



2024 CDISC + TMF
US INTERCHANGE

PHOENIX/SCOTTSDALE

23-24 OCTOBER: CONFERENCE & EXPO | 21, 22, 25 OCTOBER: TRAININGS



Driving Efficiency and Automation in TFL Generation: A Case Study of Establishing an Oncology TFL Library and Analysis Results Metadata Repository

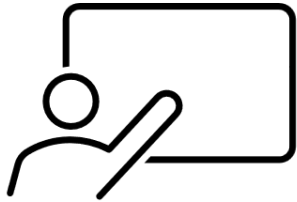
CDISC US Interchange 2024

October 24th, 2024 [Session 6C: Analysis Results Standards – eTFL]

Bhavin Busa (Clymb Clinical) & Salil Parab (Xencor, Inc)



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%**)!



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

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/>

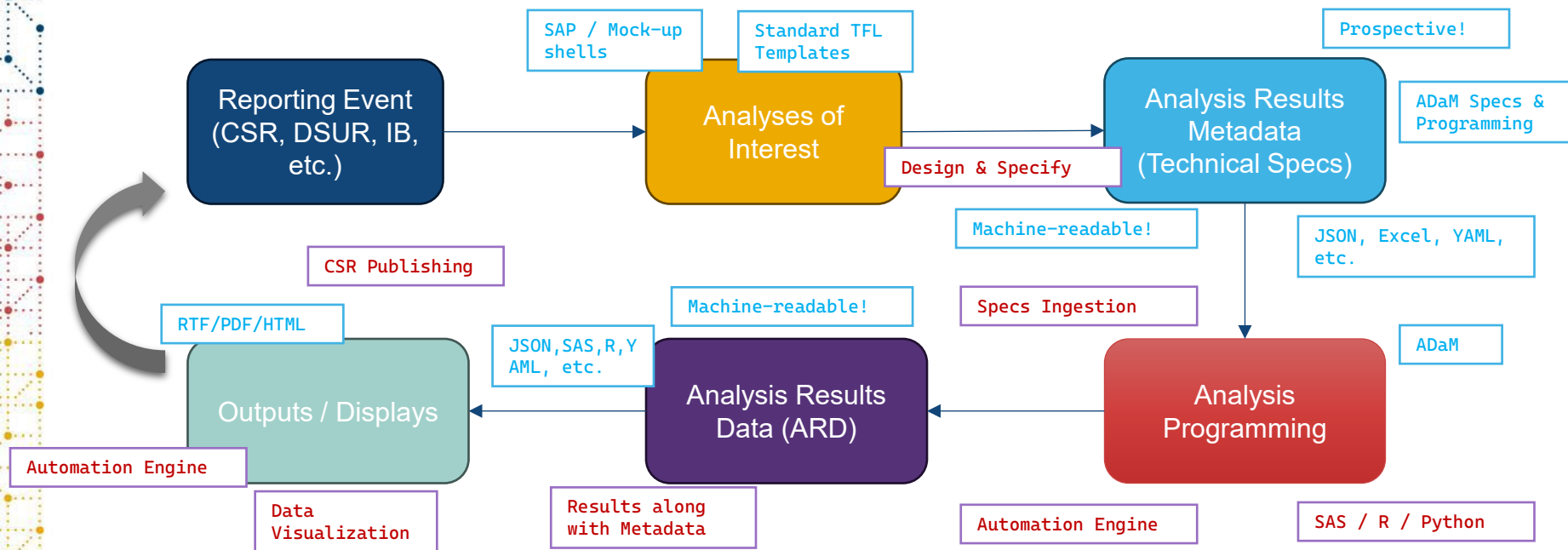
Class	Description
NamedObject	An object with a name
ReportingEvent	A set of analyses and outputs created to meet a specific requirement...
ListOfContents	A structured list of analyses and outputs

Date	Version
2024-04-19	Final

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

ARS Model Supported Workflow and Entry Points





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)



Study ADaM, ARD
and TFL outputs

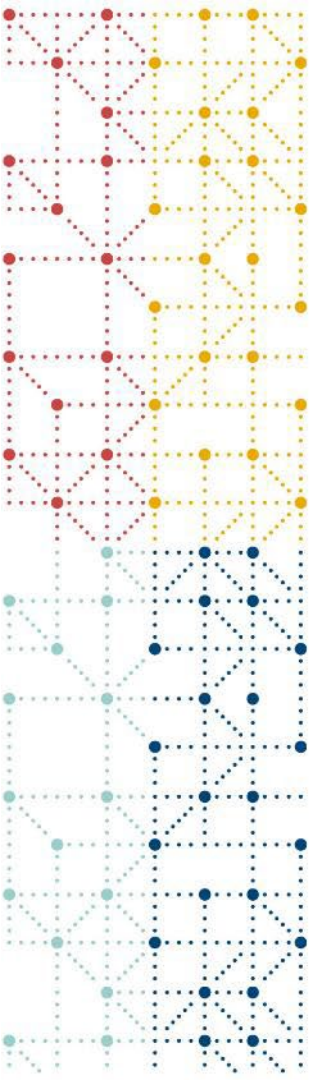
Automation Engine
(SAS, R or other
software products)



