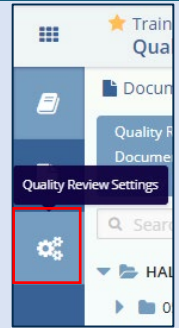
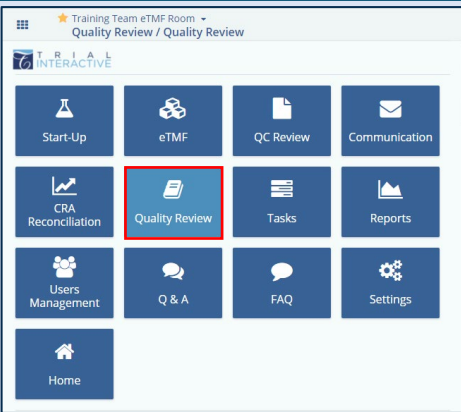


APPLICABLE TO:

- 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.

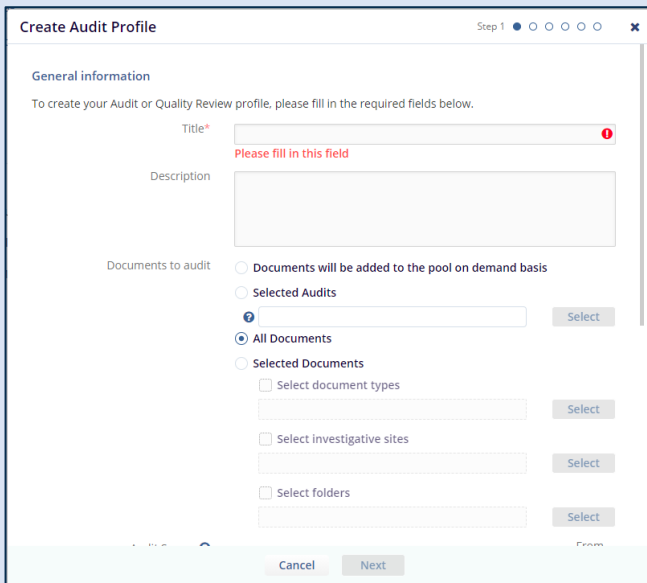


3. Review the existing status options and edit or add statuses as required.

<input type="checkbox"/> Add	<input type="checkbox"/> Edit	<input type="checkbox"/> Delete		System Status
<input type="checkbox"/>			Display Name	excluded
<input type="checkbox"/>			Excluded	failed
<input type="checkbox"/>			Fall	inProgress
<input type="checkbox"/>			In Progress	passed
<input type="checkbox"/>			Pass	pending
<input type="checkbox"/>			Pending	

