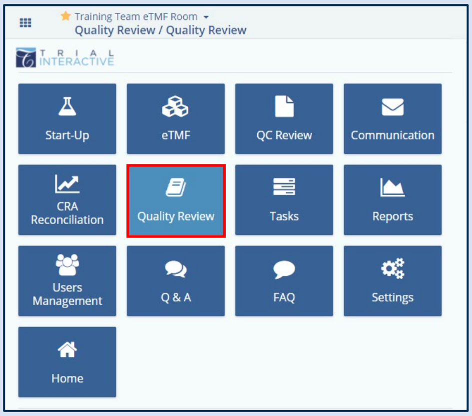
How to Create an Audit
TI v 10.3

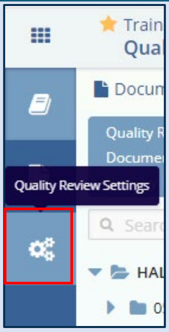
APPLICABLE TO:

- ● Administrators
- ○ Managers
- ○ Editors
- ○ Readers

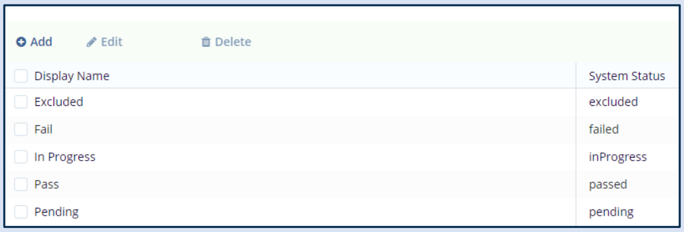
- ● eTMF
- ○ Study Start-Up
- ○ myTI



1. Navigate to the **Quality Review** module and then access the **Quality Review Settings** from the toolbar at the left side of the screen.



2. Click on the **Quality Review Status** tab.

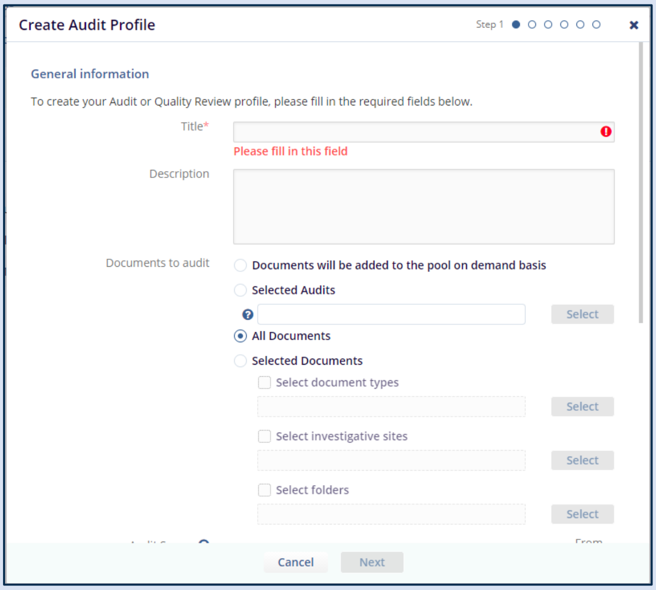


Add Edit Delete

Display Name	System Status
Excluded	excluded
Fail	failed
In Progress	inProgress
Pass	passed
Pending	pending

3. Review the existing status options and edit or add statuses as required.

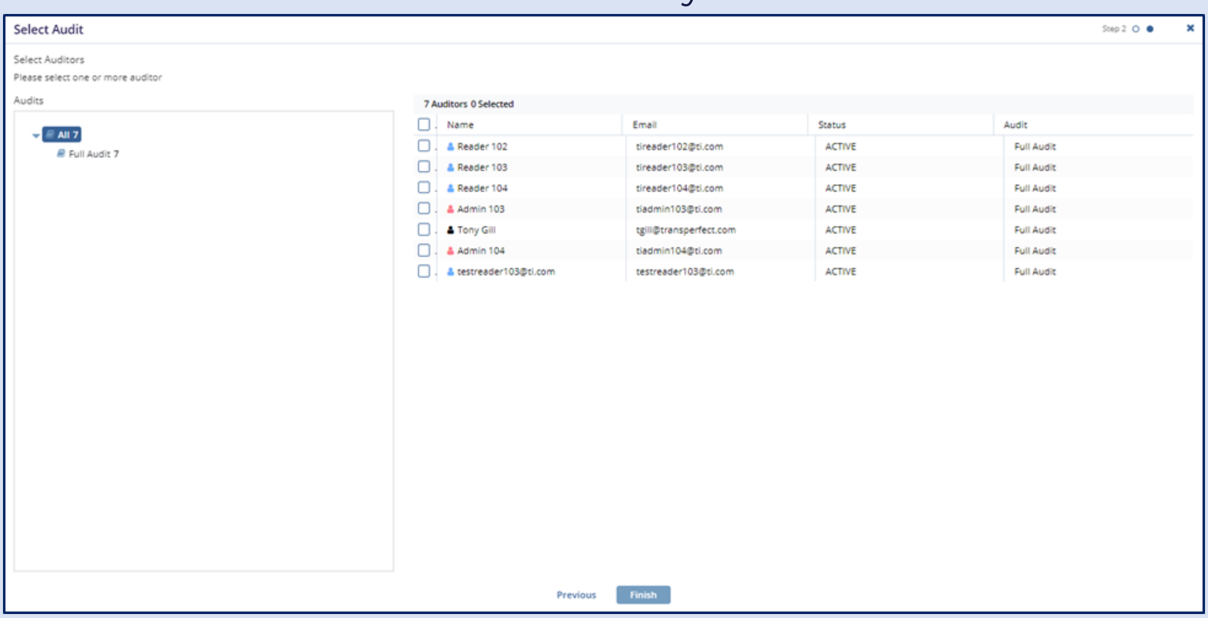
4. Click on the **Documents Quality Review Settings** tab and click Add to create a new Audit.



