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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

LLM-powered end-to-end clinical data automation: standardized eCRFs to SDTM, ADaM, and TLF with full traceability

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Speakers

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Solutions Architect
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Agenda

1. Introduction

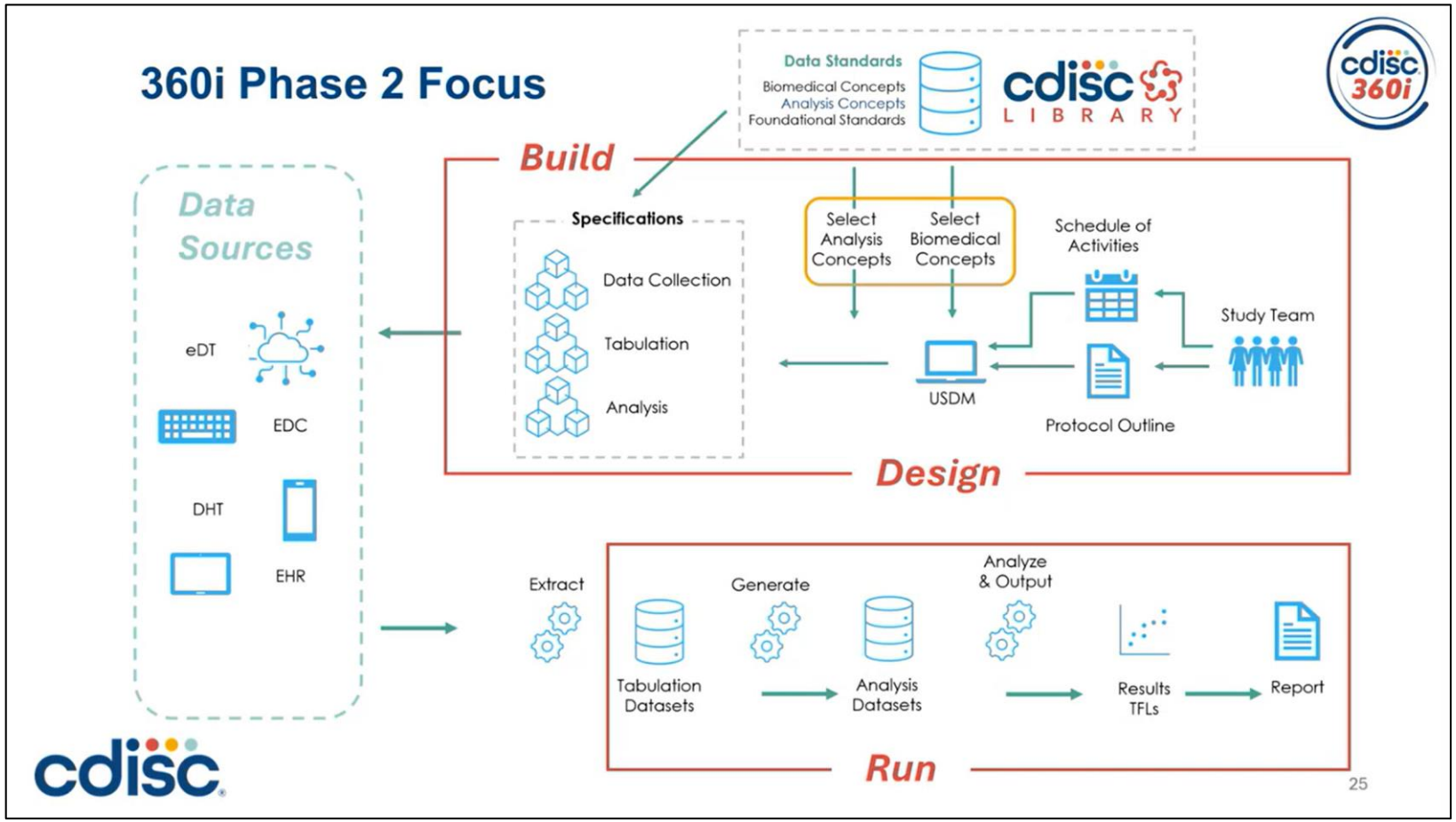
Automation in Clinical Trial workflows

2. Solutions

Generative AI in Clinical Trial workflows

3. Business Impact

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.

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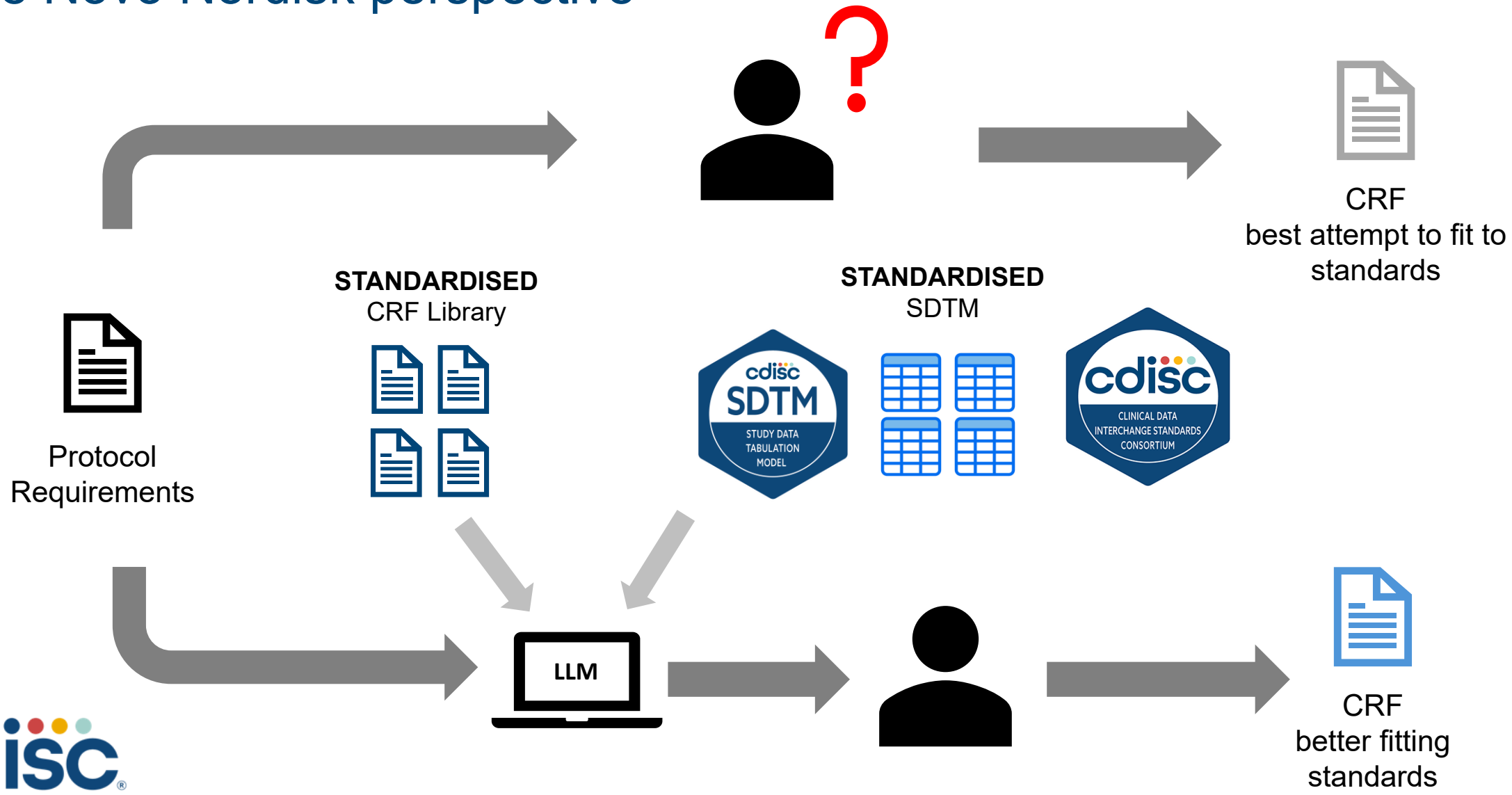
LLM Powered eCRF Builder

