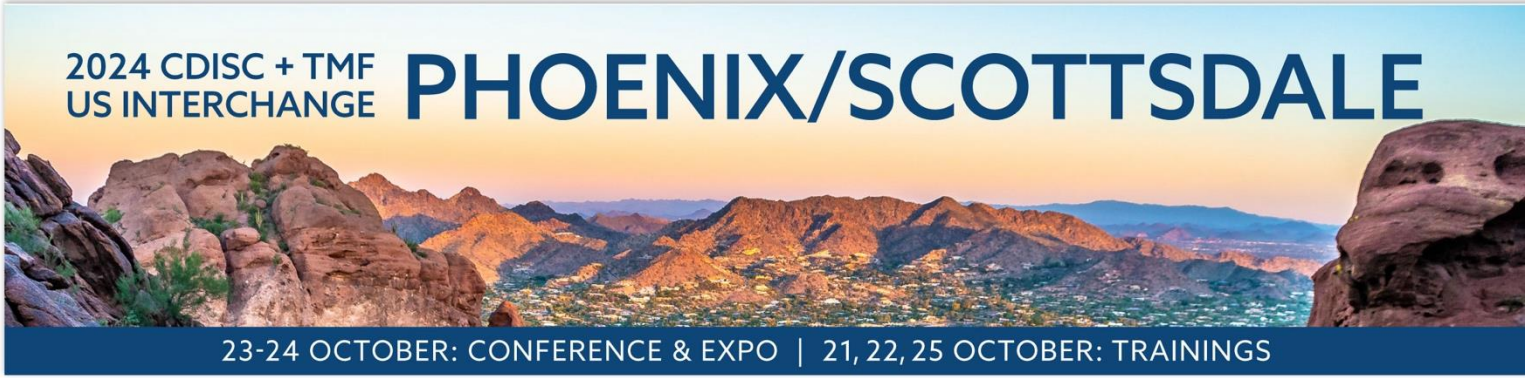


Clinical Data Transformation: AbbVie's AI Journey

Presented by Aman Thukral, Director of Clinical System & Digital Operations, AbbVie

Meet the Speakers

Aman Thukral

Title: Director, Clinical Systems & Digital Operations

Organization: AbbVie

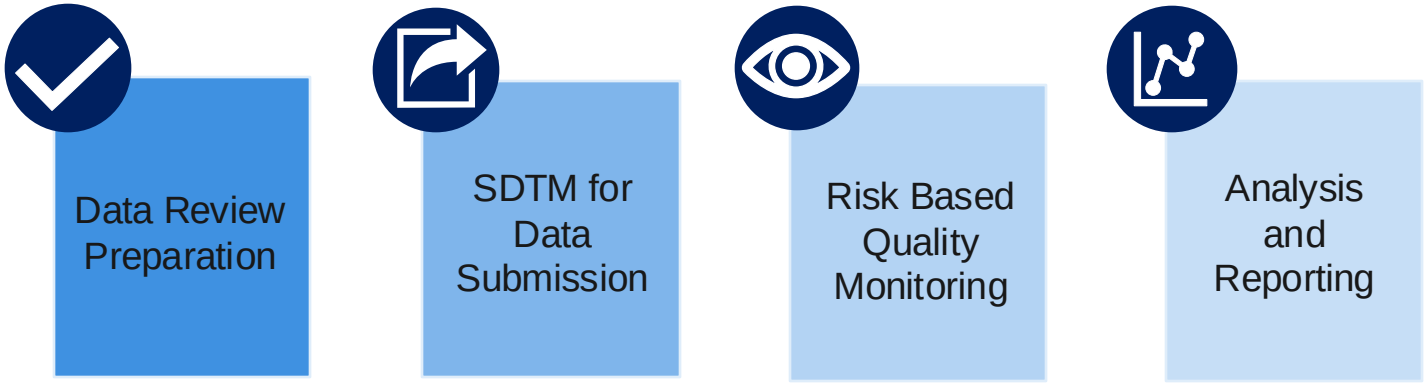
Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Agenda

- Clinical Data Transformation – Applications and Use Cases
- Data Standardization - Traditional Approaches, and Challenges
- Why AI/ML for Data Standardization
- AbbVie Case Study
- Concluding Thoughts

Clinical data transformation is converting raw data into a meaningful format



The purpose of this presentation is to highlight AbbVie's AI experience in Clinical Data Transformation

