



Launching the TFL Portal

Bess LeRoy, Head of Standards Development, CDISC

Bhavin Busa, Clymb Clinical

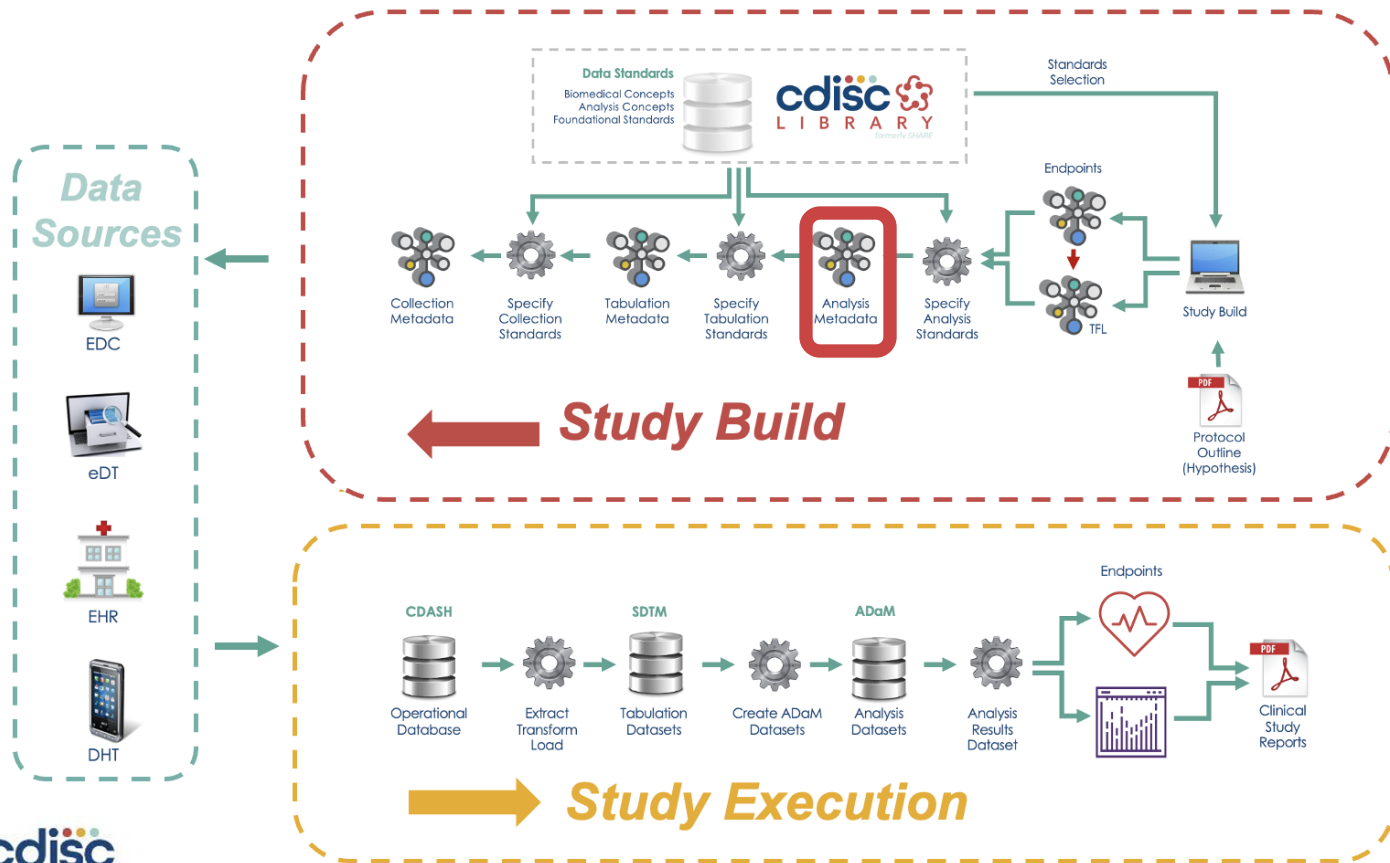




Agenda

- 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

CDISC 360

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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.

