Hands-on Workshop: ARS and eTFL Portal

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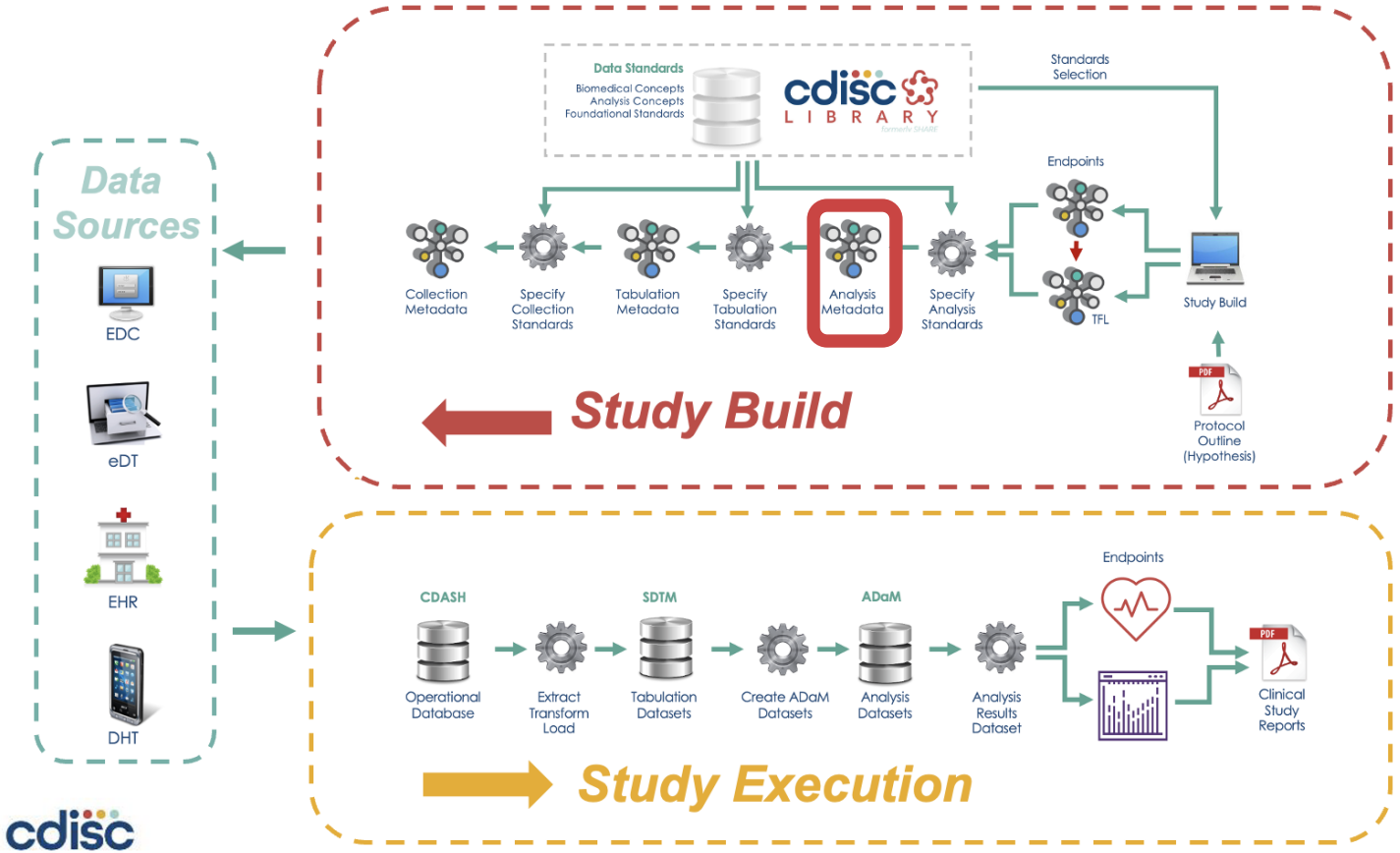
Agenda

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

Standardizing Analysis Metadata



CDISC 360

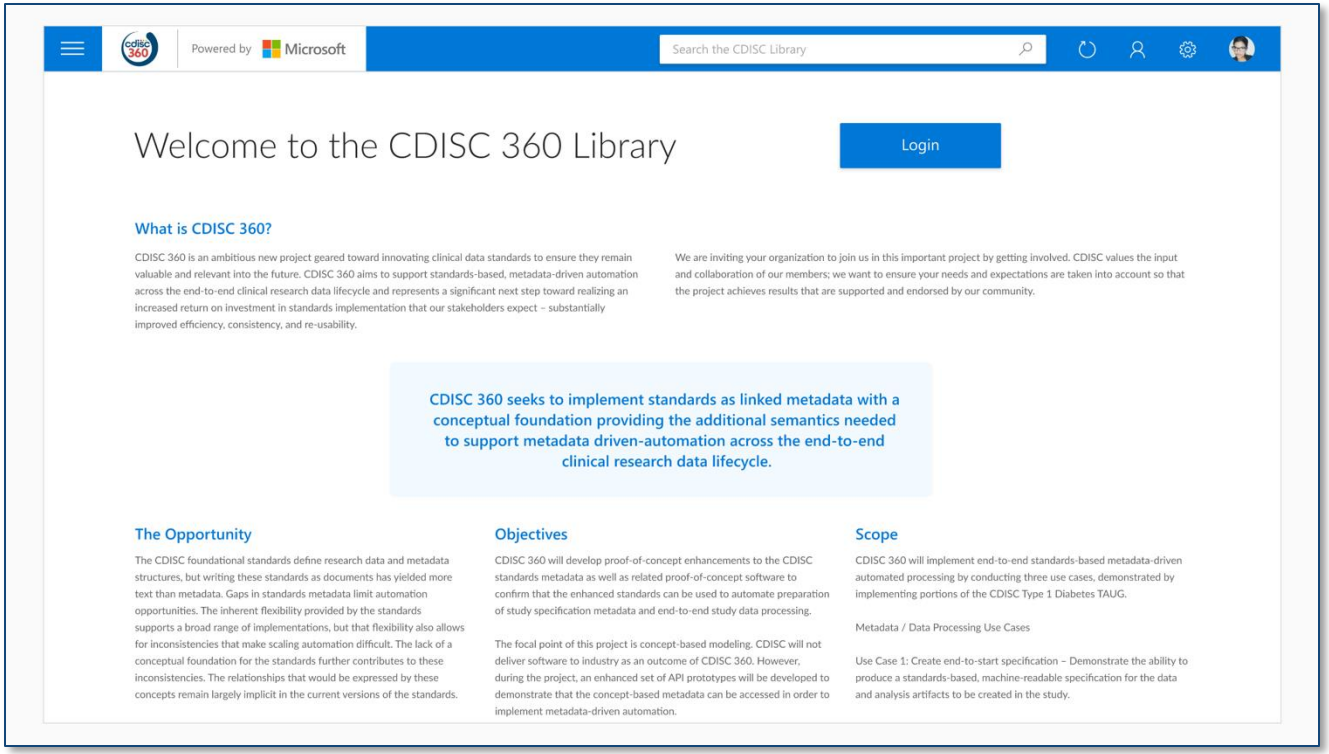
- CDISC 360 was a proof of concept that sought to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata-driven automation across the end- to-end clinical research data lifecycle.

- This will enable software developers to develop new tools (proprietary and open source) that consume this novel metadata to ease standards' implementations, while increasing data processing efficiencies.

- Reduce unnecessary variation and lower the barrier to adoption.

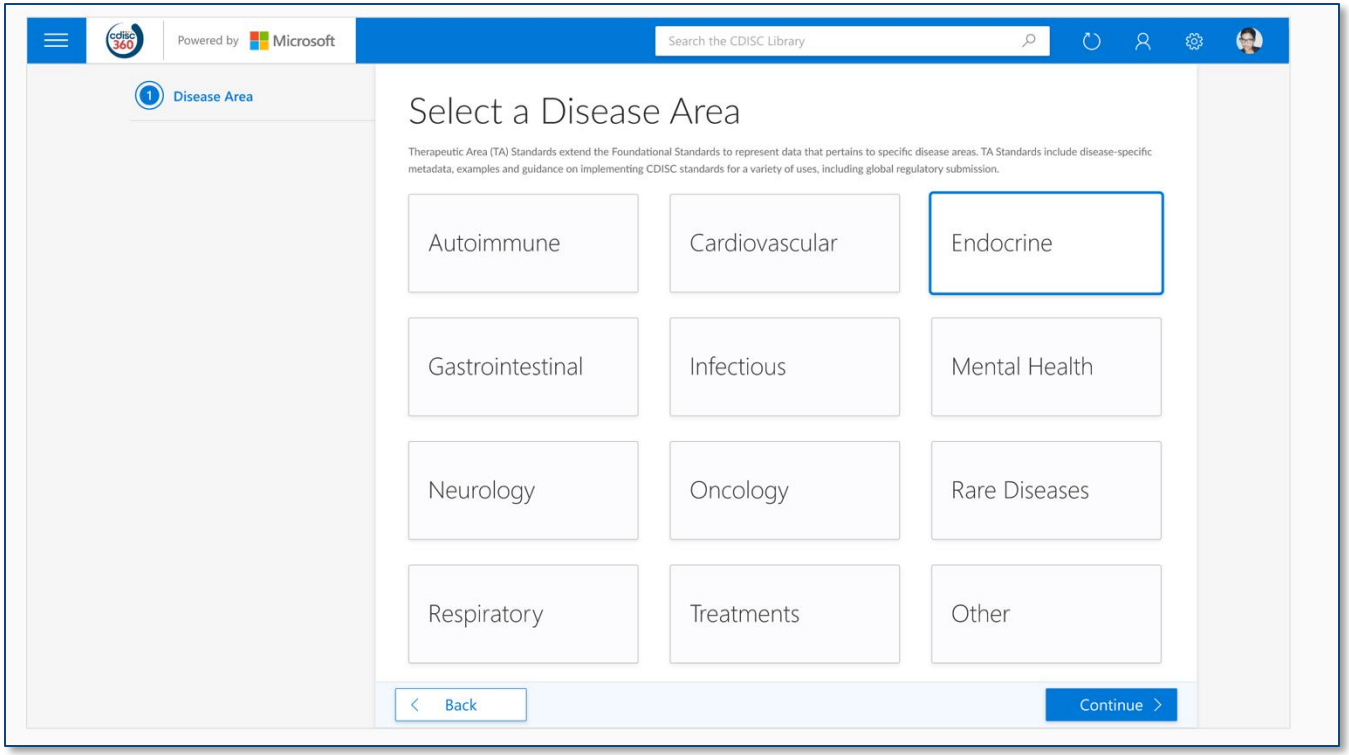
White Paper: https://www.cdisc.org/sites/default/files/2021-06/CDISC_360_Project_White_Paper.pdf

CDISC 360: The Art of the Possible

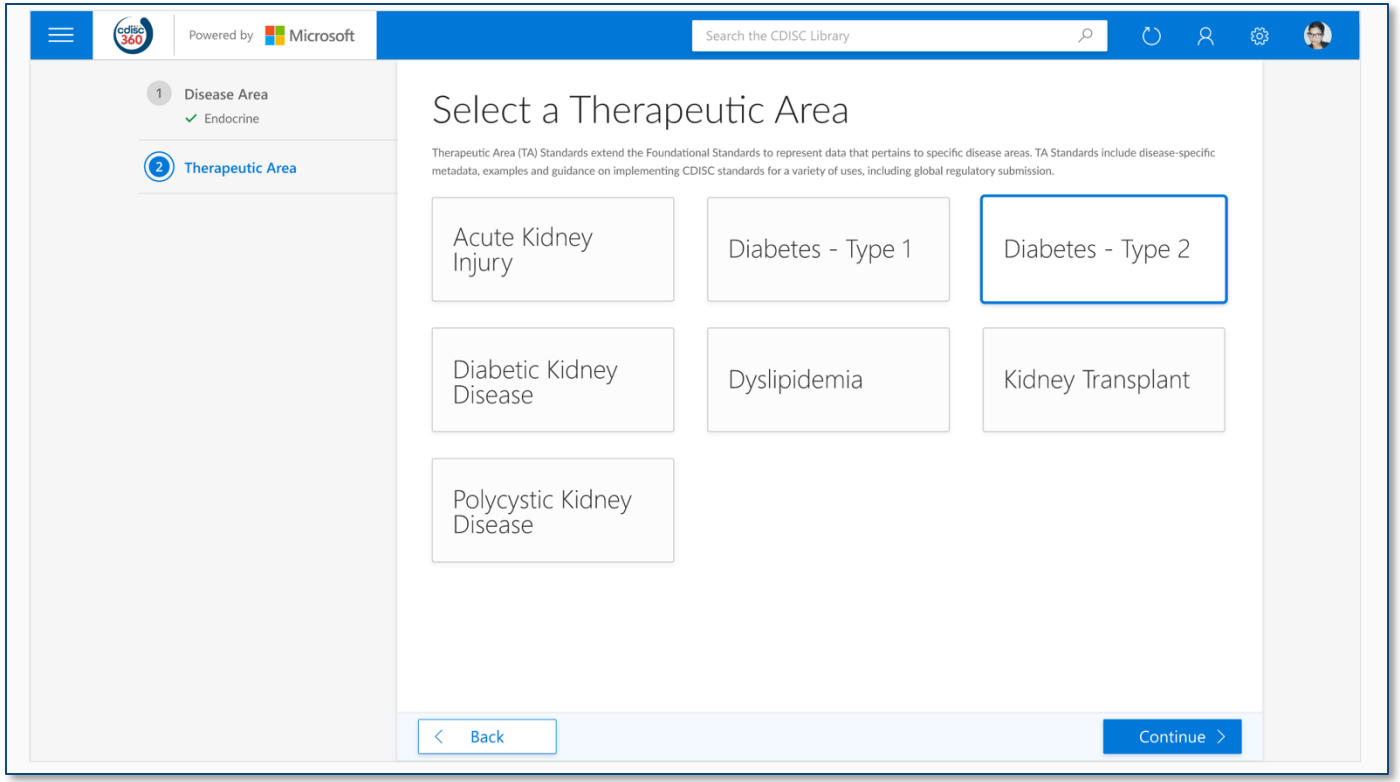


Reference: '*CDISC 360 - The Journey so Far and the Road Ahead*', *Peter Van Reusel, 28th April 2020*

