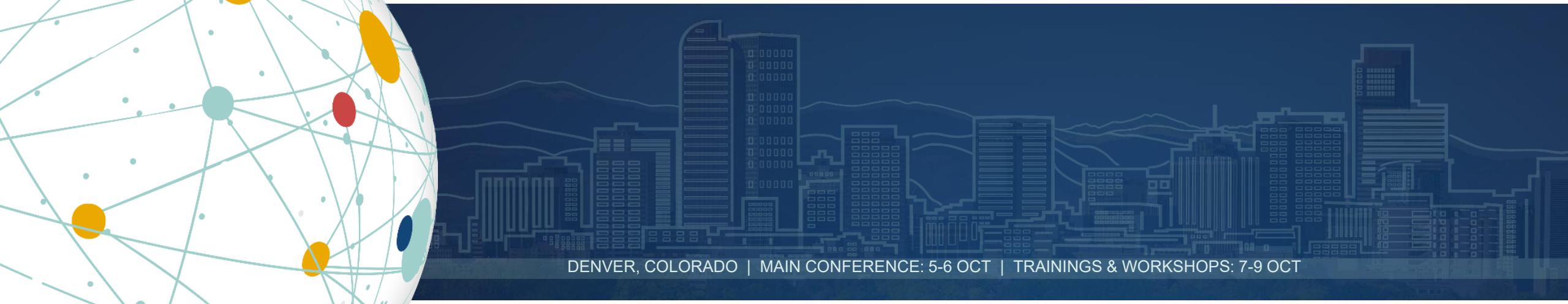


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Governance Powered CDISC Implementation: Driving Standards Reuse at Scale

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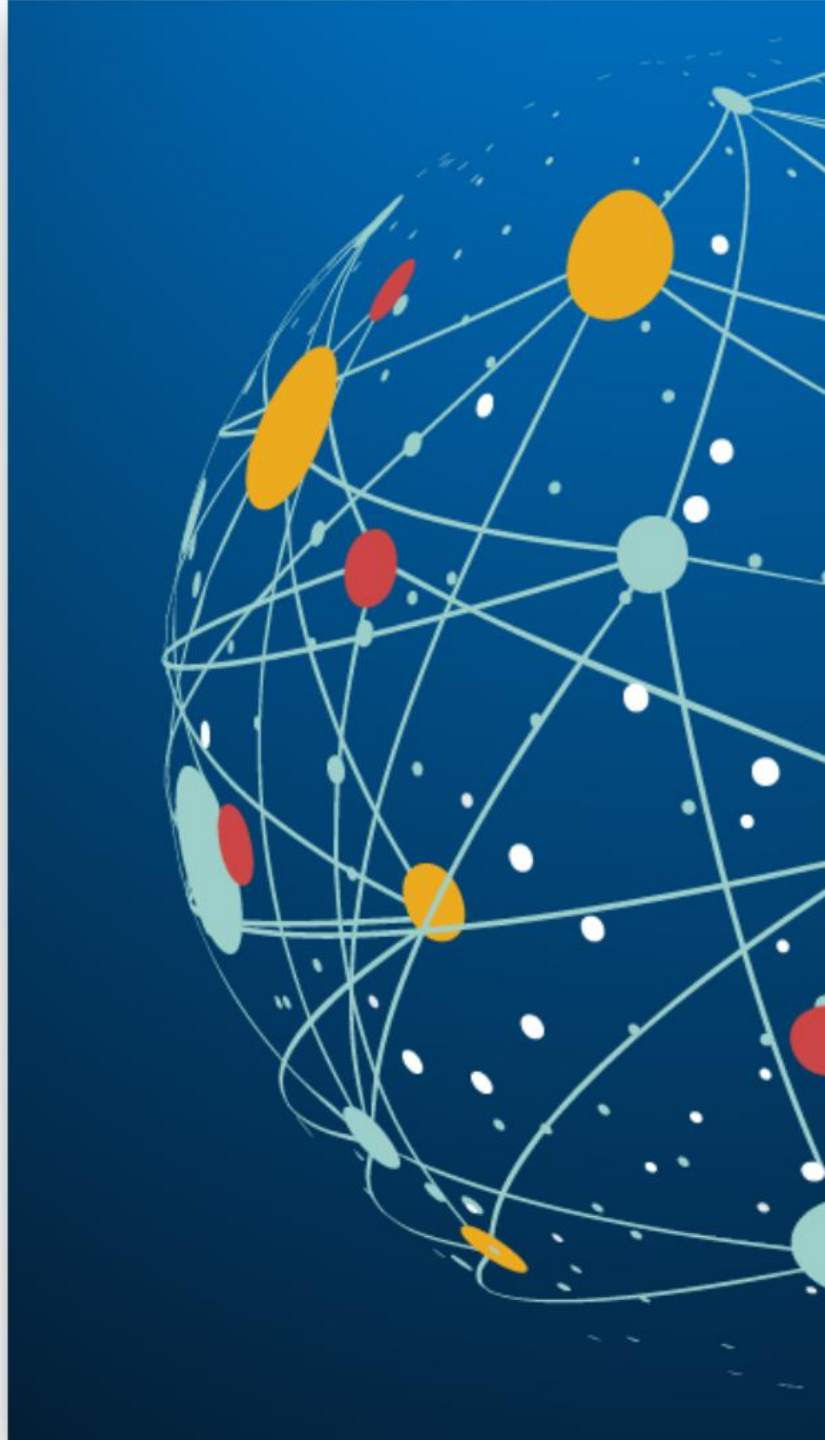
Agenda

