



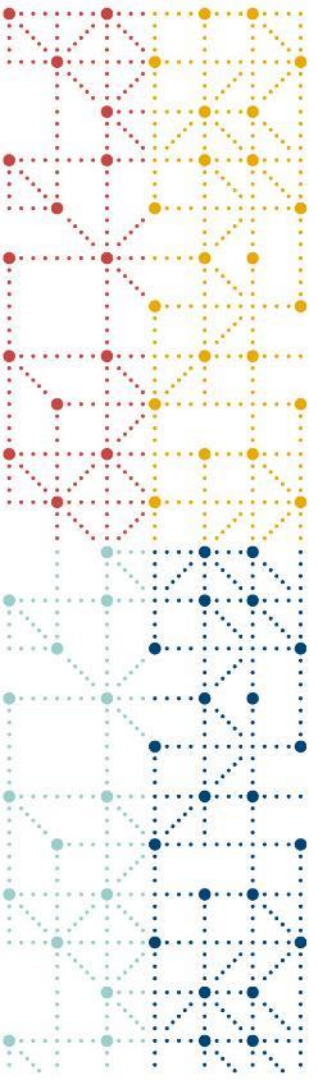
DS12: The Development of the CDISC eTFL Portal to Support the Adoption and Implementation of the Analysis Result Standard

PHUSE EU Connect 2024, Strasbourg, France

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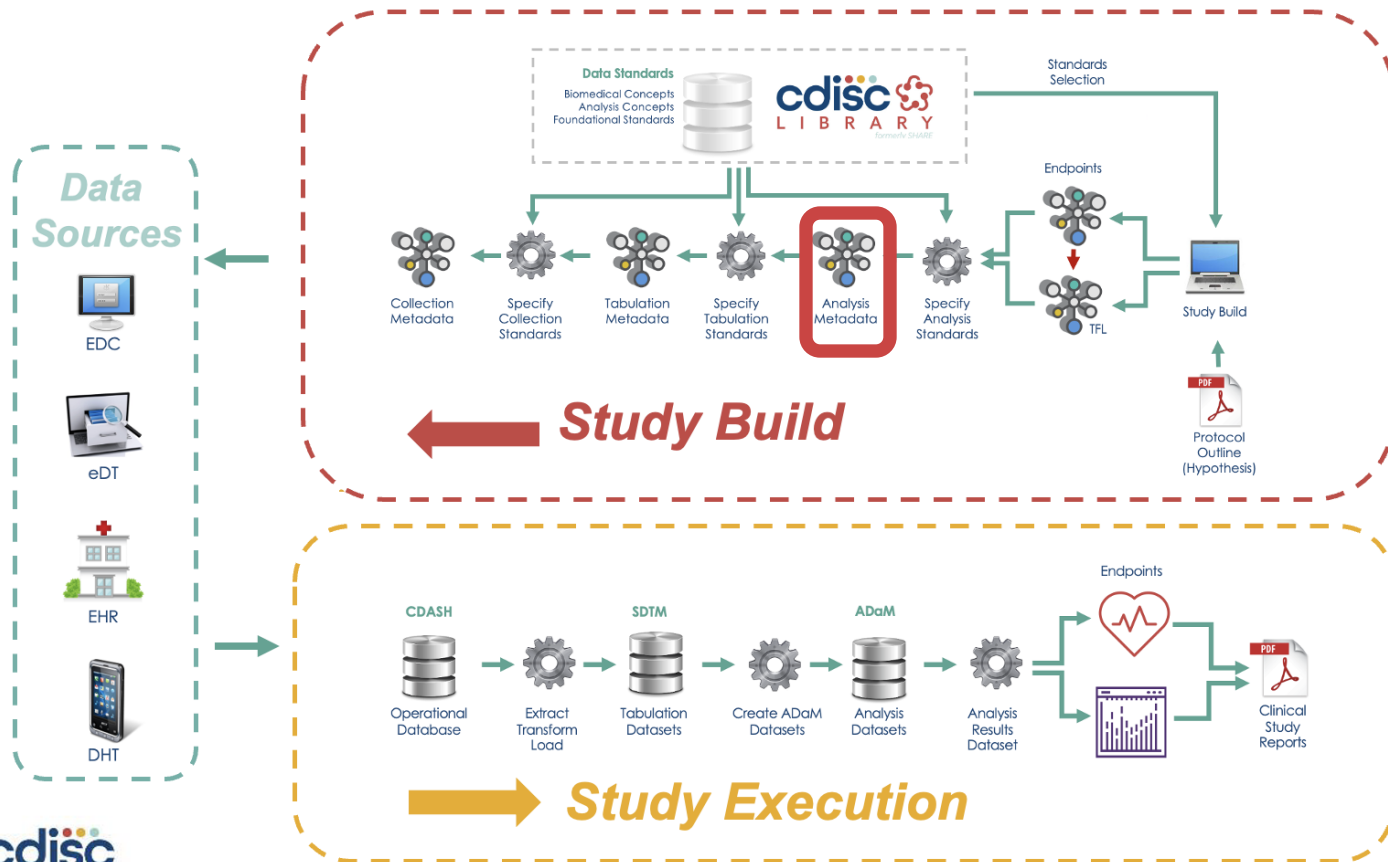




