BENGALURU, INDIA
PharmaSUG SDE
APRIL 11, 2026

Advanced Analytics and Automation with SAS Clinical Acceleration

PharmaSUG April 2026

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Accelerate clinical research

with a secure, validated statistical computing environment on SAS Viya.

sas

Statistical Compute Environment (Including CDR)

Clinical Data Repository

SAS® Clinical Acceleration Repository

Integrated IDE

SAS® Studio

Batch Submissions

SAS® Clinical Job Management

Automated Workflows

SAS® Workflow Manager

SAS® Clinical Acceleration

Regulatory-Compliant Enabling Clinical Research SCE built on SAS® Viya

High Level Overview of the Process

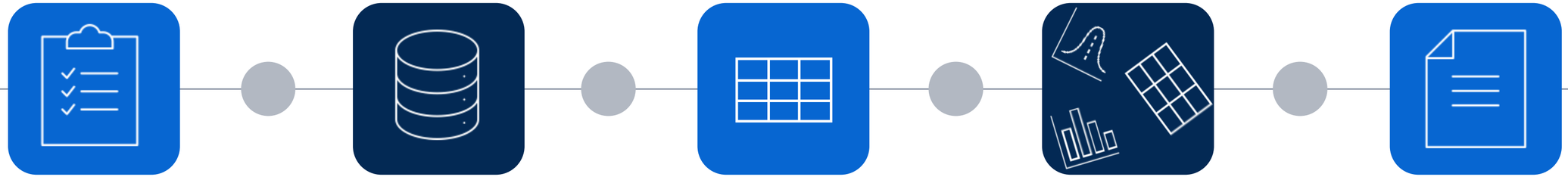
Clinical Trial Protocol

Data Collection

Data Tabulation

Statistical Analysis

Clinical Study Report



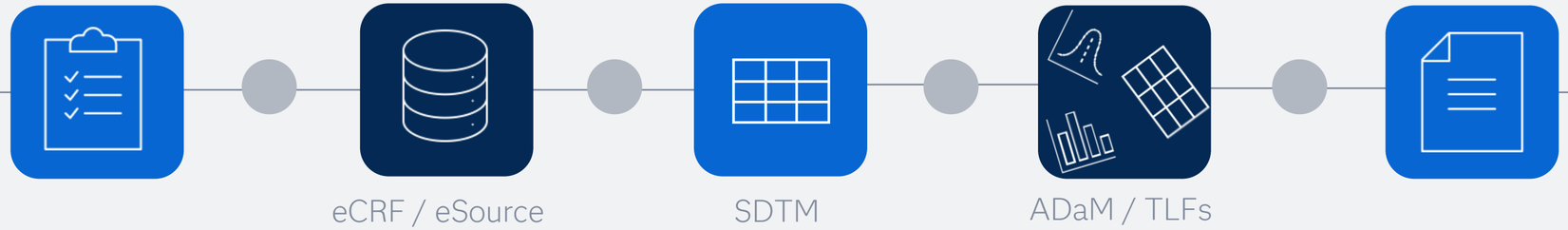
eCRF / eSource

SDTM

ADaM / TLFs

Product Management Vision

Comprehensive Overview of Clinical Data Management and Analysis



- Raw data to SDTM format
- SDTM to ADaM
- ADaM Validation
- Creation of define.xml
- Creation of TLFs

SDTM-ADaM Conversion-Data Preprocessing

User Input | Data Pre-Processing | ADaM Recommendation Workflow | ADaM Spec Integration Workflow | Code Generator Workflow

SDTM Domains

- Clinical Data Repository Integration
- Metadata Creation
- SDTM domain catalogue

