

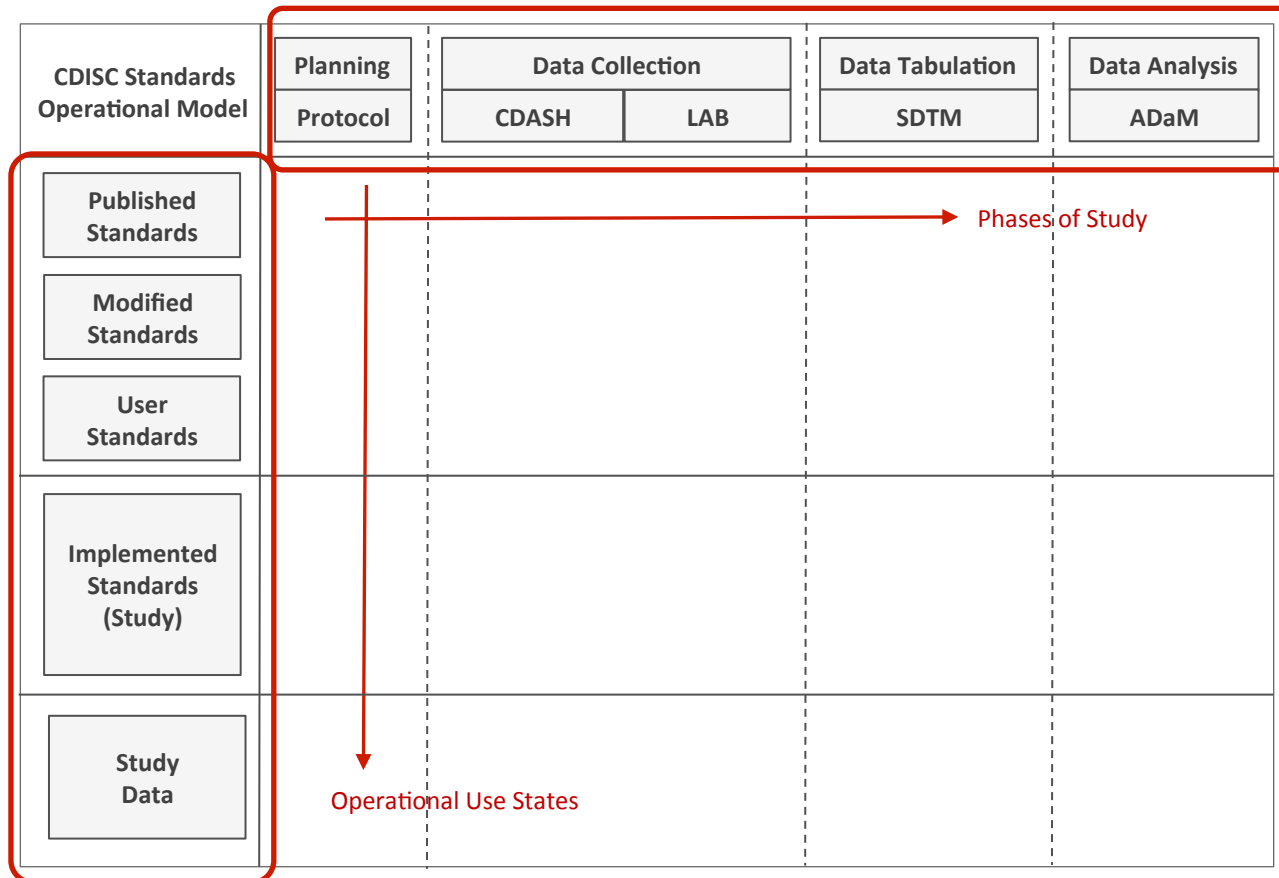
innovation

A Model for Reviewing the Operational Implementation of CDISC Standards

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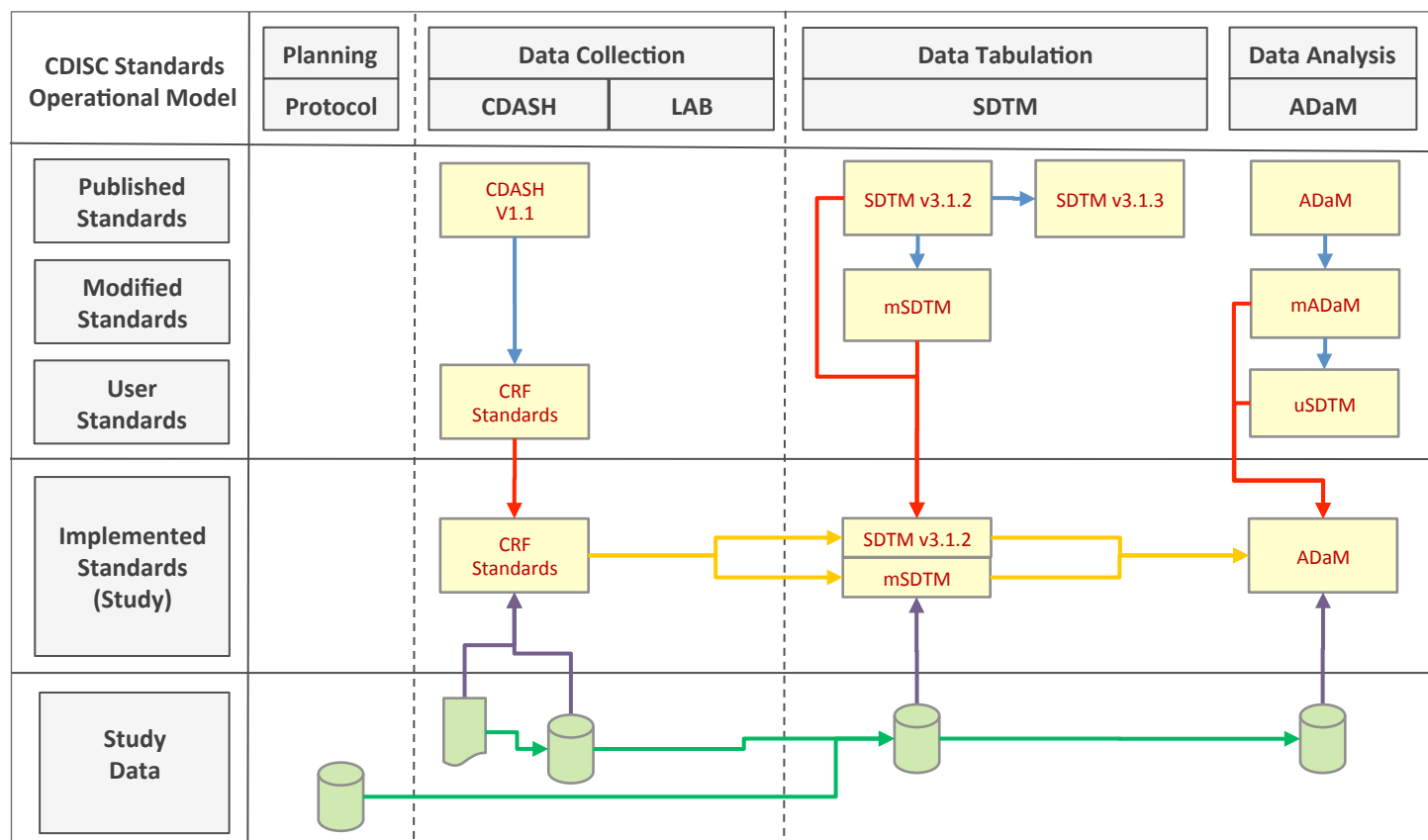
- Adoption of the CDISC standards is well established
- Implementing them into day-to-day operations is proving challenging
- Paper will present a model/method that can help with describing, reviewing, and testing how CDISC standards are implemented
 - Describe and Build the Basic Model
 - Model Framework
 - Elements and Interactions
 - Variations on the Theme
 - Using the Models
 - Some Illustrative Examples
 - Concluding Remarks

- Matrix formed from Standards of Interest * Operational States
- Standards: CDISC, Internal - over study lifecycle
- Operational States: Published, Modified, Implemented, (Applied) - in operations use order

