

CDISC ANALYSIS RESULTS STANDARD TEAM

ENHANCING ANALYSIS RESULTS AND TRACEABILITY

PHUSE EU CONNECT 2021: PAPER DS08

Jeff Abolafia, Pinnacle21

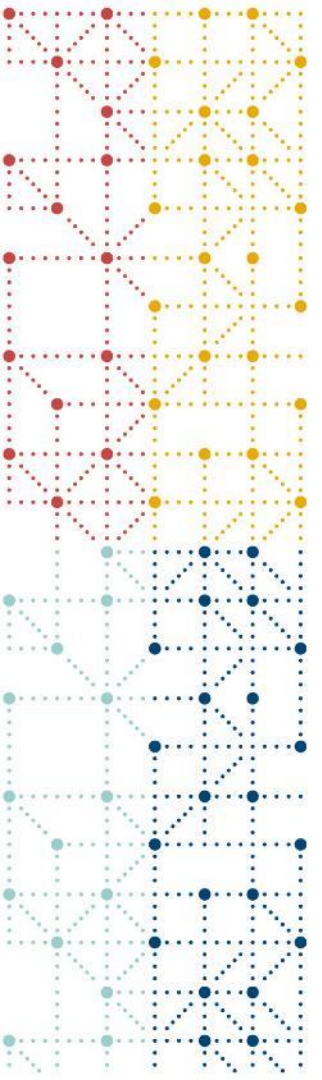
Bess LeRoy, CDISC



15th–19th November

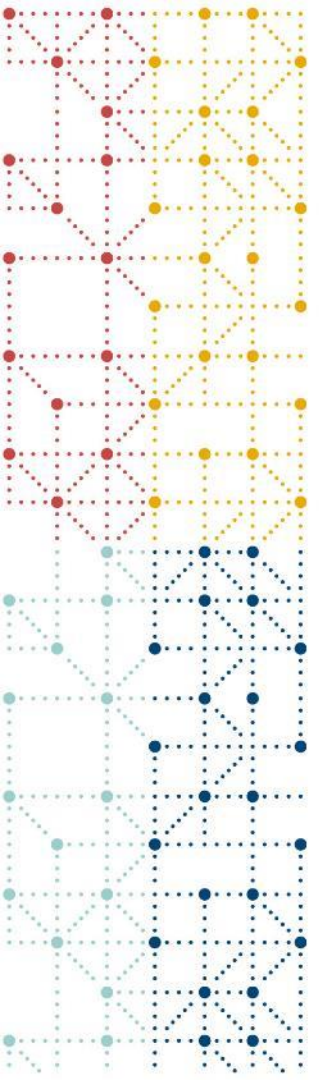
EU Connect 2021

The Clinical Data
Science Conference



Agenda

1. Purpose and Scope
2. Organization
3. Data Display Concepts
4. Analysis Results Data Model
5. Extending Analysis Results Metadata
6. Next Steps



Analysis Results Standards

Purpose and scope



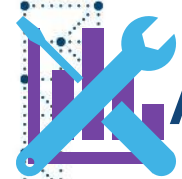
Introduction

- *Current State*

- Repetitive one-off scripting of "custom" tables
- Same result re-generated multiple times throughout a set of deliverables
- Heavy validation burden of redundantly generated results
- Lack of features in ARM v1.0 for traceability and to drive automation

- *Future State*

- Standard structure to hold the results and associated metadata
- Enhanced Analysis Results Metadata to help drive automation of computation and display of analysis results
- Improved production, quality processes, and the traceability and general communication of clinical trial results for decision-making



Analysis Results Standards Team

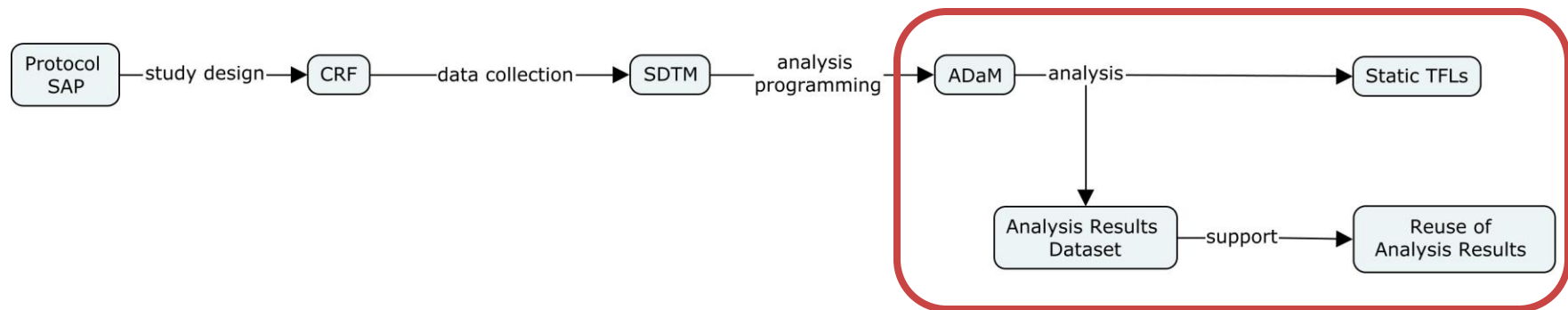
Define an analysis results data model (ARDM), to support reuse and dynamic production of data displays



Extend Analysis Results Metadata (ARM), to support traceability and creation of data displays

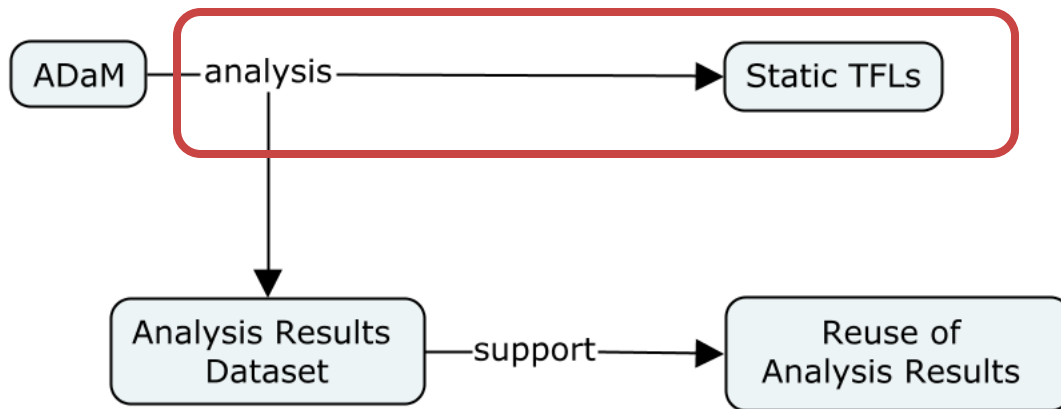
Illustrate and exercise ARDM and ARM Extensions with a set of common data displays

