The concomitant medication data will be coded using a publicly available sample of WHO Drug. Drugs not matching those in the sample will be considered "uncoded" for the purposes of this submission. The number and percent of subjects receiving each concomitant medication will be summarized. Concomitant medications will be reported by Body System and ingredient. Medications will be sorted in descending order of total incidence across treatment groups for the Body System and in descending order of total incidence for the ingredient within each Body System. If the total incidence for any two or more ingredients is equal, the events will be presented in alphabetical order.

12. REFERENCES

13. ATTACHMENTS

13.1. Table of Contents for Data Display Specifications

13.1.1. Tables

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13.1.2. Figures

1. Time to First Dermatological Event by Treatment Group (**Figure 1**)

13.1.3. General Comments for Data Displays

General programming comments: use font size 10.

Note that the templates that follow are for example only. Appropriate changes should be made to titles, as listed in Section 13.1.

13.2. Templates for Data Displays

On following pages.

Protocol: CDISCPILOT01
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.

Protocol: CDISCPILOT01
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.

Protocol: CDISCPILOT01
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.

Protocol: CDISCPILOT01
Population: All Subjects

Template 4

Summary of Number of Subjects by Site

Pooled Id	Site Id	Placebo (N=xxx)			Xanomeline Low Dose (N=xxx)			Xanomeline High Dose (N=xxx)			Total (N=xxx)		
		ITT	Eff	Com	ITT	Eff	Com	ITT	Eff	Com	ITT	Eff	Com
xxxxxx	xxxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

Note: ITT: Number of subjects in the ITT population, Eff: Number of subjects in the Efficacy population; Com: Number of subjects completing Week 24

Protocol: CDISCPILOT01
Population: Efficacy

Template 5

ADAS Cog (11) - Change from Baseline to Week xx - LOCF

	Placebo (N=xxx)	Xanomeline Low Dose (N=xxx)	Xanomeline High Dose (N=xxx)
Baseline			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
Week xx			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
Change from Baseline			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
P-value(Dose Response) [1][2]			x.xxx
P-value(Xan - Placebo) [1][3]		x.xxx	x.xxx
Diff. of LS Means (SE)		xx.x(x.xx)	xx.x(x.xx)
95% CI		(xx.xx;xx.xx)	(xx.xx;xx.xx)
P-value(Xan High - Xan Low) [1][3]			x.xxx
Diff. of LS Means (SE)			xx.x(x.xx)
95% CI			(xx.xx;xx.xx)

[1] Based on Analysis of covariance (ANCOVA) model with treatment and site as factors, and baseline ADAS Cog (11) value as a covariate.
[2] Test for a non-zero coefficient for treatment (dose) as a continuous variable.
[3] Pairwise comparison with treatment as a categorical variable: p-values without adjustment for multiple comparisons.

Protocol: CDISCPILOT01
Population: Efficacy

Template 6

CIBIC+ - Summary at Week xx - LOCF

	Placebo (N=xxx)	Xanomeline Low Dose (N=xxx)	Xanomeline High Dose (N=xxx)
Week xx			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
P-value(Dose Response) [1][2]			x.xxx
P-value(Xan - Placebo) [1][3]		x.xxx	x.xxx
Diff. of LS Means (SE)		xx.x(x.xx)	xx.x(x.xx)
95% CI		(xx.xx;xx.xx)	(xx.xx;xx.xx)
P-value(Xan High - Xan Low) [1][3]			x.xxx
Diff. of LS Means (SE)			xx.x(x.xx)
95% CI			(xx.xx;xx.xx)

[1] Based on Analysis of covariance (ANCOVA) model with treatment and site as factors.
[2] Test for a non-zero coefficient for treatment (dose) as a continuous variable.
[3] Pairwise comparison with treatment as a categorical variable: p-values without adjustment for multiple comparisons.

Protocol: CDISCPILOT01
Population: Completers

Template 7

ADAS Cog (11) - Change from Baseline to Week 24 – Completers at Week 24 - Observed Cases-Windowed

	Placebo (N=xxx)	Xanomeline Low Dose (N=xxx)	Xanomeline High Dose (N=xxx)
Baseline			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
Week 24			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
Change from Baseline			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
P-value(Dose Response) [1][2]			x.xxx
P-value(Xan - Placebo) [1][3]		x.xxx	x.xxx
Diff. of LS Means (SE)		xx.x(x.xx)	xx.x(x.xx)
95% CI		(xx.xx;xx.xx)	(xx.xx;xx.xx)
P-value(Xan High - Xan Low) [1][3]			x.xxx
Diff. of LS Means (SE)			xx.x(x.xx)
95% CI			(xx.xx;xx.xx)

[1] Based on Analysis of covariance (ANCOVA) model with treatment and site as factors, and baseline ADAS Cog (11) value as a covariate.
[2] Test for a non-zero coefficient for treatment (dose) as a continuous variable.
[3] Pairwise comparison with treatment as a categorical variable: p-values without adjustment for multiple comparisons.

