SCDM Live

August 26, 2023, Mumbai

SCDM India Single Day Event

THEME

CDM — Revisiting fundamentals in an evolving clinical research landscape

Agenda

- SDTM Evolution & Maturity Model
- Maturity Level 4 Solution Details
- Successful Case Studies
- Learnings
- Maturity Level 5 Solution Details
- Summary

Evolution of SDTM

MANUAL SAS PROGRAMMING FOR EACH STUDY

Pros

- ✓ Control over programs

Cons

- × More time and effort needed
- × Reusability restricted to limited knowledge
- × Manual effort on simple transformation

MATURITY **LEVEL 1**

GLOBAL MACROS + LIMITED STUDY SPECIFIC PROGRAMMING

Pros

- ✓ Less efforts & time required compared to stage 1
- ✓ Flexible to study specific requirements

Cons

- × Requires knowledge on template programs
- × Error prone process without governance
- × Direct transformation had to be done manually

LEVEL 2

STUDY WISE EXCEL MAPPING + TRANSFORMATION ENGINE

Pros

- ✓ Improvement in terms of efforts required
- ✓ No effort needed on direct transformation.
- ✓ Excel driven standard derivations

Cons

- × Error-prone process
- × No governance over deviation to standards
- × No access control or versioning over excel containing study mapping

LEVEL 3

MDR + TRANSFORMATION ENGINE

Pros

- ✓ MDR provided access control and version history
- ✓ Unified metadata repository
- ✓ No effort needed on direct transformation.

Cons

- × Users face difficulty while setting up metadata for study specific domains
- × One primary standard from which the setup is extracted

LEVEL 4

AI DRIVEN SDTM

Pros

- ✓ Quicker metadata setup
- ✓ Provide suggestion to user to create transformation specs
- ✓ More reliable and flexible for more than 1 standard

Cons

- × Lot of training data required
- × Debugging error and updating delta specification is bit daunting

LEVEL 5

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SDTM Maturity Level4 Solution

[MDR + Transformation Engine]

Metadata Repository – Key SDTM Maturity Level4 Solution Component

Enabling Auto Study Build Auto ADaM, eDTA along with Auto SDTM

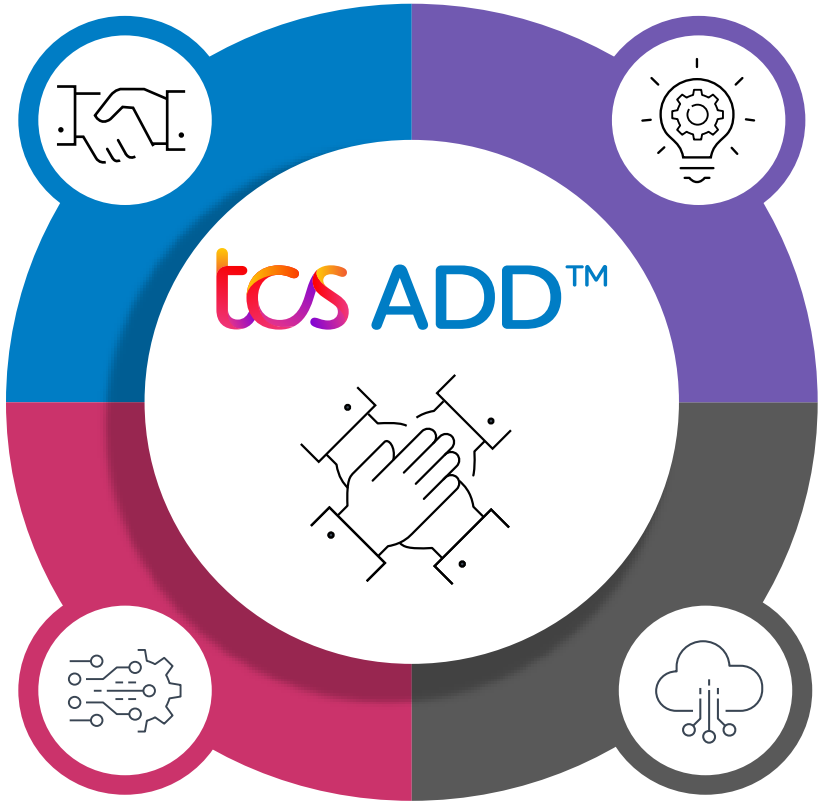
Key Solution Components

Clinical Standard Registry

- **Metadata Repository** for multiple templates and standards, cross-study & product re-usability
- Manage multiple standards (Sponsor, CDISC, HL7, NCI and others) & their relationships
- Workflow & smart governance to handle evolving standards
- Comprehensive **Impact analysis** & **Change Request Module**