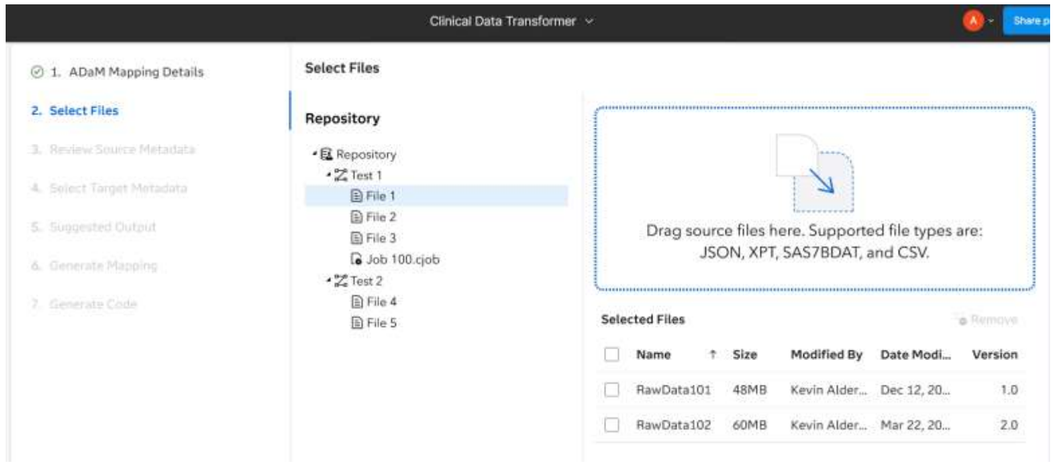
**CDISC-
SDTMIG, ADaMIG, CT**

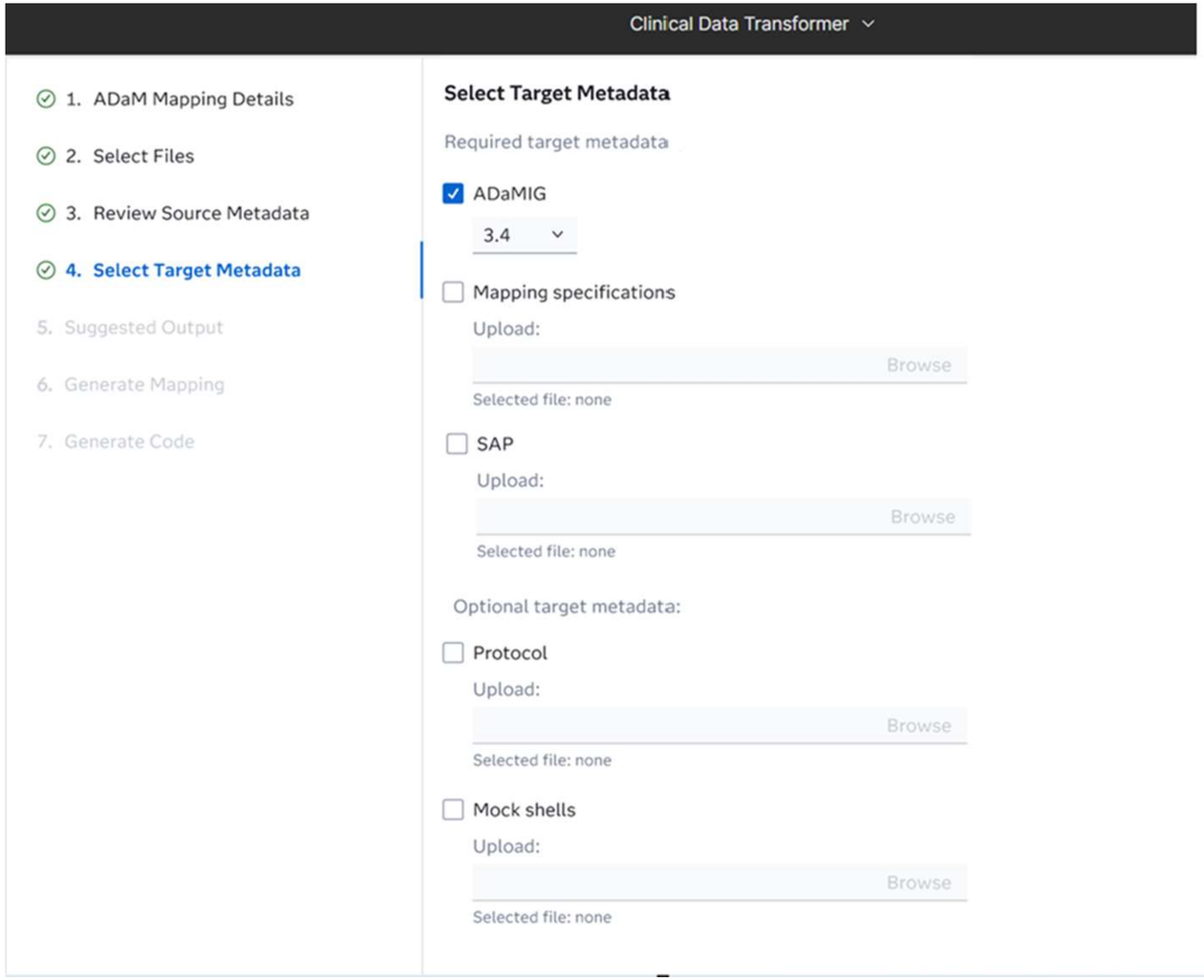
- CDISC API Integration
- Define Latent Groups
- Latent Group & ADaM Variable Mapping

