PHARMASTAT LLC

SPECIALIZING IN CLINICAL TRIAL DATA ANALYSIS, DATA STANDARDIZATION, AND FDA SUBMISSIONS

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ANALYSIS RESULTS METADATA: WHY TO DO IT AND HOW TO DO IT

- What's new in Define-XML V2.1
- Overview of Define-XML Analysis Results Metadata (ARM)
- ARM Examples
- Creating ARM from Analysis Tables

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WHAT'S NEW IN DEFINE 2.1

- Define and reference standards
- Highlight non-standard elements
- Document planned domains that were not included
- Indicate variables with only null values
- Changes to Origin

STANDARDS

Standard	Type	Status	Documentation
SDTMIG 3.1.2	IG	Final	The CDISC01 study was modeled on a very old SDTMIG and no attempt was done yet to upversion it to a newer SDTMIG
SDTMIG 3.2	IG	Final	As an example, the CDISC01 study was adjusted to include a new Domain available in SDTM IG 3.2
SDTMIG-MD 1.0	IG	Final	As an example, the CDISC01 study was adjusted to include a new Domain available in SDTMIG-MD 1.0. The XS Domain is expected to reference the device used with variable SPDEVID.
CDISC/NCI SDTM 2011-12-09	CT	Final	Assuming the CT was not upversioned for this study
CDISC/NCI SDTM 2015-12-18	CT	Final	The CT version applicable for the new Domain is the 2015-12-18 version

STANDARDS

DI [SDTMIG-MD 1.0]	Device Identifiers	SPECIAL PURPOSE	One record per device identifier per device	Tabulation	STUDYID, SPDEVID, DIPARMCD	The DI domain is included to illustrate the use of a separate complementary SDTMIG. In this example, the device ID is referenced from a Findings Domain (XS).	di.xpt
DM [SDTMIG 3.1.2]	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	See Reviewer's Guide, Section 2.1 Demographics Reviewers Guide [section2.1]	dm.xpt
EC [SDTMIG 3.2]	Exposure as Collected	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, ECSTDTC, ECENDTC, ECTRT, ECDOSE		ec.xpt

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STANDARDS

Ethnic Group [*C66790*] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
HISPANIC OR LATINO [*C17459*]
NOT HISPANIC OR LATINO [*C41222*]

Domain Abbreviation (EX) [*C66734*] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
EX [*C49587*]	Exposure

Treatment [CDISC/NCI SDTM 2011-12-09] [Non Standard]

Permitted Value (Code)
Miracle Drug
Placebo

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NON-STANDARD ELEMENTS

XS [Non Standard]	S Findings	FINDINGS	One record per finding per visit per subject	Tabulation	STUDYID, USUBJID, XSTESTCD, XSDTC, VISITNUM		xs.xpt

Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID [Non Standard]	Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (DM) • "DM" = "Demographics"	Assigned (Source: Sponsor)

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NULL DATA

XX [Non Standard] **[No Data]**	X Findings	FINDINGS	One record per finding per visit per subject	Tabulation	STUDYID, USUBJID, XXTESTCD, XXDTC, VISITNUM	Special domain contingent on rare conditions observed.	

XSORRESU **[No Data]**	Original Units	text	20	Units for S Findings Results • "g/dL" = "g/dL" • "mg/dL" = "mg/dL"	Collected (Source: Vendor) Planned Numeric tests were not performed.

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WHAT'S NEW IN DEFINE 2.1

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CHANGES TO ORIGIN

Origin / Source / Method / Comment
Protocol (Source: Sponsor)
Assigned (Source: Sponsor)
Collected (Source: Vendor)
Derived (Source: Sponsor) Sequential number identifying records within each USUBJID in the domain.
Assigned (Source: Vendor)
Assigned (Source: Vendor)
Collected (Source: Vendor) Derived (Source: Investigator) Collected (Source: Investigator) Annotated CRF [20]

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DEFINE 2.1 SDTM ORIGINS

The following table lists the allowed Origin Type and Source values for SDTM datasets. Type and Source values that do not apply to SDTM datasets are not listed. Table cells include examples that highlight cases where the specific combination of Type and Source attributes apply. Cells that include only an **X** indicate that the combination of Type and Source attributes is not valid. The Notes provide additional information about use of the Origin attributes for SDTM datasets.

Type	Source				Notes
	Subject	Investigator	Vendor	Sponsor	
Collected	ePro	CRF	Lab data, ECG	X	This term should be used for clinical data that were actually observed or recorded by a person or received from an instrument; it should not be used for data that have been interpreted, calculated, or derived from other information.
Derived	X	X	Lab data, ECG	SDTM	Derivation examples include calculations performed during data collection (e.g., --DY). Other derivation examples: calculations within ePRO (e.g., questionnaire section scores) and calculations within EDC (e.g., BMI, BSA).
Assigned	X	X	Adjudicator	SDTM	Examples of this include third-party attributions by an adjudicator, coded terms that are supplied as part of a coding process, and values that are set independently of any subject-related data values in order to complete SDTM fields such as DOMAIN and --TESTCD
Protocol	X	X	X	SDTM	An example would be VSPOS (Vital Signs Position), which could be specified in the protocol and be provided by other means (e.g. CRF, eDT).
Predecessor	X	X	X	X	Use when a value is an exact copy of another value in an SDTM dataset.

