

Business & Decision Life Sciences

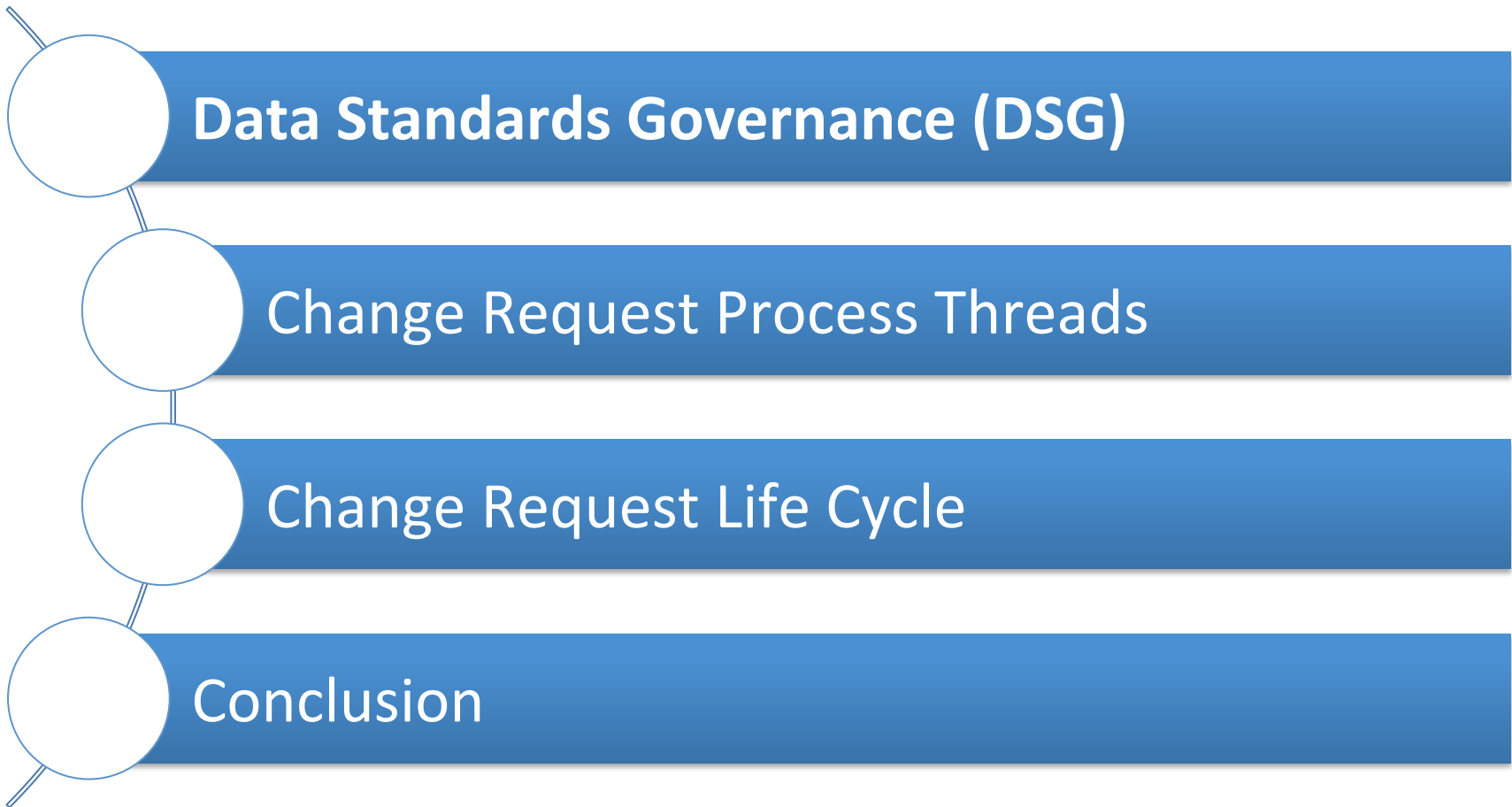
Data Governance – Keeping Control through a Well-Defined Change Request Process

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12 OCT 2015



Agenda



Data Standards Governance: Vision



Deliver End-to-End (E2E) metadata definition and management for:

- Protocol Elements; Endpoints; Assessments;



- Statistical Methods; Statistical Analysis Plan (SAP) elements;



- Data Collection Modules (DCMs);



- CDASH, SDTM, ADaM standards;



- Displays: Tables, Figures and Listings (TFLs);



- Analysis Results Metadata (ARM)



