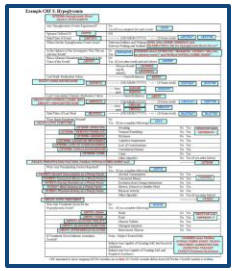
# Getting Started with the New CDISC Analysis Results Standard

Bess LeRoy, Head of Standards Innovation, CDISC

# Agenda

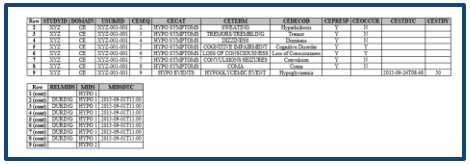
- Project Background
- ARS Model and User Guide
- Open-Source Tool Development
- Next Steps
- Q&A

# CDISC Foundational Standards



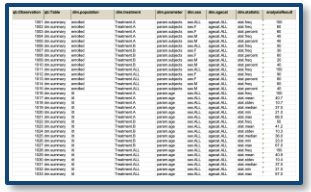
Data Collection

**CDASH**



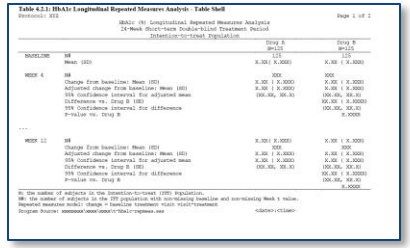
Data Aggregation

**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 |

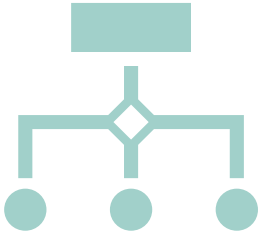
**ARM for Define.XML**

# Analysis Results Key Objectives

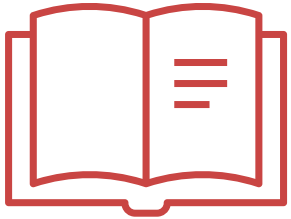
Leverage analysis results metadata to drive the automation of results

