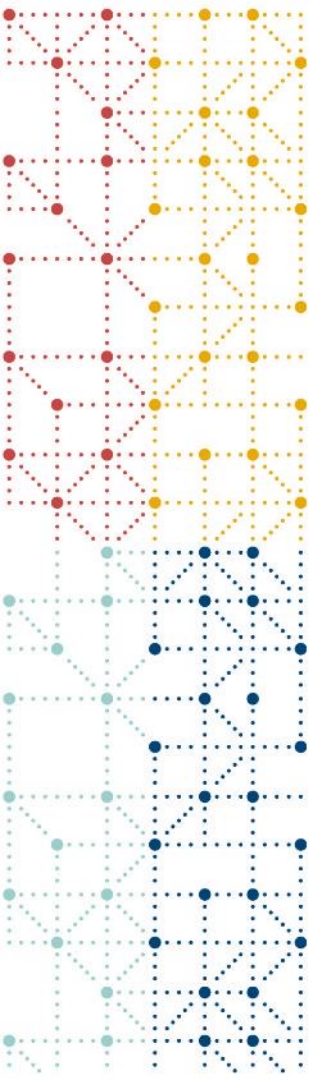




Getting Started with the New CDISC Analysis Results Standard

Bess LeRoy, Head of Standards Innovation, CDISC





Agenda

- Project Background
- ARS Model and User Guide
- Open-Source Tool Development
- Next Steps
- Q&A

[illegible]

Table 4.1: BHAT Longitudinal Repeat Measures Analysis - Table Sheet			
Treatment: 102		Model: 10 Longitudinal Repeat Measures Analysis	
		24-Week Short-term Double-blind Treatment Period	
		Intention-to-Treat Population	
		Drug A	Drug B
		N=112	N=112
		112	112
		2,500 (1,500)	2,500 (1,500)
BASELINE	SB		
	Mean (SD)	2,500 (1,500)	2,500 (1,500)
WEEK 4			
	Change from baseline: Mean (SD)	500	500
	Adjusted change from baseline: Mean (SD)	500 (1,500)	500 (1,500)
	95% confidence interval for adjusted mean	500 (1,500)	500 (1,500)
	Difference vs. Drug B (SD)	100,000 (50,000)	00,000 (50,000)
	95% confidence interval for difference		50,000 (50,000)
	P-value vs. Drug B		0.0000
...			
WEEK 12	SB	2,500 (1,500)	2,500 (1,500)
	Change from baseline: Mean (SD)	2,500 (1,500)	2,500 (1,500)
	Adjusted change from baseline: Mean (SD)	2,500 (1,500)	2,500 (1,500)
	95% confidence interval for adjusted mean	2,500 (1,500)	2,500 (1,500)
	Difference vs. Drug B (SD)	100,000 (50,000)	50,000 (50,000)
	95% confidence interval for difference		50,000 (50,000)
	P-value vs. Drug B		100,000 (50,000)
			0.0000

N= the number of subjects in the ITT population (N=224 Population).
 SD= the number of subjects in the ITT population who had missing baseline and corresponding N= value.
 Difference between Drug A and Drug B baseline values.
 Drug A mean = 2500.000; mean = 2500.000; mean = 2500.000

GSD0000102000

Results

???

Metadata Field	Metadata
DISPLAY IDENTIFIER	Table 4.2.1/Figure 4.2.1
DISPLAY NAME	Mean Change from Baseline in HbA1c (Percent) Longitudinal Repeated Measures Analysis, 24-Week Short-term Double-blind Treatment Period, Intention-to-treat Population
RESULT IDENTIFIER	Treatment difference results (LSMean, confidence interval, p-value)
PARAM	HbA1c (%)
PARAMCD	HbA1C
ANALYSIS VARIABLE	CHG (Change from baseline)
ANALYSIS REASON	SPECIFIED IN SAP
ANALYSIS PURPOSE	PRIMARY OUTCOME MEASURE
ANALYSIS DATASET	ADHbA1C



Analysis Results Key Objectives



Leverage analysis results metadata to drive the automation of results

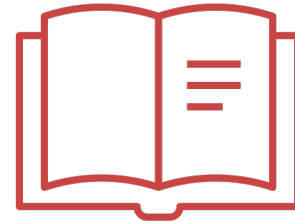


Support storage, access, processing, traceability and reproducibility of results

Analysis Results Standards Key Results

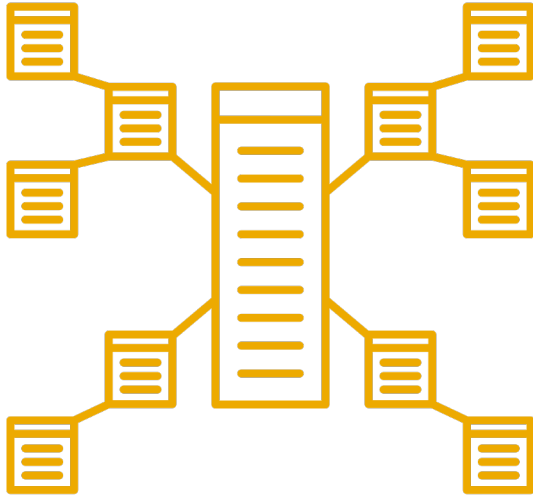


Logical Model that describes analysis results and associated metadata



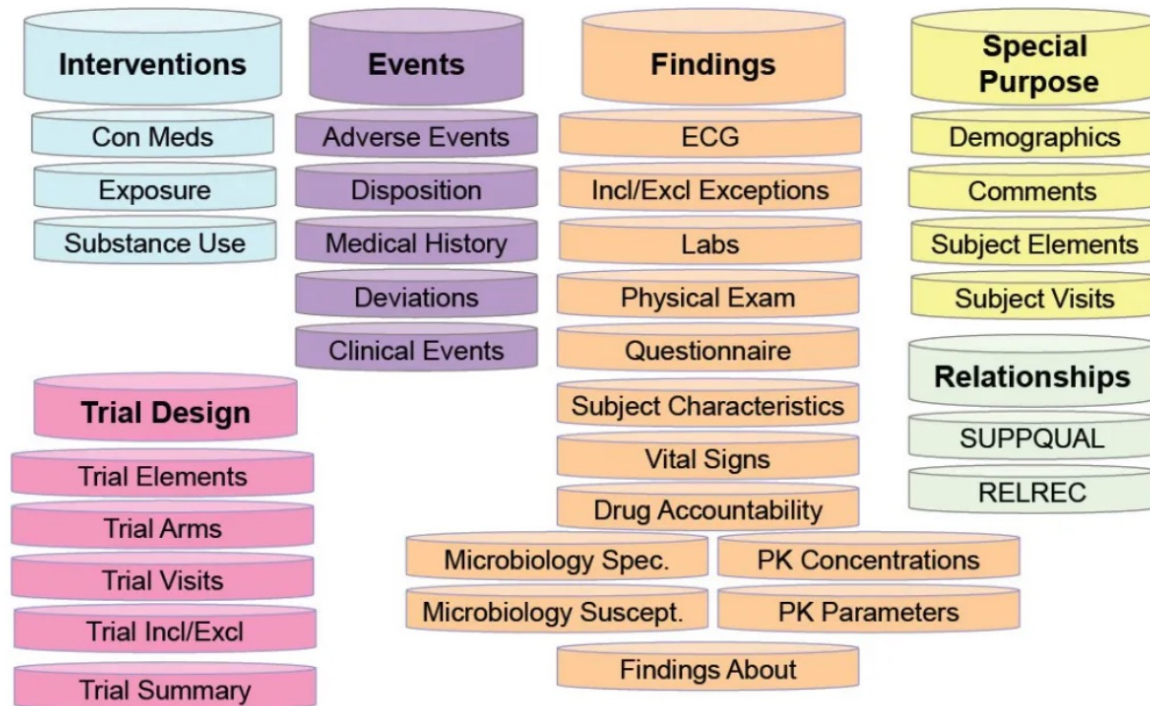
User Guide to illustrate and exercise model with common safety displays

What is a Logical Data Model?



