# How to Create an Audit

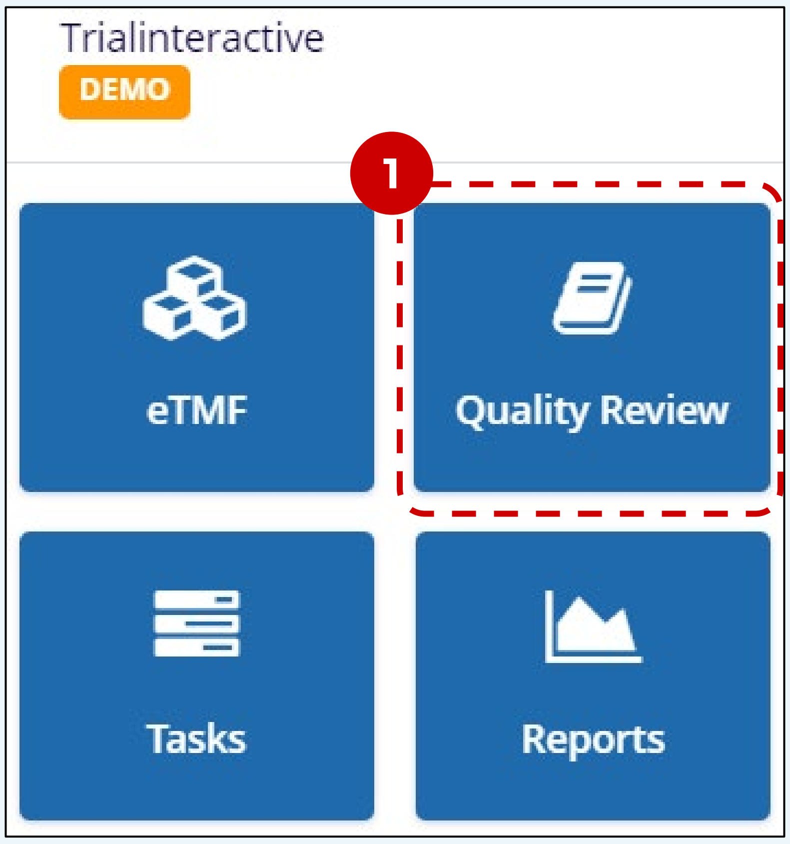
TI version 10.6

**APPLICABLE TO:**

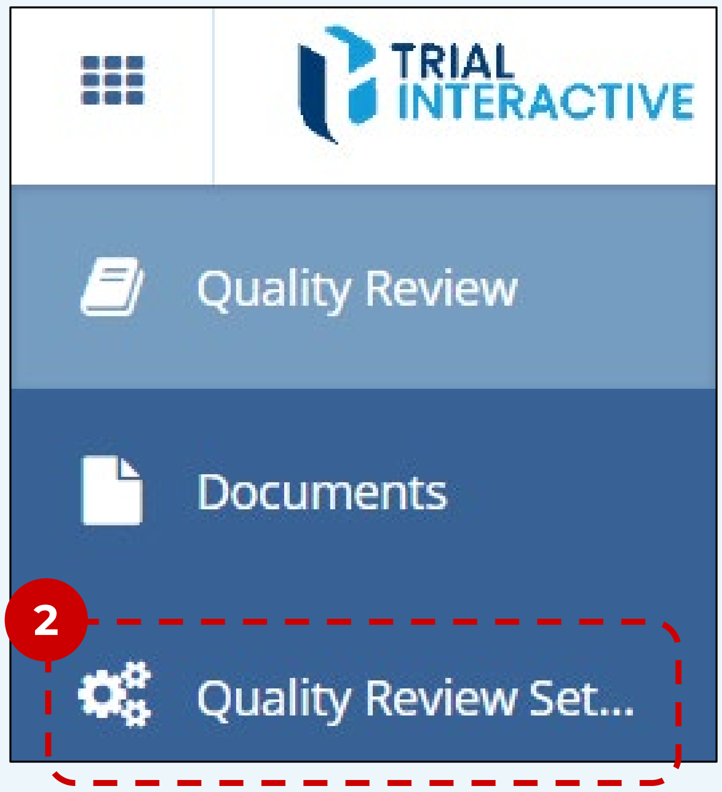
- ● Admin
- ○ Manager
- ○ Editor
- ○ Reader

