



2023

US

INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER



Analysis Results Standard Workshop

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ARS Workshop Follow Along!

- <https://tinyurl.com/ARS-Model>
- <https://tinyurl.com/ARS-UG>
- <https://tinyurl.com/ARS-Workshop>

Conference Wi-Fi Password: **cdisc2023**

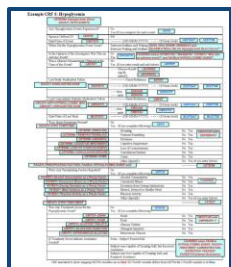




Agenda

- Project Background
- Overview of ARS Model and User Guide
- Hackathon Read Out
- Getting Started with ARS: Example
- Q&A

CDISC Foundational Standards



Data Collection
CDASH



STUDY	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM
1	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM
2	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM
3	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM
4	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM
5	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM	CDASH	SDTM

Data Aggregation
SDTM



STUDY	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM
1	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM
2	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM
3	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM
4	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM
5	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM

Analysis
ADaM



Table 4.2.2: HbA1c Longitudinal Repeated Measures Analysis Results Metadata

Page 1 of 2

PARAM	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM
1	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM
2	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM
3	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM
4	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM
5	CDASH	SDTM	ADaM	CDASH	SDTM	ADaM	CDASH	SDTM

Results
???

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
RESULT IDENTIFIER	Period, Intention-to-treat Population
PARAM	Treatment difference results (LSMean, confidence interval, p-value)
PARAMCD	HbA1c (%)
ANALYSIS VARIABLE	HBA1C
ANALYSIS REASON	CHG (Change from baseline)
ANALYSIS PURPOSE	SPECIFIED IN SAP
ANALYSIS DATASET	PRIMARY OUTCOME MEASURE
	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 consolidate 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> (cunit)			
Baseline			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n Change from Baseline >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX

Parameter (Units) Visit	Treatment X (N=XX)		Treatment Y (N=XX)		Total (N=XX)	
	Observed	CFB	Observed	CFB	Observed	CFB
<Parameter 1> (cunit)						
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



STANDARD SAFETY TABLES AND FIGURES: INTEGRATED GUIDE

Center for Drug Evaluation and Research (CDER)
Biomedical Informatics and Regulatory Review Science
(BIRRS) Team

Please email ONDbiomedicalinformatics@fda.hhs.gov with any questions.

Version Date: August 2022

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

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

Analysis Results Standard (ARS) Search

Analysis Results Standard (ARS)

Schema Diagram

Classes

Slots

Enumerations

Types

Subsets

Analysis Results Standard (ARS)

DRAFT Logical model to support both the prospective specification of analyses and the fully contextualized representation of the results of the analyses.


URI: <https://www.cdisc.org/ars/1-0> Name: ars_idm

Schema Diagram

Classes

Classes provide templates for organizing data. Data objects instantiate classes in the schema. Each class has a set of slots (aka fields, attributes) that are applicable to it. See [LinkML documentation](#) for more information.

Class	Description
NamedObject	An object with a name
ReportingEvent	A set of analyses and outputs created to meet a specific reporting requiremen...
NestedList	A list of items (analyses or outputs) that may be organized within sub-lists



Analysis Results Standard User Guide

Version 1.0 (Draft)

Prepared by the
Analysis Results Standard Team

Notes to Readers

- This is the draft Version 1.0 of the Analysis Results Standard User Guide.
- This document is based on ADaM v2.1 and Analysis Results Metadata (ARM) v1.0 for Define-XML v2.0

Revision History

Date	Version
2023-08-22	Internal Review Draft



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



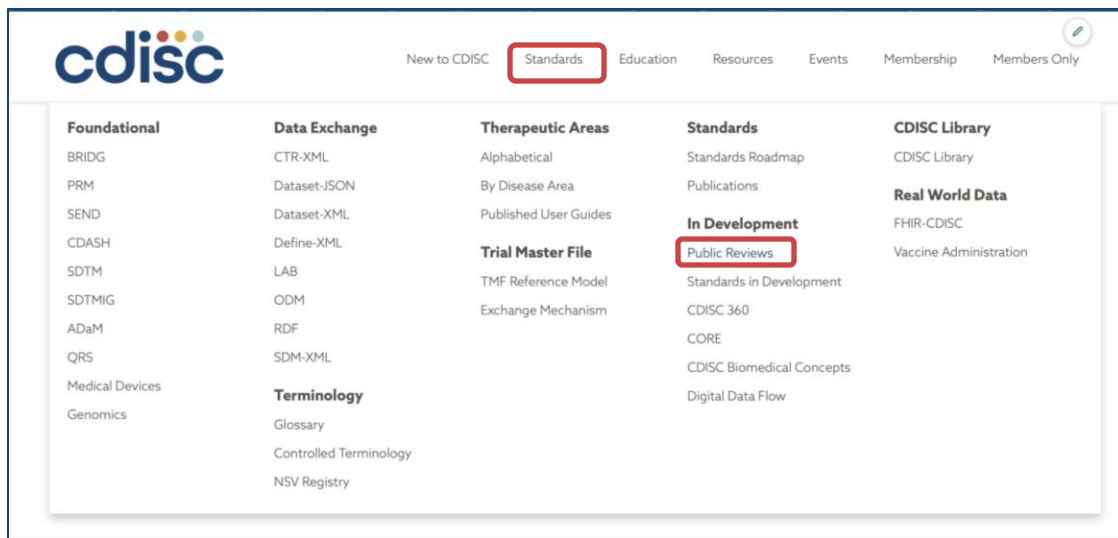
Release Plan

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 December 11th, 2023
- US Interchange Workshop: October 2023
- Anticipated Final Release: January 2023

Provide Public Review Comments!

