BEST PRACTICES: COMPLETENESS PLANNING AND TRACKING

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Veeva Vault Product Management

Session Format Overview

Veeva Best Practices

15 Minutes

Q&A

15 Minutes

Group Discussion

20 Minutes

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Veeva Best Practices

Completeness Overview in Vault eTMF

What ***should*** be filed

Expected Document Lists (EDLs) and items

What ***is*** filed

Documents in the library, matched to the corresponding Expected Document item

When it should be filed by

Milestones, within which Expected Documents and their matched documents are associated

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What Does Good Look Like in Vault eTMF?

1. **Have a completeness plan and process**
2. **Track data and events** that affect expected documentation in the system
3. **Leverage system functionality** to make the process as accurate and efficient as possible

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General Completeness Setup in Vault eTMF

1

Review TMF Index

Identify which document types are expected and their associated milestones

2

Configure EDL Template

which will be associated with the study

3

Define expected documents

within the EDL template

4

Define milestone types

to indicate when each document is expected to be filed in the TMF

5

New milestones created

as the study moves through its lifecycle (e.g., the milestone for study close will be created once the study moves to the closing state)

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Completeness Setup – Study Events

Establish a process to track unplanned study events (e.g., protocol amendments)

Then leverage:

- Ad Hoc Events
- Site Personnel
- Organizations

EDL Automation

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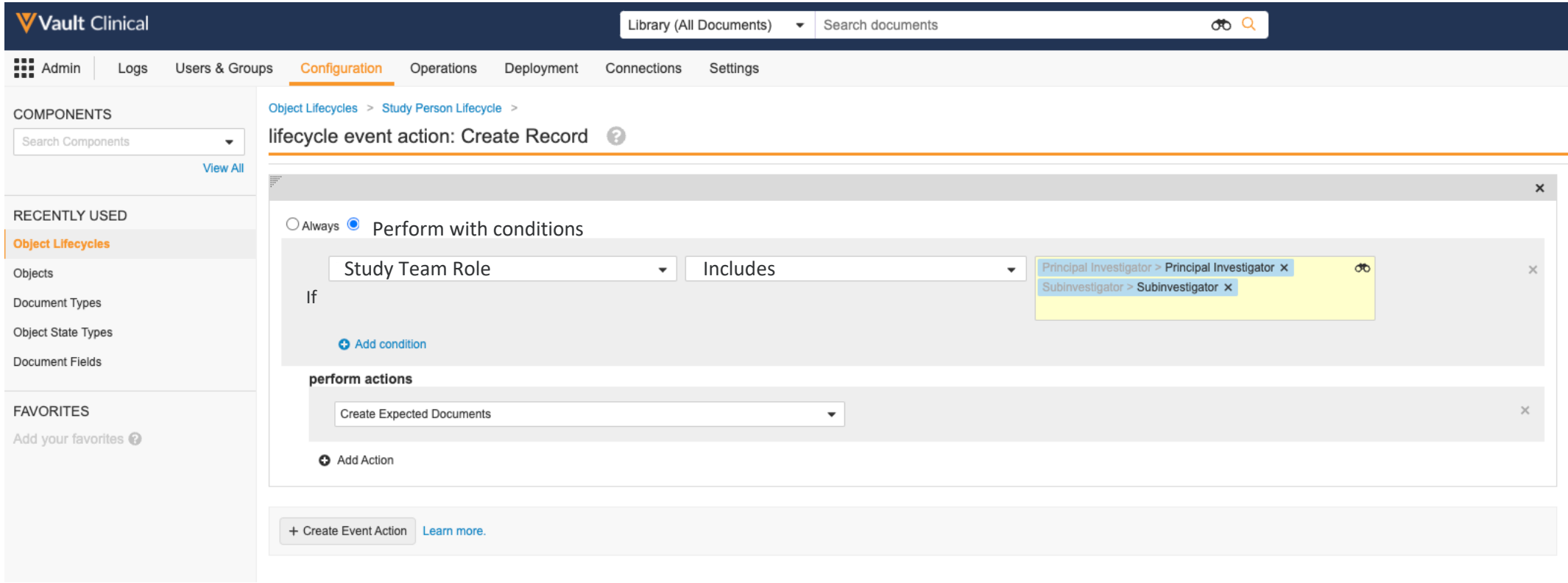
Feature Highlight – EDL Automation

