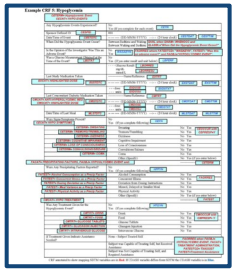
Analysis Results Public Review Webinar

Bess LeRoy, Head of Standards Innovation, CDISC
Richard Marshall, Principal Data Modeler, CDISC
Bhavin Busa, Principal & Co-Founder, Clymb Clinical

Agenda

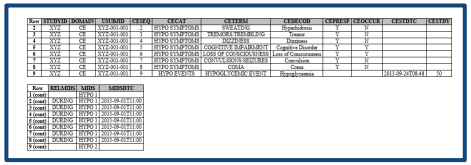
- Project Background
- Overview of ARS Model and User Guide
- Next Steps
- Q&A

CDISC Foundational Standards



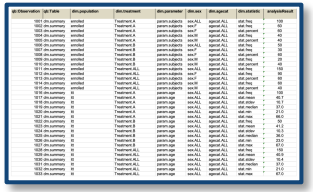
Data Collection

CDASH



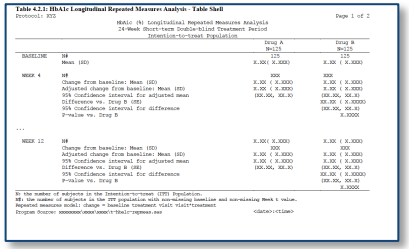
Data Aggregation

SDTM



Analysis

ADaM



Results

???

Table 4.2.2: HbA1c Longitudinal Repeated Measures Analysis Results Metadata

Metadata Field	Metadata
DISPLAY IDENTIFIER	Table 4.2.1/Figure 4.2.1
DISPLAY NAME	Mean Change from Baseline in HbA1c (Percent) Longitudinal Repeated Measures Analysis, 24-Week Short-term Double-blind Treatment Period, Intention-to-treat Population
RESULT IDENTIFIER	Treatment difference results (LSMean, confidence interval, p-value)
PARAM	HbA1c (%)
PARAMCD	HBA1C
ANALYSIS VARIABLE	CHG (Change from baseline)
ANALYSIS REASON	SPECIFIED IN SAP
ANALYSIS PURPOSE	PRIMARY OUTCOME MEASURE
ANALYSIS DATASET	ADHBA1C

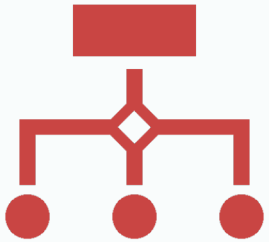
ARM for Define.XML

Analysis Results Key Objectives

Leverage analysis results metadata to drive the automation of results

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

Analysis Results Standards Key Results

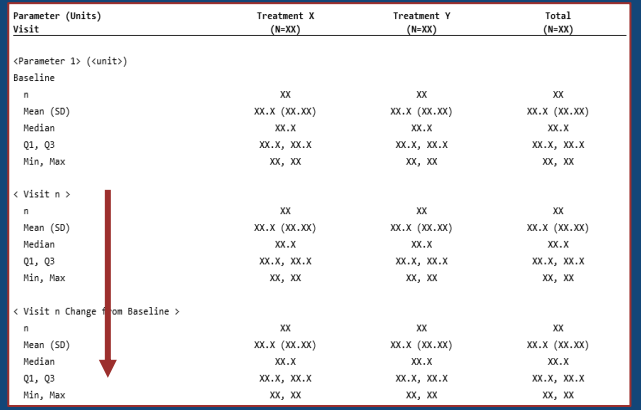


Logical model that describes analysis results and associated metadata

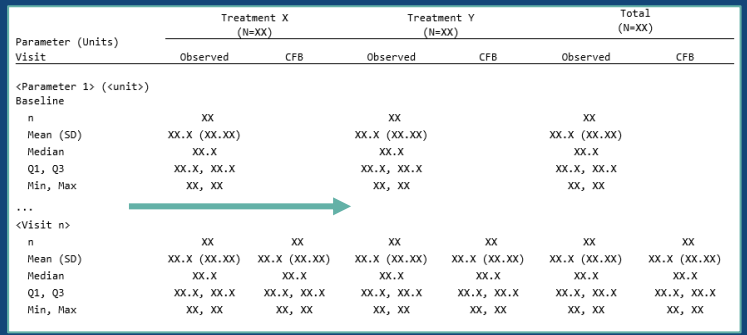
User Guide to illustrate and exercise model with common safety displays

Focus on Concepts, Not Layout

- Focus on concepts presented in data displays not on subjective layout and formatting of displays
- Representative displays therefore condense concepts
- For example, side-by-side Visit and Change-from-baseline summaries consolidates more concepts into an easy-to-read summary table

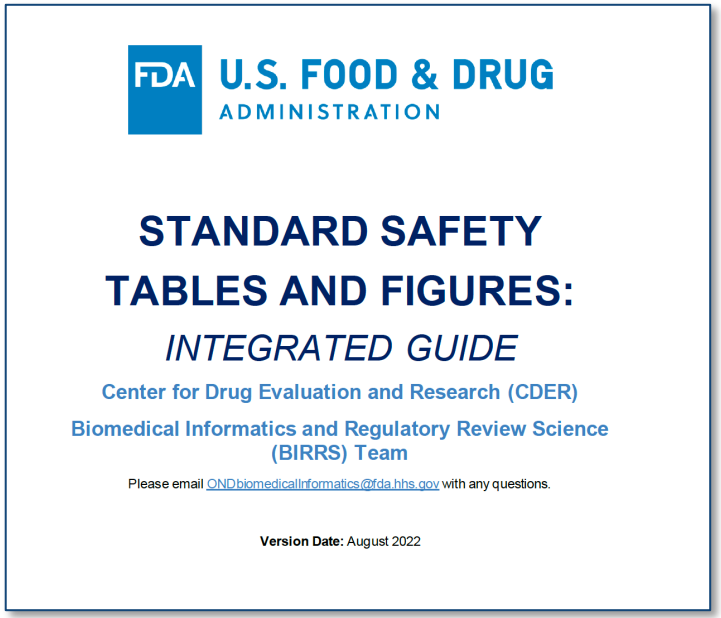


Parameter (Units) Visit	Treatment X (N=XX)	Treatment Y (N=XX)	Total (N=XX)
<Parameter 1> (<unit>)			
Baseline			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n Change from Baseline >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX



Parameter (Units)	Treatment X (N=XX)		Treatment Y (N=XX)		Total (N=XX)	
Visit	Observed	CFB	Observed	CFB	Observed	CFB
<Parameter 1> (<unit>)						
Baseline						
n	XX		XX		XX	
Mean (SD)	XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)	
Median	XX.X		XX.X		XX.X	
Q1, Q3	XX.X, XX.X		XX.X, XX.X		XX.X, XX.X	
Min, Max	XX, XX		XX, XX		XX, XX	
...						
<Visit n>						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX

FDA Standard Safety Tables and Figures: Integrated Guide



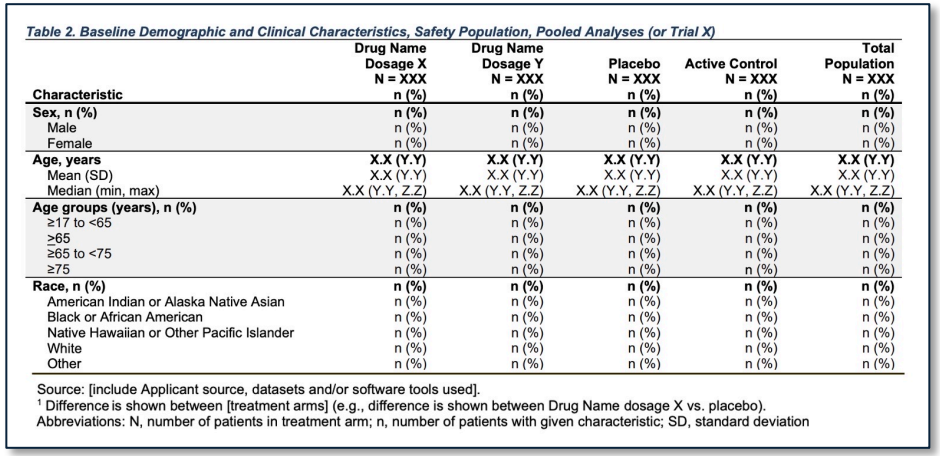


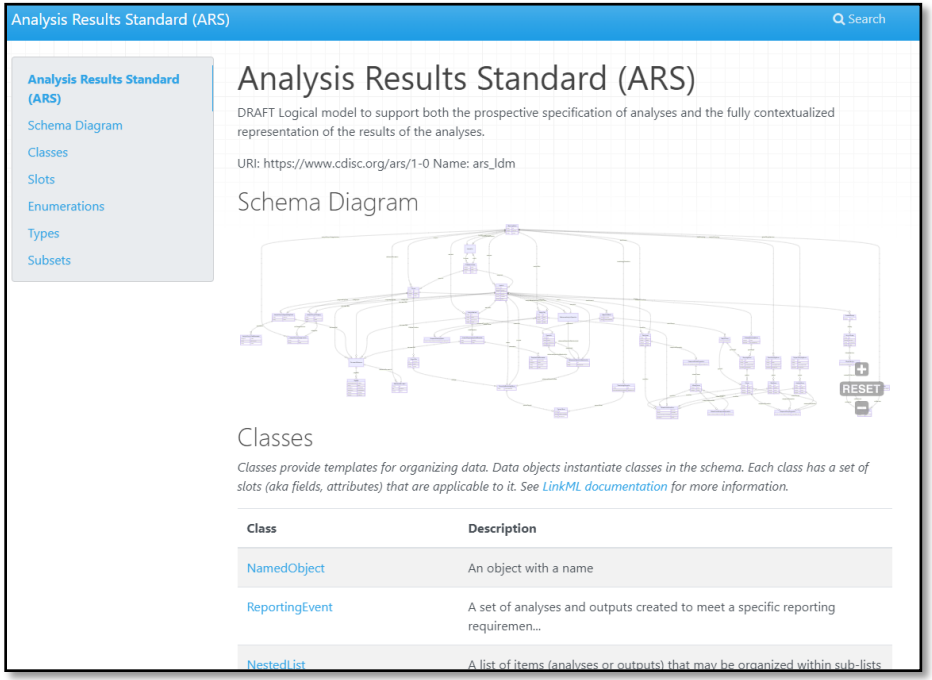
Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X)