DEFINE 2.1 ADAM ORIGINS

Type	Source	Notes
	Sponsor	
Derived	ADaM	For sponsor-performed analysis derivations in ADaM
Assigned	ADaM	
Predecessor	**X**	Use when a value is an exact copy of another value in either SDTM or ADaM dataset.

OVERVIEW OF ARM

- Draft standard released 2014 for public comment
- Final standard released 2015 with support for Define-XML V2.0 and V2.1
- Define-XML 2.0 required for NDA studies starting after 2016-12-17
- Define-XML 2.1 required for NDA studies starting after 2022-03-15
- Define ARM is currently optional, no date for future requirement

THE STYLESHEETS

There are 2 stylesheets available for use with ARM:

- define2-0-0.xls modified 2015-01-16 (Analysis Results Metadata Final Package)
- define2-1.xls modified 2019-05-08 (Final Define 2.1 release)

WHY USE ARM?

- Highlight Key Tables or Findings
- Provide Additional Analysis Details
- Enhance Traceability

WHAT ARE WE DOCUMENTING?

- Primary, secondary, or exploratory outcome measures
- Driven by the SAP and study design
- NOT every table or result

ARM CONCEPT – ANALYSIS DISPLAY

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Dummy Product
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Table 14.2.3
Laboratory Summary - Mixed Model Analysis of Bilirubin
Intent to Treat Population

	Placebo		All Active Drug	
Time Point	**Observed Value**	**Change from Baseline**	**Observed Value**	**Change from Baseline**
End of Treatment				
n	80	78	80	80
Mean (SD)	9.833 (4.2890)	0.460 (3.0772)	11.07 (5.3592)	-.021 (3.1554)
Median	8.550	0.000	10.26	0.000
Min Max	3.42 , 23.94	-10.3 , 8.55	3.42 , 30.78	-8.55 , 11.97
Within Group Least Square Mean Change				
LSM (SE) [a]		0.201 (0.3437)		0.230 (0.3398)
95% CI for LSM [a]		-0.479 , 0.880		-0.442 , 0.901
Between Group Least Square Mean Difference				
LSMD (Active-Placebo) (SE) [a]				0.029 (0.4859)
95% CI for LSMD [a]				-0.931 , 0.989
P-value [a]				0.9523

[1]Intent-to-treat population includes subjects who meet all enrollment criteria or who have been given an exemption.
[a] Results are based on a MMRM model including the change from baseline value as the dependent variable; treatment, visit (Week 2 , EOT), and treatment by visit interaction, and the continuous covariates of baseline value, as fixed effects; and subject as a random effect.

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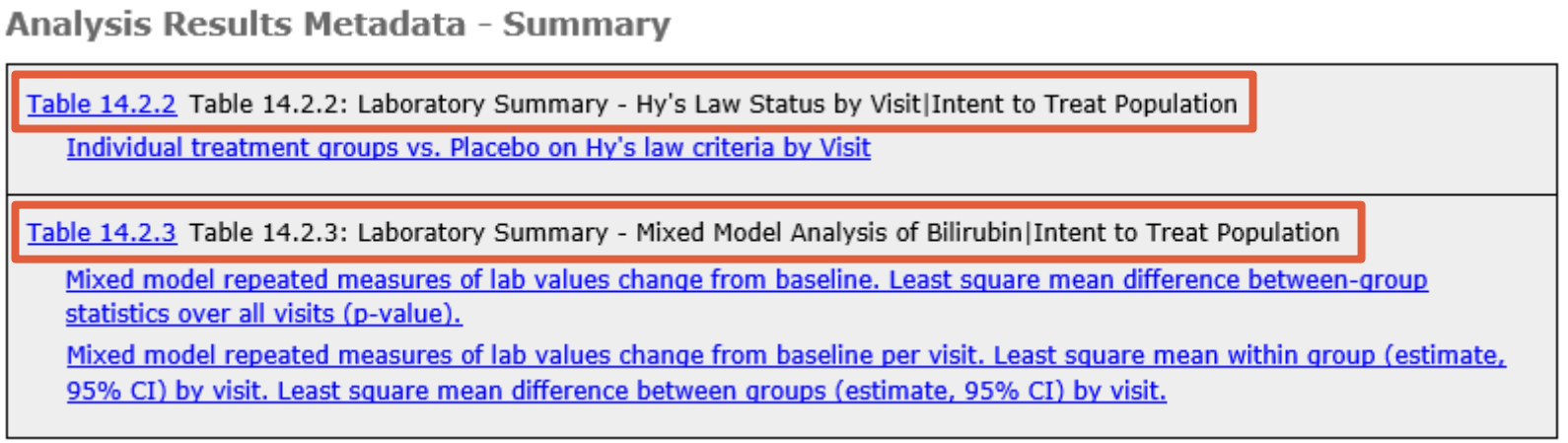
ARM CONCEPT – ANALYSIS DISPLAY



ARM CONCEPT – ANALYSIS RESULT

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ARM CONCEPT – ANALYSIS RESULT

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ARM CONCEPT – ANALYSIS RESULT

Analysis Results Metadata - Summary

Table 14.2.2 Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population Individual treatment groups vs. Placebo on Hy's law criteria by Visit
Table 14.2.3 Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population Mixed model repeated measures of lab values change from baseline. Least square mean difference between-group statistics over all visits (p-value). Mixed model repeated measures of lab values change from baseline per visit. Least square mean within group (estimate, 95% CI) by visit. Least square mean difference between groups (estimate, 95% CI) by visit.