Site Personnel and Organization – EDL Automation



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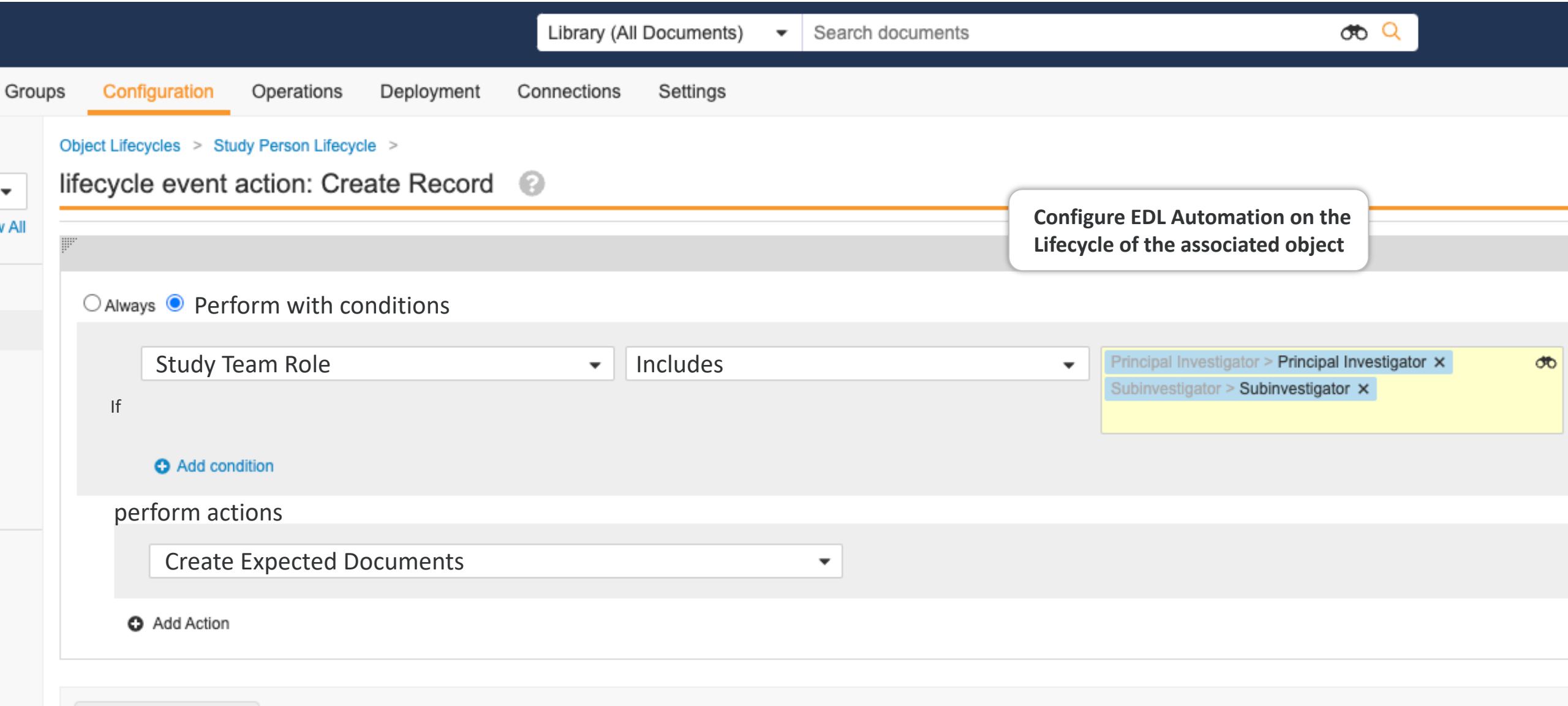
Feature Highlight – EDL Automation

