



Let the Machine Do the Coding: A SAS-based Framework for Automating TFL Generation with ARS Metadata

Paper & Presentation # SM13

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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/>

Analysis Results Standard (ARS)

Schema Diagram

Classes

Slots

Enumerations

Types

Subsets

Analysis Results Standard (ARS)

Logical model to support both the prospective specification of analyses and the fully contextualized representation of the results of the analyses.

URI: <https://www.cdisc.org/ars/1-0> Name: ars_idm

Schema Diagram

Classes

Classes provide templates for organizing data. Data objects instantiate classes and slots (aka fields, attributes) that are applicable to it. See [LinkML documentation](#).

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

cdisc

Analysis Results Standard User Guide

Version 1.0 (Final)

Prepared by the
Analysis Results Standard Team

Notes to Readers

- This is the final Version 1.0 of the Analysis Results Standard User Guide.
- This document is based on ADaM v2.1 and Analysis Results Metadata (ARM) v1.0 for Define-XML v2.0

Revision History

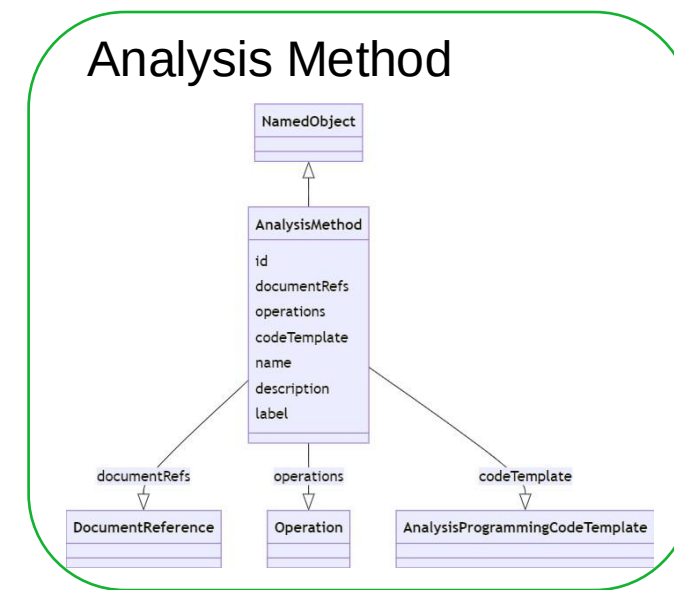
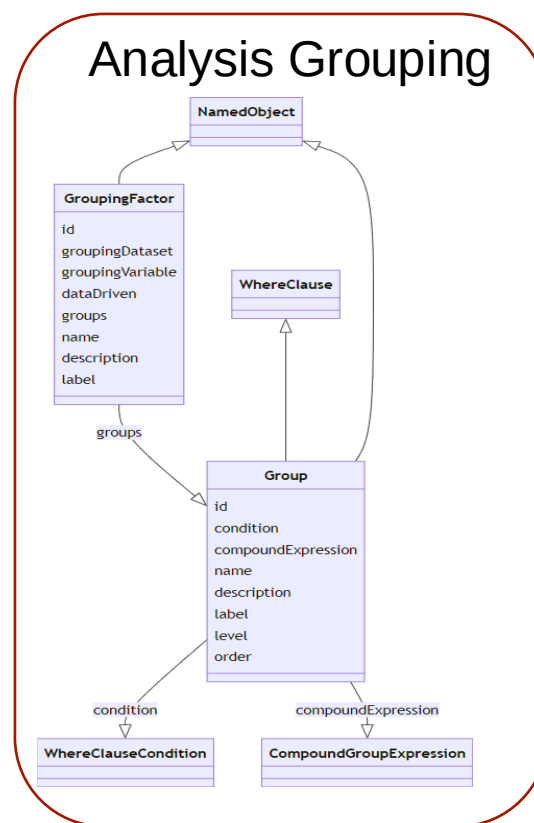
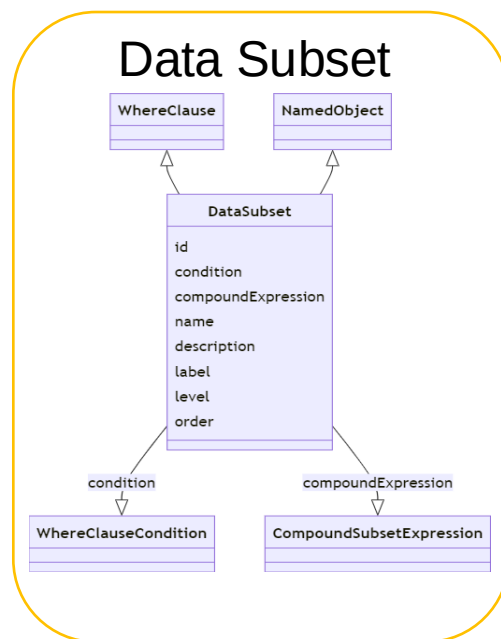
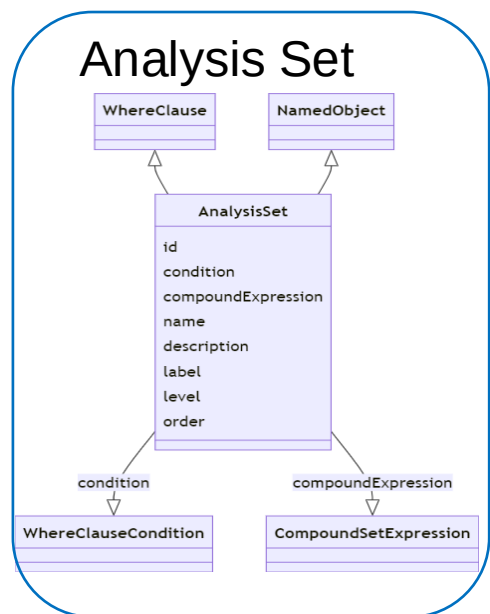
Date	Version
2024-04-19	Final

