

SAS Clinical Data Transformation: Continuous Traceability and Automation Across SDTM, ADaM and TFLs

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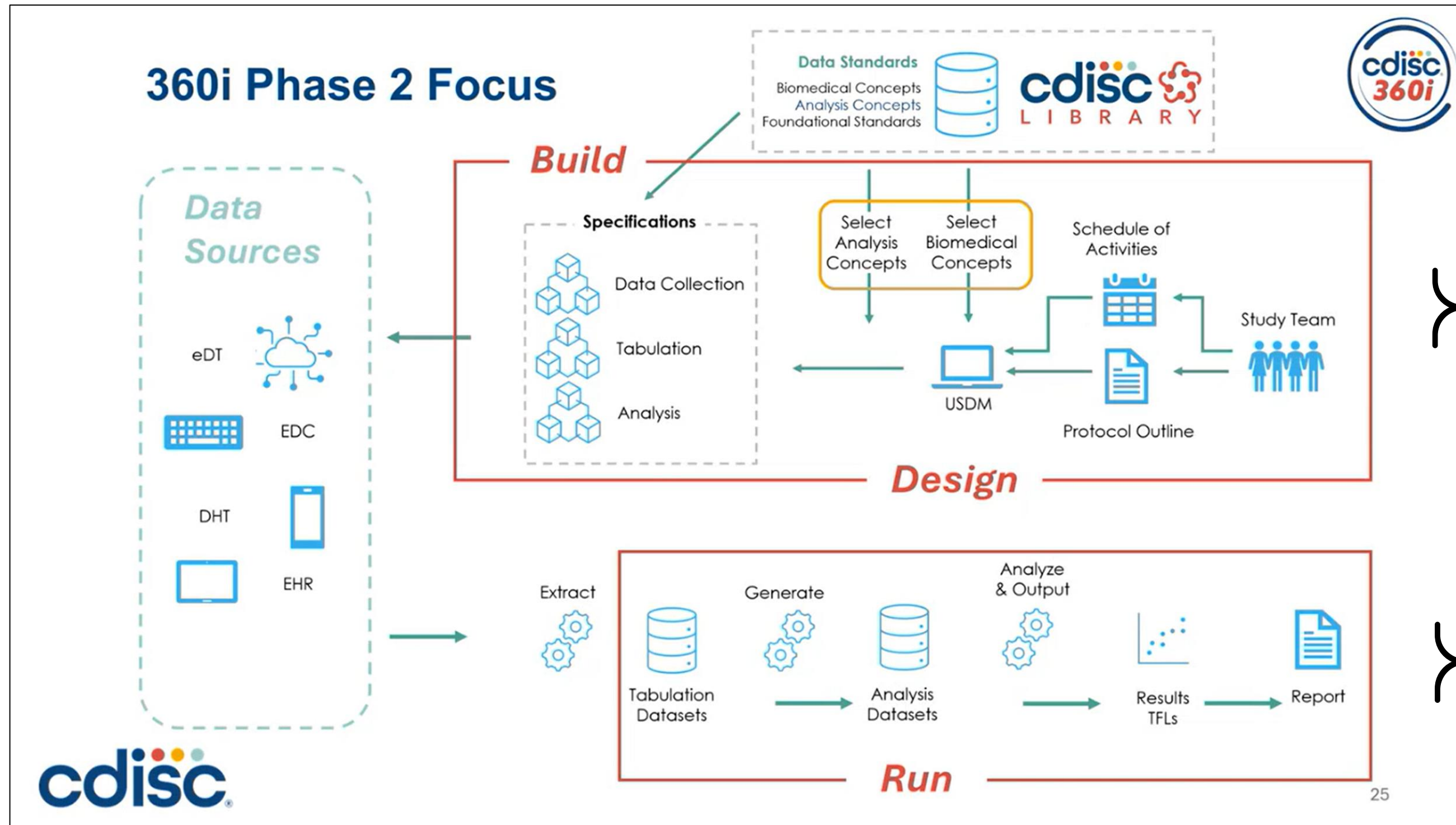
Bio



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Soundarya Palanisamy is a Principal Industry Advisor based in Germany and is part of the Global Health and Life Sciences Practice at SAS. She supports clients by providing guidance on their journey of digital transformation through the usage of AI, analytics and technology. She specializes in machine learning, text mining and analytical life cycle management enabling her to unlock insights that optimize processes and spearhead innovation in the healthcare and life sciences domains. Her extensive experience includes a deep understanding of regulatory data science. She has a bachelor's degree in computer science from Anna University and a master's degree in cognitive science from the University of Freiburg.

