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STRATEGY



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Achieving Interoperability by Automating the Generation of
CDISC Artefacts: Design Considerations for an Operational
Framework

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March 1, 2017

■ Automated CDISC Artefact Generation

- CDISC Standards as Specifications
 - Submission Products
- CDISC Standards as Operational Formats
 - Reduced Data Manipulation, Process Optimisation, Increased Efficiency

■ Example

- On demand access to CDISC compliant study data for data review
 - Operations efficiency, reduce query issues, minimise data traceability steps
 - Focus operational tasks on clinical data quality and fitness-for-purpose

■ Solution

- Requires the combination of technology with product definition and process efficiency

Design Considerations for an Operational Framework

Definitions - Standard

■ Standard

- ISO: International Standards Organisation
- A **standard** is a document that provides **requirements, specifications, guidelines or characteristics** that can be used consistently to ensure that materials, **products, processes** and services are fit for their purpose
- Common agreement, publicly available

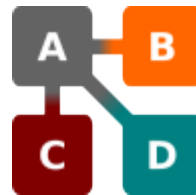
■ CDISC

- Foundational Standards

■ Interoperability

- HIMMS: Healthcare Information and Management Systems Society
- **Interoperability** is the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged. Data exchange schema and standards should permit data to be shared across clinicians, lab, hospital, pharmacy, and patient regardless of the application or application vendor.

– AFUL



Design Considerations for an Operational Framework

What Is The Goal of an Operational Framework?

■ Design:

- A **plan or drawing** produced **to show the** look and **function or workings of a** building, garment, or other **object** before it is made

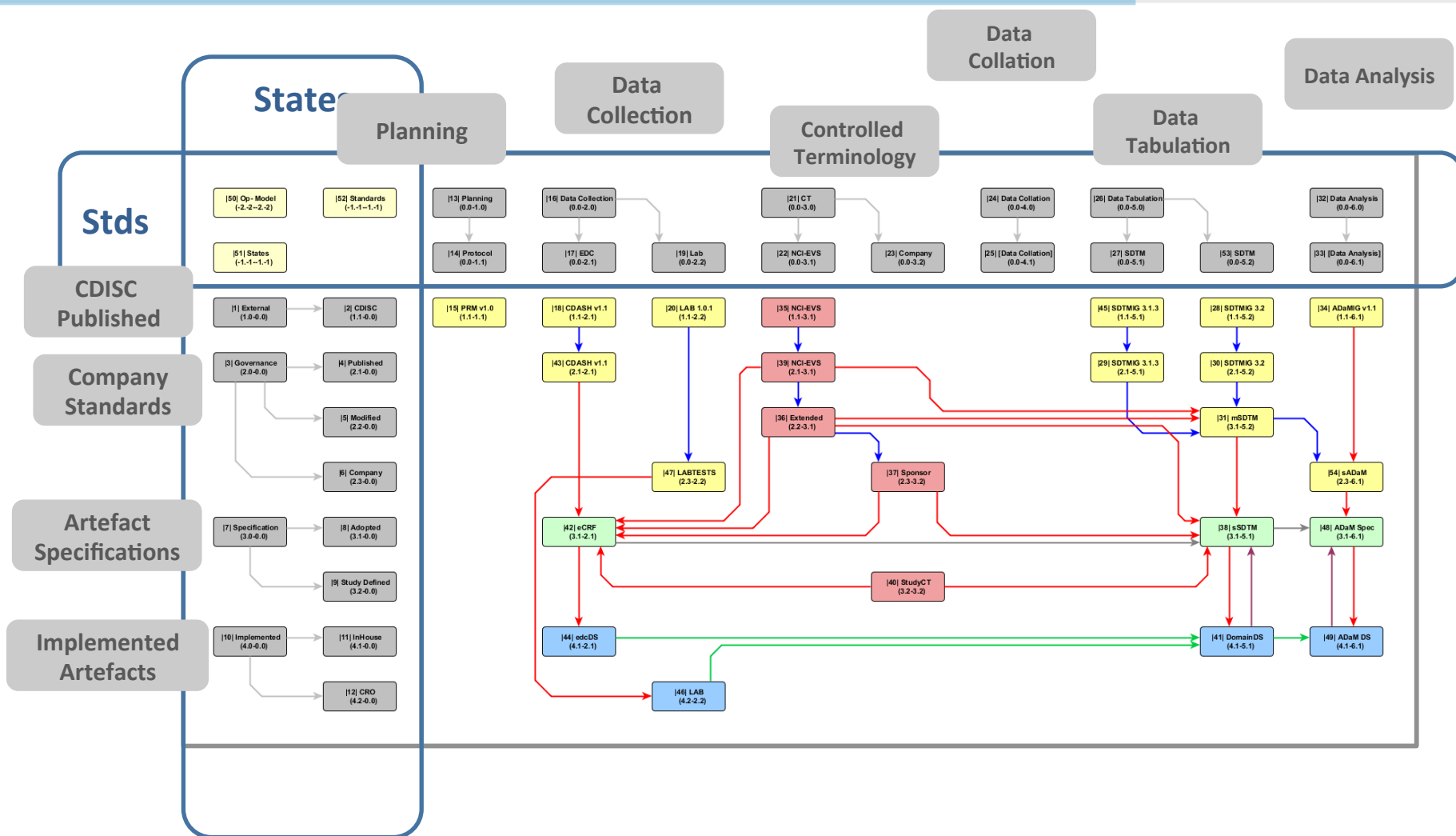
(Oxford Living Dictionaries)