1. Introduction
2. The Standards Framework
3. Governance Maturity Levels
4. End-User Value as a Driver of Adoption
5. Roadmap
6. Conclusion

Introduction

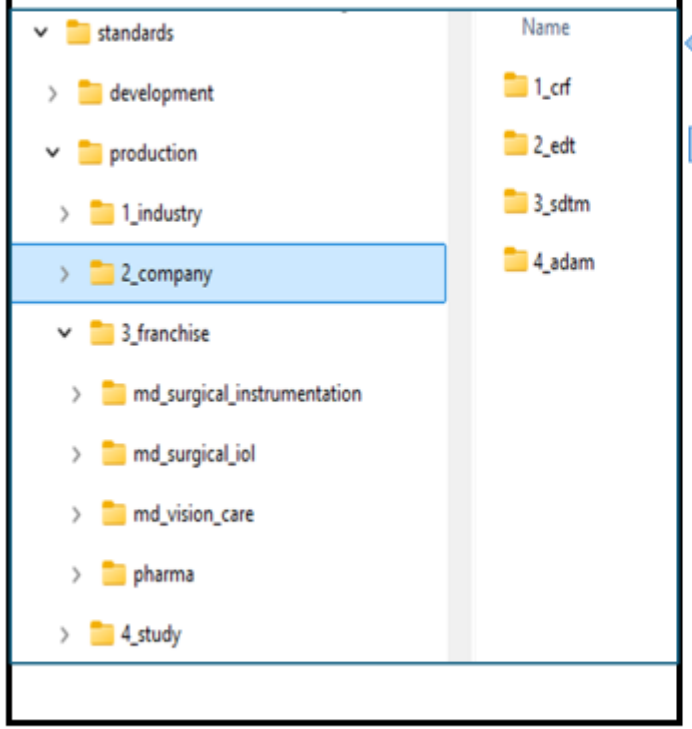
- Clinical Data Standardization Project
  - Gained internal CDISC expertise
  - Built standards library
  - Developed automation tools and applications
  - Implemented processes including some governance
- Evolved from building standards to enabling reuse

