Getting Started with the New CDISC Analysis Results Standard

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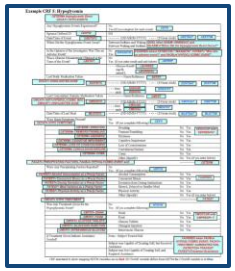
Richard Marshall, Principal Data Modeler, CDISC

Agenda

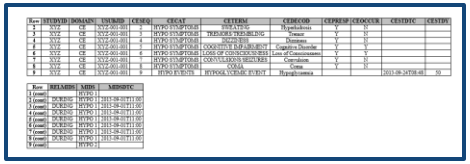
- Project Background
- ARS Model and User Guide
- Open-Source Tool Development
- Next Steps
- Q&A

CDISC Foundational Standards



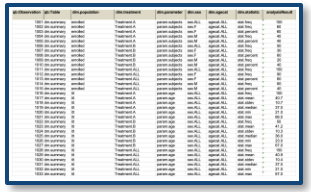
Data Collection

CDASH



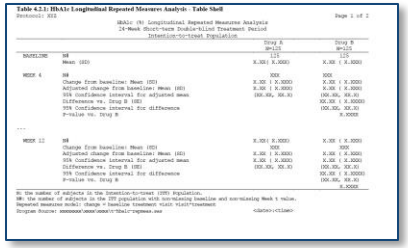
Data Aggregation

SDTM



Analysis

ADaM



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 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

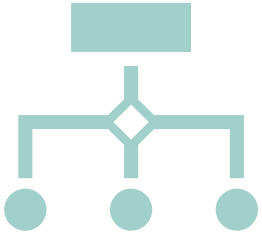
ARM for Define.XML

Analysis Results Key Objectives

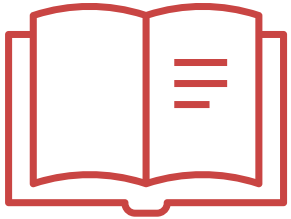
Leverage analysis results metadata to drive the automation of results

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

Analysis Results Standards Key Results

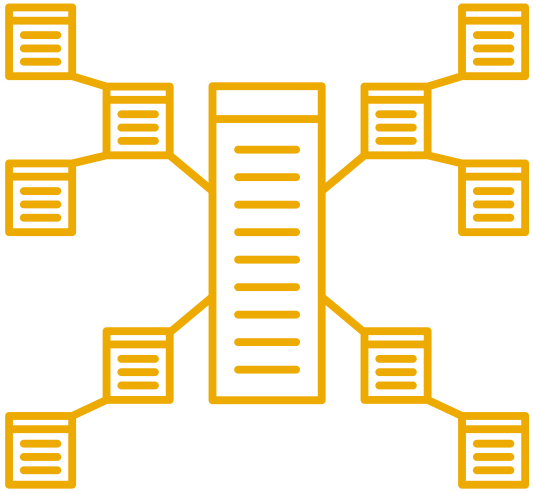


Logical Model that describes analysis results and associated metadata



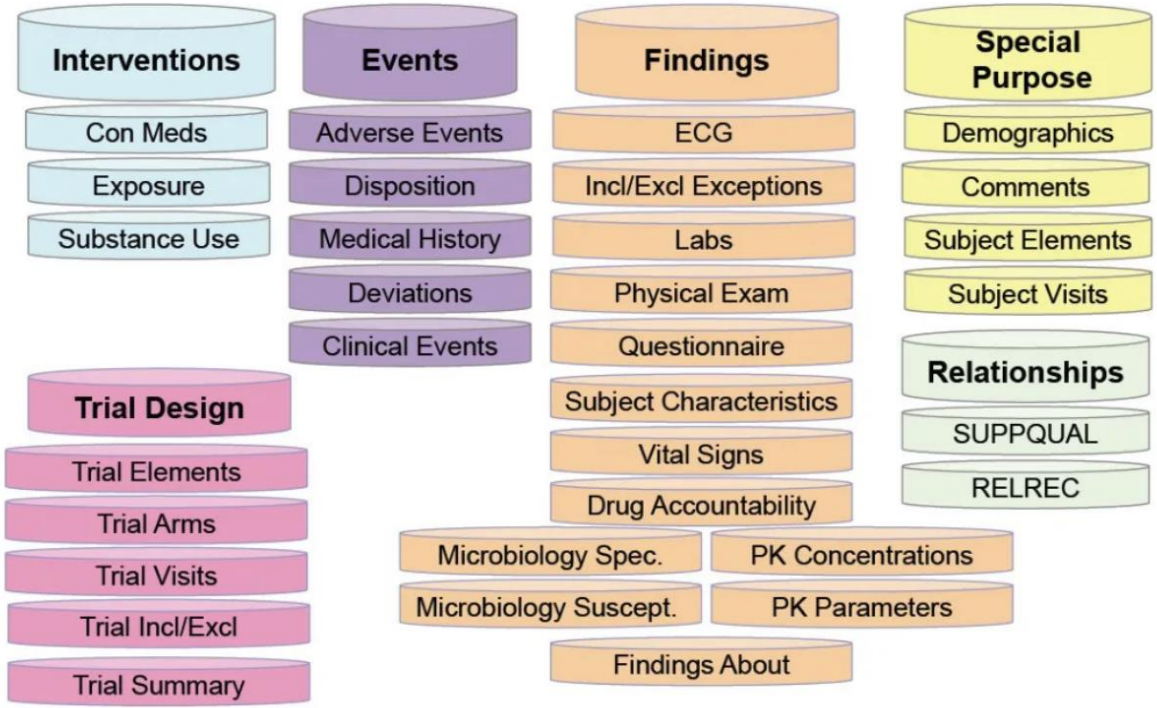
User Guide to illustrate and exercise model with common safety displays

