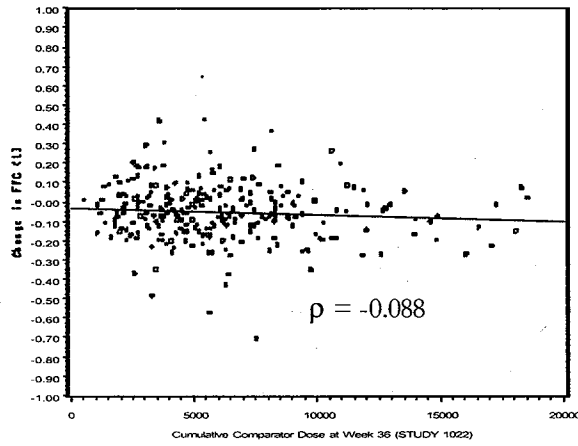
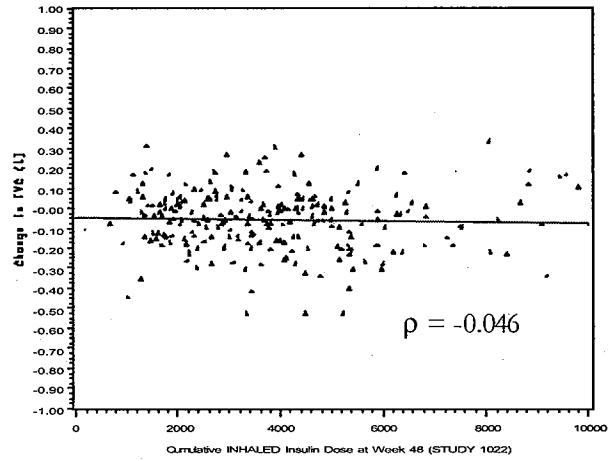
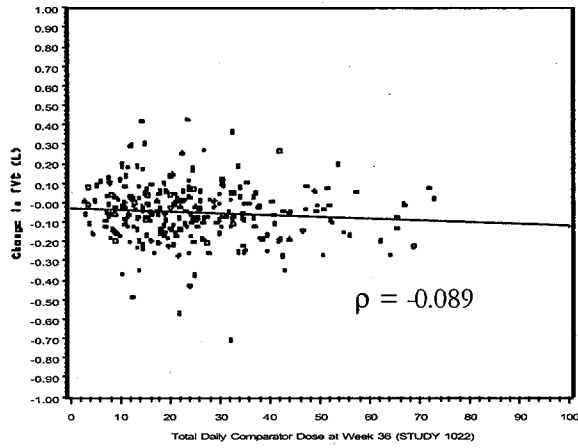
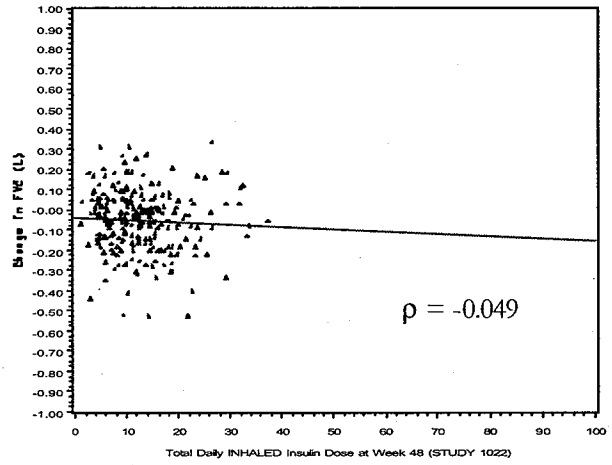
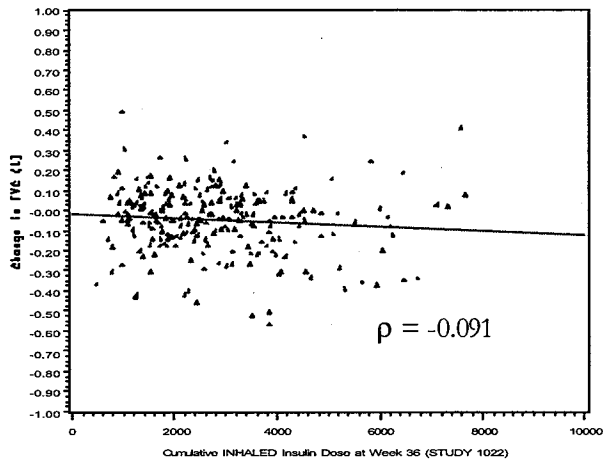
Q: Mean Change in FVC by Average and Cumulative Daily Insulin Dose at Week 24 (Study 1022)

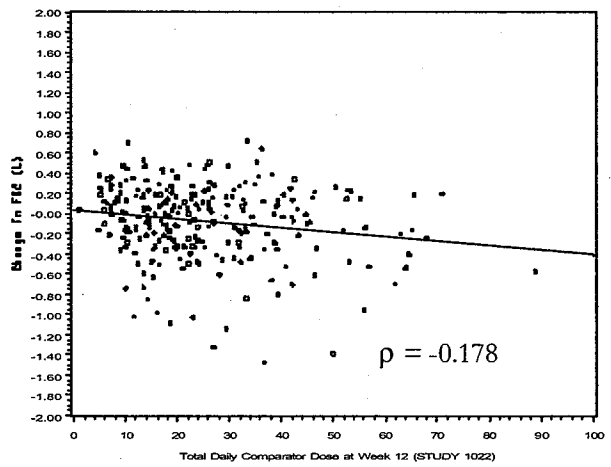
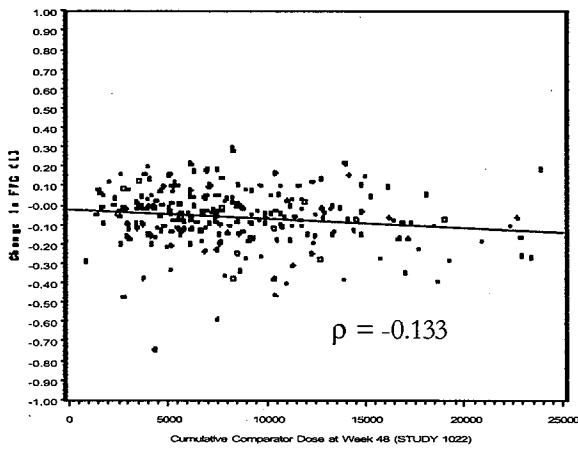


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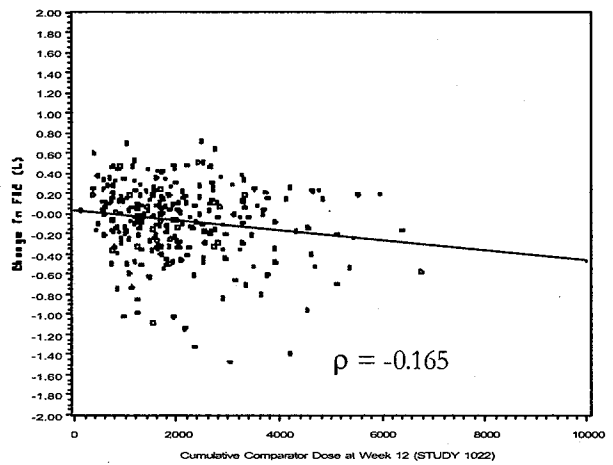
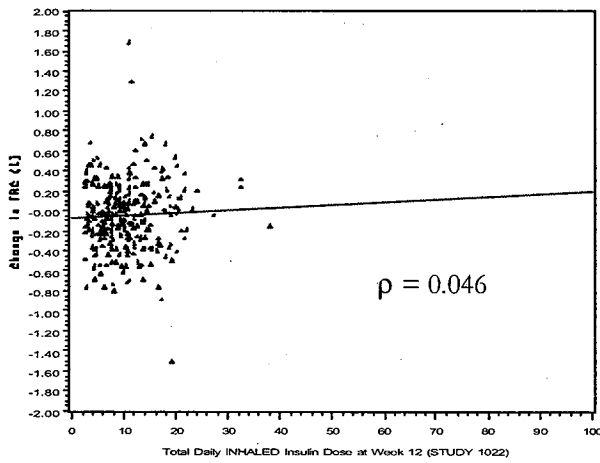


S: Mean Change in FVC by Average and Cumulative Daily Insulin Dose at Week 48 (Study 1022)

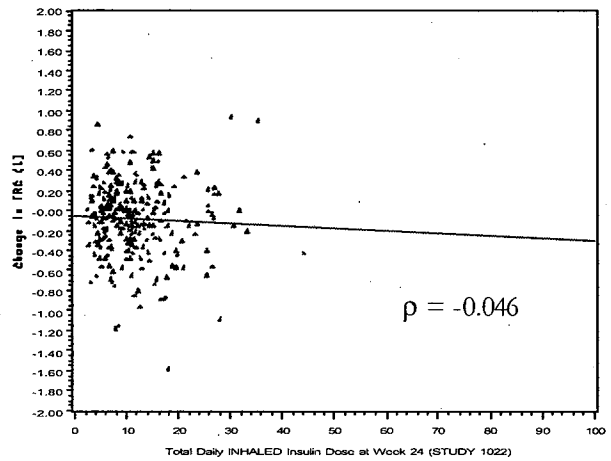
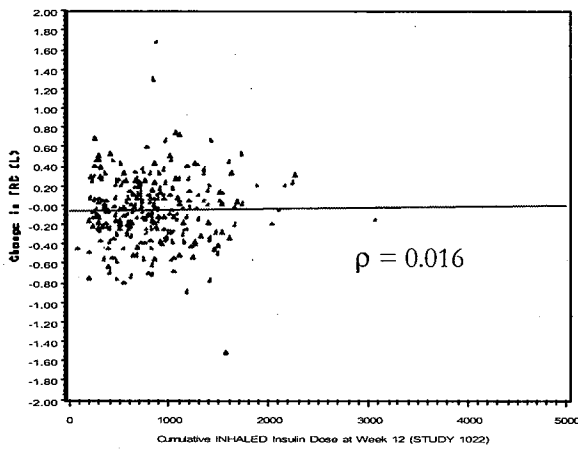




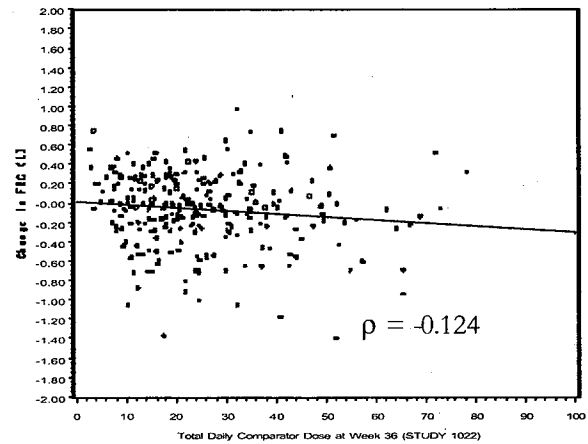
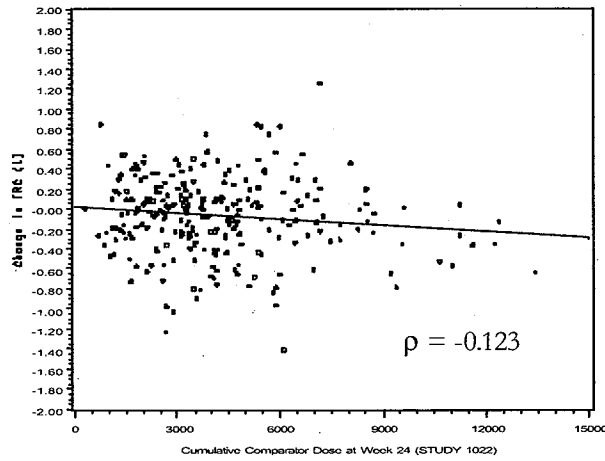
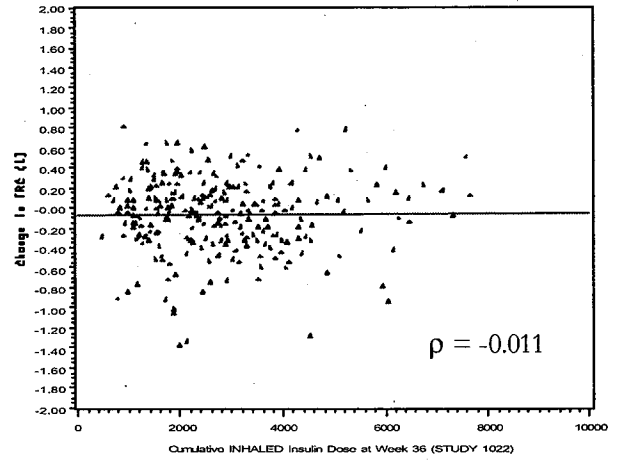
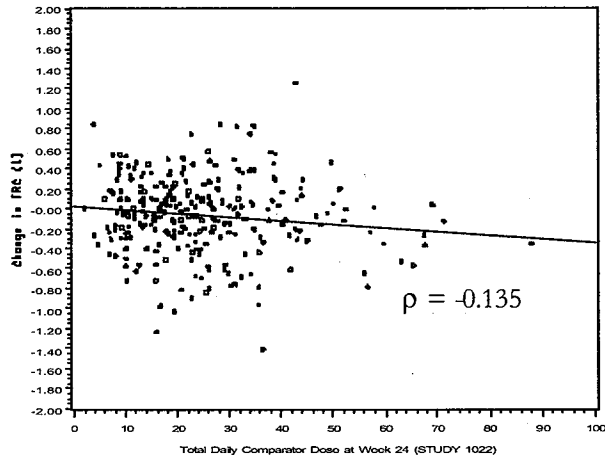
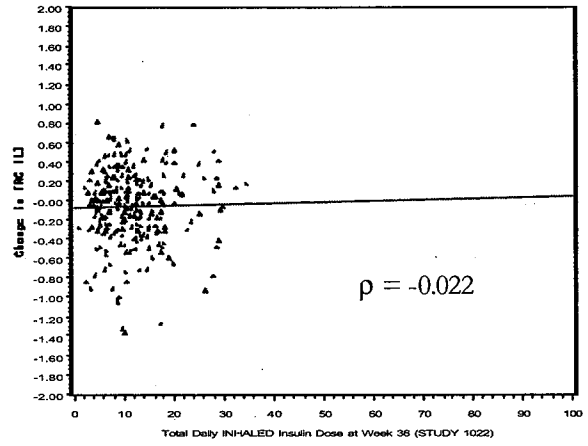
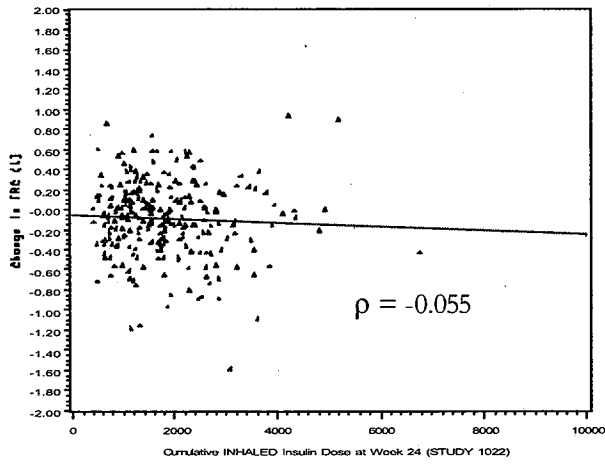
T: Mean Change in FRC by Average and Cumulative Daily Insulin Dose at Week 12 (Study 1022)

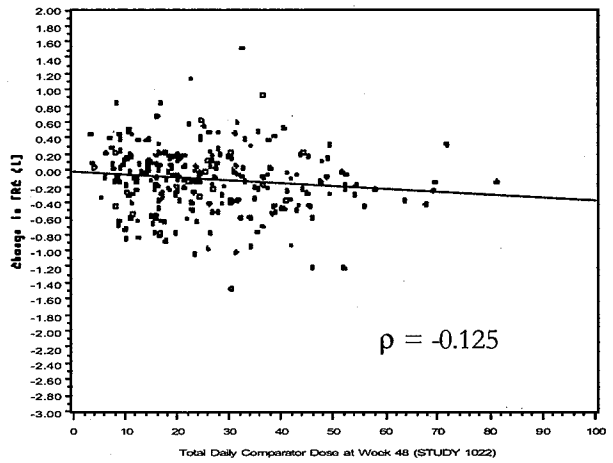
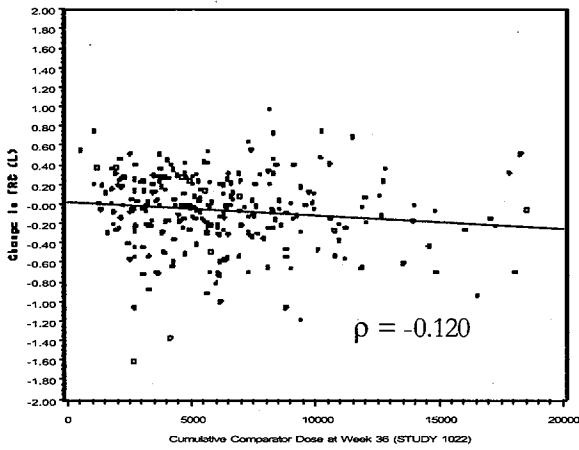


