

# All You Need to Know about the New CDISC Analysis Results Standard!

**BASUG Webinar**

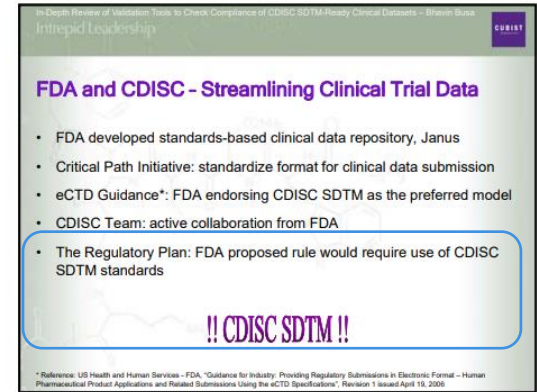
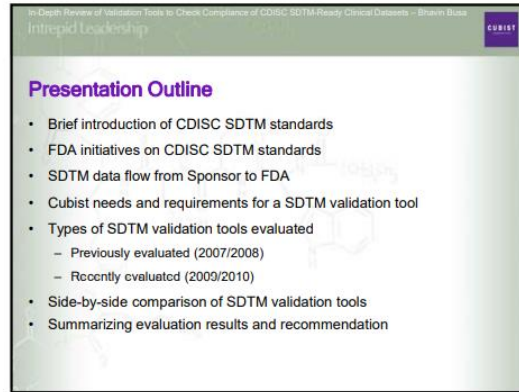
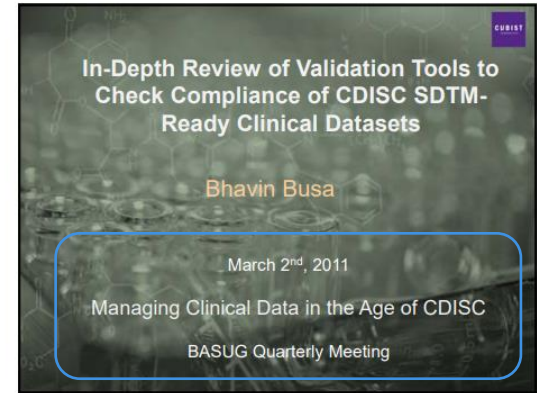
**November 1<sup>st</sup>, 2023**

Bhavin Busa, Principal & Co-Founder, Clymb Clinical



**cdisc**

# Back in the Day!





# Agenda

1. Background
2. Analysis Results Key Objectives and Results
3. Overview of ARS Model (with Examples)
4. ARS Repo on GitHub & Documentation
5. ARS Model Supported Workflow and Entry Points
6. ARS Roadmap
7. Q&A

# Analysis Results Current State

- Static results created for Clinical Study Report
- May be hundred of tables in PDF format, often difficult to navigate
- Variability between sponsors
- Expensive to generate and only used once, no or limited reusability

## Analysis Ready ADaM Dataset

**Table 3.1.1: ADHYPO Analysis Dataset**

Row	STUDYID	USUBJID	MIDS	CEDECOD	WASAEYN	ASTDTM
1	XYZ	00001	HYP0 1	Hypoglycemia	Y	07Sep2012 22:29:00
2	XYZ	00001	HYP0 2	Hypoglycemia	N	10Sep2012 09:12:00
3	XYZ	00001	HYP0 3	Hypoglycemia	N	10Sep2012 23:05:00
4	XYZ	00001	HYP0 4	Hypoglycemia	N	11Sep2012 15:24:00
5	XYZ	00001	HYP0 5	Hypoglycemia	N	18Sep2012 11:39:00
6	XYZ	00002	HYP0 1	Hypoglycemia	N	22Oct2012 13:28:00
7	XYZ	00002	HYP0 2	Hypoglycemia	N	25Oct2012 13:59:00
8	XYZ	00002	HYP0 3	Hypoglycemia	N	17Nov2012 05:01:00



**Table 4.2.1: IBA's Longitudinal Repeated Measures Analysis - Table Shell**

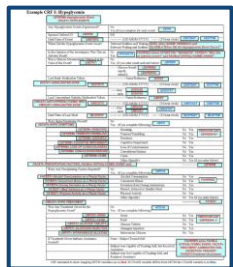
Protocol: XYZ IBA's (S) Longitudinal Repeated Measures Analysis  
24-Week Short-Term Double-Blind Treatment Period  
Intent-to-Treat Population

		Drug A n=115	Drug B n=115
<b>BASILINE:</b>	<b>SR</b>		
	Mean (SD)	X.XX (X.XXXX)	X.XX (X.XXXX)
<b>WEEK 4:</b>	<b>SR</b>		
	Change from baseline: Mean (SD)	X.XX (X.XXXX)	X.XX (X.XXXX)
	Adjusted change from baseline: Mean (SD)	X.XX (X.XXXX)	X.XX (X.XXXX)
	95% Confidence Interval: For adjusted mean	(XX.XX, XX.XX)	(XX.XX, XX.XX)
	Difference vs. Drug B (SE)		XX.XX (X.XXXX)
	95% Confidence Interval: For difference		(XX.XX, XX.XX)
	P-value vs. Drug B		X.XXXX
...			
<b>WEEK 12:</b>	<b>SR</b>		
	Change from baseline: Mean (SD)	X.XX (X.XXXX)	X.XX (X.XXXX)
	Adjusted change from baseline: Mean (SD)	X.XX (X.XXXX)	X.XX (X.XXXX)
	95% Confidence Interval: For adjusted mean	(XX.XX, XX.XX)	(XX.XX, XX.XX)
	Difference vs. Drug B (SE)		XX.XX (X.XXXX)
	95% Confidence Interval: For difference		(XX.XX, XX.XX)
	P-value vs. Drug B		X.XXXX

N: the number of subjects in the random-effects (RE) population.  
SE: the number of subjects in the RE population with non-missing baseline and non-missing Week 4 value.  
Repeated measures analysis change = baseline treatment (SR) - Week 4 (SR).  
Program Source: sasbase\user\user1\stat\rsmeas.sas (data)=11Line

## Static Display

# 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



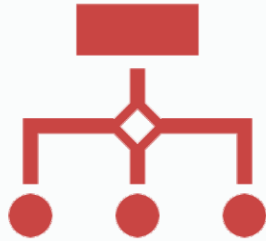
Leverage analysis results metadata to drive the automation of results



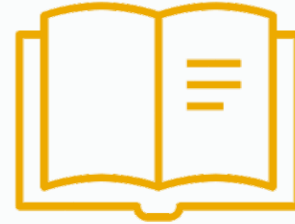
Support storage, access, processing, traceability and reproducibility of results



# 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

# 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

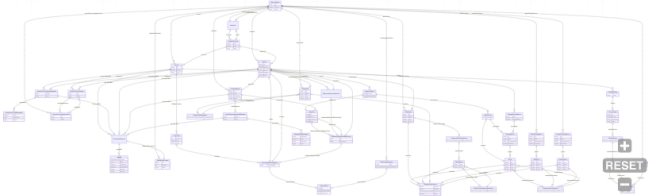
Subsets

## 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
<a href="#">NamedObject</a>	An object with a name
<a href="#">ReportingEvent</a>	A set of analyses and outputs created to meet a specific reporting requiremen...
<a href="#">NesterdList</a>	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**

