

Transforming Clinical Programming with Generative AI: Enhancing SDTM, ADaM, and TLF Processes



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Introduction to GenAI in Clinical Trials



Life sciences industry requires faster, compliant clinical trial submissions



Generative AI (GenAI) can significantly automate SDTM, ADaM, and TLF processes



LLMs can reduce manual efforts while maintaining compliance and quality standards

Current State of Clinical Programming

Clinical trials are increasingly complex

- Tighter regulations
- Intricate data sources

Many processes still rely on manual coding

- Even with CDISC standards

Manual programming can be repetitive, inefficient, and prone to errors

- Impacts submissions

The Need for Automation



Manual data mapping
and coding
Time-consuming
Resource-intensive



Automation can
improve accuracy and
reduce burden



As trials expand globally,
the demand for streamlined
processes rises

Understanding GenAI and LLMs



GenAI refers to algorithms capable of generating new content, such as code and summaries



Large Language Models (LLMs) are specialized GenAI tools trained on vast data sets

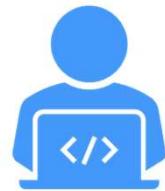


LLMs help bridge the gap between human expertise and machine automation in programming

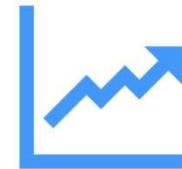
Goals of the Presentation



Demonstrate practical applications of LLMs in clinical programming workflows



Explore automation in SDTM mapping, ADaM generation, and TLF programming



Showcase real-world case studies highlighting LLM benefits in efficiency and compliance

Common Challenges Faced



Mapping SDTM and ADaM datasets remains a manual, error-prone process often leading to inconsistencies



Common TLF coding is redundantly written, increasing the risk of errors and inefficiencies



Document management is often disjointed, complicating cross-referencing and updates

Business Impact of Automation



Delivers time savings in dataset mapping and TLF production, leading to quicker outputs



Cost efficiency emerges as reliance on external resources decreases



Increased submission readiness through consistent, compliant outputs across studies

LLM Capabilities in Life Sciences

LLMs can translate natural language requirements into executable programming code

Can generate starter code for datasets by interpreting metadata specifications

Assist in identifying inconsistencies in programming documentation and logic

SAS Co-Pilot

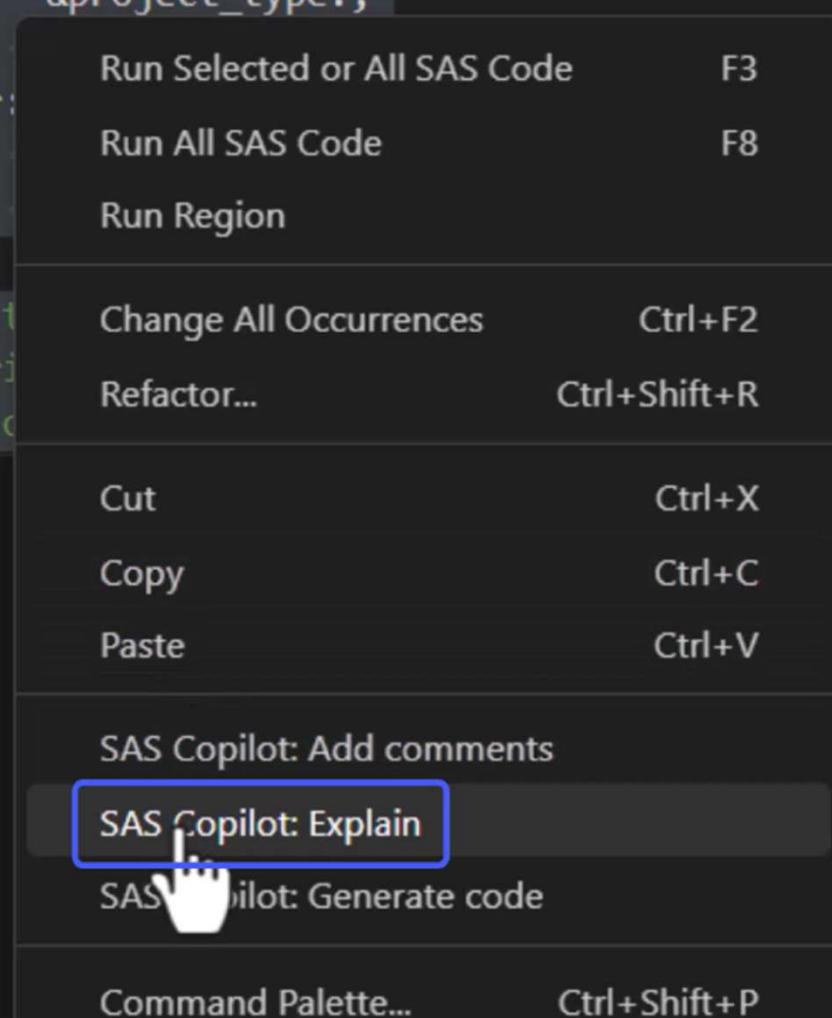
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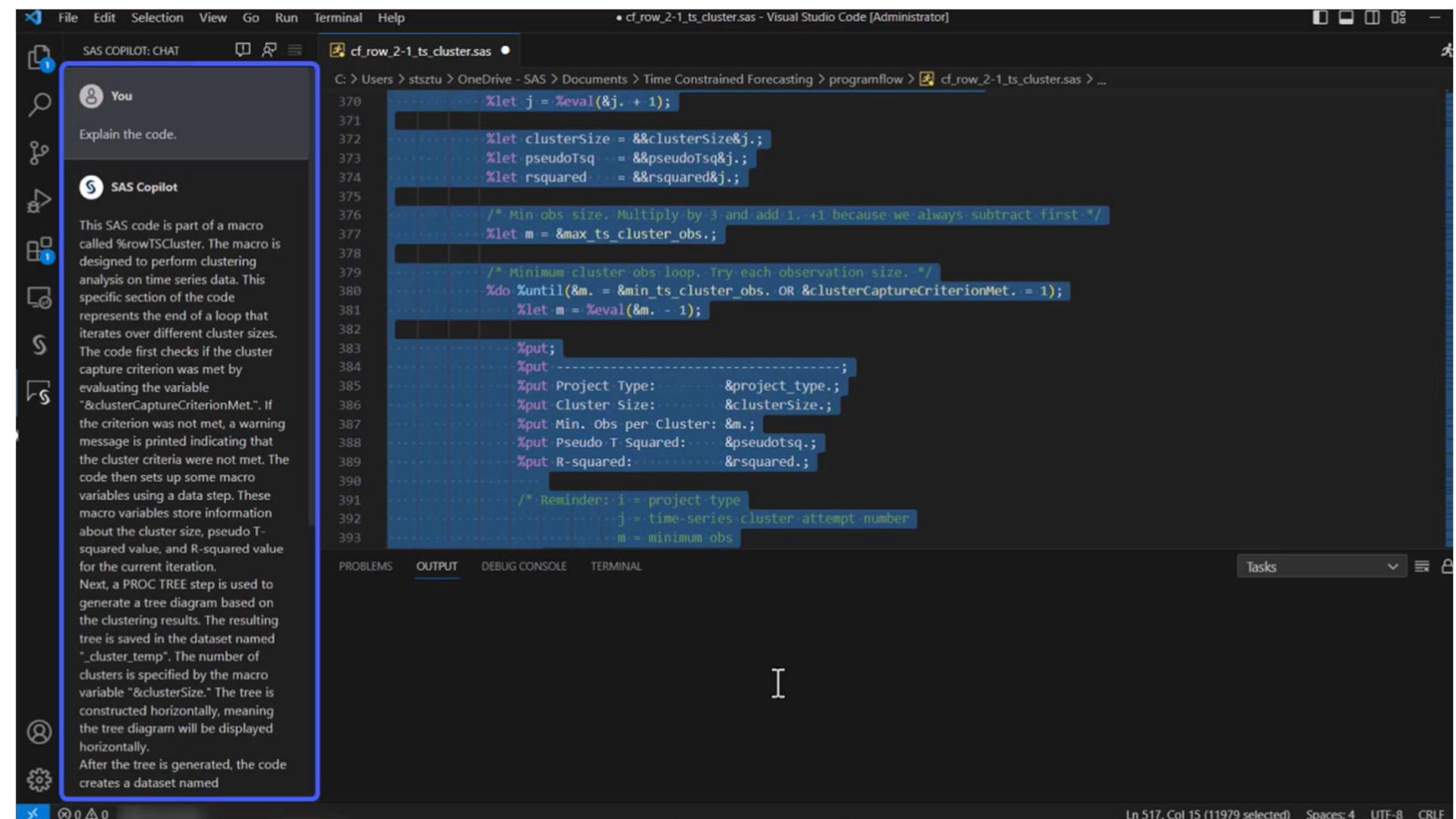


```
%put Project Type: ..... &project_type.;  
%put Cluster Size: .....  
%put Min. Obs per Cluster: .....  
%put Pseudo T Squared: .....  
%put R-squared: .....  
/* Reminder: i = project type  
   j = time-series  
   m = minimum count
```