Data Standards Governance: Mission

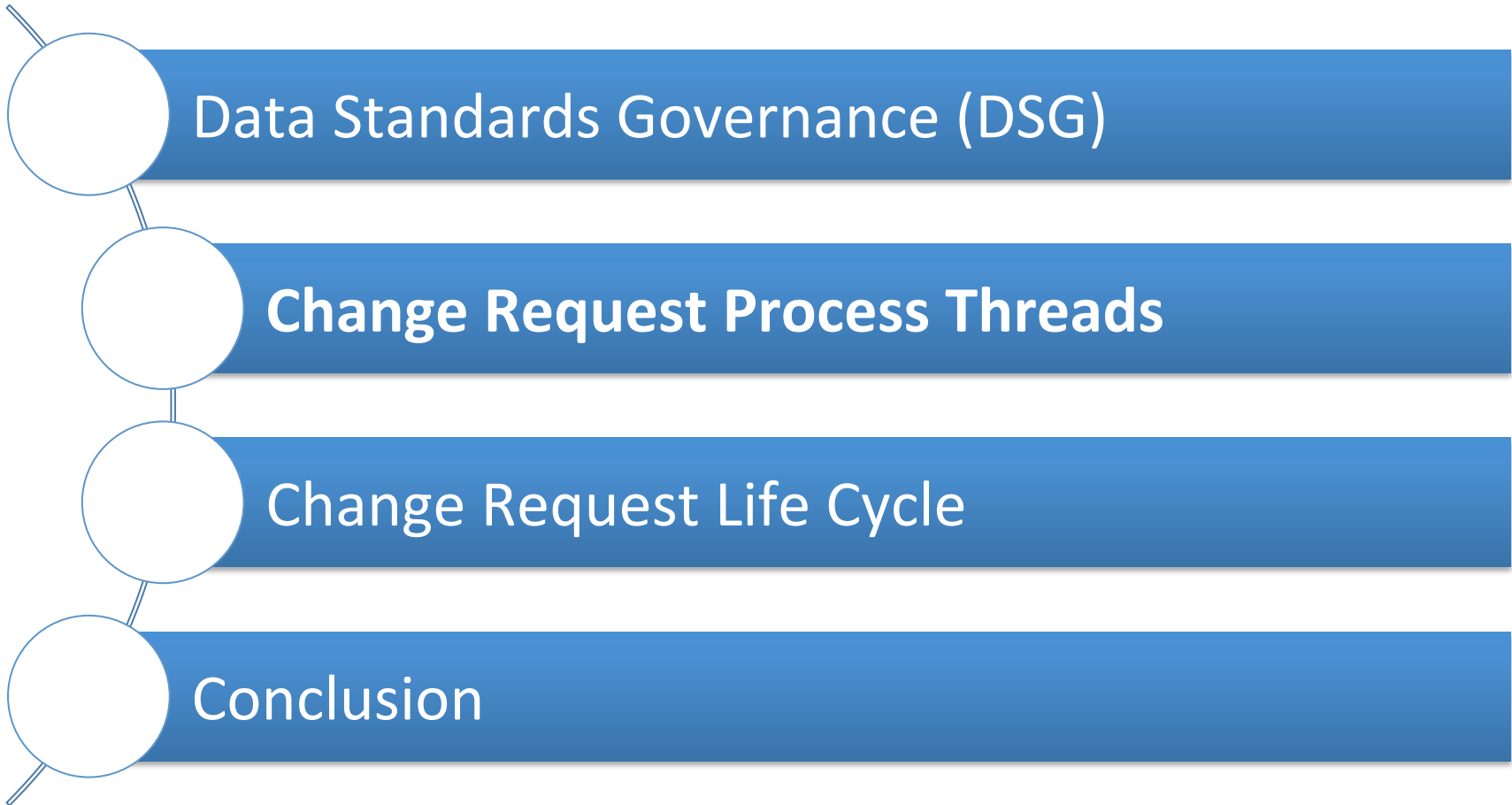


Creation of Efficient Change Request Process that:

- Enables controlled changes to a global standards repository platform
- Is nimble and open
 - Data standards defined in the repository are quickly adapted to reflect the changing needs of the business and the platform's users



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Change Request: Threads in the Process

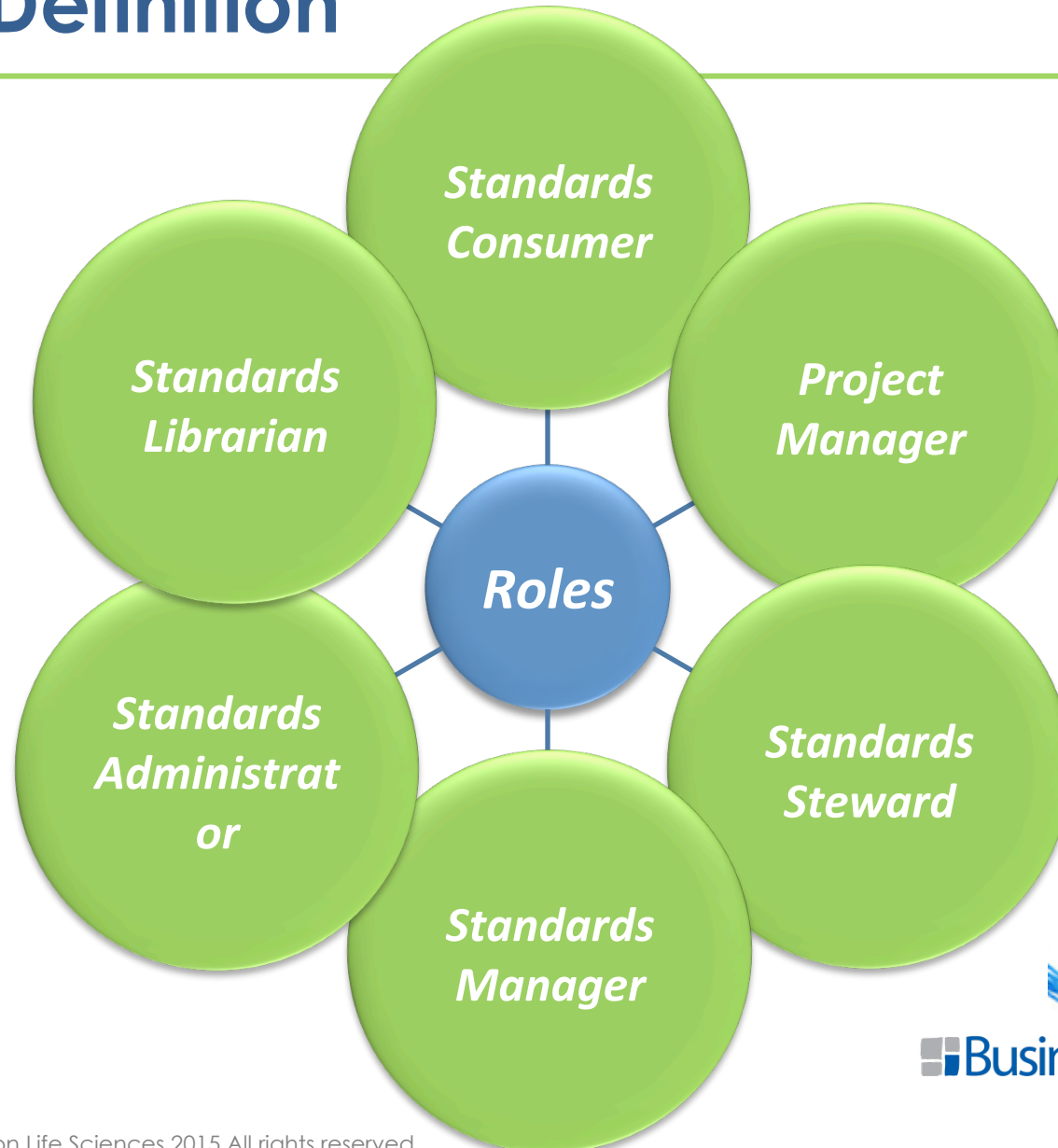


Threads of Change Request Process:

- Roles Definition
- Evaluation Criteria
- Cluster Categorization
- Impact Analysis and Work Packages
- Life Cycle



Change Request Process Threads: Roles Definition



Change Request Process Threads: Cluster Categorization



- Type of Change Request influences type of Evaluation to be performed:
 - It Influences who needs to be involved in the Change Request Evaluation Step
 - Consequently, Change Requests grouped into three Clusters



Change Request Process Threads: Cluster Categorization



■ Cluster 1: **Major** standard development initiatives

- New Disease Area or Therapeutic Area
- New Global Standard
- Upgrade to a new CDISC standard



Change Request Process Threads: Cluster Categorization



■ Cluster 2: Changes or additions related to **Implementation** of the standards

- New or updated library implementation
- Data collection / data analysis **implementation** object error
- Compliance issue



Change Request Process Threads: Cluster Categorization



■ Cluster 3: Changes or additions related to **Content** of the standards

- New or updated library content object
- Data collection / data analysis **content** object error
- A new or updated standard from Transcelerate