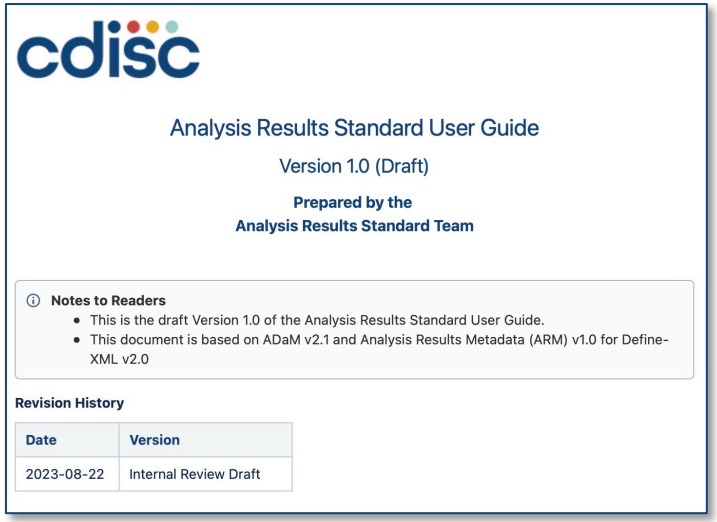
Characteristic	Drug Name Dosage X N = XXX n (%)	Drug Name Dosage Y N = XXX n (%)	Placebo N = XXX n (%)	Active Control N = XXX n (%)	Total Population N = XXX n (%)
Sex, n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Male	n (%)	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)	n (%)
Age,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

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

Analysis Results Standard Model and User Guide

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



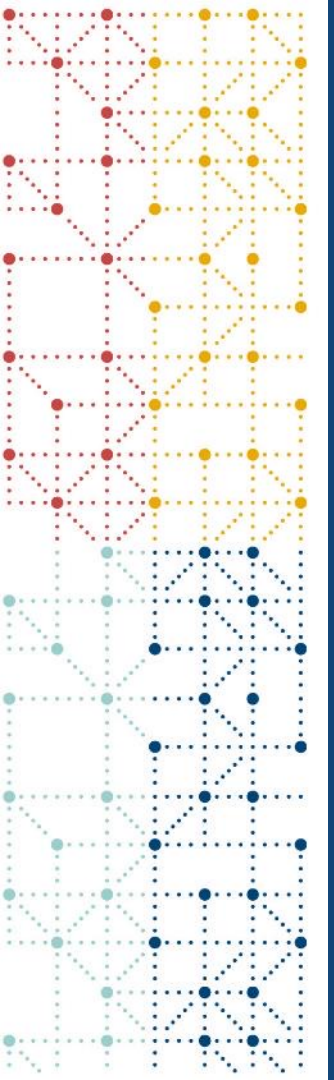


https://wiki.cdisc.org/display/ARSP/Analysis+Results+User+Guide

Wait, What About ARM for Define.XML?

- At this point, no changes to ARM for Define.XML
- Retrospective documentation to aid in traceability
- Fills a specific regulatory need

cdisc

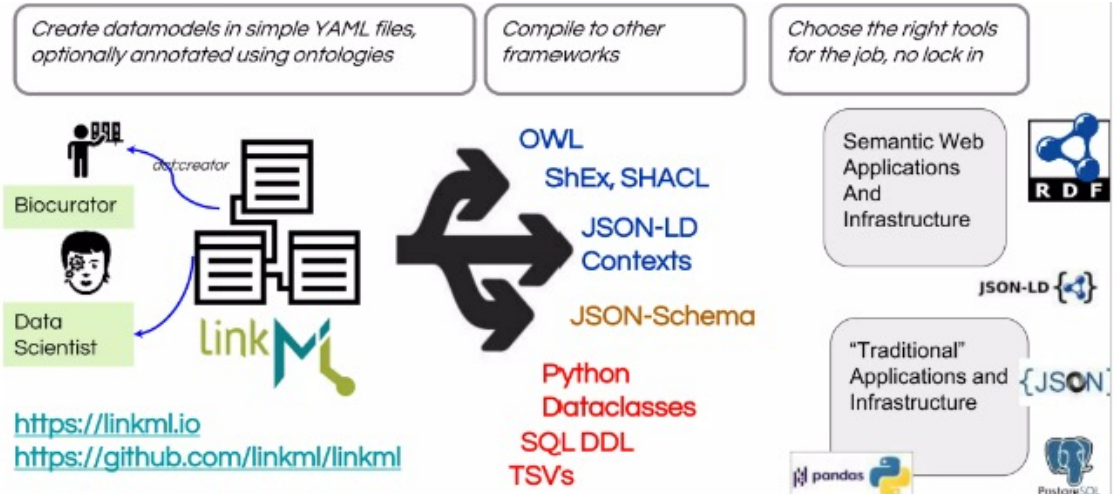


Overview of ARS Model and User Guide

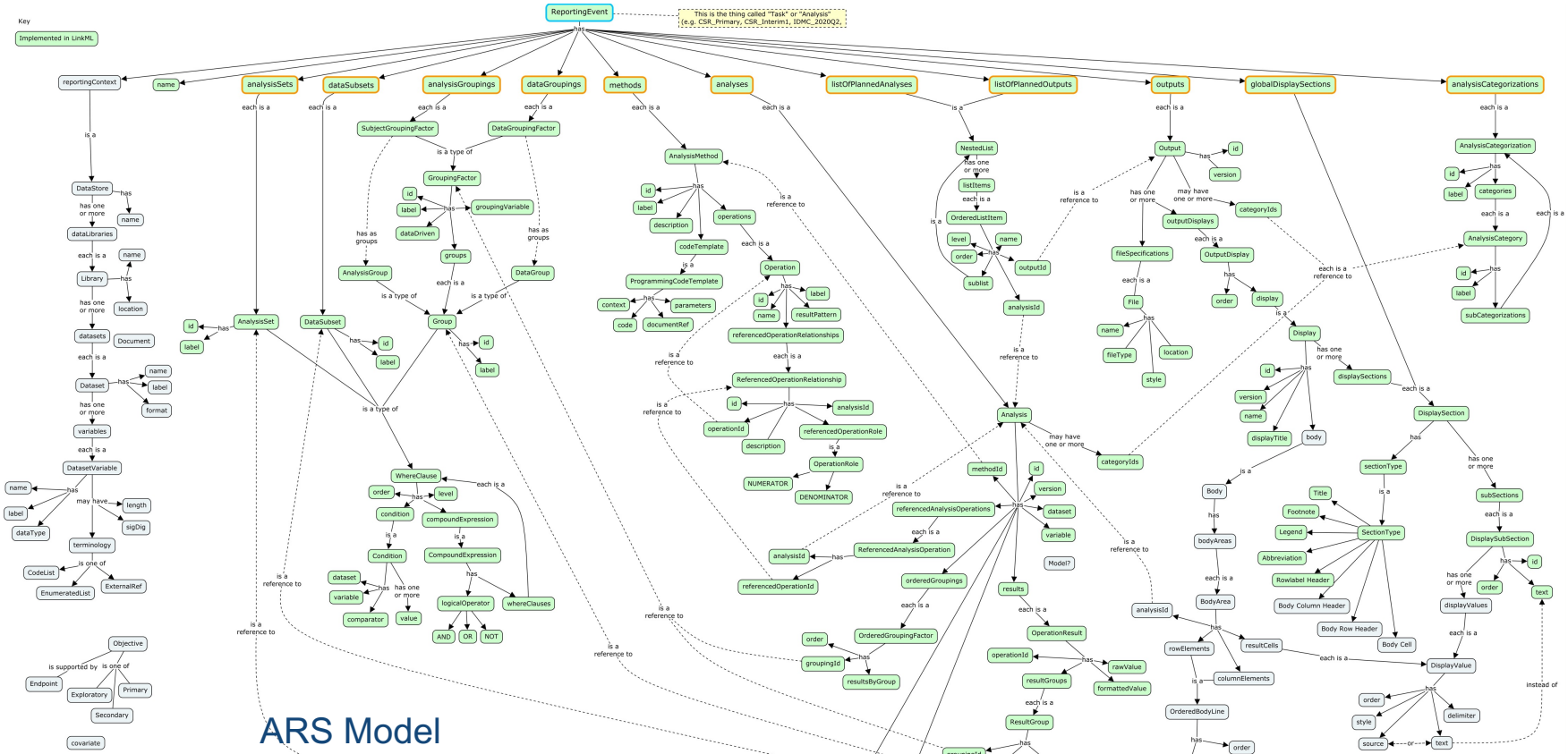
Using LinkML to Create Analysis Results Model

