

SDTM Automation: Implementation, Rollout and Lessons Learnt

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Introduction

- **Medical Device originally**
- **Pharma re-entry**
- **Value Proposition for implementing CDISC for MD**
 - One process company-wide
 - Benefit from Pharma standards library, automation tools and governance
 - Harmonized clinical data for end-to-end automation
 - Enable future use cases
 - Improved data quality and increased efficiency

Clinical Data Standardization (CDS) Project

- **Team**

- Statistical Programming
- Data Management
- Statistics
- IT business partners
- CDISC consultants

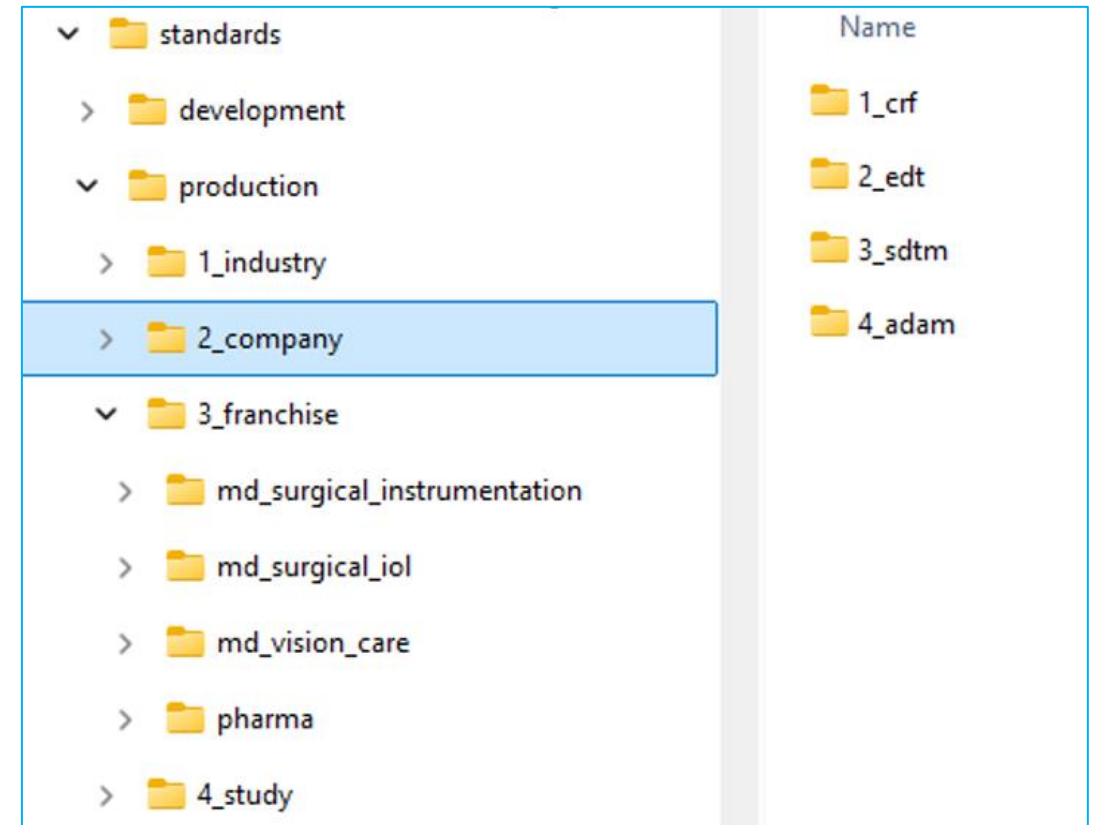
- **Project Goals**

- Build standards library
- Gain internal CDISC expertise
- Develop automation tools and processes including governance
- Get ready for Pharma Submission
- Lay the foundations for CDISC-based MD studies

Standards Library

SDTM and ADaM specifications with mappings from source datasets and machine-readable instructions for creation of SDTM datasets

- **Industry** – CDISC Models, Implementation Guides, External Dictionaries, Codelists
- **Company** – Clinical data and artifacts that apply across all franchises
- **Franchise** – Clinical data and artifacts that apply to specific franchise
- **Study** – Clinical data and artifacts that apply to a single study; specialized versions of company and franchise CRFs for a specific study.



SDTM Pipeline

- **Metadata-driven, SAS-based application**
- **Components are chained together to form a pipeline**
 - 15 mapping functions
 - Simple code can be injected
 - Complex code (multi-step) injections can be custom-built
- **Study-specific processing can be added**
- **Code and standards are managed centrally, overrides possible**
- **Quality checks** (examples)
 - Progress report – unmapped source items, % mapped overall score for the study
 - Flag records that do not meet SDTM unique key requirements
 - Identify non-printing special characters
 - Compare datasets vs. specifications (actual vs planned)

Trainings

- **Topics**

- CDISC Fundamentals
- NCI Controlled Terminologies
- P21 Conformance Checks
- Submission Package

- **Batches – aligned with project activities and roll-out of standards**

- Batch 1 – CDS project team
- Batch 2 – Programmers and statisticians for the first Pharma and MD studies
- Batch 3 – All Biometrics associates in US and Japan
- Batch 4* – All Biometrics associates in other countries

*Conducted by CDS project team

First Studies

- **Dry Run 1** – recreate SDTM, ADaM, TFLs from completed MD study
- **Dry Run 2** – completed MD study
- **Dry Run 3** – completed outsourced Pharma study
- **First NDA** – positive feedback

