



 VAULT eTMF

Tips & Tricks:
Dashboards and Reports

October, 2014

Today's Session

- Interactive session to build reports and dashboards for Vault eTMF
- Overview the capabilities of Vault reporting
- Hands-on practice building reports to answer your business questions
- Preview V10 reporting features including object reports



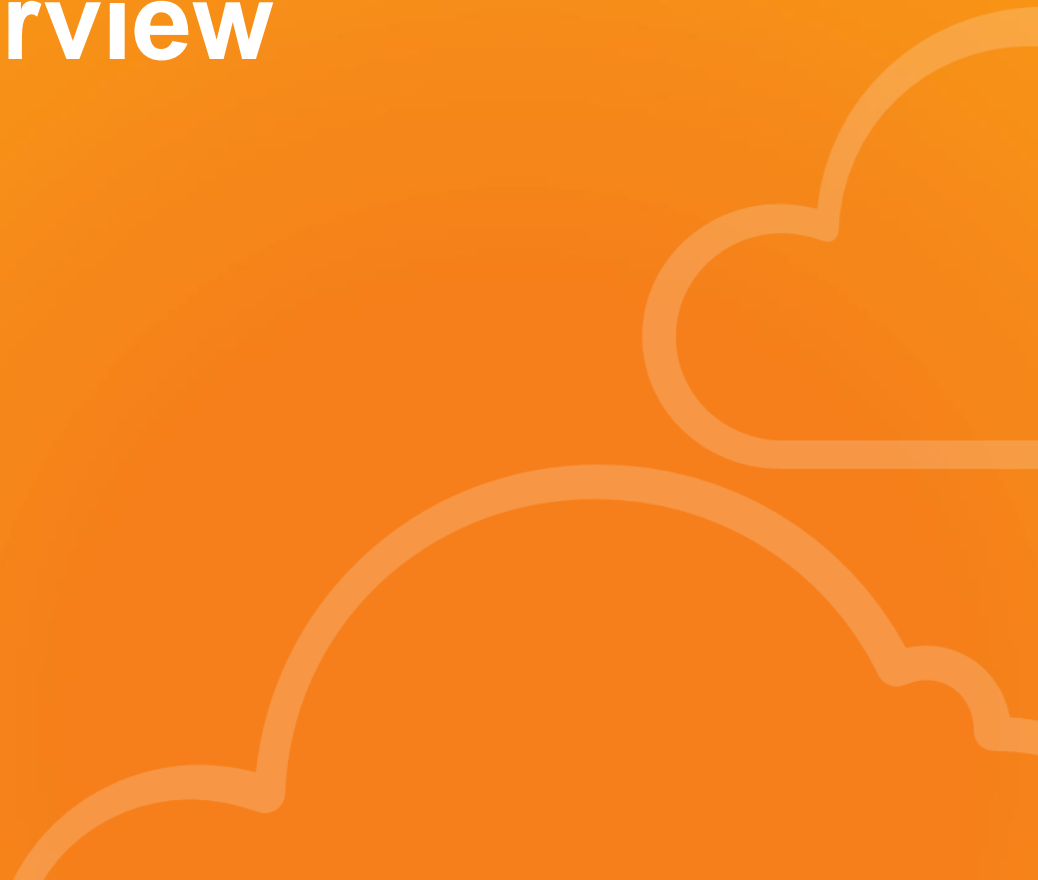
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Market Owner
Vault eTMF, R&D



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Senior Sales Engineer
Vault R&D



Vault Reporting and Dashboard Overview



Easy and Powerful Reporting

Features

- Point-and-click report building
- Available to all Full Users
- Report on documents, workflows, or Vault objects
- Private reports or shared reports

Benefits

- **Replace your tracking sheets**
- **Enable productivity enhancements**
- **Enhance compliance tracking**
- **Share your progress**



Configuration, not Customization

Considerations while you're configuring...

- What metadata do I need?
- Define calculated fields for metrics
- How can Vault Objects support my reporting objectives?



What Is Vault Reporting?