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

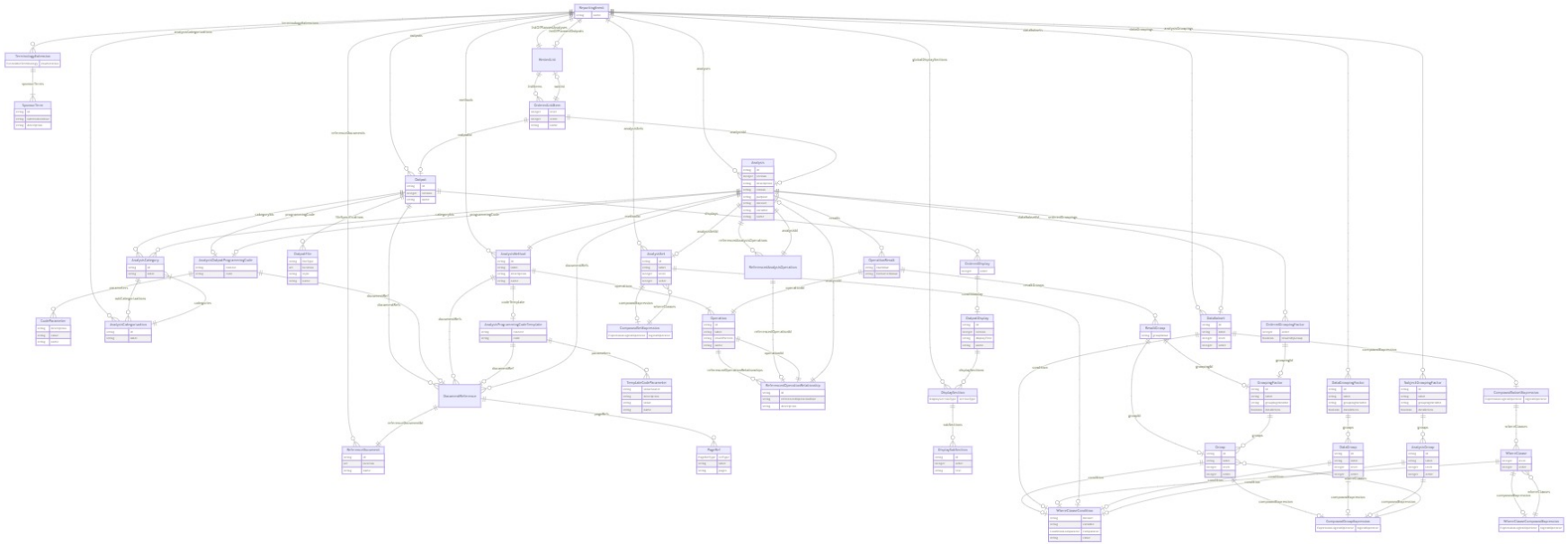
LinkML Landscape



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


Key
Implemented in LinkML
ReportingEvent
This is the thing called "Task" or "Analysis" (e.g. CSR_Primary, CSR_Interim1, IDMC_2020Q2,
reportingContext
name
analysisSets
dataSubsets
analysisGroupings
dataGroupings
methods
analyses
listOfPlannedAnalyses
listOfPlannedOutputs
outputs
globalDisplaySections
analysisCategorizations
DataStore
dataLibraries
Library
datasets
Dataset
variables
DatasetVariable
terminology
CodeList
EnumeratedList
ExternalRef
Objective
Endpoint
Exploratory
Primary
Secondary
covariate
Document
location
format
length
sigDig
dataType
AnalysisSet
DataSubset
SubjectGroupingFactor
DataGroupingFactor
GroupingFactor
groupingVariable
dataDriven
AnalysisGroup
DataGroup
Group
WhereClause
Condition
CompoundExpression
logicalOperator
whereClauses
AND
OR
NOT
comparator
AnalysisMethod
operations
codeTemplate
ProgrammingCodeTemplate
context
code
documentRef
parameters
Operation
resultPattern
referencedOperationRelationships
ReferencedOperationRelationship
operationId
referencedOperationRole
OperationRole
NUMERATOR
DENOMINATOR
NestedList
listItems
OrderedListItem
sublist
outputId
Analysis
methodId
referencedAnalysisOperations
ReferencedAnalysisOperation
analysisId
referencedOperationId
orderedGroupings
OrderedGroupingFactor
groupingId
resultsByGroup
results
OperationResult
rawValue
formattedValue
resultGroups
ResultGroup
groupId
groupValue
dataSubsetId
analysisSetId
Output
outputDisplays
OutputDisplay
fileSpecifications
File
fileType
style
categoryIds
Display
displaySections
DisplaySection
sectionType
SectionType
Title
Footnote
Legend
Abbreviation
Rowlabel Header
Body Column Header
Body Row Header
Body Cell
Body
bodyAreas
BodyArea
rowElements
resultCells
columnElements
OrderedBodyLine
analysisComponentRef
subSections
DisplaySubSection
displayValues
DisplayValue
AnalysisCategorization
categories
AnalysisCategory
subCategorizations
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 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

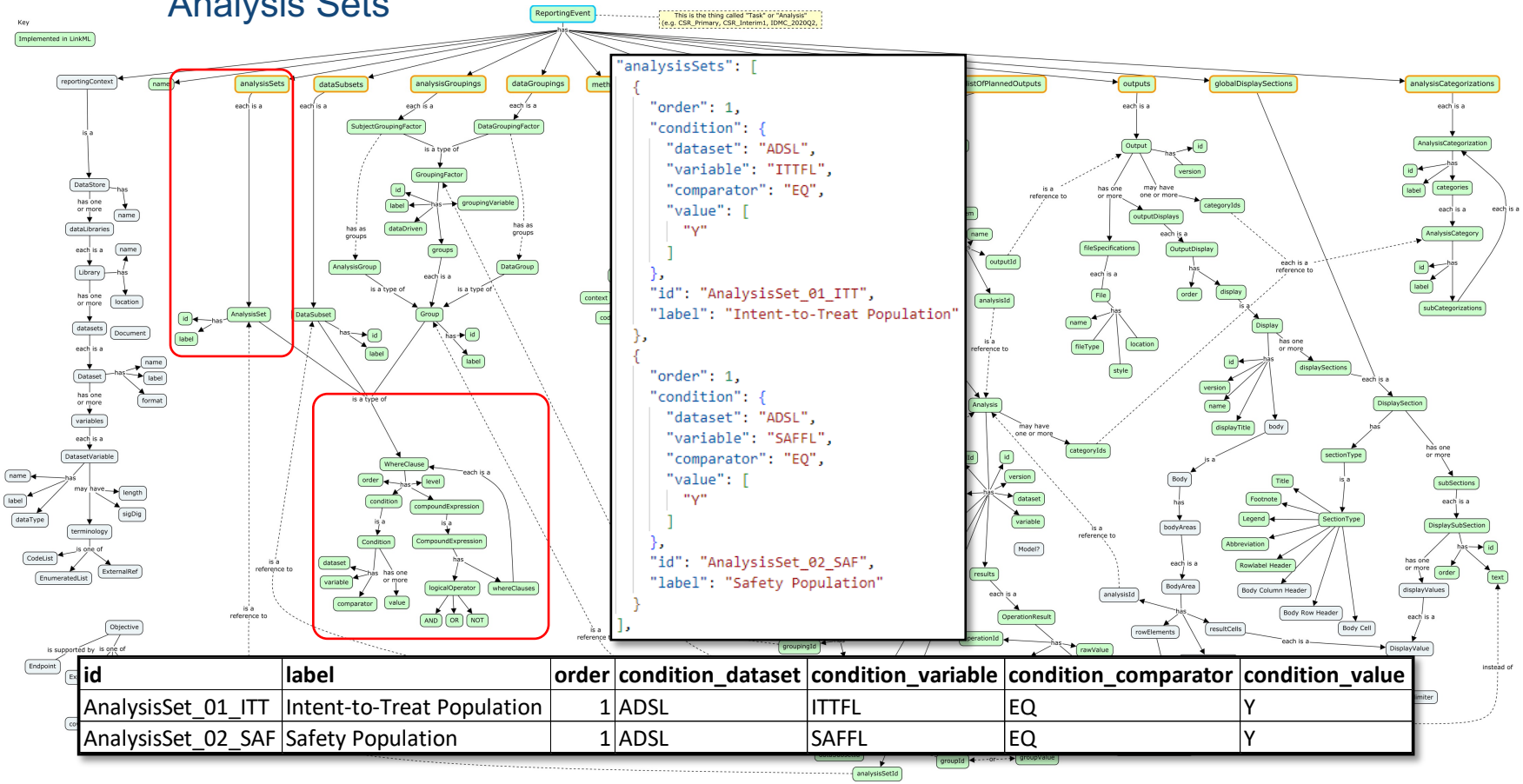
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

System Organ Class 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.

