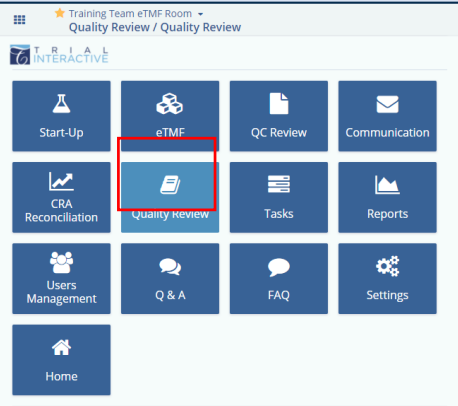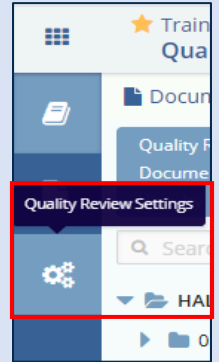**APPLICABLE TO:**

- ● Administrators
- ○ Room 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.

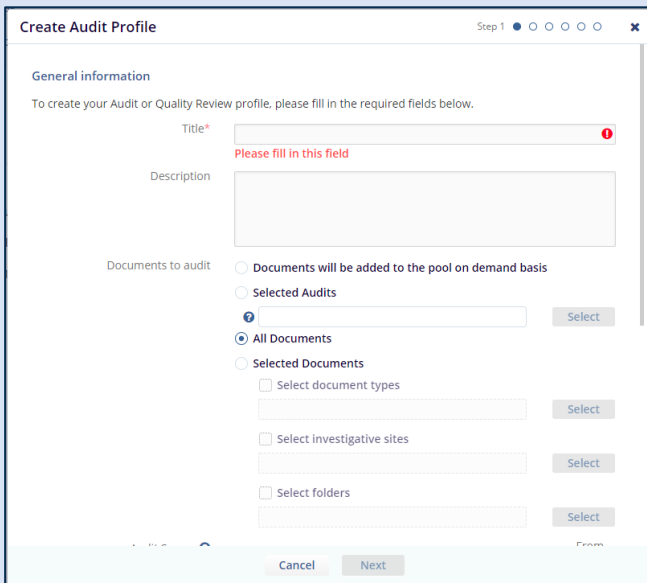**2.** Click on the **Quality Review Status** tab.

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

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

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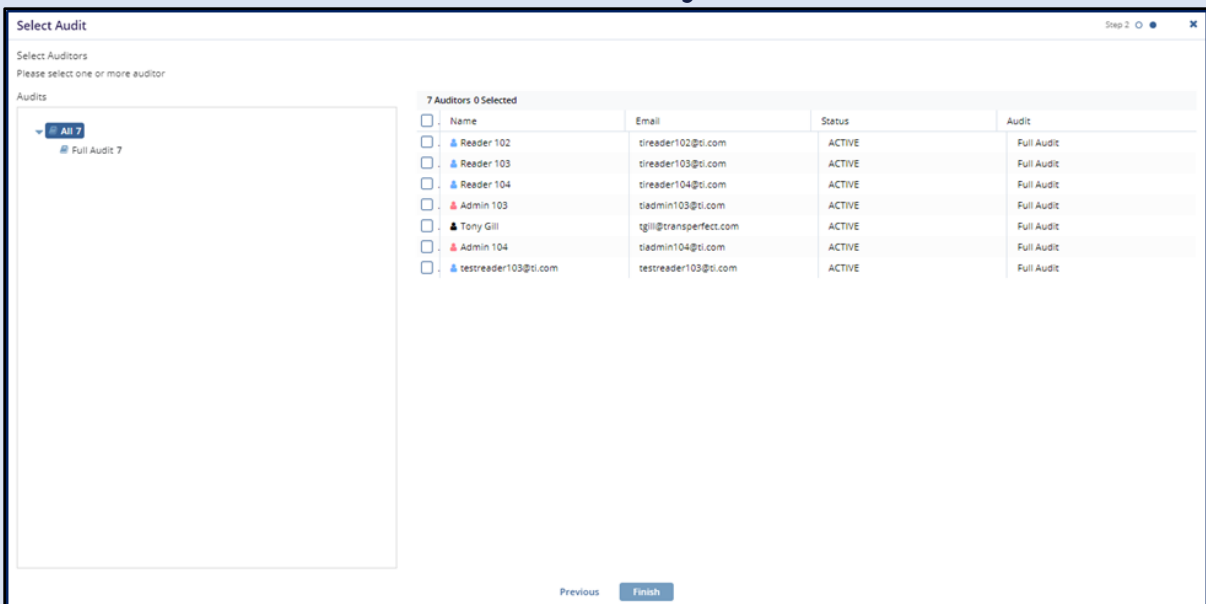
TRANSPERFECT

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 audit summary will highlight issues and prevent you from saving the audit until they are corrected.

Audit Response ⬈　　　　　　　　🚫 Major issues found. Audit profile cannot be saved

No active audits response defined. You have to define at least one active audits response person.

8. Click **Finish** at the bottom of the window. You may be asked if you want to activate the audit immediately, in which case documents will be added to the audit pool immediately. You can leave an audit dormant for later activation; in that case, it will be marked as a **Draft**.

Auditors ⬈　　　　　　　　　　　　　　✔ No issues found

The following users and groups are defined as auditors:

⊘ 👤 Reader 102

Previous　　　**Finish**

Activate and publish　　　✖

❓　Do you want to activate this audit right now?

No　　　Yes

9. Manage your audits in **Documents Quality Review Settings**. You can, among others, remove or edit audits, change their activation status, or reassign users. (You need to have an audit selected in the main panel for some buttons to work)

You may also duplicate an existing audit as an alternative to creating a new one. Doing so will retain all of the master's audit settings (including selected auditors) except for documents selection.