Focus on Analysis Results



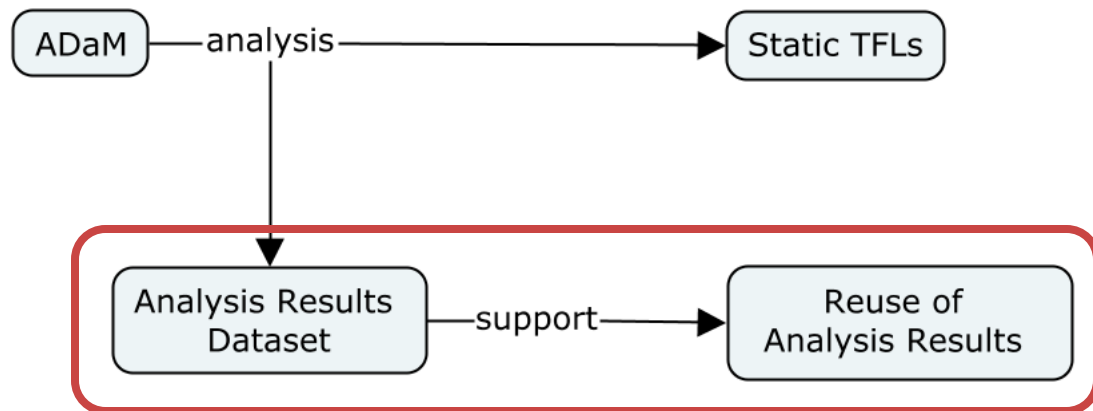


Extend ARM to Support TFL Creation



The ARM extension will be ***adding normative content*** to the existing ARM Define standard

Define ARDM to Support Reuse of Results



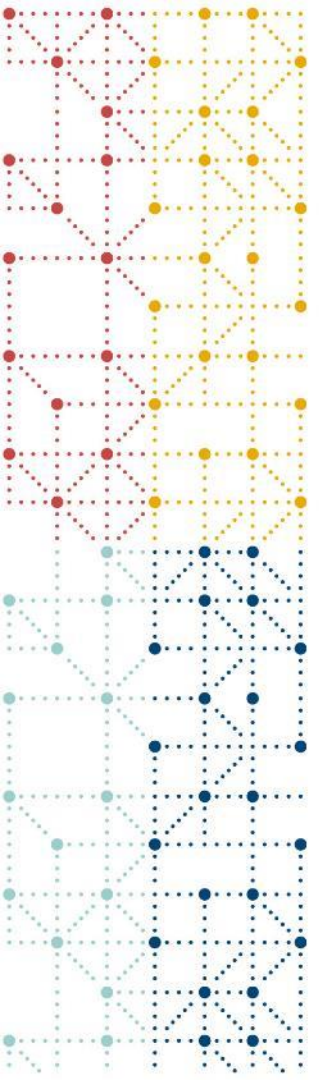
The Analysis Results Dataset will be considered a ***new CDISC foundational standard***

Use of Common Data Displays as Illustration

ARDS uses common data displays for illustration and are not considered normative content

ARDS does not specify standard data displays that must be used

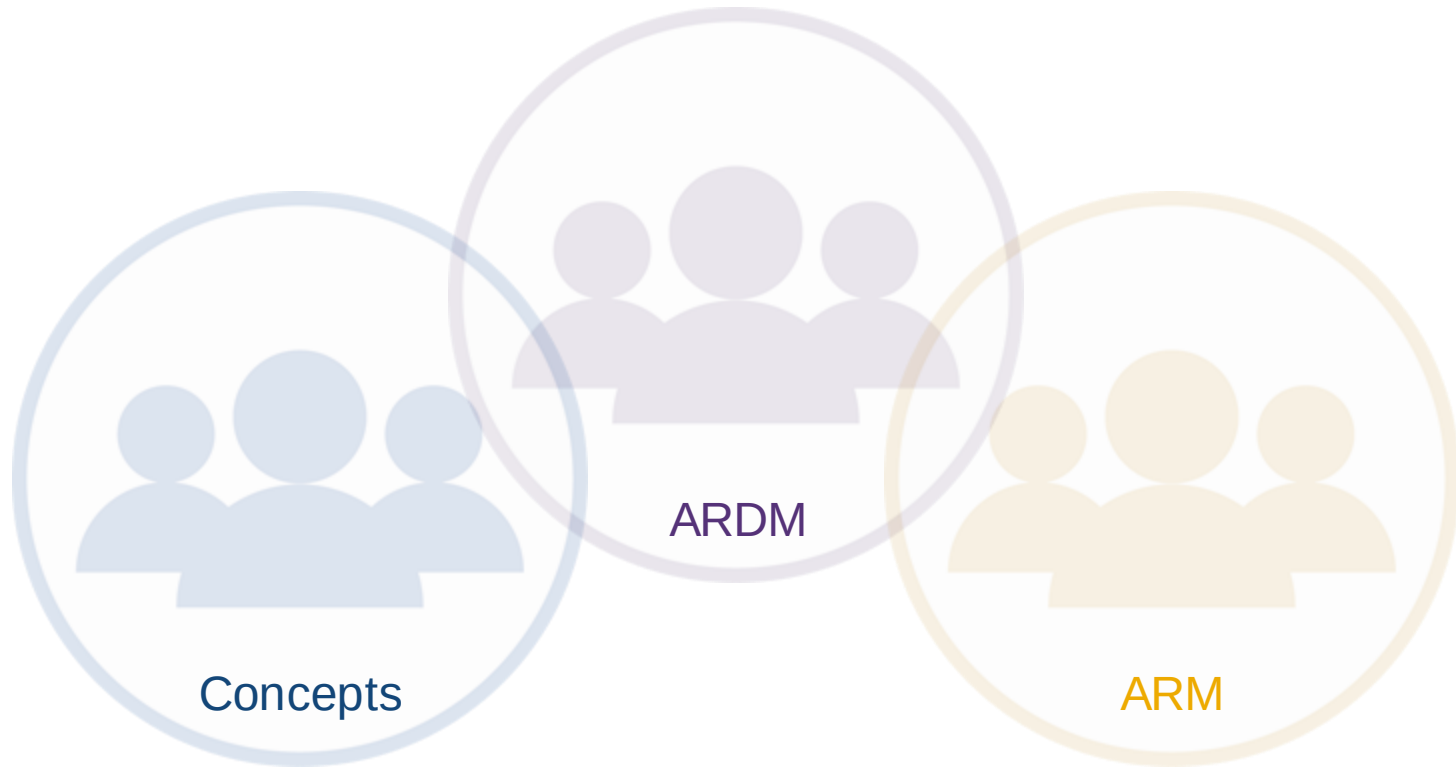
However, implementers may choose to use the example displays for use in their studies



