

Single Day Event

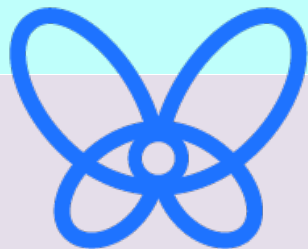
*Clinical Data Standards in the era of AI,
ML & Digital Transformation - Achieving
efficiency in Programming, Analysis &
Submission*

*Kedar Deshpande,
Lifio.ai*



Introduction

Industry undergoing significant transformation with the increasing role of AI, ML and digital technologies.



Potential to revolutionize clinical research industry with faster drug discovery, efficient trial conduct, accelerated drug to market timelines leading to improve patient outcomes.

Need for efficient clinical data standards to harness the potential of AI, ML, and digital technologies



Need for Clinical Data Standards in Clinical Data Management

Clinical data standards are past, present and future, they are here to stay.

A structured framework for organization, documentation and representation of data.

Programming

**Interoperability and
Data Exchange**

**Data Consistency
and Integrity**

- Consolidate data models
- Standard Definitions
- Standardise Data Repository

TransCelerate DDF and SDR

Analysis

**Data Interpretation
and insights**

**Efficient Data
Analysis**

- Accelerated and consistent data analysis
- Accurate data reporting and insights interpretation
- Real time and high data quality assurance

Standard for Risk based monitoring

Submission

**Regulatory
Compliance**

**Data Preservation
& Archiving**

- Submission readiness and ease of analysis for regulatory authorities.
- Ensures data integrity, transparency and traceability
- Data archiving, reproducibility and data stewardship.



Potential challenges in Programming, Analysis & Submission (without CDS)

Programming

Data Integration and Harmonization

- Challenges with integrating data with inconsistent structures from diverse sources
- Availability of organized and regulated libraries hosting standard scripts.
- Availability of solutions that can provide intelligent recommendations.

Analysis

Statistical and Methodological Challenges

- Expertise in Biostatistics and domain knowledge to implement the right statistical methods.
- Addressing challenges like confounding factors, selection bias crucial for deriving meaningful data insights.

Submission

Reproducibility and Documentation

Reproducibility and Documentation

- Reproducing analysis results critical to submission success.
- Requires organized workflows, code documentation and version control mechanisms

Scalability and Data Security

- Need for powerful computing infra and optimized algorithms.
- Maintaining patient anonymity
- Compliance to Privacy regulations.



Role of AI/ML and Digital Transformation in enhancing Clinical Data Standards

Revolutionizing Clinical Data Standards: Leveraging AI, ML, and Digital Transformation for Enhanced Healthcare Insights

Data Integration, Extraction and Abstraction

- EHRs and mobile health apps – data capture at point of care.
- Integration from diverse sources using std data formats and APIs.
- Automated extraction/abstraction of data from clinical documents using NLP algorithms.
- Ability to learn the mapping between different data formats and ontologies.

Predictive/Advanced Analytics, RTDM and Automated QA

- Identify anomaly patterns, trends and correlations. Uncover valuable insights.
- Continuous monitoring using connected devices/wearable s and RTDS systems.
- Increased data accuracy using AI-based quality checks.

Data Privacy/Data Security/Data Sharing

- Masking sensitive patient data while preserving data utility for analysis.
- AI models can learn patterns and rules to ensure compliance with privacy regulations.
- Cloud-based platforms, secure data-sharing networks, and standardized data exchange protocols

Data Submission/Regulatory Compliance

- Standardized EDC systems and electronic data interchange formats
- Seamless submission of data to regulatory authorities and research sponsors.
- Reduced admin overhead, improved data accuracy, timely regulatory review and approval.