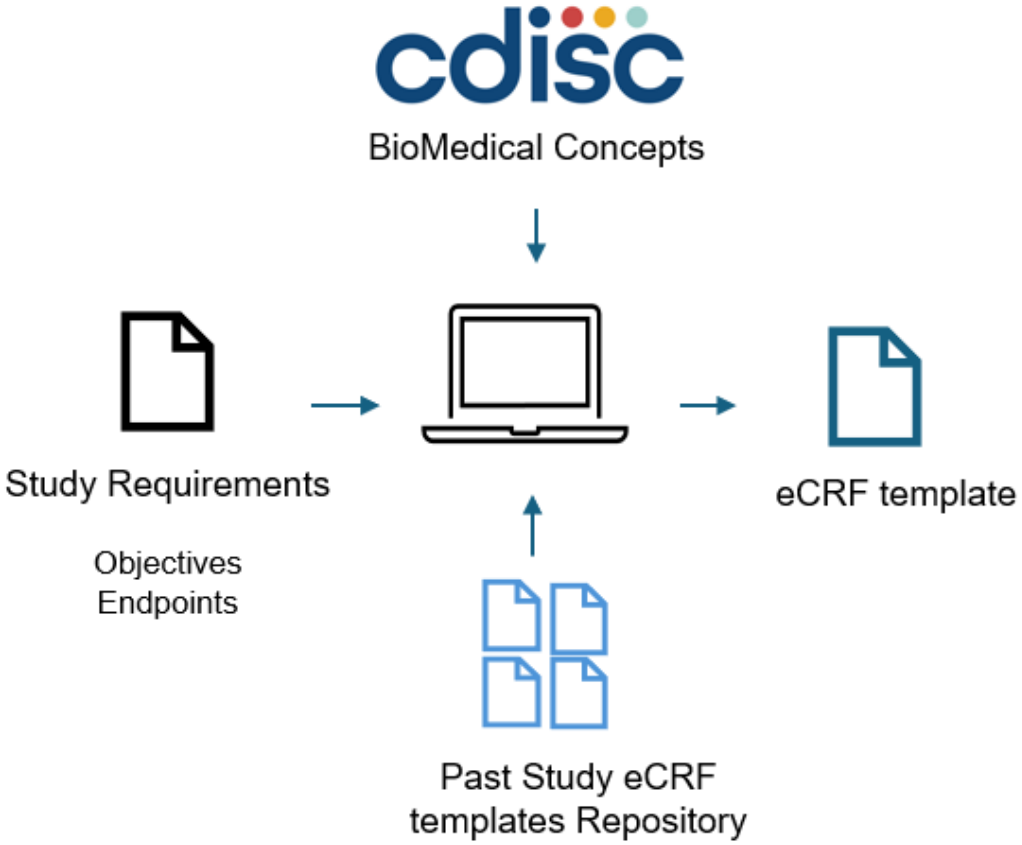
Using eCRF Templates and CDISC BioMedical Concepts Repositories