Automated SDTM / ADaM Transformation & Biomedical Concepts

- Automated creation of ready to use submission packages using Cognitive technologies like AI/ML
- SDTM Trial Design Workbench
- Industry leading accuracies
- **Biomedical Concepts**



Automated Study Build

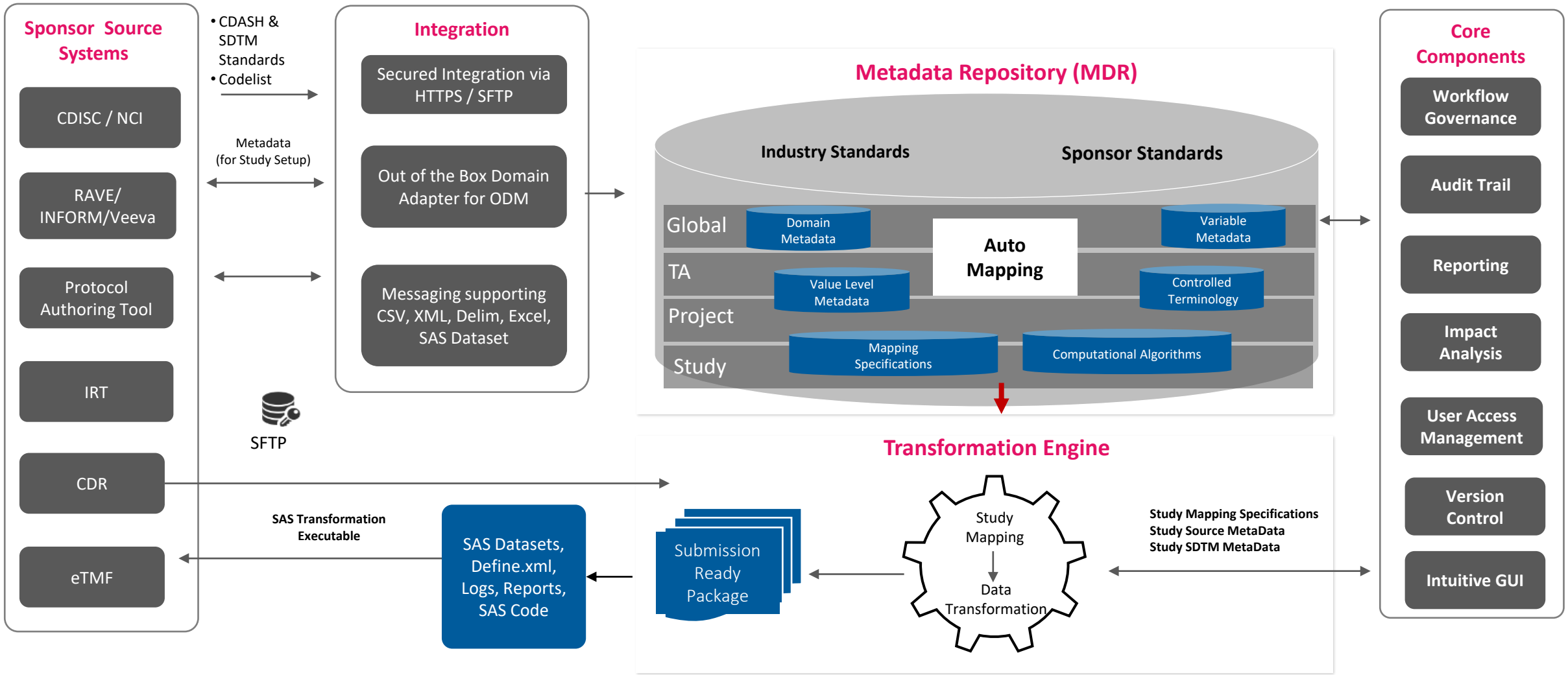
- **Automated study design** from standards & templates via bidirectional integration to EDCs.
- **Interconnected** along the entire product lifecycle

