

APPLICABLE TO:

- Administrators
- eTMF
- Managers
- Study Start-Up
- Editors
- myTI
- Readers

The Trial Master File (TMF) plays a crucial role in ensuring compliance with regulatory standards 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.

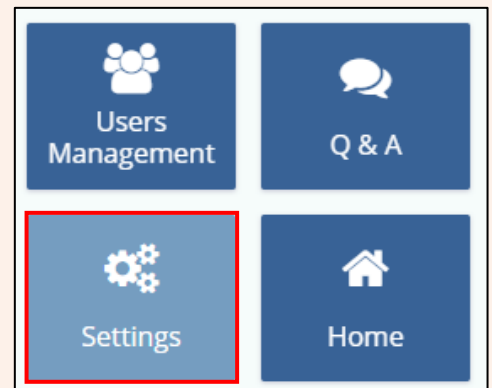
Before an inspection can begin using the inspector role, the administrator of the room must set up the following conditions.

1. If external inspectors will be involved, the room must be configured with a single document viewer, and Digital Rights Management must be enabled to prohibit the download of documents..



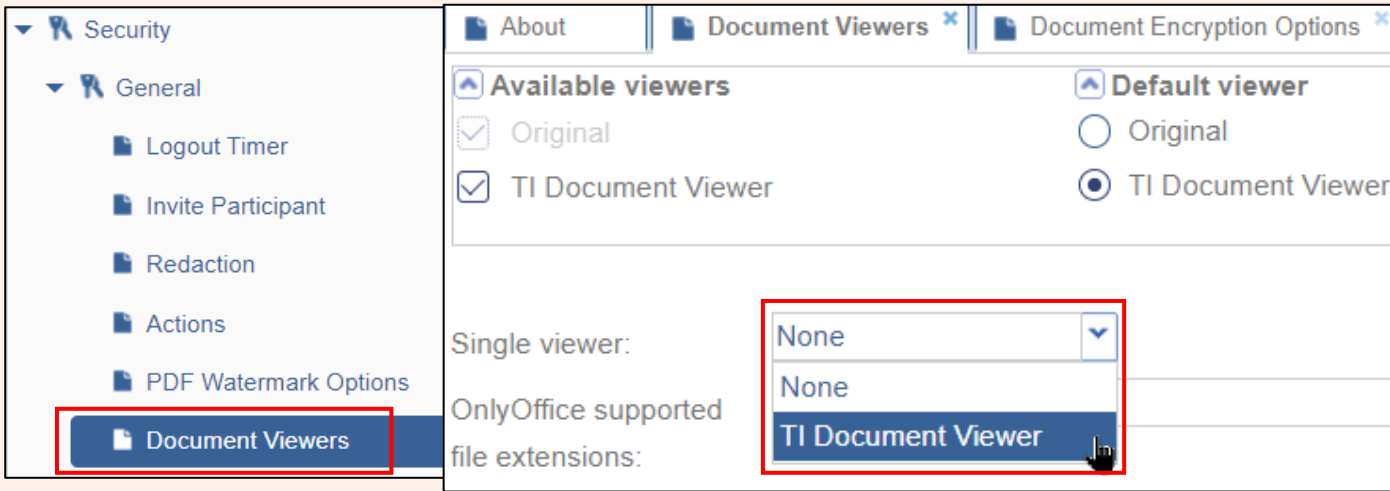
External inspectors may represent regulatory bodies or sometimes sponsors reviewing a Contract Research Organization (CRO), affiliates, or partners. In the course of their audits, they may compile notes and leave comments, but don't effect changes in the eTMF. Unlike internal inspectors, external auditors are restricted from downloading documents and must rely on the designated viewer for document review.

1a. Login to a room and navigate to Settings.

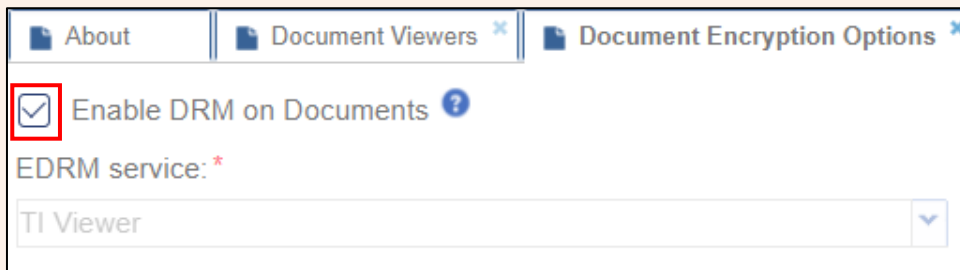


1b. Expand the **Security>General** menu to select the **Document Viewers** section.