Protocol: CDISCPILOT01
Population: Efficacy

Template 8

ADAS Cog (11) - Change from Baseline to Week 24 in Male Subjects – LOCF

	Placebo (N=xxx)	Xanomeline Low Dose (N=xxx)	Xanomeline High Dose (N=xxx)
Baseline			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
Week 24			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
Change from Baseline			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
P-value(Dose Response) [1][2]			x.xxx
P-value(Xan - Placebo) [1][3]		x.xxx	x.xxx
Diff. of LS Means (SE)		xx.x(x.xx)	xx.x(x.xx)
95% CI		(xx.xx;xx.xx)	(xx.xx;xx.xx)
P-value(Xan High - Xan Low) [1][3]			x.xxx
Diff. of LS Means (SE)			xx.x(x.xx)
95% CI			(xx.xx;xx.xx)

[1] Based on Analysis of covariance (ANCOVA) model with treatment and site as factors, and baseline ADAS Cog (11) value as a covariate.
[2] Test for a non-zero coefficient for treatment (dose) as a continuous variable.
[3] Pairwise comparison with treatment as a categorical variable: p-values without adjustment for multiple comparisons.

Protocol: CDISCPILOT01
Population: Efficacy

Template 9

ADAS Cog (11) – Mean and Mean Change from Baseline over Time

								Bsln		Change from Bsln					
		N	Mean	SD	Med	Min	Max	Mean (SD)		N	Mean	SD	Med	Min	Max
Placebo	Bsln	xxx	x.xx	x.xxx	x.xx	x.x	x.x								
	Wk 8(Windowed)	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 16(Windowed)	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 24(Windowed)	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 8 LOCF	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 16 LOCF	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 24 LOCF	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
Xan Low	Bsln	xxx	x.xx	x.xxx	x.xx	x.x	x.x								
	Wk 8(Windowed)	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 16(Windowed)	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 24(Windowed)	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 8 LOCF	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 16 LOCF	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 24 LOCF	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
Xan High	Bsln	xxx	x.xx	x.xxx	x.xx	x.x	x.x								
	Wk 8(Windowed)	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 16(Windowed)	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 24(Windowed)	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 8 LOCF	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 16 LOCF	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x
	Wk 24 LOCF	xxx	x.xx	x.xxx	x.xx	x.x	x.x	x.xx	(x.xxx)	xxx	x.xx	x.xxx	x.xx	x.x	x.x

Protocol: CDISCPILOT01
Population: Efficacy

Template 10

ADAS Cog (11) – Repeated Measures Analysis of Change from Baseline to Week 24

	Placebo (N=xxx)	Xanomeline Low Dose (N=xxx)	Xanomeline High Dose (N=xxx)
LS Means (SE)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
p-value (Xan - placebo)		x.xxx	x.xxx
Diff of LS Means (SE)		xx.x (x.xx)	xx.x (x.xx)
95% CI		(xx.xx;xx.xx)	(xx.xx;xx.xx)
p-value (Xan High - Xan Low)			x.xxx
Diff of LS Means (SE)			xx.x (x.xx)
95% CI			(xx.xx;xx.xx)

Note: The change from baseline is calculated as the post-baseline score minus the baseline score. The covariates included in the MMRM model are treatment, site, time and treatment by time interaction, baseline ADAS-Cog (11) score, and baseline ADAS-Cog (11) score by time interaction.

Protocol: CDISCPILOT01
Population: Efficacy

Template 11

Mean NPI-X Total Score from Week 4 through Week 24 - Windowed

	Placebo (N=xxx)	Xanomeline Low Dose (N=xxx)	Xanomeline High Dose (N=xxx)
Baseline			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
Mean of Weeks 4-24			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median (Range)	xx.x (xx;xxx)	xx.x (xx;xxx)	xx.x (xx;xxx)
P-value(Dose Response) [1][2]			x.xxx
P-value(Xan - Placebo) [1][3]		x.xxx	x.xxx
Diff. of LS Means (SE)		xx.x(x.xx)	xx.x(x.xx)
95% CI		(xx.xx;xx.xx)	(xx.xx;xx.xx)
P-value(Xan High - Xan Low) [1][3]			x.xxx
Diff. of LS Means (SE)			xx.x(x.xx)
95% CI			(xx.xx;xx.xx)

[1] Based on Analysis of covariance (ANCOVA) model with treatment and site as factors, and baseline NPI-X value as a covariate.
[2] Test for a non-zero coefficient for treatment (dose) as a continuous variable.
[3] Pairwise comparison with treatment as a categorical variable: p-values without adjustment for multiple comparisons.