Agenda

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

Standardizing Analysis Metadata

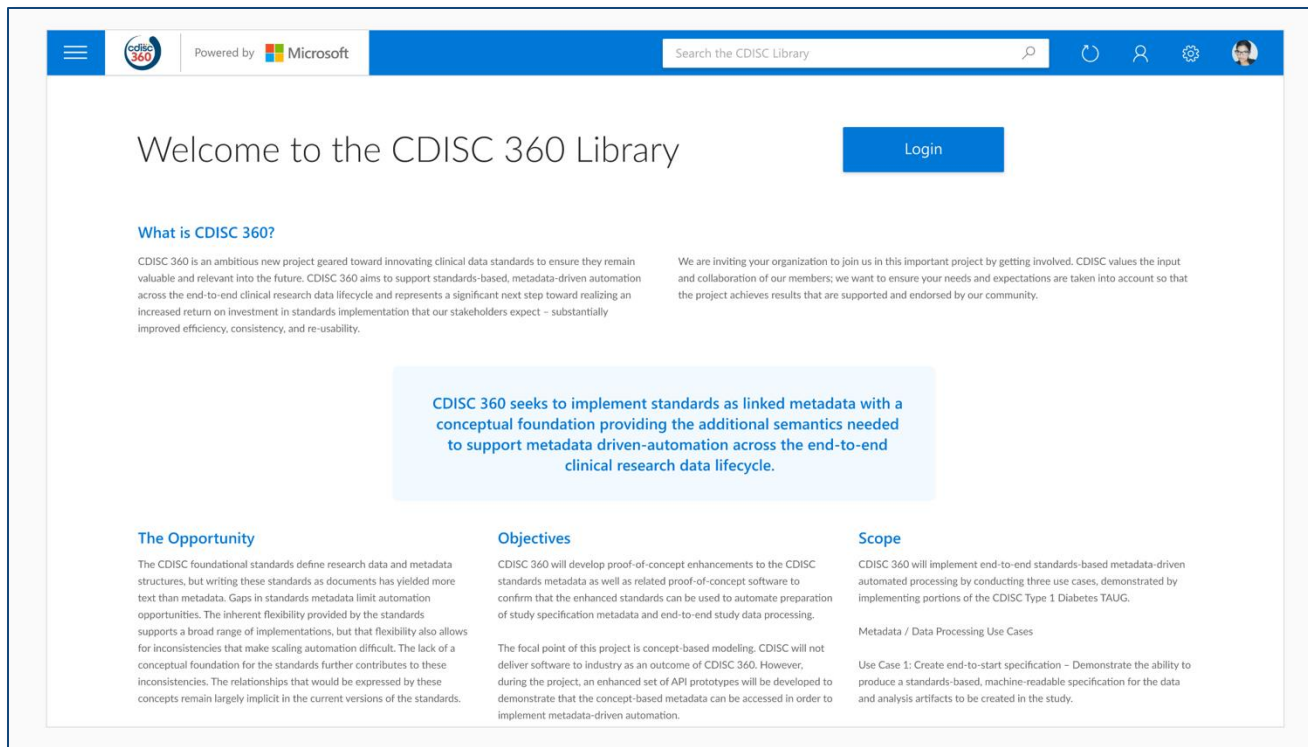


CDISC 360

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



CDISC 360: The Art of the Possible



The screenshot shows the CDISC 360 Library homepage. At the top, there is a blue header bar with the CDISC 360 logo, a 'Powered by Microsoft' badge, and a search bar labeled 'Search the CDISC Library'. Below the header, the main content area has a large heading 'Welcome to the CDISC 360 Library' and a blue 'Login' button. A section titled 'What is CDISC 360?' explains the project's goals. A central light blue box contains a key message about implementing standards as linked metadata. Below this, three columns detail 'The Opportunity', 'Objectives', and 'Scope'.

CDISC 360

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Search the CDISC Library

Welcome to the CDISC 360 Library

Login

What is CDISC 360?