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

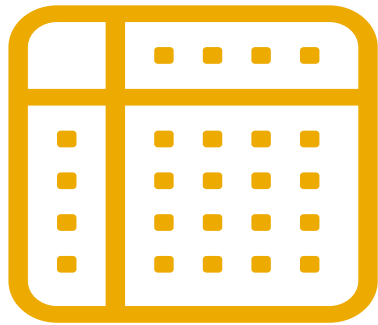


The screenshot shows the CDISC website navigation menu. The 'Standards' link in the top navigation bar is highlighted with a red box. Below the navigation bar, the 'Standards' section is highlighted with a red box, and within it, the 'Public Reviews' link is also highlighted with a red box.

Foundational	Data Exchange	Therapeutic Areas	Standards	CDISC Library
BRIDG	CTR-XML	Alphabetical	Standards Roadmap	CDISC Library
PRM	Dataset-JSON	By Disease Area	Publications	Real World Data
SEND	Dataset-XML	Published User Guides	In Development	FHIR-CDISC
CDASH	Define-XML	Trial Master File	Public Reviews	Vaccine Administration
SDTM	LAB	TMF Reference Model	Standards in Development	
SDTMIG	ODM	Exchange Mechanism	CDISC 360	
ADaM	RDF		CORE	
QRS	SDM-XML		CDISC Biomedical Concepts	
Medical Devices	Terminology		Digital Data Flow	
Genomics	Glossary			
	Controlled Terminology			
	NSV Registry			



What Is Next?: Adding Informative Content



ADaM Dataset



Analysis Results and
Associated Metadata



TFL Example

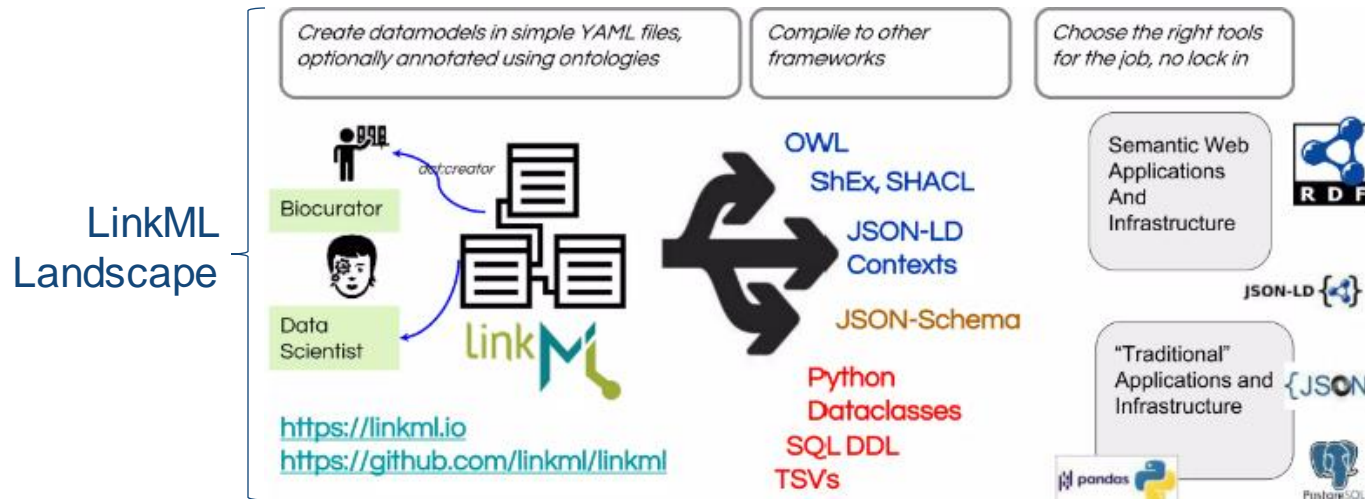
Planned Collaboration with
PHUSE Safety Analytics
Working Group