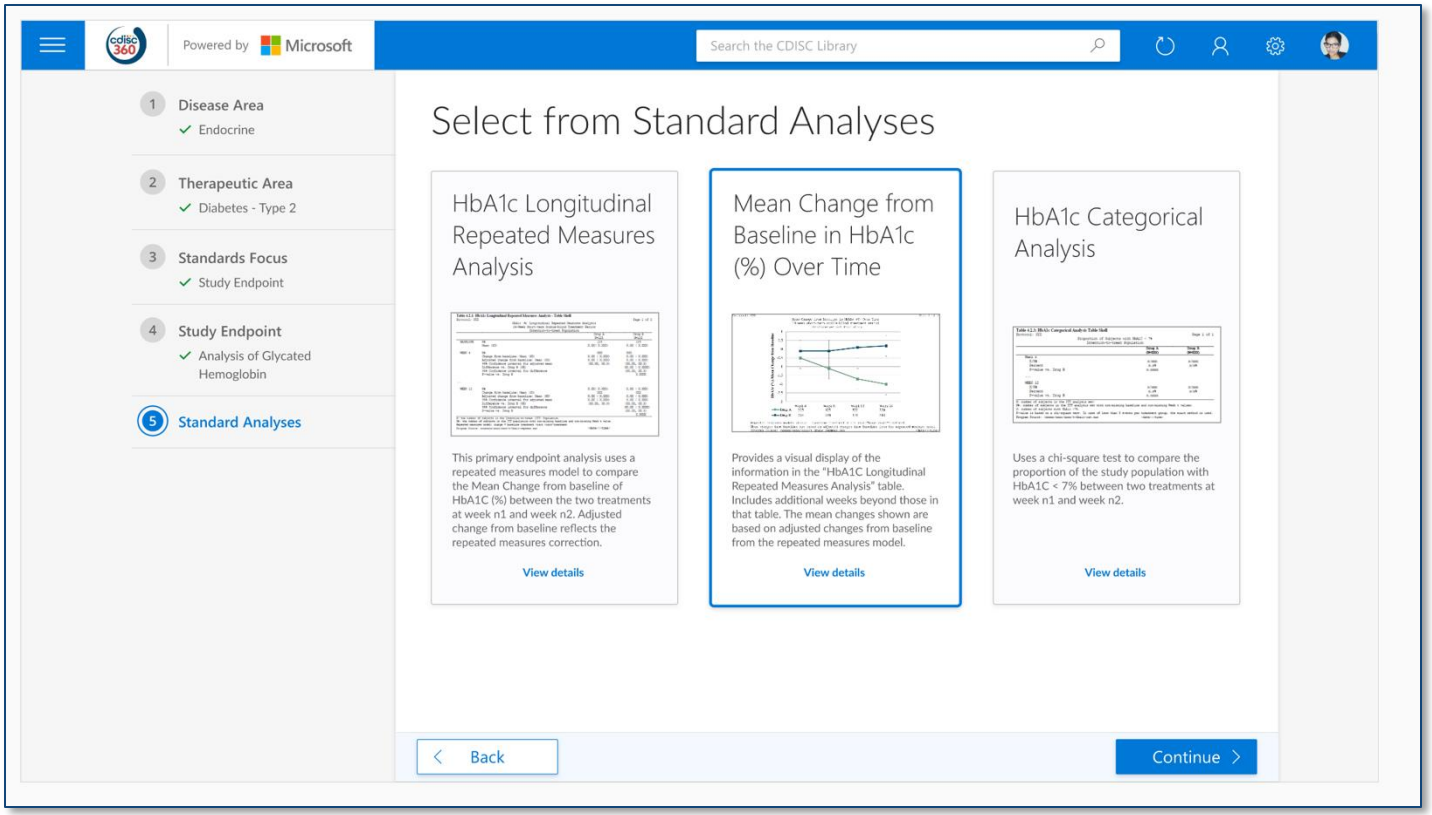
CDISC 360: The Art of the Possible



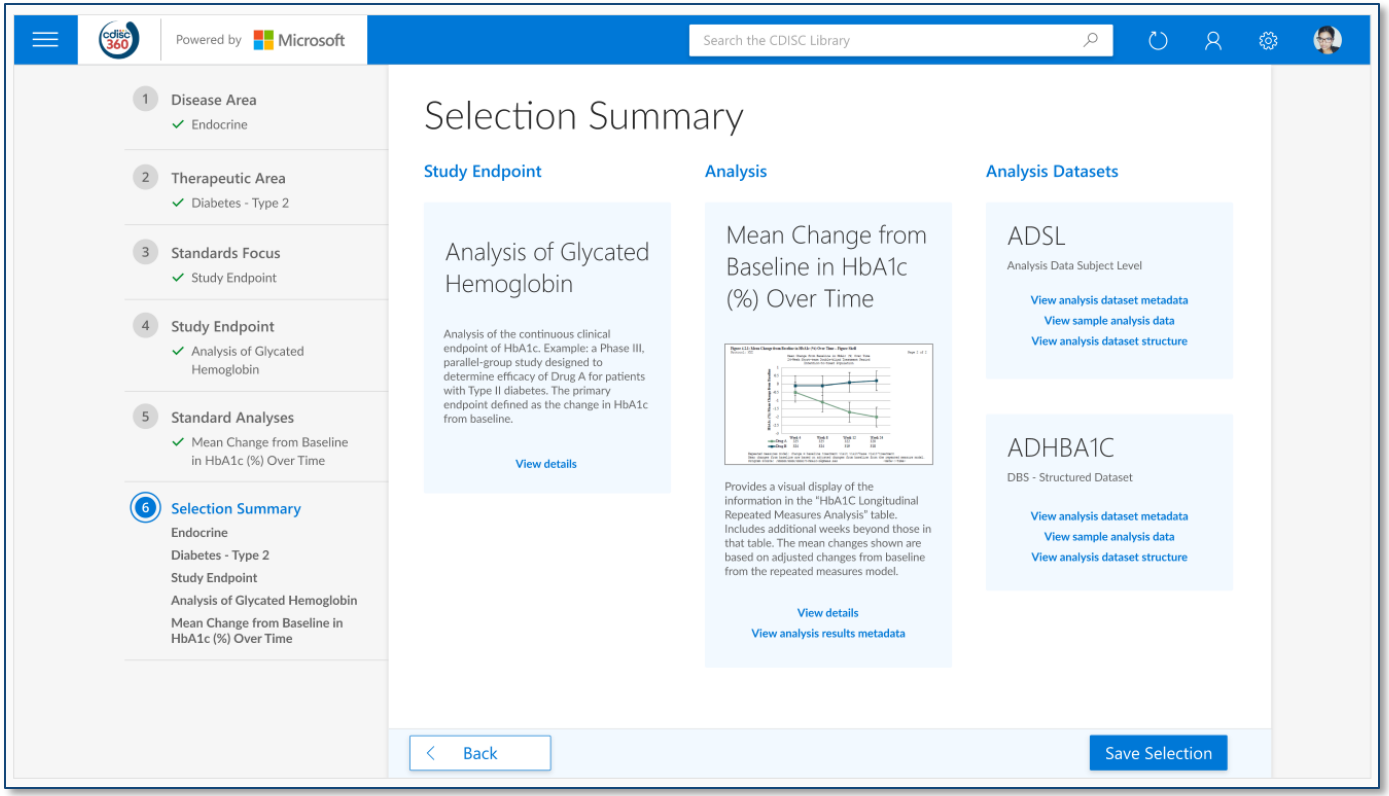
CDISC 360: The Art of the Possible

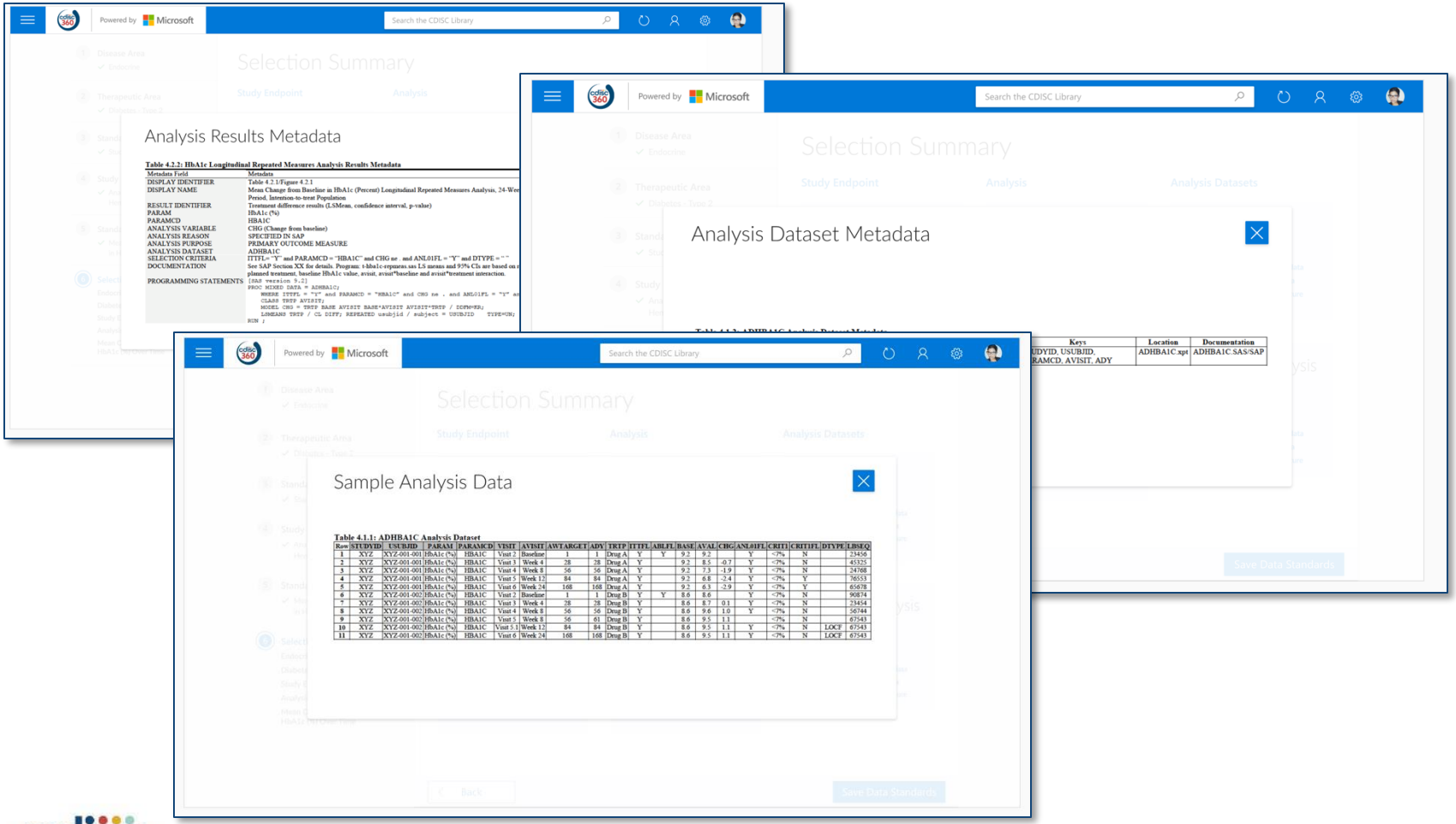


CDISC 360: The Art of the Possible

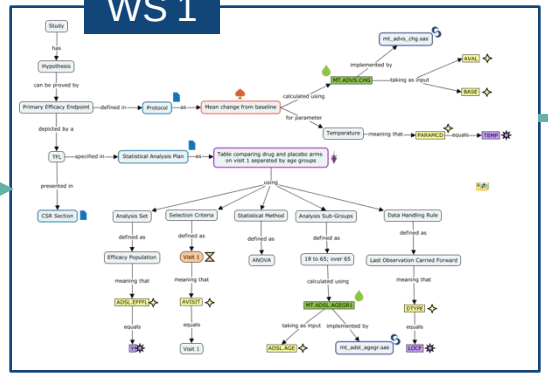


CDISC 360: The Art of the Possible




Powered by Microsoft
Search the CDISC Library
Selection Summary
Analysis Results Metadata
Table 4.2.2: HbA1c Longitudinal Repeated Measures Analysis Results Metadata
Metadata Field
Metadata
DISPLAY IDENTIFIER
Table 4.2.1/Figure 4.2.1
DISPLAY NAME
Mean Change from Baseline in HbA1c (Percent) Longitudinal Repeated Measures Analysis, 24-Wee
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
SELECTION CRITERIA
ITTFL= "Y" and PARAMCD = "HBA1C" and CHG ne . and ANL01FL = "Y" and DTYPE = " "
DOCUMENTATION
See SAP Section XX for details. Program: t-hba1c-repmeas.sas LS means and 95% CIs are based on r
planned treatment, baseline HbA1c value, avisit, avisit*baseline and avisit*treatment interaction.
PROGRAMMING STATEMENTS
[SAS version 9.2]
PROC MIXED DATA = ADHBA1C;
WHERE ITTFL = "Y" and PARAMCD = "HBA1C" and CHG ne . and ANL01FL = "Y" an
CLASS TRTP AVISIT;
MODEL CHG = TRTP BASE AVISIT BASE*AVISIT AVISIT*TRTP / DDFM=KR;
LSMEANS TRTP / CL DIFF; REPEATED usubjid / subject = USUBJID TYPE=UN;
RUN ;
Analysis Dataset Metadata
Keys
Location
Documentation
UDYID, USUBJID,
RAMCD, AVISIT, ADY
ADHBA1C.xpt
ADHBA1C.SAS/SAP
Sample Analysis Data
Table 4.1.1: ADHBA1C Analysis Dataset
Row STUDYID USUBJID PARAM PARAMCD VISIT AVISIT AWTARGET ADY TRTP ITTFL ABLFL BASE AVAL CHG ANL01FL CRIT1 CRIT1FL DTYPE LBSEQ
1 XYZ XYZ-001-001 HbA1c (%) HBA1C Visit 2 Baseline 1 1 Drug A Y Y 9.2 9.2 Y <7% N 23456
2 XYZ XYZ-001-001 HbA1c (%) HBA1C Visit 3 Week 4 28 28 Drug A Y 9.2 8.5 -0.7 Y <7% N 45325
3 XYZ XYZ-001-001 HbA1c (%) HBA1C Visit 4 Week 8 56 56 Drug A Y 9.2 7.3 -1.9 Y <7% N 24708
4 XYZ XYZ-001-001 HbA1c (%) HBA1C Visit 5 Week 12 84 84 Drug A Y 9.2 6.8 -2.4 Y <7% Y 76553
5 XYZ XYZ-001-001 HbA1c (%) HBA1C Visit 6 Week 24 168 168 Drug A Y 9.2 6.3 -2.9 Y <7% Y 65678
6 XYZ XYZ-001-002 HbA1c (%) HBA1C Visit 2 Baseline 1 1 Drug B Y Y 8.6 8.6 Y <7% N 90874
7 XYZ XYZ-001-002 HbA1c (%) HBA1C Visit 3 Week 4 28 28 Drug B Y 8.6 8.7 0.1 Y <7% N 23454
8 XYZ XYZ-001-002 HbA1c (%) HBA1C Visit 4 Week 8 56 56 Drug B Y 8.6 9.6 1.0 Y <7% N 56744
9 XYZ XYZ-001-002 HbA1c (%) HBA1C Visit 5 Week 8 56 61 Drug B Y 8.6 9.5 1.1 <7% N 67543
10 XYZ XYZ-001-002 HbA1c (%) HBA1C Visit 5.1 Week 12 84 84 Drug B Y 8.6 9.5 1.1 Y <7% N LOCF 67543
11 XYZ XYZ-001-002 HbA1c (%) HBA1C Visit 6 Week 24 168 168 Drug B Y 8.6 9.5 1.1 Y <7% N LOCF 67543

WS 1



Create concepts in knowledge graphs

WS2

Transform concepts in machine readable form

Load into library

Biomedical Concepts
Analysis Concepts
Foundational Standards

cdisc LIBRARY
formerly SHARE

API

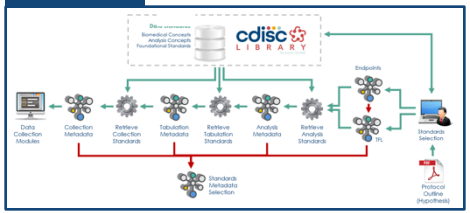
Extend API's

WS3

Add transformation semantics

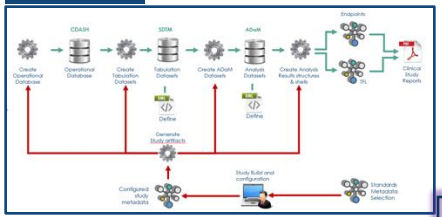
Use Case 1: Selecting standards concepts and linked metadata needed for a study
Use Case 2: Adding study design, concept configuration & generate artifacts
Use case 3: Automatic population of data into artifacts

WS 4



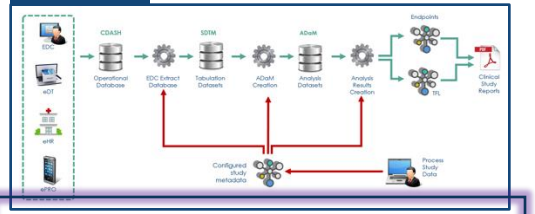
Identify and select standards specification (Use Case 1)

WS 5



Configure study specification and create artifacts (Use Case 2)