● eTMF

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




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



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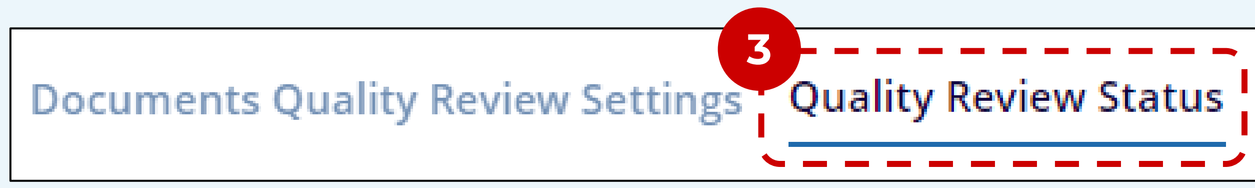
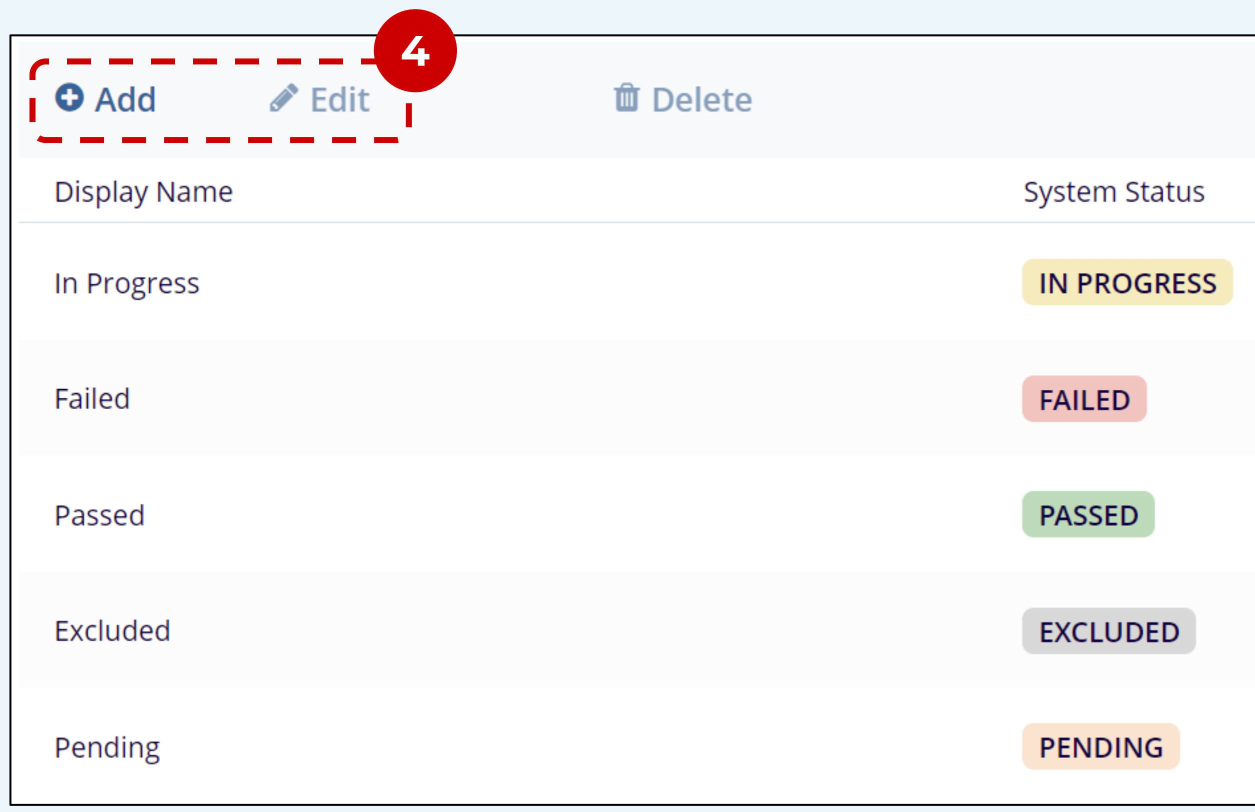
TRIAL INTERACTIVE

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.

