



Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = All Indications

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	8958	41.4	13.54	40.0	16	91	3461 ( 38.6%)	5496 ( 61.4%)	776 ( 8.7%)	6821 ( 76.1%)
	PLACEBO	5953	41.1	13.52	39.0	16	87	2323 ( 39.0%)	3630 ( 61.0%)	496 ( 8.3%)	4348 ( 73.0%)
All Depression	PAROXETINE	3720	45.3	15.47	43.0	18	91	1533 ( 41.2%)	2187 ( 58.8%)	568 ( 15.3%)	3152 ( 84.7%)
	PLACEBO	2260	45.4	15.40	43.0	18	87	892 ( 39.5%)	1368 ( 60.5%)	400 ( 17.7%)	1858 ( 82.2%)
MDD	PAROXETINE	3455	46.0	15.57	44.0	18	91	1424 ( 41.2%)	2031 ( 58.8%)	413 ( 12.0%)	3042 ( 88.0%)
	PLACEBO	1978	46.5	15.50	44.0	18	87	788 ( 39.8%)	1190 ( 60.2%)	240 ( 12.1%)	1736 ( 87.8%)
IBD	PAROXETINE	149	33.6	10.37	32.0	18	74	49 ( 32.9%)	100 ( 67.1%)	147 ( 98.7%)	2 ( 1.3%)
	PLACEBO	154	34.1	11.80	32.0	18	70	54 ( 35.1%)	100 ( 64.9%)	152 ( 98.7%)	2 ( 1.3%)
Dysthymia	PAROXETINE	81	40.8	10.68	41.0	22	73	44 ( 54.3%)	37 ( 45.7%)	2 ( 2.5%)	79 ( 97.5%)
	PLACEBO	85	42.6	11.50	42.0	22	77	30 ( 35.3%)	55 ( 64.7%)	3 ( 3.5%)	82 ( 96.5%)
Bipolar	PAROXETINE	35	42.5	10.15	42.0	24	66	16 ( 45.7%)	19 ( 54.3%)	6 ( 17.1%)	29 ( 82.9%)
	PLACEBO	43	40.4	10.66	41.0	21	66	20 ( 46.5%)	23 ( 53.5%)	5 ( 11.6%)	38 ( 88.4%)
All Non-Depression	PAROXETINE	5238	38.6	11.15	38.0	16	78	1928 ( 36.8%)	3309 ( 63.2%)	208 ( 4.0%)	3669 ( 70.0%)
	PLACEBO	3693	38.4	11.46	38.0	16	85	1431 ( 38.7%)	2262 ( 61.3%)	96 ( 2.6%)	2490 ( 67.4%)
Panic	PAROXETINE	1092	36.9	10.42	36.0	18	74	419 ( 38.4%)	673 ( 61.6%)	8 ( 0.7%)	460 ( 42.1%)
	PLACEBO	903	36.9	10.54	36.0	17	72	371 ( 41.1%)	532 ( 58.9%)	5 ( 0.6%)	318 ( 35.2%)
OCD	PAROXETINE	698	39.1	13.08	38.0	16	78	391 ( 56.0%)	307 ( 44.0%)	123 ( 17.6%)	419 ( 60.0%)
	PLACEBO	416	38.3	12.27	37.0	16	74	225 ( 54.1%)	191 ( 45.9%)	50 ( 12.0%)	215 ( 51.7%)
SAD	PAROXETINE	943	37.2	10.50	37.0	18	70	487 ( 51.6%)	456 ( 48.4%)	0 ( 0.0%)	421 ( 44.6%)
	PLACEBO	643	37.2	11.34	37.0	18	85	336 ( 52.3%)	307 ( 47.7%)	0 ( 0.0%)	304 ( 47.3%)
GAD	PAROXETINE	904	41.2	13.50	41.0	18	78	345 ( 38.2%)	559 ( 61.8%)	0 ( 0.0%)	904 (100.0%)
	PLACEBO	697	41.8	13.64	40.0	18	81	258 ( 37.0%)	439 ( 63.0%)	1 ( 0.1%)	696 ( 99.9%)
PTSD	PAROXETINE	698	41.1	11.49	41.0	18	75	245 ( 35.1%)	453 ( 64.9%)	59 ( 8.5%)	636 ( 91.1%)
	PLACEBO	510	40.1	11.90	39.5	18	78	192 ( 37.6%)	318 ( 62.4%)	34 ( 6.7%)	474 ( 92.9%)
PMDD	PAROXETINE	820	36.5	5.48	37.0	19	49	0 ( 0.0%)	820 (100.0%)	16 ( 2.0%)	774 ( 94.4%)
	PLACEBO	438	36.0	5.97	36.0	19	49	0 ( 0.0%)	438 (100.0%)	3 ( 0.7%)	426 ( 97.3%)
Detoxification in Alcoholics	PAROXETINE	57	41.8	9.19	41.0	23	60	37 ( 64.9%)	20 ( 35.1%)	2 ( 3.5%)	55 ( 96.5%)
	PLACEBO	60	39.6	8.83	37.5	26	62	42 ( 70.0%)	18 ( 30.0%)	3 ( 5.0%)	57 ( 95.0%)
Fibromyalgia	PAROXETINE	26	45.2	9.66	46.5	29	63	4 ( 15.4%)	21 ( 80.8%)	0 ( 0.0%)	0 ( 0.0%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = All Indications

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Fibromyalgia	PLACEBO	26	43.2	10.44	43.0	21	68	7 ( 26.9%)	19 ( 73.1%)	0 ( 0.0%)	0 ( 0.0%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = All Depression

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	3720	45.3	15.47	43.0	18	91	1533 ( 41.2%)	2187 ( 58.8%)	568 ( 15.3%)	3152 ( 84.7%)
	PLACEBO	2260	45.4	15.40	43.0	18	87	892 ( 39.5%)	1368 ( 60.5%)	400 ( 17.7%)	1858 ( 82.2%)
MDD	PAROXETINE	3455	46.0	15.57	44.0	18	91	1424 ( 41.2%)	2031 ( 58.8%)	413 ( 12.0%)	3042 ( 88.0%)
	PLACEBO	1978	46.5	15.50	44.0	18	87	788 ( 39.8%)	1190 ( 60.2%)	240 ( 12.1%)	1736 ( 87.8%)
IBD	PAROXETINE	149	33.6	10.37	32.0	18	74	49 ( 32.9%)	100 ( 67.1%)	147 ( 98.7%)	2 ( 1.3%)
	PLACEBO	154	34.1	11.80	32.0	18	70	54 ( 35.1%)	100 ( 64.9%)	152 ( 98.7%)	2 ( 1.3%)
Dysthymia	PAROXETINE	81	40.8	10.68	41.0	22	73	44 ( 54.3%)	37 ( 45.7%)	2 ( 2.5%)	79 ( 97.5%)
	PLACEBO	85	42.6	11.50	42.0	22	77	30 ( 35.3%)	55 ( 64.7%)	3 ( 3.5%)	82 ( 96.5%)
Bipolar	PAROXETINE	35	42.5	10.15	42.0	24	66	16 ( 45.7%)	19 ( 54.3%)	6 ( 17.1%)	29 ( 82.9%)
	PLACEBO	43	40.4	10.66	41.0	21	66	20 ( 46.5%)	23 ( 53.5%)	5 ( 11.6%)	38 ( 88.4%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = MDD

Trial	Treatment	N	-----Age-----					-----Gender-----		-Baseline Suicidal Ideation-	
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	3455	46.0	15.57	44.0	18	91	1424 ( 41.2%)	2031 ( 58.8%)	413 ( 12.0%)	3042 ( 88.0%)
	PLACEBO	1978	46.5	15.50	44.0	18	87	788 ( 39.8%)	1190 ( 60.2%)	240 ( 12.1%)	1736 ( 87.8%)
276	PAROXETINE	20	45.1	12.75	46.0	22	62	9 ( 45.0%)	11 ( 55.0%)	5 ( 25.0%)	15 ( 75.0%)
	PLACEBO	21	43.4	12.68	43.0	22	64	9 ( 42.9%)	12 ( 57.1%)	5 ( 23.8%)	16 ( 76.2%)
279	PAROXETINE	21	40.8	18.32	38.0	20	75	6 ( 28.6%)	15 ( 71.4%)	6 ( 28.6%)	15 ( 71.4%)
	PLACEBO	10	51.6	17.25	56.5	23	71	3 ( 30.0%)	7 ( 70.0%)	2 ( 20.0%)	8 ( 80.0%)
274	PAROXETINE	22	41.6	13.20	42.0	18	64	6 ( 27.3%)	16 ( 72.7%)	0 ( 0.0%)	22 (100.0%)
	PLACEBO	23	43.3	11.84	45.0	22	60	7 ( 30.4%)	16 ( 69.6%)	0 ( 0.0%)	23 (100.0%)
001	PAROXETINE	25	42.6	11.70	42.0	20	65	16 ( 64.0%)	9 ( 36.0%)	2 ( 8.0%)	23 ( 92.0%)
	PLACEBO	25	44.2	13.13	43.0	24	64	19 ( 76.0%)	6 ( 24.0%)	7 ( 28.0%)	18 ( 72.0%)
002	PAROXETINE	170	40.5	11.59	39.5	18	77	86 ( 50.6%)	84 ( 49.4%)	55 ( 32.4%)	115 ( 67.6%)
	PLACEBO	171	42.5	12.67	40.0	18	73	78 ( 45.6%)	93 ( 54.4%)	49 ( 28.7%)	122 ( 71.3%)
009	PAROXETINE	421	41.1	13.17	38.0	18	85	208 ( 49.4%)	213 ( 50.6%)	79 ( 18.8%)	342 ( 81.2%)
	PLACEBO	53	40.6	10.45	39.0	23	70	24 ( 45.3%)	29 ( 54.7%)	13 ( 24.5%)	40 ( 75.5%)
003	PAROXETINE	241	40.3	11.28	39.0	18	69	113 ( 46.9%)	128 ( 53.1%)	60 ( 24.9%)	181 ( 75.1%)
	PLACEBO	244	40.4	11.92	38.0	19	70	122 ( 50.0%)	122 ( 50.0%)	67 ( 27.5%)	177 ( 72.5%)
115	PAROXETINE	283	41.8	12.53	41.0	18	86	101 ( 35.7%)	182 ( 64.3%)	31 ( 11.0%)	252 ( 89.0%)
	PLACEBO	117	41.5	11.67	40.0	19	71	32 ( 27.4%)	85 ( 72.6%)	14 ( 12.0%)	103 ( 88.0%)
128	PAROXETINE	357	41.8	12.70	40.0	18	82	135 ( 37.8%)	222 ( 62.2%)	48 ( 13.4%)	309 ( 86.6%)
	PLACEBO	140	42.8	12.17	42.0	20	76	40 ( 28.6%)	100 ( 71.4%)	11 ( 7.9%)	129 ( 92.1%)
251	PAROXETINE	125	41.3	11.17	41.0	19	65	42 ( 33.6%)	83 ( 66.4%)	0 ( 0.0%)	125 (100.0%)
	PLACEBO	129	41.3	10.56	41.0	18	71	45 ( 34.9%)	84 ( 65.1%)	3 ( 2.3%)	126 ( 97.7%)
448	PAROXETINE	212	39.3	10.66	39.5	18	62	81 ( 38.2%)	131 ( 61.8%)	16 ( 7.5%)	196 ( 92.5%)
	PLACEBO	103	38.4	10.04	39.0	19	64	36 ( 35.0%)	67 ( 65.0%)	4 ( 3.9%)	99 ( 96.1%)
449	PAROXETINE	223	41.3	11.60	42.0	18	71	65 ( 29.1%)	158 ( 70.9%)	30 ( 13.5%)	193 ( 86.5%)
	PLACEBO	110	40.7	11.56	40.0	19	63	44 ( 40.0%)	66 ( 60.0%)	21 ( 19.1%)	89 ( 80.9%)
487	PAROXETINE	214	70.2	6.32	70.0	60	88	100 ( 46.7%)	114 ( 53.3%)	11 ( 5.1%)	203 ( 94.9%)
	PLACEBO	109	69.4	5.40	70.0	60	82	40 ( 36.7%)	69 ( 63.3%)	5 ( 4.6%)	104 ( 95.4%)
625	PAROXETINE	112	64.3	11.39	67.0	22	85	61 ( 54.5%)	51 ( 45.5%)	15 ( 13.4%)	97 ( 86.6%)
	PLACEBO	117	65.6	10.51	67.0	38	82	64 ( 54.7%)	53 ( 45.3%)	14 ( 12.0%)	103 ( 88.0%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = MDD

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
442	PAROXETINE	41	46.9	11.81	48.0	21	69	6 ( 14.6%)	35 ( 85.4%)	0 ( 0.0%)	41 (100.0%)
	PLACEBO	48	49.0	11.49	48.0	31	79	2 ( 4.2%)	46 ( 95.8%)	0 ( 0.0%)	46 ( 95.8%)
785	PAROXETINE	197	41.3	12.19	43.0	18	65	76 ( 38.6%)	121 ( 61.4%)	46 ( 23.4%)	151 ( 76.6%)
	PLACEBO	105	40.4	11.36	40.0	18	63	46 ( 43.8%)	59 ( 56.2%)	22 ( 21.0%)	83 ( 79.0%)
810	PAROXETINE	306	38.9	11.53	38.0	18	74	131 ( 42.8%)	175 ( 57.2%)	3 ( 1.0%)	303 ( 99.0%)
	PLACEBO	148	38.5	11.78	37.0	18	65	57 ( 38.5%)	91 ( 61.5%)	2 ( 1.4%)	146 ( 98.6%)
NKD20006	PAROXETINE	124	38.0	11.85	38.5	18	64	46 ( 37.1%)	78 ( 62.9%)	0 ( 0.0%)	124 (100.0%)
	PLACEBO	125	37.7	11.20	37.0	18	63	53 ( 42.4%)	72 ( 57.6%)	0 ( 0.0%)	125 (100.0%)
874	PAROXETINE	341	67.1	6.36	66.0	60	91	136 ( 39.9%)	205 ( 60.1%)	6 ( 1.8%)	335 ( 98.2%)
	PLACEBO	180	68.0	6.73	66.0	60	87	67 ( 37.2%)	113 ( 62.8%)	1 ( 0.6%)	179 ( 99.4%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = IBD

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	149	33.6	10.37	32.0	18	74	49 ( 32.9%)	100 ( 67.1%)	147 ( 98.7%)	2 ( 1.3%)
	PLACEBO	154	34.1	11.80	32.0	18	70	54 ( 35.1%)	100 ( 64.9%)	152 ( 98.7%)	2 ( 1.3%)
057	PAROXETINE	131	34.2	10.58	33.0	18	74	40 ( 30.5%)	91 ( 69.5%)	131 (100.0%)	0 ( 0.0%)
	PLACEBO	136	34.6	12.19	32.0	18	70	48 ( 35.3%)	88 ( 64.7%)	136 (100.0%)	0 ( 0.0%)
106	PAROXETINE	18	28.9	7.40	27.0	21	48	9 ( 50.0%)	9 ( 50.0%)	16 ( 88.9%)	2 ( 11.1%)
	PLACEBO	18	30.4	7.47	30.0	18	44	6 ( 33.3%)	12 ( 66.7%)	16 ( 88.9%)	2 ( 11.1%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = Dysthymia

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	81	40.8	10.68	41.0	22	73	44 ( 54.3%)	37 ( 45.7%)	2 ( 2.5%)	79 ( 97.5%)
	PLACEBO	85	42.6	11.50	42.0	22	77	30 ( 35.3%)	55 ( 64.7%)	3 ( 3.5%)	82 ( 96.5%)
327	PAROXETINE	81	40.8	10.68	41.0	22	73	44 ( 54.3%)	37 ( 45.7%)	2 ( 2.5%)	79 ( 97.5%)
	PLACEBO	85	42.6	11.50	42.0	22	77	30 ( 35.3%)	55 ( 64.7%)	3 ( 3.5%)	82 ( 96.5%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation



Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = Bipolar

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	35	42.5	10.15	42.0	24	66	16 ( 45.7%)	19 ( 54.3%)	6 ( 17.1%)	29 ( 82.9%)
	PLACEBO	43	40.4	10.66	41.0	21	66	20 ( 46.5%)	23 ( 53.5%)	5 ( 11.6%)	38 ( 88.4%)
352	PAROXETINE	35	42.5	10.15	42.0	24	66	16 ( 45.7%)	19 ( 54.3%)	6 ( 17.1%)	29 ( 82.9%)
	PLACEBO	43	40.4	10.66	41.0	21	66	20 ( 46.5%)	23 ( 53.5%)	5 ( 11.6%)	38 ( 88.4%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = All Non-Depression

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	5238	38.6	11.15	38.0	16	78	1928 ( 36.8%)	3309 ( 63.2%)	208 ( 4.0%)	3669 ( 70.0%)
	PLACEBO	3693	38.4	11.46	38.0	16	85	1431 ( 38.7%)	2262 ( 61.3%)	96 ( 2.6%)	2490 ( 67.4%)
Panic	PAROXETINE	1092	36.9	10.42	36.0	18	74	419 ( 38.4%)	673 ( 61.6%)	8 ( 0.7%)	460 ( 42.1%)
	PLACEBO	903	36.9	10.54	36.0	17	72	371 ( 41.1%)	532 ( 58.9%)	5 ( 0.6%)	318 ( 35.2%)
OCD	PAROXETINE	698	39.1	13.08	38.0	16	78	391 ( 56.0%)	307 ( 44.0%)	123 ( 17.6%)	419 ( 60.0%)
	PLACEBO	416	38.3	12.27	37.0	16	74	225 ( 54.1%)	191 ( 45.9%)	50 ( 12.0%)	215 ( 51.7%)
SAD	PAROXETINE	943	37.2	10.50	37.0	18	70	487 ( 51.6%)	456 ( 48.4%)	0 ( 0.0%)	421 ( 44.6%)
	PLACEBO	643	37.2	11.34	37.0	18	85	336 ( 52.3%)	307 ( 47.7%)	0 ( 0.0%)	304 ( 47.3%)
GAD	PAROXETINE	904	41.2	13.50	41.0	18	78	345 ( 38.2%)	559 ( 61.8%)	0 ( 0.0%)	904 (100.0%)
	PLACEBO	697	41.8	13.64	40.0	18	81	258 ( 37.0%)	439 ( 63.0%)	1 ( 0.1%)	696 ( 99.9%)
PTSD	PAROXETINE	698	41.1	11.49	41.0	18	75	245 ( 35.1%)	453 ( 64.9%)	59 ( 8.5%)	636 ( 91.1%)
	PLACEBO	510	40.1	11.90	39.5	18	78	192 ( 37.6%)	318 ( 62.4%)	34 ( 6.7%)	474 ( 92.9%)
PMDD	PAROXETINE	820	36.5	5.48	37.0	19	49	0 ( 0.0%)	820 (100.0%)	16 ( 2.0%)	774 ( 94.4%)
	PLACEBO	438	36.0	5.97	36.0	19	49	0 ( 0.0%)	438 (100.0%)	3 ( 0.7%)	426 ( 97.3%)
Fibromyalgia	PAROXETINE	26	45.2	9.66	46.5	29	63	4 ( 15.4%)	21 ( 80.8%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	26	43.2	10.44	43.0	21	68	7 ( 26.9%)	19 ( 73.1%)	0 ( 0.0%)	0 ( 0.0%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = Panic

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	1092	36.9	10.42	36.0	18	74	419 ( 38.4%)	673 ( 61.6%)	8 ( 0.7%)	460 ( 42.1%)
	PLACEBO	903	36.9	10.54	36.0	17	72	371 ( 41.1%)	532 ( 58.9%)	5 ( 0.6%)	318 ( 35.2%)
108	PAROXETINE	60	37.7	10.42	36.0	23	69	12 ( 20.0%)	48 ( 80.0%)	0 ( 0.0%)	60 (100.0%)
	PLACEBO	60	37.0	9.10	35.5	21	57	17 ( 28.3%)	43 ( 71.7%)	0 ( 0.0%)	60 (100.0%)
187	PAROXETINE	123	34.6	9.27	34.0	19	66	53 ( 43.1%)	70 ( 56.9%)	3 ( 2.4%)	120 ( 97.6%)
	PLACEBO	123	34.9	8.86	34.0	18	62	49 ( 39.8%)	74 ( 60.2%)	1 ( 0.8%)	122 ( 99.2%)
120	PAROXETINE	209	36.1	9.97	35.0	18	65	73 ( 34.9%)	136 ( 65.1%)	3 ( 1.4%)	206 ( 98.6%)
	PLACEBO	69	37.3	10.36	36.0	19	63	22 ( 31.9%)	47 ( 68.1%)	1 ( 1.4%)	68 ( 98.6%)
223	PAROXETINE	76	39.2	11.10	38.0	22	74	28 ( 36.8%)	48 ( 63.2%)	2 ( 2.6%)	74 ( 97.4%)
	PLACEBO	71	39.0	11.90	37.0	19	67	23 ( 32.4%)	48 ( 67.6%)	3 ( 4.2%)	68 ( 95.8%)
410	PAROXETINE	87	35.5	11.58	33.0	18	64	42 ( 48.3%)	45 ( 51.7%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	40	33.0	9.60	32.5	17	59	21 ( 52.5%)	19 ( 47.5%)	0 ( 0.0%)	0 ( 0.0%)
384	PAROXETINE	85	37.0	11.68	36.0	18	72	46 ( 54.1%)	39 ( 45.9%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	83	35.5	12.03	32.0	18	72	40 ( 48.2%)	43 ( 51.8%)	0 ( 0.0%)	0 ( 0.0%)
495	PAROXETINE	162	36.4	10.15	35.0	18	62	55 ( 34.0%)	107 ( 66.0%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	165	36.5	10.64	35.0	19	72	61 ( 37.0%)	104 ( 63.0%)	0 ( 0.0%)	0 ( 0.0%)
494	PAROXETINE	141	38.1	10.06	38.0	19	63	58 ( 41.1%)	83 ( 58.9%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	148	36.7	10.25	36.0	20	61	66 ( 44.6%)	82 ( 55.4%)	0 ( 0.0%)	0 ( 0.0%)
497	PAROXETINE	149	38.2	10.42	38.0	20	65	52 ( 34.9%)	97 ( 65.1%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	144	39.8	10.67	40.0	19	64	72 ( 50.0%)	72 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = OCD

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	698	39.1	13.08	38.0	16	78	391 ( 56.0%)	307 ( 44.0%)	123 ( 17.6%)	419 ( 60.0%)
	PLACEBO	416	38.3	12.27	37.0	16	74	225 ( 54.1%)	191 ( 45.9%)	50 ( 12.0%)	215 ( 51.7%)
116	PAROXETINE	259	40.8	13.84	39.0	16	78	196 ( 75.7%)	63 ( 24.3%)	84 ( 32.4%)	175 ( 67.6%)
	PLACEBO	89	43.1	12.32	44.0	20	73	60 ( 67.4%)	29 ( 32.6%)	26 ( 29.2%)	63 ( 70.8%)
118	PAROXETINE	82	41.3	11.69	39.0	19	77	44 ( 53.7%)	38 ( 46.3%)	27 ( 32.9%)	55 ( 67.1%)
	PLACEBO	77	36.3	10.71	35.0	16	67	54 ( 70.1%)	23 ( 29.9%)	19 ( 24.7%)	58 ( 75.3%)
136	PAROXETINE	201	37.8	12.07	36.0	17	72	90 ( 44.8%)	111 ( 55.2%)	12 ( 6.0%)	189 ( 94.0%)
	PLACEBO	99	37.8	12.39	36.0	19	74	44 ( 44.4%)	55 ( 55.6%)	5 ( 5.1%)	94 ( 94.9%)
414	PAROXETINE	61	36.1	15.06	31.0	17	71	29 ( 47.5%)	32 ( 52.5%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	56	34.1	12.20	31.0	16	63	28 ( 50.0%)	28 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)
660	PAROXETINE	95	37.1	11.98	37.0	16	67	32 ( 33.7%)	63 ( 66.3%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	95	38.4	12.10	38.0	16	71	39 ( 41.1%)	56 ( 58.9%)	0 ( 0.0%)	0 ( 0.0%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = SAD

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	943	37.2	10.50	37.0	18	70	487 ( 51.6%)	456 ( 48.4%)	0 ( 0.0%)	421 ( 44.6%)
	PLACEBO	643	37.2	11.34	37.0	18	85	336 ( 52.3%)	307 ( 47.7%)	0 ( 0.0%)	304 ( 47.3%)
382	PAROXETINE	94	35.9	10.10	34.0	18	59	50 ( 53.2%)	44 ( 46.8%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	93	36.7	13.19	34.0	18	76	56 ( 60.2%)	37 ( 39.8%)	0 ( 0.0%)	0 ( 0.0%)
502	PAROXETINE	139	34.7	11.56	32.0	18	67	64 ( 46.0%)	75 ( 54.0%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	151	37.3	11.44	35.0	18	85	69 ( 45.7%)	82 ( 54.3%)	0 ( 0.0%)	0 ( 0.0%)
454	PAROXETINE	289	37.7	9.98	38.0	20	70	170 ( 58.8%)	119 ( 41.2%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	95	34.7	10.41	35.0	18	65	55 ( 57.9%)	40 ( 42.1%)	0 ( 0.0%)	0 ( 0.0%)
790	PAROXETINE	186	38.7	10.50	39.0	18	69	88 ( 47.3%)	98 ( 52.7%)	0 ( 0.0%)	186 (100.0%)
	PLACEBO	184	39.0	11.52	40.0	18	67	97 ( 52.7%)	87 ( 47.3%)	0 ( 0.0%)	184 (100.0%)
661	PAROXETINE	235	37.3	10.44	36.0	18	64	115 ( 48.9%)	120 ( 51.1%)	0 ( 0.0%)	235 (100.0%)
	PLACEBO	120	36.6	9.71	36.0	20	58	59 ( 49.2%)	61 ( 50.8%)	0 ( 0.0%)	120 (100.0%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = GAD

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	904	41.2	13.50	41.0	18	78	345 ( 38.2%)	559 ( 61.8%)	0 ( 0.0%)	904 (100.0%)
	PLACEBO	697	41.8	13.64	40.0	18	81	258 ( 37.0%)	439 ( 63.0%)	1 ( 0.1%)	696 ( 99.9%)
637	PAROXETINE	187	46.5	14.93	45.0	18	78	48 ( 25.7%)	139 ( 74.3%)	0 ( 0.0%)	187 (100.0%)
	PLACEBO	185	45.4	15.00	42.0	18	78	62 ( 33.5%)	123 ( 66.5%)	0 ( 0.0%)	185 (100.0%)
641	PAROXETINE	386	40.4	12.69	40.0	18	74	172 ( 44.6%)	214 ( 55.4%)	0 ( 0.0%)	386 (100.0%)
	PLACEBO	180	40.8	12.60	40.0	18	74	79 ( 43.9%)	101 ( 56.1%)	0 ( 0.0%)	180 (100.0%)
642	PAROXETINE	164	39.6	11.99	39.0	19	69	65 ( 39.6%)	99 ( 60.4%)	0 ( 0.0%)	164 (100.0%)
	PLACEBO	166	41.0	12.32	41.0	19	80	56 ( 33.7%)	110 ( 66.3%)	1 ( 0.6%)	165 ( 99.4%)
791	PAROXETINE	167	38.6	13.60	37.0	18	76	60 ( 35.9%)	107 ( 64.1%)	0 ( 0.0%)	167 (100.0%)
	PLACEBO	166	39.5	13.72	38.0	18	81	61 ( 36.7%)	105 ( 63.3%)	0 ( 0.0%)	166 (100.0%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = PTSD

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	698	41.1	11.49	41.0	18	75	245 ( 35.1%)	453 ( 64.9%)	59 ( 8.5%)	636 ( 91.1%)
	PLACEBO	510	40.1	11.90	39.5	18	78	192 ( 37.6%)	318 ( 62.4%)	34 ( 6.7%)	474 ( 92.9%)
627	PAROXETINE	160	39.5	11.62	38.0	18	75	75 ( 46.9%)	85 ( 53.1%)	15 ( 9.4%)	142 ( 88.8%)
	PLACEBO	162	38.9	11.65	38.5	18	72	74 ( 45.7%)	88 ( 54.3%)	19 ( 11.7%)	142 ( 87.7%)
651	PAROXETINE	375	41.6	11.54	43.0	18	74	114 ( 30.4%)	261 ( 69.6%)	29 ( 7.7%)	346 ( 92.3%)
	PLACEBO	188	41.4	11.86	42.0	18	77	62 ( 33.0%)	126 ( 67.0%)	10 ( 5.3%)	177 ( 94.1%)
648	PAROXETINE	163	41.5	11.17	41.0	19	69	56 ( 34.4%)	107 ( 65.6%)	15 ( 9.2%)	148 ( 90.8%)
	PLACEBO	160	39.7	12.11	39.5	18	78	56 ( 35.0%)	104 ( 65.0%)	5 ( 3.1%)	155 ( 96.9%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = PMDD

Trial	Treatment	N	-----Age-----					-----Gender-----		-Baseline Suicidal Ideation-	
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	820	36.5	5.48	37.0	19	49	0 ( 0.0%)	820 (100.0%)	16 ( 2.0%)	774 ( 94.4%)
	PLACEBO	438	36.0	5.97	36.0	19	49	0 ( 0.0%)	438 (100.0%)	3 ( 0.7%)	426 ( 97.3%)
400	PAROXETINE	31	36.0	6.05	36.0	23	45	0 ( 0.0%)	31 (100.0%)	16 ( 51.6%)	15 ( 48.4%)
	PLACEBO	17	34.9	5.65	35.0	24	44	0 ( 0.0%)	17 (100.0%)	3 ( 17.6%)	14 ( 82.4%)
427	PAROXETINE	29	36.0	6.67	37.0	19	46	0 ( 0.0%)	29 (100.0%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	9	32.8	5.65	32.0	26	40	0 ( 0.0%)	9 (100.0%)	0 ( 0.0%)	0 ( 0.0%)
658	PAROXETINE	60	37.9	5.98	38.0	19	49	0 ( 0.0%)	60 (100.0%)	0 ( 0.0%)	60 (100.0%)
	PLACEBO	59	37.2	7.11	38.0	21	49	0 ( 0.0%)	59 (100.0%)	0 ( 0.0%)	59 (100.0%)
689	PAROXETINE	246	36.4	5.49	37.0	20	45	0 ( 0.0%)	246 (100.0%)	0 ( 0.0%)	246 (100.0%)
	PLACEBO	125	35.9	5.80	36.0	19	45	0 ( 0.0%)	125 (100.0%)	0 ( 0.0%)	125 (100.0%)
677	PAROXETINE	212	35.7	5.72	36.0	19	45	0 ( 0.0%)	212 (100.0%)	0 ( 0.0%)	212 (100.0%)
	PLACEBO	109	35.0	6.15	36.0	20	45	0 ( 0.0%)	109 (100.0%)	0 ( 0.0%)	109 (100.0%)
688	PAROXETINE	242	37.0	4.77	38.0	20	46	0 ( 0.0%)	242 (100.0%)	0 ( 0.0%)	241 ( 99.6%)
	PLACEBO	119	36.6	5.27	37.0	24	46	0 ( 0.0%)	119 (100.0%)	0 ( 0.0%)	119 (100.0%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation



Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = Detoxification in Alcoholics

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	57	41.8	9.19	41.0	23	60	37 ( 64.9%)	20 ( 35.1%)	2 ( 3.5%)	55 ( 96.5%)
	PLACEBO	60	39.6	8.83	37.5	26	62	42 ( 70.0%)	18 ( 30.0%)	3 ( 5.0%)	57 ( 95.0%)
201	PAROXETINE	57	41.8	9.19	41.0	23	60	37 ( 64.9%)	20 ( 35.1%)	2 ( 3.5%)	55 ( 96.5%)
	PLACEBO	60	39.6	8.83	37.5	26	62	42 ( 70.0%)	18 ( 30.0%)	3 ( 5.0%)	57 ( 95.0%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 1.01  
 Demographic Characteristics by Trial  
 Indication = Fibromyalgia

Trial	Treatment	N	-----Age-----				-----Gender-----		-Baseline Suicidal Ideation-		
			Mean	Standard Deviation	Median	Min	Max	Males	Females	Present	Absent
Overall	PAROXETINE	26	45.2	9.66	46.5	29	63	4 ( 15.4%)	21 ( 80.8%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	26	43.2	10.44	43.0	21	68	7 ( 26.9%)	19 ( 73.1%)	0 ( 0.0%)	0 ( 0.0%)
433	PAROXETINE	26	45.2	9.66	46.5	29	63	4 ( 15.4%)	21 ( 80.8%)	0 ( 0.0%)	0 ( 0.0%)
	PLACEBO	26	43.2	10.44	43.0	21	68	7 ( 26.9%)	19 ( 73.1%)	0 ( 0.0%)	0 ( 0.0%)

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = All Indications

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	83/8958 ( 0.93%)	65/5953 ( 1.09%)	0.9 (0.7, 1.3)	0.649	1262.9
All Depression	66/3720 ( 1.77%)	47/2260 ( 2.08%)	1.1 (0.7, 1.7)	0.671	(420.0)
MDD	31/3455 ( 0.90%)	11/1978 ( 0.56%)	1.3 (0.7, 2.8)	0.493	(527.4)
IBD	34/ 149 (22.82%)	36/ 154 (23.38%)	1.0 (0.6, 1.7)	1.000	169.7
Dysthymia	1/ 81 ( 1.23%)	0/ 85 ( 0.00%)	inf ( 0.1, inf)	0.488	(81.0)
Bipolar	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
All Non-Depression	17/5238 ( 0.32%)	18/3693 ( 0.49%)	0.7 (0.3, 1.3)	0.293	623.9
Panic	3/1092 ( 0.27%)	3/ 903 ( 0.33%)	0.7 (0.1, 4.2)	0.689	974.2
OCD	5/ 698 ( 0.72%)	4/ 416 ( 0.96%)	0.7 (0.2, 3.0)	0.723	333.1
SAD	3/ 943 ( 0.32%)	3/ 643 ( 0.47%)	0.8 (0.1, 4.7)	1.000	968.7
GAD	2/ 904 ( 0.22%)	2/ 697 ( 0.29%)	1.0 (0.1, 9.6)	1.000	(181237)
PTSD	3/ 698 ( 0.43%)	6/ 510 ( 1.18%)	0.4 (0.1, 1.5)	0.176	133.3
PMDD	1/ 820 ( 0.12%)	0/ 438 ( 0.00%)	inf ( 0.1, inf)	1.000	
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Breslow-Day test of homogeneity, p=0.963

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = All Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	66/3720 ( 1.77%)	47/2260 ( 2.08%)	1.1 (0.7, 1.7)	0.671	(420.0)
Overall (Mantel Haenszel)	66/3720 ( 1.77%)	47/2260 ( 2.08%)	1.1 (0.7, 1.6)	0.795	(899.2)
MDD	31/3455 ( 0.90%)	11/1978 ( 0.56%)	1.3 (0.7, 2.8)	0.493	(527.4)
IBD	34/ 149 (22.82%)	36/ 154 (23.38%)	1.0 (0.6, 1.7)	1.000	169.7
Dysthymia	1/ 81 ( 1.23%)	0/ 85 ( 0.00%)	inf ( 0.1, inf)	0.488	(81.0)
Bipolar	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.765

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = MDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	31/3455 ( 0.90%)	11/1978 ( 0.56%)	1.3 (0.7, 2.8)	0.493	(527.4)
Overall (Mantel Haenszel)	31/3455 ( 0.90%)	11/1978 ( 0.56%)	1.1 (0.6, 2.1)	0.709	(1437.4)
Trial 276	0/ 20 ( 0.00%)	0/ 21 ( 0.00%)	Not Enough Events		
Trial 279	2/ 21 ( 9.52%)	1/ 10 (10.00%)	0.9 (0.1, 30.9)		210.0
Trial 274	0/ 22 ( 0.00%)	0/ 23 ( 0.00%)	Not Enough Events		
Trial 001	0/ 25 ( 0.00%)	0/ 25 ( 0.00%)	Not Enough Events		
Trial 002	1/ 170 ( 0.59%)	2/ 171 ( 1.17%)	0.5 (0.0, 6.6)		172.0
Trial 009	5/ 421 ( 1.19%)	0/ 53 ( 0.00%)	inf (0.2, inf)		(84.2)
Trial 003	0/ 241 ( 0.00%)	2/ 244 ( 0.82%)	0.0 ( 0.0, 3.5)		122.0
Trial 115	5/ 283 ( 1.77%)	3/ 117 ( 2.56%)	0.7 (0.2, 3.5)		125.4
Trial 128	8/ 357 ( 2.24%)	2/ 140 ( 1.43%)	1.6 (0.4, 11.0)		(123.1)
Trial 251	2/ 125 ( 1.60%)	0/ 129 ( 0.00%)	inf (0.3, inf)		(62.5)
Trial 448	3/ 212 ( 1.42%)	0/ 103 ( 0.00%)	inf (0.3, inf)		(70.7)
Trial 449	1/ 223 ( 0.45%)	0/ 110 ( 0.00%)	inf (0.0, inf)		(223.0)
Trial 487	2/ 214 ( 0.93%)	0/ 109 ( 0.00%)	inf (0.1, inf)		(107.0)
Trial 625	1/ 112 ( 0.89%)	0/ 117 ( 0.00%)	inf (0.1, inf)		(112.0)
Trial 442	0/ 41 ( 0.00%)	0/ 48 ( 0.00%)	Not Enough Events		
Trial 785	1/ 197 ( 0.51%)	0/ 105 ( 0.00%)	inf (0.0, inf)		(197.0)
Trial 810	0/ 306 ( 0.00%)	1/ 148 ( 0.68%)	0.0 ( 0.0, 9.2)		148.0
Trial NKD20006	0/ 124 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 874	0/ 341 ( 0.00%)	0/ 180 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.566

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = IBD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	34/ 149 (22.82%)	36/ 154 (23.38%)	1.0 (0.6, 1.7)	1.000	169.7
Overall (Mantel Haenszel)	34/ 149 (22.82%)	36/ 154 (23.38%)	1.0 (0.6, 1.7)	0.903	168.7
Trial 057	28/ 131 (21.37%)	31/ 136 (22.79%)	0.9 (0.5, 1.6)		70.4
Trial 106	6/ 18 (33.33%)	5/ 18 (27.78%)	1.3 (0.3, 5.8)		(18.0)

\*Zelen's test of homogeneity, p=0.712

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Dysthymia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	1/ 81 ( 1.23%)	0/ 85 ( 0.00%)	inf ( 0.1, inf)	0.488	(81.0)
Overall (Mantel Haenszel)	1/ 81 ( 1.23%)	0/ 85 ( 0.00%)	3.2 (0.1, 79.4)	0.457	
Trial 327	1/ 81 ( 1.23%)	0/ 85 ( 0.00%)	inf (0.1, inf)		(81.0)

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Bipolar

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
Trial 352	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)



Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = All Non-Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	17/5238 ( 0.32%)	18/3693 ( 0.49%)	0.7 (0.3, 1.3)	0.293	623.9
Overall (Mantel Haenszel)	17/5238 ( 0.32%)	18/3693 ( 0.49%)	0.7 (0.4, 1.3)	0.228	697.3
Panic	3/1092 ( 0.27%)	3/ 903 ( 0.33%)	0.7 (0.1, 4.2)	0.689	974.2
OCD	5/ 698 ( 0.72%)	4/ 416 ( 0.96%)	0.7 (0.2, 3.0)	0.723	333.1
SAD	3/ 943 ( 0.32%)	3/ 643 ( 0.47%)	0.8 (0.1, 4.7)	1.000	968.7
GAD	2/ 904 ( 0.22%)	2/ 697 ( 0.29%)	1.0 (0.1, 9.6)	1.000	(181237)
PTSD	3/ 698 ( 0.43%)	6/ 510 ( 1.18%)	0.4 (0.1, 1.5)	0.176	133.3
PMDD	1/ 820 ( 0.12%)	0/ 438 ( 0.00%)	inf ( 0.1, inf)	1.000	
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.513

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Panic

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	3/1092 ( 0.27%)	3/ 903 ( 0.33%)	0.7 (0.1, 4.2)	0.689	974.2
Overall (Mantel Haenszel)	3/1092 ( 0.27%)	3/ 903 ( 0.33%)	0.7 (0.2, 2.6)	0.609	1025.0
Trial 108	0/ 60 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 187	0/ 123 ( 0.00%)	2/ 123 ( 1.63%)	0.0 ( 0.0, 3.5)		61.5
Trial 120	2/ 209 ( 0.96%)	0/ 69 ( 0.00%)	inf (0.1, inf)		(104.5)
Trial 223	0/ 76 ( 0.00%)	1/ 71 ( 1.41%)	0.0 ( 0.0, 17.8)		71.0
Trial 410	0/ 87 ( 0.00%)	0/ 40 ( 0.00%)	Not Enough Events		
Trial 384	0/ 85 ( 0.00%)	0/ 83 ( 0.00%)	Not Enough Events		
Trial 495	1/ 162 ( 0.62%)	0/ 165 ( 0.00%)	inf (0.1, inf)		(162.0)
Trial 494	0/ 141 ( 0.00%)	0/ 148 ( 0.00%)	Not Enough Events		
Trial 497	0/ 149 ( 0.00%)	0/ 144 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.324

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = OCD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	5/ 698 ( 0.72%)	4/ 416 ( 0.96%)	0.7 (0.2, 3.0)	0.723	333.1
Overall (Mantel Haenszel)	5/ 698 ( 0.72%)	4/ 416 ( 0.96%)	0.7 (0.2, 2.5)	0.603	382.5
Trial 116	2/ 259 ( 0.77%)	1/ 89 ( 1.12%)	0.7 (0.1, 20.4)		284.6
Trial 118	1/ 82 ( 1.22%)	1/ 77 ( 1.30%)	0.9 (0.0, 37.1)		1262.8
Trial 136	1/ 201 ( 0.50%)	2/ 99 ( 2.02%)	0.2 (0.0, 3.2)		65.7
Trial 414	0/ 61 ( 0.00%)	0/ 56 ( 0.00%)	Not Enough Events		
Trial 660	1/ 95 ( 1.05%)	0/ 95 ( 0.00%)	inf (0.1, inf)		(95.0)

\*Zelen's test of homogeneity, p=0.792

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = SAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	3/ 943 ( 0.32%)	3/ 643 ( 0.47%)	0.8 (0.1, 4.7)	1.000	968.7
Overall (Mantel Haenszel)	3/ 943 ( 0.32%)	3/ 643 ( 0.47%)	0.7 (0.2, 2.6)	0.593	724.0
Trial 382	0/ 94 ( 0.00%)	1/ 93 ( 1.08%)	0.0 ( 0.0, 18.8)		93.0
Trial 502	2/ 139 ( 1.44%)	1/ 151 ( 0.66%)	2.2 (0.2, 65.0)		(128.8)
Trial 454	1/ 289 ( 0.35%)	0/ 95 ( 0.00%)	inf (0.0, inf)		(289.0)
Trial 790	0/ 186 ( 0.00%)	0/ 184 ( 0.00%)	Not Enough Events		
Trial 661	0/ 235 ( 0.00%)	1/ 120 ( 0.83%)	0.0 ( 0.0, 9.7)		120.0

\*Zelen's test of homogeneity, p=0.524

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = GAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	2/ 904 ( 0.22%)	2/ 697 ( 0.29%)	1.0 (0.1, 9.6)	1.000	(181237)
Overall (Mantel Haenszel)	2/ 904 ( 0.22%)	2/ 697 ( 0.29%)	1.0 (0.2, 5.0)	0.999	229703
Trial 637	1/ 187 ( 0.53%)	0/ 185 ( 0.00%)	inf (0.1, inf)		(187.0)
Trial 641	0/ 386 ( 0.00%)	0/ 180 ( 0.00%)	Not Enough Events		
Trial 642	1/ 164 ( 0.61%)	1/ 166 ( 0.60%)	1.0 (0.0, 39.7)		(13612.0)
Trial 791	0/ 167 ( 0.00%)	1/ 166 ( 0.60%)	0.0 ( 0.0, 18.9)		166.0

\*Zelen's test of homogeneity, p=1.000

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = PTSD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	3/ 698 ( 0.43%)	6/ 510 ( 1.18%)	0.4 (0.1, 1.5)	0.176	133.3
Overall (Mantel Haenszel)	3/ 698 ( 0.43%)	6/ 510 ( 1.18%)	0.4 (0.1, 1.5)	0.161	147.2
Trial 627	1/ 160 ( 0.63%)	3/ 162 ( 1.85%)	0.3 (0.0, 3.2)		81.5
Trial 651	1/ 375 ( 0.27%)	3/ 188 ( 1.60%)	0.2 (0.0, 1.6)		75.2
Trial 648	1/ 163 ( 0.61%)	0/ 160 ( 0.00%)	inf (0.1, inf)		(163.0)

\*Zelen's test of homogeneity, p=0.406

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = PMDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	1/ 820 ( 0.12%)	0/ 438 ( 0.00%)	inf ( 0.1, inf)	1.000	
Overall (Mantel Haenszel)	1/ 820 ( 0.12%)	0/ 438 ( 0.00%)	3.0 (0.1, 75.1)	0.485	
Trial 400	0/ 31 ( 0.00%)	0/ 17 ( 0.00%)	Not Enough Events		
Trial 427	0/ 29 ( 0.00%)	0/ 9 ( 0.00%)	Not Enough Events		
Trial 658	1/ 60 ( 1.67%)	0/ 59 ( 0.00%)	inf (0.1, inf)		(60.0)
Trial 689	0/ 246 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 677	0/ 212 ( 0.00%)	0/ 109 ( 0.00%)	Not Enough Events		
Trial 688	0/ 242 ( 0.00%)	0/ 119 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Detoxification in Alcoholics

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 201	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)



Paroxetine Adult Suicidality Analysis

Table 2.01

Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Fibromyalgia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Trial 433	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = All Indications

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	72/8917 ( 0.81%)	71/5905 ( 1.20%)	0.7 (0.5, 0.9)	0.012	249.6
All Depression	55/3679 ( 1.49%)	46/2212 ( 2.08%)	0.8 (0.5, 1.2)	0.222	227.6
MDD	37/3414 ( 1.08%)	32/1930 ( 1.66%)	0.6 (0.4, 1.0)	0.050	154.3
IBD	14/ 149 ( 9.40%)	14/ 154 ( 9.09%)	1.0 (0.5, 2.3)	1.000	(326.0)
Dysthymia	2/ 81 ( 2.47%)	0/ 85 ( 0.00%)	inf ( 0.3, inf)	0.237	(40.5)
Bipolar	2/ 35 ( 5.71%)	0/ 43 ( 0.00%)	inf ( 0.4, inf)	0.198	(17.5)
All Non-Depression	17/5238 ( 0.32%)	25/3693 ( 0.68%)	0.4 (0.2, 0.8)	0.014	265.1
Panic	2/1092 ( 0.18%)	1/ 903 ( 0.11%)	1.0 (0.1, 32.5)	1.000	156121
OCD	4/ 698 ( 0.57%)	7/ 416 ( 1.68%)	0.3 (0.1, 0.9)	0.041	80.1
SAD	0/ 943 ( 0.00%)	0/ 643 ( 0.00%)	Not Enough Events		
GAD	3/ 904 ( 0.33%)	2/ 697 ( 0.29%)	1.3 (0.2, 11.3)	1.000	(1117.1)
PTSD	8/ 698 ( 1.15%)	15/ 510 ( 2.94%)	0.4 (0.2, 1.0)	0.052	58.0
PMDD	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Breslow-Day test of homogeneity, p=0.488

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = All Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	55/3679 ( 1.49%)	46/2212 ( 2.08%)	0.8 (0.5, 1.2)	0.222	227.6
MDD	37/3414 ( 1.08%)	32/1930 ( 1.66%)	0.6 (0.4, 1.0)	0.050	154.3
IBD	14/ 149 ( 9.40%)	14/ 154 ( 9.09%)	1.0 (0.5, 2.3)	1.000	(326.0)
Dysthymia	2/ 81 ( 2.47%)	0/ 85 ( 0.00%)	inf ( 0.3, inf)	0.237	(40.5)
Bipolar	2/ 35 ( 5.71%)	0/ 43 ( 0.00%)	inf ( 0.4, inf)	0.198	(17.5)

\*Breslow-Day test of homogeneity, p=0.480

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = MDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	37/3414 ( 1.08%)	32/1930 ( 1.66%)	0.6 (0.4, 1.0)	0.050	154.3
Overall (Mantel Haenszel)	37/3414 ( 1.08%)	32/1930 ( 1.66%)	0.6 (0.4, 1.0)	0.035	152.4
Trial 276	1/ 20 ( 5.00%)	0/ 21 ( 0.00%)	inf (0.1, inf)		(20.0)
Trial 279	0/ 21 ( 0.00%)	1/ 10 (10.00%)	0.0 ( 0.0, 9.0)		10.0
Trial 274	0/ 22 ( 0.00%)	0/ 23 ( 0.00%)	Not Enough Events		
Trial 001	0/ 25 ( 0.00%)	0/ 25 ( 0.00%)	Not Enough Events		
Trial 002	1/ 170 ( 0.59%)	4/ 171 ( 2.34%)	0.2 (0.0, 2.0)		57.1
Trial 009	6/ 421 ( 1.43%)	1/ 53 ( 1.89%)	0.8 (0.1, 17.7)		216.6
Trial 003	3/ 241 ( 1.24%)	7/ 244 ( 2.87%)	0.4 (0.1, 1.6)		61.6
Trial 115	5/ 283 ( 1.77%)	0/ 117 ( 0.00%)	inf (0.5, inf)		(56.6)
Trial 128	6/ 357 ( 1.68%)	5/ 140 ( 3.57%)	0.5 (0.1, 1.7)		52.9
Trial 251	2/ 125 ( 1.60%)	1/ 129 ( 0.78%)	2.1 (0.2, 61.8)		(121.2)
Trial 448	0/ 212 ( 0.00%)	1/ 103 ( 0.97%)	0.0 ( 0.0, 9.2)		103.0
Trial 449	6/ 223 ( 2.69%)	3/ 110 ( 2.73%)	1.0 (0.2, 4.9)		2725.6
Trial 487	2/ 214 ( 0.93%)	1/ 109 ( 0.92%)	1.0 (0.1, 30.3)		(5831.5)
Trial 625	1/ 112 ( 0.89%)	1/ 117 ( 0.85%)	1.0 (0.0, 41.1)		(2620.8)
Trial 785	3/ 197 ( 1.52%)	4/ 105 ( 3.81%)	0.4 (0.1, 1.9)		43.7
Trial 810	0/ 306 ( 0.00%)	2/ 148 ( 1.35%)	0.0 ( 0.0, 1.7)		74.0
Trial NKD20006	0/ 124 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 874	1/ 341 ( 0.29%)	1/ 180 ( 0.56%)	0.5 (0.0, 20.6)		381.2

\*Zelen's test of homogeneity, p=0.461

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = IBD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	14/ 149 ( 9.40%)	14/ 154 ( 9.09%)	1.0 (0.5, 2.3)	1.000	(326.0)
Overall (Mantel Haenszel)	14/ 149 ( 9.40%)	14/ 154 ( 9.09%)	1.0 (0.5, 2.3)	0.926	(323.6)
Trial 057	12/ 131 ( 9.16%)	13/ 136 ( 9.56%)	1.0 (0.4, 2.2)		250.9
Trial 106	2/ 18 (11.11%)	1/ 18 ( 5.56%)	2.1 (0.1, 66.1)		(18.0)

\*Zelen's test of homogeneity, p=1.000

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Dysthymia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	2/ 81 ( 2.47%)	0/ 85 ( 0.00%)	inf ( 0.3, inf)	0.237	(40.5)
Overall (Mantel Haenszel)	2/ 81 ( 2.47%)	0/ 85 ( 0.00%)	5.4 (0.3, 113.7)	0.229	
Trial 327	2/ 81 ( 2.47%)	0/ 85 ( 0.00%)	inf (0.3, inf)		(40.5)

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Bipolar

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	2/ 35 ( 5.71%)	0/ 43 ( 0.00%)	inf ( 0.4, inf)	0.198	(17.5)
Overall (Mantel Haenszel)	2/ 35 ( 5.71%)	0/ 43 ( 0.00%)	6.5 (0.3, 139.8)	0.176	
Trial 352	2/ 35 ( 5.71%)	0/ 43 ( 0.00%)	inf (0.4, inf)		(17.5)

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = All Non-Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	17/5238 ( 0.32%)	25/3693 ( 0.68%)	0.4 (0.2, 0.8)	0.014	265.1
Overall (Mantel Haenszel)	17/5238 ( 0.32%)	25/3693 ( 0.68%)	0.5 (0.3, 0.8)	0.008	271.7
Panic	2/1092 ( 0.18%)	1/ 903 ( 0.11%)	1.0 (0.1, 32.5)	1.000	156121
OCD	4/ 698 ( 0.57%)	7/ 416 ( 1.68%)	0.3 (0.1, 0.9)	0.041	80.1
SAD	0/ 943 ( 0.00%)	0/ 643 ( 0.00%)	Not Enough Events		
GAD	3/ 904 ( 0.33%)	2/ 697 ( 0.29%)	1.3 (0.2, 11.3)	1.000	(1117.1)
PTSD	8/ 698 ( 1.15%)	15/ 510 ( 2.94%)	0.4 (0.2, 1.0)	0.052	58.0
PMDD	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.350

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442



Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Panic

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	2/1092 ( 0.18%)	1/ 903 ( 0.11%)	1.0 (0.1, 32.5)	1.000	156121
Overall (Mantel Haenszel)	2/1092 ( 0.18%)	1/ 903 ( 0.11%)	0.8 (0.1, 5.5)	0.808	4039.9
Trial 108	0/ 60 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 187	0/ 123 ( 0.00%)	1/ 123 ( 0.81%)	0.0 ( 0.0, 19.0)		123.0
Trial 120	2/ 209 ( 0.96%)	0/ 69 ( 0.00%)	inf (0.1, inf)		(104.5)
Trial 223	0/ 76 ( 0.00%)	0/ 71 ( 0.00%)	Not Enough Events		
Trial 410	0/ 87 ( 0.00%)	0/ 40 ( 0.00%)	Not Enough Events		
Trial 384	0/ 85 ( 0.00%)	0/ 83 ( 0.00%)	Not Enough Events		
Trial 495	0/ 162 ( 0.00%)	0/ 165 ( 0.00%)	Not Enough Events		
Trial 494	0/ 141 ( 0.00%)	0/ 148 ( 0.00%)	Not Enough Events		
Trial 497	0/ 149 ( 0.00%)	0/ 144 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=1.000

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = OCD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	4/ 698 ( 0.57%)	7/ 416 ( 1.68%)	0.3 (0.1, 0.9)	0.041	80.1
Overall (Mantel Haenszel)	4/ 698 ( 0.57%)	7/ 416 ( 1.68%)	0.2 (0.1, 0.8)	0.018	79.6
Trial 116	2/ 259 ( 0.77%)	0/ 89 ( 0.00%)	inf (0.1, inf)		(129.5)
Trial 118	0/ 82 ( 0.00%)	0/ 77 ( 0.00%)	Not Enough Events		
Trial 136	2/ 201 ( 1.00%)	7/ 99 ( 7.07%)	0.1 (0.0, 0.6)		16.5
Trial 414	0/ 61 ( 0.00%)	0/ 56 ( 0.00%)	Not Enough Events		
Trial 660	0/ 95 ( 0.00%)	0/ 95 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.159

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = SAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 943 ( 0.00%)	0/ 643 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 943 ( 0.00%)	0/ 643 ( 0.00%)	Not Enough Events		
Trial 382	0/ 94 ( 0.00%)	0/ 93 ( 0.00%)	Not Enough Events		
Trial 502	0/ 139 ( 0.00%)	0/ 151 ( 0.00%)	Not Enough Events		
Trial 454	0/ 289 ( 0.00%)	0/ 95 ( 0.00%)	Not Enough Events		
Trial 790	0/ 186 ( 0.00%)	0/ 184 ( 0.00%)	Not Enough Events		
Trial 661	0/ 235 ( 0.00%)	0/ 120 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = GAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	3/ 904 ( 0.33%)	2/ 697 ( 0.29%)	1.3 (0.2, 11.3)	1.000	(1117.1)
Overall (Mantel Haenszel)	3/ 904 ( 0.33%)	2/ 697 ( 0.29%)	1.1 (0.2, 5.0)	0.912	(3851.7)
Trial 637	0/ 187 ( 0.00%)	0/ 185 ( 0.00%)	Not Enough Events		
Trial 641	1/ 386 ( 0.26%)	0/ 180 ( 0.00%)	inf (0.0, inf)		(386.0)
Trial 642	2/ 164 ( 1.22%)	1/ 166 ( 0.60%)	2.0 (0.2, 60.4)		(162.0)
Trial 791	0/ 167 ( 0.00%)	1/ 166 ( 0.60%)	0.0 ( 0.0, 18.9)		166.0

\*Zelen's test of homogeneity, p=0.614

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = PTSD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	8/ 698 ( 1.15%)	15/ 510 ( 2.94%)	0.4 (0.2, 1.0)	0.052	58.0
Overall (Mantel Haenszel)	8/ 698 ( 1.15%)	15/ 510 ( 2.94%)	0.4 (0.2, 1.0)	0.038	58.7
Trial 627	4/ 160 ( 2.50%)	6/ 162 ( 3.70%)	0.7 (0.2, 2.5)		83.1
Trial 651	3/ 375 ( 0.80%)	5/ 188 ( 2.66%)	0.3 (0.1, 1.3)		53.8
Trial 648	1/ 163 ( 0.61%)	4/ 160 ( 2.50%)	0.2 (0.0, 1.9)		53.0

\*Zelen's test of homogeneity, p=0.618

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = PMDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Trial 400	0/ 31 ( 0.00%)	0/ 17 ( 0.00%)	Not Enough Events		
Trial 427	0/ 29 ( 0.00%)	0/ 9 ( 0.00%)	Not Enough Events		
Trial 658	0/ 60 ( 0.00%)	0/ 59 ( 0.00%)	Not Enough Events		
Trial 689	0/ 246 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 677	0/ 212 ( 0.00%)	0/ 109 ( 0.00%)	Not Enough Events		
Trial 688	0/ 242 ( 0.00%)	0/ 119 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Detoxification in Alcoholics

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 201	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.02

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Fibromyalgia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Trial 433	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442



Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = All Indications

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	142/8917 ( 1.59%)	125/5905 ( 2.12%)	0.8 (0.6, 1.0)	0.067	230.7
All Depression	110/3679 ( 2.99%)	85/2212 ( 3.84%)	0.9 (0.7, 1.3)	0.628	366.0
MDD	62/3414 ( 1.82%)	40/1930 ( 2.07%)	0.8 (0.5, 1.2)	0.275	226.2
IBD	43/ 149 (28.86%)	45/ 154 (29.22%)	1.0 (0.6, 1.6)	1.000	264.2
Dysthymia	3/ 81 ( 3.70%)	0/ 85 ( 0.00%)	inf ( 0.6, inf)	0.114	(27.0)
Bipolar	2/ 35 ( 5.71%)	0/ 43 ( 0.00%)	inf ( 0.4, inf)	0.198	(17.5)
All Non-Depression	32/5238 ( 0.61%)	40/3693 ( 1.08%)	0.6 (0.4, 0.9)	0.013	221.2
Panic	5/1092 ( 0.46%)	4/ 903 ( 0.44%)	0.8 (0.2, 3.4)	0.733	999.4
OCD	7/ 698 ( 1.00%)	10/ 416 ( 2.40%)	0.3 (0.1, 0.9)	0.036	63.9
SAD	3/ 943 ( 0.32%)	3/ 643 ( 0.47%)	0.8 (0.1, 4.7)	1.000	968.7
GAD	5/ 904 ( 0.55%)	3/ 697 ( 0.43%)	1.5 (0.4, 7.9)	0.726	(433.8)
PTSD	11/ 698 ( 1.58%)	20/ 510 ( 3.92%)	0.4 (0.2, 0.9)	0.025	44.3
PMDD	1/ 820 ( 0.12%)	0/ 438 ( 0.00%)	inf ( 0.1, inf)	1.000	
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Breslow-Day test of homogeneity, p=0.335

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = All Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	110/3679 ( 2.99%)	85/2212 ( 3.84%)	0.9 (0.7, 1.3)	0.628	366.0
MDD	62/3414 ( 1.82%)	40/1930 ( 2.07%)	0.8 (0.5, 1.2)	0.275	226.2
IBD	43/ 149 (28.86%)	45/ 154 (29.22%)	1.0 (0.6, 1.6)	1.000	264.2
Dysthymia	3/ 81 ( 3.70%)	0/ 85 ( 0.00%)	inf ( 0.6, inf)	0.114	(27.0)
Bipolar	2/ 35 ( 5.71%)	0/ 43 ( 0.00%)	inf ( 0.4, inf)	0.198	(17.5)

\*Breslow-Day test of homogeneity, p=0.460

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = MDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	62/3414 ( 1.82%)	40/1930 ( 2.07%)	0.8 (0.5, 1.2)	0.275	226.2
Overall (Mantel Haenszel)	62/3414 ( 1.82%)	40/1930 ( 2.07%)	0.8 (0.5, 1.2)	0.241	223.5
Trial 276	1/ 20 ( 5.00%)	0/ 21 ( 0.00%)	inf (0.1, inf)		(20.0)
Trial 279	2/ 21 ( 9.52%)	2/ 10 (20.00%)	0.4 (0.0, 4.8)		9.5
Trial 274	0/ 22 ( 0.00%)	0/ 23 ( 0.00%)	Not Enough Events		
Trial 001	0/ 25 ( 0.00%)	0/ 25 ( 0.00%)	Not Enough Events		
Trial 002	2/ 170 ( 1.18%)	6/ 171 ( 3.51%)	0.3 (0.0, 1.6)		42.9
Trial 009	10/ 421 ( 2.38%)	1/ 53 ( 1.89%)	1.3 (0.2, 28.2)		(204.7)
Trial 003	3/ 241 ( 1.24%)	7/ 244 ( 2.87%)	0.4 (0.1, 1.6)		61.6
Trial 115	7/ 283 ( 2.47%)	3/ 117 ( 2.56%)	1.0 (0.2, 4.7)		1103.7
Trial 128	14/ 357 ( 3.92%)	7/ 140 ( 5.00%)	0.8 (0.3, 2.1)		92.7
Trial 251	4/ 125 ( 3.20%)	1/ 129 ( 0.78%)	4.2 (0.5, 105.5)		(41.2)
Trial 448	3/ 212 ( 1.42%)	1/ 103 ( 0.97%)	1.5 (0.2, 38.9)		(225.1)
Trial 449	6/ 223 ( 2.69%)	3/ 110 ( 2.73%)	1.0 (0.2, 4.9)		2725.6
Trial 487	4/ 214 ( 1.87%)	1/ 109 ( 0.92%)	2.1 (0.3, 51.3)		(105.1)
Trial 625	2/ 112 ( 1.79%)	1/ 117 ( 0.85%)	2.1 (0.2, 62.7)		(107.4)
Trial 785	3/ 197 ( 1.52%)	4/ 105 ( 3.81%)	0.4 (0.1, 1.9)		43.7
Trial 810	0/ 306 ( 0.00%)	2/ 148 ( 1.35%)	0.0 ( 0.0, 1.7)		74.0
Trial NKD20006	0/ 124 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 874	1/ 341 ( 0.29%)	1/ 180 ( 0.56%)	0.5 (0.0, 20.6)		381.2

\*Zelen's test of homogeneity, p=0.604

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = IBD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	43/ 149 (28.86%)	45/ 154 (29.22%)	1.0 (0.6, 1.6)	1.000	264.2
Overall (Mantel Haenszel)	43/ 149 (28.86%)	45/ 154 (29.22%)	1.0 (0.6, 1.6)	0.942	262.8
Trial 057	36/ 131 (27.48%)	40/ 136 (29.41%)	0.9 (0.5, 1.6)		51.8
Trial 106	7/ 18 (38.89%)	5/ 18 (27.78%)	1.6 (0.4, 7.2)		(9.0)

\*Zelen's test of homogeneity, p=0.475

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Dysthymia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	3/ 81 ( 3.70%)	0/ 85 ( 0.00%)	inf ( 0.6, inf)	0.114	(27.0)
Overall (Mantel Haenszel)	3/ 81 ( 3.70%)	0/ 85 ( 0.00%)	7.6 (0.4, 150.0)	0.118	
Trial 327	3/ 81 ( 3.70%)	0/ 85 ( 0.00%)	inf (0.6, inf)		(27.0)

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Bipolar

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	2/ 35 ( 5.71%)	0/ 43 ( 0.00%)	inf ( 0.4, inf)	0.198	(17.5)
Overall (Mantel Haenszel)	2/ 35 ( 5.71%)	0/ 43 ( 0.00%)	6.5 (0.3, 139.8)	0.176	
Trial 352	2/ 35 ( 5.71%)	0/ 43 ( 0.00%)	inf (0.4, inf)		(17.5)

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = All Non-Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	32/5238 ( 0.61%)	40/3693 ( 1.08%)	0.6 (0.4, 0.9)	0.013	221.2
Panic	5/1092 ( 0.46%)	4/ 903 ( 0.44%)	0.8 (0.2, 3.4)	0.733	999.4
OCD	7/ 698 ( 1.00%)	10/ 416 ( 2.40%)	0.3 (0.1, 0.9)	0.036	63.9
SAD	3/ 943 ( 0.32%)	3/ 643 ( 0.47%)	0.8 (0.1, 4.7)	1.000	968.7
GAD	5/ 904 ( 0.55%)	3/ 697 ( 0.43%)	1.5 (0.4, 7.9)	0.726	(433.8)
PTSD	11/ 698 ( 1.58%)	20/ 510 ( 3.92%)	0.4 (0.2, 0.9)	0.025	44.3
PMDD	1/ 820 ( 0.12%)	0/ 438 ( 0.00%)	inf ( 0.1, inf)	1.000	
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Breslow-Day test of homogeneity, p=0.381

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Panic

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	5/1092 ( 0.46%)	4/ 903 ( 0.44%)	0.8 (0.2, 3.4)	0.733	999.4
Overall (Mantel Haenszel)	5/1092 ( 0.46%)	4/ 903 ( 0.44%)	0.8 (0.2, 2.5)	0.650	914.1
Trial 108	0/ 60 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 187	0/ 123 ( 0.00%)	3/ 123 ( 2.44%)	0.0 ( 0.0, 1.7)		41.0
Trial 120	4/ 209 ( 1.91%)	0/ 69 ( 0.00%)	inf (0.3, inf)		(52.3)
Trial 223	0/ 76 ( 0.00%)	1/ 71 ( 1.41%)	0.0 ( 0.0, 17.8)		71.0
Trial 410	0/ 87 ( 0.00%)	0/ 40 ( 0.00%)	Not Enough Events		
Trial 384	0/ 85 ( 0.00%)	0/ 83 ( 0.00%)	Not Enough Events		
Trial 495	1/ 162 ( 0.62%)	0/ 165 ( 0.00%)	inf (0.1, inf)		(162.0)
Trial 494	0/ 141 ( 0.00%)	0/ 148 ( 0.00%)	Not Enough Events		
Trial 497	0/ 149 ( 0.00%)	0/ 144 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.090

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442



Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = OCD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	7/ 698 ( 1.00%)	10/ 416 ( 2.40%)	0.3 (0.1, 0.9)	0.036	63.9
Overall (Mantel Haenszel)	7/ 698 ( 1.00%)	10/ 416 ( 2.40%)	0.4 (0.1, 1.0)	0.033	67.8
Trial 116	3/ 259 ( 1.16%)	1/ 89 ( 1.12%)	1.0 (0.1, 27.4)		(2881.4)
Trial 118	1/ 82 ( 1.22%)	1/ 77 ( 1.30%)	0.9 (0.0, 37.1)		1262.8
Trial 136	2/ 201 ( 1.00%)	8/ 99 ( 8.08%)	0.1 (0.0, 0.5)		14.1
Trial 414	0/ 61 ( 0.00%)	0/ 56 ( 0.00%)	Not Enough Events		
Trial 660	1/ 95 ( 1.05%)	0/ 95 ( 0.00%)	inf (0.1, inf)		(95.0)

\*Zelen's test of homogeneity, p=0.078

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = SAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	3/ 943 ( 0.32%)	3/ 643 ( 0.47%)	0.8 (0.1, 4.7)	1.000	968.7
Overall (Mantel Haenszel)	3/ 943 ( 0.32%)	3/ 643 ( 0.47%)	0.7 (0.2, 2.6)	0.593	724.0
Trial 382	0/ 94 ( 0.00%)	1/ 93 ( 1.08%)	0.0 ( 0.0, 18.8)		93.0
Trial 502	2/ 139 ( 1.44%)	1/ 151 ( 0.66%)	2.2 (0.2, 65.0)		(128.8)
Trial 454	1/ 289 ( 0.35%)	0/ 95 ( 0.00%)	inf (0.0, inf)		(289.0)
Trial 790	0/ 186 ( 0.00%)	0/ 184 ( 0.00%)	Not Enough Events		
Trial 661	0/ 235 ( 0.00%)	1/ 120 ( 0.83%)	0.0 ( 0.0, 9.7)		120.0

\*Zelen's test of homogeneity, p=0.524

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = GAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	5/ 904 ( 0.55%)	3/ 697 ( 0.43%)	1.5 (0.4, 7.9)	0.726	(433.8)
Overall (Mantel Haenszel)	5/ 904 ( 0.55%)	3/ 697 ( 0.43%)	1.3 (0.4, 4.3)	0.695	(849.7)
Trial 637	1/ 187 ( 0.53%)	0/ 185 ( 0.00%)	inf (0.1, inf)		(187.0)
Trial 641	1/ 386 ( 0.26%)	0/ 180 ( 0.00%)	inf (0.0, inf)		(386.0)
Trial 642	3/ 164 ( 1.83%)	1/ 166 ( 0.60%)	3.1 (0.3, 81.4)		(81.5)
Trial 791	0/ 167 ( 0.00%)	2/ 166 ( 1.20%)	0.0 ( 0.0, 3.4)		83.0

\*Zelen's test of homogeneity, p=0.326

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = PTSD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	11/ 698 ( 1.58%)	20/ 510 ( 3.92%)	0.4 (0.2, 0.9)	0.025	44.3
Overall (Mantel Haenszel)	11/ 698 ( 1.58%)	20/ 510 ( 3.92%)	0.4 (0.2, 0.9)	0.019	45.0
Trial 627	5/ 160 ( 3.13%)	9/ 162 ( 5.56%)	0.5 (0.2, 1.7)		41.1
Trial 651	4/ 375 ( 1.07%)	7/ 188 ( 3.72%)	0.3 (0.1, 1.0)		37.6
Trial 648	2/ 163 ( 1.23%)	4/ 160 ( 2.50%)	0.5 (0.1, 2.8)		78.6

\*Zelen's test of homogeneity, p=0.693

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = PMDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	1/ 820 ( 0.12%)	0/ 438 ( 0.00%)	inf ( 0.1, inf)	1.000	
Overall (Mantel Haenszel)	1/ 820 ( 0.12%)	0/ 438 ( 0.00%)	3.0 (0.1, 75.1)	0.485	
Trial 400	0/ 31 ( 0.00%)	0/ 17 ( 0.00%)	Not Enough Events		
Trial 427	0/ 29 ( 0.00%)	0/ 9 ( 0.00%)	Not Enough Events		
Trial 658	1/ 60 ( 1.67%)	0/ 59 ( 0.00%)	inf (0.1, inf)		(60.0)
Trial 689	0/ 246 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 677	0/ 212 ( 0.00%)	0/ 109 ( 0.00%)	Not Enough Events		
Trial 688	0/ 242 ( 0.00%)	0/ 119 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Detoxification in Alcoholics

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 201	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.03

Number and Percent of Subjects with Composite Suicidal Behaviour and Ideation by Indication, Treatment Group and Trial  
 Indication = Fibromyalgia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Trial 433	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = All Indications

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	50/8958 ( 0.56%)	40/5953 ( 0.67%)	1.2 (0.8, 1.9)	0.483	(743.9)
Overall (Mantel Haenszel)	50/8958 ( 0.56%)	40/5953 ( 0.67%)	1.1 (0.7, 1.7)	0.721	(1851.0)
All Depression	43/3720 ( 1.16%)	36/2260 ( 1.59%)	1.2 (0.7, 1.9)	0.613	(387.6)
MDD	11/3455 ( 0.32%)	1/1978 ( 0.05%)	6.7 (1.1, 149.4)	0.058	(345.2)
IBD	32/ 149 (21.48%)	35/ 154 (22.73%)	0.9 (0.5, 1.6)	0.890	77.8
Dysthymia	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Bipolar	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
All Non-Depression	7/5238 ( 0.13%)	4/3693 ( 0.11%)	1.5 (0.4, 5.8)	0.759	(2029.9)
Panic	1/1092 ( 0.09%)	2/ 903 ( 0.22%)	0.3 (0.0, 4.8)	0.561	675.6
OCD	3/ 698 ( 0.43%)	1/ 416 ( 0.24%)	2.1 (0.2, 57.8)	0.642	(368.5)
SAD	2/ 943 ( 0.21%)	1/ 643 ( 0.16%)	2.2 (0.2, 65.0)	0.609	(544.9)
GAD	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
PTSD	1/ 698 ( 0.14%)	0/ 510 ( 0.00%)	inf ( 0.1, inf)	0.497	
PMDD	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.958

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)



Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = All Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	43/3720 ( 1.16%)	36/2260 ( 1.59%)	1.2 (0.7, 1.9)	0.613	(387.6)
Overall (Mantel Haenszel)	43/3720 ( 1.16%)	36/2260 ( 1.59%)	1.1 (0.7, 1.7)	0.820	(1129.9)
MDD	11/3455 ( 0.32%)	1/1978 ( 0.05%)	6.7 (1.1, 149.4)	0.058	(345.2)
IBD	32/ 149 (21.48%)	35/ 154 (22.73%)	0.9 (0.5, 1.6)	0.890	77.8
Dysthymia	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Bipolar	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.965  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = MDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	11/3455 ( 0.32%)	1/1978 ( 0.05%)	6.7 (1.1, 149.4)	0.058	(345.2)
Overall (Mantel Haenszel)	11/3455 ( 0.32%)	1/1978 ( 0.05%)	1.6 (0.6, 4.2)	0.363	(3515.9)
Trial 276	0/ 20 ( 0.00%)	0/ 21 ( 0.00%)	Not Enough Events		
Trial 279	1/ 21 ( 4.76%)	0/ 10 ( 0.00%)	inf (0.0, inf)		(21.0)
Trial 274	0/ 22 ( 0.00%)	0/ 23 ( 0.00%)	Not Enough Events		
Trial 001	0/ 25 ( 0.00%)	0/ 25 ( 0.00%)	Not Enough Events		
Trial 002	1/ 170 ( 0.59%)	1/ 171 ( 0.58%)	1.0 (0.0, 39.4)		(29070.0)
Trial 009	1/ 421 ( 0.24%)	0/ 53 ( 0.00%)	inf (0.0, inf)		(421.0)
Trial 003	0/ 241 ( 0.00%)	0/ 244 ( 0.00%)	Not Enough Events		
Trial 115	1/ 283 ( 0.35%)	0/ 117 ( 0.00%)	inf (0.0, inf)		(283.0)
Trial 128	1/ 357 ( 0.28%)	0/ 140 ( 0.00%)	inf (0.0, inf)		(357.0)
Trial 251	1/ 125 ( 0.80%)	0/ 129 ( 0.00%)	inf (0.1, inf)		(125.0)
Trial 448	2/ 212 ( 0.94%)	0/ 103 ( 0.00%)	inf (0.1, inf)		(106.0)
Trial 449	1/ 223 ( 0.45%)	0/ 110 ( 0.00%)	inf (0.0, inf)		(223.0)
Trial 487	0/ 214 ( 0.00%)	0/ 109 ( 0.00%)	Not Enough Events		
Trial 625	1/ 112 ( 0.89%)	0/ 117 ( 0.00%)	inf (0.1, inf)		(112.0)
Trial 442	0/ 41 ( 0.00%)	0/ 48 ( 0.00%)	Not Enough Events		
Trial 785	1/ 197 ( 0.51%)	0/ 105 ( 0.00%)	inf (0.0, inf)		(197.0)
Trial 810	0/ 306 ( 0.00%)	0/ 148 ( 0.00%)	Not Enough Events		
Trial NKD20006	0/ 124 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 874	0/ 341 ( 0.00%)	0/ 180 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=1.000  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = IBD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	32/ 149 (21.48%)	35/ 154 (22.73%)	0.9 (0.5, 1.6)	0.890	77.8
Overall (Mantel Haenszel)	32/ 149 (21.48%)	35/ 154 (22.73%)	0.9 (0.5, 1.6)	0.787	77.3
Trial 057	26/ 131 (19.85%)	30/ 136 (22.06%)	0.9 (0.5, 1.6)		45.2
Trial 106	6/ 18 (33.33%)	5/ 18 (27.78%)	1.3 (0.3, 5.8)		(18.0)

\*Zelen's test of homogeneity, p=0.705

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Dysthymia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Trial 327	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Bipolar

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
Trial 352	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = All Non-Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	7/5238 ( 0.13%)	4/3693 ( 0.11%)	1.5 (0.4, 5.8)	0.759	(2029.9)
Overall (Mantel Haenszel)	7/5238 ( 0.13%)	4/3693 ( 0.11%)	1.2 (0.4, 3.3)	0.720	(4643.2)
Panic	1/1092 ( 0.09%)	2/ 903 ( 0.22%)	0.3 (0.0, 4.8)	0.561	675.6
OCD	3/ 698 ( 0.43%)	1/ 416 ( 0.24%)	2.1 (0.2, 57.8)	0.642	(368.5)
SAD	2/ 943 ( 0.21%)	1/ 643 ( 0.16%)	2.2 (0.2, 65.0)	0.609	(544.9)
GAD	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
PTSD	1/ 698 ( 0.14%)	0/ 510 ( 0.00%)	inf ( 0.1, inf)	0.497	
PMDD	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.426

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Panic

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	1/1092 ( 0.09%)	2/ 903 ( 0.22%)	0.3 (0.0, 4.8)	0.561	675.6
Overall (Mantel Haenszel)	1/1092 ( 0.09%)	2/ 903 ( 0.22%)	0.4 (0.1, 2.7)	0.344	730.8
Trial 108	0/ 60 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 187	0/ 123 ( 0.00%)	2/ 123 ( 1.63%)	0.0 ( 0.0, 3.5)		61.5
Trial 120	1/ 209 ( 0.48%)	0/ 69 ( 0.00%)	inf (0.0, inf)		(209.0)
Trial 223	0/ 76 ( 0.00%)	0/ 71 ( 0.00%)	Not Enough Events		
Trial 410	0/ 87 ( 0.00%)	0/ 40 ( 0.00%)	Not Enough Events		
Trial 384	0/ 85 ( 0.00%)	0/ 83 ( 0.00%)	Not Enough Events		
Trial 495	0/ 162 ( 0.00%)	0/ 165 ( 0.00%)	Not Enough Events		
Trial 494	0/ 141 ( 0.00%)	0/ 148 ( 0.00%)	Not Enough Events		
Trial 497	0/ 149 ( 0.00%)	0/ 144 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=1.000  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = OCD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	3/ 698 ( 0.43%)	1/ 416 ( 0.24%)	2.1 (0.2, 57.8)	0.642	(368.5)
Overall (Mantel Haenszel)	3/ 698 ( 0.43%)	1/ 416 ( 0.24%)	1.5 (0.3, 8.2)	0.599	(774.0)
Trial 116	0/ 259 ( 0.00%)	0/ 89 ( 0.00%)	Not Enough Events		
Trial 118	1/ 82 ( 1.22%)	0/ 77 ( 0.00%)	inf (0.0, inf)		(82.0)
Trial 136	1/ 201 ( 0.50%)	1/ 99 ( 1.01%)	0.5 (0.0, 19.3)		195.1
Trial 414	0/ 61 ( 0.00%)	0/ 56 ( 0.00%)	Not Enough Events		
Trial 660	1/ 95 ( 1.05%)	0/ 95 ( 0.00%)	inf (0.1, inf)		(95.0)

\*Zelen's test of homogeneity, p=0.659

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)



Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = SAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	2/ 943 ( 0.21%)	1/ 643 ( 0.16%)	2.2 (0.2, 65.0)	0.609	(544.9)
Overall (Mantel Haenszel)	2/ 943 ( 0.21%)	1/ 643 ( 0.16%)	2.2 (0.2, 24.4)	0.515	(542.3)
Trial 382	0/ 94 ( 0.00%)	0/ 93 ( 0.00%)	Not Enough Events		
Trial 502	2/ 139 ( 1.44%)	1/ 151 ( 0.66%)	2.2 (0.2, 65.0)		(128.8)
Trial 454	0/ 289 ( 0.00%)	0/ 95 ( 0.00%)	Not Enough Events		
Trial 790	0/ 186 ( 0.00%)	0/ 184 ( 0.00%)	Not Enough Events		
Trial 661	0/ 235 ( 0.00%)	0/ 120 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = GAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
Trial 637	0/ 187 ( 0.00%)	0/ 185 ( 0.00%)	Not Enough Events		
Trial 641	0/ 386 ( 0.00%)	0/ 180 ( 0.00%)	Not Enough Events		
Trial 642	0/ 164 ( 0.00%)	0/ 166 ( 0.00%)	Not Enough Events		
Trial 791	0/ 167 ( 0.00%)	0/ 166 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = PTSD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	1/ 698 ( 0.14%)	0/ 510 ( 0.00%)	inf ( 0.1, inf)	0.497	
Overall (Mantel Haenszel)	1/ 698 ( 0.14%)	0/ 510 ( 0.00%)	3.1 (0.1, 75.6)	0.473	
Trial 627	1/ 160 ( 0.63%)	0/ 162 ( 0.00%)	inf (0.1, inf)		(160.0)
Trial 651	0/ 375 ( 0.00%)	0/ 188 ( 0.00%)	Not Enough Events		
Trial 648	0/ 163 ( 0.00%)	0/ 160 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = PMDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Trial 400	0/ 31 ( 0.00%)	0/ 17 ( 0.00%)	Not Enough Events		
Trial 427	0/ 29 ( 0.00%)	0/ 9 ( 0.00%)	Not Enough Events		
Trial 658	0/ 60 ( 0.00%)	0/ 59 ( 0.00%)	Not Enough Events		
Trial 689	0/ 246 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 677	0/ 212 ( 0.00%)	0/ 109 ( 0.00%)	Not Enough Events		
Trial 688	0/ 242 ( 0.00%)	0/ 119 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Detoxification in Alcoholics

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 201	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis  
 Table 2.04  
 Number and Percent of Subjects with Definitive Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Fibromyalgia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Trial 433	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = All Indications

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	3/8917 ( 0.03%)	2/5905 ( 0.03%)	1.0 (0.1, 8.9)	1.000	81680.6
Overall (Mantel Haenszel)	3/8917 ( 0.03%)	2/5905 ( 0.03%)	0.7 (0.2, 3.0)	0.670	11276.6
All Depression	2/3679 ( 0.05%)	2/2212 ( 0.09%)	0.6 (0.1, 7.2)	1.000	3144.9
MDD	1/3414 ( 0.03%)	0/1930 ( 0.00%)	inf ( 0.0, inf)	1.000	
IBD	1/ 149 ( 0.67%)	2/ 154 ( 1.30%)	0.5 (0.0, 6.8)	1.000	158.8
Dysthymia	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Bipolar	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
All Non-Depression	1/5238 ( 0.02%)	0/3693 ( 0.00%)	inf ( 0.0, inf)	1.000	
Panic	0/1092 ( 0.00%)	0/ 903 ( 0.00%)	Not Enough Events		
OCD	1/ 698 ( 0.14%)	0/ 416 ( 0.00%)	inf ( 0.0, inf)	1.000	
SAD	0/ 943 ( 0.00%)	0/ 643 ( 0.00%)	Not Enough Events		
GAD	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
PTSD	0/ 698 ( 0.00%)	0/ 510 ( 0.00%)	Not Enough Events		
PMDD	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.593

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = All Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	2/3679 ( 0.05%)	2/2212 ( 0.09%)	0.6 (0.1, 7.2)	1.000	3144.9
Overall (Mantel Haenszel)	2/3679 ( 0.05%)	2/2212 ( 0.09%)	0.6 (0.1, 3.0)	0.533	2812.6
MDD	1/3414 ( 0.03%)	0/1930 ( 0.00%)	inf ( 0.0, inf)	1.000	
IBD	1/ 149 ( 0.67%)	2/ 154 ( 1.30%)	0.5 (0.0, 6.8)	1.000	158.8
Dysthymia	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Bipolar	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.412