■ Key Questions:

- What is the Framework required to produce?
 - SDTM datasets, Tables and Listings...
- What is the Framework required to control?
 - Generation of products, governance of standards....
- What (business) requirement is the Framework required to support?
 - Increased productivity by minimizing manual coding,

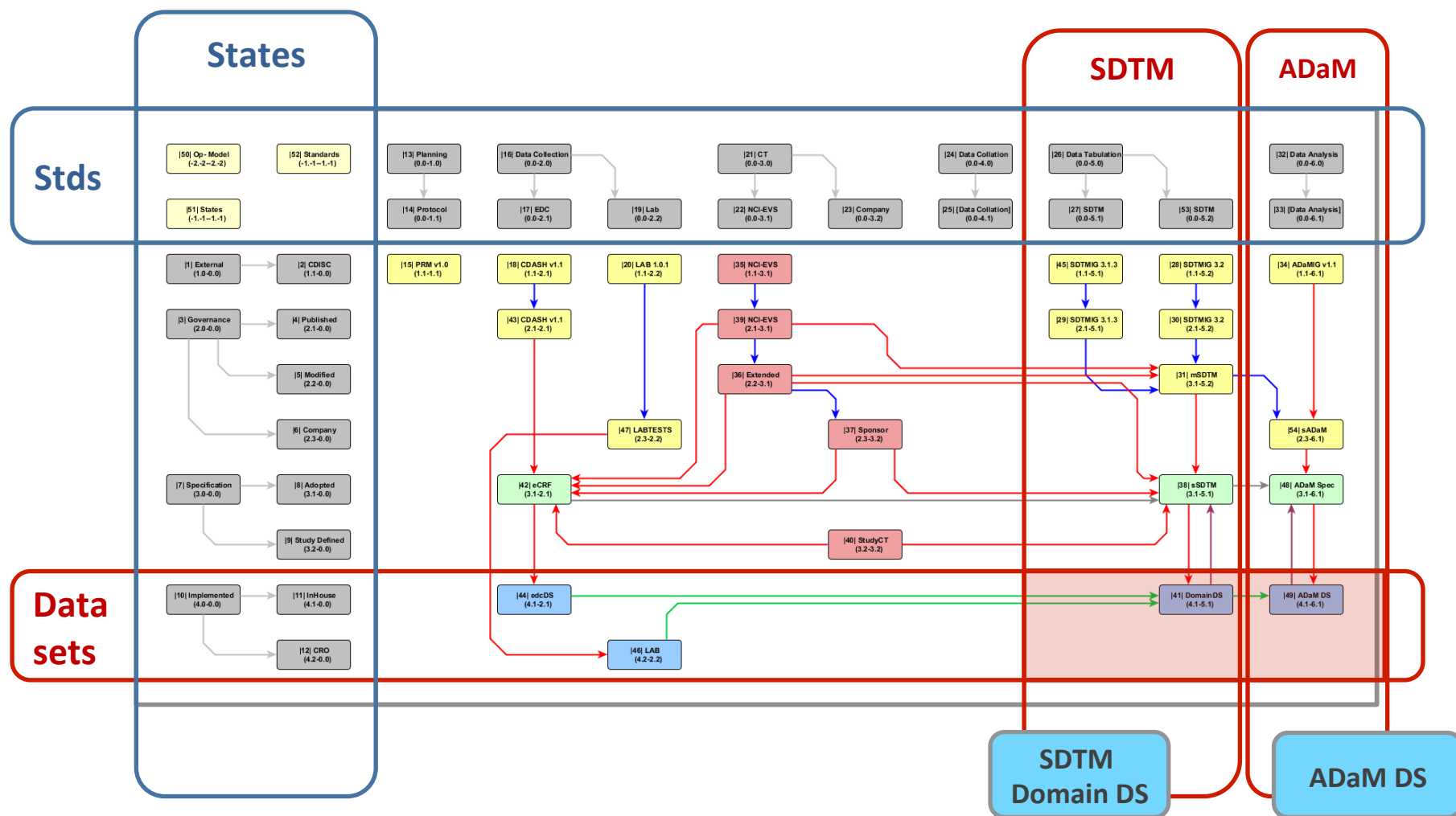
Design Considerations for an Operational Framework

