

Confirming MDR Metadata Requirements for Operational Implementation

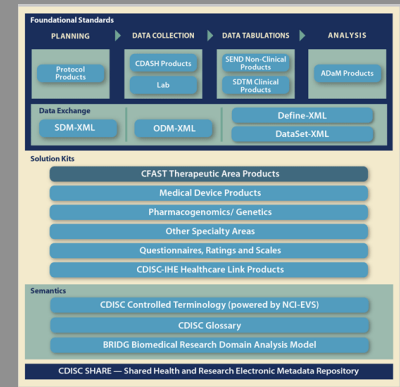
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- Introduction & Background
- Metadata Repositories: Opportunities & Challenges
- An Approach to Developing MDR Metadata Requirements
 - Identifying MDR Entities and Artefacts
 - Identifying MDR Relationships
 - Categorising Metadata Elements
 - Developing Content & Testing Metadata Specifications
 - Identifying Required MDR Functionality
- Operational Metadata Requirements within the MDR Project
- Summary & Concluding Remarks

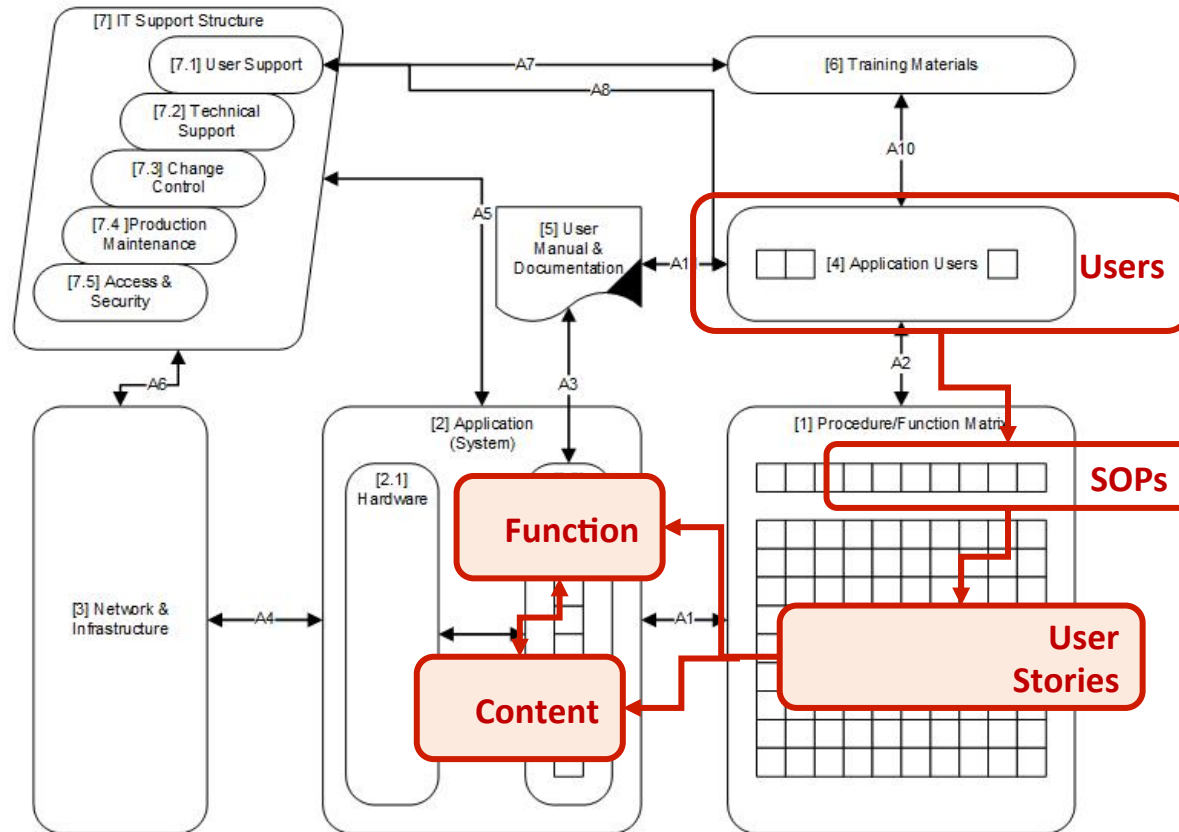
- CDISC standards are now well established and required by regulatory agencies as the submission data format
- CDISC standards support all steps in the study lifecycle data flow – for both clinical and non-clinical studies
- The range of standards and supporting implementation guides, therapeutic area user guides, technical descriptions, controlled terminology details continues to grow significantly
- The primary objective of the CDISC standards as they currently exist is to describe clinical data products and associated artefacts
- Industry objectives are to exploit the standards (a) to comply with regulatory requirements, and (b) to support efficient end-2-end clinical operations
- Standards governance and careful integration into clinical operations is required to maximize benefit of adopting clinical data standards