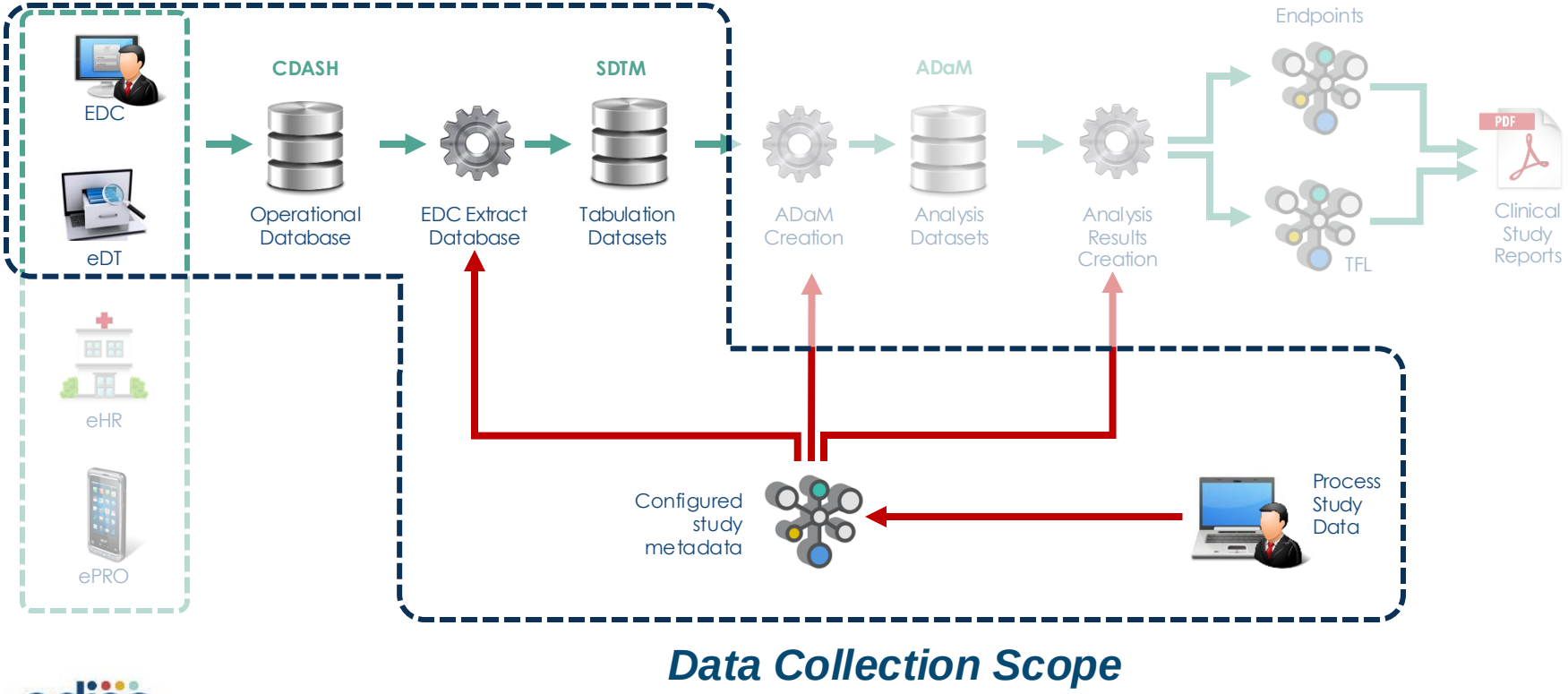
WS 6



Automatically process and transform data (Use Case 3)

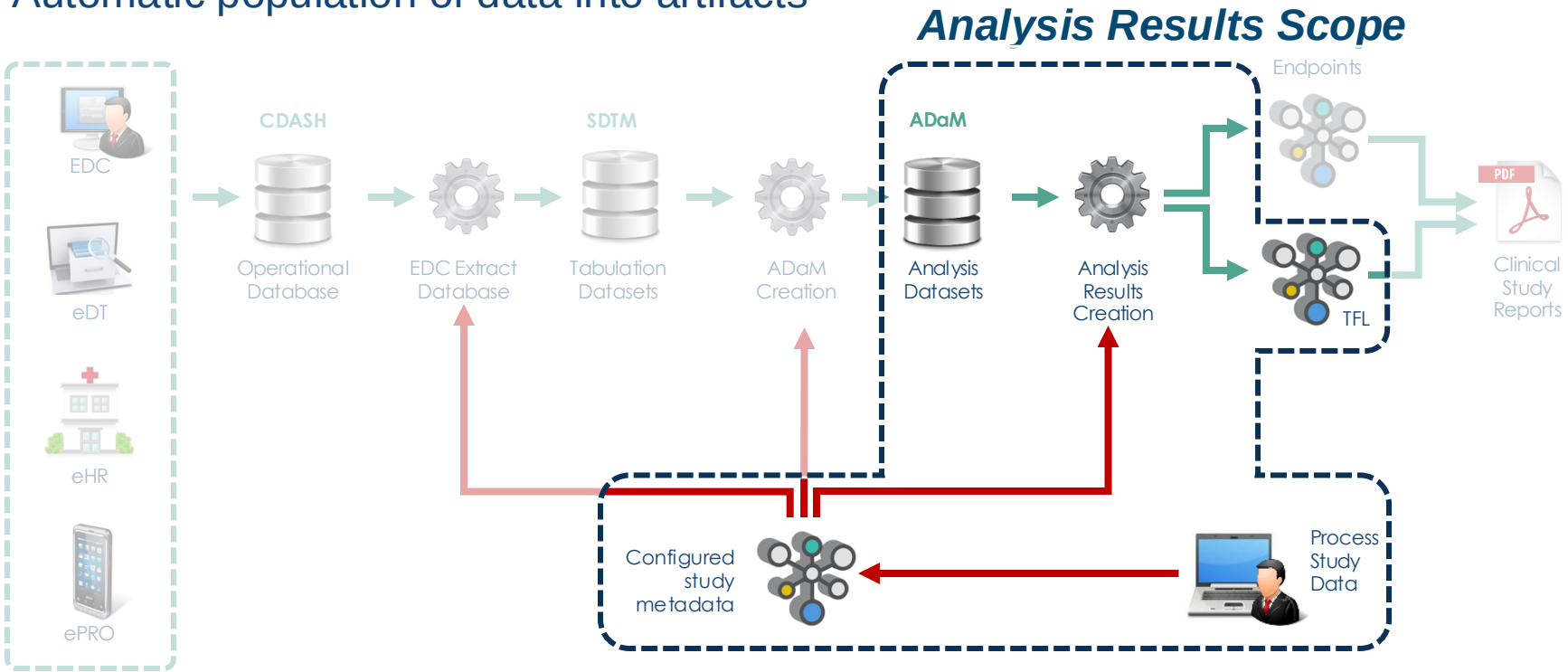
Use Case 3 : Execute

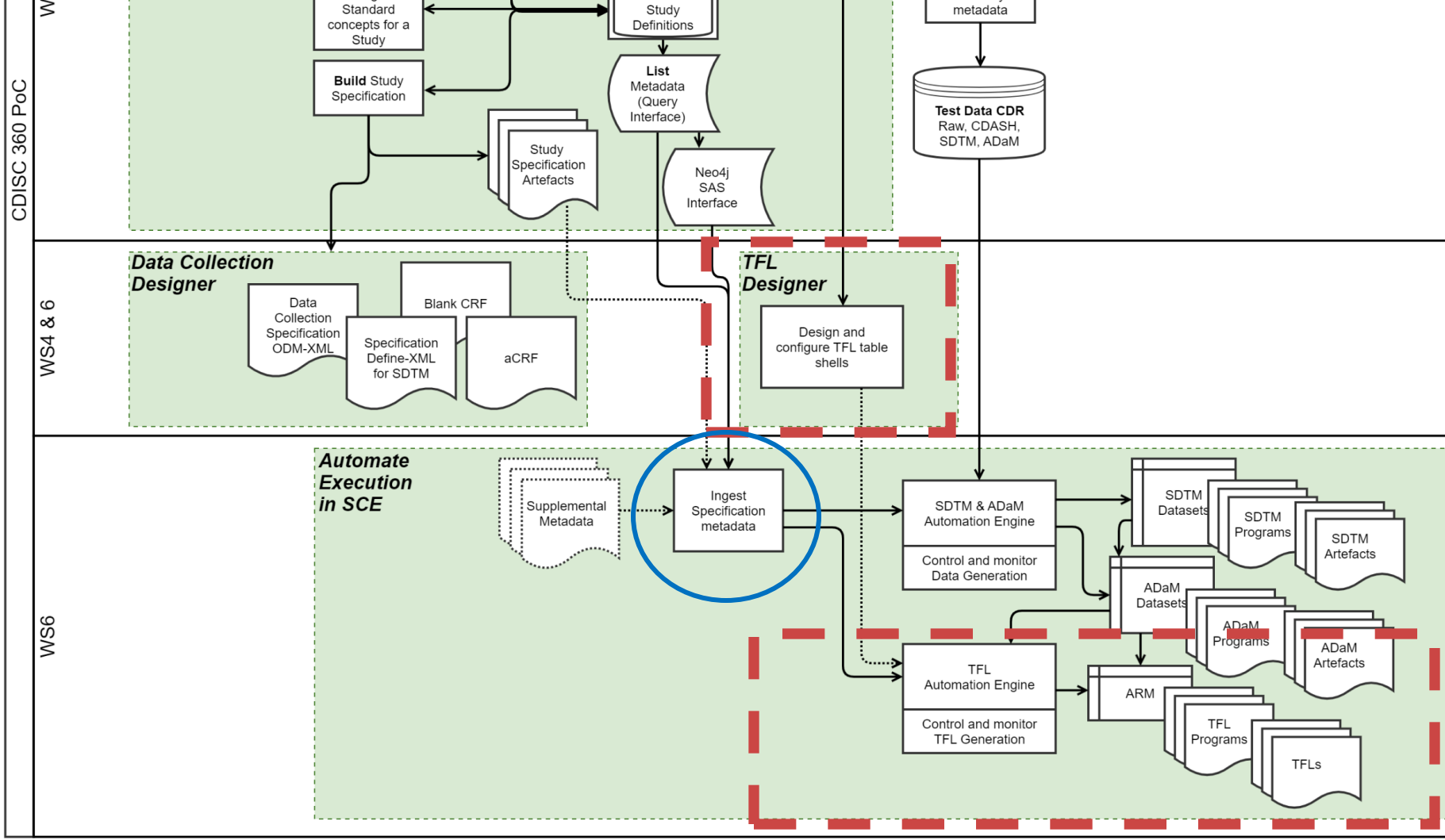
Automatic population of data into artifacts



Use Case 3 : Execute

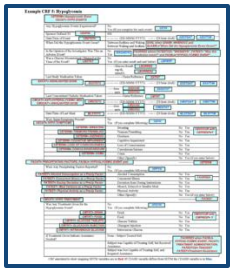
Automatic population of data into artifacts




CDISC 360 PoC
WS4 & 6
WS6
Standard concepts for a Study
Study Definitions
Build Study Specification
List Metadata (Query Interface)
Study Specification Artefacts
Neo4j SAS Interface
metadata
Test Data CDR Raw, CDASH, SDTM, ADaM
Data Collection Designer
Data Collection Specification ODM-XML
Blank CRF
Specification Define-XML for SDTM
aCRF
TFL Designer
Design and configure TFL table shells
Automate Execution in SCE
Supplemental Metadata
Ingest Specification metadata
SDTM & ADaM Automation Engine
Control and monitor Data Generation
SDTM Datasets
SDTM Programs
SDTM Artefacts
ADaM Datasets
ADaM Programs
ADaM Artefacts
TFL Automation Engine
Control and monitor TFL Generation
ARM
TFL Programs
TFLs

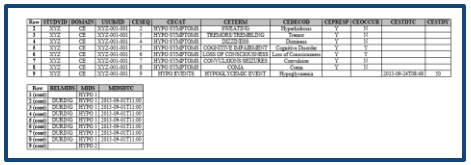
What did we learn from CDISC 360?

CDISC Foundational Standards



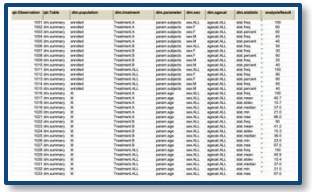
Data Collection

CDASH



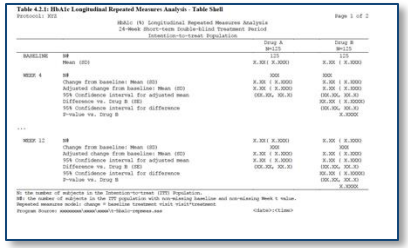
Data Aggregation

SDTM



Analysis

ADaM



Results

???

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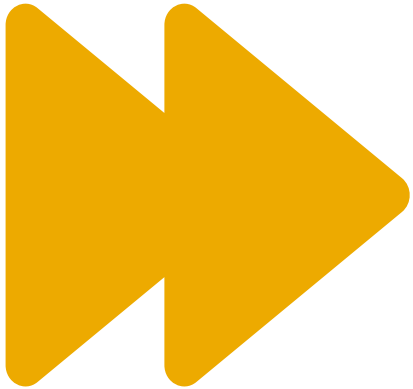
Fast Forward
Q1 2021 to Q1 2024



Analysis Results Key Objectives

Leverage analysis results metadata to drive the automation of results

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

CDISC Analysis Result Standards – Released April 19, 2024!

