

**SCDM** Live

August 26, 2023, Mumbai

# SCDM India Single Day Event

THEME

CDM — Revisiting fundamentals in an evolving  
clinical research landscape

# Introduction

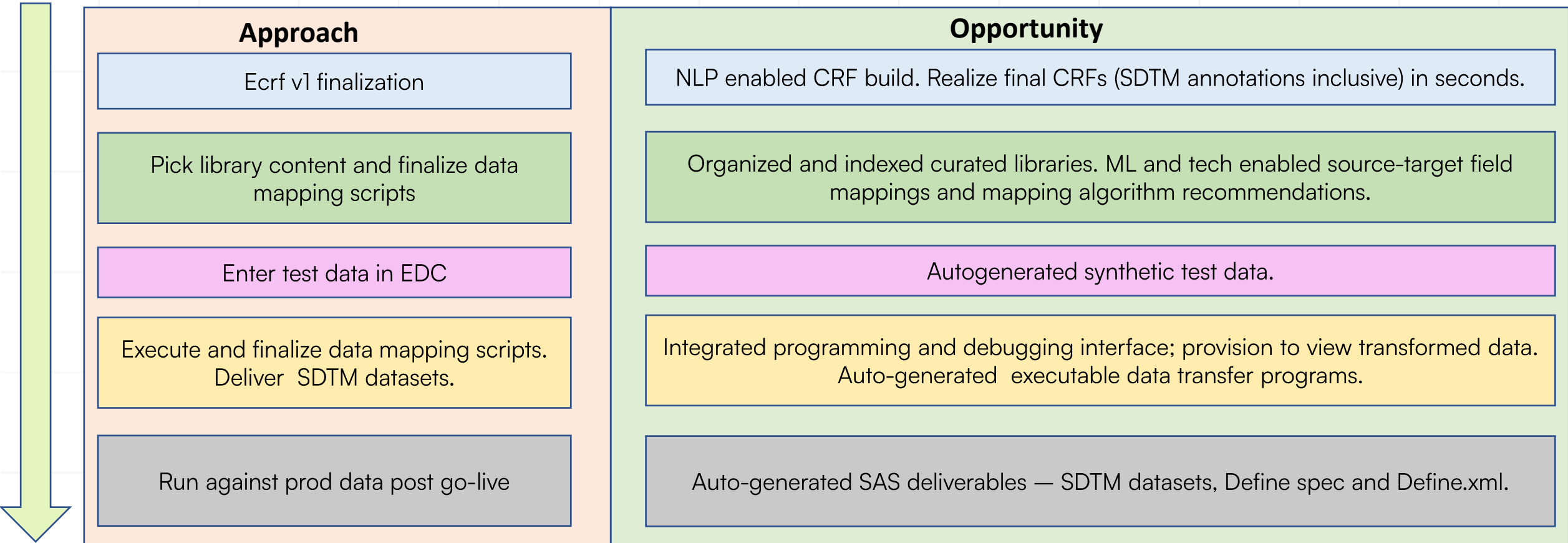


Six Sigma and Lean methods among others have supported process re-engineering initiatives over the past decade, helping identify time-traps and process waste.