Analysis Results Standards Team

Organization

Concepts, Results Data, Results Metadata



- | Study - CDISC360 | | Table 14.1.x
Summary of Analysis Populations and Subject Disposition
All Subjects | Page x of y |
|---|--|--|-------------|
| Variable
Reason (n (%)) | Study - CDISC 360 | | Page x of y |
| Screened
Enrolled
Enrolled, But Not Treated
Received Study Treatment
Discontinued Study Treatment
Adverse Event
Pregnancy
Progressive Disease
Protocol Deviation
Site Terminated by Sponsor
Study Terminated by Sponsor
Withdrawal by Subject
Other
Completed Study Treatment
Discontinued study
Adverse Event
Death
Lost to Follow-up
Pregnancy
Progressive Disease
Protocol Deviation
Screen Failure
Site Terminated by Sponsor
Study Terminated by Sponsor
Withdrawal by Subject
Other
Other Specify
Complete Study
Safety Population
Full Analysis Population
Intent-to-Treat Population
Per-Protocol Population | Table 14.1.x.c.c.y
Summary of Demographics
Safety Population | | |
| Characteristics | | Study - CDISC 360 (STUDYID=V) Value
Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs (Results display metadata (table level/title): Safety Population (ADSC, VISIT=V) table level/population) | |
| Age (years) | | Treatment X (ADSC, VISIT) (N=XX) (ADSC, VISIT=V) X Z
Treatment Y (ADSC, VISIT) (N=XX) (ADSC, VISIT=V) X Z
Total (N=XX) (ADSC, VISIT=V) X Z | |
| n | | Observed | |
| Mean (SD) | | Change from Baseline | |
| Median | | Observed | |
| Q1, Q3 | | Change from Baseline | |
| Min, Max | | Observed | |
| ADVIS, FASZED with units (ProcedureID) | | Baseline | |
| Age Group, n (%) | | n | |
| < 65 years | | XX (ADSC, VISIT) | |
| ≥ 65 years | | XX, XX (XX, XX) | |
| Median | | XX, XX | |
| Q1, Q3 | | XX, XX, XX | |
| Min, Max | | XX, XX, XX, XX | |
| Gender, n (%) | | XX, XX | |
| Male | | XX, XX | |
| Female | | XX, XX | |
| Ethnicity, n (%) | | XX (XX, XX) | |
| Hispanic or Latino | | XX, XX (XX, XX) | |
| Not Hispanic or Latino | | XX, XX (XX, XX) | |
| Source dataset: adsl, Gc | | Characteristics (N=XX) | |
| Program: cpid-eas, Out | | ... | |
| Source dataset: adsl, Generated on: | | Note: Baseline is defined as the last assessment that is non-missing prior to first dose of investigational product. | |
| Program: cpid-eas, Output: cpid-eas | | Source dataset: adsl, Generated on: CDISC/STUDYID/XX/XX/XX | |
| | | Program: cpid-eas, Output: cpid-eas.rtf, Generated on: CDISC/STUDYID/XX/XX/XX | |

ARS Data Model Team

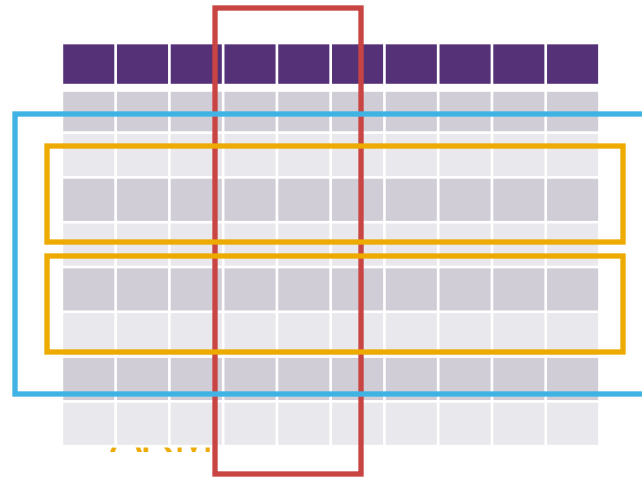


Qualifiers

Display groups

Result groups

- Results Data Model
- Relations & qualifiers
- Reuse of results
- Dynamic display
- Traceability



ARS Metadata Team



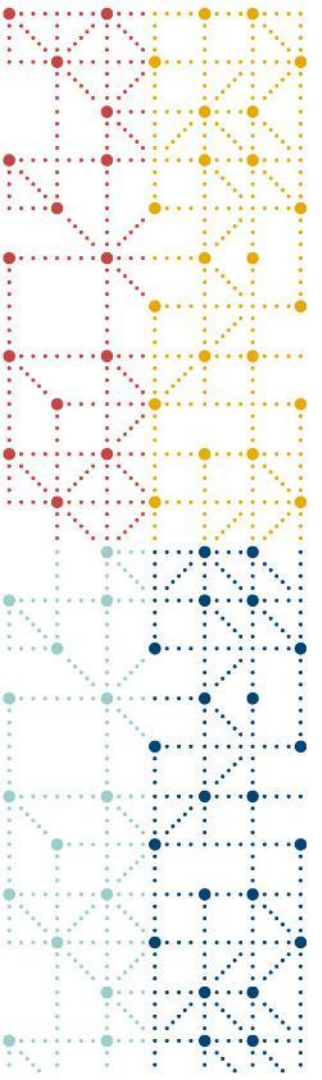
Based on CDISC ARM v1

- Addition of OUTPUT & STYLE
- Extension to DISPLAY and RESULT

Parent

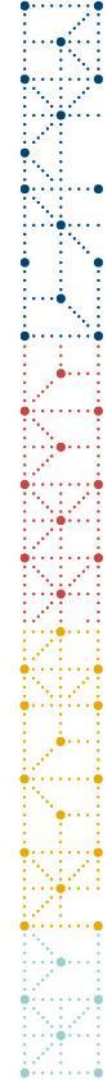
Version

Grouping and ByVar



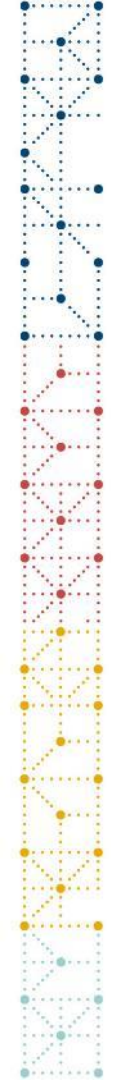
Analysis Results Standards – Part I

Data Display Concepts



Concepts Team Consulted Published Layouts

- PHUSE / FDA Working Group on Standard Analyses
 - White papers published by PHUSE
 - <https://phuse.global/Deliverables/1>
 - Summary tables can range from common (familiar) to thoughtfully innovative
- JPMA commonly used tables and ADaM annotations
- Recent FDA publications
- Sub-team knowledge of sponsor variations