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Clear data. Clear impact

Analysis Results Standard (ARS) v1.0

cdisc ARS ANALYSIS RESULTS STANDARD

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

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

Features of ARS v1.0

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

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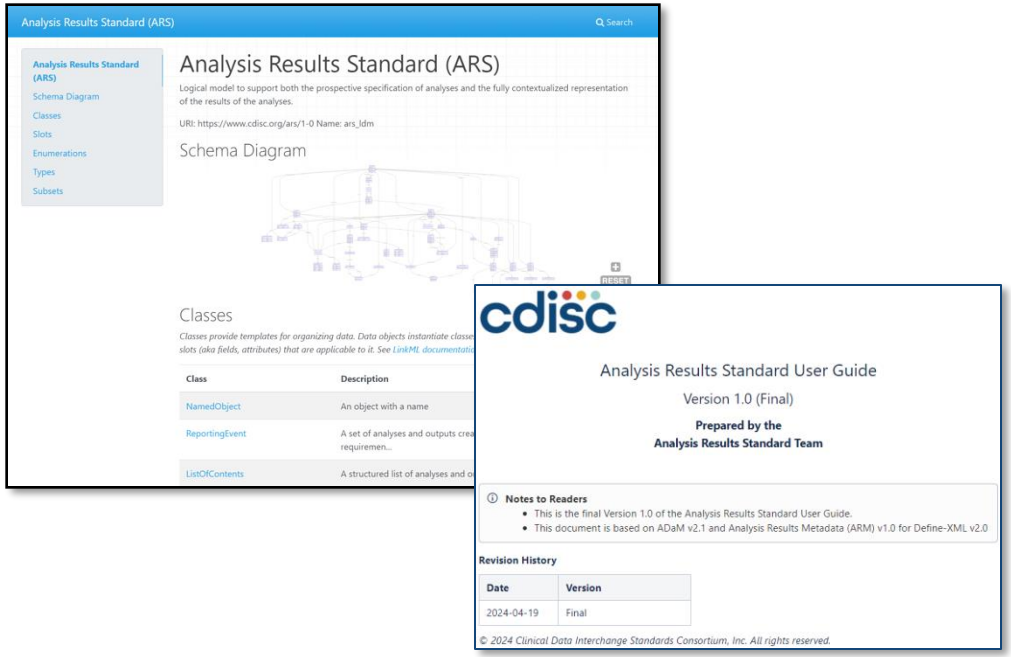
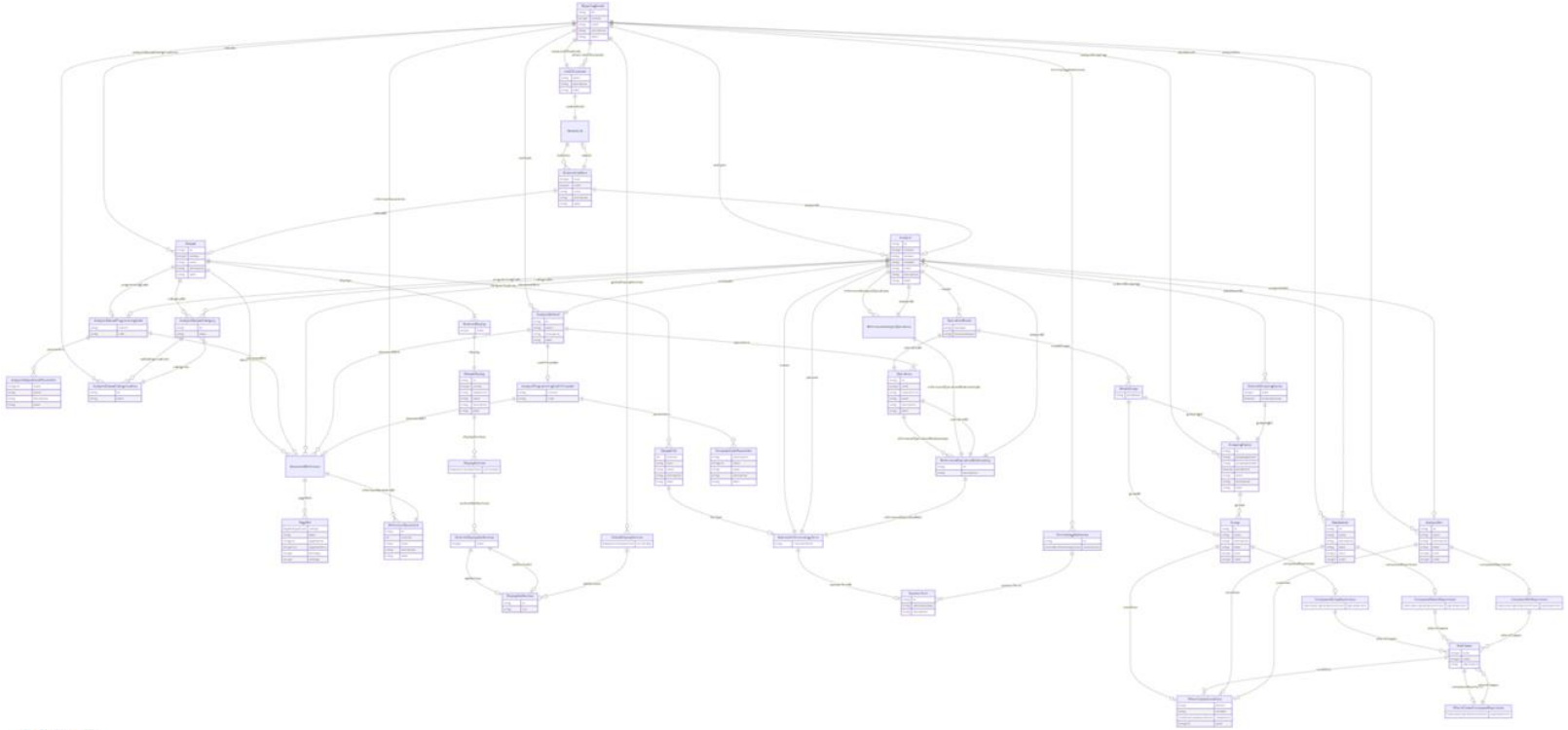
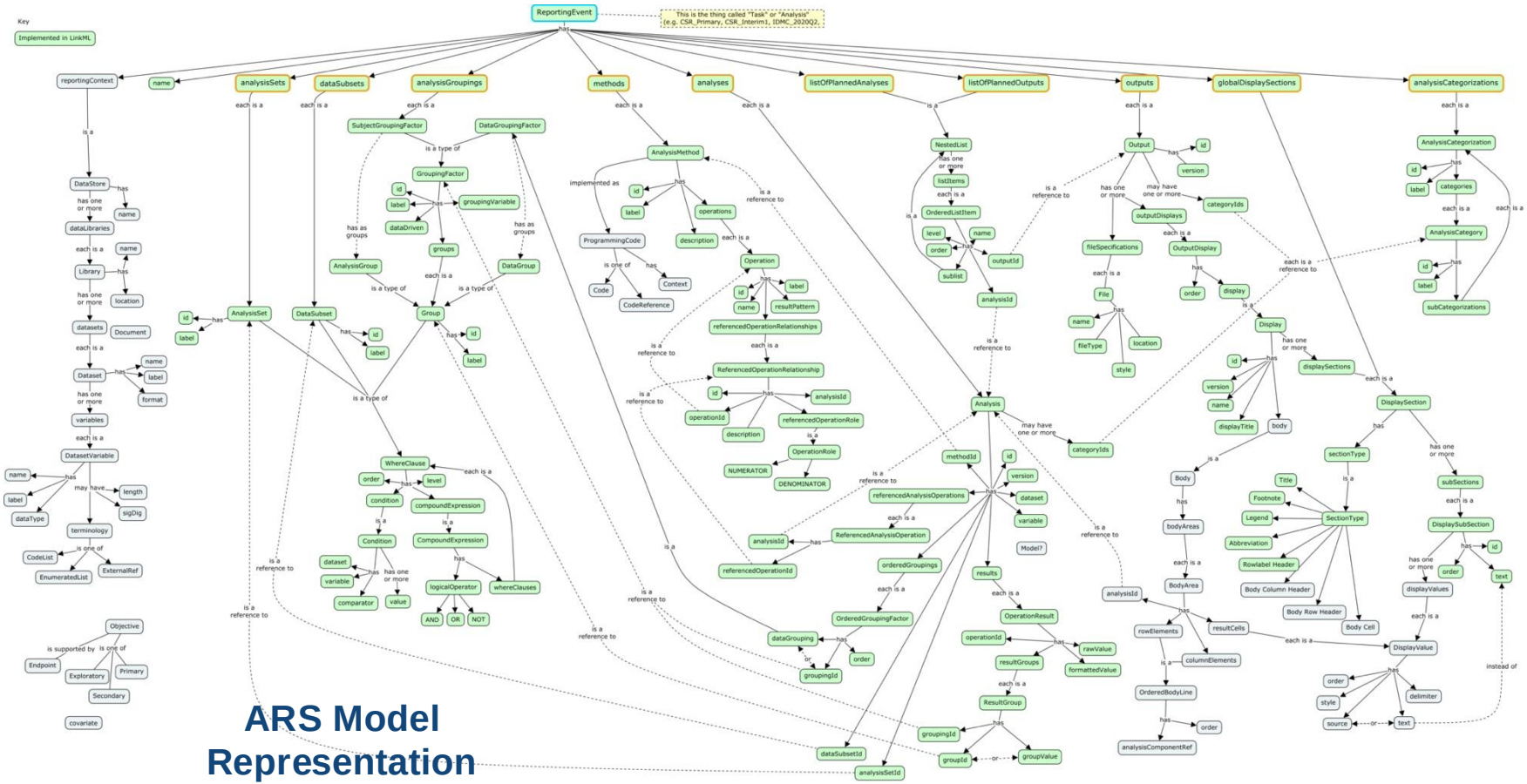
https://cdisc-org.github.io/analysis-results-standard/



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

ARS Logical Model Schema Diagram





ARS Model Representation using CMAP

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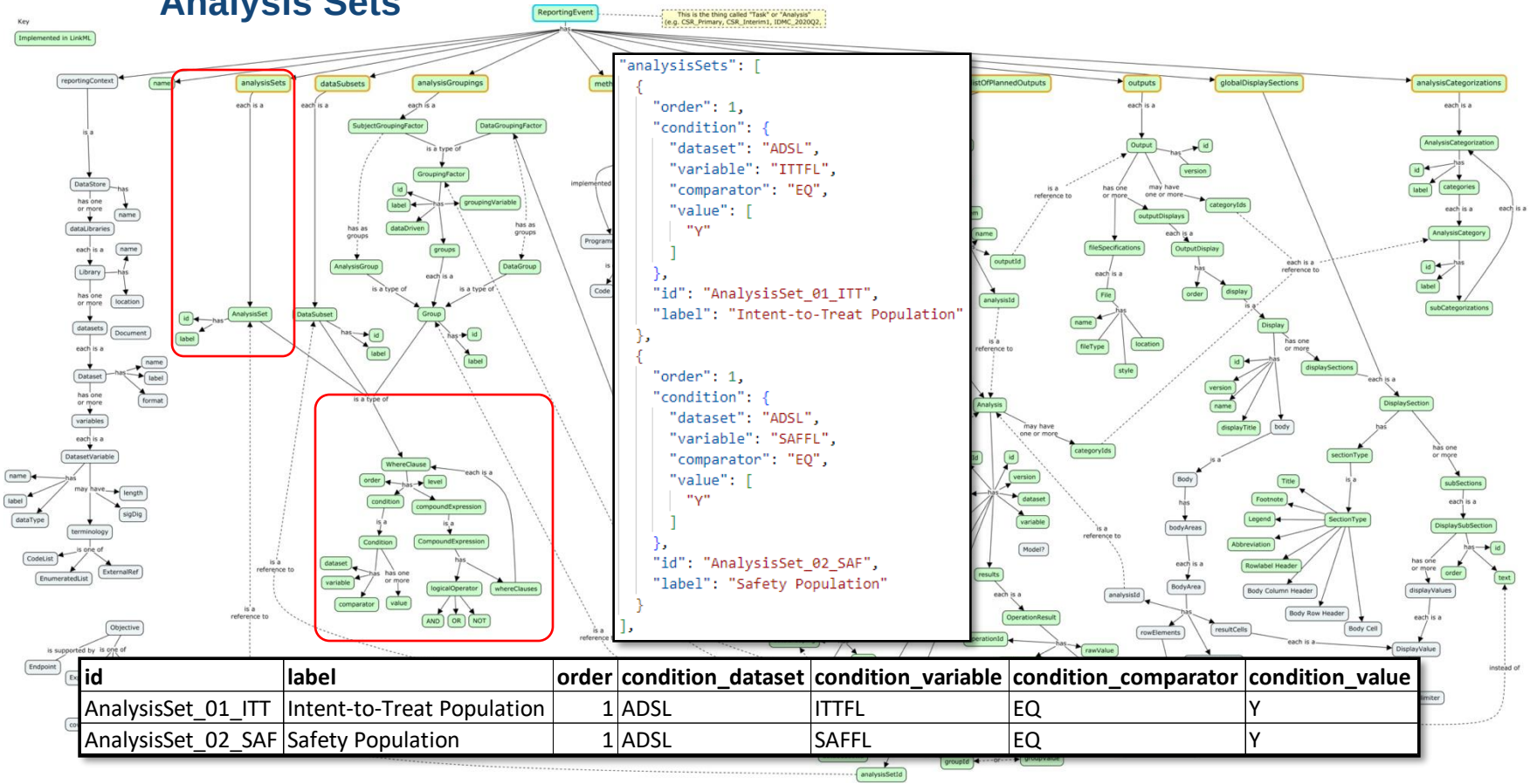
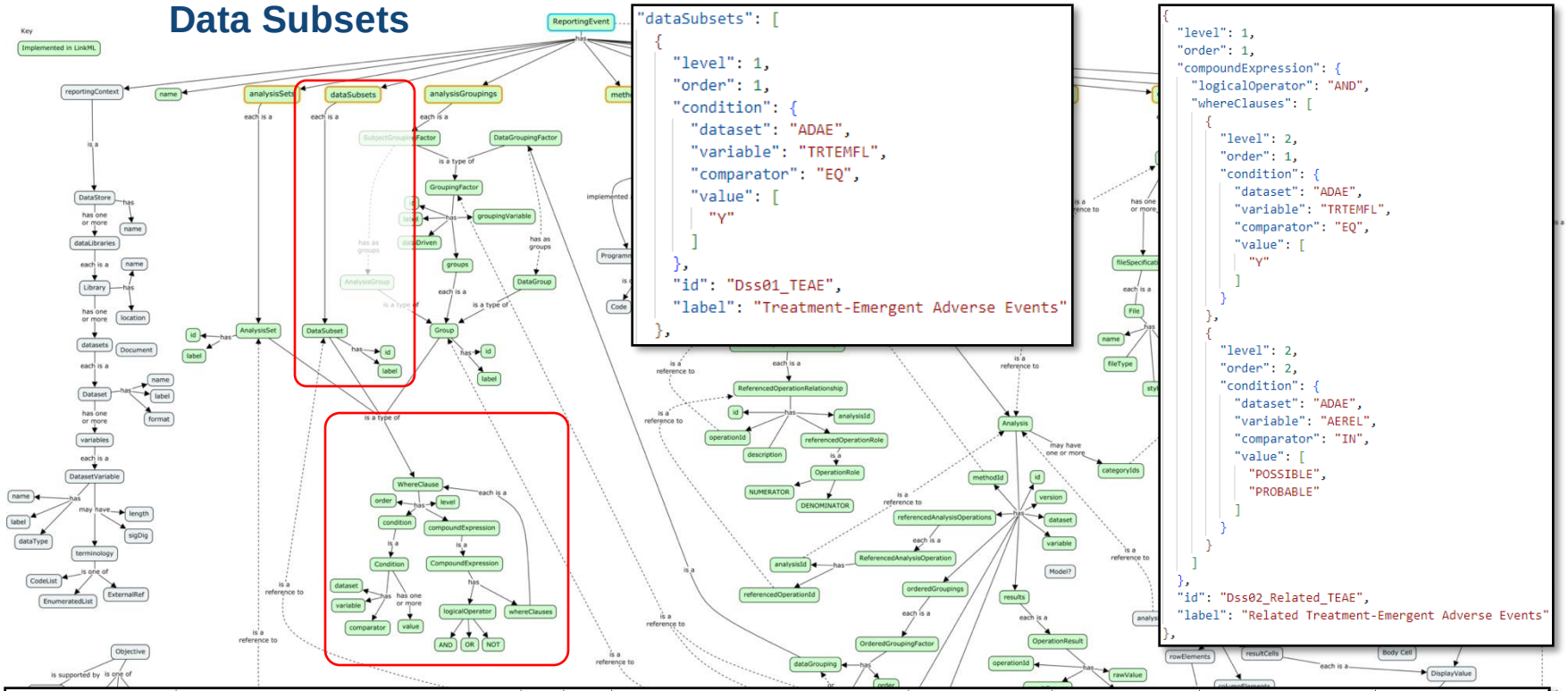
Analysis Sets



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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    "order": 1,
    "condition": {
      "dataset": "ADAE",
      "variable": "TRTEMFL",
      "comparator": "EQ",
      "value": [
        "Y"
      ]
    },
    "id": "Dss01_TEAE",
    "label": "Treatment-Emergent Adverse Events"
  },
```
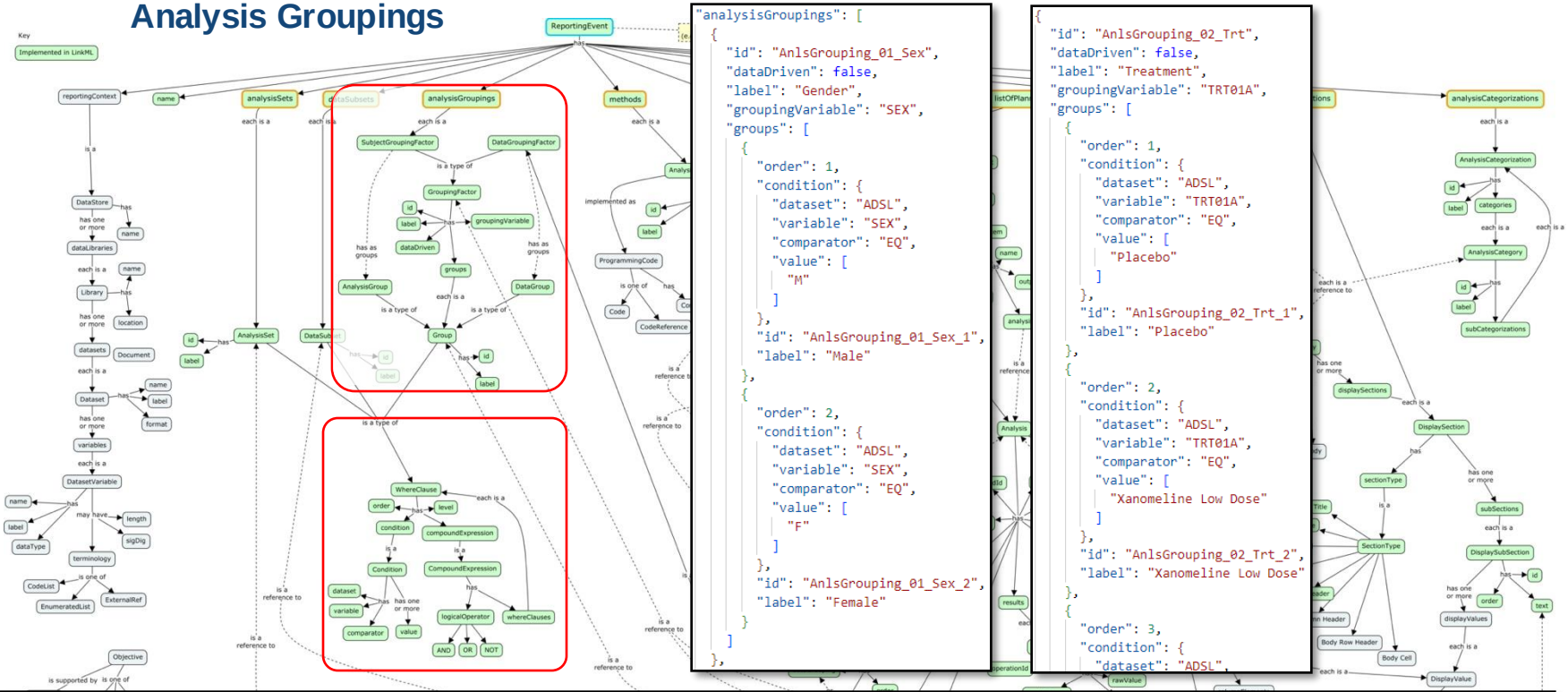