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

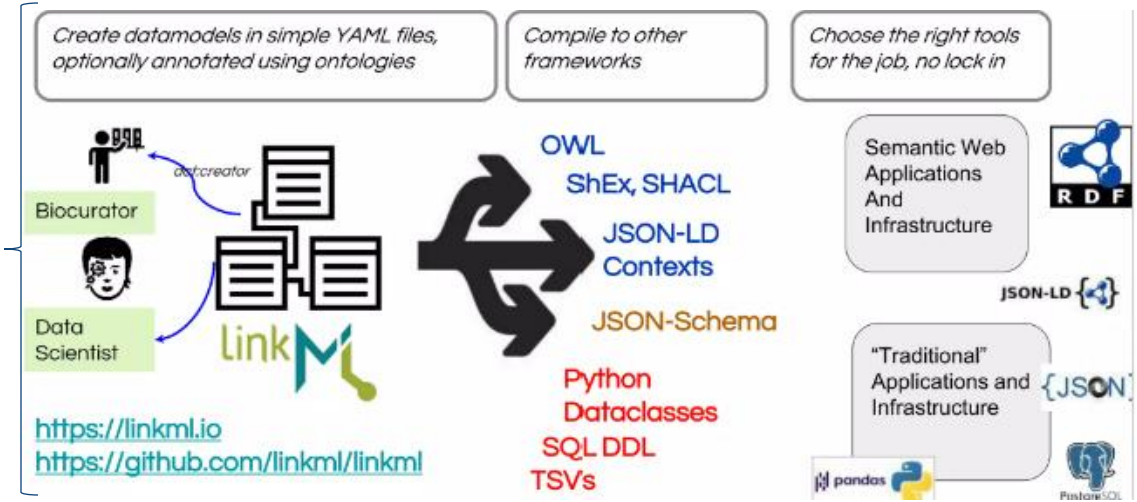
SDTM Model Representation



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

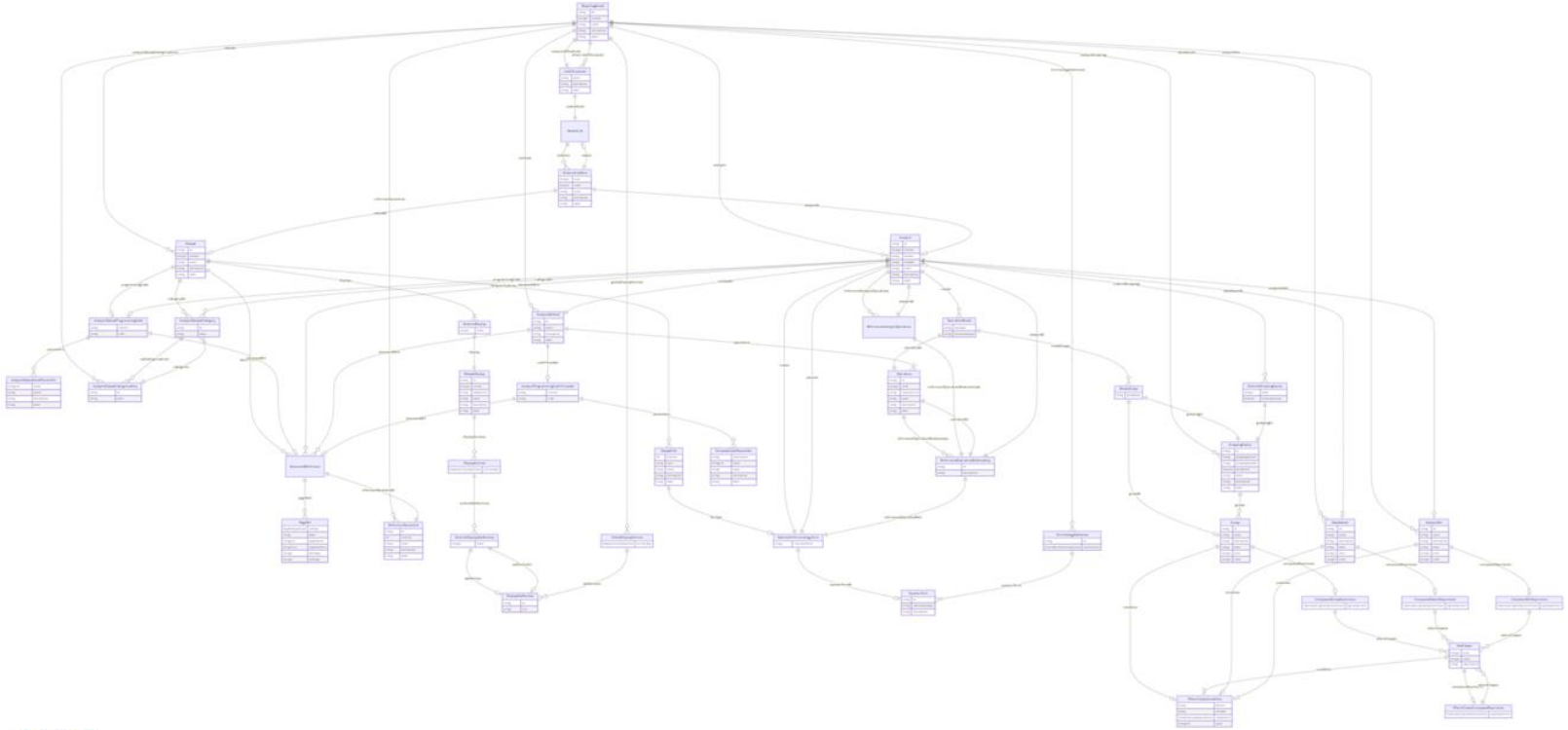
LinkML Landscape



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

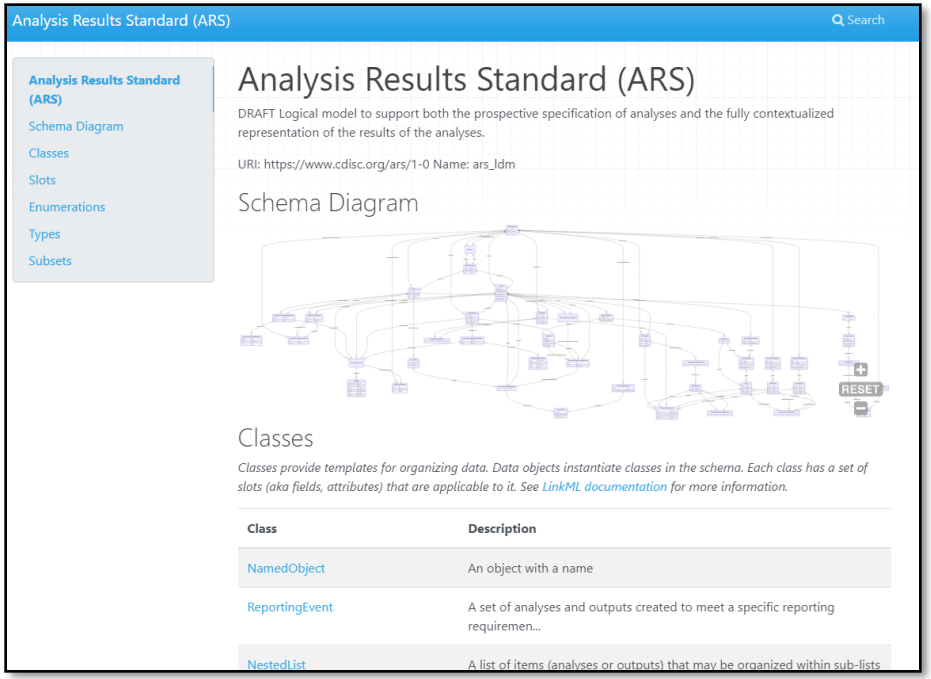
cdisc

