

Is your library a success?

A solution to manage and measure conformance to your standards across partners and projects

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DRIVE YOUR PERFORMANCE

Agenda

1

What is a successful library?

2

Tools to get you there

3

Learn from your data & metadata

4

Conclusion

A successful library...

- Is one that is used appropriately
 - Improves over time
 - Is managed efficiently
-
- Do you know if your library meets these criteria?

Appropriate use of your library

- Carrot and stick
 - Make it easy to use the library
 - Make it harder/impossible to not use the library
- Provide an interface that allows study metadata to be defined only by selecting it directly from the library
- Compare study metadata to the standards

Improvements over time

- A library is not static
- What is working well?
- Are there trends suggesting some items are easier to use than others?
- Are there items being used successfully in some programs but not others?

Manage your library efficiently

- Focus efforts on evidenced-based governance
 - Are those items that were created “just in case” actually being used?
 - Can better training on existing standards address the need more effectively than a new standard?
 - Prioritize activities based on frequency of use
- Move away from anecdotal feedback to more objective measures of success

Agenda

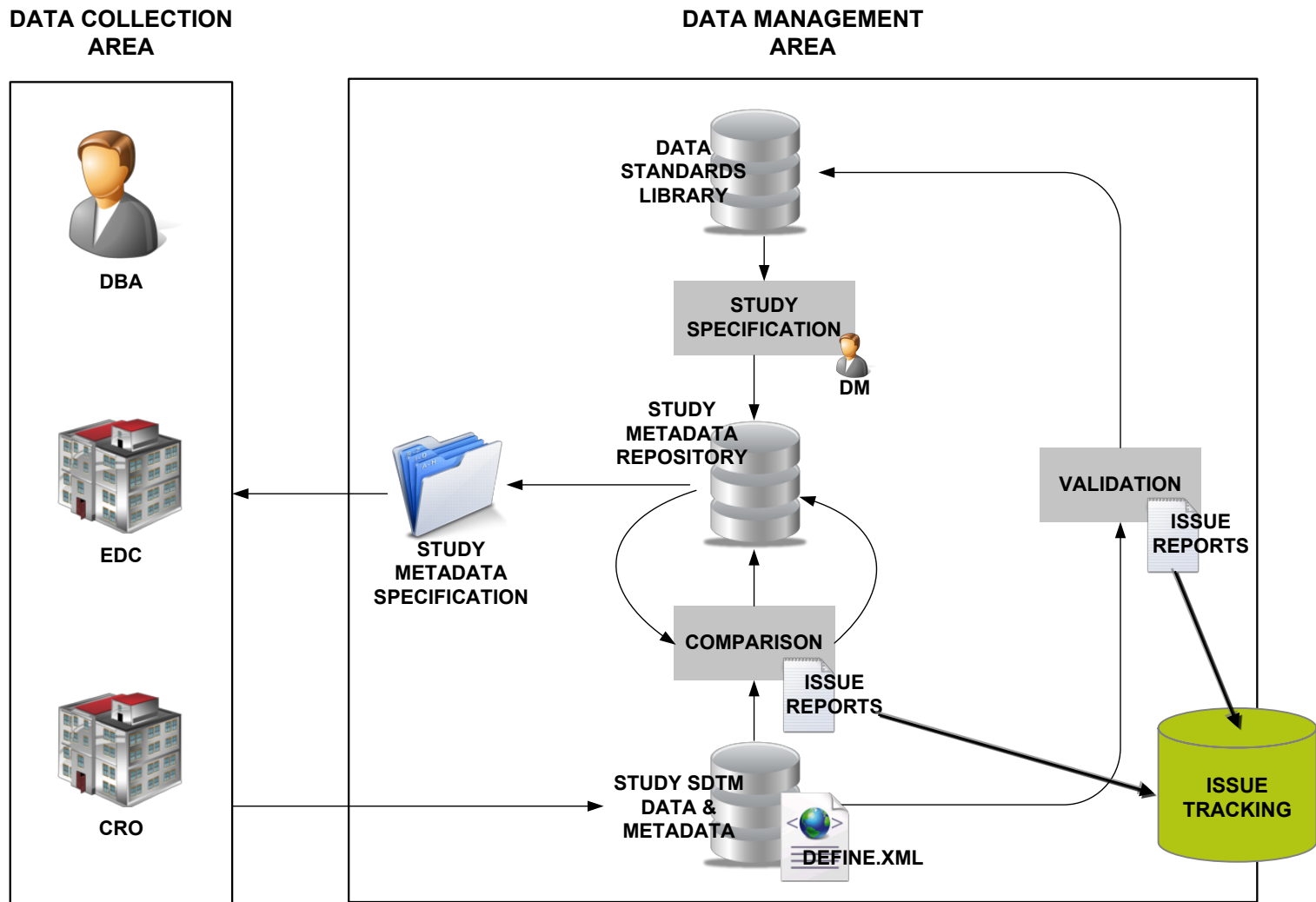
1

What is a successful library?

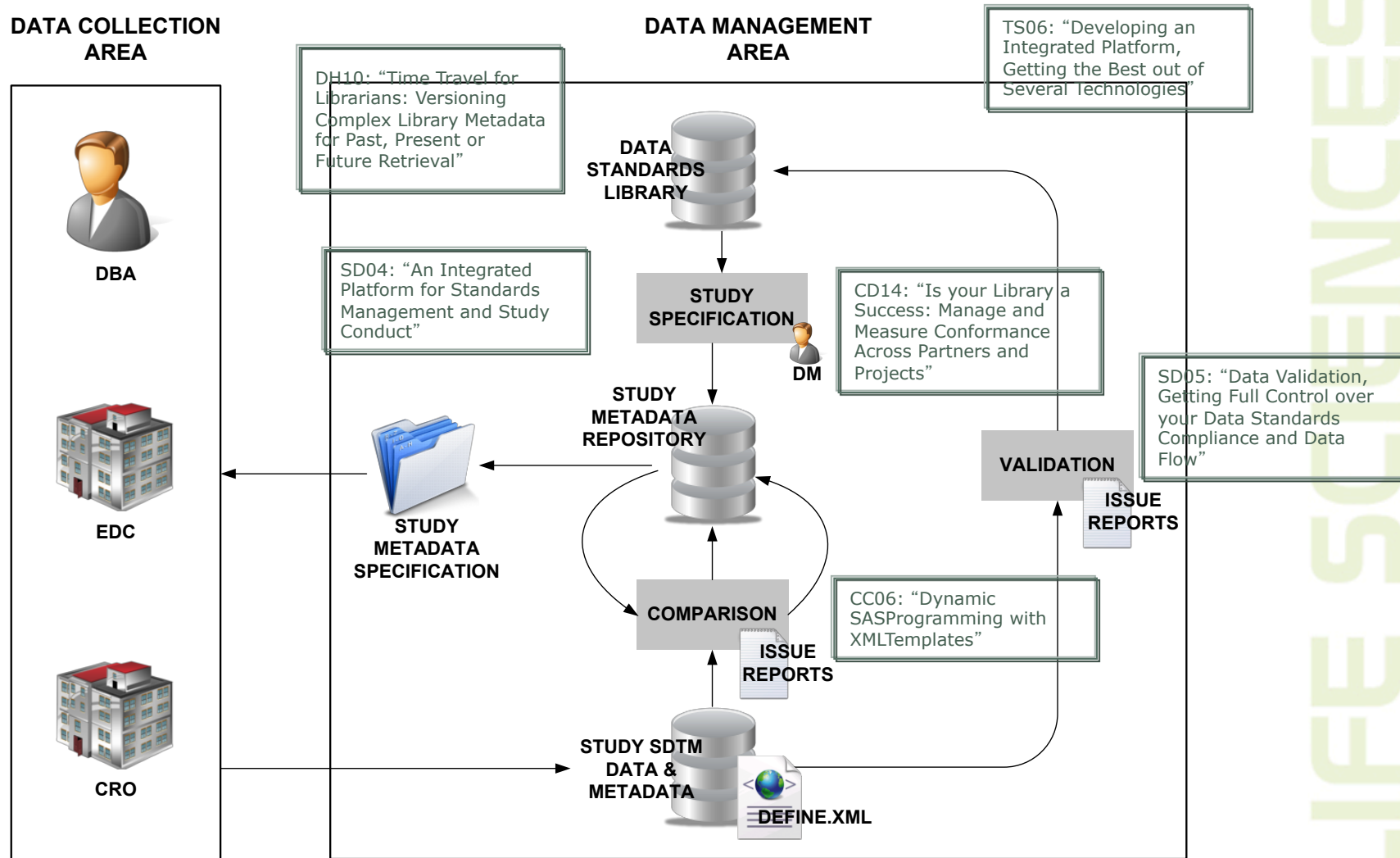
2

Tools to get you there

Overview of one approach



Process Overview



Types of issues

- Identify when study-level metadata does not comply with selected version of the library
 - Both datasets and define-xml
 - Domain, variable and controlled terminology levels
- Apply other business rules
 - SDTM checks
 - Internal standard checks