```
{
  "level": 1,
  "order": 1,
  "compoundExpression": {
    "logicalOperator": "AND",
    "whereClauses": [
      {
        "level": 2,
        "order": 1,
        "condition": {
          "dataset": "ADAE",
          "variable": "TRTEMFL",
          "comparator": "EQ",
          "value": [
    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

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

Analysis Groupings




```
"analysisGroupings": [
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    "dataDriven": false,
    "label": "Gender",
    "groupingVariable": "SEX",
    "groups": [
      {
        "order": 1,
        "condition": {
          "dataset": "ADSL",
          "variable": "SEX",
          "comparator": "EQ",
          "value": [
            "M"
          ]
        },
        "id": "AnlsGrouping_01_Sex_1",
        "label": "Male"
      },
      {
        "order": 2,
        "condition": {
          "dataset": "ADSL",
          "variable": "SEX",
          "comparator": "EQ",
          "value": [
            "F"
          ]
        },
        "id": "AnlsGrouping_01_Sex_2",
        "label": "Female"
      }
    ]
  },
```
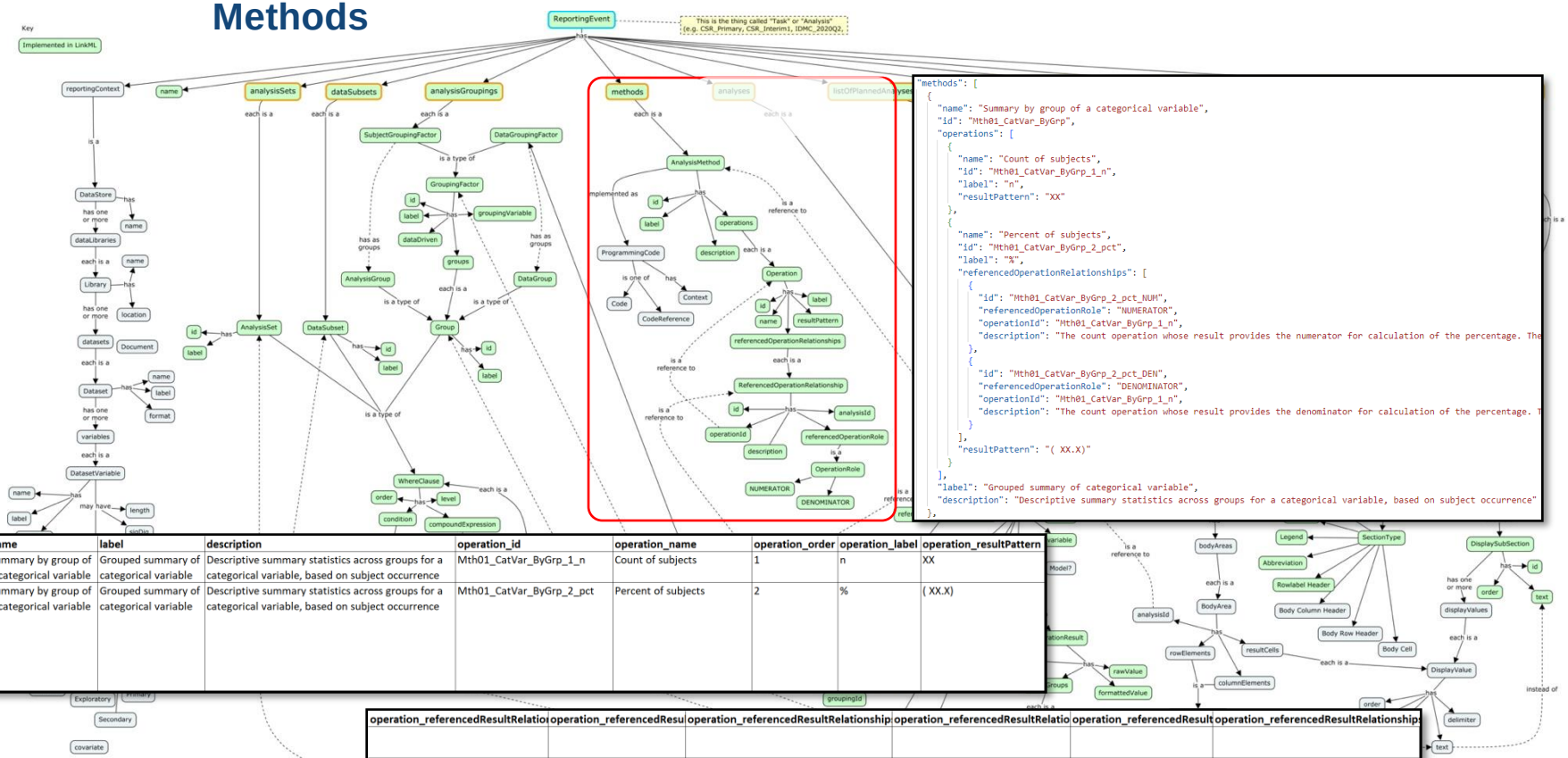

```
{
  "id": "AnlsGrouping_02_Trt",
  "dataDriven": false,
  "label": "Treatment",
  "groupingVariable": "TRT01A",
  "groups": [
    {
      "order": 1,
      "condition": {
        "dataset": "ADSL",
        "variable": "TRT01A",
        "comparator": "EQ",
        "value": [
          "Placebo"
        ]
      },
      "id": "AnlsGrouping_02_Trt_1",
      "label": "Placebo"
    },
    {
      "order": 2,
      "condition": {
        "dataset": "ADSL",
        "variable": "TRT01A",
        "comparator": "EQ",
        "value": [
          "Xanomeline Low Dose"
        ]
      },
      "id": "AnlsGrouping_02_Trt_2",
      "label": "Xanomeline Low Dose"
    },
    {
      "order": 3,
      "condition": {
        "dataset": "ADSL",
```


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




```
"methods": [
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    "name": "Summary by group of a categorical variable",
    "id": "Mth01_CatVar_ByGrp",
    "operations": [
      {
        "name": "Count of subjects",
        "id": "Mth01_CatVar_ByGrp_1_n",
        "label": "n",
        "resultPattern": "XX"
      },
      {
        "name": "Percent of subjects",
        "id": "Mth01_CatVar_ByGrp_2_pct",
        "label": "%",
        "referencedOperationRelationships": [
          {
            "id": "Mth01_CatVar_ByGrp_2_pct_NUM",
            "referencedOperationRole": "NUMERATOR",
            "operationId": "Mth01_CatVar_ByGrp_1_n",
            "description": "The count operation whose result provides the numerator for calculation of the percentage. The
          },
          {
            "id": "Mth01_CatVar_ByGrp_2_pct_DEN",
            "referencedOperationRole": "DENOMINATOR",
            "operationId": "Mth01_CatVar_ByGrp_1_n",
            "description": "The count operation whose result provides the denominator for calculation of the percentage. T
          }
        ],
        "resultPattern": "( XX.X)"
      }
    ],
    "label": "Grouped summary of categorical variable",
    "description": "Descriptive summary statistics across groups for a categorical variable, based on subject occurrence"
  },
```

name	label	description	operation_id	operation_name	operation_order	operation_label	operation_resultPattern
Summary by group of a categorical variable	Grouped summary of categorical variable	Descriptive summary statistics across groups for a categorical variable, based on subject occurrence	Mth01_CatVar_ByGrp_1_n	Count of subjects	1	n	XX
Summary by group of a categorical variable	Grouped summary of categorical variable	Descriptive summary statistics across groups for a categorical variable, based on subject occurrence	Mth01_CatVar_ByGrp_2_pct	Percent of subjects	2	%	(XX.X)

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

Analyses

id	versi	name	categoryIds	analysisSetId	groupingId1	groupingId2	groupingId3	dataSubsetId	data	variable	method_id
An03.02_AgeGrp_ByTrt	1	Summary of Subjects by Treatment and Age Group		AnalysisSet_02_SAF	AnlsGrouping_02_Trt	AnlsGrouping_03_AgeGp			ADSL	USUBJID	Mth01_CatVar_ByGrp
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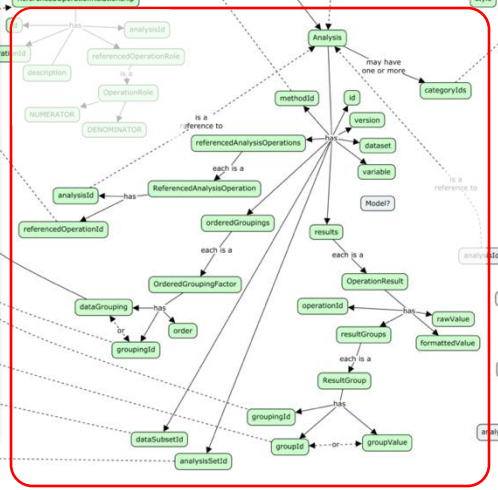

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Analysis Results

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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
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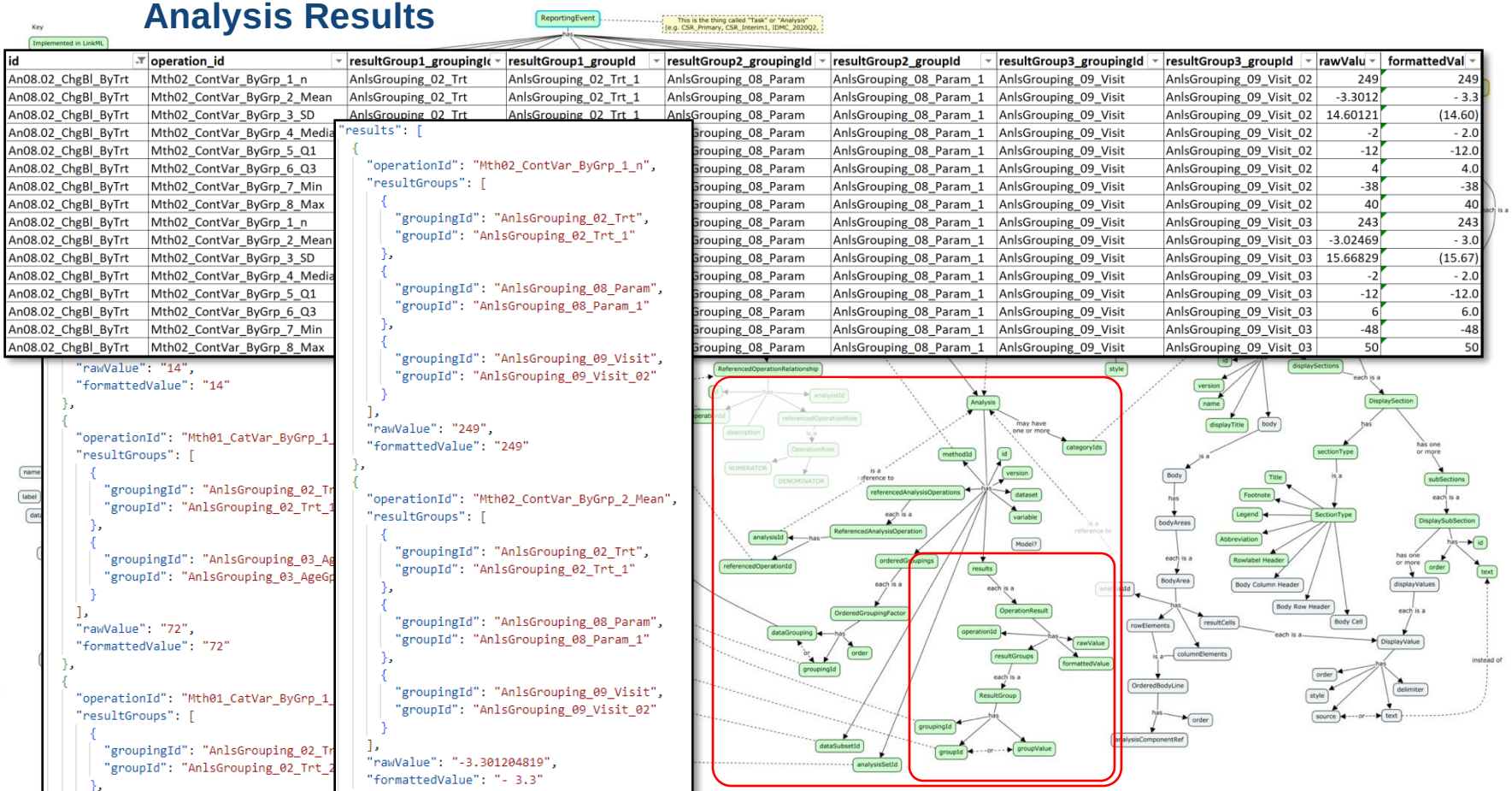

Concepts, Not Layout

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		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									
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			Mth01_CatVar_ByGrp	Operation	n	%	n	%	n	%
		AnlsGrouping_03_AgeGp								
		Age Group								
		< 65 years			14	(16.3)	8	(9.5)	11	(13.1)
		≥ 65 years			72	(83.7)	76	(90.5)	73	(86.9)

Analysis ID:	An03.2_AgeGrp_ByTrt					
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		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)

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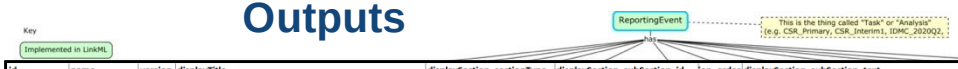
Outputs



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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
Disp14.1.1	Demog	1	Summary of Demographics	Footnote	Disp14.1.1_Fnote_2	2	Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM
Disp14.1.1	Demog	1	Summary of Demographics	Rowlabel Head			
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Disp14.3.1.1	AE_Summ	1	Overall Summary of Treatment-Emergent Adverse Events	Title			
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Table 14.1.1
Summary of Demographics
Safety Population

Characteristics	Placebo (N=XX)	Xanc Low (N
Age (years)		
n	XX	
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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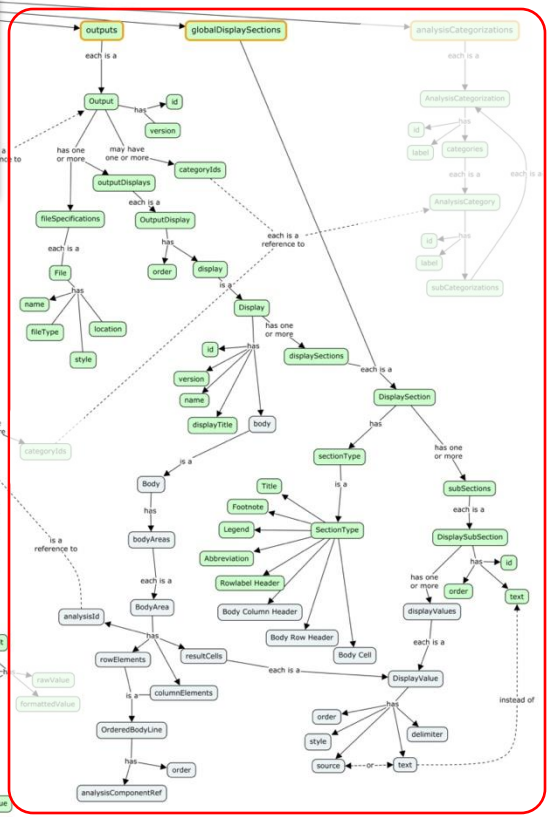

cdisc

List of Planned Analyses/Outputs


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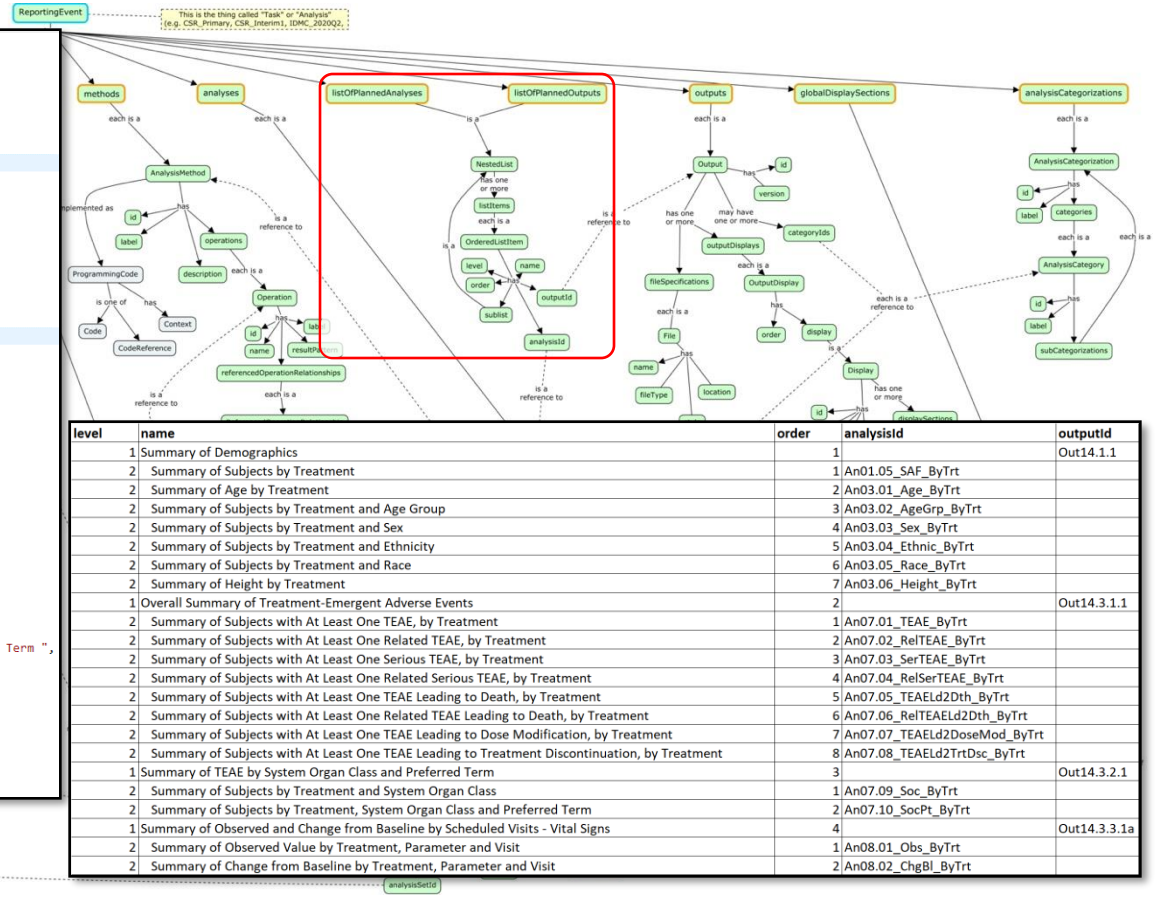