- **Metadata Repository (MDR)**
- Opportunities - Solutions
 - Single location (1-stop-shop) to hold, manage, and distribute all CDISC and related standards
 - Enable the multi-dimensionality of the standards to be managed efficiently
 - Improve standards governance process efficiency
 - Offer new approaches to support of clinical data management and analysis e.g. automatic development of study data specifications, data traceability etc.
 - Supports metadata-driven artefact creation

- **Metadata Repository (MDR)**
- Challenges
 - Standards are still evolving – proliferation of new standards address content gaps and content inconsistencies
 - Inter-standard and intra-standard relationships are complex and inconsistent
 - Companies often do NOT understand their own standards adoption and implementation landscape
 - MDRs must support both the management of the standards and their use in support of daily operational tasks
 - Current iterations of MDR solutions are immature
 - Companies have unrealistic expectations for MDRs – MDRs are not and will never be the silver bullet

Computer Systems Validation: System Anatomy 0: Overview



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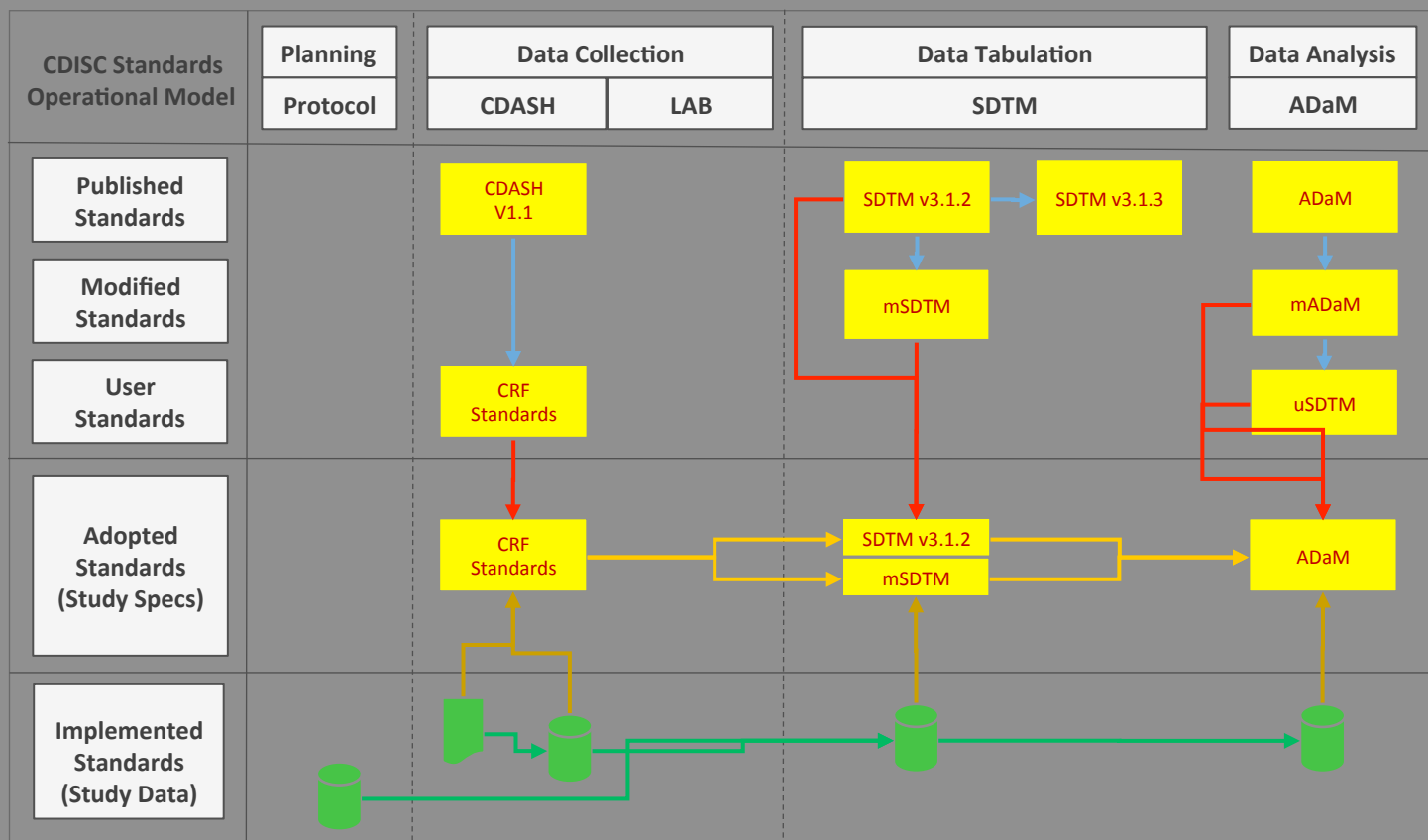
Developing MDR Metadata Requirements for Operational Implementation