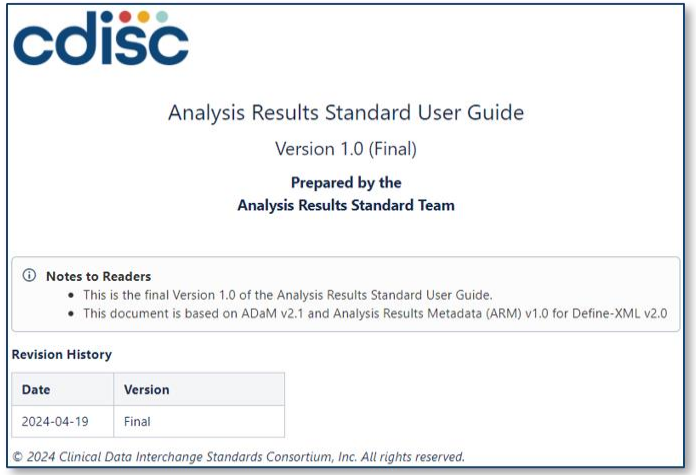
ARS Logical Model Schema Diagram



Analysis Results Standard Model and User Guide

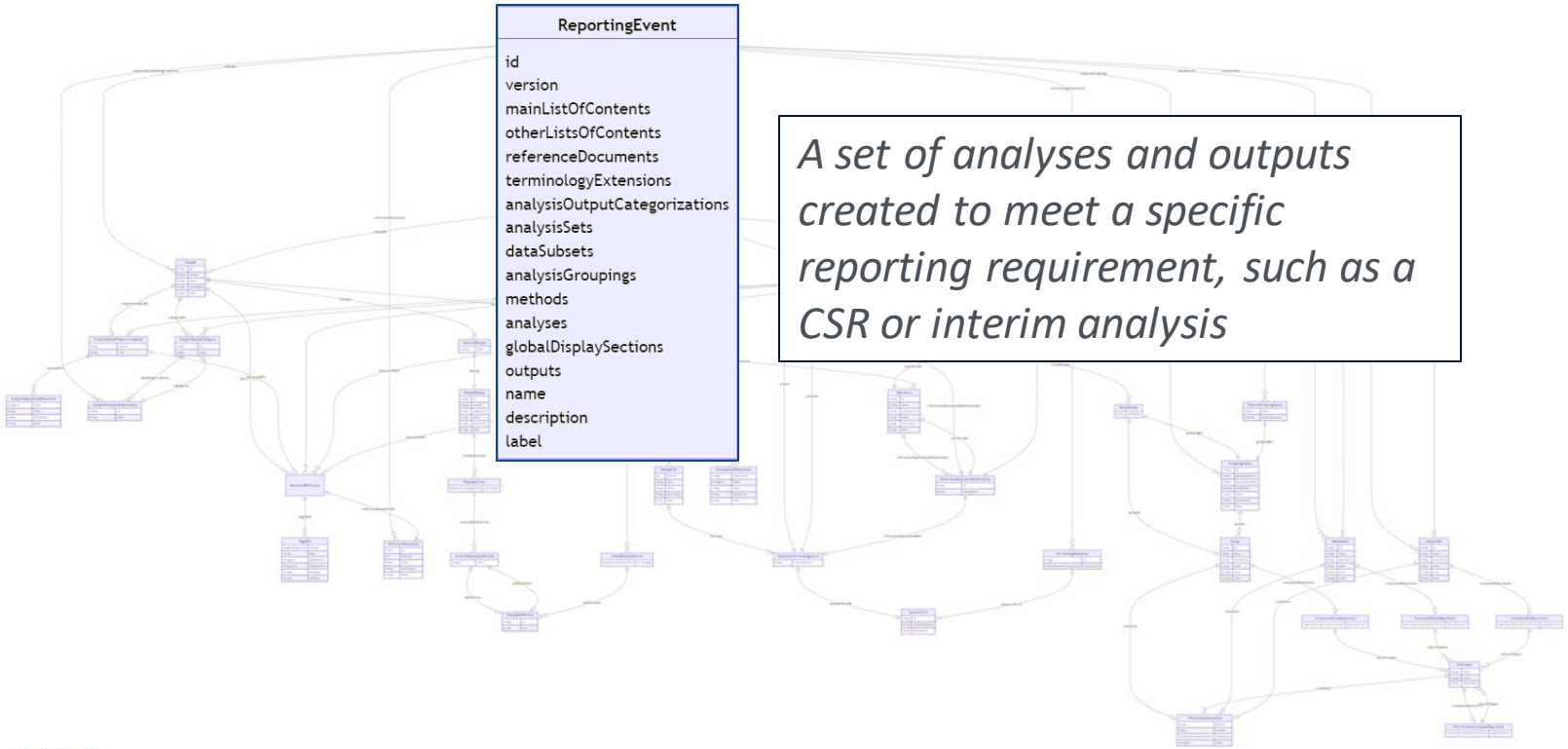
https://cdisc-org.github.io/analysis-results-standard/





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

ARS Logical Model Schema Diagram: Reporting Event



A set of analyses and outputs created to meet a specific reporting requirement, such as a CSR or interim analysis

Model Components

Reporting Event

Summary of Demographics

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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

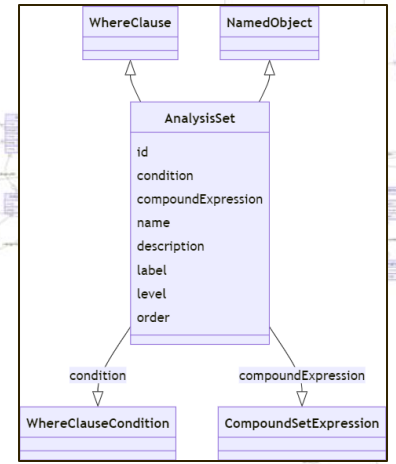
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