Change Request: Cluster / Evaluation Criteria

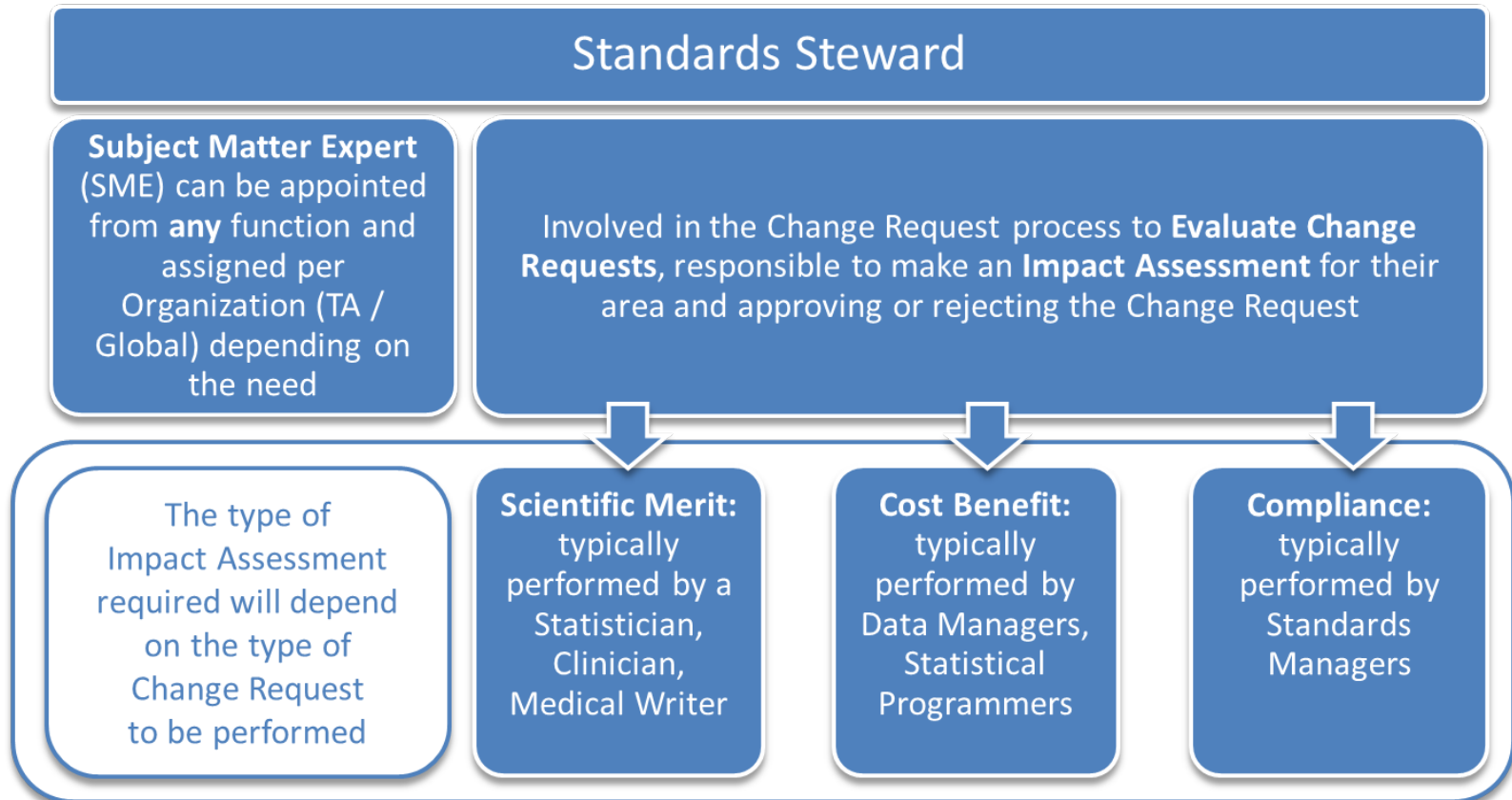


■ Evaluation Criteria combined with Cluster Categorization

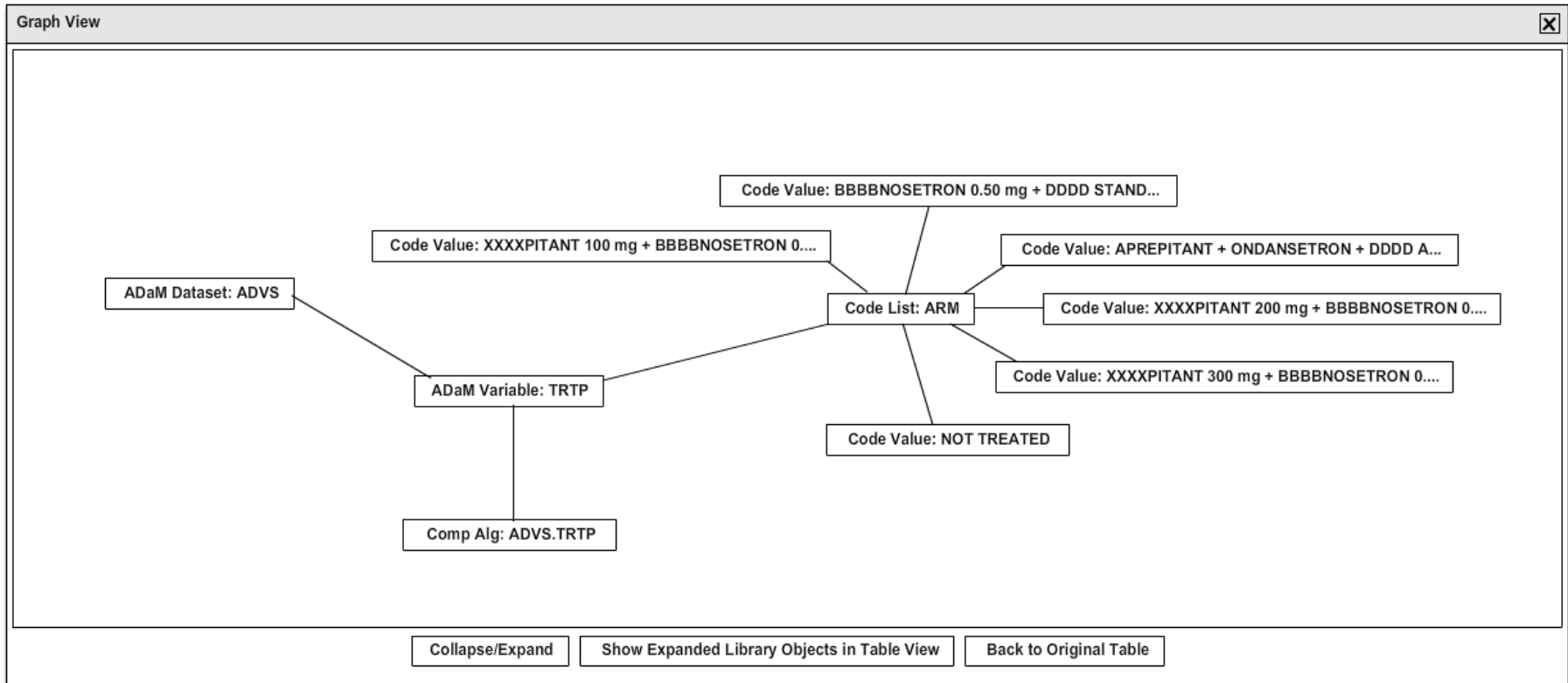
	Change Request Evaluation Criteria		
	Scientific Merit	Cost Benefit	Compliance
Cluster 1	By default, Cluster 1 Change Requests are designated to have passed all Evaluation Criteria		
Cluster 2	N/A		
Cluster 3			