- Key Requirements for an MDR are to....
 - Support the management of the CDISC and associated standards
 - Support use of the standards within clinical data operations
- Both are required for successful implementation...
 - Standards Management – relatively easy to specify requirements
 - Library, Governance...
 - Operational Integration – depends...
 - What do you want an MDR to operationally support?

Identifying Required MDR Entities and Artefacts

CDISC Standards Operational Model	Planning	Data Collection		Data Tabulation		Data Analysis	Standards
	Protocol	CDASH	LAB	SDTM		ADaM	
Published Standards		CDASH V1.1		SDTM v3.1.2	SDTM v3.1.3	ADaM	
Modified Standards				mSDTM		mADaM	
User Standards		CRF Standards				uSDTM	
Adopted Standards (Study Specs)		CRF Standards		SDTM v3.1.2 mSDTM		ADaM	
Implemented Standards (Study Data)		 					
States							

Identifying Required MDR Relationships



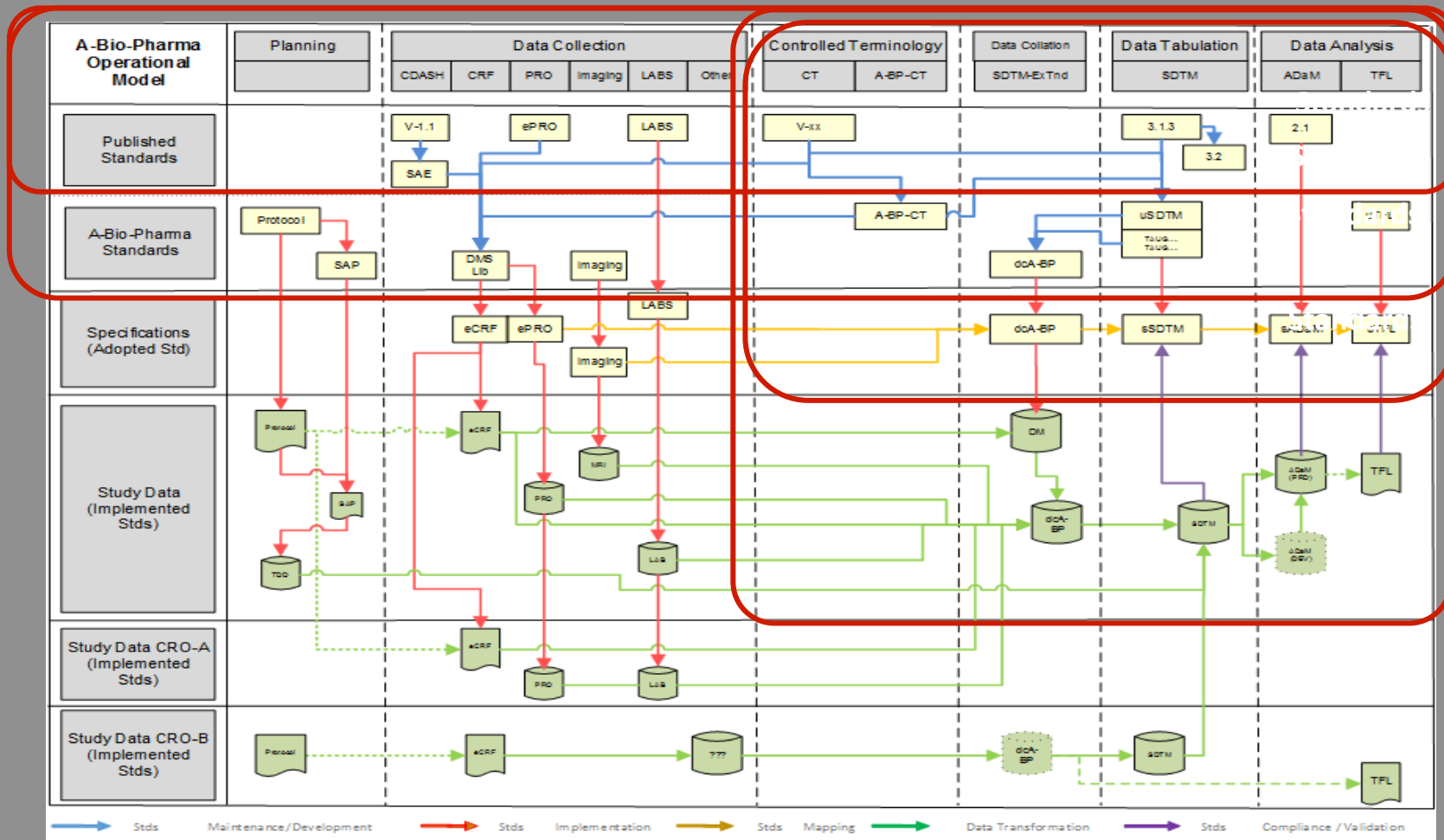
Standards		State	Artefact
Group	Entity		
Planning	Protocol	Implemented Standard	Trial Design Datasets
Data Collection	CDASH	Published Standard	CDASH v1.1
Data Collection	CDASH	User Standard	CRF Standards
Data Collection	CDASH	Adopted Standard	CRF Standards
Data Collection	Lab	Implemented Standard	EDC CRFs
Data Collection	Lab	Implemented Standard	EDC Export Dataset
Data Tabulation	SDTM	Published Standard	SDTM v3.1.2