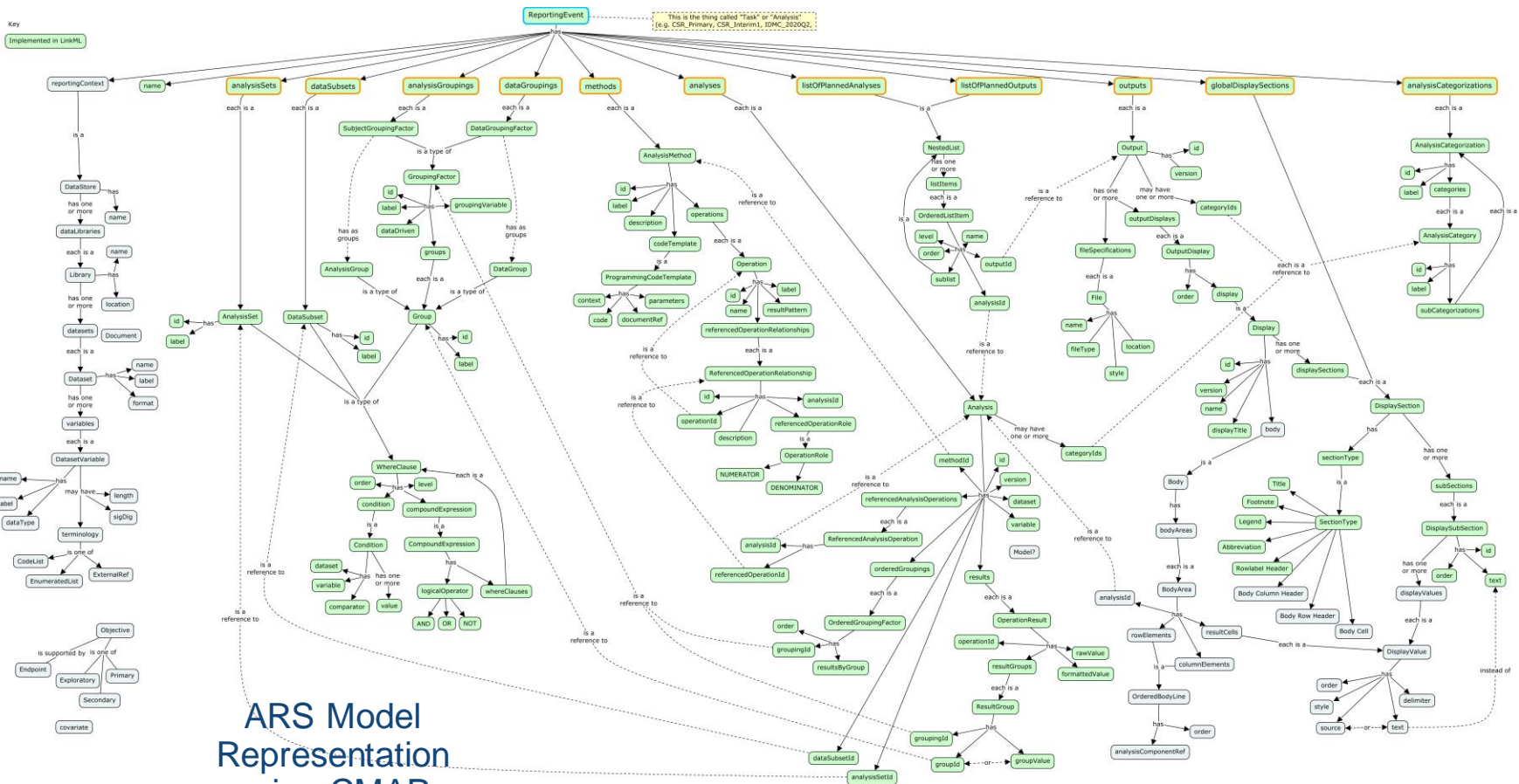
Overview of ARS Model and User Guide

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



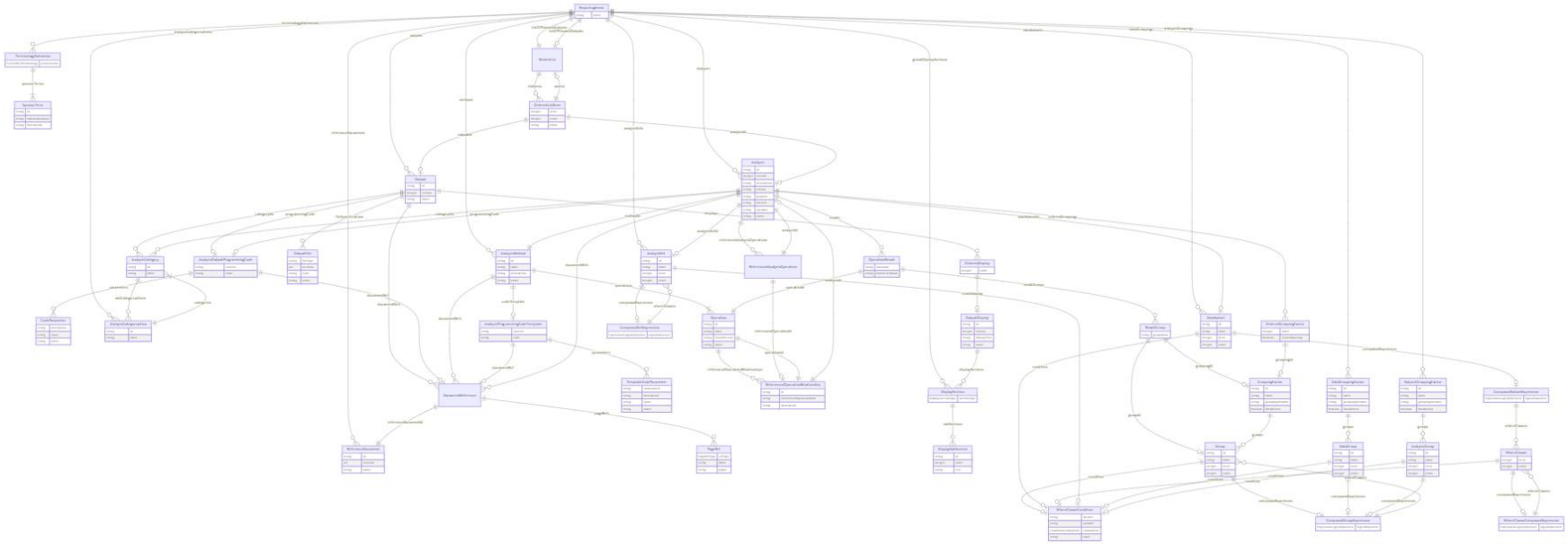
Reference: <https://www.slideshare.net/cmungall/linkml-intro-july-2022pptx>