EXAMPLE ARM TABLE

Analysis Results Metadata - Summary

Table 14.2.2 Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population

Individual treatment groups vs. Placebo on Hy's law criteria by Visit

EXAMPLE ARM TABLE

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Table 14.2.2
Laboratory Summary - Hy's Law Status by Visit
Intent to Treat Population

		Placebo (N=86)	Xanomeline Low Dose (N=84)	Xanomeline High Dose (N=84)	Fisher p-value: Placebo v. Low	Fisher p-value: Placebo v. High
Summary of Hy's Law Status by Visit						
Baseline	- Total -	86	82	84		
	N	86 (100.0%)	82 (100.0%)	84 (100.0%)		
	Y	0	0	0		
Week 2	- Total -	83	80	78		
	N	82 (98.8%)	80 (100.0%)	78 (100.0%)	1.0000	1.0000
	Y	1 (1.2%)	0	0		
Week 4	- Total -	79	72	72		
	N	78 (98.7%)	72 (100.0%)	72 (100.0%)	1.0000	1.0000
	Y	1 (1.3%)	0	0		
Week 6	- Total -	73	62	66		

[1]Intent-to-treat population includes subjects who meet all enrollment criteria or who have been given an exemption.

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EXAMPLE ARM TABLE

Table 14.2.2

Display	**Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population**
Analysis Result	**Individual treatment groups vs. Placebo on Hy's law criteria by Visit**
Analysis Parameter(s)	PARAMCD = "HYLAW" (Total Bili 1.5 x ULN and Transaminase 1.5 x ULN)
Analysis Variable(s)	ADLBHY.AVALC (Analysis Value (C))
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADLBHY [PARAMCD = "HYLAW"] Subset ADSL and ADLBHY per selection criteria. Merge subsetted ADSL and ADLBHY by USUBJID, keeping only subjects that exist in the ADSL subset.
Documentation	Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit. Statistical Analysis Plan [5 8]

Programming Statements	[SAS version 9.4]
	`proc freq data = adlbhy ;`
	`where trt01pn in ( 1 , 2 ) ;`
	`by avisitn ;`
	`tables trt01pn * avalc / chisq sparse exact alpha = .05 ;`
	`run;`
	`* Repeat for trt01pn in (1,3) *;`
	
	Laboratory Table Program - Hy's Law

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EXAMPLE ARM TABLE

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Programming Statements	[SAS version 9.4]
	`proc freq data = adlbhy ;`
	`where trt01pn in ( 1 , 2 ) ;`
	`by avisitn ;`
	`tables trt01pn * avalc / chisq sparse exact alpha = .05 ;`
	`run;`
	`* Repeat for trt01pn in (1,3) *;`
	
	Laboratory Table Program - Hy's Law

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EXAMPLE ARM TABLE

Table 14.2.3 Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population

Mixed model repeated measures of lab values change from baseline. Least square mean difference between-group statistics over all visits (p-value).

Mixed model repeated measures of lab values change from baseline per visit. Least square mean within group (estimate, 95% CI) by visit. Least square mean difference between groups (estimate, 95% CI) by visit.

EXAMPLE ARM TABLE

Table 14.2.3

Display	Clinical Study Report [1] Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population
Analysis Result	**Mixed model repeated measures of lab values change from baseline. Least square mean difference between-group statistics over all visits (p-value).**
Analysis Parameter (s)	PARAMCD = "BILI" (Bilirubin (umol/L))
Analysis Variable(s)	ADLBC.AVAL (Analysis Value) ADLBC.CHG (Change from Baseline)
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADLBC [AVISITN IN (0, 2, 99) and PARAMCD = "BILI"] Subset ADSL and ADLBC per selection criteria. Merge subsetted ADSL and ADLBC by USUBJID, keeping only subjects that exist in the ADSL subset. Generate column number (COLNUM) as: 1=AVAL where TRT01P='Placebo', 2=CHG where TRT01P= any treated, 3=AVAL where TRT01P='Placebo', 4=CHG where TRT01P=any treated.
Documentation	Calculate mixed model between groups over all visits Statistical Analysis Plan [7 9]

Programming Statements	[SAS version 9.4]
	`ods output lsmestimates = _tests3 ;`
	`proc mixed data=_aptmix2 method=reml noclprint=20 covtest;`
	`where colnum in (2,4) ;`
	`class colnum avisitn usubjid ;`
	`model chg = colnum base colnum*avisitn /s chisq ddfm=kr;`
	`repeated avisitn /subject= usubjid type=un ;`
	`lsmestimate &_column*avisitn "Between treatments 0.05" 0 1 0 -1 /CL alpha=0.05 ;`
	`run;`
	Laboratory Table Program - Mixed Model

Analysis Result	Mixed model repeated measures of lab values change from baseline per visit. Least square mean within group (estimate, 95% CI) by visit. Least square mean difference between groups (estimate, 95% CI) by visit.
Analysis Parameter (s)	PARAMCD = "BILI" (Bilirubin (umol/L))
Analysis Variable(s)	ADLBC.AVAL (Analysis Value) ADLBC.CHG (Change from Baseline)
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADLBC [AVISITN IN (0, 2, 99) and PARAMCD = "BILI"] Subset ADSL and ADLBC per selection criteria. Merge subsetted ADSL and ADLBC by USUBJID, keeping only subjects that exist in the ADSL subset. Generate column number (COLNUM) as: 1=AVAL where TRT01P='Placebo', 2=CHG where TRT01P= any treated, 3=AVAL where TRT01P='Placebo', 4=CHG where TRT01P=any treated.
Documentation	Calculate mixed model within group LS Means and comparison between groups per visit Statistical Analysis Plan [7 9]