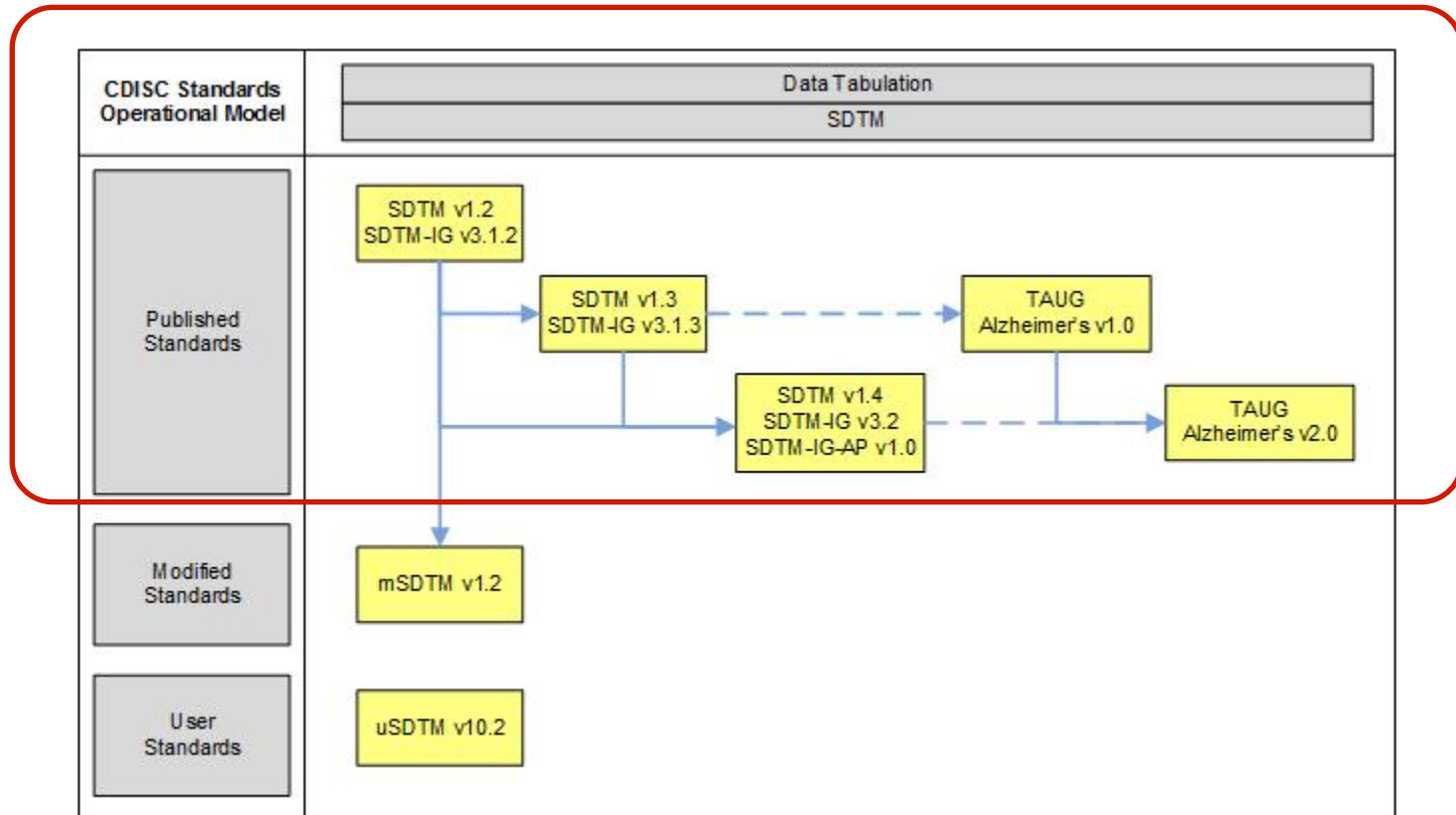


Basic Model: Elements & Interactions

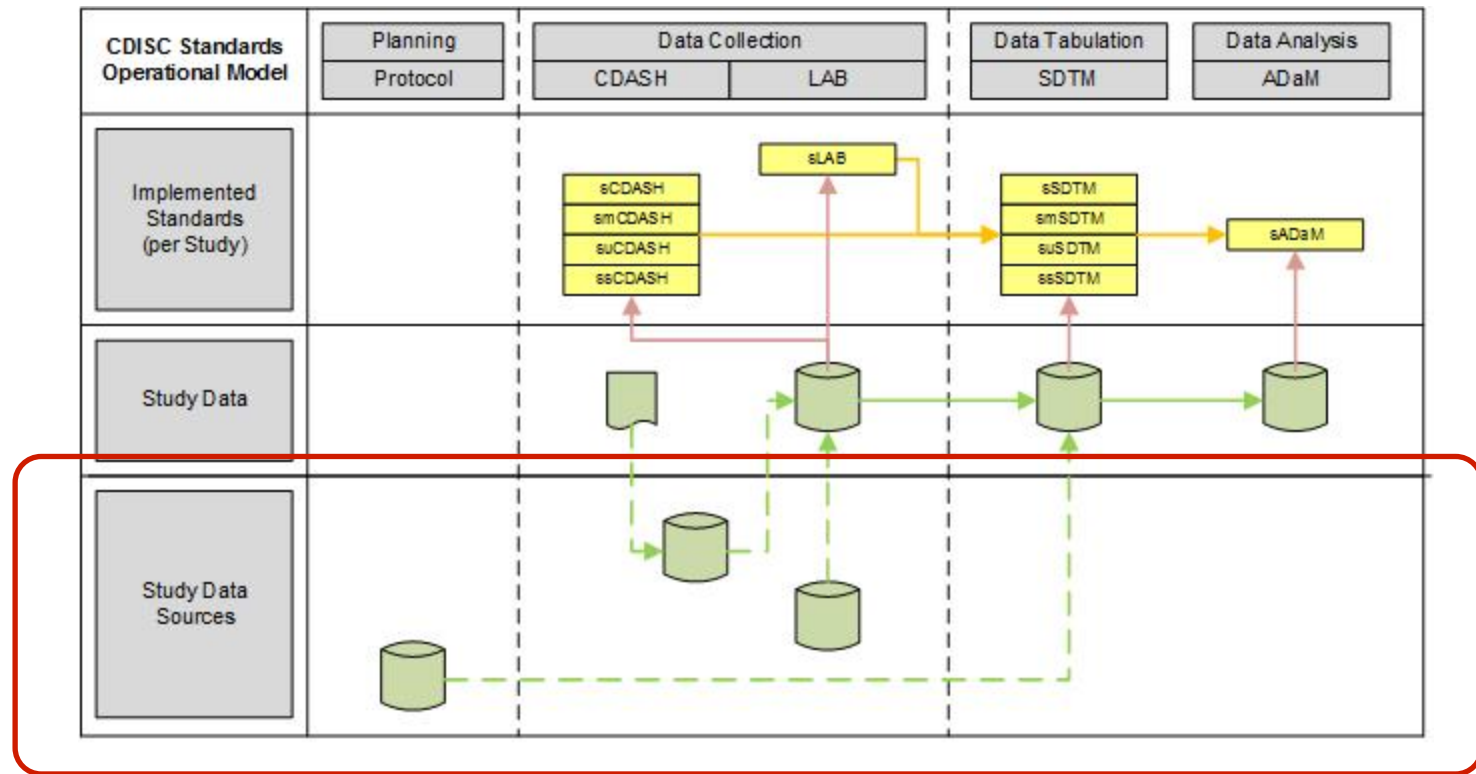
- Standards
 - Published - Modified - User - Implemented
- Study Objects
 - Forms/Datasets/Reports
- Operational Relationships
 - Between Standards
 - Implemented Standards
 - Mapping
 - Data Transformations
 - Compliance/Validation