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442



Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = MDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	1/3414 ( 0.03%)	0/1930 ( 0.00%)	inf ( 0.0, inf)	1.000	
Overall (Mantel Haenszel)	1/3414 ( 0.03%)	0/1930 ( 0.00%)	0.4 (0.0, 9.5)	0.542	
Trial 276	0/ 20 ( 0.00%)	0/ 21 ( 0.00%)	Not Enough Events		
Trial 279	0/ 21 ( 0.00%)	0/ 10 ( 0.00%)	Not Enough Events		
Trial 274	0/ 22 ( 0.00%)	0/ 23 ( 0.00%)	Not Enough Events		
Trial 001	0/ 25 ( 0.00%)	0/ 25 ( 0.00%)	Not Enough Events		
Trial 002	0/ 170 ( 0.00%)	0/ 171 ( 0.00%)	Not Enough Events		
Trial 009	1/ 421 ( 0.24%)	0/ 53 ( 0.00%)	inf (0.0, inf)		(421.0)
Trial 003	0/ 241 ( 0.00%)	0/ 244 ( 0.00%)	Not Enough Events		
Trial 115	0/ 283 ( 0.00%)	0/ 117 ( 0.00%)	Not Enough Events		
Trial 128	0/ 357 ( 0.00%)	0/ 140 ( 0.00%)	Not Enough Events		
Trial 251	0/ 125 ( 0.00%)	0/ 129 ( 0.00%)	Not Enough Events		
Trial 448	0/ 212 ( 0.00%)	0/ 103 ( 0.00%)	Not Enough Events		
Trial 449	0/ 223 ( 0.00%)	0/ 110 ( 0.00%)	Not Enough Events		
Trial 487	0/ 214 ( 0.00%)	0/ 109 ( 0.00%)	Not Enough Events		
Trial 625	0/ 112 ( 0.00%)	0/ 117 ( 0.00%)	Not Enough Events		
Trial 785	0/ 197 ( 0.00%)	0/ 105 ( 0.00%)	Not Enough Events		
Trial 810	0/ 306 ( 0.00%)	0/ 148 ( 0.00%)	Not Enough Events		
Trial NKD20006	0/ 124 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 874	0/ 341 ( 0.00%)	0/ 180 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = IBD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	1/ 149 ( 0.67%)	2/ 154 ( 1.30%)	0.5 (0.0, 6.8)	1.000	158.8
Overall (Mantel Haenszel)	1/ 149 ( 0.67%)	2/ 154 ( 1.30%)	0.7 (0.1, 4.1)	0.670	239.0
Trial 057	0/ 131 ( 0.00%)	2/ 136 ( 1.47%)	0.0 ( 0.0, 3.6)		68.0
Trial 106	1/ 18 ( 5.56%)	0/ 18 ( 0.00%)	inf (0.1, inf)		(18.0)

\*Zelen's test of homogeneity, p=0.340

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Dysthymia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Trial 327	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Bipolar

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
Trial 352	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = All Non-Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	1/5238 ( 0.02%)	0/3693 ( 0.00%)	inf ( 0.0, inf)	1.000	
Overall (Mantel Haenszel)	1/5238 ( 0.02%)	0/3693 ( 0.00%)	1.5 (0.1, 36.9)	0.807	
Panic	0/1092 ( 0.00%)	0/ 903 ( 0.00%)	Not Enough Events		
OCD	1/ 698 ( 0.14%)	0/ 416 ( 0.00%)	inf ( 0.0, inf)	1.000	
SAD	0/ 943 ( 0.00%)	0/ 643 ( 0.00%)	Not Enough Events		
GAD	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
PTSD	0/ 698 ( 0.00%)	0/ 510 ( 0.00%)	Not Enough Events		
PMDD	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Panic

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/1092 ( 0.00%)	0/ 903 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/1092 ( 0.00%)	0/ 903 ( 0.00%)	Not Enough Events		
Trial 108	0/ 60 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 187	0/ 123 ( 0.00%)	0/ 123 ( 0.00%)	Not Enough Events		
Trial 120	0/ 209 ( 0.00%)	0/ 69 ( 0.00%)	Not Enough Events		
Trial 223	0/ 76 ( 0.00%)	0/ 71 ( 0.00%)	Not Enough Events		
Trial 410	0/ 87 ( 0.00%)	0/ 40 ( 0.00%)	Not Enough Events		
Trial 384	0/ 85 ( 0.00%)	0/ 83 ( 0.00%)	Not Enough Events		
Trial 495	0/ 162 ( 0.00%)	0/ 165 ( 0.00%)	Not Enough Events		
Trial 494	0/ 141 ( 0.00%)	0/ 148 ( 0.00%)	Not Enough Events		
Trial 497	0/ 149 ( 0.00%)	0/ 144 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = OCD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	1/ 698 ( 0.14%)	0/ 416 ( 0.00%)	inf ( 0.0, inf)	1.000	
Overall (Mantel Haenszel)	1/ 698 ( 0.14%)	0/ 416 ( 0.00%)	1.5 (0.1, 36.9)	0.807	
Trial 116	0/ 259 ( 0.00%)	0/ 89 ( 0.00%)	Not Enough Events		
Trial 118	0/ 82 ( 0.00%)	0/ 77 ( 0.00%)	Not Enough Events		
Trial 136	1/ 201 ( 0.50%)	0/ 99 ( 0.00%)	inf (0.0, inf)		(201.0)
Trial 414	0/ 61 ( 0.00%)	0/ 56 ( 0.00%)	Not Enough Events		
Trial 660	0/ 95 ( 0.00%)	0/ 95 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = SAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 943 ( 0.00%)	0/ 643 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 943 ( 0.00%)	0/ 643 ( 0.00%)	Not Enough Events		
Trial 382	0/ 94 ( 0.00%)	0/ 93 ( 0.00%)	Not Enough Events		
Trial 502	0/ 139 ( 0.00%)	0/ 151 ( 0.00%)	Not Enough Events		
Trial 454	0/ 289 ( 0.00%)	0/ 95 ( 0.00%)	Not Enough Events		
Trial 790	0/ 186 ( 0.00%)	0/ 184 ( 0.00%)	Not Enough Events		
Trial 661	0/ 235 ( 0.00%)	0/ 120 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442



Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = GAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
Trial 637	0/ 187 ( 0.00%)	0/ 185 ( 0.00%)	Not Enough Events		
Trial 641	0/ 386 ( 0.00%)	0/ 180 ( 0.00%)	Not Enough Events		
Trial 642	0/ 164 ( 0.00%)	0/ 166 ( 0.00%)	Not Enough Events		
Trial 791	0/ 167 ( 0.00%)	0/ 166 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = PTSD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 698 ( 0.00%)	0/ 510 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 698 ( 0.00%)	0/ 510 ( 0.00%)	Not Enough Events		
Trial 627	0/ 160 ( 0.00%)	0/ 162 ( 0.00%)	Not Enough Events		
Trial 651	0/ 375 ( 0.00%)	0/ 188 ( 0.00%)	Not Enough Events		
Trial 648	0/ 163 ( 0.00%)	0/ 160 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = PMDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Trial 400	0/ 31 ( 0.00%)	0/ 17 ( 0.00%)	Not Enough Events		
Trial 427	0/ 29 ( 0.00%)	0/ 9 ( 0.00%)	Not Enough Events		
Trial 658	0/ 60 ( 0.00%)	0/ 59 ( 0.00%)	Not Enough Events		
Trial 689	0/ 246 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 677	0/ 212 ( 0.00%)	0/ 109 ( 0.00%)	Not Enough Events		
Trial 688	0/ 242 ( 0.00%)	0/ 119 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Detoxification in Alcoholics

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 201	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.05

Number and Percent of Subjects with Rating Scale Emergent Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Fibromyalgia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Trial 433	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = All Indications

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	52/8917 ( 0.58%)	40/5905 ( 0.68%)	1.2 (0.8, 2.0)	0.415	(619.2)
Overall (Mantel Haenszel)	52/8917 ( 0.58%)	40/5905 ( 0.68%)	1.1 (0.7, 1.7)	0.626	(1330.0)
All Depression	45/3679 ( 1.22%)	36/2212 ( 1.63%)	1.2 (0.7, 2.0)	0.530	(299.7)
MDD	12/3414 ( 0.35%)	1/1930 ( 0.05%)	6.9 (1.1, 151.9)	0.036	(329.0)
IBD	33/ 149 (22.15%)	35/ 154 (22.73%)	1.0 (0.6, 1.7)	1.000	159.2
Dysthymia	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Bipolar	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
All Non-Depression	7/5238 ( 0.13%)	4/3693 ( 0.11%)	1.5 (0.4, 5.8)	0.759	(2029.9)
Panic	1/1092 ( 0.09%)	2/ 903 ( 0.22%)	0.3 (0.0, 4.8)	0.561	675.6
OCD	3/ 698 ( 0.43%)	1/ 416 ( 0.24%)	2.1 (0.2, 57.8)	0.642	(368.5)
SAD	2/ 943 ( 0.21%)	1/ 643 ( 0.16%)	2.2 (0.2, 65.0)	0.609	(544.9)
GAD	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
PTSD	1/ 698 ( 0.14%)	0/ 510 ( 0.00%)	inf ( 0.1, inf)	0.497	
PMDD	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.949  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = All Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	45/3679 ( 1.22%)	36/2212 ( 1.63%)	1.2 (0.7, 2.0)	0.530	(299.7)
Overall (Mantel Haenszel)	45/3679 ( 1.22%)	36/2212 ( 1.63%)	1.1 (0.7, 1.7)	0.710	(668.3)
MDD	12/3414 ( 0.35%)	1/1930 ( 0.05%)	6.9 (1.1, 151.9)	0.036	(329.0)
IBD	33/ 149 (22.15%)	35/ 154 (22.73%)	1.0 (0.6, 1.7)	1.000	159.2
Dysthymia	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Bipolar	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.957  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = MDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	12/3414 ( 0.35%)	1/1930 ( 0.05%)	6.9 (1.1, 151.9)	0.036	(329.0)
Overall (Mantel Haenszel)	12/3414 ( 0.35%)	1/1930 ( 0.05%)	1.6 (0.6, 4.3)	0.340	(3239.3)
Trial 276	0/ 20 ( 0.00%)	0/ 21 ( 0.00%)	Not Enough Events		
Trial 279	1/ 21 ( 4.76%)	0/ 10 ( 0.00%)	inf (0.0, inf)		(21.0)
Trial 274	0/ 22 ( 0.00%)	0/ 23 ( 0.00%)	Not Enough Events		
Trial 001	0/ 25 ( 0.00%)	0/ 25 ( 0.00%)	Not Enough Events		
Trial 002	1/ 170 ( 0.59%)	1/ 171 ( 0.58%)	1.0 (0.0, 39.4)		(29070.0)
Trial 009	2/ 421 ( 0.48%)	0/ 53 ( 0.00%)	inf (0.0, inf)		(210.5)
Trial 003	0/ 241 ( 0.00%)	0/ 244 ( 0.00%)	Not Enough Events		
Trial 115	1/ 283 ( 0.35%)	0/ 117 ( 0.00%)	inf (0.0, inf)		(283.0)
Trial 128	1/ 357 ( 0.28%)	0/ 140 ( 0.00%)	inf (0.0, inf)		(357.0)
Trial 251	1/ 125 ( 0.80%)	0/ 129 ( 0.00%)	inf (0.1, inf)		(125.0)
Trial 448	2/ 212 ( 0.94%)	0/ 103 ( 0.00%)	inf (0.1, inf)		(106.0)
Trial 449	1/ 223 ( 0.45%)	0/ 110 ( 0.00%)	inf (0.0, inf)		(223.0)
Trial 487	0/ 214 ( 0.00%)	0/ 109 ( 0.00%)	Not Enough Events		
Trial 625	1/ 112 ( 0.89%)	0/ 117 ( 0.00%)	inf (0.1, inf)		(112.0)
Trial 785	1/ 197 ( 0.51%)	0/ 105 ( 0.00%)	inf (0.0, inf)		(197.0)
Trial 810	0/ 306 ( 0.00%)	0/ 148 ( 0.00%)	Not Enough Events		
Trial NKD20006	0/ 124 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 874	0/ 341 ( 0.00%)	0/ 180 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=1.000  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442



Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = IBD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	33/ 149 (22.15%)	35/ 154 (22.73%)	1.0 (0.6, 1.7)	1.000	159.2
Overall (Mantel Haenszel)	33/ 149 (22.15%)	35/ 154 (22.73%)	1.0 (0.6, 1.7)	0.896	158.2
Trial 057	26/ 131 (19.85%)	30/ 136 (22.06%)	0.9 (0.5, 1.6)		45.2
Trial 106	7/ 18 (38.89%)	5/ 18 (27.78%)	1.6 (0.4, 7.2)		(9.0)

\*Zelen's test of homogeneity, p=0.465  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Dysthymia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Trial 327	0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Bipolar

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
Trial 352	0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = All Non-Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	7/5238 ( 0.13%)	4/3693 ( 0.11%)	1.5 (0.4, 5.8)	0.759	(2029.9)
Overall (Mantel Haenszel)	7/5238 ( 0.13%)	4/3693 ( 0.11%)	1.2 (0.4, 3.3)	0.720	(4643.2)
Panic	1/1092 ( 0.09%)	2/ 903 ( 0.22%)	0.3 (0.0, 4.8)	0.561	675.6
OCD	3/ 698 ( 0.43%)	1/ 416 ( 0.24%)	2.1 (0.2, 57.8)	0.642	(368.5)
SAD	2/ 943 ( 0.21%)	1/ 643 ( 0.16%)	2.2 (0.2, 65.0)	0.609	(544.9)
GAD	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
PTSD	1/ 698 ( 0.14%)	0/ 510 ( 0.00%)	inf ( 0.1, inf)	0.497	
PMDD	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Detoxification in Alcoholics	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Fibromyalgia	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=0.426  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Panic

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	1/1092 ( 0.09%)	2/ 903 ( 0.22%)	0.3 (0.0, 4.8)	0.561	675.6
Overall (Mantel Haenszel)	1/1092 ( 0.09%)	2/ 903 ( 0.22%)	0.4 (0.1, 2.7)	0.344	730.8
Trial 108	0/ 60 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 187	0/ 123 ( 0.00%)	2/ 123 ( 1.63%)	0.0 ( 0.0, 3.5)		61.5
Trial 120	1/ 209 ( 0.48%)	0/ 69 ( 0.00%)	inf (0.0, inf)		(209.0)
Trial 223	0/ 76 ( 0.00%)	0/ 71 ( 0.00%)	Not Enough Events		
Trial 410	0/ 87 ( 0.00%)	0/ 40 ( 0.00%)	Not Enough Events		
Trial 384	0/ 85 ( 0.00%)	0/ 83 ( 0.00%)	Not Enough Events		
Trial 495	0/ 162 ( 0.00%)	0/ 165 ( 0.00%)	Not Enough Events		
Trial 494	0/ 141 ( 0.00%)	0/ 148 ( 0.00%)	Not Enough Events		
Trial 497	0/ 149 ( 0.00%)	0/ 144 ( 0.00%)	Not Enough Events		

\*Zelen's test of homogeneity, p=1.000  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = OCD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	3/ 698 ( 0.43%)	1/ 416 ( 0.24%)	2.1 (0.2, 57.8)	0.642	(368.5)
Overall (Mantel Haenszel)	3/ 698 ( 0.43%)	1/ 416 ( 0.24%)	1.5 (0.3, 8.2)	0.599	(774.0)
Trial 116	0/ 259 ( 0.00%)	0/ 89 ( 0.00%)	Not Enough Events		
Trial 118	1/ 82 ( 1.22%)	0/ 77 ( 0.00%)	inf (0.0, inf)		(82.0)
Trial 136	1/ 201 ( 0.50%)	1/ 99 ( 1.01%)	0.5 (0.0, 19.3)		195.1
Trial 414	0/ 61 ( 0.00%)	0/ 56 ( 0.00%)	Not Enough Events		
Trial 660	1/ 95 ( 1.05%)	0/ 95 ( 0.00%)	inf (0.1, inf)		(95.0)

\*Zelen's test of homogeneity, p=0.659  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = SAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	2/ 943 ( 0.21%)	1/ 643 ( 0.16%)	2.2 (0.2, 65.0)	0.609	(544.9)
Overall (Mantel Haenszel)	2/ 943 ( 0.21%)	1/ 643 ( 0.16%)	2.2 (0.2, 24.4)	0.515	(542.3)
Trial 382	0/ 94 ( 0.00%)	0/ 93 ( 0.00%)	Not Enough Events		
Trial 502	2/ 139 ( 1.44%)	1/ 151 ( 0.66%)	2.2 (0.2, 65.0)		(128.8)
Trial 454	0/ 289 ( 0.00%)	0/ 95 ( 0.00%)	Not Enough Events		
Trial 790	0/ 186 ( 0.00%)	0/ 184 ( 0.00%)	Not Enough Events		
Trial 661	0/ 235 ( 0.00%)	0/ 120 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = GAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
Trial 637	0/ 187 ( 0.00%)	0/ 185 ( 0.00%)	Not Enough Events		
Trial 641	0/ 386 ( 0.00%)	0/ 180 ( 0.00%)	Not Enough Events		
Trial 642	0/ 164 ( 0.00%)	0/ 166 ( 0.00%)	Not Enough Events		
Trial 791	0/ 167 ( 0.00%)	0/ 166 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442



Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = PTSD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	1/ 698 ( 0.14%)	0/ 510 ( 0.00%)	inf ( 0.1, inf)	0.497	
Overall (Mantel Haenszel)	1/ 698 ( 0.14%)	0/ 510 ( 0.00%)	3.1 (0.1, 75.6)	0.473	
Trial 627	1/ 160 ( 0.63%)	0/ 162 ( 0.00%)	inf (0.1, inf)		(160.0)
Trial 651	0/ 375 ( 0.00%)	0/ 188 ( 0.00%)	Not Enough Events		
Trial 648	0/ 163 ( 0.00%)	0/ 160 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = PMDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Trial 400	0/ 31 ( 0.00%)	0/ 17 ( 0.00%)	Not Enough Events		
Trial 427	0/ 29 ( 0.00%)	0/ 9 ( 0.00%)	Not Enough Events		
Trial 658	0/ 60 ( 0.00%)	0/ 59 ( 0.00%)	Not Enough Events		
Trial 689	0/ 246 ( 0.00%)	0/ 125 ( 0.00%)	Not Enough Events		
Trial 677	0/ 212 ( 0.00%)	0/ 109 ( 0.00%)	Not Enough Events		
Trial 688	0/ 242 ( 0.00%)	0/ 119 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.06  
 Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Detoxification in Alcoholics

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Trial 201	0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis

Table 2.06

Number and Percent of Subjects with Composite Suicidal Behaviour by Indication, Treatment Group and Trial  
 Indication = Fibromyalgia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)*	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Overall (Mantel Haenszel)	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Trial 433	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		

\*Test of homogeneity not carried out due to insufficient data  
 Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 NOTE: Composite Suicidal Behaviour data was not available in Study 442

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = All Indications

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	6787/8239 (82.38%)	3856/5417 (71.18%)	1.8 (1.7, 2.0)	<0.001	(9.5)
All Depression	3058/3679 (83.12%)	1575/2212 (71.20%)	1.9 (1.7, 2.2)	<0.001	(8.9)
MDD	2843/3414 (83.27%)	1370/1930 (70.98%)	1.9 (1.7, 2.2)	<0.001	(8.7)
IBD	111/ 149 (74.50%)	100/ 154 (64.94%)	1.6 (1.0, 2.6)	0.071	(10.4)
Dysthymia	72/ 81 (88.89%)	65/ 85 (76.47%)	2.5 (1.0, 5.8)	0.036	(8.1)
Bipolar	32/ 35 (91.43%)	40/ 43 (93.02%)	0.8 (0.2, 4.2)	0.794	62.7
All Non-Depression	3729/4560 (81.78%)	2281/3205 (71.17%)	1.7 (1.6, 2.0)	<0.001	(10.0)
Panic	788/ 920 (85.65%)	602/ 780 (77.18%)	1.7 (1.3, 2.2)	<0.001	(12.9)
OCD	476/ 542 (87.82%)	224/ 265 (84.53%)	1.3 (0.9, 2.1)	0.189	(29.0)
SAD	586/ 708 (82.77%)	356/ 523 (68.07%)	1.9 (1.5, 2.6)	<0.001	(8.0)
GAD	736/ 904 (81.42%)	474/ 697 (68.01%)	1.9 (1.5, 2.5)	<0.001	(8.0)
PTSD	548/ 698 (78.51%)	348/ 510 (68.24%)	1.6 (1.2, 2.1)	<0.001	(10.8)
PMDD	549/ 731 (75.10%)	231/ 370 (62.43%)	1.8 (1.4, 2.4)	<0.001	(7.9)
Detoxification in Alcoholics	46/ 57 (80.70%)	46/ 60 (76.67%)	1.3 (0.5, 3.1)	0.596	(24.8)

\*Breslow-Day test of homogeneity, p=0.280

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = All Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	3058/3679 (83.12%)	1575/2212 (71.20%)	1.9 (1.7, 2.2)	<0.001	(8.9)
MDD	2843/3414 (83.27%)	1370/1930 (70.98%)	1.9 (1.7, 2.2)	<0.001	(8.7)
IBD	111/ 149 (74.50%)	100/ 154 (64.94%)	1.6 (1.0, 2.6)	0.071	(10.4)
Dysthymia	72/ 81 (88.89%)	65/ 85 (76.47%)	2.5 (1.0, 5.8)	0.036	(8.1)
Bipolar	32/ 35 (91.43%)	40/ 43 (93.02%)	0.8 (0.2, 4.2)	0.794	62.7

\*Breslow-Day test of homogeneity, p=0.215

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = MDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	2843/3414 (83.27%)	1370/1930 (70.98%)	1.9 (1.7, 2.2)	<0.001	(8.7)
Trial 276	16/ 20 (80.00%)	13/ 21 (61.90%)	2.4 (0.6, 11.1)		(5.5)
Trial 279	20/ 21 (95.24%)	8/ 10 (80.00%)	4.7 (0.3, 154.1)		(6.6)
Trial 274	19/ 22 (86.36%)	13/ 23 (56.52%)	4.7 (1.1, 24.9)		(3.4)
Trial 001	18/ 25 (72.00%)	9/ 25 (36.00%)	4.4 (1.4, 15.6)		(2.8)
Trial 002	138/ 170 (81.18%)	99/ 171 (57.89%)	3.1 (1.9, 5.1)		(4.3)
Trial 009	327/ 421 (77.67%)	31/ 53 (58.49%)	2.5 (1.3, 4.5)		(5.2)
Trial 003	209/ 241 (86.72%)	169/ 244 (69.26%)	2.9 (1.8, 4.6)		(5.7)
Trial 115	260/ 283 (91.87%)	99/ 117 (84.62%)	2.1 (1.0, 4.0)		(13.8)
Trial 128	328/ 357 (91.88%)	116/ 140 (82.86%)	2.3 (1.3, 4.2)		(11.1)
Trial 251	105/ 125 (84.00%)	103/ 129 (79.84%)	1.3 (0.7, 2.5)		(24.1)
Trial 448	190/ 212 (89.62%)	82/ 103 (79.61%)	2.2 (1.1, 4.3)		(10.0)
Trial 449	200/ 223 (89.69%)	89/ 110 (80.91%)	2.0 (1.1, 3.9)		(11.4)
Trial 487	196/ 214 (91.59%)	95/ 109 (87.16%)	1.6 (0.7, 3.4)		(22.6)
Trial 625	43/ 112 (38.39%)	37/ 117 (31.62%)	1.3 (0.8, 2.3)		(14.8)
Trial 785	157/ 197 (79.70%)	80/ 105 (76.19%)	1.2 (0.7, 2.2)		(28.5)
Trial 810	245/ 306 (80.07%)	113/ 148 (76.35%)	1.2 (0.8, 2.0)		(26.9)
Trial NKD20006	97/ 124 (78.23%)	82/ 125 (65.60%)	1.9 (1.1, 3.3)		(7.9)
Trial 874	275/ 341 (80.65%)	132/ 180 (73.33%)	1.5 (1.0, 2.3)		(13.7)

\*Breslow-Day test of homogeneity, p=0.157

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = IBD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	111/ 149 (74.50%)	100/ 154 (64.94%)	1.6 (1.0, 2.6)	0.071	(10.4)
Trial 057	96/ 131 (73.28%)	84/ 136 (61.76%)	1.7 (1.0, 2.9)		(8.7)
Trial 106	15/ 18 (83.33%)	16/ 18 (88.89%)	0.6 (0.1, 4.8)		18.0

\*Breslow-Day test of homogeneity, p=0.315

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433



Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = Dysthymia

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	72/ 81 (88.89%)	65/ 85 (76.47%)	2.5 (1.0, 5.8)	0.036	(8.1)
Trial 327	72/ 81 (88.89%)	65/ 85 (76.47%)	2.4 (1.1, 6.0)		(8.1)

\*Breslow-Day test of homogeneity, p<0.001

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = Bipolar

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	32/ 35 (91.43%)	40/ 43 (93.02%)	0.8 (0.2, 4.2)	0.794	62.7
Trial 352	32/ 35 (91.43%)	40/ 43 (93.02%)	0.8 (0.1, 5.0)		62.7

\*Breslow-Day test of homogeneity, p<0.001

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = All Non-Depression

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	3729/4560 (81.78%)	2281/3205 (71.17%)	1.7 (1.6, 2.0)	<0.001	(10.0)
Panic	788/ 920 (85.65%)	602/ 780 (77.18%)	1.7 (1.3, 2.2)	<0.001	(12.9)
OCD	476/ 542 (87.82%)	224/ 265 (84.53%)	1.3 (0.9, 2.1)	0.189	(29.0)
SAD	586/ 708 (82.77%)	356/ 523 (68.07%)	1.9 (1.5, 2.6)	<0.001	(8.0)
GAD	736/ 904 (81.42%)	474/ 697 (68.01%)	1.9 (1.5, 2.5)	<0.001	(8.0)
PTSD	548/ 698 (78.51%)	348/ 510 (68.24%)	1.6 (1.2, 2.1)	<0.001	(10.8)
PMDD	549/ 731 (75.10%)	231/ 370 (62.43%)	1.8 (1.4, 2.4)	<0.001	(7.9)
Detoxification in Alcoholics	46/ 57 (80.70%)	46/ 60 (76.67%)	1.3 (0.5, 3.1)	0.596	(24.8)

\*Breslow-Day test of homogeneity, p=0.437

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = Panic

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	788/ 920 (85.65%)	602/ 780 (77.18%)	1.7 (1.3, 2.2)	<0.001	(12.9)
Trial 108	44/ 60 (73.33%)	30/ 60 (50.00%)	2.7 (1.3, 6.0)		(4.3)
Trial 187	89/ 123 (72.36%)	83/ 123 (67.48%)	1.3 (0.7, 2.2)		(20.5)
Trial 120	188/ 209 (89.95%)	63/ 69 (91.30%)	0.9 (0.3, 2.1)		74.0
Trial 223	69/ 76 (90.79%)	58/ 71 (81.69%)	2.2 (0.8, 6.2)		(11.0)
Trial 495	138/ 162 (85.19%)	125/ 165 (75.76%)	1.8 (1.1, 3.3)		(10.6)
Trial 494	124/ 141 (87.94%)	122/ 148 (82.43%)	1.6 (0.8, 3.1)		(18.1)
Trial 497	136/ 149 (91.28%)	121/ 144 (84.03%)	2.0 (1.0, 4.2)		(13.8)

\*Breslow-Day test of homogeneity, p=0.502

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = OCD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	476/ 542 (87.82%)	224/ 265 (84.53%)	1.3 (0.9, 2.1)	0.189	(29.0)
Trial 116	236/ 259 (91.12%)	79/ 89 (88.76%)	1.3 (0.6, 2.8)		(42.5)
Trial 118	77/ 82 (93.90%)	67/ 77 (87.01%)	2.3 (0.7, 7.7)		(14.5)
Trial 136	163/ 201 (81.09%)	78/ 99 (78.79%)	1.2 (0.6, 2.1)		(43.4)

\*Breslow-Day test of homogeneity, p=0.563

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = SAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	586/ 708 (82.77%)	356/ 523 (68.07%)	1.9 (1.5, 2.6)	<0.001	(8.0)
Trial 382	84/ 94 (89.36%)	66/ 93 (70.97%)	3.4 (1.6, 7.9)		(5.4)
Trial 502	102/ 139 (73.38%)	101/ 151 (66.89%)	1.4 (0.8, 2.3)		(15.4)
Trial 454	256/ 289 (88.58%)	78/ 95 (82.11%)	1.7 (0.9, 3.2)		(15.4)
Trial 790	144/ 186 (77.42%)	111/ 184 (60.33%)	2.2 (1.4, 3.6)		(5.9)

\*Breslow-Day test of homogeneity, p=0.213

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = GAD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	736/ 904 (81.42%)	474/ 697 (68.01%)	1.9 (1.5, 2.5)	<0.001	(8.0)
Trial 637	109/ 187 (58.29%)	93/ 185 (50.27%)	1.4 (0.9, 2.1)		(12.5)
Trial 641	341/ 386 (88.34%)	135/ 180 (75.00%)	2.5 (1.6, 4.0)		(7.5)
Trial 642	146/ 164 (89.02%)	116/ 166 (69.88%)	3.5 (1.9, 6.4)		(5.2)
Trial 791	140/ 167 (83.83%)	130/ 166 (78.31%)	1.4 (0.8, 2.5)		(18.1)

\*Breslow-Day test of homogeneity, p=0.030

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = PTSD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	548/ 698 (78.51%)	348/ 510 (68.24%)	1.6 (1.2, 2.1)	<0.001	(10.8)
Trial 627	113/ 160 (70.63%)	89/ 162 (54.94%)	2.0 (1.2, 3.1)		(6.4)
Trial 651	305/ 375 (81.33%)	140/ 188 (74.47%)	1.5 (1.0, 2.3)		(14.6)
Trial 648	130/ 163 (79.75%)	119/ 160 (74.38%)	1.4 (0.8, 2.3)		(18.6)

\*Breslow-Day test of homogeneity, p=0.527

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433



Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = PMDD

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	549/ 731 (75.10%)	231/ 370 (62.43%)	1.8 (1.4, 2.4)	<0.001	(7.9)
Trial 400	24/ 31 (77.42%)	11/ 17 (64.71%)	1.8 (0.5, 7.1)		(7.9)
Trial 689	189/ 246 (76.83%)	81/ 125 (64.80%)	1.8 (1.1, 2.9)		(8.3)
Trial 677	145/ 212 (68.40%)	62/ 109 (56.88%)	1.6 (1.0, 2.6)		(8.7)
Trial 688	191/ 242 (78.93%)	77/ 119 (64.71%)	2.0 (1.2, 3.3)		(7.0)

\*Breslow-Day test of homogeneity, p=0.940

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
 Table 2.07  
 Number and Percent of Subjects with Any Adverse Event by Indication, Treatment Group and Trial  
 Indication = Detoxification in Alcoholics

Trial	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)*	46/ 57 (80.70%)	46/ 60 (76.67%)	1.3 (0.5, 3.1)	0.596	(24.8)
Trial 201	46/ 57 (80.70%)	46/ 60 (76.67%)	1.3 (0.5, 3.1)		(24.8)

\*Breslow-Day test of homogeneity, p<0.001

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

NOTE: Adverse event data was not available in Studies 442, 410, 384, 414, 660, 661, 427, 658 and 433

Paroxetine Adult Suicidality Analysis  
Table 2.08  
Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
by Indication, Treatment Group and Risk Factors  
Indication = All Indications

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)		83/8958 ( 0.93%)	65/5953 ( 1.09%)	0.9 (0.7, 1.3)	0.649	1262.9
Baseline Suicidal Ideation	Missing	5/1361 ( 0.37%)	2/1109 ( 0.18%)	2.0 (0.4, 10.5)		(534.7)
	Absent	33/6821 ( 0.48%)	17/4348 ( 0.39%)	1.2 (0.7, 2.2)		(1077.4)
	Present	45/ 776 ( 5.80%)	46/ 496 ( 9.27%)	0.6 (0.4, 0.9)		28.8
Age Group	<18	1/ 10 (10.00%)	0/ 6 ( 0.00%)	Not Enough Events		(10.0)
	18-24	20/ 776 ( 2.58%)	7/ 542 ( 1.29%)	2.0 (0.8, 4.8)		(77.8)
	25-64	59/7543 ( 0.78%)	57/5000 ( 1.14%)	0.7 (0.5, 1.0)		279.5
	>=65	3/ 629 ( 0.48%)	1/ 405 ( 0.25%)	1.9 (0.2, 18.7)		(434.7)
Gender	Female	52/5496 ( 0.95%)	38/3630 ( 1.05%)	0.9 (0.6, 1.4)		993.2
	Male	31/3461 ( 0.90%)	27/2323 ( 1.16%)	0.8 (0.5, 1.3)		375.1

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Asymptotic analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.050, 0.100, 0.636

Paroxetine Adult Suicidality Analysis  
 Table 2.08  
 Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = All Depression

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)		66/3720 ( 1.77%)	47/2260 ( 2.08%)	1.1 (0.7, 1.6)	0.795	(899.2)
Baseline Suicidal Ideation	Missing	0/ 0	0/ 2 ( 0.00%)	Not Enough Events		
	Absent	24/3152 ( 0.76%)	7/1858 ( 0.38%)	2.0 (0.9, 4.7)		(260.0)
	Present	42/ 568 ( 7.39%)	40/ 400 (10.00%)	0.7 (0.5, 1.1)		38.4
Age Group	18-24	15/ 272 ( 5.51%)	6/ 149 ( 4.03%)	1.4 (0.5, 3.7)		(67.2)
	25-64	48/2931 ( 1.64%)	40/1797 ( 2.23%)	0.7 (0.5, 1.1)		170.0
	>=65	3/ 517 ( 0.58%)	1/ 314 ( 0.32%)	1.8 (0.2, 17.6)		(382.0)
Gender	Female	40/2187 ( 1.83%)	27/1368 ( 1.97%)	0.9 (0.6, 1.5)		691.1
	Male	26/1533 ( 1.70%)	20/ 892 ( 2.24%)	0.8 (0.4, 1.4)		183.1

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Asymptotic analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.030, 0.378, 0.597

Paroxetine Adult Suicidality Analysis  
 Table 2.08  
 Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = MDD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		31/3455 ( 0.90%)	11/1978 ( 0.56%)	1.3 (0.7, 2.8)	0.493	(527.4)
Baseline Suicidal Ideation	Missing	0/ 0	0/ 2 ( 0.00%)	Not Enough Events		
	Absent	24/3042 ( 0.79%)	7/1736 ( 0.40%)	2.0 (0.9, 4.9)		(259.2)
	Present	7/ 413 ( 1.69%)	4/ 240 ( 1.67%)	1.0 (0.3, 4.0)		(3540.0)
Age Group	18-24	5/ 230 ( 2.17%)	0/ 104 ( 0.00%)	inf ( 0.6, inf)		(46.0)
	25-64	23/2713 ( 0.85%)	10/1567 ( 0.64%)	1.3 (0.6, 2.9)		(477.1)
	>=65	3/ 512 ( 0.59%)	1/ 307 ( 0.33%)	1.8 (0.2, 47.6)		(384.3)
Gender	Female	18/2031 ( 0.89%)	5/1190 ( 0.42%)	2.1 (0.8, 6.4)		(214.5)
	Male	13/1424 ( 0.91%)	6/ 788 ( 0.76%)	1.2 (0.5, 3.4)		(660.1)

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.439, 0.810, 0.492

Paroxetine Adult Suicidality Analysis  
 Table 2.08  
 Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = IBD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		34/ 149 (22.82%)	36/ 154 (23.38%)	1.0 (0.6, 1.7)	1.000	169.7
Baseline Suicidal Ideation	Absent	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)	Not Enough Events		
	Present	34/ 147 (23.13%)	36/ 152 (23.68%)	1.0 (0.6, 1.7)		180.2
Age Group	18-24	10/ 35 (28.57%)	6/ 38 (15.79%)	2.1 (0.7, 7.1)		(7.8)
	25-64	24/ 112 (21.43%)	30/ 113 (26.55%)	0.8 (0.4, 1.4)		19.5
	>=65	0/ 2 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Gender	Female	21/ 100 (21.00%)	22/ 100 (22.00%)	0.9 (0.5, 1.9)		100.0
	Male	13/ 49 (26.53%)	14/ 54 (25.93%)	1.0 (0.4, 2.5)		(165.4)

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Tests of heterogeneity for Age Group and Gender are 0.194 and 1.000

Paroxetine Adult Suicidality Analysis  
 Table 2.08  
 Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = Dysthymia

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		1/ 81 ( 1.23%)	0/ 85 ( 0.00%)	inf ( 0.1, inf)	0.488	
Baseline Suicidal Ideation	Absent	0/ 79 ( 0.00%)	0/ 82 ( 0.00%)	Not Enough Events		
	Present	1/ 2 (50.00%)	0/ 3 ( 0.00%)	inf ( 0.1, inf)		(2.0)
Age Group	18-24	0/ 6 ( 0.00%)	0/ 4 ( 0.00%)	Not Enough Events		
	25-64	1/ 73 ( 1.37%)	0/ 78 ( 0.00%)	inf ( 0.1, inf)		(73.0)
	>=65	0/ 2 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Gender	Female	1/ 37 ( 2.70%)	0/ 55 ( 0.00%)	inf ( 0.1, inf)		(37.0)
	Male	0/ 44 ( 0.00%)	0/ 30 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
Table 2.08  
Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
by Indication, Treatment Group and Risk Factors  
Indication = Bipolar

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
Baseline Suicidal Ideation	Absent	0/ 29 ( 0.00%)	0/ 38 ( 0.00%)	Not Enough Events		
	Present	0/ 6 ( 0.00%)	0/ 5 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 1 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
	25-64	0/ 33 ( 0.00%)	0/ 39 ( 0.00%)	Not Enough Events		
	>=65	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 19 ( 0.00%)	0/ 23 ( 0.00%)	Not Enough Events		
	Male	0/ 16 ( 0.00%)	0/ 20 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
Note. Exact analyses were used in all computations  
Note. Heterogeneity tests were not performed due to lack of data



Paroxetine Adult Suicidality Analysis  
 Table 2.08  
 Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = All Non-Depression

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		17/5238 ( 0.32%)	18/3693 ( 0.49%)	0.7 (0.3, 1.3)	0.293	623.9
Baseline Suicidal Ideation	Missing	5/1361 ( 0.37%)	2/1107 ( 0.18%)	2.0 (0.4, 15.2)		(535.6)
	Absent	9/3669 ( 0.25%)	10/2490 ( 0.40%)	0.6 (0.2, 1.5)		639.8
	Present	3/ 208 ( 1.44%)	6/ 96 ( 6.25%)	0.2 (0.0, 0.9)		20.8
Age Group	<18	1/ 10 (10.00%)	0/ 6 ( 0.00%)	inf ( 0.0, inf)		(10.0)
	18-24	5/ 504 ( 0.99%)	1/ 393 ( 0.25%)	3.9 (0.5, 93.7)		(135.6)
	25-64	11/4612 ( 0.24%)	17/3203 ( 0.53%)	0.4 (0.2, 1.0)		342.2
	>=65	0/ 112 ( 0.00%)	0/ 91 ( 0.00%)	Not Enough Events		
Gender	Female	12/3309 ( 0.36%)	11/2262 ( 0.49%)	0.7 (0.3, 1.7)		808.7
	Male	5/1928 ( 0.26%)	7/1431 ( 0.49%)	0.5 (0.2, 1.7)		435.1

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.410, 0.044, 0.730

Paroxetine Adult Suicidality Analysis  
 Table 2.08  
 Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = Panic

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		3/1092 ( 0.27%)	3/ 903 ( 0.33%)	0.7 (0.1, 4.2)	0.689	974.2
Baseline Suicidal Ideation	Missing	1/ 624 ( 0.16%)	0/ 580 ( 0.00%)	inf ( 0.0, inf)		(624.0)
	Absent	2/ 460 ( 0.43%)	2/ 318 ( 0.63%)	0.7 (0.1, 6.7)		515.1
	Present	0/ 8 ( 0.00%)	1/ 5 (20.00%)	0.0 (0.0, 11.9)		5.0
Age Group	<18	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
	18-24	1/ 121 ( 0.83%)	0/ 117 ( 0.00%)	inf ( 0.1, inf)		(121.0)
	25-64	2/ 962 ( 0.21%)	3/ 782 ( 0.38%)	0.5 (0.1, 3.6)		569.0
	>=65	0/ 9 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Gender	Female	3/ 673 ( 0.45%)	1/ 532 ( 0.19%)	2.4 (0.3, 62.7)		(387.9)
	Male	0/ 419 ( 0.00%)	2/ 371 ( 0.54%)	0.0 (0.0, 3.1)		185.5

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 1.000, 0.457, 0.401

Paroxetine Adult Suicidality Analysis  
 Table 2.08  
 Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = OCD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		5/ 698 ( 0.72%)	4/ 416 ( 0.96%)	0.7 (0.2, 3.0)	0.723	333.1
Baseline Suicidal Ideation	Missing	1/ 156 ( 0.64%)	0/ 151 ( 0.00%)	inf ( 0.1, inf)		(156.0)
	Absent	2/ 419 ( 0.48%)	3/ 215 ( 1.40%)	0.3 (0.0, 2.3)		108.9
	Present	2/ 123 ( 1.63%)	1/ 50 ( 2.00%)	0.8 (0.1, 24.4)		267.4
Age Group	<18	1/ 10 (10.00%)	0/ 5 ( 0.00%)	inf ( 0.0, inf)		(10.0)
	18-24	1/ 87 ( 1.15%)	0/ 51 ( 0.00%)	inf ( 0.0, inf)		(87.0)
	25-64	3/ 568 ( 0.53%)	4/ 346 ( 1.16%)	0.5 (0.1, 2.2)		159.3
	>=65	0/ 33 ( 0.00%)	0/ 14 ( 0.00%)	Not Enough Events		
Gender	Female	4/ 307 ( 1.30%)	3/ 191 ( 1.57%)	0.8 (0.2, 4.5)		373.5
	Male	1/ 391 ( 0.26%)	1/ 225 ( 0.44%)	0.6 (0.0, 22.5)		530.0

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 1.000, 1.000, 1.000

Paroxetine Adult Suicidality Analysis  
 Table 2.08  
 Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = SAD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		3/ 943 ( 0.32%)	3/ 643 ( 0.47%)	0.8 (0.1, 4.7)	1.000	968.7
Baseline Suicidal Ideation	Missing	3/ 522 ( 0.57%)	2/ 339 ( 0.59%)	1.0 (0.1, 8.2)		6554.0
	Absent	0/ 421 ( 0.00%)	1/ 304 ( 0.33%)	0.0 (0.0, 13.7)		304.0
Age Group	18-24	2/ 114 ( 1.75%)	0/ 89 ( 0.00%)	inf ( 0.2, inf)		(57.0)
	25-64	1/ 825 ( 0.12%)	3/ 542 ( 0.55%)	0.2 (0.0, 2.1)		231.3
	>=65	0/ 4 ( 0.00%)	0/ 12 ( 0.00%)	Not Enough Events		
Gender	Female	1/ 456 ( 0.22%)	2/ 307 ( 0.65%)	0.3 (0.0, 4.4)		231.4
	Male	2/ 487 ( 0.41%)	1/ 336 ( 0.30%)	1.4 (0.1, 40.9)		(884.5)

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Tests of heterogeneity for Age Group and Gender are 0.166 and 0.544

Paroxetine Adult Suicidality Analysis  
Table 2.08  
Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
by Indication, Treatment Group and Risk Factors  
Indication = GAD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		2/ 904 ( 0.22%)	2/ 697 ( 0.29%)	1.0 (0.1, 9.6)	1.000	(181237)
Baseline Suicidal Ideation	Absent	2/ 904 ( 0.22%)	1/ 696 ( 0.14%)	1.5 (0.1, 45.5)		(1289.3)
	Present	0/ 0	1/ 1 (100.0%)	Not Enough Events		
Age Group	18-24	1/ 103 ( 0.97%)	0/ 68 ( 0.00%)	inf ( 0.0, inf)		(103.0)
	25-64	1/ 748 ( 0.13%)	2/ 580 ( 0.34%)	0.4 (0.0, 5.1)		473.6
	>=65	0/ 53 ( 0.00%)	0/ 49 ( 0.00%)	Not Enough Events		
Gender	Female	2/ 559 ( 0.36%)	1/ 439 ( 0.23%)	1.6 (0.1, 46.5)		(769.3)
	Male	0/ 345 ( 0.00%)	1/ 258 ( 0.39%)	0.0 (0.0, 14.2)		258.0

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
Note. Exact analyses were used in all computations  
Note. Tests of heterogeneity for Age Group and Gender are 1.000 and 0.488

Paroxetine Adult Suicidality Analysis  
 Table 2.08  
 Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = PTSD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		3/ 698 ( 0.43%)	6/ 510 ( 1.18%)	0.4 (0.1, 1.5)	0.176	133.3
Baseline Suicidal Ideation	Missing	0/ 3 ( 0.00%)	0/ 2 ( 0.00%)	Not Enough Events		
	Absent	2/ 636 ( 0.31%)	3/ 474 ( 0.63%)	0.5 (0.1, 3.3)		314.0
	Present	1/ 59 ( 1.69%)	3/ 34 ( 8.82%)	0.2 (0.0, 1.8)		14.0
Age Group	18-24	0/ 51 ( 0.00%)	1/ 51 ( 1.96%)	0.0 (0.0, 19.0)		51.0
	25-64	3/ 634 ( 0.47%)	5/ 447 ( 1.12%)	0.4 (0.1, 1.8)		154.9
	>=65	0/ 13 ( 0.00%)	0/ 12 ( 0.00%)	Not Enough Events		
Gender	Female	1/ 453 ( 0.22%)	4/ 318 ( 1.26%)	0.2 (0.0, 1.4)		96.4
	Male	2/ 245 ( 0.82%)	2/ 192 ( 1.04%)	0.8 (0.1, 7.6)		443.8

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.572, 1.000, 0.506

Paroxetine Adult Suicidality Analysis  
Table 2.08  
Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
by Indication, Treatment Group and Risk Factors  
Indication = PMDD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		1/ 820 ( 0.12%)	0/ 438 ( 0.00%)	inf ( 0.1, inf)	1.000	
Baseline Suicidal Ideation	Missing	0/ 30 ( 0.00%)	0/ 9 ( 0.00%)	Not Enough Events		
	Absent	1/ 774 ( 0.13%)	0/ 426 ( 0.00%)	inf ( 0.0, inf)		(774.0)
	Present	0/ 16 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 27 ( 0.00%)	0/ 16 ( 0.00%)	Not Enough Events		
	25-64	1/ 793 ( 0.13%)	0/ 422 ( 0.00%)	inf ( 0.0, inf)		(793.0)
Gender	Female	1/ 820 ( 0.12%)	0/ 438 ( 0.00%)	inf ( 0.0, inf)		(820.0)

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
Note. Exact analyses were used in all computations  
Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
 Table 2.08  
 Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = Detoxification in Alcoholics

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Baseline Suicidal Ideation	Absent	0/ 55 ( 0.00%)	0/ 57 ( 0.00%)	Not Enough Events		
	Present	0/ 2 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 1 ( 0.00%)	0/ 0	Not Enough Events		
	25-64	0/ 56 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 20 ( 0.00%)	0/ 18 ( 0.00%)	Not Enough Events		
	Male	0/ 37 ( 0.00%)	0/ 42 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data



Paroxetine Adult Suicidality Analysis  
 Table 2.08  
 Number and Percent of Subjects with Definitive Suicidal Behaviour and Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = Fibromyalgia

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Baseline Suicidal Ideation	Missing	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
	25-64	0/ 26 ( 0.00%)	0/ 24 ( 0.00%)	Not Enough Events		
	>=65	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 21 ( 0.00%)	0/ 19 ( 0.00%)	Not Enough Events		
	Male	0/ 4 ( 0.00%)	0/ 7 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
Table 2.09  
Number and Percent of Subjects with Definitive Suicidal Behaviour  
by Indication, Treatment Group and Risk Factors  
Indication = All Indications

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		50/8958 ( 0.56%)	40/5953 ( 0.67%)	1.2 (0.8, 1.9)	0.483	(743.9)
Baseline Suicidal Ideation	Missing	3/1361 ( 0.22%)	1/1109 ( 0.09%)	2.4 (0.3, 64.5)		(767.7)
	Absent	13/6821 ( 0.19%)	3/4348 ( 0.07%)	2.8 (0.8, 12.1)		(822.4)
	Present	34/ 776 ( 4.38%)	36/ 496 ( 7.26%)	0.6 (0.4, 1.0)		34.8
Age Group	<18	1/ 10 (10.00%)	0/ 6 ( 0.00%)	inf ( 0.0, inf)		(10.0)
	18-24	17/ 776 ( 2.19%)	5/ 542 ( 0.92%)	2.4 (0.9, 7.3)		(78.9)
	25-64	32/7543 ( 0.42%)	34/5000 ( 0.68%)	0.6 (0.4, 1.0)		391.0
	>=65	0/ 629 ( 0.00%)	1/ 405 ( 0.25%)	0.0 (0.0, 12.2)		405.0
Gender	Female	30/5496 ( 0.55%)	24/3630 ( 0.66%)	0.8 (0.5, 1.4)		867.3
	Male	20/3461 ( 0.58%)	16/2323 ( 0.69%)	0.8 (0.4, 1.6)		901.7

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.024, 0.020, 1.000

Paroxetine Adult Suicidality Analysis  
Table 2.09  
Number and Percent of Subjects with Definitive Suicidal Behaviour  
by Indication, Treatment Group and Risk Factors  
Indication = All Depression

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		43/3720 ( 1.16%)	36/2260 ( 1.59%)	1.2 (0.7, 1.9)	0.613	(387.6)
Baseline Suicidal Ideation	Missing	0/ 0	0/ 2 ( 0.00%)	Not Enough Events		
	Absent	9/3152 ( 0.29%)	0/1858 ( 0.00%)	inf ( 1.5, inf)		(350.2)
	Present	34/ 568 ( 5.99%)	36/ 400 ( 9.00%)	0.6 (0.4, 1.1)		33.2
Age Group	18-24	13/ 272 ( 4.78%)	5/ 149 ( 3.36%)	1.4 (0.5, 4.6)		(70.2)
	25-64	30/2931 ( 1.02%)	30/1797 ( 1.67%)	0.6 (0.4, 1.0)		154.8
	>=65	0/ 517 ( 0.00%)	1/ 314 ( 0.32%)	0.0 (0.0, 11.5)		314.0
Gender	Female	26/2187 ( 1.19%)	23/1368 ( 1.68%)	0.7 (0.4, 1.2)		203.1
	Male	17/1533 ( 1.11%)	13/ 892 ( 1.46%)	0.8 (0.4, 1.6)		287.0

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.008, 0.170, 1.000

Paroxetine Adult Suicidality Analysis  
 Table 2.09  
 Number and Percent of Subjects with Definitive Suicidal Behaviour  
 by Indication, Treatment Group and Risk Factors  
 Indication = MDD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		11/3455 ( 0.32%)	1/1978 ( 0.05%)	6.7 (1.1, 149.4)	0.058	(345.2)
Baseline Suicidal Ideation	Missing	0/ 0	0/ 2 ( 0.00%)	Not Enough Events		
	Absent	9/3042 ( 0.30%)	0/1736 ( 0.00%)	inf ( 1.4, inf)		
	Present	2/ 413 ( 0.48%)	1/ 240 ( 0.42%)	1.2 (0.1, 34.4)		(1479.4)
Age Group	18-24	3/ 230 ( 1.30%)	0/ 104 ( 0.00%)	inf ( 0.3, inf)		
	25-64	8/2713 ( 0.29%)	0/1567 ( 0.00%)	inf ( 1.3, inf)		
	>=65	0/ 512 ( 0.00%)	1/ 307 ( 0.33%)	0.0 (0.0, 11.4)		
Gender	Female	7/2031 ( 0.34%)	1/1190 ( 0.08%)	4.1 (0.6, 93.5)		
	Male	4/1424 ( 0.28%)	0/ 788 ( 0.00%)	inf ( 0.5, inf)		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.254, 0.091, 1.000

Paroxetine Adult Suicidality Analysis  
 Table 2.09  
 Number and Percent of Subjects with Definitive Suicidal Behaviour  
 by Indication, Treatment Group and Risk Factors  
 Indication = IBD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		32/ 149 (21.48%)	35/ 154 (22.73%)	0.9 (0.5, 1.6)	0.890	77.8
Baseline Suicidal Ideation	Absent	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)	Not Enough Events		
	Present	32/ 147 (21.77%)	35/ 152 (23.03%)	0.9 (0.5, 1.6)		79.5
Age Group	18-24	10/ 35 (28.57%)	5/ 38 (13.16%)	2.6 (0.8, 9.4)		(6.5)
	25-64	22/ 112 (19.64%)	30/ 113 (26.55%)	0.7 (0.4, 1.3)		14.5
	>=65	0/ 2 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Gender	Female	19/ 100 (19.00%)	22/ 100 (22.00%)	0.8 (0.4, 1.7)		33.3
	Male	13/ 49 (26.53%)	13/ 54 (24.07%)	1.1 (0.5, 2.8)		(40.7)

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Tests of heterogeneity for Age Group and Gender are 0.055 and 0.774

Paroxetine Adult Suicidality Analysis  
Table 2.09  
Number and Percent of Subjects with Definitive Suicidal Behaviour  
by Indication, Treatment Group and Risk Factors  
Indication = Dysthymia

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 81 ( 0.00%)	0/ 85 ( 0.00%)	Not Enough Events		
Baseline Suicidal Ideation	Absent	0/ 79 ( 0.00%)	0/ 82 ( 0.00%)	Not Enough Events		
	Present	0/ 2 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 6 ( 0.00%)	0/ 4 ( 0.00%)	Not Enough Events		
	25-64	0/ 73 ( 0.00%)	0/ 78 ( 0.00%)	Not Enough Events		
	>=65	0/ 2 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 37 ( 0.00%)	0/ 55 ( 0.00%)	Not Enough Events		
	Male	0/ 44 ( 0.00%)	0/ 30 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
Note. Exact analyses were used in all computations  
Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
 Table 2.09  
 Number and Percent of Subjects with Definitive Suicidal Behaviour  
 by Indication, Treatment Group and Risk Factors  
 Indication = Bipolar

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 35 ( 0.00%)	0/ 43 ( 0.00%)	Not Enough Events		
Baseline Suicidal Ideation	Absent	0/ 29 ( 0.00%)	0/ 38 ( 0.00%)	Not Enough Events		
	Present	0/ 6 ( 0.00%)	0/ 5 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 1 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
	25-64	0/ 33 ( 0.00%)	0/ 39 ( 0.00%)	Not Enough Events		
	>=65	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 19 ( 0.00%)	0/ 23 ( 0.00%)	Not Enough Events		
	Male	0/ 16 ( 0.00%)	0/ 20 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
 Table 2.09  
 Number and Percent of Subjects with Definitive Suicidal Behaviour  
 by Indication, Treatment Group and Risk Factors  
 Indication = All Non-Depression

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		7/5238 ( 0.13%)	4/3693 ( 0.11%)	1.5 (0.4, 5.8)	0.759	(2029.9)
Baseline Suicidal Ideation	Missing	3/1361 ( 0.22%)	1/1107 ( 0.09%)	2.4 (0.3, 64.4)		(768.7)
	Absent	4/3669 ( 0.11%)	3/2490 ( 0.12%)	0.9 (0.2, 4.9)		8725.7
	Present	0/ 208 ( 0.00%)	0/ 96 ( 0.00%)	Not Enough Events		
Age Group	<18	1/ 10 (10.00%)	0/ 6 ( 0.00%)	inf ( 0.0, inf)		(10.0)
	18-24	4/ 504 ( 0.79%)	0/ 393 ( 0.00%)	inf ( 0.7, inf)		(126.0)
	25-64	2/4612 ( 0.04%)	4/3203 ( 0.12%)	0.3 (0.0, 2.0)		1226.7
	>=65	0/ 112 ( 0.00%)	0/ 91 ( 0.00%)	Not Enough Events		
Gender	Female	4/3309 ( 0.12%)	1/2262 ( 0.04%)	2.7 (0.3, 67.7)		(1304.2)
	Male	3/1928 ( 0.16%)	3/1431 ( 0.21%)	0.7 (0.1, 4.3)		1850.4

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Tests of heterogeneity for Age Group and Gender are 0.057 and 0.553



Paroxetine Adult Suicidality Analysis  
 Table 2.09  
 Number and Percent of Subjects with Definitive Suicidal Behaviour  
 by Indication, Treatment Group and Risk Factors  
 Indication = Panic

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		1/1092 ( 0.09%)	2/ 903 ( 0.22%)	0.3 (0.0, 4.8)	0.561	675.6
Baseline Suicidal Ideation	Missing	0/ 624 ( 0.00%)	0/ 580 ( 0.00%)	Not Enough Events		
	Absent	1/ 460 ( 0.22%)	2/ 318 ( 0.63%)	0.3 (0.0, 4.5)		243.0
	Present	0/ 8 ( 0.00%)	0/ 5 ( 0.00%)	Not Enough Events		
Age Group	<18	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
	18-24	1/ 121 ( 0.83%)	0/ 117 ( 0.00%)	inf ( 0.1, inf)		(121.0)
	25-64	0/ 962 ( 0.00%)	2/ 782 ( 0.26%)	0.0 (0.0, 2.8)		391.0
	>=65	0/ 9 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Gender	Female	1/ 673 ( 0.15%)	0/ 532 ( 0.00%)	inf ( 0.0, inf)		(673.0)
	Male	0/ 419 ( 0.00%)	2/ 371 ( 0.54%)	0.0 (0.0, 3.1)		185.5

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Tests of heterogeneity for Age Group and Gender are 0.296 and 0.358

Paroxetine Adult Suicidality Analysis  
 Table 2.09  
 Number and Percent of Subjects with Definitive Suicidal Behaviour  
 by Indication, Treatment Group and Risk Factors  
 Indication = OCD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		3/ 698 ( 0.43%)	1/ 416 ( 0.24%)	2.1 (0.2, 57.8)	0.642	(368.5)
Baseline Suicidal Ideation	Missing	1/ 156 ( 0.64%)	0/ 151 ( 0.00%)	inf ( 0.1, inf)		(156.0)
	Absent	2/ 419 ( 0.48%)	1/ 215 ( 0.47%)	1.0 (0.1, 30.4)		(8189.5)
	Present	0/ 123 ( 0.00%)	0/ 50 ( 0.00%)	Not Enough Events		
Age Group	<18	1/ 10 (10.00%)	0/ 5 ( 0.00%)	inf ( 0.0, inf)		(10.0)
	18-24	1/ 87 ( 1.15%)	0/ 51 ( 0.00%)	inf ( 0.0, inf)		(87.0)
	25-64	1/ 568 ( 0.18%)	1/ 346 ( 0.29%)	0.6 (0.0, 23.8)		885.3
	>=65	0/ 33 ( 0.00%)	0/ 14 ( 0.00%)	Not Enough Events		
Gender	Female	3/ 307 ( 0.98%)	1/ 191 ( 0.52%)	1.9 (0.2, 49.6)		(220.4)
	Male	0/ 391 ( 0.00%)	0/ 225 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Age Group and Gender are 1.000 and XXX

Paroxetine Adult Suicidality Analysis  
 Table 2.09  
 Number and Percent of Subjects with Definitive Suicidal Behaviour  
 by Indication, Treatment Group and Risk Factors  
 Indication = SAD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		2/ 943 ( 0.21%)	1/ 643 ( 0.16%)	2.2 (0.2, 65.0)	0.609	(544.9)
Baseline Suicidal Ideation	Missing	2/ 522 ( 0.38%)	1/ 339 ( 0.29%)	1.3 (0.1, 38.5)		(1134.3)
	Absent	0/ 421 ( 0.00%)	0/ 304 ( 0.00%)	Not Enough Events		
Age Group	18-24	2/ 114 ( 1.75%)	0/ 89 ( 0.00%)	inf ( 0.2, inf)		(57.0)
	25-64	0/ 825 ( 0.00%)	1/ 542 ( 0.18%)	0.0 (0.0, 12.5)		542.0
	>=65	0/ 4 ( 0.00%)	0/ 12 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 456 ( 0.00%)	0/ 307 ( 0.00%)	Not Enough Events		
	Male	2/ 487 ( 0.41%)	1/ 336 ( 0.30%)	1.4 (0.1, 40.9)		(884.5)

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Tests of heterogeneity for Age Group and Gender are 0.294 and XXX

Paroxetine Adult Suicidality Analysis  
 Table 2.09  
 Number and Percent of Subjects with Definitive Suicidal Behaviour  
 by Indication, Treatment Group and Risk Factors  
 Indication = GAD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 904 ( 0.00%)	0/ 697 ( 0.00%)	Not Enough Events		
Baseline Suicidal Ideation	Absent	0/ 904 ( 0.00%)	0/ 696 ( 0.00%)	Not Enough Events		
	Present	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 103 ( 0.00%)	0/ 68 ( 0.00%)	Not Enough Events		
	25-64	0/ 748 ( 0.00%)	0/ 580 ( 0.00%)	Not Enough Events		
	>=65	0/ 53 ( 0.00%)	0/ 49 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 559 ( 0.00%)	0/ 439 ( 0.00%)	Not Enough Events		
	Male	0/ 345 ( 0.00%)	0/ 258 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
 Table 2.09  
 Number and Percent of Subjects with Definitive Suicidal Behaviour  
 by Indication, Treatment Group and Risk Factors  
 Indication = PTSD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		1/ 698 ( 0.14%)	0/ 510 ( 0.00%)	inf ( 0.1, inf)	0.497	
Baseline Suicidal Ideation	Missing	0/ 3 ( 0.00%)	0/ 2 ( 0.00%)	Not Enough Events		
	Absent	1/ 636 ( 0.16%)	0/ 474 ( 0.00%)	inf ( 0.0, inf)		(636.0)
	Present	0/ 59 ( 0.00%)	0/ 34 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 51 ( 0.00%)	0/ 51 ( 0.00%)	Not Enough Events		
	25-64	1/ 634 ( 0.16%)	0/ 447 ( 0.00%)	inf ( 0.0, inf)		(634.0)
	>=65	0/ 13 ( 0.00%)	0/ 12 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 453 ( 0.00%)	0/ 318 ( 0.00%)	Not Enough Events		
	Male	1/ 245 ( 0.41%)	0/ 192 ( 0.00%)	inf ( 0.0, inf)		(245.0)

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
 Table 2.09  
 Number and Percent of Subjects with Definitive Suicidal Behaviour  
 by Indication, Treatment Group and Risk Factors  
 Indication = PMDD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		
Baseline Suicidal Ideation	Missing	0/ 30 ( 0.00%)	0/ 9 ( 0.00%)	Not Enough Events		
	Absent	0/ 774 ( 0.00%)	0/ 426 ( 0.00%)	Not Enough Events		
	Present	0/ 16 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 27 ( 0.00%)	0/ 16 ( 0.00%)	Not Enough Events		
	25-64	0/ 793 ( 0.00%)	0/ 422 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 820 ( 0.00%)	0/ 438 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
Table 2.09  
Number and Percent of Subjects with Definitive Suicidal Behaviour  
by Indication, Treatment Group and Risk Factors  
Indication = Detoxification in Alcoholics

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 57 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Baseline Suicidal Ideation	Absent	0/ 55 ( 0.00%)	0/ 57 ( 0.00%)	Not Enough Events		
	Present	0/ 2 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 1 ( 0.00%)	0/ 0	Not Enough Events		
	25-64	0/ 56 ( 0.00%)	0/ 60 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 20 ( 0.00%)	0/ 18 ( 0.00%)	Not Enough Events		
	Male	0/ 37 ( 0.00%)	0/ 42 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
Note. Exact analyses were used in all computations  
Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
 Table 2.09  
 Number and Percent of Subjects with Definitive Suicidal Behaviour  
 by Indication, Treatment Group and Risk Factors  
 Indication = Fibromyalgia

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Baseline Suicidal Ideation	Missing	0/ 26 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
	25-64	0/ 26 ( 0.00%)	0/ 24 ( 0.00%)	Not Enough Events		
	>=65	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 21 ( 0.00%)	0/ 19 ( 0.00%)	Not Enough Events		
	Male	0/ 4 ( 0.00%)	0/ 7 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data





Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = All Indications

Age (years)	Paroxetine	Placebo
16	1/ 4 (25.00%)	0/ 5 ( 0.00%)
17	0/ 6 ( 0.00%)	0/ 1 ( 0.00%)
18	2/ 55 ( 3.64%)	0/ 36 ( 0.00%)
19	1/ 87 ( 1.15%)	0/ 49 ( 0.00%)
20	6/102 ( 5.88%)	1/ 54 ( 1.85%)
21	2/ 99 ( 2.02%)	2/ 85 ( 2.35%)
22	3/135 ( 2.22%)	1/ 92 ( 1.09%)
23	4/140 ( 2.86%)	2/105 ( 1.90%)
24	2/158 ( 1.27%)	1/121 ( 0.83%)
25	3/157 ( 1.91%)	2/131 ( 1.53%)
26	1/199 ( 0.50%)	5/144 ( 3.47%)
27	4/208 ( 1.92%)	2/140 ( 1.43%)
28	4/226 ( 1.77%)	3/152 ( 1.97%)
29	4/262 ( 1.53%)	2/146 ( 1.37%)
30	2/199 ( 1.01%)	2/161 ( 1.24%)
31	1/258 ( 0.39%)	4/161 ( 2.48%)
32	3/246 ( 1.22%)	3/187 ( 1.60%)
33	0/259 ( 0.00%)	1/192 ( 0.52%)
34	5/289 ( 1.73%)	3/171 ( 1.75%)
35	3/259 ( 1.16%)	2/160 ( 1.25%)
36	1/260 ( 0.38%)	1/165 ( 0.61%)
37	3/278 ( 1.08%)	1/177 ( 0.56%)
38	4/290 ( 1.38%)	2/199 ( 1.01%)
39	1/280 ( 0.36%)	3/195 ( 1.54%)
40	0/285 ( 0.00%)	0/184 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = All Indications

Age (years)	Paroxetine	Placebo
41	0/280 ( 0.00%)	4/185 ( 2.16%)
42	2/258 ( 0.78%)	0/178 ( 0.00%)
43	0/258 ( 0.00%)	2/159 ( 1.26%)
44	2/257 ( 0.78%)	0/146 ( 0.00%)
45	4/247 ( 1.62%)	4/163 ( 2.45%)
46	2/183 ( 1.09%)	1/133 ( 0.75%)
47	1/179 ( 0.56%)	1/108 ( 0.93%)
48	2/169 ( 1.18%)	0/114 ( 0.00%)
49	3/177 ( 1.69%)	1/116 ( 0.86%)
50	0/144 ( 0.00%)	2/116 ( 1.72%)
51	3/144 ( 2.08%)	0/ 85 ( 0.00%)
52	0/151 ( 0.00%)	0/100 ( 0.00%)
53	0/117 ( 0.00%)	4/ 74 ( 5.41%)
54	0/113 ( 0.00%)	1/ 80 ( 1.25%)
55	0/116 ( 0.00%)	0/ 59 ( 0.00%)
56	0/104 ( 0.00%)	0/ 64 ( 0.00%)
57	0/ 85 ( 0.00%)	0/ 57 ( 0.00%)
58	1/ 74 ( 1.35%)	0/ 59 ( 0.00%)
59	0/ 69 ( 0.00%)	0/ 54 ( 0.00%)
60	0/120 ( 0.00%)	1/ 70 ( 1.43%)
61	0/102 ( 0.00%)	0/ 71 ( 0.00%)
62	0/ 88 ( 0.00%)	0/ 50 ( 0.00%)
63	0/ 74 ( 0.00%)	0/ 53 ( 0.00%)
64	0/ 79 ( 0.00%)	0/ 41 ( 0.00%)
65	0/ 59 ( 0.00%)	0/ 40 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = All Indications

Age (years)	Paroxetine	Placebo
66	0/ 65 ( 0.00%)	0/ 35 ( 0.00%)
67	0/ 61 ( 0.00%)	1/ 47 ( 2.13%)
68	0/ 55 ( 0.00%)	0/ 30 ( 0.00%)
69	0/ 51 ( 0.00%)	0/ 20 ( 0.00%)
70	0/ 43 ( 0.00%)	0/ 27 ( 0.00%)
71	0/ 47 ( 0.00%)	0/ 36 ( 0.00%)
72	1/ 48 ( 2.08%)	0/ 22 ( 0.00%)
73	0/ 35 ( 0.00%)	0/ 25 ( 0.00%)
74	0/ 30 ( 0.00%)	0/ 23 ( 0.00%)
75	1/ 23 ( 4.35%)	0/ 19 ( 0.00%)
76	0/ 20 ( 0.00%)	0/ 20 ( 0.00%)
77	0/ 19 ( 0.00%)	0/ 12 ( 0.00%)
78	0/ 20 ( 0.00%)	0/ 18 ( 0.00%)
79	0/ 10 ( 0.00%)	0/ 9 ( 0.00%)
80	0/ 7 ( 0.00%)	0/ 7 ( 0.00%)
81	0/ 3 ( 0.00%)	0/ 5 ( 0.00%)
82	1/ 8 (12.50%)	0/ 5 ( 0.00%)
83	0/ 6 ( 0.00%)	0/ 1 ( 0.00%)
84	0/ 7 ( 0.00%)	0/ 1 ( 0.00%)
85	0/ 3 ( 0.00%)	0/ 1 ( 0.00%)
86	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
87	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
88	0/ 3 ( 0.00%)	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0

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anal\_alladsui\_gsk\_2005\_list\_ages.sas 16MAR2006:15:19 kk45592

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = All Indications

Age (years)	Paroxetine	Placebo
91	0/ 1 ( 0.00%)	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = All Depression

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 0
18	2/ 21 ( 9.52%)	0/ 12 ( 0.00%)
19	1/ 31 ( 3.23%)	0/ 19 ( 0.00%)
20	3/ 32 ( 9.38%)	1/ 14 ( 7.14%)
21	2/ 40 ( 5.00%)	1/ 22 ( 4.55%)
22	2/ 45 ( 4.44%)	1/ 24 ( 4.17%)
23	3/ 51 ( 5.88%)	2/ 29 ( 6.90%)
24	2/ 52 ( 3.85%)	1/ 29 ( 3.45%)
25	2/ 54 ( 3.70%)	2/ 41 ( 4.88%)
26	1/ 64 ( 1.56%)	3/ 38 ( 7.89%)
27	3/ 66 ( 4.55%)	2/ 49 ( 4.08%)
28	3/ 74 ( 4.05%)	1/ 54 ( 1.85%)
29	4/ 89 ( 4.49%)	1/ 46 ( 2.17%)
30	2/ 80 ( 2.50%)	2/ 55 ( 3.64%)
31	1/ 86 ( 1.16%)	4/ 54 ( 7.41%)
32	3/101 ( 2.97%)	3/ 56 ( 5.36%)
33	0/ 87 ( 0.00%)	0/ 58 ( 0.00%)
34	5/ 95 ( 5.26%)	2/ 50 ( 4.00%)
35	2/ 90 ( 2.22%)	1/ 46 ( 2.17%)
36	1/ 94 ( 1.06%)	1/ 46 ( 2.17%)
37	1/ 90 ( 1.11%)	0/ 52 ( 0.00%)
38	3/ 95 ( 3.16%)	2/ 67 ( 2.99%)
39	1/ 92 ( 1.09%)	2/ 56 ( 3.57%)
40	0/ 95 ( 0.00%)	0/ 57 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = All Depression

Age (years)	Paroxetine	Placebo
41	0/ 87 ( 0.00%)	4/ 65 ( 6.15%)
42	1/ 72 ( 1.39%)	0/ 60 ( 0.00%)
43	0/ 95 ( 0.00%)	2/ 57 ( 3.51%)
44	2/ 92 ( 2.17%)	0/ 40 ( 0.00%)
45	3/ 92 ( 3.26%)	3/ 57 ( 5.26%)
46	2/ 81 ( 2.47%)	1/ 49 ( 2.04%)
47	1/ 74 ( 1.35%)	0/ 41 ( 0.00%)
48	2/ 68 ( 2.94%)	0/ 48 ( 0.00%)
49	3/ 72 ( 4.17%)	1/ 35 ( 2.86%)
50	0/ 59 ( 0.00%)	0/ 48 ( 0.00%)
51	1/ 57 ( 1.75%)	0/ 33 ( 0.00%)
52	0/ 64 ( 0.00%)	0/ 40 ( 0.00%)
53	0/ 54 ( 0.00%)	1/ 32 ( 3.13%)
54	0/ 53 ( 0.00%)	1/ 37 ( 2.70%)
55	0/ 58 ( 0.00%)	0/ 31 ( 0.00%)
56	0/ 55 ( 0.00%)	0/ 29 ( 0.00%)
57	0/ 39 ( 0.00%)	0/ 24 ( 0.00%)
58	1/ 34 ( 2.94%)	0/ 29 ( 0.00%)
59	0/ 38 ( 0.00%)	0/ 25 ( 0.00%)
60	0/ 82 ( 0.00%)	1/ 51 ( 1.96%)
61	0/ 72 ( 0.00%)	0/ 47 ( 0.00%)
62	0/ 70 ( 0.00%)	0/ 32 ( 0.00%)
63	0/ 53 ( 0.00%)	0/ 34 ( 0.00%)
64	0/ 58 ( 0.00%)	0/ 28 ( 0.00%)
65	0/ 44 ( 0.00%)	0/ 30 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = All Depression

Age (years)	Paroxetine	Placebo
66	0/ 53 ( 0.00%)	0/ 22 ( 0.00%)
67	0/ 46 ( 0.00%)	1/ 30 ( 3.33%)
68	0/ 43 ( 0.00%)	0/ 24 ( 0.00%)
69	0/ 38 ( 0.00%)	0/ 16 ( 0.00%)
70	0/ 36 ( 0.00%)	0/ 24 ( 0.00%)
71	0/ 40 ( 0.00%)	0/ 27 ( 0.00%)
72	1/ 40 ( 2.50%)	0/ 17 ( 0.00%)
73	0/ 29 ( 0.00%)	0/ 18 ( 0.00%)
74	0/ 23 ( 0.00%)	0/ 17 ( 0.00%)
75	1/ 19 ( 5.26%)	0/ 17 ( 0.00%)
76	0/ 17 ( 0.00%)	0/ 17 ( 0.00%)
77	0/ 18 ( 0.00%)	0/ 11 ( 0.00%)
78	0/ 18 ( 0.00%)	0/ 16 ( 0.00%)
79	0/ 10 ( 0.00%)	0/ 9 ( 0.00%)
80	0/ 7 ( 0.00%)	0/ 6 ( 0.00%)
81	0/ 3 ( 0.00%)	0/ 4 ( 0.00%)
82	1/ 8 (12.50%)	0/ 5 ( 0.00%)
83	0/ 6 ( 0.00%)	0/ 1 ( 0.00%)
84	0/ 7 ( 0.00%)	0/ 1 ( 0.00%)
85	0/ 3 ( 0.00%)	0/ 0
86	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
87	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
88	0/ 3 ( 0.00%)	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0



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anal\_alladsui\_gsk\_2005\_list\_ages.sas 16MAR2006:15:19 kk45592

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = All Depression

Age (years)	Paroxetine	Placebo
91	0/ 1 ( 0.00%)	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = MDD

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 0
18	2/ 17 (11.76%)	0/ 6 ( 0.00%)
19	1/ 30 ( 3.33%)	0/ 12 ( 0.00%)
20	1/ 28 ( 3.57%)	0/ 9 ( 0.00%)
21	1/ 36 ( 2.78%)	0/ 13 ( 0.00%)
22	0/ 36 ( 0.00%)	0/ 20 ( 0.00%)
23	0/ 42 ( 0.00%)	0/ 18 ( 0.00%)
24	0/ 41 ( 0.00%)	0/ 26 ( 0.00%)
25	1/ 49 ( 2.04%)	0/ 33 ( 0.00%)
26	0/ 56 ( 0.00%)	1/ 35 ( 2.86%)
27	1/ 62 ( 1.61%)	1/ 42 ( 2.38%)
28	1/ 67 ( 1.49%)	0/ 44 ( 0.00%)
29	2/ 76 ( 2.63%)	0/ 34 ( 0.00%)
30	2/ 72 ( 2.78%)	0/ 47 ( 0.00%)
31	1/ 80 ( 1.25%)	2/ 50 ( 4.00%)
32	0/ 91 ( 0.00%)	0/ 40 ( 0.00%)
33	0/ 78 ( 0.00%)	0/ 52 ( 0.00%)
34	2/ 84 ( 2.38%)	1/ 47 ( 2.13%)
35	1/ 82 ( 1.22%)	0/ 39 ( 0.00%)
36	1/ 89 ( 1.12%)	0/ 39 ( 0.00%)
37	0/ 82 ( 0.00%)	0/ 48 ( 0.00%)
38	3/ 88 ( 3.41%)	1/ 60 ( 1.67%)
39	0/ 84 ( 0.00%)	1/ 47 ( 2.13%)
40	0/ 88 ( 0.00%)	0/ 50 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = MDD

Age (years)	Paroxetine	Placebo
41	0/ 78 ( 0.00%)	1/ 47 ( 2.13%)
42	1/ 68 ( 1.47%)	0/ 54 ( 0.00%)
43	0/ 87 ( 0.00%)	0/ 48 ( 0.00%)
44	0/ 82 ( 0.00%)	0/ 32 ( 0.00%)
45	1/ 83 ( 1.20%)	0/ 47 ( 0.00%)
46	1/ 74 ( 1.35%)	0/ 40 ( 0.00%)
47	0/ 68 ( 0.00%)	0/ 35 ( 0.00%)
48	0/ 60 ( 0.00%)	0/ 46 ( 0.00%)
49	3/ 69 ( 4.35%)	1/ 33 ( 3.03%)
50	0/ 58 ( 0.00%)	0/ 43 ( 0.00%)
51	1/ 53 ( 1.89%)	0/ 26 ( 0.00%)
52	0/ 56 ( 0.00%)	0/ 36 ( 0.00%)
53	0/ 50 ( 0.00%)	0/ 29 ( 0.00%)
54	0/ 49 ( 0.00%)	0/ 32 ( 0.00%)
55	0/ 56 ( 0.00%)	0/ 29 ( 0.00%)
56	0/ 52 ( 0.00%)	0/ 27 ( 0.00%)
57	0/ 39 ( 0.00%)	0/ 21 ( 0.00%)
58	1/ 31 ( 3.23%)	0/ 27 ( 0.00%)
59	0/ 38 ( 0.00%)	0/ 24 ( 0.00%)
60	0/ 82 ( 0.00%)	1/ 49 ( 2.04%)
61	0/ 72 ( 0.00%)	0/ 42 ( 0.00%)
62	0/ 70 ( 0.00%)	0/ 32 ( 0.00%)
63	0/ 52 ( 0.00%)	0/ 33 ( 0.00%)
64	0/ 58 ( 0.00%)	0/ 28 ( 0.00%)
65	0/ 44 ( 0.00%)	0/ 30 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = MDD

Age (years)	Paroxetine	Placebo
66	0/ 52 ( 0.00%)	0/ 21 ( 0.00%)
67	0/ 45 ( 0.00%)	1/ 27 ( 3.70%)
68	0/ 42 ( 0.00%)	0/ 24 ( 0.00%)
69	0/ 38 ( 0.00%)	0/ 16 ( 0.00%)
70	0/ 36 ( 0.00%)	0/ 23 ( 0.00%)
71	0/ 40 ( 0.00%)	0/ 26 ( 0.00%)
72	1/ 40 ( 2.50%)	0/ 17 ( 0.00%)
73	0/ 28 ( 0.00%)	0/ 18 ( 0.00%)
74	0/ 22 ( 0.00%)	0/ 17 ( 0.00%)
75	1/ 19 ( 5.26%)	0/ 17 ( 0.00%)
76	0/ 17 ( 0.00%)	0/ 17 ( 0.00%)
77	0/ 18 ( 0.00%)	0/ 10 ( 0.00%)
78	0/ 18 ( 0.00%)	0/ 16 ( 0.00%)
79	0/ 10 ( 0.00%)	0/ 9 ( 0.00%)
80	0/ 7 ( 0.00%)	0/ 6 ( 0.00%)
81	0/ 3 ( 0.00%)	0/ 4 ( 0.00%)
82	1/ 8 (12.50%)	0/ 5 ( 0.00%)
83	0/ 6 ( 0.00%)	0/ 1 ( 0.00%)
84	0/ 7 ( 0.00%)	0/ 1 ( 0.00%)
85	0/ 3 ( 0.00%)	0/ 0
86	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
87	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
88	0/ 3 ( 0.00%)	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0

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Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = MDD

Age (years)	Paroxetine	Placebo
91	0/ 1 ( 0.00%)	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = IBD

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 0
18	0/ 4 ( 0.00%)	0/ 6 ( 0.00%)
19	0/ 1 ( 0.00%)	0/ 7 ( 0.00%)
20	2/ 4 (50.00%)	1/ 5 (20.00%)
21	1/ 4 (25.00%)	1/ 7 (14.29%)
22	2/ 8 (25.00%)	1/ 3 (33.33%)
23	3/ 8 (37.50%)	2/ 7 (28.57%)
24	2/ 6 (33.33%)	1/ 3 (33.33%)
25	1/ 5 (20.00%)	2/ 4 (50.00%)
26	0/ 3 ( 0.00%)	2/ 3 (66.67%)
27	2/ 3 (66.67%)	1/ 4 (25.00%)
28	2/ 5 (40.00%)	1/ 8 (12.50%)
29	2/ 8 (25.00%)	1/ 8 (12.50%)
30	0/ 8 ( 0.00%)	2/ 6 (33.33%)
31	0/ 4 ( 0.00%)	2/ 2 (100.0%)
32	3/ 6 (50.00%)	3/ 12 (25.00%)
33	0/ 3 ( 0.00%)	0/ 2 ( 0.00%)
34	3/ 8 (37.50%)	1/ 1 (100.0%)
35	1/ 7 (14.29%)	1/ 3 (33.33%)
36	0/ 2 ( 0.00%)	1/ 4 (25.00%)
37	1/ 4 (25.00%)	0/ 1 ( 0.00%)
38	0/ 3 ( 0.00%)	1/ 6 (16.67%)
39	1/ 5 (20.00%)	1/ 5 (20.00%)
40	0/ 3 ( 0.00%)	0/ 2 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = IBD

Age (years)	Paroxetine	Placebo
41	0/ 4 ( 0.00%)	3/ 7 (42.86%)
42	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)
43	0/ 2 ( 0.00%)	2/ 4 (50.00%)
44	2/ 8 (25.00%)	0/ 1 ( 0.00%)
45	2/ 3 (66.67%)	3/ 6 (50.00%)
46	1/ 4 (25.00%)	1/ 4 (25.00%)
47	1/ 3 (33.33%)	0/ 1 ( 0.00%)
48	2/ 2 (100.0%)	0/ 1 ( 0.00%)
49	0/ 0	0/ 1 ( 0.00%)
50	0/ 0	0/ 2 ( 0.00%)
51	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
52	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
53	0/ 1 ( 0.00%)	1/ 2 (50.00%)
54	0/ 2 ( 0.00%)	1/ 2 (50.00%)
55	0/ 1 ( 0.00%)	0/ 0
56	0/ 0	0/ 0
57	0/ 0	0/ 1 ( 0.00%)
58	0/ 0	0/ 0
59	0/ 0	0/ 1 ( 0.00%)
60	0/ 0	0/ 2 ( 0.00%)
61	0/ 0	0/ 1 ( 0.00%)
62	0/ 0	0/ 0
63	0/ 1 ( 0.00%)	0/ 0
64	0/ 0	0/ 0
65	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = IBD

Age (years)	Paroxetine	Placebo
66	0/ 0	0/ 0
67	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
68	0/ 0	0/ 0
69	0/ 0	0/ 0
70	0/ 0	0/ 1 ( 0.00%)
71	0/ 0	0/ 0
72	0/ 0	0/ 0
73	0/ 0	0/ 0
74	0/ 1 ( 0.00%)	0/ 0
75	0/ 0	0/ 0
76	0/ 0	0/ 0
77	0/ 0	0/ 0
78	0/ 0	0/ 0
79	0/ 0	0/ 0
80	0/ 0	0/ 0
81	0/ 0	0/ 0
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 0
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0



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Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = IBD