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

# Analysis Results Standards Key Results

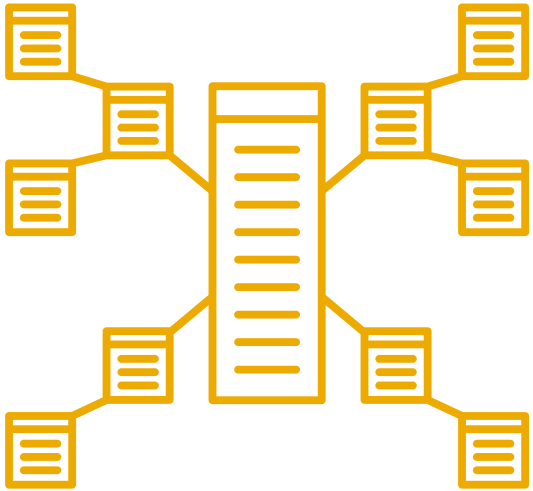


***Logical Model*** that describes analysis results and associated metadata



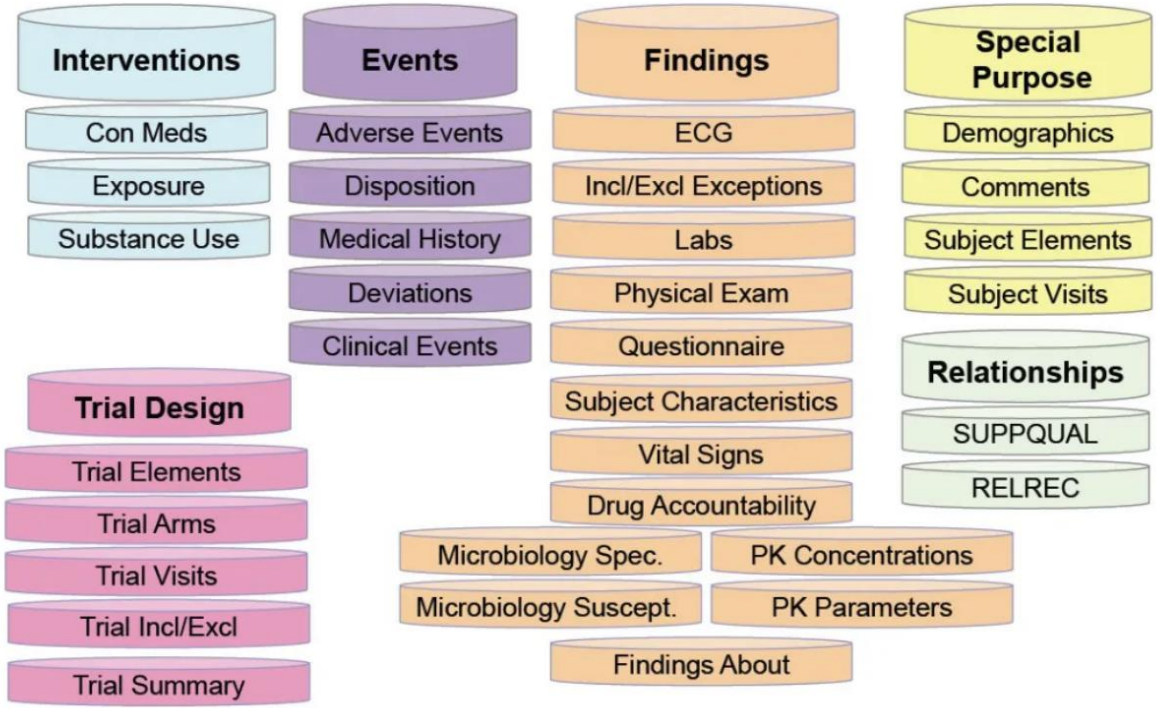
***User Guide*** to illustrate and exercise model with common safety displays