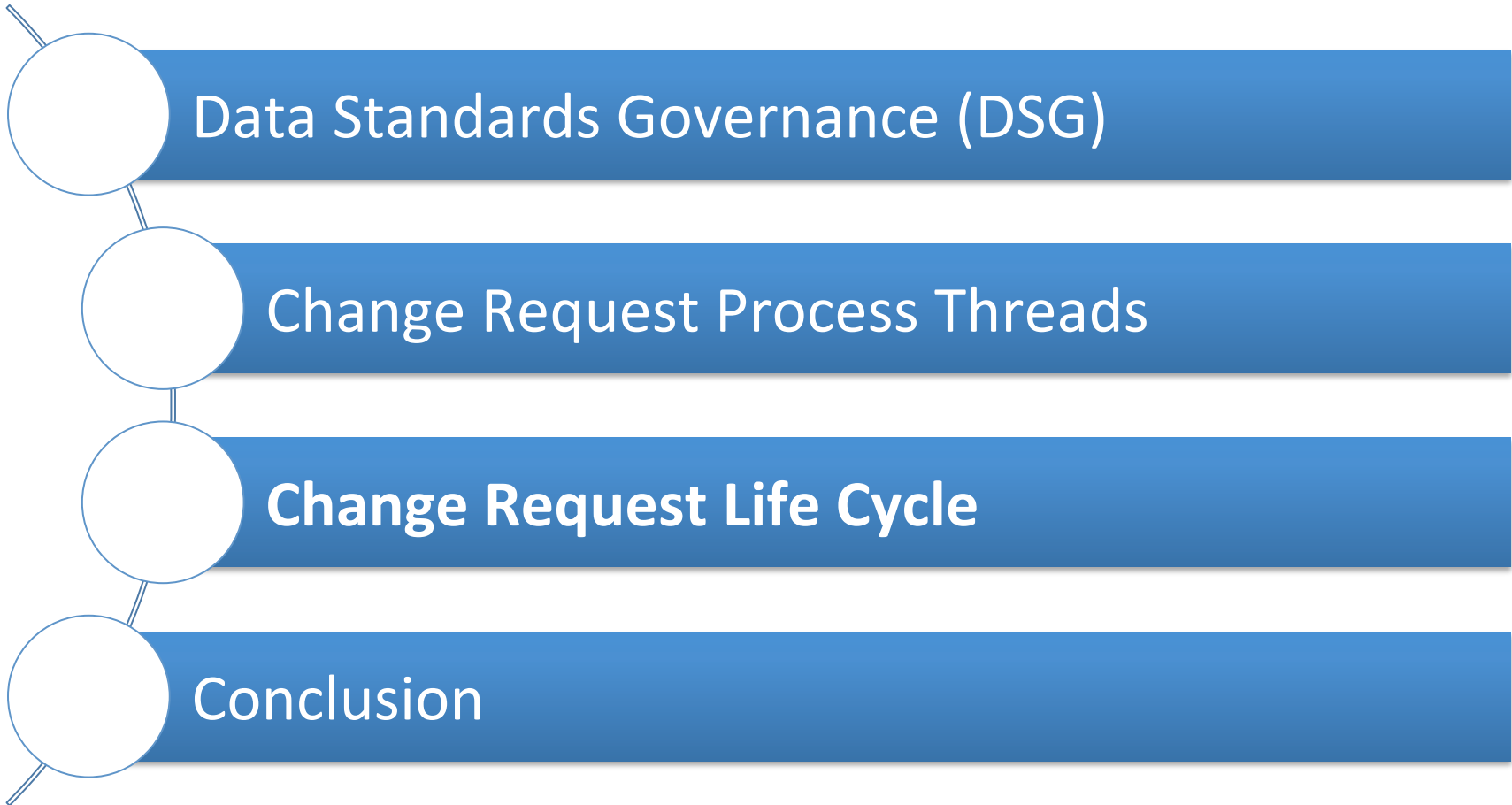
Change Request: Role / Evaluation Criteria



