
# TFL Designer – Streamlining Analysis Results Generation

Bhavin Busa

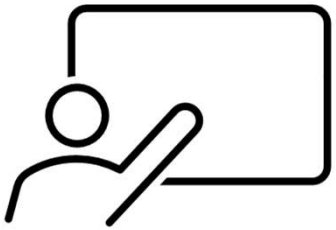
German CDISC User Group Meeting

March 14, 2024

# Current State: Analysis Results Deliverables

- Manual process in designing TFL shells/layout and ADaM specifications
- Programmer writes the SAS code to generate analysis deliverables (sometime with macros or re-using the code)
- Too much variability across studies, disease areas, and organization
- Static results with No or limited linking facility (e.g., to Protocol, SAP, ADaM data)
- There is no industry standards for analysis results

## Poll Summary*



** Results from the live poll (**n=253 responders**) conducted during the TFL Designer Virtual Design Thinking Workshop (Part I), 13th Sep 2022, Bhavin Busa*

**Who attended the workshop**:
- Clinical / Statistical Programmer (**63%**)
- Biostatisticians (**14%**)
- Data Standards Expert (**13%**)
- Other (**12%**)

**Top 5 pain points:**
1. Too much variability across studies / disease areas / organizations
2. No industry-wide standards exist
3. TFL metadata and shells are not machine-readable
4. Multiple manual steps in the process
5. Limited or no automation exist

Programming is more of a Science (**50%**) than it is an Art (**39%**)!

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**74%** organization have TFL standards or templates

Who generates TFL shells (mock-ups)?
**57%** - Biostatistician
**31%** - Biostats & Programmers

**87%** responders confirmed their TFL shells are NOT machine-readable

**65%** responders uses MS Word / RTF for TFL shells generation

**40%** annotate their TFL mock-up shells to provide results metadata information

**76%** do not generate analysis results metadata prospectively to use in their TFL program

**82%** confirmed not having machine-readable TFL analysis results metadata

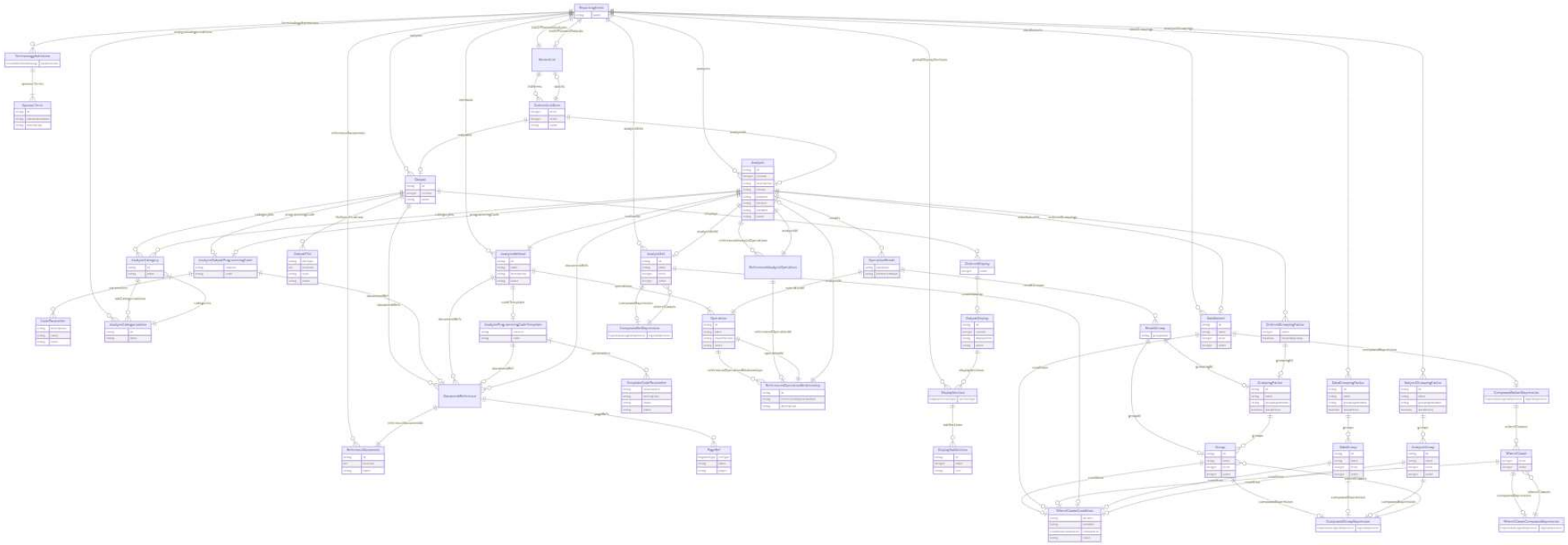
Out of the responders who use machine-readable ARM: MS Excel (**14%**) and SAS (**10%**) are top 2 format choices

# DS04: Getting Started with the New CDISC Analysis Results Standard

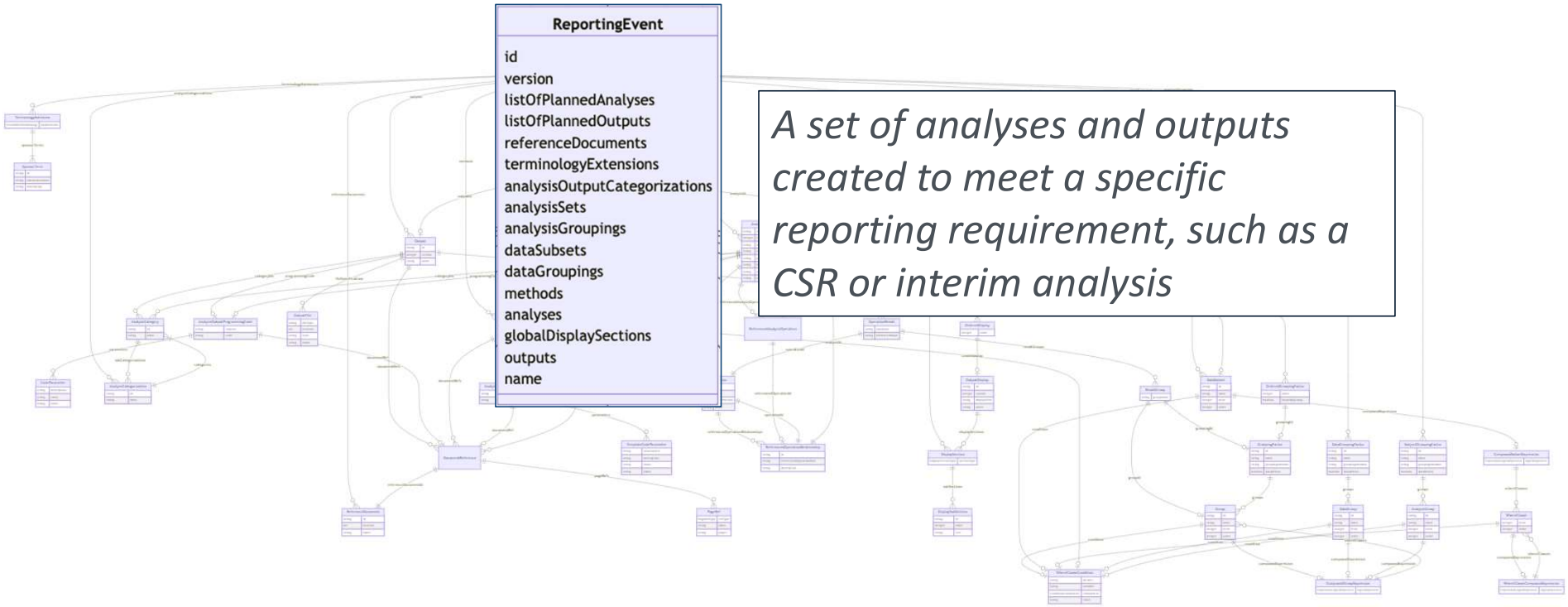
**Bess LeRoy, Head of Standards Innovation, CDISC**

