



# Getting Started with the New CDISC Analysis Results Standard

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# Agenda

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

# CDISC Foundational Standards

Example CDASH Data Collection Interface

Data Collection  
**CDASH**



STUDY	CDISC	CDASH	CDISC	CDASH	CDISC	CDASH	CDISC	CDASH	CDISC	CDASH
1	US	CD	US	CD	US	CD	US	CD	US	CD
2	US	CD	US	CD	US	CD	US	CD	US	CD
3	US	CD	US	CD	US	CD	US	CD	US	CD
4	US	CD	US	CD	US	CD	US	CD	US	CD
5	US	CD	US	CD	US	CD	US	CD	US	CD
6	US	CD	US	CD	US	CD	US	CD	US	CD
7	US	CD	US	CD	US	CD	US	CD	US	CD
8	US	CD	US	CD	US	CD	US	CD	US	CD
9	US	CD	US	CD	US	CD	US	CD	US	CD
10	US	CD	US	CD	US	CD	US	CD	US	CD

Data Aggregation  
**SDTM**



STUDY	CDISC	CDASH	CDISC	CDASH	CDISC	CDASH	CDISC	CDASH	CDISC	CDASH
1	US	CD	US	CD	US	CD	US	CD	US	CD
2	US	CD	US	CD	US	CD	US	CD	US	CD
3	US	CD	US	CD	US	CD	US	CD	US	CD
4	US	CD	US	CD	US	CD	US	CD	US	CD
5	US	CD	US	CD	US	CD	US	CD	US	CD
6	US	CD	US	CD	US	CD	US	CD	US	CD
7	US	CD	US	CD	US	CD	US	CD	US	CD
8	US	CD	US	CD	US	CD	US	CD	US	CD
9	US	CD	US	CD	US	CD	US	CD	US	CD
10	US	CD	US	CD	US	CD	US	CD	US	CD

Analysis  
**ADaM**



STUDY	CDISC	CDASH	CDISC	CDASH	CDISC	CDASH	CDISC	CDASH	CDISC	CDASH
1	US	CD	US	CD	US	CD	US	CD	US	CD
2	US	CD	US	CD	US	CD	US	CD	US	CD
3	US	CD	US	CD	US	CD	US	CD	US	CD
4	US	CD	US	CD	US	CD	US	CD	US	CD
5	US	CD	US	CD	US	CD	US	CD	US	CD
6	US	CD	US	CD	US	CD	US	CD	US	CD
7	US	CD	US	CD	US	CD	US	CD	US	CD
8	US	CD	US	CD	US	CD	US	CD	US	CD
9	US	CD	US	CD	US	CD	US	CD	US	CD
10	US	CD	US	CD	US	CD	US	CD	US	CD

Results  
**???**



Table 4.2.2: HbA1c Longitudinal Repeated Measures Analysis Results Metadata	
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
RESULT IDENTIFIER	Period, Intention-to-treat Population
PARAM	Treatment difference results (LSMean, confidence interval, p-value)
PARAMCD	HbA1c (%)
ANALYSIS VARIABLE	HBA1C
ANALYSIS REASON	CHG (Change from baseline)
ANALYSIS PURPOSE	SPECIFIED IN SAP
ANALYSIS DATASET	PRIMARY OUTCOME MEASURE
	ADHBA1C

**ARM for Define.XML**



# Analysis Results Key Objectives

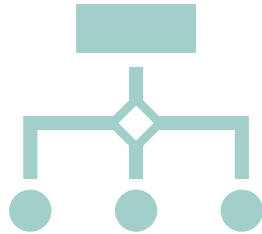


Leverage analysis results metadata to drive the automation of results

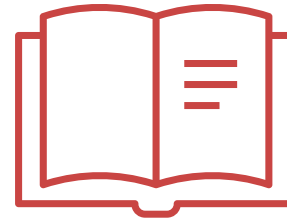


Support storage, access, processing, traceability and reproducibility of results

# Analysis Results Standards Key Results

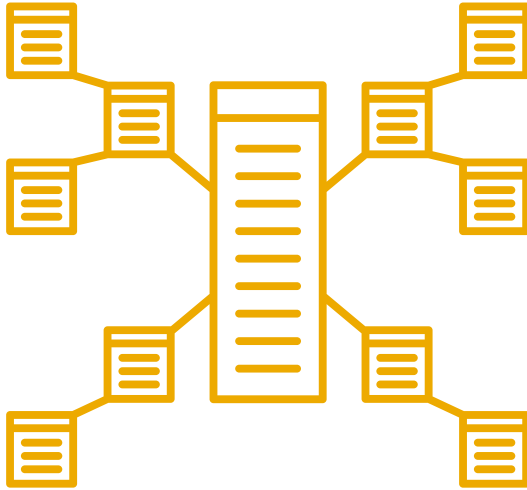


**Logical Model** that describes analysis results and associated metadata



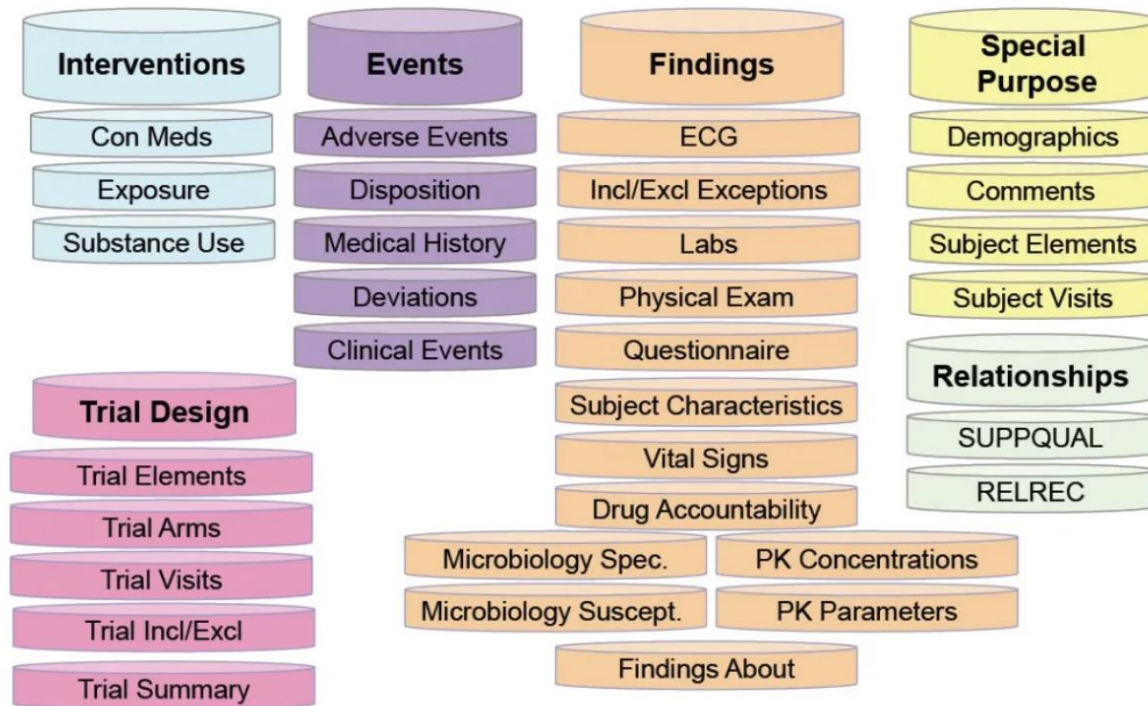
**User Guide** to illustrate and exercise model with common safety displays

