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THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



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AI-Assisted Workflows for Enhanced Consistency and Auditability of SDTM generation

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Agenda

1. Using SDTM: from compliance to added value
2. Current State of SDTM Mapping
 - Key Challenges Across Studies
 - Limitation of existing Automation
3. Our Approach – Moving Beyond Automation
4. Adoption insights & Lessons Learned
5. Key Takeaways & Closing



Using SDTM: from compliance to added value



Setting the Context

- SDTM remains a core requirement for regulatory submissions
- It ensures consistent structure for regulatory review
- It has become a central data standardization tool across studies and sponsors
- **Standardization is established, but execution remains nuanced**





Current State of SDTM Mapping

Key Challenges Across Studies

Limitations of Existing Automations

An algorithmic, EDC-agnostic approach to SDTM mapping

"Due to the differences in raw data structures and data collection standards, it may seem impossible to develop a common approach for programming SDTM datasets."

[Pharmaverse - sdtm.oak](https://pharmaverse.org/sdtm.oak)



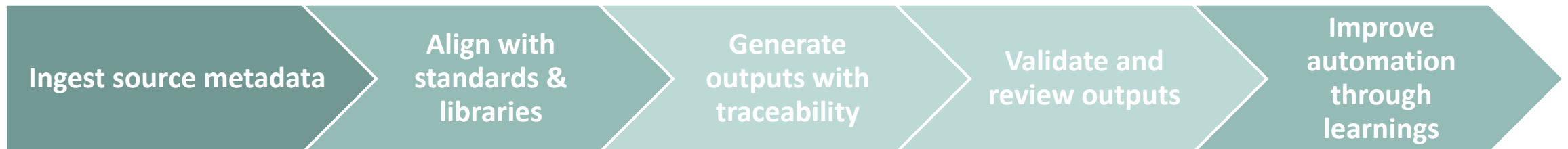
**Automating ~ 80%
of SDTM domains**

Current State of SDTM Mapping

- SDTM mapping is moving from a **document-heavy, manual translation exercise**



- ...to a **metadata-driven automated** engineering workflow.





Key Challenges Across Studies

- Heterogenous raw data
- Use of proprietary standards instead of CDASH
- Some domains are harder to standardize (e.g. associated person, SUPP/NSV and RELREC domains)
- Nontrivial validation and CT management