Data Standards Overview

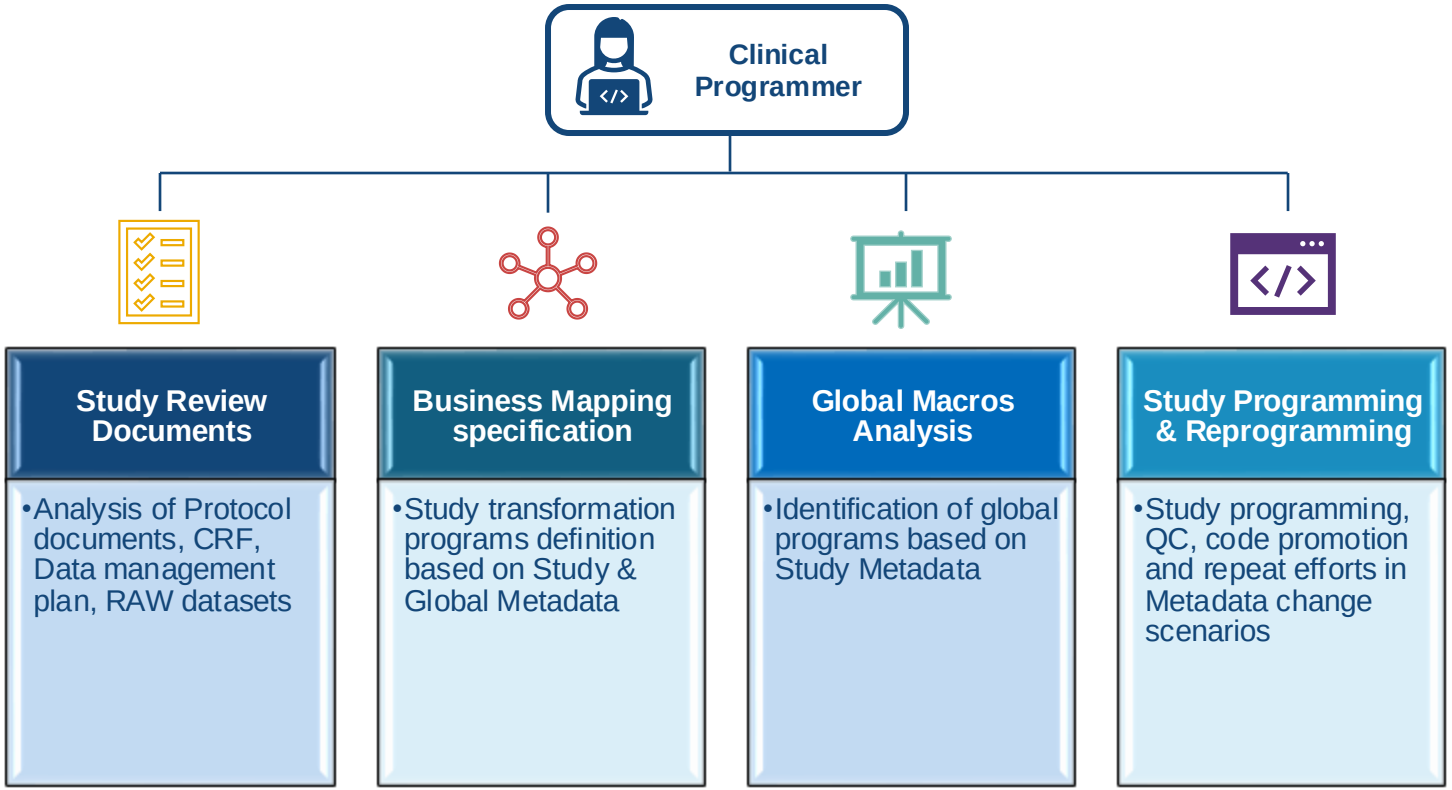
A standard developed by CDISC for organizing and formatting clinical trial data

Regulatory mandate in many countries because it ensures quality and accuracy of data

Improves efficiency of data review and analysis

Made up of different components: Domains, elements and tables

SDTM Standardization – Traditional Approach

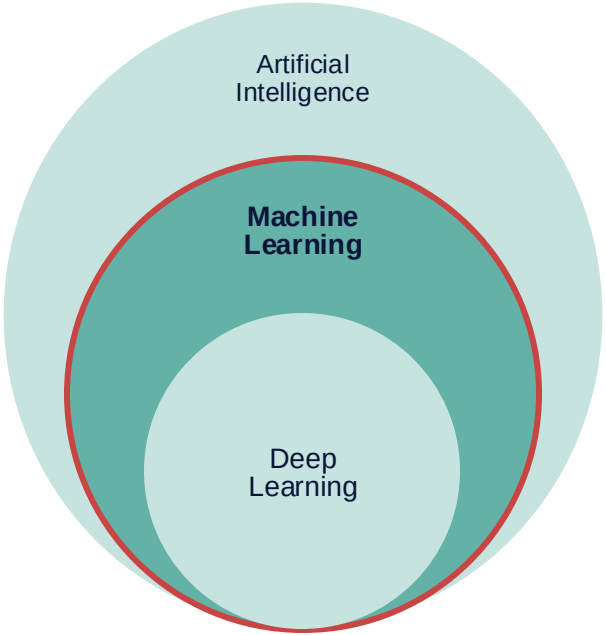


Why AI/ML for SDTM?

