

Operational Implementation of Metadata Defined Standards

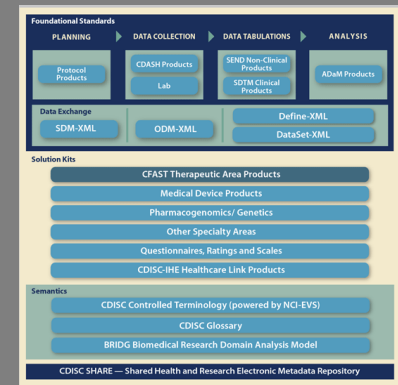
...with reference to Define.XML

Andy Richardson

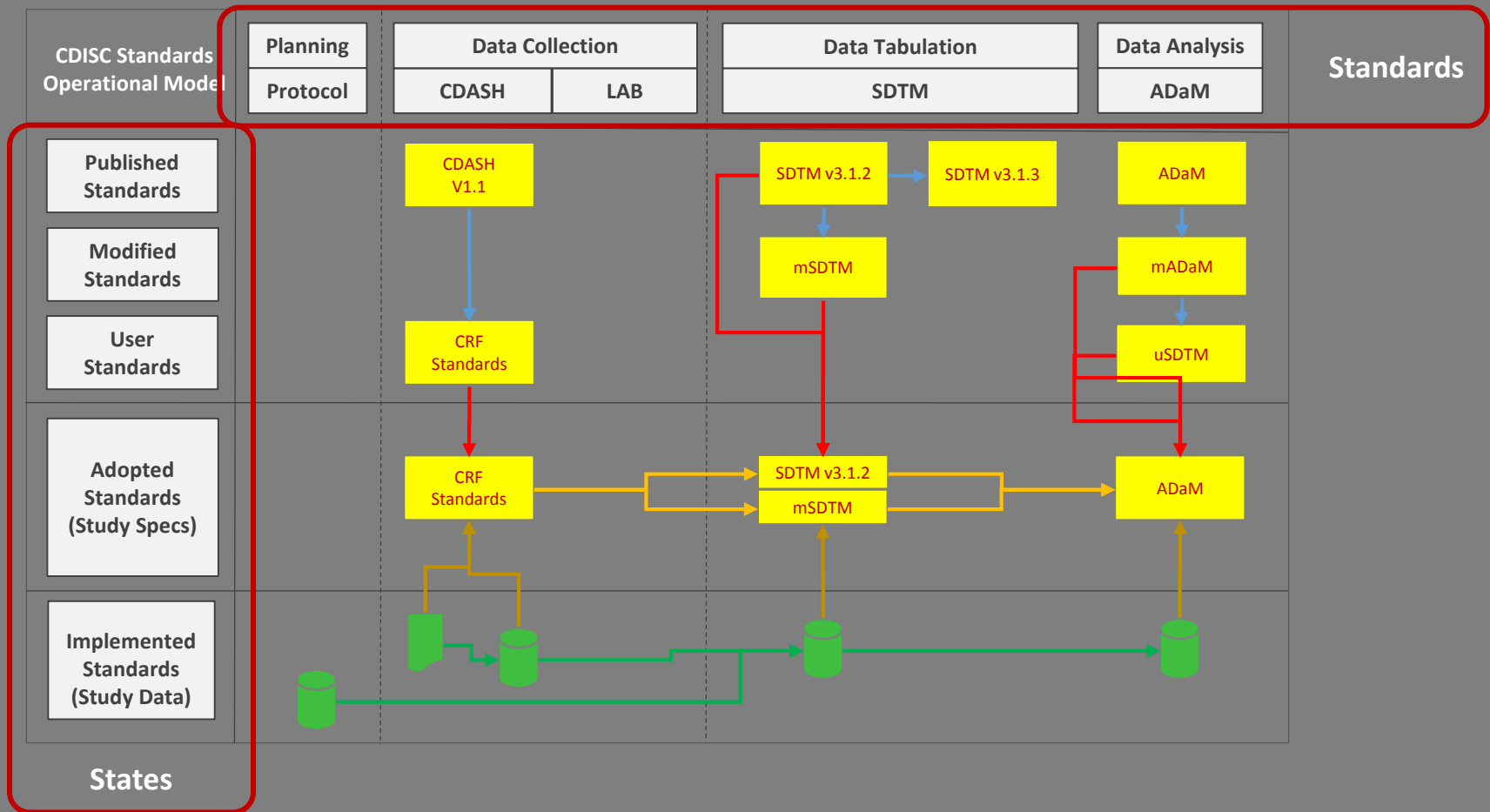
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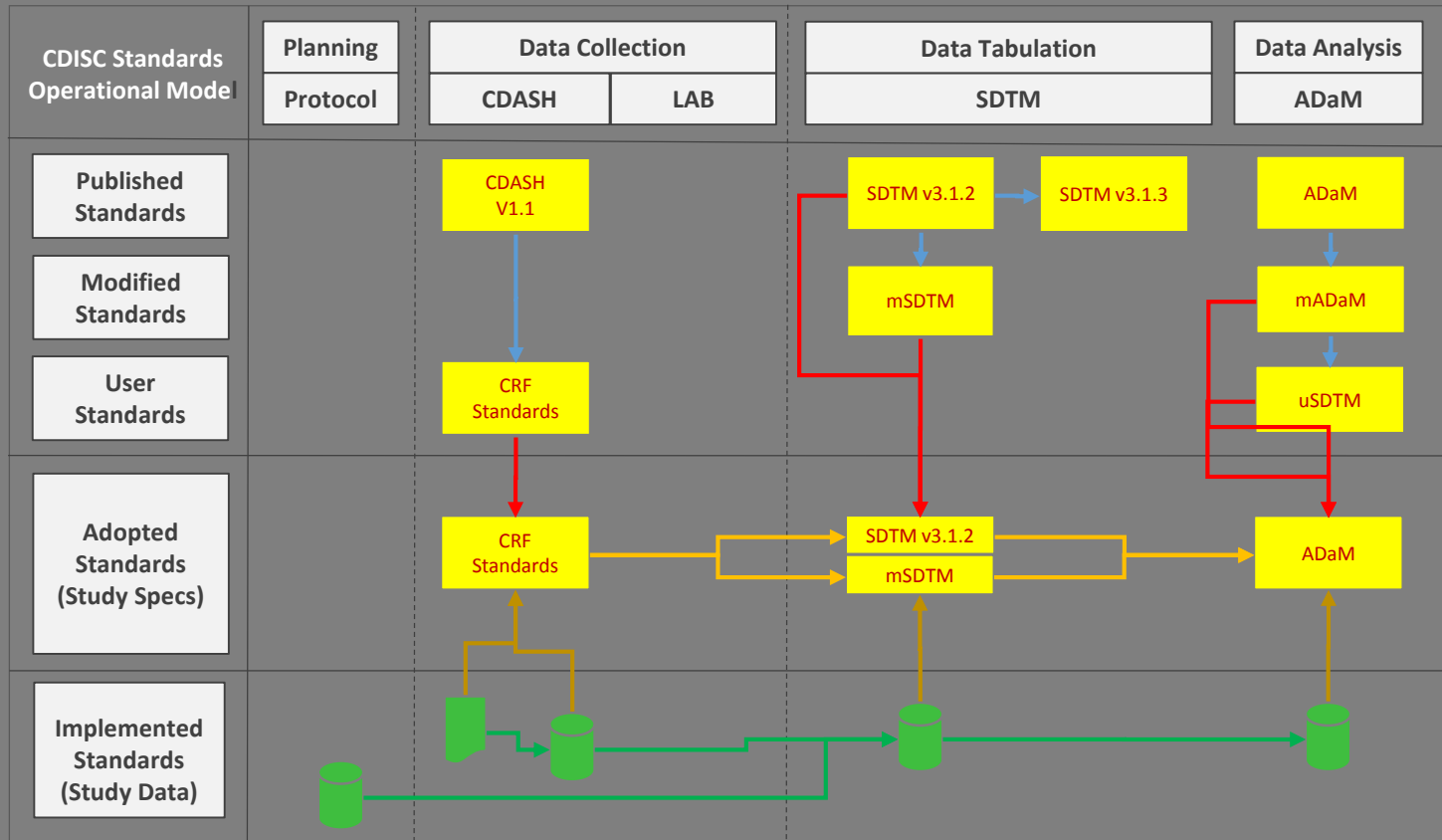
- The primary objective of the CDISC standards is to describe clinical/non-clinical data products and associated artefacts
- Industry objectives are to exploit the standards
 - to comply with regulatory requirements
 - to support efficient end-2-end clinical operations
 - for other data interchange
- Standards need to be carefully integrated into clinical operations in order to maximize the benefits of adoption
- The operational role for each adopted standard needs to be fully understood



