



Hands-on Workshop: ARS and eTFL Portal

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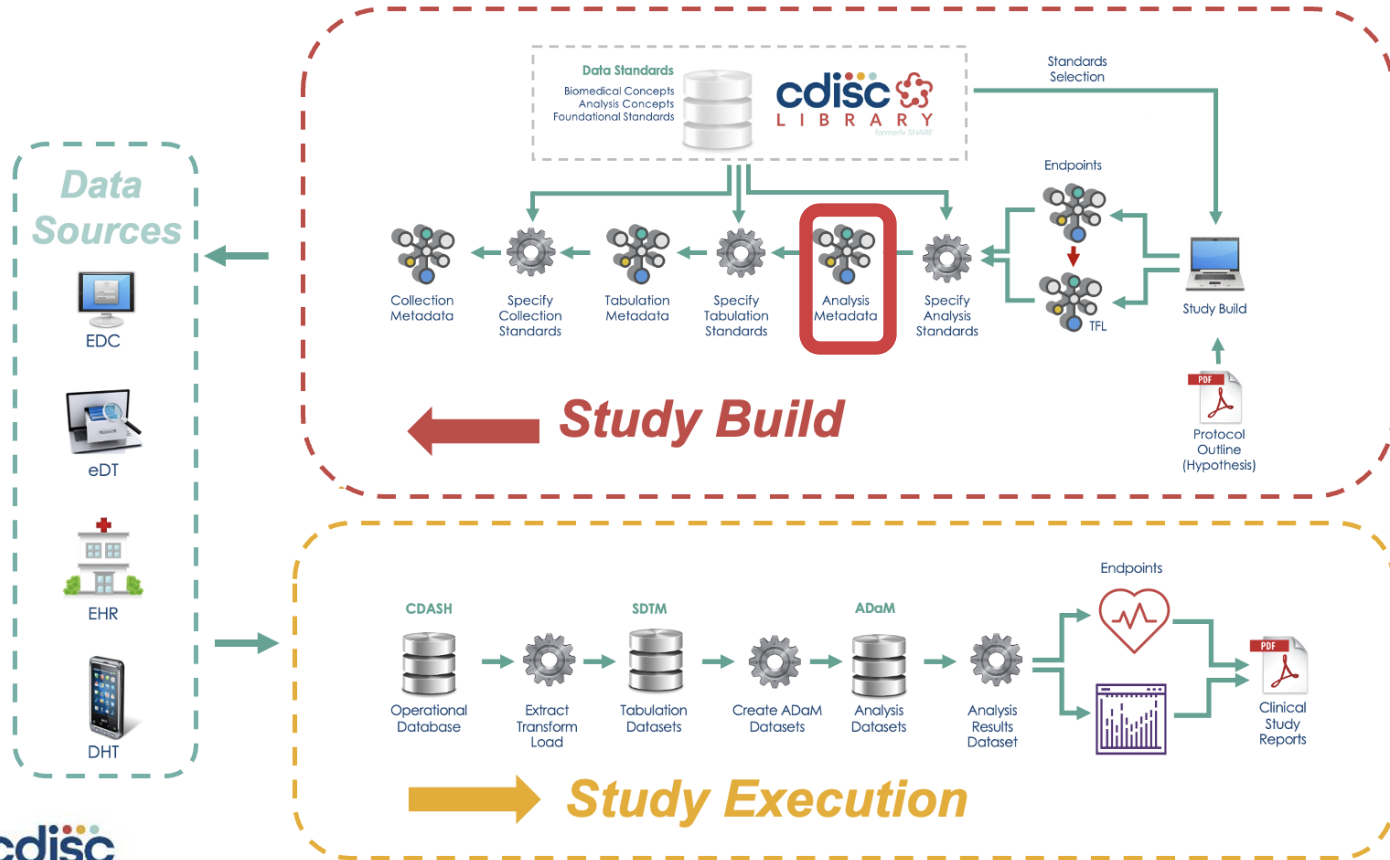




Agenda

- Where we started
- Development of the Analysis Results Standard (ARS)
- Expanding content through the eTFL Portal
- Creating ARS metadata using TFL Designer
- Q&A

Standardizing Analysis Metadata



CDISC 360

- CDISC 360 was a proof of concept that sought to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata-driven automation across the end- to-end clinical research data lifecycle.
- This will enable software developers to develop new tools (proprietary and open source) that consume this novel metadata to ease standards' implementations, while increasing data processing efficiencies.
- Reduce unnecessary variation and lower the barrier to adoption.



CDISC 360: The Art of the Possible

CDISC 360

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What is CDISC 360?

CDISC 360 is an ambitious new project geared toward innovating clinical data standards to ensure they remain valuable and relevant into the future. CDISC 360 aims to support standards-based, metadata-driven automation across the end-to-end clinical research data lifecycle and represents a significant next step toward realizing an increased return on investment in standards implementation that our stakeholders expect - substantially improved efficiency, consistency, and re-usability.

We are inviting your organization to join us in this important project by getting involved. CDISC values the input and collaboration of our members; we want to ensure your needs and expectations are taken into account so that the project achieves results that are supported and endorsed by our community.

CDISC 360 seeks to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata driven-automation across the end-to-end clinical research data lifecycle.

The Opportunity

The CDISC foundational standards define research data and metadata structures, but writing these standards as documents has yielded more text than metadata. Gaps in standards metadata limit automation opportunities. The inherent flexibility provided by the standards supports a broad range of implementations, but that flexibility also allows for inconsistencies that make scaling automation difficult. The lack of a conceptual foundation for the standards further contributes to these inconsistencies. The relationships that would be expressed by these concepts remain largely implicit in the current versions of the standards.

Objectives

CDISC 360 will develop proof-of-concept enhancements to the CDISC standards metadata as well as related proof-of-concept software to confirm that the enhanced standards can be used to automate preparation of study specification metadata and end-to-end study data processing.

The focal point of this project is concept-based modeling. CDISC will not deliver software to industry as an outcome of CDISC 360. However, during the project, an enhanced set of API prototypes will be developed to demonstrate that the concept-based metadata can be accessed in order to implement metadata-driven automation.

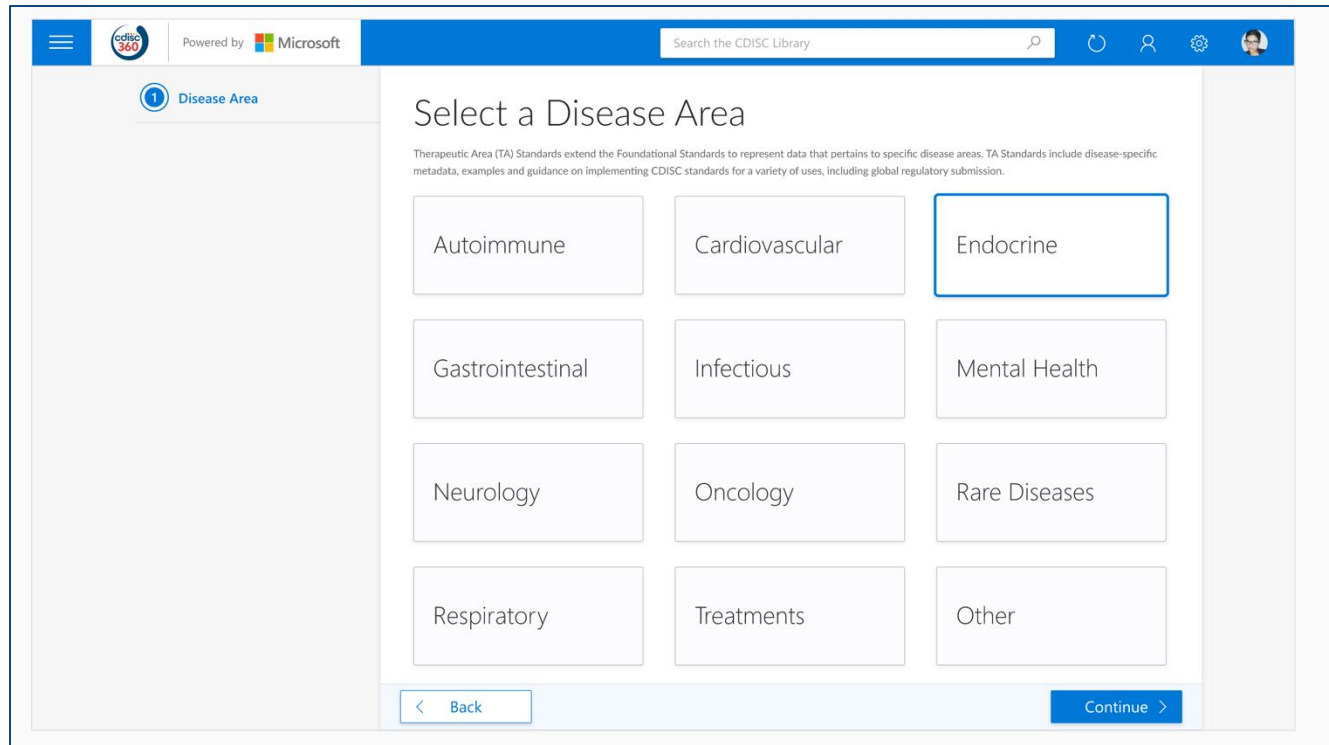
Scope

CDISC 360 will implement end-to-end standards-based metadata-driven automated processing by conducting three use cases, demonstrated by implementing portions of the CDISC Type 1 Diabetes TAUG.

Metadata / Data Processing Use Cases

Use Case 1: Create end-to-start specification - Demonstrate the ability to produce a standards-based, machine-readable specification for the data and analysis artifacts to be created in the study.

CDISC 360: The Art of the Possible



The screenshot displays the CDISC 360 web application interface. At the top, there is a blue header bar containing the CDISC 360 logo, the text "Powered by Microsoft", a search bar labeled "Search the CDISC Library", and several utility icons (refresh, user profile, settings, and a user avatar). Below the header, a sidebar on the left shows a "Disease Area" section with a blue circle containing the number "1". The main content area is titled "Select a Disease Area" and includes a brief description: "Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. TA Standards include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submission." Below this text is a grid of 12 buttons representing different disease areas: Autoimmune, Cardiovascular, Endocrine, Gastrointestinal, Infectious, Mental Health, Neurology, Oncology, Rare Diseases, Respiratory, Treatments, and Other. The "Endocrine" button is highlighted with a blue border. At the bottom of the main content area, there are two buttons: a light blue "Back" button with a left-pointing arrow and a dark blue "Continue" button with a right-pointing arrow.