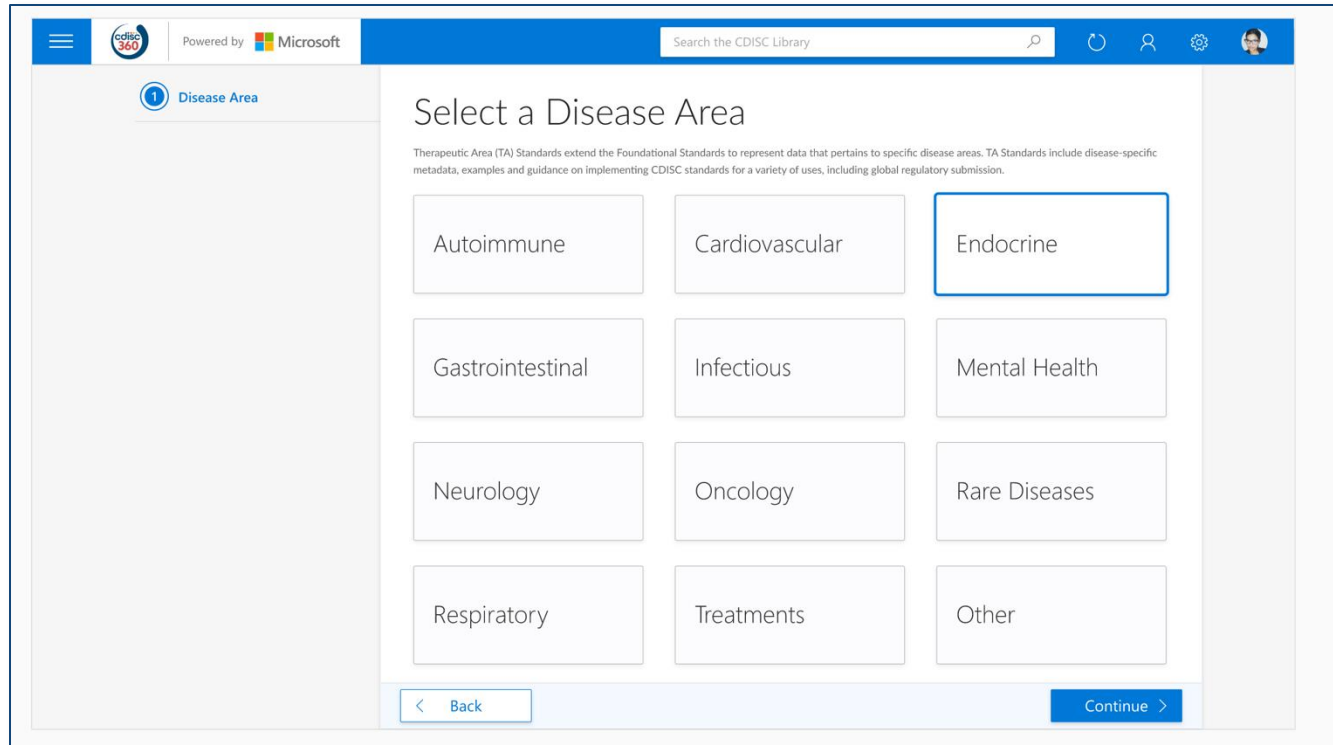
Scope

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



The screenshot displays the CDISC 360 web application interface. At the top, there is a blue navigation bar containing the CDISC 360 logo, the text "Powered by Microsoft", a search bar labeled "Search the CDISC Library", and several utility icons (refresh, user profile, settings, and a user avatar). Below the navigation bar, the main content area is titled "1 Disease Area" and "Select a Disease Area". A descriptive paragraph explains that Therapeutic Area (TA) Standards extend Foundational Standards to represent data for specific disease areas, including disease-specific metadata, examples, and guidance on implementing CDISC standards. The interface features a grid of 12 selectable disease area categories: Autoimmune, Cardiovascular, Endocrine, Gastrointestinal, Infectious, Mental Health, Neurology, Oncology, Rare Diseases, Respiratory, Treatments, and Other. The "Endocrine" category is currently selected, indicated by a blue border. At the bottom of the grid, there are two buttons: a light blue "Back" button with a left arrow and a dark blue "Continue" button with a right arrow.

