



Standards Governance Strengthened by MDR Technology

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ICON

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Data Standards & Governance Stream – DS08

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Agenda

- Basics of Standards Governance
- Pain Points and Obstacles
- Considerations During Implementation of a Metadata Repository (MDR)

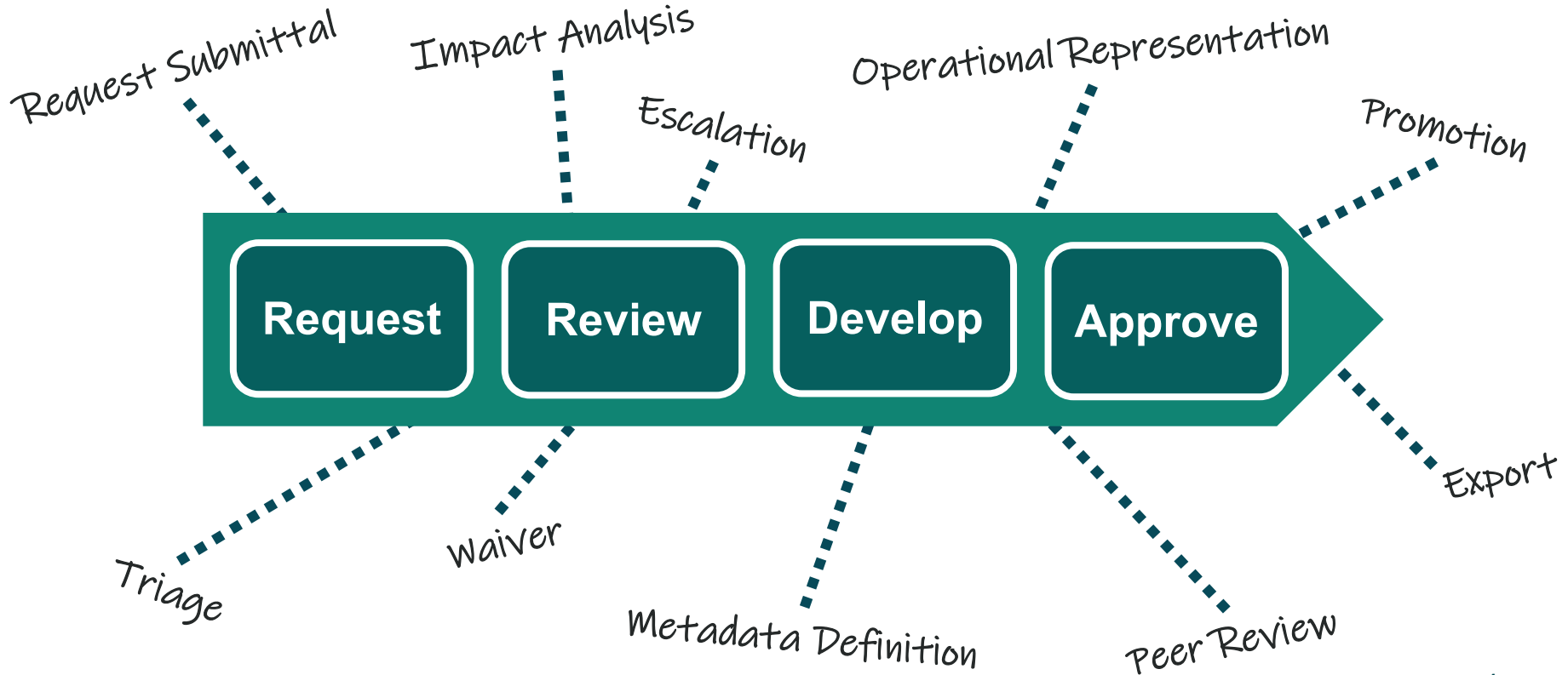


Basics of Standards Governance

Basic Standards Governance Fundamentals



Basic Standards Governance Process





Pain Points and Obstacles

Process



Standards singularly tied to FPI, regardless of time required to develop standards metadata

Turnaround time for processing and approving requests

Disconnect between the tracking of requests and the resulting developed metadata

Low reusability of standards (too many study-specific one-offs)

Inability to accurately assess impact of a change on existing standards

Metadata Management



What can be managed within the standards group vs what can only be managed within the functions

Difficult to integrate standards metadata between clinical lifecycle stages (Collection-SDTM-ADaM)

