

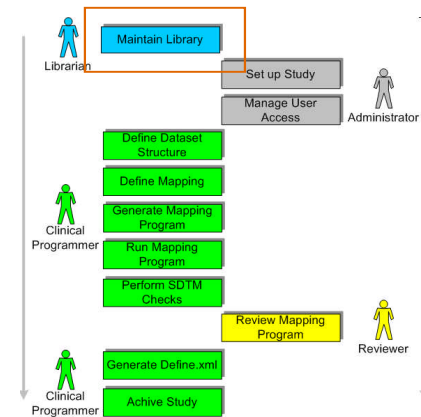
Supporting tools: meta-data library and mapping tool

Requirements

- Flexibility to support data models and workflows
- Reusability of work results
 - Re-usability of standard mapping objects created within the library
 - Re-usability of standard mapping objects created at study level
- Global accessibility
 - Users can access mapping objects across trials
- User access right management
 - User access based on user's role (librarian, clinical programmer etc.)
- Traceability
 - Maintain audit trail of all activities with date and time stamp
- 21 CFR Part 11 compliant and validated
- Scalability
 - Ability to handle growing amount of work
- Extensibility
 - Open for future change and advancements

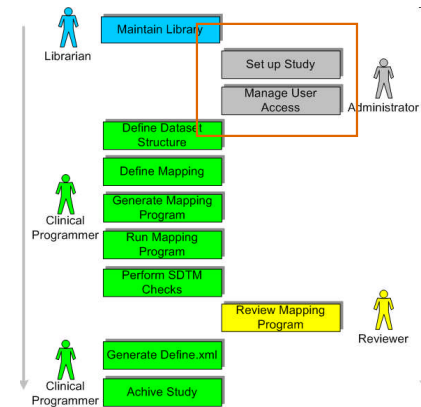
Mapping Process: Maintain Library

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



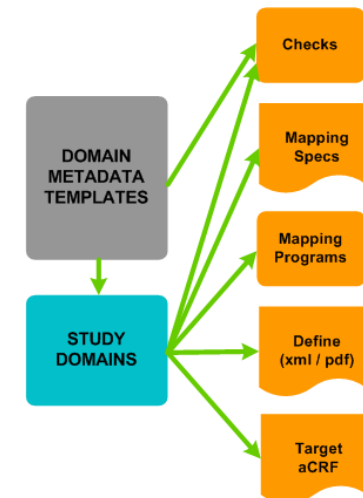
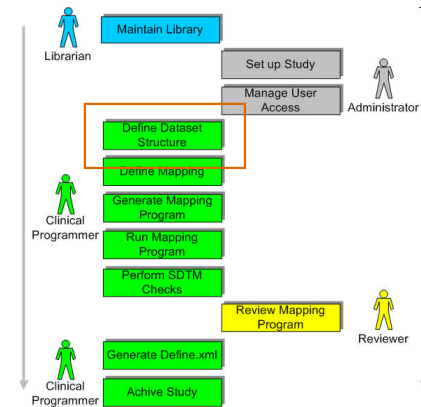
Mapping Process: Set up Study, Manage User Access

- Set up Study:
 - Use templates of study folder structures
 - Configure study infra-structures (e.g. macro and format search paths, metametadata)
 - Populate required standards
- Manage User Access:
 - Define user roles
 - Assign users to roles



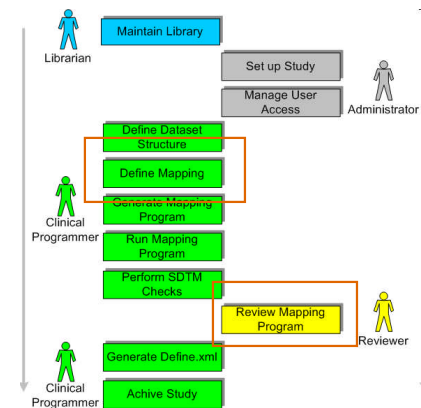
Mapping Process: Define Dataset Structures

- Define Dataset Structures:
 - Use templates
 - Derive from datasets, metametadata
 - “Metametadata”:
 - Configuration rules for metadata structures
 - Metadata check rules
- Example:
seq – integer, unique, starts with 1*



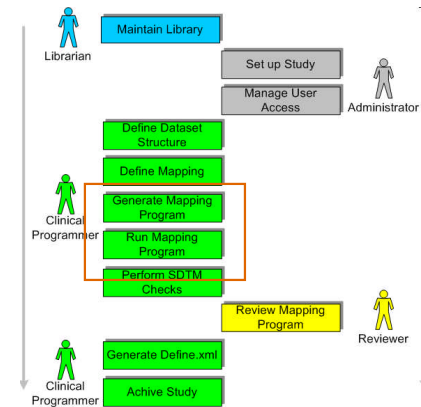
Mapping Process: Define Mapping and Review Mapping Program