# What is a Logical Data Model?



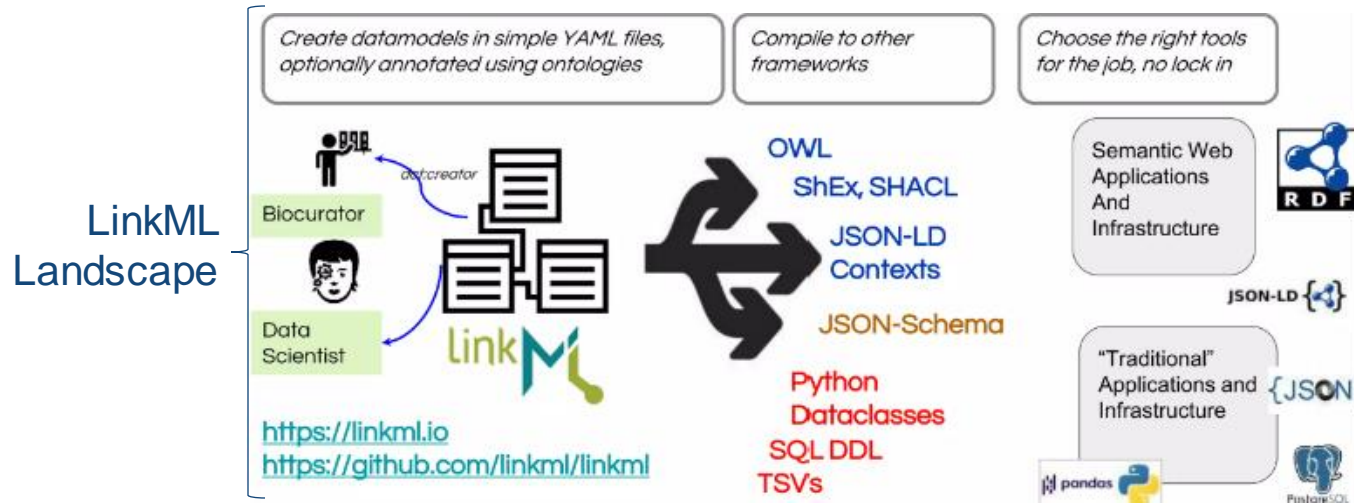
- A logical data model establishes the structure of data components and the relationships between them
- Designed to accurately represent complexity of all components
- It is independent of the physical database design

# SDTM Model Representation



# Using LinkML to Create Analysis Results Model

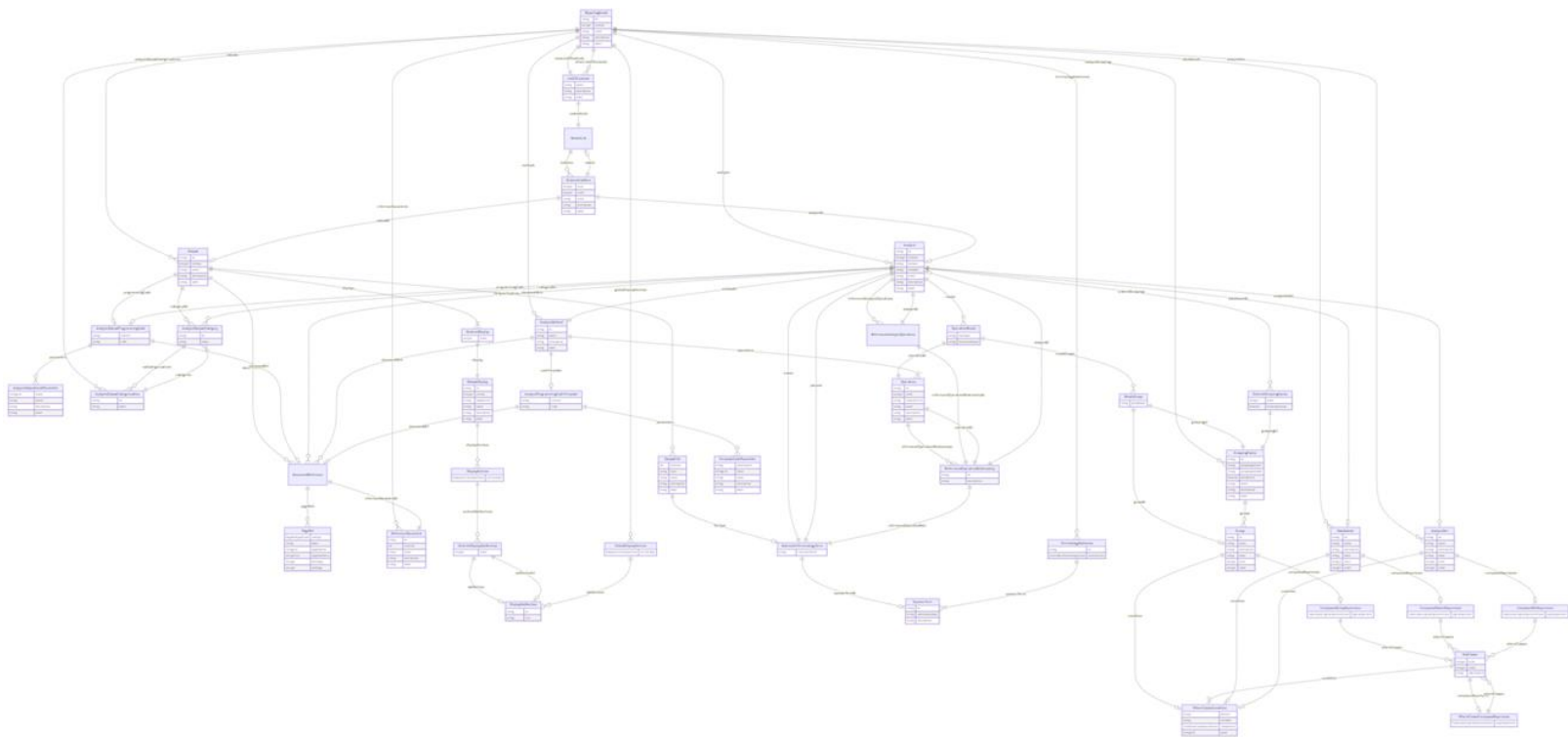
- LinkML is a general-purpose modeling language that can be used with linked data, JSON, and other formalisms