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = Dysthymia

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 0
18	0/ 0	0/ 0
19	0/ 0	0/ 0
20	0/ 0	0/ 0
21	0/ 0	0/ 0
22	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
23	0/ 1 ( 0.00%)	0/ 3 ( 0.00%)
24	0/ 4 ( 0.00%)	0/ 0
25	0/ 0	0/ 2 ( 0.00%)
26	1/ 5 (20.00%)	0/ 0
27	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
28	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
29	0/ 2 ( 0.00%)	0/ 3 ( 0.00%)
30	0/ 0	0/ 2 ( 0.00%)
31	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
32	0/ 3 ( 0.00%)	0/ 2 ( 0.00%)
33	0/ 5 ( 0.00%)	0/ 2 ( 0.00%)
34	0/ 3 ( 0.00%)	0/ 0
35	0/ 0	0/ 3 ( 0.00%)
36	0/ 3 ( 0.00%)	0/ 2 ( 0.00%)
37	0/ 0	0/ 1 ( 0.00%)
38	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
39	0/ 3 ( 0.00%)	0/ 4 ( 0.00%)
40	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = Dysthymia

Age (years)	Paroxetine	Placebo
41	0/ 4 ( 0.00%)	0/ 7 ( 0.00%)
42	0/ 0	0/ 2 ( 0.00%)
43	0/ 4 ( 0.00%)	0/ 2 ( 0.00%)
44	0/ 1 ( 0.00%)	0/ 4 ( 0.00%)
45	0/ 4 ( 0.00%)	0/ 2 ( 0.00%)
46	0/ 2 ( 0.00%)	0/ 5 ( 0.00%)
47	0/ 3 ( 0.00%)	0/ 5 ( 0.00%)
48	0/ 5 ( 0.00%)	0/ 1 ( 0.00%)
49	0/ 2 ( 0.00%)	0/ 1 ( 0.00%)
50	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
51	0/ 2 ( 0.00%)	0/ 5 ( 0.00%)
52	0/ 6 ( 0.00%)	0/ 0
53	0/ 2 ( 0.00%)	0/ 1 ( 0.00%)
54	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
55	0/ 0	0/ 2 ( 0.00%)
56	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)
57	0/ 0	0/ 1 ( 0.00%)
58	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
59	0/ 0	0/ 0
60	0/ 0	0/ 0
61	0/ 0	0/ 2 ( 0.00%)
62	0/ 0	0/ 0
63	0/ 0	0/ 1 ( 0.00%)
64	0/ 0	0/ 0
65	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Dysthymia

Age (years)	Paroxetine	Placebo
66	0/ 0	0/ 0
67	0/ 0	0/ 1 ( 0.00%)
68	0/ 1 ( 0.00%)	0/ 0
69	0/ 0	0/ 0
70	0/ 0	0/ 0
71	0/ 0	0/ 1 ( 0.00%)
72	0/ 0	0/ 0
73	0/ 1 ( 0.00%)	0/ 0
74	0/ 0	0/ 0
75	0/ 0	0/ 0
76	0/ 0	0/ 0
77	0/ 0	0/ 1 ( 0.00%)
78	0/ 0	0/ 0
79	0/ 0	0/ 0
80	0/ 0	0/ 0
81	0/ 0	0/ 0
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 0
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0

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Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Dysthymia

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = Bipolar

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 0
18	0/ 0	0/ 0
19	0/ 0	0/ 0
20	0/ 0	0/ 0
21	0/ 0	0/ 2 ( 0.00%)
22	0/ 0	0/ 0
23	0/ 0	0/ 1 ( 0.00%)
24	0/ 1 ( 0.00%)	0/ 0
25	0/ 0	0/ 2 ( 0.00%)
26	0/ 0	0/ 0
27	0/ 0	0/ 1 ( 0.00%)
28	0/ 1 ( 0.00%)	0/ 0
29	0/ 3 ( 0.00%)	0/ 1 ( 0.00%)
30	0/ 0	0/ 0
31	0/ 1 ( 0.00%)	0/ 0
32	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
33	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
34	0/ 0	0/ 2 ( 0.00%)
35	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
36	0/ 0	0/ 1 ( 0.00%)
37	0/ 4 ( 0.00%)	0/ 2 ( 0.00%)
38	0/ 0	0/ 0
39	0/ 0	0/ 0
40	0/ 2 ( 0.00%)	0/ 3 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Bipolar

Age (years)	Paroxetine	Placebo
41	0/ 1 ( 0.00%)	0/ 4 ( 0.00%)
42	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)
43	0/ 2 ( 0.00%)	0/ 3 ( 0.00%)
44	0/ 1 ( 0.00%)	0/ 3 ( 0.00%)
45	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)
46	0/ 1 ( 0.00%)	0/ 0
47	0/ 0	0/ 0
48	0/ 1 ( 0.00%)	0/ 0
49	0/ 1 ( 0.00%)	0/ 0
50	0/ 0	0/ 2 ( 0.00%)
51	0/ 1 ( 0.00%)	0/ 0
52	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
53	0/ 1 ( 0.00%)	0/ 0
54	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
55	0/ 1 ( 0.00%)	0/ 0
56	0/ 1 ( 0.00%)	0/ 0
57	0/ 0	0/ 1 ( 0.00%)
58	0/ 2 ( 0.00%)	0/ 0
59	0/ 0	0/ 0
60	0/ 0	0/ 0
61	0/ 0	0/ 2 ( 0.00%)
62	0/ 0	0/ 0
63	0/ 0	0/ 0
64	0/ 0	0/ 0
65	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Bipolar

Age (years)	Paroxetine	Placebo
66	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
67	0/ 0	0/ 0
68	0/ 0	0/ 0
69	0/ 0	0/ 0
70	0/ 0	0/ 0
71	0/ 0	0/ 0
72	0/ 0	0/ 0
73	0/ 0	0/ 0
74	0/ 0	0/ 0
75	0/ 0	0/ 0
76	0/ 0	0/ 0
77	0/ 0	0/ 0
78	0/ 0	0/ 0
79	0/ 0	0/ 0
80	0/ 0	0/ 0
81	0/ 0	0/ 0
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 0
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0



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Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Bipolar

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = All Non-Depression

Age (years)	Paroxetine	Placebo
16	1/ 4 (25.00%)	0/ 5 ( 0.00%)
17	0/ 6 ( 0.00%)	0/ 1 ( 0.00%)
18	0/ 34 ( 0.00%)	0/ 24 ( 0.00%)
19	0/ 56 ( 0.00%)	0/ 30 ( 0.00%)
20	3/ 70 ( 4.29%)	0/ 40 ( 0.00%)
21	0/ 59 ( 0.00%)	1/ 63 ( 1.59%)
22	1/ 90 ( 1.11%)	0/ 68 ( 0.00%)
23	1/ 89 ( 1.12%)	0/ 76 ( 0.00%)
24	0/106 ( 0.00%)	0/ 92 ( 0.00%)
25	1/103 ( 0.97%)	0/ 90 ( 0.00%)
26	0/135 ( 0.00%)	2/106 ( 1.89%)
27	1/142 ( 0.70%)	0/ 91 ( 0.00%)
28	1/152 ( 0.66%)	2/ 98 ( 2.04%)
29	0/173 ( 0.00%)	1/100 ( 1.00%)
30	0/119 ( 0.00%)	0/106 ( 0.00%)
31	0/172 ( 0.00%)	0/107 ( 0.00%)
32	0/145 ( 0.00%)	0/131 ( 0.00%)
33	0/172 ( 0.00%)	1/134 ( 0.75%)
34	0/194 ( 0.00%)	1/121 ( 0.83%)
35	1/169 ( 0.59%)	1/114 ( 0.88%)
36	0/166 ( 0.00%)	0/119 ( 0.00%)
37	2/188 ( 1.06%)	1/125 ( 0.80%)
38	1/195 ( 0.51%)	0/132 ( 0.00%)
39	0/188 ( 0.00%)	1/139 ( 0.72%)
40	0/190 ( 0.00%)	0/127 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = All Non-Depression

Age (years)	Paroxetine	Placebo
41	0/193 ( 0.00%)	0/120 ( 0.00%)
42	1/186 ( 0.54%)	0/118 ( 0.00%)
43	0/163 ( 0.00%)	0/102 ( 0.00%)
44	0/165 ( 0.00%)	0/106 ( 0.00%)
45	1/155 ( 0.65%)	1/106 ( 0.94%)
46	0/102 ( 0.00%)	0/ 84 ( 0.00%)
47	0/105 ( 0.00%)	1/ 67 ( 1.49%)
48	0/101 ( 0.00%)	0/ 66 ( 0.00%)
49	0/105 ( 0.00%)	0/ 81 ( 0.00%)
50	0/ 85 ( 0.00%)	2/ 68 ( 2.94%)
51	2/ 87 ( 2.30%)	0/ 52 ( 0.00%)
52	0/ 87 ( 0.00%)	0/ 60 ( 0.00%)
53	0/ 63 ( 0.00%)	3/ 42 ( 7.14%)
54	0/ 60 ( 0.00%)	0/ 43 ( 0.00%)
55	0/ 58 ( 0.00%)	0/ 28 ( 0.00%)
56	0/ 49 ( 0.00%)	0/ 35 ( 0.00%)
57	0/ 46 ( 0.00%)	0/ 33 ( 0.00%)
58	0/ 40 ( 0.00%)	0/ 30 ( 0.00%)
59	0/ 31 ( 0.00%)	0/ 29 ( 0.00%)
60	0/ 38 ( 0.00%)	0/ 19 ( 0.00%)
61	0/ 30 ( 0.00%)	0/ 24 ( 0.00%)
62	0/ 18 ( 0.00%)	0/ 18 ( 0.00%)
63	0/ 21 ( 0.00%)	0/ 19 ( 0.00%)
64	0/ 21 ( 0.00%)	0/ 13 ( 0.00%)
65	0/ 15 ( 0.00%)	0/ 10 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = All Non-Depression

Age (years)	Paroxetine	Placebo
66	0/ 12 ( 0.00%)	0/ 13 ( 0.00%)
67	0/ 15 ( 0.00%)	0/ 17 ( 0.00%)
68	0/ 12 ( 0.00%)	0/ 6 ( 0.00%)
69	0/ 13 ( 0.00%)	0/ 4 ( 0.00%)
70	0/ 7 ( 0.00%)	0/ 3 ( 0.00%)
71	0/ 7 ( 0.00%)	0/ 9 ( 0.00%)
72	0/ 8 ( 0.00%)	0/ 5 ( 0.00%)
73	0/ 6 ( 0.00%)	0/ 7 ( 0.00%)
74	0/ 7 ( 0.00%)	0/ 6 ( 0.00%)
75	0/ 4 ( 0.00%)	0/ 2 ( 0.00%)
76	0/ 3 ( 0.00%)	0/ 3 ( 0.00%)
77	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
78	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)
79	0/ 0	0/ 0
80	0/ 0	0/ 1 ( 0.00%)
81	0/ 0	0/ 1 ( 0.00%)
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 1 ( 0.00%)
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0

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Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = All Non-Depression

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = Panic

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 1 ( 0.00%)
18	0/ 6 ( 0.00%)	0/ 5 ( 0.00%)
19	0/ 11 ( 0.00%)	0/ 9 ( 0.00%)
20	1/ 13 ( 7.69%)	0/ 13 ( 0.00%)
21	0/ 15 ( 0.00%)	0/ 18 ( 0.00%)
22	0/ 26 ( 0.00%)	0/ 19 ( 0.00%)
23	0/ 23 ( 0.00%)	0/ 26 ( 0.00%)
24	0/ 27 ( 0.00%)	0/ 27 ( 0.00%)
25	0/ 33 ( 0.00%)	0/ 23 ( 0.00%)
26	0/ 37 ( 0.00%)	0/ 24 ( 0.00%)
27	0/ 39 ( 0.00%)	0/ 29 ( 0.00%)
28	0/ 39 ( 0.00%)	0/ 25 ( 0.00%)
29	0/ 41 ( 0.00%)	0/ 30 ( 0.00%)
30	0/ 28 ( 0.00%)	0/ 27 ( 0.00%)
31	0/ 38 ( 0.00%)	0/ 32 ( 0.00%)
32	0/ 34 ( 0.00%)	0/ 34 ( 0.00%)
33	0/ 46 ( 0.00%)	0/ 30 ( 0.00%)
34	0/ 44 ( 0.00%)	0/ 36 ( 0.00%)
35	1/ 40 ( 2.50%)	1/ 36 ( 2.78%)
36	0/ 34 ( 0.00%)	0/ 22 ( 0.00%)
37	0/ 43 ( 0.00%)	1/ 30 ( 3.33%)
38	0/ 32 ( 0.00%)	0/ 33 ( 0.00%)
39	0/ 28 ( 0.00%)	0/ 35 ( 0.00%)
40	0/ 26 ( 0.00%)	0/ 23 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Panic

Age (years)	Paroxetine	Placebo
41	0/ 27 ( 0.00%)	0/ 24 ( 0.00%)
42	0/ 41 ( 0.00%)	0/ 27 ( 0.00%)
43	0/ 28 ( 0.00%)	0/ 27 ( 0.00%)
44	0/ 36 ( 0.00%)	0/ 20 ( 0.00%)
45	0/ 28 ( 0.00%)	0/ 27 ( 0.00%)
46	0/ 24 ( 0.00%)	0/ 16 ( 0.00%)
47	0/ 31 ( 0.00%)	0/ 20 ( 0.00%)
48	0/ 22 ( 0.00%)	0/ 16 ( 0.00%)
49	0/ 32 ( 0.00%)	0/ 17 ( 0.00%)
50	0/ 16 ( 0.00%)	1/ 17 ( 5.88%)
51	1/ 12 ( 8.33%)	0/ 16 ( 0.00%)
52	0/ 11 ( 0.00%)	0/ 18 ( 0.00%)
53	0/ 6 ( 0.00%)	0/ 5 ( 0.00%)
54	0/ 8 ( 0.00%)	0/ 8 ( 0.00%)
55	0/ 12 ( 0.00%)	0/ 6 ( 0.00%)
56	0/ 7 ( 0.00%)	0/ 7 ( 0.00%)
57	0/ 7 ( 0.00%)	0/ 12 ( 0.00%)
58	0/ 7 ( 0.00%)	0/ 4 ( 0.00%)
59	0/ 2 ( 0.00%)	0/ 9 ( 0.00%)
60	0/ 6 ( 0.00%)	0/ 4 ( 0.00%)
61	0/ 2 ( 0.00%)	0/ 6 ( 0.00%)
62	0/ 3 ( 0.00%)	0/ 2 ( 0.00%)
63	0/ 6 ( 0.00%)	0/ 3 ( 0.00%)
64	0/ 6 ( 0.00%)	0/ 2 ( 0.00%)
65	0/ 4 ( 0.00%)	0/ 0

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Panic

Age (years)	Paroxetine	Placebo
66	0/ 2 ( 0.00%)	0/ 0
67	0/ 0	0/ 1 ( 0.00%)
68	0/ 0	0/ 0
69	0/ 1 ( 0.00%)	0/ 0
70	0/ 0	0/ 0
71	0/ 0	0/ 0
72	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
73	0/ 0	0/ 0
74	0/ 1 ( 0.00%)	0/ 0
75	0/ 0	0/ 0
76	0/ 0	0/ 0
77	0/ 0	0/ 0
78	0/ 0	0/ 0
79	0/ 0	0/ 0
80	0/ 0	0/ 0
81	0/ 0	0/ 0
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 0
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0



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Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Panic

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = OCD

Age (years)	Paroxetine	Placebo
16	1/ 4 (25.00%)	0/ 5 ( 0.00%)
17	0/ 6 ( 0.00%)	0/ 0
18	0/ 6 ( 0.00%)	0/ 0
19	0/ 12 ( 0.00%)	0/ 4 ( 0.00%)
20	0/ 11 ( 0.00%)	0/ 5 ( 0.00%)
21	0/ 13 ( 0.00%)	0/ 6 ( 0.00%)
22	1/ 9 (11.11%)	0/ 11 ( 0.00%)
23	0/ 15 ( 0.00%)	0/ 12 ( 0.00%)
24	0/ 21 ( 0.00%)	0/ 13 ( 0.00%)
25	0/ 8 ( 0.00%)	0/ 17 ( 0.00%)
26	0/ 20 ( 0.00%)	0/ 10 ( 0.00%)
27	0/ 19 ( 0.00%)	0/ 7 ( 0.00%)
28	1/ 21 ( 4.76%)	0/ 10 ( 0.00%)
29	0/ 28 ( 0.00%)	0/ 11 ( 0.00%)
30	0/ 7 ( 0.00%)	0/ 11 ( 0.00%)
31	0/ 32 ( 0.00%)	0/ 13 ( 0.00%)
32	0/ 20 ( 0.00%)	0/ 13 ( 0.00%)
33	0/ 26 ( 0.00%)	0/ 13 ( 0.00%)
34	0/ 18 ( 0.00%)	0/ 11 ( 0.00%)
35	0/ 15 ( 0.00%)	0/ 13 ( 0.00%)
36	0/ 11 ( 0.00%)	0/ 19 ( 0.00%)
37	0/ 16 ( 0.00%)	0/ 19 ( 0.00%)
38	0/ 21 ( 0.00%)	0/ 10 ( 0.00%)
39	0/ 22 ( 0.00%)	0/ 6 ( 0.00%)
40	0/ 21 ( 0.00%)	0/ 18 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = OCD

Age (years)	Paroxetine	Placebo
41	0/ 17 ( 0.00%)	0/ 8 ( 0.00%)
42	1/ 18 ( 5.56%)	0/ 13 ( 0.00%)
43	0/ 17 ( 0.00%)	0/ 6 ( 0.00%)
44	0/ 22 ( 0.00%)	0/ 9 ( 0.00%)
45	0/ 21 ( 0.00%)	0/ 13 ( 0.00%)
46	0/ 12 ( 0.00%)	0/ 14 ( 0.00%)
47	0/ 11 ( 0.00%)	1/ 7 (14.29%)
48	0/ 12 ( 0.00%)	0/ 10 ( 0.00%)
49	0/ 12 ( 0.00%)	0/ 4 ( 0.00%)
50	0/ 10 ( 0.00%)	0/ 7 ( 0.00%)
51	1/ 17 ( 5.88%)	0/ 4 ( 0.00%)
52	0/ 21 ( 0.00%)	0/ 9 ( 0.00%)
53	0/ 9 ( 0.00%)	3/ 8 (37.50%)
54	0/ 7 ( 0.00%)	0/ 5 ( 0.00%)
55	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
56	0/ 8 ( 0.00%)	0/ 2 ( 0.00%)
57	0/ 9 ( 0.00%)	0/ 3 ( 0.00%)
58	0/ 7 ( 0.00%)	0/ 5 ( 0.00%)
59	0/ 5 ( 0.00%)	0/ 2 ( 0.00%)
60	0/ 5 ( 0.00%)	0/ 5 ( 0.00%)
61	0/ 6 ( 0.00%)	0/ 1 ( 0.00%)
62	0/ 6 ( 0.00%)	0/ 2 ( 0.00%)
63	0/ 3 ( 0.00%)	0/ 5 ( 0.00%)
64	0/ 4 ( 0.00%)	0/ 2 ( 0.00%)
65	0/ 6 ( 0.00%)	0/ 1 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = OCD

Age (years)	Paroxetine	Placebo
66	0/ 4 ( 0.00%)	0/ 3 ( 0.00%)
67	0/ 4 ( 0.00%)	0/ 4 ( 0.00%)
68	0/ 4 ( 0.00%)	0/ 0
69	0/ 5 ( 0.00%)	0/ 0
70	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
71	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)
72	0/ 1 ( 0.00%)	0/ 0
73	0/ 3 ( 0.00%)	0/ 1 ( 0.00%)
74	0/ 0	0/ 1 ( 0.00%)
75	0/ 1 ( 0.00%)	0/ 0
76	0/ 0	0/ 0
77	0/ 1 ( 0.00%)	0/ 0
78	0/ 1 ( 0.00%)	0/ 0
79	0/ 0	0/ 0
80	0/ 0	0/ 0
81	0/ 0	0/ 0
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 0
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0

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Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = OCD

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = SAD

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 0
18	0/ 8 ( 0.00%)	0/ 8 ( 0.00%)
19	0/ 7 ( 0.00%)	0/ 6 ( 0.00%)
20	1/ 19 ( 5.26%)	0/ 6 ( 0.00%)
21	0/ 11 ( 0.00%)	0/ 14 ( 0.00%)
22	0/ 28 ( 0.00%)	0/ 17 ( 0.00%)
23	1/ 20 ( 5.00%)	0/ 13 ( 0.00%)
24	0/ 21 ( 0.00%)	0/ 25 ( 0.00%)
25	1/ 24 ( 4.17%)	0/ 17 ( 0.00%)
26	0/ 34 ( 0.00%)	1/ 27 ( 3.70%)
27	0/ 35 ( 0.00%)	0/ 23 ( 0.00%)
28	0/ 29 ( 0.00%)	1/ 25 ( 4.00%)
29	0/ 28 ( 0.00%)	0/ 13 ( 0.00%)
30	0/ 21 ( 0.00%)	0/ 17 ( 0.00%)
31	0/ 27 ( 0.00%)	0/ 17 ( 0.00%)
32	0/ 31 ( 0.00%)	0/ 21 ( 0.00%)
33	0/ 18 ( 0.00%)	0/ 25 ( 0.00%)
34	0/ 37 ( 0.00%)	1/ 11 ( 9.09%)
35	0/ 35 ( 0.00%)	0/ 17 ( 0.00%)
36	0/ 37 ( 0.00%)	0/ 15 ( 0.00%)
37	0/ 19 ( 0.00%)	0/ 18 ( 0.00%)
38	0/ 32 ( 0.00%)	0/ 23 ( 0.00%)
39	0/ 35 ( 0.00%)	0/ 25 ( 0.00%)
40	0/ 39 ( 0.00%)	0/ 22 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = SAD

Age (years)	Paroxetine	Placebo
41	0/ 29 ( 0.00%)	0/ 24 ( 0.00%)
42	0/ 29 ( 0.00%)	0/ 15 ( 0.00%)
43	0/ 26 ( 0.00%)	0/ 17 ( 0.00%)
44	0/ 29 ( 0.00%)	0/ 20 ( 0.00%)
45	0/ 28 ( 0.00%)	0/ 18 ( 0.00%)
46	0/ 21 ( 0.00%)	0/ 18 ( 0.00%)
47	0/ 16 ( 0.00%)	0/ 9 ( 0.00%)
48	0/ 24 ( 0.00%)	0/ 9 ( 0.00%)
49	0/ 15 ( 0.00%)	0/ 18 ( 0.00%)
50	0/ 22 ( 0.00%)	0/ 16 ( 0.00%)
51	0/ 16 ( 0.00%)	0/ 4 ( 0.00%)
52	0/ 13 ( 0.00%)	0/ 8 ( 0.00%)
53	0/ 16 ( 0.00%)	0/ 9 ( 0.00%)
54	0/ 14 ( 0.00%)	0/ 8 ( 0.00%)
55	0/ 6 ( 0.00%)	0/ 6 ( 0.00%)
56	0/ 8 ( 0.00%)	0/ 6 ( 0.00%)
57	0/ 6 ( 0.00%)	0/ 4 ( 0.00%)
58	0/ 5 ( 0.00%)	0/ 5 ( 0.00%)
59	0/ 4 ( 0.00%)	0/ 2 ( 0.00%)
60	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
61	0/ 5 ( 0.00%)	0/ 2 ( 0.00%)
62	0/ 3 ( 0.00%)	0/ 2 ( 0.00%)
63	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)
64	0/ 3 ( 0.00%)	0/ 3 ( 0.00%)
65	0/ 0	0/ 3 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = SAD

Age (years)	Paroxetine	Placebo
66	0/ 0	0/ 1 ( 0.00%)
67	0/ 1 ( 0.00%)	0/ 3 ( 0.00%)
68	0/ 0	0/ 0
69	0/ 2 ( 0.00%)	0/ 1 ( 0.00%)
70	0/ 1 ( 0.00%)	0/ 0
71	0/ 0	0/ 1 ( 0.00%)
72	0/ 0	0/ 0
73	0/ 0	0/ 0
74	0/ 0	0/ 1 ( 0.00%)
75	0/ 0	0/ 0
76	0/ 0	0/ 1 ( 0.00%)
77	0/ 0	0/ 0
78	0/ 0	0/ 0
79	0/ 0	0/ 0
80	0/ 0	0/ 0
81	0/ 0	0/ 0
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 1 ( 0.00%)
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0



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Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = SAD

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = GAD

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 0
18	0/ 8 ( 0.00%)	0/ 5 ( 0.00%)
19	0/ 12 ( 0.00%)	0/ 6 ( 0.00%)
20	1/ 13 ( 7.69%)	0/ 9 ( 0.00%)
21	0/ 14 ( 0.00%)	0/ 13 ( 0.00%)
22	0/ 17 ( 0.00%)	0/ 10 ( 0.00%)
23	0/ 19 ( 0.00%)	0/ 11 ( 0.00%)
24	0/ 20 ( 0.00%)	0/ 14 ( 0.00%)
25	0/ 16 ( 0.00%)	0/ 13 ( 0.00%)
26	0/ 28 ( 0.00%)	1/ 23 ( 4.35%)
27	0/ 24 ( 0.00%)	0/ 13 ( 0.00%)
28	0/ 22 ( 0.00%)	0/ 12 ( 0.00%)
29	0/ 27 ( 0.00%)	0/ 13 ( 0.00%)
30	0/ 18 ( 0.00%)	0/ 15 ( 0.00%)
31	0/ 20 ( 0.00%)	0/ 17 ( 0.00%)
32	0/ 23 ( 0.00%)	0/ 24 ( 0.00%)
33	0/ 26 ( 0.00%)	1/ 22 ( 4.55%)
34	0/ 14 ( 0.00%)	0/ 22 ( 0.00%)
35	0/ 17 ( 0.00%)	0/ 17 ( 0.00%)
36	0/ 14 ( 0.00%)	0/ 16 ( 0.00%)
37	1/ 28 ( 3.57%)	0/ 15 ( 0.00%)
38	0/ 18 ( 0.00%)	0/ 16 ( 0.00%)
39	0/ 26 ( 0.00%)	0/ 21 ( 0.00%)
40	0/ 18 ( 0.00%)	0/ 24 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = GAD

Age (years)	Paroxetine	Placebo
41	0/ 23 ( 0.00%)	0/ 18 ( 0.00%)
42	0/ 29 ( 0.00%)	0/ 18 ( 0.00%)
43	0/ 32 ( 0.00%)	0/ 24 ( 0.00%)
44	0/ 20 ( 0.00%)	0/ 18 ( 0.00%)
45	0/ 30 ( 0.00%)	0/ 13 ( 0.00%)
46	0/ 18 ( 0.00%)	0/ 14 ( 0.00%)
47	0/ 19 ( 0.00%)	0/ 15 ( 0.00%)
48	0/ 23 ( 0.00%)	0/ 15 ( 0.00%)
49	0/ 22 ( 0.00%)	0/ 19 ( 0.00%)
50	0/ 20 ( 0.00%)	0/ 16 ( 0.00%)
51	0/ 22 ( 0.00%)	0/ 11 ( 0.00%)
52	0/ 21 ( 0.00%)	0/ 12 ( 0.00%)
53	0/ 14 ( 0.00%)	0/ 11 ( 0.00%)
54	0/ 14 ( 0.00%)	0/ 14 ( 0.00%)
55	0/ 12 ( 0.00%)	0/ 8 ( 0.00%)
56	0/ 14 ( 0.00%)	0/ 12 ( 0.00%)
57	0/ 16 ( 0.00%)	0/ 9 ( 0.00%)
58	0/ 12 ( 0.00%)	0/ 10 ( 0.00%)
59	0/ 11 ( 0.00%)	0/ 11 ( 0.00%)
60	0/ 14 ( 0.00%)	0/ 4 ( 0.00%)
61	0/ 10 ( 0.00%)	0/ 7 ( 0.00%)
62	0/ 2 ( 0.00%)	0/ 7 ( 0.00%)
63	0/ 6 ( 0.00%)	0/ 6 ( 0.00%)
64	0/ 5 ( 0.00%)	0/ 5 ( 0.00%)
65	0/ 3 ( 0.00%)	0/ 6 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = GAD

Age (years)	Paroxetine	Placebo
66	0/ 6 ( 0.00%)	0/ 7 ( 0.00%)
67	0/ 9 ( 0.00%)	0/ 5 ( 0.00%)
68	0/ 5 ( 0.00%)	0/ 5 ( 0.00%)
69	0/ 3 ( 0.00%)	0/ 2 ( 0.00%)
70	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
71	0/ 5 ( 0.00%)	0/ 5 ( 0.00%)
72	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
73	0/ 3 ( 0.00%)	0/ 6 ( 0.00%)
74	0/ 5 ( 0.00%)	0/ 4 ( 0.00%)
75	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)
76	0/ 3 ( 0.00%)	0/ 2 ( 0.00%)
77	0/ 0	0/ 0
78	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
79	0/ 0	0/ 0
80	0/ 0	0/ 1 ( 0.00%)
81	0/ 0	0/ 1 ( 0.00%)
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 0
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0

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Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = GAD

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = PTSD

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 0
18	0/ 6 ( 0.00%)	0/ 6 ( 0.00%)
19	0/ 10 ( 0.00%)	0/ 4 ( 0.00%)
20	0/ 10 ( 0.00%)	0/ 6 ( 0.00%)
21	0/ 3 ( 0.00%)	1/ 8 (12.50%)
22	0/ 6 ( 0.00%)	0/ 10 ( 0.00%)
23	0/ 7 ( 0.00%)	0/ 11 ( 0.00%)
24	0/ 9 ( 0.00%)	0/ 6 ( 0.00%)
25	0/ 15 ( 0.00%)	0/ 13 ( 0.00%)
26	0/ 9 ( 0.00%)	0/ 14 ( 0.00%)
27	1/ 14 ( 7.14%)	0/ 8 ( 0.00%)
28	0/ 19 ( 0.00%)	1/ 14 ( 7.14%)
29	0/ 17 ( 0.00%)	1/ 16 ( 6.25%)
30	0/ 21 ( 0.00%)	0/ 8 ( 0.00%)
31	0/ 20 ( 0.00%)	0/ 9 ( 0.00%)
32	0/ 14 ( 0.00%)	0/ 12 ( 0.00%)
33	0/ 19 ( 0.00%)	0/ 16 ( 0.00%)
34	0/ 21 ( 0.00%)	0/ 12 ( 0.00%)
35	0/ 14 ( 0.00%)	0/ 12 ( 0.00%)
36	0/ 17 ( 0.00%)	0/ 17 ( 0.00%)
37	1/ 17 ( 5.88%)	0/ 13 ( 0.00%)
38	1/ 33 ( 3.03%)	0/ 18 ( 0.00%)
39	0/ 11 ( 0.00%)	1/ 22 ( 4.55%)
40	0/ 20 ( 0.00%)	0/ 10 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = PTSD

Age (years)	Paroxetine	Placebo
41	0/ 19 ( 0.00%)	0/ 20 ( 0.00%)
42	0/ 18 ( 0.00%)	0/ 17 ( 0.00%)
43	0/ 25 ( 0.00%)	0/ 12 ( 0.00%)
44	0/ 24 ( 0.00%)	0/ 13 ( 0.00%)
45	0/ 25 ( 0.00%)	1/ 14 ( 7.14%)
46	0/ 22 ( 0.00%)	0/ 18 ( 0.00%)
47	0/ 21 ( 0.00%)	0/ 11 ( 0.00%)
48	0/ 17 ( 0.00%)	0/ 12 ( 0.00%)
49	0/ 20 ( 0.00%)	0/ 20 ( 0.00%)
50	0/ 15 ( 0.00%)	1/ 10 (10.00%)
51	0/ 18 ( 0.00%)	0/ 14 ( 0.00%)
52	0/ 20 ( 0.00%)	0/ 11 ( 0.00%)
53	0/ 17 ( 0.00%)	0/ 6 ( 0.00%)
54	0/ 17 ( 0.00%)	0/ 8 ( 0.00%)
55	0/ 21 ( 0.00%)	0/ 7 ( 0.00%)
56	0/ 11 ( 0.00%)	0/ 6 ( 0.00%)
57	0/ 6 ( 0.00%)	0/ 4 ( 0.00%)
58	0/ 7 ( 0.00%)	0/ 6 ( 0.00%)
59	0/ 7 ( 0.00%)	0/ 5 ( 0.00%)
60	0/ 6 ( 0.00%)	0/ 5 ( 0.00%)
61	0/ 7 ( 0.00%)	0/ 6 ( 0.00%)
62	0/ 4 ( 0.00%)	0/ 4 ( 0.00%)
63	0/ 3 ( 0.00%)	0/ 3 ( 0.00%)
64	0/ 3 ( 0.00%)	0/ 1 ( 0.00%)
65	0/ 2 ( 0.00%)	0/ 0

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = PTSD

Age (years)	Paroxetine	Placebo
66	0/ 0	0/ 2 ( 0.00%)
67	0/ 1 ( 0.00%)	0/ 4 ( 0.00%)
68	0/ 3 ( 0.00%)	0/ 0
69	0/ 2 ( 0.00%)	0/ 1 ( 0.00%)
70	0/ 1 ( 0.00%)	0/ 0
71	0/ 0	0/ 1 ( 0.00%)
72	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)
73	0/ 0	0/ 0
74	0/ 1 ( 0.00%)	0/ 0
75	0/ 1 ( 0.00%)	0/ 0
76	0/ 0	0/ 0
77	0/ 0	0/ 1 ( 0.00%)
78	0/ 0	0/ 1 ( 0.00%)
79	0/ 0	0/ 0
80	0/ 0	0/ 0
81	0/ 0	0/ 0
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 0
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0



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Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = PTSD

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = PMDD

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 0
18	0/ 0	0/ 0
19	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
20	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
21	0/ 3 ( 0.00%)	0/ 3 ( 0.00%)
22	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
23	0/ 4 ( 0.00%)	0/ 3 ( 0.00%)
24	0/ 8 ( 0.00%)	0/ 7 ( 0.00%)
25	0/ 7 ( 0.00%)	0/ 7 ( 0.00%)
26	0/ 6 ( 0.00%)	0/ 7 ( 0.00%)
27	0/ 10 ( 0.00%)	0/ 10 ( 0.00%)
28	0/ 21 ( 0.00%)	0/ 11 ( 0.00%)
29	0/ 30 ( 0.00%)	0/ 14 ( 0.00%)
30	0/ 23 ( 0.00%)	0/ 23 ( 0.00%)
31	0/ 33 ( 0.00%)	0/ 16 ( 0.00%)
32	0/ 22 ( 0.00%)	0/ 25 ( 0.00%)
33	0/ 33 ( 0.00%)	0/ 24 ( 0.00%)
34	0/ 57 ( 0.00%)	0/ 24 ( 0.00%)
35	0/ 46 ( 0.00%)	0/ 17 ( 0.00%)
36	0/ 50 ( 0.00%)	0/ 26 ( 0.00%)
37	0/ 61 ( 0.00%)	0/ 23 ( 0.00%)
38	0/ 55 ( 0.00%)	0/ 27 ( 0.00%)
39	0/ 66 ( 0.00%)	0/ 29 ( 0.00%)
40	0/ 59 ( 0.00%)	0/ 28 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = PMDD

Age (years)	Paroxetine	Placebo
41	0/ 74 ( 0.00%)	0/ 23 ( 0.00%)
42	0/ 47 ( 0.00%)	0/ 27 ( 0.00%)
43	0/ 32 ( 0.00%)	0/ 11 ( 0.00%)
44	0/ 32 ( 0.00%)	0/ 24 ( 0.00%)
45	1/ 22 ( 4.55%)	0/ 17 ( 0.00%)
46	0/ 3 ( 0.00%)	0/ 3 ( 0.00%)
47	0/ 2 ( 0.00%)	0/ 3 ( 0.00%)
48	0/ 0	0/ 2 ( 0.00%)
49	0/ 2 ( 0.00%)	0/ 1 ( 0.00%)
50	0/ 0	0/ 0
51	0/ 0	0/ 0
52	0/ 0	0/ 0
53	0/ 0	0/ 0
54	0/ 0	0/ 0
55	0/ 0	0/ 0
56	0/ 0	0/ 0
57	0/ 0	0/ 0
58	0/ 0	0/ 0
59	0/ 0	0/ 0
60	0/ 0	0/ 0
61	0/ 0	0/ 0
62	0/ 0	0/ 0
63	0/ 0	0/ 0
64	0/ 0	0/ 0
65	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = PMDD

Age (years)	Paroxetine	Placebo
66	0/ 0	0/ 0
67	0/ 0	0/ 0
68	0/ 0	0/ 0
69	0/ 0	0/ 0
70	0/ 0	0/ 0
71	0/ 0	0/ 0
72	0/ 0	0/ 0
73	0/ 0	0/ 0
74	0/ 0	0/ 0
75	0/ 0	0/ 0
76	0/ 0	0/ 0
77	0/ 0	0/ 0
78	0/ 0	0/ 0
79	0/ 0	0/ 0
80	0/ 0	0/ 0
81	0/ 0	0/ 0
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 0
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0

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anal\_alladsui\_gsk\_2005\_list\_ages.sas 16MAR2006:15:19 kk45592

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = PMDD

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = Detoxification in Alcoholics

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 0
18	0/ 0	0/ 0
19	0/ 0	0/ 0
20	0/ 0	0/ 0
21	0/ 0	0/ 0
22	0/ 0	0/ 0
23	0/ 1 ( 0.00%)	0/ 0
24	0/ 0	0/ 0
25	0/ 0	0/ 0
26	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
27	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
28	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
29	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
30	0/ 0	0/ 4 ( 0.00%)
31	0/ 0	0/ 2 ( 0.00%)
32	0/ 0	0/ 2 ( 0.00%)
33	0/ 4 ( 0.00%)	0/ 4 ( 0.00%)
34	0/ 3 ( 0.00%)	0/ 4 ( 0.00%)
35	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)
36	0/ 3 ( 0.00%)	0/ 3 ( 0.00%)
37	0/ 4 ( 0.00%)	0/ 4 ( 0.00%)
38	0/ 4 ( 0.00%)	0/ 4 ( 0.00%)
39	0/ 0	0/ 1 ( 0.00%)
40	0/ 3 ( 0.00%)	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = Detoxification in Alcoholics

Age (years)	Paroxetine	Placebo
41	0/ 3 ( 0.00%)	0/ 3 ( 0.00%)
42	0/ 3 ( 0.00%)	0/ 1 ( 0.00%)
43	0/ 3 ( 0.00%)	0/ 3 ( 0.00%)
44	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
45	0/ 1 ( 0.00%)	0/ 3 ( 0.00%)
46	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
47	0/ 4 ( 0.00%)	0/ 1 ( 0.00%)
48	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
49	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)
50	0/ 0	0/ 2 ( 0.00%)
51	0/ 2 ( 0.00%)	0/ 2 ( 0.00%)
52	0/ 0	0/ 1 ( 0.00%)
53	0/ 0	0/ 0
54	0/ 0	0/ 0
55	0/ 2 ( 0.00%)	0/ 0
56	0/ 1 ( 0.00%)	0/ 0
57	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
58	0/ 1 ( 0.00%)	0/ 0
59	0/ 2 ( 0.00%)	0/ 0
60	0/ 2 ( 0.00%)	0/ 0
61	0/ 0	0/ 2 ( 0.00%)
62	0/ 0	0/ 1 ( 0.00%)
63	0/ 0	0/ 0
64	0/ 0	0/ 0
65	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Detoxification in Alcoholics

Age (years)	Paroxetine	Placebo
66	0/ 0	0/ 0
67	0/ 0	0/ 0
68	0/ 0	0/ 0
69	0/ 0	0/ 0
70	0/ 0	0/ 0
71	0/ 0	0/ 0
72	0/ 0	0/ 0
73	0/ 0	0/ 0
74	0/ 0	0/ 0
75	0/ 0	0/ 0
76	0/ 0	0/ 0
77	0/ 0	0/ 0
78	0/ 0	0/ 0
79	0/ 0	0/ 0
80	0/ 0	0/ 0
81	0/ 0	0/ 0
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 0
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0



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anal\_alladsui\_gsk\_2005\_list\_ages.sas 16MAR2006:15:19 kk45592

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Detoxification in Alcoholics

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
 Table 2.10  
 Subjects with Definitive Suicidal Behaviour and Ideation by Age  
 Indication = Fibromyalgia

Age (years)	Paroxetine	Placebo
16	0/ 0	0/ 0
17	0/ 0	0/ 0
18	0/ 0	0/ 0
19	0/ 0	0/ 0
20	0/ 0	0/ 0
21	0/ 0	0/ 1 ( 0.00%)
22	0/ 0	0/ 0
23	0/ 0	0/ 0
24	0/ 0	0/ 0
25	0/ 0	0/ 0
26	0/ 0	0/ 0
27	0/ 0	0/ 0
28	0/ 0	0/ 0
29	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
30	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
31	0/ 2 ( 0.00%)	0/ 1 ( 0.00%)
32	0/ 1 ( 0.00%)	0/ 0
33	0/ 0	0/ 0
34	0/ 0	0/ 1 ( 0.00%)
35	0/ 0	0/ 0
36	0/ 0	0/ 1 ( 0.00%)
37	0/ 0	0/ 3 ( 0.00%)
38	0/ 0	0/ 1 ( 0.00%)
39	0/ 0	0/ 0
40	0/ 4 ( 0.00%)	0/ 2 ( 0.00%)

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Fibromyalgia

Age (years)	Paroxetine	Placebo
41	0/ 1 ( 0.00%)	0/ 0
42	0/ 1 ( 0.00%)	0/ 0
43	0/ 0	0/ 2 ( 0.00%)
44	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
45	0/ 0	0/ 1 ( 0.00%)
46	0/ 1 ( 0.00%)	0/ 0
47	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
48	0/ 2 ( 0.00%)	0/ 1 ( 0.00%)
49	0/ 1 ( 0.00%)	0/ 0
50	0/ 2 ( 0.00%)	0/ 0
51	0/ 0	0/ 1 ( 0.00%)
52	0/ 1 ( 0.00%)	0/ 1 ( 0.00%)
53	0/ 1 ( 0.00%)	0/ 3 ( 0.00%)
54	0/ 0	0/ 0
55	0/ 1 ( 0.00%)	0/ 0
56	0/ 0	0/ 2 ( 0.00%)
57	0/ 1 ( 0.00%)	0/ 0
58	0/ 1 ( 0.00%)	0/ 0
59	0/ 0	0/ 0
60	0/ 1 ( 0.00%)	0/ 0
61	0/ 0	0/ 0
62	0/ 0	0/ 0
63	0/ 1 ( 0.00%)	0/ 0
64	0/ 0	0/ 0
65	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Fibromyalgia

Age (years)	Paroxetine	Placebo
66	0/ 0	0/ 0
67	0/ 0	0/ 0
68	0/ 0	0/ 1 ( 0.00%)
69	0/ 0	0/ 0
70	0/ 0	0/ 0
71	0/ 0	0/ 0
72	0/ 0	0/ 0
73	0/ 0	0/ 0
74	0/ 0	0/ 0
75	0/ 0	0/ 0
76	0/ 0	0/ 0
77	0/ 0	0/ 0
78	0/ 0	0/ 0
79	0/ 0	0/ 0
80	0/ 0	0/ 0
81	0/ 0	0/ 0
82	0/ 0	0/ 0
83	0/ 0	0/ 0
84	0/ 0	0/ 0
85	0/ 0	0/ 0
86	0/ 0	0/ 0
87	0/ 0	0/ 0
88	0/ 0	0/ 0
89	0/ 0	0/ 0
90	0/ 0	0/ 0

GSK Confidential. /bioenv/dart10/sbbr129060\_cda/legal2/list/anal\_alladsui\_gsk\_2005\_list\_ages.lst  
anal\_alladsui\_gsk\_2005\_list\_ages.sas 16MAR2006:15:19 kk45592

Paroxetine Adult Suicidality Analysis  
Table 2.10  
Subjects with Definitive Suicidal Behaviour and Ideation by Age  
Indication = Fibromyalgia

Age (years)	Paroxetine	Placebo
91	0/ 0	0/ 0

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Indications

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
02.001.009	002	PLACEBO	67	Female	Yes	Yes	No
02.004.089	002	PAROXETINE	19	Female	No	Yes	No
057.002.0204	057	PAROXETINE	46	Female	Yes	Yes	No
057.002.0207	057	PLACEBO	29	Female	Yes	Yes	No
057.004.0410	057	PLACEBO	54	Female	Yes	Yes	No
057.004.0413	057	PLACEBO	43	Female	Yes	Yes	No
057.005.0508	057	PLACEBO	32	Male	Yes	Yes	No
057.005.0514	057	PAROXETINE	25	Male	Yes	Yes	No
057.005.0516	057	PAROXETINE	22	Male	Yes	Yes	No
057.006.0603	057	PLACEBO	41	Female	Yes	Yes	No
057.008.0802	057	PAROXETINE	48	Male	Yes	Yes	No
057.008.0803	057	PLACEBO	21	Male	Yes	Yes	No
057.011.1421	057	PAROXETINE	35	Male	Yes	Yes	No
057.012.1204	057	PAROXETINE	28	Female	Yes	Yes	No
057.012.1207	057	PAROXETINE	44	Male	Yes	Yes	No
057.012.1208	057	PAROXETINE	45	Female	Yes	Yes	No
057.012.1211	057	PLACEBO	46	Female	Yes	Yes	No
057.012.1212	057	PLACEBO	22	Female	Yes	Yes	No
057.012.1213	057	PLACEBO	31	Female	Yes	Yes	No
057.012.1215	057	PAROXETINE	32	Male	Yes	Yes	No
057.012.1217	057	PLACEBO	32	Male	Yes	Yes	No
057.012.1218	057	PLACEBO	28	Female	Yes	Yes	No
057.012.1221	057	PAROXETINE	29	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Indications

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
057.012.1223	057	PLACEBO	43	Female	Yes	Yes	No
057.012.1227	057	PLACEBO	53	Male	Yes	Yes	No
057.012.1229	057	PLACEBO	30	Female	Yes	Yes	No
057.012.1231	057	PAROXETINE	28	Male	Yes	Yes	No
057.012.1232	057	PLACEBO	39	Male	Yes	Yes	No
057.012.1234	057	PLACEBO	41	Male	Yes	Yes	No
057.012.1238	057	PAROXETINE	20	Male	Yes	Yes	No
057.012.1239	057	PLACEBO	45	Female	Yes	Yes	No
057.012.1240	057	PLACEBO	27	Male	Yes	Yes	No
057.012.1334	057	PAROXETINE	23	Female	Yes	Yes	No
057.012.1335	057	PLACEBO	41	Female	Yes	Yes	No
057.012.1336	057	PAROXETINE	44	Male	Yes	Yes	No
057.012.1339	057	PAROXETINE	32	Male	Yes	Yes	No
057.012.1340	057	PLACEBO	34	Male	Yes	Yes	No
057.012.1540	057	PAROXETINE	34	Female	Yes	Yes	No
057.013.1304	057	PLACEBO	32	Female	Yes	Yes	No
057.013.1310	057	PLACEBO	35	Male	Yes	Yes	Yes
057.013.1315	057	PLACEBO	30	Male	Yes	Yes	No
057.013.1318	057	PLACEBO	45	Male	Yes	Yes	No
057.013.1321	057	PLACEBO	45	Male	Yes	Yes	No
057.014.1401	057	PAROXETINE	29	Female	Yes	Yes	No
057.015.1504	057	PLACEBO	26	Female	Yes	Yes	No
057.015.1505	057	PLACEBO	26	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Indications

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
057.015.1511	057	PLACEBO	20	Female	Yes	Yes	No
057.017.1713	057	PAROXETINE	32	Female	Yes	Yes	No
057.017.1732	057	PAROXETINE	47	Female	Yes	Yes	No
057.017.1735	057	PAROXETINE	45	Female	Yes	Yes	No
057.018.1806	057	PAROXETINE	39	Female	Yes	Yes	No
057.018.1810	057	PAROXETINE	20	Male	Yes	Yes	No
057.019.0221	057	PAROXETINE	23	Female	Yes	Yes	No
057.019.0222	057	PAROXETINE	34	Female	Yes	Yes	No
057.019.0223	057	PLACEBO	25	Female	Yes	Yes	Yes
057.019.0226	057	PAROXETINE	22	Female	Yes	Yes	No
057.019.0227	057	PLACEBO	24	Male	Yes	Yes	No
057.019.0229	057	PAROXETINE	27	Female	Yes	Yes	No
09.01A.006	009	PAROXETINE	35	Male	No	No	Yes
09.01E.260	009	PAROXETINE	51	Female	No	Yes	No
1 12 037	279	PAROXETINE	20	Male	Yes	Yes	No
106.001.0001	106	PAROXETINE	48	Female	Yes	Yes	No
106.001.0002	106	PLACEBO	38	Female	Yes	Yes	No
106.001.0003	106	PAROXETINE	29	Female	No	No	Yes
106.001.0006	106	PLACEBO	23	Female	Yes	Yes	No
106.001.0013	106	PLACEBO	31	Female	Yes	Yes	No
106.001.0015	106	PLACEBO	36	Female	Yes	Yes	No
106.001.0018	106	PLACEBO	25	Female	Yes	Yes	No
106.001.0020	106	PAROXETINE	37	Female	Yes	Yes	No



Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Indications

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
106.001.0024	106	PAROXETINE	24	Male	Yes	Yes	No
106.001.0025	106	PAROXETINE	24	Female	Yes	Yes	No
106.001.0029	106	PAROXETINE	23	Male	Yes	Yes	No
106.001.0030	106	PAROXETINE	21	Female	Yes	Yes	No
115.003.0062	115	PAROXETINE	29	Female	No	Yes	No
118.003.0155	118	PAROXETINE	22	Female	No	Yes	No
120.011.0065	120	PAROXETINE	20	Female	No	Yes	No
128.001.0759	128	PAROXETINE	30	Male	No	Yes	No
136.067.0403	136	PAROXETINE	51	Female	No	Yes	Yes
136.067.0436	136	PLACEBO	53	Female	No	Yes	No
187.011.0531	187	PLACEBO	35	Male	No	Yes	No
187.035.0510	187	PLACEBO	37	Male	No	Yes	No
251.002.0285	251	PAROXETINE	30	Male	No	Yes	No
448.010.00044	448	PAROXETINE	25	Female	No	Yes	No
448.019.00391	448	PAROXETINE	27	Female	No	Yes	No
449.021.00788	449	PAROXETINE	18	Female	No	Yes	No
502.003.05511	502	PAROXETINE	20	Male	Missing	Yes	No
502.037.05146	502	PAROXETINE	23	Male	Missing	Yes	No
502.045.05077	502	PLACEBO	34	Male	Missing	Yes	No
625.500.02062	625	PAROXETINE	49	Male	Yes	Yes	No
627.603.01028	627	PAROXETINE	27	Male	No	Yes	No
660.23502	660	PAROXETINE	16	Female	Missing	Yes	No
785.720.00695	785	PAROXETINE	34	Female	No	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Depression

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
02.001.009	002	PLACEBO	67	Female	Yes	Yes	No
02.004.089	002	PAROXETINE	19	Female	No	Yes	No
057.002.0204	057	PAROXETINE	46	Female	Yes	Yes	No
057.002.0207	057	PLACEBO	29	Female	Yes	Yes	No
057.004.0410	057	PLACEBO	54	Female	Yes	Yes	No
057.004.0413	057	PLACEBO	43	Female	Yes	Yes	No
057.005.0508	057	PLACEBO	32	Male	Yes	Yes	No
057.005.0514	057	PAROXETINE	25	Male	Yes	Yes	No
057.005.0516	057	PAROXETINE	22	Male	Yes	Yes	No
057.006.0603	057	PLACEBO	41	Female	Yes	Yes	No
057.008.0802	057	PAROXETINE	48	Male	Yes	Yes	No
057.008.0803	057	PLACEBO	21	Male	Yes	Yes	No
057.011.1421	057	PAROXETINE	35	Male	Yes	Yes	No
057.012.1204	057	PAROXETINE	28	Female	Yes	Yes	No
057.012.1207	057	PAROXETINE	44	Male	Yes	Yes	No
057.012.1208	057	PAROXETINE	45	Female	Yes	Yes	No
057.012.1211	057	PLACEBO	46	Female	Yes	Yes	No
057.012.1212	057	PLACEBO	22	Female	Yes	Yes	No
057.012.1213	057	PLACEBO	31	Female	Yes	Yes	No
057.012.1215	057	PAROXETINE	32	Male	Yes	Yes	No
057.012.1217	057	PLACEBO	32	Male	Yes	Yes	No
057.012.1218	057	PLACEBO	28	Female	Yes	Yes	No
057.012.1221	057	PAROXETINE	29	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Depression

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
057.012.1223	057	PLACEBO	43	Female	Yes	Yes	No
057.012.1227	057	PLACEBO	53	Male	Yes	Yes	No
057.012.1229	057	PLACEBO	30	Female	Yes	Yes	No
057.012.1231	057	PAROXETINE	28	Male	Yes	Yes	No
057.012.1232	057	PLACEBO	39	Male	Yes	Yes	No
057.012.1234	057	PLACEBO	41	Male	Yes	Yes	No
057.012.1238	057	PAROXETINE	20	Male	Yes	Yes	No
057.012.1239	057	PLACEBO	45	Female	Yes	Yes	No
057.012.1240	057	PLACEBO	27	Male	Yes	Yes	No
057.012.1334	057	PAROXETINE	23	Female	Yes	Yes	No
057.012.1335	057	PLACEBO	41	Female	Yes	Yes	No
057.012.1336	057	PAROXETINE	44	Male	Yes	Yes	No
057.012.1339	057	PAROXETINE	32	Male	Yes	Yes	No
057.012.1340	057	PLACEBO	34	Male	Yes	Yes	No
057.012.1540	057	PAROXETINE	34	Female	Yes	Yes	No
057.013.1304	057	PLACEBO	32	Female	Yes	Yes	No
057.013.1310	057	PLACEBO	35	Male	Yes	Yes	Yes
057.013.1315	057	PLACEBO	30	Male	Yes	Yes	No
057.013.1318	057	PLACEBO	45	Male	Yes	Yes	No
057.013.1321	057	PLACEBO	45	Male	Yes	Yes	No
057.014.1401	057	PAROXETINE	29	Female	Yes	Yes	No
057.015.1504	057	PLACEBO	26	Female	Yes	Yes	No
057.015.1505	057	PLACEBO	26	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Depression

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
057.015.1511	057	PLACEBO	20	Female	Yes	Yes	No
057.017.1713	057	PAROXETINE	32	Female	Yes	Yes	No
057.017.1732	057	PAROXETINE	47	Female	Yes	Yes	No
057.017.1735	057	PAROXETINE	45	Female	Yes	Yes	No
057.018.1806	057	PAROXETINE	39	Female	Yes	Yes	No
057.018.1810	057	PAROXETINE	20	Male	Yes	Yes	No
057.019.0221	057	PAROXETINE	23	Female	Yes	Yes	No
057.019.0222	057	PAROXETINE	34	Female	Yes	Yes	No
057.019.0223	057	PLACEBO	25	Female	Yes	Yes	Yes
057.019.0226	057	PAROXETINE	22	Female	Yes	Yes	No
057.019.0227	057	PLACEBO	24	Male	Yes	Yes	No
057.019.0229	057	PAROXETINE	27	Female	Yes	Yes	No
09.01A.006	009	PAROXETINE	35	Male	No	No	Yes
09.01E.260	009	PAROXETINE	51	Female	No	Yes	No
1 12 037	279	PAROXETINE	20	Male	Yes	Yes	No
106.001.0001	106	PAROXETINE	48	Female	Yes	Yes	No
106.001.0002	106	PLACEBO	38	Female	Yes	Yes	No
106.001.0003	106	PAROXETINE	29	Female	No	No	Yes
106.001.0006	106	PLACEBO	23	Female	Yes	Yes	No
106.001.0013	106	PLACEBO	31	Female	Yes	Yes	No
106.001.0015	106	PLACEBO	36	Female	Yes	Yes	No
106.001.0018	106	PLACEBO	25	Female	Yes	Yes	No
106.001.0020	106	PAROXETINE	37	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Depression

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
106.001.0024	106	PAROXETINE	24	Male	Yes	Yes	No
106.001.0025	106	PAROXETINE	24	Female	Yes	Yes	No
106.001.0029	106	PAROXETINE	23	Male	Yes	Yes	No
106.001.0030	106	PAROXETINE	21	Female	Yes	Yes	No
115.003.0062	115	PAROXETINE	29	Female	No	Yes	No
128.001.0759	128	PAROXETINE	30	Male	No	Yes	No
251.002.0285	251	PAROXETINE	30	Male	No	Yes	No
448.010.00044	448	PAROXETINE	25	Female	No	Yes	No
448.019.00391	448	PAROXETINE	27	Female	No	Yes	No
449.021.00788	449	PAROXETINE	18	Female	No	Yes	No
625.500.02062	625	PAROXETINE	49	Male	Yes	Yes	No
785.720.00695	785	PAROXETINE	34	Female	No	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = MDD

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
02.001.009	002	PLACEBO	67	Female	Yes	Yes	No
02.004.089	002	PAROXETINE	19	Female	No	Yes	No
09.01A.006	009	PAROXETINE	35	Male	No	No	Yes
09.01E.260	009	PAROXETINE	51	Female	No	Yes	No
1 12 037	279	PAROXETINE	20	Male	Yes	Yes	No
115.003.0062	115	PAROXETINE	29	Female	No	Yes	No
128.001.0759	128	PAROXETINE	30	Male	No	Yes	No
251.002.0285	251	PAROXETINE	30	Male	No	Yes	No
448.010.00044	448	PAROXETINE	25	Female	No	Yes	No
448.019.00391	448	PAROXETINE	27	Female	No	Yes	No
449.021.00788	449	PAROXETINE	18	Female	No	Yes	No
625.500.02062	625	PAROXETINE	49	Male	Yes	Yes	No
785.720.00695	785	PAROXETINE	34	Female	No	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = IBD

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
057.002.0204	057	PAROXETINE	46	Female	Yes	Yes	No
057.002.0207	057	PLACEBO	29	Female	Yes	Yes	No
057.004.0410	057	PLACEBO	54	Female	Yes	Yes	No
057.004.0413	057	PLACEBO	43	Female	Yes	Yes	No
057.005.0508	057	PLACEBO	32	Male	Yes	Yes	No
057.005.0514	057	PAROXETINE	25	Male	Yes	Yes	No
057.005.0516	057	PAROXETINE	22	Male	Yes	Yes	No
057.006.0603	057	PLACEBO	41	Female	Yes	Yes	No
057.008.0802	057	PAROXETINE	48	Male	Yes	Yes	No
057.008.0803	057	PLACEBO	21	Male	Yes	Yes	No
057.011.1421	057	PAROXETINE	35	Male	Yes	Yes	No
057.012.1204	057	PAROXETINE	28	Female	Yes	Yes	No
057.012.1207	057	PAROXETINE	44	Male	Yes	Yes	No
057.012.1208	057	PAROXETINE	45	Female	Yes	Yes	No
057.012.1211	057	PLACEBO	46	Female	Yes	Yes	No
057.012.1212	057	PLACEBO	22	Female	Yes	Yes	No
057.012.1213	057	PLACEBO	31	Female	Yes	Yes	No
057.012.1215	057	PAROXETINE	32	Male	Yes	Yes	No
057.012.1217	057	PLACEBO	32	Male	Yes	Yes	No
057.012.1218	057	PLACEBO	28	Female	Yes	Yes	No
057.012.1221	057	PAROXETINE	29	Female	Yes	Yes	No
057.012.1223	057	PLACEBO	43	Female	Yes	Yes	No
057.012.1227	057	PLACEBO	53	Male	Yes	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = IBD

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
057.012.1229	057	PLACEBO	30	Female	Yes	Yes	No
057.012.1231	057	PAROXETINE	28	Male	Yes	Yes	No
057.012.1232	057	PLACEBO	39	Male	Yes	Yes	No
057.012.1234	057	PLACEBO	41	Male	Yes	Yes	No
057.012.1238	057	PAROXETINE	20	Male	Yes	Yes	No
057.012.1239	057	PLACEBO	45	Female	Yes	Yes	No
057.012.1240	057	PLACEBO	27	Male	Yes	Yes	No
057.012.1334	057	PAROXETINE	23	Female	Yes	Yes	No
057.012.1335	057	PLACEBO	41	Female	Yes	Yes	No
057.012.1336	057	PAROXETINE	44	Male	Yes	Yes	No
057.012.1339	057	PAROXETINE	32	Male	Yes	Yes	No
057.012.1340	057	PLACEBO	34	Male	Yes	Yes	No
057.012.1540	057	PAROXETINE	34	Female	Yes	Yes	No
057.013.1304	057	PLACEBO	32	Female	Yes	Yes	No
057.013.1310	057	PLACEBO	35	Male	Yes	Yes	Yes
057.013.1315	057	PLACEBO	30	Male	Yes	Yes	No
057.013.1318	057	PLACEBO	45	Male	Yes	Yes	No
057.013.1321	057	PLACEBO	45	Male	Yes	Yes	No
057.014.1401	057	PAROXETINE	29	Female	Yes	Yes	No
057.015.1504	057	PLACEBO	26	Female	Yes	Yes	No
057.015.1505	057	PLACEBO	26	Female	Yes	Yes	No
057.015.1511	057	PLACEBO	20	Female	Yes	Yes	No
057.017.1713	057	PAROXETINE	32	Female	Yes	Yes	No



Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = IBD

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
057.017.1732	057	PAROXETINE	47	Female	Yes	Yes	No
057.017.1735	057	PAROXETINE	45	Female	Yes	Yes	No
057.018.1806	057	PAROXETINE	39	Female	Yes	Yes	No
057.018.1810	057	PAROXETINE	20	Male	Yes	Yes	No
057.019.0221	057	PAROXETINE	23	Female	Yes	Yes	No
057.019.0222	057	PAROXETINE	34	Female	Yes	Yes	No
057.019.0223	057	PLACEBO	25	Female	Yes	Yes	Yes
057.019.0226	057	PAROXETINE	22	Female	Yes	Yes	No
057.019.0227	057	PLACEBO	24	Male	Yes	Yes	No
057.019.0229	057	PAROXETINE	27	Female	Yes	Yes	No
106.001.0001	106	PAROXETINE	48	Female	Yes	Yes	No
106.001.0002	106	PLACEBO	38	Female	Yes	Yes	No
106.001.0003	106	PAROXETINE	29	Female	No	No	Yes
106.001.0006	106	PLACEBO	23	Female	Yes	Yes	No
106.001.0013	106	PLACEBO	31	Female	Yes	Yes	No
106.001.0015	106	PLACEBO	36	Female	Yes	Yes	No
106.001.0018	106	PLACEBO	25	Female	Yes	Yes	No
106.001.0020	106	PAROXETINE	37	Female	Yes	Yes	No
106.001.0024	106	PAROXETINE	24	Male	Yes	Yes	No
106.001.0025	106	PAROXETINE	24	Female	Yes	Yes	No
106.001.0029	106	PAROXETINE	23	Male	Yes	Yes	No
106.001.0030	106	PAROXETINE	21	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Non-Depression

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
118.003.0155	118	PAROXETINE	22	Female	No	Yes	No
120.011.0065	120	PAROXETINE	20	Female	No	Yes	No
136.067.0403	136	PAROXETINE	51	Female	No	Yes	Yes
136.067.0436	136	PLACEBO	53	Female	No	Yes	No
187.011.0531	187	PLACEBO	35	Male	No	Yes	No
187.035.0510	187	PLACEBO	37	Male	No	Yes	No
502.003.05511	502	PAROXETINE	20	Male	Missing	Yes	No
502.037.05146	502	PAROXETINE	23	Male	Missing	Yes	No
502.045.05077	502	PLACEBO	34	Male	Missing	Yes	No
627.603.01028	627	PAROXETINE	27	Male	No	Yes	No
660.23502	660	PAROXETINE	16	Female	Missing	Yes	No

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anal\_alladsui\_gsk\_2005\_list\_pids.sas 16MAR2006:16:48 kk45592

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = Panic

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
120.011.0065	120	PAROXETINE	20	Female	No	Yes	No
187.011.0531	187	PLACEBO	35	Male	No	Yes	No
187.035.0510	187	PLACEBO	37	Male	No	Yes	No

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anal\_alladsui\_gsk\_2005\_list\_pids.sas 16MAR2006:16:48 kk45592

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = OCD

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
118.003.0155	118	PAROXETINE	22	Female	No	Yes	No
136.067.0403	136	PAROXETINE	51	Female	No	Yes	Yes
136.067.0436	136	PLACEBO	53	Female	No	Yes	No
660.23502	660	PAROXETINE	16	Female	Missing	Yes	No

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anal\_alladsui\_gsk\_2005\_list\_pids.sas 16MAR2006:16:48 kk45592

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = SAD

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
502.003.05511	502	PAROXETINE	20	Male	Missing	Yes	No
502.037.05146	502	PAROXETINE	23	Male	Missing	Yes	No
502.045.05077	502	PLACEBO	34	Male	Missing	Yes	No

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anal\_alladsui\_gsk\_2005\_list\_pids.sas 16MAR2006:16:48 kk45592

Paroxetine Adult Suicidality Analysis

Table 2.11

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = PTSD

Subject ID	Study Number	Randomized Treatment	Age (years)	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
627.603.01028	627	PAROXETINE	27	Male	No	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Indications  
 Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
16	660.23502	660	Female	Missing	Yes	No
18	449.021.00788	449	Female	No	Yes	No
19	02.004.089	002	Female	No	Yes	No
20	057.012.1238	057	Male	Yes	Yes	No
	057.018.1810	057	Male	Yes	Yes	No
	120.011.0065	120	Female	No	Yes	No
	1 12 037	279	Male	Yes	Yes	No
	502.003.05511	502	Male	Missing	Yes	No
21	106.001.0030	106	Female	Yes	Yes	No
22	057.005.0516	057	Male	Yes	Yes	No
	057.019.0226	057	Female	Yes	Yes	No
	118.003.0155	118	Female	No	Yes	No
23	057.012.1334	057	Female	Yes	Yes	No
	057.019.0221	057	Female	Yes	Yes	No
	106.001.0029	106	Male	Yes	Yes	No
	502.037.05146	502	Male	Missing	Yes	No
24	106.001.0024	106	Male	Yes	Yes	No
	106.001.0025	106	Female	Yes	Yes	No
25	057.005.0514	057	Male	Yes	Yes	No
	448.010.00044	448	Female	No	Yes	No
27	057.019.0229	057	Female	Yes	Yes	No
	448.019.00391	448	Female	No	Yes	No
	627.603.01028	627	Male	No	Yes	No
28	057.012.1204	057	Female	Yes	Yes	No
	057.012.1231	057	Male	Yes	Yes	No
29	057.012.1221	057	Female	Yes	Yes	No
	057.014.1401	057	Female	Yes	Yes	No
	106.001.0003	106	Female	No	No	Yes
	115.003.0062	115	Female	No	Yes	No
30	128.001.0759	128	Male	No	Yes	No
	251.002.0285	251	Male	No	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Indications  
 Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
32	057.012.1215	057	Male	Yes	Yes	No
	057.012.1339	057	Male	Yes	Yes	No
	057.017.1713	057	Female	Yes	Yes	No
34	057.012.1540	057	Female	Yes	Yes	No
	057.019.0222	057	Female	Yes	Yes	No
	785.720.00695	785	Female	No	Yes	No
35	09.01A.006	009	Male	No	No	Yes
	057.011.1421	057	Male	Yes	Yes	No
37	106.001.0020	106	Female	Yes	Yes	No
39	057.018.1806	057	Female	Yes	Yes	No
44	057.012.1207	057	Male	Yes	Yes	No
	057.012.1336	057	Male	Yes	Yes	No
45	057.012.1208	057	Female	Yes	Yes	No
	057.017.1735	057	Female	Yes	Yes	No
46	057.002.0204	057	Female	Yes	Yes	No
47	057.017.1732	057	Female	Yes	Yes	No
48	057.008.0802	057	Male	Yes	Yes	No
	106.001.0001	106	Female	Yes	Yes	No
49	625.500.02062	625	Male	Yes	Yes	No
51	09.01E.260	009	Female	No	Yes	No
	136.067.0403	136	Female	No	Yes	Yes



Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Indications  
 Treatment group = PLACEBO

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
20	057.015.1511	057	Female	Yes	Yes	No
21	057.008.0803	057	Male	Yes	Yes	No
22	057.012.1212	057	Female	Yes	Yes	No
23	106.001.0006	106	Female	Yes	Yes	No
24	057.019.0227	057	Male	Yes	Yes	No
25	057.019.0223	057	Female	Yes	Yes	Yes
	106.001.0018	106	Female	Yes	Yes	No
26	057.015.1504	057	Female	Yes	Yes	No
	057.015.1505	057	Female	Yes	Yes	No
27	057.012.1240	057	Male	Yes	Yes	No
28	057.012.1218	057	Female	Yes	Yes	No
29	057.002.0207	057	Female	Yes	Yes	No
30	057.012.1229	057	Female	Yes	Yes	No
	057.013.1315	057	Male	Yes	Yes	No
31	057.012.1213	057	Female	Yes	Yes	No
	106.001.0013	106	Female	Yes	Yes	No
32	057.005.0508	057	Male	Yes	Yes	No
	057.012.1217	057	Male	Yes	Yes	No
	057.013.1304	057	Female	Yes	Yes	No
34	057.012.1340	057	Male	Yes	Yes	No
	502.045.05077	502	Male	Missing	Yes	No
35	057.013.1310	057	Male	Yes	Yes	Yes
	187.011.0531	187	Male	No	Yes	No
36	106.001.0015	106	Female	Yes	Yes	No
37	187.035.0510	187	Male	No	Yes	No
38	106.001.0002	106	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis  
 Table 2.11a  
 Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Indications  
 Treatment group = PLACEBO

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
39	057.012.1232	057	Male	Yes	Yes	No
41	057.006.0603	057	Female	Yes	Yes	No
	057.012.1234	057	Male	Yes	Yes	No
	057.012.1335	057	Female	Yes	Yes	No
43	057.004.0413	057	Female	Yes	Yes	No
	057.012.1223	057	Female	Yes	Yes	No
45	057.012.1239	057	Female	Yes	Yes	No
	057.013.1318	057	Male	Yes	Yes	No
	057.013.1321	057	Male	Yes	Yes	No
46	057.012.1211	057	Female	Yes	Yes	No
53	057.012.1227	057	Male	Yes	Yes	No
	136.067.0436	136	Female	No	Yes	No
54	057.004.0410	057	Female	Yes	Yes	No
67	02.001.009	002	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Depression  
 Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
18	449.021.00788	449	Female	No	Yes	No
19	02.004.089	002	Female	No	Yes	No
20	057.012.1238	057	Male	Yes	Yes	No
	057.018.1810	057	Male	Yes	Yes	No
	1 12 037	279	Male	Yes	Yes	No
21	106.001.0030	106	Female	Yes	Yes	No
22	057.005.0516	057	Male	Yes	Yes	No
	057.019.0226	057	Female	Yes	Yes	No
23	057.012.1334	057	Female	Yes	Yes	No
	057.019.0221	057	Female	Yes	Yes	No
	106.001.0029	106	Male	Yes	Yes	No
24	106.001.0024	106	Male	Yes	Yes	No
	106.001.0025	106	Female	Yes	Yes	No
25	057.005.0514	057	Male	Yes	Yes	No
	448.010.00044	448	Female	No	Yes	No
27	057.019.0229	057	Female	Yes	Yes	No
	448.019.00391	448	Female	No	Yes	No
28	057.012.1204	057	Female	Yes	Yes	No
	057.012.1231	057	Male	Yes	Yes	No
29	057.012.1221	057	Female	Yes	Yes	No
	057.014.1401	057	Female	Yes	Yes	No
	106.001.0003	106	Female	No	No	Yes
	115.003.0062	115	Female	No	Yes	No
30	128.001.0759	128	Male	No	Yes	No
	251.002.0285	251	Male	No	Yes	No
32	057.012.1215	057	Male	Yes	Yes	No
	057.012.1339	057	Male	Yes	Yes	No
	057.017.1713	057	Female	Yes	Yes	No
34	057.012.1540	057	Female	Yes	Yes	No
	057.019.0222	057	Female	Yes	Yes	No
	785.720.00695	785	Female	No	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Depression  
 Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
35	09.01A.006	009	Male	No	No	Yes
	057.011.1421	057	Male	Yes	Yes	No
37	106.001.0020	106	Female	Yes	Yes	No
39	057.018.1806	057	Female	Yes	Yes	No
44	057.012.1207	057	Male	Yes	Yes	No
	057.012.1336	057	Male	Yes	Yes	No
45	057.012.1208	057	Female	Yes	Yes	No
	057.017.1735	057	Female	Yes	Yes	No
46	057.002.0204	057	Female	Yes	Yes	No
47	057.017.1732	057	Female	Yes	Yes	No
48	057.008.0802	057	Male	Yes	Yes	No
	106.001.0001	106	Female	Yes	Yes	No
49	625.500.02062	625	Male	Yes	Yes	No
51	09.01E.260	009	Female	No	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Depression  
 Treatment group = PLACEBO

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
20	057.015.1511	057	Female	Yes	Yes	No
21	057.008.0803	057	Male	Yes	Yes	No
22	057.012.1212	057	Female	Yes	Yes	No
23	106.001.0006	106	Female	Yes	Yes	No
24	057.019.0227	057	Male	Yes	Yes	No
25	057.019.0223	057	Female	Yes	Yes	Yes
	106.001.0018	106	Female	Yes	Yes	No
26	057.015.1504	057	Female	Yes	Yes	No
	057.015.1505	057	Female	Yes	Yes	No
27	057.012.1240	057	Male	Yes	Yes	No
28	057.012.1218	057	Female	Yes	Yes	No
29	057.002.0207	057	Female	Yes	Yes	No
30	057.012.1229	057	Female	Yes	Yes	No
	057.013.1315	057	Male	Yes	Yes	No
31	057.012.1213	057	Female	Yes	Yes	No
	106.001.0013	106	Female	Yes	Yes	No
32	057.005.0508	057	Male	Yes	Yes	No
	057.012.1217	057	Male	Yes	Yes	No
	057.013.1304	057	Female	Yes	Yes	No
34	057.012.1340	057	Male	Yes	Yes	No
35	057.013.1310	057	Male	Yes	Yes	Yes
36	106.001.0015	106	Female	Yes	Yes	No
38	106.001.0002	106	Female	Yes	Yes	No
39	057.012.1232	057	Male	Yes	Yes	No
41	057.006.0603	057	Female	Yes	Yes	No
	057.012.1234	057	Male	Yes	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Depression  
 Treatment group = PLACEBO

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
41	057.012.1335	057	Female	Yes	Yes	No
43	057.004.0413	057	Female	Yes	Yes	No
	057.012.1223	057	Female	Yes	Yes	No
45	057.012.1239	057	Female	Yes	Yes	No
	057.013.1318	057	Male	Yes	Yes	No
	057.013.1321	057	Male	Yes	Yes	No
46	057.012.1211	057	Female	Yes	Yes	No
53	057.012.1227	057	Male	Yes	Yes	No
54	057.004.0410	057	Female	Yes	Yes	No
67	02.001.009	002	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis  
 Table 2.11a  
 Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = MDD  
 Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
18	449.021.00788	449	Female	No	Yes	No
19	02.004.089	002	Female	No	Yes	No
20	1 12 037	279	Male	Yes	Yes	No
25	448.010.00044	448	Female	No	Yes	No
27	448.019.00391	448	Female	No	Yes	No
29	115.003.0062	115	Female	No	Yes	No
30	128.001.0759	128	Male	No	Yes	No
	251.002.0285	251	Male	No	Yes	No
34	785.720.00695	785	Female	No	Yes	No
35	09.01A.006	009	Male	No	No	Yes
49	625.500.02062	625	Male	Yes	Yes	No
51	09.01E.260	009	Female	No	Yes	No

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anal\_alladsui\_gsk\_2005\_list\_pids\_211a.sas 22MAR2006:14:49 exp45559

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = MDD  
Treatment group = PLACEBO

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
67	02.001.009	002	Female	Yes	Yes	No



Paroxetine Adult Suicidality Analysis  
 Table 2.11a  
 Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = IBD  
 Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
20	057.012.1238	057	Male	Yes	Yes	No
	057.018.1810	057	Male	Yes	Yes	No
21	106.001.0030	106	Female	Yes	Yes	No
22	057.005.0516	057	Male	Yes	Yes	No
	057.019.0226	057	Female	Yes	Yes	No
23	057.012.1334	057	Female	Yes	Yes	No
	057.019.0221	057	Female	Yes	Yes	No
	106.001.0029	106	Male	Yes	Yes	No
24	106.001.0024	106	Male	Yes	Yes	No
	106.001.0025	106	Female	Yes	Yes	No
25	057.005.0514	057	Male	Yes	Yes	No
27	057.019.0229	057	Female	Yes	Yes	No
28	057.012.1204	057	Female	Yes	Yes	No
	057.012.1231	057	Male	Yes	Yes	No
29	057.012.1221	057	Female	Yes	Yes	No
	057.014.1401	057	Female	Yes	Yes	No
	106.001.0003	106	Female	No	No	Yes
32	057.012.1215	057	Male	Yes	Yes	No
	057.012.1339	057	Male	Yes	Yes	No
	057.017.1713	057	Female	Yes	Yes	No
34	057.012.1540	057	Female	Yes	Yes	No
	057.019.0222	057	Female	Yes	Yes	No
35	057.011.1421	057	Male	Yes	Yes	No
37	106.001.0020	106	Female	Yes	Yes	No
39	057.018.1806	057	Female	Yes	Yes	No
44	057.012.1207	057	Male	Yes	Yes	No
	057.012.1336	057	Male	Yes	Yes	No
45	057.012.1208	057	Female	Yes	Yes	No
	057.017.1735	057	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = IBD  
Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
46	057.002.0204	057	Female	Yes	Yes	No
47	057.017.1732	057	Female	Yes	Yes	No
48	057.008.0802	057	Male	Yes	Yes	No
	106.001.0001	106	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis  
 Table 2.11a  
 Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = IBD  
 Treatment group = PLACEBO

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
20	057.015.1511	057	Female	Yes	Yes	No
21	057.008.0803	057	Male	Yes	Yes	No
22	057.012.1212	057	Female	Yes	Yes	No
23	106.001.0006	106	Female	Yes	Yes	No
24	057.019.0227	057	Male	Yes	Yes	No
25	057.019.0223	057	Female	Yes	Yes	Yes
	106.001.0018	106	Female	Yes	Yes	No
26	057.015.1504	057	Female	Yes	Yes	No
	057.015.1505	057	Female	Yes	Yes	No
27	057.012.1240	057	Male	Yes	Yes	No
28	057.012.1218	057	Female	Yes	Yes	No
29	057.002.0207	057	Female	Yes	Yes	No
30	057.012.1229	057	Female	Yes	Yes	No
	057.013.1315	057	Male	Yes	Yes	No
31	057.012.1213	057	Female	Yes	Yes	No
	106.001.0013	106	Female	Yes	Yes	No
32	057.005.0508	057	Male	Yes	Yes	No
	057.012.1217	057	Male	Yes	Yes	No
	057.013.1304	057	Female	Yes	Yes	No
34	057.012.1340	057	Male	Yes	Yes	No
35	057.013.1310	057	Male	Yes	Yes	Yes
36	106.001.0015	106	Female	Yes	Yes	No
38	106.001.0002	106	Female	Yes	Yes	No
39	057.012.1232	057	Male	Yes	Yes	No
41	057.006.0603	057	Female	Yes	Yes	No
	057.012.1234	057	Male	Yes	Yes	No

Paroxetine Adult Suicidality Analysis  
 Table 2.11a  
 Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = IBD  
 Treatment group = PLACEBO

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
41	057.012.1335	057	Female	Yes	Yes	No
43	057.004.0413	057	Female	Yes	Yes	No
	057.012.1223	057	Female	Yes	Yes	No
45	057.012.1239	057	Female	Yes	Yes	No
	057.013.1318	057	Male	Yes	Yes	No
	057.013.1321	057	Male	Yes	Yes	No
46	057.012.1211	057	Female	Yes	Yes	No
53	057.012.1227	057	Male	Yes	Yes	No
54	057.004.0410	057	Female	Yes	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
 Indication = All Non-Depression  
 Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
16	660.23502	660	Female	Missing	Yes	No
20	120.011.0065	120	Female	No	Yes	No
	502.003.05511	502	Male	Missing	Yes	No
22	118.003.0155	118	Female	No	Yes	No
23	502.037.05146	502	Male	Missing	Yes	No
27	627.603.01028	627	Male	No	Yes	No
51	136.067.0403	136	Female	No	Yes	Yes

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = All Non-Depression  
Treatment group = PLACEBO

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
34	502.045.05077	502	Male	Missing	Yes	No
35	187.011.0531	187	Male	No	Yes	No
37	187.035.0510	187	Male	No	Yes	No
53	136.067.0436	136	Female	No	Yes	No

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anal\_alladsui\_gsk\_2005\_list\_pids\_211a.sas 22MAR2006:14:49 axp45559

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = Panic  
Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
20	120.011.0065	120	Female	No	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = Panic  
Treatment group = PLACEBO

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
35	187.011.0531	187	Male	No	Yes	No
37	187.035.0510	187	Male	No	Yes	No



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anal\_alladsui\_gsk\_2005\_list\_pids\_211a.sas 22MAR2006:14:49 axp45559

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = OCD  
Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
16	660.23502	660	Female	Missing	Yes	No
22	118.003.0155	118	Female	No	Yes	No
51	136.067.0403	136	Female	No	Yes	Yes

GSK Confidential. /bioenv/dart10/sbbrl29060\_cda/legal2/list/anal\_alladsui\_gsk\_2005\_list\_pids\_211a.lst  
anal\_alladsui\_gsk\_2005\_list\_pids\_211a.sas 22MAR2006:14:49 exp45559

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = OCD  
Treatment group = PLACEBO

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
53	136.067.0436	136	Female	No	Yes	No

GSK Confidential. /bioenv/dart10/sbbrl29060\_cda/legal2/list/anal\_alladsui\_gsk\_2005\_list\_pids\_211a.lst  
anal\_alladsui\_gsk\_2005\_list\_pids\_211a.sas 22MAR2006:14:49 axp45559

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = SAD  
Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
20	502.003.05511	502	Male	Missing	Yes	No
23	502.037.05146	502	Male	Missing	Yes	No

GSK Confidential. /bioenv/dart10/sbbr129060\_cda/legal2/list/anal\_alladsui\_gsk\_2005\_list\_pids\_211a.lst  
anal\_alladsui\_gsk\_2005\_list\_pids\_211a.sas 22MAR2006:14:49 axp45559

Paroxetine Adult Suicidality Analysis  
Table 2.11a  
Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = SAD  
Treatment group = PLACEBO

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
34	502.045.05077	502	Male	Missing	Yes	No

GSK Confidential. /bioenv/dart10/sbbrl29060\_cda/legal2/list/anal\_alladsui\_gsk\_2005\_list\_pids\_211a.lst  
anal\_alladsui\_gsk\_2005\_list\_pids\_211a.sas 22MAR2006:14:49 axp45559

Paroxetine Adult Suicidality Analysis

Table 2.11a

Subjects with Either Definitive Suicidal Behaviour or Rating Scale Emergent Suicidal Behaviour  
Indication = PTSD  
Treatment group = PAROXETINE

Age (years)	Subject ID	Study Number	Gender	Baseline Suicidal Ideation	Definitive Suicidal Behaviour	Rating Scale Emergent Suicidal Behaviour
27	627.603.01028	627	Male	No	Yes	No

Paroxetine Adult Suicidality Analysis

Table 2.12

Number and Percent of Patients by Indication, Treatment Group and Age Group

Indication	Age Group		Paroxetine		Placebo	
All Non-Depression	<18		10/ 5238	( 0.2%)	6/ 3693	( 0.2%)
	18-24		504/ 5238	( 9.6%)	393/ 3693	( 10.6%)
	18-30		1328/ 5238	( 25.4%)	984/ 3693	( 26.6%)
	31-40		1779/ 5238	( 34.0%)	1249/ 3693	( 33.8%)
	41-50		1360/ 5238	( 26.0%)	918/ 3693	( 24.9%)
	51-60		559/ 5238	( 10.7%)	371/ 3693	( 10.0%)
	>=61		202/ 5238	( 3.9%)	165/ 3693	( 4.5%)
IBD	<18		0/149	( 0.0%)	0/154	( 0.0%)
	18-24		35/ 149	( 23.5%)	38/ 154	( 24.7%)
	18-30		67/ 149	( 45.0%)	71/ 154	( 46.1%)
	31-40		45/ 149	( 30.2%)	38/ 154	( 24.7%)
	41-50		28/ 149	( 18.8%)	29/ 154	( 18.8%)
	51-60		6/ 149	( 4.0%)	12/ 154	( 7.8%)
	>=61		3/ 149	( 2.0%)	4/ 154	( 2.6%)
MDD	<18		0/3455	( 0.0%)	0/1978	( 0.0%)
	18-24		230/ 3455	( 6.7%)	104/ 1978	( 5.3%)
	18-30		612/ 3455	( 17.7%)	339/ 1978	( 17.1%)
	31-40		846/ 3455	( 24.5%)	472/ 1978	( 23.9%)
	41-50		727/ 3455	( 21.0%)	425/ 1978	( 21.5%)
	51-60		506/ 3455	( 14.6%)	300/ 1978	( 15.2%)
	>=61		764/ 3455	( 22.1%)	442/ 1978	( 22.3%)