DEBUG CONSOLE

TERMINAL





File Edit Selection View Go Run Terminal Help

• cf_row_2-1_ts_cluster.sas - Visual Studio Code [Administrator]

SAS COPILOT: CHAT

You Explain the code.

SAS Copilot

This SAS code is part of a macro called %rowTScluster. The macro is designed to perform clustering analysis on time series data. This specific section of the code represents the end of a loop that iterates over different cluster sizes. The code first checks if the cluster capture criterion was met by evaluating the variable "&clusterCaptureCriterionMet". If the criterion was not met, a warning message is printed indicating that the cluster criteria were not met. The code then sets up some macro variables using a data step. These macro variables store information about the cluster size, pseudo T-squared value, and R-squared value for the current iteration. Next, a PROC TREE step is used to generate a tree diagram based on the clustering results. The resulting tree is saved in the dataset named "_cluster_temp". The number of clusters is specified by the macro variable "&clusterSize." The tree is constructed horizontally, meaning the tree diagram will be displayed horizontally. After the tree is generated, the code creates a dataset named

```
370      %let j = %eval(&j. + 1);
371
372      %let clusterSize = &&clusterSize&j.;
373      %let pseudoTsq = &&pseudoTsq&j.;
374      %let rsquared = &&rsquared&j.;
375
376      /* Min. obs. size. Multiply by 3 and add 1, +1 because we always subtract first */
377      %let m = &max_ts_cluster_obs.;
378
379      /* Minimum cluster obs loop. Try each observation size. */
380      %do %until(&m. = &min_ts_cluster_obs. OR &clusterCaptureCriterionMet. = 1);
381          %let m = %eval(&m. - 1);
382
383          %put;
384          %put -----;
385          %put Project Type: &project_type.;
386          %put Cluster Size: &clusterSize.;
387          %put Min. Obs per Cluster: &m.;
388          %put Pseudo T-Squared: &pseudotsq.;
389          %put R-squared: &rsquared.;
390
391          /* Reminder: i = project type
392             j = time-series cluster attempt number
393             m = minimum obs
```

PROBLEMS OUTPUT DEBUG CONSOLE TERMINAL

Tasks

Ln 517, Col 15 (11979 selected) Spaces:4 UTF-8 CRLF

cf_row_2-1_ts_cluster.sas • clt_medic_v2.sas cf_row_1_data.sas

C: > Users > stsztu > OneDrive - SAS > Documents > git > sas > parallel-proc

Add comments | Explain

```
27 options autosignon=yes
28     →     → noconnectwait →     →
29     →     → noconnectpersist →
30     →     → sascmd='!sascmd' →
31     →     → ;
32
33 %macro parallel(data=, workers=);
34     →     → %let dsid= %sysfunc(open(&data.));
35     →     → %let n= %sysfunc(attrn(&dsid., nlobs));
36     →     → %let rc= %sysfunc(close(&dsid.));
```

```
27 /* options */
28 options tosignon=yes /* enable automatic sign-on */
29   connectwait /* do not wait for remote sessions to finish */
30   noconnectpersist /* do not persist remote sessions */
31   sascmd='!sascmd'; /* specify the SAS command to execute */
32
33 /* declare macro */
34 %macro parallel(data=, workers=);
35
36 /* open the data set and gather necessary information */
37 %let dsid = %sysfunc(open(&data.));
38 %let n = %sysfunc(attrn(&dsid, nlobs));
39 %let rc = %sysfunc(close(&dsid));
40
41 /* create a libname for local work directory */
42 libname workdir "%sysfunc(getoption(work))";
43
44 /* loop through the number of workers */
45 %do w = 1 %to &workers.;
46
47   /* calculate observations for each worker */
48   %let obs = %eval(&n/&workers.);
```

```
57 run;  
58  
59 %cleanTempFiles(kill=yes);  
60  
Add comments | Explain | Generate code  
61 /* Create a gradient boosting model that uses _CL  
62   Add the following features:  
63   1. Partitioning with a 70/30 Train/Validation  
64   2. Autotuning  
65 */
```

Add comments | Explain | Generate code

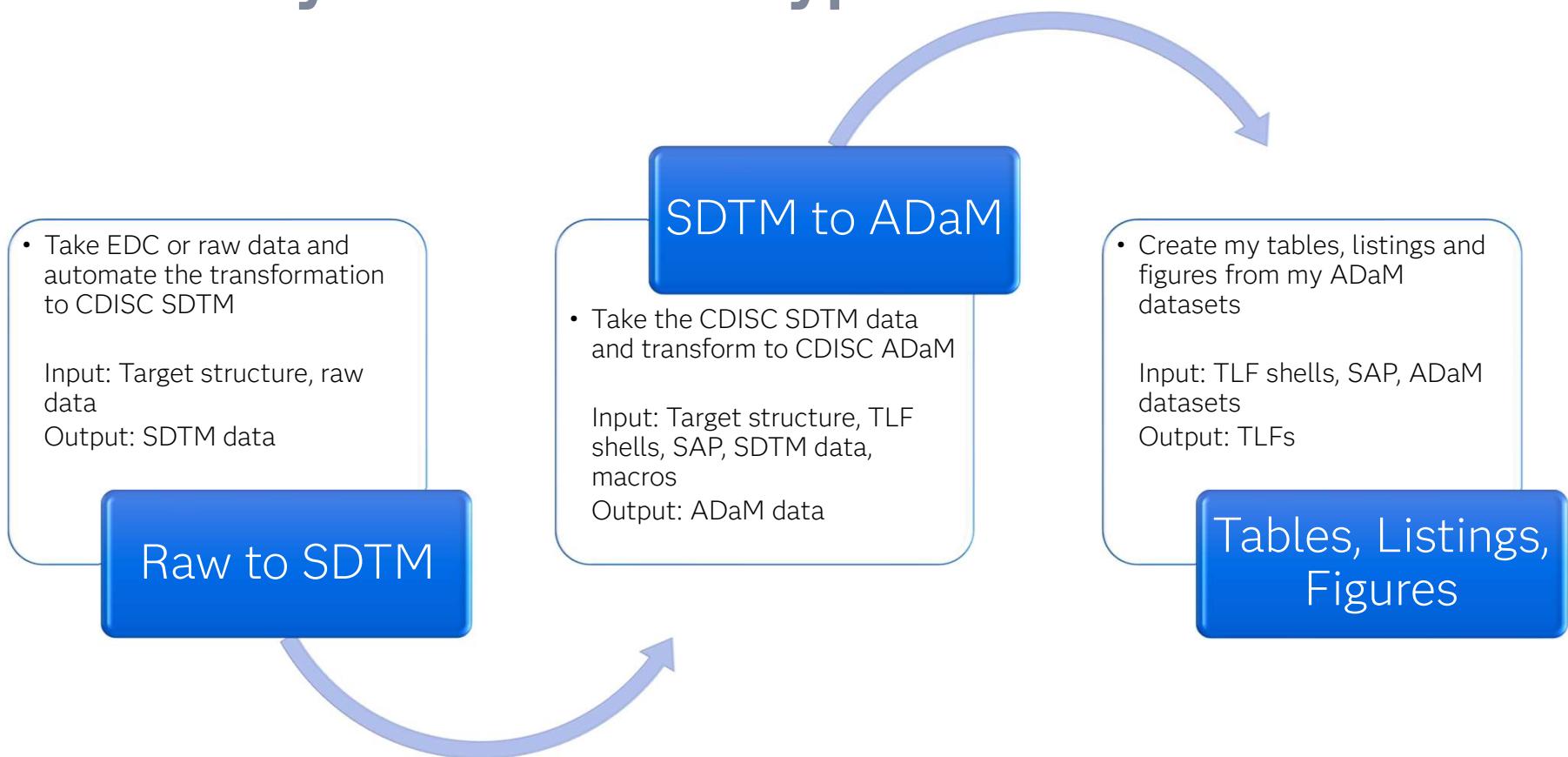
```
51 /* Create a gradient boosting model that uses _CLUSTER_ID_ as the target from whouse.cf_row_c
52 ... Add the following features: [REDACTED]
53 ... 1. Partitioning with a 70/30 Train/Validation fit
54 ... 2. Autotuning [REDACTED]
55 */
56 proc gradboost data=whouse.cf_row_cluster_lookup;
57   partition fraction(validate=0.3);
58   target _CLUSTER_ID_ / level=nominal;
59   autotune tuningparameters=(ntrees samplingrate vars_to_try learningrate lasso ridge);
60 run;
```