U: Mean Change in FRC by Average and Cumulative Daily Insulin Dose at Week 24 (Study 1022)

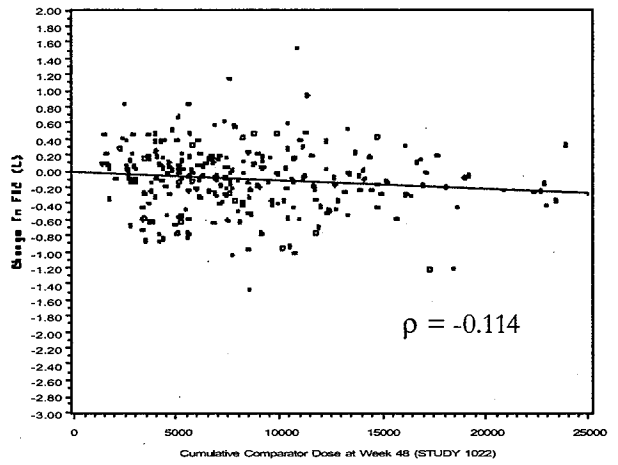
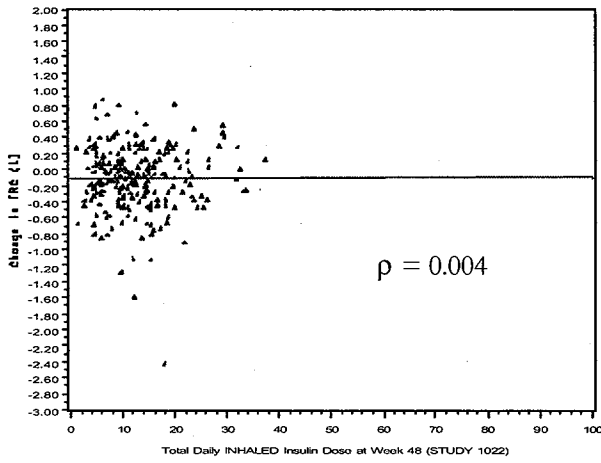


V: Mean Change in FRC by Average and Cumulative Daily Insulin Dose at Week 36 (Study 1022)

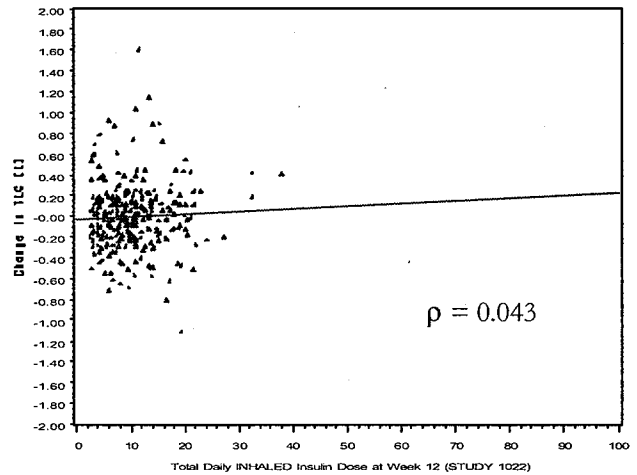
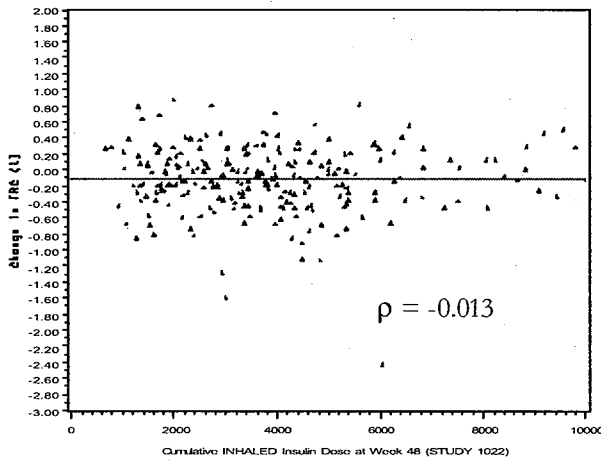




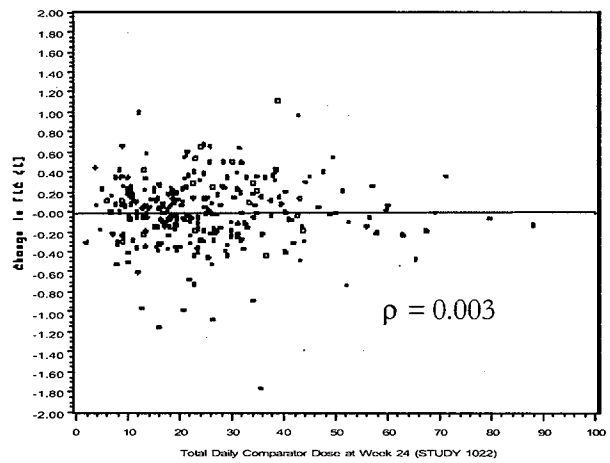
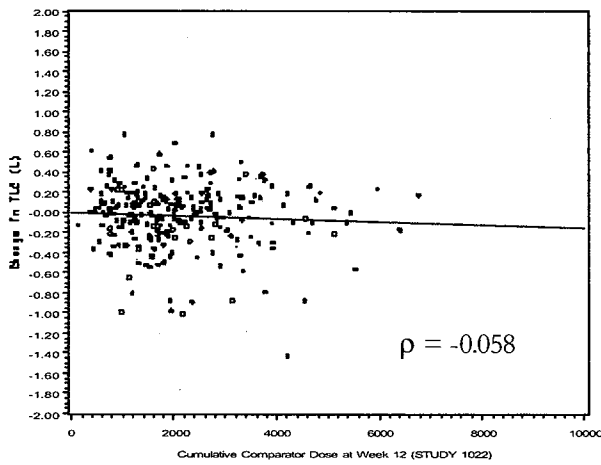
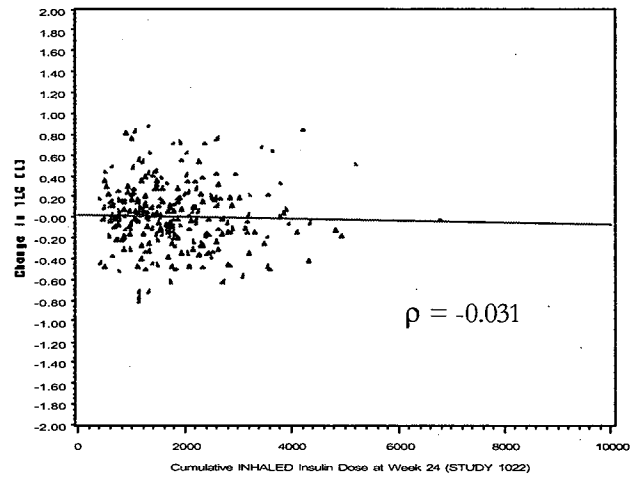
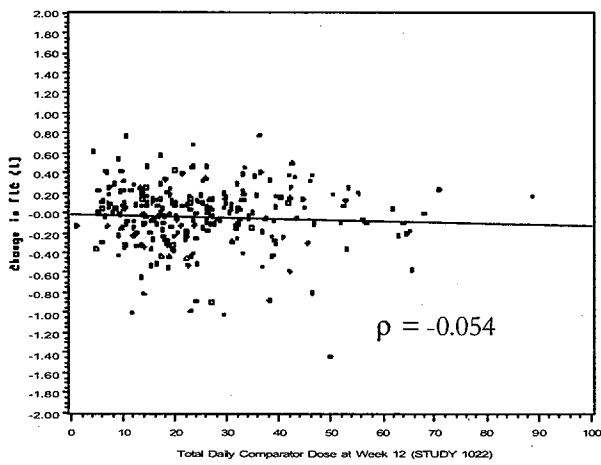
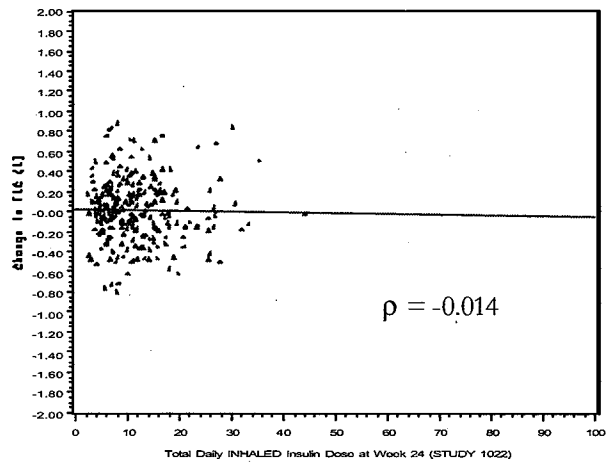
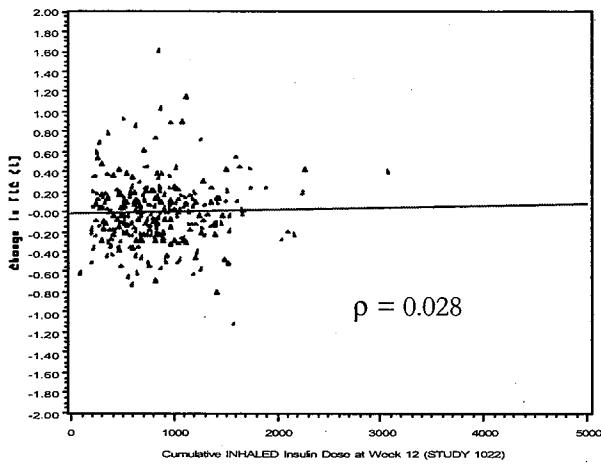
W: Mean Change in FRC by Average and Cumulative Daily Insulin Dose at Week 48 (Study 1022)

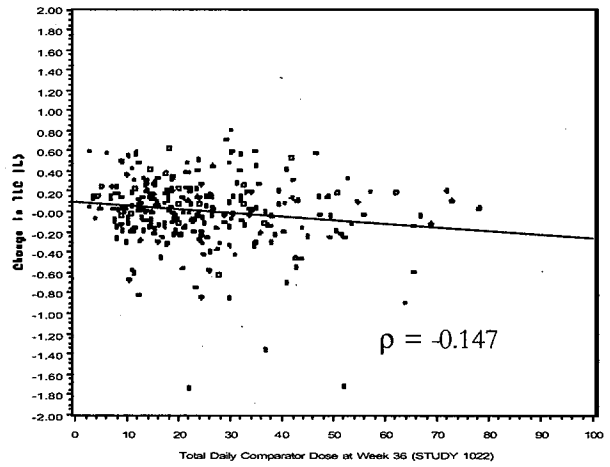
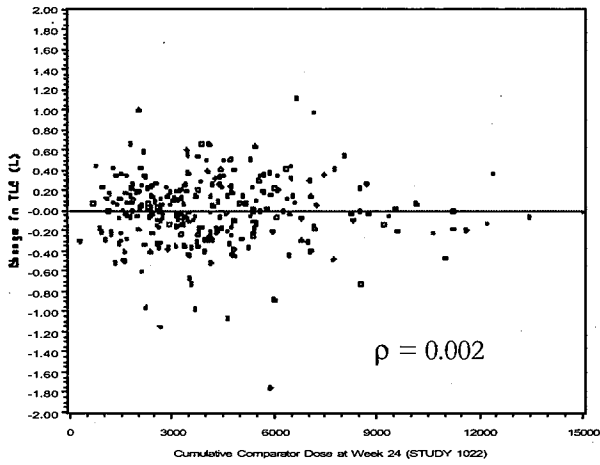


X: Mean Change in TLC by Average and Cumulative Daily Insulin Dose at Week 12 (Study 1022)

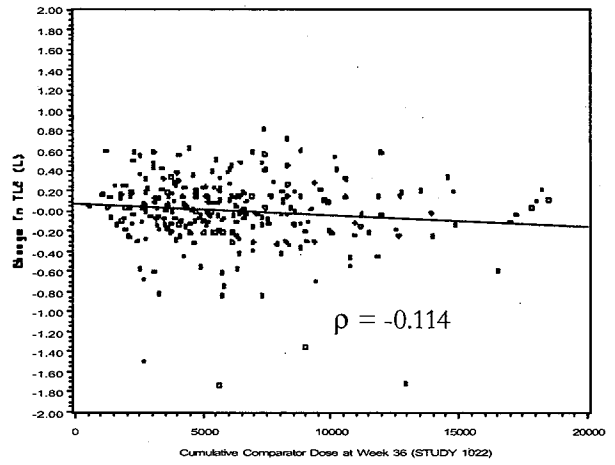
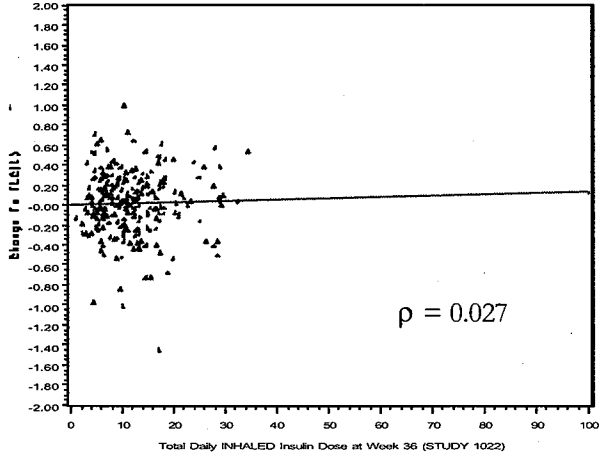


Y: Mean Change in TLC by Average and Cumulative Daily Insulin Dose at Week 24 (Study 1022)

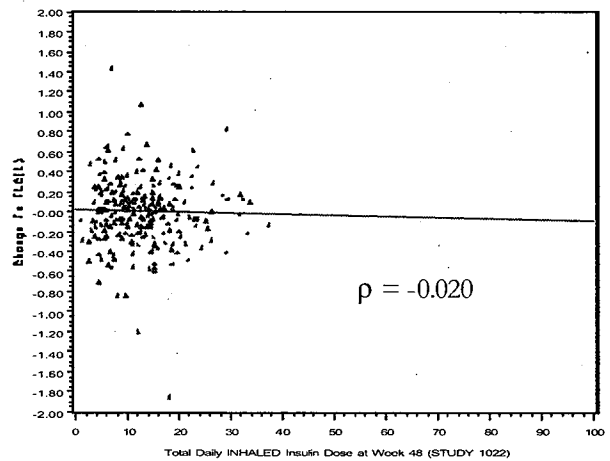
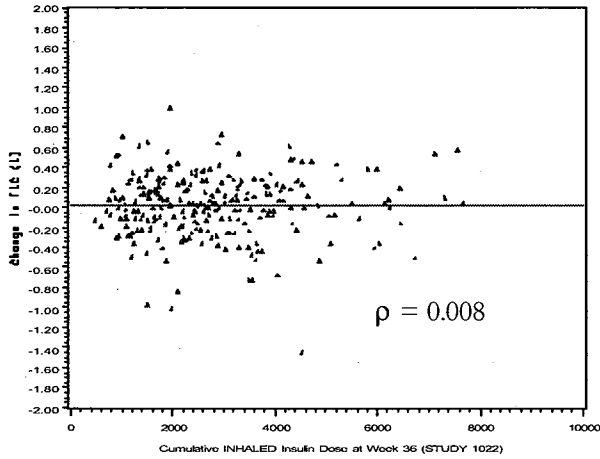


