# Introduction to the CDISC Analysis Results Standard

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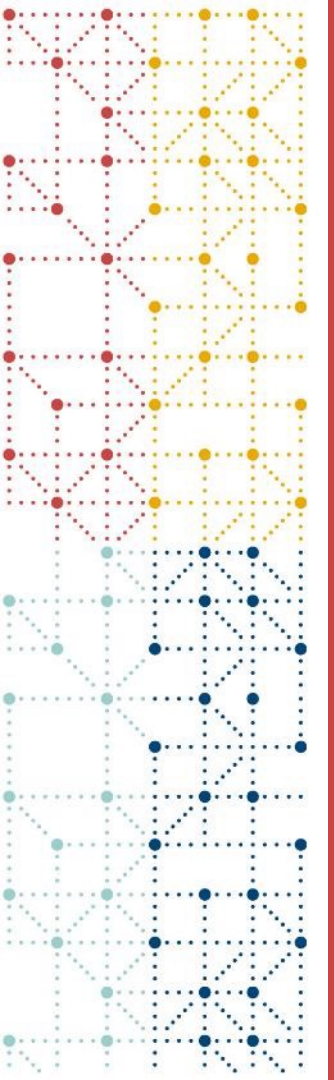
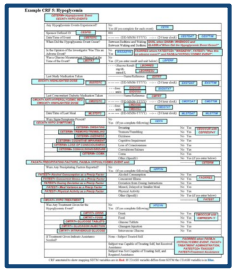


# Agenda

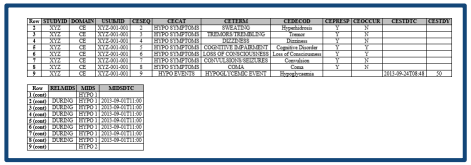
1. Rationale
2. Analysis Results Key Objectives and Key Results
3. Project Overview
4. Overview of Analysis Results Standard Model w/ Examples
5. ARS on GitHub
6. Reference implementation
7. Release Plan
8. Q&A

# CDISC Foundational Standards



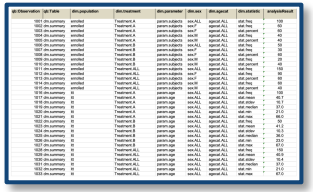
Data Collection

**CDASH**



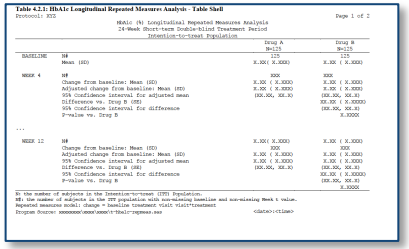
Data Aggregation

**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

- Use analysis results metadata to drive the automation of results
- Support storage, access, processing and reproducibility of results
- Improved navigation and reusability of analyses and results
- Traceability to Protocol/SAP and to input ADaM data

# Analysis Results Standards Key Results

Develop a technical specification to prospectively leverage Analysis Results Metadata to drive automation

Develop a structure to represent Analysis Results as data

Develop a logical model to support a technical specification and an analysis results dataset

Illustrate and exercise with a set of common data displays

# Concepts Team Consulted Published Layouts

- PH
  -
  -
  -
- JPI
- Re
- Su

**Scatterplot and Shift Table Summary of Absolute Lab values – Lab Test 1 Minimum Baseline vs Minimum Post-baseline**

| Treatment |
|---|
| T1 (N = xxx) |
| T2 (N = xxx) |
| PL (N = xxx) |

N = number of su
of subjects in ea
using the referer
demographics.

3.14安全性の解析（バイタルサイン、身体的所見及び安全性に関連する

Table summary of vital signs by visit

<Prameter> *BDS.PARAM*
<Visit> *BDS.AVISIT*
n
Mean (SD) *BDS.AVAL*
Median
Min - Max

上記例は、絶対値の集計の場合。
バイタルサインのベースラインからの変化量を集計する必要がある場合
る場合は *BDS.PCHG* を使用する

**Table 3. Laboratory Abnormalities that Worsened from Baseline to Grade 3 or 4 Occurring in ≥1% of Patients with dMMR Endometrial Cancer Receiving Product in Study**

| Laboratory Test | Product N = 104 | |
|---|---|---|
| | All Grades[a] % | Grade 3 or 4[a] % |
| Hematology | | |
| Decreased lymphocytes | 37 | 9 |
| Decreased leukocytes | 21 | 2.9 |
| Chemistry | | |
| Decreased albumin | 30 | 2.9 |
| Increased creatinine | 27 | 2.9 |
| Increased alkaline phosphatase | 25 | 2.9 |
| Increased aspartate aminotransferase | 16 | 1.9 |
| Increased alanine aminotransferase | 15 | 2.9 |
| Electrolytes | | |
| Decreased sodium | 26 | 4.8 |
| Increased calcium | 15 | 1.9 |
| Decreased potassium | 15 | 1.9 |

[a] Consists of new onset of laboratory abnormality or worsening of baseline laboratory abnormality.

# Focus on Concepts, Not Layout

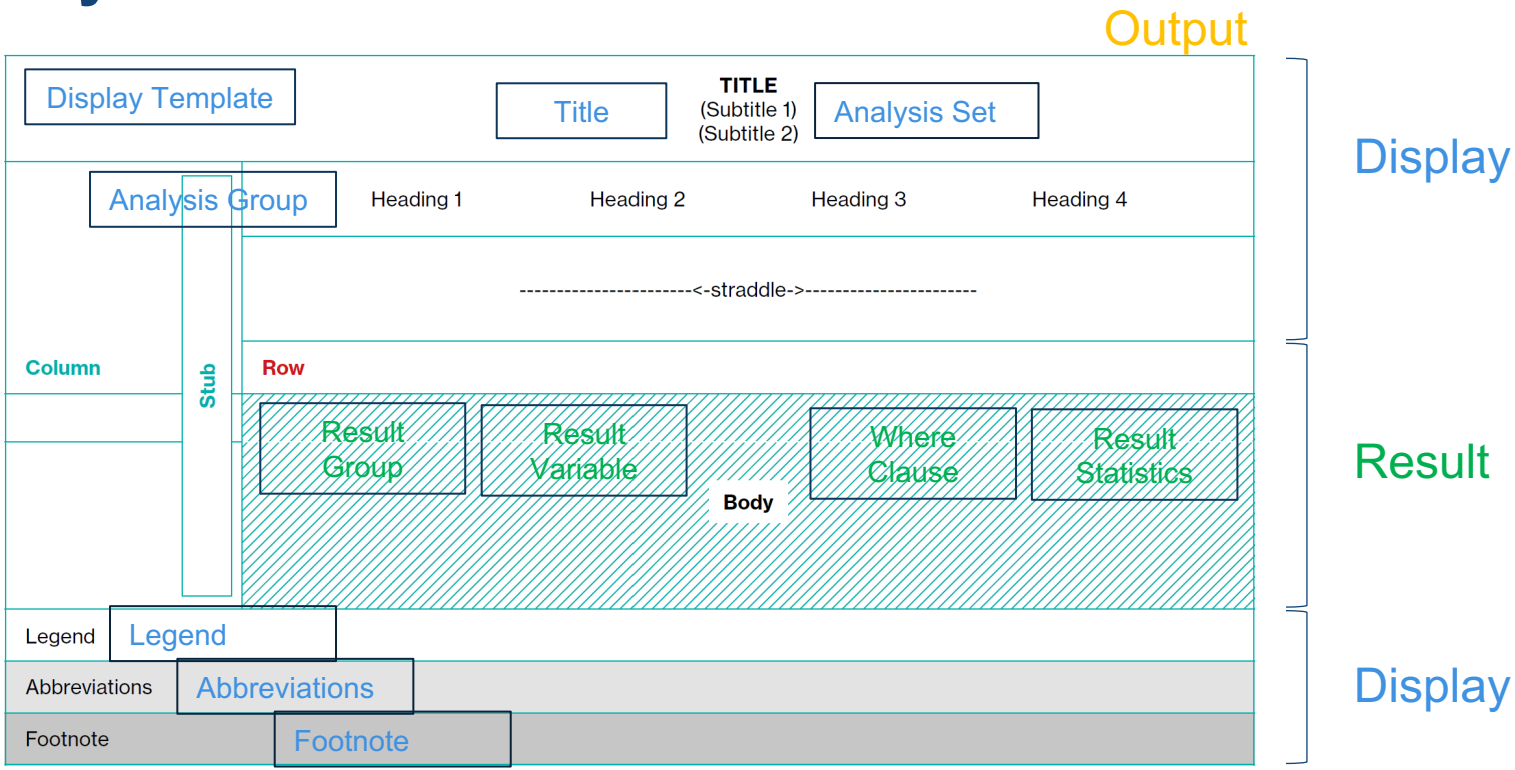
lays not on subjective

s

| 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 | | | |
| Mean (SD) | X | | |
| Median | | | |
| Q1, Q3 | ) | | |
| Min, Max | | | |
| < Visit n Change from Baseline > | | | |
| n | | | |
| Mean (SD) | XX | | |
| Median | | | |
| Q1, Q3 | ) | | |
| Min, Max | | | |

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

# Key Metadata Elements of a Table




Reference: PHUSE White Paper "*General Output Tips and Considerations*", Doc ID: WP-034, Version 1.0, Aug 2020

# Demographics Analysis Results and Metadata

Display Template | Title | Analysis Set

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

Analysis Group

| 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 (%)** |
| ≥17 to <65 | | | | | n (%) |
| ≥65 | | | | | n (%) |
| ≥65 to <75 | | | | | 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 (%) |

Result Group | Result Variable | Where Clause | Result Statistics

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

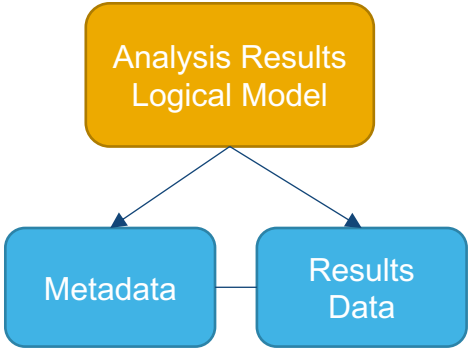
Footnote | Abbreviations | Legend

# Analysis Results and Associated Metadata Example

| Identifiers | | Analysis Group | | | Result Variable | | | Results Statistic | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Name | Title | Dataset | Variable | Value | Variable | Value | Label | Value | Name | Label |
| Table 2 | Baseline Demographics and Clinical Characteristics, Safety Population | ADSL | TR01X | Drug Name Dosage X | SEX | M | Male | 53 | Count | n |
| Table 2 | Baseline Demographics and Clinical Characteristics, Safety Population | ADSL | TR01X | Drug Name Dosage X | SEX | M | Male | 61.6 | Percent | % |
| Table 2 | Baseline Demographics and Clinical Characteristics, Safety Population | ADSL | TR01X | Drug Name Dosage X | SEX | F | Female | 33 | Count | n |
| Table 2 | Baseline Demographics and Clinical Characteristics, Safety Population | ADSL | TR01X | Drug Name Dosage X | SEX | F | Female | 38.4 | Percent | % |

