

**How to improve quality control in
a data conversion process?
By extended usage of metadata!**

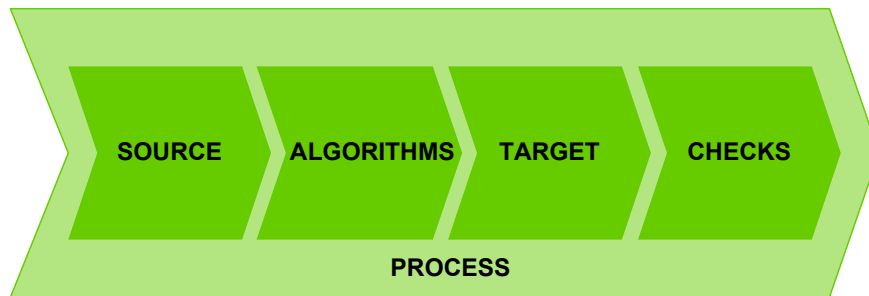
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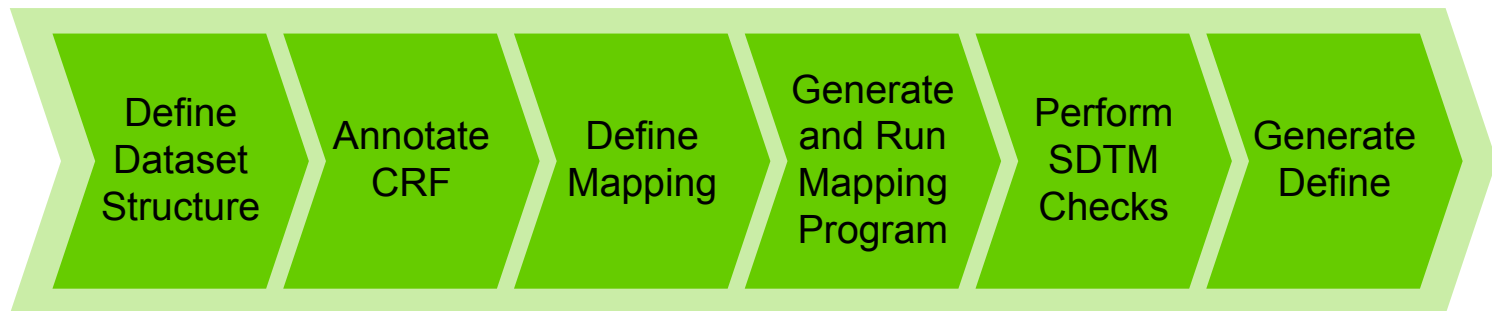
Data Conversion Process