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

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

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

The Opportunity

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

Objectives

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

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

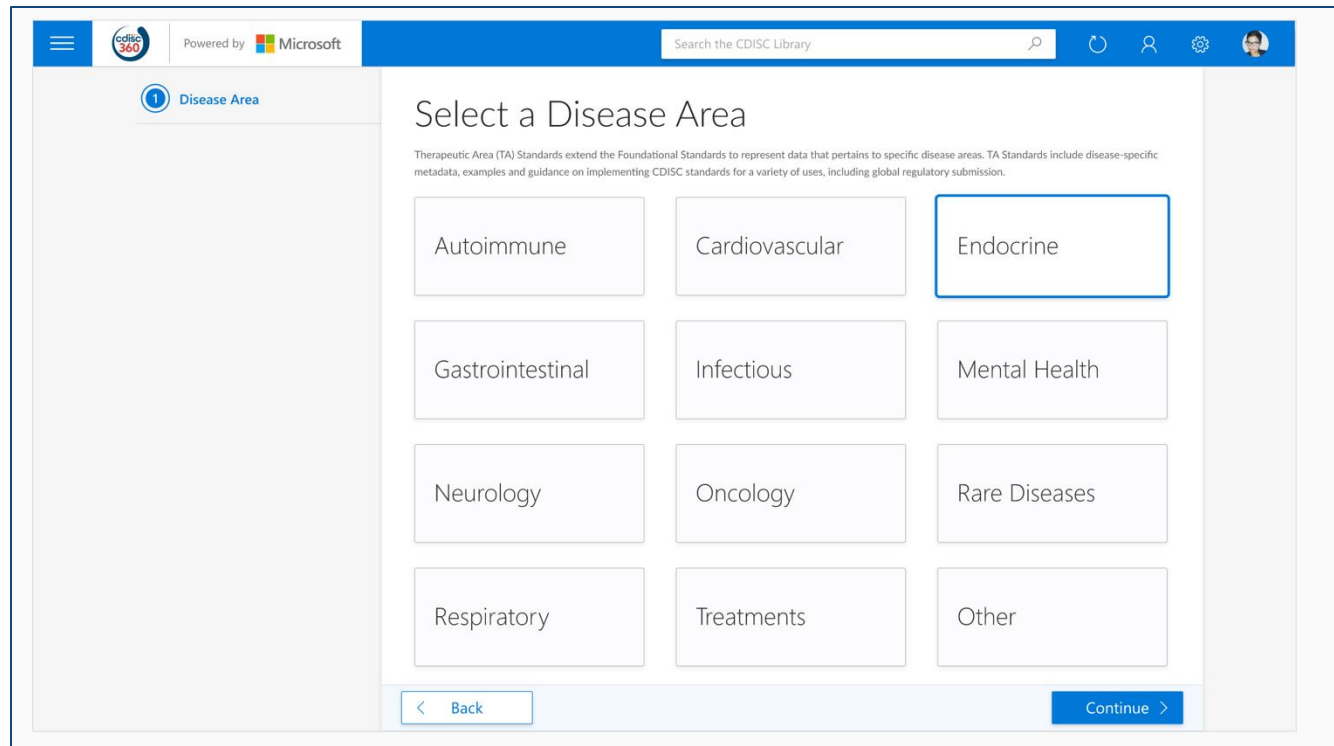
Scope

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

Metadata / Data Processing Use Cases

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

CDISC 360: The Art of the Possible



CDISC 360: The Art of the Possible

The screenshot displays the CDISC 360 web application interface. The top navigation bar is blue and contains the CDISC 360 logo, the text 'Powered by Microsoft', a search bar labeled 'Search the CDISC Library', and icons for refresh, user profile, settings, and a user avatar. On the left, a sidebar shows a progress indicator with two steps: '1 Disease Area' (marked with a green check and 'Endocrine') and '2 Therapeutic Area' (highlighted with a blue circle). The main content area is titled 'Select a Therapeutic Area' and includes a descriptive paragraph: 'Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. TA Standards include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submission.' Below this, seven buttons represent different therapeutic areas: 'Acute Kidney Injury', 'Diabetes - Type 1', 'Diabetes - Type 2' (which is highlighted with a blue border), 'Diabetic Kidney Disease', 'Dyslipidemia', 'Kidney Transplant', and 'Polycystic Kidney Disease'. At the bottom, there are two buttons: a light blue 'Back' button with a left arrow and a blue 'Continue' button with a right arrow.