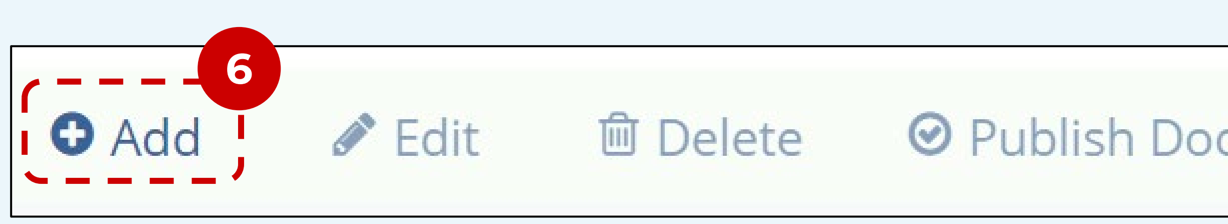



**4** Review the list and if necessary, Edit or Add any Display Name entry to match your needs.




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


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



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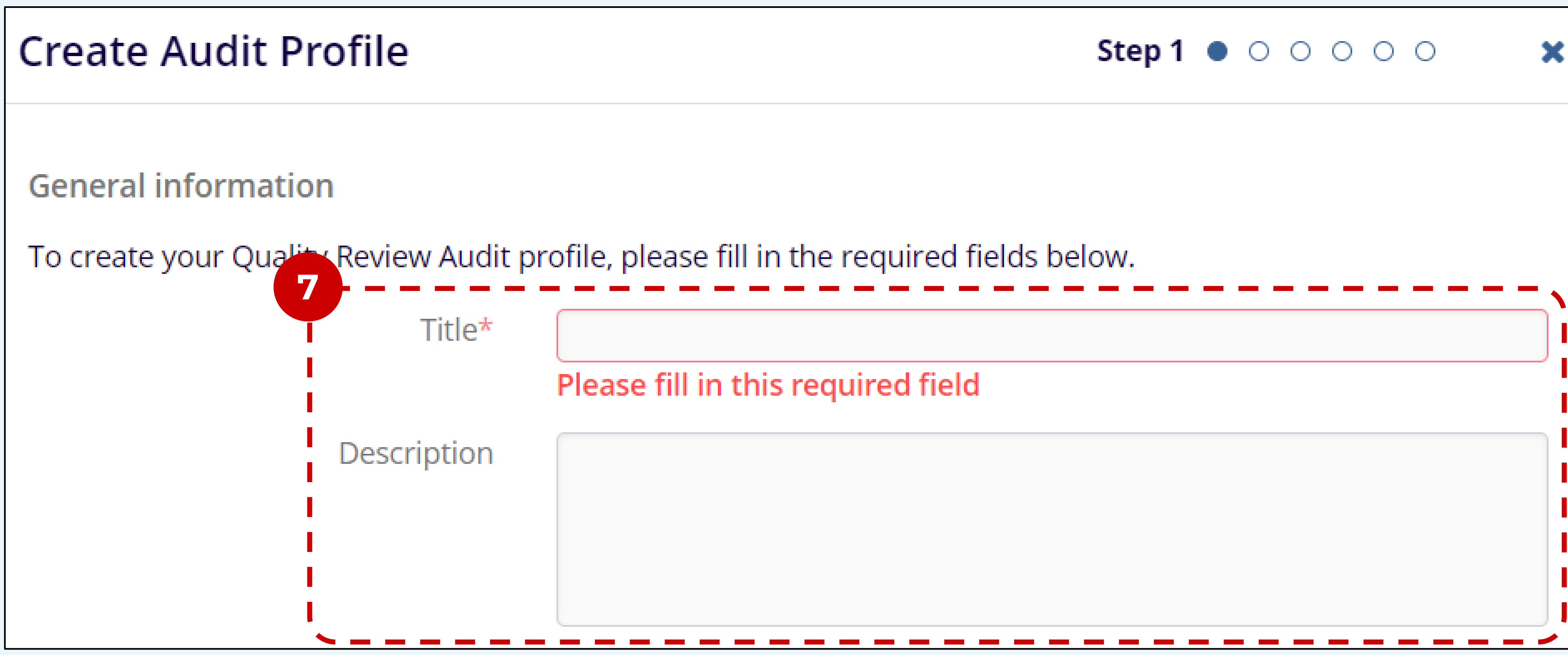
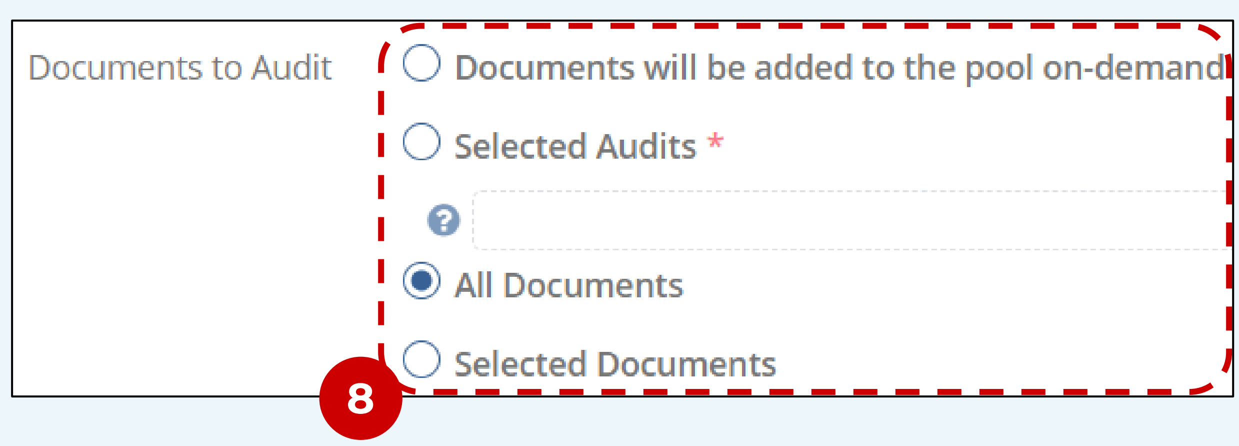
**7** Step 1 of the setup contains all the basic settings of an audit: what documents will be included, how, and what parameters the audit will follow. Start with giving a name and, optionally, a description to your audit.