# Moving Towards a Logical Model

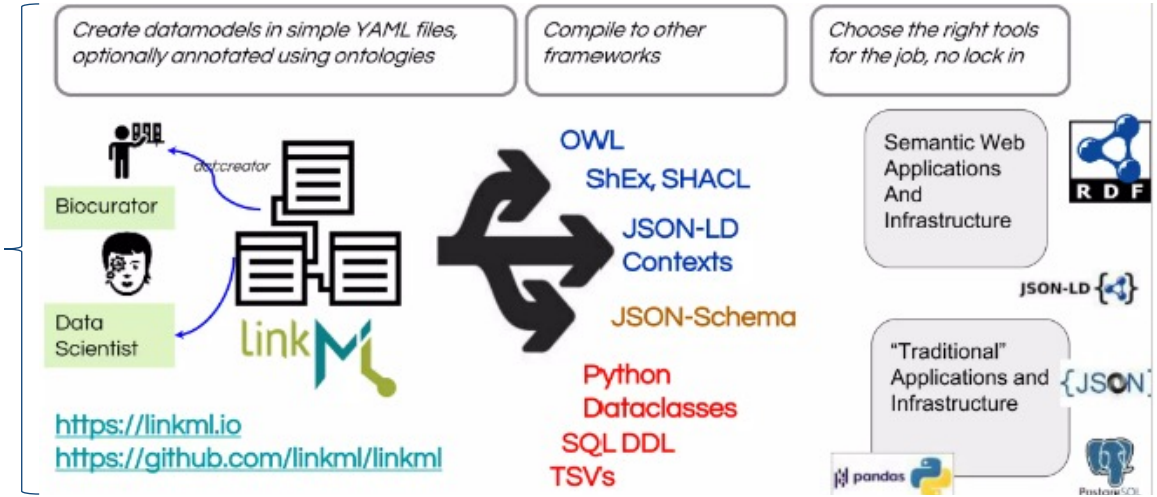
- Logical model will incorporate the elements for both analysis results and associated metadata
- Model definition and documentation
- Illustrate and exercise with a common safety displays
  - Vital signs
  - Demographics
  - Adverse Events



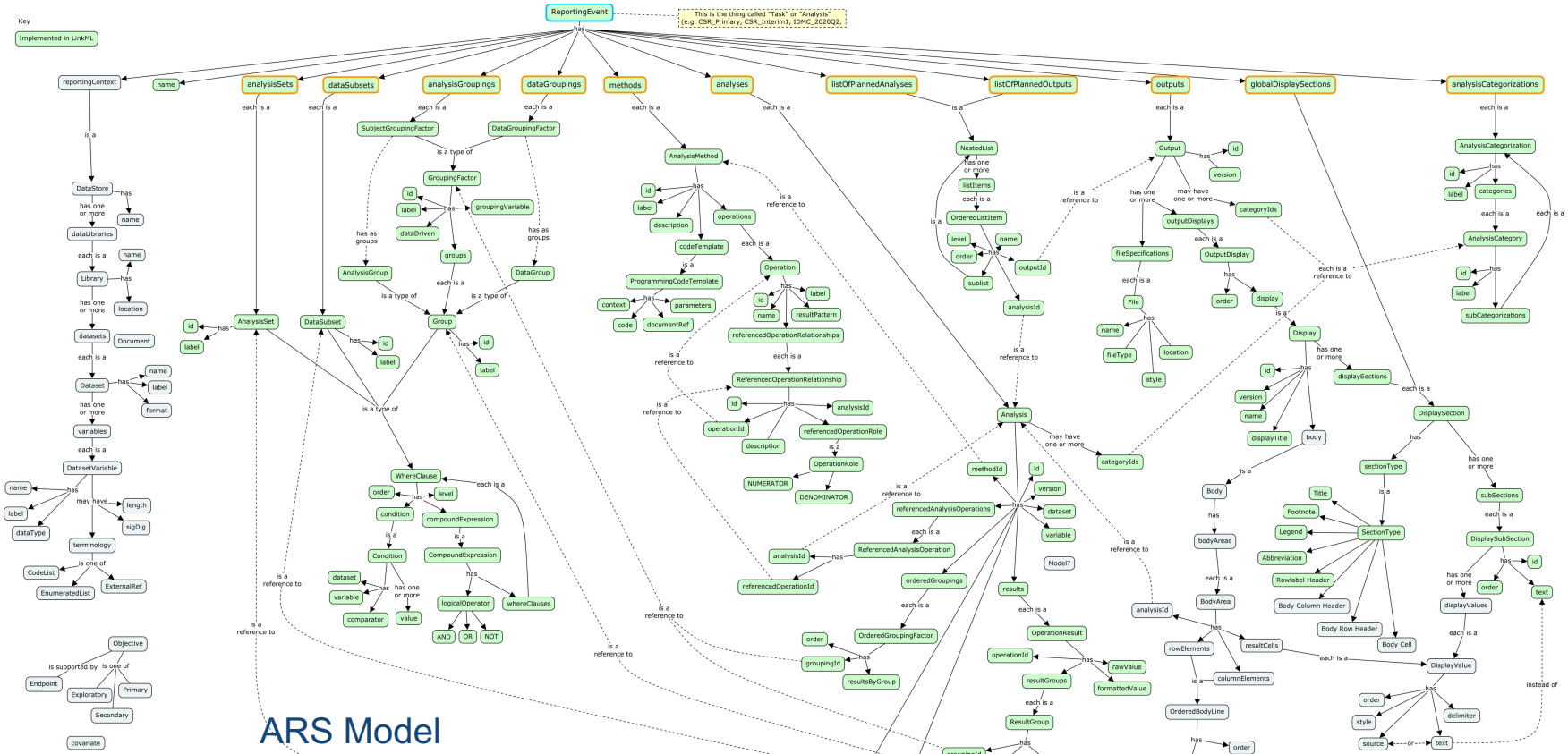
# Using LinkML to Create Analysis Results Model

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

LinkML Landscape

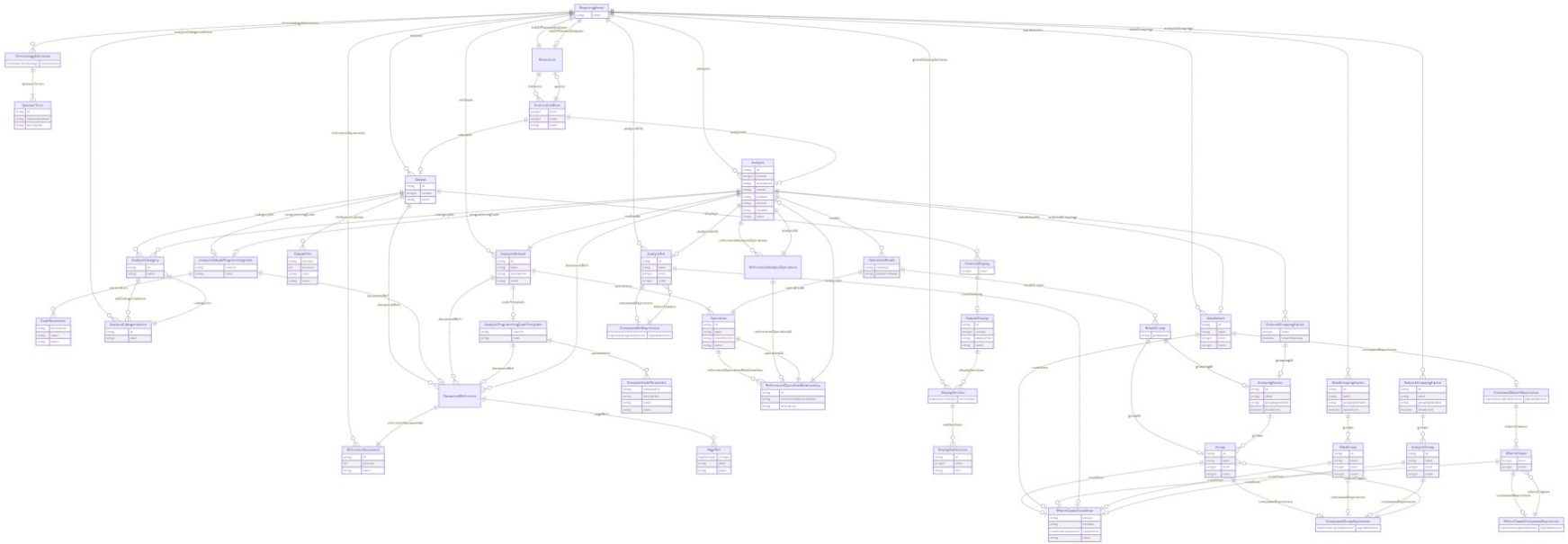



Reference: https://www.slideshare.net/cmungall/linkml-intro-july-2022pptx




# ARS Model Representation using CMAP (DRAFT)

# ARS Model Representation using Mermaid Markdown (DRAFT)



# Review Examples

Analysis Set | Data Subset | Analysis Grouping | Data Grouping | Method | Analysis | 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

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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

# Review Examples

## 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

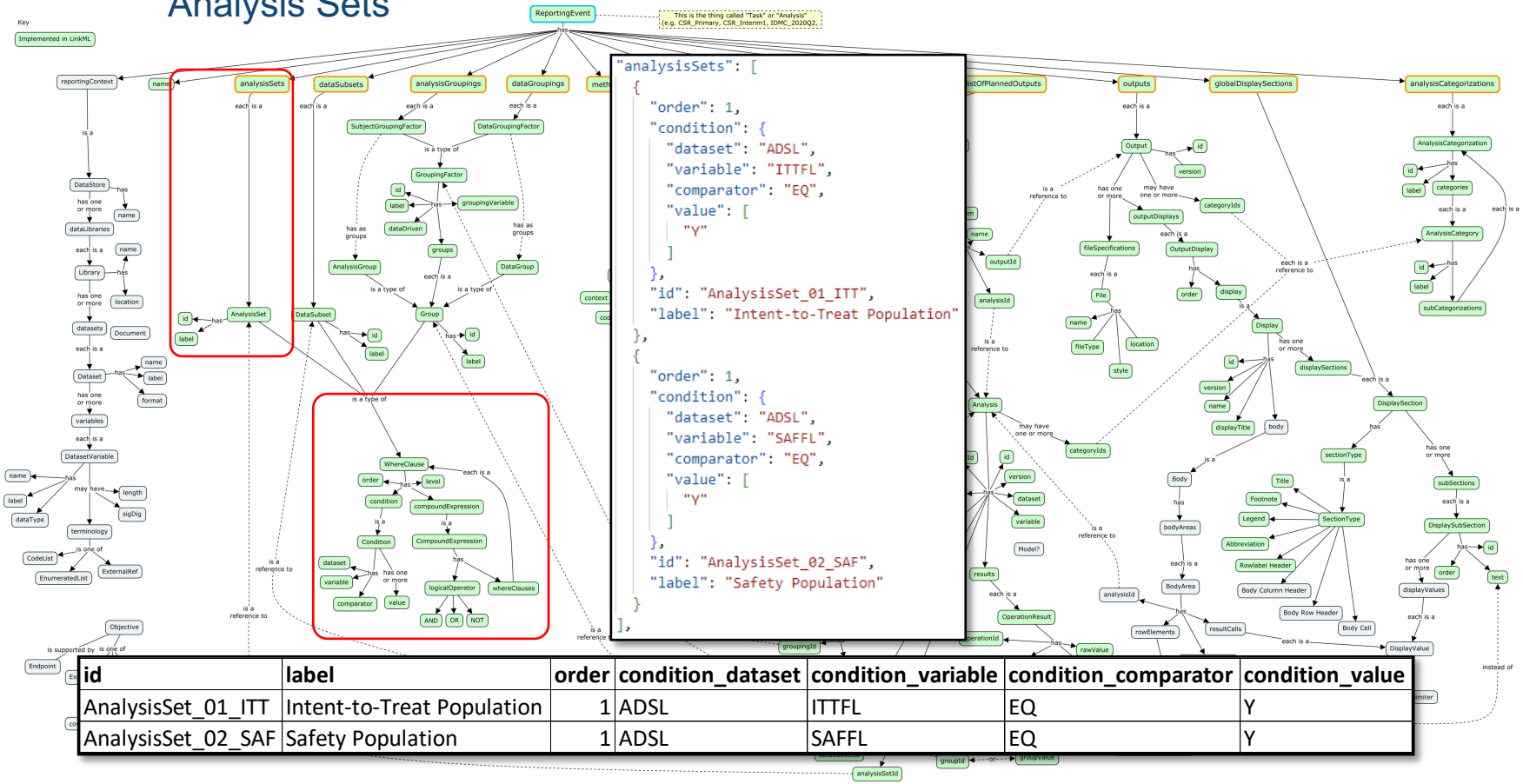
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| 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

