How to Set Up an Inspection

TI version 10.6

**TRIAL INTERACTIVE**

APPLICABLE TO:

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

● eTMF

The Trial Master File (TMF) plays a crucial role in ensuring compliance with regulatory standards, verified through thorough inspections. Trial Interactive is equipped to cater to the nuanced requirements of both internal and external inspectors, aligned with the organization's strategic objectives. This short guide details the preparatory steps that will enable either type of inspector to perform their task within Trial Interactive.
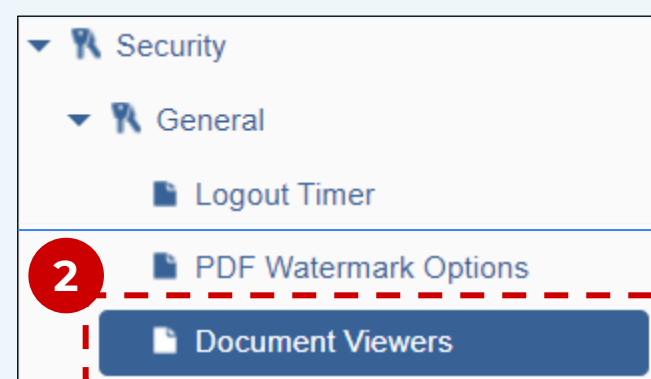
Part 1: Settings