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



# ARS Logical Model Schema Diagram



# Analysis Results Standard Model and User Guide

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

Analysis Results Standard (ARS) 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
<a href="#">NamedObject</a>	An object with a name
<a href="#">ReportingEvent</a>	A set of analyses and outputs created to meet a specific reporting requiremen...
<a href="#">NestedList</a>	A list of items (analyses or outputs) that may be organized within sub-lists



## Analysis Results Standard User Guide

Version 1.0 (Final)

Prepared by the  
Analysis Results Standard Team

### Notes to Readers

- This is the final 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

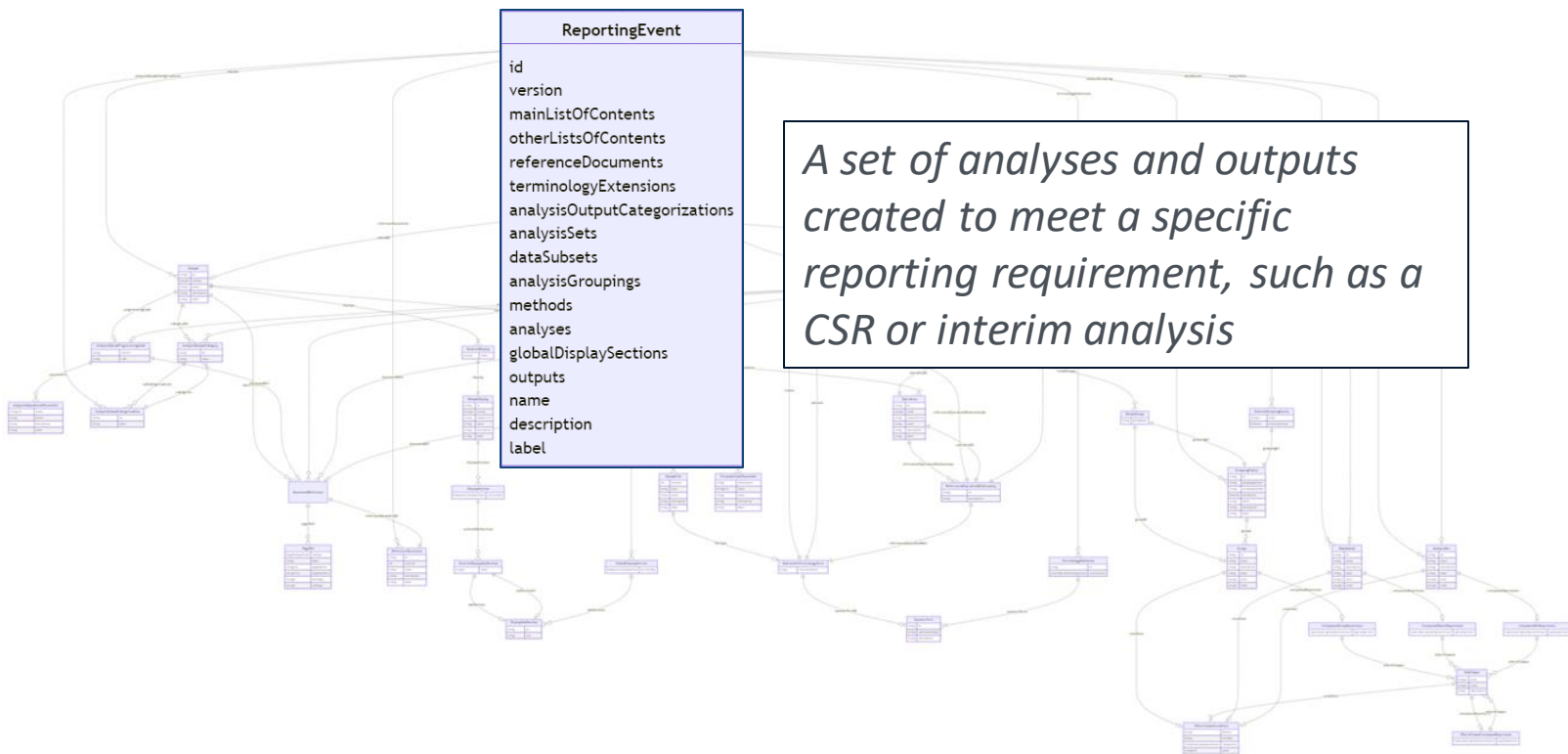
Date	Version
2024-04-19	Final

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<https://wiki.cdisc.org/display/ARSP/Analysis+Results+User+Guide>

