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

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Bio

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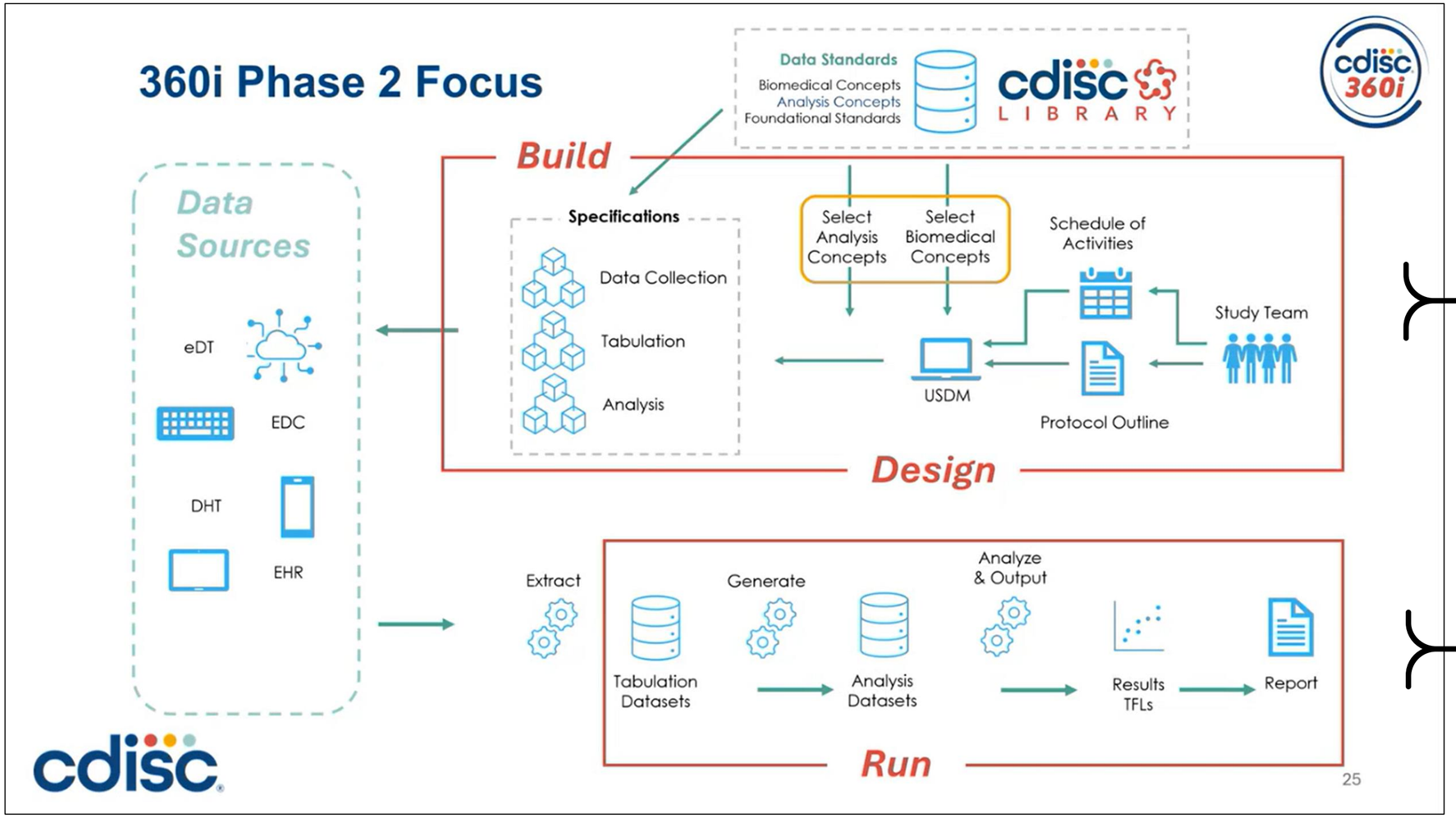
Soundarya Palanisamy is a Principal Industry Advisor based in Germany and is part of the Global Health and Life Sciences Practice at SAS. She supports clients by providing guidance on their journey of digital transformation through the usage of AI, analytics and technology. She specializes in machine 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