CDISC 360: The Art of the Possible

The screenshot displays the CDISC 360 web application interface. At the top, there is a blue header bar containing the CDISC 360 logo, the text "Powered by Microsoft", a search bar labeled "Search the CDISC Library", and several utility icons (refresh, user profile, settings, and a user avatar). On the left side, a vertical navigation pane shows two steps: "1 Disease Area" with a checkmark and "Endocrine" selected, and "2 Therapeutic Area" which is currently active. 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 text, seven rectangular buttons are arranged in a grid, each representing a therapeutic area: "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 of the interface, there are two buttons: a "Back" button with a left-pointing arrow and a "Continue" button with a right-pointing arrow.

CDISC 360: The Art of the Possible

The screenshot displays the CDISC 360 web application interface. At the top, there is a navigation bar with the CDISC 360 logo, the text "Powered by Microsoft", a search bar labeled "Search the CDISC Library", and icons for home, user profile, settings, and a user avatar. On the left side, there is a vertical navigation menu with five items: "1 Disease Area" (checked Endocrine), "2 Therapeutic Area" (checked Diabetes - Type 2), "3 Standards Focus" (checked Study Endpoint), "4 Study Endpoint" (checked Analysis of Glycated Hemoglobin), and "5 Standard Analyses" (highlighted in blue). The main content area is titled "Select from Standard Analyses" and features three analysis options, each with a preview image and a "View details" link. The first option, "HbA1c Longitudinal Repeated Measures Analysis", includes a table titled "Table 11.1 HbA1c Longitudinal Repeated Measures Analysis Table 11.1". The second option, "Mean Change from Baseline in HbA1c (%) Over Time", includes a line graph showing mean change over time for two groups. The third option, "HbA1c Categorical Analysis", includes a table titled "Table 11.2 HbA1c Categorical Analysis Table 11.2". At the bottom of the main content area, there are "Back" and "Continue" navigation buttons.

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 360: The Art of the Possible

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Selection Summary

Study Endpoint

Analysis of Glycated Hemoglobin

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.

[View details](#)

Analysis

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](#)
[View analysis results metadata](#)

Analysis Datasets

ADSL

Analysis Data Subject Level

[View analysis dataset metadata](#)
[View sample analysis data](#)
[View analysis dataset structure](#)

ADHBA1C

DBS - Structured Dataset

[View analysis dataset metadata](#)
[View sample analysis data](#)
[View analysis dataset structure](#)

[Back](#) [Save Selection](#)

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Selection Summary

Study Endpoint Analysis

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-Week Period, Intention-to-treat Population
ANALYSIS REASON	Treatment difference results (LSMean, confidence interval, p-value)
RESULT IDENTIFIER	HBA1c (%)
PARAM	HBA1C
PARAMCD	CHG (Change from baseline)
ANALYSIS VARIABLE	ADHBA1C
ANALYSIS DATASET	SPICEDIN SAS
ANALYSIS PURPOSE	PRIMARY OUTCOME MEASURE
SELECTION CRITERIA	ADHBA1C ITYPE = "Y" and PARAMCD = "HBA1C" and CRG se and ANLQFL = "Y" and DTYPE = ""
DOCUMENTATION	See SAP Section XX for details. Program: s_hba1c_erp_sas LS means and 95% CIs are based on planned treatment, baseline HBA1c value, visit, event/baseline and event/treatment interaction.
PROGRAMMING STATEMENTS	<pre> [SQL version 3.2] PROC MIXED DATA = ADHBA1C; WHERE ITYPE = "Y" and PARAMCD = "HBA1C" and CRG se and ANLQFL = "Y" and CLASS TRTY AVISIT; MODEL CRG = TRTY BASE AVISIT BASE*AVISIT AVISIT*TRTY / COV=PSY; LAMBDA TRTY / CL DTYPE REPEATED variable = ADHBA1C / DTYPE= TYPE=MC; RUN ; </pre>

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Selection Summary

Study Endpoint Analysis Analysis Datasets

Analysis Dataset Metadata

Keys	Location	Documentation
ADYID, USUBJID,	ADHBA1C.sas	ADHBA1C.SAS.SAP
PARAMCD, AVISIT, ADY		

