LLM Powered Clinical Data Flow with Traceability - From Siloed Pipelines to a Semantic Fabric

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Matt Becker, Life Sciences Strategic Advisor, SAS

Bio

Pankaj Attri
Pre-Sales Solutions Architect
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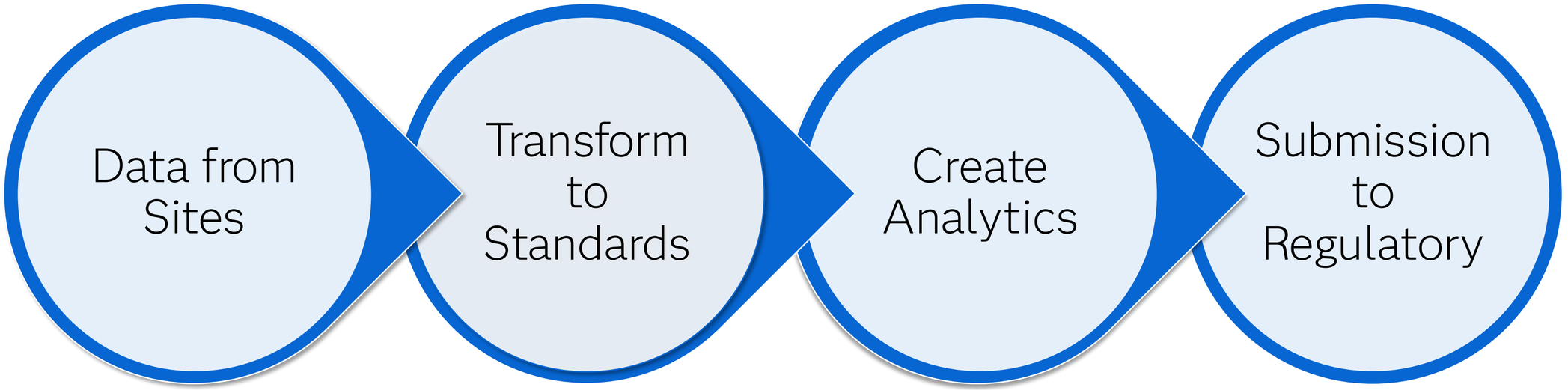
Pankaj Attri is an AI/ML Solutions Architect focused on leveraging advanced data science and artificial intelligence to support customers in the Life Sciences and Healthcare industries at SAS. He partners with these organizations to design and implement state-of-the-art custom solutions that accelerate innovation across research, development, and clinical operations.

Pankaj brings together a background in Chemical Engineering (B.Tech) from IIT Bombay, India and a Master's in Computer Science from NC State University, USA.

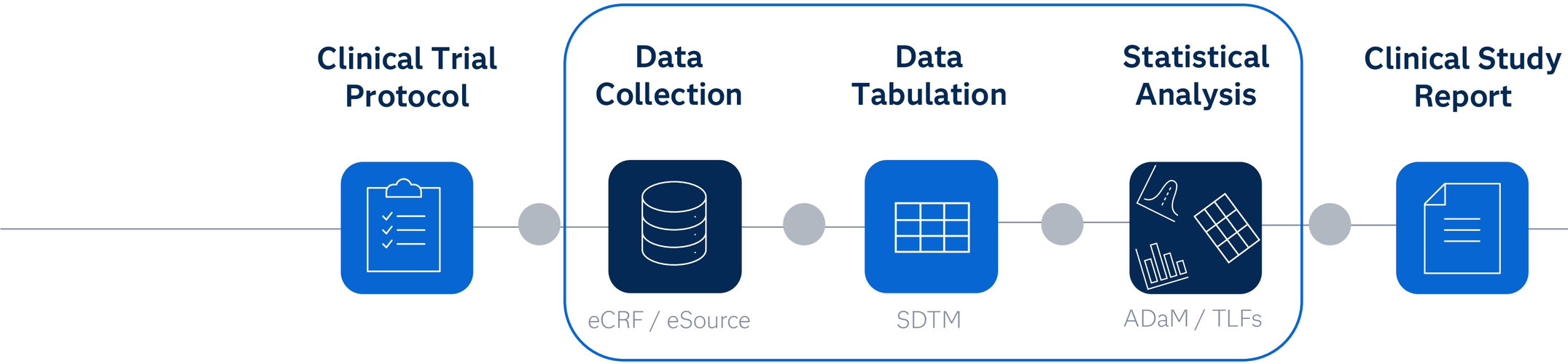
Matt Becker
Life Sciences Strategic Advisor
SAS, Healthcare and Life Sciences Industry Solutions

Matt Becker serves as a Life Science Strategic Advisor within the SAS Health Care and Life Sciences Industry Solutions division. Mr. Becker brings to this role over 35 years of experience in the life sciences, including more than 13 years with SAS. His areas of focus include next-generation clinical trials, clinical analytic platforms, data management, advanced analytics, and deployment options within the Life Science sector.

