STATISTICAL ANALYSIS PLAN -- MOCK UP DISPLAYS

Title: An Open-Label Safety, Tolerability, and Efficacy Study in Male and Female Subjects with Androgenetic Alopecia Treated with ATI-50002 Topical Solution

Protocol: **ATI-50002-AGA-201**

Study Drug: ATI-50002

Sponsor: Aclaris Therapeutics, Inc.

Date: 23 April 2019

Status: **Final 1.0**

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Table 14.1.1.1
Study Population and Patient Disposition

	Female n (%)	Male n (%)	Total n (%)
Population/Group			
Intent-to-Treat (ITT) Population	xx (100)	xx (100	xx (100
Safety Population	xx (100)	xx (100	xx (100
Entered 6 Month Extension	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentages based on the number of patients receiving at least 1 treatment application

Table 14.1.1.2
Reasons for Discontinuation from Study
ITT Population

	Female (N=xxx) n (%)	**Male (N=xxx) n (%)**	**Total (N=xxx) n (%)**
ENTIRE STUDY[a]:			
Number (%) of Patients Discontinued	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol Violation	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE/SAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Follow-Up	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrew Consent	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed 26 Week Study	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed Optional 6 Month Extension	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ongoing as of "cut-off date"	xx (xx.x)	xx (xx.x)	xx (xx.x)
FIRST 26 WEEKS:			
Number (%) of Patients Discontinued	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol Violation	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE/SAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Follow-Up	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrew Consent	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ongoing as of "cut-off date"	xx (xx.x)	xx (xx.x)	xx (xx.x)

[a] Includes all discontinuations/completions from the first 26 weeks and optional 6 month extension. Patents completing both the initial 26 weeks and the 6 month extension periods are counted on both corresponding rows.
[b] Used as denominator for percentages calculated under 6 month extension.

Table 14.1.1.2
Reasons for Discontinuation from Study
ITTSafety Population

	Female (N=xxx) n (%)	**Male (N=xxx) n (%)**	**Total (N=xxx) n (%)**
6 MONTH EXTENSION:			
Number of Patients Entering[b]	xx	xx	xx
Number (%) of Patients Discontinued	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol Violation	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE/SAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Follow-Up	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrew Consent	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ongoing as of "cut-off date"	xx (xx.x)	xx (xx.x)	xx (xx.x)

[a] Includes all discontinuations/completions from the first 26 weeks and optional 6 month extension. Patents completing both the initial 26 weeks and the 6 month extension periods are counted on both corresponding rows.
[b] Used as denominator for percentages calculated under 6 month extension.

Table 14.1.2
Patient Demographics and Other Baseline Characteristics
ITT Population

	Female (N=xxx)	**Male (N=xxx)**	**Total (N=xxx)**
Age (years)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx,xx	xx,xx	xx,xx
Age Category (years), n (%)			
< 35	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥ 35	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gender, n (%)			
Male			xx (xx.x)
Female			xx (xx.x)
Race, n (%)			
White	xx (xx.x)	xx (xx.x)	xx (xx.x)
Black or African American	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)
American Indian or Alaska Native	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity, n (%)			
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported			

Data Source: XX **Program: XYZ.SAS**

Table 14.1.2
Patient Demographics and Other Baseline Characteristics
ITT Population

	Female (N=xxx)	**Male (N=xxx)**	**Total (N=xxx)**
Height (cm)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Weight (kg)			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Fitzpatrick Skin Type, n (%)			
1	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	xx (xx.x)	xx (xx.x)	xx (xx.x)
5	xx (xx.x)	xx (xx.x)	xx (xx.x)
6	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sinclar Grade (Females), n (%)			
2	xx (xx.x)		
3	xx (xx.x)		
4	xx (xx.x)		

Table 14.1.2
Patient Demographics and Other Baseline Characteristics
ITT Population

	Female (N=xxx)	**Male (N=xxx)**	**Total (N=xxx)**
Norwood-Hamilton Classificiation (Males), n (%)			
III vertex		xx (xx.x)	
IV		xx (xx.x)	
IVa		xx (xx.x)	
V		xx (xx.x)	

Table 14.1.3
Diagnosis and Prior Treatments for Androgenetic Alopecia
Safety Population

	Female (N=xx)	Male (N=xx)	Total (N=xx)
Prior Therapies for Androgenetic Alopecia, n (%)			
ANY therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Minoxidil	xx (xx.x)	xx (xx.x)	xx (xx.x)
Finasteride	xx (xx.x)	xx (xx.x)	xx (xx.x)
Device	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
{Will need to review for appropriate categories}	xx (xx.x)	xx (xx.x)	xx (xx.x)
Time since Diagnosis of Androgenetic Alopecia (Weeks)[a]			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Age at Diagnosis of Androgenetic Alopecia (Years)			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

[a] (date of first application of study medication – date of diagnosis)/7.

Table 14.1.4
Exposure to Study Medication
Safety Population

Parameter	Female (N=xx)	Male (N=xx)	Total (N=xx)
Duration of Treatment (Weeks)[a]			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Total Weight Administered (gm)			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Total Volume Administered (mL)			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

[a] (Date of last application of study medication – date of first application of study medication +1) / 7. Includes exposure in optional six month extension, if applicable.
[b] Each patient's average volume across all applications is calculated first.

Table 14.1.5
Exposure to Study Medication
Safety Population

Parameter	Female (N=xx)	Male (N=xx)	Total (N=xx
Total Number of Applications (Total of Each Patient)			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Total Applications (All Patients Total)	xxxx	xxxx	xxxx
Average Volume Per Application (mL)[b]			
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

[a] (Date of last application of study medication – date of first application of study medication +1) / 7. Includes exposure in optional six month extension, if applicable.
[b] Each patient's average volume across all applications is calculated first.

Table 14.2.1.1
Non-Vellus Target Area Hair Count (TAHC): Mean and Mean Change from Baseline (hairs/cm^2)
ITT Population

		Female		Male		Total	
Visit	**Statistic**	**Value**	**Change**	**Value**	**Change**	**Value**	**Change**
Baseline[a]	n	xx		xx		xx	
	Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
	SE	x.xx		x.xx		x.xx	
	Median	xxx.x		xxx.x		xxx.x	
	(Min, Max)	(xxx ,xxx)		(xxx ,xxx)		(xxx ,xxx)	
V5 – Week 8	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	SE	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
	[95% CI][b]		[xx.x, xx.x]		[xx.x, xx.x]		[xx.x, xx.x]
V7– Week 16	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	SE	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
	[95% CI][b]		[xx.x, xx.x]		[xx.x, xx.x]		[xx.x, xx.x]

[a] Baseline is selected as the last measurement prior to the first application of study medication.
[b] Confidence interval for the change from baseline.