Protocol: CDISCPILOT01
Population: Safety

Template 12

Summary of Planned Exposure to Study Drug, as of End of Study

		Completers at Week 24			Safety Population [1]		
		Placebo (N=100)	Xanomeline Low Dose (N=100)	Xanomeline High Dose (N=100)	Placebo (N=100)	Xanomeline Low Dose (N=100)	Xanomeline High Dose (N=100)
Average daily dose (mg)	n	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Min.	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Max.	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Cumulative dose at end of study [2]	n	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Min.	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Max.	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

[1] Includes completers and early terminations.
[2] End of Study refers to Week 26/Early Termination.

Protocol: CDISCPILOT01
Population: Safety

Template 13

Incidence of Treatment Emergent Adverse Events by Treatment Group

SYSTEM ORGAN CLASS PREFERRED TERM	Placebo (N=xxx) n (%)	Total Events	Xanomeline Low Dose (N=xxx) n (%)	Total Events	Xanomeline High Dose (N=xxx) n (%)	Total Events	Placebo vs. Xan Low Dose p-value[1]	Placebo vs. Xan High Dose p-value[1]
Subjects with at least one AE	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Cardiac Disorders								
At Least One Event	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Hypertension	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Palpitation	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
etc..	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Infections and Infestations								
At Least One Event	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Cold, Common	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Infections	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
etc…	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Nervous System Disorders								
At Least One Event	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
etc…	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx

Note: Treatment emergent events are defined as events which start or worsen or recur 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.
Note: Total Events represent the total number of times an event was recorded within each treatment group.

Protocol: CDISCPILOT01 Page 1 of n
Population: Safety

Template 14

Incidence of Treatment Emergent Serious Adverse Events by Treatment Group

SYSTEM ORGAN CLASS PREFERRED TERM	Placebo (N=xxx) n (%)	 Total Events	Xanomeline Low Dose (N=xxx) n (%)	 Total Events	Xanomeline High Dose (N=xxx) n (%)	 Total Events	Placebo vs. Xan Low Dose p-value[1]	Placebo vs. Xan High Dose p-value[1]
Subjects with at least one AE	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Cardiac Disorders								
At Least One Event	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Hypertension	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Palpitation	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
etc..	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Infections and Infestations								
At Least One Event	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Cold, Common	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Infections	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
etc…	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
Nervous System Disorders								
At Least One Event	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx
etc…	xx (xx%)	xxx	xx (xx%)	xxx	xx (xx%)	xxx	0.xxx	0.xxx

Note: Treatment emergent events are defined as events which start or worsen or recur 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.
Note: Total Events represent the total number of times an event was recorded within each treatment group.

Protocol: CDISCPILOT01
Population: Safety

Template 15

Summary Statistics for Continuous Laboratory Values

Hemoglobin

	Placebo			Xanomeline Low			Xanomeline High		
Week	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)	N	Mean (SD)	Change from Bsln Mean (SD)
Bsln	xxx	x.x(x.xx)		xxx	x.x(x.xx)		xxx	x.x(x.xx)	
2	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)
4	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)
6	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)
8	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)
12	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)
16	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)
20	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)
24	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)
26	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)	xxx	x.x(x.xx)	x.x(x.xx)
End [1]									

[1] Last observed value while on treatment (prior to or at Week 24).

Repeat for for each of the continuous lab tests hematology and chemistry analyte.