[REDACTED]

PROBLEMS [OUTPUT](#) DEBUG CONSOLE TERMINAL

Agentic AI for Clinical Data Flow

Minimally Viable Prototype - Goals



Welcome, sinpan

Logout

Create New Clinical Study Project

CDISC_PILOT_Study_Project

Data Specifications

Base Directory

/nfsshare/sashls2/data/sinpan/Clinical_Data_Flow_Ai

Raw Data folder name

raw-data

SDTM datasets folder name

tabulations-sdtm

ADaM datasets folder name

analysis-adam

Programs folder name

programs

LLM Specifications

Gemini 2.0 Pro

SAS (Fine Tuned LLM)

gpt-4o

Set Temperature (0-1)

0.1

Start New Project

Retrieve Existing Clinical Study

No existing projects found.

Clinical Data Flow

General Study Information

SDTM IG version: **SDTMIG v3.4** 

ADaM IG version: **ADaMIG v1.3** 

SDTM Domains for Study:

<input type="checkbox"/> AE	<input type="checkbox"/> CO	<input type="checkbox"/> DS
<input type="checkbox"/> AG	<input type="checkbox"/> CP	<input type="checkbox"/> DV
<input type="checkbox"/> BE	<input type="checkbox"/> CV	<input type="checkbox"/> EC
<input type="checkbox"/> BS	<input type="checkbox"/> DA	<input type="checkbox"/> EG
<input type="checkbox"/> CE	<input type="checkbox"/> DD	<input type="checkbox"/> EX
<input type="checkbox"/> CM	<input type="checkbox"/> DM	<input type="checkbox"/> FA

Convert Raw Data to SDTM standards

Start here as the first step. Press Begin next to 'Identify' to get SDTM datasets, variables, and mapping logic. Once satisfied, click Start next to 'Generate' to produce SDTM Datasets & SAS code.

Identify SDTM Datasets: **Begin**

Generate SDTM Datasets: **Start**

State: **In-Process** 

Extract TLF shells logic

After indicating valid SDTM and ADaM IG versions and SDTM domains upload the TLF shells document. After uploading, press Start to extract TLF shell details. When content is satisfactory, select "Approved" in status to proceed.

TLF Shells: **Choose File** **No file chosen**

Extract

State: **In-Process** 

Clinical Data Flow AI Assistant

Agent Outputs

S

Dataset Name	Variable	Type	Description	Mapping Rule	Action
No data available					

Clinical Data Flow AI Assistant

Study

SDTM
the SD

SDTM Domains for Study:

<input type="checkbox"/> SS	<input checked="" type="checkbox"/> TE	<input checked="" type="checkbox"/> TV
<input type="checkbox"/> SU	<input checked="" type="checkbox"/> TI	<input type="checkbox"/> UR
<input type="checkbox"/> SUPPQUAL	<input type="checkbox"/> TM	<input type="checkbox"/> VS
<input checked="" type="checkbox"/> SV	<input type="checkbox"/> TR	
<input checked="" type="checkbox"/> TA	<input checked="" type="checkbox"/> TS	
<input type="checkbox"/> TD	<input type="checkbox"/> TU	

Convert Raw Data to SDTM standards

Start here as the first step. Press Begin next to 'Identify' to get SDTM datasets, variables, and mapping logic. Once satisfied, click Start next to 'Generate' to produce SDTM Datasets & SAS code.

Identify SDTM Datasets: Begin

Generate SDTM Datasets: Start

State: In-Process

Extract TLF shells logic

After indicating valid SDTM and ADaM IG versions and SDTM domains upload the TLF shells document. After uploading, press Start to extract TLF shell details. When content is satisfactory, select "Approved" in status to proceed.

TLF Shells: Choose File No file chosen

Extract

State: In-Process

Identify and Generate ADaM Datasets

Upload the SAP document and press Begin next to 'Identify' to get ADaM datasets, variables, and mapping logic. Once satisfied, click Start next to 'Generate' to produce ADaM Datasets & SAS code.

SAP: Choose File No file chosen

Agent Outputs

SDTM Datasets SDTM Code TLF Logic ADaM Datasets ADaM Code TLF Code

Edit

Dataset Name	Variable	Type	Description	Mapping Rule	Action
AE	STUDYID	Required	Unique identifier for a study	Set to 'CDISCPILOT01', the study identifier for	
AE	DOMAIN	Required	Two-character abbreviation	Set to 'AE'.	
AE	USUBJID	Required	Identifier used to uniquely identify the subject	Map from ADVERSE_EVENTS.UNIQUE_SUBJ_ID.	
AE	AESEQ	Required	Sequence number given to the adverse event	Generate a unique sequence number for each adverse event	
AE	AESPID	Permissible	Sponsor-defined identifier. I	Map from ADVERSE_EVENTS.AE_ID.	
AE	AETERM	Required	Verbatim name of the event	Map from ADVERSE_EVENTS.AE_TERM.	
AE	AEDECOD	Required	Dictionary-derived text description	Map from ADVERSE_EVENTS.AE_DESC.	
AE	AELLT	Expected	Dictionary-derived text description	Map from ADVERSE_EVENTS.AE_LLT.	
AE	AELTCD	Expected	Dictionary-derived code for the event	Not available in raw data. A coding dictionary would be	
AE	AEPTCD	Expected	Dictionary-derived code for the event	Not available in raw data. A coding dictionary would be	
AE	AEHLT	Expected	Dictionary-derived text description	Map from ADVERSE_EVENTS.AE_HLT.	
AE	AEHLTCD	Expected	Dictionary-derived code for the event	Not available in raw data. A coding dictionary would be	
AE	AEHLGT	Expected	Dictionary-derived text description	Map from ADVERSE_EVENTS.AE_HLT.	
				Not available in raw	

Clinical Data Flow AI Assistant

SDTM Domains for Study:

<input type="checkbox"/> SS	<input checked="" type="checkbox"/> TE	<input checked="" type="checkbox"/> TV
<input type="checkbox"/> SU	<input checked="" type="checkbox"/> TI	<input type="checkbox"/> UR
<input type="checkbox"/> SUPPQUAL	<input type="checkbox"/> TR	<input checked="" type="checkbox"/> VS
<input checked="" type="checkbox"/> SV	<input type="checkbox"/> TS	
<input checked="" type="checkbox"/> TA	<input checked="" type="checkbox"/> TS	
<input type="checkbox"/> TD	<input type="checkbox"/> TU	