An interactive view into Vault data, making it easy to answer important questions about your business in **REAL TIME**

Label Distribution		Packaging Site			Product
Name ▲	Container Type	Name	Site Contact Name	Address	Product Name
► Product Name: Cholecap (8)					
▼ Product Name: VeevaProm (9)					
100 Mg Korea	Aerosol spray	Tokyo	Tak Okamura	Ebisu Business Tower 5F Ebisu 1-19-19, Shibuya ku. Tokyo 150-0013 Japan	VeevaProm
100 Mg VeevaProm	Aerosol spray	San Diego	Mary Robinson	27 First St. San Diego, CA	VeevaProm
100 Mg VeevaProm	Aerosol spray	Tokyo	Tak Okamura	Ebisu Business Tower 5F Ebisu 1-19-19, Shibuya ku. Tokyo 150-0013 Japan	VeevaProm
100 Mg VeevaProm China	Blister pack	Beijing	Cindy Zhang	中海广场中楼1001室 北京市朝阳区光华东里8号院	VeevaProm
200 Mg VeevaProm	Aerosol spray	Tokyo	Tak Okamura	Ebisu Business Tower 5F Ebisu 1-19-19, Shibuya ku. Tokyo 150-0013 Japan	VeevaProm
200 Mg VeevaProm China	Aerosol spray	Beijing	Cindy Zhang	中海广场中楼1001室 北京市朝阳区光华东里8号院	VeevaProm
50 Mg VeevaProm	Aluminium bottle	San Diego	Mary Robinson	27 First St. San Diego, CA	VeevaProm
50 Mg VeevaProm	Aerosol spray	Tokyo	Tak Okamura	Ebisu Business Tower 5F Ebisu 1-19-19, Shibuya ku. Tokyo 150-0013 Japan	VeevaProm
50 Mg VeevaProm Indonesia	Aerosol spray	Beijing	Cindy Zhang	中海广场中楼1001室 北京市朝阳区光华东里8号院	VeevaProm
► Product Name: VeevaProm XR (4)					
► Product Name: (None) (5)					

What Can Vault Reporting Do?

Forward Looking Reports

Which documents are approaching expiration/review?

Which documents are on this month's meeting agenda?

What is the workload for CRAs?
For CROs?

Historical Reports

What is the breakdown of documents in my vault? By CRO, department, doc type, or status?

How many documents have been reviewed and approved?

What is the duration documents spent in each workflow?

Custom Metrics

How long are my review cycles?

What are the bottlenecks in my process?

How many iterations do I need to conduct with each site prior to completion?



Power Reporting Tips



- **Formula Properties**

- Find out how long it took for a doc field to go from one value
- Find out how many times a doc field was in a particular value