Table 14.2.1.1
Non-Vellus Target Area Hair Count: Mean and Mean Change from Baseline (hairs/cm^2)
ITT Population

		Female		Male		Total	
Visit	**Statistic**	**Value**	**Change**	**Value**	**Change**	**Value**	**Change**
V10–Week 26	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	SE	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
	[95% CI][b]		[xx.x, xx.x]		[xx.x, xx.x]		[xx.x, xx.x]
V16–Week 52	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	SE	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
	[95% CI][b]		[xx.x, xx.x]		[xx.x, xx.x]		[xx.x, xx.x]

[a] Baseline is selected as the last measurement prior to the first application of study medication.
[b] Confidence interval for the change from baseline.

Repeat Format for
Table 14.2.1.2 Vellus Target Area Hair Count: Mean and Mean Change from Baseline (hairs/cm^2) ITT Population
Table 14.2.1.3 Total (Non-Vellus + Vellus) Target Area Hair Count: Mean and Mean Change from Baseline (hairs/cm^2) ITT Population
Table 14.2.1.4 Non-Vellus Target Area Hair Width: Mean and Mean Change from Baseline (cm) ITT Population
Table 14.2.1.5 Vellus Target Area Hair Width: Mean and Mean Change from Baseline (cm) ITT Population
Table 14.2.1.6 Total (Non-Vellus + Vellus) Target Area Hair Width: Mean and Mean Change from Baseline (cm) ITT Population
Table 14.2.1.7 Average Non-Vellus Hair Width: Mean and Mean Change from Baseline (cm) ITT Population
Footnote for 14.2.1.7: Note: Average non-vellus hair width is calculated for each patient as the non-vellus target area count divided by the non-vellus target area hair width

Data Source: XX **Program: XYZ.SAS**

Table 14.2.2.1
Investigator Global Assessment
ITT Population

Visit	Statistic	Female	Male	Total
V5 – Week 8	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V7– Week 16	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V10–Week 26	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V13–Week 39	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V16 – Week 52	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
FU/Early Termination	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)

Repeat Format for
Table 14.2.2.2 Subject Self-Assessment ITT Population

Data Source: XX **Program: XYZ.SAS**

Table 14.2.3.1
Investigator Global Assessment: Patients with Slightly Increased Hair Growth or Better (Grade +1 to +3)
ITT Population

Visit	Statistic	Female	Male	Total
V5 – Week 8	N[a] n (%)	xx xx (xx.x)	xx xx (xx.x)	xx xx (xx.x)
V7– Week 16	N[a] n (%)	xx xx (xx.x)	xx xx (xx.x)	xx xx (xx.x)
V10–Week 26	N[a] n (%)	xx xx (xx.x)	xx xx (xx.x)	xx xx (xx.x)
V13–Week 39	N[a] n (%)	xx xx (xx.x)	xx xx (xx.x)	xx xx (xx.x)
V16 – Week 52	N[a] n (%)	xx xx (xx.x)	xx xx (xx.x)	xx xx (xx.x)
FU/Early Termination	N[a] n (%)	xx xx (xx.x)	xx xx (xx.x)	xx xx (xx.x)

[a] The number of patents with an assessement at the visit. Used as denominator for percentages.

Repeat Format for
Table 14.2.3.2 Subject Self-Assessment: Patients with Slightly Increased Hair Growth or Better (Grade +1 to +3) ITT Population

Table 14.2.4
Improvement from Baseline in Norwood-Hamilton Scale in Males
ITT Population

Visit Shift Detail[a]	N[b]	Improved by ≥ 1 Level n (%)	Improved by ≥ 2 Levels n (%)
V7 – Week 16	xx	xx (xx.x)	xx (xx.x)
IV – IIIa		xx (xx.x)	xx (xx.x)
IV – III vertex		xx (xx.x)	
etc			
V10 – Week 26	xx	xx (xx.x)	xx (xx.x)
IV – IIIa		xx (xx.x)	xx (xx.x)
IV – III vertex		xx (xx.x)	
etc			
V16 – Week 52	xx	xx (xx.x)	xx (xx.x)
IV – IIIa		xx (xx.x)	xx (xx.x)
IV – III vertex		xx (xx.x)	
etc			
FU/Early Termination[c]	xx	xx (xx.x)	xx (xx.x)
IV – IIIa		xx (xx.x)	xx (xx.x)
IV – III vertex		xx (xx.x)	
etc			
Early Term, 1st 26 Weeks	xx	xx (xx.x)	xx (xx.x)
IV – IIIa		xx (xx.x)	xx (xx.x)
IV – III vertex		xx (xx.x)	
etc			

[a] The Baseline Score →Timepoint Score combination that met the ≥ 1 level improvement criteria.
[b] The number of patients with a non-missing score baseline and at the visit indicated. Used as denominator for percentages.
[c] Includes early terminations or follow-ups collected during the first 26 Weeks or during the additional six months for patients opting to continue treatment in the optional six month extension. Additional rows provided to further sub-divide based on the period (1st 26 Weeks vs 6 Month Extension) and termination status (early termination vs follow-up).

Table 14.2.4
Improvement from Baseline in Norwood-Hamilton Scale in Males
ITT Population

Visit Shift Detail[a]	N[b]	Improved by ≥ 1 Level n (%)	Improved by ≥ 2 Levels n (%)
Follow-Up 1st 26 Weeks	xx	xx (xx.x)	xx (xx.x)
IV – IIIa		xx (xx.x)	xx (xx.x)
IV – III vertex		xx (xx.x)	
etc			
Early Term, 6 Month Extension	xx	xx (xx.x)	xx (xx.x)
IV – IIIa		xx (xx.x)	xx (xx.x)
IV – III vertex		xx (xx.x)	
etc			
Follow-Up, 6 Month Extension	xx	xx (xx.x)	xx (xx.x)
IV – IIIa		xx (xx.x)	xx (xx.x)
IV – III vertex		xx (xx.x)	
etc			

[a] The Baseline Score →Timepoint Score combination that met the ≥ 1 level improvement criteria.
[b] The number of patients with a non-missing score baseline and at the visit indicated. Used as denominator for percentages.
[c] Includes early terminations or follow-ups collected during the first 26 Weeks or during the additional six months for patients opting to continue treatment in the optional six month extension. Additional rows provided to further sub-divide based on the period (1st 26 Weeks vs 6 Month Extension) and termination status (early termination vs follow-up).

PROGRAMMING NOTE: Add rows for each combination that shows an improvement starting from greatest improvement and highest baseline score.