Case Study – The SDTM Package for Submission

AI based system with 80%+ accuracies on live studies and 84%-time efficiency

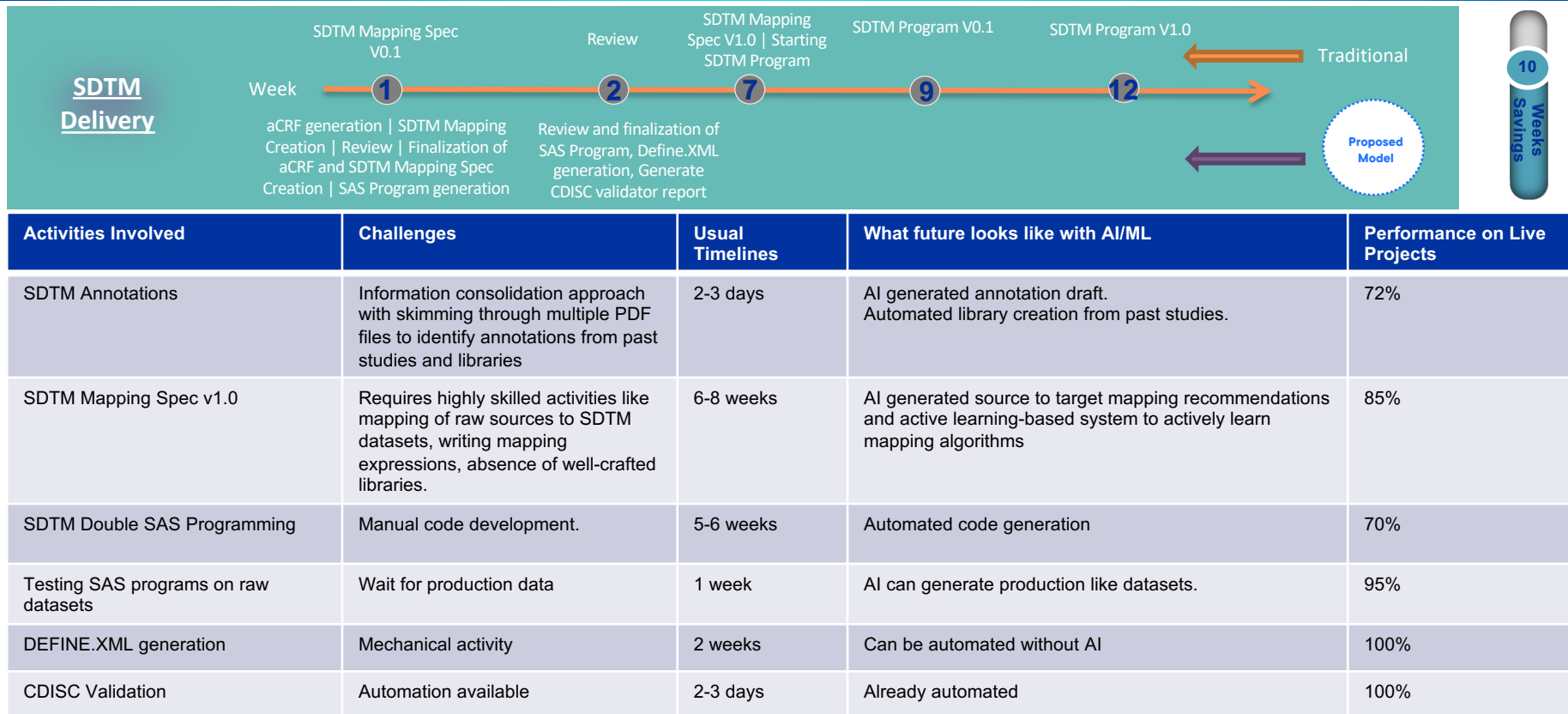
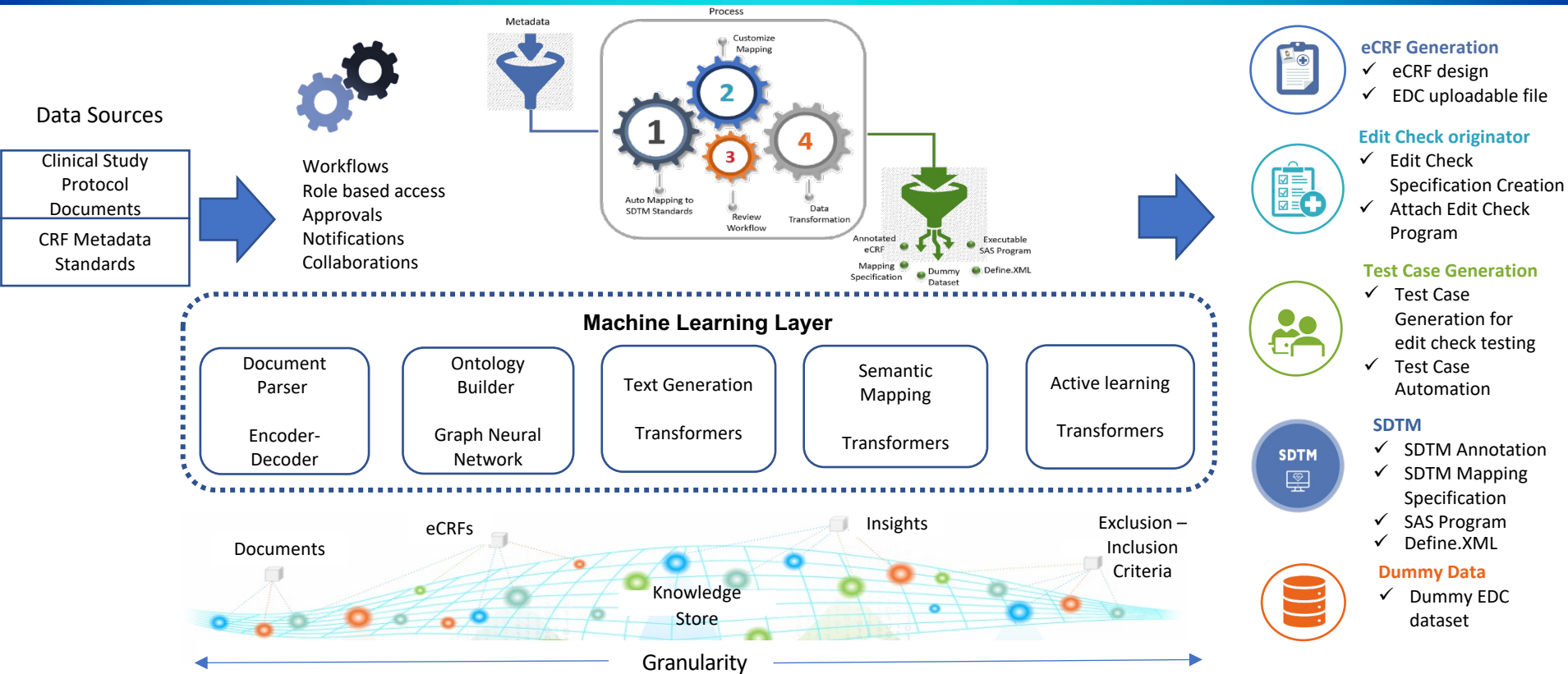




Illustration of AI/ML implementation





Conclusion

- ✓ SDTM Case study proves faster program, analysis and submissions are possible in compliance with standards.
- ✓ Clinical Data Standards plays vital role in the era of AI, ML, and digital transformation – enables data interoperability, enhances data quality and consistency, streamlines data analysis, accelerates research and innovation directly reducing cost.
- ✓ Significantly improves patient outcomes and decision-making in healthcare.
- ✓ By adhering to efficient clinical data standards, the healthcare industry can unlock the transformative power of AI, ML, and digital technologies to improve patient care, accelerate research, and drive innovation.