- **Use Run-Time Inputs**

- Build a report, get results under different context

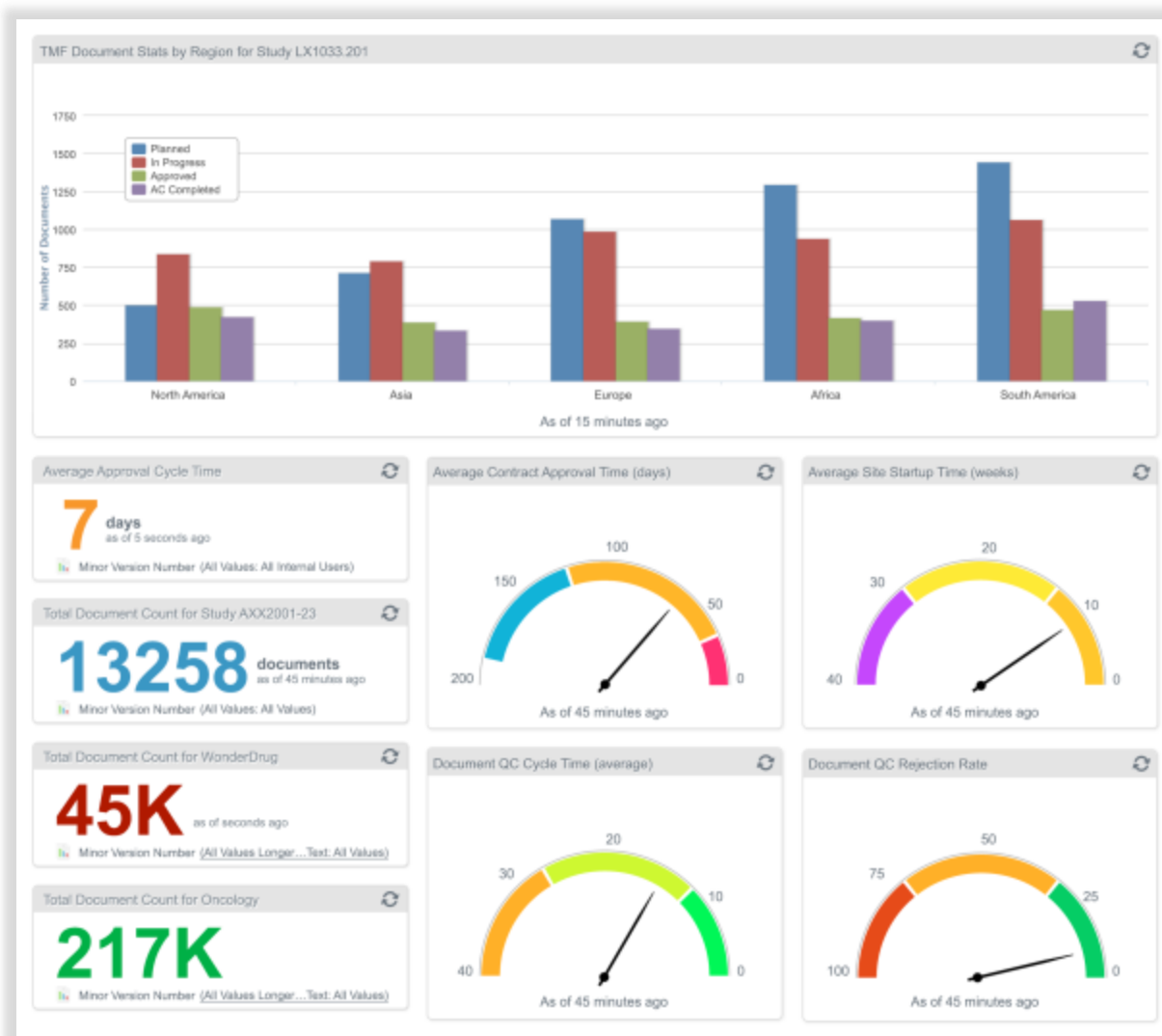
- **Reporting on Objects (New for v10)**

- Use relationships between documents and objects
- Use relationships between objects
- Grouping and summary calculations



What Are Vault Dashboards?

At-a-glance visualizations of key metrics derived from Vault reports



What Can Vault Dashboards Do?

- **Provide a graphical representation of the underlying data**
- **Populate monthly reports or presentations to management**
 - Charts can be downloaded as image files (.png) and included in presentations or other materials
- **Vary the chart type to reflect the business metric**
 - Chart types include: gauge, bar, column, and number charts



Dashboard Component Chart Types



Gauge



Column



Bar



Number

Dashboard Tips



- **Use stacked bar/columns for multi-level grouping**
- **Add target values in chart to compare to goals**
- **Export chart images to include in PowerPoint**
- **Coming soon:**
 - Showing trends over time
 - Use run-time input to create one dashboard that can be used under different context



How This Helps Me



Reports and Dashboards for Vault eTMF

Milestone and Process-based TMF Evaluation

Business Case

- TMF management is outsourced to a CRO
- CRO using sponsor's Vault to manage sites and TMF
- Sponsor trial manager accountable for oversight

What to Evaluate

- TMF completeness in relation to study/site milestones
- Essential document collection and site start-up
- CRO performance

Benefits

- TMF completeness accuracy
- Site start-up/conduct progress
- Sponsor/CRO oversight and monitoring



Reports and Dashboards for Vault eTMF

Inspection Readiness Monitoring

Business Case

- Sponsor conduct quarterly GCP audits of complete TMF
- Findings/issues are categorized and tracked
- Resolution of findings are tracked to completion

What to Evaluate

- TMF quality, specifically accuracy
- Outstanding findings and duration of time to resolve
- Types of findings and associated problem areas

Benefits

- TMF quality and inspection readiness
- Analysis of inspection readiness KPIs across a program

Top Reports Customers Leverage

- **Study Completeness Reports**

- Missing Documents by Site/Country/Study — Any non-approved (Draft, Planned, etc.) document filed at a given level

- **All Documents by Site/Country/Study**

- **Expiration Reports — Documents expiring within # of days**

- **All Documents by Department**

- For QC purposes — filtered by the assigned department to see the documents their functional area is responsible