Operational Efficiency	Automate the process of mapping data to SDTM, reducing manual effort and time required for creating mappings
Accuracy	Improve the accuracy of mappings by identifying patterns and relationships in the data that may be missed by human analysts
Consistency	Ensure mappings are consistent across different datasets and studies, reducing the risk of errors and inconsistencies
Scalability	AI/ML can handle large volumes of data and mappings, making it easier to manage complex datasets
Adaptability	Learn and adapt to changing data and mapping requirements, improving the flexibility and agility of the mapping process
Integration	Seamless integration of AI/ML capabilities into the existing data workflow, without disrupting current processes

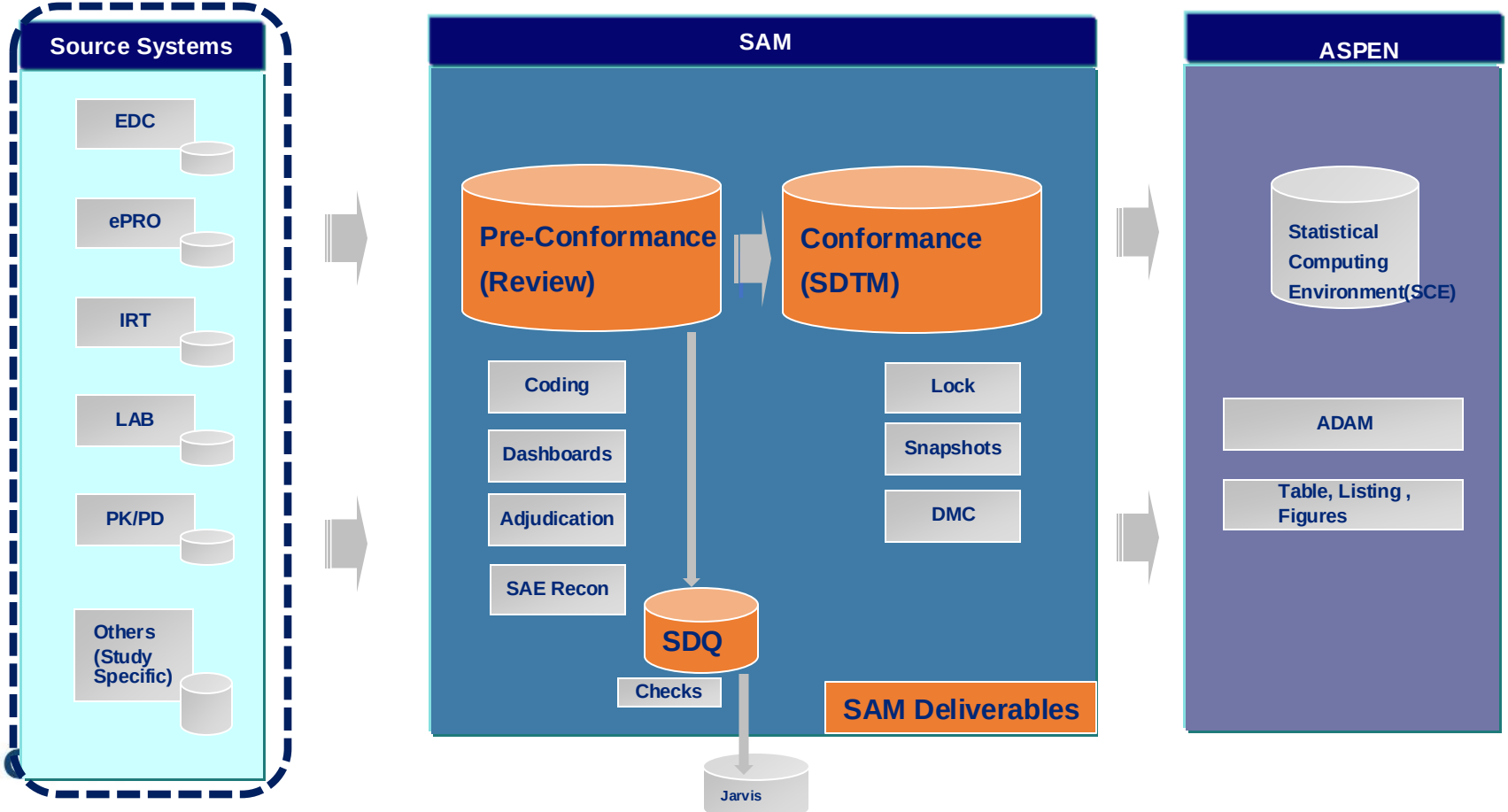
AbbVie is using machine Learning for SDTM Transformation