**PHUSE US Connect 24**

# ARS Logical Model Schema Diagram



# ARS Logical Model Schema Diagram: Reporting Event




*A set of analyses and outputs created to meet a specific reporting requirement, such as a CSR or interim analysis*

# Model Components

Reporting Event

## Summary of Demographics

Study – CDISC 360 Page x of y

Table 14.1.1
Summary of Demographics
Safety Population

| Characteristics | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Age (years) | | | |
| n | XX | XX | XX |
| Mean (SD) | XX.X (XX.XX) | XX.X (XX.XX) | XX.X (XX.XX) |
| Median | XX.X | XX.X | XX.X |
| Q1, Q3 | XX.X, XX.X | XX.X, XX.X | XX.X, XX.X |
| Min, Max | XX, XX | XX, XX | XX, XX |
| Age Group, n (%) | | | |
| < 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ≥ 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Gender, n (%) | | | |
| Male | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Female | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Ethnicity, n (%) | | | |
| Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Not Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

## Summary of TEAE by SOC and PT

Study – CDISC 360 Page x of y

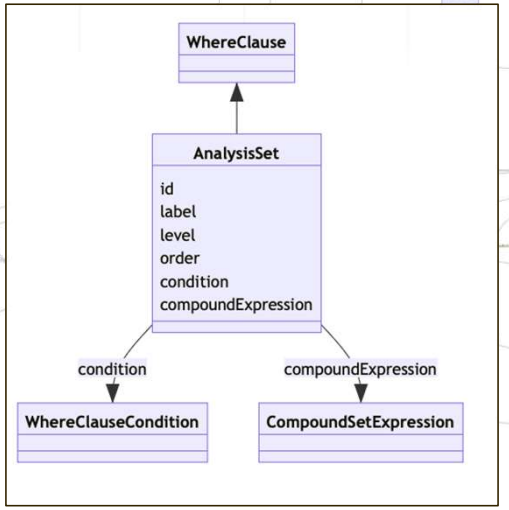
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| System Organ Class<br>Preferred Term [a], n (%) | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Number of subjects with at least one event | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 2> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

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

# ARS Logical Model Schema Diagram: Analysis Set




*The analysis sets (subject populations) defined for the reporting event*

# Model Components

Analysis Set

## Summary of Demographics

Study – CDISC 360 Page x of y

Table 14.1.1
Summary of Demographics
Safety Population

| Characteristics | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Age (years) | | | |
| n | XX | XX | XX |
| Mean (SD) | XX.X (XX.XX) | XX.X (XX.XX) | XX.X (XX.XX) |
| Median | XX.X | XX.X | XX.X |
| Q1, Q3 | XX.X, XX.X | XX.X, XX.X | XX.X, XX.X |
| Min, Max | XX, XX | XX, XX | XX, XX |
| Age Group, n (%) | | | |
| < 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ≥ 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Gender, n (%) | | | |
| Male | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Female | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Ethnicity, n (%) | | | |
| Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Not Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

## Summary of TEAE by SOC and PT

Study – CDISC 360 Page x of y

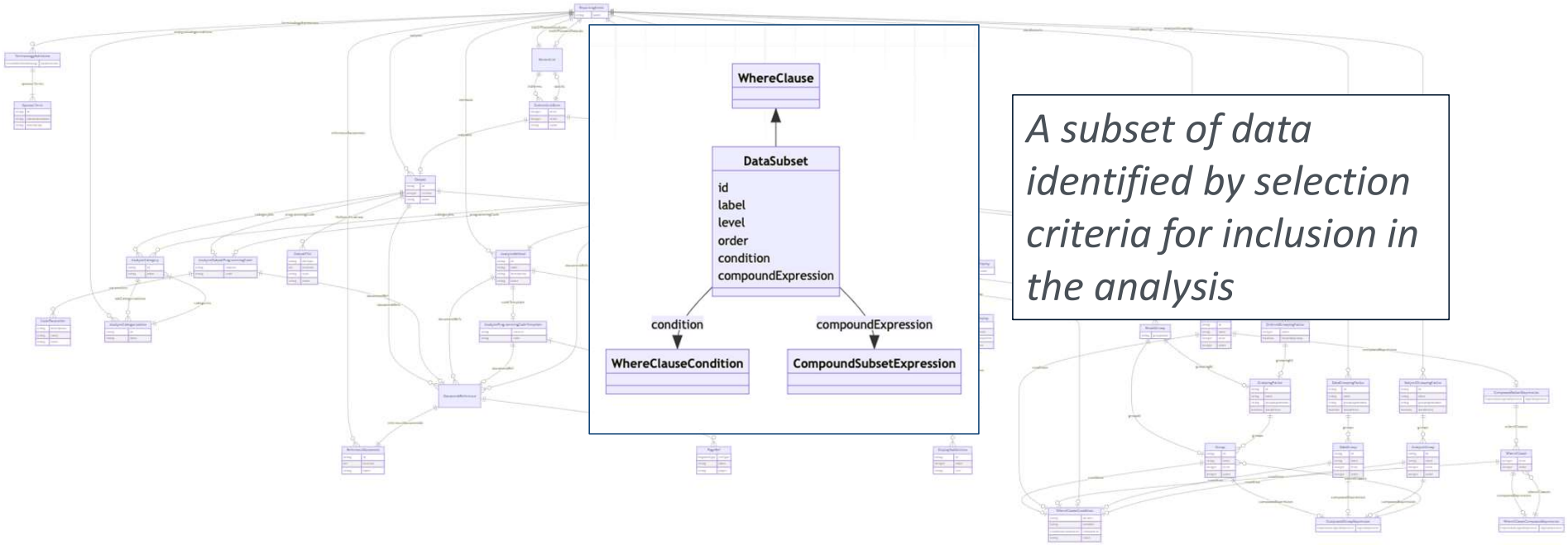
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| System Organ Class<br>Preferred Term [a], n (%) | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Number of subjects with at least one event | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 2> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