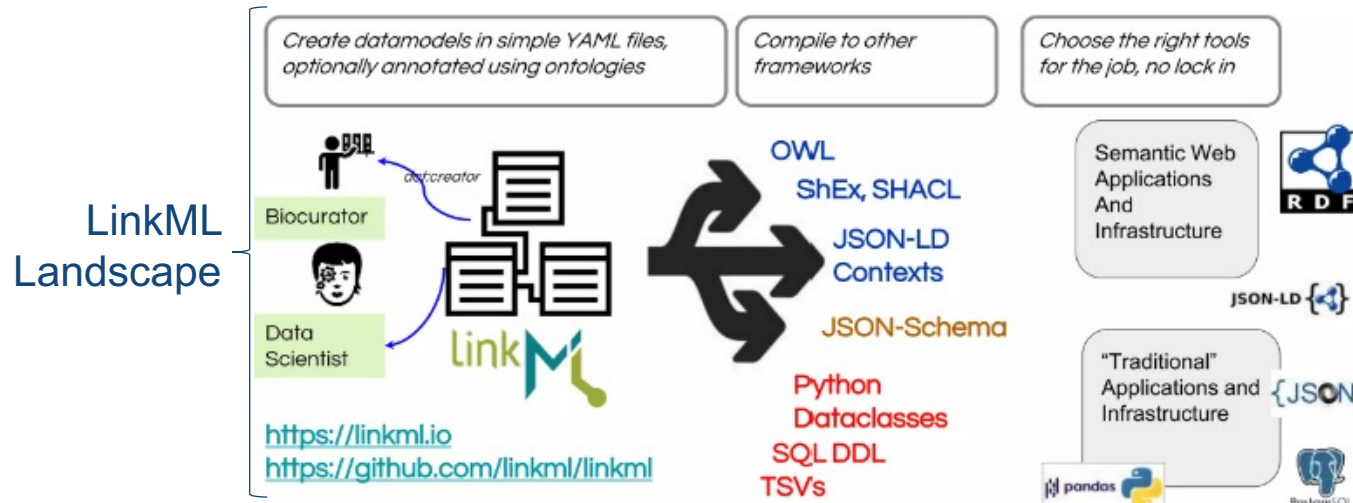
- A logical data model establishes the structure of data components and the relationships between them
- Designed to accurately represent complexity of all components
- It is independent of the physical database design

SDTM Model Representation



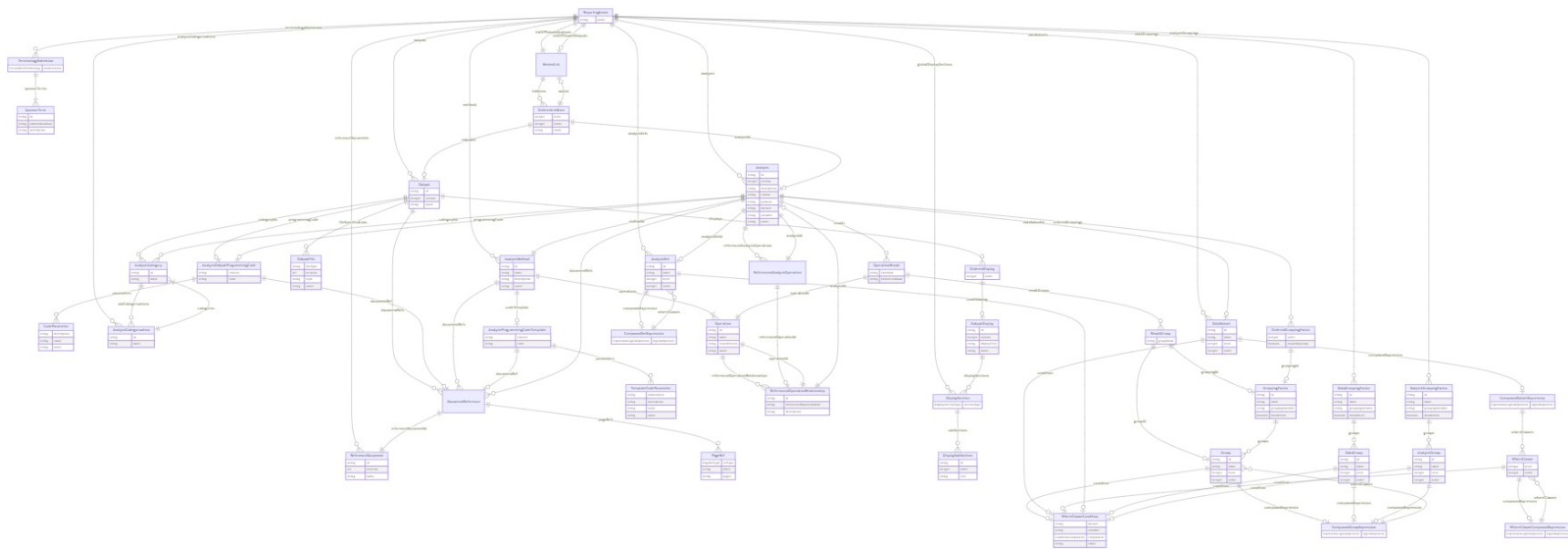
Using LinkML to Create Analysis Results Model

- LinkML is a general-purpose modeling language that can be used with linked data, JSON, and other formalisms