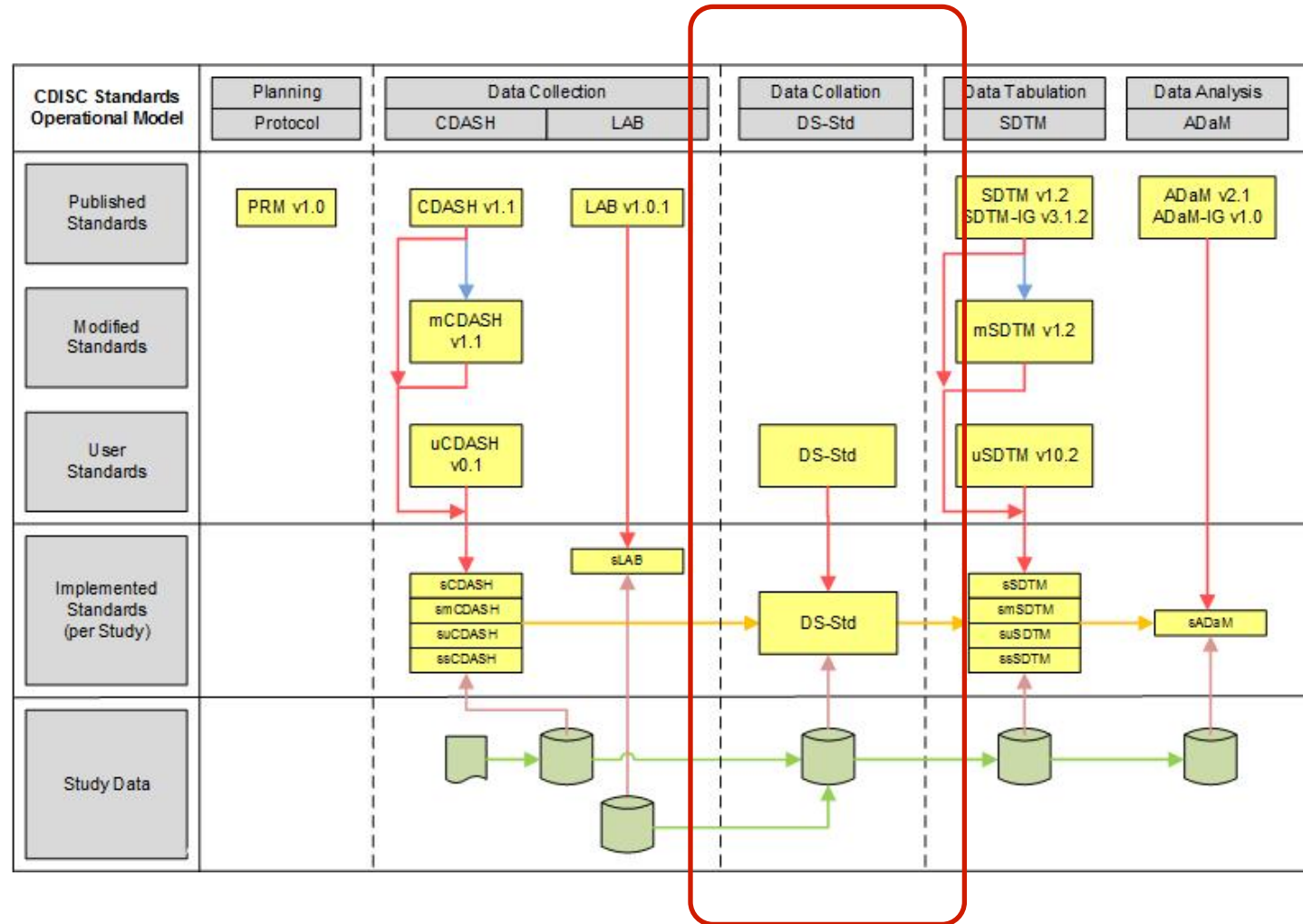
- Versioning



- Addition of Study Data Sources



- Internal Data Collation Standard



General Model Review and Use Methods

- Inclusion or exclusion of standards or operational states
e.g. include only adopted standards, exclude disallowed states
- Recognising, confirming or establishing specific relationships
e.g. where mapping relationships are defined
- Masking
e.g. to highlight roles and responsibilities
- Specification
e.g. to document standards to be used/in use for a specific study
- Analysis/Assessment
e.g. to systematically explore, compare and contrast different standards implementations

Maximising Model Value: Testing the Models

To support the...

- Creation of Accurate and High Quality Clinical Data Products

To ensure...