Paroxetine Adult Suicidality Analysis

Table 2.13

Individual study contribution to the overall Mantel-Haenszel estimate for Definitive Suicidal Behaviour  
 and Ideation (table 2.01)  
 All Studies

Trial	Paroxetine	Placebo	Study weight contribution to MH estimate (%)*	Contribution to MH estimate
001	0/ 25	0/ 25	0.0	No contribution
002	1/ 170	2/ 171	2.7	No zeros
003	0.5/ 242	2.5/ 245	3.4	CC used
009	5.5/ 422	0.5/ 54	1.2	CC used
057	28/ 131	31/ 136	32.4	No zeros
106	6/ 18	5/ 18	4.5	No zeros
108	0/ 60	0/ 60	0.0	No contribution
115	5/ 283	3/ 117	5.6	No zeros
116	2/ 259	1/ 89	2.0	No zeros
118	1/ 82	1/ 77	1.4	No zeros
120	2.5/ 210	0.5/ 70	1.0	CC used
128	8/ 357	2/ 140	3.8	No zeros
136	1/ 201	2/ 99	3.6	No zeros
187	0.5/ 124	2.5/ 124	3.4	CC used
201	0/ 57	0/ 60	0.0	No contribution
223	0.5/ 77	1.5/ 72	2.1	CC used
251	2.5/ 126	0.5/ 130	0.7	CC used
274	0/ 22	0/ 23	0.0	No contribution
276	0/ 20	0/ 21	0.0	No contribution
279	2/ 21	1/ 10	1.7	No zeros
327	1.5/ 82	0.5/ 86	0.6	CC used
352	0/ 35	0/ 43	0.0	No contribution
382	0.5/ 95	1.5/ 94	2.0	CC used
384	0/ 85	0/ 83	0.0	No contribution
400	0/ 31	0/ 17	0.0	No contribution
410	0/ 87	0/ 40	0.0	No contribution
414	0/ 61	0/ 56	0.0	No contribution
427	0/ 29	0/ 9	0.0	No contribution
433	0/ 26	0/ 26	0.0	No contribution
442	0/ 41	0/ 48	0.0	No contribution
448	3.5/ 213	0.5/ 104	0.9	CC used
449	1.5/ 224	0.5/ 111	0.9	CC used
454	1.5/ 290	0.5/ 96	1.0	CC used
487	2.5/ 215	0.5/ 110	0.9	CC used
494	0/ 141	0/ 148	0.0	No contribution
495	1.5/ 163	0.5/ 166	0.7	CC used
497	0/ 149	0/ 144	0.0	No contribution
502	2/ 139	1/ 151	1.3	No zeros
625	1.5/ 113	0.5/ 118	0.7	CC used
627	1/ 160	3/ 162	4.0	No zeros
637	1.5/ 188	0.5/ 186	0.7	CC used
641	0/ 386	0/ 180	0.0	No contribution
642	1/ 164	1/ 166	1.3	No zeros

\*Study weight calculated as:  
 (no. of pats. without events who took paroxetine/no. of pats with events who took placebo)/total no. of pats in trial

Paroxetine Adult Suicidality Analysis

Table 2.13

Individual study contribution to the overall Mantel-Haenszel estimate for Definitive Suicidal Behaviour  
 and Ideation (table 2.01)  
 All Studies

Trial	Paroxetine	Placebo	Study weight contribution to MH estimate (%)*	Contribution to MH estimate
648	1.5/ 164	0.5/ 161	0.7	CC used
651	1/ 375	3/ 188	5.4	No zeros
658	1.5/ 61	0.5/ 60	0.7	CC used
660	1.5/ 96	0.5/ 96	0.7	CC used
661	0.5/ 236	1.5/ 121	2.7	CC used
677	0/ 212	0/ 109	0.0	No contribution
688	0/ 242	0/ 119	0.0	No contribution
689	0/ 246	0/ 125	0.0	No contribution
785	1.5/ 198	0.5/ 106	0.9	CC used
790	0/ 186	0/ 184	0.0	No contribution
791	0.5/ 168	1.5/ 167	2.0	CC used
810	0.5/ 307	1.5/ 149	2.7	CC used
874	0/ 341	0/ 180	0.0	No contribution
NKD20006	0/ 124	0/ 125	0.0	No contribution

\*Study weight calculated as:  
 (no. of pats. without events who took paroxetine/no. of pats with events who took placebo)/total no. of pats in trial



Paroxetine Adult Suicidality Analysis

Table 2.13

Individual study contribution to the overall Mantel-Haenszel estimate for Definitive Suicidal Behaviour  
 and Ideation (table 2.01)  
 Studies with continuity correction

Trial	Paroxetine	Placebo	Study weight contribution to MH estimate (%)	Contribution to MH estimate
003	0.5/ 242	2.5/ 245	3.4	CC used
009	5.5/ 422	0.5/ 54	1.2	CC used
120	2.5/ 210	0.5/ 70	1.0	CC used
187	0.5/ 124	2.5/ 124	3.4	CC used
223	0.5/ 77	1.5/ 72	2.1	CC used
251	2.5/ 126	0.5/ 130	0.7	CC used
327	1.5/ 82	0.5/ 86	0.6	CC used
382	0.5/ 95	1.5/ 94	2.0	CC used
448	3.5/ 213	0.5/ 104	0.9	CC used
449	1.5/ 224	0.5/ 111	0.9	CC used
454	1.5/ 290	0.5/ 96	1.0	CC used
487	2.5/ 215	0.5/ 110	0.9	CC used
495	1.5/ 163	0.5/ 166	0.7	CC used
625	1.5/ 113	0.5/ 118	0.7	CC used
637	1.5/ 188	0.5/ 186	0.7	CC used
648	1.5/ 164	0.5/ 161	0.7	CC used
658	1.5/ 61	0.5/ 60	0.7	CC used
660	1.5/ 96	0.5/ 96	0.7	CC used
661	0.5/ 236	1.5/ 121	2.7	CC used
785	1.5/ 198	0.5/ 106	0.9	CC used
791	0.5/ 168	1.5/ 167	2.0	CC used
810	0.5/ 307	1.5/ 149	2.7	CC used

\*Study weight calculated as:  
 (no. of pats. without events who took paroxetine/no. of pats with events who took placebo)/total no. of pats in trial

Paroxetine Adult Suicidality Analysis  
Table 3.01  
Change from Baseline on HAMD Total Score to LOCF Endpoint by Treatment Group  
Indication = All Depression

Population	Category	N	Paroxetine LS mean	Placebo LS mean	Estimated Treatment Effect	95% CI	P-value
Overall		4837	-10.8	-8.3	-2.6	( -3.0, -2.1)	<0.001
Baseline Suicidal Ideation	Missing	2	.	.	.		
	Absent	4302	-10.8	-8.3	-2.5	( -3.0, -2.0)	
	Present	533	-11.1	-7.9	-3.2	( -4.8, -1.6)	
Age Group	18-24	294	-10.9	-9.5	-1.4	( -3.2, 0.5)	
	25-64	3881	-10.8	-8.1	-2.7	( -3.2, -2.2)	
	>=65	662	-11.3	-8.7	-2.6	( -3.8, -1.4)	
Gender	Female	2869	-11.4	-8.3	-3.1	( -3.7, -2.5)	
	Male	1968	-10.0	-8.2	-1.8	( -2.6, -1.1)	

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 3.01  
 Change from Baseline on HAMD Total Score to LOCF Endpoint by Treatment Group  
 Indication = MDD

Population	Category	N	Paroxetine LS mean	Placebo LS mean	Estimated Treatment Effect	95% CI	P-value
Overall		4609	-10.9	-8.4	-2.5	( -3.0, -2.1)	<0.001
Baseline Suicidal Ideation	Missing	2	.	.	.		
	Absent	4090	-10.9	-8.5	-2.5	( -2.9, -2.0)	
	Present	517	-11.1	-8.0	-3.1	( -4.7, -1.5)	
Age Group	18-24	282	-10.8	-9.9	-0.9	( -2.8, 0.9)	
	25-64	3671	-10.9	-8.2	-2.7	( -3.2, -2.1)	
	>=65	656	-11.3	-8.8	-2.5	( -3.7, -1.4)	
Gender	Female	2745	-11.5	-8.5	-3.0	( -3.6, -2.4)	
	Male	1864	-10.1	-8.3	-1.8	( -2.6, -1.1)	

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
Table 3.01  
Change from Baseline on HAMD Total Score to LOCF Endpoint by Treatment Group  
Indication = Dysthymia

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		152	-7.9	-4.6	-3.2	( -5.2, -1.2)	0.002
Baseline Suicidal Ideation	Absent	147	-7.9	-4.9	-3.0	( -5.0, -1.0)	
	Present	5	-7.4	1.6	-9.0	(-47.4, 29.3)	
Age Group	18-24	8	-12.2	-0.3	-12.0	(-26.9, 2.9)	
	25-64	140	-7.6	-4.8	-2.8	( -4.9, -0.7)	
	>=65	4	-7.0	-3.7	-3.3	(-33.3, 26.6)	
Gender	Female	83	-10.0	-4.0	-6.1	( -8.8, -3.4)	
	Male	69	-6.2	-6.0	-0.2	( -3.2, 2.8)	

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
 Table 3.01  
 Change from Baseline on HAMD Total Score to LOCF Endpoint by Treatment Group  
 Indication = Bipolar

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		76	-10.6	-8.1	-2.5	( -5.9, 0.9)	0.152
Baseline Suicidal Ideation	Absent	65	-10.1	-7.8	-2.4	( -6.1, 1.4)	
	Present	11	-12.1	-10.7	-1.4	(-13.2, 10.3)	
Age Group	18-24	4	-21.8	-7.1	-14.7	(-27.3, -2.2)	
	25-64	70	-10.2	-8.2	-2.0	( -5.6, 1.6)	
	>=65	2	.	.	.		
Gender	Female	41	-9.2	-7.9	-1.3	( -6.4, 3.8)	
	Male	35	-12.2	-8.2	-4.0	( -8.8, 0.8)	

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Paroxetine Adult Suicidality Analysis  
Table 3.02  
Change from Baseline on MADRS Total Score to LOCF Endpoint by Treatment Group  
Indication = All Depression

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		1995	-11.0	-7.8	-3.3	( -4.2, -2.3)	<0.001
Baseline Suicidal Ideation	Absent	1364	-11.7	-7.9	-3.8	( -4.8, -2.7)	
	Present	631	-9.6	-7.3	-2.2	( -4.1, -0.4)	
Age Group	18-24	160	-7.5	-7.1	-0.4	( -3.9, 3.2)	
	25-64	1657	-11.3	-7.6	-3.7	( -4.7, -2.7)	
	>=65	178	-11.9	-9.8	-2.1	( -4.9, 0.8)	
Gender	Female	1058	-11.1	-7.5	-3.7	( -5.0, -2.4)	
	Male	937	-10.9	-8.1	-2.8	( -4.1, -1.5)	

Paroxetine Adult Suicidality Analysis  
Table 3.02  
Change from Baseline on MADRS Total Score to LOCF Endpoint by Treatment Group  
Indication = MDD

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		1759	-12.2	-8.5	-3.7	( -4.7, -2.7)	<0.001
Baseline Suicidal Ideation	Absent	1361	-11.8	-8.0	-3.8	( -4.9, -2.7)	
	Present	398	-13.7	-10.4	-3.2	( -5.6, -0.8)	
Age Group	18-24	105	-11.9	-8.9	-3.1	( -7.7, 1.6)	
	25-64	1479	-12.2	-8.3	-3.9	( -5.0, -2.8)	
	>=65	175	-12.1	-9.8	-2.3	( -5.2, 0.5)	
Gender	Female	903	-12.7	-8.5	-4.3	( -5.7, -2.9)	
	Male	856	-11.6	-8.6	-3.0	( -4.4, -1.6)	

Paroxetine Adult Suicidality Analysis  
 Table 3.02  
 Change from Baseline on MADRS Total Score to LOCF Endpoint by Treatment Group  
 Indication = IBD

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		236	-2.6	-1.9	-0.7	( -3.4, 2.0)	0.594
Baseline Suicidal Ideation	Absent	3	-8.0	19.0	-27.0		
	Present	233	-2.8	-2.0	-0.8	( -3.6, 1.9)	
Age Group	18-24	55	1.5	-2.9	4.4	( -1.3, 10.1)	
	25-64	178	-3.8	-1.5	-2.3	( -5.3, 0.7)	
	>=65	3	51.7	-128	180.0		
Gender	Female	155	-2.3	-1.5	-0.7	( -4.4, 2.9)	
	Male	81	-3.6	-2.3	-1.4	( -5.4, 2.6)	



Paroxetine Adult Suicidality Analysis  
Table 3.03  
Change from Baseline on HAMD Item 3 to LOCF Endpoint by Treatment Group  
Indication = All Depression

Population	Category	N	Paroxetine LS mean	Placebo LS mean	Estimated Treatment Effect	95% CI	P-value
Overall		4752	-0.6	-0.4	-0.2	( -0.2, -0.1)	<0.001
Baseline Suicidal Ideation	Absent	4219	-0.5	-0.4	-0.2	( -0.2, -0.1)	
	Present	533	-1.4	-1.0	-0.4	( -0.6, -0.2)	
Age Group	18-24	293	-0.7	-0.7	-0.0	( -0.2, 0.2)	
	25-64	3805	-0.6	-0.4	-0.2	( -0.2, -0.1)	
	>=65	654	-0.5	-0.4	-0.2	( -0.2, -0.1)	
Gender	Female	2792	-0.6	-0.5	-0.2	( -0.2, -0.1)	
	Male	1960	-0.6	-0.4	-0.2	( -0.2, -0.1)	

Note. Baseline HAMD Item 3 Scores were not available in study 442

Paroxetine Adult Suicidality Analysis  
 Table 3.03  
 Change from Baseline on HAMD Item 3 to LOCF Endpoint by Treatment Group  
 Indication = MDD

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		4524	-0.6	-0.5	-0.2	( -0.2, -0.1)	<0.001
Baseline Suicidal Ideation	Absent	4007	-0.5	-0.4	-0.2	( -0.2, -0.1)	
	Present	517	-1.4	-1.0	-0.4	( -0.6, -0.2)	
Age Group	18-24	281	-0.7	-0.7	0.0	( -0.1, 0.2)	
	25-64	3595	-0.6	-0.4	-0.2	( -0.2, -0.2)	
	>=65	648	-0.5	-0.4	-0.1	( -0.2, -0.1)	
Gender	Female	2668	-0.7	-0.5	-0.2	( -0.2, -0.1)	
	Male	1856	-0.6	-0.4	-0.2	( -0.3, -0.1)	

Note. Baseline HAMD Item 3 Scores were not available in study 442

Paroxetine Adult Suicidality Analysis  
 Table 3.03  
 Change from Baseline on HAMD Item 3 to LOCF Endpoint by Treatment Group  
 Indication = Dysthymia

Population	Category	N	Paroxetine		Placebo		Estimated Treatment		P-value
			LS mean	LS mean	LS mean	LS mean	Effect	95% CI	
Overall		152	-0.3	-0.2	-0.1	( -0.3, 0.0)		0.059	
Baseline Suicidal Ideation	Absent	147	-0.3	-0.2	-0.1	( -0.3, 0.0)			
	Present	5	0.3	-0.2	0.5	( -2.1, 3.1)			
Age Group	18-24	8	-0.6	0.4	-1.0	( -2.9, 0.9)			
	25-64	140	-0.3	-0.2	-0.1	( -0.3, 0.0)			
	>=65	4	.	.	.				
Gender	Female	83	-0.3	-0.2	-0.1	( -0.3, 0.1)			
	Male	69	-0.3	-0.2	-0.2	( -0.4, 0.1)			

Note. Baseline HAMD Item 3 Scores were not available in study 442

Paroxetine Adult Suicidality Analysis  
 Table 3.03  
 Change from Baseline on HAMD Item 3 to LOCF Endpoint by Treatment Group  
 Indication = Bipolar

Population	Category	N	Paroxetine		Placebo		Estimated Treatment		P-value
			LS mean	LS mean	LS mean	LS mean	Effect	95% CI	
Overall		76	-0.5	-0.4	-0.1	( -0.5, 0.3)		0.571	
Baseline Suicidal Ideation	Absent	65	-0.3	-0.3	-0.1	( -0.4, 0.3)			
	Present	11	-1.6	-1.1	-0.5	( -2.6, 1.6)			
Age Group	18-24	4	-3.0	0.0	-3.0				
	25-64	70	-0.5	-0.4	-0.0	( -0.5, 0.4)			
	>=65	2	-1.0	0.0	-1.0				
Gender	Female	41	-0.6	-0.5	-0.1	( -0.7, 0.5)			
	Male	35	-0.4	-0.3	-0.2	( -0.7, 0.3)			

Note. Baseline HAMD Item 3 Scores were not available in study 442

Paroxetine Adult Suicidality Analysis  
Table 3.04  
Change from Baseline on MADRS Item 10 to LOCF Endpoint by Treatment Group  
Indication = All Depression

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		1995	-0.9	-0.5	-0.3	( -0.4, -0.2)	<0.001
Baseline Suicidal Ideation	Absent	1364	-0.6	-0.3	-0.3	( -0.4, -0.2)	
	Present	631	-1.4	-1.0	-0.4	( -0.6, -0.2)	
Age Group	18-24	160	-0.6	-0.6	-0.0	( -0.4, 0.4)	
	25-64	1657	-0.9	-0.6	-0.4	( -0.5, -0.2)	
	>=65	178	-0.7	-0.4	-0.2	( -0.5, 0.0)	
Gender	Female	1058	-0.8	-0.5	-0.3	( -0.5, -0.2)	
	Male	937	-0.9	-0.6	-0.3	( -0.4, -0.2)	

Paroxetine Adult Suicidality Analysis  
Table 3.04  
Change from Baseline on MADRS Item 10 to LOCF Endpoint by Treatment Group  
Indication = MDD

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		1759	-0.9	-0.6	-0.3	( -0.4, -0.2)	<0.001
Baseline Suicidal Ideation	Absent	1361	-0.6	-0.3	-0.3	( -0.4, -0.2)	
	Present	398	-1.9	-1.4	-0.5	( -0.8, -0.3)	
Age Group	18-24	105	-0.9	-0.4	-0.5	( -1.0, -0.1)	
	25-64	1479	-1.0	-0.6	-0.3	( -0.5, -0.2)	
	>=65	175	-0.7	-0.4	-0.3	( -0.5, -0.0)	
Gender	Female	903	-0.9	-0.5	-0.4	( -0.5, -0.3)	
	Male	856	-0.9	-0.6	-0.3	( -0.4, -0.1)	

Paroxetine Adult Suicidality Analysis  
 Table 3.04  
 Change from Baseline on MADRS Item 10 to LOCF Endpoint by Treatment Group  
 Indication = IBD

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		236	-0.5	-0.4	-0.1	( -0.5, 0.3)	0.549
Baseline Suicidal Ideation	Absent	3	5.3	1.3	4.0		
	Present	233	-0.5	-0.4	-0.2	( -0.6, 0.3)	
Age Group	18-24	55	0.0	-0.7	0.7	( -0.2, 1.5)	
	25-64	178	-0.7	-0.3	-0.4	( -0.9, 0.1)	
	>=65	3	.	.	.		
Gender	Female	155	-0.3	-0.3	0.0	( -0.5, 0.6)	
	Male	81	-0.9	-0.4	-0.5	( -1.2, 0.1)	

Paroxetine Adult Suicidality Analysis  
Table 3.05  
Number and Percent of Subjects with Declining Suicidal Ideation  
by Indication, Treatment Group and Risk Factors  
Indication = All Indications

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)		335/ 776 (43.17%)	168/ 496 (33.87%)	1.5 (1.1, 2.0)	0.004	10.5
Age Group	<18	0/ 1 ( 0.00%)	0/ 0	Not Enough Events		
	18-24	29/ 81 (35.80%)	23/ 66 (34.85%)	1.0 (0.5, 2.1)		104.8
	25-64	283/ 661 (42.81%)	137/ 410 (33.41%)	1.5 (1.2, 1.9)		10.6
	>=65	23/ 33 (69.70%)	8/ 20 (40.00%)	3.5 (1.1, 11.0)		3.4
Gender	Female	201/ 438 (45.89%)	103/ 273 (37.73%)	1.4 (1.0, 1.9)		12.3
	Male	134/ 338 (39.64%)	65/ 223 (29.15%)	1.6 (1.1, 2.3)		9.5

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
Note. Asymptotic analyses were used in all computations  
Note. Tests of heterogeneity for Age Group and Gender are 0.213 and 0.587



Paroxetine Adult Suicidality Analysis  
Table 3.05  
Number and Percent of Subjects with Declining Suicidal Ideation  
by Indication, Treatment Group and Risk Factors  
Indication = All Depression

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)		296/ 568 (52.11%)	155/ 400 (38.75%)	1.5 (1.1, 2.0)	0.008	10.5
Age Group	18-24	26/ 64 (40.63%)	21/ 57 (36.84%)	1.2 (0.6, 2.4)		26.4
	25-64	248/ 476 (52.10%)	126/ 325 (38.77%)	1.7 (1.3, 2.3)		7.5
	>=65	22/ 28 (78.57%)	8/ 18 (44.44%)	4.6 (1.3, 16.7)		2.9
Gender	Female	173/ 342 (50.58%)	92/ 232 (39.66%)	1.6 (1.1, 2.2)		9.1
	Male	123/ 226 (54.42%)	63/ 168 (37.50%)	2.0 (1.3, 3.0)		5.9

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
Note. Asymptotic analyses were used in all computations  
Note. Tests of heterogeneity for Age Group and Gender are 0.192 and 0.364

Paroxetine Adult Suicidality Analysis  
 Table 3.05  
 Number and Percent of Subjects with Declining Suicidal Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = MDD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)		263/ 413 (63.68%)	121/ 240 (50.42%)	1.7 (1.2, 2.4)	0.002	7.6
Age Group	18-24	18/ 28 (64.29%)	10/ 19 (52.63%)	1.6 (0.5, 5.3)		8.6
	25-64	223/ 359 (62.12%)	104/ 206 (50.49%)	1.6 (1.1, 2.3)		8.6
	>=65	22/ 26 (84.62%)	7/ 15 (46.67%)	6.3 (1.4, 27.4)		2.6
Gender	Female	154/ 237 (64.98%)	71/ 129 (55.04%)	1.5 (1.0, 2.3)		10.1
	Male	109/ 176 (61.93%)	50/ 111 (45.05%)	2.0 (1.2, 3.2)		5.9

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Asymptotic analyses were used in all computations  
 Note. Declining Suicidal Ideation was not assessable in study 442  
 Note. Tests of heterogeneity for Age Group and Gender are 0.194 and 0.417

Paroxetine Adult Suicidality Analysis  
Table 3.05  
Number and Percent of Subjects with Declining Suicidal Ideation  
by Indication, Treatment Group and Risk Factors  
Indication = IBD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		28/ 147 (19.05%)	29/ 152 (19.08%)	1.0 (0.6, 1.8)	1.000	2924.6
Age Group	18-24	7/ 35 (20.00%)	11/ 38 (28.95%)	0.6 (0.2, 1.8)		(11.2)
	25-64	21/ 110 (19.09%)	17/ 111 (15.32%)	1.3 (0.6, 2.7)		26.5
	>=65	0/ 2 ( 0.00%)	1/ 3 (33.33%)	0.0 (0.0, 28.5)		(3.0)
Gender	Female	15/ 99 (15.15%)	18/ 99 (18.18%)	0.8 (0.4, 1.7)		(33.0)
	Male	13/ 48 (27.08%)	11/ 53 (20.75%)	1.4 (0.6, 3.6)		15.8

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
Note. Exact analyses were used in all computations  
Note. Tests of heterogeneity for Age Group and Gender are 0.406 and 0.380

Paroxetine Adult Suicidality Analysis  
 Table 3.05  
 Number and Percent of Subjects with Declining Suicidal Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = Dysthymia

Description	Subgroup	Paroxetine		Placebo		OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		1/	2 (50.00%)	2/	3 (66.67%)	0.6 (0.0, 38.3)	1.000	(7.6)
Age Group	25-64	1/	2 (50.00%)	2/	3 (66.67%)	0.6 (0.0, 38.3)		(6.0)
Gender	Female	1/	2 (50.00%)	1/	2 (50.00%)	1.0 (0.0, 76.5)		
	Male	0/	0	1/	1 (100.0%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
 Table 3.05  
 Number and Percent of Subjects with Declining Suicidal Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = Bipolar

Description	Subgroup	Paroxetine		Placebo		OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		4/	6 (66.67%)	3/	5 (60.00%)	1.3 (0.1, 19.4)	1.000	16.5
Age Group	18-24	1/	1 (100.0%)	0/	0	Not Enough Events		
	25-64	3/	5 (60.00%)	3/	5 (60.00%)	1.0 (0.1, 15.7)		
Gender	Female	3/	4 (75.00%)	2/	2 (100.0%)	0.0 (0.0, 38.0)		(4.0)
	Male	1/	2 (50.00%)	1/	3 (33.33%)	1.7 (0.0, 115.0)		6.0

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Test of heterogeneity for Gender is 1.000

Paroxetine Adult Suicidality Analysis  
 Table 3.05  
 Number and Percent of Subjects with Declining Suicidal Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = All Non-Depression

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)		39/ 208 (18.75%)	13/ 96 (13.54%)	1.7 (0.8, 3.6)	0.211	14.2
Age Group	<18	0/ 1 ( 0.00%)	0/ 0	Not Enough Events		
	18-24	3/ 17 (17.65%)	2/ 9 (22.22%)	0.8 (0.1, 5.6)		(21.9)
	25-64	35/ 185 (18.92%)	11/ 85 (12.94%)	1.6 (0.8, 3.3)		16.7
	>=65	1/ 5 (20.00%)	0/ 2 ( 0.00%)	Not Enough Events		5.0
Gender	Female	28/ 96 (29.17%)	11/ 41 (26.83%)	1.1 (0.5, 2.5)		42.8
	Male	11/ 112 ( 9.82%)	2/ 55 ( 3.64%)	2.9 (0.6, 13.5)		16.2

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Asymptotic analyses were used in all computations  
 Note. Tests of heterogeneity for Age Group and Gender are 0.789 and 0.281

Paroxetine Adult Suicidality Analysis  
 Table 3.05  
 Number and Percent of Subjects with Declining Suicidal Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = Panic

Description	Subgroup	Paroxetine		Placebo		OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		6/	8 (75.00%)	2/	5 (40.00%)	3.9 (0.3, 117.8)	0.300	3.1
Age Group	18-24	1/	2 (50.00%)	0/	0	Not Enough Events		2.3
	25-64	5/	6 (83.33%)	2/	5 (40.00%)			
Gender	Female	3/	5 (60.00%)	2/	3 (66.67%)	0.8 (0.0, 18.0)		(15.0)
	Male	3/	3 (100.0%)	0/	2 (0.00%)	inf (0.6, inf)		1.0

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Test of heterogeneity for Gender is 0.268

Paroxetine Adult Suicidality Analysis  
 Table 3.05  
 Number and Percent of Subjects with Declining Suicidal Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = OCD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		7/ 123 ( 5.69%)	3/ 50 ( 6.00%)	0.9 (0.1, 7.0)	1.000	(178.0)
Age Group	<18	0/ 1 ( 0.00%)	0/ 0	Not Enough Events		
	18-24	1/ 13 ( 7.69%)	0/ 6 ( 0.00%)	inf ( 0.0, inf)		13.0
	25-64	6/ 105 ( 5.71%)	3/ 42 ( 7.14%)	0.8 (0.2, 4.0)		(70.0)
	>=65	0/ 4 ( 0.00%)	0/ 2 ( 0.00%)	Not Enough Events		
Gender	Female	4/ 32 (12.50%)	2/ 14 (14.29%)	0.9 (0.1, 7.5)		(56.0)
	Male	3/ 91 ( 3.30%)	1/ 36 ( 2.78%)	1.2 (0.1, 32.3)		192.7

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Tests of heterogeneity for Age Group and Gender are 1.000 and 1.000



Paroxetine Adult Suicidality Analysis  
 Table 3.05  
 Number and Percent of Subjects with Declining Suicidal Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = GAD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
Age Group	25-64	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
Gender	Male	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
Table 3.05  
Number and Percent of Subjects with Declining Suicidal Ideation  
by Indication, Treatment Group and Risk Factors  
Indication = PTSD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		26/ 59 (44.07%)	8/ 34 (23.53%)	1.8 (0.7, 5.2)	0.321	7.9
Age Group	18-24	1/ 1 (100.0%)	2/ 3 (66.67%)	inf ( 0.0, inf)		3.0
	25-64	24/ 57 (42.11%)	6/ 31 (19.35%)	3.0 (1.1, 9.1)		4.4
	>=65	1/ 1 (100.0%)	0/ 0	Not Enough Events		
Gender	Female	21/ 43 (48.84%)	7/ 21 (33.33%)	1.9 (0.6, 5.9)		6.5
	Male	5/ 16 (31.25%)	1/ 13 ( 7.69%)	5.2 (0.6, 139.7)		4.2

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
Note. Exact analyses were used in all computations  
Note. Tests of heterogeneity for Age Group and Gender are 1.000 and 0.598

Paroxetine Adult Suicidality Analysis  
 Table 3.05  
 Number and Percent of Subjects with Declining Suicidal Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = PMDD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 16 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 1 ( 0.00%)	0/ 0	Not Enough Events		
	25-64	0/ 15 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 16 ( 0.00%)	0/ 3 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
 Table 3.05  
 Number and Percent of Subjects with Declining Suicidal Ideation  
 by Indication, Treatment Group and Risk Factors  
 Indication = Detoxification in Alcoholics

Description	Subgroup	Paroxetine		Placebo		OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/	2 ( 0.00%)	0/	3 ( 0.00%)	Not Enough Events		
Age Group	25-64	0/	2 ( 0.00%)	0/	3 ( 0.00%)	Not Enough Events		
Gender	Male	0/	2 ( 0.00%)	0/	3 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
 Table 3.06  
 Number and Percent of Subjects with Response ( $\geq 50\%$  Reduction in HAMD or MADRS Baseline Score)  
 by Indication, Treatment Group and Risk Factors  
 Indication = All Depression

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)		1779/3445 (51.64%)	776/2136 (36.33%)	1.8 (1.6, 2.0)	<0.001	7.2
Baseline Suicidal Ideation	Missing	0/ 0	0/ 2 ( 0.00%)	Not Enough Events		
	Absent	1556/2940 (52.93%)	668/1779 (37.55%)	1.9 (1.7, 2.1)		6.5
	Present	223/ 505 (44.16%)	108/ 355 (30.42%)	1.8 (1.4, 2.4)		7.3
Age Group	18-24	111/ 246 (45.12%)	54/ 133 (40.60%)	1.2 (0.8, 1.9)		22.1
	25-64	1397/2707 (51.61%)	601/1703 (35.29%)	2.0 (1.7, 2.2)		6.1
	$\geq 65$	271/ 492 (55.08%)	121/ 300 (40.33%)	1.8 (1.4, 2.5)		6.8
Gender	Female	1077/2014 (53.48%)	467/1281 (36.46%)	2.0 (1.7, 2.3)		5.9
	Male	702/1431 (49.06%)	309/ 855 (36.14%)	1.7 (1.4, 2.0)		7.7

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Asymptotic analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.833, 0.098, 0.156

Paroxetine Adult Suicidality Analysis  
 Table 3.06  
 Number and Percent of Subjects with Response (>=50% Reduction in HAMD or MADRS Baseline Score)  
 by Indication, Treatment Group and Risk Factors  
 Indication = MDD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)		1688/3227 (52.31%)	702/1890 (37.14%)	1.8 (1.6, 2.0)	<0.001	7.2
Baseline Suicidal Ideation	Missing	0/ 0	0/ 2 ( 0.00%)	Not Enough Events		
	Absent	1500/2843 (52.76%)	625/1661 (37.63%)	1.9 (1.6, 2.1)		6.6
	Present	188/ 384 (48.96%)	77/ 227 (33.92%)	1.9 (1.3, 2.6)		6.6
Age Group	18-24	102/ 214 (47.66%)	45/ 98 (45.92%)	1.1 (0.7, 1.7)		57.3
	25-64	1317/2525 (52.16%)	538/1497 (35.94%)	1.9 (1.7, 2.2)		6.2
	>=65	269/ 488 (55.12%)	119/ 295 (40.34%)	1.8 (1.4, 2.5)		6.8
Gender	Female	1022/1887 (54.16%)	424/1129 (37.56%)	2.0 (1.7, 2.3)		6.0
	Male	666/1340 (49.70%)	278/ 761 (36.53%)	1.7 (1.4, 2.1)		7.6

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Asymptotic analyses were used in all computations

Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.960, 0.062, 0.264

Paroxetine Adult Suicidality Analysis  
Table 3.06  
Number and Percent of Subjects with Response (>=50% Reduction in MADRS Baseline Score)  
by Indication, Treatment Group and Risk Factors  
Indication = IBD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		31/ 114 (27.19%)	29/ 122 (23.77%)	1.2 (0.6, 2.1)	0.648	33.1
Baseline Suicidal Ideation	Absent	0/ 1 ( 0.00%)	0/ 2 ( 0.00%)	Not Enough Events		
	Present	31/ 113 (27.43%)	29/ 120 (24.17%)	1.2 (0.7, 2.1)		30.6
Age Group	18-24	4/ 26 (15.38%)	7/ 29 (24.14%)	0.6 (0.1, 2.3)		(11.4)
	25-64	26/ 86 (30.23%)	21/ 92 (22.83%)	1.5 (0.7, 2.9)		13.5
	>=65	1/ 2 (50.00%)	1/ 1 (100.0%)	0.0 (0.0, 38.0)		(2.0)
Gender	Female	24/ 79 (30.38%)	18/ 76 (23.68%)	1.4 (0.7, 2.9)		14.9
	Male	7/ 35 (20.00%)	11/ 46 (23.91%)	0.8 (0.3, 2.3)		(25.6)

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
Note. Exact analyses were used in all computations  
Note. Tests of heterogeneity for Age Group and Gender are 0.338 and 0.518

Paroxetine Adult Suicidality Analysis  
Table 3.06  
Number and Percent of Subjects with Response ( $\geq 50\%$  Reduction in HAMD Baseline Score)  
by Indication, Treatment Group and Risk Factors  
Indication = Dysthymia

Description	Subgroup	Paroxetine		Placebo		OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		41/	71 (57.75%)	28/	81 (34.57%)	2.6 (1.3, 5.0)	0.005	4.3
Baseline Suicidal Ideation	Absent	40/	69 (57.97%)	28/	78 (35.90%)	2.4 (1.3, 4.8)		4.5
	Present	1/	2 (50.00%)	0/	3 ( 0.00%)	inf ( 0.1, inf)		2.0
Age Group	18-24	4/	5 (80.00%)	0/	3 ( 0.00%)	inf ( 0.8, inf)		1.3
	25-64	37/	65 (56.92%)	27/	75 (36.00%)	2.3 (1.2, 4.7)		4.8
	$\geq 65$	0/	1 ( 0.00%)	1/	3 (33.33%)	0.0 (0.0, 57.0)		(3.0)
Gender	Female	22/	30 (73.33%)	16/	53 (30.19%)	6.2 (2.3, 17.7)		2.3
	Male	19/	41 (46.34%)	12/	28 (42.86%)	1.1 (0.4, 3.1)		28.7

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 1.000, 0.442, 0.034



Paroxetine Adult Suicidality Analysis  
 Table 3.06  
 Number and Percent of Subjects with Response ( $\geq 50\%$  Reduction in HAMD Baseline Score)  
 by Indication, Treatment Group and Risk Factors  
 Indication = Bipolar

Description	Subgroup	Paroxetine		Placebo		OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		19/ 33 (57.58%)	17/ 43 (39.53%)	2.1 (0.8, 5.3)		0.165	5.6	
Baseline Suicidal Ideation	Absent	16/ 27 (59.26%)	15/ 38 (39.47%)	2.2 (0.8, 6.2)			5.1	
	Present	3/ 6 (50.00%)	2/ 5 (40.00%)	1.4 (0.1, 20.6)			10.0	
Age Group	18-24	1/ 1 (100.0%)	2/ 3 (66.67%)	inf ( 0.0, inf)			3.0	
	25-64	17/ 31 (54.84%)	15/ 39 (38.46%)	1.9 (0.7, 5.1)			6.1	
	$\geq 65$	1/ 1 (100.0%)	0/ 1 ( 0.00%)	inf ( 0.1, inf)			1.0	
Gender	Female	9/ 18 (50.00%)	9/ 23 (39.13%)	1.5 (0.4, 5.6)			9.2	
	Male	10/ 15 (66.67%)	8/ 20 (40.00%)	2.9 (0.7, 12.8)			3.8	

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 1.000, 1.000, 0.644

Paroxetine Adult Suicidality Analysis

Table 3.07

Number and Percent of Subjects with Response (CGI of Very Much Improved or Much Improved at LOCF endpoint)  
 by Indication, Treatment Group and Risk Factors  
 Indication = All Non-Depression

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)		2867/4877 (58.79%)	1424/3565 (39.94%)	2.3 (2.1, 2.5)	<0.001	4.8
Baseline Suicidal Ideation	Missing	705/1267 (55.64%)	377/1070 (35.23%)	2.3 (2.0, 2.7)		4.9
	Absent	2085/3419 (60.98%)	1026/2402 (42.71%)	2.1 (1.9, 2.3)		5.5
	Present	77/ 191 (40.31%)	21/ 93 (22.58%)	2.3 (1.3, 4.1)		5.6
Age Group	<18	5/ 10 (50.00%)	2/ 6 (33.33%)	2.0 (0.2, 16.4)		6.0
	18-24	280/ 473 (59.20%)	163/ 378 (43.12%)	1.9 (1.5, 2.5)		6.2
	25-64	2533/4288 (59.07%)	1218/3090 (39.42%)	2.2 (2.0, 2.4)		5.1
	>=65	49/ 106 (46.23%)	41/ 91 (45.05%)	1.0 (0.6, 1.8)		85.4
Gender	Female	1892/3020 (62.65%)	910/2162 (42.09%)	2.3 (2.1, 2.6)		4.9
	Male	975/1856 (52.53%)	514/1403 (36.64%)	1.9 (1.7, 2.2)		6.3

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Asymptotic analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.734, 0.059, 0.043

Paroxetine Adult Suicidality Analysis

Table 3.07

Number and Percent of Subjects with Response (CGI of Very Much Improved or Much Improved at LOCF endpoint)  
 by Indication, Treatment Group and Risk Factors  
 Indication = Panic

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (Mantel Haenszel)		712/1043 (68.26%)	418/ 882 (47.39%)	2.5 (2.0, 3.0)	<0.001	4.7
Baseline Suicidal Ideation	Missing	379/ 598 (63.38%)	244/ 562 (43.42%)	2.3 (1.8, 2.9)		5.0
	Absent	327/ 439 (74.49%)	173/ 315 (54.92%)	2.4 (1.8, 3.3)		5.1
	Present	6/ 6 (100.0%)	1/ 5 (20.00%)	Not Enough Events		1.3
Age Group	<18	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
	18-24	87/ 115 (75.65%)	61/ 113 (53.98%)	2.6 (1.5, 4.7)		4.6
	25-64	622/ 919 (67.68%)	356/ 765 (46.54%)	2.4 (2.0, 2.9)		4.7
	>=65	3/ 9 (33.33%)	1/ 3 (33.33%)	1.0 (0.1, 16.0)		
Gender	Female	436/ 638 (68.34%)	250/ 518 (48.26%)	2.3 (1.8, 2.9)		5.0
	Male	276/ 405 (68.15%)	168/ 364 (46.15%)	2.5 (1.9, 3.3)		4.5

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Asymptotic analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.076, 0.776, 0.695

Paroxetine Adult Suicidality Analysis

Table 3.07

Number and Percent of Subjects with Response (CGI of Very Much Improved or Much Improved at LOCF endpoint)  
 by Indication, Treatment Group and Risk Factors  
 Indication = OCD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		258/ 673 (38.34%)	96/ 412 (23.30%)	2.1 (1.6, 2.9)	<0.001	6.2
Baseline Suicidal Ideation	Missing	63/ 156 (40.38%)	36/ 151 (23.84%)	2.2 (1.3, 3.6)		6.0
	Absent	158/ 401 (39.40%)	54/ 213 (25.35%)	1.9 (1.3, 2.8)		7.1
	Present	37/ 116 (31.90%)	6/ 48 (12.50%)	3.3 (1.3, 9.1)		5.2
Age Group	<18	5/ 10 (50.00%)	2/ 5 (40.00%)	1.5 (0.1, 17.0)		10.0
	18-24	30/ 84 (35.71%)	16/ 51 (31.37%)	1.2 (0.6, 2.6)		23.0
	25-64	212/ 549 (38.62%)	73/ 342 (21.35%)	2.3 (1.7, 3.2)		5.8
	>=65	11/ 30 (36.67%)	5/ 14 (35.71%)	1.0 (0.3, 4.2)		105.0
Gender	Female	125/ 298 (41.95%)	47/ 190 (24.74%)	2.2 (1.5, 3.3)		5.8
	Male	133/ 375 (35.47%)	49/ 222 (22.07%)	1.9 (1.3, 2.9)		7.5

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.351, 0.281, 0.674

Paroxetine Adult Suicidality Analysis

Table 3.07

Number and Percent of Subjects with Response (CGI of Very Much Improved or Much Improved at LOCF endpoint)  
 by Indication, Treatment Group and Risk Factors  
 Indication = SAD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		486/ 902 (53.88%)	197/ 633 (31.12%)	2.8 (2.2, 3.5)	<0.001	4.1
Baseline Suicidal Ideation	Missing	262/ 485 (54.02%)	95/ 329 (28.88%)	2.9 (2.1, 3.9)		4.0
	Absent	224/ 417 (53.72%)	102/ 304 (33.55%)	2.3 (1.7, 3.1)		5.0
Age Group	18-24	63/ 106 (59.43%)	26/ 86 (30.23%)	3.4 (1.8, 6.2)		3.4
	25-64	421/ 792 (53.16%)	167/ 535 (31.21%)	2.5 (2.0, 3.1)		4.6
	>=65	2/ 4 (50.00%)	4/ 12 (33.33%)	1.9 (0.2, 24.6)		6.0
Gender	Female	248/ 431 (57.54%)	93/ 301 (30.90%)	3.0 (2.2, 4.1)		3.8
	Male	238/ 471 (50.53%)	104/ 332 (31.33%)	2.2 (1.7, 3.0)		5.2

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Tests of heterogeneity for Age Group and Gender are 0.634 and 0.191

Paroxetine Adult Suicidality Analysis

Table 3.07

Number and Percent of Subjects with Response (CGI of Very Much Improved or Much Improved at LOCF endpoint)  
 by Indication, Treatment Group and Risk Factors  
 Indication = GAD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		564/ 875 (64.46%)	338/ 684 (49.42%)	1.9 (1.5, 2.3)	<0.001	6.6
Baseline Suicidal Ideation	Absent	564/ 875 (64.46%)	338/ 683 (49.49%)	1.9 (1.5, 2.3)		6.7
	Present	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
Age Group	18-24	63/ 99 (63.64%)	34/ 66 (51.52%)	1.6 (0.9, 3.1)		8.3
	25-64	474/ 724 (65.47%)	278/ 569 (48.86%)	2.0 (1.6, 2.5)		6.0
	>=65	27/ 52 (51.92%)	26/ 49 (53.06%)	1.0 (0.4, 2.1)		(87.9)
Gender	Female	363/ 538 (67.47%)	221/ 429 (51.52%)	2.0 (1.5, 2.5)		6.3
	Male	201/ 337 (59.64%)	117/ 255 (45.88%)	1.7 (1.3, 2.4)		7.3

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Tests of heterogeneity for Age Group and Gender are 0.188 and 0.668

Paroxetine Adult Suicidality Analysis

Table 3.07

Number and Percent of Subjects with Response (CGI of Very Much Improved or Much Improved at LOCF endpoint)  
 by Indication, Treatment Group and Risk Factors  
 Indication = PTSD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		372/ 639 (58.22%)	193/ 487 (39.63%)	2.1 (1.7, 2.7)	<0.001	5.4
Baseline Suicidal Ideation	Missing	0/ 3 ( 0.00%)	2/ 2 (100.0%)	0.0 (0.0, 1.7)		(1.0)
	Absent	348/ 583 (59.69%)	179/ 452 (39.60%)	2.3 (1.8, 2.9)		5.0
	Present	24/ 53 (45.28%)	12/ 33 (36.36%)	1.4 (0.6, 3.6)		11.2
Age Group	18-24	27/ 48 (56.25%)	21/ 48 (43.75%)	1.6 (0.7, 3.7)		8.0
	25-64	339/ 580 (58.45%)	167/ 427 (39.11%)	2.2 (1.7, 2.8)		5.2
	>=65	6/ 11 (54.55%)	5/ 12 (41.67%)	1.6 (0.3, 9.4)		7.8
Gender	Female	253/ 409 (61.86%)	129/ 305 (42.30%)	2.2 (1.6, 3.0)		5.1
	Male	119/ 230 (51.74%)	64/ 182 (35.16%)	2.0 (1.3, 3.0)		6.0

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 0.344, 0.751, 0.701

Paroxetine Adult Suicidality Analysis

Table 3.07

Number and Percent of Subjects with Response (CGI of Very Much Improved or Much Improved at LOCF endpoint)  
by Indication, Treatment Group and Risk Factors  
Indication = PMDD

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		462/ 671 (68.85%)	163/ 385 (42.34%)	3.0 (2.3, 4.0)	<0.001	3.7
Baseline Suicidal Ideation	Missing	1/ 1 (100.0%)	0/ 0	Not Enough Events		
	Absent	452/ 656 (68.90%)	162/ 382 (42.41%)	3.0 (2.3, 3.9)		3.8
	Present	9/ 14 (64.29%)	1/ 3 (33.33%)	3.3 (0.2, 117.0)		3.2
Age Group	18-24	10/ 20 (50.00%)	5/ 13 (38.46%)	1.6 (0.4, 7.1)		8.7
	25-64	452/ 651 (69.43%)	158/ 372 (42.47%)	3.1 (2.4, 4.0)		3.7
Gender	Female	462/ 671 (68.85%)	163/ 385 (42.34%)	3.0 (2.3, 3.9)		3.8

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 1.000, 0.447, XXX



Paroxetine Adult Suicidality Analysis

Table 3.07

Number and Percent of Subjects with Response (CGI of Very Much Improved or Much Improved at LOCF endpoint)  
 by Indication, Treatment Group and Risk Factors  
 Indication = Detoxification in Alcoholics

Description	Subgroup	Paroxetine		Placebo		OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		13/	50 (26.00%)	19/	56 (33.93%)	0.7 (0.3, 1.6)	0.404	(12.7)
Baseline Suicidal Ideation	Absent	12/	48 (25.00%)	18/	53 (33.96%)	0.7 (0.3, 1.6)		(11.2)
	Present	1/	2 (50.00%)	1/	3 (33.33%)	1.7 (0.0, 115.0)		6.0
Age Group	18-24	0/	1 ( 0.00%)	0/	0	Not Enough Events		
	25-64	13/	49 (26.53%)	19/	56 (33.93%)	0.7 (0.3, 1.6)		(13.5)
Gender	Female	5/	16 (31.25%)	7/	15 (46.67%)	0.5 (0.1, 2.4)		(6.5)
	Male	8/	34 (23.53%)	12/	41 (29.27%)	0.7 (0.3, 2.1)		(17.4)

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)

Note. Exact analyses were used in all computations

Note. Tests of heterogeneity for Baseline Suicidal Ideation, Age Group and Gender are 1.000, XXX, 1.000

Paroxetine Adult Suicidality Analysis

Table 3.07

Number and Percent of Subjects with Response (CGI of Very Much Improved or Much Improved at LOCF endpoint)  
 by Indication, Treatment Group and Risk Factors  
 Indication = Fibromyalgia

Description	Subgroup	Paroxetine	Placebo	OR (95% CI)	P-value	NNT
Overall (exact, adjusted)		0/ 24 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Baseline Suicidal Ideation	Missing	0/ 24 ( 0.00%)	0/ 26 ( 0.00%)	Not Enough Events		
Age Group	18-24	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
	25-64	0/ 24 ( 0.00%)	0/ 24 ( 0.00%)	Not Enough Events		
	>=65	0/ 0	0/ 1 ( 0.00%)	Not Enough Events		
Gender	Female	0/ 19 ( 0.00%)	0/ 19 ( 0.00%)	Not Enough Events		
	Male	0/ 4 ( 0.00%)	0/ 7 ( 0.00%)	Not Enough Events		

Note. NNT numbers in brackets denote number-needed-to-harm (NNH)  
 Note. Exact analyses were used in all computations  
 Note. Heterogeneity tests were not performed due to lack of data

Paroxetine Adult Suicidality Analysis  
Table 3.08  
Change from Baseline on YBOCS Total Score to LOCF Endpoint by Treatment Group  
Indication = OCD

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		1080	-6.8	-4.1	-2.7	( -3.7, -1.8)	<0.001
Baseline Suicidal Ideation	Missing	302	.	.	.		
	Absent	614	-7.2	-4.5	-2.7	( -4.0, -1.4)	
	Present	164	-5.7	-3.2	-2.4	( -4.8, -0.0)	
Age Group	18-24	135	-6.9	-3.8	-3.1	( -6.0, -0.2)	
	25-64	886	-6.8	-4.1	-2.7	( -3.7, -1.7)	
	<18	15	-5.8	-4.8	-1.0	(-16.7, 14.7)	
	>=65	44	-6.8	-4.1	-2.7	( -8.2, 2.7)	
Gender	Female	485	-7.3	-4.2	-3.2	( -4.6, -1.8)	
	Male	595	-6.4	-4.0	-2.4	( -3.7, -1.1)	

Paroxetine Adult Suicidality Analysis  
Table 3.09  
Change from Baseline on LSAS Total Score to LOCF Endpoint by Treatment Group  
Indication = SAD

Population	Category	N	Paroxetine LS mean	Placebo LS mean	Estimated Treatment Effect	95% CI	P-value
Overall		1522	-28.1	-16.6	-11.5	(-14.2, -8.9)	<0.001
Baseline Suicidal Ideation	Missing	801	.	.	.		
	Absent	721	-27.8	-18.1	-9.7	(-13.2, -6.2)	
Age Group	18-24	190	-31.9	-18.7	-13.2	(-21.0, -5.3)	
	25-64	1317	-27.6	-16.1	-11.5	(-14.4, -8.7)	
	>=65	15	-35.9	-27.9	-8.0	(-50.4, 34.5)	
Gender	Female	726	-29.3	-14.6	-14.7	(-18.6, -10.8)	
	Male	796	-27.1	-18.4	-8.7	(-12.3, -5.1)	

Paroxetine Adult Suicidality Analysis  
Table 3.10  
Change from Baseline on HAMA Total Score to LOCF Endpoint by Treatment Group  
Indication = GAD

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		1558	-12.7	-10.9	-1.8	( -2.6, -1.1)	<0.001
Baseline Suicidal Ideation	Absent	1557	-12.7	-10.9	-1.8	( -2.6, -1.1)	
	Present	1	.	.	.		
Age Group	18-24	165	-12.5	-11.3	-1.1	( -3.7, 1.4)	
	25-64	1292	-13.0	-10.9	-2.1	( -2.9, -1.3)	
	>=65	101	-10.0	-9.9	-0.1	( -3.1, 2.9)	
Gender	Female	966	-12.9	-11.3	-1.6	( -2.6, -0.6)	
	Male	592	-12.3	-10.3	-2.1	( -3.3, -0.8)	

Paroxetine Adult Suicidality Analysis  
 Table 3.11  
 Change from Baseline on CAPS-2 Total Score to LOCF Endpoint by Treatment Group  
 Indication = PTSD

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		1037	-36.8	-26.7	-10.1	(-13.2, -6.9)	<0.001
Baseline Suicidal Ideation	Missing	4	.	.	.		
	Absent	953	-36.7	-26.9	-9.8	(-13.0, -6.5)	
	Present	80	-37.7	-22.7	-15.0	(-29.2, -0.9)	
Age Group	18-24	86	-35.9	-26.3	-9.5	(-20.7, 1.7)	
	25-64	930	-36.8	-26.8	-10.0	(-13.3, -6.6)	
	>=65	21	-46.3	-22.1	-24.2	(-44.8, -3.5)	
Gender	Female	649	-39.5	-28.1	-11.4	(-15.4, -7.4)	
	Male	388	-32.1	-24.3	-7.9	(-13.0, -2.8)	

Paroxetine Adult Suicidality Analysis  
 Table 3.12  
 Change from Baseline on Mean Luteal Phase VAS Mood Score to LOCF Endpoint by Treatment Group  
 Indication = PMDD

Population	Category	N	Paroxetine LS mean	Placebo LS mean	Estimated Treatment Effect	95% CI	P-value
Overall		1092	-35.6	-24.9	-10.8	(-13.7, -7.8)	<0.001
Baseline Suicidal Ideation	Missing	1	.	.	.		
	Absent	1073	-34.8	-24.4	-10.4	(-13.3, -7.5)	
	Present	18	-78.8	-31.9	-46.9	( -116, 22.3)	
Age Group	18-24	32	-43.9	-36.4	-7.5	(-34.7, 19.6)	
	25-64	1060	-35.4	-24.7	-10.7	(-13.6, -7.8)	
Gender	Female	1092	-35.6	-24.9	-10.8	(-13.7, -7.8)	

Paroxetine Adult Suicidality Analysis  
 Table 3.13  
 Change from Baseline on Total Daily Alcohol Consumption to LOCF Endpoint by Treatment Group  
 Indication = Detoxification in Alcoholics

Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		98	1.8	3.5	-1.8	( -4.3, 0.8)	0.170
Baseline Suicidal Ideation	Absent	94	1.8	3.7	-1.8	( -4.5, 0.8)	
	Present	4	0.5	0.0	0.5	( -1.7, 2.7)	
Age Group	18-24	1	.	.	.		
	25-64	97	1.8	3.5	-1.7	( -4.3, 0.8)	
Gender	Female	28	0.4	1.2	-0.9	( -3.2, 1.5)	
	Male	70	2.4	4.5	-2.1	( -5.4, 1.3)	



Paroxetine Adult Suicidality Analysis  
 Table 3.14  
 Change from Baseline on VAS Score to LOCF Endpoint by Treatment Group  
 Indication = Fibromyalgia

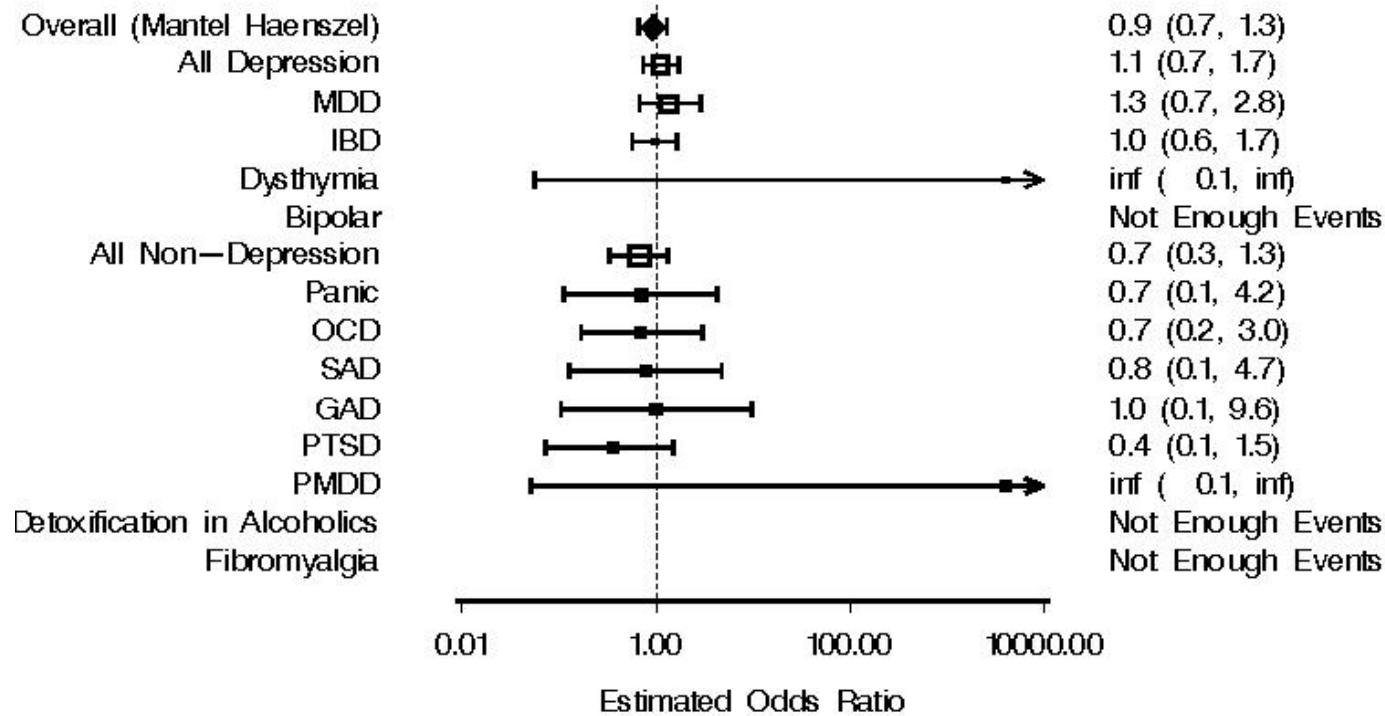
Population	Category	N	Paroxetine	Placebo	Estimated	95% CI	P-value
			LS mean	LS mean	Treatment Effect		
Overall		50	-15.0	-13.5	-1.5	(-16.0, 12.9)	0.831
Age Group	18-24	1	.	.	.		
	25-64	48	-14.7	-11.5	-3.2	(-17.1, 10.7)	
	>=65	1	.	.	.		
Gender	Missing	1	.	.	.		
	Female	38	-7.5	-15.8	8.3	( -5.8, 22.3)	
	Male	11	-48.3	-7.7	-40.6	(-87.6, 6.3)	



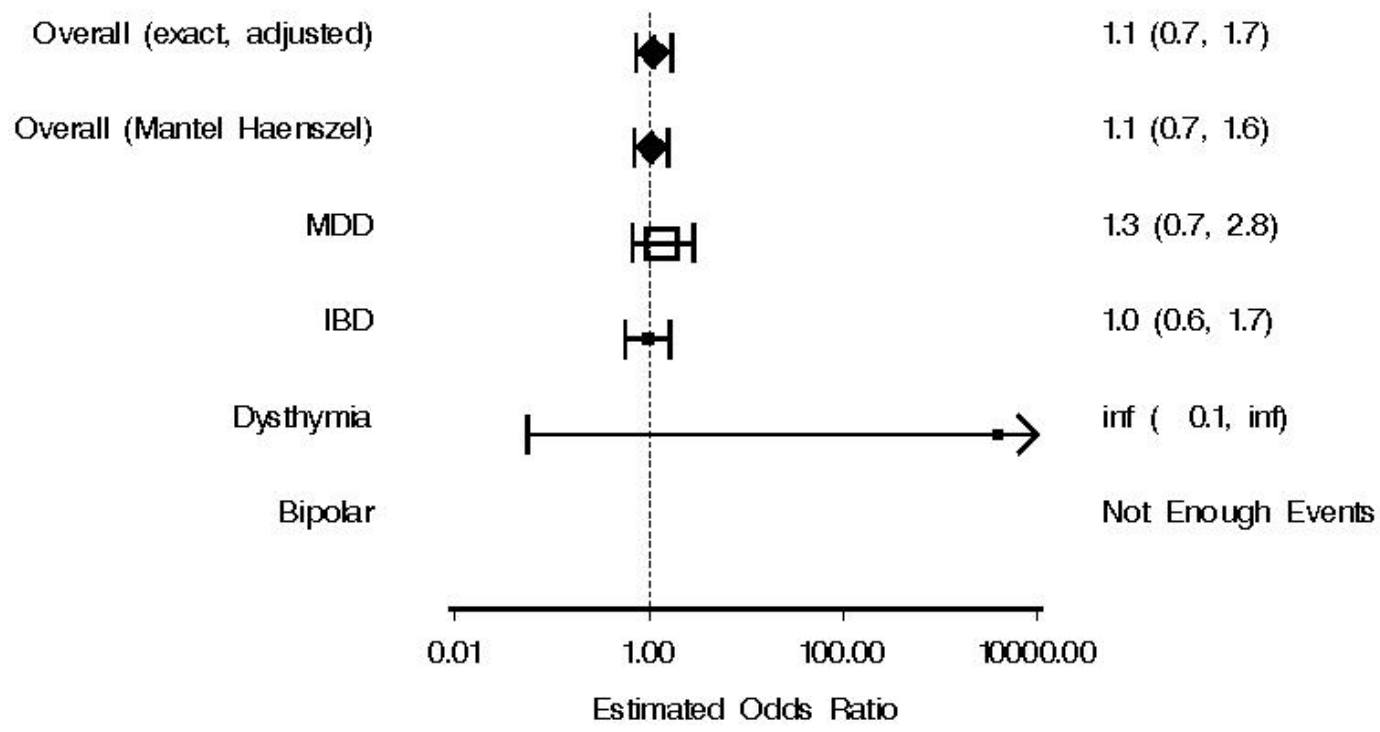
Paroxetine Adult Suicidality Analysis

Figure 2.01. Definitive Suicidal Behaviour and Ideation

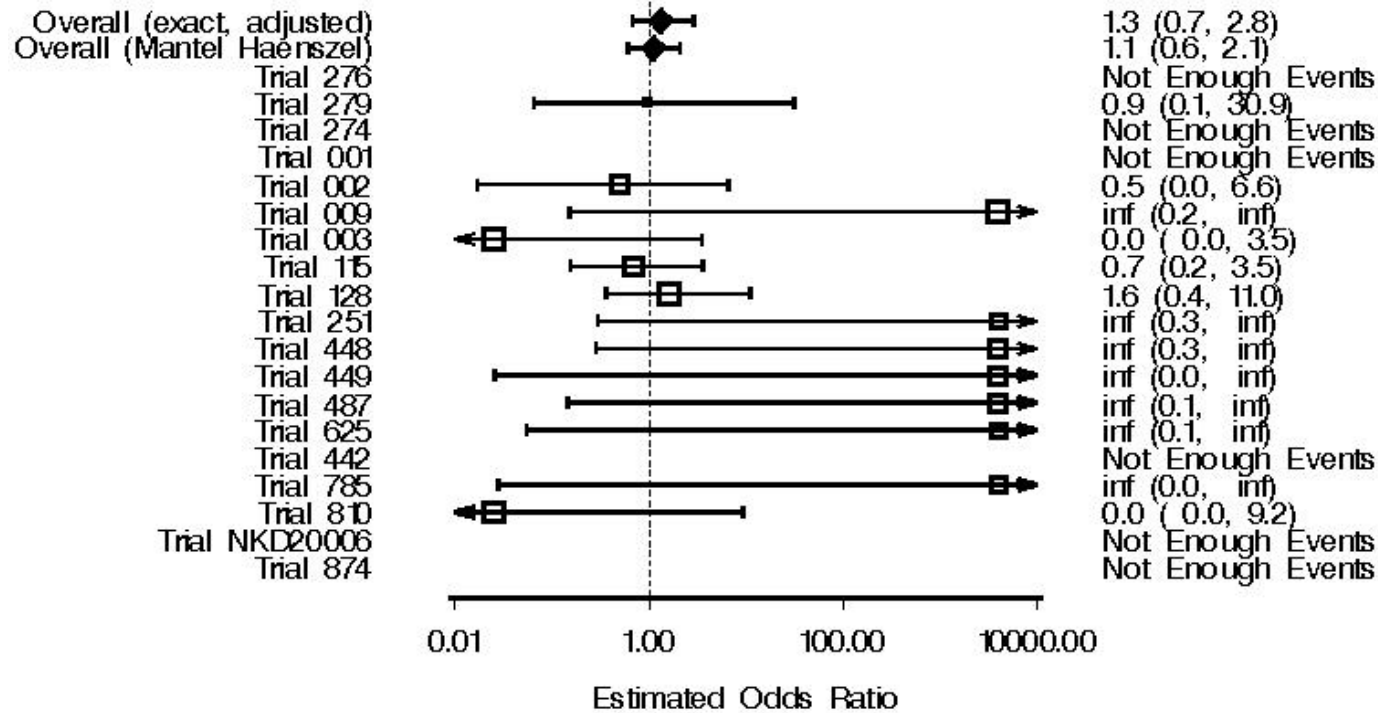
Indication = All Indications



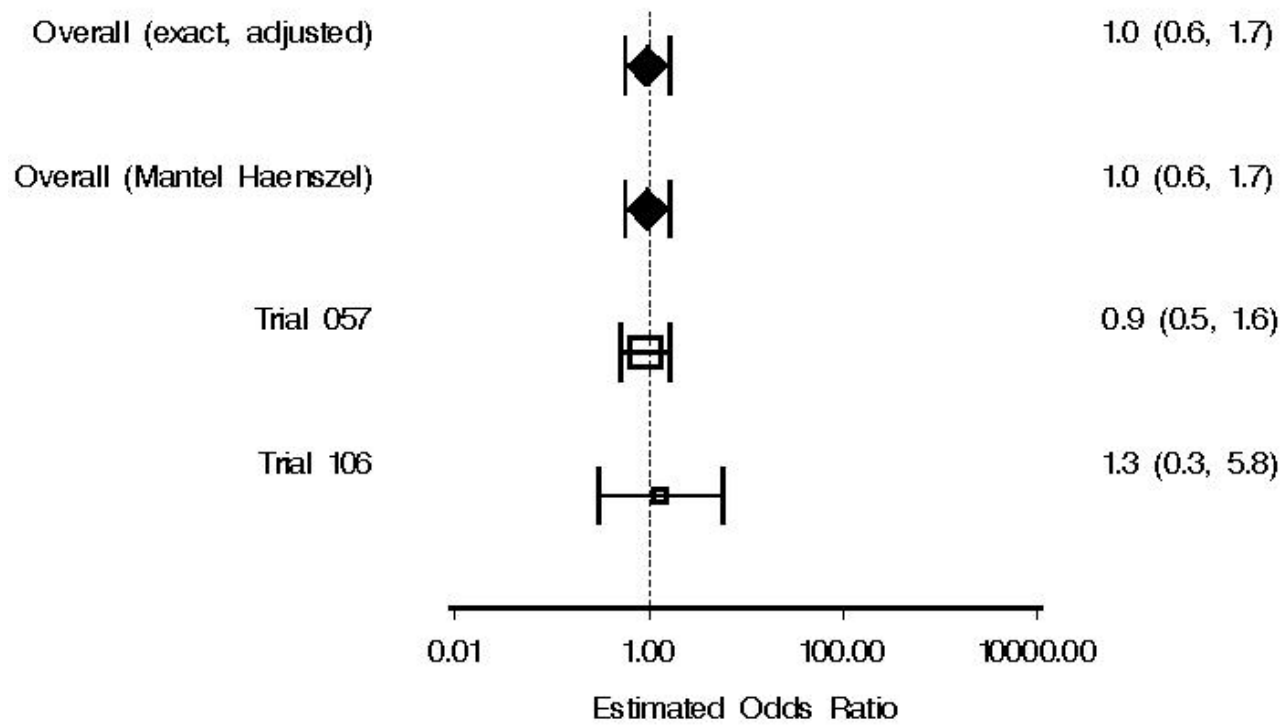
Paroxetine Adult Suicidality Analysis  
Figure 2.01. Definitive Suicidal Behaviour and Ideation  
Indication = All Depression



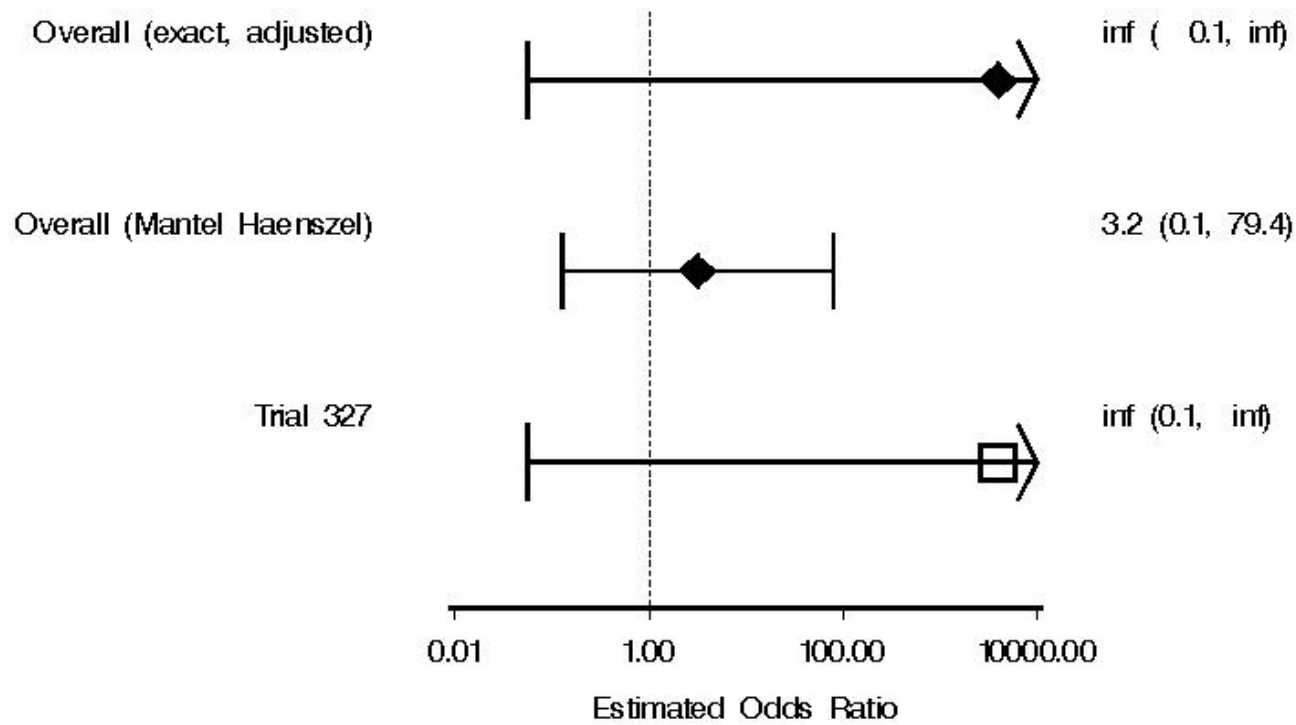
Paroxetine Adult Suicidality Analysis  
 Figure 2.01. Definitive Suicidal Behaviour and Ideation  
 Indication = MDD



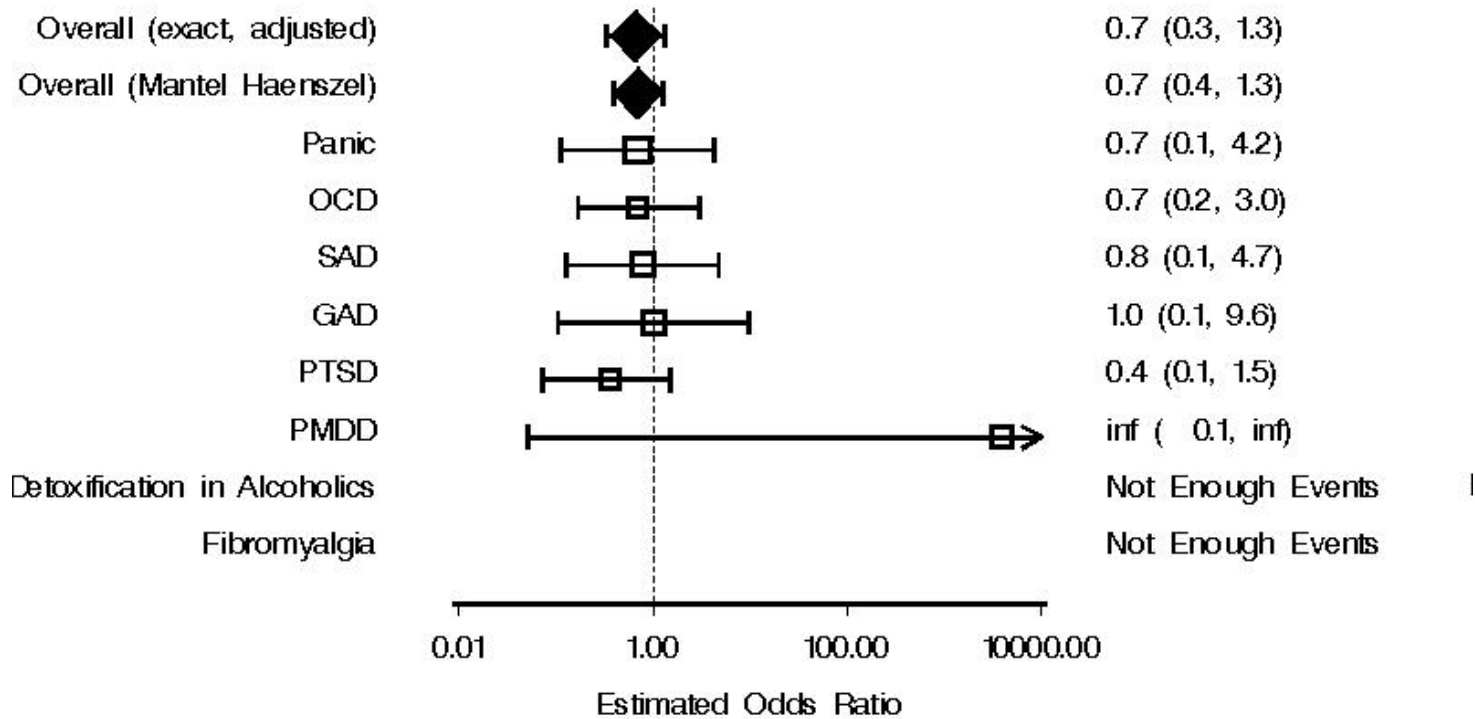
Paroxetine Adult Suicidality Analysis  
Figure 2.01. Definitive Suicidal Behaviour and Ideation  
Indication = IBD



Paroxetine Adult Suicidality Analysis  
Figure 2.01. Definitive Suicidal Behaviour and Ideation  
Indication = Dysthymia

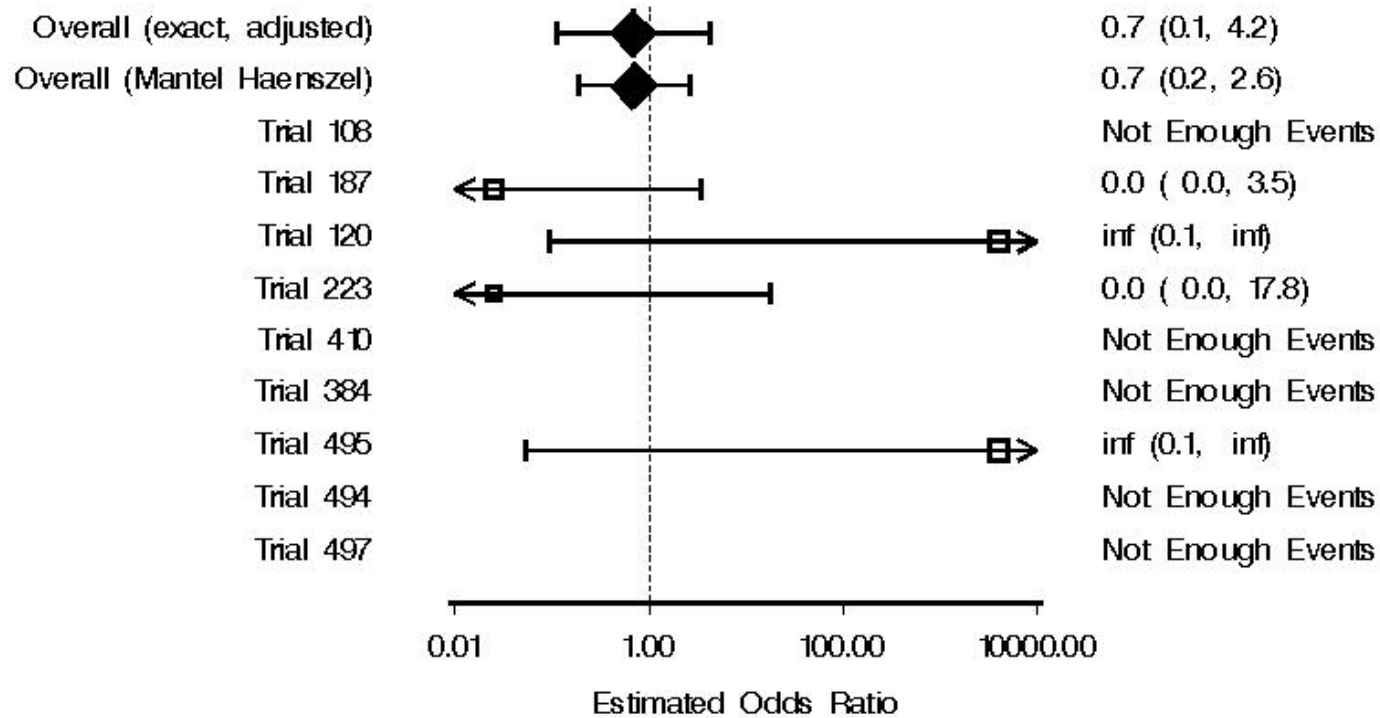


**Paroxetine Adult Suicidality Analysis**  
**Figure 2.01. Definitive Suicidal Behaviour and Ideation**  
**Indication = All Non-Depression**

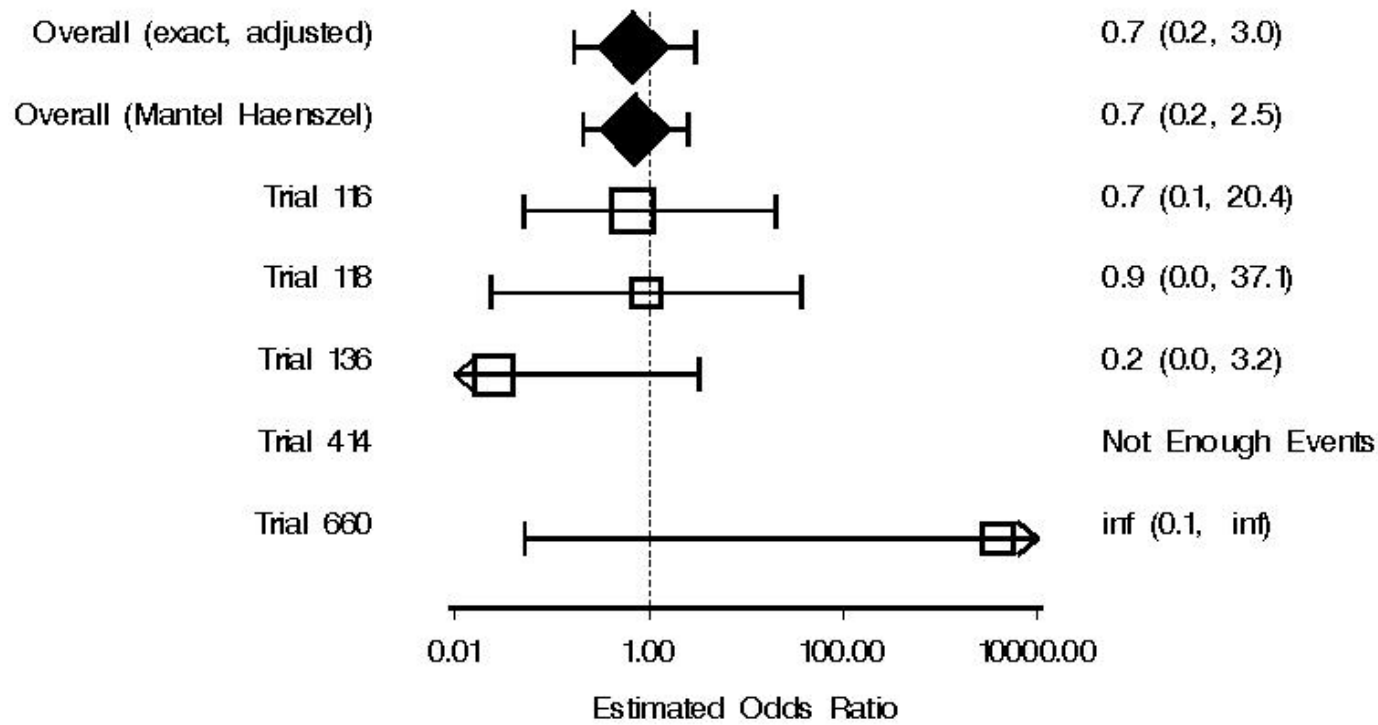




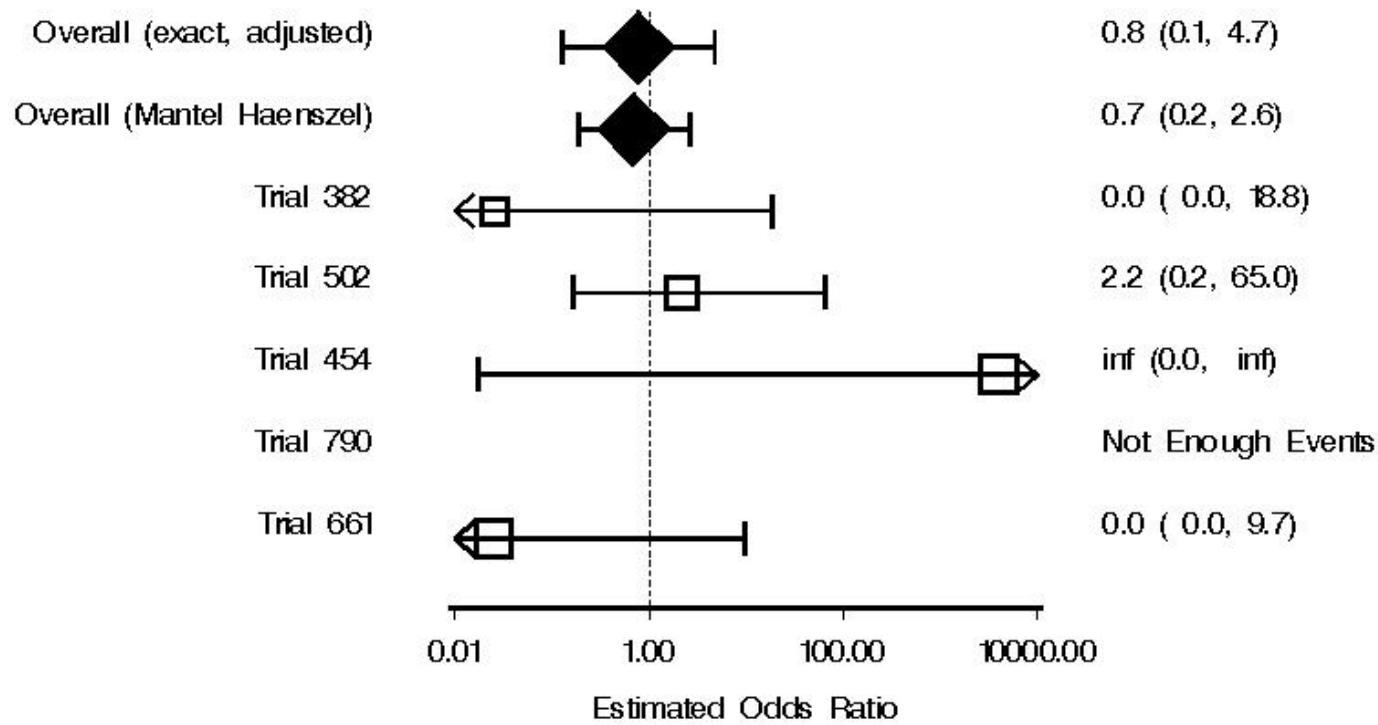
Paroxetine Adult Suicidality Analysis  
 Figure 2.01. Definitive Suicidal Behaviour and Ideation  
 Indication = Panic