Inability to weave CDISC Controlled Terminology and Sponsor-specific CT into a single terminology package

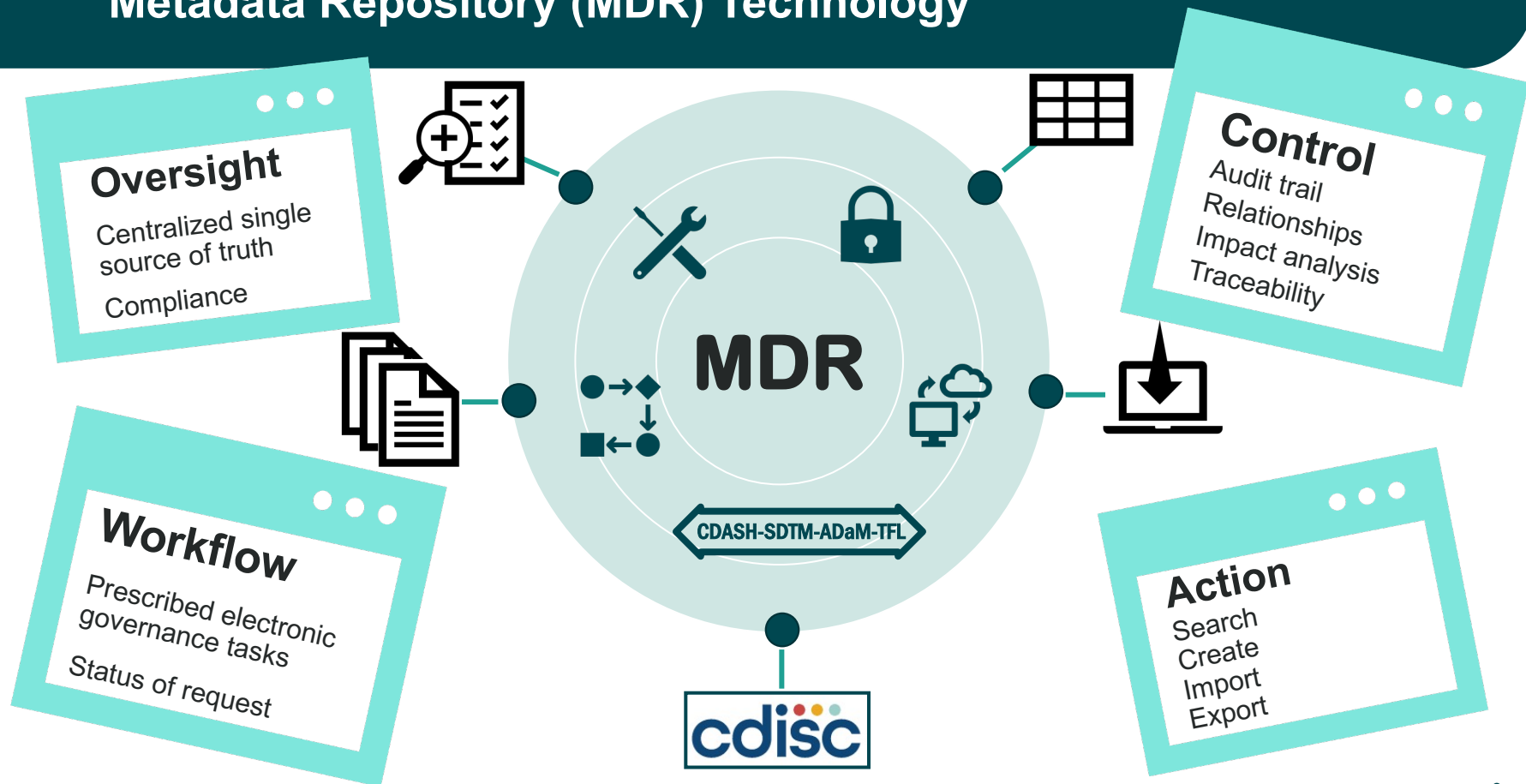
Ineffective version control of standards metadata using spreadsheets

Storage of standards from different groups in different locations, formats, and models