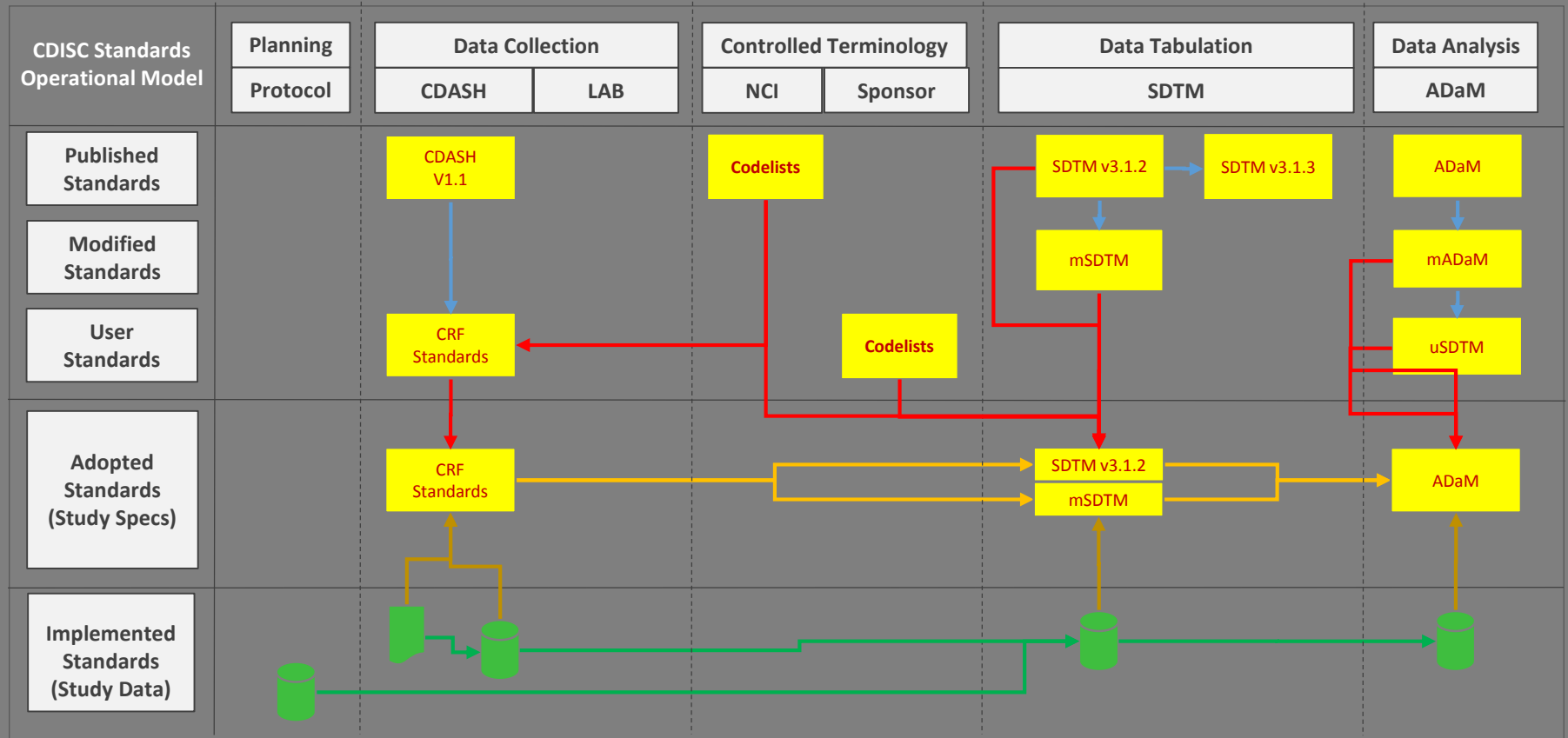
Standards Operational Model



Standards Operational Model

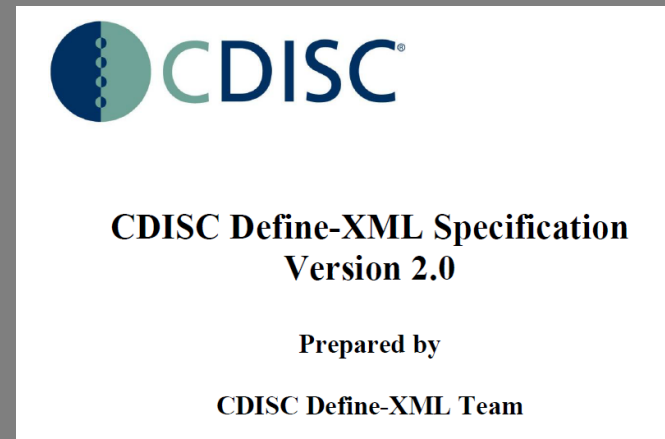


Standards Operational Model - Extended



- Define-XML Purpose...