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

# ARS Logical Model Schema Diagram: Data Subset




*A subset of data identified by selection criteria for inclusion in the analysis*

# Model Components

Data Subset

## Summary of Demographics

Study – CDISC 360 Page x of y

Table 14.1.1
Summary of Demographics
Safety Population

| Characteristics | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Age (years) | | | |
| n | XX | XX | XX |
| Mean (SD) | XX.X (XX.XX) | XX.X (XX.XX) | XX.X (XX.XX) |
| Median | XX.X | XX.X | XX.X |
| Q1, Q3 | XX.X, XX.X | XX.X, XX.X | XX.X, XX.X |
| Min, Max | XX, XX | XX, XX | XX, XX |
| Age Group, n (%) | | | |
| < 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ≥ 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Gender, n (%) | | | |
| Male | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Female | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Ethnicity, n (%) | | | |
| Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Not Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

## Summary of TEAE by SOC and PT

Study – CDISC 360 Page x of y

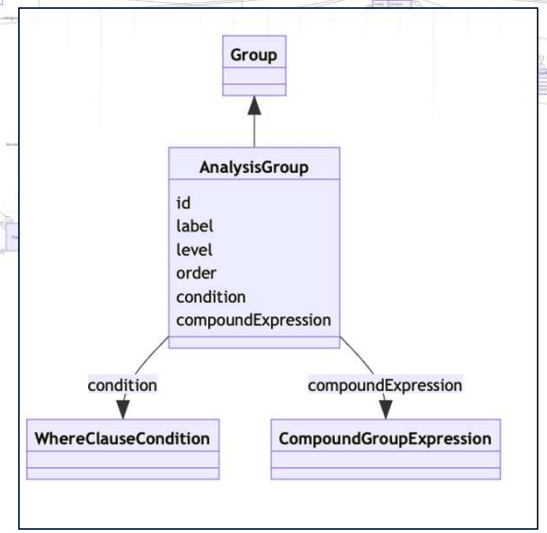
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| System Organ Class<br>Preferred Term [a], n (%) | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Number of subjects with at least one event | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 2> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

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

# ARS Logical Model Schema Diagram: Analysis Grouping




*A subdivision of the subject population based on a defined factor (e.g., subjects whose treatment is Drug A, subjects whose gender is male)*

# Model Components

Analysis Grouping

## Summary of Demographics

Study – CDISC 360 Page x of y

Table 14.1.1
Summary of Demographics
Safety Population

| Characteristics | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Age (years) | | | |
| n | XX | XX | XX |
| Mean (SD) | XX.X (XX.XX) | XX.X (XX.XX) | XX.X (XX.XX) |
| Median | XX.X | XX.X | XX.X |
| Q1, Q3 | XX.X, XX.X | XX.X, XX.X | XX.X, XX.X |
| Min, Max | XX, XX | XX, XX | XX, XX |
| Age Group, n (%) | | | |
| < 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ≥ 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Gender, n (%) | | | |
| Male | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Female | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Ethnicity, n (%) | | | |
| Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Not Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

## Summary of TEAE by SOC and PT

Study – CDISC 360 Page x of y

Table 14.3.1.1
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| System Organ Class<br>Preferred Term [a], n (%) | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Number of subjects with at least one event | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 2> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

Notes: TEAE=Treatment-Emergent Adverse Events.
Subjects are counted once within each system organ class and preferred term.
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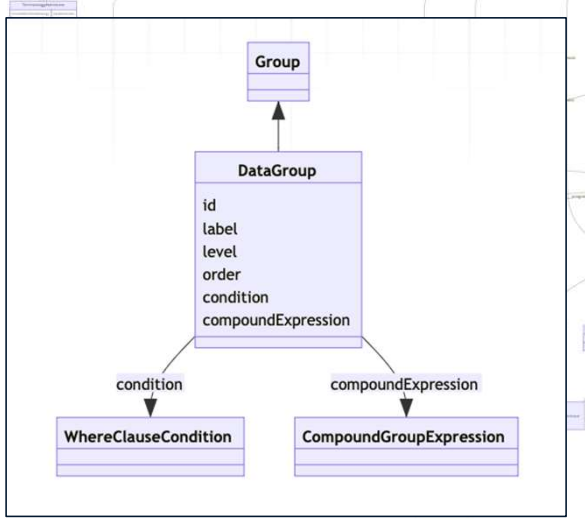
Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM

# ARS Logical Model Schema Diagram: Data Grouping




*A subdivision of the analysis dataset records based on a defined factor*

# Model Components

Data Grouping

## Summary of Demographics

Study – CDISC 360 Page x of y

Table 14.1.1
Summary of Demographics
Safety Population

| Characteristics | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Age (years) | | | |
| n | XX | XX | XX |
| Mean (SD) | XX.X (XX.XX) | XX.X (XX.XX) | XX.X (XX.XX) |
| Median | XX.X | XX.X | XX.X |
| Q1, Q3 | XX.X, XX.X | XX.X, XX.X | XX.X, XX.X |
| Min, Max | XX, XX | XX, XX | XX, XX |
| Age Group, n (%) | | | |
| < 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ≥ 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Gender, n (%) | | | |
| Male | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Female | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Ethnicity, n (%) | | | |
| Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Not Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

## Summary of TEAE by SOC and PT

Study – CDISC 360 Page x of y

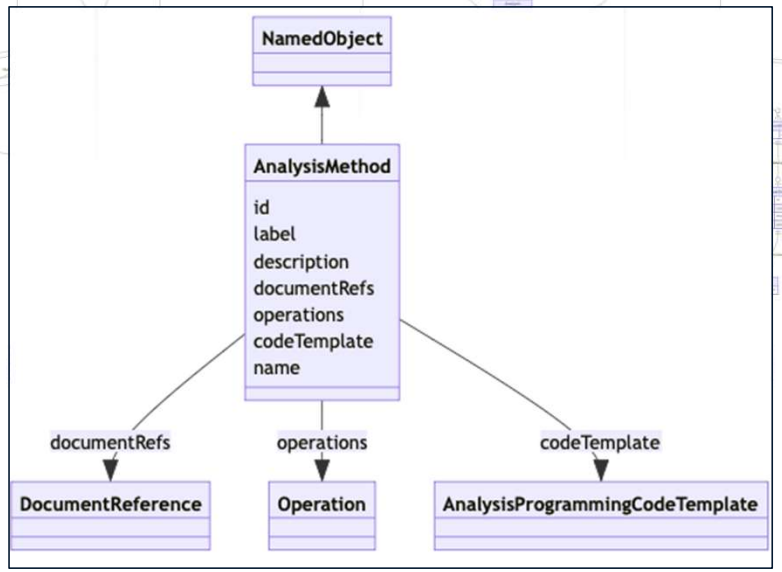
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| System Organ Class<br>Preferred Term [a], n (%) | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Number of subjects with at least one event | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 2> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