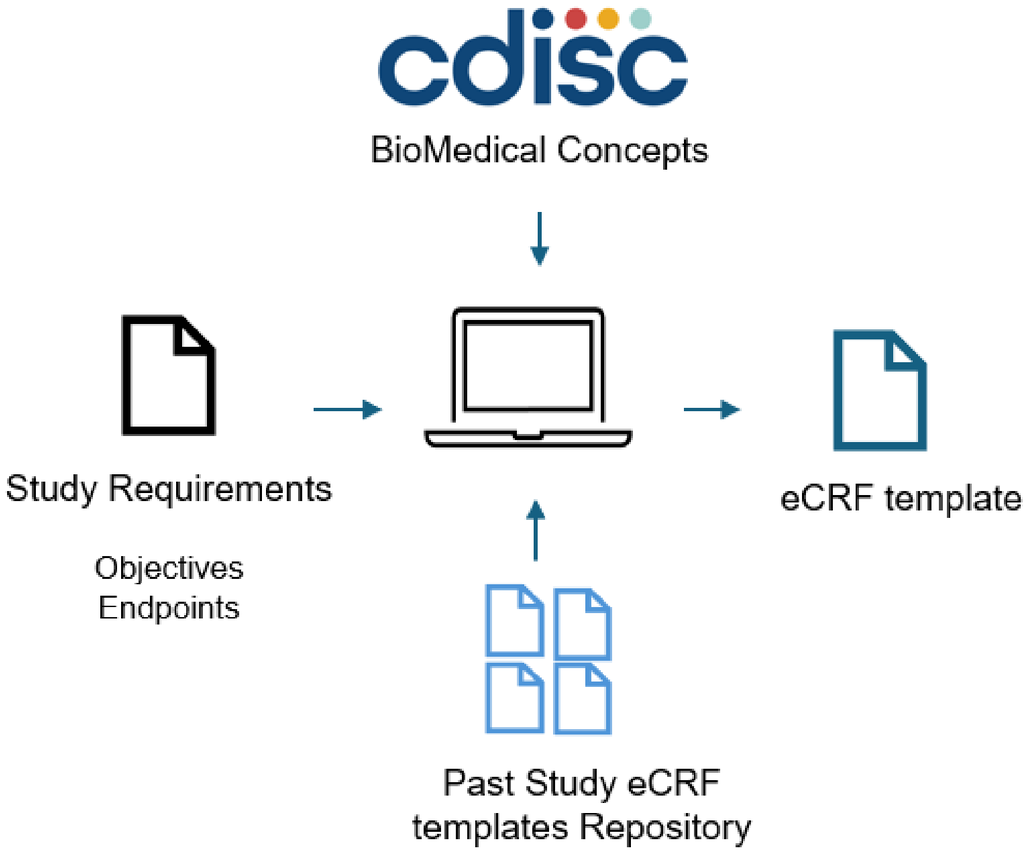


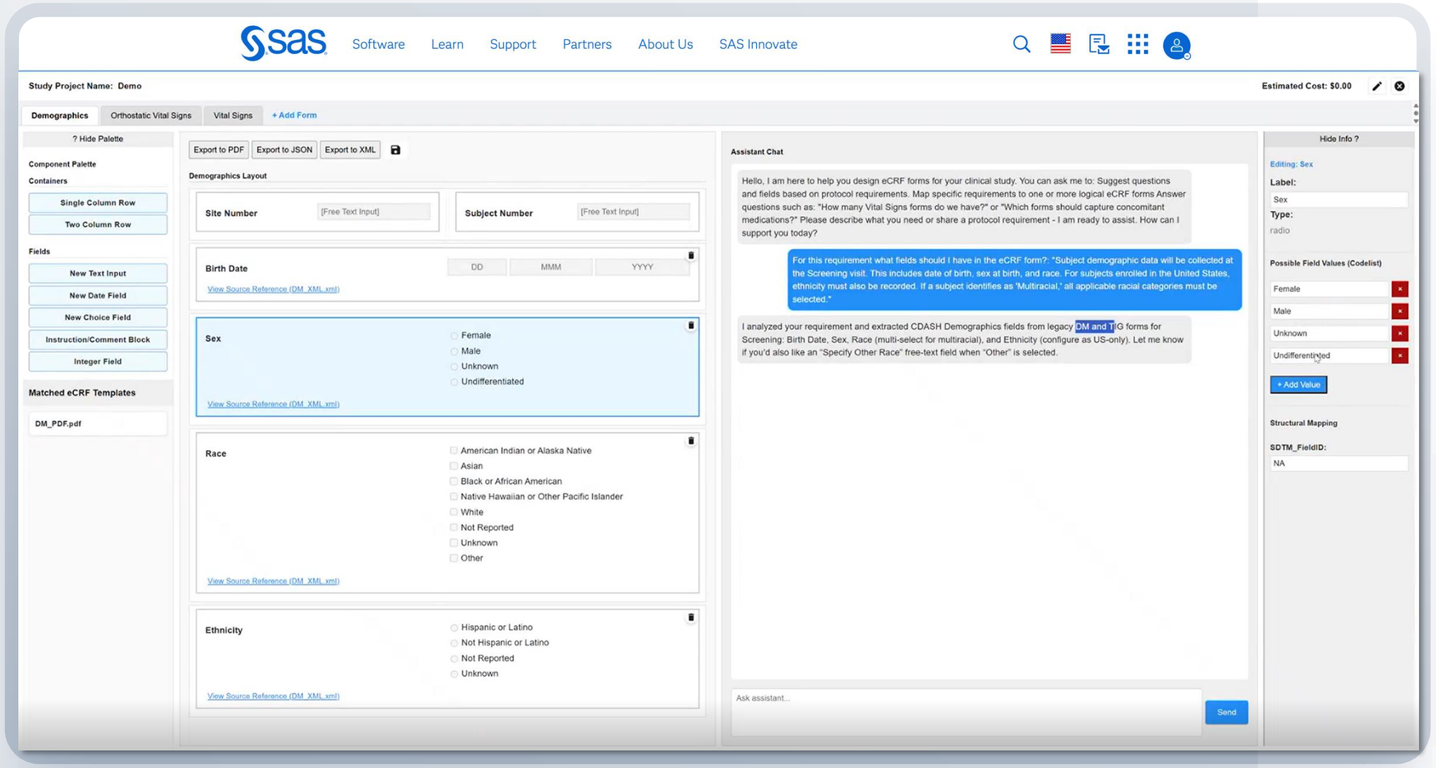
Accelerated, standards-driven eCRF design with prequalified metadata and controlled terminology, ensuring data are “SDTM-ready” by design for the RAW→SDTM pipeline.

