



TRIAL INTERACTIVE ETMF V10.7 - USER GUIDE V1.0

**TRANSPERFECT**  
LIFE SCIENCES

## CONTENTS

|                                                         |     |
|---------------------------------------------------------|-----|
| VERSION HISTORY .....                                   | 3   |
| About this User Guide .....                             | 4   |
| Chapter 1. What's New in Trial Interactive v10.7? ..... | 5   |
| Chapter 2. Getting Started .....                        | 6   |
| Chapter 3. Trial Interactive User Management .....      | 15  |
| Chapter 4. Trial Interactive Home Page .....            | 54  |
| Chapter 5. Username Menu .....                          | 64  |
| Chapter 6. Trial Interactive eTMF module .....          | 75  |
| Chapter 7. Events Module .....                          | 315 |
| Chapter 8. Tasks .....                                  | 330 |
| Chapter 9. eSignature .....                             | 336 |
| Chapter 10. Search In TI .....                          | 340 |
| Chapter 11. Room Settings .....                         | 352 |
| Chapter 12. CRA Reconciliation .....                    | 522 |
| Chapter 13. Quality Control .....                       | 536 |
| Chapter 14. Quality Review .....                        | 547 |
| Chapter 15. Queries Module .....                        | 609 |
| Chapter 16. Communications .....                        | 635 |
| Chapter 17. Q&A Module .....                            | 644 |
| Chapter 18. FAQ Management .....                        | 652 |
| Chapter 19. Reports .....                               | 661 |
| Chapter 20. Literature Monitoring Solution .....        | 664 |

## VERSION HISTORY

| Author                                                           | Revision | Date        | Change History            |
|------------------------------------------------------------------|----------|-------------|---------------------------|
| Samuel Pawar<br>Salil Joshi<br>Mansi Kandhare<br>Janki Prajapati | 1.0      | 29-Apr-2025 | Initial Document Creation |

## ABOUT THIS USER GUIDE

This guide provides a comprehensive overview of the features and components of the TI eTMF application, enabling users to work efficiently and securely manage their tasks within the platform.

It includes instructions on the user interface, step-by-step processes, and visual aids to enhance understanding and ease of use. This guide is exclusively designed for clients who have purchased the Trial Interactive platform.

The contents of this guide are the intellectual property of [TransPerfect Trial Interactive](#) and may not be distributed without explicit permission from TransPerfect Trial Interactive.



## CHAPTER 1. WHAT'S NEW IN TRIAL INTERACTIVE V10.7?

### Metadata Import modal title

The title displayed on the import modal, used for importing metadata fields, currently reads 'Document Import'.

To more accurately reflect the functionality of uploading metadata through a template, the modal title has been updated to 'Metadata Import'.

### Coding Panel Enhancements

An Edit button has been introduced in the Coding Panel of the Quality Review module, specifically within the Metadata and Audit tabs. This new functionality enables users to update relevant fields directly from the panel.

### Document History Improvements

The Document History view is enhanced for performance and UI improvements.

For large documents, paging has been implemented to boost performance and responsiveness when loading document history. The Activity Type filter has been upgraded to a multiselect control, allowing users to filter by multiple activity types simultaneously instead of being limited to a single selection.

### Acknowledgement Tab Header Changes

When using the 'Add Users to Acknowledgement' modal, the header has been updated to display 'Add Users to [Acknowledgement Name]' for better visibility.

## CHAPTER 2. GETTING STARTED

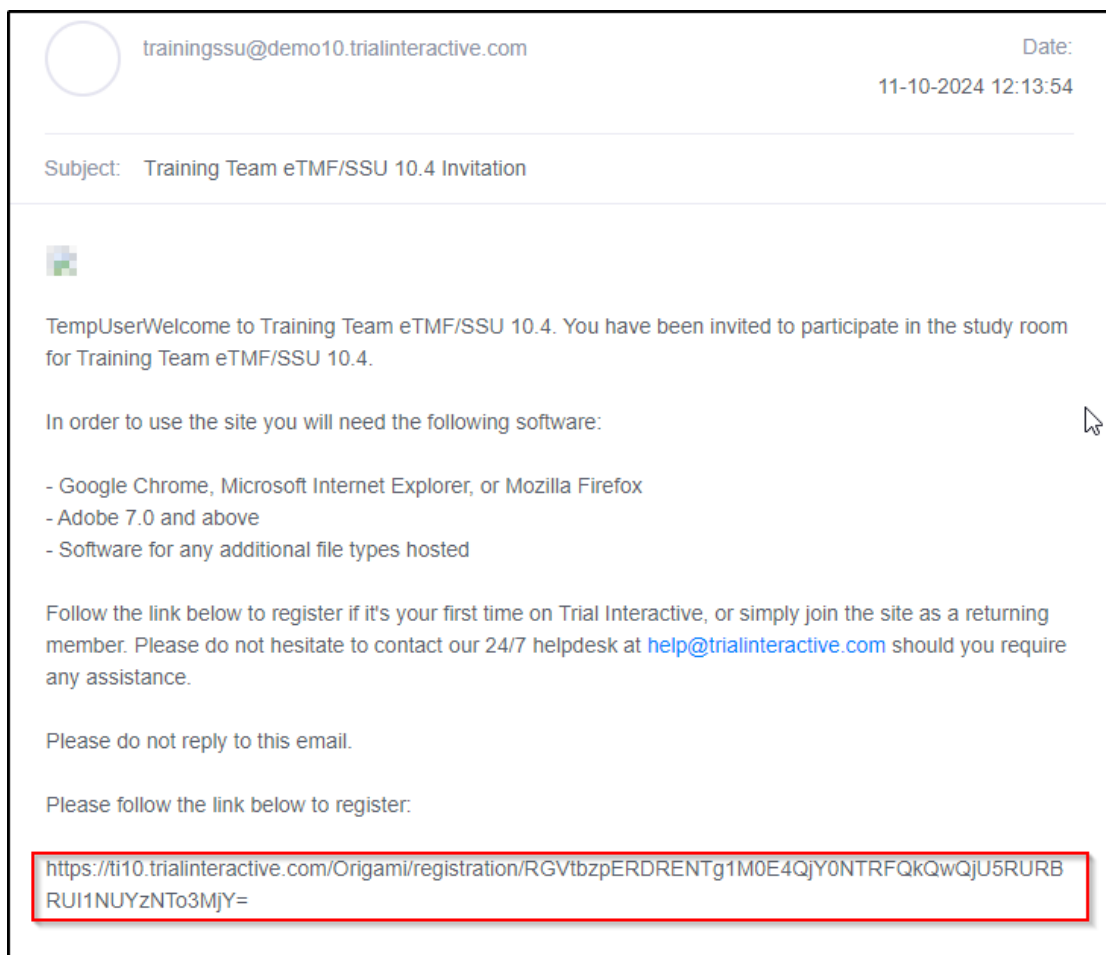
This section describes the signing-in, room invitations, and user registration in Trial Interactive v10.7

Trial Interactive helps clinical teams build an eTMF for clinical trials and manage content from author to archive. It all starts with workflow, metadata, and content strategy — define your essential documents, determine your required metadata, configure your index structure, and manage eTMF health in quality reviews, reports, and dashlets. Along the way, Trial Interactive helps you prioritize the eTMF and content workflows, collect the documents required to activate your investigative sites, collaborate with the study teams at the sponsor, CRO, and site, as well as integrate with other Clinical platforms so that you can sync with other teams and other types of data. This online help contains a descriptive overview of the Trial Interactive tool and step-by-step procedures of Trial Interactive functions.

If you are new to Trial Interactive, we recommend that you access the online version of this User Guide and view the job aids and videos stored there. They will walk you through many of the most common functions of Trial Interactive.

### Signing in to Trial Interactive for the First Time

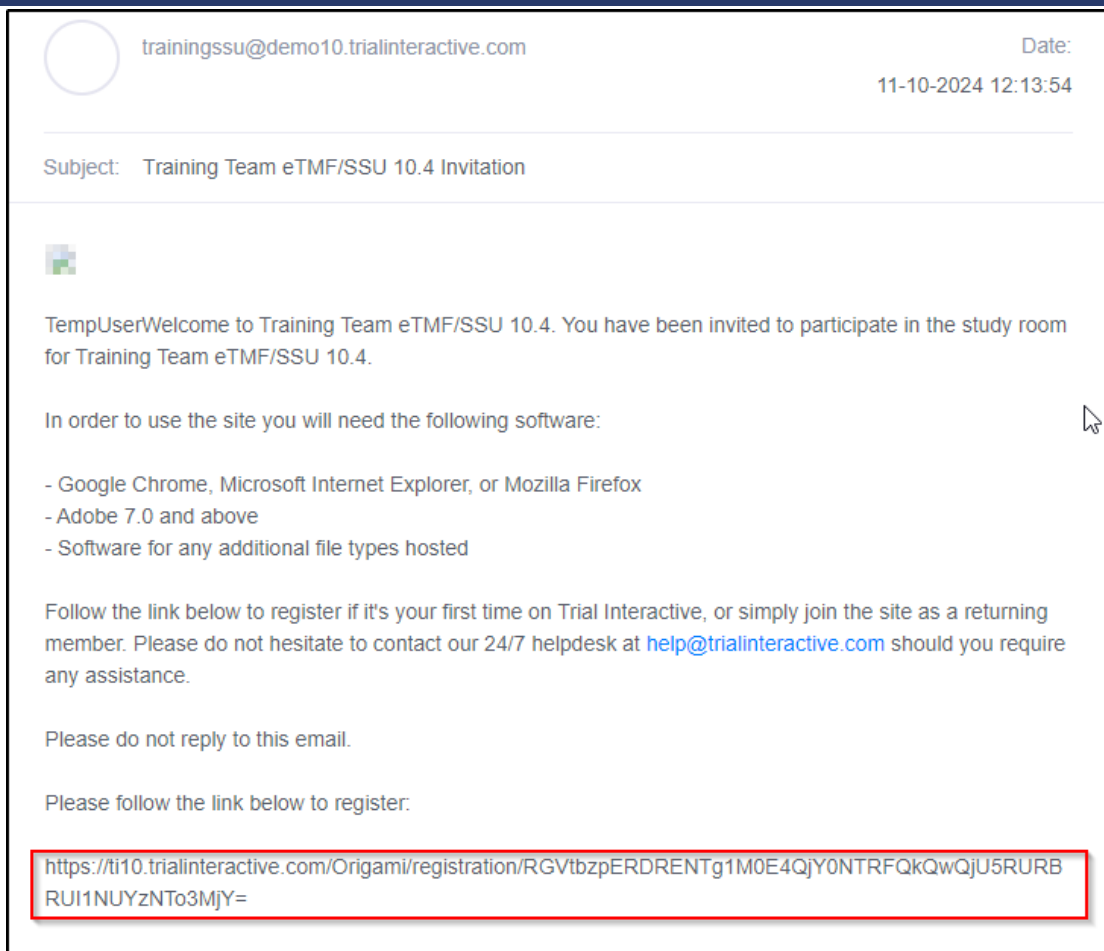
1. Once a Trial Interactive room Administrator has sent you an invitation, you will receive an email message with a registration link. Refer to the screenshot below.

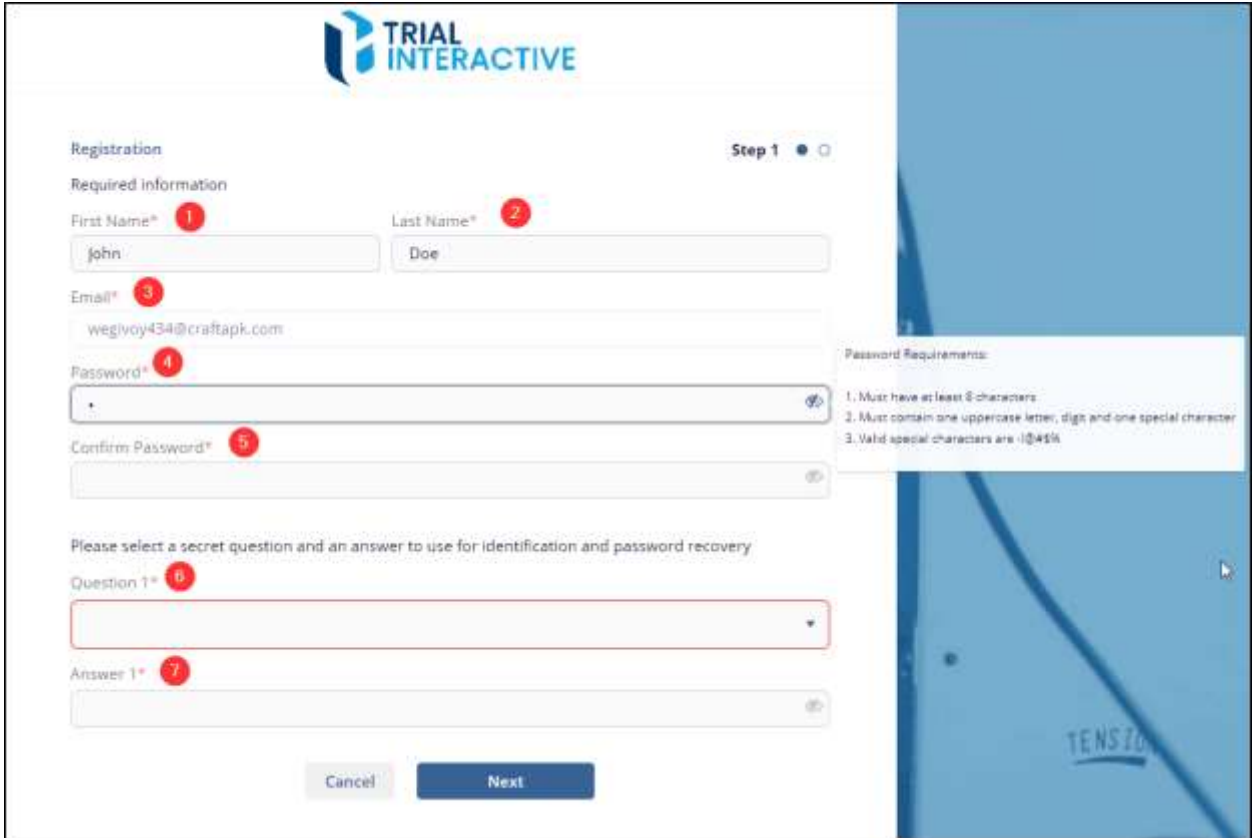


Note: Complete a one-time registration when you receive your first email notification for room access. Once registered, you can sign into your room directly. If you're invited to additional rooms, no further registration is required. New rooms will automatically appear on your Home page under your list of accessible rooms. You will continue to receive email notifications for any future room invitations.

### Steps for Registration:

1. Click the Registration link near the bottom of the message, and you will be directed to the Trial Interactive user account registration page.





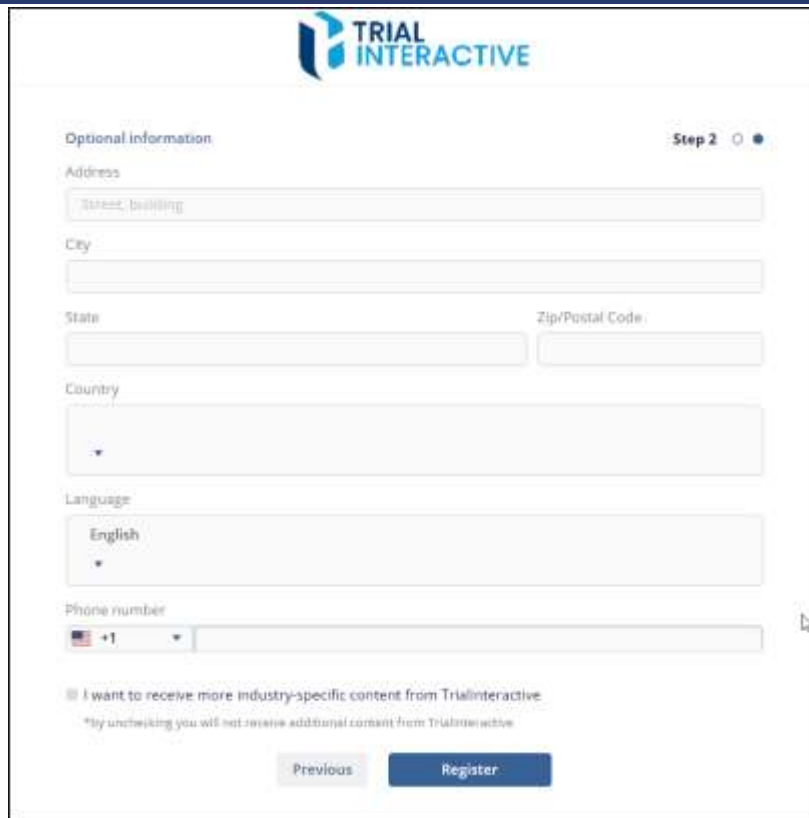
2. Enter your first name and last name in the provided field.
3. Email address will be automatically filled by the system.
4. Create a secure password, then re-enter it in the Confirm Password field to verify.

Note: Hover over the Password field to view the tooltip with specific password requirements.

5. Select your password recovery question from the dropdown list.
6. Type in your answer in the Answer field and click Next to take you to Step 2.

## Step 2: Registration - Optional Information

1. On this page, enter your contact address, phone number, and any other relevant details. Click on Register to proceed.



**TRIAL INTERACTIVE**

Optional information Step 2

Address

City

State  Zip/Postal Code

Country

Language

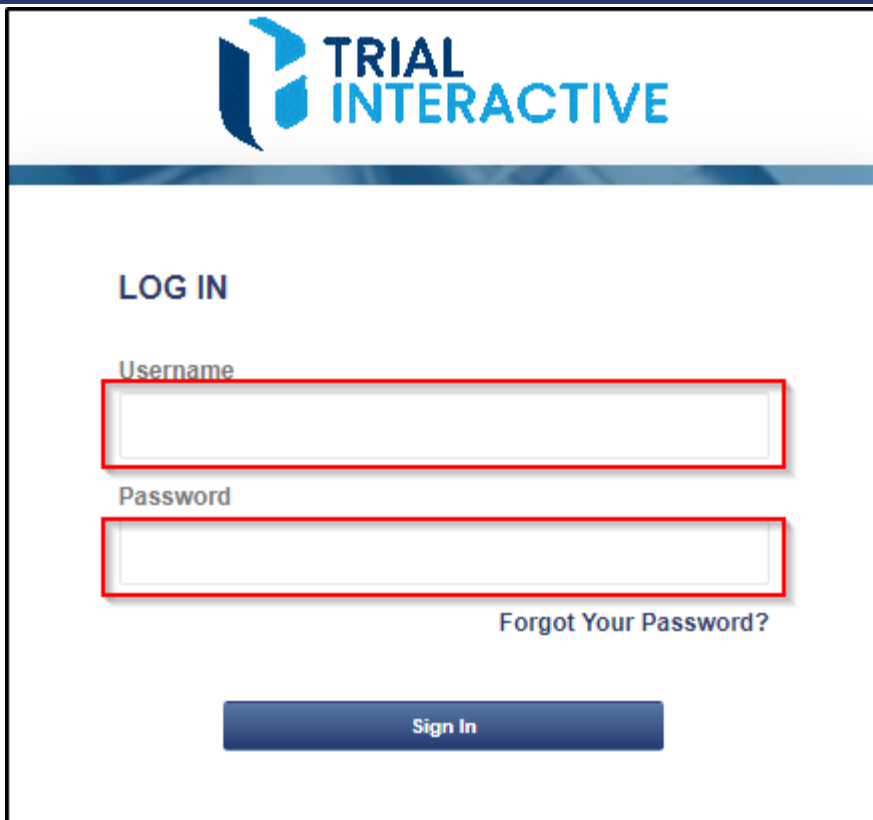
Phone number

☒ I want to receive more industry-specific content from TrialInteractive.  
\*By unchecking you will not receive additional content from TrialInteractive.

2. After clicking the registration button, a confirmation pop-up will appear, indicating that you have successfully registered. The pop-up will also include a link to the room that has been assigned to you.
3. Click on the bottom link to access the room. Refer to the screenshot below.



4. It will be redirected to the Trial Interactive login page. Enter the username and password you provided during the registration process, then click the Sign In button to log in.



The login page features the Trial Interactive logo at the top. Below it, the text "LOG IN" is centered. There are two input fields: "Username" and "Password", both highlighted with red rectangles. To the right of the "Password" field is a link that says "Forgot Your Password?". At the bottom center is a blue button labeled "Sign In".

- it will be redirected to the Trial Interactive Home Page. Refer to the below screen.

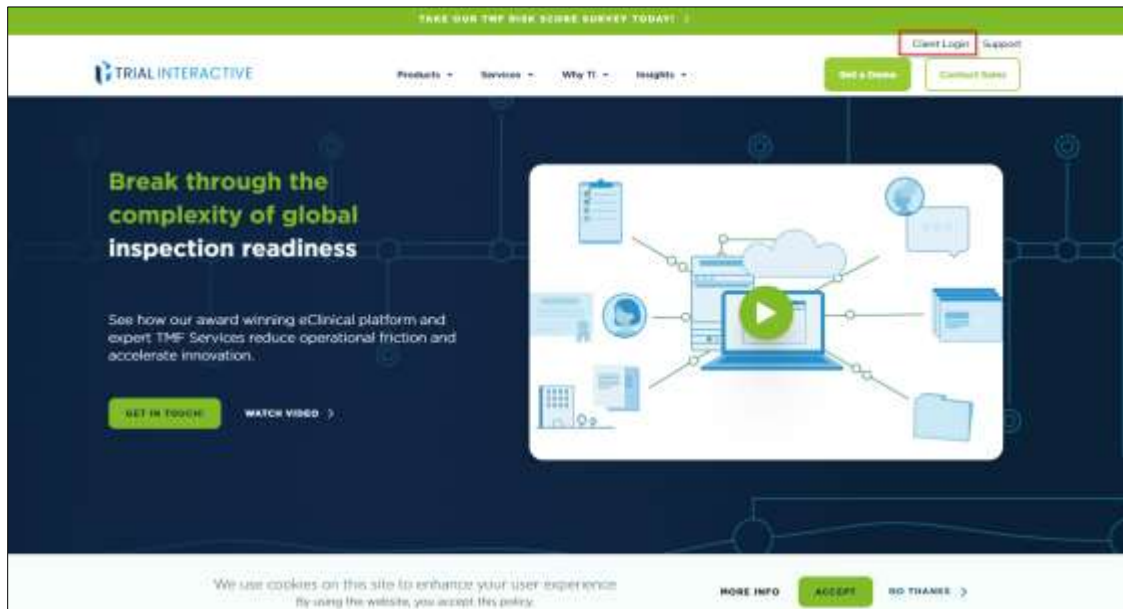


- To learn more about Trial Interactive Home Page [Click here.](#)

## Signing in on Subsequent Visits

### How to log in to Trial Interactive

1. Using your preferred internet browser, navigate to <https://www.trialinteractive.com/>
2. Click the Client Login button located at the top-right corner of the page.



3. The Trial Interactive Login page appears.
4. Enter your Username and Password. Your Username is the full email address that was submitted by the client-appointed Administrator and is likely the one to which the initial invitation was sent.
5. Once you click on the Sign in button, it will redirect you to the Trial Interactive Home page.

## Sign in



Email

Password

☒ Remember Login

[Sign in](#)

[Forgot your password?](#)



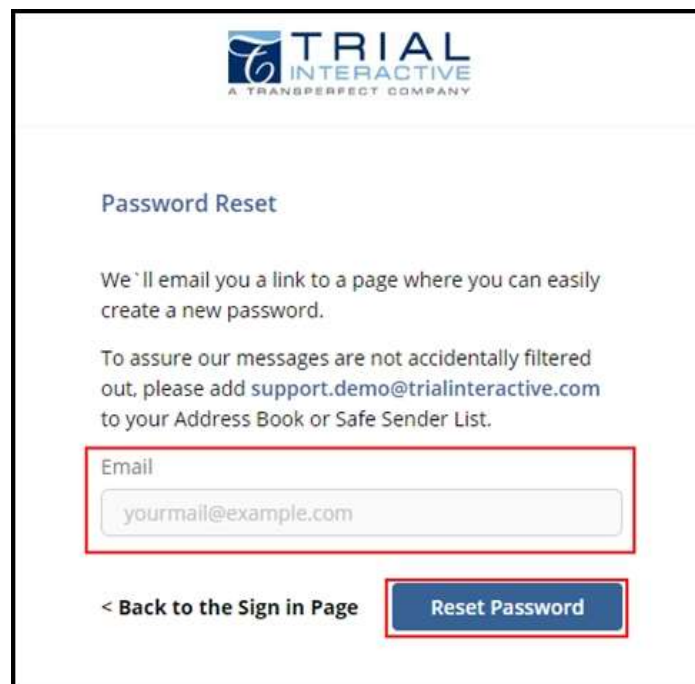
## Requesting a Password Reset

In the event that you have forgotten your password, click 'Forgot Your Password?' at the bottom of the login window to initiate an account password reset.

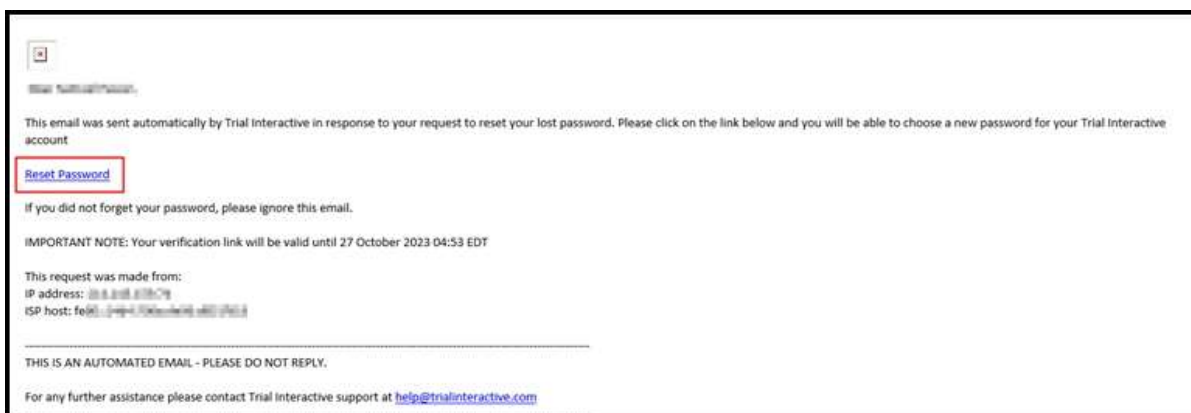
Users do not need to contact the Service Desk. In most cases, the user can perform the Password Reset operations without any outside help. When you click the 'Forgot your Password?' link, a password reset email will be sent to the email address associated with your user account.

Follow these steps to reset your password:

1. Enter your Email address in the field provided and click the Reset Password button.



2. You will receive an email with the Reset Password link.



3. Once you click the Reset Password link. It will redirect you to the Trial Interactive Password Reset page. Respond to the security questions and click the Next button.



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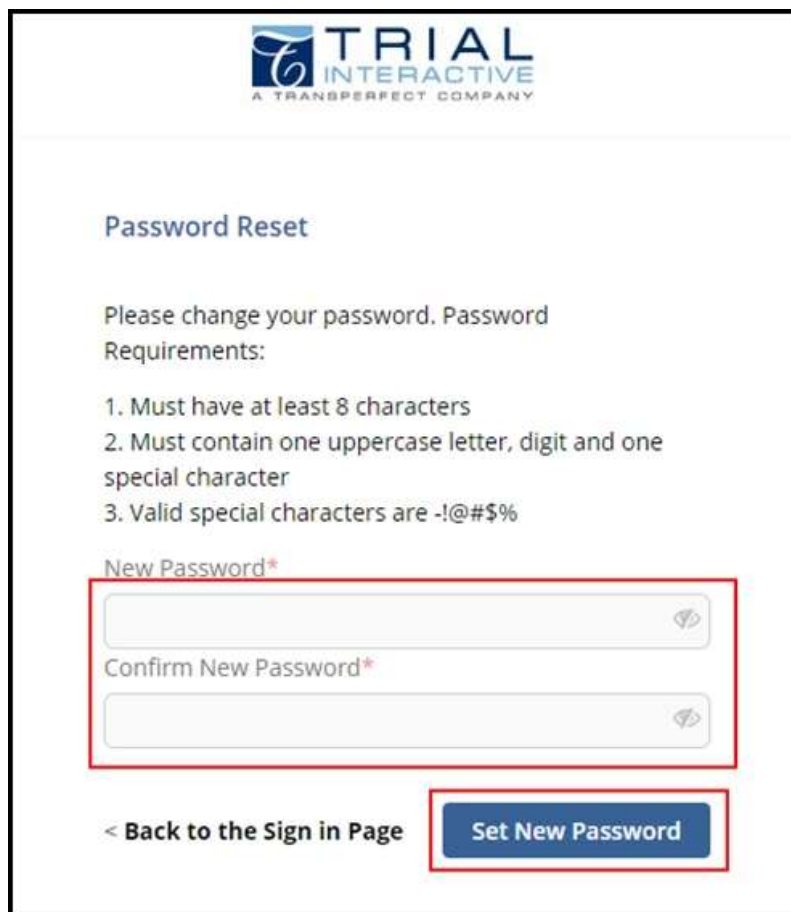
### Password Reset

Please answer secret questions

What was the name of your first pet?

< Back to the Sign in Page   Next

4. Enter your New Password and Confirm the New Password; follow the Password Requirements mentioned in the screenshot below and Click on the Set New Password button.



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### Password Reset

Please change your password. Password Requirements:

1. Must have at least 8 characters
2. Must contain one uppercase letter, digit and one special character
3. Valid special characters are -!@#\$\$%

New Password\*

Confirm New Password\*

< Back to the Sign in Page   Set New Password

5. The system confirms that the password was successfully reset. Click Back to the login page to log in with your new password.

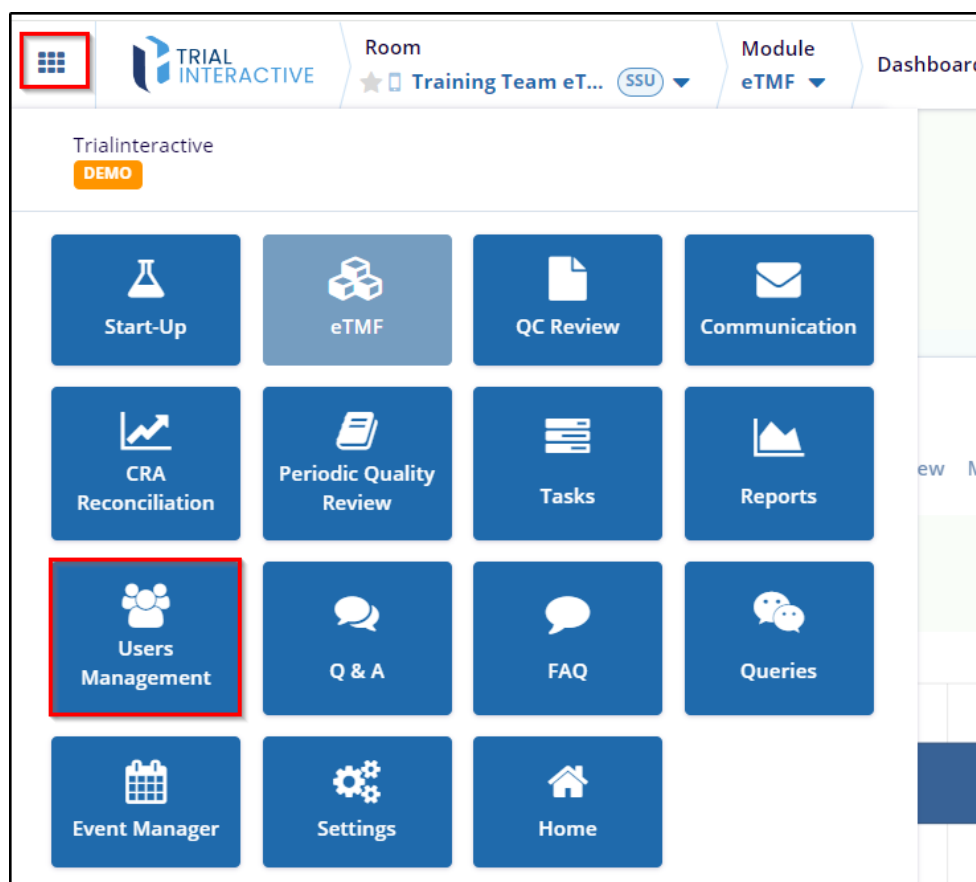
## CHAPTER 3. TRIAL INTERACTIVE USER MANAGEMENT

The User Management Module allows room administrators to manage Contacts, Groups, and Users.

Administrators can do the following from within this application:

- Invite new users to a room/study
- Create groups of users
- View lists of room users under different categories
- Edit user profiles
- Change the access level of users in a room and groups to which they are assigned
- Resend invitations to room users
- Filter and Export users
- Revoke a user's access

You can reach this page from the Navigation Grid at the top-left corner of the screen.



## User Management - User

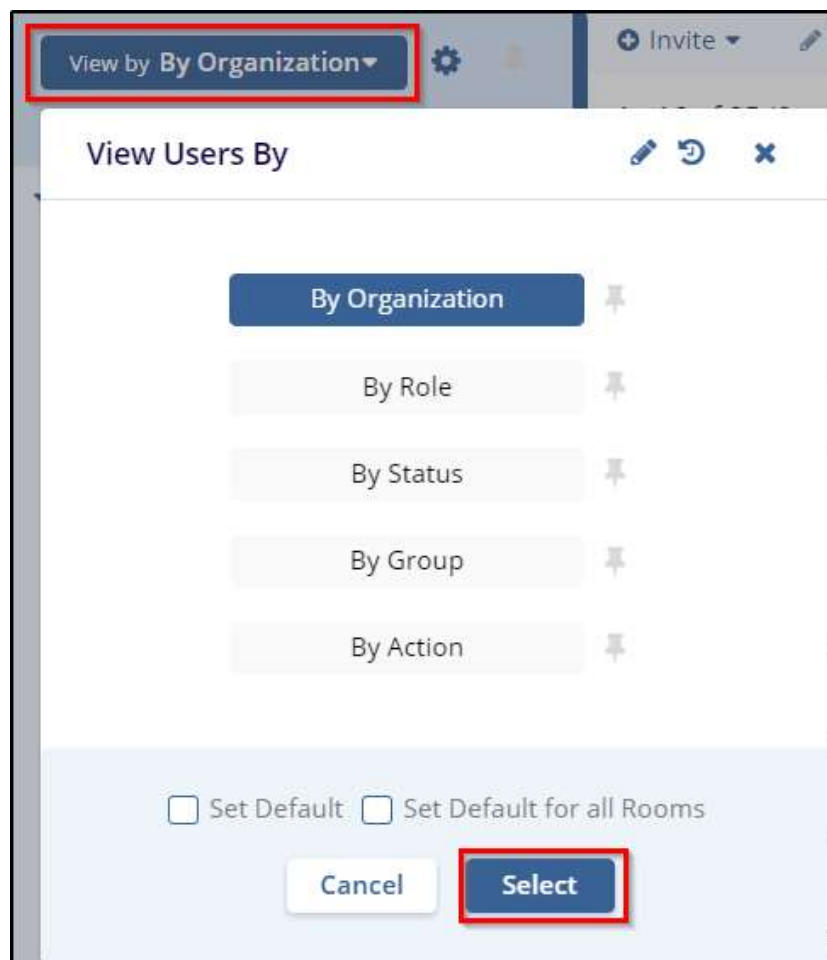
From this page, you can do the following:

- Invite users
- Edit user profiles
- View user access to the room
- Export user data

### How to view users

In Trial Interactive, users are categorized for easier access and viewing. You can filter users by different categories using the following steps:

1. Click the View By dropdown in the left panel.
2. A list of available categories will appear.
3. Select the category you'd like to use to filter the users in the room.
4. Click Select at the bottom of the popup window.
5. Additionally, you have two options for setting the default view:
6. Set Default: By checking the Set Default box, you can set the selected category as the default view for the current room.



## User Profile Fields

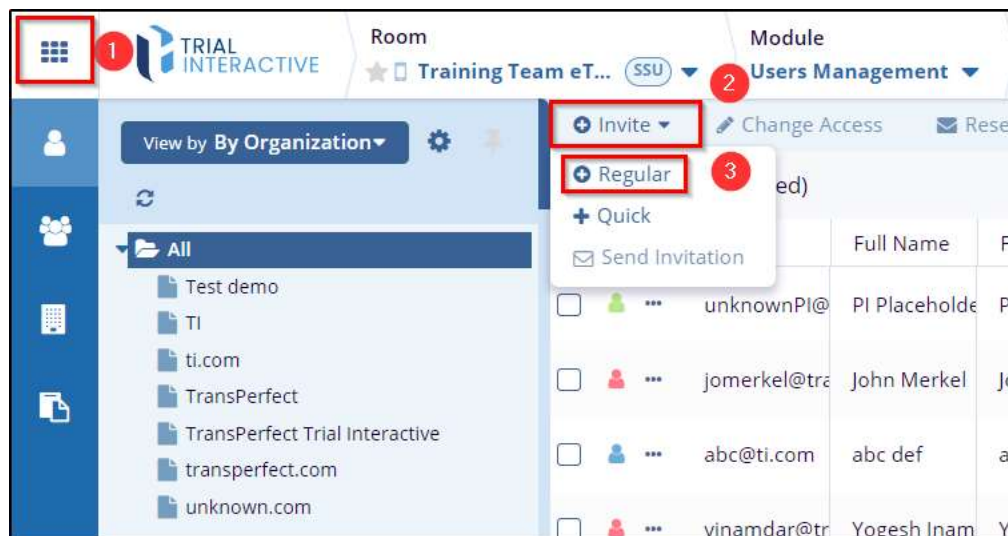
The fields of importance are discussed below:

1. User Email: This is used as a unique identifier to log in to Trial Interactive. This can be typed in or, in the case of users who are already in the system, searched by clicking the magnifying lens icon at the end of the field.
2. If you type in an email address that does not adhere to an email ID format, you will receive a validation error message asking you to enter the correct one.
3. Role: Choose the role from the dropdown.
4. Actions: These are tasks that the user would be allowed to perform in addition to the basic rights associated with their user access role.
5. Expiration Date: Enter this date if you want the user's access to be revoked on a certain date.
6. Organization: Choose from the dropdown the organization to which the user belongs. The Administrator can also create an organization, if not available from the list, by clicking the + sign at the end of the textbox.
7. Invite Later: Click the toggle bar if you want to create a user for the room but do not want to send the invitation yet.
8. Regulatory Agency Inspector: Users who are invited as Regulatory Agency Inspectors will have reduced access to the multiplicity of dashboards and modules that regular TI users need to be trained on prior to granting system access. These users will only have access to the Quality Review module and the FAQ module and will, therefore, require significantly less initial training than a standard room user.

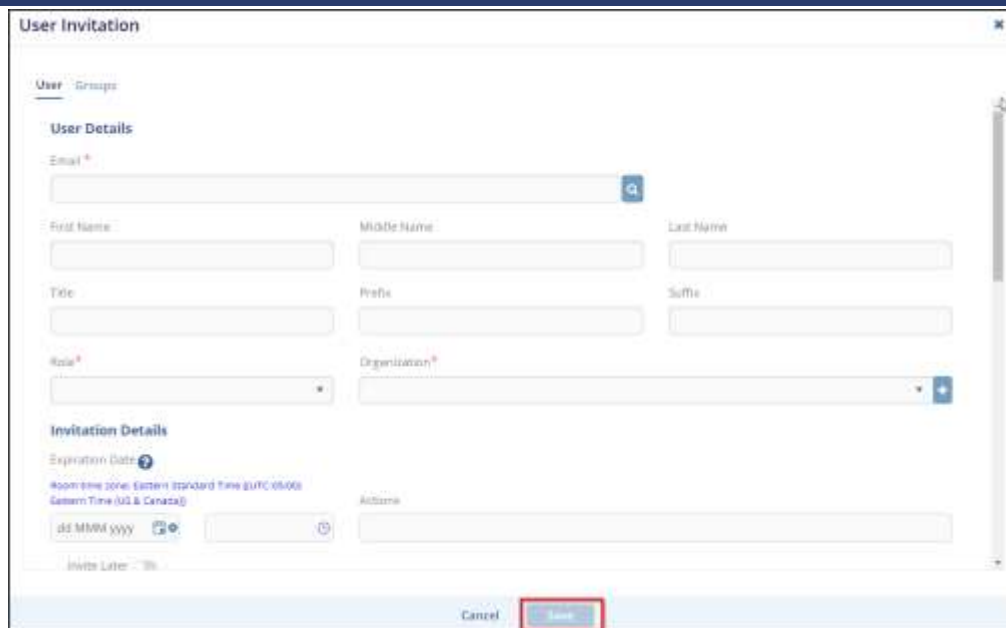
## How to Invite New Users via the Regular Invitation

Here's a streamlined process for inviting new users using the Regular Invitation method:

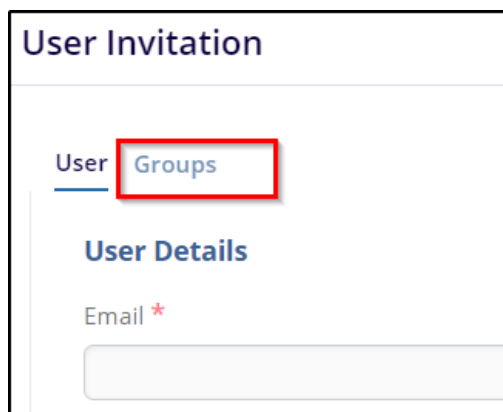
1. Navigate to Users Management: Go to the Navigation Grid → Users Management → Users.



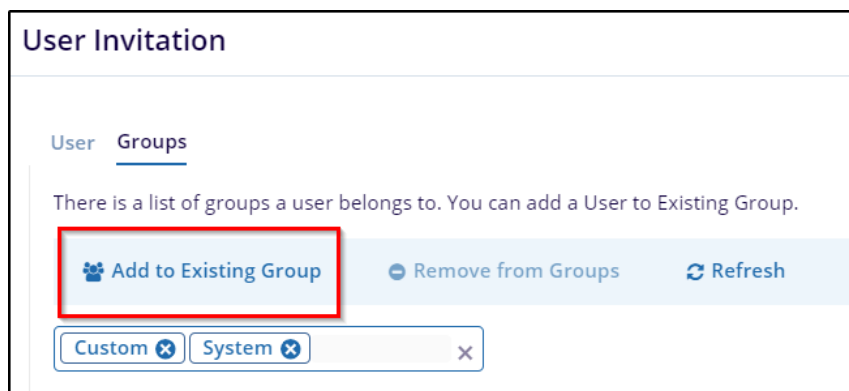
2. Click the Invite dropdown in the top menu bar, then select 'Regular' from the list.
3. Fill in the required details on the form that appears. To Understand All mandatory fields, Click [Here](#).



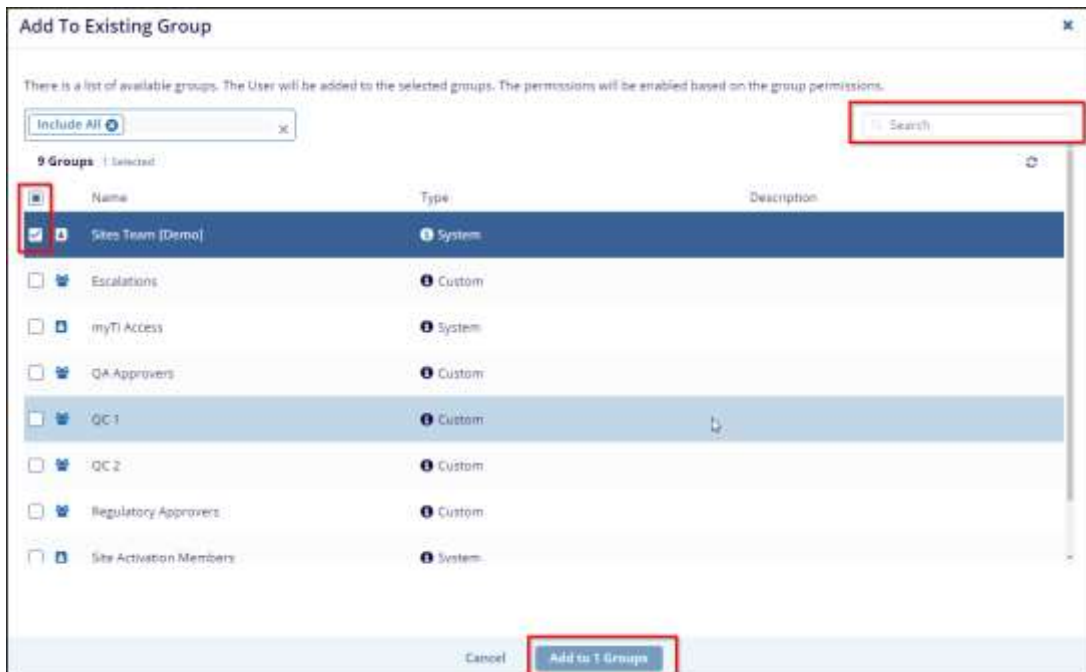
4. Assign Groups (Optional): To assign the user to a group, click on the Groups tab at the top.



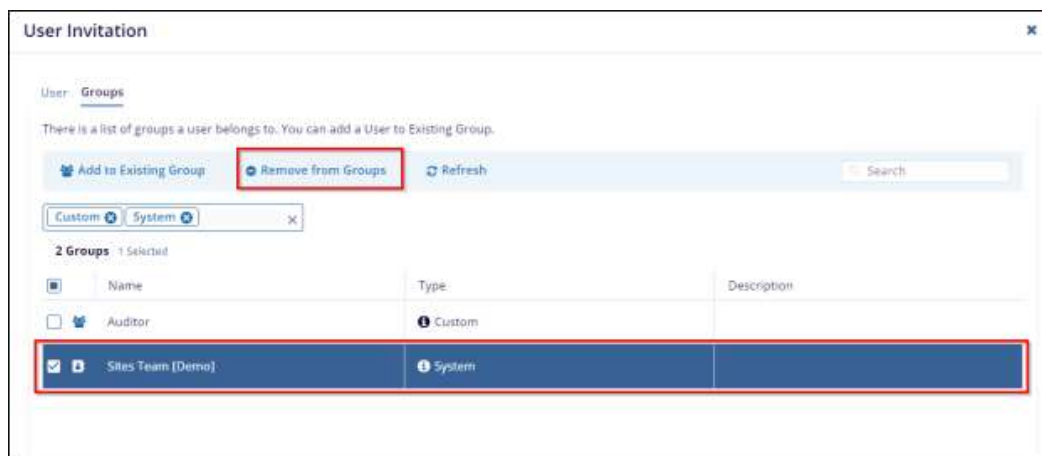
5. Select "Add to Existing Group" from the top.



6. The Add to Existing Group window will appear. Select the group(s) by checking the corresponding checkboxes. You can also search for a group from the left side of the screen.

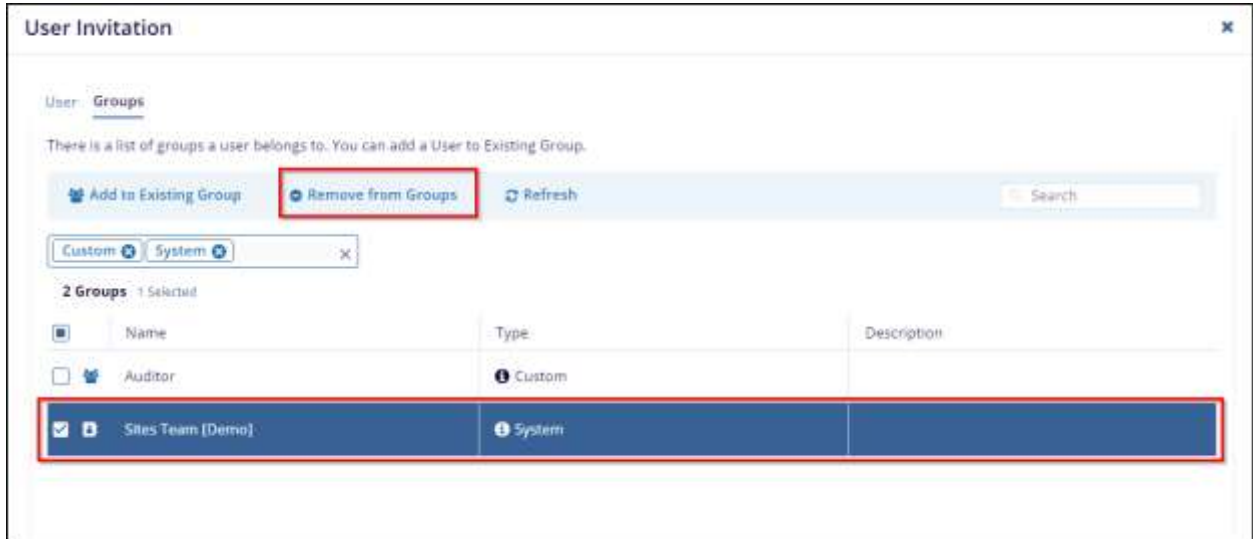


7. Once selected the required groups, click on the “Add to Group” button at the bottom.
8. To remove the user from a group, check the group’s checkbox and click on the “Remove from Group” button at the top.



9. After assigning the user to the group(s), return to the User Invitation screen and click Save to complete the process.

10. Add to Existing Group Window will appear select the group by clicking on the checkbox and Click on the “Add to Group” button from the bottom. From the left side of the screen, the user can search the group as well.
11. To remove the user from the group, click on the checkbox of the group and click the “Remove from Groups” button from the top.



12. After adding to the group come by to user screen and click the save button. Completed the user invitation process using a regular invite.

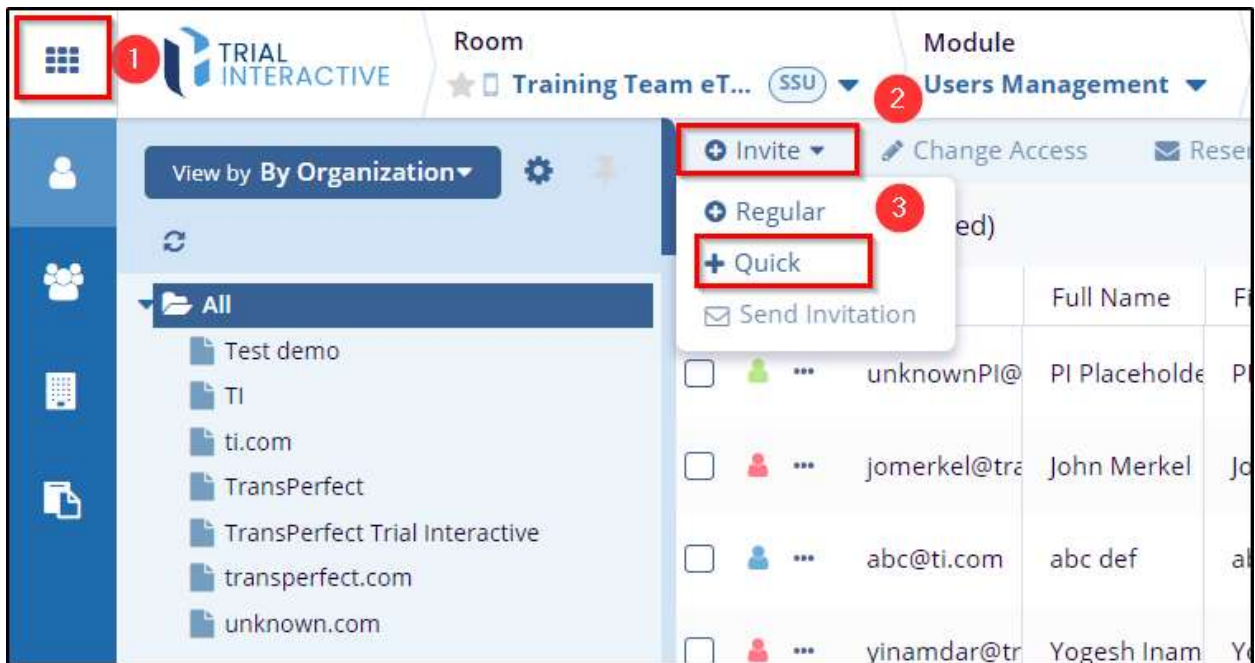


## Inviting New Users via the Quick Invitation

You can use the Quick Invite to invite a set of users with the same role, actions, access period, and belonging to the same groups all at once.

Follow the steps below to use the Quick Invitation to invite one or more users:

1. From Users Management → Users, click the Invite dropdown from the top menu bar and then select Quick from the list of options that appear.



2. The Quick Invite page opens.
3. Enter the email addresses of all the users to be created.
4. Complete the required fields, adding email addresses for each user and selecting the role they will all have in common.
5. Select the Invite Later if appropriate.
6. Click the Groups text box to assign the users to any appropriate groups.
7. Click Add.

Refer to the screenshot below:

Quick Invite

Email List\*

This field is required

Role\*

This field is required

Expiration Date

dd MMM y

Actions

Invite Later

Groups

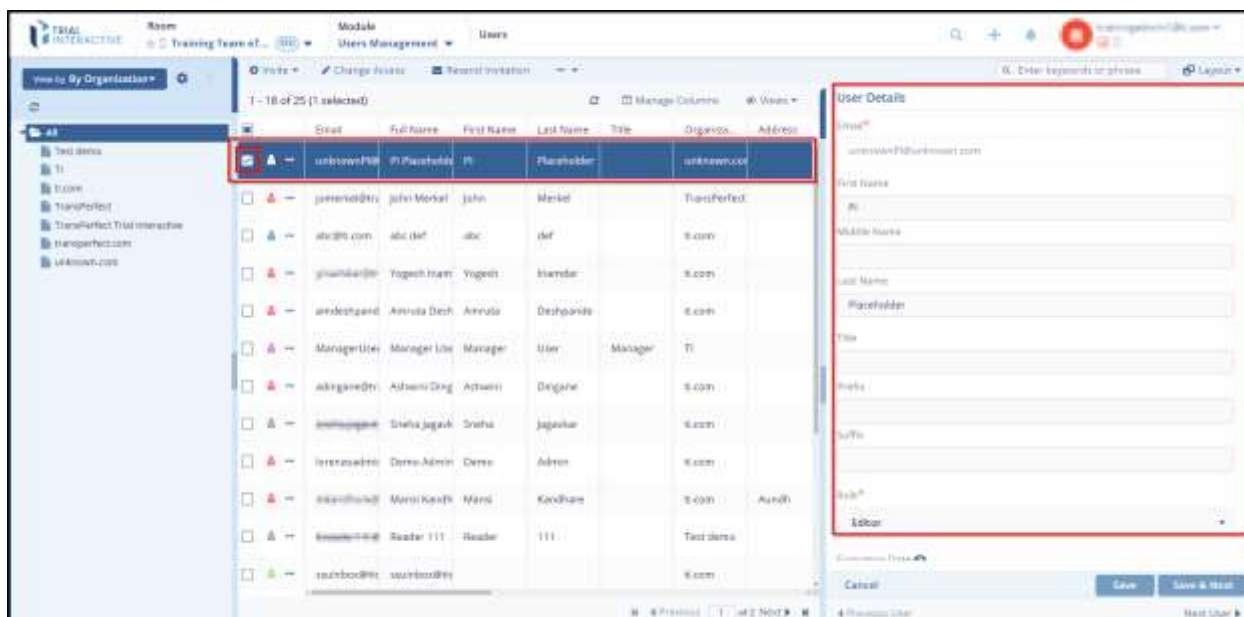
Cancel

Add

## Editing a User's Profile

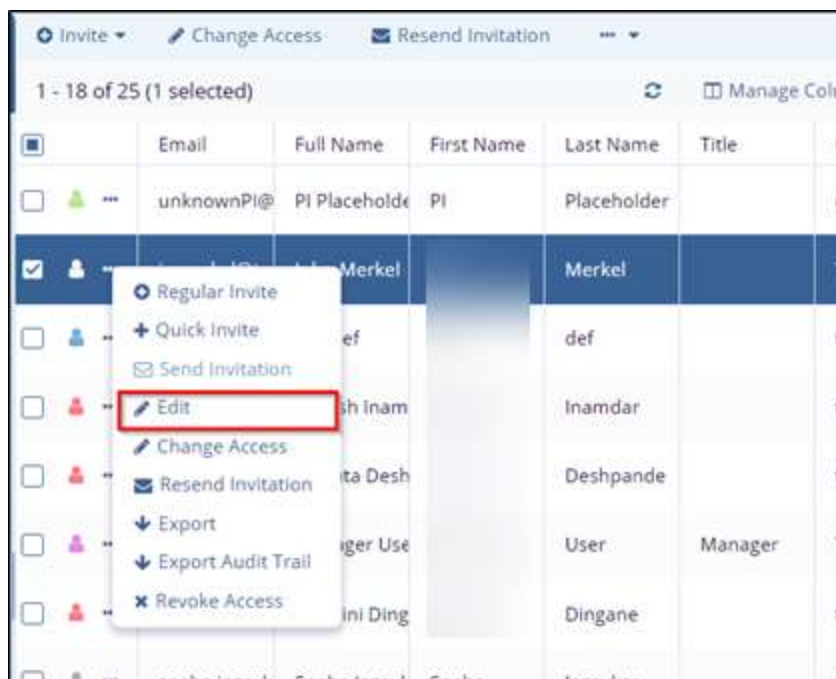
User access can be adjusted at any time from the **User's Management** module. Follow these steps to edit a user's profile:

1. Click on the username or checkbox from the list of displayed users. This will open the User Details window from right side.

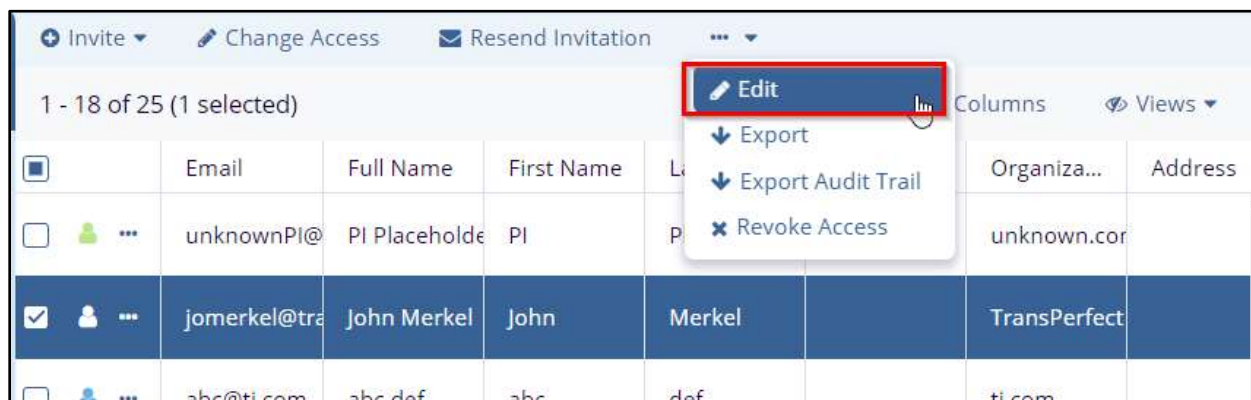


| Email           | Full Name       | First Name | Last Name   | Title   | Organization | Address |
|-----------------|-----------------|------------|-------------|---------|--------------|---------|
| us@newmail      | Pl Placeholder  | Pl         | Placeholder |         | us@newmail   |         |
| john@newmail    | John Merkel     | John       | Merkel      |         | TransPerfect |         |
| abc@def.com     | abc def         | abc        | def         |         | s.com        |         |
| yogesh@newmail  | Yogesh Nam      | Yogesh     | Namdar      |         | s.com        |         |
| anurag@newmail  | Anurag Desh     | Anurag     | Deshgande   |         | s.com        |         |
| Manager@newmail | Manager Loh     | Manager    | User        | Manager | TI           |         |
| aditya@newmail  | Aditya Singh    | Aditya     | Deshgande   |         | s.com        |         |
| shreya@newmail  | Shreya Jagtap   | Shreya     | Jagtap      |         | s.com        |         |
| denis@newmail   | Denis Admin     | Denis      | Admin       |         | s.com        |         |
| manish@newmail  | Manish Kulkarni | Manish     | Kulkarni    |         | s.com        |         |
| Reader@newmail  | Reader 111      | Reader     | 111         |         | Test demo    |         |
| us@newmail      | us@newmail      |            |             |         | s.com        |         |

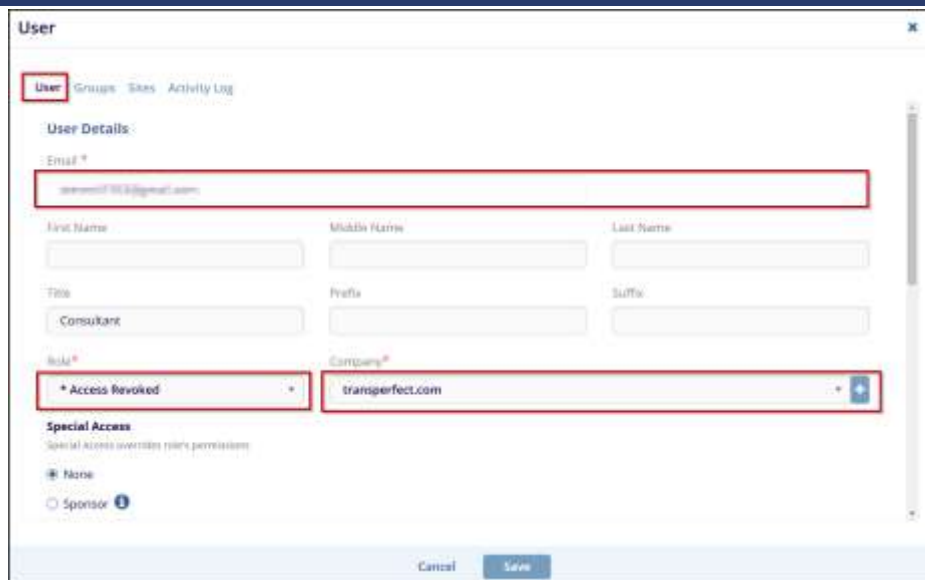
2. If the panel on the right side of the screen does not open automatically, you may need to expand it manually by clicking on Open.
3. Select the user from the displayed list and use the right panel to edit the necessary details, such as name, role, or other profile information.
4. Alternatively, you can use the three dots located on the user's grid entry to open the menu of actions associated with user accounts. From here, select Edit to modify the User, Groups, Sites, and Activity Log.



5. There is one more option to reach the User Details window. Click on the three dots from the menu ribbon above the grid.

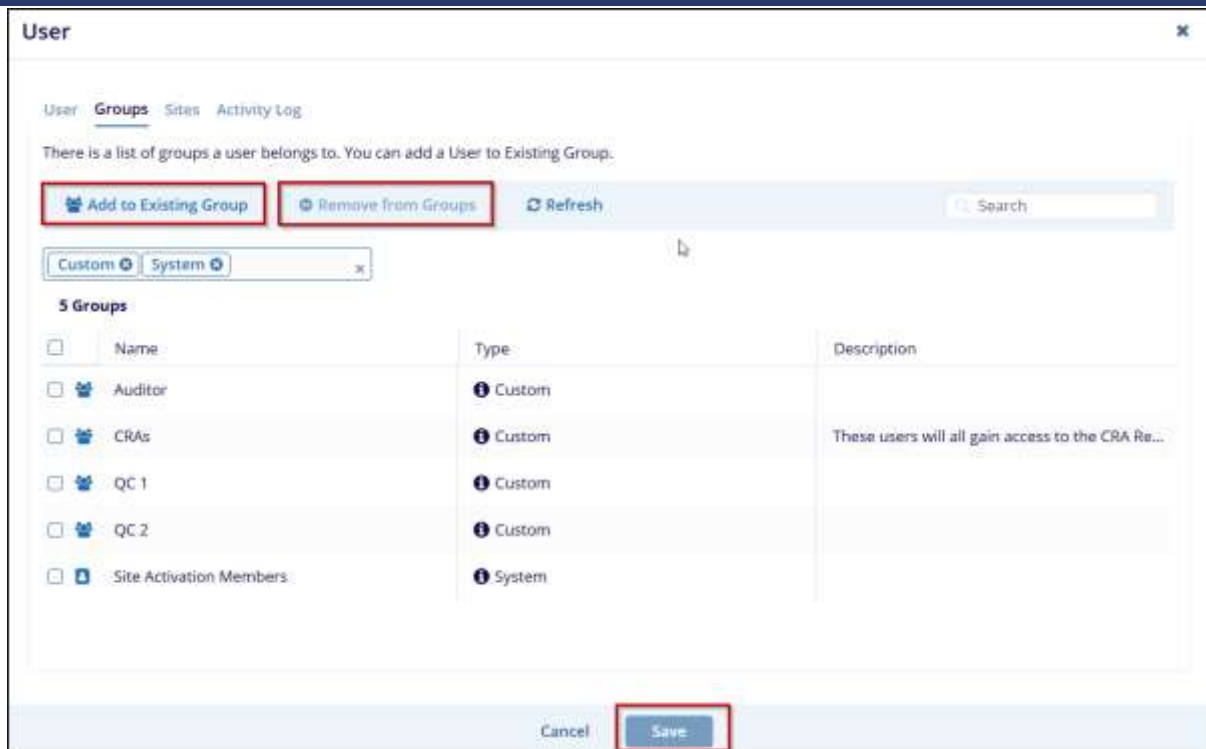


6. The User details window will open, allowing you to modify the user's information. Follow the on-screen instructions to edit the user details as needed.