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

# ARS Logical Model Schema Diagram: Analysis Method




*A set of one or more statistical operations*

# Model Components

## Analysis Method

### Summary of Demographics

Study – CDISC 360 Page x of y

Table 14.1.1
Summary of Demographics
Safety Population

| Characteristics | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Age (years) | | | |
| n | XX | XX | XX |
| Mean (SD) | XX.X (XX.XX) | XX.X (XX.XX) | XX.X (XX.XX) |
| Median | XX.X | XX.X | XX.X |
| Q1, Q3 | XX.X, XX.X | XX.X, XX.X | XX.X, XX.X |
| Min, Max | XX, XX | XX, XX | XX, XX |
| Age Group, n (%) | | | |
| < 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ≥ 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Gender, n (%) | | | |
| Male | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Female | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Ethnicity, n (%) | | | |
| Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Not Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

### Summary of TEAE by SOC and PT

Study – CDISC 360 Page x of y

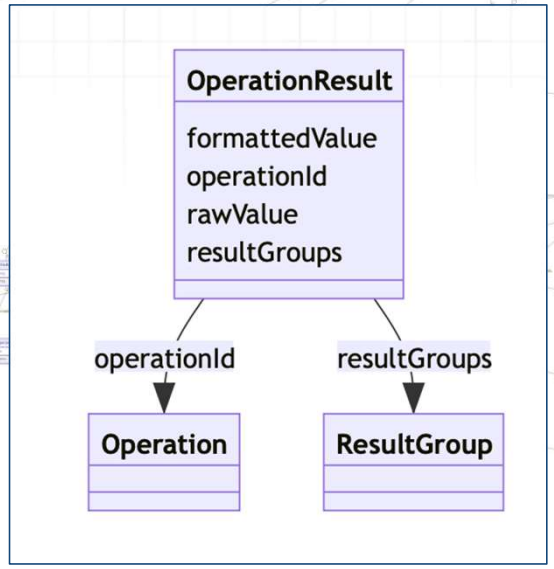
Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

| System Organ Class<br>Preferred Term [a], n (%) | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Number of subjects with at least one event | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 2> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

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

# ARS Logical Model Schema Diagram: Results




*The result of an analysis method operation performed on a subdivision of subjects or data records*

# Model Components

Results

## Summary of Demographics

Study – CDISC 360 Page x of y

Table 14.1.1
Summary of Demographics
Safety Population

| Characteristics | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Age (years) | | | |
| n | XX | XX | XX |
| Mean (SD) | XX.X (XX.XX) | XX.X (XX.XX) | XX.X (XX.XX) |
| Median | XX.X | XX.X | XX.X |
| Q1, Q3 | XX.X, XX.X | XX.X, XX.X | XX.X, XX.X |
| Min, Max | XX, XX | XX, XX | XX, XX |
| Age Group, n (%) | | | |
| < 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ≥ 65 years | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Gender, n (%) | | | |
| Male | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Female | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Ethnicity, n (%) | | | |
| Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| Not Hispanic or Latino | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

## Summary of TEAE by SOC and PT

Study – CDISC 360 Page x of y

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

| System Organ Class<br>Preferred Term [a], n (%) | Placebo (N=XX) | Xanomeline Low Dose (N=XX) | Xanomeline High Dose (N=XX) |
|---|---|---|---|
| Number of subjects with at least one event | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <SOC 2> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term 1> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| ... | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |
| <Preferred Term n> | XX ( XX.X) | XX ( XX.X) | XX ( XX.X) |

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

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

# 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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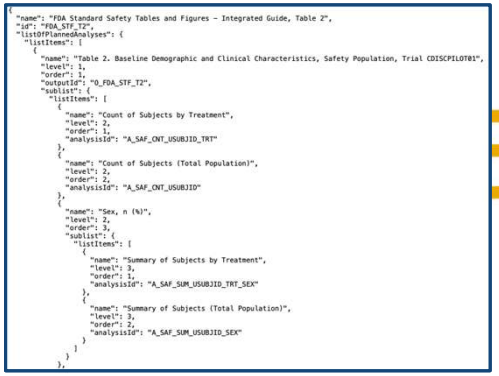
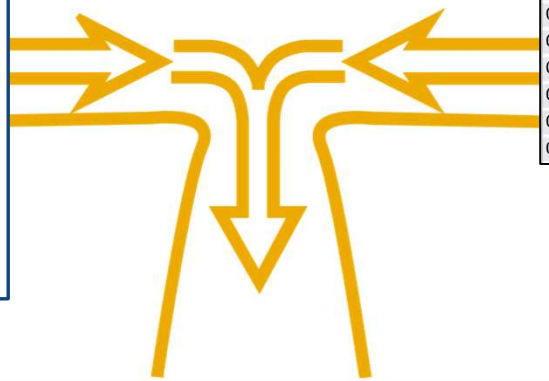
# Leveraging ARS Metadata to Drive Results Automation