Without Governance → Build Standards	With Governance → Enable Standards Reuse
Study A → Build (maps data one way) Study B → Rebuild (maps the same concept differently) Study C → Rebuild again	Study A → Build Study B → Reuse Study C → Reuse
Compliance, Quality, Higher Costs	Consistency, Efficiency



The Standards Framework

Standards Library
(conformance & consistency checks)



Automation Tools
(built-in quality checks)

CRF Impact assessment

Create combined specifications

Machine-readable instructions

Mappings from input datasets

Create P21 input file

Applications

SDTM/ADAM Pipelines
(built-in quality checks)

Datasets

Double Programming

Pinnacle 21

define.xml

Standards Governance

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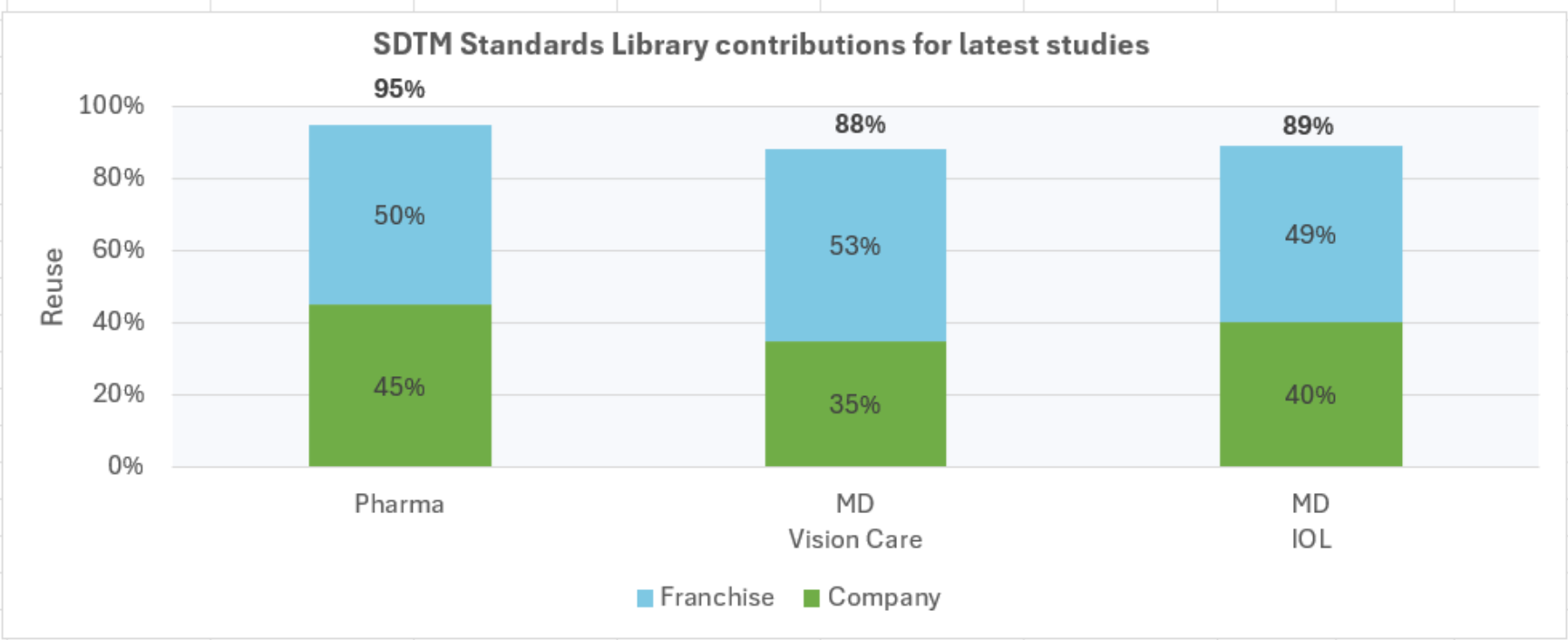
Governance Maturity Levels