Dry Run 1 Issues	Enhancements
Manual harvesting of specifications from the library	Developed programs that automatically harvest specifications from the library to create combined study specifications for all applicable domains. These specifications include mappings from source datasets and machine-readable instructions for creation of SDTM datasets.
Separate specifications for P21 define.xml causing redundant manual work	Enriched the mapping specifications to also include all information needed for P21 define.xml Developed programs that automatically create near complete P21 define input files from the enriched specifications – needing few manual/final updates
SDTM and ADaM specifications had very different structures	Harmonized the SDTM and ADaM mapping specifications as much as possible
Change of mindset from study-specific to consuming standards	Evolved processes and reports to enable optional items to be excluded where not used and enable additions

Keys to Success

Consultants' CDISC expertise plus Alcon's strong process orientation

- **One-Size-Fits-All Studies**

- Optimized sequence of activities
- Streamlined and automated tasks
- Repeatable processes – Users Guide, Checklists
- Standards mindset is enterprise level
 - Office hour sessions
 - CDISC training sessions
 - Small group and/or one-on-one mentoring

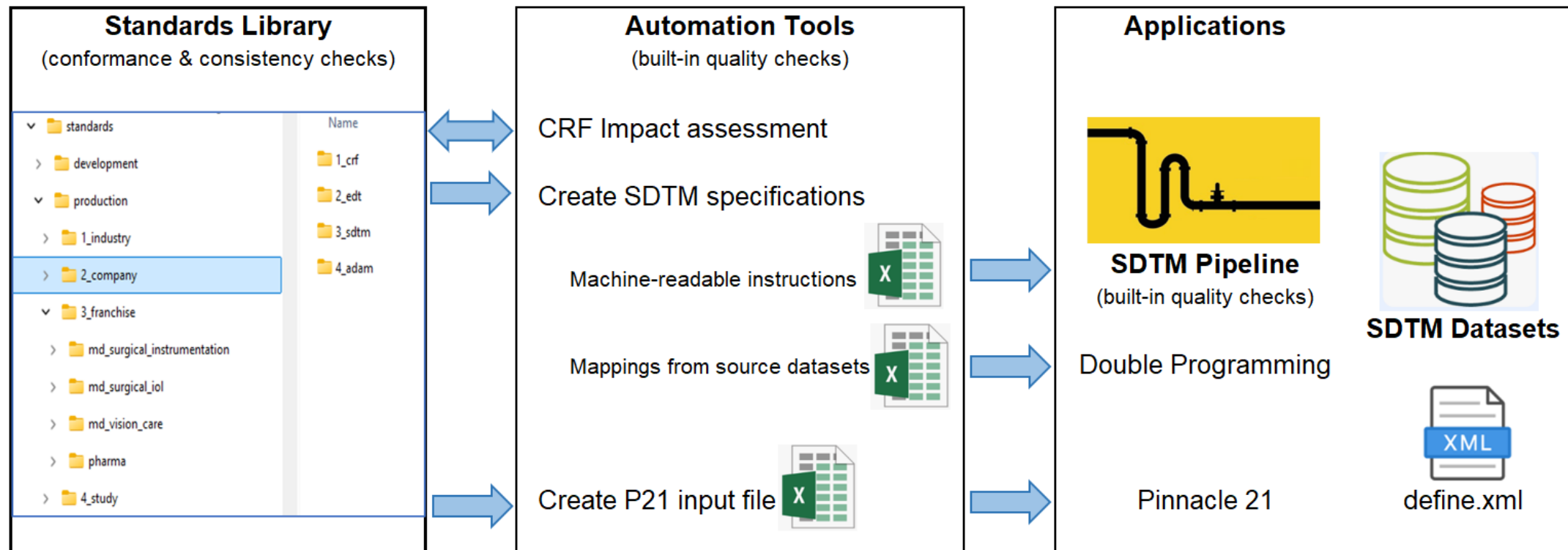
SDTM Standards Library contributions for latest studies (by franchise)

Level	Pharma	MD Vision Care	MD IOL	MD Instrumentation
Company	45%	35%	35%	Not started
Franchise	45%	40%	45%	
Total	90%	75%	80%	

Keys to Success

- Automation Tools

The SDTM Framework



Keys to Success

- **Standards Management and Governance**

- Guidance and support to programming teams
 - Partner with study team to ensure correct implementation
 - Monitor deviations from the library
 - Check the library metadata for integrity, conformance as well as consistency
 - Ensure that the library is complete, accurate and high quality
- Conduct lessons learnt sessions
- Maintain a tracker for fixes, enhancements, and wish lists

- **Internal CDISC Expertise**

- Layered support pyramid
- Standards Manager
- CDS Project Team
- Subject Matter Experts

Roadmap

- **Extend the library for MD**
- **More automation**
 - Enable dataflow from protocol & CTMS for creation of SDTM TDs, CDISC package
 - Generate SDTM+ by FPFV for selected MD studies
 - Create ADaM pipeline
- **Improve management of standards**
 - Use of workflows, versioning, audit trail, rollback and other capabilities
- **Explore AI use cases** (e.g., map new CRF to SDTM, annotate CRF)

Conclusion

- **Number, size and complexity of data in MD continue to increase**
- **Transition to CDISC standards**
 - Plan holistically, implement incrementally
 - Embrace the iterative nature of standards implementation
 - Aim to streamline but do not cut essential steps
 - Consider speed, simplicity and long-term efficiency
- **Unified standards framework** (standards library, SDTM pipeline), **automation tools and governance** can achieve high quality submission deliverables with less manual effort and rework
- **One set of well-planned applications, processes and tools** for both Pharma and MD

Thank You!