Agent Outputs

SDTM Datasets **SDTM Code** TLF Logic ADaM Datasets ADaM Code TLF Code

AE	CM	DM	DS	EX	LB	MH	QS	RELREC	SC	SE	SV	TA	TI	TS	TV	VS
Code				Last Run Log				Last Run Output				Last Run Code				

[Run Code](#) [Save Code](#) Run Status: **Success**

```
*****  
/* PROGRAM: create_sdtm_vs.sas */  
/* DESCRIPTION: Creates the SDTM Vital Signs (VS) domain from raw data. */  
/* INPUT: raw.vital_signs, raw.patient_information */  
/* OUTPUT: sdtm.vs */  
/*  
/* AUTHOR: Clinical Data Programmer AI */  
/* DATE: 20 August 2025 */  
/*  
/* NOTES: This program adheres to the provided SDTM specifications. */  
/* Version 2: Corrected variable renaming in helper dataset and moved LENGTH */  
/* statement to prevent warnings and errors. */  
/*  
*****  
  
options nocenter ls=132 ps=64;  
  
*-----*  
* Define LIBNAMES for source Raw data and target SDTM datasets. *;  
*-----*  
libname RAW "/nfsshare/sashis2/data/sinpan/Clinical_Data_AutomationwithLLMs/CDISCPILOT_DEMO/raw-data";  
libname SDTM "/nfsshare/sashis2/data/sinpan/Clinical_Data_AutomationwithLLMs/CDISCPILOT_DEMO/tabulations-sdtm";  
  
*-----*  
* 1. PRE-PROCESSING: Create a helper dataset with subject-level reference dates. *;  
*-----*  
/* Create a dataset with one record per subject containing the treatment start date. */  
/* This date will be used as the reference for calculating VSVD and VSLOBXFL. */  
data dm_info;  
  /* Use RENAME= dataset option to correctly rename the variable. */  
  set RAW.PATIENT_INFORMATION(  
    keep=UNIQUE_SUBJ_ID FIRST_TREATMENT_DATE  
    rename=(UNIQUE_SUBJ_ID = USUBJID)  
  );  
  
  /* Create numeric reference date RFXSTDTC from FIRST_TREATMENT_DATE. */  
  if FIRST_TREATMENT_DATE ne '' then RFXSTDTC = input(FIRST_TREATMENT_DATE, yymmdd10.);  
  format RFXSTDTC yymmdd10.;  
  
  keep USUBJID RFXSTDTC;  
run;  
  
/* Ensure one record per subject. */  
proc sort data=dm_info nodupkey;  
  by USUBJID;  
run;
```

Convert Raw Data to SDTM standards

Start here as the first step. Press Begin next to 'Identify' to get SDTM datasets, variables, and mapping logic. Once satisfied, click Start next to 'Generate' to produce SDTM Datasets & SAS code.

Identify SDTM Datasets: [Begin](#)

Generate SDTM Datasets: [Start](#)

State: **In-Process**

Extract TLF shells logic

After indicating valid SDTM and ADaM IG versions and SDTM domains upload the TLF shells document. After uploading, press Start to extract TLF shell details. When content is satisfactory, select "Approved" in status to proceed.

TLF Shells: [Choose File](#) **No file chosen**

Extract

State: **In-Process**

Identify and Generate ADaM Datasets

Upload the SAP document and press Begin next to 'Identify' to get ADaM datasets, variables, and mapping logic. Once satisfied, click Start next to 'Generate' to produce ADaM Datasets & SAS code.

SAP: [Choose File](#) **No file chosen**

Identify ADaM

Start Page ae.sas7bdat +

TEMP1.ae Columns: 33 Rows: 1,191

Enter expression

#	STUDYID	DOMAIN	USUBID	AESEQ	AESPID	AETERM	AEDECOD	AELLT
1	CDISCIPILOT01	AE	01-701-1015	1	E07	APPLICATION SITE ERYTHEMA	APPLICATION SITE ERYTHEMA	APPLICATION
2	CDISCIPILOT01	AE	01-701-1015	2	E08	APPLICATION SITE PRURITUS	APPLICATION SITE PRURITUS	APPLICATION
3	CDISCIPILOT01	AE	01-701-1015	3	E06	DIARRHOEA	DIARRHOEA	DIARRHEA
4	CDISCIPILOT01	AE	01-701-1023	1	E08	ERYTHEMA	ERYTHEMA	ERYTHEMA
5	CDISCIPILOT01	AE	01-701-1023	2	E09	ERYTHEMA	ERYTHEMA	LOCALIZED
6	CDISCIPILOT01	AE	01-701-1023	3	E08	ERYTHEMA	ERYTHEMA	ERYTHEMA
7	CDISCIPILOT01	AE	01-701-1023	4	E10	ATRIOVENTRICULAR BLOCK SECOND DEGREE	ATRIOVENTRICULAR BLOCK SECOND DEGREE	AV BLOCK
8	CDISCIPILOT01	AE	01-701-1028	1	E04	APPLICATION SITE ERYTHEMA	APPLICATION SITE ERYTHEMA	APPLICATION
9	CDISCIPILOT01	AE	01-701-1028	2	E05	APPLICATION SITE PRURITUS	APPLICATION SITE PRURITUS	APPLICATION
10	CDISCIPILOT01	AE	01-701-1034	1	E08	APPLICATION SITE PRURITUS	APPLICATION SITE PRURITUS	APPLICATION
11	CDISCIPILOT01	AE	01-701-1034	2	E07	FATIGUE	FATIGUE	FATIGUE
12	CDISCIPILOT01	AE	01-701-1047	1	E06	HIATUS HERNIA	HIATUS HERNIA	HERNIA H
13	CDISCIPILOT01	AE	01-701-1047	2	E06	HIATUS HERNIA	HIATUS HERNIA	HERNIA H
14	CDISCIPILOT01	AE	01-701-1047	3	E08	UPPER RESPIRATORY TRACT INFECTION	UPPER RESPIRATORY TRACT INFECTION	UPPER RE
15	CDISCIPILOT01	AE	01-701-1047	4	E09	BUNDLE BRANCH BLOCK LEFT	BUNDLE BRANCH BLOCK LEFT	LEFT BUN
16	CDISCIPILOT01	AE	01-701-1097	1	E04	ERYTHEMA	ERYTHEMA	ERYTHEMA
17	CDISCIPILOT01	AE	01-701-1097	2	E07	APPLICATION SITE VESICLES	APPLICATION SITE VESICLES	APPLICATION
18	CDISCIPILOT01	AE	01-701-1097	3	E05	PRURITUS GENERALISED	PRURITUS GENERALISED	GENERAL
19	CDISCIPILOT01	AE	01-701-1097	4	E06	APPLICATION SITE PRURITUS	APPLICATION SITE PRURITUS	APPLICATION
20	CDISCIPILOT01	AE	01-701-1097	5	E06	APPLICATION SITE PRURITUS	APPLICATION SITE PRURITUS	APPLICATION
21	CDISCIPILOT01	AE	01-701-1097	6	E08	PRURITUS GENERALISED	PRURITUS GENERALISED	GENERAL
22	CDISCIPILOT01	AE	01-701-1097	7	E12	PRURITUS GENERALISED	PRURITUS GENERALISED	GENERAL
23	CDISCIPILOT01	AE	01-701-1097	8	E11	NASAL CONGESTION	NASAL CONGESTION	NASAL CO
24	CDISCIPILOT01	AE	01-701-1097	9	E10	PHARYNGOLARYNGEAL PAIN	PHARYNGOLARYNGEAL PAIN	SORE THR