Dimension	Reference Standards	Controlled Standards	Governance Powered Standards
Focus	**Compliance**	**Consistency**	**Reuse and Scale**
Coverage	**Static reference** standards	Controlled and **versioned** standards with **structured metadata**	**Machine-readable** standards with embedded **conformance, consistency and quality checks**
Ownership and Decision-Making	**Manual** study-level interpretation and implementation - Training and implementation guidance - Limited oversight and monitoring - Ad hoc maintenance	**Centralized and owned by a Standards Team** or Governance Board - Defined ownership and accountability - **Governance through people, meetings, and processes** - Formal change review and approval processes - Deviations are reviewed and controlled	Strategically **embedded in the framework** - Rules are built into workflows and tools - Users are guided toward preferred decision - **Standards managed as enterprise assets** - Standards Manager reviews only exceptions, focuses on **higher-value tasks** and continuous improvements
Reuse	**Encouraged** but largely manual Variability across studies	**Actively promoted** through oversight Consistent interpretation and implementation	**Default choice** in workflows and tools **Cross-study consistency** Metrics-driven
Business Value	Compliance and study-level quality Automation is very limited Limited efficiency gains	Improved compliance and quality Automation is possible Some efficiency gains	**Quality by design** **Automation leads to efficiency** Faster SDTM and ADaM development AI-ready
Examples	Cut and paste to study documents	Standards Manager approves a new variable Governance Board reviews a CRF deviation	CRF comparison recommends existing standards Deviation of new mappings are auto-flagged

Note: Illustrative progression of governance maturity rather than a fixed model

End-User Value as a Driver of Adoption

Percentage of Reuse



Note: CDISC is not yet used for MD Instrumentation

CRF impact assessment – A report against the Study Design Specifications identifies which company and franchise standards must be used

Percentage of Reuse

Step 1: CRF impact assessment

				SDTM Source to Target Mappings in Standards Library			
Form	Source	# Standards (Library)	% Standards (Used in Study)	# Items Removed	Items Removed	# Items Added	Items Added
DM001	COMPANY	11	100%				
AE003	FRANCHISE	32	94%	2	AERELNST,LINKEDITEM		
XI004	Study XYZ205E001	7	57%	3	XIMETHOD,XIMETHODSP_1,XITIM	1	lbl_XI004
YC001	*<Not in SDTM library>*	0					