# Analysis Sets

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      "value": [
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      ]
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    "label": "Intent-to-Treat Population"
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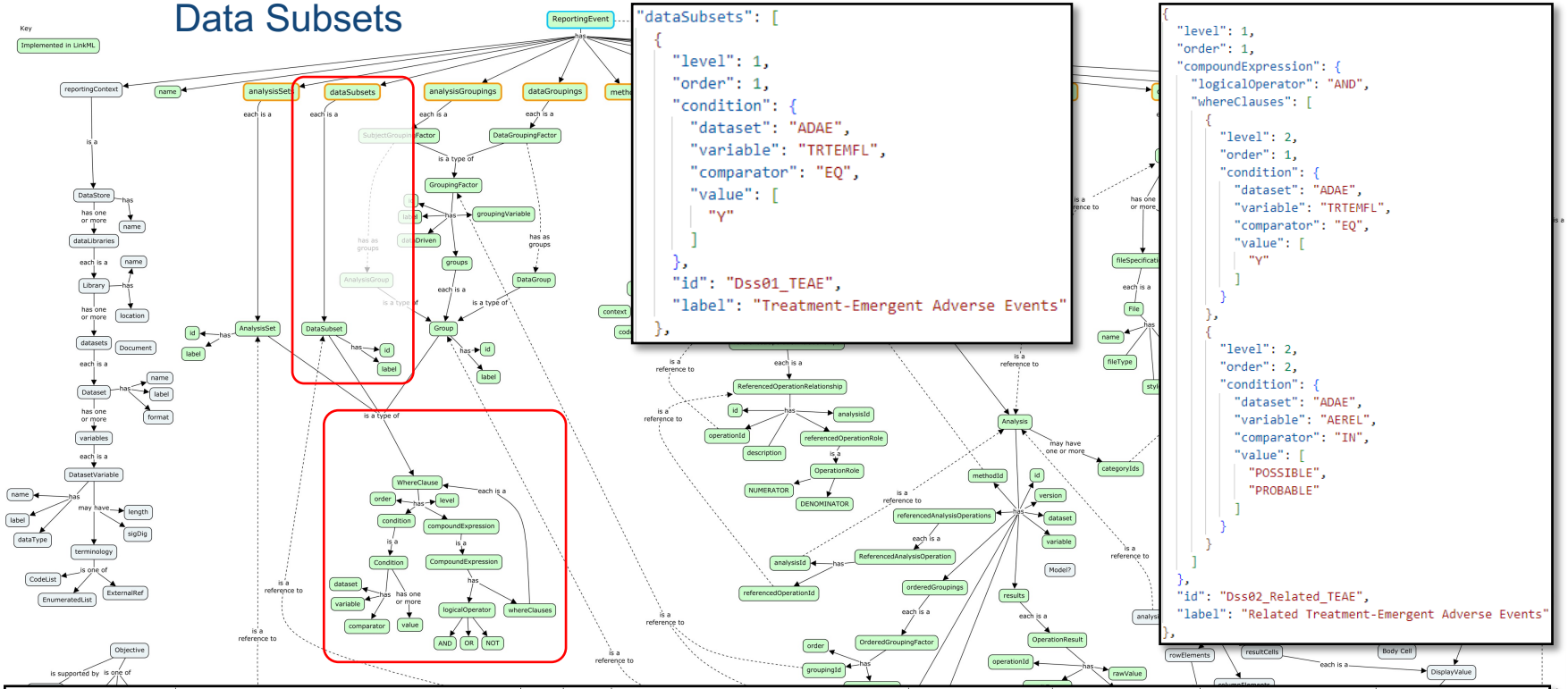
      "variable": "SAFFL",
      "comparator": "EQ",
      "value": [
        "Y"
      ]
    },
    "id": "AnalysisSet_02_SAF",
    "label": "Safety Population"
  }
],
```

| id | label | order | condition_dataset | condition_variable | condition_comparator | condition_value |
|---|---|---|---|---|---|---|
| AnalysisSet_01_ITT | Intent-to-Treat Population | 1 | ADSL | ITTFL | EQ | Y |
| AnalysisSet_02_SAF | Safety Population | 1 | ADSL | SAFFL | EQ | Y |

# Data Subsets

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   "value": [
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   ]
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  "id": "Dss01_TEAE",
  "label": "Treatment-Emergent Adverse Events"
 },
```

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    "condition": {
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     "value": [
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     ]
    }
   },
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    "order": 2,
    "condition": {
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     "variable": "AEREL",
     "comparator": "IN",
     "value": [
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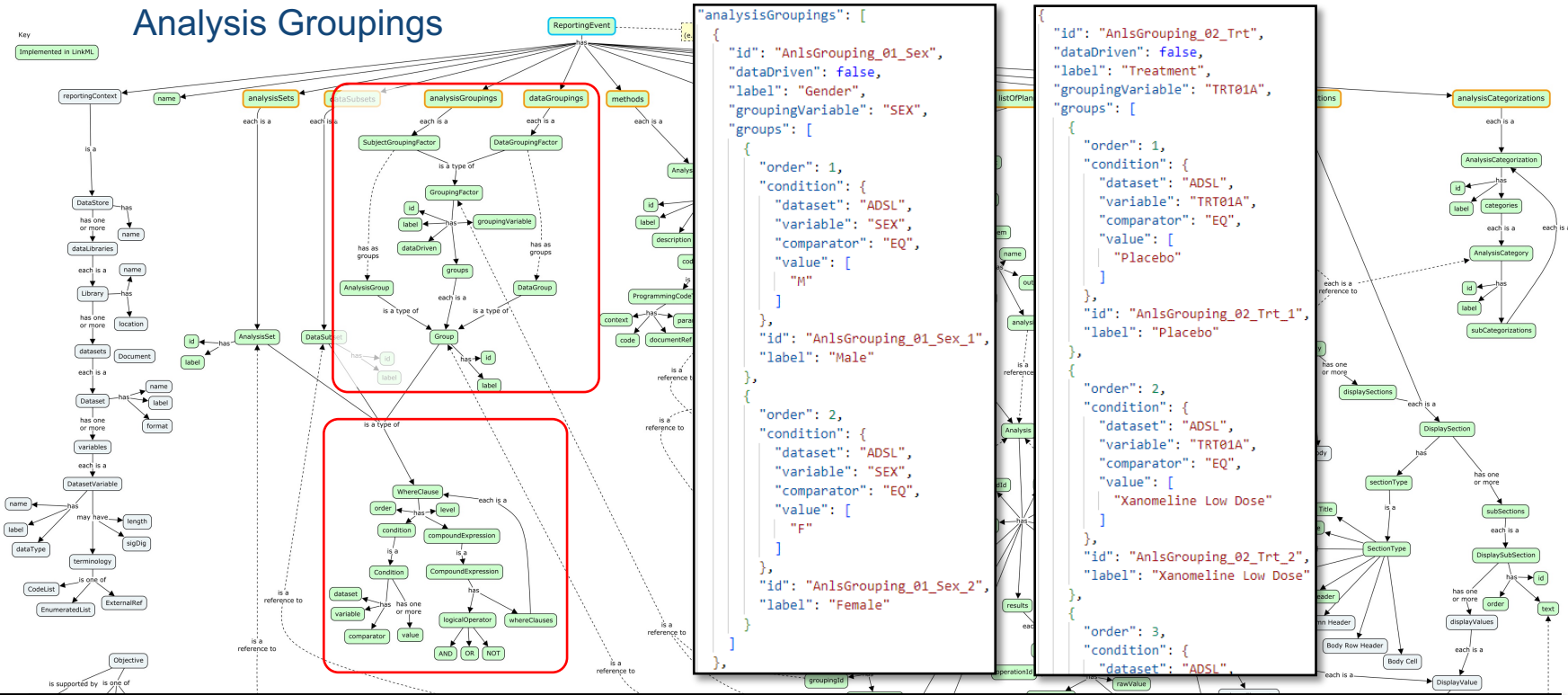
      "PROBABLE"
     ]
    }
   }
  ]
 },
 "id": "Dss02_Related_TEAE",
 "label": "Related Treatment-Emergent Adverse Events"
},
```

| id | label | level | order | compoundExpression_logicalOperator | condition_dataset | condition_variable | condition_comparator | condition_value |
|---|---|---|---|---|---|---|---|---|
| Dss01_TEAE | Treatment-Emergent Adverse Events | 1 | 1 | | ADAE | TRTEMFL | EQ | Y |
| Dss02_Related_TEAE | Related Treatment-Emergent Adverse Events | 1 | 1 | AND | | | | |
| Dss02_Related_TEAE | Related Treatment-Emergent Adverse Events | 2 | 1 | | ADAE | TRTEMFL | EQ | Y |
| Dss02_Related_TEAE | Related Treatment-Emergent Adverse Events | 2 | 2 | | ADAE | AEREL | IN | POSSIBLE \| PROBABLE |

# Analysis Groupings





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          "dataset": "ADSL",
          "variable": "SEX",
          "comparator": "EQ",
          "value": [
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          ]
        },
        "id": "AnlsGrouping_01_Sex_1",
        "label": "Male"
      },
      {
        "order": 2,
        "condition": {
          "dataset": "ADSL",
          "variable": "SEX",
          "comparator": "EQ",
          "value": [
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      }
    ]
  },
```



