



Features You Should Be Using

Quality Issues

TMF owners are increasingly adopting purpose-built eTMF solutions to achieve more active trial management and oversight to ensure a constant state of inspection readiness.

We recognize this desire for ongoing TMF improvement and are focused on continuous innovation to ensure Vault eTMF supports you in streamlining processes, driving efficiencies, and improving collaboration.

In this edition of "Vault eTMF Features You Should Start Using", we are focusing on the Quality Issues object to show how this can help you optimize your TMF processes. Read on for more about this feature and how to enable it.

What is the Quality Issues object?

The Quality Issues object allows you to create and assign issues during quality checks, track who is responsible for resolving specific issues, and report on the number of open issues in Vault. This object helps users track, manage, and report quality issues on documents in an efficient and easy manner.

Quality Issues assign tasks to users to fix the issue. Upon creating a Quality Issue for a document, Vault automatically sends an email notification to the assigned user. The user can click on the task to view the related document, issue type, and issue comments. Afterwards, the user can complete the task (Resolved, Unresolved, or Non-Issue) or reassign it to another user.

Quality Issues can be logged before or after a document is approved. Depending on when they are logged, Quality Issues are classified as pre-approval Issues or post-approval Issues.

Reports and dashboards are used to track quality issues by organization or department, document type, or user. For example, you may want to know if a department has more quality issues than another, if there are more quality issues on a particular document type like Monitoring Visit Report, or if a user has a lot of issues and may need some retraining.

The TMF Homepage uses Quality Issues as part of the standard toolkit - it provides an easy to navigate interface for you to quickly identify and examine the key performance and management data about your study/country/site.

Why is the Quality Issues object important?

The Quality Issues object drives greater speed and efficiency by offering the possibility to track, manage, and report on quality issues. This enables users to resolve document issues easily and support inspection readiness. It also helps minimize the use of external to-do lists by using the Quality Issues Tasks option.

By providing a way to measure your control of the TMF and associated business processes, Quality Issues data can provide business information used for supporting improvements, which in turn help you to align with best practices

and differentiate your business from the competition.

Furthermore, the Quality Issues can be leveraged to configure a controlled document deletion process. To learn more, contact your assigned managed services consultant or customer success manager.

Note that it is in Veeva's route map to create Quality Issues as part of future AI feature.

How do I turn the Quality Issues object on?

Quality Issues require some initial setup before you can use them in your Vault:

1. Add the # of Open Issues, # of Closed Issues, and # of Total Issues document fields to document types that need quality issue tracking.
2. Add the Create Related Record user action to document lifecycle states where you want Quality Issues available.
3. Enter an Action Label and select Quality Issue as the object, and Related Documents as the Field to Default.
4. Add Read permission for the Quality Issues object on relevant permission sets.

Once you have completed setup, you can start logging quality issues for your documents:

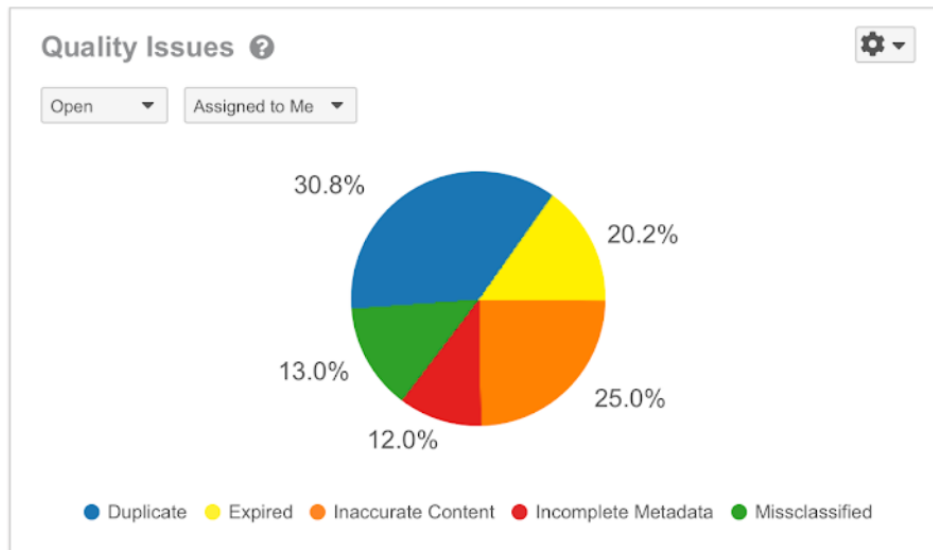
1. From the document's Actions menu, select Log Quality Issue. This is normally performed as part of a QC review workflow (pre and post-approval), as well as part of multi-document workflows.
2. In the dialog, choose the user to assign this task to.
3. Select the Issue Type and enter any issue comments.
4. Click Save.

▼ Details

Quality Issue ID	Due Date*		
Object Type	Pre-Approval Issue	# of Days Open	
Assigned To*		Days until Due	
QC Issue Type*		Verdict	
QC Issue Comments*		Verdict Date	
Related Document*		Verdict Reason	
Version*			

Upon saving, Vault automatically assigns the selected recipient a Quality Issue Task to fix the issue, sends an email notification, and populates the following fields on the Quality Issue object record: Quality Issue ID, Due Date, Number of Days Open, and Days until Due.

Both open and closed Quality Issues can be seen on the TMF Homepage.



If you desire more in-depth configuration steps for enabling Quality Issues, ask for the Configuration Guide to your assigned managed services consultant or customer success manager.

How to resolve Quality Issues tasks?

As with other tasks, the recipient sees the newly created Quality Issue in Home > My Tasks. The recipient can click on the task to view the related document, issue type, and issue comments. They can also re-assign the task using the Reassign action on the task in the Workflow Timeline.

Once the recipient has resolved the issue or decides the issue cannot or should not be resolved, they can close the Quality Issue. The recipient navigates back to the Quality issue either through the Home > My Tasks page or by clicking the Quality Issue from the list of metadata on the document. The recipient will then click complete to close the Quality Issue.

At this point, Vault prompts the recipient to provide a verdict for the issue: Resolved, Unresolvable, or Non-issue. Vault requires a reason for the Unresolvable and Non-issue verdict.

Resolve Quality Issue

Fix the listed issue or mark as non-issue or unresolvable with the appropriate reason.

Verdict*

☐ Resolved

☐ Unresolvable

☐ Non-issue

*Required to proceed

Cancel

Complete

To see the Quality Issues in action, watch this 10-minute demo: <https://wi.st/2XvU9Hu>.