Site Personnel and Organization – EDL Automation



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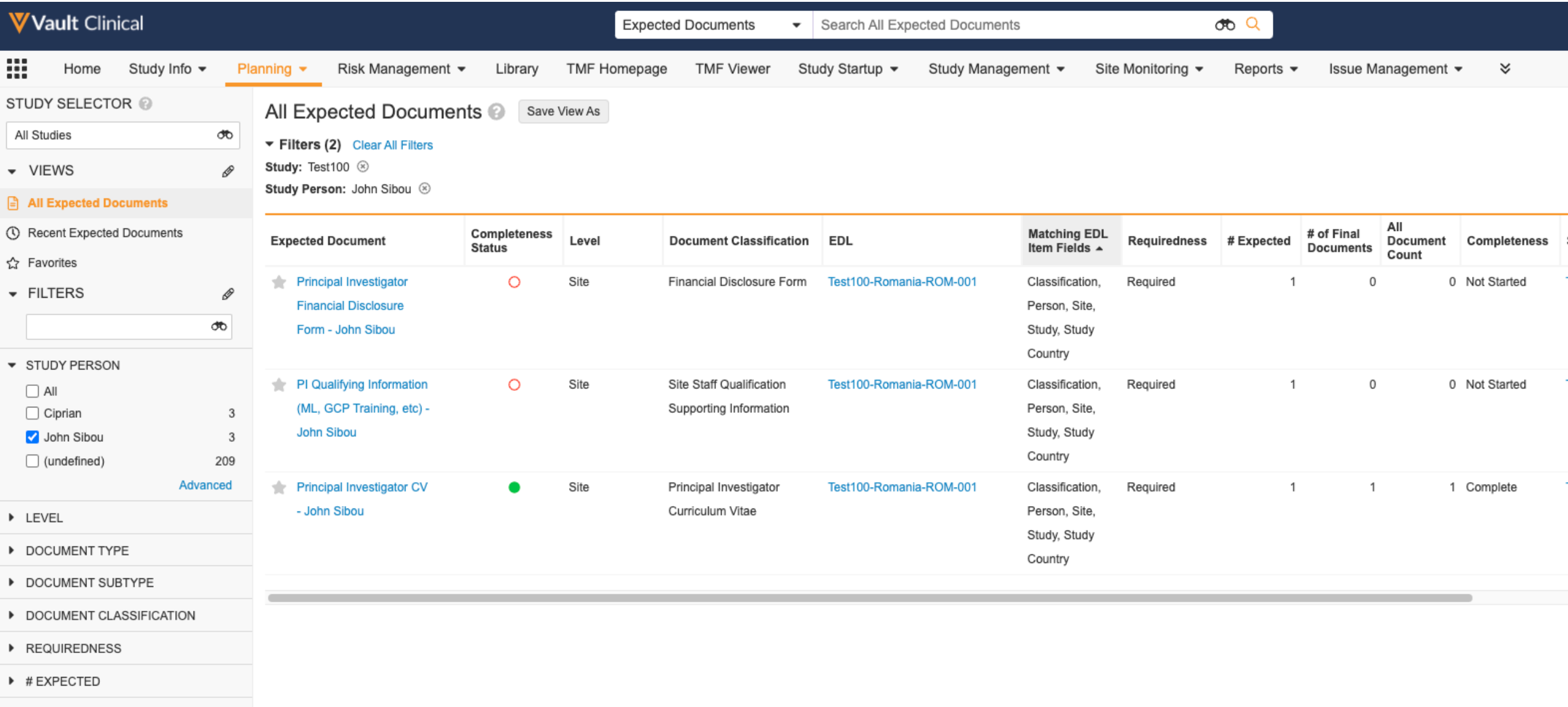