Issue Tracking Details

Project / Study	BBBB / BBBB-00001	Unique Id	33564
Override For Acceptance	☐	Feedback Created Manually	☐
Description *	For custom domains: check the variable names are correct as described in the SDTM V1.2	Error Message	The variable name is not as described in SDTM V1.2.
Documentation		Source	
Status *	ON_HOLD	Assigned group	CRO
Severity *	high	Category	Category 2
Domain Dataset	VS Select	Check	Check1130
Feedback Position (Key1CD)		Feedback Position Value (Key1)	
Unique Subject Id		Last Check Run Time	unknown
Assigner User			
Attached Document	^ (none) ^ Delete attachment + Attach a file		

Comments [+ Add Comment](#)

Date ↕	Comment ↕	Has Attachment ↕	Download Attachment
No records found.			

Status History

Date ↕	Status ↕
2013-07-25 11:09:58	ON_HOLD
2013-07-25 09:54:35	OPEN
2013-07-09 10:00:45	NEW

Variable Details

Date ↕	Name ↕	Value ↕
2013-07-09 10:00:45	COLUMN	VSTEST
2013-07-09 10:00:45	GL_LABEL	
2013-07-09 10:00:45	SRC_LABE	Vital Signs Test Name

Issue tracking

- Timing
 - When was the issue identified
 - When was it resolved
- Identifiers
 - To which library object is it linked
 - In which study or program is it found
 - To whom is the resolution assigned
- Other
 - Categories for types of checks
 - Severity of issues
 - Status of issue (Open, Pending, Closed), etc.

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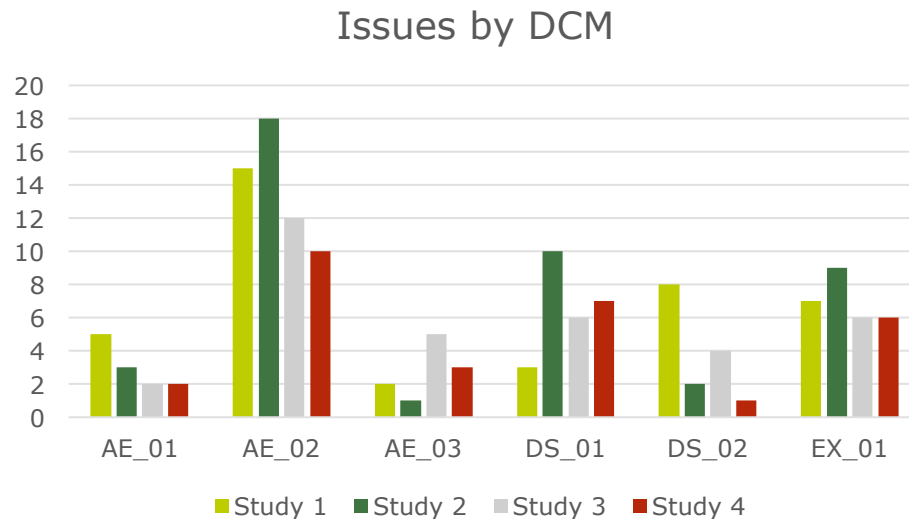
Learn from your data & metadata

Once you have your data...

- There are many possibilities
 - Frequency analyses
 - Time to resolution
 - Trends
 - within programs/studies/partners
 - across programs/studies/partners
- How can you use this?

Which library items have the most issues?