eDTA Management

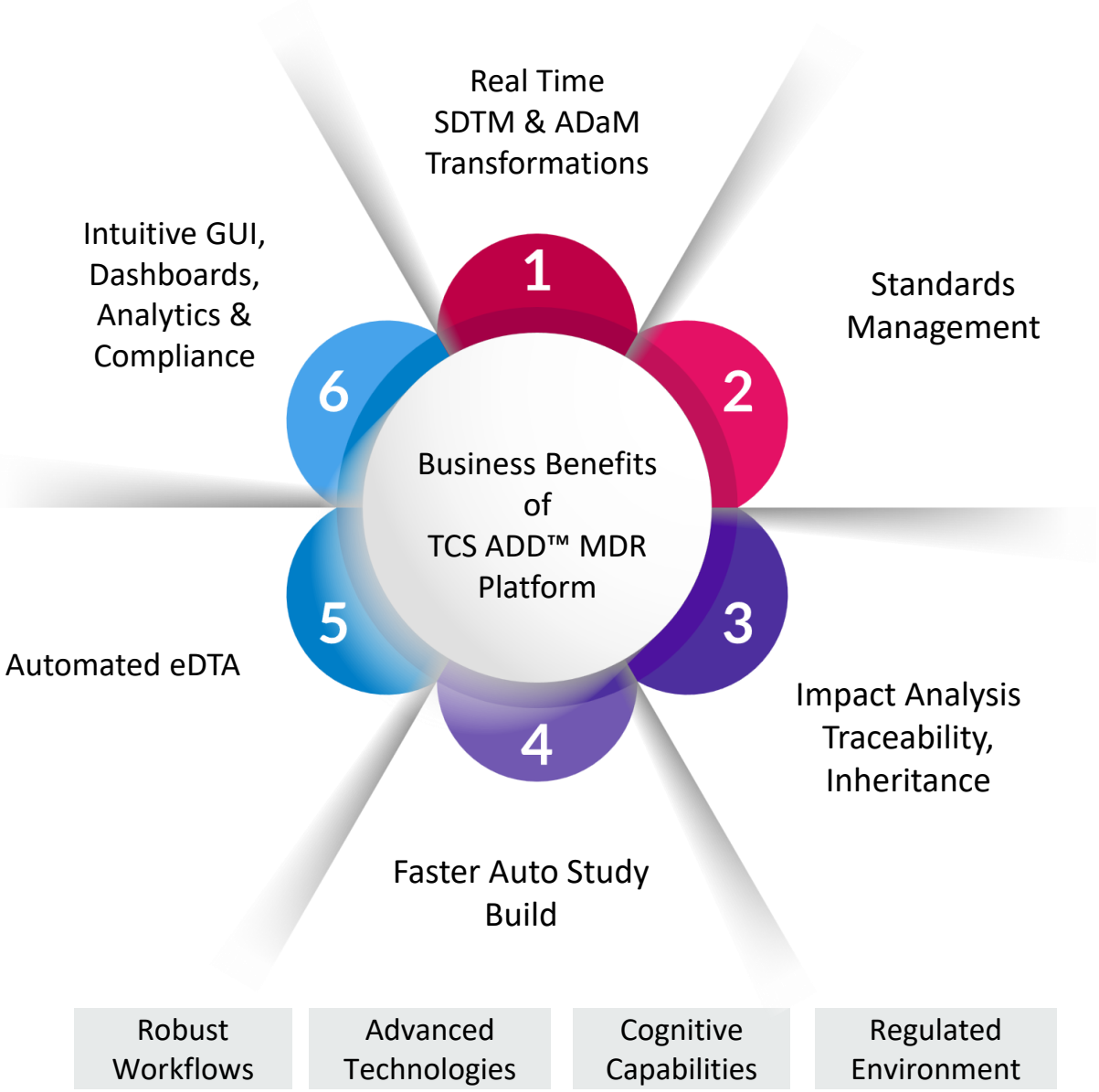
- **Setup of reusable Data Transfer Agreements (DTAs)** through configurations based on custom data sets, data models and data transfer specifications
- **Configurable & reusable workflows**, alerts and triggers (email based)
- **Download / extract customized DTA** in word format

