

Implementation of CDISC standards supported by global mapping process and metadata library (Case Study)

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Global teams – Different time zones

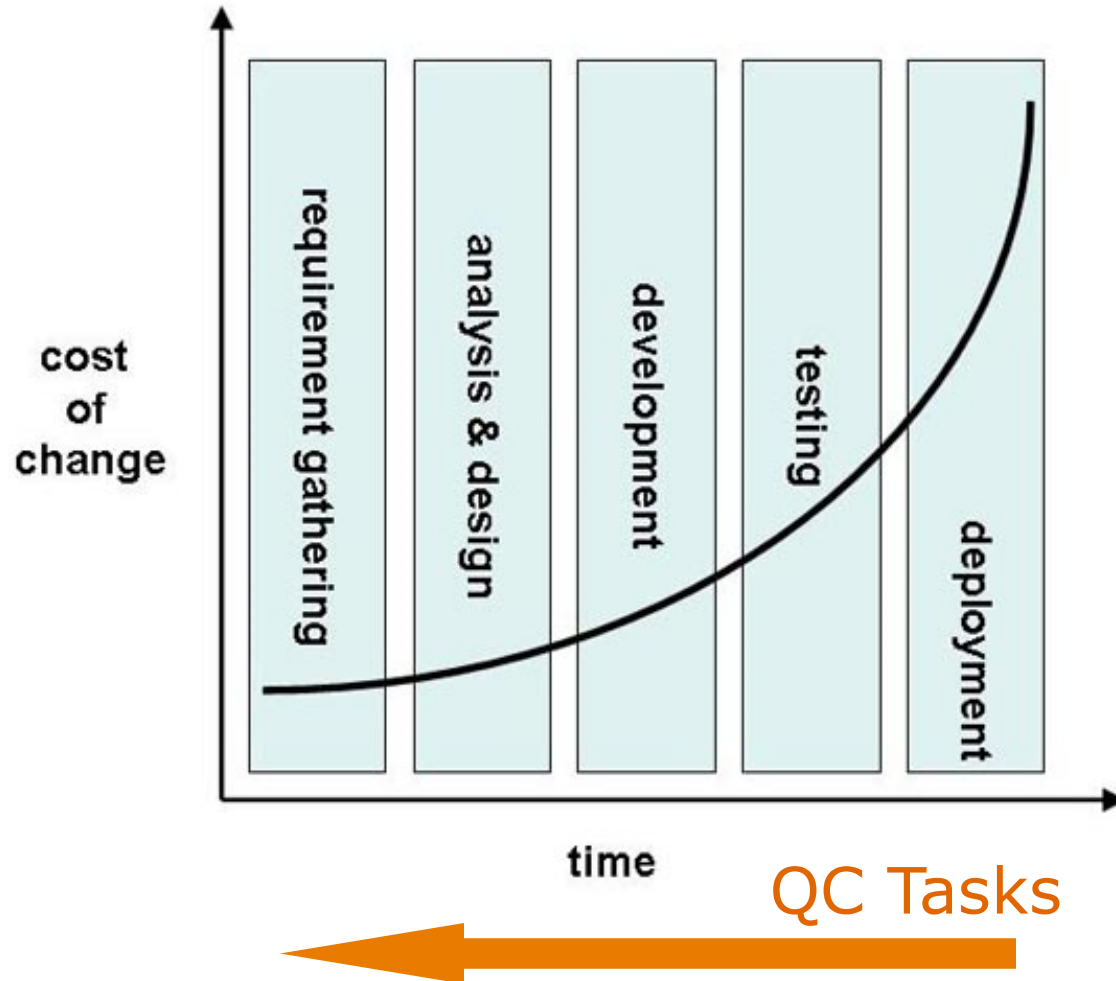


Outline

- Past situation
 - Challenges of mapping to CDISC SDTM with global, virtual teams
- Implementation approach
 - Global process
 - Enabling environment with meta library
- Results | Conclusions

Cost of Change Curve

Early QC Paradigm



Mapping to CDISC SDTM with global, virtual teams

Past challenges (1/2)

- Teams and team members distributed globally
- Multiple tasks involved
 - Creating specifications
 - Programming SDTM datasets
 - Technical review of specifications and programs
 - Functional review of the datasets
- Working differently
 - No consistent approach in creating specifications and programs (examples: data transfer, define)
 - Re-usability was difficult to achieve
- Strict time lines

Mapping to CDISC SDTM with global, virtual teams

Past challenges (2/2)

- Studies:
 - New and legacy
 - Coming from different systems
 - Source database extracts available in different structures
 - Have to be made ready for CDISC submissions
 - Metadata are often limited/not available
 - No re-usable objects available
- Standards:
 - Many levels and versions simultaneously
 - Multiple customer specific standard enhancements
 - Growing complexity of standards

Mapping to CDISC SDTM with global, virtual teams

- Efficient generation of SDTM compliant data sets requires establishment of new processes!!!