CDISC 360: The Art of the Possible

1 Disease Area
✓ Endocrine

2 Therapeutic Area
✓ Diabetes - Type 2

3 Standards Focus
✓ Study Endpoint

4 Study Endpoint
✓ Analysis of Glycated Hemoglobin

5 Standard Analyses

Select from Standard Analyses

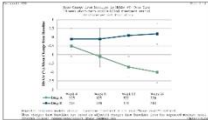
HbA1c Longitudinal Repeated Measures Analysis



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

[View details](#)

Mean Change from Baseline in HbA1c (%) Over Time



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

[View details](#)

HbA1c Categorical Analysis



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

[View details](#)

[< Back](#)[Continue >](#)

cdisc

8

CDISC 360: The Art of the Possible

The screenshot displays the CDISC 360 web application interface. The top navigation bar includes the CDISC 360 logo, "Powered by Microsoft", a search bar labeled "Search the CDISC Library", and icons for refresh, user profile, settings, and a user avatar. The left sidebar contains a vertical list of six items, each with a numbered circle and a checkmark:

- 1 Disease Area
✓ Endocrine
- 2 Therapeutic Area
✓ Diabetes - Type 2
- 3 Standards Focus
✓ Study Endpoint
- 4 Study Endpoint
✓ Analysis of Glycated Hemoglobin
- 5 Standard Analyses
✓ Mean Change from Baseline in HbA1c (%) Over Time
- 6 Selection Summary

The main content area is titled "Selection Summary" and is divided into three columns:

- Study Endpoint:** Contains a box titled "Analysis of Glycated Hemoglobin" with a description: "Analysis of the continuous clinical endpoint of HbA1c. Example: a Phase III, parallel-group study designed to determine efficacy of Drug A for patients with Type II diabetes. The primary endpoint defined as the change in HbA1c from baseline." and a "View details" link.
- Analysis:** Contains a box titled "Mean Change from Baseline in HbA1c (%) Over Time" with a line graph showing two data series over time (Weeks 0, 12, 24, 36, 48, 60). The graph shows a downward trend for both series, with the second series (green) showing a steeper decline. Below the graph is a description: "Provides a visual display of the information in the 'HbA1c Longitudinal Repeated Measures Analysis' table. Includes additional weeks beyond those in that table. The mean changes shown are based on adjusted changes from baseline from the repeated measures model." and links for "View details" and "View analysis results metadata".
- Analysis Datasets:** Contains two boxes: "ADSL" (Analysis Data Subject Level) with links for "View analysis dataset metadata", "View sample analysis data", and "View analysis dataset structure"; and "ADHBA1C" (DBS - Structured Dataset) with links for "View analysis dataset metadata", "View sample analysis data", and "View analysis dataset structure".

At the bottom of the main content area, there is a "Back" button on the left and a "Save Selection" button on the right.

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Search the CDISC Library

Selection Summary

Study Endpoint Analysis

Analysis Results Metadata

Table 4.2.3: HBa1c Longitudinal Repeated Measures Analysis Results Metadata

Metadata Field	Metadata
DISPLAY IDENTIFIER	Table 4.2.3 Figure 4.2.1
DISPLAY NAME	Mean Change from Baseline in HBa1c (Percent) Longitudinal Repeated Measures Analysis, 24-Week 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)
SPECIFIED IN SAP	YES
ANALYSIS PURPOSE	PRIMARY OUTCOME MEASURE
ANALYSIS DATASET	ADHBa1c
SELECTION CRITERIA	ITPTFL = "Y" and PARAMCD = "HBa1c" and CHG ne . and ANLO1FL = "Y" and DTYPE = ""
DOCUMENTATION	See SAP Section XX for details. Program: %b1c1c outputs SAS L3 means and 95% CIs are based on planned treatment, baseline HBa1c value, event, event*baseline and event*treatment interaction.
PROGRAMMING STATEMENTS	<pre> SAS version 9.2.1 PROC MIXED DATA = ADHBa1c; WHERE ITPTFL = "Y" and PARAMCD = "HBa1c" and CHG ne . and ANLO1FL = "Y" and CLASS TRT AVISIT; MODEL CHG = TRT BASE AVISIT BASE*AVISIT AVISIT*TRT / DDFM=SS3; LSMEANS TRT / CL DDFM=REPEATED UNCL / ADJUST = UNCL; RUN ; </pre>

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Search the CDISC Library

Selection Summary

Study Endpoint Analysis Analysis Datasets

Analysis Dataset Metadata

Keys	Location	Documentation
ADYID, USUBID,	ADHBa1c.xpt	ADHBa1c.SAS/SAP
PARAMCD, AVISIT, ADY		