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**.



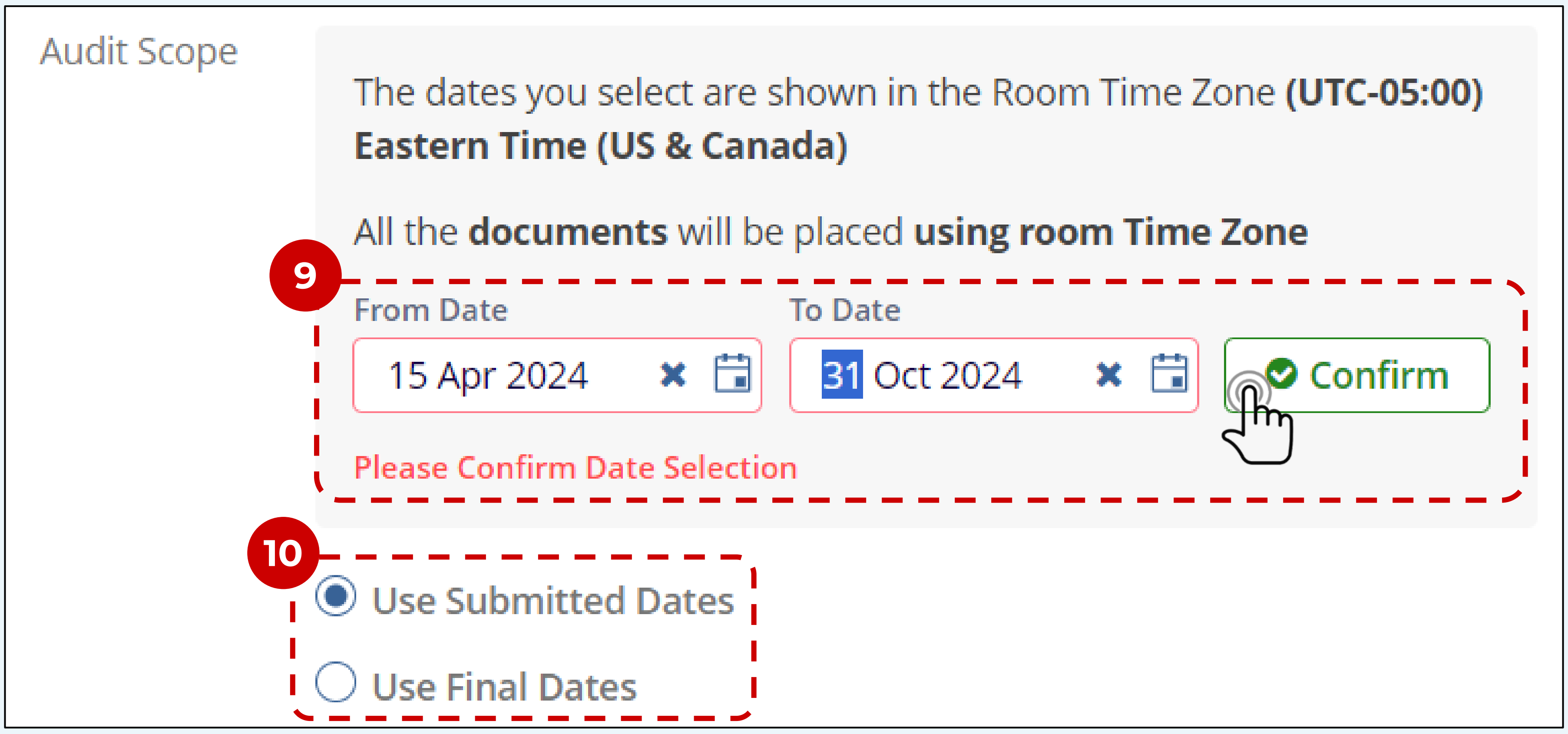

**Documents will be added to the pool on Demand:** no documents included immediately, allows for manual selection of documents via the Documents Cart.

