Implementation of CDISC SDTM supported by a globally distributed mapping process

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Table of Contents

- Problem: Mapping to CDISC SDTM with global, virtual teams
  - Manage mapping functions in a consistent way across sponsors
  - Increase possibility of re-use within organization
- Approach: Global process for global, virtual teams
- Supporting tools: Meta-data library and mapping tool
- Way forward: Vision on data standards

Problem: Mapping to CDISC SDTM with global, virtual teams SDTM is now accepted by FDA

- SDTM is now accepted by the FDA
  - 21-Jul-2004 FDA starts to accept SDTM submissions
  - 01-Aug-2005 FDA urges submissions with SDTM datasets
  - 01-Aug-2007 FDA announces to accept SDTM V1.1 & SDTM IG V3.1.1
  - 30-Oct-2009 FDA announces to accept SDTM V1.2 & SDTM IG V3.1.2

- Generation of SDTM compliant data sets requires establishment of new processes

Problem: Mapping to CDISC SDTM with global, virtual teams
Global teams – different time zones

Problem: Mapping to CDISC SDTM with global, virtual teams Challenges (1/2)

- Teams distributed globally
  - Example: Team members located in the UK, US, India, China etc.
- Working differently
  - No consistent approach in creating specifications and programs
  - Example: If data transfer programs are done for a sponsor trial in China using SAS macros, for the same sponsor the transfer programs for another trial might be programmed manually in another location as sas programs.
  - Re-usability was difficult to achieve
- Multiple tasks involved
  - Creating specifications
  - Programming SDTM datasets
  - Technical review of specifications and programs
  - Functional review of the datasets
- Strict time lines

Problem: Mapping to CDISC SDTM with global, virtual teams Challenges (2/2)

- Studies:
  - New and legacy
  - Coming from different systems
    - Example: many EDC systems like Inform, Rave etc. are available for different customers
  - Source extracts from the Database available in different structures
  - Metadata are often limited/not available
  - No re-usable objects available
  - Have to be made ready for submission (converted to SDTM, enhanced by ADaM/Define)
- Standards:
  - Many levels and versions simultaneously
  - Multiple customer specific standard enhancements/requirements
  - Growing complexity of standards
    - Example: CDASH (CRF standards) linked with SDTM

Approach: Global process for global, virtual teams
Working Worldwide – Goals (1/2)

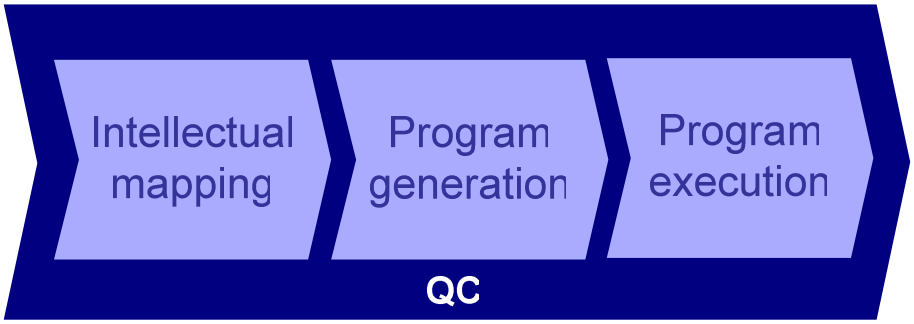
- Re-usability of work for PAREXEL standards
- Consistency if sponsor-specific standards are used
- Definition of a globally distributed process:
  - Starting from existing local best practices
    - Example: Access set-up for blinded vs unblinded programmers, technical programming code review process
  - Creating common use cases
    - Example: Creating consistent UAT test cases for quality and efficiency

Approach: Global process for global, virtual teams
Working Worldwide – Goals (2/2)

