# Launching theTFL Portal

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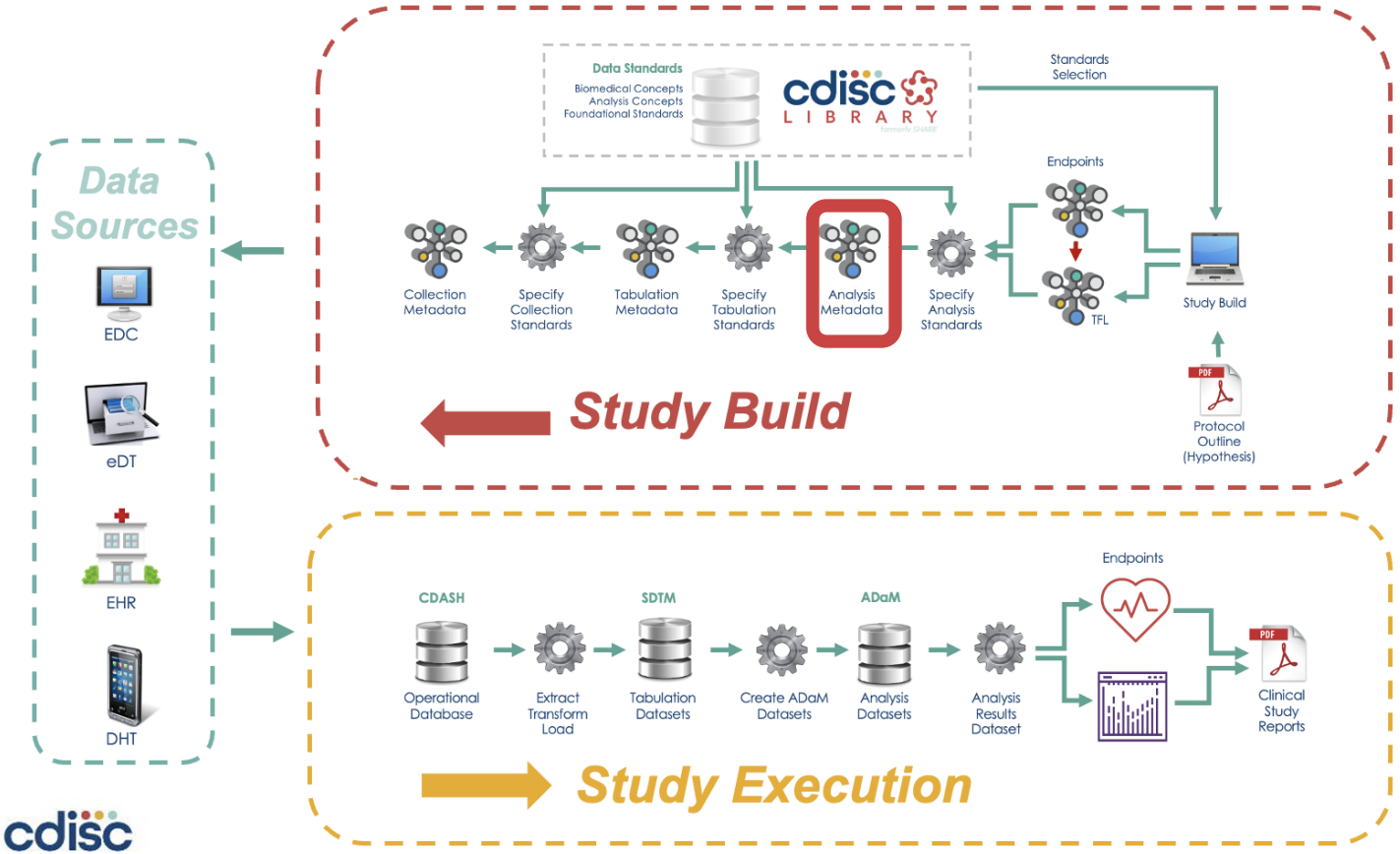
# Agenda

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

# Standardizing Analysis Metadata



# CDISC 360

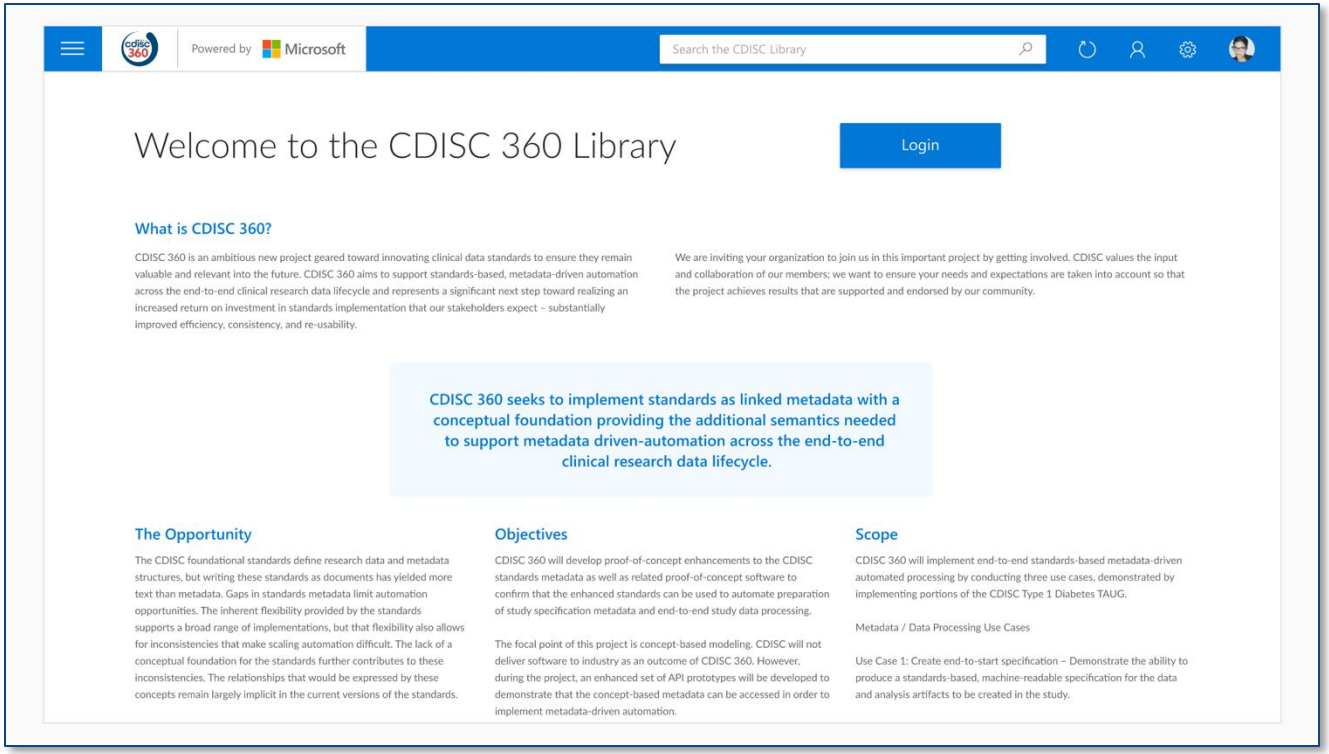
- CDISC 360 was a proof of concept that sought to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata-driven automation across the end- to-end clinical research data lifecycle.

- 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.