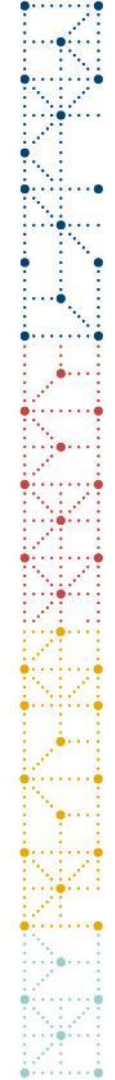


Focus on Concepts, Not Layout

- ARS team is focusing on concepts presented in data displays and ***not*** on subjective layout and formatting of displays
- Representative displays therefore condense concepts
- For example, side-by-side Visit and Change-from-baseline summaries consolidates more concepts into an easy-to-read summary table

Parameter (Units)	Treatment X (N=XX)	Treatment Y (N=XX)	Total (N=XX)
Visit			
<Parameter 1> (<unit>)			
Baseline			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n Change from Baseline >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX

Parameter (Units)	Treatment X (N=XX)		Treatment Y (N=XX)		Total (N=XX)	
	Observed	CFB	Observed	CFB	Observed	CFB
<Parameter 1> (<unit>)						
Baseline						
n	XX		XX		XX	
Mean (SD)	XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)	
Median	XX.X		XX.X		XX.X	
Q1, Q3	XX.X, XX.X		XX.X, XX.X		XX.X, XX.X	
Min, Max	XX, XX		XX, XX		XX, XX	
...						
<Visit n>						
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	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX



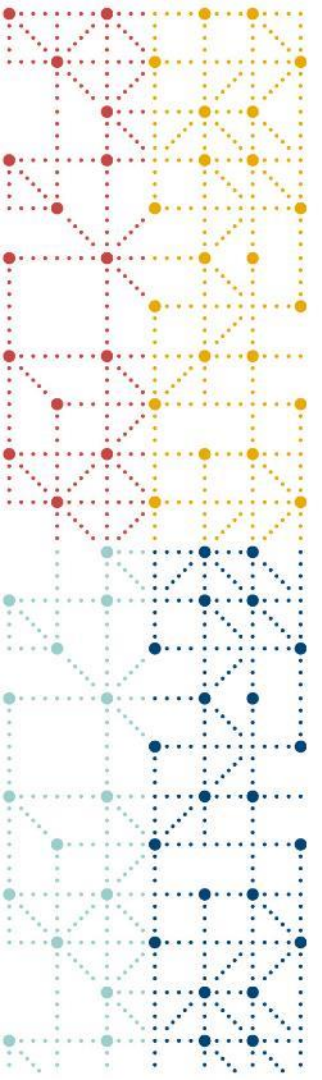
List of Working Data Displays, Concepts

- Summaries of
 - Analysis Populations and Subject Disposition
 - Protocol Deviations
 - Demographics and Other Baseline Characteristics
 - Medical History
 - Prior and Concomitant Medications
 - Subject Incidence of Adverse Events
 - Treatment Emergent Adverse Events by SOC and PT
 - TEAE SOC and PT by Maximum Severity
 - Laboratory Tests by Visit
 - Change in Vital Signs by Visit

Vital Signs Example

Summary of change from baseline by visit

Parameter (Units) Visit	Treatment X (N=XX)		Treatment Y (N=XX)		Total (N=XX)	
	Observed	CFB	Observed	CFB	Observed	CFB
<Parameter 1> (<unit>)						
Baseline						
n	XX		XX		XX	
Mean (SD)	XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)	
Median	XX.X		XX.X		XX.X	
Q1, Q3	XX.X, XX.X		XX.X, XX.X		XX.X, XX.X	
Min, Max	XX, XX		XX, XX		XX, XX	
...						
<Visit n>						
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	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX



Analysis Results Standards – Part II

Analysis Results Data Model

Analysis Results Data Model: Why

Create a standard data structure for result

Support reuse of results

Facilitate dynamic generation of results

Improved navigation of results

Current state

- Results created for CSR
- Thousands of pages in static PDF format
- Often difficult to navigate
- Expensive to generate and only used once
- Decker (PHUSE US Connect 2019)¹
 - FDA doesn't review these outputs in detail, FDA generates their own analysis
 - capture the contextual information tied to an analysis result

1. <https://www.lexjansen.com/phuse-us/2019/dh/DH12.pdf>

Draft Analysis Results Dataset Specification (ARDS)

Metadata Describing the ARDS

Analysis Results Dataset Specification – One record per result

Variable Name	Variable Label	Type	Code list/ Controlled Terms	Core CDISC Notes	PARAMCD	Analysis Parameter	C			The description of the analysis parameter (i.e., Supine Systolic Blood Pressure (mm Hg)). Typically, only used with BDS datasets.
STUDYID	Study Identifier	C		Unique identifier for a study						
RESULTID	Result Identifier	C		Unique identifier for a result	ANAL_VAR	Analysis Variable	C			Analysis variable needed to create the respective analysis result.
TABLEID	Display Identifier	C		Sponsor defined identifier to tie a group of related results together	AVAR_VAL	Analysis Variable Value	C			Value of analysis. Typically, only used for categorical variables
ADSNS	Source Datasets	C		List of source datasets separated by commas (i.e., ADSL, ADAE)	STATNAME	Name of Statistic	C			
POPULATION	Analysis Population	C		Description of population (i.e., Safety Population)	STATVAL	Value of Statistic	Float			
TIME	Description of Time Frame	C		Time frame used in analysis (i.e., Visit 1 or 12 weeks)	STATDESC	Description of Statistic	C			
WHERE	Description of Subsetting Criteria	C		selection criterion needed to select the required subset of records from the specified analysis dataset						
<u>BYVARz</u>	Name of <u>BYVARz</u>	C		The lower-case letter "z" in the variable name is the <u>z</u> th By-Variable, where "z" is replaced with a one-digit integer between 1 and 9.						
<u>BYVALz</u>	Value of <u>BYVARz</u>			The lower-case letter "z" in the variable name is the <u>z</u> th By-Variable, where "z" is replaced with a one-digit integer between 1 and 9.						
TRTVAR	Treatment variable name	C		Name of treatment variable used in analysis (i.e. TRTP, TRT01P)						
TRTVAL	Treatment value	C		Value of TRTVAR for a given record						

Analysis Result Dataset: ADSL Structure Example

Protocol: CDISCPLOT01
Population: Intent-to-Treat

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Table 14-2.01
Summary of Demographic and Baseline Characteristics