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        "variable": "TRT01A",
        "comparator": "EQ",
        "value": [
          "Placebo"
        ]
      },
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        "variable": "TRT01A",
        "comparator": "EQ",
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        ]
      },
      "id": "AnlsGrouping_02_Trt_2",
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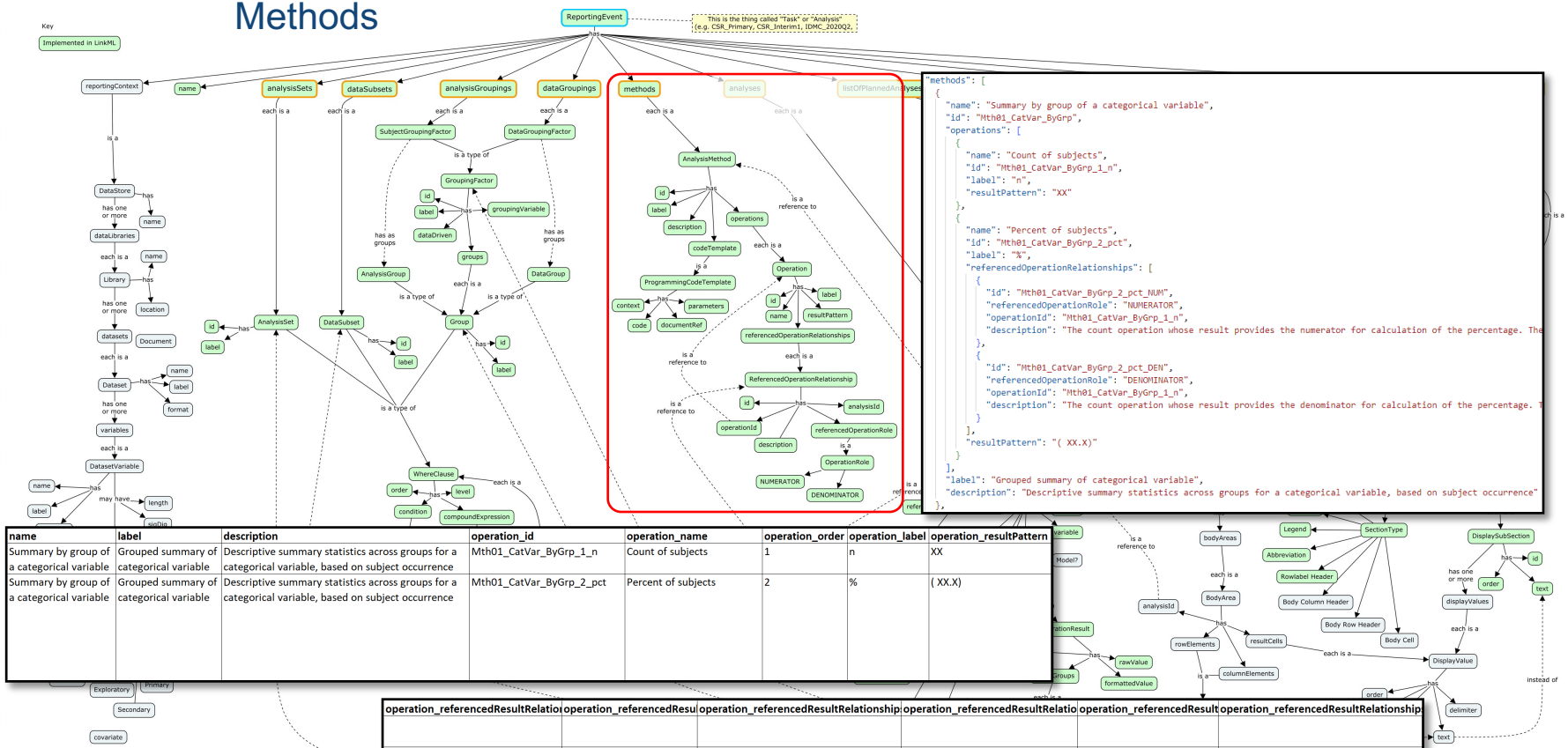
|---|---|---|---|---|---|---|---|---|---|---|
| AnlsGrouping_01_Sex | Gender | SEX | FALSE | AnlsGrouping_01_Sex_1 | Male | 1 | ADSL | SEX | EQ | M |
| AnlsGrouping_01_Sex | Gender | SEX | FALSE | AnlsGrouping_01_Sex_2 | Female | 2 | ADSL | SEX | EQ | F |
| AnlsGrouping_02_Trt | Treatment | TRT01A | FALSE | AnlsGrouping_02_Trt_1 | Placebo | 1 | ADSL | TRT01A | EQ | Placebo |
| AnlsGrouping_02_Trt | Treatment | TRT01A | FALSE | AnlsGrouping_02_Trt_2 | Xanomeline Low Dose | 2 | ADSL | TRT01A | EQ | Xanomeline Low Dose |
| AnlsGrouping_02_Trt | Treatment | TRT01A | FALSE | AnlsGrouping_02_Trt_3 | Xanomeline High Dose | 3 | ADSL | TRT01A | EQ | Xanomeline High Dose |

# Methods

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|---|---|---|---|---|---|---|---|
| Summary by group of a categorical variable | Grouped summary of categorical variable | Descriptive summary statistics across groups for a categorical variable, based on subject occurrence | Mth01_CatVar_ByGrp_1_n | Count of subjects | 1 | n | XX |
| Summary by group of a categorical variable | Grouped summary of categorical variable | Descriptive summary statistics across groups for a categorical variable, based on subject occurrence | Mth01_CatVar_ByGrp_2_pct | Percent of subjects | 2 | % | ( XX.X) |

| operation_referencedResultRelatio | operation_referencedResu | operation_referencedResultRelationship | operation_referencedResultRelatio | operation_referencedResult | operation_referencedResultRelationship |
|---|---|---|---|---|---|
| Mth01_CatVar_ByGrp_2_pct_NUM | Mth01_CatVar_ByGrp_1_n | The count operation whose result provides the numerator for calculation of the percentage. The referenced analysis should be the analysis that contains this percent operation. | Mth01_CatVar_ByGrp_2_pct_DEN | Mth01_CatVar_ByGrp_1_n | The count operation whose result provides the denominator for calculation of the percentage. The referenced analysis should have the same analysis set and subject grouping(s) as the analysis containing this percent operation. |

# Analyses

| id | versi | name | categoryIds | analysisSetId | groupingId1 | groupingId2 | groupingId3 | dataSubsetId | data | variable | method_id |
|---|---|---|---|---|---|---|---|---|---|---|---|
| An03.02_AgeGrp_ByTrt | 1 | Summary of Subjects by Treatment and Age Group | | AnalysisSet_02_SAF | AnlsGrouping_02_Trt | AnlsGrouping_03_AgeGp | | | ADSL | USUBJID | Mth01_CatVar_ByGrp |
| An08.02_ChgBl_ByTrt | 1 | Summary of Change from Baseline by Treatment, Parameter and Visit | | AnalysisSet_02_SAF | AnlsGrouping_02_Trt | AnlsGrouping_08_Param | AnlsGrouping_09_Visit | Dss10_VS_NonBl_AnRec | ADVS | CHG | Mth02_ContVar_ByGrp |

| referencedAnalysisOperations_r | referencedAnalysisOp | referencedAnalysisOperations_ | referencedAnaly |
|---|---|---|---|
| Mth01_CatVar_ByGrp_2_pct_NUM | An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_2_pct_DEN | An01.05_SAF_ByTrt |


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      "order": 3,
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# Analysis Results

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|---|---|---|---|---|---|---|---|---|---|
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_1 | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | 249 | 249 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_2_Mean | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_1 | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | -3.3012 | - 3.3 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_3_SD | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_1 | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | 14.60121 | (14.60) |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_4_Media | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | -2 | - 2.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_5_Q1 | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | -12 | -12.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_6_Q3 | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | 4 | 4.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_7_Min | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | -38 | -38 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_8_Max | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | 40 | 40 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_1_n | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | 243 | 243 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_2_Mean | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | -3.02469 | - 3.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_3_SD | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | 15.66829 | (15.67) |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_4_Media | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | -2 | - 2.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_5_Q1 | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | -12 | -12.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_6_Q3 | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | 6 | 6.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_7_Min | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | -48 | -48 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_8_Max | | | Grouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | 50 | 50 |


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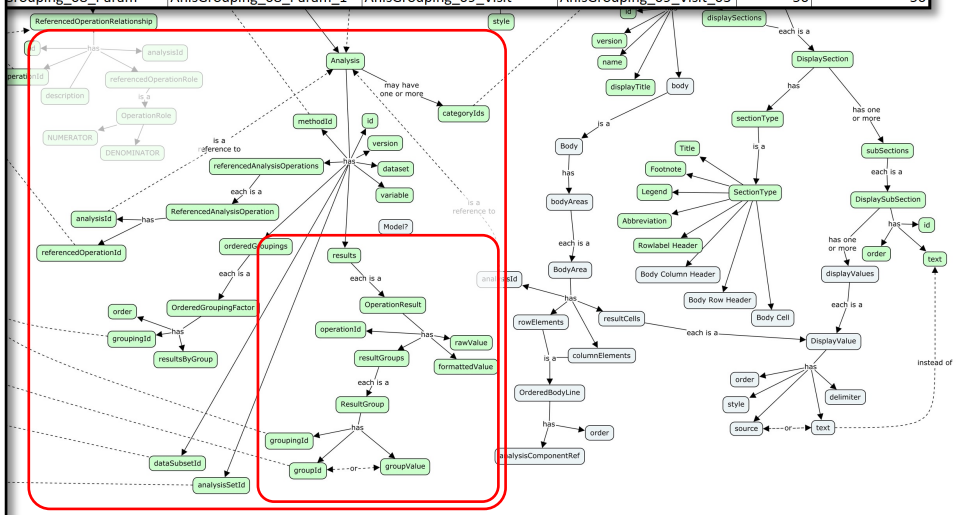