Only required if **external** inspectors will be involved, this part will guide in setting up the room with a single document viewer, and enabling Digital Rights Management, in order to prevent the download of documents.
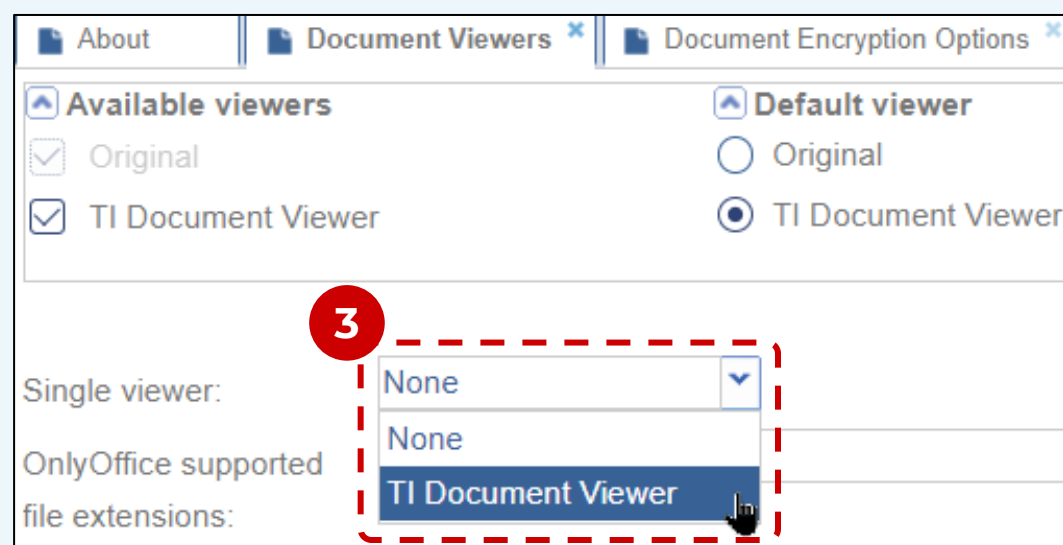
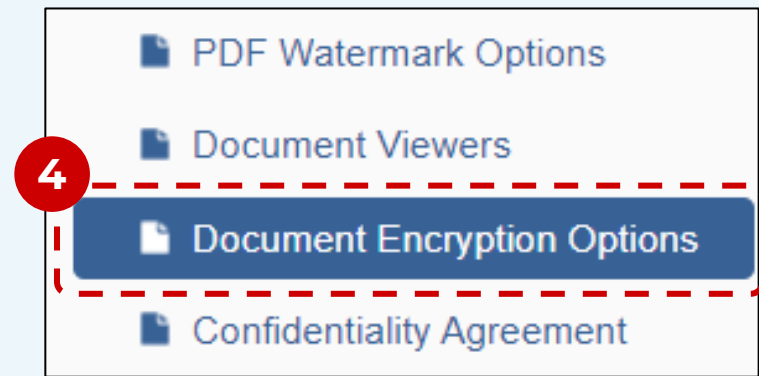**1** Navigate to the **Settings** module.
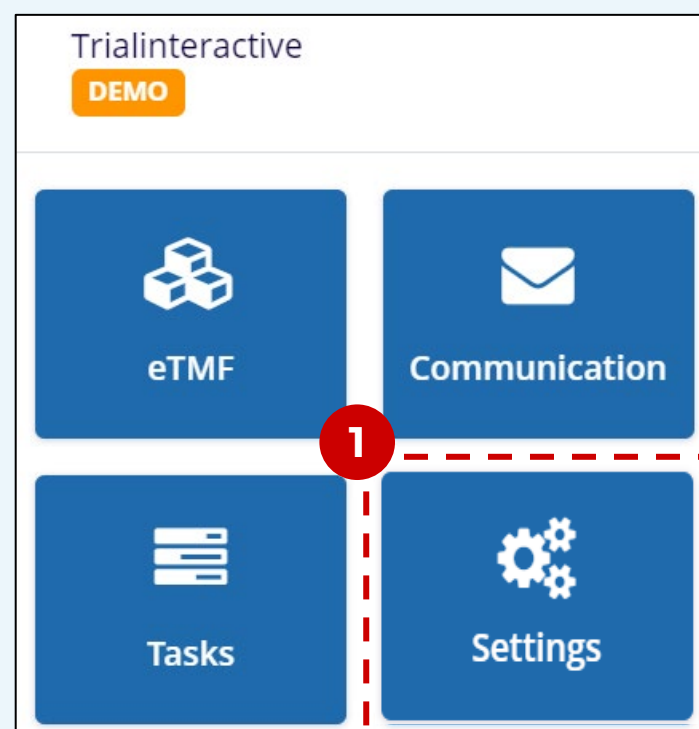
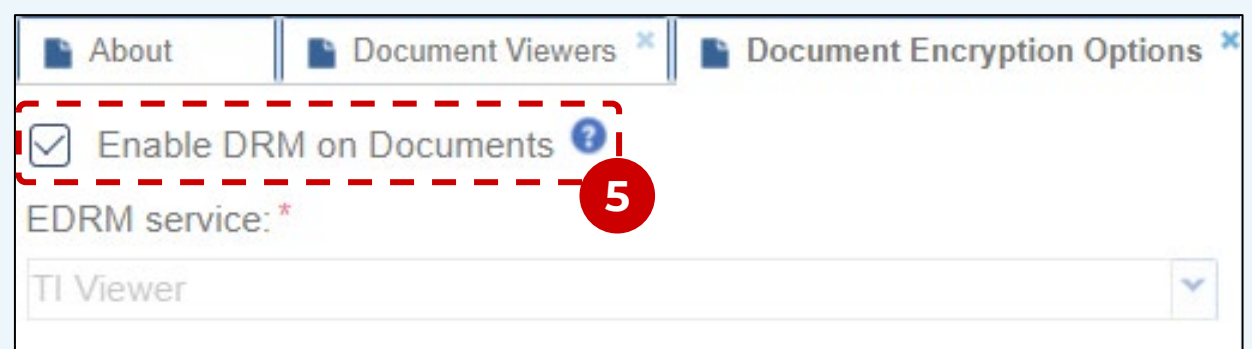**2** Expand the **Security>General** menu to select the **Document Viewers** section.

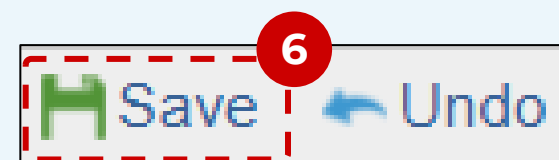**3** In the 'Single viewer' option, switch to **TI Document Viewer**.

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4 Enter the **Document Encryption Options** menu.