7. Click Save to apply the changes. For further changes move to the Group section.
8. In the Groups tab, you can manage the groups a user belongs to. You have the option to:
  - Add the user to an existing group by selecting the desired group(s) and clicking Add to Existing Group.
  - Remove the user from selected groups by marking the checkbox next to the group and clicking Remove from Groups.

Refer to the below screenshot



**User**

User Groups Sites Activity Log

There is a list of groups a user belongs to. You can add a User to Existing Group.

**Add to Existing Group** **Remove from Groups** Refresh Search

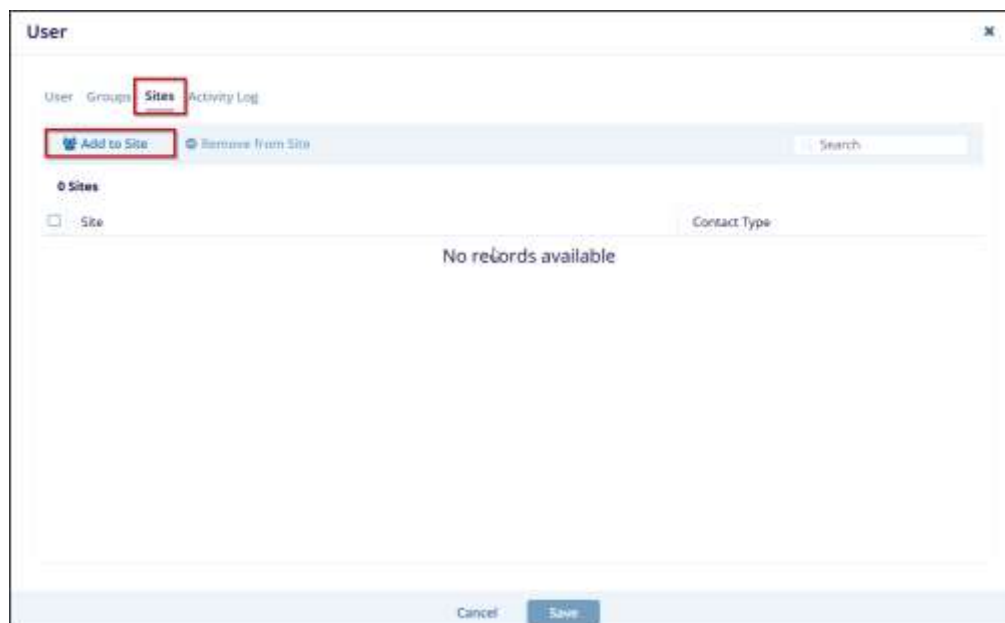
Custom System

**5 Groups**

| <input type="checkbox"/> | Name                    | Type   | Description                                       |
|--------------------------|-------------------------|--------|---------------------------------------------------|
| <input type="checkbox"/> | Auditor                 | Custom |                                                   |
| <input type="checkbox"/> | CRAs                    | Custom | These users will all gain access to the CRA Re... |
| <input type="checkbox"/> | QC 1                    | Custom |                                                   |
| <input type="checkbox"/> | QC 2                    | Custom |                                                   |
| <input type="checkbox"/> | Site Activation Members | System |                                                   |

Cancel **Save**

9. Once you've made the desired changes, click Save to confirm. If further modifications are needed, such as How to Assign a User to Sites, you can navigate to the Sites tab.
10. Click on the Add to Sites button to add the site to the user.



**User**

User Groups **Sites** Activity Log

**Add to Site** Remove from Site Search

0 Sites

| <input type="checkbox"/> | Site | Contact Type |
|--------------------------|------|--------------|
| No records available     |      |              |

Cancel **Save**

11. In the Add to Site window, you can assign the user to multiple sites:
  - Use the Search bar to find specific sites if needed.

- Select the checkboxes next to the sites you want to add the user to. You can select multiple sites, and the count of selected sites will be displayed.
- Once you've made your selections, click Add to [Number] Site(s) to confirm.

Refer to the below screenshot

Add To Site

There is a list of available Sites. The User will be added to the selected Sites.

Search

49 Sites 2 Selected

| <input type="checkbox"/>            | Site              | Principal Investi... | Status  | Country        |
|-------------------------------------|-------------------|----------------------|---------|----------------|
| <input type="checkbox"/>            |                   | Borris J             | PENDING | United Kingdom |
| <input checked="" type="checkbox"/> | D John            | John Keats           | ACTIVE  |                |
| <input checked="" type="checkbox"/> | John d            | Ashwini Dingane      | PENDING |                |
| <input type="checkbox"/>            | Site - 100 Editor | Editor 100           | PENDING | United States  |
| <input type="checkbox"/>            | Site - 107 Admin  | Admin 107            | PENDING | United States  |
| <input type="checkbox"/>            | Site - 107 Admin  | Admin 107            | PENDING |                |
| <input type="checkbox"/>            | Site - 107 Admin  | Admin 107            | PENDING |                |
| <input type="checkbox"/>            | Site - 107 Admin  | Admin 107            | PENDING | India          |

Previous 1 of 5 Next

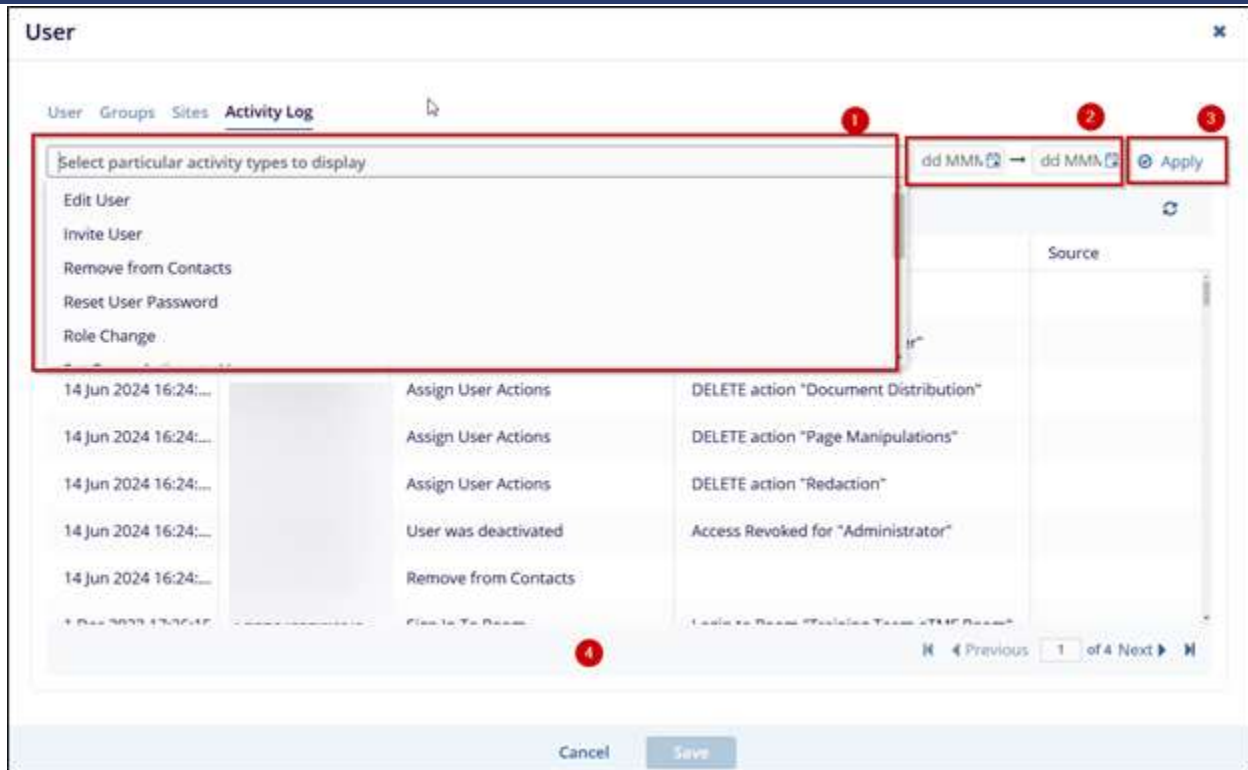
Cancel

Add to 2 Site

12. To make more modifications move to the next section Activity Logs

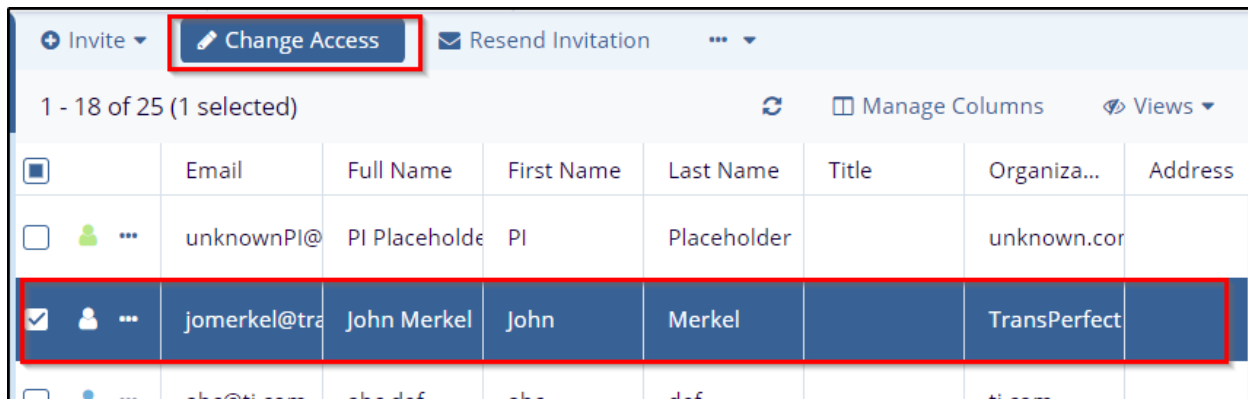
13. To filter and view specific user activity logs, follow these steps:

- Click on the Select particular activity types to display a dropdown to see a list of activity types. Choose the relevant activity types you wish to view.
- Select the date range by clicking on the date fields.
- Click Apply to display the filtered activities.
- Review the displayed activities, and if you wish to save any changes or selections, click Save.



## Change User Access

1. Select the user from the list of users displayed and click Change Access from the menu ribbon above the grid.
2. This does not open the user profile but does provide an opportunity to adjust the user's general access privileges and can be used to edit multiple users at once.

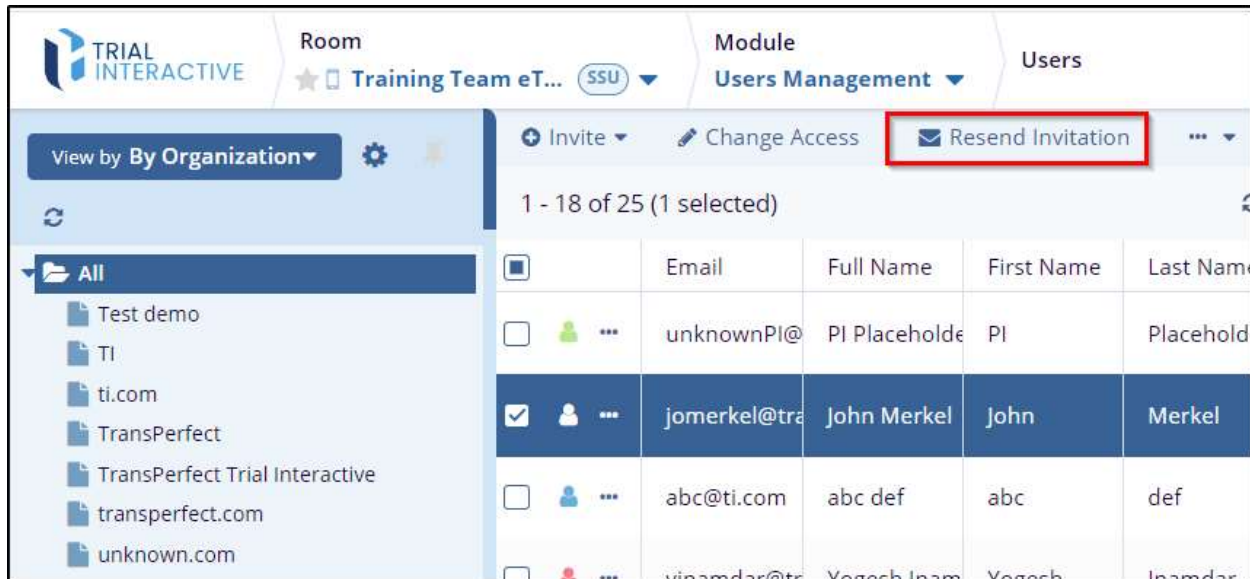


## Resending an Invitation

As an Administrator, you can resend an invitation to a user if the user has been invited but has not visited the room.

To resend an invitation:

1. From the left pane, select the preferred category to view the users.
2. From the list of users displayed in the right pane under the selected category, tick the checkbox for users to whom you want to resend the invitations.
3. From the top ribbon bar, click the Resend Invitation icon. A popup window will appear, asking you to confirm.



4. Click the Yes button.



5. The invitations will be resent to the selected users, and a confirmation notification will appear.



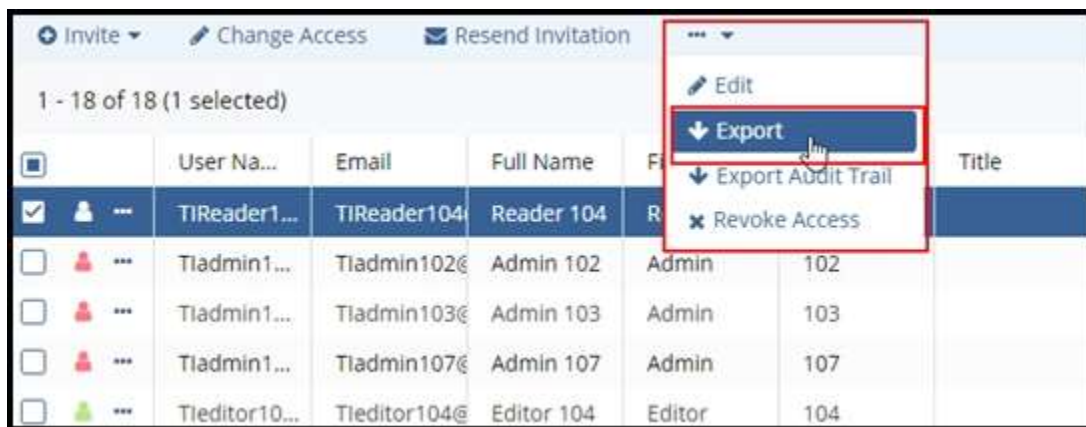


## Exporting User Information

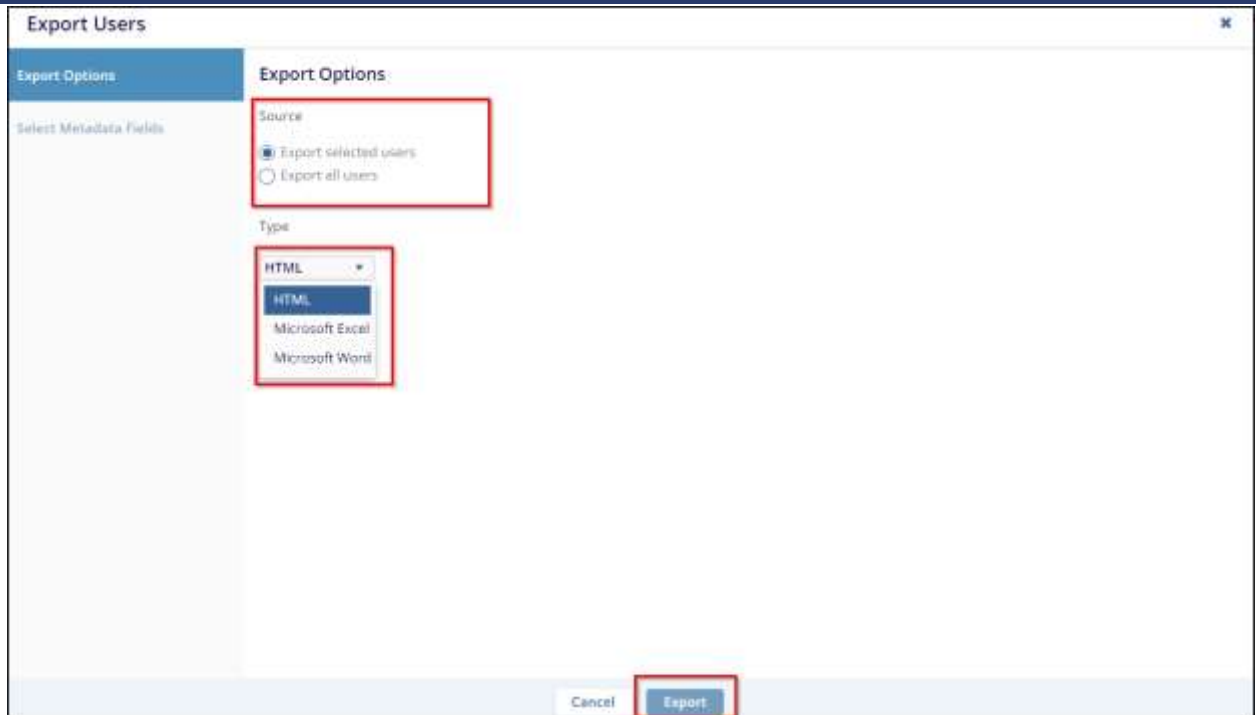
There are two options for exporting user information, an **export of the user's profile** data OR an export of audit trail data.

### Exporting Selected User Profile Information

1. Navigate to User Management → Users.
2. Locate the users whose information want to export.
3. Tick the checkboxes of the users.
4. From the top ribbon bar, click the three dots and then click Export from the options that appear.



5. The Export Users popup opens with the Export Selected Users radio button highlighted.
6. Select the Type of export file format. You can select HTML, Microsoft Excel, or Microsoft Word.



7. Click Export.
8. You will receive a notification about the job completion.
9. Click Get Job Result to download the document.

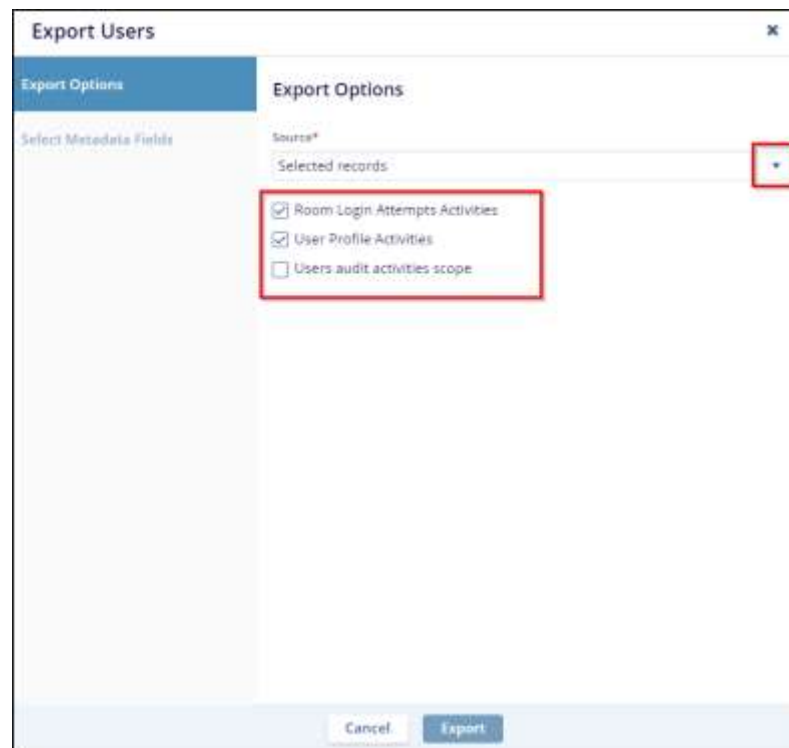


## How to export User Audit Data

1. Navigate to User Management → Users.
2. Locate the users whose information needs to be exported.
3. Tick the checkboxes of the users.
4. From the top ribbon bar, click the three dots and then click Export Audit Trail from the options that appear.

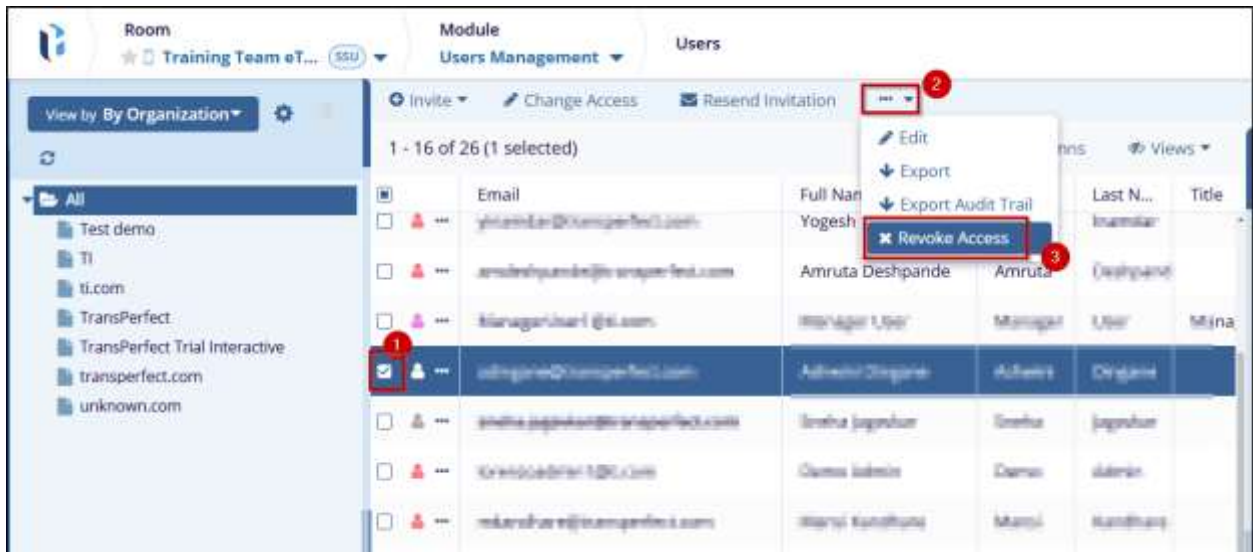


5. The Export Users window will open.
6. Use the options given to identify which user data selection should be exported. When you have completed setting export criteria, Click the Export button.

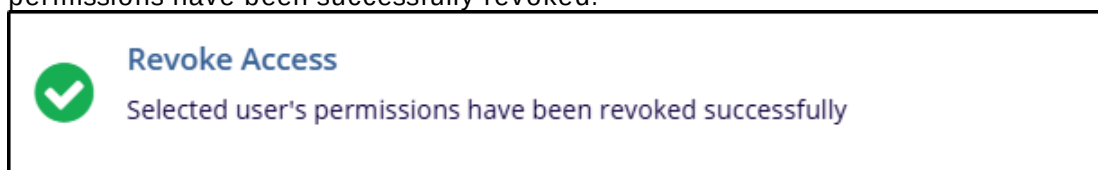


## How to Revoke User access

1. Navigate to User Management → Users.
2. Locate the users whose information needs to be exported.
3. Tick the checkboxes of the users.
4. From the top ribbon bar, click the three dots and then click Revoke Access from the options that appear.

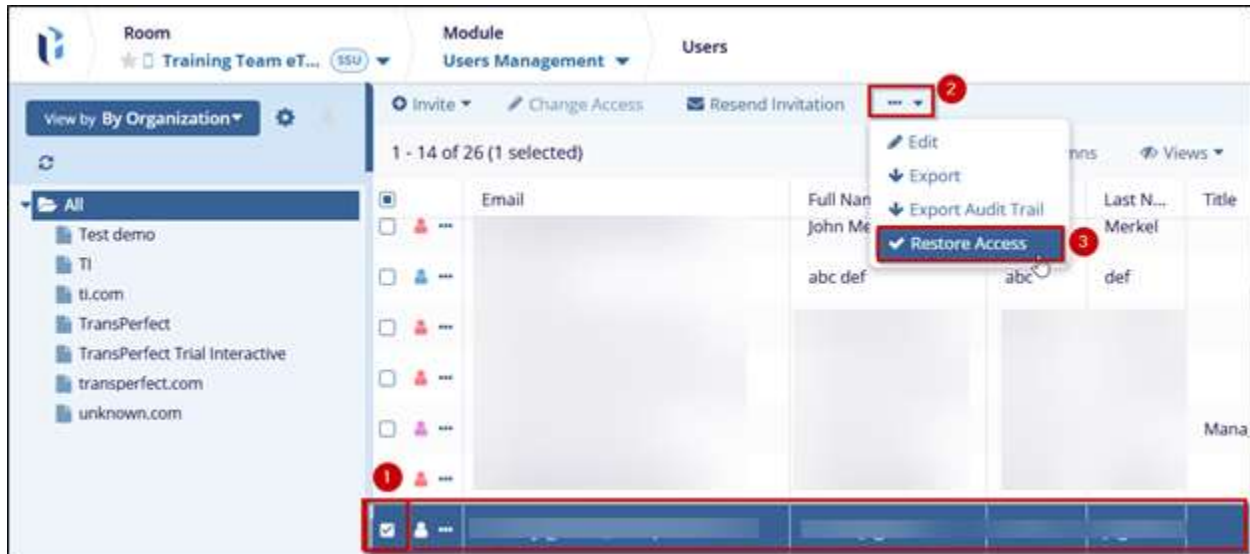


5. The Revoke Access confirmation window appears. Select Yes to proceed with the revoke access process, or choose No to cancel.
6. Once you click Yes, a notification window appears confirming that the selected user's permissions have been successfully revoked.

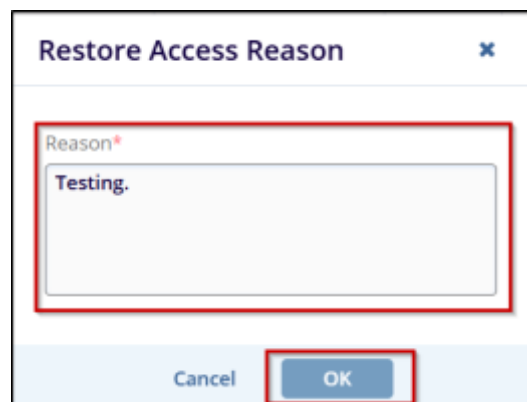


## How to Restore User Access

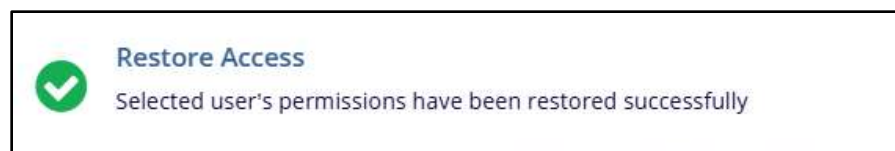
1. Navigate to User Management → Users.
2. Locate the users whose permissions you want to restore.
3. Tick the checkboxes next to the users' names.
4. In the top ribbon bar, click the three-dot icon and select Restore Access from the dropdown options.



5. The Restore Access confirmation window appears. Enter a mandatory reason for restoring access, then click OK to proceed with the process, or choose Cancel to exit.



6. After confirmation, a notification window will appear, confirming that the selected user's permissions have been successfully restored.



7. Ability to Assign User to Site in User Management Module

## User Management - Groups

Administrators have full control over managing user groups, including creating, deleting, and assigning users to these groups. Specifically, administrators can manage:

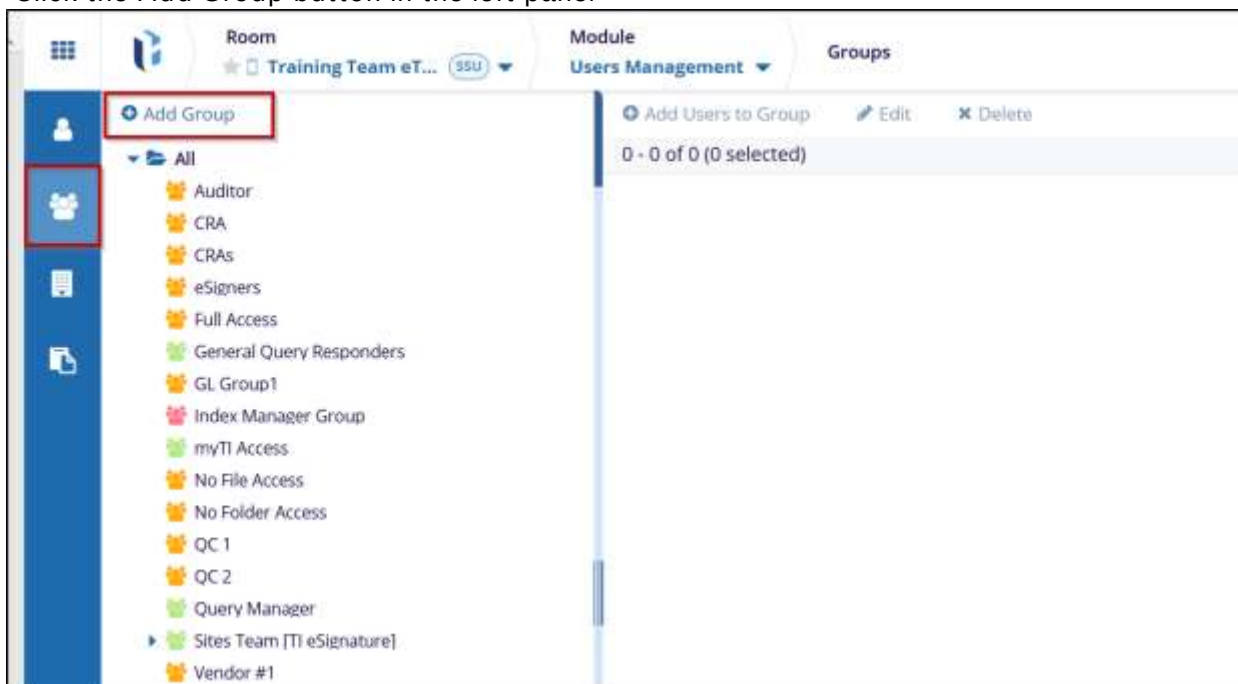
- Group names
- Group descriptions
- Group security rights
- Actions assigned to group members

Groups are essential for granting users access to specific folders, files, and actions. In the Groups area, room administrators can:

- Add a new group
- Add a child group
- Edit a group
- Delete a group

### How to Add a New Group

1. In User Management, click the Groups icon in the left menu.
2. Click the Add Group button in the left pane.



3. The Create New Group window opens. Enter a name for the new group and Add a description for the group. Refer to the below screenshot.

Note: You can clone security settings from an existing group. If the new group requires identical settings to an already established group, select that group from the dropdown menu.

Create New Group

Name\*

Description

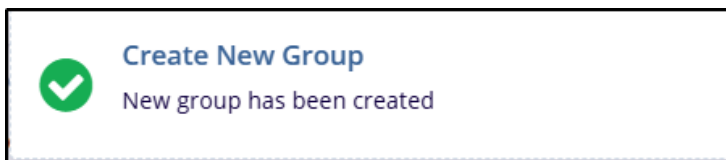
Copy security from an existing group:

Actions

Cancel

Create

4. Assign actions that members of the group can perform by selecting from the list of actions in the dropdown menu.
5. Click Create. A notification confirms that the group has been created successfully.

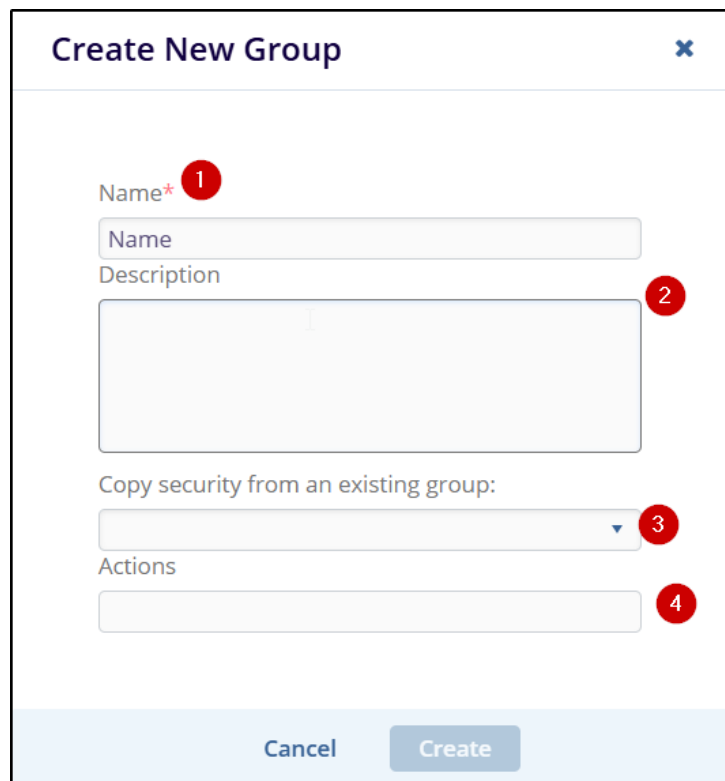


## How to Add New/Existing Child Group

1. In User Management, click the Groups icon on the left menu to access the Groups page.
2. Click the Add Child Group dropdown in the top menu. You have two options Refer to the screenshot below.



3. Add New Child Group: This opens a window to create a new child group. Enter the required details and click Create to add the new child group.



### Create New Group

Name\* **1**

Description **2**

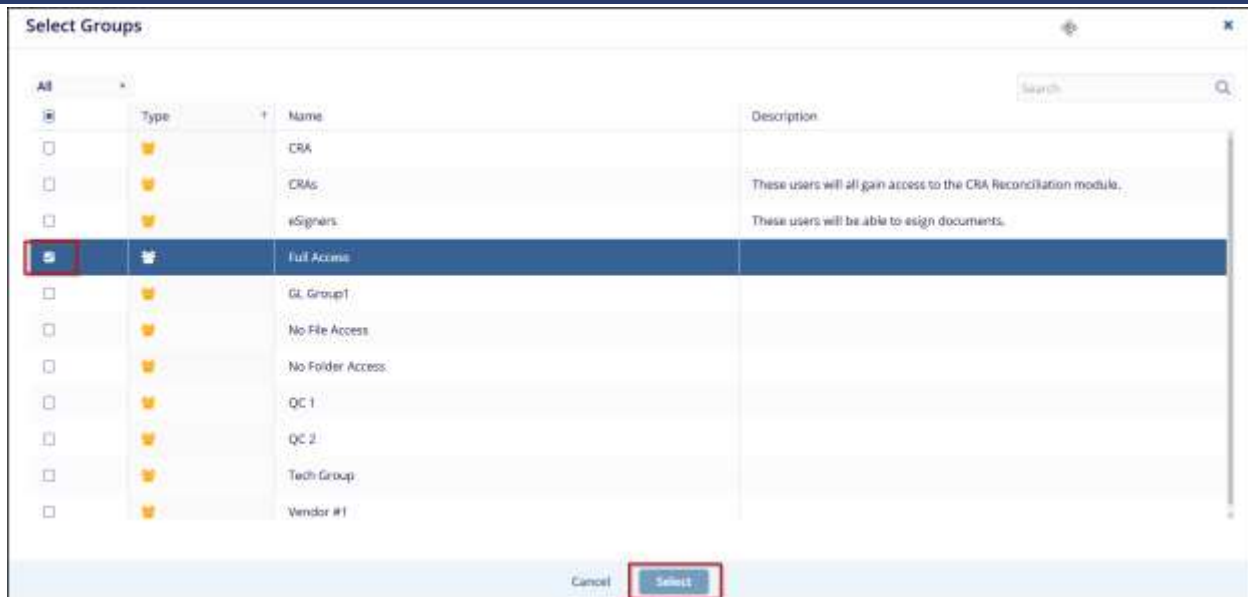
Copy security from an existing group: **3**

Actions **4**

**Cancel** **Create**

4. Add Existing Child Group: Opens the Select Groups popup. Select an existing group from the list to designate it as a child group of the selected parent group, then click Select. Refer to the below screenshot.





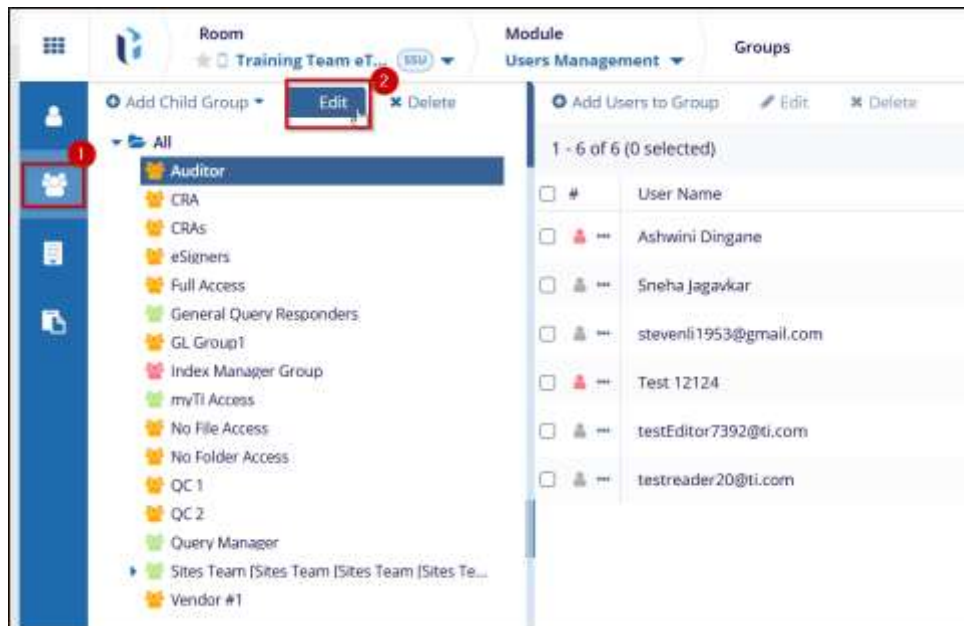
## Child Groups

Child groups have been changed

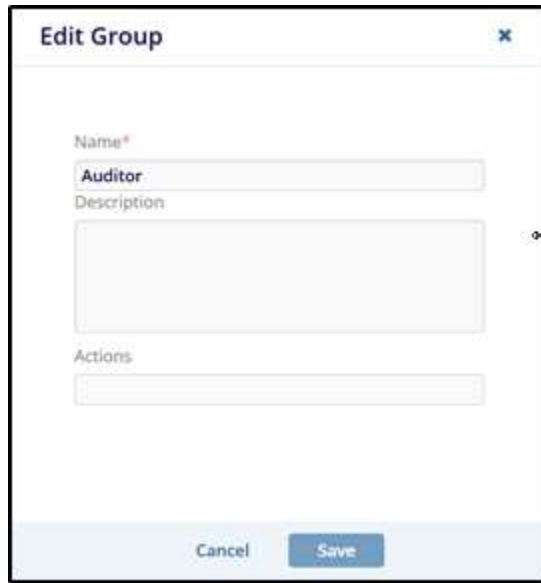
## How to Edit a Group

To edit a group in the User Management module, follow these steps:

1. Click the Groups icon in the left menu to open the Groups page.
2. In the left pane, select the group you want to edit.
3. Click the Edit button in the top ribbon bar.



5. The Edit Group popup will appear.
6. Update the group details as needed.
7. Click Save to apply the changes.



**Edit Group** [X]

Name\*  
Auditor

Description

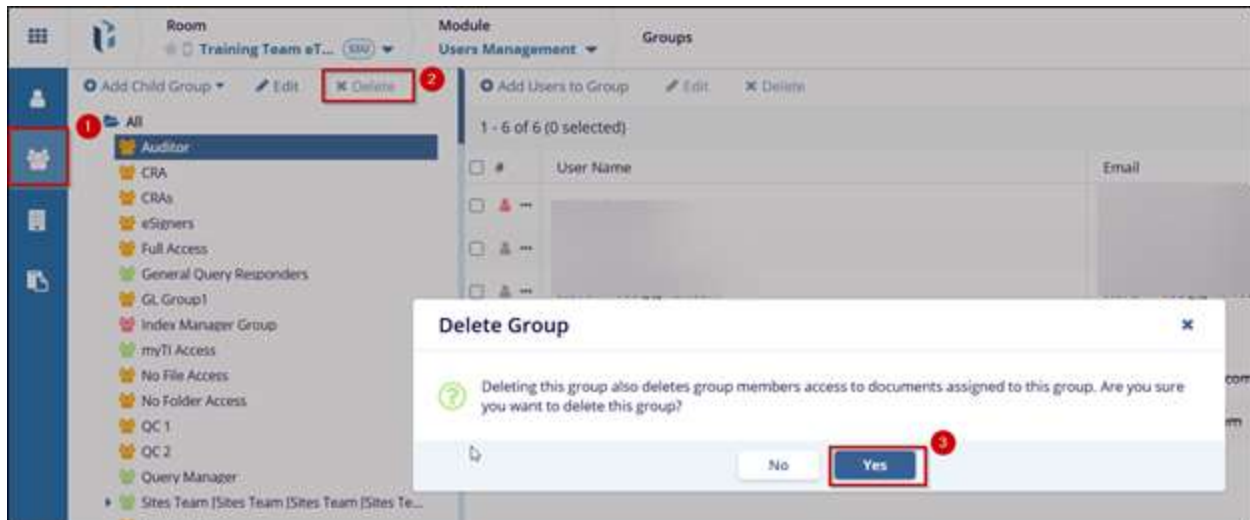
Actions

Cancel Save

## How to Delete a Group

To delete a group, follow these steps:

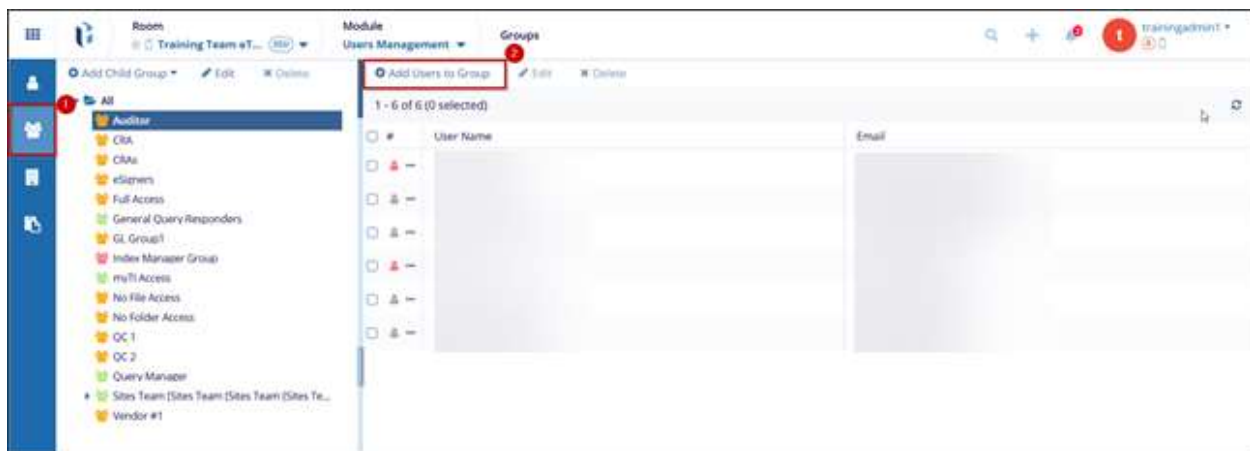
1. In the left pane, select the group you want to delete and Click Delete in the top menu.
2. A confirmation window will appear, notifying you that deleting this group will remove group members' access to the group's assigned privileges but will not delete the users themselves.
3. Click Yes to confirm the deletion. Refer to the screenshot below



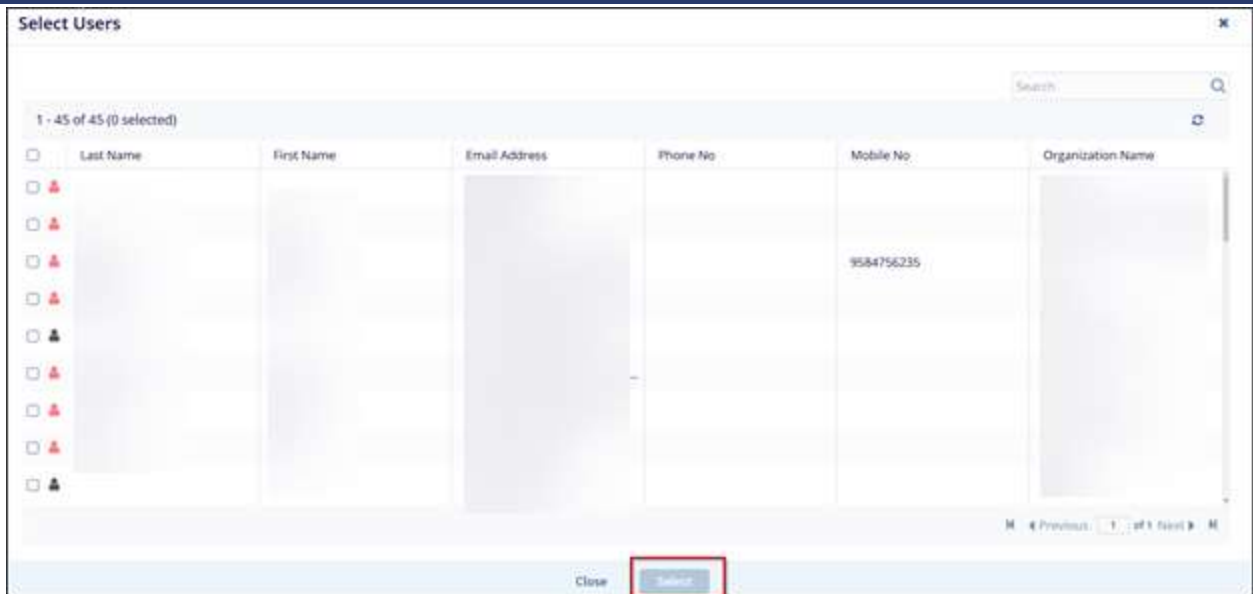
## How to Add Users to the Group

To add users to a group, follow these steps:

1. In User Management, click the Groups icon in the left pane.
2. Select the group you want to add users to from the list in the left pane. The group's current user list appears in the right pane.
3. Click Add Users to Group in the top menu bar.

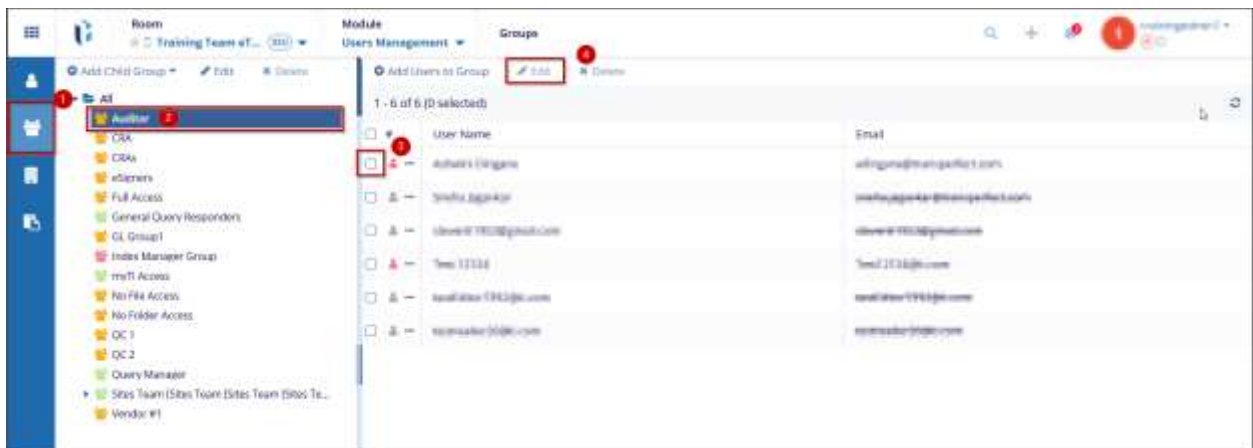


4. The Select Users window opens and Choose the users you want to add to the group, then click Select. Refer to the below screenshot.

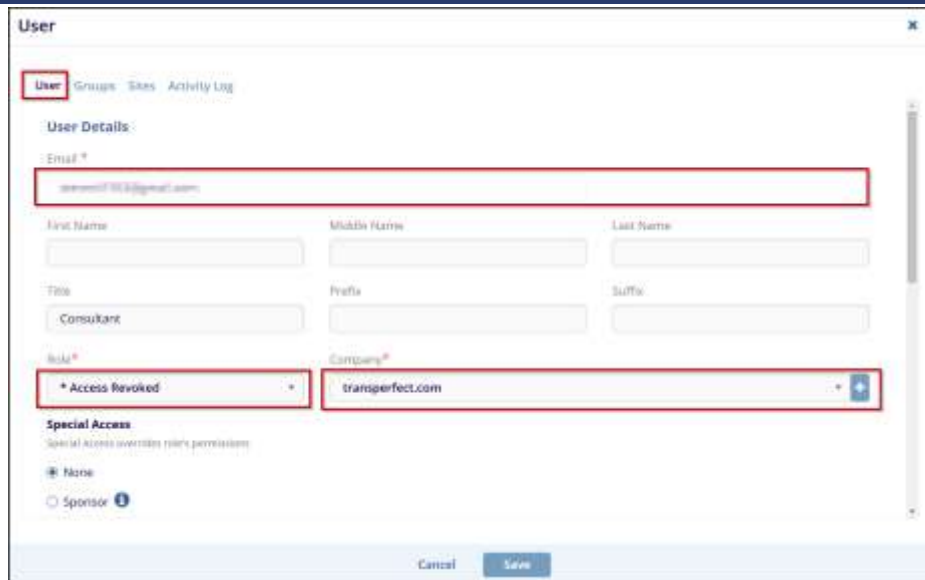


## How to Edit Users from a Group

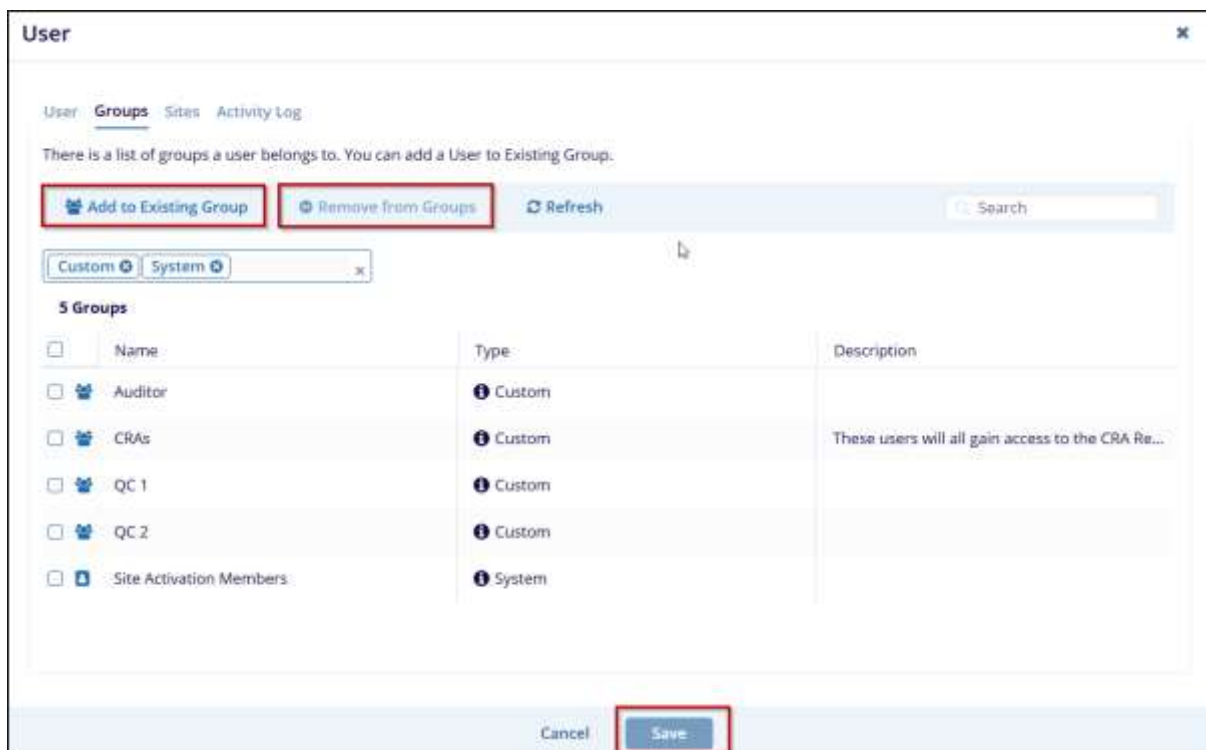
3. In User Management, click the Groups icon in the left menu.
4. Select the group containing the user you want to edit from the list in the left pane. The list of group members will appear on the right.
5. Select the checkbox next to the user's name and Click Edit in the top menu.



6. The User details window will open, allowing you to modify the user's information. Follow the on-screen instructions to edit the user details as needed.



7. Click Save to apply the changes. For further changes move to the Group section.
8. In the Groups tab, you can manage the groups a user belongs to. You have the option to:
  - Add the user to an existing group by selecting the desired group(s) and clicking Add to Existing Group.
  - Remove the user from selected groups by marking the checkbox next to the group and clicking Remove from Groups.



There is a list of groups a user belongs to. You can add a User to Existing Group.

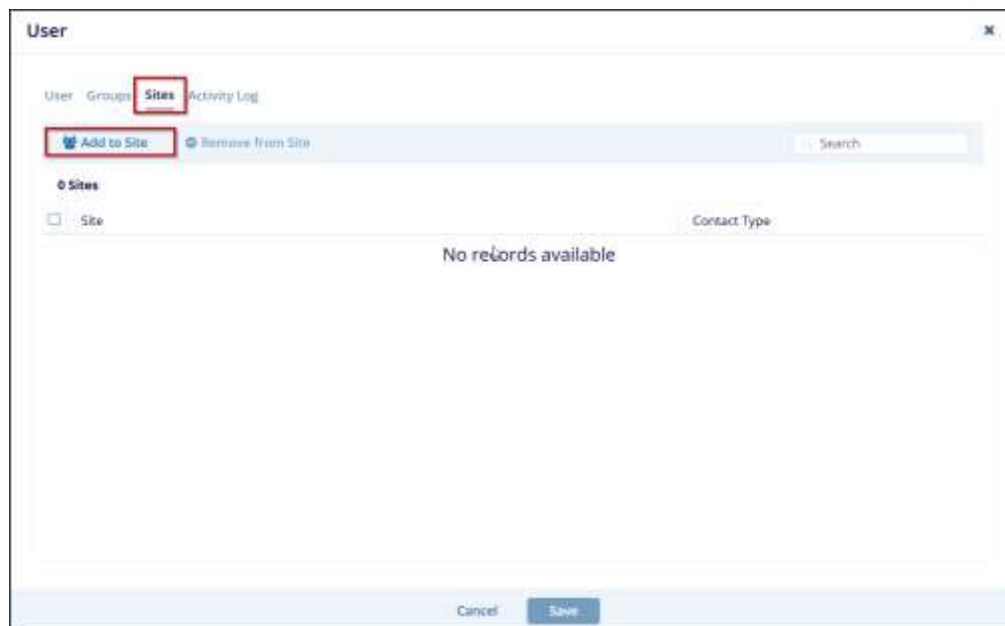
Custom System

**5 Groups**

| <input type="checkbox"/> | Name                    | Type   | Description                                       |
|--------------------------|-------------------------|--------|---------------------------------------------------|
| <input type="checkbox"/> | Auditor                 | Custom |                                                   |
| <input type="checkbox"/> | CRAs                    | Custom | These users will all gain access to the CRA Re... |
| <input type="checkbox"/> | QC 1                    | Custom |                                                   |
| <input type="checkbox"/> | QC 2                    | Custom |                                                   |
| <input type="checkbox"/> | Site Activation Members | System |                                                   |

Cancel

9. Once you've made the desired changes, click Save to confirm. If further modifications are needed, such as How to Assign a User to Sites, you can navigate to the Sites tab.
10. Click on the Add to Sites button to add site to the user.



11. In the Add to Site window, you can assign the user to multiple sites:
  - Use the Search bar to find specific sites if needed.
  - Select the checkboxes next to the sites you want to add the user to. You can select multiple sites, and the count of selected sites will be displayed.
  - Once you've made your selections, click Add to [Number] Site(s) to confirm.

### Add To Site ✕

There is a list of available Sites. The User will be added to the selected Sites.

**49 Sites** 2 Selected

| <input type="checkbox"/> Site                             | Principal Investi... | Status  | <span>1</span> Country |
|-----------------------------------------------------------|----------------------|---------|------------------------|
| <input type="checkbox"/>                                  | Borris J             | PENDING | United Kingdom         |
| <span>2</span> <input checked="" type="checkbox"/> D John | John Keats           | ACTIVE  |                        |
| <input checked="" type="checkbox"/> John d                | Ashwini Dingane      | PENDING |                        |
| <input type="checkbox"/> Site - 100 Editor                | Editor 100           | PENDING | United States          |
| <input type="checkbox"/> Site - 107 Admin                 | Admin 107            | PENDING | United States          |
| <input type="checkbox"/> Site - 107 Admin                 | Admin 107            | PENDING |                        |
| <input type="checkbox"/> Site - 107 Admin                 | Admin 107            | PENDING |                        |
| <input type="checkbox"/> Site - 107 Admin                 | Admin 107            | PENDING | India                  |

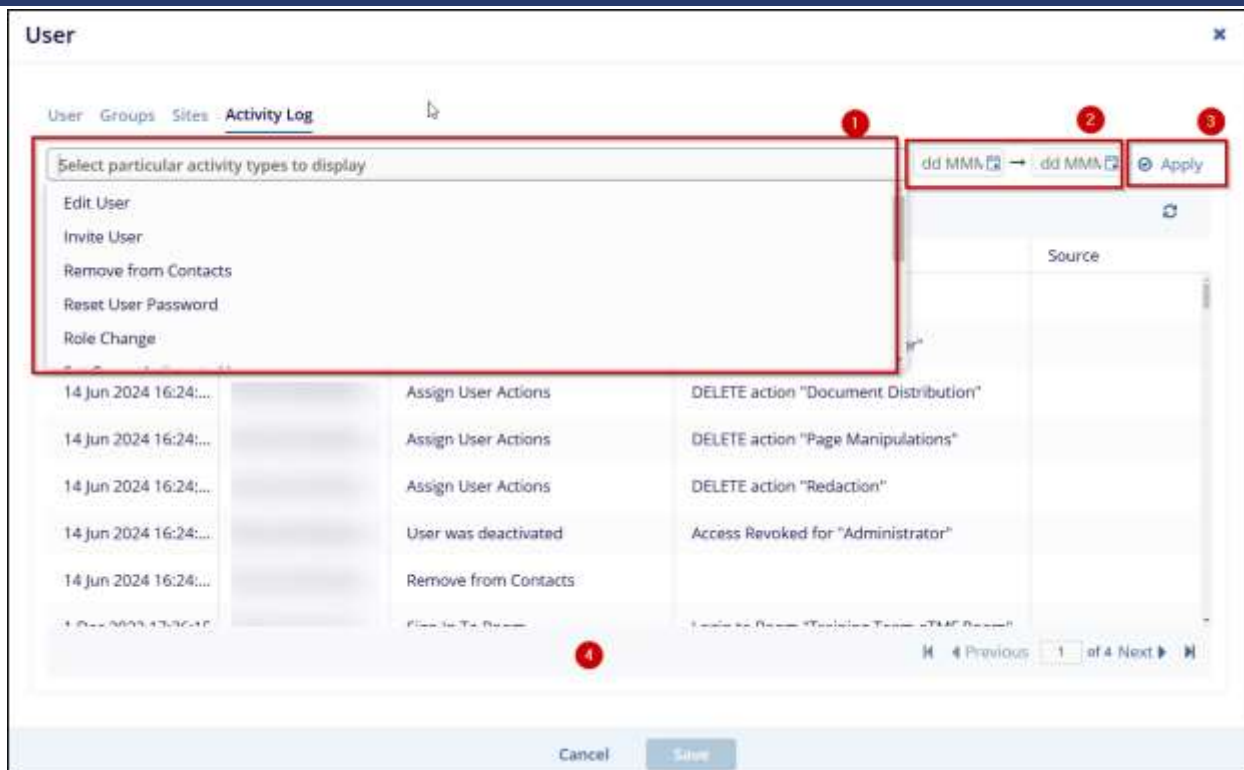
⏪ ⏩ Previous 1 of 5 Next ⏭

Cancel Add to 2 Site 3

12. To make more modifications move to the next section Activity Logs

13. To filter and view specific user activity logs, follow these steps:

- Click on the Select particular activity types to display a dropdown to see a list of activity types. Choose the relevant activity types you wish to view.
- Select the date range by clicking on the date fields.
- Click Apply to display the filtered activities.
- Review the displayed activities, and if you wish to save any changes or selections, click Save.



## User Management – Departments

This section explains the configuration of the Departments in the User Management.

### How to create a new department

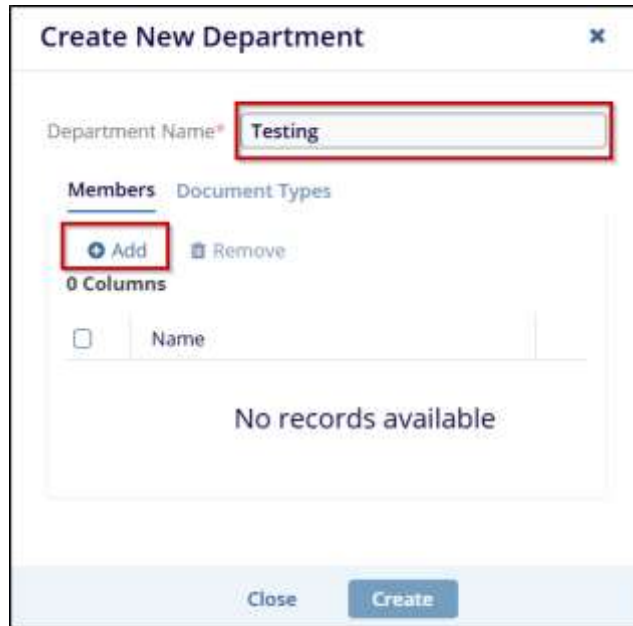
Steps to Create New Department:

- 1 In User Management, click the Department icon in the left pane. This will open the Department screen. Click on the Add button at the top of the screen.