Save Data Standards

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Search the CDISC Library

Selection Summary

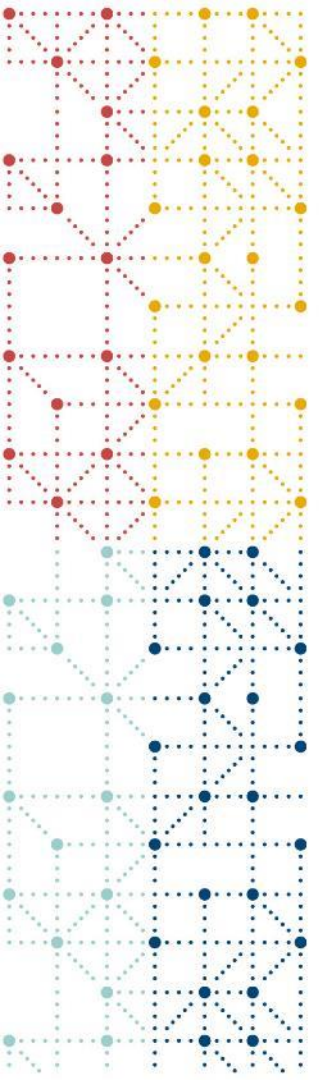
Study Endpoint Analysis Analysis Datasets

Sample Analysis Data

Table 4.1.1: ADHBa1c Analysis Dataset

Row	STUDYID	USUBID	PARAM	PARAMCD	VSITE	AVISIT	AWT	TARGET	ADY	TRTP	ITPTFL	LABFL	BAS	AVAL	CHG	ANLO1FL	CRIT1	CRITFL	DTYPE	LSMEQ
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 8	28	28	Drug A	Y	Y	8.2	8.5	-0.7	Y	<7%	N			43532
3	XYZ	XYZ-001-001	HBa1c (%)	HBa1c	Visit 5	Week 8	56	56	Drug A	Y	Y	9.2	7.3	-1.9	Y	<7%	N			24768
4	XYZ	XYZ-001-001	HBa1c (%)	HBa1c	Visit 5	Week 12	84	84	Drug A	Y	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	Y	9.2	6.3	-2.9	Y	<7%	Y			65078
6	XYZ	XYZ-001-002	HBa1c (%)	HBa1c	Visit 2	Baseline	1	1	Drug B	Y	Y	8.6	8.6	Y	<7%	N				90874
7	XYZ	XYZ-001-002	HBa1c (%)	HBa1c	Visit 3	Week 8	28	28	Drug B	Y	Y	8.6	8.7	0.1	Y	<7%	N			23454
8	XYZ	XYZ-001-002	HBa1c (%)	HBa1c	Visit 4	Week 8	56	56	Drug B	Y	Y	8.6	9.6	1.0	Y	<7%	N			50744
9	XYZ	XYZ-001-002	HBa1c (%)	HBa1c	Visit 5	Week 1	56	61	Drug B	Y	Y	8.6	9.5	1.1	Y	<7%	N			67543
10	XYZ	XYZ-001-002	HBa1c (%)	HBa1c	Visit 5	Week 12	84	84	Drug B	Y	Y	8.6	9.5	1.1	Y	<7%	N	LOCF		67543
11	XYZ	XYZ-001-002	HBa1c (%)	HBa1c	Visit 6	Week 24	168	168	Drug B	Y	Y	8.6	9.5	1.1	Y	<7%	N	LOCF		67543

Back Save Data Standards



What did we learn from CDISC 360?

CDISC Foundational Standards

Example CDASH Form

Data Collection
CDASH

Table 4.2.1: Example of a CDASH Form

Data Aggregation
SDTM

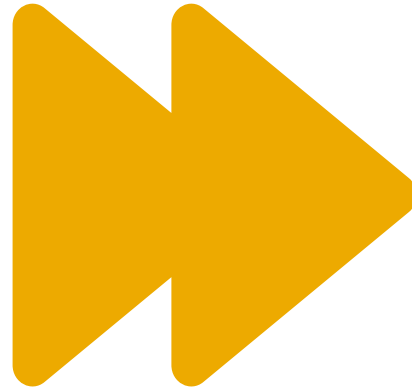
Table 4.2.2: Example of a CDASH Form

Analysis
ADaM

Table 4.2.3: Example of a CDASH Form

Results
???

Fast Forward Q1 2021 to Q1 2024



CDISC Analysis Result Standards – Released April 19, 2024!



Analysis Results Standard (ARS) v1.0



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

To address these inefficiencies, CDISC has developed the [Analysis Results Standard \(ARS\)](https://cdisc-org.github.io/analysis-results-standard/), which aim to facilitate automation, reproducibility, reusability, and traceability of analysis results data.