Clinical Trial Biometrics High Level Data Flow



End to End Clinical Data Flow



Raw data to SDTM format

SDTM to ADaM

ADaM Creation & Validation

Creation of define.xml

Creation of TLFs

Challenges in Current State of Clinical Trial Biometrics

Clinical trials are increasingly complex

- Tighter regulations
- Intricate data sources
- Traceability requirements

Many processes still rely on manual mapping definitions / programming

- Even with target metadata standards

Manual programming can be repetitive, inefficient, and prone to errors

- Double Programming
- Repetitive coding tasks
- Impacts submission deadlines

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

AI Agents and LLMs: Impact on Clinical Programming

- Agentic AI and LLMs augment clinical programmers across the clinical data flow lifecycle.
- Streamline validation cycles by accelerating QC and reducing iterative review overhead.
- Ensure synchronization between data and metadata from ingestion through analysis and outputs.

Goals of the Session

- Present practical strategies for using LLMs to automate mapping and code generation while adhering to CDISC standards to shorten time-to-submission.

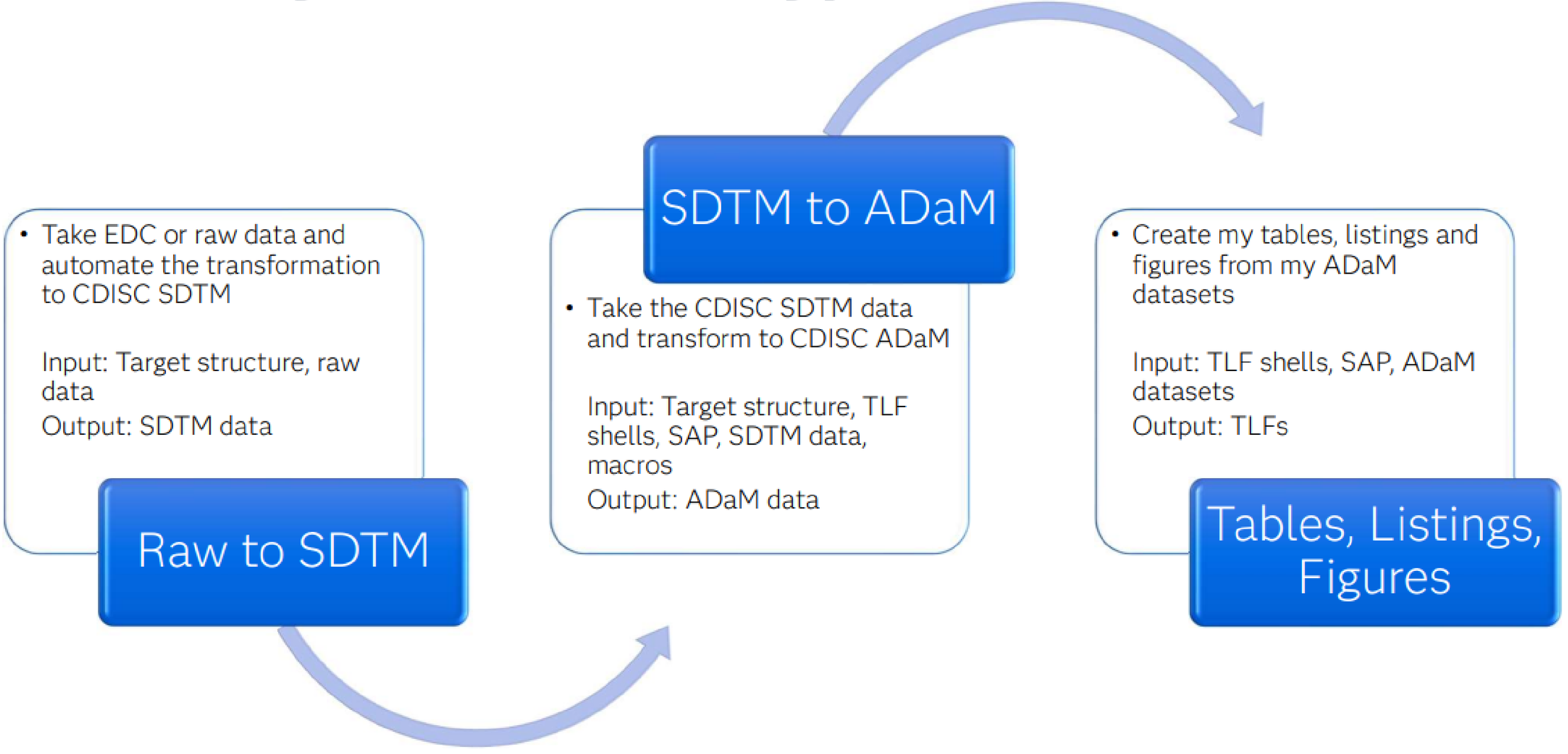
- Show how AI enhances end-to-end traceability and auditability.