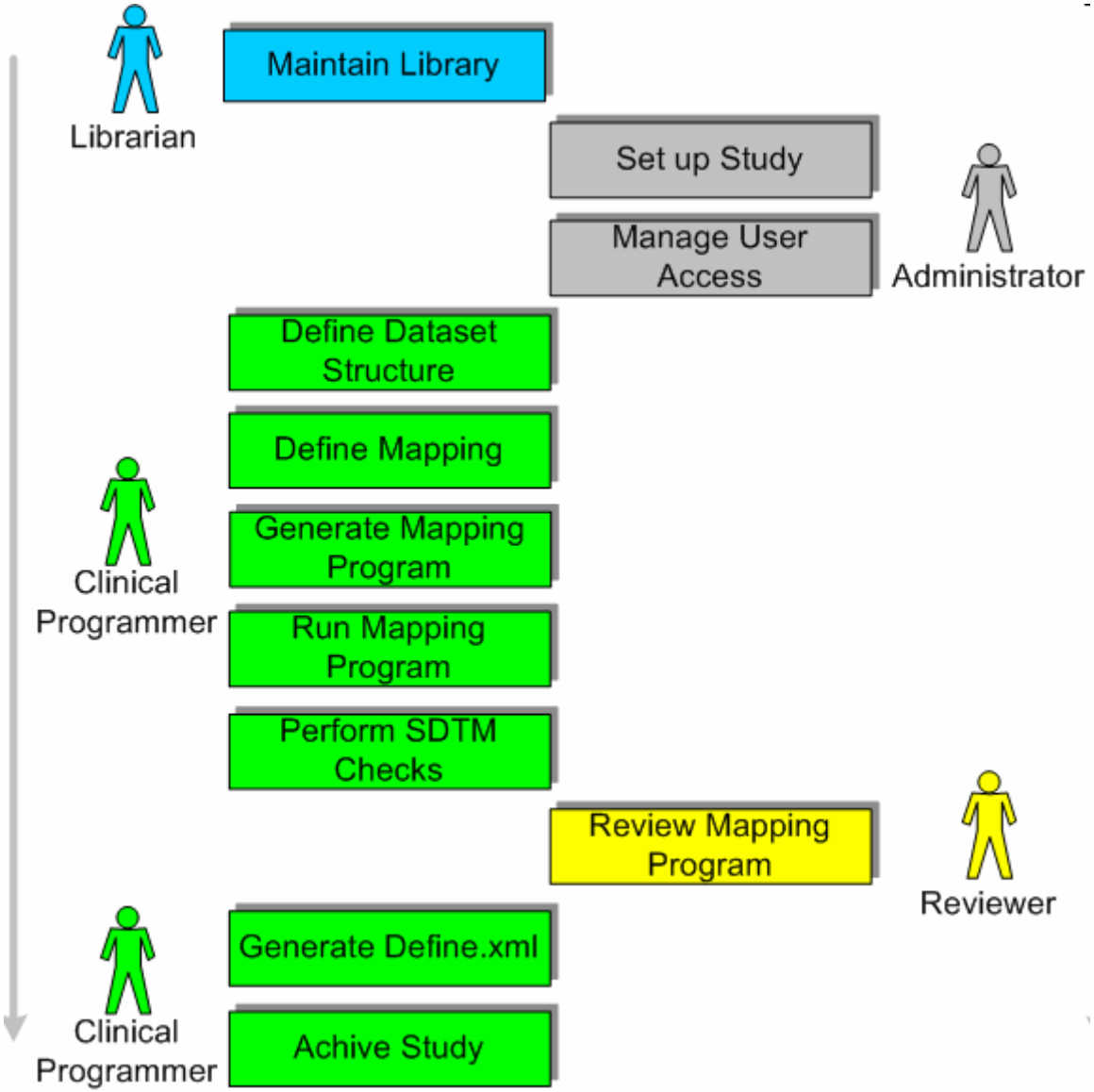
- Definition of a globally distributed process:
  - Streamlining processes
    - Process maps created for all data conversion scenarios
    - Example: Data conversion process for legacy trials, new trials etc.
  - Using advantages of a global player
    - Global teams to have access to the streamlined process
    - Data conversions created consistently across the globe
  - Looking for productive tool to support processes
    - All the components are available in one central location to easier implement best practices

Approach: Global process for global, virtual teams
Mapping Process (1/2)

- Face-lifting: Designed to allow for splitting of tasks
  - Intellectual mapping
    - Determine how to map the trial data into SDTM
    - Create re-usable mapping templates
  - Program generation
    - Automate generation of mapping programs
  - Program execution
    - Create environment for controlled and traceable program execution (SCE)
  - QC
    - Technical review of trial-specific mappings at trial level
- Roles
  - Administrator
  - Clinical Programmer
  - Reviewer
  - Librarian



Approach: Global process for global, virtual teams
Mapping Process (2/2)



