Appendix H CRFs for All Patients with Adverse Experiences Leading to Withdrawal, Serious Adverse Experiences and Deaths

Adverse Experiences Leading to Withdrawal

PID
329.001.00061
329.001.00063
329.001.00065
329.001.00066
329.001.00067
329.001.00070
329.002.00050
329.002.00056
329.001.00205
329.003.00073
329.003.00088
329.004.00014
329.002.00243
329.002.00245
329.005.00003
329.005.00005
329.002.00321
329.002.00322
329.003.00290
329.005.00110
329.004.00211
329.003.00313
329.005.00113
329.004.00215
329.006.00038
329.006.00040
329.005.00152
329.007.00139
329.007.00141
329.007.00143
329.007.00269
329.007.00270
329.007.00307
329.009.00127
329.009.00128
329.009.00171
329.009.00195

329.009.00203
329.009.00236
329.009.00240
329.009.00302
329.009.00330
329.011.00163
329.012.00217
329.012.00226

Serious Adverse Experiences

PID
329.001.00065
329.001.00123
329.002.00106
329.003.00089
329.002.00245
329.002.00321
329.003.00248
329.003.00250
329.003.00313
329.004.00215
329.006.00038
329.005.00333
329.007.00270
329.007.00307
329.009.00201
329.009.00240
329.012.00217
329.012.00223

Paroxetine - Protocol 329
Table 13.37
Number (%) of Patient Having CGI Global Improvement of 1 or 2
Acute Phase
Intent to Treat Population

	PAROXETINE n/N	%	IMIPRAMINE n/N	%	PLACEBO n/N	%	-- Pairwise Comparisons --- Par vs Pla		Imp vs Pla
Week 1	6 /88	(6.8)	3 /90	(3.3)	3 /84	(3.6)	0.481		0.892
Week 2	17 /80	(21.3)	16 /89	(18.0)	17 /79	(21.5)	0.992		0.677
Week 3	33 /76	(43.4)	22 /78	(28.2)	23 /75	(30.7)	0.095		0.986
Week 4	39 /76	(51.3)	25 /69	(36.2)	32 /73	(43.8)	0.314		0.496
Week 5	33 /72	(45.8)	35 /68	(51.5)	31 /70	(44.3)	0.853		0.202
Week 6	44 /73	(60.3)	37 /61	(60.7)	41 /66	(62.1)	0.825		0.980
Week 7	43 /66	(65.2)	34 /53	(64.2)	38 /63	(60.3)	0.602		0.710
Week 8	53 /67	(79.1)	38 /56	(67.9)	40 /66	(60.6)	0.020	*	0.506
Endpoint	59 /90	(65.6)	49 /94	(52.1)	42 /87	(48.3)	0.020	*	0.642

Only patients with one or more on-therapy evaluations are included.
* - significantly different from placebo for alpha = 0.05
Treatment p-value obtained from categorical analysis using a model with effects for treatment and investigator.

Appendix H:
CRF for all Patient with Adverse Experiences Leading to Withdrawal, Serious Adverse Experiences and Deaths

sent under separate cover