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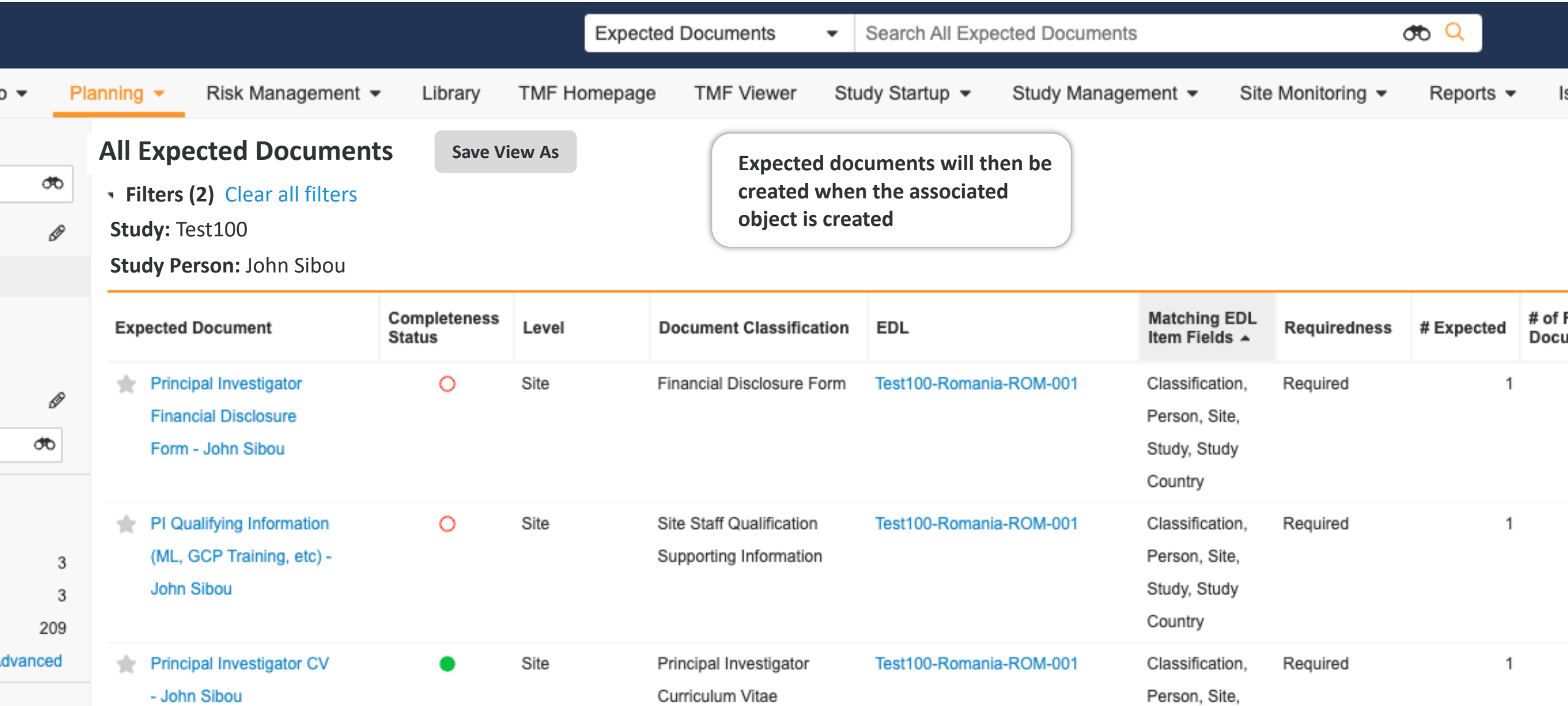
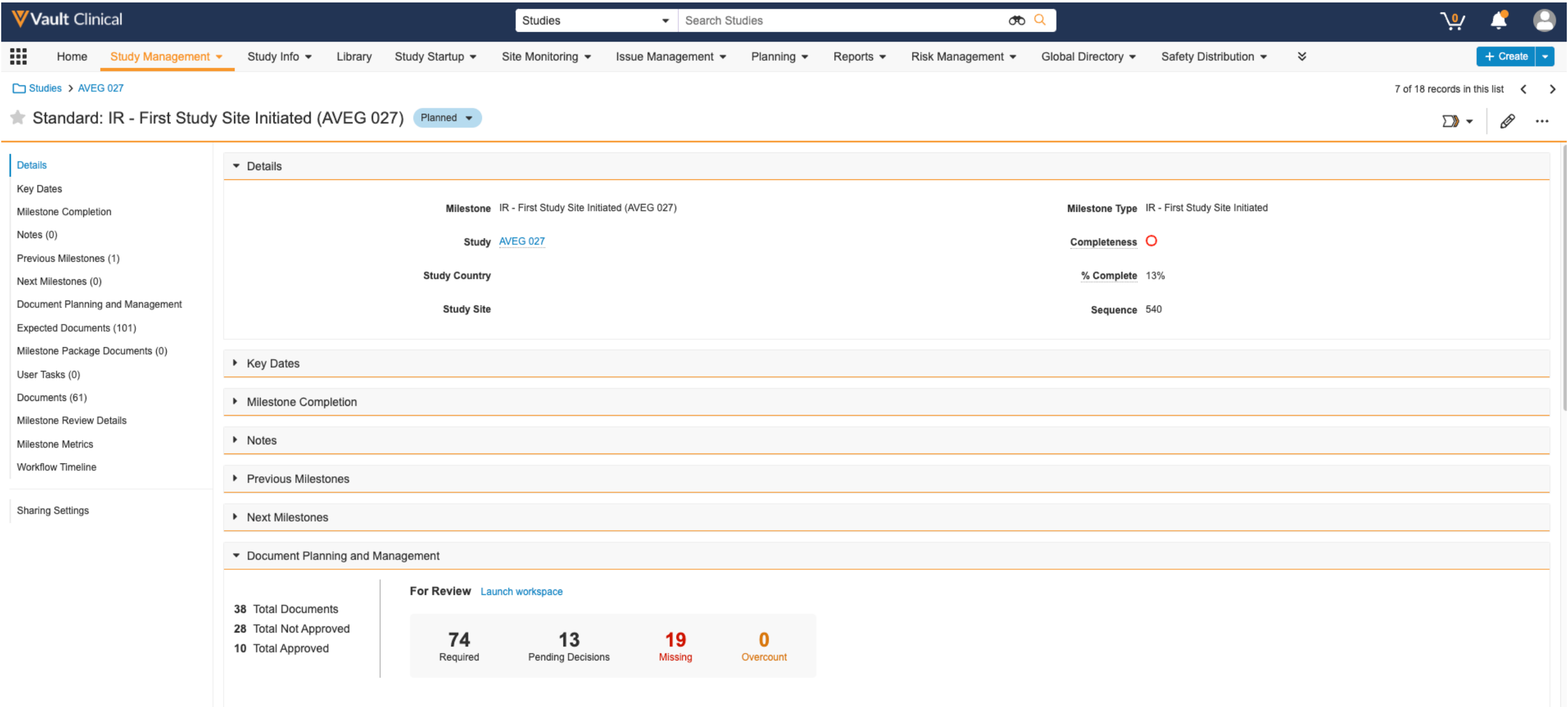