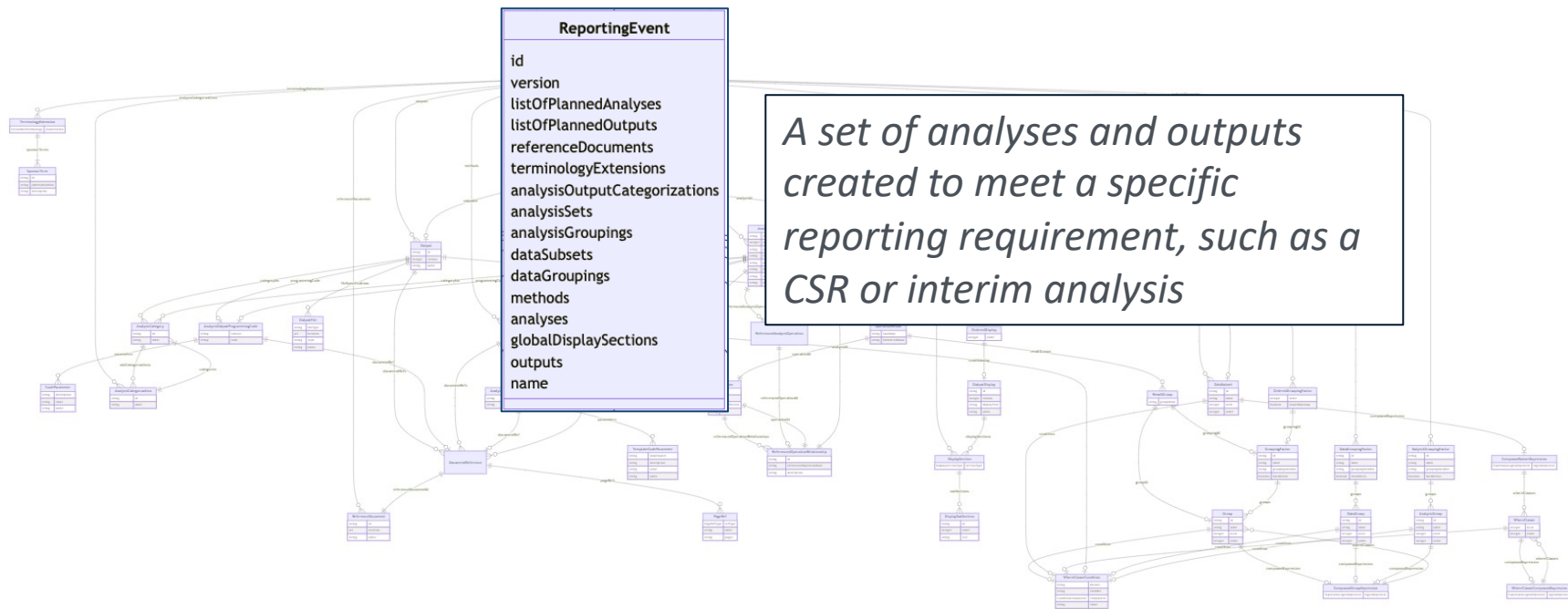


Reference: <https://www.slideshare.net/cmungall/linkml-intro-july-2022pptx>

ARS Logical Model Schema Diagram



ARS Logical Model Schema Diagram: Reporting Event



Model Components

Reporting Event

Summary of Demographics

Study - CDISC 360		Table 14.1.1.1 Summary of Demographics Safety Population		Page x of y
Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	
Age (years)				
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	
Age Group, n (%)				
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Gender, n (%)				
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Ethnicity, n (%)				
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Source dataset: adsl, Generated on: DDMONYYYY:HH:MM Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM				

Summary of TEAE by SOC and PT

Study - CDISC 360		Table 14.3.1.1 Summary of TEAE by System Organ Class and Preferred Term Safety Population		Page x of y
System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)	
<SOC 1>	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)	XX (XX.X)	
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)	
<SOC 2>	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)	XX (XX.X)	
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Notes: TEAE=Treatment-Emergent Adverse Events. Subjects are counted once within each system organ class and preferred term. [a] All investigators adverse events were coded using MedDRA version xx.x. Source dataset: adae, Generated on: DDMONYYYY:HH:MM Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM				



Model Components

Analysis Set

Summary of Demographics

Study - CDISC 360

Page x of y

Table 14.1.1
Summary of Demographics
Safety Population

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Age (years)			
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
Age Group, n (%)			
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gender, n (%)			
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity, n (%)			
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)

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

Summary of TEAE by SOC and PT

Study - CDISC 360

Page x of y

Table 14.3.1.1

Summary of TEAE by System Organ Class and Preferred Term

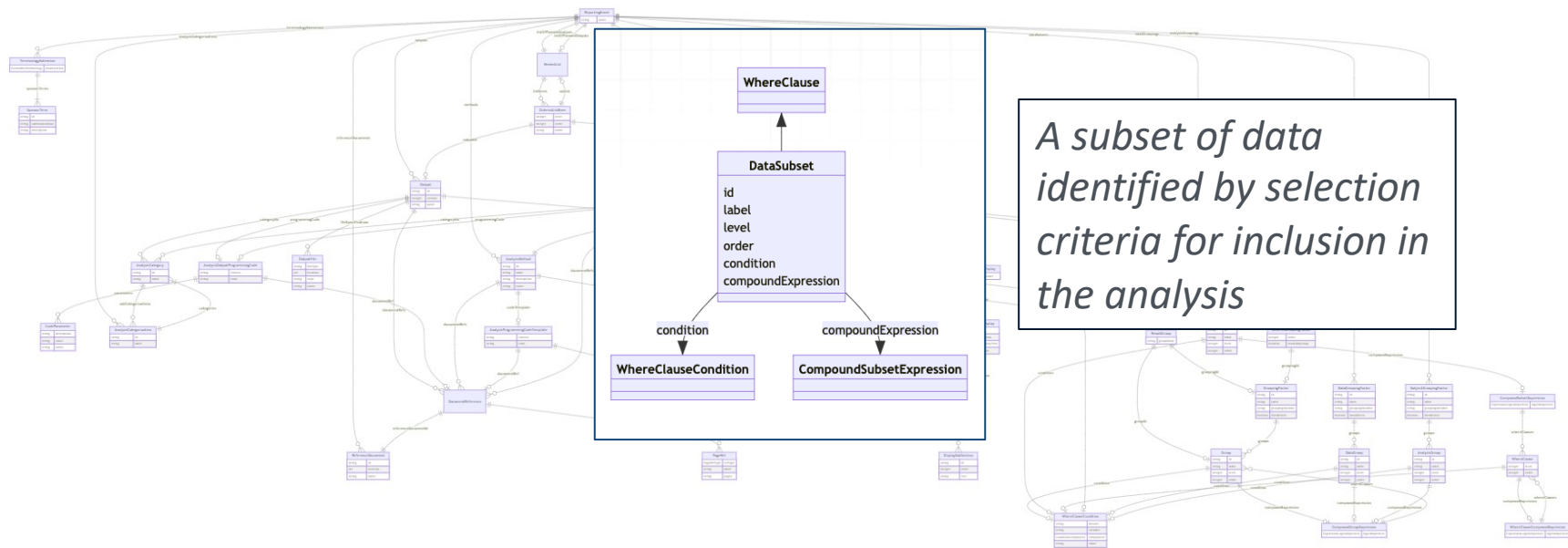
Safety Population

System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 1>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 2>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)

Notes: TEAE=Treatment-Emergent Adverse Events.
Subjects are counted once within each system organ class and preferred term.
[a] All investigators adverse events were coded using MedDRA version xx.x.

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

ARS Logical Model Schema Diagram: Data Subset



Model Components

Data Subset

Summary of Demographics

Study - CDISC 360

Table 14.1.1
Summary of Demographics
Safety Population

Page x of y

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Age (years)			
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
Age Group, n (%)			
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gender, n (%)			
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity, n (%)			
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)

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

Summary of TEAE by SOC and PT

Study - CDISC 360

Page x of y

Table 14.3.1.1

Summary of **TEAE** by System Organ Class and Preferred Term

Safety Population

System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 1>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 2>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)

Notes: TEAE=Treatment-Emergent Adverse Events.
Subjects are counted once within each system organ class and preferred term.
[a] All investigators adverse events were coded using MedDRA version xx.x.