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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|---|---|---|---|---|---|---|---|
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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) |
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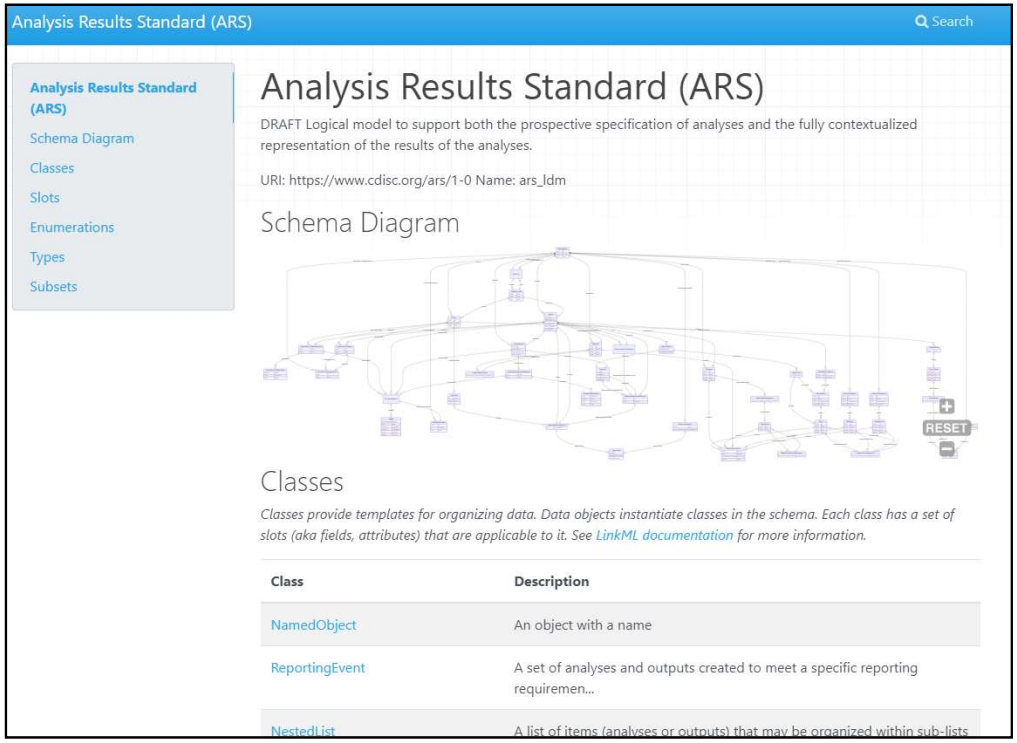
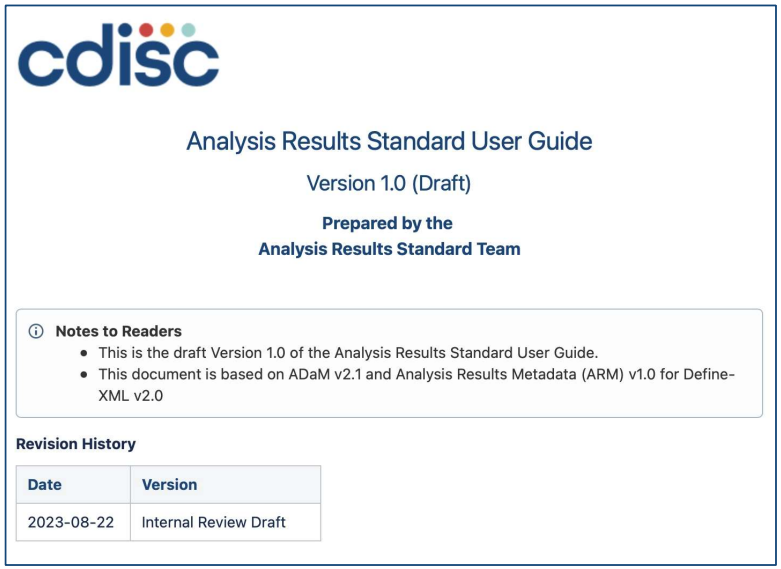
Analysis Results Dataset

# Analysis Results Standard Model and User Guide

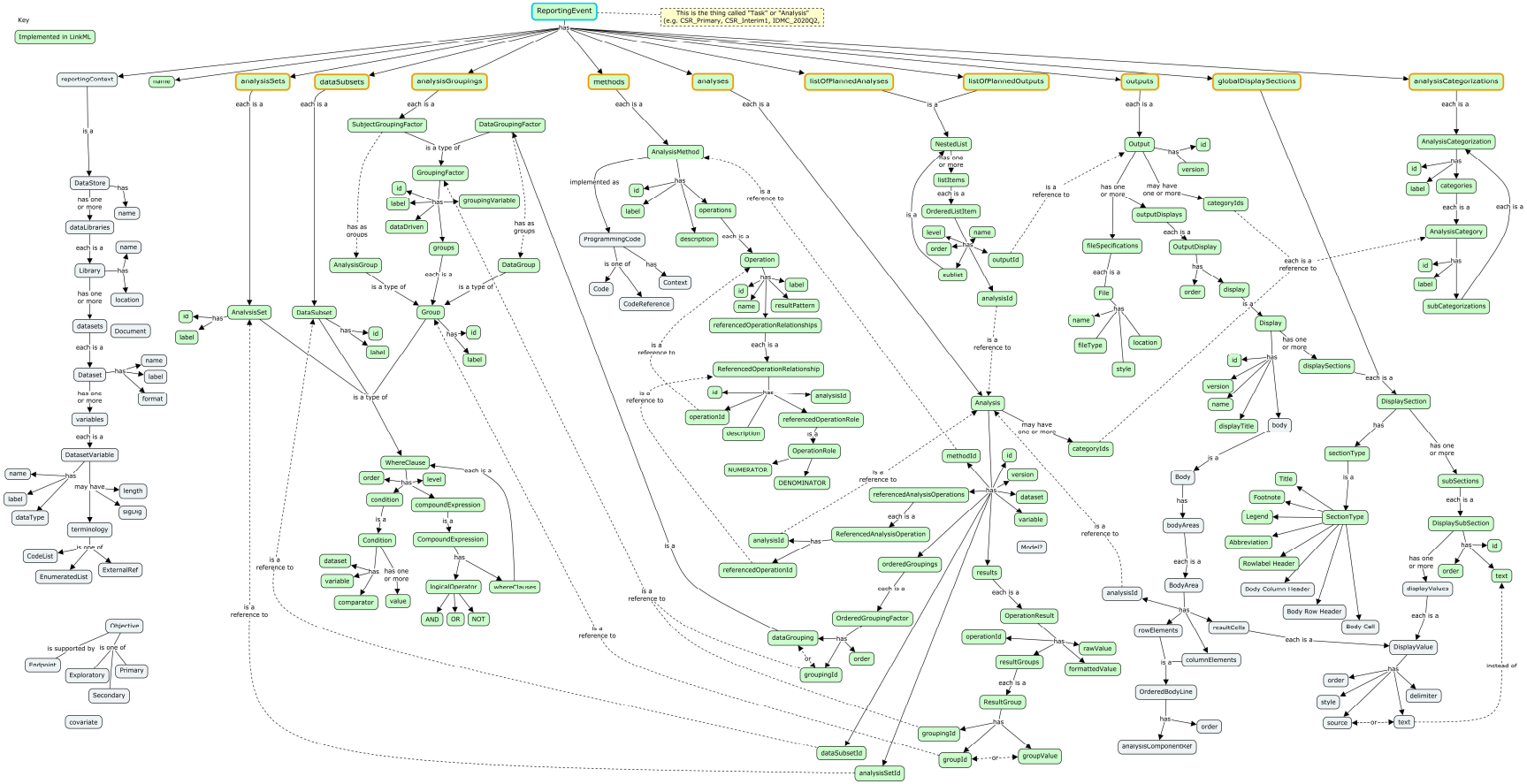
https://cdisc-org.github.io/analysis-results-standard/