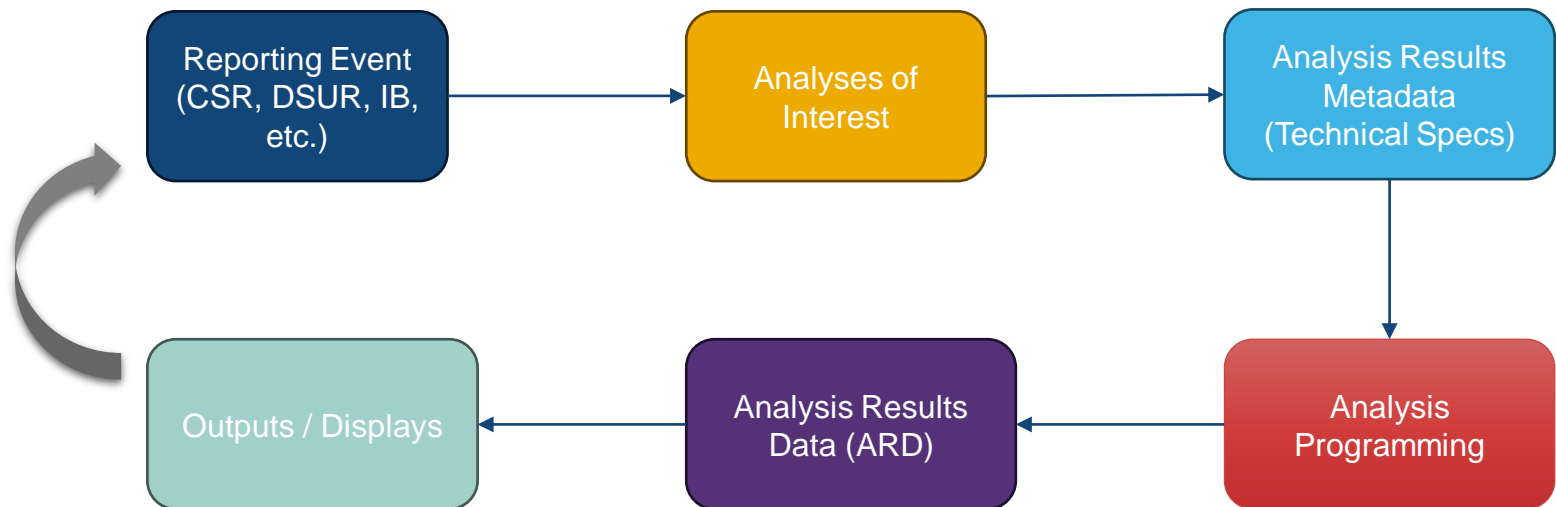
- This is the draft Version 1.0 of the Analysis Results Standard User Guide.
- This document is based on ADaM v2.1 and Analysis Results Metadata (ARM) v1.0 for Define-XML v2.0