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





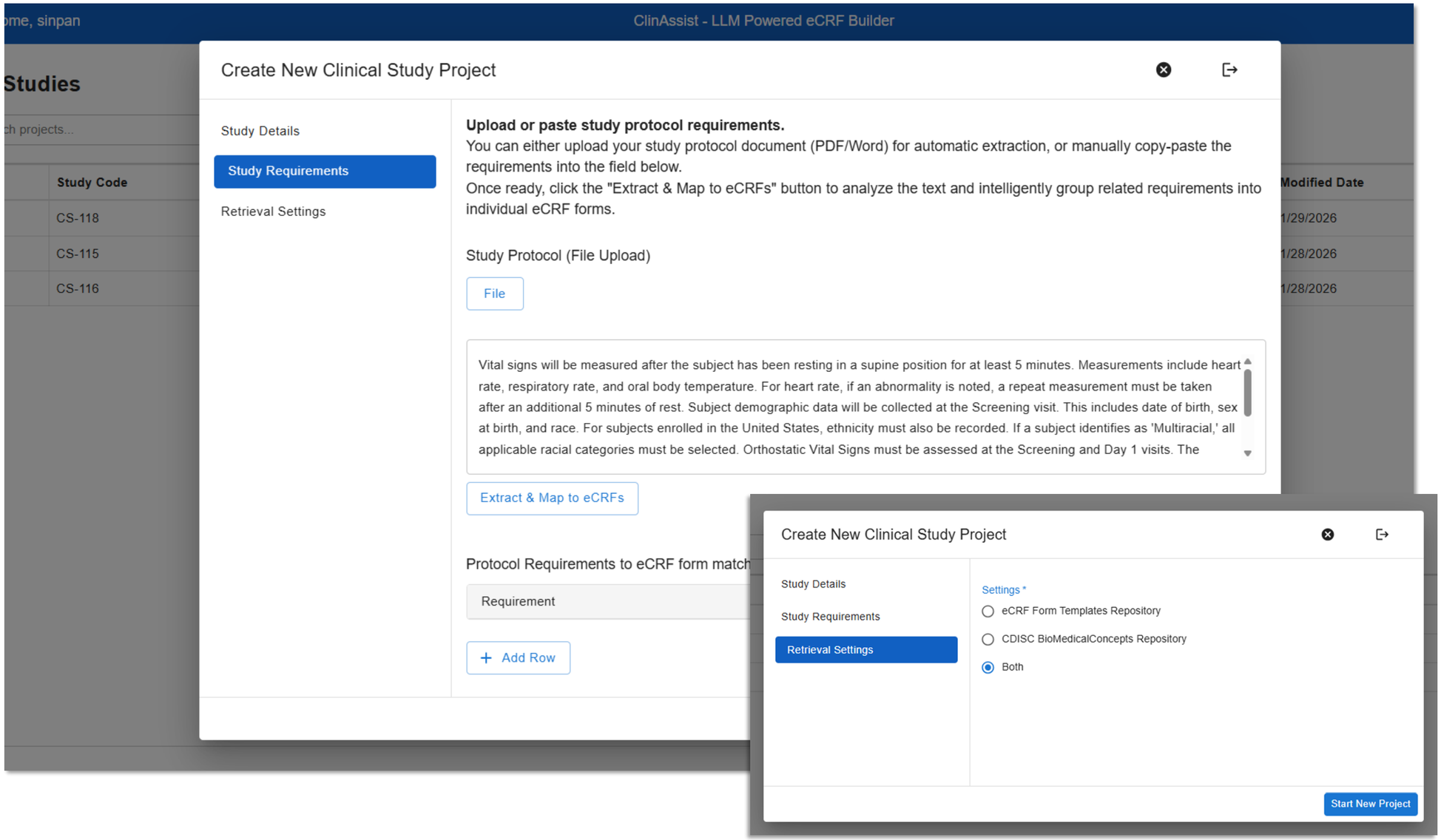
AI Assisted eCRF Creation - Prototype

Clinical Trials eCRF Build Automation

1

Map Requirements to eCRFs

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

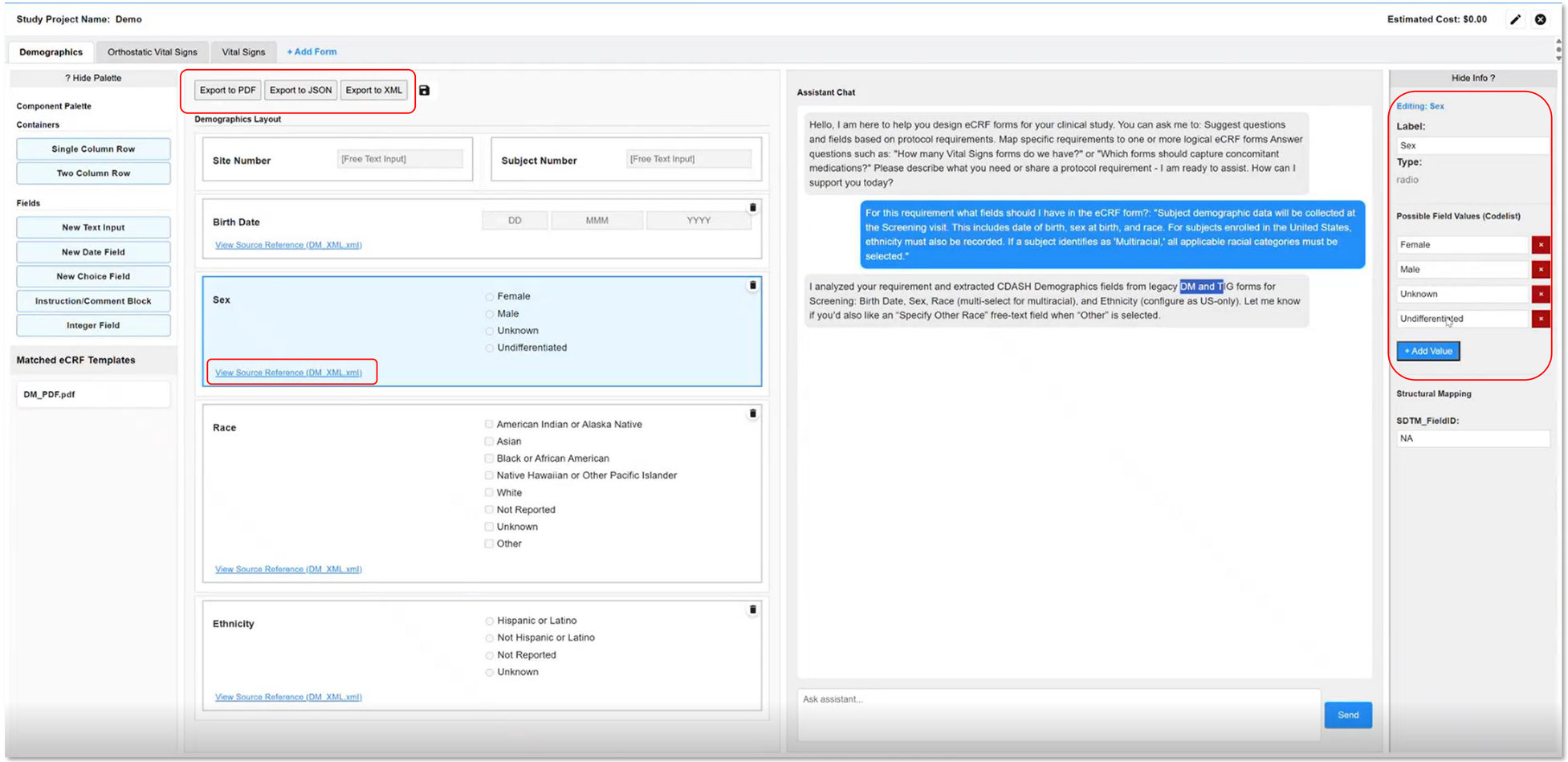