What is the Framework Required to Produce?



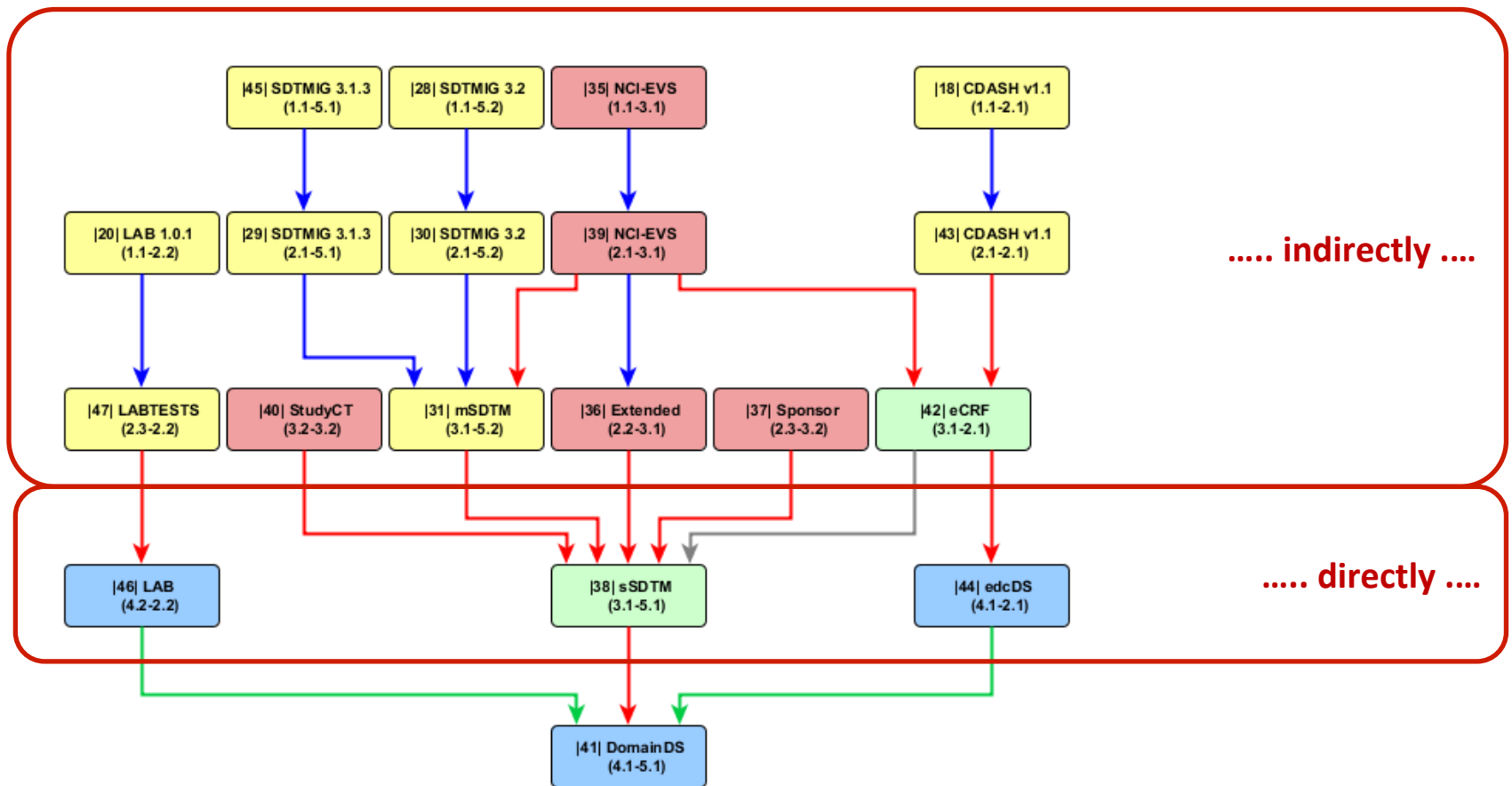
Design Considerations for an Operational Framework