# 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

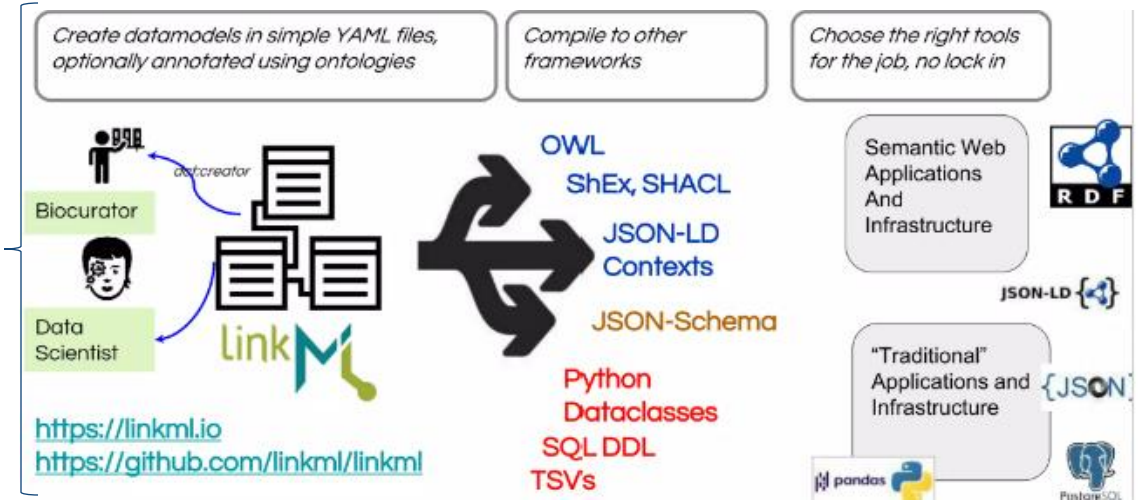
# SDTM Model Representation



# Using LinkML to Create Analysis Results Model

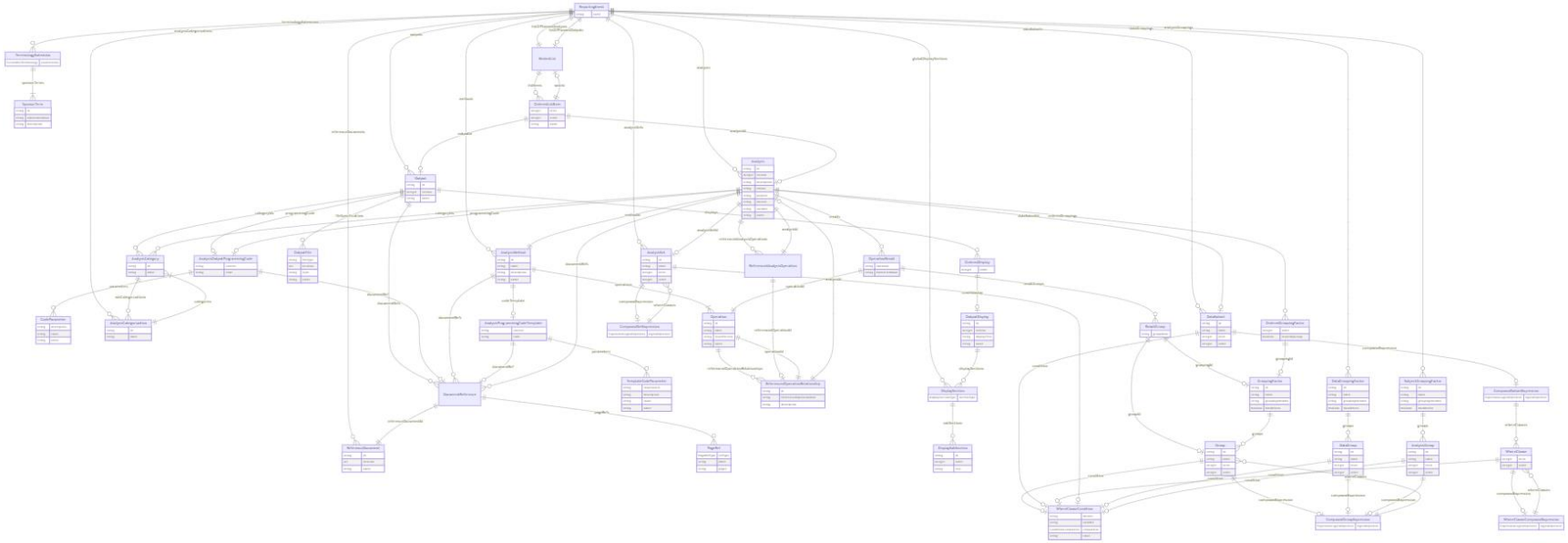
- LinkML is a general-purpose modeling language that can be used with linked data, JSON, and other formalisms