Operationalizing 360i vision

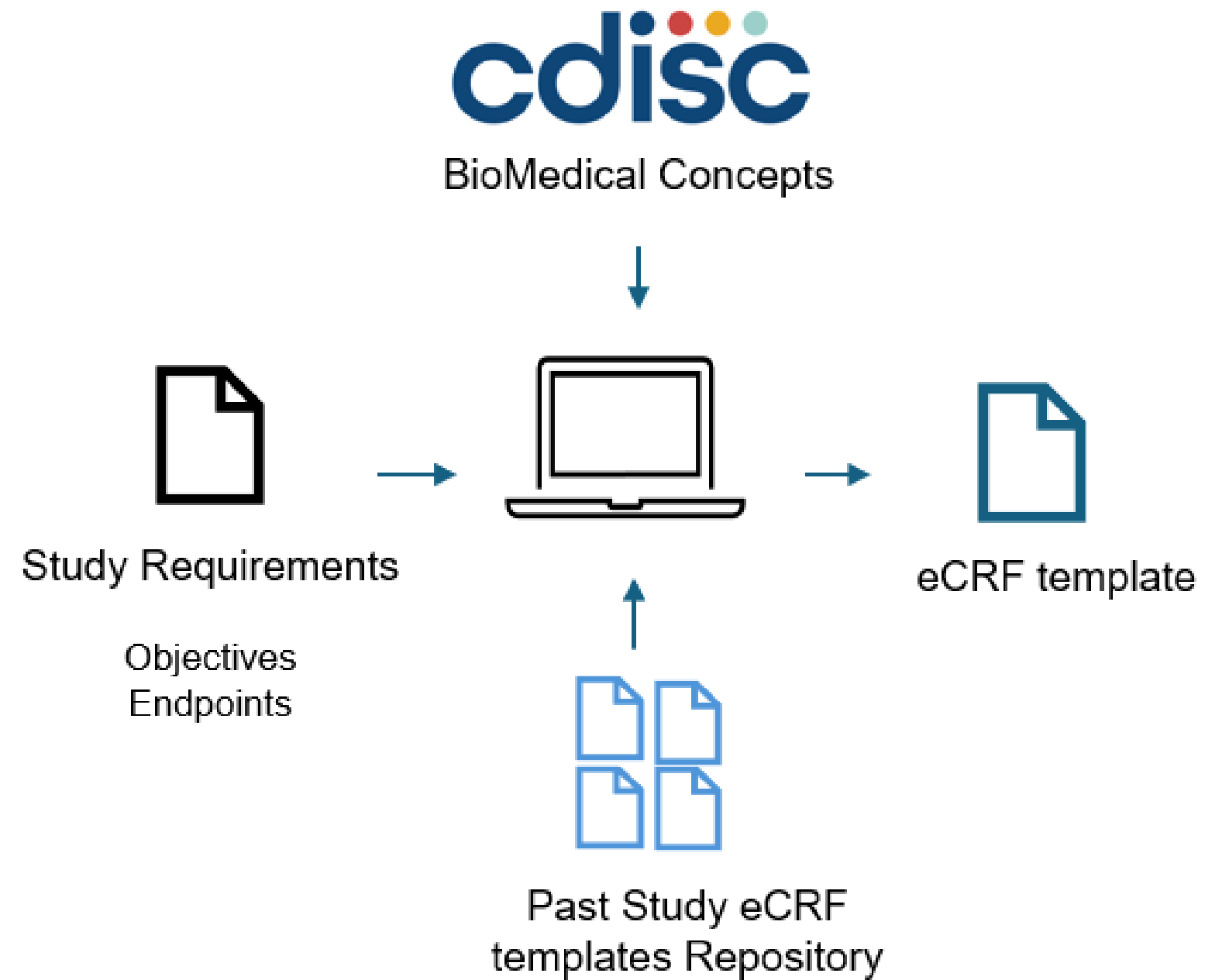


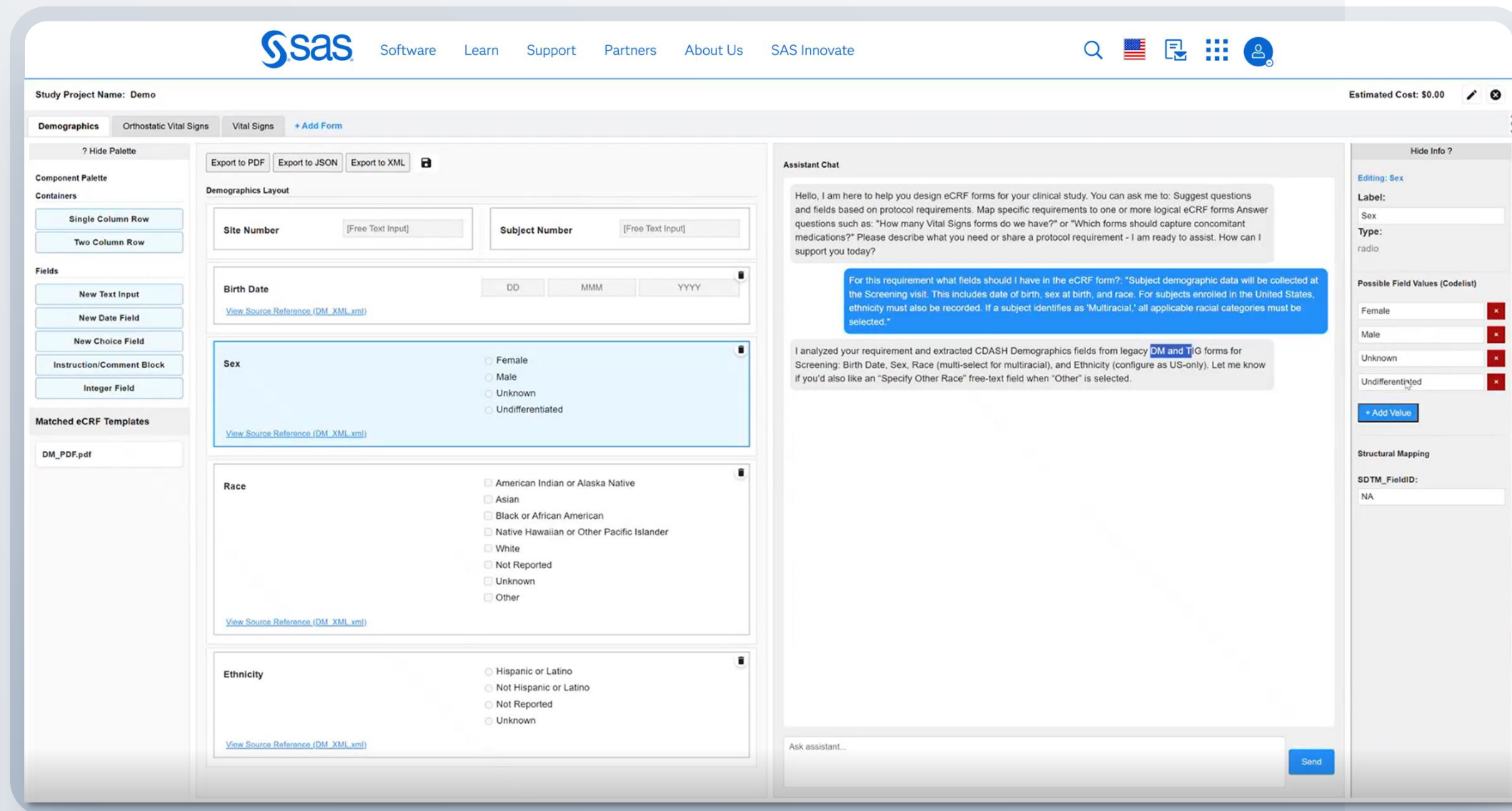
Accelerated, standards-driven eCRF design with prequalified metadata and controlled terminology, ensuring data are “SDTM-ready” by design for the RAW→SDTM pipeline.

Automated transformation from RAW to SDTM, ADaM, and TLFs with end-to-end lineage for audit-ready traceability.

eCRF Build Automation

AI Assisted eCRF form Creation





AI Assisted eCRF Creation - Prototype

Clinical Trials eCRF Build Automation

1

Map Requirements to eCRFs

Upload Protocol, other digital documents, OR copy/paste study requirements.

ome, sinpan

ClinAssist - LLM Powered eCRF Builder

Studies

ch projects...

Study Code
CS-118
CS-115
CS-116

Create New Clinical Study Project

Study Details

Study Requirements

Retrieval Settings

Upload or paste study protocol requirements.