Table 14.2.5
Improvement from Baseline in Sinclair Scale in Females
Safety Population

Visit Shift Detail[a]	N[b]	Improved by ≥ 1 Level n (%)	Improved by ≥ 2 Levels n (%)
V7 – Week 16	xx	xx (xx.x)	xx (xx.x)
4 - 3		xx (xx.x)	xx (xx.x)
3 - 2		xx (xx.x)	
etc			
V10 – Week 26	xx	xx (xx.x)	xx (xx.x)
4 - 3		xx (xx.x)	xx (xx.x)
3 - 2		xx (xx.x)	
etc			
V16 – Week 52	xx	xx (xx.x)	xx (xx.x)
4 - 3		xx (xx.x)	xx (xx.x)
3 - 2		xx (xx.x)	
etc			
FU/Early Termination[c]	xx	xx (xx.x)	xx (xx.x)
4 - 3		xx (xx.x)	xx (xx.x)
3 - 2		xx (xx.x)	
etc			
Early Term, 1st 26 Weeks	xx	xx (xx.x)	xx (xx.x)
4 - 3		xx (xx.x)	xx (xx.x)
3 - 2		xx (xx.x)	
etc			

[a] The Baseline Score →Timepoint Score combination that met the ≥ 1 level improvement criteria.
[b] The number of patients with a non-missing score baseline and at the visit indicated. Used as denominator for percentages.
[c] Includes early terminations or follow-ups collected during the first 26 Weeks or during the additional six months for patients opting to continue treatment in the optional six month extension. Additional rows provided to further sub-divide based on the period (1st 26 Weeks vs 6 Month Extension) and termination status (early termination vs follow-up).

Data Source: XX **Program: XYZ.SAS**

Table 14.2.5
Improvement from Baseline in Sinclair Scale in Females
Safety Population

Visit Shift Detail[a]	N[b]	Improved by ≥ 1 Level n (%)	Improved by ≥ 2 Levels n (%)
Follow-Up 1st 26 Weeks	xx	xx (xx.x)	xx (xx.x)
4 - 3		xx (xx.x)	xx (xx.x)
4 - 2		xx (xx.x)	
etc			
Early Term, 6 Month Extension	xx	xx (xx.x)	xx (xx.x)
4 - 3		xx (xx.x)	xx (xx.x)
4 - 2		xx (xx.x)	
etc			
Follow-Up, 6 Month Extension	xx	xx (xx.x)	xx (xx.x)
4 - 3		xx (xx.x)	xx (xx.x)
4 - 2		xx (xx.x)	
etc			

[a] The Baseline Score →Timepoint Score combination that met the ≥ 1 level improvement criteria.
[b] The number of patients with a non-missing score baseline and at the visit indicated. Used as denominator for percentages.
[c] Includes early terminations or follow-ups collected during the first 26 Weeks or during the additional six months for patients opting to continue treatment in the optional six month extension. Additional rows provided to further sub-divide based on the period (1st 26 Weeks vs 6 Month Extension) and termination status (early termination vs follow-up).

PROGRAMMING NOTE: Add rows for each combination that shows an improvement starting from greatest improvement and highest baseline score.

Table 14.2.6
Correlation of Selected Effiacy Measures
ITT Population

Visit	Parameter → ↓	Change in Nonvellus Target Area Hair Count	Change in Nonvellus Target Area Hair Width	Change in Nonvellus Target Average Area Hair Width	Investigator Global Assessment	Subject Self Assessment
V5 – Week 8	**Change in Nonvellus Target Area Hair Count**	Corr=1	Corr=0.xx P-Value=0.xxxx	Corr=0.xx P-Value=0.xxxx	Corr=0.xx P-Value=0.xxxx	Corr=0.xx P-Value=0.xxxx
	Change in Nonvellus Target Area Hair Width		Corr=1	Corr=0.xx P-Value=0.xxxx	Corr=0.xx P-Value=0.xxxx	Corr=0.xx P-Value=0.xxxx
	Change in Nonvellus Target Area Average Hair Width			Corr=1	Corr=0.xx P-Value=0.xxxx	Corr=0.xx P-Value=0.xxxx
	Investigator Global Assessment				Corr=1	Corr=0.xx P-Value=0.xxxx
V7–Week 16 **V10–Week 26** **V16 – Week 52**						

Note: Correaltions are Pearson Correaltions

Data Source: XX **Program: XYZ.SAS**

Table 14.2.7
Correlation of Nonvellus Hair Count and Width Measures with Time Since Diagnosis of Androgenetic Alopecia
ITT Population

Visit	Parameter → ↓	Time Since Diagnosis of Androgenetic Alopecia
V5 – Week 8	**Change in Nonvellus Target Area Hair Count**	Corr=0.xx P-Value=0.xxxx
	Change in Nonvellus Target Area Hair Width	Corr=0.xx P-Value=0.xxxx
	Change in Nonvellus Target Area Average Hair Width	Corr=0.xx P-Value=0.xxxx
V7–Week 16		
V10–Week 26		
V16 – Week 52		

Note: Correaltions are Pearson Correaltions

Table 14.3.1
Summary of Treatment-Emergent Adverse Events
Safety Population

	Female (N=xx) n (%)	**Male (N=xx) n (%)**	**Total (N=xx) n (%)**
Any Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Treatment-Related Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Adverse Event Resulting in Study Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)

n = number of patients with treatment emergent adverse event(s).
NOTE: Patients with multiple occurrences of a preferred term are counted only once for that term.

Table 14.3.1.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

MedDRA SOC Preferred Term	Female (N=xx) n (%)	Male (N=xx) n (%)	Total (N=xx) n (%)
Any Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term _	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term _	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term _	xx (xx.x)	xx (xx.x)	xx (xx.x)

n = number of patients with treatment emergent adverse event(s).
NOTE: Patients with multiple occurrences of a preferred term are counted only once for that term.

PROGRAMMING NOTE: to be carried out for:
Table 14.3.1.2 Treatment-Emergent Study Treatment-Related Adverse Events by System Organ Class and Preferred Term Safety Population
Table 14.3.1.3 Treatment-Emergent Adverse Events Resulting in Discontinuation of Study Treatment by System Organ Class and Preferred Term Safety Population
Table 14.3.1.4 Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term Safety Population

Data Source: XX **Program: XYZ.SAS**

Table 14.3.1.5
Treatment-Emergent Adverse Events by Descending Order of Frequency for ATI-50002
Safety Population

Preferred Term	Female (N=xx) n (%)	Male (N=xx) n (%)	Total (N=xx) n (%)
AE Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term _	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term _	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term _	xx (xx.x)	xx (xx.x)	xx (xx.x)

n = number of patients with treatment emergent adverse event(s).
NOTE: Events presented in descending order of frequency (i.e. percentage of patients with the event) in the Total AT-50002 treatment group. Patients with multiple occurrences of a preferred term are counted only once for that term.

Table 14.3.1.6
Treatment-Emergent Adverse Events by Maximum Severity
Safety Population

	Female, n (%) [a]				
MedDRA SOC	**Severity**				
Preferred Term	**Mild**	**Moderate**	**Severe**	**Missing[a]**	**Total**
Total Adverse Events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[a] Missing is referring to an event that has missing severity and no other event with severity provided for the same preferred term.

NOTE: If a patient had more than one adverse event within an SOC, the patient was counted in the category of greatest known severity.
If a patient had multiple occurrences of the same adverse event, the patient was counted in the category of greatest known severity.

Table 14.3.1.7 Treatment-Emergent Study Medication Related Adverse Events by Maximum Severity Safety Population

PROGAMMING NOTE: Separate pages for Female. Male and Total.