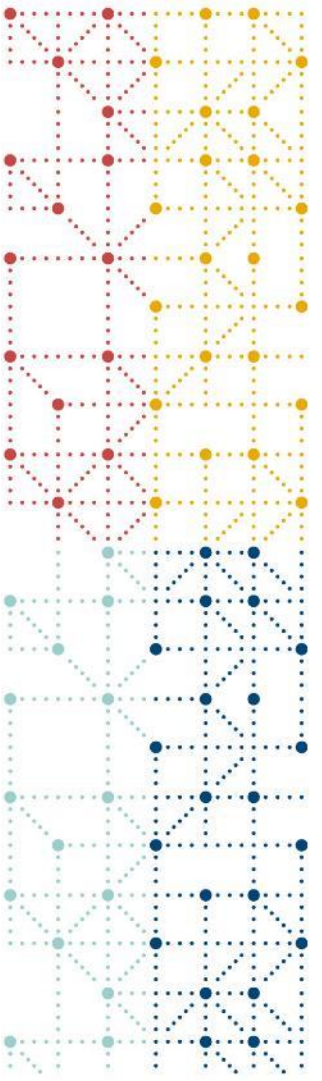
**Revision History**

Date	Version
2023-08-22	Internal Review Draft



# ARS Model Supported Workflow

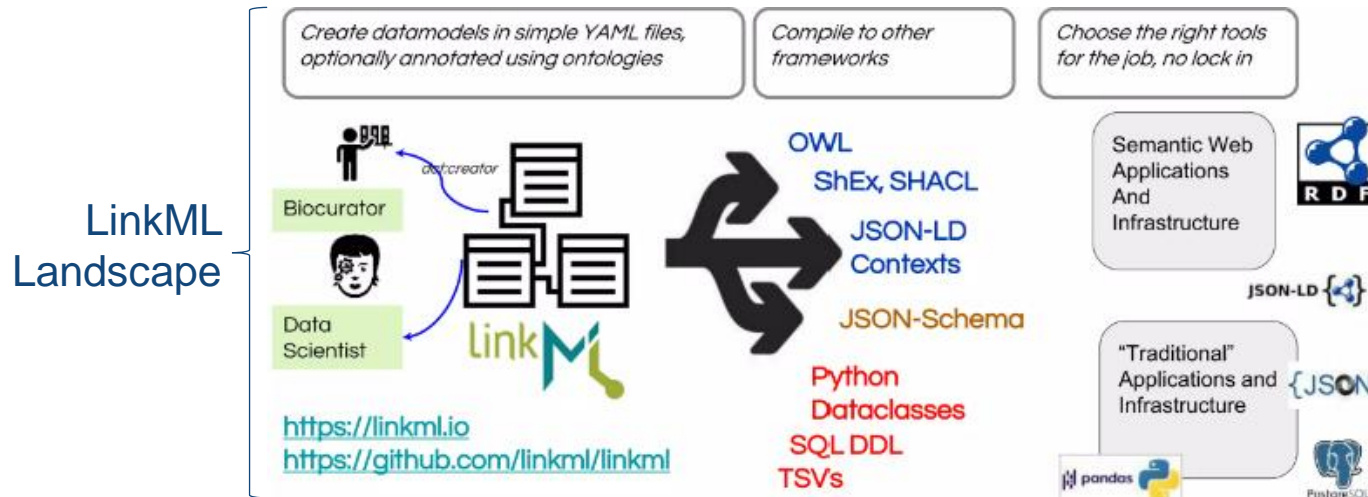




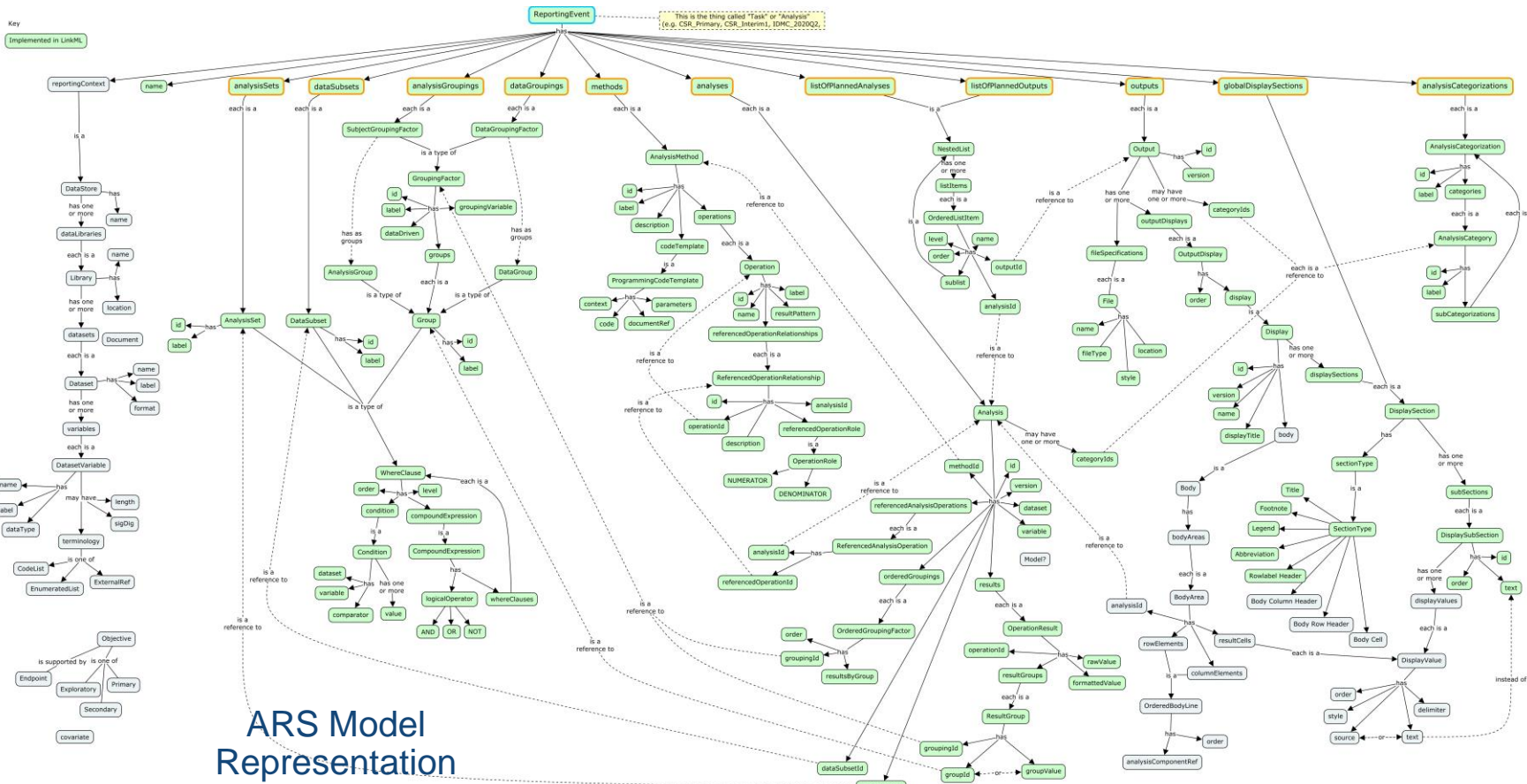
# Overview of ARS Model and User Guide

# 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



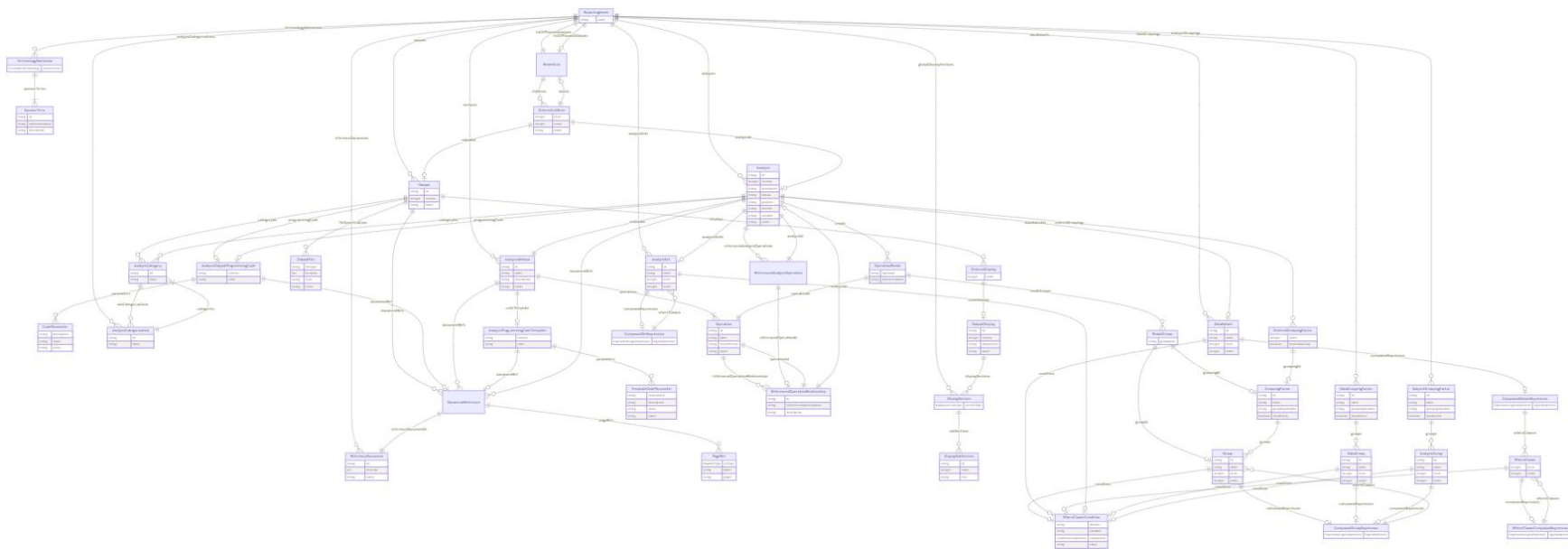
Reference: <https://www.slideshare.net/cmungall/linkml-intro-july-2022pptx>



# 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)
<b>Age (years)</b>			
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
<b>Age Group, n (%)</b>			
< 65 years	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
≥ 65 years	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<b>Gender, n (%)</b>			
Male	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
Female	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<b>Ethnicity, n (%)</b>			
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