- Present a Minimally Viable Prototype for integrating AI into clinical workflows to mitigate regulatory risks and accelerate FDA submission timelines.

Clinical Data Flow (CDF)

Minimum Viable Prototype

Minimally Viable Prototype - Goals



Features

1

Data Mapping

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

2

Code Generation

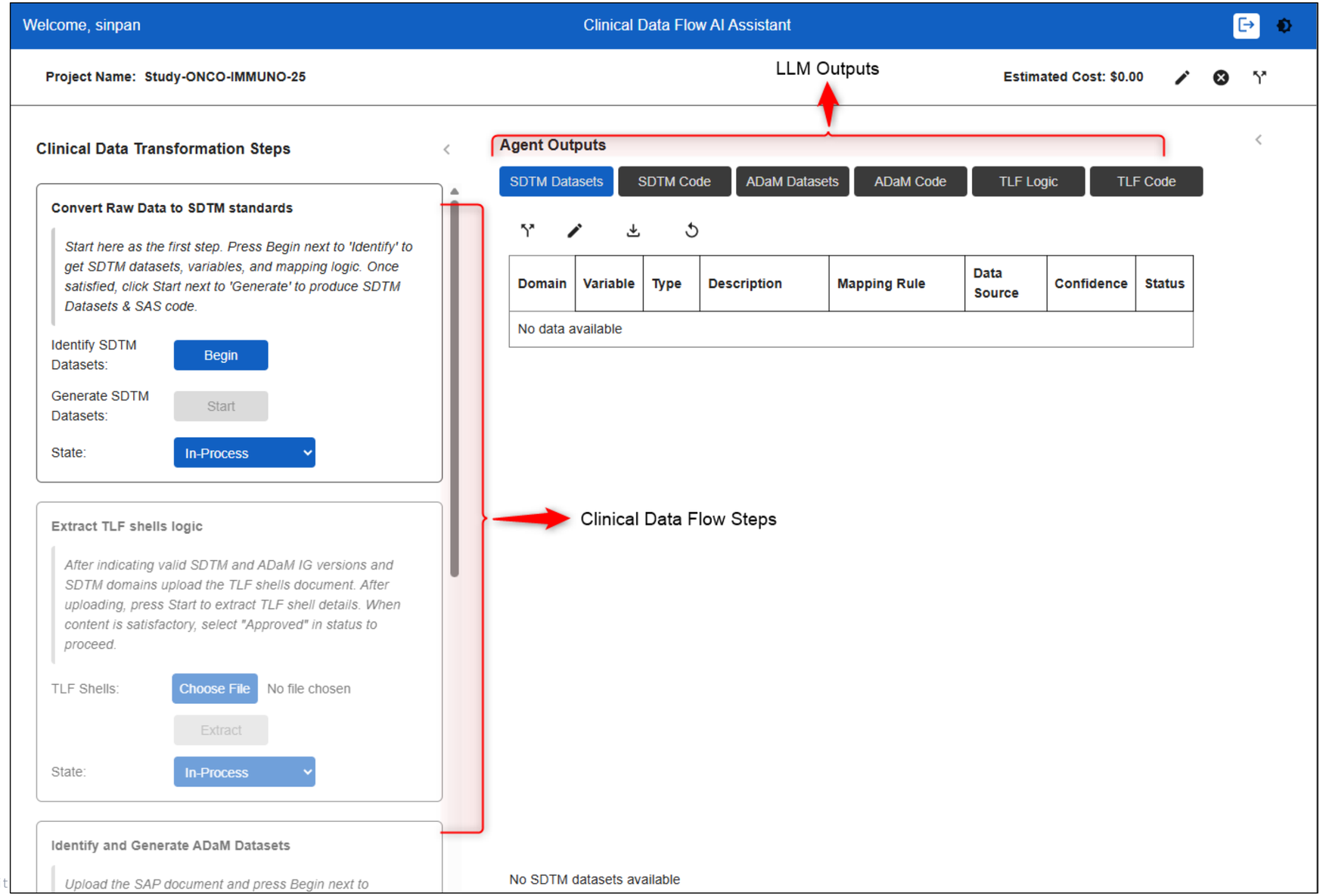
- SAS Code generation with error feedback loop.
- Ensure Cyclic dependencies are taken care of when generating datasets.