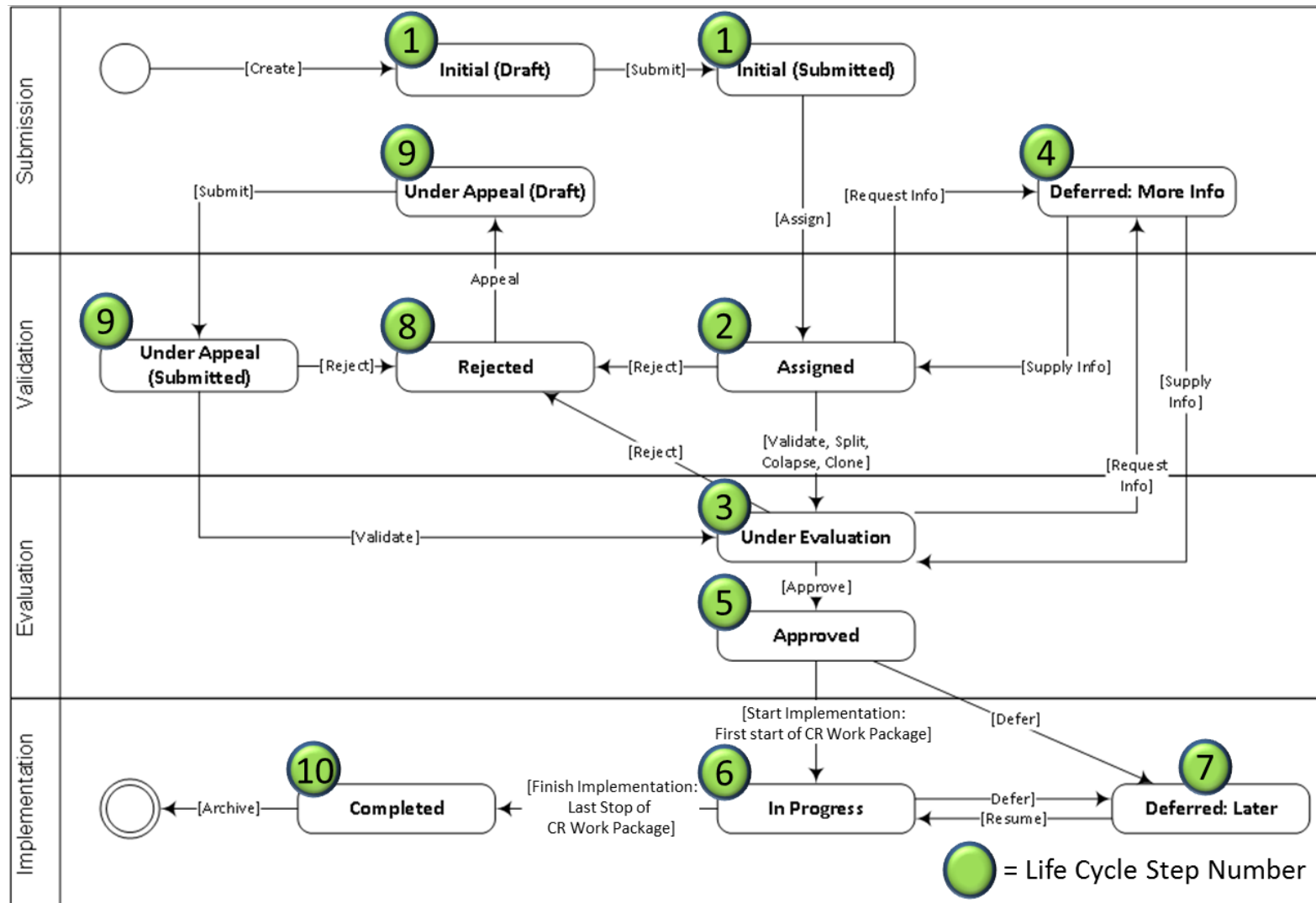
Change Request Process Threads: Impact Analysis & Work Package



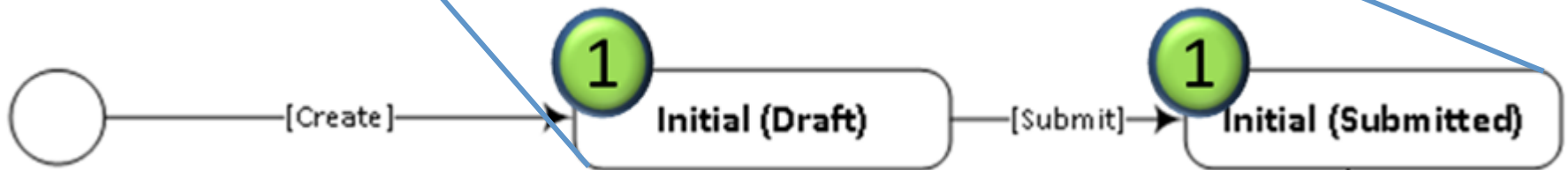
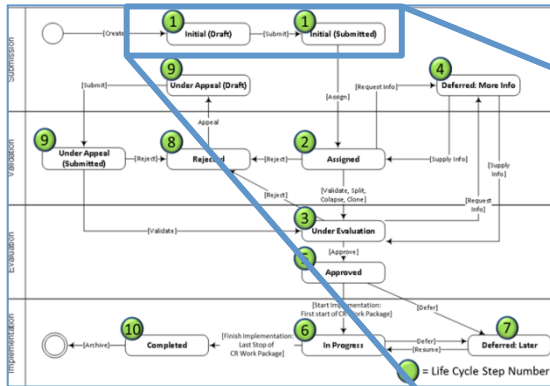
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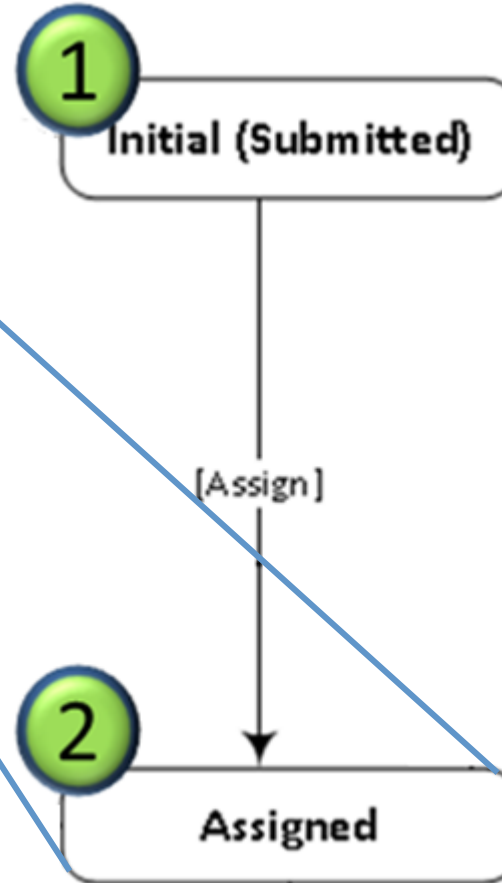
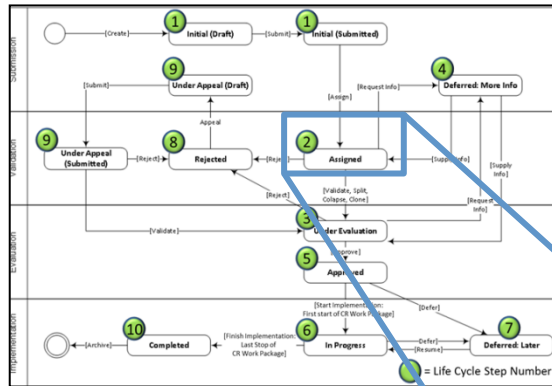
Data Standards Governance Change Request: Overview