Statistical Analysis Plan / Specification (Optional)

- Document Processing
- Chunking by sections (deterministic)

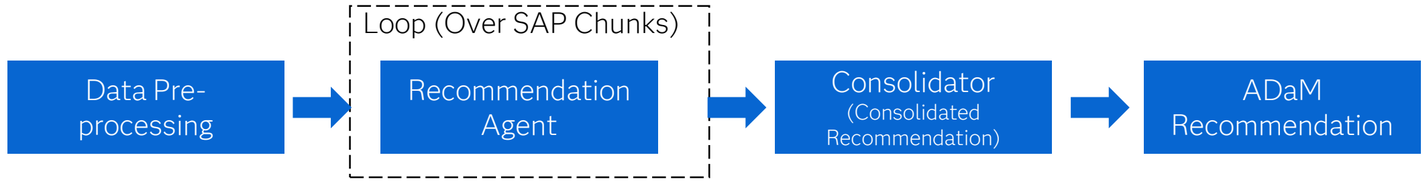
Figma-ADaM Input





SDTM-ADaM Conversion-Recommendation

User Input | Data Pre-Processing | **ADaM Recommendation Workflow** | ADaM Spec Integration Workflow | Code Generator Workflow

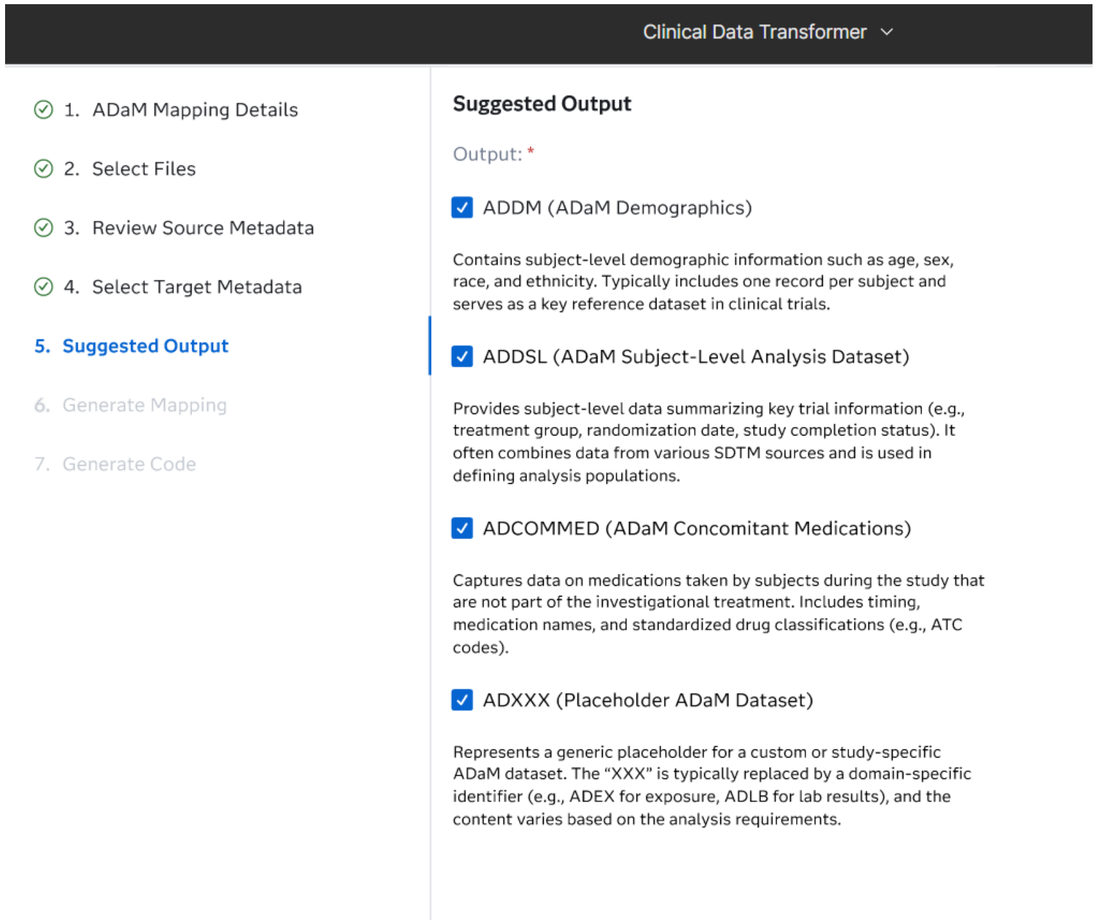


Output - Recommendation

- ADaM Table Names
- SAP References
- SDTM Domain Mappings

ADaM Recommendation

Figma Design



Workflow Generated Output

ADaM Table Name	Recommendation	SAP Sections	Given SDTM Domains	Not Given SDTM Domains	ADaM Dependencies
ADSL	Yes	1.1 Study objectives, 1.2 Study design, 1.3 Expected sample size, 14.1.1.1 Analysis Sets SCR	DM, DS, EX, SV	DS, PE	
ADAE	Yes	4.1.1 Analysis sets, 4.4.1 Calculation of descriptive statistics and percentages, Definition of terms, List of abbreviations	AE		ADSL
ADCM	Yes	1.2 Study design, 4.1.1 Analysis sets, List of abbreviations	CM		ADSL
ADLB	Yes	4.2.2 Baseline and change from baseline, 4.2.4 Analysis visits, 4.4.1 Calculation of descriptive statistics and percentages	LB		ADSL
ADVS	Yes	1.2 Study design, 14.3.3.1 Descriptive Statistics of Vital Signs Actual Values, 14.3.3.2 Descriptive Statistics of Changes from Baseline in Vital Signs FAS, 4.2.4 Analysis visits, 4.4.1 Calculation of descriptive statistics and percentages	VS		ADSL
ADaPER	Yes	4.1.1 Analysis sets	AE, DM, DS, EX, SV		ADSL

ADaM Variable Classes- Latent Groups

Subject-Level Analysis Datasets

Latent Groups	Variable Set
Group 1	Identifier & Keys
	Subject Demographics
	Stratification & grouping
Group 2	Treatment Timing
	Period, Subperiod, and Phase Timing
Group 3	Population Indicator
	Treatment & Dose
Group 4	Trial Experience
	Baseline demographics & Covariates
	Disposition & study

