



# 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



# 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

# What Does Good Look Like in Vault eTMF?

1

**Have a completeness plan  
and process**

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2

**Track data and events**  
that affect expected documentation  
in the system

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3

**Leverage system functionality**  
to make the process as accurate  
and efficient as possible



# 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)



# 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

# Feature Highlight – EDL Automation

## Site Personnel and Organization – EDL Automation

The screenshot shows the Vault Clinical configuration interface. The top navigation bar includes the Vault Clinical logo, a search bar for documents, and icons for shopping cart, notifications, and user profile. The main navigation menu is located below the search bar, with 'Configuration' highlighted. The left sidebar contains sections for 'COMPONENTS', 'RECENTLY USED', and 'FAVORITES'. The main content area displays the configuration for a 'lifecycle event action: Create Record'. The configuration is set to 'Perform with conditions'. The condition is defined as 'Study Team Role' includes 'Principal Investigator > Principal Investigator' and 'Subinvestigator > Subinvestigator'. The action is 'Create Expected Documents'. A '+ Create Event Action' button and a 'Learn more.' link are visible at the bottom of the configuration area.

**COMPONENTS**  
Search Components  
View All

**RECENTLY USED**  
Object Lifecycles  
Objects  
Document Types  
Object State Types  
Document Fields

**FAVORITES**  
Add your favorites

Library (All Documents) Search documents

Admin Logs Users & Groups **Configuration** Operations Deployment Connections Settings

Object Lifecycles > Study Person Lifecycle >  
lifecycle event action: Create Record ?

Cancel Save

Always  Perform with conditions

Study Team Role Includes Principal Investigator > Principal Investigator x  
Subinvestigator > Subinvestigator x

If

+ Add condition

**perform actions**

Create Expected Documents

+ Add Action

+ Create Event Action Learn more.





# Feature Highlight – EDL Automation

## Site Personnel and Organization – EDL Automation

Library (All Documents) Search documents

Groups Configuration Operations Deployment Connections Settings

Object Lifecycles > Study Person Lifecycle >

lifecycle event action: Create Record ?

Configure EDL Automation on the Lifecycle of the associated object

Always  Perform with conditions

If

Study Team Role Includes

Principal Investigator > Principal Investigator x  
Subinvestigator > Subinvestigator x

+ Add condition

perform actions

Create Expected Documents

+ Add Action

# Feature Highlight – EDL Automation

## Site Personnel and Organization – EDL Automation

**Vault Clinical** | Expected Documents | Search All Expected Documents

Home | Study Info | **Planning** | Risk Management | Library | TMF Homepage | TMF Viewer | Study Startup | Study Management | Site Monitoring | Reports | Issue Management

**STUDY SELECTOR**  
All Studies | VIEWS | **All Expected Documents** | Recent Expected Documents | Favorites | FILTERS | STUDY PERSON: All (3), Ciprian (3), **John Sibou (3)**, (undefined) (209) | LEVEL | DOCUMENT TYPE | DOCUMENT SUBTYPE | DOCUMENT CLASSIFICATION | REQUIREDNESS | # EXPECTED

### All Expected Documents

Filters (2) | Clear All Filters  
Study: Test100 | Study Person: John Sibou

Expected Document	Completeness Status	Level	Document Classification	EDL	Matching EDL Item Fields	Requiredness	# Expected	# of Final Documents	All Document Count	Completeness
★ <a href="#">Principal Investigator Financial Disclosure Form - John Sibou</a>	○	Site	Financial Disclosure Form	<a href="#">Test100-Romania-ROM-001</a>	Classification, Person, Site, Study, Study Country	Required	1	0	0	Not Started
★ <a href="#">PI Qualifying Information (ML, GCP Training, etc) - John Sibou</a>	○	Site	Site Staff Qualification Supporting Information	<a href="#">Test100-Romania-ROM-001</a>	Classification, Person, Site, Study, Study Country	Required	1	0	0	Not Started
★ <a href="#">Principal Investigator CV - John Sibou</a>	●	Site	Principal Investigator Curriculum Vitae	<a href="#">Test100-Romania-ROM-001</a>	Classification, Person, Site, Study, Study Country	Required	1	1	1	Complete