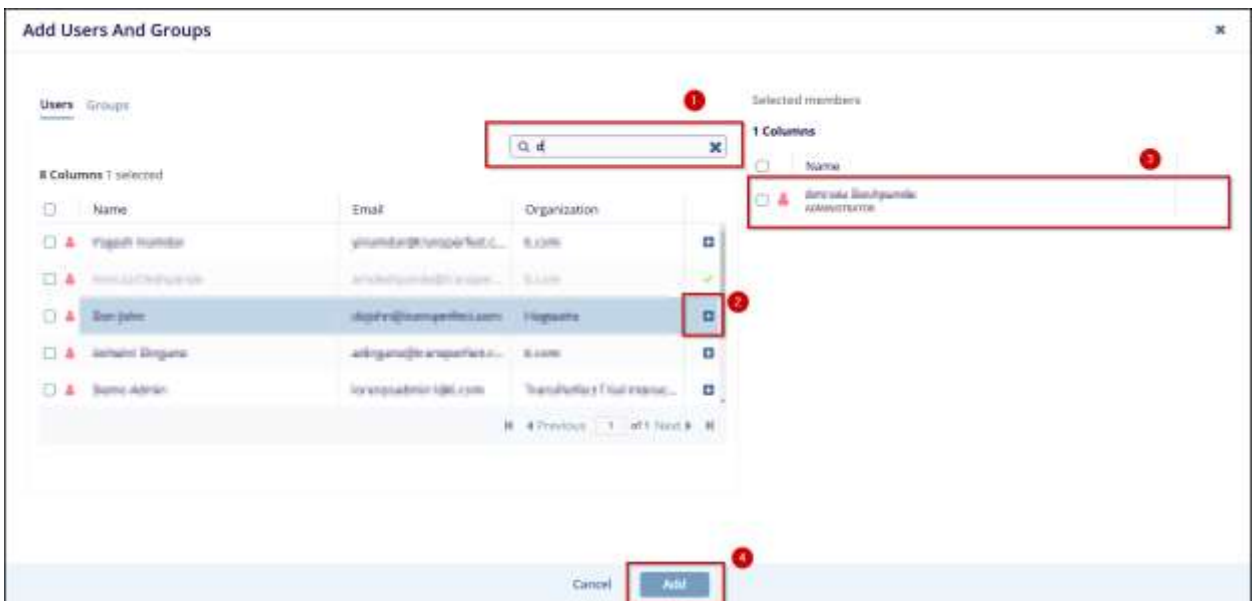




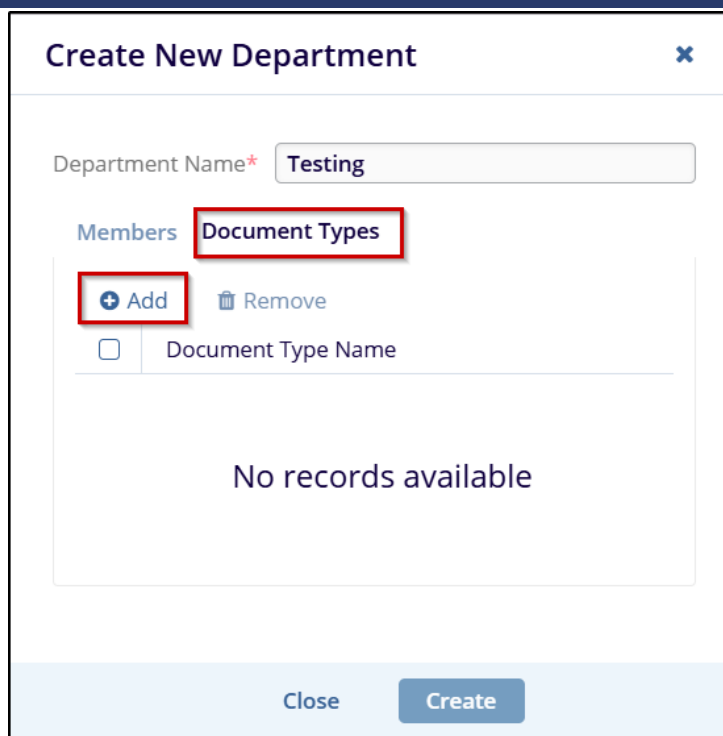
- In the Create New Department window, enter the Department Name in the mandatory field. To add members to this new department, click on the Add button in the Members section.



- The Add Users and Groups modal will display. Use the search bar to locate users and click the + icon next to the user to select them. The selected user(s) will appear in the Selected Members section on the right. After confirming the selection, click Add.



- To assign document types, switch to the Document Types tab within the Create New Department window. Click on the Add button to open the Browse Document Types modal.



**Create New Department** [X]

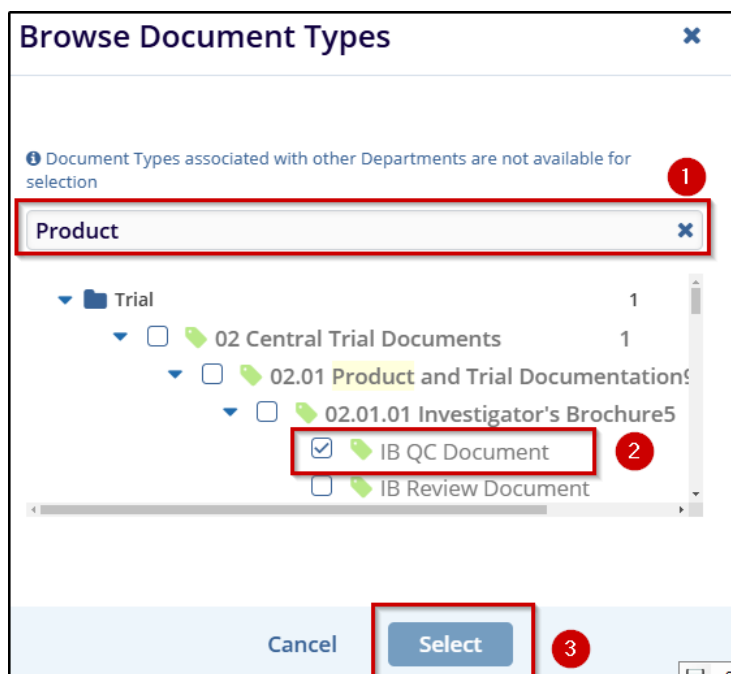
Department Name\*

**Members** **Document Types**

☐ Document Type Name

No records available

- In the Browse Document Types modal, use the search bar to locate the required document type. Select it by clicking the checkbox next to the document type, then click Select.



**Browse Document Types** [X]

Document Types associated with other Departments are not available for selection

[X]

- ▼ Trial 1
  - ▼ ☐ 02 Central Trial Documents 1
    - ▼ ☐ 02.01 Product and Trial Documentation!
      - ▼ ☐ 02.01.01 Investigator's Brochure5
        - ☒ IB QC Document 2
        - ☐ IB Review Document

3

- After adding members and document types, click Create to finalize and create the new department.

Create New Department

Department Name\* Testing

Members

Document Types

+ Add

Remove

☐ Document Type Name
 ☒ Trial\02 Central Trial Documents\02.01 Produc...

Close

Create

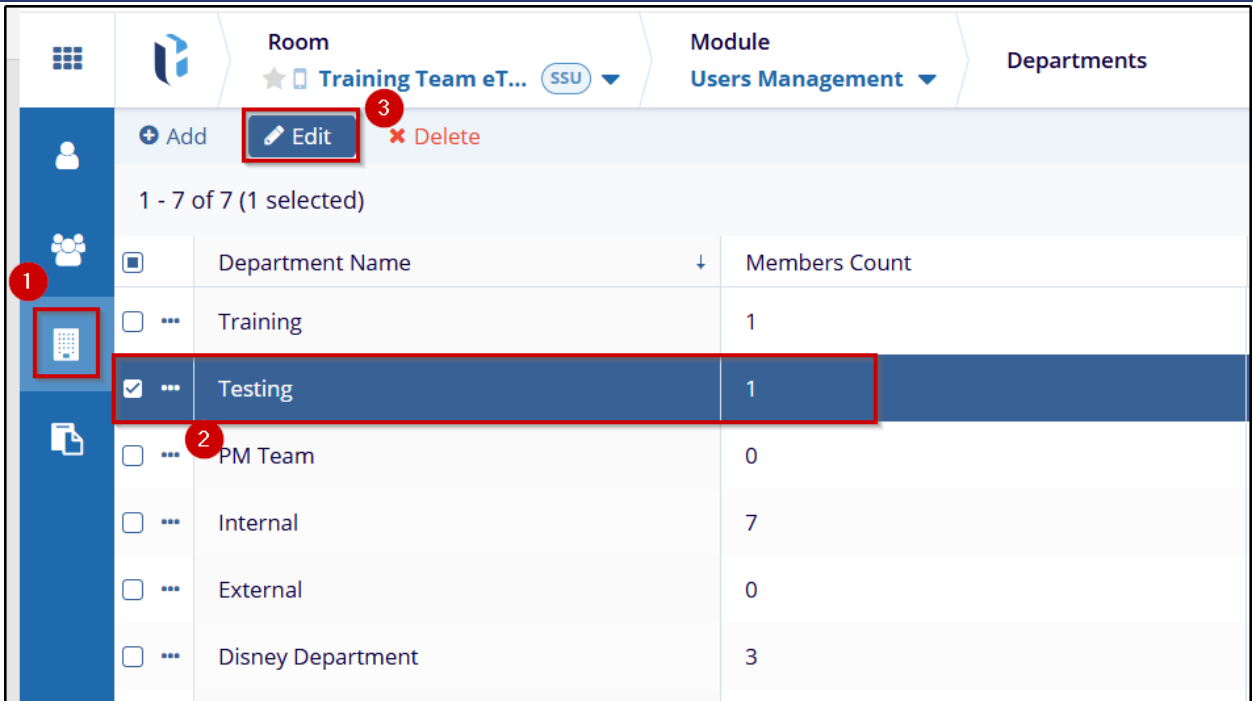
- A notification will appear, confirming that the department was successfully created.



## How to Edit/Modify the Department

### Steps to Edit the Department

- In User Management, click the Department icon in the left pane. This will open the Department screen.
- From the list of departments, select the checkbox next to the department you want to edit (e.g., the "Testing" department in the screenshot).
- Click the Edit button at the top of the screen.



Room: Training Team eT... SSU

Module: Users Management

Departments

+ Add Edit Delete

1 - 7 of 7 (1 selected)

| Department Name   | Members Count |
|-------------------|---------------|
| Training          | 1             |
| Testing           | 1             |
| PM Team           | 0             |
| Internal          | 7             |
| External          | 0             |
| Disney Department | 3             |

4. In the Edit Department window, you can modify both Members and Document Types for the selected department.
  - To manage members, click the Members tab. You can add or remove users by clicking the Add or Remove buttons. For adding members, a modal will display where you can search and select users. Once done, they will appear in the Members list.

Edit Department

Department Name\*
Testing

Members

Document Types

Add
Remove

1 Columns

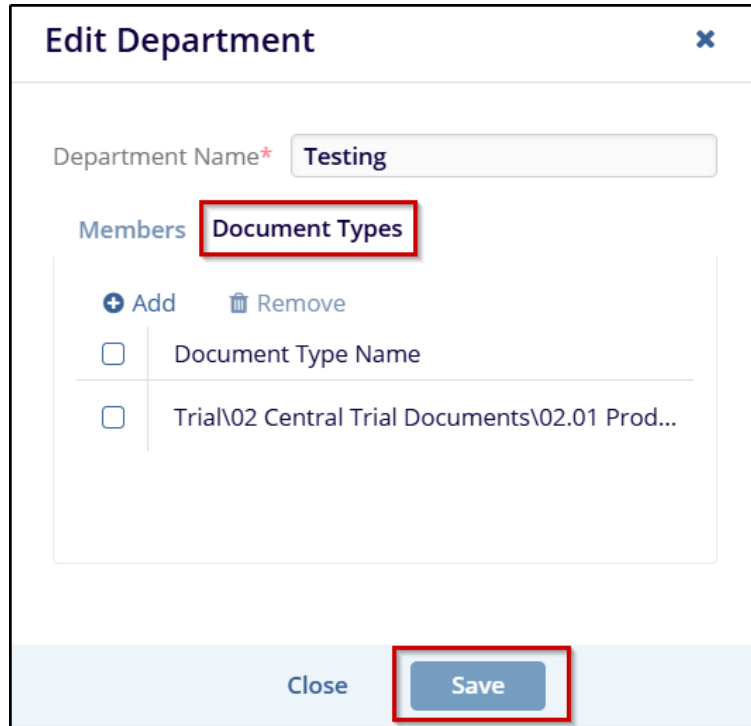
Name

test123@ti.com

Close

Save

- To manage document types, click the Document Types tab. You can add or remove document types by clicking the Add or Remove buttons. For adding document types, a modal will display where you can search and select the document type needed.



**Edit Department** ✕

Department Name\*

**Members** **Document Types**

➕ Add 🗑 Remove

| <input type="checkbox"/> | Document Type Name                             |
|--------------------------|------------------------------------------------|
| <input type="checkbox"/> | Trial\02 Central Trial Documents\02.01 Prod... |

Close Save

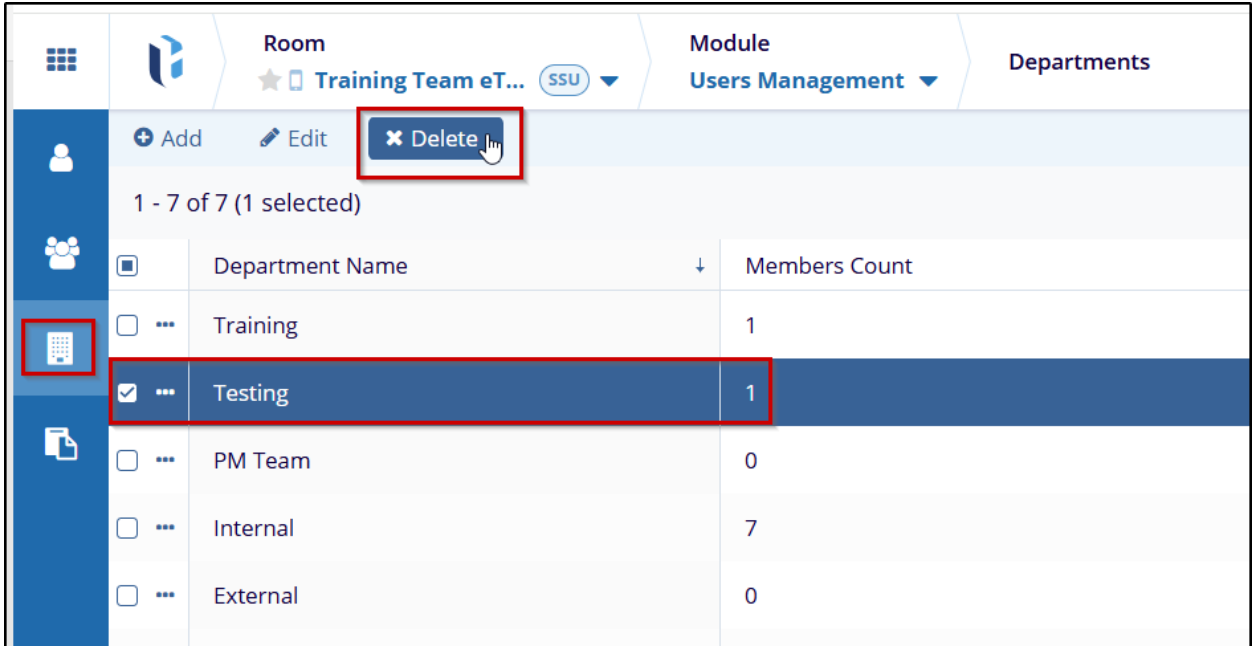
- After making the necessary changes, click Save to apply the updates to the department.



## How to Remove the Department

### Steps to Removed Department:

- In User Management, click the Department icon in the left pane. This will open the Department screen.
- From the list of departments, select the checkbox next to the department you want to remove (e.g., the "Testing" department in the screenshot).
- Click the Delete button at the top of the screen.

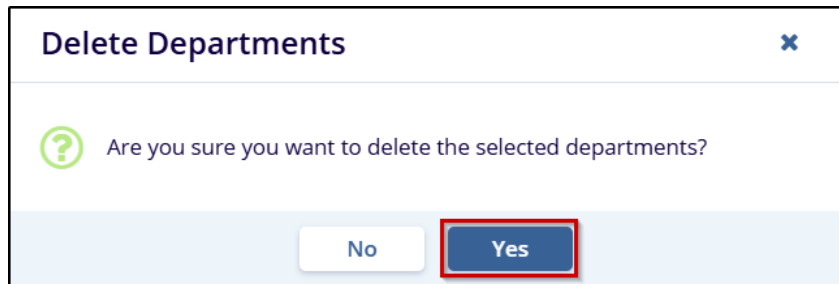


The screenshot shows the 'Users Management' module with the 'Departments' tab selected. In the top navigation bar, the 'Delete' button is highlighted with a red box. Below the navigation bar, the 'Departments' table is displayed with the following data:

| Department Name | Members Count |
|-----------------|---------------|
| Training        | 1             |
| Testing         | 1             |
| PM Team         | 0             |
| Internal        | 7             |
| External        | 0             |

The 'Testing' department is selected, and its row is highlighted in blue. The 'Delete' button in the top bar is also highlighted with a red box.

4. A confirmation dialog will appear, asking if you are sure you want to delete the selected department(s). Click Yes to confirm.
5. The department will be removed, and a notification will confirm the successful deletion.

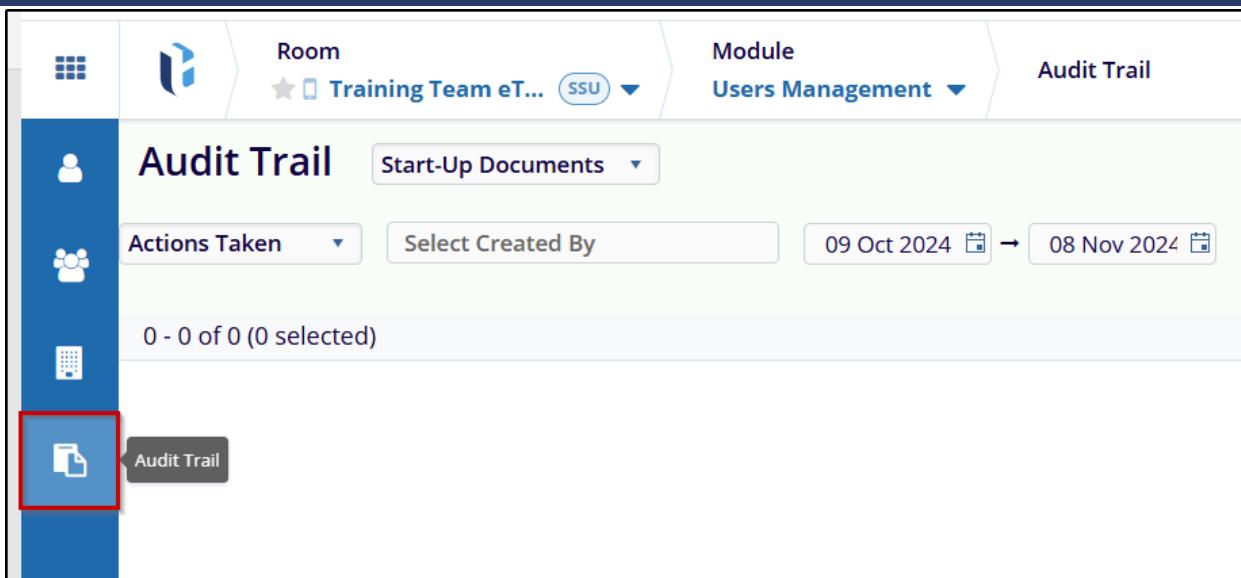


The screenshot shows a confirmation dialog titled 'Delete Departments'. The dialog contains a green question mark icon and the text 'Are you sure you want to delete the selected departments?'. At the bottom of the dialog, there are two buttons: 'No' and 'Yes'. The 'Yes' button is highlighted with a red box.

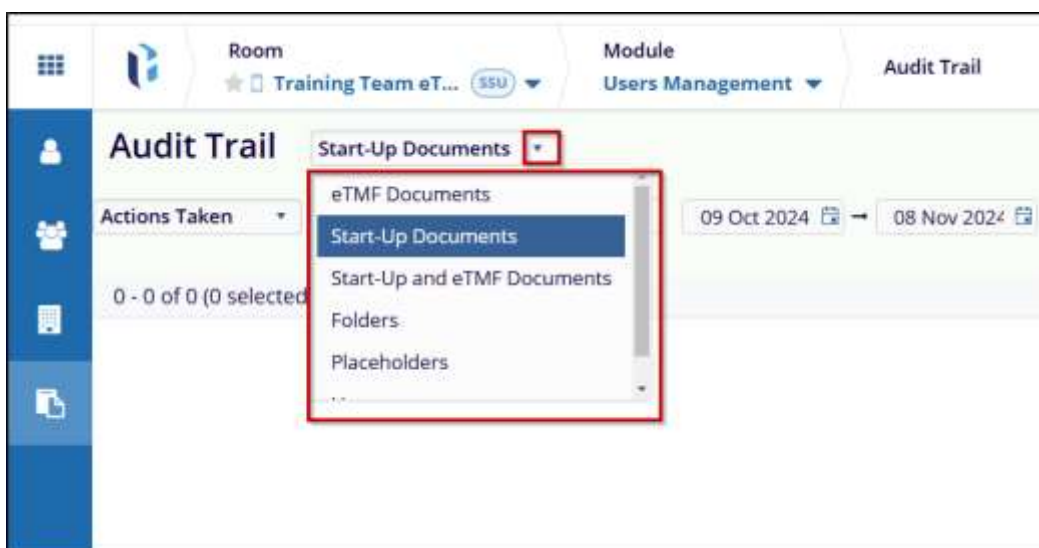
## User Management – Audit Trail

Steps to Search Documents in Audit Trail from User Management:

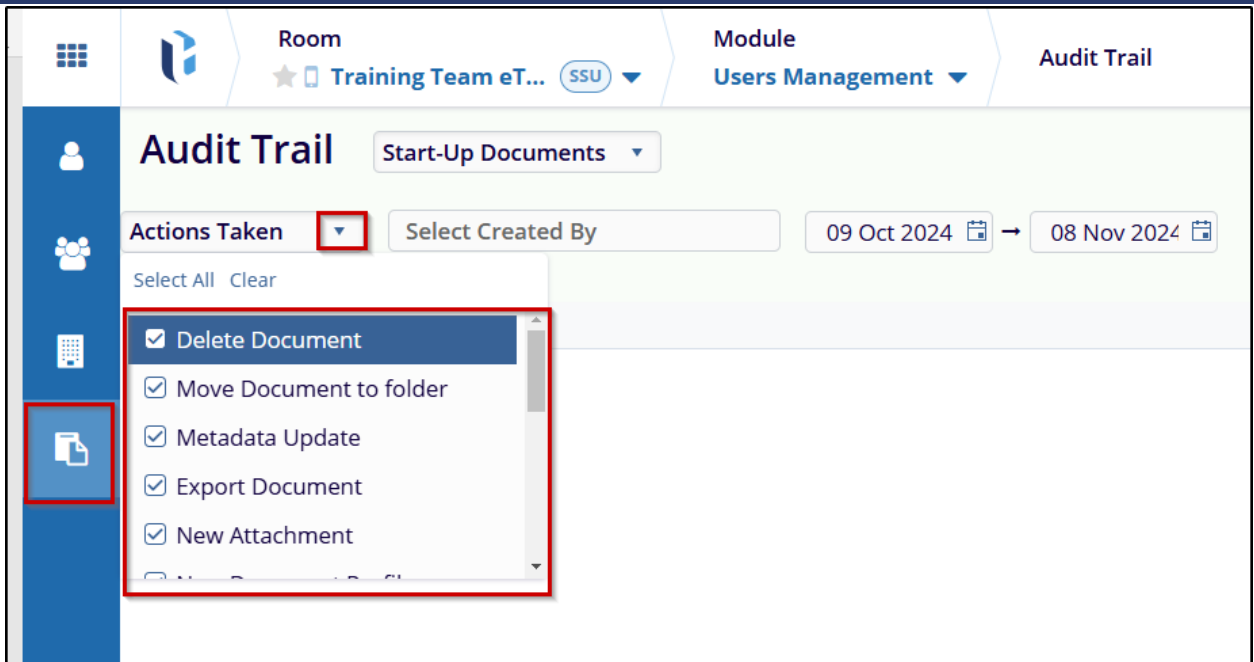
1. In User Management, click the Audit Trail icon in the left pane. This will open the Audit Trail screen.



- Click the dropdown arrow next to Audit Trail and select the required category (e.g., Start-Up Documents, eTMF Documents).



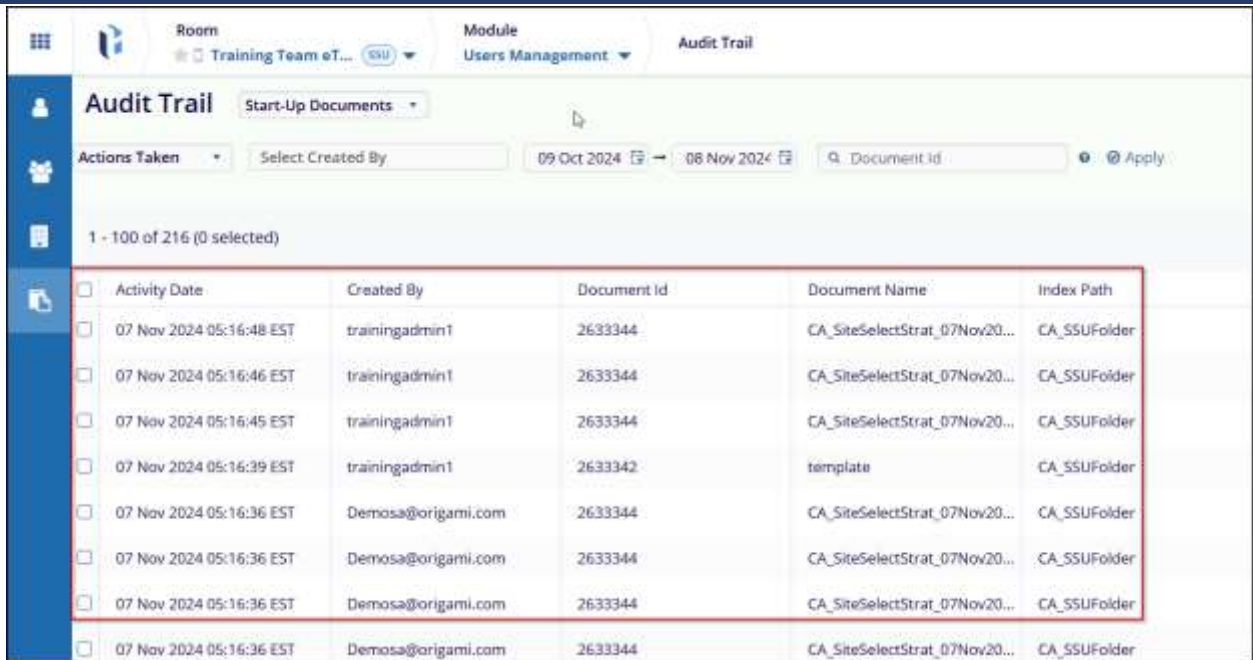
- Click the dropdown arrow next to Actions Taken. Select the actions you want to filter by checking the boxes (e.g., Delete Document, Move Document to Folder).



4. In the Created By field, select the user if necessary.
5. Enter the Start Date and End Date to specify a date range.
6. If you want to search for a specific document, type its Document ID in the search field.
7. Click the Apply button to display the search results.



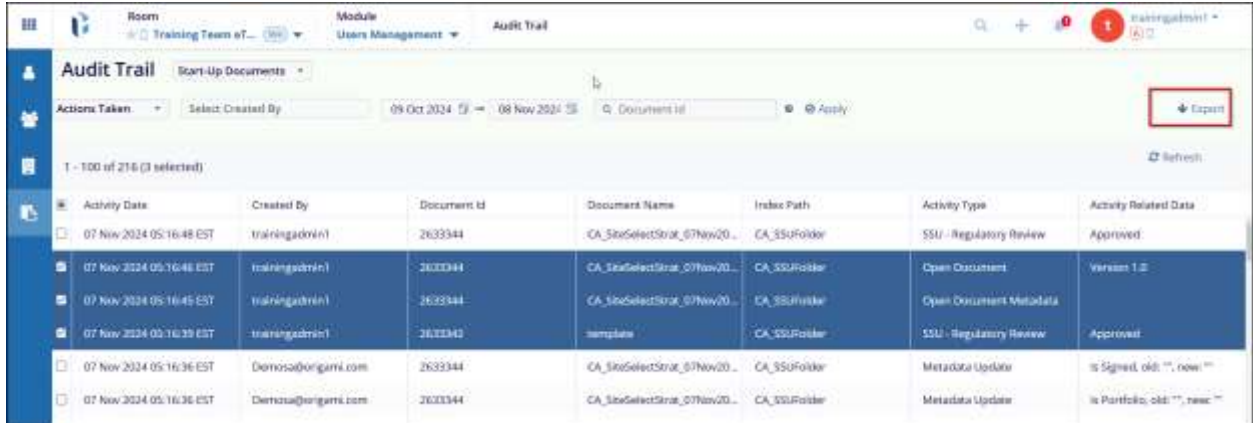




| Activity Date            | Created By         | Document Id | Document Name                 | Index Path   |
|--------------------------|--------------------|-------------|-------------------------------|--------------|
| 07 Nov 2024 05:16:48 EST | trainingadmin1     | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder |
| 07 Nov 2024 05:16:46 EST | trainingadmin1     | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder |
| 07 Nov 2024 05:16:45 EST | trainingadmin1     | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder |
| 07 Nov 2024 05:16:39 EST | trainingadmin1     | 2633342     | template                      | CA_SSUFolder |
| 07 Nov 2024 05:16:36 EST | Demosa@origami.com | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder |
| 07 Nov 2024 05:16:36 EST | Demosa@origami.com | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder |
| 07 Nov 2024 05:16:36 EST | Demosa@origami.com | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder |
| 07 Nov 2024 05:16:36 EST | Demosa@origami.com | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder |

Exporting Audit Trail Data from User Management:

8. To export the data, select the checkbox for the documents you want to export.
9. Click the Export button at the top right of the screen



| Activity Date            | Created By         | Document Id | Document Name                 | Index Path   | Activity Type           | Activity Related Data          |
|--------------------------|--------------------|-------------|-------------------------------|--------------|-------------------------|--------------------------------|
| 07 Nov 2024 05:16:48 EST | trainingadmin1     | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder | SSU - Regulatory Review | Approved                       |
| 07 Nov 2024 05:16:46 EST | trainingadmin1     | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder | Open Document           | Version 1.0                    |
| 07 Nov 2024 05:16:45 EST | trainingadmin1     | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder | Open Document Metadata  |                                |
| 07 Nov 2024 05:16:39 EST | trainingadmin1     | 2633342     | template                      | CA_SSUFolder | SSU - Regulatory Review | Approved                       |
| 07 Nov 2024 05:16:36 EST | Demosa@origami.com | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder | Metadata Update         | is Signed, old: "", new: ""    |
| 07 Nov 2024 05:16:36 EST | Demosa@origami.com | 2633344     | CA_SiteSelectStrat_07Nov20... | CA_SSUFolder | Metadata Update         | is Portfolio, old: "", new: "" |

## CHAPTER 4. TRIAL INTERACTIVE HOME PAGE

This section provides all the functionalities of the homepage and an overview of all the rooms assigned to the user.

Once signed in to Trial Interactive, users are automatically directed to the **Trial Interactive Home Screen**, as shown in the screenshot below.

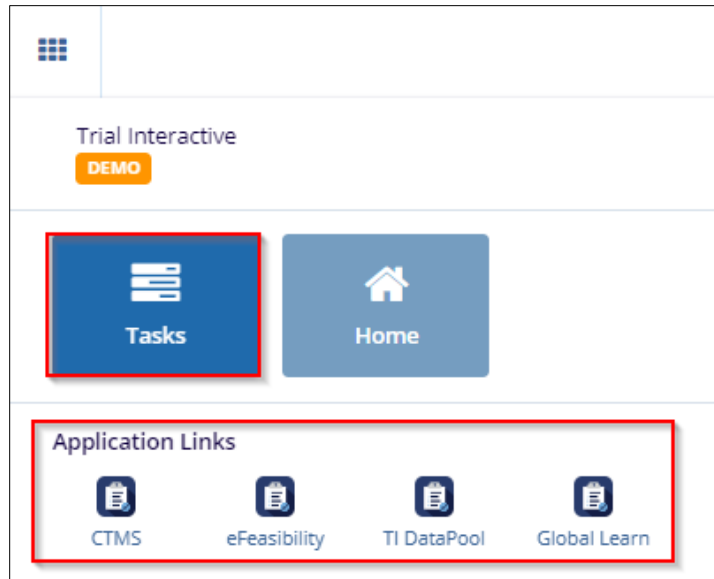


### Home Page Grid View.

1. Click on the Grid icon at the top left corner.

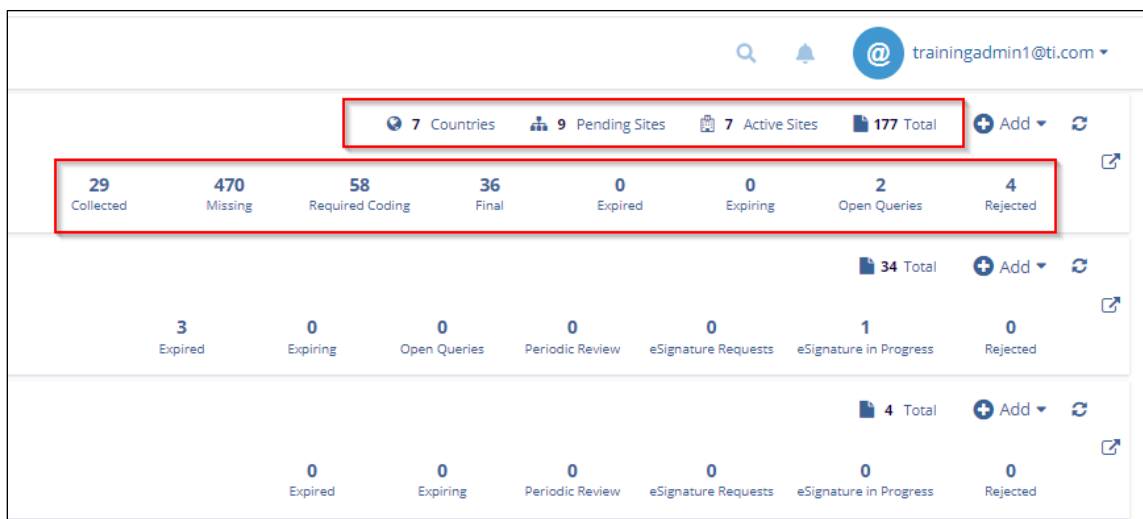


2. It displays the Tasks and Application Links.
3. To check the assigned task, click on the Task. It will redirect the user to the Task grid view.
4. Additionally, the user can access the application by clicking on the Application Name. Refer to the screenshot below.



### Rooms Documents view on Homepage

1. On the right side of the Home Page, users can view the total number of Countries, Pending Sites, Active Sites, and the total number of documents available in the room.
2. The Home Page provides an overview of document statuses, including the number of Collected, Missing, Required Coding Final, Expired, Expiring, Open Queries, and Rejected documents.



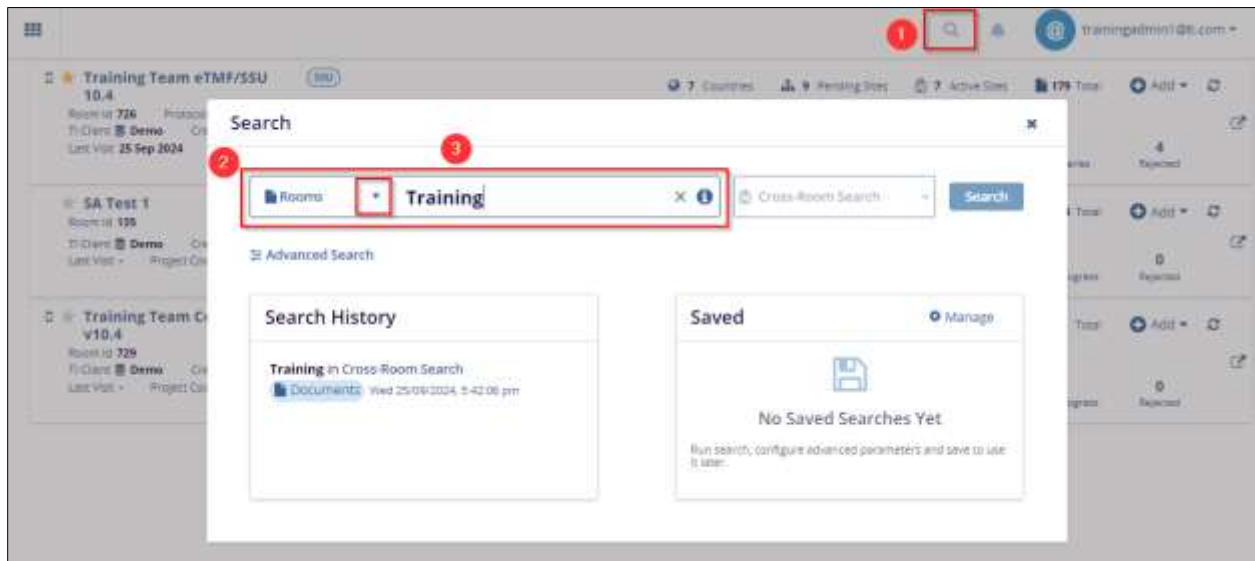
3. Below all the entities have been explained.
  - Countries: This is the number of countries in the room. It is available for eTMF or Collaborate rooms.
  - Pending sites: This is the number of non-active investigative sites. It is available for eTMF or Study Start-Up rooms.
  - Active sites: The number of active investigative sites. It is available for eTMF or Study Start-Up rooms.

- **Expired documents:** This is the number of expired documents in the room. A document is considered to be expired when it has an expiration date earlier than today. It is available for eTMF, Study Start-Up, Collaborate, and TI Docs rooms
- **Total documents:** The overall number of documents in the room. This number includes only "documents" in all modules in a room, no deleted, purged, or missing documents. It is available for all rooms.
- **Collected documents:** The number of collected documents. This number includes all documents marked as required for the eTMF, which we consider to be collected. It is available for eTMF or Study Start-Up rooms.
- **Missing documents:** The number of missing documents. This number includes all eTMF placeholders that have no document that can be considered as collected. This number represents the difference between the number of all required documents in a room and the number of required documents that we have already collected. It is available for eTMF or Study Start-Up rooms.  
In the corresponding grid, we see all placeholders we still have to submit a document and all submitted documents we do not consider as collected. For one placeholder, we may have several submitted documents, and that makes a difference in the number of missing documents we have in the KPI dashboard and the grid.
- **Required coding:** This is the number of non-final documents which are in a workflow. TI does not consider rejected documents or those documents which have been excluded from the workflow. It is available for eTMF or Study Start-Up rooms with a Workflow enabled and only for Editors and higher-level users.
- **Final documents:** This is the number of documents with a status of Final, regardless of whether the document was submitted as Final or published via the workflow. It is available for eTMF or Study Start-Up rooms with a workflow-enabled
- **Expiring documents:** This is the number of expiring documents. The expiring period is configurable on a room level via the room settings. It is available for eTMF, Study Start-Up, Collaborate, and TI Docs rooms.
- **Open queries:** This is the number of "Pending" and "In Progress" queries in the room. It is available for all rooms with queries.
- **eSignature requests:** This is the number of documents that were sent to the eSignature workflow stage and have not been signed yet. It is available for Collaborate and TI Docs rooms with eSignature enabled.
- **eSignature in progress:** This is the number of documents that were sent to the eSignature workflow stage, and signing is in progress. It is available for Collaborate and TI Docs rooms with eSignature enabled.
- **Periodic review:** This is the number of documents that require periodic review. It is available for Collaborate and TI Docs rooms with the eSignature module enabled and only for Editor-level users and higher.
- **Rejected Documents:** This is the number of Rejected documents in the room. When we click on the Rejected Symbol. The Rejected Documents window appears with the list of rejected documents presented in the room. Users can go to the document by clicking on the left-pointing arrow symbol.

## Room Search and Accessing Trial Interactive Room

1. At the top right of the application, you'll find a magnifying glass icon for searching assigned rooms.
2. Click the magnifying glass icon to open the search screen.

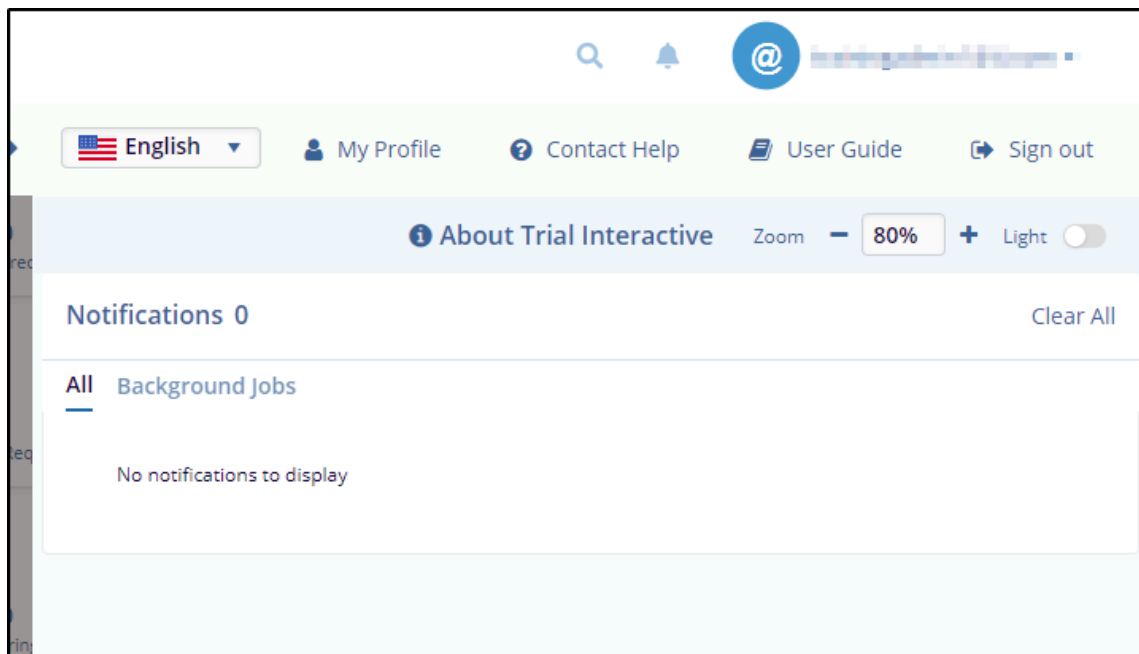
3. From there, select a room entity from the drop-down menu and type the room name to search.
4. Click on the room name in the panel to enter the room. Refer to the below screenshot



5. To learn how to perform advanced search in TI, click [Advanced Search](#).

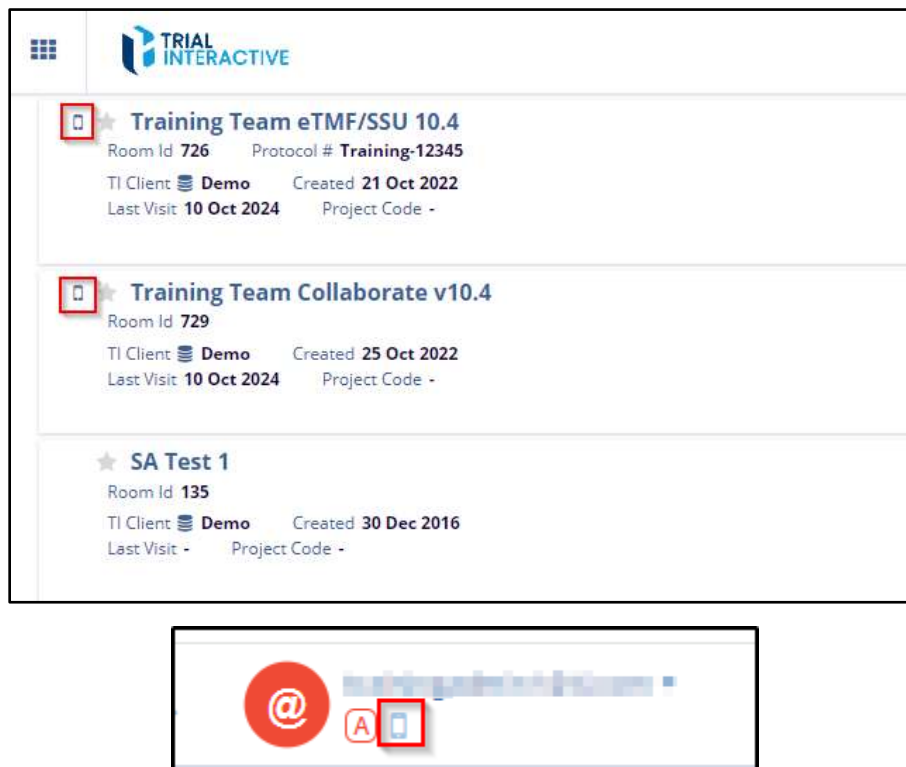
## Homepage username menu

1. Click on the Bell Icon, @Symbol or Username on the top left corner. These three options will display a side window user can check Profile, Contact Help, User Guide, About Trial Interactive and Notifications.



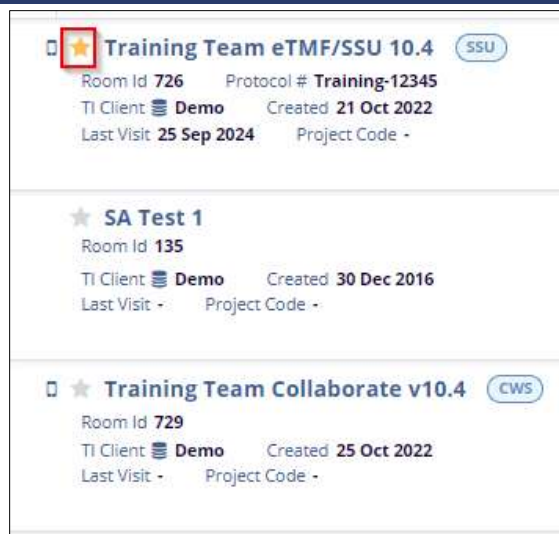
## myTI Enabled Rooms

To make it easier to keep track of the rooms you have access to through both the standard online application and myTI, an icon will now appear next to any room accessible via myTI. This icon will also be visible within the room itself and will be added to your Username Menu dot for quick identification.



## Mark Room as Favorite

1. On the left side of the Home Page, users can view a list of all assigned rooms, along with detailed room-specific information. Key details, including Room ID, Creation Date, Last Visit, Protocol, TI Client, and Project Code, are displayed for convenient reference. Users can also mark a room as a favorite by clicking the Star Icon.



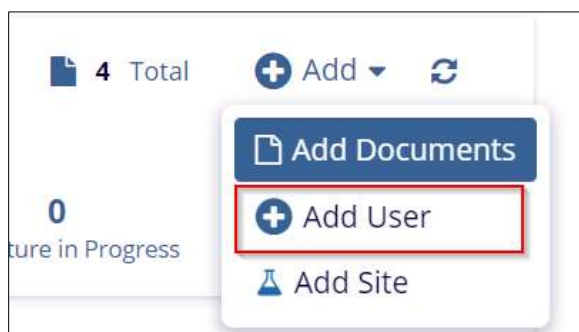
## Add Users to a Room from the Home page

Steps to Add Users to a Room from the Home Page:

1. Click the 'Add' dropdown on the right side of the room line on the home page.



2. From the dropdown list, select 'Add Users'. This will open the User Invitation window.





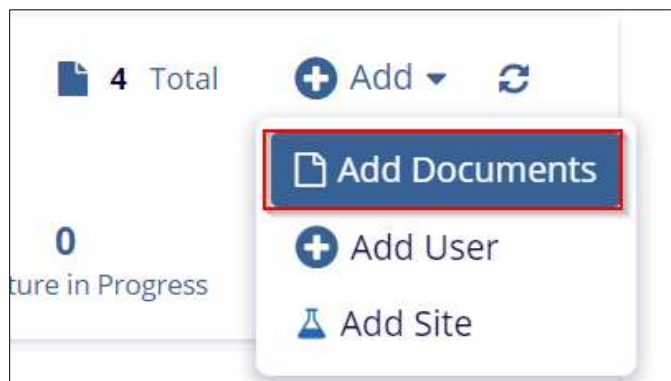
3. Insert all Mandatory fields. We have three sections User details, Invitation Details, and Contact Details.
4. Select any Groups if you want to add the user to a group.
5. From the Organization dropdown, choose the relevant organization. You can also create a new organization by clicking the (+) sign.
6. In the Invitation Details section, we can select the appropriate Expiration Date and Time. It is used to remove user access from a particular room after a specific period.

## Import Documents to a Room from Home Page

1. Click the Add dropdown button located on the right side of the room on the home page.



2. Select 'Add Documents' from the dropdown. The Import Documents window will appear.



3. Drag and drop the files into the window, or click 'Browse' at the bottom of the page to locate and upload the required document.





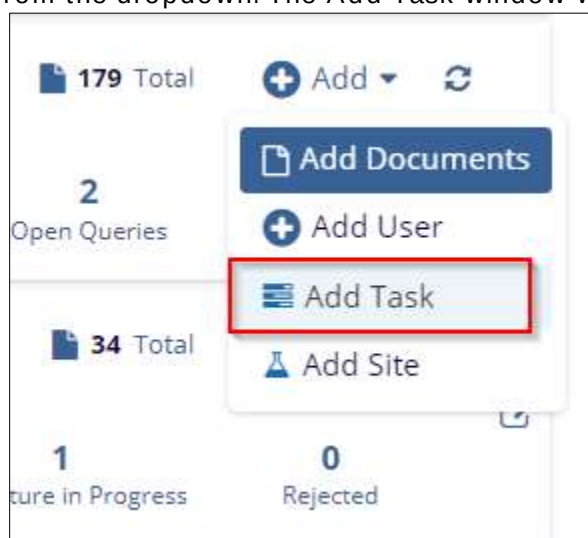
4. After uploading the document user can apply Metadata.

### Add Task to a Room from the Home Page

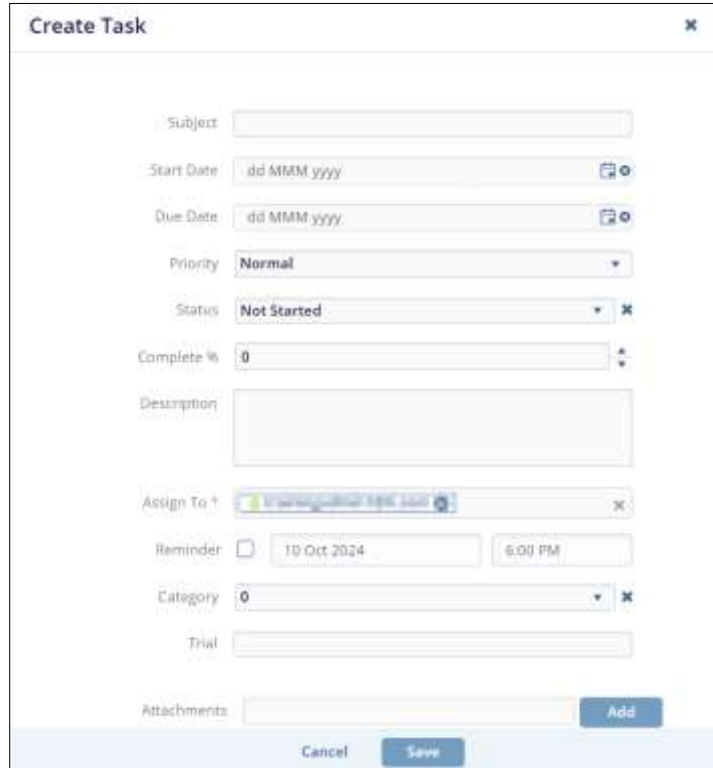
1. Click the Add dropdown button located on the right side of the room on the home page.



2. Select 'Add Task' from the dropdown. The Add Task window will appear.



3. The **Create Task** window will open.
4. Enter the required details as prompted on the screen.



The 'Create Task' window displays the following fields and controls:

- Subject:** A text input field.
- Start Date:** A date picker showing 'dd MMM yyyy'.
- Due Date:** A date picker showing 'dd MMM yyyy'.
- Priority:** A dropdown menu currently set to 'Normal'.
- Status:** A dropdown menu currently set to 'Not Started'.
- Complete %:** A numeric input field currently set to '0'.
- Description:** A large text area for detailed notes.
- Assign To:** A dropdown menu with a search icon and a close button.
- Reminder:** A checkbox, a date field set to '10 Oct 2024', and a time field set to '6:00 PM'.
- Category:** A dropdown menu currently set to '0'.
- Trial:** A text input field.
- Attachments:** A text input field with an 'Add' button next to it.

At the bottom of the window are 'Cancel' and 'Save' buttons.

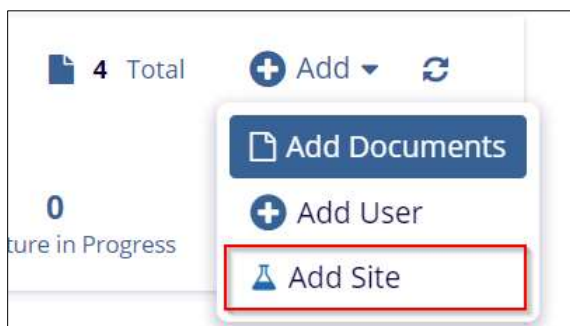
5. Once all the information is entered, click **Save** to complete the task creation.

## Add Sites to a Room from the Home Page

1. Click the Add dropdown button on the home page's right side of the room.



2. Select 'Add Sites' from the dropdown. The New Site window will appear.



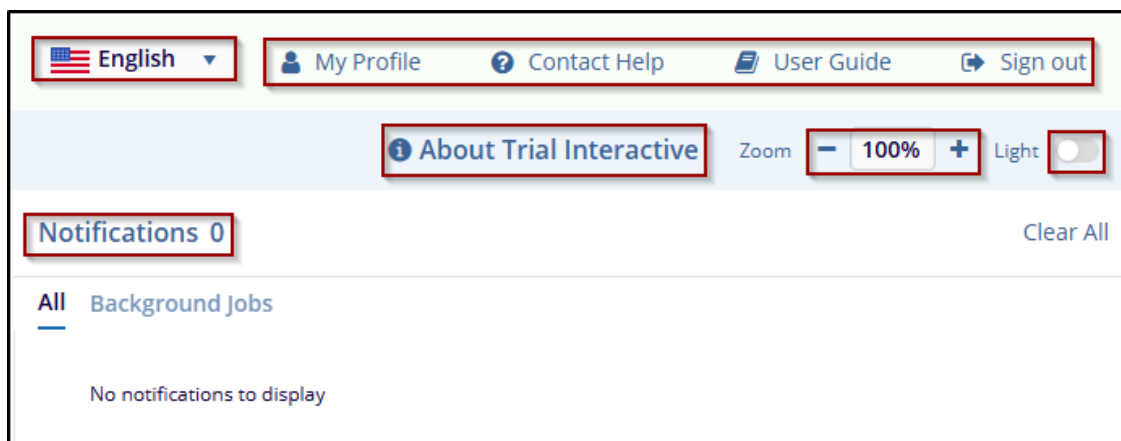
## CHAPTER 5. USERNAME MENU

This section describes the functions and features under the Username Menu.

To Navigate the user menu, click on the user's name or the drop-down arrow displayed in the top right corner of the homepage

Through the Username Menu, you can access the following:

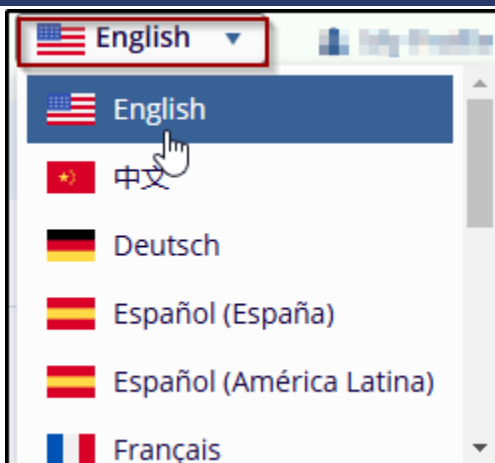
- Language Settings
- My Profile
- Contact Help (Contact Support)
- User Guide
- Sign Out
- About Trial Interactive
- Zoom
- Dark Mode/Light Mode
- Notifications



### Language Setting

To set your preferred language:

1. Click on the Language dropdown.
2. Scroll down to locate your preferred language.
3. Click on the language to select it.
4. The room menu and field labels will change to the selected language.

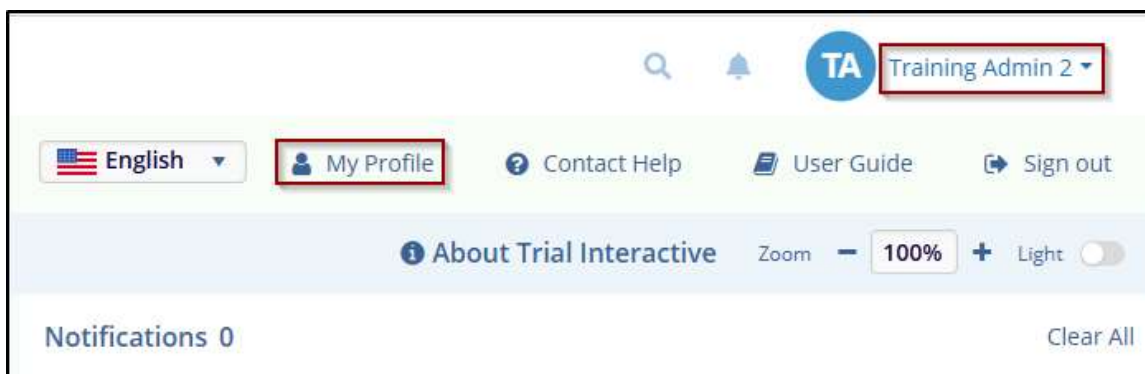


## My Profile

By clicking on the 'My Profile' option. The User can manage the profile. Please note that these settings are user-specific and are not room-specific, any changes made in this area impact the overall user account and are not contained in any single TI room.

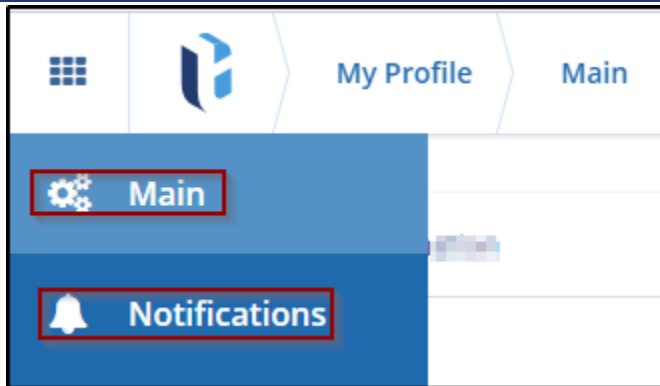
To access My Profile:

1. Click the Username dropdown located at the top right corner
2. From the pop-up that appears, click 'My Profile.'
3. You will be taken to your profile settings page.



My Profile area is divided into two sections:

- Main (My Profile Settings)
- Notifications



Navigate to the vertical menu at the left to choose sections. Click on the Main section from the left panel.

In this Section, you will find the following User Profile Dashlet.

- General Information
- Password Recovery - Secret Questions
- User Avatar
- Change Password
- Site Filtering Options



## General Information

To set the preferred language and date applicable:

1. Click on the Language dropdown.
2. Scroll down to locate your preferred language.
3. Click on the language to select it.
4. The user profile dashlet and field labels will change to the selected language.
5. Click on the checkbox to enable custom date input.
6. Enter the date format preferred by user. Date format should contain day ("D", "DD"), month ("M", "MM", "MMM", "MMMM"), year ("YY", "YYYY") and separator ("/", "-", ":")
7. Once done, Save the changes. By clicking on the Save button.

▲ General Information

Language

English ▼

☐ Enable custom date input

Date Format

*ⓘ* Date format should contain day ("D", "DD"), month ("M", "MM", "MMM", "MMMM"), year ("YY", "YYYY") and separator ("/", "-", ".")

Cancel

Save

## Password Recovery – Secret Question

You are required to set the answers to secret questions to help recover passwords in case they forget their Password.

To set the secret questions and their answers:

1. Click the down arrow in the "Question 1" field. Scroll through the list of questions in the popup and select your preferred question.
2. Click on the question of your choice to select it.
3. Enter your answer in the "Answer" field.
4. To confirm your password, click on the "Unmask answer" icon.
5. A pop-up will appear "Please provide your password to unmask the answer". Provide your answer and click on the "Ok" button.
6. Click the "Save" button.

▲ Password Recovery - Secret Questions

Question1\*

What is your favorite hobby?

Answer\*

.....

Question2\*

What was the name of the first company for which you ...

Answer\*

...

Question3\*

What was the name of the city you lived in at age 16?

Answer\*

.....

Cancel Save

**Provide Your Password** ✕

Please provide your password to unmask the answers.\*

Cancel OK

## Change password

In this section, you can change the existing password to set a new one.

To set the password:

1. Enter the "Current password" in the text field
2. In the next text field enter the "New password".
3. Re-enter the new password in the Confirm New Password field.



4. Click the Save button for the new password to be applicable.

Note: Password Requirements:

- Must have at least 8 characters.
- Must contain one uppercase letter, digit, and one special character.
- Valid special characters are -!@#\$%

▲ Change Password

Please change your password

Password Requirements:

1. Must have at least 8 characters  
2. Must contain one uppercase letter, digit and one special character  
3. Valid special characters are -!@#\$%

Current Password\*

New Password\*

Confirm New Password\*

Cancel

Save

## Sites Filtering Options

You can choose to view only those sites where you are assigned as a CRA or as a Study Startup Specialist in either the Sites sub-module or in the SSU application in Trial Interactive.

▲ Site Filtering Options

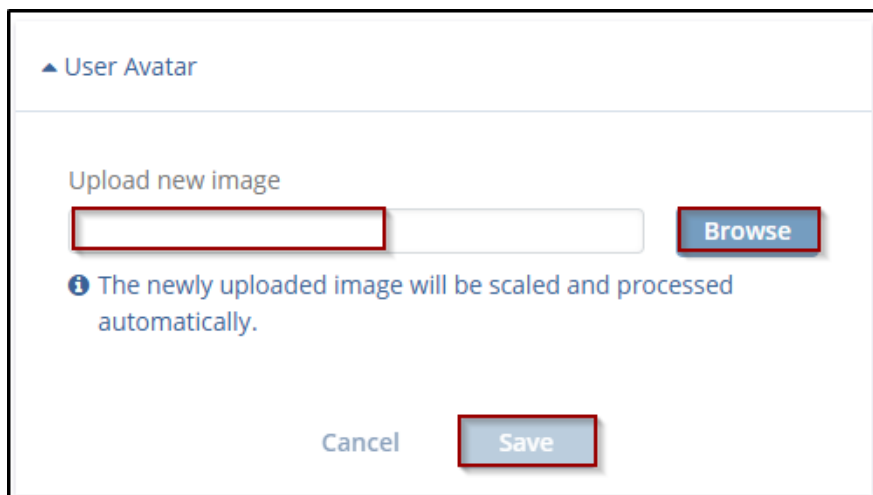
☒ Show only my sites (my favorite sites, and the sites where I am CRA / Start Up Specialist)

Cancel

Save

## User Avatar

Click on the “Browse” button to upload a new image for your login, and click the “Save” button.



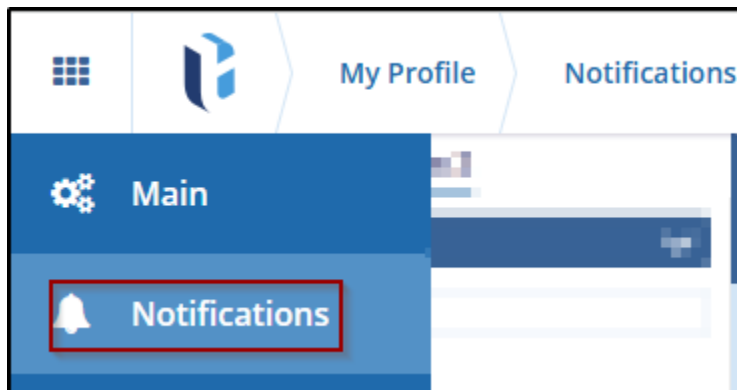
▲ User Avatar

Upload new image

*i* The newly uploaded image will be scaled and processed automatically.

## My Profile Notifications

You also have the Notifications section that allows you to specify which email notifications you would like to enable for your account for each of the rooms to which you have access.