LinkML Landscape

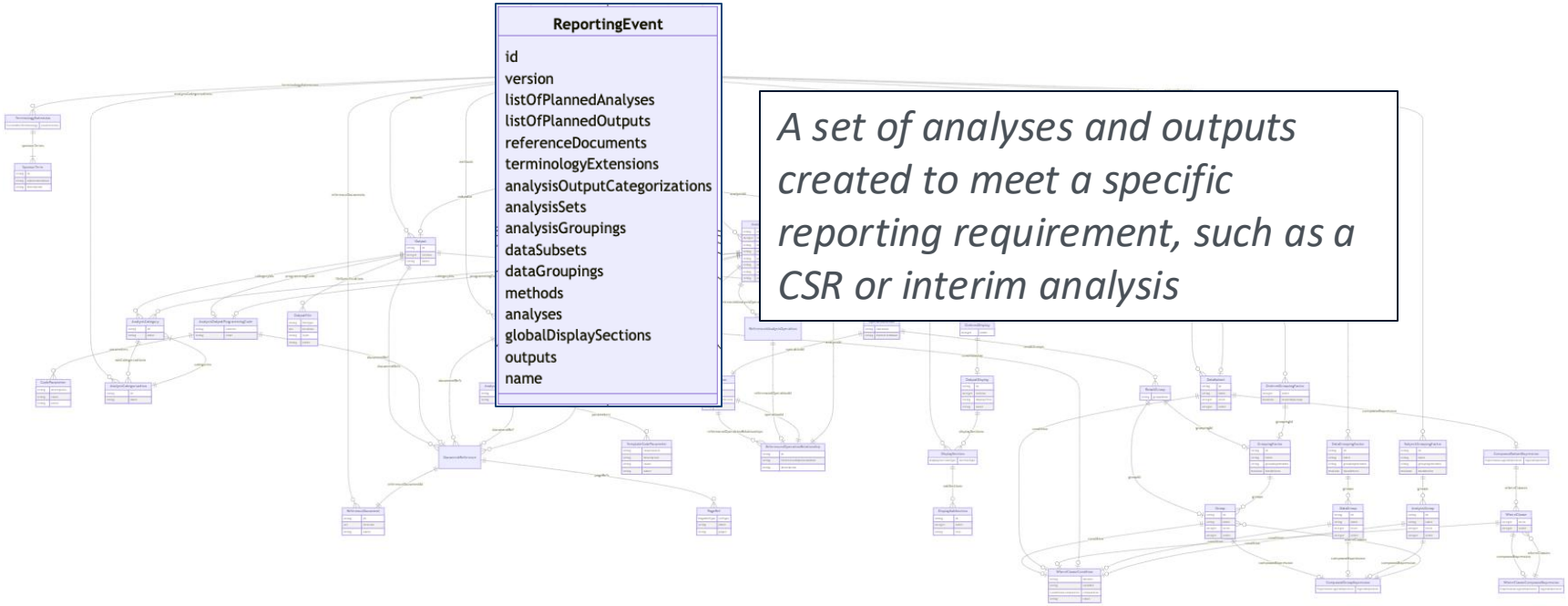



Reference: https://www.slideshare.net/cmungall/linkml-intro-july-2022pptx

# ARS Logical Model Schema Diagram



# 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

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

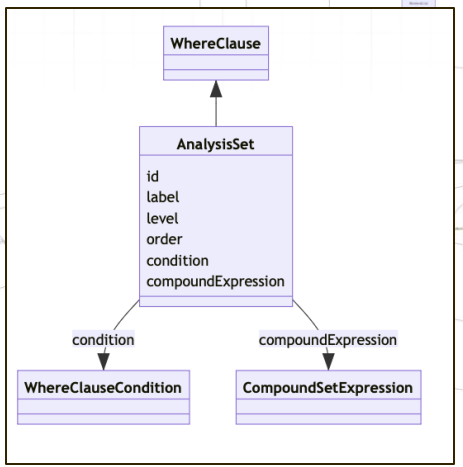
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| System Organ Class<br>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

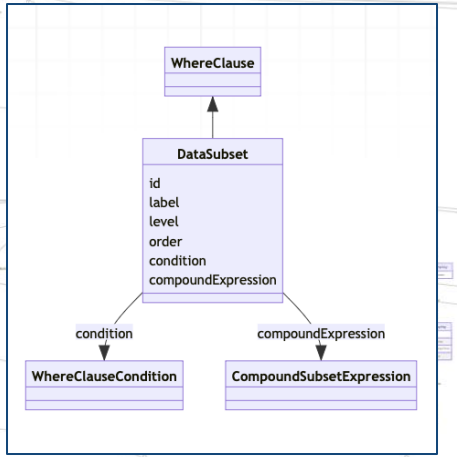
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| System Organ Class<br>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

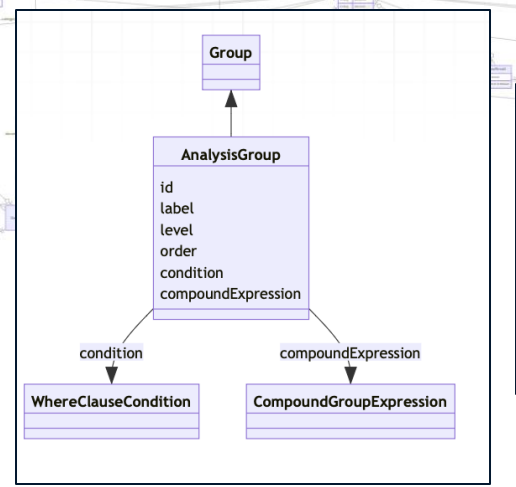
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| System Organ Class<br>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




*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 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

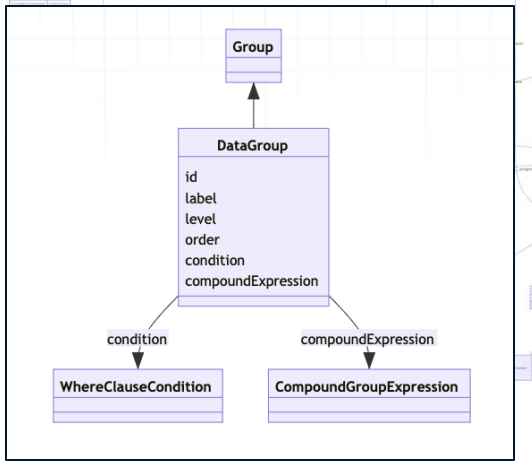
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| System Organ Class<br>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 Grouping