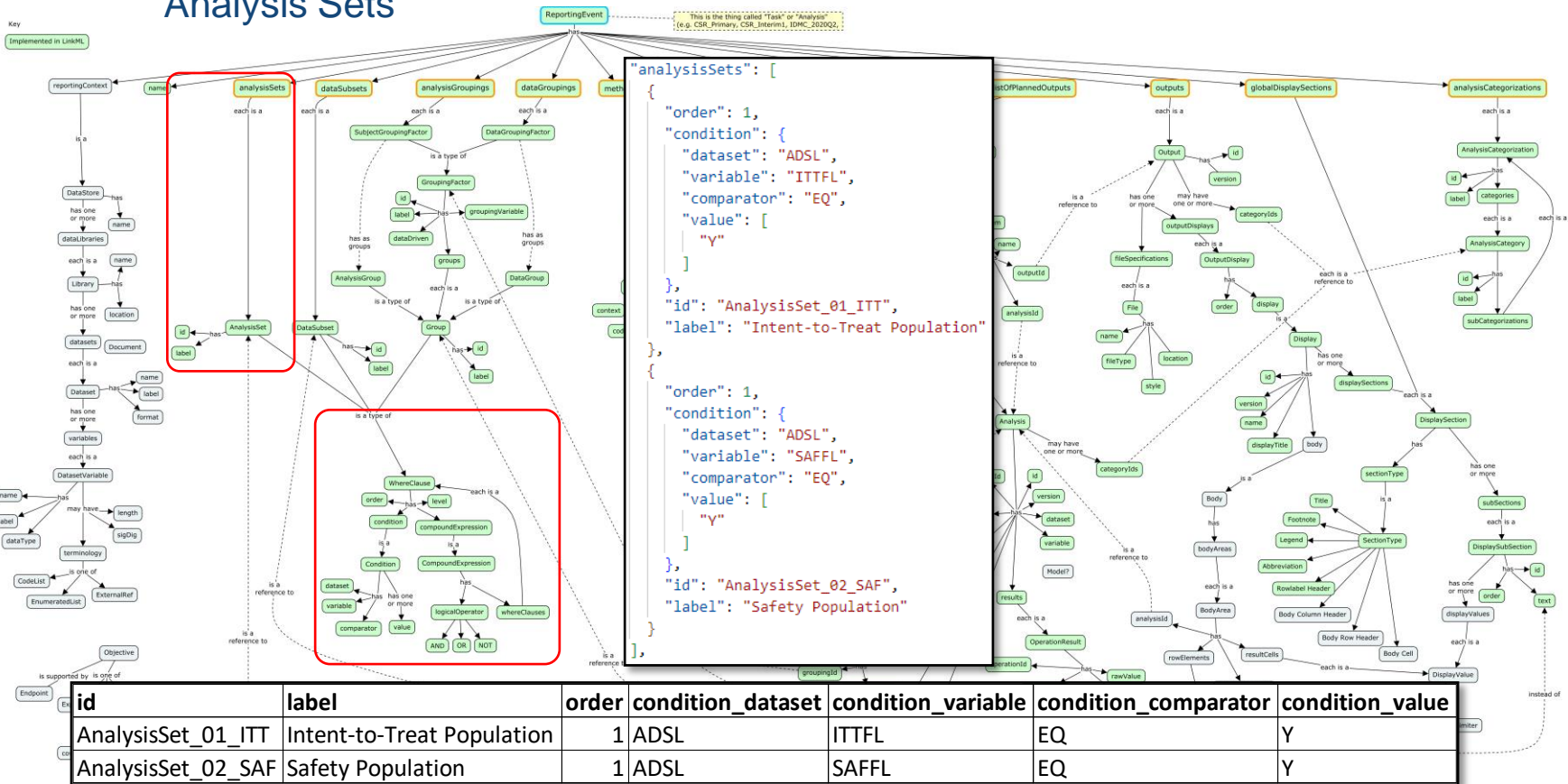
Table 14.3.1.1  
Summary of TEAE by System Organ Class and Preferred Term  
Safety Population

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)

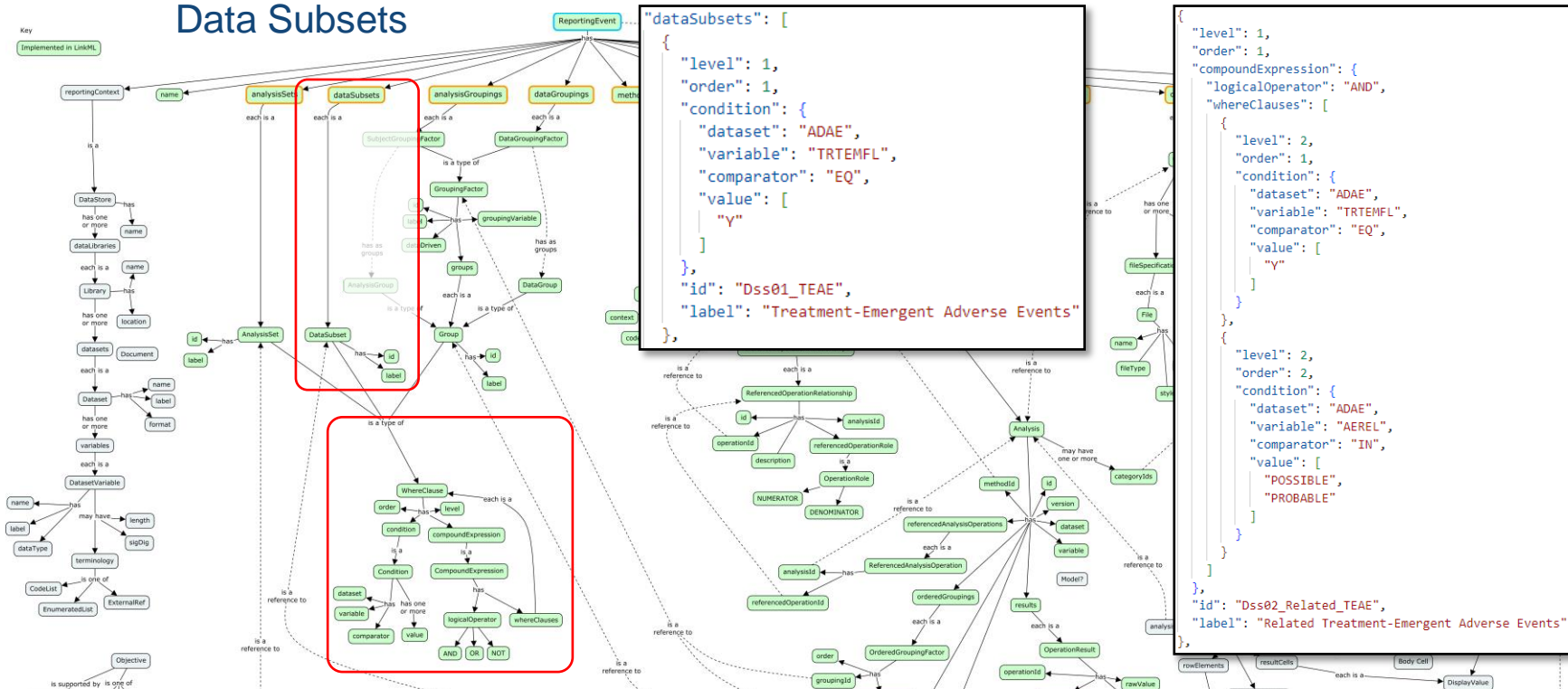
Notes: TEAE=Treatment-Emergent Adverse Events.  
Subjects are counted once within each system organ class and preferred term.  
[a] All investigators adverse events were coded using MedDRA version xx.x.