Table 14.3.1.8
Local Skin Reactions – Highest Grade Any Time Post-Baseline
Safety Population

		Highest Severity, n (%)							
		Female				Male			
Assessor	**Sign**	**Mild**	**Moderate**	**Severe**	**Total**	**Mild**	**Moderate**	**Severe**	**Total**
Any	Any	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Investigator	Any	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Erythema	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Scaling	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Dryness	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject	Any	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Stinging/burning	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Itching	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[a] Percentages are based on the total number of patients safety population for the group.
NOTE: Patients are counted only once foreach sign at the highest severity grade.

Table 14.3.1.8
Local Skin Reactions – Highest Grade Any Time Post-Baseline
Safety Population

		Highest Severity, n (%)			
		Total			
Assessor	**Sign**	**Mild**	**Moderate**	**Severe**	**Total**
Any	Any	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Investigator	Any	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Erythema	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Scaling	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Dryness	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject	Any	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Stinging/burning	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Itching	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[a] Percentages are based on the total number of patients safety population for the group.
NOTE: Patients are counted only once foreach sign at the highest severity grade.

Table 14.3.1.9
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Patients Who Discontinued in First 26 Weeks
Safety Population

MedDRA SOC Preferred Term	Female (N=xx) n (%)	Male (N=xx) n (%)	Total (N=xx) n (%)
Any Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
SOC Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term _	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term _	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE Preferred Term _	xx (xx.x)	xx (xx.x)	xx (xx.x)

n = number of patients with treatment emergent adverse event(s).
NOTE: Patients with multiple occurrences of a preferred term are counted only once for that term.

PROGRAMMING NOTE: to be carried out for:
Table 14.3.1.10 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Patients Who Completed 26 Weeks and Did not Enter Six Month Extension Safety Population
Table 14.3.1.11 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Patients Who Completed 26 Weeks and Entered Six Month Extension Safety Population

Table 14.3.2.1
Vital Signs: Systolic Blood Pressure (mmHg)
Safety Population

		Female		Male		Total	
Visit	**Statistic**	**Value**	**Change**	**Value**	**Change**	**Value**	**Change**
Baseline[a]	n	xx		xx		xx	
	Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
	Median	xxx.x		xxx.x		xxx.x	
	(Min, Max)	(xxx ,xxx)		(xxx ,xxx)		(xxx ,xxx)	
V3 – Week 3	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V4 – Week 4	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V5 – Week 8	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V6 – Week 12	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)

[a] Baseline is selected as the last measurement prior to the first application of study medication.
[b] Includes early terminations or follow-ups collected during the first 26 weeks or during the additional six months for patients opting to continue treatment in the optional six month extension.

Table 14.3.2.1
Vital Signs: Systolic Blood Pressure (mmHg)
Safety Population

		Female		Male		Total	
Visit	**Statistic**	**Value**	**Change**	**Value**	**Change**	**Value**	**Change**
V7 – Week 16	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V8 – Week 20	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V9 – Week 24	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V10 – Week 26	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V10 – Week 26	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)

[a] Baseline is selected as the last measurement prior to the first application of study medication.
[b] Includes early terminations or follow-ups collected during the first 26 weeks or during the additional six months for patients opting to continue treatment in the optional six month extension.

Table 14.3.2.1
Vital Signs: Systolic Blood Pressure (mmHg)
Safety Population

		Female		Male		Total	
Visit	**Statistic**	**Value**	**Change**	**Value**	**Change**	**Value**	**Change**
V10 – Week 26	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V11 – Week 30	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V12 – Week 35	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V13 – Week 39	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V14 –Week 44	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)

[a] Baseline is selected as the last measurement prior to the first application of study medication.
[b] Includes early terminations or follow-ups collected during the first 26 weeks or during the additional six months for patients opting to continue treatment in the optional six month extension.

Data Source: XX **Program: XYZ.SAS**

Table 14.3.2.1
Vital Signs: Systolic Blood Pressure (mmHg)
Safety Population

		Female		Male		Total	
Visit	**Statistic**	**Value**	**Change**	**Value**	**Change**	**Value**	**Change**
V15 – Week 48	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
V16 – Week 52	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)
FU/Early Termination[b]	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	(Min, Max)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)	(xxx ,xxx)

[a] Baseline is selected as the last measurement prior to the first application of study medication.
[b] Includes early terminations or follow-ups collected during the first 26 weeks or during the additional six months for patients opting to continue treatment in the optional six month extension.

PROGRAMMING NOTE: to be repeated for the following:

Table 14.3.2.2 Vital Signs: Diastolic Blood Pressure (mmHg) Safety Population
Table 14.3.2.3 Vital Signs: Heart Rate (bpm) Safety Population
Table 14.3.2.4 Vital Signs: Respiratory Rate (bpm) Safety Population
Table 14.3.2.5 Vital Signs: Temperature (Degrees C) Safety Population

Table 14.3.3
ECG Interpretation: Shift from Baseline to Worst Assessment Post Baseline
Safety Population

Group Baseline Interpretation	Worst Post-Baseline Interpretation, n (%) Normal	Abnormal, NCS	Abnormal, CS	Missing	Total
Female (N[a]=xx)					
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal, NCS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal, CS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Male (N[a]=xx)					
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal, NCS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal, CS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total (N[a]=xx)					
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal, NCS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal, CS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[a] The number of all patients in the safety population for the group.
Note: The worst assessment post baseline includes any unscheduled assessment(s) as well the post-treatment assessment.

PROGRAMMING NOTE: The following tables use for the format of the vital sign mean and mean change tables. Timepoints Baseline, V5 – Week 8, V7 – Week 16, V9 – Week 24, V10 – Week 26, V13 – Week 39, V14 – Week 44, V16 – Week 52, FU/Early Termination.

Table 14.3.4.1 Descriptive Statistics for Chemistry Parameters Safety Population
Table 14.3.4.2 Descriptive Statistics for Hematology Parameters Safety Population
Table 14.3.4.3 Descriptive Statistics for Hormone Parameters Safety Population

Table 14.3.5
Number and Percent of Patients Meeting Criteria for Hepatobiliary Laboratory Abnormalities
Safety Population

Criteria	Female (N=xx) n (%)	Male (N=xx) n (%)	Total (N=xx) n (%)
>3xULN ALT or AST[a]	x (x.x)	x (x.x)	x (x.x)
>3xULN ALT	x (x.x)	x (x.x)	x (x.x)
>3xULN AST	x (x.x)	x (x.x)	x (x.x)
>5xULN ALT or AST[a]	x (x.x)	x (x.x)	x (x.x)
>5xULN ALT	x (x.x)	x (x.x)	x (x.x)
>5xULN AST	x (x.x)	x (x.x)	x (x.x)
>10xULN ALT or AST[a]	x (x.x)	x (x.x)	x (x.x)
>10xULN ALT	x (x.x)	x (x.x)	x (x.x)
>10xULN AST	x (x.x)	x (x.x)	x (x.x)
>20xULN ALT or AST[a]	x (x.x)	x (x.x)	x (x.x)
>20xULN ALT	x (x.x)	x (x.x)	x (x.x)
>20xULN AST	x (x.x)	x (x.x)	x (x.x)
Elevation of Bilirubin			
>1.5 xULN	x (x.x)	x (x.x)	x (x.x)
>2xULN	x (x.x)	x (x.x)	x (x.x)
>1.5xULN Alk Phos	x (x.x)	x (x.x)	x (x.x)
Elevation of AT[b] and Bilirubin			
>3xULN AT and >1.5xULN Bilirubin	x (x.x)	x (x.x)	x (x.x)
>3xULN AT and >2xULN Bilirubin	x (x.x)	x (x.x)	x (x.x)
>3xULN AT and >=2xULN Bilirubin and Alkaline Phosphatase <2xULN or missing	x (x.x)	x (x.x)	x (x.x)