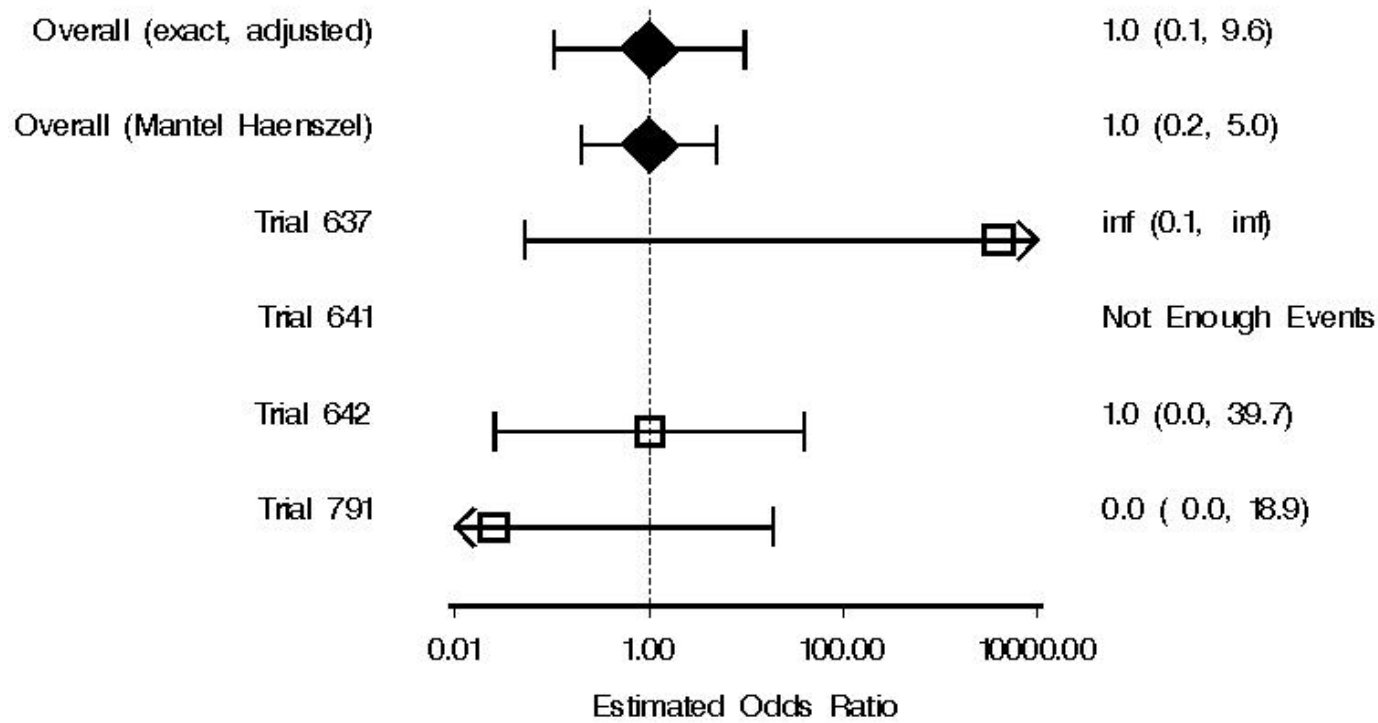
Paroxetine Adult Suicidality Analysis  
 Figure 2.01. Definitive Suicidal Behaviour and Ideation  
 Indication = OCD



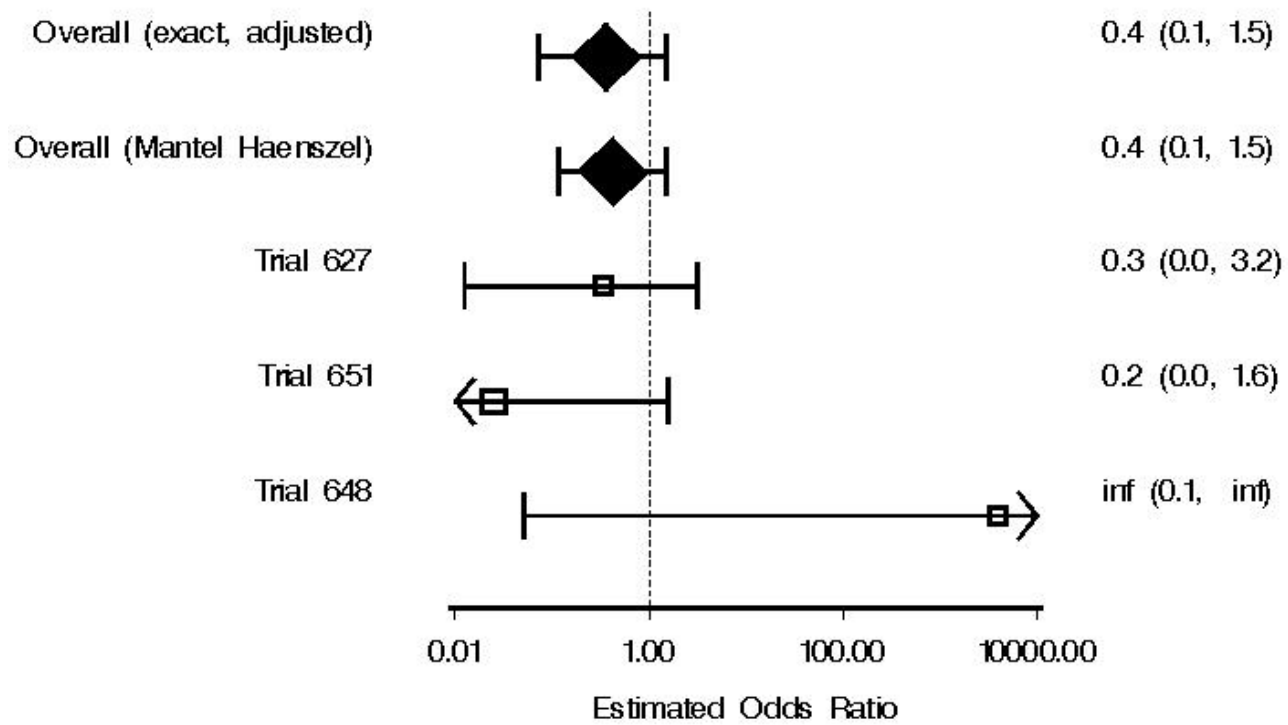
Paroxetine Adult Suicidality Analysis  
 Figure 2.01. Definitive Suicidal Behaviour and Ideation  
 Indication = SAD



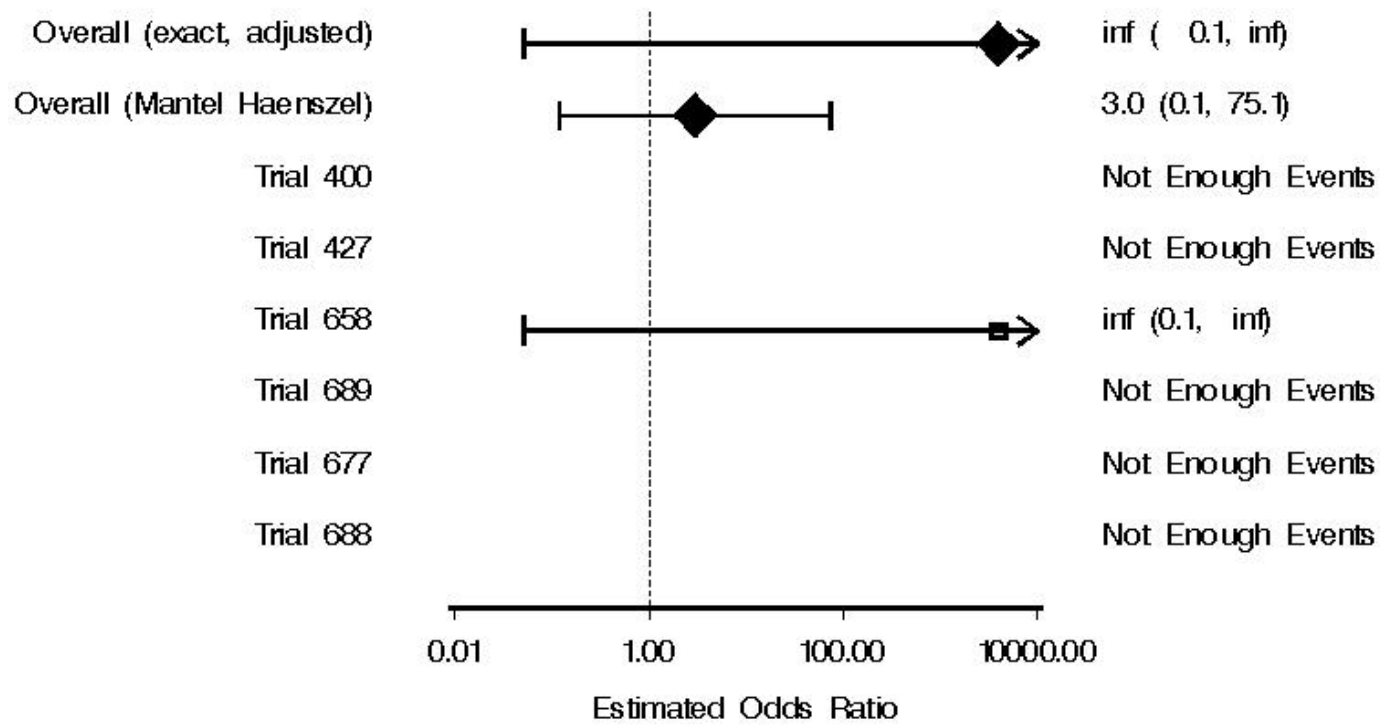
**Paroxetine Adult Suicidality Analysis**  
**Figure 2.01. Definitive Suicidal Behaviour and Ideation**  
**Indication = GAD**



Paroxetine Adult Suicidality Analysis  
Figure 2.01. Definitive Suicidal Behaviour and Ideation  
Indication = PTSD

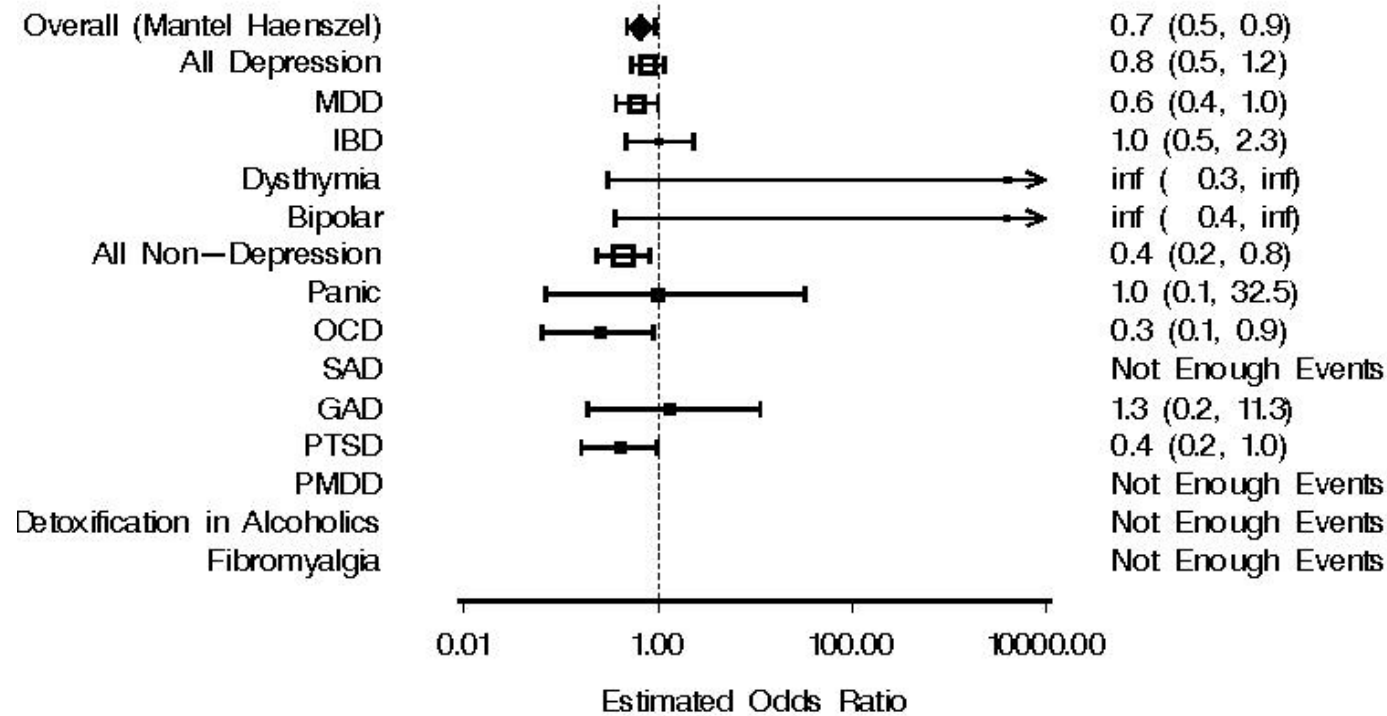


Paroxetine Adult Suicidality Analysis  
Figure 2.01. Definitive Suicidal Behaviour and Ideation  
Indication = PMDD

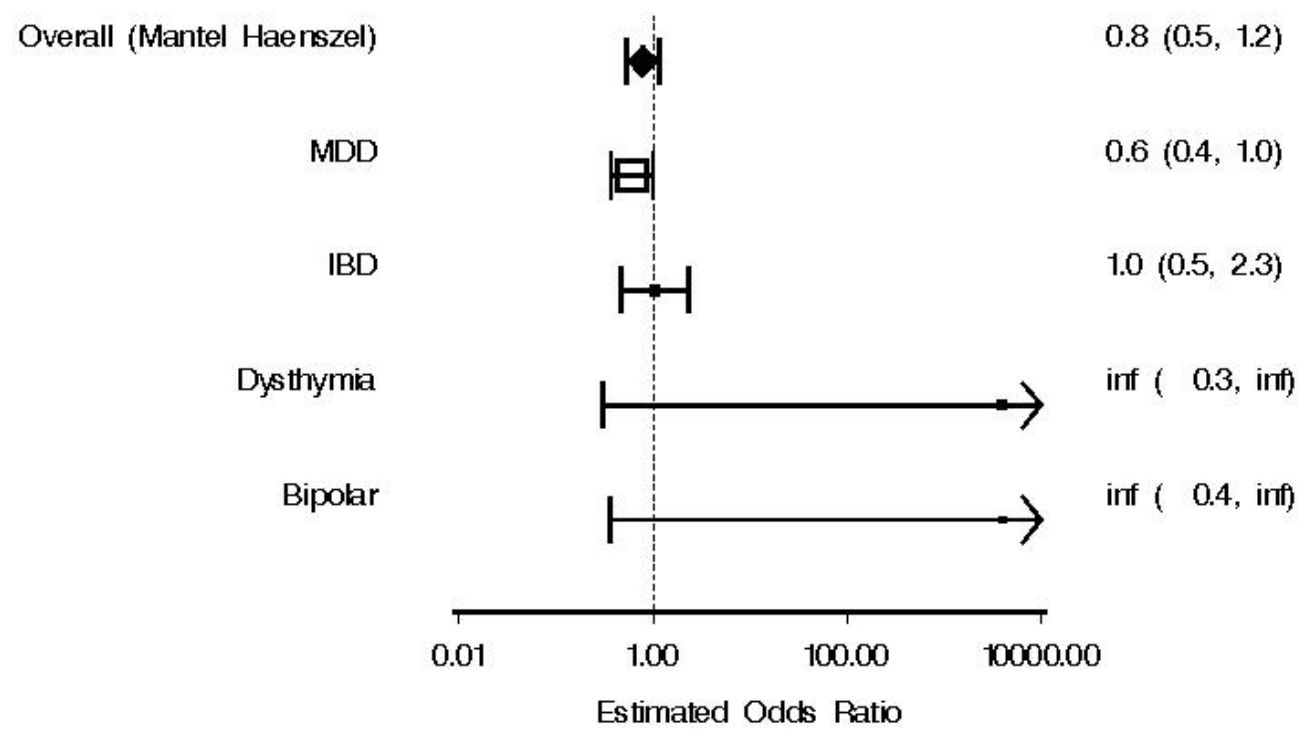


Paroxetine Adult Suicidality Analysis

Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation  
Indication = All Indications



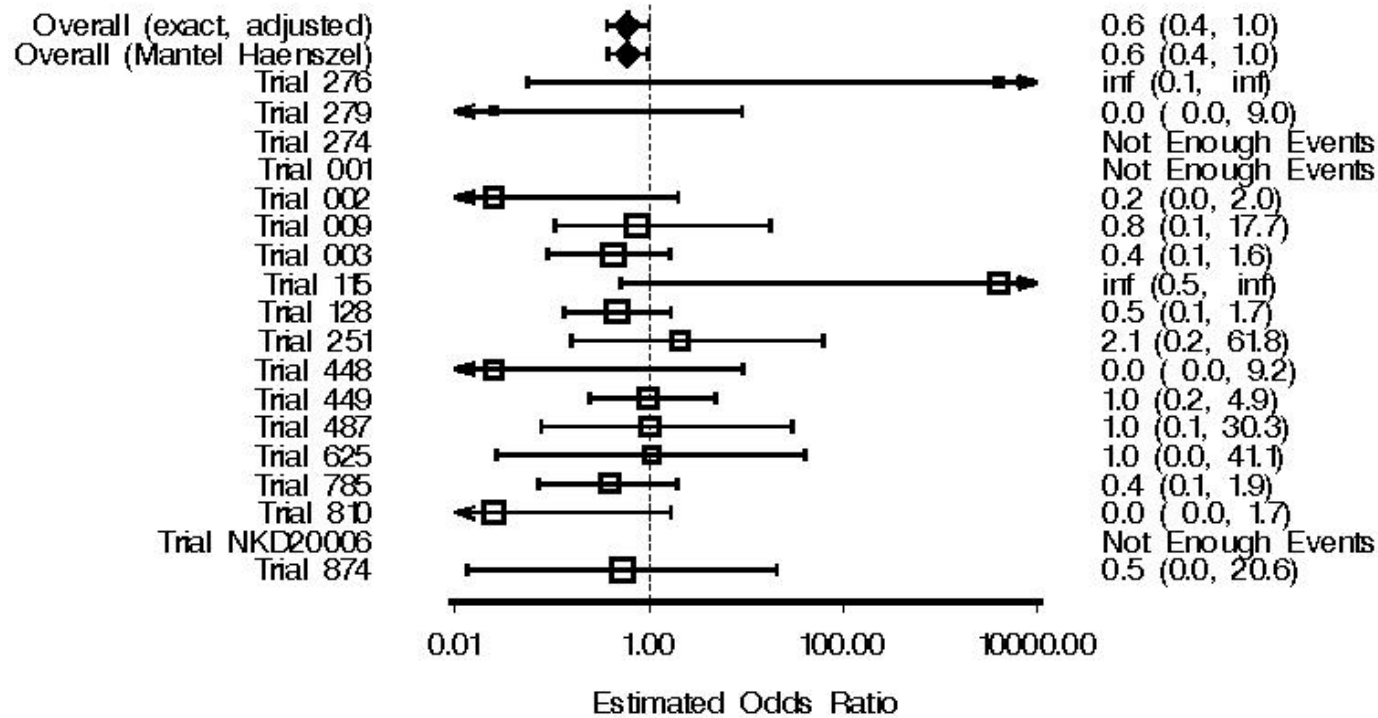
Paroxetine Adult Suicidality Analysis  
Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation  
Indication = All Depression





Paroxetine Adult Suicidality Analysis

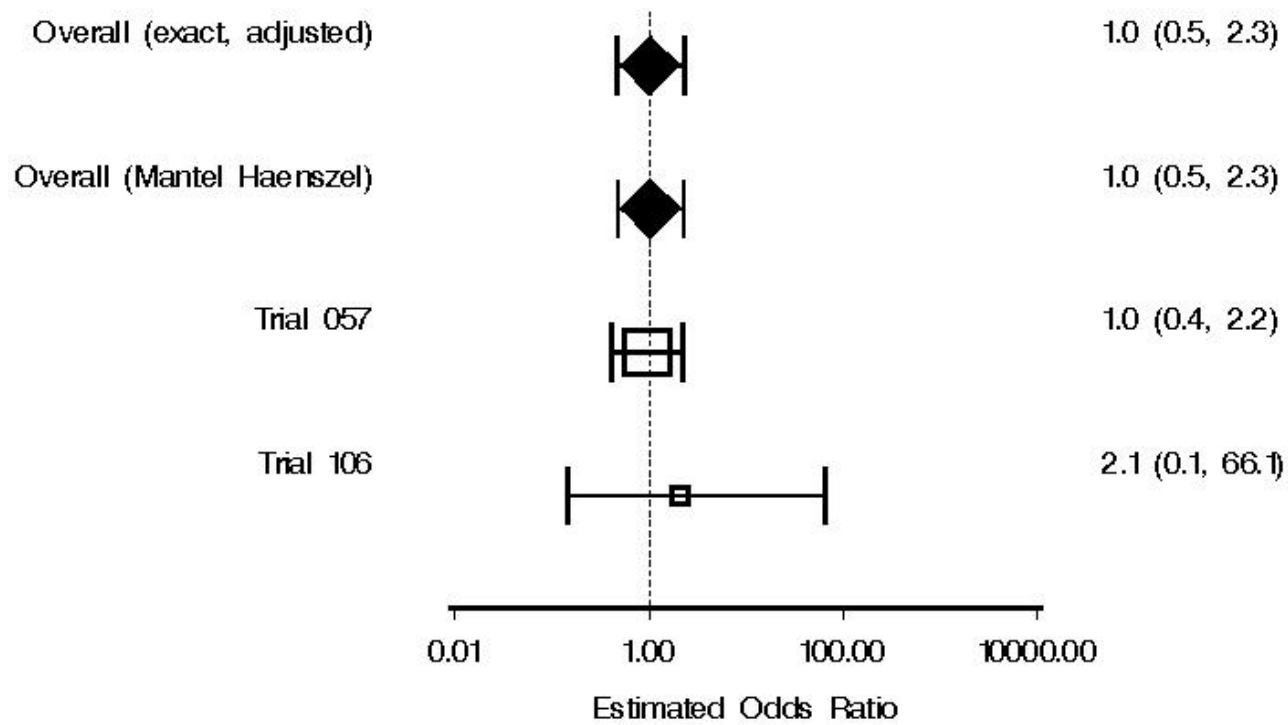
Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation  
Indication = MDD



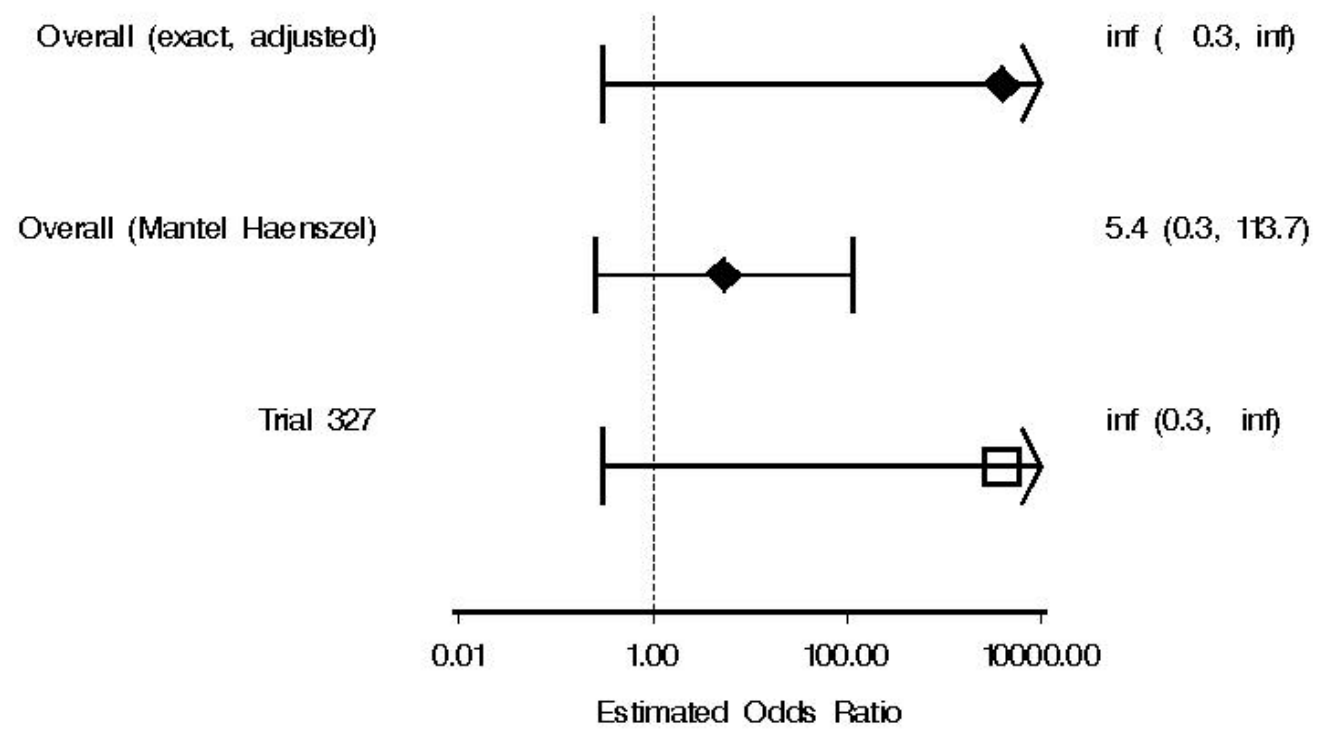
NOTE: Rating Scale Emergent Suicidal Behaviour and Ideation data was not available in Study 442

### Paroxetine Adult Suicidality Analysis

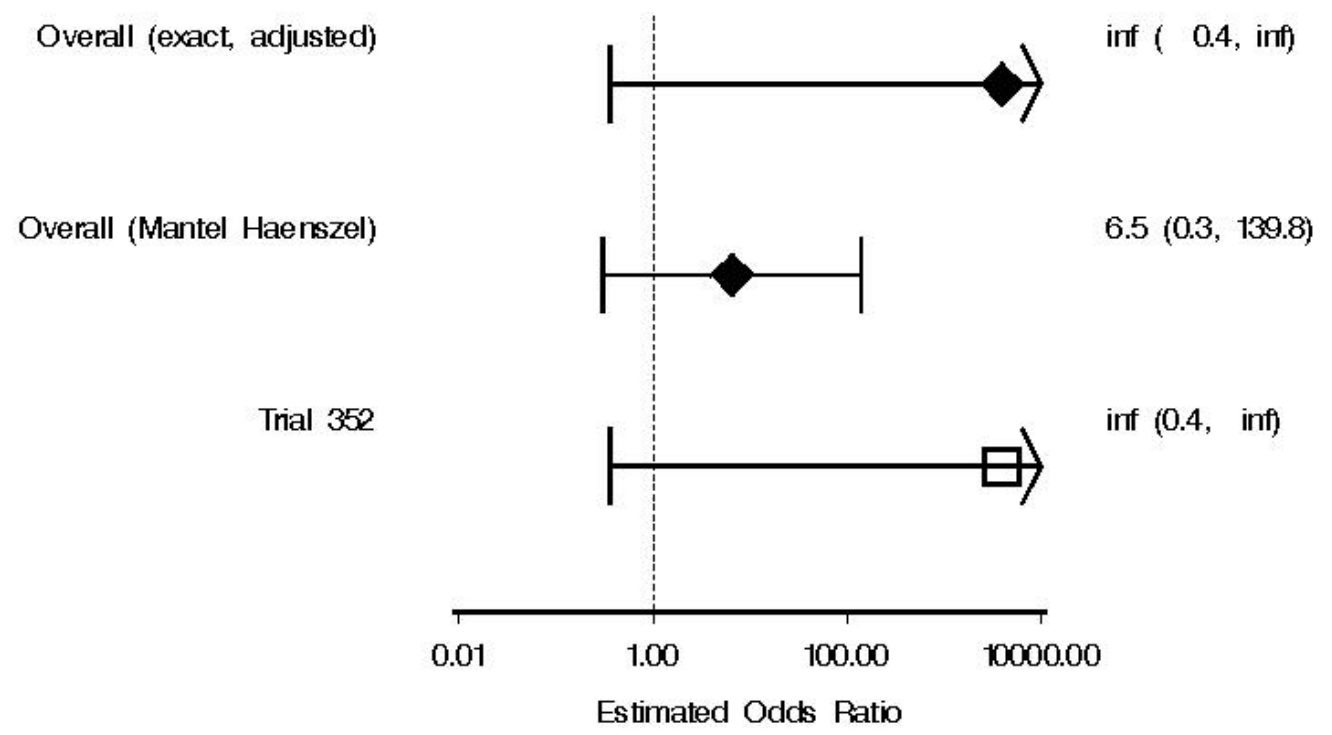
Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation  
Indication = IBD



Paroxetine Adult Suicidality Analysis  
Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation  
Indication = Dysthymia

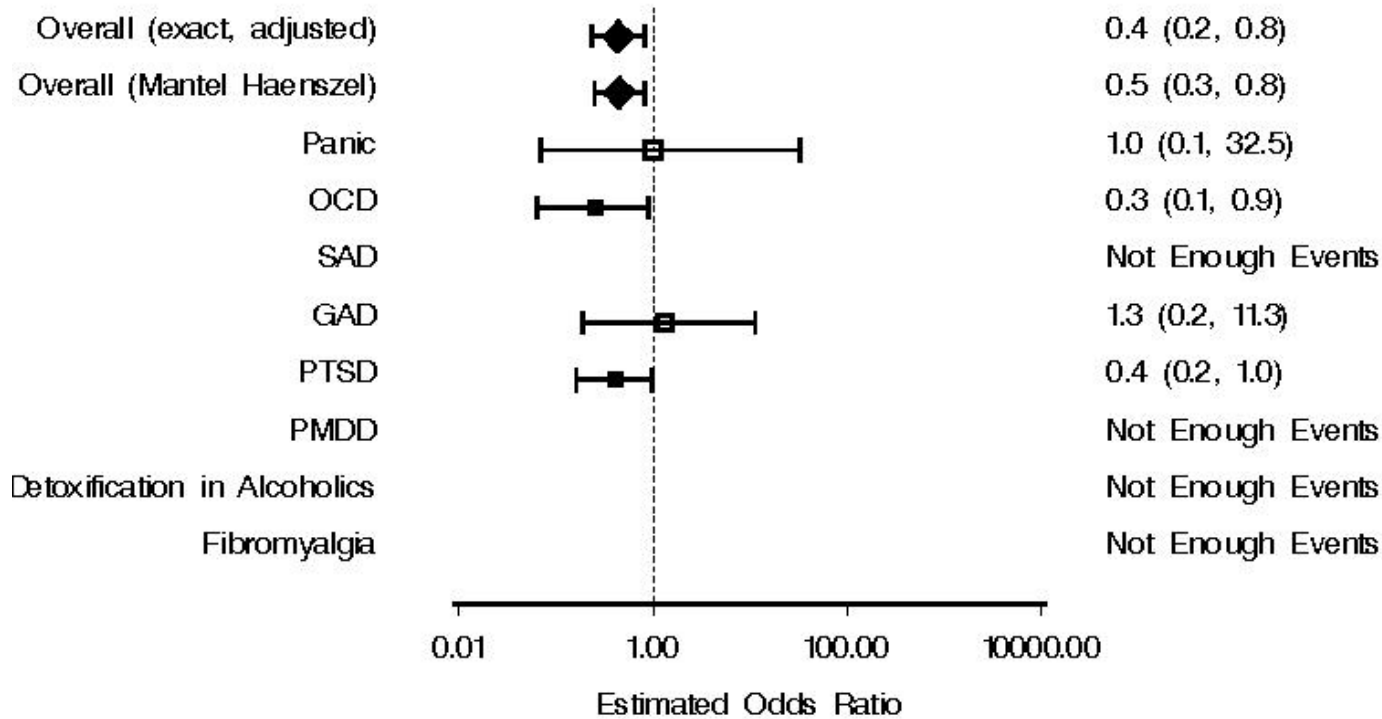


Paroxetine Adult Suicidality Analysis  
Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation  
Indication = Bipolar



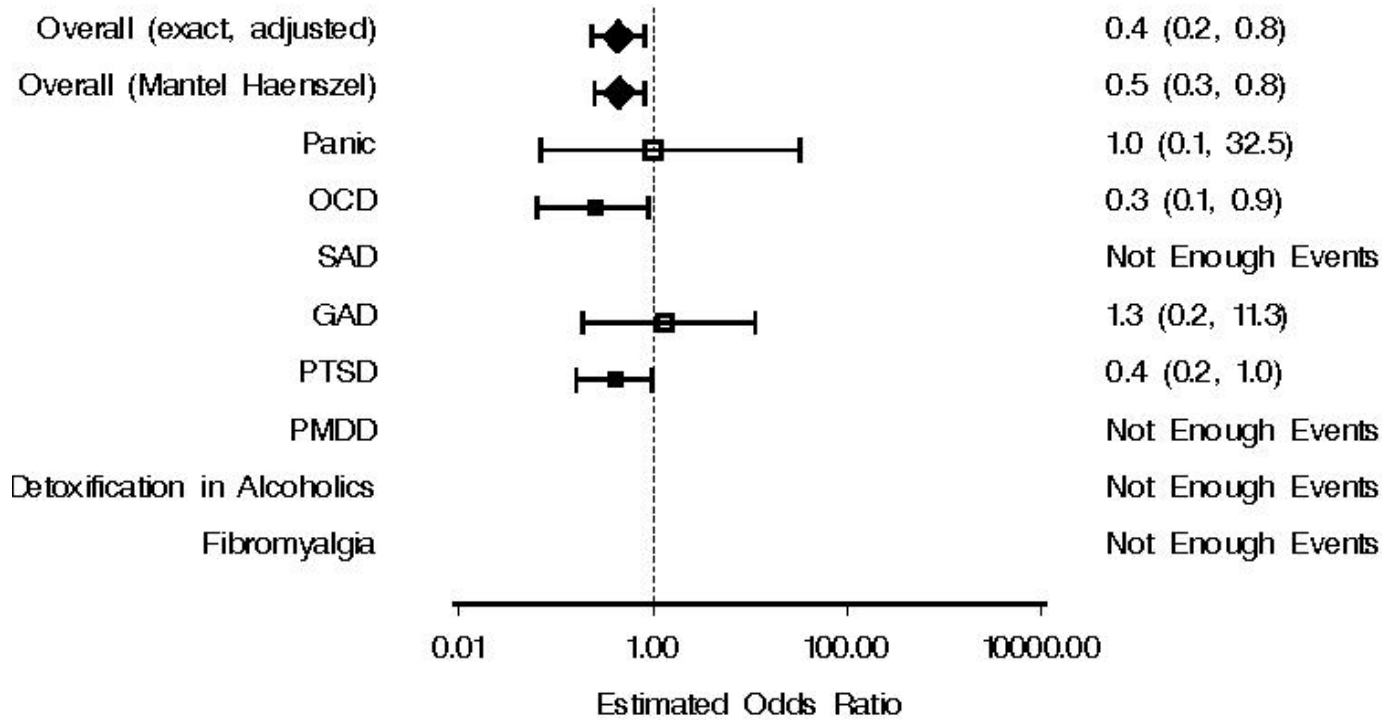
Paroxetine Adult Suicidality Analysis

Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation  
 Indication = All Non-Depression



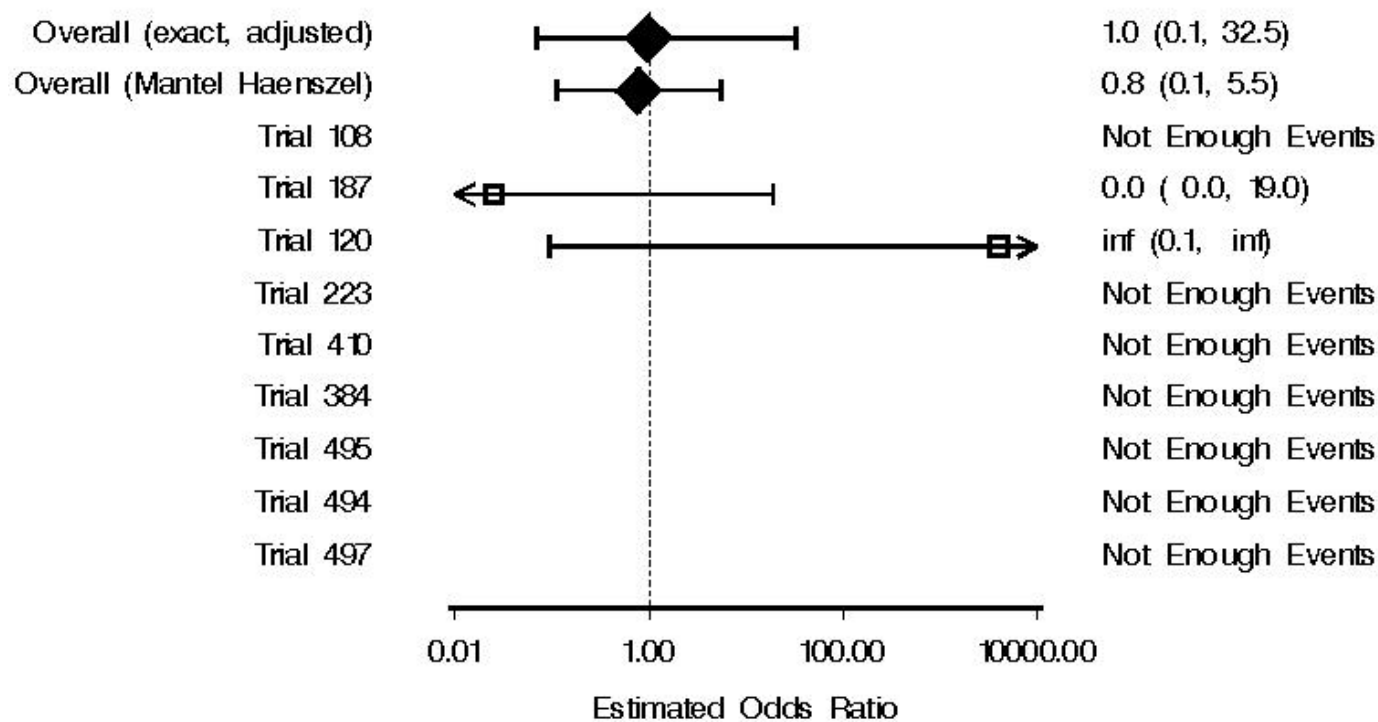
Paroxetine Adult Suicidality Analysis

Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation  
 Indication = All Non-Depression



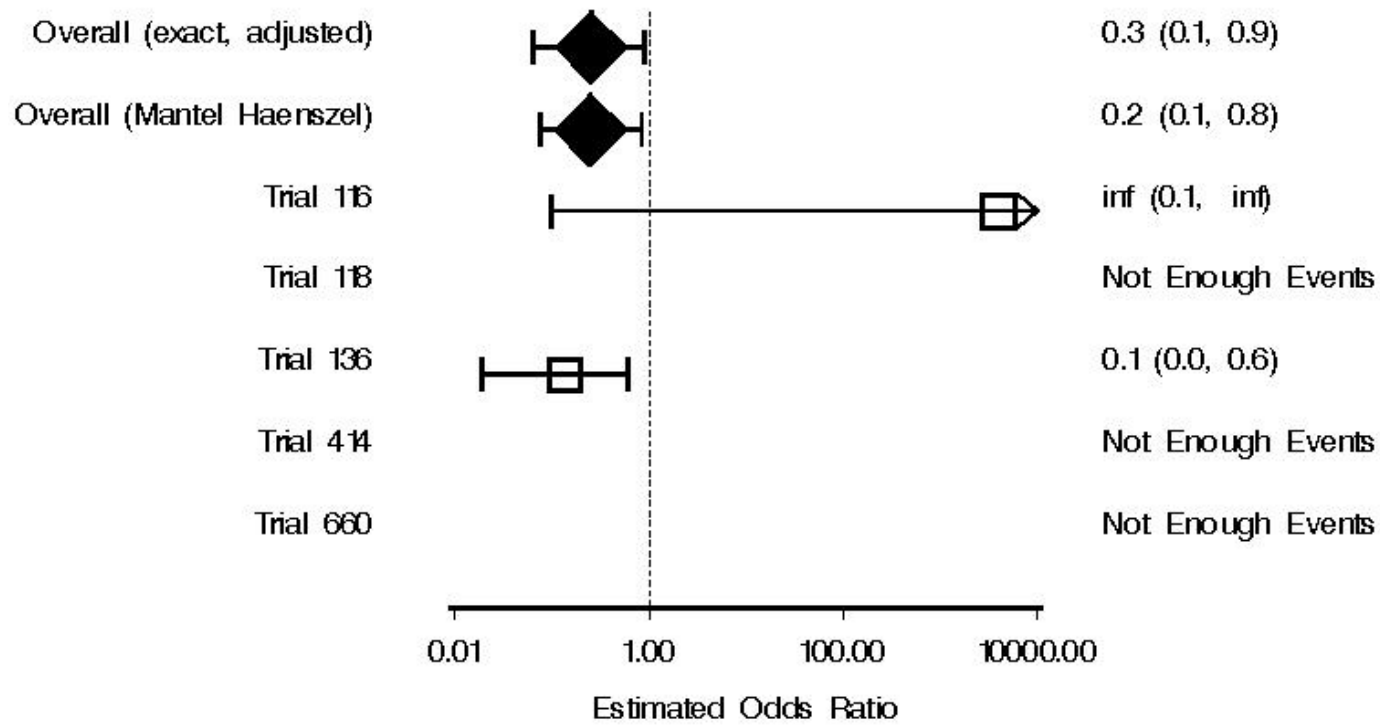
Paroxetine Adult Suicidality Analysis

Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation  
Indication = Panic



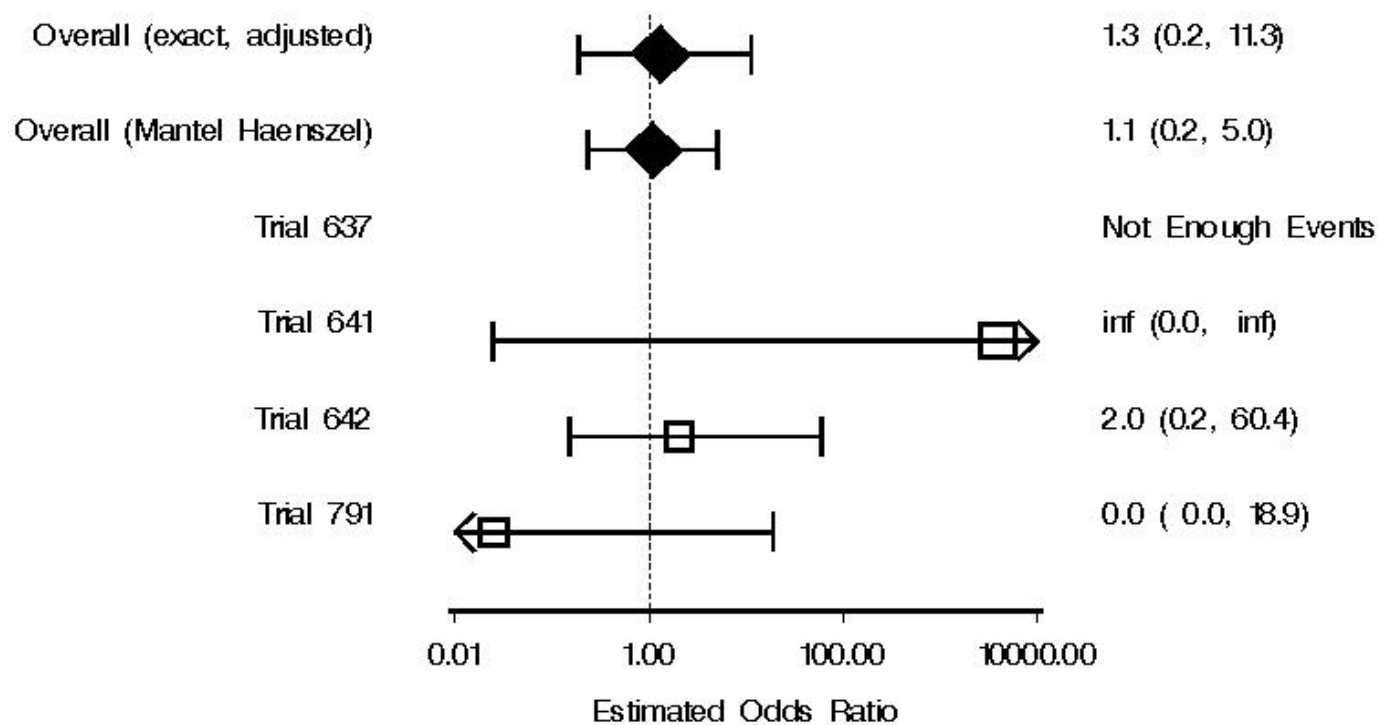
Paroxetine Adult Suicidality Analysis

Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation  
Indication = OCD

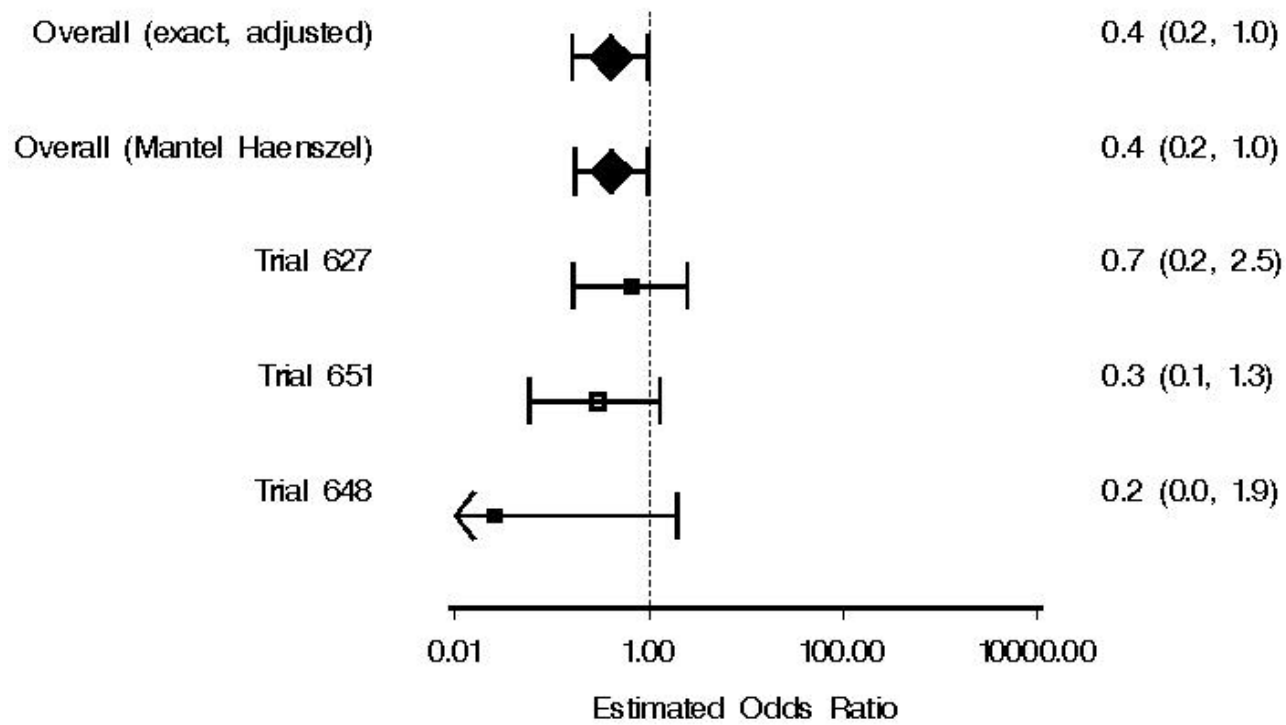




**Paroxetine Adult Suicidality Analysis**  
**Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation**  
**Indication = GAD**



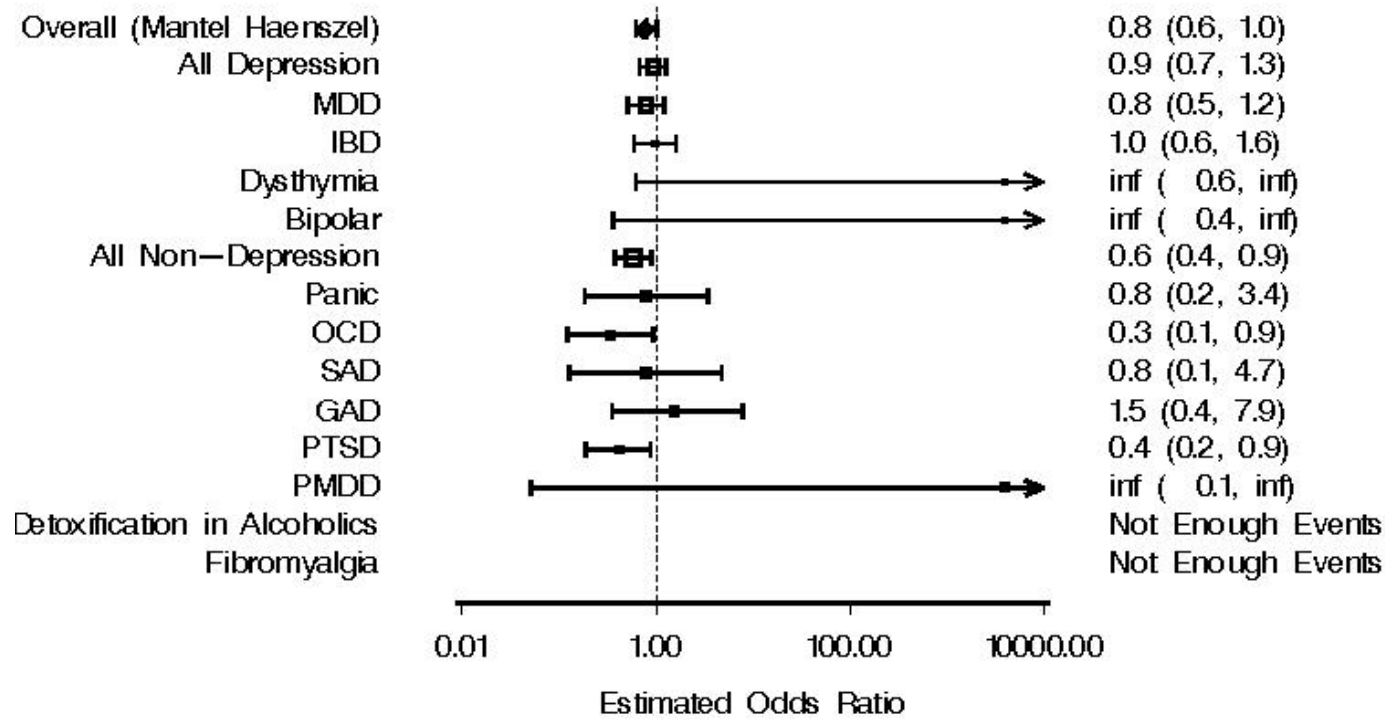
Paroxetine Adult Suicidality Analysis  
Figure 2.02. Rating Scale Emergent Suicidal Behaviour and Ideation  
Indication = PTSD



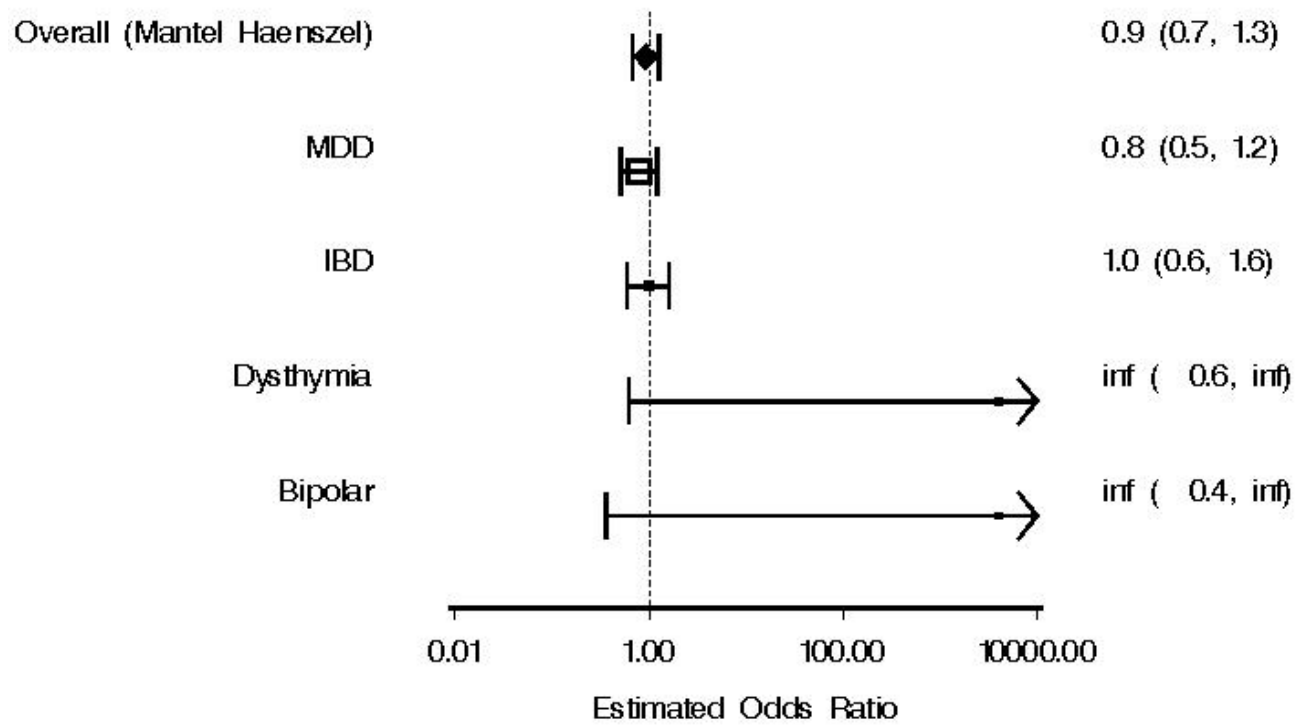
Paroxetine Adult Suicidality Analysis

Figure 2.03. Composite Suicidal Behaviour and Ideation

Indication = All Indications



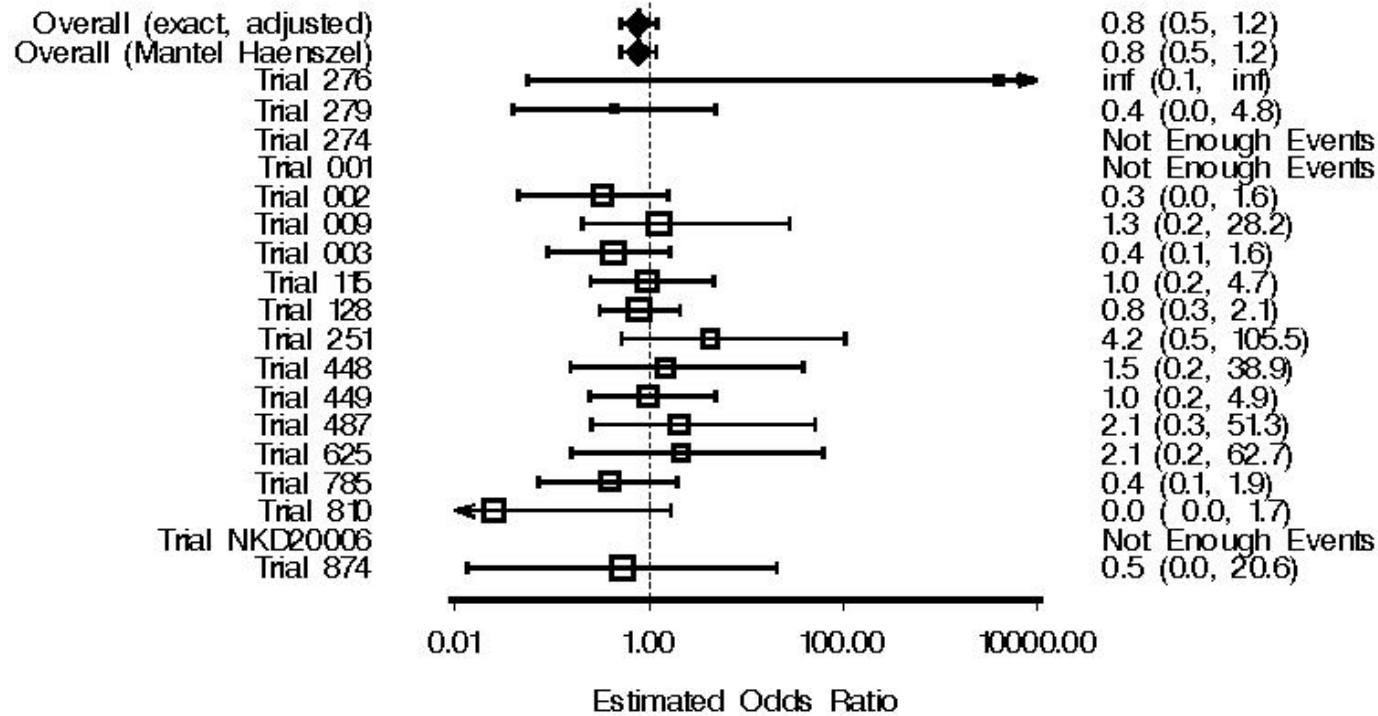
Paroxetine Adult Suicidality Analysis  
Figure 2.03. Composite Suicidal Behaviour and Ideation  
Indication = All Depression



Paroxetine Adult Suicidality Analysis

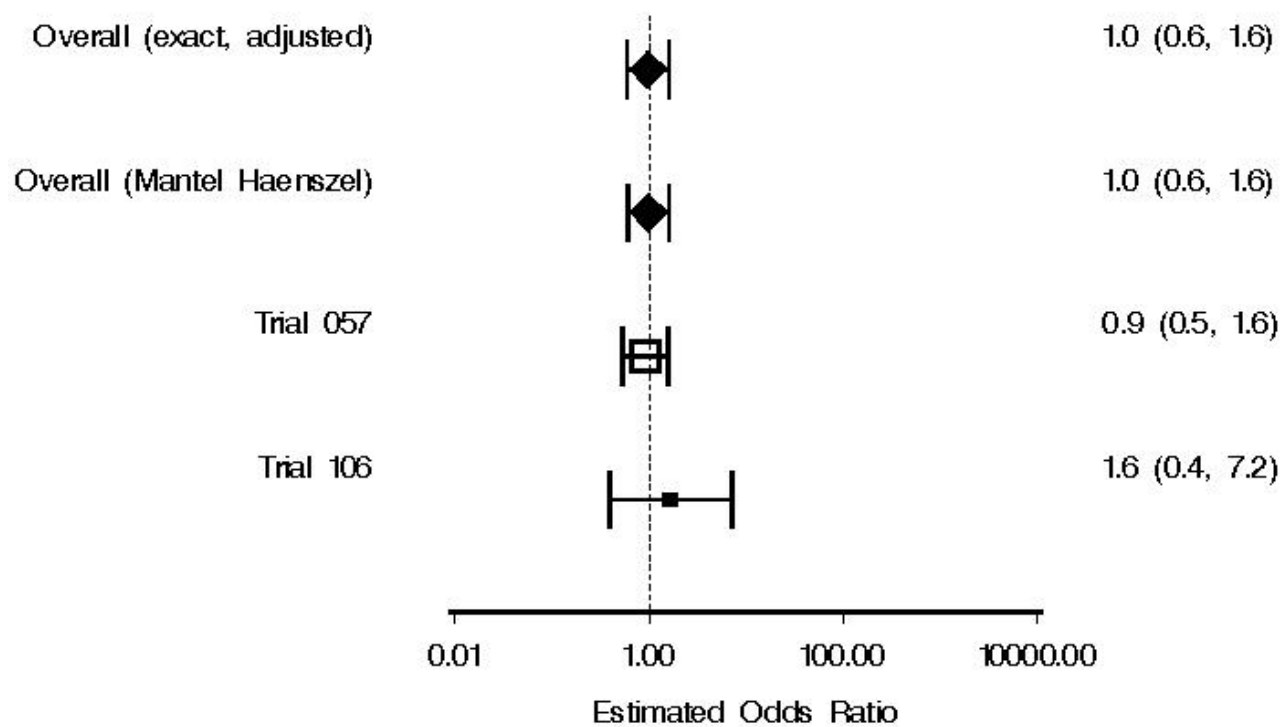
Figure 2.03. Composite Suicidal Behaviour and Ideation

Indication = MDD

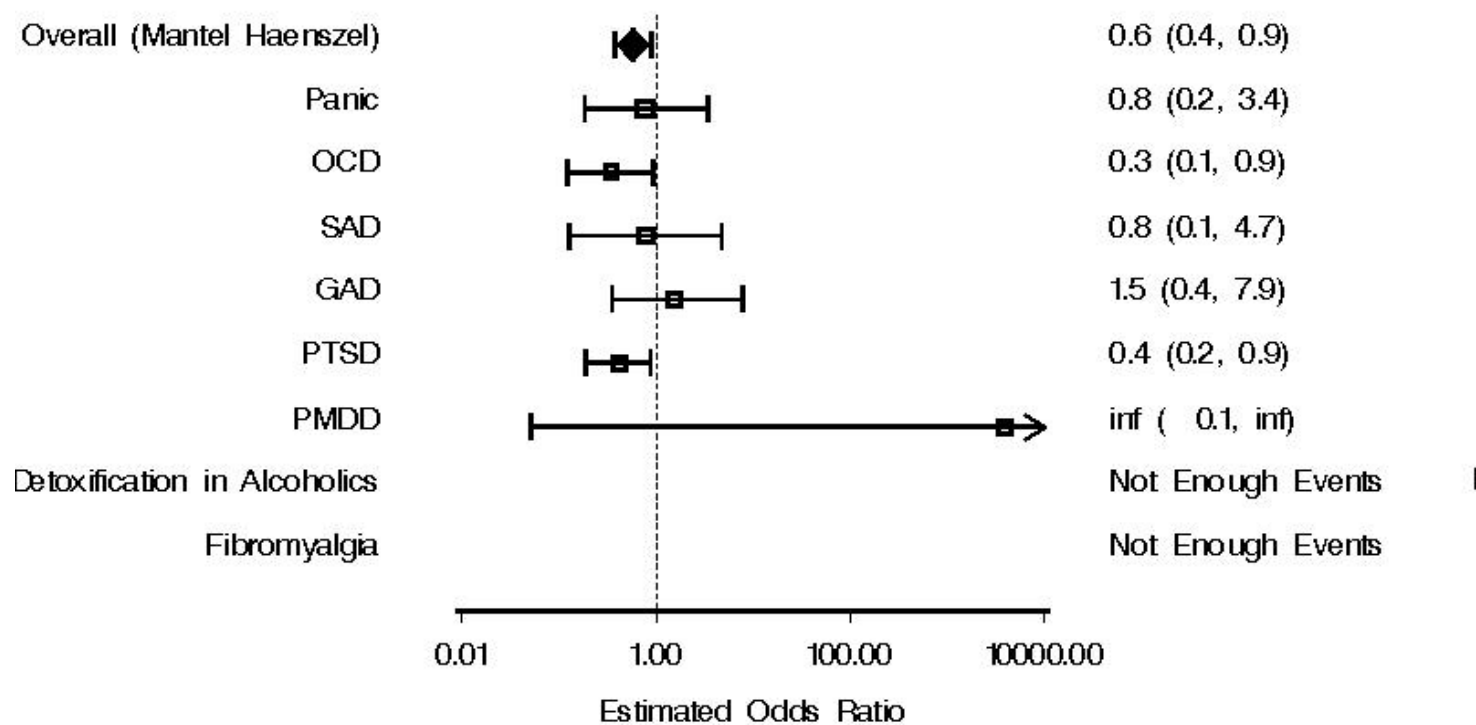


NOTE: Composite Suicidal Behaviour and Ideation data was not available in Study 442

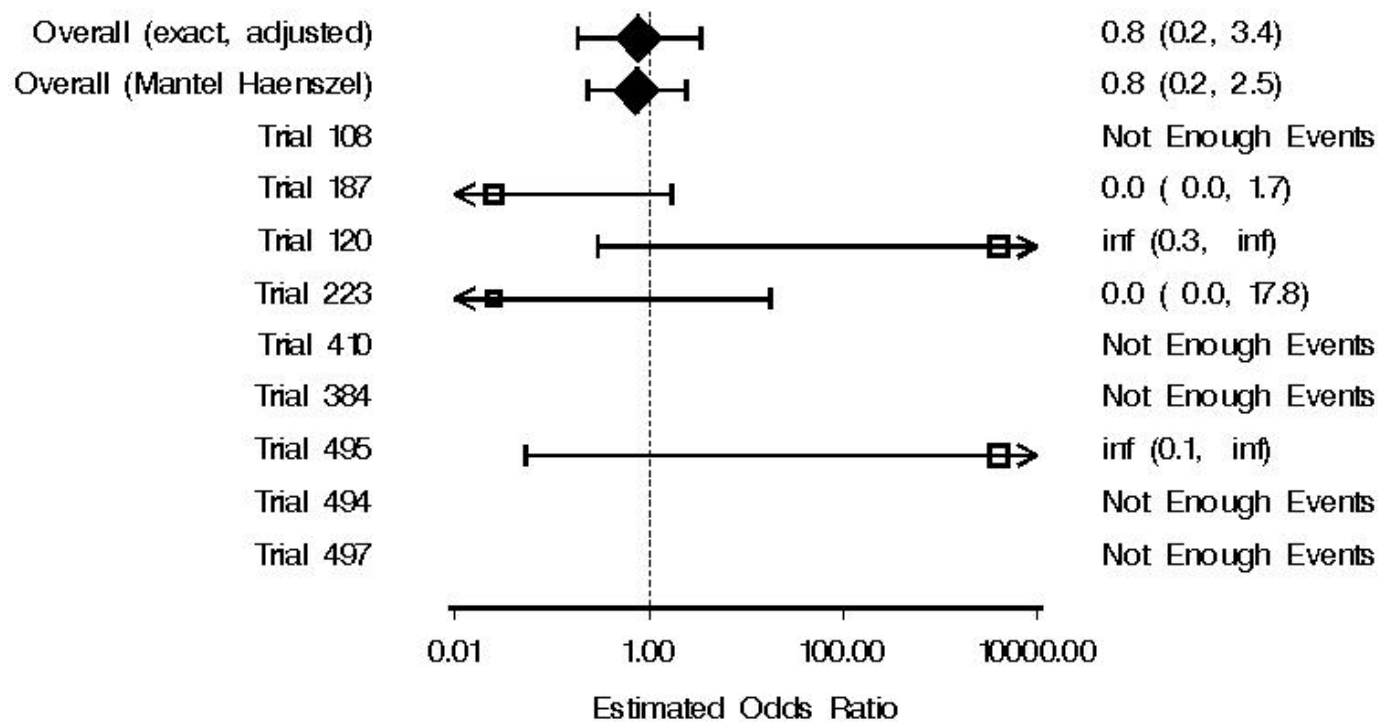
Paroxetine Adult Suicidality Analysis  
Figure 2.03. Composite Suicidal Behaviour and Ideation  
Indication = IBD



Paroxetine Adult Suicidality Analysis  
 Figure 2.03. Composite Suicidal Behaviour and Ideation  
 Indication = All Non-Depression

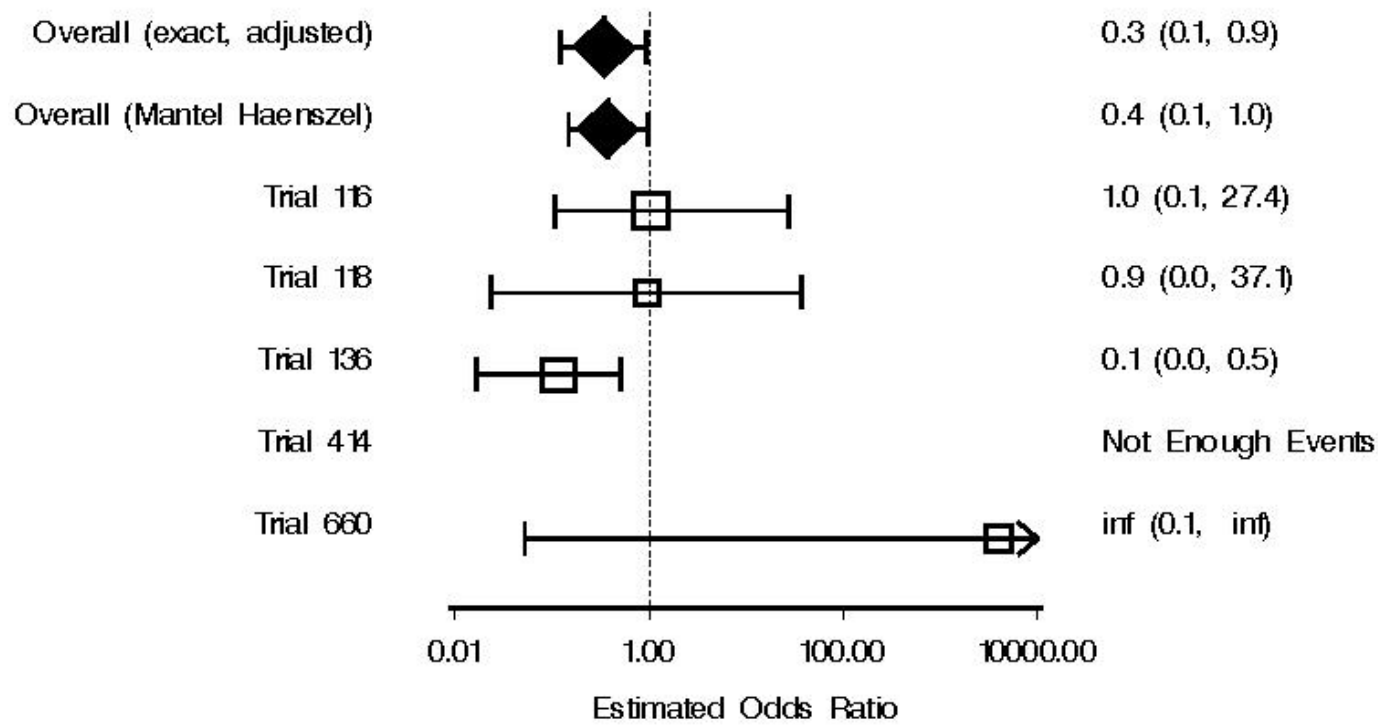


Paroxetine Adult Suicidality Analysis  
 Figure 2.03. Composite Suicidal Behaviour and Ideation  
 Indication = Panic

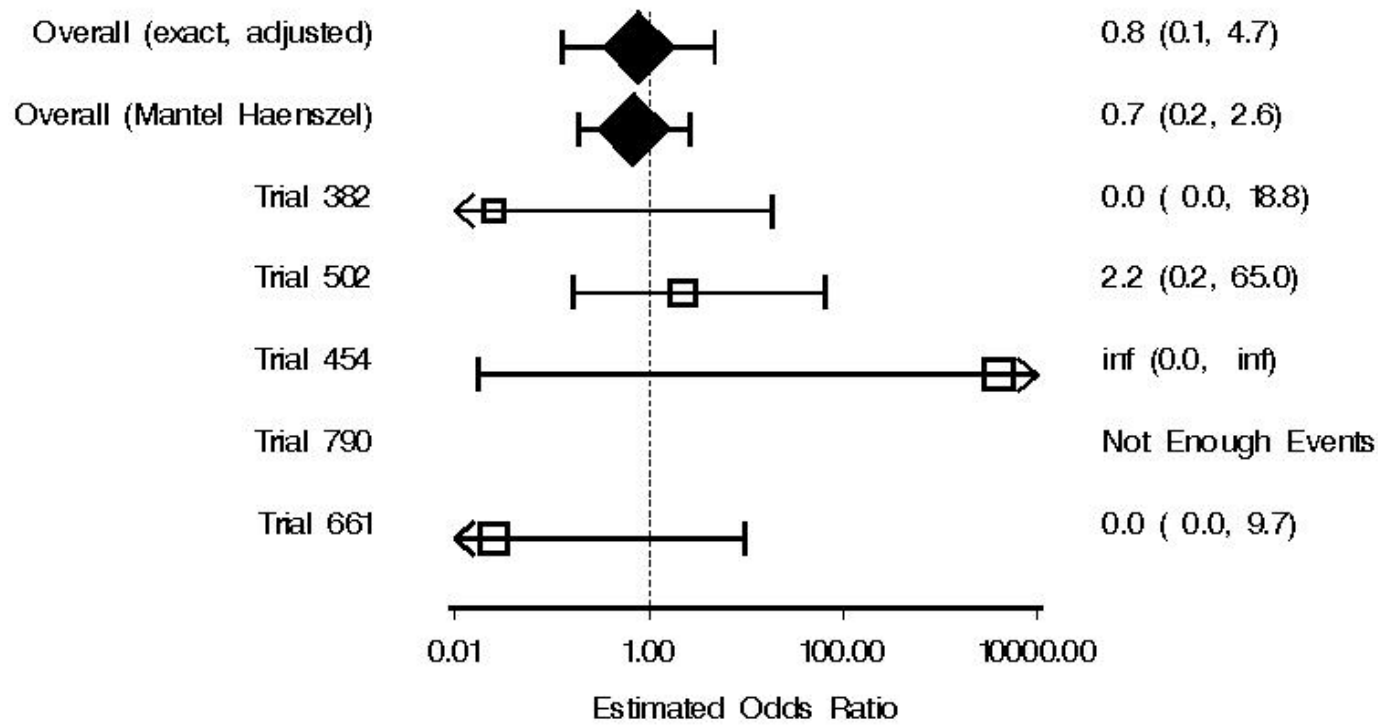




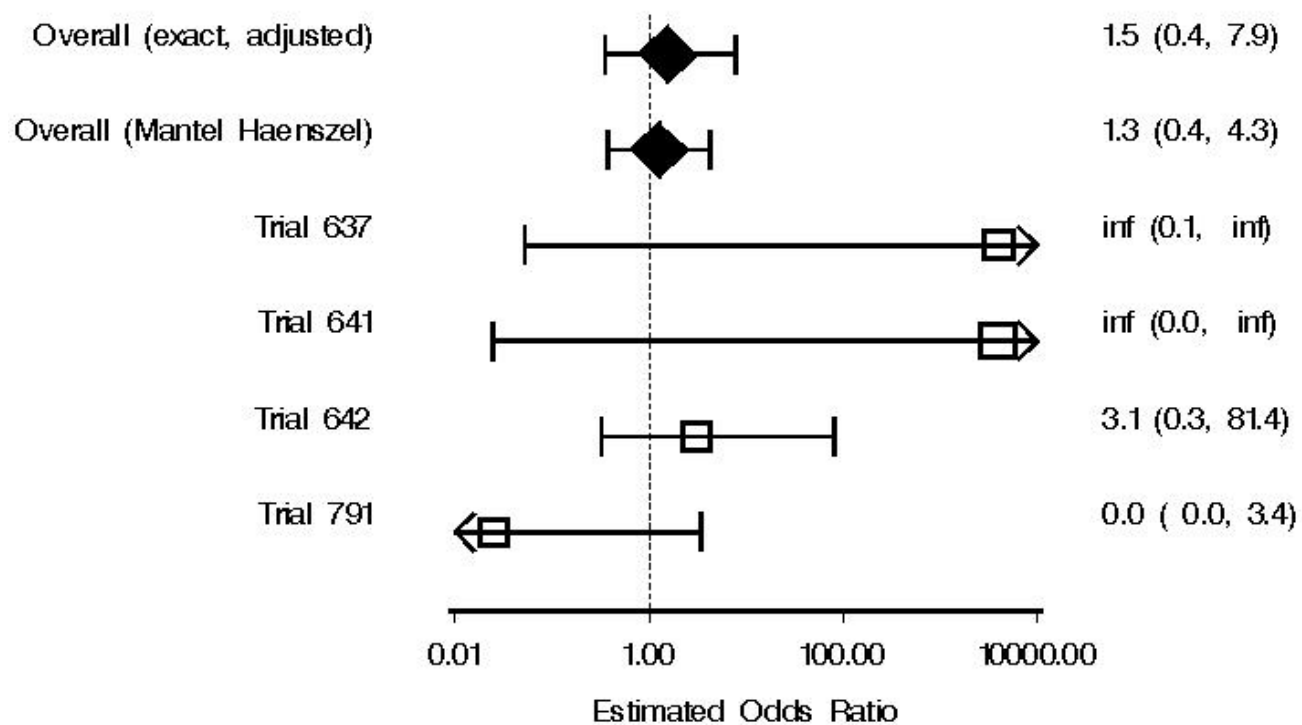
Paroxetine Adult Suicidality Analysis  
 Figure 2.03. Composite Suicidal Behaviour and Ideation  
 Indication = OCD



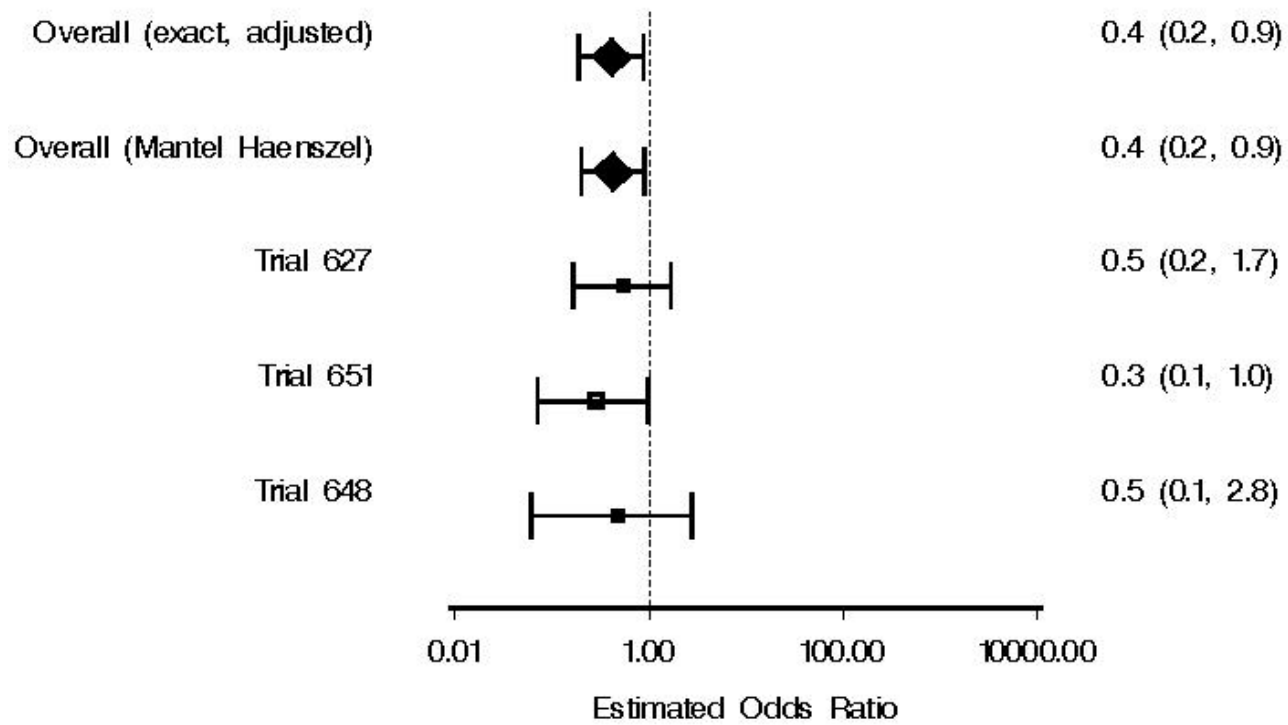
**Paroxetine Adult Suicidality Analysis**  
**Figure 2.03. Composite Suicidal Behaviour and Ideation**  
**Indication = SAD**



Paroxetine Adult Suicidality Analysis  
 Figure 2.03. Composite Suicidal Behaviour and Ideation  
 Indication = GAD

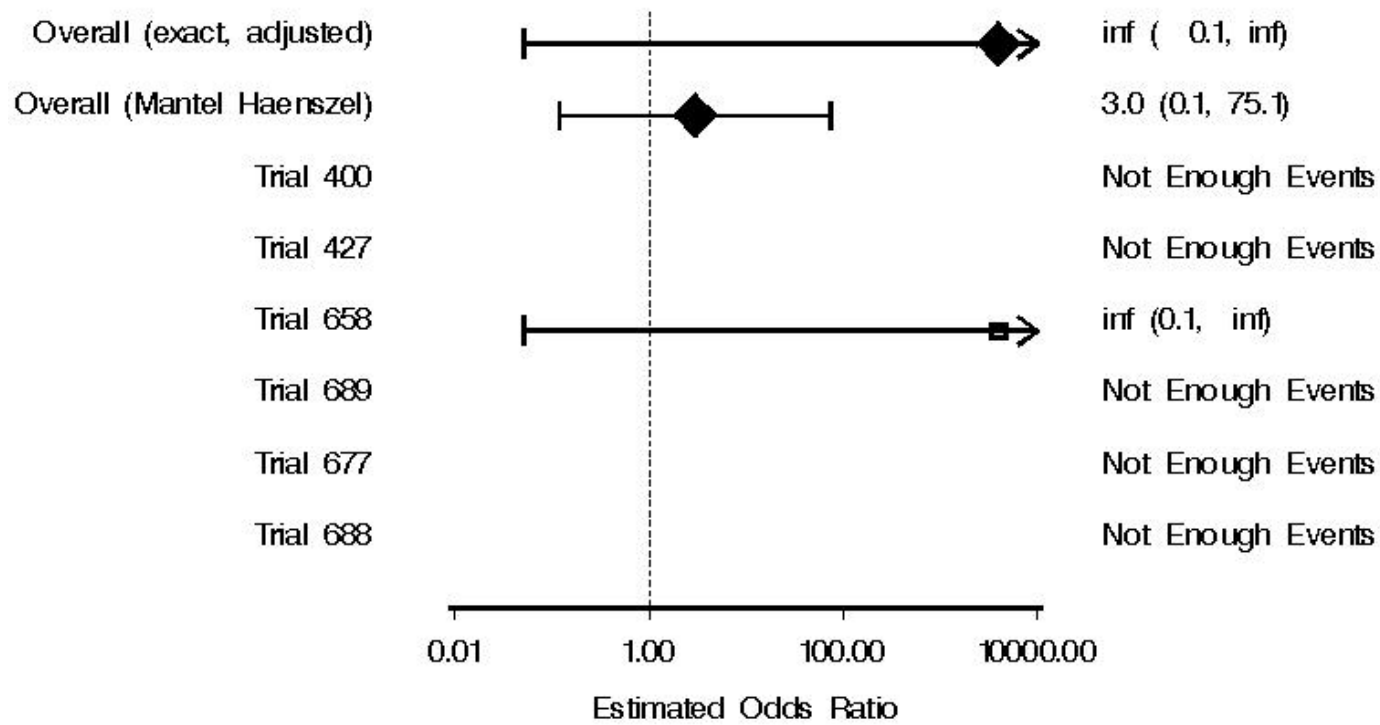


Paroxetine Adult Suicidality Analysis  
 Figure 2.03. Composite Suicidal Behaviour and Ideation  
 Indication = PTSD