Hands-on Exercises



Exercise #1

Milestone and Process-based TMF Evaluation

Business Case

TMF management is outsourced to a CRO

CRO is using sponsor's Vault to manage TMF

Sponsor trial manager is accountable for TMF and sponsor oversight

Assumptions

All parties trained on using Vault to manage processes

Investigator Portal used to manage site content

Sponsor manages expected content and placeholders in Vault

Some level of configuration may be required on existing Vaults



Exercise #1

Milestone and Process Based TMF Evaluation

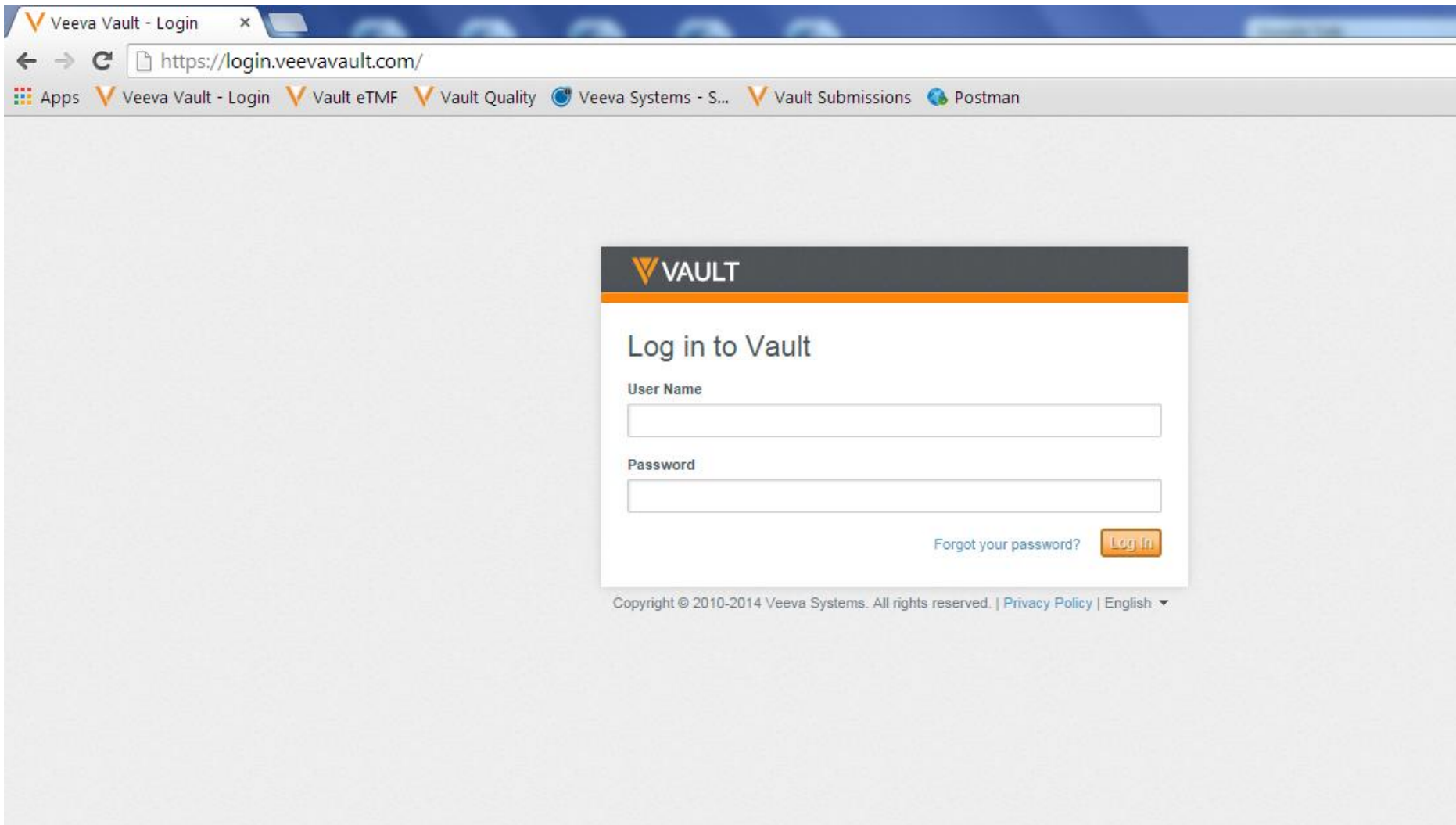
Exercise Steps

Add Report

1. Login
2. Navigate to “Reports”
3. Click “Create”
4. Complete Report Form, then click “next”
5. Add filters & edit columns as required
6. Click “Save & Run”