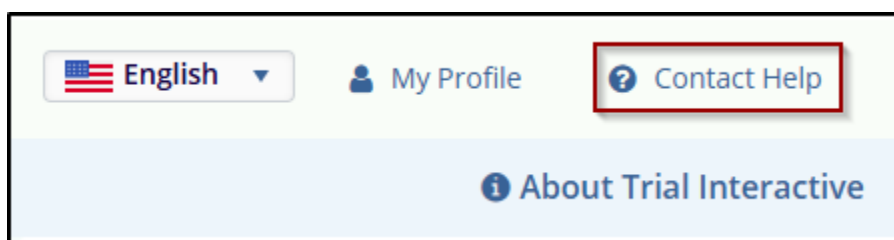
Select the desired room from the list of studies in the left pane of the Notifications panel. Using the options grid on the right of the Subscriptions window, you can select which notifications you would like to receive. Administrators can choose which notifications are available for you, and they can make some choices default or mandatory:

You can select to receive either a mini summary of notifications or you can choose nightly newsletters recapping all of the new events in the past 24 hours for each of the notification categories. The room administrator selects the frequency of mini-notifications in the Settings module.



## Contact Help

In this section, where you need any help related to Trial Interactive, you can contact the Service Desk by clicking on “Contact Help” from the Username Menu.



This opens the Contact Support window, which allows you to enter the details for the request needed and send it to the service desk. Refer to the screenshot below.

**Contact Support**
✕

Hello Training, please fill out this form to reach the Service Desk for assistance.

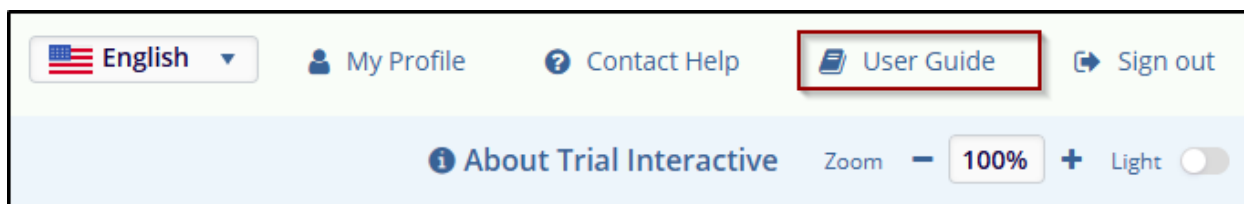
Room Name\*

Email Address\*

Open Sans
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B I U S
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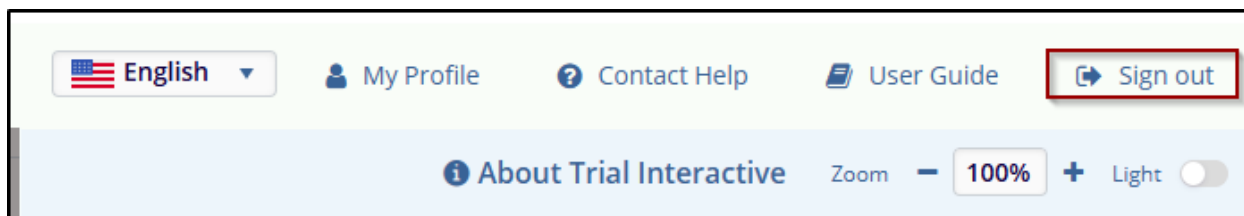
## User Guide

This section takes you to the “Online User Guide” which contains the full contents of this document, in addition to job aids and videos designed to help you perform many of the most common tasks in Trial Interactive.



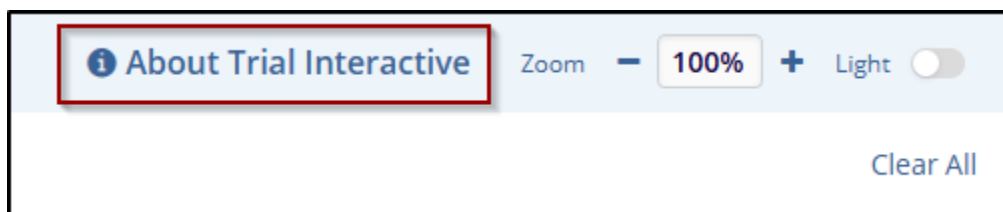
## Sign Out

Click on the Sign-out button at the top right corner, as shown in the below screenshot and you will be logged out of your account.

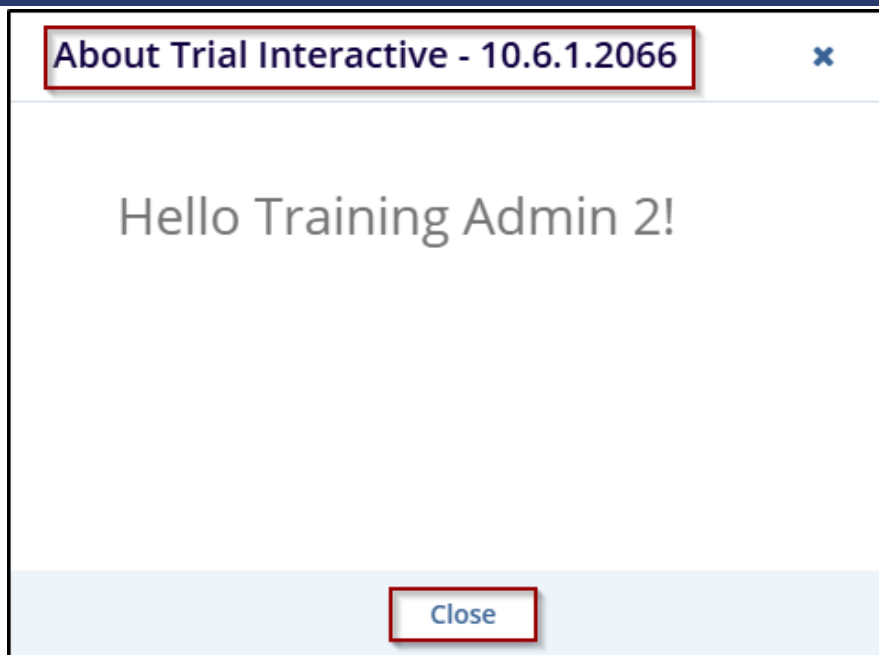


## About Trial Interactive

Click on the “**About Trial Interactive**” link to reveal the About Trial Interactive. Administrator-level users typically configure this to welcome new users and provide them with information about the Trial Interactive version.

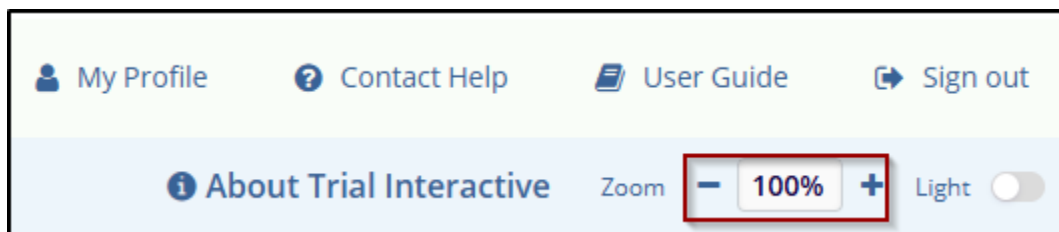


Click on “close button” at the bottom, to close the pop-up window of Trial Interactive



## Zoom

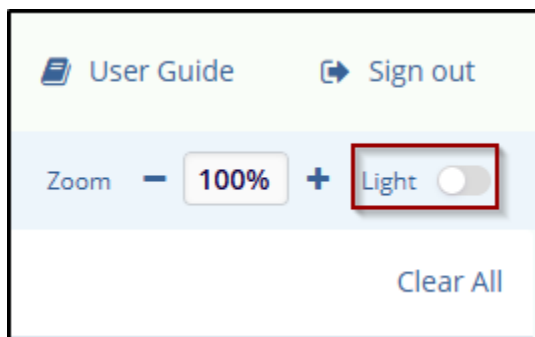
To zoom in on a room, press on “+ sign” to enlarge the content size. To zoom out, press on “- sign” to decrease the content size, as shown in the below screenshot.

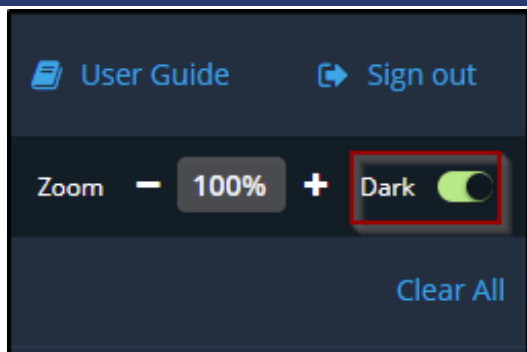


## Dark mode/light mode

To switch between Dark Mode and Light Mode. Choose Dark Mode for a low-light-friendly interface or Light Mode for a brighter look, switch based on your system preferences.

As shown in the below screenshot.

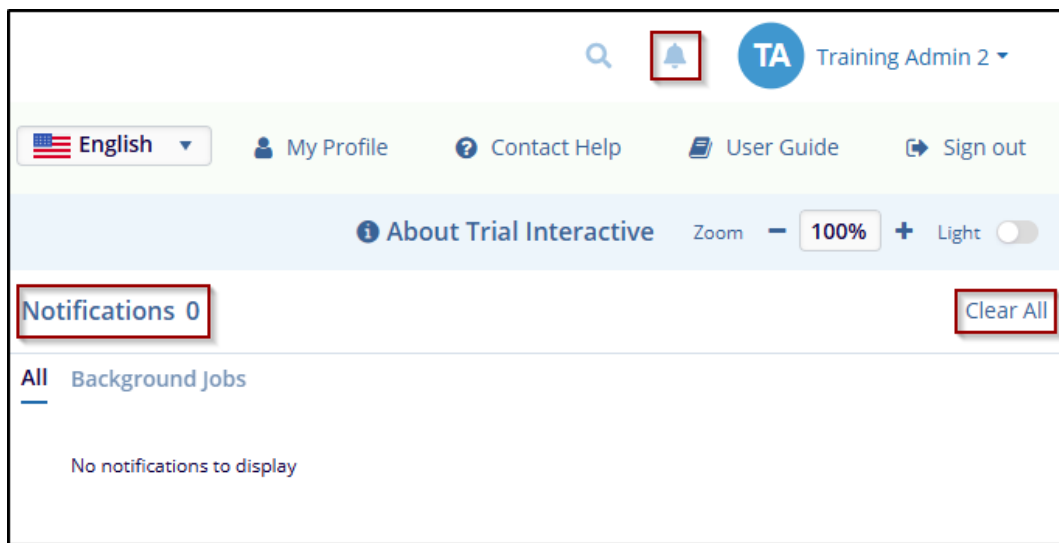




## Notifications

When the Username Menu slides out from the side of the screen, the lower portion is dedicated to the Notifications panel. From here, you can view messages associated with tasks that you have performed in the system. When you request an export or download, if you miss the initial notification option to get the job result, the notification will still be available in this section until you leave the room. The number of notifications for your current TI session is indicated by a number in a red circle next to the bell icon at the top-right of the screen.

Refer to the screenshot below:



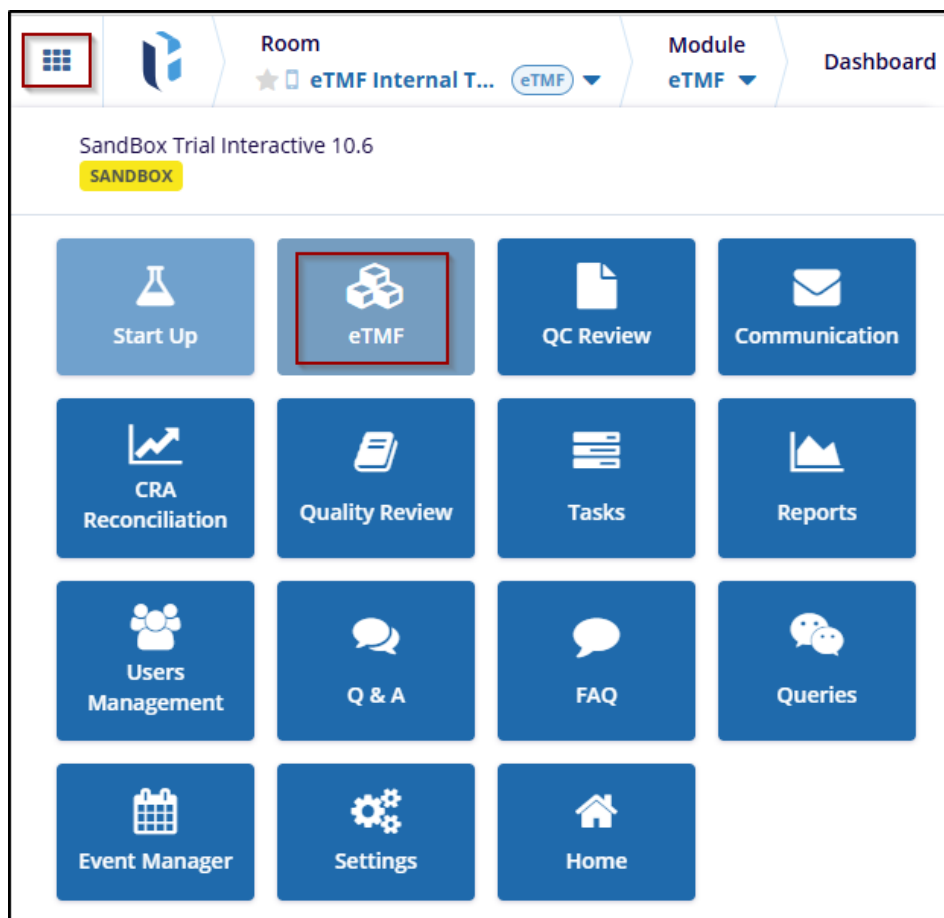
This section displays the following tabs:

- **All:** Click this tab to get a list of all the tasks that are ongoing, pending, or overdue. This is a shortcut that provides you with an overview of all the tasks in your current room.
- **Background Jobs:** Through this tab, you are notified about a background job that is executed or completed.
  - Some messages, like downloading/mass coding documents, provide the Get Job Result button that you click to get further details on the action, like a message or a downloadable file.
- **Clear All:** Click on this tab to immediately clear all notifications.

## CHAPTER 6. TRIAL INTERACTIVE ETMF MODULE

The eTMF module serves as a central access point for Clinical Trial Documents, eTMF Sites, Contacts, eTMF Completeness, and CRA Reconciliation Reports for clinical trial activities. It also provides access to IRB (Institutional Review Board) Integration and Potential Sites.

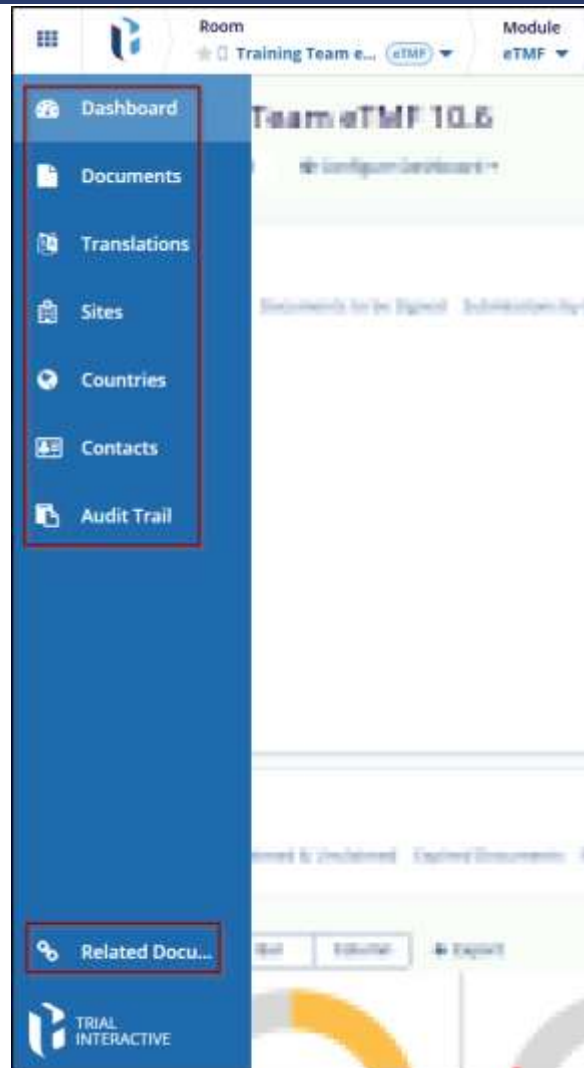
Users can access this module from the 'Navigation Grid' in the upper-left corner of the screen, where the eTMF module is listed below.



The eTMF module includes:

- Dashboard
- Documents
- Translations
- Sites
- Countries
- Contacts
- Audit Trial
- Related Documents Settings

Refer to the screenshot below:



Note: The Toolbar options are available per the room settings and user access.

Navigate to the Toolbar on the left panel of the screen and click on the Dashboard section.

## Dashboards

The Dashboard allows users to customize their workspace by adding, removing, or rearranging tabs based on user preferences. Administrator-level users can configure default dashboards for users according to the user access levels. Unless restricted, users can modify their dashboards to suit the user's needs.





The dashboard includes the following edit options:

- Edit Dashboard
- Configure Dashboard

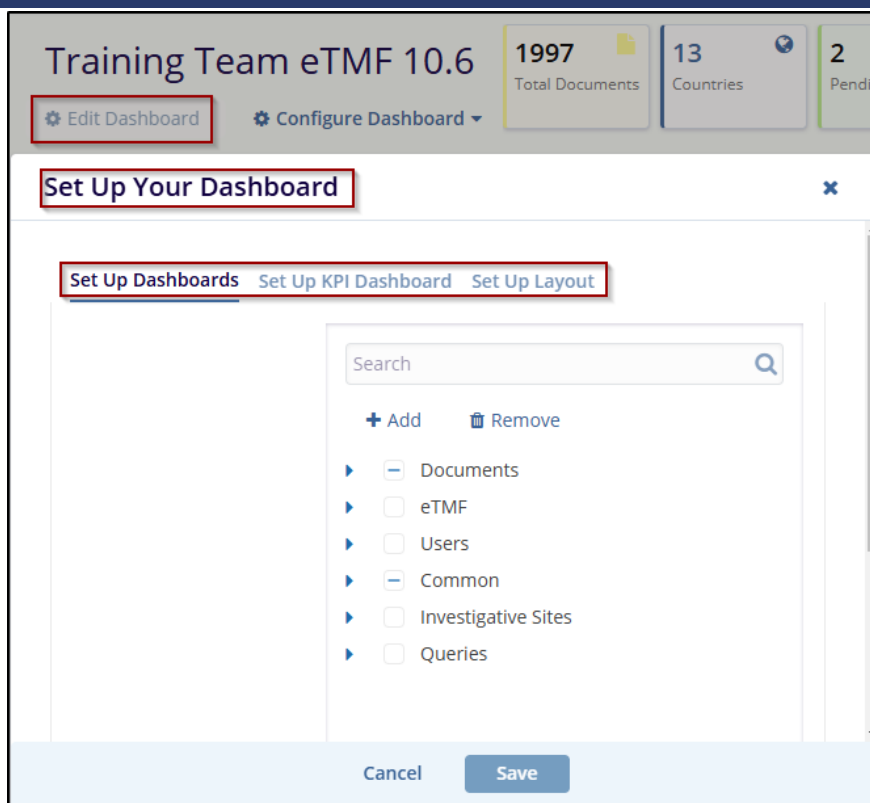


## Edit Dashboard

The Edit Dashboard allows users to customize the dashboard by adding or removing tabs, reorganizing layout options, and customizing the dashboard to show the information that is most important to the user. It ensures a personalized view for better accessibility of required data.

Steps to Edit the Dashboard:

1. Navigate to the Dashboard section in the eTMF module.
2. Click on the Edit Dashboard button located at the top left of the Toolbar.
3. Once clicked on Edit Dashboard, the Set Up Your Dashboard window will appear.
4. It includes the relevant options, such as:
  - Set Up Dashboards: For selecting or adding widgets.
  - Set Up KPI Dashboard: For managing key performance indicators.
  - Set Up Layout: For customizing the layout.

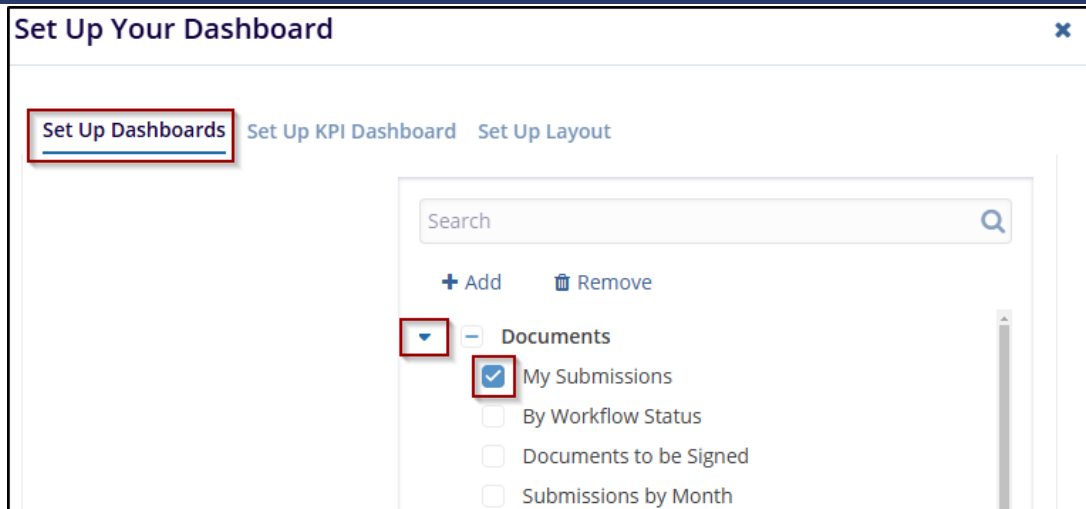


### *Set Up Dashboards*

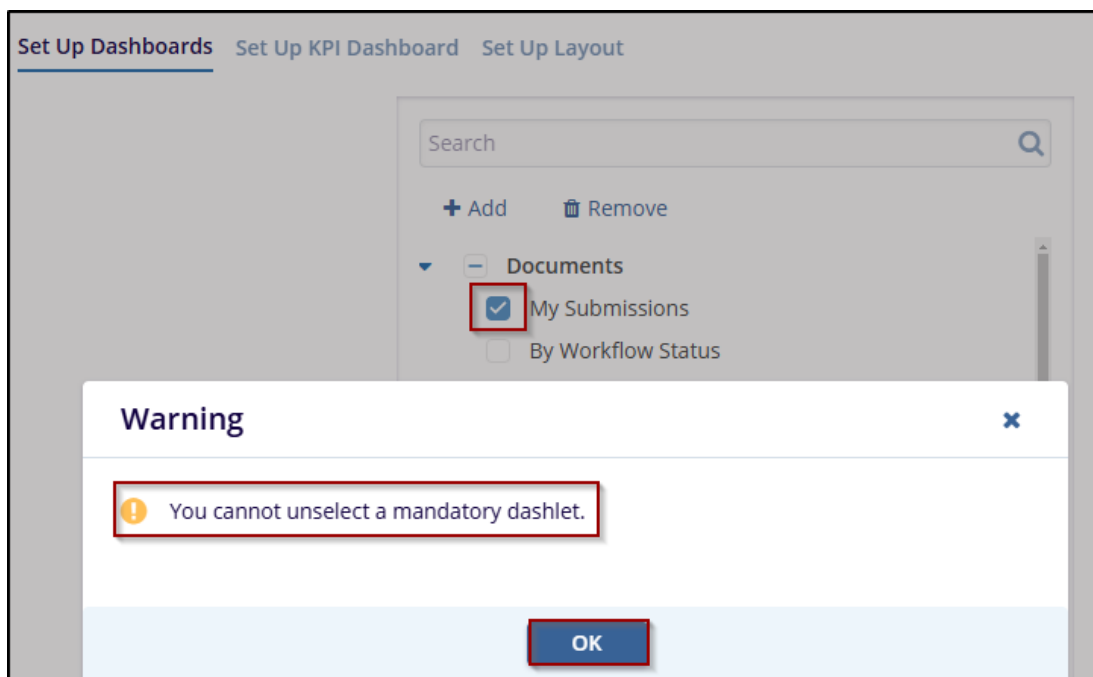
The Set-Up Dashboards allow users to customize their dashboards by adding, removing, or managing dashlets. Dashlets are individual components that display specific types of data or functionality on the dashboard, helping users personalize their view to highlight the most relevant information.

Steps to set up the dashboard.

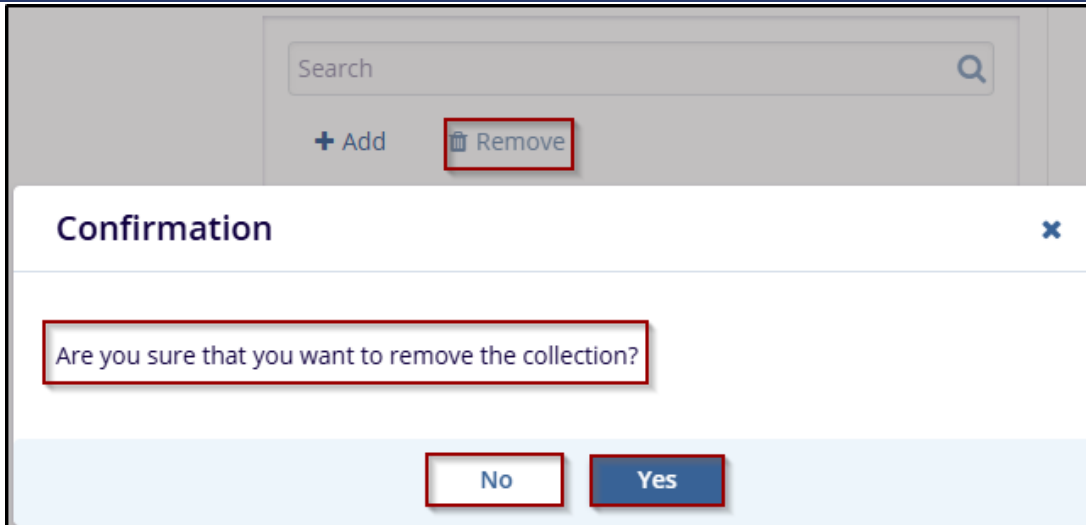
1. The Set Up Your Dashboard window appears. By default, the Set-Up Dashboard option is displayed. Expand the fields using the arrow and select the required checkbox.



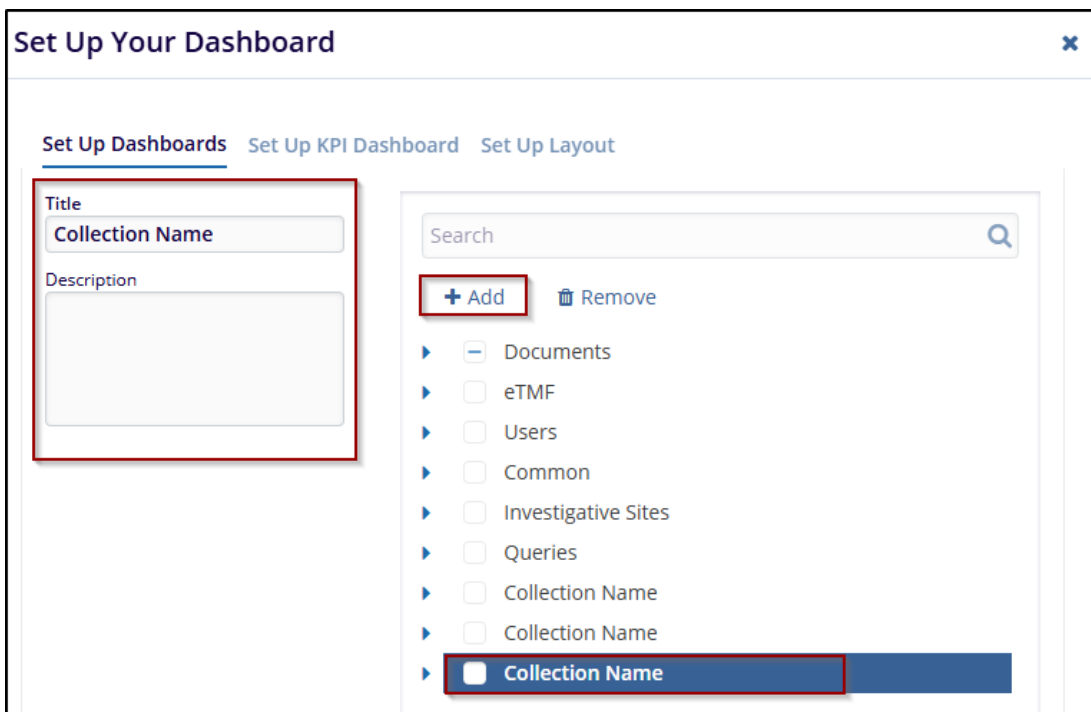
2. In the Document dashlet, unselecting the checkbox for My Submissions, a warning message window will pop up stating: **'You cannot unselect a mandatory dashlet.'**
3. Click the OK button to close the warning window.



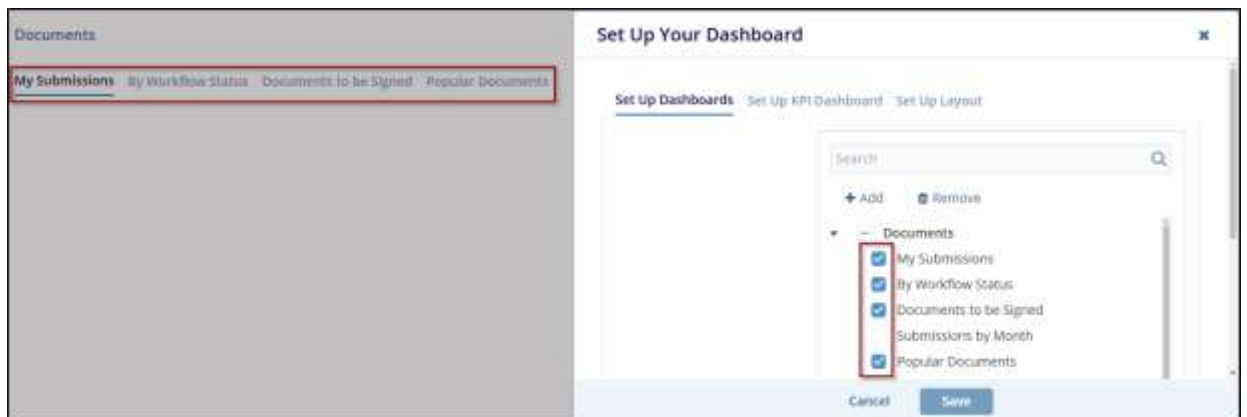
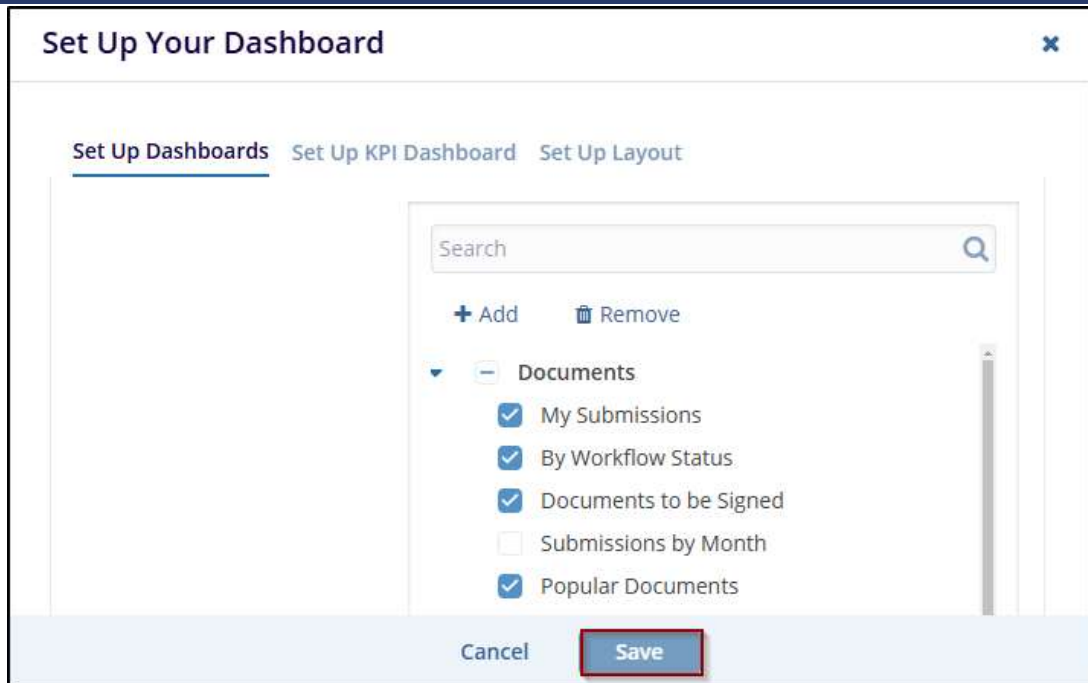
4. Click the Remove button to initiate the removal process. A confirmation window will appear with the message: 'Are you sure that you want to remove the collection?'. Also, the user can only remove the newly added fields and not the pre-defined fields.
5. Click Yes to confirm and remove the collection or click No to cancel the action and keep the collection.



6. Click on the Add button, and a new entry will appear under the list of available dashlet as (collection Name). While adding a new dashlet, the user has to mention the Title and Description in the left-side fields.



7. Once all necessary changes are completed. Click the Save button at the bottom of the popup window to apply the changes.



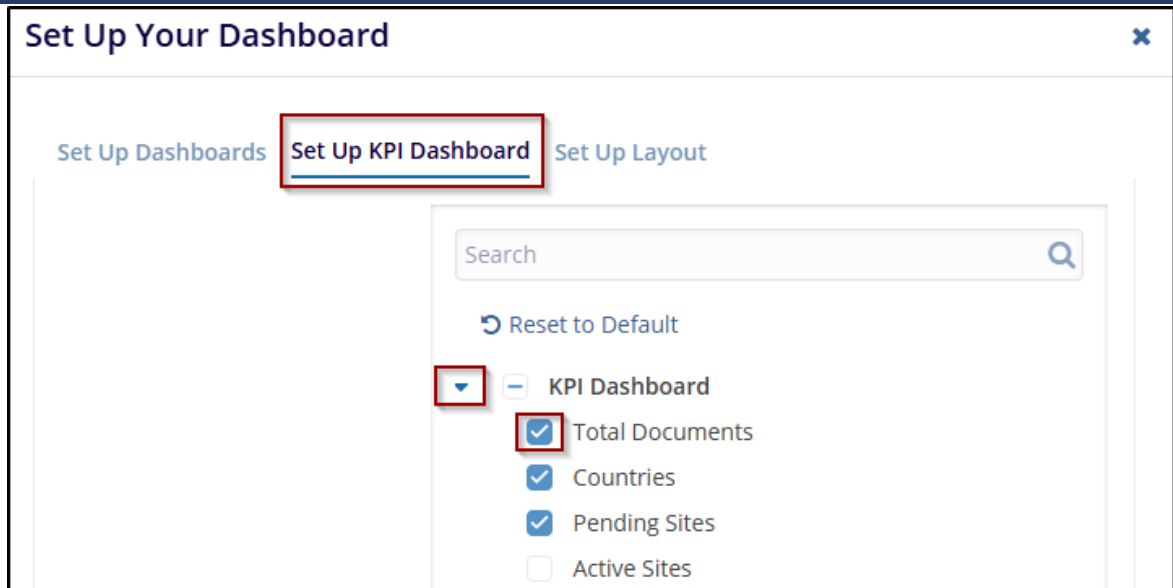
Note: The checkbox(s) selected for each dashlet from the set up your dashboard window will only display those tabs in the Dashboard. Refer to the above screenshot.

### Set Up KPI Dashboard

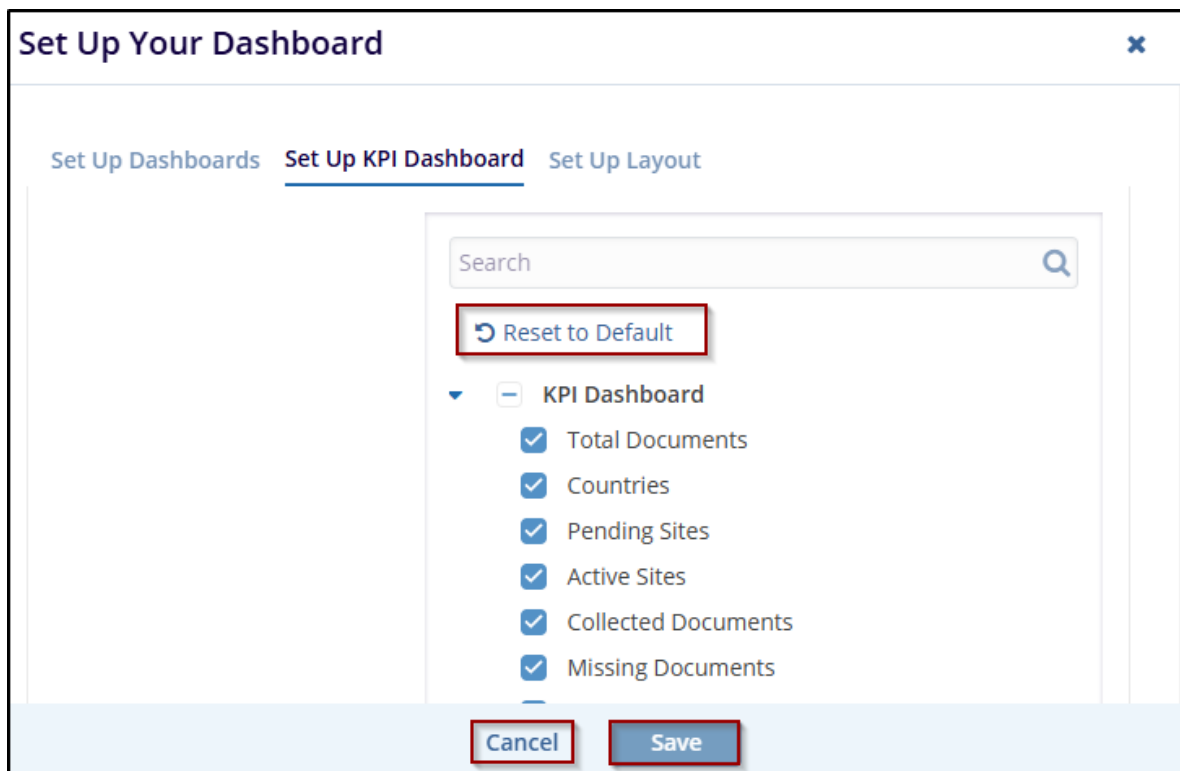
The Set Up KPI Dashboard allows users to configure key performance indicator (KPI) metrics on the user's dashboard. The selected dashlets are displayed on the top right corner of the screen.

Steps to set up the KPI dashboard.

1. From the Set Up Your Dashboard window. Click on the Set Up KPI Dashboard option.
2. Expand the KPI Dashboard fields using the arrow and select the required checkbox.



- Click on Reset to Default to revert all KPI configurations to the original system-defined settings
- Once all necessary changes are completed. Click the Save button at the bottom of the popup window to apply the changes or click the Cancel button to discard changes.



- The selected tabs are displayed on the top right of the screen.

Refer to the below screenshot:



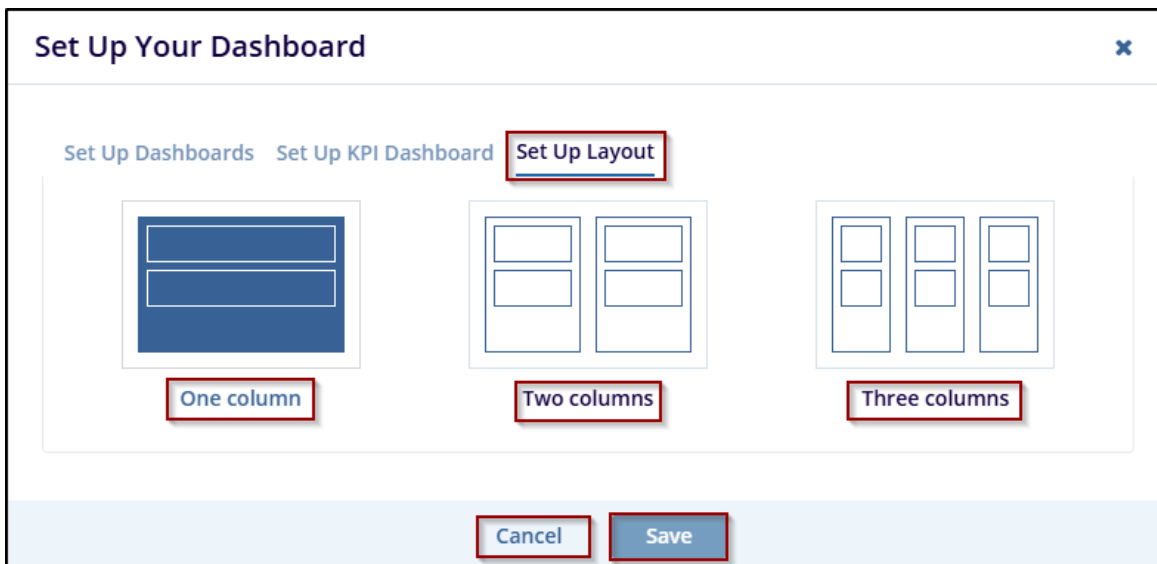
### Set Up Layout

The Set-Up Layout allows users to customize the visual structure of the dashboard by choosing a column-based layout. This ensures that the dashboard is organized according to user preferences. The user has the option to select from – One, Two, or Three Columns.

Steps to set up Layout:

1. From the Set Up Your Dashboard window. Click on the Set-Up Layout.
2. Select one of the available options of Layout:
  - One Column: Arrange all dashlets in a single vertical column.
  - Two Columns: Splits dashlets into two evenly spaced columns.
  - Three Columns: Divides dashlets across three narrower columns.
3. Click the Save button to confirm and apply the selected layout or Use the Cancel button to discard the changes.

Refer to the below screenshot:



## Configure Dashboard

The Configure Dashboard helps the user to arrange the dashboard as required.

This includes two dashboards:

- Configure Dashlets
- Configure KPIs

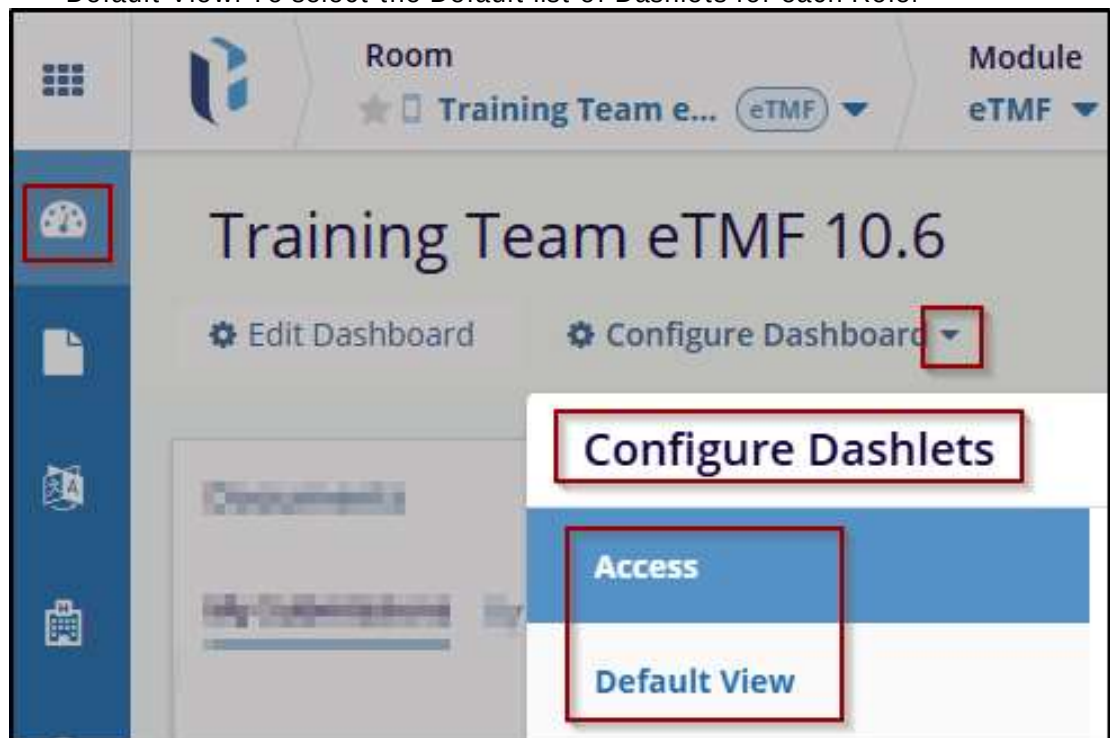


### Configure Dashlets

The Configure Dashlets allows administrators to manage the availability and visibility of dashlets on the dashboard for different user roles. Dashlets are individual components that display specific data or functionality, such as documents, users, or key metrics, making the dashboard customizable and role-specific.

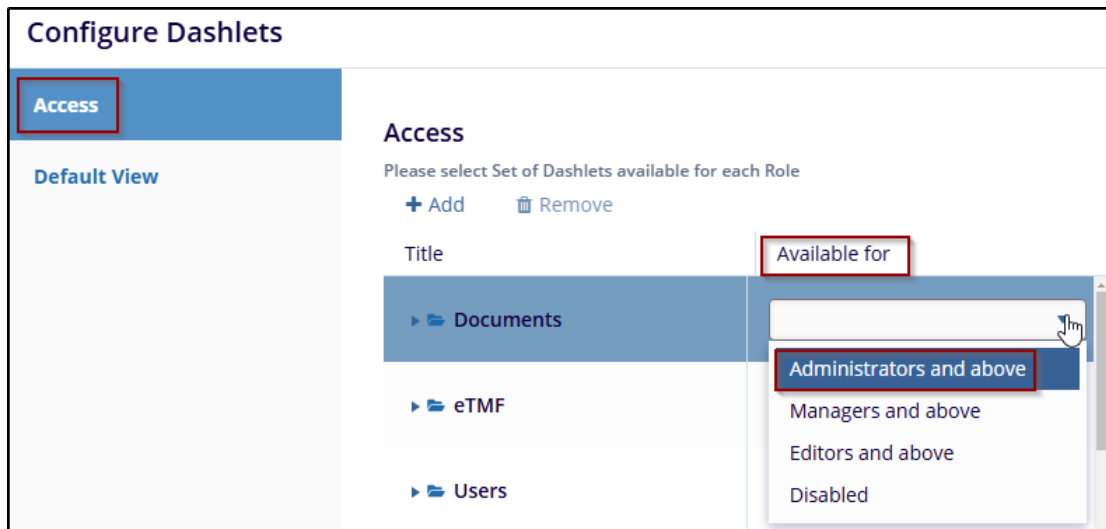
Steps to Configure the Dashlets.

1. Click the Configure Dashboard button next to the Edit Dashboard button. The user can see the dropdown menu, Configure Dashlets, and Configure KPIs.
2. Click on the Configure Dashlets, and the Configure Dashlets window will pop up.
3. The Configure Dashlets window will display two tabs on the left:
  - Access: To select a Set of Dashlets available for each Role
  - Default View: To select the Default list of Dashlets for each Role.

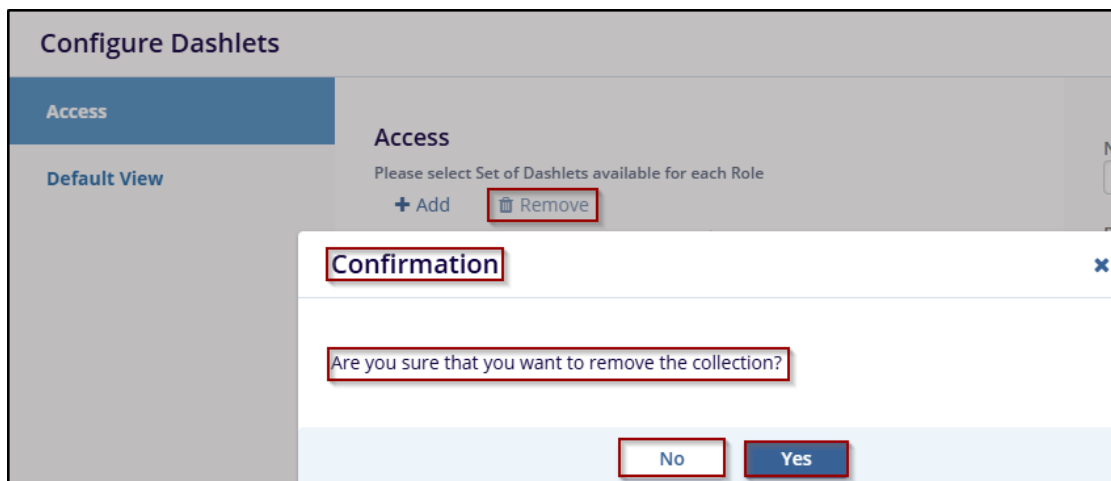




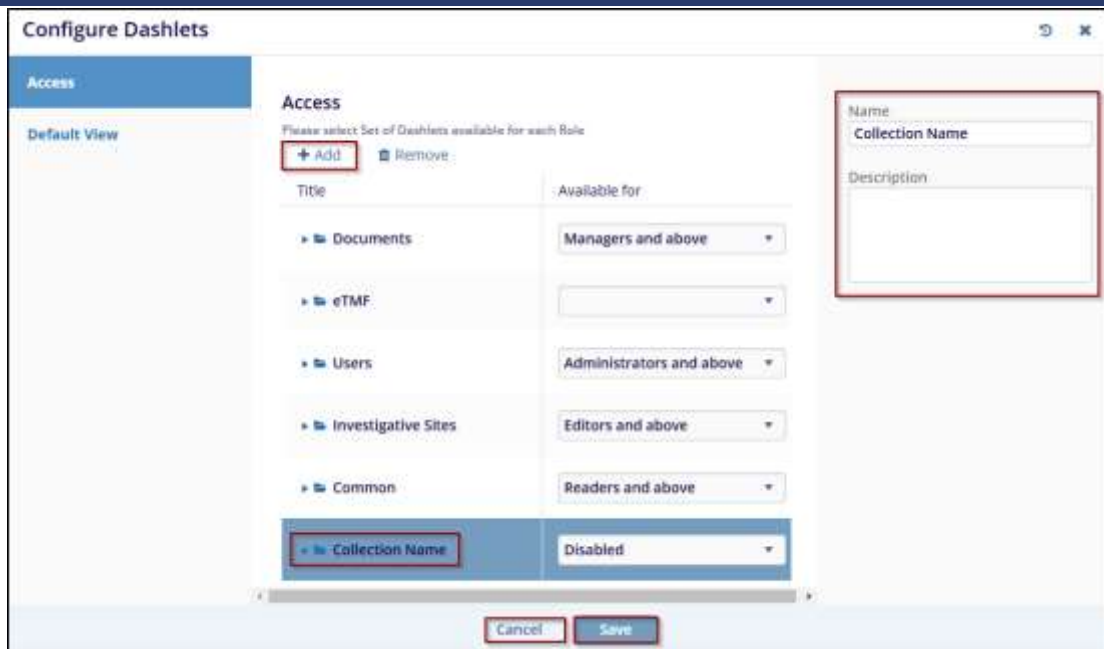
4. In the Access tab, the user can select the roles from the dropdown menu under the available for the column to assign dashlets to specific roles.



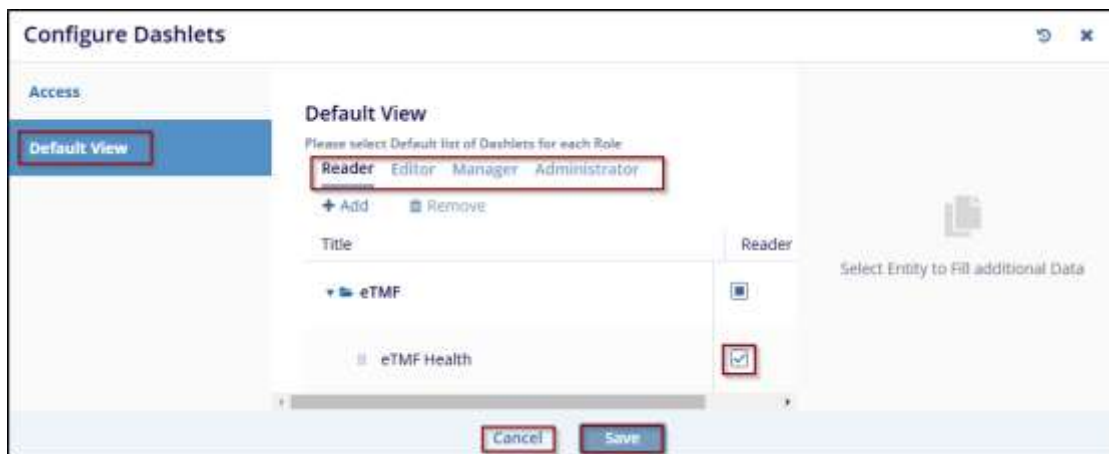
5. Click the Remove button to initiate the removal process. A confirmation window will appear with the message: 'Are you sure that you want to remove the collection?' Also, the user can only remove the newly added fields and not the pre-defined fields



6. Click the Yes button to confirm and remove the collection or click the No button to cancel the action and keep the collection.
7. Click on the Add button, and a new entry will appear under the list of available dashlet as (collection Name). While adding a new dashlet, the user has to mention the Name and Description in the right-side fields.



8. Switch to the Default View tab, and select the required and appropriate checkboxes for the roles mentioned – Reader, Editor, Manager, and Administrator.
9. Click on the Save button at the bottom of the popup window, to save the changes or click Cancel to discard your changes.



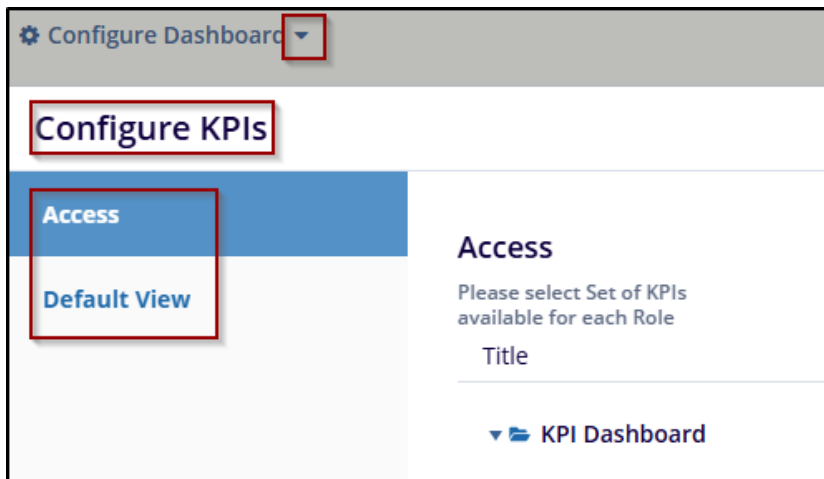
### Configure KPIs

The Configure KPIs allow administrators to manage the key performance indicators (KPIs) displayed on the user dashboard. It enables role-based customization of KPI metrics, ensuring that users see the most relevant data based on their responsibilities.

Steps to set up the Configure KPIs:

1. Click the Configure Dashboard button. The user can see the dropdown menu, and from that, click on Configure KPIs, and a new window will open.
2. The Configure KPIs window will display two tabs on the left:
  - Access: To select a Set of Dashlets available for each Role.

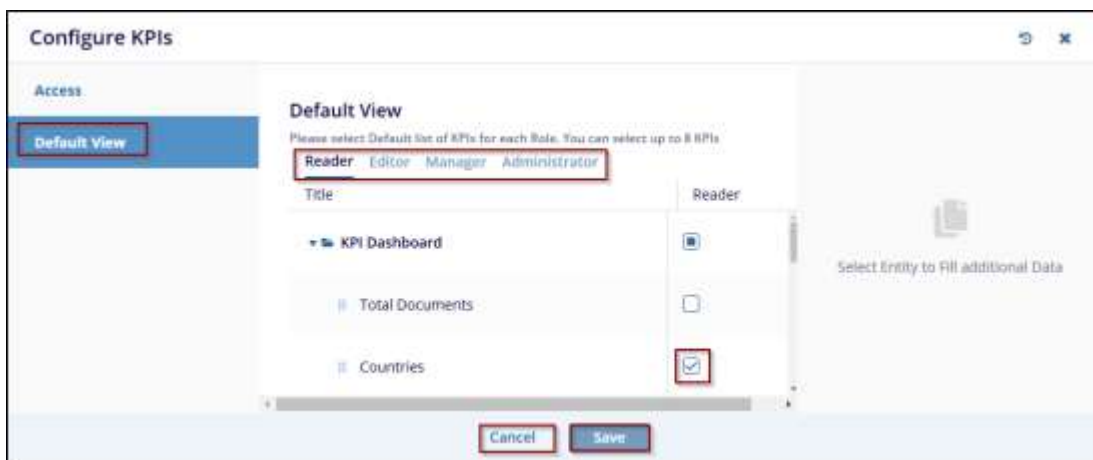
- Default View: To select the Default list of Dashlets for each Role.



3. By default, Access is selected, expand the KPI Dashboard fields using the arrow and select the roles from the dropdown menu under the Available for the column to assign dashlets to specific roles.



4. Switch to the Default View tab, and select the required and appropriate checkboxes for the roles mentioned – Reader, Editor, Manager, and Administrator.



- Click on the Save button at the bottom of the popup window, to save the changes or click Cancel to discard your changes.
- The selected tabs are displayed on the top right of the screen.



## Documents

The Documents section in the dashboard provides users with quick access to document-related actions and information.

### *My Submissions*

The My Submission dashlet will allow users to view the files that have been uploaded right from the document index.

Steps to view and manage my submissions:

- Navigate to the Dashboard section in the eTMF module, located at the top left of the Toolbar.
- Once clicked on Dashboard, the user can see the Document section in the dashboard.
- By default, My Submissions is selected and it is a mandatory dashlet. In this, the user can view the Submitted Documents Chart through the Donut, Bar, and Column view by selecting it.



- Next to Charts, the user can see the blue arrow Export button. The user can export this data by clicking the Export button. The Export chart window will be a popup and the user can export the data in – Image, Excel, or Clipboard format.



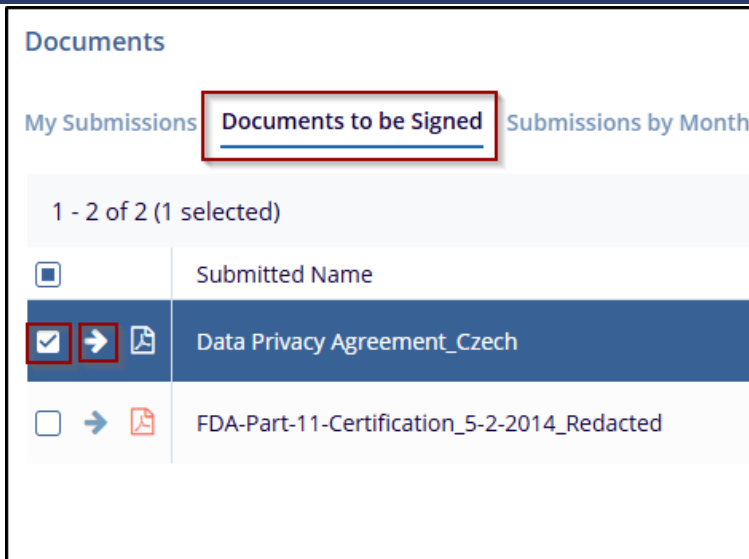
5. Click on Cancel to discard the changes to Export Charts.

### *Documents to be Signed*

In the Documents section, select Documents to be Signed from the options at the top. This view will display a list of documents awaiting signatures, along with details like the document's submitted name and current signer status.

Steps to view and manage Documents to be signed:

1. Click on Documents to be Signed, next to My Submissions.
2. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.



3. Click on the PDF icon will open a new window, The PDF opens in the window, allowing the user to navigate through the pages using the controls at the top (e.g., Print, Download, Page Navigation arrows, Zoom options, Full page, Turn page, Search Icon, Image processing menu, Show and Hide).



4. The metadata panel on the right side of the PDF window displays a Tab that includes detailed document information, such as Document ID, Document name, submitted name, Metadata, Info, Related, Versions, Queries, signature, and History.
5. Click on the Metadata Tab.
  - o Document Metadata holds metadata details as needed, select or modify the category, site, contact, and document type from the dropdown menus, fields marked with an asterisk (\*) are mandatory
  - o Add or update comments related to the document.
  - o Save changes using the Save button or cancel to discard the changes.
  - o Workflow History shows the last history record.

285407  
★ SiteMgmtDataPrvcyAgrmt  
Submitted Name  
Data Privacy Agreement\_Czech

☰

Metadata

Info  
Related  
Versions  
Queries  
eSignature  
History

### Metadata

Document Metadata

Category \*  

Site

Site \*

Contact \*  

Not specified

Document Type \* Select  

Site Management: Data Privacy Agrē

Submitted Name \*  

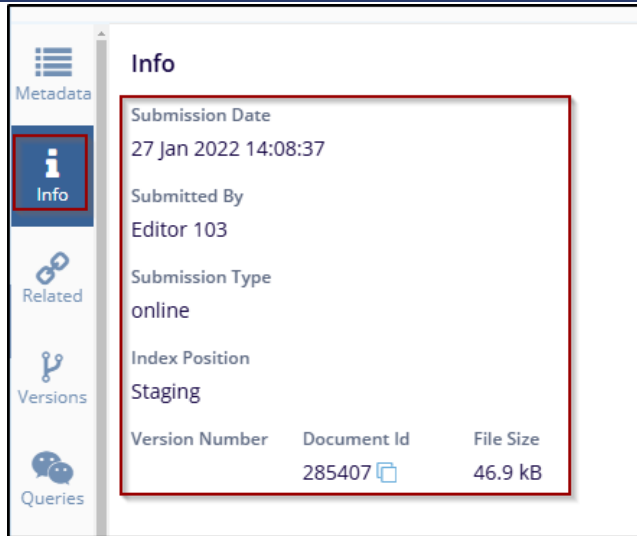
Data Privacy Agreement\_Czech

Comments ?

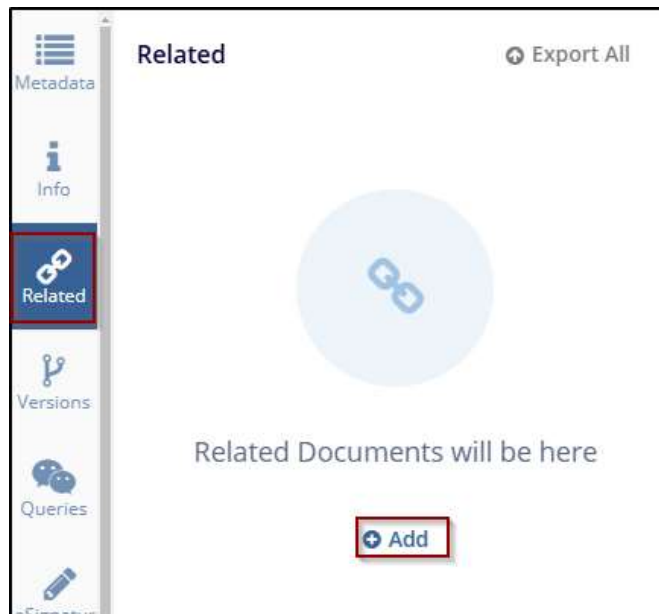
Generated Name  

SiteMgmtDataPrvcyAgrmt

6. Click on the Info Tab
  - Info field displays document Submission date, Submitted by, Submission type, Index position, Version Number, etc.



7. Click on the Related Tab.



- Click the + Add button to open a new window to add related documents.
- From the pop-up window, select the relation type from the dropdown menu, and by clicking on the browser document, the document will be browsed from the document index folder and click on save to apply the changes or click the cancel to discard the changes.
- Use the Export All option at the top-right to download all related documents as a batch.



Add Related Documents

×

Select type of relations and documents which will be related.

Relation Type\*

New Version

Search for Docs to Add / Quick Select

≡ Search

Browse Documents

No Related Docs have been selected yet

Cancel

Save

8. Click on the Version Tab.
  - Check both the checkbox to select the version and use the Compare option to identify changes between both versions.

Metadata

Info

Related

**Versions**

Queries

eSignature

History

Versions

Compare

☒

2.0

27 Jan 2022 02:28:19 PM

...

