

Table 14-5.02
Incidence of Treatment Emergent Serious Adverse Events by Treatment Group

System Organ Class/ Preferred Term	n (%)	[AES]	Placebo	Xanomeline Low (N=84)	Xanomeline High (N=84)	Fisher's Exact p-values	
			((N=86))			Placebo vs. Placebo	vs. Low Dose
				n (%)	[AES]	n (%)	[AES]
ANY BODY SYSTEM	0			1 (1.2%) [1]		2 (2.4%) [2]	0.494
NERVOUS SYSTEM DISORDERS	0			1 (1.2%) [1]		2 (2.4%) [2]	0.494
SYNCOPE	0			1 (1.2%) [1]		1 (1.2%) [1]	0.494
PARTIAL SEIZURES WITH SECONDARY GENERA	0			0		1 (1.2%) [1]	0.494

Note: Treatment emergent events are defined as events which start on or after the start of treatment.

Note: Adverse events are coded using MedDRA.

Note: Percentages are based on the number of subjects in the safety population within each treatment group.

Note: P-values are based on Fisher's Exact test for the comparison of placebo versus each active treatment group. An asterisk is appended to p-values that are less than 0.15.

Note: The column [AE] represents the total number of times an event was recorded.

Source: C:\cdisc_pilot\PROGRAMS\DR AFT\TFLs\saetable.sas

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