		Placebo (N=86)	Xanomeline Low Dose (N=84)	Xanomeline High Dose (N=84)	Total (N=254)	p-value [1]
Age (y)	n	86	84	84	254	0.5934
	Mean	75.2	75.7	74.4	75.1	
	SD	8.59	8.29	7.89	8.25	
	Median	76.0	77.5	76.0	77.0	
	Min	52.0	51.0	56.0	51.0	
	Max	89.0	88.0	88.0	89.0	
	<65 yrs	14 (16%)	8 (10%)	11 (13%)	33 (13%)	0.1439
	65-80 yrs	42 (49%)	47 (56%)	55 (65%)	144 (57%)	
	>80 yrs	30 (35%)	29 (35%)	18 (21%)	77 (30%)	
Sex	n	86	84	84	254	0.1409
	Male	33 (38%)	34 (40%)	44 (52%)	111 (44%)	
	Female	53 (62%)	50 (60%)	40 (48%)	143 (56%)	
Race (Origin)	n	86	84	84	254	0.6477
	Caucasian	75 (87%)	72 (86%)	71 (85%)	218 (86%)	
	African Descent	8 (9%)	6 (7%)	9 (11%)	23 (9%)	
	Hispanic	3 (3%)	6 (7%)	3 (4%)	12 (5%)	
	Other	0	0	1 (1%)	1 (<1%)	
MMSE	n	86	84	84	254	0.5947
	Mean	18.0	17.9	18.5	18.1	
	SD	4.27	4.22	4.16	4.21	
	Median	19.5	18.0	20.0	19.0	

Analysis Result Dataset: ADSL Structure Example

Result

IDENTIFIERS			DATA / POPULATION			BY VARIABLES					ANALYSIS VARIABLES			STATISTICS				
StudyID	ResultID	TableID	ADSNs	Population	Where	Time	ByVar1	ByVal1	ByVar2	ByVal2	TrtVar	TrtVal	ParamCD	Anal_Var	Anal_Var_Val	Stat_Name	Stat_Val	Stat_Desc
1234	SL01A1	SL01A	ADSL	Safety							TRTP01P	D1		Sex	M	N	xx	# Subjects
1234	SL01A2	SL01A	ADSL	Safety							TRTP01P	D1		Sex	M	Percent	xx.xx	percent of subjects
1234	SL01A3	SL01A	ADSL	Safety							TRTP01P	P1		Sex	M	N	xx	in treatment group
1234	SL01A4	SL01A	ADSL	Safety							TRTP01P	P1		Sex	M	Percent	xx.xx	
1234	SL01A5	SL01A	ADSL	Safety							TRTP01P	D1		Sex	F	N	xx	
1234	SL01A6	SL01A	ADSL	Safety							TRTP01P	D1		Sex	F	Percent	xx.xx	
1234	SL01A7	SL01A	ADSL	Safety							TRTP01P	P1		Sex	F	N	xx	
1234	SL01A8	SL01A	ADSL	Safety							TRTP01P	P1		Sex	F	Percent	xx.xx	
1234	SL01A9	SL01A	ADSL	Safety							TRTP01P	D1		AGE		Mean	xx.xx	Mean Age in
1234	SL01A10	SL01A	ADSL	Safety							TRTP01P	P1		AGE		Mean	xx.xx	treatment group
1234	SL01A11	SL01A	ADSL	Safety							TRTP01P	D1		AGE		STD	xx.xx	STD in treatment
1234	SL01A12	SL01A	ADSL	Safety							TRTP01P	P1		AGE		STD	xx.xx	group
1234	SL01A13	SL01A	ADSL	Safety							TRTP01P	D1 - P1		AGE		Mean	x.xxxx	P-Value for ANOVA
																		treatment group
																		comparison

Meaning/Context: Result is a count(N) | for SEX='M' | TRT=D1 | Safety Population

Analysis Result Dataset: BDS Structure Example

Parameter (Units)	Treatment X (N=XX)		Treatment Y (N=XX)		Total (N=XX)	
	Observed	CFB	Observed	CFB	Observed	CFB
<Parameter 1> (<unit>)						
Baseline						
n	XX		XX		XX	
Mean (SD)	XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)	
Median	XX.X		XX.X		XX.X	
Q1, Q3	XX.X, XX.X		XX.X, XX.X		XX.X, XX.X	
Min, Max	XX, XX		XX, XX		XX, XX	
...						
<Visit n>						
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	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX

Analysis Result Dataset: BDS Structure Example

Protocol: CDISCPLOT01

Population: Safety

Page 1 of 1

Table 14-7.03
Summary of Weight Change from Baseline at End of Treatment

Measure	Treatment	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Weight (kg)	Placebo	86	Baseline	86	62.8	12.77	60.6	34.0	86.2
			Week 24	59	63.2	12.58	63.5	34.0	86.6
			End of Trt.	84	63.3	12.66	64.0	34.0	86.6
	Xan.Low	84	Baseline	83	67.3	14.13	64.9	45.4	106.1
			Week 24	27	67.4	14.07	62.6	45.5	106.1
			End of Trt.	84	66.7	14.32	65.9	41.7	106.1
	Xan.High	84	Baseline	84	70.0	14.65	69.2	41.7	108.0
			Week 24	30	71.1	15.82	68.7	49.9	105.7
			End of Trt.	81	69.7	14.00	70.3	42.2	105.7
Weight Change from Baseline	Placebo	86	Week 24	59	0.1	2.30	0.0	-4.5	8.2
			End of Trt.	84	0.2	2.05	0.0	-4.5	8.2
	Xan.Low	84	Week 24	27	-0.3	2.04	0.0	-5.4	3.2
			End of Trt.	83	-0.4	2.41	0.0	-14.5	5.9
	Xan.High	84	Week 24	30	1.0	6.47	-0.2	-4.5	33.3
			End of Trt.	81	0.1	4.19	-0.4	-5.5	33.3