BDS

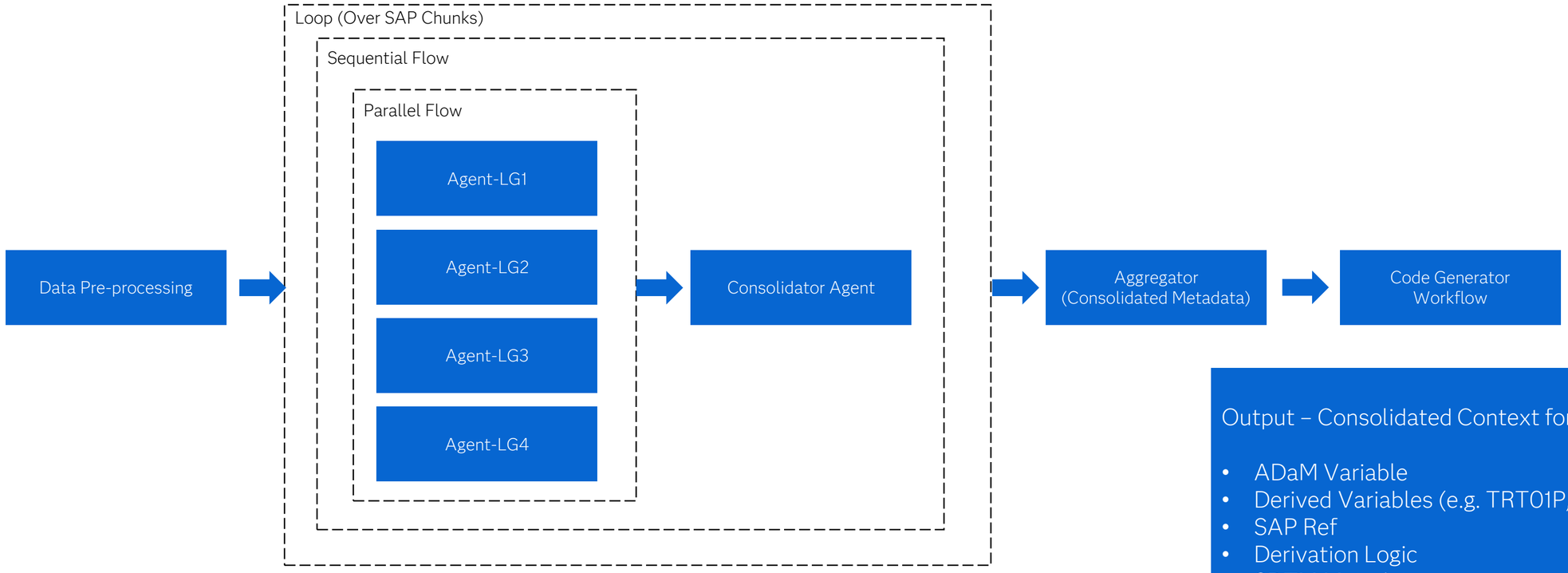
Latent Groups	Variable Set
Group 1	Identifier & keys
	Record-Level Treatment & Dose
	Datapoint Traceability
Group 2	Analysis Parameter
	Analysis Parameter Criteria
	Analysis Descriptor
	Analysis Visit Windowing
Group 3	Time-to-Event
	Toxicity and Range
Group 4	Flag variables
	Population Indicators
Group 5	Timing
	Period, Subperiod, and Phase Start and End Timing

OCCDS

Latent Groups	Variable Set
Group 1	Identifier
	Row Identifier
Group 2	MedDRA Dictionary Coding
	WHO Drug Dictionary Coding
	Other Categorization
Group 3	Timing
Group 4	SDTM Indicator
	OCCDS Indicator
	Adverse Event and Concomitant Medications Indicator
Group 5	Occurrence Flag
	MedDRA Occurrence Flag
Group 6	Treatment/Dose
Group 7	Adverse Event Descriptive
	Concomitant Medications Descriptive
	Standardized MedDRA Query
Group 8	Original or Prior MedDRA Coding
	Original or Prior WHO Drug Coding

SDTM-ADaM Conversion-Spec Integration

User Input | Data Pre-Processing | ADaM Recommendation Workflow | **ADaM Spec Integration Workflow** | Code Generator Workflow