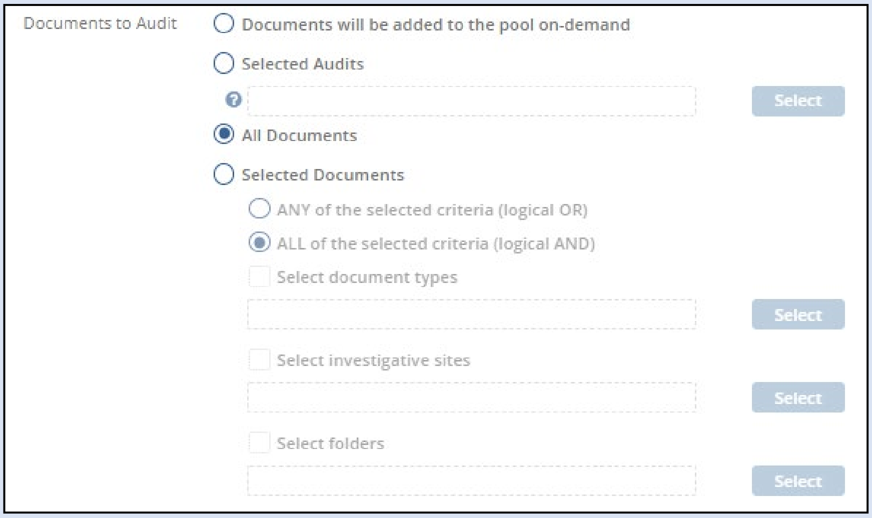
5. The **Create Audit Profile** wizard will open. Complete the required fields as indicated with red asterisks.

***For a full discussion of the options available when creating a new Audit, please speak to your TI representative about our Quality Review training courses.**

6a. The **Documents to Audit** area has several options to choose from: 'Documents will be added to the pool on-demand': This option will create a blank audit with no documents in it. Users can then add documents to the audit manually via the Documents Cart.



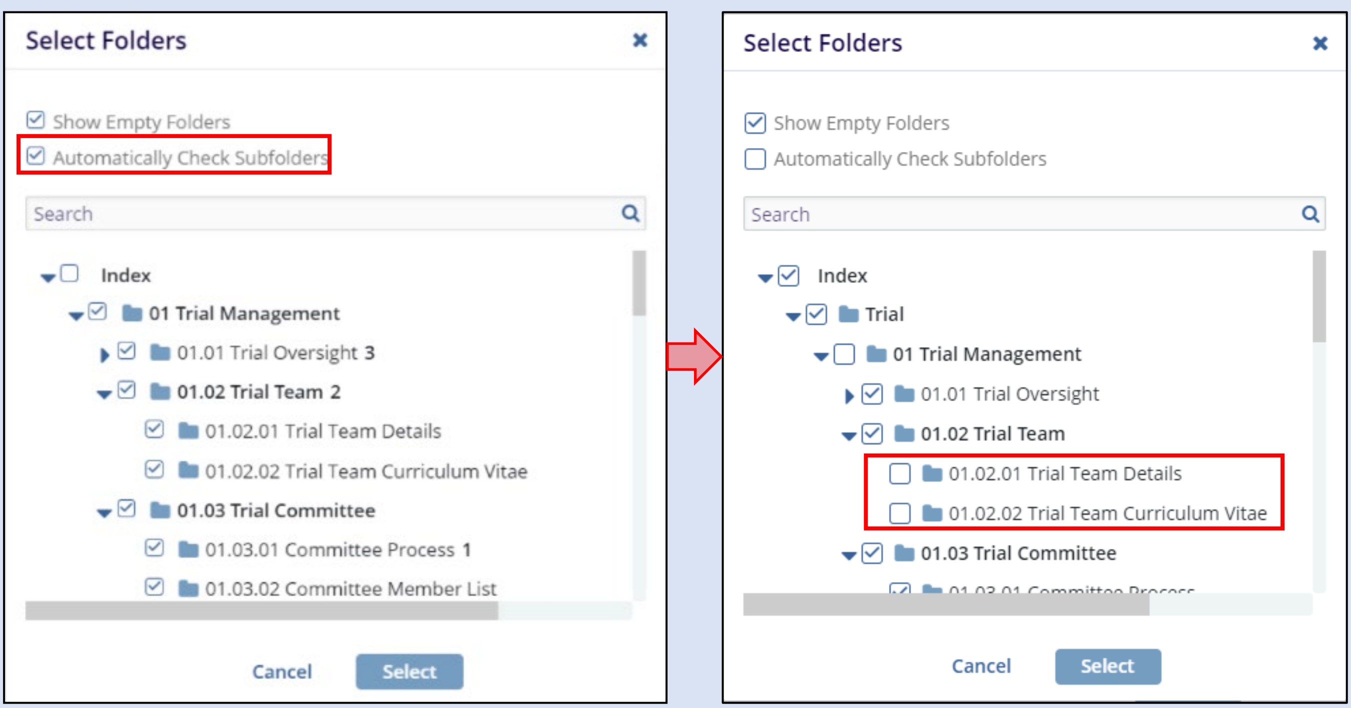
6b. 'Selected Audits': This option indicates that the audit will be reviewing the work done in a prior audit or set of audits, essentially mirroring previous reviews.