Analysis Result Dataset: BDS Structure Example

IDENTIFIERS			DATA / POPULATION			BY VARIABLES					ANALYSIS VARIABLES				STATISTICS			
StudyID	ResultID	TableID	ADSNs	Population	Where	Time	ByVar1	ByVal1	ByVar2	ByVal2	TrtVar	TrtVal	ParamCD	Anal_Var	Anal_Var_Val	Stat_Name	Stat_Val	Stat_Desc
1234	BDS01a1	BDS01a	ADVS	Safety		Visit 1					TRTP	D1	Weight	AVAL		N	xx	# Subjects
1234	BDS01a2	BDS01a	ADVS	Safety		Visit 1					TRTP	P1	Weight	AVAL		N	xx	
1234	BDS01a3	BDS01a	ADVS	Safety		Visit 1					TRTP	D1	Weight	AVAL		Mean	xx.xx	Mean Weight in treatment group
1234	BDS01a4	BDS01a	ADVS	Safety		Visit 1					TRTP	P1	Weight	AVAL		Mean	xx.xx	
1234	BDS01a5	BDS01a	ADVS	Safety		Visit 1					TRTP	D1	Weight	AVAL		Median	xx.xx	Median Weight in treatment group
1234	BDS01a6	BDS01a	ADVS	Safety		Visit 1					TRTP	P1	Weight	AVAL		Median	xx.xx	
1234	BDS01a7	BDS01a	ADVS	Safety		Visit 4					TRTP	D1	Weight	AVAL		N	xx	
1234	BDS01a8	BDS01a	ADVS	Safety		Visit 4					TRTP	P1	Weight	AVAL		N	xx	
1234	BDS01a9	BDS01a	ADVS	Safety		Visit 4					TRTP	D1	Weight	AVAL		Mean	xx.xx	
1234	BDS01a10	BDS01a	ADVS	Safety		Visit 4					TRTP	P1	Weight	AVAL		Mean	xx.xx	
1234	BDS01a11	BDS01a	ADVS	Safety		Visit 4					TRTP	D1	Weight	AVAL		Median	xx.xx	
1234	BDS01a12	BDS01a	ADVS	Safety		Visit 4					TRTP	P1	Weight	AVAL		Median	xx.xx	
1234	BDS01a13	BDS01a	ADVS	Safety		Visit 4					TRTP	D1	Weight	CHG		Mean	xx.xx	Mean Change from Baseline in treatment group
1234	BDS01a14	BDS01a	ADVS	Safety		Visit 4					TRTP	P1	Weight	CHG		Mean	xx.xx	
1234	BDS01a15	BDS02	ADVS	Safety		Visit 1					TRTP	D1	Systolic BP	AVAL (CATy)	<120	N	xx	
1234	BDS01a16	BDS02	ADVS	Safety		Visit 1					TRTP	P1	Systolic BP	AVAL (CATy)	<120	N	xx	
1234	BDS01a17	BDS02	ADVS	Safety		Visit 1					TRTP	D1	Systolic BP	AVAL (CATy)	<120	Percent	xx.xx	
1234	BDS01a18	BDS02	ADVS	Safety		Visit 1					TRTP	P1	Systolic BP	AVAL (CATy)	<120	Percent	xx.xx	
1234	BDS01a19	BDS02	ADVS	Safety		Visit 1					TRTP	D1	Systolic BP	AVAL (CATy)	120-140	N	xx	
1234	BDS01a20	BDS02	ADVS	Safety		Visit 1					TRTP	P1	Systolic BP	AVAL (CATy)	120-140	N	xx	
1234	BDS01a21	BDS02	ADVS	Safety		Visit 1					TRTP	D1	Systolic BP	AVAL (CATy)	120-140	Percent	xx.xx	
1234	BDS01a22	BDS02	ADVS	Safety		Visit 1					TRTP	P1	Systolic BP	AVAL (CATy)	120-140	Percent	xx.xx	
1234	BDS01a23	BDS02	ADVS	Safety		Visit 1					TRTP	D1	Systolic BP	AVAL (CATy)	>140	N	xx	
1234	BDS01a24	BDS02	ADVS	Safety		Visit 1					TRTP	P1	Systolic BP	AVAL (CATy)	>140	N	xx	
1234	BDS01a25	BDS02	ADVS	Safety		Visit 1					TRTP	D1	Systolic BP	AVAL (CATy)	>140	Percent	xx.xx	
1234	BDS01a26	BDS02	ADVS	Safety		Visit 1					TRTP	P1	Systolic BP	AVAL (CATy)	>140	Percent	xx.xx	

Analysis Result Dataset: OCCDS Structure Example

Protocol: CDISCPLOT01

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Population: Safety

Table 14-5.01
Incidence of Treatment Emergent Adverse Events by Treatment Group

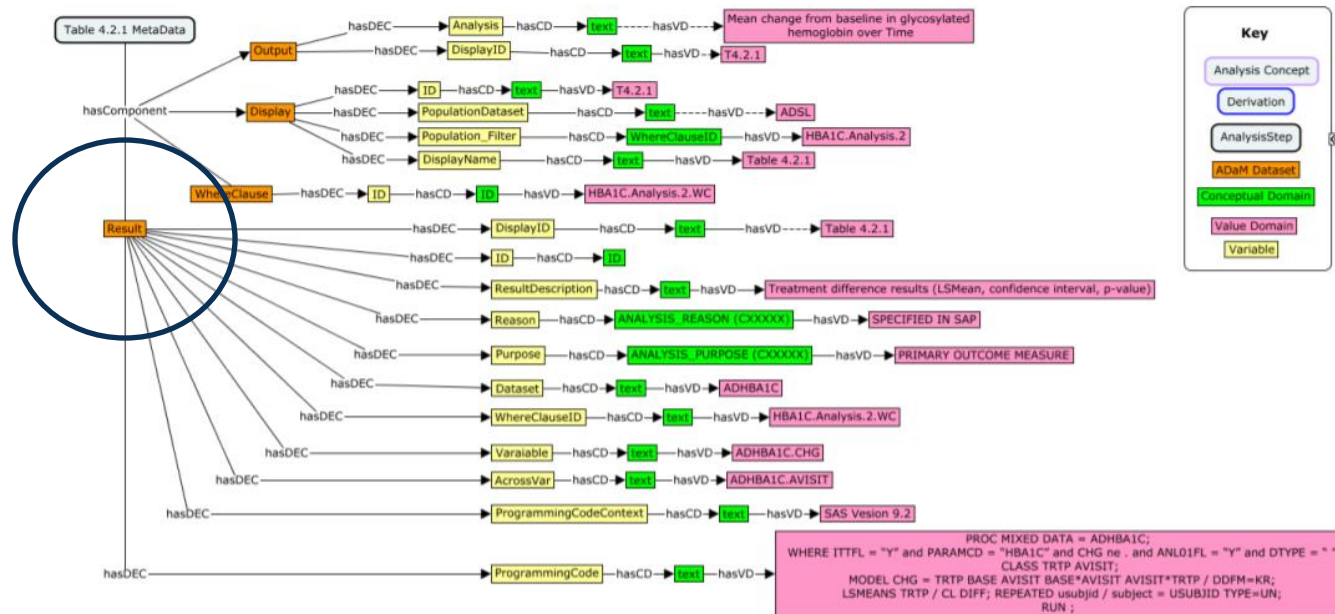
System Organ Class/ Preferred Term	Placebo (N=86)		Xanomeline Low (N=84)		Xanomeline High (N=84)		Fisher's Exact p-values	
	n(%)	[AEs]	n(%)	[AEs]	n(%)	[AEs]	Placebo vs. Low Dose	Placebo vs. High Dose
ANY BODY SYSTEM	65 (75.6%)	[281]	77 (91.7%)	[412]	76 (90.5%)	[433]	0.007*	0.014*
CARDIAC DISORDERS	12 (14.0%)	[26]	13 (15.5%)	[30]	15 (17.9%)	[30]	0.831	0.534
SINUS BRADYCARDIA	2 (2.3%)	[2]	7 (8.3%)	[10]	8 (9.5%)	[12]	0.097*	0.056*
MYOCARDIAL INFARCTION	4 (4.7%)	[4]	2 (2.4%)	[4]	4 (4.8%)	[8]	0.682	>0.99
ATRIAL FIBRILLATION	1 (1.2%)	[1]	1 (1.2%)	[1]	3 (3.6%)	[5]	>0.99	0.365
ATRIAL FLUTTER	0		1 (1.2%)	[1]	1 (1.2%)	[2]	0.494	0.494
CARDIAC DISORDER	0		0		1 (1.2%)	[1]	0.494	0.494
SUPRAVENTRICULAR	1 (1.2%)	[2]	1 (1.2%)	[2]	1 (1.2%)	[1]	>0.99	>0.99
EXTRASYSTOLES								
VENTRICULAR EXTRASYSTOLES	0		2 (2.4%)	[4]	1 (1.2%)	[1]	0.243	0.494
ATRIAL HYPERTROPHY	1 (1.2%)	[2]	0		0		>0.99	>0.99
ATRIOVENTRICULAR BLOCK	1 (1.2%)	[1]	1 (1.2%)	[1]	0		>0.99	>0.99
FIRST DEGREE								
ATRIOVENTRICULAR BLOCK	1 (1.2%)	[1]	0		0		>0.99	>0.99
SECOND DEGREE								
BRADYCARDIA	1 (1.2%)	[4]	0		0		>0.99	>0.99
BUNDLE BRANCH BLOCK LEFT	1 (1.2%)	[1]	0		0		>0.99	>0.99
BUNDLE BRANCH BLOCK RIGHT	1 (1.2%)	[2]	1 (1.2%)	[1]	0		>0.99	>0.99