SDTM Example

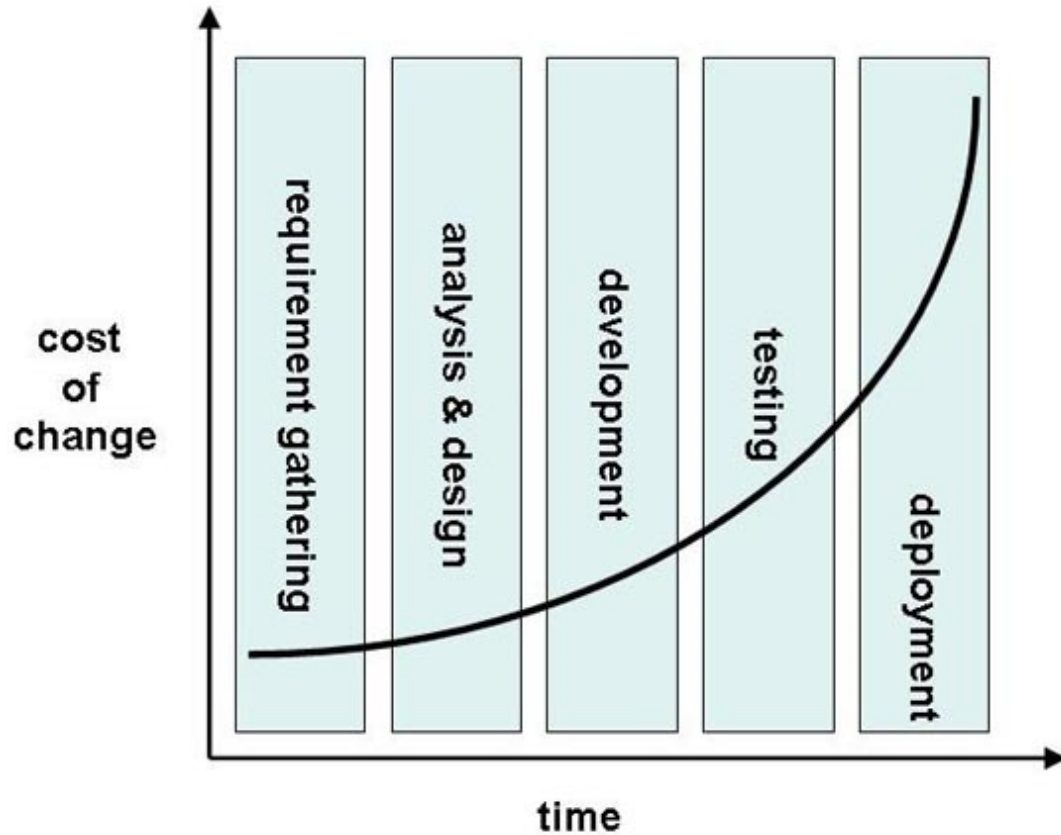
Generic view



Core process



Cost of Change Curve

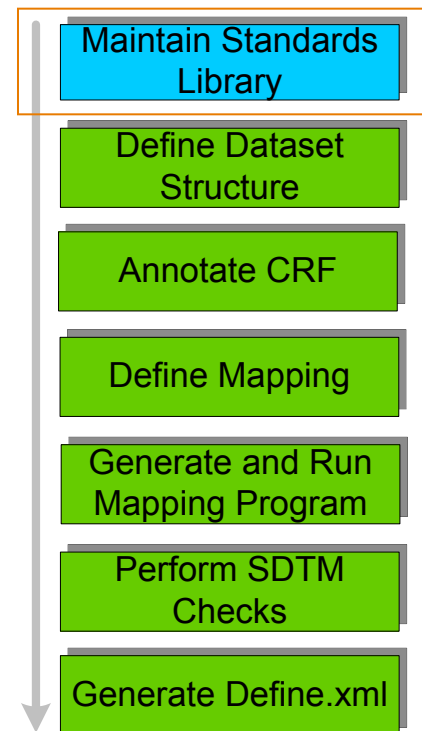


Early QC
Paradigm

← QC Tasks

Maintain Standards Library

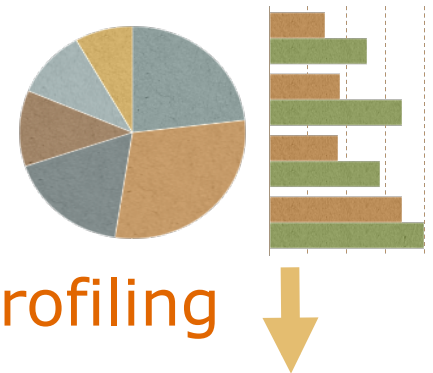
- **Invest effort into standards definition!**
- Metadata Types
 - Dataset descriptions (industry or company domains)
 - Conversion algorithms (text and code)
 - Mappings
 - Terminology...
- Challenges
 - Global, project, trial and study levels
 - Multiple standards / versions
 - Interlinked dimensions
 - Reusability



Analysis of cross-level and cross-study dependencies required!

Standards Metadata Profiling

- Compare metadata domain definitions
- **Detect and review discrepancies as early as possible!**