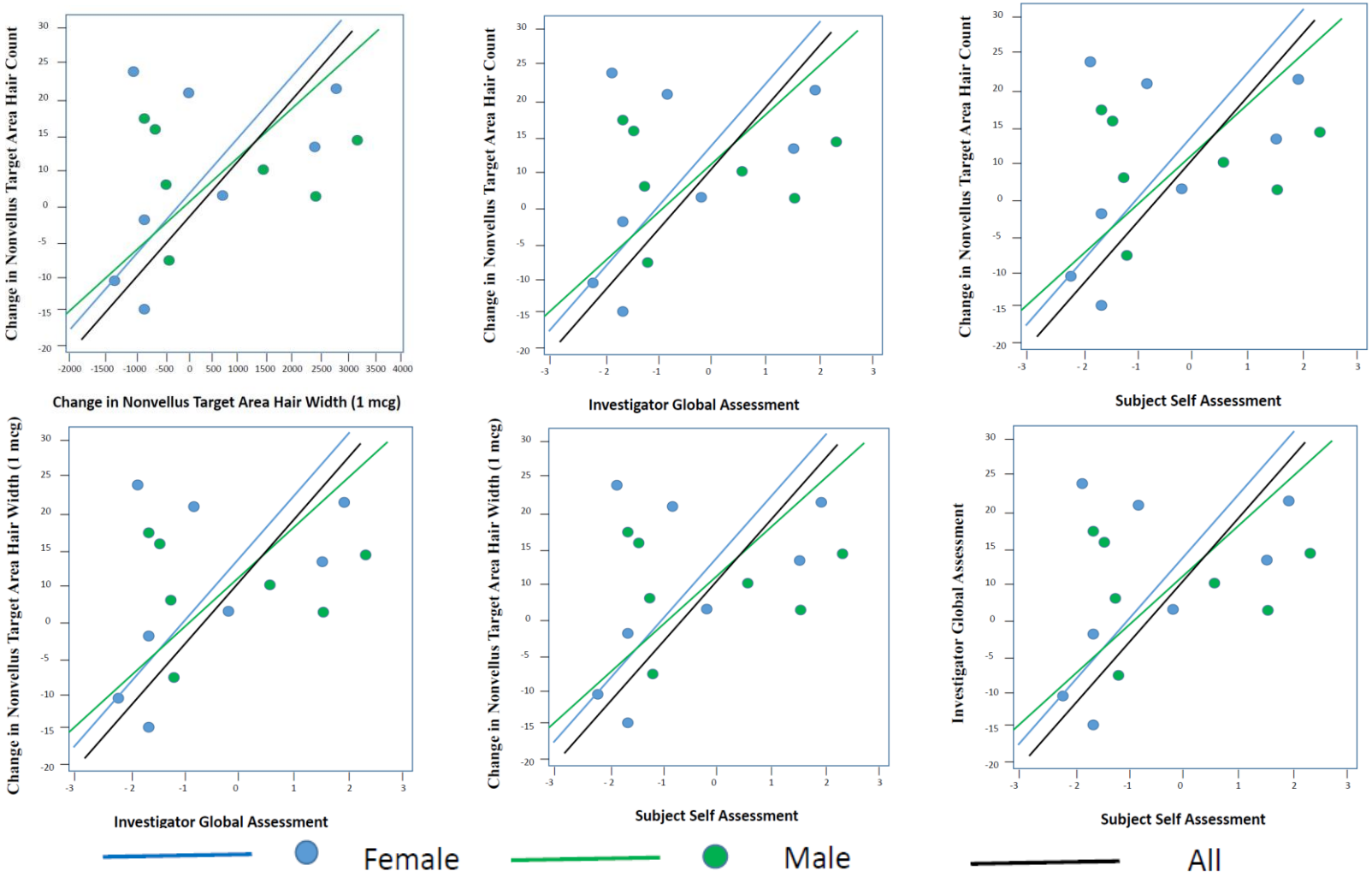
[a] Patients with both ALT and AST abnormalities for the same lab draw (same date and time) are counted as one event.
[b] AT = aminotransferase. Either AST or ALT (or both) elevated.
PROGRAMMING NOTE: It is intentional that the last criterion has '=' added to the bilirubin threshold – to match exactly FDA Guidance doc

Data Source: XX **Program: XYZ.SAS**

Table 14.3.6
Number and Percent of Patients Meeting Laboratory Criteria for Potential Renal Impairment
Safety Population

Criteria	Female (N=xx) n (%)	Male (N=xx) n (%)	Total (N=xx) n (%)
Change from Baseline ≥ 0.5 mg/dL	x (x.x)	x (x.x)	x (x.x)
>1.5xULN Creatinine	x (x.x)	x (x.x)	x (x.x)
EITHER Change from Baseline >=0.5 mg/dL or >1.5xULN Creatinine	x (x.x)	x (x.x)	x (x.x)
BOTH Change from Baseline >=0.5 mg/dL and >1.5xULN Creatinine	x (x.x)	x (x.x)	x (x.x)

Figure 14.1
Association of Selected Efficacy Measures with Fit Linear Regression Line
ITT Population: Visit = V5 Week 8



Data Source: XX **Program: XYZ.SAS**

Reperat for:

Figure 14.2 Association of Selected Efficacy Measures with Fit Linear Regression Line, ITT Population: Visit=V7 Week 16
Figure 14.3 Association of Selected Efficacy Measures with Fit Linear Regression Line, ITT Population: Visit=V10 Week 26
Figure 14.4 Association of Selected Efficacy Measures with Fit Linear Regression Line, ITT Population: Visit=V16 Week 52

For the following plot change in averge hair wdth (vertical) vs Investigaor Global Assessment [4 figures – All timepoints on page]. Indicate timepoint at top of each of the visits. Separate color for males and females and linear regression line as per figure 14.1.Add Foonote: Note Lines represent fit linerar regression line.

Figure 14.5 Association of Change in Nonvellus Target Area Average Hair Width with Investigator Global Assessment, ITT Population

For the following plot change in averge hair wdth (vertical) vs Subject Self Assessment [4 figures – All timepoints on page] Indicate timepoint at top of each of the visits. Separate color for males and females and linear regression line as per figure 14.1.Add Foonote: Note Lines represent fit linerar regression line.