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

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

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

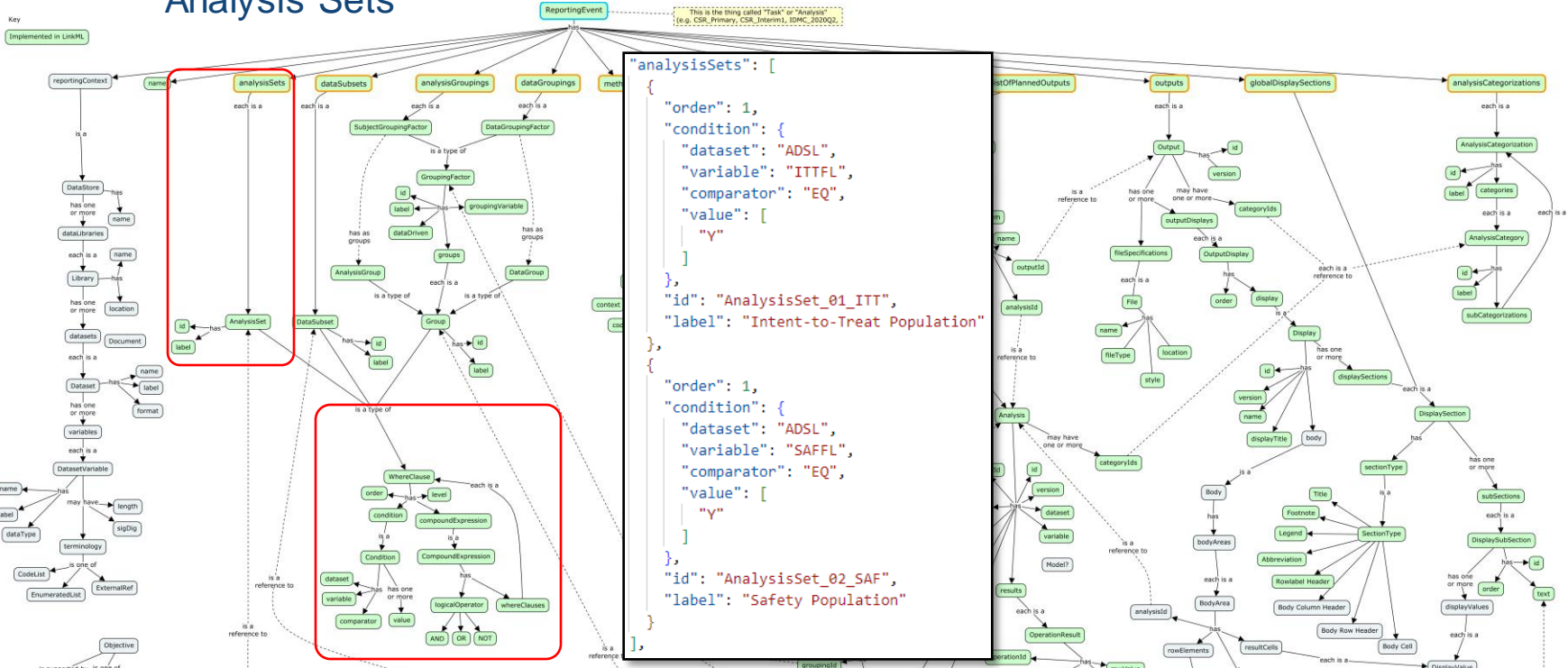
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

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)

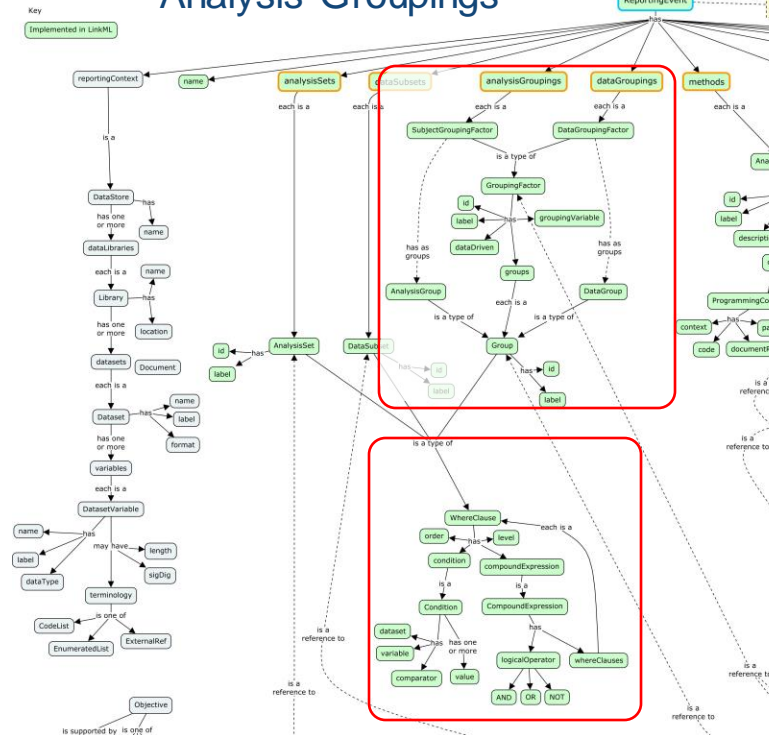
Notes: TEAE=Treatment-Emergent Adverse Events.
Subjects are counted once within each system organ class and preferred term.
[a] All investigators adverse events were coded using MedDRA version xx.x.

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

Analysis Sets



Analysis Groupings

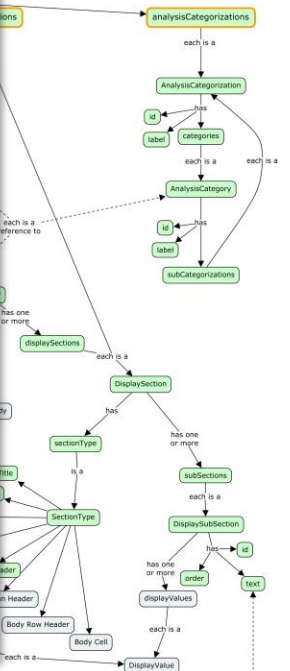


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          ]
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          "comparator": "EQ",
          "value": [
            "F"
          ]
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      }
    ]
  }
]
    
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    },
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    }
  ]
}
    