*A subdivision of the analysis dataset records based on a defined factor*

# Model Components

Data 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

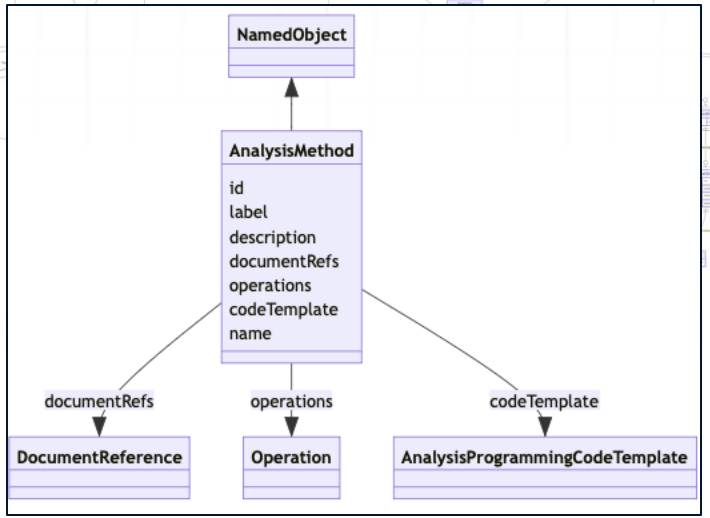
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| System Organ Class<br>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

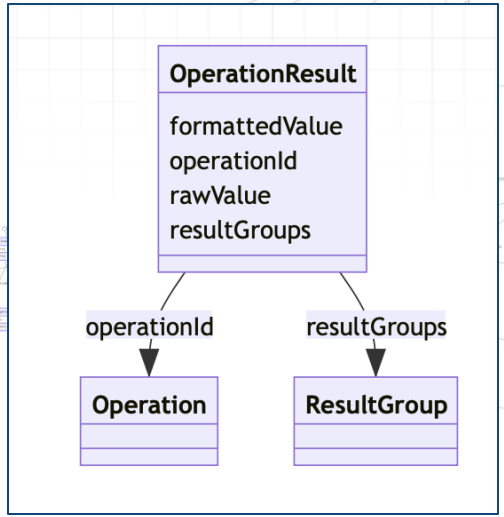
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| System Organ Class<br>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<br>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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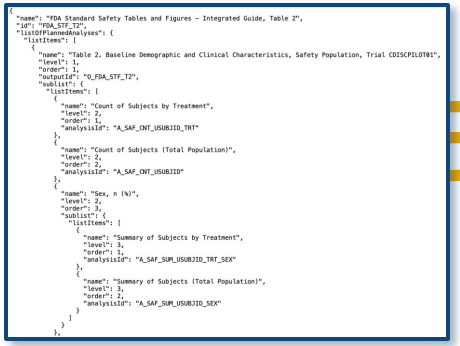
# Leveraging ARS Metadata to Drive Results Automation

ARS Metadata



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      },
      {
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       "level": 2,
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       "analysisId": "A_SAF_CNT_USUBJID"
      },
      {
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       "level": 2,
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         },
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          "level": 3,
          "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 | rawValu | formattedVal |
|---|---|---|---|---|---|---|---|
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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) |

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) |

Displays

Publications

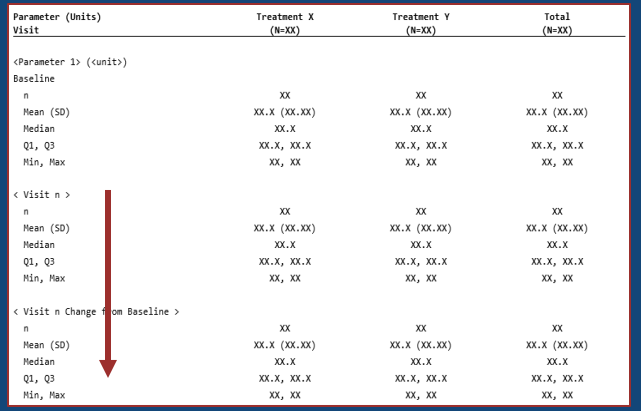
Clinical Study Report

Meta Analysis

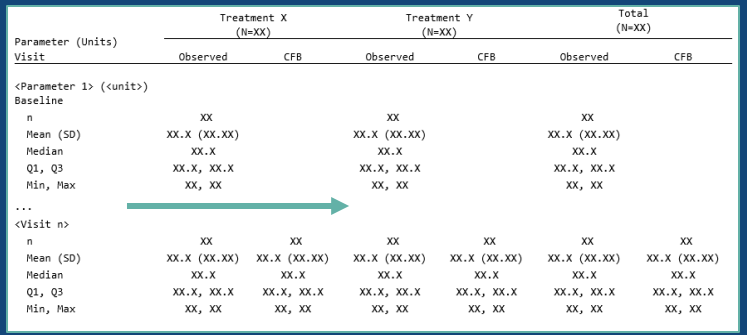
cdisc

# 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)<br>Visit | Treatment X<br>(N=XX) | Treatment Y<br>(N=XX) | Total<br>(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 |