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

Group

AnalysisGroup

id
label
level
order
condition
compoundExpression

WhereClauseCondition

CompoundGroupExpression

A subdivision of the subject population based on a defined factor (e.g., subjects whose treatment is Drug A, subjects whose gender is male)

A subdivision of the subject population based on a defined factor (e.g., subjects whose treatment is Drug A, subjects whose gender is male)

Model Components

Analysis Grouping

Summary of Demographics

Study - CDISC 360

Table 14.1.1
Summary of Demographics
Safety Population

Page x of y

Characteristics	Placebo	Xanomeline	Xanomeline
	(N=XX)	Low Dose (N=XX)	High Dose (N=XX)
Age (years)			
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
Age Group, n (%)			
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gender, n (%)			
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity, n (%)			
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)

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

Summary of TEAE by SOC and PT

Study - CDISC 360

Table 14.3.1.1

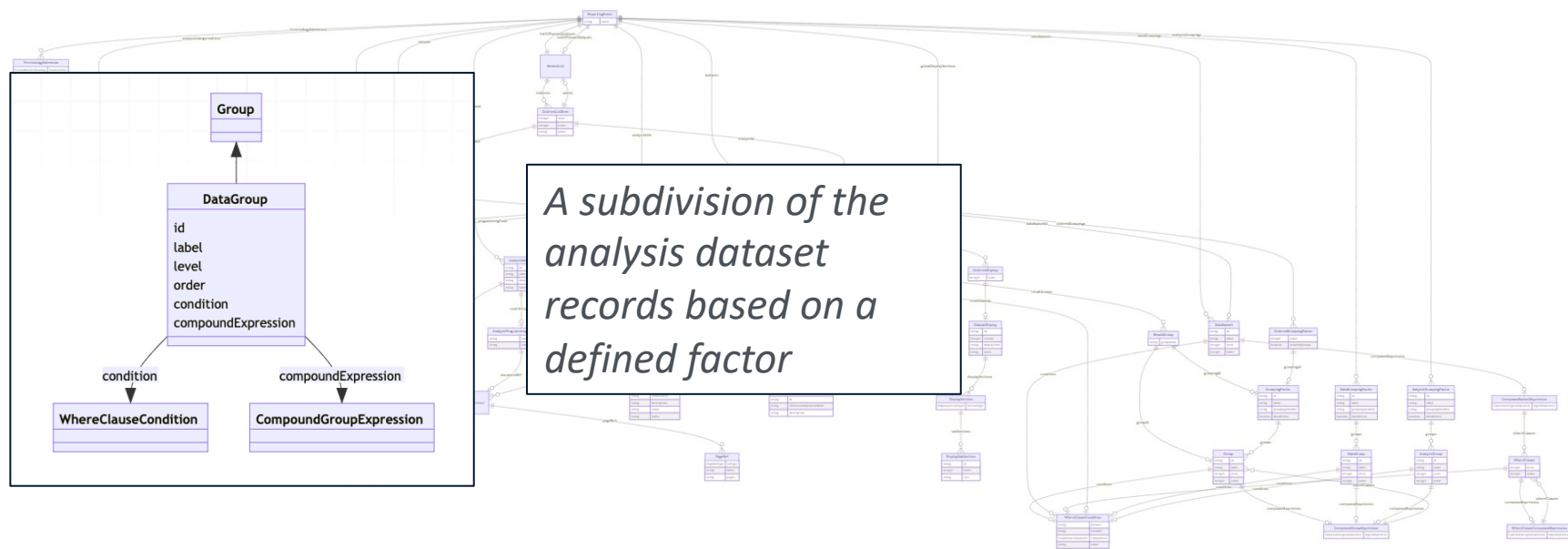
Summary of TEAE by System Organ Class and Preferred Term

Safety Population

Page x of y

System Organ Class	Placebo	Xanomeline	Xanomeline
Preferred Term [a], n (%)	(N=XX)	Low Dose (N=XX)	High Dose (N=XX)
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 1>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 2>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)
Notes: TEAE=Treatment-Emergent Adverse Events. Subjects are counted once within each system organ class and preferred term. [a] All investigators adverse events were coded using MedDRA version xx.x. Source dataset: adae, Generated on: DDMONYYYY:HH:MM Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM			

ARS Logical Model Schema Diagram: Data Grouping



Model Components

Data Grouping

Summary of Demographics

Study - CDISC 360

Table 14.1.1
Summary of Demographics
Safety Population

Page x of y

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Age (years)			
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
Age Group, n (%)			
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gender, n (%)			
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity, n (%)			
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)

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

Summary of TEAE by SOC and PT

Study - CDISC 360

Page x of y

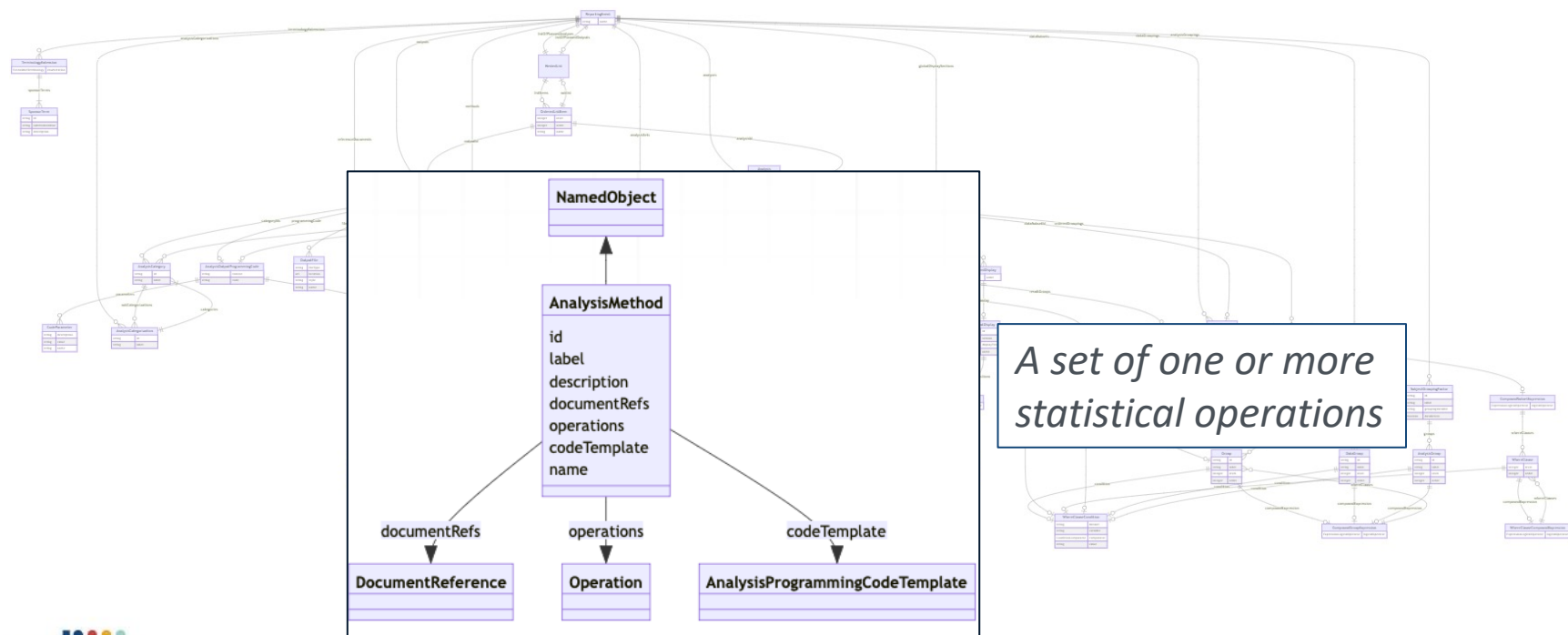
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 1>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 2>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)

