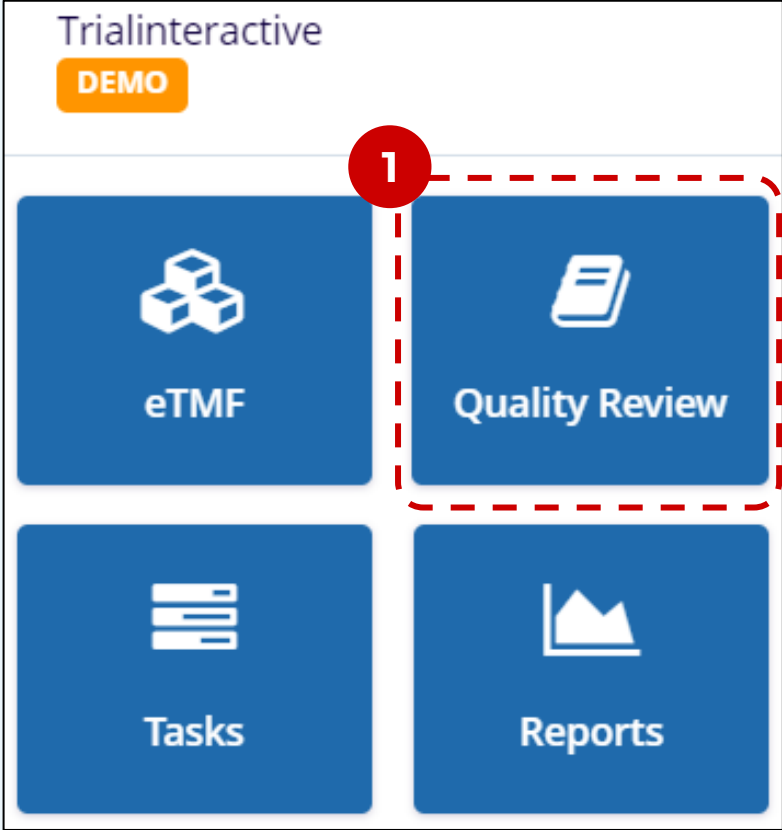


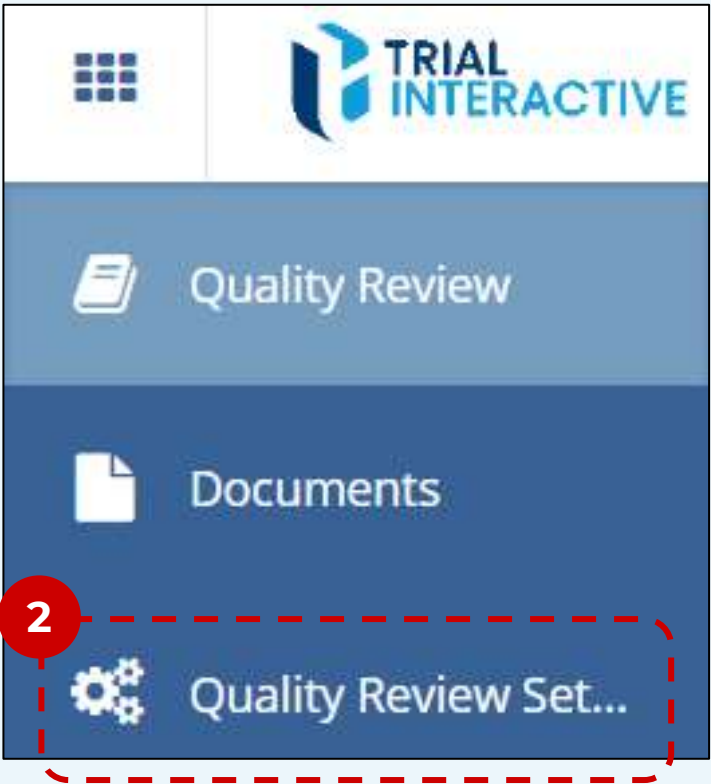
APPLICABLE TO:

- ☒ Admin
- ☐ Manager
- ☐ Editor
- ☐ Reader
- ☒ eTMF
- ☒ Collaborate

1 Navigate to the **Quality Review** module.



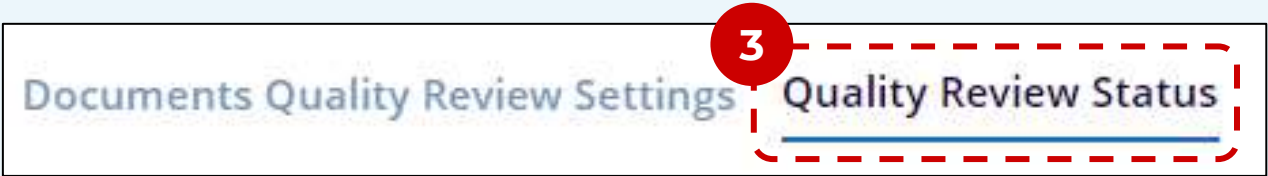
2 Access the **Quality Review Settings** menu.