You can either upload your study protocol document (PDF/Word) for automatic extraction, or manually copy-paste the requirements into the field below.

Once ready, click the "Extract & Map to eCRFs" button to analyze the text and intelligently group related requirements into individual eCRF forms.

Study Protocol (File Upload)

File

Vital signs will be measured after the subject has been resting in a supine position for at least 5 minutes. Measurements include heart rate, respiratory rate, and oral body temperature. For heart rate, if an abnormality is noted, a repeat measurement must be taken after an additional 5 minutes of rest. Subject demographic data will be collected at the Screening visit. This includes date of birth, sex at birth, and race. For subjects enrolled in the United States, ethnicity must also be recorded. If a subject identifies as 'Multiracial,' all applicable racial categories must be selected. Orthostatic Vital Signs must be assessed at the Screening and Day 1 visits. The

Extract & Map to eCRFs

Protocol Requirements to eCRF form match

Requirement

+ Add Row

Create New Clinical Study Project

Study Details

Study Requirements

Retrieval Settings

Settings *

☐ eCRF Form Templates Repository

☐ CDISC BioMedicalConcepts Repository

☒ Both

Start New Project

Clinical Trials eCRF Build Automation

2

Edit and Export eCRFs

Edit metadata, add/edit new fields to eCRF form, export to PDF/JSON/XML.

Study Project Name: Demo Estimated Cost: \$0.00

Demographics | Orthostatic Vital Signs | Vital Signs | [+ Add Form](#)

? Hide Palette

Component Palette

Containers

- Single Column Row
- Two Column Row

Fields

- New Text Input
- New Date Field
- New Choice Field
- Instruction/Comment Block
- Integer Field

Matched eCRF Templates

- DM_PDF.pdf

Demographics Layout

[Export to PDF](#) [Export to JSON](#) [Export to XML](#)

Site Number [Free Text Input] **Subject Number** [Free Text Input]

Birth Date DD MMM YYYY [View Source Reference \(DM_XML.xml\)](#)

Sex ☐ Female ☐ Male ☐ Unknown ☐ Undifferentiated [View Source Reference \(DM_XML.xml\)](#)

Race ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Not Reported ☐ Unknown ☐ Other [View Source Reference \(DM_XML.xml\)](#)

Ethnicity ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Not Reported ☐ Unknown [View Source Reference \(DM_XML.xml\)](#)

Assistant Chat

Hello, I am here to help you design eCRF forms for your clinical study. You can ask me to: Suggest questions and fields based on protocol requirements. Map specific requirements to one or more logical eCRF forms Answer questions such as: "How many Vital Signs forms do we have?" or "Which forms should capture concomitant medications?" Please describe what you need or share a protocol requirement - I am ready to assist. How can I support you today?

For this requirement what fields should I have in the eCRF form?: "Subject demographic data will be collected at the Screening visit. This includes date of birth, sex at birth, and race. For subjects enrolled in the United States, ethnicity must also be recorded. If a subject identifies as 'Multiracial,' all applicable racial categories must be selected."

I analyzed your requirement and extracted CDASH Demographics fields from legacy **DM** and **TIG** forms for Screening: Birth Date, Sex, Race (multi-select for multiracial), and Ethnicity (configure as US-only). Let me know if you'd also like an "Specify Other Race" free-text field when "Other" is selected.

Ask assistant... Send

Hide Info ?

Editing: Sex

Label: Sex

Type: radio

Possible Field Values (Codelist)

- Female
- Male
- Unknown
- Undifferentiated

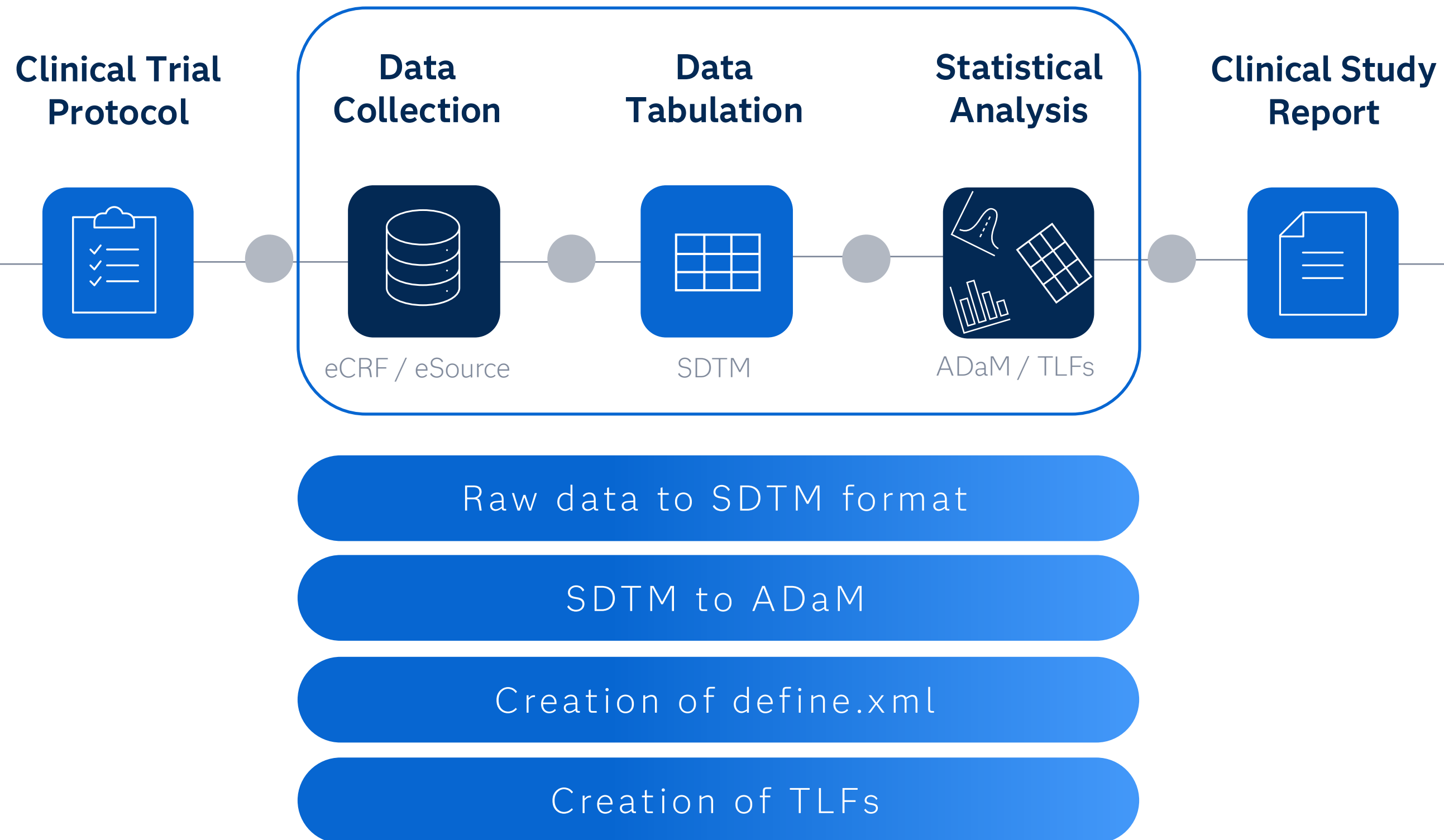
[+ Add Value](#)