3

Traceability

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

1 CDF App –Mapping Rules Generation



1 CDF App –Mapping Rules Generation - SDTM

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 study treatment as a result of the event.	Map from ADVERSE_EVENTS.ACTION_TAKEN; if empty, leave null. If sponsor codelist requires, map site terms to ICH E2B (e.g., 'DOSE NOT CHANGED', 'DRUG WITHDRAWN').	ADVERSE_EVENTS.ACTION_TAKEN	Medium	
AE	AEBDSYCD	Expected	Code for the body system or organ class used by the sponsor.	Not available in raw data. Set to null.		Low	
AE	AEBODSYS	Expected	Body system or organ class used by the sponsor.	Map directly from ADVERSE_EVENTS.AE_BODSYS.	ADVERSE_EVENTS.AE_BODSYS	High	
AE	AEDECOD	Required	Dictionary-derived text description of AETERM (Preferred Term).	Map directly from ADVERSE_EVENTS.AE_DECOD.	ADVERSE_EVENTS.AE_DECOD	High	
AE	AEENDTC	Expected	End date/time of the adverse event in ISO 8601 character format.	Map directly from ADVERSE_EVENTS.END_DATE; may be blank if ongoing or not recorded.	ADVERSE_EVENTS.END_DATE	High	
AE	AEENDY	Permissible	Study day of end of adverse event relative to RFSTDTC.	Derive as AEENDY = (AEENDTC - RFSTDTC) + 1 where RFSTDTC = PATIENT_INFORMATION.FIRST_TREATMENT_DATE; null if AEENDTC missing.	ADVERSE_EVENTS.END_DATE,PATIENT_INFORMATION.FIRST_TREATMENT_DATE	Medium	
AE	AEHLGT	Expected	High Level Group Term.	Map directly from ADVERSE_EVENTS.AE_HLGT.	ADVERSE_EVENTS.AE_HLGT	High	
AE	AEHLGTCD	Expected	Code for the High Level Group Term.	Derive numeric code by extracting digits from ADVERSE_EVENTS.AE_HLGT values like 'HLGT_0192' -> 192.	ADVERSE_EVENTS.AE_HLGT	Medium	