Entities/Artefacts

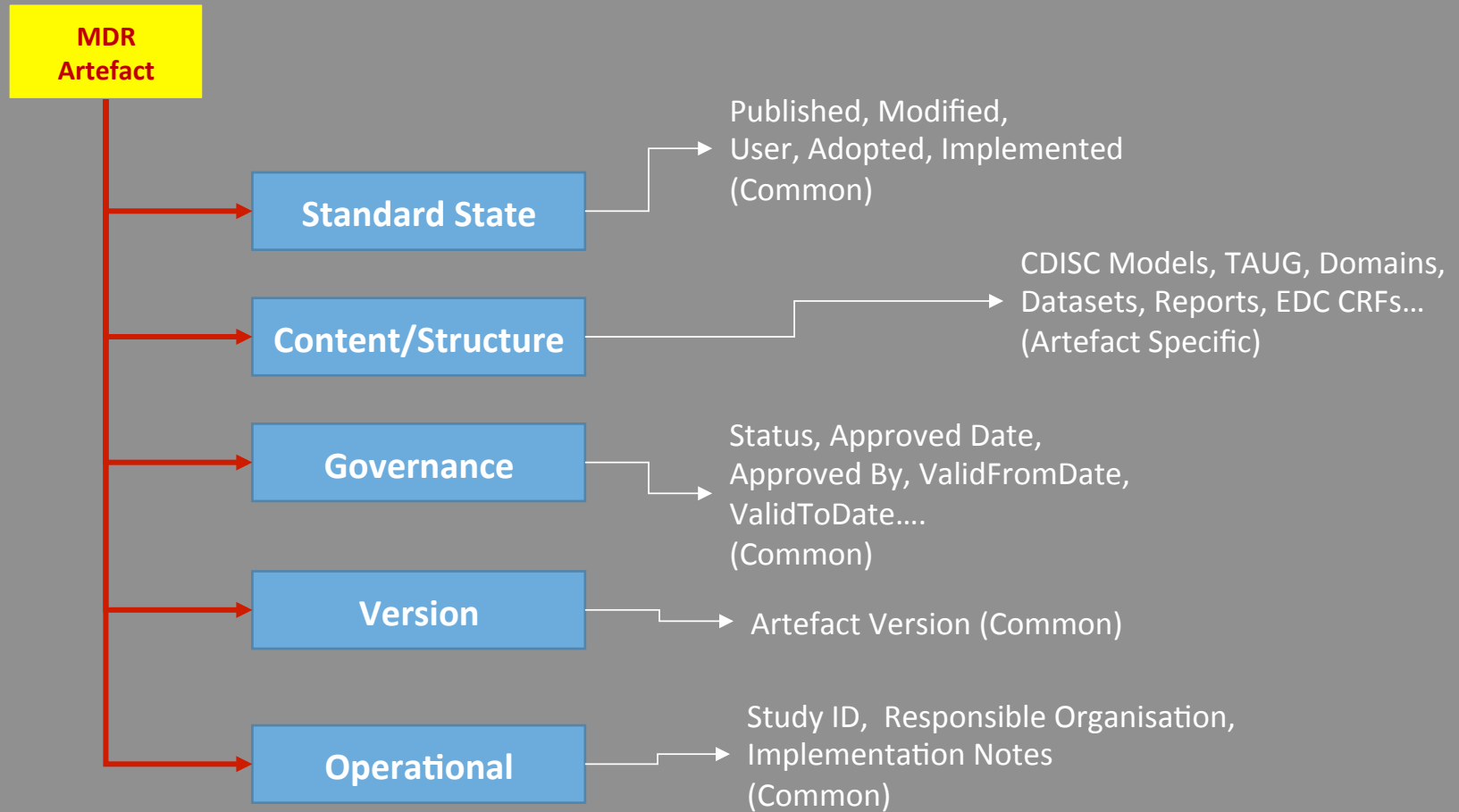
Relationships

Standards		State	Artefact		Standards		State	Artefact
Group	Entity				Group	Entity		
Planning	Protocol	Implemented Standard	Trial Design Datasets	<>	Data Tabulation	SDTM	Implemented Standard	Study Domain Dataset
Data Collection	CDASH	Published Standard	CDASH v1.1	<>	Data Collection	CDASH	User Standard	CRF Standards
Data Collection	CDASH	User Standard	CRF Standards	<>	Data Collection	CDASH	Adopted Standard	CRF Standards
Data Collection	CDASH	Adopted Standard	CRF Standards	<>	Data Collection	Lab	Implemented Standard	EDC CRFs
Data Collection	CDASH	Adopted Standard	CRF Standards	<>	Data Collection	Lab	Implemented Standard	EDC CRFs
Data Tabulation	SDTM	Published Standard	SDTM v3.1.2	<>	Data Tabulation	SDTM	Published Standard	SDTM v3.1.3
Data Tabulation	SDTM	Published Standard	SDTM v3.1.2	<>	Data Tabulation	SDTM	Adopted Standard	mSDTM
Data Tabulation	SDTM	Published Standard	SDTM v3.1.2	<>	Data Tabulation	SDTM	Adopted Standard	SDTM v3.1.2
Data Tabulation	SDTM	Modified Standard	mSDTM	<>	Data Tabulation	SDTM	Adopted Standard	mSDTM
Data Tabulation	SDTM	Adopted Standard	SDTM v3.1.2	<>	Data Tabulation	SDTM	Implemented Standard	Study Domain Dataset
Data Tabulation	SDTM	Adopted Standard	mSDTM	<>	Data Tabulation	SDTM	Implemented Standard	Study Domain Dataset
Data Analysis	ADaM	Published Standard	ADaM v2.1	<>	Data Analysis	ADaM	Modified Standard	mADaM
Data Analysis	ADaM	Modified Standard	mADaM	<>	Data Analysis	ADaM	User Standard	uADaM
Data Analysis	ADaM	Modified Standard	mADaM	<>	Data Analysis	ADaM	Adopted Standard	mADaM