CDISC 360: The Art of the Possible

The screenshot displays the CDISC 360 web application interface. At the top, there is a blue header bar containing the CDISC 360 logo, the text "Powered by Microsoft", a search bar labeled "Search the CDISC Library", and several utility icons (refresh, user profile, settings, and a user avatar). On the left side, a vertical navigation pane shows two steps: "1 Disease Area" with a checkmark and "Endocrine" selected, and "2 Therapeutic Area" which is currently active. The main content area is titled "Select a Therapeutic Area" and includes a descriptive paragraph: "Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. TA Standards include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submission." Below this text, seven rectangular buttons are arranged in a grid, each representing a therapeutic area: "Acute Kidney Injury", "Diabetes - Type 1", "Diabetes - Type 2" (which is highlighted with a blue border), "Diabetic Kidney Disease", "Dyslipidemia", "Kidney Transplant", and "Polycystic Kidney Disease". At the bottom of the interface, there are two buttons: a "Back" button with a left-pointing arrow and a "Continue" button with a right-pointing arrow.

CDISC 360: The Art of the Possible

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Search the CDISC Library

1 Disease Area
✓ Endocrine

2 Therapeutic Area
✓ Diabetes - Type 2


3 Standards Focus
✓ Study Endpoint

4 Study Endpoint
✓ Analysis of Glycated Hemoglobin

5 Standard Analyses

Select from Standard Analyses

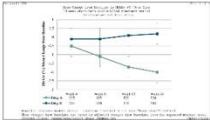
HbA1c Longitudinal Repeated Measures Analysis



This primary endpoint analysis uses a repeated measures model to compare the Mean Change from baseline of HbA1c (%) between the two treatments at week n1 and week n2. Adjusted change from baseline reflects the repeated measures correction.

[View details](#)


Mean Change from Baseline in HbA1c (%) Over Time



Provides a visual display of the information in the "HbA1c Longitudinal Repeated Measures Analysis" table. Includes additional weeks beyond those in that table. The mean changes shown are based on adjusted changes from baseline from the repeated measures model.

[View details](#)

HbA1c Categorical Analysis



Uses a chi-square test to compare the proportion of the study population with HbA1c < 7% between two treatments at week n1 and week n2.

[View details](#)

[Back](#) [Continue](#)

CDISC 360: The Art of the Possible

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Selection Summary

Study Endpoint

Analysis of Glycated Hemoglobin

Analysis of the continuous clinical endpoint of HbA1c. Example: a Phase III, parallel-group study designed to determine efficacy of Drug A for patients with Type II diabetes. The primary endpoint defined as the change in HbA1c from baseline.

[View details](#)

Analysis

Mean Change from Baseline in HbA1c (%) Over Time

Provides a visual display of the information in the "HbA1c Longitudinal Repeated Measures Analysis" table. Includes additional weeks beyond those in that table. The mean changes shown are based on adjusted changes from baseline from the repeated measures model.

[View details](#)
[View analysis results metadata](#)

Analysis Datasets

ADSL

Analysis Data Subject Level

[View analysis dataset metadata](#)
[View sample analysis data](#)
[View analysis dataset structure](#)

ADHBA1C

DBS - Structured Dataset

[View analysis dataset metadata](#)
[View sample analysis data](#)
[View analysis dataset structure](#)

[Back](#) [Save Selection](#)

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Selection Summary

Study Endpoint Analysis

Analysis Results Metadata

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 Period, Intention-to-treat Population |
| ANALYSIS REASON | Treatment difference results (LSMean, confidence interval, p-value) |
| RESULT IDENTIFIER | HBA1c (%) |
| PARAM | HBA1C |
| PARAMCD | CHG (Change from baseline) |
| ANALYSIS VARIABLE | ADHBA1C |
| ANALYSIS DATASET | SPICEDIN SAS |
| ANALYSIS PURPOSE | PRIMARY OUTCOME MEASURE |
| SELECTION CRITERIA | ADHBA1C ITYPE = "Y" and PARAMCD = "HBA1C" and CHG se and ANLQ1FL = "Y" and DTYPE = "" |
| DOCUMENTATION | See SAP Section XX for details. Program: s_hba1c_01rptm sas L3 means and 95% CIs are based on planned treatment, baseline HBA1c value, visit, event/baseline and event/treatment interaction. |
| PROGRAMMING STATEMENTS | <pre> [SQL version 3.2] PROC MIXED DATA = ADHBA1C; WHERE ITYPE = "Y" and PARAMCD = "HBA1C" and CHG se and ANLQ1FL = "Y" and CLASS TRTP AVISIT; MODEL CHG = TRTP BASE AVISIT BASE*AVISIT AVISIT*TRTP / COV=PSY; LAMBDA TRTP / CL DTYPE REPEATED variable = ADHBA1C DTYPE= TYPE=RM; RUN ; </pre> |

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Selection Summary

Study Endpoint Analysis Analysis Datasets

Analysis Dataset Metadata

| Keys | Location | Documentation |
|----------------------|-------------|-----------------|
| ADYID, USUBJID, | ADHBA1C.sas | ADHBA1C.SAS.SAP |
| PARAMCD, AVISIT, ADY | | |

Save Data Standards

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Selection Summary

Study Endpoint Analysis Analysis Datasets

Sample Analysis Data

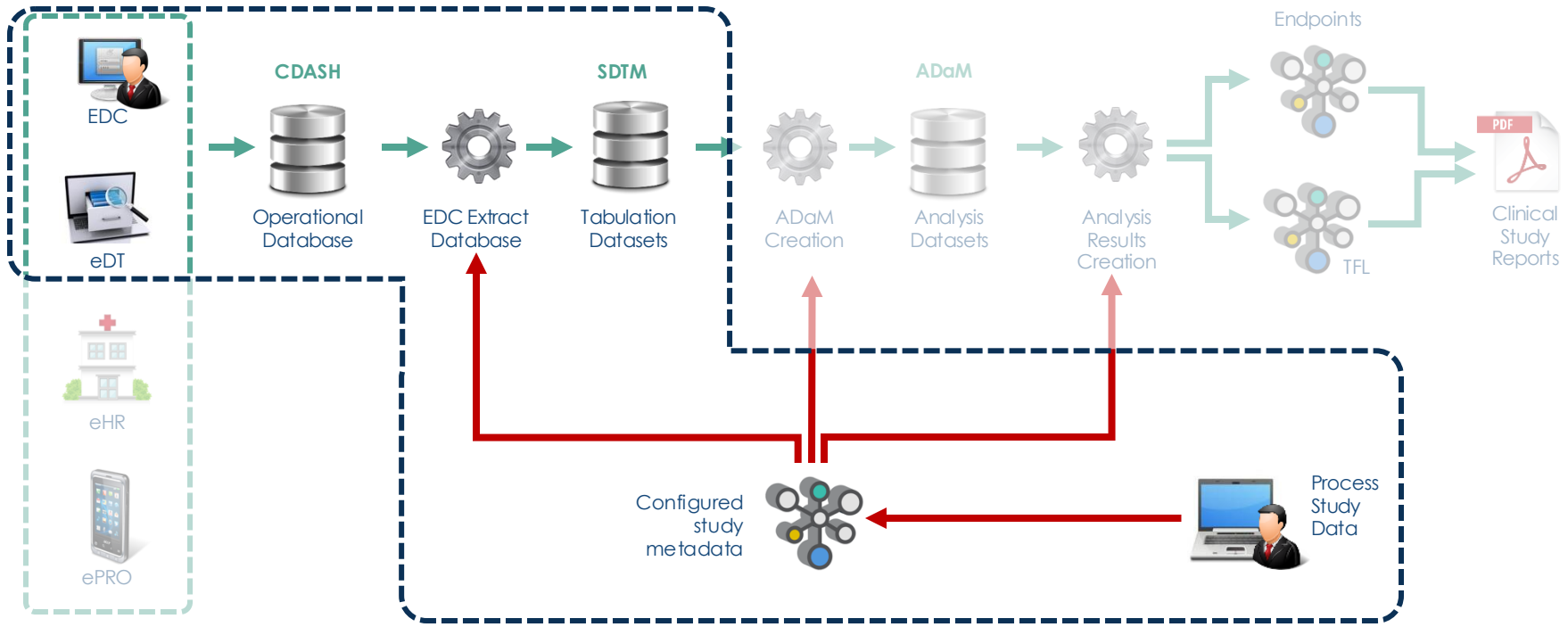
Table 4.1.1: ADHBA1C Analysis Dataset

| Row | STUDYID | USUBJID | PARAM | PARAMCD | VSMT | AVISIT | AWT | TARGET | ADY | TRTP | ITYPE | LABFL | BASL | AVAL | CBG | ANLQ1FL | CRIT1 | CRIT1FL | DTYPE | LSMEQ |
|-----|---------|-------------|-----------|---------|---------|----------|-----|--------|----------|------|-------|-------|------|------|-----|---------|-------|---------|-------|-------|
| 1 | XYZ | XYZ-001-001 | HBA1C (%) | HBA1C | Visit 2 | Baseline | 1 | 1 | [Drug A] | Y | Y | 9.2 | 9.2 | Y | <7% | Y | <7% | N | 23456 | |
| 2 | XYZ | XYZ-001-001 | HBA1C (%) | HBA1C | Visit 3 | Week 8 | 28 | 28 | [Drug A] | Y | Y | 9.2 | 8.5 | 0.7 | Y | <7% | Y | <7% | N | 45125 |
| 3 | XYZ | XYZ-001-001 | HBA1C (%) | HBA1C | Visit 3 | Week 8 | 56 | 56 | [Drug A] | Y | Y | 9.2 | 7.3 | 1.9 | Y | <7% | Y | <7% | N | 24768 |
| 4 | XYZ | XYZ-001-001 | HBA1C (%) | HBA1C | Visit 3 | Week 12 | 84 | 84 | [Drug A] | Y | Y | 9.2 | 6.8 | 2.4 | Y | <7% | Y | <7% | Y | 76553 |
| 5 | XYZ | XYZ-001-001 | HBA1C (%) | HBA1C | Visit 3 | Week 24 | 168 | 168 | [Drug A] | Y | Y | 9.2 | 6.3 | 2.9 | Y | <7% | Y | <7% | Y | 65078 |
| 6 | XYZ | XYZ-001-002 | HBA1C (%) | HBA1C | Visit 2 | Baseline | 1 | 1 | [Drug B] | Y | Y | 8.6 | 8.6 | Y | <7% | Y | <7% | N | 90874 | |
| 7 | XYZ | XYZ-001-002 | HBA1C (%) | HBA1C | Visit 3 | Week 8 | 28 | 28 | [Drug B] | Y | Y | 8.6 | 8.7 | 0.1 | Y | <7% | Y | <7% | N | 23454 |
| 8 | XYZ | XYZ-001-002 | HBA1C (%) | HBA1C | Visit 4 | Week 8 | 56 | 56 | [Drug B] | Y | Y | 8.6 | 9.6 | 1.0 | Y | <7% | Y | <7% | N | 50744 |
| 9 | XYZ | XYZ-001-002 | HBA1C (%) | HBA1C | Visit 5 | Week 8 | 56 | 61 | [Drug B] | Y | Y | 8.6 | 9.5 | 1.1 | Y | <7% | Y | <7% | N | 67543 |
| 10 | XYZ | XYZ-001-002 | HBA1C (%) | HBA1C | Visit 5 | Week 12 | 84 | 81 | [Drug B] | Y | Y | 8.6 | 9.5 | 1.1 | Y | <7% | N | LOCF | 67543 | |
| 11 | XYZ | XYZ-001-002 | HBA1C (%) | HBA1C | Visit 6 | Week 24 | 168 | 168 | [Drug B] | Y | Y | 8.6 | 9.5 | 1.1 | Y | <7% | N | LOCF | 67543 | |