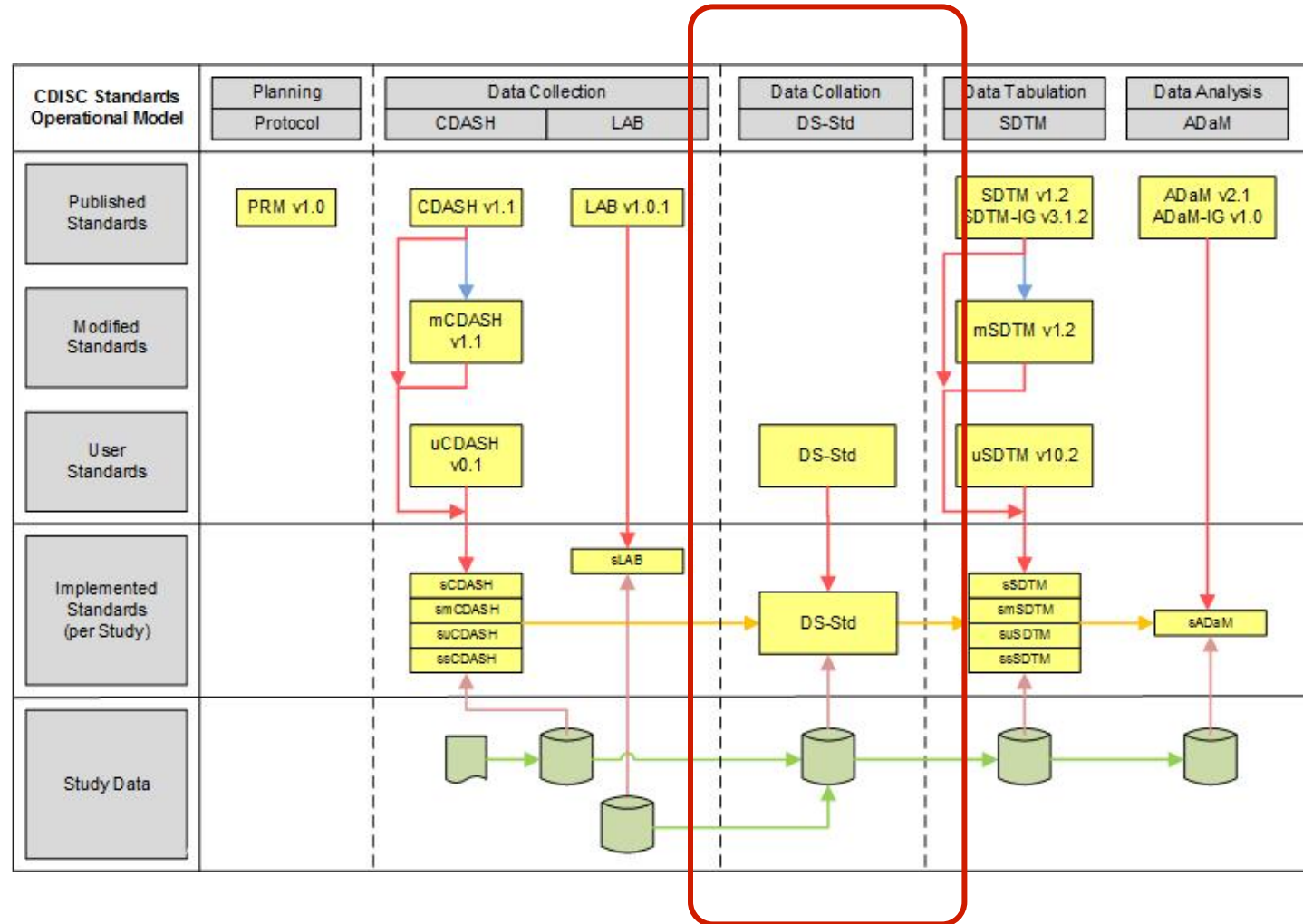
- Compliance with Regulatory Authority Data Submission Requirements

To support...

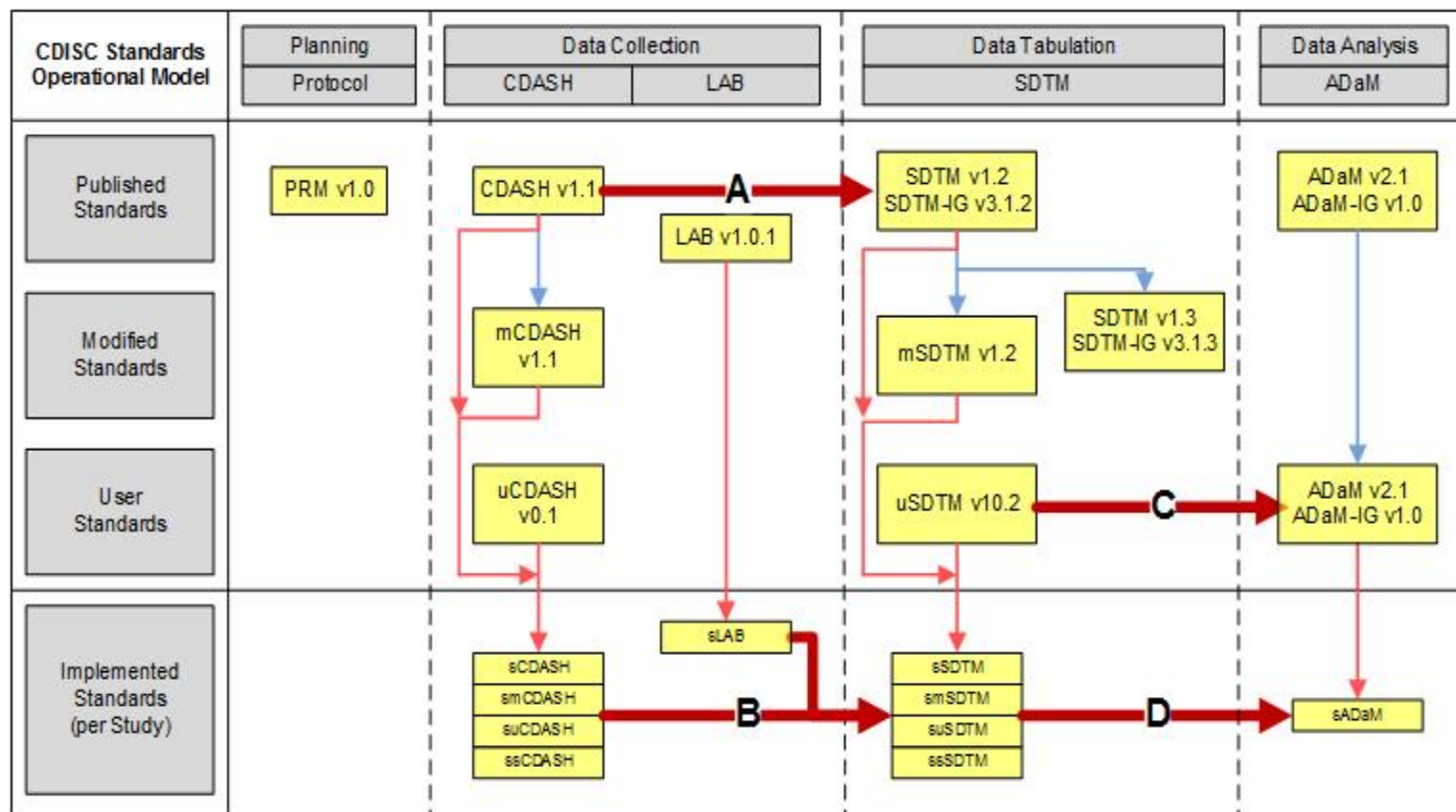
- Operational Efficiencies

What is the Primary Standards Implementation Goal?