# Concepts, Not Layout

| Analysis ID: | An03.2_AgeGrp_ByTrt | | | | | | |
|---|---|---|---|---|---|---|---|
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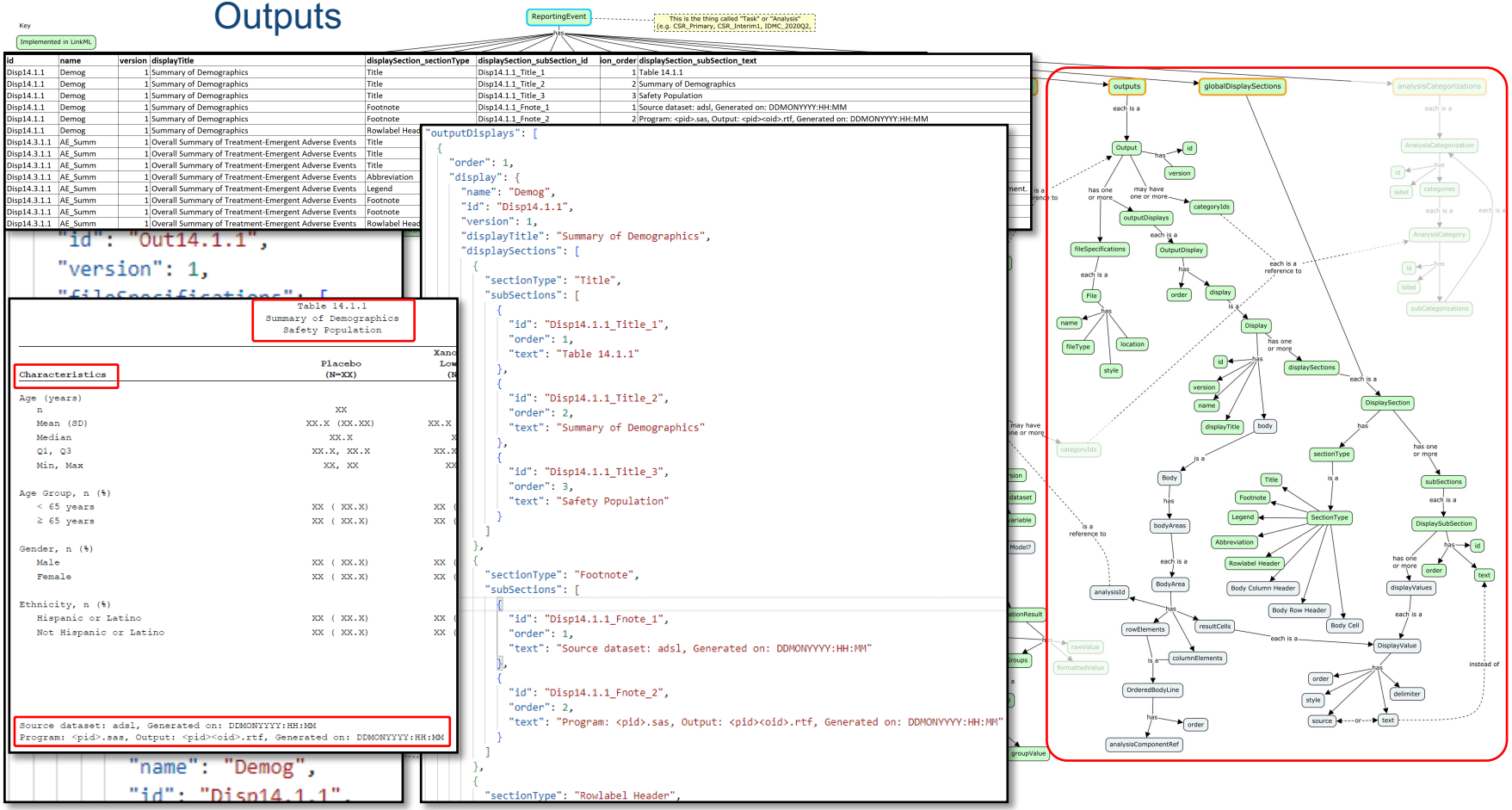
| | | | AnlsGrouping_02_Trt | Treatment | Placebo | Xanomeline Low Dose | Xanomeline High Dose |
| | | AnlsGrouping_03_AgeGp | Mth01_CatVar_ByGrp | | | | |
| | | Age Group | Operation | | | | |
| | | < 65 years | n | | 14 | 8 | 11 |
| | | < 65 years | % | | ( 16.3) | ( 9.5) | ( 13.1) |
| | | ≥ 65 years | n | | 72 | 76 | 73 |
| | | ≥ 65 years | % | | ( 83.7) | ( 90.5) | ( 86.9) |

| Analysis ID: | An03.2_AgeGrp_ByTrt | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Display Value: | formattedValue | | | | | | | | | |
| | | | AnlsGrouping_02_Trt | Treatment | Placebo | Placebo | Xanomeline Low Dose | Xanomeline Low Dose | Xanomeline High Dose | Xanomeline High Dose |
| | | | Mth01_CatVar_ByGrp | Operation | n | % | n | % | n | % |
| | | | AnlsGrouping_03_AgeGp | | | | | | | |
| | | | Age Group | | | | | | | |
| | | | < 65 years | | 14 | ( 16.3) | 8 | ( 9.5) | 11 | ( 13.1) |
| | | | ≥ 65 years | | 72 | ( 83.7) | 76 | ( 90.5) | 73 | ( 86.9) |

| Analysis ID: | An03.2_AgeGrp_ByTrt | | | | | |
|---|---|---|---|---|---|---|
| Display Value: | formattedValue | | | | | |
| | | | Mth01_CatVar_ByGrp | Operation | n | % |
| | | AnlsGrouping_02_Trt | AnlsGrouping_03_AgeGp | | | |
| | | Treatment | Age Group | | | |
| | | Placebo | < 65 years | | 14 | ( 16.3) |
| | | Placebo | ≥ 65 years | | 72 | ( 83.7) |
| | | Xanomeline Low Dose | < 65 years | | 8 | ( 9.5) |
| | | Xanomeline Low Dose | ≥ 65 years | | 76 | ( 90.5) |
| | | Xanomeline High Dose | < 65 years | | 11 | ( 13.1) |
| | | Xanomeline High Dose | ≥ 65 years | | 73 | ( 86.9) |

# Outputs


Key
Implemented in LinkML
ReportingEvent
has
This is the thing called "Task" or "Analysis" (e.g. CSR_Primary, CSR_Interim1, IDMC_2020Q2,
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Disp14.1.1 | Demog | 1 | Summary of Demographics | Title | Disp14.1.1_Title_1 | 1 | Table 14.1.1
Disp14.1.1 | Demog | 1 | Summary of Demographics | Title | Disp14.1.1_Title_2 | 2 | Summary of Demographics
Disp14.1.1 | Demog | 1 | Summary of Demographics | Title | Disp14.1.1_Title_3 | 3 | Safety Population
Disp14.1.1 | Demog | 1 | Summary of Demographics | Footnote | Disp14.1.1_Fnote_1 | 1 | Source dataset: adsl, Generated on: DDMONYYYY:HH:MM
Disp14.1.1 | Demog | 1 | Summary of Demographics | Footnote | Disp14.1.1_Fnote_2 | 2 | Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM
Disp14.1.1 | Demog | 1 | Summary of Demographics | Rowlabel Head
Disp14.3.1.1 | AE_Summ | 1 | Overall Summary of Treatment-Emergent Adverse Events | Title
Disp14.3.1.1 | AE_Summ | 1 | Overall Summary of Treatment-Emergent Adverse Events | Title
Disp14.3.1.1 | AE_Summ | 1 | Overall Summary of Treatment-Emergent Adverse Events | Title
Disp14.3.1.1 | AE_Summ | 1 | Overall Summary of Treatment-Emergent Adverse Events | Abbreviation
Disp14.3.1.1 | AE_Summ | 1 | Overall Summary of Treatment-Emergent Adverse Events | Legend
Disp14.3.1.1 | AE_Summ | 1 | Overall Summary of Treatment-Emergent Adverse Events | Footnote
Disp14.3.1.1 | AE_Summ | 1 | Overall Summary of Treatment-Emergent Adverse Events | Footnote
Disp14.3.1.1 | AE_Summ | 1 | Overall Summary of Treatment-Emergent Adverse Events | Rowlabel Head
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Safety Population
Characteristics
Placebo (N=XX)
Age (years)
n XX
Mean (SD) XX.X (XX.XX)
Median XX.X
Q1, Q3 XX.X, XX.X
Min, Max XX, XX
Age Group, n (%)
< 65 years XX ( XX.X)
≥ 65 years XX ( XX.X)
Gender, n (%)
Male XX ( XX.X)
Female XX ( XX.X)
Ethnicity, n (%)
Hispanic or Latino XX ( XX.X)
Not Hispanic or Latino XX ( XX.X)
Source dataset: adsl, Generated on: DDMONYYYY:HH:MM
Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM
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globalDisplaySections
analysisCategorizations
Output
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version
outputDisplays
categoryIds
fileSpecifications
OutputDisplay
order
display
File
name
fileType
location
style
Display
displaySections
DisplaySection
displayTitle
body
sectionType
Body
Title
Footnote
Legend
Abbreviation
Rowlabel Header
Body Column Header
Body Row Header
Body Cell
SectionType
subSections
DisplaySubSection
displayValues
bodyAreas
BodyArea
analysisId
rowElements
resultCells
columnElements
OrderedBodyLine
analysisComponentRef
DisplayValue
rawValue
formattedValue
AnalysisCategorization
label
categories
AnalysisCategory
subCategorizations
delimiter
source
text
each is a
has
has one or more
may have one or more
each is a reference to
is a reference to
is a
instead of

# List of Planned Analyses/Outputs


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            "level": 2,
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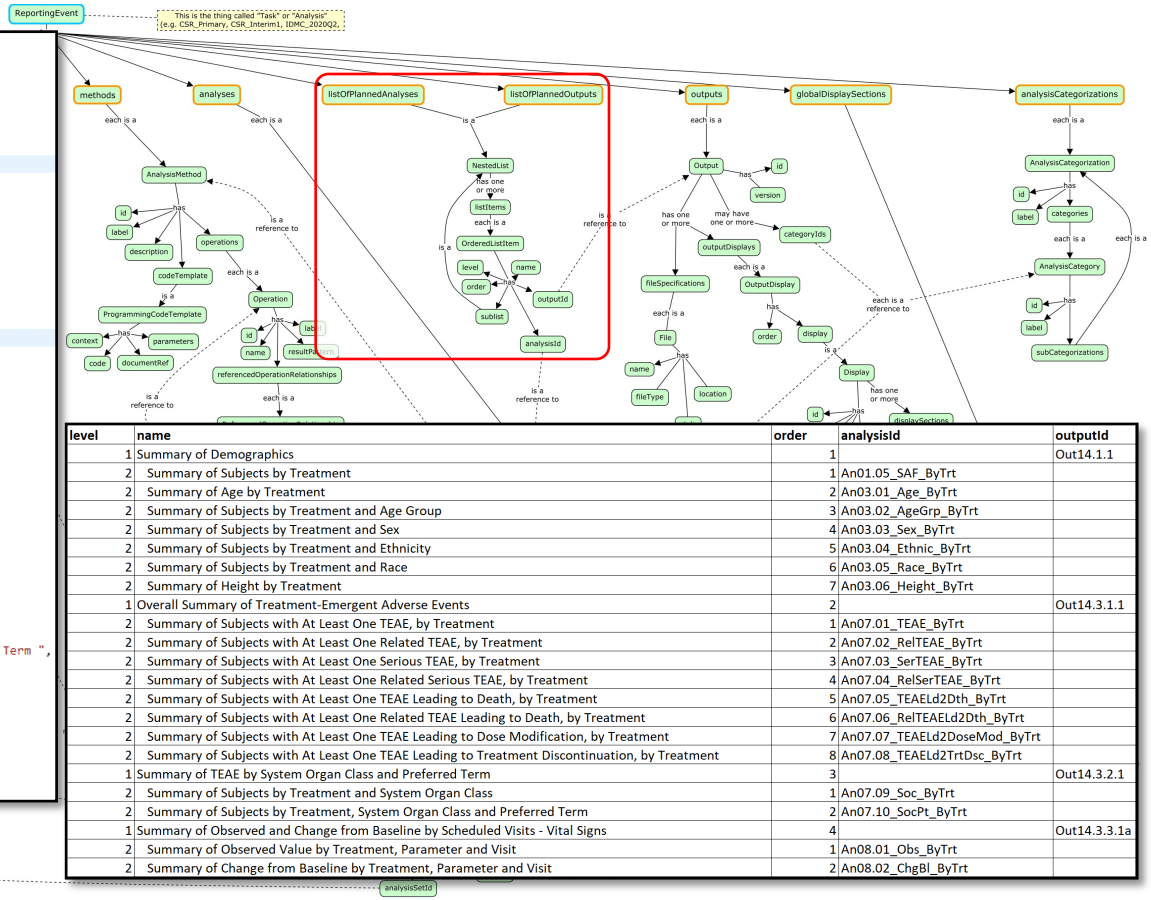