Features of ARS v1.0

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

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

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

Analysis Results Key Objectives

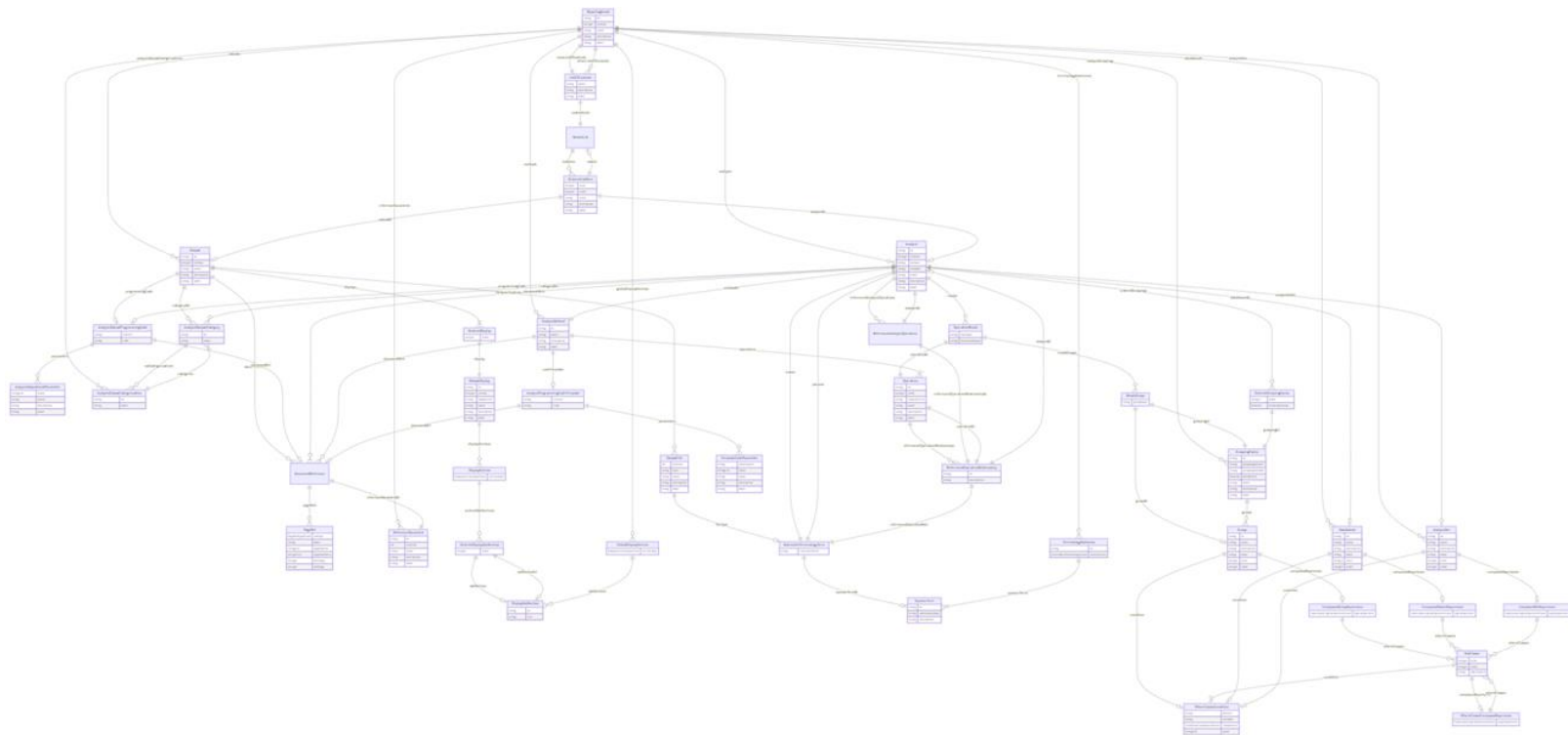


Leverage analysis results metadata to drive the automation of results

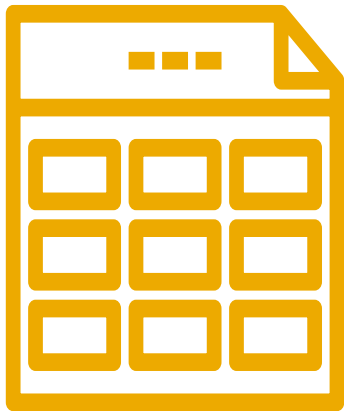


Support storage, access, processing, traceability and reproducibility of results

ARS Logical Model Schema Diagram



ARS User Guide Reporting Events Example



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

Creating Analysis Results Metadata: JSON

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

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

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

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Leveraging ARS Metadata to Drive Results Automation