TFL **DESIGNER**

TFL Designer – Key Highlights

- Digitizing your analysis results (TFL)
- Community & Enterprise versions
- Aligned with CDISC Analysis Results Standard (ARS)
- Automate generation of TFL shells and provides machine-readable metadata
- Support downstream automation (TFL code and output generation)
- CDISC 360 Vision: From PoC to Reality



Case Study Background



- Biotech using plug and play technology to create powerful & effective antibodies
- Pasadena and San Diego, CA based
- Primary focus on Oncology and Autoimmune indications

Biostats and Statistical Programming at Xencor

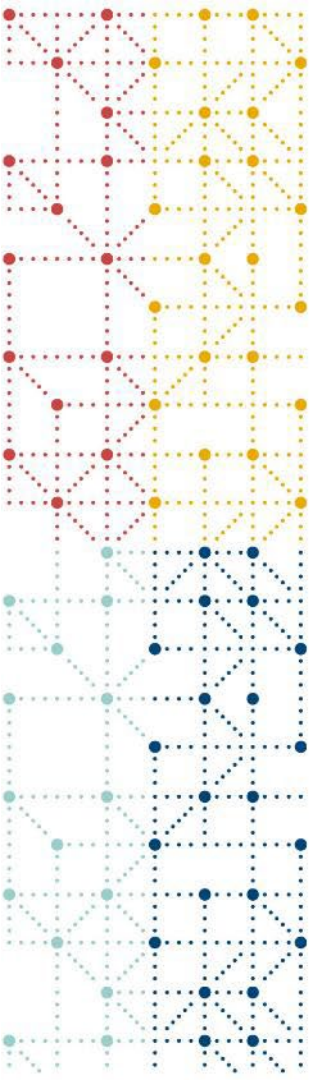
- Small team supporting regulatory filings including DERC, DSUR, IB, Publications, CSR, Exploratory analysis, etc., and hybrid outsourcing with collaborative production work
- Focus is to maximize standardization & automation to gain efficiencies



Mock shell preparation was manual

- Primary tool is MS Word
- Considerable time spent on formatting
- Copy and paste of repeat TFLs
- TOC and hyperlinks
- Annotation of TFLs/ ADaM metadata
- Team would enter feedback in Word document resulting in a tedious process to review and respond to feedback

All the above needs to be repeated to insert/ delete TFLs after team review



Establishing Safety & Oncology Specific TFL Library and Analysis Results Metadata Repository

Xencor Template Library (for DSUR, IB and CSR)

TFL DESIGNER

My Studies **Tables** All **Xencor** Community My Library In Review Q

Name	Analysis Of Interest	Compound	Reporting Event	Disease Area	Therapeutic Area	Created	Action
Table 5 Cumulative Summary of irAEs by System Organ Class and Preferred Term	Adverse Events	XmAb 20717	DSUR	Oncology	Program	29 May 2024	:
Table 4 Cumulative Serious Adverse Reactions by System Organ Class and Preferred Term	Adverse Events	XmAb 20717	DSUR	Oncology	Program	29 May 2024	:
Table 3 Cumulative Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term	Adverse Events	XmAb 20717	DSUR	Oncology	Program	29 May 2024	:
Table 2 Cumulative Subject Exposure by Race	Exposure	XmAb 20717	DSUR	Oncology	Program	29 May 2024	:
Table 1 Cumulative Subject Exposure by Age and Sex	Exposure	XmAb 20717	DSUR	Oncology	Program	29 May 2024	:
Table 11 Treatment-Related Adverse Events by Preferred Term and Maximum Severity Grade	Adverse Events	XmAb 20717	IB	Oncology	Multi-Indication	29 May 2024	:
Table 8 Treatment-emergent Adverse Events with CTCAE Grade >= 3 by Preferred Term in Decreasing Frequency	Adverse Events	XmAb 20717	IB	Oncology	Multi-Indication	29 May 2024	:
Table 7 Treatment-emergent Adverse Events by Preferred Term in Decreasing Frequency	Adverse Events	XmAb 20717	IB	Oncology	Multi-Indication	29 May 2024	:
Table 6 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Adverse Events	XmAb 20717	IB	Oncology	Multi-Indication	29 May 2024	:
Table 5 Overview of Treatment-Emergent Adverse Events	Adverse Events	XmAb 20717	IB	Oncology	Multi-Indication	29 May 2024	:
Table 4 Study Drug Exposure	Exposure	XmAb 20717	IB	Oncology	Multi-Indication	29 May 2024	:
Table 3 Baseline Characteristics	Demographics	XmAb 20717	IB	Oncology	Multi-Indication	29 May 2024	:
Table 2 Demographics	Demographics	XmAb 20717	IB	Oncology	Multi-Indication	29 May 2024	:
Table 1 Disposition	Disposition	XmAb 20717	IB	Oncology	Multi-Indication	29 May 2024	:
SZZT1401A Observed Value, Change from Baseline, and Percent Change from Baseline - Parameter	Others	XmAbXXX	CSR	Oncology	Solid Tumors	23 Apr 2024	:
SVST1401A Categorical Summary of Observed Values and Change from Baseline - QTCF	Vital Signs	XmAbXXX	CSR	Oncology	Solid Tumors	23 Apr 2024	:

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Examples of Oncology Templates Developed

- ECOG: Observed Values, Change from Baseline, and Percent Change from Baseline
- RECIST 1.1 (irRC or imRECIST): Best Overall Responses, Time to Response, Duration of Response, Progression-Free Survival, Overall Survival
- Tumor Burden by RECIST 1.1
- Kaplan-Meier Plots for Progression-Free Survival and Overall Survival
- Best Percent Change in RECIST 1.1 Sum of Diameters
- Swimmer Plots for Subject Disposition and Response

Automation for Biostats and Stat Programmers

The screenshot displays the TFL Designer software interface. The top navigation bar includes the TFL Designer logo, a menu (File, Edit, Help), and the project name "Neurology / Alzheimer's / Clymb Pilot 01". Below the navigation bar, a breadcrumb trail shows "All Tables Figures Listings Table Of Contents". A search bar is present in the top left of the main content area. On the left side, a sidebar lists the table of contents items, each with a small icon and a vertical ellipsis menu. The main content area displays the "Table of Contents" for "Clymb Pilot 01", listing 13 items with their respective titles and population groups.

Table of Contents
Clymb Pilot 01

1. Table 14.1.1.1: Summary of Analysis Populations (All Subjects)
2. Table 14.1.1.2.1: Summary of Subject Disposition (ITT Population)
3. Table 14.3.2.2: Summary of Observed and Change from Baseline by Scheduled Visits - Chemistry Laboratory Test (ITT Population)
4. Table 14.1.1.2.2: Summary of Subject Disposition (Safety Population)
5. Table 14.1.1.3.1: Summary of Demographic and Baseline Characteristics (ITT Population)
6. Table 14.1.1.3.2: Summary of Demographic and Baseline Characteristics (Safety Population)
7. Table 14.1.2.1: Summary of Medical History by System Organ Class and Preferred Term (All Subjects)
8. Table 14.1.2.2: Summary of Concomitant Medications by Anatomic Classification and Preferred Term (Safety Population)
9. Table 14.3.1.1: Overall Summary of Treatment Emergent Adverse Events (Safety Population)
10. Table 14.3.1.2: Summary of TEAE by System Organ Class and Preferred Term (Safety Population)
11. Table 14.3.3.1: Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs (Safety Population)
12. Figure 14.2.1: Box Plot (All Subjects)
13. Table 14.3.2.1: Summary of Observed and Change from Baseline by Scheduled Visits - Hematology Laboratory Test (ITT Population)

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Automation for Biostats and Stat Programmers

The screenshot displays the TFL Designer software interface. The main window shows a table titled "Clymb Pilot 01" with columns for Age, Mean, Median, Q1, Minimum, Maximum, Age Group, Ethnicity, and Gender. The table data is as follows:

Age	Mean	Median	Q1	Minimum	Maximum	Age Group	Ethnicity	Gender
< 65							Hispanic	
65 to							Non-Hispanic	
> 80							Female	
							Male	

An "Edit Study" dialog box is open, showing the "Display Configuration" tab. The dialog is titled "CONFIDENTIAL" and has a "Split header 1" section. The "Split header 1" section includes a "Header" field with a blue bar, a "Title" field, and a "Subtitles" field. The "Column Headings" section includes "Analysis Stubs" and "Result Values" fields. The "Legends" section includes an "Abbreviations" field. The "Footnotes" section includes a "Footnotes" field. The "Programming Notes" section includes a "Programming Notes" field. The "Footer" section includes a "Footer" field. The dialog also has a "Style" section and an "Add More" button. The dialog has "Cancel", "Previous", and "Save" buttons at the bottom.

The background interface shows a sidebar with a search bar and a list of tables. The top bar shows "Neurology / Alzheimer's / Clymb Pilot 01". The right sidebar shows "Properties" and "Outline" tabs.

Automation for Biostats and Stat Programmers

The screenshot displays the TFL Designer software interface. The top navigation bar includes 'File', 'Edit', and 'Help' menus, and the current project is identified as 'Neurology / Alzheimer's / Clymb Pilot 01'. The main workspace shows a document titled 'Clymb Pilot 01' with a 'CONFIDENTIAL' watermark. The document content includes a table caption: 'Table 14.1.1.3.1 Summary of Demographic and Baseline Characteristics ITT Population'. The table below compares characteristics across three groups: Placebo (N=XX), Xanomeline Low Dose (N=XX), and Xanomeline High Dose (N=XX). The table is organized into sections for Age, Age Group, and Ethnicity. A left-hand sidebar contains a table of contents, with the current table highlighted. The CDISC logo is visible in the bottom left corner.