Clinical Trials eCRF Build Automation

2

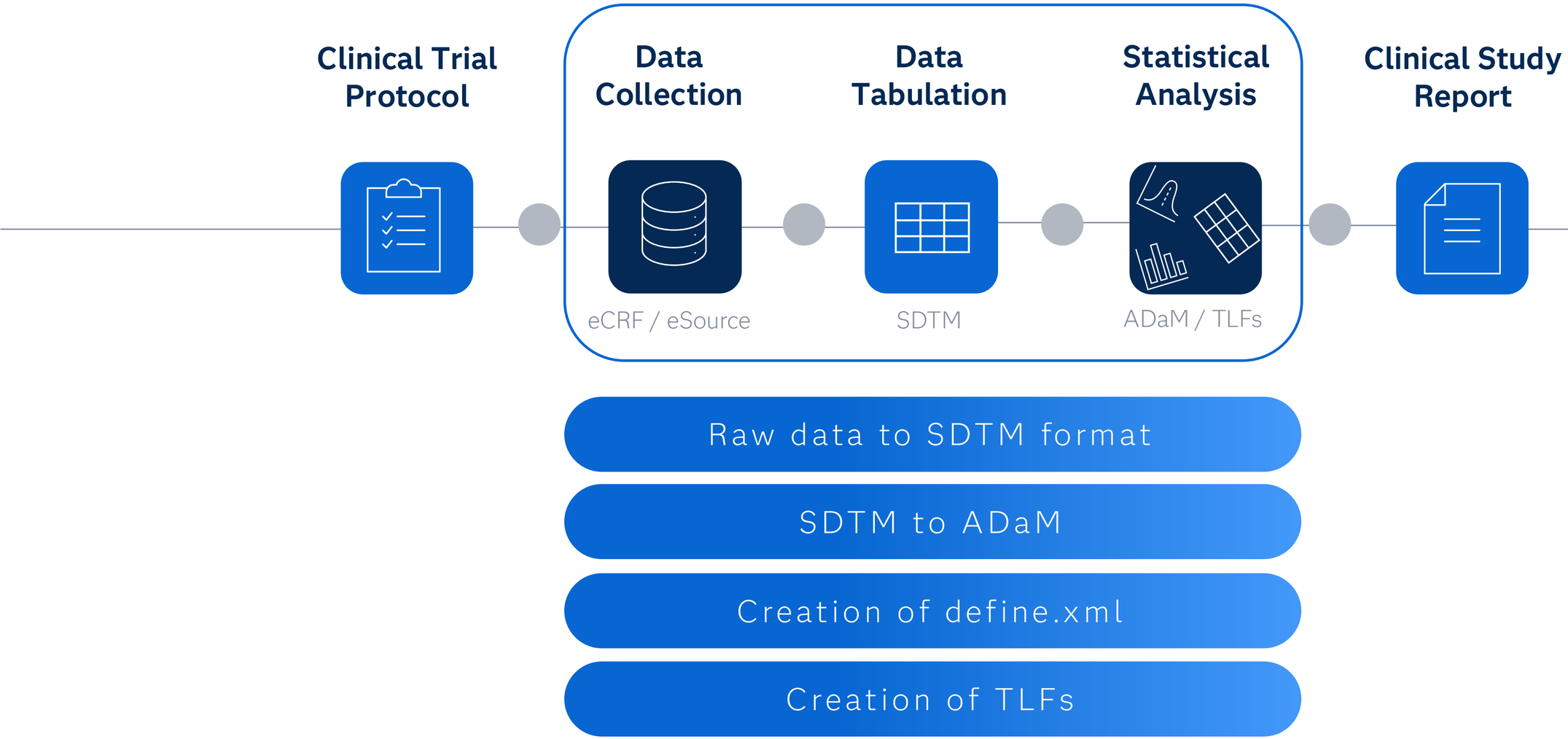
Edit and Export eCRFs

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



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.

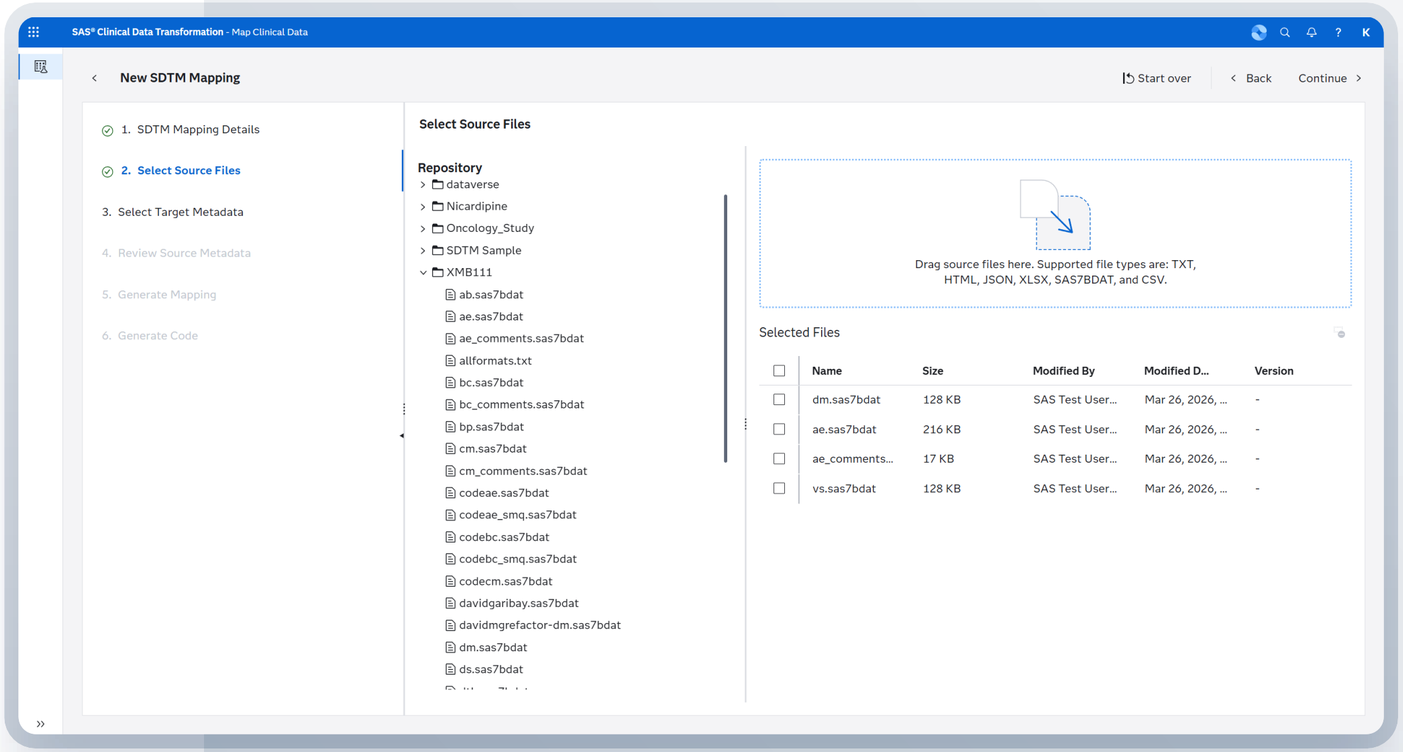
A First Look :
Clinical Data Transformation