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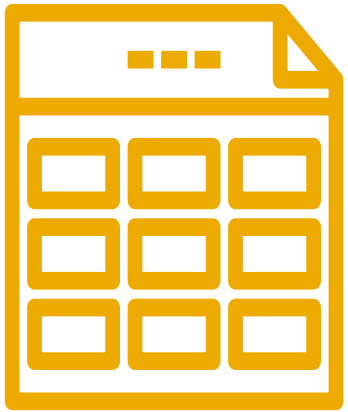
2	Summary of Age by Treatment	2	An03.01_Age_ByTrt	
2	Summary of Subjects by Treatment and Age Group	3	An03.02_AgeGrp_ByTrt	
2	Summary of Subjects by Treatment and Sex	4	An03.03_Sex_ByTrt	
2	Summary of Subjects by Treatment and Ethnicity	5	An03.04_Ethnic_ByTrt	
2	Summary of Subjects by Treatment and Race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

ARS User Guide Reporting Events Example



- Common Safety Displays
  - Summary of Demographics
  - Overall Summary of Treatment-Emergent Adverse Events
  - Summary of TEAE by System Organ Class and Preferred Term
  - Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs
  - Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs <Vertical Layout>
- FDA Standard Safety Tables and Figures
  - Table 2: Baseline Demographic and Clinical Characteristics, Safety Population

Creating Analysis Results Metadata: JSON

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

Characteristic	Drug Name Dosage X N = XXX n (%)	Drug Name Dosage Y N = XXX n (%)	Placebo N = XXX n (%)	Active Control N = XXX n (%)	Total Population N = XXX n (%)
Sex, n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Male	n (%)	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)	n (%)
Age, years	**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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Leveraging ARS Metadata to Drive Results Automation

ARS Metadata

ADaM Dataset

USUBJID	ARM	AGE	AGEGR1	AGEU	RACE	SEX
01-701-1015	Placebo	63	<65	YEARS	WHITE	F
01-701-1023	Placebo	64	<65	YEARS	WHITE	M
01-701-1028	Xanomeline High Dose	71	65+	YEARS	WHITE	M
01-701-1033	Xanomeline Low Dose	74	65+	YEARS	WHITE	M
01-701-1034	Xanomeline High Dose	77	65+	YEARS	WHITE	F
01-701-1047	Placebo	85	65+	YEARS	WHITE	F

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An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	72	72
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	8	8
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	76	76
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	11	11
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	73	73
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	16.27907	(16.3)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	83.72093	(83.7)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	9.52381	(9.5)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	90.47619	(90.5)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	13.09524	(13.1)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	86.90476	(86.9)

Analysis Results Dataset

Analysis Results: Create Once, Use Many Times

id	operation_id	resultGroup1_groupingId	resultGroup1_groupId	resultGroup2_groupingId	resultGroup2_groupId	rawValu	formattedVal
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	14	14
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	72	72
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	8	8
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	76	76
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	11	11
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	73	73
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	16.27907	(16.3)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	83.72093	(83.7)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	9.52381	(9.5)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	90.47619	(90.5)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	13.09524	(13.1)
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	86.90476	(86.9)

Displays

Publications

Clinical Study Report

Meta Analysis

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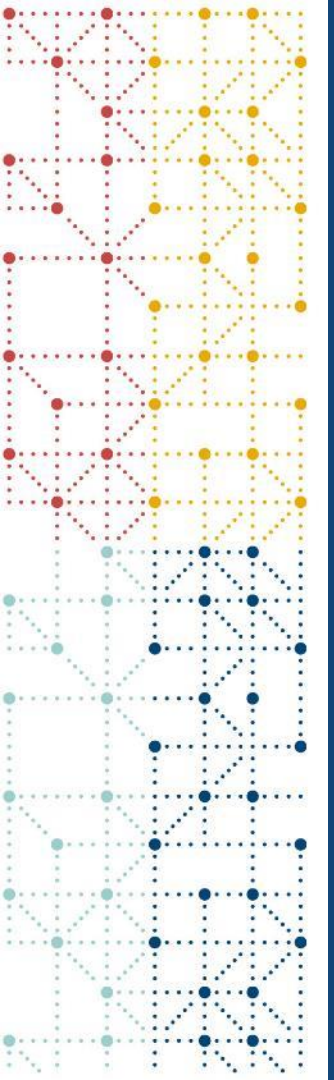

Questions?

What's Next?

eTFL Portal!

Expanding Content through CDISC eTFL Portal

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

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eTFL Portal Benefits

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

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Launching the eTFL Portal

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

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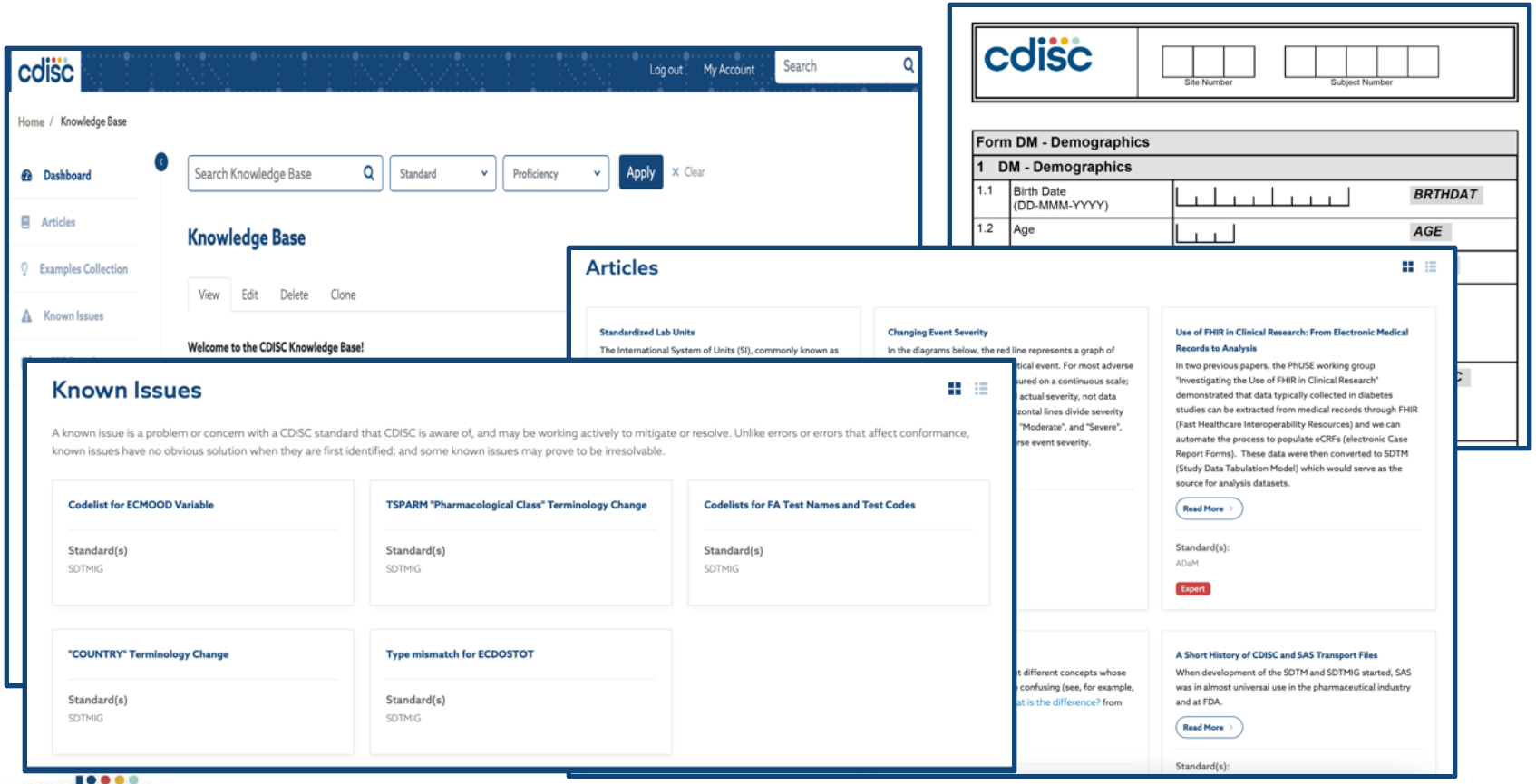
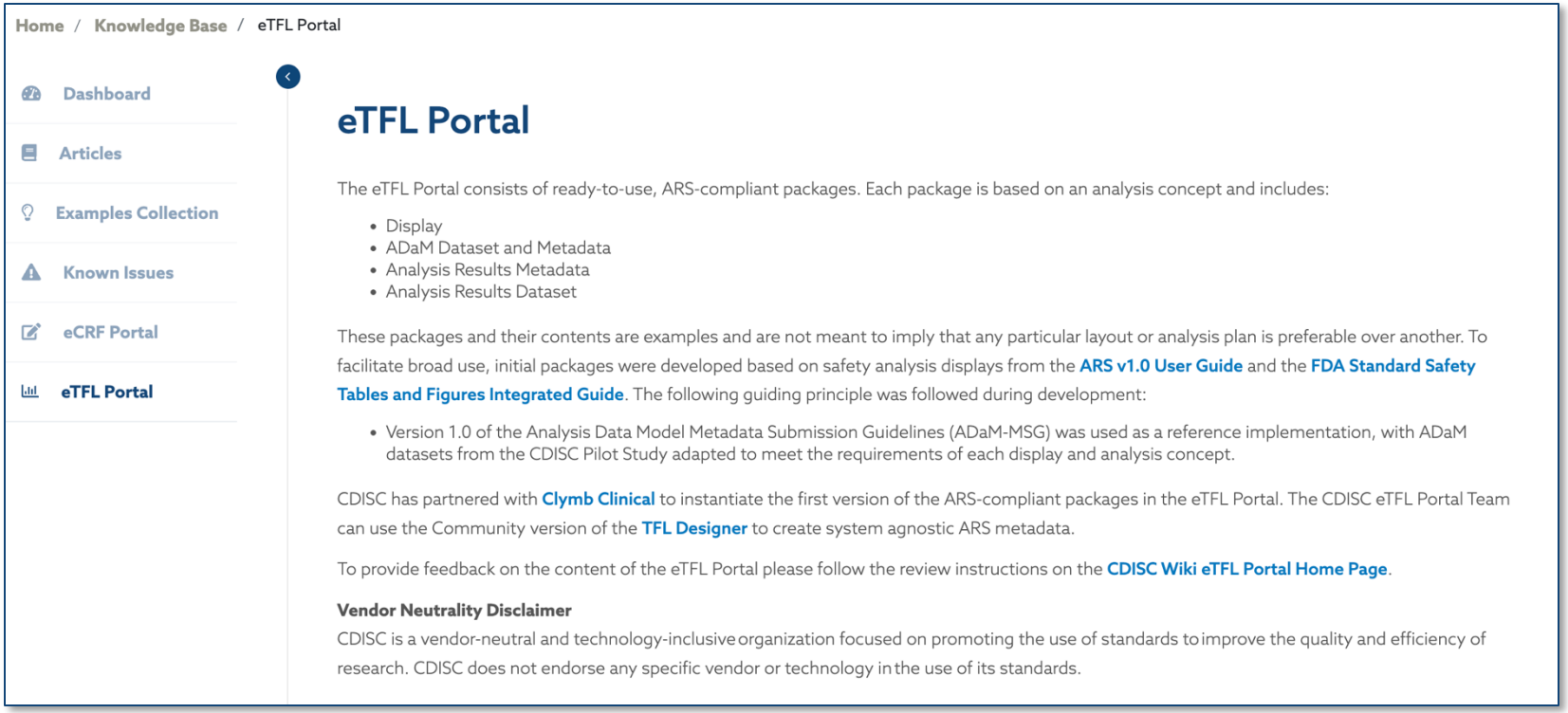
CDISC Knowledge Base