Notes: TEAE=Treatment-Emergent Adverse Events.
Subjects are counted once within each system organ class and preferred term.
[a] All investigators adverse events were coded using MedDRA version xx.x.

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

ARS Logical Model Schema Diagram: Analysis Method



Model Components

Analysis Method

Summary of Demographics

Study - CDISC 360

Table 14.1.1
Summary of Demographics
Safety Population

Page x of y

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Age (years)			
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
Age Group, n (%)			
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gender, n (%)			
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity, n (%)			
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)

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

Summary of TEAE by SOC and PT

Study - CDISC 360

Page x of y

Table 14.3.1.1

Summary of TEAE by System Organ Class and Preferred Term

Safety Population

System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 1>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 2>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)

Notes: TEAE=Treatment-Emergent Adverse Events.

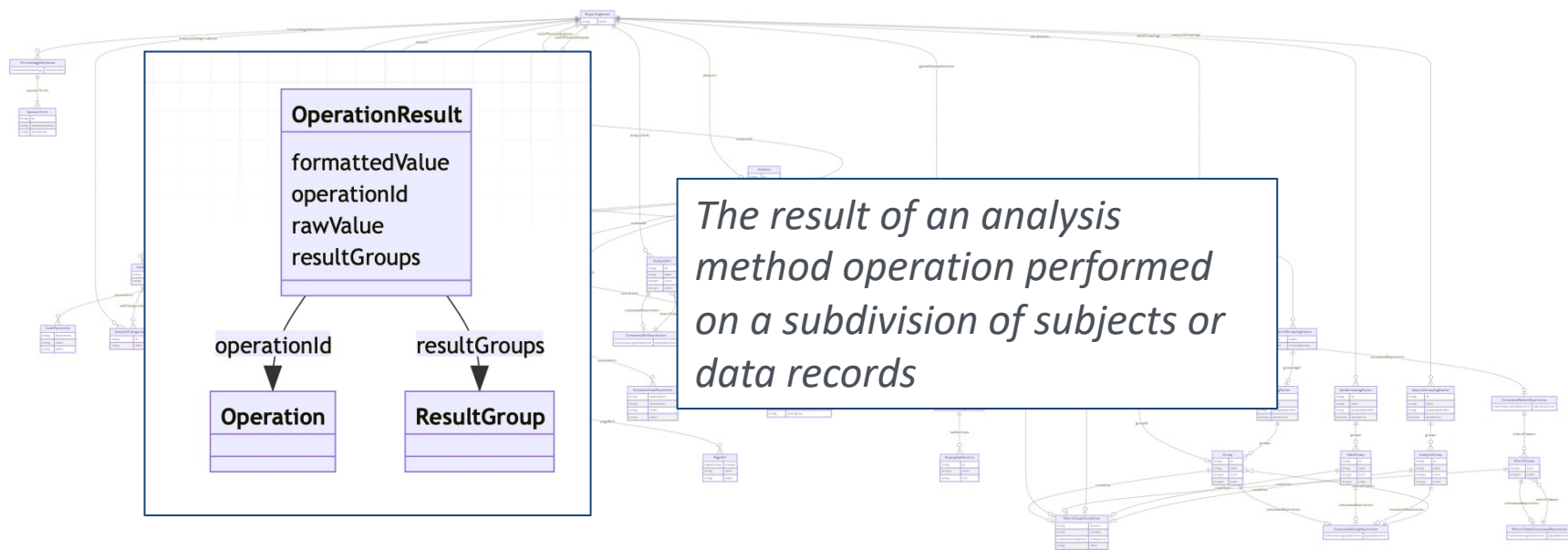
Subjects are counted once within each system organ class and preferred term.

[a] All investigators adverse events were coded using MedDRA version xx.x.

Source dataset: adae, Generated on: DDMONYYYY:HH:MM

Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM

ARS Logical Model Schema Diagram: Results



Model Components

Results

Summary of Demographics

Study - CDISC 360

Table 14.1.1
Summary of Demographics
Safety Population

Page x of y

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Age (years)			
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
Age Group, n (%)			
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gender, n (%)			
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity, n (%)			
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)

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

Summary of TEAE by SOC and PT

Study - CDISC 360

Table 14.3.1.1

Summary of TEAE by System Organ Class and Preferred Term

Safety Population

Page x of y

System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 1>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 2>	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)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)

Notes: TEAE=Treatment-Emergent Adverse Events.

Subjects are counted once within each system organ class and preferred term.

[a] All investigators adverse events were coded using MedDRA version xx.x.

Source dataset: adae, Generated on: DDMONYYYY:HH:MM

Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM

Creating Analysis Results Metadata: JSON

Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X)

Characteristic	Drug Name Dosage X N = XXX n (%)	Drug Name Dosage Y N = XXX n (%)	Placebo N = XXX n (%)	Active Control N = XXX n (%)	Total Population N = XXX n (%)
Sex, n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Male	n (%)	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)	n (%)
Age, years	XX (Y,Y)	XX (Y,Y)	XX (Y,Y)	XX (Y,Y)	XX (Y,Y)
Mean (SD)	XX (Y,Y)	XX (Y,Y)	XX (Y,Y)	XX (Y,Y)	XX (Y,Y)
Median (min, max)	XX (Y,Y,Z,Z)	XX (Y,Y,Z,Z)	XX (Y,Y,Z,Z)	XX (Y,Y,Z,Z)	XX (Y,Y,Z,Z)
Age groups (years), n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
≤17 to <65	n (%)	n (%)	n (%)	n (%)	n (%)
≥65	n (%)	n (%)	n (%)	n (%)	n (%)
≥65 to <75	n (%)	n (%)	n (%)	n (%)	n (%)
≥75	n (%)	n (%)	n (%)	n (%)	n (%)
Race, n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
American Indian or Alaska Native Asian	n (%)	n (%)	n (%)	n (%)	n (%)
Black or African American	n (%)	n (%)	n (%)	n (%)	n (%)
Native Hawaiian or Other Pacific Islander	n (%)	n (%)	n (%)	n (%)	n (%)
White	n (%)	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)	n (%)

Source: [include Applicant source, datasets and/or software tools used].
¹ Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo).
 Abbreviations: N, number of patients in treatment arm; n, number of patients with given characteristic; SD, standard deviation