... [a] model... used to describe CDISC SDTM, SEND and ADaM datasets for the purpose of submissions to the FDA, .. [and] proprietary [non-CDISC] standards



- TOCs...

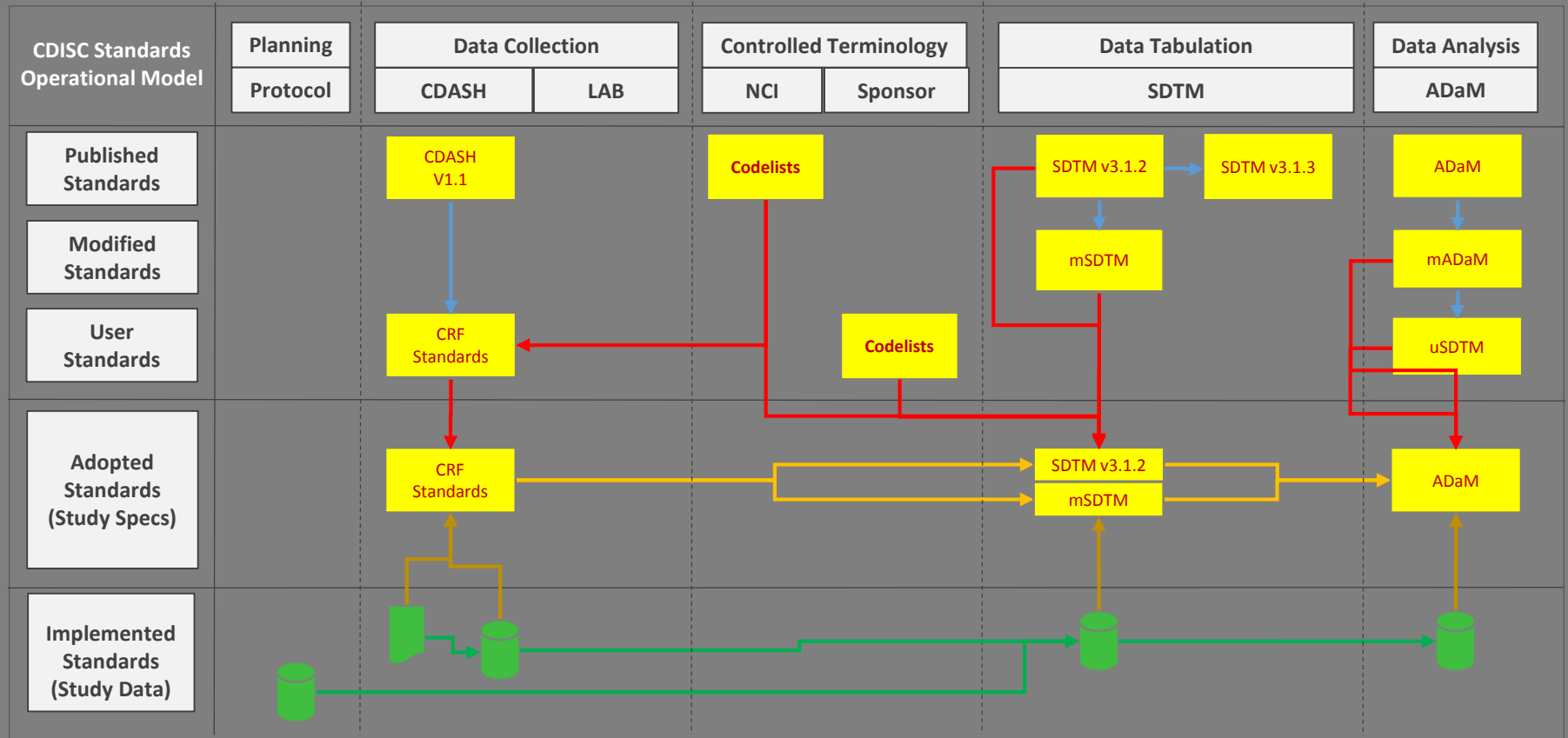
SDTM-IG 3.1.2

- Annotated Case Report Form
- Reviewers Guide
- Complex Algorithms
- ▶ Tabulation Datasets
- ▶ Value Level Metadata
- ▶ Controlled Terminology
- ▶ Computational Algorithms
- ▶ Comments