Programming Statements	[SAS version 9.4]
	`ods output lsmeans = _lsmeans ;`
	`ods output diffs = _diffs ;`
	`proc mixed data=_mix method=reml noclprint=20 covtest;`
	`where colnum in (2,4) ;`
	`class colnum avisitn usubjid ;`
	`model chg = colnum base colnum*avisitn /s chisq ddfm=kr;`
	`repeated avisitn /subject= usubjid type=un ;`
	`lsmeans colnum*avisitn /cl pdiff e;`
	`run;`
	Laboratory Table Program - Mixed Model

EXAMPLE ARM TABLE

Table 14.2.3

Display	Clinical Study Report [1] Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population
Analysis Result	**Mixed model repeated measures of lab values change from baseline. Least square mean difference between-group statistics over all visits (p-value).**
Analysis Parameter (s)	PARAMCD = "BILI" (Bilirubin (umol/L))
Analysis Variable(s)	ADLBC.AVAL (Analysis Value) ADLBC.CHG (Change from Baseline)
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADLBC [AVISITN IN (0, 2, 99) and PARAMCD = "BILI"] Subset ADSL and ADLBC per selection criteria. Merge subsetted ADSL and ADLBC by USUBJID, keeping only subjects that exist in the ADSL subset. Generate column number (COLNUM) as: 1=AVAL where TRT01P='Placebo', 2=CHG where TRT01P= any treated, 3=AVAL where TRT01P='Placebo', 4=CHG where TRT01P=any treated.
Documentation	Calculate mixed model between groups over all visits Statistical Analysis Plan [7 9]

Programming Statements	[SAS version 9.4]
	`ods output lsmestimates = _tests3 ;`
	`proc mixed data=_aptmix2 method=reml noclprint=20 covtest;`
	`where colnum in (2,4) ;`
	`class colnum avisitn usubjid ;`
	`model chg = colnum base colnum*avisitn /s chisq ddfm=kr;`
	`repeated avisitn /subject= usubjid type=un ;`
	`lsmestimate &_column*avisitn "Between treatments 0.05" 0 1 0 -1 /CL alpha=0.05 ;`
	`run;`
	Laboratory Table Program - Mixed Model

Analysis Result	Mixed model repeated measures of lab values change from baseline per visit. Least square mean within group (estimate, 95% CI) by visit. Least square mean difference between groups (estimate, 95% CI) by visit.
Analysis Parameter (s)	PARAMCD = "BILI" (Bilirubin (umol/L))
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Documentation	Calculate mixed model within group LS Means and comparison between groups per visit Statistical Analysis Plan [7 9]

Programming Statements	[SAS version 9.4]
	`ods output lsmeans = _lsmeans ;`
	`ods output diffs = _diffs ;`
	`proc mixed data=_mix method=reml noclprint=20 covtest;`
	`where colnum in (2,4) ;`
	`class colnum avisitn usubjid ;`
	`model chg = colnum base colnum*avisitn /s chisq ddfm=kr;`
	`repeated avisitn /subject= usubjid type=un ;`
	`lsmeans colnum*avisitn /cl pdiff e;`
	`run;`
	Laboratory Table Program - Mixed Model

ARM SUMMARY STRUCTURE

ID	Title	Document	Pages
ARD.Table14.2.2	Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population	CSR	1
ARD.Table14.2.3	Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population	CSR	1

Define Stylesheet

Analysis Results Metadata - Summary

Table 14.2.2 Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population
Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Table 14.2.3 Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population
Mixed model repeated measures of lab values change from baseline. Least square mean difference between-group statistics over all visits (p-value).
Mixed model repeated measures of lab values change from baseline per visit. Least square mean within group (estimate, 95% CI) by visit. Least square mean difference between groups (estimate, 95% CI) by visit.

Pinnacle21 Analysis Displays

Pinnacle21 Analysis Results

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit
ARD.Table14.2.3	t_labmmrm.01_itt	Mixed model repeated measures of lab values change from baseline. Least square mean difference between-group statistics over all visits (p-value).
ARD.Table14.2.3	t_labmmrm.02_itt	Mixed model repeated measures of lab values change from baseline per visit. Least square mean within group (estimate, 95% CI) by visit. Least square mean difference between groups (estimate, 95% CI) by visit.

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ARM STRUCTURE

ID	Title	Document	Pages
ARD.Table14.2.2	Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population	CSR	1
ARD.Table14.2.3	Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population	CSR	1

Pinnacle21 Analysis Displays

Define Stylesheet

Analysis Results Metadata - Summary

Table 14.2.2 Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population

Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Table 14.2.3 Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population

Mixed model repeated measures of lab values change from baseline. Least square mean difference between-group statistics over all visits (p-value).

Mixed model repeated measures of lab values change from baseline per visit. Least square mean within group (estimate, 95% CI) by visit. Least square mean difference between groups (estimate, 95% CI) by visit.

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Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit
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ARM SUMMARY STRUCTURE

ID	Title	Document	Pages
ARD.Table14.2.2	Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population	CSR	1
ARD.Table14.2.3	Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population	CSR	1

Define Stylesheet

Analysis Results Metadata - Summary

Table 14.2.2 Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population

Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Table 14.2.3 Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population

Mixed model repeated measures of lab values change from baseline. Least square mean difference between-group statistics over all visits (p-value).