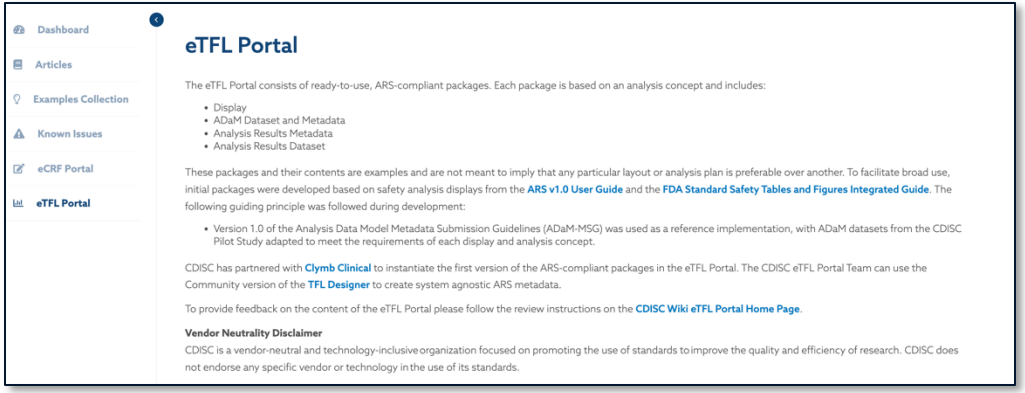
eTFL Portal in the CDISC Knowledge Base

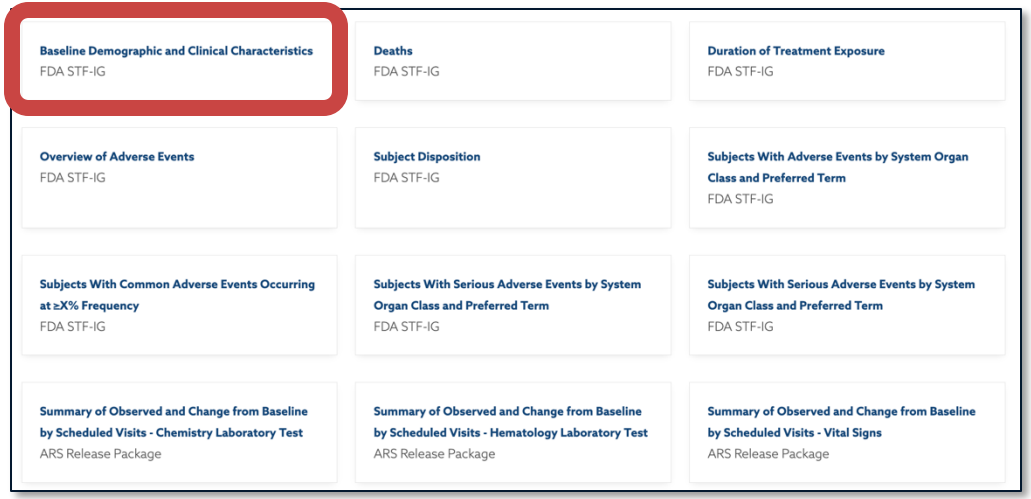


https://cdisc.org/kb/etfl

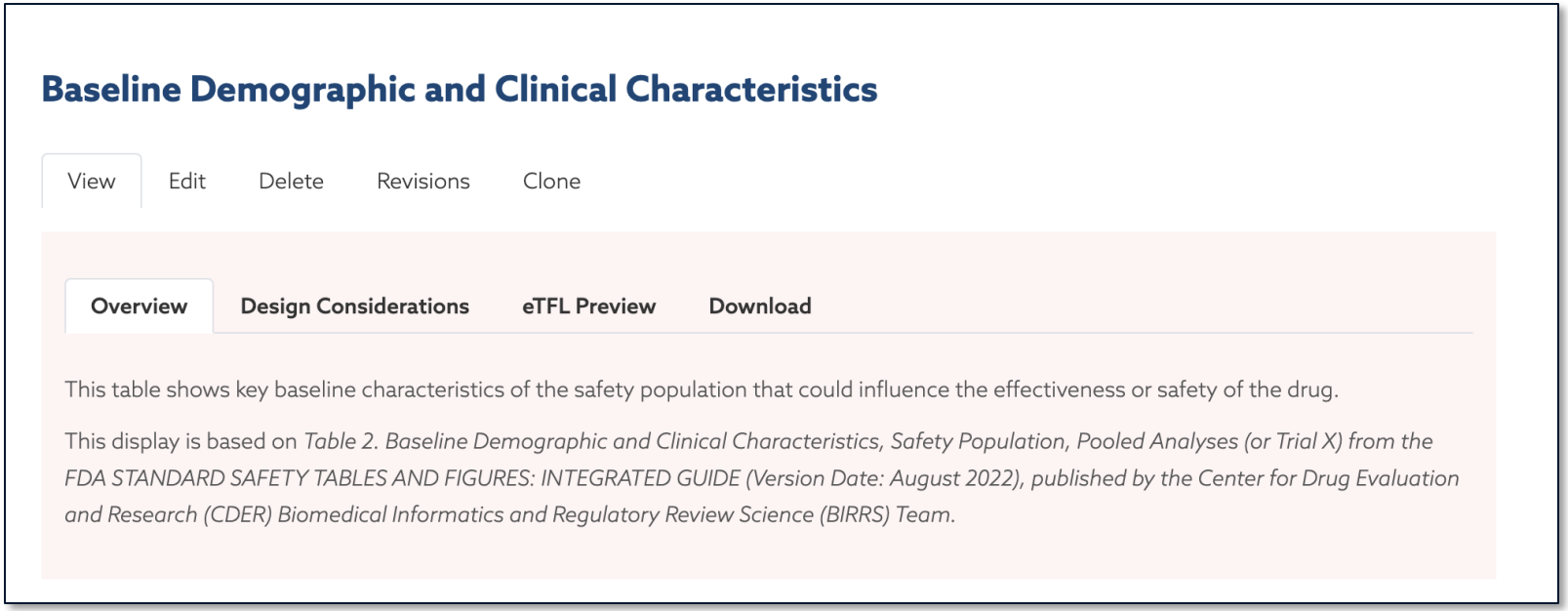
eTFL Portal

- To facilitate broad use, initial packages were developed based on safety analysis displays from the ARS v1.0 User Guide and and the FDA Standard Safety Tables and Figures Integrated Guide.
- Version 1.0 of the Analysis Data Model Metadata Submission Guidelines (ADaM-MSG) was used as a reference implementation, with ADaM datasets from the CDISC Pilot Study adapted to meet the requirements of each display and analysis concept.
- Each Package contains
  - Analysis overview, design considerations, and TFL preview
  - Download
    - ADaM Dataset and Metadata
    - ARS Metadata
    - Analysis Results Dataset
    - Display

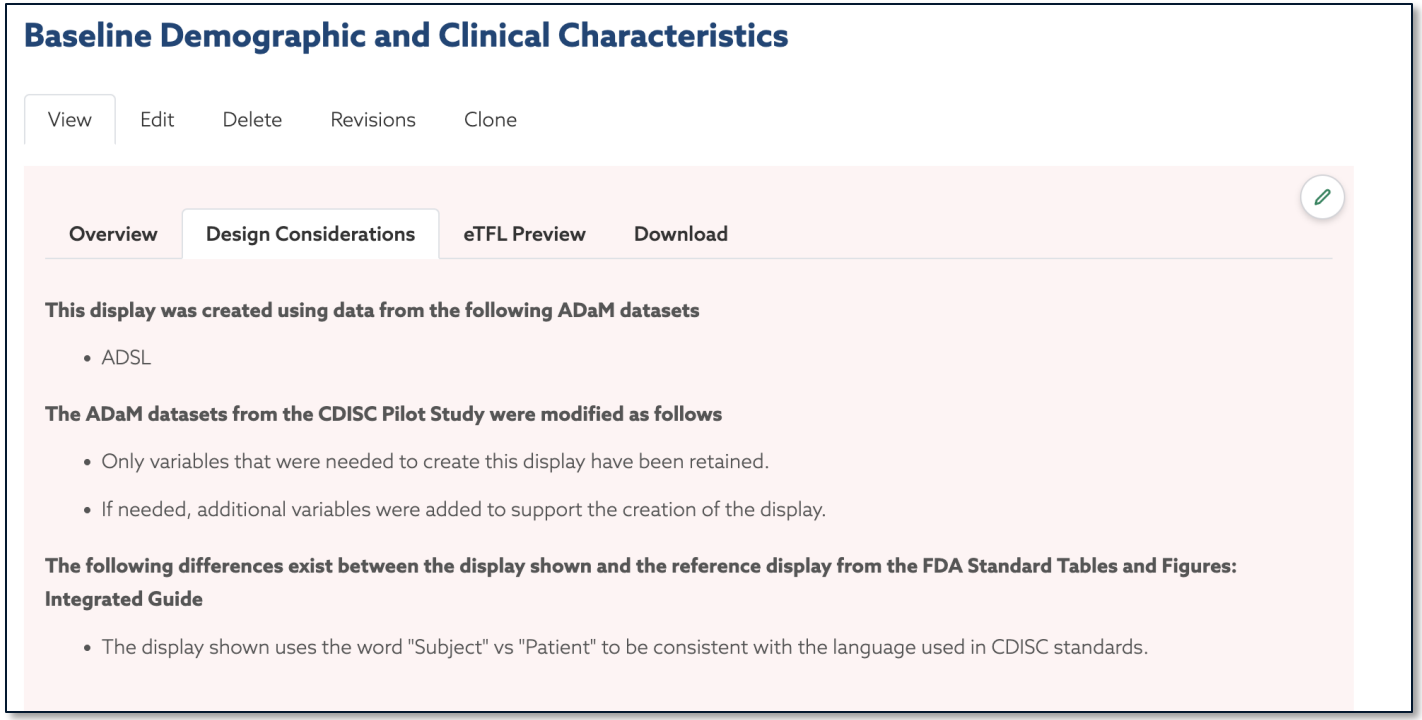




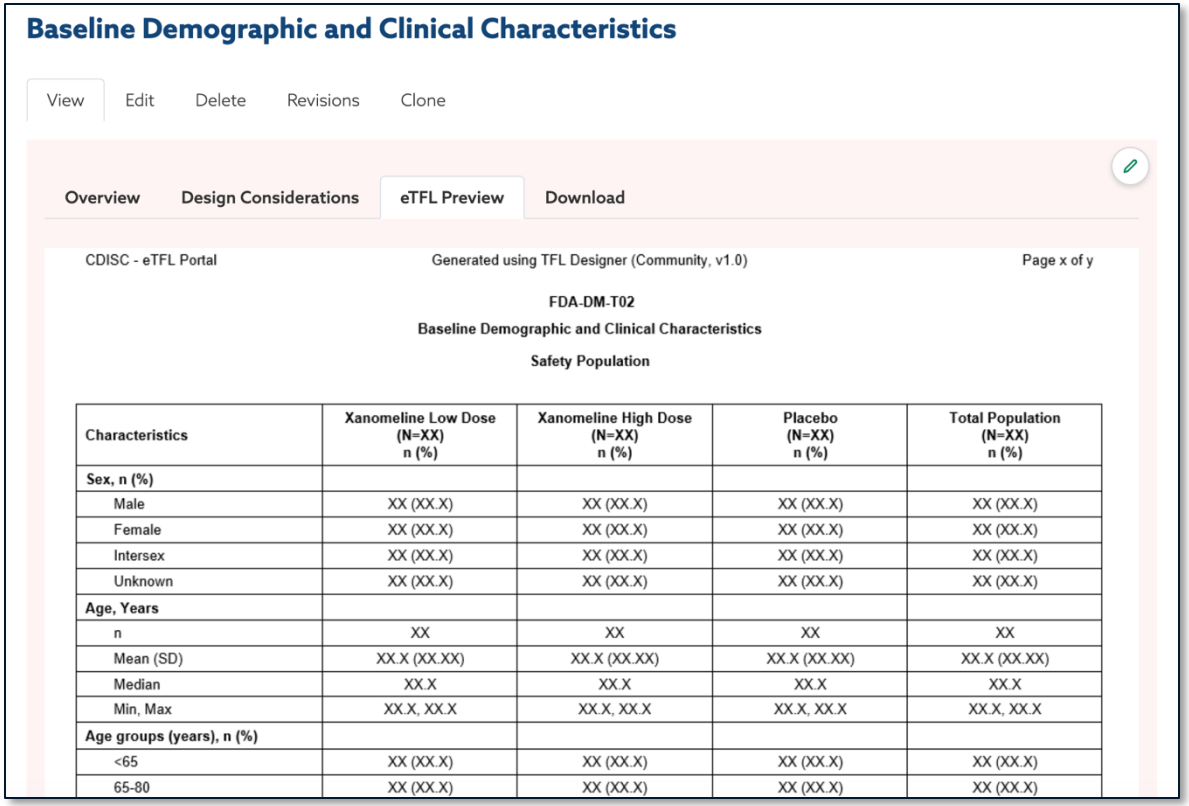
Overview


Baseline Demographic and Clinical Characteristics
View
Edit
Delete
Revisions
Clone
Overview
Design Considerations
eTFL Preview
Download
This table shows key baseline characteristics of the safety population that could influence the effectiveness or safety of the drug.
This display is based on Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X) from the FDA STANDARD SAFETY TABLES AND FIGURES: INTEGRATED GUIDE (Version Date: August 2022), published by the Center for Drug Evaluation and Research (CDER) Biomedical Informatics and Regulatory Review Science (BIRRS) Team.

Design Considerations



eTFL Preview



Baseline Demographic and Clinical Characteristics

View | Edit | Delete | Revisions | Clone

Overview | Design Considerations | eTFL Preview | Download

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

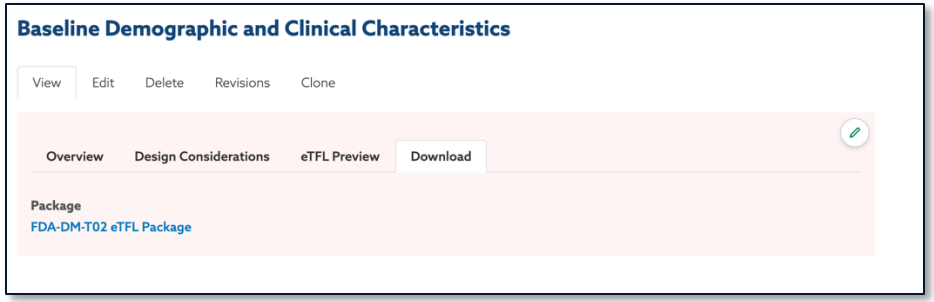
FDA-DM-T02

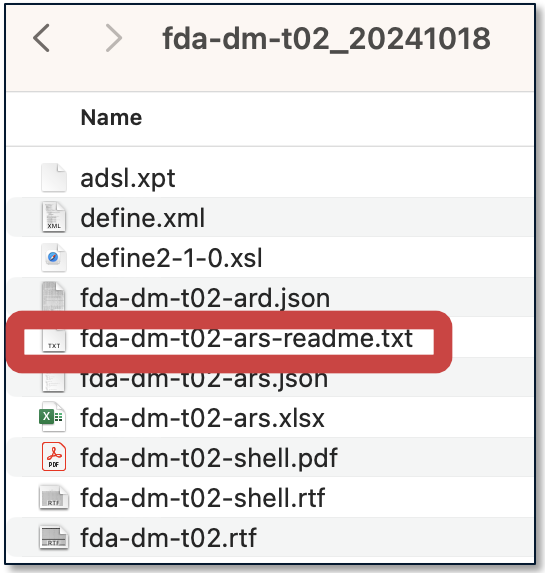
Baseline Demographic and Clinical Characteristics

