



Today's Standards Governance: Getting a Boost from Leveraging an MDR

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Agenda

- **Governance Under the Microscope** 
- **What Can Technology Do for You?** 
- **Blending Process & Technology** 
- **Questions** 

Agenda

● **Governance Under the Microscope**



● What Can Technology Do for You?



● Blending Process & Technology

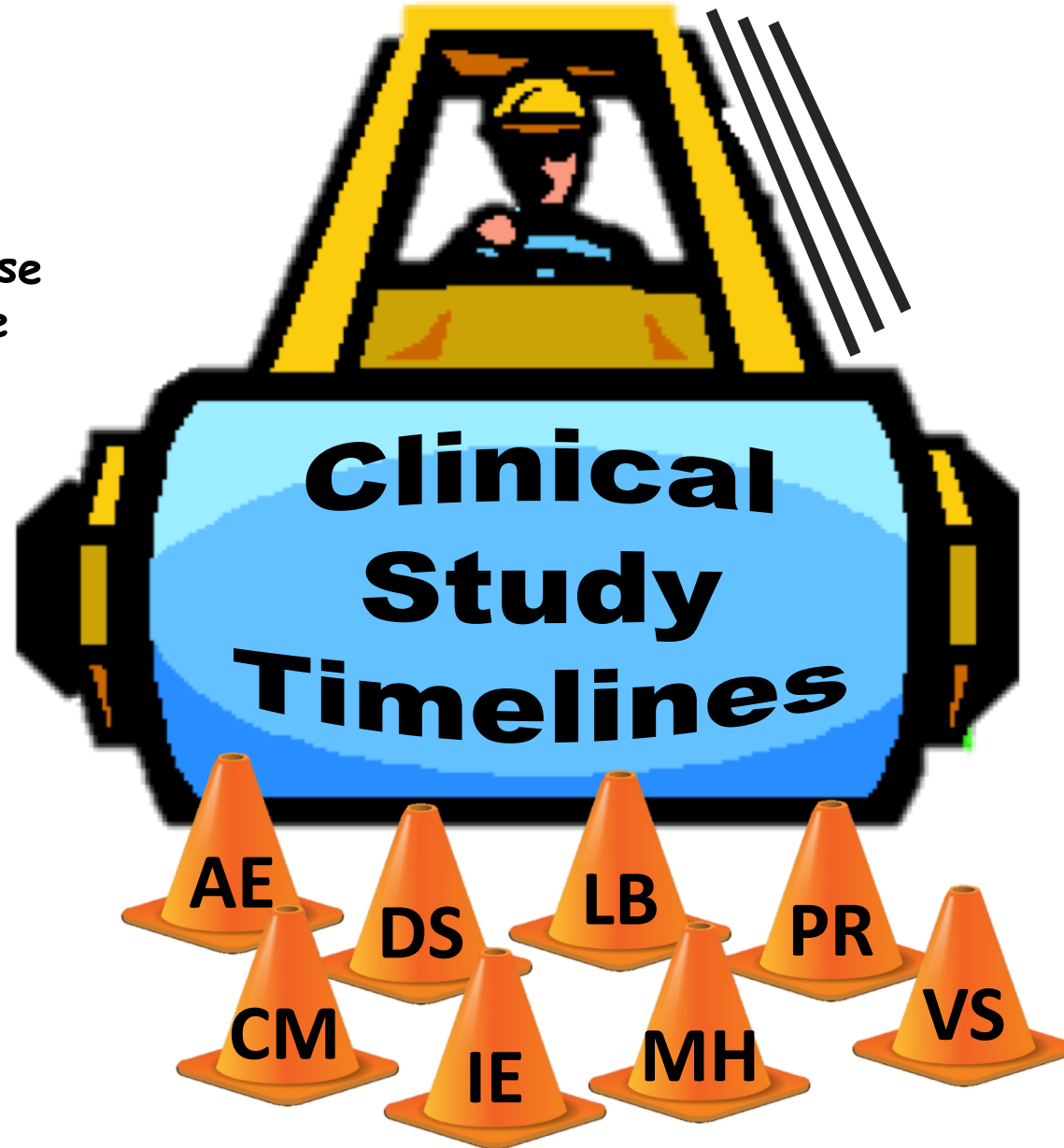


● Questions



Awesome! We finally got those standards in place for all the clinical teams to use!