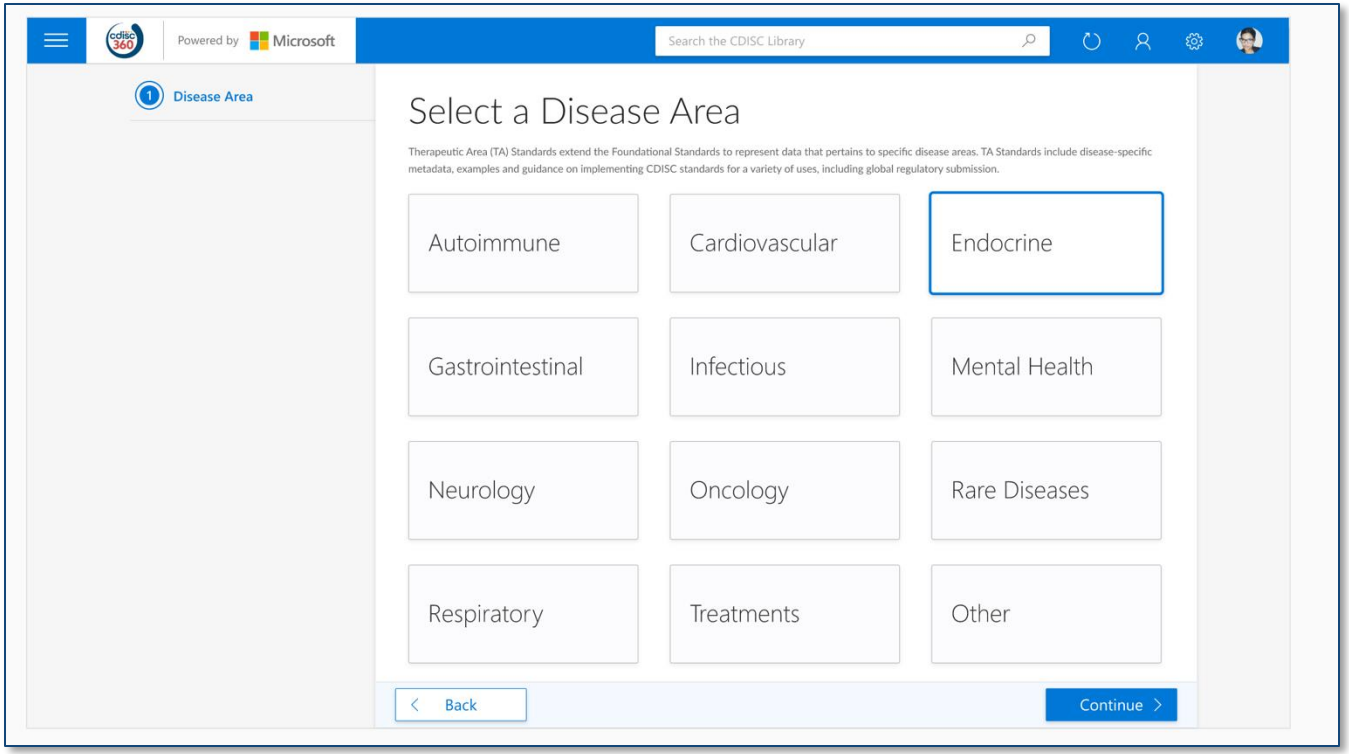
White Paper: https://www.cdisc.org/sites/default/files/2021-06/CDISC_360_Project_White_Paper.pdf

# CDISC 360: The Art of the Possible

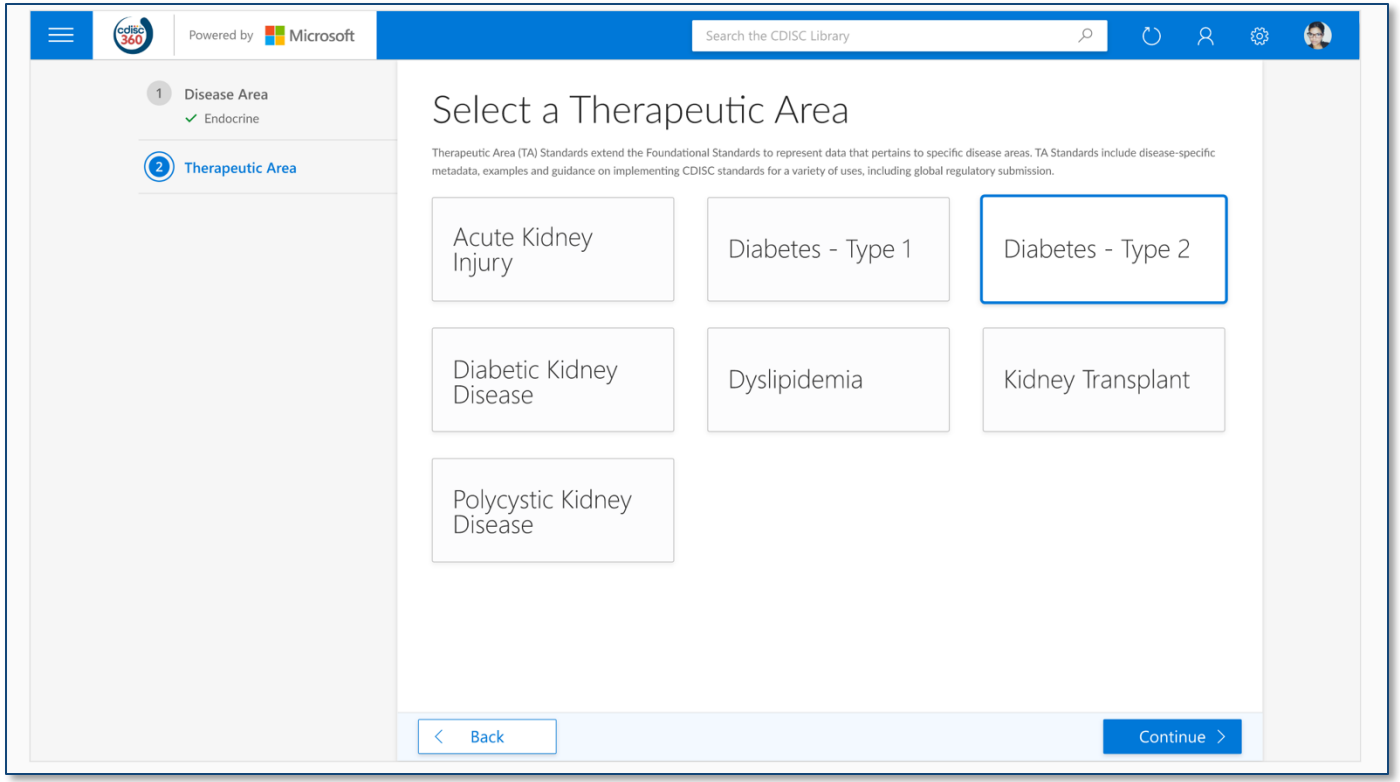



Reference: '*CDISC 360 - The Journey so Far and the Road Ahead*', *Peter Van Reusel, 28th April 2020*