Save Data Standards

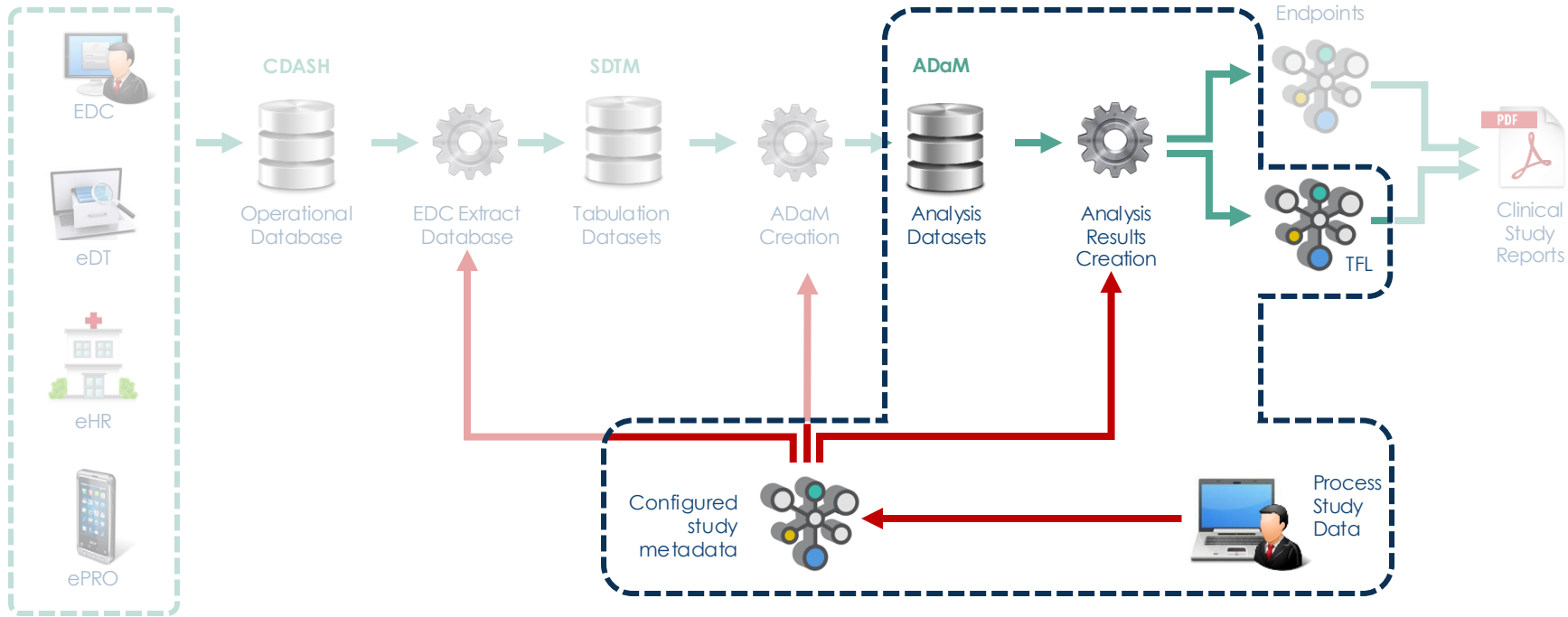
Use Case 3 : Execute

Automatic population of data into artifacts



Use Case 3 : Execute

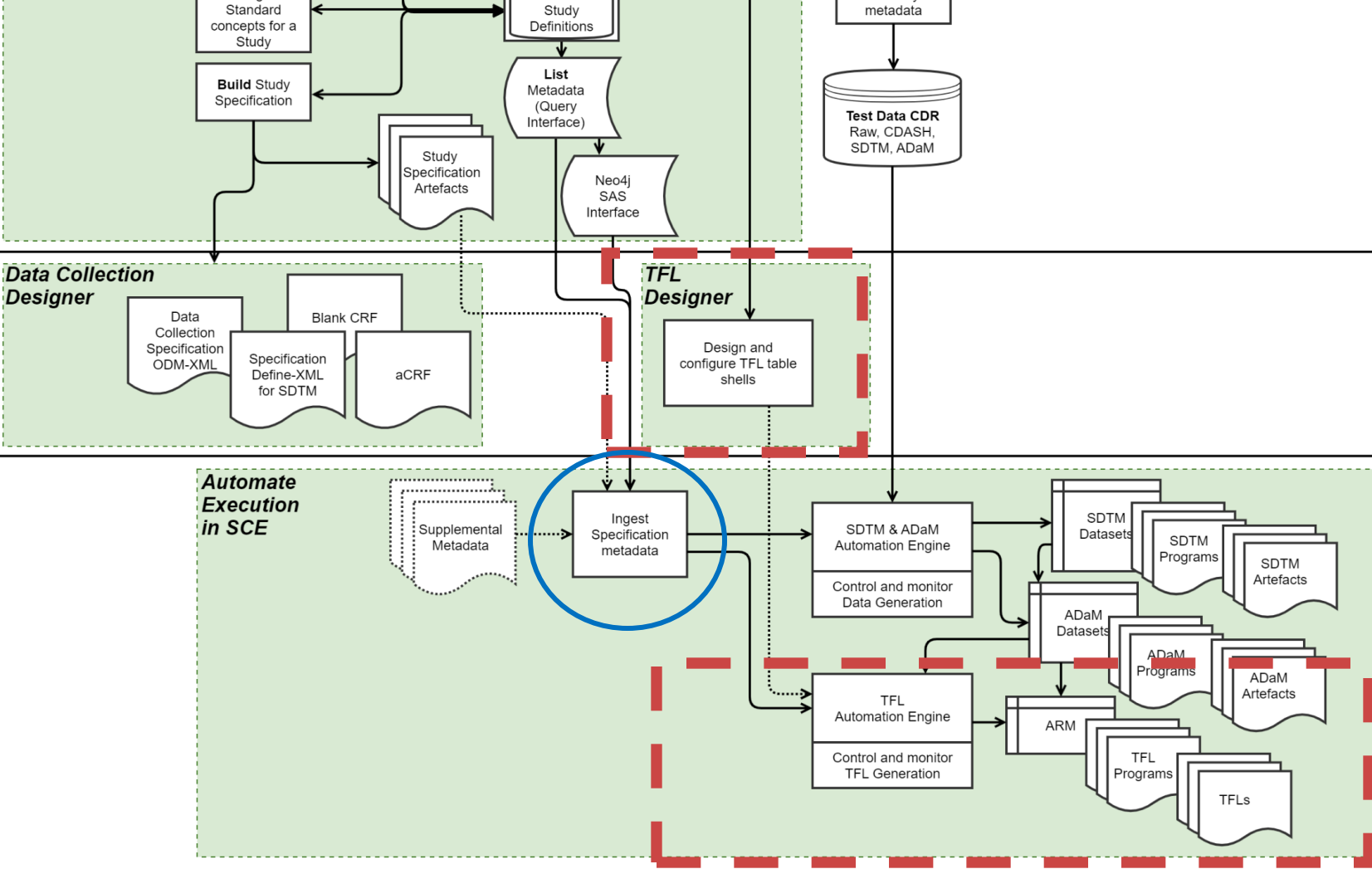
Automatic population of data into artifacts



CDISC 360 PoC

WS4 & 6

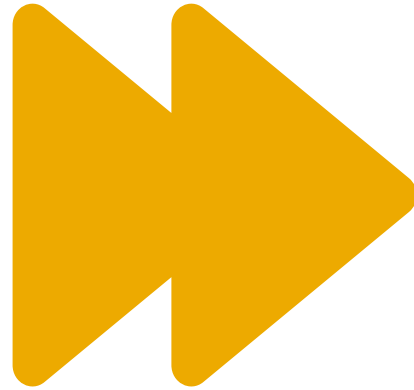
WS6





What did we learn from CDISC 360?

Fast Forward
Q1 2021 to Q1 2024



Analysis Results Key Objectives



Leverage analysis results metadata to drive the automation of results



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

CDISC Analysis Result Standards – Released April 19, 2024!