Add Dashboard

1. Navigate to “Dashboards”
2. Click “Create”
3. Enter a name
4. Add Component
5. Update as required



[« Back to reports](#)

Create Report


Continue

Cancel

Report Type*

[Expand all](#) [Collapse all](#)

▼ DOCUMENT

 Document

▶ WORKFLOW

▶ READ & UNDERSTOOD

▶ COUNTRY

▶ PRODUCT

▶ STUDY

▶ STUDY SITE

Type

All Documents

Subtype

Classification

Name

027 Site Startup

Description

Report Format*

☒ Tabular☐ Matrix

Shows fields in columns and individual records in rows.

[Back to reports](#)

AVEG 027 Site Setup ★ [✎](#)

[Run](#) [Save](#) [Cancel](#)

Report Type Document

▼ **Filters (optional)**

Study	equals	AVEG 027	⊕	🔍	⊖	⊕
Process Name	in	Set up site(s)	⊕	▼	⊖	⊕
Classification	is not equal to	Protocol Amendment Signature Page	▼		⊖	⊕
Study Site	is not blank				⊖	⊕

► **Prompts (optional)**

[Edit columns](#)

	Document Name ▲	Document Number	Document Status	Created By
Group rows by Study Site ?				
↳ Document Status				

[« Back to reports](#)

AVEG 027 Site Setup ★

Report Type Document

▼ Filters (optional)

Study

equals

Process Name

in

Classification

is not equal to

Study Site

is not blank

► Prompts (optional)

Group rows by Study Site

Document Status

Edit Column to Display

Search:

Available Columns

of days remaining
of Days to Complete MVR
of days to resolve
Actual first country approval
Actual first site initiated
Additional Comments
Alerted
Annotations (All)
Annotations (Anchors)
Annotations (Lines)
Annotations (Links)
Annotations (Notes)
Annotations (Resolved)
Annotations (Unresolved)
Approval Complete Date
Approval Cycles Started
Approval Start Date
Approver
Archivist
Auditor
Binder
CEC
CEC Approval Date
Checksum



Displayed Columns

[Restore](#)

Document Name
Document Number
Document Status
Created By



OK

Cancel

V VAULT eTMF

Search all documents...