Data Analysis	ADaM	User Standard	uADaM	<>	Data Analysis	ADaM	Adopted Standard	uADaM
Data Analysis	ADaM	Adopted Standard	mADaM	<>	Data Analysis	ADaM	Implemented Standard	Study Analysis Dataset
Data Analysis	ADaM	Adopted Standard	uADaM	<>	Data Analysis	ADaM	Implemented Standard	Study Analysis Dataset
Data Tabulation	SDTM	Implemented Standard	Study Domain Dataset	<>	Data Tabulation	SDTM	Adopted Standard	SDTM v3.1.2
Data Tabulation	SDTM	Implemented Standard	Study Domain Dataset	<>	Data Tabulation	SDTM	Adopted Standard	mSDTM
Data Collection	CDASH	Adopted Standard	CRF Standards	<>	Data Tabulation	SDTM	Adopted Standard	SDTM v3.1.2
Data Collection	CDASH	Adopted Standard	CRF Standards	<>	Data Tabulation	SDTM	Adopted Standard	mSDTM

MDR Scope: What's In, What's Out



Categorising Metadata Elements: Artefact Metadata Categories



Categorising Metadata Elements: Artefact Metadata Categories

Standards		State	Artefact	Metadata Category
Group	Entity			
Data Tabulation	SDTM	Published Standard	SDTM v3.1.2	Content/Structure
				Governance
				Version
				Operational
Data Tabulation	SDTM	Published Standard	SDTM v3.1.3	Content/Structure
				Governance
				Version
				Operational
Data Tabulation	SDTM	Modified Standard	mSDTM	Content/Structure
				Governance
				Version
				Operational
Data Tabulation	SDTM	Adopted Standard	SDTM v3.1.2	Content/Structure
				Governance
				Version
				Operational
Data Tabulation	SDTM	Adopted Standard	mSDTM	Content/Structure
				Governance
				Version
				Operational
Data Tabulation	SDTM	Implemented Standard	Study Domain Dataset	Content/Structure
				Governance
				Version
				Operational