File Name

Contact Details\_List.pdf

Created By

ti\_editor103@ti.com

Full Name

Editor 103

Comments

Updated Copy

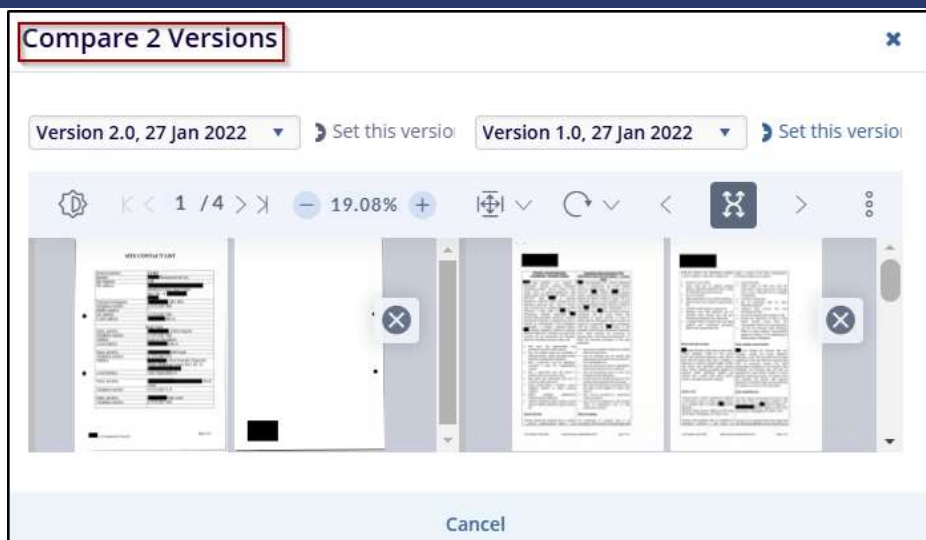
☒

1.0

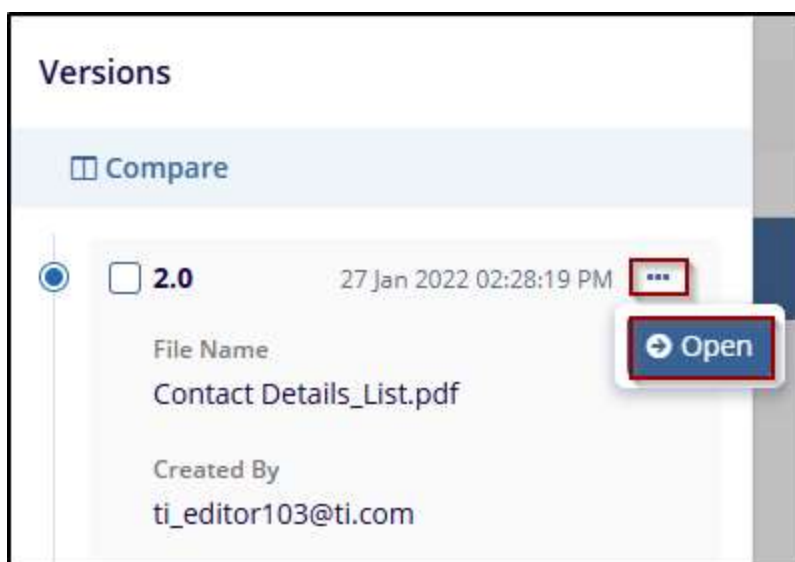
27 Jan 2022 02:08:36 PM

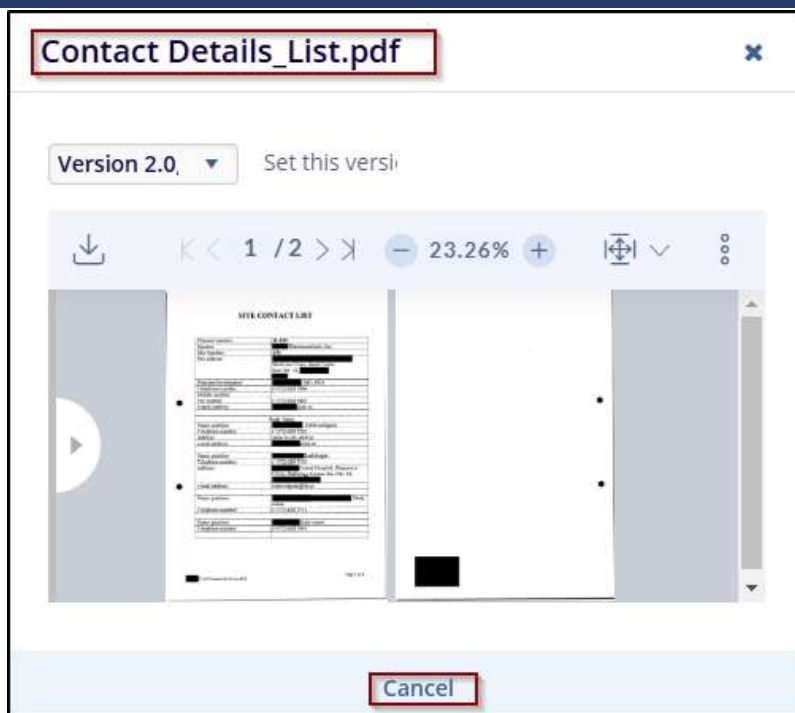
...

- Click the compare option to open a new Compare 2 Version window.

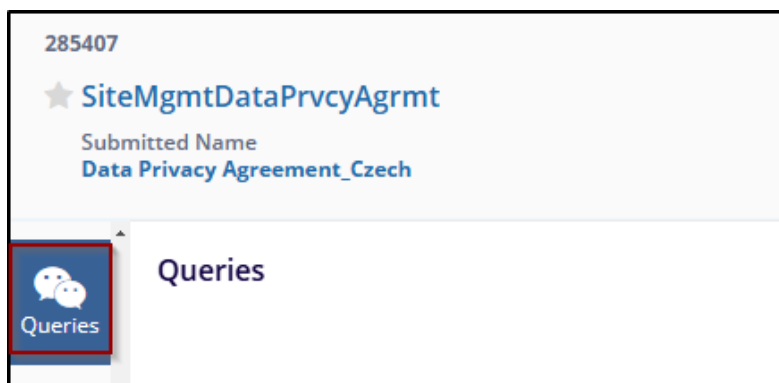


- Click on three dots (...) next to the version number gives the option to open the contact details PDF, and click the cancel to close it.





9. Click on the Queries Tab.
  - It will address the document-related queries in this section.



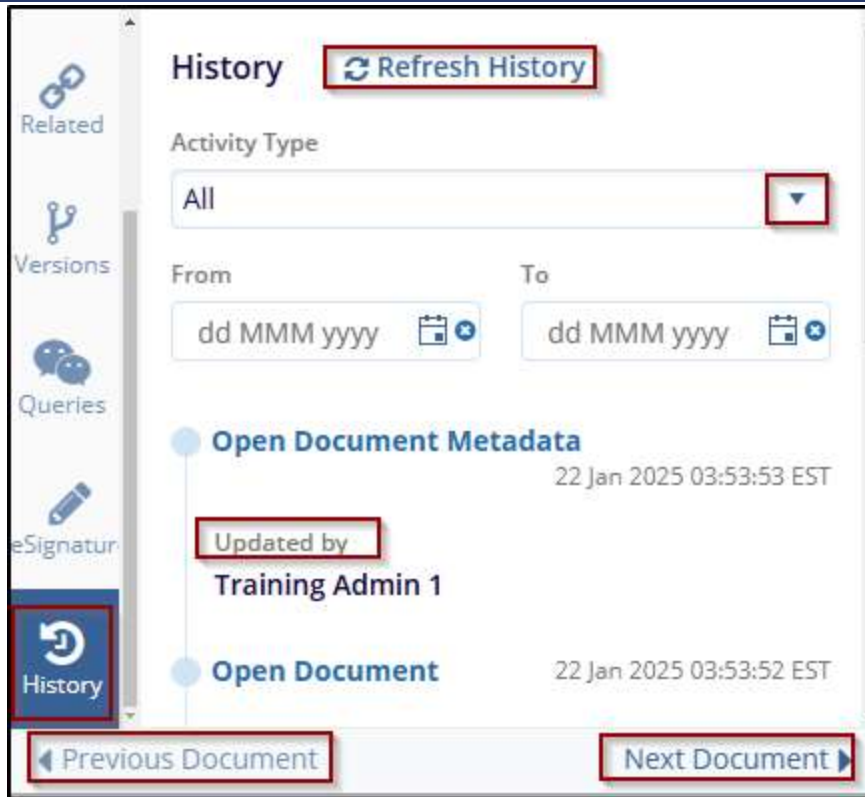
10. Click on the eSignature Tab.
  - The user can check and review the eSignature type workflow, and eSignature status.



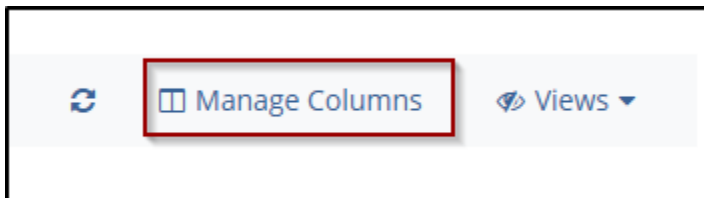
- Click the Cancel eSignature button to stop the current eSignature process, a confirmation pop-up appears with the message: *'Are you sure you want to cancel the eSignature process?'*



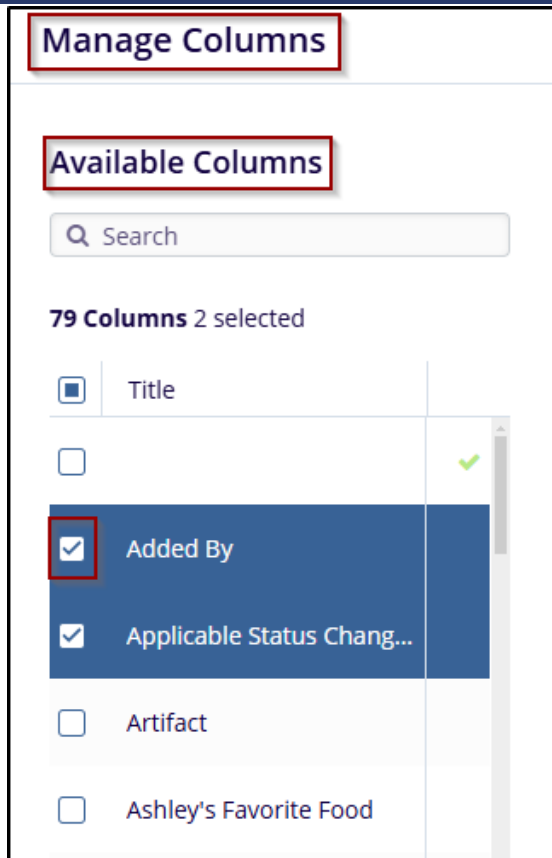
11. Click on the History Tab.
  - This will display a history of the document, that is updated by and with dates. The user can filter activities by Activity Type or specify a date range using the From and To fields. Use the Refresh History option to update the log with the latest actions.



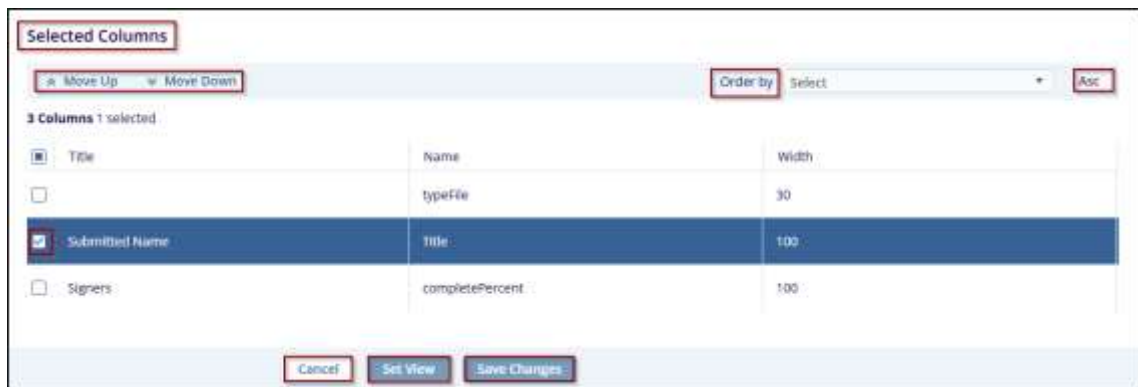
- Use the Previous Document and Next Document buttons to navigate to other documents in the queue or list.
- 12. To customize the columns displayed in the Document Dashboard, click the Manage Columns, and a new window will pop up.



- 13. On the left side of the manage column window, a list of Available Columns is used to add a title to the table.
- 14. Users can use the search bar to find columns. Check the checkbox available for the title that the user wants to add to their view.



15. In the Selected Columns section, the user can use the Move Up and Move Down buttons to reorder the columns in the selected list. For each selected column, the user can see its Title, Name, and Width.
16. Use the Order by dropdown menu to select a column for sorting the data. Choose whether the user wants the sorting to be Ascending or Descending.
17. After customizing the columns, click on Save Changes to apply the settings or the user can click Set View to apply and see the updated view. If the user wants to discard the changes, click on the Cancel button.
18. To set your current selections and order as the default view, click Set View. After finalizing your column selections and order, click Save Changes to apply them to the document view.



19. Once the changes are applied, the user can click the Refresh icon to refresh the Columns.



### Submissions by Month

In the Documents section, select Submissions by Month from the menu at the top. This view displays a bar chart representing the number of document submissions per month, categorized by submission status.

Each bar in the chart is color-coded to indicate the status of the documents:

- Blue represents documents that have been submitted.
- Green represents final documents.
- Red represents rejected documents.



### Popular Documents

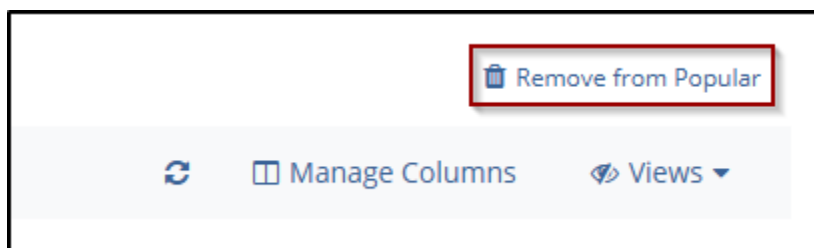
In the Documents Dashboard, select Popular Documents from the menu at the top. This view lists documents that are frequently accessed or marked as popular, along with details such as the Submitted Name and Category or Country. This is similar to My Submissions.

Steps to view and manage popular Documents:

1. Click the Popular Documents, next to Submissions by month.
2. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.



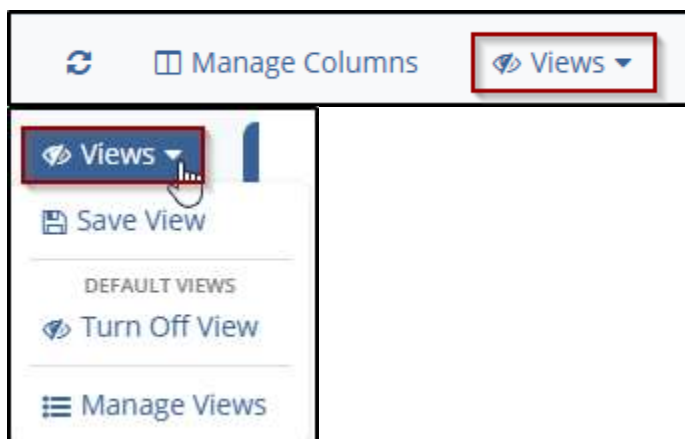
3. To remove a selected document from the Popular document list, click on the “Remove from Popular” button on the top right side of the Document dashboard.



4. To customize the columns displayed in the document list, click Manage Columns (for detailed steps please refer to My Submission (manage columns))
5. Once the changes are applied, the user can click the Refresh icon to refresh the Columns.



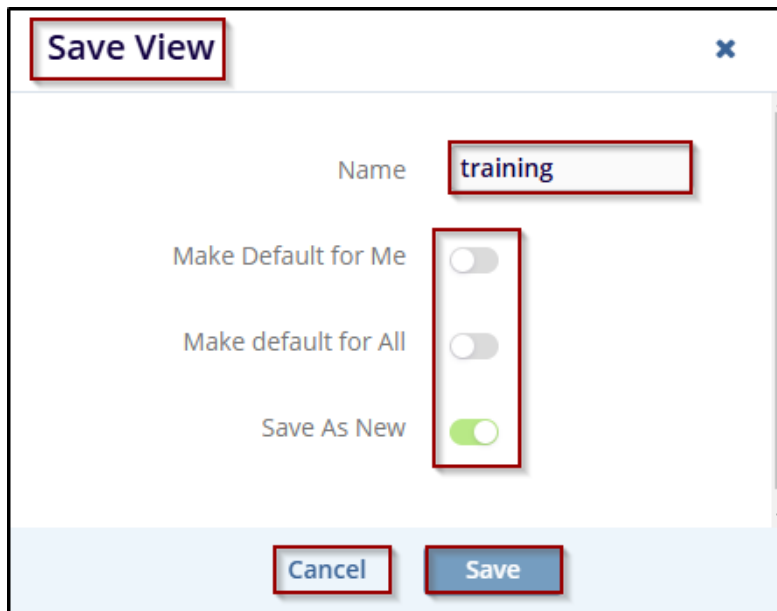
6. Use the Views option for saving views, managing and turning off customized views
7. Click on the Views Dropdown menu, next to the Manage columns. The user can see options Save View, Share View, Turn off View, Recent View, and Manage Views.



8. Click Save View from the dropdown menu, The Save Views window will pop up.
9. In the Save View window, enter a Name for view.
10. Make Default for Me: Toggle the switch to make this view the default for the user.
11. Make Default for All: Toggle the switch to make this view the default for all users.

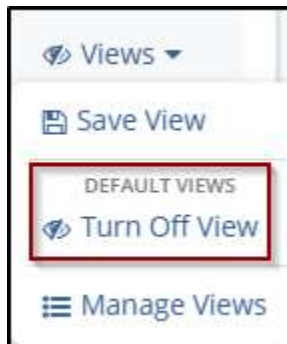


12. To save the current view as a new view, ensure the Save As New option is enabled.

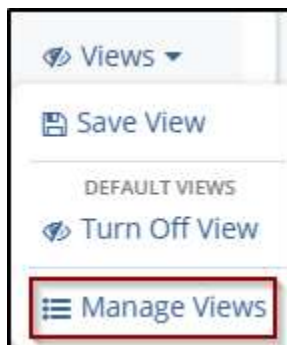


The 'Save View' dialog box is shown. It has a title bar with 'Save View' and a close button. Inside, there is a 'Name' field with the text 'training'. Below it are three toggle switches: 'Make Default for Me' (disabled), 'Make default for All' (disabled), and 'Save As New' (enabled). At the bottom are 'Cancel' and 'Save' buttons.

13. Click the Save button to save the current view, If the user decides not to save the view, click the Cancel button to discard changes.
14. Click Turn Off View from the dropdown menu. If the user wants to revert to the default view or disable the current saved view.



15. Click on Manage Views from the dropdown menu, Manage Views window will pop up.
- 16.



17. In the Manage Views window, the user can see all available view options under tabs such as All, Created by Me, Shared by Me, Shared with Me, and Default Views. The users can browse through the views by selecting the appropriate tab.
18. Check the box next to the view to manage.
19. After selecting a view, the user can delete it by clicking the Delete button.
20. Once finished managing views, click the Cancel button to discard any changes, or click Select to apply the changes to the selected view.



### Documents View

This tab displays the documents in a grid column with a selection tab for – Unread, Unclaimed, and Pending.

Steps to review documents view:

1. Click the Documents Views, next to popular Documents.
2. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
3. To view the Document, click on the PDF icon (for detailed steps, refer Document to be Signed tab above)
4. To customize the columns displayed in the document list, click Manage Columns and select or deselect columns as required to view.



5. By clicking on the Word icon, the Word file window will open with the document.

| 1 - 100 of 2,000 (1 selected)                                                                                |                                        |               |
|--------------------------------------------------------------------------------------------------------------|----------------------------------------|---------------|
| <input checked="" type="checkbox"/>                                                                          | Submitted Name                         | Document Date |
| <input type="checkbox"/>  → | InformedConsentsample1                 |               |
| <input type="checkbox"/>  → | Investigator Financial Disclosure Form | 28 Nov 2023   |
| <input type="checkbox"/>  → | SiteSignatureSheet                     |               |
| <input type="checkbox"/>  → | permit to import                       | 20 Dec 2021   |

6. User can perform various actions, such as (Print, download, Page navigation arrows, Zoom options, Full page, Turn page, Search Icon, Image processing menu, Show and Hide)

1234\_1112\_Magnificent\_FinanDoc\_28Nov2023




<< 1 / 1 >>
- 54.55% +



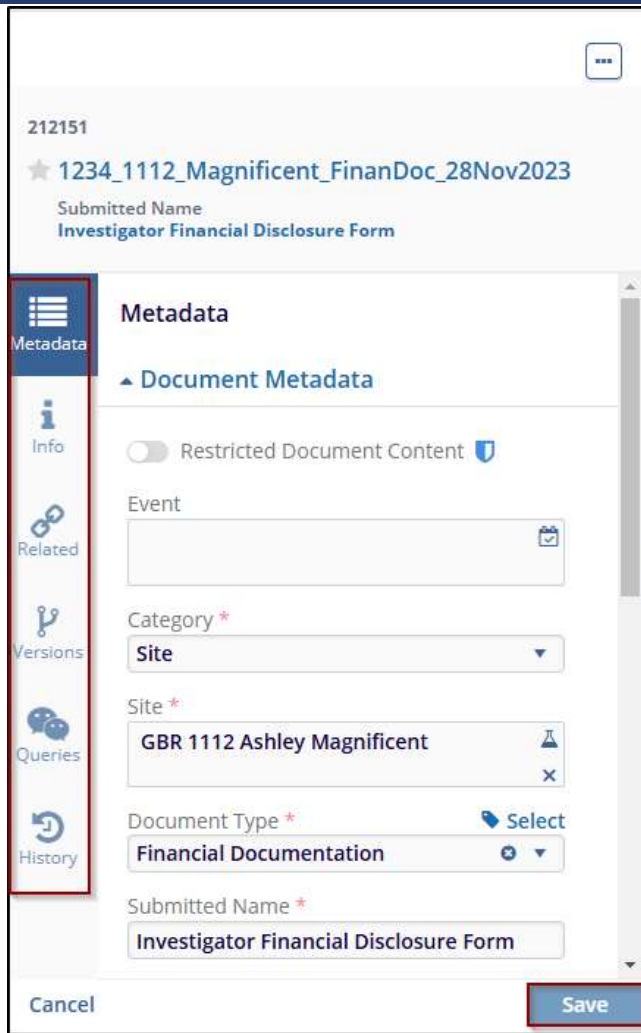


SPONSOR STUDY INFO  
CERTIFICATION/DECLARATION FORM  
Financial Disclosure by Clinical Investigators

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Please complete all of the information below and retain a copy of this form for your records.                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Study Name: Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 18-Month Safety and Efficacy Study                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 1. Study Number:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 2. Investigator (Last, First, Middle Initial):                                                                                                                                                                                                                                                                                                                                                                                                                                                       | John Doe, MD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 3. Investigator Signature Name:                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | John Doe, MD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 4. Address:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 123 Main St, Suite 500, New York, NY 10001                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 5. Telephone:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | (212) 555-1234                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 6. Indicate by marking YES or NO if any of the financial interests or arrangements of interest as FDA and disclosure below apply to you, your spouse, or dependent children:                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| YES NO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Financial arrangements whereby the value of the compensation could be influenced by the outcome of the study. This could include, for example, compensation that is explicitly greater for a favorable outcome, or compensation in the form of an equity interest in the sponsor or in the form of compensation that is tied to sales of the product, such as a royalty interest.                                                                                                                  |
| YES NO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Significant payments of other sort, including the costs of conducting the study or other clinical studies. This would include, for example, payments made to the investigator or the investigator's spouse or dependent children for a commercial purpose, or payments for consulting, or for other services, or for other financial interests, where value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company exceeding \$10,000. |
| YES NO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | A proprietary or financial interest in the test product such as a patent, trademark, copyright, or licensing agreement.                                                                                                                                                                                                                                                                                                                                                                            |
| YES NO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | A significant equity interest in the sponsor of the study. This would include, for example, any ownership interest, stock option, or other financial interest where value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company exceeding \$10,000.                                                                                                                                                                                   |
| or:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| I, _____, hereby certify that none of the financial interests or arrangements listed above exist for myself, my spouse, or my dependent children.                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| In accordance with 21 CFR Part 31.54.1 to 31.54.6, I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct, and complete. Furthermore, if any financial interests and arrangements, or those of my spouse and dependent children, change from the information provided above during the course of the study or within one year after the last person has completed the study as specified in the protocol, I will notify SPONSOR immediately. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 8. Signature:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 10. Date:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

7. On the right side of the word file, where the user can find the document Metadata, Info, related, version, queries, and history section, after updating metadata or making any necessary changes, click Save to apply the changes. (For detailed steps refer to Documents to be signed 4<sup>th</sup> step)

Refer to the below screenshot



212151

★ 1234\_1112\_Magnificent\_FinanDoc\_28Nov2023

Submitted Name  
Investigator Financial Disclosure Form

**Metadata**

Document Metadata

☐ Restricted Document Content

Event

Category \*

Site

Site \*

GBR 1112 Ashley Magnificent

Document Type \*

Financial Documentation

Submitted Name \*

Investigator Financial Disclosure Form

Cancel Save

### My Favorite Documents

The My Favorite Documents tab displays the list of documents that have been marked favorite from the Document Index and allows quick access to frequently used documents.

Steps to view and add documents to my favorite:

1. Click on the My Favorite Documents tab from the Documents dashboard.
2. Review the list of documents marked as favorites from the document index, displayed with their details (e.g., Submitted Name, Index, Last Updated By).
3. Click on Export to Download the document to the local system.
4. Click the star icon or the Remove from Favorites button to unmark the document as a favorite.
5. Use the pencil icon or Edit Comments option to add or update comments.
6. Delete any existing comments using the Remove Comments button.
7. Click Manage Columns to adjust the visible information in the table.
8. Use the navigation controls Previous and Next to switch between pages of documents.

- Click the Refresh icon to update the list with any recent changes.

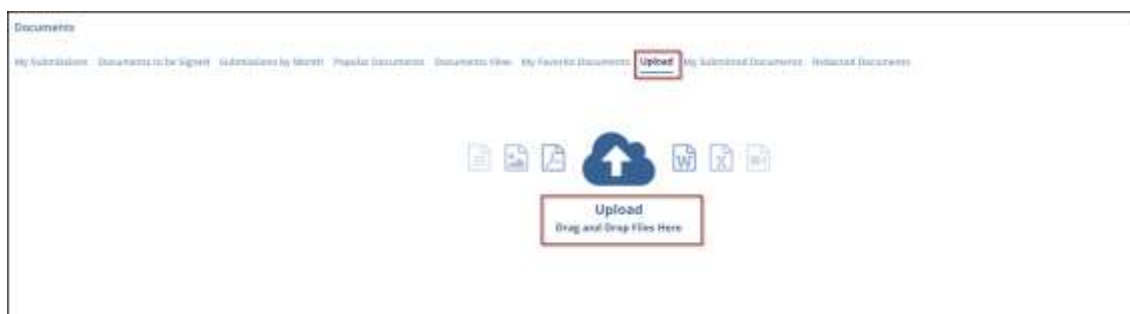


## Upload

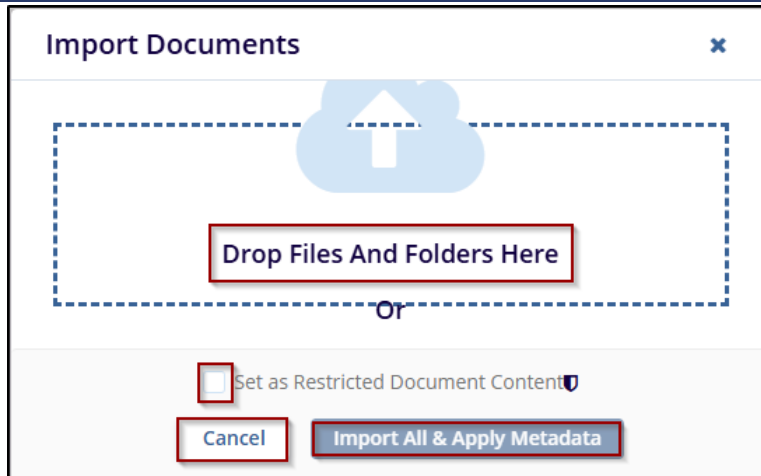
The Upload dashlet allows users to drop files from their desktop into the room with assistance so that documents can be quickly uploaded and indexed. The function of the dashlet is impacted by the user's specific role in the system, and it will assist in directing the user's document to the correct folder as appropriate.

Steps to upload the document:

- Navigate to the Documents dashboard and select the Upload tab.



- In the upload section, the user can drag and drop files directly into the designated Upload box or click on drop file and folder to Browse File or Browse Folders to locate files from the system.
- After selecting the files, the user can set them as Restricted Document Content by checking the box if necessary.
- Once files are ready, click Import All & Apply Metadata to complete the upload process or click Cancel to discard the changes.



### *My Submitted Documents*

The My Submitted Documents dashboard represents a user interface component that lists documents that have been uploaded or submitted by the user. This view displays a list of submitted documents, showing details such as the Submitted Name and Index.

Steps to view my submitted documents:

1. In the Documents Dashboard, select the My Submitted Documents tab.
2. Review the list of documents displayed with their details (e.g., Submitted Name, Index, Last Updated By).
3. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
4. Use the pencil icon to edit the Dashboard name at the top right corner.
5. Click Manage Columns to adjust the visible information in the table.
6. Use the navigation controls Previous and Next to switch between pages of documents.
7. Click the Refresh icon to update the list with any recent changes.



## Redacted Documents

The Redacted Documents dashboard shows a set of documents that have undergone or are undergoing redaction, a process where sensitive or confidential information is removed from documents before they are shared or published.

Steps to Managing Redacted Document:

1. In the Documents Dashboard, select the Redacted Document tab, where documents undergoing redaction are listed.
2. The user can use the status filters at the top right to sort documents by redaction stage:
  - Not Yet Started Redaction for documents pending redaction.
  - In Progress for documents currently being redacted.
  - Completed for documents where redaction is finalized.
3. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
4. The blue icon shows the document is waiting for redaction.
5. Use the pencil icon to edit the Dashboard name at the top right corner.
6. Click Manage Columns to adjust the visible information in the table.
7. Use the navigation controls Previous and Next to switch between pages of documents.
8. Click the refresh icon to update the list with any recent changes.



## By Workflow Status

The By Workflow Status refers to the process tasks that documents go through in the system. Workflows are typically defined by stages such as submission, review, approval, redaction, or other processes. The By Workflow Status provides a breakdown of documents within different workflow stages.

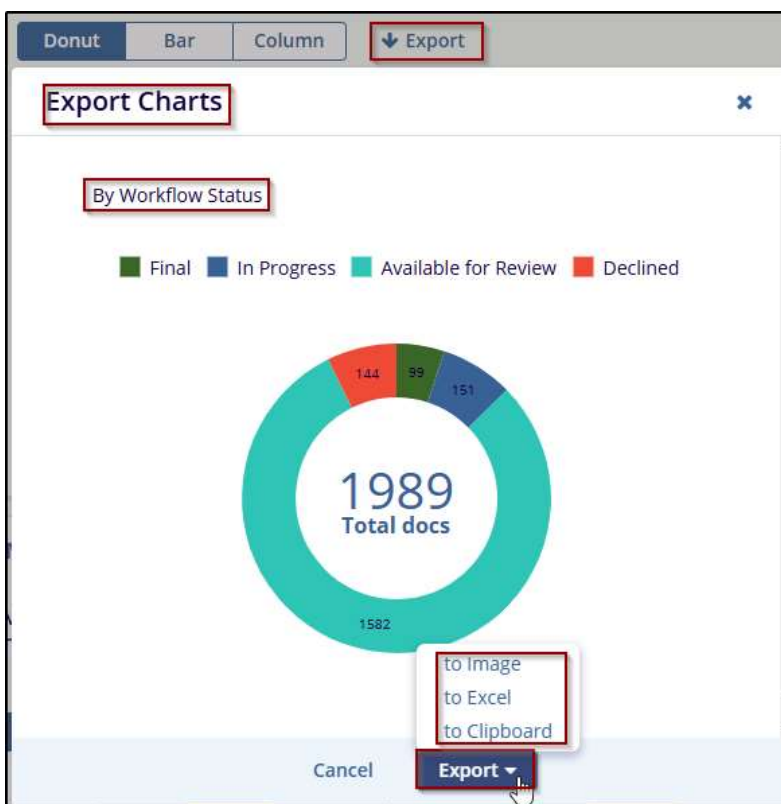
Steps to managing workflow Status:

1. Click on the By Workflow Status to view the workflow chart through the Donut, Bar, and Column view by selecting it.
2. On the right side of the document dashboard, there is a drop-down menu. By default, the Room Summary option is selected, where the user can view the document processing status, and complete Room Summary, with these options
  - 1-Step workflow
  - DM workflow
  - QC1 group





- The user can export this data by clicking the “Export” button. The “Export chart” window will be a popup and the user can export the data in – Image, Excel, or Clipboard format.



## eTMF

The eTMF (Electronic Trial Master File) dashboard provides a visual representation of trial-related document health and status. The eTMF ensures that clinical trial documents are easily accessible, properly stored, and secure.

It includes the following tabs:

### *eTMF Health*

The eTMF Health tab provides an overview of the overall health and progress of the trial master file. It helps monitor the completeness and compliance of documents in different

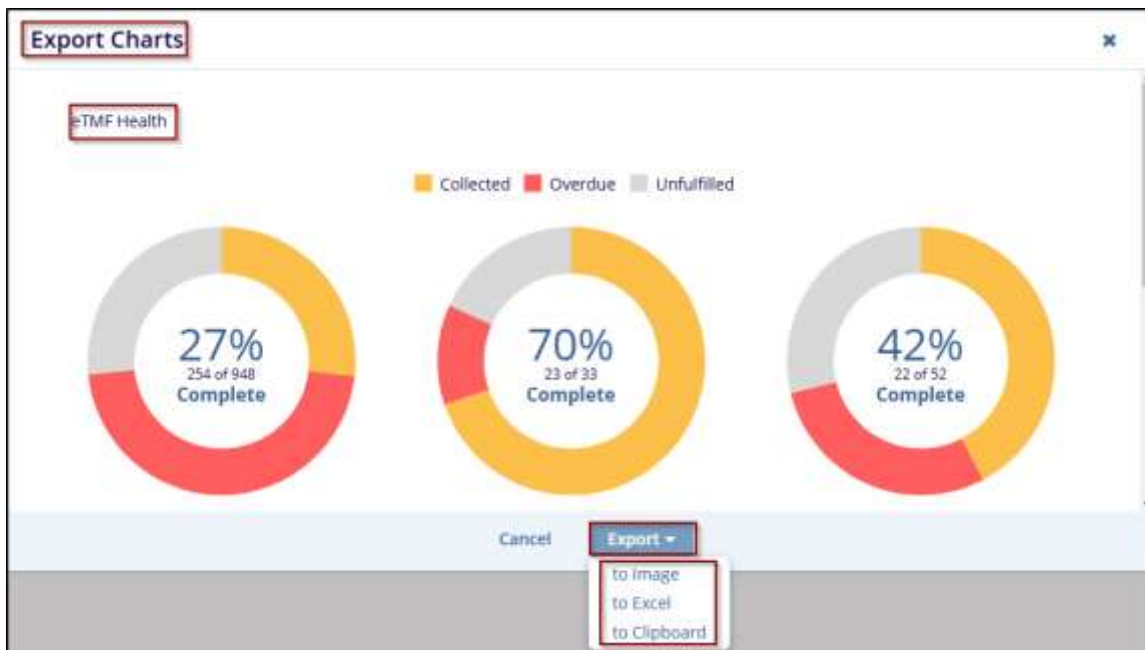
stages of the clinical trial by visualizing key metrics such as the percentage of completed documents in categories such as Trial, Country, Investigative Site, and overall.

Steps to view eTMF Health:

1. Navigate to the eTMF dashboard, and click on the eTMF Health tab.
2. By default, the eTMF Health tab is selected and the user can view the eTMF Health Chart through the Donut, Bar, and Column view by selecting it.
3. To export the displayed data, click Export, which allows the user to download the information for further analysis.



4. Once clicked on the Export chart window will be a popup and the user can export the data in - Image, Excel, or Clipboard format



### Claimed & Unclaimed

In the eTMF dashboard, Claimed & Unclaimed refer to the status of documents, who is responsible for them, or who has taken action on them.

Steps to view Claimed & Unclaimed Documents:

1. Navigate to the eTMF dashboard and click on the Claimed & Unclaimed tab.
2. The Claimed & Unclaimed tab is selected and the user can view the Claimed & Unclaimed Chart through the Donut, Bar, and Column view by selecting it.
3. Use the dropdown on the right to filter the documents by their workflow stage, such as 2-Step Workflow.
4. To export the displayed data, click Export, which allows the user to download the information for further analysis.



### Expired Documents

The Expired Documents tab, lists documents that are either expiring or already expired, based on the specified expiration period. The Expired Document tab allows users to track these documents, monitor their expiration, and take action.

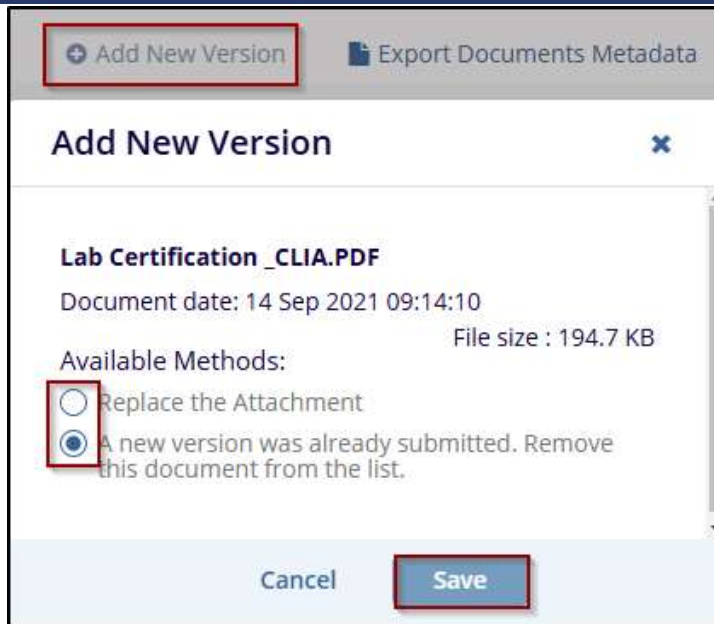
Steps to manage Expired documents by replacing them with updated versions:

1. Navigate to the eTMF dashboard, and select the Expired Document tab.
2. The user can apply the filter to view Expired or Expiring documents. Select the option to focus on documents that are already expired or those approaching expiration.
3. Check the checkbox next to the blue arrow and click the +Add New Version button at the top-right of the dashboard.



| Document Name              | Document Date | Document Type                           | Expiration Date |
|----------------------------|---------------|-----------------------------------------|-----------------|
| 04_Park-CA                 | 80 Dec 2021   | Principal Investigator Curriculum Vitae | 31 Jul 2022     |
| Lab Certificates - CUA.PDF | 25 Jul 2023   | CUA Certificate                         | 19 Nov 2024     |
| Test Doc JS                | 22 Apr 2022   | IRB IEC Notification of Site Closure    | 12 Aug 2023     |
| Test Doc JS                | 28 Apr 2022   | Investigator's Brochure                 | 28 Apr 2023     |

4. This will open the new Add New Version window and select the appropriate option.



### Add New Version

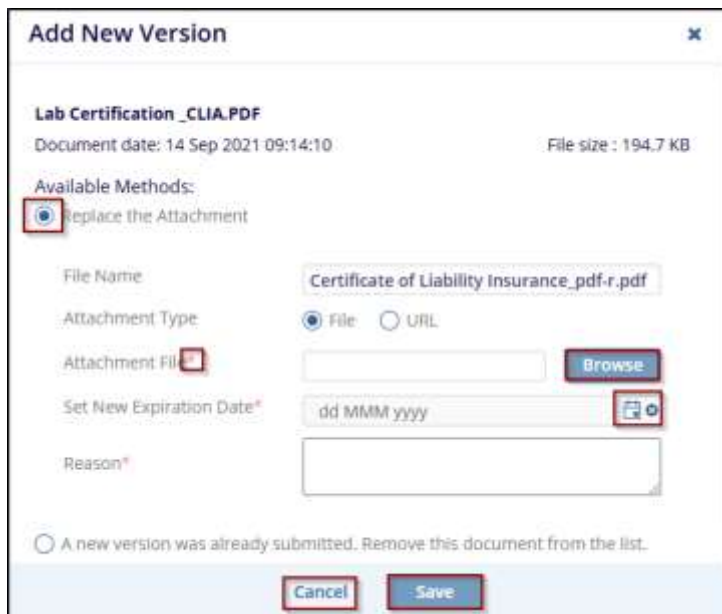
**Lab Certification\_CLIA.PDF**

Document date: 14 Sep 2021 09:14:10      File size : 194.7 KB

Available Methods:

☐ Replace the Attachment  
☒ A new version was already submitted. Remove this document from the list.

5. The options available are configurable by the room administrator in the Settings area.
6. If Replace the Attachment is chosen, click the Browse button and locate the new version of the file.
7. Set the new expiration date, and give the reason for the replacement in the comment box.
8. If the 'A new version was already submitted. Remove this document from the list. Nothing else needs to be done. The document will be removed from the list of expiring documents.
9. Press Save to save the changes or click Cancel to discard the changes.



### Add New Version

**Lab Certification\_CLIA.PDF**

Document date: 14 Sep 2021 09:14:10      File size : 194.7 KB

Available Methods:

☒ Replace the Attachment

File Name: Certificate of Liability Insurance\_pdf-r.pdf

Attachment Type: ☒ File ☐ URL

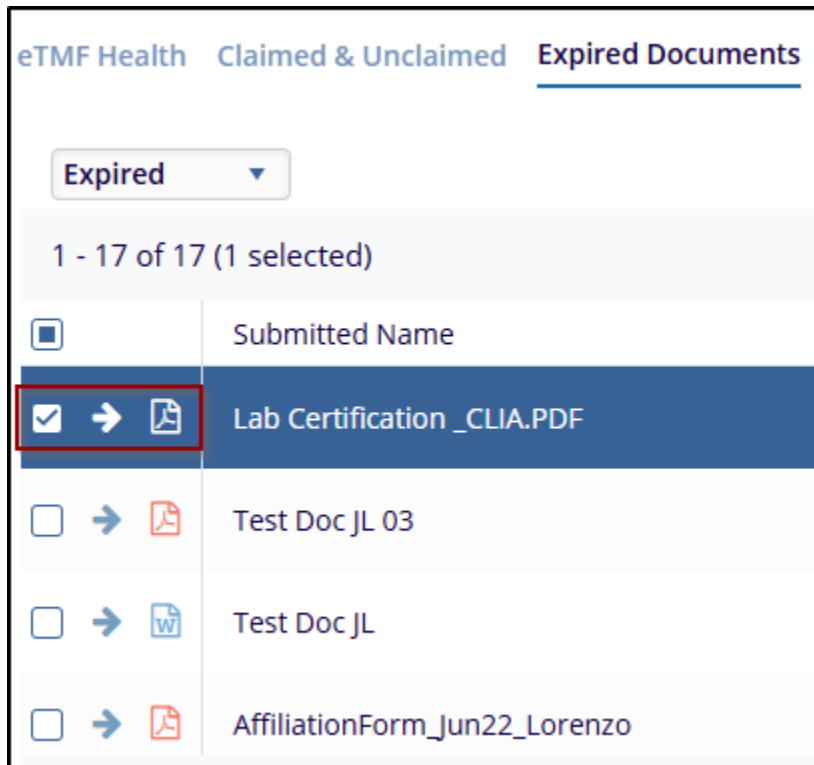
Attachment File:

Set New Expiration Date\*: dd MMM yyyy

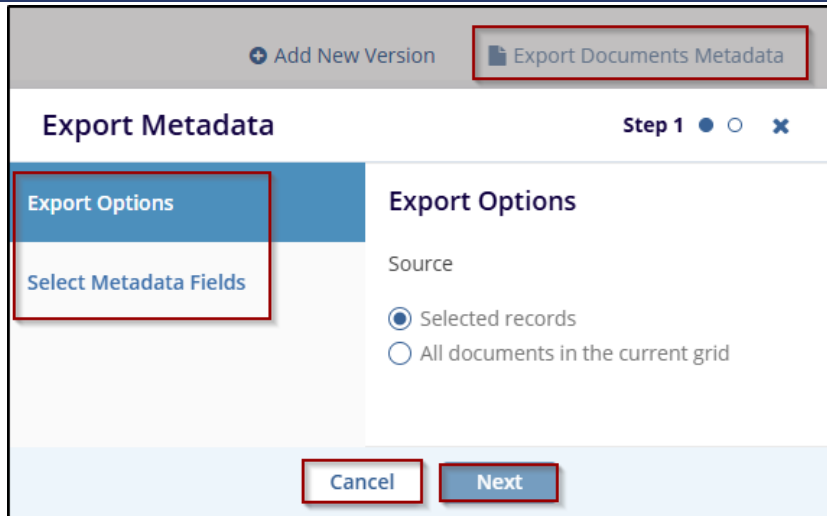
Reason\*:

☐ A new version was already submitted. Remove this document from the list.

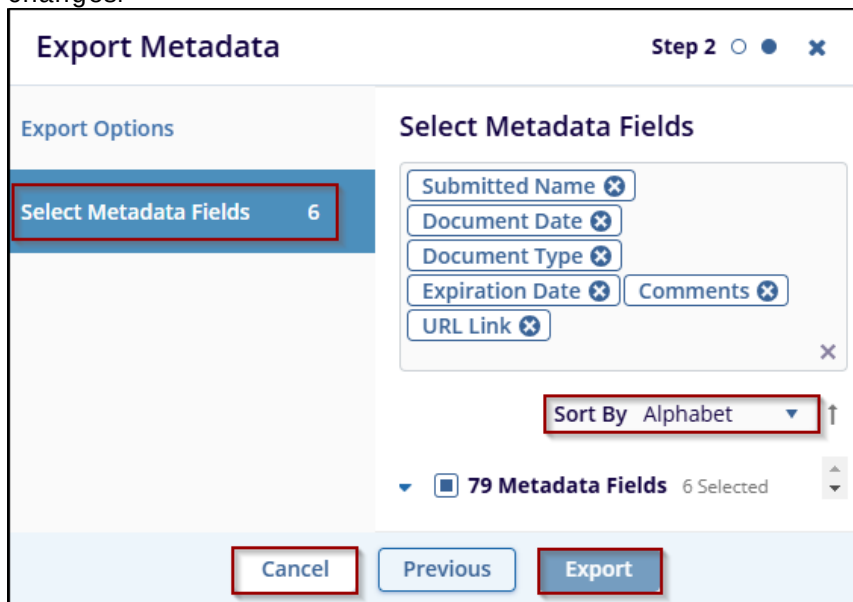
10. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
11. Click on the PDF icon will open a new window, The PDF opens in the window, allowing the user to navigate through the pages using the controls at the top (e.g., Print, Download, page Navigation arrows, Zoom options, Full page, Turn page, Search Icon, Image processing menu, Show and Hide).



12. click on the Export Documents Metadata button, and a new window will pop up with 2 options:  
Export option and Select Metadata fields.
13. Select the Export option will give 2 sources:
  - Selected records: Choose this option to export metadata only for specific selected documents.
  - All documents in the current grid: Choose this option to export metadata for all documents currently displayed in the grid.



14. Click Next to proceed to Select Metadata Fields, where the user can choose the metadata fields to include in the export.
15. The user can use the Sort By dropdown to sort the available metadata fields alphabetically or logically.
16. Click Export to download the document metadata file in the preferred format, if the user wishes to go back click on the Previous button or click Cancel to discard the changes.



### *Rejected and In-Clarification Documents*

The Rejected and In-Clarification Documents tab displays documents that have either been rejected or are currently in a state requiring clarification. These documents may need to be reviewed, corrected, and resubmitted before they can be approved and processed further in the workflow. This overview helps identify common reasons for rejection and areas where clarification is frequently needed.

Steps to Manage Rejected and In-Clarification Documents:

1. Navigate to the eTMF dashboard, and select the Expired Document tab to view the list of documents associated with a specific rejection or clarification reason.
2. Click on the + sign next to the reason will expand the section, and reveal individual documents, including details such as the Submitted Name, Created Date, and Comments.
3. Click on the – sign will minimize the section.
4. Additional options, like Export and Manage Columns, allow the user to export the data or customize the column view to focus on relevant information.

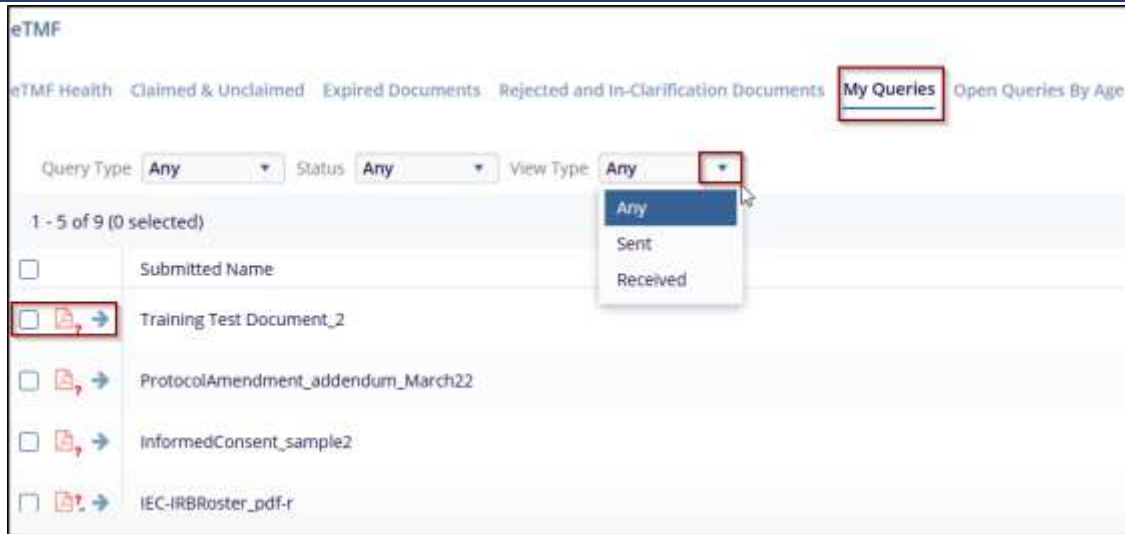


### My Queries

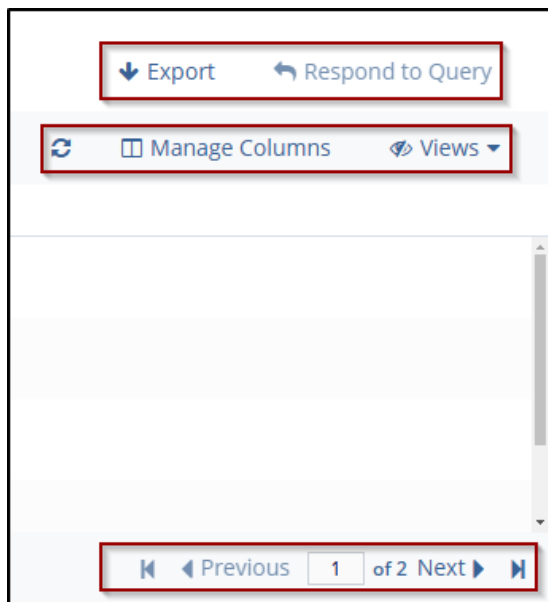
My Queries in the eTMF allows the users to view and manage queries related to the documents they are working on. Queries could be either sent (by the user to someone else) or received (from others to the user). This helps to track the status of queries and allows the user to take actions such as responding to or exporting query details.

Steps to use My Queries:

1. Navigate to the eTMF dashboard, and select the My Queries tab.
2. Use the Query Type dropdown to filter the queries:
  - Select Any to view all queries.
  - Choose Sent to see the queries you have sent.
  - Choose Received to view queries you have received.
3. Review the list of documents displayed with their details (e.g., Submitted Name)
4. Select the required and appropriate checkboxes from the Submitted name option to select the document, next to the checkboxes, the user can click on the blue arrow (Go to the document), which will navigate to the document index.
5. Click on the PDF icon will open a new window of the document which has an open query, The PDF opens in the window, allowing the user to navigate through the pages using the controls at the top



6. If needed, click the Export button to download the query data in a suitable format (e.g., CSV or Excel) for further analysis or reporting.
7. Click on the Respond to Query option next to the relevant document. Follow the on-screen prompts to provide your response.
8. Click the Manage Columns to adjust the visible information in the table.
9. Use the navigation controls Previous and Next to switch between pages of documents.
10. Click on the Views dropdown to select different views or filtering options.
11. Click the refresh icon to update the list with any recent changes.



### Open Queries by Age

The Open Queries by Age tab displays documents that are older than 30 days or more, and provides a document count for easy tracking. The user can select a query type from the dropdown menu located at the top left, including Any, Workflow, or Audit options.



Steps to open queries by age:

1. Navigate to the eTMF dashboard, and select the Open Queries by Age tab.
2. Use the Query Type dropdown to filter the queries:
  - Select Any to view all queries.
  - Choose Workflow to see the action related to a specific workflow process.
  - Choose Audit to show only those that are related to audit activities.
3. Review the list of documents displayed with their details (e.g., Submitted Name)
4. Click on the + sign next to the reason will expand the section, and reveal individual documents, including details such as the Submitted Name, Created Date, and Comments.
5. Click on the – sign will minimize the section.
6. Additional options, like Export and Manage Columns, allow the user to export the data or customize the column view to focus on relevant information.



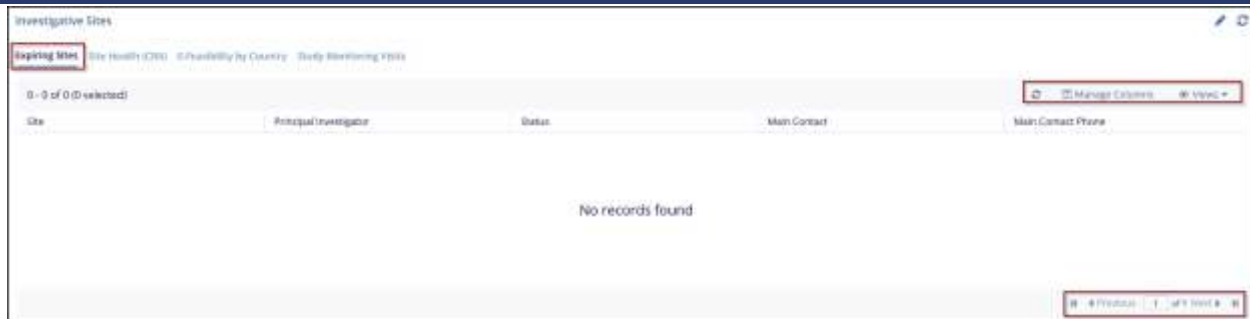
## Investigative Sites

The Investigative Sites dashboard provides a list of sites involved in clinical trials or studies, displaying details for Expiring Sites, Site Health (CRA), Recently Updated Sites, Site Activation Status, eFeasibility by Country, and Study Monitoring Visits.

It includes the following tabs:

### *Expiring Sites*

The Expiring Sites tab provides a list of all sites that have an upcoming expiration date. This tab includes columns displaying details such as Expiration Date, Site, Principal Investigator, Status, Main Contact, and Main Contact Phone. Users can further customize the view by clicking Manage Columns to add or remove specific columns as needed. This feature helps users track sites with approaching expiration dates, ensuring timely actions can be taken.



### Site Health (CRA)

The Site Health (CRA) tab provides a summary of the completion status for multiple sites, allowing users to monitor site progress effectively. This tab features three chart types—Donut, Bar, and Column—that display the percentage of tasks completed out of the total for each site. Users can also Export the data for external reporting or analysis. Additionally, the All-Sites dropdown menu allows for filtering, enabling users to narrow down the view to specific sites or groups as needed.

#### Steps to view Site Health (CRA)

1. Navigate to the Investigative Site dashboard, and click on the Site Health (CRA) tab.
2. The user can view the Site Health (CRA) Chart through the Donut, Bar, and Column view by selecting it.  
This will update the display of each site's completion status in the chosen format.
3. Use the All-Sites dropdown menu to filter which sites appear in the view. This is helpful to users if they want to focus on specific site data.
4. Click on the Export button to download the data currently displayed. This option allows the user to save the information for further review or to include it in reports.



### Recently Updated Sites

The Recently Updated Sites tab provides a list of sites that have recent updates, allowing users to monitor site progress and activity status. This tab displays details including Site, Principal Investigator, Status, and Progress %. Users can customize the display by managing columns, refreshing the data, and viewing all sites. This tab helps users keep track of site activity and status updates, which can be essential for ensuring that all sites meet project requirements.

- Click the View All Sites in the top right corner if the user wants to see the complete list of sites without any filters applied.
- Use the Refresh button to update the information displayed in the list. This ensures the user is viewing the most current data.
- Click the Manage Columns to customize the information displayed. The user can add or remove columns need to focus on specific details relevant to the review.



| Site                   | Principal Investigator | Status  |
|------------------------|------------------------|---------|
| USA 001 PI Placeholder | PI Placeholder         | Active  |
| Site - 004 PI          | 004 PI                 | Active  |
| Bahama Hospital        | Admin-100              | Pending |
| Site - 123 test        | 123 test               | Pending |
| USA PI Placeholder     | PI Placeholder         | Pending |

### Site Activation Status

The Site Activation Status tab displays a bar chart showing the activation progress of sites over time. This tab allows users to filter by site groups and activation progress type, making it easier to track which sites are moving through the activation stages. The chart provides a representation of site activation on specific dates, helping users quickly assess activation trends and identify any sites that may require further action.

- Use the All-Sites dropdown menu to filter the chart by specific site groups, allowing the users to focus on a subset of sites relevant to the review.
- In the second dropdown menu, choose the desired Site Activation Progress type to adjust the chart based on specific activation criteria or milestones.
- Review the bar chart to see the number of sites activated on specific dates. Each bar represents the count of sites that reached the activation milestone on that date.

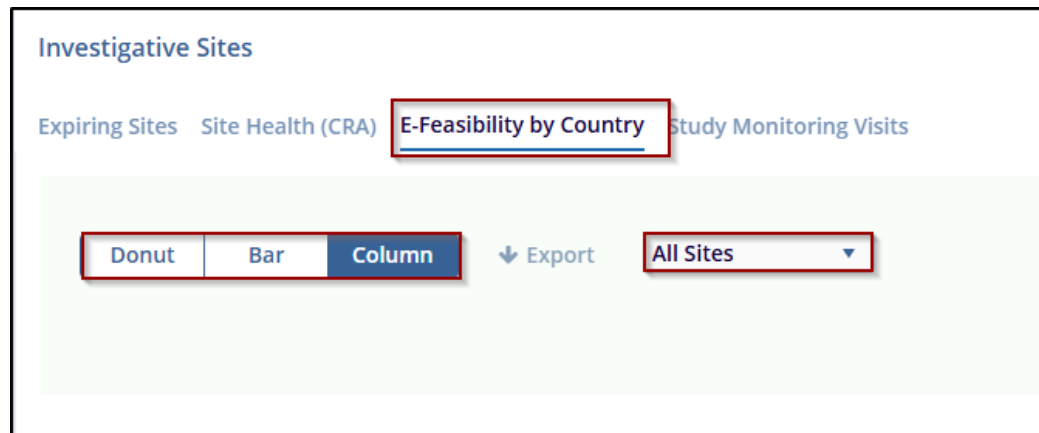


### eFeasibility by country

The eFeasibility by Country tab provides an overview of the feasibility assessments sent to sites in different countries. The data is presented in a chart format that can be viewed as a Donut, Bar, or Column chart, giving flexibility in how the information is displayed. This tab

also includes an Export option to download the data for external analysis or reporting. The All-Sites dropdown allows users to filter the sites by specific groups, focusing the view on particular sets of sites or regions. This feature helps users quickly see the distribution and count of feasibility assessments across countries.

1. Select the preferred chart format by clicking Donut, Bar, or Column. This will change how the feasibility data is displayed, allowing the user to choose the visualization that best suits the analysis.
2. Use the All-Sites dropdown to filter the data by specific site groups or regions, making it easy to focus on certain countries or subsets of sites.
3. Click on the Export button to download the feasibility data currently displayed in the chart. This option is useful for creating reports or conducting further analysis outside of the system.
4. The chart shows the total number of sites with feasibility assessments for each country. For example, the Donut chart format indicates 1 Total site in India with a feasibility status of "Sent."



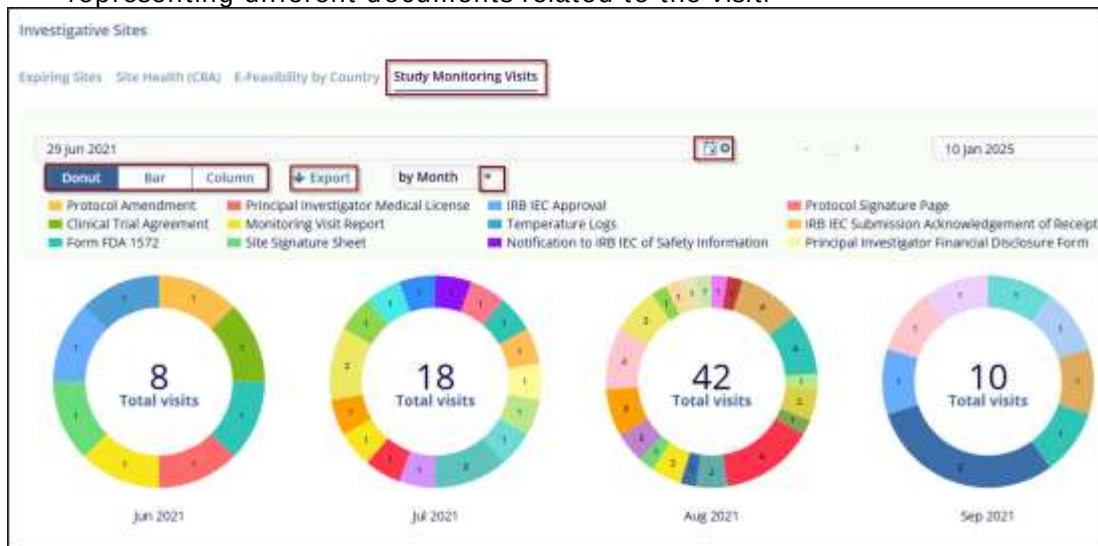
### Study Monitoring Visits

The Study Monitoring Visits tab provides a breakdown of the monitoring visits conducted over specific periods. Users can view visit data by month and year, with each circular chart displaying the total number of visits for that time and color-coded segments representing various document types (e.g., PI Curriculum Vitae, Protocol Amendment, Administrative Changes). The tab offers flexibility to change the chart type between Donut, Bar, and Column views, and an Export button to download the data. The date range can be adjusted using the date fields to focus on specific periods, helping users track and analyze visit trends over time.

Steps to manage study monitoring Visits:

1. Navigate to the Investigative Site dashboard, and click on the Study Monitoring Visits tab.
2. Choose the date range for the data by selecting the start date (on the left) and end date (on the right). This will update the charts to show visits within the specified time frame.
3. Select Donut, Bar, or Column to choose the preferred chart format. This will change the display of the visit data, allowing the user to view the information in a format that best suits their needs.

4. Use the By Month dropdown to organize the data by monthly intervals. This option can help in viewing trends over each month within the selected date range.
5. Click on the Export button to download the current view's data. This is useful for external analysis or reporting needs.
6. Each circular chart shows the Total visits for a specific month or period, with color-coded segments indicating different document types or actions completed during those visits. For example, May 2023 shows "2 Total Visits," with each color representing different documents related to the visit.



## Common

The users can view and modify the room's Welcome message, which is displayed to all users upon accessing the room. This message area serves as a space for sharing essential information about the study, such as updates, reminders, or key details. Only users with Administrator or Manager access can edit this dashboard by pressing the Edit button with the Pencil icon at the left-side of the dashboard. After making the desired updates, clicking save will apply the changes, making them instantly visible to all users in the room, ensuring everyone has access to the latest study-related information.