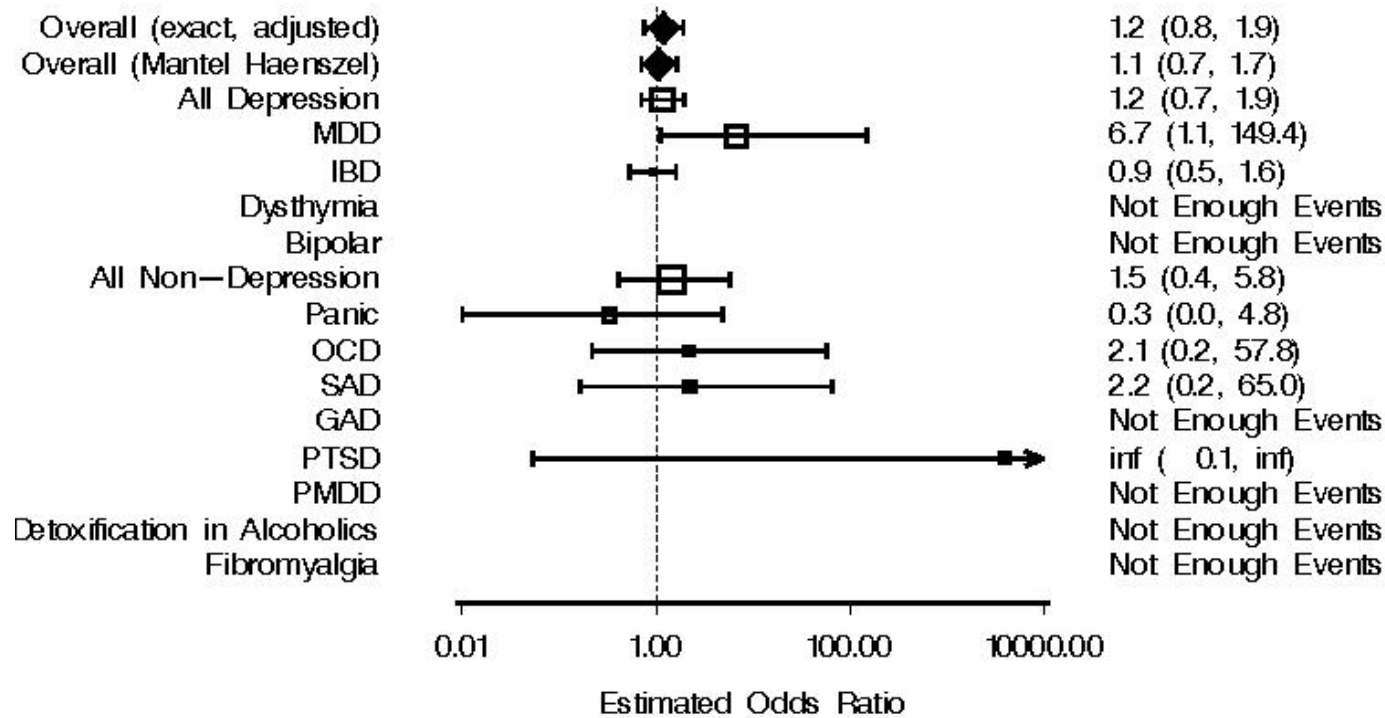


Paroxetine Adult Suicidality Analysis

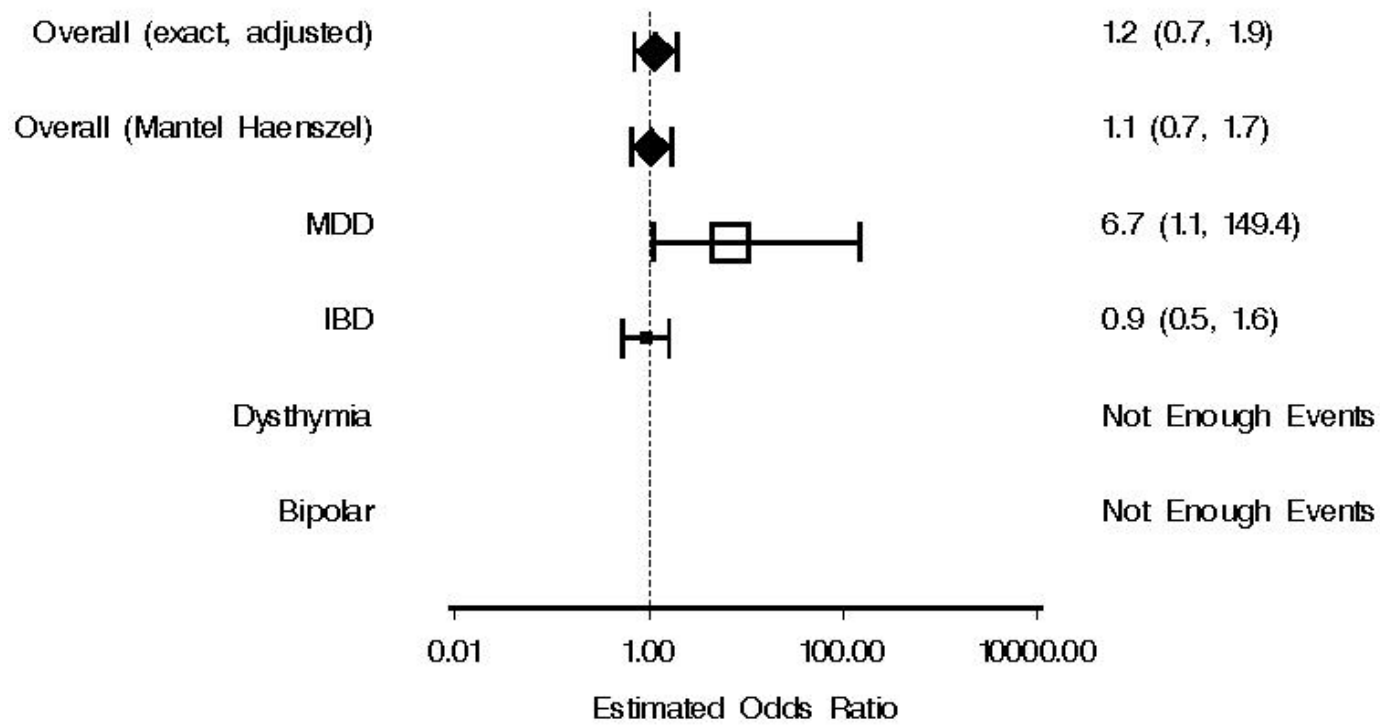
Figure 2.03. Composite Suicidal Behaviour and Ideation  
Indication = PMDD



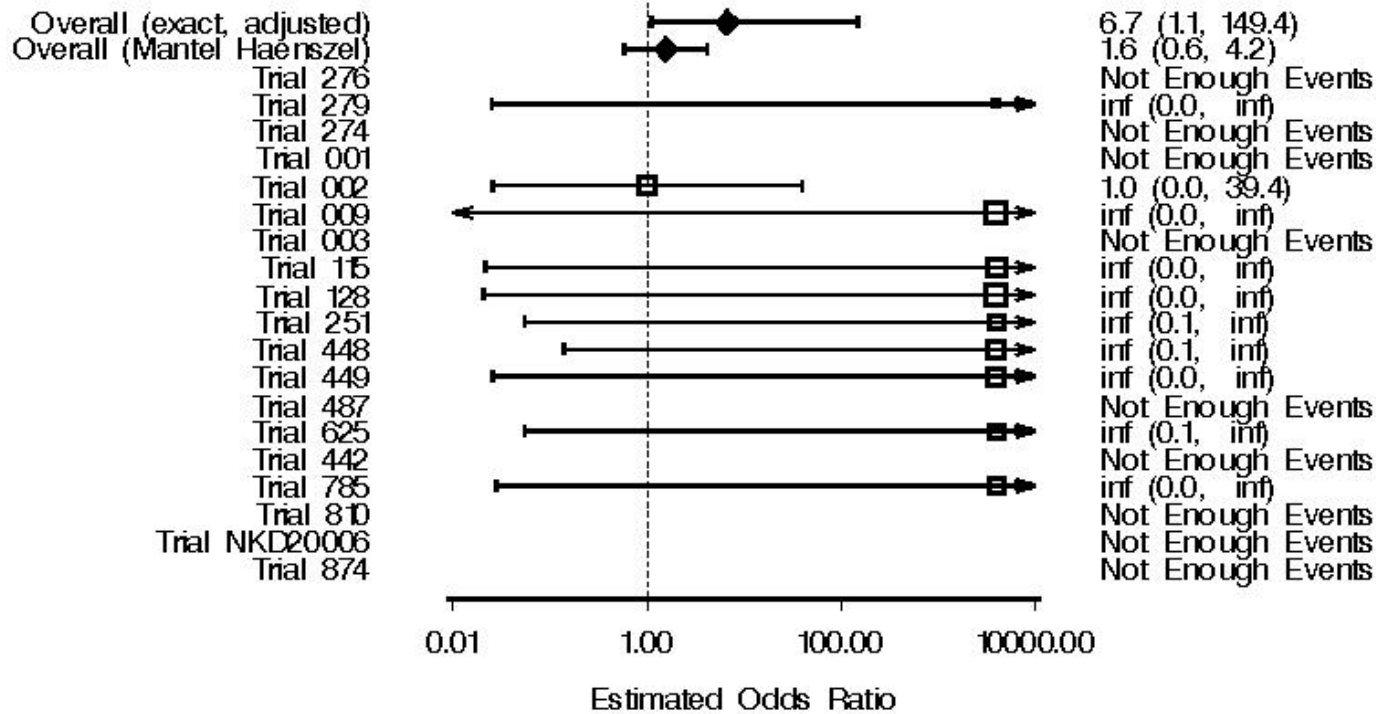
Paroxetine Adult Suicidality Analysis  
 Figure 2.04. Definitive Suicidal Behaviour  
 Indication = All Indications



Paroxetine Adult Suicidality Analysis  
Figure 2.04. Definitive Suicidal Behaviour  
Indication = All Depression

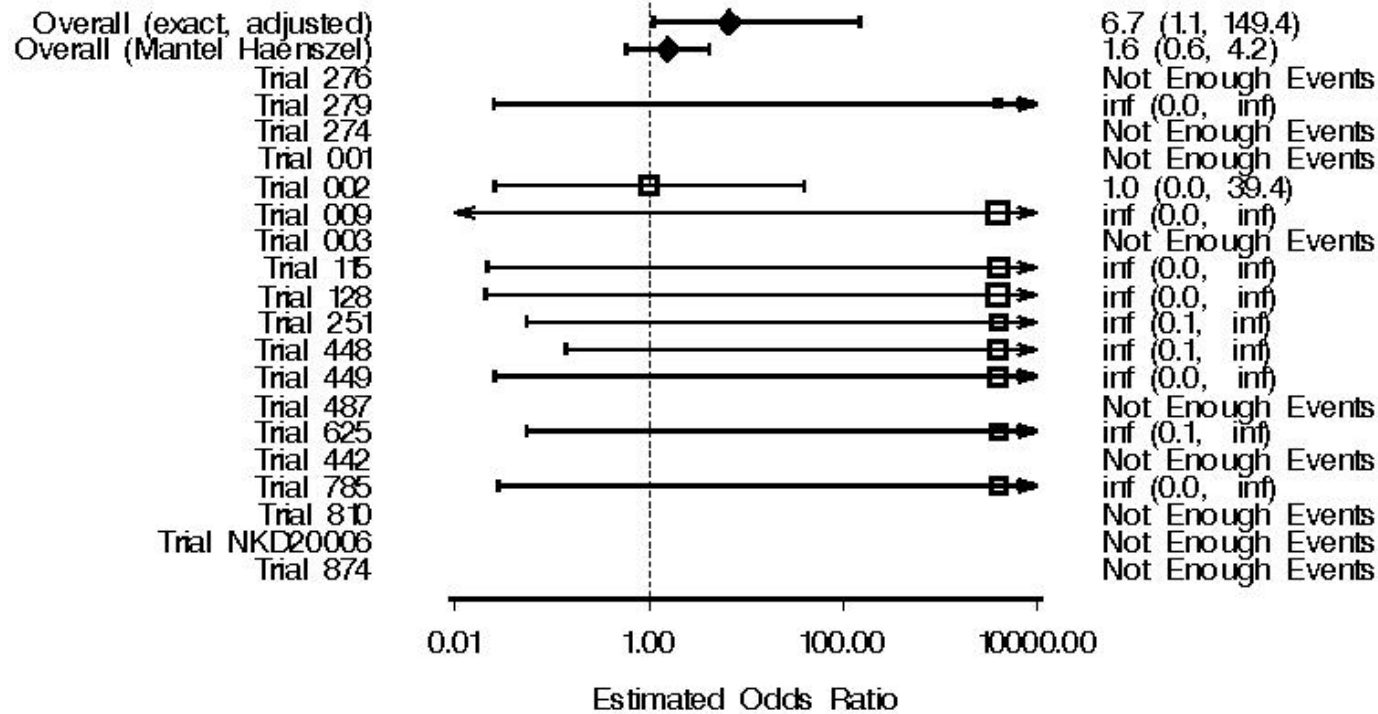


Paroxetine Adult Suicidality Analysis  
 Figure 2.04. Definitive Suicidal Behaviour  
 Indication = MDD

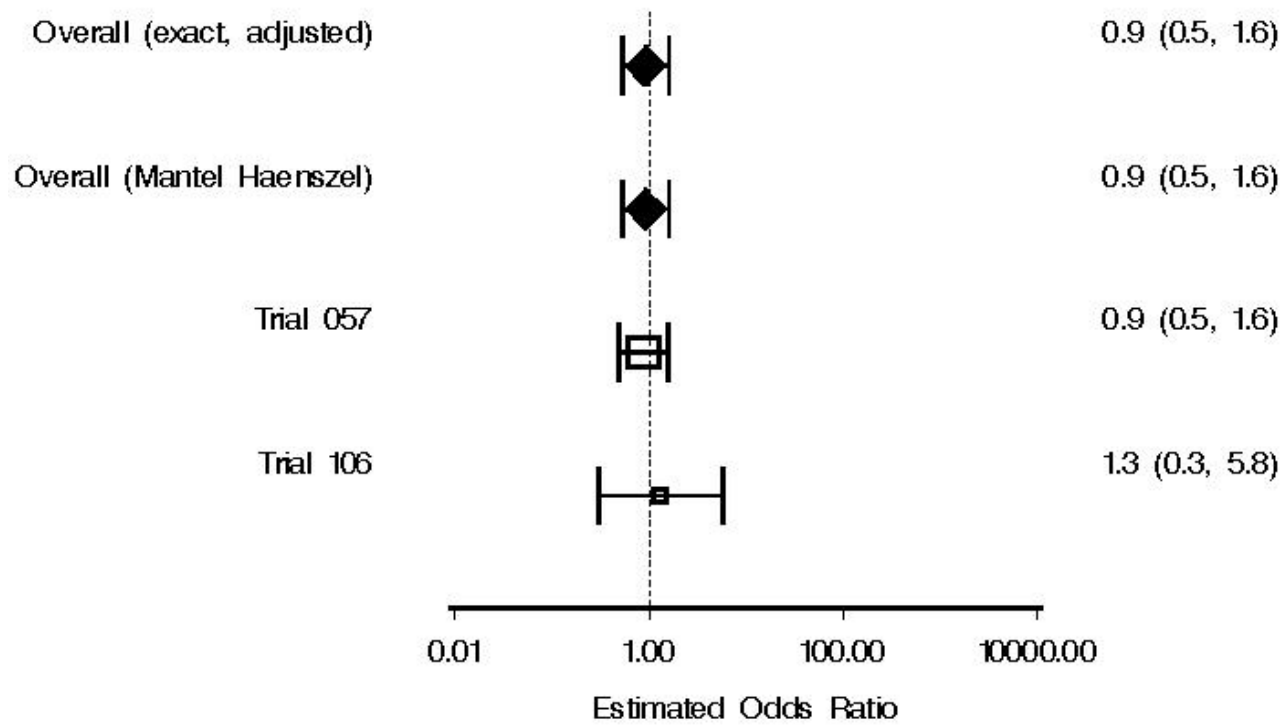




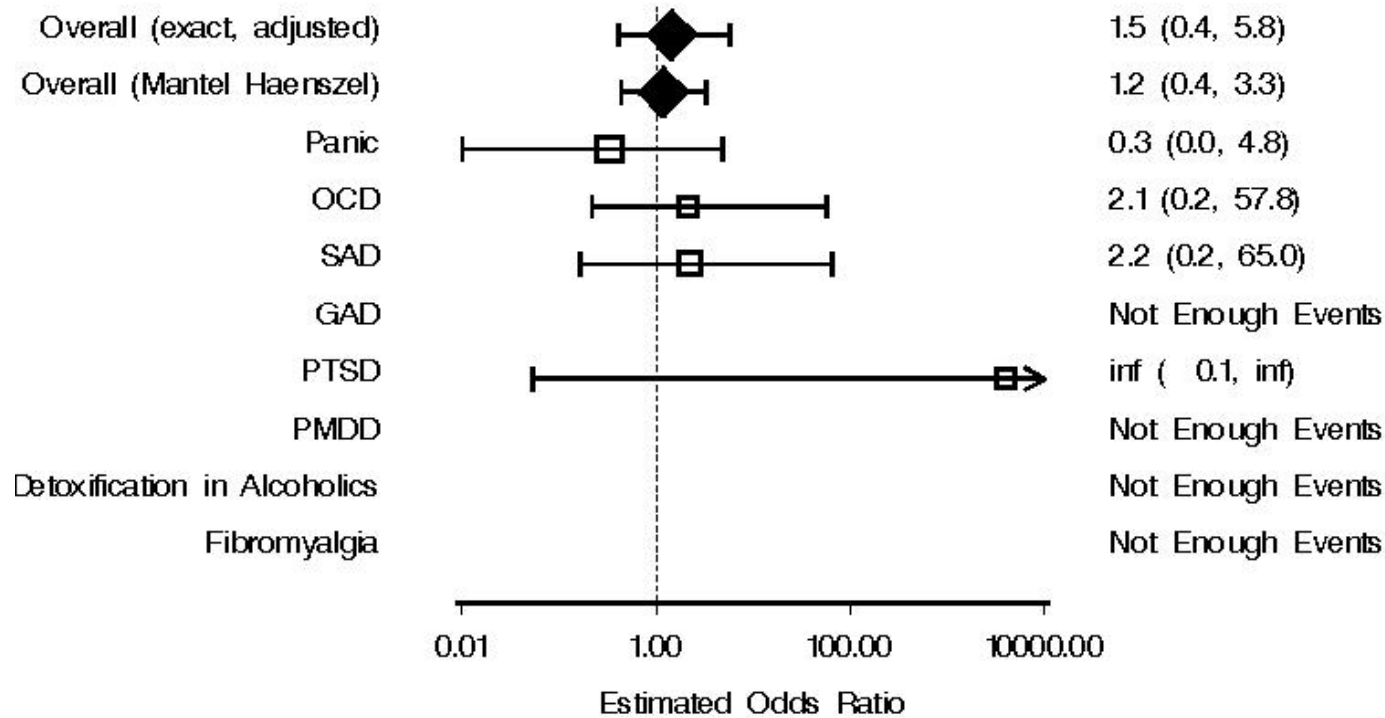
Paroxetine Adult Suicidality Analysis  
 Figure 2.04. Definitive Suicidal Behaviour  
 Indication = MDD



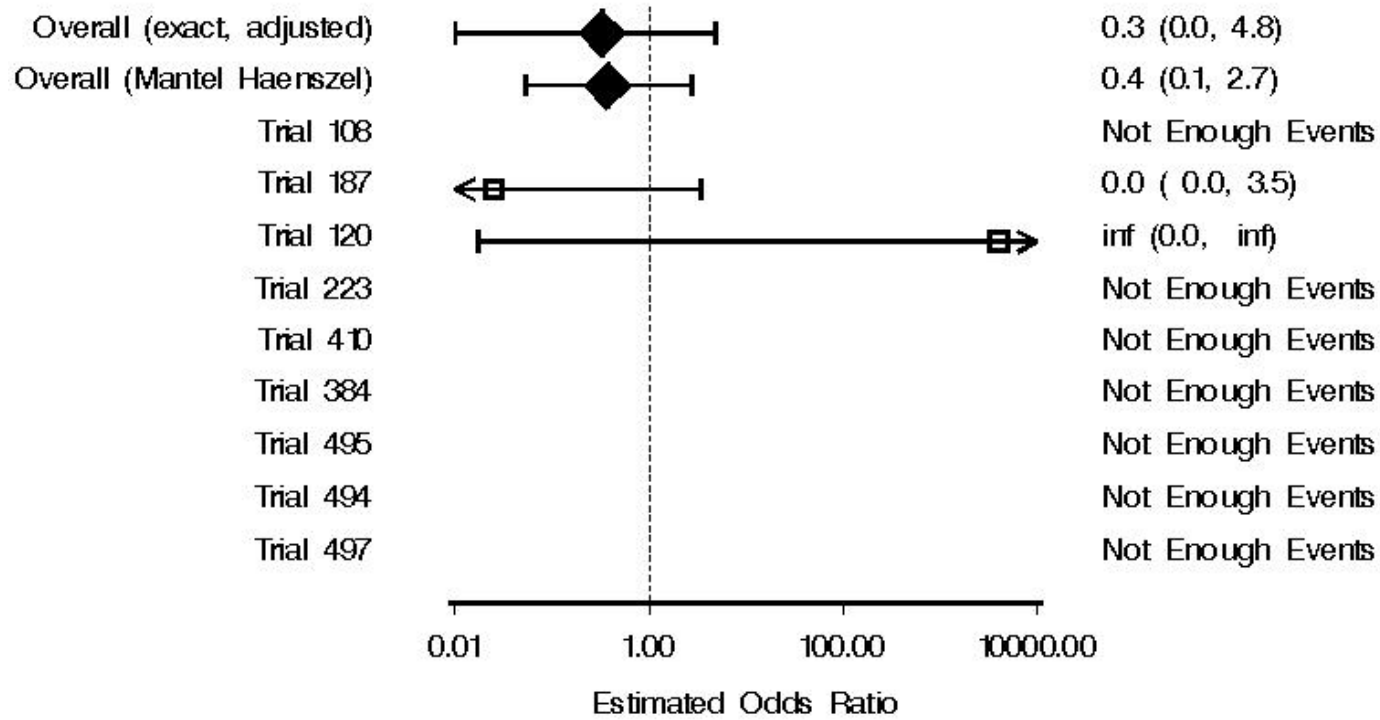
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Figure 2.04. Definitive Suicidal Behaviour  
Indication = IBD



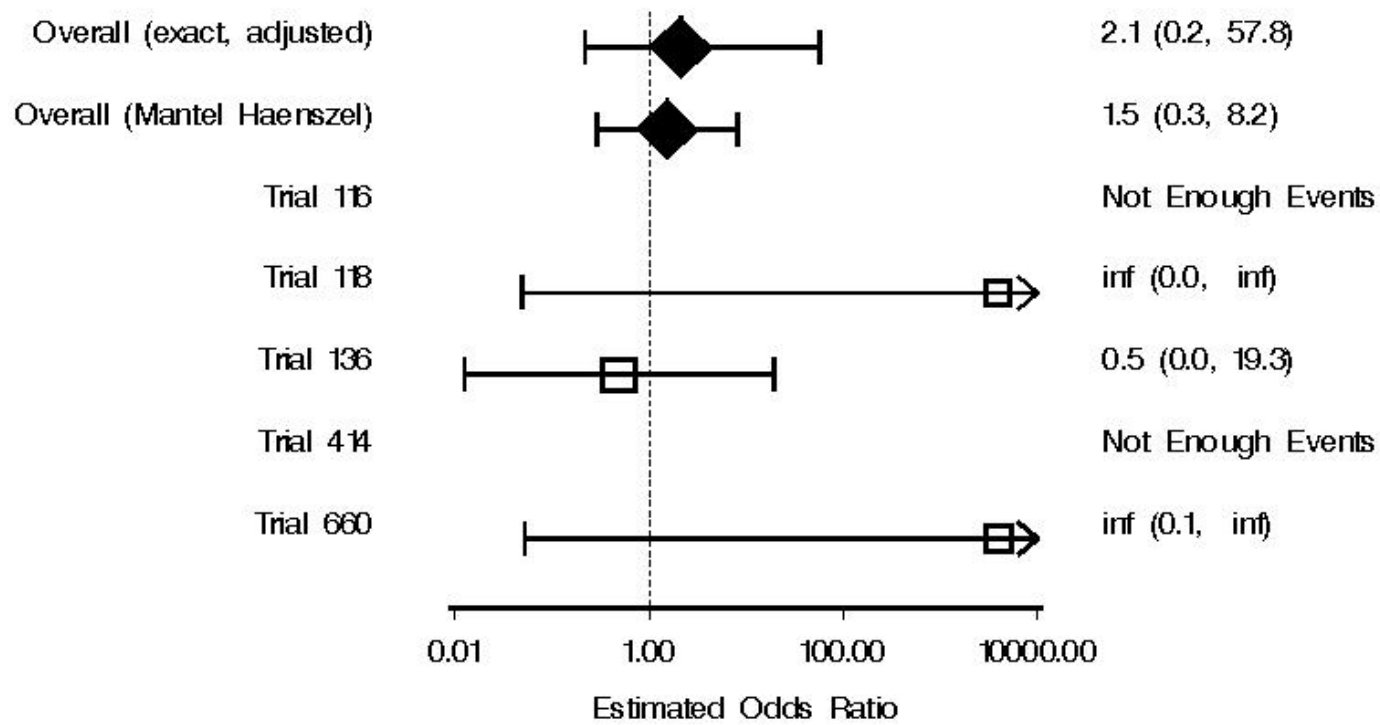
Paroxetine Adult Suicidality Analysis  
 Figure 2.04. Definitive Suicidal Behaviour  
 Indication = All Non-Depression



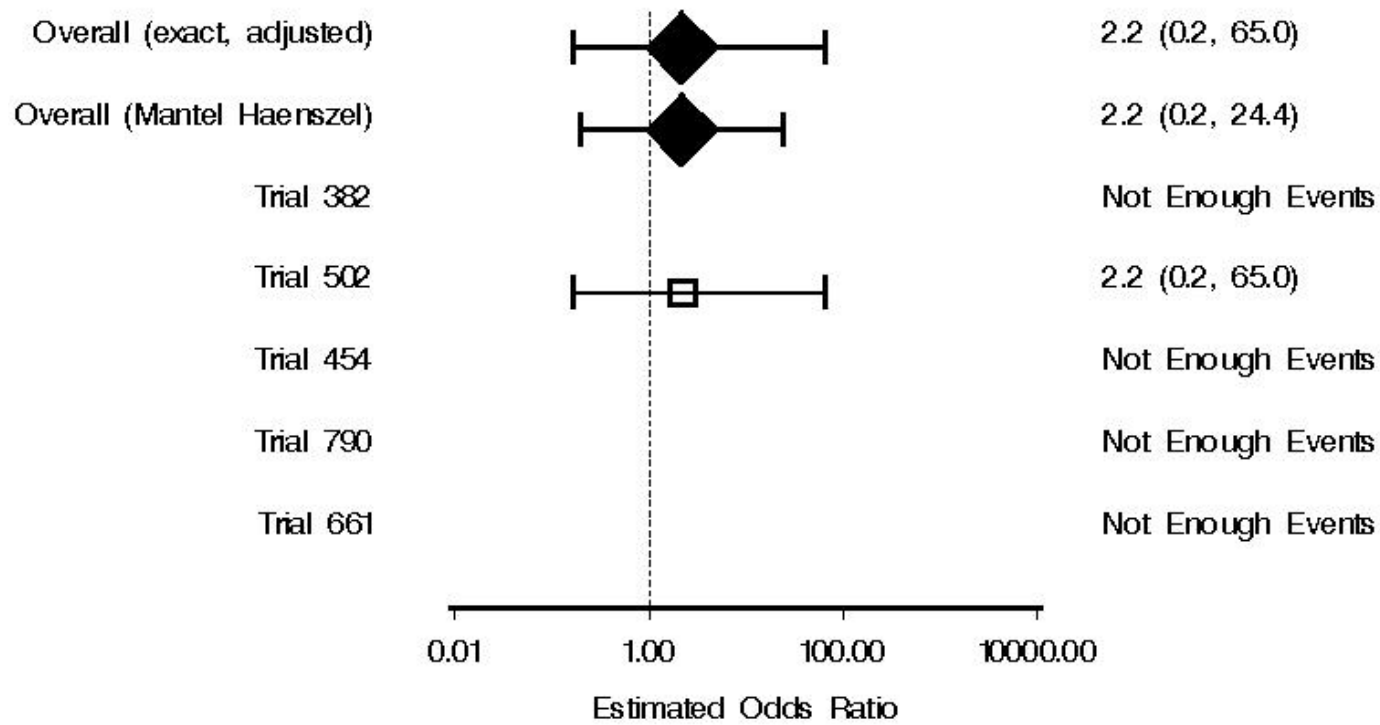
Paroxetine Adult Suicidality Analysis  
 Figure 2.04. Definitive Suicidal Behaviour  
 Indication = Panic



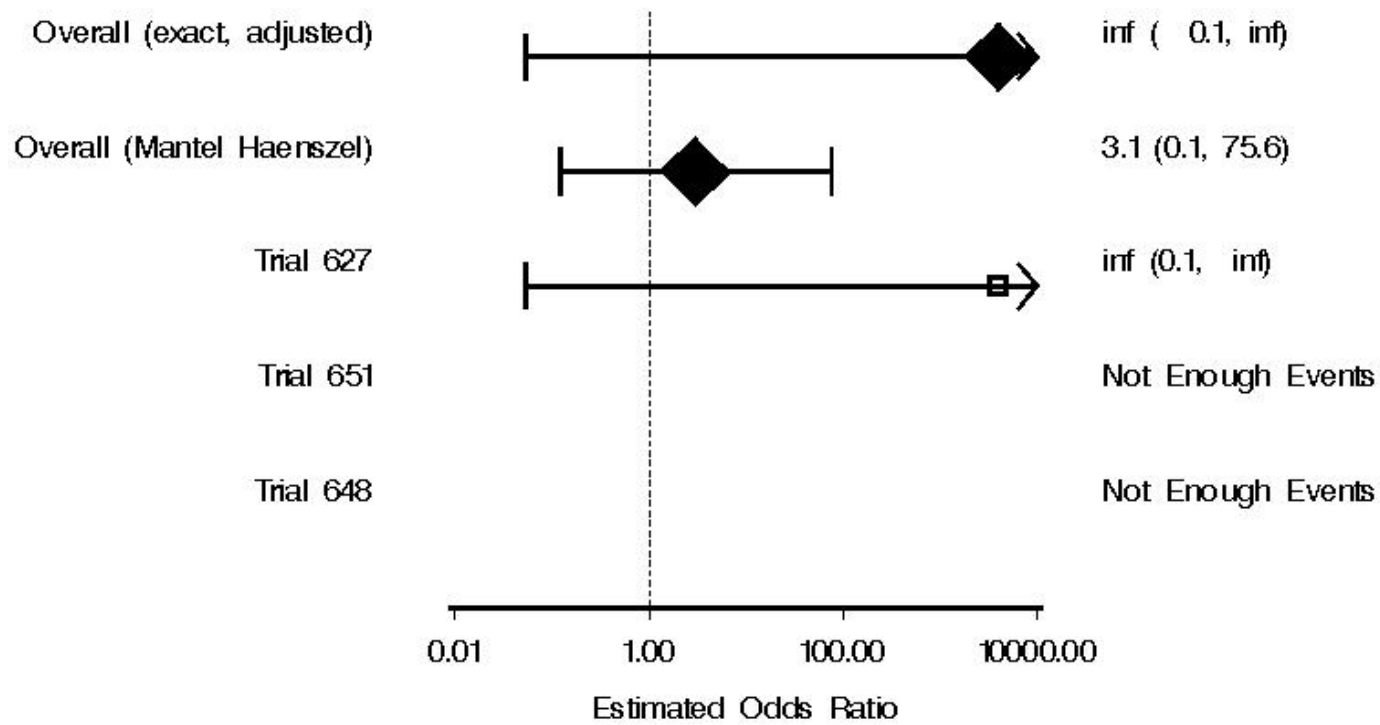
Paroxetine Adult Suicidality Analysis  
Figure 2.04. Definitive Suicidal Behaviour  
Indication = OCD



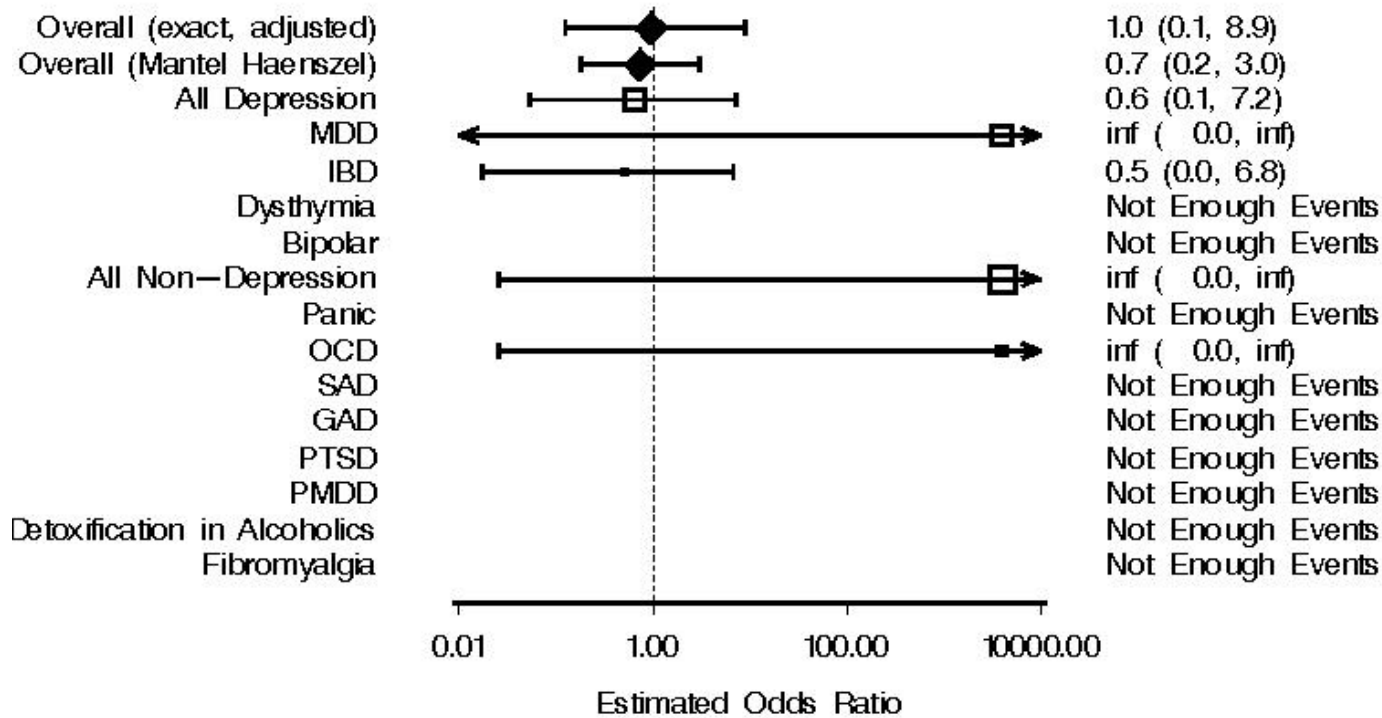
Paroxetine Adult Suicidality Analysis  
Figure 2.04. Definitive Suicidal Behaviour  
Indication = SAD



Paroxetine Adult Suicidality Analysis  
Figure 2.04. Definitive Suicidal Behaviour  
Indication = PTSD

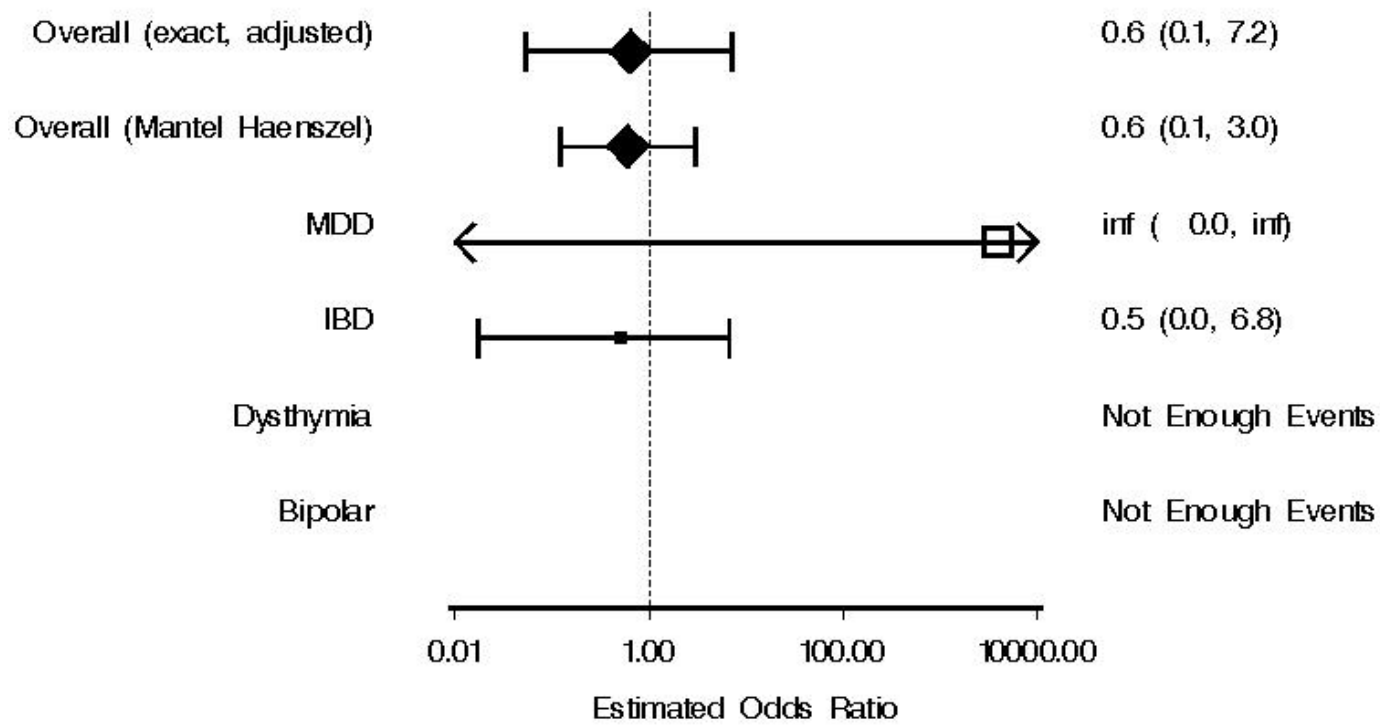


Paroxetine Adult Suicidality Analysis  
 Figure 2.05. Rating Scale Emergent Suicidal Behaviour  
 Indication = All Indications

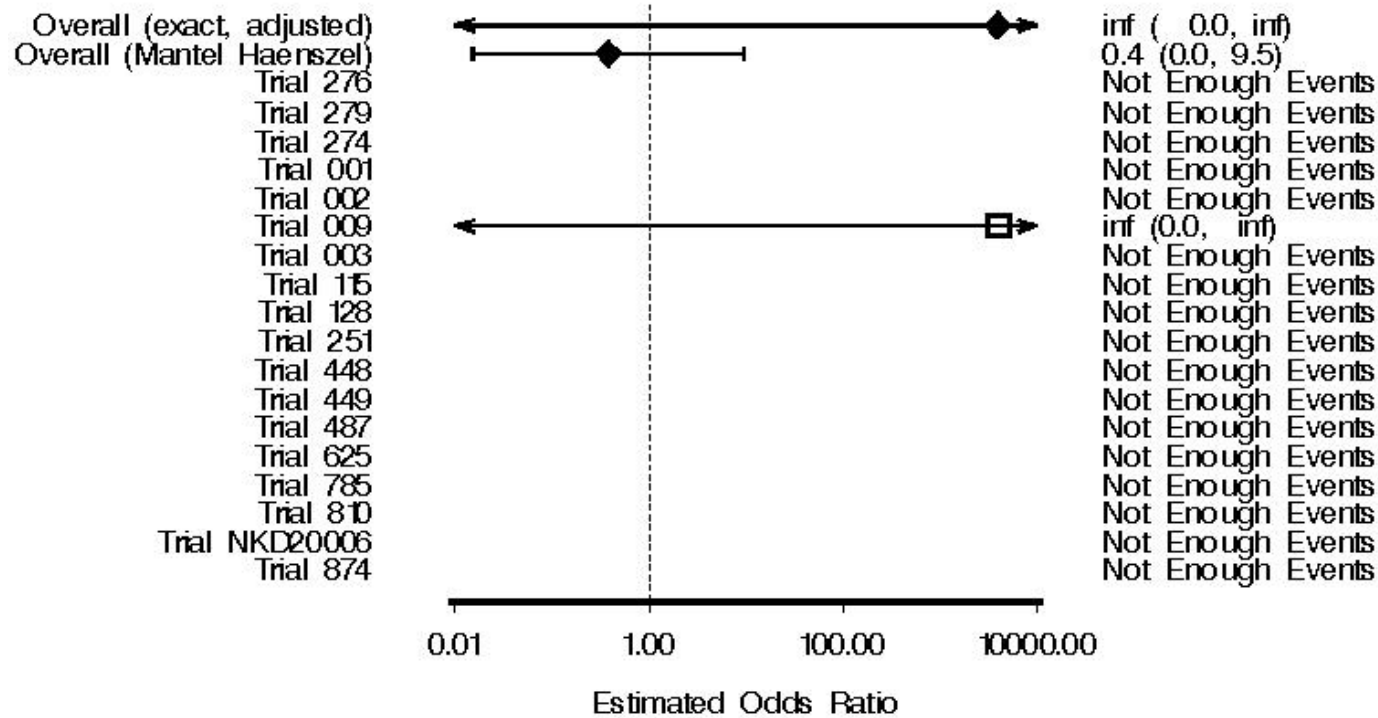




Paroxetine Adult Suicidality Analysis  
 Figure 2.05. Rating Scale Emergent Suicidal Behaviour  
 Indication = All Depression

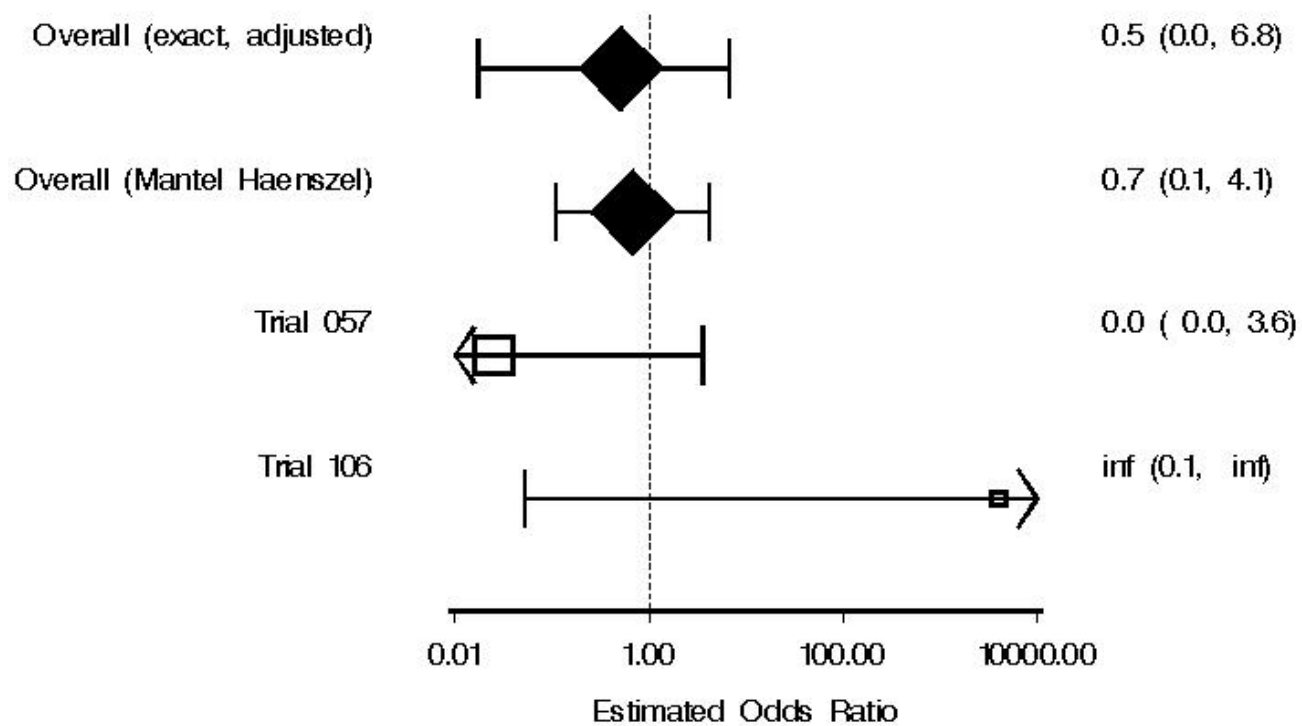


Paroxetine Adult Suicidality Analysis  
 Figure 2.05. Rating Scale Emergent Suicidal Behaviour  
 Indication = MDD

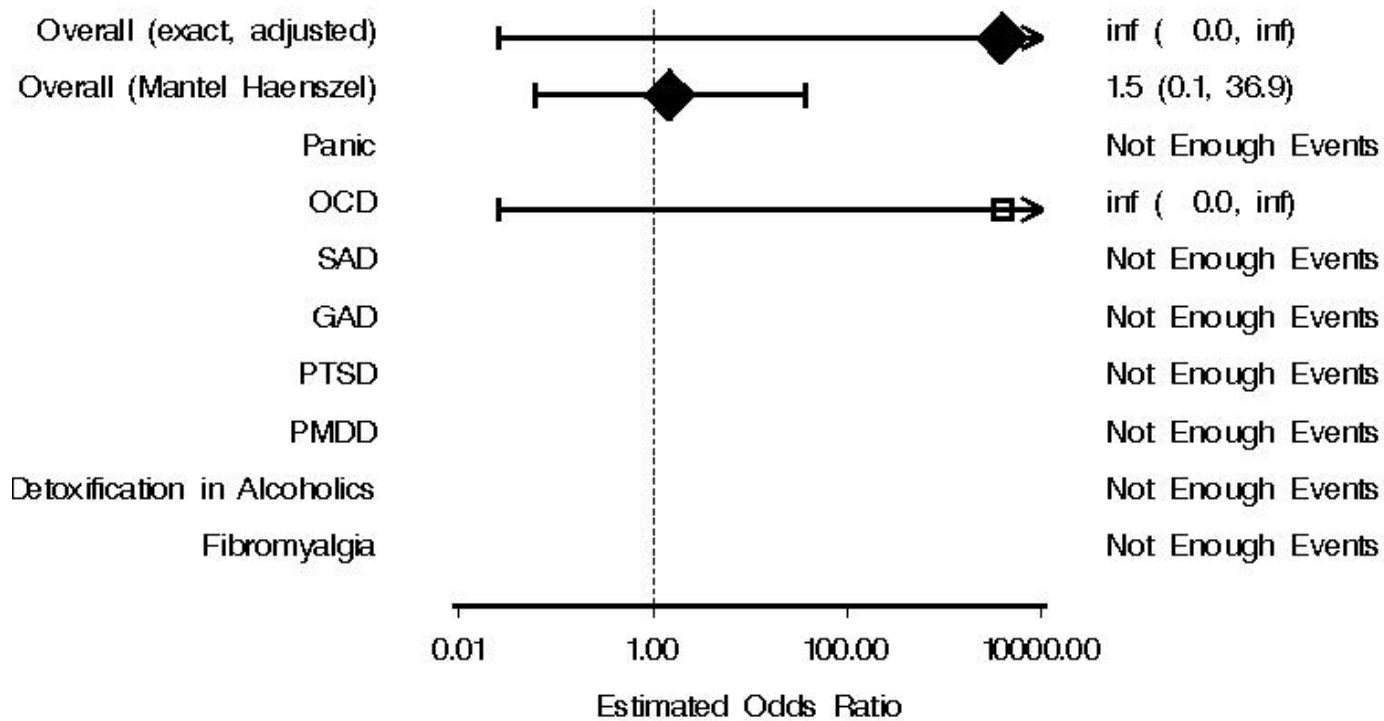


NOTE: Rating Scale Emergent Suicidal Behaviour data was not available in Study 442

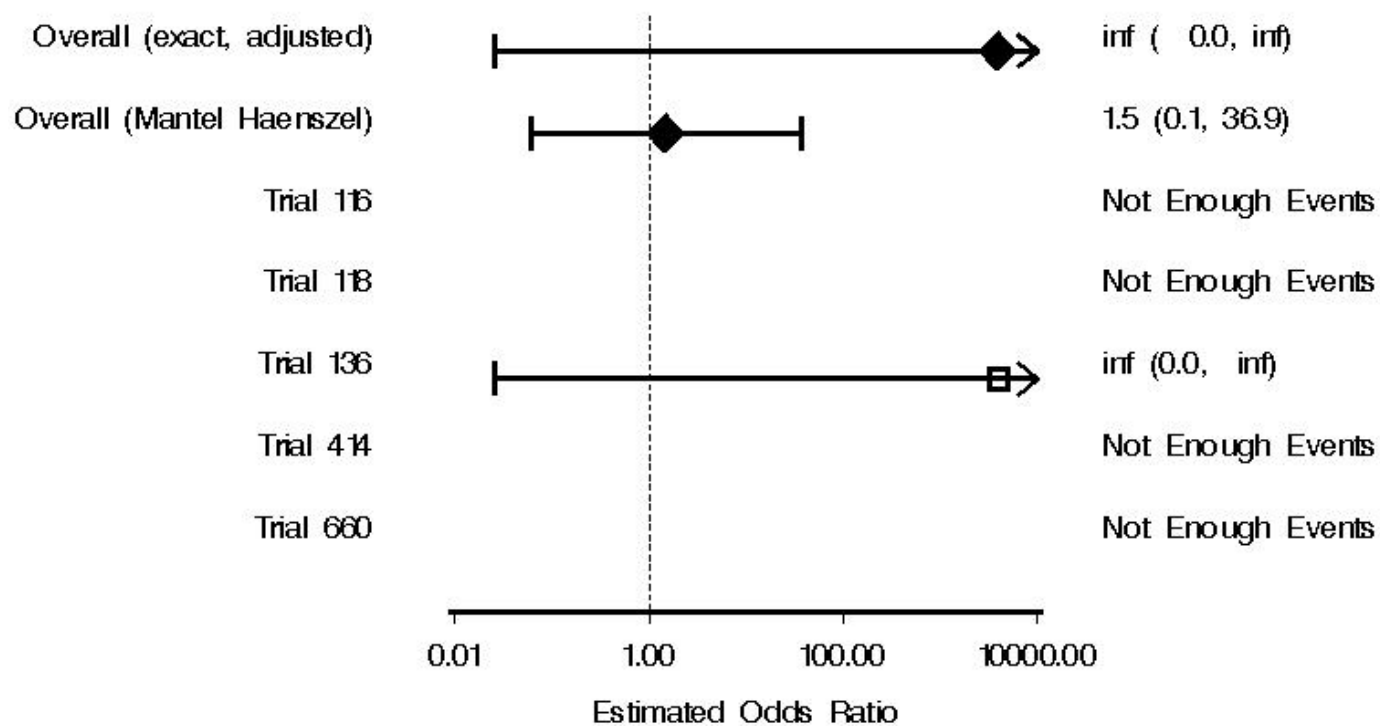
Paroxetine Adult Suicidality Analysis  
Figure 2.05. Rating Scale Emergent Suicidal Behaviour  
Indication = IBD



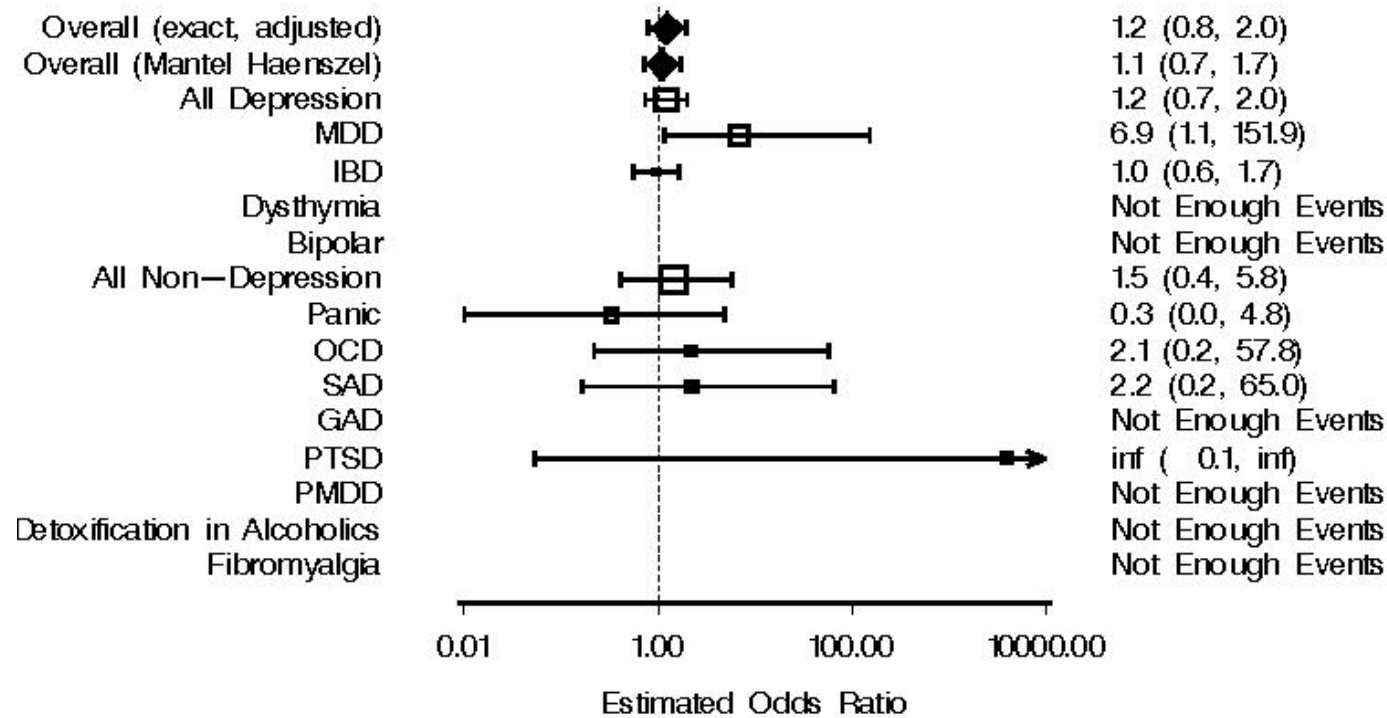
Paroxetine Adult Suicidality Analysis  
 Figure 2.05. Rating Scale Emergent Suicidal Behaviour  
 Indication = All Non-Depression



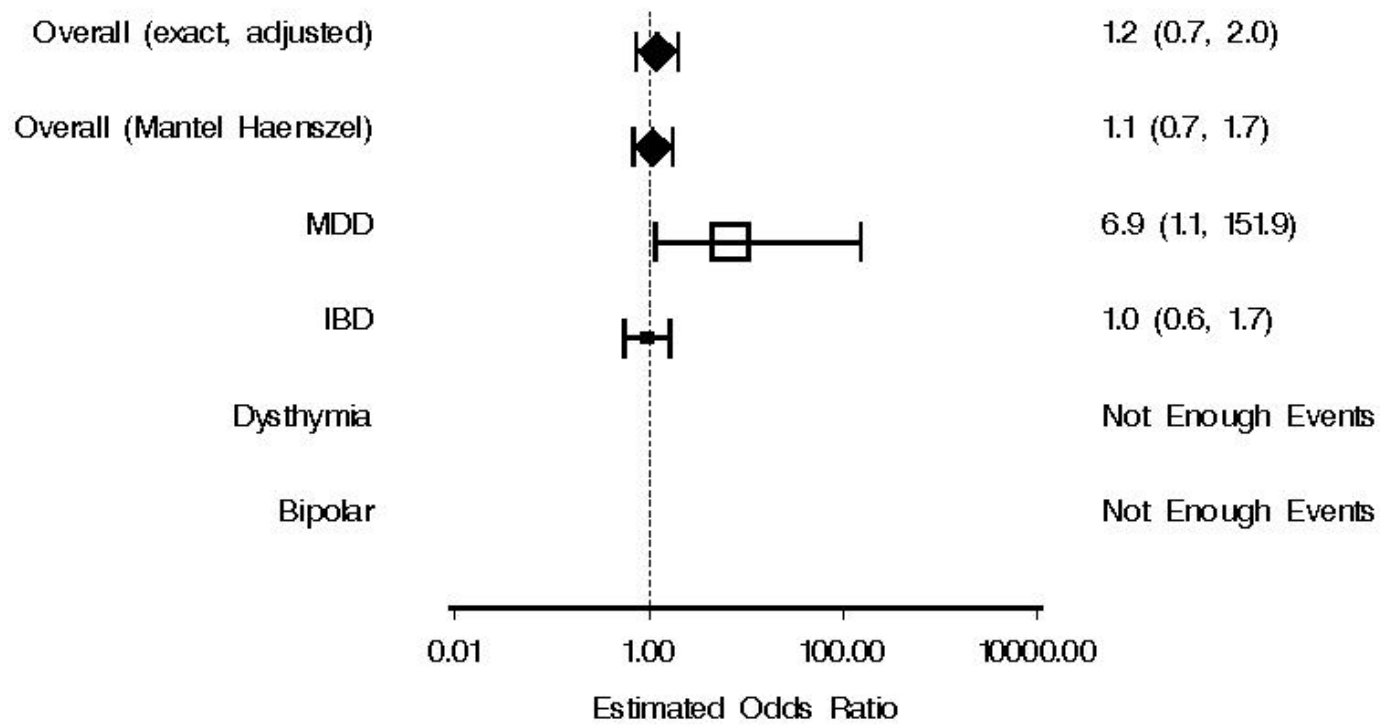
Paroxetine Adult Suicidality Analysis  
 Figure 2.05. Rating Scale Emergent Suicidal Behaviour  
 Indication = OCD



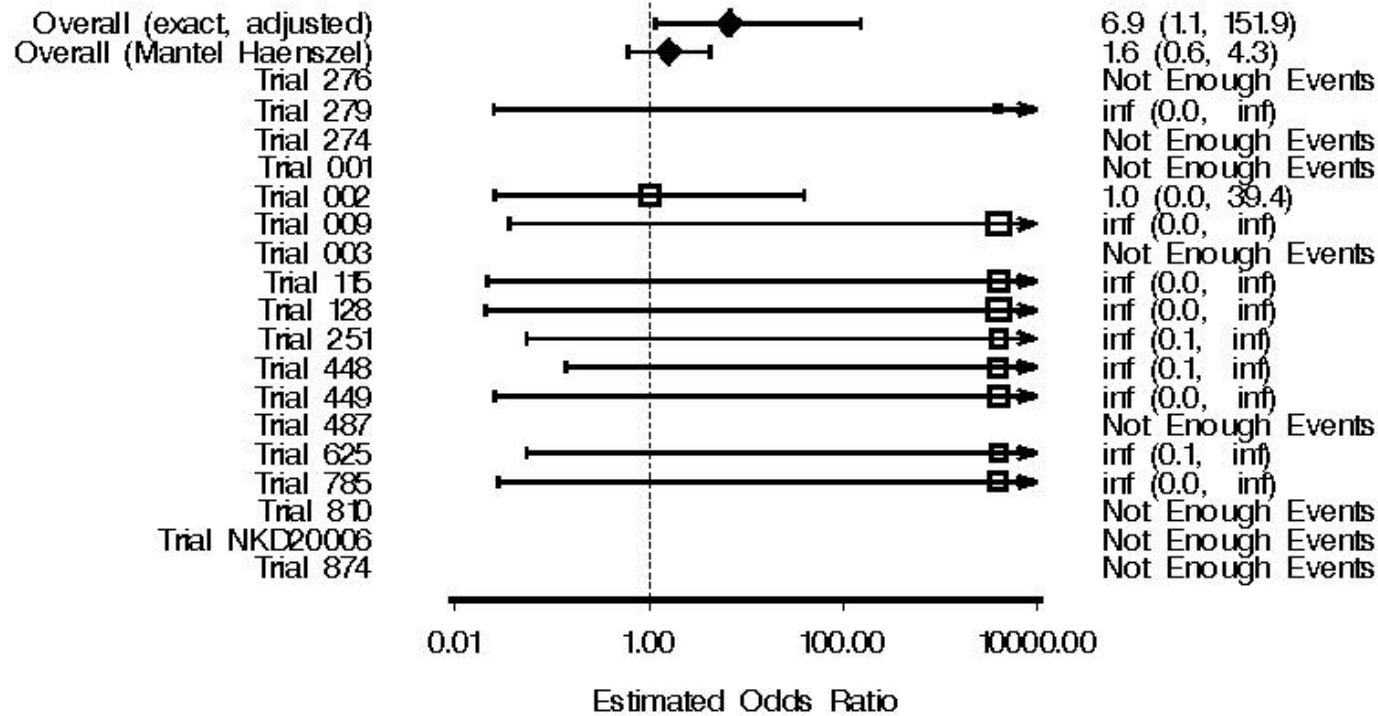
Paroxetine Adult Suicidality Analysis  
 Figure 2.06. Composite Suicidal Behaviour  
 Indication = All Indications



Paroxetine Adult Suicidality Analysis  
Figure 2.06. Composite Suicidal Behaviour  
Indication = All Depression



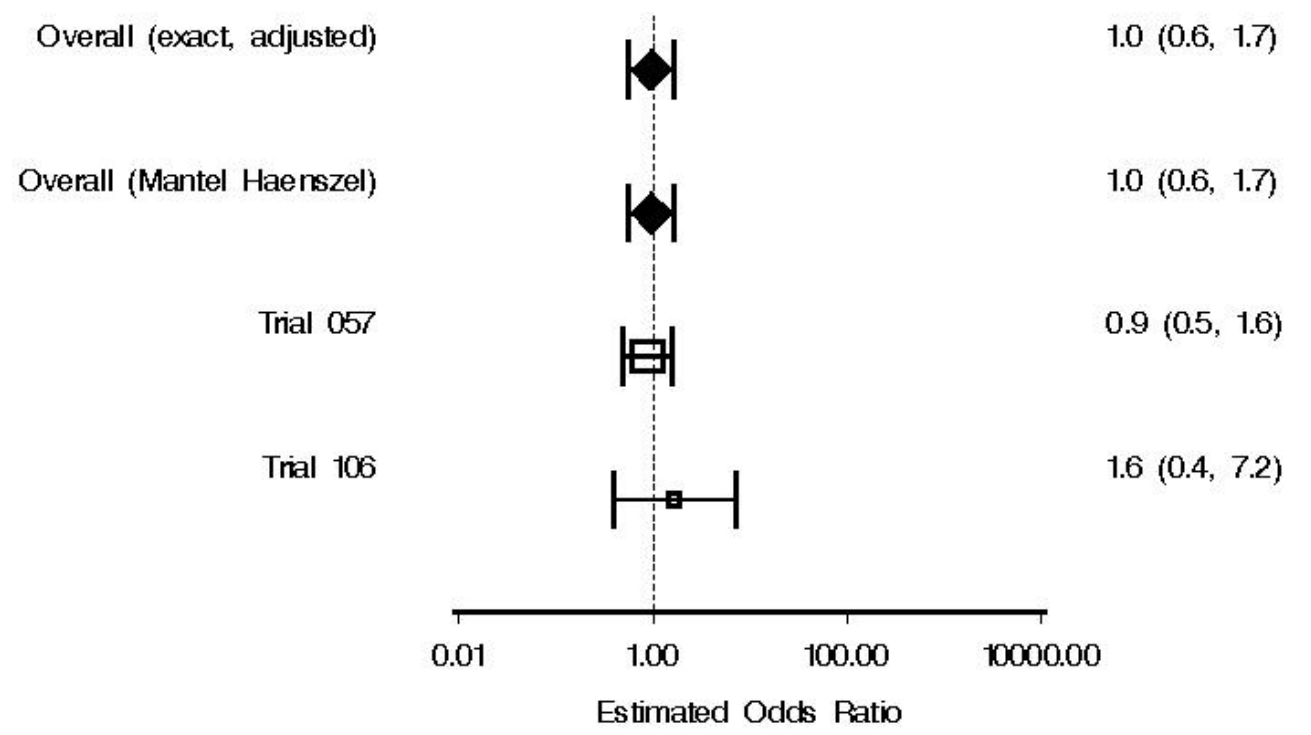
Paroxetine Adult Suicidality Analysis  
 Figure 2.06. Composite Suicidal Behaviour  
 Indication = MDD



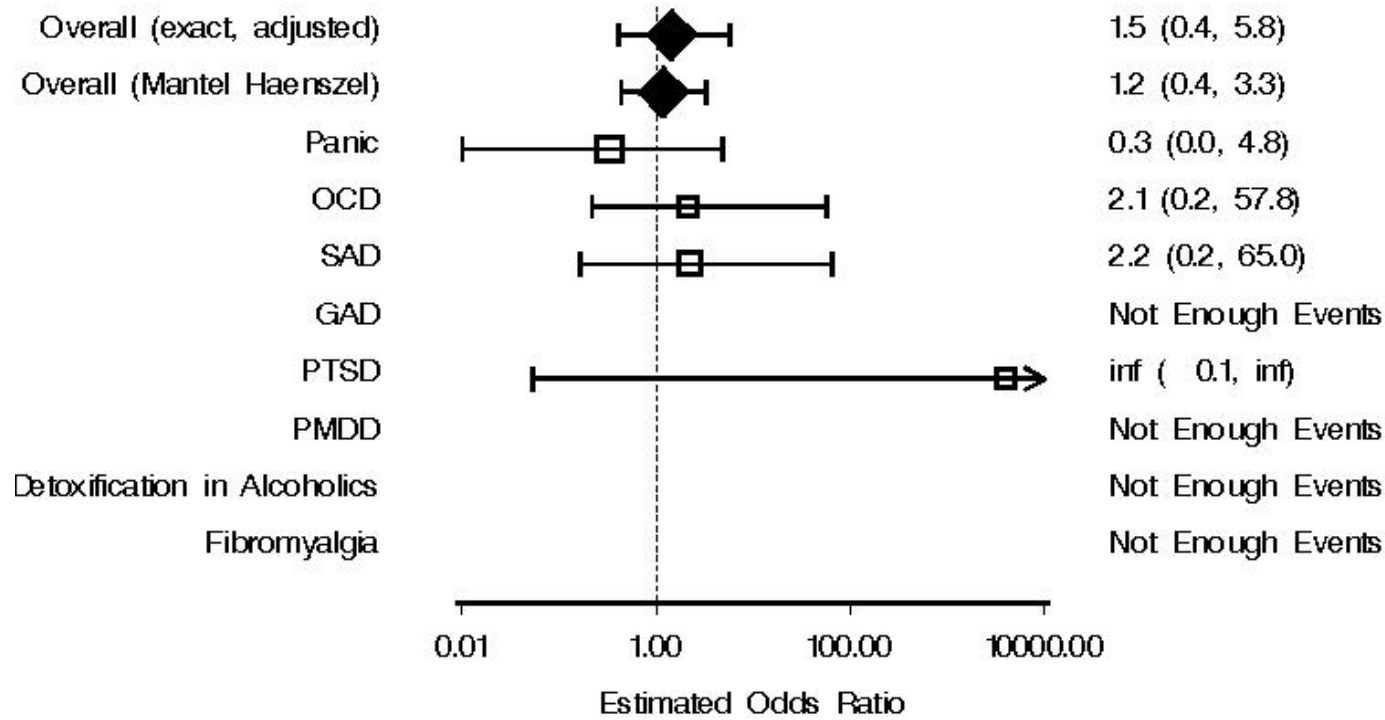
NOTE: Composite Suicidal Behaviour data was not available in Study 442



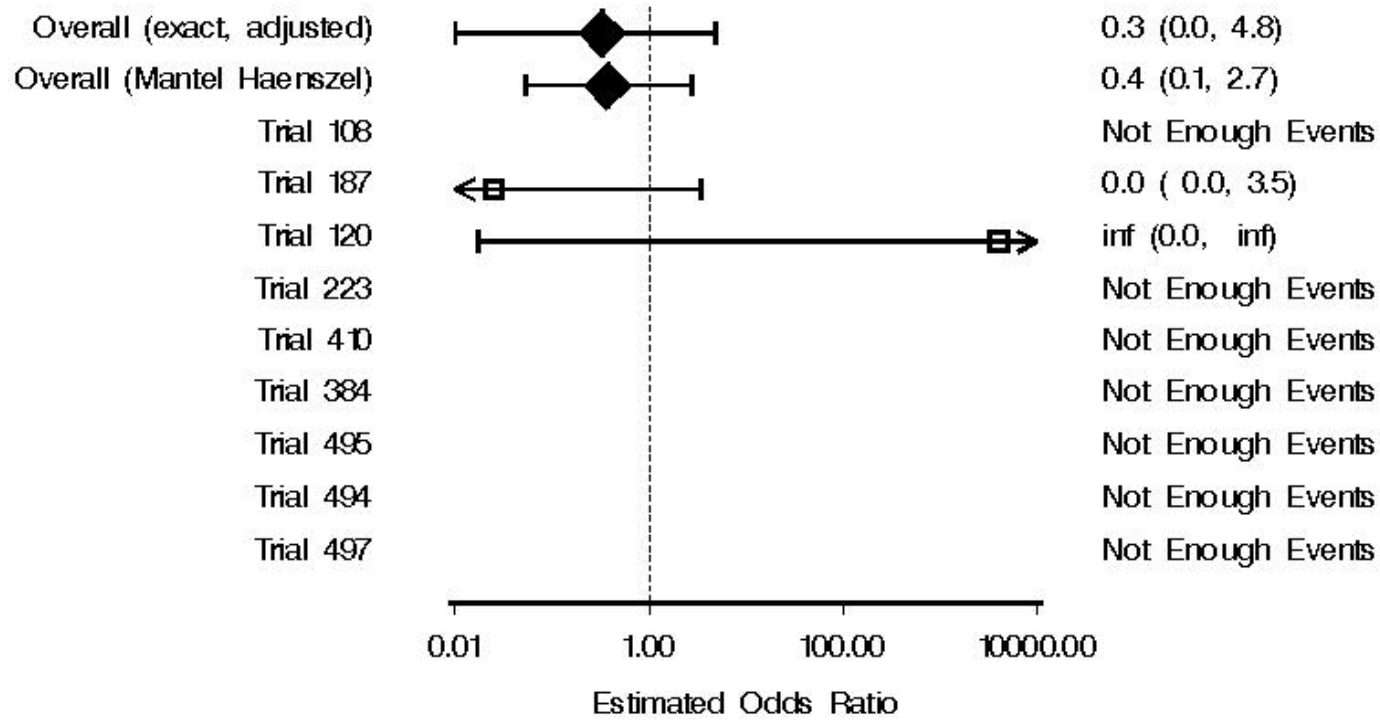
Paroxetine Adult Suicidality Analysis  
Figure 2.06. Composite Suicidal Behaviour  
Indication = IBD



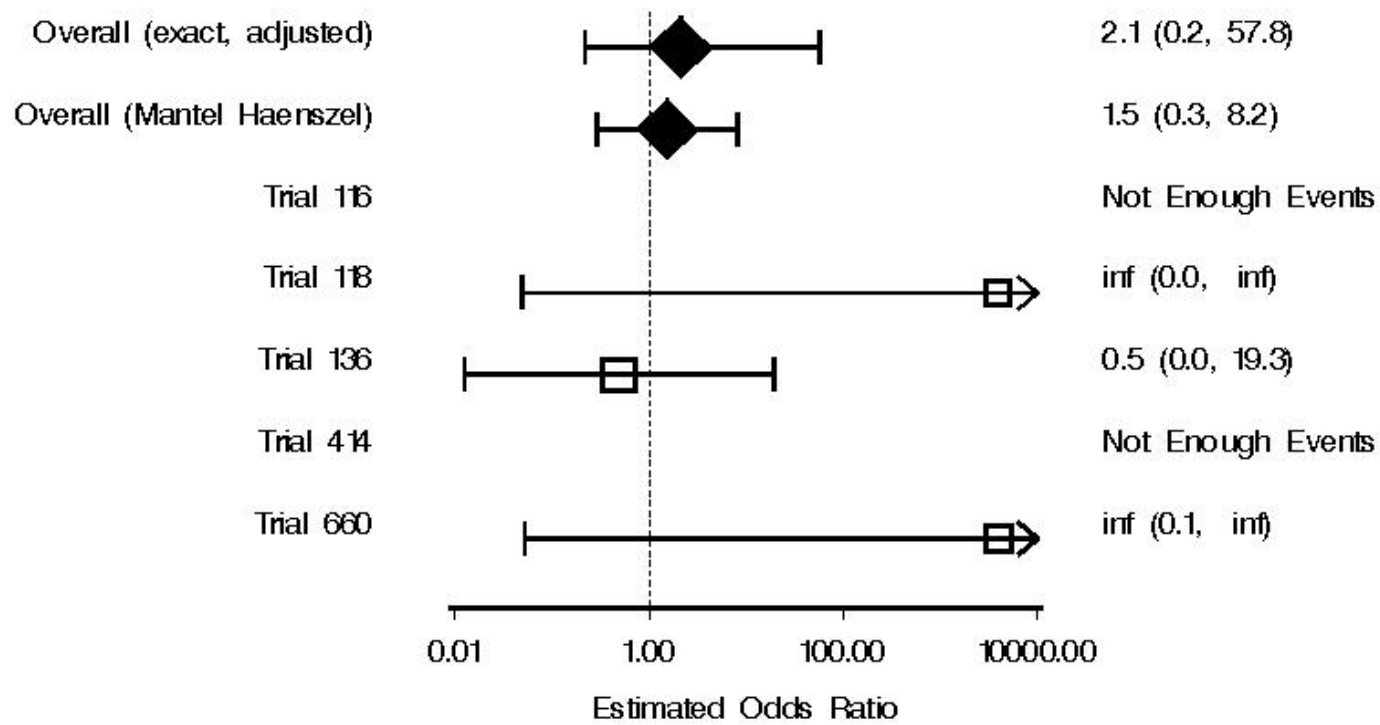
Paroxetine Adult Suicidality Analysis  
 Figure 2.06. Composite Suicidal Behaviour  
 Indication = All Non-Depression



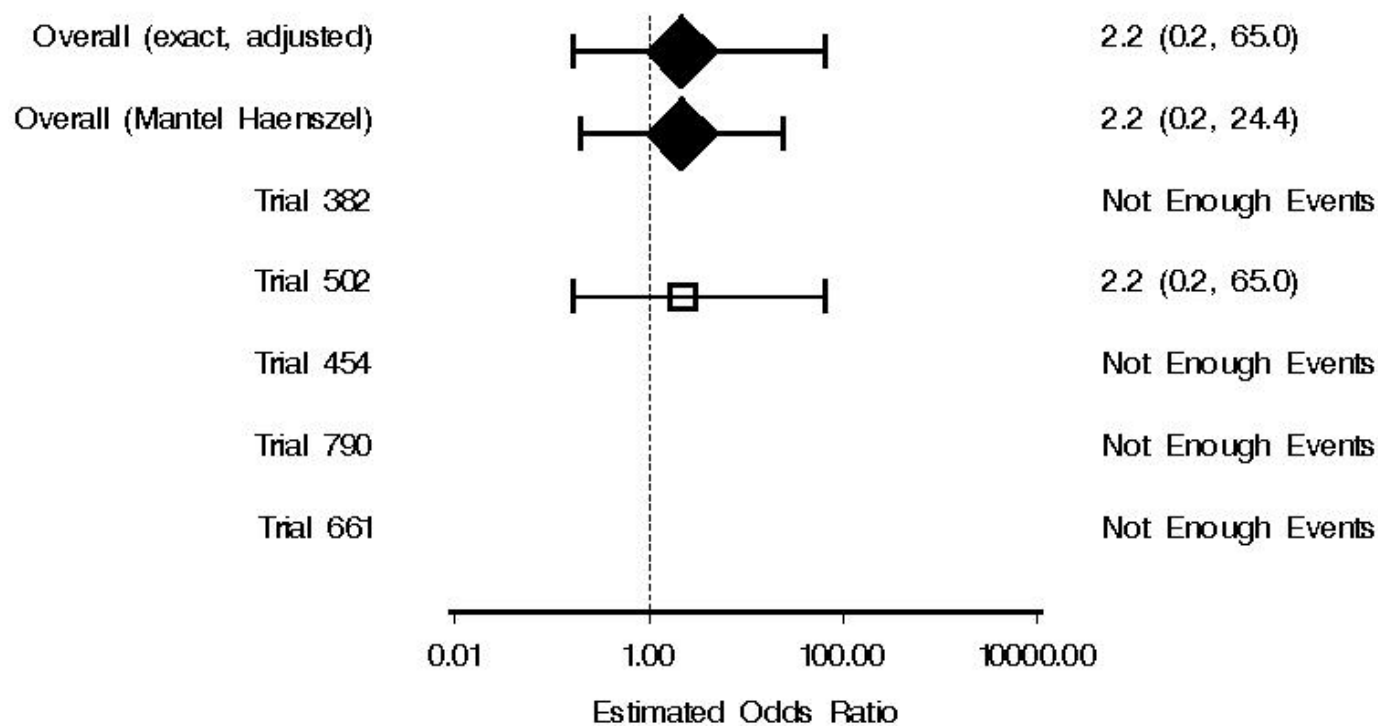
Paroxetine Adult Suicidality Analysis  
 Figure 2.06. Composite Suicidal Behaviour  
 Indication = Panic



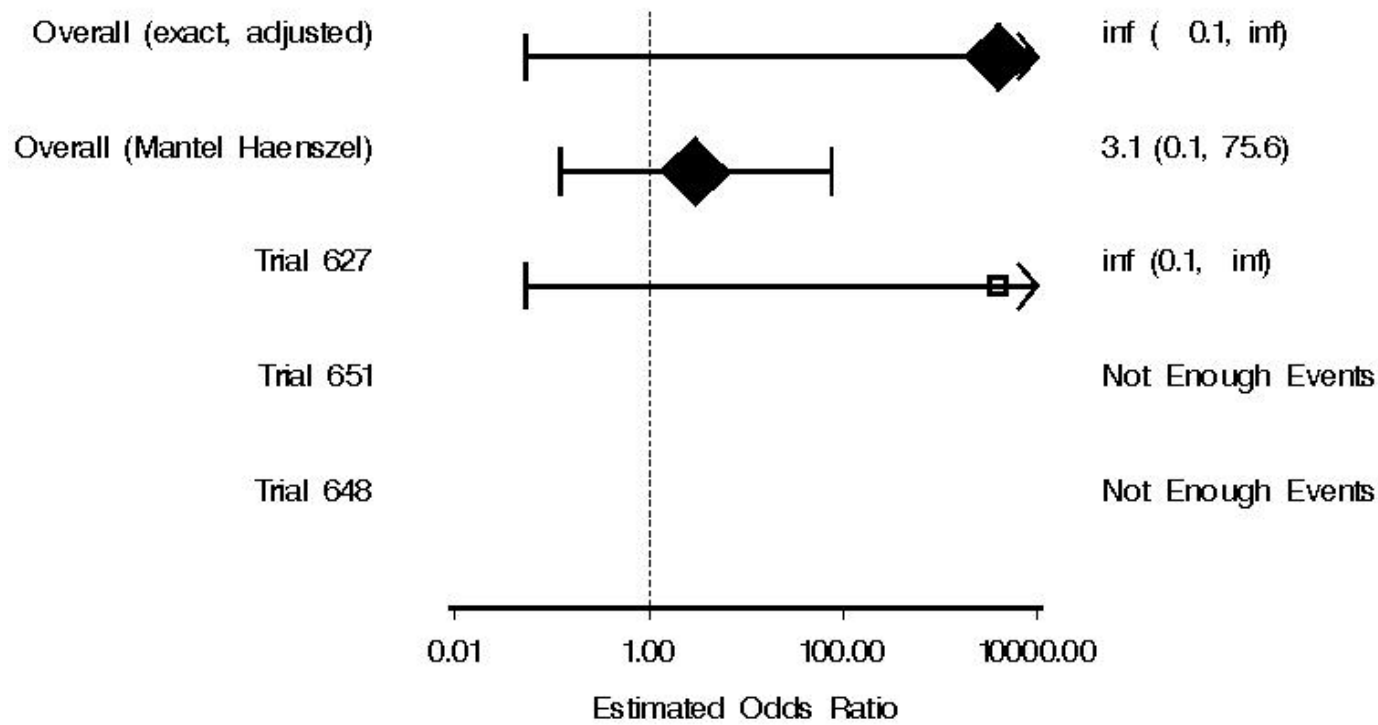
Paroxetine Adult Suicidality Analysis  
 Figure 2.06. Composite Suicidal Behaviour  
 Indication = OCD



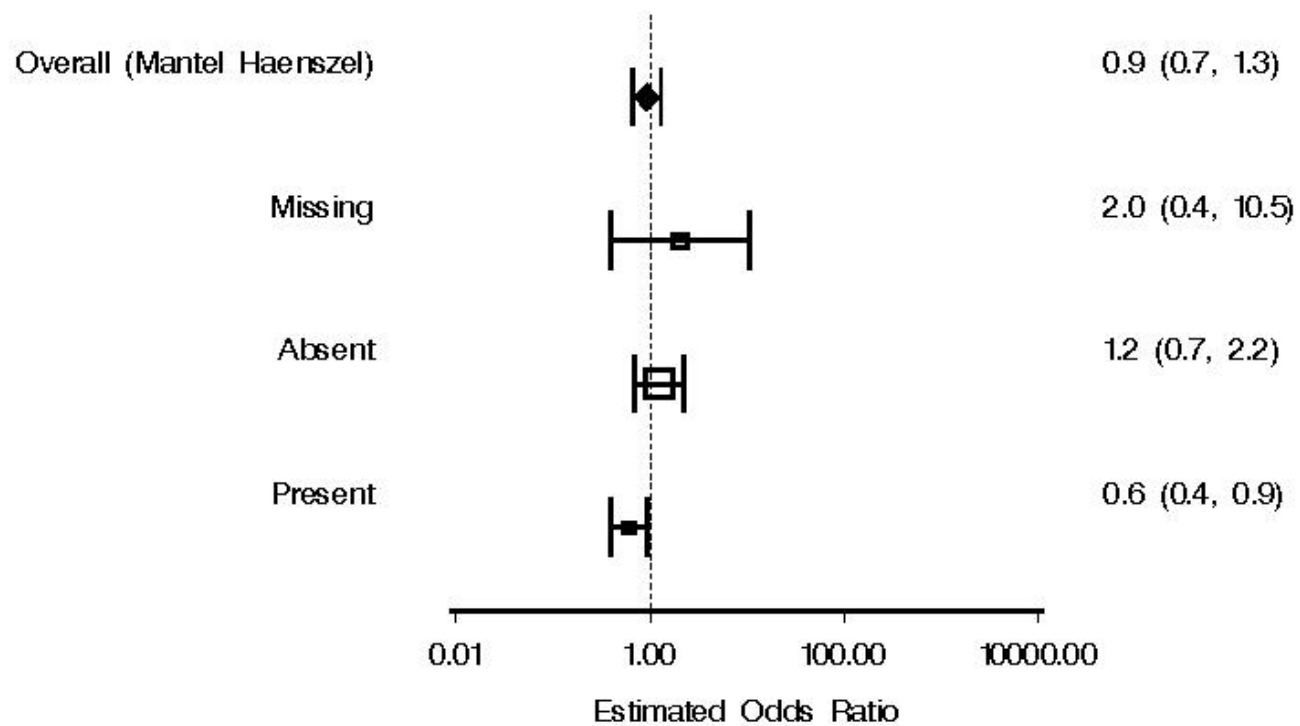
Paroxetine Adult Suicidality Analysis  
 Figure 2.06. Composite Suicidal Behaviour  
 Indication = SAD



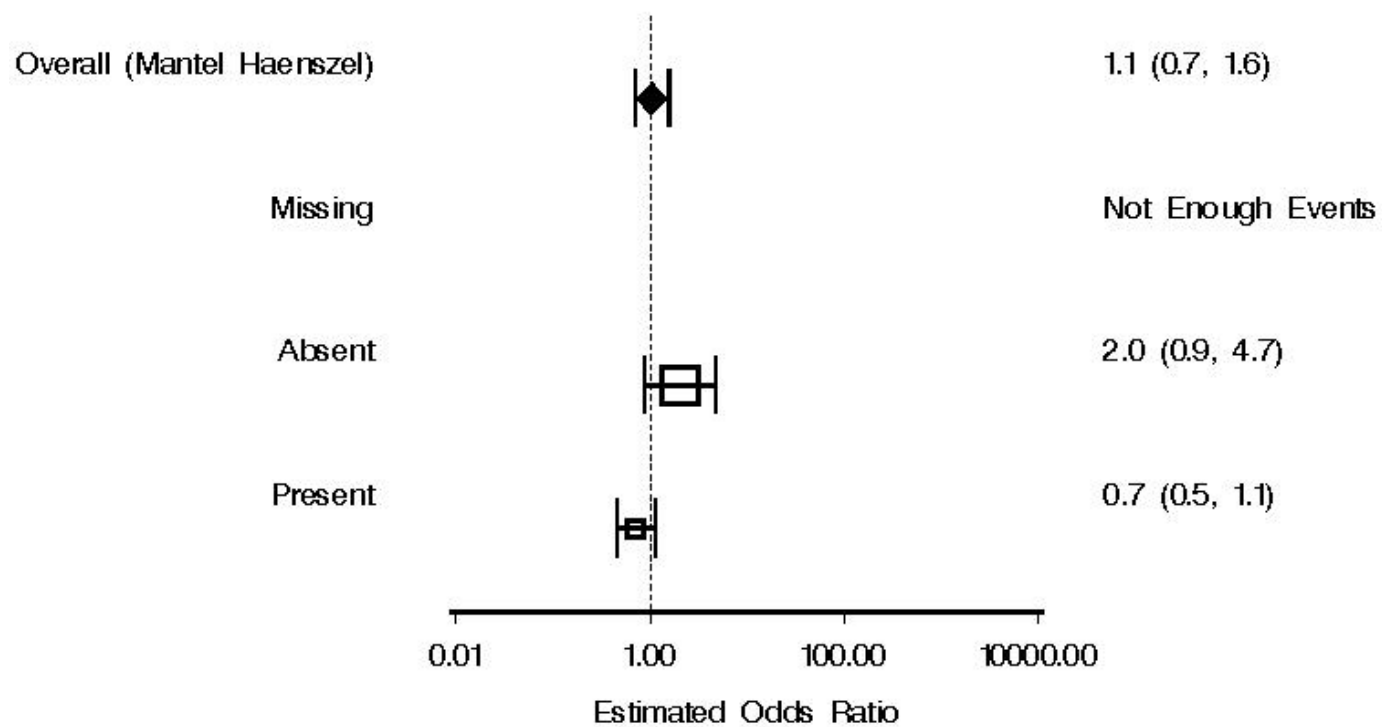
Paroxetine Adult Suicidality Analysis  
Figure 2.06. Composite Suicidal Behaviour  
Indication = PTSD