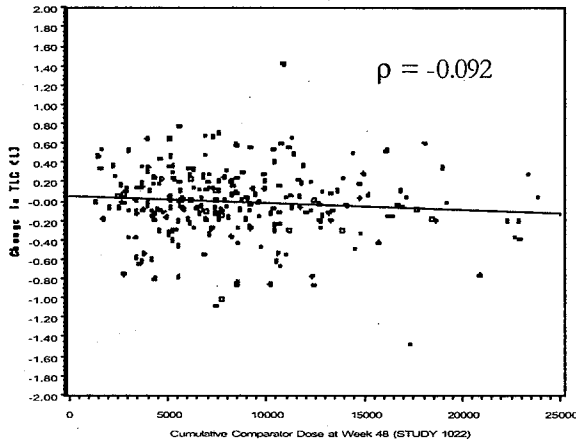
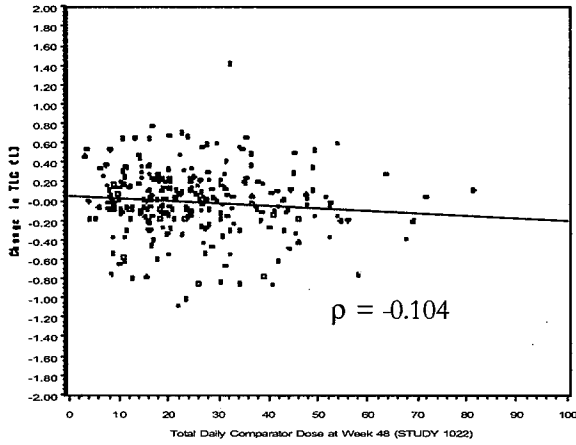
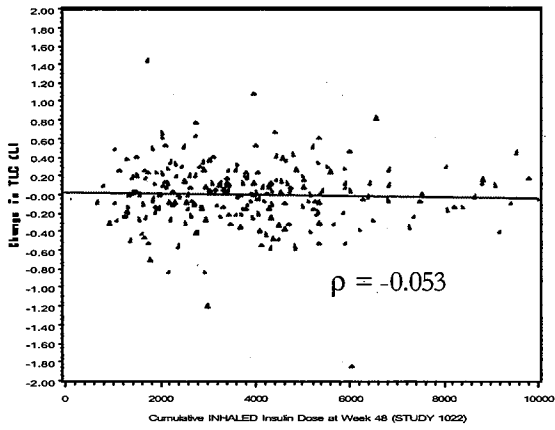


Z: Mean Change in TLC by Average and Cumulative Daily Insulin Dose at Week 36 (Study 1022)



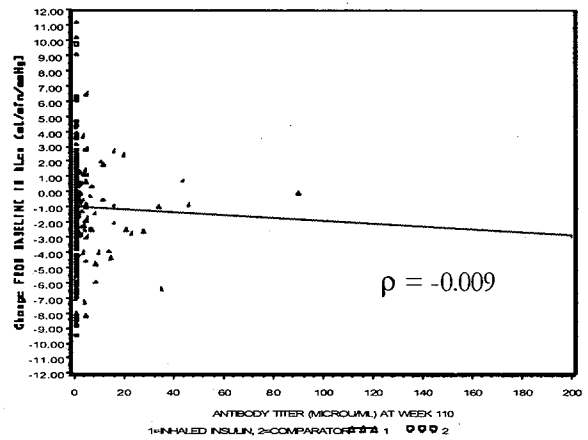
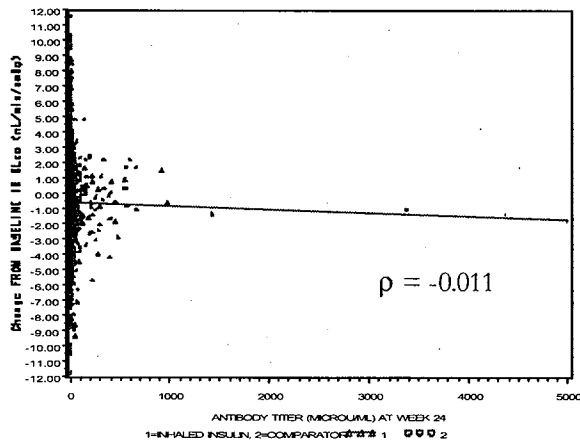
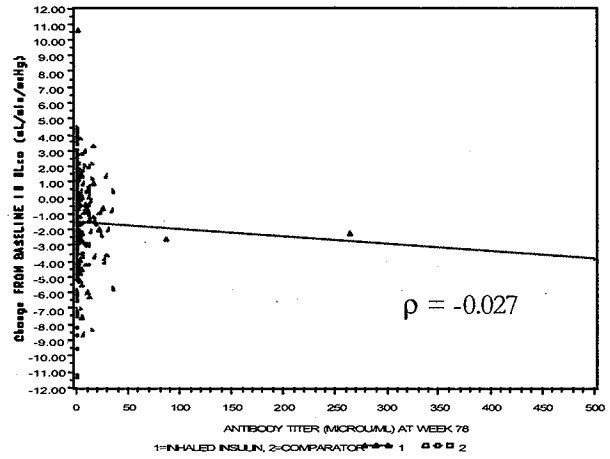
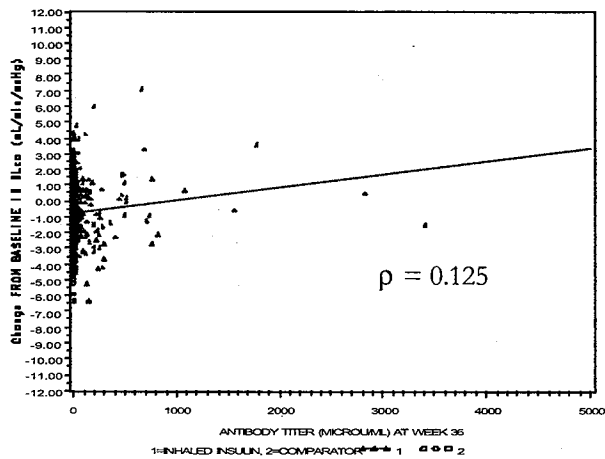
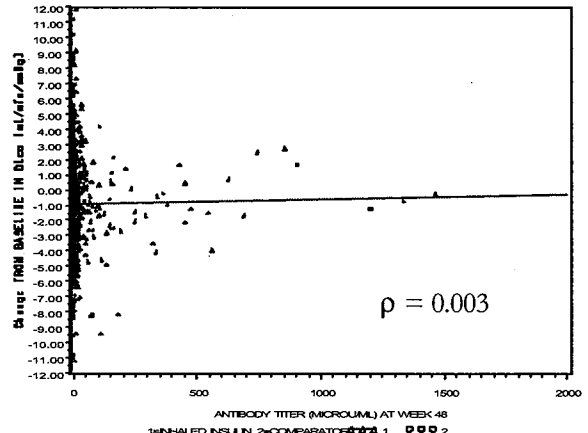
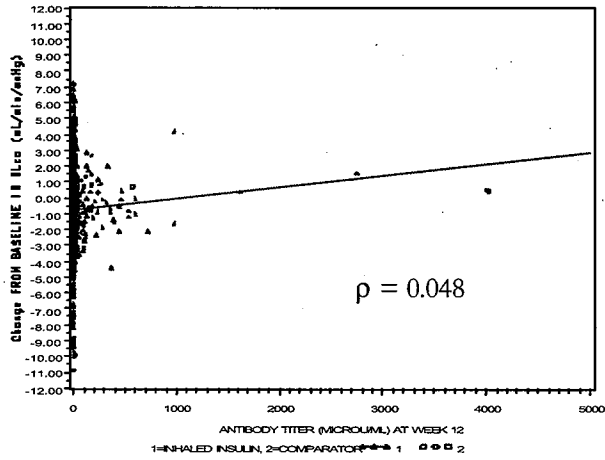
AA: Mean Change in TLC by Average and Cumulative Daily Insulin Dose at Week 48 (Study 1022)

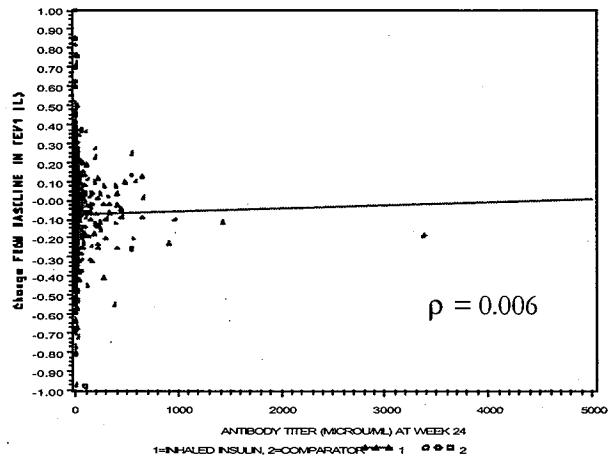
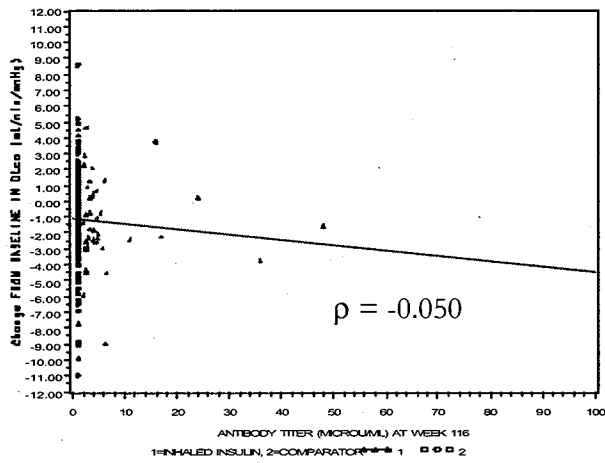
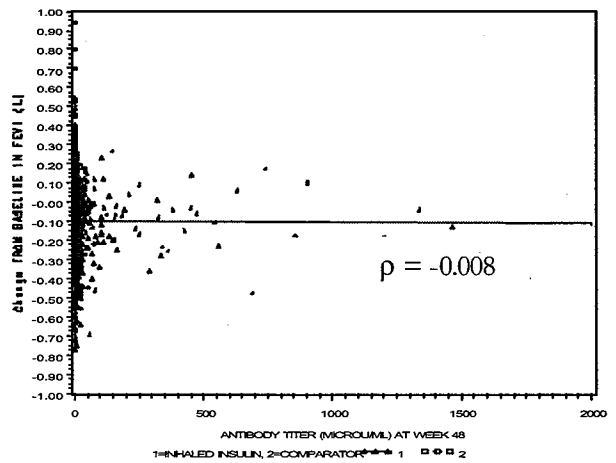
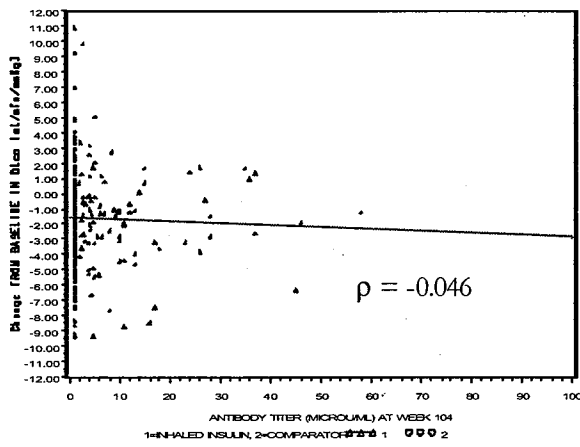




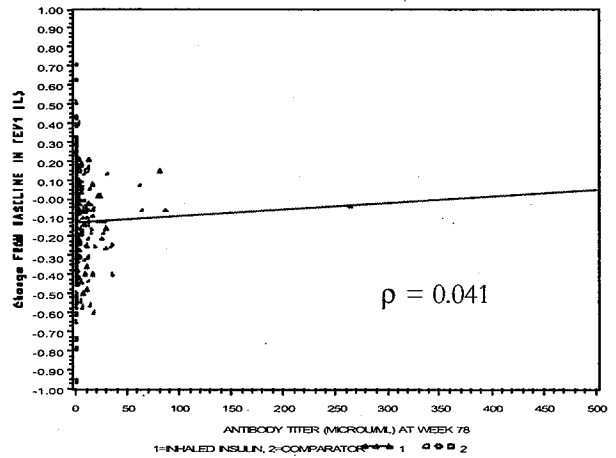
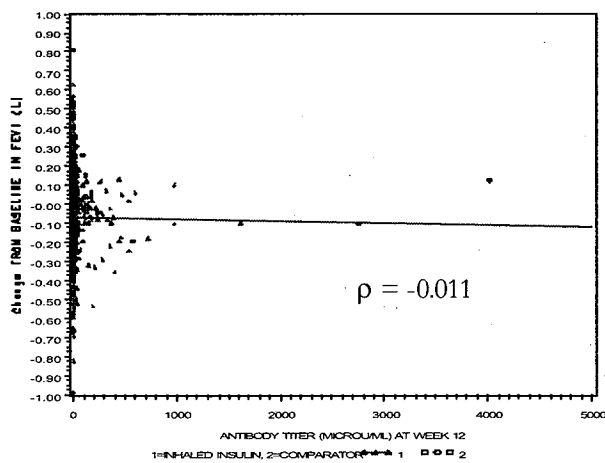
II. Type 2 Data

A: Change from Baseline in DLco by Antibody Titer

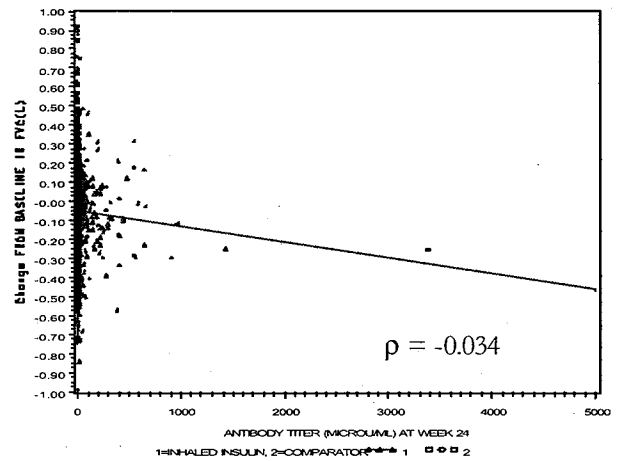
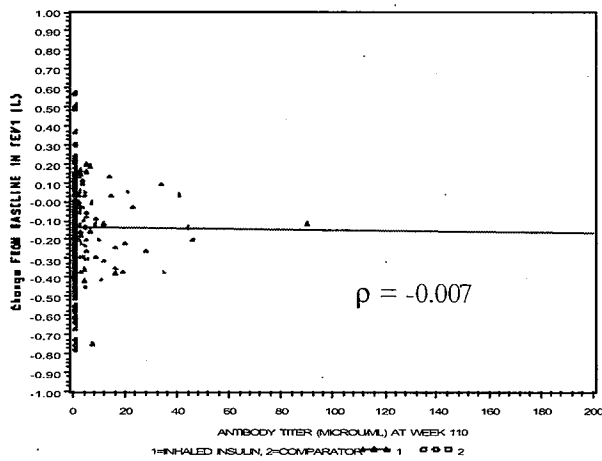
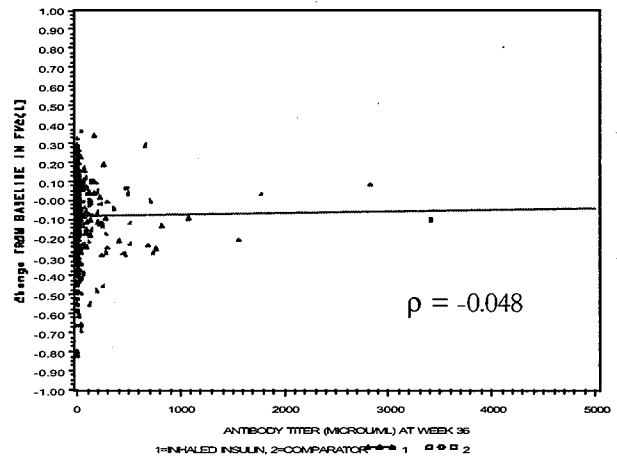
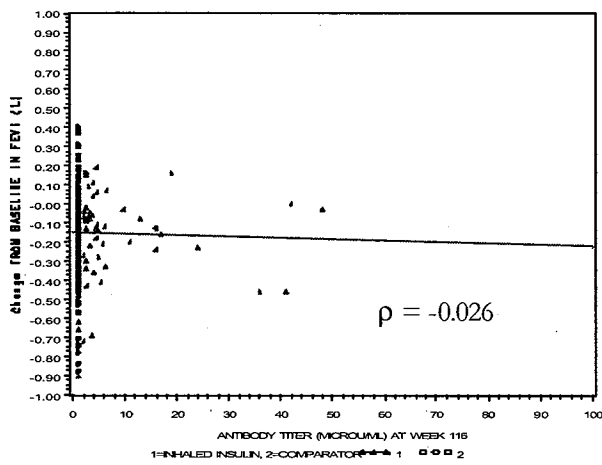
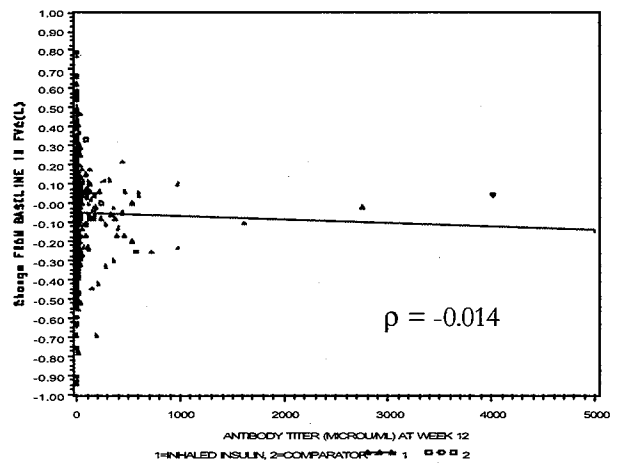
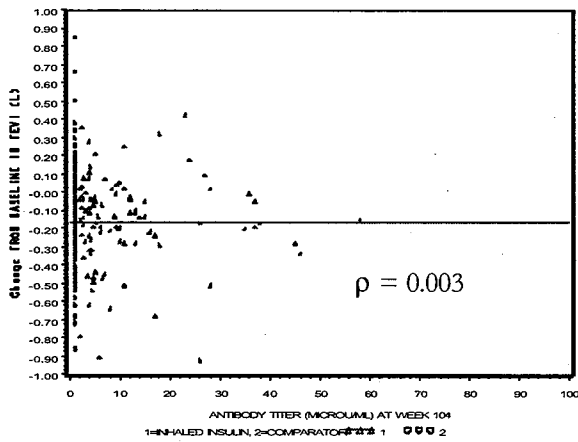