Approach: Global process for global, virtual teams

Working Worldwide – Goals (1/2)

- Consistency and re-usability of standards (incl. sponsor-specific)
- Definition of a global process:
 - Start from existing local best practices
 - Example: Set-up for blinded vs. unblinded programmers, technical programming code review
 - Create common use cases
 - Example: Creating consistent test cases for quality and efficiency

Approach: Global process for global, virtual teams

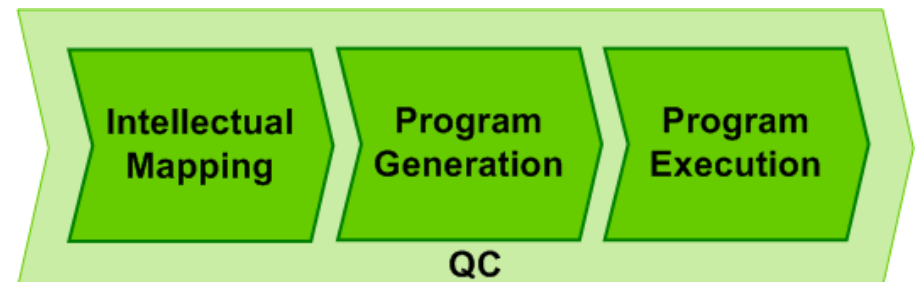
Working Worldwide – Goals (2/2)

- Definition of a global process:
 - Streamline processes
 - Create process maps for all data conversion scenarios
 - Use advantages of a global player
 - Global teams to follow the streamlined process
 - Convert data consistently across the globe
 - Look for productive tool to support processes
 - All components available in one central location to easier implement best practices
 - Global accessibility of the enabling environment
 - 21 CFR Part 11 compliant and validated
 - Flexible and scalable

Approach: Global process for global, virtual teams

Mapping Process (1/2) – Generic View

- **Face-lifting:** Designed to allow for task splitting
 - Intellectual mapping
 - Determine how to map trial data into SDTM
 - Detect and create re-usable mapping templates
 - Program generation
 - Automate generation of mapping programs
 - Program execution
 - Create environment for controlled and traceable program execution (SCE)
 - QC
 - Multi-stage QC

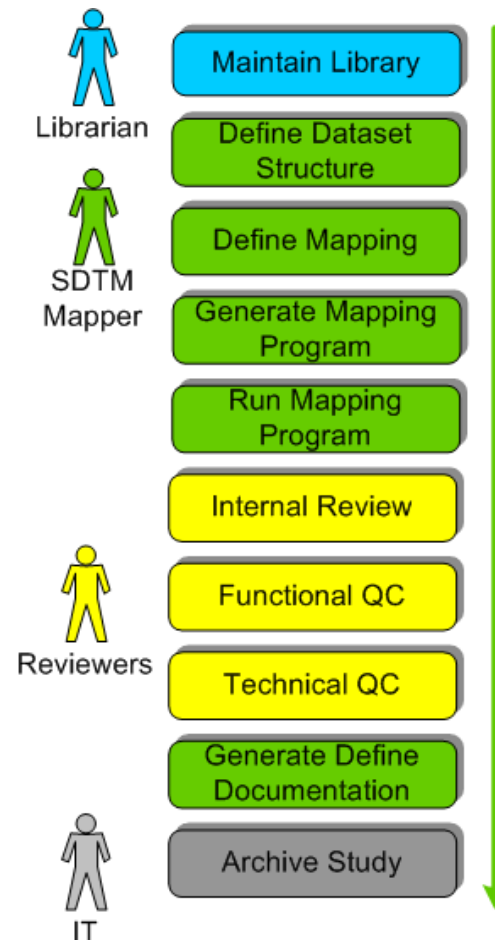


Approach: Global process for global, virtual teams

Mapping Process (2/2) – Generic View

- Roles

- Librarian
- SDTM Mapper
- Reviewer(s)
- IT



Mapping Process: Maintain Library (1)