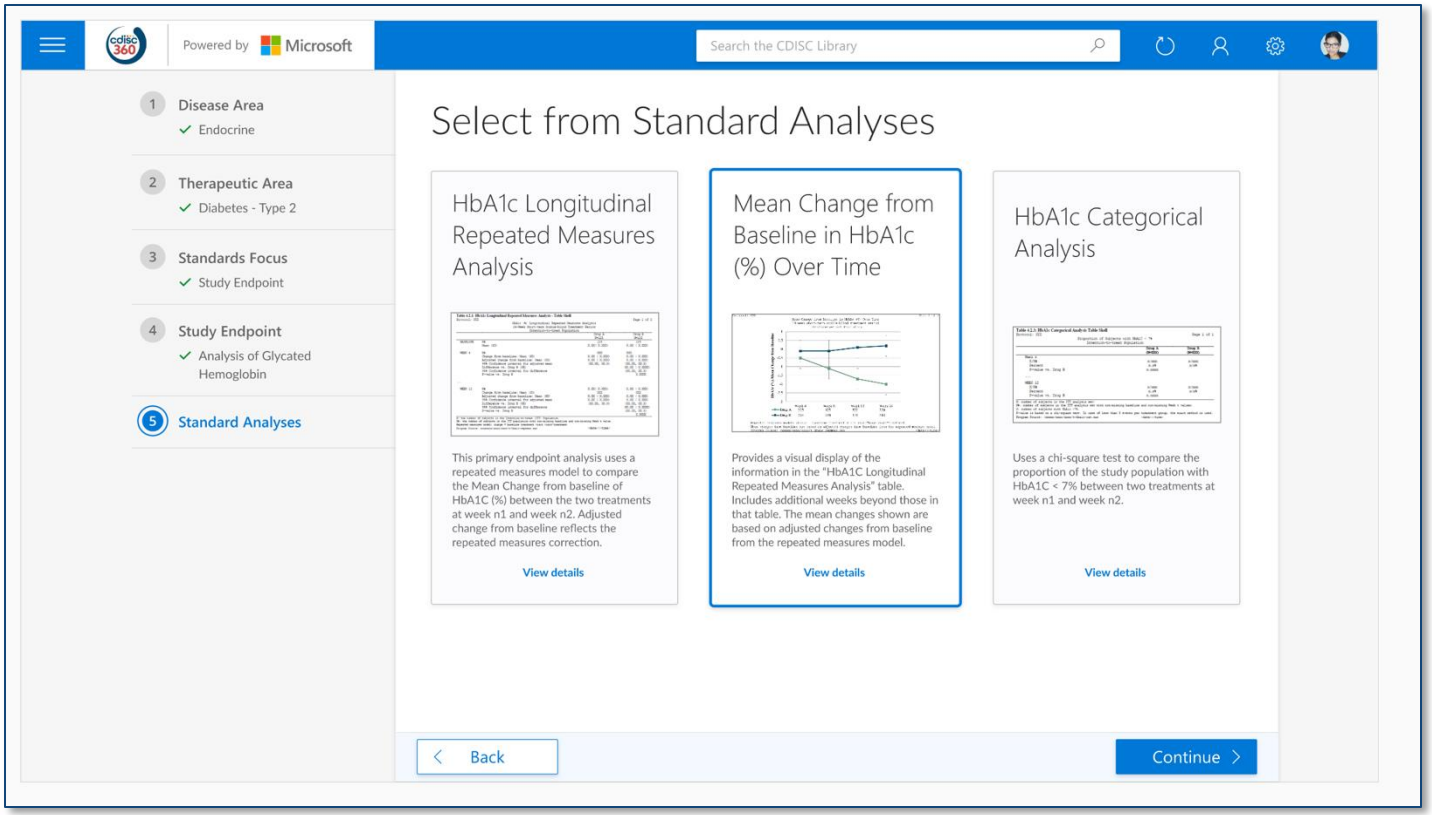
# CDISC 360: The Art of the Possible



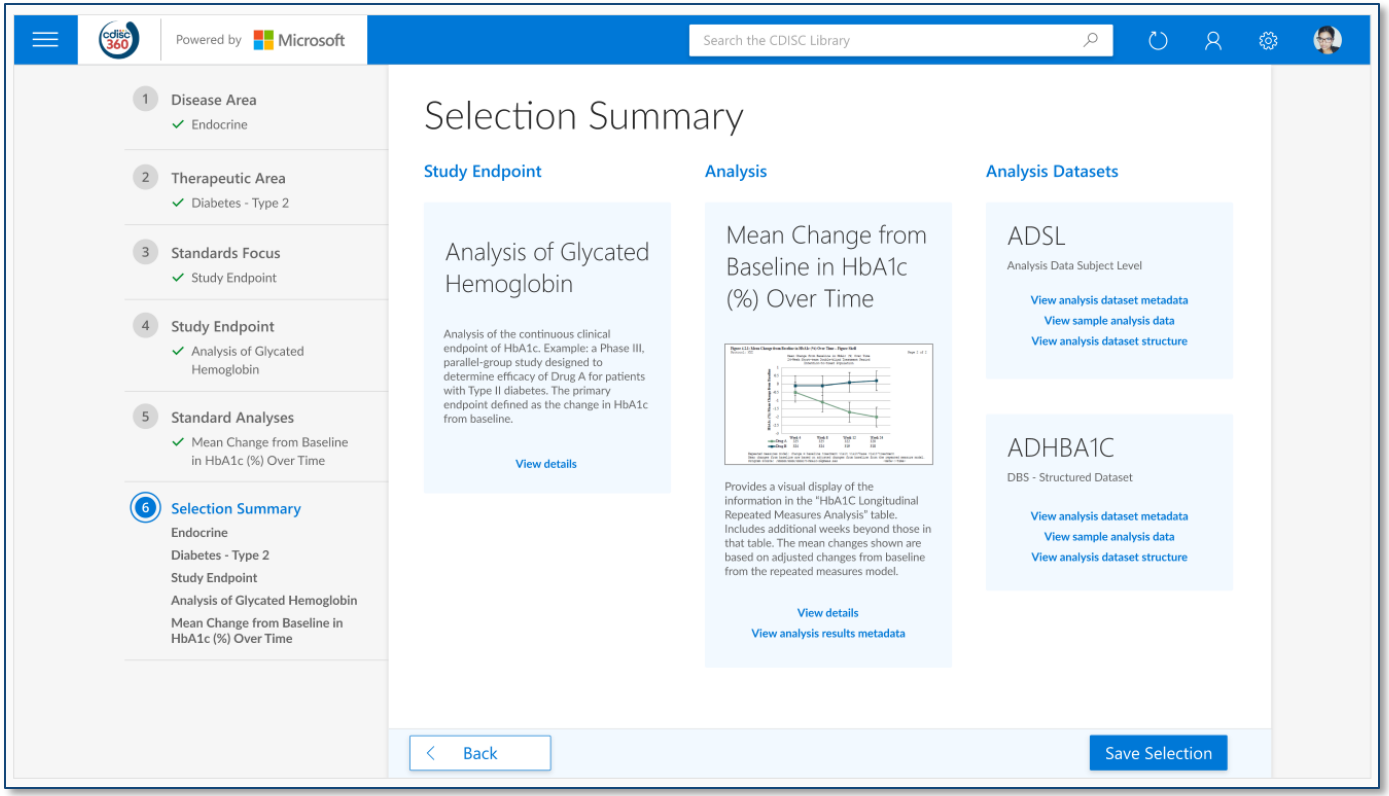
# CDISC 360: The Art of the Possible

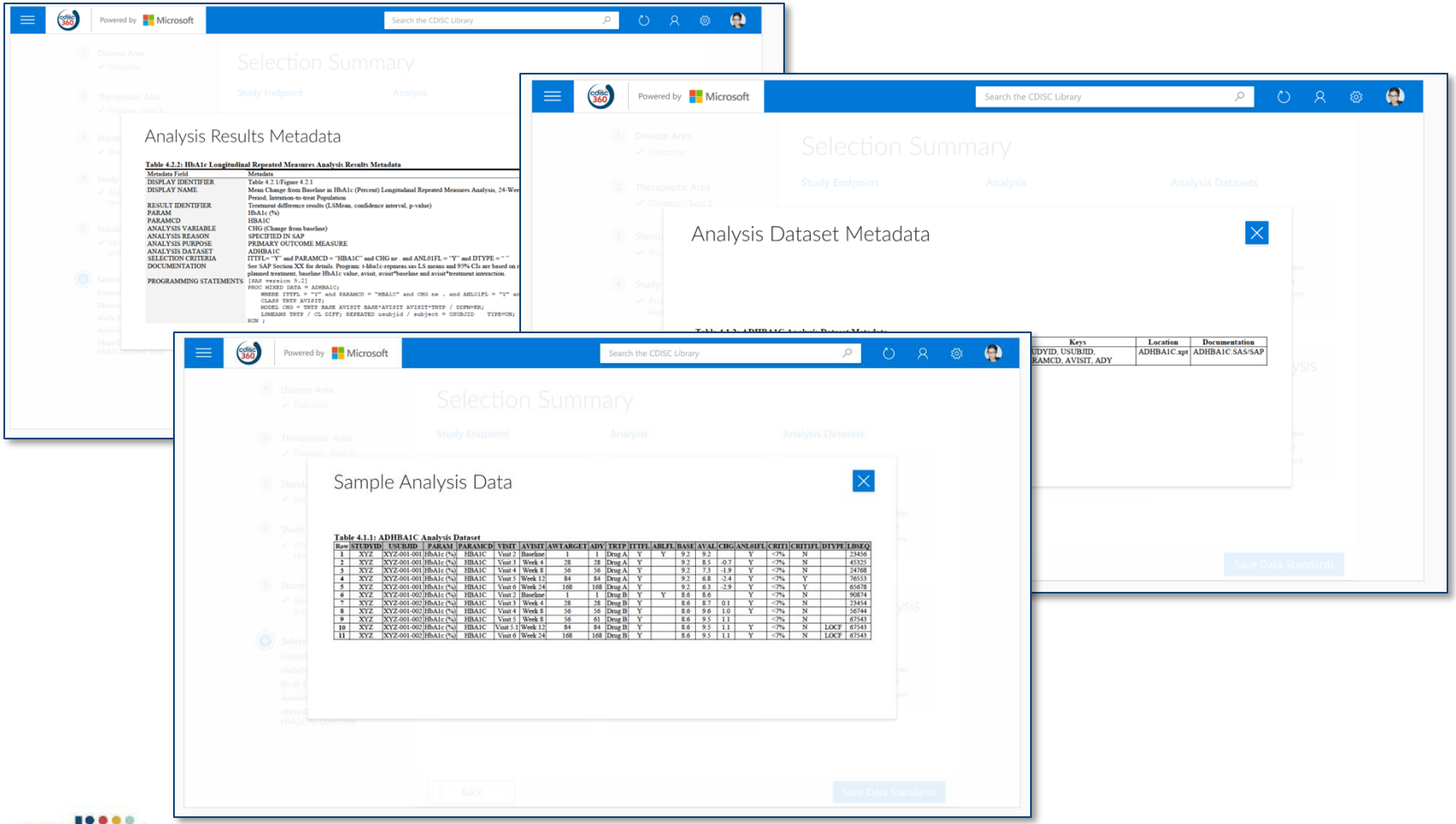


# CDISC 360: The Art of the Possible



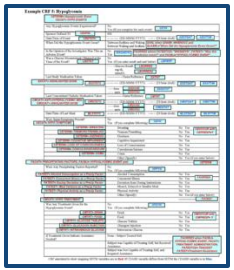
# CDISC 360: The Art of the Possible




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" a
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

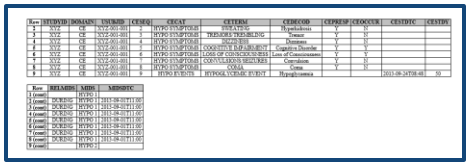
# What did we learn from CDISC 360?