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 Set



The analysis sets (subject populations) defined for the reporting event

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

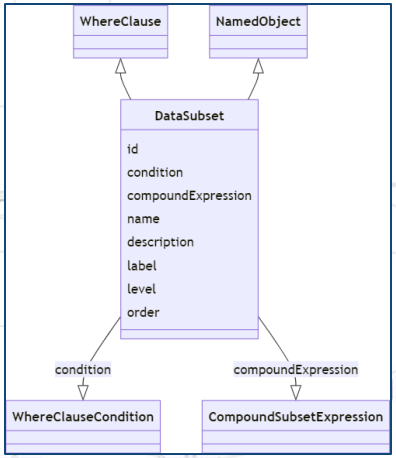
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

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



A subset of data identified by selection criteria for inclusion in the analysis

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.

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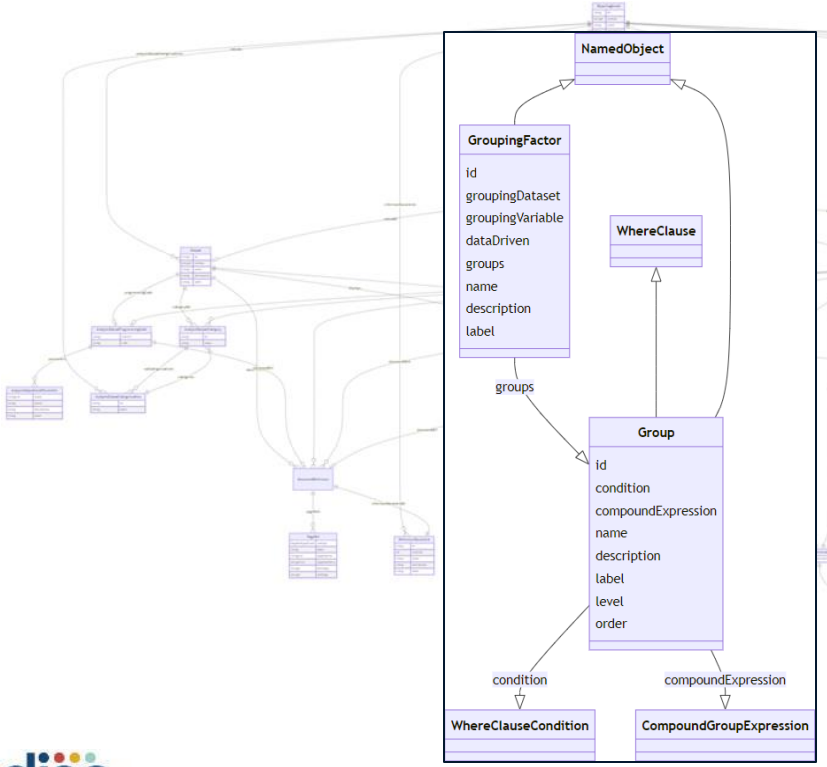
Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM

ARS Logical Model Schema Diagram: Analysis Grouping



***Grouping Factor**: A factor used to subdivide either the subject population or data records in an analysis dataset for analysis (e.g., treatment, sex, system organ class, visit)*

***Group**: A subdivision of the subject population based on a defined factor (e.g., subjects whose treatment is Drug A, AE records where SOC is "cardiac disorders")*

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

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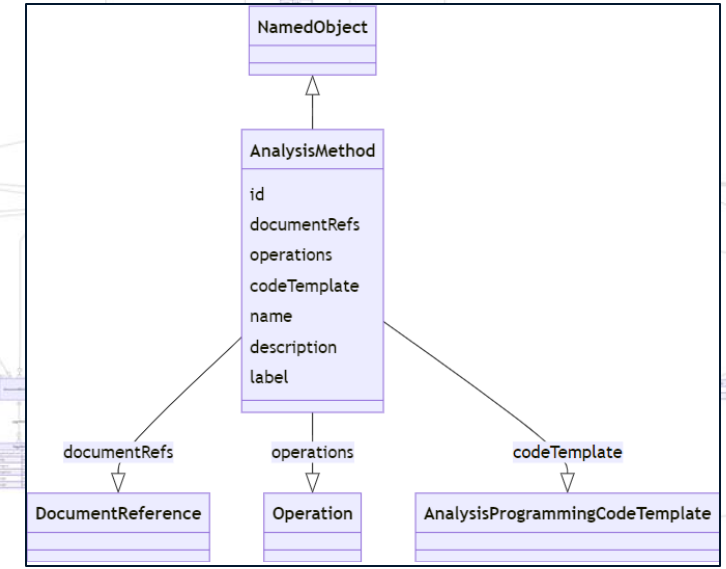
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

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



A set of one or more statistical operations

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)
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