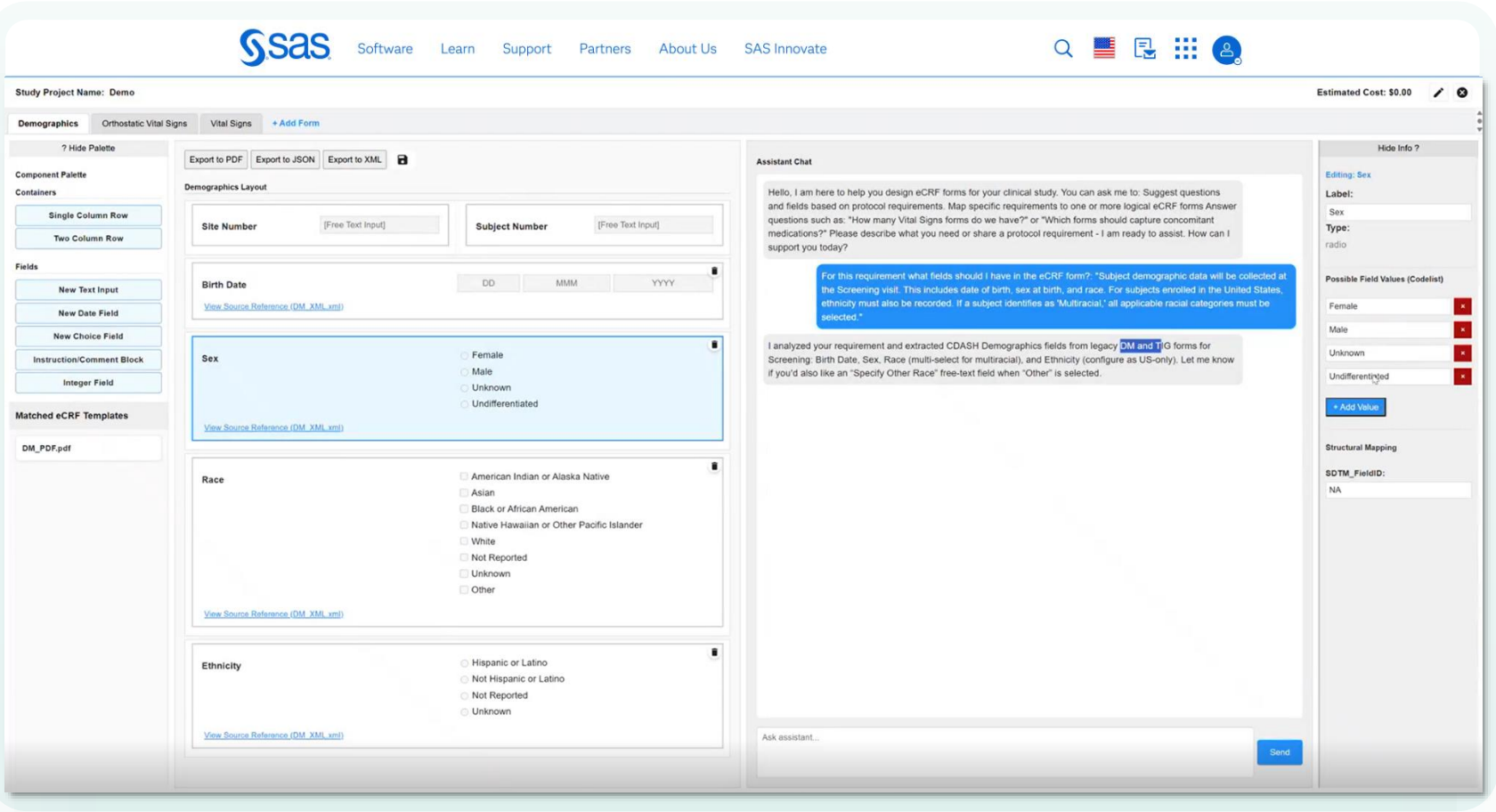
Challenges of standardisation

The Novo Nordisk perspective



AI Assisted eCRF form Creation





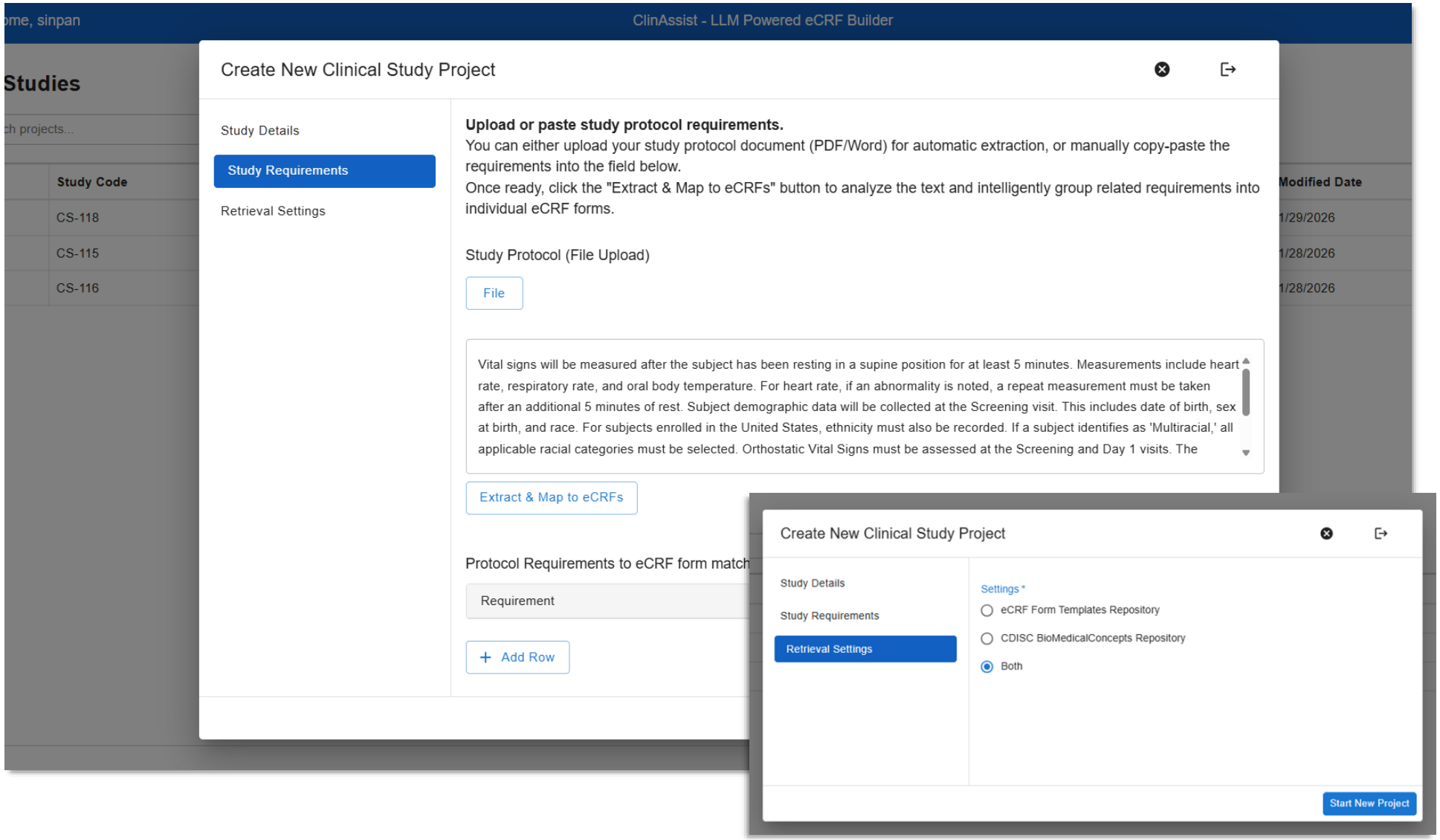
AI Assisted eCRF Creation - Prototype

Clinical Trials eCRF Build Automation

1

Map Requirements to eCRFs

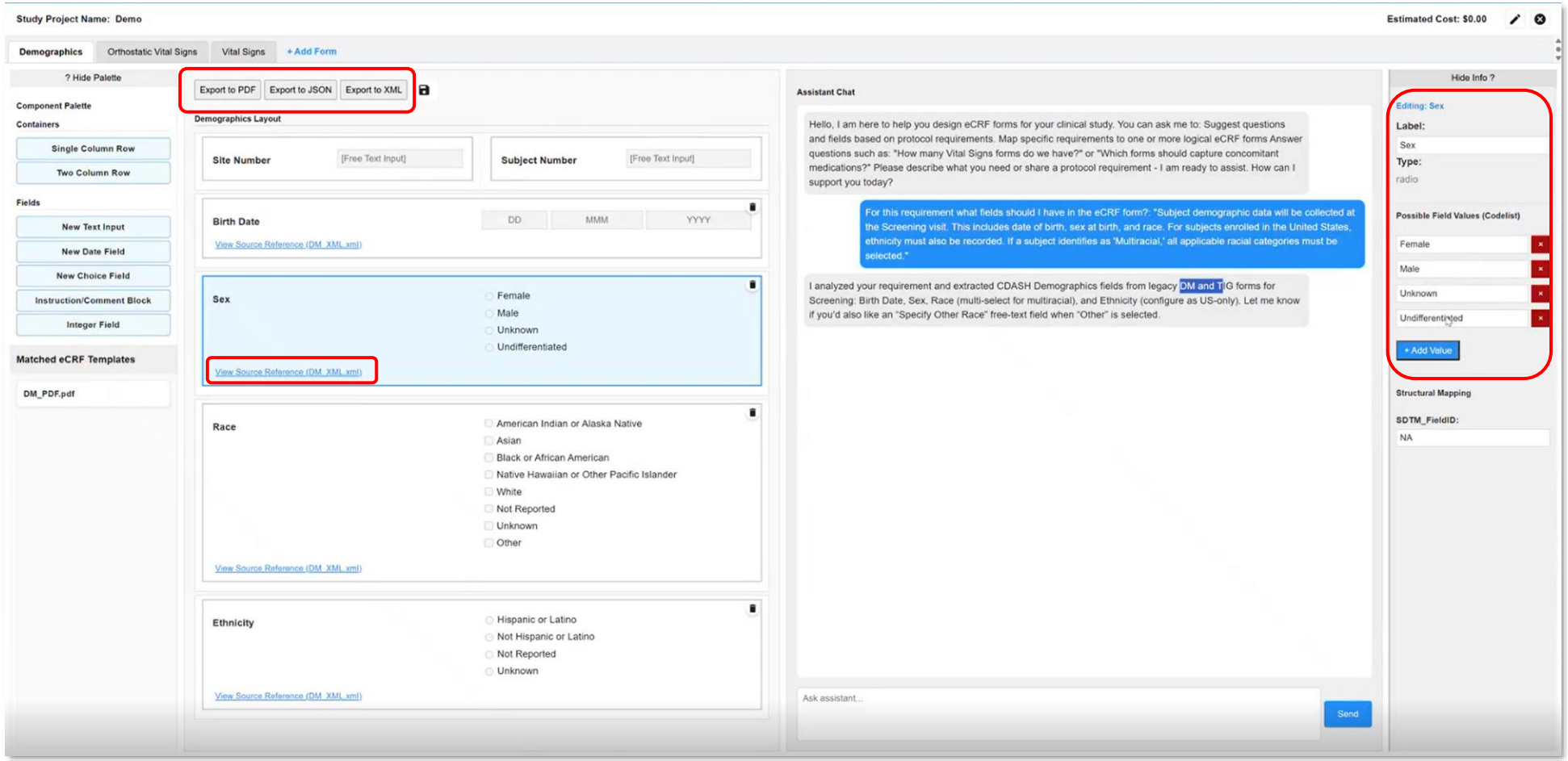
Upload Protocol, other digital documents, OR copy/paste study requirements.