Clinical Data Transformation

Raw to SDTM

01

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

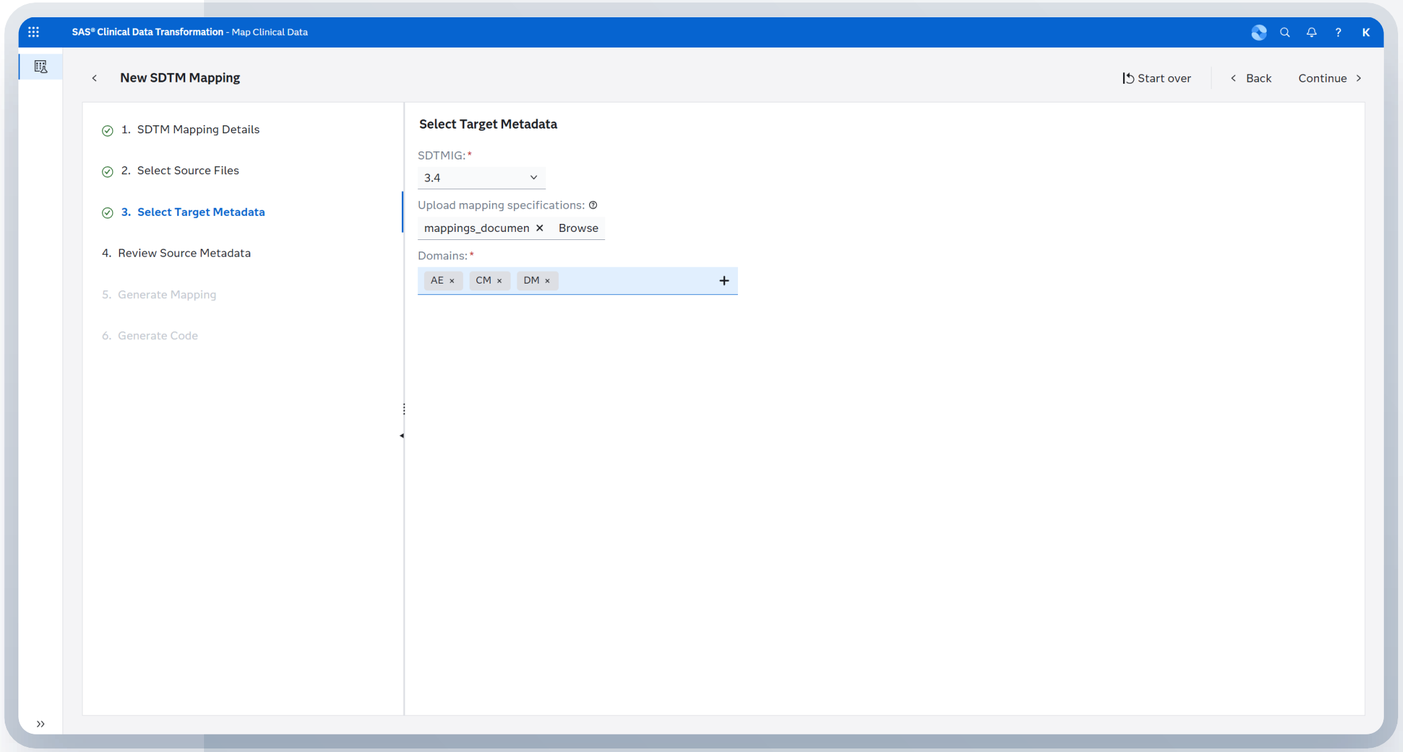


Clinical Data Transformation

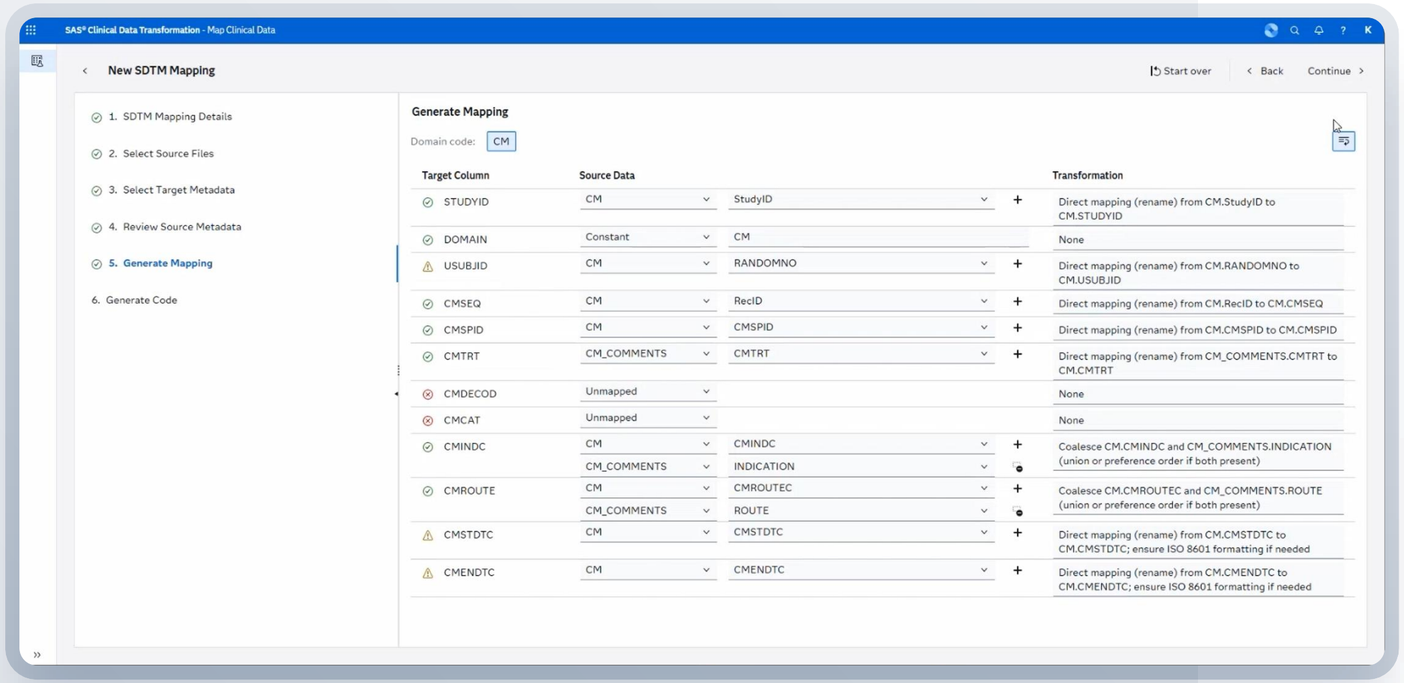
Raw to SDTM

02

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



Raw to SDTM

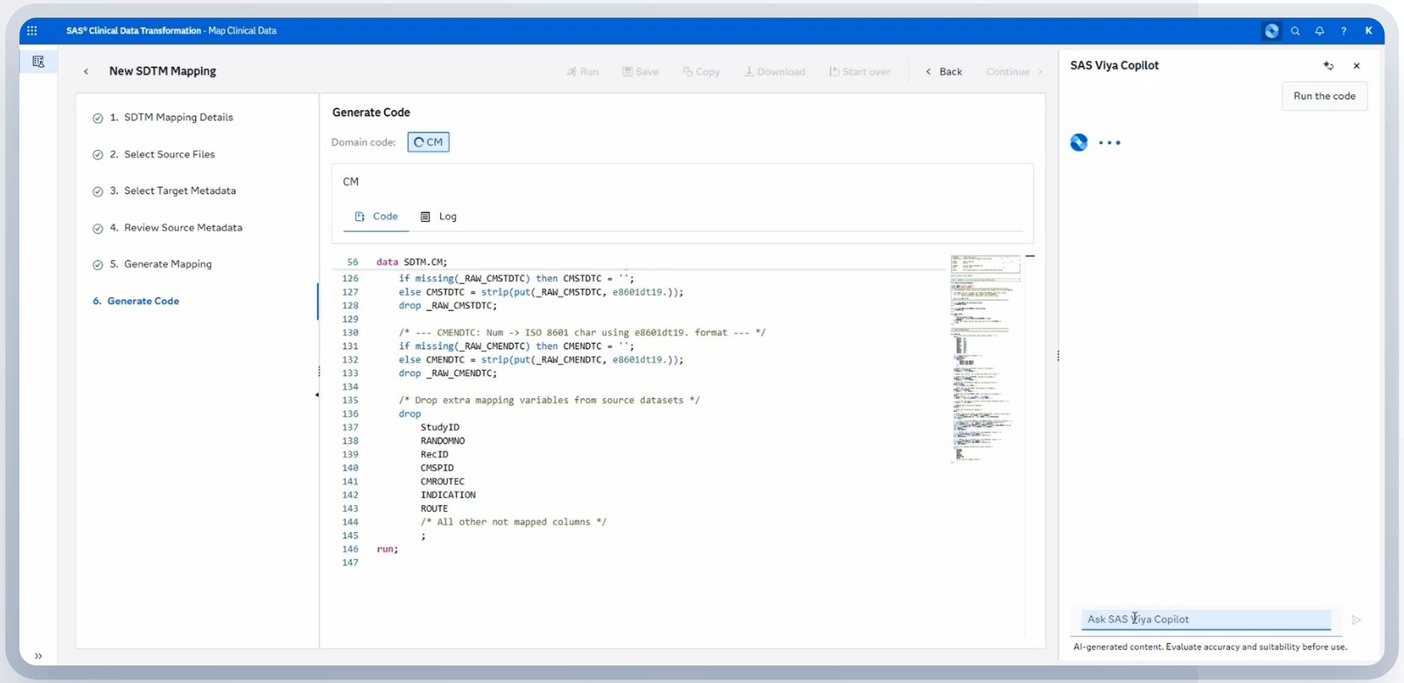


Clinical Data Transformation

03

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

Raw to SDTM

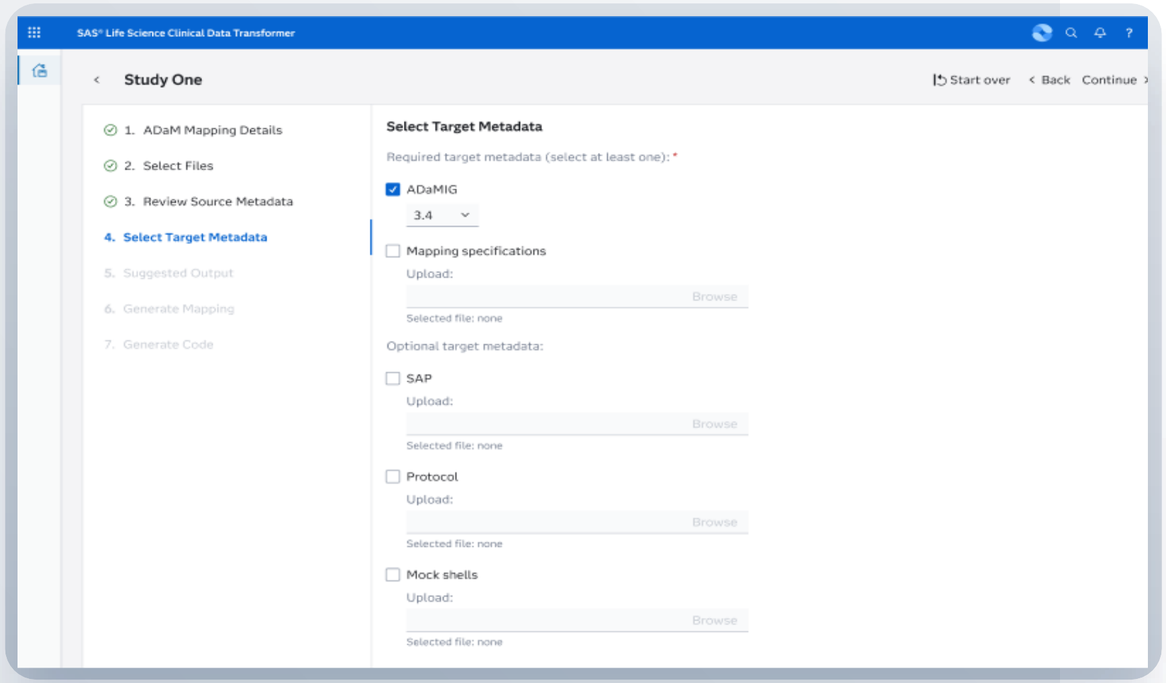


Clinical Data Transformation