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Age			
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.X, XX.X	XX.X, XX.X	XX.X, XX.X
Age Group			
< 65 yrs	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
65 to 80 yrs	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
> 80 yrs	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Ethnicity			
Hispanic	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Non-Hispanic	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)

Automation for Biostats and Stat Programmers

TFL DESIGNER File Edit Help Neurology / Alzheimer's / Clymb Pilot 01

All Tables Figures Listings Table of Contents Summary of Subject Dispos... x Summary of Demographic a... x Summary of Demographic a... x

Search **FL**

Table of Contents
Clymb Pilot 01

- Table 14.1.1.1 : 1. Summary of Analysis Populations
- Table 14.1.1.2.1 : 2. Summary of Subject Disposition
- Table 14.1.1.2.2 : 3. Summary of Subject Disposition
- Table 14.1.1.3.1 : 4. Summary of Demographic and Baseline Characteristics
- Table 14.1.1.3.2 : 5. Summary of Demographic and Baseline Characteristics
- Table 14.1.2.1 : 6. Summary of Medical History by System Organ Class and...
- Table 14.1.2.2 : 7. Summary of Concomitant Medications by Anatomic...
- Table 14.3.1.1 : 8. Overall Summary of Treatment Emergent Adverse...
- Table 14.3.1.2 : 9. Summary of TEAE by System Organ Class and Preferred Term
- Table 14.3.2.1 : 10. Summary of Observed and Change from Baseline by...
- Table 14.3.2.2 : 11. Summary of Observed and Change from Baseline by...
- Table 14.3.3.1 : 12. Summary of Observed and Change from Baseline by...

13 Shells

CONFIDENTIAL

Table 14.1.1.3.1
Summary of Demographic and Baseline Characteristics

ITT Population

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Age			
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.X, XX.X	XX.X, XX.X	XX.X, XX.X
Age Group			
< 65 yrs	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
65 to 80 yrs	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
> 80 yrs	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Ethnicity			
Hispanic	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Non-Hispanic	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Gender			
Female	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Male	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)

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Properties Outline

Analysis Dataset

Analysis Category

Analysis Of Interest

> Data Subset for Table

Split Statistics Column

Population Set

Population Dataset

> Where Clause for ITT Population

Treatment Arm Set

Sub Group Properties

Sub Group Variable

Sub Group Label

> Where Clause for Sub Group

Automation for Biostats and Stat Programmers

TFL DESIGNER File Edit Help Neurology / Alzheimer's / Clymb Pilot 01

T Sans-serif Tr 14 T1 20 B I U [Table Icons] #000000 #ffff

All Tables Figures Listings Table Of Contents Summary of Demographic a... x

Search F1

Table of Contents Clymb Pilot 01

Table 14.1.1.1 1. Summary of Analysis Populations

Table 14.1.1.2.1 2. Summary of Subject Disposition

Table 14.1.1.2.2 3. Summary of Subject Disposition

Table 14.1.1.3.1 4. Summary of Demographic and Baseline Characteristics

Table 14.1.1.3.2 5. Summary of Demographic and Baseline Characteristics

Table 14.1.2.1 6. Summary of Medical History by System Organ Class and...

Table 14.1.2.2 7. Summary of Concomitant Medications by Anatomic...

Table 14.3.1.1 8. Overall Summary of Treatment Emergent Adverse...

Table 14.3.1.2 9. Summary of TEAE by System Organ Class and Preferred Term

Table 14.3.2.1 10. Summary of Observed and Change from Baseline by...

Table 14.3.2.2 11. Summary of Observed and Change from Baseline by...

Table 14.3.3.1

13 Shells

Clymb Pilot 01

CONFIDENTIAL

Table 14.1.1.3.1
Summary of Demographic and Baseline Characteristics
ITT Population

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Age			
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.X, XX.X	XX.X, XX.X	XX.X, XX.X
Age Group			
< 65 yrs	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
65 to 80 yrs	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
> 80 yrs	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Ethnicity			
Hispanic	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Non-Hispanic	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Gender			
Female	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)

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Properties Outline

Result Description

Age

Dataset ADSL

Variable AGE

> Where Clause for Age Configure

Statistics Set

Statistics Set 1

Advanced

Reason

SPECIFIED IN SAP

Purpose

Summary of Demographics and Baseli...

GroupingByVar

Enter GroupingByVar

GroupingByOrdFmt

Enter GroupingByOrdFmt

Documentation

SAP Section 9.2

Programming Code Context

Summary Stats Continuous Var

Programming Code

%univars

Code Reference

SAS Macro call

Format

best

Automation for Biostats and Stat Programmers

The screenshot displays the TFL Designer software interface for a study titled "Neurology / Alzheimer's / Clymb Pilot 01". A "Save Changes" dialog box is open in the center, asking "Are you sure you want to save these changes?". The dialog offers four options:

- Save (the changes will not be implemented on the existing shells)
- Apply to selected shell
- Save & apply to selected shell
- Save & apply to all shells in this study (might take time)
- Save & apply to all shells without changing statistics (might take time)

The background interface shows the "Edit Study" configuration screen. It includes a "Where Clause" section with three treatment arms:

- Treatment Arm 2: Xanomeline Low Dose (N=XX), Where Clause: (TRT01A EQ 'Xanomeline Low D...'), No. of Straddles: 0
- Treatment Arm 3: Xanomeline High Dose (N=XX), Where Clause: (TRT01A EQ 'Xanomeline High D...'), No. of Straddles: 0
- Treatment Arm 4: All Patients (N=XX), Where Clause: (TRT01A), No. of Straddles: 0

The interface also shows a table of characteristics for "Age" and "Ethnicity".