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 Generative AI in Clinical Data Flow

Challenges in Current State of Clinical Trial Biometrics

Complex Clinical trials

- More trials globally
- Intricate data sources
- Traceability requirements

Manual data mapping coding

- Even with CDISC standards
- Time consuming
- Resource intensive

Double Programming

- Repetitive coding tasks
- Impacts submission deadlines

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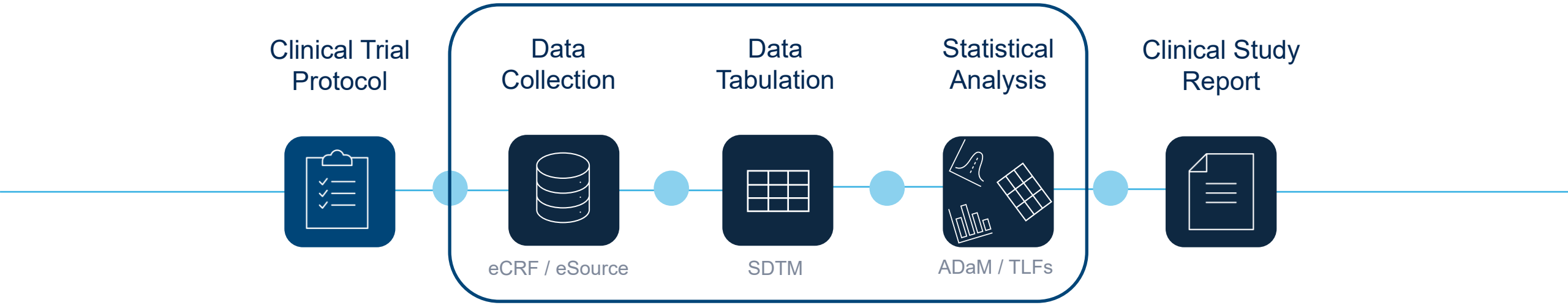
End to End Clinical Data Flow



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

Clinical Data Flow (CDF) Prototype

- Will be part of SAS Clinical Acceleration

Features

Data Mapping

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

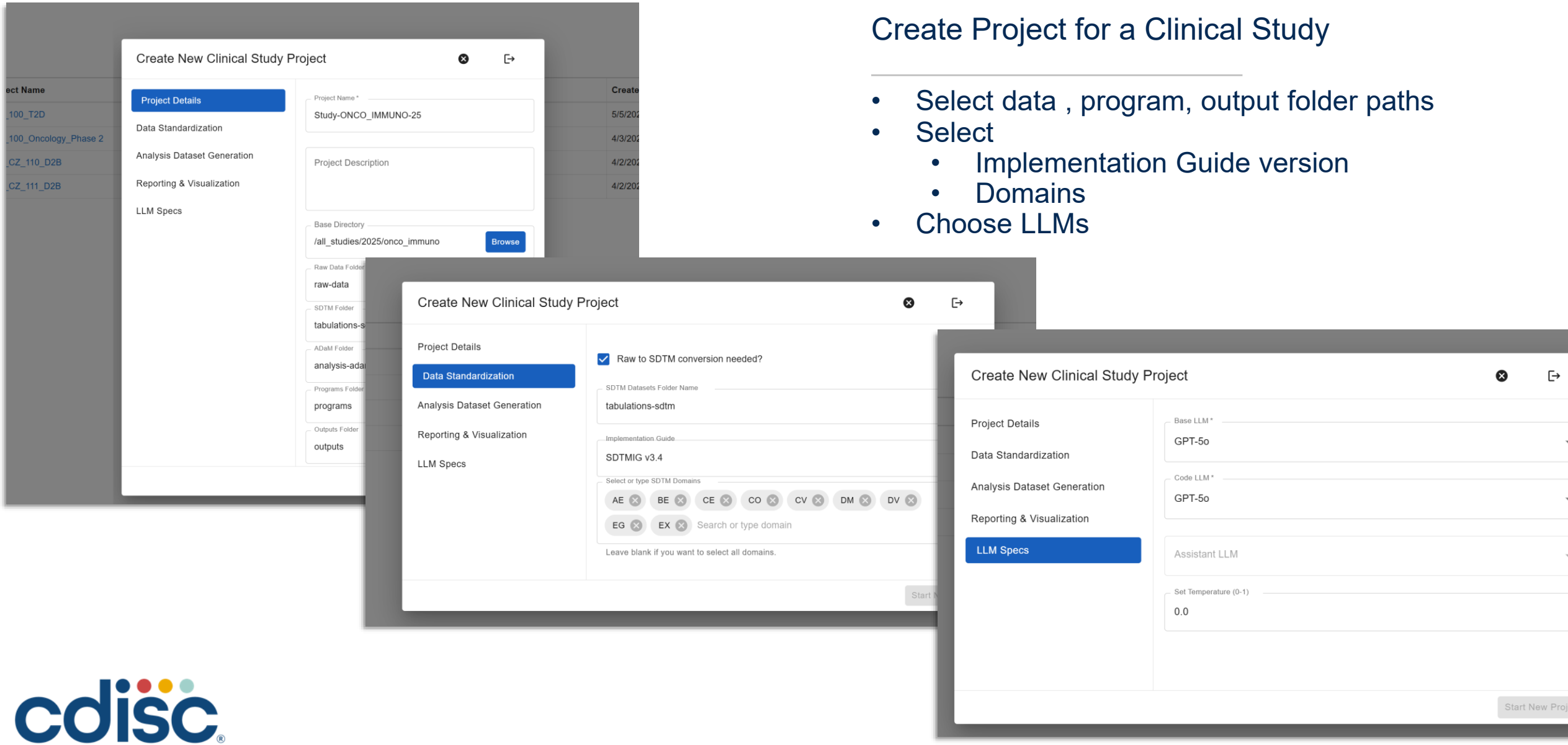
Code Generation

- 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.