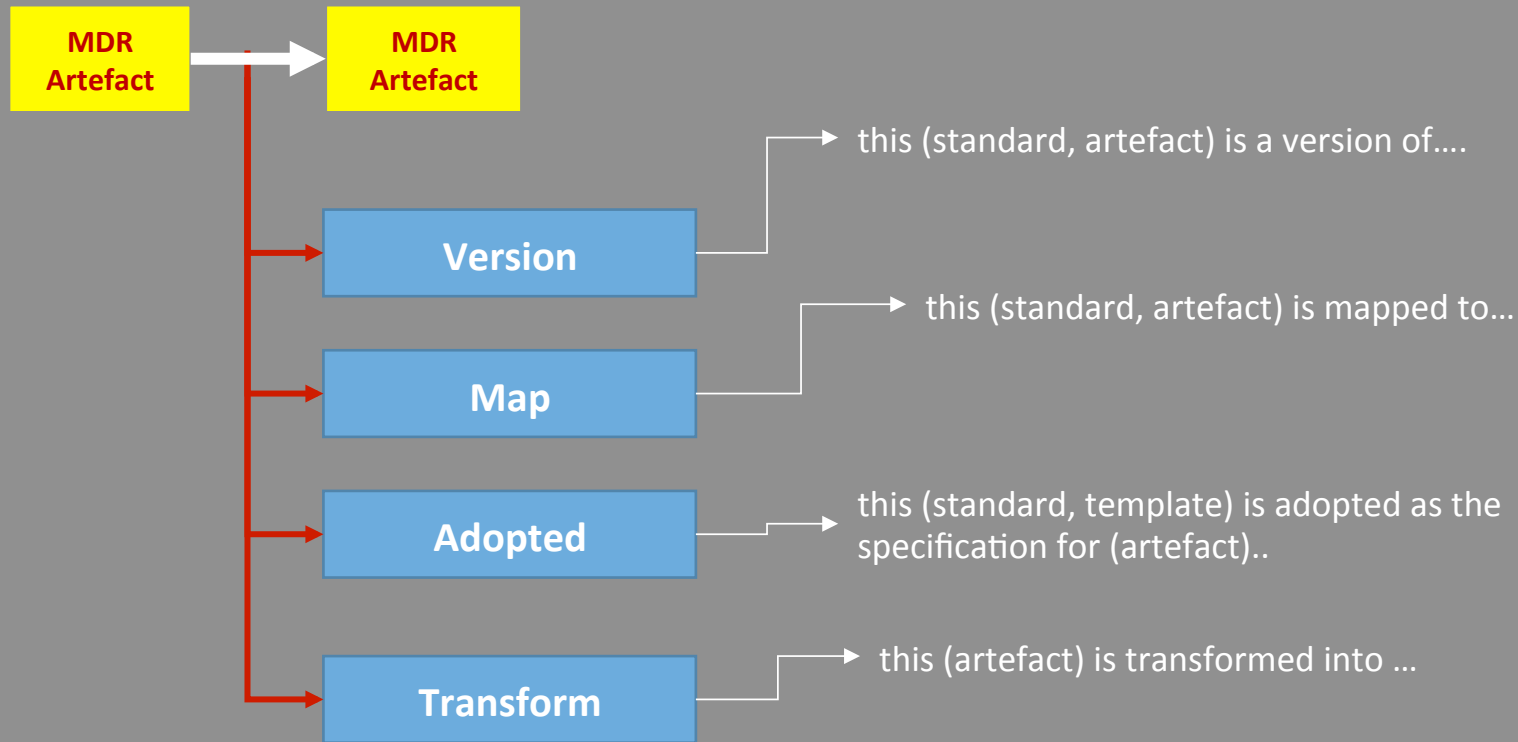
Categorising Metadata Elements: Artefact Metadata Categories

Standards		State	Artefact	Metadata Category	Metadata Element
Group	Entity				
Data Tabulation	SDTM	Published Standard	SDTM v3.1.2	Content/Structure	
				Governance	Status
					Approved Date
					Approved By
				Version	Version
				Operational	
Data Tabulation	SDTM	Published Standard	SDTM v3.1.3	Content/Structure	
				Governance	Status
					Approved Date
					Approved By
				Version	Version
				Operational	
Data Tabulation	SDTM	User Standard		Content/Structure	
				Governance	
				Version	
				Operational	
Data Tabulation	SDTM	Adopted Standard	SDTM v3.1.2	Content/Structure	
				Governance	Status
					Approved Date
					Approved By
				Version	Version
				Operational	
Data Tabulation	SDTM	Adopted Standard	mSDTM	Content/Structure	
				Governance	Status
					Approved Date
					Approved By
				Version	Version
				Operational	