Characteristic	n	Mean (SD)	Median	Q1, Q3	Min, Max
Age Group					
< 65 yrs					
65 to 80 yrs					
> 80 yrs					
Ethnicity					
Hispanic					
Non-Hispanic					
Gender					
Female					

Figures and Listings Mock-ups

TFL DESIGNER Oncology / Solid Tumors / Xencor Shell Library

File View Help

All Tables Figures Listings Table Of Contents Best Overall Responses and ... X Kaplan-Meier Plot for Progr... X Kaplan-Meier Plot Overall S... X Best Percent Change from B... X Best Percent Change from B... X Observed Prostate Specific... X Swimmer Plot

Search

Table of Contents
Xencor Shell Library

Figure 14.2.10.1
1. Kaplan-Meier Plot for Progression Free Survival...

Figure 14.2.11.1
2. Kaplan-Meier Plot Overall Survival

Figure 14.2.2.2
3. Best Percent Change from Baseline in RECIST 1.1 Sum of...

Figure 14.2.3.2
4. Best Percent Change from Baseline in Prostate Specific...

Figure 14.2.4.2
5. Observed Prostate Specific Antigen (OPSA) by Study Day

Figure 14.2.6.1
6. Swimmer Plot - Subject Disposition and RECIST 1.1...

Figure 14.2.6.2
7. Swimmer Plot - Subject Disposition and RECIST 1.1...

7 Sheets

Xencor, Inc.
Protocol ABC-MD-XX [XXXXXXXXXX]

Page n of N
Data snapshot/cutoff

Study is under review

Figure 14.2.10.1
Kaplan-Meier Plot for Progression Free Survival-PCWG3
Efficacy Analysis Set - Dose Expansion

TFL DESIGNER Oncology / Solid Tumors / Xencor Shell Library

File View Help

All Tables Figures Listings Table Of Contents Subject Disposition X

Search

Table of Contents
Xencor Shell Library

Listing 16.2.1.1
1. Subject Disposition

Listing 16.2.1.3
2. Subject Disposition-Long Term Follow-up and Survival

Listing 16.2.1
3. Demographics

Listing 16.2.2
4. Concomitant Procedures

Listing 16.2.7
5. Adverse Events

Listing 16.2.7.3
6. Treatment-Related Adverse Events

Xencor, Inc.
Protocol ABC-MD-XX [XXXXXXXXXX]

Page n of n
Data snapshot/cutoff

Listing 16.2.1.1
Subject Disposition
Safety Analysis Set

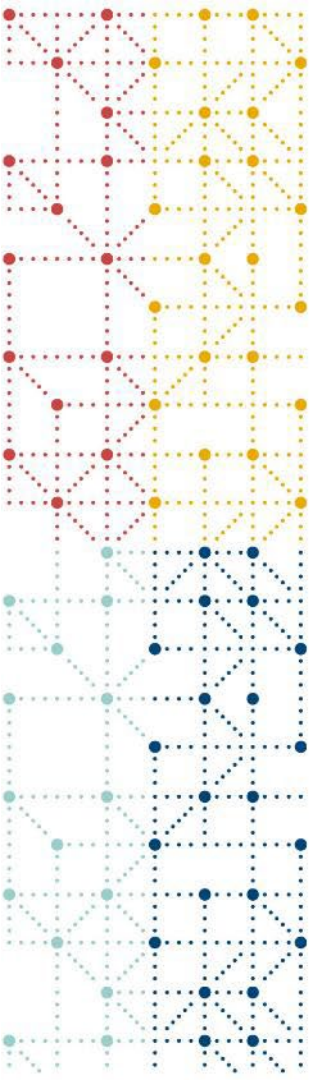
Cohort Dose Level	Subject	Safety (S)	Efficacy (E)	Analysis Set			Enter Label	First Last Date Date (Study Day)	Primary Reason	(Date) (Study Day)
				Modified Per Protocol (M)	PK (P)	PD (D)				
xxx.xx mg/kg	xxx-xxxxx	No	No	No	No	No	EOTEOS	ddmm/yyyy / ddmm/yyyy	WITHDRAWAL BY SUBJECT	(ddmm/yyyy) (00)
xxx.xx mg/kg	xxx-xxxxx	Yes	Yes	Yes	Yes	Yes	EOTEOS	ddmm/yyyy / ddmm/yyyy	WITHDRAWAL BY SUBJECT	(ddmm/yyyy) (00)
xxx.xx mg/kg	xxx-xxxxx						EOTEOS	ddmm/yyyy / ddmm/yyyy	PROGRESSIVE DISEASE	(ddmm/yyyy) (00)
xxx.xx mg/kg	xxx-xxxxx						EOTEOS	ddmm/yyyy / ddmm/yyyy		(ddmm/yyyy) (00)

EOT=end of treatment; EOS=end of study; PK= Pharmacokinetics; PD= Pharmacodynamic