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

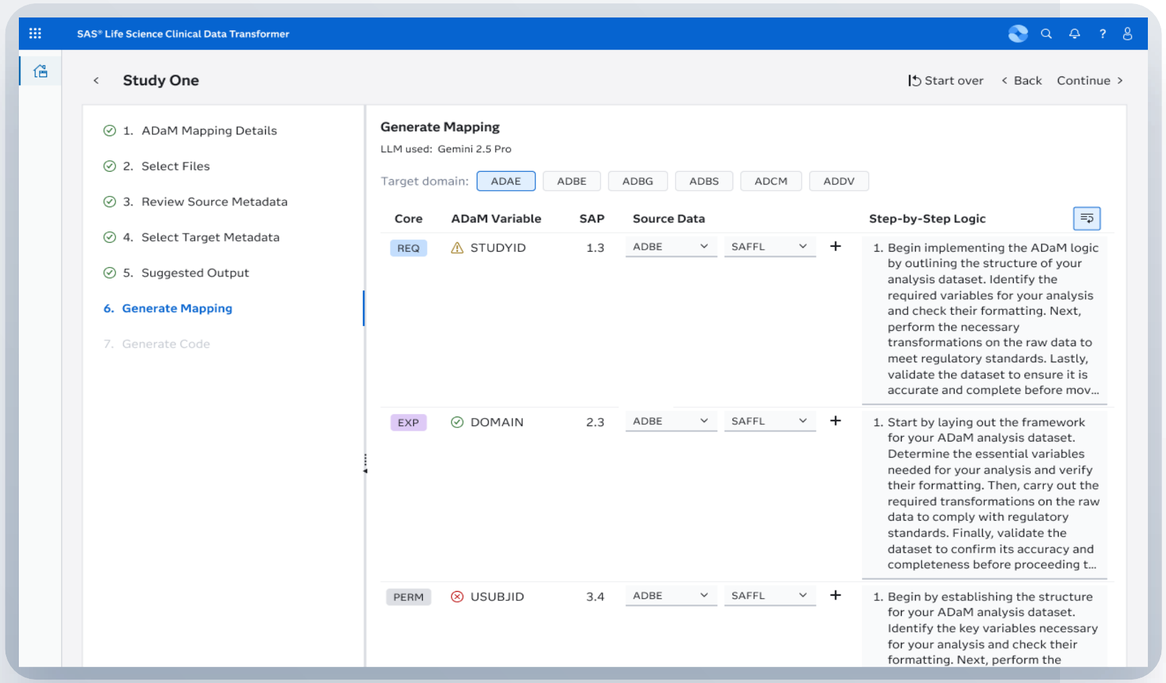


Clinical Data Transformation

05

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

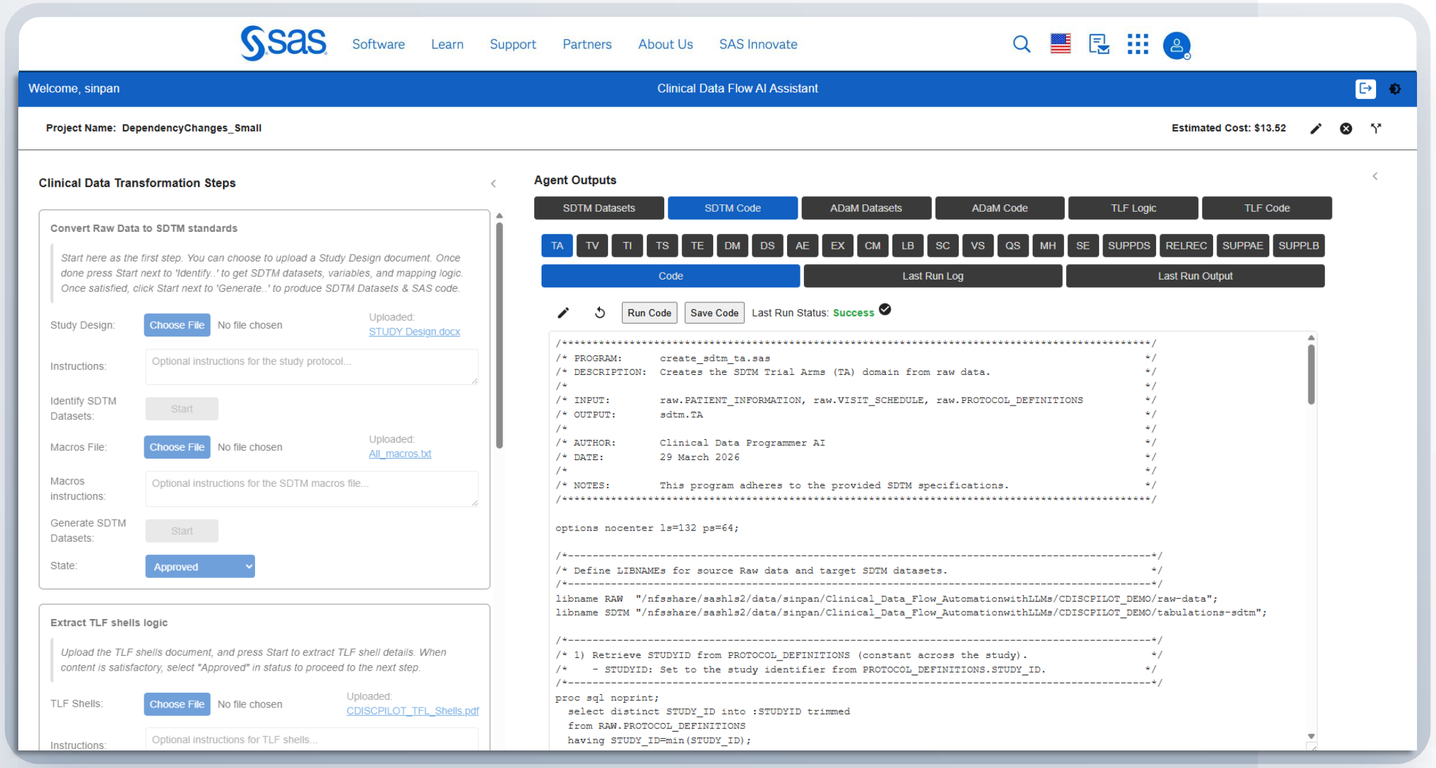
SDTM to ADaM



Clinical Data Transformation

06

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

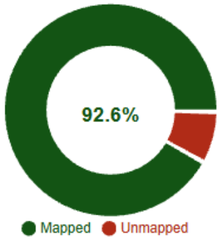


Clinical Data Flow Prototype

CDF App – Traceability and Data Coverage Reports

Data Mapping Analysis

Overall Raw Data Coverage



Total Variables: 149

Raw Dataset Mapping Details

Dataset	Total Vars	Mapped	Unmapped
ADVERSE_EVENTS	23	23	0
CONCOMITANT_MEDICATIONS	11	11	0
DRUG_ADMINISTRATION	9	9	0
INCLUSION_EXCLUSION	3	0	3
LABORATORY_RESULTS	18	18	0
MEDICAL_HISTORY	6	6	0
PATIENT_DISPOSITION	8	7	1
PATIENT_INFORMATION	25	25	0
PROTOCOL_DEFINITIONS	4	4	0
QUESTIONNAIRES	12	12	0
STUDY_SCHEDULE	10	4	6
VISIT_SCHEDULE	9	8	1
VITAL_SIGNS	11	11	0

SDTM Unmapped Variables

Domain	Variables (Rule: Not in Raw)
AE	AEACNDEV, AEACNOTH, AEBDSYCD, AELLTCD, AELOC, AEPATT, AEPTCD, AESOCCD
CM	CMDOSFRM
DM	ACTARMUD
EX	EXADJ, EXCAT, EXSPID, TAETORD