Solution Logical View

Highly Scalable and Flexible Solution to meet Sponsor Specific Needs



Key Benefits



Real Time SDTM & ADaM Availability	• SDTM UAT Package ***@ GO LIVE*** • ***SDTM 1st Package <= 3 days from FPI*** • SDTM re-runs ***@ Real Time,*** *E2E traceability* • ***ADaM Automation*** • Comprehensive Roadmap for ARDS & TFL
End to End Standards Management	• ***100% compliance to CDISC/Sponsor standards*** • Acts as single source of truth
Impact Analysis, Traceability & Inheritance	• Impact Analysis, Inheritance, Traceability • ***Change Request*** • ***End to End Data Lineage***
Faster Auto Study Build	• ***Reduce study build time: to 4-6 weeks*** • Integration with EDCs
Automated eDTA	• ***Reduced turn around time & oversight for DTA creation*** • Notification driven Multistep Review workflow
Enhanced User Experience	• ***User friendly*** GUI and processes • ***E2E Orchestration*** in alignment with Clinical Data Flow

Case Study 1: Standard Management & Auto Study Build

Global Top-15 Pharma Enables Automated & Integrated Study-Standards Management

Challenges

- Inefficient management, maintenance and oversight of Clinical Standards and Versions
- No integration with EDC resulting in limited use of standards in study build and lack of downstream automation
- Multiple versions of SDTM & Controlled Terminologies

TCS Solution

- Single source of data in a central repository, with multiple versions
- Integrated standards & auto study build
- Enhanced enterprise level governance model with configurable workflows
- Maintains treatment standards and configurable metadata driven trial design workbench
- Auto integration with EDC and auto-creation of annotation
- Inheritance, Cascade & Promotion functionalities

Benefits

- Streamlined and structured metadata management, enabling easy search, governance & reuse
- Cross-departmental data lineage oversight
- Quicker study set-up due to automation

40% Time reduction for study build | 30% Cost reduction

Case Study 2 : End to End Standard Management & Auto SDTM Case Study

Global Top-15 Pharma Enables Automated SDTM & Integrated Study-Standards Management

Challenges

- Reliance on slow and outdated legacy systems that provides limited coverage for metadata and study setup
- Absence of single repository for metadata of downstream activities such as EDC, Non-CRF, SDTM, ADaM, Lab reference tables, SDTMIG+, etc.
- Tedious and complex process for formatting data from one form to another, especially for text formatting
- Entire process led to improper governance, multiple versions and inefficient maintenance of standards

TCS Solution

Pharma leveraged TCS ADD™ Metadata Repository, a ready-to-use, interoperable metadata driven AI platform, comprising:

- Single harmonized, connected standards as backbone for all types of metadata
- Impact analyzer assesses the impact of any change to controlled terminology
- Regulatory compliant audit-trail with data integrity and in-built versioning framework
- CRF creation via customized governance of Instructions, Data Verification Standards (DVS) & Lab Reference Tables (LRT)
- Quality metadata based on configurable Business rules

Results & Benefits

- Reduced study SDTM timelines owing to automation and **near real-time publishing** for study teams
- **Impact Analyzer** resolved integrity issues within the current system including CRF, DVS, etc.
- **Automated SDTM**
- Flexible and configurable governance with **user driven workflows** to cater different downstream Business needs.
- **End-to-End data lineage** with study metadata and SDTM
- **Fastest ever go-live** of 9 months for implementing the unified metadata platform