Step 2: Create combined specifications

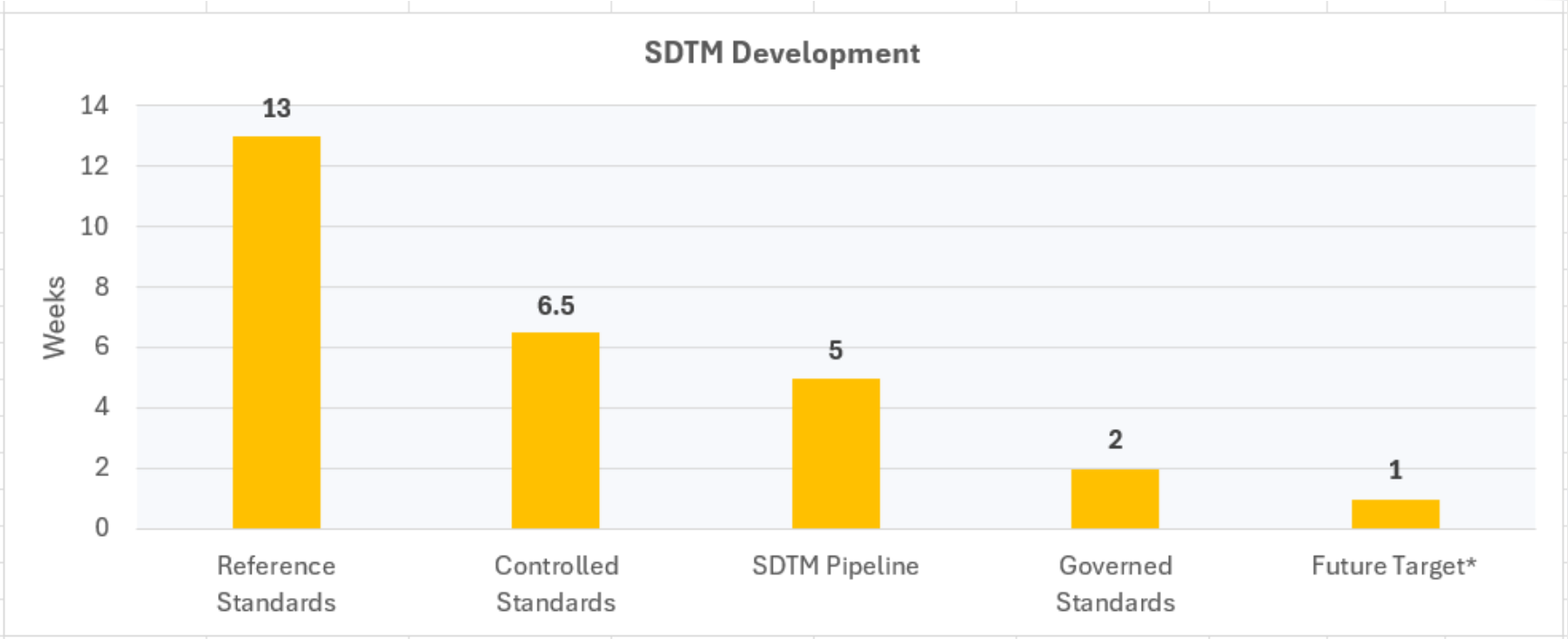
- Automatically harvests company and franchise standards from library
- New specifications are automatically flagged for Standards Manager review

Step 3: Pipelines – allow controlled study-specific adaptations

- Drop items from library that do not apply to the study
- Allow additional study-specific items



Cycle Time Metrics



* Interconnected systems, End-to-end standards, Full automation, Use of AI

We reduced development time significantly by adding capabilities and incorporating governance into the standards framework

End-User Value

Standards Library	Automation Tools (CRF Impact assessment, Create specifications, Create P21 input file)	Applications (SDTM and ADaM Pipelines)
Routine conformance and consistency checks - File level checks - Variable level checks - Other checks e.g., correct attributes, duplicate mapping of same source	Users are guided toward reuse while retaining flexibility for justified study-specific needs Embedded quality checks & reports e.g., - CT is missing from library - Item or entire source is not mapped - Comparison of datasets with specifications (actual vs planned)	Embedded conformance, company-specific metadata and data checks - Critical errors stop processing - Warnings highlight issues
High quality, reliable, builds trust	Easy to use, reliable guidance	Right first time
Reuse is easier and more beneficial than creating study-specific solutions	Reuse is default choice in workflows and tools	Identifying issues earlier than downstream P21 reduces rework making reuse more efficient

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Roadmap

- Strengthen CDISC SME Core Team and increase availability for day-to-day support
  Standards Manager
  - Enterprise-wide stewardship of the standards framework
    - Timely review of study-specific specifications
    - Upstream and downstream impact assessment
  - Coordination of priorities and resource needs

- Consolidate user guides and checklists in a visual, searchable Wiki
- Replace free-text Excel entry with a UI and a central database
  - Controlled selections, smart defaults, and real-time checks
  - Use a database as a single metadata source for specifications and mappings

- Establish a direct connection to source datasets enabling upstream quality checks
- End-to-end standards to enable more automation and the responsible use of AI

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When governance makes standards reliable and easy to use, reuse becomes the preferred choice — not just a mandate.



Reference
Compliance

Controlled
Consistency

Governance Powered
Reuse at Scale

Thank You!



Questions?