5 Check the **Enable DRM** box.

6 Reminder: don't forget to **Save** changes at each menu within Settings**.**
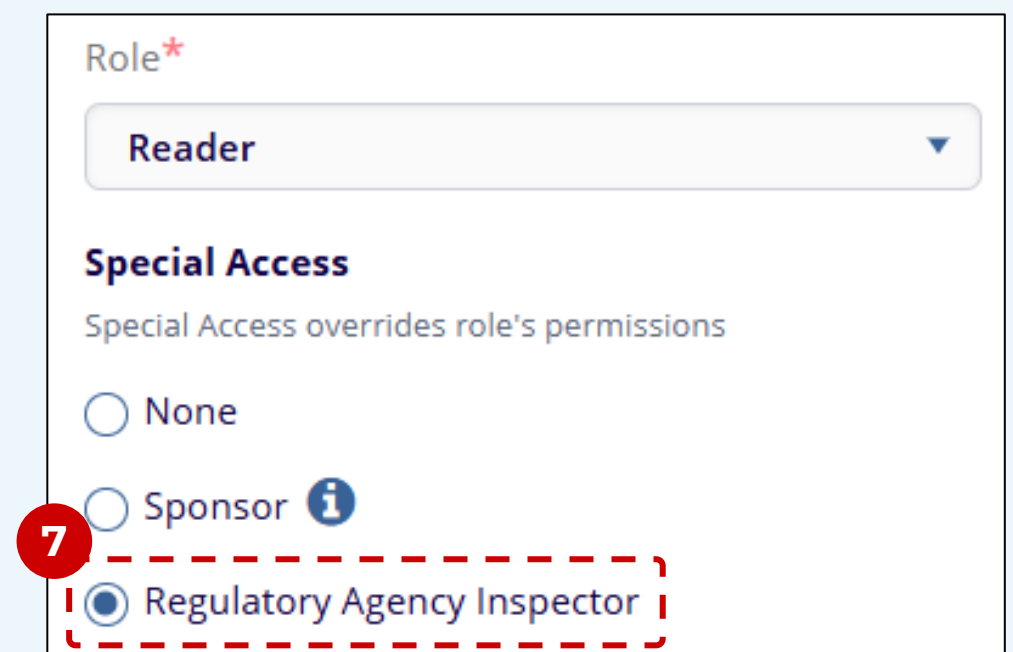
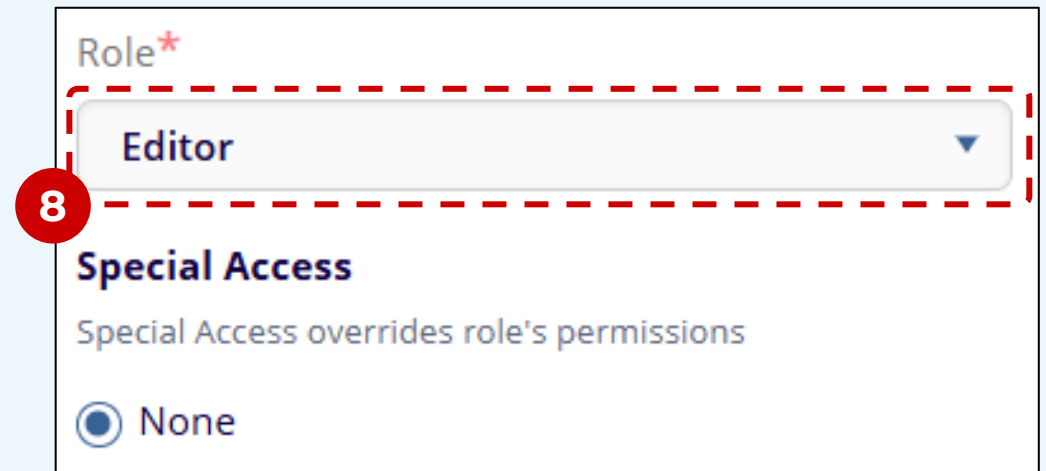

Part 2: Users Invite

A complete set of steps to invite users is detailed in the job aid: **How to Invite Room Users**.

7 For <u>External</u> Inspectors:
It is customary to limit the access to a **Reader** user-type and use the **Regulatory Agency Inspector** option.

A user with such access will be unable to browse the larger eTMF, being restricted to the Quality Review area instead.

8 For Internal Inspectors:
The **Editor** user role is preferred – an internal user may already have or need wider access in the system. Editor access also allows for correction of metadata if desired.