### *About this room*

The About This Room tab provides a welcome message and important information regarding the use of the room. This space can be customized to include study details, access requirements, and relevant support information. It mentions the need for Adobe Acrobat Reader for viewing certain documents and includes a link to download it. Users with Administrator or Manager roles can edit this content to ensure that all participants have up-to-date information and resources.

Steps to use the common section:

1. Navigate to the Common dashboard, and click on the About this room tab.
2. Review the welcome message and any instructions provided. This message might contain important details about study access, document requirements, and support contacts.

3. Click the Click here to get it link to download Adobe Acrobat Reader, as it is necessary to view some documents in the room.
4. If the user is an Administrator or Manager, click the Edit button with the Pencil icon in the top right corner to make changes to the welcome message.
5. Update the text with any new information or instructions, as needed.
6. After making edits, click Save to apply the changes. The updated message will be immediately visible to all users in the room or click on Cancel to discard the changes.



### Bulletin Board

The Bulletin Board tab is set up by administrators to provide important messages and updates to the team. It can include information related to the room, study-related announcements, or updates about any issues or actions needed. This section serves as a central communication hub for keeping all team members informed. Both Administrators and Managers have permission to edit the content in this area, ensuring that relevant information can be updated as needed.

Steps to use the Bulletin Board:

1. Navigate to the Common dashboard, and click on the Bulletin Board tab.
2. The Bulletin Board tab will display messages or updates provided by administrators. If there are no messages, it may show "No records available."
3. If the user is an Administrator or Manager and needs to add or update information, click the Edit button located at the bottom right of the screen.



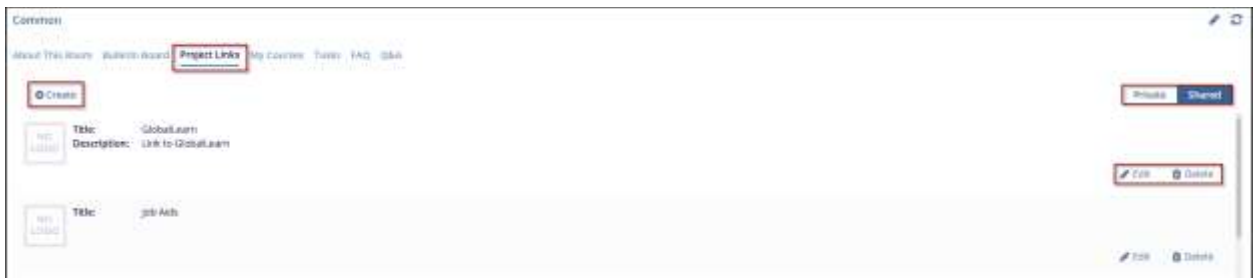
4. In Edit mode, enter the message or update the wish to communicate to the team. This can include announcements, study updates, or any relevant instructions.
5. After entering the message, click Save to apply the changes. The updated message will then be visible to all team members on the Bulletin Board.



## Project Links

The Project Links tab displays links to various websites and resources used in the study, allowing team members quick access to important external content. Users with Editor-level permissions and above can create new links by clicking the Create button. Each link can be set as Private (visible only to the user) or Shared (visible to all users). This setup allows users to organize and manage external resources effectively.

1. Navigate to the Common dashboard, and click on the Project Links tab
2. Click the Create button to add a new link to the tab.
3. During the link creation process, the user can set the visibility of the link by selecting Private (for personal use) or Shared (for all users to see). This can be done by checking or unchecking the relevant option.
4. If the user needs to modify or remove an existing link, click Edit or Delete next to the respective link. Editing allows the user to change details such as the title or URL while deleting removes the link from the tab.
5. The list of created links will be displayed under the Project Links tab. Each link entry shows the title and associated details, giving users quick access to frequently used websites.



## Tasks

The Tasks tab allows users to track and manage their tasks related to various activities. Each task is associated with specific details such as Subject, Status, Priority, Start and Due dates, and Completion percentage. This section helps users stay organized by displaying all tasks in one place and offering options to filter, sort, and update task statuses.

Steps to Manage Tasks:

1. Navigate to the Common dashboard, and click on the Tasks tab



2. Select the Status and the Assignee from their respective dropdown menus to get the task details, including the subject, status, priority, and due date to stay on top of your responsibilities.
3. If the user working on a task, update the status to reflect your progress (e.g., from Not Started to In Progress or Completed).
4. Monitor the Complete % to assess how much of the task has been finished.
5. To manage the view toggle between All tasks and My tasks views.
6. Click Export to download a copy of the task information for further review or reporting.



## FAQ

The FAQ tab will display a list of common questions and answers related to the system, processes, or project-specific information. This section helps users quickly find answers to frequently asked questions without needing to contact support or ask team members. It can be used for both operational guidance and addressing common queries about how to use the platform or navigate through processes.

Steps to Use the FAQ tab:

1. Navigate to the Common dashboard, and click on the FAQ tab.
2. Click the + sign next to the checkbox to expand and view its answer.
3. Use the Date dropdown to sort the FAQs by their creation date (e.g., newest to oldest).
4. Use the Category dropdown to filter FAQs by categories like Regulatory Issues, Site Health, etc.
5. Use the filter option to search for keywords or phrases in the FAQ section.
6. Click Export to save the FAQ data in a suitable format.
7. Click view FAQs and take to the FAQ Module, where the user can filter questions and answer with more options.



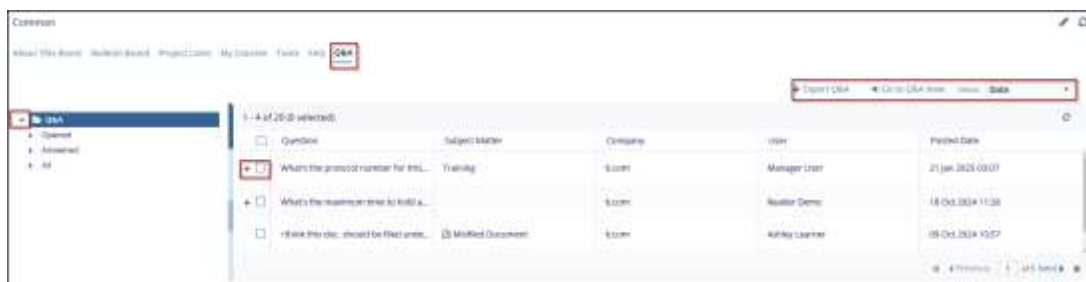


## Q&A

The Q&A tab is designed to help users post questions and receive answers related to various topics. It allows users to interact, resolve doubts, and track questions based on their status (opened or answered). This section also helps in sharing common queries that might be helpful for others.

### Steps to Use the Q&A tab:

1. Navigate to the Common dashboard, and click on the Q&A tab.
2. Use the filter options on the left to view questions based on their status:
  - Opened: To see all open and unanswered questions.
  - Answered: To view questions that have been answered.
  - All: To view both open and answered questions.
3. Each question will have a title (e.g., "What's the protocol number for this study?") along with relevant details such as the Subject Matter, Company, User, and Posted Date.
4. Click the + sign next to the checkbox to expand and view its answer.
5. Click Export Q&A to download the list of questions and answers for further reference or reporting.
6. Select from the Views dropdown to sort the questions by Date or other available criteria to prioritize your review of questions.



## Documents Module

The Trial Interactive eTMF Documents is the central repository for all the clinical trial documents in their original digital format with Digital Signatures wherever applicable, records, or documents converted from one format to another like paper documents, images converted to PDFs, videos and recordings pertaining to trials.

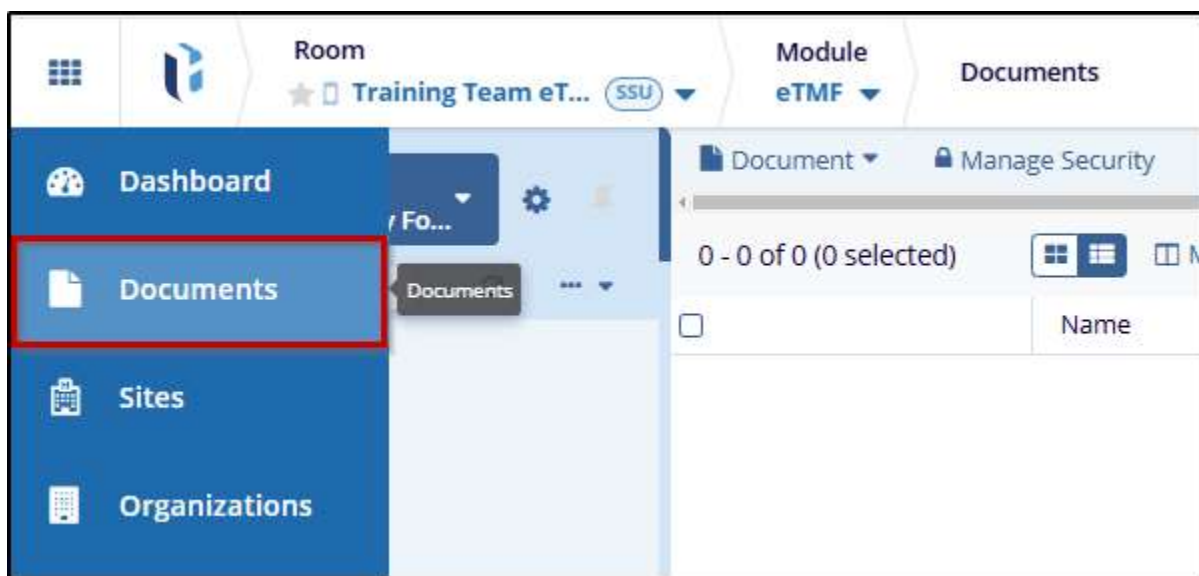
Here, users can configure and store essential documents about clinical trials, view and edit document attachments, manage security privileges, import and export documents and their metadata, and mail them to other users in addition to many other functions.

To comply with eTMF Completeness, users can track the progress right from document collection to the finalization of a document. This application also provides with the facility to post Questions and Answers along with the generation of FAQs for further insights.

The documents are then subjected to Quality Control, and Quality Review checks as specified by the FDA.

To access the documents modal, follow the steps below.

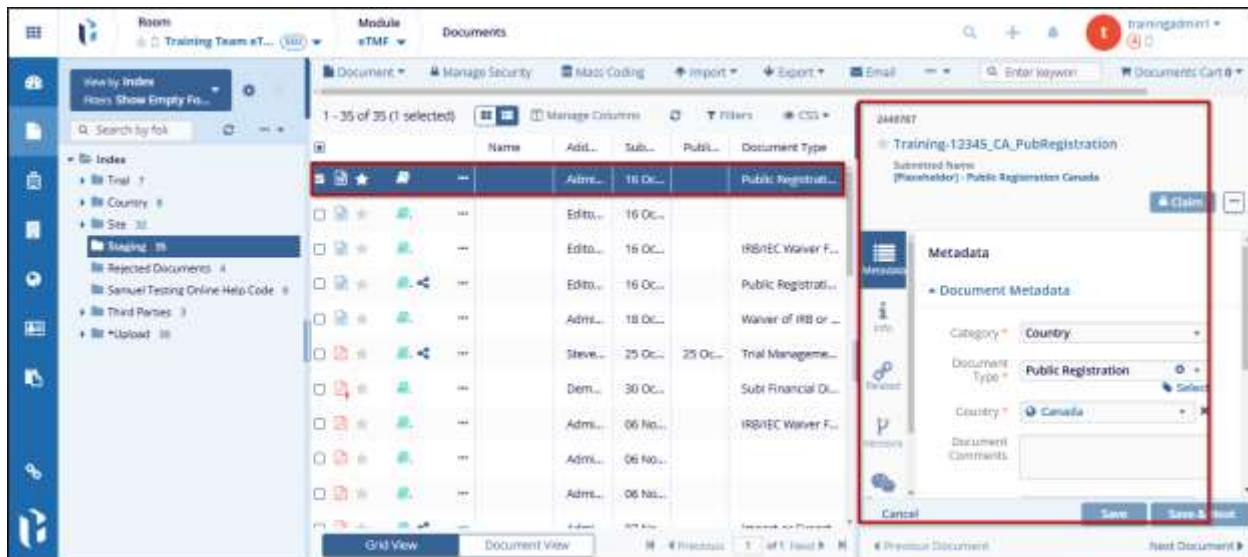
1. Select the eTMF module from the Module dropdown.
2. Click on the Documents modal from the left-hand navigation menu.



## The Room Index

The Room Index is structured as a tree-like system, with Index as the root folder. It consists of parent and child folders, which can either be cloned during room creation or created from scratch. Each Trial Interactive room can have a completely customized index structure, as no two index configurations are necessarily identical. Documents emailed to a room's inbox address are stored in each user's Inbox folder unless the room is configured otherwise. Documents uploaded directly to the room without metadata appear in each user's Upload folder, while those uploaded with metadata are placed in the default folder location, typically the Staging folder. Depending on room configuration, documents can also be uploaded

directly to other index folders. If a folder contains subfolders, clicking the arrow next to the folder or double-clicking it will expand and display the child folders. Similarly, an expanded folder can be collapsed by clicking the arrow next to it. Viewing documents within a folder requires selecting the folder, which then displays the stored documents in the documents grid at the center of the screen. Selecting a document from the grid loads its metadata in the Metadata Pane on the right side of the screen. In addition to the Metadata tab, the Metadata Pane may also include Workflow, Queries, Versions, History, and eSignature tabs, depending on the documents context.



## Configuring the Index Structure

The index structure of a room will be cloned from an existing room or a client-specific template room. Normally, any changes to the standard layout would be indicated in the configuration manual and addressed before the room is used. However, administrator-level users can make changes to the room index structure.

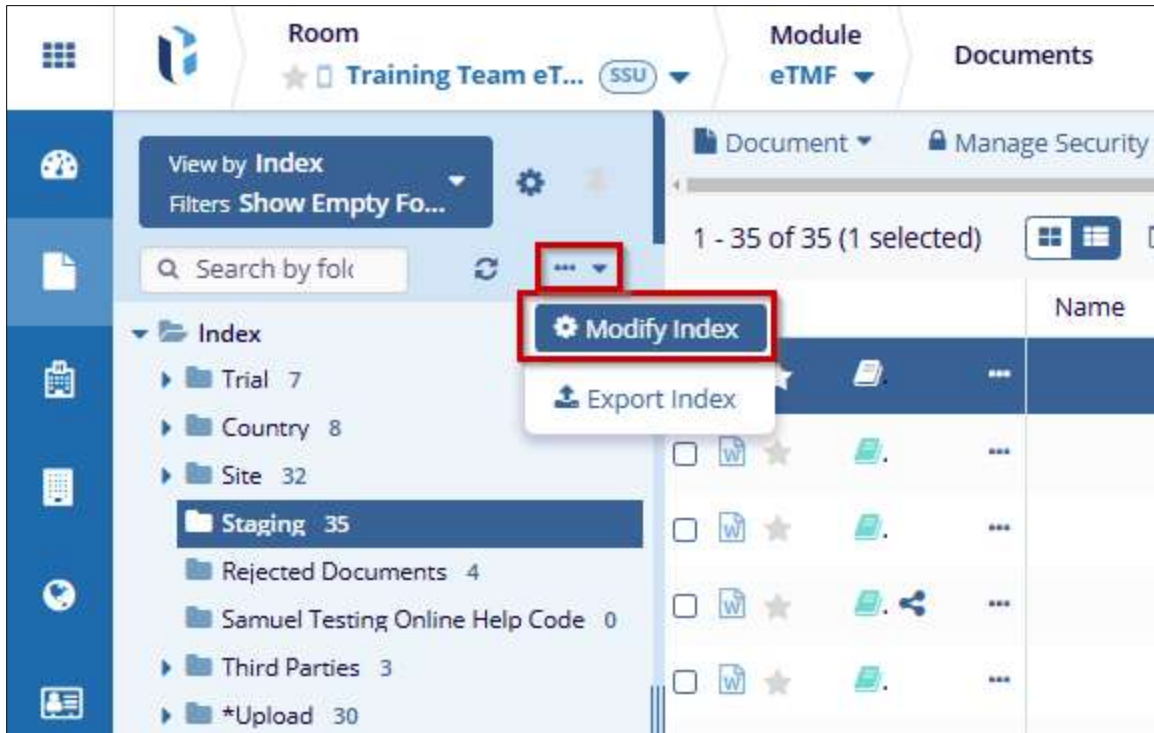
**Note:** It is recommended to be fully trained by a Trial Interactive Product Trainer to ensure the changes need to be made. Deleting a folder containing documents will immediately delete all of the documents within. It is highly recommended that to work with the Trial Interactive Service Desk if to make any alterations to the index structure of a study room.

### Add New Folders

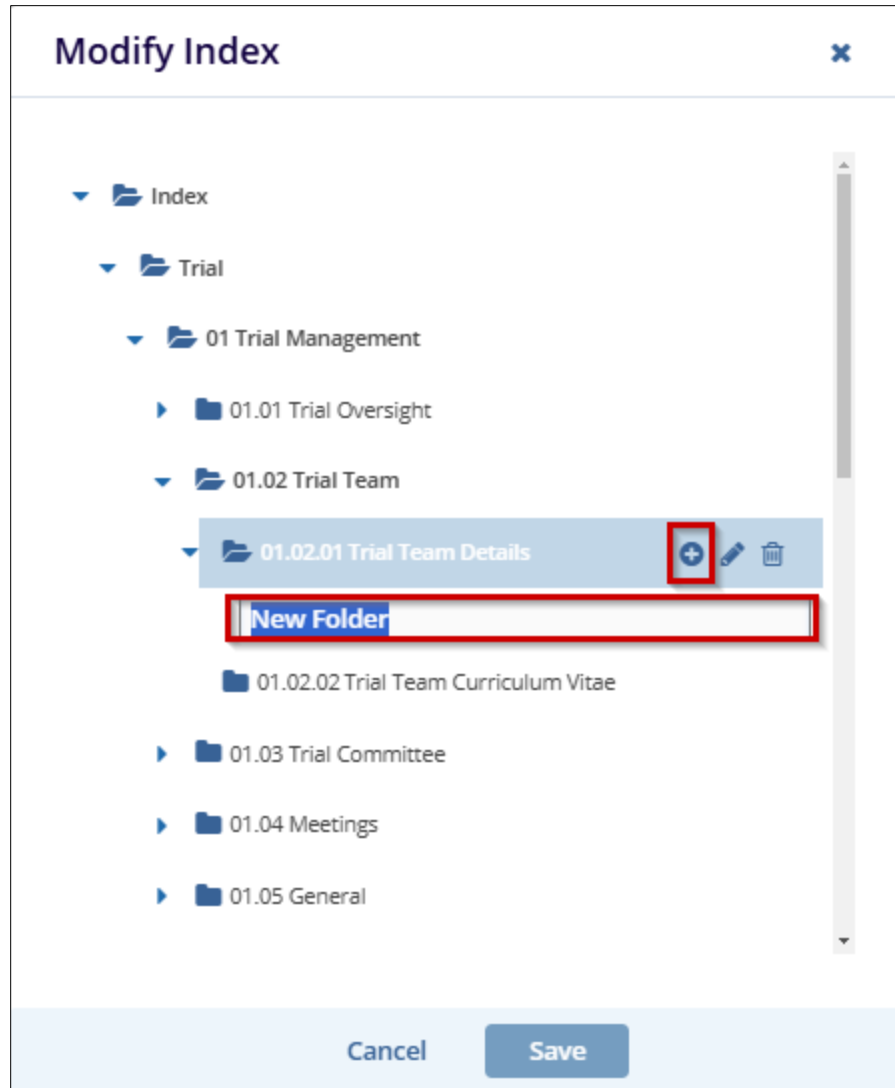
Administrator-level users can add new folders to the index structure of the documents module from the Index pane. There is a three-dot menu under the view selector menu.

To add new folders, follow the steps below.

1. Click on the three-dot menu and select the Modify Index option from the dropdown options. The Modify Index window opens.



2. Hover over the parent folder, or hover over the index to create a new sub-folder, and click the + icon to add a new folder.  
Note: The index structure may appear different from the one shown in the image above since index structures can be customized on a room-by-room basis.
3. When the folder is created, name the folder and press the Enter Key to save the name.
4. Perform any other desired index modifications and click on the Save button.

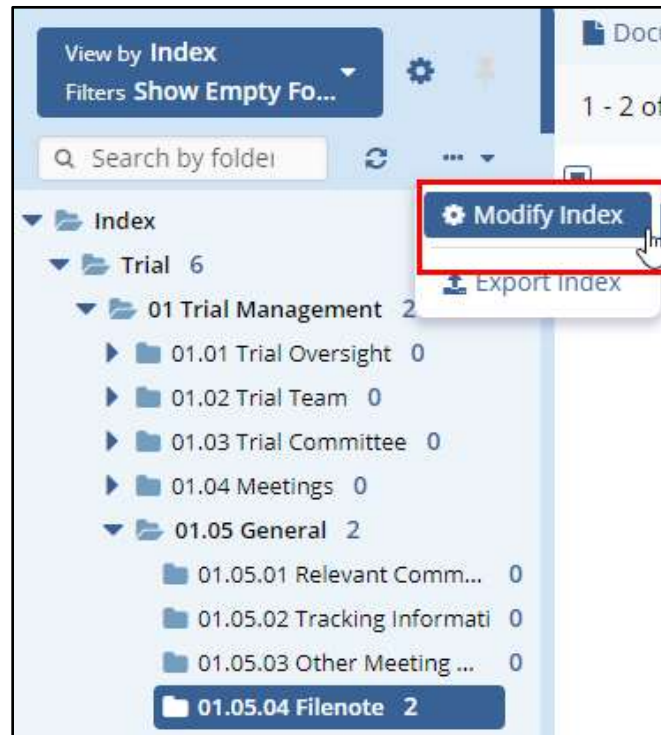


### *Edit or Delete an Existing Index Folder*

Administrator-level users can delete or edit the names of existing folders to the index structure of the documents module from the Index pane by accessing the three-dot menu under the view selector menu.

To edit or delete an index folder, follow the steps below.

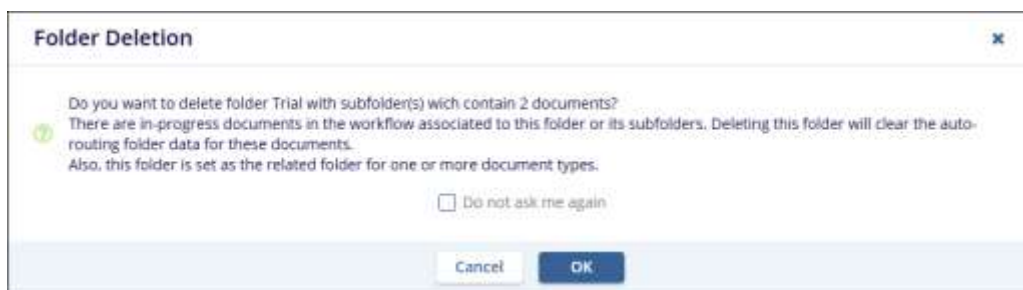
1. Click on the three-dot menu and select the Modify Index option. The Modify Index window opens.



2. Click on the edit (pencil) icon and modify the folder name.



- Click on the Delete icon and confirm the folder deletion by clicking on the OK button on the Folder Deletion confirmation popup.



- Perform any other desired index modifications and click on the Save button.

Note: It is recommended to be fully trained by a Trial Interactive Product Trainer to ensure the changes need to be made. Deleting a folder containing documents will immediately delete all of the documents within. It is highly recommended that to work with the Trial Interactive Service Desk if to make ANY alterations to the index structure of a study room.

#### *Edit Country and Site Level Folders*

The country and site-level folders are greyed out and are not editable from the Modify Index window. These folders are controlled by the template folder settings.

Note: Refer to the Countries Template Folder and Site Template Folder settings from the Settings module.

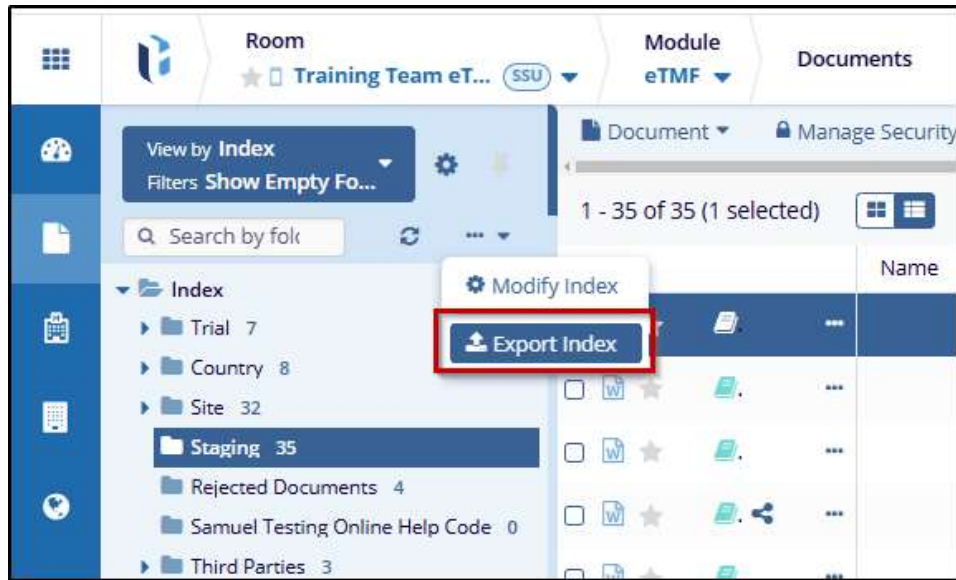


### Exporting the Index Structure

Export index allows to export the index structure of the room. Users can choose to export the index for the chosen folder or only the index outline. The index can be exported in either HTML, Microsoft Excel or Microsoft Word format. Besides these, users can also choose to export empty, or system folders as well as documents unpublished to the eTMF.

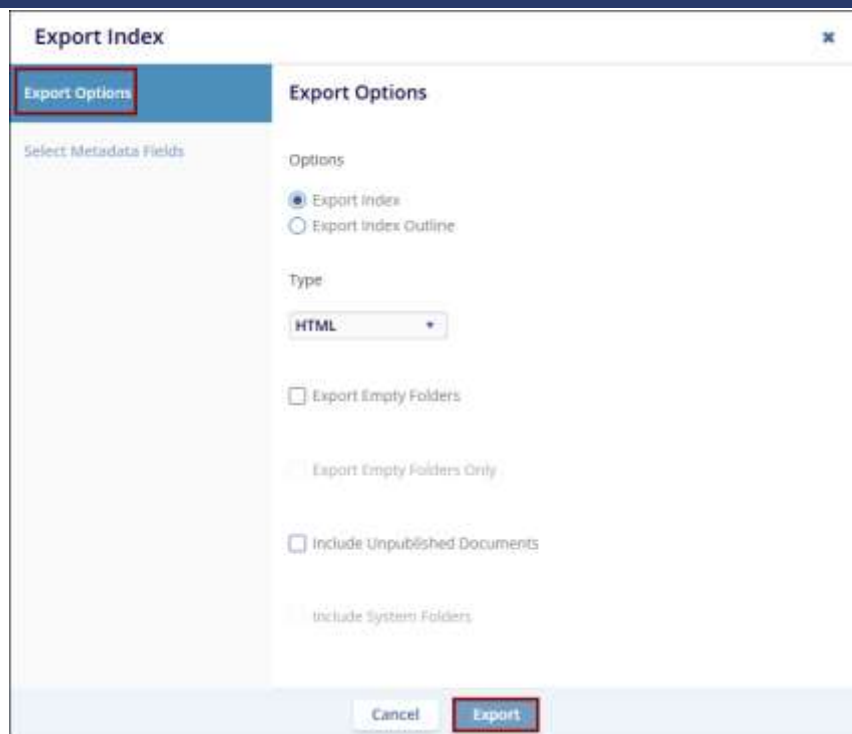
To export the index, follow the steps below:

1. Click on the three-dot menu and select the Modify Index option from the dropdown options. The Export Index window opens.

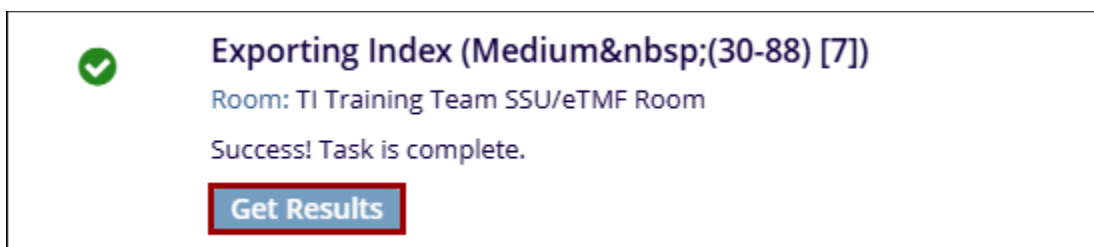


2. On the Export Index window, perform the following.
  1. Select Export Index or Export Index Outline by clicking on the radio buttons.
  2. Select HTML, Microsoft Excel, or Microsoft Word from the Type dropdown options.
  3. Click on the Export Empty Folders checkbox to retrieve empty folders as well.
  4. Click on the Export Empty Folders Only checkbox to retrieve just the empty folders.
  5. Click on the Include Unpublished Documents checkbox to retrieve unpublished documents.
3. Click on the Export button.

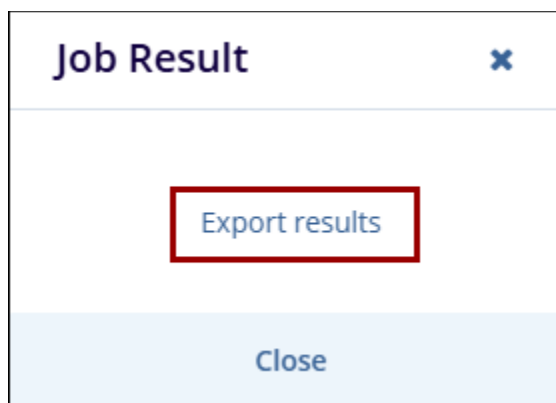




4. On the success message popup, click on the Get Results button.



5. On the Job Result window, click on the Export Results link.



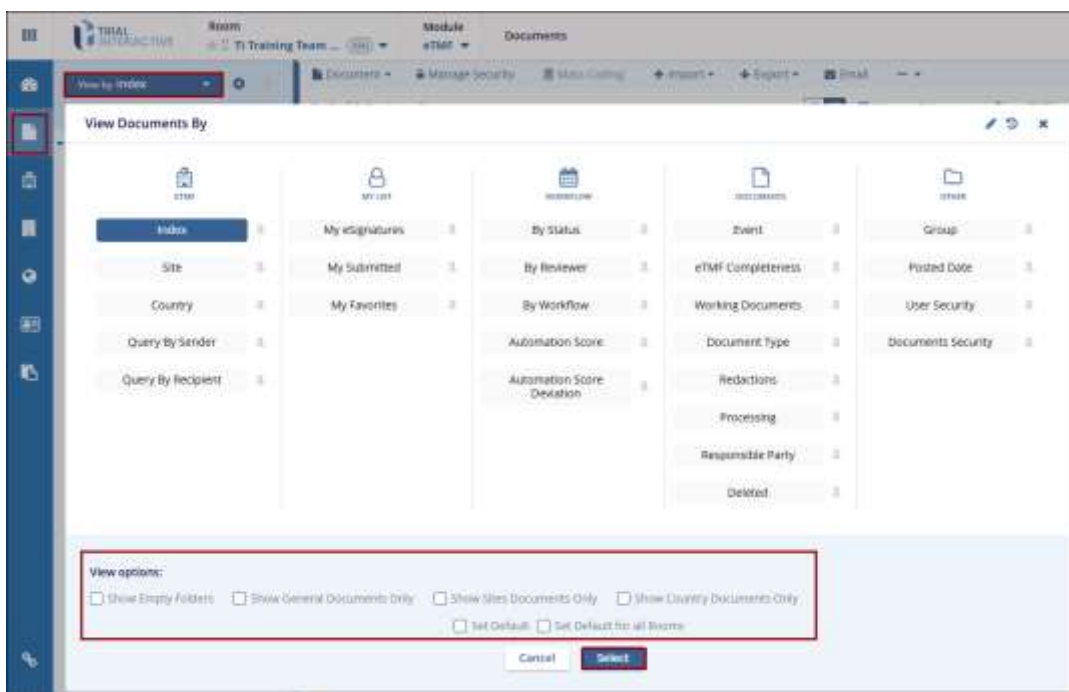
## Views

The Views functionality enables users to customize the left-hand navigation pane in the Documents module and select documents based on specific categories.

### Apply a View

To access and apply different views, follow the steps below:

1. Open the Documents modal from the left-hand navigation pane and click the View By dropdown. The index view is applied by default.
2. On the View Documents By screen, choose a view from the available categories.
3. Click the pin icon to pin a view if needed.
4. Use the View Options to customize the selected view.
5. Click on the Select button once the require view and view option is selected.

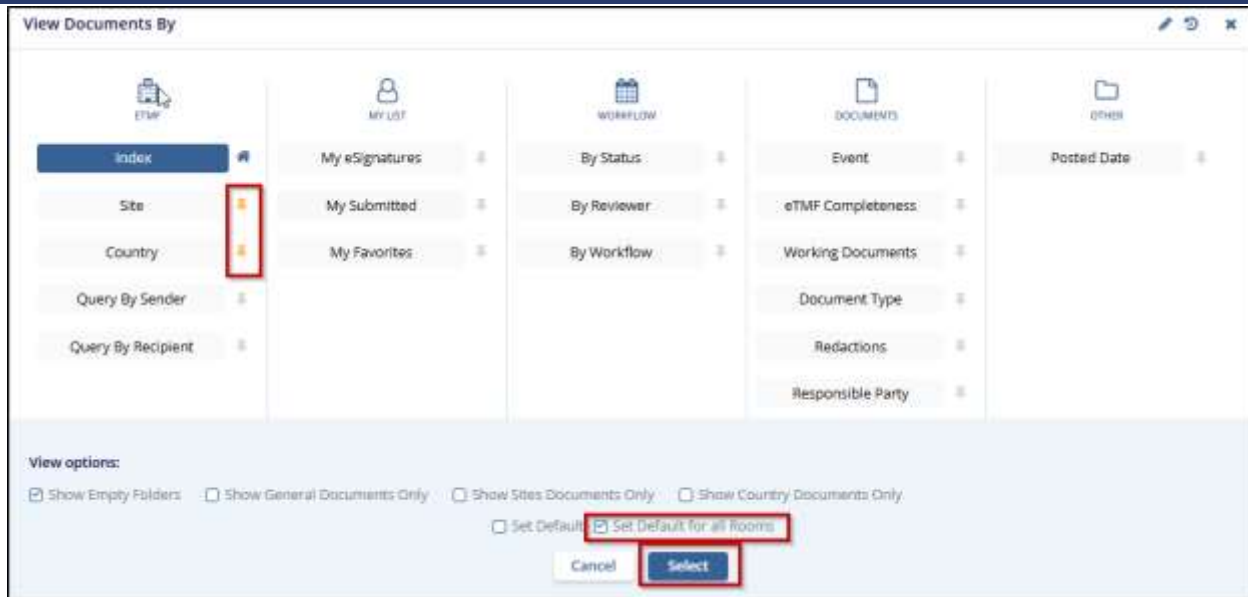


Note: View Options differ based upon the view selected.

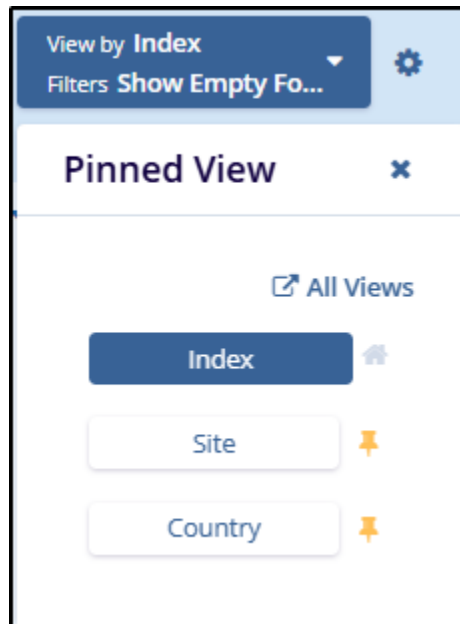
### Pin and Set Default View

To pin and set a default view, follow the steps below.

1. Select a view and check the Set Default for all Rooms checkbox to make that view default across rooms.



- Click the pin icon to pin the view. Pinned views appear in the View By dropdown. To view all available options, click the All Views button.

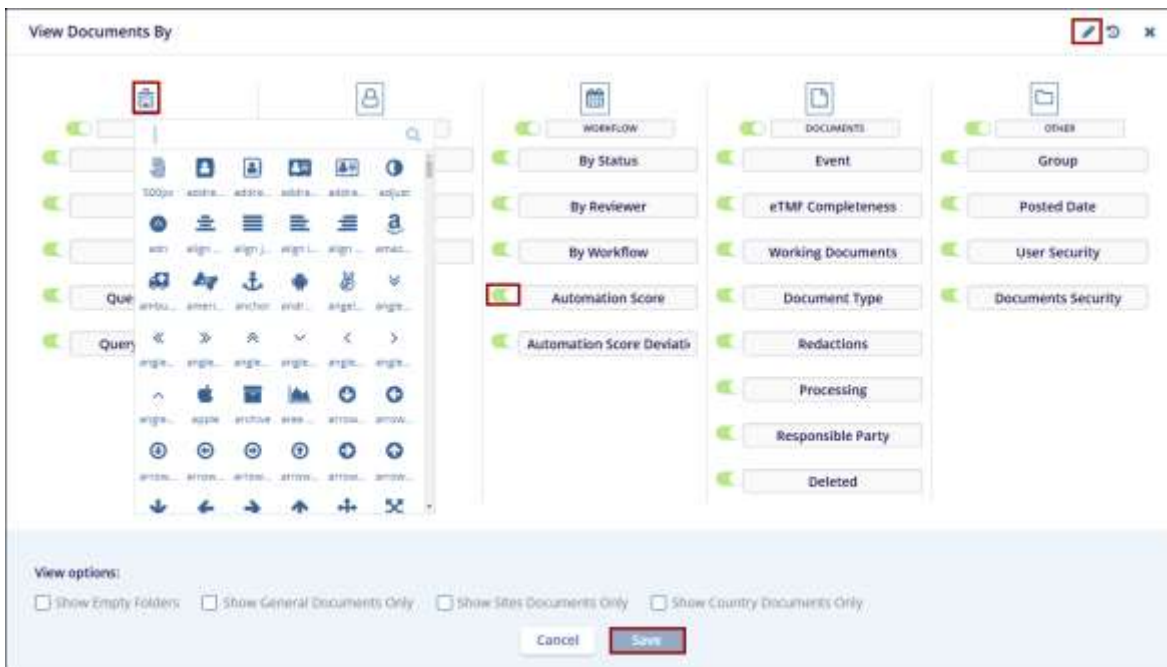


### Edit View Documents By screen

To edit the View Documents By screen, follow the steps below.

- Open the View Documents By screen and click on the Edit icon.
- Click on the Group Name icon and select an icon from the available list to have a different icon for the group.

3. Enable or disable the toggle switch of a Group Name and View Name to control their visibility.
4. Modify the Group or View Name if required.
5. Click on the Save button once all the changes are made.



6. Click on the Change Log icon to view the Change Log History.



### View Descriptions

Each view is organized into different groups.

| View Name | Description                                                       |
|-----------|-------------------------------------------------------------------|
| Index     | Displays all documents in the room based on their index location. |

| View Name                  | Description                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Document Type              | Organizes documents according to their assigned document types.                                                                                                                                                                                                                                                                                                                                                                               |
| Site                       | Shows documents organized by their site association.                                                                                                                                                                                                                                                                                                                                                                                          |
| Country                    | Displays documents grouped by their country association.                                                                                                                                                                                                                                                                                                                                                                                      |
| Tag                        | A metadata field that links documents. This view groups documents by their assigned tags, with one document potentially linked to multiple tags.                                                                                                                                                                                                                                                                                              |
| My eSignatures             | Displays documents requiring eSignature, allowing users to perform eSignature-related functions.                                                                                                                                                                                                                                                                                                                                              |
| My Submitted               | Shows documents that the user has submitted or uploaded.                                                                                                                                                                                                                                                                                                                                                                                      |
| My Favorites               | Displays documents marked as favorites by the user.                                                                                                                                                                                                                                                                                                                                                                                           |
| Query by Sender            | Organizes queries by the sender. Users will see different queries depending on their access level. Administrators can view all queries in the room or choose to see only their own. Other users will only see their own queries unless granted additional privileges.                                                                                                                                                                         |
| Query by Recipient         | Organizes queries by the recipient. Depending on the user's access level, administrators can view all queries or choose to see only their own, while other users will only see their own queries unless granted additional privileges.                                                                                                                                                                                                        |
| Submissions                | Displays all documents ever submitted by the user to the room, excluding deleted documents.                                                                                                                                                                                                                                                                                                                                                   |
| My QC/Reviews              | Available only to users involved in the rooms QC workflow. Users can perform related functions based on the workflow settings. Documents added to the room are automatically added to the workflow, and can be viewed from the My Reviews view or the Quality Control module under unclaimed documents.<br><br>Note: If assigned to a QC group, this view is automatically activated and mirrors the QC Review module in the Navigation Grid. |
| Audit Findings             | Available to users assigned the role of Audit Responder. This view allows Audit Responders to perform functions related to correcting audit findings.                                                                                                                                                                                                                                                                                         |
| By Status                  | Groups documents by their QC Workflow status (e.g., QC 1 Approved, Final).                                                                                                                                                                                                                                                                                                                                                                    |
| By Reviewer                | Shows documents currently claimed by QC workflow personnel. Administrators can reassign claimed documents to other reviewers.                                                                                                                                                                                                                                                                                                                 |
| By Workflow                | Organizes documents by their workflow association.                                                                                                                                                                                                                                                                                                                                                                                            |
| Automation Score           | Groups documents by their assigned automation scores.                                                                                                                                                                                                                                                                                                                                                                                         |
| Automation Deviation Score | Groups documents by the automation deviation scores.                                                                                                                                                                                                                                                                                                                                                                                          |
| Event                      | Available in rooms using the Event Manager. Displays documents and placeholders related to specific events.                                                                                                                                                                                                                                                                                                                                   |
| eTMF Completeness          | Organizes documents and placeholders by the related entity (e.g., Study, Countries, Sites, or IRB/EC).                                                                                                                                                                                                                                                                                                                                        |
| Working Documents          | Focuses on missing documents and placeholders, allowing users to drag documents onto placeholders for coding and fulfillment. The Staging, Upload, and Inbox folders are available from the lower panel.                                                                                                                                                                                                                                      |
| Document Type              | Displays documents grouped by Trial, Country and Site.                                                                                                                                                                                                                                                                                                                                                                                        |

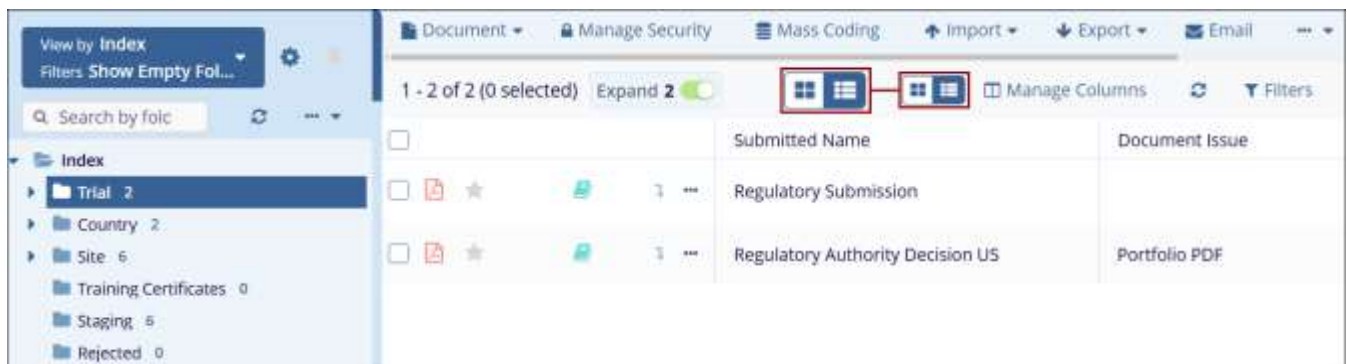
| View Name           | Description                                                                                                                                                                                                                                                                            |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Redactions          | Shows documents identified as containing protected content, organized by the state of their redaction.                                                                                                                                                                                 |
| Processing          | Shows documents bifurcated within the following categories <ul style="list-style-type: none"> <li>• Documents Auto Coded</li> <li>• Optical Character Recognition</li> <li>• Page Count</li> <li>• PDF Conversion</li> <li>• Thumbnail Generation</li> <li>• Virus Scanning</li> </ul> |
| Responsible Party   | Displays collected and missing documents organized by their Responsible Party association, requiring responsible parties to be in use in the room.                                                                                                                                     |
| Deleted Documents   | Displays all deleted documents, with options to restore or permanently purge them from the system.                                                                                                                                                                                     |
| User Security       | Groups documents by their affiliated security access group.                                                                                                                                                                                                                            |
| Group               | Displays documents organized by their affiliated group.                                                                                                                                                                                                                                |
| Posted Date         | Shows documents organized by the date they were added to the study room.                                                                                                                                                                                                               |
| Processed Documents | Shows documents that have undergone processing, such as conversion to PDF or OCR application.                                                                                                                                                                                          |
| Documents Security  | Organizes documents that have specific document-level security applied.                                                                                                                                                                                                                |

## Documents Grid Views

Immediately above the Documents Grid are the Grid and Card View options which allow the user to switch between Grid View and Card View.

To apply different views to the Documents modal, follow the steps below.

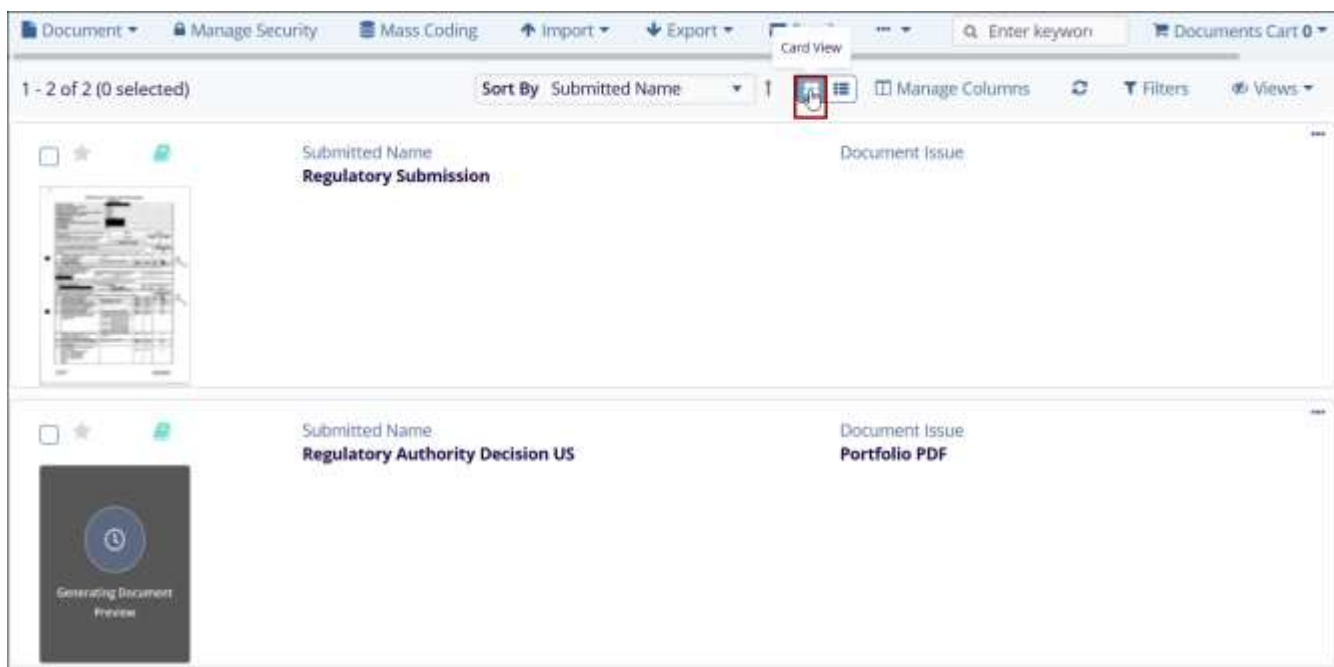
1. Select a folder with documents in it and the documents will be listed in the Documents Grid.
2. Navigate to the top section of the Documents modal switch between Grid View and Card View by selecting the respective view buttons.



- Click on the Grid View icon to view all documents within a folder in a list format.



4. Click on the Card View icon to view documents within a folder as individual cards. Each card represents a document and includes key information and a thumbnail image to visually represent the documents content.



## Manage Columns

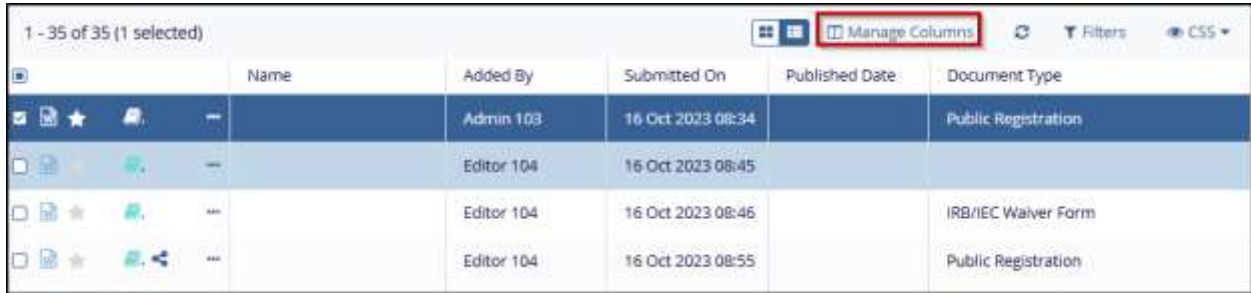
Users can configure which columns are displayed in the Document Grid irrespective of the Card or Grid View selected. This function is not limited to the Documents module and any grid in the system can be configured to the users' preferences.

### Manage Columns – Card View

To manage columns within the Card View, follow the steps below.

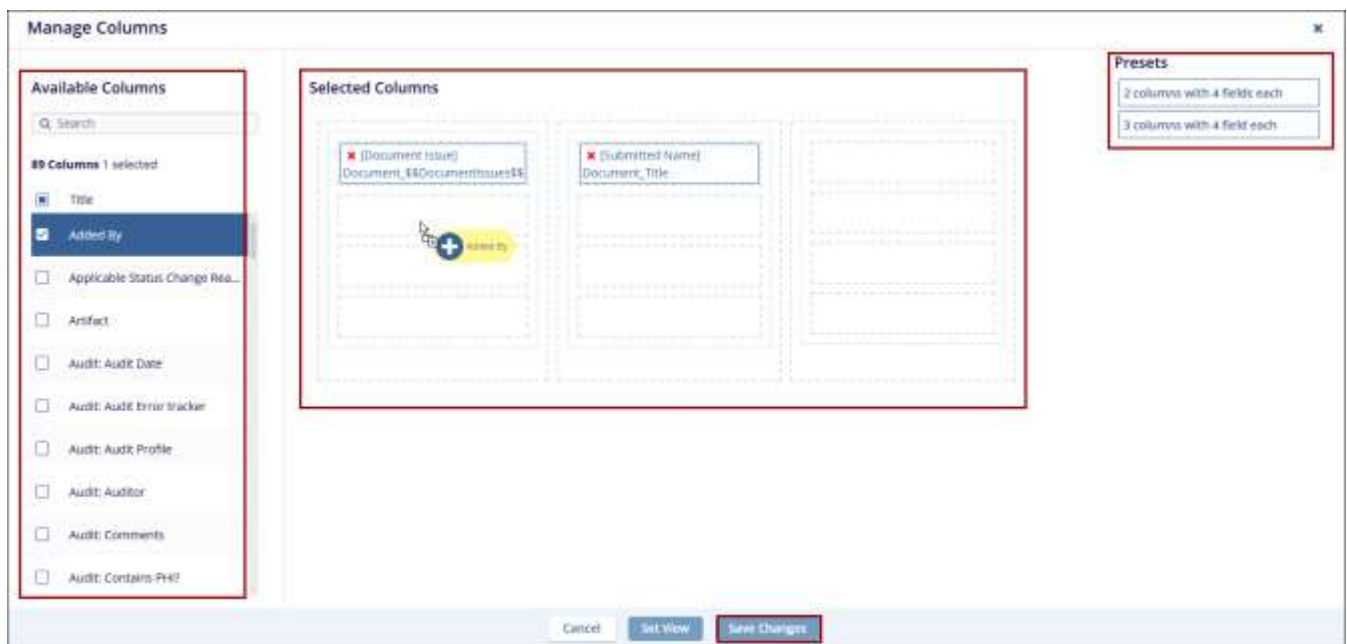


1. Click the Manage Columns button from the top-right corner of the documents grid. This opens the Manage Columns window.



|                                                                                                                                                                                                                                                       | Name | Added By   | Submitted On      | Published Date | Document Type       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|------------|-------------------|----------------|---------------------|
|    |      | Admin 103  | 16 Oct 2023 08:34 |                | Public Registration |
|    |      | Editor 104 | 16 Oct 2023 08:45 |                |                     |
|    |      | Editor 104 | 16 Oct 2023 08:46 |                | IRB/IEC Waiver Form |
|    |      | Editor 104 | 16 Oct 2023 08:55 |                | Public Registration |

2. The Manage Columns window will open which displays the following panels:
  - a. Available Columns Panel: This panel displays the list of all available columns in a room.
  - b. Selected Columns Panel: This panel displays the list of all columns that are selected and added from the Available Columns.
  - c. Presets:
3. To add a column to the Selected Columns pane from the Available Columns pane, drag & drop a column within the selected preset in the Selected Columns panel.
4. Alternatively, double-click on the columns in the Available Columns to add to the Selected Columns.
5. To remove the columns, click on the x icon of a particular column within the Selected Columns section.
6. Rearrange the columns sequence by dragging and dropping the columns into the desired order.
7. Click on the Save Changes button.





8. On the Save View popup window, perform the following
  - a. Name: If the view is new, provide a unique name. For an existing view, leave the name unchanged, if required.
  - b. Make Default for Me: Choose whether this view shall be set as default by enabling the toggle switch.
  - c. Make Default for All: (Admins Only) Select whether this view should be the default for all users in the room. Users can change their default view later, but this will initially set the view for all users.
  - d. Save As New: Decide whether to save this as a new view by enabling the toggle switch. For editing an existing view, do not select the option to save it as a new view.
9. Click on the Save button.
10. Once saved, the view will be listed in the available views, which can be accessed from the Views dropdown menu at the top-right of the Grid.



The image shows a 'Save View' popup window. It has a title bar with 'Save View' and a close button (X). The main content area contains three toggle switches, all of which are currently turned on (green). The first toggle is labeled 'Name' and has a text input field next to it containing 'View 1'. The second toggle is labeled 'Make Default for Me'. The third toggle is labeled 'Make default for All'. Below these is a fourth toggle labeled 'Save As New'. At the bottom of the window, there are two buttons: 'Cancel' and 'Save'.

Once the view(s) are configured, users can perform the following

- Save View
- Share View
- Manage Views

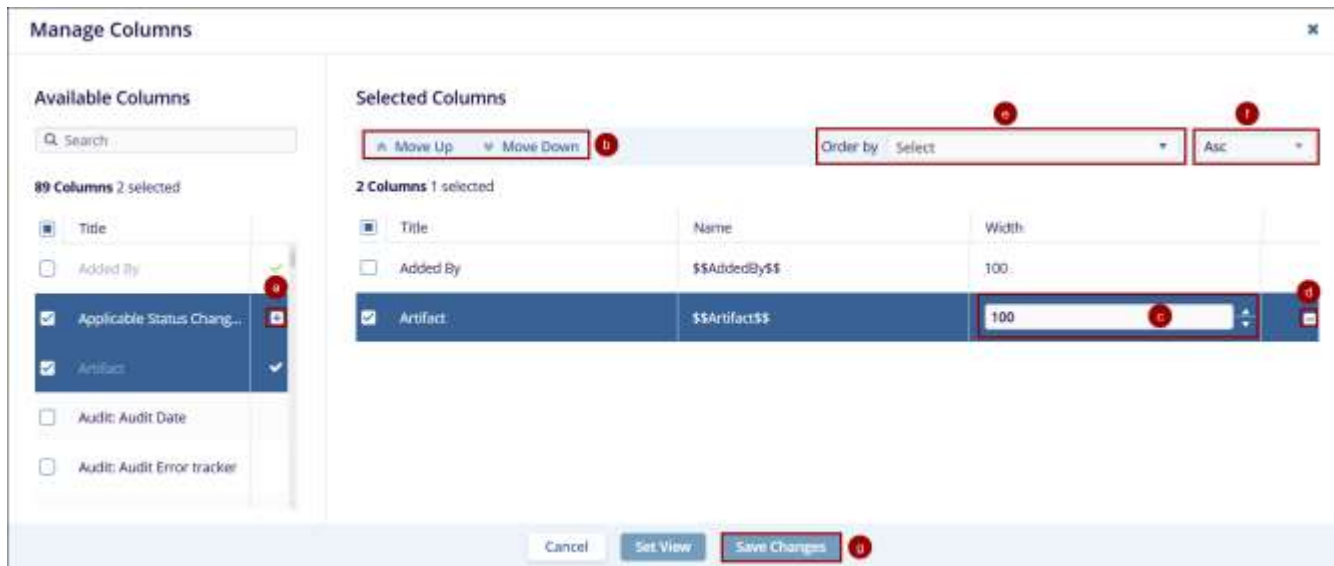
#### Manage Columns – Grid View

To manage columns within a Card View, follow the steps below.

1. With the Grid View selected, click on the Manage Columns button.



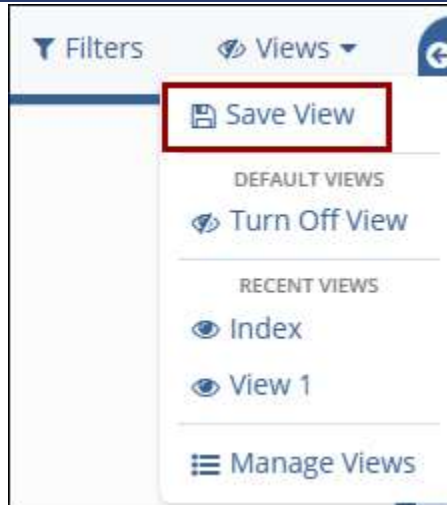
2. On the Manage Columns screen, perform the following
  - a. Select column headers from the Available Columns section and add them to the Selected Columns section.
  - b. In the Selected Columns section, select a column and click on the Move Up and Move Down arrows to re-arrange the order of the columns.
  - c. Adjust the width of the column by increasing or decreasing the value.
  - d. Click on the - sign to remove the column from the Selected Columns list.
  - e. Click on the Order by dropdown and select the criterion from the available dropdown options.
  - f. Sort the columns in Ascending and descending order by selecting the necessary option.
  - g. Click on the Save Changes button.



## Save View

To Save the view using another method follow the steps below.

1. On the Documents screen, click on the Views dropdown and select Save View option.



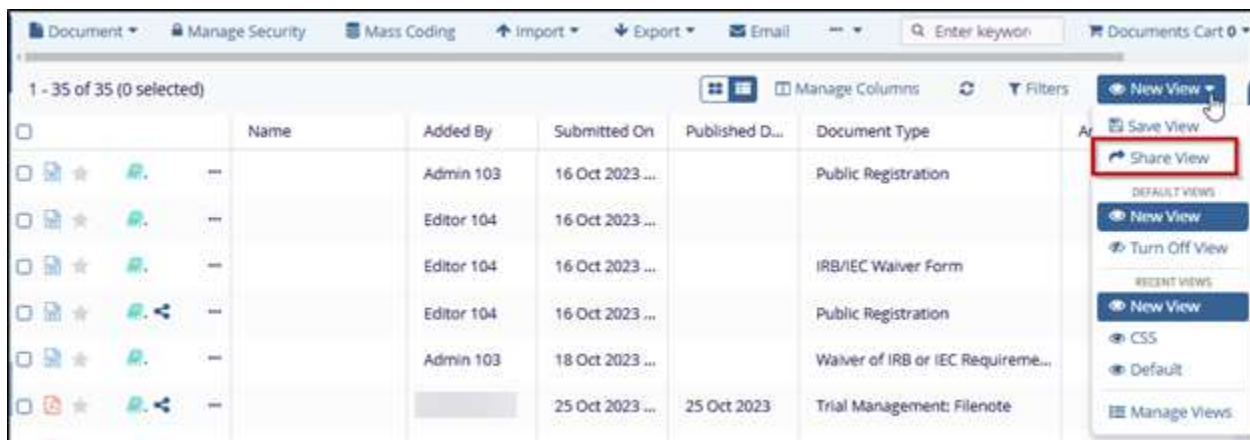
2. Make the necessary configurations within the Save View popup as mentioned above.
3. Once the view is saved, it will be available in the list of all views. This list is accessible from the Views dropdown menu at the top-right of the Grid.

## Share View

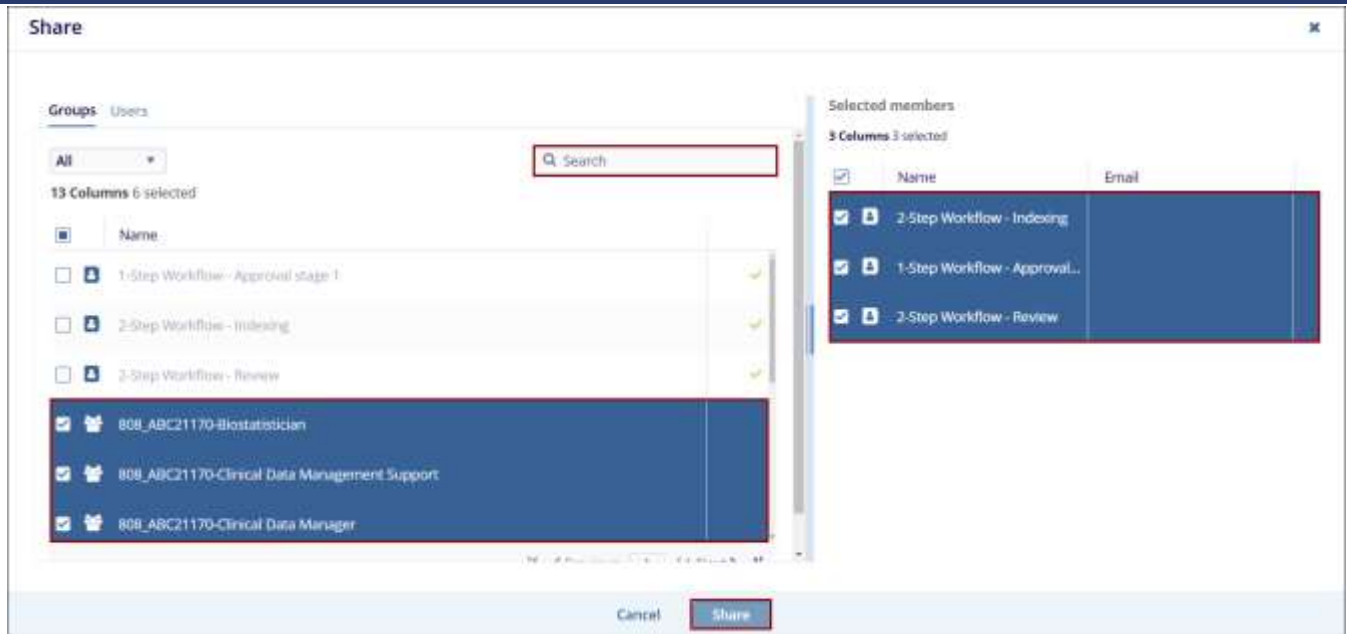
Once the view has been saved, it can be shared with any other room user. This is particularly useful when a new team member is brought on, as they may not be familiar enough with Trial Interactive to easily find the necessary information via the Grid.

To share the view, follow the steps below.

1. Open the View menu at the top-right of the Grid and select the Share View option. This opens the Share window.



2. Choose users or groups of users from the list at the left. Move these users to the right-hand panel by clicking and dragging or by hovering over the listing and using the + symbol at the right side of the line.
3. Click on the Share button.