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              "level": 2,
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                {
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          }
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  }
}
```

ARS Metadata

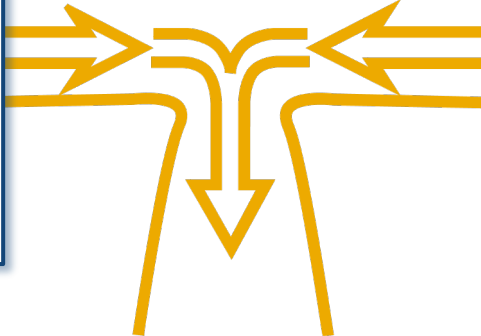
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            "order": 3,
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            "multi": {
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                  "name": "Count of Subjects [Total Population]",
                  "level": 2,
                  "order": 2,
                  "analysisId": "A_SAF_OUT_US03JID"
                }
              ]
            }
          },
          {
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            "level": 3,
            "order": 3,
            "multi": {
              "listItems": [
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                  "level": 3,
                  "order": 3,
                  "analysisId": "A_SAF_SUM_US03JID_TRT_SEX"
                }
              ]
            }
          },
          {
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            "order": 2,
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      }
    }
  ]
}

```

ADaM Dataset

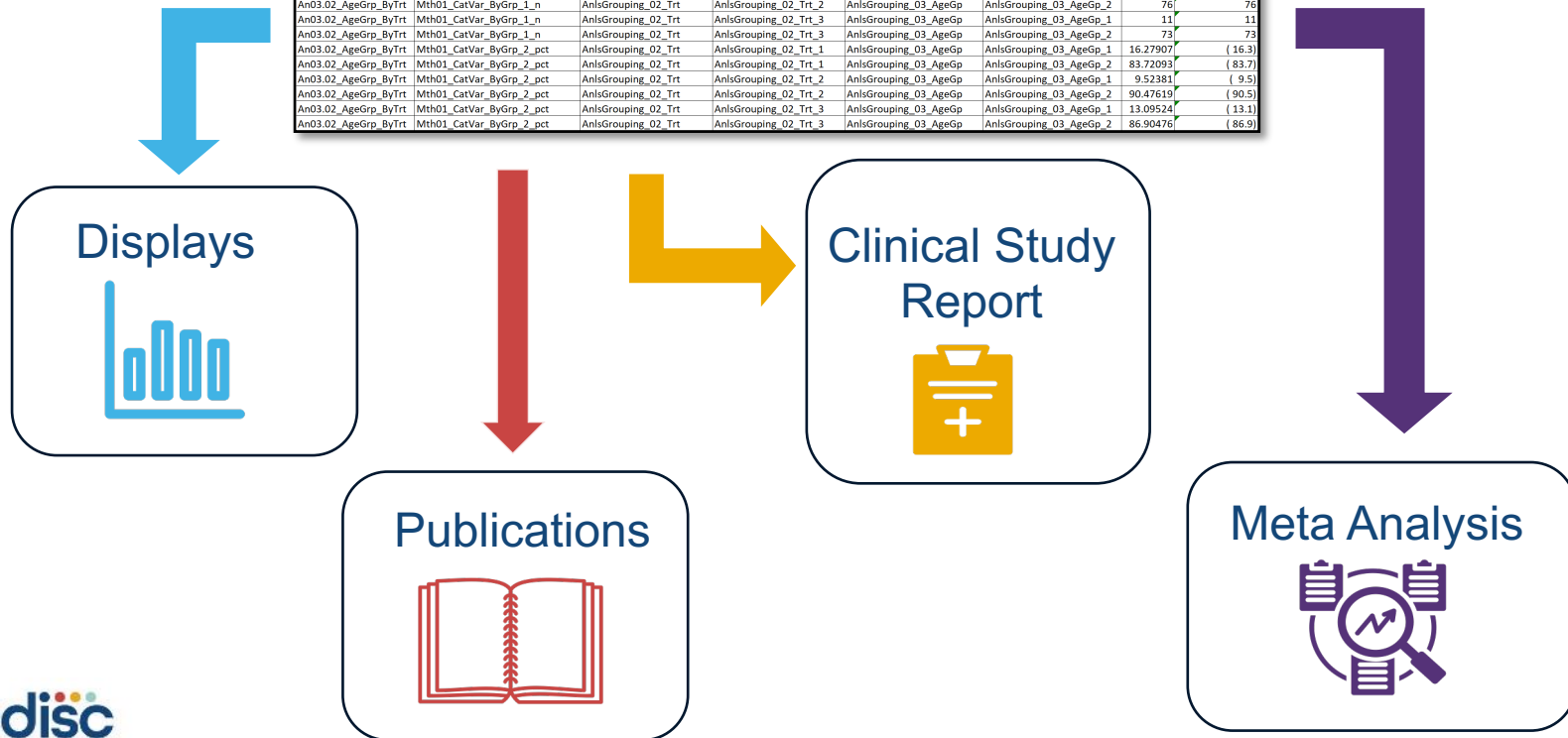
USUBJID	ARM	AGE	AGEGR1	AGEU	RACE	SEX
01-701-1015	Placebo	63	<65	YEARS	WHITE	F
01-701-1023	Placebo	64	<65	YEARS	WHITE	M
01-701-1028	Xanomeline High Dose	71	65+	YEARS	WHITE	M
01-701-1033	Xanomeline Low Dose	74	65+	YEARS	WHITE	M
01-701-1034	Xanomeline High Dose	77	65+	YEARS	WHITE	F
01-701-1047	Placebo	85	65+	YEARS	WHITE	F



id	operation_id	resultGroup1_groupingId	resultGroup1_groupId	resultGroup2_groupingId	resultGroup2_groupId	rawVal	formattedVal
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_1	14	14
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_2	72	72
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_1	8	8
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_2	76	76
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_1	11	11
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_2	73	73
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_1	16.27907	(16.3)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_2	83.72093	(83.7)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_1	9.52381	(9.5)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_2	90.47619	(90.5)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_1	13.09524	(13.1)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGrp	AnlsGrouping_03_AgeGrp_2	86.90476	(86.9)

Analysis Results: Create Once, Use Many Times

id	operation_id	resultGroup1_groupingId	resultGroup1_groupId	resultGroup2_groupingId	resultGroup2_groupId	rawValue	formattedValue
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	14	14
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	72	72
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	8	8
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	76	76
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	11	11
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	73	73
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	16.27907	(16.3)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	83.72093	(83.7)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	9.52381	(9.5)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	90.47619	(90.5)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	13.09524	(13.1)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	86.90476	(86.9)



Focus on Concepts, Not Layout

- Focus on concepts presented in data displays 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) Visit	Treatment X (N=XX)	Treatment Y (N=XX)	Total (N=XX)
<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) 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

FDA Standard Safety Tables and Figures: Integrated Guide



STANDARD SAFETY TABLES AND FIGURES: *INTEGRATED GUIDE*

Center for Drug Evaluation and Research (CDER)
Biomedical Informatics and Regulatory Review Science
(BIRRS) Team

Please email ONDbiomedicalinformatics@fda.hhs.gov with any questions.