Prior to creating audits, it is recommended the user verify or establish the statuses that will be used (assigned to documents) in the audit.

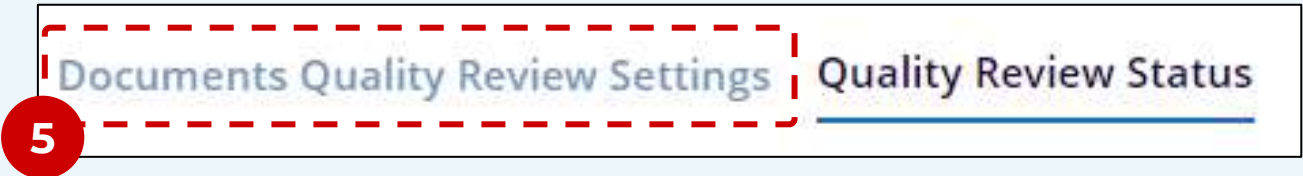
- 3
- Switch to the **Quality Review Status** tab.



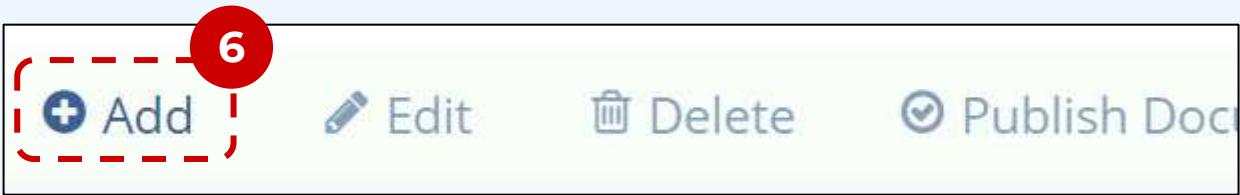
- 4
- Review the list and if necessary, Edit or Add any Display Name entry to match your needs.

+ Add Edit Delete	
Display Name	System Status
In Progress	IN PROGRESS
Failed	FAILED
Passed	PASSED
Excluded	EXCLUDED
Pending	PENDING

- 5
- Switch to the **Documents Quality Review Settings** tab.



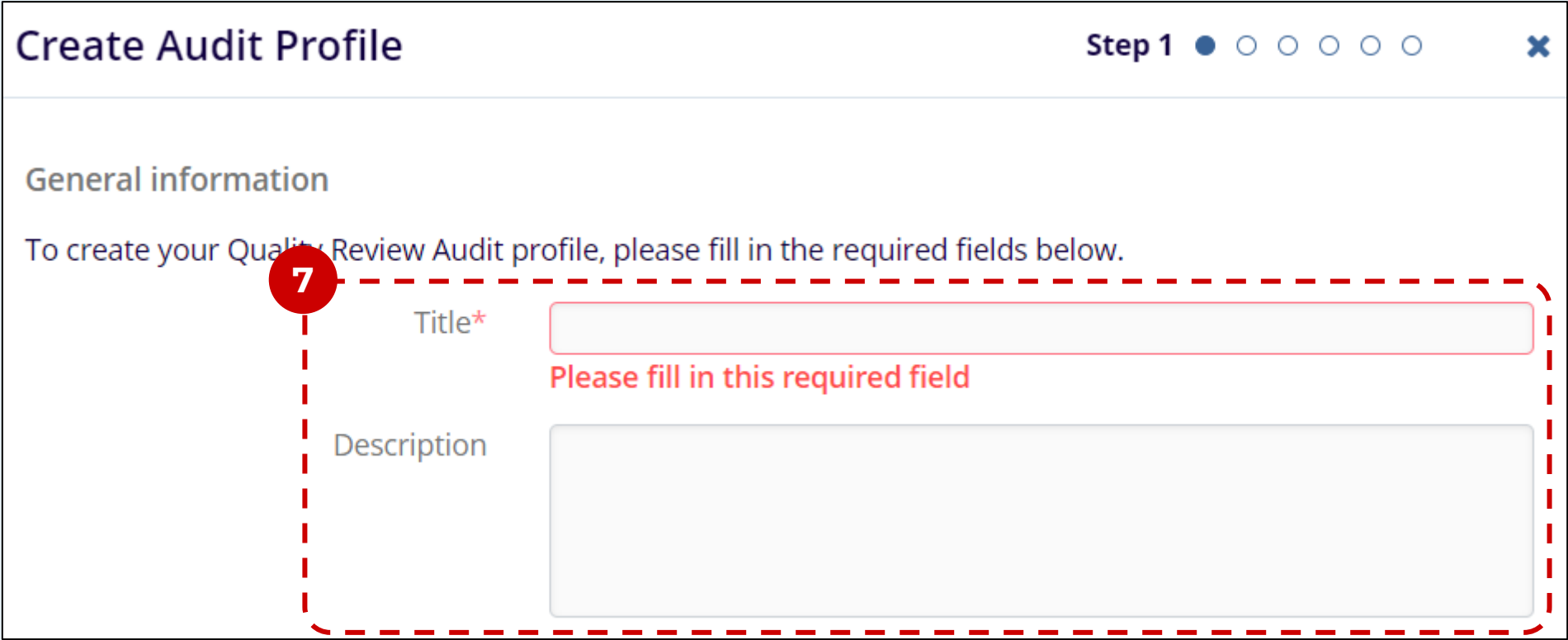
- 6
- Click on the **Add** button to open the audit setup wizard.