Categorising Metadata Elements: Artefact Metadata Categories

Standards		State	Artefact	Metadata Category	Metadata Element
Group	Entity				
Data Tabulation	SDTM	Published Standard	SDTM v3.1.2	Content/Structure	
Data Tabulation	SDTM	Published Standard	SDTM v3.1.3	Content/Structure	
Data Tabulation	SDTM	Modified Standard	mSDTM	Content/Structure	
Data Tabulation	SDTM	User Standard		Content/Structure	
Data Tabulation	SDTM	Adopted Standard	SDTM v3.1.2	Content/Structure	
Data Tabulation	SDTM	Adopted Standard	mSDTM	Content/Structure	
Data Tabulation	SDTM	Implemented Standard	Study Domain Dataset	Content/Structure	
All	All	All	All	Governance	Status
All	All	All	All		Approved Date
All	All	All	All		Approved By
All	All	All	All	Version	Version
All	All	All	All	Operational	

Categorising Metadata Elements: Relationship Metadata Categories



Categorising Metadata Elements: Relationship Metadata Categories

Standards		State	Link	Metadata Category	Metadata Element
Group	Entity				
All	Relationship	All	CDASH-SDTM	Map	Source
					Target
					Mapping
All	Relationship	All	CDASH-SDTM	Transform	Source
					Target
					Method

Developing Content & Testing Metadata Elements

Data Tabulation	SDTM	Adopted Standard	SDTM Domain	Content/Structure	Observation Class	Special Purpose	Special Purpose
					Domain Code	DM	DM
					Dataset	dm.xpt	dm.xpt
					Description	Demographics Domain	Demographics Domain
					Structure	One record per subject	One record per subject
					Keys	STUDYID, DOMAIN, USUBJID/SUBJID	STUDYID, DOMAIN, USUBJID
					Purpose	...set of essential standard variables that describe each subject in a clinical study.	...set of essential standard variables that describe each subject in a clinical study.
				Governance	Status	Approved	Approved
					Approved Date	3-MAR-200*	7-NOV-201*
					Approved By	DSO	DSO
				Version	Version	1	2
				Operational	Study ID	[STUDYID]	[STUDYID]
					Location	.../[STUDYID]/SDTM/...	.../[STUDYID]/SDTM/...
					Sponsor Notes		USUBJID must be available

Reason for Revision

Insufficient Information – Requires ValidFrom & ValidTo Elements

Identifying Required MDR Functionality

- Understand the metadata requirements for standards management and day-to-day operationalization
- Identify the user roles and systems that interface with the MDR
- Recognize standards development, maintenance, and governance processes the MDR must support
- Recognize the operational processes the MDR must support
- Document functional requirements agnostic to the toolsets being evaluated
- Determine the user experience needs for each functional requirement (i.e. function over form or function and form)

Operational Metadata Requirements within the MDR Project

- Approach enables an MDR-solution independent specification of the required metadata to both manage (govern) and use the CDISC and associated clinical data standards to be developed.
- The method unambiguously identifies all objects (entities/artefacts/relationships) being used over the study life cycle – both those to be managed by an MDR and those that will not.
- The approach is extensible – future requirements can be added or subtracted from the metadata definitions.
- The component parts (entities/artefacts/relationships) are easily developed, with confidence that they will fit into the complete set.

Operational Metadata Requirements within the MDR Project

- The resulting specifications can be used for
 - MDR Solution evaluation
 - Validation and test case development
 - Development of solution configurations
 - Development & testing of operational metadata principles
 - Creation of MDR content for implementation loading
 - Developing MDR report, export, API and load specifications
- When combined with functionality specifications (user stories, user requirements) completes a full description of the content and functionality for an operational MDR

- Understand your standards adoption and implementation landscape before evaluating and implementing technical solutions
 - Why are we investing in data standards?
 - What standards must be supported?
 - What operational activities must be supported?
- Presented an overview of a systematic method for developing MDR metadata specifications
- Ensure metadata definitions support standards development, maintenance, and governance processes and operational business processes
- Ensure MDR functional requirements are aligned with metadata definitions and processes

- Thank you for your attention...
- For more information

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