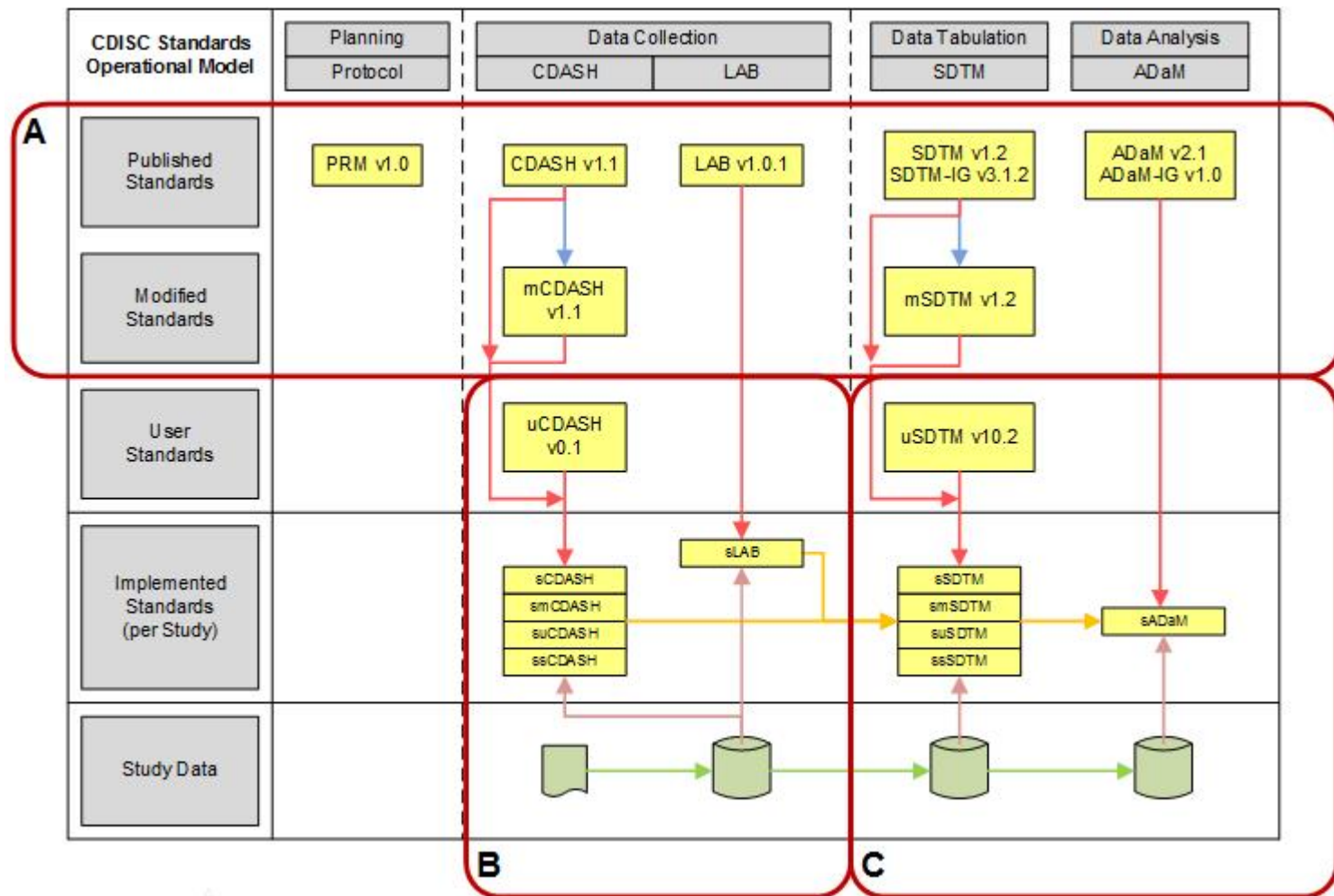
- INCLUSION of an Internal Data Collation Standard