Protocol: CDISCPILOT01
Population: Safety

Template 16

Frequency of Normal and Abnormal (Beyond Normal Range) Laboratory Values during Treatment

	Placebo (N=xxx)			Xan. Low (N=xxx)			Xan. High (N=xxx)			
Lab	Low	Normal	High	Low	Normal	High	Low	Normal	High	p-val
Analyte	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	[1]
Hematology										
Hemoglobin	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	x.xxx
Hematocrit	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	x.xxx
…										
Chemistry										
Sodium	xx (xx%)	xx (xx%)	xx (xx%)	xxx	xx (xx%)	xx (xx%)	xxx	xx (xx%)	xx (xx%)	x.xxx
Potassium	xx (xx%)	xx (xx%)	xx (xx%)	xxx	xx (xx%)	xx (xx%)	xxx	xx (xx%)	xx (xx%)	x.xxx
…										

Note: The summary reflects one observation per patient with a patient categorized as low or high if any scheduled lab assessment was considered to be abnormally low or abnormally high based on Normal Range
[1] Fisher’s exact test

Protocol: CDISCPILOT01
Population: Safety

Template 17

Frequency of Normal and Abnormal (Clinically Significant Change from Previous Visit)
Laboratory Values during Treatment

	Placebo (N=xxx)			Xan. Low (N=xxx)			Xan. High (N=xxx)			
Lab	Low	Normal	High	Low	Normal	High	Low	Normal	High	p-val
Analyte	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	[1]
Hematology										
Hemoglobin	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	x.xxx
Hematocrit	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	x.xxx
…										
Chemistry										
Sodium	xx (xx%)	xx (xx%)	xx (xx%)	xxx	xx (xx%)	xx (xx%)	xxx	xx (xx%)	xx (xx%)	x.xxx
Potassium	xx (xx%)	xx (xx%)	xx (xx%)	xxx	xx (xx%)	xx (xx%)	xxx	xx (xx%)	xx (xx%)	x.xxx
…										

Note: The summary reflects one observation per patient with a patient categorized as abnormal (low or high) if any scheduled lab assessment was considered to be abnormal based on change from observation taken at previous scheduled visit
[1] Fisher’s exact test

Protocol: CDISCPILOT01
Population: Safety

Template 18

Shifts of Laboratory Values During Treatment, Categorized Based on Threshold Ranges, by Visit

			Placebo			Xanomeline Low Dose			Xanomeline High Dose		
Lab Analyte	Week	Shift to	Low at Baseline n (%)	Norm. at Baseline n (%)	High at Baseline n (%)	Low at Baseline n (%)	Norm. at Baseline n (%)	High at Baseline n (%)	Low at Baseline n (%)	Norm. at Baseline n (%)	High at Baseline n (%)
HEMATOLOGY											
Hemoglobin	2	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		Low	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
		Normal	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
		High	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Hemoglobin	4	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		Low	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
		Normal	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
		High	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

Note: For each lab parameter, present weeks 2, 4, 6, 8, 12, 16, 20, 24, and 26.

Protocol: CDISCPILOT01
Population: Safety

Template 19

Shifts of Laboratory Values During Treatment, Categorized Based on Threshold Ranges

		Placebo			Xan. Low			Xan. High			
	Shift	Low at Baseline	Norm. at Baseline	High at Baseline	Low at Baseline	Norm. at Baseline	High at Baseline	Low at Baseline	Norm. at Baseline	High at Baseline	p-val
Lab Analyte	[1]	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	[2]
HEMATOLOGY											
Hemoglobin	n	xx	xx	xx	xx	xx	xx	xx	xx	xx	x.xxx
	Low	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
	Normal	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
	High	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	

[1] A subject is counted only once for each analyte. A change will be considered shifting from normal at baseline to abnormal or from abnormal at baseline to normal at any visit during the treatment. The treatment period is defined as any planned visit after Week 0 (Visit 3), up to and including Week 24 (Visit 12).

[2] CMH test for general association, controlling for status at baseline.

Protocol: CDISCPILOT01
Population: Safety

Template 20

Shifts of Hy's Law Values During Treatment

Shift during treatment [1]	Placebo Normal at Bsln n (%)	Placebo Abnormal at Bsln n (%)	Xanomeline Low Dose Normal at Bsln n (%)	Xanomeline Low Dose Abnormal at Bsln n (%)	Xanomeline High Dose Normal at Bsln n (%)	Xanomeline High Dose Abnormal at Bsln n (%)	p-val [2]
Transaminase 1.5 x ULN							
n	xx	xx	xx	xx	xx	xx	x.xxx
No change	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Change	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Bilirubin 2 x ULN and Transaminase 1.5 x ULN							
n	xx	xx	xx	xx	xx	xx	x.xxx
No change	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	
Change	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	

[1] A subject is counted only once for each analyte. A change will be considered shifting from normal at baseline to abnormal or from abnormal at baseline to normal at any visit during the treatment. The treatment period is defined as any planned visit after Week 0 (Visit 3), up to and including Week 24 (Visit 12).
[2] CMH test for general association, controlling for status at baseline.