(S) Safety Analysis Set includes all subjects who received at least one infusion of XmAb20717.
 (E) The Efficacy Analysis Set consists of all subjects who are enrolled in the study and received at least 1 infusion of any amount of XmAb20717.
 (M) The Modified Per Protocol Analysis Set consists of all subjects who are treated at least first 2 cycles with full doses (i.e. 4 doses) of XmAb20717, have evaluable baseline and at least 1 post-baseline radiology scans.
 (P) PK (PD) Analysis Set is defined as all subjects who receive at least 1 dose of study drug and have at least 1 post-baseline PK (PD) data available.
 Source: ADRS, Program_L_16_2_1_1.csv, Output_L_16_2_1_1_Subject Disposition Safety Analysis Set, Generated on: 2018P0201301.09.03

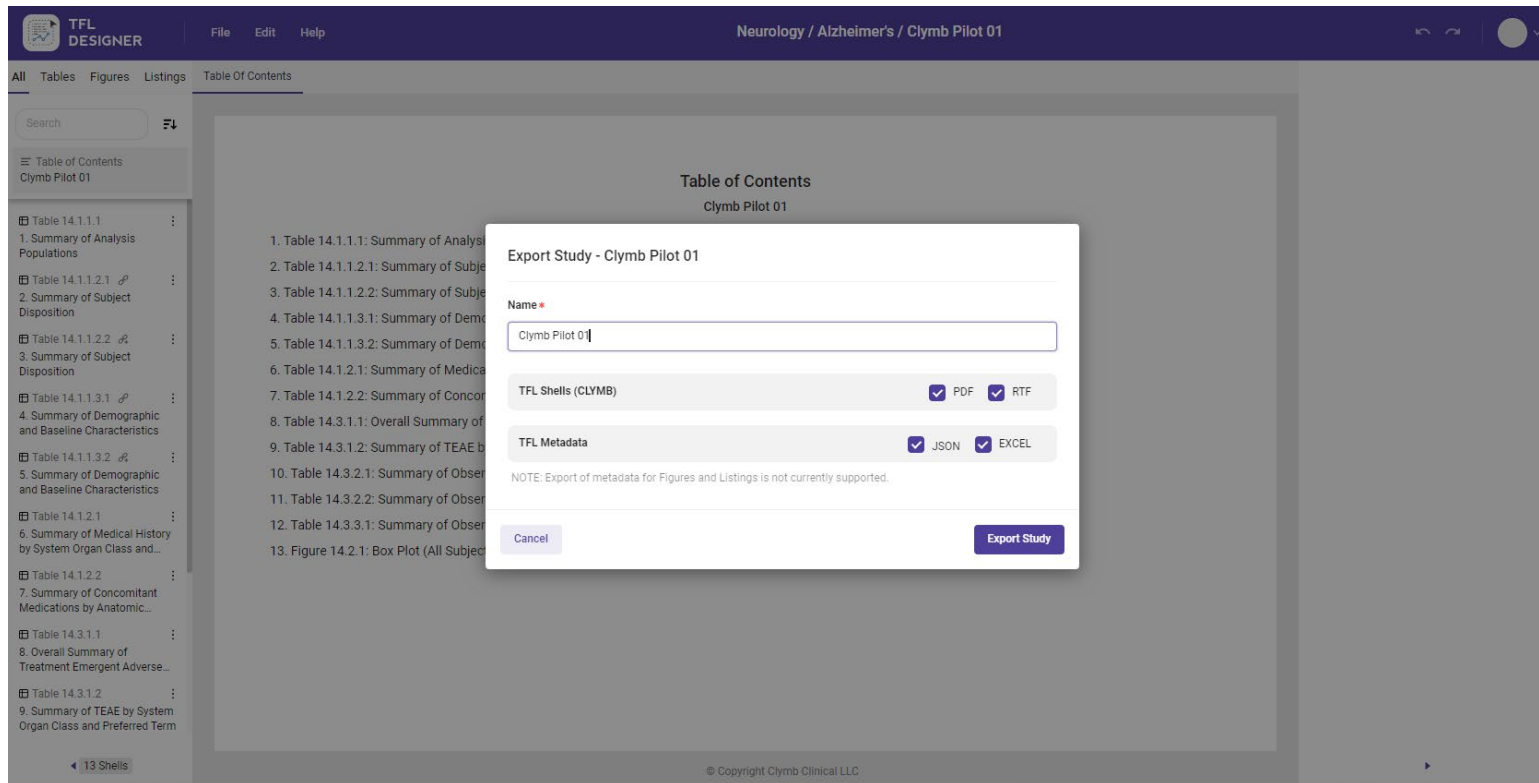
7 Sheets

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Export TFL Shells and Metadata

Export TFL Shells and ARS Metadata



The screenshot displays the TFL Designer interface. The top navigation bar includes 'TFL DESIGNER', 'File', 'Edit', and 'Help'. The main window title is 'Neurology / Alzheimer's / Clymb Pilot 01'. The left sidebar shows a 'Table of Contents' for 'Clymb Pilot 01' with a search bar and a list of 13 tables. The main content area shows a 'Table of Contents' for 'Clymb Pilot 01' with a list of 13 items. A modal dialog titled 'Export Study - Clymb Pilot 01' is open, featuring a 'Name' field with 'Clymb Pilot 01' entered. Below the field are two sections: 'TFL Shells (CLYMB)' with checkboxes for 'PDF' and 'RTF', and 'TFL Metadata' with checkboxes for 'JSON' and 'EXCEL'. A note states: 'NOTE: Export of metadata for Figures and Listings is not currently supported.' The dialog has 'Cancel' and 'Export Study' buttons. The bottom of the interface shows '13 Shells' and '© Copyright Clymb Clinical LLC'.