# CDISC Foundational Standards



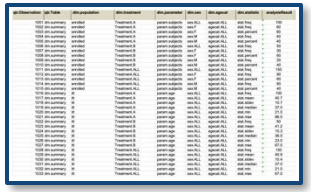
Data Collection

**CDASH**



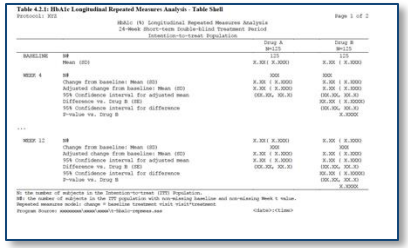
Data Aggregation

**SDTM**



Analysis

**ADaM**



Results

**???**

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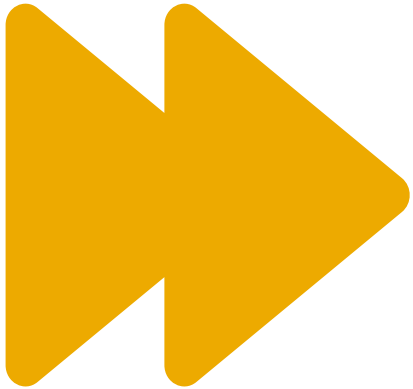
# Fast Forward
# Q1 2021 to Q1 2024



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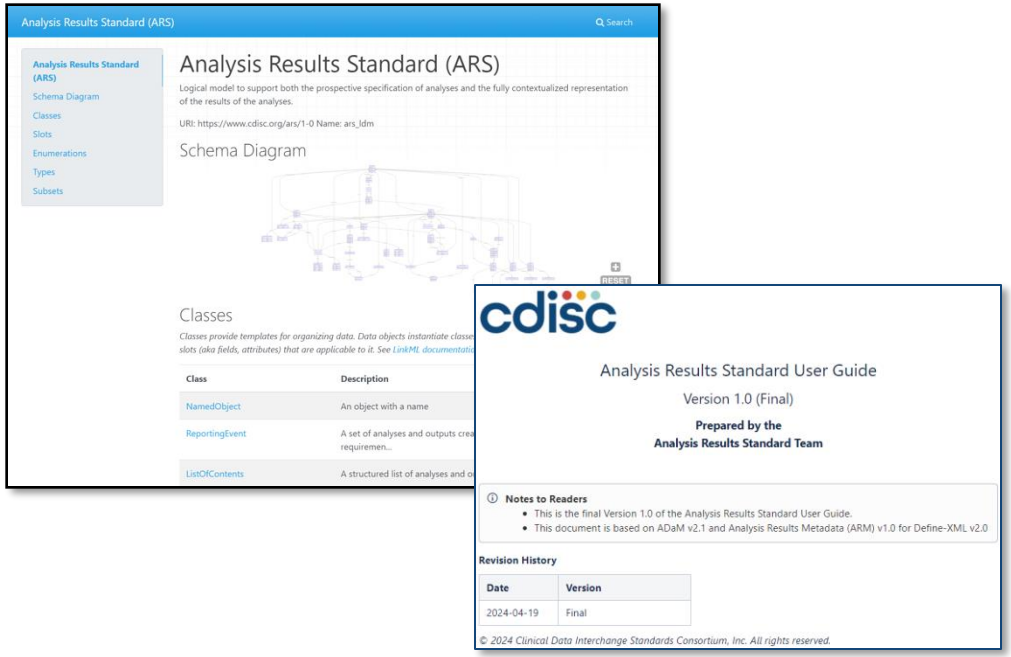
https://cdisc-org.github.io/analysis-results-standard/



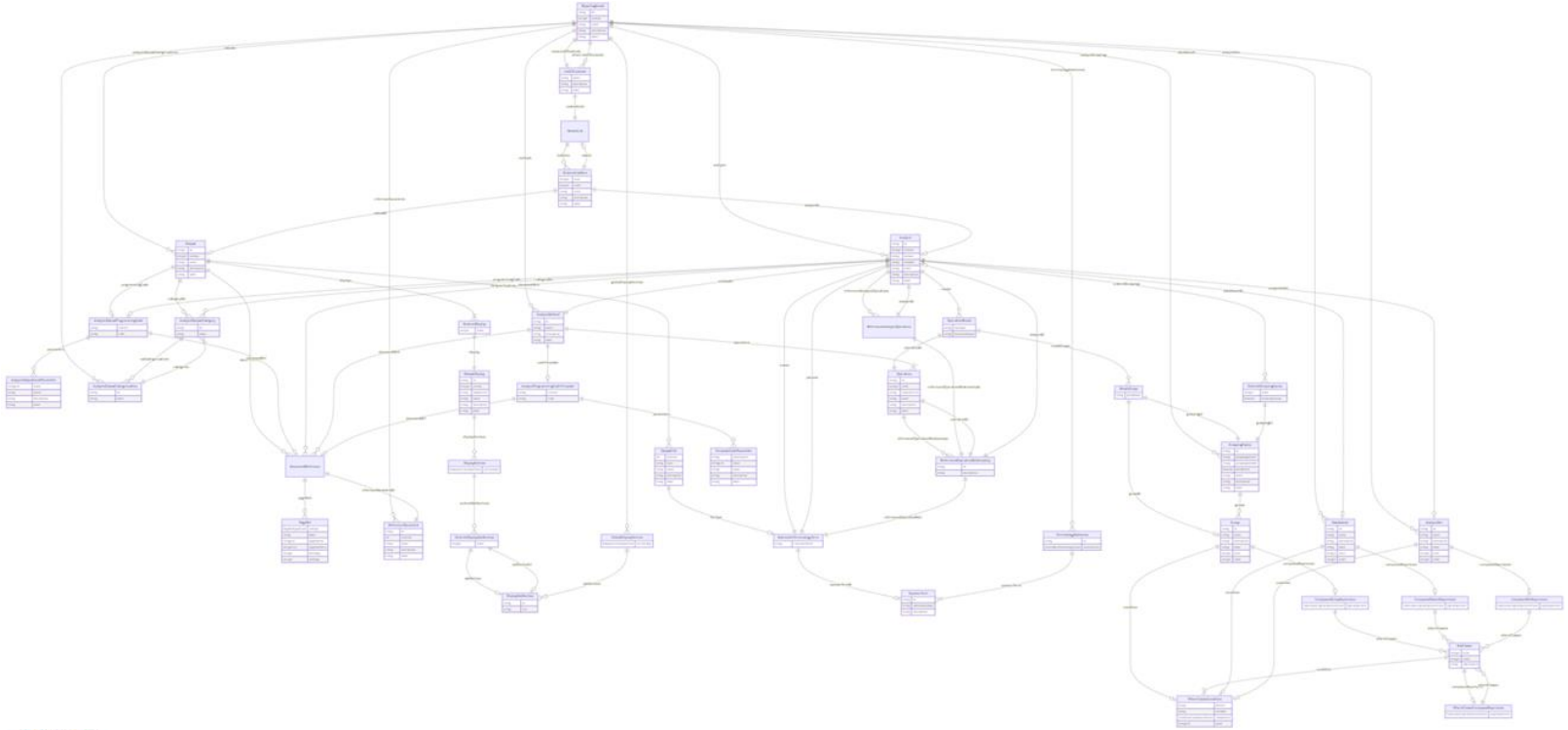

https://wiki.cdisc.org/display/ARSP/Analysis+Results+Standard+User+Guide+v1.0

# Analysis Results Key Objectives

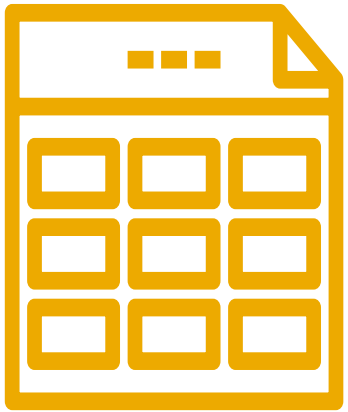
Leverage analysis results metadata to drive the automation of results