# ARS Logical Model Schema Diagram: Reporting Event



# Model Components

## Reporting Event

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

### Summary of TEAE by SOC and PT

Study - CDISC 360 Page x of y

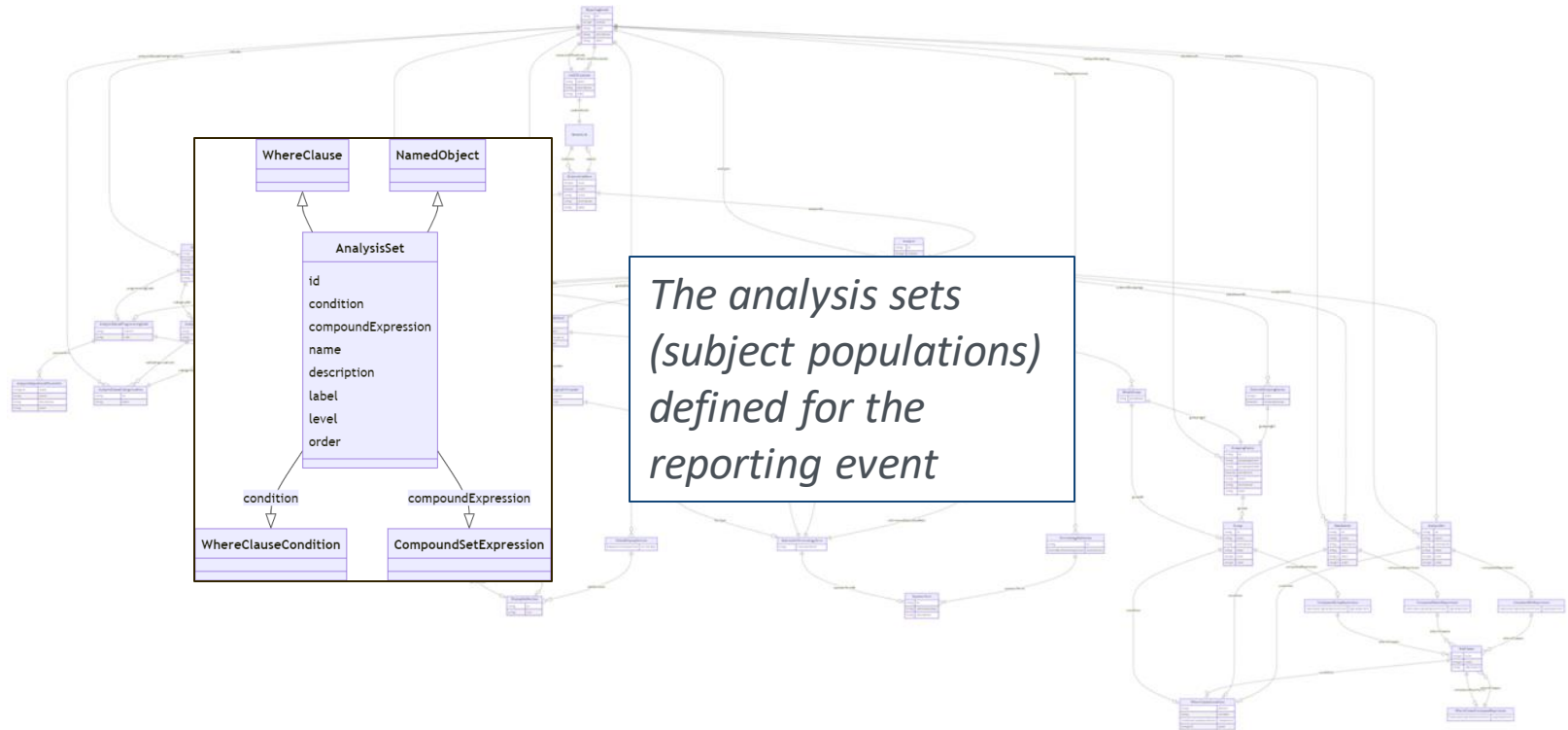
Table 14.3.1.1  
Summary of TEAE by System Organ Class and Preferred Term  
Safety Population

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

# ARS Logical Model Schema Diagram: Analysis Set



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

### Summary of TEAE by SOC and PT

Study - CDISC 360 Page x of y

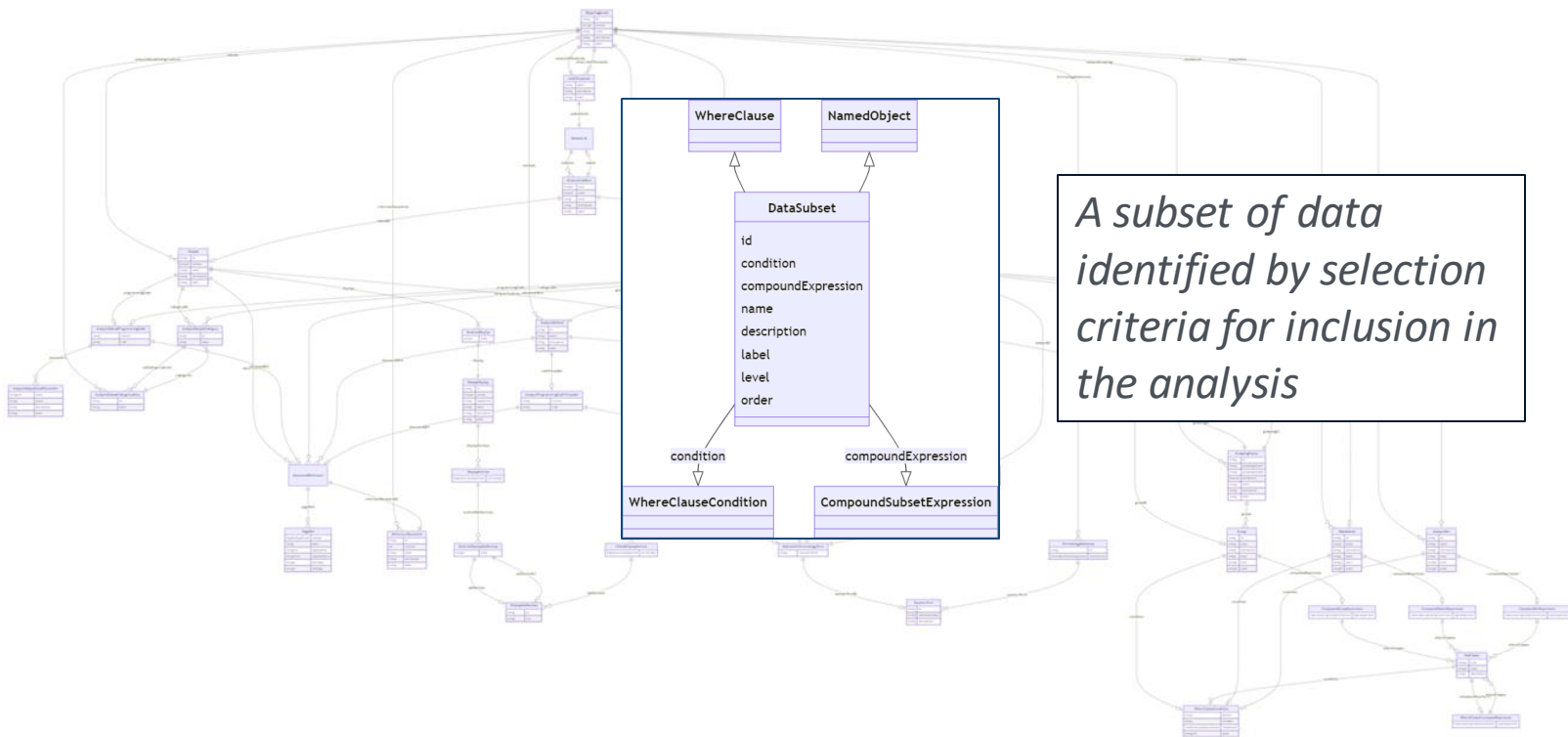
Table 14.3.1.1  
Summary of TEAE by System Organ Class and Preferred Term  
**Safety Population**