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

CDISC ARS Metadata

One **Output** has many **Analyses**. One **Analysis** has the following:



One **Analysis Method** consists of one or more **Operations**

CDISC ARS Metadata

Analysis Set

Data Subset

Analysis Grouping

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

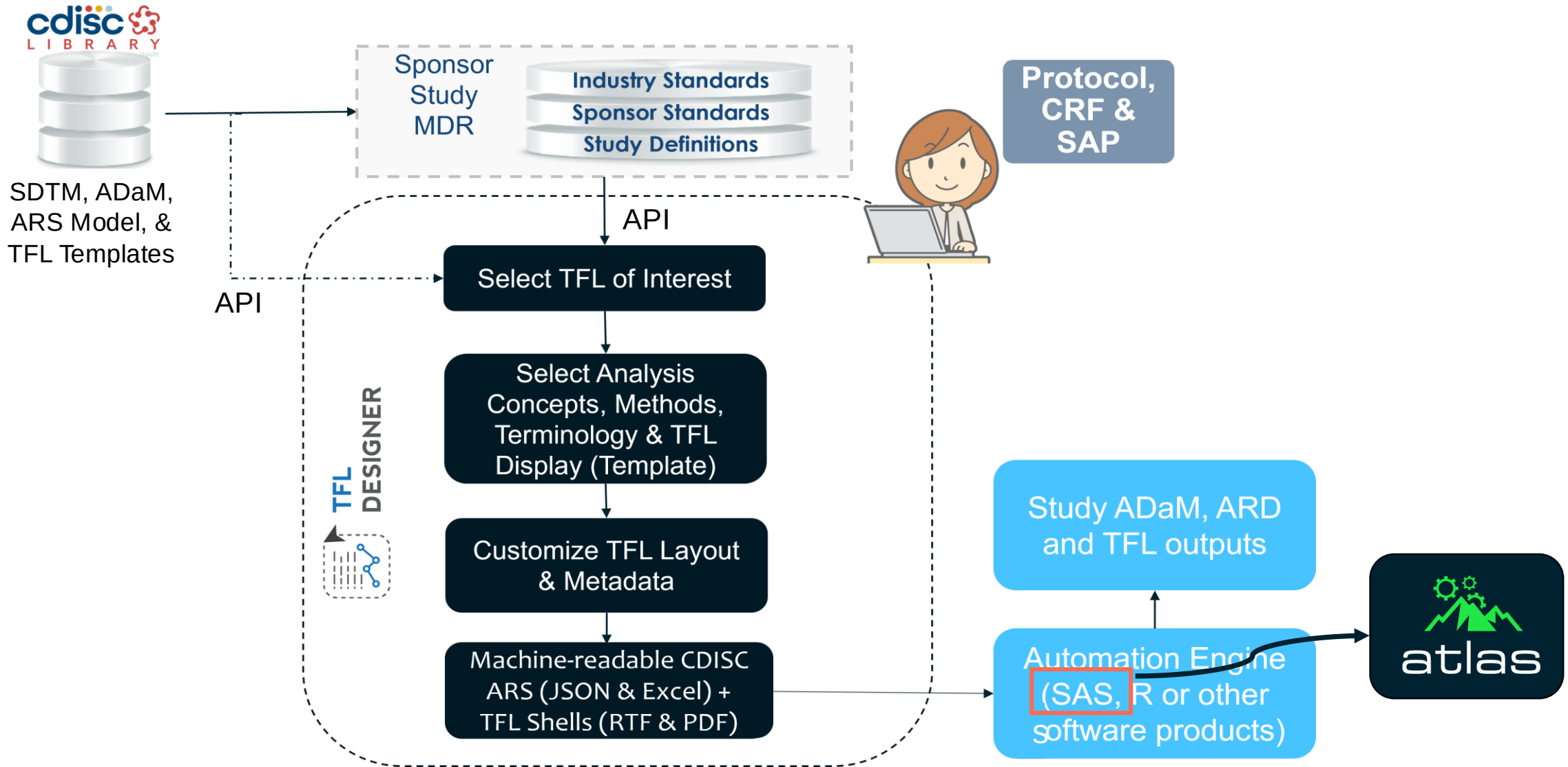
Safety Population

System Organ Class 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

Metadata-driven TFL Deliverable Workflow



CDISC eTFL Portal

Generated using TFL Designer (Community v1.0)

FDA DM T02

Baseline Demographic and Clinical Characteristics

Study Population

Characteristics	Xanomeline Low Dose (n/N)	Xanomeline High Dose (n/N)	Placebo (n/N)	Total Population (n/N)
Sex, N(%)				
Male	100 (100.0)	100 (100.0)	100 (100.0)	300 (100.0)
Female	100 (100.0)	100 (100.0)	100 (100.0)	300 (100.0)
Unknown	100 (100.0)	100 (100.0)	100 (100.0)	300 (100.0)
Age, Years				
Mean (SD)				
Median				
Min-Max				
Age groups (years), n (%)				

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    "version": "1.4.0",
    "note": "The metadata provided herein has been generated using the TFL Designer Enterprise version 1.4.0. The representation of metadata fields is as follows."
  },
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    "studyTitle": "Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease",
    "phase": "Phase II",
    "compoundUnderStudy": "Xanomeline Transdermal",
    "description": "",
    "diseaseArea": "Neurology",
    "therapeuticArea": "Alzheimer's"
  },
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  "type": "CSR",
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    "label": "LPA",
    "contentList": {
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          "level": 1,
          "order": 1,
          "outputId": "Out_01",
          "subList": {
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              {
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                "level": 2,
                "order": 1,
                "analysisId": "An_01"
              },
              {
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                "level": 2,
                "order": 2,
                "subList": {
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                    {
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                      "level": 3,
                      "order": 1,
                      "analysisId": "An_02"
                    }
                  ]
                }
              }
            ]
          }
        }
      ]
    }
  }
}
```