Protocol: CDISCPILOT01
 Population: Intent-to-Treat

Page 1 of n

Template 3
 Summary of Demographic and Baseline Characteristics

	Placebo (N=100)	Xanomeline Low Dose (N=100)	Xanomeline High Dose (N=100)	Total (N=300)	p-value [1]
Age (y)	n	xx	xx	xx	
	Mean	xx,x	xx,x	xx,x	0.000
	SD	x,xx	x,xx	x,xx	
	Median	xx,x	xx,x	xx,x	
	Min.	xx,x	xx,x	xx,x	
	Max.	xx,x	xx,x	xx,x	*
	<65 yrs	xx (xx%)	xx (xx%)	xx (xx%)	0.000
	65-80 yrs	xx (xx%)	xx (xx%)	xx (xx%)	
	>80 yrs	xx (xx%)	xx (xx%)	xx (xx%)	
Sex	n	xxx	xxx	xxx	0.000
	Female	xx (xx%)	xx (xx%)	xx (xx%)	
	Male	xx (xx%)	xx (xx%)	xx (xx%)	
Origin	n	xxx	xxx	xxx	0.000
	Black	xx (xx%)	xx (xx%)	xx (xx%)	
	White	xx (xx%)	xx (xx%)	xx (xx%)	
	-				

Also summarize: MMSE, Duration of disease (cont. and as <12 months, >=12 months), Years of education, Baseline Weight, Baseline Height, Baseline BMI (cont. and as normal(<25), overweight(25-<30), obese(>30))

[1] P-values are results of ANOVA treatment group comparisons for continuous variables and Pearson's chi-square test for categorical variables.

NOTE: Duration of disease is computed as months between date of enrollment and date of onset of the first definite symptoms of Alzheimer's disease.

FINAL SAP

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Page 1 of n

Protocol: CDISCPILOT01
 Population: All Subjects

Template 1
 Summary of Populations

Population	Placebo (N=xxx)	Xanomeline Low Dose (N=xxx)	Xanomeline High Dose (N=xxx)	Total (N=xxx)
Intent-To-Treat (ITT)	xxx (xx%)	xxx (xx%)	xxx (xx%)	xxx (xx%)
Safety	xxx (xx%)	xxx (xx%)	xxx (xx%)	xxx (xx%)
Efficacy	xxx (xx%)	xxx (xx%)	xxx (xx%)	xxx (xx%)
Completer Week 24	xxx (xx%)	xxx (xx%)	xxx (xx%)	xxx (xx%)
Complete Study	xxx (xx%)	xxx (xx%)	xxx (xx%)	xxx (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 Efficacy population includes all subjects in the safety population who also have at least one post-baseline ADAS-Cog and CIBIC+ assessment.

Clinical Data Flow AI Assistant

Generate SDTM Datasets:

State:

Extract TLF shells logic

After indicating valid SDTM and AdAM IG versions and SDTM domains upload the TLF shells document. After uploading, press Start to extract TLF shell details. When content is satisfactory, select "Approved" in status to proceed.

TLF Shells:

State:

Identify and Generate AdAM Datasets

Upload the SAP document and press Begin next to 'Identify' to get ADAM datasets, variables, and mapping logic. Once satisfied, click Start next to 'Generate' to produce AdAM Datasets & SAS code.

SAP:

Identify AdAM Datasets:

Macros File:

Generate AdAM Datasets:

State:

Generate TLFs

Use this section to generate the TLF reports using specifications derived in Step 1 and 2.

Start:

State:

SDTM Datasets	SDTM Code	TLF Logic	ADaM Datasets	ADaM Code	TLF Code
---------------	-----------	-----------	---------------	-----------	----------

<input type="button" value="TLF 1"/>	<input type="button" value="TLF 2"/>	<input type="button" value="TLF 3"/>
--------------------------------------	--------------------------------------	--------------------------------------

Agent Outputs

SDTM Datasets SDTM Code TLF Logic ADaM Datasets ADaM Code TLF Code

Tables Layout:**
 * **Title**: Template 1 Summary of Populations
 * **Column Headers**: Placebo (N=xxx), Xanomeline > Low Dose (N=xxx), Xanomeline > High Dose (N=xxx), Total (N=xxx)
 * **Sub-Column Headers (under each treatment arm)**:
 * **Row Headers**:
 * Intent-to-Treat (ITT)
 * Safety
 * Efficacy
 * Completer Week 24
 * Complete Study
 * **Data Population Rules**:
 * **Population**: All Subjects
 * **N for columns**: N in column headers represents the number of subjects entered in study (i.e., signed informed consent) for each respective treatment arm or the total.
 * **Intent-To-Treat (ITT)**:
 * Value: 'XXX (XXX)'
 * N: Count of subjects belonging to the Intent-To-Treat population within the respective column.
 * Percentage: Based on the "N" for the column.
 * Definition: The ITT population includes all subjects randomized.
 * **Safety**:
 * Value: 'XXX (XXX)'
 * N: count of subjects belonging to the safety population within the respective column.
 * Percentage: Based on the "N" for the column.
 * Definition: The Safety population includes all randomized subjects known to have taken at least one dose of randomized study drug.
 * **Efficacy**:
 * Value: 'XXX (XXX)'
 * N: count of subjects belonging to the Efficacy population within the respective column.
 * Percentage: Based on the "N" for the column.
 * Definition: The Efficacy population includes all subjects in the safety population who also have at least one post-baseline ADAS-Cog and CIBIC+ assessment.
 * **Completer Week 24**:
 * Value: 'XXX (XXX)'
 * N: count of subjects who completed Week 24 within the respective column.
 * Percentage: Based on the "N" for the column.
 * **Complete Study**:
 * Value: 'XXX (XXX)'
 * N: count of subjects who completed the entire study within the respective column.
 * Percentage: Based on the "N" for the column.
 * **Footnotes/Notes**:
 * 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 Efficacy population includes all subjects in the safety population who also have at least one post-baseline ADAS-Cog and CIBIC+ assessment.

had probable Alzheimer's disease according to the NINCDS-ADRDA criteria, and an MMSE score of 10 to 23. The duration of treatment was 26 weeks, with 24 weeks of active treatment. A total of 295 patients were randomized into 1 of 3 treatment groups: xanomeline high dose, 97 patients; xanomeline low dose, 98 patients; and placebo, 100 patients; 166 were females and 129 were males.

2. PURPOSE OF THIS ANALYSIS PLAN

This analysis plan describes the analyses to be performed in the context of the first iteration of the CDISC SDTM/ADaM Pilot Submission, CDISCPILOT01. It should be noted that this document is not meant to represent all of the measures assessed or analyses performed in the original study.

3. STUDY OBJECTIVE(S) AND ENDPOINT(S)

3.1. Study Objective(s)

3.1.1. Primary

The primary objectives of this study are

- To determine if there is a statistically significant relationship (overall Type 1 error rate, $\alpha=.05$) between the change in both the ADAS-Cog (11) and CIBIC+ scores, and drug dose (0, 50 cm^2 [54 mg], and 75 cm^2 [81 mg]).
- To document the safety profile of the xanomeline TTS.

3.1.2. Secondary

Clinical Data Flow AI Assistant

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TFL
List

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the

Datasets: Begin

Generate SDTM Datasets: Start

State: Approved

Extract TLF shells logic

After indicating valid SDTM and ADaM IG versions and SDTM domains upload the TLF shells document. After uploading, press Start to extract TLF shell details. When content is satisfactory, select "Approved" in status to proceed.

TLF Shells: Choose File CDISCPILOT...ells_Small.pdf

Extract

State: Approved

Identify and Generate ADaM Datasets

Upload the SAP document and press Begin next to 'Identify' to get ADaM datasets, variables, and mapping logic. Once satisfied, click Start next to 'Generate' to produce ADaM Datasets & SAS code.

SAP: Choose File CDISCPILOT_SAP.pdf

Identify ADaM Datasets: Begin

Macros File: Choose File No file chosen

Generate ADaM Datasets: Start

State: In-Process

Generate TLFs

Use this section to generate the TLF reports using specifications derived in Step 1 and 2.