Paroxetine Adult Suicidality Analysis  
Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = All Indications



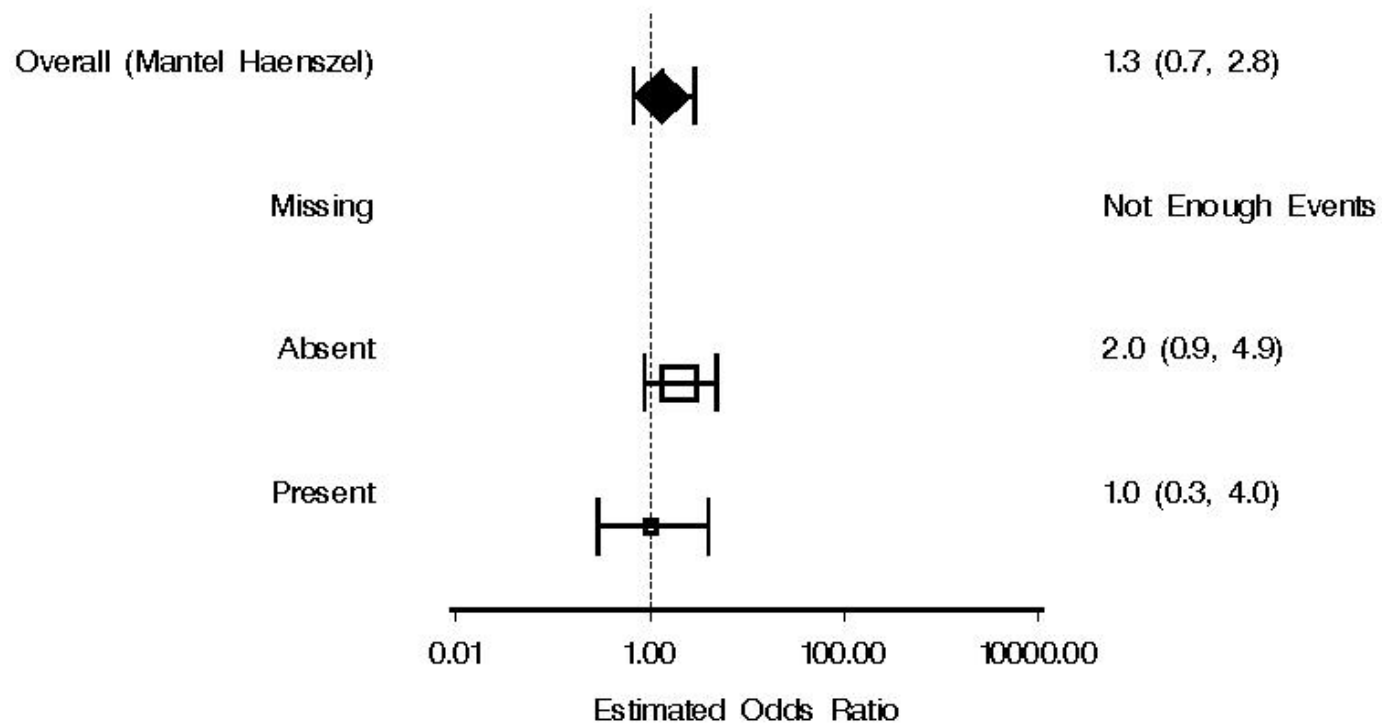
Paroxetine Adult Suicidality Analysis  
Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = All Depression





### Paroxetine Adult Suicidality Analysis

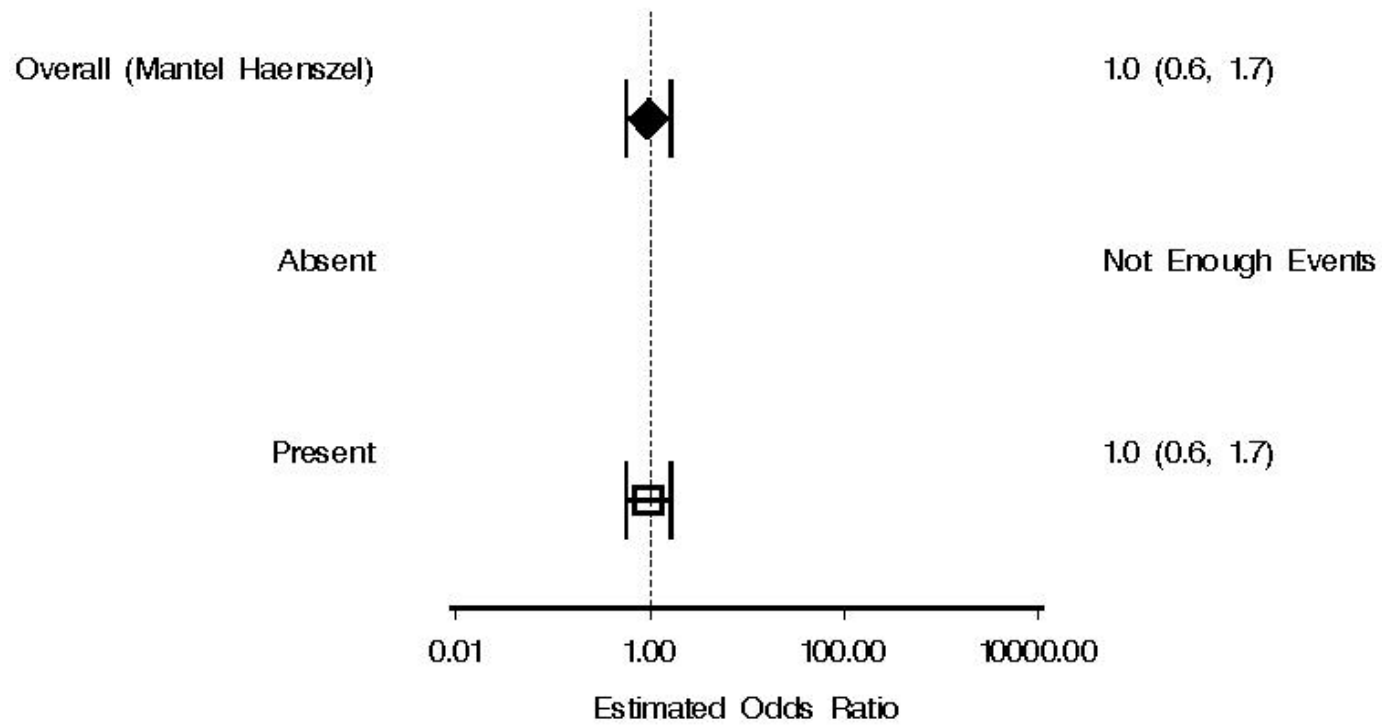
Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = MDD



Note. For two subjects in study 442 it was not possible to assess baseline suicidal ideation

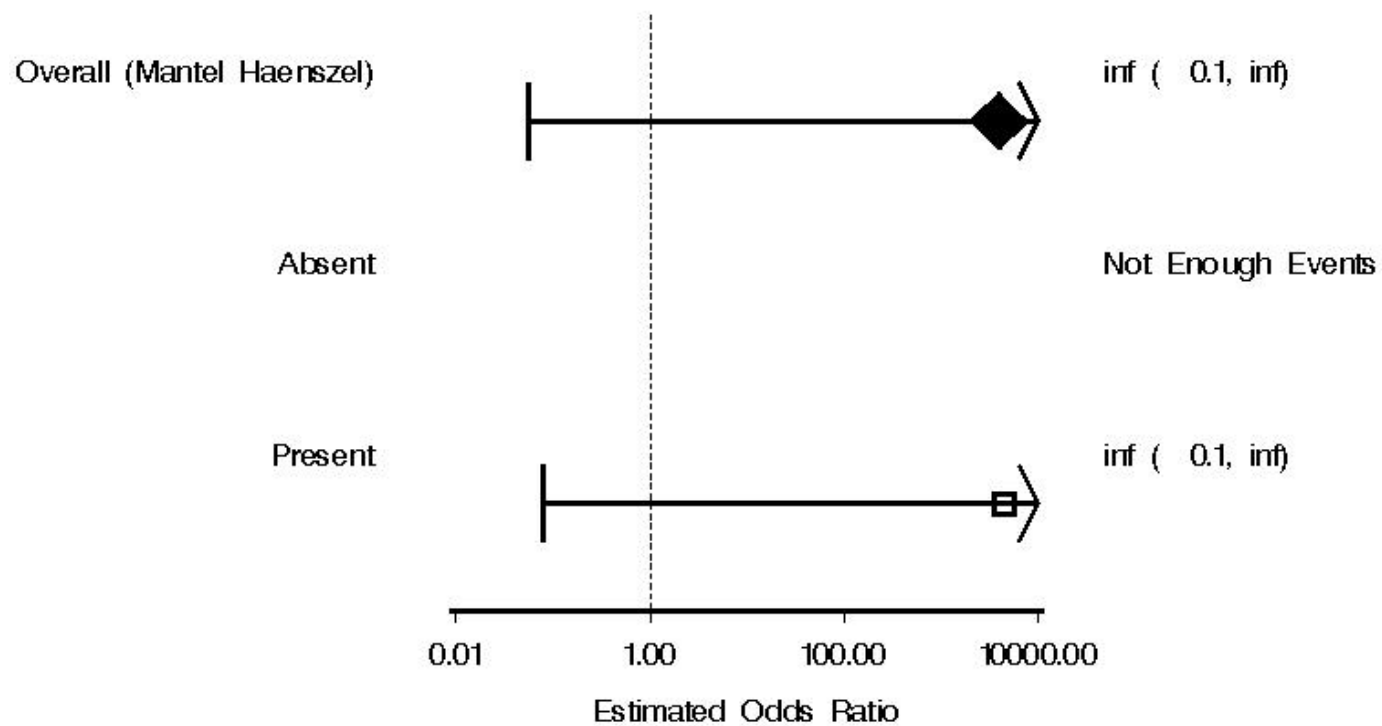
### Paroxetine Adult Suicidality Analysis

Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = IBD



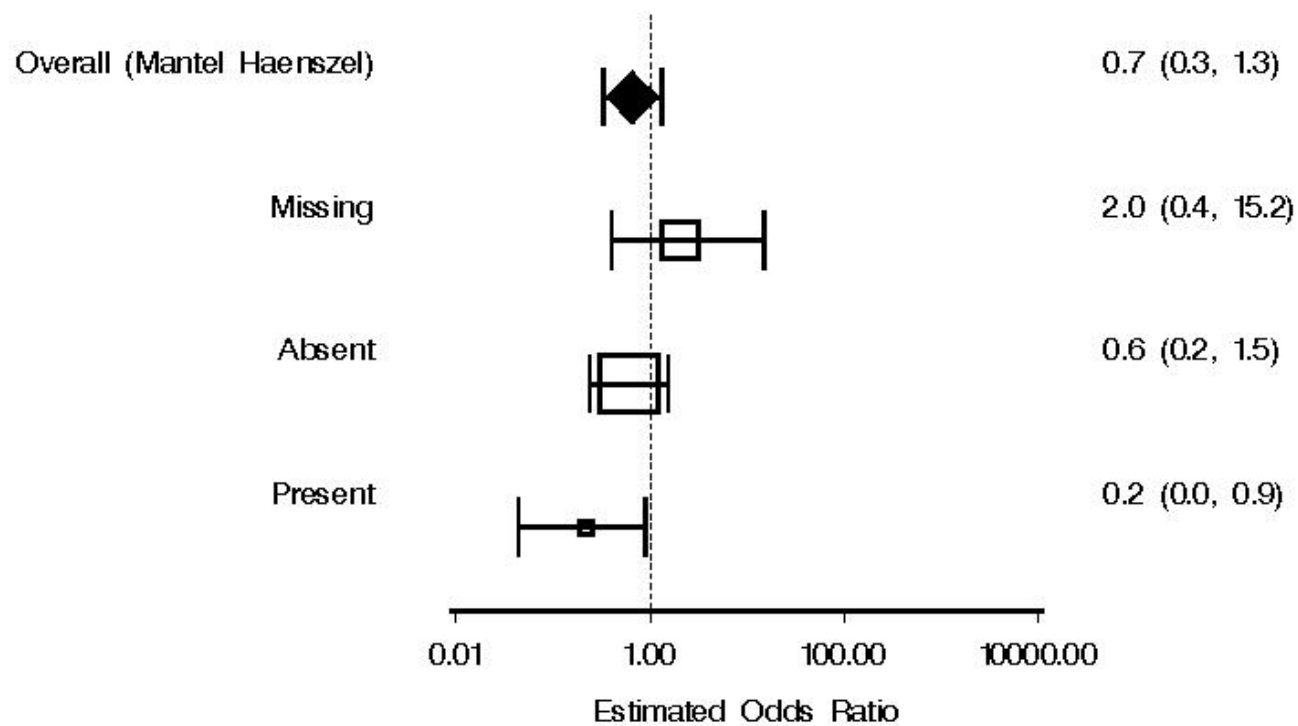
### Paroxetine Adult Suicidality Analysis

Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = Dysthymia



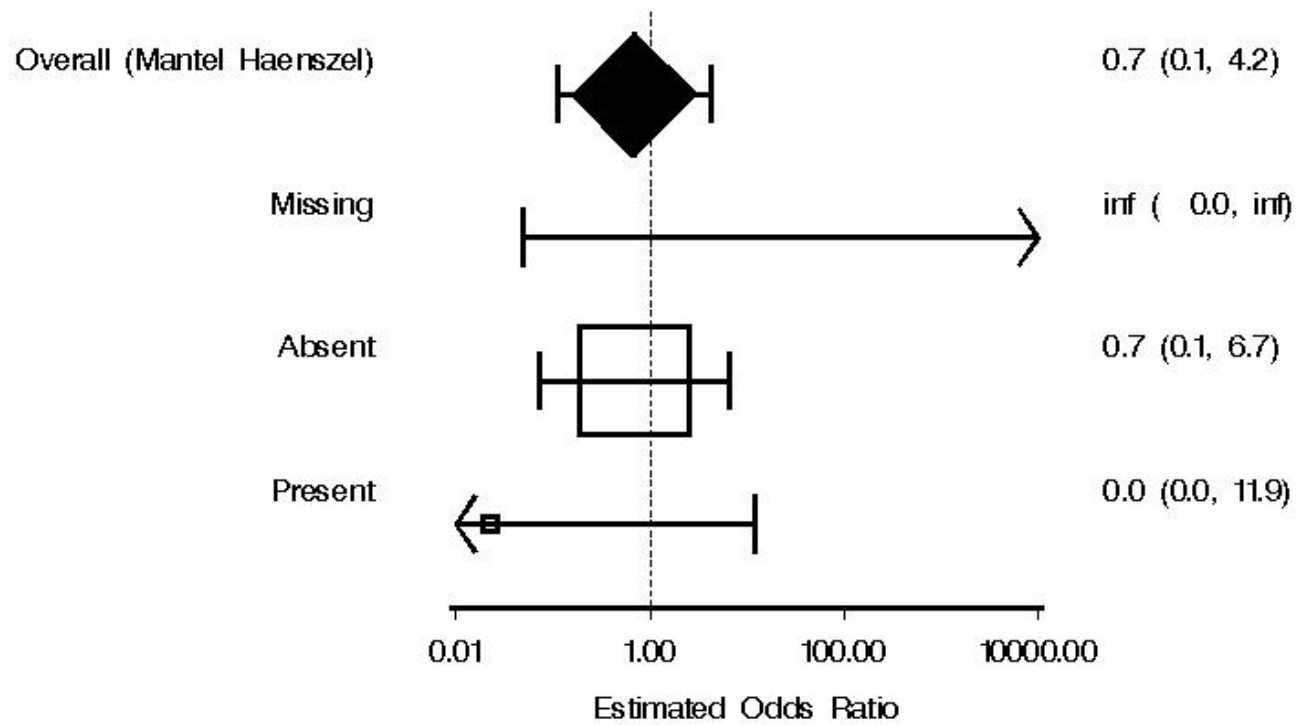
### Paroxetine Adult Suicidality Analysis

Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = All Non-Depression



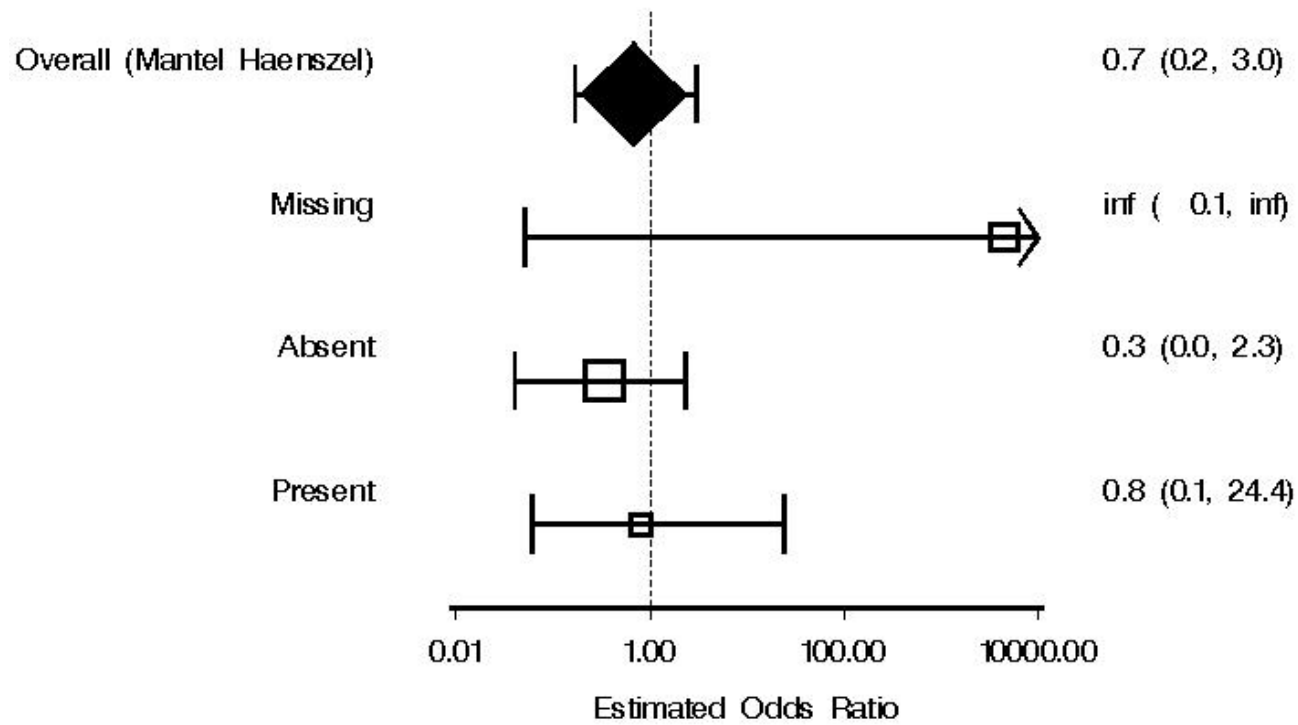
### Paroxetine Adult Suicidality Analysis

Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = Panic



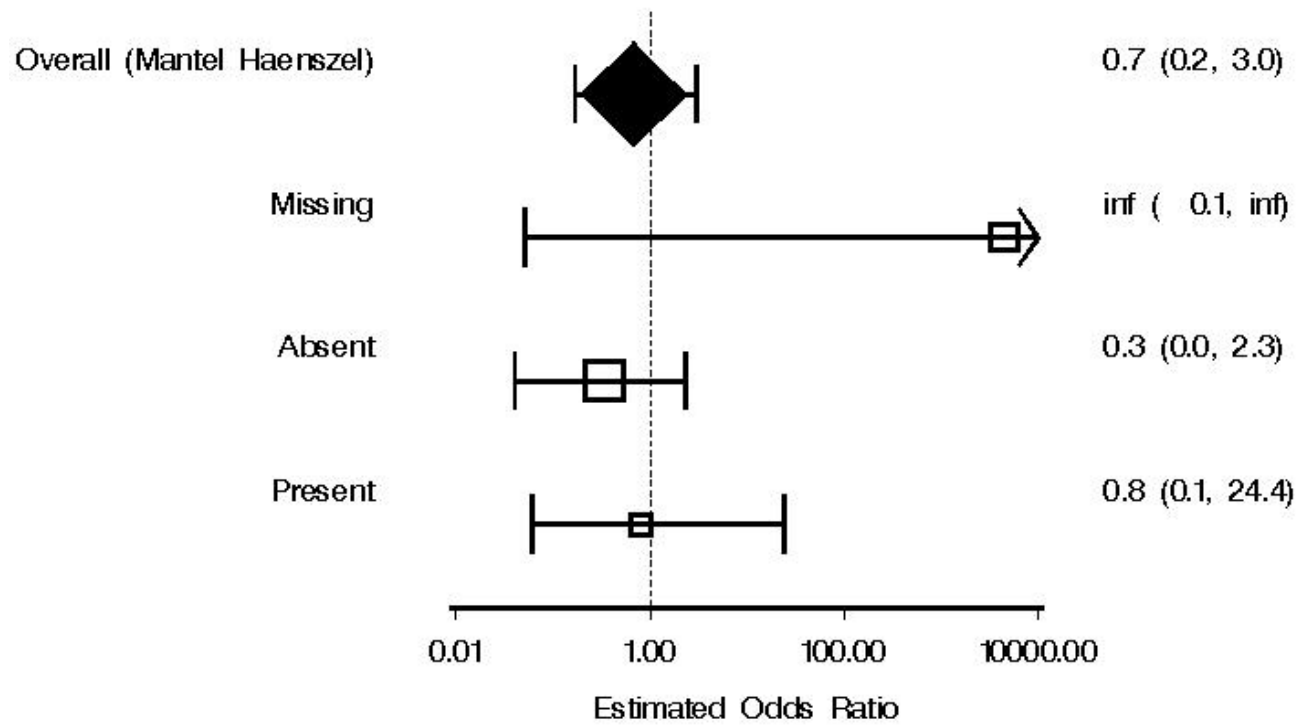
### Paroxetine Adult Suicidality Analysis

Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = OCD



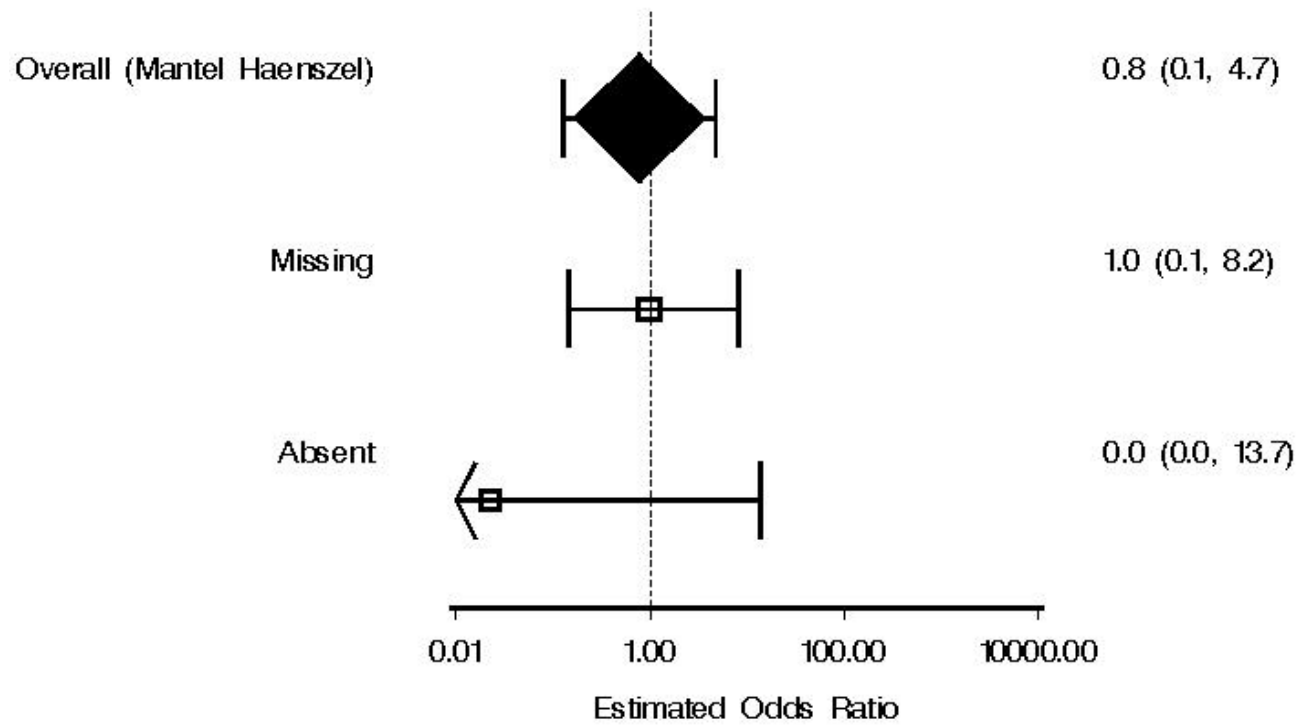
### Paroxetine Adult Suicidality Analysis

Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = OCD



### Paroxetine Adult Suicidality Analysis

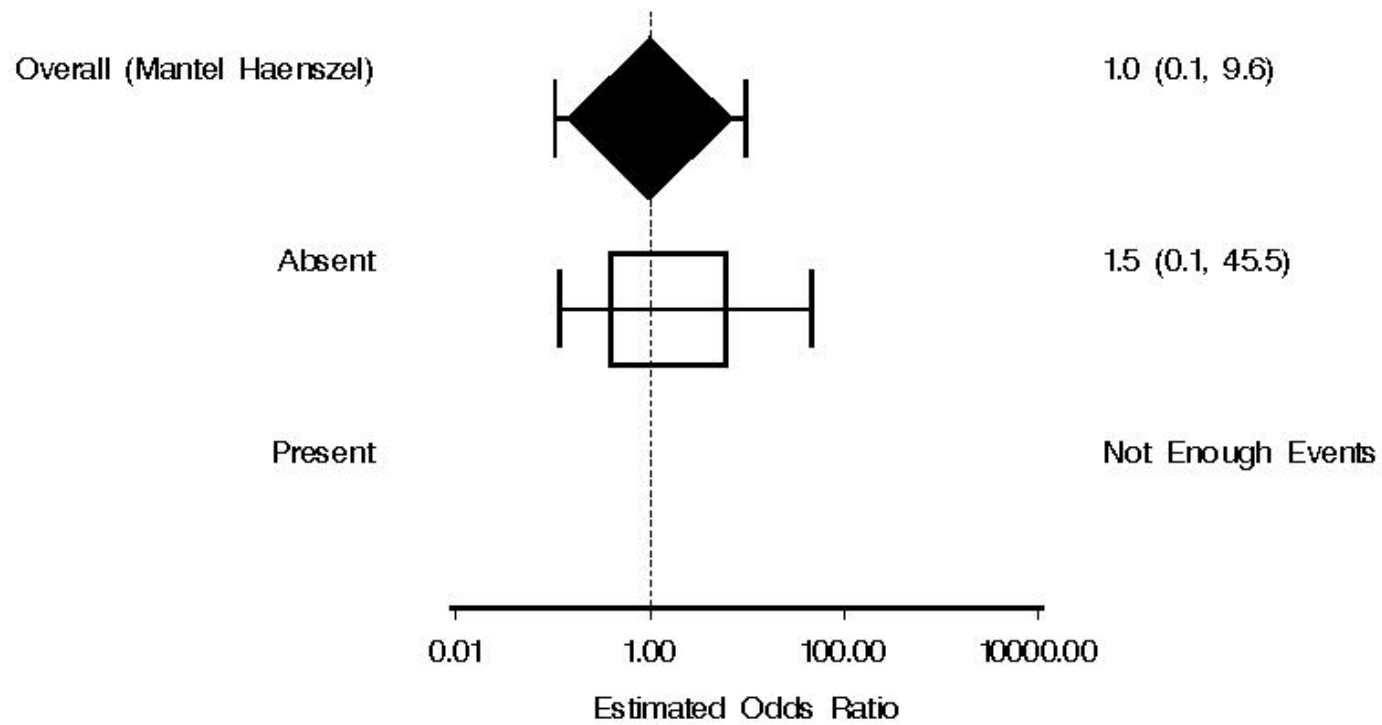
Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = SAD





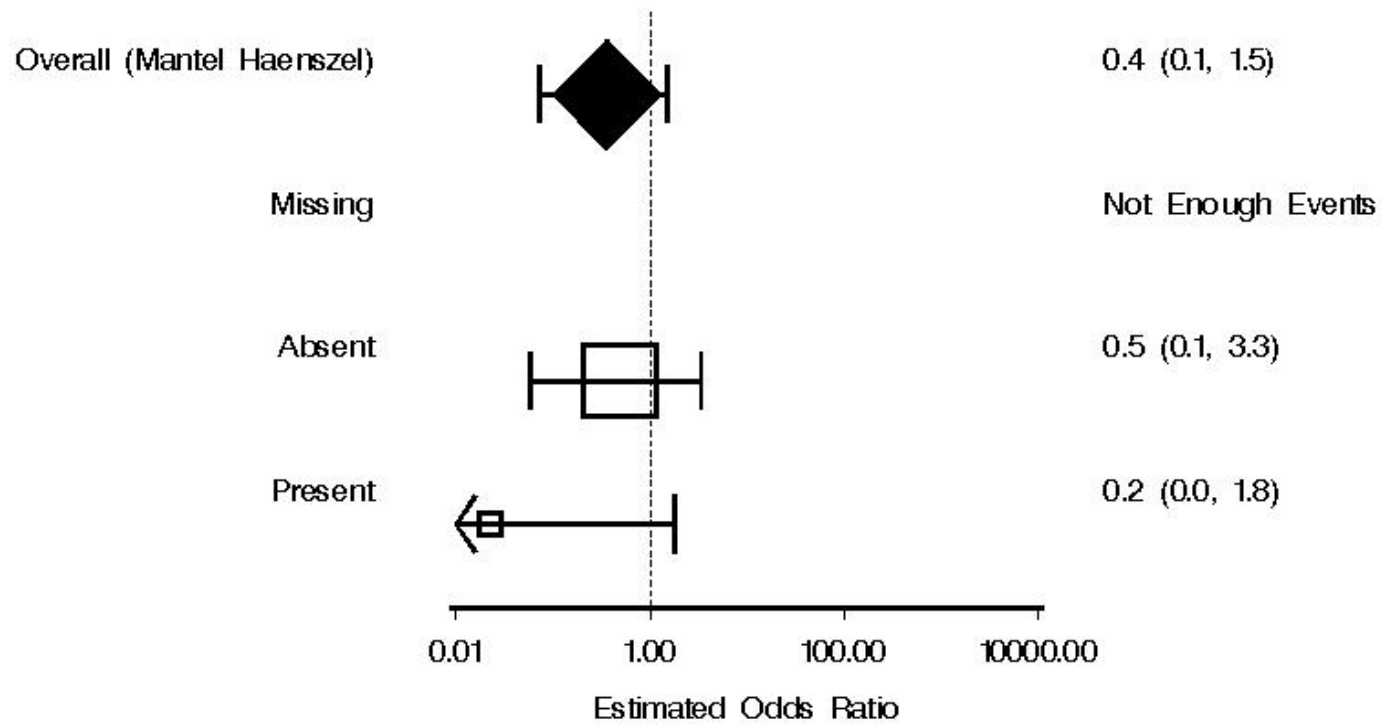
### Paroxetine Adult Suicidality Analysis

Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = GAD



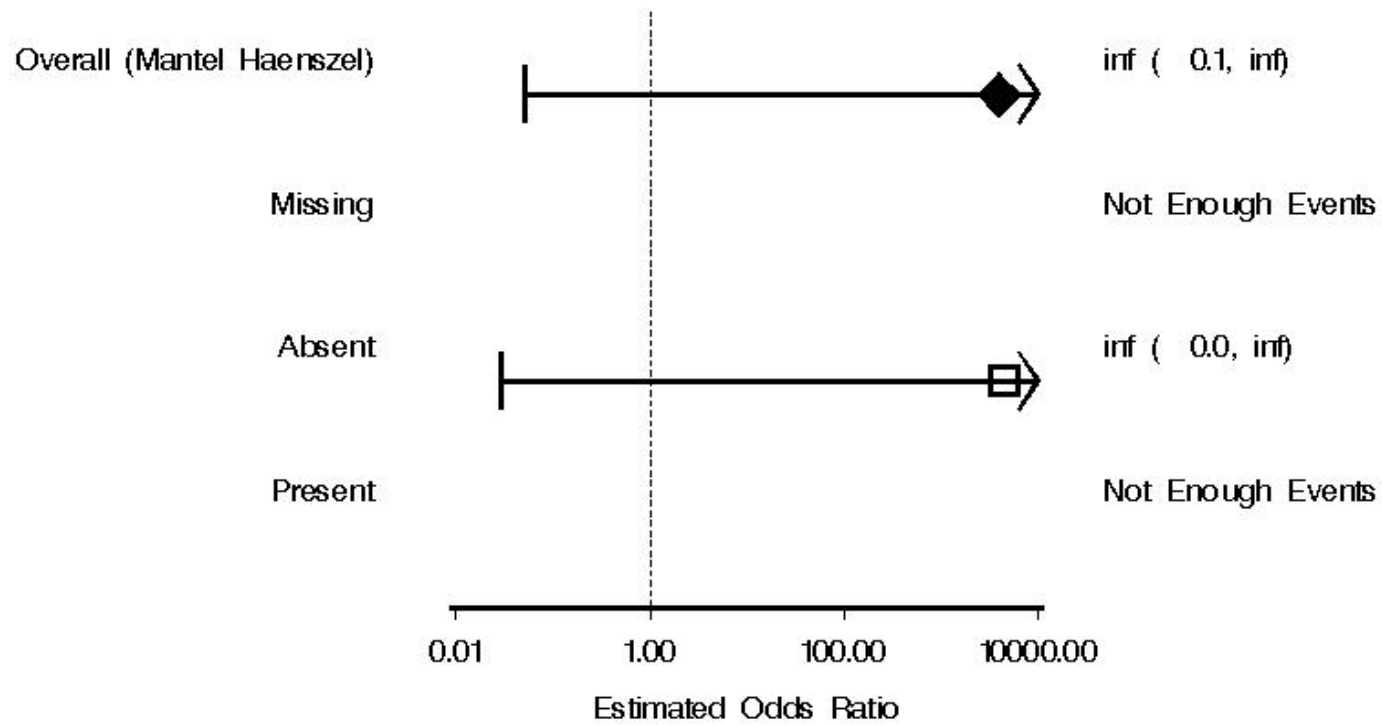
### Paroxetine Adult Suicidality Analysis

Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = PTSD

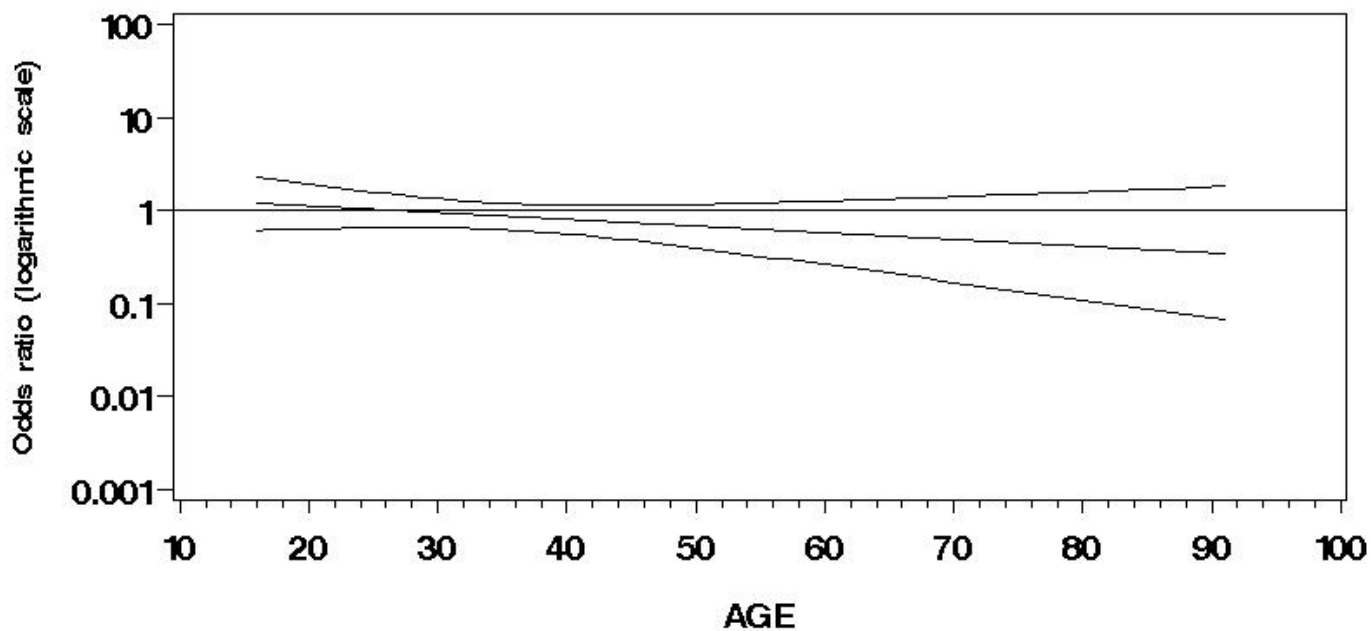


### Paroxetine Adult Suicidality Analysis

Figure 2.07. Definitive Suicidal Behaviour and Ideation by Baseline Suicidal Ideation  
Indication = PMDD

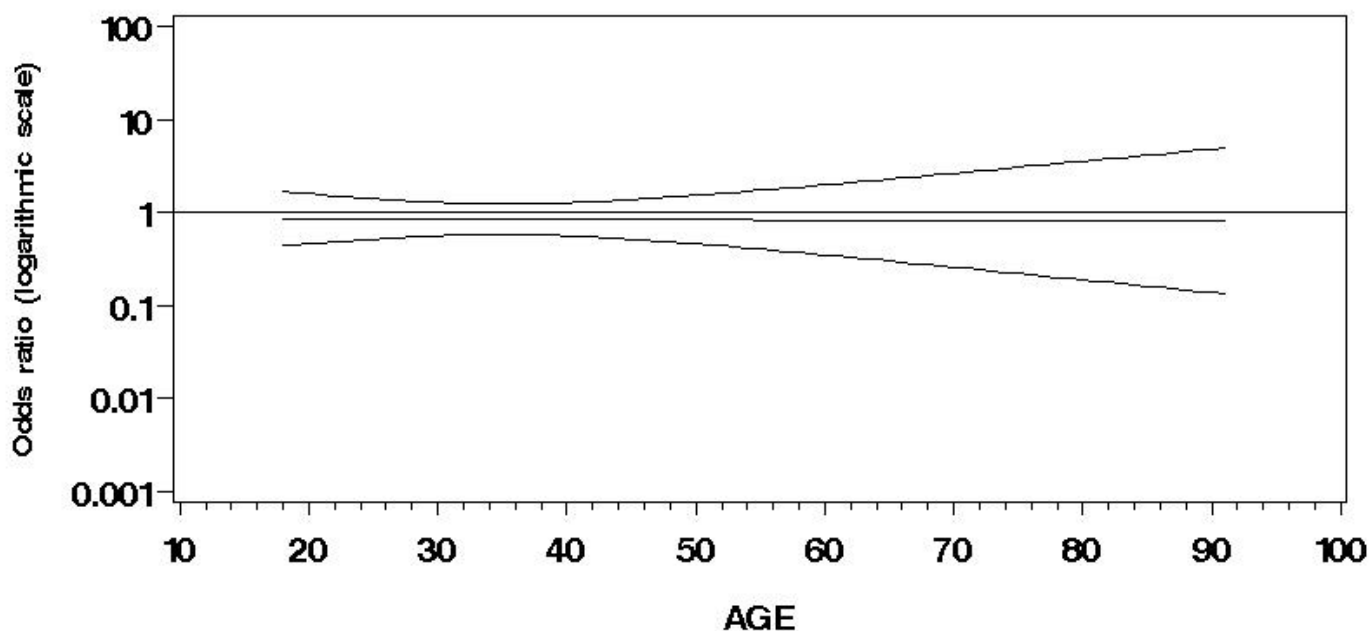


Paroxetine Adult Suicidality Analysis  
Figure 2.08: Definitive Suicidal Behaviour and Ideation by indication and Age  
Indication=All Indications  
Odds Ratio and 95% Confidence Intervals



An odds ratio < 1 corresponds to a paroxetine benefit  
Model:  $\text{logit}(y) = \text{treatment} + \text{age} + \text{treatment} * \text{age}$   
Note: treatment\*age term not sig. at 10% level: added to model for plotting purposes

Paroxetine Adult Suicidality Analysis  
Figure 2.08: Definitive Suicidal Behaviour and Ideation by indication and Age  
Indication=All Depression  
Odds Ratio and 95% Confidence Intervals



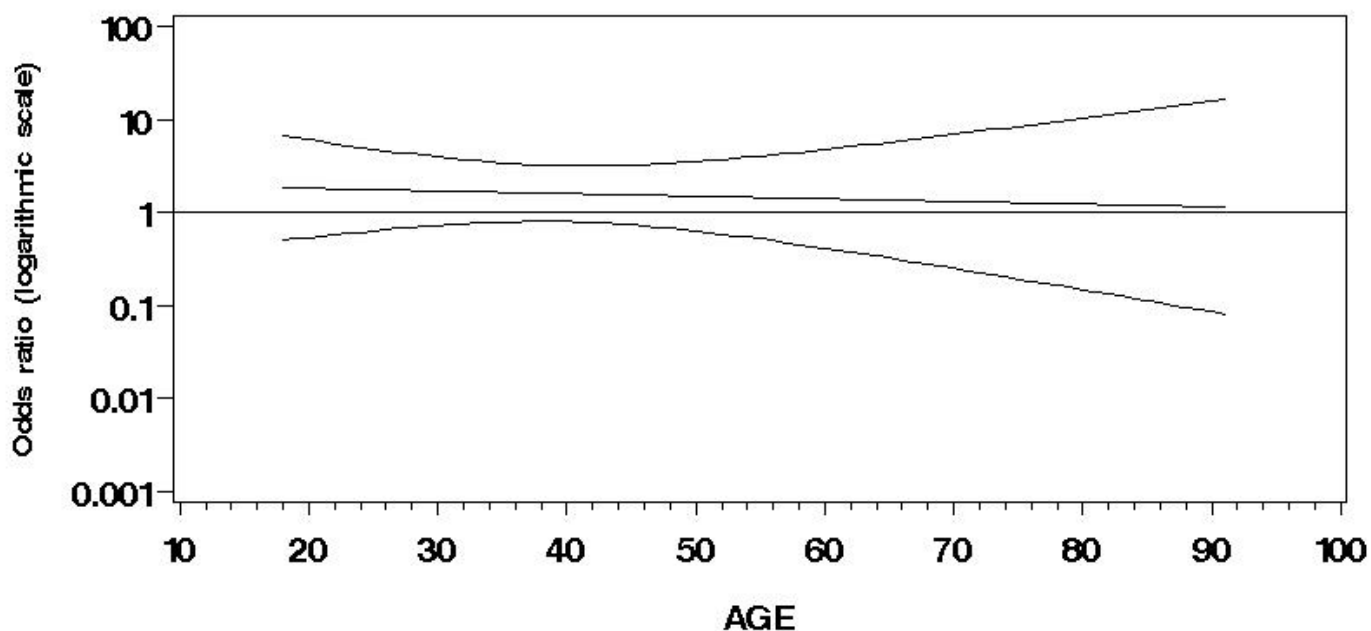
An odds ratio < 1 corresponds to a paroxetine benefit  
Model:  $\text{logit}(y) = \text{treatment} + \text{age} + \text{treatment} * \text{age}$   
Note: treatment\*age term not sig. at 10% level: added to model for plotting purposes

Paroxetine Adult Suicidality Analysis

Figure 2.08: Definitive Suicidal Behaviour and Ideation by indication and Age

Indication= MDD

Odds Ratio and 95% Confidence Intervals

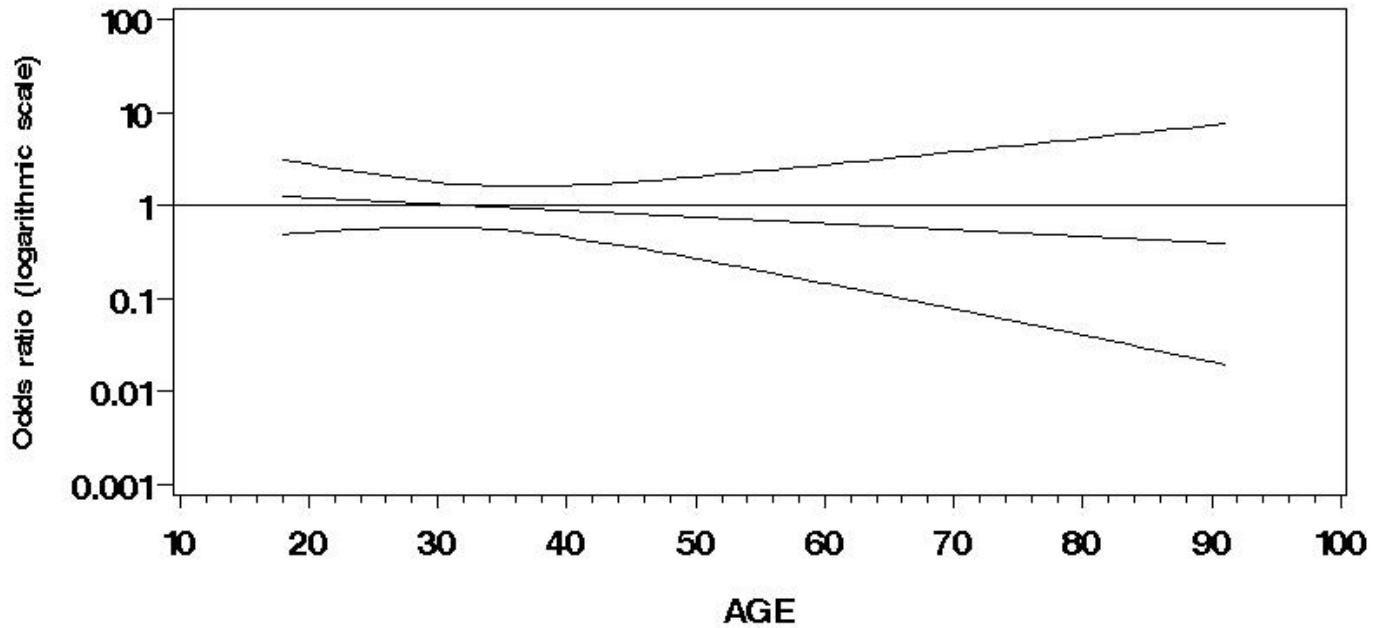


An odds ratio < 1 corresponds to a paroxetine benefit

Model:  $\text{logit}(y) = \text{treatment} + \text{age} + \text{treatment} * \text{age}$

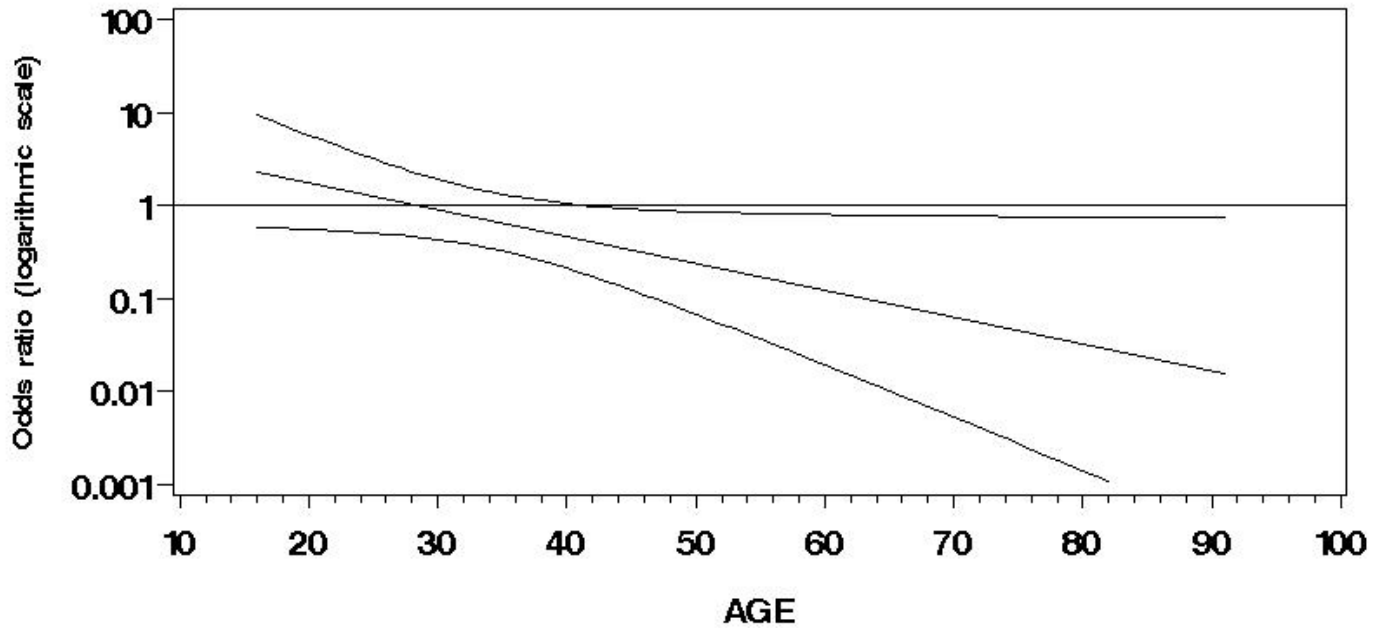
Note: treatment\*age term not sig. at 10% level; added to model for plotting purposes

Paroxetine Adult Suicidality Analysis  
Figure 2.08: Definitive Suicidal Behaviour and Ideation by indication and Age  
Indication=IBD  
Odds Ratio and 95% Confidence Intervals



An odds ratio < 1 corresponds to a paroxetine benefit  
Model:  $\text{logit}(y) = \text{treatment} + \text{age} + \text{treatment} * \text{age}$   
Note: treatment\*age term not sig. at 10% level: added to model for plotting purposes

Paroxetine Adult Suicidality Analysis  
Figure 2.08: Definitive Suicidal Behaviour and Ideation by indication and Age  
Indication=All Non-Depression  
Odds Ratio and 95% Confidence Intervals

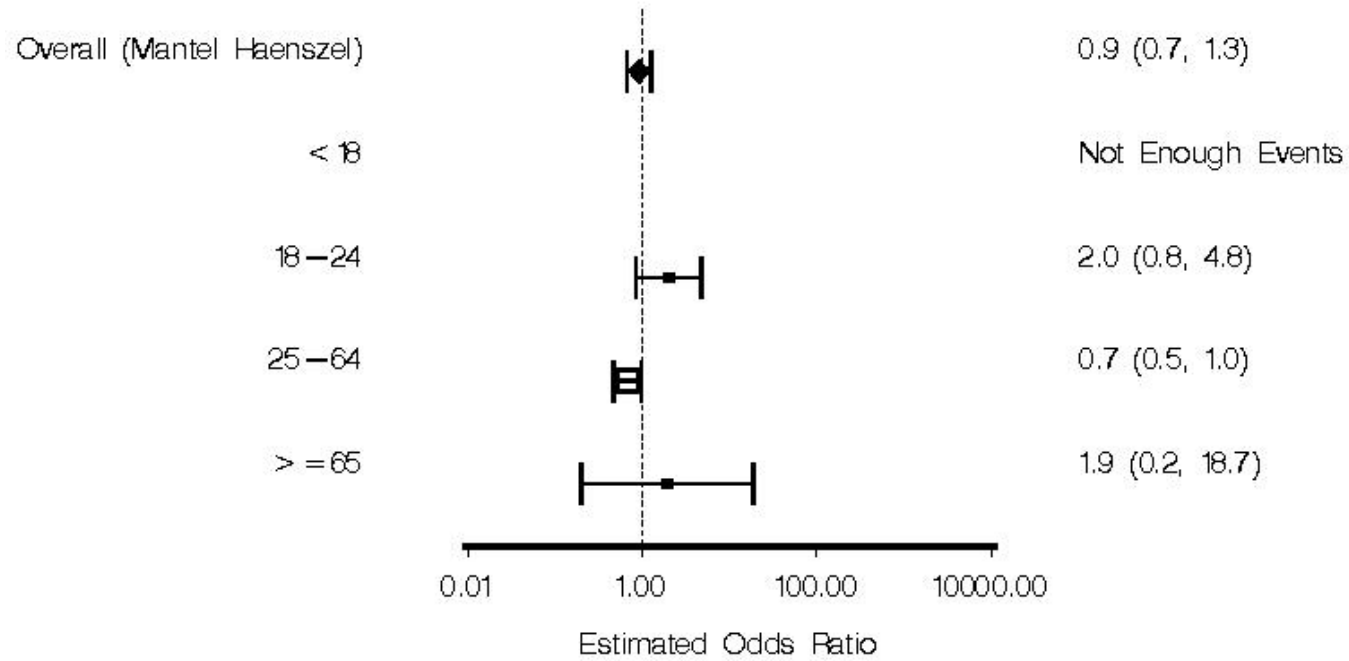


An odds ratio < 1 corresponds to a paroxetine benefit  
Model:  $\text{logit}(y) = \text{treatment} + \text{age} + \text{treatment} * \text{age}$   
Note: treatment\*age term sig. at 10% level:  $p = 0.050$



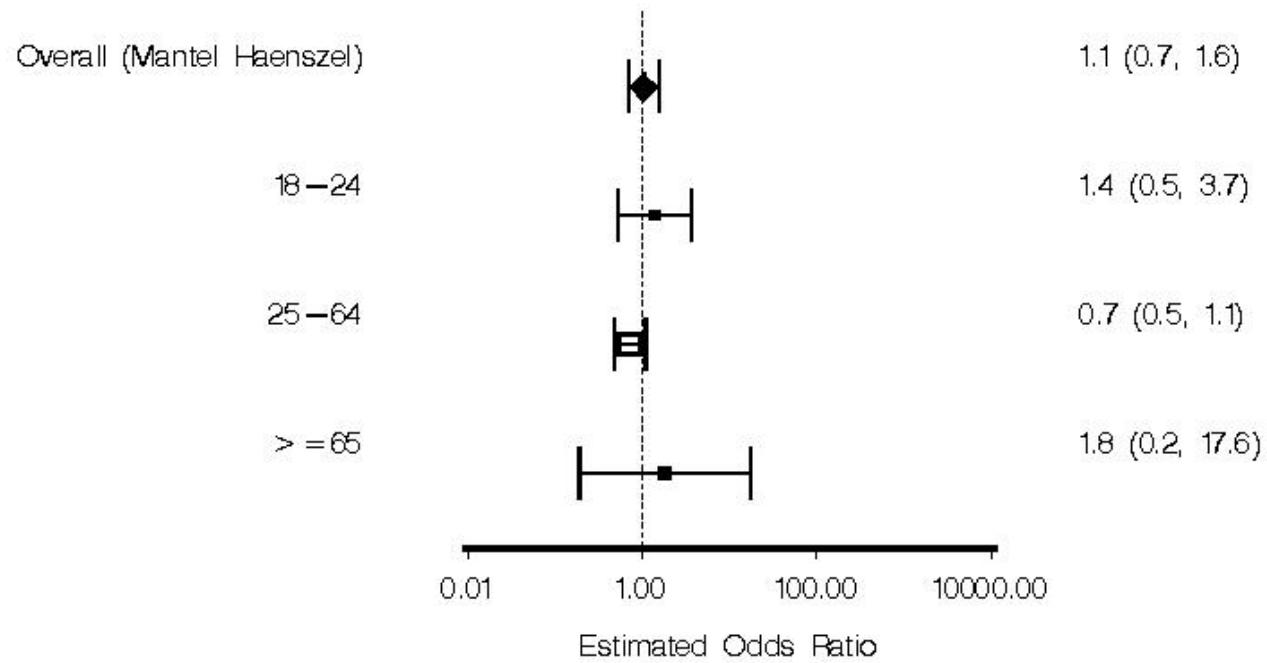
### Paroxetine Adult Suicidality Analysis

Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group  
Indication = All Indications

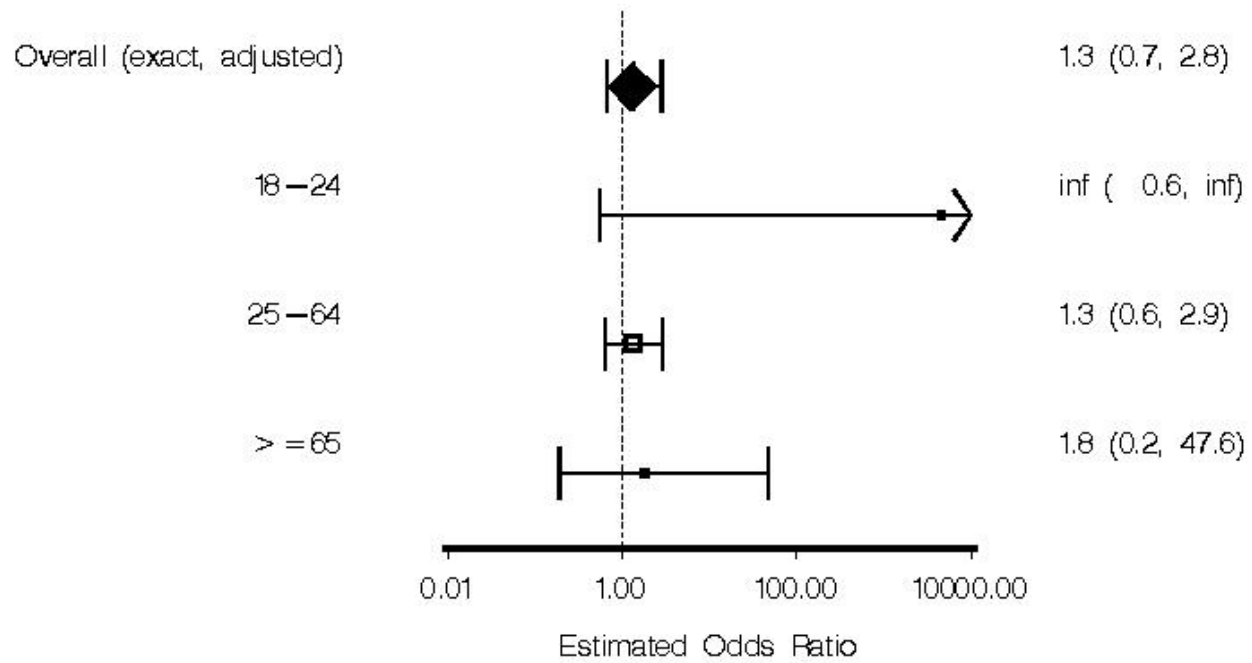


Paroxetine Adult Suicidality Analysis

Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group  
 Indication = All Depression

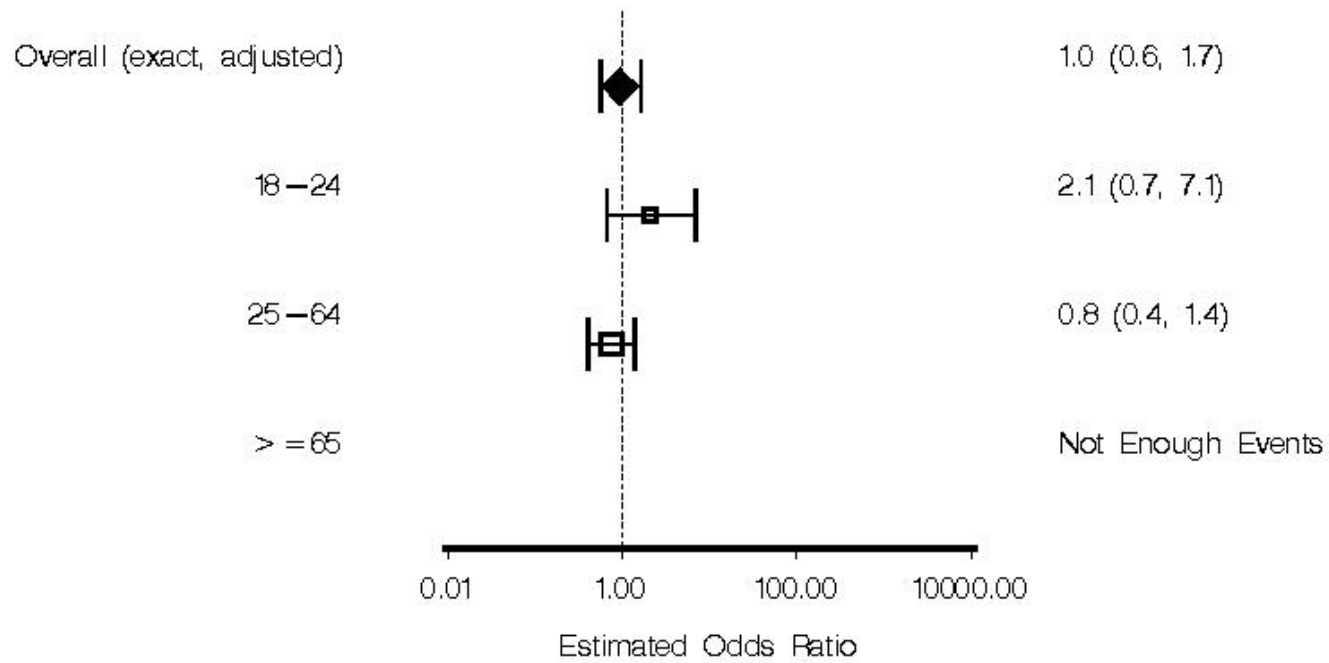


Paroxetine Adult Suicidality Analysis  
Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group  
Indication = MDD



Paroxetine Adult Suicidality Analysis

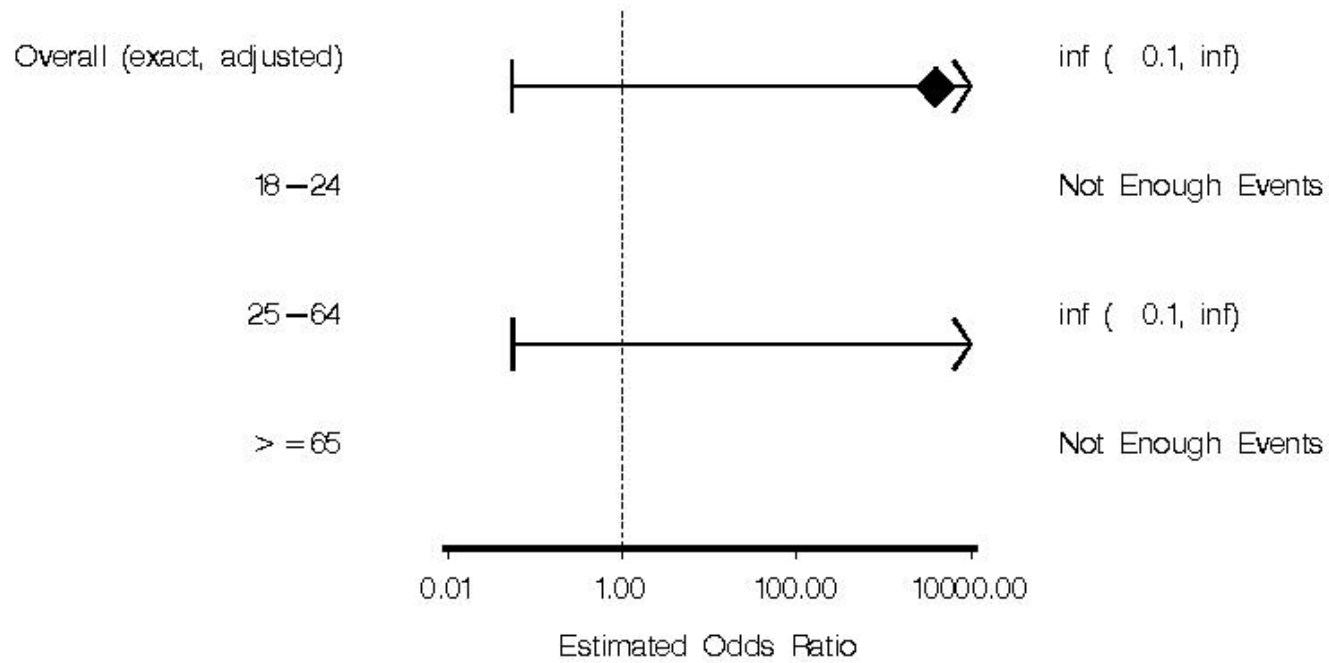
Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group  
Indication = IBD



### Paroxetine Adult Suicidality Analysis

Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group

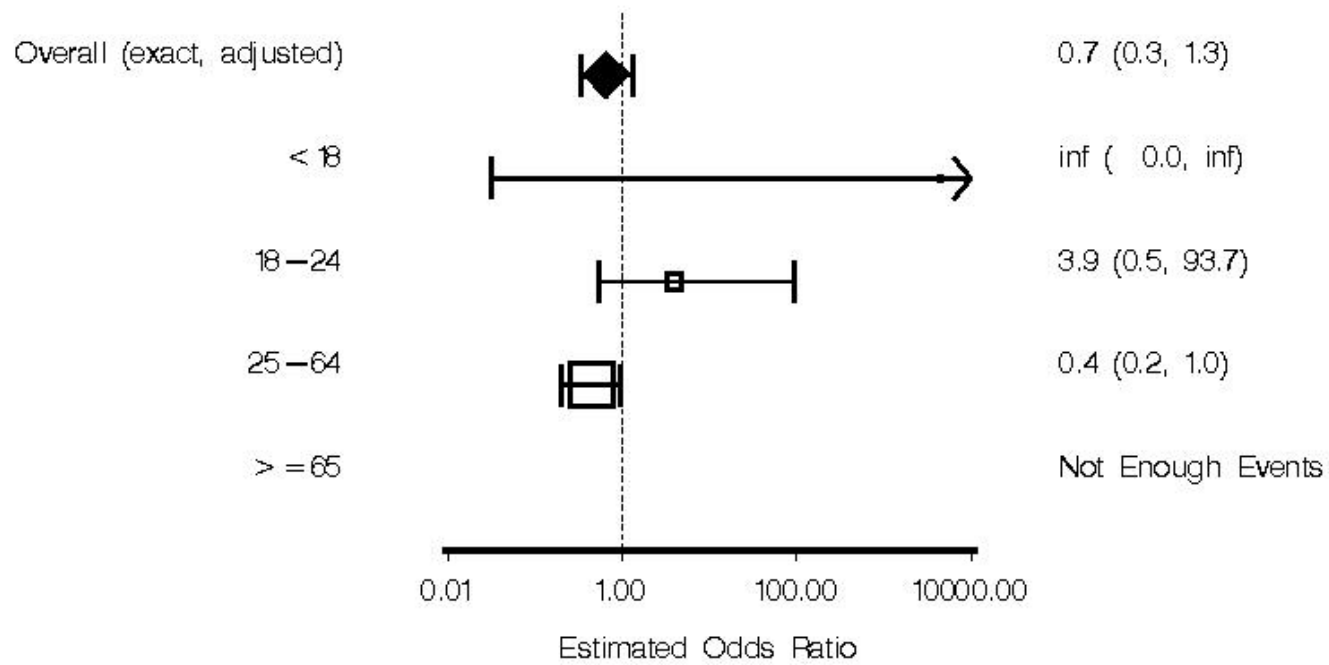
Indication = Dysthymia



Paroxetine Adult Suicidality Analysis

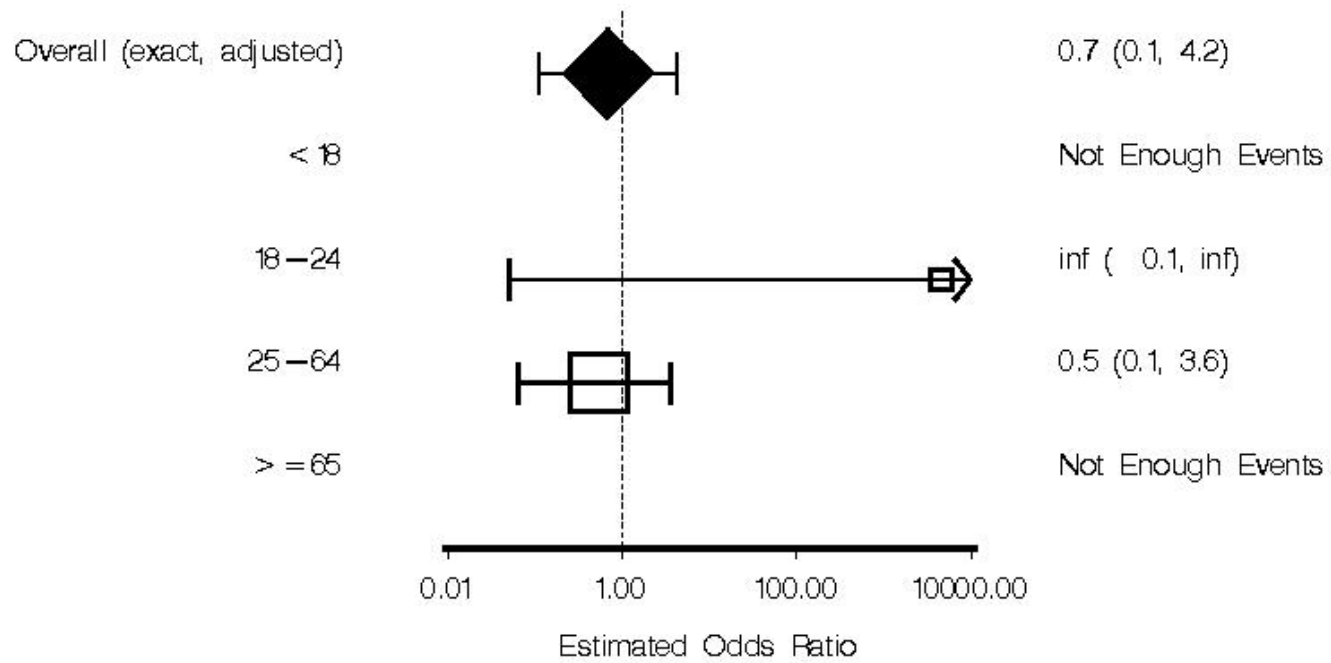
Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group

Indication = All Non-Depression



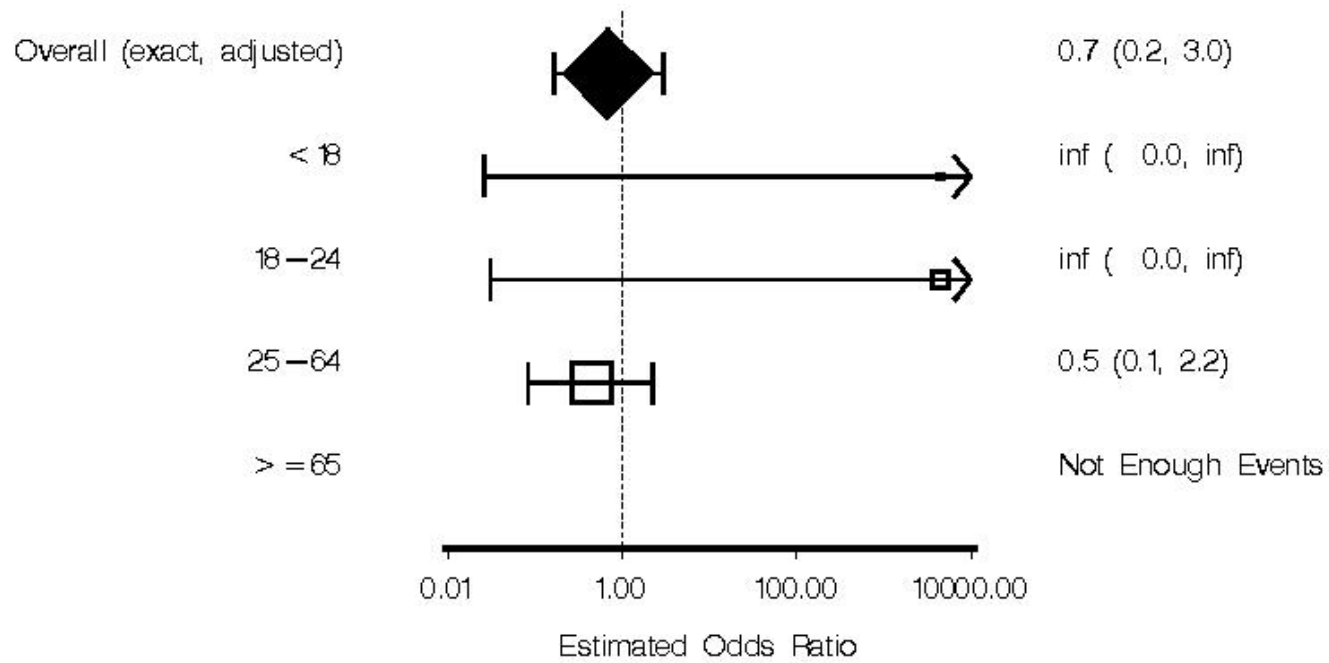
Paroxetine Adult Suicidality Analysis

Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group  
Indication = Panic



Paroxetine Adult Suicidality Analysis

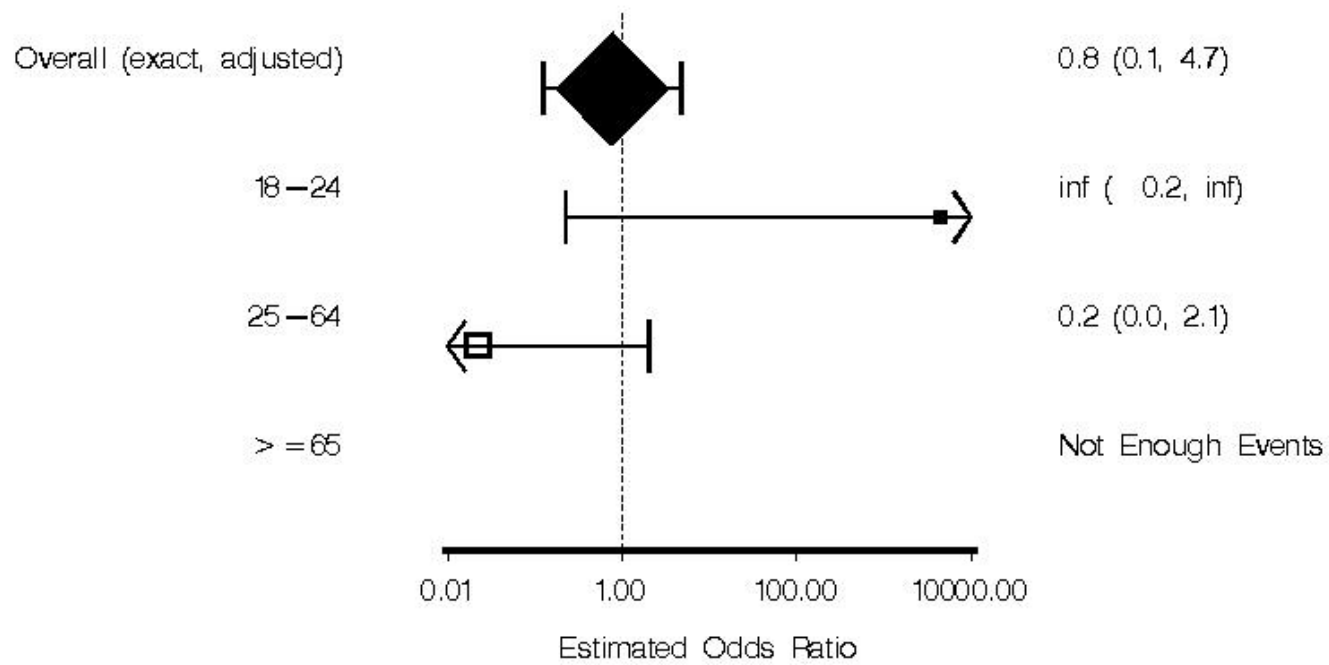
Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group  
Indication = OCD





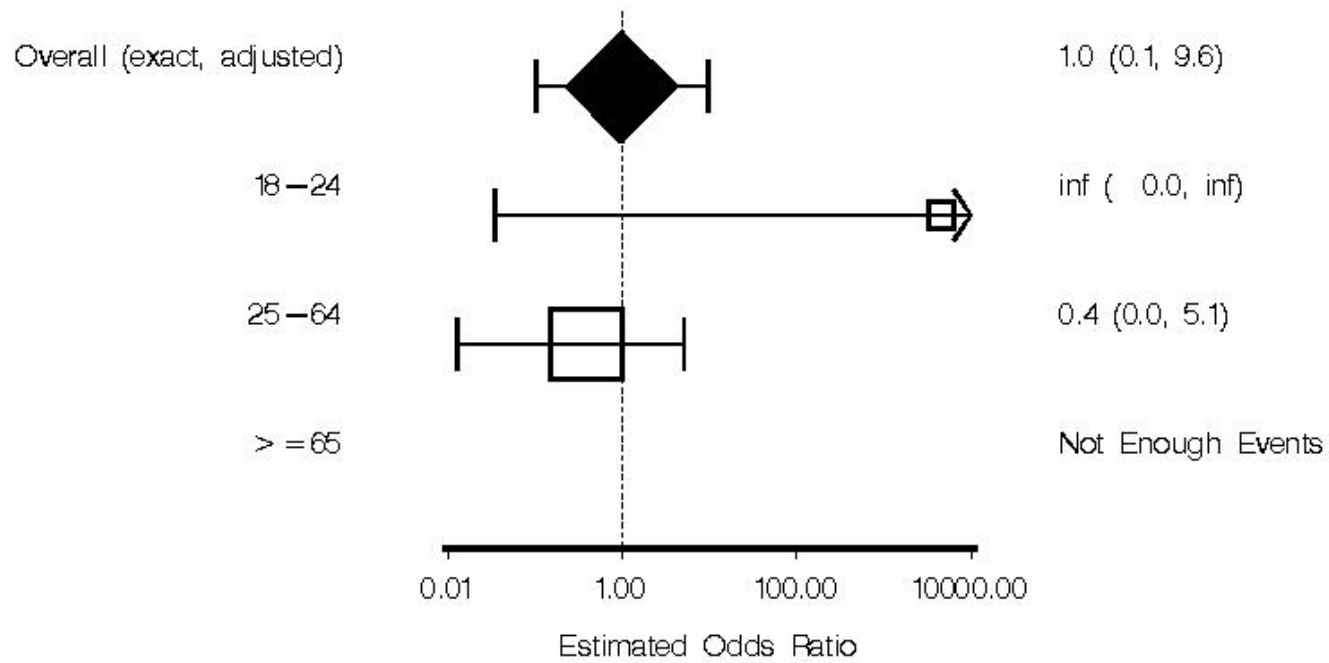
### Paroxetine Adult Suicidality Analysis

Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group  
Indication = SAD



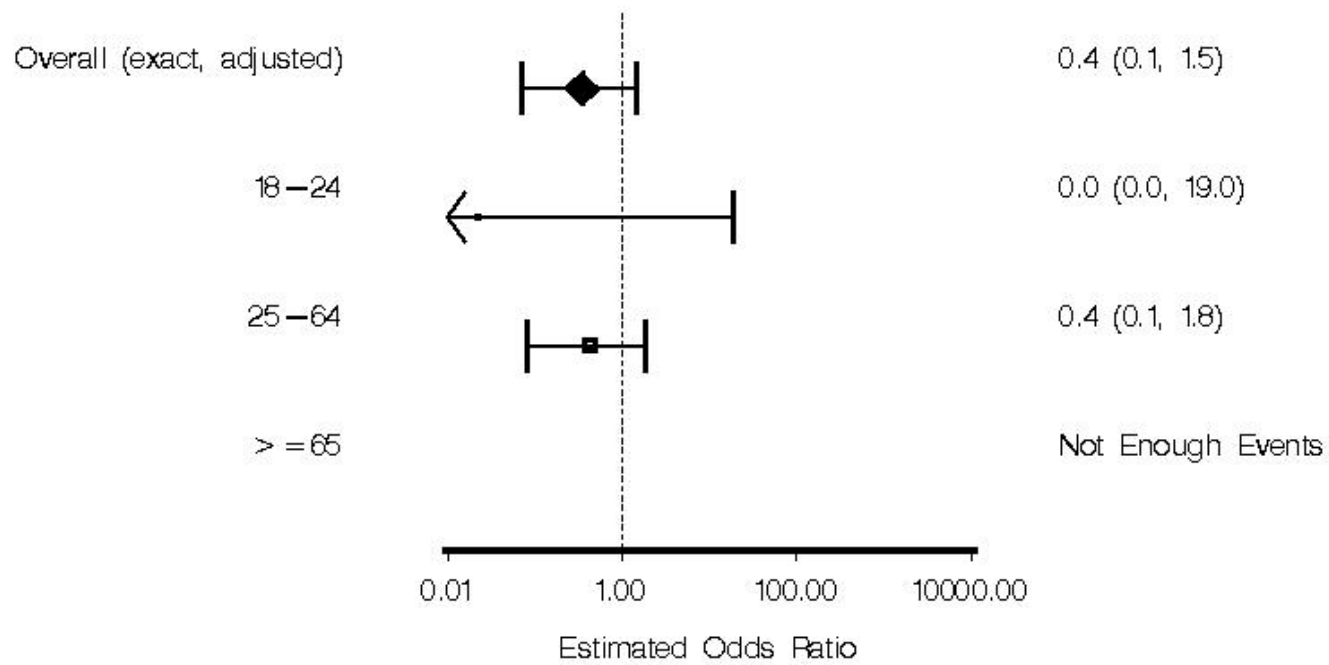
Paroxetine Adult Suicidality Analysis

Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group  
Indication = GAD



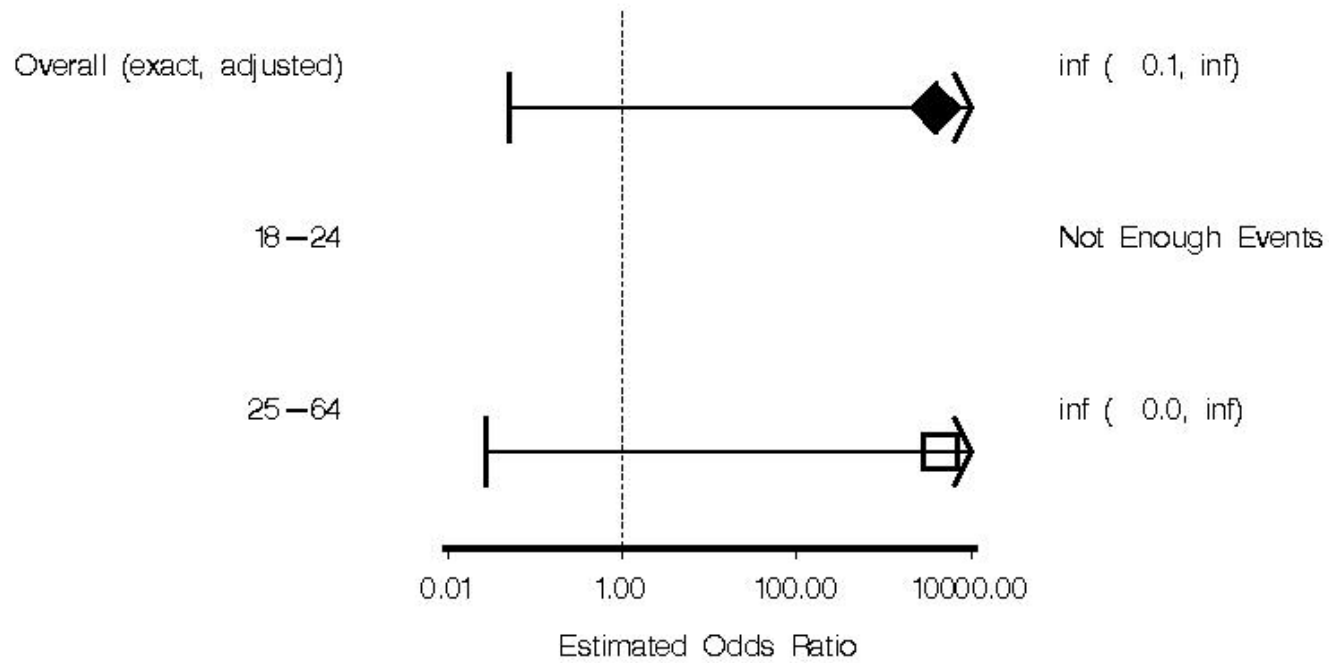
Paroxetine Adult Suicidality Analysis

Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group  
Indication = PTSD



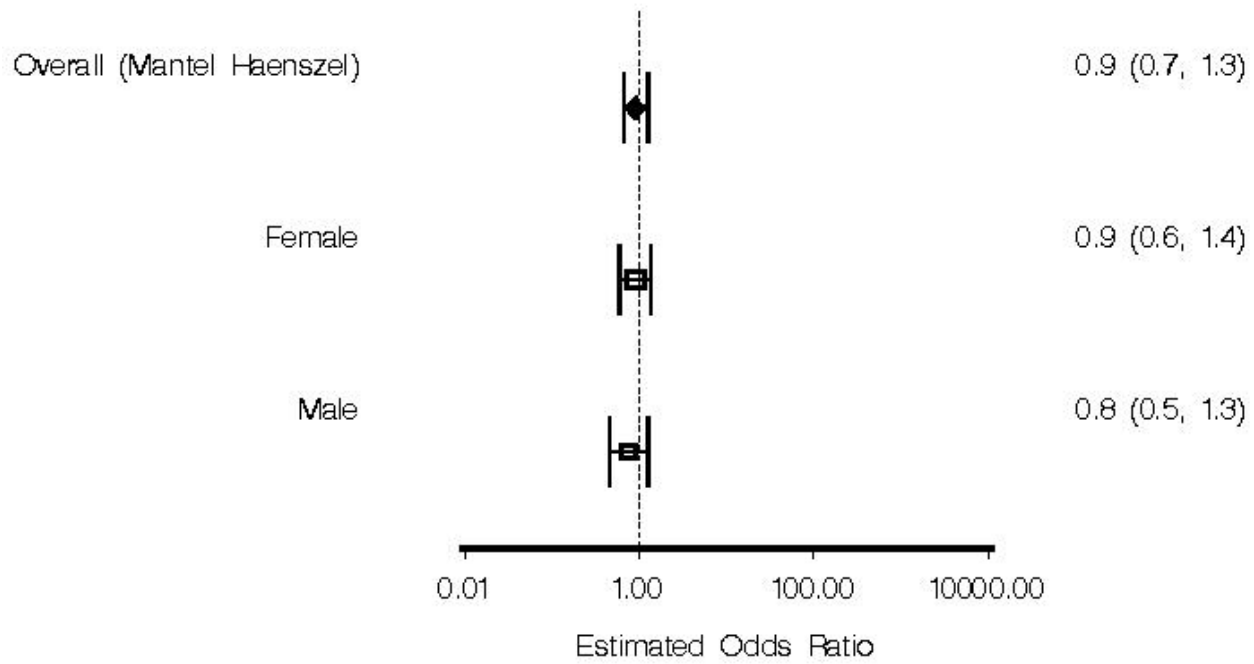
### Paroxetine Adult Suicidality Analysis