Analysis Results Standard (ARS) v1.0



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

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

Features of ARS v1.0

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

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

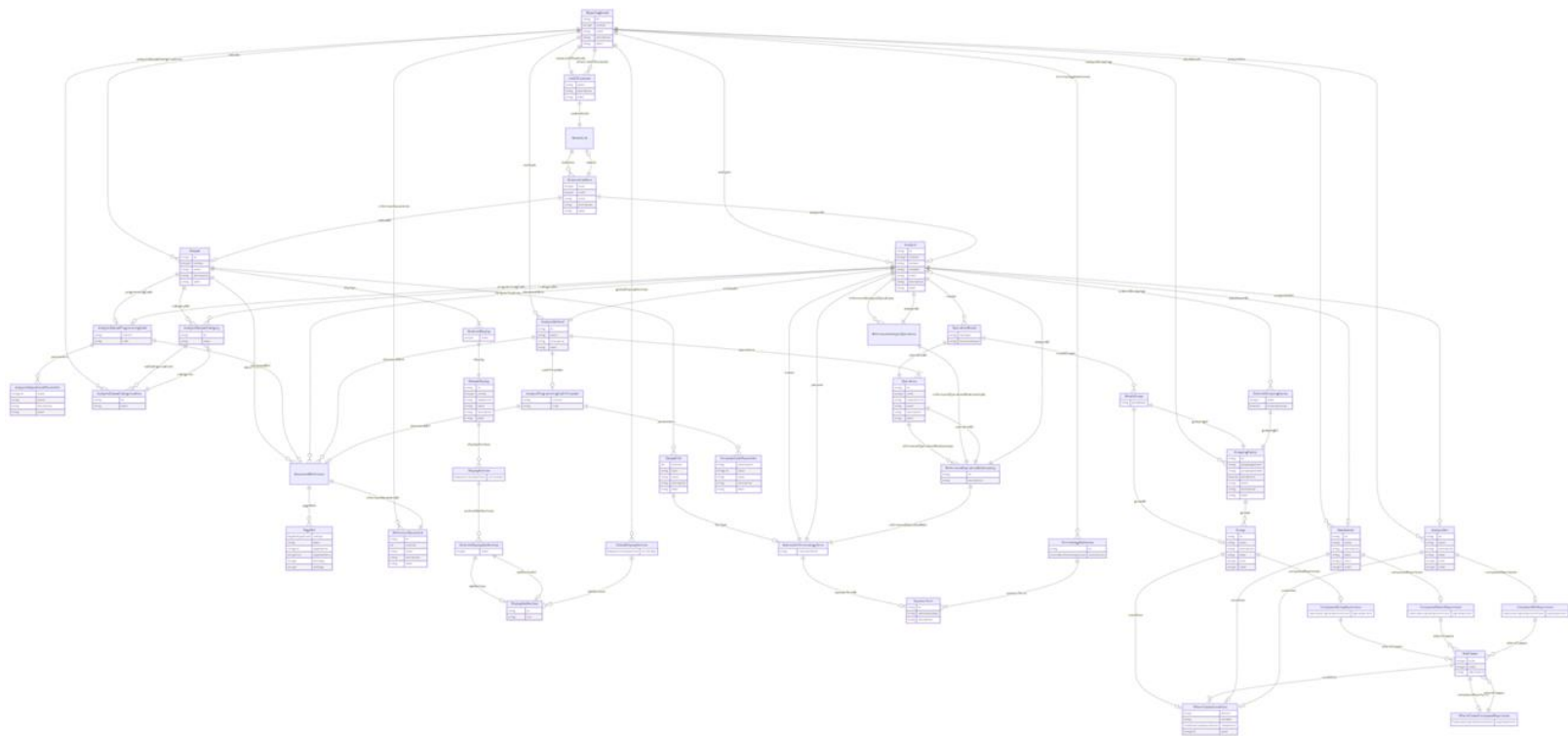
| Class | Description |
|----------------|---|
| NamedObject | An object with a name |
| ReportingEvent | A set of analyses and outputs created to meet requirements... |
| ListOfContents | A structured list of analyses and outputs... |

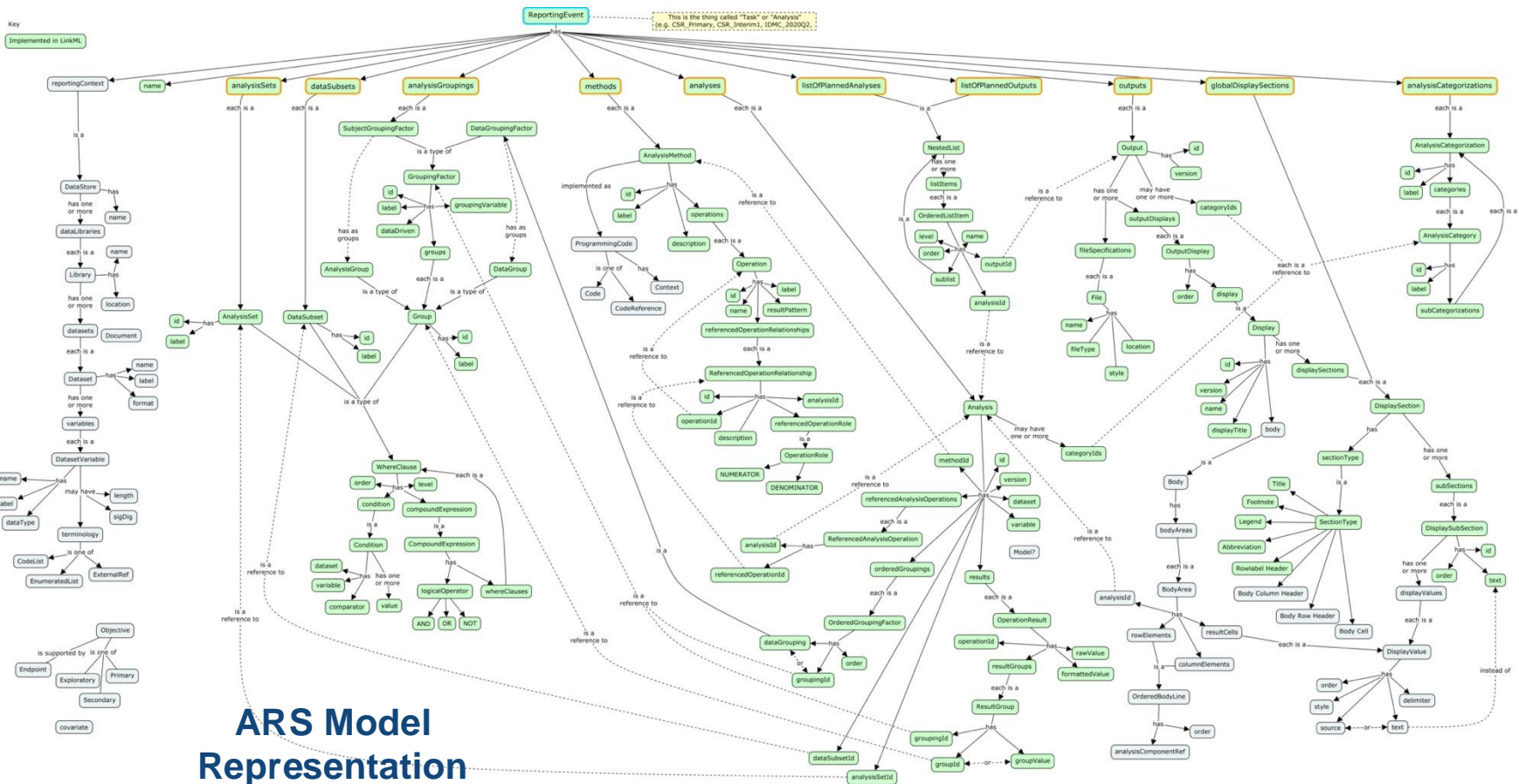
| Date | Version |
|------------|---------|
| 2024-04-19 | Final |

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<https://wiki.cdisc.org/display/ARSP/Analysis+Results+Standard+User+Guide+v1.0>

ARS Logical Model Schema Diagram





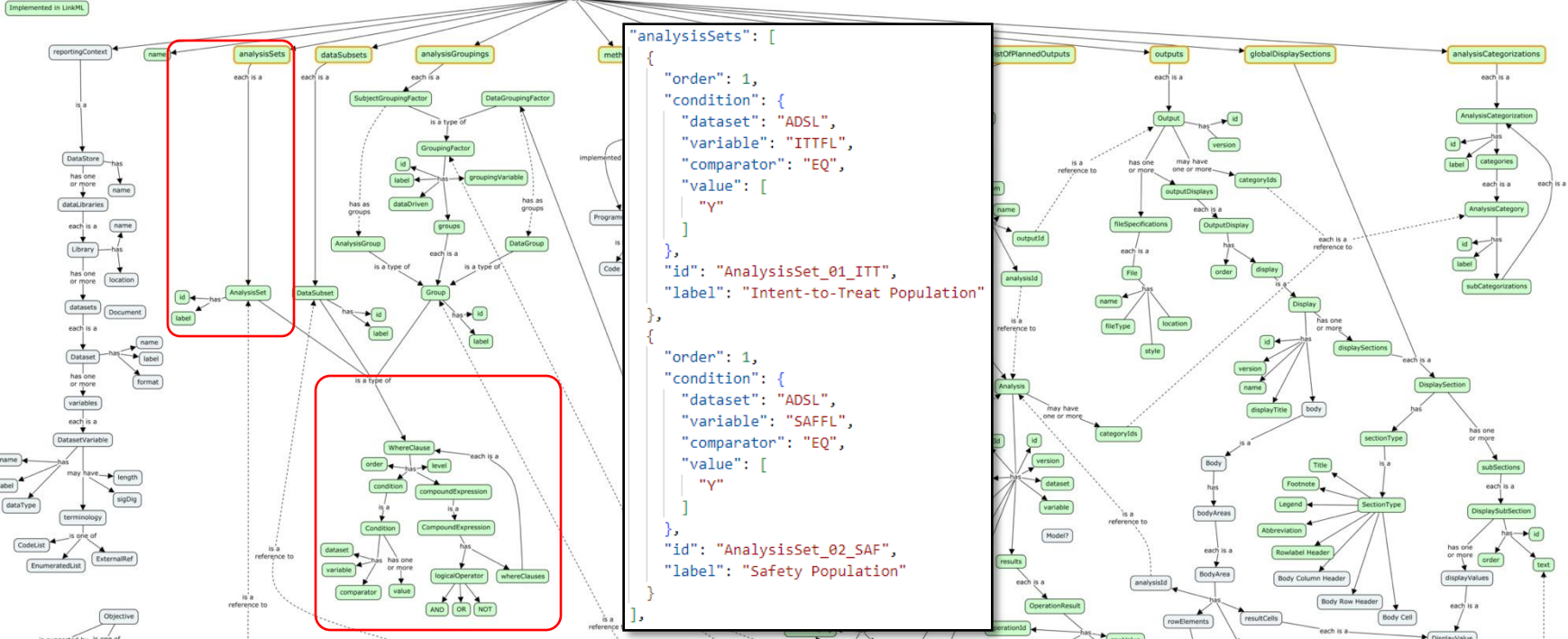
ARS Model Representation using CMAP



Analysis Sets

Key
Implemented in LinkML

This is the thing called "Task" or "Analysis" (e.g. CSR_Primary, CSR_Interim), IDMC_2020Q2