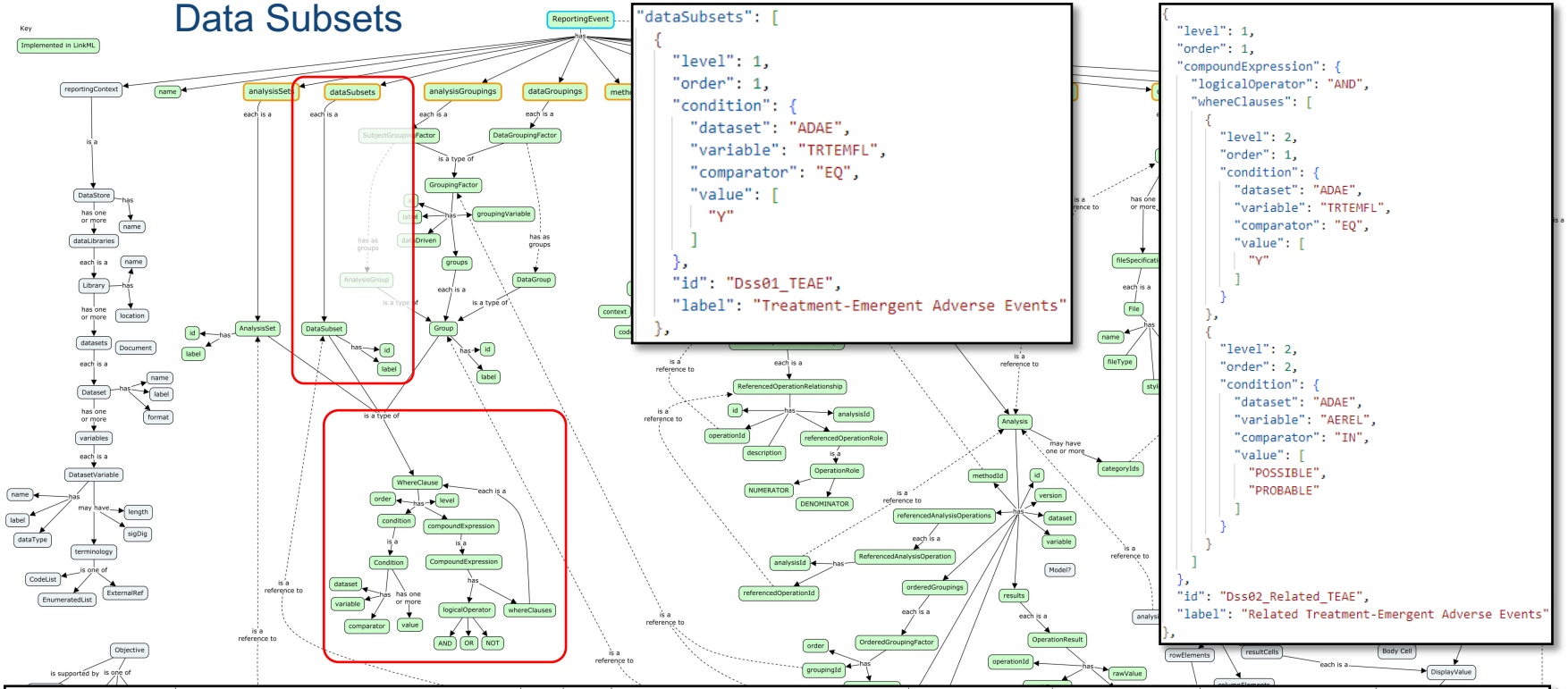
Source dataset: adae, Generated on: DDMONYYYY:HH:MM
Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM

Analysis Sets



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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          "variable": "TRTEMFL",
          "comparator": "EQ",
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      },
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        "order": 2,
        "condition": {
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          "variable": "AEREL",
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          "value": [
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            "PROBABLE"
          ]
        }
      }
    ]
  },
  "id": "Dss02_Related_TEAE",
  "label": "Related Treatment-Emergent Adverse Events"
},
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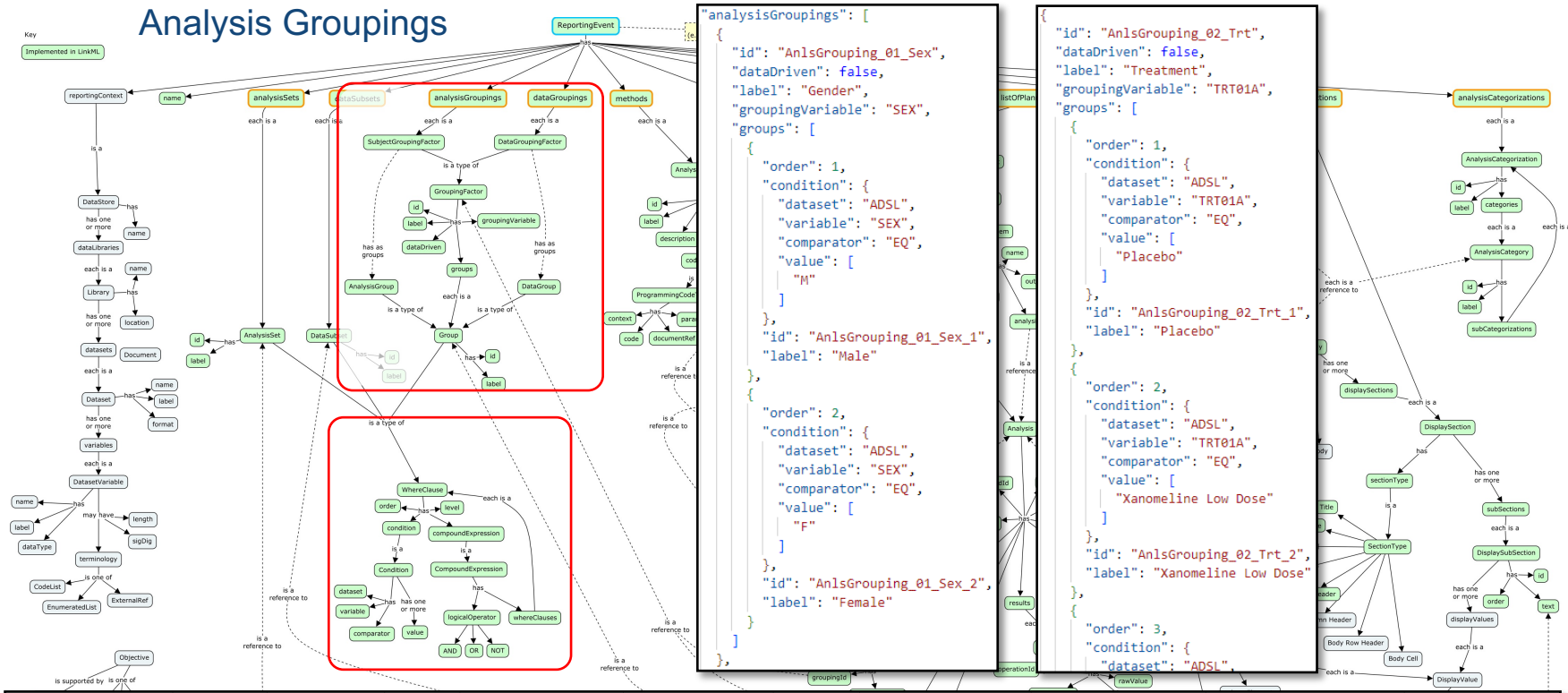
Dss01_TEAE	Treatment-Emergent Adverse Events	1	1		ADAE	TRTEMFL	EQ	Y
Dss02_Related_TEAE	Related Treatment-Emergent Adverse Events	1	1	AND				
Dss02_Related_TEAE	Related Treatment-Emergent Adverse Events	2	1		ADAE	TRTEMFL	EQ	Y
Dss02_Related_TEAE	Related Treatment-Emergent Adverse Events	2	2		ADAE	AEREL	IN	POSSIBLE | PROBABLE