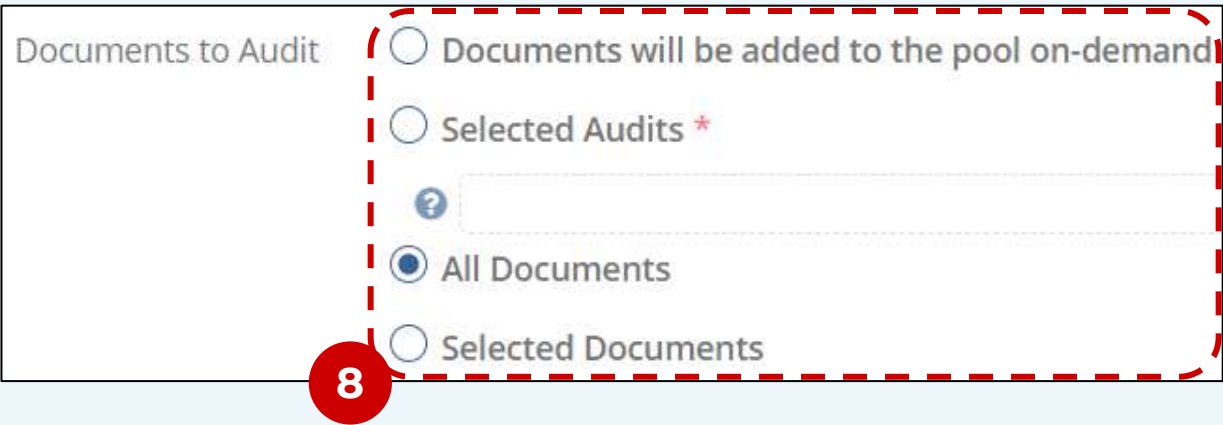
7 Step 1 of the setup contains all the basic settings of an audit: what documents will be included, how, and what parameters the audit will follow. Start with giving a name and, optionally, a description to your audit.



In the interest of brevity, this job aid will not detail the full array of available options. Please consider a long-form training material or live session instead.



8 After choosing a title and description, select the document inclusion method in **Documents to Audit**.



Documents will be added to the pool on Demand: no documents included immediately, allows for manual selection of documents via the Documents Cart.

Selected Audits: choose a previous audit to review the same documents.

All Documents: review of all documents in a certain time window.

Selected Documents: use the fields below ‘Selected Documents’ to establish parameters for inclusion, like index position or document type.

- 9

Depending on your selection in step #8, you might have access to the **Audit Scope** panel. Set a time window with a Start and End date, and validate it with the **Confirm** button.

Audit Scope

The dates you select are shown in the Room Time Zone (UTC-05:00)
Eastern Time (US & Canada)

All the documents will be placed using room Time Zone

9

From Date

15 Apr 2024

✕

📅

To Date

31 Oct 2024

✕

📅

10

☒ Use Submitted Dates

☐ Use Final Dates

Confirm

10

Choose the **Date Type** for selection.

11

The next section of Step 1 contains various audit criteria. You can hover on the tooltip '?' icon to see a description of most fields.

Do not include already audited documents

☐

Final documents only

☐

Add modified documents back into the audit pool

☐

Percentage of new documents

100

Update Interval / Frequency

week

This is the time interval for re-queuing documents into the audit. If left blank, no new documents are added to the audit after it starts

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12 Continuing from the previous step, select your preferences for users access and notifications. Availability of some options depends on your previous choices.