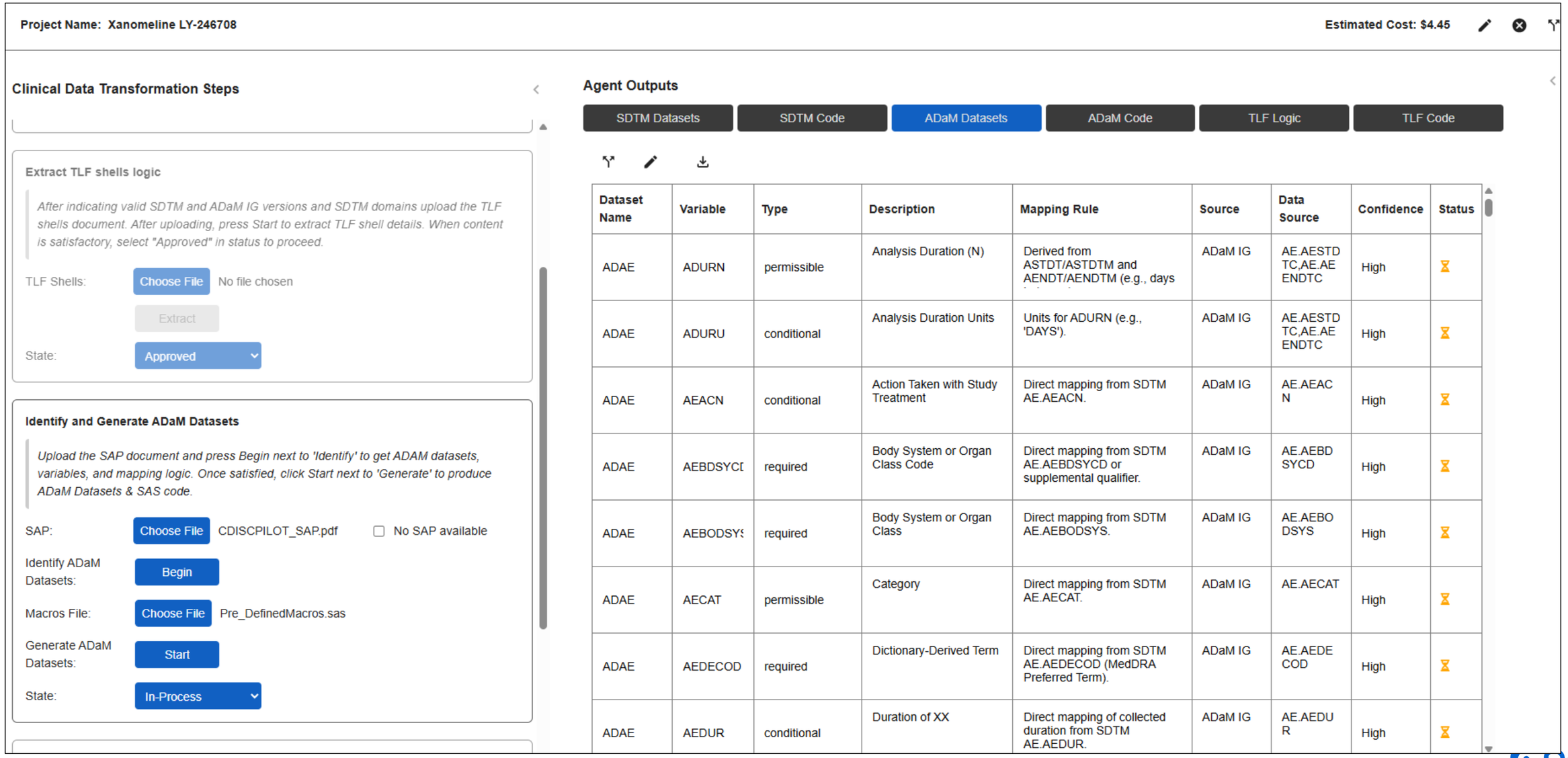
1 CDF App –Mapping Rules Generation - SDTM