What is the Framework Required to Produce?



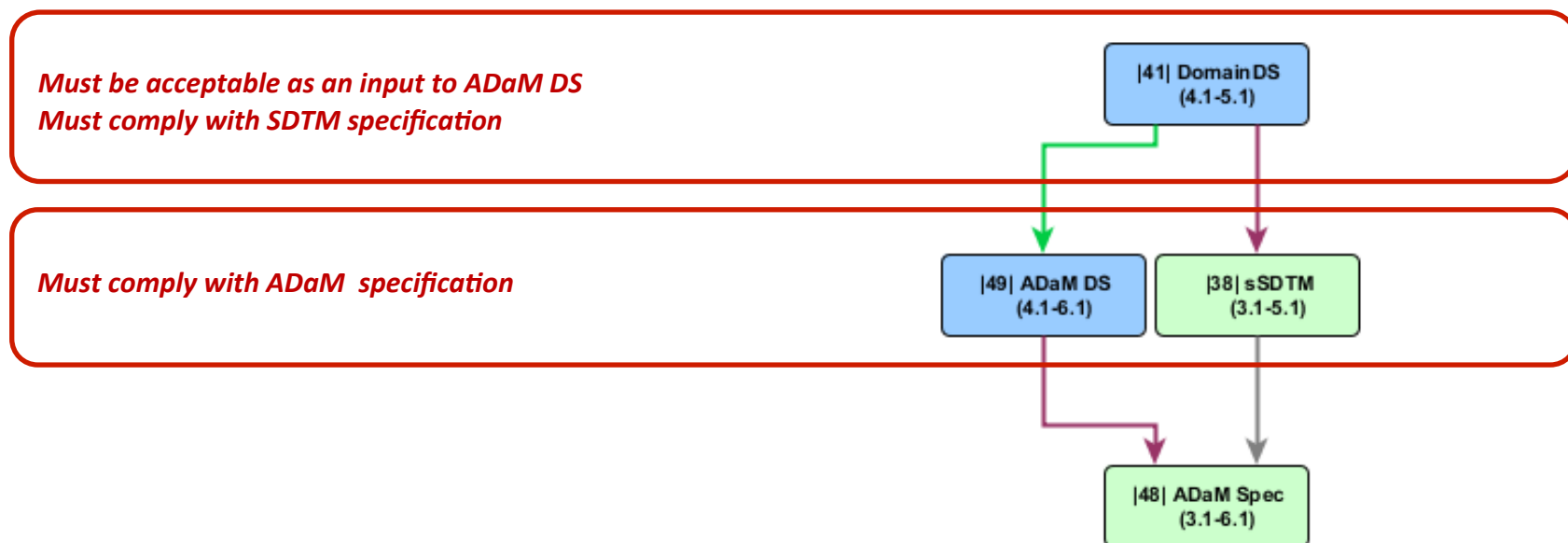
Design Considerations for an Operational Framework

What Contributes to the Product Definition?