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

# ARS Logical Model Schema Diagram: Data Subset



# Model Components

## Data Subset

### 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

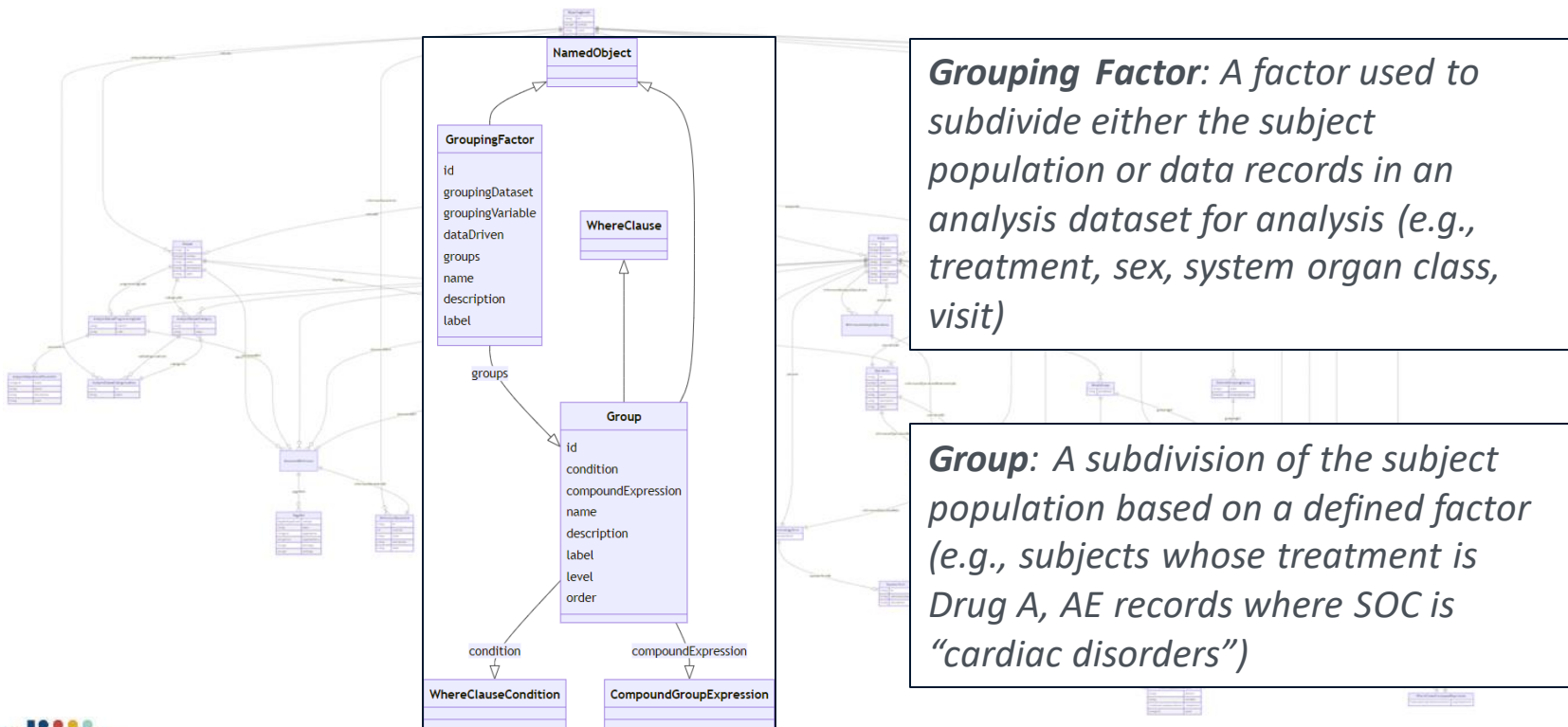
System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<SOC 1>	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<Preferred Term 1>	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
...	XX ( XX.X)	XX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



# Model Components

## Analysis Grouping

### 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

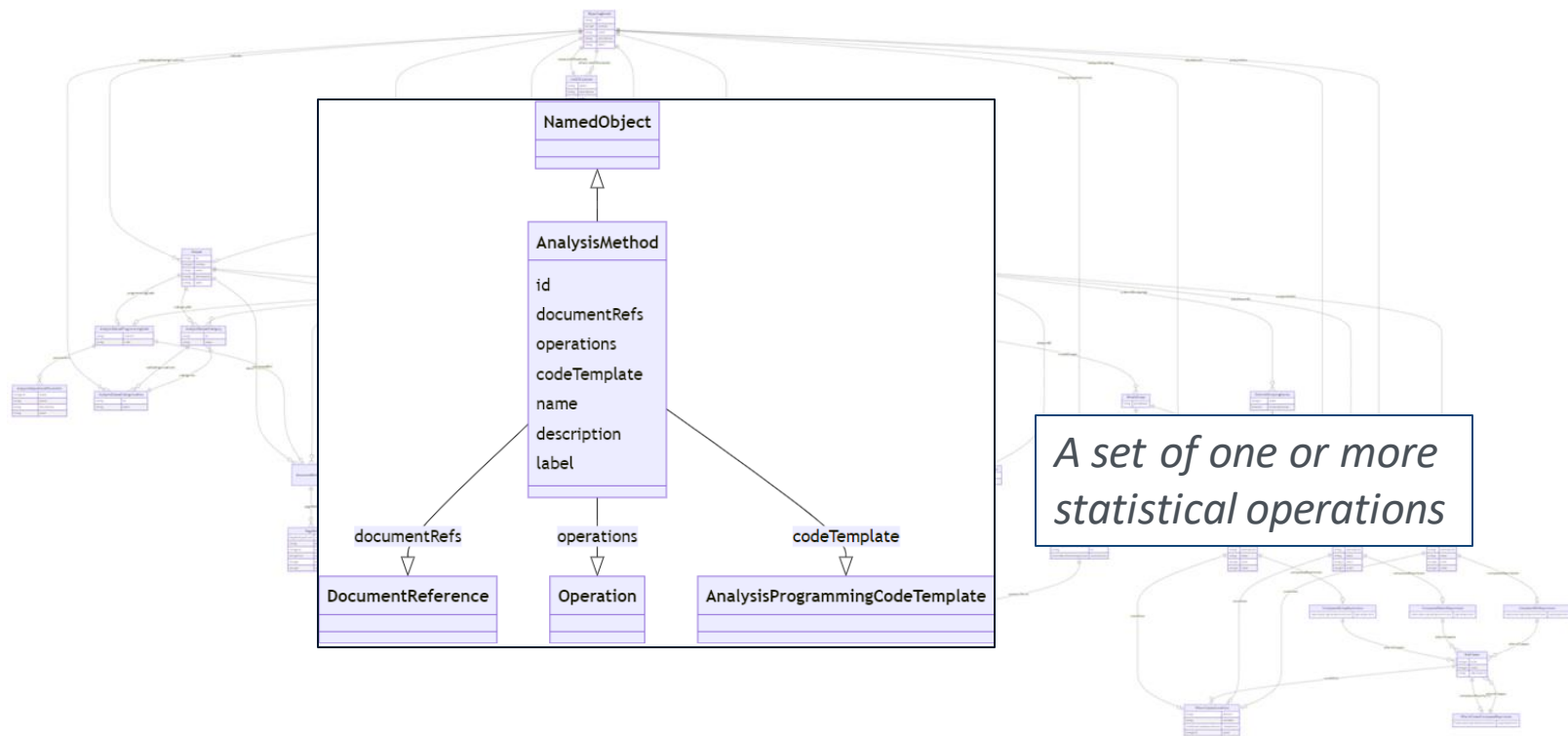
Table 14.3.1.1  
Summary of TEAE by System Organ Class and Preferred Term  
Safety Population