Auditor access level

☒ View only, no download

☐ Full Access

Contains PHI ? ☐

Send a notification when the documents are added into audit pool ☐

Send a notification for audit issues ☐

13 Move to the **Next** panel (the button is located at the bottom of the window).

Cancel

Next

14 Steps 2,3, and 4 consist of similar user selection panels. Step 2 is for Auditors, 3 is for Audit Managers, and 4 is for Audit Responders.

In each step, use the **Add** button to open the user selection screen.

Auditors

At least one active Auditor must be assigned to this Audit.

All

Name	Status
------	--------

15 In user selection, **drag** your selection from left to right to add users/groups.

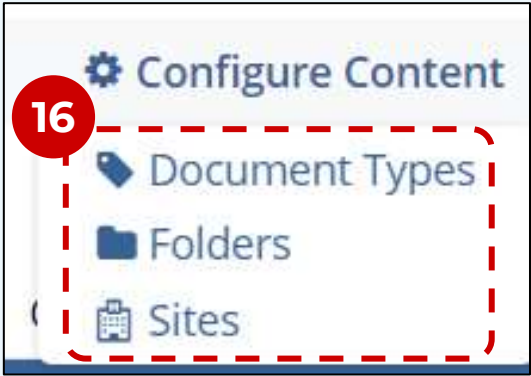
50 Columns 1 selected

Selected members

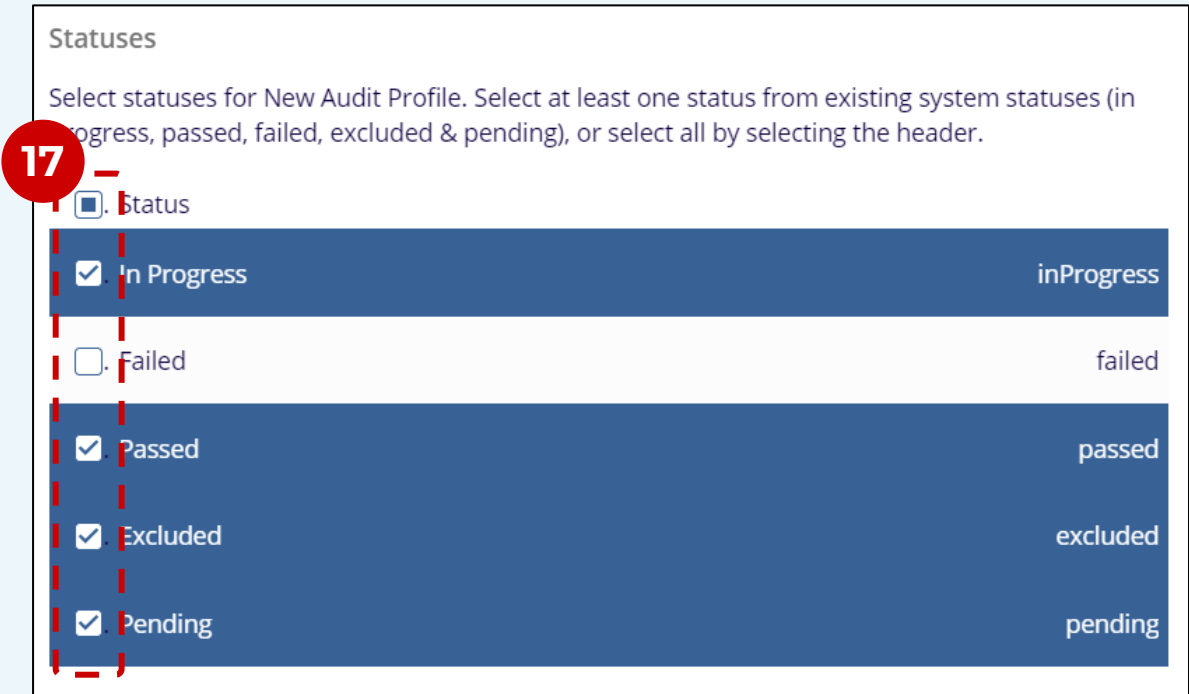
2 Columns

Name	Status
test integration	

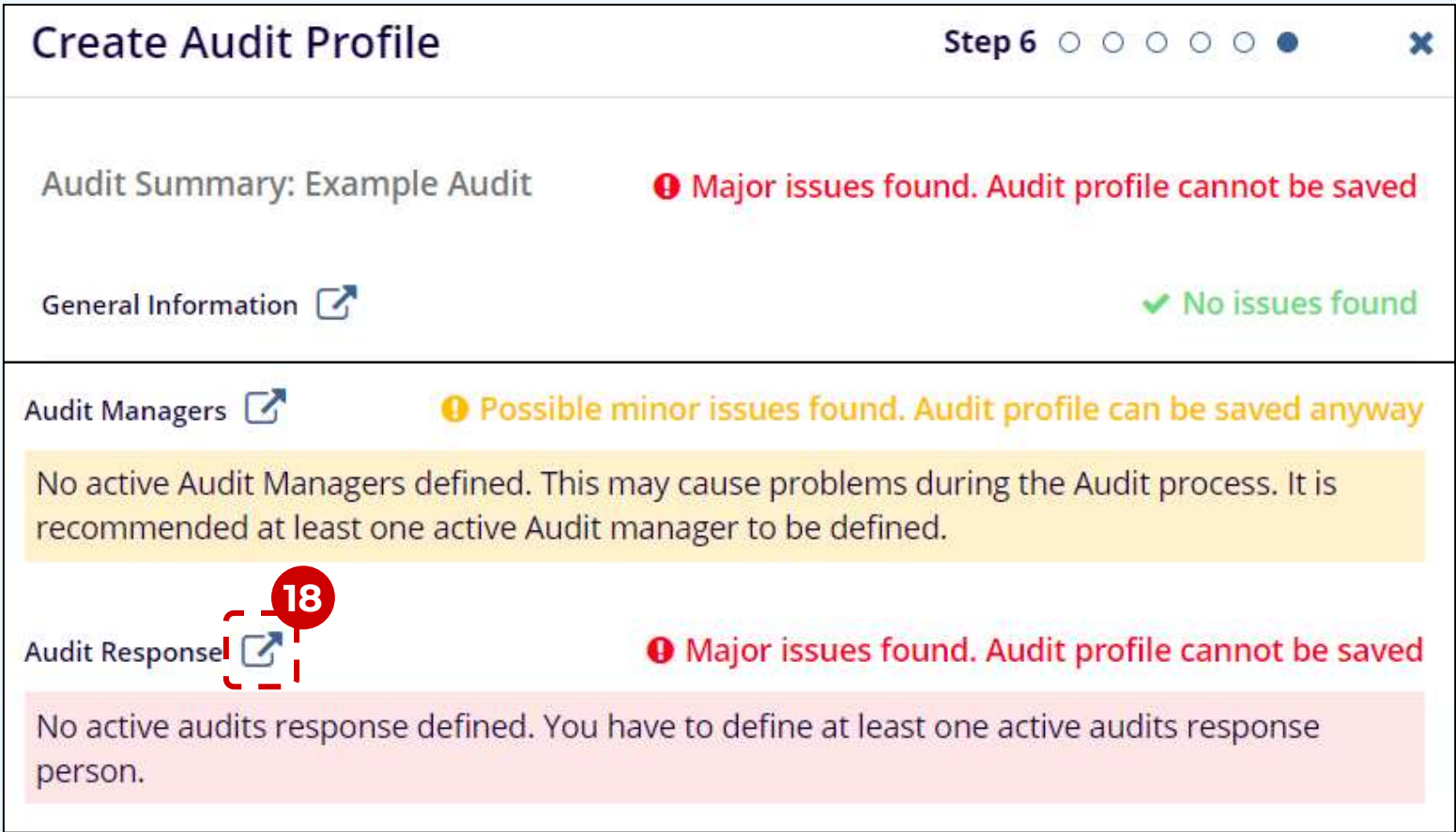
16 Uniquely to Step 2 (add auditors), individuals can be assigned to review specific content by type or location. Use the **Configure Content** button above the auditors list to make your selection.



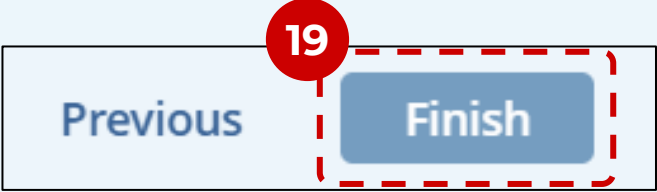
17 Proceed through the steps to panel 5, where you'll select the statuses to be used in the audit. You may proceed to Step 6 only after selecting one of each system status at a minimum.



18 Step 6 reviews your setup and analyzes it for potential issues. Major issues will need to be fixed before you can save the audit profile. The panel will indicate in what step an error is found and a shortcut is provided.



19 Once all issues are fixed, the Audit can be created. Click the **Finish** button at the bottom of the window.



20 You will be prompted to **activate the audit** now. If you select 'No' the audit will be saved in an editable Draft status.