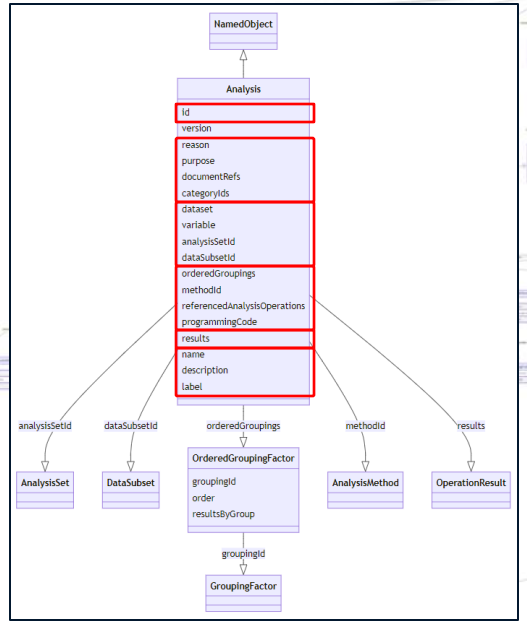
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

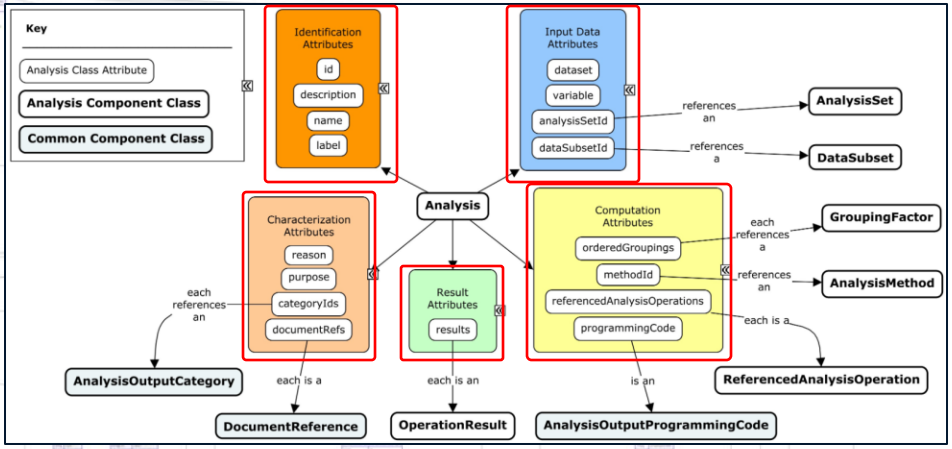
System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Preferred Term 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)
...	XX (XX.X)	XX (XX.X)	XX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





A set of operations performed on a specified analysis variable for any specified subset of data records for a given subject population which may be subdivided by 1 or more factors

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

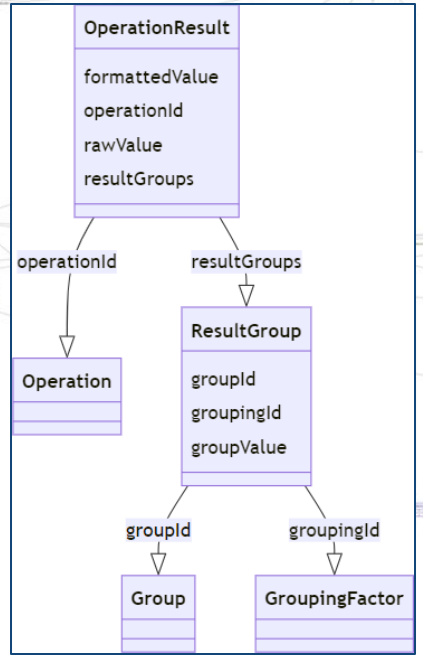
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

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



The result of an analysis method operation performed on a subdivision of subjects or data records