Design Considerations for an Operational Framework

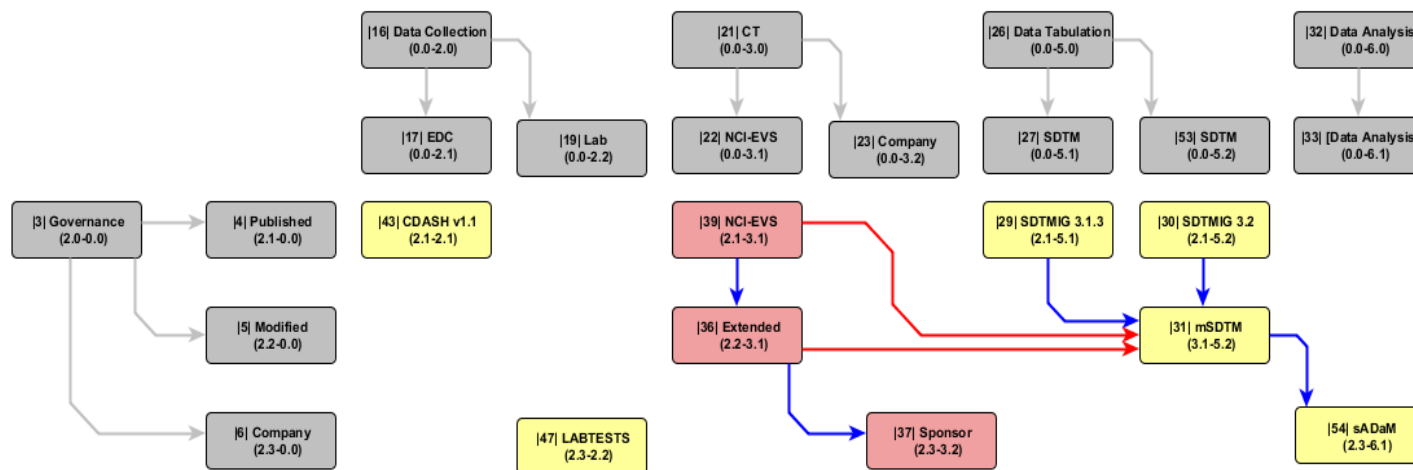
What are the Product Acceptance Criteria?



Design Considerations for an Operational Framework

What Functional/Control Requirements does the Product Require?

■ Example: Standards Governance



- 9 Standards, Variouslly Defined, *to maintain*
- 7 Inter-Standards Relationships, *to manage*

Design Considerations for an Operational Framework

What Functional/Control Requirements apply to the Product?

■ Metadata Categorisation:

[StandardsModel]				Content					Governance			Operational		
sm1	sm2	sm3	sm4	c1	c2	c3	c4	c5	a1	a2	a3	o1	o2	o3
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

SDTM-Model		Example Expected MDR Records	
Metadata Category	Metadata Element		
Content	Model_Version	1.4	1.4
Content	Reference_URL	<>	<>
Content	Observation_Class	All Classes	All Classes
Content	Structure		
Content	Variable_Order	2	2
Content	Variable_Name	DOMAIN	DOMAIN
Content	Variable_Label	Domain Abbreviation	Domain Abbreviation
Content	Variable_Type	Char	Char
Content	Variable_Role	Identifier	Identifier
Content	Variable_Description	Two-character...	Two-character...
Governance	Status	Active	Active
Governance	ValidFromDate	Aug-20xx	Aug-20xx
Governance	ValidToDate		
Operational	StudyID		WDYT-091-001

Interoperability:

All categories defined?

How will the required data be interchanged?

Richardson & Bahlavooni, 2016, Developing MDR Metadata Requirements for Operational Implementation, Poster PP06, PhUSE Annual Conference, Barcelona

Design Considerations for an Operational Framework

What is Required to Create the Product?

- Each Product (SDTM dataset, TFL etc..) needs to be considered as a separate object, and have object properties developed or be available.
- Answer the question: What is the generic structure of the typical (SAS...) program used to create this Product? Identify general and specific modules required.
- Develop metadata to define/specify each type of module – i.e. a Machine Language – that can be used to create the final Product.
- Develop programs to read and turn the metadata definitions into executable code for the final Product.

