Transforming the Creation of Study Instance Metadata using a Metadata Repository

Presented by Prathima Surabhi, Director Standards Developer, AstraZeneca

Meet the Speaker

Prathima Surabhi

Title: Director, Standards Developer

Organization: AstraZeneca

Over 15 years of industry experience as a clinical data standards expert and statistical programmer. Volunteering experience in CDISC ADaM team. Passionate about learning new industry trends and leading transformative cross-functional initiatives.

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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Agenda

1. Vision
2. Problem Areas
3. Benefits
4. Journey
5. Implementation Challenges
6. Conclusion

Vision: Bringing Cures to Patients Faster

A robust standards metadata repository lays a strong foundation upon which automations and other cycle time reductions can be built

Enables the creation of one source of truth that links together end-to-end standards components from data acquisition (CDASH) to tabulation (SDTM) to analysis (ADaM)

It is important to have a system that provides the standards metadata in a machine-readable format to be easily consumed by other systems to enable ingestion checks, visualizations, and other automated deliverables

Problem Areas

Lack of machine-understandable data specifications limiting automations for study build, data cleaning, and analysis

High level of manual activities for routine tasks

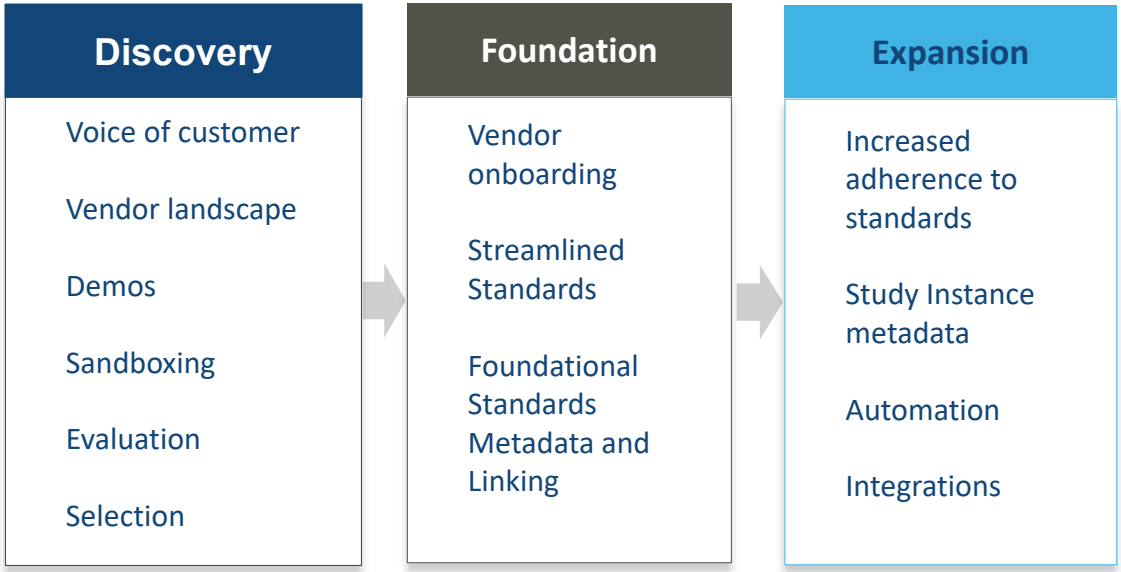
There was variability across studies in the implementation of clinical data standards.

Downstream teams did not have confidence that the data specifications (i.e. study metadata) completely and comprehensively reflect what they would see in the actual data

Benefits

- Facilitates study set-up for data collection (EDC build) as well as Analysis & Reporting (Study specifications, Define.xml)
- Provides machine-readable Study Instance Metadata
- Ensures consistent study specifications process and structure
- Enables consistent use of standards and checking adherence to standards
- Compare metadata across standards, studies, version control, change logs
- Ensures improved maintenance of standards metadata libraries for collection (CDASH), tabulation (SDTM), and analysis (ADaM)
- Acts as a link between standard components to facilitate impact analysis
- Library of metadata allow faster sister study builds
- Enhanced adoption to newer version of CDISC standards

Journey


Discovery
Voice of customer
Vendor landscape
Demos
Sandboxing
Evaluation
Selection
Foundation
Vendor onboarding
Streamlined Standards
Foundational Standards Metadata and Linking
Expansion
Increased adherence to standards
Study Instance metadata
Automation
Integrations

Implementation Challenges

- There is no perfect product
- Adoption to new technology, ways of working
- Agile technology deployment - mindset change
- System performance issues
- Technical issues for Integration
- Delivering scope under aggressive timelines

Conclusion

- The AstraZeneca experience is a great example of the journey to implementing a COTS solution for metadata management
- We have laid a strong foundation that will allow us consistent re-use of metadata and metadata driven automation across the organization
- The journey continues…

Thank You!