Start: Start

State: In-Process

Agent Outputs

SDTM Datasets		SDTM Code		TLF Logic		ADaM Datasets		ADaM Code		TLF Code																																																																																																																																																																																					
<table border="1"> <thead> <tr> <th colspan="2">Dataset Name</th> <th>Variable</th> <th>Type</th> <th colspan="2">Description</th> <th colspan="2">Mapping Rule</th> <th colspan="2">Source</th> <th colspan="2">Action</th> </tr> </thead> <tbody> <tr> <td colspan="2">ADSL</td> <td>STUDYID</td> <td>required</td> <td colspan="2">Study Identifier</td> <td colspan="2">Direct mapping from SDTM DM.STUDYID</td> <td colspan="2">ADaM IG</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>USUBJID</td> <td>required</td> <td colspan="2">Unique Subject Identifier</td> <td colspan="2">Direct mapping from SDTM DM.USUBJID</td> <td colspan="2">ADaM IG</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>SUBJID</td> <td>required</td> <td colspan="2">Subject Identifier for the St</td> <td colspan="2">Direct mapping from SDTM DM.SUBJID. This is required in ADSL</td> <td colspan="2">ADaM IG</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>SITEID</td> <td>required</td> <td colspan="2">Study Site Identifier</td> <td colspan="2">Direct mapping from SDTM DM.SITEID. This is required in ADSL</td> <td colspan="2">ADaM IG</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>SITEGR1</td> <td>permissible</td> <td colspan="2">Pooled Site Group 1</td> <td colspan="2">Derived by grouping SITEID values according to pooling</td> <td colspan="2">SAP/TFL- Q6</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>AGE</td> <td>required</td> <td colspan="2">Age</td> <td colspan="2">Direct mapping from SDTM DM.AGE. If a different age is</td> <td colspan="2">ADaM IG</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>AGEU</td> <td>required</td> <td colspan="2">Age Units</td> <td colspan="2">Direct mapping from SDTM DM.AGEU.</td> <td colspan="2">ADaM IG</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>AGEGR1</td> <td>permissible</td> <td colspan="2">Pooled Age Group 1</td> <td colspan="2">Derived by grouping AGE values into categories (<65, 65-)</td> <td colspan="2">SAP/TFL: TFL 3</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>AGEGR1N</td> <td>permissible</td> <td colspan="2">Pooled Age Group 1 (N)</td> <td colspan="2">Numeric representation of AGEGR1N. There must</td> <td colspan="2">SAP/TFL: TFL 3</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>SEX</td> <td>required</td> <td colspan="2">Sex</td> <td colspan="2">Direct mapping from SDTM DM.SEX.</td> <td colspan="2">ADaM IG</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>RACE</td> <td>required</td> <td colspan="2">Race</td> <td colspan="2">Direct mapping from SDTM DM.RACE.</td> <td colspan="2">ADaM IG</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>ITTFL</td> <td>conditional</td> <td colspan="2">Intent-To-Treat Population F</td> <td colspan="2">Derived flag ('Y'/'N') indicating if the subject</td> <td colspan="2">SAP/TFL: TFL 1</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">ADSL</td> <td>SAFFL</td> <td>conditional</td> <td colspan="2">Safety Population Flag</td> <td colspan="2">Derived flag ('Y'/'N') indicating if the subject</td> <td colspan="2">SAP/TFL: TFL 1</td> <td colspan="2"></td> </tr> <tr> <td colspan="2"></td> <td></td> <td></td> <td colspan="2"></td> <td colspan="2">Derived flag</td> <td colspan="2"></td> <td colspan="2"></td> </tr> </tbody> </table>												Dataset Name		Variable	Type	Description		Mapping Rule		Source		Action		ADSL		STUDYID	required	Study Identifier		Direct mapping from SDTM DM.STUDYID		ADaM IG				ADSL		USUBJID	required	Unique Subject Identifier		Direct mapping from SDTM DM.USUBJID		ADaM IG				ADSL		SUBJID	required	Subject Identifier for the St		Direct mapping from SDTM DM.SUBJID. This is required in ADSL		ADaM IG				ADSL		SITEID	required	Study Site Identifier		Direct mapping from SDTM DM.SITEID. This is required in ADSL		ADaM IG				ADSL		SITEGR1	permissible	Pooled Site Group 1		Derived by grouping SITEID values according to pooling		SAP/TFL- Q6				ADSL		AGE	required	Age		Direct mapping from SDTM DM.AGE. If a different age is		ADaM IG				ADSL		AGEU	required	Age Units		Direct mapping from SDTM DM.AGEU.		ADaM IG				ADSL		AGEGR1	permissible	Pooled Age Group 1		Derived by grouping AGE values into categories (<65, 65-)		SAP/TFL: TFL 3				ADSL		AGEGR1N	permissible	Pooled Age Group 1 (N)		Numeric representation of AGEGR1N. There must		SAP/TFL: TFL 3				ADSL		SEX	required	Sex		Direct mapping from SDTM DM.SEX.		ADaM IG				ADSL		RACE	required	Race		Direct mapping from SDTM DM.RACE.		ADaM IG				ADSL		ITTFL	conditional	Intent-To-Treat Population F		Derived flag ('Y'/'N') indicating if the subject		SAP/TFL: TFL 1				ADSL		SAFFL	conditional	Safety Population Flag		Derived flag ('Y'/'N') indicating if the subject		SAP/TFL: TFL 1										Derived flag					
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Datasets: Begin

Generate SDTM Datasets: Start

State: Approved

Extract TLF shells logic

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TLF Shells: Choose File CDISCPILOT...ells_Small.pdf

Extract

State: Approved

Identify and Generate ADaM Datasets

Upload the SAP document and press Begin next to 'Identify' to get ADaM datasets, variables, and mapping logic. Once satisfied, click Start next to 'Generate' to produce ADaM Datasets & SAS code.

SAP: Choose File CDISCPILOT_SAP.pdf

Identify ADaM Datasets: Begin

Macros File: Choose File Pre_DefineMacros.sas

Generate ADaM Datasets: Start

State: In-Process

Generate TLFs

Use this section to generate the TLF reports using specifications derived in Step 1 and 2.

Start: Start

State: In-Process

Clinical Data Flow AI Assistant

Study Lineage L

Agent Outputs

SDTM Datasets	SDTM Code	TLF Logic	ADaM Datasets	ADaM Code	TLF Code
ADSL	ADADAS	ADCIBIC	ADNPI	ADLB	ADVS
ADTTE	ADAE	ADCM	ADEX		

Code
Last Run Log
Last Run Output
Last Run Code

Run Code
Save Code
Run Status: Success ✓

```

*****  

/* PROGRAM: ADADAS.sas */  

/* DESCRIPTION: Creates the ADAS-Cog Analysis Dataset (ADADAS). */  

/* This dataset contains one record per subject per analysis visit for the */  

/* Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog) total score. */  

/*  

/* INPUT: sdtm.qs, sdtm_dm */  

/* OUTPUT: adam.adadas */  

/*  

/* AUTHOR: Clinical Data Programmer AI */  

/* DATE: 20 August 2025 */  

/*  

/* NOTES: This program adheres to the provided ADAM specifications. */  

/* It uses the predefined macro %mstudyd for study day calculation. */  

/*  

*****  

options nocenter ls=132 ps=64;  

* Define LIBNAMES for source SDTM data and target ADAM datasets. *;  

*-----*;  

libname SDTM "/nfsshare/sashis2/data/sinpan/Clinical_Data_Flow_AutomationwithLLMs/CDISCPILOT_DEMO/tabulations-sdtm";  

libname ADAM "/nfsshare/sashis2/data/sinpan/Clinical_Data_Flow_AutomationwithLLMs/CDISCPILOT_DEMO/analysis-adam";  

*-----*;  

* Define pre-defined macro(s) required for the program. *;  

*-----*;  

%macro mstudyd (todate=, basedate=, studyday=studyday);  

  %if &todate= |&basedate= |&studyday= %then %do;  

    put 'missing parameters - aborting...';  

  %end;  

  %else %do;  

    &studyday=&todate-&basedate+(&todate ge &basedate);  

  %end;  

%end; mstudyd;  

*-----*;  

* 1. PRE-PROCESSING: Create helper datasets. *;  

*-----*;  

* 1a. Create a subject-level dataset with Treatment Start Date (TRTSDT) from SDTM.DM. *;  

* This information is analogous to what would be found in ADSL. *;  

proc sort data=sdtm_dm out=dm_sorted (keep=STUDYID USUBJID RFXSTDTC ACTARMCD);  

  by USUBJID;  

run;  

data adsl_vars;  

  set dm_sorted;

```

SDTM dataset/variables the SDTM Datasets tab.

