

Protocol: CDISCPILOT01

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Population: All Subjects

Template 1
Summary of Populations

Population	Placebo (N=xxx)	Xanomeline Low Dose (N=xxx)	Xanomeline High Dose (N=xxx)	Total (N=xxx)
Intent-To-Treat (ITT)	xxx (xx%)	xxx (xx%)	xxx (xx%)	xxx (xx%)
Safety	xxx (xx%)	xxx (xx%)	xxx (xx%)	xxx (xx%)
Efficacy	xxx (xx%)	xxx (xx%)	xxx (xx%)	xxx (xx%)
Completer Week 24	xxx (xx%)	xxx (xx%)	xxx (xx%)	xxx (xx%)
Complete Study	xxx (xx%)	xxx (xx%)	xxx (xx%)	xxx (xx%)

NOTE: N in column headers represents number of subjects entered in study (i.e., signed informed consent). The ITT population includes all subjects randomized. The Safety population includes all randomized subjects known to have taken at least one dose of randomized study drug. The Efficacy population includes all subjects in the safety population who also have at least one post-baseline ADAS-Cog and CIBIC+ assessment.

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Population: Intent-to-Treat

Template 2
Summary of End of Study Data

	Placebo (N=xxx)	Xanomeline Low Dose (N=xxx)	Xanomeline High Dose (N=xxx)	Total (N=xxx)	p-value[1]
Completion Status					
Completed Week 24	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	0 .xxx
Early Termination (prior to Week 24)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Missing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Reason for Early Termination (prior to Week 24)					
Adverse event	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	0 .xxx
Death	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Lack of efficacy [2]	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	0 .xxx
Lost to follow-up	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Subject decided to withdraw	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Physician decided to withdraw subject	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Protocol criteria not met	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Protocol violation	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Sponsor decision	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Missing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	

[1] Fisher's exact test.

[2] Based on either patient/caregiver perception or physician perception.

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Population: Intent-to-Treat

Template 3

Summary of Demographic and Baseline Characteristics

		Placebo (N=100)	Xanomeline Low Dose (N=100)	Xanomeline High Dose (N=100)	Total (N=300)	p-value [1]
Age (y)	n	xx	xx	xx	xx	
	Mean	xx.x	xx.x	xx.x	xx.x	0.xxx
	SD	x.xx	x.xx	x.xx	x.xx	
	Median	xx.x	xx.x	xx.x	xx.x	
	Min.	xx.x	xx.x	xx.x	xx.x	
	Max.	xx.x	xx.x	xx.x	xx.x	
	<65 yrs	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	0.xxx
	65-80 yrs	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
	>80 yrs	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Sex	n	xxx	xxx	xxx	xxx	0.xxx
	Female	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
	Male	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Origin	n	xxx	xxx	xxx	xxx	0.xxx
	Black	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
	White	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
	...					

Also summarize: MMSE, Duration of disease (cont. and as <12 months, >=12 months), Years of education, Baseline Weight, Baseline Height, Baseline BMI (cont. and as normal(<25), overweight(25-<30), obese(>=30))

[1] P-values are results of ANOVA treatment group comparisons for continuous variables and Pearson's chi-square test for categorical variables.

NOTE: Duration of disease is computed as months between date of enrollment and date of onset of the first definite symptoms of Alzheimer's disease.