Save Data Standards

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Selection Summary

Study Endpoint Analysis Analysis Datasets

Sample Analysis Data

Table 4.1.1: ADHBA1C Analysis Dataset

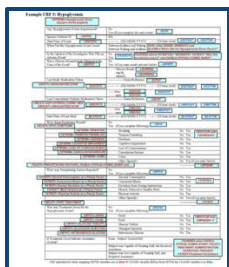
Row	STUDYID	USUBJID	PARAM	PARAMCD	VSMT	AVISIT	AWT	TARGET	ADY	TRTP	ITYPE	LABFL	BASL	AVAL	CRG	ANLQFL	CRIT1	CRITFL	DTYPE	LSMEQ		
1	XYZ	XYZ-001-001	HBA1C (%)	HBA1C	Visit 2	Baseline	1	1	[Drug A]	Y	Y	9.2	9.2	Y	<7%	N			<7%	N	23456	
2	XYZ	XYZ-001-001	HBA1C (%)	HBA1C	Visit 3	Week 8	28	28	[Drug A]	Y	Y	9.2	8.5	-0.7	Y	<7%	N			<7%	N	45125
3	XYZ	XYZ-001-001	HBA1C (%)	HBA1C	Visit 3	Week 8	56	56	[Drug A]	Y	Y	9.2	7.3	-1.9	Y	<7%	N			<7%	N	24768
4	XYZ	XYZ-001-001	HBA1C (%)	HBA1C	Visit 3	Week 12	84	84	[Drug A]	Y	Y	9.2	6.8	-2.4	Y	<7%	Y			<7%	Y	76553
5	XYZ	XYZ-001-001	HBA1C (%)	HBA1C	Visit 3	Week 24	168	168	[Drug A]	Y	Y	9.2	6.3	-2.9	Y	<7%	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			<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			<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			<7%	N	50744
9	XYZ	XYZ-001-002	HBA1C (%)	HBA1C	Visit 5	Week 8	56	61	[Drug B]	Y	Y	8.6	9.5	1.1	Y	<7%	N			<7%	N	67543
10	XYZ	XYZ-001-002	HBA1C (%)	HBA1C	Visit 5	Week 12	84	81	[Drug B]	Y	Y	8.6	9.5	1.1	Y	<7%	N			<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			<7%	N	LOCF 67543

Save Data Standards



What did we learn from CDISC 360?

CDISC Foundational Standards



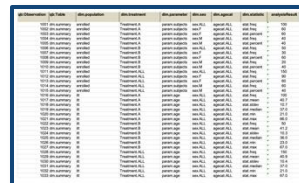
Example CDASH Data Collection Form

Data Collection
CDASH



SDTM Data Aggregation Table

Data Aggregation
SDTM



ADaM Analysis Table

Analysis
ADaM

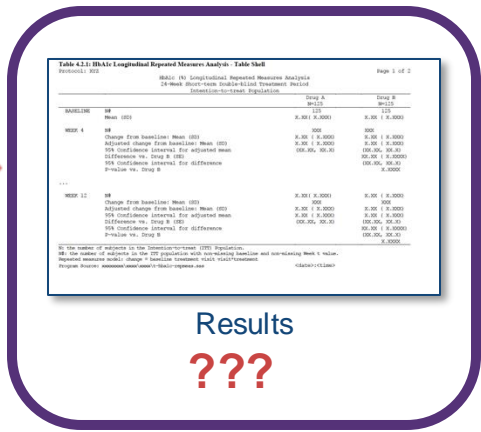


Table 4.2.1: BLAA Longitudinal Repeat Measures Analysis: Table 4.2.1

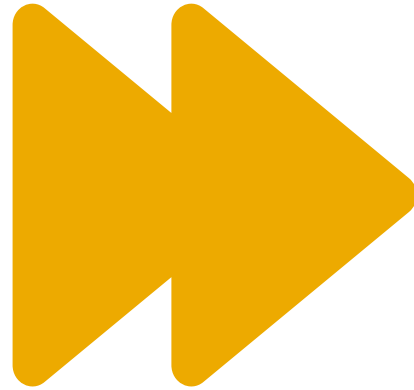
	Group A	Group B
MEAN (SD)	11.0	11.0
SD (95% CI)	5.50 (5.000)	5.50 (5.000)
WEEK 4		
Change from baseline: Mean (SD)	5.00 (5.000)	5.00 (5.000)
Adjusted change from baseline: Mean (SD)	5.00 (5.000)	5.00 (5.000)
95% Confidence Interval for adjusted mean	(00.00, 10.00)	(00.00, 10.00)
Difference vs. Group B (95% CI)	00.00 (00.00)	00.00 (00.00)
95% Confidence Interval for difference	(00.00, 00.00)	00.0000
Proportion vs. Group B		