Raw to Data Standards Lineage

Filter Raw Datasets

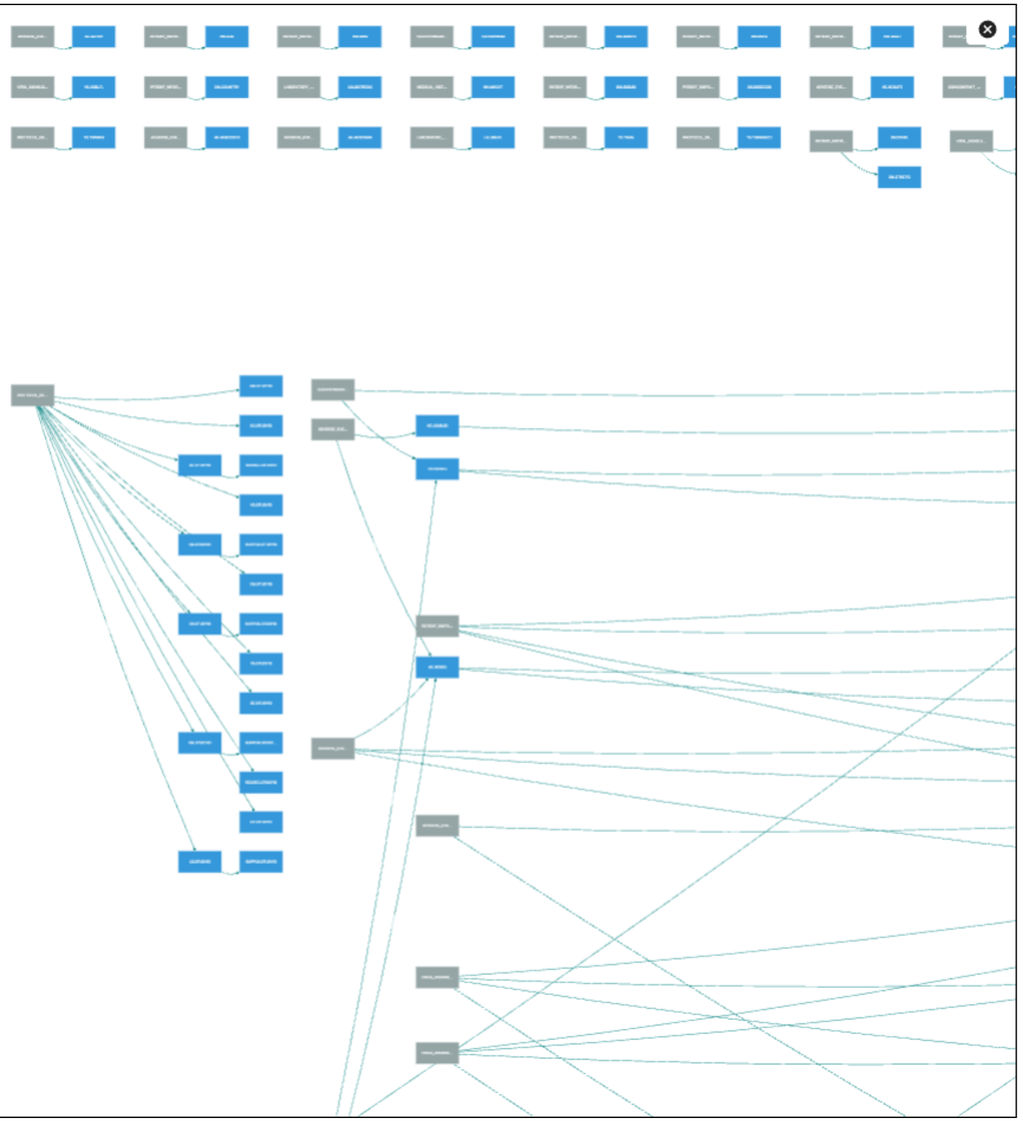
Clear Filter (0 selected)

Filter SDTM Datasets

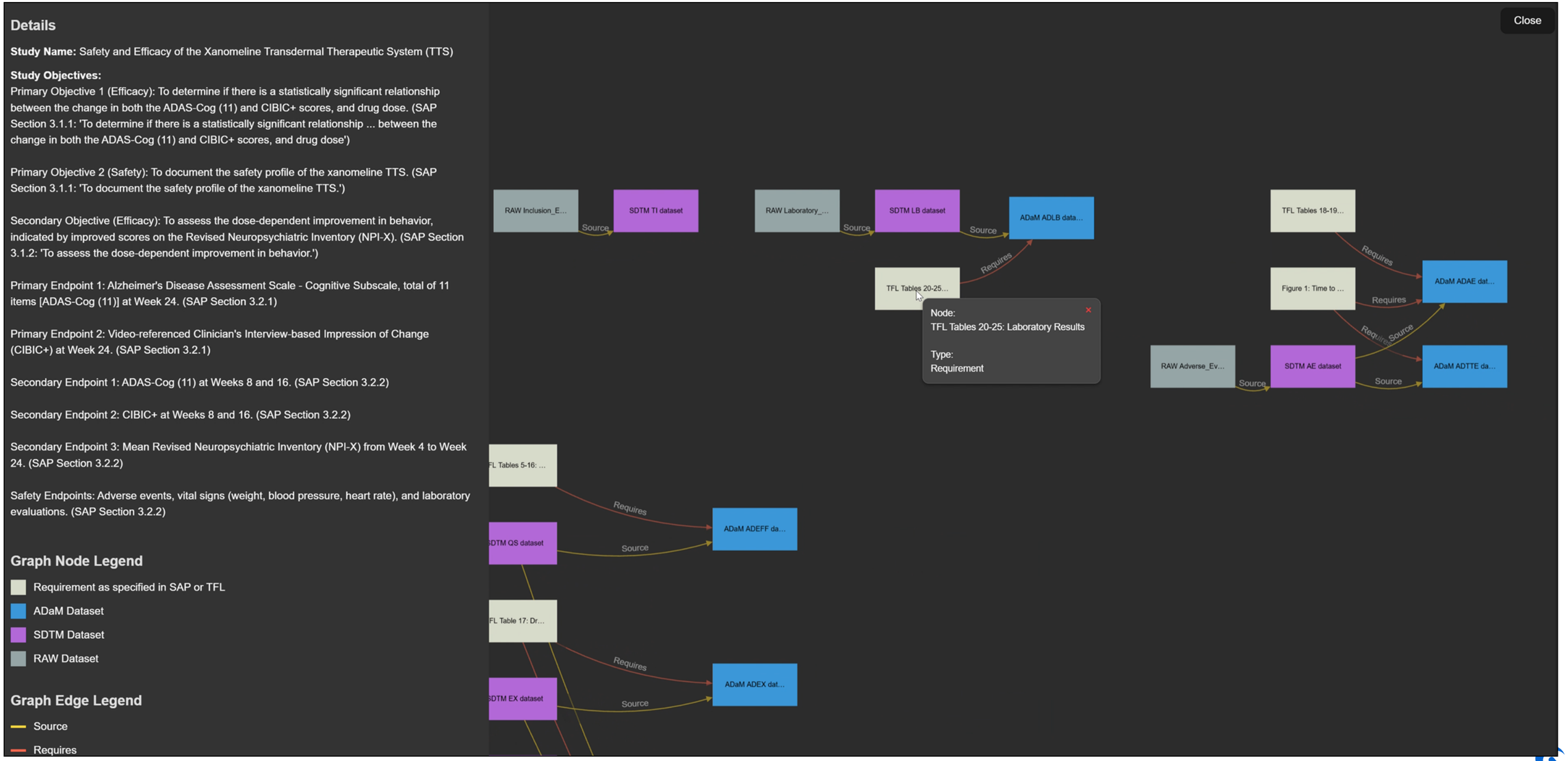
Clear Filter (0 selected)

Graph Legends

- Raw Dataset
- SDTM Dataset



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

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on tour 2026

The data and AI conference

Jetzt registrieren

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Question and Answers

For any questions contact:
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