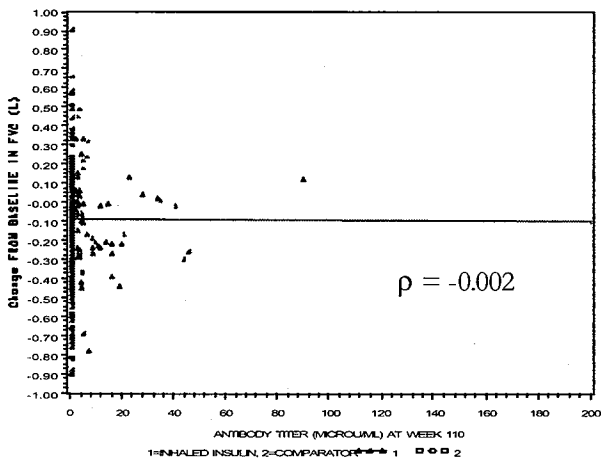
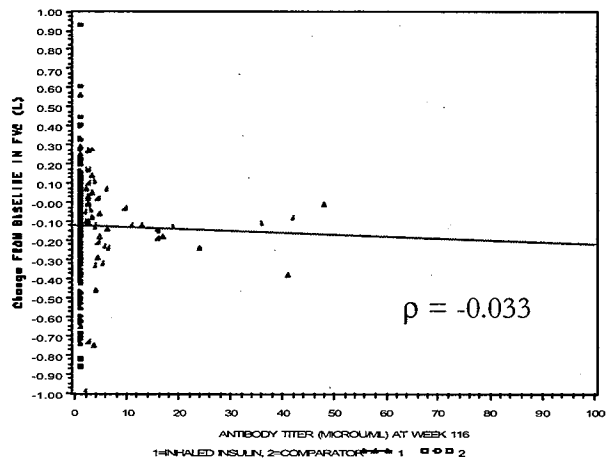
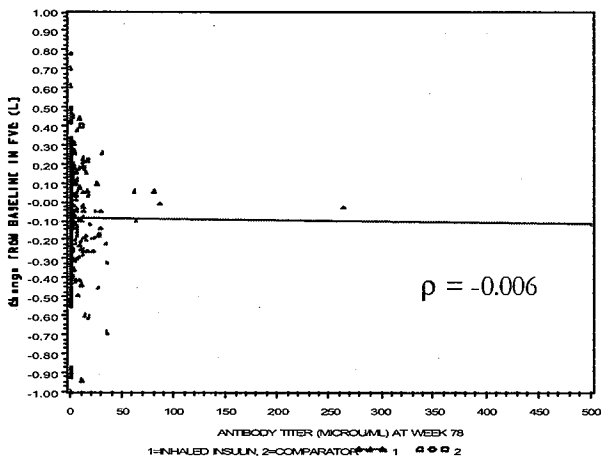
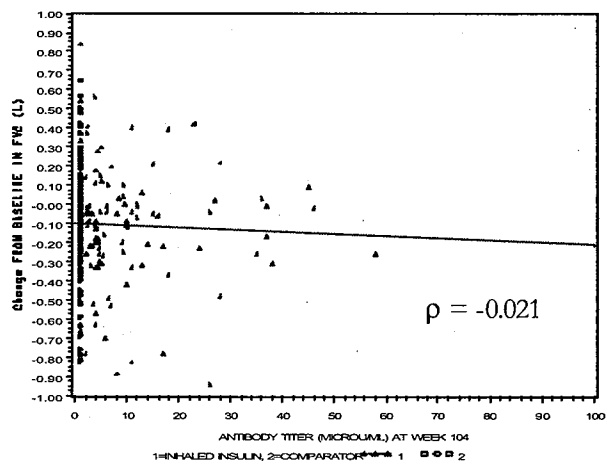
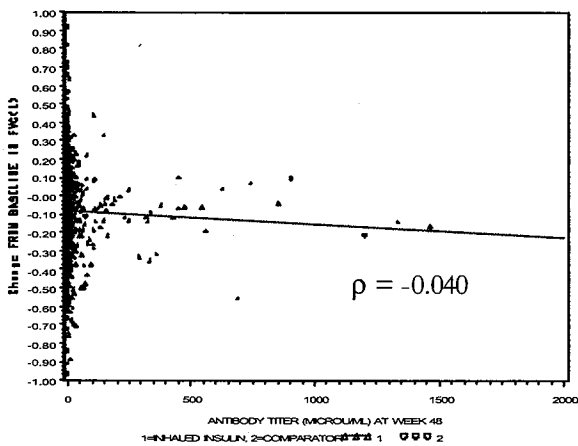


B: Change from Baseline in FEV1 by Antibody Titer

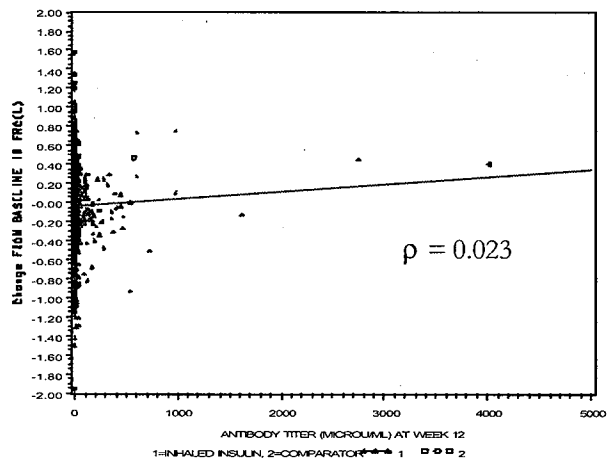


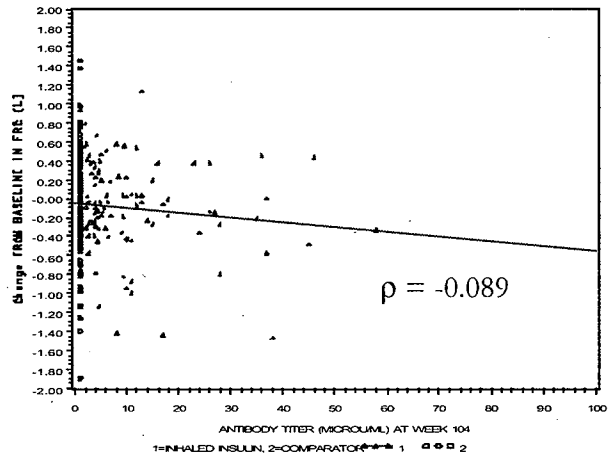
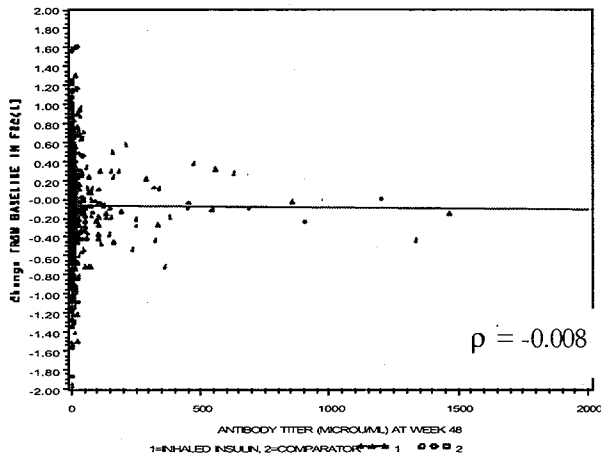
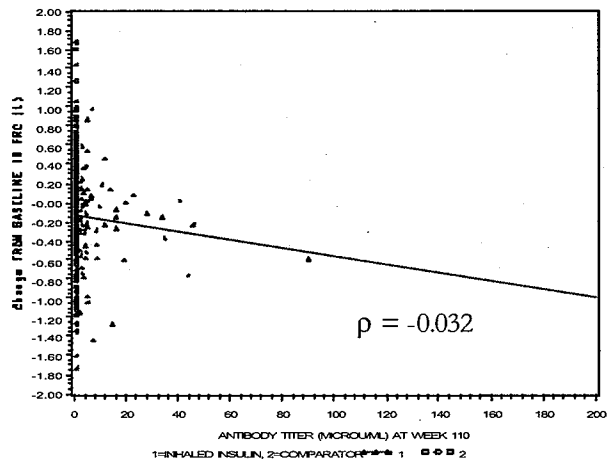
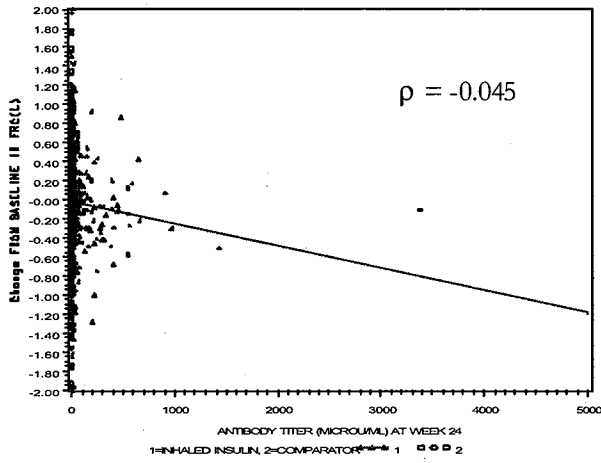
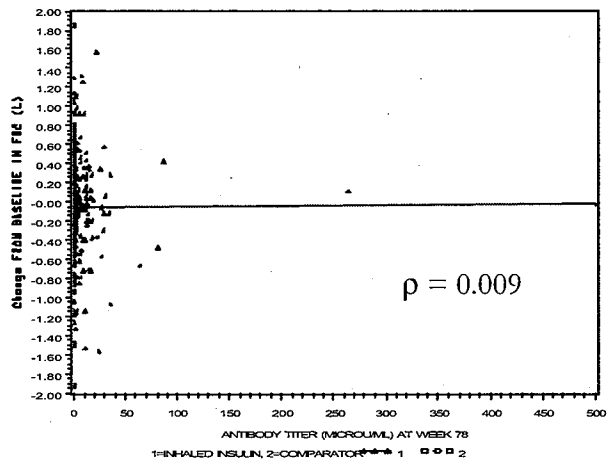
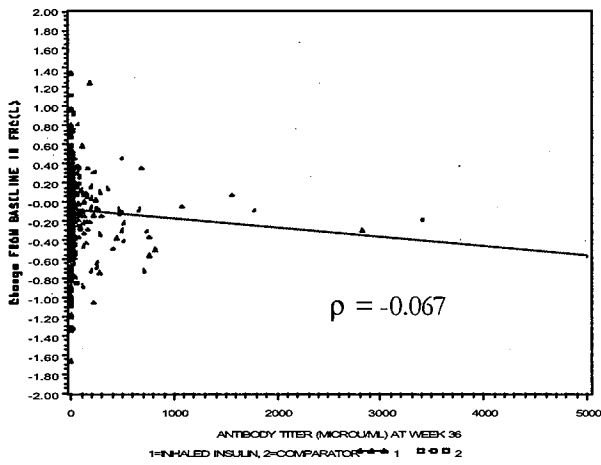
C: Change from Baseline in FVC by Antibody Titer in Pooled Study

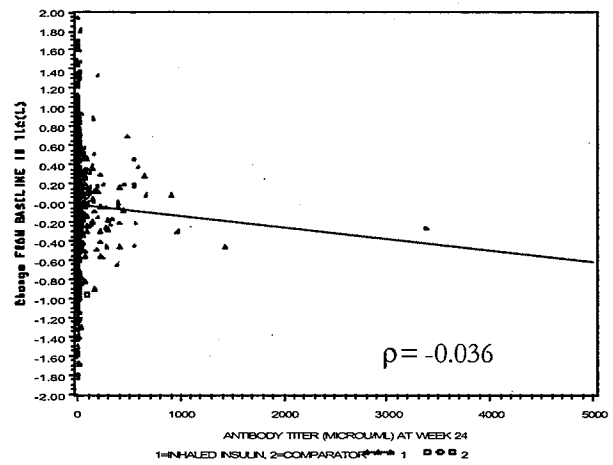
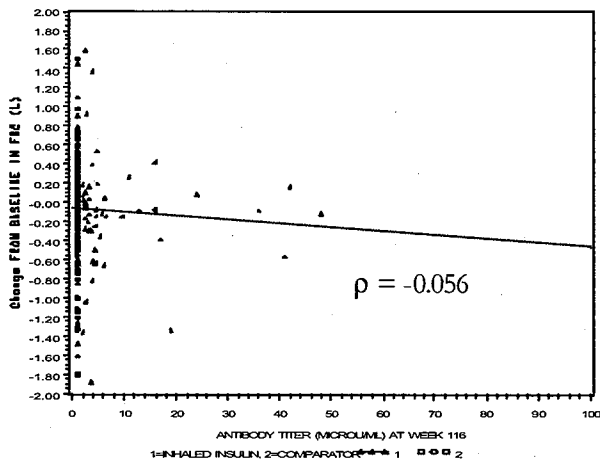




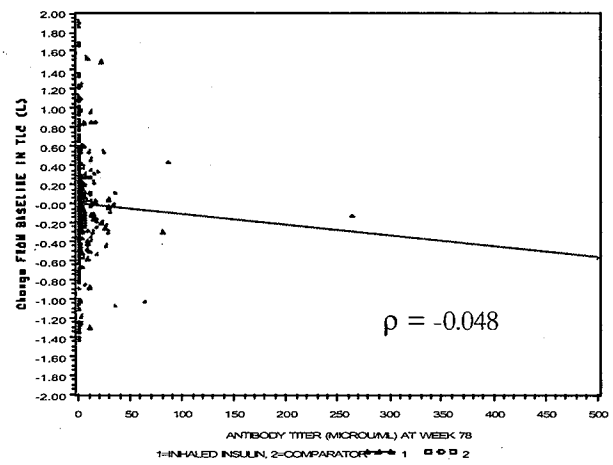
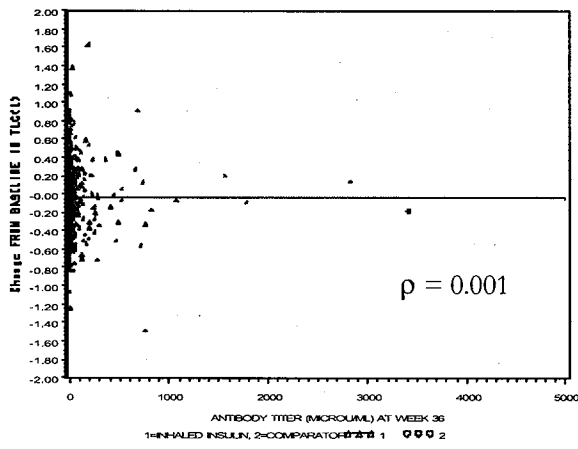
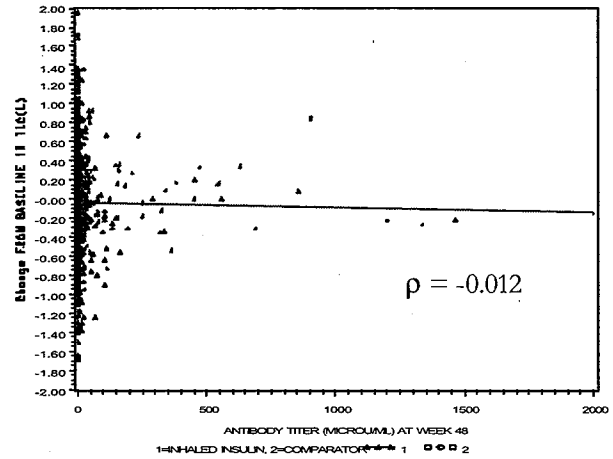
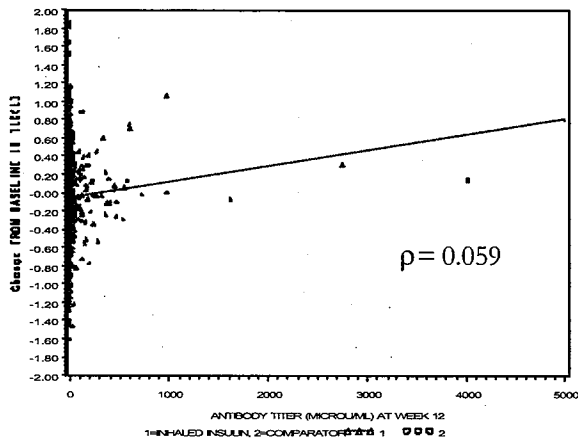
D: Change from Baseline in FRC by Antibody Titer