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

# Analysis Sets

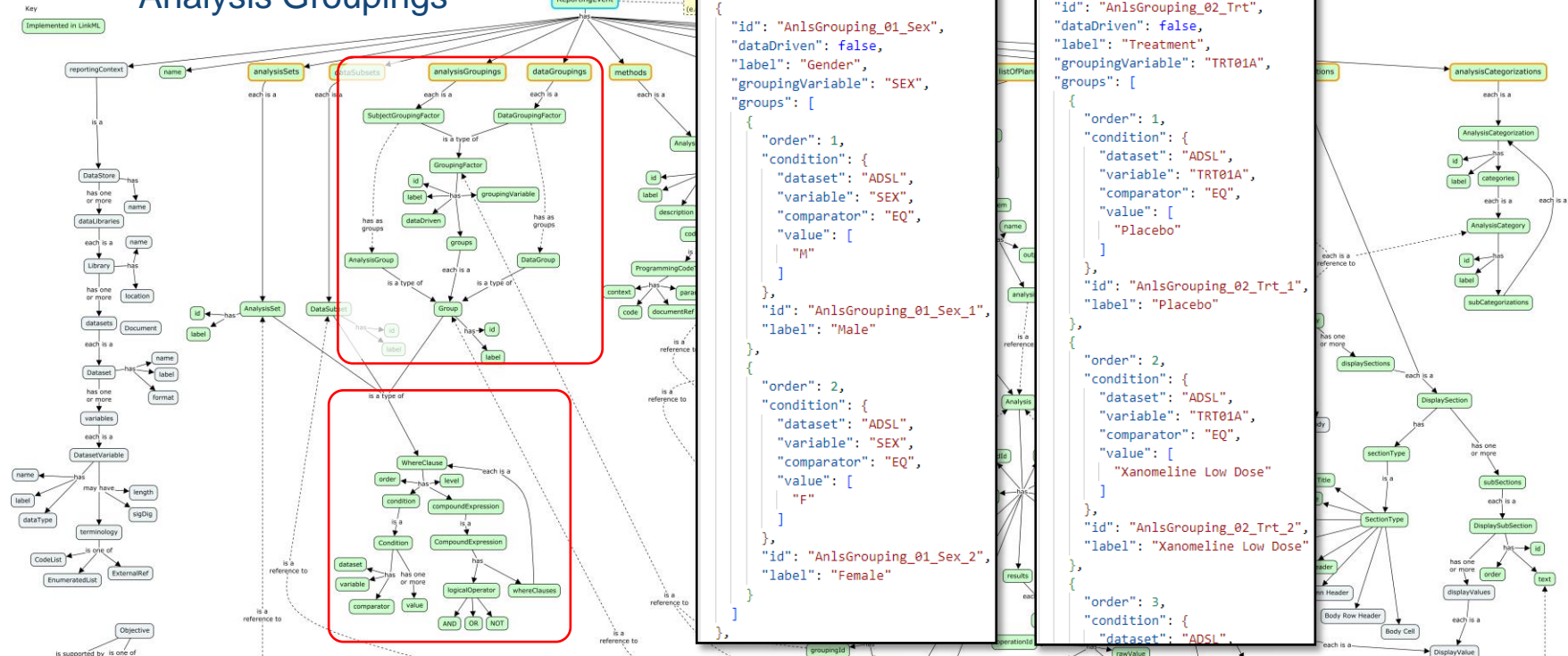


# Data Subsets



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



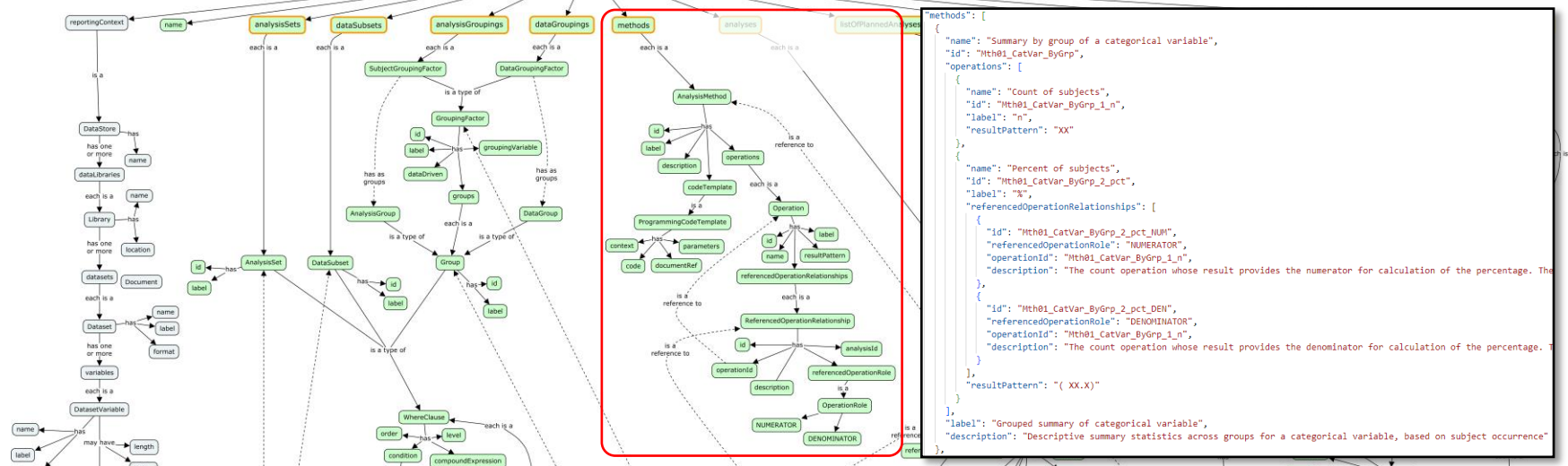
id	label	groupingVariable	dataDriven	group_id	group_label	group_order	group_condition_dataset	group_condition_variable	group_condition_comparator	group_condition_value
AnlsGrouping_01_Sex	Gender	SEX	FALSE	AnlsGrouping_01_Sex_1	Male	1	ADSL	SEX	EQ	M
AnlsGrouping_01_Sex	Gender	SEX	FALSE	AnlsGrouping_01_Sex_2	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

Key  
Implemented in LinkML

ReportingEvent  
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_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 LINKML