Feature Highlight – Milestone Workspace

Consolidated view of completeness in Vault eTMF



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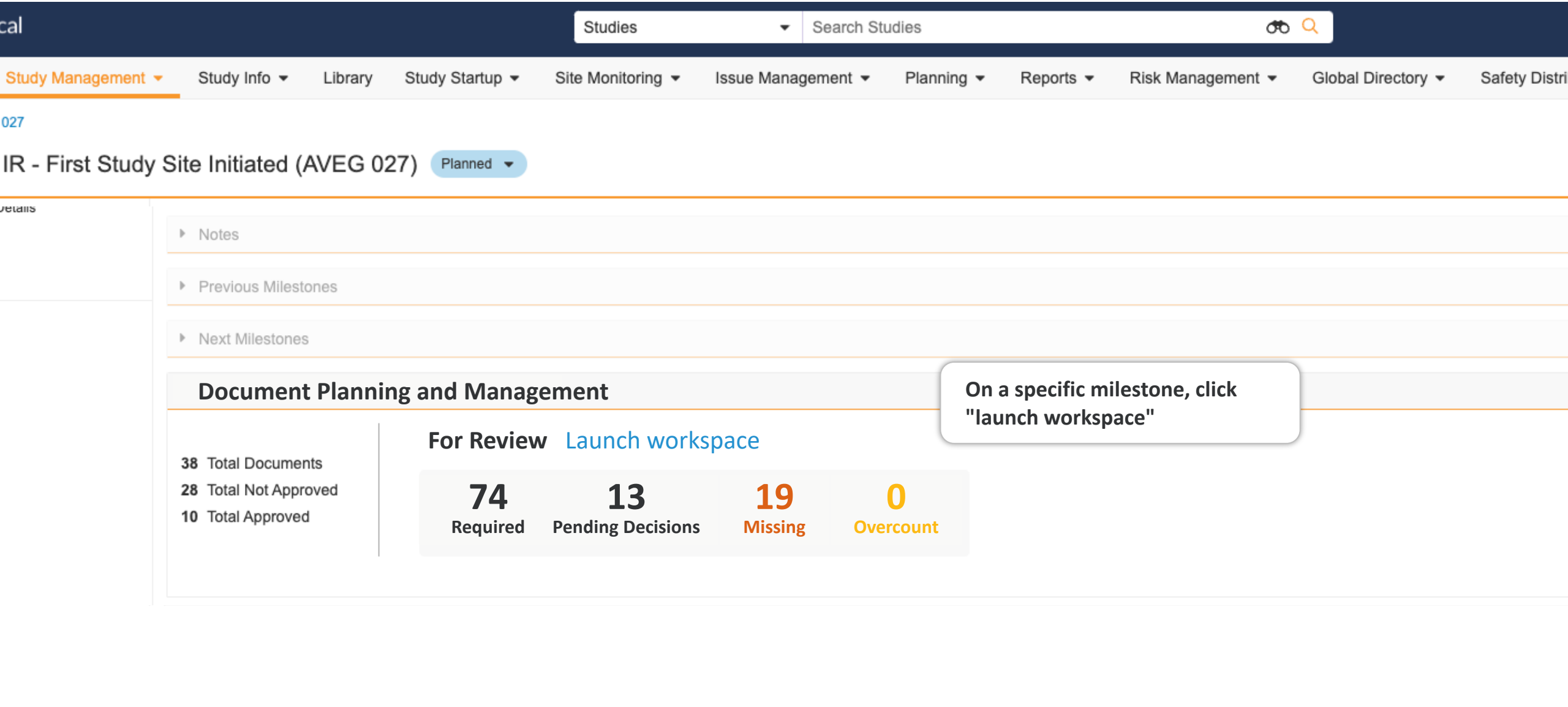