HOME LIBRARY REPORTS **DASHBOARDS** + Create Upload

STUDY SELECTOR All Studies

Sort by Modified Date (Newest First) Show 25

All Dashboards

New Dashboard

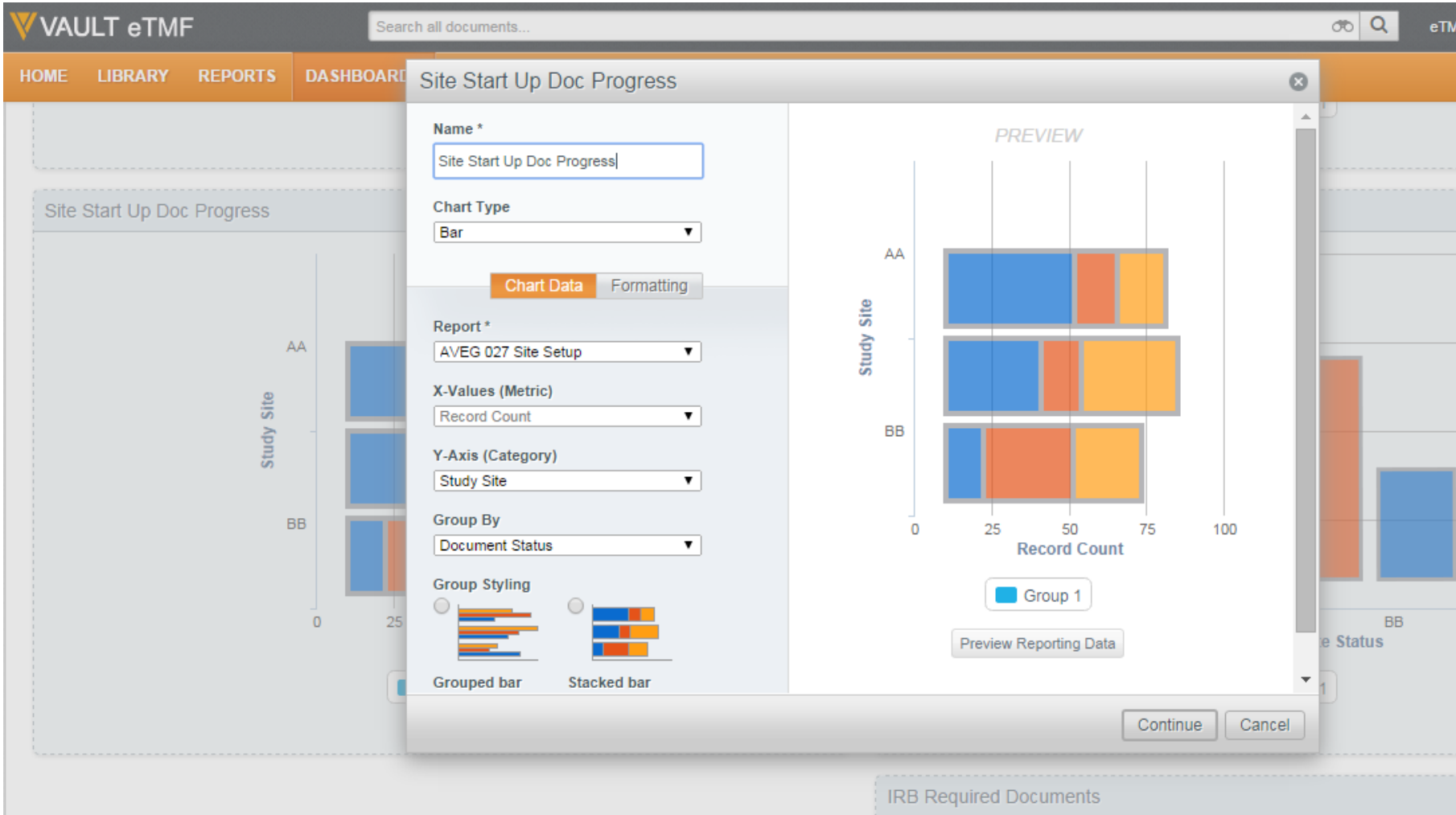
Name *
Trial Completeness

Description

Continue Cancel

- ETB 050 UK Study Start-up
Created by Eric Trialmgr - August 19
- VPR 001 CTA Monitoring
Created by Eric Trialmgr - January 13
VPR 001 CTA Monitoring
- Cross Trial Trending
Created by Eric Trialmgr - December 16, 2013
Cross Trial Trending
- AVEG 027 Issue Resolution
Created by Eric Trialmgr - December 16, 2013
AVEG 027 Issue Resolution

avault.com/ui/



Study Resource Planning

Name *

Study Resource Planning

Chart Type

Pie

Chart Data

Formatting

Report *

AVEG 027 Trial Resource Plannin
g

Metric

Record Count

Group By

Document Status

PREVIEW

Preview Reporting Data

Continue

Cancel

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Exercise #2

Inspection Readiness Monitoring

Business Case

Sponsor conduct quarterly GCP audits of complete TMF

Findings and issues are categorized and tracked

Resolution of findings are tracked to completion

Assumptions

Someone is conducting GCP audit on routine basis

Document properties are set up and used to track document issues, types, etc.