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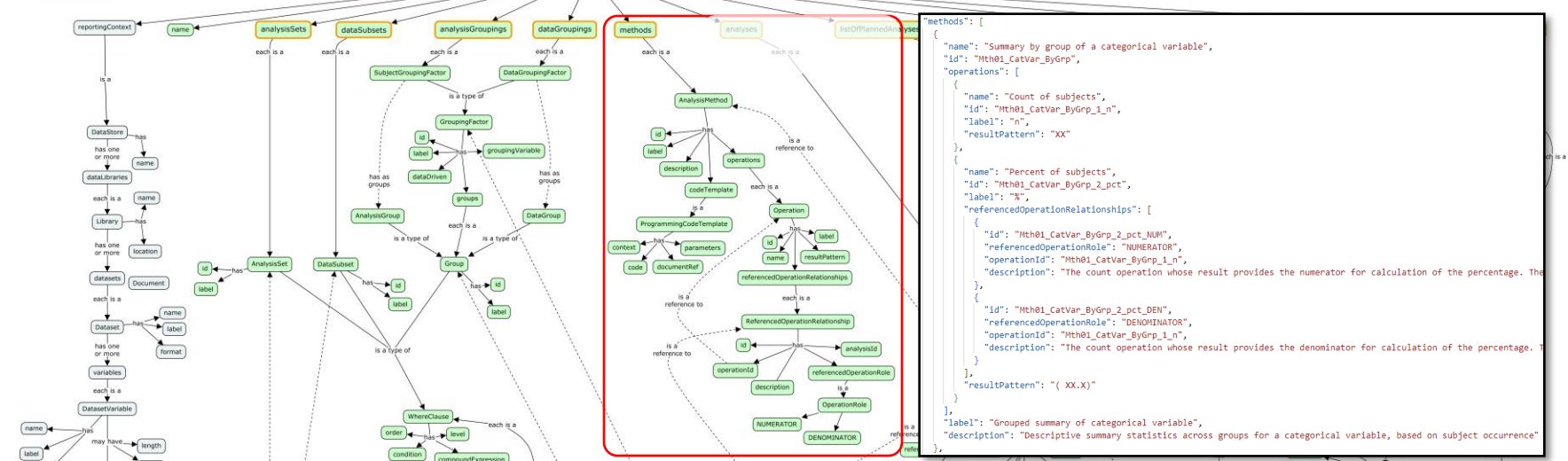


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AnlsGrouping_01_Sex	Gender	SEX	FALSE	AnlsGrouping_01_Sex_2	Female	2	ADSL	SEX	EQ	F
AnlsGrouping_02_Trt	Treatment	TRT01A	FALSE	AnlsGrouping_02_Trt_1	Placebo	1	ADSL	TRT01A	EQ	Placebo
AnlsGrouping_02_Trt	Treatment	TRT01A	FALSE	AnlsGrouping_02_Trt_2	Xanomeline 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

Key
Implemented in LinkML

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



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_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	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.



Analysis Results

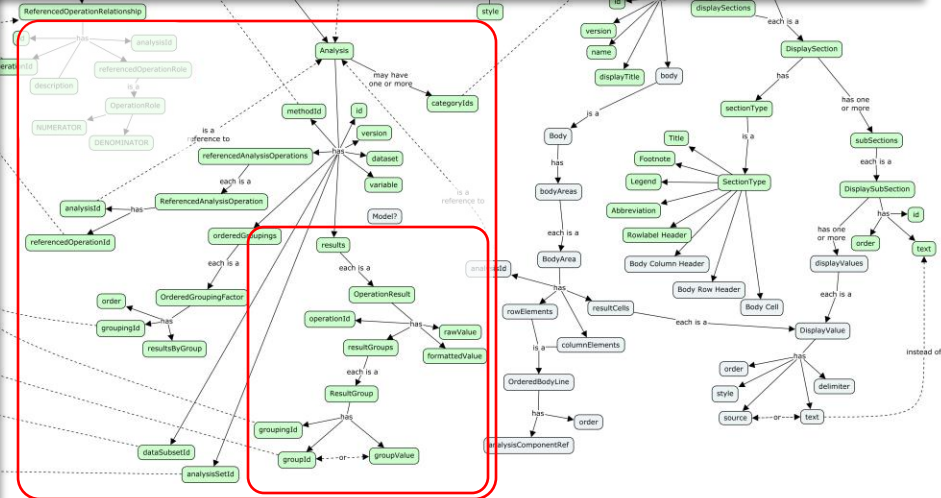
Key
(Implemented in LinkML)

ReportingEvent
This is the thing called "Task" or "Analysis"
(e.g. CSR_Primary, CSR_Interim1, IDMC_2020Q2)

id	operation_id	resultGroup1_groupingId	resultGroup1_groupId	resultGroup2_groupingId	resultGroup2_groupId	resultGroup3_groupingId	resultGroup3_groupId	rawValue	formattedVal
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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
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	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	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	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	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	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_03	AnlsGrouping_09_Visit	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	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	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	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	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	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	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	AnlsGrouping_09_Visit_03	50	50

```

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      }
    ],
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        "groupId": "AnlsGrouping_09_Visit_03"
      }
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    "formattedValue": "50"
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]
    
```



Concepts, Not Layout

Analysis ID:	An03.2_AgeGrp_ByTrt						
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		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
		Mth01_CatVar_ByGrp	Operation		n	%	n	%	n
		AnlsGrouping_03_AgeGp							
		Age Group							
		< 65 years			14	(16.3)	8	(9.5)	11
		≥ 65 years			72	(83.7)	76	(90.5)	73
									(13.1)
									(86.9)