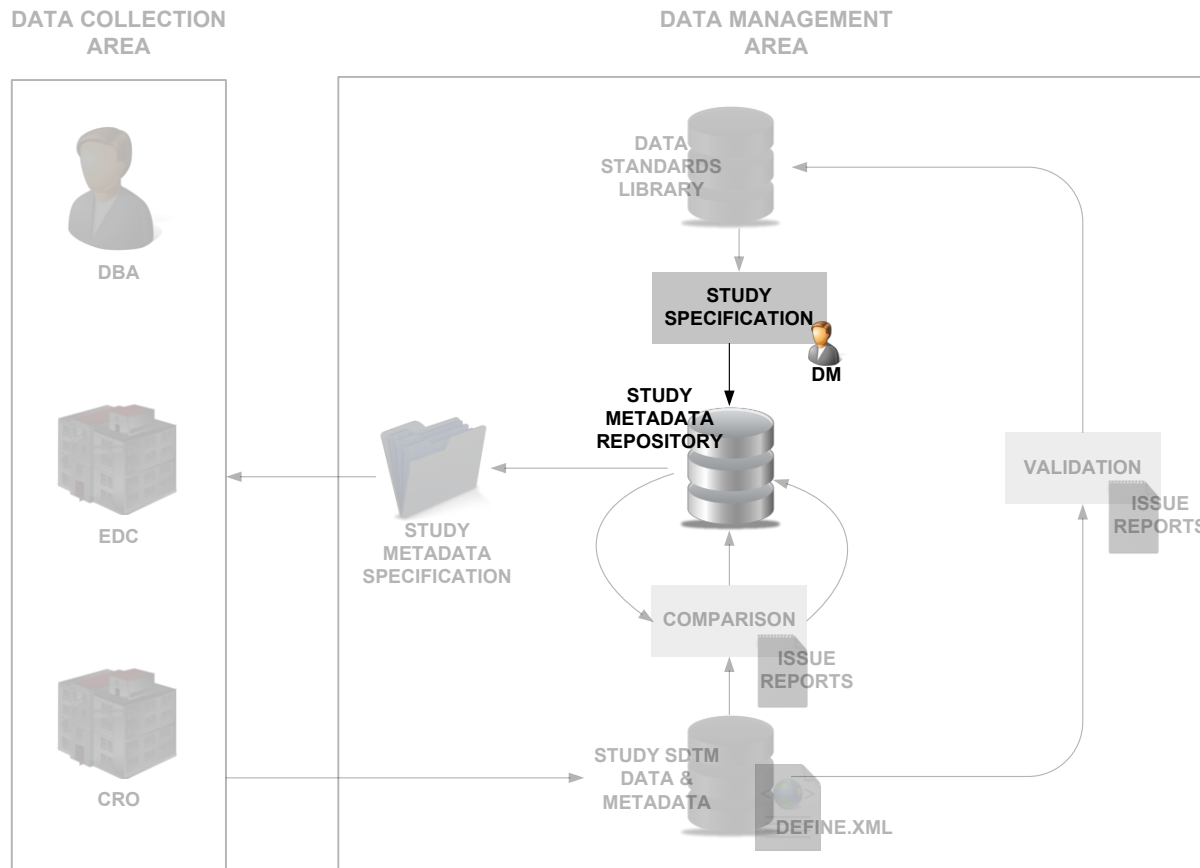
- Are there items that repeatedly being identified with issues?



- Are these items having the same kinds of issues across all projects or are there patterns?

Using your study metadata repository

- Generating study metadata by selecting Data Collection Modules from the Data Standards Library



Frequency of usage

- Can prioritize updates to focus on most frequently used items
- Items rarely or never used
 - Are these necessary to continue to maintain?
- Have a better picture of how often “just in case” really occurs

Trends and metrics across teams

- Time-to-resolution metrics can be used to objectively assess performance of internal and external partners
- Are some partners/project teams generating more issues than others?
- What are reasonable performance metrics to apply?

Trends and metrics over time

- Are the process improvements working?
- Compare frequency of issues
 - Before and after retraining
 - Before and after updates to the library
- Better collaboration with partners
 - Can provide clear feedback on problem areas
 - Can measure improvements

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Summary

- Don't lose information from your checking reports – keep it in a database
- Rely on objective measurements of success rather than stories
- Use data to direct continuous improvement
- Don't just govern your library – understand how it is being used

Conclusion

- Better collaboration between partners
- Supports continuous process improvement by minimizing the risk that your library is not being used appropriately
- Allows for the objective measurement of the use of your library across projects and across partners.
- Metrics can then be used to improve conformance such as identifying areas for process improvements or training needs.