Version Date: August 2022

Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X)

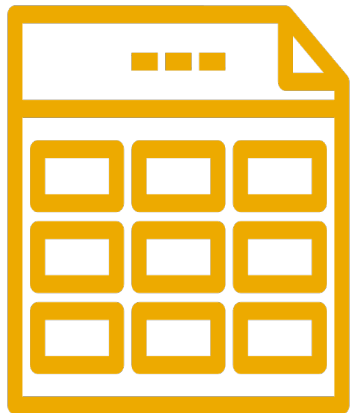
Characteristic	Drug Name Dosage X N = XXX n (%)	Drug Name Dosage Y N = XXX n (%)	Placebo N = XXX n (%)	Active Control N = XXX n (%)	Total Population N = XXX n (%)
Sex, n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Male	n (%)	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)	n (%)
Age, years	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)
Mean (SD)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)
Median (min, max)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)
Age groups (years), n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
≥17 to <65	n (%)	n (%)	n (%)	n (%)	n (%)
≥65	n (%)	n (%)	n (%)	n (%)	n (%)
≥65 to <75	n (%)	n (%)	n (%)	n (%)	n (%)
≥75	n (%)	n (%)	n (%)	n (%)	n (%)
Race, n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
American Indian or Alaska Native	n (%)	n (%)	n (%)	n (%)	n (%)
Asian	n (%)	n (%)	n (%)	n (%)	n (%)
Black or African American	n (%)	n (%)	n (%)	n (%)	n (%)
Native Hawaiian or Other Pacific Islander	n (%)	n (%)	n (%)	n (%)	n (%)
White	n (%)	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)	n (%)

Source: [include Applicant source, datasets and/or software tools used].

¹ Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo).

Abbreviations: N, number of patients in treatment arm; n, number of patients with given characteristic; SD, standard deviation

ARS User Guide Reporting Events Example



- Common Safety Displays
 - Summary of Demographics
 - Overall Summary of Treatment-Emergent Adverse Events
 - Summary of TEAE by System Organ Class and Preferred Term
 - Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs
 - Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs <Vertical Layout>
- FDA Standard Tables and Figures Integrated Guide
 - Table 2: Baseline Demographic and Clinical Characteristics, Safety Population

Analysis Results Standard Model and User Guide

<https://cdisc-org.github.io/analysis-results-standard/>

Analysis Results Standard (ARS)

Q Search

Analysis Results Standard (ARS)

Schema Diagram

Classes

Slots

Enumerations

Types

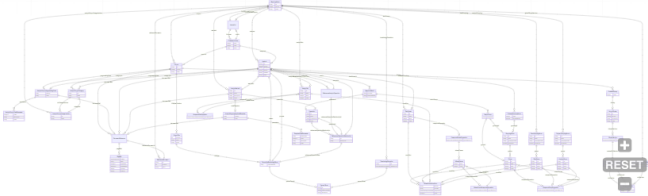
Subsets

Analysis Results Standard (ARS)

DRAFT Logical model to support both the prospective specification of analyses and the fully contextualized representation of the results of the analyses.

URI: <https://www.cdisc.org/ars/1-0> Name: ars_idm

Schema Diagram



Classes

Classes provide templates for organizing data. Data objects instantiate classes in the schema. Each class has a set of slots (aka fields, attributes) that are applicable to it. See [LinkML documentation](#) for more information.

Class	Description
NamedObject	An object with a name
ReportingEvent	A set of analyses and outputs created to meet a specific reporting requiremen...
NestedList	A list of items (analyses or outputs) that may be organized within sub-lists



Analysis Results Standard User Guide

Version 1.0 (Draft)

Prepared by the
Analysis Results Standard Team

Notes to Readers

- This is the draft Version 1.0 of the Analysis Results Standard User Guide.
- This document is based on ADaM v2.1 and Analysis Results Metadata (ARM) v1.0 for Define-XML v2.0

Revision History

Date	Version
2023-08-22	Internal Review Draft

ARS Model Will Drive Automation and Open-Source Tool Development



CDISC Open Source Alliance (COSA)



Supports, promotes, and sometimes sponsors open-source software projects that create tools for implementing or developing CDISC standards to drive innovation in the CDISC community

<https://www.cdisc.org/cosa>



TFL DESIGNER

- A community tool to create study specific analysis displays
- Export analysis results metadata per the CDISC ARS model in JSON and Excel formats

Source: Bhavin Busa, Clymb Clinical;
<https://tfl designer.org/>



Table 02
 Baseline Demographic and Clinical Characteristics [FDA STF-IG]
 Safety Population
 Pooled Analyses (or Trial X)

Characteristics	Drug Name Dosage X N = XXX n (%)	Drug Name Dosage Y N = XXX n (%)	Placebo N = XXX n (%)	Active Control N = XXX n (%)	Total Population N = XXX n (%)
Ethnicity, n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Hispanic	n (%)	n (%)	n (%)	n (%)	n (%)
Not Hispanic or Latino	n (%)	n (%)	n (%)	n (%)	n (%)
Unknown	n (%)	n (%)	n (%)	n (%)	n (%)
Age, Years					
Mean (SD)	X (Y)	X (Y)	X (Y)	X (Y)	X (Y)
Median (Min, Max)	X (Y, Z)	X (Y, Z)	X (Y, Z)	X (Y, Z)	X (Y, Z)
Interquartile range -	X - Y	X - Y	X - Y	X - Y	X - Y
Total exposure (person years)	X (Y)	X (Y)	X (Y)	X (Y)	X (Y)



```
{
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  "id": "FDA_STF_T2",
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    "listItems": [
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        "level": 1,
        "order": 1,
        "outputId": "0_FDA_STF_T2",
        "subList": {
          "listItems": [
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              "level": 2,
              "order": 1,
              "analysisId": "A_SAF_CNT_USUBJID_TRT"
            },
            {
              "name": "Count of Subjects (Total Population)",
              "level": 2,
              "order": 2,
              "analysisId": "A_SAF_CNT_USUBJID"
            },
            {
              "name": "Sex, n (%)",
              "level": 2,
              "order": 3,
              "subList": {
                "listItems": [
                  {
                    "name": "Summary of Subjects by Treatment",
                    "level": 3,
                    "order": 1,
                    "analysisId": "A_SAF_SUM_USUBJID_TRT_SEX"
                  },
                  {
                    "name": "Summary of Subjects (Total Population)",
                    "level": 3,
                    "order": 2,
                    "analysisId": "A_SAF_SUM_USUBJID_SEX"
                  }
                ]
              }
            }
          ]
        }
      }
    ]
  }
}
```