- Artificial Narrow Intelligence
- Artificial General Intelligence
- Artificial Super intelligence



- Supervised Learning
- Unsupervised Learning
- Reinforcement Learning

SDTM Architecture and Data Flow



AbbVie's Journey

Industrialization
- 75 Studies live
- 25 studies in pipeline

Pilot
- 5 Studies
- ML Output vs. trad. SDTM

Model Development
- Model Training & Validation
- Model Deployment

Platform Enablement
- Integration: API, Files, DB, etc.
- Realtime data flow

Landscape Assessment
- Business Case Development
- Build vs. Buy
- Vendor Assessment

Domain Prediction Model → **Variable Prediction Model** → **Function & Tech logic scripts**

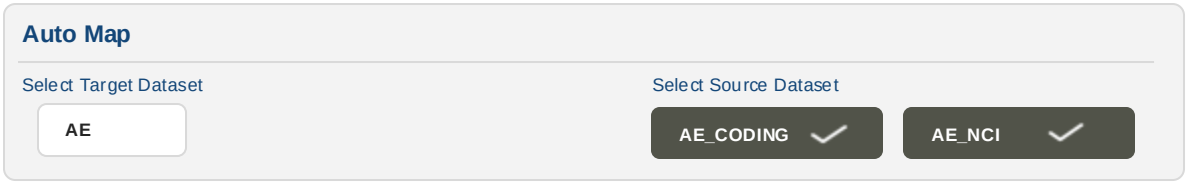
HITL

Raw Data → Data Review Model → Conformance

- Pre-conformance contains additional domains for internal reviews
- Conformance is pure SDTM submission data

Automapping – User Interaction (An example)

Transformation Maps Creation Options



Automapping - Selection of Target

Data Level — Column Level 2

		Source		Mapping Rules		Target			
		Variable	Variable Label	Function	Function Logic	Domain	Variable	Variable Label	Confidence
☑	+	AELLT		COLLAPSE	{"Source Column..	AE	AELLT	Lowest Level Term	**99%**
☑	+	AELLT		DROP	NaN	AE	NaN	Lowest Level Term Code	**99%**

Prediction Accuracy

LLM Concept for Auto Mapping

1 SOURCE DATA

STDAT	ENDAT	SER	SEV	ACN	OUT
9-11-19	9-11-19	No	Mild	NA	RECOVERED/RESOLVED
7-11-19	7-11-19	No	Moderate	NA	RECOVERED/RESOLVED

2 SOURCE METADATA

Name	Type	Length	Label
STDAT	Char	20	Start date of AE
ENDAT	Char	20	End date of AE

- Sources for Model Inference
- Components for model training/ Re-training
- Model Inference components

5 Input Sources

4 Custom LLM

11 SME Input

12 Re-Training

6 Domain Class Prediction

7 Domain Prediction

8 Column mapping Prediction

9 Transformation function and parameter Prediction

METADATA MAPPING (ML Generated)

10

CLASS	DOMAIN	SOURCE VARIABLE	TARGET VARIABLE	FUNCTION	PARAMETERS
Events	AE	STDAT	AESTDTC	date_convert	{format:"dd-mm-yy"}
Events	AE	ENDAT	AEENDTC	date_convert	{format:"dd-mm-yy"}

3 **Model Training Components**

- Codelists
- Annotated CRFs
- Target Metadata (SDTM IG)
- Historical study maps

Concluding Thoughts…

Implementing AI/ML in SDTM generation can indeed be a time-consuming process.

To ensure comprehensive model training, it is necessary to select a diverse range of therapeutic areas/studies and CDISC Implementation Guidelines.

Continuous learning is essential in AI/ML enablement as it requires ongoing model enhancements to consistently deliver improved results.

Usage of AI in SDTM may require overhauling people and processes, necessitating upskilling and change management.

AI Won't Replace Humans — But Humans With AI Will Replace Humans Without AI

- Karim Lakhani, Harvard Business School

Thank You!