ARS Metadata

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                {
                  "name": "Summary of Subjects (Total Population)",
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        ]
      ]
    }
  ]
}
```

ADaM Dataset

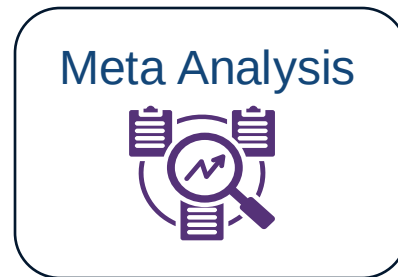
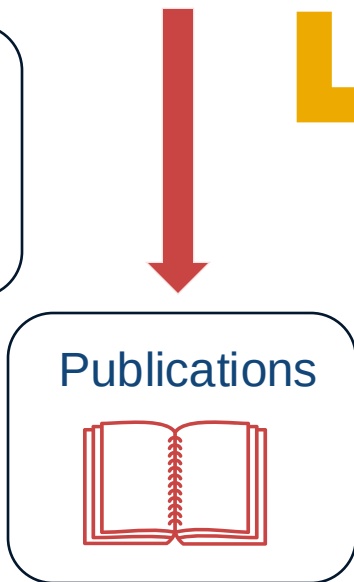
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01-701-1023	Placebo	64	<65	YEARS	WHITE	M
01-701-1028	Xanomeline High Dose	71	65+	YEARS	WHITE	M
01-701-1033	Xanomeline Low Dose	74	65+	YEARS	WHITE	M
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01-701-1047	Placebo	85	65+	YEARS	WHITE	F

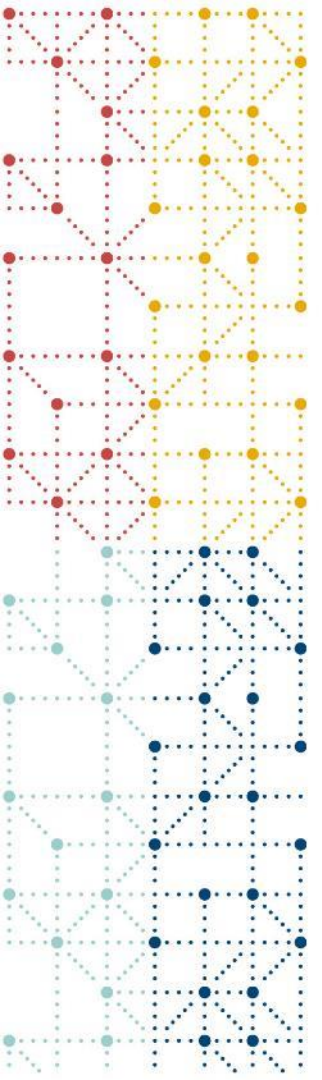
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Analysis Results Dataset

Analysis Results: Create Once, Use Many Times

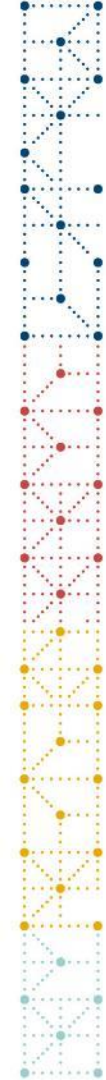
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An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_1	8	8
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	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)





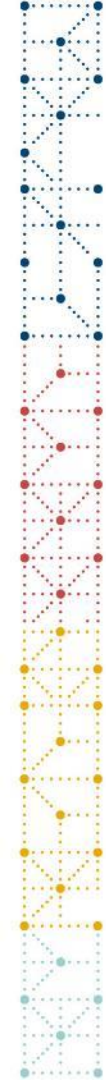
What's Next?

eTFL Portal!



Expanding Content through CDISC eTFL Portal

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



eTFL Portal Benefits

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

Launching the eTFL Portal

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



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Site Number Subject Number

Form DM - Demographics

1 DM - Demographics

1.1	Birth Date (DD-MMM-YYYY)		BRTHDAT
1.2	Age		AGE

Known Issues

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

Codelist for ECMOOD Variable

Standard(s)
SDTMIG

TSPARM "Pharmacological Class" Terminology Change

Standard(s)
SDTMIG

Codelists for FA Test Names and Test Codes

Standard(s)
SDTMIG

"COUNTRY" Terminology Change

Standard(s)
SDTMIG

Type mismatch for ECDOSTOT

Standard(s)
SDTMIG

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

Changing Event Severity
In the diagrams below, the red line represents a graph of

ical event. For most adverse
ured on a continuous scale;
actual severity, not data
zontal lines divide severity
"Moderate", and "Severe",
se event severity.

Use of FHIR in Clinical Research: From Electronic Medical Records to Analysis

In two previous papers, the PhUSE working group "Investigating the Use of FHIR in Clinical Research" demonstrated that data typically collected in diabetes studies can be extracted from medical records through FHIR (Fast Healthcare Interoperability Resources) and we can automate the process to populate eCRFs (electronic Case Report Forms). These data were then converted to SDTM (Study Data Tabulation Model) which would serve as the source for analysis datasets.