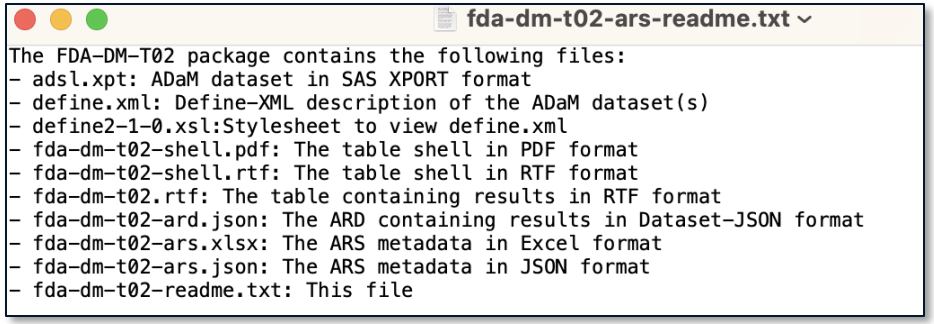
Safety Population

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

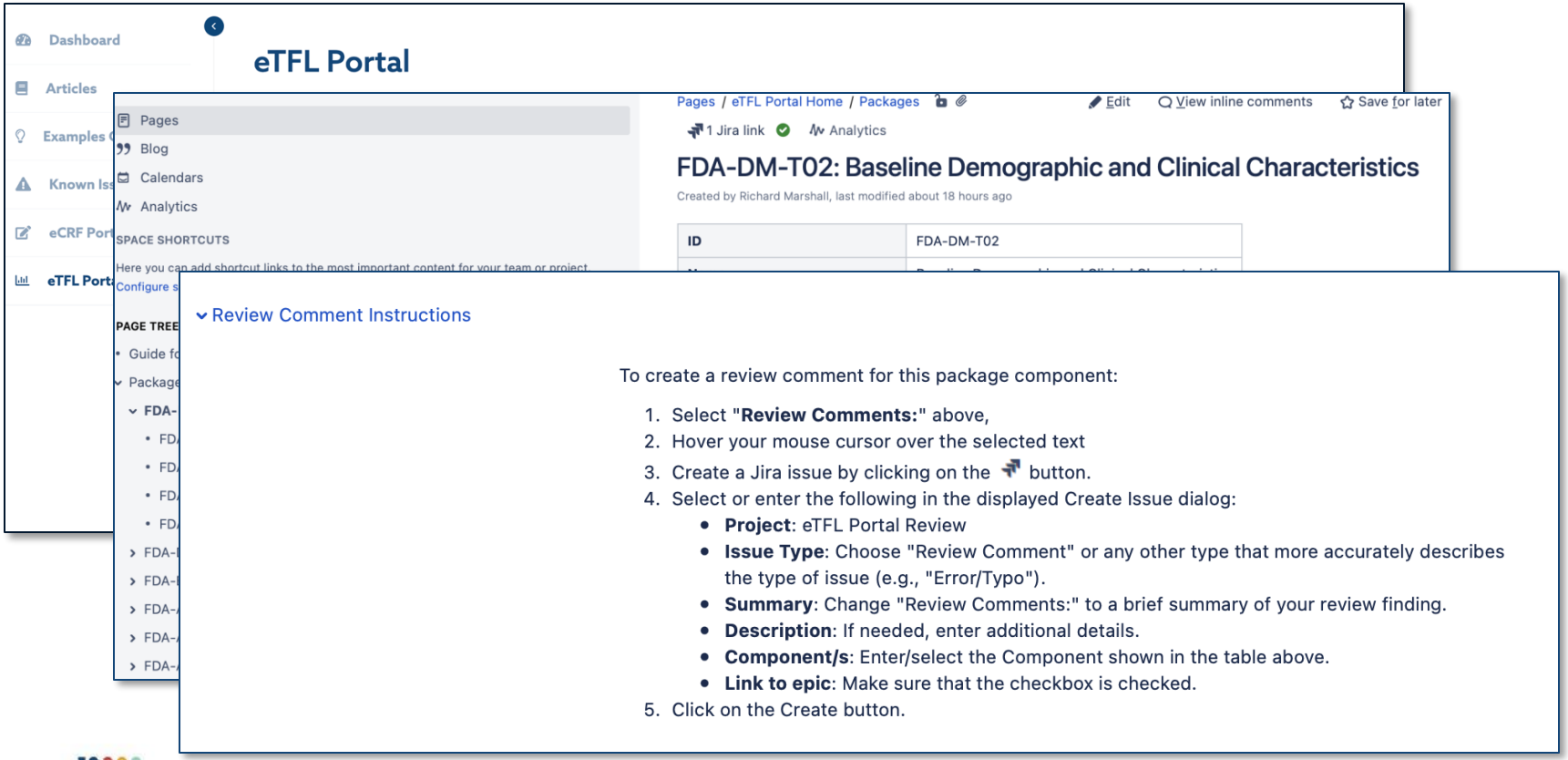
Package Download



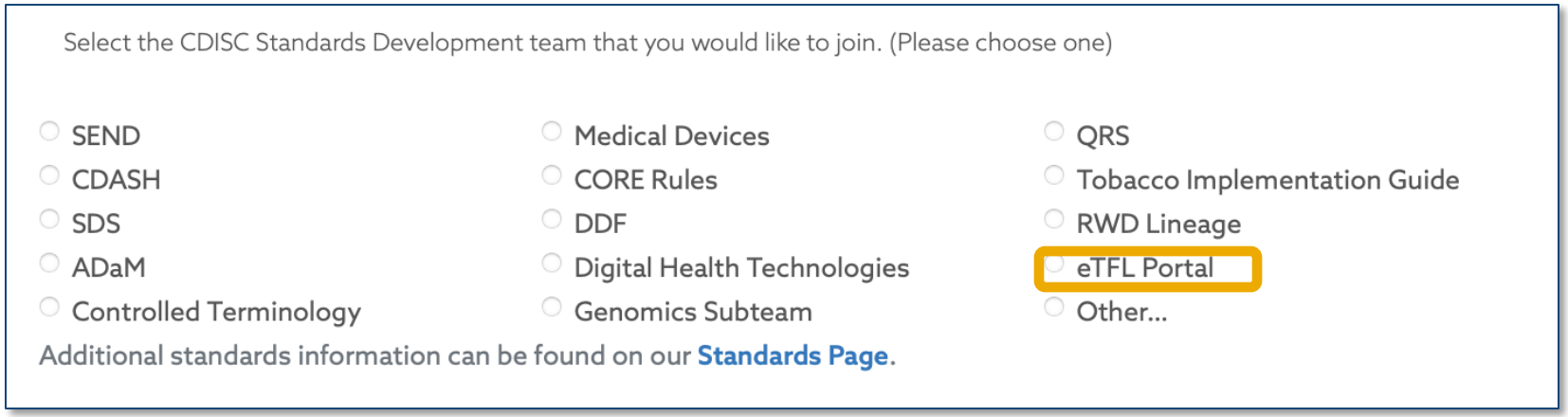




Provide Feedback!

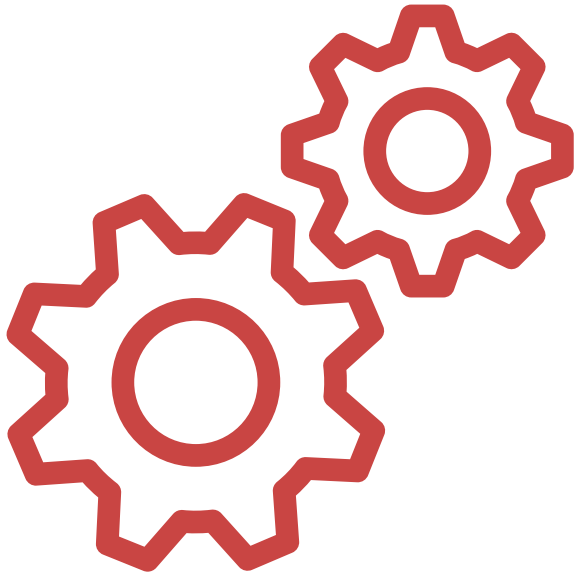


Volunteer!



https://www.cdisc.org/volunteer/form

ARS Model Will Drive Automation and Tool Development



ARS model is complex!

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

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

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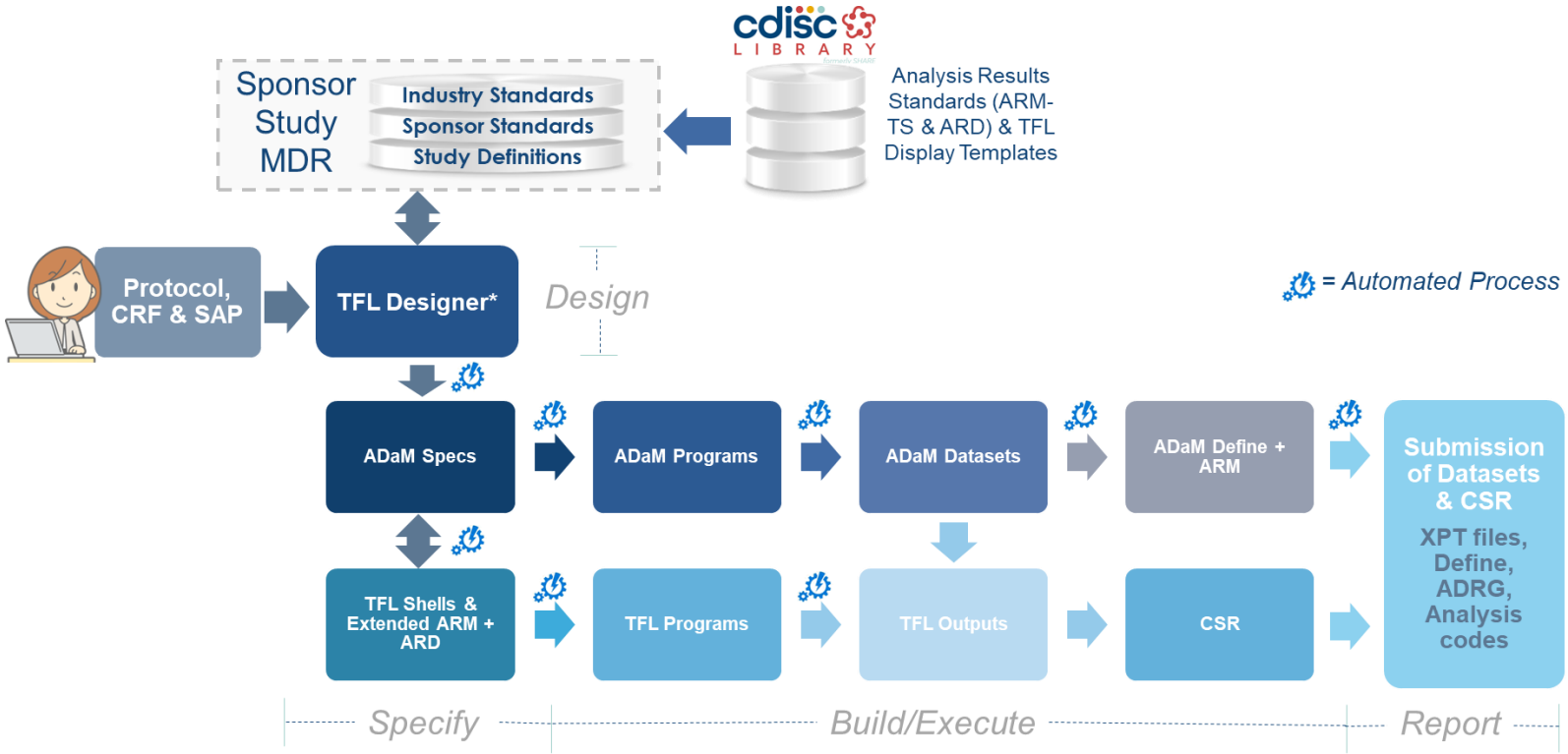
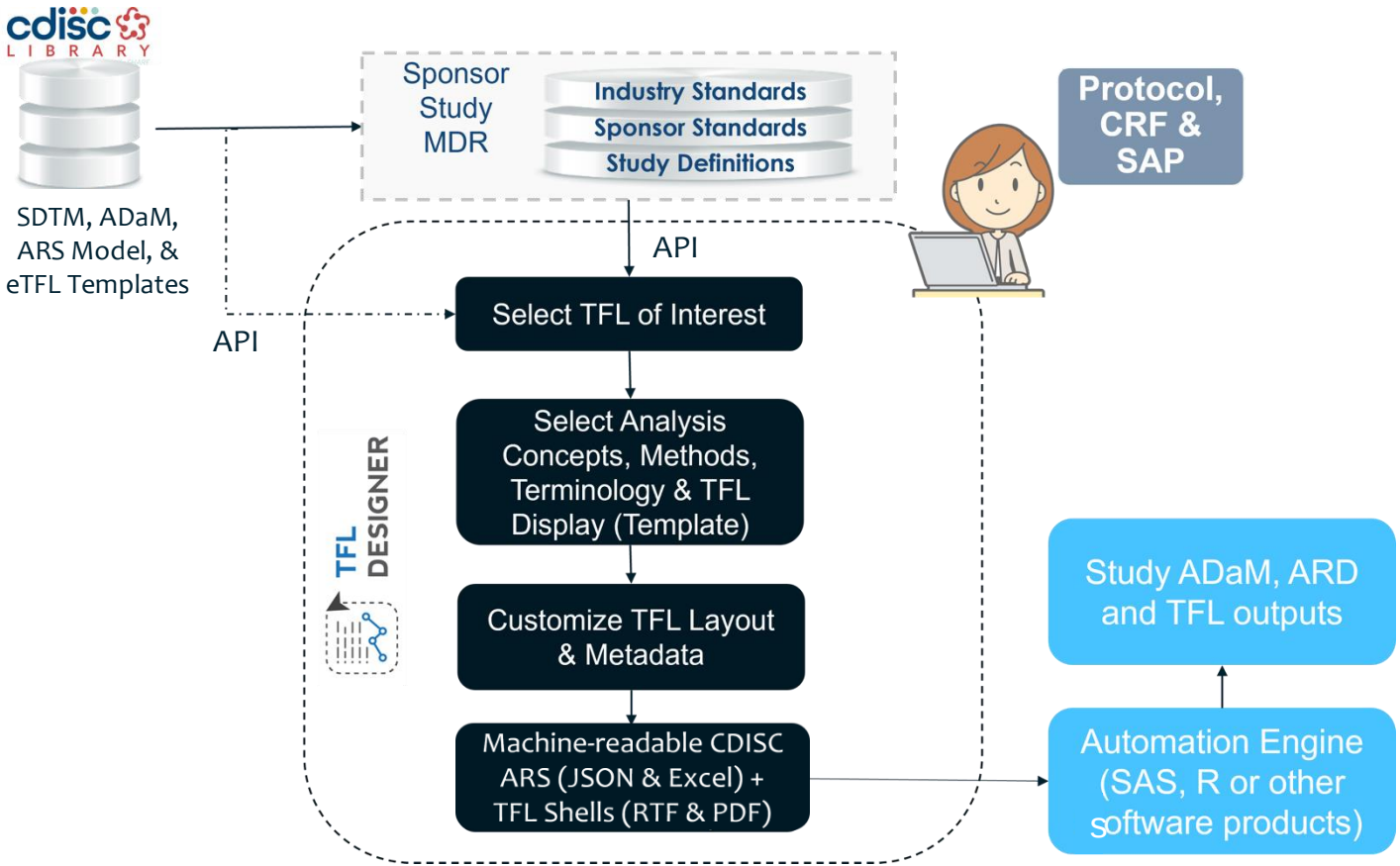
Analysis Results Workflow w/ TFL Designer




cdisc LIBRARY
SDTM, ADaM, ARS Model, & eTFL Templates
Sponsor Study MDR
Industry Standards
Sponsor Standards
Study Definitions
Protocol, CRF & SAP
API
API
Select TFL of Interest
Select Analysis Concepts, Methods, Terminology & TFL Display (Template)
Customize TFL Layout & Metadata
Machine-readable CDISC ARS (JSON & Excel) + TFL Shells (RTF & PDF)
TFL DESIGNER
Study ADaM, ARD and TFL outputs
Automation Engine (SAS, R or other software products)

TFL Designer: Key Functionalities

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

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

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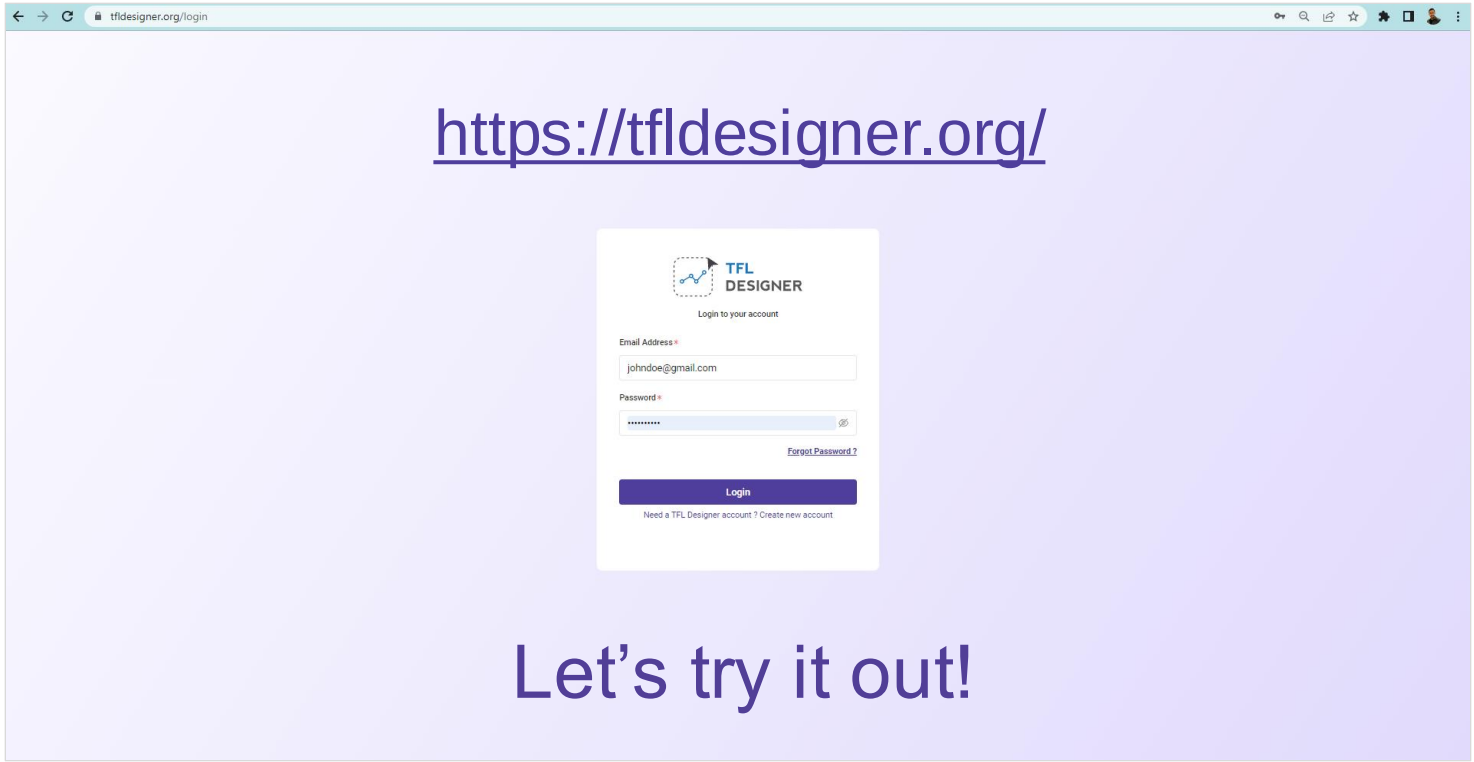
Utilizing eTFL Artifacts w/ TFL Designer (Community Version)



Thank you!

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Richard Marshall
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