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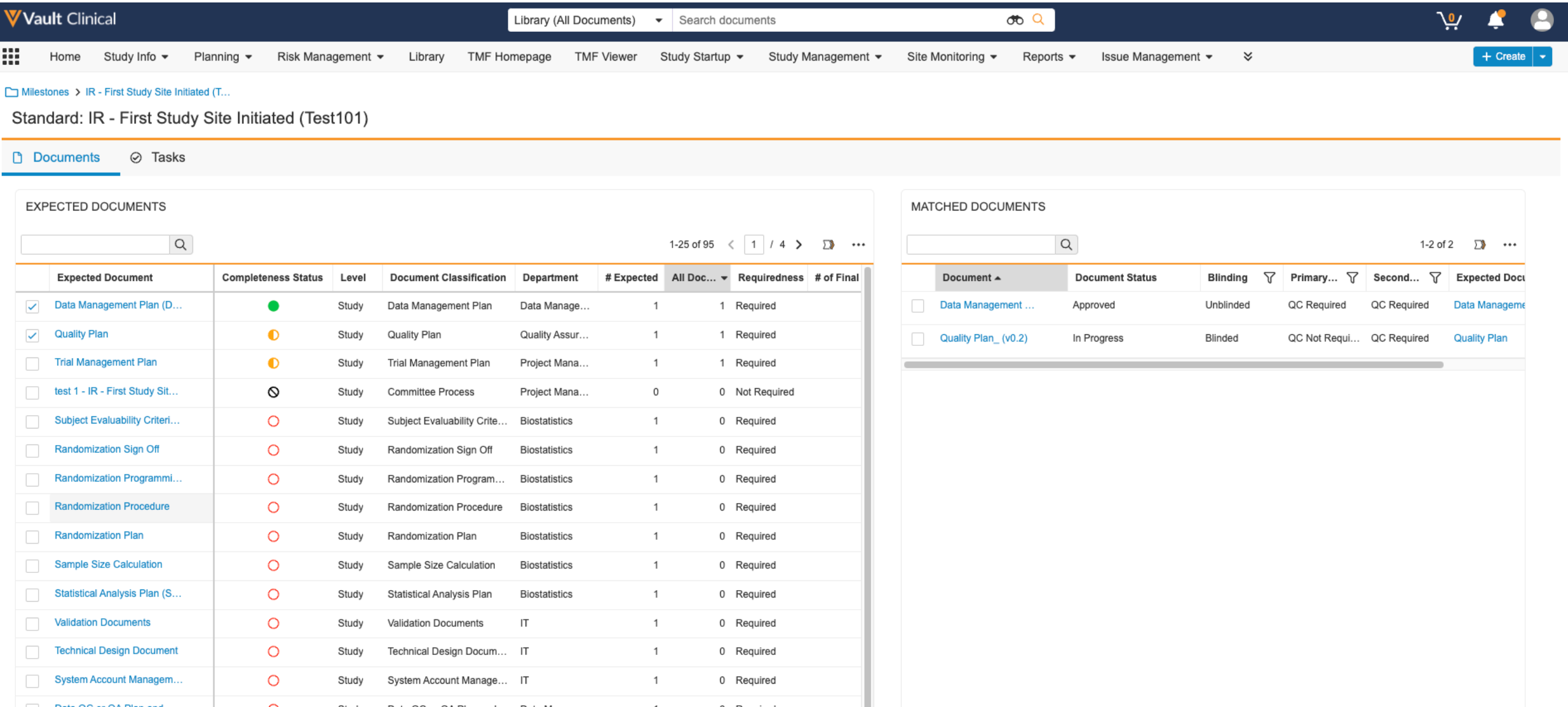