Structural Mapping

SDTM_FieldID: NA

Introducing SAS Clinical Data Transformation

End to End Clinical Data Flow



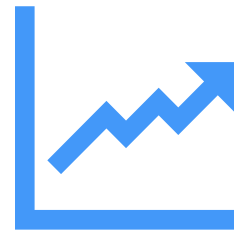
The Need for Automation



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

Features



Data Mapping

- Auto generate data transformation rules. (Raw -> SDTM -> ADaM)
- Investigate documents such as Study Protocols, SAP, TLF Shells to generate mapping specifications.



Code Generation

- SAS Code generation with error feedback loop.
- Ensure Cyclic dependencies are taken care of when generating datasets.



Traceability

- Lineage view to track source to target data transformation.
- Source data coverage, missed variables reports.

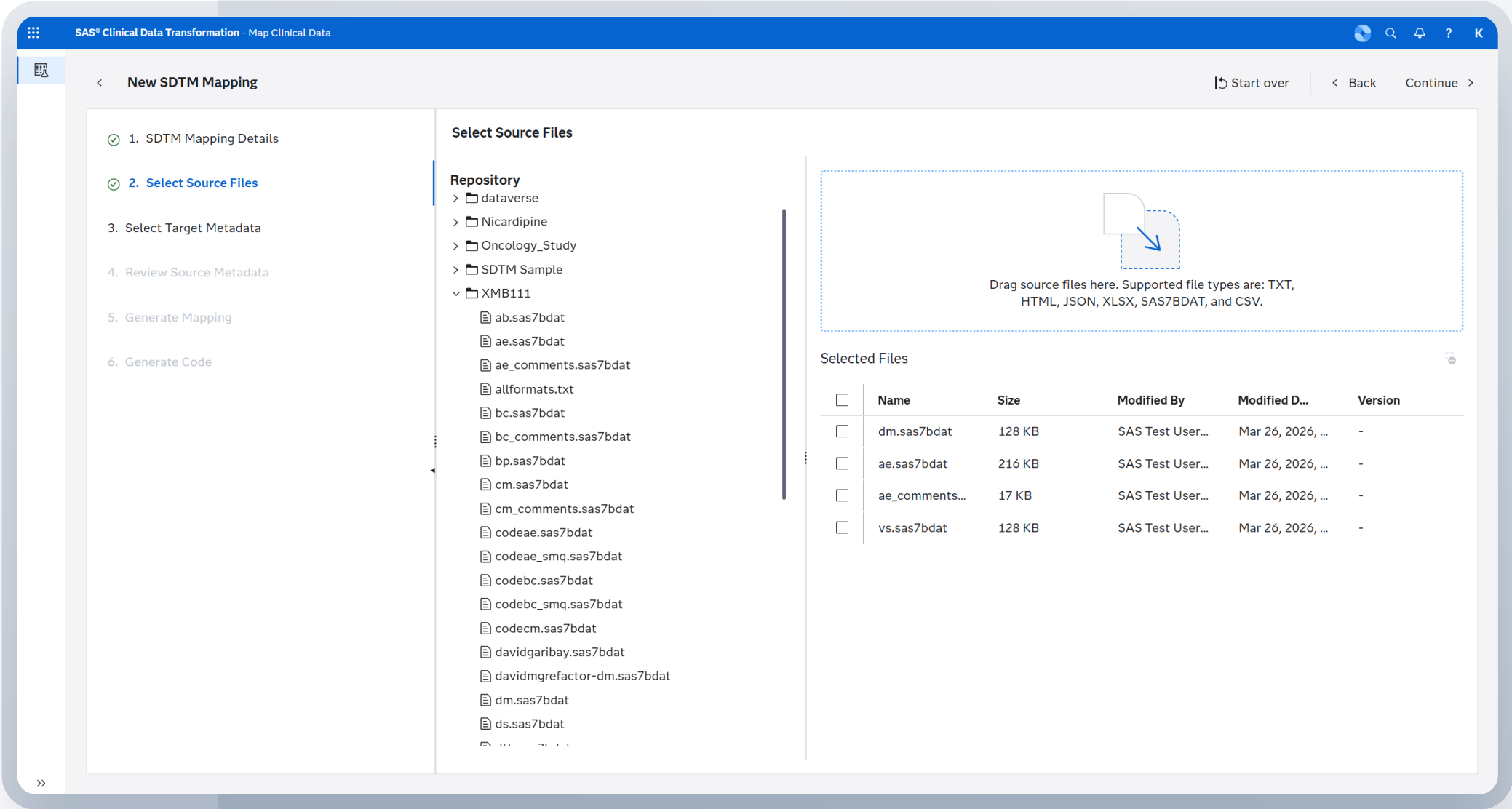
A First Look : Clinical Data Transformation

Clinical Data Transformation

Raw to SDTM

01

Select source data
from Clinical Acceleration
Repository select the
dataset(s) you'd like to map



Clinical Data Transformation

Raw to SDTM

02

Select target data structure

by selecting IG from CDISC importing previous mapping specifications or specific target structure

The screenshot displays the SAS Clinical Data Transformation - Map Clinical Data interface. The main heading is "New SDTM Mapping". On the left, a vertical list of steps is shown: 1. SDTM Mapping Details, 2. Select Source Files, 3. Select Target Metadata (highlighted with a blue bar), 4. Review Source Metadata, 5. Generate Mapping, and 6. Generate Code. The main content area is titled "Select Target Metadata". It includes a dropdown menu for "SDTMIG:" with the value "3.4" selected. Below this is a section for "Upload mapping specifications:" with a file named "mappings_document" and a "Browse" button. At the bottom, there is a "Domains:" section with a list of domains: "AE x", "CM x", and "DM x", followed by a plus sign (+) to add more domains. The interface also features a top navigation bar with "Start over", "Back", and "Continue" buttons.