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ARM SUMMARY STRUCTURE

ID	Title	Document	Pages
ARD.Table14.2.2	Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population	CSR	1
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Pinnacle21 Analysis Displays

Define Stylesheet

Analysis Results Metadata - Summary

Table 14.2.2 Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population
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ID	Title	Document	Pages
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ARD.Table14.2.3	Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population	CSR	1

Pinnacle21 Analysis Displays

Define Stylesheet

Analysis Results Metadata - Summary

Table 14.2.2 Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population
Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Table 14.2.3 Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population
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ARM SUMMARY STRUCTURE

ID	Title	Document	Pages
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Pinnacle21 Analysis Displays

Define Stylesheet

Analysis Results Metadata - Summary

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Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Table 14.2.3 Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population

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Pinnacle21 Analysis Results

Display	ID	Description
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ARD.Table14.2.3	t_labmmrm.01_itt	Mixed model repeated measures of lab values change from baseline. Least square mean difference between-group statistics over all visits (p-value).
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ID	Title	Document	Pages
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ARD.Table14.2.3	Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population	CSR	1

Pinnacle21 Analysis Displays

Define Stylesheet

Analysis Results Metadata - Summary

Table 14.2.2 Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population

Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Table 14.2.3 Table 14.2.3: Laboratory Summary - Mixed Model Analysis of Bilirubin|Intent to Treat Population

Mixed model repeated measures of lab values change from baseline. Least square mean difference between-group statistics over all visits (p-value).

Mixed model repeated measures of lab values change from baseline per visit. Least square mean within group (estimate, 95% CI) by visit. Least square mean difference between groups (estimate, 95% CI) by visit.

Pinnacle21 Analysis Results

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit
ARD.Table14.2.3	t_labmmrm.01_itt	Mixed model repeated measures of lab values change from baseline. Least square mean difference between-group statistics over all visits (p-value).
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ANALYSIS DISPLAY STRUCTURE

Table 14.2.2

Display	**Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population**
Analysis Result	**Individual treatment groups vs. Placebo on Hy's law criteria by Visit**
Analysis Parameter(s)	PARAMCD = "HYLAW" (Total Bili 1.5 x ULN and Transaminase 1.5 x ULN)
Analysis Variable(s)	ADSL.ITTFL (Intent-To-Treat Population Flag) ADLBHY.AVALC (Analysis Value (C))
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADSL [ITTFL = "Y"] ADLBHY [PARAMCD = "HYLAW"] Subset ADSL and ADLBHY per selection criteria. Merge subsetted ADSL and ADLBHY by USUBJID, keeping only subjects that exist in the ADSL subset.
Documentation	Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit. Statistical Analysis Plan [5 8]

Programming Statements	[SAS version 9.4]
	`proc freq data = adlbhy ;`
	`where trt01pn in ( 1 , 2 ) ;`
	`by avisitn ;`
	`tables trt01pn * avalc / chisq sparse exact alpha = .05 ;`
	`run;`
	`* Repeat for trt01pn in (1,3) *;`
	
	Laboratory Table Program - Hy's Law

ID	Title
ARD.Table14.2.2	Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population

Document	Pages
CSR	1

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ANALYSIS DISPLAY STRUCTURE

Table 14.2.2

Display	Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population

ID	Title	Document	Pages
ARD.Table14.2.2	Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population	CSR	1

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ANALYSIS DISPLAY STRUCTURE

Table 14.2.2

Display	Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population

ID	Title	Document	Pages
ARD.Table14.2.2	Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population	CSR	1

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ANALYSIS DISPLAY STRUCTURE

Table 14.2.2

Display	Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population

ID	Title	Document	Pages
ARD.Table14.2.2	Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population	CSR	1

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ANALYSIS RESULT STRUCTURE

Table 14.2.2

Display	**Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population**
Analysis Result	**Individual treatment groups vs. Placebo on Hy's law criteria by Visit**
Analysis Parameter(s)	PARAMCD = "HYLAW" (Total Bili 1.5 x ULN and Transaminase 1.5 x ULN)
Analysis Variable(s)	ADSL.ITTFL (Intent-To-Treat Population Flag) ADLBHY.AVALC (Analysis Value (C))
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADSL [ITTFL = "Y"] ADLBHY [PARAMCD = "HYLAW"] Subset ADSL and ADLBHY per selection criteria. Merge subsetted ADSL and ADLBHY by USUBJID, keeping only subjects that exist in the ADSL subset.
Documentation	Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit. Statistical Analysis Plan [5 8]

Programming Statements	[SAS version 9.4]
	`proc freq data = adlbhy ;`
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	`by avisitn ;`
	`tables trt01pn * avalc / chisq sparse exact alpha = .05 ;`
	`run;`
	`* Repeat for trt01pn in (1,3) *;`
	
	Laboratory Table Program - Hy's Law

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Variables	Reason	Purpose
ADSL.ITTFL, ADLBHY.AVALC	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE

Selection Criteria	Join Comment
ADSL[ITTFL EQ Y]	
ADLBHY[PARAMCD EQ HYLAW]	t_lab.01_itt

Documentation	Documentation Refs
Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit.	SAP (5 8)

Programming Context	Programming Code
	proc freq data = adlbhy ; where trt01pn in (1 , 2) ; by avisitn ; tables trt01pn * avalc / chisq sparse exact alpha = .05 ; run;
SAS version 9.4	* Repeat for trt01pn in (1,3) *;

