

Common-Sense Tips for Weaving Governance into an MDR

Ken Stoltzfus
Nurocor

*PhUSE US Connect 2020
Data Standards & Governance Stream - DS14
March 11, 2020*

Agenda

● Governance & MDR in a Nutshell 

● Analysis & Design 

● Managing the Project 

● Questions 

Agenda

● **Governance & MDR in a Nutshell**



● **Analysis & Design**



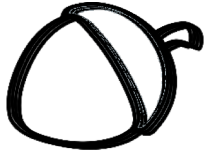
● **Managing the Project**



● **Questions**



Standards Governance in a Nutshell



Oversight

- Decision-making on all standards issues
- Both industry and sponsor-specific clinical data standards

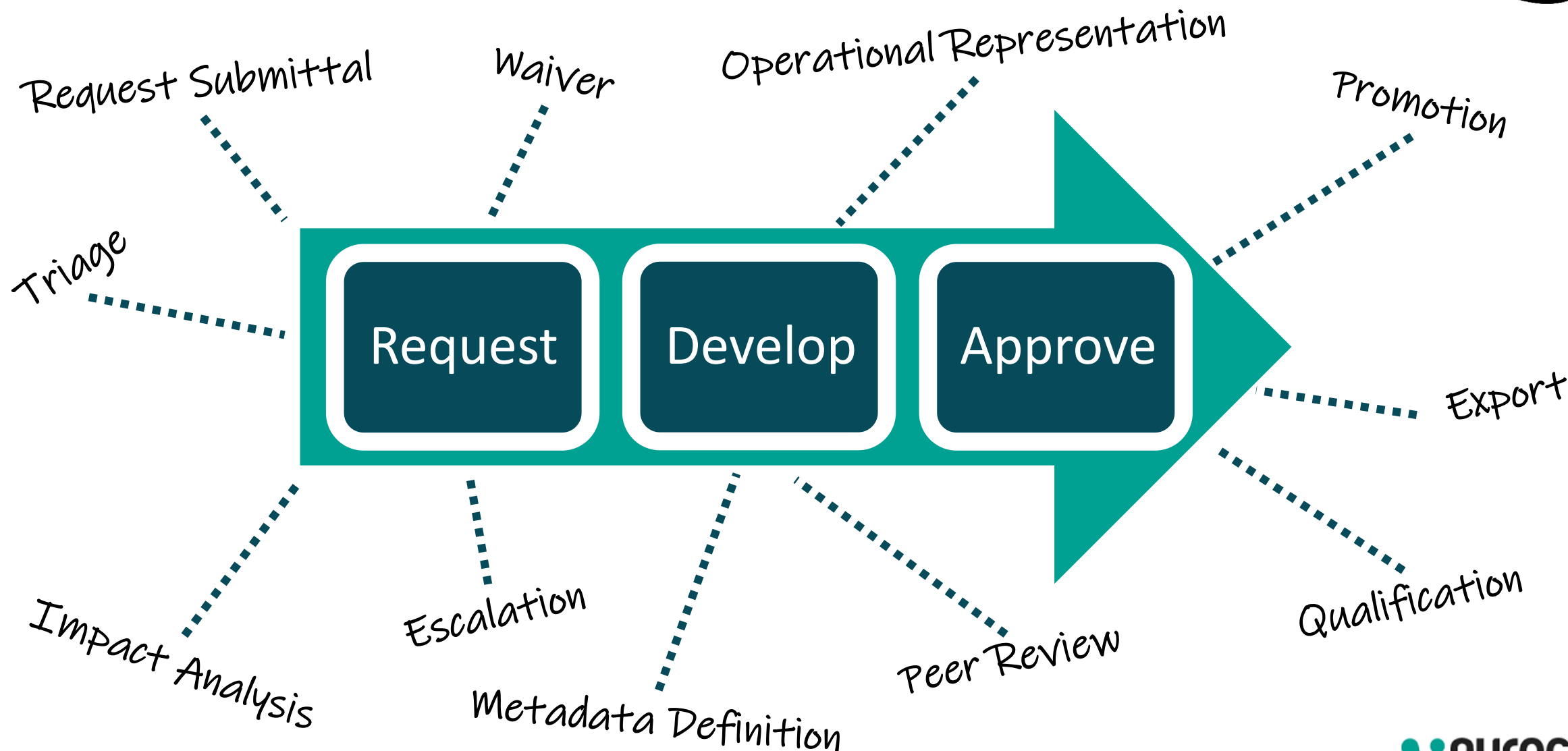
Maintenance

- Quick and efficient development
- Modifications with an eye on compliance and reusability

Efficiencies

- Consistent usage across the clinical organization
- Facilitation of standards-based processes
- Focus on maximum clinical process efficiency

Basic Governance Process



Standards Pain Points



Challenges

Standards released “at risk” before approval, being only partially developed and vetted

Inefficient delivery of approved standards due to the disconnect between the tracking of requests and the resulting developed metadata