Change the 'Single viewer' option to **TI Document Viewer**. This enforces protection of documents from download.



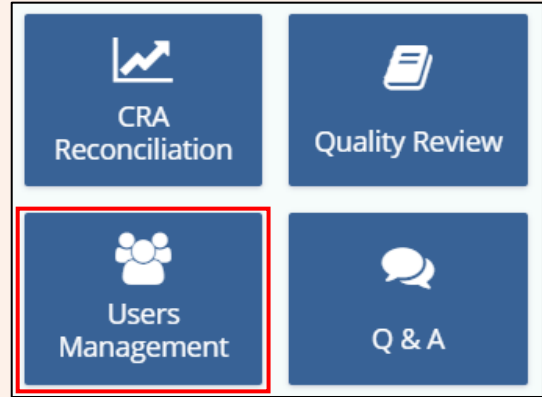
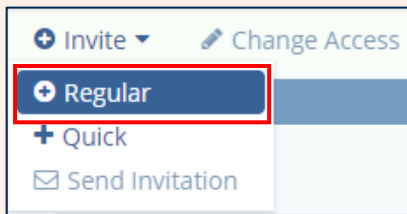
1c. Switch to **Document Encryption Options** and then **Enable DRM** as per images below.



2. For External Inspectors, it is appropriate to invite them to the room as **Readers** with the **Regulatory Inspector** option activated.

2a. Navigate to Users Management.

2b. Click **Invite** (top-left corner) and select **Regular** from the drop-down menu.




2c. Complete all required user data fields, and make sure you enable the **Regulatory Agency Inspector** option (switch positioned on green).

Click **Save**.

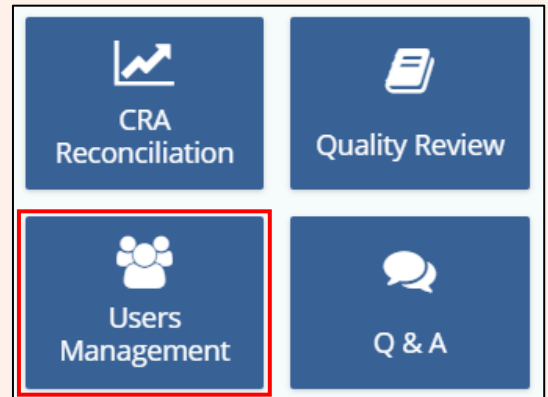
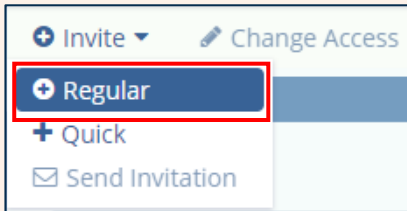
A screenshot of a 'User Invitation' form. The form has two tabs: 'User' (selected) and 'Group Membership'. Under 'General Information', there are fields for 'Email *' (sample@email.net), 'First Name' (Sample), and 'Last Name' (Inspector). Under 'User Details', there is a 'Role*' dropdown menu with 'Reader' selected (highlighted with a red box) and an 'Organization*' field with 'TI'. Under 'User Profile Details', there is a 'Regulatory Agency Inspector' toggle switch that is turned on (green, highlighted with a red box). At the bottom, there are 'Cancel' and 'Save' buttons.