```
*****
* PROGRAM: t_FDA_DM_T02_demo.sas
* DATE: 10FEB2025
* AUTHOR
* INPUT PATH and data: F:\TFL Designer\TFL-Automation\data\adam\sm-13\adam.ADSL
* OUTPUT PATH and output name: t_FDA_DM_T02_demo.rfi, t_FDA_DM_T02_demo.sas7bdat
* ASSUMPTION:
* -----
* CHANGE HISTORY:
* Date Author Code Change History Description
* -----
* yyyymmdd A. Prog <Code Change description/reason>
*****
proc datasets library=work kill nolist;
quit;

%include 'F:\TFL Designer\TFL-Automation\tools\sm13_setup.sas';

%let tfldsn = t_FDA_DM_T02_demo ;

***Summary of Subjects by Treatment and Sex, n (%)***
%eventfreq(inds=adam.ADSL,
acrossvar= TRT01A,
freqvar= ASEX,
freqvarfat= NONE,
order= 2,
rowlabel=%quote(Sex, n (%)),
fmtlib=work
);

***Summary of Subjects by Treatment and Age groups (years), n (%)***
%eventfreq(inds=adam.ADSL,
acrossvar= TRT01A,
freqvar= AGEGR1,
freqvarfat= NONE,
order= 4,
rowlabel=%quote(Age groups (years), n (%)),
fmtlib=work
);

***Summary of Subjects by Treatment and Race, n (%)***
%eventfreq(inds=adam.ADSL,
acrossvar= TRT01A,
freqvar= ABACE,
freqvarfat= NONE,
order= 5,
rowlabel=%quote(Race, n (%)),
fmtlib=work
);

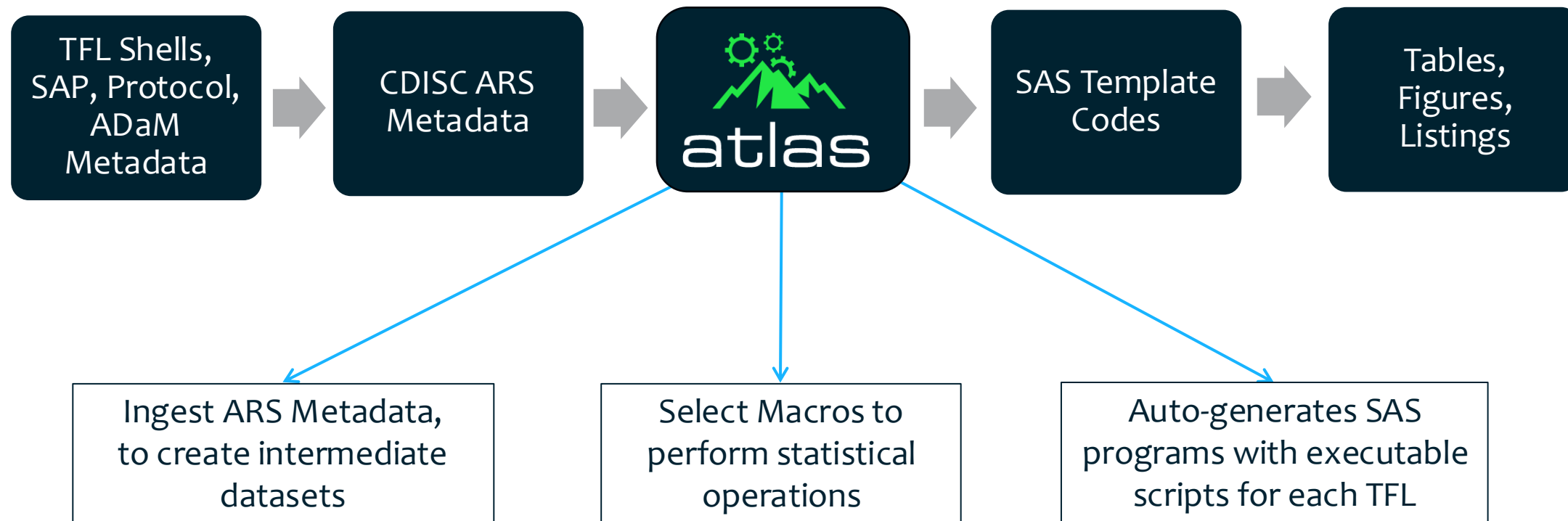
***Summary of Subjects by Treatment and Ethnicity, n (%)***
%eventfreq(inds=adam.ADSL,
acrossvar= TRT01A,
freqvar= AETHNIC,
freqvarfat= NONE,
order= 6,
rowlabel=%quote(Ethnicity, n (%)),
fmtlib=work
);
```

What is atlas?



atlas is a **SAS-based** automation engine developed by Clymb that ingests **CDISC ARS** metadata, applies statistical operations, and generates **ready-to-use, executable SAS** programs for each TFL.

High-level **atlas** meta-programming process flow: Shells -> TFLs



Export Analysis Results Metadata from TFL Designer: JSON

TFL DESIGNER File Edit View Help Neurology / Alzheimer's / CDISC - eTFL Portal

Table of Contents: Baseline Demographic and Clinical Characteristics

Generated using TFL Designer (Community, v1.0)

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)	XXX (XX.XX)	XXX (XX.XX)	XXX (XX.XX)	XXX (XX.XX)
Median	XXX	XXX	XXX	XXX
Min, Max	XXX, XXX	XXX, XXX	XXX, XXX	XXX, XXX
Age groups (years), n (%)				