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

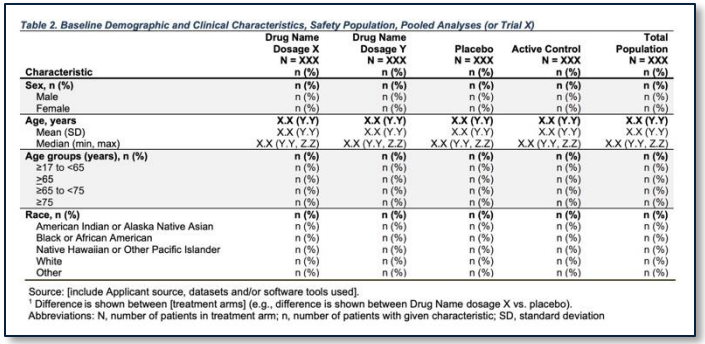


*Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X)*

| 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** | **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 |

| 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 |
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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_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 |
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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_2 | 83.72093 | ( 83.7) |
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| 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

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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 |
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| 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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## 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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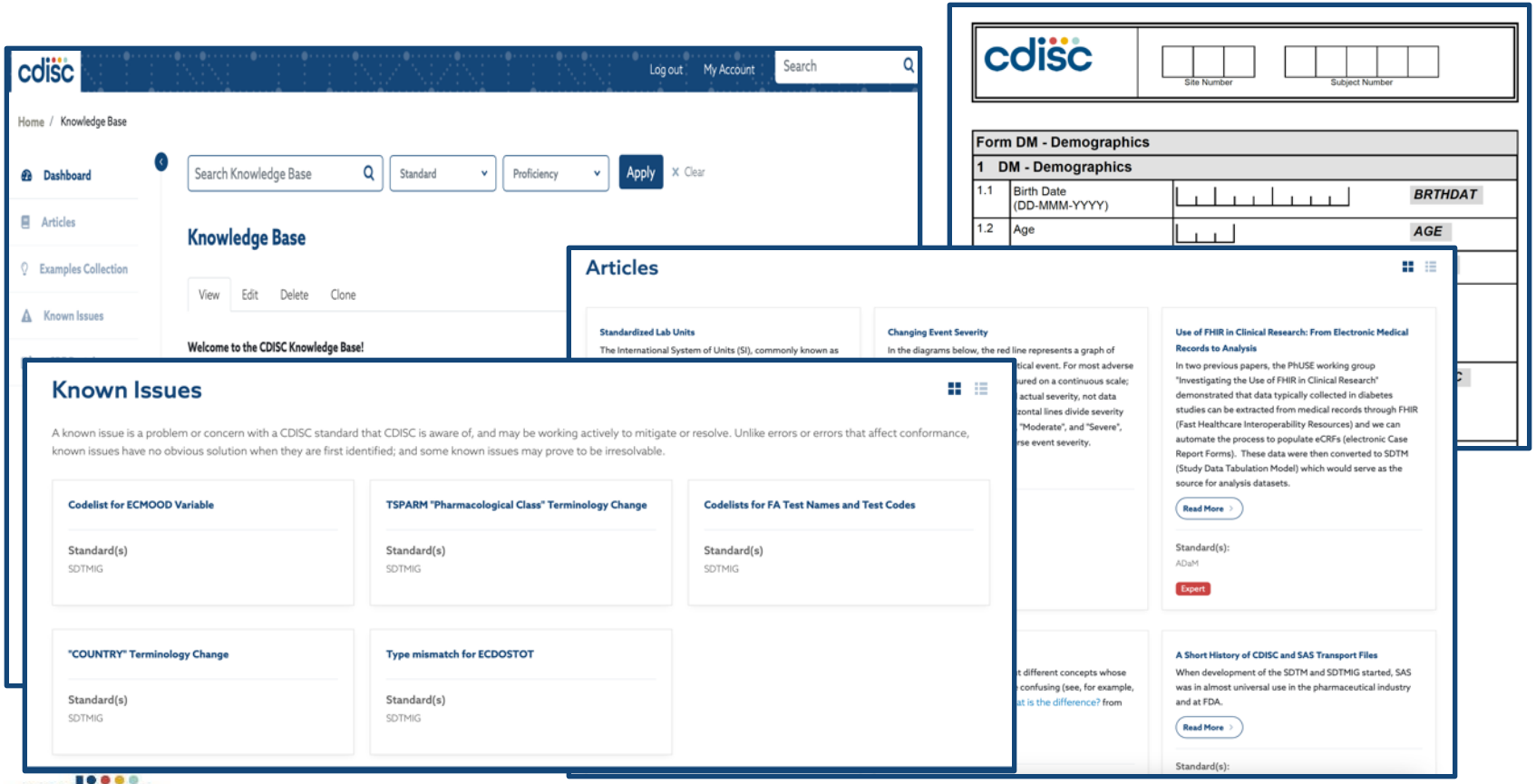
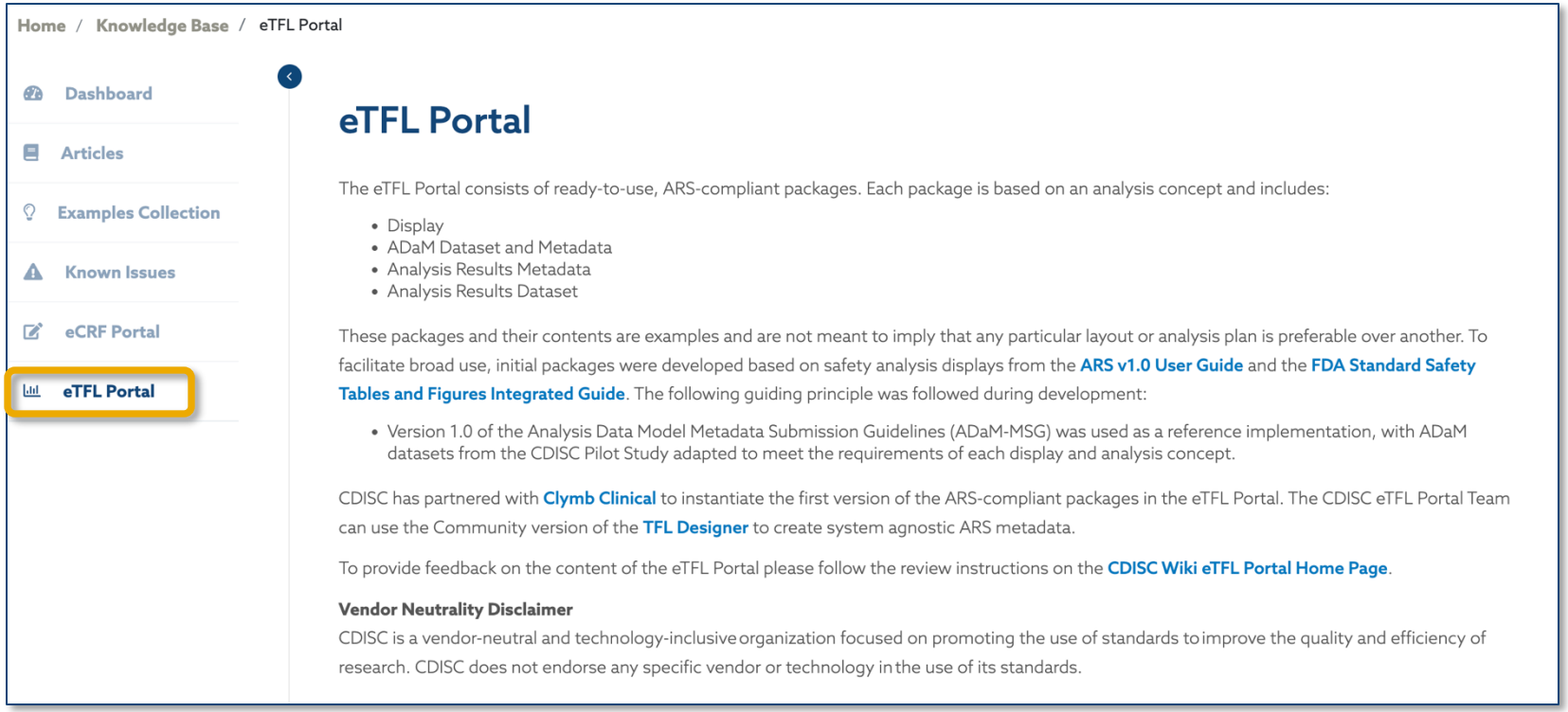
# CDISC Knowledge Base