# Feature Highlight – EDL Automation

## Site Personnel and Organization – EDL Automation

Expected Documents

Planning Risk Management Library TMF Homepage TMF Viewer Study Startup Study Management Site Monitoring Reports

### All Expected Documents Save View As

Filters (2) [Clear all filters](#)

Study: Test100

Study Person: John Sibou

Expected documents will then be created when the associated object is created

Expected Document	Completeness Status	Level	Document Classification	EDL	Matching EDL Item Fields	Requiredness	# Expected	# of F Docu
★ <a href="#">Principal Investigator Financial Disclosure Form - John Sibou</a>	○	Site	Financial Disclosure Form	<a href="#">Test100-Romania-ROM-001</a>	Classification, Person, Site, Study, Study Country	Required	1	
★ <a href="#">PI Qualifying Information (ML, GCP Training, etc) - John Sibou</a>	○	Site	Site Staff Qualification Supporting Information	<a href="#">Test100-Romania-ROM-001</a>	Classification, Person, Site, Study, Study Country	Required	1	
★ <a href="#">Principal Investigator CV - John Sibou</a>	●	Site	Principal Investigator Curriculum Vitae	<a href="#">Test100-Romania-ROM-001</a>	Classification, Person, Site,	Required	1	

# Feature Highlight – Milestone Workspace

Consolidated view of completeness in Vault eTMF

**Vault Clinical** | Studies | Search Studies | | |

Home | **Study Management** | Study Info | Library | Study Startup | Site Monitoring | Issue Management | Planning | Reports | Risk Management | Global Directory | Safety Distribution |

Studies > AVEG 027 | 7 of 18 records in this list < >

★ Standard: IR - First Study Site Initiated (AVEG 027) | Planned

**Details**

<b>Milestone</b>	IR - First Study Site Initiated (AVEG 027)	<b>Milestone Type</b>	IR - First Study Site Initiated
<b>Study</b>	<a href="#">AVEG 027</a>	<b>Completeness</b>	
<b>Study Country</b>		<b>% Complete</b>	13%
<b>Study Site</b>		<b>Sequence</b>	540

▶ Key Dates

▶ Milestone Completion

▶ Notes

▶ Previous Milestones

▶ Next Milestones

**Document Planning and Management**

<b>38</b> Total Documents	<b>For Review</b> <a href="#">Launch workspace</a>
<b>28</b> Total Not Approved	<b>74</b> Required
<b>10</b> Total Approved	<b>13</b> Pending Decisions
	<b>19</b> Missing
	<b>0</b> Overcount

# Feature Highlight – Milestone Workspace

Consolidated view of completeness in Vault eTMF

cal

Studies Search Studies

Study Management Study Info Library Study Startup Site Monitoring Issue Management Planning Reports Risk Management Global Directory Safety Distri

027

IR - First Study Site Initiated (AVEG 027) Planned

Details

- Notes
- Previous Milestones
- Next Milestones

### Document Planning and Management

38 Total Documents  
28 Total Not Approved  
10 Total Approved

For Review [Launch workspace](#)

<b>74</b> Required	<b>13</b> Pending Decisions	<b>19</b> Missing	<b>0</b> Overcount
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On a specific milestone, click "launch workspace"

# Feature Highlight – Milestone Workspace

## Consolidated view of completeness in Vault eTMF

Milestones > IR - First Study Site Initiated (T...

Standard: IR - First Study Site Initiated (Test101)

Documents Tasks

EXPECTED DOCUMENTS

1-25 of 95 < 1 / 4 > ...