ReportingEvent

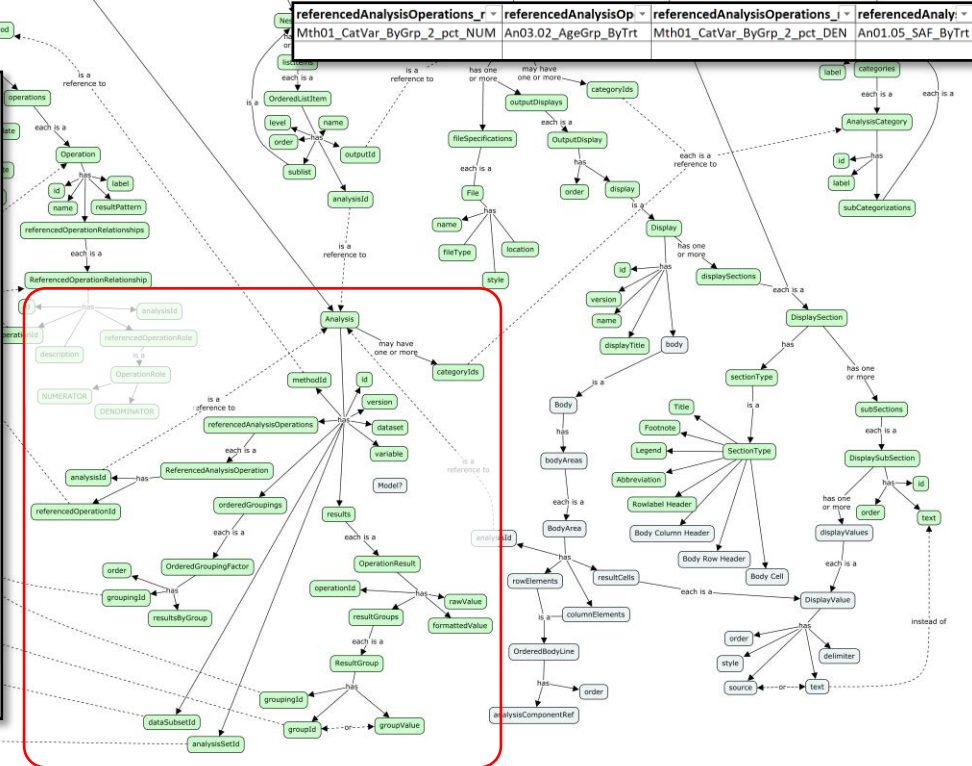
This is the thing called "Task" or "Analysis"  
(e.g. CSR\_Primary, CSR\_Interim1, IDMC\_2020Q2)

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_Trt	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_Trt	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_Trt"
      },
      {
        "order": 2,
        "groupingId": "AnlsGrouping_08_Param"
      },
      {
        "order": 3,
        "groupingId": "AnlsGrouping_09_Visit"
      }
    ],
    "dataSubsetId": "Dss10_VS_NonBl_AnRec",
    "dataset": "ADVS",
    "variable": "CHG",
    "results": [
    ]
  }
]

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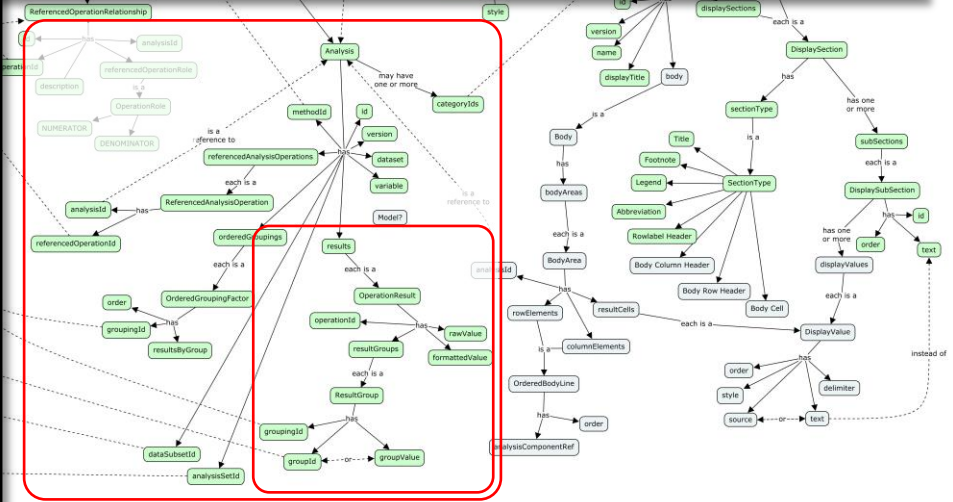




# Analysis Results

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

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  "rawValue": "14",
  "formattedValue": "14"
},
{
  "operationId": "Mth01_CatVar_ByGrp_1",
  "resultGroups": [
    {
      "groupingId": "AnlsGrouping_02_Trt",
      "groupId": "AnlsGrouping_02_Trt_1"
    },
    {
      "groupingId": "AnlsGrouping_03_Age",
      "groupId": "AnlsGrouping_03_AgeGrp"
    }
  ],
  "rawValue": "72",
  "formattedValue": "72"
},
{
  "operationId": "Mth01_CatVar_ByGrp_1",
  "resultGroups": [
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      "groupId": "AnlsGrouping_02_Trt_1"
    },
    {
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      "groupId": "AnlsGrouping_02_Trt_1"
    },
    {
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      "groupId": "AnlsGrouping_09_Visit_02"
    }
  ],
  "rawValue": "-3.301204819",
  "formattedValue": "-3.3"
},
{
  "operationId": "Mth02_ContVar_ByGrp_3_SD",
  "resultGroups": [
```



# Concepts, Not Layout

Analysis ID:	An03.2_AgeGrp_ByTrt						
Display Value:	formattedValue						
			AnlsGrouping_02_Trtr	Treatment	Placebo	Xanomeline Low Dose	Xanomeline High Dose
		AnlsGrouping_03_AgeGp	Mth01_CatVar_ByGrp				
		Age Group	Operation				
		< 65 years	n		14	8	11
		< 65 years	%		( 16.3)	( 9.5)	( 13.1)
		≥ 65 years	n		72	76	73
		≥ 65 years	%		( 83.7)	( 90.5)	( 86.9)

Analysis ID:	An03.2_AgeGrp_ByTrt								
Display Value:	formattedValue								
		AnlsGrouping_02_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						
			Mth01_CatVar_ByGrp	Operation	n	%	
		AnlsGrouping_02_Trtr	AnlsGrouping_03_AgeGp				
		Treatment	Age Group				
		Placebo	< 65 years		14	( 16.3)	
		Placebo	≥ 65 years		72	( 83.7)	
		Xanomeline Low Dose	< 65 years		8	( 9.5)	
		Xanomeline Low Dose	≥ 65 years		76	( 90.5)	
		Xanomeline High Dose	< 65 years		11	( 13.1)	
		Xanomeline High Dose	≥ 65 years		73	( 86.9)	

# Outputs

ReportingEvent

This is the thing called "Task" or "Analysis" (e.g. CSR\_Primary, CSR\_Interim1, IDMC\_2020Q2)

Key

Implemented in LinkML

id	name	version	displayTitle	displaySection_sectionType	displaySection_sectionId	json_order/displaySection_subSection_text
Disp14.1.1	Demog	1	Summary of Demographics	Title	Disp14.1.1_Title_1	1:Table 14.1.1
Disp14.1.1	Demog	1	Summary of Demographics	Title	Disp14.1.1_Title_2	2:Summary of Demographics
Disp14.1.1	Demog	1	Summary of Demographics	Title	Disp14.1.1_Title_3	3:Safety Population
Disp14.1.1	Demog	1	Summary of Demographics	Footnote	Disp14.1.1_Fnote_1	1:Source dataset: adsl, Generated on: DDMONYYYY:HH:MM
Disp14.1.1	Demog	1	Summary of Demographics	Footnote	Disp14.1.1_Fnote_2	2:Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM

```

"outputDisplays": [
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      "version": 1,
      "displayTitle": "Summary of Demographics",
      "displaySections": [
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          "sectionType": "Title",
          "subSections": [
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              "id": "Disp14.1.1_Title_1",
              "order": 1,
              "text": "Table 14.1.1"
            },
            {
              "id": "Disp14.1.1_Title_2",
              "order": 2,
              "text": "Summary of Demographics"
            },
            {
              "id": "Disp14.1.1_Title_3",
              "order": 3,
              "text": "Safety Population"
            }
          ]
        },
        {
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              "order": 1,
              "text": "Source dataset: adsl, Generated on: DDMONYYYY:HH:MM"
            },
            {
              "id": "Disp14.1.1_Fnote_2",
              "order": 2,
              "text": "Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM"
            }
          ]
        }
      ]
    }
  }
]
  
```

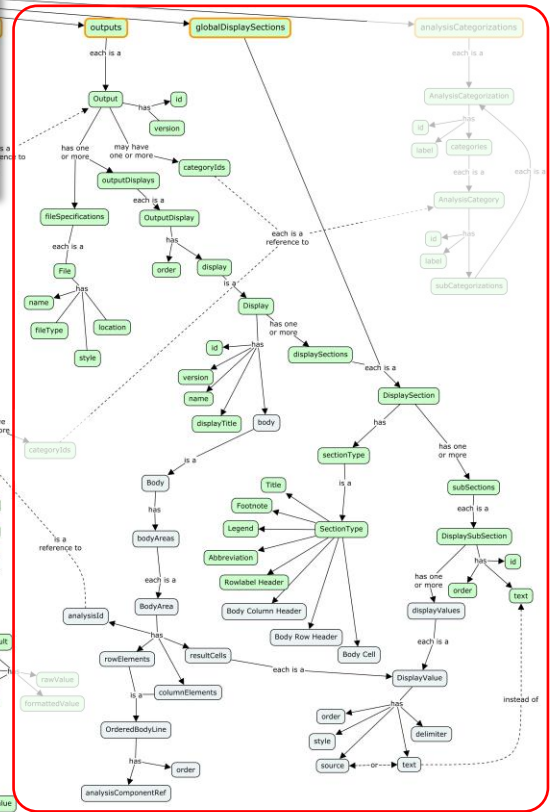
Table 14.1.1  
Summary of Demographics  
Safety Population

	Placebo (N=XX)	Xang Low (N=XX)
<b>Characteristics</b>		
Age (years)		
n	XXX	XXX
Mean (SD)	XX.X (XX.XXX)	XX.X (XX.XXX)
Median	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX
Age Group, n (%)		
< 65 years	XX (XX.X)	XX (XX.X)
≥ 65 years	XX (XX.X)	XX (XX.X)
Gender, n (%)		
Male	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)
Ethnicity, n (%)		
Hispanic or Latino	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	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

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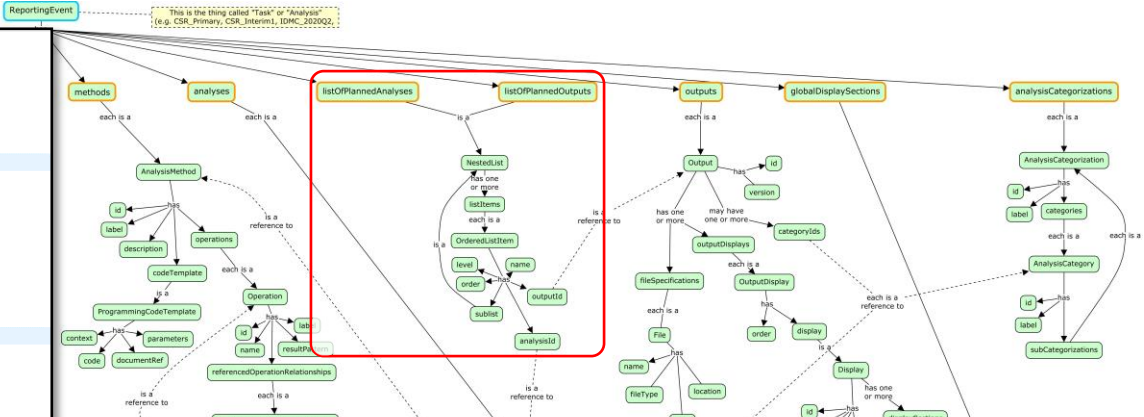


# List of Planned Analyses/Outputs

```

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        "listItems": [ ... ]
      }
    },
    {
      "name": "Overall Summary of Treatment-Emergent Adverse Events",
      "level": 1,
      "order": 2,
      "sublist": {
        "listItems": [ ... ]
      }
    },
    {
      "name": "Summary of TEAE by System Organ Class and Preferred Term",
      "level": 1,
      "order": 3,
      "sublist": {
        "listItems": [
          {
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            "level": 2,
            "order": 1,
            "analysisId": "An07.09_Soc_ByTrt"
          },
          {
            "name": "Summary of Subjects by Treatment, System Organ Class and Preferred Term ",
            "level": 2,
            "order": 2,
            "analysisId": "An07.10_SocPt_ByTrt"
          }
        ]
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    }
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  "outputId": "Out14.1.1"
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{
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  "order": 3,
  "sublist": {
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      {
        "name": "Summary of Subjects by Treatment and System Organ Class ",
        "level": 2,
        "order": 1,
        "analysisId": "An07.09_Soc_ByTrt"
      },
      {
        "name": "Summary of Subjects by Treatment, System Organ Class and Preferred Term ",
        "level": 2,
        "order": 2,
        "analysisId": "An07.10_SocPt_ByTrt"
      }
    ]
  }
},
{
  "name": "Summary of TEAE by System Organ Class and Preferred Term",
  "level": 1,
  "order": 3,
  "sublist": {
    "listItems": [
      {
        "name": "Summary of Subjects by Treatment and System Organ Class ",
        "level": 2,
        "order": 1,
        "analysisId": "An07.09_Soc_ByTrt"
      },
      {
        "name": "Summary of Subjects by Treatment, System Organ Class and Preferred Term ",
        "level": 2,
        "order": 2,
        "analysisId": "An07.10_SocPt_ByTrt"
      }
    ]
  }
},
  ],
  "outputId": "Out14.3.2.1"
},
},
}
    