Uh....don't look now, but....





Standards Governance Strategic Tasks

- ❖ Oversight for the development and maintenance of clinical data standards

- ⚠ *Decision-making without full authority*

- ❖ Ensuring that a standard is developed efficiently, consistently, and properly used across the clinical trials organization

- ⚠ *Having to sometimes be the policeman*

- ❖ Insurance that maximum clinical process efficiency from a standards-based clinical data lifecycle is achievable

- ⚠ *Metrics, metrics, and more metrics*



Basic Process





Basic Process

Request

Submittal

Evaluation

Waiver

Triage

Escalation

Impact Analysis

- ☒ Activities surrounding a request to the Standards Group explaining the need for a new standard or revision to an existing one



Basic Process

Develop

Operational Representation

Metadata Definition

Peer Review

- ☒ Leveraging the decisions and information from the Request stage to tangibly create or modify the metadata that describes the standard



Basic Process

Approve

Promotion

Qualification

Export



The completion of the governance process in readying the decision of the request for general consumption by the larger clinical organization



Business Roles



Peer Reviewer



Metadata Developer



Requestor



Standards Committee



Request Triage



Business Roles Responsibilities

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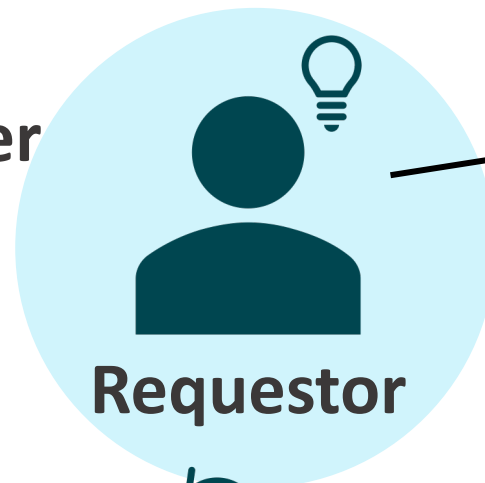
Peer Reviewer



Metadata Developer



Standards Committee



Requestor



Request Triage

- ➔ Well-informed messenger of the business need from the study team to the standards group
- ➔ Physically submits the request into the system, supplying all necessary information
- ➔ Reviews the standards team output of the request if needed