Export TFL Shells and ARS Metadata

The screenshot displays two overlapping windows of Microsoft Word. The background window shows a document with a table of contents on the left side, listing items such as 'Table 14.1.1', 'Table 14.1.1.1', and 'Figure 14.2'. The foreground window shows a document page with the following content:

Clymb Pilot 01

CONFIDENTIAL

Table 14.1.1.1
Summary of Analysis Populations
All Subjects

Analysis Population, n (#)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	All Patients (N=XX)
Enrolled	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Safety	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Intent-To-Treat (ITT)	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Full Analysis Set	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Per-Protocol	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)
Completed Study	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)	XX (XX.XX)

NOTE: N in column headers represents number of subjects entered in study (i.e., signed informed consent). The ITT population includes all subjects randomized. The Safety population includes all randomized subjects known to have taken at least one dose of randomized study drug. The Full Analysis Set population includes all subjects in the safety population who also have at least one post-baseline ADAS-Cog and CIBIC+assessment.
Source: adxx; Program name; Program run date/time

Page x of y

Page 2 of 21 2628 words Text Predictions: On Accessibility: Unavailable

Export TFL Shells and ARS Metadata

The screenshot displays a software interface with two main components: a JSON editor on the left and a data table on the right.

JSON Editor (Left): Shows a file named "Clymb Pilot 01.json" with the following content:

```
{
  "about": {
    "generatedUsing": "TFL-Designer-Community"
    "version": "
    "note": "The
  },
  "studyInfo": {
    "studyId": "
    "studyTitle"
    "phase": "Ph
    "compoundUnd
    "description
    "diseaseArea
    "therapeutic
  },
  "name": "Clinica
  "id": "CSR",
  "mainListOfConte
    "name": "Lis
    "label": "LC
    "contentsLis
      "listIt
  {

```

Data Table (Right): A table with columns A through G. The data is as follows:

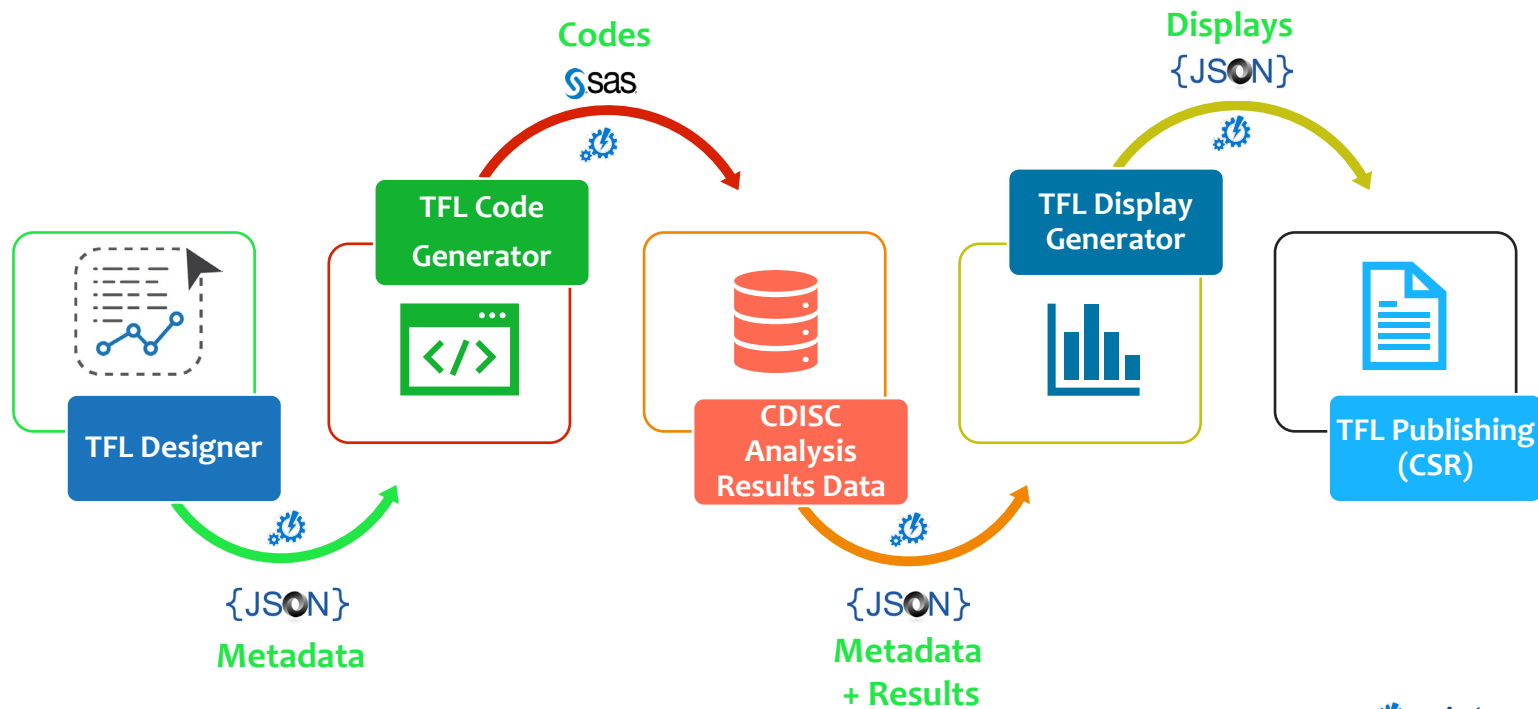
A	B	C	D	E	F	G
1	id	name	version	displayTitle	Section_section	orderedDisplaySection_subSection
2	Disp_01	Summary	1	Summary of Analysis Populations	Title	1 Disp_01_Title_1
3	Disp_01	Summary	1	Summary of Analysis Populations	Title	2 Disp_01_Title_2
4	Disp_01	Summary	1	Summary of Analysis Populations	Title	3 Disp_01_Title_3
5	Disp_01	Summary	1	Summary of Analysis Populations	Footnote	1 Disp_01_Footnote_01
6	Disp_01	Summary	1	Summary of Analysis Populations	Footnote	2 Disp_01_Footnote_02
7	Disp_01	Summary	1	Summary of Analysis Populations	Rowlabel Hea	1 Disp_01_Rowlabel Head
8	Disp_02	Summary	1	Summary of Subject Disposition	Title	1 Disp_02_Title_01
9	Disp_02	Summary	1	Summary of Subject Disposition	Title	2 Disp_02_Title_02
10	Disp_02	Summary	1	Summary of Subject Disposition	Title	3 Disp_02_Title_03
11	Disp_02	Summary	1	Summary of Subject Disposition	Footnote	1 Disp_02_Footnote_01
12	Disp_02	Summary	1	Summary of Subject Disposition	Rowlabel Hea	1 Disp_02_Rowlabel Head
13	Disp_03	Summary	1	Summary of Subject Disposition	Title	1 Disp_03_Title_01
14	Disp_03	Summary	1	Summary of Subject Disposition	Title	2 Disp_03_Title_02
15	Disp_03	Summary	1	Summary of Subject Disposition	Title	3 Disp_03_Title_03
16	Disp_03	Summary	1	Summary of Subject Disposition	Footnote	1 Disp_03_Footnote_01
17	Disp_03	Summary	1	Summary of Subject Disposition	Rowlabel Hea	1 Disp_03_Rowlabel Head
18	Disp_04	Summary	1	Summary of Demographic and Base	Title	1 Disp_04_Title_01
19	Disp_04	Summary	1	Summary of Demographic and Base	Title	2 Disp_04_Title_02
20	Disp_04	Summary	1	Summary of Demographic and Base	Title	3 Disp_04_Title_03
21	Disp_04	Summary	1	Summary of Demographic and Base	Footnote	1 Disp_04_Footnote_01
22	Disp_04	Summary	1	Summary of Demographic and Base	Rowlabel Hea	1 Disp_04_Rowlabel Head
23	Disp_05	Summary	1	Summary of Demographic and Base	Title	1 Disp_05_Title_01
24	Disp_05	Summary	1	Summary of Demographic and Base	Title	2 Disp_05_Title_02
25	Disp_05	Summary	1	Summary of Demographic and Base	Title	3 Disp_05_Title_03
26	Disp_05	Summary	1	Summary of Demographic and Base	Footnote	1 Disp_05_Footnote_01
27	Disp_05	Summary	1	Summary of Demographic and Base	Rowlabel Hea	1 Disp_05_Rowlabel Head



Improvements after TFL Designer

- Reduction in manual formatting
- Create repository for TFL standardization
- Improved process for review and feedback of mock shell
- Automation of TFL metadata
- Improved collaboration with multiple vendors/CROs
- Ability to export to RTF/PDF

Next Steps: Utilizing Analysis Results Metadata to Automate Downstream Processes



 = Automated Process



Lessons Learned

- Be open to using newer tools that drive automation and efficiency
- Proactively train the team
- Available to answer questions
- Cost can be justified based on real improvements in efficiency, standardization, and automation of Biostatistics and programming processes, when other functions are implementing AI tools with uncertain benefits.



General Recommendations

- Involve stakeholders from the beginning to ensure buy-in and collaboration.
- Regularly update the TFL repository to incorporate the latest standards and lessons learned.
- Leverage machine learning and automation tools to further reduce manual effort and increase accuracy.



Thank You!

Bhavin Busa

Clymb Clinical

bhavin@clymbclinical.com

Salil Parab

Xencor, Inc

sparab@xencor.com

The logo for CDISC, featuring the lowercase letters "cdisc" in a dark blue font. Above the letter "i" are three small colored dots: a red one, a yellow one, and a light blue one.