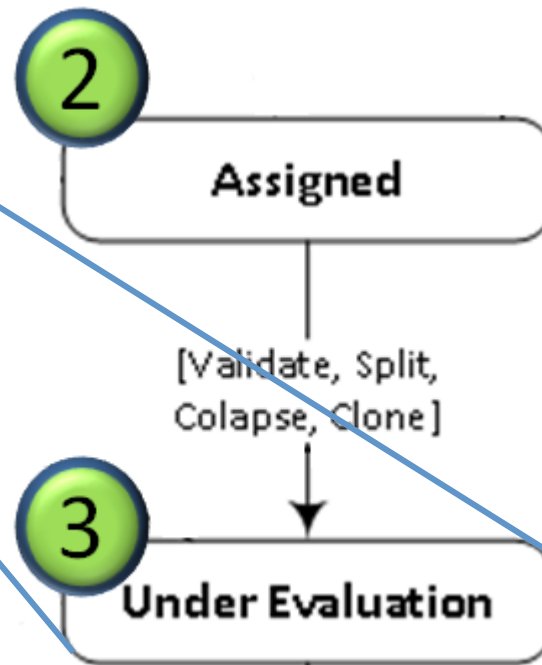
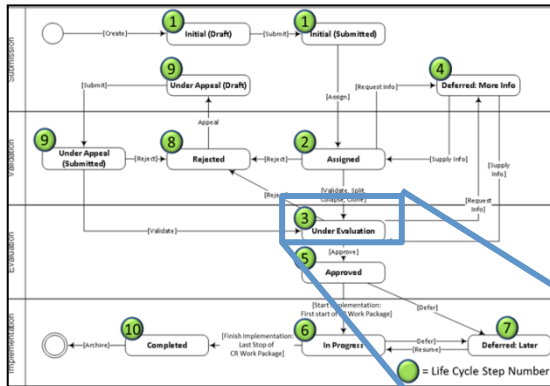
Data Standards Governance Change Request: Life Cycle



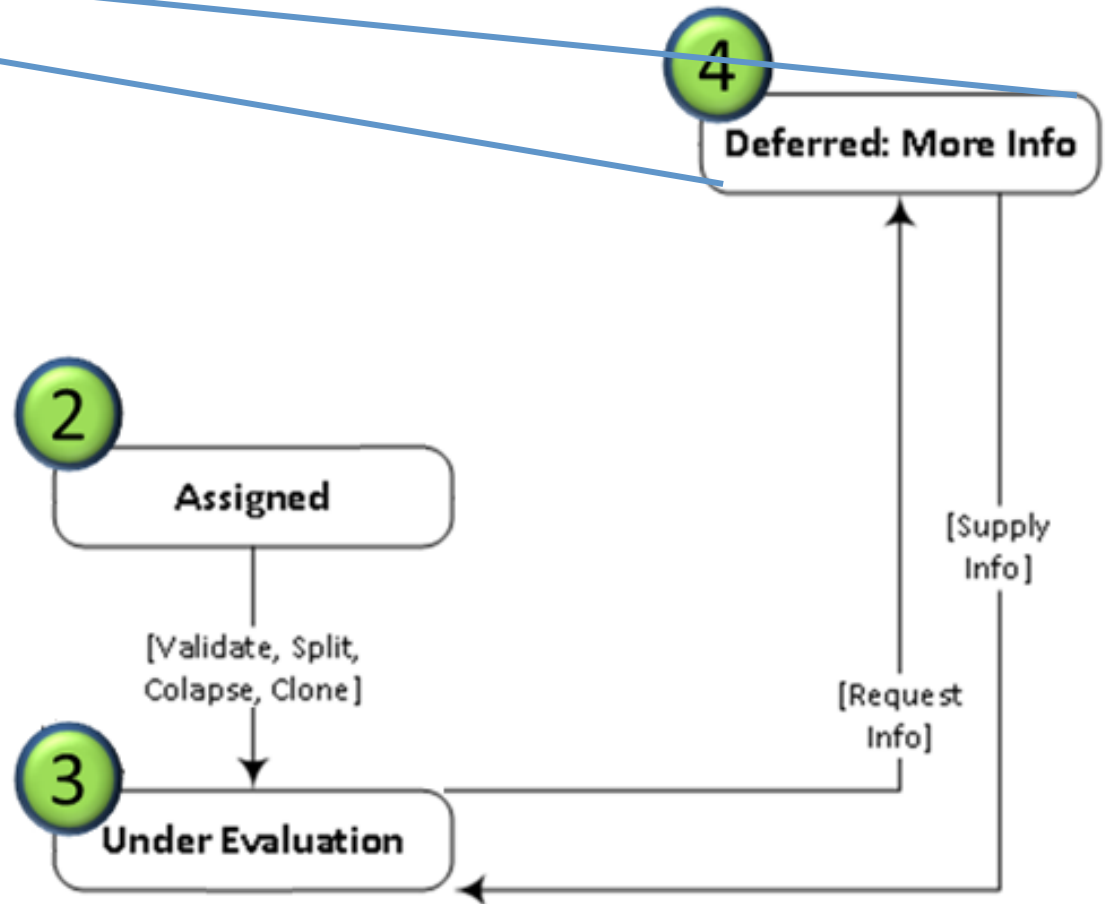
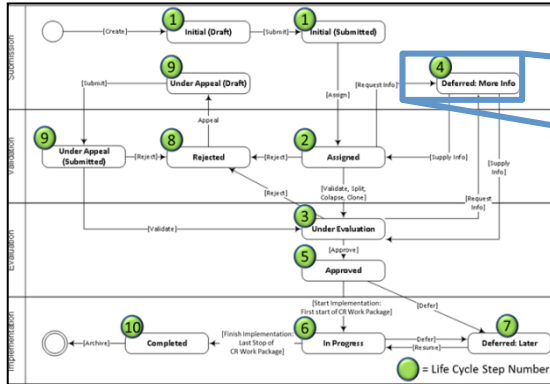
Data Standards Governance Change Request: Life Cycle



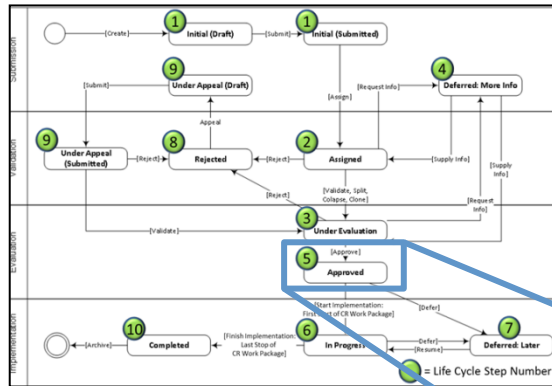
Data Standards Governance Change Request: Life Cycle