- Library:
 - Common global library
 - Customer specific models
- Supports of different standard types:
 - Terminology, codelists, format catalogs
 - Study folder structures
 - Standard macros, mappings
 - Central lab specifications
 - Sponsor guidelines...
- Standards governance:
 - Versioned storage of parallel versions
 - Controlled access via roles

Mapping Process: Maintain Library (2) - Librarian

- Role Types:
 - Data Standards librarian
 - SDTM Mapping librarian
 - TLF Shells librarian
- Tasks:
 - Maintain information model and logical data models
 - Develop mapping templates and standard algorithms
 - Develop standard codelists, macros
 - Maintain consistency of variables (content, process)
 - Prepare recommendations for standards governance

Mapping Process: Maintain Library (3)

- Requests are submitted via standard electronic request form (including links to spec and code)
- User group evaluates requests
- Decision is communicated to requester
- If decided, object is created/amended
- After documented QC by independent librarian, new standard is released

“Metametadata” Concept

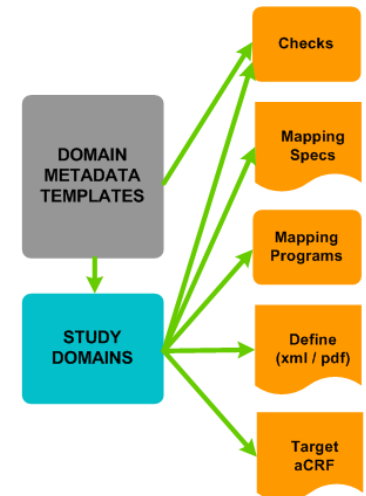
- “Metametadata” – Rules for metadata definitions
 - Define content/column structure for domain definitions
 - Define values for column content to support checks
 - Contain check rules for domain definitions

Rule examples:

*CDISC type – character, mandatory, {value space}
attribute sequence – integer, unique, starts with 1*

Mapping Process: Define Dataset Structures

- Define Dataset Structures:
 - Use SDTM domain templates to create target structures
 - *Optional: Derive source structures from datasets*
 - Import codelists and create format catalogs
 - Metadata check rules apply!



Mapping Process: Define Mapping

- Intellectual mapping - Define mapping specification
 - Define mapping with entimICE for each domain
- Standards exploited for:
 - Dataset structures
 - Standard conversion algorithms
 - Pre- / post-processing tasks
- Quality means:
 - Consistency checks in the mapping definition
 - Interactive review mode
 - Source side data in the mapping program

Mapping Process: Generate and Run Mapping Program

- Mapping programs are generated from mapping definitions
 - Programs contain parameters for datasets
- Programs are executed with set parameters
- Logs are reviewed
- SDTM check program is executed with standard and additional checks
- Mapping program is marked as ready for 1st QC step

Mapping Process: Quality Control

- 3-stage QC:
 - Internal review
 - Functional QC
 - Technical QC
- QC steps includes:
 - Logical checks (e.g. dates, visits)
 - Runs of SDTM check program
 - Assessment of pre-defined check criteria (e-forms)