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

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

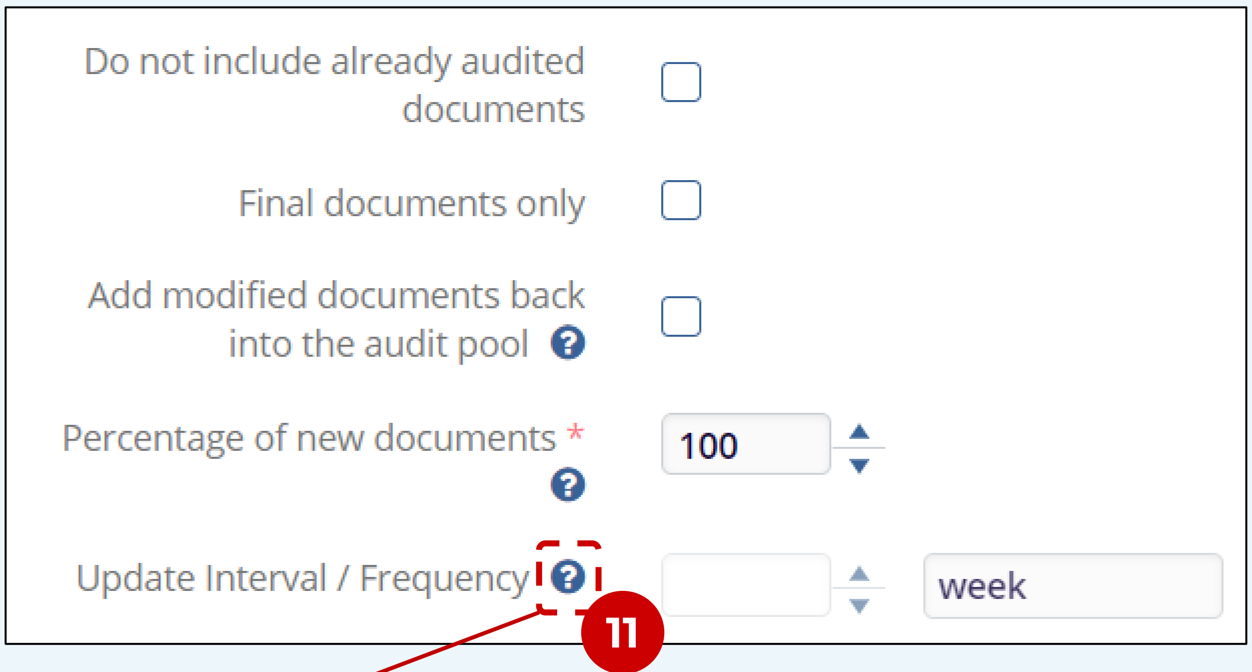
**Selected Documents:** use the fields below ‘Selected Documents’ to establish parameters for inclusion, like index position or document type.