Role*

Editor ▼

8

Special Access
Special Access overrides role's permissions

◉ None

Part 3: Creating Audits

Trialinteractive

DEMO

9

eTMF

Quality Review

Tasks

Reports

9 An Audit Profile must be generated to conduct inspections. We recommend a new profile be generated for recurring and mock inspections too.
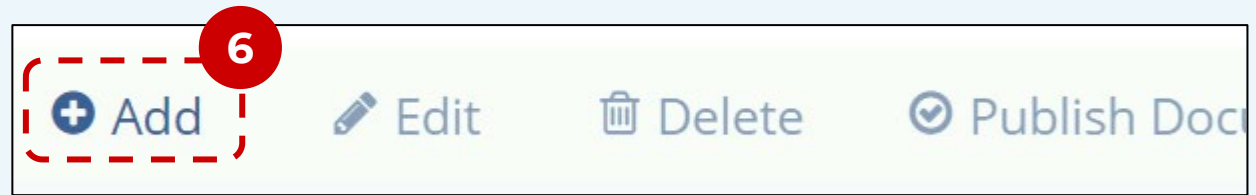
Navigate to the **Quality Review** area.

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Quality Review

Documents

10
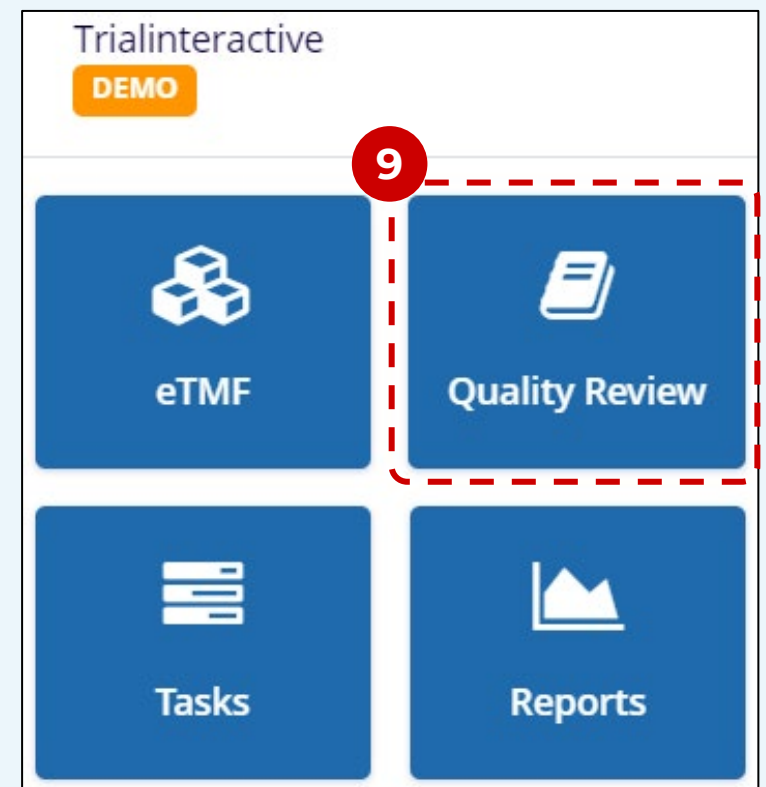
Quality Review Set...

10 Access the **Quality Review Settings** area.

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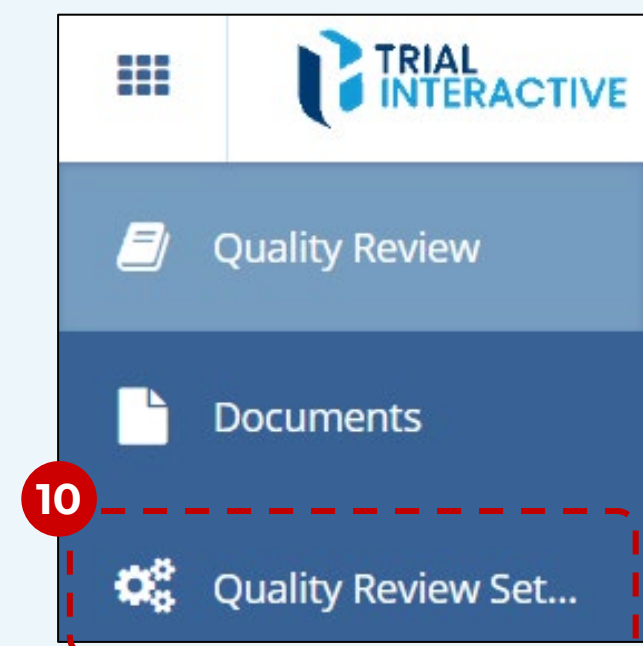
11 Click on the **Add** button to open the audit setup wizard.