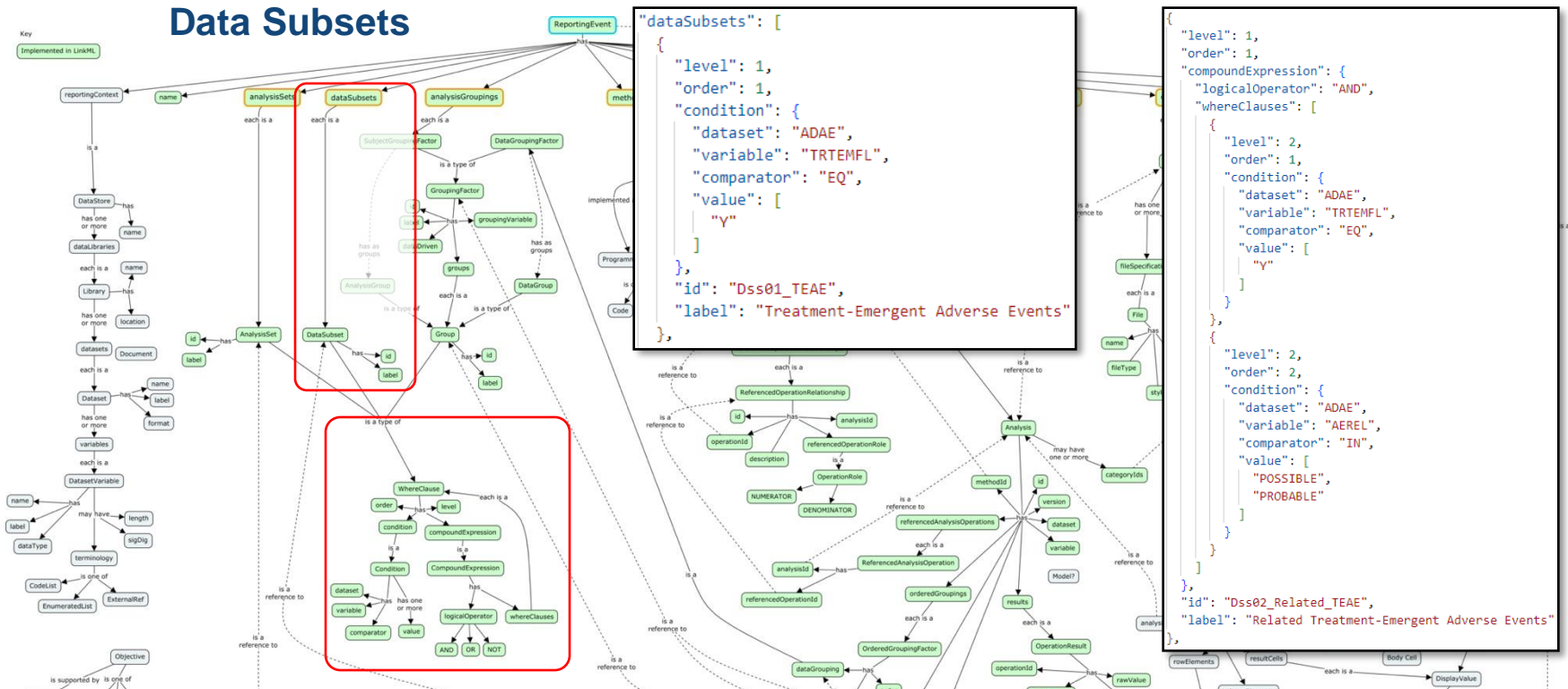
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      ]
    },
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    "label": "Intent-to-Treat Population"
  },
  {
    "order": 1,
    "condition": {
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      "variable": "SAFFL",
      "comparator": "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 |

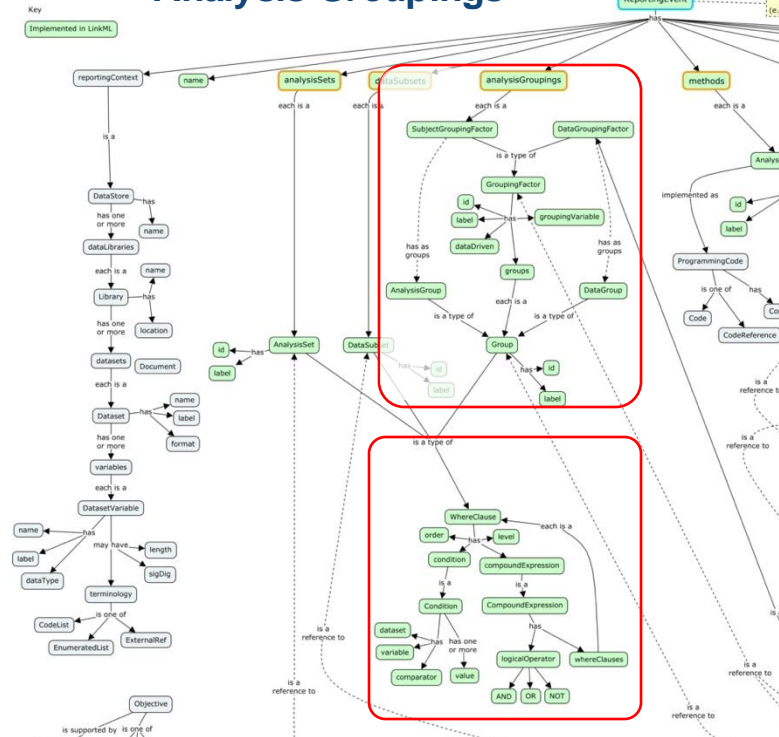


Data Subsets



| 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

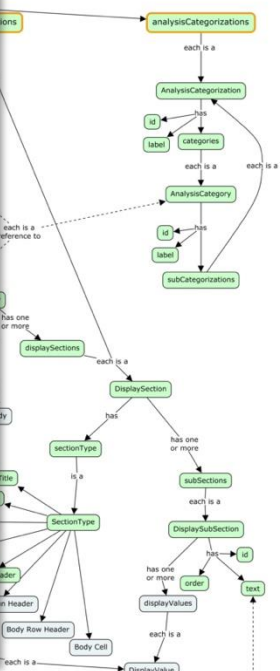


```

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      {
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        "condition": {
          "dataset": "ADSL",
          "variable": "SEX",
          "comparator": "EQ",
          "value": [
            "M"
          ]
        }
      },
      {
        "order": 2,
        "condition": {
          "dataset": "ADSL",
          "variable": "SEX",
          "comparator": "EQ",
          "value": [
            "F"
          ]
        }
      }
    ]
  },
  {
    "id": "AnlsGrouping_01_Sex_1",
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  },
  {
    "id": "AnlsGrouping_01_Sex_2",
    "label": "Female"
  }
]
    
```

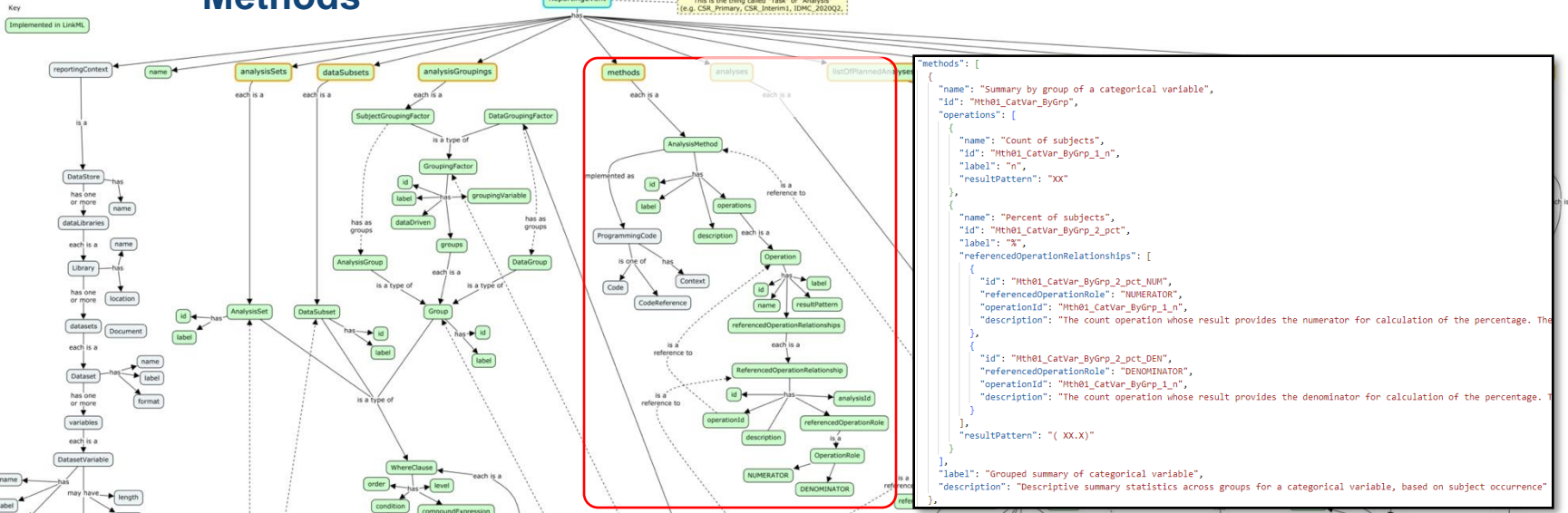
```

{
  "id": "AnlsGrouping_02_Trt",
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  "label": "Treatment",
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      "order": 1,
      "condition": {
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        "variable": "TRT01A",
        "comparator": "EQ",
        "value": [
          "Placebo"
        ]
      }
    },
    {
      "order": 2,
      "condition": {
        "dataset": "ADSL",
        "variable": "TRT01A",
        "comparator": "EQ",
        "value": [
          "Xanomeline Low Dose"
        ]
      }
    },
    {
      "order": 3,
      "condition": {
        "dataset": "ADSL",
        "variable": "TRT01A",
        "comparator": "EQ",
        "value": [
          "Xanomeline High Dose"
        ]
      }
    }
  ]
}
    
```



| id | label | groupingVariable | dataDriven | group_id | group_label | group_order | group_condition_dataset | group_condition_variable | group_condition_comparator | group_condition_value |
|---------------------|-----------|------------------|------------|-----------------------|----------------------|-------------|-------------------------|--------------------------|----------------------------|-----------------------|
| 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



| name | label | description | operation_id | operation_name | operation_order | operation_label | operation_resultPattern |
|--|---|--|--------------------------|---------------------|-----------------|-----------------|-------------------------|
| Summary by group of a categorical variable | Grouped summary of a 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 a 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_referencedResultRelation | operation_referencedResultRelation | operation_referencedResultRelationship | operation_referencedResultRelation | 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 |