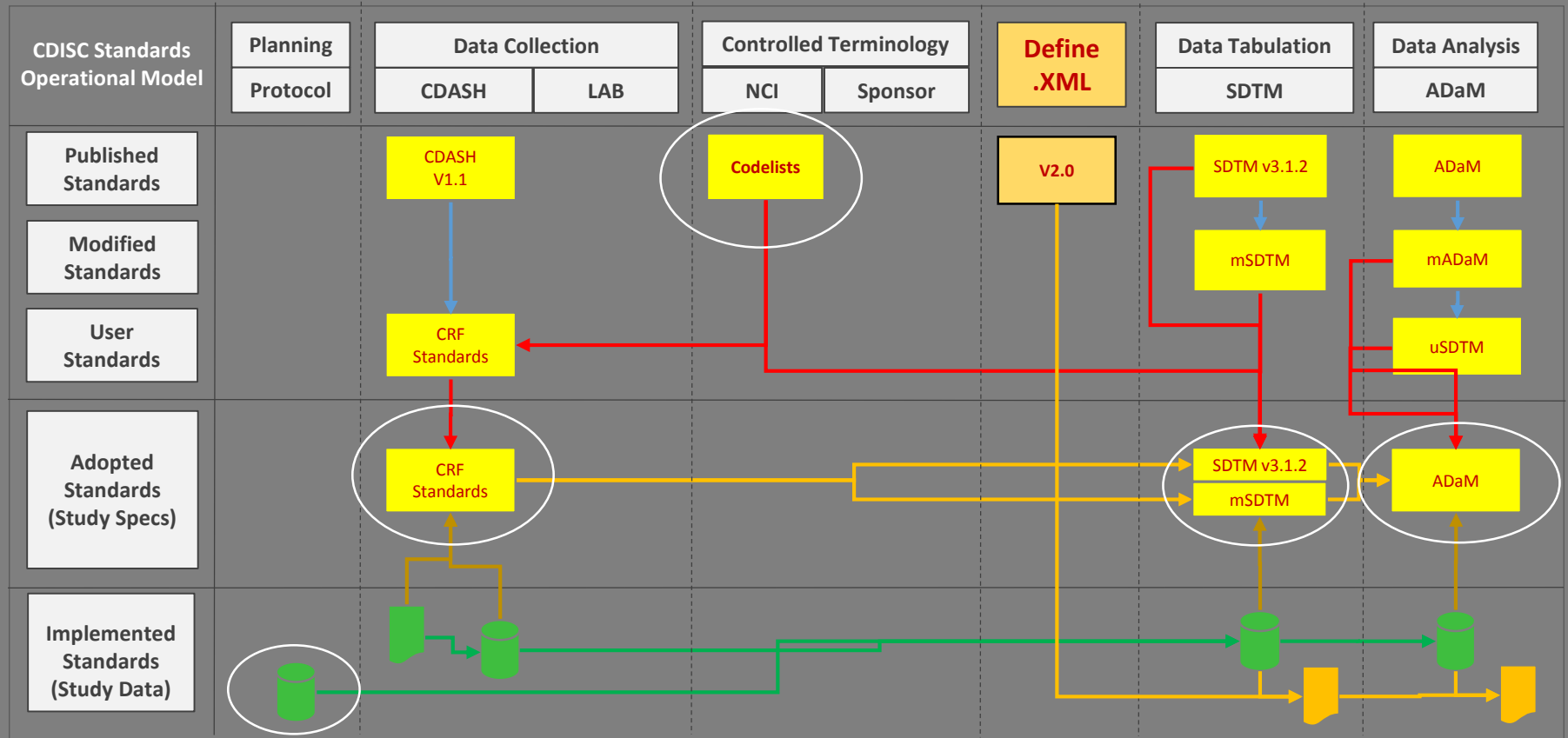
ADaM-IG 1.0

- Analysis Data Reviewer's Guide
- ▶ Analysis Datasets
- ▶ Parameter Value Level Metadata
- ▶ Controlled Terminology
- ▶ Analysis Derivations
- ▶ Comments

Standards Operational Model - Extended



Standards Operational Model – Extended – Define.XML



Operational Implementation

- Requires careful consideration of the standards role within the operation...
 - *Define.XML – for dataset DESCRIPTION or dataset DEFINITION (REVIEW/APPROVAL)?*
- Needs to understand how and where it interacts with other operational deliverables...
 - *Define.XML – aCRF, Controlled Terminology, Trial Datasets, Complex and Computation Algorithms, Reviewers Guides etc...*
- Needs to be part of the governance, data traceability, production, versioning processes and procedures...
 - *Define.XML – Primary starting point for data traceability? QC methods?*



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