Agent Outputs

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

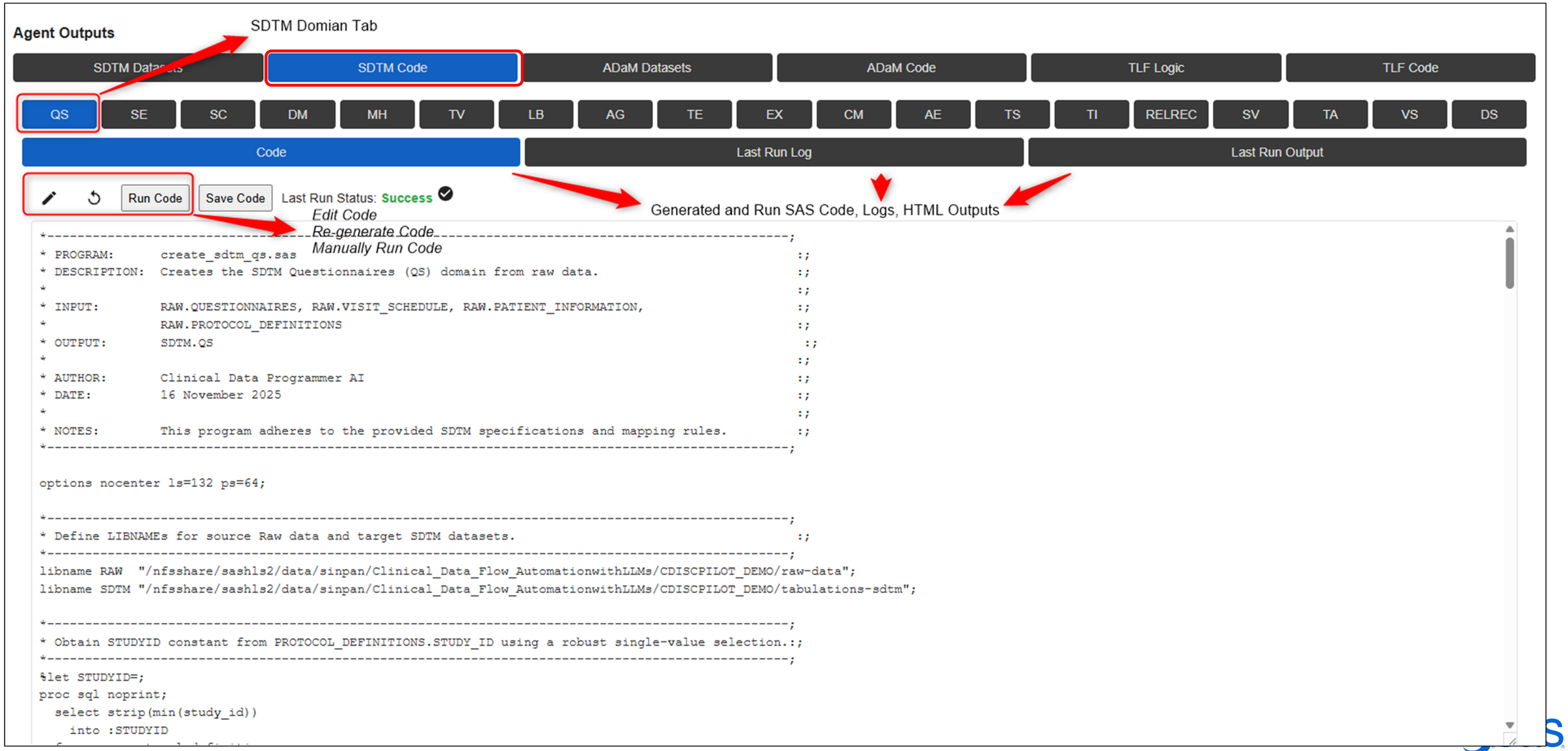
Domain	Variable	Type	Description	Mapping Rule	Data Source	Confidence	Status	Action
SE	USUBJID	Required	studies.		OBJ_ID	High		Delete
SUPPAE	IDVAR	Expected	Identifying Variable	ASSIGN_CONSTANT | [AESEQ]		High		Delete
SUPPAE	IDVARVAL	Expected	Identifying Variable Value	DIRECT_COPY | [AE.AESEQ]	AE.AESEQ	High		Delete
SUPPAE	QEVAL	Expected	Evaluator	ASSIGN_NULL | []		High		Delete
SUPPAE	QLABEL	Required	Qualifier Variable Label	TRANSPOSE_LABEL | [Treatment Emergent Flag]	ADVERSE_EVENTS.TREATMENT_EMERGENT_FL	High		Delete
SUPPAE	QNAM	Required	Qualifier Variable Name	TRANSPOSE_ID | [TRTEMERG<=ADVERSE_EVENTS.TREATMENT_EMERGENT_FL]	ADVERSE_EVENTS.TREATMENT_EMERGENT_FL	High		Delete
SUPPAE	QORIG	Required	Origin	ASSIGN_CONSTANT | [Derived]		Medium		Delete
SUPPAE	QVAL	Required	Qualifier Variable Value	TRANSPOSE_VALUE | [ADVERSE_EVENTS.TREATMENT_EMERGENT_FL]	ADVERSE_EVENTS.TREATMENT_EMERGENT_FL	High		Delete

1 CDF App –Mapping Rules Generation - ADaM



Dataset Name	Variable	Type	Description	Mapping Rule	Source	Data Source	Confidence	Status
ADAE	ADURN	permissible	Analysis Duration (N)	Derived from ASTDT/ASTDTM and AENDT/AENDTM (e.g., days	ADaM IG	AE.AESTDTC,AE.AEENDTC	High	
ADAE	ADURU	conditional	Analysis Duration Units	Units for ADURN (e.g., 'DAYS').	ADaM IG	AE.AESTDTC,AE.AEENDTC	High	
ADAE	AEACN	conditional	Action Taken with Study Treatment	Direct mapping from SDTM AE.AEACN.	ADaM IG	AE.AEACN	High	
ADAE	AEBDSYCI	required	Body System or Organ Class Code	Direct mapping from SDTM AE.AEBDSYCD or supplemental qualifier.	ADaM IG	AE.AEBDSYCD	High	
ADAE	AEBODSYS	required	Body System or Organ Class	Direct mapping from SDTM AE.AEBODSYS.	ADaM IG	AE.AEBODSYS	High	
ADAE	AECAT	permissible	Category	Direct mapping from SDTM AE.AECAT.	ADaM IG	AE.AECAT	High	
ADAE	AEDECOD	required	Dictionary-Derived Term	Direct mapping from SDTM AE.AEDECOD (MedDRA Preferred Term).	ADaM IG	AE.AEDECOD	High	
ADAE	AEDUR	conditional	Duration of XX	Direct mapping of collected duration from SDTM AE.AEDUR.	ADaM IG	AE.AEDUR	High	