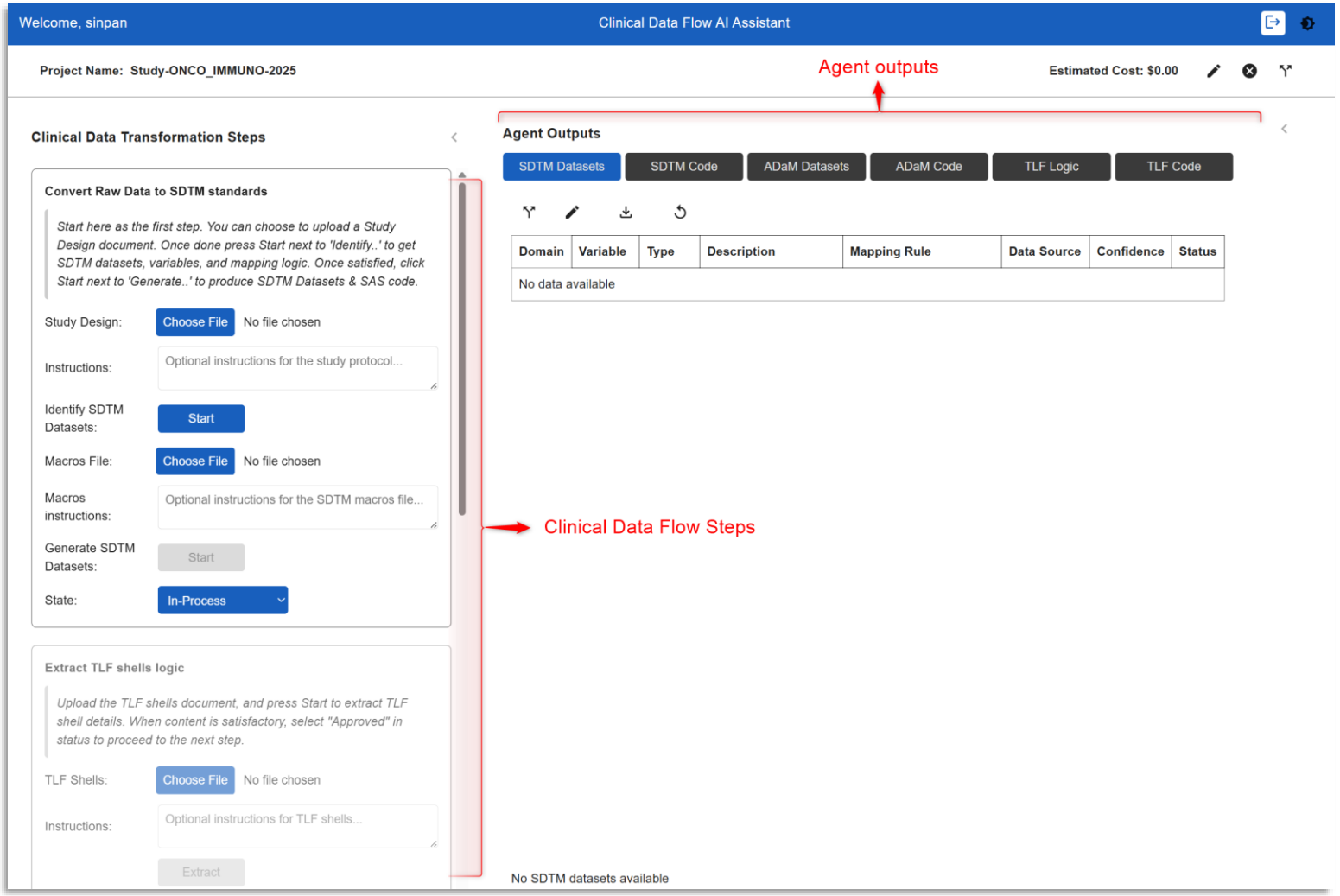
CDF Prototype - Create Project for Study



Create Project for a Clinical Study

- Select data , program, output folder paths
- Select
  - Implementation Guide version
  - Domains
- Choose LLMs