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: Analysis Method



# Model Components

## Analysis Method

### 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)
<b>Age (years)</b>			
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
<b>Age Group, n (%)</b>			
< 65 years	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
≥ 65 years	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<b>Gender, n (%)</b>			
Male	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
Female	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<b>Ethnicity, n (%)</b>			
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

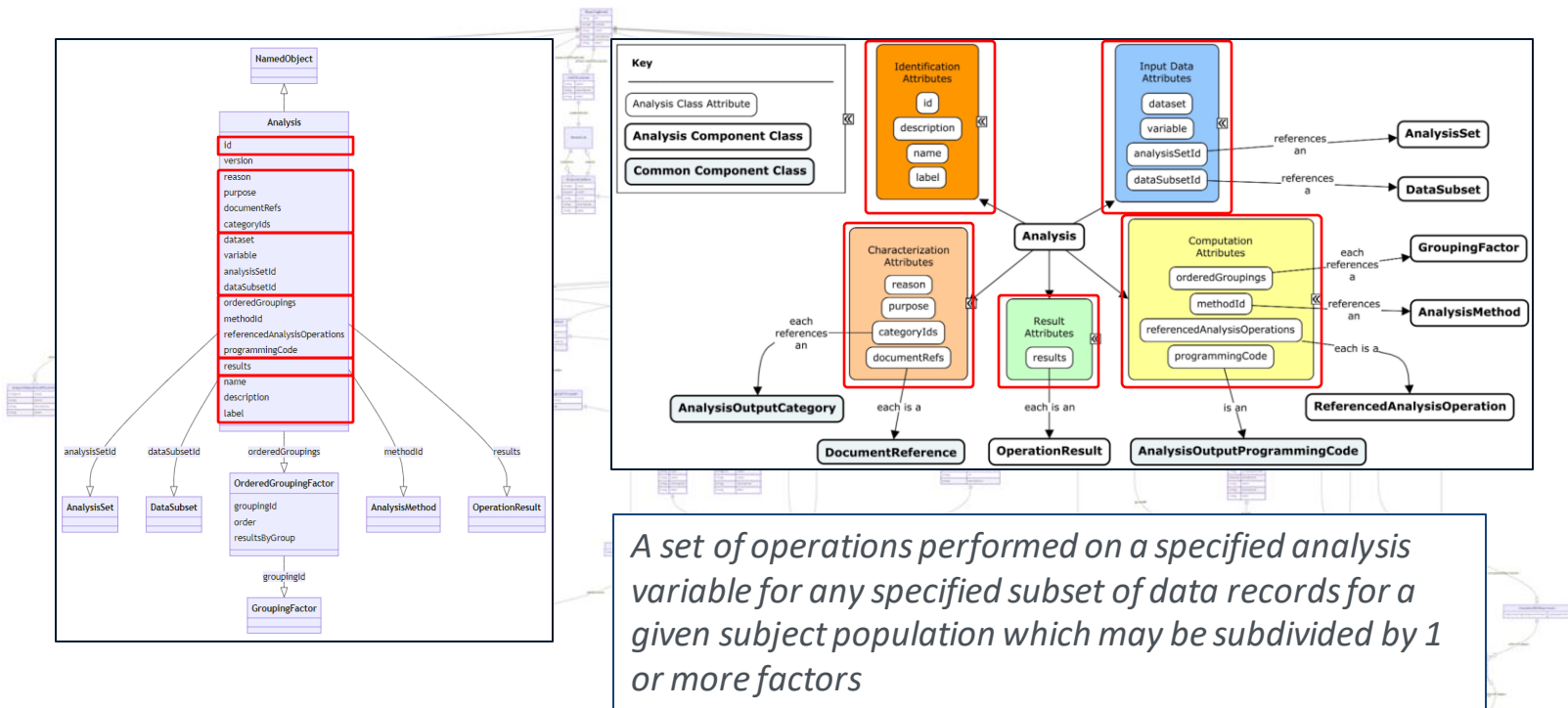
Table 14.3.1.1  
Summary of TEAE by System Organ Class and Preferred Term  
Safety Population