WEEK 12		
Change from baseline: Mean (SD)	5.00 (5.000)	5.00 (5.000)
Adjusted change from baseline: Mean (SD)	5.00 (5.000)	5.00 (5.000)
95% Confidence Interval for adjusted mean	5.00 (5.000)	5.00 (5.000)
Difference vs. Group B (95% CI)	(00.00, 10.00)	(00.00, 10.00)
95% Confidence Interval for difference	(00.00, 00.00)	(00.00, 00.00)
Proportion vs. Group B		

SD: the number of subjects in the denominator is the number of subjects in the denominator of the population.
95%: the number of subjects in the 95% population with specified baseline and non-zero Week 4 value.
Adjusted measure (mean): change = baseline treatment - last visit/treatment.
Proportion measure: comparison (mean) = (mean) - (proportion) - (mean)

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 \(ARS\)](#), 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/>

Class	Description
NamedObject	An object with a name
ReportingEvent	A set of analyses and outputs created to meet requirements...
ListOfContents	A structured list of analyses and outputs...

Date	Version
2024-04-19	Final

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

Analysis Results Key Objectives

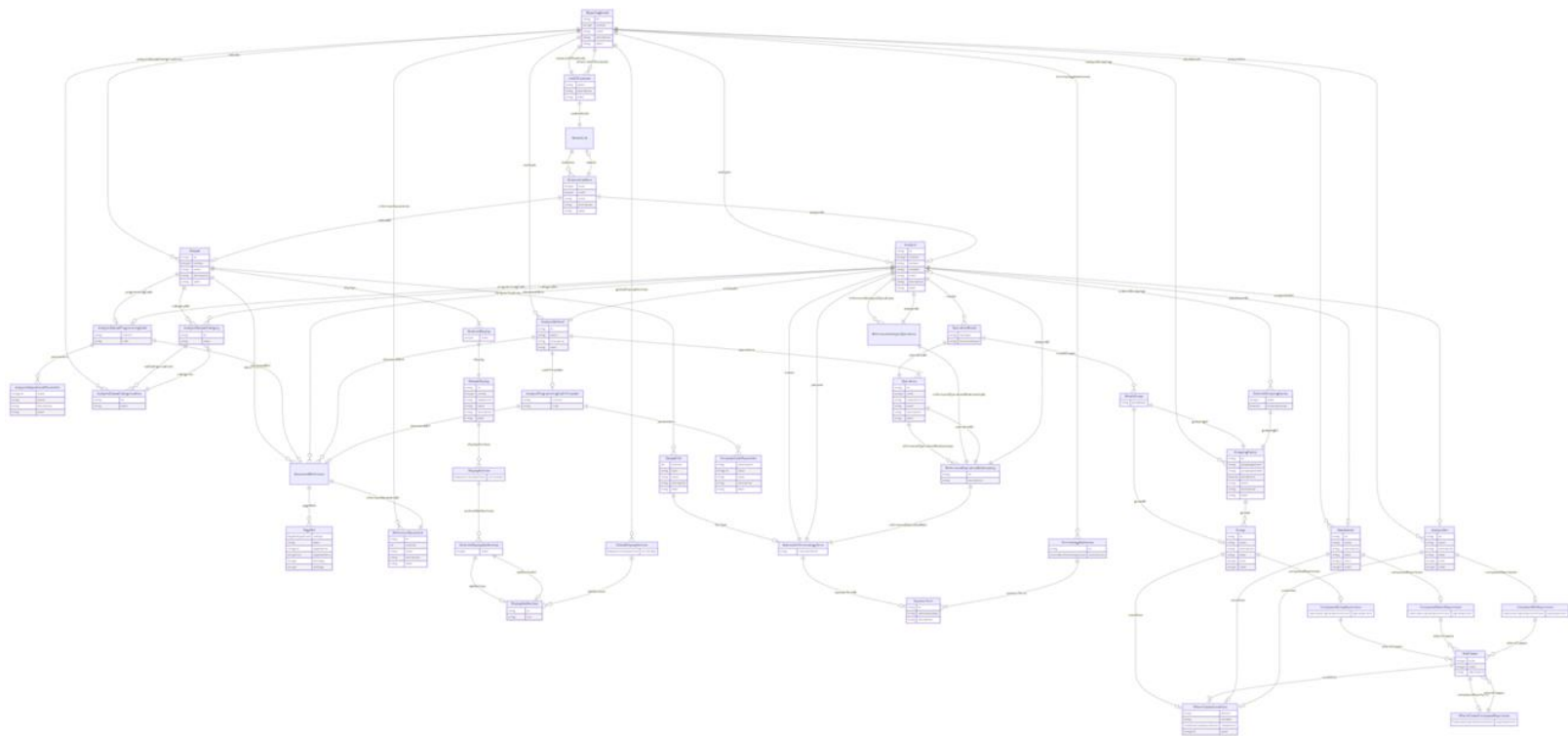


Leverage analysis results metadata to drive the automation of results

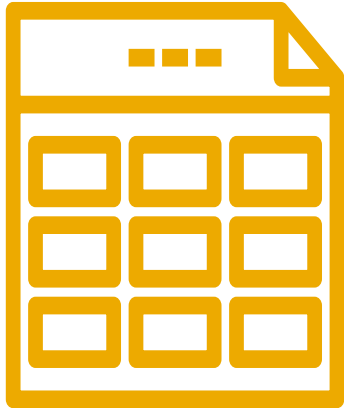


Support storage, access, processing, traceability and reproducibility of results

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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                {
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                  "level": 3,
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ADaM Dataset

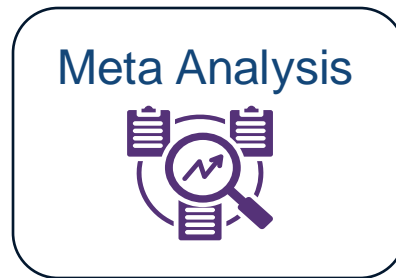
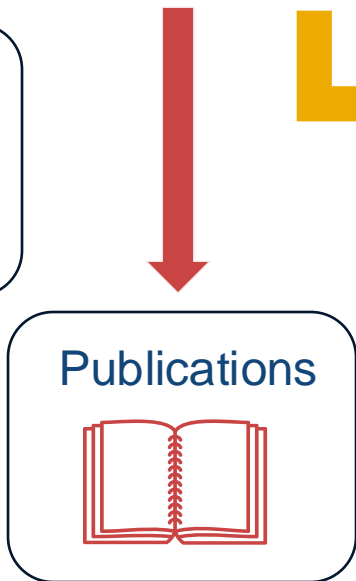
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01-701-1023	Placebo	64	<65	YEARS	WHITE	M
01-701-1028	Xanomeline High Dose	71	65+	YEARS	WHITE	M
01-701-1033	Xanomeline Low Dose	74	65+	YEARS	WHITE	M
01-701-1034	Xanomeline High Dose	77	65+	YEARS	WHITE	F
01-701-1047	Placebo	85	65+	YEARS	WHITE	F

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An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_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)





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.



CDISC Knowledge Base

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Knowledge Base

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Welcome to the CDISC Knowledge Base!

cdisc Site Number Subject Number

Form DM - Demographics

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

Articles

- 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