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

# ARS Model Representation using CMAP

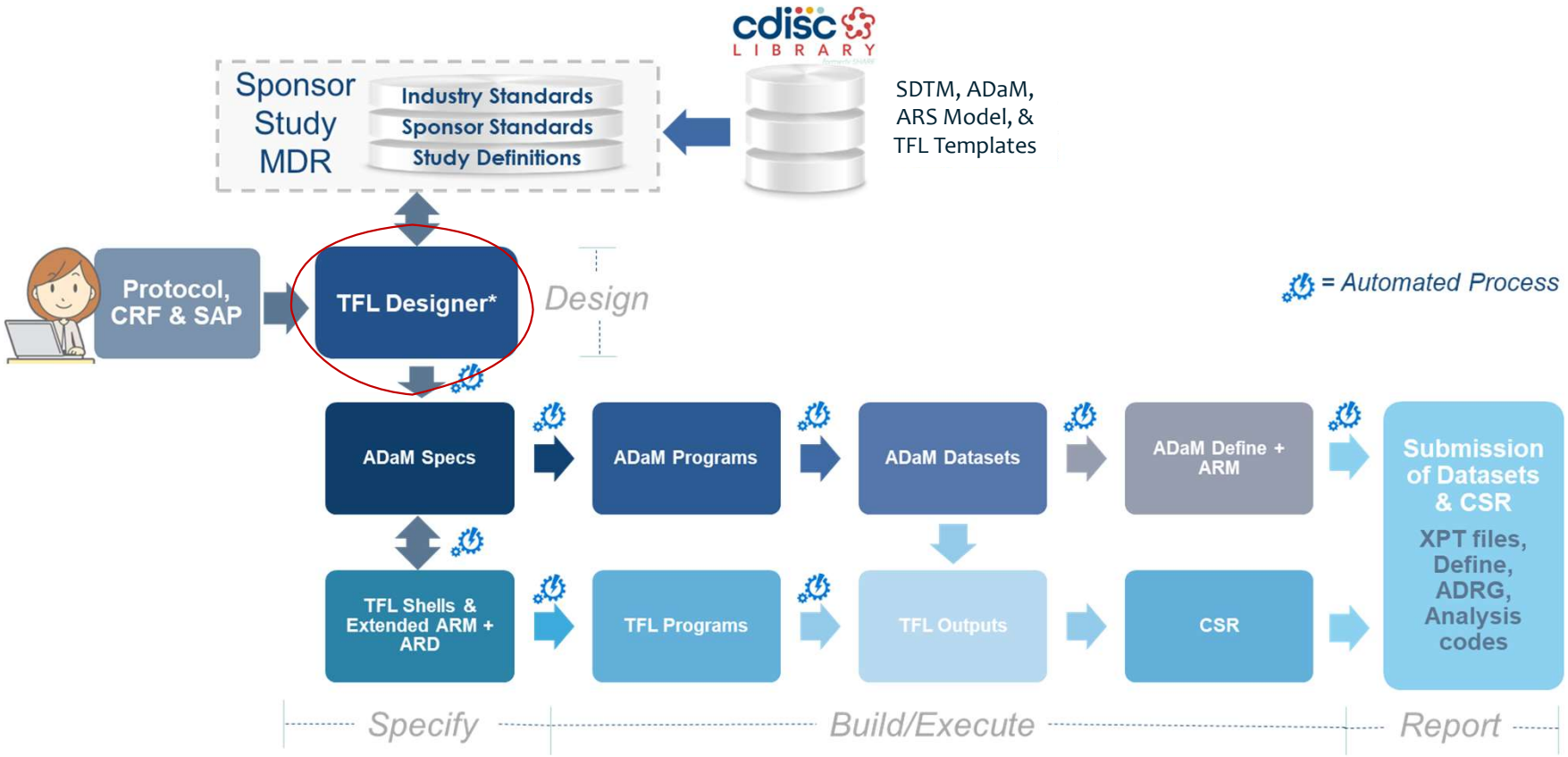


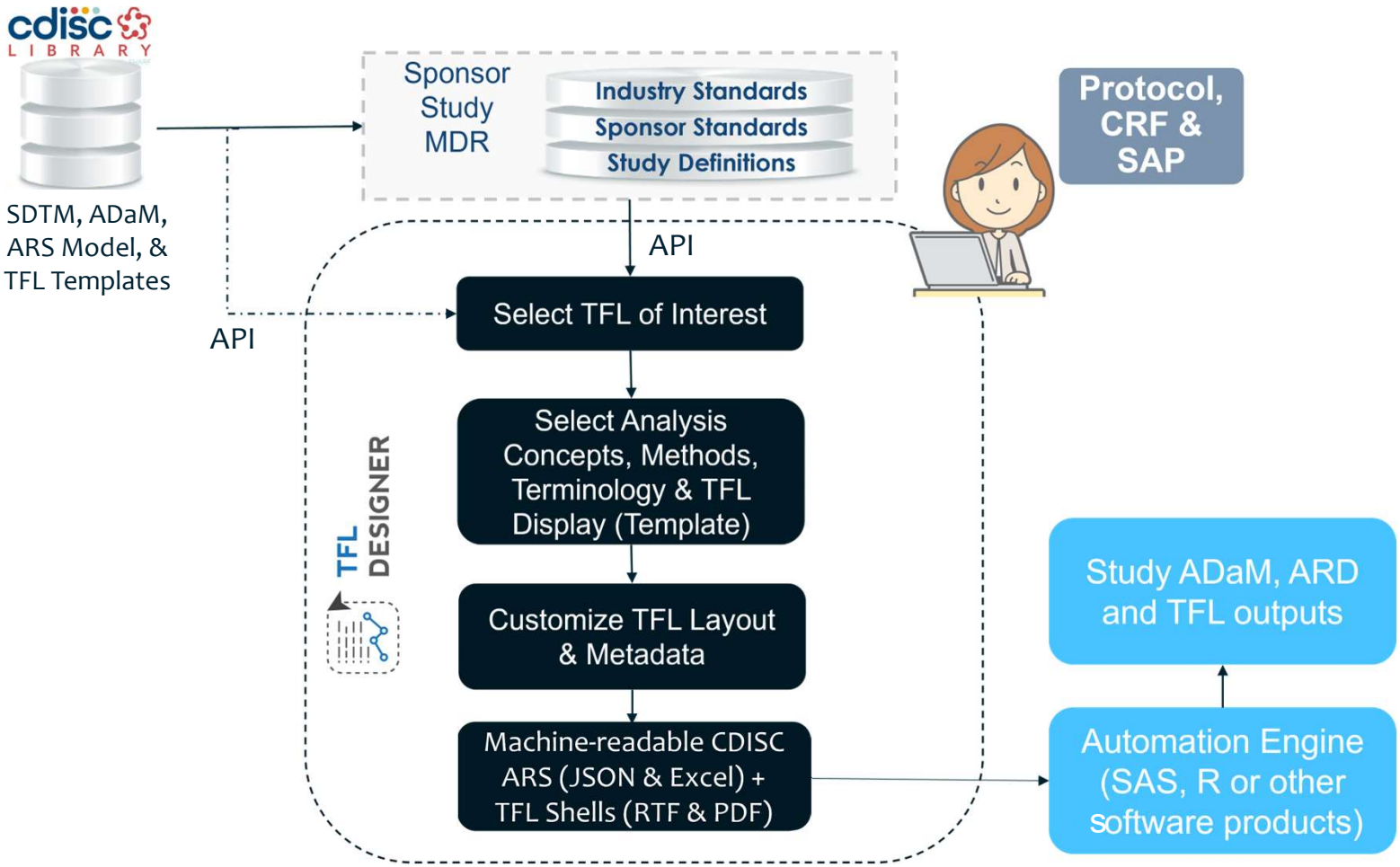
**ARS model is complex!**

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


CLYMB CLINICAL

# Analysis Results Workflow w/ TFL Designer




cdisc LIBRARY
SDTM, ADaM, ARS Model, & TFL 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