CDISC ARS Hackathon

Drive adoption of CDISC
Analysis Results Standard

Foster open-source software
tools for operationalization

Leveraging hackathon
learnings to enhance the
standards

ARD Generator

Metadata-driven analysis using the Analysis Results Standard

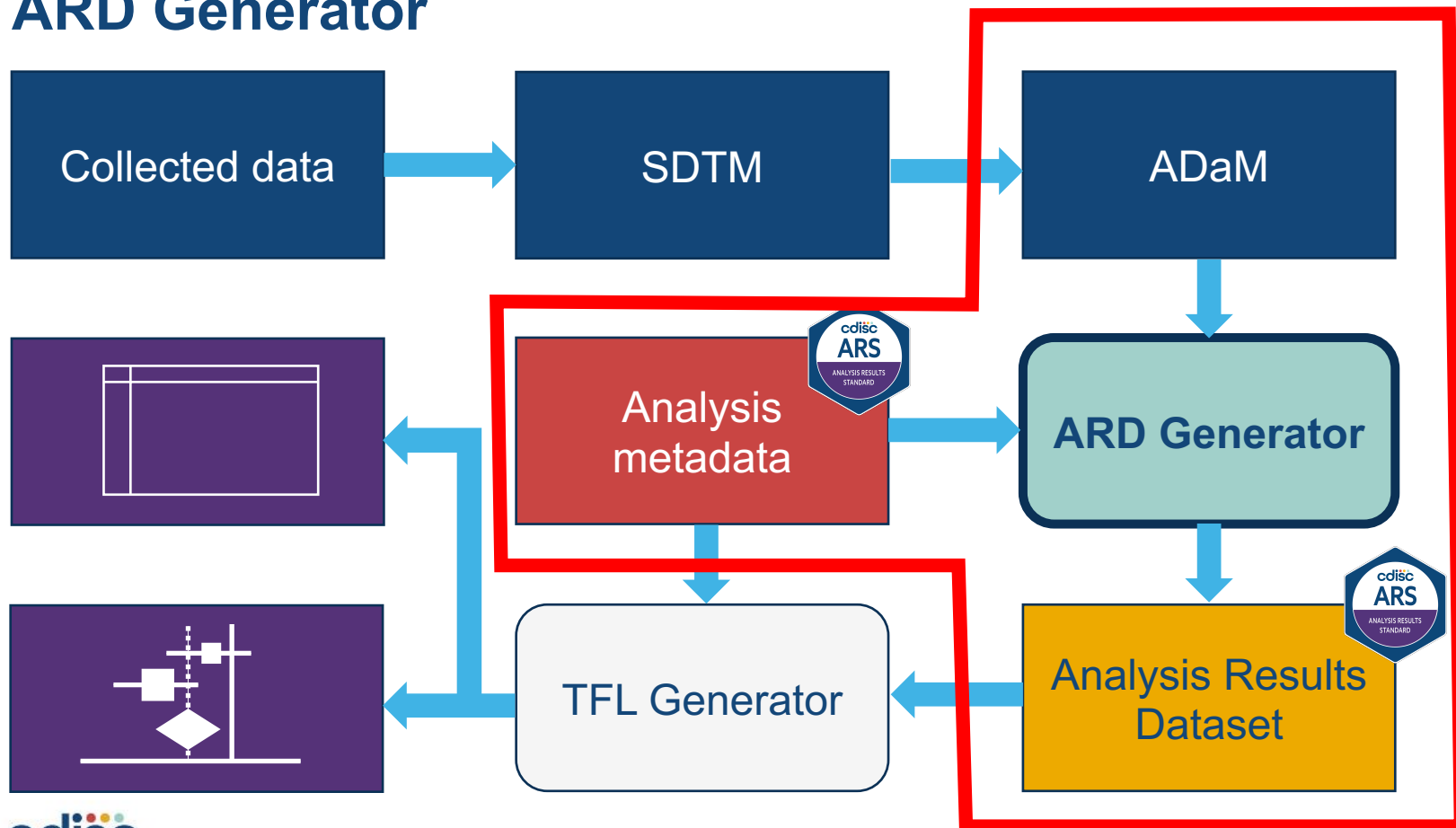


20 September 2023

Karl Wallendszus, University of Oxford



ARD Generator



Analysis Results Data with {cards} R Package



September 20, 2023

Daniel D. Sjoberg



Genentech
A Member of the Roche Group

R package: {cards}: CDISC Analysis Results Data Sets

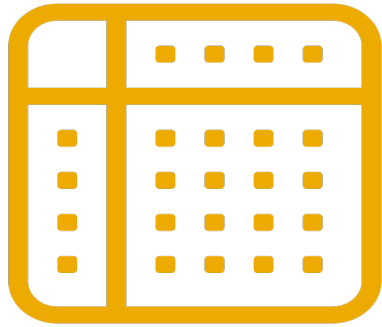
Continuous Summaries

To get a continuous variable summary, we will use the `ard_continuous()` function from the **{cards}** package.

```
df_continuous_ard <-  
  ard_continuous(  
    ADSL,  
    by = ARM,  
    variables = AGE,  
    statistic = ~ continuous_summary_fns(c("median", "p25", "p75", "mean", "sd", "m-  
  )  
df_continuous_ard |> head(5)  
#> {cards} data frame: 5 x 10  
#>   group1 group1_level variable stat_name stat_label  stat  
#> 1   ARM      Placebo      AGE      median      Median    76  
#> 2   ARM      Placebo      AGE      p25      25th Per...   69  
#> 3   ARM      Placebo      AGE      p75      75th Per...   82  
#> 4   ARM      Placebo      AGE      mean      Mean    75.209  
#> 5   ARM      Placebo      AGE      sd        SD      8.59  
#> i 4 more variables: context, fmt_fn, warning, error
```



What Is Next?: Adding Informative Content



Example ADaM
Datasets



Example of an Analysis
Results Dataset and
Associated Metadata



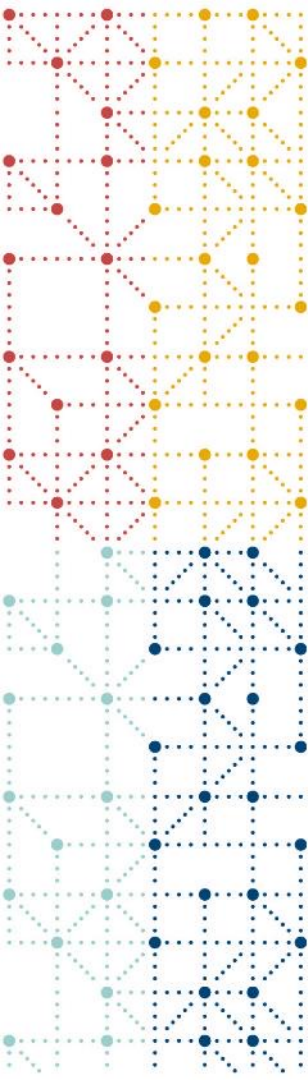
TFL Example

Proposed Collaboration with
PHUSE Safety Analytics
Working Group

Release Plan

Version 1.0

- Logical Data Model
- User Guide
- Common safety examples based on team and FDA developed tables
- CDISC ARS Hackathon: July 12th, 2023
- US Interchange Workshop: October 2023
- CDISC Public Review: Through January 15th, 2024
- Final Release: Q1/Q2 2024
- EU Interchange Workshop: April 2024



Thank you!



Bess LeRoy

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Bhavin Busa

ARS Product Owner & Co-Lead

bhavin@clymbclinical.com

Richard Marshall

Principal Data Modeler

rmarshall@accuratesystems.co.uk



What About ARM for Define.XML?

- At this point, no changes to ARM for Define.XML
- Retrospective documentation to aid in traceability
- Created to fill a specific regulatory need