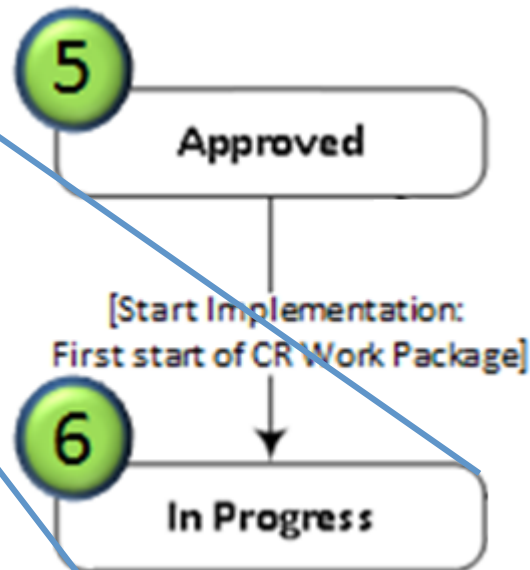
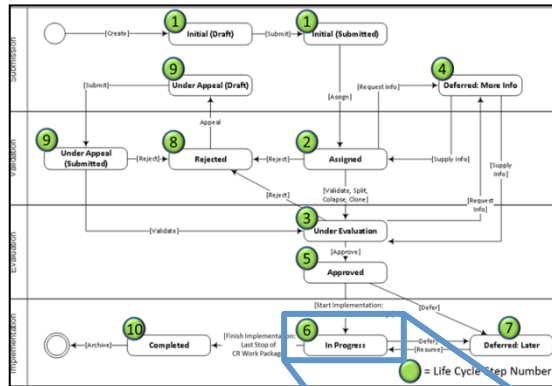
Data Standards Governance Change Request: Life Cycle

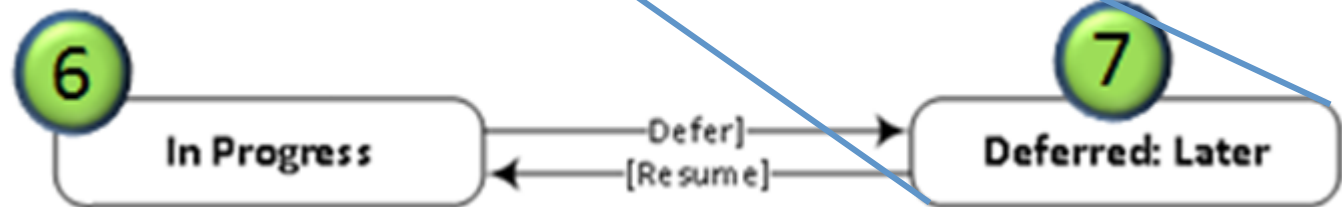


Data Standards Governance Change Request: Life Cycle

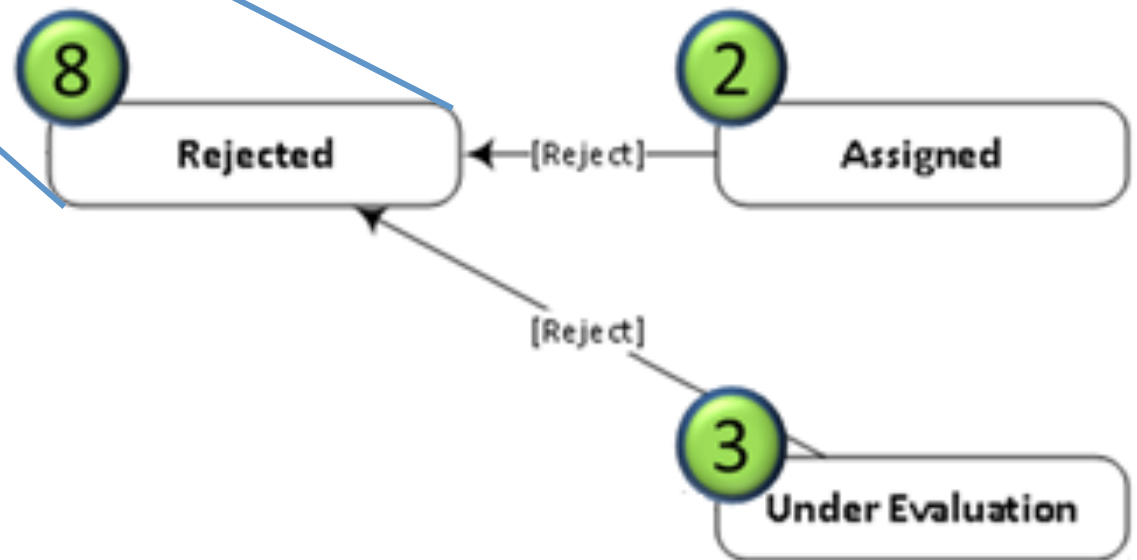
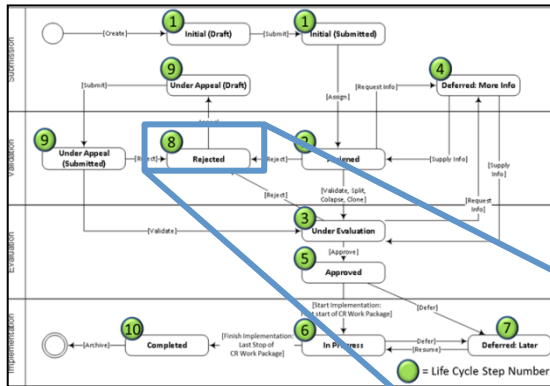


Data Standards Governance Change Request: Life Cycle

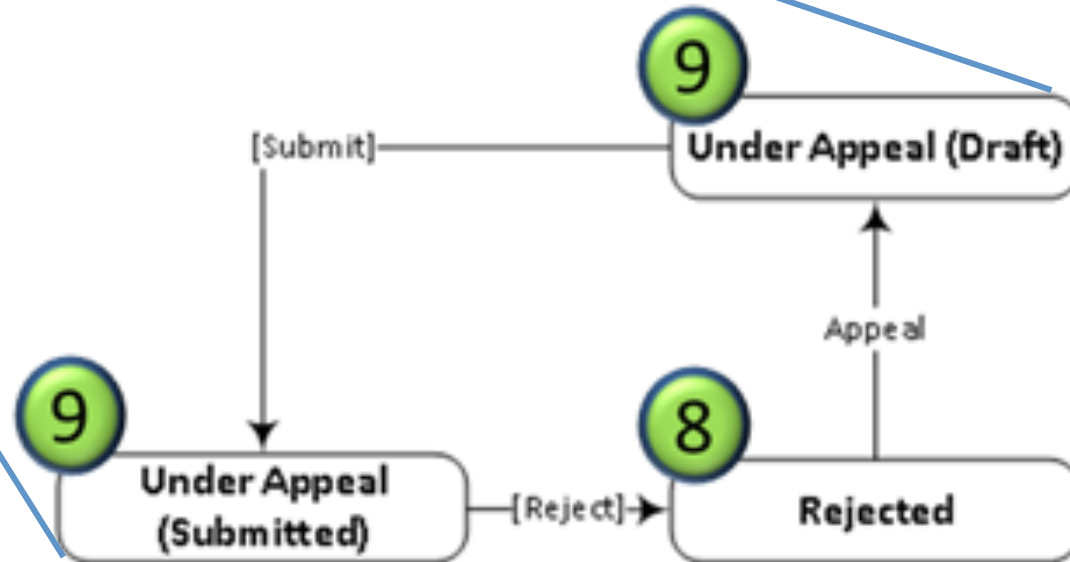
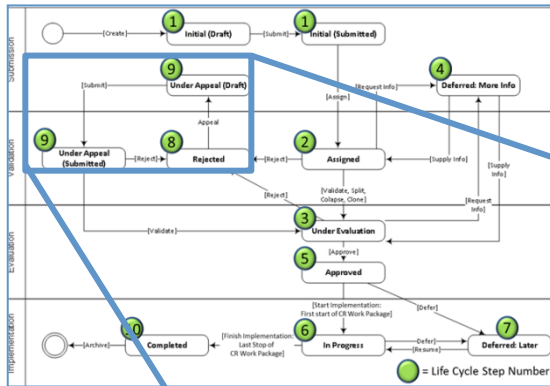