# TFL Designer – Key Highlights

- Web-based solution
- Digitizes your analysis results (TFL)
- Aligned with CDISC Analysis Results Standards
- Central repository for your TFL standards, display templates, conventions and metadata
- Automates generation of TFL shells and provides machine-readable metadata
- Community & Enterprise versions

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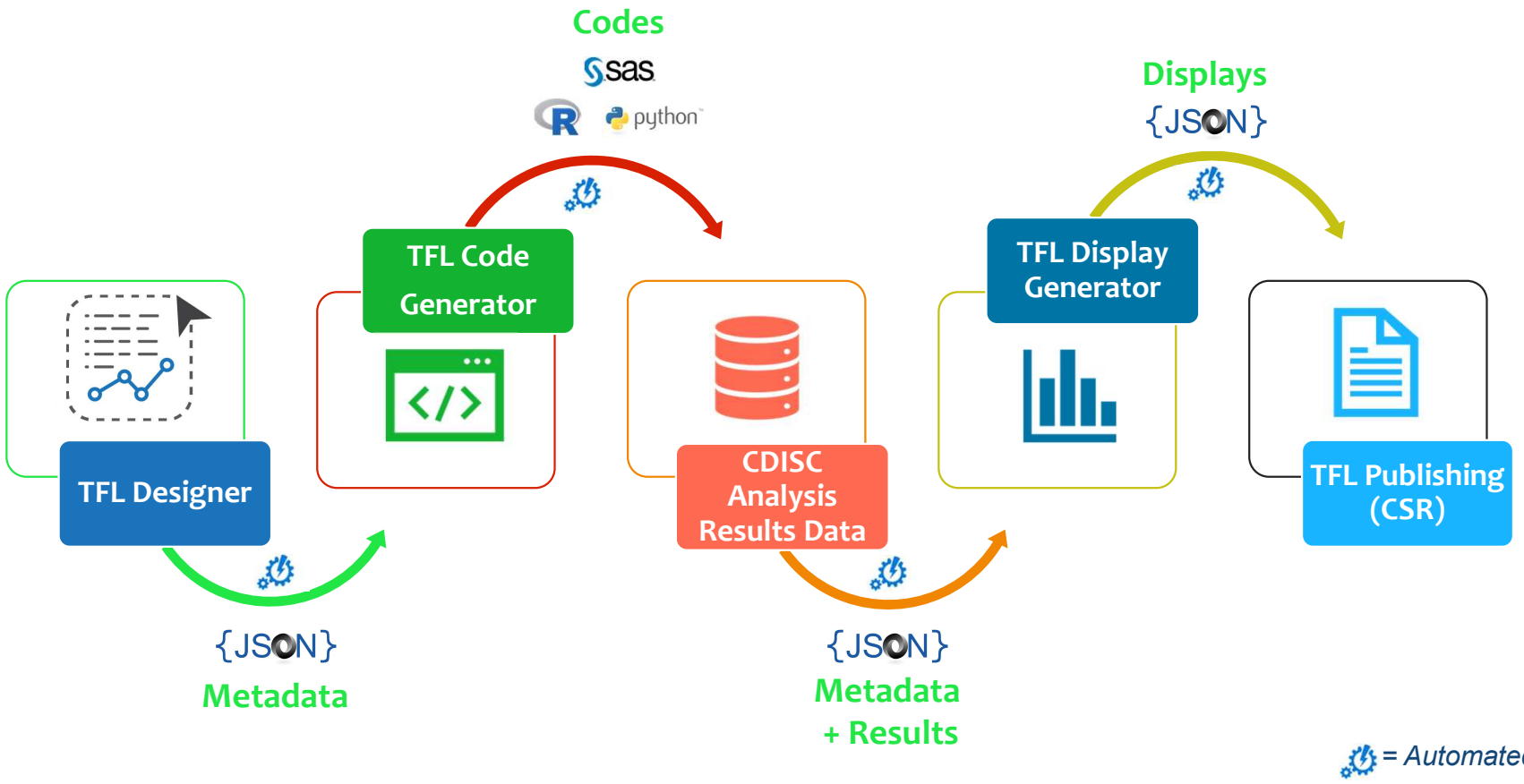
TFL DESIGNER®

# 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*
*[Will include PMDA, & PHUSE display templates in future updates]*

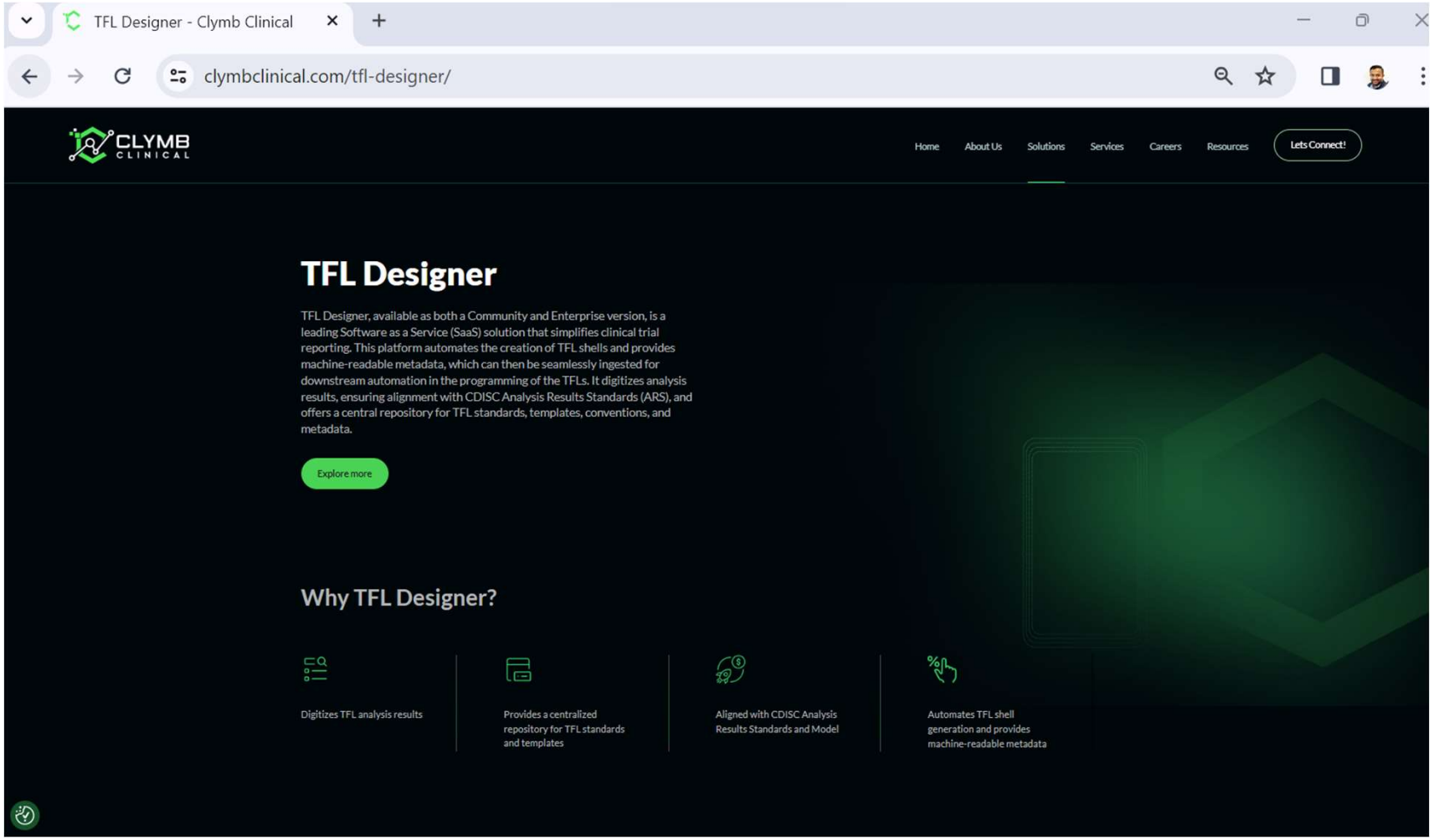
# TFL / Analysis Results – Clymb's Development