SDTM Datasets creation tab for details.

TLF logic extraction com Listings' tab.

ADaM dataset/variables the ADaM Datasets tab.

ADaM Datasets creation tab for details.

Type your message here

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Code and Flows

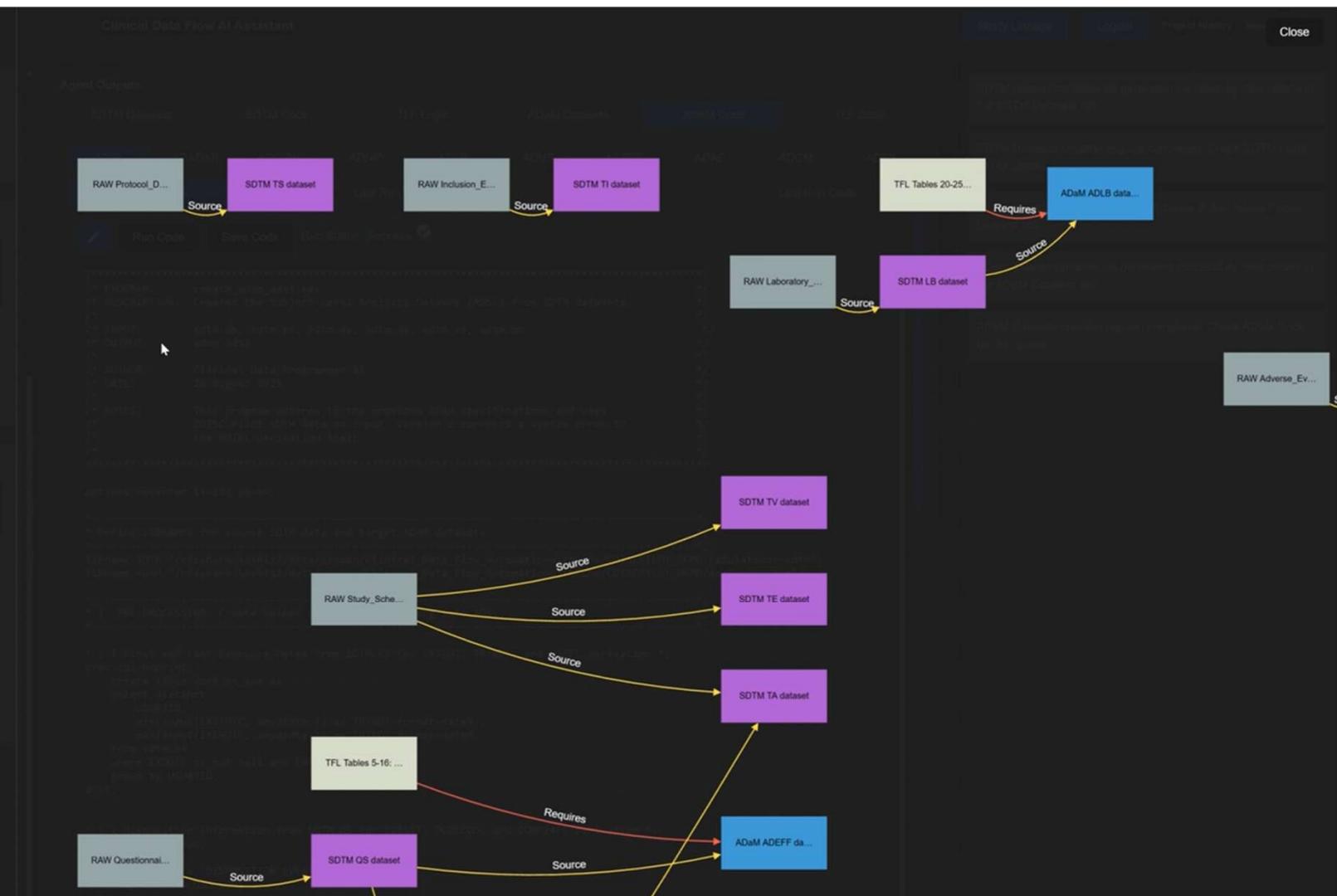
Open Save All SAS

Start Page adae.sas7bdat +

_TEMP1.adae Columns: 11 Rows: 1,191

Enter expression

#	STUDYID	USUBJID	AESEQ	AETERM	AEDECOD	AEBODSYS
1	CDISCPILOT01	01-701-1015	1	APPLICATION SITE ERYTHEMA	APPLICATION SITE ERYTHEMA	GENERAL DISORDERS AND ADMINISTRATI
2	CDISCPILOT01	01-701-1015	2	APPLICATION SITE PRURITUS	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATI
3	CDISCPILOT01	01-701-1015	3	DIARRHOEA	DIARRHOEA	GASTROINTESTINAL DISORDERS
4	CDISCPILOT01	01-701-1023	1	ERYTHEMA	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORD
5	CDISCPILOT01	01-701-1023	2	ERYTHEMA	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORD
6	CDISCPILOT01	01-701-1023	3	ERYTHEMA	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORD
7	CDISCPILOT01	01-701-1023	4	ATRIOVENTRICULAR BLOCK SECOND DEGREE	ATRIOVENTRICULAR BLOCK SECOND DEGREE	CARDIAC DISORDERS
8	CDISCPILOT01	01-701-1028	1	APPLICATION SITE ERYTHEMA	APPLICATION SITE ERYTHEMA	GENERAL DISORDERS AND ADMINISTRATI
9	CDISCPILOT01	01-701-1028	2	APPLICATION SITE PRURITUS	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATI
10	CDISCPILOT01	01-701-1034	1	APPLICATION SITE PRURITUS	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATI
11	CDISCPILOT01	01-701-1034	2	FATIGUE	FATIGUE	GENERAL DISORDERS AND ADMINISTRATI
12	CDISCPILOT01	01-701-1047	1	HIATUS HERNIA	HIATUS HERNIA	GASTROINTESTINAL DISORDERS
13	CDISCPILOT01	01-701-1047	2	HIATUS HERNIA	HIATUS HERNIA	GASTROINTESTINAL DISORDERS
14	CDISCPILOT01	01-701-1047	3	UPPER RESPIRATORY TRACT INFECTION	UPPER RESPIRATORY TRACT INFECTION	INFECTIONS AND INFESTATIONS
15	CDISCPILOT01	01-701-1047	4	BUNDLE BRANCH BLOCK LEFT	BUNDLE BRANCH BLOCK LEFT	CARDIAC DISORDERS
16	CDISCPILOT01	01-701-1097	1	ERYTHEMA	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORD
17	CDISCPILOT01	01-701-1097	2	APPLICATION SITE VESICLES	APPLICATION SITE VESICLES	GENERAL DISORDERS AND ADMINISTRATI
18	CDISCPILOT01	01-701-1097	3	PRURITUS GENERALISED	PRURITUS GENERALISED	SKIN AND SUBCUTANEOUS TISSUE DISORD
19	CDISCPILOT01	01-701-1097	4	APPLICATION SITE PRURITUS	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATI
20	CDISCPILOT01	01-701-1097	5	APPLICATION SITE PRURITUS	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATI
21	CDISCPILOT01	01-701-1097	6	PRURITUS GENERALISED	PRURITUS GENERALISED	SKIN AND SUBCUTANEOUS TISSUE DISORD
22	CDISCPILOT01	01-701-1097	7	PRURITUS GENERALISED	PRURITUS GENERALISED	SKIN AND SUBCUTANEOUS TISSUE DISORD
23	CDISCPILOT01	01-701-1097	8	NASAL CONGESTION	NASAL CONGESTION	RESPIRATORY, THORACIC AND MEDIASTIN
24	CDISCPILOT01	01-701-1097	9	PHARYNGOLARYNGEAL PAIN	PHARYNGOLARYNGEAL PAIN	RESPIRATORY, THORACIC AND MEDIASTIN



Clinical Data Flow AI Assistant

Study Lineage

TLF Shells:

Choose File CDISCPILOT...ells_Small.pdf

Extract

State: Approved

Identify and Generate ADaM Datasets

Upload the SAP document and press Begin next to 'Identify' to get ADaM datasets, variables, and mapping logic. Once satisfied, click Start next to 'Generate' to produce ADaM Datasets & SAS code.