| level | name | order | analysisId | outputId |
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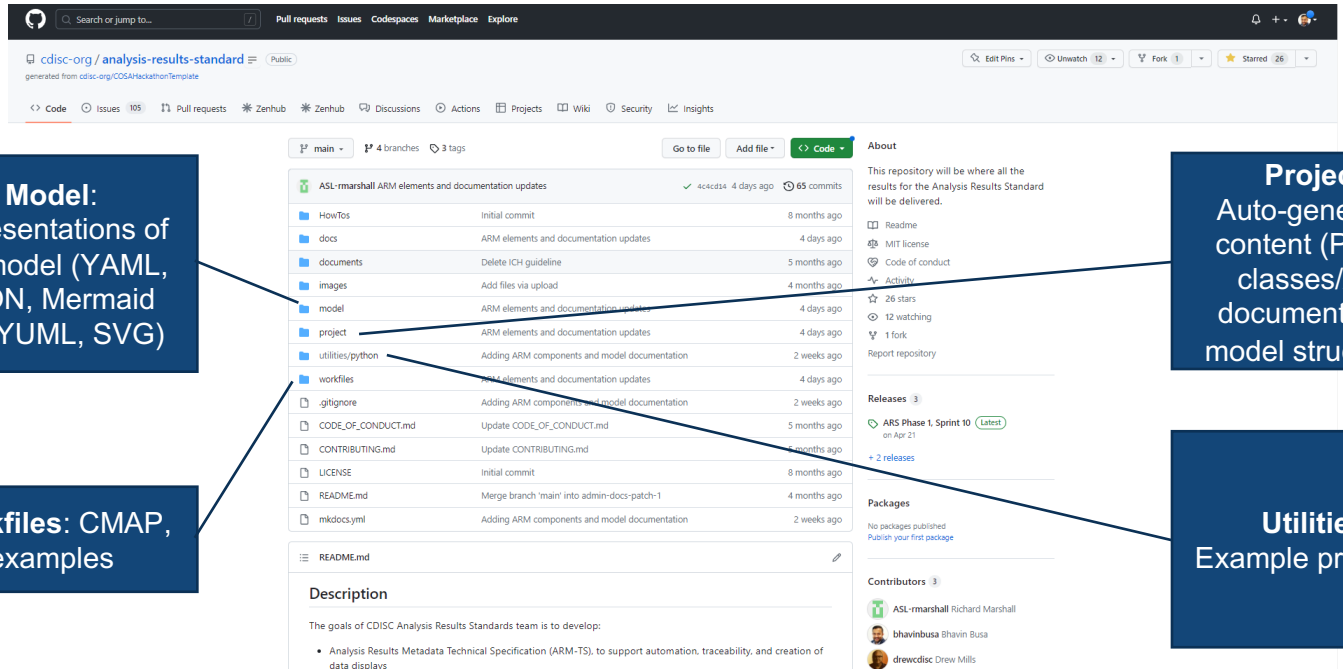
| 1 | Summary of Demographics | 1 | | Out14.1.1 |
| 2 | Summary of Subjects by Treatment | 1 | An01.05_SAF_ByTrt | |
| 2 | Summary of Age by Treatment | 2 | An03.01_Age_ByTrt | |
| 2 | Summary of Subjects by Treatment and Age Group | 3 | An03.02_AgeGrp_ByTrt | |
| 2 | Summary of Subjects by Treatment and Sex | 4 | An03.03_Sex_ByTrt | |
| 2 | Summary of Subjects by Treatment and Ethnicity | 5 | An03.04_Ethnic_ByTrt | |
| 2 | Summary of Subjects by Treatment and Race | 6 | An03.05_Race_ByTrt | |
| 2 | Summary of Height by Treatment | 7 | An03.06_Height_ByTrt | |
| 1 | Overall Summary of Treatment-Emergent Adverse Events | 2 | | Out14.3.1.1 |
| 2 | Summary of Subjects with At Least One TEAE, by Treatment | 1 | An07.01_TEAE_ByTrt | |
| 2 | Summary of Subjects with At Least One Related TEAE, by Treatment | 2 | An07.02_RelTEAE_ByTrt | |
| 2 | Summary of Subjects with At Least One Serious TEAE, by Treatment | 3 | An07.03_SerTEAE_ByTrt | |
| 2 | Summary of Subjects with At Least One Related Serious TEAE, by Treatment | 4 | An07.04_RelSerTEAE_ByTrt | |
| 2 | Summary of Subjects with At Least One TEAE Leading to Death, by Treatment | 5 | An07.05_TEAELd2Dth_ByTrt | |
| 2 | Summary of Subjects with At Least One Related TEAE Leading to Death, by Treatment | 6 | An07.06_RelTEAELd2Dth_ByTrt | |
| 2 | Summary of Subjects with At Least One TEAE Leading to Dose Modification, by Treatment | 7 | An07.07_TEAELd2DoseMod_ByTrt | |
| 2 | Summary of Subjects with At Least One TEAE Leading to Treatment Discontinuation, by Treatment | 8 | An07.08_TEAELd2TrtDsc_ByTrt | |
| 1 | Summary of TEAE by System Organ Class and Preferred Term | 3 | | Out14.3.2.1 |
| 2 | Summary of Subjects by Treatment and System Organ Class | 1 | An07.09_Soc_ByTrt | |
| 2 | Summary of Subjects by Treatment, System Organ Class and Preferred Term | 2 | An07.10_SocPt_ByTrt | |
| 1 | Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs | 4 | | Out14.3.3.1a |
| 2 | Summary of Observed Value by Treatment, Parameter and Visit | 1 | An08.01_Obs_ByTrt | |
| 2 | Summary of Change from Baseline by Treatment, Parameter and Visit | 2 | An08.02_ChgBl_ByTrt | |

# Implementations

```
        > Mth02_ContVar_ByGrp_7_Min: Minimum (Min)
        > Mth02_ContVar_ByGrp_8_Max: Maximum (Max)
1.3. Summary of Subjects by Treatment and Age Group
  Analysis: An03.02_AgeGrp_ByTrt
    Population: Safety Population [ADSL.SAFFL EQ 'Y']
    Groupings:
      1. Treatment:
         1. Placebo [ADSL.TRT01A EQ 'Placebo']
         2. Xanomeline Low Dose [ADSL.TRT01A EQ 'Xanomeline Low Dose']
         3. Xanomeline High Dose [ADSL.TRT01A EQ 'Xanomeline High Dose']
      2. Age Group:
         1. < 65 years [ADSL.AGEGR1 EQ '<65']
         2. ≥ 65 years [ADSL.AGEGR1 IN ('65-80', '>80')]
    Analysis Variable: ADSL.USUBJID
    Method: Summary by group of a categorical variable
      Operations:
        > Mth01_CatVar_ByGrp_1_n: Count of subjects (n)
        > Mth01_CatVar_ByGrp_2_pct: Percent of subjects (%)
          - Numerator: result of operation Mth01_CatVar_ByGrp_1_n for this analysis
          - Denominator: result of operation Mth01_CatVar_ByGrp_1_n for analysis An01.05_SAF_ByTrt
1.4. Summary of Subjects by Treatment and Sex
  Analysis: An03.03_Sex_ByTrt
    Population: Safety Population [ADSL.SAFFL EQ 'Y']
    Groupings:
      1. Treatment:
         1. Placebo [ADSL.TRT01A EQ 'Placebo']
         2. Xanomeline Low Dose [ADSL.TRT01A EQ 'Xanomeline Low Dose']
         3. Xanomeline High Dose [ADSL.TRT01A EQ 'Xanomeline High Dose']
      2. Gender:
         1. Male [ADSL.SEX EQ 'M']
         2. Female [ADSL.SEX EQ 'F']
```

# Analysis Results Standard Repo on GitHub

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




**Model**: representations of the model (YAML, JSON, Mermaid ER, YUML, SVG)

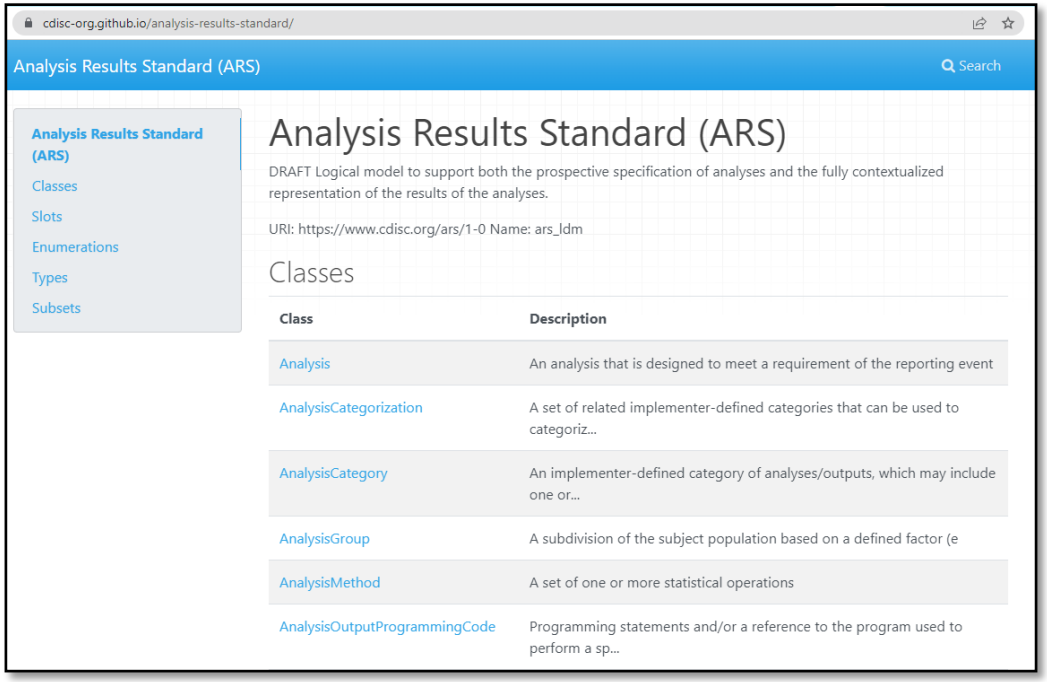
**Workfiles**: CMAP, examples

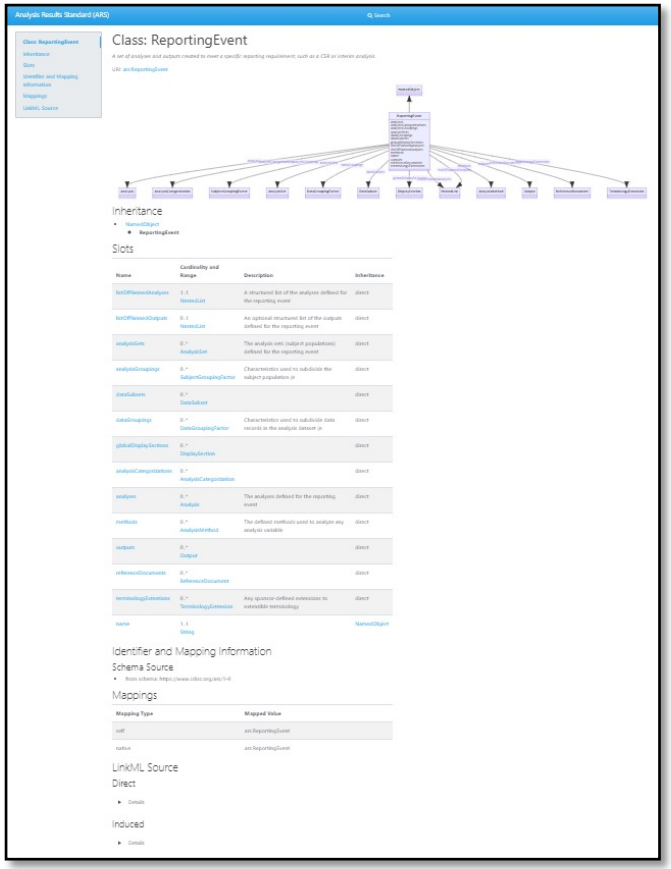
**Project**: Auto-generated content (Python classes/API, documentation, model structures)