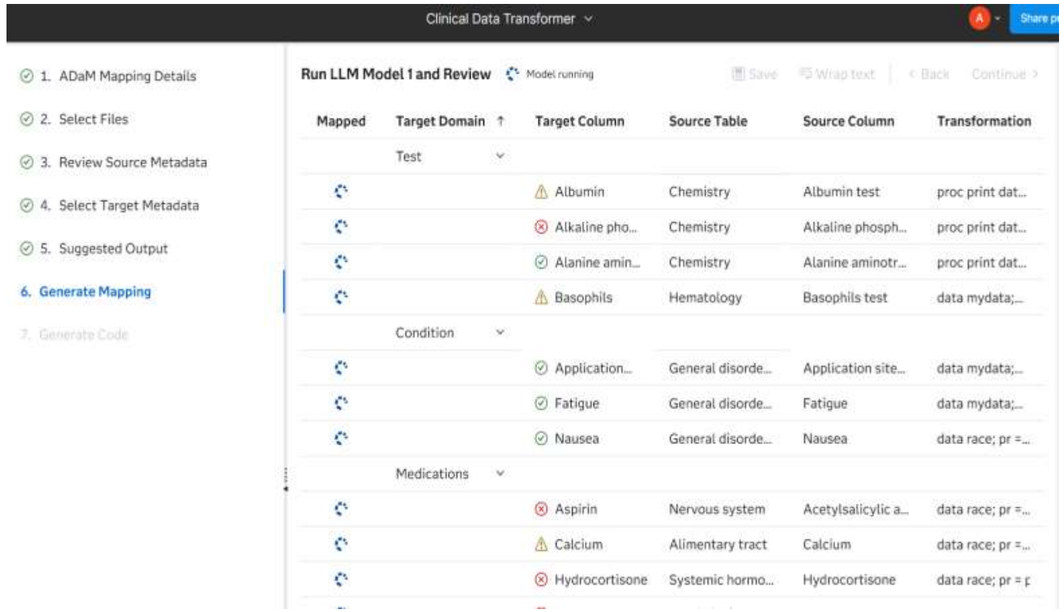


Output – Consolidated Context for ADaM Variables

- ADaM Variable
- Derived Variables (e.g. TRT01P, BMIBL etc.)
- SAP Ref
- Derivation Logic
- SDTM Metadata
- ADaMIG Notes

ADaM Mapping

Figma Design



Workflow Generated Output

variable_name	source_datasets	latent_group	derivation_logic	sap_references	sas_code_hint
ETHNIC	DM	Demographics	Direct copy from DM.ETHNIC.	3.2.1 Available data|7.2 Listings	length ETHNIC $200;|label ETHNIC = "Ethnicity";|ETHNIC = DM.ETHNIC;
APHASE1	DM|DS|TA|TE|EX	Phase Timing Variables	PH1 interval = RFICDTC (earliest consent) ? day before first EXSTDTC, labelled "Screening" if	Definition of terms|Study design|Participant disposition	length APHASE1 $50;|assign 'Screening' or protocol phase name based on ELEMENT.
BMIBL	VS	Baseline Demographics & Covariates	BMIBL = WEIGHTBL / (HEIGHTBL/100)^2, only when both baseline weight & height exist.	Demographics presentation, standardized unit	length BMIBL 8;|format BMIBL 8.2;|if not missing(WEIGHTBL) and not missing(HEIGHTBL) then BMIBL = WEIGHTBL / ((HEIGHTBL/100)**2);
SMOKTYPE	SU	Baseline Demographics & Covariates	Smoking status from SU: SUOCCUR=Y ? smoker SUOCCUR=N + SUENDTC ? ex?smoker Otherwise ? non?smoker If missing ? fallback to EX/CM.	Demographics: smoking habits, SAP section on tobacco history	length SMOKTYPE $40;|if SUOCCUR='Y' then SMOKTYPE='smoker';|else if SUOCCUR='N' and not missing(SUENDTC) then SMOKTYPE='ex-smoker';|else SMOKTYPE='non smoker';

Thank you