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

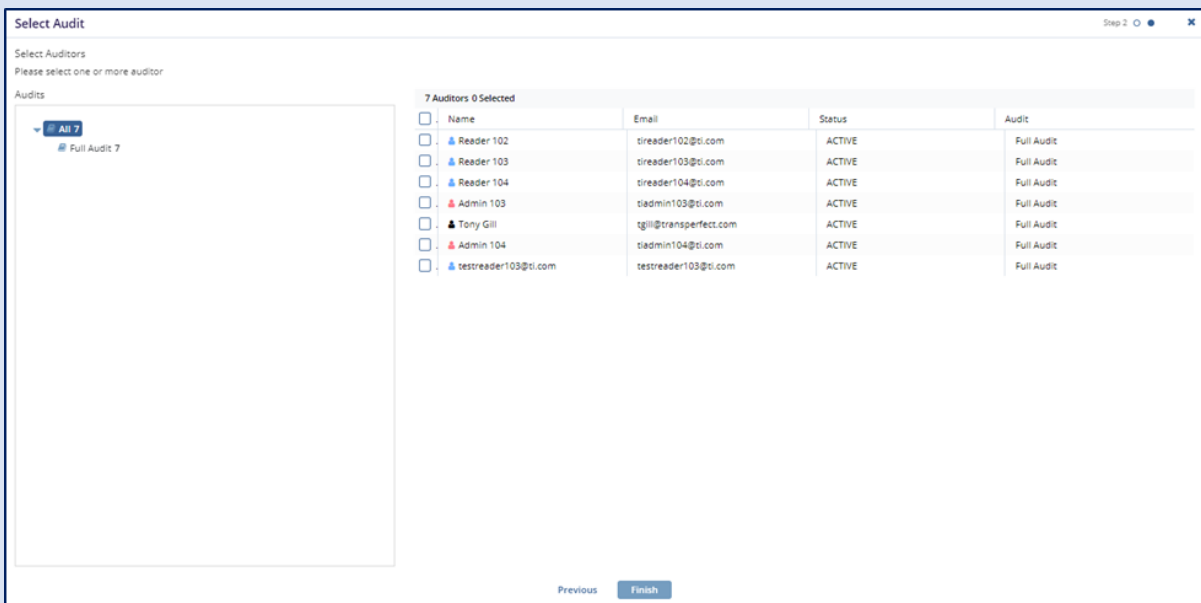




5. The **Create Audit Profile** wizard will open. Complete the required fields as indicated with **red** asterisks.

***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.



Name	Email	Status	Audit
Reader 102	tireader102@ti.com	ACTIVE	Full Audit
Reader 103	tireader103@ti.com	ACTIVE	Full Audit
Reader 104	tireader104@ti.com	ACTIVE	Full Audit
Admin 103	tiedmin103@ti.com	ACTIVE	Full Audit
Tony Gill	tgill@transperfect.com	ACTIVE	Full Audit
Admin 104	tiadmin104@ti.com	ACTIVE	Full Audit
testreader103@ti.com	testreader103@ti.com	ACTIVE	Full Audit

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.

Documents to Audit

Documents will be added to the pool on-demand

Selected Audits

All Documents

Selected Documents

ANY of the selected criteria (logical OR)

ALL of the selected criteria (logical AND)

Select document types

Select investigative sites

Select folders

Select Select Select Select

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.

Select Folders

Show Empty Folders

Automatically Check Subfolders

Search

- Index
 - 01 Trial Management
 - 01.01 Trial Oversight 3
 - 01.02 Trial Team 2
 - 01.02.01 Trial Team Details
 - 01.02.02 Trial Team Curriculum Vitae
 - 01.03 Trial Committee
 - 01.03.01 Committee Process 1
 - 01.03.02 Committee Member List

Cancel Select

Select Folders

Show Empty Folders

Automatically Check Subfolders

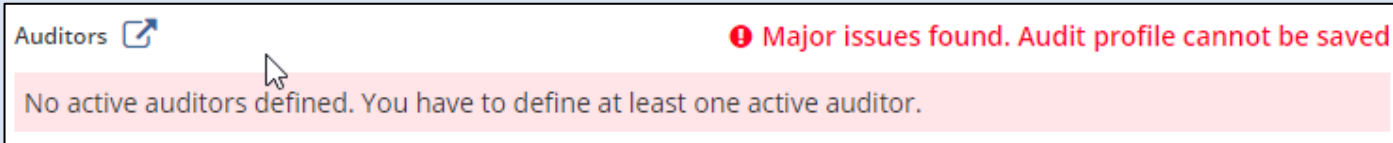
Search

- Index
 - Trial
 - 01 Trial Management
 - 01.01 Trial Oversight
 - 01.02 Trial Team
 - 01.02.01 Trial Team Details
 - 01.02.02 Trial Team Curriculum Vitae
 - 01.03 Trial Committee
 - 01.03.01 Committee Process

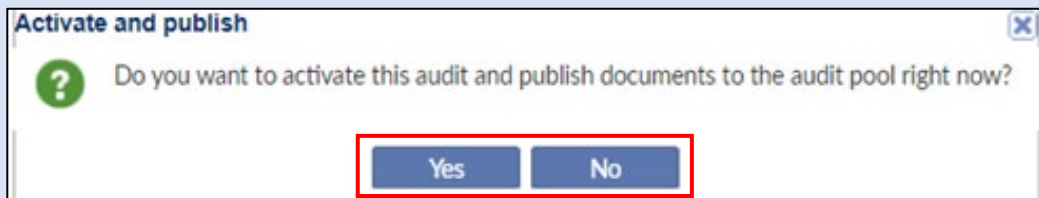
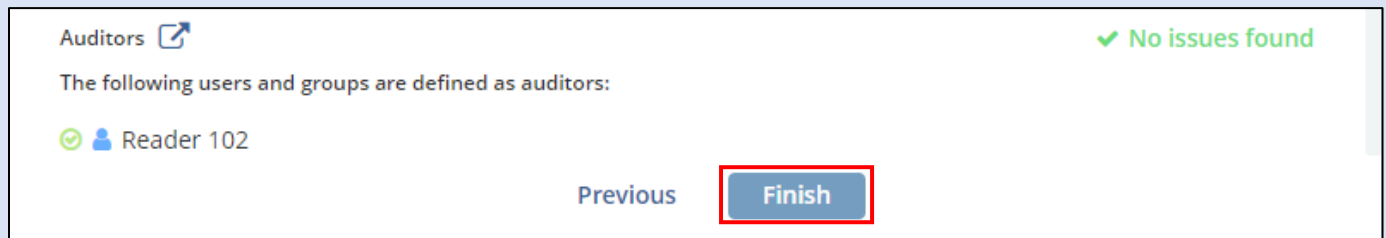
Cancel Select



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**.