3. For Internal Inspectors, the Editor user role is preferred - with the **Regulatory Inspector** option discretionary.

 *Internal inspectors are integral to conducting mock inspections, which is considered a best practice. These inspectors engage in comprehensive audits of documentation and may prefer to initiate queries during their evaluation process. Additionally, they are often granted the ability to make edits within the TMF.*

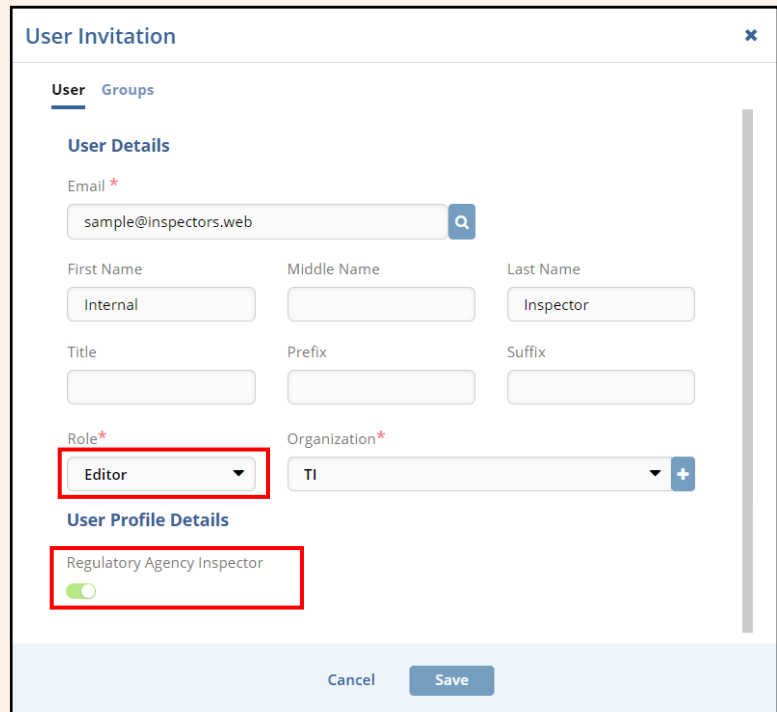
3a. Navigate to Users Management.

3b. Click **Invite** (top-left corner) and select **Regular** from the drop-down menu.



3c. Complete all required user data fields, and make sure you select **Editor** for the role, then enable the **Regulatory Agency Inspector** option (switch positioned on green).

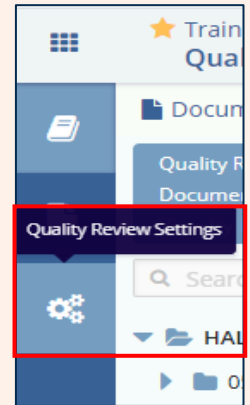
Click **Save**.



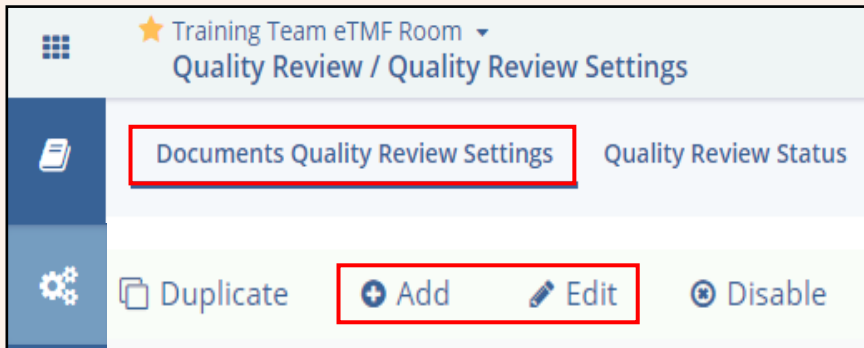
A screenshot of the 'User Invitation' form. The form has tabs for 'User' and 'Groups'. Under 'User Details', there are fields for Email (sample@inspectors.web), First Name (Internal), Middle Name, Last Name (Inspector), Title, Prefix, and Suffix. The 'Role*' dropdown is set to 'Editor' and is highlighted with a red box. The 'Organization*' dropdown is set to 'TI'. Under 'User Profile Details', the 'Regulatory Agency Inspector' option is checked with a green switch and is highlighted with a red box. At the bottom, there are 'Cancel' and 'Save' buttons.

4. An inspection audit profile must be created to represent all of the documents involved in the inspection. The inspection lead should be assigned as the audit manager, and the inspectors should be assigned as auditors.

4a. Navigate to the **Quality Review** module and then access the **Quality Review Settings** from the toolbar at the left side of the screen.



4b. Click on the **Documents Quality Review Settings** tab and click **Add** to create a new Audit or **Edit** to assign inspectors to existing audits.



Review the **How to Setup an Audit job** aid for details of audit generation.