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

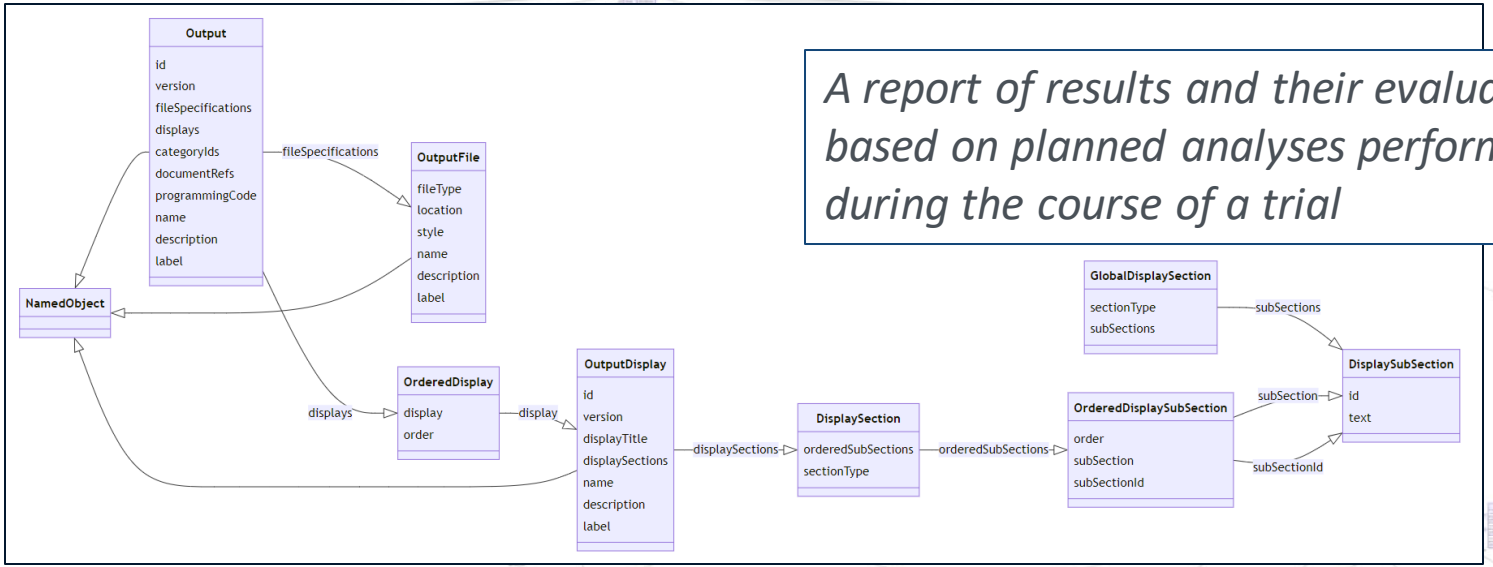
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

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



A report of results and their evaluation based on planned analyses performed during the course of a trial

Model Components

Output

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

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	**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 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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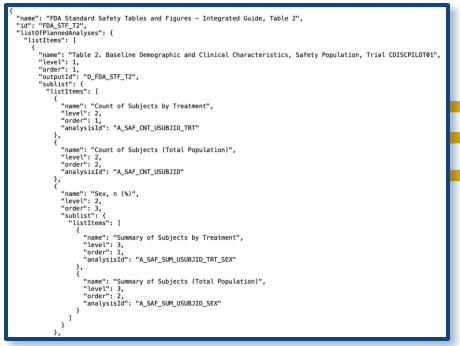
Leveraging ARS Metadata to Drive Results Automation

ARS Metadata



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         },
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          "name": "Summary of Subjects (Total Population)",
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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_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
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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)

Analysis Results Dataset

cdisc

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
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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)

Displays

Publications

Clinical Study Report

Meta Analysis

cdisc

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

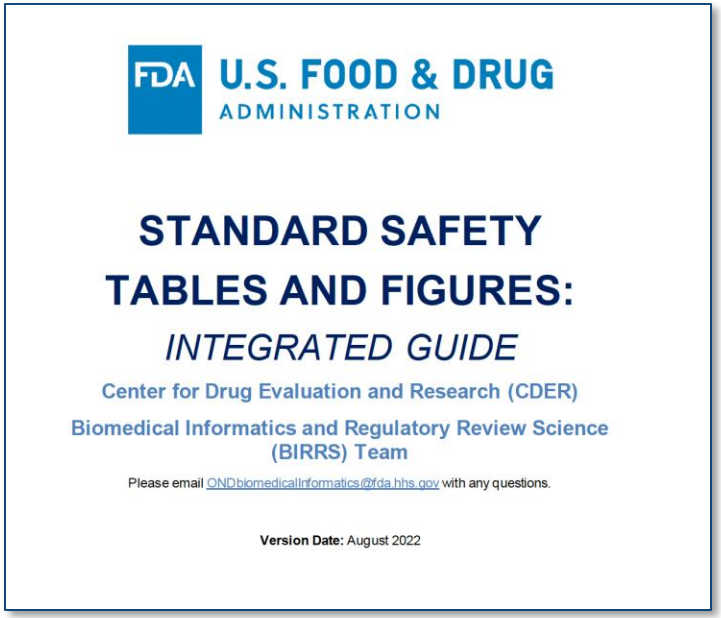
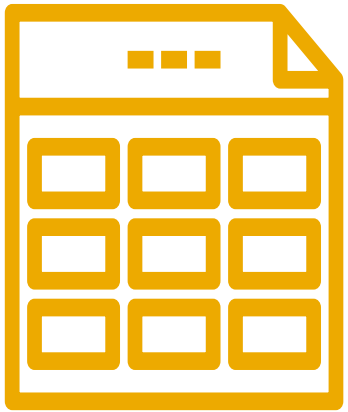


Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X)

Characteristic	Drug Name Dosage X N = XXX	Drug Name Dosage Y N = XXX	Placebo N = XXX	Active Control N = XXX	Total Population N = XXX
	n (%)	n (%)	n (%)	n (%)	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 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