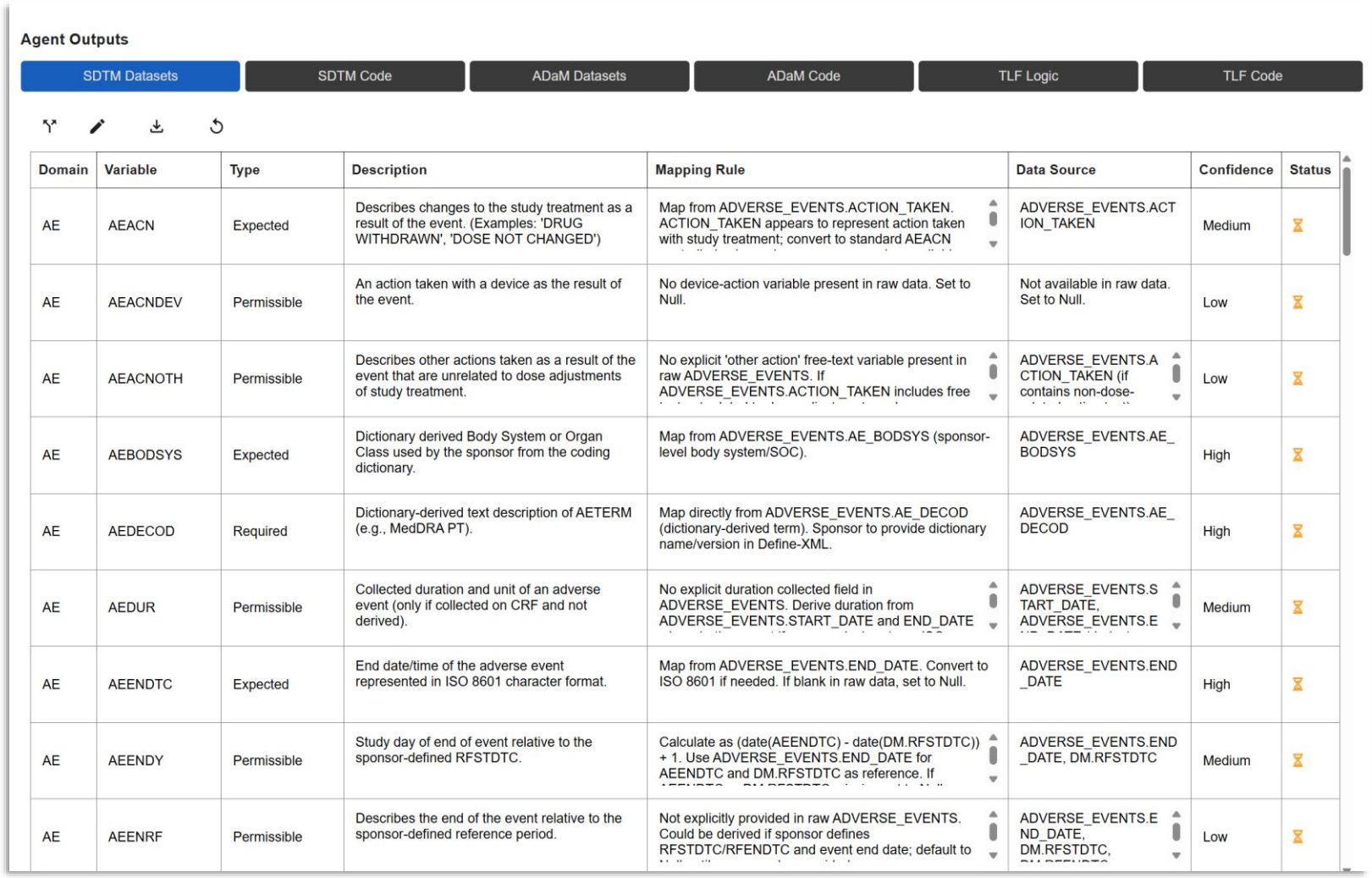
CDF Prototype - Project Details Screen



Project details

- Steps on the Left
- Agent (LLM) outputs on the right

CDF Prototype – SDTM Mapping



Agent Outputs

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

Domain	Variable	Type	Description	Mapping Rule	Data Source	Confidence	Status
AE	AEACN	Expected	Describes changes to the study treatment as a result of the event. (Examples: 'DRUG WITHDRAWN', 'DOSE NOT CHANGED')	Map from ADVERSE_EVENTS.ACTION_TAKEN. ACTION_TAKEN appears to represent action taken with study treatment; convert to standard AEACN	ADVERSE_EVENTS.ACTION_TAKEN	Medium	
AE	AEACNDEV	Permissible	An action taken with a device as the result of the event.	No device-action variable present in raw data. Set to Null.	Not available in raw data. Set to Null.	Low	
AE	AEACNOTH	Permissible	Describes other actions taken as a result of the event that are unrelated to dose adjustments of study treatment.	No explicit 'other action' free-text variable present in raw ADVERSE_EVENTS. If ADVERSE_EVENTS.ACTION_TAKEN includes free	ADVERSE_EVENTS.ACTION_TAKEN (if contains non-dose-	Low	
AE	AEBODSYS	Expected	Dictionary derived Body System or Organ Class used by the sponsor from the coding dictionary.	Map from ADVERSE_EVENTS.AE_BODSYS (sponsor-level body system/SOC).	ADVERSE_EVENTS.AE_BODSYS	High	
AE	AEDECOD	Required	Dictionary-derived text description of AETERM (e.g., MedDRA PT).	Map directly from ADVERSE_EVENTS.AE_DECOD (dictionary-derived term). Sponsor to provide dictionary name/version in Define-XML.	ADVERSE_EVENTS.AE_DECOD	High	
AE	AEDUR	Permissible	Collected duration and unit of an adverse event (only if collected on CRF and not derived).	No explicit duration collected field in ADVERSE_EVENTS. Derive duration from ADVERSE_EVENTS.START_DATE and END_DATE	ADVERSE_EVENTS.START_DATE, ADVERSE_EVENTS.E	Medium	
AE	AEENDTC	Expected	End date/time of the adverse event represented in ISO 8601 character format.	Map from ADVERSE_EVENTS.END_DATE. Convert to ISO 8601 if needed. If blank in raw data, set to Null.	ADVERSE_EVENTS.END_DATE	High	
AE	AEENDY	Permissible	Study day of end of event relative to the sponsor-defined RFSTDTC.	Calculate as (date(AEENDTC) - date(DM.RFSTDTC)) + 1. Use ADVERSE_EVENTS.END_DATE for AEENDTC and DM.RFSTDTC as reference. If	ADVERSE_EVENTS.END_DATE, DM.RFSTDTC	Medium	
AE	AEENRF	Permissible	Describes the end of the event relative to the sponsor-defined reference period.	Not explicitly provided in raw ADVERSE_EVENTS. Could be derived if sponsor defines RFSTDTC/RFENDTC and event end date; default to	ADVERSE_EVENTS.END_DATE, DM.RFSTDTC,	Low	

SDTM Mappings

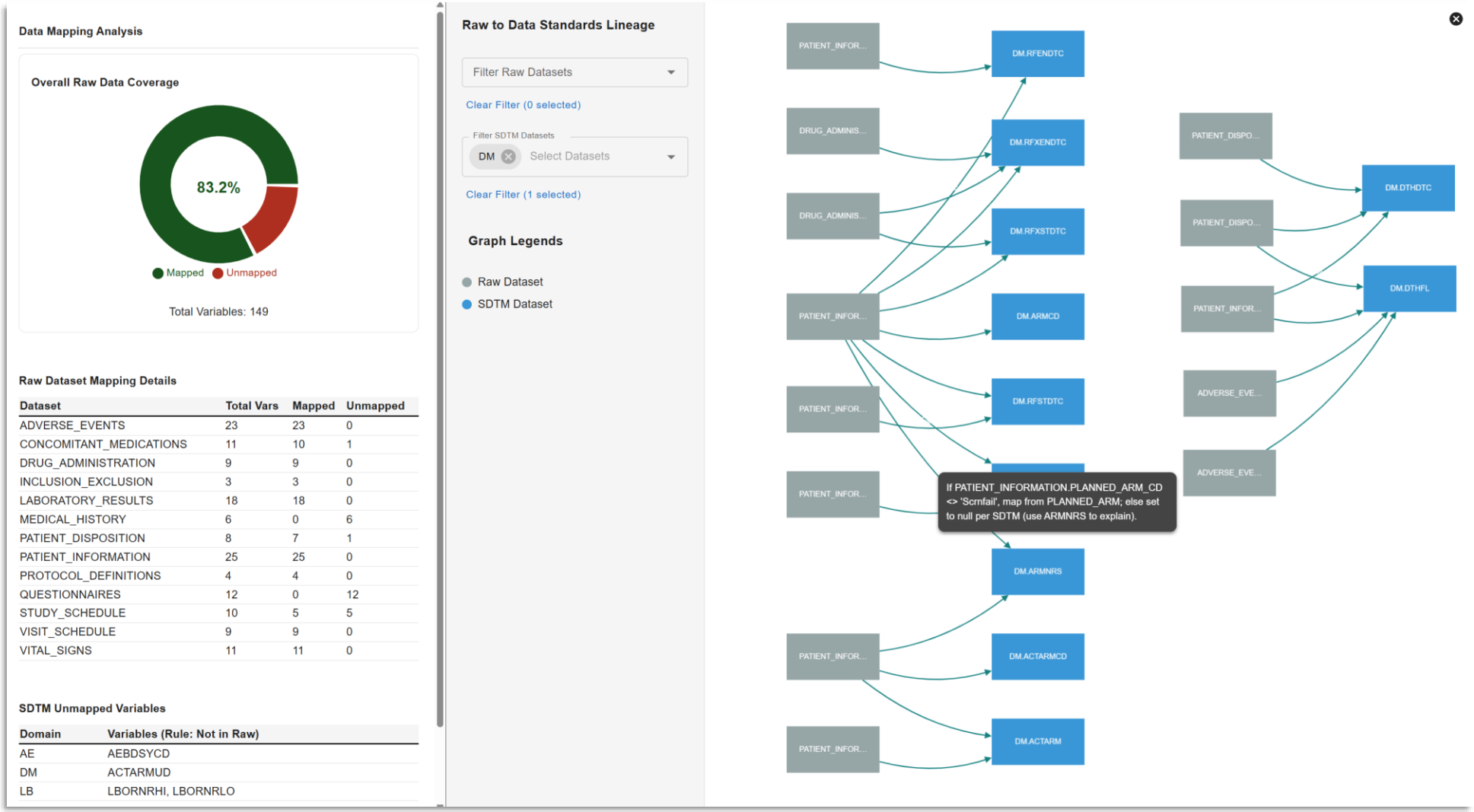
Inputs:

- Raw Data Schema
- Study Design Documents
- SDTMIG/Custom

Outputs:

- Editable Field Level mappings

CDF prototype - Traceability and Data Coverage



Lineage View

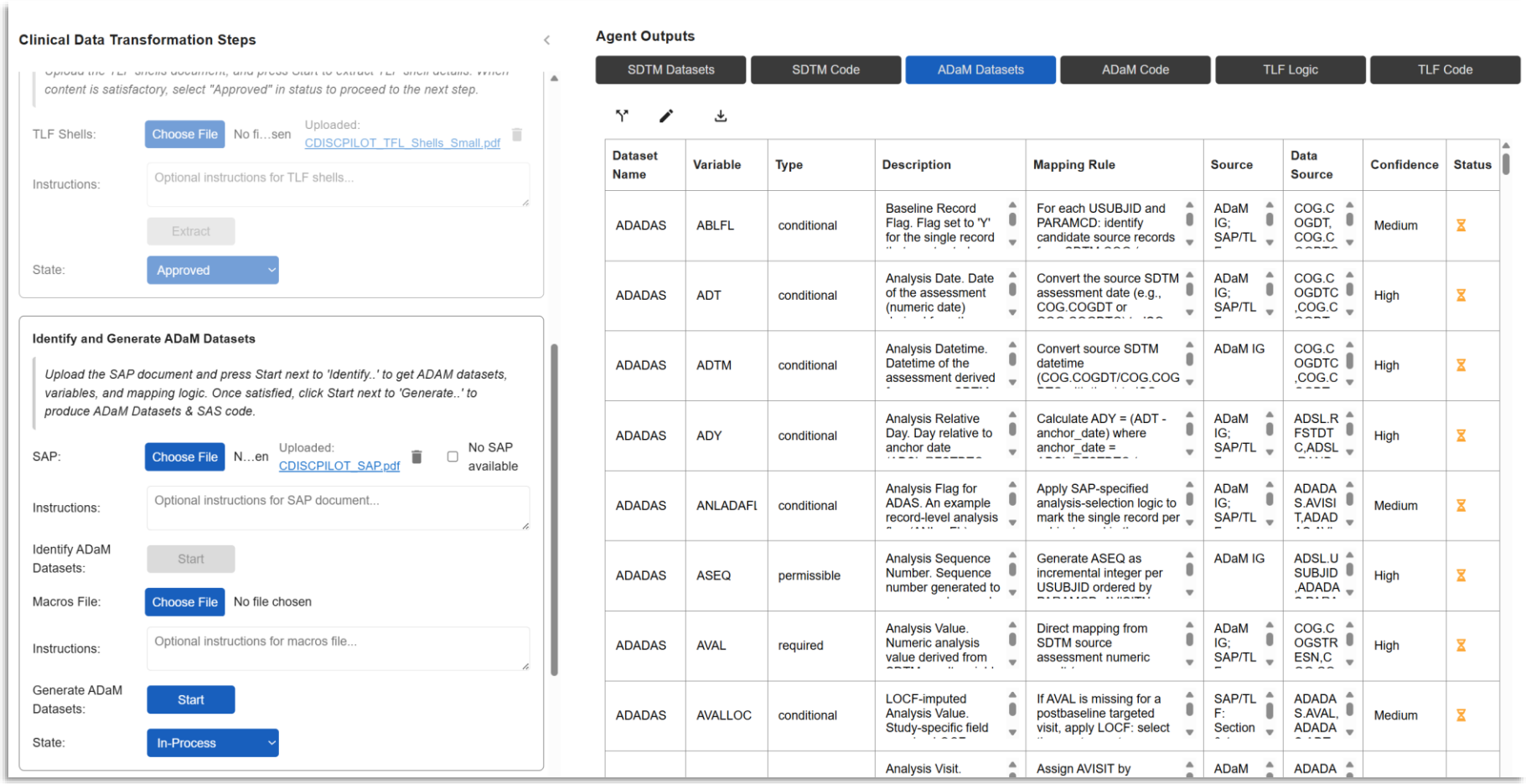
- Raw Data coverage reports.
- Variables with missing mappings.
- Graph view to track lineage.

CDF prototype – SDTM Code

SDTM Code

- Code generated with error feedback loop.
- Edit, re-generate, re-run code form this screen.