| | Treatment X (N=XX) | | Treatment Y (N=XX) | | Total (N=XX) | |
|---|---|---|---|---|---|---|
| Parameter (Units)<br>Visit | 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

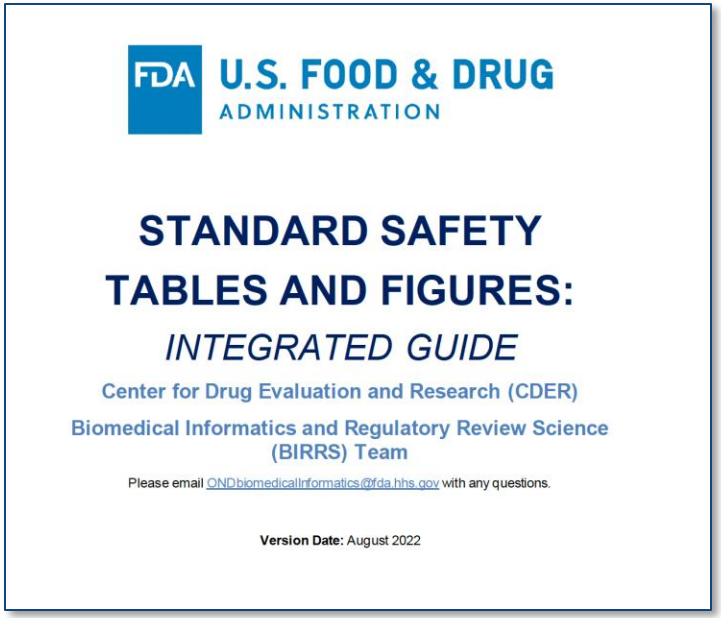
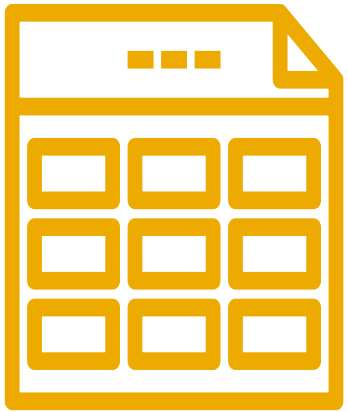



*Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X)*

| 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

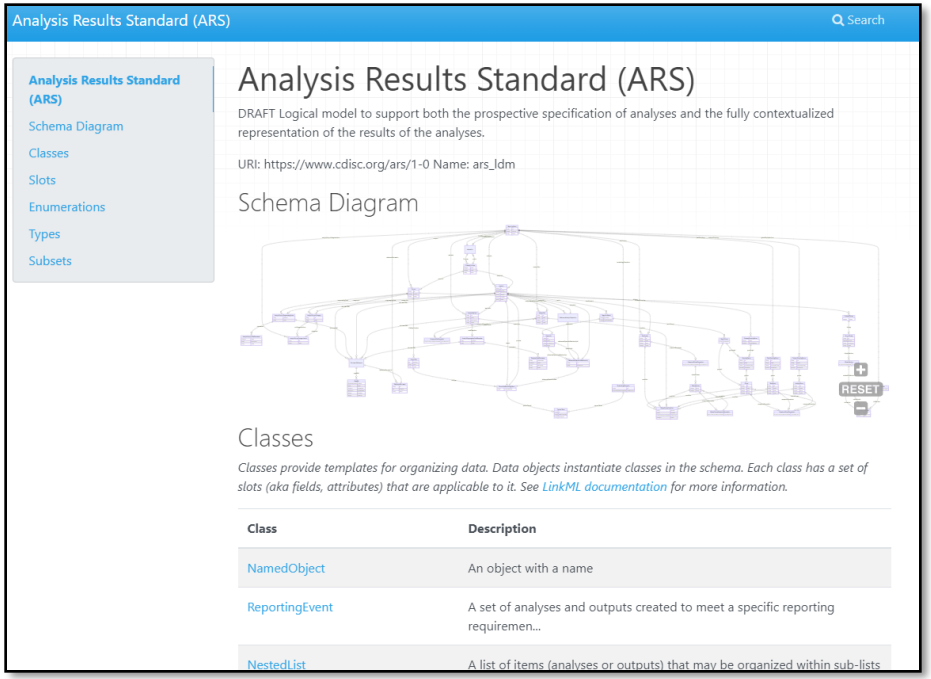


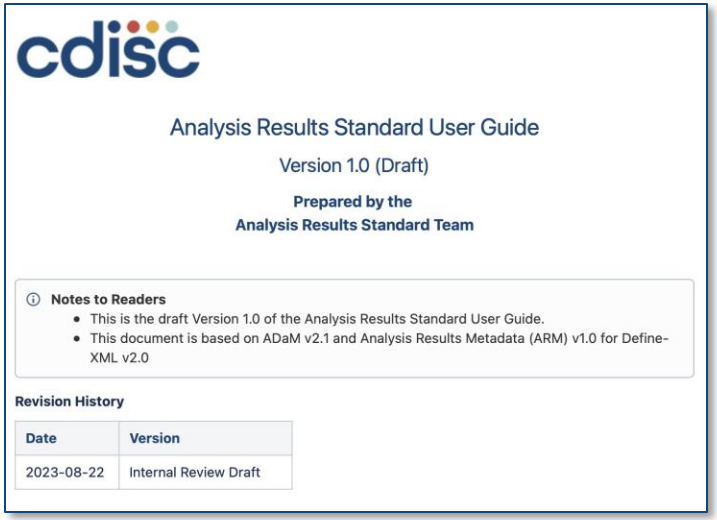
- Common Safety Displays
  - Summary of Demographics
  - Overall Summary of Treatment-Emergent Adverse Events
  - Summary of TEAE by System Organ Class and Preferred Term
  - Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs
  - Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs <Vertical Layout>