Programming Document	Pages
t_lab.sas	

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HEADER AREA

Table 14.2.2

Display	**Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population**
Analysis Result	**Individual treatment groups vs. Placebo on Hy's law criteria by Visit**
Analysis Parameter(s)	PARAMCD = "HYLAW" (Total Bili 1.5 x ULN and Transaminase 1.5 x ULN)
Analysis Variable(s)	ADSL.ITTFL (Intent-To-Treat Population Flag) ADLBHY.AVALC (Analysis Value (C))
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADSL [ITTFL = "Y"] ADLBHY [PARAMCD = "HYLAW"] Subset ADSL and ADLBHY per selection criteria. Merge subsetted ADSL and ADLBHY by USUBJID, keeping only subjects that exist in the ADSL subset.
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Programming Statements	[SAS version 9.4]
	`proc freq data = adlbhy ;`
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	`tables trt01pn * avalc / chisq sparse exact alpha = .05 ;`
	`run;`
	`* Repeat for trt01pn in (1,3) *;`
	
	Laboratory Table Program - Hy's Law

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Variables	Reason	Purpose
ADSL.ITTFL, ADLBHY.AVALC	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE

Selection Criteria	Join Comment
ADSL[ITTFL EQ Y]	
ADLBHY[PARAMCD EQ HYLAW]	t_lab.01_itt

Documentation	Documentation Refs
Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit.	SAP (5 8)

Programming Context	Programming Code
	proc freq data = adlbhy ; where trt01pn in (1 , 2) ; by avisitn ; tables trt01pn * avalc / chisq sparse exact alpha = .05 ; run;
SAS version 9.4	* Repeat for trt01pn in (1,3) *;

Programming Document	Pages
t_lab.sas	

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HEADER AREA

Table 14.2.2

Display	Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population
Analysis Result	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

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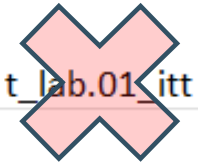
HEADER AREA

Table 14.2.2

Display	Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population
Analysis Result	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit



HEADER AREA

Table 14.2.2

Display	Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population
Analysis Result	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

ANALYSIS PARAMETERS

Table 14.2.2

Display	Clinical Study Report [1]] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population
Analysis Result	**Individual treatment groups vs. Placebo on Hy's law criteria by Visit**
Analysis Parameter(s)	PARAMCD = "HYLAW" (Total Bili 1.5 x ULN and Transaminase 1.5 x ULN)
Analysis Variable(s)	ADSL.ITTFL (Intent-To-Treat Population Flag) ADLBHY.AVALC (Analysis Value (C))
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADSL [ITTFL = "Y"] ADLBHY [PARAMCD = "HYLAW"] Subset ADSL and ADLBHY per selection criteria. Merge subsetted ADSL and ADLBHY by USUBJID, keeping only subjects that exist in the ADSL subset.
Documentation	Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit. Statistical Analysis Plan [5 8]

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	Laboratory Table Program - Hy's Law

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Variables	Reason	Purpose
ADSL.ITTFL, ADLBHY.AVALC	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE

Selection Criteria	Join Comment
ADSL[ITTFL EQ Y]	
ADLBHY[PARAMCD EQ HYLAW]	t_lab.01_itt

Documentation	Documentation Refs
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	proc freq data = adlbhy ; where trt01pn in (1 , 2) ; by avisitn ; tables trt01pn * avalc / chisq sparse exact alpha = .05 ; run;
SAS version 9.4	* Repeat for trt01pn in (1,3) *;

Programming Document	Pages
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ANALYSIS PARAMETERS

Analysis Parameter(s)	PARAMCD = "HYLAW" (Total Bili 1.5 x ULN and Transaminase 1.5 x ULN)

ID	Term	Decoded Value
PARAMCD_ADLBHY	ALT	Alanine Aminotransferase (U/L)
PARAMCD_ADLBHY	AST	Aspartate Aminotransferase (U/L)
PARAMCD_ADLBHY	BILI	Bilirubin (umol/L)
PARAMCD_ADLBHY	BILIHY	Bilirubin 1.5 x ULN
PARAMCD_ADLBHY	TRANSHY	Transaminase 1.5 x ULN
PARAMCD_ADLBHY	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN

VARIABLES, REASON, PURPOSE

Table 14.2.2

Display	**Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population**
Analysis Result	**Individual treatment groups vs. Placebo on Hy's law criteria by Visit**
Analysis Parameter(s)	PARAMCD = "HYLAW" (Total Bili 1.5 x ULN and Transaminase 1.5 x ULN)
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	Laboratory Table Program - Hy's Law

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Variables	Reason	Purpose
ADSL.ITTFL, ADLBHY.AVALC	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE

Selection Criteria	Join Comment
ADSL[ITTFL EQ Y]	
ADLBHY[PARAMCD EQ HYLAW]	t_lab.01_itt

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Programming Document	Pages
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VARIABLES, REASON, PURPOSE

Analysis Variable(s)	ADSL.ITTFL (Intent-To-Treat Population Flag) ADLBHY.AVALC (Analysis Value (C))
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE

Variables	Reason	Purpose
ADSL.ITTFL, ADLBHY.AVALC	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE

VARIABLES, REASON, PURPOSE

Analysis Variable(s)	ADSL.ITTFL (Intent-To-Treat Population Flag) ADLBHY.AVALC (Analysis Value (C))
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE

Variables	Reason	Purpose
ADSL.ITTFL, ADLBHY.AVALC	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE

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VARIABLES, REASON, PURPOSE

Analysis Variable(s)	ADSL.ITTFL (Intent-To-Treat Population Flag) ADLBHY.AVALC (Analysis Value (C))
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE

Variables	Reason	Purpose
ADSL.ITTFL, ADLBHY.AVALC	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE

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DATA REFERENCES

Table 14.2.2

Display	**Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population**
Analysis Result	**Individual treatment groups vs. Placebo on Hy's law criteria by Visit**
Analysis Parameter(s)	PARAMCD = "HYLAW" (Total Bili 1.5 x ULN and Transaminase 1.5 x ULN)
Analysis Variable(s)	ADSL.ITTFL (Intent-To-Treat Population Flag) ADLBHY.AVALC (Analysis Value (C))
Analysis Reason	SPECIFIED IN SAP
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Data References (incl. Selection Criteria)	ADSL [ITTFL = "Y"] ADLBHY [PARAMCD = "HYLAW"] Subset ADSL and ADLBHY per selection criteria. Merge subsetted ADSL and ADLBHY by USUBJID, keeping only subjects that exist in the ADSL subset.
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	`tables trt01pn * avalc / chisq sparse exact alpha = .05 ;`
	`run;`
	`* Repeat for trt01pn in (1,3) *;`
	
	Laboratory Table Program - Hy's Law

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Variables	Reason	Purpose
ADSL.ITTFL, ADLBHY.AVALC	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE

Selection Criteria	Join Comment
ADSL[ITTFL EQ Y]	
ADLBHY[PARAMCD EQ HYLAW]	t_lab.01_itt

Documentation	Documentation Refs
Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit.	SAP (5 8)

Programming Context	Programming Code
	proc freq data = adlbhy ; where trt01pn in (1 , 2) ; by avisitn ; tables trt01pn * avalc / chisq sparse exact alpha = .05 ; run;
SAS version 9.4	* Repeat for trt01pn in (1,3) *;

Programming Document	Pages
t_lab.sas	

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DATA REFERENCES

Data References (incl. Selection Criteria)	ADSL [ITTFL = "Y"] ADLBHY [PARAMCD = "HYLAW"] Subset ADSL and ADLBHY per selection criteria. Merge subsetted ADSL and ADLBHY by USUBJID, keeping only subjects that exist in the ADSL subset.

Selection Criteria	Join Comment
ADSL[ITTFL EQ Y]	
ADLBHY[PARAMCD EQ HYLAW]	t_lab.01_itt

DATA REFERENCES

Data References (incl. Selection Criteria)	ADSL [ITTFL = "Y"] ADLBHY [PARAMCD = "HYLAW"] Subset ADSL and ADLBHY per selection criteria. Merge subsetted ADSL and ADLBHY by USUBJID, keeping only subjects that exist in the ADSL subset.

Selection Criteria	Join Comment
ADSL[ITTFL EQ Y]	
ADLBHY[PARAMCD EQ HYLAW]	t_lab.01_itt

ID	Description
t_lab.01_itt	Subset ADSL and ADLBHY per selection criteria. Merge subsetted ADSL and ADLBHY by USUBJID, keeping only subjects that exist in the ADSL subset.

DOCUMENTATION

Table 14.2.2

Display	**Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population**
Analysis Result	**Individual treatment groups vs. Placebo on Hy's law criteria by Visit**
Analysis Parameter(s)	PARAMCD = "HYLAW" (Total Bili 1.5 x ULN and Transaminase 1.5 x ULN)
Analysis Variable(s)	ADSL.ITTFL (Intent-To-Treat Population Flag) ADLBHY.AVALC (Analysis Value (C))
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADSL [ITTFL = "Y"] ADLBHY [PARAMCD = "HYLAW"] Subset ADSL and ADLBHY per selection criteria. Merge subsetted ADSL and ADLBHY by USUBJID, keeping only subjects that exist in the ADSL subset.
Documentation	Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit. Statistical Analysis Plan [5 8]

Programming Statements	[SAS version 9.4]
	`proc freq data = adlbhy ;`
	`where trt01pn in ( 1 , 2 ) ;`
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	`tables trt01pn * avalc / chisq sparse exact alpha = .05 ;`
	`run;`
	`* Repeat for trt01pn in (1,3) *;`
	
	Laboratory Table Program - Hy's Law

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Variables	Reason	Purpose
ADSL.ITTFL, ADLBHY.AVALC	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE

Selection Criteria	Join Comment
ADSL[ITTFL EQ Y]	
ADLBHY[PARAMCD EQ HYLAW]	t_lab.01_itt

Documentation	Documentation Refs
Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit.	SAP (5 8)

Programming Context	Programming Code
	proc freq data = adlbhy ; where trt01pn in (1 , 2) ; by avisitn ; tables trt01pn * avalc / chisq sparse exact alpha = .05 ; run;
SAS version 9.4	* Repeat for trt01pn in (1,3) *;

Programming Document	Pages
t_lab.sas	

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DOCUMENTATION

Documentation	Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit. Statistical Analysis Plan [FISH]

Documentation	Documentation Refs
Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit.	SAP (FISH)

DOCUMENTATION

Documentation	Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit. Statistical Analysis Plan [FISH]

Documentation	Documentation Refs
Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit.	SAP (FISH)