Analyses

Key
Implemented in LiskML

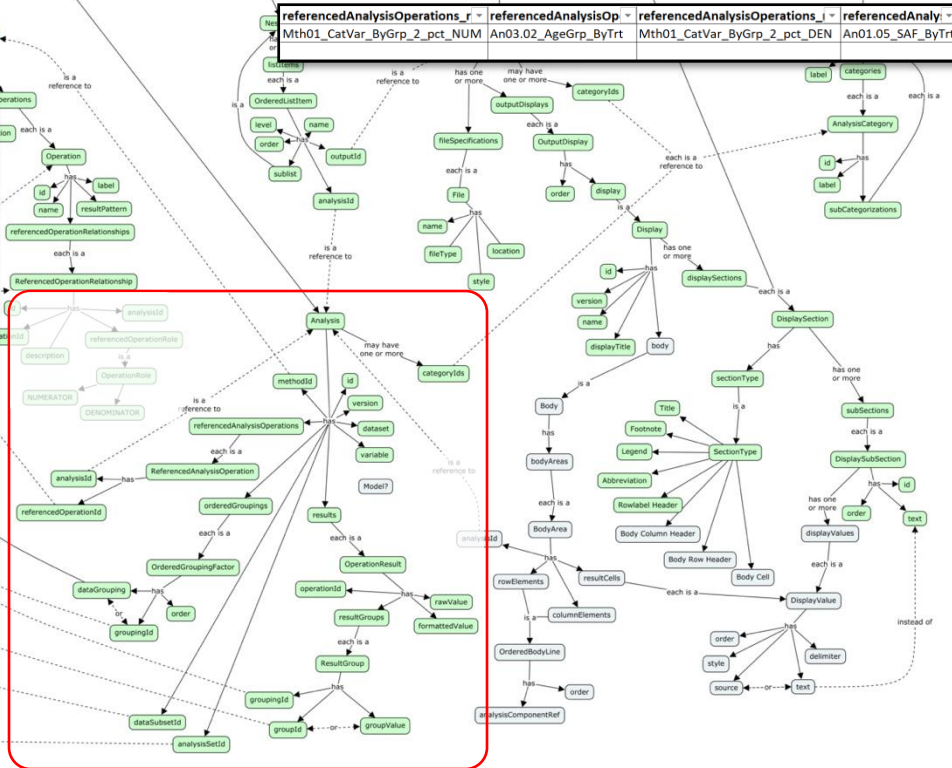
ReportingEvent

This is the thing called "Task" or "Analysis"
(e.g. CSR_Primary, CSR_Interim, IDMC_2020Q2)

| 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_Trtr | AnlsGrouping_03_AgeGrp | | | 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_Trtr | AnlsGrouping_08_Param | AnlsGrouping_09_Visit | Dss10_VS_NonBl_AnRec | ADVS | CHG | Mth02_ContVar_ByGrp |

```

"analyses": [
  {
    ...
  },
  {
    "name": "Summary of Change from Baseline by Treatment, Parameter and Visit",
    "id": "An08.02_ChgBl_ByTrt",
    "methodId": "Mth02_ContVar_ByGrp",
    "version": 1,
    "analysisSetId": "AnalysisSet_02_SAF",
    "orderedGroupings": [
      {
        "order": 1,
        "groupingId": "AnlsGrouping_02_Trtr"
      },
      {
        "order": 2,
        "groupingId": "AnlsGrouping_08_Param"
      },
      {
        "order": 3,
        "groupingId": "AnlsGrouping_09_Visit"
      }
    ],
    "dataSubsetId": "Dss10_VS_NonBl_AnRec",
    "dataset": "ADVS",
    "variable": "CHG",
    "results": [ ...
  ]
  ],
  "results": [ ...
  ],
  ]
  
```



Analysis Results

Key
Implemented in LinkML

ReportingEvent

This is the thing called "Task" or "Analysis"
(e.g. CSR_Primary, CSR_Interim), IDMC_202002

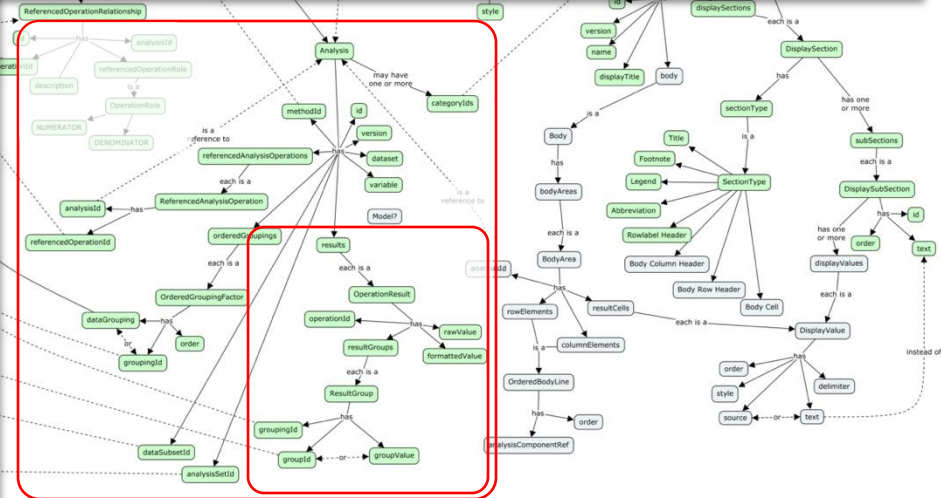
| id | operation_id | resultGroup1_groupingId | resultGroup1_groupId | resultGroup2_groupingId | resultGroup2_groupId | resultGroup3_groupingId | resultGroup3_groupId | rawValue | formattedVal |
|---------------------|-----------------------------|-------------------------|-------------------------|-------------------------|--------------------------|--------------------------|--------------------------|----------|--------------|
| 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 | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | AnlsGrouping_09_Visit_02 | AnlsGrouping_09_Visit_02 | -2 | -2.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_5_Q1 | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | AnlsGrouping_09_Visit_02 | AnlsGrouping_09_Visit_02 | -12 | -12.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_6_Q3 | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | AnlsGrouping_09_Visit_02 | AnlsGrouping_09_Visit_02 | 4 | 4.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_7_Min | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | AnlsGrouping_09_Visit_02 | AnlsGrouping_09_Visit_02 | -38 | -38 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_8_Max | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | AnlsGrouping_09_Visit_02 | AnlsGrouping_09_Visit_02 | 40 | 40 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_1_n | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_02 | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | 243 | 243 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_2_Mean | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | -3.02469 | -3.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_3_SD | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | 15.66829 | (15.67) |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_4_Media | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | -2 | -2.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_5_Q1 | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | -12 | -12.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_6_Q3 | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | 6 | 6.0 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_7_Min | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | -48 | -48 |
| An08.02_ChgBl_ByTrt | Mth02_ContVar_ByGrp_8_Max | AnlsGrouping_08_Param | AnlsGrouping_08_Param_1 | AnlsGrouping_09_Visit | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | AnlsGrouping_09_Visit_03 | 50 | 50 |

```

"results": [
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```



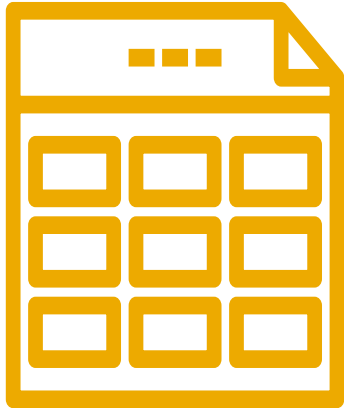
Concepts, Not Layout

| | | | | | | | |
|----------------|---------------------|-----------------------|-----------|--|---------|---------------------|----------------------|
| Analysis ID: | An03.2_AgeGrp_ByTrt | | | | | | |
| Display Value: | formattedValue | | | | | | |
| | | AnlsGrouping_02_Trtr | Treatment | | Placebo | Xanomeline Low Dose | Xanomeline High Dose |
| | | Mth01_CatVar_ByGrp | | | | | |
| | | AnlsGrouping_03_AgeGp | Operation | | | | |
| | | Age Group | | | | | |
| | | < 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_Trtr | 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 | | | | | | |
| | | AnlsGrouping_02_Trtr | Operation | | n | % | |
| | | 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) | |

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

Creating Analysis Results Metadata: JSON

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

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

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