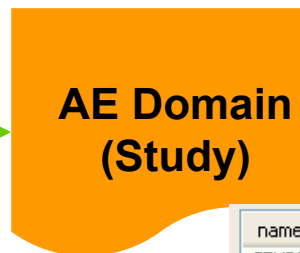


Data Profiling

Metadata



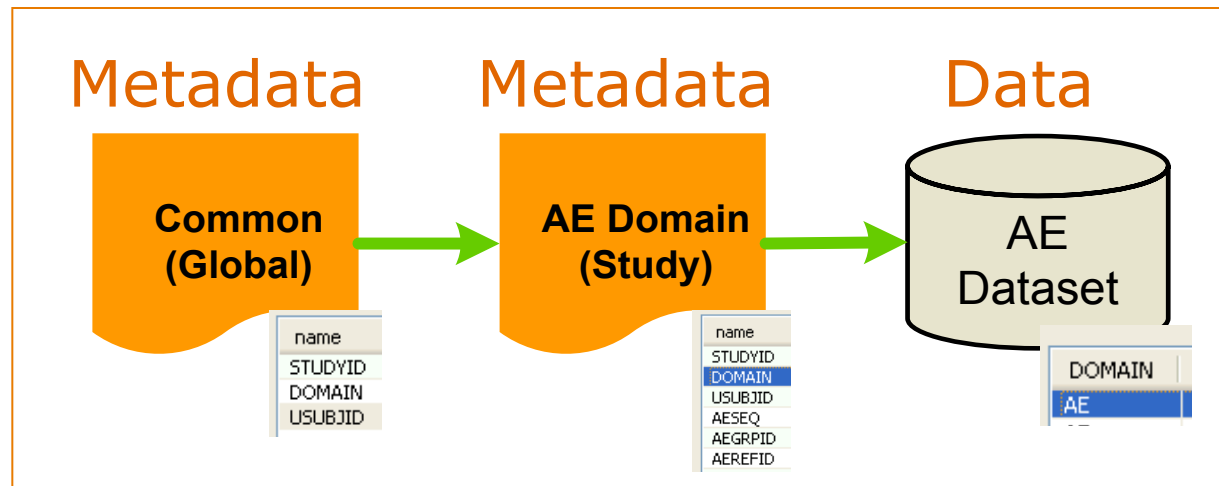
Metadata



46	1	1.77	24.5
44	0	1.62	30.2
46	0	1.66	33.1
62	1	1.80	21.9

Standards Impact Analysis

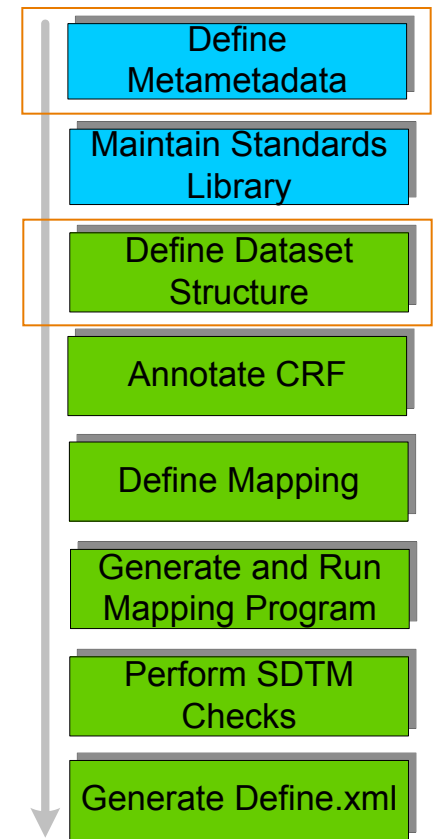
- **Track deviations between (changed) standards and related targets!**
- Analysis/update shall include impact on datasets linked to standards
- Versioning/audit trail required for updates



Define Metametadata

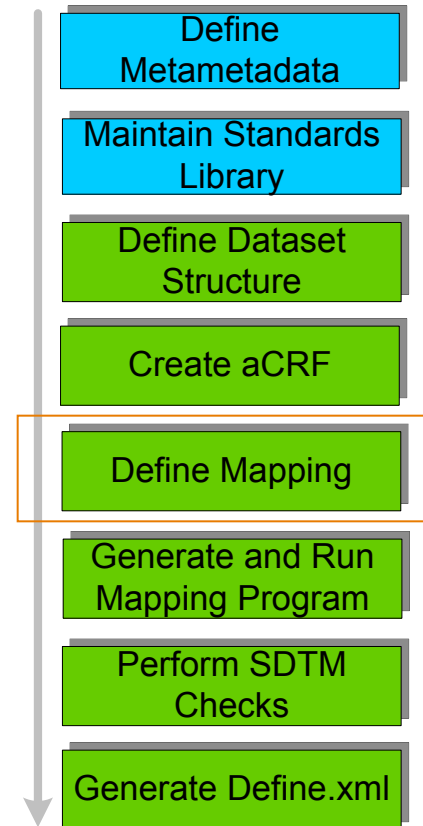
Define Dataset Structures

- Define “Metametadata”
(description of dataset metadata):
 - Columns
 - Formats to support checks
 - Configuration rules for metadata
 - *Rule examples:*
CDISC type – character, mandatory
seq – integer, unique, starts with 1
- Define Dataset Structures:
 - Use metadata domain templates
 - Derive from datasets, metametadata