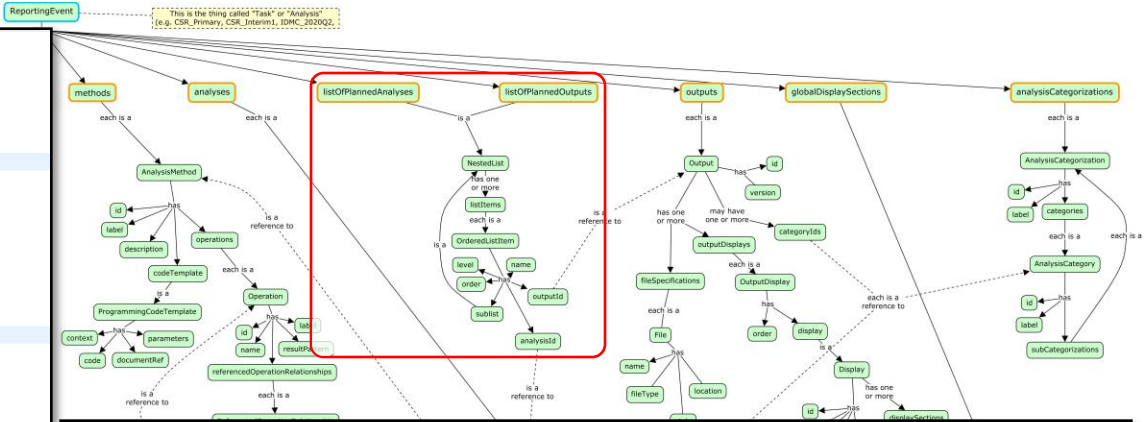
Analysis ID:	An03.2_AgeGrp_ByTrt						
Display Value:	formattedValue						
		AnlsGrouping_02_Trtr	Operation		n	%	
		AnlsGrouping_03_AgeGp					
		Treatment	Age Group				
		Placebo	< 65 years		14	(16.3)	
		Placebo	≥ 65 years		72	(83.7)	
		Xanomeline Low Dose	< 65 years		8	(9.5)	
		Xanomeline Low Dose	≥ 65 years		76	(90.5)	
		Xanomeline High Dose	< 65 years		11	(13.1)	
		Xanomeline High Dose	≥ 65 years		73	(86.9)	

List of Planned Analyses/Outputs

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    },
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      "order": 3,
      "sublist": {
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          {
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            "level": 2,
            "order": 2,
            "analysisId": "An07.10_SocPt_ByTrt"
          }
        ]
      }
    },
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      "level": 1,
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            "level": 2,
            "order": 1,
            "analysisId": "An07.09_Soc_ByTrt"
          },
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            "level": 2,
            "order": 2,
            "analysisId": "An07.10_SocPt_ByTrt"
          }
        ]
      }
    }
  ]
}
  
```

covariate



level	name	order	analysisId	outputId
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			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	

analysisId

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>

cdisc-org / analysis-results-standard

main 4 branches 3 tags

File/Folder	Description	Last Commit
ASL-rmarshall ARM elements and documentation updates		4 commits 4 days ago
HowTos	Initial commit	8 months ago
docs	ARM elements and documentation updates	4 days ago
documents	Delete ICH guideline	5 months ago
images	Add files via upload	4 months ago
model	ARM elements and documentation updates	4 days ago
project	ARM elements and documentation updates	4 days ago
utilities/python	Adding ARM components and model documentation	2 weeks ago
workfiles	ARM elements and documentation updates	4 days ago
.gitignore	Adding ARM components and model documentation	2 weeks ago
CODE_OF_CONDUCT.md	Update CODE_OF_CONDUCT.md	5 months ago
CONTRIBUTING.md	Update CONTRIBUTING.md	5 months ago
LICENSE	Initial commit	8 months ago
README.md	Merge branch 'main' into admin-docs-patch-1	4 months ago
mkdocs.yml	Adding ARM components and model documentation	2 weeks ago

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

README.md

Description

The goals of CDISC Analysis Results Standards team is to develop:

- Analysis Results Metadata Technical Specification (ARM-TS), to support automation, traceability, and creation of data disallows



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>

1 INTRODUCTION

- 1.1 Background and Purpose
- 1.2 Relationship to Other CDISC Standards
- 1.3 How to Read this Document

2 ANALYSIS RESULTS MODEL

- 2.1 ReportingEvent
- 2.2 [Common Components](#)
 - 2.2.1 NestedList
 - 2.2.2 AnalysisOutputCategorization
 - 2.2.3 ReferenceDocument
 - 2.2.3.1 DocumentReference
 - 2.2.4 TerminologyExtension
 - 2.2.4.1 ExtensibleTerminologyTerm
 - 2.2.5 AnalysisOutputProgrammingCode
- 2.3 Analysis Components
 - 2.3.1 WhereClause
 - 2.3.1.1 WhereClauseCondition
 - 2.3.1.2 WhereClauseCompoundExpression
 - 2.3.2 AnalysisSet
 - 2.3.3 DataSubset
 - 2.3.4 GroupingFactor
 - 2.3.4.1 SubjectGroupingFactor
 - 2.3.4.2 DataGroupingFactor
 - 2.3.5 AnalysisMethod
 - 2.3.5.1 Operation
 - 2.3.5.2 AnalysisProgrammingCodeTemplate
 - 2.3.6 Analysis
 - 2.3.6.1 OperationResult

2.4 Output Components

- 2.4.1 GlobalDisplaySection
- 2.4.2 Output
 - 2.4.2.1 OutputDisplay

3 EXAMPLE REPORTING EVENTS

- 3.1 Common Safety Displays
 - 3.1.1 Summary of Demographics
 - 3.1.2 Overall Summary of Treatment-Emergent Adverse Events
 - 3.1.3 Summary of TEAE by System Organ Class and Preferred Term
 - 3.1.4 Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs
 - 3.1.5 Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs <Vertical Layout>
- 3.2 FDA STF
 - 3.2.1 Table 2: Baseline Demographic and Clinical Characteristics, Safety Population

APPENDICES

- Appendix A: Glossary and Abbreviations
- Appendix B: Representations and Warranties, Limitations of Liability, and Disclaimers

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 of the **variable** attribute are compared to the **value** attribute.
- 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 example shows the following:

- 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 349 Page x of y

Table 14.3-1.1
Overall Summary of Treatment-Emergent Adverse Events
Safety Population

Categories, n (%)	Placebo (N=95)	Randomized Low Dose (N=95)	Randomized High Dose (N=95)
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 New 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 Reduction; Drug Interrupted in the AE section taken with study treatment.

Source dataset: adae, Generated on: 20230816T11:11:30Z
Program: /s40/adae, Output: /s40/ADAE_TAE, Generated on: 20230816T11:11:30Z

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:

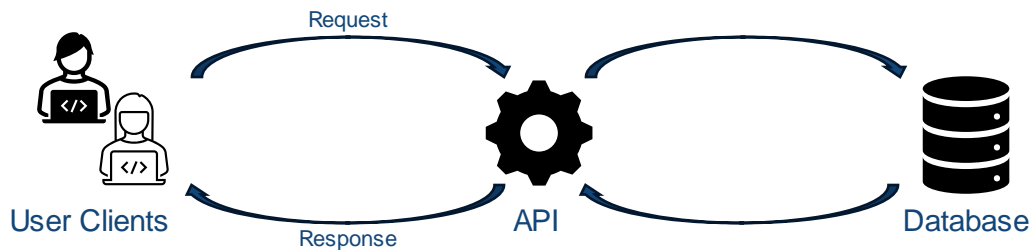
1. Disp14-3-1-1 (AE_Summ)

Display Title: Overall Summary of Treatment-Emergent Adverse Events

Sections:

> Title:

Analysis Results Standard Application Programming Interface (API)