Figure 14.6 Association of Change in Nonvellus Target Area Average Hair Width with Subject Self Assessment, ITT Population

For the following plot change nonvellus target area hair count (vertical), change nonvellus target area hair width (vertical) and change nonvellus target area average hair width (vertical), vs time since diagnosis of androgenetic alopecia [4 figures on page – all timepoints on page] Indicate timepoint at top of each of the visits. Separate color for males and females and linear regression line as per figure 14.1.Add Foonote: Note Lines represent fit linerar regression line.

Figure 14.7 Association of Change in Nonvellus Target Area Hair Count with Time Since Diagnosis of Androgenetic Alopecia, ITT Population
Figure 14.8 Association of Change in Nonvellus Target Area Hair Width with Time Since Diagnosis of Androgenetic Alopecia, ITT Population
Figure 14.9 Association of Change in Nonvellus Target AreaAverage Hair Width with Time Since Diagnosis of Androgenetic Alopecia, ITT Population

Appendix 16.2.1.1
Disposition

Group: Female, Male

Patient	Date of Last Application[a]	Date of DC/ Completion	Days from Last Application[b]	DC/ Completion Study Day[c]	Reason DC from Study	Period of Study Discontinuation/ Completion
xx-xxx	mmdddyy	mmdddyy	xx	xx	Adverse Event/SAE: list AE, link by AE number Protocol Violation Lost to Follow-Up Withdrew Consent Pregnancy Other: *specify* Completed	First 26 Weeks 6 Month Extension

[a] Date of last dose of application of study medication.
[b] DC date/Completion Date– date last application +1.
[c] DC date/ Completion Date – date of first application of study medication +1.

NOTE: DC=Discontinued.

Appendix 16.2.1.2
Demographics

Group: Female, Male

Patient	Age[a] (Years)	Gender	Race	Ethnicity	Fitzpatrick Skin Type	Height[b] (inches)	Weight[b] (lbs)
							xxx
xx-xxx	xx	Male Female	Caucasian/White Black Asian/Oriental American Indian or Alaska Native Native Hawaiian or Pacific Islander Other - *specify*	Hispanic/Latino Not Hispanic/Latino Not Willing to Provide	1,2,3,4,5,6	xx.x	xxx.x

[a] At Date of signed informed consent.
[b] FromV-2 Day 1 vitals page.

Appendix 16.2.1.3
History of Androgenetic Alopecia: Diagnosis and Prior Treatment and Therapies

Group: Female, Male

Patient	Onset Date of Diagnosis	Years Since Diagnosis[a]	Prior Treatment/ Therapy Type	Treatment or Therapy Coded/Verbatim	Start Date/ Stop Date	Start Day[b]/ Stop Day[b]
xx-xxx	ddmmmyyyy	xx.x	Pharmaceutical	Minoxidil/	01Jan2018	55
				Rogaine/	03Jan2018	57
			Pharmaceutical	Finasteride/	01Jan2018	55
				Propecia	03Jan2018	57
			Device	*Coded term/ verbatim*		
			Other	*Coded term/ verbatim*		

[a] (Date of Diagnosis - Date of first application of study medication) / 365.
[b] Start date – date of first application of study medication
NOTE: Date of Diagnosis from medical history page of CRF

PROGRAMMING NOTE: Will need to review prior treatment and therapies to assign "Type" i.e. "Pharmaceutical", "Device" and "other"

Appendix 16.2.1.4
Medical History

Group: Female, Male

Patient	Body System	Diagnosis	Onset Date (Study Day[a])	Resolution Date (Study Day[a])	Ongoing at Time of Randomization?
xx-xxx	Skin	*Free Text*	ddmmmyyyy (xx)	ddmmmyyyy (xx)	Yes
	Central nervous system				
	Ophthalmologic				
	Ear, nose, throat				
	Respiratory				
	Gastrointestinal				
	Hepatic				
	Renal				
	Cardiovascular				
	Hematologic				
	Genitourinary				
	Endocrine/Lymphatic				
	Musculoskeletal				
	Systemic Infection				
	Drug Allergy				
	Substance Abuse				
	Psychiatric				
	Other				

[a] Study Day = Start/stop date – date of first application of study medication.

PROGRAMMING NOTE: List dates as entered - i.e., display partial dates. Imputed dates in database are used to calculate study day. If patient has no entries, put "None" under Body System.

Appendix 16.2.1.5
Prior and Concomitant Therapies

Group: Female, Male

Patient	WHO ATC Level III/ WHO Preferred Term/ Verbatim Term	Dose (unit) [Route] Frequency	Study Period(s) in Which Received[a]	Start Date/ Stop Date	Start Day[b]/ Stop Day[b]	Indication	Associated with AE (AE#)
		xx (mg) [oral] QD	P O F P,O O,F P,O,F	01Jan2018 03Jan2018 **Note: if "ongoing", put "ongoing" under Stop Date**	55 57	*Free Text*	No Yes (xx)

[a] **P = Prior medication; O = Treatment Period; F=Post-Therapy**
[b] **Start date – date of first application of study medication (+1 if ≥ first application of study medication).**

NOTE: – = data not available

Appendix 16.2.1.6
ATI-50002 Accountability

Group: Female, Male

Patient	Date Dispensed	Study Day[a] Dispensed	Dispensed Bottle Weight (gm)	Date Collected	Study Day[a] Collected	Collected Bottle Weight (gm)	Amount Used[b] (gm)	Volume (mL)[c]	Volume (mL) Per Application[c]
xx-xxx	ddmmmyyyy	xx	xx	ddmmmyyyy	xx	xx	xx	xx	
	ddmmmyyyy	xx	xx	ddmmmyyyy	xx	xx	xx	xx	
	ddmmmyyyy	xx	xx	ddmmmyyyy	xx	xx	xx	xx	
	ddmmmyyyy	xx	xx	ddmmmyyyy	xx	xx	xx	xx	
	ddmmmyyyy	xx	xx	ddmmmyyyy	xx	xx	xx	xx	
	ddmmmyyyy	xx	xx	ddmmmyyyy	xx	xx	xx	xx	
						TOTAL:	xx	xxx	xx.x

[a] Dispensed Date (or Collection Date) – Date first Application +1.
[b] Weight dispensed – Weight collected (returned).
[c] The density of study agent is 1 g/mL which is used to convert differences in bottle weights between dispensed and returned (ie weight of study agent used) to mLs.

Appendix 16.2.1.7
ATI-50002 Accountability Comments

Group: Female, Male

Patient	Date Dispensed	Study Day[a] Dispensed	Date Collected	Study Day[a] Collected	Comment
xx-xxx	ddmmmyyyy	xx	ddmmmyyyy	xx	*Free Text*
	ddmmmyyyy	xx	ddmmmyyyy	xx	
	ddmmmyyyy	xx	ddmmmyyyy	xx	
	ddmmmyyyy	xx	ddmmmyyyy	xx	
	ddmmmyyyy	xx	ddmmmyyyy	xx	
	ddmmmyyyy	xx	ddmmmyyyy	xx	
	ddmmmyyyy	xx	ddmmmyyyy	xx	
	ddmmmyyyy	xx	ddmmmyyyy	xx	
	ddmmmyyyy	xx	ddmmmyyyy	xx	

[a] Dispensed Date (or Collection Date) – Date first Application +1.