6
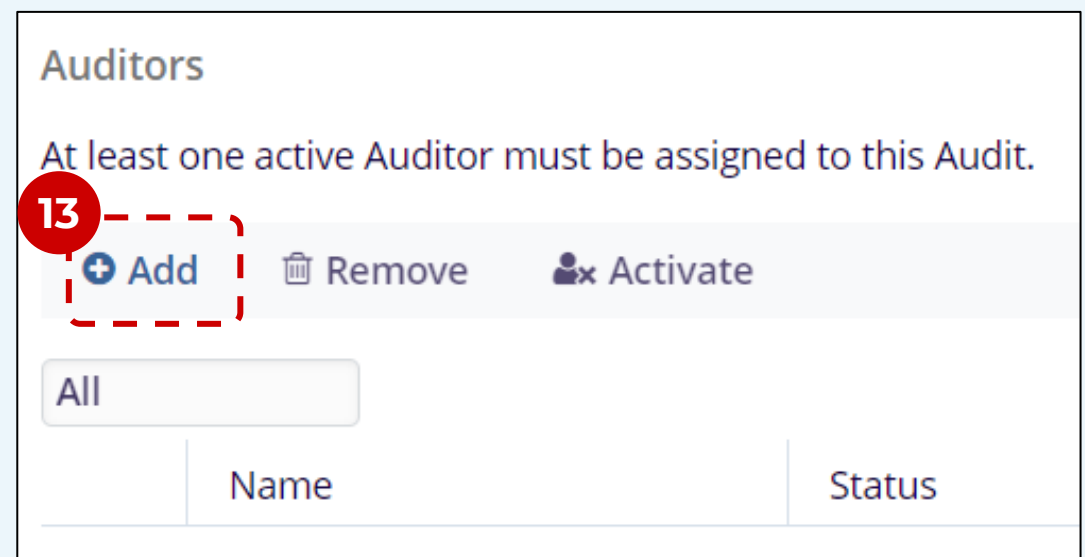● Add   ✏ Edit   🗑 Delete   ⊘ Publish Doc

A complete guide to setting up a new Audit is available in the **How to Set Up an Audit** job aid.

12 Set up the basic properties of the Audit profile.

General Information 🔗   ✔ No issues found

Title
Inspection Mock-Up: Bi-Annually
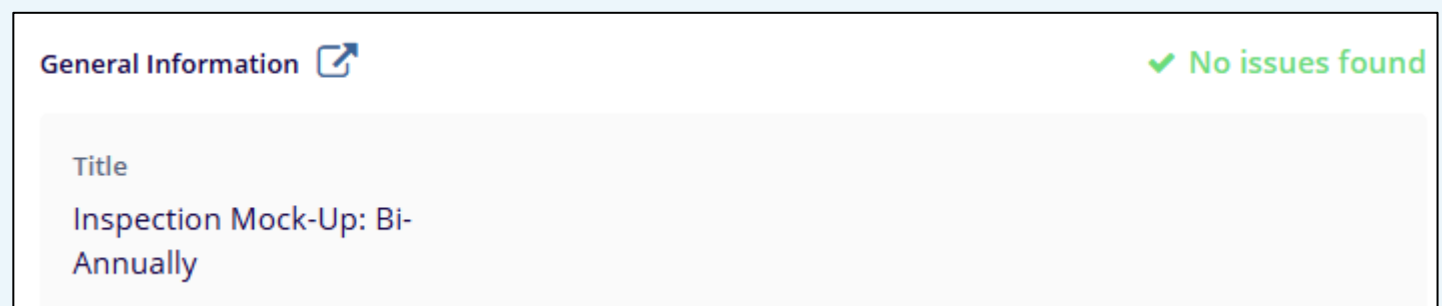
13 The main aspect to consider is what user will be assigned each role. Inspectors should be **Auditors**, while the supervisor or process owner should be an *Audit Manager*.

Auditors

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

13
● Add   🗑 Remove   👤× Activate

All

Name	Status

14 Complete all the steps in the audit creation wizard and **Activate** the Audit at the appropriate time.

14
🗐 Duplicate   ● Add   ✏ Edit   ⊗ Disable   ⊘ Activate   🗑 Delete

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