CDF prototype – ADaM Mappings



ADaM Mappings

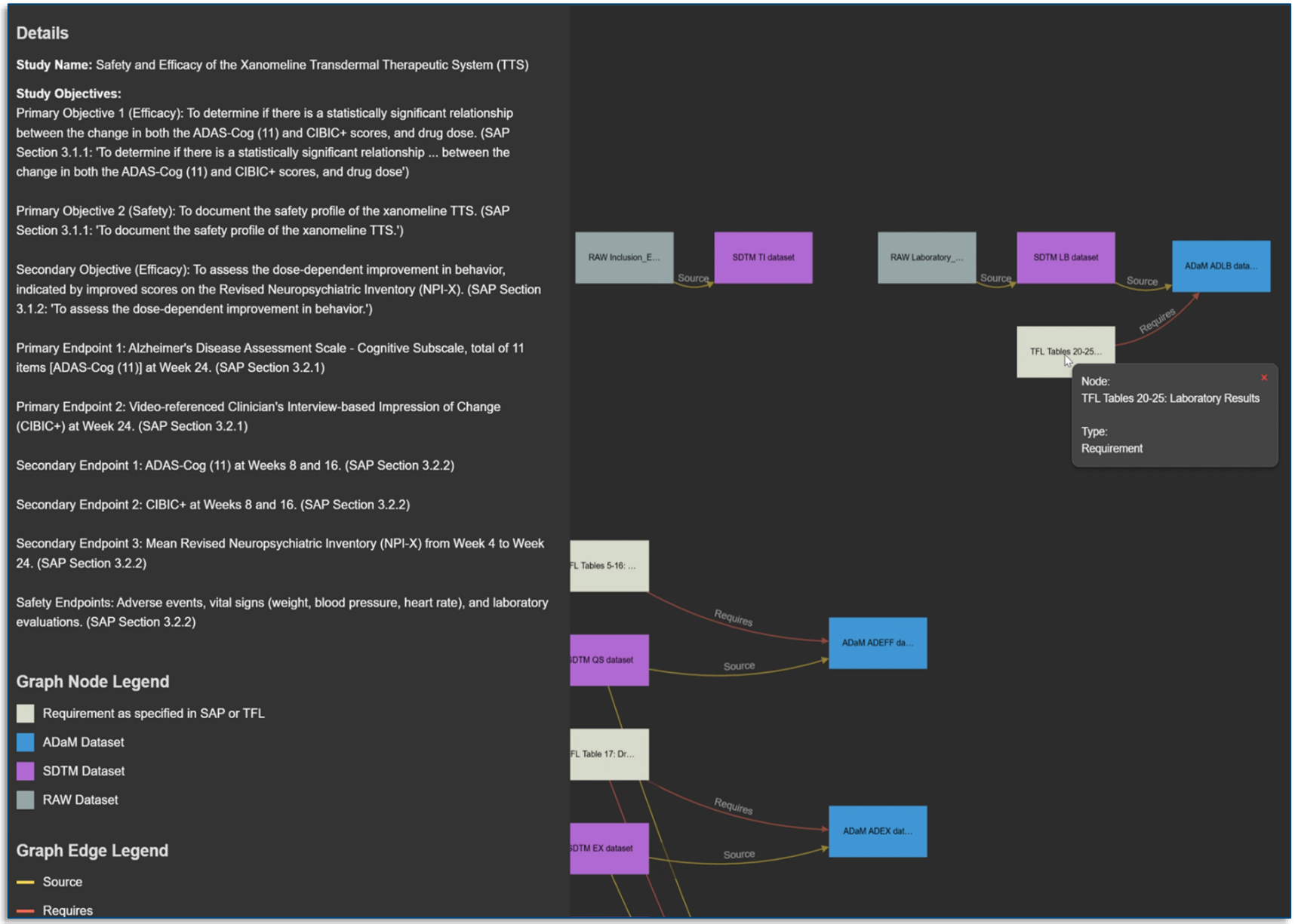
Inputs:

- TLF Shells Logic
- SAP
- SDTM datasets schema

Outputs:

- Editable Field Level mappings

CDF prototype - End to end traceability



Tracing SAP/TLFs requirements from Raw data to SDTM and ADaM datasets

Business Impact

Automated mapping & code generation

Faster builds, lower cost

AI AS ASSISTANT

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

COMPRESS TIMELINES

Mapping, SDTM/ADaM, and TLF generation shrink from months to days.

JUMP-START BUT NOT TURNKEY

Automate bulk of the upstream process to create a robust baseline; humans finalize for submission readiness.

REALLOCATE EXPERTISE

Reallocate expertise to high-value work (e.g., complex efficacy datasets), high-level validation, scientific analyses.

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Other AI tools supporting Standards Development in Novo Nordisk

Chatbot with domain knowledge

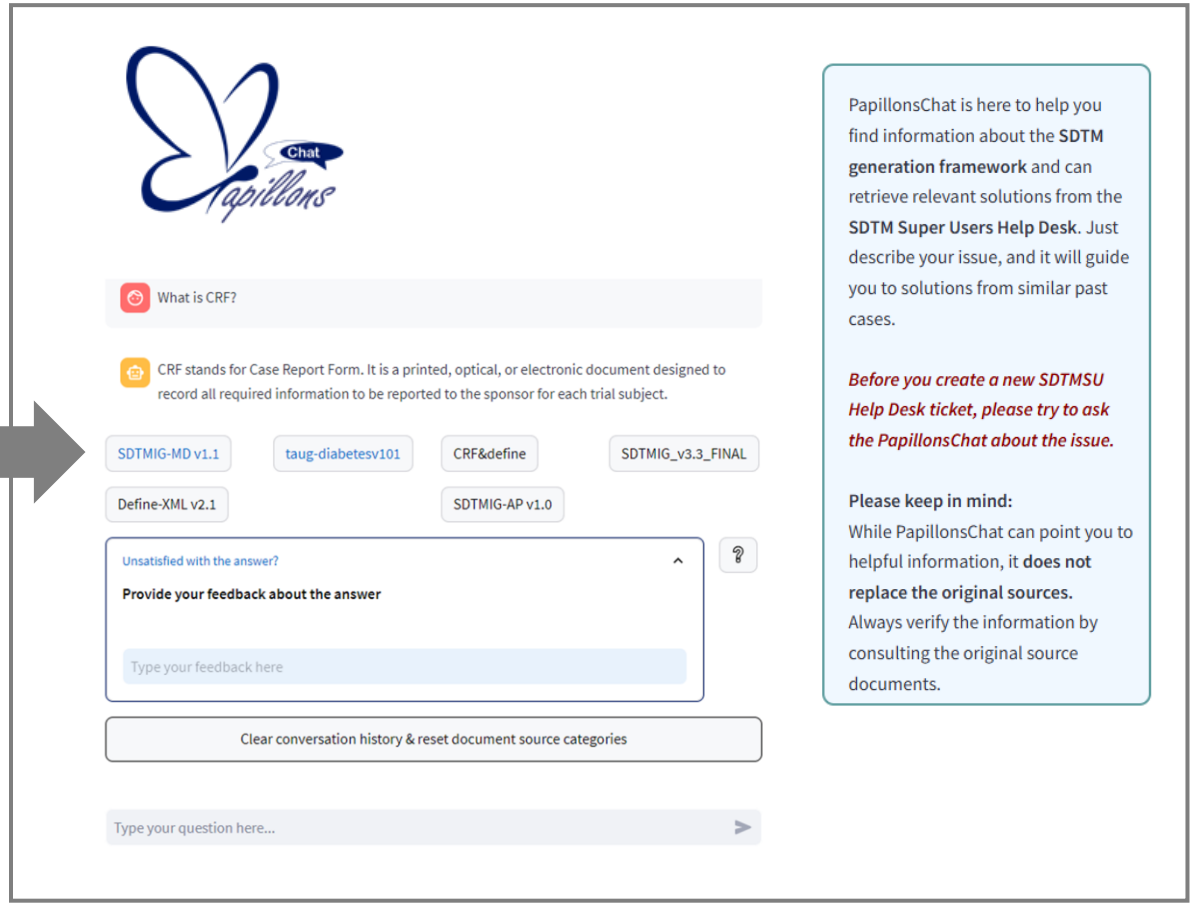
SharePoint lists

Internal documents about SDTM

Programs

SDTM training transcripts

Trusted websites



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