END-TO-END STANDARDS AUTOMATION FOR 750+ FORMS, 20k+ ITEMS & 4k+ CODELISTS

96% Automation for SDTM deliverables

81% Automation for ADaM deliverables

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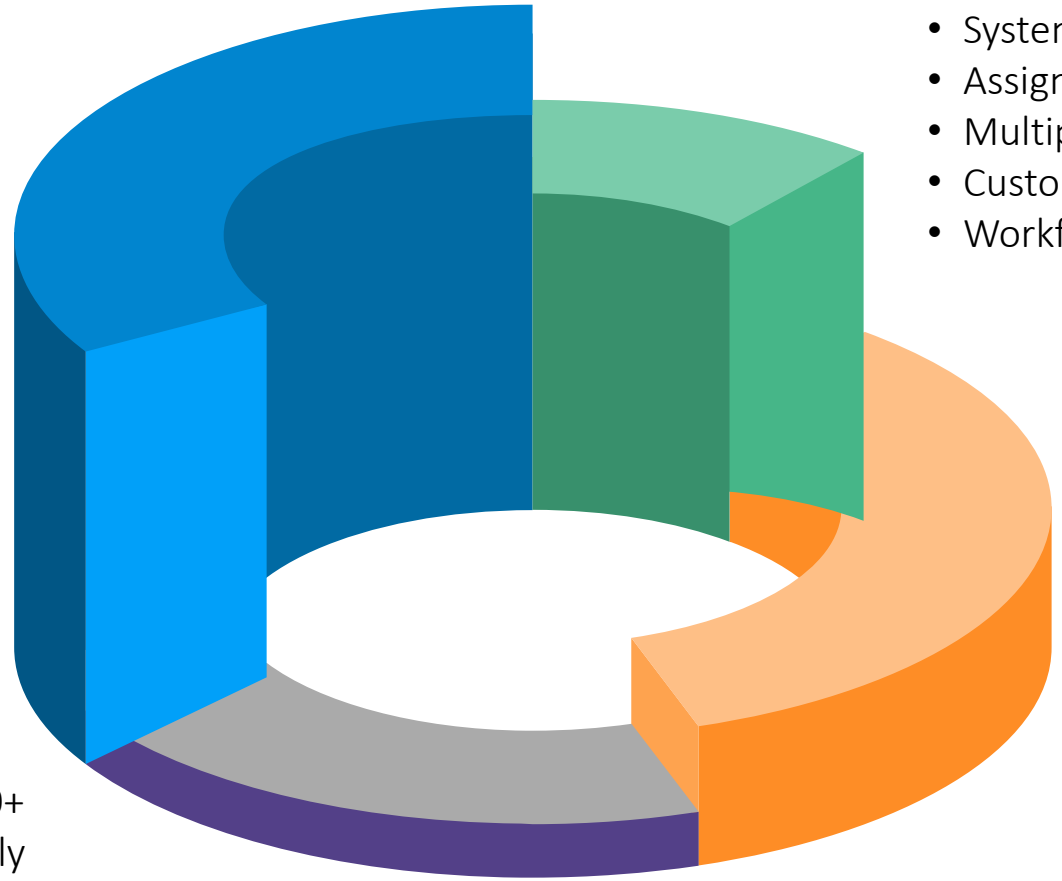
Case Study| Learnings

Change Management

- Stake holder alignment
- Process maps, SOPs and training finalization
- Role and responsibility assignment
- End user buy-in and onboarding
- Standards migration with no business impact

Agile Framework

- 6 work streams to manage various components
- Conference Room Pilots (CRP) to test system post key milestone
- Rigorous client UAT with more than 50+ users testing the system simultaneously



Evolving Features & Functionalities

- System hierarchy and concept finalization
- Assignment / Management of forms & fields
- Multiple request with conflicting strategies
- Customization vs. standard features
- Workflow related flexibility

Evolving Standards

- Managing NCI CT and Client specific CT
- CDISC standards management
- Multiple versions of client standards
- Good to have vs. Mandatory components

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SDTM Maturity Level 5 Solution

SDTM Maturity Level 5 : AI Enabled SDTM

Intelligent, automated metadata discovery and transformation of clinical data from diversity of sources such as CRFs, ePROs, devices and EHR