ID	Title	Href
SAP	Statistical Analysis Plan	..\..\..\sap.pdf

DOCUMENTATION

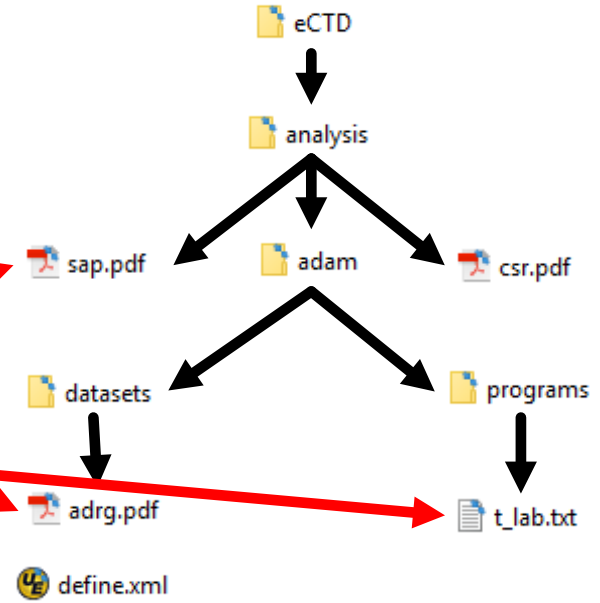
Documentation	Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit. Statistical Analysis Plan [FISH]

Documentation	Documentation Refs
Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit.	SAP (FISH)

ID	Title	Href
ADRG	Analysis Data Reviewer's Guide	adrg.pdf
SAP	Statistical Analysis Plan	..\..\..\sap.pdf
t_lab.sas	Laboratory Table Program - Hy's Law	..\programs\t_lab.txt

DOCUMENTATION

ID	Title	Href
ADRG	Analysis Data Reviewer's Guide	adrg.pdf
SAP	Statistical Analysis Plan	..\..\..\sap.pdf
t_lab.sas	Laboratory Table Program - Hy's Law	..\programs\t_lab.txt



PROGRAMMING STATEMENTS

Table 14.2.2

Display	**Clinical Study Report [1] Table 14.2.2: Laboratory Summary - Hy's Law Status by Visit|Intent to Treat Population**
Analysis Result	**Individual treatment groups vs. Placebo on Hy's law criteria by Visit**
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Programming Statements	[SAS version 9.4]
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	`run;`
	`* Repeat for trt01pn in (1,3) *;`
	
	Laboratory Table Program - Hy's Law

Display	ID	Description
ARD.Table14.2.2	t_lab.01_itt	Individual treatment groups vs. Placebo on Hy's law criteria by Visit

Variables	Reason	Purpose
ADSL.ITTFL, ADLBHY.AVALC	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE

Selection Criteria	Join Comment
ADSL[ITTFL EQ Y]	
ADLBHY[PARAMCD EQ HYLAW]	t_lab.01_itt

Documentation	Documentation Refs
Calculate Fisher's exact test of each active group vs placebo, on the categorical status (Y/N) of whether subject met Hy's law criteria. Fisher's exact test of Hy's law status by visit.	SAP (5 8)

Programming Context	Programming Code
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Programming Document	Pages
t_lab.sas	

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PROGRAMMING STATEMENTS

Programming Statements

[SAS version 9.4]

```
proc freq data = adlbhy ;
where trt01pn in ( 1 , 2 ) ;
by avisitn ;
tables trt01pn * avalc / chisq sparse exact alpha = .05 ;
run;
* Repeat for trt01pn in (1,3) *;
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Laboratory Table Program - Hy's Law

Programming Context	Programming Code	Programming Document	Pages
SAS version 9.4	proc freq data = adlbhy ; where trt01pn in (1 , 2) ; by avisitn ; tables trt01pn * avalc / chisq sparse exact alpha = .05 ; run; * Repeat for trt01pn in (1,3) *;	t_lab.sas	

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PROGRAMMING STATEMENTS

Programming Statements	[SAS version 9.4]

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proc freq data = adlbhy ;
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tables trt01pn * avalc / chisq sparse exact alpha = .05 ;
run;
* Repeat for trt01pn in (1,3) *;
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Laboratory Table Program - Hy's Law

Programming Context	Programming Code	Programming Document	Pages
SAS version 9.4	proc freq data = adlbhy ; where trt01pn in (1 , 2) ; by avisitn ; tables trt01pn * avalc / chisq sparse exact alpha = .05 ; run; * Repeat for trt01pn in (1,3) *;	t_lab.sas	

PROGRAMMING STATEMENTS

Programming Statements	[SAS version 9.4] proc freq data = adlbhy ; where trt01pn in (1 , 2) ; by avisitn ; tables trt01pn * avalc / chisq sparse exact alpha = .05 ; run; * Repeat for trt01pn in (1,3) *; Laboratory Table Program - Hy's Law

Programming Context	Programming Code	Programming Document	Pages
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ID	Title	Href
t_lab.sas	Laboratory Table Program - Hy's Law	..\programs\t_lab.txt

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IN SUMMARY

- Help your reviewer – provide ARM
- Describe Primary, Secondary, and Exploratory outcome measures
- Use plain language descriptions
- Provide additional detail with links to the SAP and programs

CONTACT INFORMATION

For questions, contact:
David Brega, dbrega@pharmastat.com

For professional inquiries, contact
info@pharmastat.com

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