...tical event. For most adverse
...ured on a continuous scale;
... actual severity, not data
... zontal lines divide severity
... "Moderate", and "Severe",
... rse 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):

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
- Codellists for FA Test Names and Test Codes**
Standard(s): SDTMIG
- "COUNTRY" Terminology Change**
Standard(s): SDTMIG
- Type mismatch for ECDOSTOT**
Standard(s): SDTMIG

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

- 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.
- 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



eTFL Portal

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

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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 \geqX% 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

View

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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

Baseline Demographic and Clinical Characteristics

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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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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

Baseline Demographic and Clinical Characteristics

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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 XPOR 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

Provide Feedback!

The screenshot shows the eTFL Portal interface. On the left is a sidebar menu with options like Dashboard, Articles, Examples, Known Issues, eCRF Portal, and eTFL Portal. The main content area displays a page titled "FDA-DM-T02: Baseline Demographic and Clinical Characteristics" with a table containing one row with ID "FDA-DM-T02". An overlay titled "Review Comment Instructions" is positioned in the foreground.

Review Comment Instructions

To create a review comment for this package component:

1. Select "**Review Comments:**" above,
2. Hover your mouse cursor over the selected text
3. Create a Jira issue by clicking on the  button.
4. Select or enter the following in the displayed Create Issue dialog:
 - **Project:** eTFL Portal Review
 - **Issue Type:** Choose "Review Comment" or any other type that more accurately describes the type of issue (e.g., "Error/Typo").
 - **Summary:** Change "Review Comments:" to a brief summary of your review finding.
 - **Description:** If needed, enter additional details.
 - **Component/s:** Enter/select the Component shown in the table above.
 - **Link to epic:** Make sure that the checkbox is checked.
5. Click on the Create button.