Feature Highlight – Milestone Workspace

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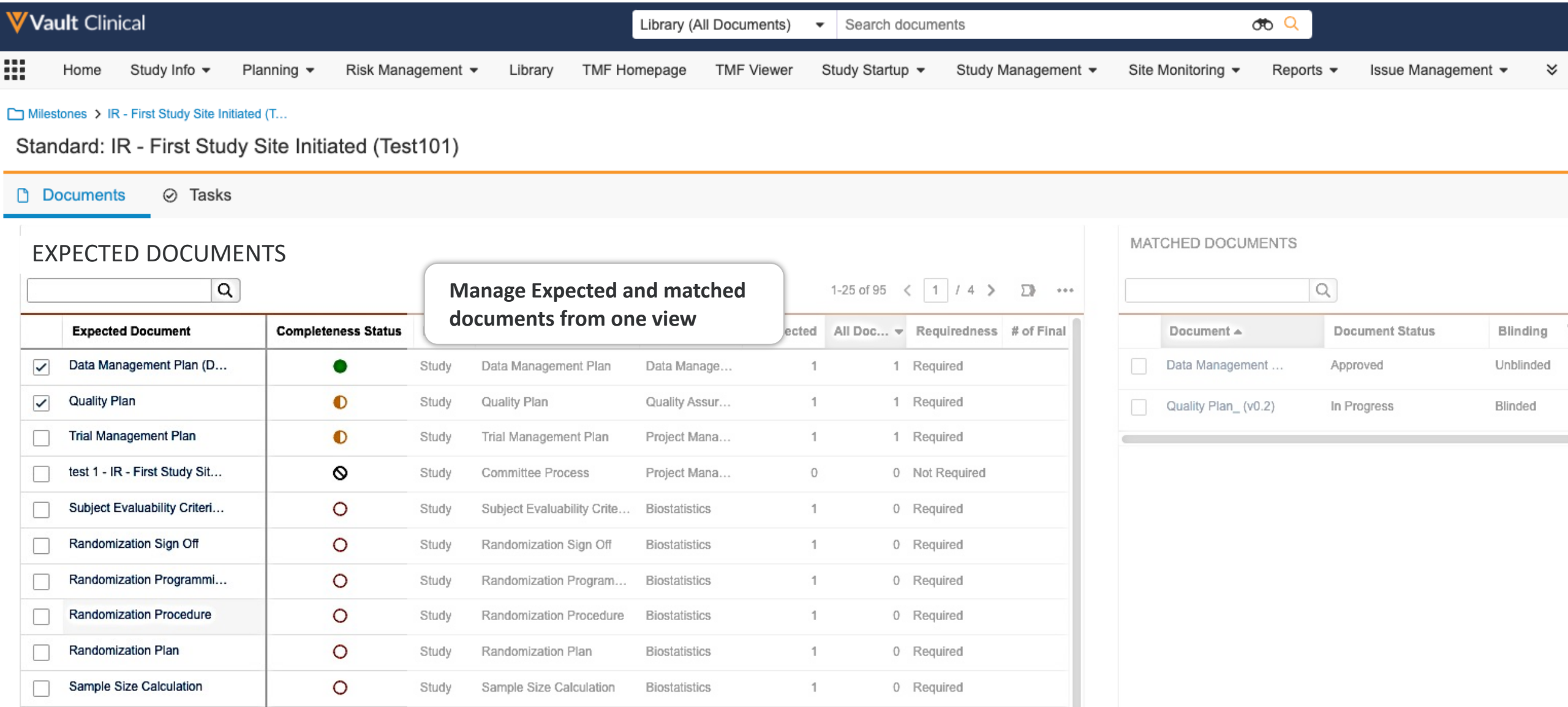

Questions

Group Discussion

Group Discussion

- Are you currently using the milestone workspace? If so, what learnings can you share?
- Are you currently using EDL automation? If so, what learnings can you share?
- What other best practices can you share for inspection readiness reviews? What are your wins?
- Given what's available for completeness tracking today, what else would you like to see in the product?

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