Approach: Global process for global, virtual teams
Critical Role: Librarian

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

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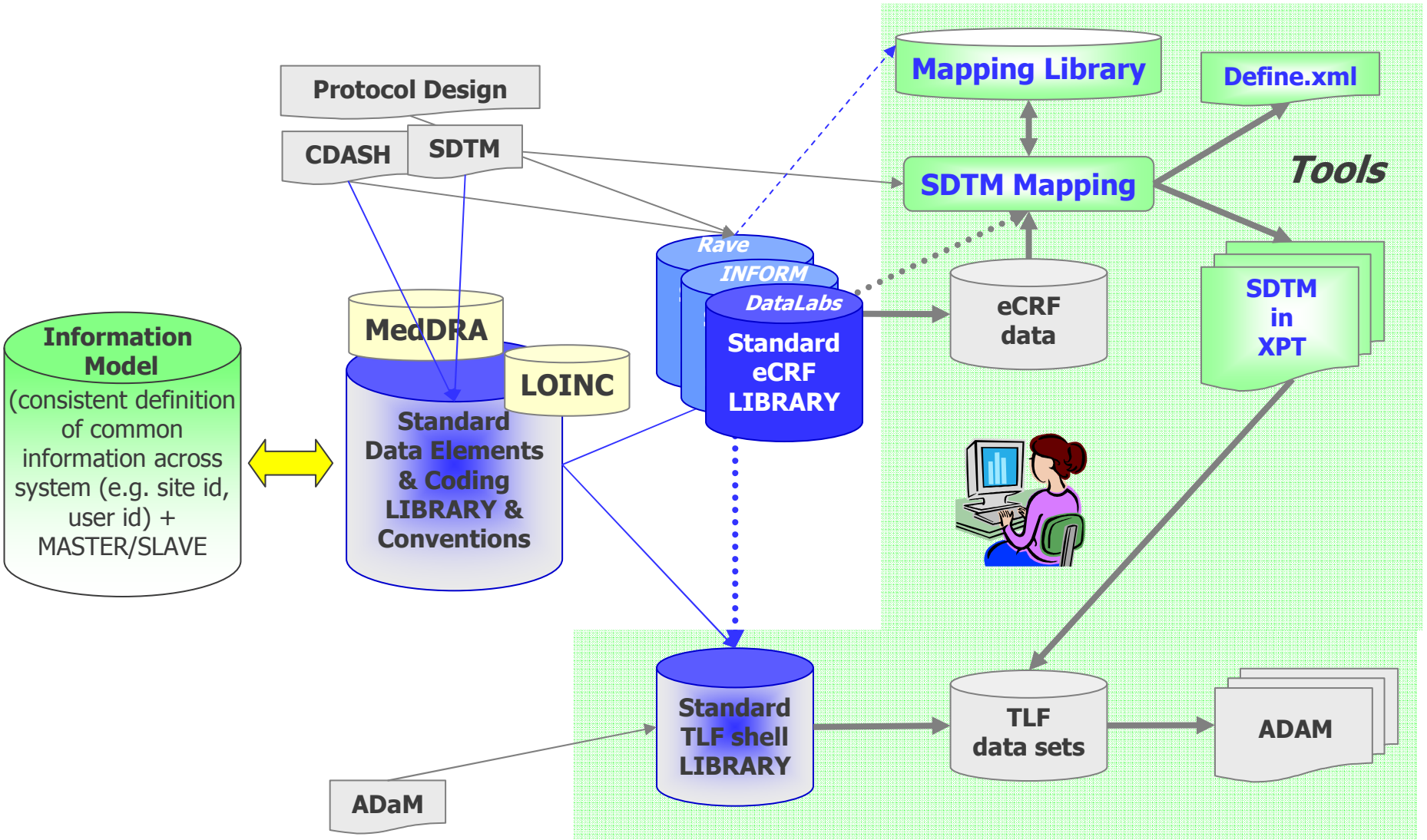
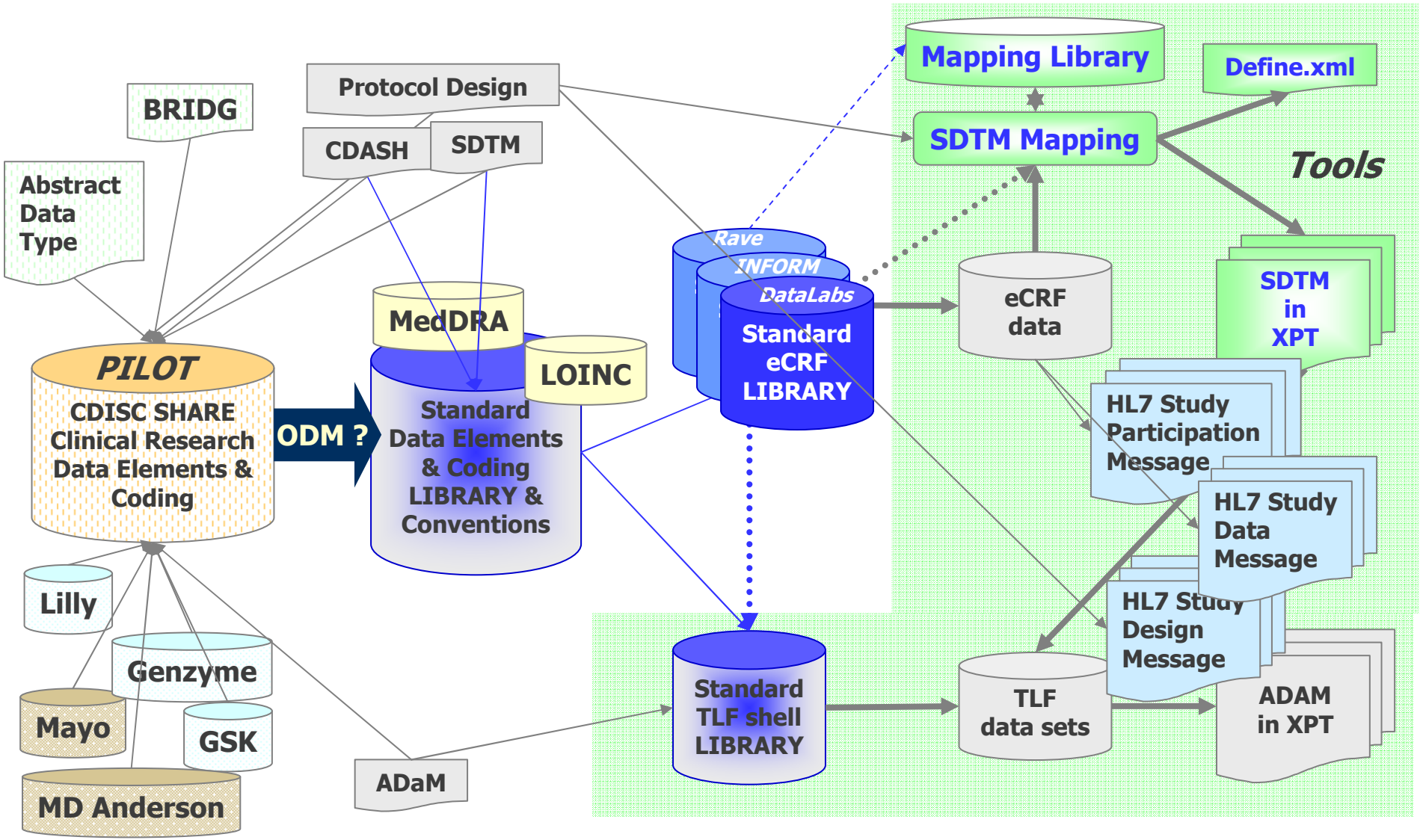
Expected Results