Some level of configuration may be required on existing Vault's



Exercise #2

Inspection Readiness Monitoring

Exercise Steps

Add Report

1. Login
2. Navigate to “Reports”
3. Click “Create”
4. Complete Report Form, then click “next”
5. Add filters & edit columns as required
6. Click “Save & Run”

Add Dashboard

1. Navigate to “Dashboards”
2. Click “Create”
3. Enter a name
4. Add Component
5. Update as required

Report Type Document

Filters (optional)

Issue Type
in

Signature Not Present
Incomplete Metadata
Misclassified (Misfiled)
Inaccurate Content
Duplicate
Expired

Study
in

AVEG 027
BL 010
VPR 001

Classification
is not equal to
Investigator Brochure

Prompts (optional)

Edit columns

	Document Name	Document Status	Issue Type	Issue Date	Issue Resolved?	Resoluti
Group rows by	Study			Σ		Σ
Issue Type						

↳ Issue Type

Cancel

VAULT eTMF

Search all documents...

eTMF V6b

HOME

LIBRARY

REPORTS

DASHBOARD

« Back to dashboards

Cross Trial Trending

Cross Trial Trending

Audit Analysis

AA

BB

0

Audit Analysis

Chart Type

Bar

Chart Data

Formatting

Report *

Issue Not Blank

X-Values (Metric)

Record Count

Y-Axis (Category)

Study

Group By

Issue Type

Group Styling

Grouped bar

Stacked bar

PREVIEW

Study

AA

BB

0

25

50

75

100

Record Count

Group 1

Preview Reporting Data

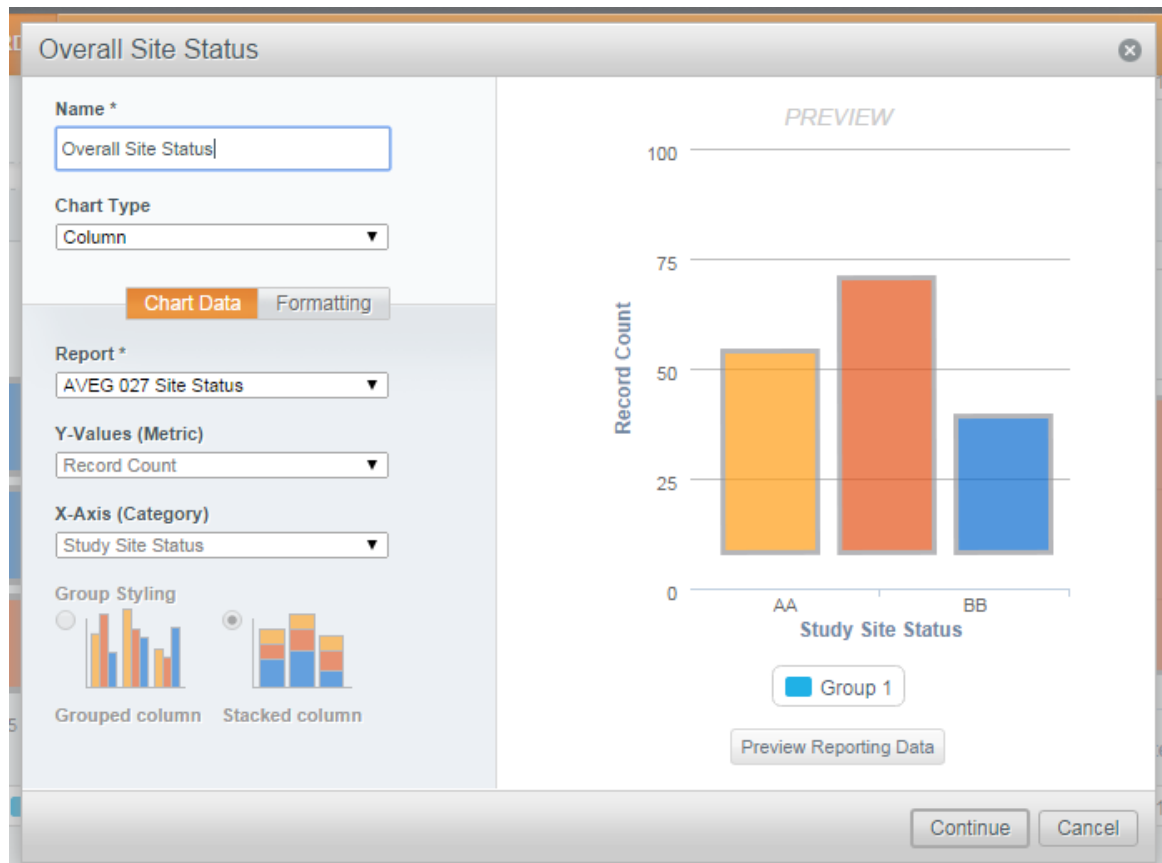
Continue

Cancel

Group 1

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Thank You