Appendix 16.2.1.8
ATI-50002 Application Changes and Missed Doses

Group: Female, Male

Patient	Application Frequency Started	Study Day[a] Dispensed	Application Frequency Ended	Study Day[a] Collected	Applications/Day
xx-xxx	ddmmmyyyy	xx	ddmmmyyyy	xx	xx
	ddmmmyyyy	xx	ddmmmyyyy	xx	xx
	ddmmmyyyy	xx	ddmmmyyyy	xx	xx
	ddmmmyyyy	xx	ddmmmyyyy	xx	xx
	ddmmmyyyy	xx	ddmmmyyyy	xx	xx
	ddmmmyyyy	xx	ddmmmyyyy	xx	xx
	ddmmmyyyy	xx	ddmmmyyyy	xx	xx
	ddmmmyyyy	xx	ddmmmyyyy	xx	xx
	ddmmmyyyy	xx	ddmmmyyyy	xx	xx

[a] Dispensed Date (or Collection Date) – Date first Application +1.

Appendix 16.2.1.9
Eligibility Criteria

Group: Female, Male

Patient	Inclusion Criteria Not Met	Exclusion Criteria Not Met
	1,2 ….13	None
	None	1,2 ..16

Appendix 16.2.1.10
Protocol Violations

Group: Female, Male

Patient	Violation

Appendix 16.2.2.1
Target Area Hair Count and Width

Group: Female, Male

Patient	Visit	Assessment Date	Study Day[a]	TAHC (hairs/cm^2)	TAHW (cm)
xx-xxx	V2 – Day 1	ddmmmyyyy	xx	xxx	xxx
	V5 – Week 8	ddmmmyyyy	xx	xxx	xxx
	V7 – Week 16	ddmmmyyyy	xx	xxx	xxx
	V10 – Week 26	ddmmmyyyy	xx	xxx	xxx
	V16 – Week 52	ddmmmyyyy	xx	xxx	xxx

[a] **Assessment date – date of first application of study medication (+1 if ≥ first application of study medication).**

Appendix 16.2.2.2
Investigator and Subject Global Assessments

Group: Female, Male

Patient	Visit	Assessment Date	Study Day[a]	Investigator Global Assessment[b]	Subject Global Assessment[b]
xx-xxx	V5 – Week 8	ddmmmyyyy	xx	-3	-3
	V7 – Week 16	ddmmmyyyy	xx	-2	-2
	V10 – Week 26	ddmmmyyyy	xx	-1	-1
	V13 – Week 39	ddmmmyyyy	xx	0	0
	V16 – Week 52	ddmmmyyyy	xx	1	1
	Early Term 1st 26 Weeks	ddmmmyyyy	xx	2	2
	Follow-Up 1st 26 Weeks			3	3
	Early Term 6 Month Extension				
	Follow-Up 6 Month Extension				

[a] Assessment date – date of first application of study medication (+1 if ≥ first application of study medication).
[b] -3: Greatly decreased hair growth; -2: Moderately decreased hair growth; -1: Slightly decreased hair growth; 0: No Change; +1: Slightly increased hair growth; +2: Moderately increased hair growth; +3: Greatly increased hair growth.

Programming note: Differentiation between Early term and Follow-up is based on the availability of V10 (1st 26 Weeks) or V16 (patients entering extension) data for ANY data (not just global assessments). If a patient does not enter the extension and had no data collected for V10 and had discontinued the trial the follow-up is considered "Early Term 1st 26 Weeks". If they had V10 and did not enter the extension then it's "Follow-Up 6 Month Extension". Similarly for those entering extension, those without a V16 who discontinued the study are assigned "Early Term 6 Month Extension" and those with V16 are assigned to "Follow-Up 6 Month Extension".

Appendix 16.2.2.3
Norwood-Hamilton Scale in Males

Group: Male

Patient	Visit	Assessment Date	Study Day[a]	N-H Score	Improvement from Baseline (Yes/No)[c]
xx-xxx	V1 - Screening	ddmmmyyyy	xx	I	Yes/No
	V2 – Day 1	ddmmmyyyy	xx	II[b]	
	V7 – Week 16	ddmmmyyyy	xx	IIa	
	V10 – Week 26	ddmmmyyyy	xx	III	
	V16 – Week 52	ddmmmyyyy	xx	IIIa	
	Early Term 1st 26 Weeks	ddmmmyyyy	xx	III Vertex	
	Follow-Up 1st 26 Weeks			IV	
	Early Term 6 Month Extension			IVa	
	Follow-Up 6 Month Extension			V	
				Va	
				VI	
				VII	

[a] Assessment date – date of first application of study medication (+1 if ≥ first application of study medication).
[b] Used as baseline for analysis.
[c] Yes – score improved by ≥1 level including shifts in "sub-level" (e.g. IIIa to III is considered a 1 level improvement).

Programming note: Differentiation between Early term and Follow-up is based on the availability of V10 (1st 26 Weeks) or V16 (patients entering extension) data for ANY data (not just Norwood-Hamilton). If a patient does not enter the extension and had no data collected for V10 and had discontinued the trial the follow-up is considered "Early Term 1st 26 Weeks". If they had V10 and did not enter the extension then it's "Follow-Up 1st 26 Weeks". Similarly for those entering extension, those without a V16 who discontinued the study are assigned "Early Term 6 Month Extension" and those with V16 are assigned to "Follow-Up 6 Month Extension".

Appendix 16.2.2.4
Sinclair Scale in Females

Group: Female

Patient	Visit	Assessment Date	Study Day[a]	Sinclair Score	Improvement from Baseline (Yes/No)
xx-xxx	V1 - Screening	ddmmmyyyy	xx	1	Yes/No
	V2 – Day 1	ddmmmyyyy	xx	2[b]	
	V7 – Week 16	ddmmmyyyy	xx	3	
	V10 – Week 26	ddmmmyyyy	xx	4	
	V16 – Week 52	ddmmmyyyy	xx	5	
	Early Term 1st 26 Weeks	ddmmmyyyy	xx		
	Follow-Up 1st 26 Weeks				
	Early Term 6 Month Extension				
	Follow-Up 6 Month Extension				

[a] Assessment date – date of first application of study medication (+1 if ≥ first application of study medication).
[b] Used as baseline for analysis.

Programming note: Differentiation between Early term and Follow-up is based on the availability of V10 (1st 26 Weeks) or V16 (patients entering extension) data for ANY data (not just Sinclair score). If a patient does not enter the extension and had no data collected for V10 and had discontinued the trial the follow-up is considered "Early Term 1st 26 Weeks". If they had V10 and did not enter the extension then it's "Follow-Up 1st 26 Weeks". Similarly for those entering extension, those without a V16 who discontinued the study are assigned "Early Term 6 Month Extension" and those with V16 are assigned to "Follow-Up 6 Month Extension".

