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

Jason Methia
Market Owner
Vault eTMF, R&D

Tom Frattarola
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**
## What Can Vault Reporting Do?

<table>
<thead>
<tr>
<th>Forward Looking Reports</th>
<th>Historical Reports</th>
<th>Custom Metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which documents are approaching expiration/review?</td>
<td>What is the breakdown of documents in my vault? By CRO, department, doc type, or status?</td>
<td>How long are my review cycles?</td>
</tr>
<tr>
<td>Which documents are on this month’s meeting agenda?</td>
<td>How many documents have been reviewed and approved?</td>
<td>What are the bottlenecks in my process?</td>
</tr>
<tr>
<td>What is the workload for CRAs? For CROs?</td>
<td>What is the duration documents spent in each workflow?</td>
<td>How many iterations do I need to conduct with each site prior to completion?</td>
</tr>
</tbody>
</table>
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

NEW

NEW

NEW

NEW
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

<table>
<thead>
<tr>
<th>Business Case</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TMF management is outsourced to a CRO</td>
</tr>
<tr>
<td></td>
<td>CRO using sponsor’s Vault to manage sites and TMF</td>
</tr>
<tr>
<td></td>
<td>Sponsor trial manager accountable for oversight</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What to Evaluate</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TMF completeness in relation to study/site milestones</td>
</tr>
<tr>
<td></td>
<td>Essential document collection and site start-up</td>
</tr>
<tr>
<td></td>
<td>CRO performance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Benefits</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TMF completeness accuracy</td>
</tr>
<tr>
<td></td>
<td>Site start-up/conduct progress</td>
</tr>
<tr>
<td></td>
<td>Sponsor/CRO oversight and monitoring</td>
</tr>
</tbody>
</table>
### 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

<table>
<thead>
<tr>
<th>Business Case</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMF management is outsourced to a CRO</td>
<td>All parties trained on using Vault to manage processes</td>
</tr>
<tr>
<td>CRO is using sponsor’s Vault to manage TMF</td>
<td>Investigator Portal used to manage site content</td>
</tr>
<tr>
<td>Sponsor trial manager is accountable for TMF and sponsor oversight</td>
<td>Sponsor manages expected content and placeholders in Vault</td>
</tr>
<tr>
<td></td>
<td>Some level of configuration may be required on existing Vaults</td>
</tr>
</tbody>
</table>
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
### AVEG 027 Site Setup

**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):**

<table>
<thead>
<tr>
<th>Group rows by</th>
<th>Document Name</th>
<th>Document Number</th>
<th>Document Status</th>
<th>Created By</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Site</strong></td>
<td>Document Name</td>
<td>Document Number</td>
<td>Document Status</td>
<td>Created By</td>
</tr>
</tbody>
</table>

---

**VAULT eTMF**

Copyright © 2010-2014 Veeva Systems. All rights reserved.
Exercise #2
Inspection Readiness Monitoring

<table>
<thead>
<tr>
<th>Business Case</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor conduct quarterly GCP audits of complete TMF</td>
<td>Someone is conducting GCP audit on routine basis</td>
</tr>
<tr>
<td>Findings and issues are categorized and tracked</td>
<td>Document properties are set up and used to track document issues, types, etc.</td>
</tr>
<tr>
<td>Resolution of findings are tracked to completion</td>
<td>Some level of configuration may be required on existing Vault’s</td>
</tr>
</tbody>
</table>
# 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
The image displays a screenshot of a user interface for the VAULT eTMF system. The interface allows users to search and filter documents based on various criteria. The filters include:

- **Issue Type**: Options include Signature Not Present, Incomplete Metadata, Misclassified (Misfiled), Inaccurate Content, Duplicate, and Expired.
- **Study**: Options include AVEG 027, BL 010, and VPR 001.
- **Classification**: Options include is not equal to Investigator Brochure.

The interface also includes prompts for further customization of the search and filtering options. The layout is designed for ease of use, with clear labelings and intuitive navigation options.