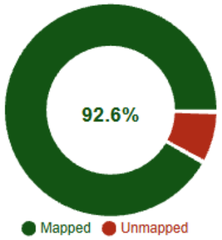
2 CDF App – Code Generation



3 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

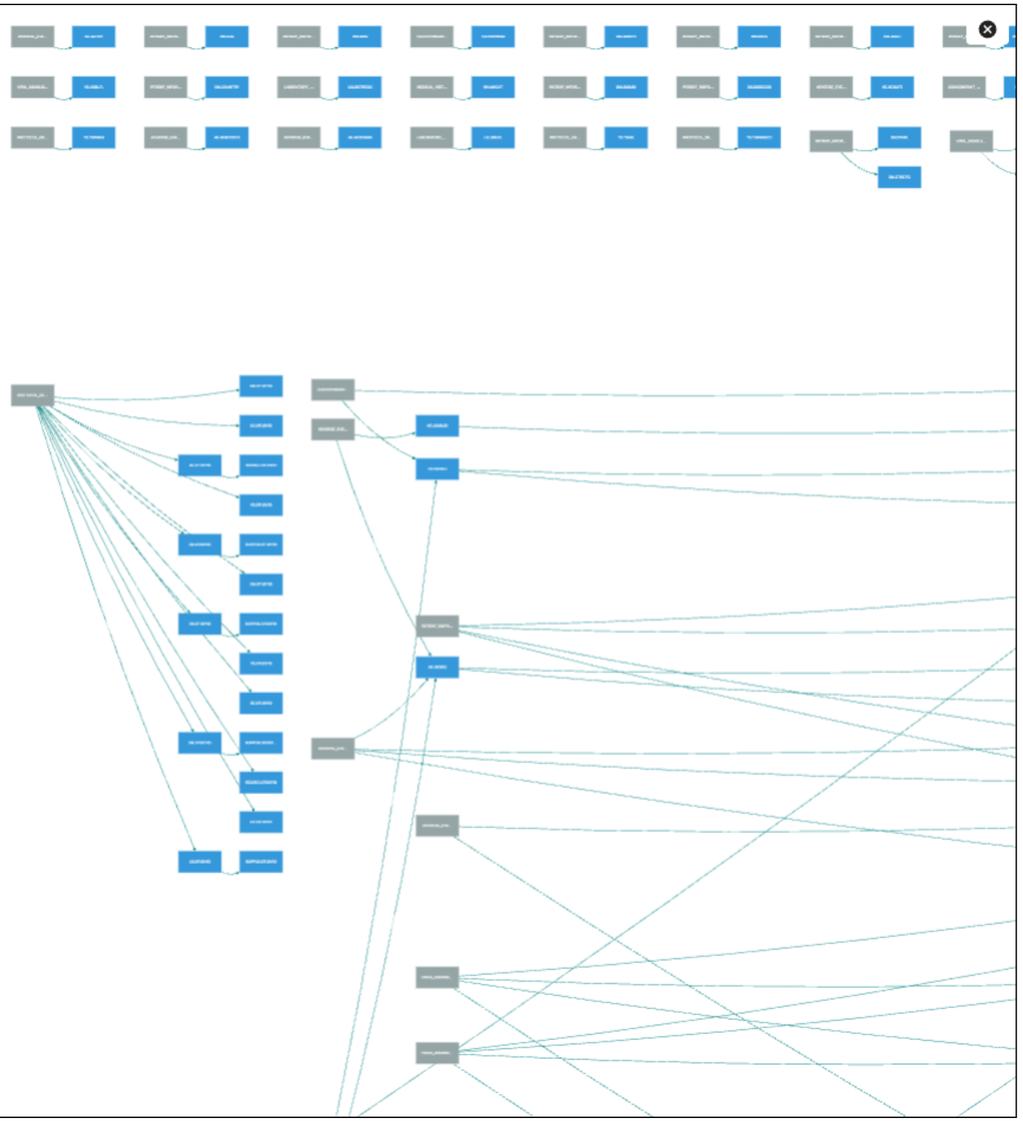
Clear Filter (0 selected)