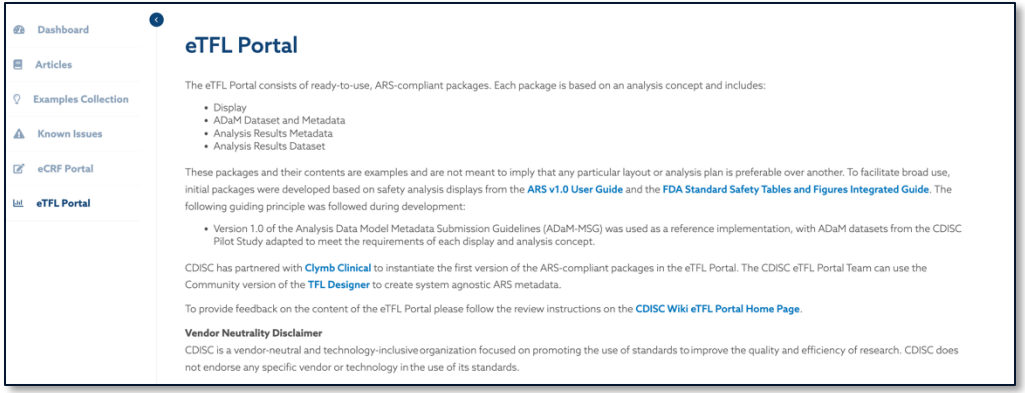
# eTFL Portal in the CDISC Knowledge Base