```
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 is operation."
          },
          {
            "id": "Mth01_CatVar_Summ_ByGrp_2_pct_DEN",
            "referencedOperationRole": "DENOMINATOR",
            "operationId": "Mth01_CatVar_Summ_ByGrp_1_n",
            "description": "The count operation whose result is operation."
          }
        ]
      }
    ]
  }
]
```

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
GET	/mdr/ars/methods/{method_id}/operations/	Get All Methods Operations

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

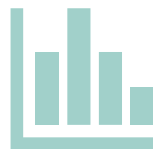


ARS model will drive automation and open-source tool development



ARS Hackathon Readout

CDISC ARS: Hackathon Objectives



Drive adoption of
CDISC Analysis
Results Standard



Foster open-source
software tools for
operationalization

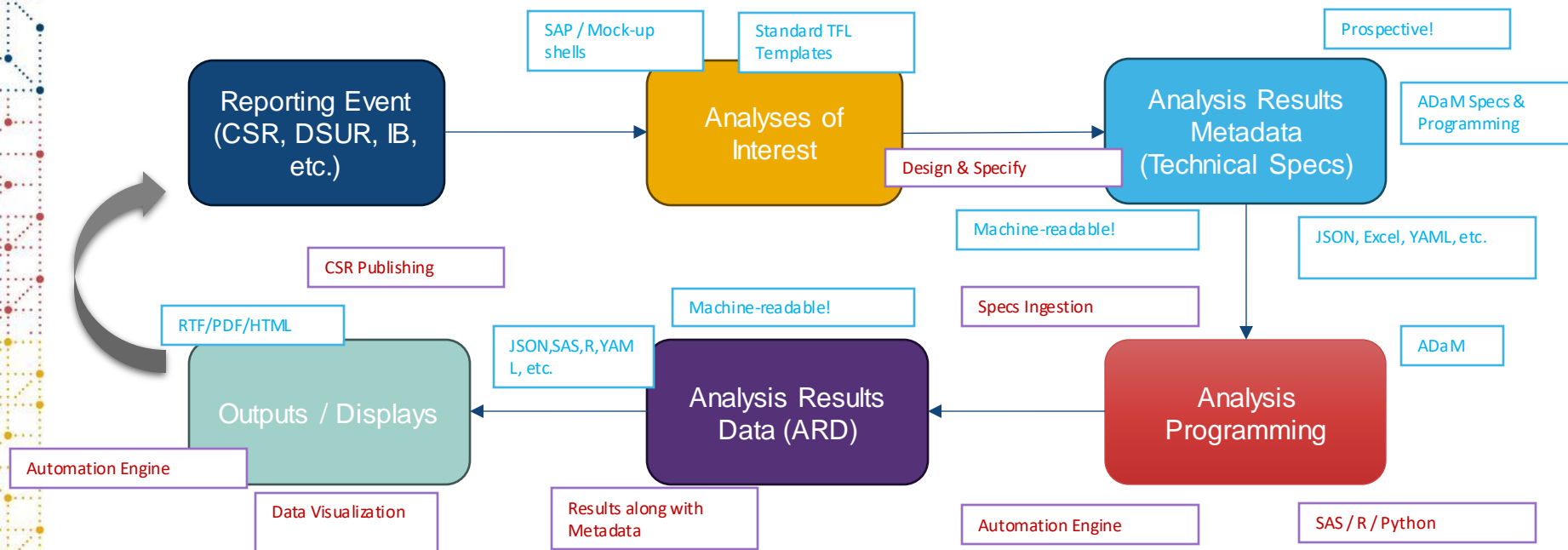


Leveraging hackathon
learnings to enhance
the standards

Hackathon Timeline



ARS Model Supported Workflow and Entry Points



ARD Generator

Metadata-driven analysis using the Analysis Results Standard



20 September 2023

Karl Wallendszus, University of Oxford



Analysis Results Data with {cards} R Package



September 20, 2023

Daniel D. Sjoberg

cdisc

Genentech

A Member of the Roche Group

What do the results look like?