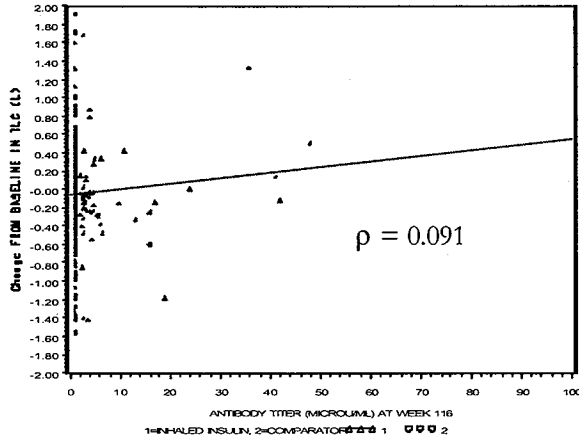
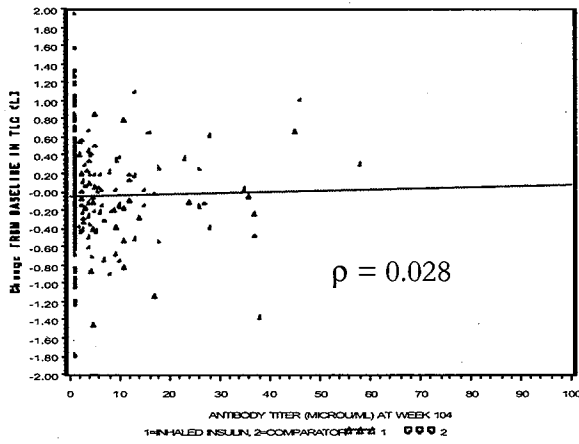
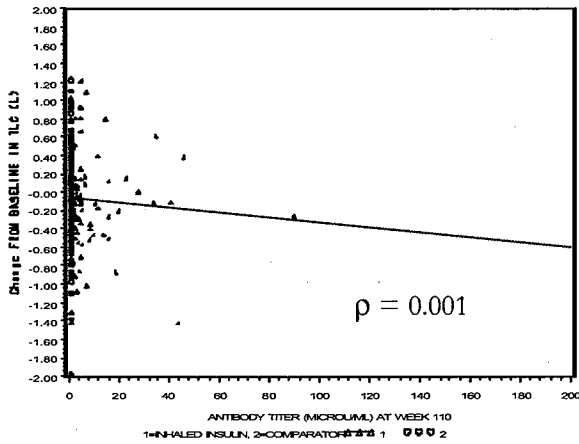






E: Change from Baseline in TLC by Antibody





F: Mean Daily Insulin Dose (mg) over Time, All Subjects (Studies 1001 - 1002)

Week	N	Mean	SD	Min – Max
2	454	8.27	4.06	1.0 – 24.0
4	445	9.97	4.67	0.42 – 33.0
6	447	11.07	5.51	2.0 – 42.5
10	444	11.74	6.12	2.0 – 52.8
14	434	12.16	6.65	0 – 57.1
18	431	12.51	6.86	2.0 – 57.4
24	439	12.76	6.57	2.0 – 54.1
30	323	13.38	6.91	0.24 – 58.7
36	329	13.79	7.38	0 – 56.8
44	325	14.46	8.22	1.0 – 65.7
52	314	14.70	8.28	1.7 – 69.3
65	168	15.39	7.79	2.0 – 35.7
78	167	15.62	7.92	2.0 – 35.4
91	161	15.93	8.02	0.8 – 40.3
104	154	16.82	8.24	1.5 – 39.0

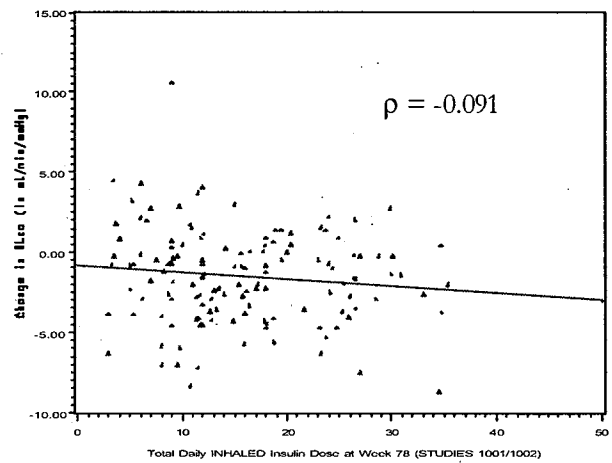
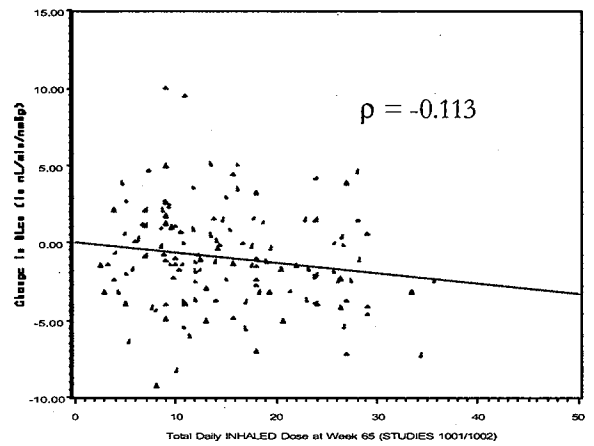
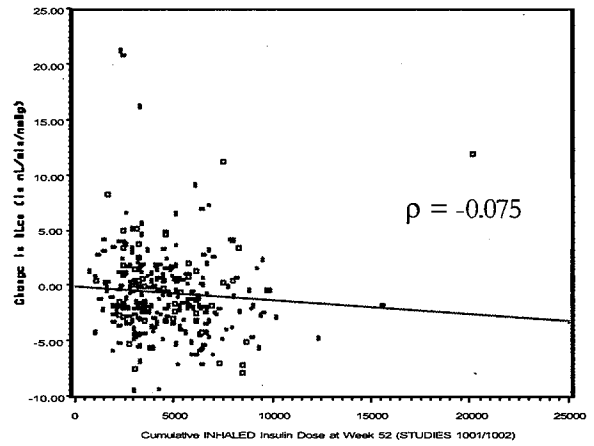
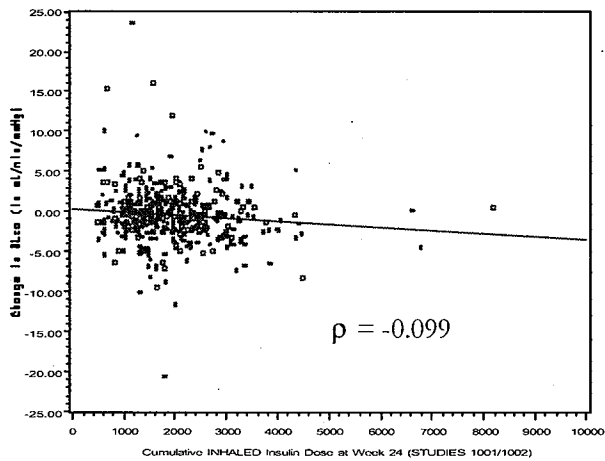
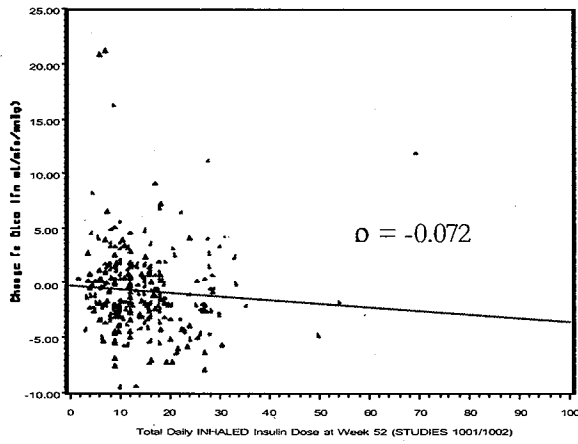
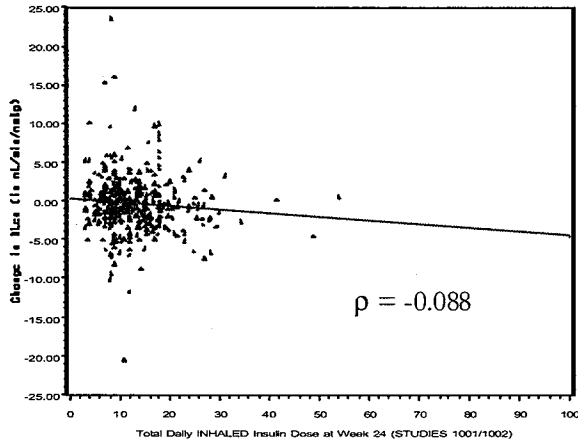
G: Average Total Daily Inhaled Insulin Dose (mg) Merged with PFT, Protocols 1001-1002

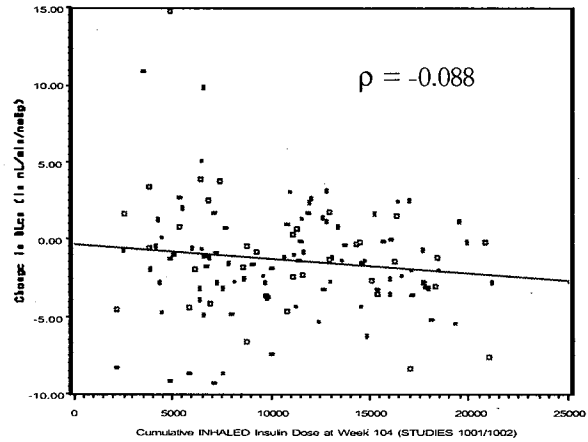
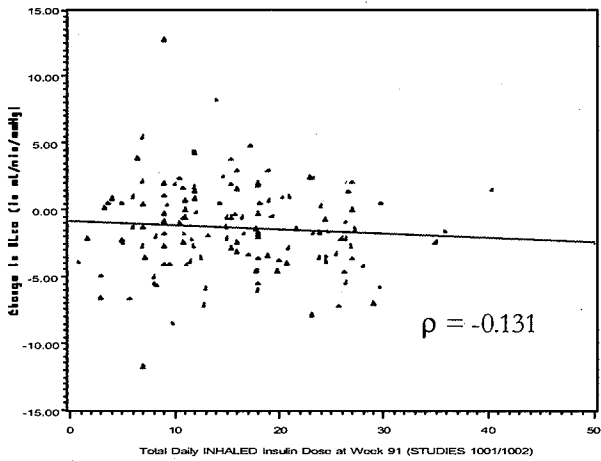
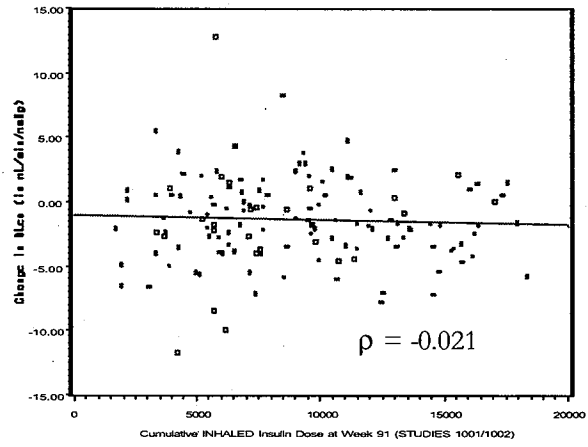
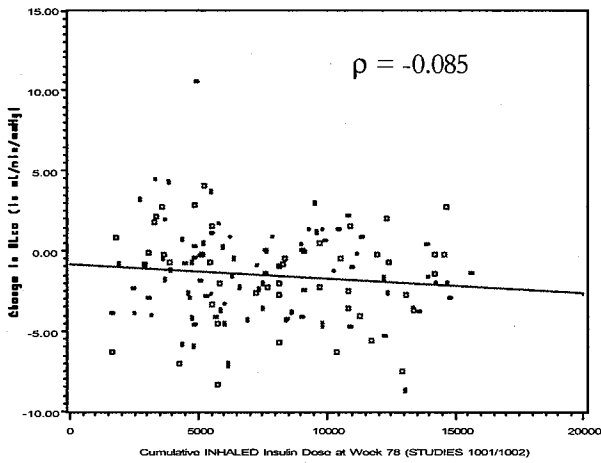
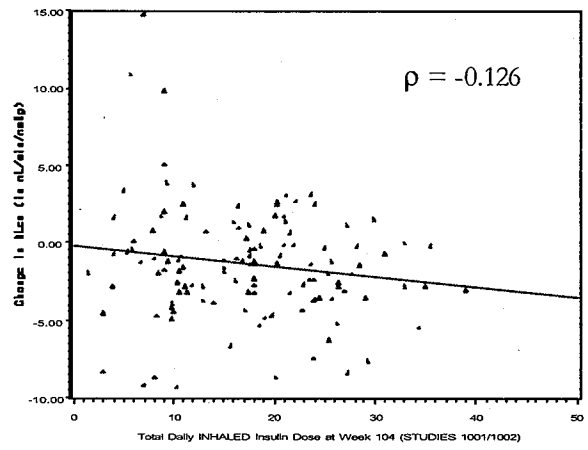
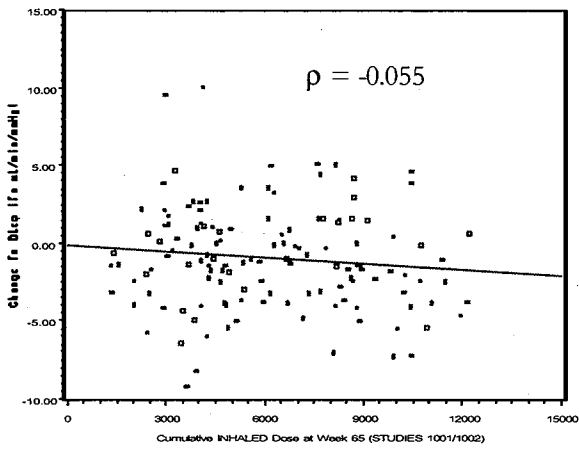
Week	N	Mean	SD	Min – Max
24	426	12.69	6.59	2.0 – 54.1
36	308	13.87	7.50	0 – 56.8
52	302	14.74	8.34	1.7 – 69.3
65	155	15.13	7.76	2.0 – 35.7
78	160	15.72	7.99	2.0 – 35.4
91	152	15.69	8.00	0.8 – 40.3
104	141	17.14	8.32	1.5 – 39.0

H: Mean Change in DLco by Average and Cumulative
Daily Insulin Dose (Studies 1001 - 1002)