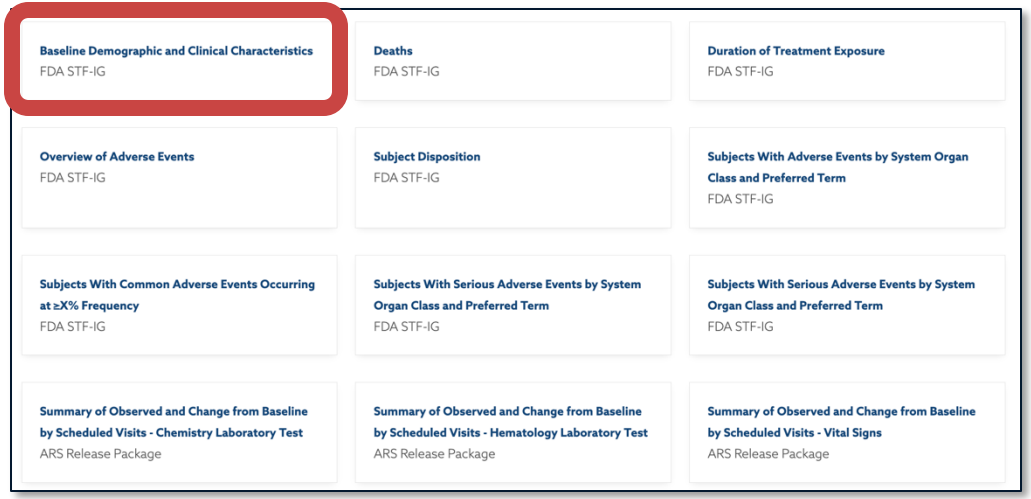



https://cdisc.org/kb/etfl

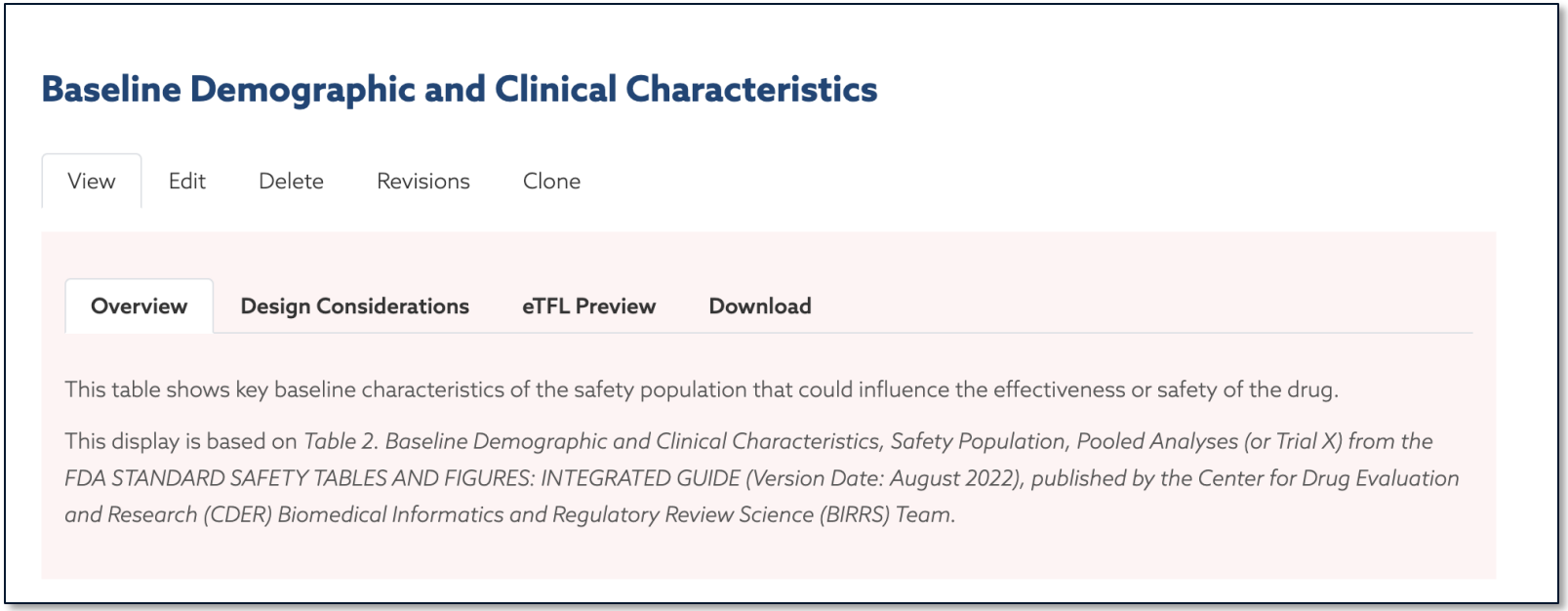
# eTFL Portal

- 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

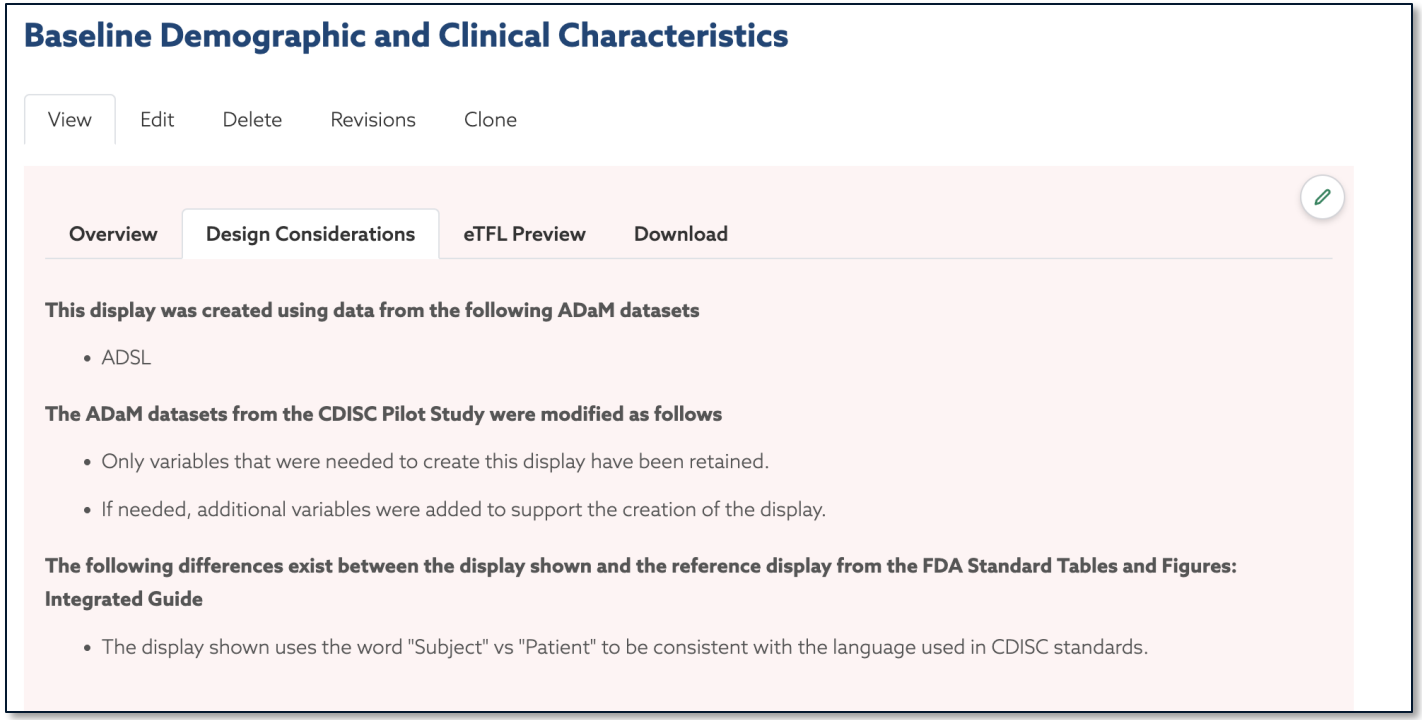


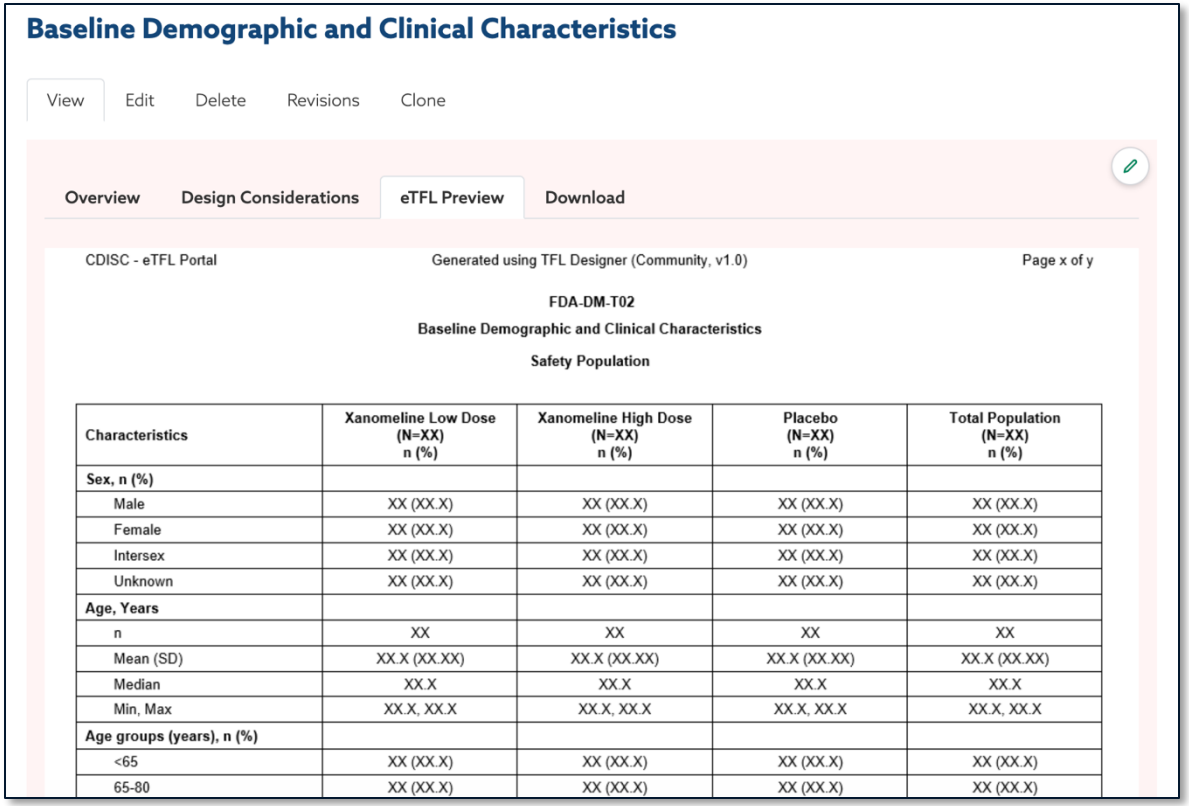
# Overview


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

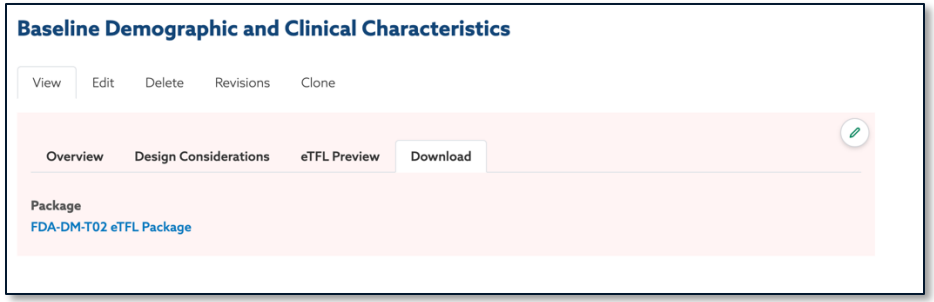
**FDA-DM-T02**

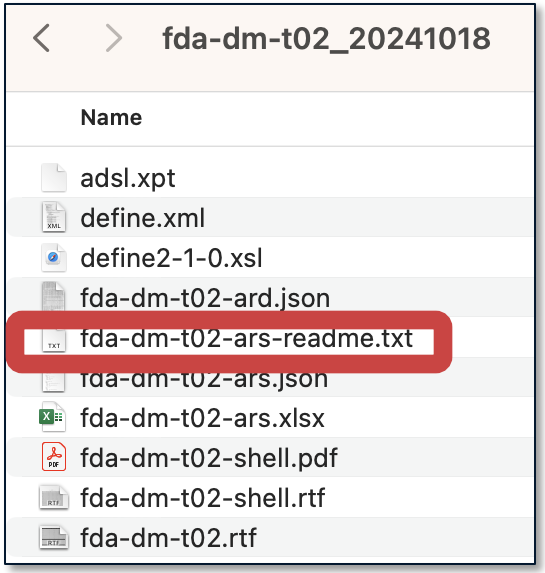
**Baseline Demographic and Clinical Characteristics**