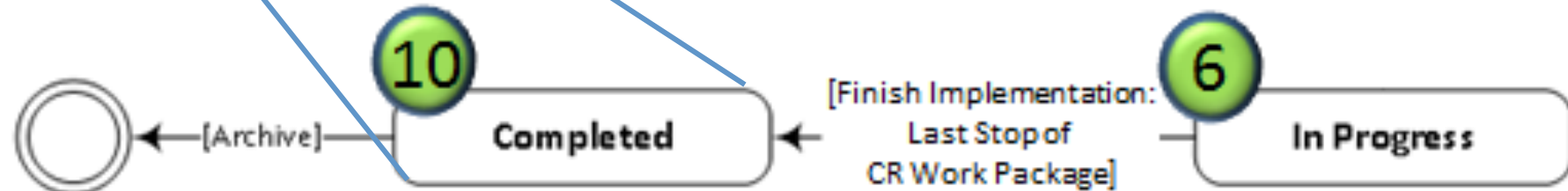
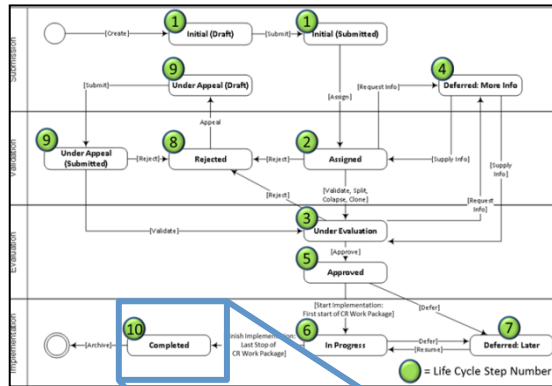
Data Standards Governance Change Request: Life Cycle



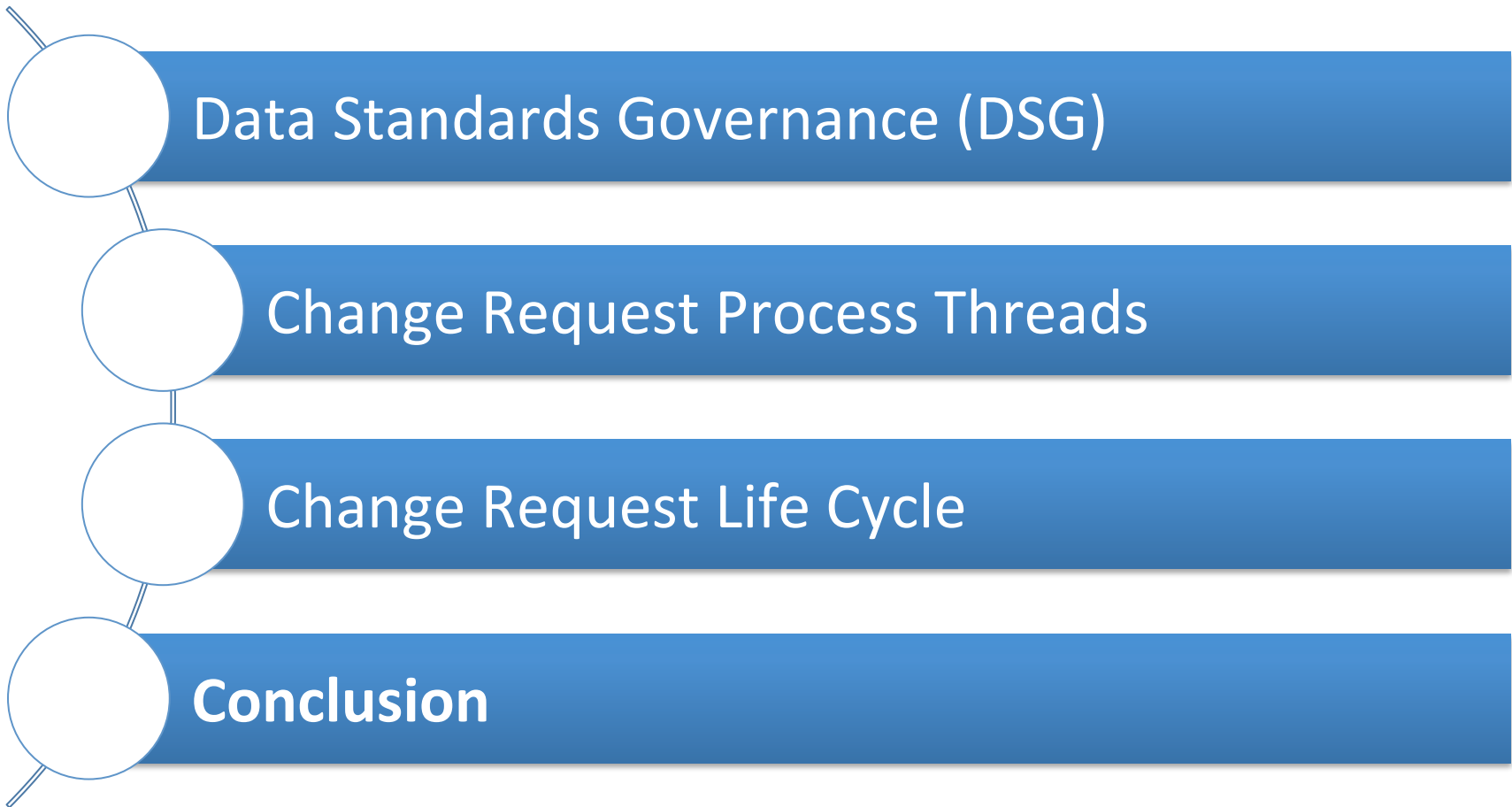
Data Standards Governance Change Request: Life Cycle



Data Standards Governance Change Request: Life Cycle



Agenda



- A well-designed Data Governance Change Requests process can be developed through understanding:
 - The Roles involved in the Change Request Process
 - The types of changes to be performed
 - The criteria for evaluation
 - Impact of a change requests

Questions & Answers



Thank you for your attention.

Join us for a coffee at our stand.

Vienna, Austria, 12 OCT 2015





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