Considerations During Implementation of an MDR

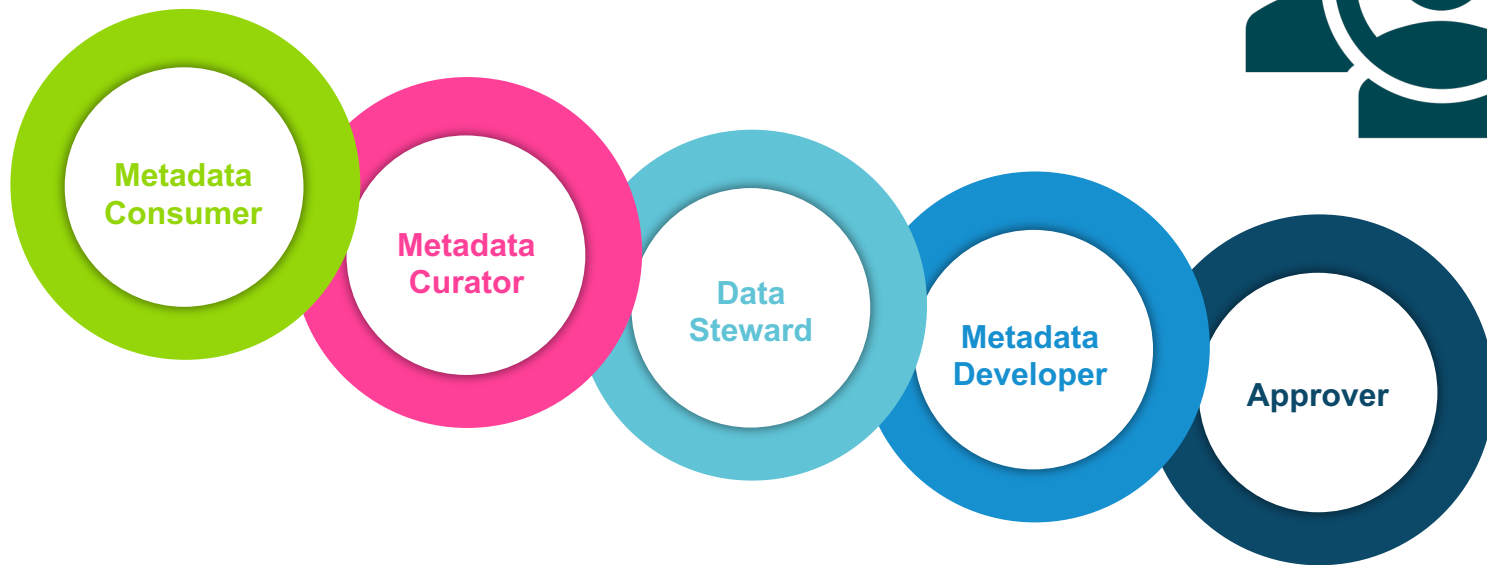
Metadata Repository (MDR) Technology



Considerations During Implementation



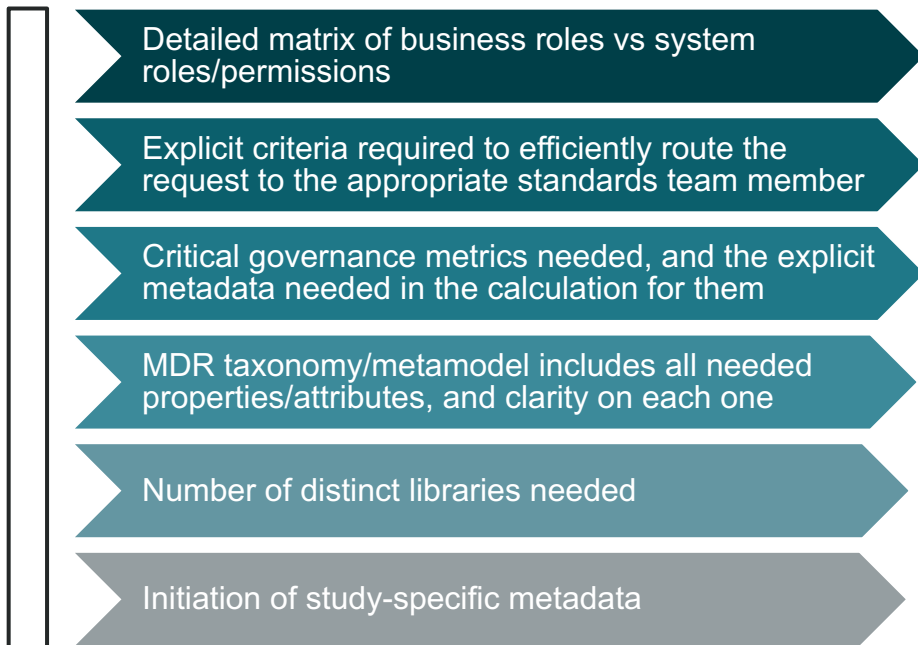
Which MDR roles are needed by the business?