Mapping Process: Generate Define Documents

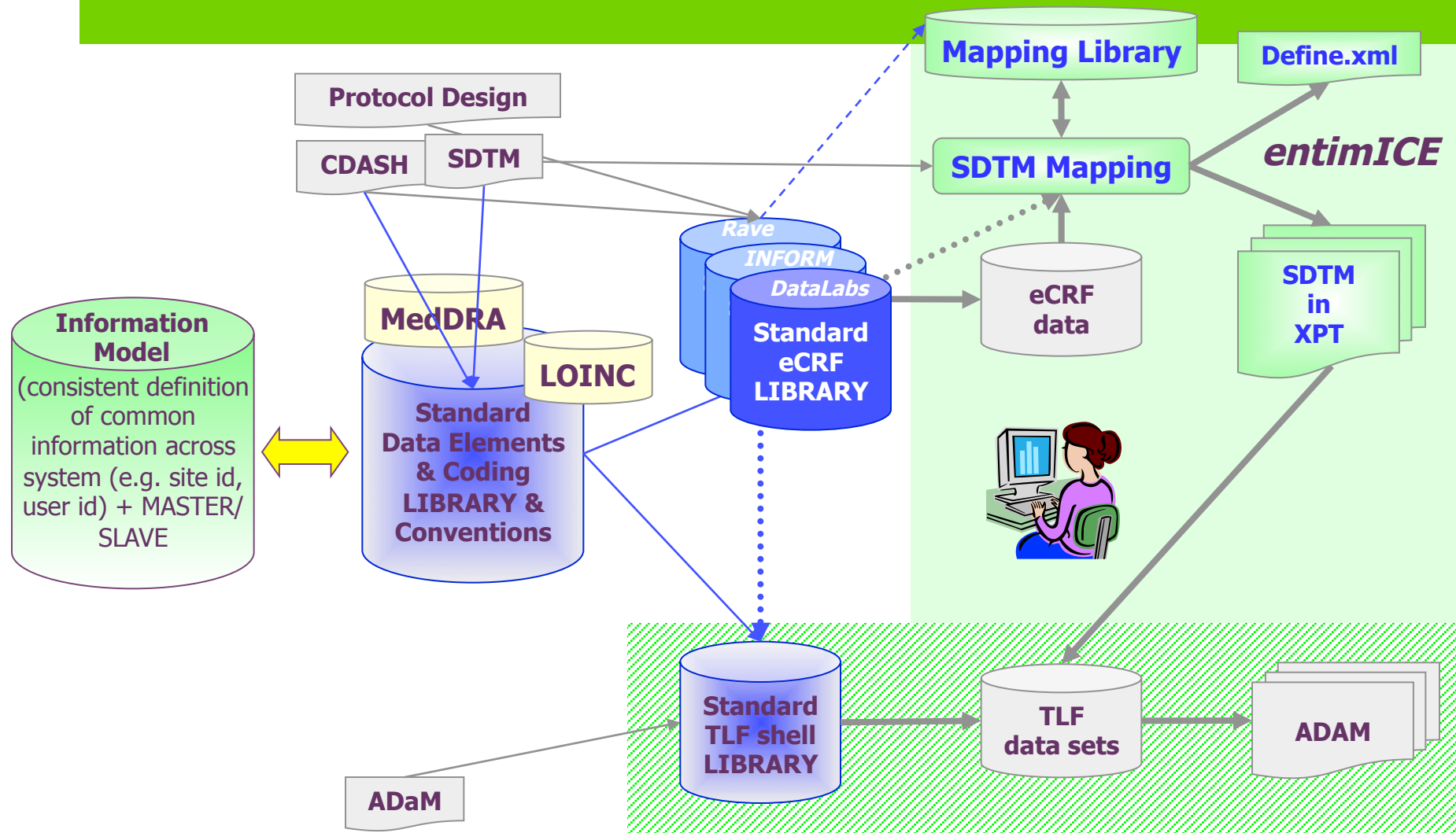
- Necessary elements are created (value level metadata, algorithms...)
- Domain metadata are reused to create define (used for mapping definition)
- All SDTM domains are linked to elements
- CRF annotation are scanned for pages
- Define is generated
- QC of define documentation is done workflow-based

Archive Study

- Requested study is exported as hierarchy with all reports and objects
- Access rights are removed
- Requester is notified

Data Standards

How does it fit together

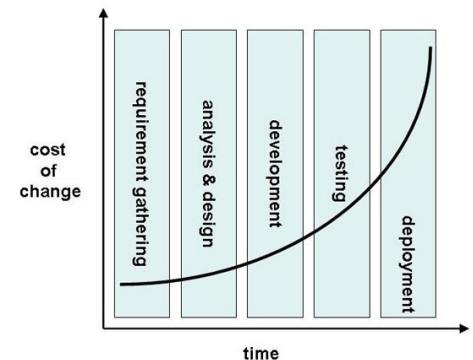


Results

- Teams work consistently across the globe
 - Process is defined and broken down into smaller tasks
 - Clear task responsibilities defined
- Same look and feel
 - Easier training of new colleagues
 - Tasks shared between remote team members
- Re-use of standard elements
 - Growing library saves time, increases quality
 - Efficiency in the data conversion process
- Continuous QC with multiple QC stops
 - Secures outcome quality

Conclusions

- Providing SDTM data transfers to sponsors is becoming habitual task
- Processes and tools to support this task need to be in place
- QC has crucial importance (the earlier, the better!)
- Flexibility required to support ongoing development and changes
- Vision: Standard eCRF plus a well-filled metadata store make life much easier



END

Many thanks for your attention!
Questions...?

VISION STARTS NOW!