Analysis Groupings

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          "variable": "SEX",
          "comparator": "EQ",
          "value": [
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          ]
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      {
        "order": 2,
        "condition": {
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          "variable": "SEX",
          "comparator": "EQ",
          "value": [
            "F"
          ]
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        "label": "Female"
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    ]
  },
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        "value": [
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        ]
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    },
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      "condition": {
        "dataset": "ADSL",
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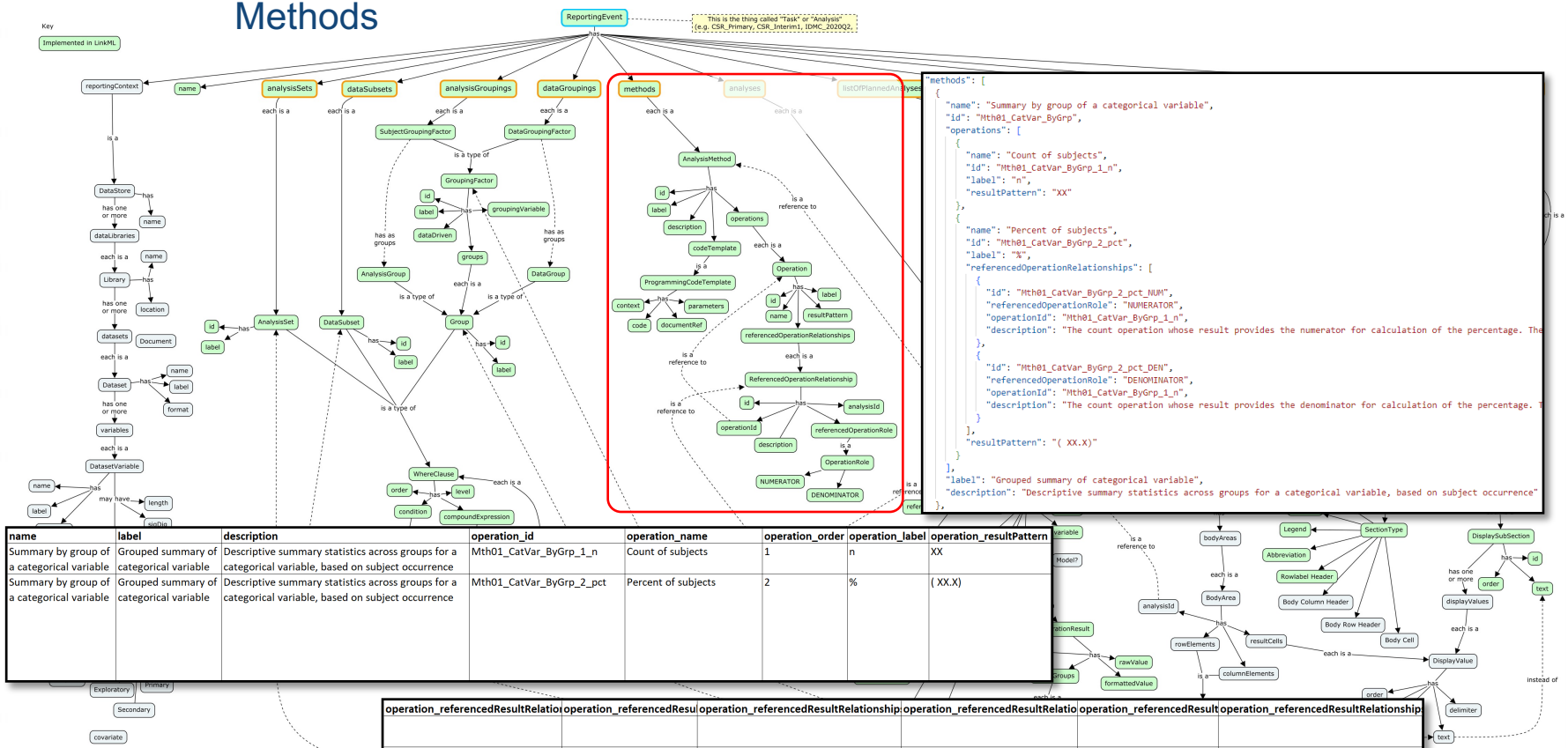
AnlsGrouping_01_Sex	Gender	SEX	FALSE	AnlsGrouping_01_Sex_2	Female	2	ADSL	SEX	EQ	F
AnlsGrouping_02_Trt	Treatment	TRT01A	FALSE	AnlsGrouping_02_Trt_1	Placebo	1	ADSL	TRT01A	EQ	Placebo
AnlsGrouping_02_Trt	Treatment	TRT01A	FALSE	AnlsGrouping_02_Trt_2	Xanomeline Low Dose	2	ADSL	TRT01A	EQ	Xanomeline Low Dose
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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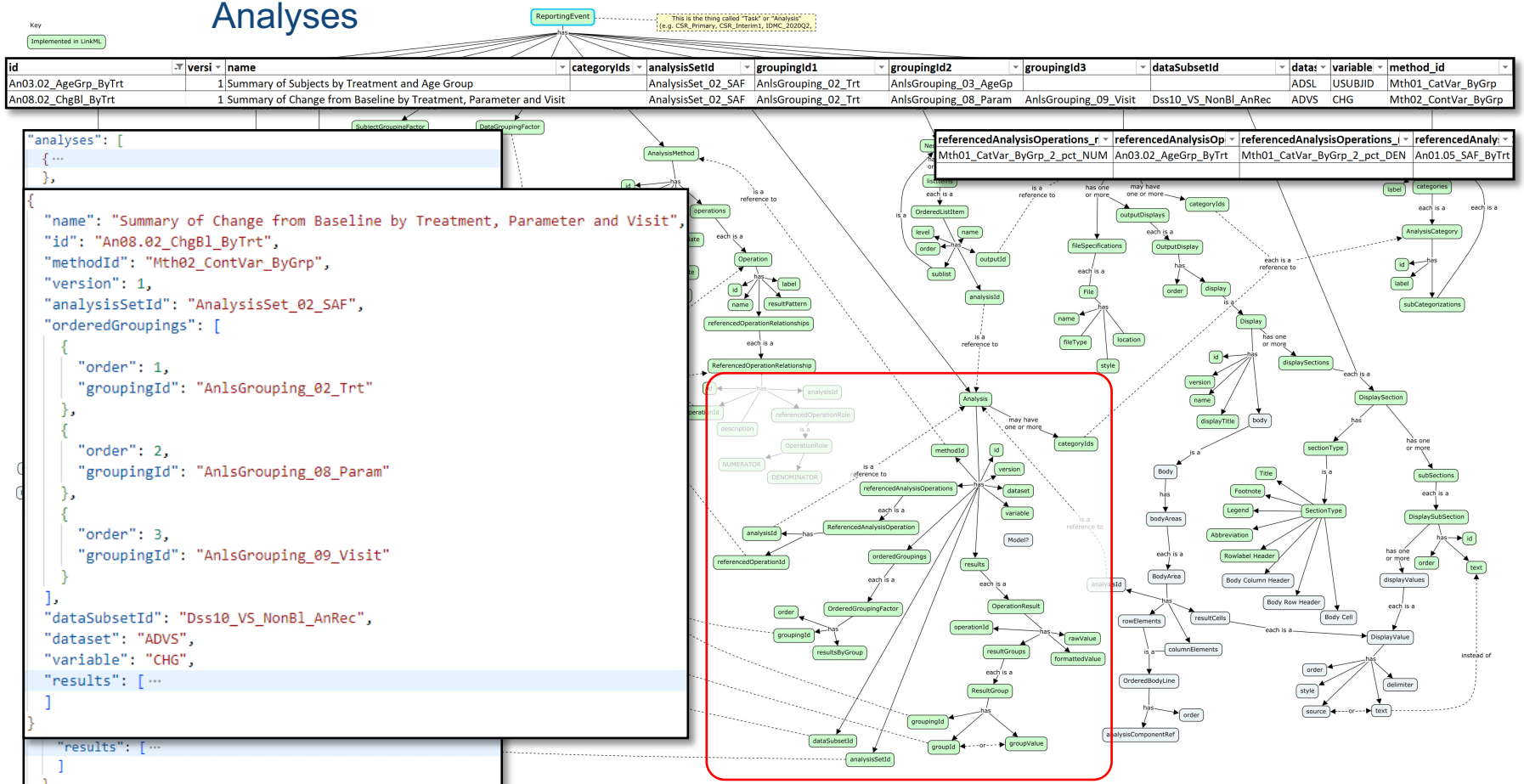
Summary by group of a categorical variable	Grouped summary of categorical variable	Descriptive summary statistics across groups for a categorical variable, based on subject occurrence	Mth01_CatVar_ByGrp_1_n	Count of subjects	1	n	XX
Summary by group of a categorical variable	Grouped summary of categorical 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_referencedResul	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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Implemented in LinkML
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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
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referencedOperationRelationships
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DENOMINATOR
description
AnalysisMethod
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delimiter
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text
instead of

Analysis Results

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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
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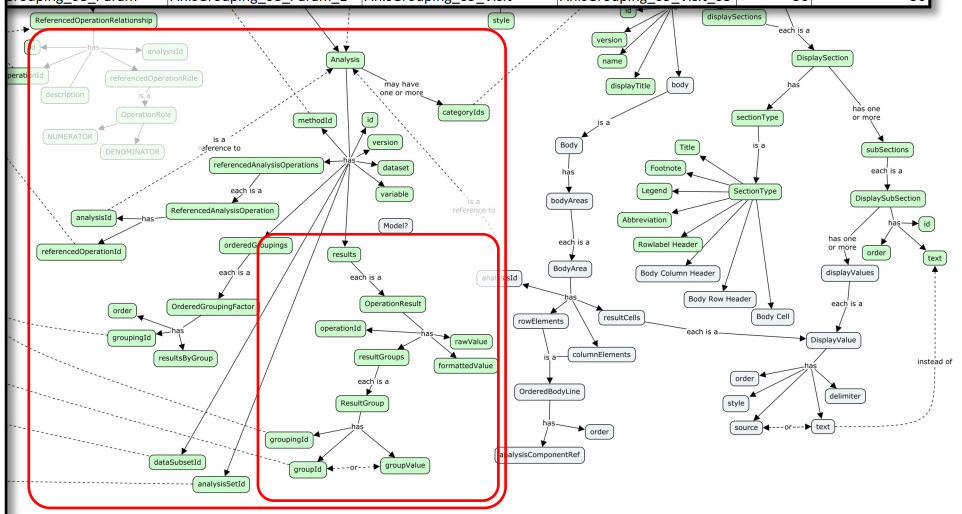