```
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    "generatedUsing": "TFL Designer Enterprise",
    "version": "1.4.0",
    "note": "The metadata provided herein has been generated using the TFL Designer Enterprise version 1.4.0. The representation of metadata fields av"
  },
  "studyInfo": {
    "studyId": "CDISC - eTFL Portal",
    "studyTitle": "Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease.",
    "phase": "Phase II",
    "compoundUnderStudy": "Xanomeline Transdermal",
    "description": "",
    "diseaseArea": "Neurology",
    "therapeuticArea": "Alzheimer's"
  },
  "name": "Clinical Study Report",
  "id": "CSR",
  "mainListofContents": {
    "name": "List of Planned Analyses",
    "label": "LOPA",
    "contentsList": {
      "listItems": [
        {
          "name": "Baseline Demographic and Clinical Characteristics",
          "level": 1,
          "order": 1,
          "outputId": "Out_01",
          "sublist": {
            "listItems": [
              {
                "name": "Summary of Subjects by Treatment",
                "level": 2,
                "order": 1,
                "analysisId": "An_01"
              },
              {
                "name": "Sex, n (%)",
                "level": 2,
                "order": 2,
                "sublist": {
                  "listItems": [
                    {
                      "name": "Summary of Subjects by Treatment and Sex, n (%)",
                      "level": 3,
                      "order": 1,
                      "analysisId": "An_02"
                    }
                  ]
                }
              }
            ]
          }
        }
      ]
    }
  }
}
```

Contents of 'Classds'

- About
- Analysis
- Analysismethod
- Analysisoutputcategorization
- Analysisoutputcategory
- Analysisoutputprogrammingcode
- Analysispurpose
- Analysisreason
- Analysisset
- Ars_analyses
- Ars_dummygroups
- Compoundgroupexpression
- Compoundsubsetexpression
- Datasubset
- Displaysection
- Displaysubsection
- Globaldisplaysection
- Group
- Groupingfactor
- Listofcontents
- Nestedlist
- Operation
- Operationresult
- Operationrole
- Ordereddisplay
- Orderedgroupingfactor
- Orderedlistitem

Select Metadata of Interest from Class Datasets

Contents of 'Classds'	
	About
	Analysis
	Analysismethod
	Analysisoutputcategorization
	Analysisoutputcategory
	Analysisoutputprogrammingcode
	Analysispurpose
	Analysisreason
	Analysisset
	Ars_analyses
	Ars_dummygroups
	Compoundgroupexpression
	Compoundsubsetexpression
	Datasubset
	Displaysection
	Displaysubsection
	Globaldisplaysection
	Group
	Groupingfactor
	Listofcontents
	Nestedlist
	Operation
	Operationresult
	Operationrole
	Ordereddisplay
	Orderedgroupingfactor
	Orderedlistitem



VIEWTABLE: Classds.Analysisoutputcategory				
	tablepath	datapath	id	label
1	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01	Safety
2	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_01	Vital Signs
3	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_02	Laboratory Test Results
4	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_03	Adverse Events
5	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_04	Demographics
6	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_05	Disposition
7	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_06	Exposure

VIEWTABLE: TMP1.analysis						
	datapath	name	methodId	categoryIds2	id	dataset
1	/analyses/0	Summary of Subjects by Treatment	Mth_01	ANSET_01_ANINT_05	An_01	ADSL
2	/analyses/1	Summary of Subjects by Treatment and Subjects randomized	Mth_04	ANSET_01_ANINT_05	An_02	ADSL
3	/analyses/2	Summary of Subjects by Treatment and ITT population [3]	Mth_04	ANSET_01_ANINT_05	An_03	ADSL
4	/analyses/3	Summary of Subjects by Treatment and Safety population [4]	Mth_04	ANSET_01_ANINT_05	An_04	ADSL
5	/analyses/4	Summary of Subjects by Treatment and Per-protocol population [5]	Mth_04	ANSET_01_ANINT_05	An_05	ADSL
6	/analyses/5	Summary of Subjects by Treatment and Discontinued study drug [6]	Mth_04	ANSET_01_ANINT_05	An_06	ADSL

VIEWTABLE: TMP1.operation						
	datapath	name	id	order	resultPattern	label
1	/methods/0/operations/0	Count of subjects	Mth_01_01_n	1 (N=)	n	
2	/methods/1/operations/0	n	Mth_02_01_n	1 XX	n	
3	/methods/1/operations/1	%	Mth_02_02_%	2 (XX.XX)	%	
4	/methods/2/operations/0	n	Mth_03_01_n	1 XX	n	
5	/methods/2/operations/1	%	Mth_03_02_%	2 (XX.X)	%	
6	/methods/2/operations/2	Risk Difference %	Mth_03_03_Risk_Difference_%	3 XX.X	Risk Difference %	