Design Considerations for an Operational Framework

What Metadata (Categories) are Required to Create the Product?

■ Minimum Metadata Categories for the Automatic Generation of CDISC Artefacts

Metadata Category	Function	
Artefact Definition	To uniquely recognise an artefact	e.g. AE SDTM dataset
Artefact Structure	Product metadata	i.e. Content Metadata
Artefact Construction	Define required code modules and define calling sequence	*Key metadata*
Artefact Mapping Rules	Metadata descriptions to develop code statements, function calls, assignments	e.g. CDASH to SDTM Transformations
Artefact Mapping Joins	Rules to merge data sources	e.g. SQL joins
Artefact Lookup	Lookup (codelist) metadata	

Design Considerations for an Operational Framework

Metadata Driven Artefact Generation: Challenges

■ Flexibility in Artefact Specification

- CDISC artefacts often require specific data manipulations; can, or how does, the design support the integration of custom functions/code?
- Configuration or Custom Specification?

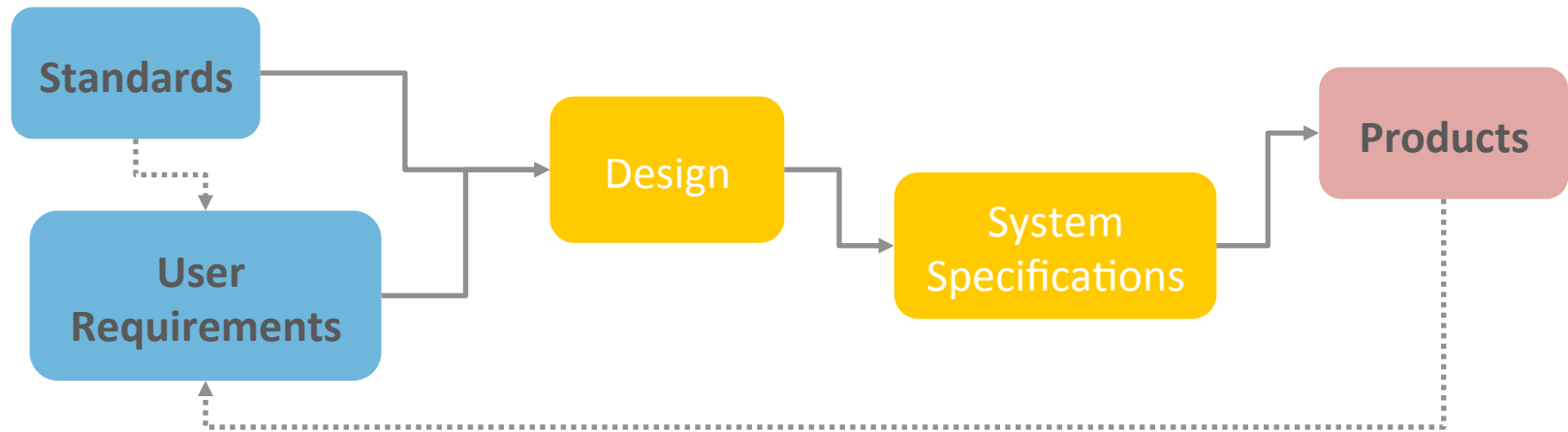
■ Software Validation

- Degree of testing, expected level of user reliance on generated products without further QC.

■ What methods are to be employed to associate functional information into the final products?

- For example, CDISC Standard Version, Artefact Version

Design Considerations for an Operational Framework Summary



- Highlight Key Design Considerations for
 - Product Definition/Specification vs Functional/Process Requirements
 - Relationship to Application: Independent vs Specific
- Comments/Observations on Interoperability

Design Considerations for an Operational Framework

Summary

		Metadata Categories	
		Product (Artefact)	Functional/Process
Relationship to Application	Independent	Standards Definition Content Construction*	Governance <i>Procedure</i> Versioning Data Traceability
	Specific	Construction* Mapping Transformation Formats Joins	<i>Configuration</i> <i>Authorisation</i> <i>Error Checking</i> <i>Audit Trails</i>

[Red] Metadata Required for Interoperability

■ Acknowledgement

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