Concepts, Not Layout

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		< 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)

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			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)

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		Placebo	≥ 65 years		72	(83.7)
		Xanomeline Low Dose	< 65 years		8	(9.5)
		Xanomeline Low Dose	≥ 65 years		76	(90.5)
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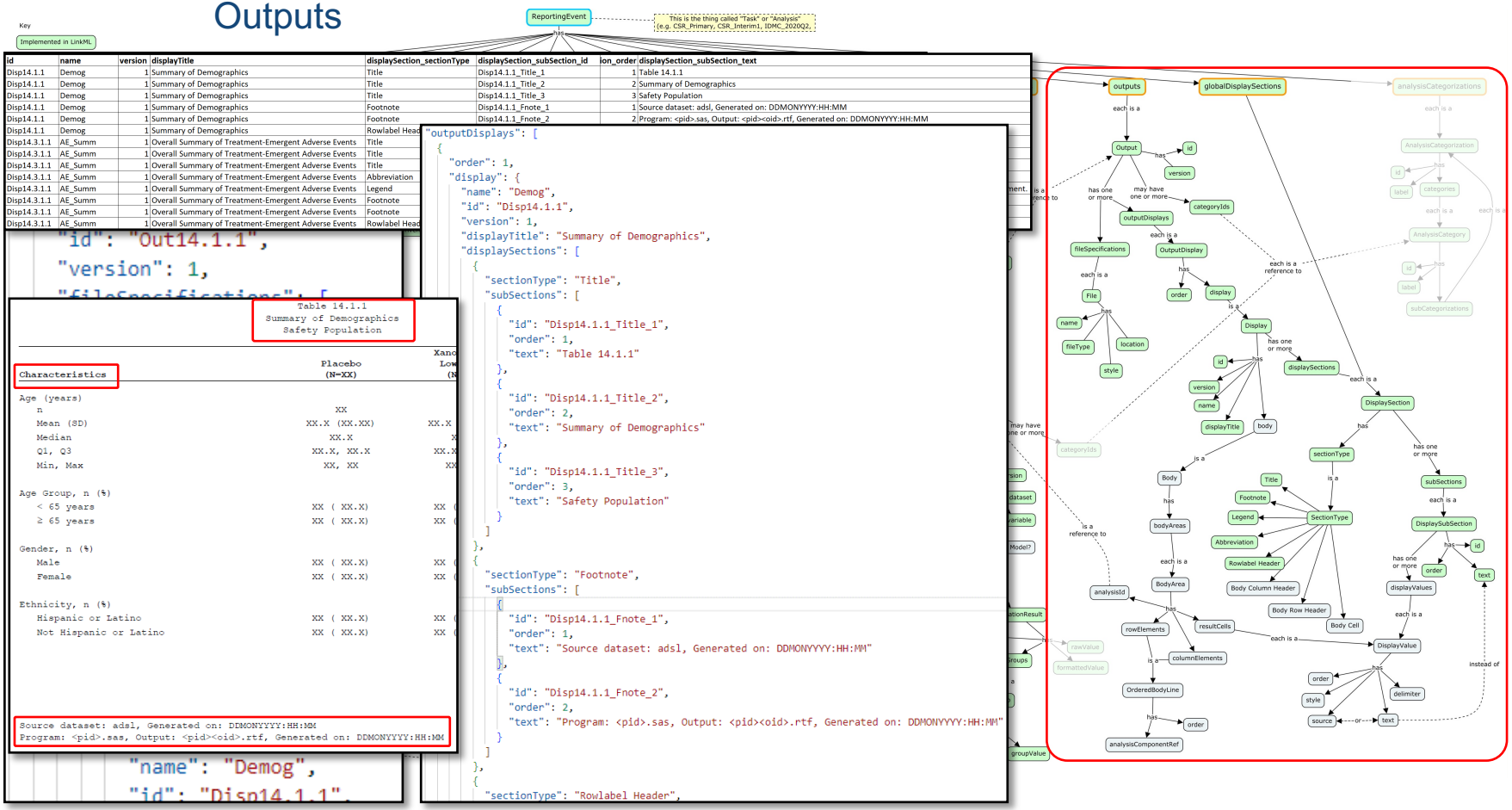
Outputs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Disp14.1.1 | Demog | 1 | Summary of Demographics | Title | Disp14.1.1_Title_2 | 2 | Summary of Demographics
Disp14.1.1 | Demog | 1 | Summary of Demographics | Title | Disp14.1.1_Title_3 | 3 | Safety Population
Disp14.1.1 | Demog | 1 | Summary of Demographics | Footnote | Disp14.1.1_Fnote_1 | 1 | Source dataset: adsl, Generated on: DDMONYYYY:HH:MM
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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
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Mean (SD) XX.X (XX.XX) XX.X
Median XX.X X
Q1, Q3 XX.X, XX.X XX.X
Min, Max XX, XX XX
Age Group, n (%)
< 65 years XX (XX.X) XX
≥ 65 years XX (XX.X) XX
Gender, n (%)
Male XX (XX.X) XX
Female XX (XX.X) XX
Ethnicity, n (%)
Hispanic or Latino XX (XX.X) XX
Not Hispanic or Latino XX (XX.X) XX
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List of Planned Analyses/Outputs


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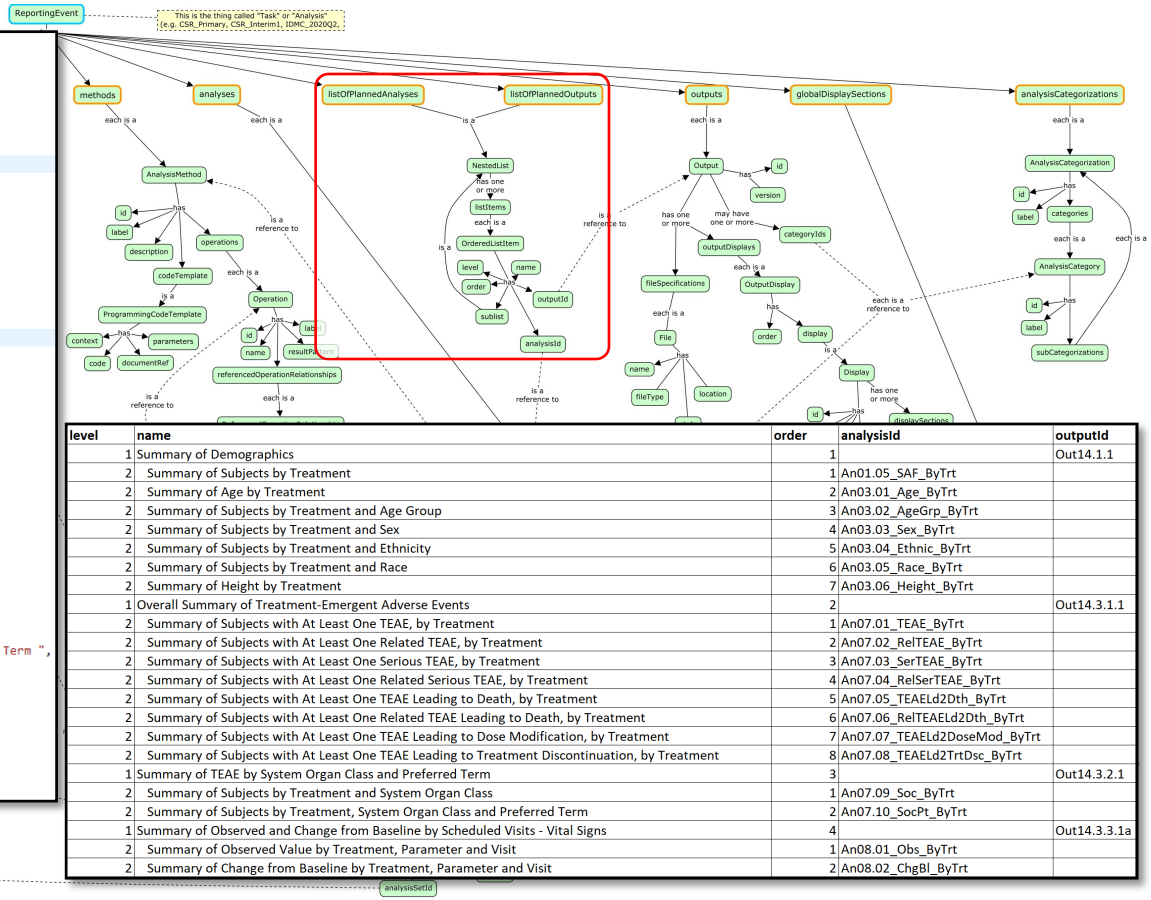

