



Advanced Analytics and Automation with SAS Clinical Acceleration

PharmaSUG April 2026

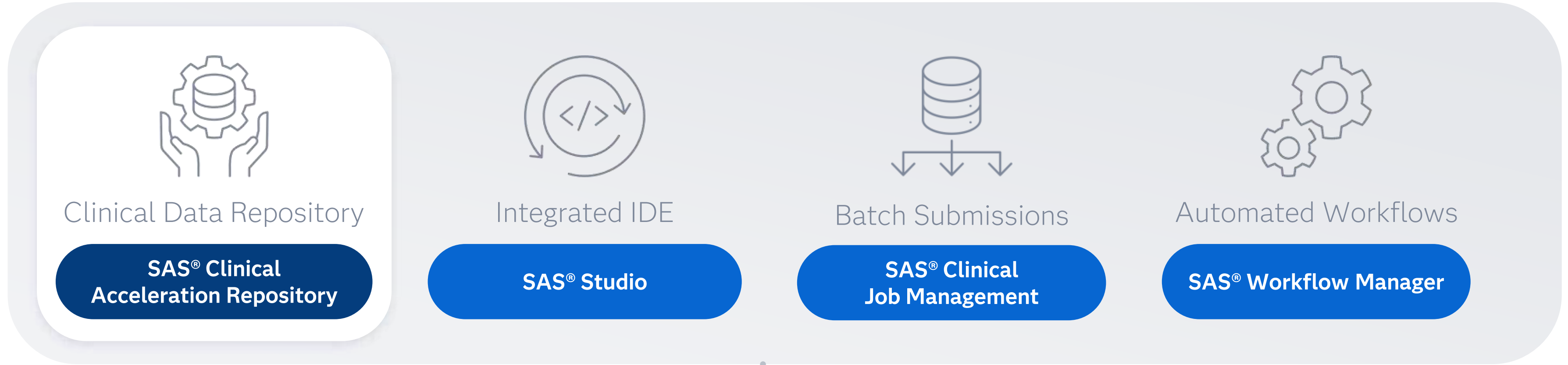
Sudeshna Guhaneogi





**Accelerate
clinical research**
with a secure, validated
statistical computing
environment on SAS Viya.

Statistical Compute Environment (Including CDR)



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

High Level Overview of the Process

**Clinical Trial
Protocol**

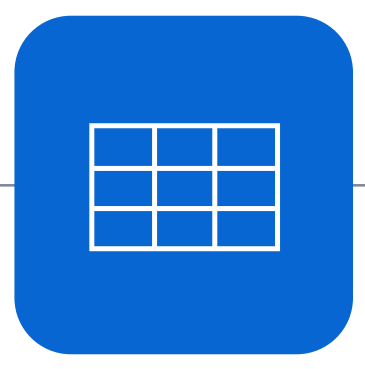


**Data
Collection**



eCRF / eSource

**Data
Tabulation**



SDTM

**Statistical
Analysis**



ADaM / TLFs

**Clinical Study
Report**



Product Management Vision

Comprehensive Overview of Clinical Data Management and Analysis

Clinical Trial
Protocol

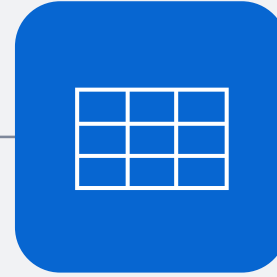


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SDTM

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Clinical Study
Report



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

Clinical Data Transformer

1. ADaM Mapping Details
 2. **Select Files**
 3. Review Source Metadata
 4. Select Target Metadata
 5. Suggested Output
 6. Generate Mapping
 7. Generate Code

Select Files

Repository

- Repository
 - Test 1
 - File 1
 - File 2
 - File 3
 - Job 100.cjob
 - Test 2
 - File 4
 - File 5

Drag source files here. Supported file types are: JSON, XPT, SAS7BDAT, and CSV.

Selected Files

<input type="checkbox"/>	Name	Size	Modified By	Date Modi...	Version
<input type="checkbox"/>	RawData101	48MB	Kevin Alder...	Dec 12, 20...	1.0
<input type="checkbox"/>	RawData102	60MB	Kevin Alder...	Mar 22, 20...	2.0

Clinical Data Transformer

1. ADaM Mapping Details
 2. Select Files
 3. Review Source Metadata
 4. **Select Target Metadata**
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Select Target Metadata

Required target metadata

ADaMIG
 3.4

Mapping specifications
 Upload: Browse
 Selected file: none

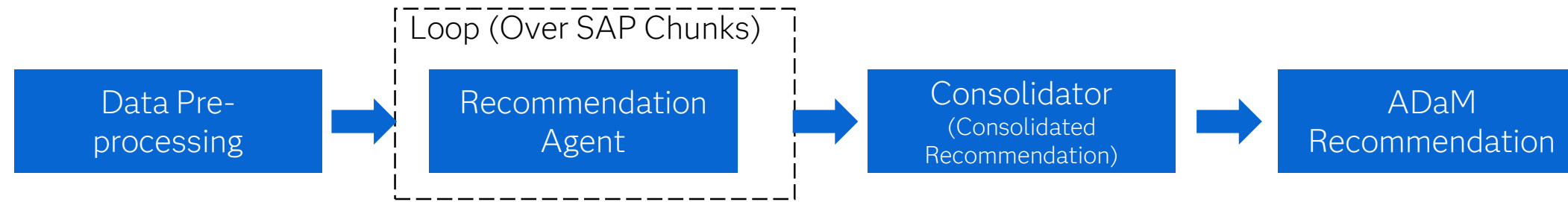
SAP
 Upload: Browse
 Selected file: none