**Utilities**: Example programs

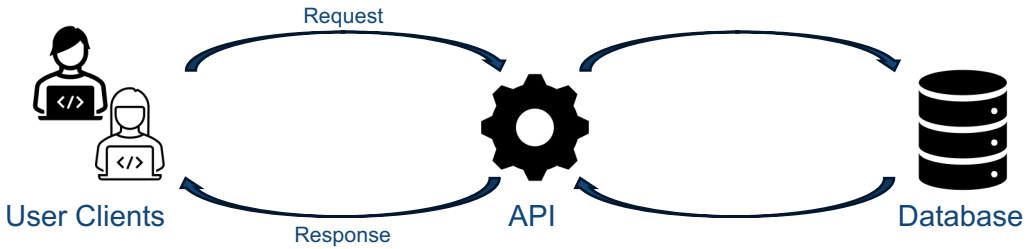
# Analysis Results Standard Model Documentation

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



# Analysis Results Standard Application Programming Interface (API)




GET /mdr/ars/packages/ Get All Ars Packages

GET /mdr/ars/packages/{package_id}/reportingevents/ Get All Package Reporting Events

GET /mdr/ars/reportingevents/{reportingevent_id}/ Get Reporting Event

GET /mdr/ars/reportingevents/{reportingevent_id}/methods/ Get All Reportingevents Methods

GET /mdr/ars/methods/{method_id}/ Get Method

Curl

```
curl -X 'GET' \
  'http://127.0.0.1:8000/mdr/ars/reportingevents/0/methods/' \
  -H 'accept: application/json'
```

Request URL

```
http://127.0.0.1:8000/mdr/ars/reportingevents/0/methods/
```

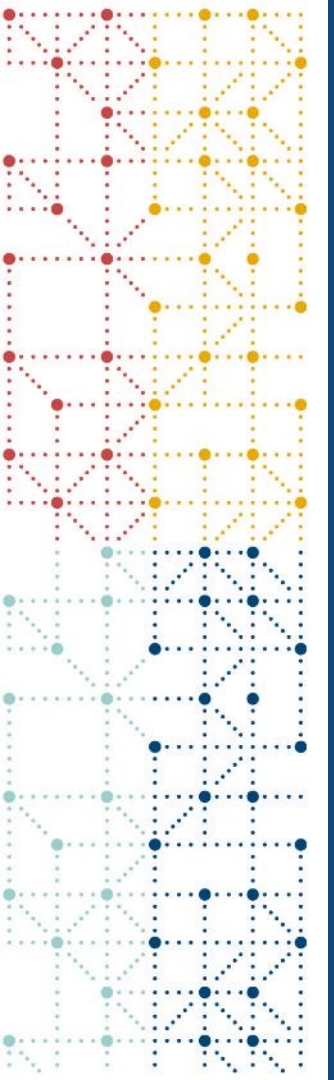
Server response

| Code | Details |
|---|---|
| 200 | Response body |


```
[
  {
    "name": "Summary by group of a categorical variable",
    "id": "Mth01_CatVar_Summ_ByGrp",
    "operations": [
      {
        "name": "Count of subjects",
        "id": "Mth01_CatVar_Summ_ByGrp_1_n",
        "label": "n",
        "resultPattern": "XX"
      },
      {
        "name": "Percent of subjects",
        "id": "Mth01_CatVar_Summ_ByGrp_2_pct",
        "label": "%",
        "referencedOperationRelationships": [
          {
            "id": "Mth01_CatVar_Summ_ByGrp_2_pct_NUM",
            "referencedOperationRole": "NUMERATOR",
            "operationId": "Mth01_CatVar_Summ_ByGrp_1_n",
            "description": "The count operation whose result
t operation."
          },
          {
            "id": "Mth01_CatVar_Summ_ByGrp_2_pct_DEN",
            "referencedOperationRole": "DENOMINATOR",
            "operationId": "Mth01_CatVar_Summ_ByGrp_1_n",
            "description": "The count operation whose result
```


https://github.com/cdisc-org/analysis-results-standard-api

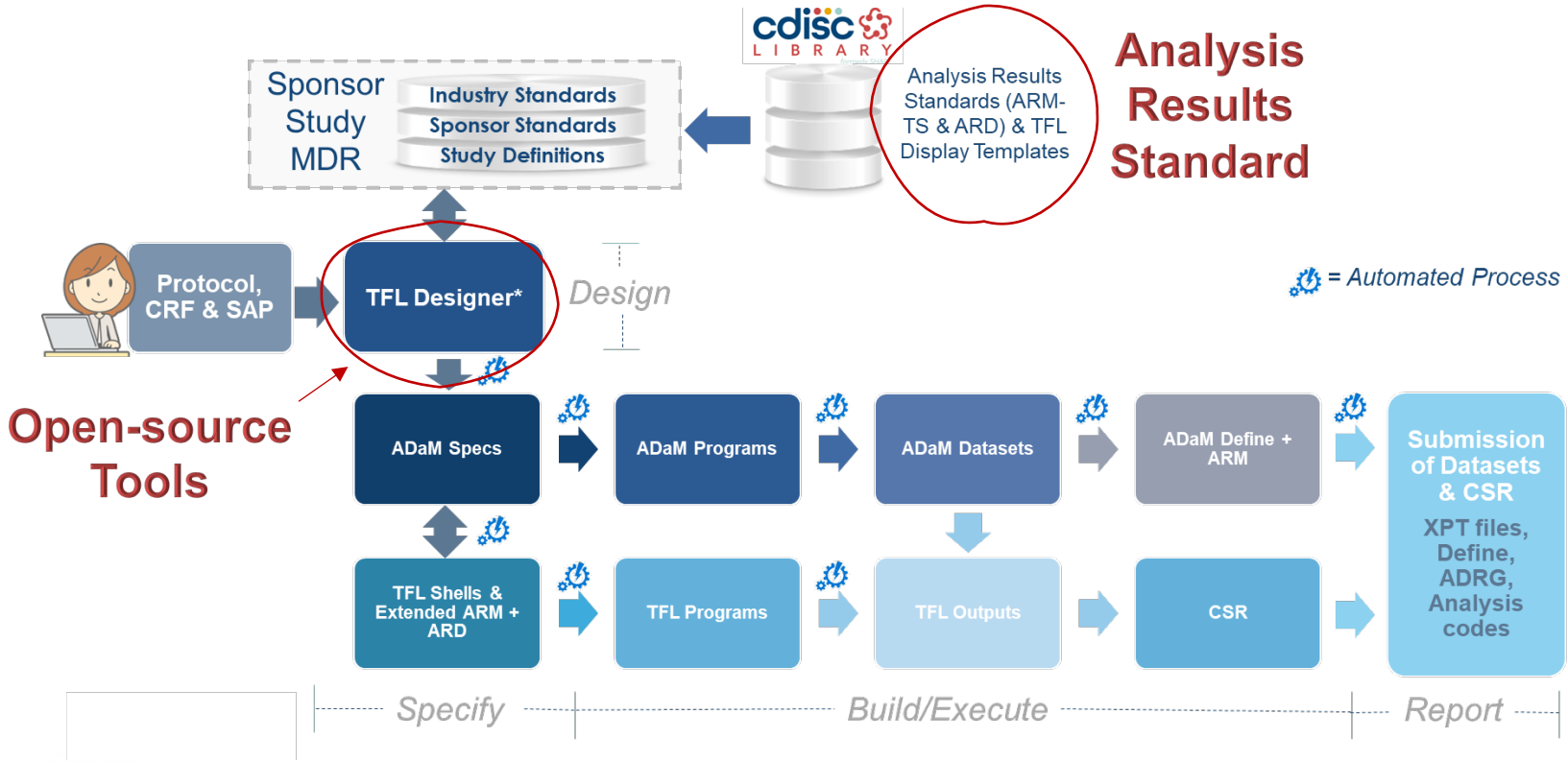
# ARS model will drive automation and open-source tool development



# Reference Implementation: TFL Designer*

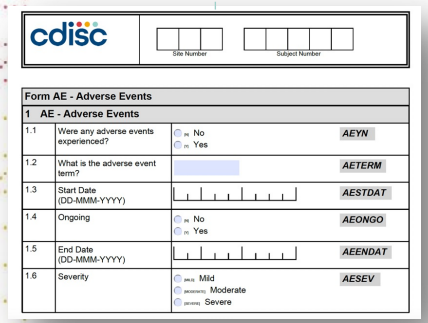
* Not a CDISC developed solution

# Analysis Results Deliverables with ARS and TFL Designer



# Streamlining Analysis Data Flow

CDASH (Collection) → SDTM (Tabulation) → ADaM (Analysis) → Analysis Results → TFL



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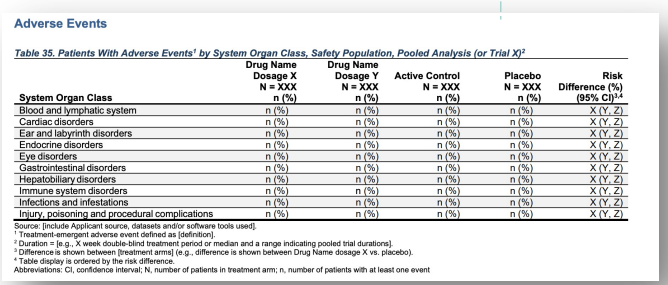
Site Number | Subject Number