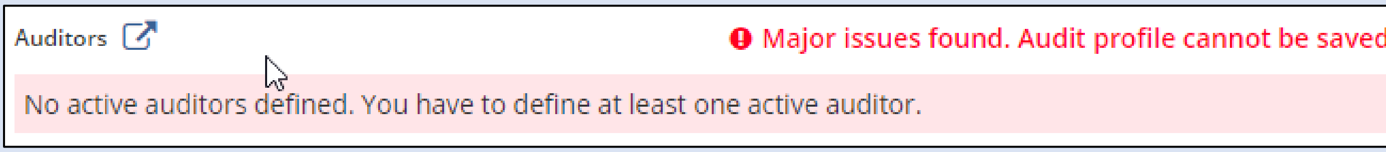
6c. 'All Documents': This option will tell the system to treat all documents as available for inclusion.

6d. 'Selected Documents': This option allows the user to specify the criteria to be used in gathering documents for review.

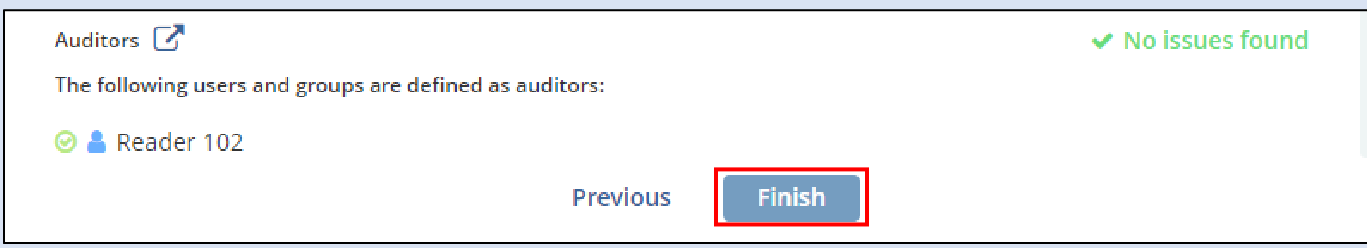
Note. When selecting document folders manually for inclusion in an audit, the system always applies "**Automatically Check Subfolders"**. This includes documents from all subfolders for each main folder you do select. Be sure to deselect the checkbox first thing if you **do not** wish to include all subfolders in the audit.

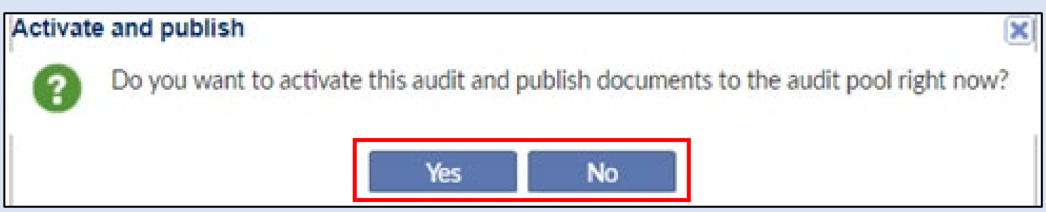


7. If there are any errors detected in the way that the audit is created (e.g. a step was missed) the wizard will highlight issues and prevent you from saving the audit until they are corrected.



8. Click **Finish** in the wizard. A window will open asking you if you want to activate the audit. Click **Yes** to activate and publish the documents to the audit pool, or **No** if you prefer to activate the audit at a later time.





Choose to Edit, Delete, or Stop the audit at any time under **Documents Quality Review Settings.**