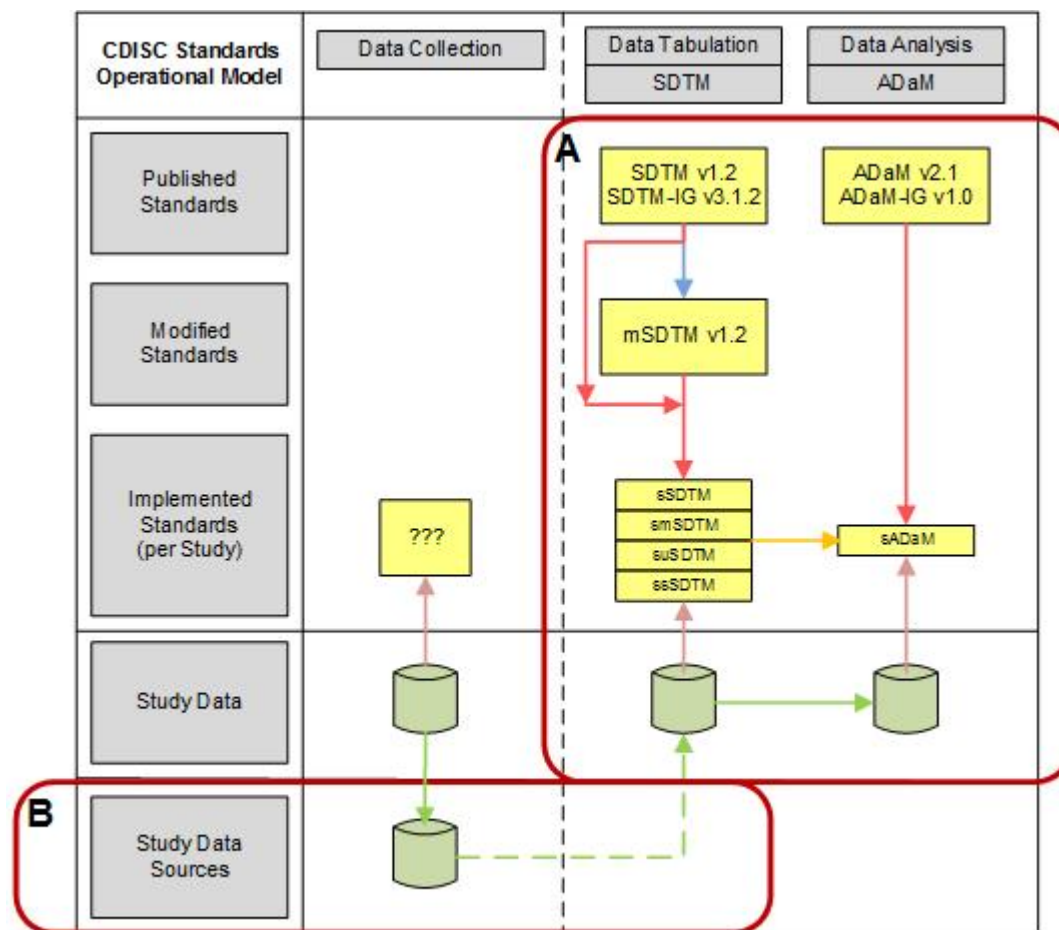
CONFIRMING Mapping Relationships



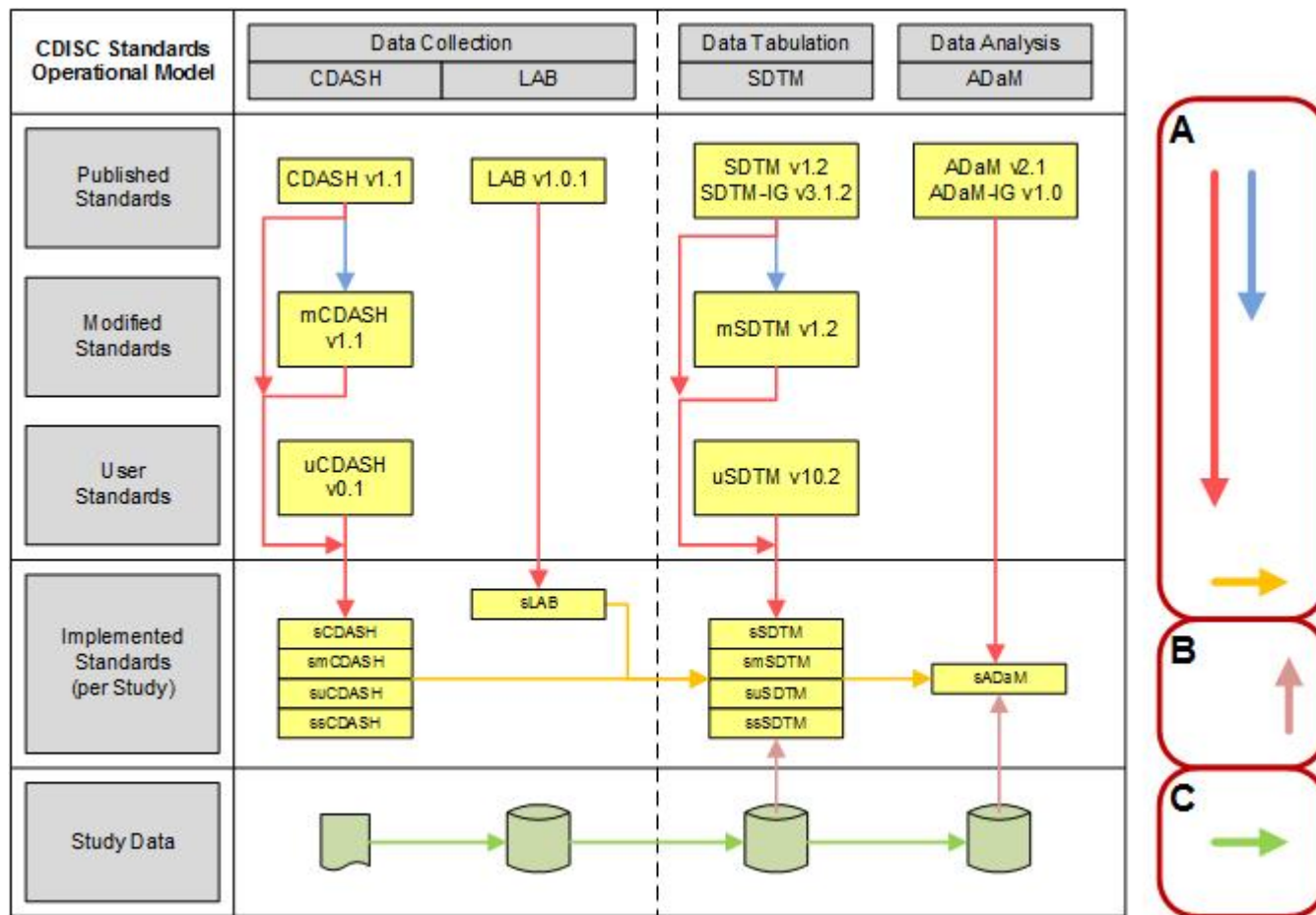
- Standards Roles & Responsibilities (MASKING)