- Standards exploited at maximum
 - Standard dataset structures
 - Standard conversion algorithms
 - Standard mappings
- Graphical definition of algorithms with parametrization
- Quality means:
 - Consistency checks in the definition
 - Source structure checks in the program
- Review can be done in the interactive overview



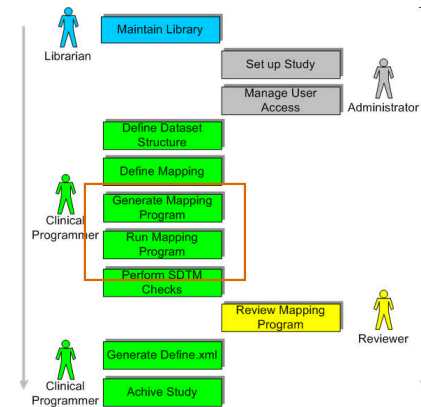
Mapping Process: Generate and Run Mapping Program

- Program Management
 - Versioned storage
 - Test and production area
 - Macro and format search paths, global variables
 - Parameter support
- Job Management
 - Online and batch, server side job execution
 - Full tracing of inputs and outputs



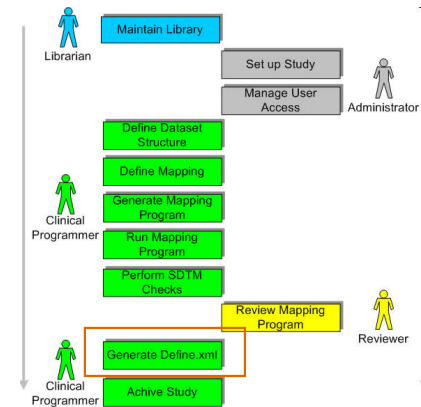
Mapping Process: Perform SDTM Checks

- Check program integrated into the conversion process (incl. execution tracing)
- Checks from the 1st domain on!
 - All standard SDTM conformance checks
 - Available customer checks
- Reusability of parameter definitions



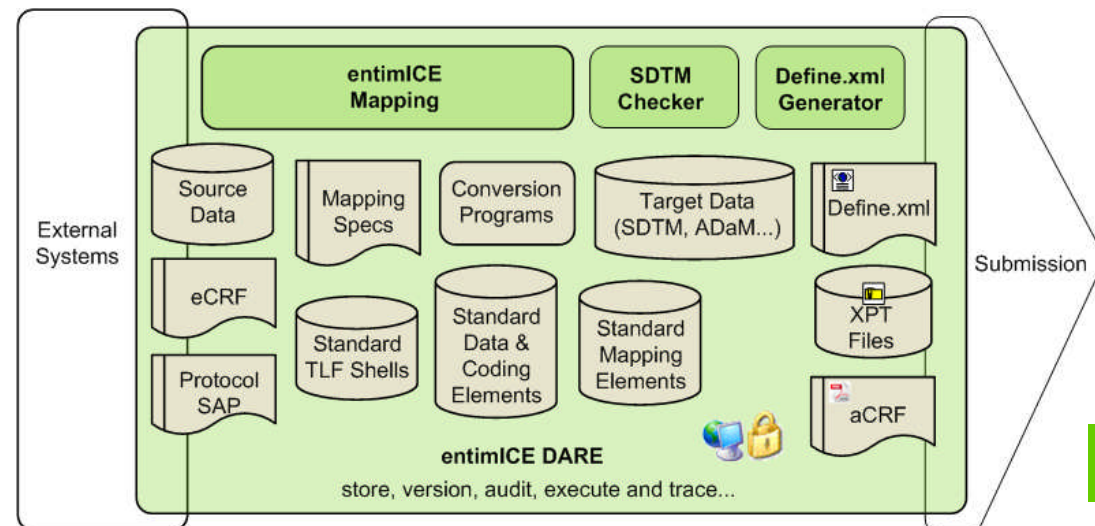
Mapping Process: Generate Define.xml

- Reuse domain metadata to create define (used for mapping definition)
- Create necessary elements (value level metadata, CT...)
- Scan CRF annotations for page numbers
- Link all elements and generate define



Architecture

- Standard components based on entimICE platform
- Modular design with connectors/interfaces
- Scalable, distributable architecture
- Citrix for client deployment
- Process from analysis to submission:



[Click me](#)

Entimo - Profile and Vision

- Focus: High quality IT solutions and services
- Expertise: SAS and emerging technologies in IT and pharma domains
- *Vision: Seamless support of customer processes from analysis to submission with metadata driven tool chain (entimICE)*
- **PhUSE 2010 (Berlin): Research Project on Metadata Extraction, Exploration and Pooling (DH10)**

VISION STARTS NOW!





Many thanks
for your attention!