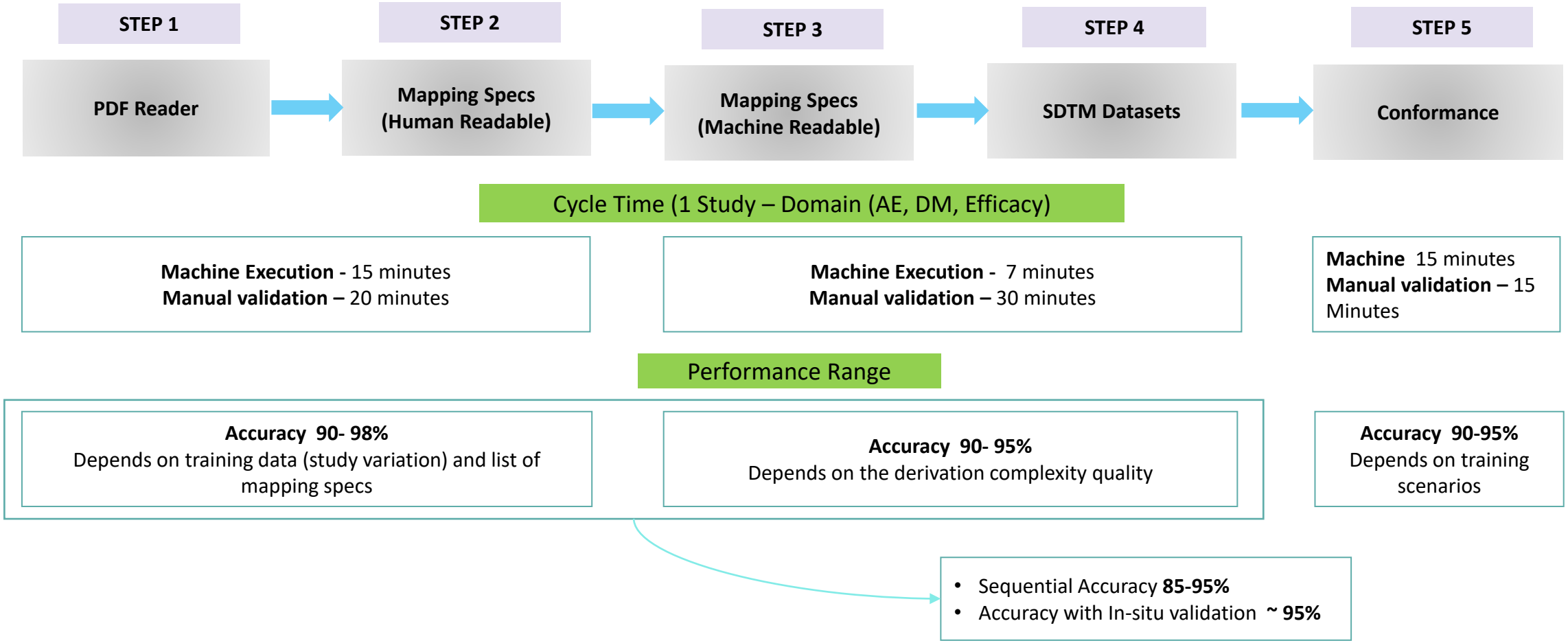
RoboSPA

Automated ingestion of data from new sources

In-stream generation of standards-aligned output such as SDTM

Zero study-specific effort to generate standard outputs

TCS Smart Universal Translator – Model Training & Accuracy Depiction

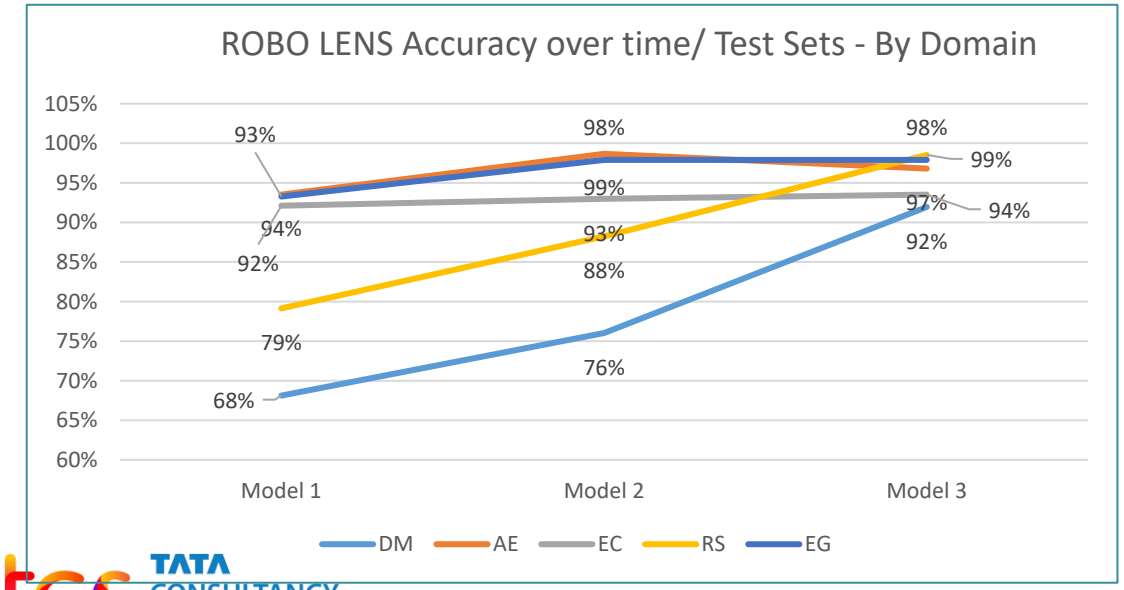


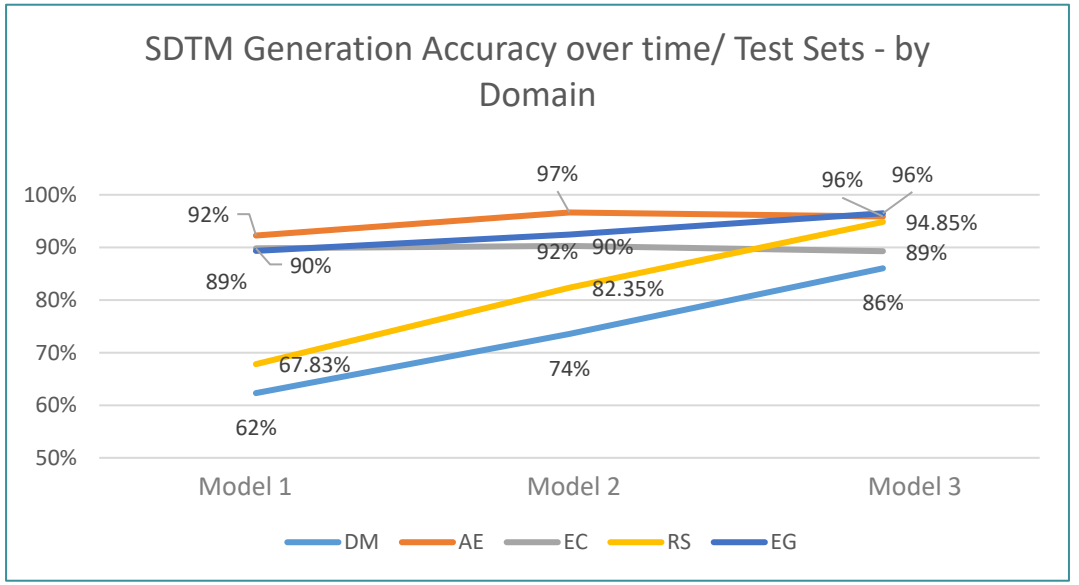
- In-situ manual validation involves minor checks, fixes, manual mappings but no re-runs
- The performance estimation is averaged across domains

TCS Smart Universal Translator – Model Training & Accuracy Depiction

Model Ver.	ROBO LENS (Human Readable Specs)			SDTM Generation		
	Accuracy	Precision	Recall	Accuracy	Precision	Recall
Model 1	92%	92%	88%	89%	88%	84%
Model 2	93%	94%	89%	91%	92%	88%
Model 3	96%	97%	95%	94%	95%	93%

- Run on set of 10 studies for testing and training/ retraining the model(s) over time
- Model 1 is the first model and Test Set 3 model is the most advanced model, baselined with complete training data set
- Model accuracy was calculated based on predicted data and actual data. Actual data here is derived from SME validation on predicted data





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SUMMARY

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MANUAL SAS PROGRAMMING FOR EACH STUDY	GLOBAL MACROS + LIMITED STUDY SPECIFIC PROGRAMMING	STUDY WISE EXCEL MAPPING + TRANSFORMATION ENGINE	MDR + TRANSFORMATION ENGINE	AI DRIVEN SDTM
MATURITY LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5

- ✓ Industry is moving fast towards fully automating SDTM
- ✓ Bringing Automation in SDTM is no more Optional – It not only saves effort but also helps in making SDTM available early in the Clinical Cycle.
- ✓ An Efficient process along with Level4 Maturity can have SDTM done with :
  - *2 Stat Analyst FTE with 2 Person Days Effort*
  - *3 days after FPV SDTM availability*
- ✓ At the minimum, Level3 Maturity Level is must for any organization today
- ✓ Level 4 is preferable and bring lot of Efficiency & Value Adds
- ✓ Level 5 is for larger organizations who are looking for automation in 100% Studies. Due to partner studies & new Companies being acquired by these companies, it is not possible for them to have standards for all studies. Hence, AI is must to bring automation.

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Thank You