Filter SDTM Datasets

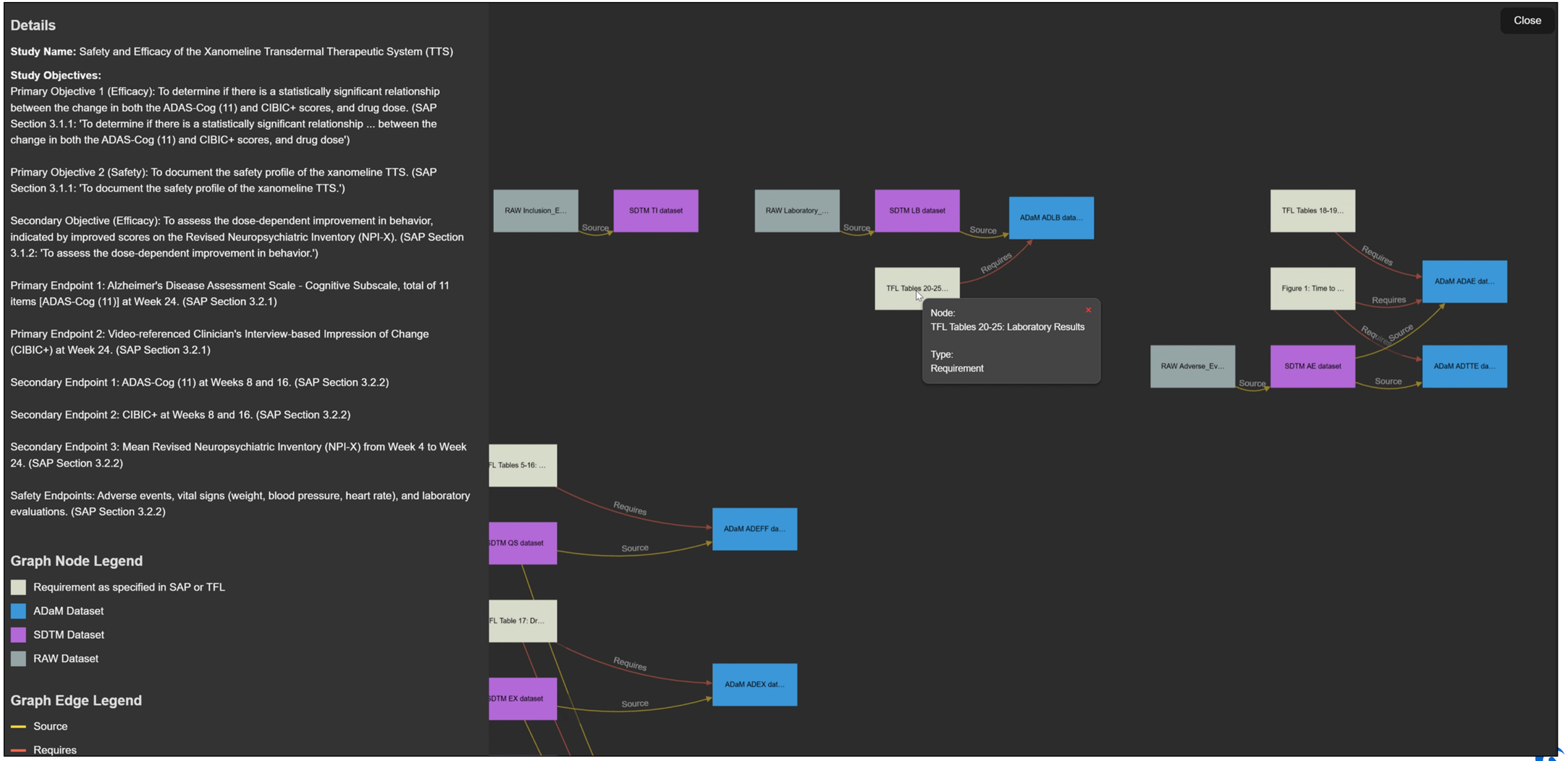
Clear Filter (0 selected)

Graph Legends

- Raw Dataset
- SDTM Dataset



3 CDF App – Traceability and Data Coverage Reports



Business Impact

Automated mapping & code generation - faster builds, lower cost

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/hours.

Jump-start, not turnkey: automate ~70–80% to create a robust baseline; humans finalize for submission readiness.

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

Responsible Adoption of Gen AI

Responsible Adoption

Mitigate risks associated with LLMs through secure, private models and human oversight.

Validation of AI-generated outputs is essential to ensure coding accuracy.

Create New Business processes around consumption of Gen AI technologies.

Question and Answers

For any questions contact:
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