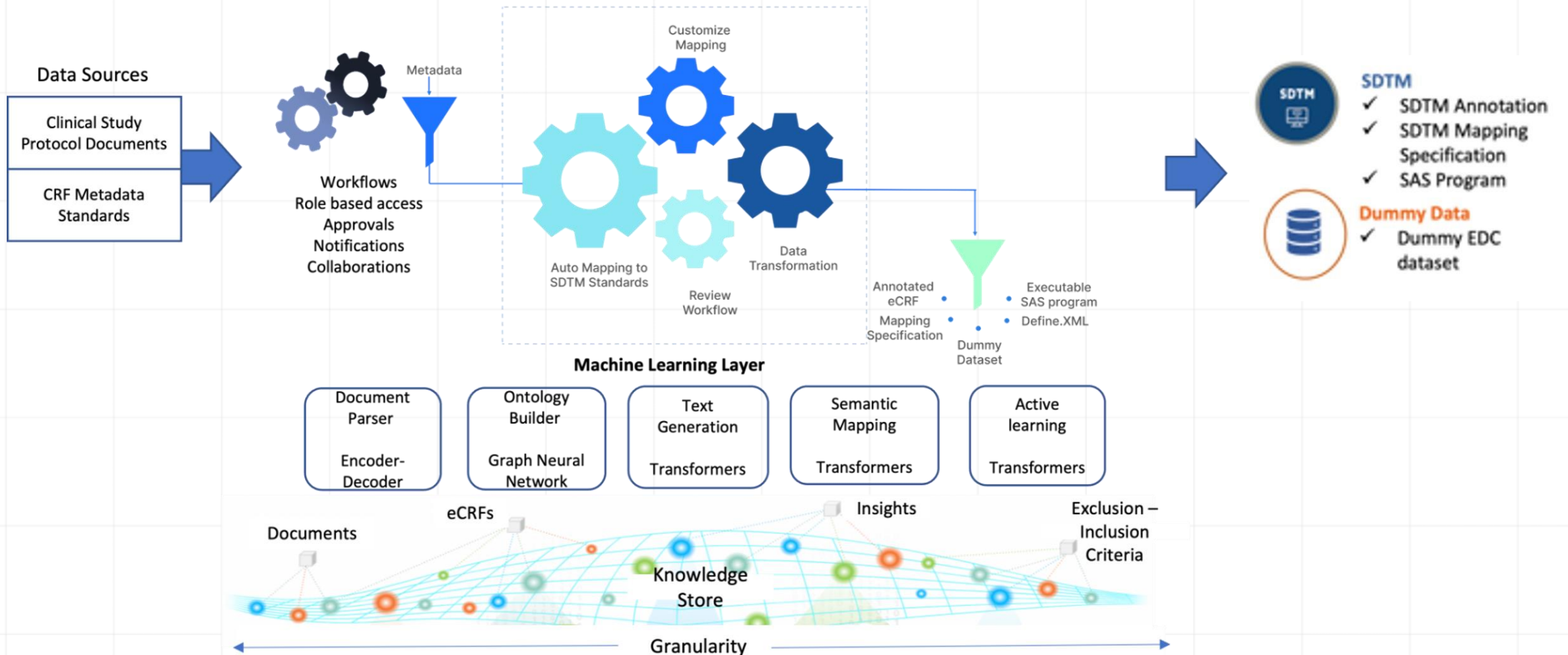
Optimized process models have had a positive impact on SDTM delivery approach, accelerating creation of SDTM datasets.

New tech enablers like RPA, NLP, AI/ML together with integrated and comprehensive product design can further revolutionize the SDTM delivery model, by generating purposeful recommendations and accelerating creation of SDTM deliverables.

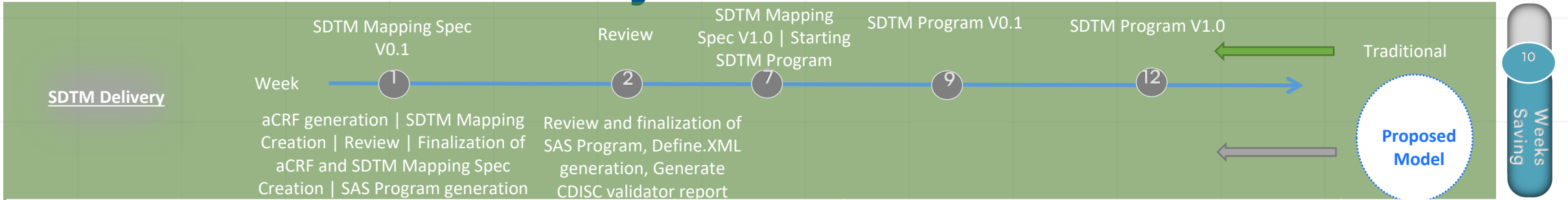
# Traditional approach and opportunities



# Re-imagined SDTM delivery model



# SCDM Live Case Study



Activities	Challenges	Usual Timelines	What future looks like	Performance on Live Projects
SDTM Annotations	Information consolidation approach with skimming through multiple PDF files to identify annotations from past studies and libraries	2-3 days	Auto-generated SDTM annotations Systematic assimilation of data from past studies. Curated and organized annotation library for quick fetch and retrieve.	72%
SDTM Mapping Spec v1.0	Requires SDTM expertise to map raw structures to SDTM delivery structures, program mapping expressions. Absence of curated libraries.	6-8 weeks	ML driven source to target mapping recommendations. Active learning-based system that assimilates and matures over time. ML and smart code enabled mapping algorithm recommendations. Curated and organized libraries for quick fetch and retrieve.	85%
SDTM Double SAS Programming	Manual code development.	5-6 weeks	Autogenerated programs.	70%
Testing SAS programs on raw datasets	Wait for production data	1 week	Systematically generate production-like dummy data. Productized approach to execution, debugging and generation of SDTM datasets.	95%
DEFINE.XML generation	Mechanical activity	2 weeks	Auto-generated delivery-ready define.XML.	100%
CDISC Validation	Automation available	2-3 days	Integrated within the productized solution. UI driven approach to review and resolution.	100%

# Conclusion



SDTM delivery will only get better and quicker, helping business realize accelerated and high-quality deliverables consistently.

Advancements in data science and technology will enable this transformational journey.

Like with all productized solutions in general and ML powered solutions in particular, adherence to ethical cognisance and data/metadata confidentiality considerations is a must.