Considerations During Implementation



Getting the most out of the business requirements



Considerations During Implementation



Getting the most out of the business requirements

- Detailed matrix of business roles vs system roles/permissions
- Identify critical roles required to efficiently make the request to the appropriate standards team member
- Critical governance metrics needed, and the explicit metadata needed by the requester for them
- MDR System permissions include all needed properties/attributes, and clarity on each one
- Number of distinct business needed
- Initiation of study-specific metadata

Detailed matrix of business roles vs system roles/permissions

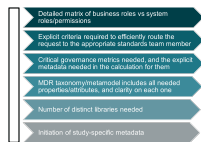
Business Role	Requestor	Triage	Developer	SDTM Steward	ADaM Steward	Standards Group	MDR User	
MDR System Role								
Metadata Consumer	X	X	X	X	X	X	X	
Metadata Developer		X	X	X	X			
Metadata Curator		X	X					
Approver		X		X	X	X		
Data Steward				X	X	X		
.....								



Considerations During Implementation



Getting the most out of the business requirements



Explicit criteria required to efficiently route the request to the appropriate standards team member

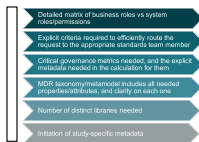
- Sufficient information provided in request
- Impact analysis of change request
- Informational Revision only needed
- Cross-functional review/development needed
- Study-specific standard vs existing standard
- High-level issue requiring full Standards Team decision



Considerations During Implementation



Getting the most out of the business requirements



Critical governance metrics needed, and the explicit metadata needed in the calculation for them

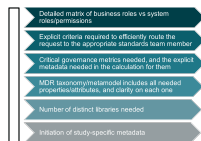
- ☐ Percent Usage of Standards (by TA, by Study)
- ☐ Time to Approval
- ☐ Percent of Rejected Requests
- ☐ Status of Requests In-Process
- ☐ On-Hold Requests



Considerations During Implementation



Getting the most out of the business requirements



MDR taxonomy/metamodel includes all needed properties/attributes, and clarity on each one



EDC specific

- Edit Check Name
- Form Changes Allowed?
- Mandatory
- Required
- EDC Implementation Notes

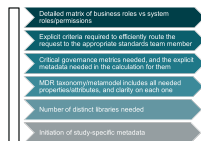
SDTM specific

- SUPPQUAL ID Field
- SUPPQUAL.QVAL Field
- Macro Name
- Macro Input Parameters
- Record Definition Variable
- Record Definition Variable Value

Considerations During Implementation



Getting the most out of the business requirements



Number of distinct libraries needed

Common Core Standards

Oncology TA

CV TA

Respiratory TA

Oncology TA Core

CV TA Core

Respiratory TA Core



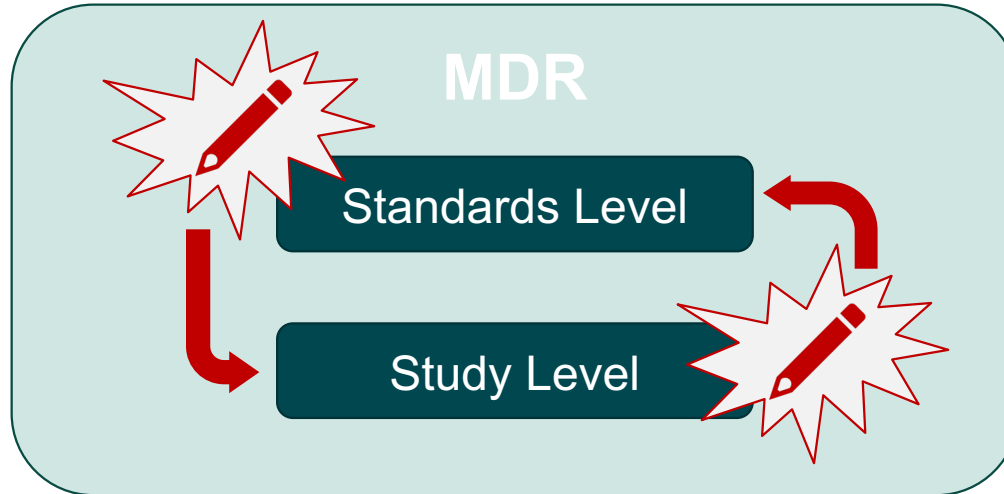
Considerations During Implementation



Getting the most out of the business requirements

- Detailed matrix of business roles vs system requirements
- Request forms required to efficiently route the request to the appropriate standards team member
- Critical governance metrics needed, and the explicit metadata needed to the calculation for them
- MDR team responsibilities include all needed properties/attributes, and clarity on each one
- Number of distinct libraries needed
- Initiation of study-specific metadata