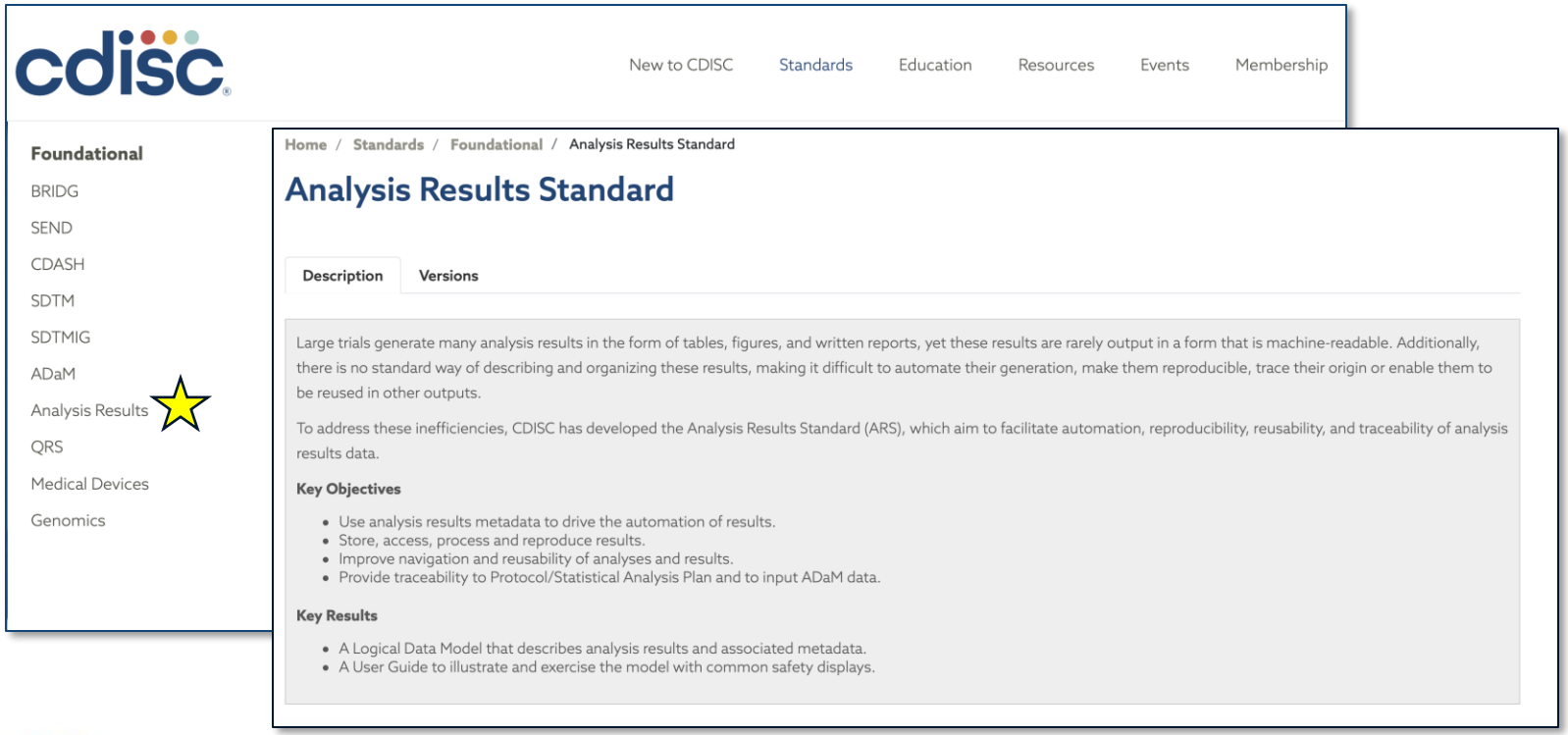
ARS User Guide Reporting Events Example



- 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 Safety Tables and Figures
  - Table 2: Baseline Demographic and Clinical Characteristics, Safety Population

Analysis Results Standard Published!



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ARS Model Will Drive Automation and Open-Source Tool Development

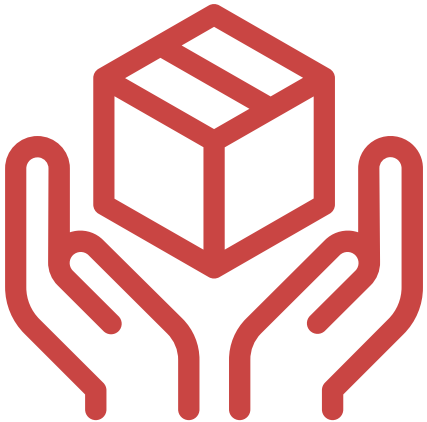
CDISC ARS Hackathon

Drive adoption of CDISC Analysis Results Standard

Foster open-source software tools for operationalization

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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