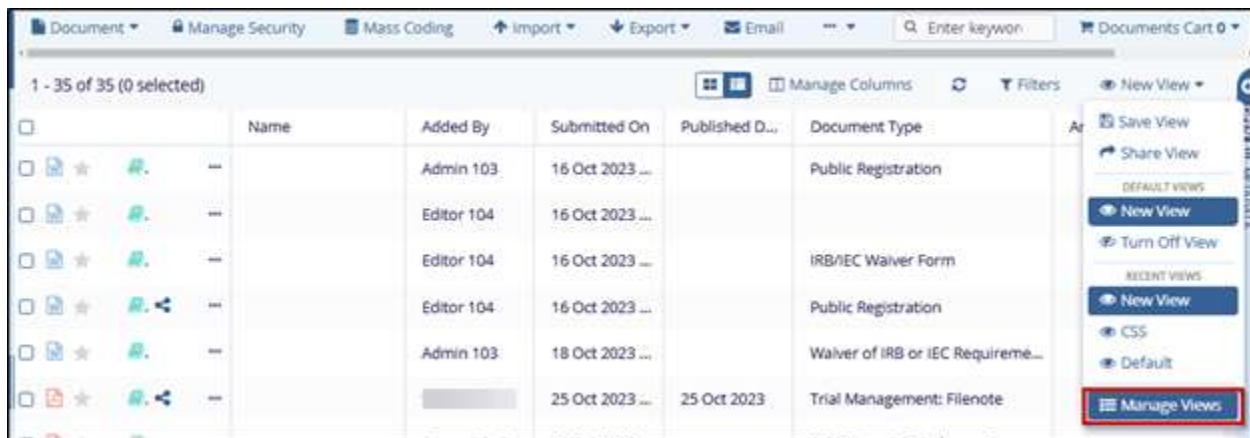


## Manage Views

If the room has multiple views created in a room, and if they are visible to all users, it is possible to see all the views in a room.

To display all views, follow the steps below.

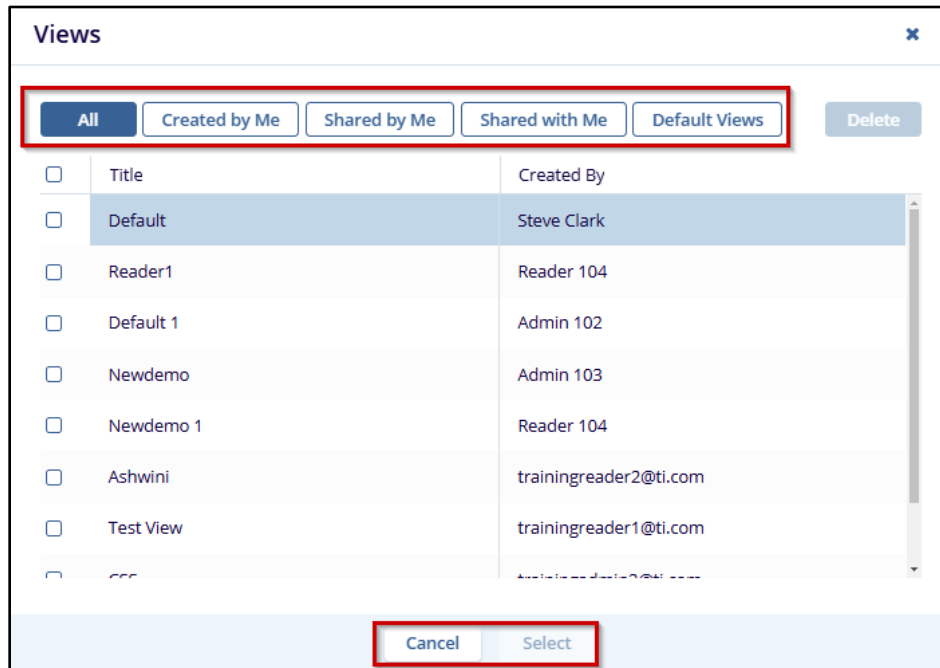
1. Select the Manage Views option from the from the Views dropdown.



2. The Views window opens which contains the following tabs:

- a. All: This displays the list of all the views in a room.
- b. Created by me: This displays the list of all views that are created by the user.
- c. Shared by me: This displays the list of all the views that are shared by the user to the other users.
- d. Shared with me: This displays the list of all the views that are shared with the user by the other users.

- e. Default Views: This displays the list of all default views.



3. To delete a view, select a view from the list and click the Delete button at the top right corner of the window.

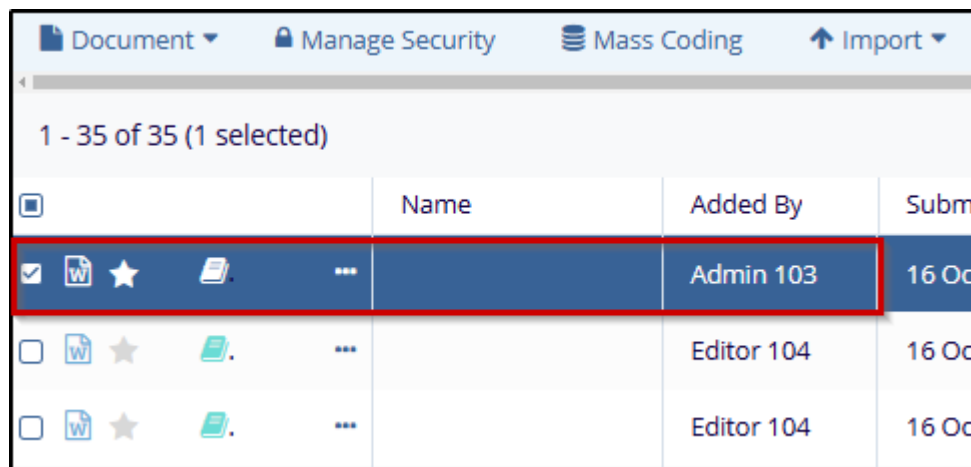
## Previewing and Viewing a Document and its Metadata

The Document Metadata panel allows users to view the document metadata and the document in separate panels in the eTMF/Document's module.

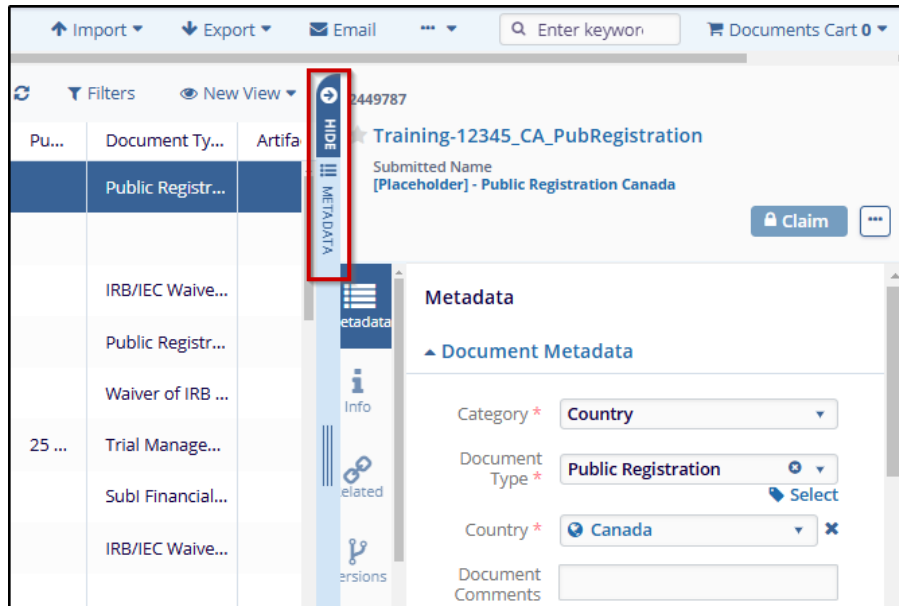
### Viewing Document Metadata

To access the Document Metadata, follow the steps below:

- From the Documents module, select the document from the grid.



2. Click on the Hide arrow to open the Metadata Panel.
3. The Metadata Pane opens and displays the Document Metadata by default.



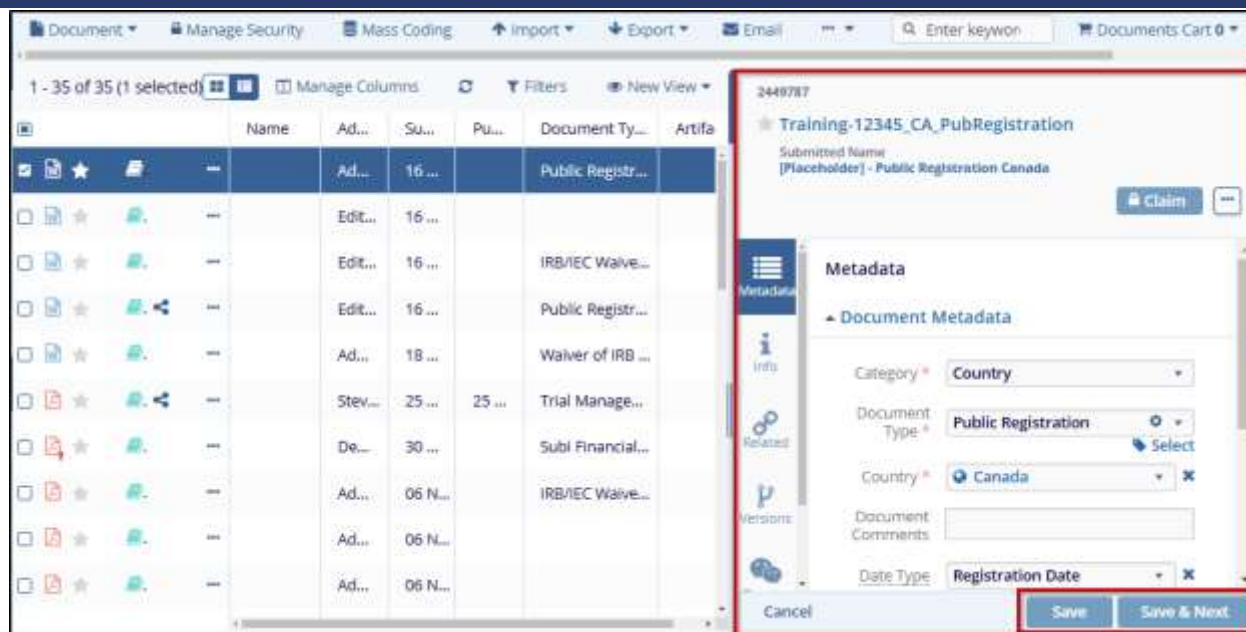
### Editing Document Metadata

Users with appropriate access levels can edit document metadata as follows:

- Administrator-level users can edit metadata for all documents.
- Editor-level users and Manager-level users with Document Manager permission can edit metadata for all documents.
- Editor and Manager-level users can edit metadata for non-final documents.
- Reader-level users do not have permission to edit metadata for any document.

To edit document metadata, follow the steps below.

1. Select a document by checking the checkbox.
2. Modify the fields in the metadata panel.
3. Click Save to apply the changes.
4. Click Save & Next to edit metadata for the next document in the grid.



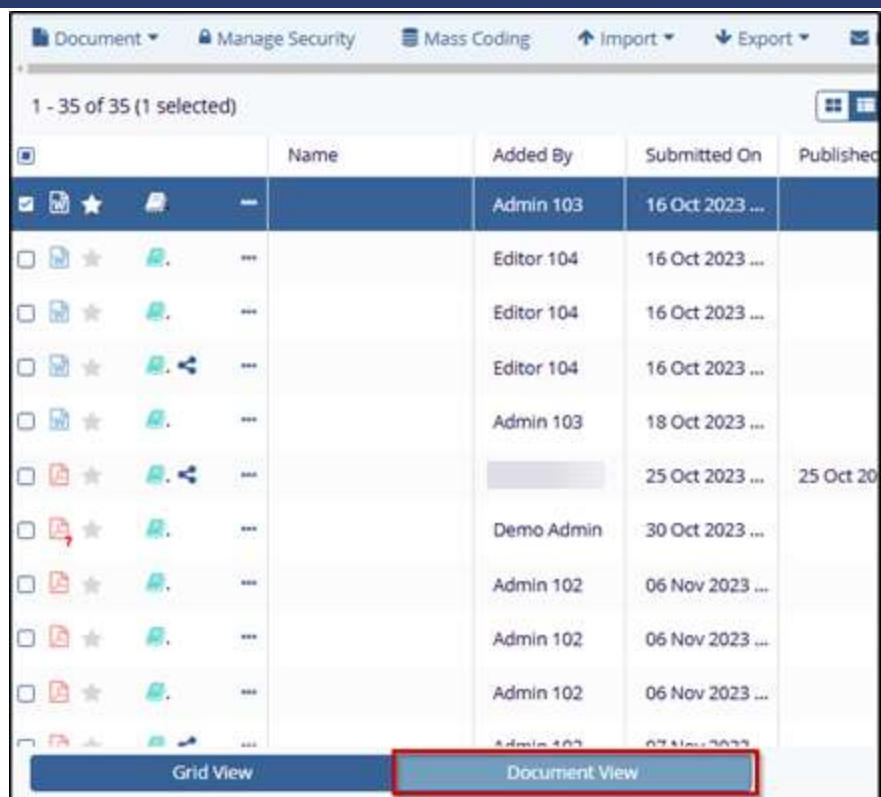
Note: For rooms where Causality Tracking is enabled (refer to Document Settings), users who attempt to alter metadata for a document in Final status are required to give a reason for altering the value.

### Viewing Documents in Document Viewer

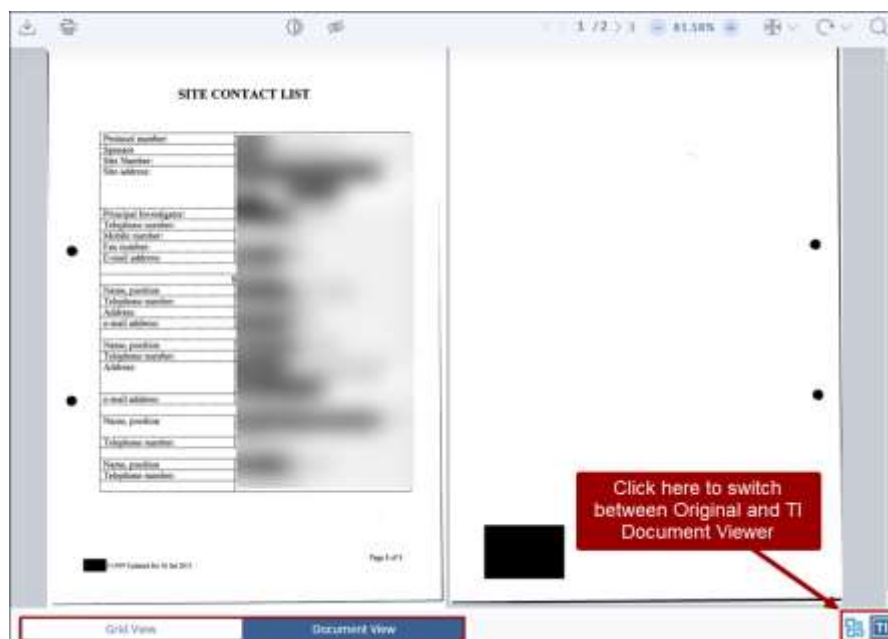
To view the documents in the document viewer, follow the steps below.

1. Select a document from the grid by clicking on the checkbox.



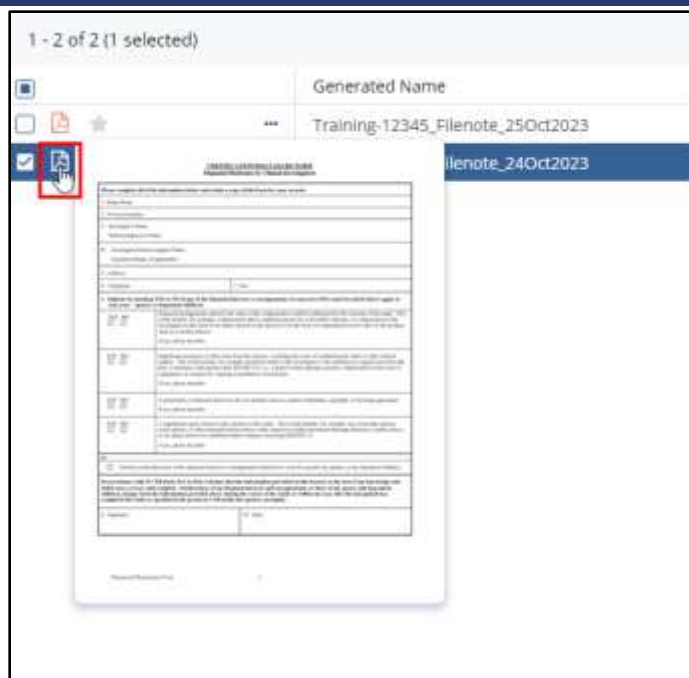


- Click on the Document View tab at the bottom of the grid. The Document and viewed in the Original as well as the TI Document Viewer.



Note: Documents can also be previewed by hovering over the document icon within the grid view as in the screenshot below.



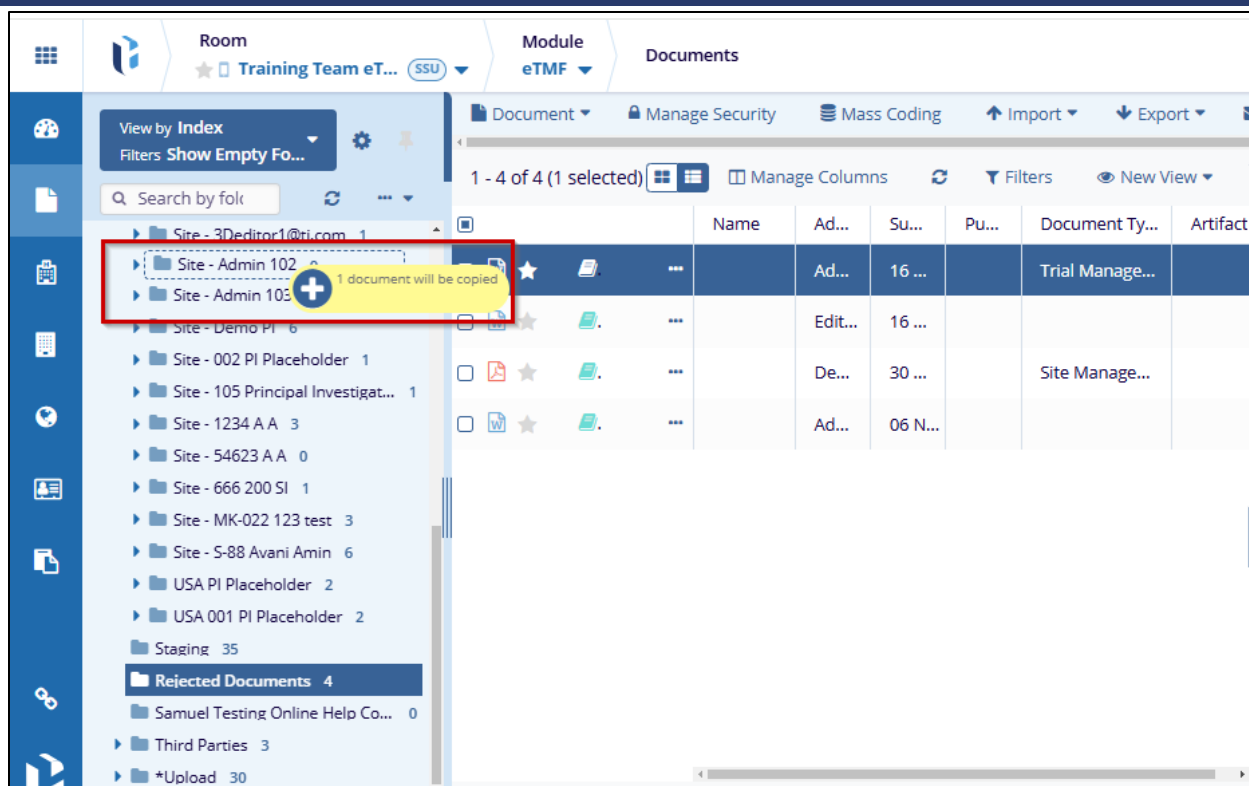


### Copying or Moving Documents

Users with necessary access permissions can drag and drop documents from one folder to another. Dragging and dropping documents across folders will not alter the metadata applied to the document. However, if a document manually copied from one folder to another, users need to re-code the document.

To move documents to other folders, follow the steps below.

1. Select the document(s) to be copied or moved from the grid.
2. Drag and drop the document to the intended folder in the Index Pane.



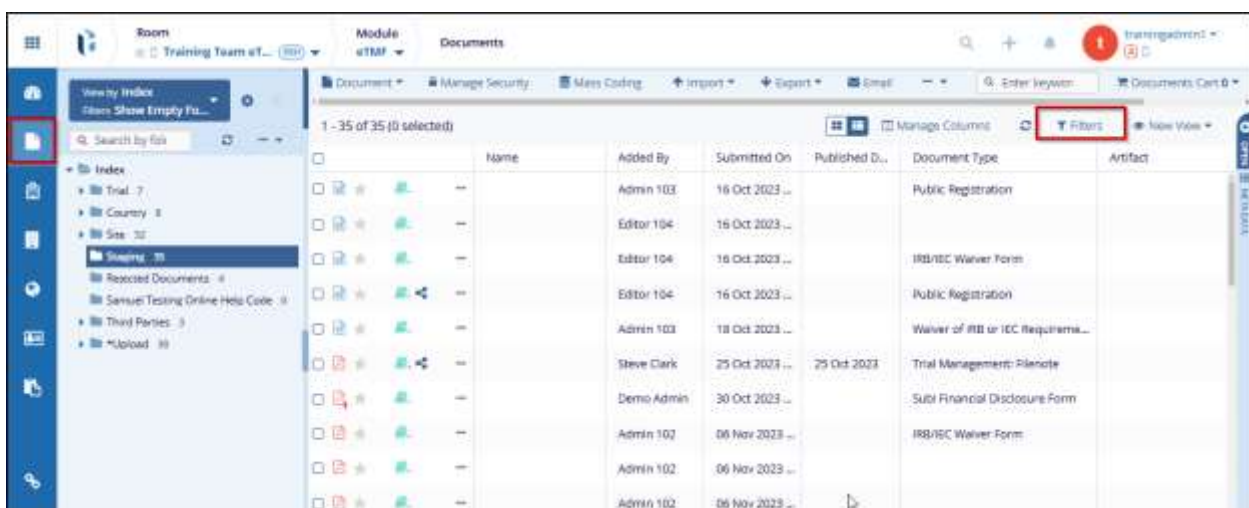
## Grid Filters

This section explains the filters in the document grid.

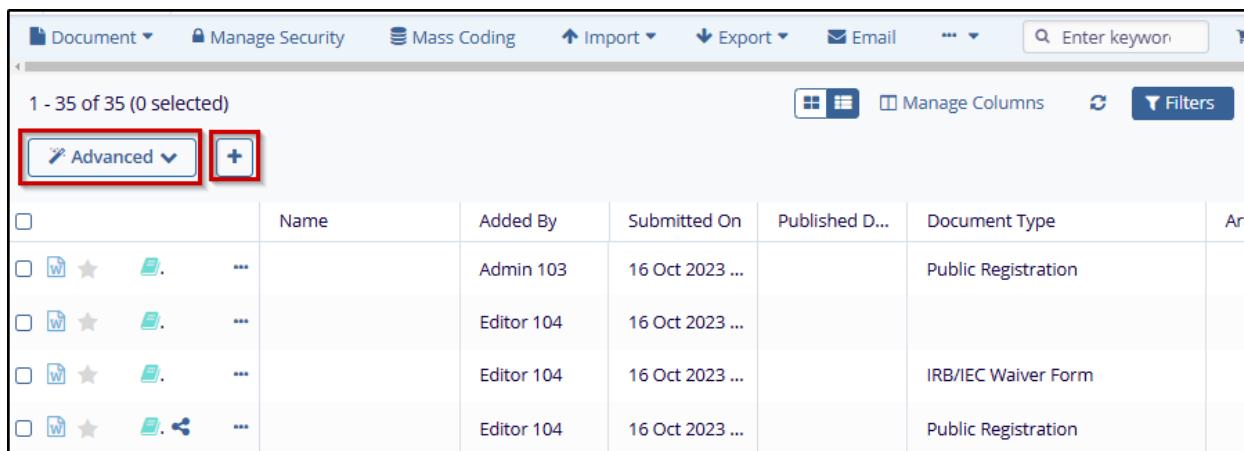
### Filters

To apply standard and advanced filters, follow the steps below.

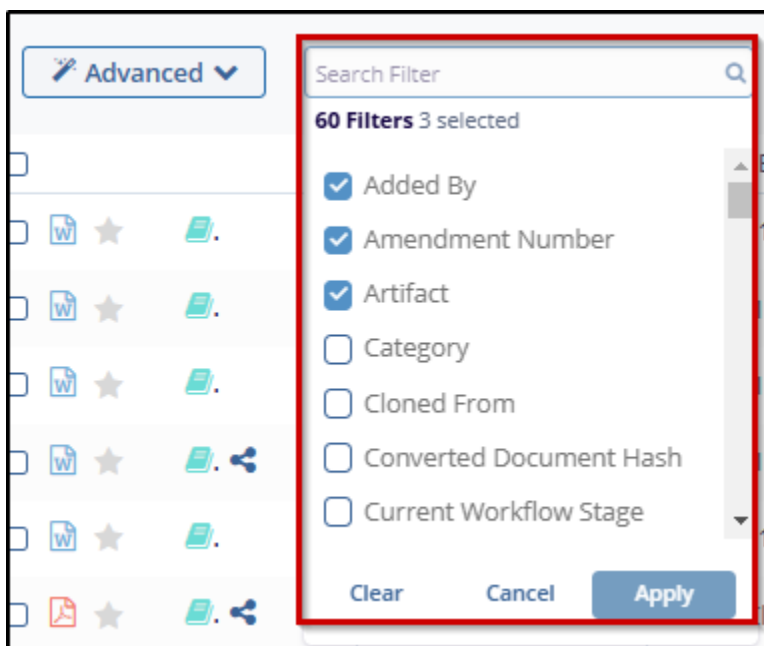
1. In the eTMF module, click on the Filters option.



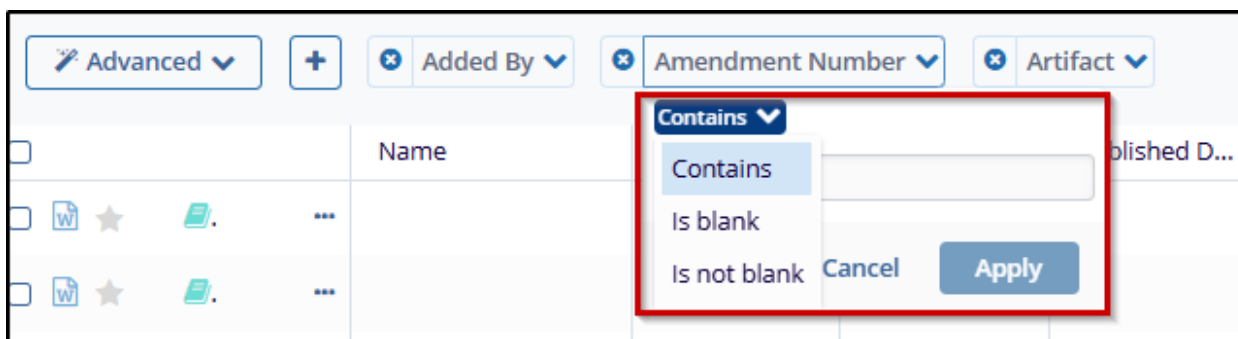
- Two options appear: Advanced and +. Click the + icon to add a filter.



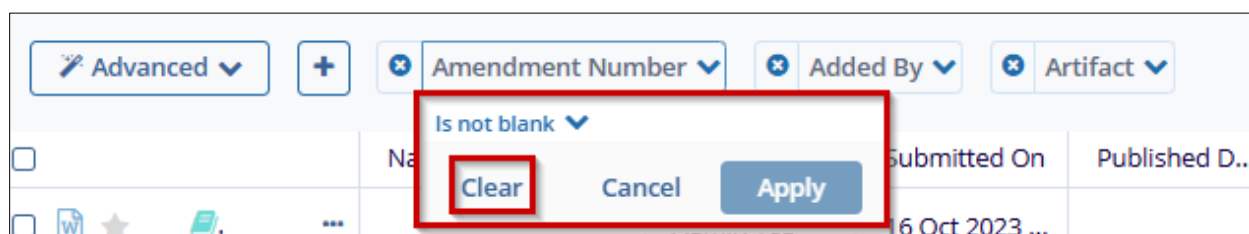
- Within the dropdown menu with various field names, select the desired filter fields and click on the Apply button.



- The selected filters will display above the grid. Use the dropdown arrow next to each filter to apply specific conditions as needed.



5. To remove a filter, select the Clear option within the filter dropdown.



### Creating a New Filter

To create a new filter, follow the steps below.

1. Click on the Advanced button and select the + Create New Filter option above the documents grid. The Create Filter window opens.



2. On the Create Filter screen, enter a title for the filter and click the + Add Filter button.

Create Filter

Title

Include records that match

all

any

none

of the following filters

+ Add Filter

+ Add Group

Cancel

Create

- Click the dropdown and select a field to apply filters for.

### Create Filter

Title

Include records that match **all** **any** **none** of the following filters

Search

Restricted Document Content (\$NeedRe

Cloned From (\$ClonedFrom\$)

Zone (\$\$Zone\$)

Section (\$\$Section\$)

Artifact (\$\$Artifact\$)

- Select the logical operator and enter the value for the selected field.

### Create Filter

Filters

Include records that match **all** **any** **none** of the following filters

+ Add Filter + Add Group

Current Workflow Stage (\$\$Curre... like Not Set

like

not like

greater than

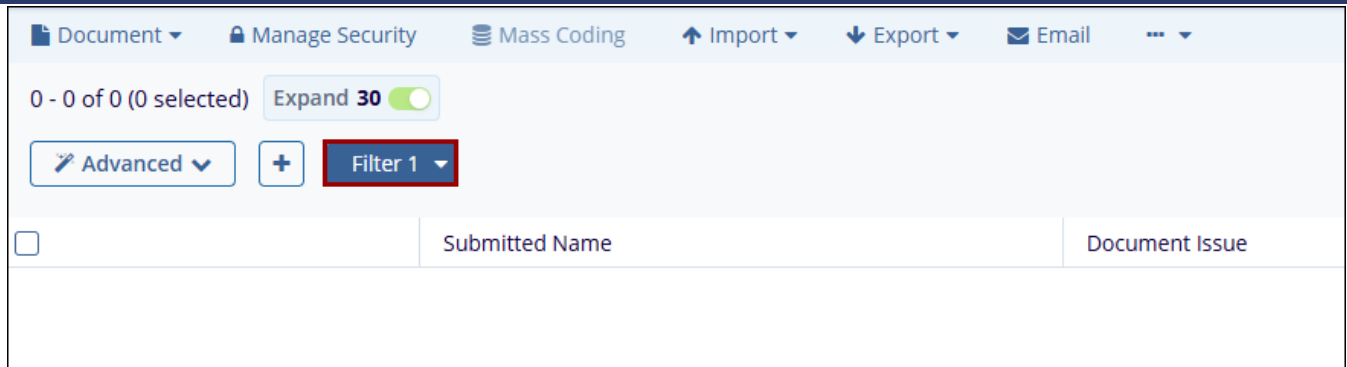
equal or greater th

equal

not equal

equal or less than

- Click on the Create button.
- The filter will appear above the grid. Select the filter to apply it to the grid contents

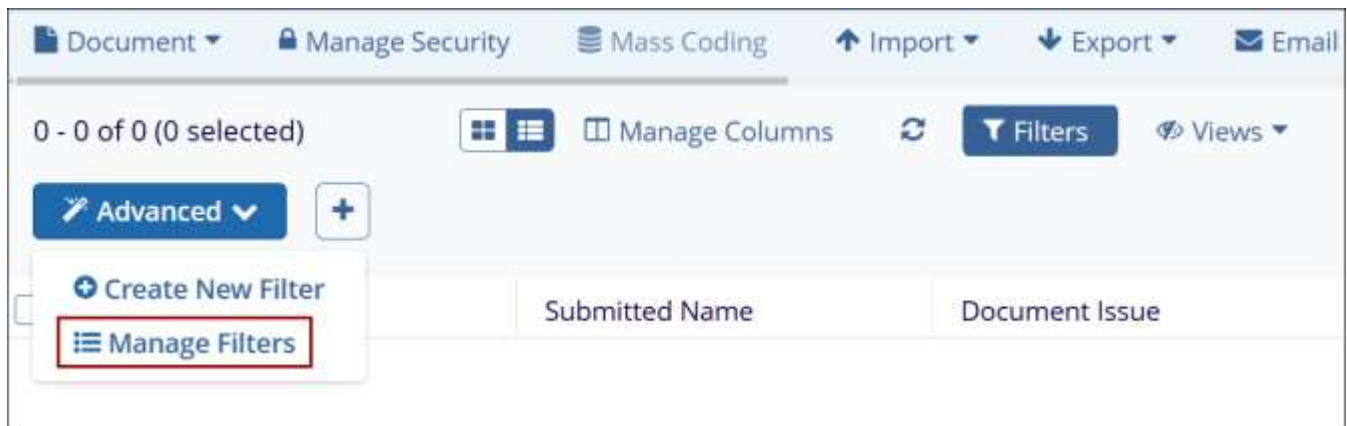


### *Add Existing Filters or Manage Filters*

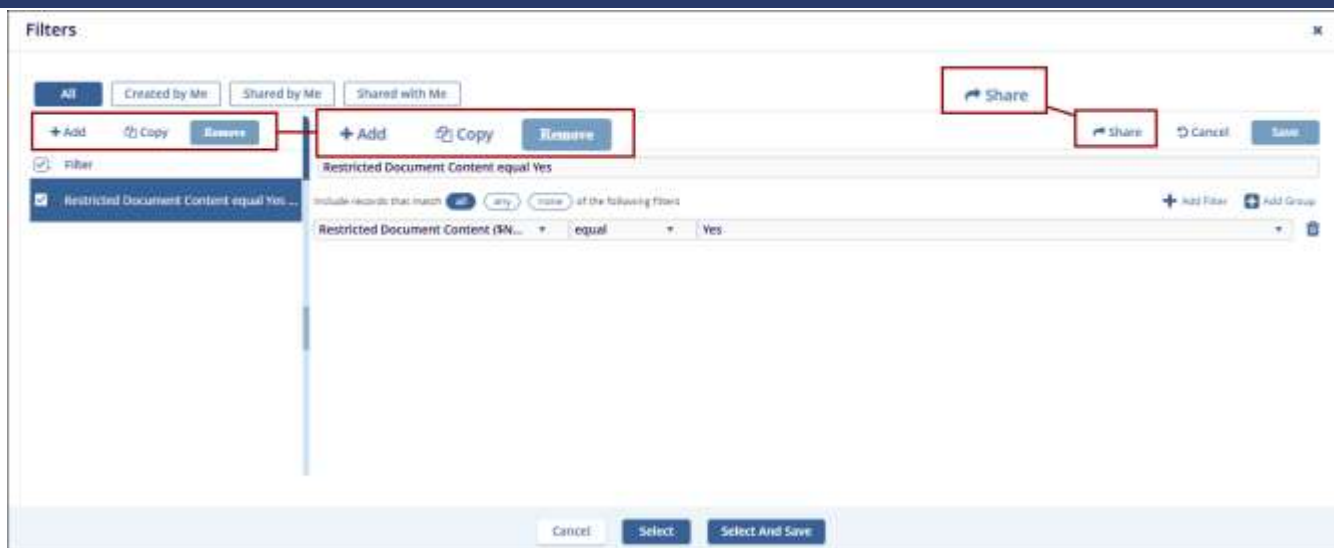
Manage filters allows users to view and share the created filters.

To manage the existing filters, follow the steps below.

1. Click on the Advanced button and select the Manage Filters option.



2. On the Filters screen, select the filter and it appears in the right pane with +Add, Copy, Remove and Share options enabled.

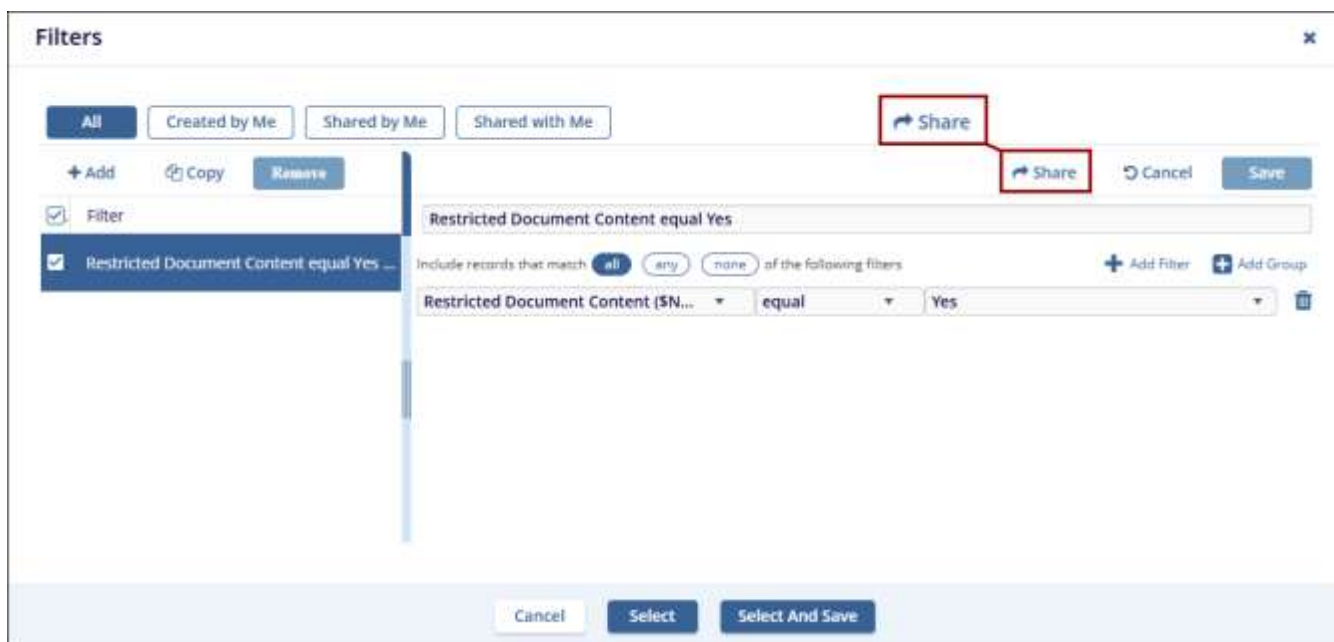


Users can perform the following activities on the filters in the Manage Filters window:

### Share Filters

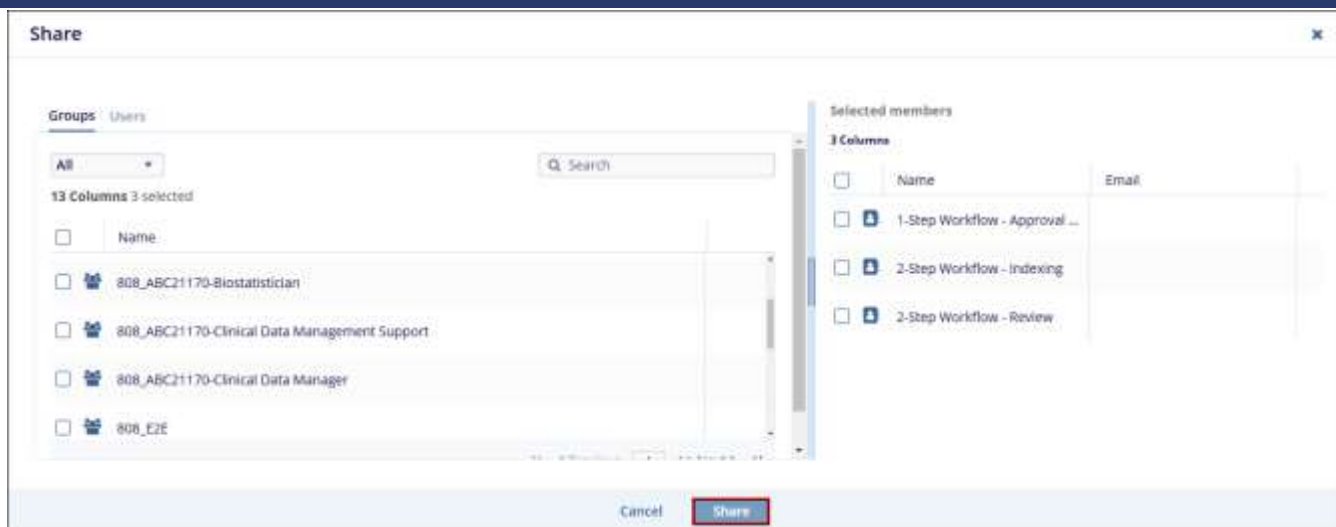
To share a filter, follow the steps below.

1. Select a filter and click on the Share button. The Share window opens.



2. Select the Users / Groups by accessing the respective sections and add them to the Selected member's section.
3. Click on the Share button once the necessary users and/or groups are added.



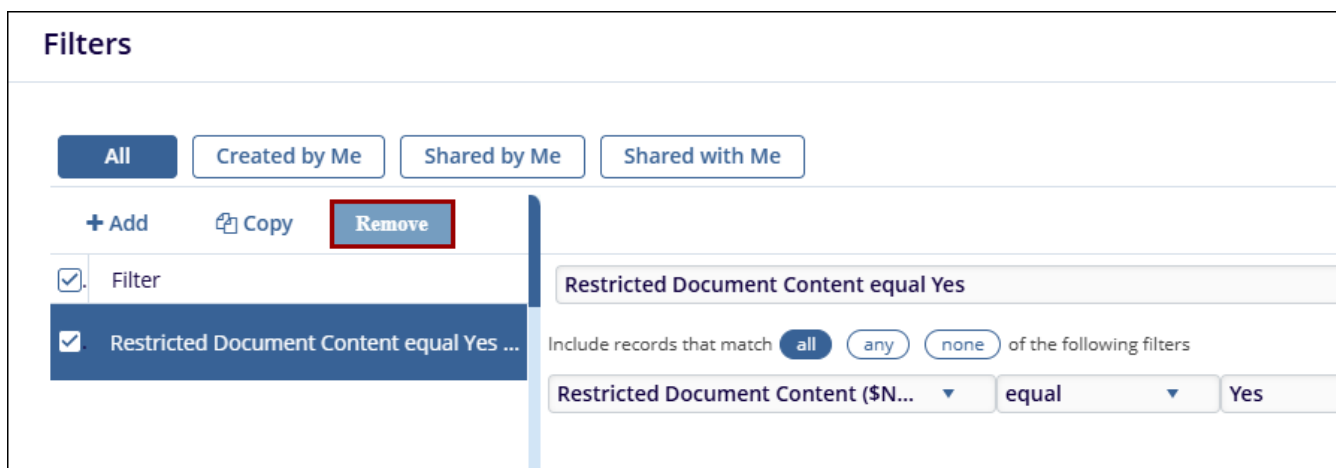


## Remove Filters

To remove filters, follow the steps below.

To remove the filters, follow the steps below.

1. Select the filter from the list.
2. Click on the Remove button to remove the filter from the list.



## View Shared Filters

Users can view the filters that are created, shared by and shared with them by clicking the required tabs in the Filters window.

- All
- Created by Me
- Shared by Me
- Shared with Me

### Filters

All

Created by Me

Shared by Me

Shared with Me

+ Add

Copy

Remove

☒ Filter

☒ Restricted Document Content equal Yes ...

Restricted Document Content equal Yes

Include records that match
 

all

any

none

 of the following filters

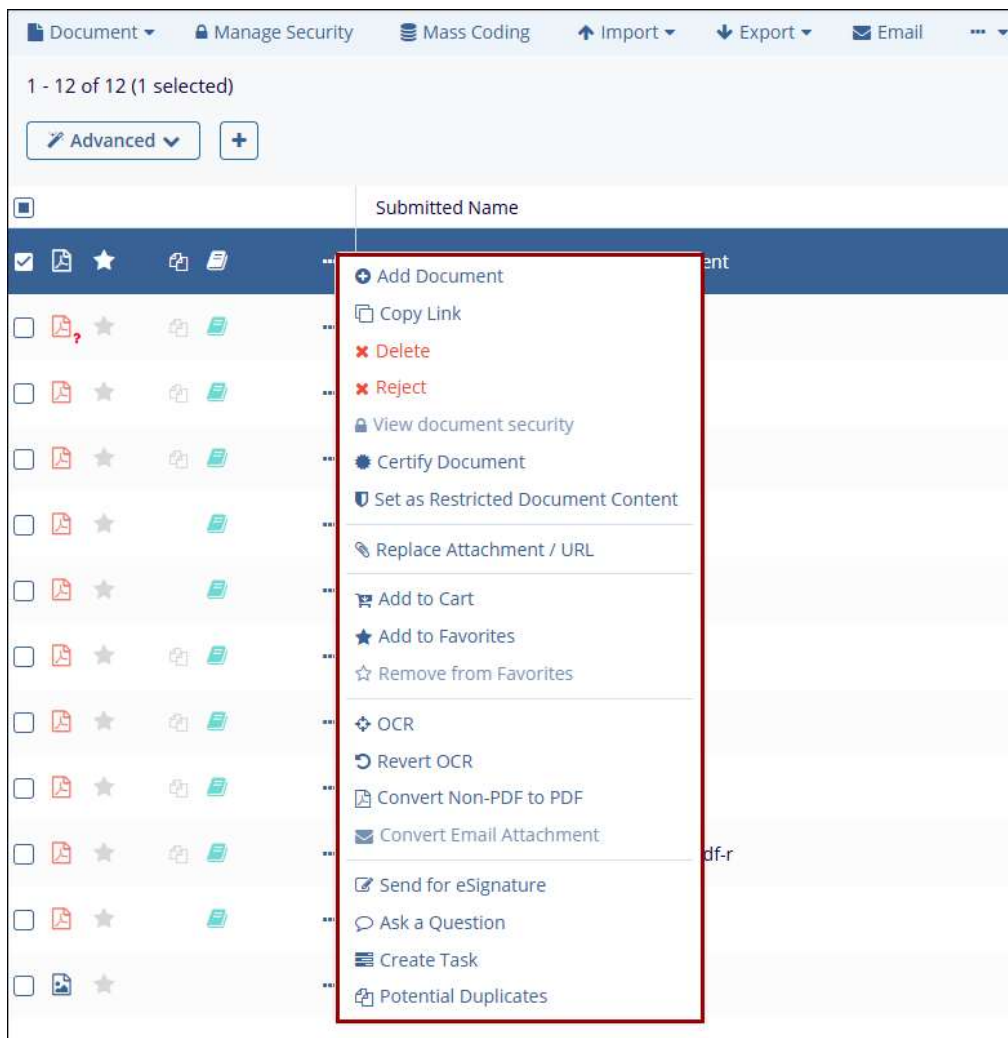
Restricted Document Content (\$N...

equal

Yes

## Document Activities Menu

The Document Activities Menu provides access to various actions based on the user's access rights. To open this menu, select a document or placeholder from the Grid and either right-click or click on the three-dot menu.



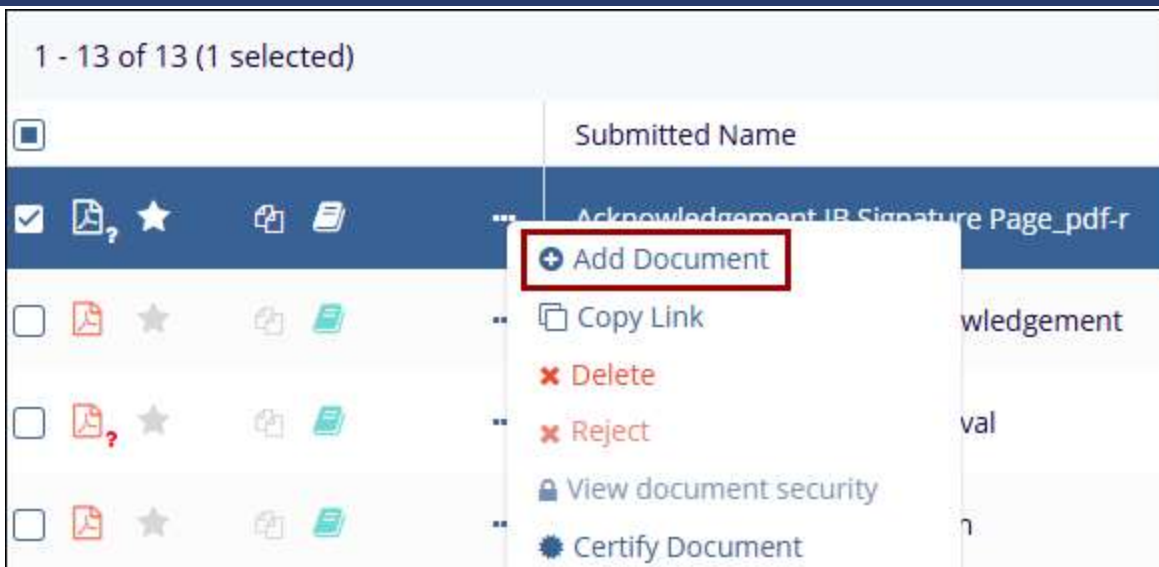
Note: The view displayed above is that of a Room Administrator. The options available will vary based on the individual user's access rights.

### Add Document

Users with sufficient access (editors and above) can open the Document Activities Menu and select the Add Document option. In locations within Trial Interactive where this is an option, the system will open an import interface that will apply the coding relevant to the placeholder so that the document can be added to the system pre-coded.

To add a document, follow the steps below

1. Click on the three-dot menu and select the +Add Document option.



- On the New Document form, select the whether the uploaded file will be a File or URL.
- Click on the Browse button and select a file to upload.
- Fill in all the mandatory metadata fields highlighted with red asterisk (\*) mark.
- Click on the Finish button once all the details are added.

New Document

Metadata

Document Metadata

File ☒ URL ☐

Attachment \*

Test\_CoreDocList.pdf

Browse

☐

Set as Restricted Document Content

Event

Category

Country

Document Type

Select

Submitted Name

20240412-1351\_TrialTeamDetails\_02Dec2024.sda test - aniket i

Comments

File Name

Generated Name

Date Type

Safety Notification Type

Cancel

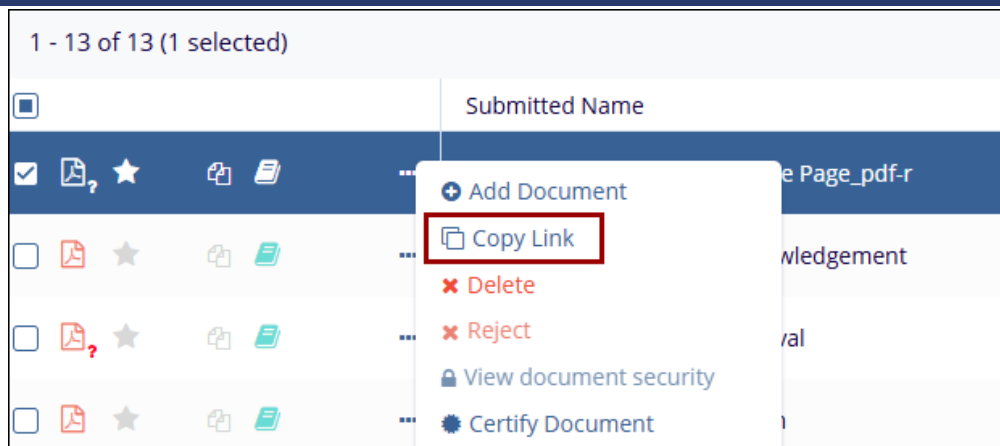
Finish

### Copy Link

If referencing a specific document to another room user for review, the Document ID Number can be provided or the Document Activities menu can be opened to select Copy Link, which will copy a direct URL link to the clipboard. Anyone using the link must have sufficient access to the study room in order to view the document.

To copy link, follow the steps below.

1. Select a document by clicking on the checkbox.
2. Select the Copy Link option.

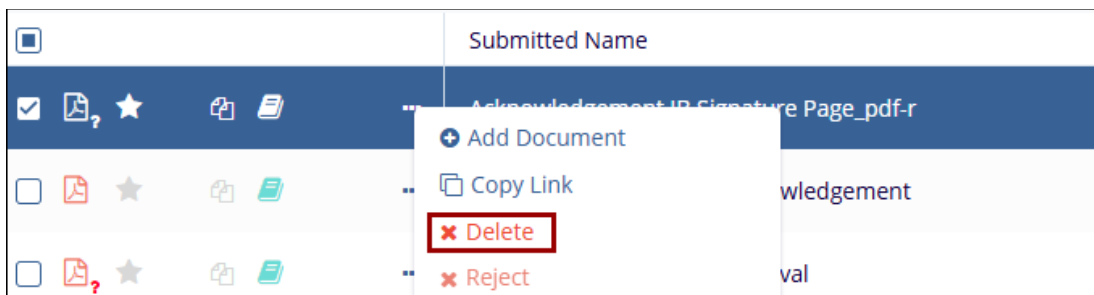


### Delete

Administrator-level users can select Delete from the Document Activities menu for any document in the room, except those currently claimed for review in an Audit Response or the QC Workflow. Editor and Manager-level users can delete documents only if they uploaded the document and it has not been claimed by the QC workflow. Once a document is marked as final, Editor and Manager-level users cannot delete it unless additional permissions are granted.

To delete documents, follow the steps below.

1. Select a document and click on the Delete button from the document activities menu.



2. Enter the reason for deletion on the confirmation popup and click on the Delete button.

Delete Selected Documents

Reason for deletion\*

Delete document

Cancel Delete

- Deleted documents can be viewed in the Deleted Documents section of the Documents module, which is accessible only to Administrators.

View Documents By

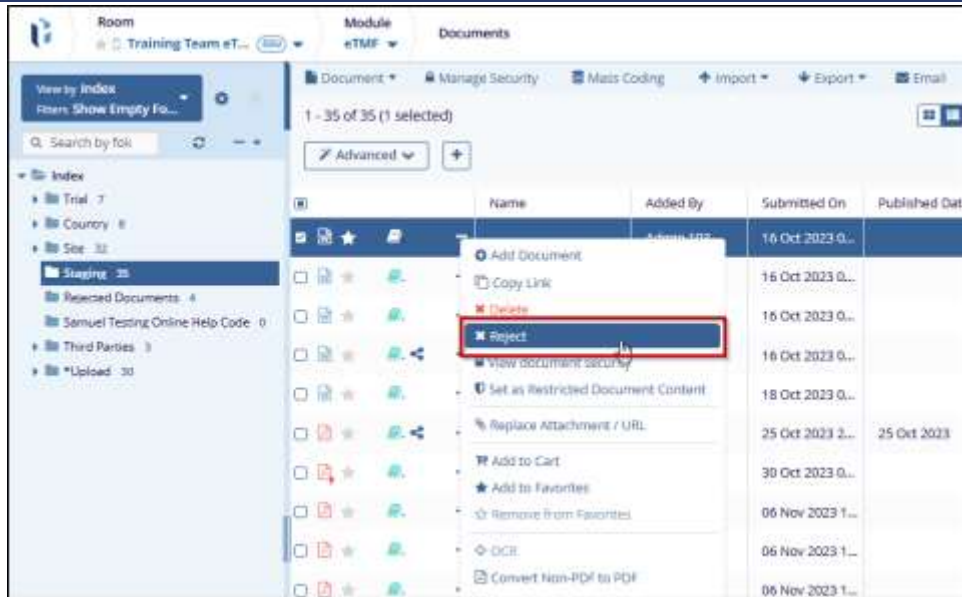
|                                                                                                                              |                                                                                              |                                                                                                                                                          |                                                                                                                                                                                                                      |                                                                                                                 |
|------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| <div>ETMF</div> <div>Index</div> <div>Site</div> <div>Country</div> <div>Query By Sender</div> <div>Query By Recipient</div> | <div>MY LIST</div> <div>My eSignatures</div> <div>My Submitted</div> <div>My Favorites</div> | <div>WORKFLOW</div> <div>By Status</div> <div>By Reviewer</div> <div>By Workflow</div> <div>Automation Score</div> <div>Automation Score Deviation</div> | <div>DOCUMENTS</div> <div>Event</div> <div>eTMF Completeness</div> <div>Working Documents</div> <div>Document Type</div> <div>Redactions</div> <div>Processing</div> <div>Responsible Party</div> <div>Deleted</div> | <div>OTHER</div> <div>Group</div> <div>Posted Date</div> <div>User Security</div> <div>Documents Security</div> |
|------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|

### Reject

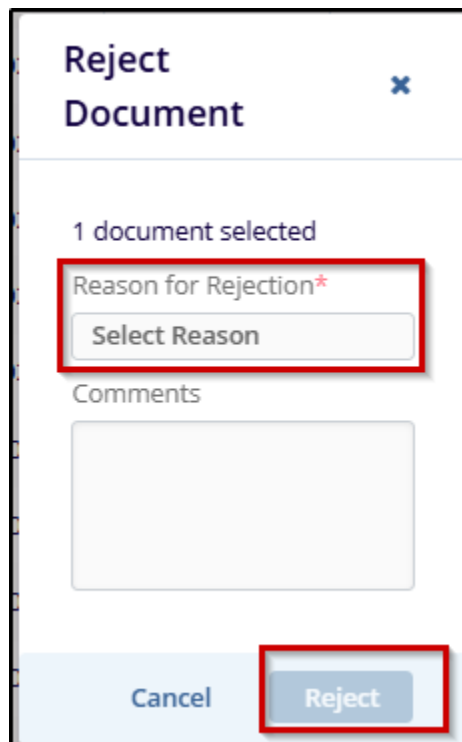
A new setting is added to support a Rejected folder within the eTMF for Room Administrators, and a new Document Rejection function is now available to Admins, Document Managers, and Room Managers. Any documents in Upload, Inbox, Staging, and Rejected Folders are not considered to be Final. A Reason for Rejection dropdown is now available for workflow documents and documents in the rejected folder/status are now excluded from eTMF health calculations.

To reject a document, follow the steps below.

- Select a document by clicking on the checkbox.
- Right-click on the document or the three-dot menu in the grid and select the Reject option from the document actions menu.



3. Provide a rejection reason on the Reject Document popup and click on the Reject button.



The screenshot shows the 'Reject Document' popup form. It has a title bar with a close button. Below the title, it says '1 document selected'. There is a text input field labeled 'Reason for Rejection\*' with a red asterisk, and a button labeled 'Select Reason' below it. Below that is a text area labeled 'Comments'. At the bottom, there are two buttons: 'Cancel' and 'Reject'. The 'Reject' button is highlighted with a red box.

Note:

- Users will not be able to drag and drop documents into this folder to prevent awarding an erroneous status should a non-rejected document be placed in this folder.



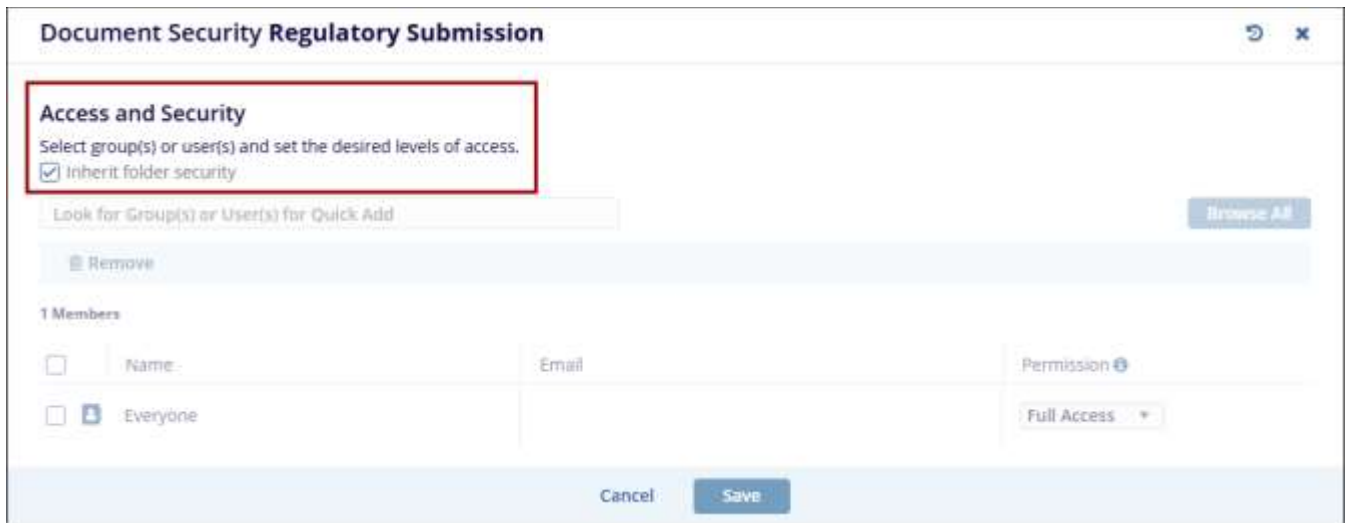
- To reject a document outside of the standard workflow steps, the user must either be an administrator or they must have the Document Manager action enabled on their user account.

### [View Document Security](#)

Administrator-level users can apply specific document-level security via the Document Activities menu. Selecting View Document Security will open the Document Security window.

To view the document security, follow the steps below.

- Click on the three-dot menu and select the View Document Security option.
- The Documents Security window will display the users or groups with the access permissions by default if the Inherit folder security is enabled.



**Document Security Regulatory Submission**

**Access and Security**  
Select group(s) or user(s) and set the desired levels of access.

☒ Inherit folder security

Look for Group(s) or User(s) for Quick Add Browse All

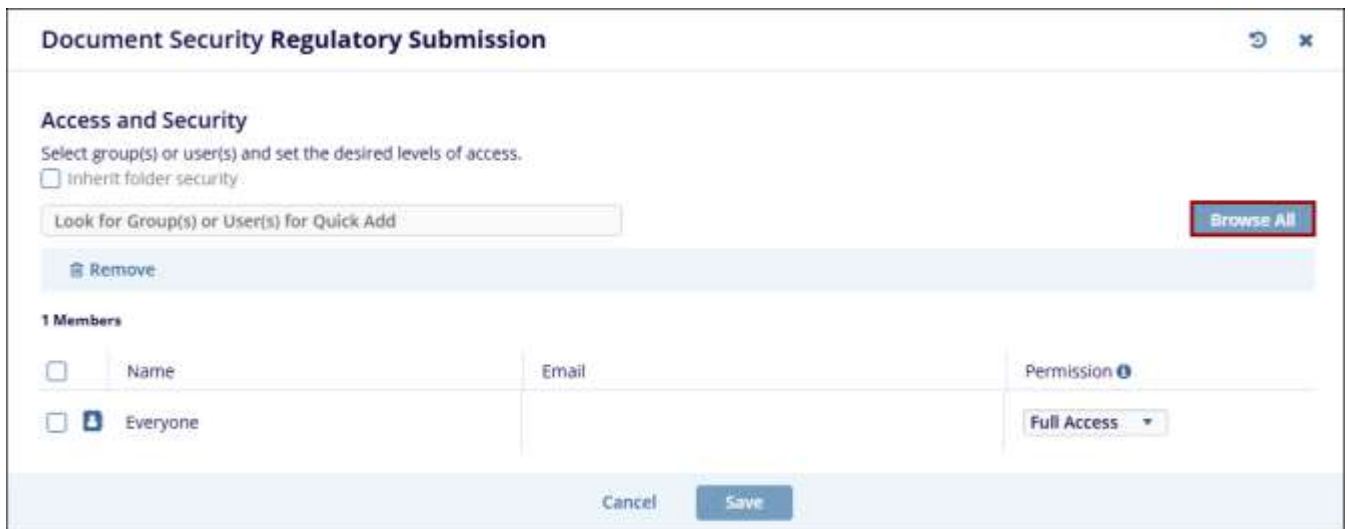
Remove

**1 Members**

| Name                              | Email | Permission  |
|-----------------------------------|-------|-------------|
| <input type="checkbox"/> Everyone |       | Full Access |

Cancel Save

- To add additional users or groups, disable the Inherit folder security setting and click on the Browse All button.