Business Roles Responsibilities

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Requestor



Peer Reviewer



Metadata Developer



Standards Committee



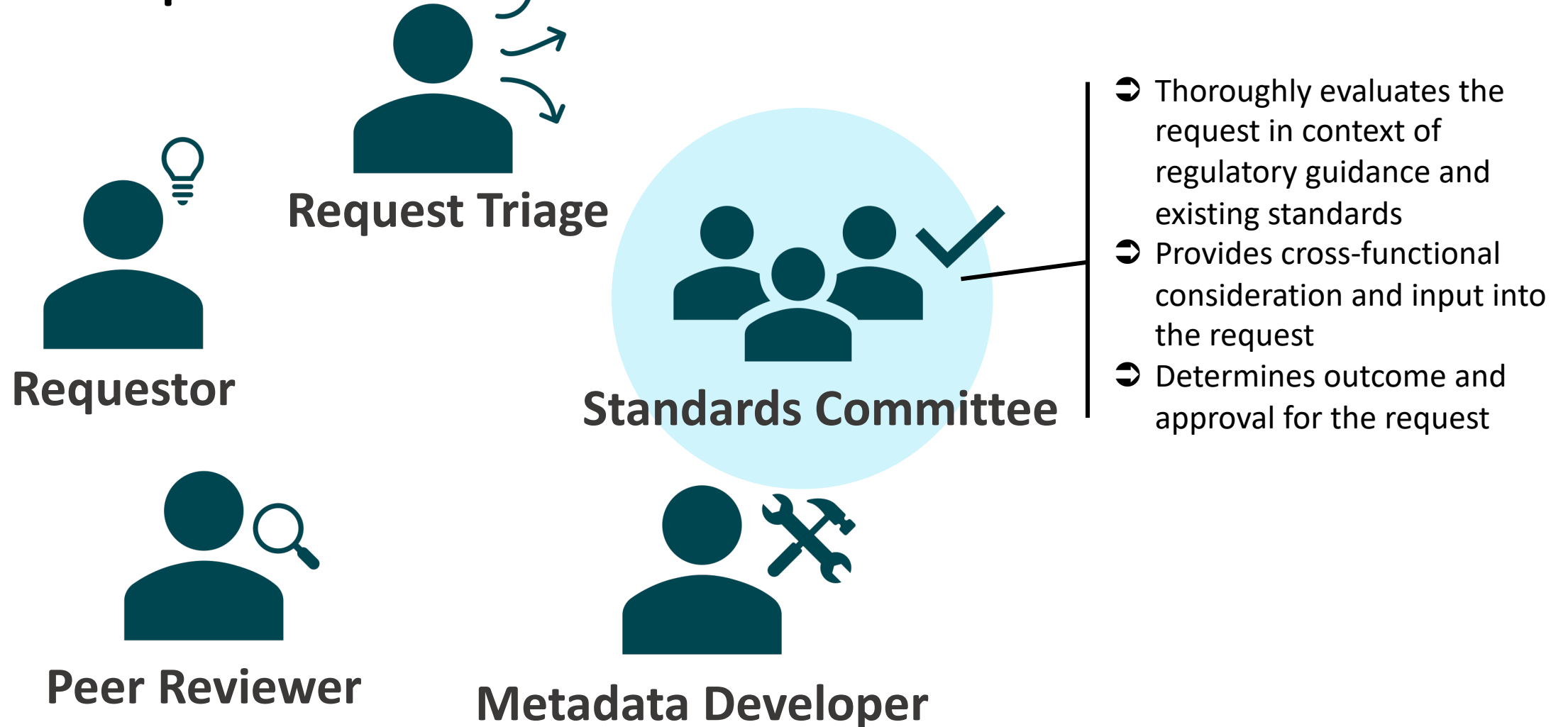
Request Triage

- ➔ Performs initial assessment on the request to expedite processing
- ➔ Ensures completeness of request and communicates with Requestor
- ➔ Routes the request to a Developer if appropriate
- ➔ Escalates the request if necessary



Business Roles Responsibilities

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Business Roles Responsibilities

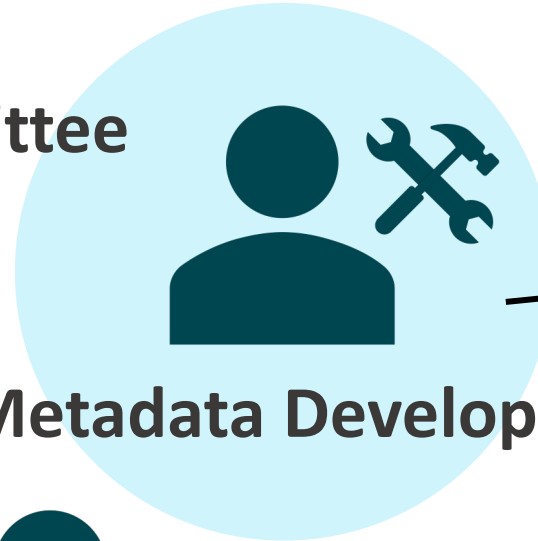
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Standards Committee