- SPECIFICATION of External Service Provider Data Transfer Formats

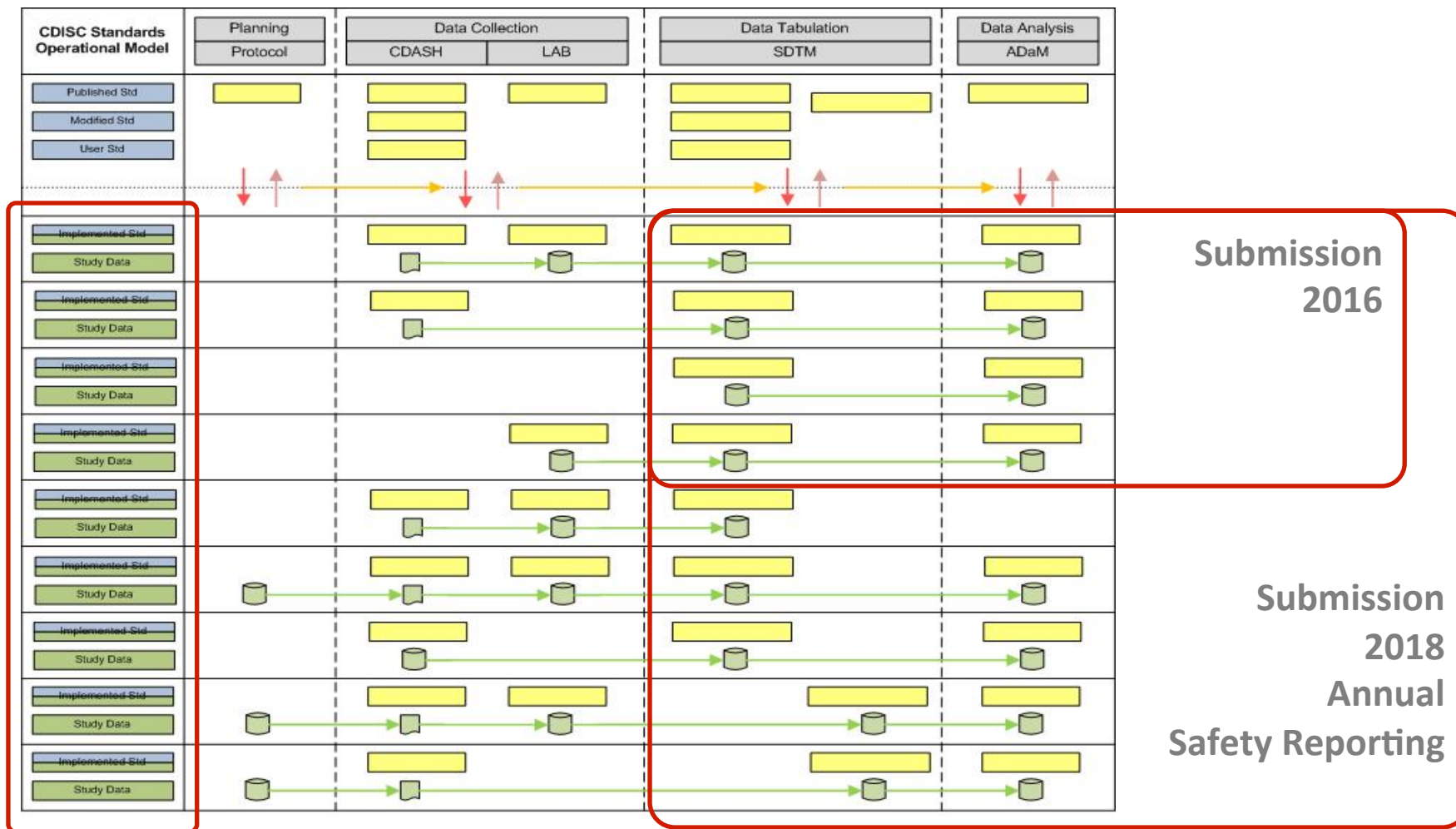


ANALYSIS of the Scope/Requirement of Specific Technical Solutions



- Illustrates clearly the implementation dilemma of needing to ensure that “downward” CDISC standards management and governance is in sympathy with study-by-study operational use.
- The models highlight clearly which standards are in use, their operational role, and how they interact across the study lifecycle.
- “Variations on the Theme” can be used to explore more or less granularity with respect to any or all of the CDISC standards.
- Illustrating unambiguously where and how roles & responsibilities, software solutions, processes, etc. interact with the CDISC standards assists with recognising issues and optimising solutions.

Project X : Study Submission Standards Summary



- A model has been presented to describe and review how the CDISC standards are being adopted and used within an organisation.
- By using a variety of review methods many different aspects of an organisations CDISC standards management and governance, their inter-relationships, how and where software solutions use the CDISC standards etc. can be clearly documented and analysed.
- The value of the model is best realised at higher levels of granularity, and they are designed to complement other well established methods for developing processes, describing technical requirements etc.

Thank you for your attention...

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