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2	Summary of Age by Treatment	2	An03.01_Age_ByTrt	
2	Summary of Subjects by Treatment and Age Group	3	An03.02_AgeGrp_ByTrt	
2	Summary of Subjects by Treatment and Sex	4	An03.03_Sex_ByTrt	
2	Summary of Subjects by Treatment and Ethnicity	5	An03.04_Ethnic_ByTrt	
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

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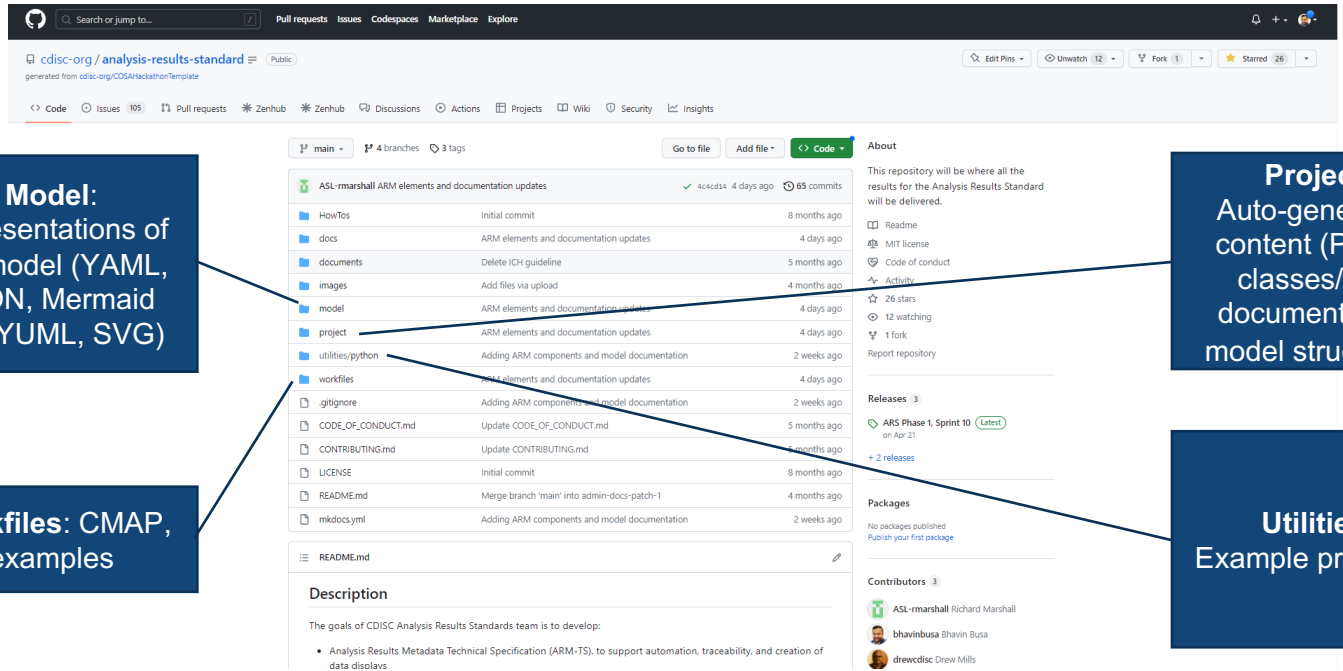
      1. Treatment:
         1. Placebo [ADSL.TRT01A EQ 'Placebo']
         2. Xanomeline Low Dose [ADSL.TRT01A EQ 'Xanomeline Low Dose']
         3. Xanomeline High Dose [ADSL.TRT01A EQ 'Xanomeline High Dose']
      2. Age Group:
         1. < 65 years [ADSL.AGEGR1 EQ '<65']
         2. ≥ 65 years [ADSL.AGEGR1 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']
```

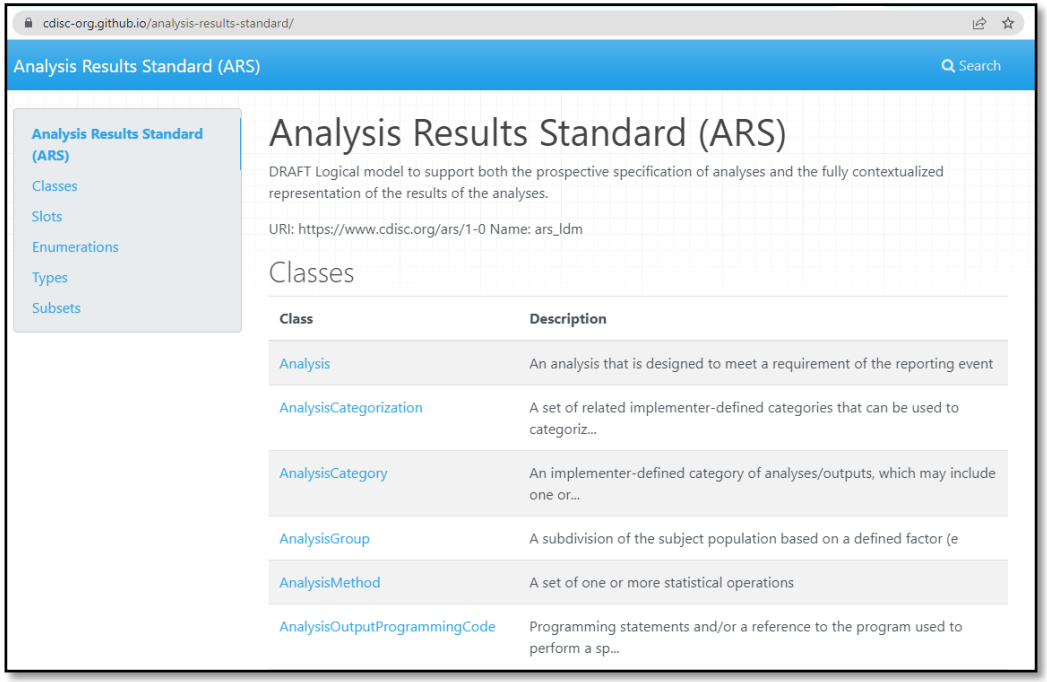
Analysis Results Standard Repo on GitHub

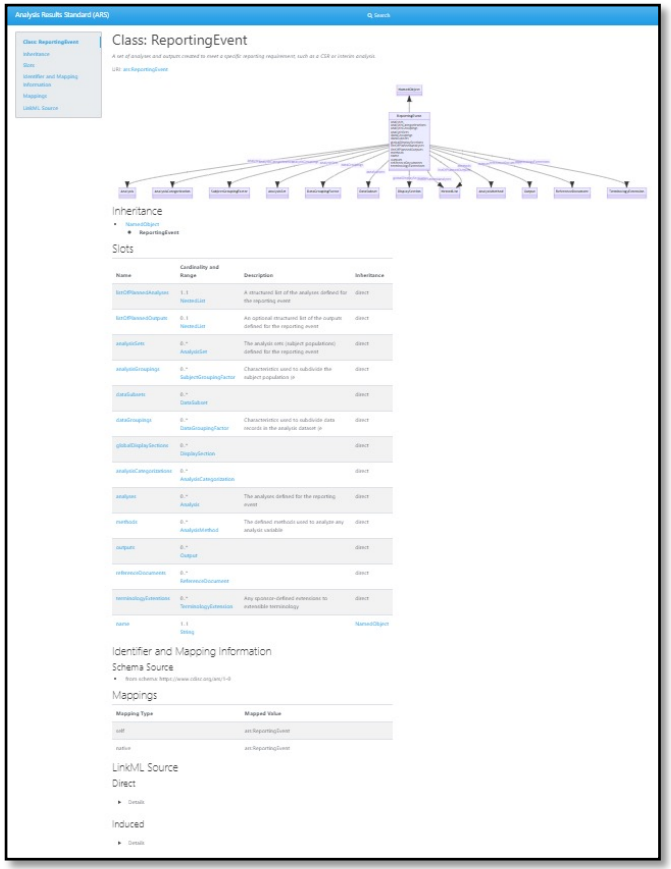
- https://github.com/cdisc-org/analysis-results-standard



Analysis Results Standard Model Documentation

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





Example Reporting Events

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

User Guide

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

User Guide Page Layouts

Class Descriptions

WhereClauseCondition

Created by Richard Marshall, last modified on Aug 14, 2023

Model Documentation
Class: WhereClauseCondition

The WhereClauseCondition class is used to define simple selection criteria conditions in the **condition** attribute of the WhereClause class (or any of its specializations).

ER Diagram: WhereClauseCondition

WhereClauseCondition	
string	dataset
string	variable
ConditionComparatorEnum	comparator
stringList	value

In each instance of the WhereClauseCondition class:

- The **dataset** attribute contains the name of the dataset in which the condition is being applied.
- The **variable** attribute contains the name of the variable (within the specified dataset) to which the condition applies.
- The **comparator** attribute contains a value from the ConditionComparatorEnum enumeration ("EQ" for "is equal to", "LT" for "is less than", etc.) to indicate how values o
- The **value** attribute specifies the selection value, or values, for comparison with values in the specified dataset variable. If the value of the **comparator** attribute is:
  - "IN" or "NOTIN", there should be at least 2 values specified in the **value** attribute; otherwise there should be no more than 1 value specified in the **value** attribute.
  - "EQ" or "NE", the **value** attribute may contain no value to indicate a condition based on a missing value (i.e., "is missing" or "is not missing" respectively).

Example 1

This example shows an instance of the WhereClause class (or one of its specializations) that defines a simple condition based on a single specified selection value. The examp

- `ADSL.SAFFL EQ 'Y'`

Note that some attributes (such as the expected **level** and **order** attributes) have been excluded from this example.

YAML Example