Limitation of existing Automation



Training data



Limited domain coverage



Sponsor context

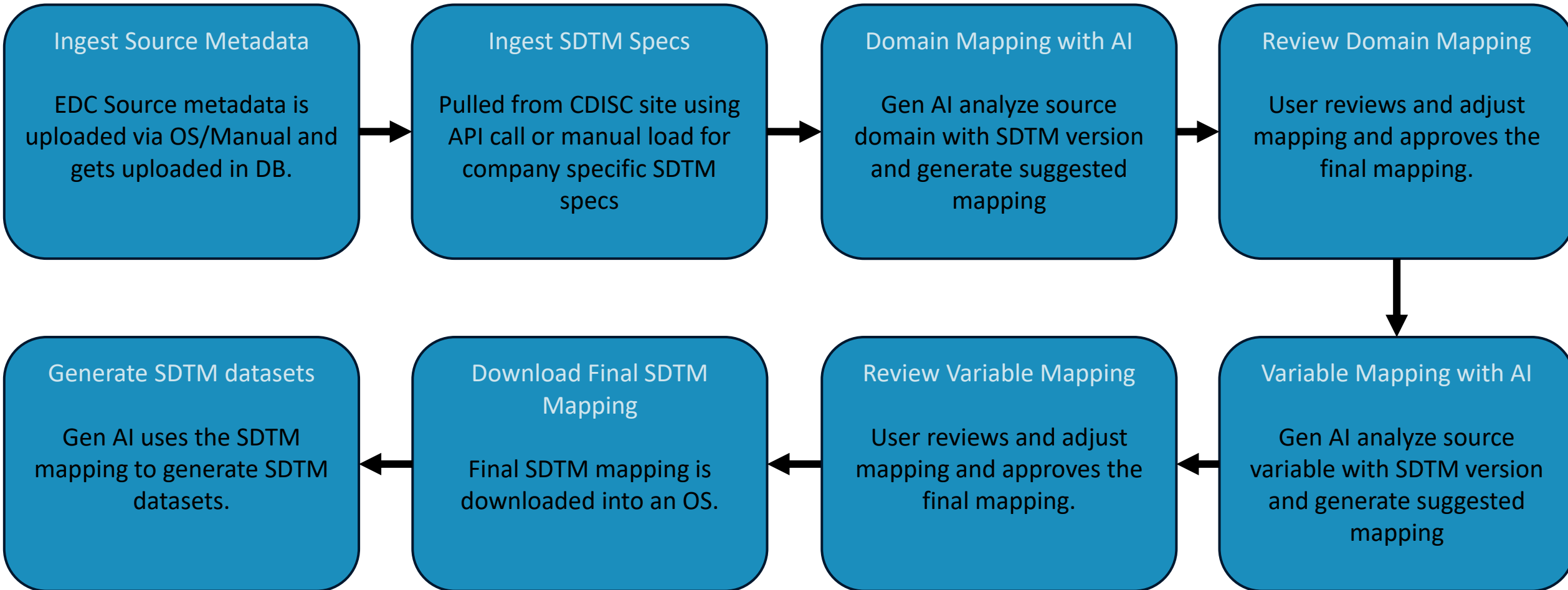


Semantic
interpretation



Relational, contextual, and
study-specific constructs

Our Approach – Moving Beyond Automation



Ingest Source Metadata

SDTM Mapping Builder

smore

Manual Metadata Upload

Metadata Type

Select Domain or Variable metadata files from your local system, preview the parsed data, and confirm the load.

☒ Domain ☐ Variable

Upload File

Select a File to upload

Loaded File

domain_metadata_STUDY001.csv

Load Data

Clear Data

Select domain metadata file

Preview

Preview the selected file and confirm the data before loading it into the system.

Preview

	STUDY_NAME	DOMAIN	DESCRIPTION	ORACLE_NAME	SAS_NAME	ALIAS
1	STUDY001	ECG	12-Lead ECG	ECG	ECG	ECG
3	STUDY001	AE_RPT	Adverse Events	AE_RPT	AE_RPT	AE_RPT
4	STUDY001	BM1	Body Measurements	BM1	BM1	BM1

SDTM Mapping Builder

smore

Manual Metadata Upload

Metadata Type

Select Domain or Variable metadata files from your local system, preview the parsed data, and confirm the load.

☐ Domain ☒ Variable

Upload File

Select a File to upload

Loaded File

variable_metadata_STUDY001.csv

Load Data

Clear Data

Select Variable metadata file

Preview

Preview the selected file and confirm the data before loading it into the system.

Preview

	STUDY_NAME	DOMAIN	VARIABLE	DESCRIPTION	ORDER	TYPE	LENGTH	PRECISION	NULLABLE	DEFAULT_VALUE
2	STUDY001	ECG	TENANT	TENANT	1	Varchar2	64		Yes	
3	STUDY001	ECG	TENANT_ID	TENANT_ID	2	Varchar2	32		Yes	
4	STUDY001	ECG	STUDY	STUDY	3	Varchar2	64		Yes	

Ingest SDTM Specifications

SDTM Mapping Builder

SDTM Loader

SDTM Metadata Loader

Choose Option
CDISC Library Import

Select CDISC Standard

sdm
sdmrig

Select Version

Refresh Version Import from CDISC Library

Select CDISC Standard

SDTM Mapping Builder

SDTM Loader

SDTM Metadata Loader

Choose Option
CDISC Library Import

Select CDISC Standard
sdmrig

Select Version

3-1-2
3-1-3
3-2
3-3
3-4
ap-1-0
md-1-0
md-1-1

Select CDISC Version

SDTM Loader

SDTM Metadata Loader

Choose Option
Manual Upload

Upload Domains
3.3-VAX-01_SDTM_Domain.csv

Upload Variables
3.3-VAX-01_SDTM_Variable.csv

UploadSDTMSpecs

Select SDTM Spec Files

Domain Mapping with Gen AI

Select Study

Select Domain(s)

Select SDTM Version

Generated Mapping Suggestions

SDTM Mapping Builder

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Domain Mapping

Study Criteria

Select a Study

STUDY001

Required

SDTM Version

SDTMIG v3.3

Required

Select a Domain/s

TM

TR

TS

TU

TV

UR

>>

>

<

<<

AE

DM

VS

<

<

>

>

Map Domain

Domain Mapping

Search: All Text Columns

Go

Actions

SDTM Domain	SDTM Description	Source Domain	Source Description	Confidence	Reasoning	Mapping Status
AE	Adverse Events	AE_RPT	AE_RPT (Adverse...	100%	Exact match found in the SOURCE metadata.	Mapped
DM	Demographics	DM	DM (Demography...	100%	Exact match found between SDTM dataset name and source domain code.	Mapped
VS	Vital Signs	VSS	VSS (Vital Signs):...	100%	Exact match found in the SOURCE metadata.	Mapped

Total 59

Review Domain Mapping

SDTM Mapping Builder

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Domain Mapping Approval (STUDY001 / SDTMIG v3.3)