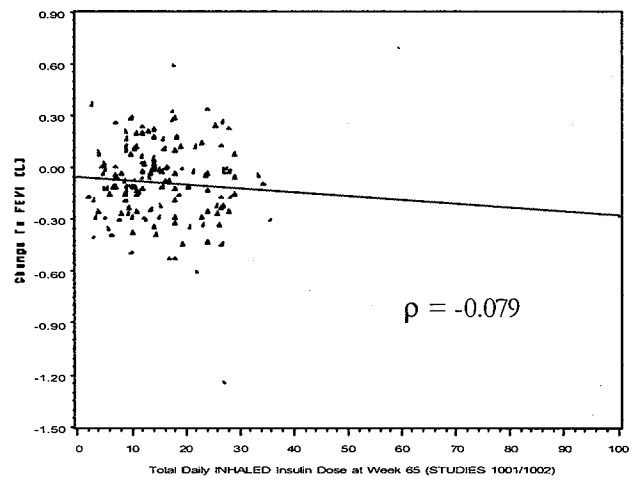
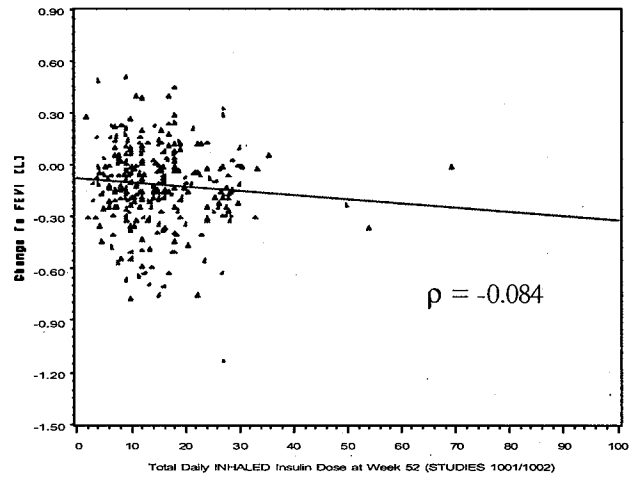
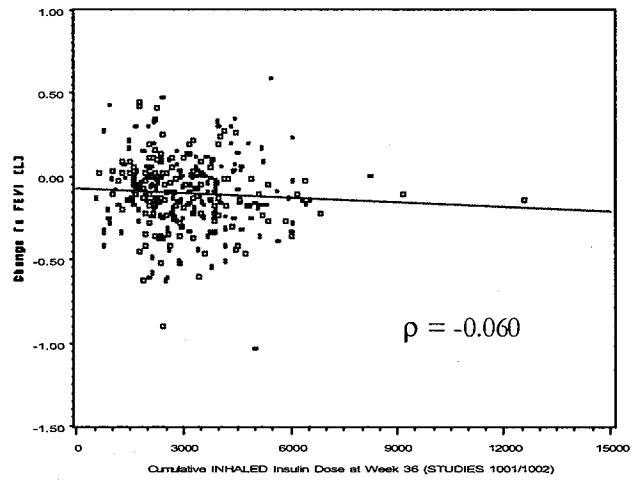
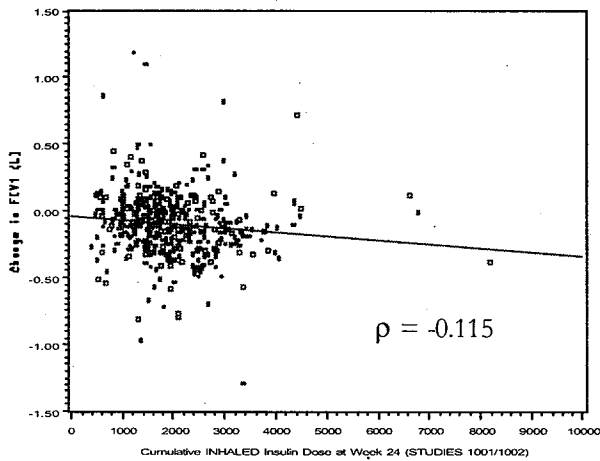
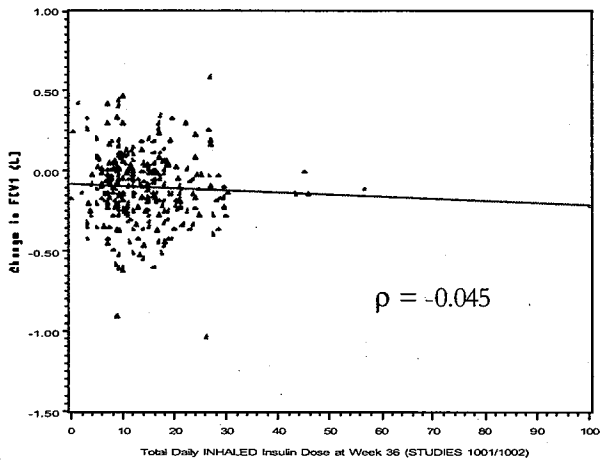
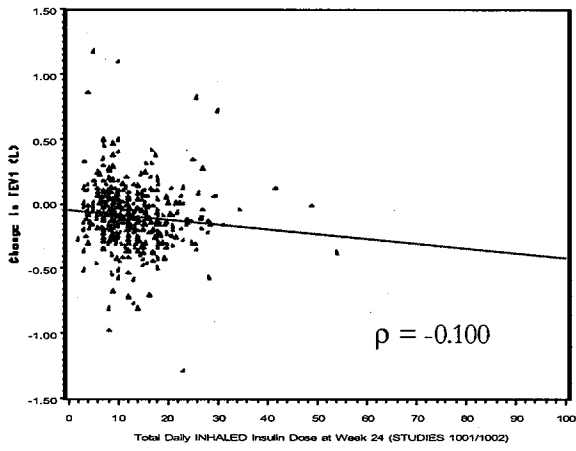
Red: INHALED GROUP

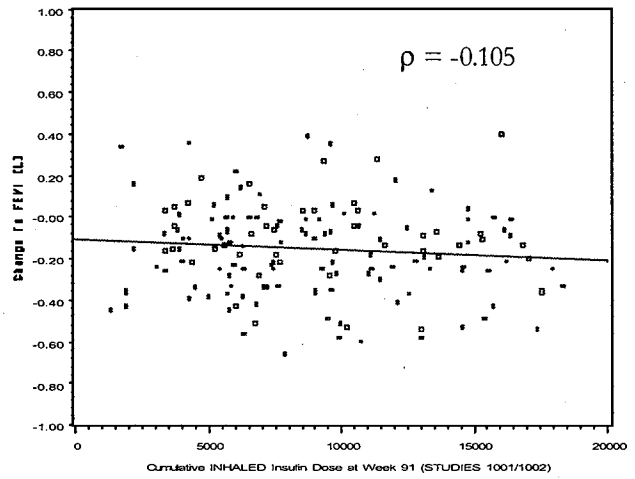
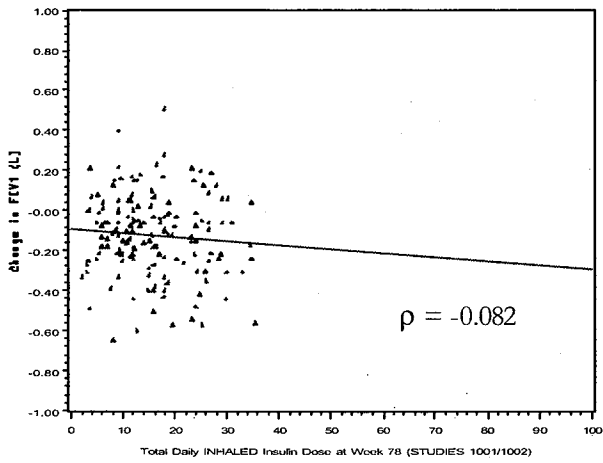
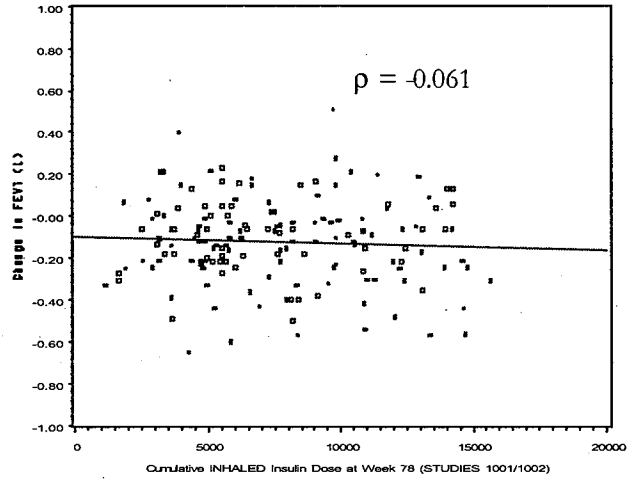
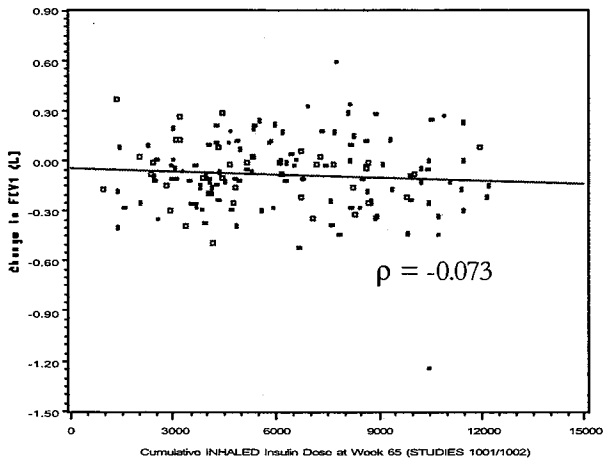
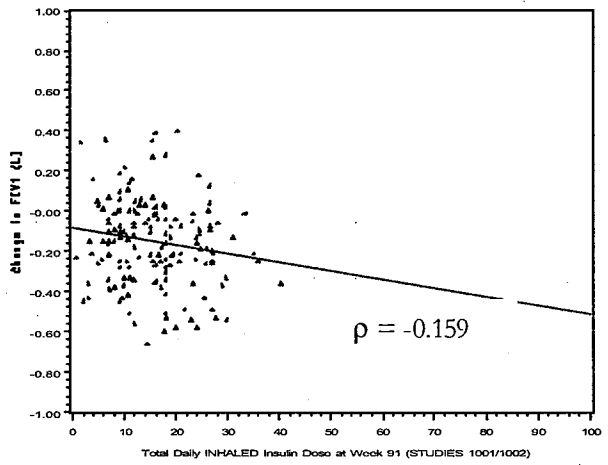
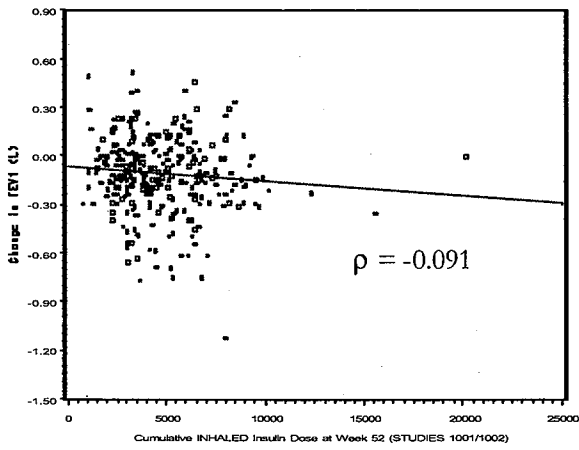
GREEN: COMPARATOR GROUP

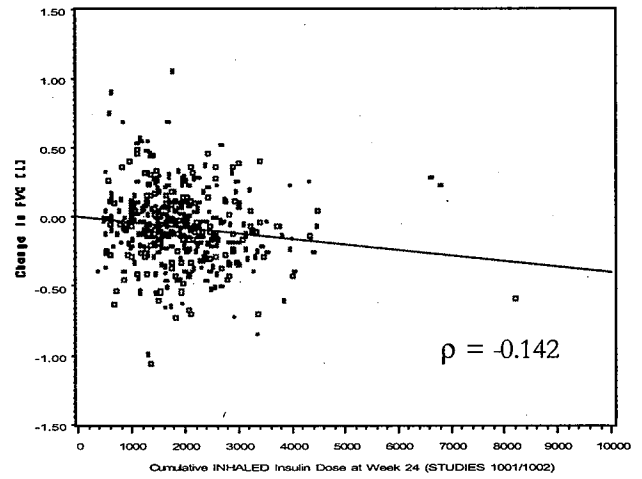
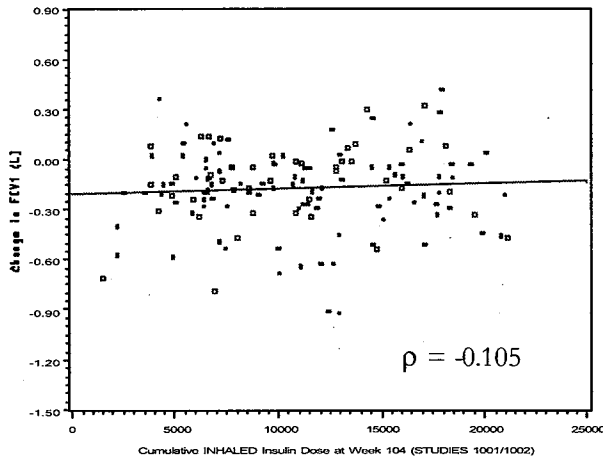
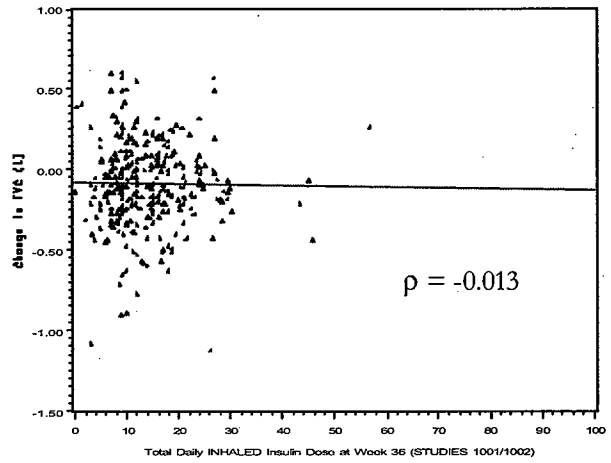
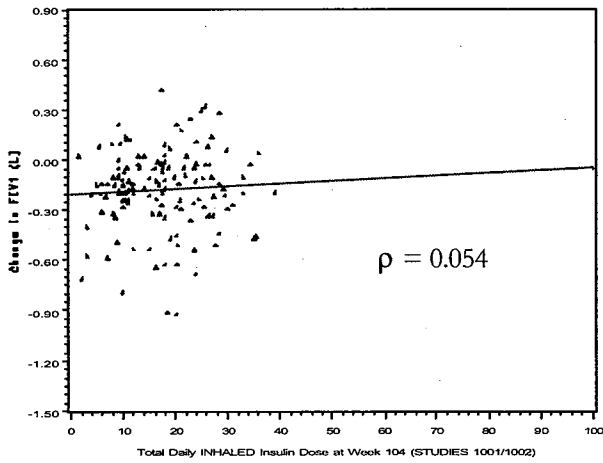




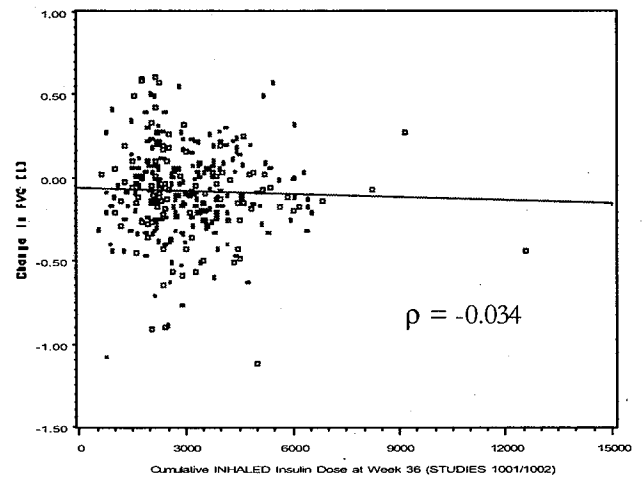
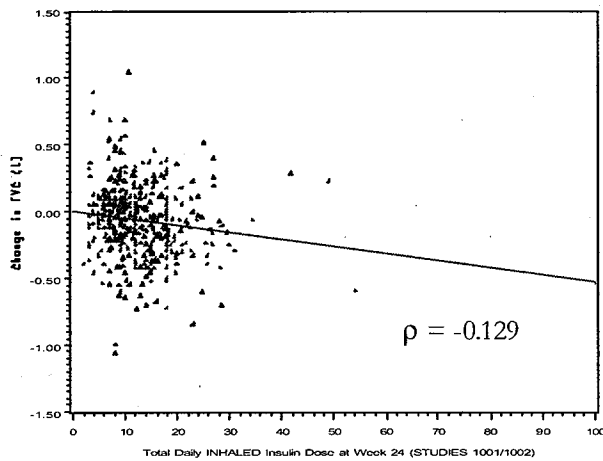
I: Mean Change in FEV1 by Average and Cumulative Daily Insulin Dose (Studies 1001 - 1002)