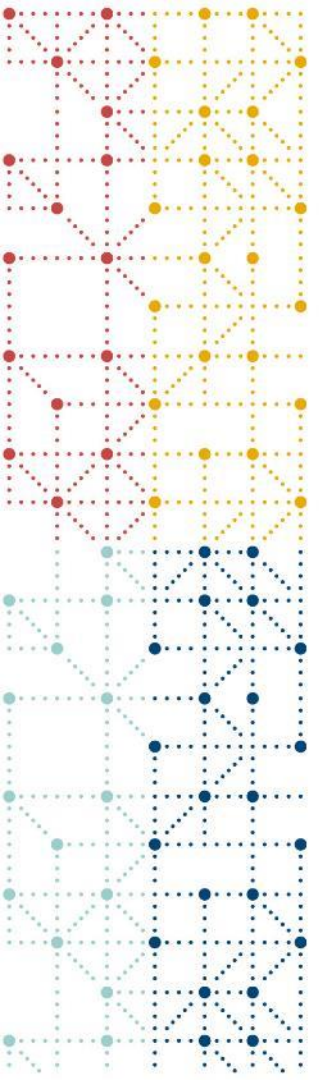
Analysis Result Dataset: OCCDS Structure Example

IDENTIFIERS			DATA / POPULATION			BY VARIABLES						ANALYSIS VARIABLES			STATISTICS			
StudyID	ResultID	TableID	ADSNs	Population	Where	Time	ByVar1	ByVal1	ByVar2	ByVal2	TrtVar	TrtVal	ParamCD	Anal_Var	Anal_Var_Val	Stat_Name	Stat_Val	Stat_Desc
1234	AE01a1	AE01a	ADAE, ADSL	Safety							TRTP	D1		AE Incidence		N	xx	# subjects with event
1234	AE01a2	AE01a	ADAE, ADSL	Safety							TRTP	P1		AE Incidence		N	xx	
1234	AE01a3	AE01a	ADAE, ADSL	Safety							TRTP	D1		AE Incidence		Percent	xx.xx	% of subjects in treatment group with event
1234	AE01a4	AE01a	ADAE, ADSL	Safety							TRTP	P1		AE Incidence		Percent	xx.xx	
1234	AE01a5	AE01a	ADAE, ADSL	Safety			Body System	Blood and lymphatic system disorders			TRTP	D1		AE Incidence		N	xx	# subjects with event
1234	AE01a6	AE01a	ADAE, ADSL	Safety			Body System	Blood and lymphatic system disorders			TRTP	P1		AE Incidence		N	xx	
1234	AE01a7	AE01a	ADAE, ADSL	Safety			Body System	Blood and lymphatic system disorders			TRTP	D1		AE Incidence		Percent	xx.xx	% of subjects in treatment group with event
1234	AE01a8	AE01a	ADAE, ADSL	Safety			Body System	Blood and lymphatic system disorders			TRTP	P1		AE Incidence		Percent	xx.xx	
1234	AE01a9	AE01a	ADAE, ADSL	Safety			Body System	Blood and lymphatic system disorders	PT	Anaemia	TRTP	D1		AE Incidence		N	xx	# subjects with event
1234	AE01a10	AE01a	ADAE, ADSL	Safety			Body System	Blood and lymphatic system disorders	PT	Anaemia	TRTP	P1		AE Incidence		N	xx	
1234	AE01a11	AE01a	ADAE, ADSL	Safety			Body System	Blood and lymphatic system disorders	PT	Anaemia	TRTP	D1		AE Incidence		Percent	xx.xx	% of subjects in treatment group with event
1234	AE01a12	AE01a	ADAE, ADSL	Safety			Body System	Blood and lymphatic system disorders	PT	Anaemia	TRTP	P1		AE Incidence		Percent	xx.xx	

Analysis Result Dataset: Link Result to Metadata

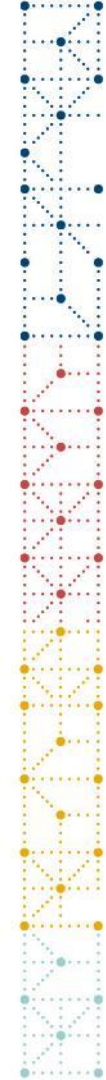
Analysis Result Concept





Analysis Results Standards – Parts III

Analysis Results Metadata



Why ARM++

Enhance analysis result
metadata

Automate results/display
production

Improved traceability and
understanding of results

Link results metadata with
other CDISC metadata

CDISC 360: ARM v1 Metadata Extensions

Output

(Study, Analysis, Group, Filename/Type, Style)

Result

Version
DisplayPattern
Grouping
- AnalysisVar
- ByVar
CodeReference

Study - CDISC 360

Table 14.1.1.1
Demographic characteristics (Safety Population)

Characteristics	METFORMIN (N=XX)	HUMAN INSULIN (N=XX)
Age (years)		
n	XX	XX
Mean	XX.X	XX.X
SD	XX.XX	XX.XX
Min	XX	XX
Q25	XX.X	XX.X
Median	XX.X	XX.X
Q75	XX.X	XX.X
Max	XX	XX
Age Group - n (%)		
15 - <30 years	XX (XX.X)	XX (XX.X)
30 - <45 years	XX (XX.X)	XX (XX.X)
>=45 years	XX (XX.X)	XX (XX.X)
Gender - n (%)		
Male	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)

Max = Maximum. Min = Minimum. N = Number of subjects in treatment group. n = Number of subjects included in analysis. SD = Standard deviation.