**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.

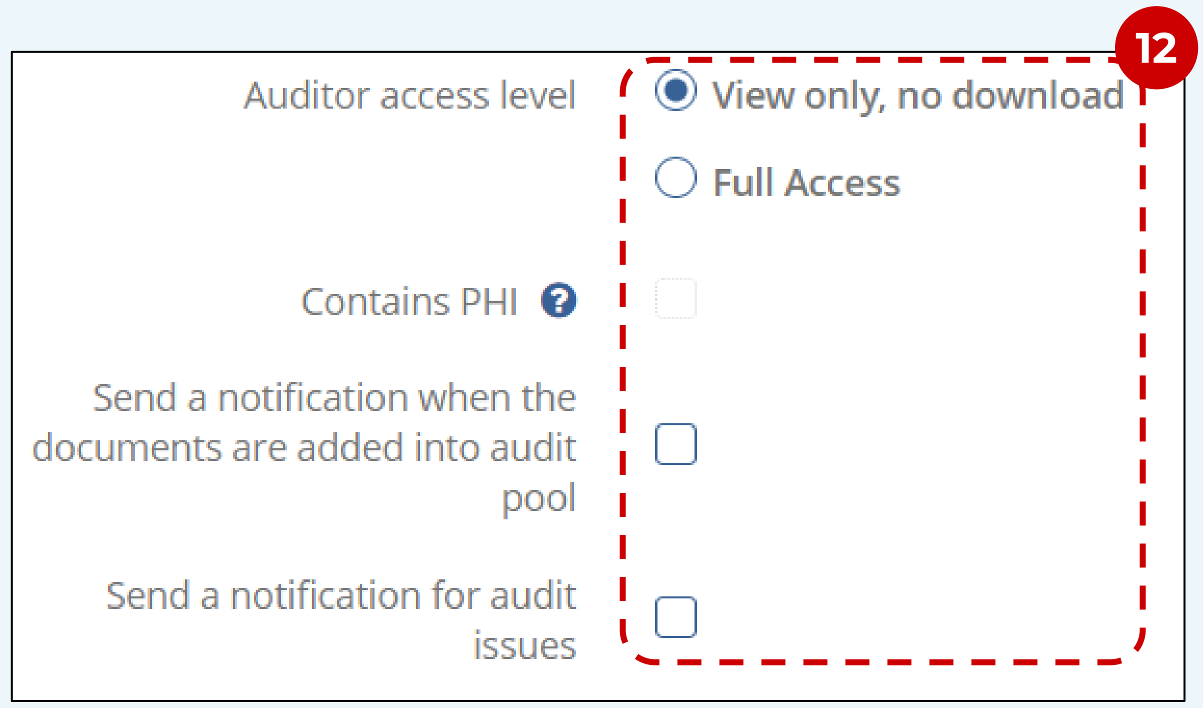



**10** Choose the **Date Type** for selection.

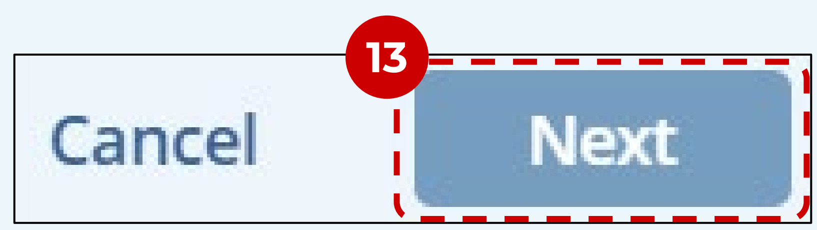
**11** The next section of Step 1 contains various audit criteria. You can hover on the tooltip '?' icon to see a description of most fields.