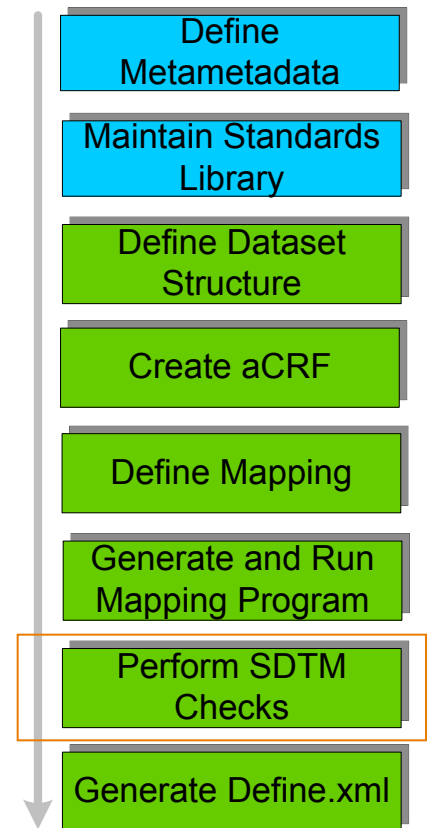
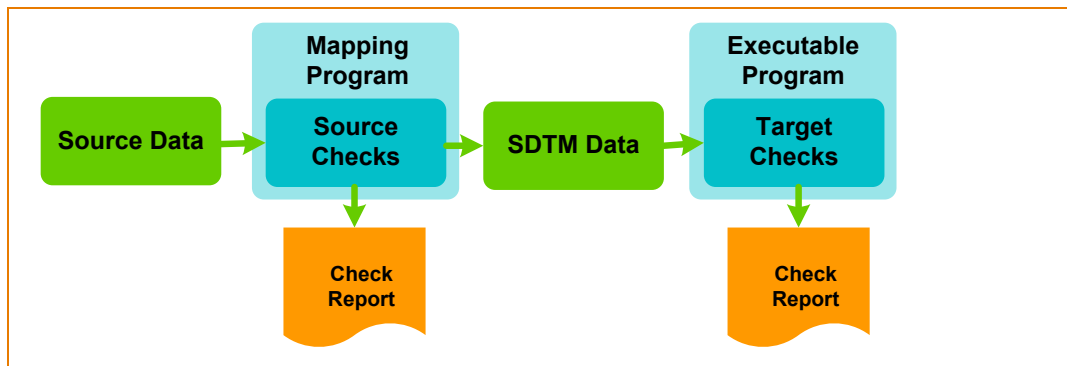
Define Mapping

- Challenges:
 - Repeated algorithms
 - Scarce experts
 - Redundancy
- **Exploit standards at maximum!**
 - Standard metadata (domains)
 - Standard conversion algorithms
 - Standard mappings
- Quality checks in the mapping definition:
 - Consistency checks
 - Review can be done language-independent



Perform SDTM Checks

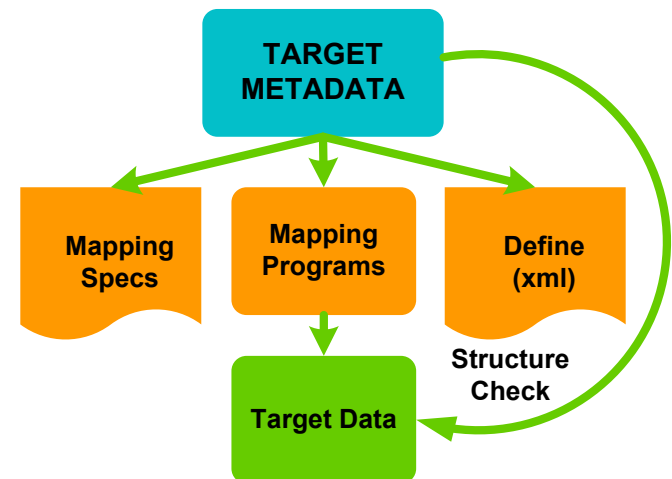
- **Integrate checks into conversion workflow!** (*incl. tracing*)
- Flexible definition of check criteria required:
 - Standard SDTM conformance checks
 - Customer checks
- **Checks from the 1st domain on!**



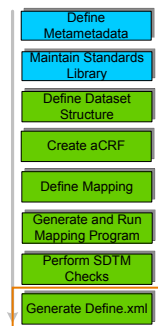
Generate Define Structural Checks

- Metadata driven, template based definition
- Check of data vs. metadata prior to:
 - Import/production
 - Define creation

Metadata Driven Process



Conservative Process

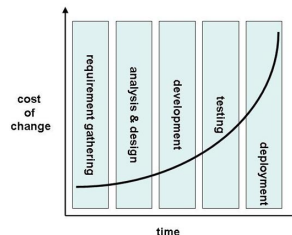


Metadata Challenges

- **Model related challenges:**
 - Metadata variation vs. metadata “inflation”
 - Interlinked dimensions
 - Automatic collection and processing
- **Organization related challenges:**
 - Effort for standard development
 - Consistent metadata management
 - Model independence
 - Different business processes
 - Regulatory requirements

Metadata Based Data Conversion Process

- **Metadata QC leveraged by smart tools/systems help you:**
 - Increase data quality and consistency
 - Reduce cost of errors
 - Flexibly support available and future standards
 - Increase reusability of process components
 - Set up controlled and traceable process



END

Many thanks for your attention!
Questions...?

VISION STARTS NOW!

Visit at entimo's booth or email to
dku[at]entimo.de