```
library(cards)
```

```
# use the default set of stats (can easily be updated!)
```

```
ard_continuous(  
  data = ADSL,  
  variables = "AGE"  
)
```

```
#>   variable stat_name  stat_label statistic_fmt_fn  statistic warning error  context  
#> 1     AGE         N          N          xx          254    NULL  NULL  continuous  
#> 2     AGE      length Vector Length          xx          254    NULL  NULL  continuous  
#> 3     AGE        mean          Mean        xx.x    75.08661    NULL  NULL  continuous  
#> 4     AGE         sd           SD        xx.x    8.246234    NULL  NULL  continuous  
#> 5     AGE         min          Min        xx.x         51    NULL  NULL  continuous  
#> 6     AGE         max          Max        xx.x         89    NULL  NULL  continuous
```


Analysis Explorer



20 September 2023

Dr Rosanna Cretney

Oxford Population Health

The CDISC logo, consisting of the word "cdisc" in a blue, lowercase, sans-serif font. Above the letters "i", "s", and "c" are three small colored dots: a red dot above the "i", a yellow dot above the "s", and a green dot above the "c".

Progress so far

- MongoDB + REST API + React JS

The image shows a hand-drawn wireframe of a reporting event creation form on graph paper. The form is organized into several sections:

- Event Properties**
- List of planned analyses**
- Reference Documents**
- Terminology Extensions**
- Analysis sets**
- Analysis Groupings** (+)
 - > Treatment
 - > Gender
 - > Age groups
 - > Age sub-groups

On the right side of the form, there are several input fields and controls:

- Select Reporting Event** (dropdown menu)
- + Create Reporting Event** (button)
- ID:** [input field]
- Label:** [input field]
- Grouping variable:** [input field]
- Data-driven:**
- Groups:** (+) [input field]
- Three empty square boxes representing group containers.

Analysis Results Standard (ARS) – Basic Front End



Driven from ADaM data set JSON files

20th September 2023

Paul Thomas, ASUP Ltd.

The CDISC logo, consisting of the word "cdisc" in a dark blue, lowercase, sans-serif font. Above the letters "i", "s", and "c" are three small colored dots: a red one above the "i", a yellow one above the "s", and a green one above the "c".

Front End Application written in REACT + TypeScript utilizing ARS Model

Data url	https://raw.githubusercontent.com/cdisc-org/DataExchange-DatasetJson/master/examples/adam/adsl.json	
studyOID	TDF_ADaM.ADaMIG.1.1	Show <input type="radio"/> Items <input type="radio"/> Data <input checked="" type="radio"/> Summary table
metaDataVersionOID	MDV.TDF_ADaM.ADaMIG.1.1	
name	ADSL	
label	Subject-Level Analysis	

Summary table for: ADSL

Load Save ⌵ ARS

EFFFL

COMP8FL

COMP16FL

COMP24FL

DISCONFL

DSRAEFL

DTHFL

BMIBL

BMIBLGR1

HEIGHTBL

WEIGHTBL

EDUCLVL

DISONSDT

DURDIS

DURDSGR1

VISIT1DT

▼ Groups

id (x)

Label Treatment

Values from TRT01A

Order by TRT01AN

Big N?

Show levels

data
analysis

0 filters applied...

	Placebo	Xanomeline Low Dose	Xanomeline High Dose	Total
BMIBL				
n	n(Baseline BMI (kg/m ²) x Treatment["Placebo"])	n(Baseline BMI (kg/m ²) x Treatment["Xanomeline Low Dose"])	n(Baseline BMI (kg/m ²) x Treatment["Xanomeline High Dose"])	n(Baseline BMI (kg/m ²) x Treatment["Total"])
pct	pct(Baseline BMI (kg/m ²) x Treatment["Placebo"])	pct(Baseline BMI (kg/m ²) x Treatment["Xanomeline Low Dose"])	pct(Baseline BMI (kg/m ²) x Treatment["Xanomeline High Dose"])	pct(Baseline BMI (kg/m ²) x Treatment["Total"])
mean	mean(Baseline BMI (kg/m ²) x Treatment["Placebo"])	mean(Baseline BMI (kg/m ²) x Treatment["Xanomeline Low Dose"])	mean(Baseline BMI (kg/m ²) x Treatment["Xanomeline High Dose"])	mean(Baseline BMI (kg/m ²) x Treatment["Total"])
sd	sd(Baseline BMI (kg/m ²) x Treatment["Placebo"])	sd(Baseline BMI (kg/m ²) x Treatment["Xanomeline Low Dose"])	sd(Baseline BMI (kg/m ²) x Treatment["Xanomeline High Dose"])	sd(Baseline BMI (kg/m ²) x Treatment["Total"])
p0	p0(Baseline BMI (kg/m ²) x Treatment["Placebo"])	p0(Baseline BMI (kg/m ²) x Treatment["Xanomeline Low Dose"])	p0(Baseline BMI (kg/m ²) x Treatment["Xanomeline High Dose"])	p0(Baseline BMI (kg/m ²) x Treatment["Total"])

What the ARS Model can do for us



ARS Hackathon Results Sharing

20 September 2023

Malan Bosman



What if I told you...



each result
for all outputs in a study
Can be calculated...

- with **one click**
- referencing **only metadata**
- using **open-source** technology

Now, it's possible!



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