Optional target metadata:

Protocol
 Upload: Browse
 Selected file: none

Mock shells
 Upload: Browse
 Selected file: none

SDTM-ADaM Conversion-Recommendation



- Output - Recommendation
- ADaM Table Names
 - SAP References
 - SDTM Domain Mappings

ADaM Recommendation

Figma Design

Workflow Generated Output

Clinical Data Transformer ▾

1. ADaM Mapping Details
2. Select Files
3. Review Source Metadata
4. Select Target Metadata
- 5. Suggested Output**
6. Generate Mapping
7. Generate Code

Suggested Output

Output: *

- ADDM (ADaM Demographics)

Contains subject-level demographic information such as age, sex, race, and ethnicity. Typically includes one record per subject and serves as a key reference dataset in clinical trials.
- ADDSL (ADaM Subject-Level Analysis Dataset)

Provides subject-level data summarizing key trial information (e.g., treatment group, randomization date, study completion status). It often combines data from various SDTM sources and is used in defining analysis populations.
- ADCOMMED (ADaM Concomitant Medications)

Captures data on medications taken by subjects during the study that are not part of the investigational treatment. Includes timing, medication names, and standardized drug classifications (e.g., ATC codes).
- ADXXX (Placeholder ADaM Dataset)

Represents a generic placeholder for a custom or study-specific ADaM dataset. The "XXX" is typically replaced by a domain-specific identifier (e.g., ADEX for exposure, ADLB for lab results), and the content varies based on the analysis requirements.

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

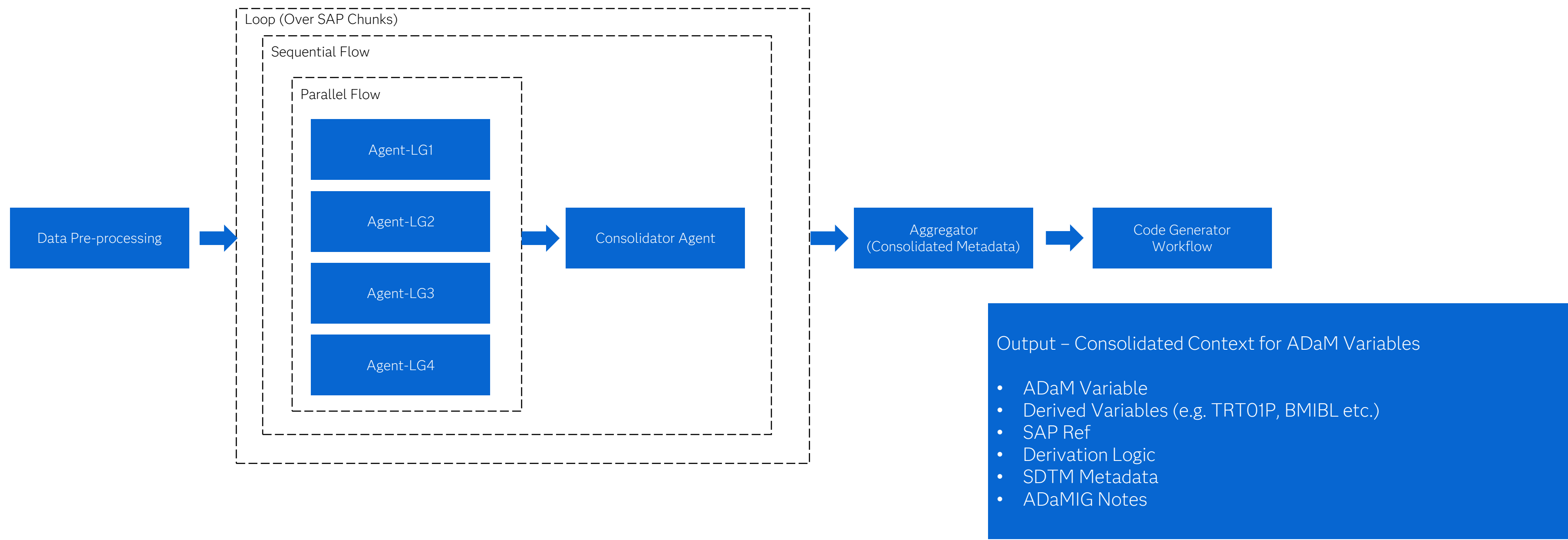
BDS

Latent Groups	Variable Set
Group 1	Identifier & keys
	Record-Level Treatment & Dose
	Datapoint Traceability
Group 2	Analysis Parameter
	Analysis Parameter Criteria
	Analysis 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



ADaM Mapping

Figma Design

Clinical Data Transformer

Run LLM Model 1 and Review

Mapped	Target Domain	Target Column	Source Table	Source Column	Transformation
	Test				
		Albumin	Chemistry	Albumin test	proc print dat...
		Alkaline pho...	Chemistry	Alkaline phosph...	proc print dat...
		Alanine amin...	Chemistry	Alanine aminotr...	proc print dat...
		Basophils	Hematology	Basophils test	data mydata;...
	Condition				
		Application...	General disorde...	Application site...	data mydata;...
		Fatigue	General disorde...	Fatigue	data mydata;...
		Nausea	General disorde...	Nausea	data race; pr =...
	Medications				
		Aspirin	Nervous system	Acetylsalicylic a...	data race; pr =...
		Calcium	Alimentary tract	Calcium	data race; pr =...
		Hydrocortisone	Systemic hormo...	Hydrocortisone	data race; pr = p

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

