Population: Efficacy

Table 14-3.13
CIBIC+ - Categorical Analysis - LOCF

	Assessment	Placebo (N=79)	Xanomeline Low Dose (N=81)	Xanomeline High Dose (N=74)	p-value [1]
Week 8	n	77	81	73	0.2727
	Marked improvement	0	0	0	
	Moderate improvement	1 (1%)	2 (2%)	1 (1%)	
	Minimal improvement	19 (25%)	16 (20%)	13 (18%)	
	No Change	45 (58%)	48 (59%)	38 (52%)	
	Minimal worsening	10 (13%)	14 (17%)	20 (27%)	
	Moderate worsening	2 (3%)	1 (1%)	1 (1%)	
	Marked worsening	0	0	0	
Week 16	n	79	81	74	0.4003
	Marked improvement	0	0	0	
	Moderate improvement	0	3 (4%)	2 (3%)	
	Minimal improvement	12 (15%)	12 (15%)	13 (18%)	
	No Change	41 (52%)	46 (57%)	39 (53%)	
	Minimal worsening	25 (32%)	19 (23%)	20 (27%)	
	Moderate worsening	1 (1%)	1 (1%)	0	
	Marked worsening	0	0	0	
Week 24	n	79	81	74	0.6180
	Marked improvement	0	0	0	
	Moderate improvement	1 (1%)	1 (1%)	0	
	Minimal improvement	9 (11%)	14 (17%)	11 (15%)	
	No Change	38 (48%)	37 (46%)	33 (45%)	
	Minimal worsening	28 (35%)	27 (33%)	25 (34%)	
	Moderate worsening	3 (4%)	2 (2%)	5 (7%)	
	Marked worsening	0	0	0	

[1] Overall comparison of treatments using CMH test (Pearson Chi-Square), controlling for site group.
Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rtf_eff_cat.sas   21:06 Monday, June 26, 2006