7	/methods/2/operations/3	95% CI Low	Mth_03_04_95%_CI_Low	4 XX.X	95% CI Low	
8	/methods/2/operations/4	95% CI High	Mth_03_05_95%_CI_High	5 XX.X	95% CI High	

Create Intermediate Metadata Dataset

VIEWTABLE: Classds.Analysisoutputcategory

	tablepath	datapath	id	label
1	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01	Safety
2	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_01	Vital Signs
3	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_02	Laboratory Test Results
4	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_03	Adverse Events
5	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_04	Demographics
6	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_05	Disposition
7	/root/analysisOutputCategorizations/cate	/analysisOutputCategorizations/0/catego	ANSET_01_ANINT_06	Exposure

VIEWTABLE: TMP1.analysis

	datapath	name	methodid	categoryids2	id	dataset
1	/analyses/0	Summary of Subjects by Treatment	Mth_01	ANSET_01_ANINT_05	An_01	ADSL
2	/analyses/1	Summary of Subjects by Treatment and Subjects randomized	Mth_04	ANSET_01_ANINT_05	An_02	ADSL
3	/analyses/2	Summary of Subjects by Treatment and ITT population [3]	Mth_04	ANSET_01_ANINT_05	An_03	ADSL
4	/analyses/3	Summary of Subjects by Treatment and Safety population [4]	Mth_04	ANSET_01_ANINT_05	An_04	ADSL
5	/analyses/4	Summary of Subjects by Treatment and Perprotocol population [5]	Mth_04	ANSET_01_ANINT_05	An_05	ADSL
6	/analyses/5	Summary of Subjects by Treatment and Discontinued study drug [6]	Mth_04	ANSET_01_ANINT_05	An_06	ADSL

VIEWTABLE: TMP1.operation

	datapath	name	id	order	resultPattern	label
1	/methods/0/operations/0	Count of subjects	Mth_01_01_n	1 (N+)	n	
2	/methods/1/operations/0	n	Mth_02_01_n	1 XX	n	
3	/methods/1/operations/1	%	Mth_02_02_%	2 (XXXX)	%	
4	/methods/2/operations/0	n	Mth_03_01_n	1 XX	n	
5	/methods/2/operations/1	%	Mth_03_02_%	2 (XXXX)	%	
6	/methods/2/operations/2	Risk Difference %	Mth_03_03_Risk_Difference_%	3 XXX	Risk Difference %	
7	/methods/2/operations/3	95% CI Low	Mth_03_04_95%_CI_Low	4 XXX	95% CI Low	
8	/methods/2/operations/4	95% CI High	Mth_03_05_95%_CI_High	5 XXX	95% CI High	

tfl_id	tfltitle	catlabel	anlsdisplabel	dataset	groupingid1var	groupingid2var	analysisid	methodid	grouped_results
Out_02	FDA-DM-T02	Demographics		ADSL	TRT01A	USUBJID	An_08	Mth_01	n
Out_02	FDA-DM-T02	Demographics	Sex, n (%)	ADSL	TRT01A	ASEX	An_09	Mth_04	n %
Out_02	FDA-DM-T02	Demographics	Age, Years	ADSL	TRT01A	AGE	An_10	Mth_07	n MeanSD Median MinMax Q1 Q3
Out_02	FDA-DM-T02	Demographics	Age groups (years), n (%)	ADSL	TRT01A	AGEGR1	An_11	Mth_04	n %
Out_02	FDA-DM-T02	Demographics	Race, n (%)	ADSL	TRT01A	ARACE	An_12	Mth_04	n %
Out_02	FDA-DM-T02	Demographics	Ethnicity, n (%)	ADSL	TRT01A	AETHNIC	An_13	Mth_04	n %
Out_02	FDA-DM-T02	Demographics	Country of participation, n (%)	ADSL	TRT01A	ACOUNTRY	An_14	Mth_04	n %
Out_02	FDA-DM-T02	Demographics	Baseline Weight (kg)	ADSL	TRT01A	WEIGHTBL	An_15	Mth_07	n MeanSD Median MinMax Q1 Q3
Out_02	FDA-DM-T02	Demographics	Baseline Height (cm)	ADSL	TRT01A	HEIGHTBL	An_16	Mth_07	n MeanSD Median MinMax Q1 Q3
Out_02	FDA-DM-T02	Demographics	Baseline BMI (kg/m^2)	ADSL	TRT01A	BMIBL	An_17	Mth_07	n MeanSD Median MinMax Q1 Q3
Out_02	FDA-DM-T02	Demographics	Duration of Disease (Months)	ADSL	TRT01A	DURDIS	An_18	Mth_07	n MeanSD Median MinMax Q1 Q3

Assign SAS Macros by Statistic Operation

tfl_id	tfltitle	catlabel	anlsdisplabel	dataset	groupingid1var	groupingid2var	analysisid	methodid	grouped_results
Out_02	FDA-DM-T02	Demographics		ADSL	TRT01A	USUBJID	An_08	Mth_01	n
Out_02	FDA-DM-T02	Demographics	Sex, n (%)	ADSL	TRT01A	ASEX	An_09	Mth_04	n %
Out_02	FDA-DM-T02	Demographics	Age, Years	ADSL	TRT01A	AGE	An_10	Mth_07	n MeanSD Median MinMax Q1 Q3
Out_02	FDA-DM-T02	Demographics	Age groups (years), n (%)	ADSL	TRT01A	AGEGR1	An_11	Mth_04	n %
Out_02	FDA-DM-T02	Demographics	Race, n (%)	ADSL	TRT01A	ARACE	An_12	Mth_04	n %
Out_02	FDA-DM-T02	Demographics	Ethnicity, n (%)	ADSL	TRT01A	AETHNIC	An_13	Mth_04	n %
Out_02	FDA-DM-T02	Demographics	Country of participation, n (%)	ADSL	TRT01A	ACOUNTRY	An_14	Mth_04	n %
Out_02	FDA-DM-T02	Demographics	Baseline Weight (kg)	ADSL	TRT01A	WEIGHTBL	An_15	Mth_07	n MeanSD Median MinMax Q1 Q3
Out_02	FDA-DM-T02	Demographics	Baseline Height (cm)	ADSL	TRT01A	HEIGHTBL	An_16	Mth_07	n MeanSD Median MinMax Q1 Q3
Out_02	FDA-DM-T02	Demographics	Baseline BMI (kg/m ²)	ADSL	TRT01A	BMIBL	An_17	Mth_07	n MeanSD Median MinMax Q1 Q3
Out_02	FDA-DM-T02	Demographics	Duration of Disease (Months)	ADSL	TRT01A	DURDIS	An_18	Mth_07	n MeanSD Median MinMax Q1 Q3