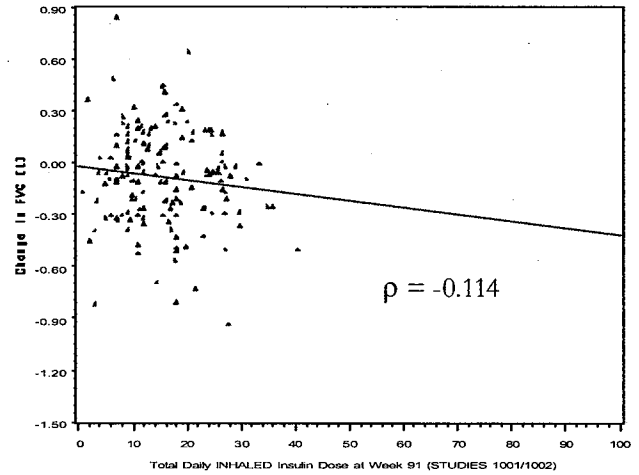
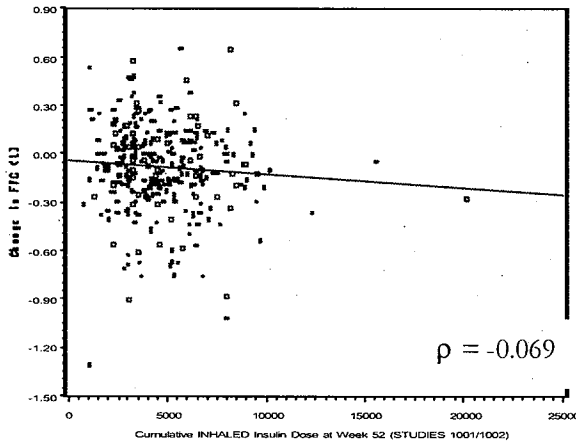
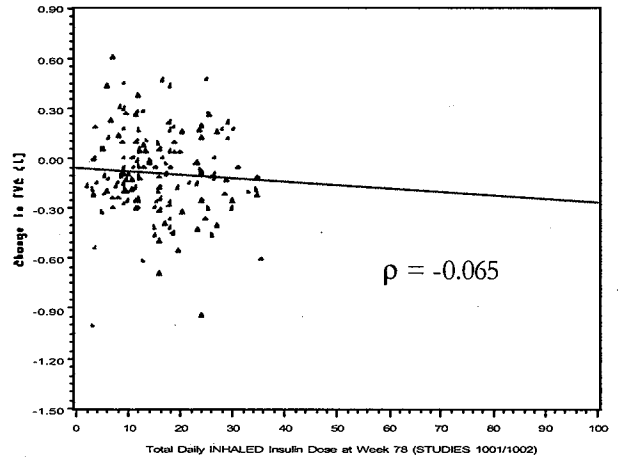
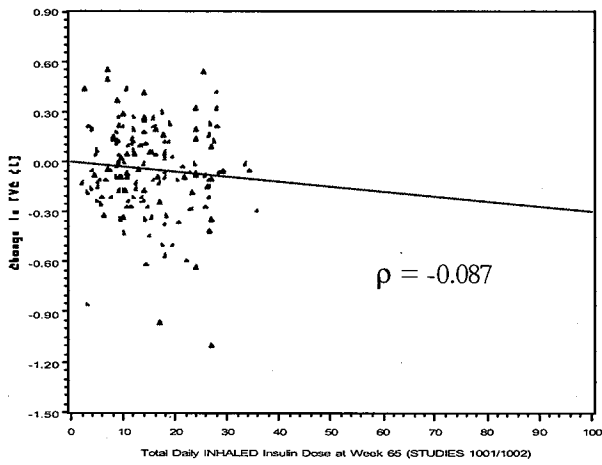
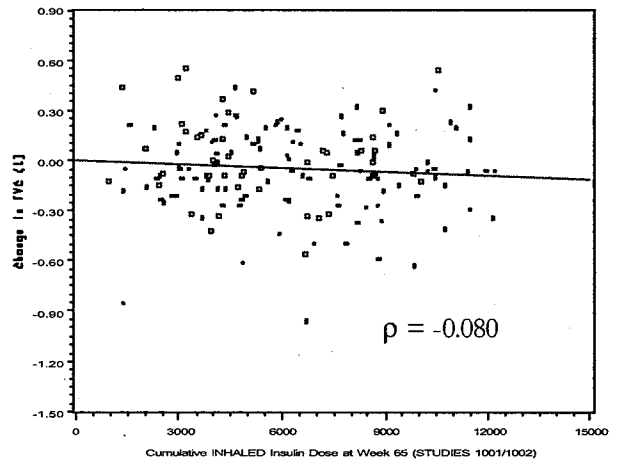
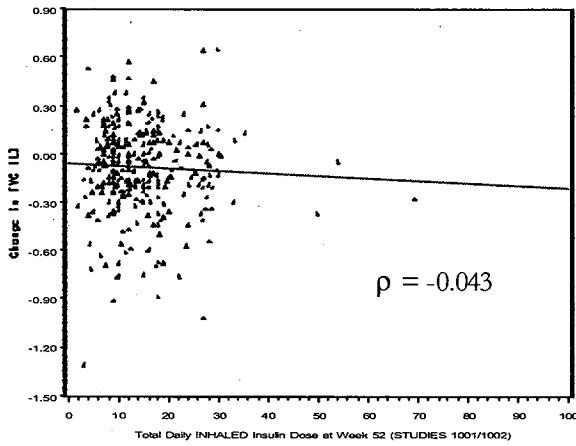


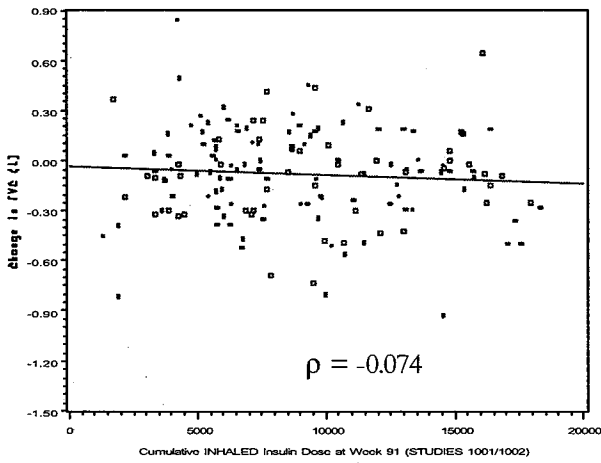
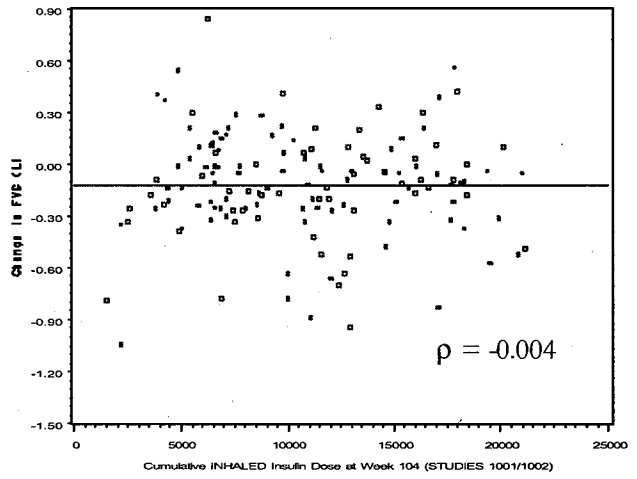
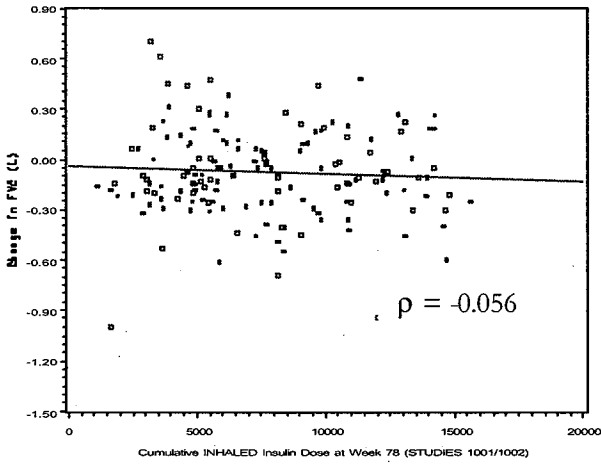




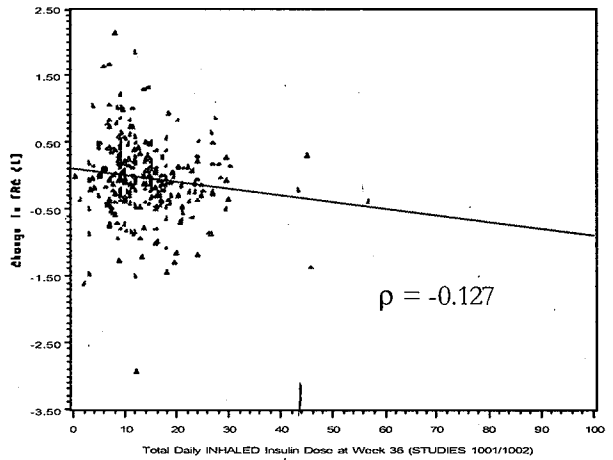
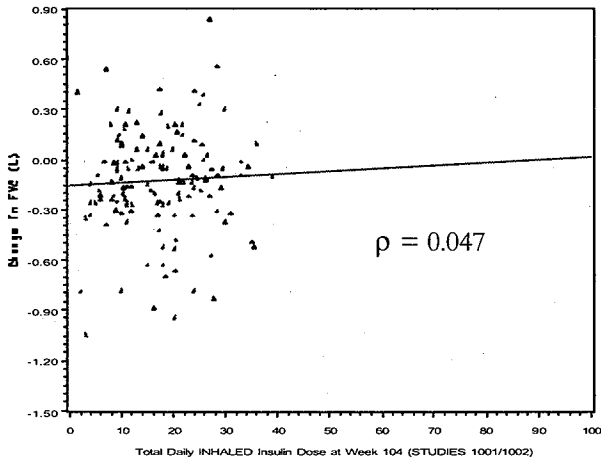
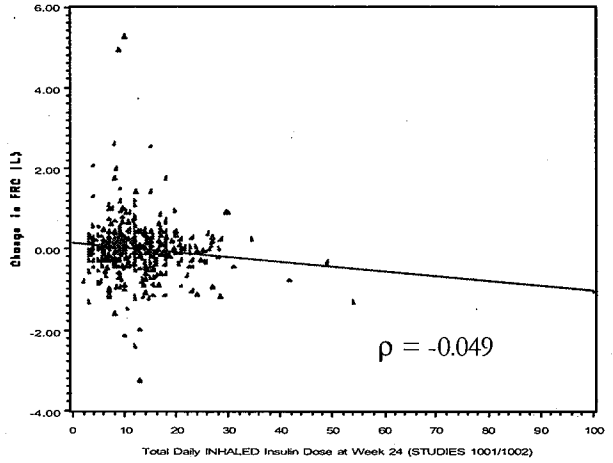
J: Mean Change in FVC by Average and Cumulative Daily Insulin Dose (Studies 1001 - 1002)

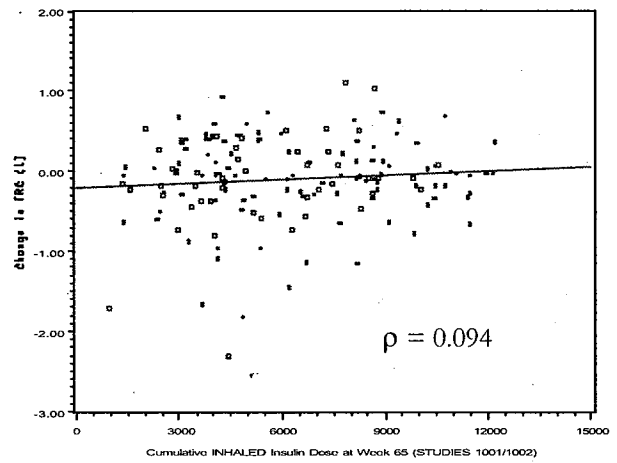
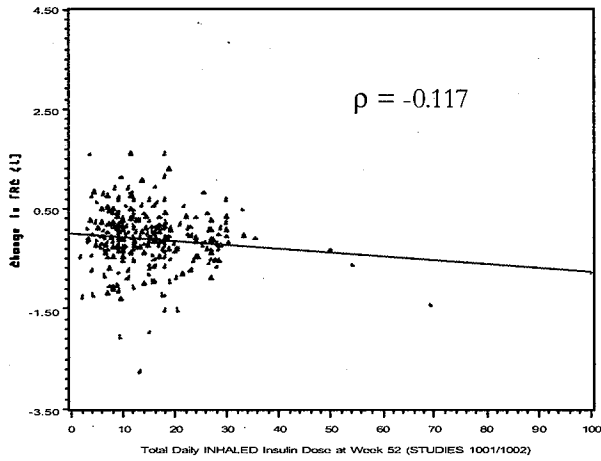
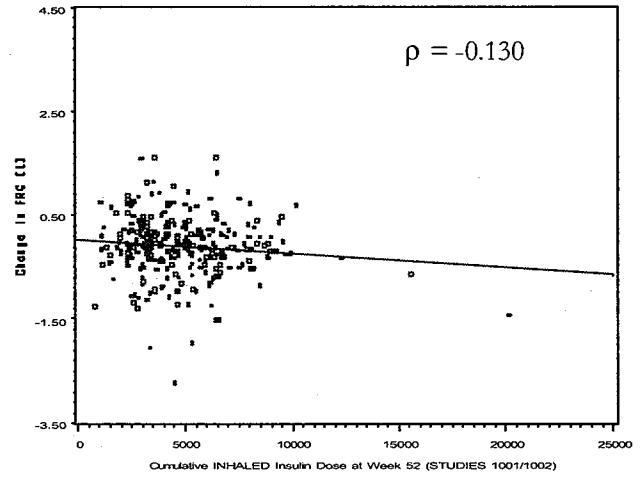
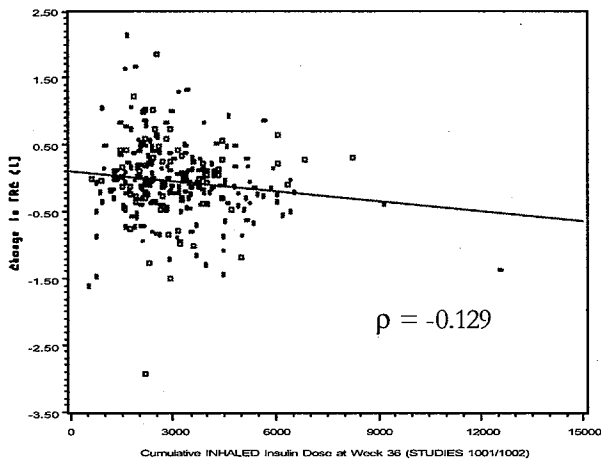
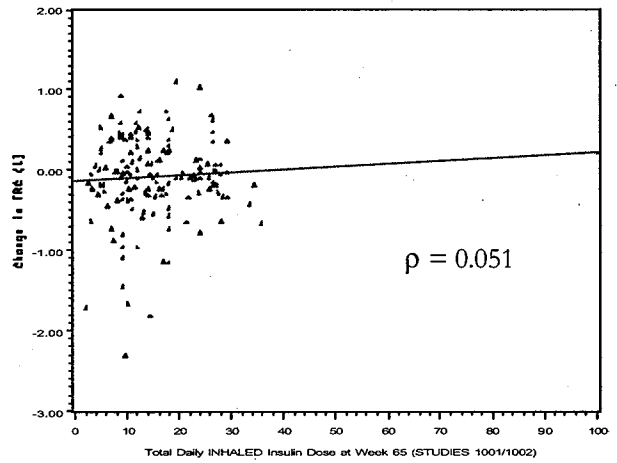
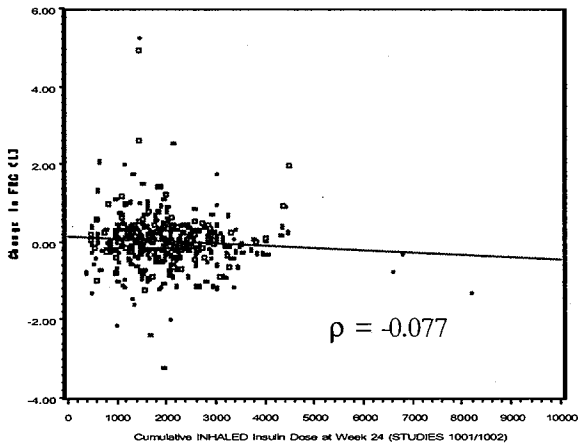