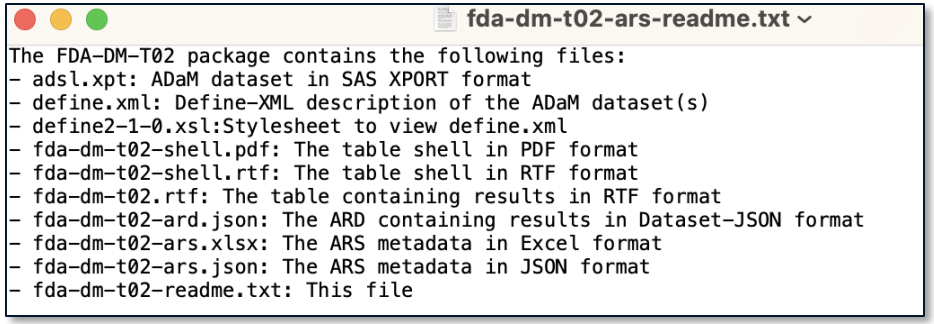
**Safety Population**

| 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) |

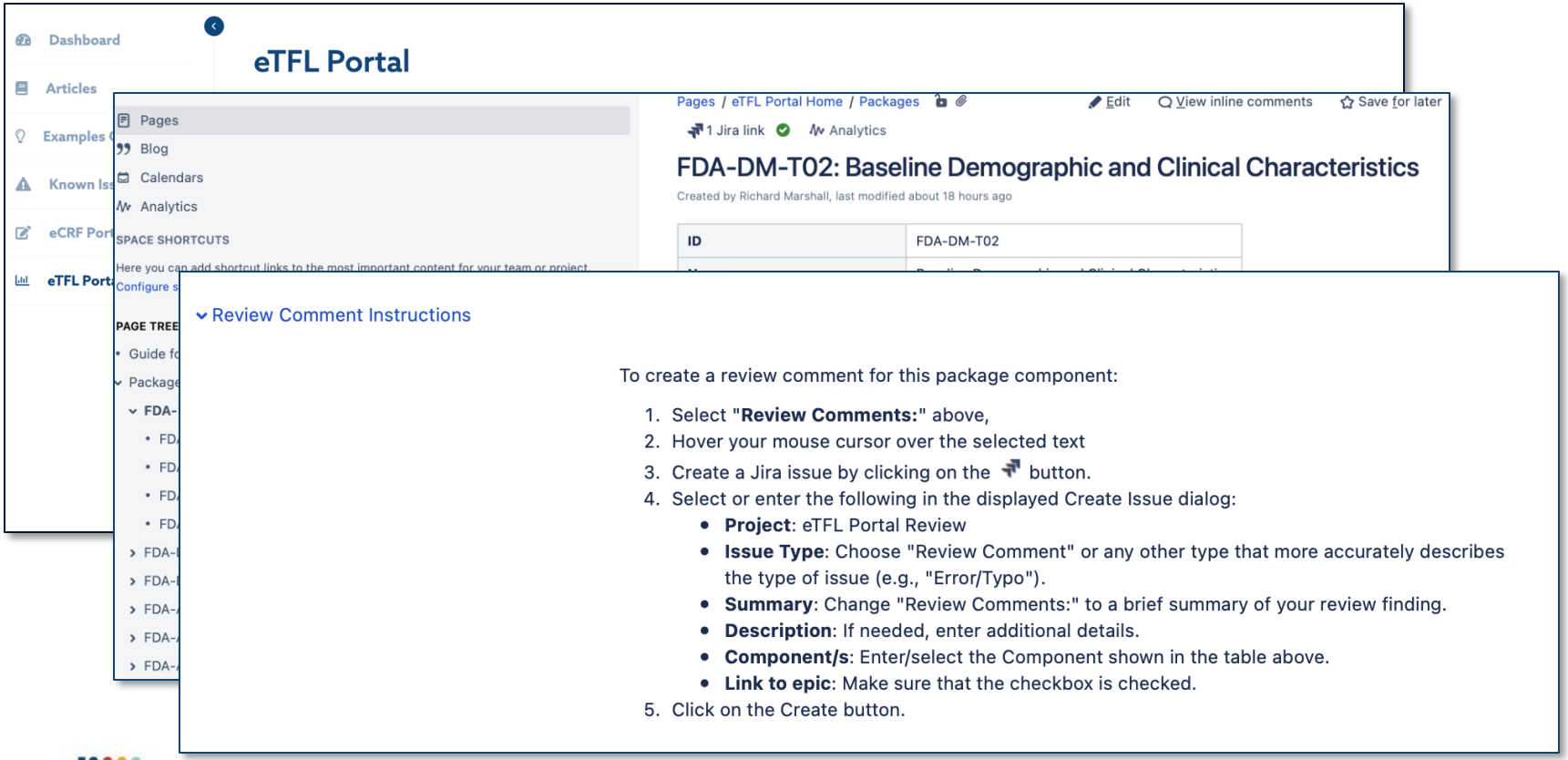
# Package Download



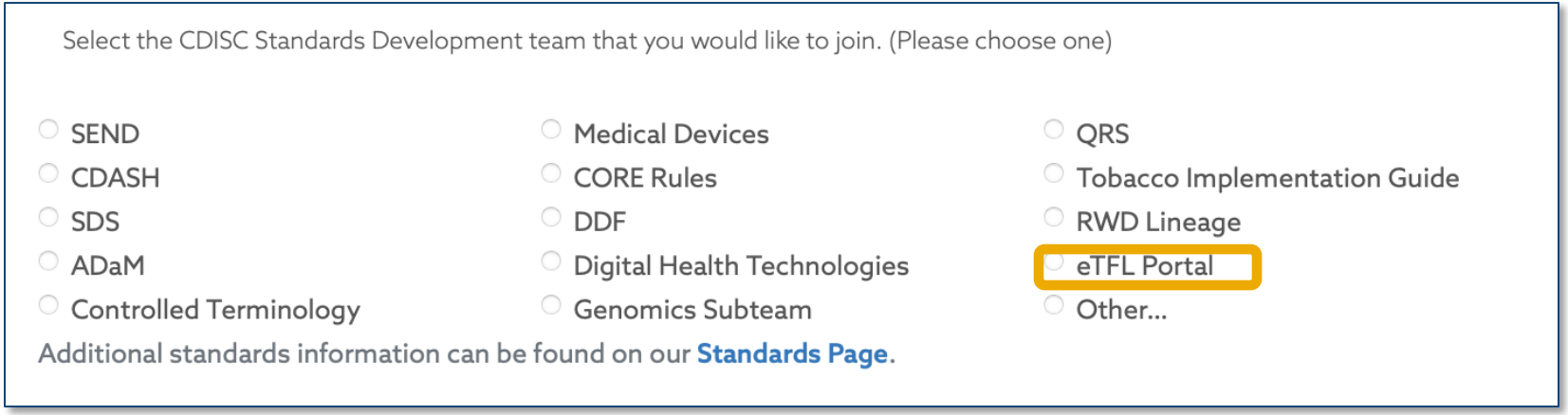



# Provide Feedback!

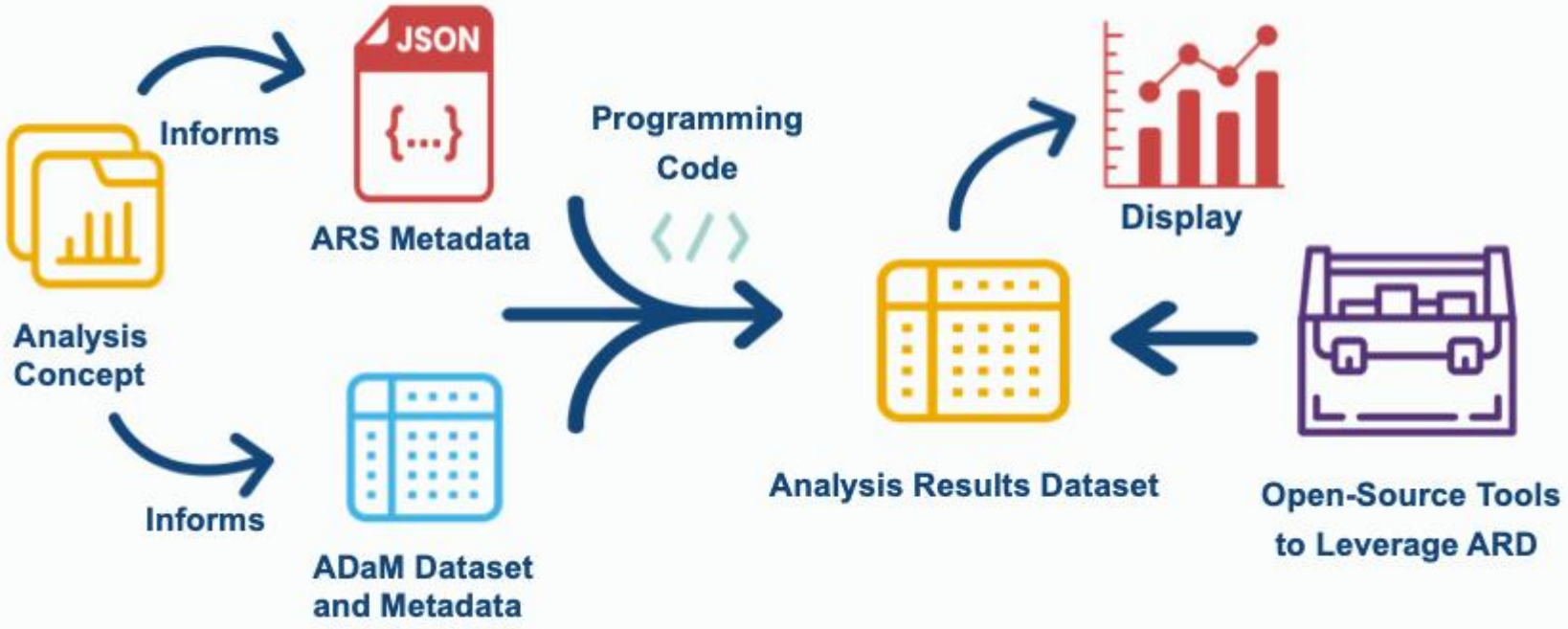


# Volunteer!




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

# eTFL Portal Vision



# Thank you!

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