```
proc sql ;
  select count (mthdord) into :mthdord from analyses&j;
quit;
```

```
%do k=1 %to &mthdord.;
  data mthdord&k.;
    set analyses&j;
    where mthdord = &k.;
    if catlabel = "Demographics" then do;
```

```
  if methodId = "Mth_04" then do;
    call symputx(cats('anlsnam', &k.), analysisname);
    call symputx(cats('dsn', &k.), dsn );
    call symputx(cats('grpvar1', &k.), grpvar1);
    call symputx(cats('grpvar2', &k.), grpvar2);
    call symputx(cats('resfmt', &k.), resfmt);
    call symputx(cats('anlsord', &k.), anlsord);
    call symputx(cats('library', &k.), library);
    call symputx(cats('anlslabel', &k.), anlsdisplabel);
  end;
```

```
  else if methodId = "Mth_07" then do;
    call symputx(cats('anlsnam', &k.), analysisname);
    call symputx(cats('dsn', &k.), dsn );
    call symputx(cats('grpvar1', &k.), grpvar1);
    call symputx(cats('grpvar2', &k.), grpvar2);
    call symputx(cats('grpreslt', &k.), grouped_results);
    call symputx(cats('nmaxdig', &k.), nmaxdig);
    call symputx(cats('vmaxdig', &k.), vmaxdig);
    call symputx(cats('n_dec', &k.), n_dec);
    call symputx(cats('anlsord', &k.), anlsord);
    call symputx(cats('anlslabel', &k.), anlsdisplabel);
  end;
```

```
end;
```

```
run;
```

```
%end;
```

Generate Individual TFL Programs with TFL Metadata and SAS Template Codes

```
proc sql ;
  select count (mthdord) into :mthdord from analyses&j;
quit;
```

```
%do k=1 %to &mthdord.;
  data mthdord&k.;
    set analyses&j;
    where mthdord = &k.;
    if catlabel = "Demographics" then do;
```

```
      if methodId = "Mth_04" then do;
        call symputx(cats('anlsnam', &k.), analysisname);
        call symputx(cats('dsn', &k.), dsn );
        call symputx(cats('grpvar1', &k.), grpvar1);
        call symputx(cats('grpvar2', &k.), grpvar2);
        call symputx(cats('resfmt', &k.), resfmt);
        call symputx(cats('anlsord', &k.), anlsord);
        call symputx(cats('library', &k.), library);
        call symputx(cats('anlslab', &k.), anlsdisplay);
      end;
```

```
      else if methodId = "Mth_07" then do;
        call symputx(cats('anlsnam', &k.), analysisname);
        call symputx(cats('dsn', &k.), dsn );
        call symputx(cats('grpvar1', &k.), grpvar1);
        call symputx(cats('grpvar2', &k.), grpvar2);
        call symputx(cats('grpreslt', &k.), grouped_results);
        call symputx(cats('nmaxdigt', &k.), nmaxdigt);
        call symputx(cats('vmaxdigt', &k.), vmaxdigt);
        call symputx(cats('n_dec', &k.), n_dec);
        call symputx(cats('anlsord', &k.), anlsord);
        call symputx(cats('anlslab', &k.), anlsdisplay);
      end;
```

```
    end;
```

```
  run;
```

```
%end;
```

```
/* Step 3: Dynamically generate the TFL SAS program with executable scripts */
filename prog&j "File location\&tfl_type._&pgmtitle._&tfl_cat..sas";
data _null_;
```

```
  file prog&j;
  *Add header properties;
  put "*****";
  put "** PROGRAM:           &tfl_type._&pgmtitle._&tfl_cat..sas";
  put "** DATE:             &currdate.";
  put "** AUTHOR            ";
  put "** INPUT PATH and data: F:\TFL Designer\TFL-Automation\data\adam\sm-13\adam.&tfl_dsn.";
  put "** INPUT PATH and data: File location\adam.&tfl_dsn.";
  put "** OUTPUT PATH and output name: F:\TFL Designer\TFL-Automation\outputs\tables\primary
&tfl_type._&pgmtitle._&tfl_cat..rtf,";
  put "**                   &tfl_type._&pgmtitle._&tfl_cat..sas7bdat";
```

```
  *add other study level maros and libraries as needed;
  put "%include 'F:\TFL Designer\TFL-Automation\tools\sm13_setup.sas'";
  put " ";
  put "%nrstr(%let) tfldsn = &tfl_type._&pgmtitle._&tfl_cat. ;";
  put " ";
```

```
  *Assign macro based on methodid and analysis category;
```

```
  %if &Mth04_min. > 0 %then %do m = &Mth04_min. %to &Mth04_max.;
    put " ";
    put "*****&anlsnam&m.***";
    put "%nrstr(%eventfreq) (inds=&dsn&m., ";
    put "      acrossvar= &grpvar1&m., ";
    put "      freqvar= &grpvar2&m., ";
    put "      freqvarfmt= &resfmt&m., ";
    put "      order= &anlsord&m., ";
    put "      rowlabel=%nrstr(%bquote) (&anlslab&m.), ";
    put "      fmtlib=&library&m.";
    put "      );";
  %end;
```

```
  %if &Mth04_min. > 1 or &Mth07_min. > 1 %then %do;
    put "%nrstr(%stack) (outs=%nrstr(&tfldsn.),";
    put "      varlist=&anlsvar&j.);";
  %end;
```


Ready-to-use Executable SAS Program