Protocol: CDISCPILOT01
Population: Safety

Template 21

Summary of Vital Signs at Baseline and End of Treatment

Measure	Position	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Systolic BP (mmHg)	AFTER LYING DOWN 5 MIN.	Placebo	xxx	Baseline	xxx	xx.x	xx.xx	xx.x	xx	xxx
				Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
				End of treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
		Xan. Low	xxx	Baseline	xxx	xx.x	xx.xx	xx.x	xx	xxx
				Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
				End of treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
		Xan. High	xxx	Baseline	xxx	xx.x	xx.xx	xx.x	xx	xxx
				Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
				End of treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
	AFTER STANDING 1 MIN.	Placebo	xxx	Baseline	xxx	xx.x	xx.xx	xx.x	xx	xxx
				Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
				End of treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
		…								
Include:										
Systolic BP	AFTER STANDING 3 MIN.									
Diastolic BP	AFTER LYING DOWN 5 MIN.									
(mmHg)	AFTER STANDING 1 MIN.									
	AFTER STANDING 3 MIN.									
Heart Rate	AFTER LYING DOWN 5 MIN.									
(bpm)	AFTER STANDING 1 MIN.									
	AFTER STANDING 3 MIN.									

End of treatment is the last on-treatment visit (on or before the Week 24 visit).

Protocol: CDISCPILOT01
Population: Safety

Template 22

Summary of Vital Signs Change from Baseline at End of Treatment

Measure	Position	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Systolic BP (mmHg)	AFTER LYING DOWN 5 MIN.	Placebo	xxx	Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
				End of treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
		Xan. Low	xxx	Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
				End of treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
		Xan. High	xxx	Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
				End of treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
	AFTER STANDING 1 MIN.	Placebo	xxx	Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
				End of treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
		…								
Include:										
Systolic BP	AFTER STANDING 3 MIN.									
Diastolic BP	AFTER LYING DOWN 5 MIN.									
(mmHg)	AFTER STANDING 1 MIN.									
	AFTER STANDING 3 MIN.									
Heart Rate (bpm)	AFTER LYING DOWN 5 MIN.									
	AFTER STANDING 1 MIN.									
	AFTER STANDING 3 MIN.									

End of treatment is the last on-treatment visit (on or before the Week 24 visit).

Protocol: CDISCPILOT01
Population: Safety

Template 23

Summary of Weight Change from Baseline at End of Treatment

Measure	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Weight (kg)	Placebo	xxx	Baseline	xxx	xx.x	xx.xx	xx.x	xx	xxx
			Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
			End of Treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
	Xan. Low	xxx	Baseline	xxx	xx.x	xx.xx	xx.x	xx	xxx
			Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
			End of Treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
	Xan. High	xxx	Baseline	xxx	xx.x	xx.xx	xx.x	xx	xxx
			Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
			End of Treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
Weight Change from Baseline	Placebo	xxx	Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
			End of Treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
	Xan. Low	xxx	Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
			End of Treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx
	Xan. High	xxx	Week 24	xxx	xx.x	xx.xx	xx.x	xx	xxx
			End of Treatment	xxx	xx.x	xx.xx	xx.x	xx	xxx

End of treatment is the last on-treatment visit (on or before the Week 24 visit).

Protocol: CDISCPILOT01
Population: All Subjects

Template 24

Summary of Concomitant Medications (Number of Subjects)

ATC Level 1 Ingredient	Placebo (N=xxx)	Xanomeline Low Dose (N=xxx)	Xanomeline High Dose (N=xxx)
Any medication	xx (xx%)	xx (xx%)	xx (xx%)
Endocrine & Metabolic			
Any medication	xx (xx%)	xx (xx%)	xx (xx%)
Fluticasone propionate	xx (xx%)	xx (xx%)	xx (xx%)
Beclomethasone dipropionate	xx (xx%)	xx (xx%)	xx (xx%)
Anti-infectives & immunologicals			
Any medication	xx (xx%)	xx (xx%)	xx (xx%)
Amoxycillin	xx (xx%)	xx (xx%)	xx (xx%)
Amoxycillin trihydrate	xx (xx%)	xx (xx%)	xx (xx%)
Clamoxyl	xx (xx%)	xx (xx%)	xx (xx%)
Cefaclor	xx (xx%)	xx (xx%)	xx (xx%)
Cefproxil	xx (xx%)	xx (xx%)	xx (xx%)

Note: A medication may be included in more than one ATC Level category and appear more than once.

Protocol: CDISCPILOT01
Population: Safety

Figure 1
Time to First Dermatological Event by Treatment Group