SAP: Choose File No file chosen

Identify ADaM Datasets: Begin

Macros File: Choose File No file chosen

Generate ADaM Datasets: Start

State: Approved

Generate TLFs

Use this section to generate the TLF reports using specifications derived in Step 1 and 2.

Start: Start

State: In-Process

Agent Outputs

SDTM Datasets SDTM Code TLF Logic ADaM Datasets ADaM Code TLF Code

TLF 1

TLF 2

TLF 3

Code

Last Run Log

Last Run Output

Last Run Code

Run Code

Save Code

Run Status: Success

```
*****
/* PROGRAM: t_populations.sas
/* DESCRIPTION: Creates the table that summarizes analysis populations.
*/
/* INPUT: ADaM.ADSL, ADaM.AADAS, ADaM.ADCIBIC
/* OUTPUT: t_populations.rtf, t_populations.html
*/
/* AUTHOR: Clinical Data Programmer AI
/* DATE: 26-OCT-2023
/* VERSION: 6.0 - Corrected errors from previous execution.
*/
/* NOTES: This program adheres to the provided TLF layout specifications to
create the summary of populations table.
v6.0 fixes:
1. Re-architected the summarization and formatting logic to be more robust.
Instead of transposing, the code now processes each treatment column
independently and then merges them horizontally. This resolves the
persistent "Variable not on file" error by ensuring the final dataset
structure is always created correctly.
*/
options nodate nonumber nonotes orientation=portrait leftmargin=1in rightmargin=1in;
* Define output paths and formats;
%let output_folder_path =
/nfsshare/sashls2/data/sinpan/Clinical_Data_Flow_AutomationwithLLMs/CDISCPILOT_DEMO/outputs;
%let output_filename = t_populations;

ods rtf file="&output_folder_path/&output_filename..rtf";
ods html5 file="&output_folder_path/&output_filename..html";
```

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Type you

SAS® Studio - Develop Code and Flows

New Options View Open Save All SAS Studio compute context

SAS Server

Name

- NFScontent
- sashls2
- data
- sinp
- C

AutoSave Off

Start Page t_populations.html

File Home Insert Draw Design Layout References Mailings Review View Help Acrobat Table Design Table Layout

Display

Template 1 Summary of Populations

1 Summary of Populations

	Low Dose~(N=96)	Xanomeline High Dose~(N=72)	Total~(N=254)
(100.0%)	72 (100.0%)	254 (100.0%)	
(100.0%)	72 (100.0%)	254 (100.0%)	
7 (90.6%)	68 (94.4%)	234 (92.1%)	
5 (26.0%)	27 (37.5%)	110 (43.3%)	
5 (26.0%)	27 (37.5%)	110 (43.3%)	

population includes all subjects randomized. The Safety population includes all randomized subjects known to have taken at least one dose of the post-baseline ADAS-Cog and CIBIC+ assessment.

t_populations: 337 characters (an approximate value).

Display Settings Focus

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SAS® Studio - Develop Code and Flows

New Options View Open Save All

SAS Studio compute context

SAS Server

Name

- NFScontent
 - sashls2
 - data
 - sinpan
 - Clinical_Data_Flow_Automationwith...
 - CDISCPILOT_DEMO
 - analysis-adam
 - outputs
 - demographics_summary.html
 - demographics_summary.rtf
 - t_populations.html
 - t_populations.rtf
 - programs
 - raw-data
 - tabulations-sdtm
 - CDISCPILOT_Study
 - SampleData
 - Study01
 - RawDataPreprocessing.sas
 - CyTOF_all_subjects_100KCells
 - CyTOF_all_subjects_100KCells_Meta...
 - CyTOF_SDY112_Data
 - Derived Variables - LLM
 - Forecasting

Start Page t_populations.html demographics_summary.html +

Display

Chi-Square

4	1.4720	0.9313
4	2.0929	0.7187
1	0.3671	0.5446
Phi Coefficient	0.0761	
Contingency Coefficient	0.0759	
Cramer's V	0.0538	

WARNING: 33% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Sample Size = 254

Template 3 Summary of Demographic and Baseline Characteristics

	Placebo (N=86)	Xanomelene Low Dose (N=84)	Xanomelene High Dose (N=84)	Total (N=254)	p-value[1]																		
Age (y)	<table border="1"> <tr> <td><65 yrs</td> <td>14(16)</td> <td>8(10)</td> <td>11(13)</td> <td>33(13)</td> <td></td> </tr> <tr> <td>65-80 yrs</td> <td>42(49)</td> <td>47(56)</td> <td>55(65)</td> <td>144(57)</td> <td></td> </tr> <tr> <td>>80 yrs</td> <td>30(35)</td> <td>29(35)</td> <td>18(21)</td> <td>77(30)</td> <td></td> </tr> </table>	<65 yrs	14(16)	8(10)	11(13)	33(13)		65-80 yrs	42(49)	47(56)	55(65)	144(57)		>80 yrs	30(35)	29(35)	18(21)	77(30)					
<65 yrs	14(16)	8(10)	11(13)	33(13)																			
65-80 yrs	42(49)	47(56)	55(65)	144(57)																			
>80 yrs	30(35)	29(35)	18(21)	77(30)																			
Sex	<table border="1"> <tr> <td>n</td> <td>86</td> <td>84</td> <td>84</td> <td>254</td> <td></td> </tr> <tr> <td>Female</td> <td>53(62)</td> <td>50(60)</td> <td>40(48)</td> <td>143(56)</td> <td></td> </tr> <tr> <td>Male</td> <td>33(38)</td> <td>34(40)</td> <td>44(52)</td> <td>111(44)</td> <td></td> </tr> </table>	n	86	84	84	254		Female	53(62)	50(60)	40(48)	143(56)		Male	33(38)	34(40)	44(52)	111(44)					
n	86	84	84	254																			
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Male	33(38)	34(40)	44(52)	111(44)																			
Origin	<table border="1"> <tr> <td>n</td> <td>86</td> <td>84</td> <td>84</td> <td>254</td> <td></td> </tr> <tr> <td>Black</td> <td>8(9)</td> <td>6(7)</td> <td>9(11)</td> <td>23(9)</td> <td></td> </tr> <tr> <td>White</td> <td>78(91)</td> <td>78(93)</td> <td>74(88)</td> <td>230(91)</td> <td></td> </tr> </table>	n	86	84	84	254		Black	8(9)	6(7)	9(11)	23(9)		White	78(91)	78(93)	74(88)	230(91)					
n	86	84	84	254																			
Black	8(9)	6(7)	9(11)	23(9)																			
White	78(91)	78(93)	74(88)	230(91)																			

AI as a Copilot for Programmers



LLMs enhance rather than replace human programmers, transforming routines into streamlined processes



The new workflow allows AI to draft code, which is then reviewed and validated by experts



Augmented intelligence fosters collaboration and preserves human oversight in programming tasks

Responsible Adoption of GenAI

Mitigate risks associated with LLMs through secure, private models and human oversight

Validation of AI-generated outputs is essential to ensure coding accuracy

Organizations must prepare for responsible, intelligent integration of AI in clinical operations

Thank you!

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