```
/* Step 3: Dynamically generate the TFL SAS program with executable scripts */
filename prog&j "File location\&tfl_type._&pgmtitle._&tfl_cat..sas";
data _null_;
```

```
file prog&j;
*Add header properties;
put "*****";
put "PROGRAM:           &tfl_type._&pgmtitle._&tfl_cat..sas";
put "DATE:              &currdate.";
put "AUTHOR             ";
put "INPUT PATH and data: F:\TFL Designer\TFL-Automation\data\adam\sm-13\adam.&tfl_dsn.";
put "INPUT PATH and data: File location\adam.&tfl_dsn.";
put "OUTPUT PATH and output name: F:\TFL Designer\TFL-Automation\outputs\tables\primary
&tfl_type._&pgmtitle._&tfl_cat..rtf,";
put "                   &tfl_type._&pgmtitle._&tfl_cat..sas7bdat";
```

```
*add other study level maros and libraries as needed;
put "%include 'F:\TFL Designer\TFL-Automation\tools\sm13_setup.sas'";
put " ";
put "%nrstr(%let) tfldsn = &tfl_type._&pgmtitle._&tfl_cat. ";
put " ";
```

```
*Assign macro based on methodid and analysis category;
%if &Mth04_min. > 0 %then %do m = &Mth04_min. %to &Mth04_max.;
  put " ";
  put "*****&anlsnam&m.***";
  put "%nrstr(%eventfreq) (inds=&&dsn&m., ";
  put "      acrossvar= &&grpvar1&m., ";
  put "      freqvar= &&grpvar2&m., ";
  put "      freqvarfmt= &&resfmt&m., ";
  put "      order= &&anlsord&m., ";
  put "      rowlabel=%nrstr(%bquote) (&&anlslab&m.), ";
  put "      fmtlib=&&library&m.";
  put "      );";
%end;

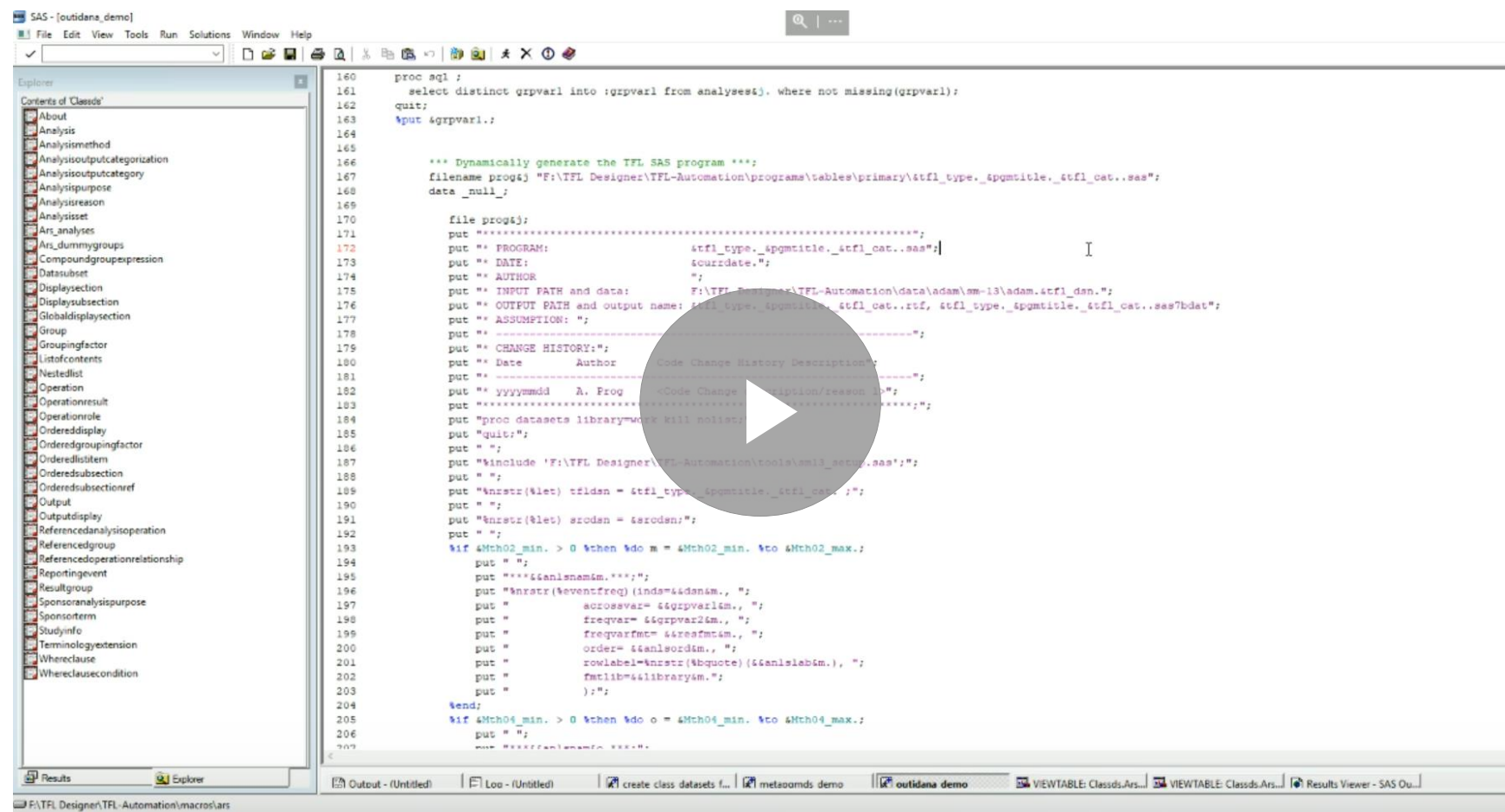
%if &Mth04_min. > 1 or &Mth07_min. > 1 %then %do;
  put "%nrstr(%stack) (outds=%nrstr(&tfldsn.),";
  put "      varlist=&&anlsvar&j.);";
%end;
```