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

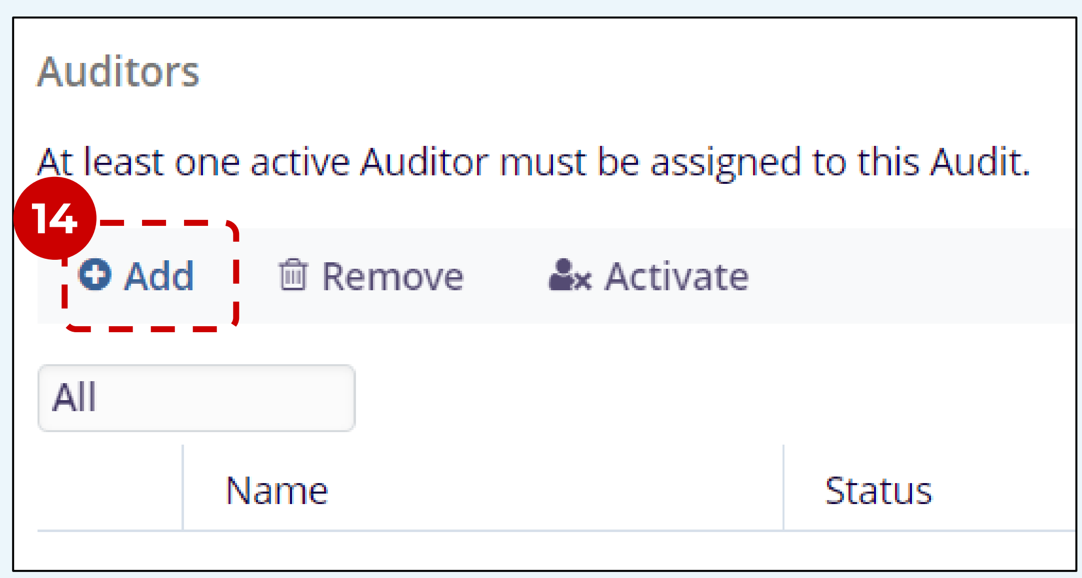



**13** Move to the **Next** panel (the button is located at the bottom of the window).

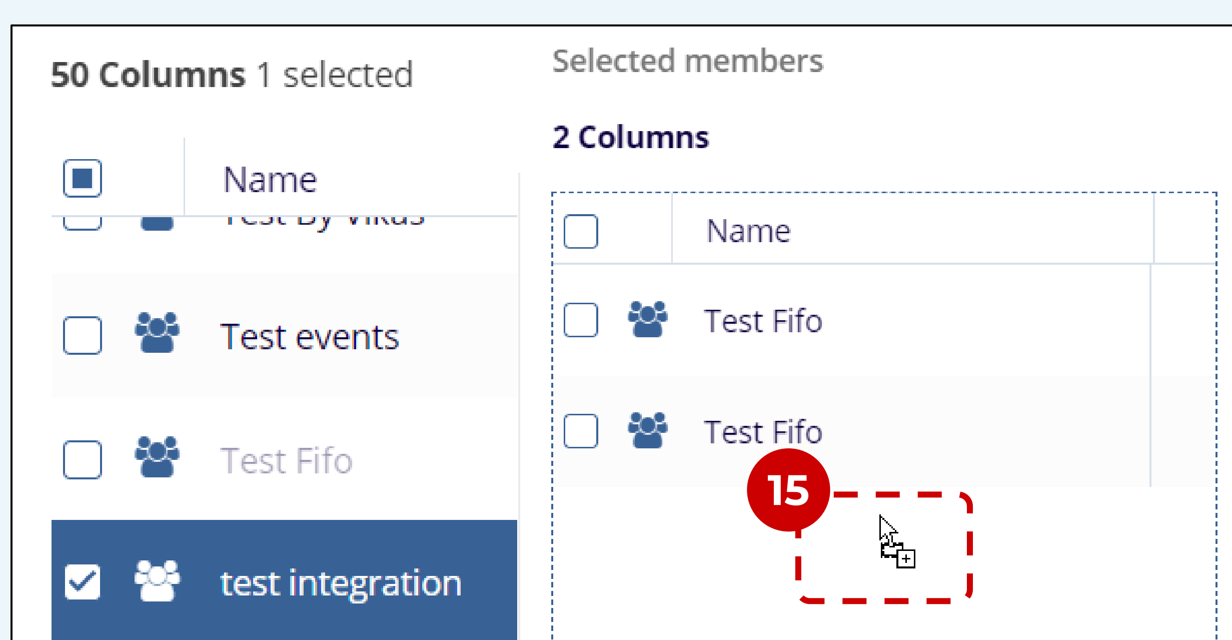



**14** Steps 2,3, and 4 consist of similar user selection panels. Step 2 is for _Auditors_; 3 is for _Audit Managers_; and 4 is for _Audit Responders_.

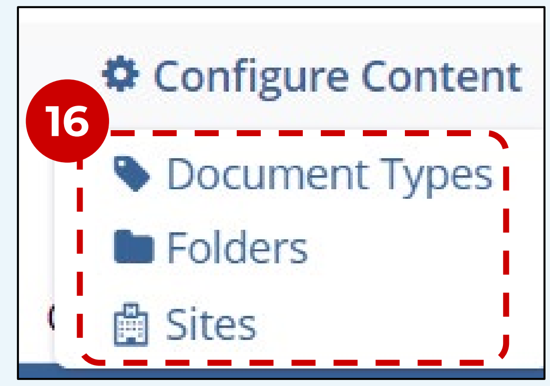
In each step, use the **Add** button to open the user selection screen.