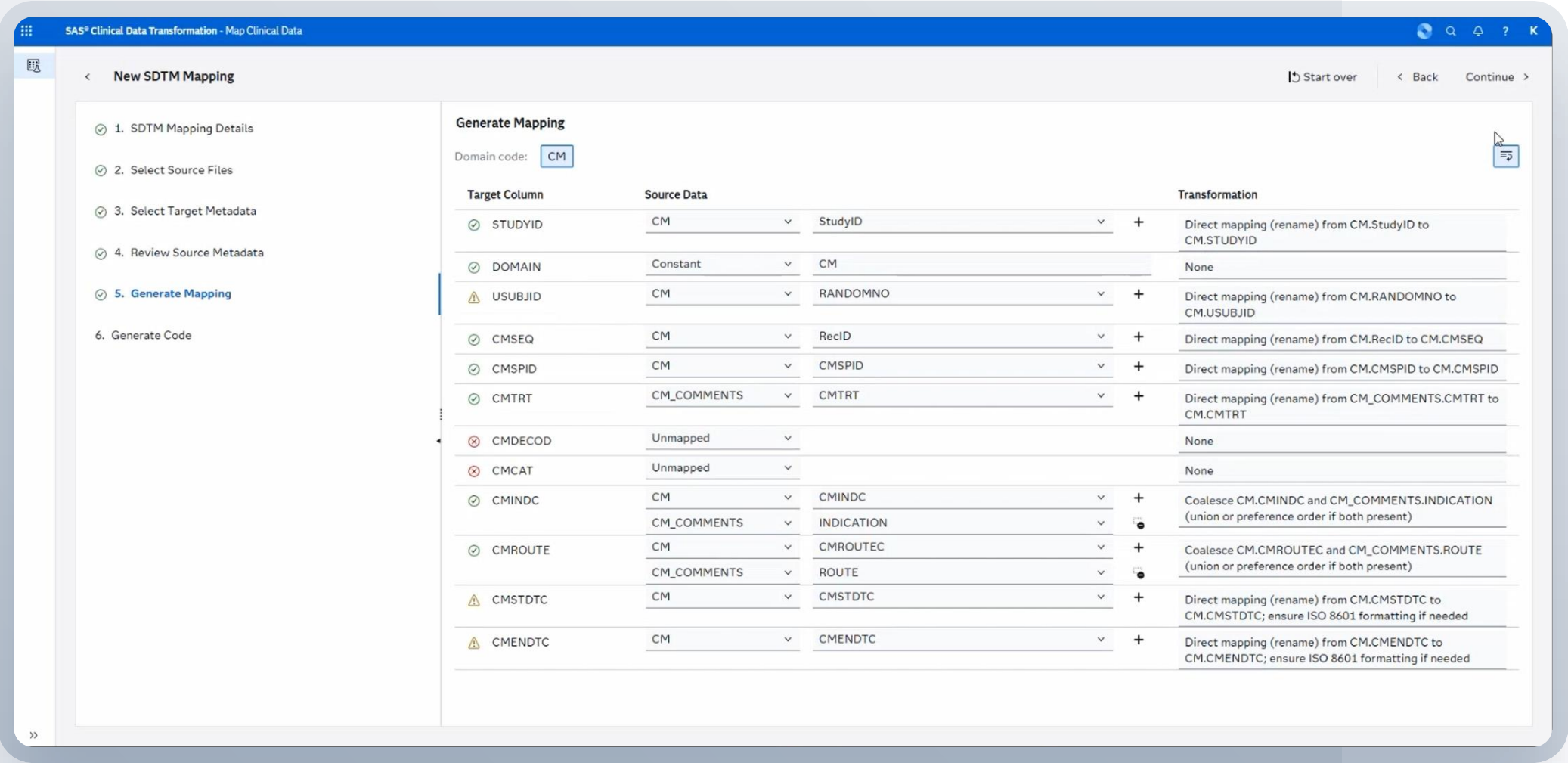
Raw to SDTM

Clinical Data Transformation

03

Run Agent

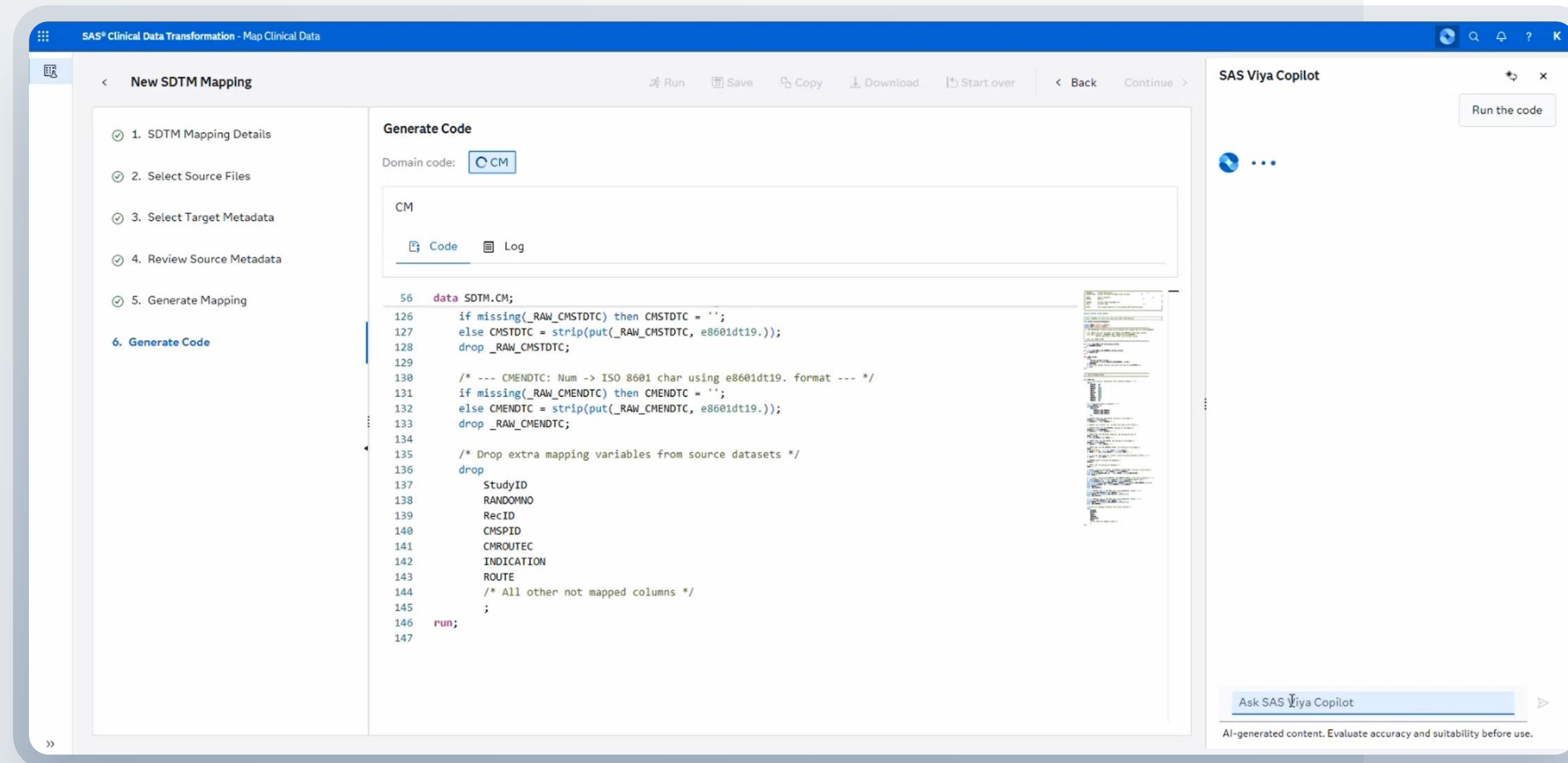
to map from source to target with access to edit mapping and transformation directly via the UI