**Form AE - Adverse Events**

**1 AE - Adverse Events**

| | | | |
|---|---|---|---|
| 1.1 | Were any adverse events experienced? | No / Yes | AEYN |
| 1.2 | What is the adverse event term? | | AETERM |
| 1.3 | Start Date (DD-MMM-YYYY) | | AESTDAT |
| 1.4 | Ongoing | No / Yes | AEONGO |
| 1.5 | End Date (DD-MMM-YYYY) | | AEENDAT |
| 1.6 | Severity | Mild / Moderate / Severe | AESEV |



**Adverse Events**

*Table 35. Patients With Adverse Events[1] by System Organ Class, Safety Population, Pooled Analysis (or Trial X)[2]*

| System Organ Class | Drug Name Dosage X N = XXX n (%) | Drug Name Dosage Y N = XXX n (%) | Active Control N = XXX n (%) | Placebo N = XXX n (%) | Risk Difference (%) (95% CI)[3,4] |
|---|---|---|---|---|---|
| Blood and lymphatic system | n (%) | n (%) | n (%) | n (%) | X (Y, Z) |
| Cardiac disorders | n (%) | n (%) | n (%) | n (%) | X (Y, Z) |
| Ear and labyrinth disorders | n (%) | n (%) | n (%) | n (%) | X (Y, Z) |
| Endocrine disorders | n (%) | n (%) | n (%) | n (%) | X (Y, Z) |
| Eye disorders | n (%) | n (%) | n (%) | n (%) | X (Y, Z) |
| Gastrointestinal disorders | n (%) | n (%) | n (%) | n (%) | X (Y, Z) |
| Hepatobiliary disorders | n (%) | n (%) | n (%) | n (%) | X (Y, Z) |
| Immune system disorders | n (%) | n (%) | n (%) | n (%) | X (Y, Z) |
| Infections and infestations | n (%) | n (%) | n (%) | n (%) | X (Y, Z) |
| Injury, poisoning and procedural complications | n (%) | n (%) | n (%) | n (%) | X (Y, Z) |

Source: [include Applicant source, datasets and/or software tools used].
[1] Treatment-emergent adverse event defined as [definition].
[2] Duration = [e.g., X week double-blind treatment period or median and a range indicating pooled trial durations].
[3] Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo).
[4] Table display is ordered by the risk difference.
Abbreviations: CI, confidence interval; N, number of patients in treatment arm; n, number of patients with at least one event

Keeping End in Mind

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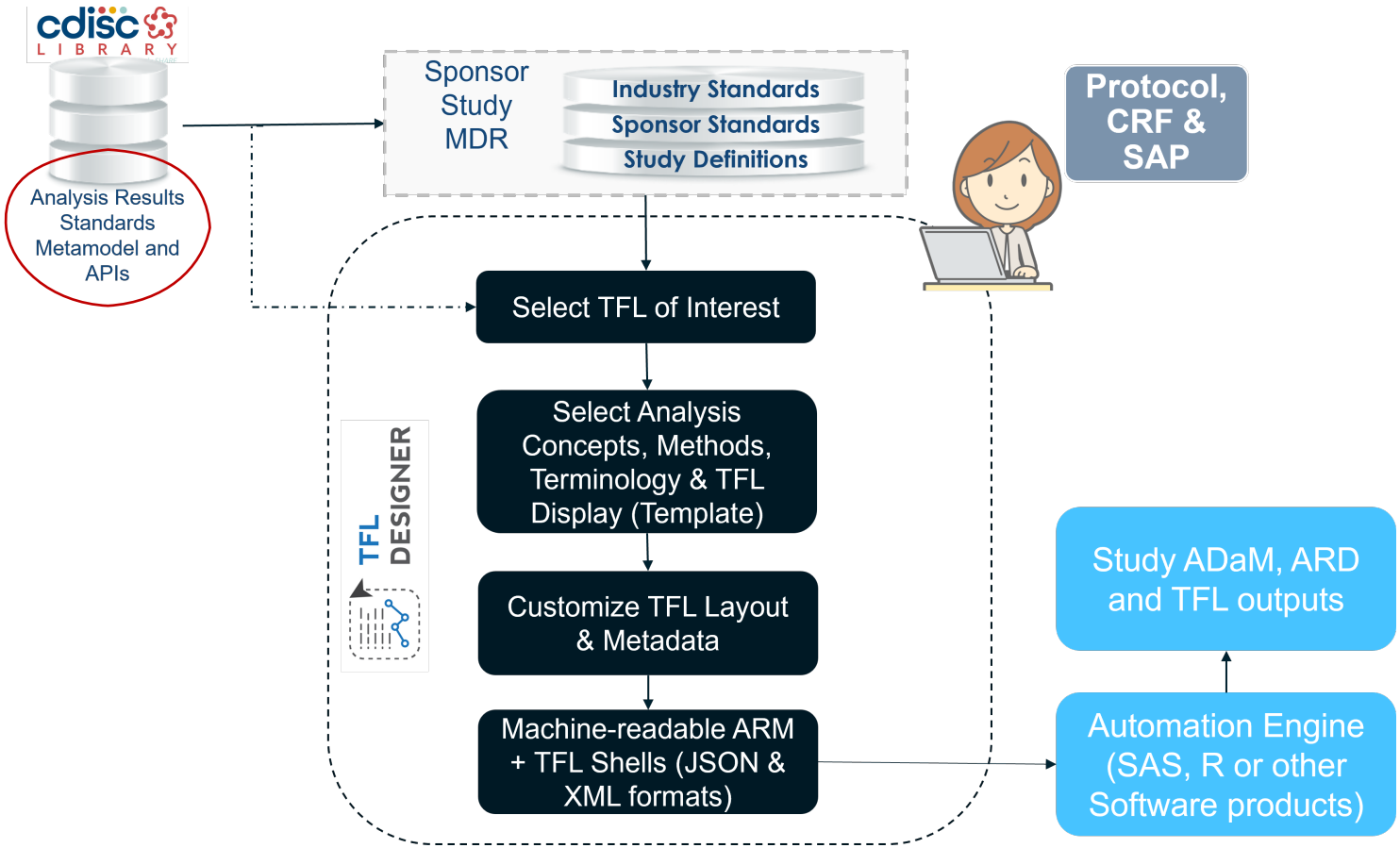
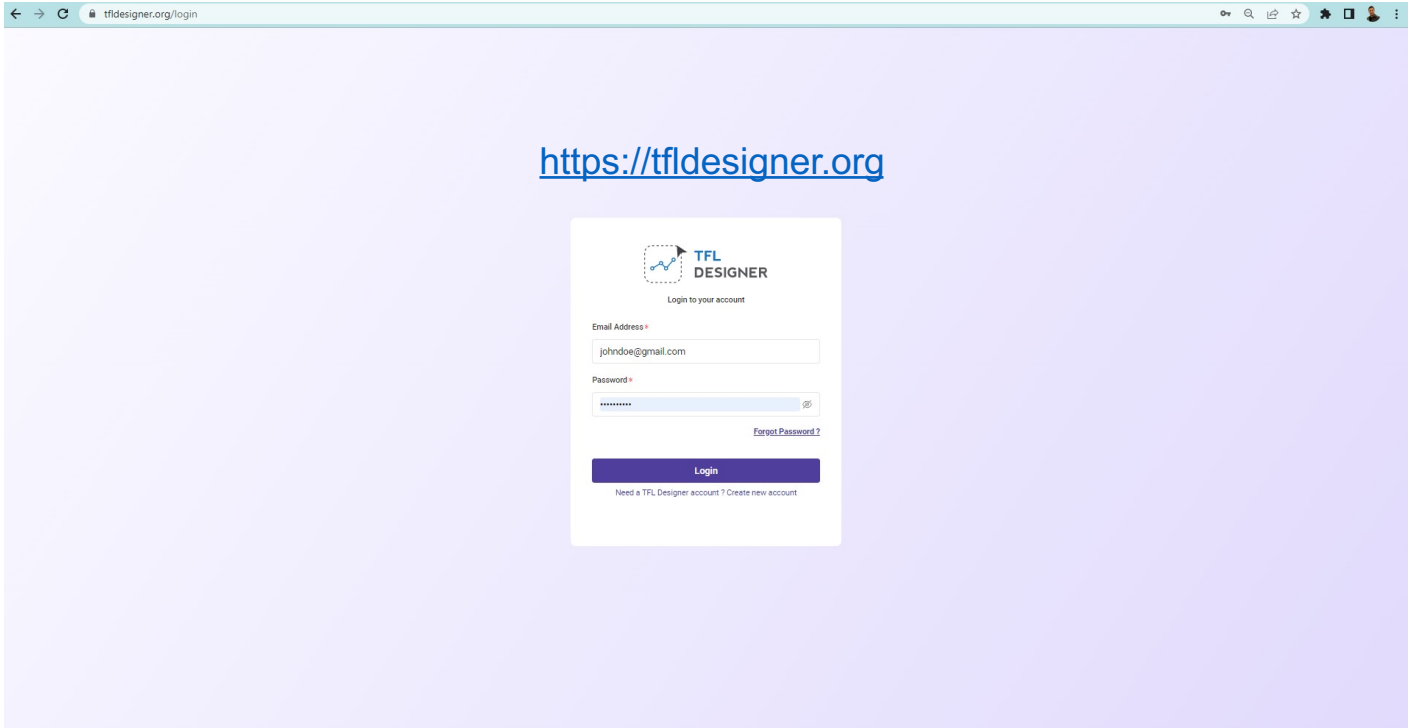

cdisc LIBRARY
Analysis Results Standards Metamodel and APIs
Sponsor Study MDR
Industry Standards
Sponsor Standards
Study Definitions
Protocol, CRF & SAP
Select TFL of Interest
Select Analysis Concepts, Methods, Terminology & TFL Display (Template)
Customize TFL Layout & Metadata
Machine-readable ARM + TFL Shells (JSON & XML formats)
TFL DESIGNER
Study ADaM, ARD and TFL outputs
Automation Engine (SAS, R or other Software products)

# TFL Designer (Community): Beta version




[Stay Tuned @ Clymb Clinical]

# Release Plan

**Version 1.0**

- Logical Model
- Common safety examples based on team developed tables
  - Demographics
  - Adverse Events
  - Vital signs

- CDISC ARS Hackathon: July 12th, 2023
- Anticipated CDISC Internal Review: July 21st, 2023
- Anticipated CDISC Public Review: October-November, 2023
- US Interchange Workshop: October 2023
- Anticipated Final Release: December 2023/January 2024

# CDISC ARS Hackathon – Important Dates

- 🚀 Unleash your creativity and collaborate with the CDISC community to operationalize the analysis results model
- June 15th: Look for the ARS Hackathon e-Blast following today's webinar
- June 29th: Hear more about the ARS Hackathon at the COSA Quarterly Spotlight Webinar
- July 12th: ARS Hackathon Kick-off Webinar

Register at https://www.cdisc.org/events/webinars/upcoming

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# References


1. All You Need to Know about the New CDISC Analysis Result Standards!, PharmaSUG 2023: Paper # MM327, Bhavin Busa, Richard Marshall, Bess LeRoy

2. CDISC Analysis Results Standard GitHub, 2023: https://github.com/cdisc-org/analysis-results-standard

3. The Linked Data Modeling Language: A framework for describing and integrating rich biomedical data, 2022: https://www.slideshare.net/cmungall/linkml-intro-july-2022pptx

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