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



# Model Components

## Analysis

### 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

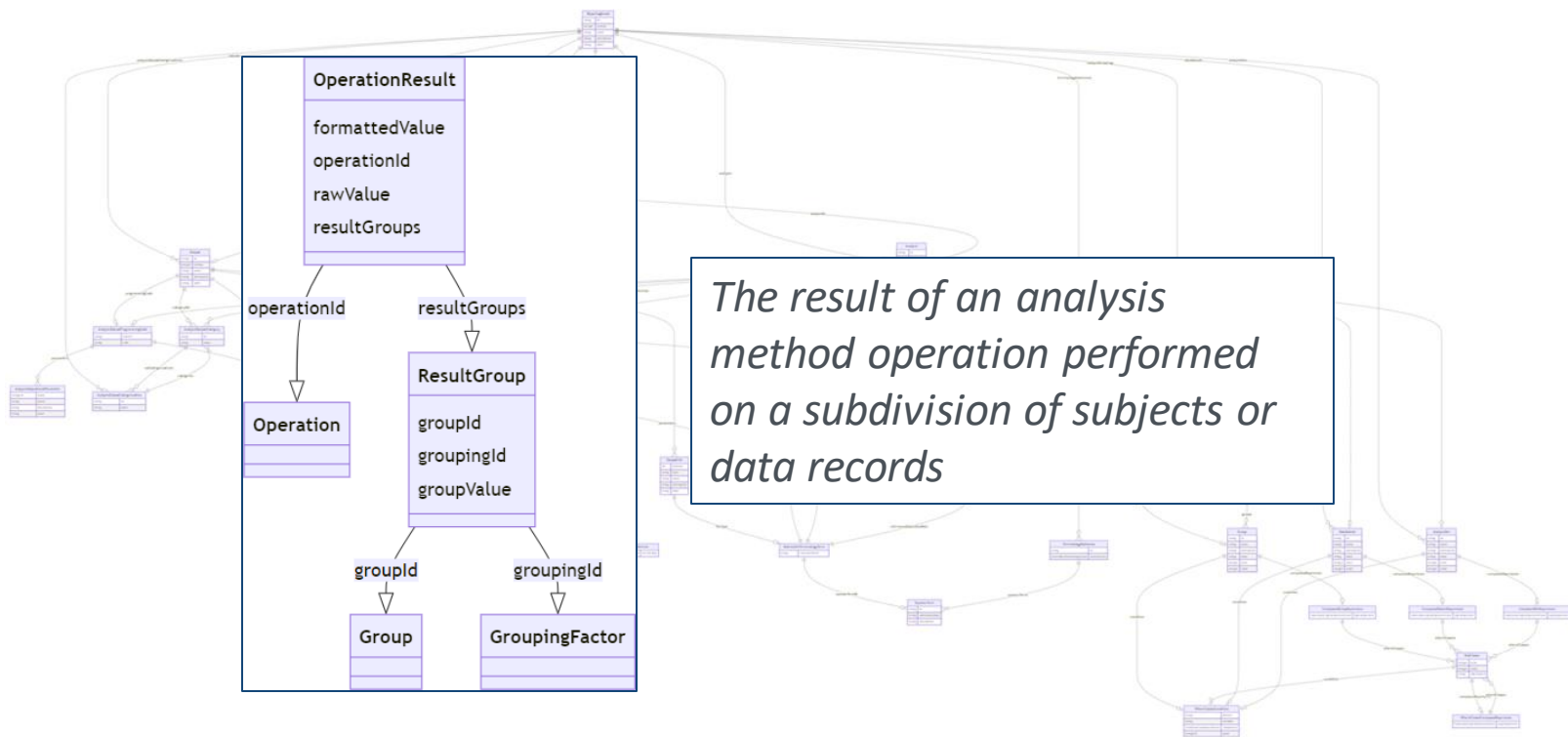
Table 14.3.1.1  
Summary of TEAE by System Organ Class and Preferred Term  
Safety Population

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: Results



# Model Components

## Results

### 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

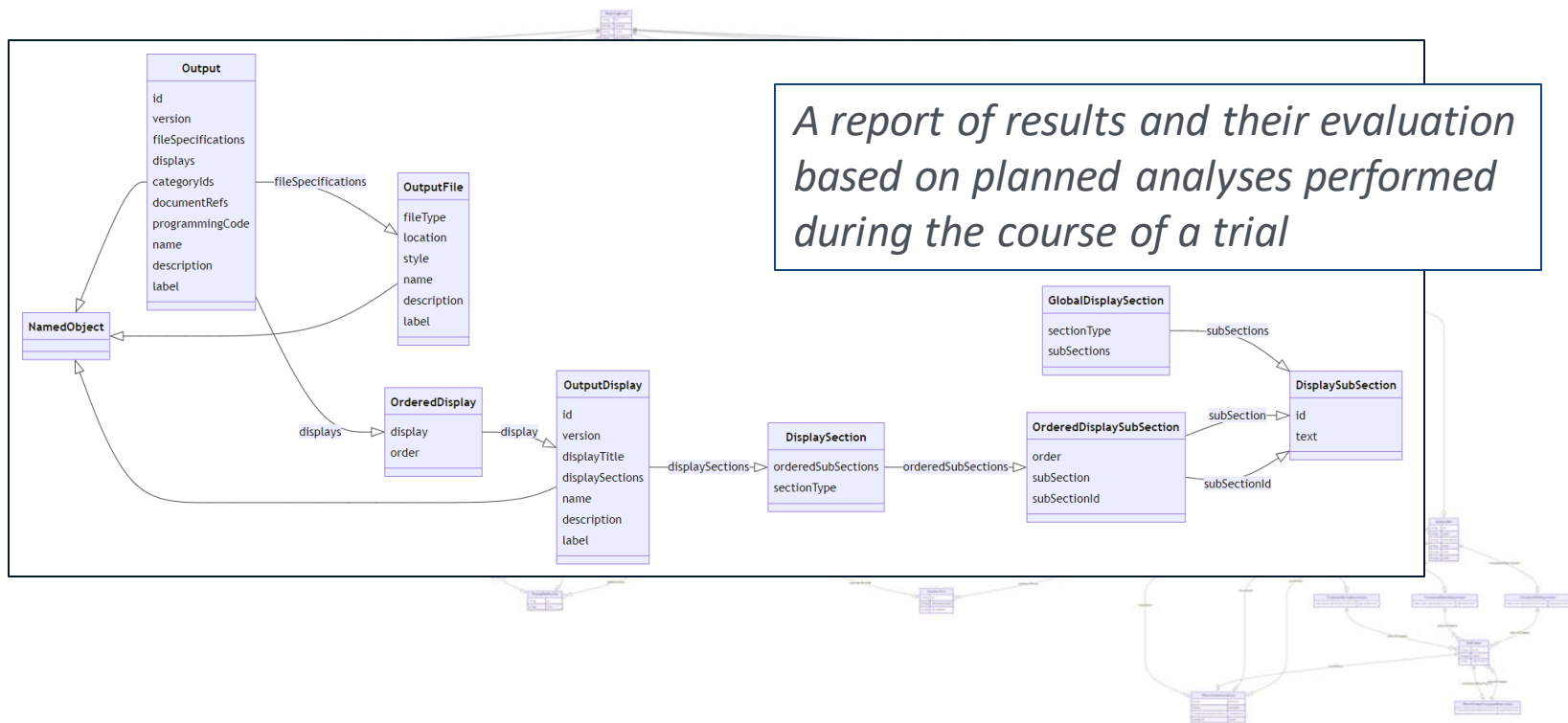
System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<SOC 1>	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<Preferred Term 1>	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
...	XX ( XX.X)	XX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