# What are we trying to accomplish?

- Build an industry leading software solution that automates TFL design and generation process [community & enterprise versions]
- Partner with companies to improve their internal TFL standards and processes
- Quantify process improvements and continue to build future state automation (target 40-50% efficiency)
- Accelerate study timelines to allow your team to get data quicker
- CDISC 360 Vision: From PoC to Reality

# Live Demo


TFL Designer - Clymb Clinical
clymbclinical.com/tfl-designer/
CLYMB CLINICAL
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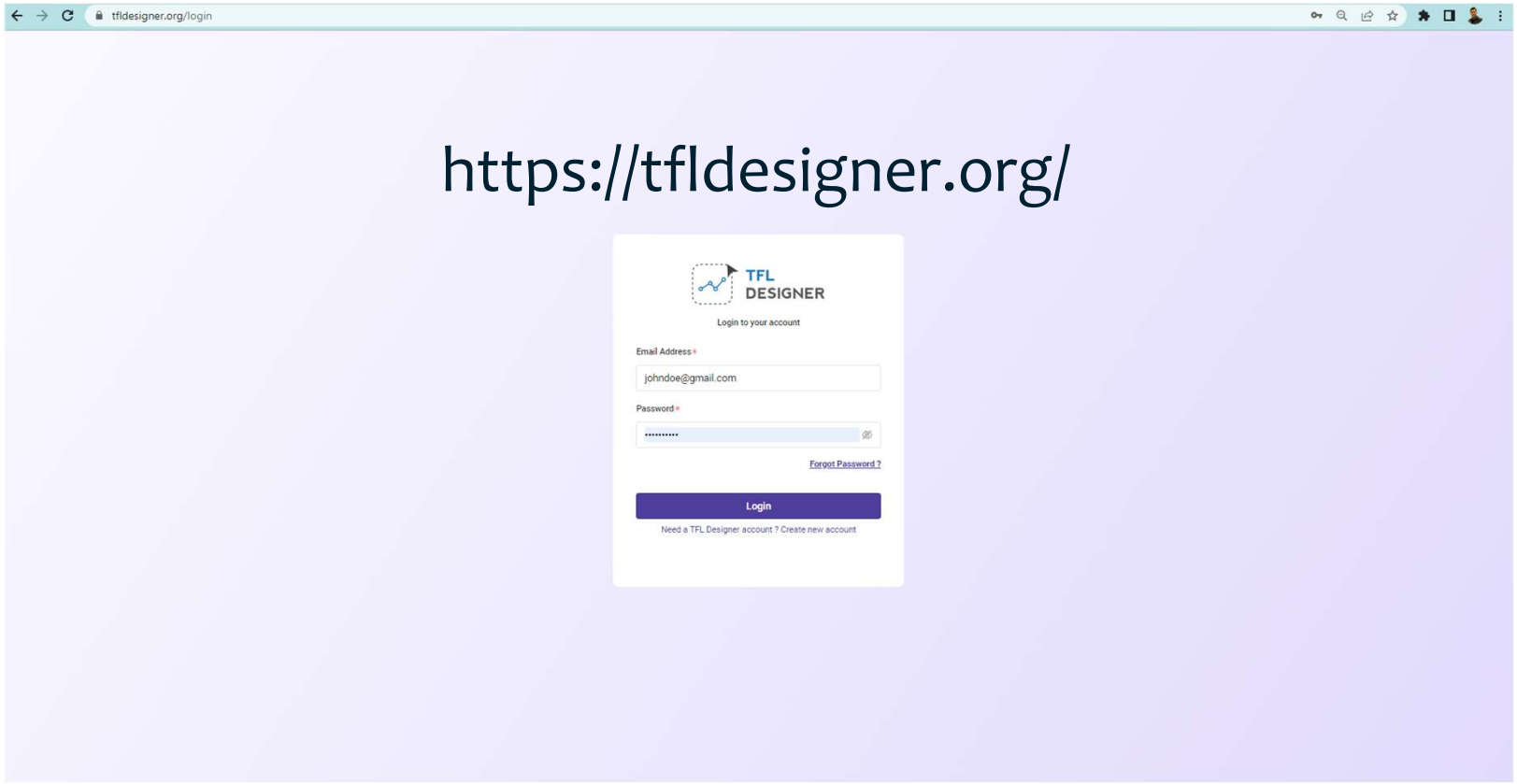
TFL Designer
TFL Designer, available as both a Community and Enterprise version, is a leading Software as a Service (SaaS) solution that simplifies clinical trial reporting. This platform automates the creation of TFL shells and provides machine-readable metadata, which can then be seamlessly ingested for downstream automation in the programming of the TFLs. It digitizes analysis results, ensuring alignment with CDISC Analysis Results Standards (ARS), and offers a central repository for TFL standards, templates, conventions, and metadata.
Explore more
Why TFL Designer?
Digitizes TFL analysis results
Provides a centralized repository for TFL standards and templates
Aligned with CDISC Analysis Results Standards and Model
Automates TFL shell generation and provides machine-readable metadata

# TFL Designer (Community version)



# Download files

http://bit.ly/3uKMAAv

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CLYMB CLINICAL

Bhavin Busa, Principal & Co-founder
bhavin@clymbclinical.com
631-220-5446

Navin Dedhia, Director of Technology Solutions & Engineering
ndedhia@clymbclinical.com
631-576-9596

**EMAIL**
info@clymbclinical.com

**WEBSITE**
www.clymbclinical.com

**PHONE**
781-692-3613