- FDA Standard 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/




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

# ARS Model Will Drive Automation and Tool Development

# 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, Climb Clinical;
https://github.com/bhavinbusa/tfldesigner

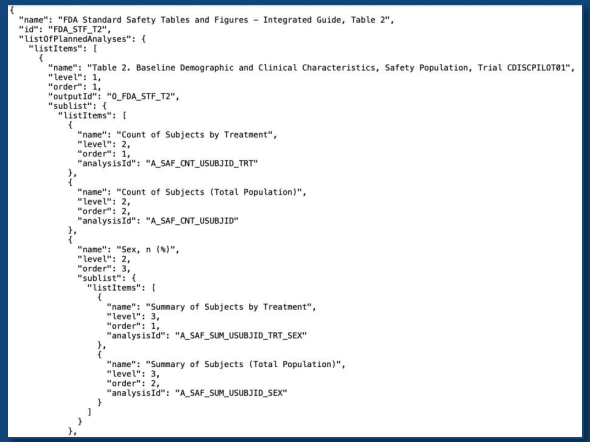
*Table 02*

*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) |




```
{
 "name": "FDA Standard Safety Tables and Figures – Integrated Guide, Table 2",
 "id": "FDA_STF_T2",
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    {
      "name": "Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Trial CDISCPILOT01",
      "level": 1,
      "order": 1,
      "outputId": "O_FDA_STF_T2",
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           "level": 2,
           "order": 1,
           "analysisId": "A_SAF_CNT_USUBJID_TRT"
         },
         {
           "name": "Count of Subjects (Total Population)",
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           "order": 2,
           "analysisId": "A_SAF_CNT_USUBJID"
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               {
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                 "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

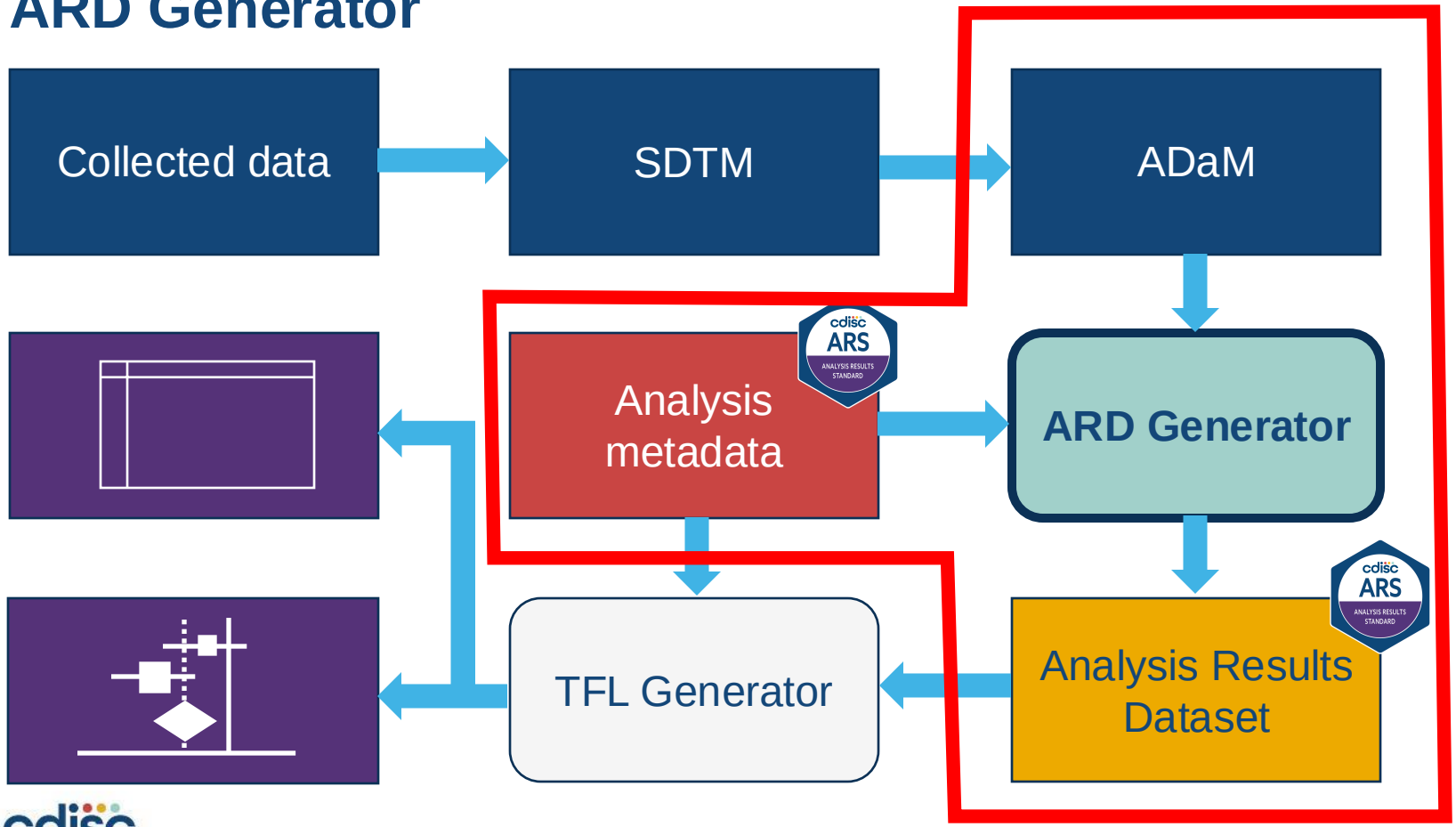


20 September 2023

Karl Wallendszus, University of Oxford

cdisc

# ARD Generator



# Analysis Results Data with {cards} R Package


September 20, 2023

Daniel D. Sjoberg

cdisc

Genentech

*A Member of the Roche Group*

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

## Continuous Summaries

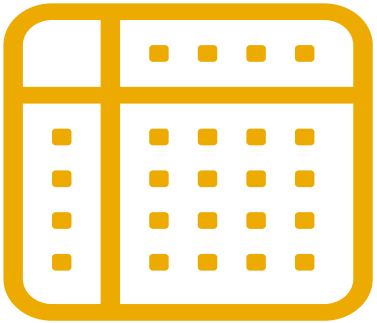
To get a continuous variable summary, we will use the `ard_continuous()` function from the **{cards}** package.

```
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
```



- Sjoberg D, Krouse B (2024). *cards: Analysis Results Data*. R package version 0.0.0.9051, https://insightsengineering.github.io/cards/, https://github.com/insightsengineering/cards.

# 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: April 2024

# Thank you!

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