# Model Components

## Output

### 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 (%)
<b>Sex, n (%)</b>	n (%)	n (%)	n (%)	n (%)	n (%)
Male	n (%)	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)	n (%)
<b>Age, years</b>	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)
<b>Age groups (years), n (%)</b>	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 (%)
<b>Race, n (%)</b>	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].  
<sup>1</sup> 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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# Leveraging ARS Metadata to Drive Results Automation

## ARS Metadata

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}
    
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## ADaM Dataset

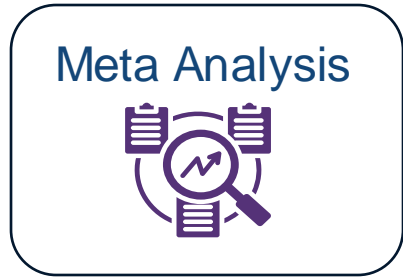
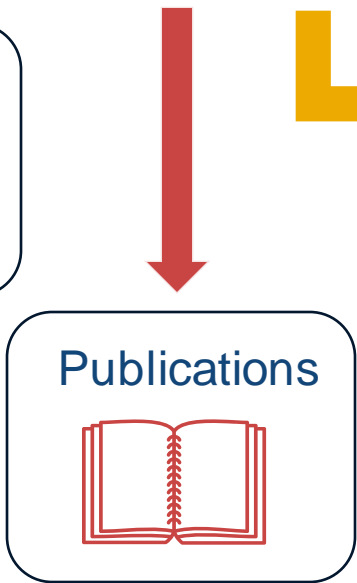
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01-701-1023	Placebo	64	<65	YEARS	WHITE	M
01-701-1028	Xanomeline High Dose	71	65+	YEARS	WHITE	M
01-701-1033	Xanomeline Low Dose	74	65+	YEARS	WHITE	M
01-701-1034	Xanomeline High Dose	77	65+	YEARS	WHITE	F
01-701-1047	Placebo	85	65+	YEARS	WHITE	F

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An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeSp	AnlsGrouping_03_AgeGrp_2	72	72
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeSp	AnlsGrouping_03_AgeGrp_1	8	8
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeSp	AnlsGrouping_03_AgeGrp_2	76	76
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An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeSp	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_AgeSp	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_AgeSp	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_AgeSp	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_AgeSp	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_AgeSp	AnlsGrouping_03_AgeGrp_2	86.90476	( 86.9)

## Analysis Results Dataset

# Analysis Results: Create Once, Use Many Times

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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 consolidate 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> (cunit)			
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> (cunit)						
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](mailto: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)

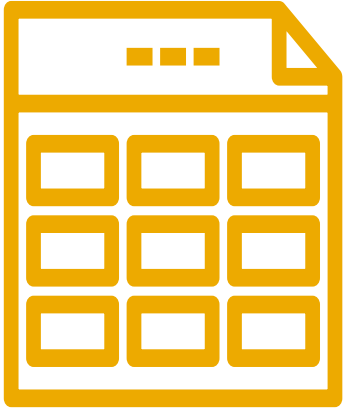
Characteristic	Drug Name	Drug Name	Placebo	Active Control	Total
	Dosage X	Dosage Y			
	N = XXX	N = XXX	N = XXX	N = XXX	Population
	n (%)	n (%)	n (%)	n (%)	N = XXX
	n (%)	n (%)	n (%)	n (%)	n (%)
<b>Sex, n (%)</b>	n (%)	n (%)	n (%)	n (%)	n (%)
Male	n (%)	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)	n (%)
<b>Age, years</b>	<b>X.X (Y.Y)</b>	<b>X.X (Y.Y)</b>	<b>X.X (Y.Y)</b>	<b>X.X (Y.Y)</b>	<b>X.X (Y.Y)</b>
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)
<b>Age groups (years), n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>
≥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 (%)
<b>Race, n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>
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].

<sup>1</sup> 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 Safety Tables and Figures
  - Table 2: Baseline Demographic and Clinical Characteristics, Safety Population



# Analysis Results Standard Published!



[New to CDISC](#) [Standards](#) [Education](#) [Resources](#) [Events](#) [Membership](#)

## Foundational

[BRIDG](#)

[SEND](#)

[CDASH](#)

[SDTM](#)

[SDTMIG](#)

[ADaM](#)

[Analysis Results](#)

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## Analysis Results Standard

**Description**

**Versions**

Large trials generate many analysis results in the form of tables, figures, and written reports, yet these results are rarely output in a form that is machine-readable. Additionally, there is no standard way of describing and organizing these results, making it difficult to automate their generation, make them reproducible, trace their origin or enable them to be reused in other outputs.

To address these inefficiencies, CDISC has developed the Analysis Results Standard (ARS), which aim to facilitate automation, reproducibility, reusability, and traceability of analysis results data.

### Key Objectives

- Use analysis results metadata to drive the automation of results.
- Store, access, process and reproduce results.
- Improve navigation and reusability of analyses and results.
- Provide traceability to Protocol/Statistical Analysis Plan and to input ADaM data.

### Key Results

- A Logical Data Model that describes analysis results and associated metadata.
- A User Guide to illustrate and exercise the model with common safety displays.



**ARS Model Will Drive  
Automation and  
Open-Source Tool  
Development**





## CDISC ARS Hackathon

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Drive adoption of CDISC  
Analysis Results Standard

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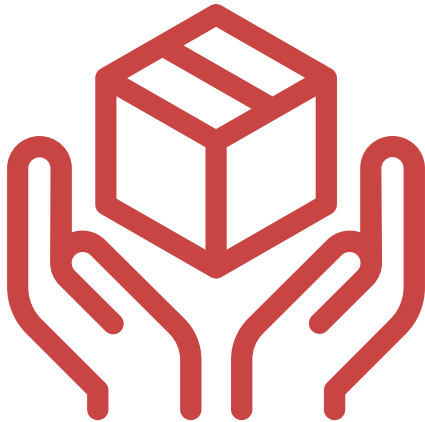
Foster open-source software  
tools for operationalization

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Leveraging hackathon  
learnings to enhance the  
standards

# What's Next?

## eTFL Portal Package



- Analysis Concept
- ADaM Dataset and Metadata
- ARS Metadata
- Analysis Results Dataset
- Display



**Thank you!**



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