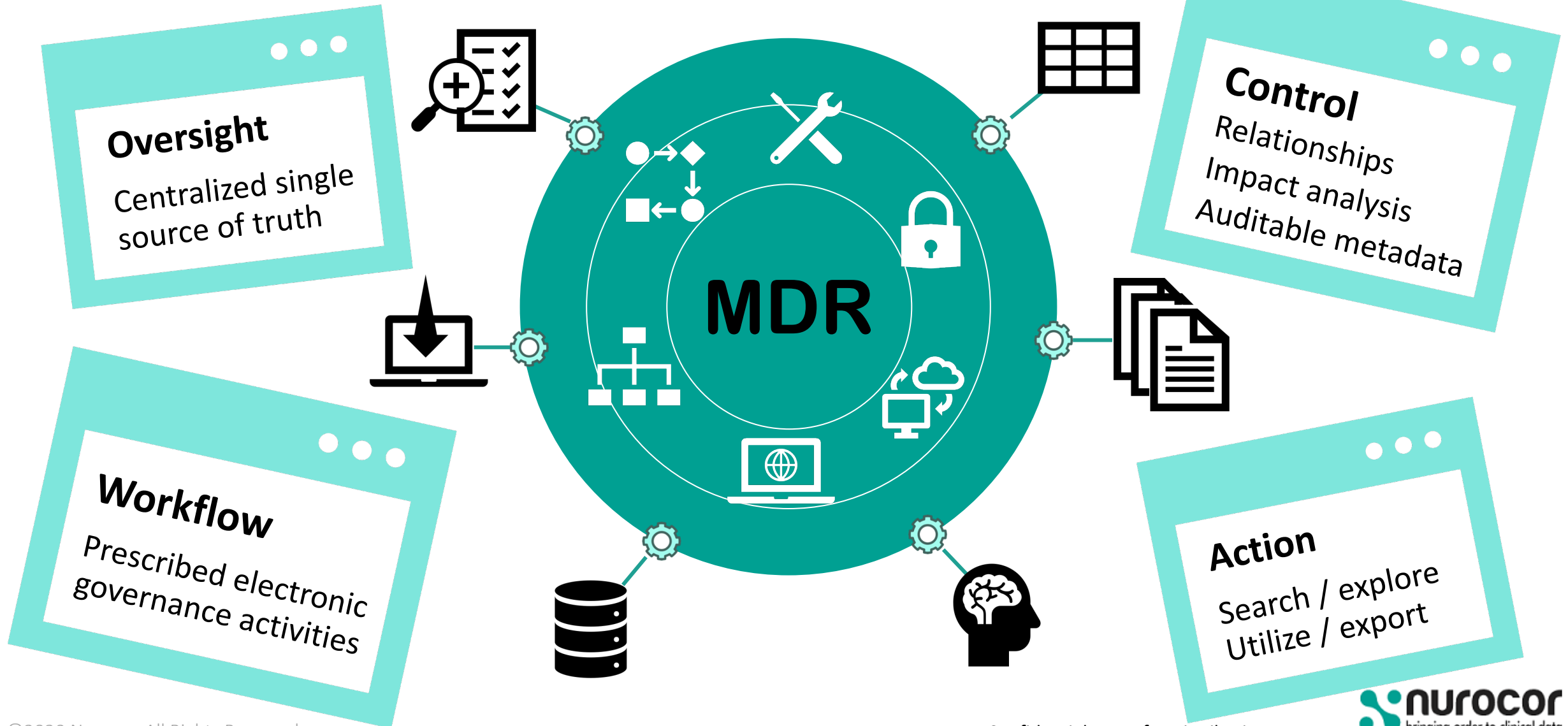
High rate of usage of “one-off” structures due to frequent clinical team insistence upon exceptions for their specific study

Lack of connected metadata between related standards across the clinical data lifecycle

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

Uncoordinated handoffs during standards development that prolongs delivery times and places standards on the critical path

MDR Technology in a Nutshell



Agenda

● Governance & MDR in a Nutshell



● Analysis & Design



● Managing the Project



● Questions





Proactive Analysis Considerations

- ➔ Evaluate the existing governance processes honestly and comprehensively
- ➔ Opportunity for process improvement
- ➔ Pressure-test analysis against industry best practices
- ➔ Describe and document the criteria upon which the triage part of the process is based
- ➔ How far should the scope of standards governance reach



Proactive Design Considerations

	Business Requirements
☒	Explicit information critical for the impact analysis
☒	Detailed matrix of business roles vs system roles/permissions
☒	Criteria and steps that describe the escalation of a request
☒	Explicit criteria required to efficiently route the request to the appropriate standards team member
☒	Critical governance metrics needed, and the explicit metadata needed in the calculation for them

Agenda

● Governance & MDR in a Nutshell 

● Analysis & Design 

● **Managing the Project** 

● Questions 



Project Management Considerations

General

- Real-world use of tool by the users before making the final tweaks of the workflows
- Resist the temptation to incorporate every idea that surfaces beyond the development phase
- Metadata Migration should be addressed throughout the technical implementation



Project Management Considerations

Subject Matter Experts (SME)

- SMEs know how the standards metadata is used and how the governance processes function
- Firm commitment from the correct subject matter experts (SME) resources to do quick off-line review when required
- Users/SMEs be heavily involved in User Acceptance Testing (UAT) from the ground up

Project Management Considerations



Prioritization

- The critical functions within the governance processes are the mandatory pieces to include in the tool's workflow
- Translation of high-priority requests in the governance process into the workflow
- Early engagement with leadership to ensure priority of work on the implementation when in competition with project work



Questions



Contact Information

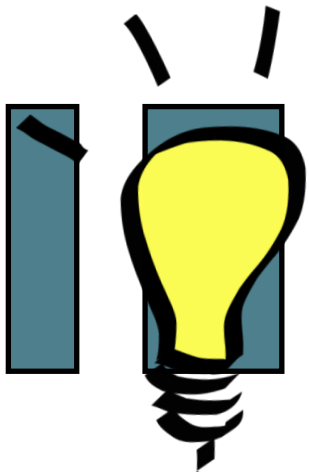


Ken Stoltzfus

Director, Consulting Solutions

Nurocor

ken.stoltzfus@nurocor.com



***Feel free to visit the Nurocor booth for
more information on Nurocor solutions***