```
***Summary of Subjects by Treatment and Country of participation,
%eventfreq(inds=adam.ADSL,
  acrossvar= TRT01A,
  freqvar= AOUNTRY,
  freqvarfmt= NONE, |
  order= 7,
  rowlabel=%bquote(Country of participation, n (%)),
  fmtlib=work
);
```

```
***Summary of Subjects by Treatment and Age, Years***;
%univars(inds=adam.ADSL,
  acrossvar= TRT01A,
  univars= AGE,
  stats= n MeanSD Median MinMax Q1 Q3,
  ndig= 2,
  ndvar= 3,
  ndecm=0,
  order= 3,
  rowlabel=%bquote(Age, Years),
);
```

Let's see atlas in operation!



Video Presentation



video link: <https://www.loom.com/share/0a46a34356014dbea99de144ffc706ed>

atlas Impact and Learnings

Impact

 Metadata setup
 Manual programming

 Time spent on complex tasks
 Time spent on repetitive tasks

 Quality and efficiency
 Overall Cost

Learnings

- Need of a design tool to generate both ARM and ADM metadata
- Training, creation, and implementation of automation process takes time.
- Macro availability and structure can be limiting.
- Multiple aspects of the programming workflow may have to change:
 - ADAM structure
 - Specification development
 - Validation process

Generated using TFL Designer (Community v1.0)

FDA DM T02

Baseline Demographic and Clinical Characteristics

Study Population

Characteristics	Xanomeline Low Dose (n/N)	Xanomeline High Dose (n/N)	Placebo (n/N)	Total Population (n/N)
Sex, N(%)				
Male	100 (100.0)	100 (100.0)	100 (100.0)	300 (100.0)
Female	100 (100.0)	100 (100.0)	100 (100.0)	300 (100.0)
Unknown	100 (100.0)	100 (100.0)	100 (100.0)	300 (100.0)
Age, Years				
Mean (SD)				
Median				
Min-Max				
Age groups (years), n (%)				

```

{
  "about": {
    "generatedUsing": "TFL Designer Enterprise",
    "version": "1.4.0",
    "note": "The metadata provided herein has been generated using the TFL Designer Enterprise version 1.4.0. The representation of metadata fields is as follows."
  },
  "studyInfo": {
    "studyId": "CDISC - eTFL Portal",
    "studyTitle": "Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease",
    "phase": "Phase II",
    "compoundUnderStudy": "Xanomeline Transdermal",
    "description": "",
    "diseaseArea": "Neurology",
    "therapeuticArea": "Alzheimer's",
    "name": "Clinical Study Report",
    "type": "CSR"
  },
  "mainListofContents": {
    "name": "List of Planned Analyses",
    "label": "LOPA",
    "contentList": {
      "listItems": [
        {
          "name": "Baseline Demographic and Clinical Characteristics",
          "level": 1,
          "order": 1,
          "outputId": "Out_01",
          "subList": {
            "listItems": [
              {
                "name": "Summary of Subjects by Treatment",
                "level": 2,
                "order": 1,
                "analysisId": "An_01"
              }
            ]
          }
        },
        {
          "name": "Sex, n (%)",
          "level": 2,
          "order": 2,
          "subList": {
            "listItems": [
              {
                "name": "Summary of Subjects by Treatment and Sex, n (%)",
                "level": 3,
                "order": 1,
                "analysisId": "An_02"
              }
            ]
          }
        }
      ]
    }
  }
}

```

```

*****
* PROGRAM: t_FDA_DM_T02_demo.sas
* DATE: 10FEB2025
* AUTHOR
* INPUT PATH and data: F:\TFL Designer\TFL-Automation\data\adam\sm-13\adam.ADSL
* OUTPUT PATH and output name: t_FDA_DM_T02_demo.rfi, t_FDA_DM_T02_demo.sas7bdat
* ASSUMPTION:
* -----
* CHANGE HISTORY:
* Date Author Code Change History Description
* -----
* yyyymmdd A. Prog <Code Change description/reason>
*****
proc datasets library=work kill nolist;
quit;

%include 'F:\TFL Designer\TFL-Automation\tools\sm13_setup.sas';

%let tfldsn = t_FDA_DM_T02_demo ;

***Summary of Subjects by Treatment and Sex, n (%)***
%eventfreq(inds=adam.ADSL,
acrossvar= TRT01A,
freqvar= ASEX,
freqvarfat= NONE,
order= 2,
rowlabel=%quote(Sex, n (%)),
fmtlib=work
);

***Summary of Subjects by Treatment and Age groups (years), n (%)***
%eventfreq(inds=adam.ADSL,
acrossvar= TRT01A,
freqvar= AGGR1,
freqvarfat= NONE,
order= 4,
rowlabel=%quote(Age groups (years), n (%)),
fmtlib=work
);

***Summary of Subjects by Treatment and Race, n (%)***
%eventfreq(inds=adam.ADSL,
acrossvar= TRT01A,
freqvar= ABACE,
freqvarfat= NONE,
order= 5,
rowlabel=%quote(Race, n (%)),
fmtlib=work
);

***Summary of Subjects by Treatment and Ethnicity, n (%)***
%eventfreq(inds=adam.ADSL,
acrossvar= TRT01A,
freqvar= AETHNIC,
freqvarfat= NONE,
order= 6,
rowlabel=%quote(Ethnicity, n (%)),
fmtlib=work
);

```



atlas Next Steps



Build Macro Library for more complex analyses



Add functionalities to detect changes with Metadata updates



Integrating metadata with tracker functions



Thank you!

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