```
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  "id": "FDA_STF_T2",
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          }
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      }
    ]
  }
}
```

Leveraging ARS Metadata to Drive Results Automation

ARS Metadata

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            "level": 2,
            "order": 1,
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            "level": 2,
            "order": 2,
            "analysisID": "A_SAF_CNT_USUBJID"
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            "level": 2,
            "order": 3,
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                  "level": 3,
                  "order": 1,
                  "analysisID": "A_SAF_SUM_USUBJID_TRT_SEX"
                },
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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 |
|----------------------|--------------------------|-------------------------|-----------------------|-------------------------|-------------------------|----------|--------------|
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_1 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 14 | 14 |
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_1 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 72 | 72 |
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_2 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 8 | 8 |
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_2 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 76 | 76 |
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_3 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 11 | 11 |
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_3 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 73 | 73 |
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_1 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 16.27907 | (16.3) |
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_1 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 83.72093 | (83.7) |
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_2 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 9.52381 | (9.5) |
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_2 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 90.47619 | (90.5) |
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_3 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 13.09524 | (13.1) |
| An03.02_AgeGrp_ByTrt | MTH01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_3 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 86.90476 | (86.9) |

Analysis Results Dataset

Analysis Results: Create Once, Use Many Times

| id | operation_id | resultGroup1_groupingId | resultGroup1_groupid | resultGroup2_groupingId | resultGroup2_groupid | rawValu | formattedVal |
|----------------------|--------------------------|-------------------------|-----------------------|-------------------------|-------------------------|----------|--------------|
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_1 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 14 | 14 |
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_1 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 72 | 72 |
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_2 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 8 | 8 |
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_2 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 76 | 76 |
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_3 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 11 | 11 |
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_1_n | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_3 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 73 | 73 |
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_1 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 16.27907 | (16.3) |
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_1 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 83.72093 | (83.7) |
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_2 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 9.52381 | (9.5) |
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_2 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 90.47619 | (90.5) |
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_3 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_1 | 13.09524 | (13.1) |
| An03.02_AgeGrp_ByTrt | Mth01_CatVar_ByGrp_2_pct | AnlsGrouping_02_Trt | AnlsGrouping_02_Trt_3 | AnlsGrouping_03_AgeGp | AnlsGrouping_03_AgeGp_2 | 86.90476 | (86.9) |



Displays

Publications



Clinical Study Report



Meta Analysis



Questions?



What's Next?

eTFL Portal!



Expanding Content through CDISC eTFL Portal

- ARS model and documentation is complex, the eTFL portal will promote implementation.
- Informative content (example driven) not normative
 - Standard library of TFLs
 - Safety
 - Therapeutic area-specific (future addition)
 - Components
 - Overview
 - Display
 - ADaM Dataset and associated Metadata
 - Analysis Results Metadata
 - Analysis Results Dataset



eTFL Portal Benefits

- Simplifies complex ARS model implementation
- Informative and example-driven
- Standardized TFL library
- Metadata integration (ADaM and analysis results for now; SDTM, CDASH and integration with other standards in future)
- In-line with regulatory expectations (e.g. FDA STF-IG) and PHUSE best practices
- Future support for Therapeutic areas
- Automation and improved efficiency (time and money)
- Collaboration and knowledge sharing

Launching the eTFL Portal

- CDISC has partnered with Clymb Clinical to instantiate the first version of the ARS-compliant packages in the eTFL Portal.
- The CDISC eTFL Portal Team will use the Community version of the [TFL Designer](#) to create system agnostic ARS metadata.



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| | | | |
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| 1.2 | Age | | AGE |

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The International System of Units (SI), commonly known as

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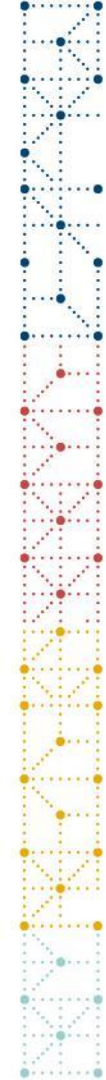
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Known Issues

A known issue is a problem or concern with a CDISC standard that CDISC is aware of, and may be working actively to mitigate or resolve. Unlike errors or errors that affect conformance, known issues have no obvious solution when they are first identified; and some known issues may prove to be irresolvable.

- Codelist for ECMOOD Variable
Standard(s): SDTMIG
- TSPARM "Pharmacological Class" Terminology Change
Standard(s): SDTMIG
- Codellists for FA Test Names and Test Codes
Standard(s): SDTMIG
- "COUNTRY" Terminology Change
Standard(s): SDTMIG
- Type mismatch for ECDOSTOT
Standard(s): SDTMIG

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eTFL Portal

eTFL Portal

The eTFL Portal consists of ready-to-use, ARS-compliant packages. Each package is based on an analysis concept and includes:

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

These packages and their contents are examples and are not meant to imply that any particular layout or analysis plan is preferable over another. To facilitate broad use, initial packages were developed based on safety analysis displays from the [ARS v1.0 User Guide](#) and the [FDA Standard Safety Tables and Figures Integrated Guide](#). The following guiding principle was followed during development:

- Version 1.0 of the Analysis Data Model Metadata Submission Guidelines (ADaM-MSG) was used as a reference implementation, with ADaM datasets from the CDISC Pilot Study adapted to meet the requirements of each display and analysis concept.

CDISC has partnered with [Clymb Clinical](#) to instantiate the first version of the ARS-compliant packages in the eTFL Portal. The CDISC eTFL Portal Team can use the Community version of the [TFL Designer](#) to create system agnostic ARS metadata.

To provide feedback on the content of the eTFL Portal please follow the review instructions on the [CDISC Wiki eTFL Portal Home Page](#).

Vendor Neutrality Disclaimer

CDISC is a vendor-neutral and technology-inclusive organization focused on promoting the use of standards to improve the quality and efficiency of research. CDISC does not endorse any specific vendor or technology in the use of its standards.

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- Version 1.0 of the Analysis Data Model Metadata Submission Guidelines (ADaM-MSG) was used as a reference implementation, with ADaM datasets from the CDISC Pilot Study adapted to meet the requirements of each display and analysis concept.