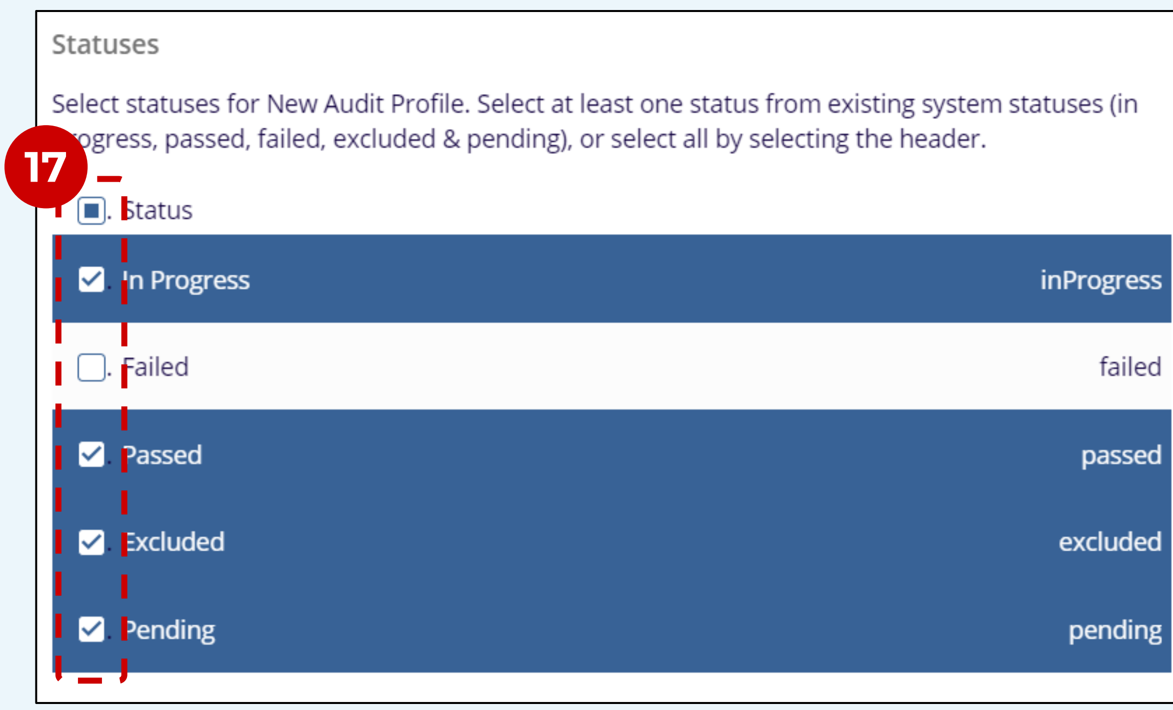

**15** In user selection, **drag** your selection from left to right to add users/groups.



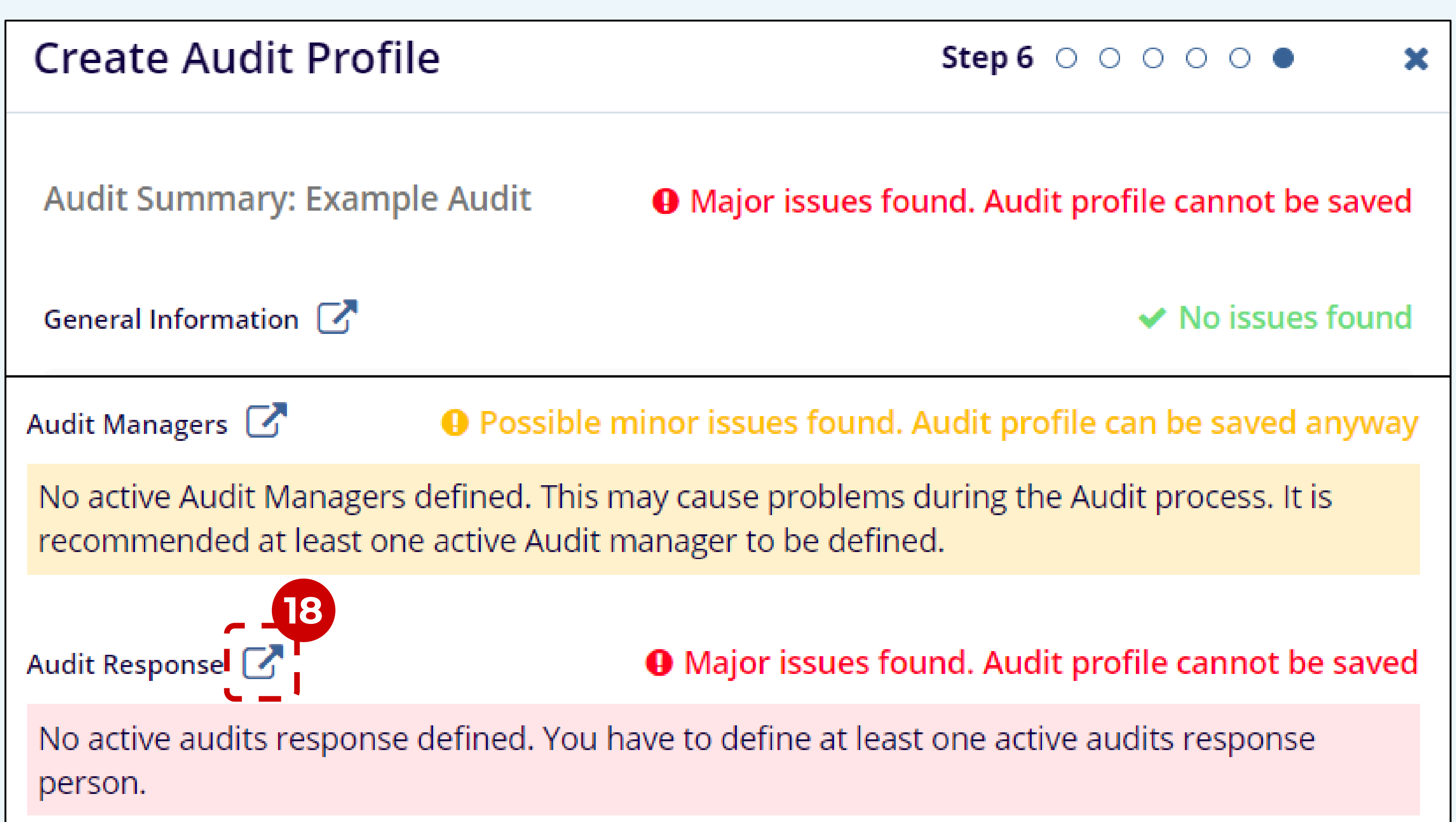
**16** Uniquely to Step 2 (add auditors), individuals can be assigned to review specific content by type or location. Use the **Configure Content** button above the auditors list to make your selection.



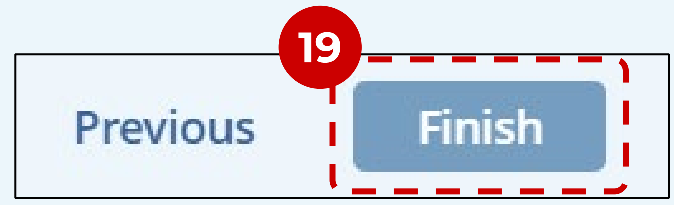

**17** Proceed through the steps to panel 5, where you'll select the statuses to be used in the audit. You may proceed to Step 6 only after selecting one of each system status at a minimum.




**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.