```

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	
3	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

# Analysis Results Standard Repo on GitHub

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

The screenshot shows the GitHub repository page for 'cdisc-org/analysis-results-standard'. The repository is public and has 65 commits, 105 issues, and 26 stars. The file list includes folders like 'model', 'project', and 'utilities/python', and files like 'README.md', 'LICENSE', and 'CONTRIBUTING.md'. The 'About' section states that this repository will be where all the results for the Analysis Results Standard will be delivered. The 'Releases' section shows 'ARS Phase 1, Sprint 10' as the latest release. The 'Packages' section indicates no packages are published. The 'Contributors' section lists ASL-rmarshall, bhavinbusa, and drewcdisc.

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

**Workfiles:** CMAP, examples

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

**Utilities:** Example programs



# Analysis Results Standard Model Documentation

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

The screenshot shows the main page of the Analysis Results Standard (ARS) documentation. The page title is "Analysis Results Standard (ARS)". A navigation sidebar on the left lists "Analysis Results Standard (ARS)", "Classes", "Slots", "Enumerations", "Types", and "Subsets". The main content area features the title "Analysis Results Standard (ARS)" followed by a draft notice: "DRAFT Logical model to support both the prospective specification of analyses and the fully contextualized representation of the results of the analyses." Below this, the URI is listed as "https://www.cdisc.org/ars/1-0" with the name "ars\_idm". A "Classes" section follows, listing several classes with their descriptions:

Class	Description
<a href="#">Analysis</a>	An analysis that is designed to meet a requirement of the reporting event
<a href="#">AnalysisCategorization</a>	A set of related implementer-defined categories that can be used to categoriz...
<a href="#">AnalysisCategory</a>	An implementer-defined category of analyses/outputs, which may include one or...
<a href="#">AnalysisGroup</a>	A subdivision of the subject population based on a defined factor (e
<a href="#">AnalysisMethod</a>	A set of one or more statistical operations
<a href="#">AnalysisOutputProgrammingCode</a>	Programming statements and/or a reference to the program used to perform a sp...

The screenshot shows the detailed documentation for the "Class: ReportingEvent". It includes a class hierarchy diagram, inheritance information, and a table of slots. The class is defined as "A set of analyses and outputs created to meet a specific reporting requirement, such as a CSR or clinical analysis" with the URI "ars:ReportingEvent".

**Inheritance**

- ReportingEvent
- ReportingEvent

**Slots**

Name	Cardinality and Range	Description	Inheritance
<a href="#">slotOfAnalysis</a>	1..1 NonEmptySet	A structured list of the analyses defined for the reporting event.	class
<a href="#">slotOfOutput</a>	0..1 NonEmptySet	An optional structured list of the outputs defined for the reporting event.	class
<a href="#">analysis</a>	0..* AnalysisSet	The analyses sets (subject population) defined for the reporting event.	class
<a href="#">analysisGrouping</a>	0..* SubjectGroupingFactor	Characteristics used to subdivide the subject population in.	class
<a href="#">category</a>	0..* CategorySet		class
<a href="#">dataGrouping</a>	0..* SubjectGroupingFactor	Characteristics used to subdivide data records in the analysis dataset in.	class
<a href="#">displayGrouping</a>	0..* DisplayDivision		class
<a href="#">analysisCategorization</a>	0..* AnalysisCategorization		class
<a href="#">analysis</a>	0..* Analysis	The analyses defined for the reporting event.	class
<a href="#">method</a>	0..* AnalysisMethod	The defined methods used to analyze any analysis results.	class
<a href="#">input</a>	0..1 Object		class
<a href="#">referenceToSource</a>	0..1 ReferenceToSource		class
<a href="#">terminologyExtension</a>	0..* TerminologyExtension	Any sponsor defined extensions to standard terminology.	class
<a href="#">name</a>	1..1 String		NamedObject

**Identifier and Mapping Information**

**Schema Source**

- From schema: <https://cdisc.org/ars/1-0>

**Mappings**

Mapping Type	Mapped Slot
uri	ars:ReportingEvent
uri	ars:ReportingEvent

**LinkML Source**

**Direct**

- Class

**Induced**

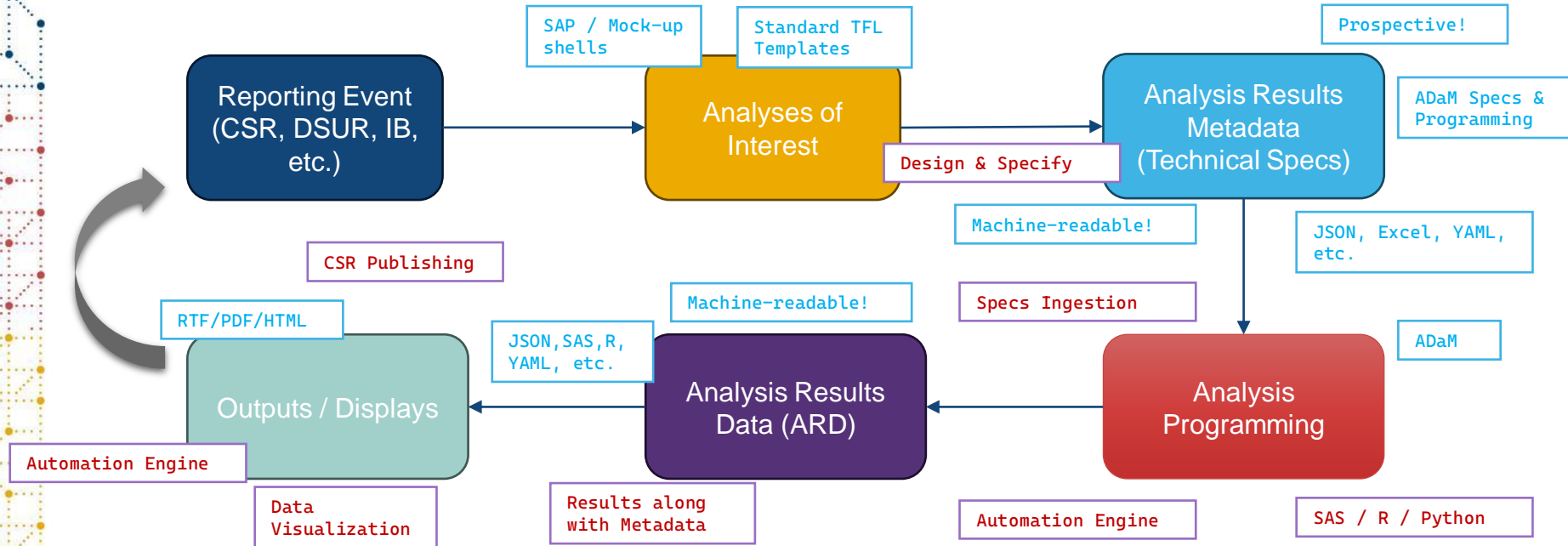
- Class





**ARS model will drive automation and  
open-source & enterprise tool development**

# 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 December 11<sup>th</sup>, 2023
- ✓ US Interchange Workshop: October 2023
- **Anticipated Final Release: January 2023**



# Contact Details

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# References

1. [All You Need to Know about the New CDISC Analysis Result Standards!](#), PharmaSUG 2023: Paper # MM327, Bhavin Busa, Richard Marshall, Bess LeRoy
2. CDISC Analysis Results Standard GitHub, 2023: <https://github.com/cdisc-org/analysis-results-standard>
3. CDISC Analysis Results Standard Model Documentation, 2023: <https://cdisc-org.github.io/analysis-results-standard/>



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## 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