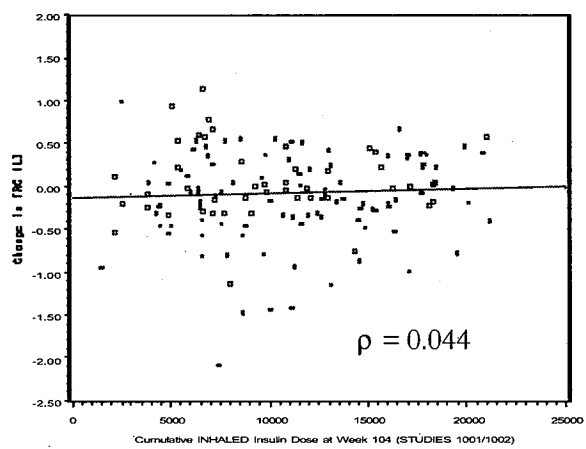
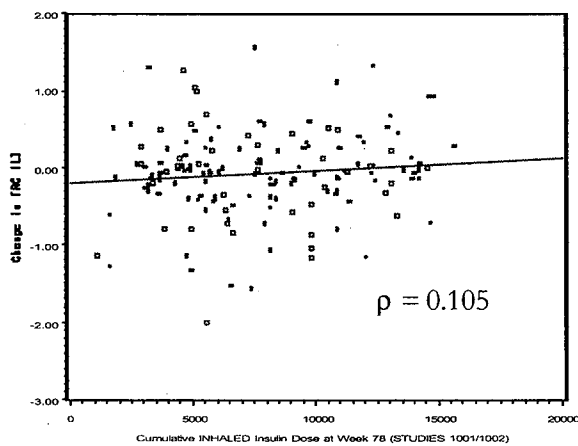
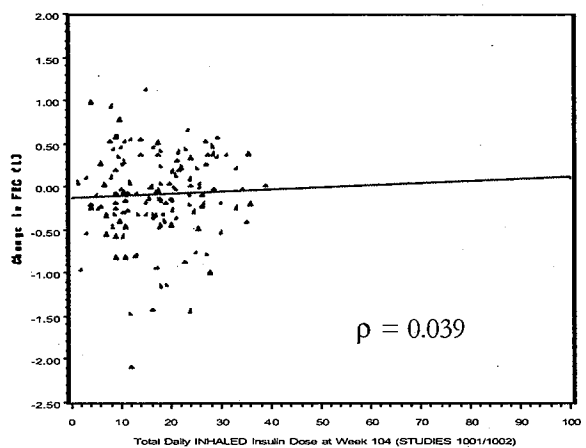
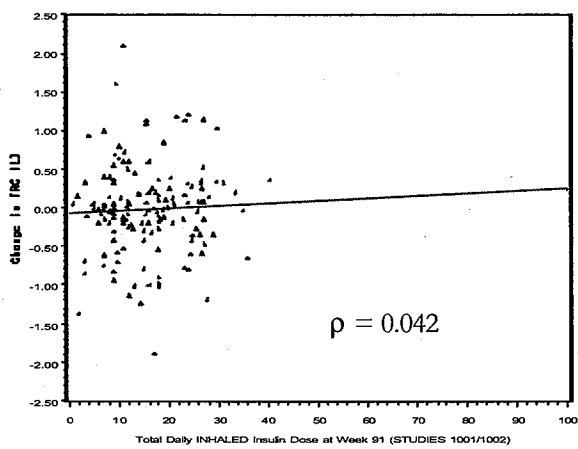
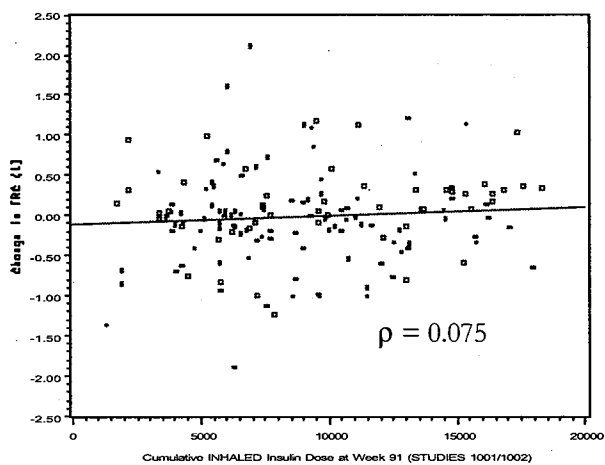
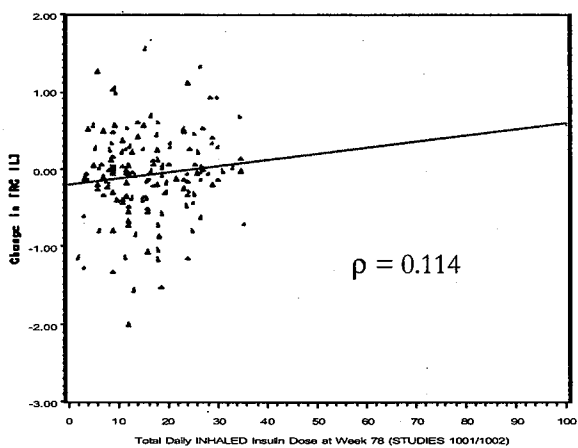




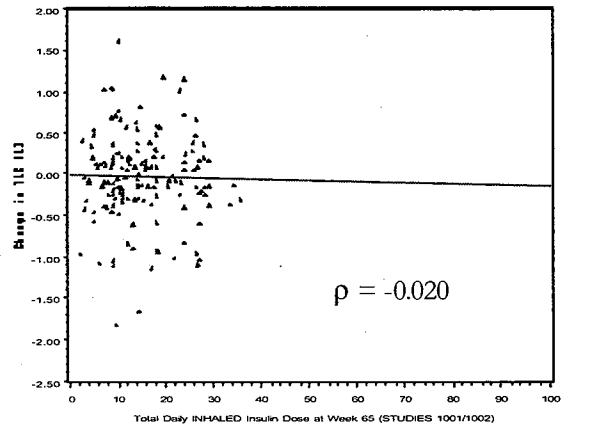
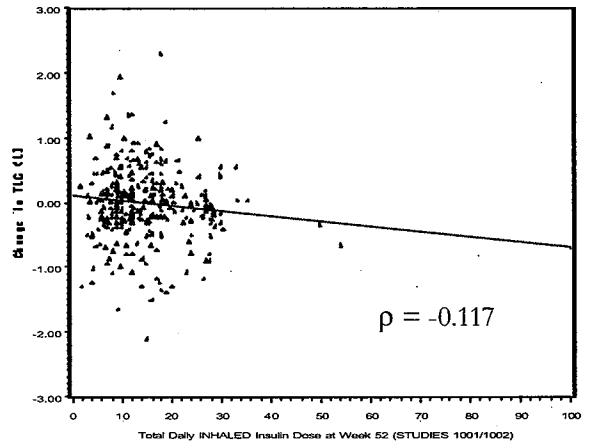
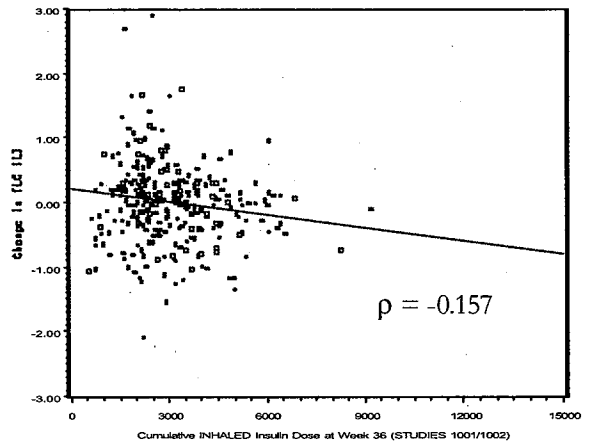
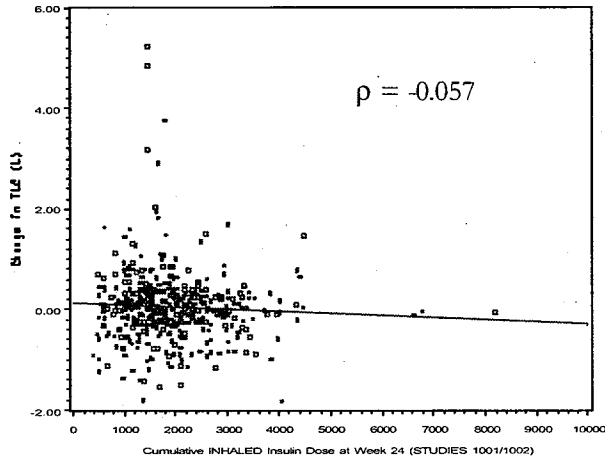
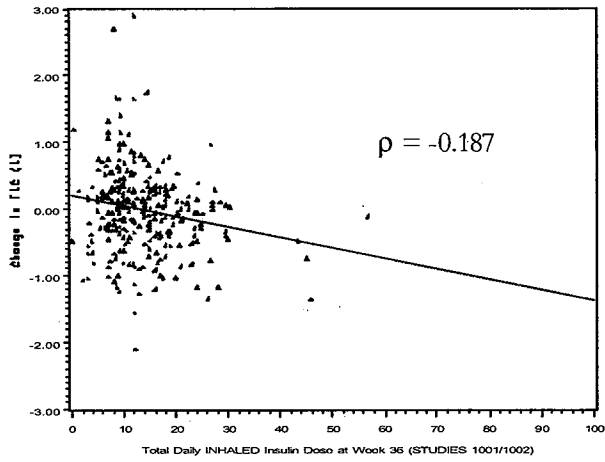
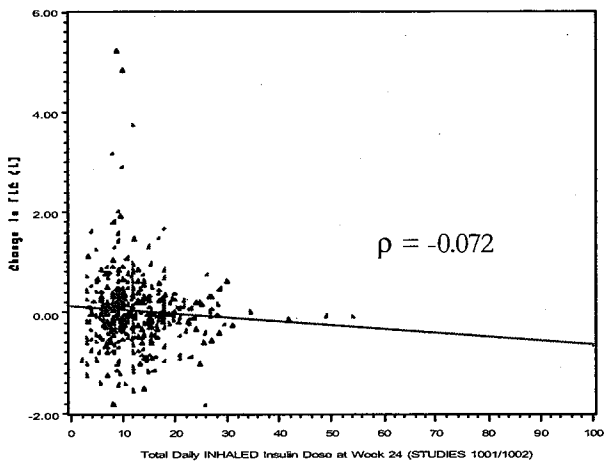
K: Mean Change in FRC by Average and Cumulative Daily Insulin Dose (Studies 1001 - 1002)

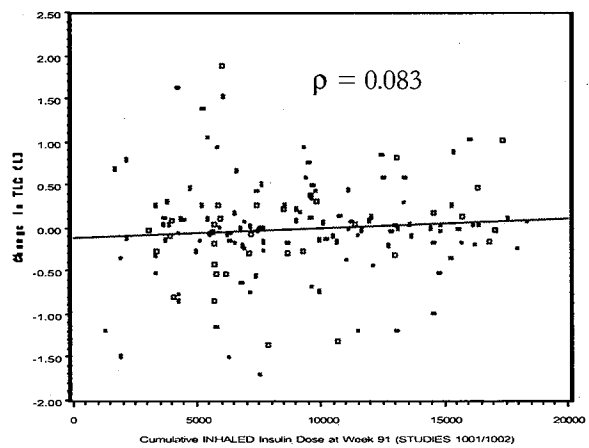
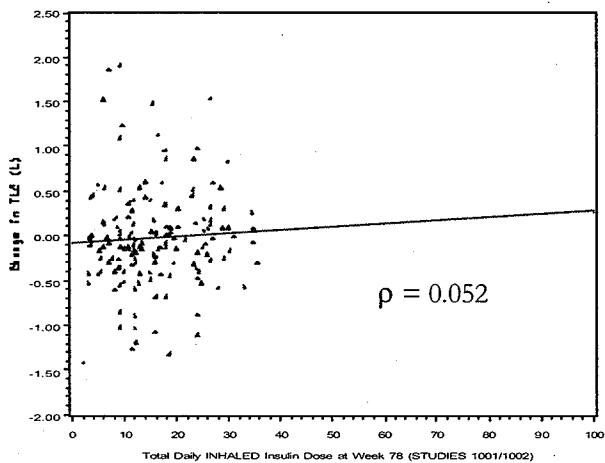
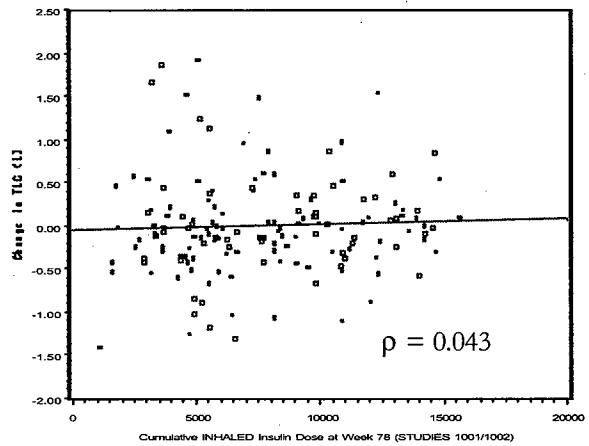
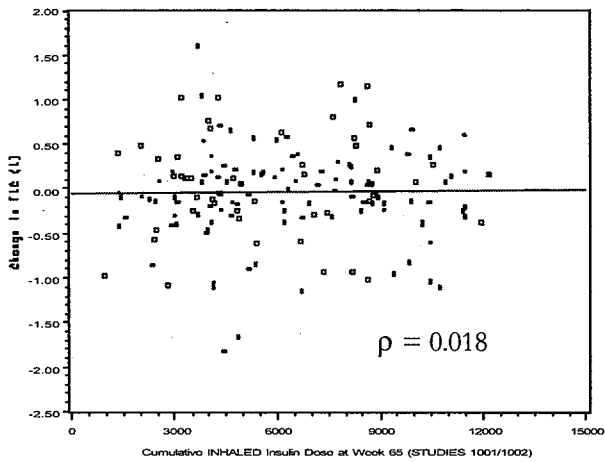
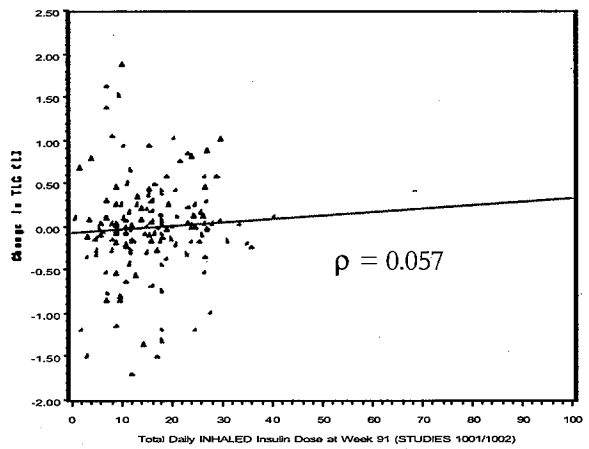
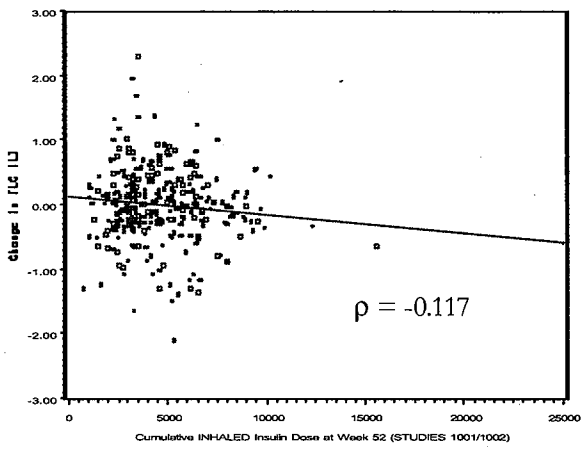


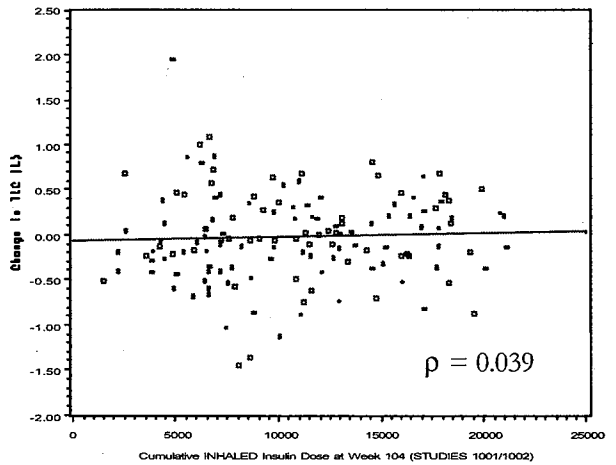
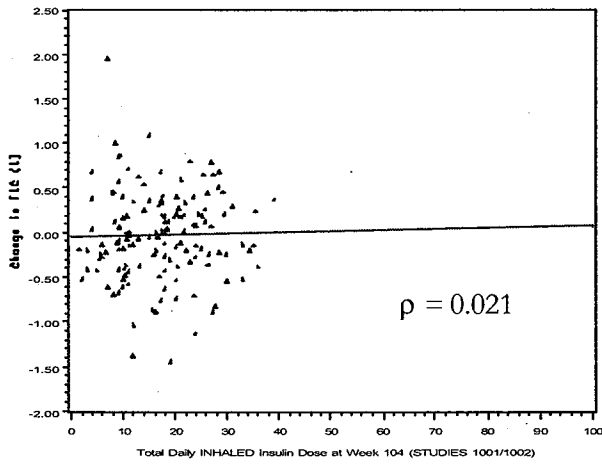




L: Mean Change in TLC by Average and Cumulative Daily Insulin Dose (Studies 1001-1002)







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Concur with review.