Initiation of study-specific metadata



Considerations During Implementation



Availability of knowledgeable business resources to write and execute UAT (User Acceptance Testing)



Scenario Author



Scenario Reviewer

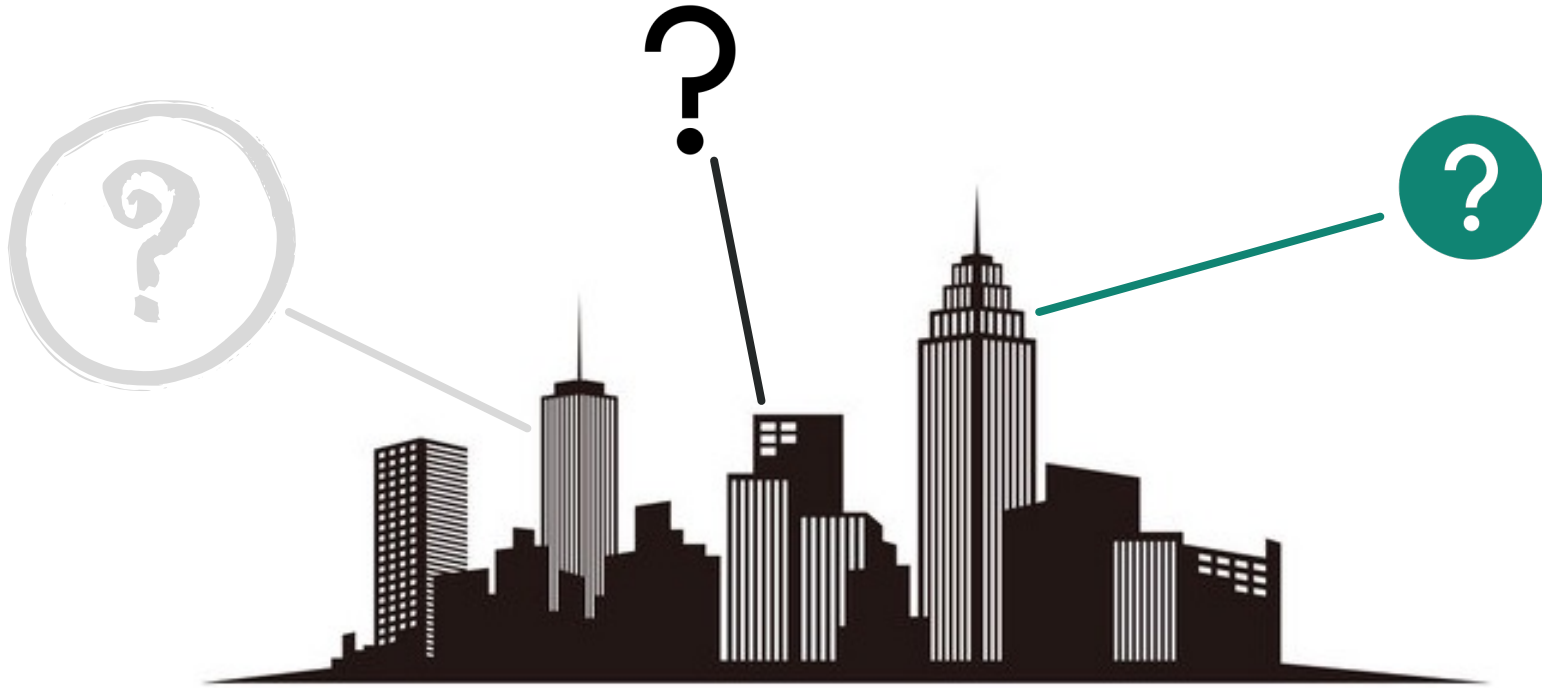


Script Author



Script Executor

Questions



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