Figure 2.09. Definitive Suicidal Behaviour and Ideation by Age Group  
Indication = PMDD



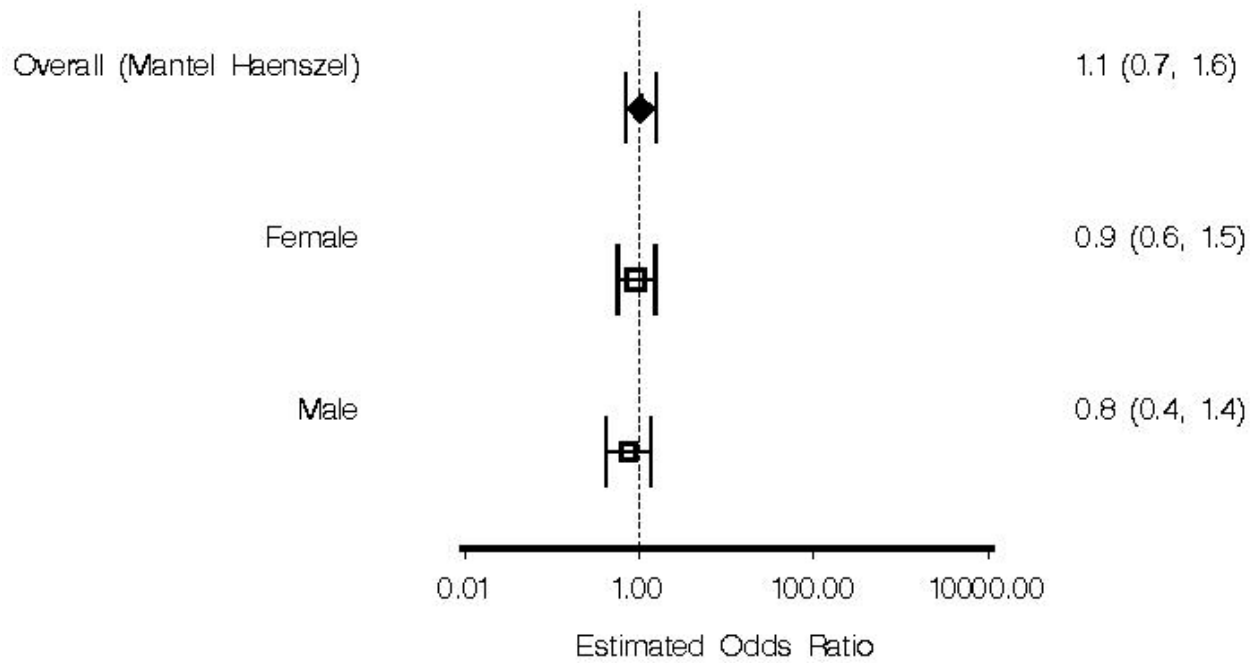
### Paroxetine Adult Suicidality Analysis

Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender  
Indication = All Indications



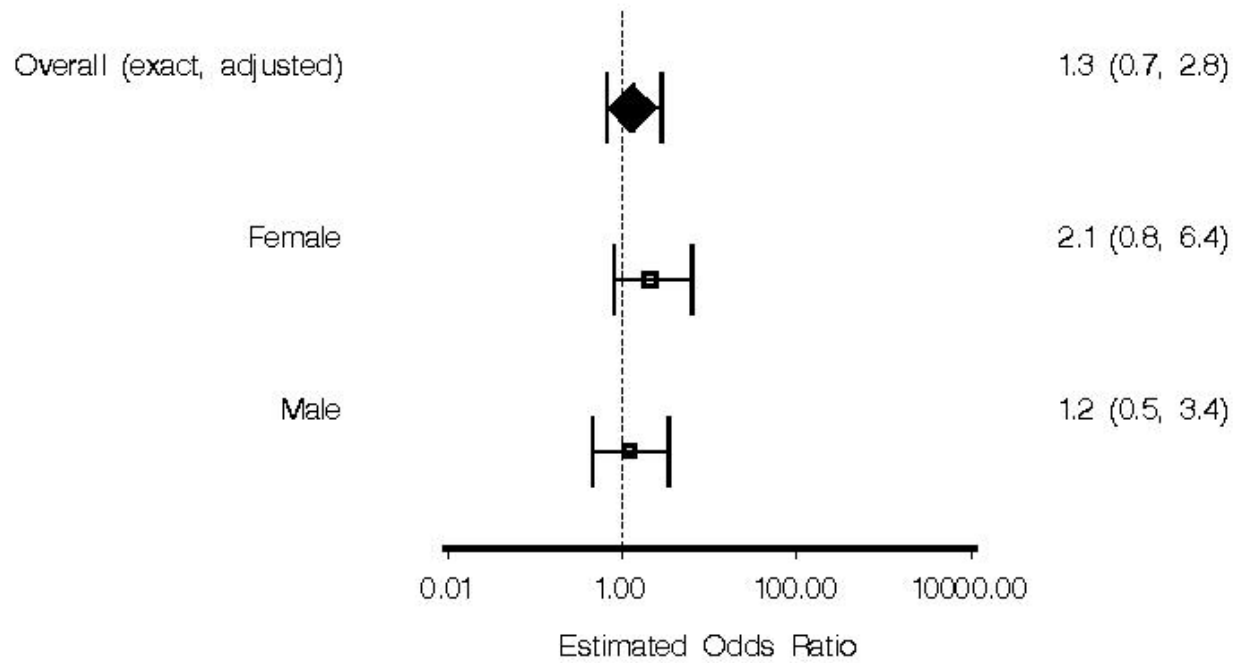
### Paroxetine Adult Suicidality Analysis

Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender  
Indication = All Depression



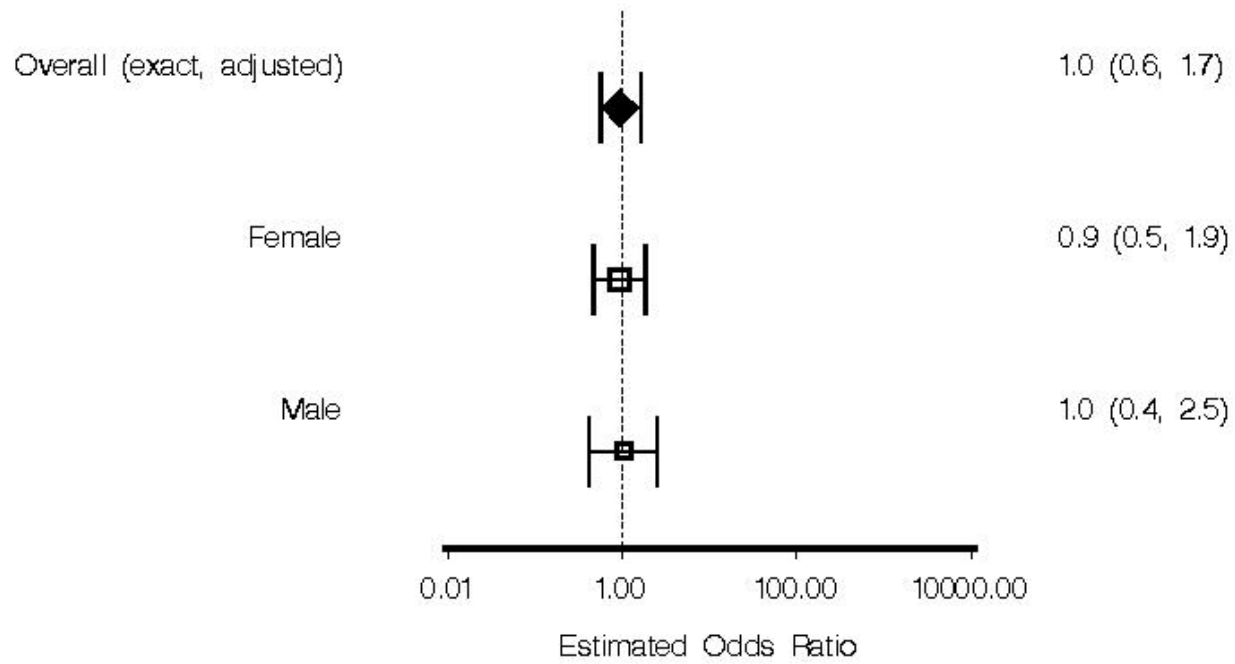
### Paroxetine Adult Suicidality Analysis

Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender  
Indication = MDD



Paroxetine Adult Suicidality Analysis

Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender  
Indication = IBD

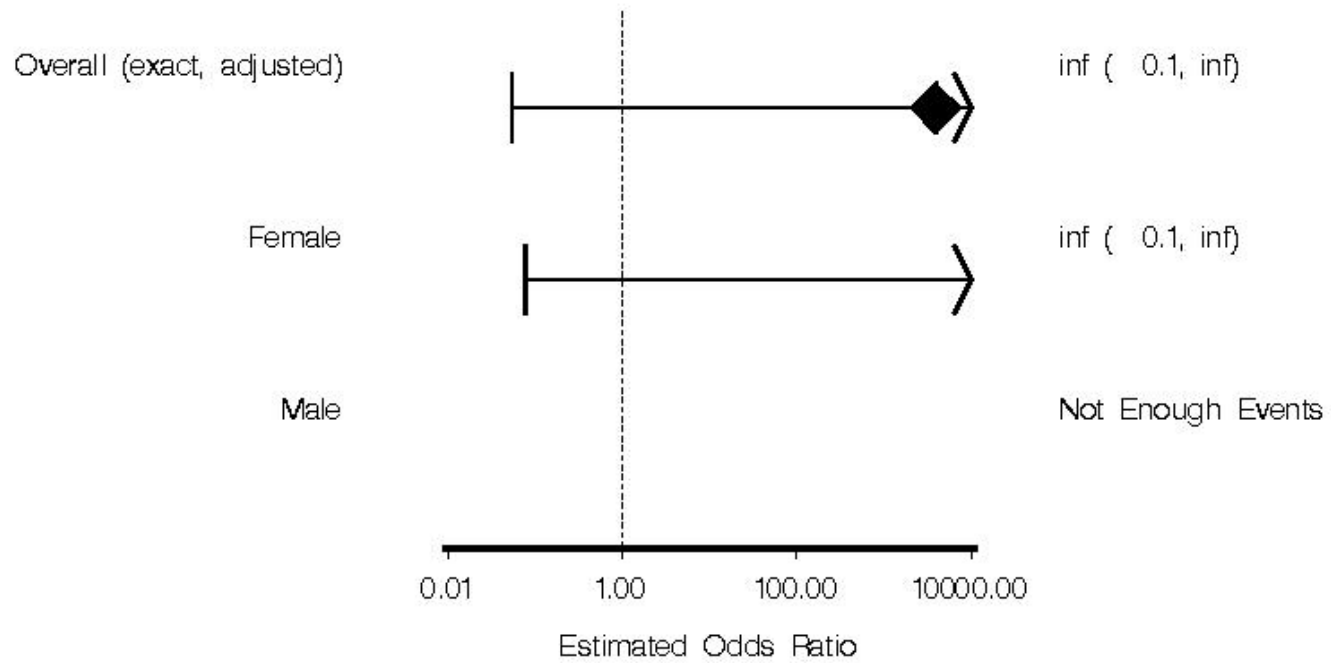




### Paroxetine Adult Suicidality Analysis

Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender

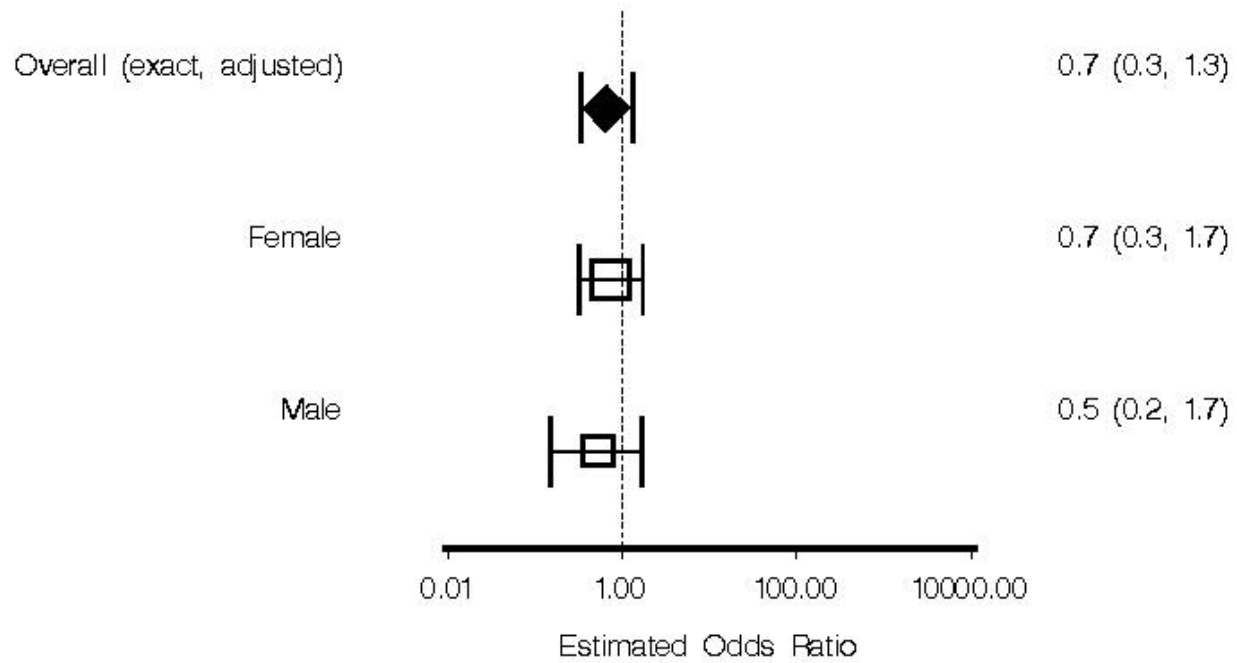
Indication = Dysthymia



### Paroxetine Adult Suicidality Analysis

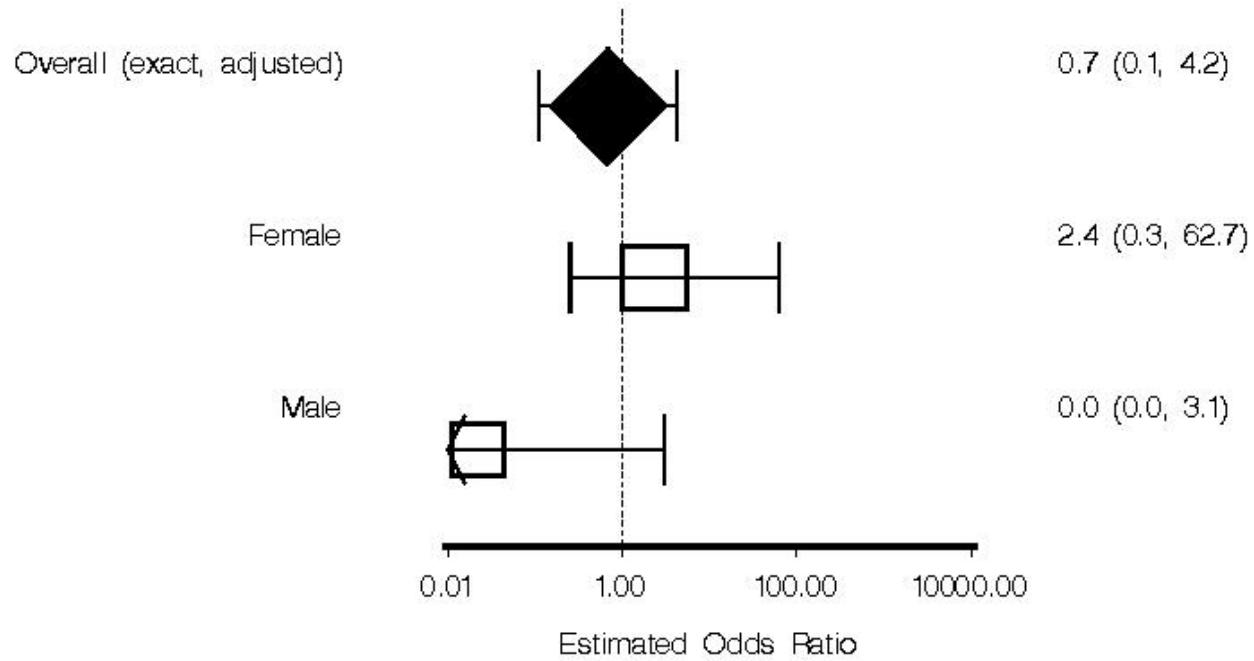
Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender

Indication = All Non-Depression



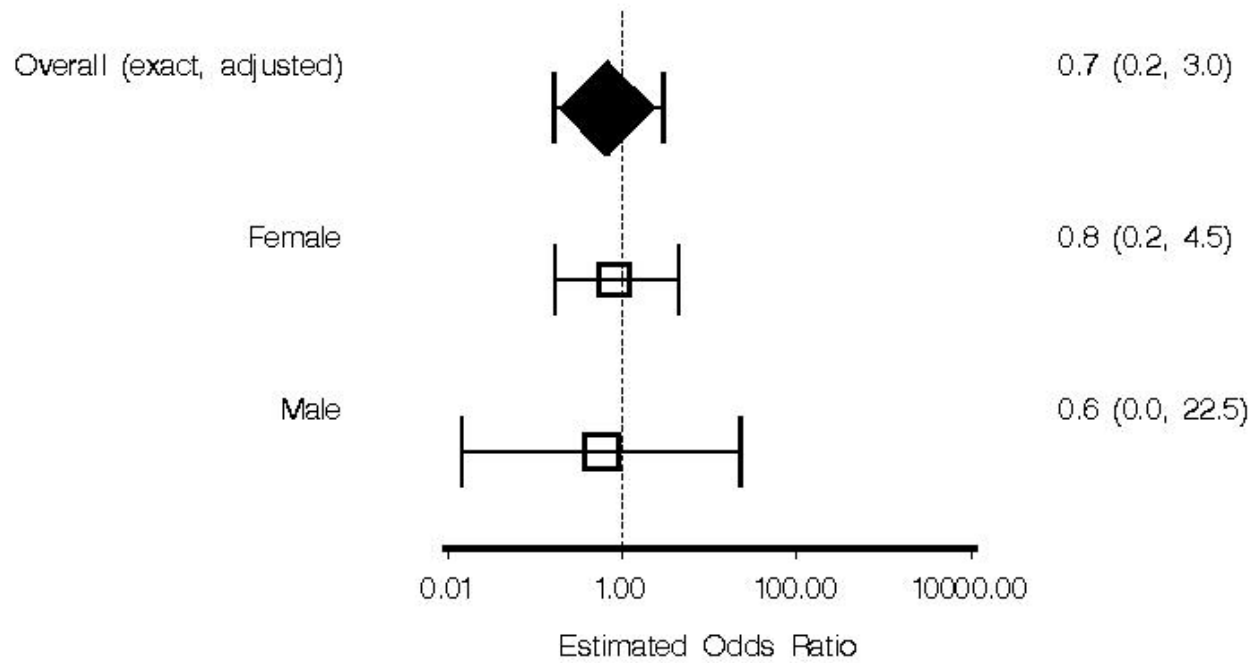
Paroxetine Adult Suicidality Analysis

Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender  
Indication = Panic



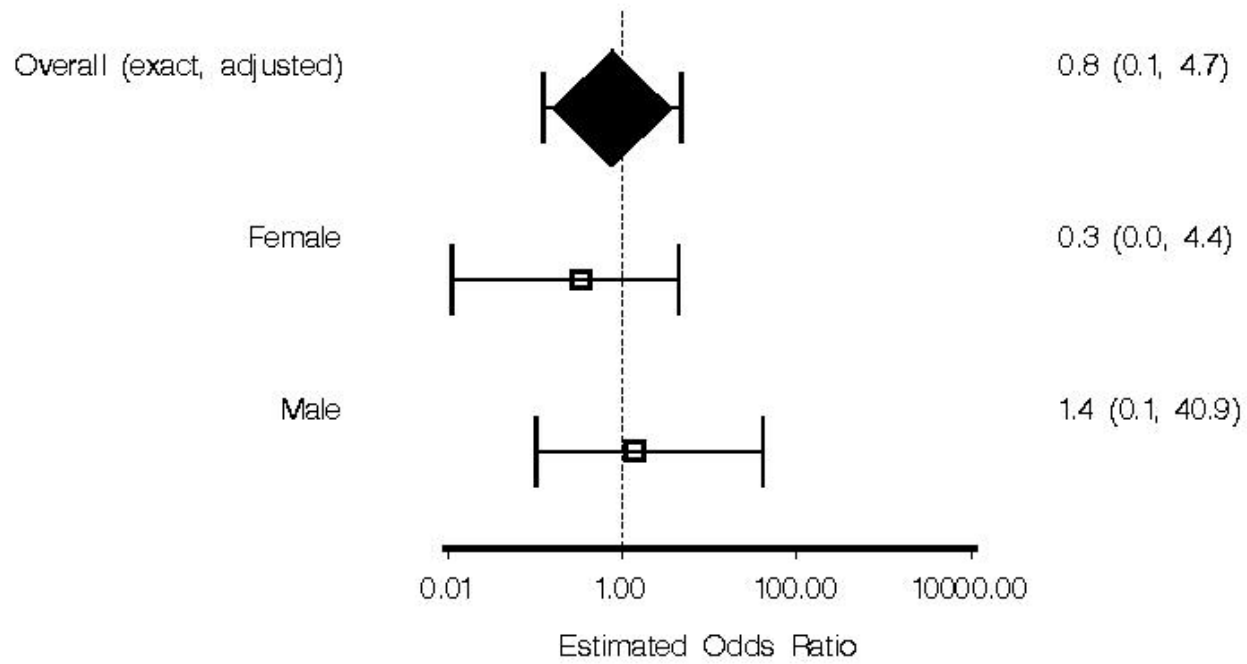
Paroxetine Adult Suicidality Analysis

Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender  
Indication = OCD



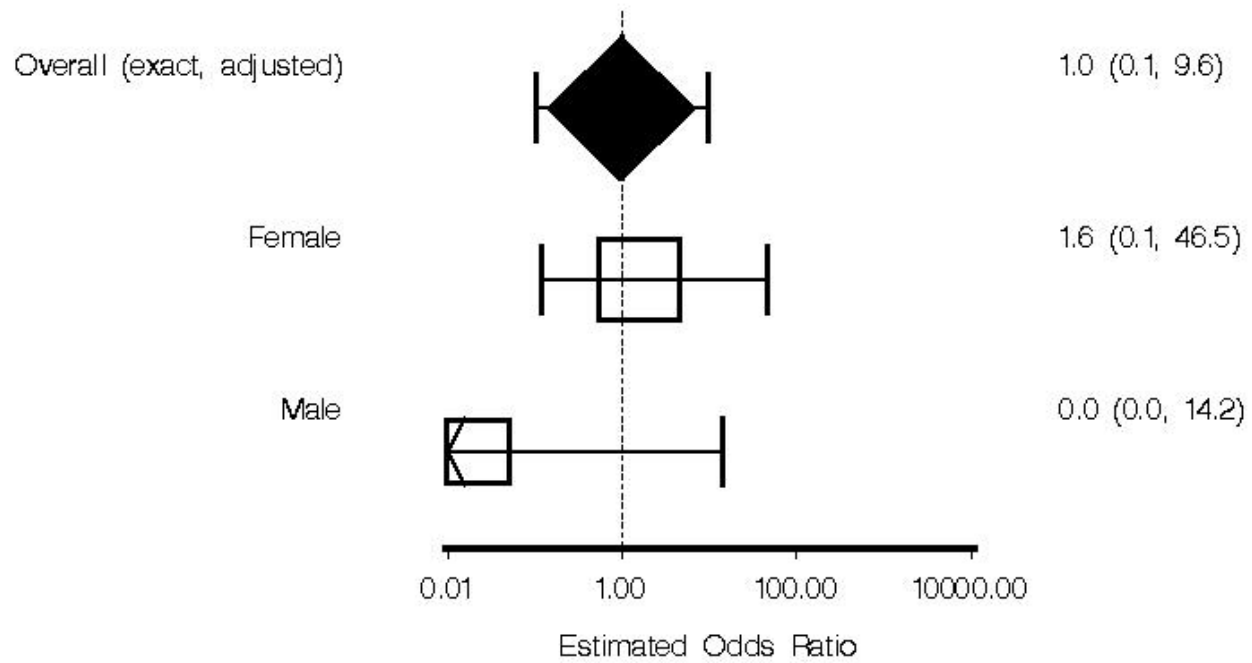
Paroxetine Adult Suicidality Analysis

Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender  
Indication = SAD



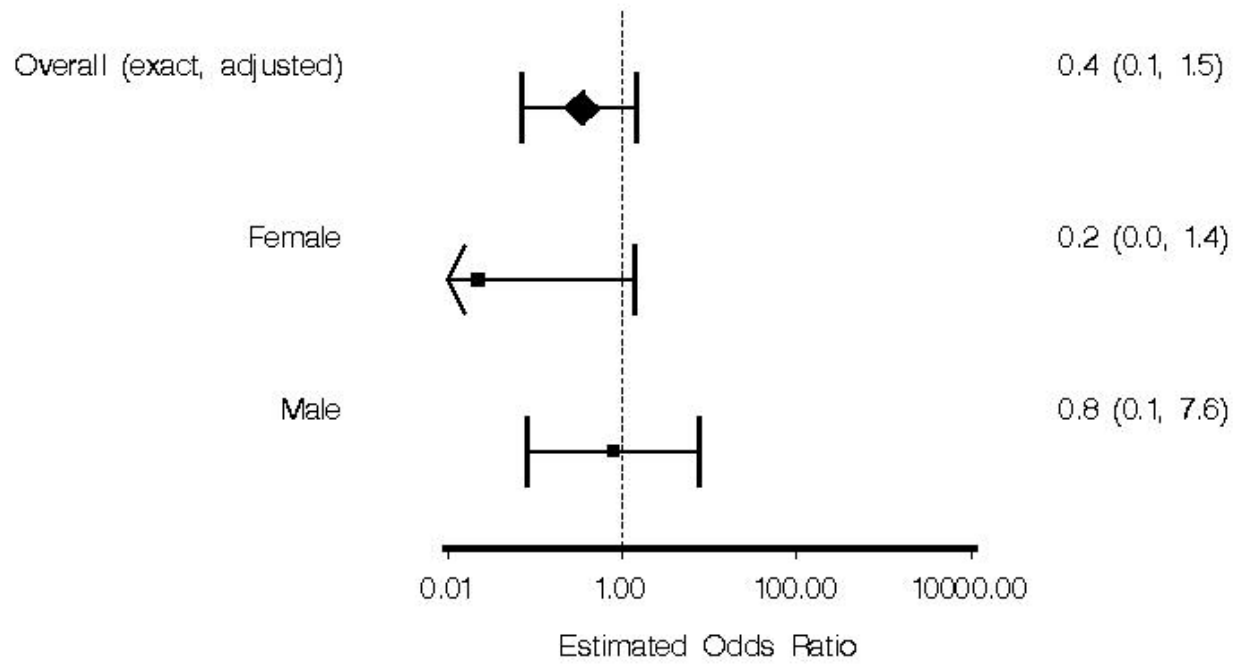
Paroxetine Adult Suicidality Analysis

Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender  
Indication = GAD



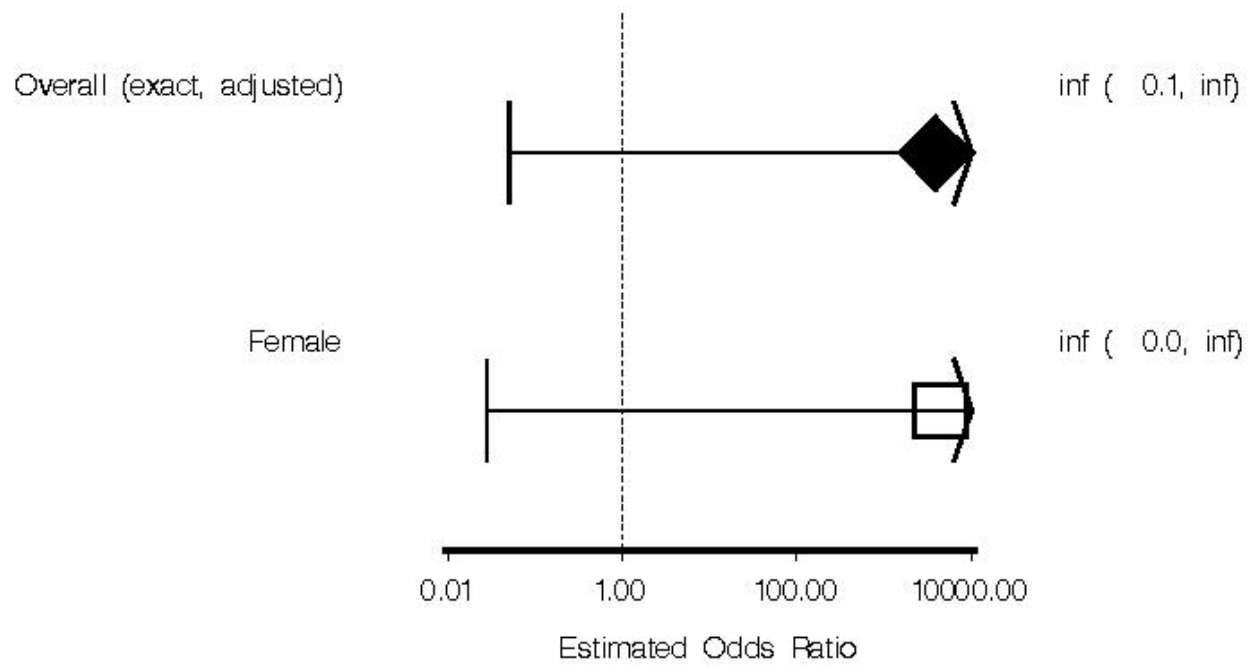
### Paroxetine Adult Suicidality Analysis

Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender  
Indication = PTSD



### Paroxetine Adult Suicidality Analysis

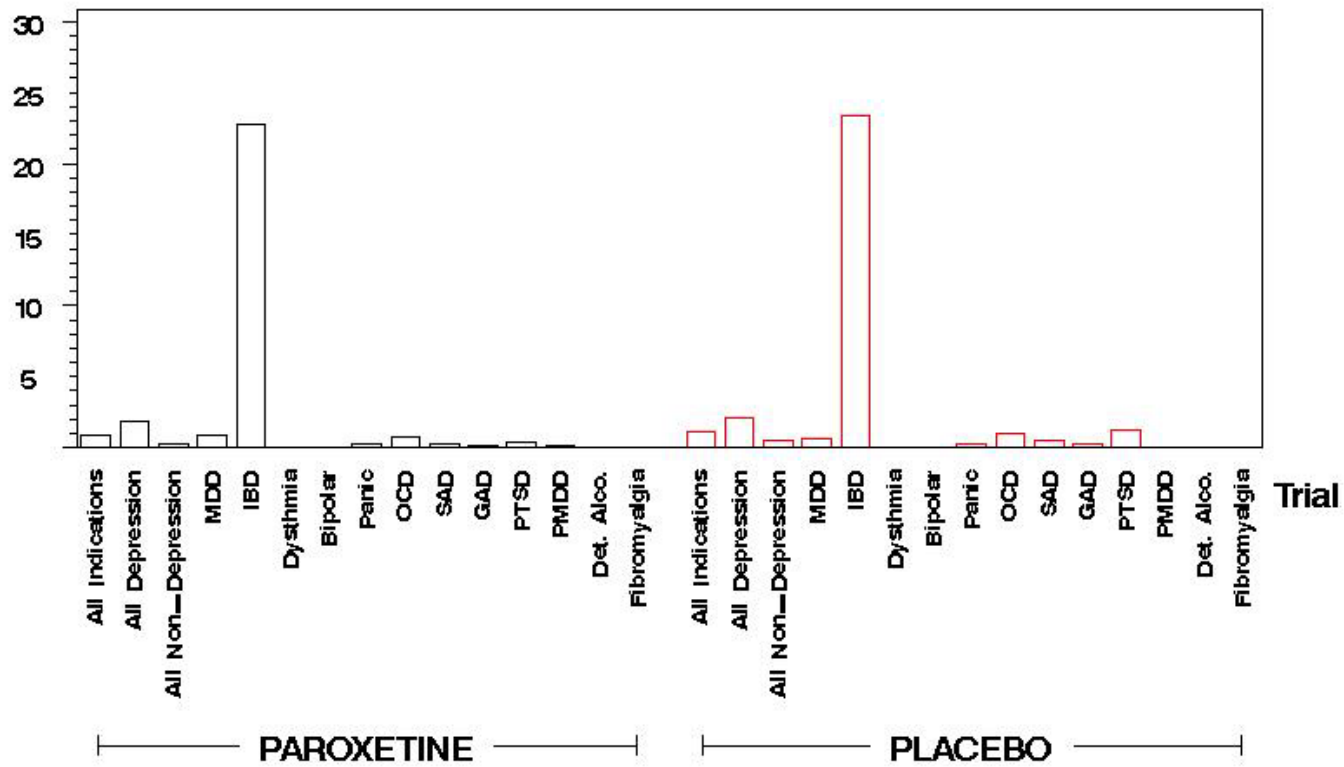
Figure 2.10. Definitive Suicidal Behaviour and Ideation by Gender  
Indication = PMDD





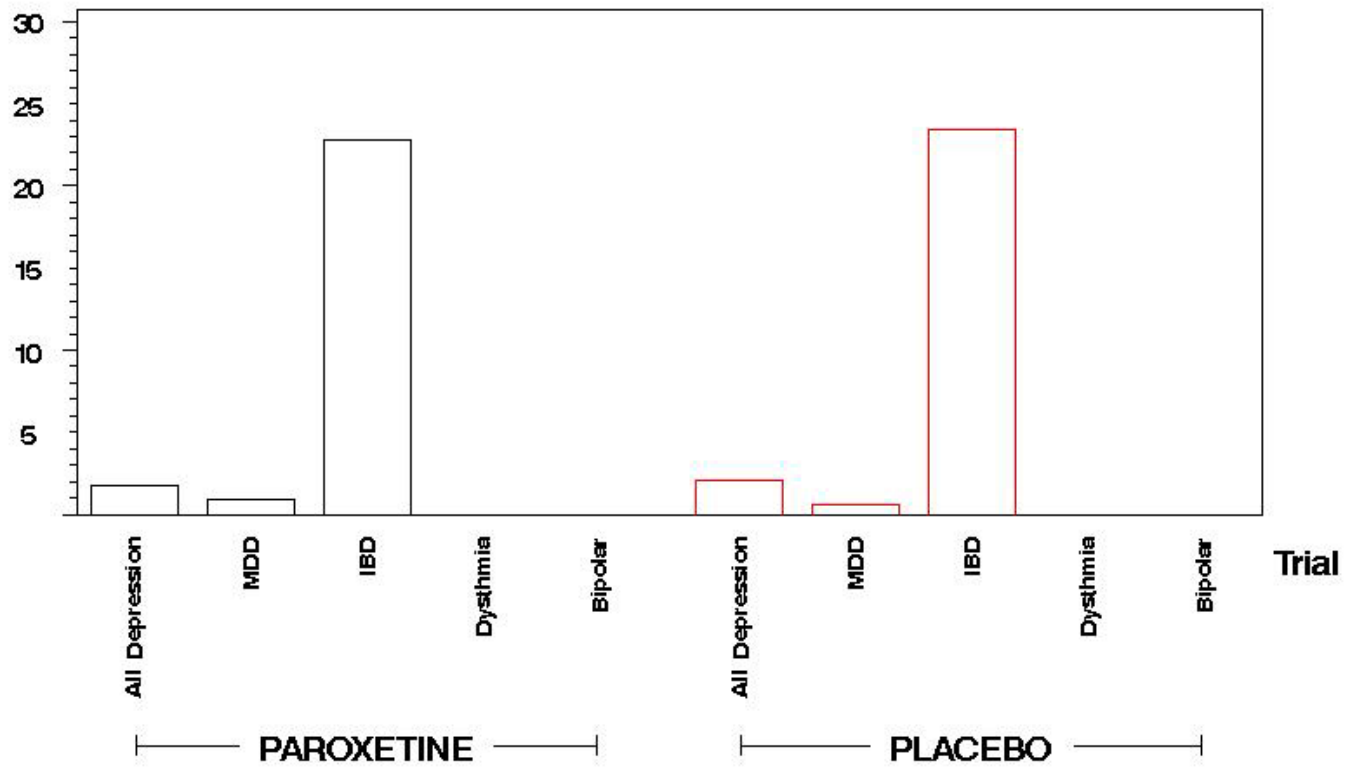
### Paroxetine Adult Suicidality Analysis

Figure 2.11: Percentage of Patients with Definitive Suicidal Behaviour and Ideation  
by Treatment group and Trial  
Indication=All Indications

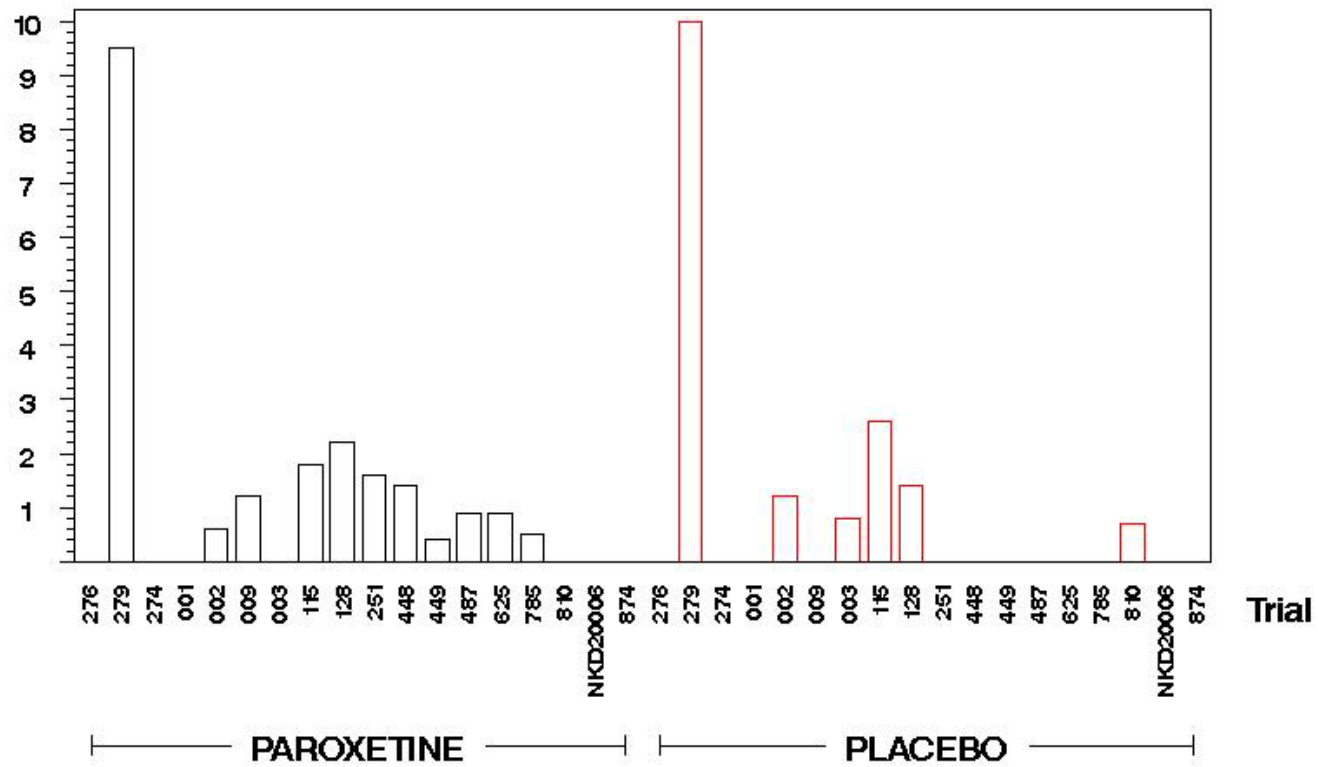


Paroxetine Adult Suicidality Analysis

Figure 2.11: Percentage of Patients with Definitive Suicidal Behaviour and Ideation  
by Treatment group and Trial  
Indication=All Depression

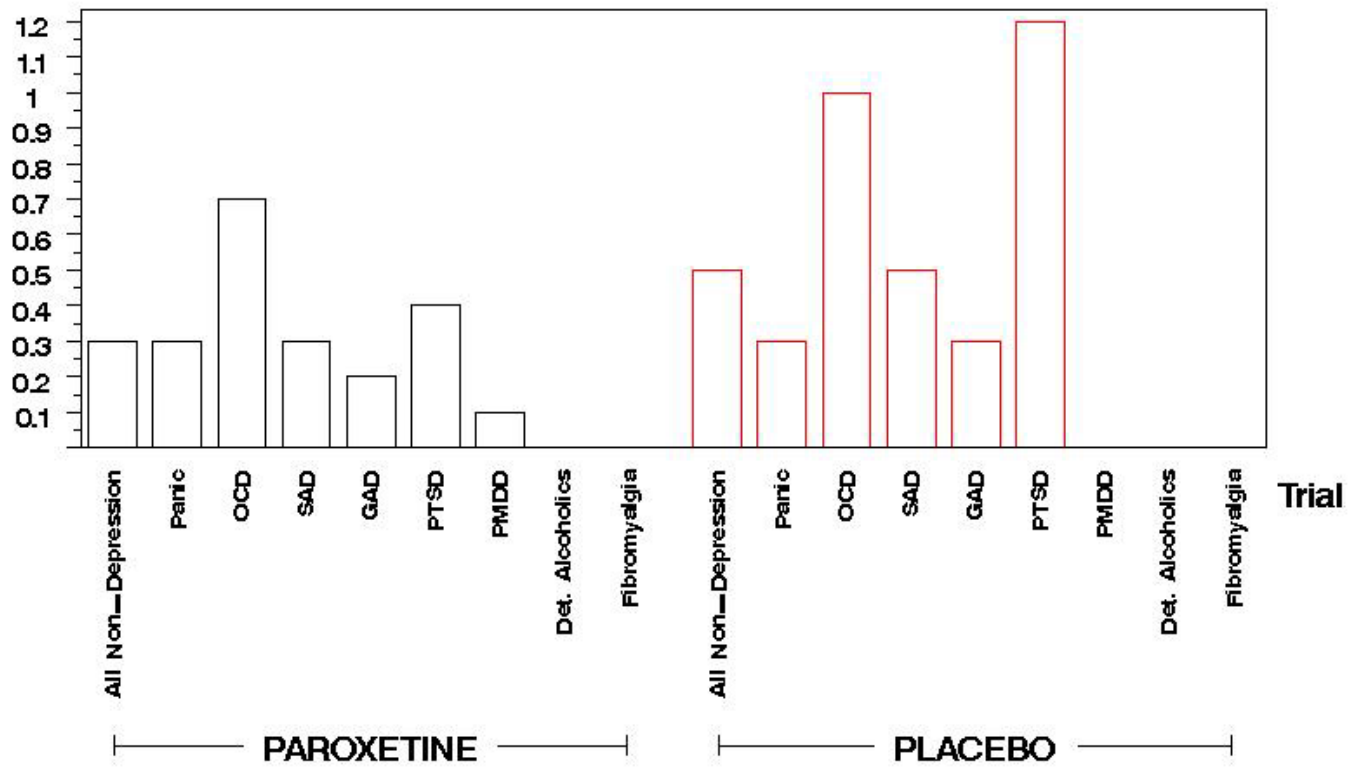


Paroxetine Adult Suicidality Analysis  
Figure 2.11: Percentage of Patients with Definitive Suicidal Behaviour and Ideation  
by Treatment group and Trial  
Indication=MDD



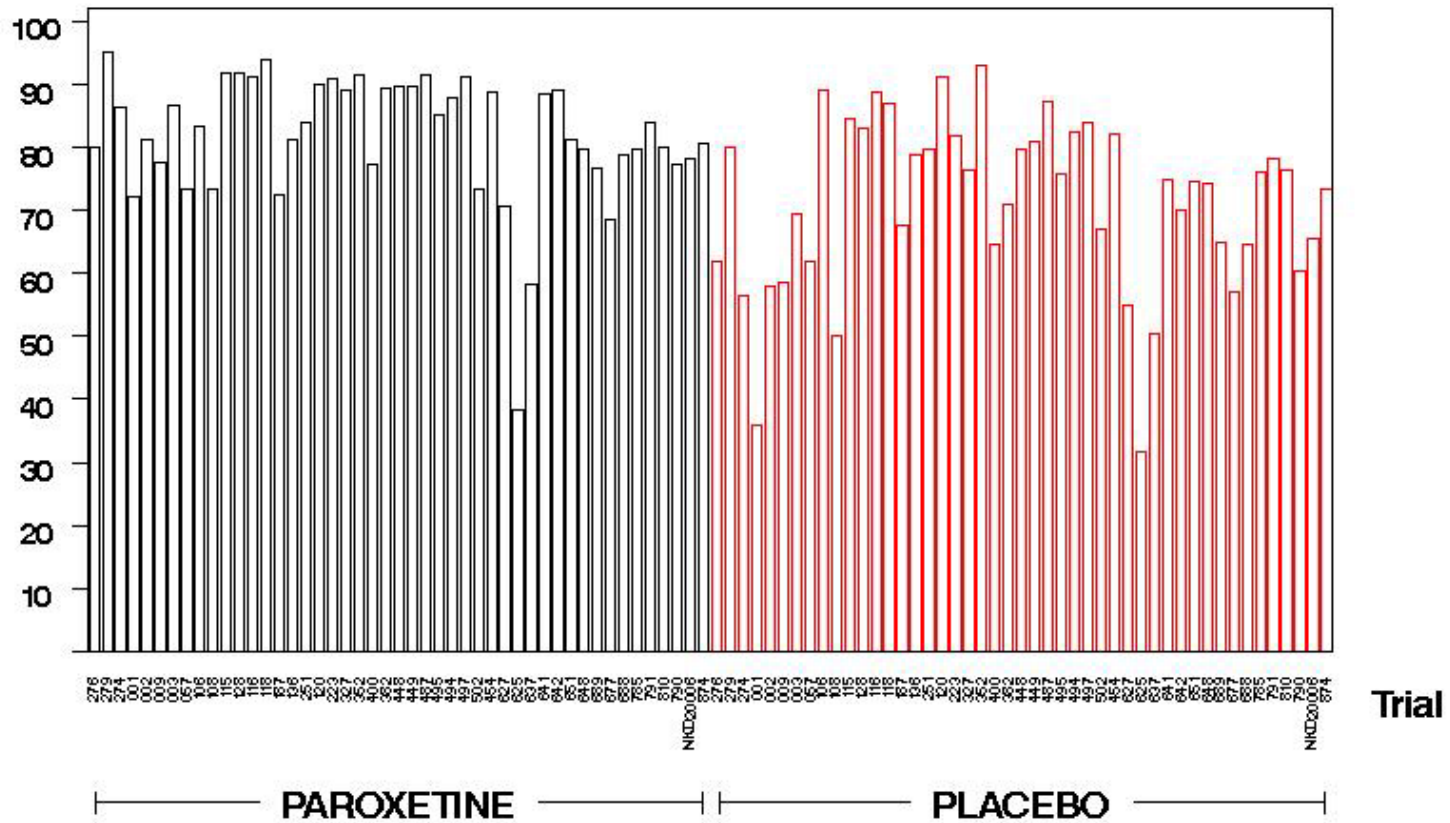
### Paroxetine Adult Suicidality Analysis

Figure 2.11: Percentage of Patients with Definitive Suicidal Behaviour and Ideation  
by Treatment group and Trial  
Indication = All Non-Depression



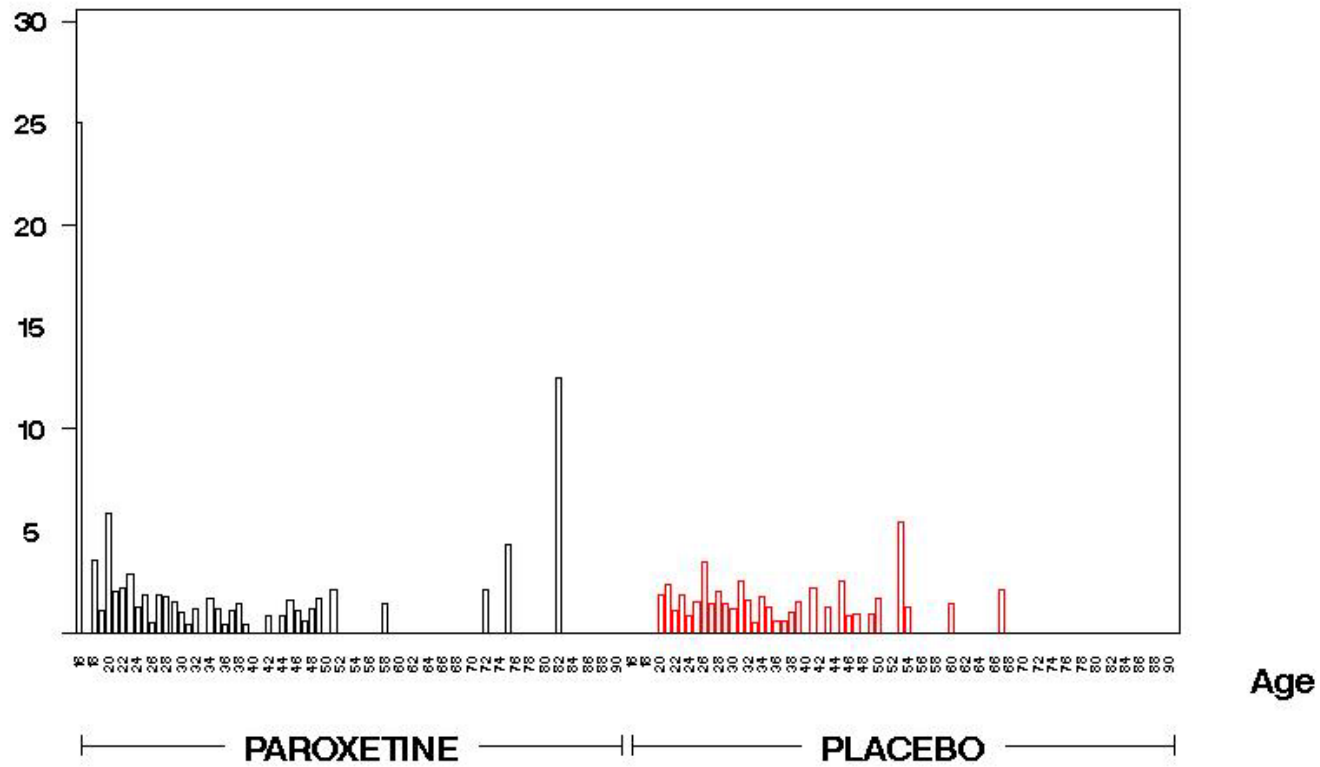
Paroxetine Adult Suicidality Analysis

Figure 2.12: Percentage of Patients with Any Adverse Event by Treatment group and Trial  
 Indication=All Indications

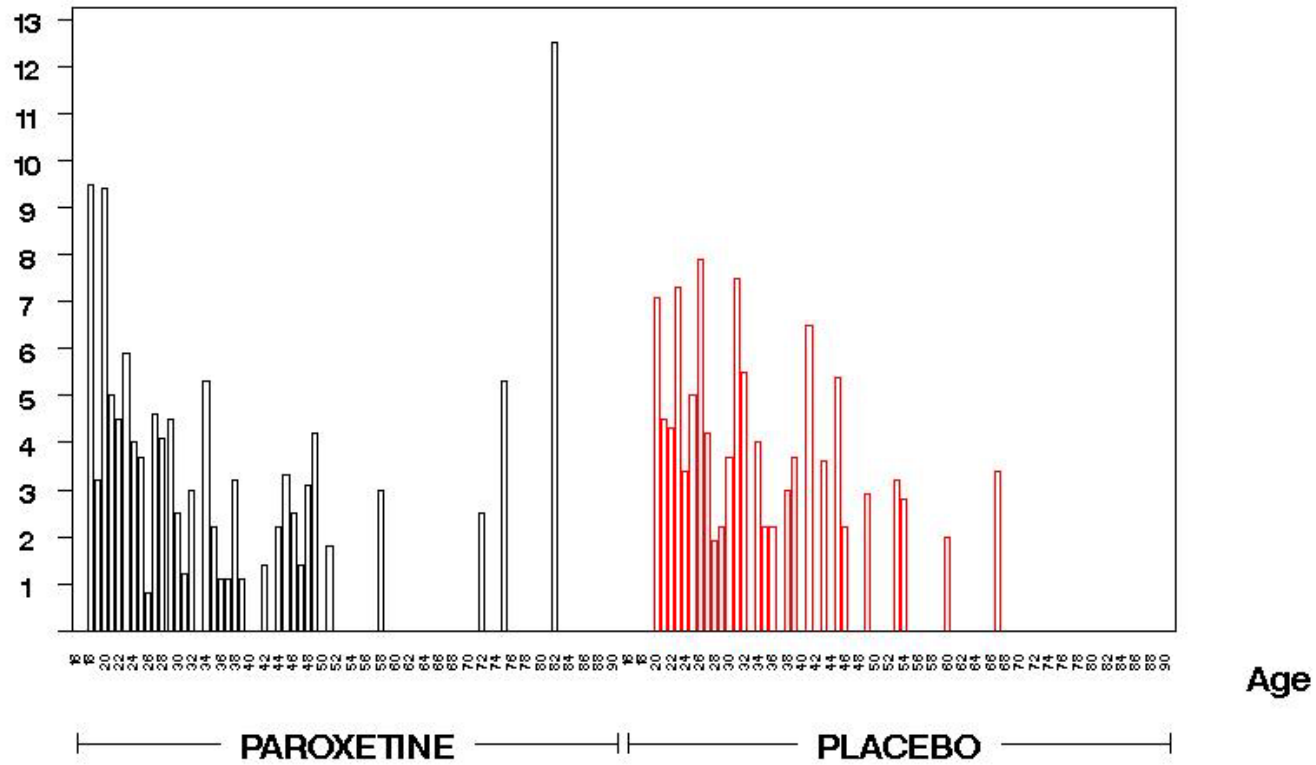


Note: AE information was not available for studies 364, 410, 414, 442, 433, 627, 658, 660, 661

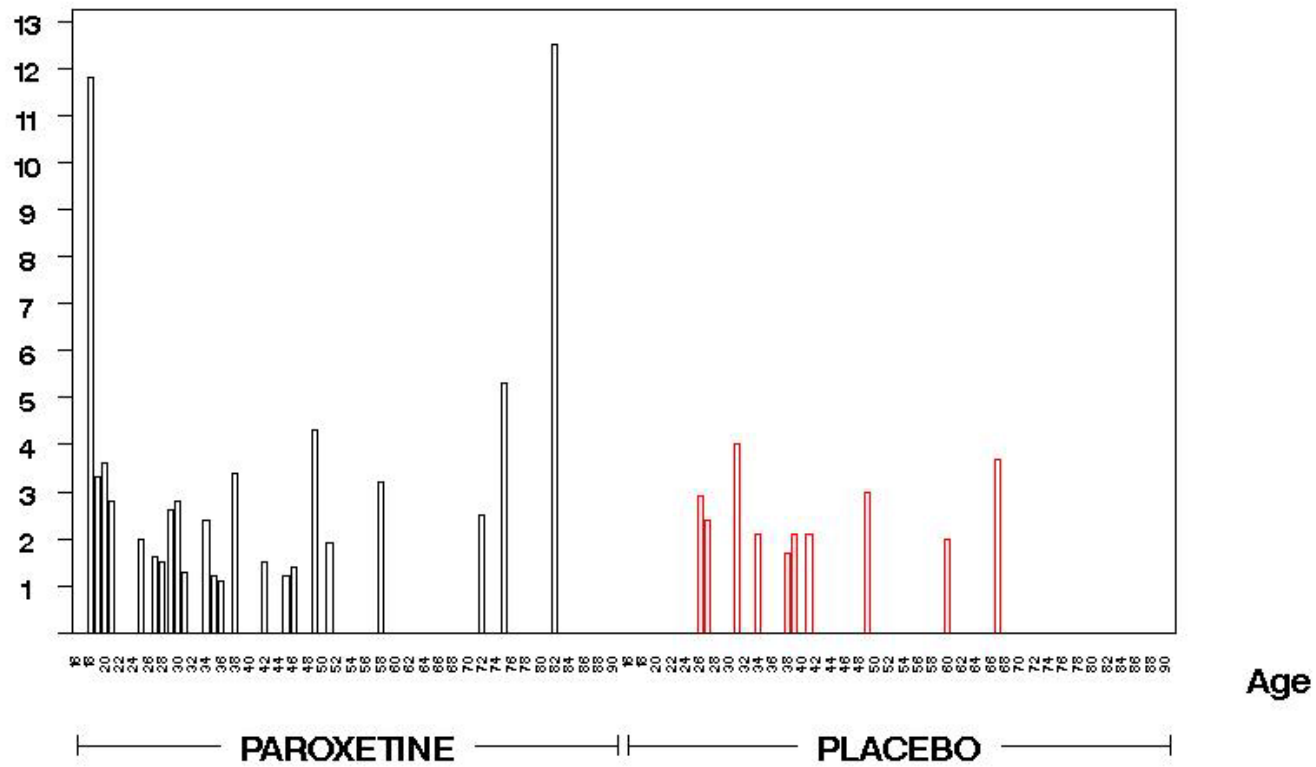
Paroxetine Adult Suicidality Analysis  
Figure 2.13: Percentage of Patients with Definitive Suicidal Behaviour and Ideation  
by Treatment group and Age  
Indication=All Indications



Paroxetine Adult Suicidality Analysis  
Figure 2.13: Percentage of Patients with Definitive Suicidal Behaviour and Ideation  
by Treatment group and Age  
Indication=All Depression

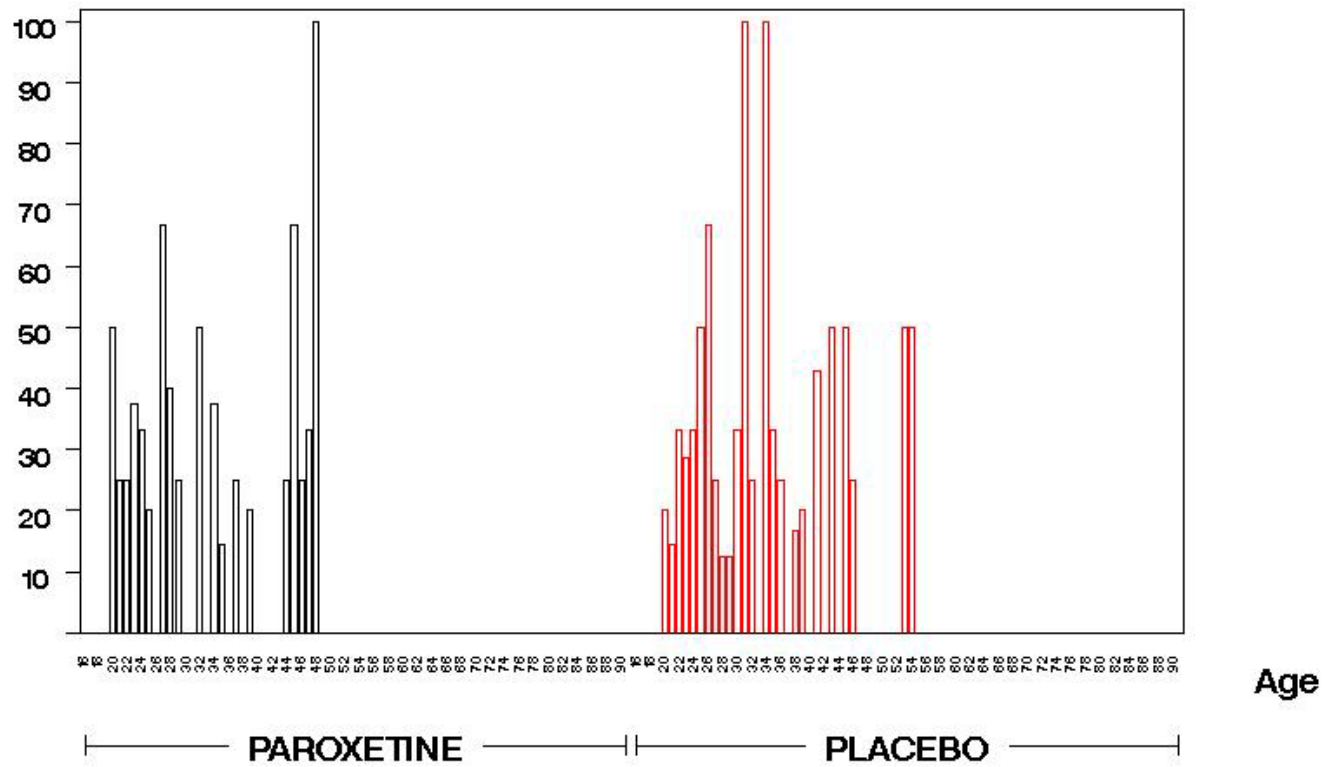


Paroxetine Adult Suicidality Analysis  
Figure 2.13: Percentage of Patients with Definitive Suicidal Behaviour and Ideation  
by Treatment group and Age  
Indication = MDD



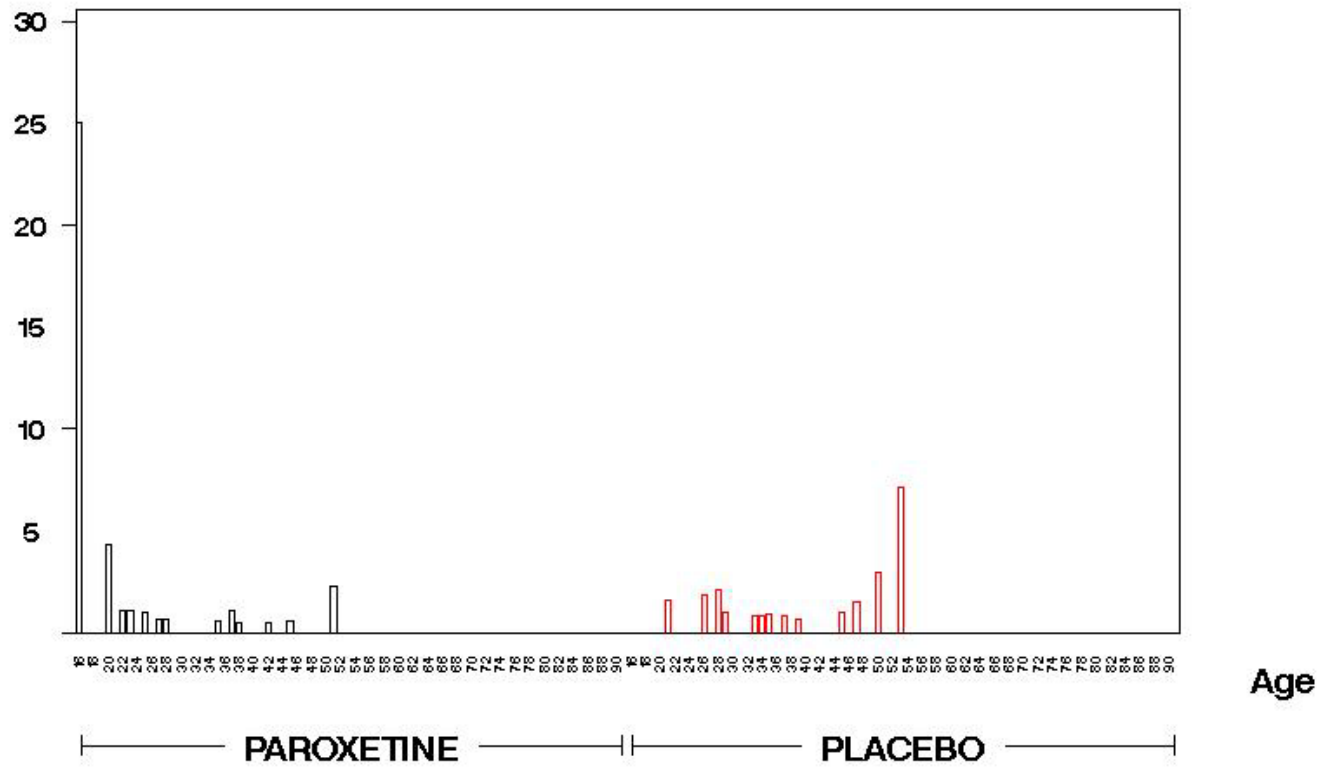


Paroxetine Adult Suicidality Analysis  
Figure 2.13: Percentage of Patients with Definitive Suicidal Behaviour and Ideation  
by Treatment group and Age  
Indication=IBD

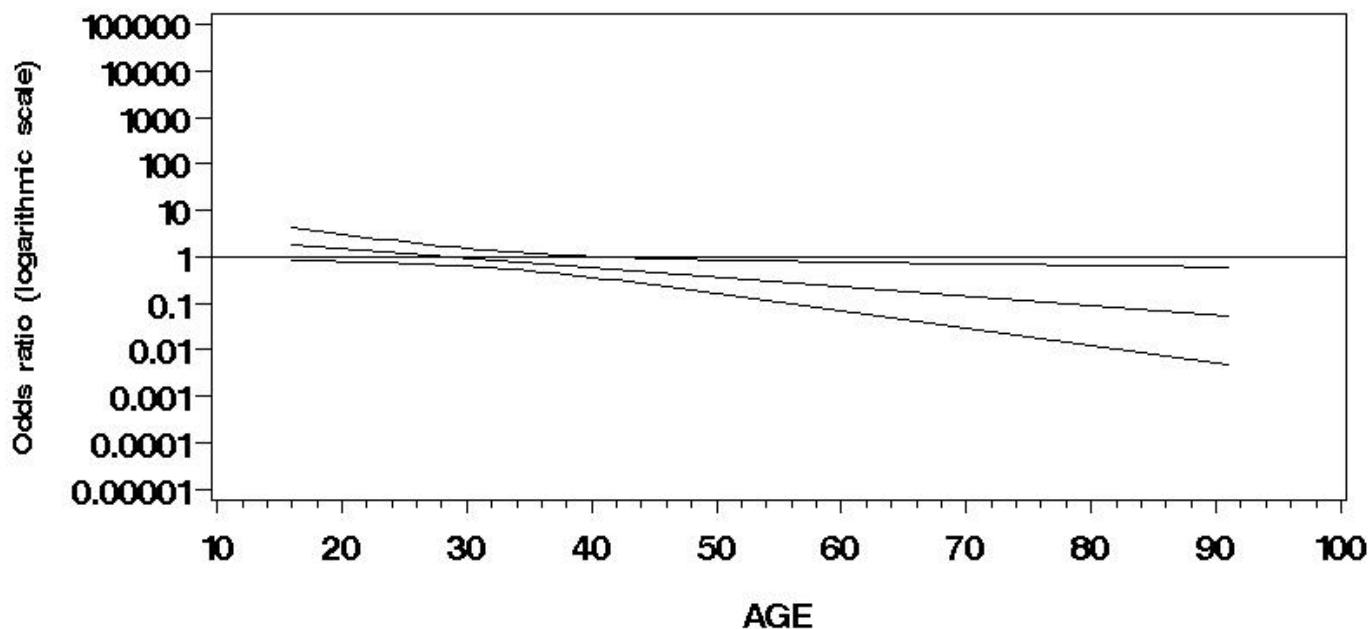


Paroxetine Adult Suicidality Analysis

Figure 2.13: Percentage of Patients with Definitive Suicidal Behaviour and Ideation  
 by Treatment group and Age  
 Indication = All Non-Depression

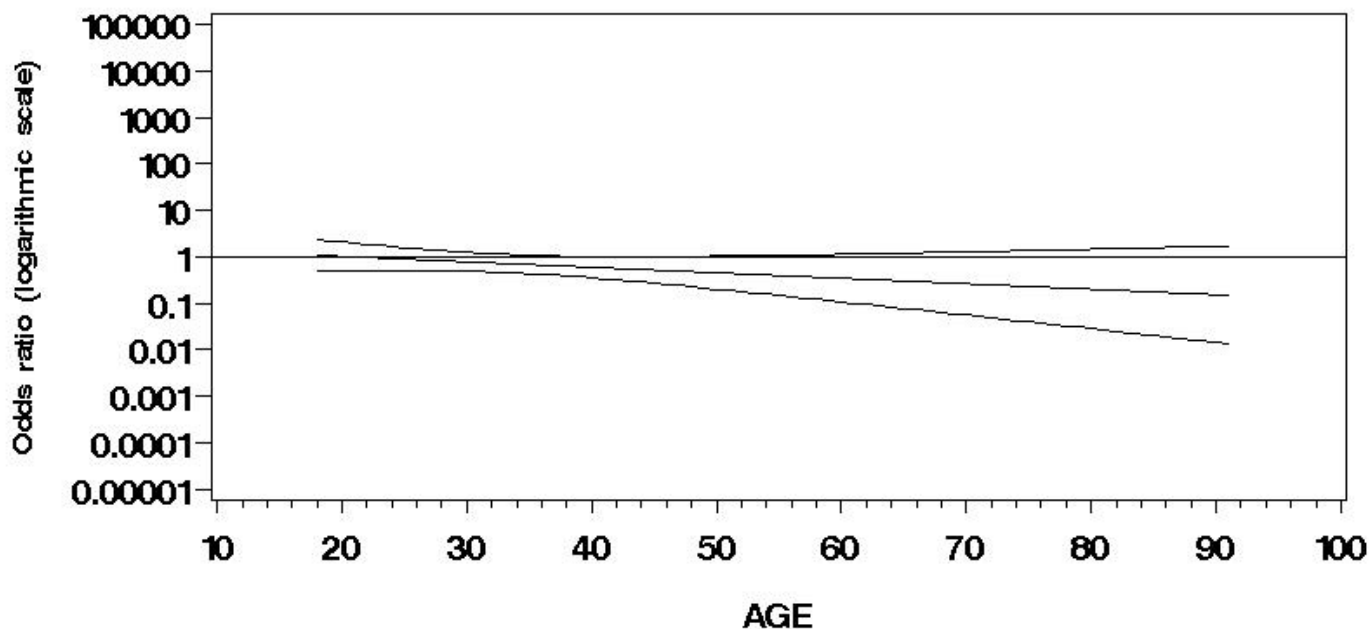


Paroxetine Adult Suicidality Analysis  
Figure 2.14: Definitive Suicidal Behaviour by indication and Age  
Indication=All Indications  
Odds Ratio and 95% Confidence Intervals



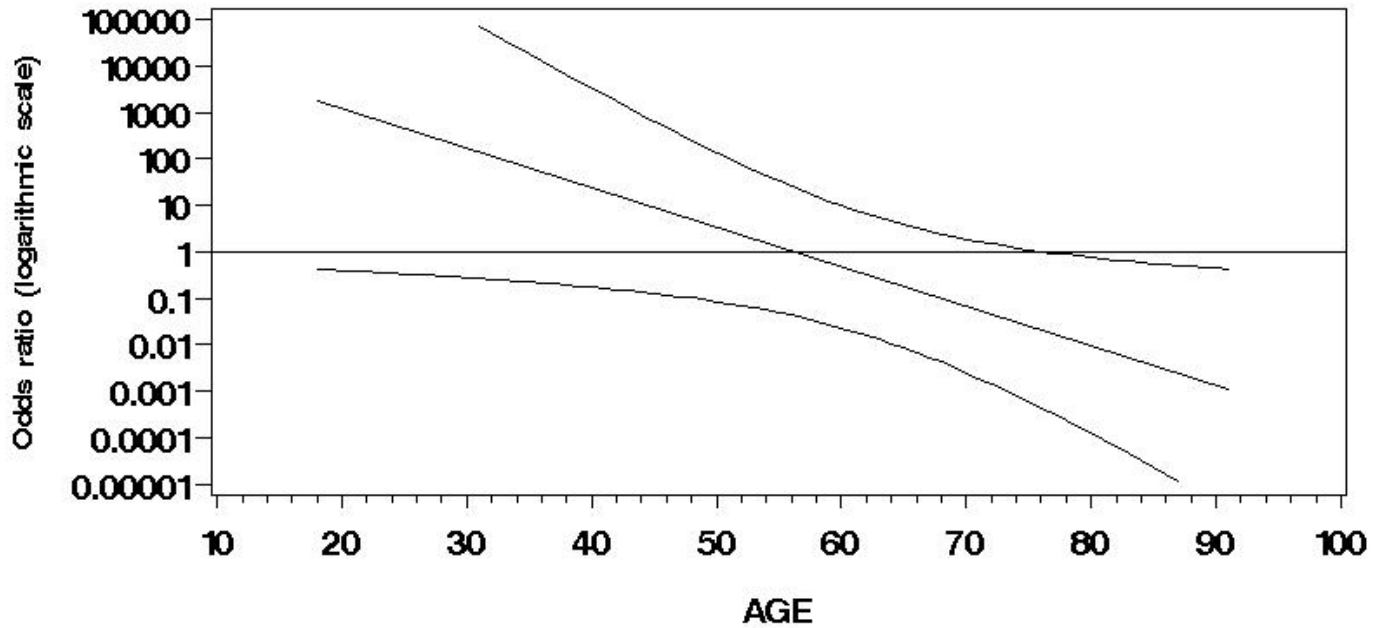
An odds ratio < 1 corresponds to a paroxetine benefit  
Model:  $\text{logit}(y) = \text{treatment} + \text{age} + \text{treatment} * \text{age}$   
Note:  $\text{treatment} * \text{age}$  term sig. at 10% level:  $p = 0.024$

Paroxetine Adult Suicidality Analysis  
Figure 2.14: Definitive Suicidal Behaviour by indication and Age  
Indication=All Depression  
Odds Ratio and 95% Confidence Intervals



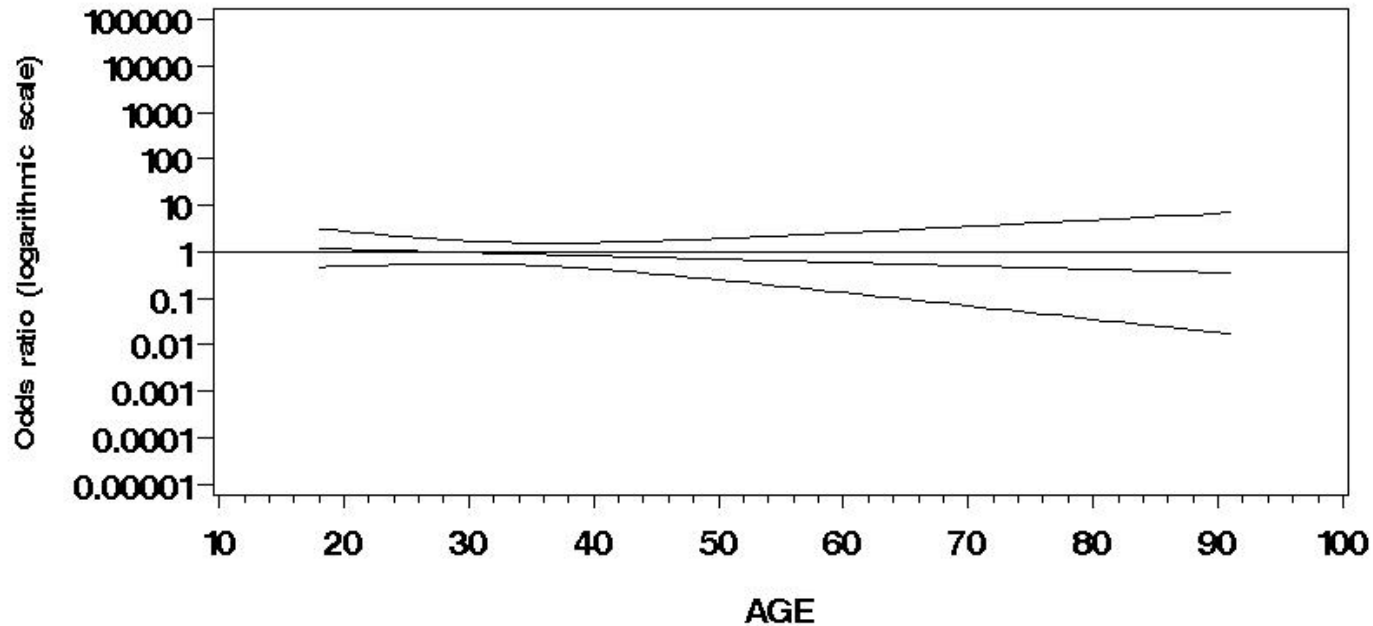
An odds ratio < 1 corresponds to a paroxetine benefit  
Model:  $\text{logit}(y) = \text{treatment} + \text{age} + \text{treatment} * \text{age}$   
Note: treatment\*age term not sig. at 10% level: added to model for plotting purposes

Paroxetine Adult Suicidality Analysis  
Figure 2.14: Definitive Suicidal Behaviour by indication and Age  
Indication= MDD  
Odds Ratio and 95% Confidence Intervals



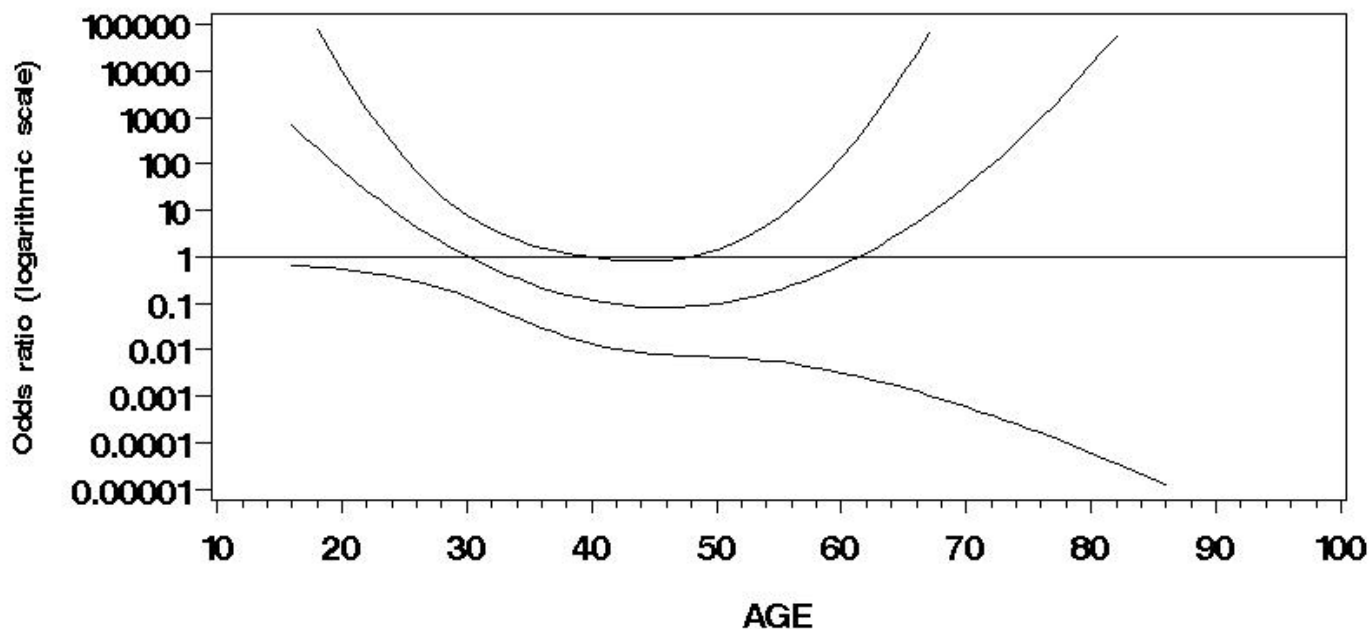
An odds ratio < 1 corresponds to a paroxetine benefit  
Model:  $\text{logit}(y) = \text{treatment} + \text{age} + \text{treatment} * \text{age}$   
Note:  $\text{treatment} * \text{age}$  term sig. at 10% level:  $p = 0.030$

Paroxetine Adult Suicidality Analysis  
Figure 2.14: Definitive Suicidal Behaviour by indication and Age  
Indication=IBD  
Odds Ratio and 95% Confidence Intervals



An odds ratio < 1 corresponds to a paroxetine benefit  
Model:  $\text{logit}(y) = \text{treatment} + \text{age} + \text{treatment} * \text{age}$   
Note: treatment\*age term not sig. at 10% level: added to model for plotting purposes

Paroxetine Adult Suicidality Analysis  
Figure 2.14: Definitive Suicidal Behaviour by indication and Age  
Indication=All Non-Depression  
Odds Ratio and 95% Confidence Intervals



An odds ratio < 1 corresponds to a paroxetine benefit  
Model:  $\text{logit}(y) = \text{treatment} + \text{age} + \text{treatment} * \text{age} + \text{age}^2 + \text{treatment} * \text{age}^2$   
Note:  $\text{treatment} * \text{age}^2$  term sig. at 10% level:  $p = 0.10$