Datasets used - adsl

Executed by <Username> on DDMONYYYY:HH:MM

Display

Parent
Version
Grouping:
- Dataset
- WhereClause
- AnalysisVar
- ByVar
Template
Title 1..N
RowLabelHeader
Header 1..N
Footer 1..N

CDISC 360: Extended Analysis Results Metadata Sample

Study - CDISC 360

Table 14.1.1.1
Demographic characteristics (Safety Population)

Characteristics	METFORMIN (N=XX)	HUMAN INSULIN (N=XX)
Age (years)		
n	XX	XX
Mean	XX.X	XX.X
SD	XX.XX	XX.XX
Min	XX	XX
Q25	XX.X	XX.X
Median	XX.X	XX.X
Q75	XX.X	XX.X
Max	XX	XX
Age Group - n (%)		
15 - <30 years	XX (XX.X)	XX (XX.X)
30 - <45 years	XX (XX.X)	XX (XX.X)
>=45 years	XX (XX.X)	XX (XX.X)
Gender - n (%)		
Male	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)

Max = Maximum. Min = Minimum. N = Number of subjects in treatment group. n = Number of subjects included in analysis. SD = Standard deviation.
Datasets used - adsl
Executed by <Username> on DDMMYYYY:HH:MM

Study	Analysis	Group	Order	DisplayID	DisplayVersion	Filename	Type	StyleID
CDISC	CDISC 360	Safety	1	T14111_SAF_DEMOG	1	tdemog_saf	rtf	table_rtf
CDISC	CDISC 360	Safety	2	T14131_SAF_AE2TIER	1	tae_soc_pt_saf	rtf	table_rtf
CDISC	CDISC 360	Efficacy	3	T1421_EFF	1	tmace_edpt_fas	rtf	table_rtf

Output Display Result WhereClause Style TFL Metadata Tables TFL Metadata ...

DisplayID	DisplayName	DisplayTitle	Title1	Title2	Title3
T14111_SAF_DEMOG	Table 14.1.1.1	Demographic characteristics (SAF)	Study - CDISC 360	Table 14.1.1.1	Demographic characteristics (Safety Population)

Output Display Result WhereClause Style TFL Metadata Tables TFL Metadata Variables ...

ResultDisplayOID	AnalysisResultOID	Version	ResultDescription	DisplayPattern
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	n	xxx
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Mean	XX.X
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	SD	XX.XX
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Min	XX
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Q25	XX.X
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Median	XX.X
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Q75	XX.X

Output Display Result WhereClause Style TFL Metadata Tables TFL Metadata Variables ...

WhereClauseOID	Dataset	Variable	Comparator	Value
T14111_02_SAF_DEMOG_01	ADSL	AGEGR1	EQ	15 <= to <30 years
T14111_02_SAF_DEMOG_02	ADSL	AGEGR1	EQ	30 <= to <45 years
T14111_02_SAF_DEMOG_03	ADSL	AGEGR1	EQ	>=45 years
T14111_03_SAF_DEMOG_01	ADSL	SEX	EQ	M
T14111_03_SAF_DEMOG_02	ADSL	SEX	EQ	F

Output Display Result WhereClause Style TFL Metadata Tables TFL Metadata Variables ...

Vital Signs Change from Baseline Example – Work In Progress

Result.DisplayOID	Display.Header1	Display.Subheader1	Display.Subheader2	Display.ID
Result.AnalysisResultOID	Display.Subheader1	Display.Subheader2	Display.Subheader3	Display.ParentDisplayID
Result.Version	Display.Header2	Display.Subheader3	Display.Subheader4	Display.Version
Result.DisplayPattern	Display.Subheader2	Display.Subheader3	Display.Subheader5	Display.DisplayTemplate
Result.ResultDescription	Display.Subheader3	Display.Subheader4	Display.Subheader6	
Result.Reason	Display.Subheader4	Display.Subheader5		
Result.Purpose	Display.Subheader5	Display.Subheader6		
Study - CDISC 360	Display.Title1	Display.DisplayName	Page x of y	
	Display.Title2	Table 14.3.3.<x>.<y>	Display.DisplayTitle	
	Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs	Display.Title3	Display.Title3	
	Display.Title4	Safety Population	Display.GroupingDataset	
	Treatment X	Treatment Y	Total	Display.GroupingWhereVar
	(N=XX)	(N=XX)	(N=XX)	Display.GroupingAnalysisVar
				Display.GroupingByVar
Display.RowLabelHeader	Observed	Change from Baseline	Observed	Change from Baseline
Parameter (Units)				
Visit				
Result.Dataset	<Parameter 1> (<unit>)	ResultAcrossVar	ResultAcrossOrdFmt	
Baseline	Result.ResultDescription			
n	XX	XX	XX	
Mean (SD)	XX.X (XX.XX)	Result.AnalysisVariable	XX.X (XX.XX)	
Median	XX.X	Result.SignificantDigits	XX.X	
Q1, Q3	XX.X, XX.X	Result.GroupingAnalysisVar	XX.X, XX.X	Result.ProgrammingCodeContext
Min, Max	XX, XX	Result.GroupingByVar	XX, XX	Result.ProgrammingCode
...				Result.Documentation
<Visit n>				
n	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX
<Parameter n> (<unit>)				
...				

Note: Baseline is defined as the last assessment that is non-missing prior to first dose of investigational product.

Source dataset: advs, Generated on: DOMONYYY:HH:MM
Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DOMONYYY:HH:MM

Display.Footnote1/2..n

Analysis Results
Standards
(ARM+ & ARDS)
& TFL Display
Templates

Sponsor
Study
MDR

Industry Standards
Sponsor Standards
Study Definitions

SAP

Select TFL of
Interest

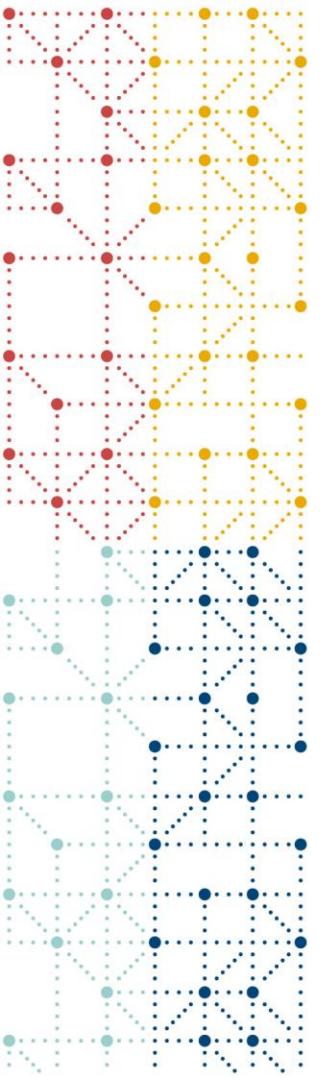
Select Analysis
Concepts & TFL
Display (Template)

Customize TFL
Layout & Metadata

Machine-readable
ARM + TFL Shells

Study ADaM and
TFL outputs

Automation Engine
(SAS, R or other
Software products)



Analysis Results Standards

Next Steps

Next Steps

Continue to develop the Analysis Results Dataset Model (ARDM) and Approach

Continue to develop the Analysis Results Metadata Model (ARM)

Continue to develop concepts/examples

Testing and POC

Develop Results level biomedical concepts and link to other CDISC metadata

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Thank You!

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