Raw to SDTM

Clinical Data Transformation

04



Produce your code
and run it directly within
Clinical Data Transformation,
engage with Code Assist or
Co-Pilot or save to your
workspace to begin work

SDTM to ADaM

Clinical Data Transformation

05

The screenshot displays the SAS Life Science Clinical Data Transformer web application. The interface is titled 'Study One' and includes navigation links for 'Start over', 'Back', and 'Continue'. A sidebar on the left lists the workflow steps: 1. ADaM Mapping Details, 2. Select Files, 3. Review Source Metadata, 4. Select Target Metadata (highlighted), 5. Suggested Output, 6. Generate Mapping, and 7. Generate Code. The main content area is titled 'Select Target Metadata' and contains the instruction 'Required target metadata (select at least one): *'. Under this, the 'ADaMIG' option is selected with a checkbox, and a dropdown menu shows '3.4'. Below this, there are three unselected options: 'Mapping specifications', 'SAP', 'Protocol', and 'Mock shells'. Each of these options has an 'Upload:' label, a text input field, and a 'Browse' button. The 'Selected file' status for each is currently 'none'.

Select target data structure by selecting IG from CDISC and importing study design documents.

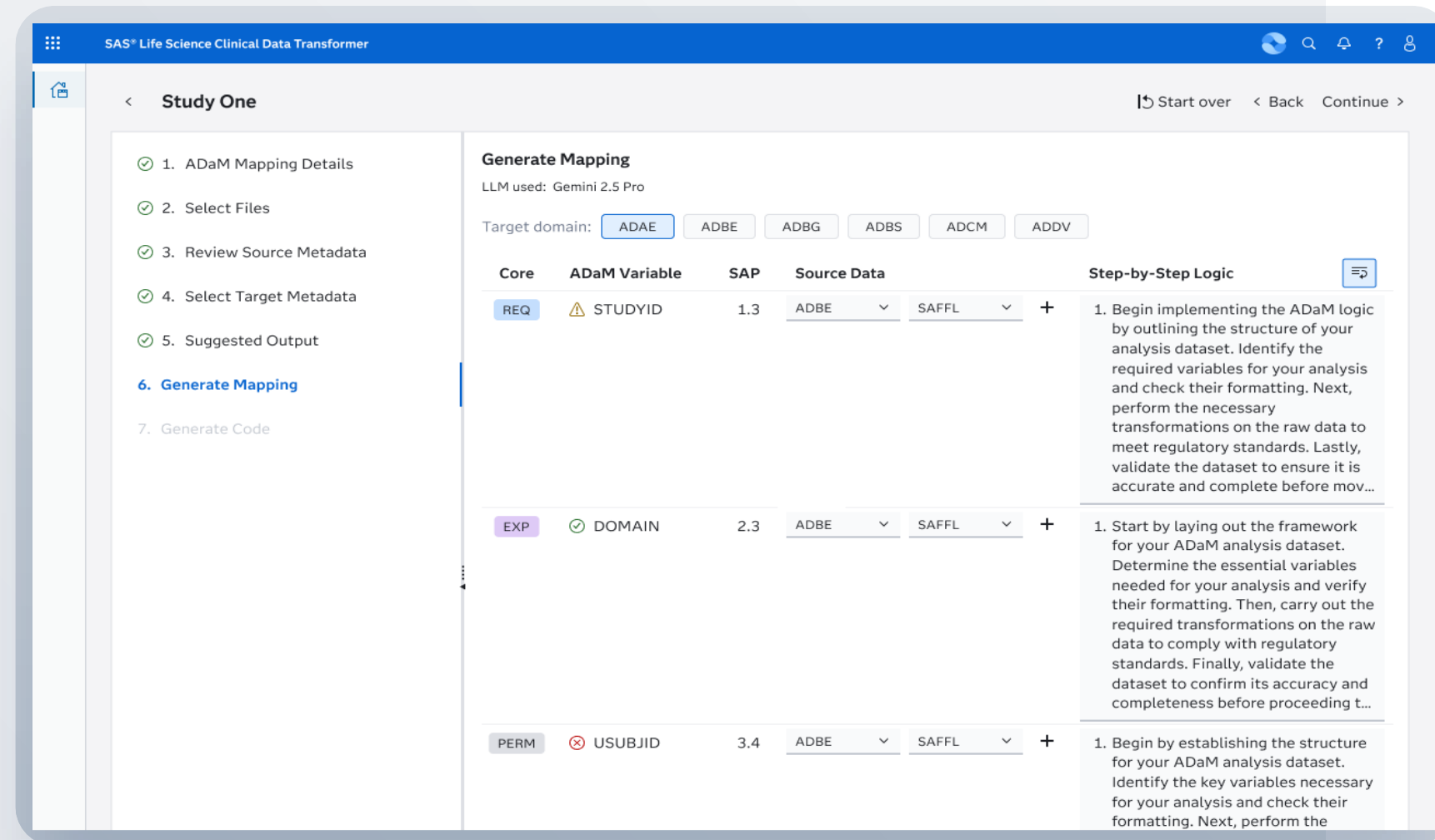
SDTM to ADaM

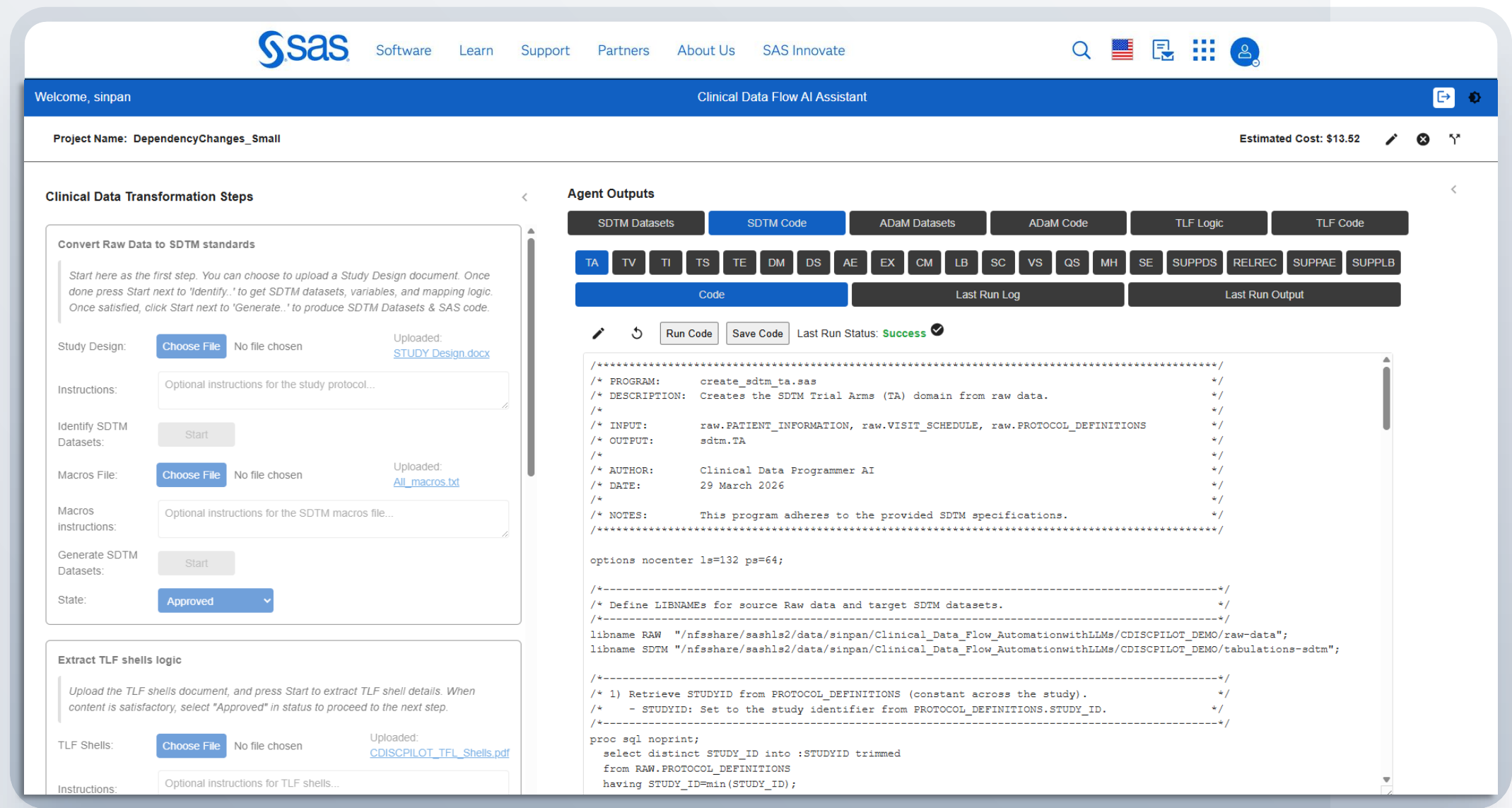
Clinical Data Transformation

06

Run Agent

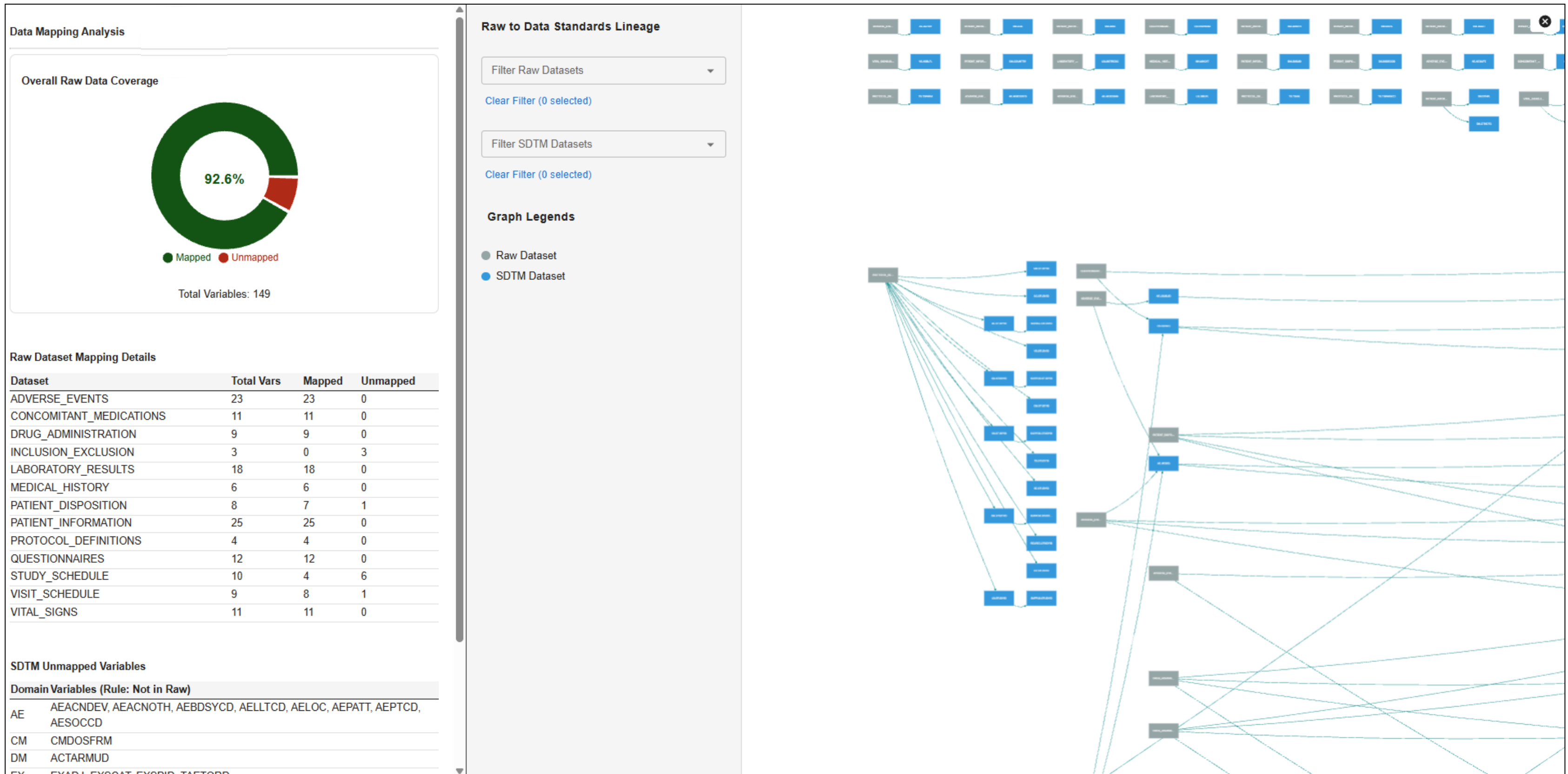
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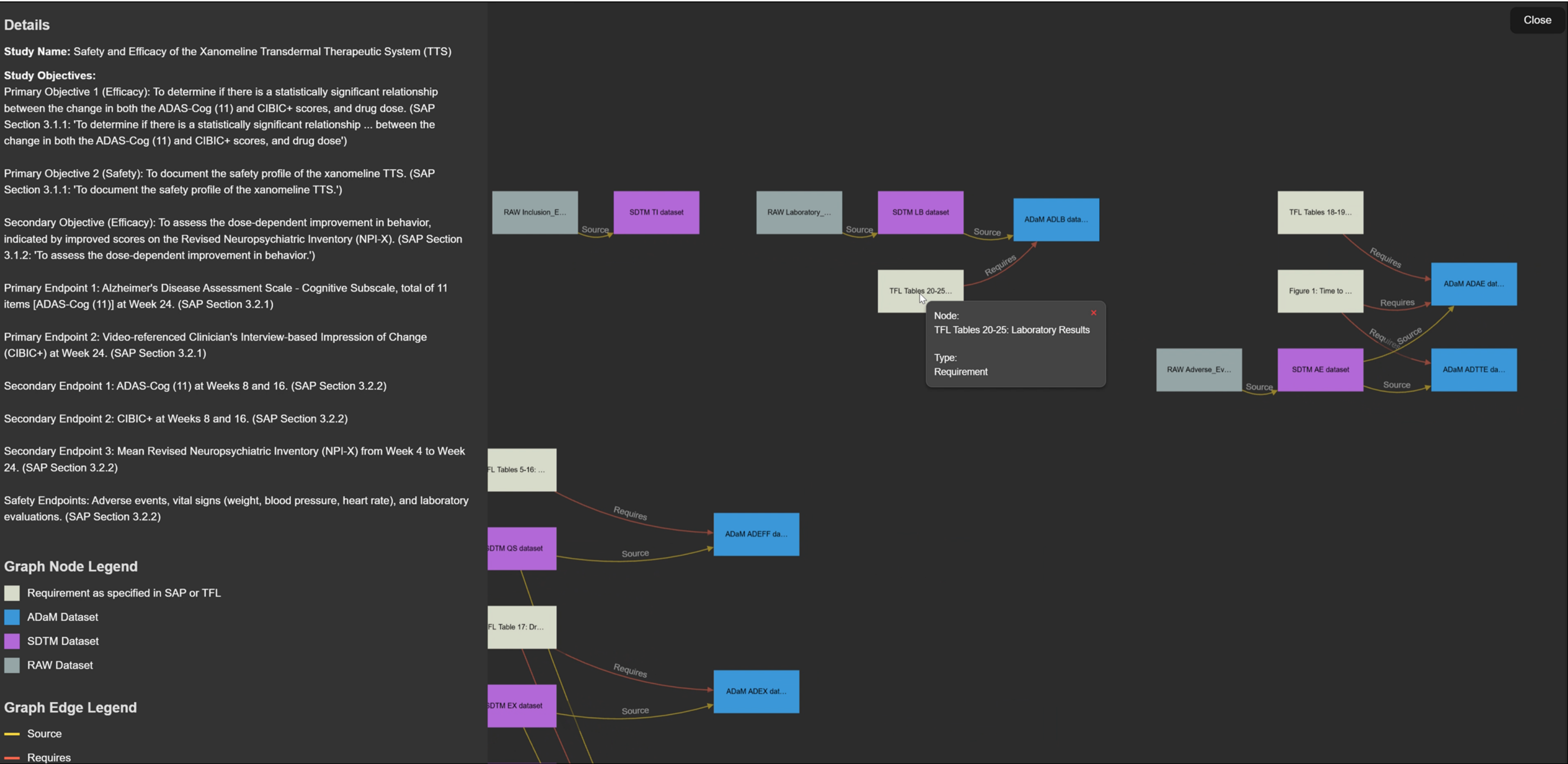


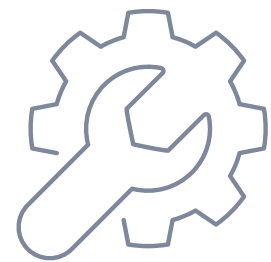
Clinical Data Flow Prototype

CDF App – Traceability and Data Coverage Reports



CDF App – Traceability and Data Coverage Reports





Clinical Trials Workflow Vision

Raw data to SDTM format

SDTM to ADaM

→ Creation of define.xml

→ Creation of TLFs

**Clinical Trial
Protocol**



**Data
Collection**



eCRF / eSource

**Data
Tabulation**



SDTM

**Statistical
Analysis**



ADaM / TLFs

**Clinical Study
Report**



Key Features /Advantages



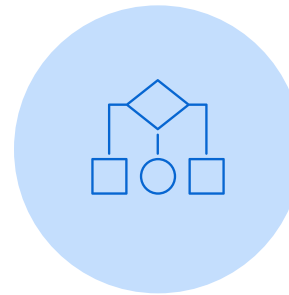
Importance of Human in the loop
– Regeneration – after expert input?



Governance



**Context engineering – importance
of input files**



Semantic Chunking



Curated Prompt quality

Frankfurt • 21. Mai

sas innovate

on tour 2026

The data and AI conference

Jetzt registrieren

sas.com/innovate-on-tour/germany



Question and Answers

For any questions contact:
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