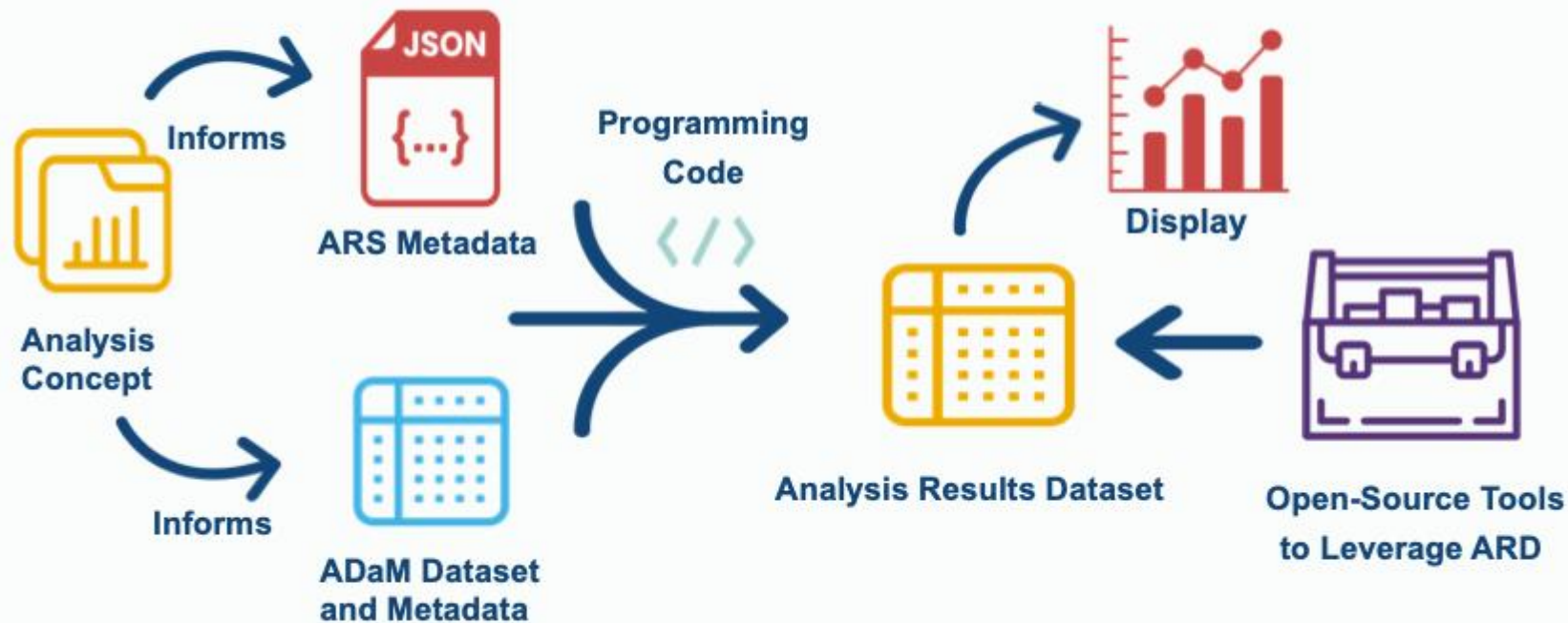
Volunteer!

Select the CDISC Standards Development team that you would like to join. (Please choose one)

- SEND
- CDASH
- SDS
- ADaM
- Controlled Terminology
- Medical Devices
- CORE Rules
- DDF
- Digital Health Technologies
- Genomics Subteam
- QRS
- Tobacco Implementation Guide
- RWD Lineage
- eTFL Portal
- Other...

Additional standards information can be found on our [Standards Page](#).

eTFL Portal Vision





Thank you!



Bess LeRoy

Head of Standards Innovation, CDISC

bleroy@cdisc.org

Bhavin Busa

ARS Product Owner & Co-Lead

bhavin@clymbclinical.com

Richard Marshall

Principal Data Modeler

rmarshall@accuratesystems.co.uk