```
...
condition:
  dataset: ADSL
  variable: SAFFL
  comparator: EQ
  value:
  - Y
```

This condition could be represented in tabular form as:

dataset	variable	comparator	value
ADSL	SAFFL	EQ	Y

Other conditions based on a single value (i.e., with a **comparator** value of "EQ", "NE", "LT", "LE", "GT", or "GE") would be represented in a similar way.

Example Reporting Events

Overall Summary of Treatment-Emergent Adverse Events

Created by Richard Marshall, last modified on Aug 16, 2023

Study - CDISC 360 Page x of y

Table 14.3.1.1
Overall Summary of Treatment-Emergent Adverse Events
Safety Population

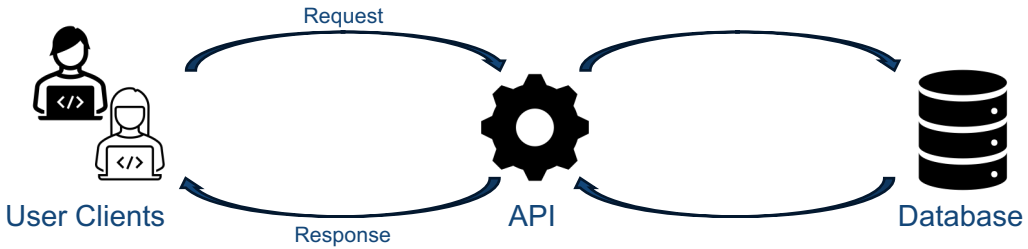
Categories, n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event			
TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Serious TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related Serious TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Death	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE Leading to Death	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Dose Modification [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Treatment Discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: TEAE=Treatment-Emergent Adverse Events
[a] Dose Modification includes Dose Reduced; Drug Interrupted in the AE action taken with study treatment.

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

2. Overall Summary of Treatment-Emergent Adverse Events
Output: Out14-3-1-1 (Overall Summary of Treatment-Emergent Adverse Events)
Documentation:
> AE Summary Table Shell (./AE_Summary_Table_Shell.pdf)
Categories:
> Safety
> Adverse Events
Output File(s):
> RTF Format: t14-3-1-1-teae-summ (.)
> PDF Format: t14-3-1-1-teae-summ (.)
Displays:
1. Disp14-3-1-1 (AE_Summ)
Display Title: Overall Summary of Treatment-Emergent Adverse Events
Sections:
> Title:

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

CDISC ARS: Hackathon Objectives

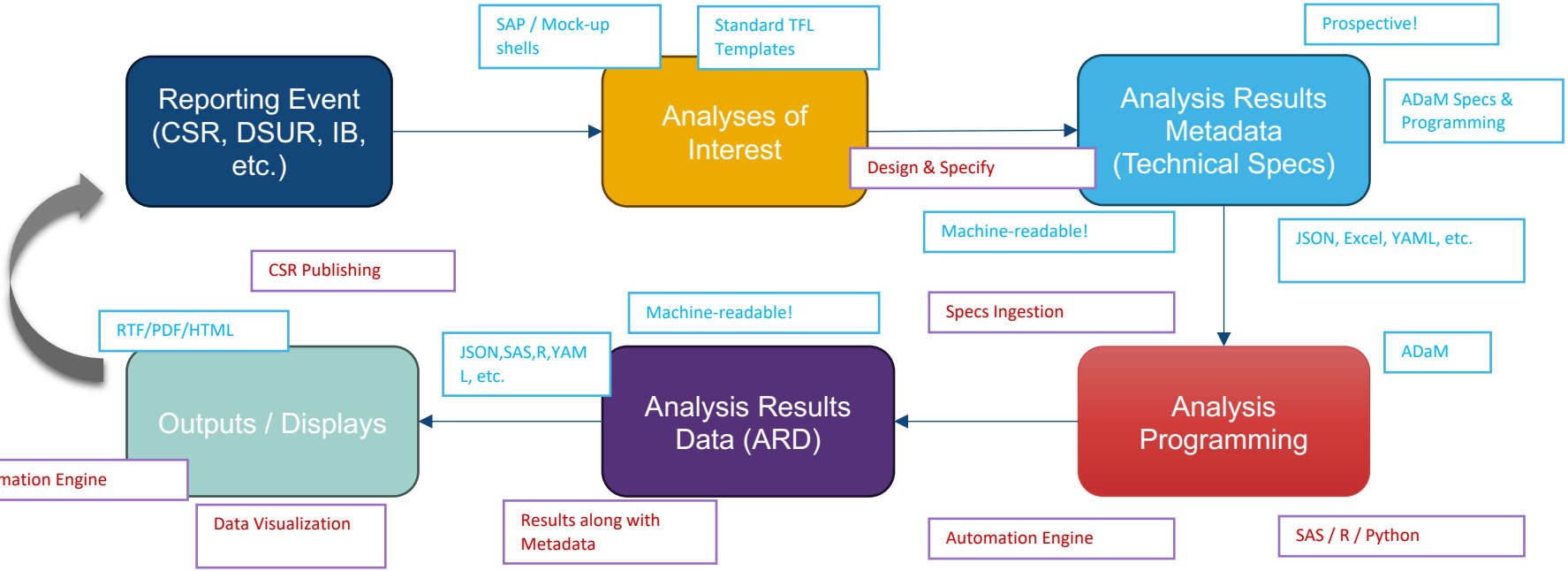
Drive adoption of CDISC Analysis Results Standard

Foster open-source software tools for operationalization

Leveraging hackathon learnings to enhance the standards

Hackathon Timeline

ARS Model Supported Workflow and Entry Points



Release Plan

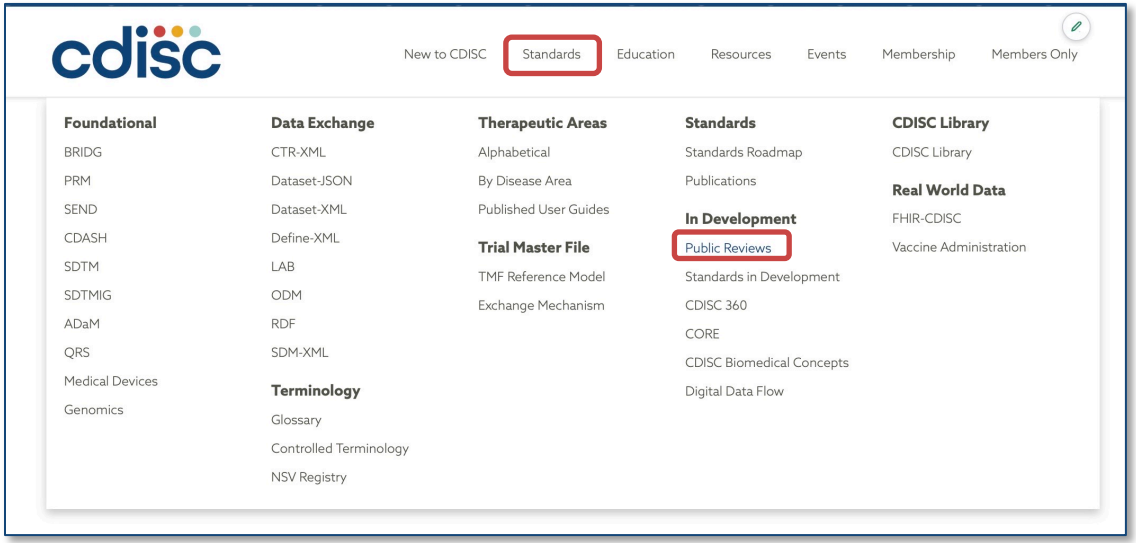
Version 1.0

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

- CDISC ARS Hackathon: July 12th, 2023
- CDISC Internal Review: August 18th, 2023
- CDISC Public Review: Through January 15th, 2023
- US Interchange Workshop: October 2023
- Anticipated Final Release: Q1 2024

Provide Public Review Comments by January 15th!

- https://www.cdisc.org/public-review/analysis-results-standard-v1-0



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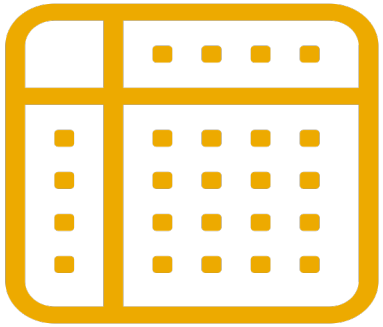
What Is Next?: Adding Informative Content



ADaM Dataset

Analysis Results and Associated Metadata

TFL Example

Planned Collaboration with PHUSE Safety Analytics Working Group

cdisc

Contact Details

Bhavin Busa
ARS Product Owner & Co-Lead
bhavin@clymbclinical.com

Richard Marshall
Principal Data Modeler
rmarshall@accuratesystems.co.uk

Bess LeRoy
Head of Standards Innovation, CDISC
bleroy@cdisc.org