Appendix 16.2.3.1
All Adverse Events

Group: Female, Male

Patient	MedDRA SOC/ MedDRA Preferred Term/ CRF Verbatim Term (AE No.)	Onset Study Day[a] Resolution Study Day[b] Duration (Days)[c]	Onset Date/ Stop Date Cutaneous AE?	Relationship/ Action Taken/ Therapy Required	Serious/ Severity/ Outcome
501-01	Cardiovascular System /	62	01Sep12	Related	Yes/No
	Bradycardia /	64		Not Related	
	Slow Heart Rate (xx)[d]	3	03Sep12		Mild/Moderate/Severe
			Ongoing	Dose not changed	
				Dose Reduced	Recoverd/Resolved
			Yes (Scalp),	Dose Interrupted	Not Recovered/Resolved
			Yes (not Scalp),	Drug Withdrawn	Recovered/Resolved w/ Seq.
			No	Unknown	Fatal
					Unknown
				Yes/No	

[a] AE onset date – date of first application of study medication (+1 if ≥ first application).
[b] AE resolution date – date of first application of study medication (+1 if ≥ first application).
[c] Resolution Date – Onset Date +1
[d] Not treatment emergent = Onset either prior to the first application or > 30 days after the last application of study medication.

PROGRAMMING NOTES: Sort by group, patient, onset date, SOC and PREF term. Display partial dates as entered in raw data. Use derived dates for study day and duration

Appendix 16.2.3.2 Serious Adverse Events
Appendix 16.2.3.3 Adverse Events Resulting in Discontinuation of Study Treatment
Appendix 16.2.3.4 Adverse Events Resulting in Outcome of Death

Appendix 16.2.3.5
Local Skin Reactions

Group: Female, Male

Patient	Visit	Assessment Date	Study Day[a]	Assessor	Sign[b]	Grade
	V2 – Day 1	ddmmmyyyy	1	Investigator	Erythema	1
					Scaling	2
					Dryness	3
				Subject	Stinging/burning	
					Itching	
				Investigator	NO SIGN GRADED >0	
				Subject/Legal Guardian	NO SIGN GRADED >0	
	V3 – Week 3	ddmmmyyyy	21			

[a] Assessment Date – Date first Application +1.
[b] Only signs with grade > 0 are displayed. Within assessor, if all signs were grade 0 (or not done) appear as "NO SIGN GRADED > 0".

Appendix 16.2.3.6
Physical Exam

Group: Female, Male

Patient	Assessment Date	Visit	Study Day[a]	Body System	Finding[b]	Description of Finding
xx-xxx	ddmmmyyyy	V1 – Screening ET/Follow-Up	xx		Normal, no findings	
				Body System a	Abnormal, CS	xxxxxxxxxxxxxx
				Body System b	Abnormal, NCS	xxxxxxxxxxxx

[a] **Assessment Date – Date of First Application (+1 if ≥ first application of study medication).**
[b] **CS = Clinically Significant; NCS = Not Clinically Significant**

NOTE: Listing includes only lists body systems that were assessed with Abnormalities. Patients with only "normal" findings are listed as "Normal, no findings" (can have some body systems "not done" so long as those that were assessed are all "normal". Not done are not listed.)

Appendix 16.2.3.7
Vital Signs

Group: Female, Male

Patient	Visit	Study Day[a]	Heart Rate (bpm)	Respiratory Rate (bpm)	Temperature (Degrees C)	Blood Pressure Systolic / Diastolic (mmHg)
xx-xxx	V1 – Screening	xx	xxx	xx	xx	xxx / xxx
	V2 – Day 1					
	V3 – Week 3					
	V4 – Week 4					
	V5 – Week 8					
	V6 – Week 12					
	V7 – Week 16					
	V8 – Week 20					
	V9 – Week 24					
	V10 – Week 26					
	ET/Follow-Up					
	V11 – Week 30					
	V12 – Week 35					
	V13 – Week 39					
	V14 – Week 44					
	V15 – Week 48					
	V15 – Week 52					
	Follow-Up/ Early Termination[b]					

[a] Assessment Date – Date of First Application (+1 if ≥ first application of study medication).
[b] Includes early terminations or follow-ups collected during the first 26 Weeks or during the additional six months for patients opting to continue treatment in the optional six month extension.

Appendix 16.2.3.8
Electrocardiogram – Evaluator Interpretation

Group: Female, Male

Patient	Visit	Study Day[a]	Interpretation[b]	Specify – if abnormal
xx-xxx		xx	Normal	
		xx	Abnormal, CS	Sinus Bradycardia
		xx	Abnormal, NCS	Inverted T Waves; T Wave Abnormality: Biphasic T Waves
		xx	Abnormal, NCS	

[a] Assessment Date – Date of First Application (+1 if ≥ first application of study medication).
[b] CS = Clinically Significant; NCS = Not Clinically Significant

Programming Note: Suggestion is to list all abnormalities at a given collection be listed according to "interpretation" (ie CS and/or NCS). So if there are multiple reasons, as in the hypothetical example above for NCS, separate them by semi-colons.

Appendix 16.2.3.9
Clinical Laboratory Assessments: Hematology

Group: Female, Male

Patient	Age (years)	Gender	Parameter (unit)	Visit	Study Day[a]	Value	Normal Range		List Criteria Met, if applicable, for Hold of Study Medication
xx-xxx	60	Female	Hemoglobin (g/dL)		-10	xxx	xx.x-xx.x	L	< 8 g/dL or decrease > 2 g/dL
					-1 [b]	xxx		H	
					28	xxx			
					38	xxx			
			Hematocrit (%)						

[a] **Assessment Date – Date of First Application (+1 if ≥ first application of study medication).**
[b] **Value used for baseline.**

PROGRAMMING NOTE: Sort by group, patient, parameter, and study day. For criteria for holding study medication see protocol – Section 10.2.4.1

Repeat format for:
Appendix 16.2.3.10 Clinical Laboratory Assessments: Biochemistry
Appendix 16.2.3.11 Clinical Laboratory Assessments: Hormones

Appendix 16.2.3.12
Clinical Laboratory Assessments: Urinalysis

Group: Female, Male

Patient	Age (years)	Gender	Parameter	Visit	Study Day[a]	Value
	60	Female	Glucose		-10	Positive
					-1 [b]	Negative
						Trace
					xx	
			Protein			
			RBC			
			WBC			
			Urobilinogen			

[a] **Assessment Date – Date of First Application (+1 if ≥ first application of study medication).**
[b] **Value used for baseline.**

PROGRAMMING NOTES: Display parameters in alphabetical order.
Sort by group, patient, parameter, and study day.

Appendix A
MedDRA System Organ Class/Preferred Term and CRF Verbatim Terms

MedDRA System Organ Class	MedDRA Preferred Term	CRF Verbatim Term

NOTE: Events coded using MedDRA Version 21.1