[Read More](#)

Standard(s):

ADaM

[Expert](#)

A Short History of CDISC and SAS Transport Files

When development of the SDTM and SDTMIG started, SAS was in almost universal use in the pharmaceutical industry and at FDA.

[Read More](#)

Standard(s):

eTFL Portal in the CDISC Knowledge Base

[Home](#) / [Knowledge Base](#) / [eTFL Portal](#)

 Dashboard

 Articles

 Examples Collection

 Known Issues

 eCRF Portal

 eTFL Portal

eTFL Portal

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

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

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

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

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

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

Vendor Neutrality Disclaimer

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

eTFL Portal

- Each Package contains
 - Analysis overview, design considerations, and TFL preview
 - Download
 - ADaM Dataset and Metadata
 - ARS Metadata
 - Analysis Results Dataset
 - Display

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

Overview

Baseline Demographic and Clinical Characteristics

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

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

Design Considerations

Baseline Demographic and Clinical Characteristics

View

Edit

Delete

Revisions

Clone

Overview

Design Considerations

eTFL Preview

Download



This display was created using data from the following ADaM datasets

- ADSL

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

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

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

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

eTFL Preview

Baseline Demographic and Clinical Characteristics

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OverviewDesign ConsiderationseTFL PreviewDownload

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

FDA-DM-T02

Baseline Demographic and Clinical Characteristics

Safety Population

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

Package Download

Baseline Demographic and Clinical Characteristics

View Edit Delete Revisions Clone

Overview Design Considerations eTFL Preview **Download**

Package
FDA-DM-T02 eTFL Package

fda-dm-t02-ars-readme.txt

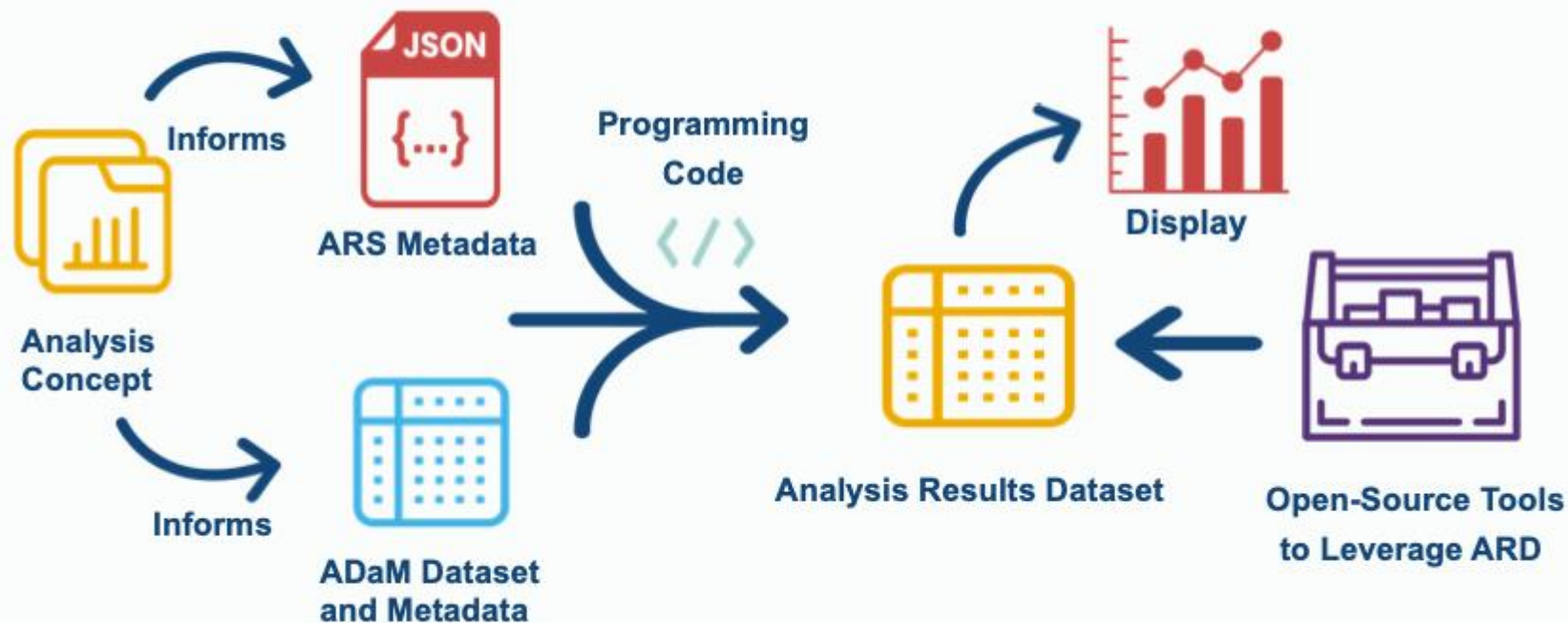
The FDA-DM-T02 package contains the following files:

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

< > fda-dm-t02_20241018

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

eTFL Portal Vision





Thank you!



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