Request Triage



Metadata Developer

- ➔ Develops the metadata that defines the standard according to the Request
- ➔ Provides subject matter expertise into development
- ➔ Consults other area experts if necessary



Requestor



Peer Reviewer



Business Roles Responsibilities

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Standards Committee



Metadata Developer



Peer Reviewer

- ➔ Reviews the developed standards metadata against the Request
- ➔ Determines readiness of developed standard for implementation



Request Triage



Requestor

Agenda

● Governance Under the Microscope



● **What Can Technology Do for You?**



● Blending Process & Technology



● Questions





Business Requirements

☒ Oversight

☒ Control

☒ Workflow

☒ Action



Business Requirements

☒ Oversight

- Centralized single source of truth for the standards
- Logging of standards requests
- Tracking of standards requests
- Transparency to the overall clinical organization
- Administrative ability to manage access to the standards metadata



Business Requirements

☒ Control

- Standards requests that are linked to the actual standards metadata
- Provide an impact analysis that reveals the impact that a change would have upon existing standards
- Well-defined, yet adaptable versioning of standards metadata that enables use of multiple versions
- Relationships between metadata that defines the structure of the standard (e.g. variable ↔ codelist ↔ values)
- Traceability of results back to sources and of auditable changes in metadata (who/where/when)



Business Requirements

☒ Workflow

- Enable electronic governance activities in a prescribed approach in an asynchronous manner
- Move a standards request from submittal to approval
- Automated notifications where appropriate
- Meaningful metrics for the performance of the standards governance activities
- Quantification of adherence to standards



Business Requirements

☒ Action

- Enable clinical teams to search, explore, and utilize a central repository of standards that are most appropriate for their trials
- Export of standards metadata to clinical systems across the clinical data lifecycle
- Enable efficient, standardized metadata-driven processes within the clinical data flow



An MDR Can Enable.....

- ★ Consistent usage of the same metadata for multiple uses by multiple users
- ★ Inheritance between standards via relationships in the metadata, regardless of taxonomy or structure
- ★ Efficient standards governance and maintenance of metadata according to SOP-compliant workflows and approvals
- ★ Faster, better informed standards decisions based on thorough impact analysis results
- ★ Usage of medical concepts for the metadata to group and tie together relevant data elements under a single medical meaning
- ★ Consistent, compliant data meaning for clinical systems upstream and downstream

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● What Can Technology Do for You?

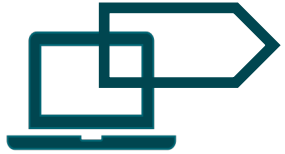


● **Blending Process & Technology**



● Questions



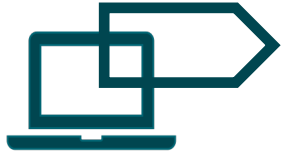


Use Case 1

Situation:

- Clinical team determines standards needed for a study based on the protocol
- Antagonistic negotiation with standards team over allowable uses and changes

- Standards team member present in the clinical team meeting
- Dynamic assessment of the protocol's requirements within the open MDR application
- Reduction in time to finalize list of standards needed as per protocol
- *De facto* training for the clinical team on the optimal practice of completing the standards request form
- Standards team member spreads the “standards message” in a positive & collaborative manner



Use Case 2

Situation:

- A new/revised standard needs approval from a non-data clinical expert
- Clinical expert is not technologically savvy and remains outside of the user group for the MDR

- Exclude this specific clinical operations approval task from the electronic workflow
- Standards team member directly interacts with the clinical operations resource to obtain the approval
- Standards team member enters the approval verbiage into the tool as the documented, auditable response
- Prevent the workflow bottleneck and maintain efficiencies brought by an MDR
- Foster cooperation and partnership with the non-data clinical resources for the standards effort



Questions