- Each Package contains
 - Analysis overview, design considerations, and TFL preview
 - Download
 - ADaM Dataset and Metadata
 - ARS Metadata
 - Analysis Results Dataset Display



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| | | |
|--|---|--|
| Baseline Demographic and Clinical Characteristics FDA STF-IG | Deaths FDA STF-IG | Duration of Treatment Exposure FDA STF-IG |
| Overview of Adverse Events FDA STF-IG | Subject Disposition FDA STF-IG | Subjects With Adverse Events by System Organ Class and Preferred Term FDA STF-IG |
| Subjects With Common Adverse Events Occurring at \geqX% Frequency FDA STF-IG | Subjects With Serious Adverse Events by System Organ Class and Preferred Term FDA STF-IG | Subjects With Serious Adverse Events by System Organ Class and Preferred Term FDA STF-IG |
| Summary of Observed and Change from Baseline by Scheduled Visits - Chemistry Laboratory Test ARS Release Package | Summary of Observed and Change from Baseline by Scheduled Visits - Hematology Laboratory Test ARS Release Package | Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs ARS Release Package |

Overview

Baseline Demographic and Clinical Characteristics

View

Edit

Delete

Revisions

Clone

Overview

Design Considerations

eTFL Preview

Download

This table shows key baseline characteristics of the safety population that could influence the effectiveness or safety of the drug.

This display is based on *Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X) from the FDA STANDARD SAFETY TABLES AND FIGURES: INTEGRATED GUIDE (Version Date: August 2022)*, published by the Center for Drug Evaluation and Research (CDER) Biomedical Informatics and Regulatory Review Science (BIRRS) Team.

Design Considerations

Baseline Demographic and Clinical Characteristics

View Edit Delete Revisions Clone

Overview Design Considerations eTFL Preview Download

This display was created using data from the following ADaM datasets

- ADSL

The ADaM datasets from the CDISC Pilot Study were modified as follows

- Only variables that were needed to create this display have been retained.
- If needed, additional variables were added to support the creation of the display.

The following differences exist between the display shown and the reference display from the FDA Standard Tables and Figures: Integrated Guide

- The display shown uses the word "Subject" vs "Patient" to be consistent with the language used in CDISC standards.

eTFL Preview

Baseline Demographic and Clinical Characteristics

View Edit Delete Revisions Clone

Overview Design Considerations **eTFL Preview** Download

CDISC - eTFL Portal Generated using TFL Designer (Community, v1.0) Page x of y

FDA-DM-T02
Baseline Demographic and Clinical Characteristics
Safety Population

| Characteristics | Xanomeline Low Dose (N=XX) n (%) | Xanomeline High Dose (N=XX) n (%) | Placebo (N=XX) n (%) | Total Population (N=XX) n (%) |
|----------------------------------|--|---|----------------------------|-------------------------------------|
| Sex, n (%) | | | | |
| Male | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Female | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Intersex | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Unknown | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Age, Years | | | | |
| n | XX | XX | XX | XX |
| Mean (SD) | 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 |
| Min, Max | XX.X, XX.X | XX.X, XX.X | XX.X, XX.X | XX.X, XX.X |
| Age groups (years), n (%) | | | | |
| <65 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 65-80 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |

Package Download

Baseline Demographic and Clinical Characteristics

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Overview Design Considerations eTFL Preview **Download**

Package
FDA-DM-T02 eTFL Package

fda-dm-t02-ars-readme.txt

The FDA-DM-T02 package contains the following files:

- adsl.xpt: ADaM dataset in SAS XPOR format
- define.xml: Define-XML description of the ADaM dataset(s)
- define2-1-0.xsl: Stylesheet to view define.xml
- fda-dm-t02-shell.pdf: The table shell in PDF format
- fda-dm-t02-shell.rtf: The table shell in RTF format
- fda-dm-t02.rtf: The table containing results in RTF format
- fda-dm-t02-ard.json: The ARD containing results in Dataset-JSON format
- fda-dm-t02-ars.xlsx: The ARS metadata in Excel format
- fda-dm-t02-ars.json: The ARS metadata in JSON format
- fda-dm-t02-readme.txt: This file

< > fda-dm-t02_20241018

Name


- adsl.xpt
- define.xml
- define2-1-0.xsl
- fda-dm-t02-ard.json
- fda-dm-t02-ars-readme.txt**
- fda-dm-t02-ars.json
- fda-dm-t02-ars.xlsx
- fda-dm-t02-shell.pdf
- fda-dm-t02-shell.rtf
- fda-dm-t02.rtf

Provide Feedback!

The screenshot shows the eTFL Portal interface. On the left is a sidebar menu with items like Dashboard, Articles, Examples, Known Issues, eCRF Portal, and eTFL Portal. The main content area displays a page titled "FDA-DM-T02: Baseline Demographic and Clinical Characteristics" with a table containing one row with ID "FDA-DM-T02". A "Review Comment Instructions" overlay is positioned in the foreground, partially obscuring the table and sidebar.

Review Comment Instructions

To create a review comment for this package component:

1. Select "**Review Comments:**" above,
2. Hover your mouse cursor over the selected text
3. Create a Jira issue by clicking on the  button.
4. Select or enter the following in the displayed Create Issue dialog:
 - **Project:** eTFL Portal Review
 - **Issue Type:** Choose "Review Comment" or any other type that more accurately describes the type of issue (e.g., "Error/Typo").
 - **Summary:** Change "Review Comments:" to a brief summary of your review finding.
 - **Description:** If needed, enter additional details.
 - **Component/s:** Enter/select the Component shown in the table above.
 - **Link to epic:** Make sure that the checkbox is checked.
5. Click on the Create button.

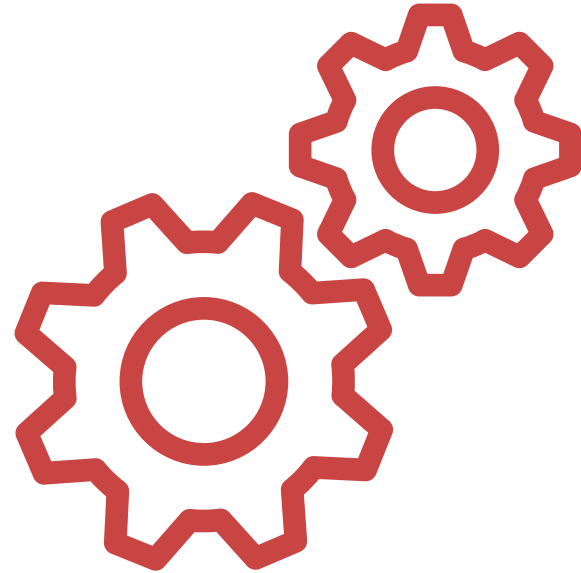
Volunteer!

Select the CDISC Standards Development team that you would like to join. (Please choose one)

- SEND
- CDASH
- SDS
- ADaM
- Controlled Terminology
- Medical Devices
- CORE Rules
- DDF
- Digital Health Technologies
- Genomics Subteam
- QRS
- Tobacco Implementation Guide
- RWD Lineage
- eTFL Portal
- Other...

Additional standards information can be found on our [Standards Page](#).

**ARS Model Will Drive
Automation and Tool
Development**



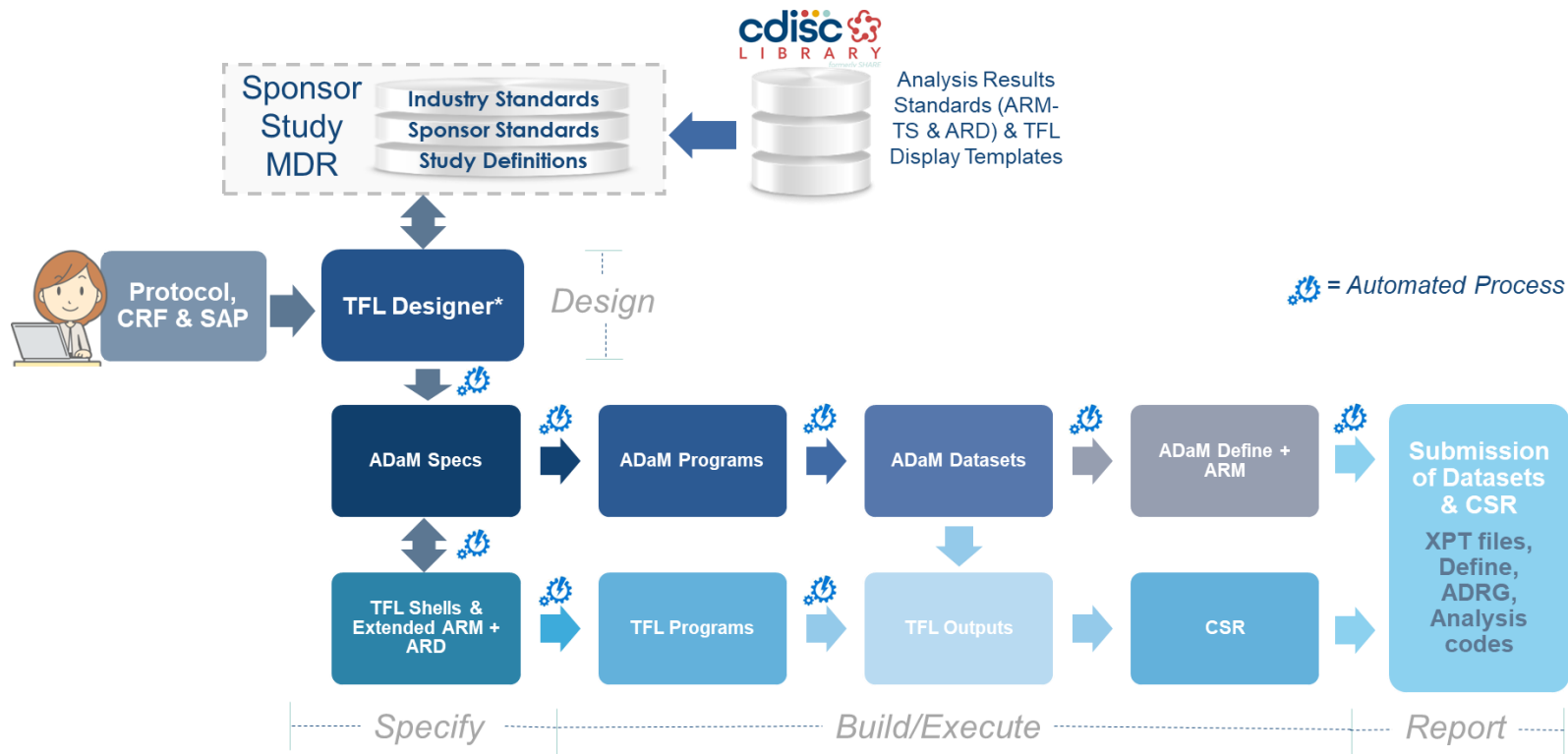
ARS model is complex!

How do I operationalize it and generate analysis results metadata prospectively?

How can I get started with the artifacts available on the eTFL portal?



Analysis Results Workflow w/ TFL Designer





SDTM, ADaM,
ARS Model, &
eTFL Templates

Sponsor
Study
MDR

Industry Standards
Sponsor Standards
Study Definitions

Protocol,
CRF &
SAP

API

API

Select TFL of Interest

Select Analysis
Concepts, Methods,
Terminology & TFL
Display (Template)

Customize TFL Layout
& Metadata

Machine-readable CDISC
ARS (JSON & Excel) +
TFL Shells (RTF & PDF)

TFL
DESIGNER



Study ADaM, ARD
and TFL outputs

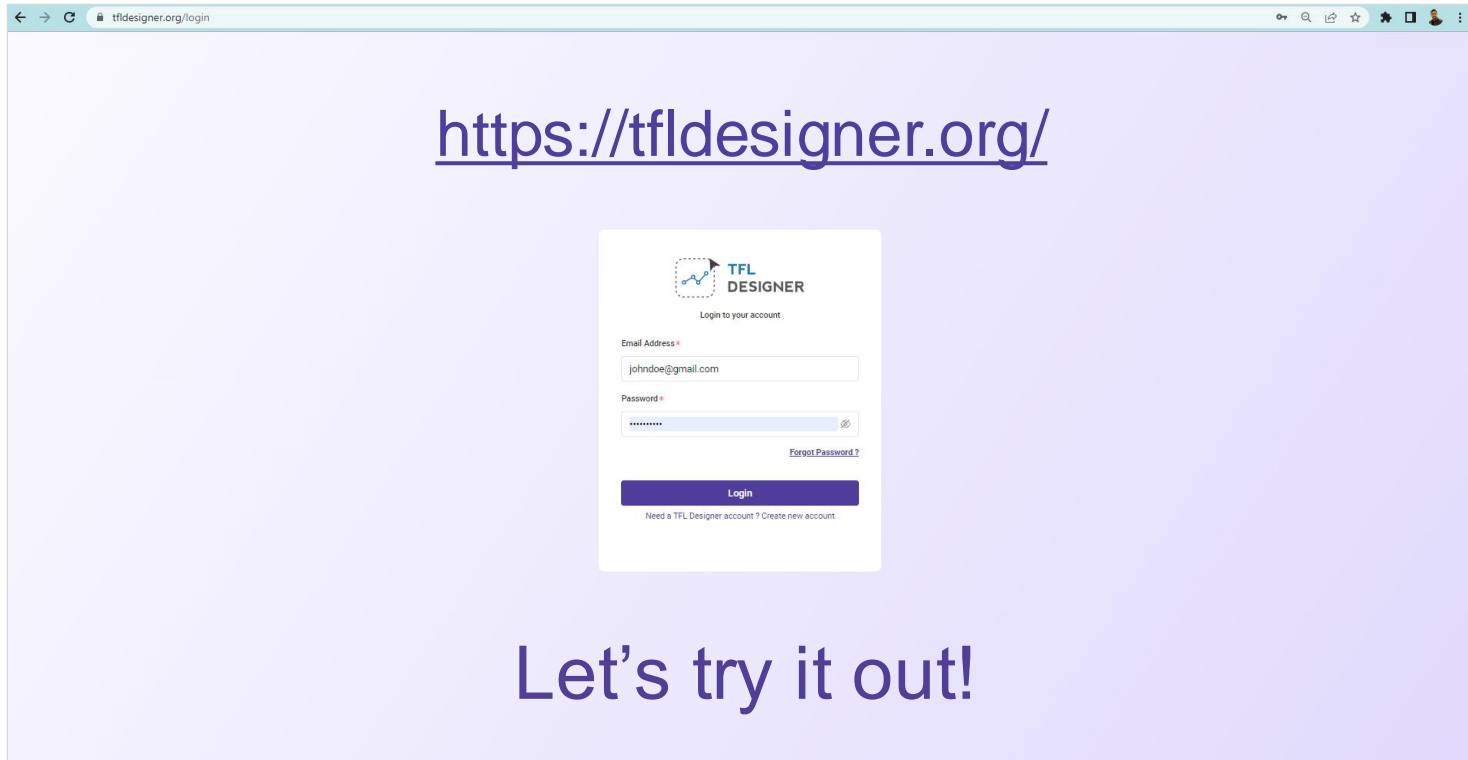
Automation Engine
(SAS, R or other
software products)

TFL Designer: Key Functionalities

- *Central repository for your TFL standards/templates, conventions and metadata*
- *Access to library of TFL templates (community* and user generated) by disease areas, TA, and indication*
- *Access to CDISC Standards (SDTM, ADaM, CT) via API to CDISC Library*
- *Develop new mock-up shells, edit/delete items*
- *Automatically populate items based on user inputs*
- *Export TFL shells in RTF & PDF formats*
- *Export analysis results metadata per the CDISC ARS model in JSON and Excel formats*

** including FDA STF-IG, JPMA and eTFL Templates*

Utilizing eTFL Artifacts w/ TFL Designer (Community Version)



The screenshot shows a web browser window with the address bar displaying `tfl designer.org/login`. The main content area has a light purple gradient background. At the top center, the URL <https://tfl designer.org/> is displayed in a large, dark purple font. Below this, a white login form is centered. The form features the TFL Designer logo (a blue square with a white line graph) and the text "TFL DESIGNER". Underneath the logo is the text "Login to your account". The form includes two input fields: "Email Address" with the value "johndoe@gmail.com" and "Password" with masked characters. A "Forgot Password?" link is positioned below the password field. A dark purple "Login" button is at the bottom of the form, with the text "Need a TFL Designer account? Create new account" below it.

Let's try it out!



Thank you!



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