Filter by Confidence

High

Medium

Low

All

Approve

Search: All Text Columns

Go

Actions

Edit

Save

☐		SDTM Domain	SDTM Description	Source Domain Description	Mapping Type	Expression	Approved Flag	Confidence	Reasoning
☒		DM	Demographics	DM (Demography) × IC (Informed Consent) × EOS (End of Study) × EOT (End of Treatment) ×	JOIN	DM.STUDY_ID (+) = IC.STUD...	☒	100%	Exact match found between SDTM
☐		AE	Adverse Events	AE_RPT (Adverse Events)			☒	100%	Exact match found in the SOURCE
☐		VS	Vital Signs	VSS (Vital Signs), VS_R_RPT (Vital Signs ...	UNION		☐	100%	Exact match found in the SOURCE

1 rows selected

Total 3

Edit mapping

Select multiple source if needed.

Approve Mapping

Variable Mapping with Gen AI

SDTM Mapping Builder

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Variable Mapping

▼ Variable Mapping

Study Name
STUDY001

SDTM Version
SDTMIG v3.3

Select a Domain/s

AE

DM

Map Variable

Study & SDTM Version pre-populated

Generated Mapping Suggestions

Search: All Text Columns

Go

Actions

SDTM Domain	SDTM Variable	SDTM Variable Description	Source Domain	Source Variable	Confidence	Reasoning	Mapping Status
DM	INVNAM	Investigator Name	DM	INVESTIGATOR	95%	The source variable INVESTIGATOR directly corresponds to the investigator ...	Mapped
DM	RACE	Race	DM	EHR_RACE0001\$	90%	The source variable EHR_RACE0001\$ has a description indicating race, whic...	Mapped
DM	RFICDTC	Date/Time of Infor...	IC	ICDATE0001\$	85%	The source variable ICDATE0001\$ from the IC domain relates to the date of i...	Mapped

total 17/23

Review Variable Mapping

Approve Mapping

SDTM Mapping Builder

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Variable Mapping Approval (STUDY001 / SDTMIG v3.3)

Filter by Confidence

High Low Medium All

Approve

Search: All Text Columns Go Actions Edit Save

	SDTM Domain	SDTM Variable	SDTM Variable Description	Source Domain	Source Variable	Expression	Confidence	Reasoning	Approved Flag
☒	DM	USUBJID	Unique Subject Iden...	DM	SUBJECT_ID		70%	SUBJECT_ID is a possible match for USUBJID,...	☒
☐	DM	AGE	Age	DM	NUMBER_01 - Age (...)		90%	The source variable NUMBER_010001\$ has a ...	☒
☐	DM	AGEU	Age Units			Years	1%	No direct match for AGEU in the source meta...	☒
☐	DM	BRTHDTC	Date/Time of Birth	DM	BRTHDAT - Subject'...		80%	The source variable BRTHDAT0001\$ relates t...	☒
☐	DM	COUNTRY	Country	DM	COUNTRY - Country		95%	The source variable COUNTRY0001\$ has a d...	☒
☐	DM	DOMAIN	Domain Abbreviation			DM	1%	No exact match for DOMAIN in the source m...	☒
☐	DM	DTHDTC	Date/Time of Death	EOS	DEATHDT - Date of ...	FN_ISO(DEATHDT)	85%	The source variable DEATHDT0001\$ from the...	☒
☐	DM	ETHNIC	Ethnicity	DM	EHR_ETH - Ethnicity			The source variable DEATHDT0001\$ from the EOS domain relates to the date of death, which aligns with the target variable DTHDTC.	
☐	DM	INVID	Investigator Identifier	DM	INVESTIGATOR_ID		95%	The source variable INVESTIGATOR_ID directl...	☒
☐	DM	INVNAM	Investigator Name	DM	INVESTIGATOR		95%	The source variable INVESTIGATOR directly c...	☒
☐	DM	RACE	Race	DM	EHR RACE - Race		90%	The source variable EHR RACE0001\$ has a d...	☒

1 rows selected

total 30



Adoption insights

- Initial hesitation in trusting AI-generated mappings
- High variability in sponsor standards and study designs
- Integration with existing workflows required careful alignment



Lessons Learned

- Start with AI-assisted mode, not full automation.
- Keep human-in-the-loop for validation and trust building
- Prioritize explainability (rationale + confidence)
- Leverage existing mappings to drive reuse and learning





Key Takeaways & Closing

- SDTM mapping remains manual, complex, and inconsistent
- Traditional automation alone is insufficient.
- AI can enhance mapping, but combining AI + human expertise delivers the best outcomes
- Built-in traceability ensures regulatory readiness





We are not just accelerating SDTM mapping; we are making it smarter, consistent, and inspection-ready.





Thank You!



Questions?