Expected Document	Completeness Status	Level	Document Classification	Department	# Expected	All Doc...	Requiredness	# of Final
<input checked="" type="checkbox"/> Data Management Plan (D...	●	Study	Data Management Plan	Data Manage...	1	1	Required	
<input checked="" type="checkbox"/> Quality Plan	●	Study	Quality Plan	Quality Assur...	1	1	Required	
<input type="checkbox"/> Trial Management Plan	●	Study	Trial Management Plan	Project Mana...	1	1	Required	
<input type="checkbox"/> test 1 - IR - First Study Sit...	⊘	Study	Committee Process	Project Mana...	0	0	Not Required	
<input type="checkbox"/> Subject Evaluability Crite...	○	Study	Subject Evaluability Crite...	Biostatistics	1	0	Required	
<input type="checkbox"/> Randomization Sign Off	○	Study	Randomization Sign Off	Biostatistics	1	0	Required	
<input type="checkbox"/> Randomization Programmi...	○	Study	Randomization Program...	Biostatistics	1	0	Required	
<input type="checkbox"/> Randomization Procedure	○	Study	Randomization Procedure	Biostatistics	1	0	Required	
<input type="checkbox"/> Randomization Plan	○	Study	Randomization Plan	Biostatistics	1	0	Required	
<input type="checkbox"/> Sample Size Calculation	○	Study	Sample Size Calculation	Biostatistics	1	0	Required	
<input type="checkbox"/> Statistical Analysis Plan (S...	○	Study	Statistical Analysis Plan	Biostatistics	1	0	Required	
<input type="checkbox"/> Validation Documents	○	Study	Validation Documents	IT	1	0	Required	
<input type="checkbox"/> Technical Design Document	○	Study	Technical Design Docum...	IT	1	0	Required	
<input type="checkbox"/> System Account Managem...	○	Study	System Account Manage...	IT	1	0	Required	
<input type="checkbox"/> Data QC as QA Plan and	○	Study	Data QC as QA Plan and	Biostatistics	1	0	Required	

MATCHED DOCUMENTS

1-2 of 2 ...

Document	Document Status	Blinding	Primary...	Second...	Expected Doc
<input type="checkbox"/> Data Management ...	Approved	Unblinded	QC Required	QC Required	Data Managem...
<input type="checkbox"/> Quality Plan_ (v0.2)	In Progress	Blinded	QC Not Requi...	QC Required	Quality Plan

# Feature Highlight – Milestone Workspace

Consolidated view of completeness in Vault eTMF

**Vault Clinical** Library (All Documents) Search documents

Home Study Info Planning Risk Management Library TMF Homepage TMF Viewer Study Startup Study Management Site Monitoring Reports Issue Management

Milestones > IR - First Study Site Initiated (T...)

## Standard: IR - First Study Site Initiated (Test101)

Documents Tasks

### EXPECTED DOCUMENTS

Manage Expected and matched documents from one view

1-25 of 95 < 1 / 4 > [ ] [ ] [ ] [ ]

Expected Document	Completeness Status	Expected	All Doc...	Requiredness	# of Final		
<input checked="" type="checkbox"/> Data Management Plan (D...	<span style="color: green;">●</span>	Study	Data Management Plan	Data Manage...	1	1	Required
<input checked="" type="checkbox"/> Quality Plan	<span style="color: orange;">●</span>	Study	Quality Plan	Quality Assur...	1	1	Required
<input type="checkbox"/> Trial Management Plan	<span style="color: orange;">●</span>	Study	Trial Management Plan	Project Mana...	1	1	Required
<input type="checkbox"/> test 1 - IR - First Study Sit...	<span style="color: grey;">⊘</span>	Study	Committee Process	Project Mana...	0	0	Not Required
<input type="checkbox"/> Subject Evaluability Crite...	<span style="color: red;">○</span>	Study	Subject Evaluability Crite...	Biostatistics	1	0	Required
<input type="checkbox"/> Randomization Sign Off	<span style="color: red;">○</span>	Study	Randomization Sign Off	Biostatistics	1	0	Required
<input type="checkbox"/> Randomization Programmi...	<span style="color: red;">○</span>	Study	Randomization Program...	Biostatistics	1	0	Required
<input type="checkbox"/> Randomization Procedure	<span style="color: red;">○</span>	Study	Randomization Procedure	Biostatistics	1	0	Required
<input type="checkbox"/> Randomization Plan	<span style="color: red;">○</span>	Study	Randomization Plan	Biostatistics	1	0	Required
<input type="checkbox"/> Sample Size Calculation	<span style="color: red;">○</span>	Study	Sample Size Calculation	Biostatistics	1	0	Required

### MATCHED DOCUMENTS

Document	Document Status	Blinding
<input type="checkbox"/> Data Management ...	Approved	Unblinded
<input type="checkbox"/> Quality Plan_ (v0.2)	In Progress	Blinded



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?