- Work in a consistently across the globe
  - Process is defined and broken down into smaller tasks
- Same look and feel
  - Easier to train new colleagues
  - Tasks can be shared between team members located remotely
- Consistent re-use of standard elements
  - Saves time, increases quality and consistency
- Supported by tools open for future changes and advancements

Data Standards
How does it fit together

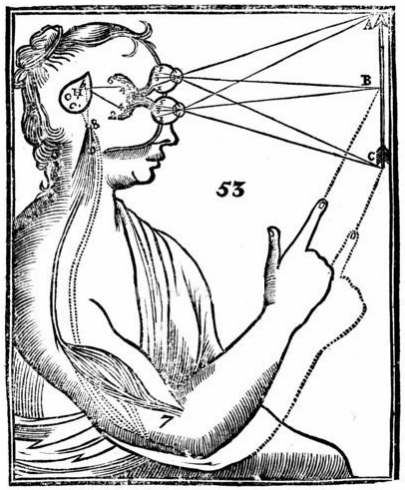


Data Standards
The problem space by 2015: HL7 messages



Conclusions

- Providing SDTM data transfers to sponsors is becoming mandatory and habitual task
- Efficiency in the data conversion process is required
- Processes and tool to support this task need to be in place
- Flexibility to support ongoing development and changes
- Vision: Standard eCRF plus a well-filled metadata store makes life much easier



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