**Document Security Regulatory Submission**

**Access and Security**  
Select group(s) or user(s) and set the desired levels of access.

☐ Inherit folder security

Look for Group(s) or User(s) for Quick Add Browse All

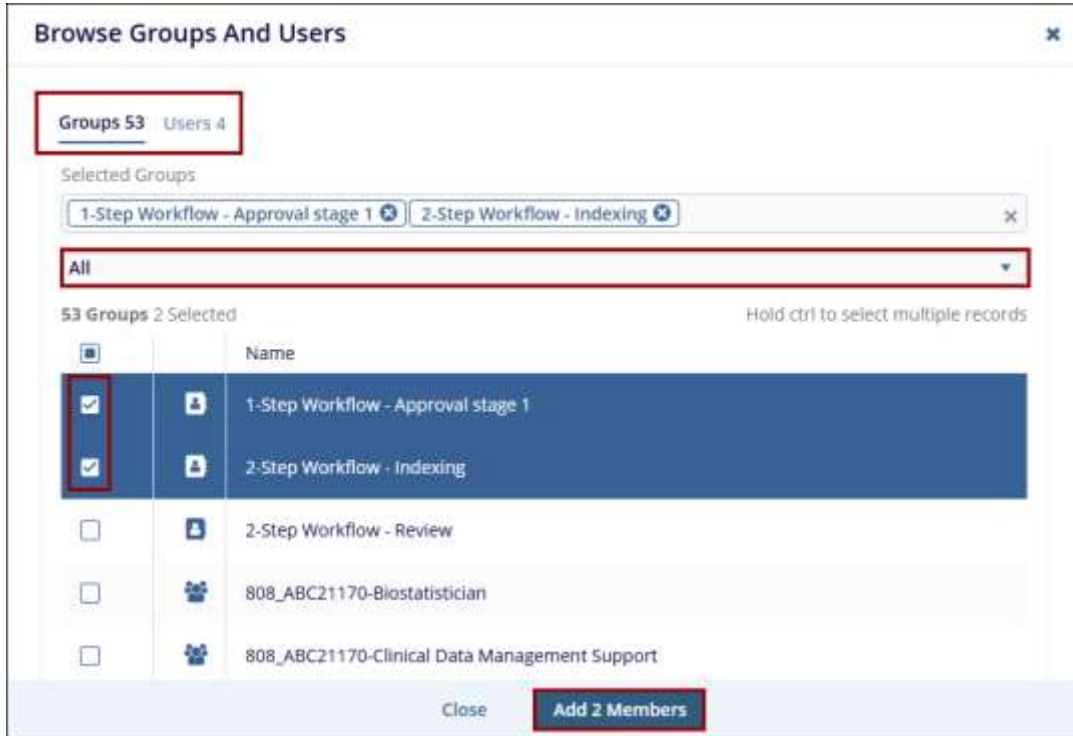
Remove

**1 Members**

| Name                              | Email | Permission  |
|-----------------------------------|-------|-------------|
| <input type="checkbox"/> Everyone |       | Full Access |

Cancel Save

4. In the Browse Groups and Users window, switch between the Groups and Users tabs and select the desired groups or users.
5. On the Groups tab, use the dropdown menu to filter groups by category.
6. After selecting the required groups or users, click the Add (number of members) Members button.



**Browse Groups And Users**

Groups 53 Users 4

Selected Groups

1-Step Workflow - Approval stage 1 2-Step Workflow - Indexing

All

53 Groups 2 Selected Hold ctrl to select multiple records

|                                     | Name                                          |
|-------------------------------------|-----------------------------------------------|
| <input checked="" type="checkbox"/> | 1-Step Workflow - Approval stage 1            |
| <input checked="" type="checkbox"/> | 2-Step Workflow - Indexing                    |
| <input type="checkbox"/>            | 2-Step Workflow - Review                      |
| <input type="checkbox"/>            | 808_ABC21170-Biostatistician                  |
| <input type="checkbox"/>            | 808_ABC21170-Clinical Data Management Support |

Close Add 2 Members

7. After adding the groups or users, click the Permissions dropdown to assign the appropriate access level, such as Full Access, View Only, or No Access and click on the Save button.



**Document Security Regulatory Submission**

**Access and Security**  
Select group(s) or user(s) and set the desired levels of access.

☐ Inherit folder security

Look for Group(s) or User(s) for Quick Add Browse All

Remove

**3 Members** 1 selected

| <input type="checkbox"/>            | Name                               | Email | Permission                                                            |
|-------------------------------------|------------------------------------|-------|-----------------------------------------------------------------------|
| <input type="checkbox"/>            | Everyone                           |       | Full Access                                                           |
| <input checked="" type="checkbox"/> | 1-Step Workflow - Approval stage 1 |       | <div> No Access<br/> Full Access<br/> View Only<br/> No Access </div> |
| <input type="checkbox"/>            | 2-Step Workflow - Indexing         |       |                                                                       |

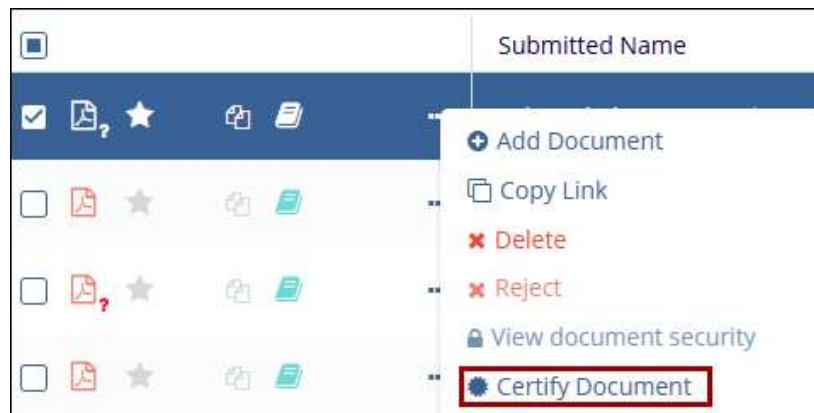
Cancel Save

### Certify Document

For studies in which the document certification option is in use, a user can either choose to indicate that a document is a certified copy upon upload or it can be done via the Document Activities Menu.

To certify a document, follow the steps below:

1. Open the Document Activities menu by right-clicking on a document or using the three-dot icon on the grid.
2. Select Certify Document



3. Read the criteria and press Finish if the document meets all expectations.

Certify Document

PLEASE CONFIRM THAT YOU'VE VERIFIED ALL OF THE ITEMS

- I confirm the image(s) are an exact copy of the original document
- Prior to scanning I removed all wallets/staples/binding/paperclips
- All pages were scanned and are present in the correct sequence and orientation
- No headers, footers, or corners of the pages and document are cut off
- Nothing is blocking document content, such as bent corners
- The scanned pages are clear and the content, signature(s) and all text is legible
- The scanned copies reflect all and any attributes of the paper document that are in color which are critical to the interpretation of the content in the document
- No content from the original document was removed such as the fax header information

Cancel

Finish

- Use the username and login to complete the process.

Email

Password

Password

☒ Remember Login

Sign in

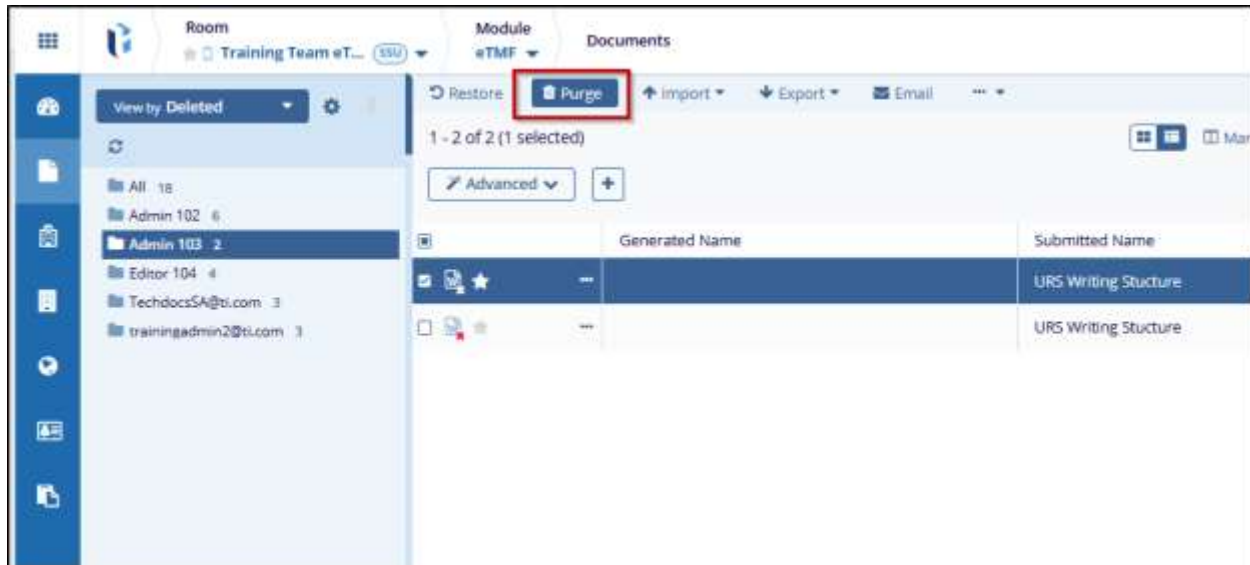
### *Purging a Deleted Document*

Once a document has been deleted, an administrator-level user will be able to navigate to the Deleted Documents view of the Documents module and, if desired, purge the document. Most deleted documents do not need to be purged from a study room unless necessitated by an internal SOP. However, some documents, such as those that contain PHI or PII, would likely be purged out of an abundance of caution.

To purge a document, follow the steps below:

- Navigate to the Deleted Documents view.

2. Locate the document that was deleted. Documents are sorted by the user who deleted them and additional column selection and filtering are available as in other areas of the system.
3. Click on the Purge button.



4. Mandatorily provide a reason on the Permanently Delete Selected Documents popup.
5. Press the Delete button on the confirmation popup.

### Permanently Delete Selected Documents ✕

Reason:\*

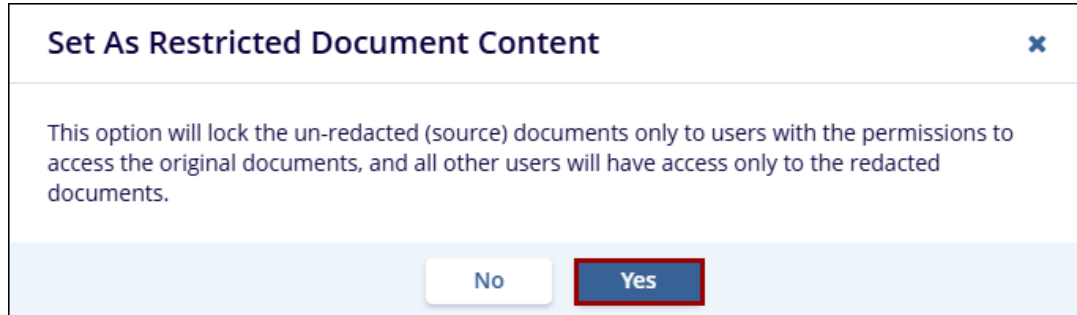
Cancel
Delete

#### Set as Restricted Document Content

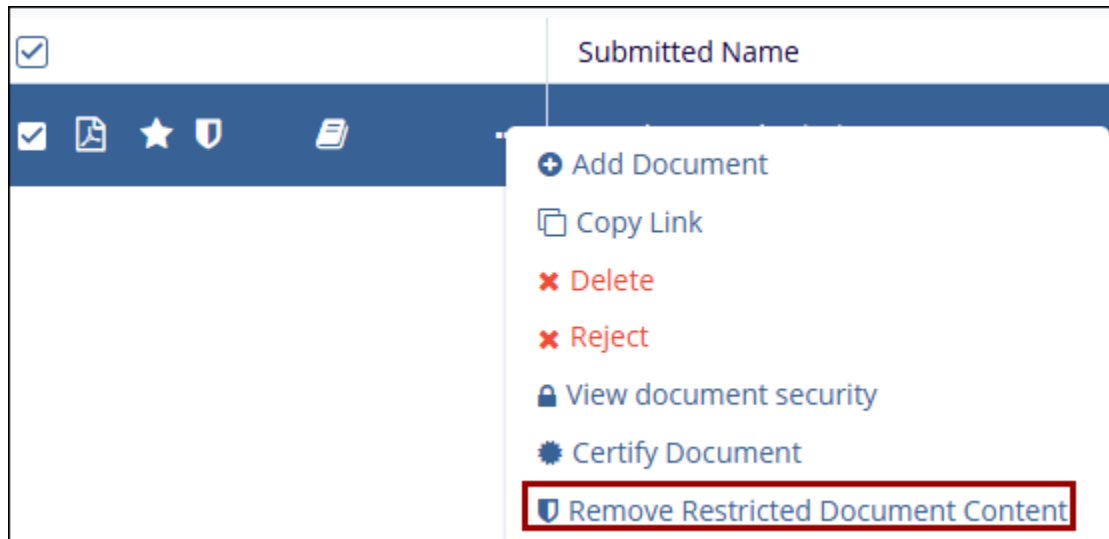
The Set as Restricted Document Content option locks the un-redacted (source) documents only to users with the permissions to access the original documents. All other users will have access only to the redacted documents.

To enable this setting, follow the steps below.

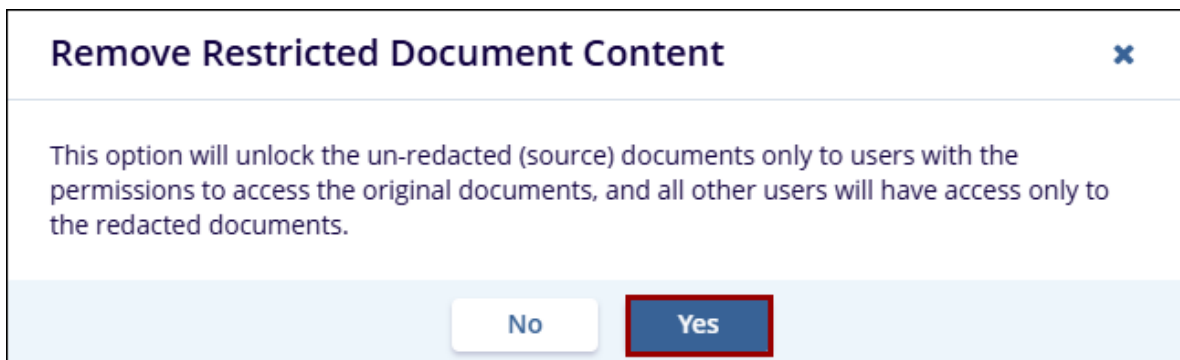
1. Click on the three-dot menu and select the Set as Restricted Document Content option.
2. On the Set As Restricted Document Content popup, click on the Yes button.



3. To remove the restricted documents content, click on the three-dot menu and select the Remove Restricted Document Content option.



4. On the Remove Restricted Document Content popup, click on the Yes button.



### Replace Attachment/URL

This option enables users to replace the current uploaded document attachment or URL link with a new one.

To replace an existing attachment or URL with a new one, follow these steps:

1. Click the three-dot menu and select the Replace Attachment / URL option.
2. In the Replace Attachment / URL window, choose either the File or URL option.
3. If the File option is selected, upload the new document into the Attachment File\* field.
4. If the URL option is selected, enter the new URL in the URL\* field.
5. Provide a reason for replacing the attachment or URL.
6. Click the Apply button after adding the new attachment or URL.

Replace Attachment / URL

Regulatory Submission

Document Date: 11 Nov 2024 10:32:04

File Size: 2.1 KB

File Name

Regulatory Submission.pdf

Attachment Type

☒ File
 ☐ URL

Attachment File\*

Doc 5.pdf

Browse

Reason\*

Updating the document attachment

Cancel

Apply

### Add to Cart

Adding a document to the Documents Cart can be done with a simple click and drag from the grid to the cart but, if that does not work, a document can be added to the cart via the Add to Cart option in the Document Activities Menu.

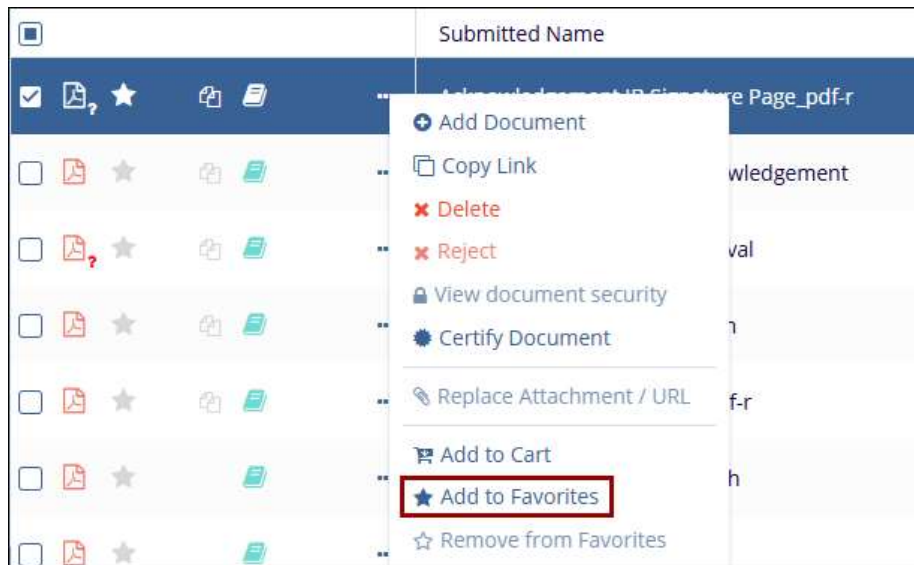
Refer to the Documents Cart section for detailed steps to manage documents from the Documents cart.

### Add to Favorites

Marking a document as a favorite makes it appear in the My Favorite Documents dashlet on the dashboard and provides a direct link to the document from that dashlet.

To mark a document as a favorite, follow the steps below.

1. Click the star icon on the document line in the grid.
2. Additionally, open the Document Activities menu by right-clicking or clicking on the three-dot icon and selecting Add to Favorites.



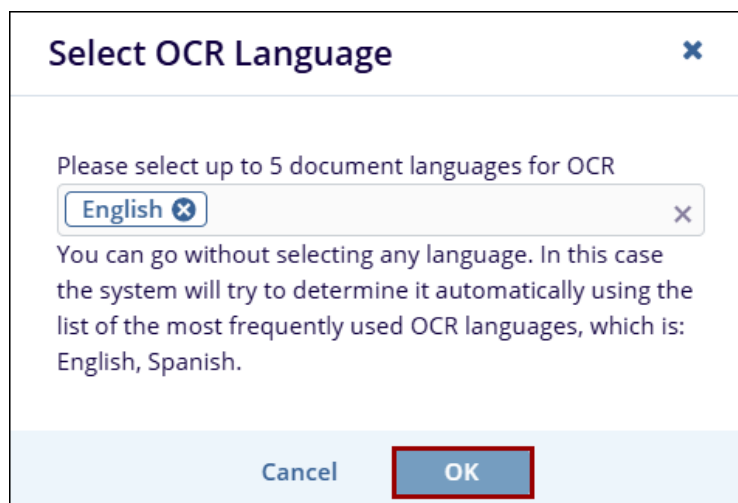
3. Similarly, select Remove from Favorites. Option to remove the document from the favorites list.

### OCR and Revert OCR

Some functions, such as text-specific redaction, require that the document has OCR (Optical Character Recognition) applied.

To apply OCR to a document, follow the steps below.

1. Select the OCR option from the Document Activities menu.
2. On the Select OCR Language popup, select up to 5 languages for the OCR.
3. Click on the OK button.





- Once the document is successfully processed, the OCR column within the documents grid displays the processed status.

1 - 2 of 2 (0 selected) Expand 2 

Manage Columns 

Filters 

| <input type="checkbox"/> |                                                                                                                                                                                                                                                             | Submitted Name                | Document Issue | OCR                                                                                 |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|----------------|-------------------------------------------------------------------------------------|
| <input type="checkbox"/> |    1 ... | Regulatory Submission         |                |  |
| <input type="checkbox"/> |    1 ... | Regulatory Authority Decis... | Portfolio PDF  |  |

- To revert OCR, select the Revert OCR option from the Document Activities menu.
- On the Revert OCR confirmation popup, click on the Yes button.

## Revert OCR

You are about to restore the original document from the backup and to erase the document version with OCR. Do you want to proceed?

- Once OCR is successfully reverted, the OCR column within the documents grid displays the corresponding status.

1 - 2 of 2 (0 selected)

Expand 2 





 Manage Columns



 Filters

| <input type="checkbox"/>                                                                                                                                                                                                                                                                   |  | Submitted Name                | Document Issue | OCR                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-------------------------------|----------------|--------------------------------------------------------------------------------------------------|
| <input type="checkbox"/>    1 ... |  | Regulatory Submission         |                | <div></div> |
| <input type="checkbox"/>    1 ... |  | Regulatory Authority Decis... | Portfolio PDF  |             |

### Convert Non-PDF to PDF

To convert non-PDF files into PDF files, follow the steps below.

- Select the Convert Non-PDF to PDF option from the Document Activities menu.
- Access the View by dropdown and select the Processing view.

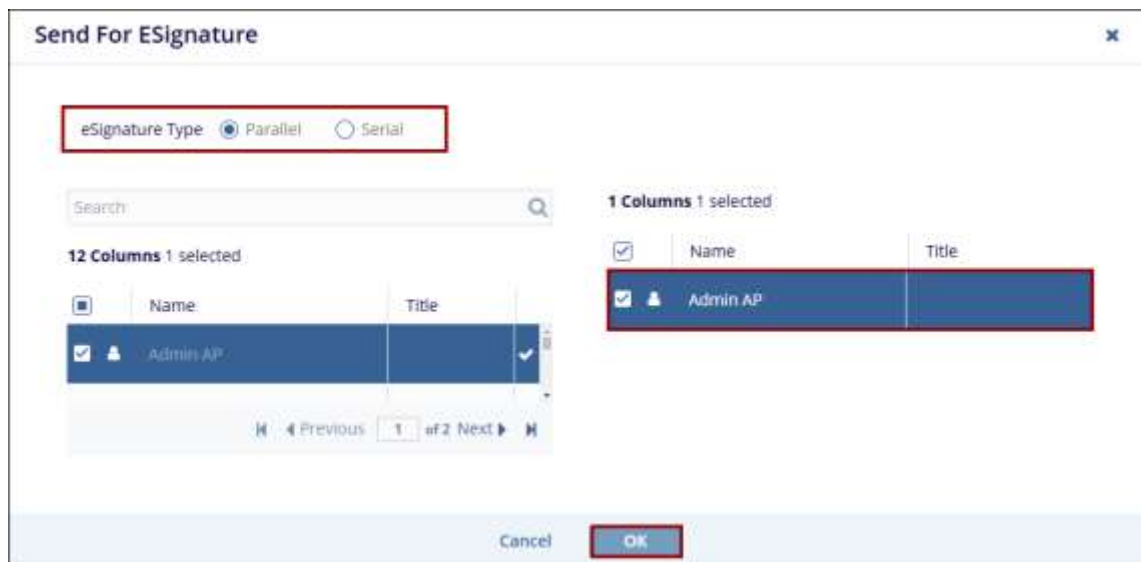
- Expand the PDF Conversion folder and select the Processed sub-folder to view the document converted into a PDF file.



### Send for eSignature

To send a document for eSignature through the document activities menu, follow the steps below.

- Select the Send for eSignature option from the Document Activities menu.
- On the Send for ESignature screen, select the eSignature type as Parallel or Serial.
- Add the users to whom the document is to be sent for ESignature.
- Click on the OK button.



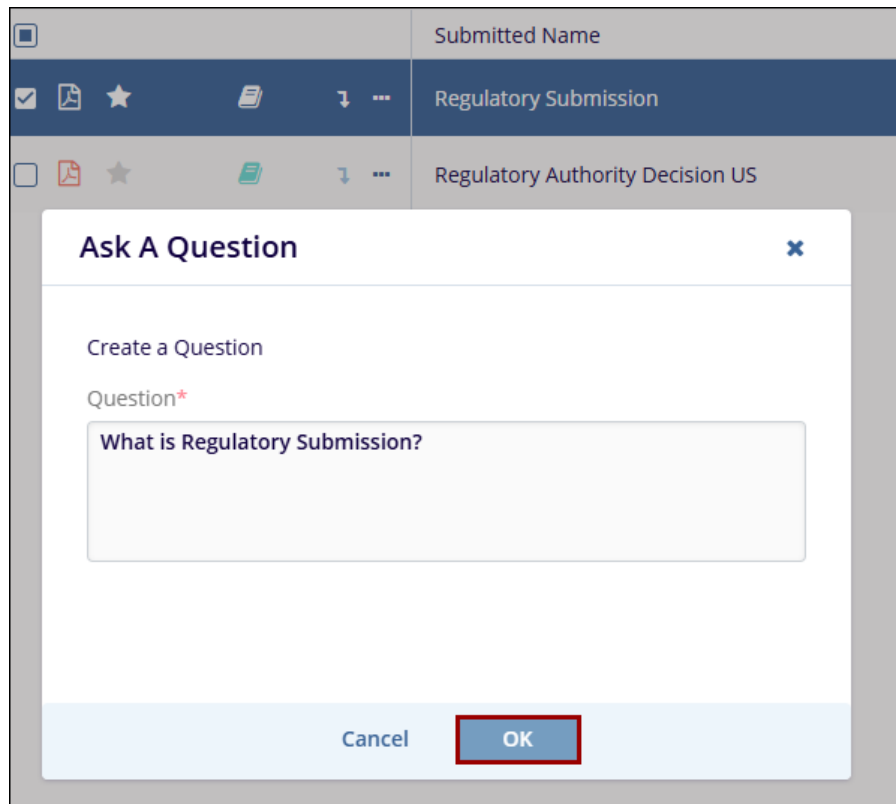
Note: To understand the ESignature process in detail refer to the eSigning Document section.

### Ask a Question

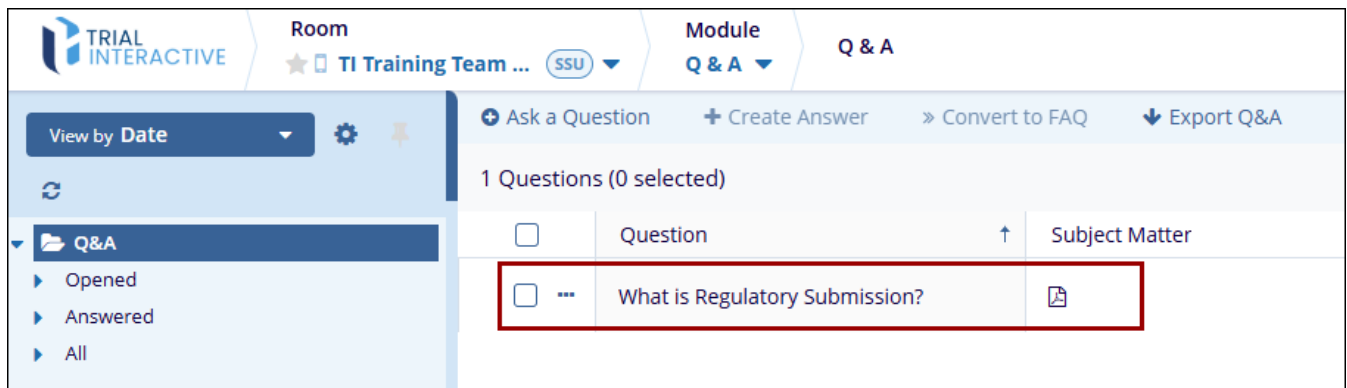
This option allows users to submit a document-specific question directly to the Q&A module of the room.

To submit a document to Q&A module, follow the steps below.

1. Select the Ask a Question option from the Document Activities menu.
2. Within the Ask a Question dialog box, enter the question into the respective field and click on the OK button.



3. Once successfully created, the question displays in the Q&A module.



### Create Task

To create a task, follow the steps below.

1. Select the Create Task option from the Document Activities menu.
2. On the Create Task form, fill in the necessary details and click on the Save button.

Create Task

The task will be created for the following document(-s):

Regulatory Submission

Subject

Start Date

dd MMM yyyy

Due Date

dd MMM yyyy

Priority

Normal

Status

Not Started

Complete %

0

Description

Assign To \*

Reminder

☐

06 Feb 2025

12:30 AM

Category

0

Attachments

Add

Documents

Cancel

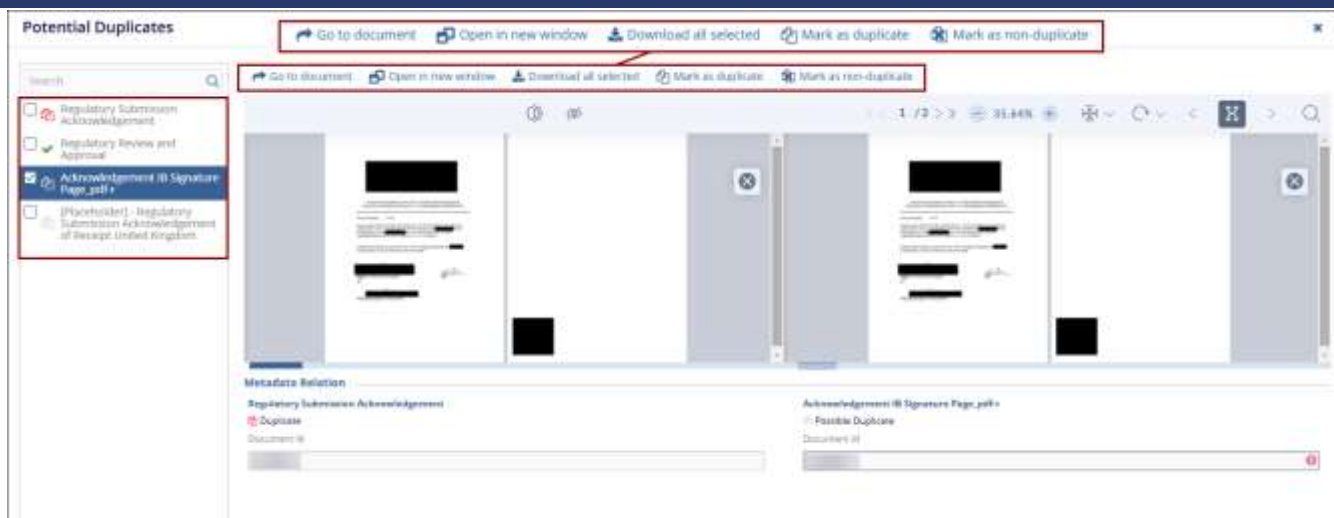
Save

### Potential Duplicates

When the system identifies potential duplicates of an uploaded document, it is marked with a duplicate icon. Users can access the Potential Duplicates option from the dropdown menu to view and manage the identified documents.

To view the potential duplicates of a document, follow the steps below.

1. Click on the three-dot menu and select the Potential Duplicates option.
2. The Potential Documents screen displays side-by-side previews of the versions of a document, allowing users to compare them.
3. Access the options from the top menu bar and perform the related functions.
  - Go to document – Opens the document in TI viewer.
  - Open in new window – Opens document in a separate window.
  - Download all selected – Enables bulk downloading of documents.
  - Mark as duplicate – Confirms the document as a duplicate.
  - Mark as non-duplicate – Rejects the duplicate suggestion.



### Note

- Documents marked with a red linked-document icon, indicating a duplicate document.
- Documents marked with a green checkmark, indicate that they are not marked as duplicates.

---

## Document Metadata Panel

From the metadata panel located at the right of the documents grid, users can view the following tabs after selecting a document from the grid.

- Metadata
- Info
- Related
- Versions
- Queries
- History tab
- eSignature tab
- Workflow History

Users with sufficient access privileges can not only view a documents metadata but can also change the content of some of the Metadata fields. The buttons at the bottom of the panel provide access to several essential functions, such as saving changes and moving to the next document in the metadata panel.

Users can expand or hide this panel by hovering the mouse to the right of the grid and clicking the Open/Hide arrow.

Users can also shuffle back and forth between documents in the grid by clicking the Previous Document and Next Document links at the bottom of the Metadata panel.

2449787

★ Training-12345\_CA\_PubRegistration

Submitted Name  
[Placeholder] - Public Registration Canada

Claim

Metadata

Info

Related

Versions

Queries

History

### Metadata

#### Document Metadata

Category \*
Country

Document Type \*
Public Registration
Select

Country \*
Canada

Document Comments

Date Type
Registration Date

Document Date \*
dd MMM yyyy

Document Description

Generated Name
Training-12345\_CA\_PubRegistration

Source

#### Workflow History

Cancel
Save
Save & Next

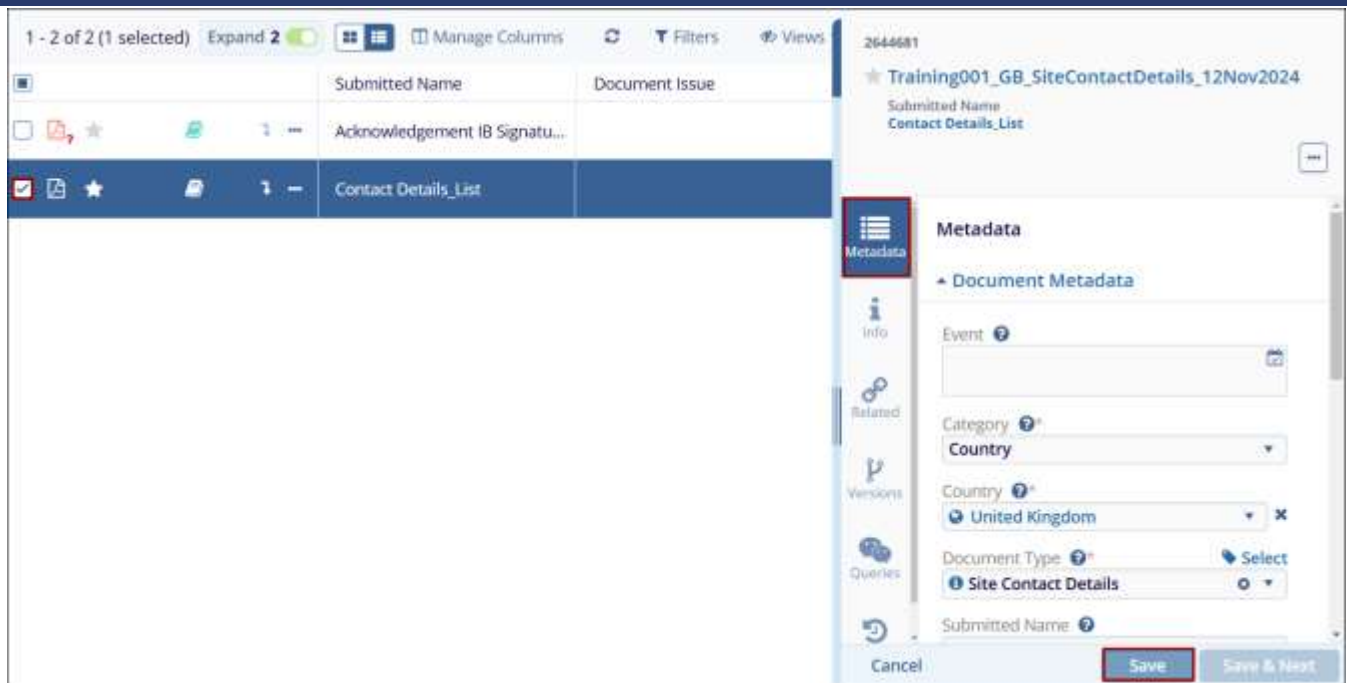
Previous Document
Next Document

### Metadata tab

The Metadata tab in the Metadata panel displays all details entered during the document addition process. Users with the required permissions can edit metadata fields.

To edit the metadata fields, follow the steps below.

1. Select a document by checking the box.
2. Open the metadata panel
3. Make necessary edits in the metadata tab.
4. Click on the Save button.



5. Additionally, click on the horizontal ellipsis (three-dot menu) to access the following options.

- Copy Field
- Paste Field
- Certify Document
- Create General Query
- Reject





### Info tab

The Info tab within the Metadata panel of a document provides a comprehensive overview of key document details. This tab includes essential document information that help users track documents details. The information includes the following.

- Submission Date: The date when the document was added to the system.
- Submitted By: The name of the user who uploaded or submitted the document.
- Submission Type: The method or category under which the document was submitted
- Index Position: The assigned position of the document within the structured index
- Version Number: The current version of the document
- Document ID: A unique identifier assigned to the document
- File Size: The size of the document file, displayed in bytes, kilobytes (KB), or megabytes (MB).

2644555


**Training001\_US\_IRBIECAoRSafetyInfo\_This is a test description of this document for training purposes\_21Nov2024**

Submitted Name  
Acknowledgement IB Signature Page\_pdf-r

...

Metadata

Info

Related

Versions

Queries

History

Info

Submission Date  
11 Nov 2024 10:32:04

Submitted By  
Admin AP

Submission Type  
online

Index Position  
Country \United States\04 IRB IEC and Other Approvals\04.03 Trial Status Reporting\04.03.01 Notification to IRB IEC of Safety Information

Version Number

Document Id

File Size

2644555

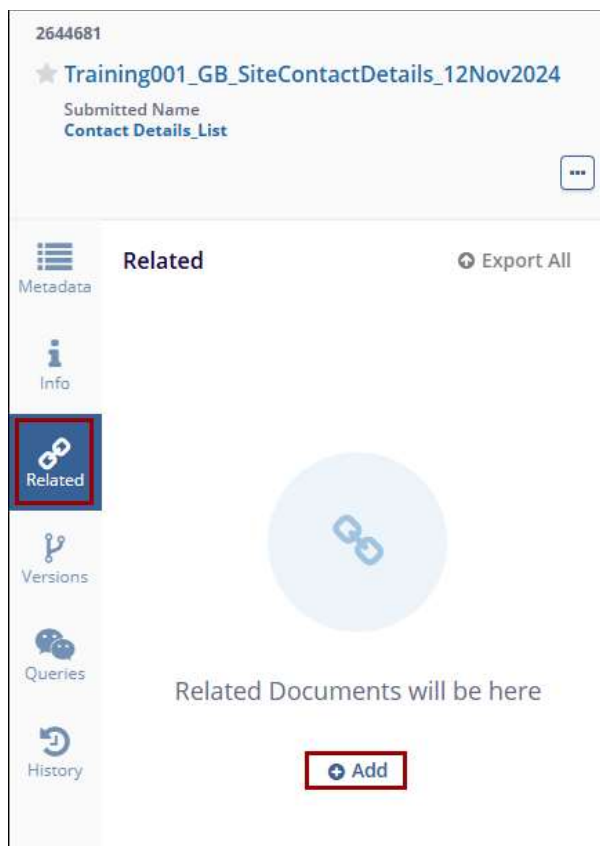
15.5 kB

### Related Tab

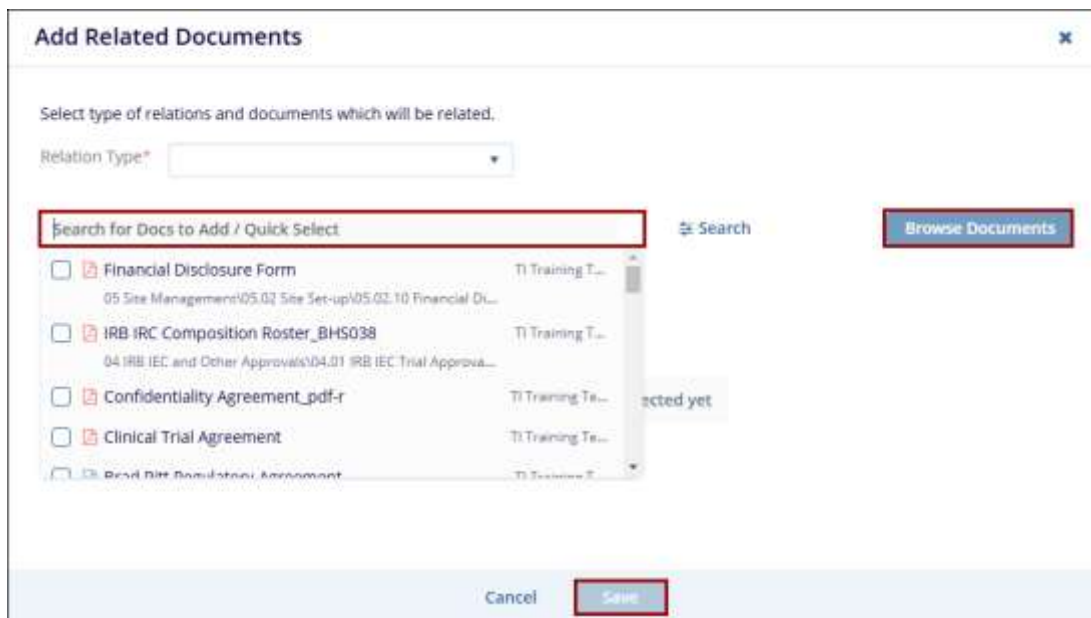
The Related tab in the Metadata panel displays all documents associated with a specific document. Users can also add additional related documents from this section.

To add a related document, follow the steps below.

1. Click on the +Add button within the Related tab.



2. Select the Related Type from the dropdown options and the document using the Quick Select functionality else click on the Browse Documents button.
3. Once the necessary documents are added, click on the Save button.

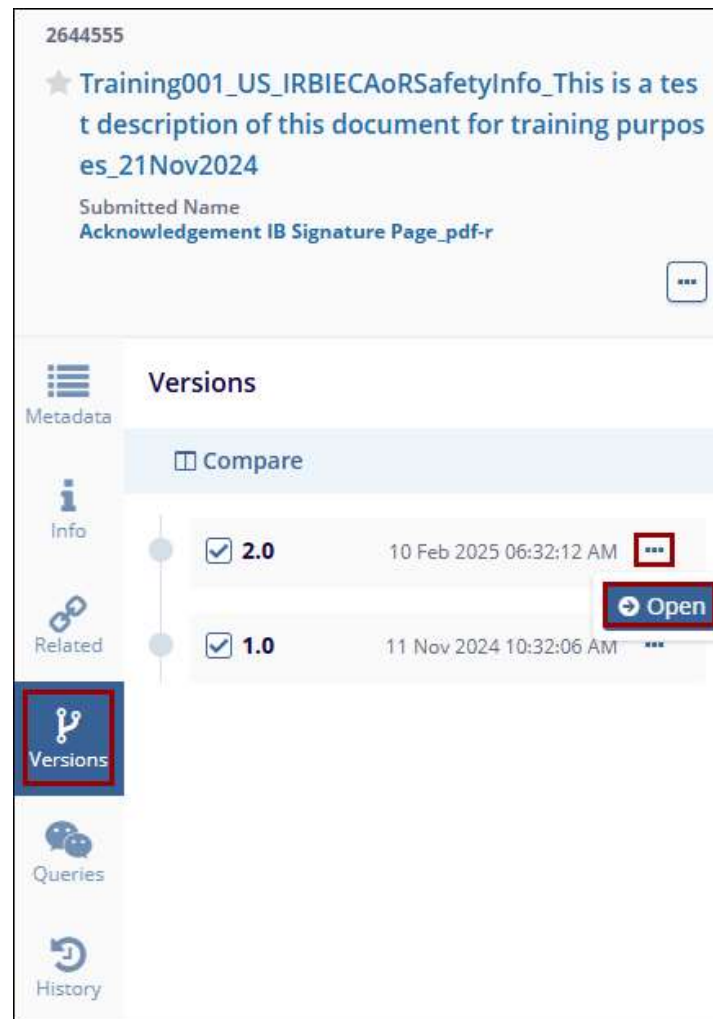


### Versions Tab

The Versions tab allows users to view and compare the different versions of a document. This is most commonly applicable in Trial Interactive rooms such as TI Collaborate rooms where documents are created, edited, and reviewed prior to becoming effective. However, this can also apply to a study room where expired or expiring documents have been replaced with newer copies.

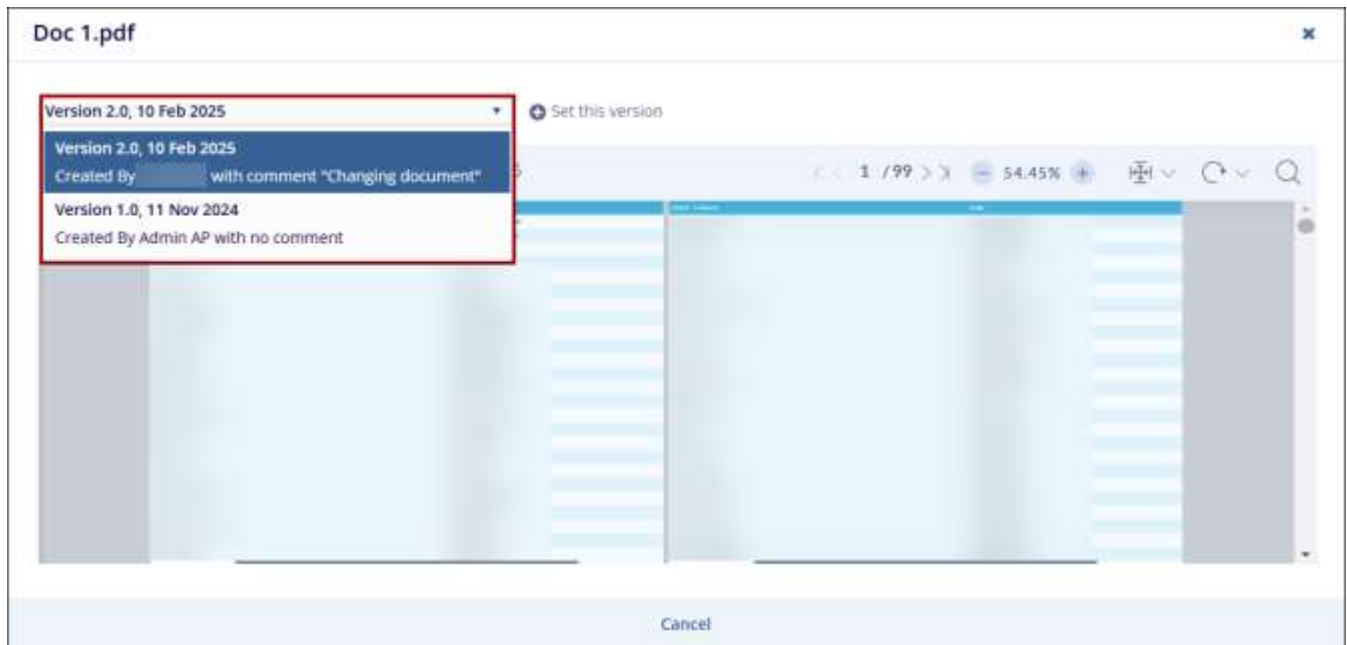
To view the different versions, follow the steps below.

1. Select a document from the grid and click the Versions tab from the Metadata panel.
2. Click on the horizontal ellipsis (three-dot) icon and select the Open option to view the document in the TI Document Viewer.

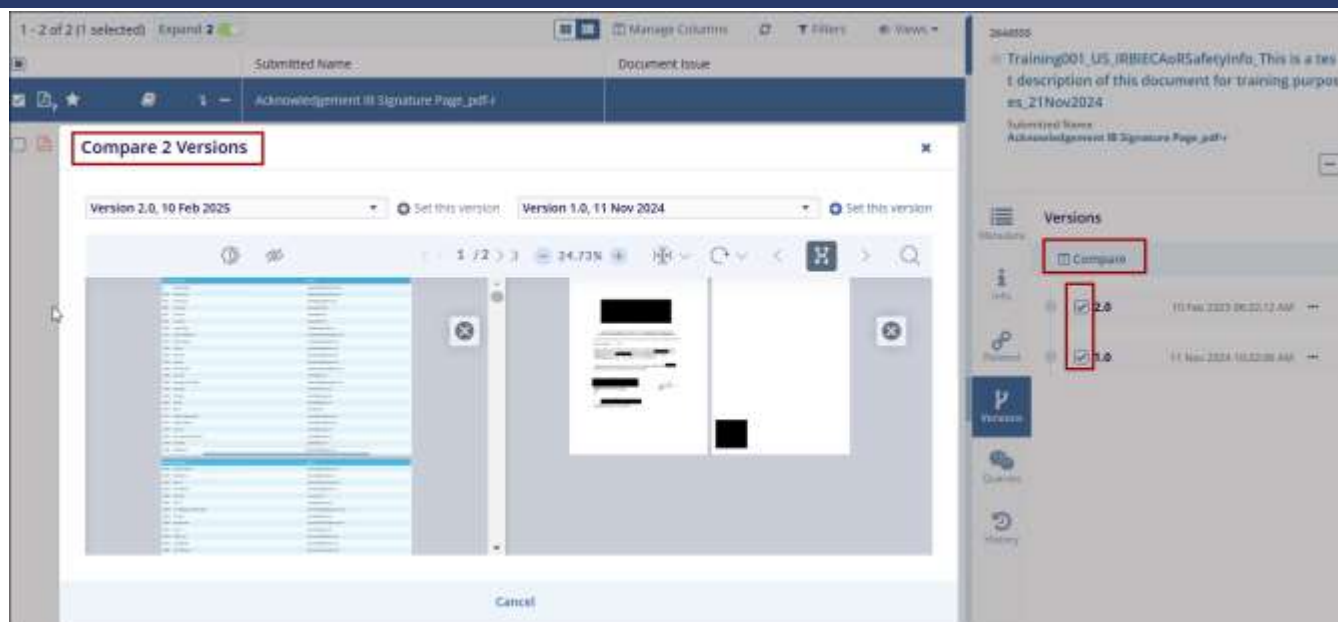


3. Click on the dropdown menu to access the different document versions.

4. Click on the Set this version button, to set a specific version as the active one.
5. Access the Navigation menu that allows the user to:
  - Download
  - Print
  - Zoom in/out
  - Adjust brightness, contrast, and colors
  - Adjust height and width
  - Rotate
  - Navigate through pages
  - Search



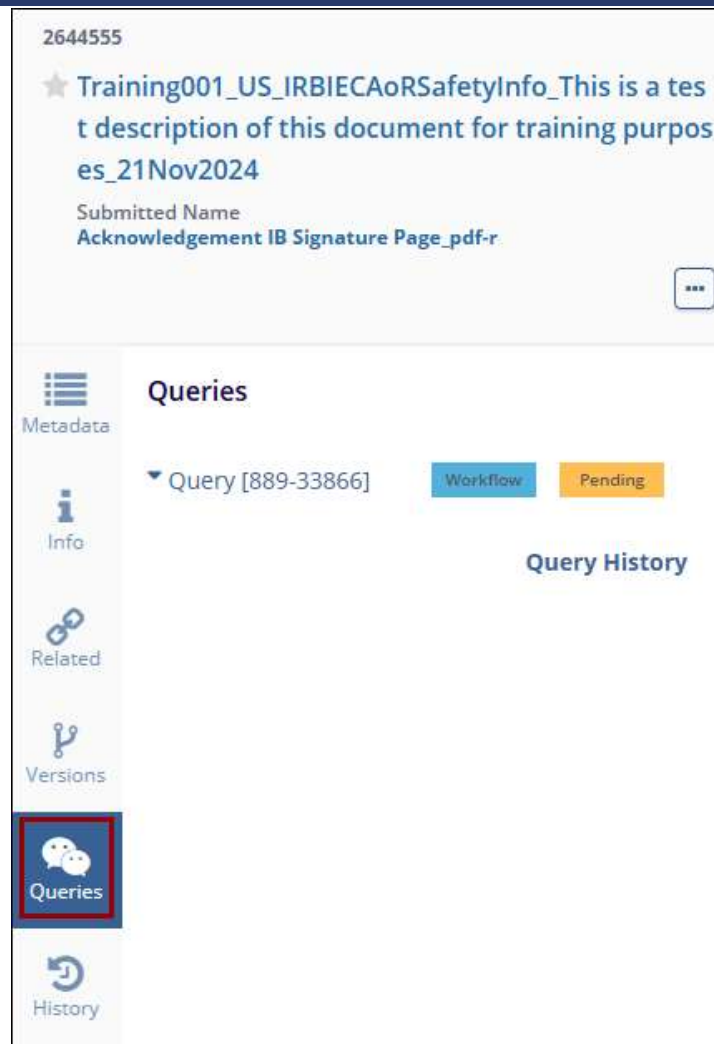
6. Select the documents and click on the Compare button to display documents from both the versions in a side-by-side view.



### Queries

This tab is visible only if a query is assigned to the users. Users can perform all query-related activities from the metadata panel.

For additional information on viewing and working queries, refer to the Queries module.

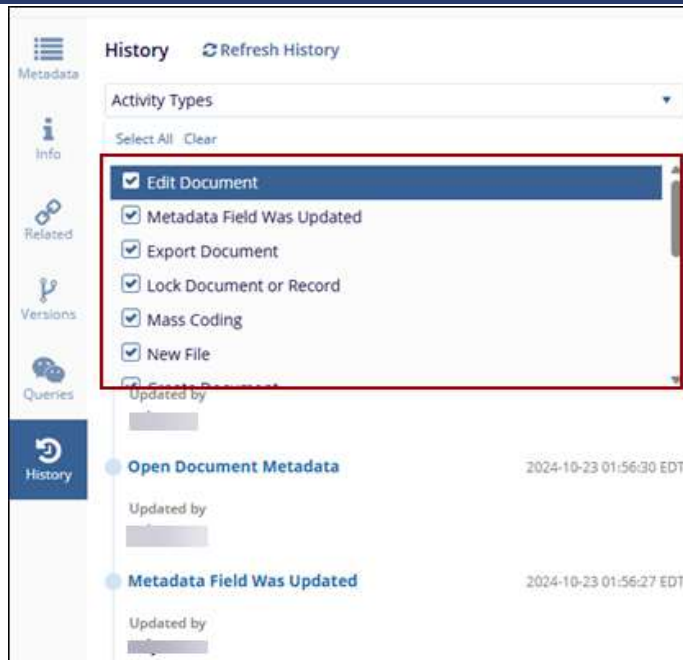


### History Tab

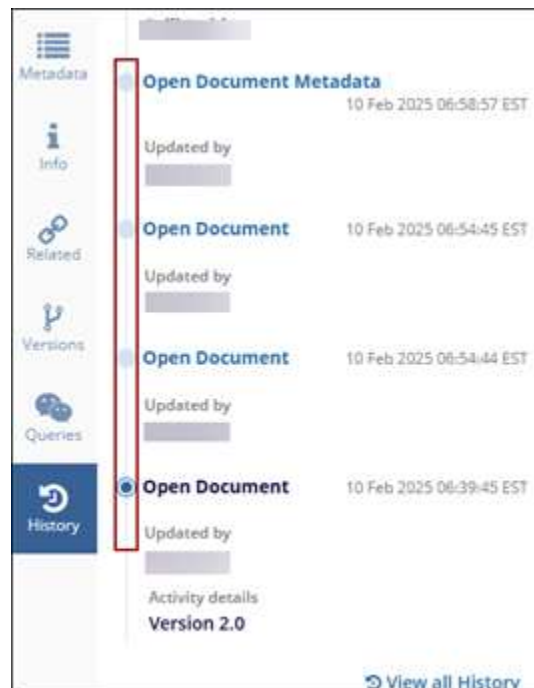
The History tab gives an overview of the document's history. The History tab displays the top five entries of the activities performed on the document. Here, users can apply the Activity Type and From & To filters to view the history of a document. Additionally, users can view the entire document history by selecting the View all History option.

To access and perform various functions within the History tab, follow the steps below.

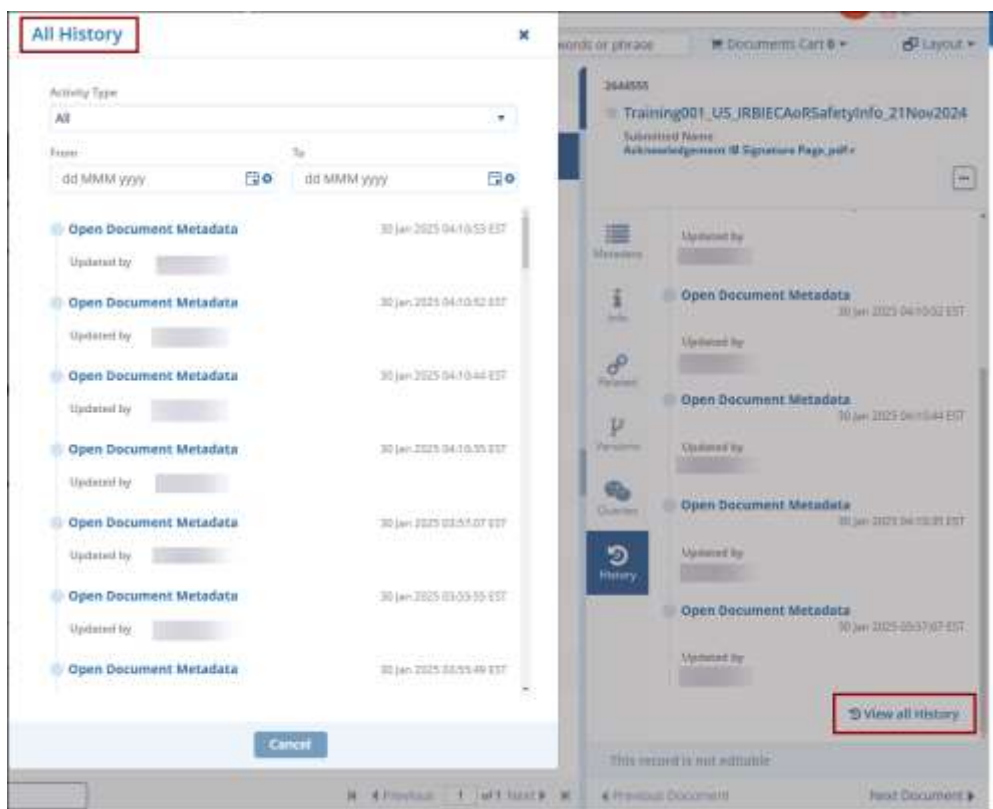
1. Select a document from the grid and click the Versions tab from the Metadata panel.
2. Apply the following filters to and filters to view history pertaining to specific activity and time range.
  - Activity Type: Use this drop-down to view the document history by the activity performed on it. Users can select multiple activity types and view history for the selected activity types.
  - From & To: Use this filter to view the document history within the set date range.



3. Every activity in the History panel is denoted by a node. Click the node to view the description, date, time, and name of the person who performed the activity on the document.



4. Click on the View All History button to display the complete history of a document and filter the document history based on the Organization, Activity Type, and Duration.





## Documents Upload

Uploading documents refers to the process of transferring files—such as PDFs, Word documents, images, or spreadsheets. The process generally involves selecting the file to upload, assigning any necessary metadata, and confirming the upload.

### Rooms

- eTMF
- Collaborate

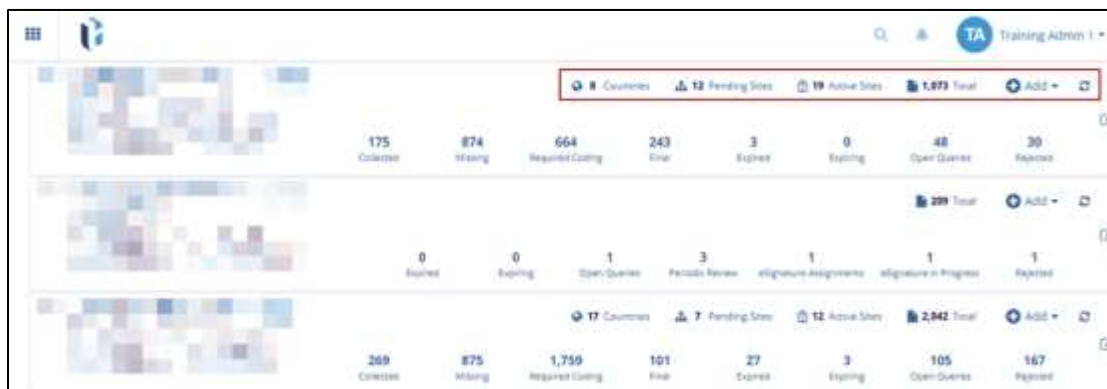
### Users

- Admin
- Manager
- Editor

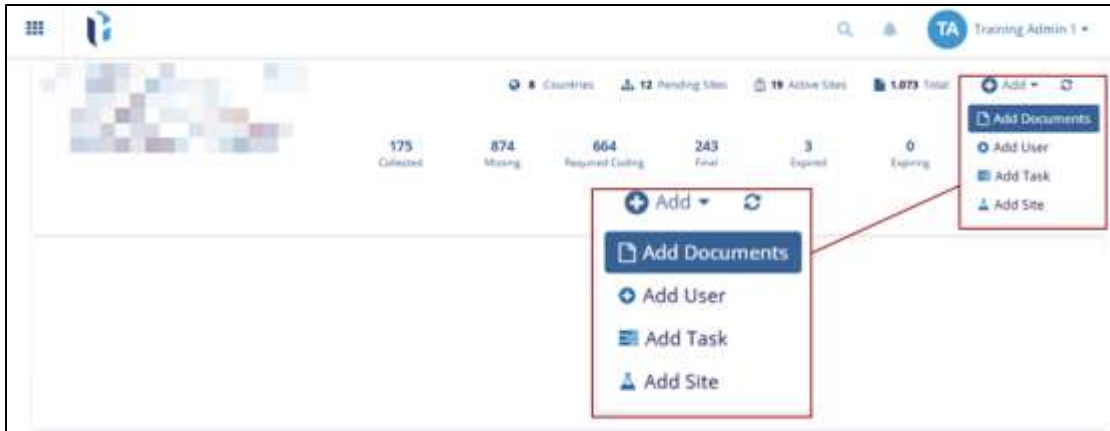
### Home Screen Upload

The document uploading method is convenient when users have multiple documents to add, but do not need to specify their location or configure their metadata within the room. The documents will be stored in the Upload system folder.

1. Log in to the application, and the Home Screen is displayed with the available rooms.
2. Each room displays the count of the Countries, Sites (Pending, Active), Total, and the +Add button with a Refresh icon.



3. Click the +Add button the drop-down is displayed. Click the Add Documents option.



4. The Import Documents screen is displayed with the Drop Files And Folders Here or Browse File/Browse Folders options.
5. Browse File/Folder should open the Windows Explorer, where the user can select the files/folders.
6. Drop Files And Folders Here, the user can drag and drop the files/folders directly.



7. The two options below on the Import Documents screen are used:
  - Unpack Zip Archives option – Enables if the user has the documents in a zip file and needs to upload the contents of the zip file as separate documents.
  - Convert Non-PDF files to PDF – Enables if the user needs to convert any non-PDF documents to a PDF document.

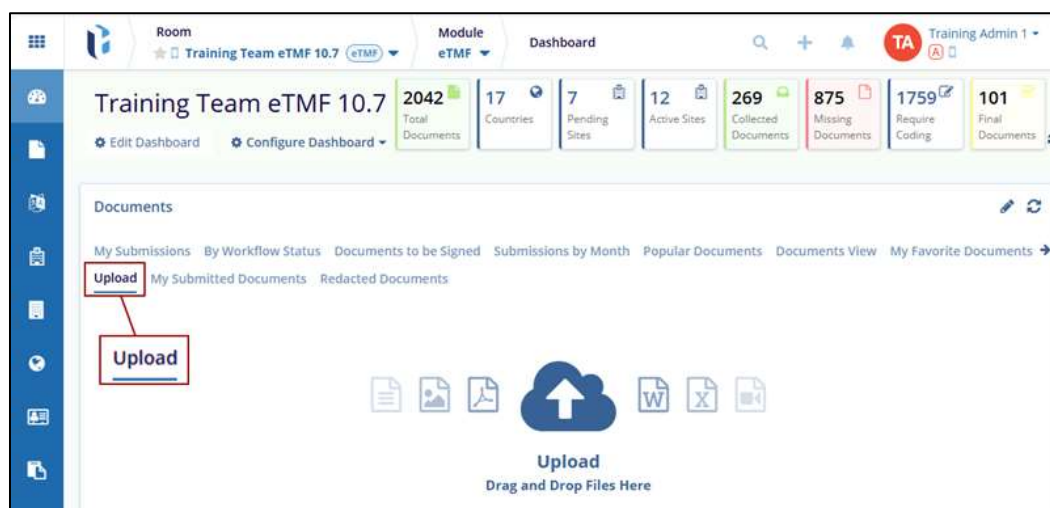


8. Once the uploading document process is completed, click the Import All Documents button to finalize.

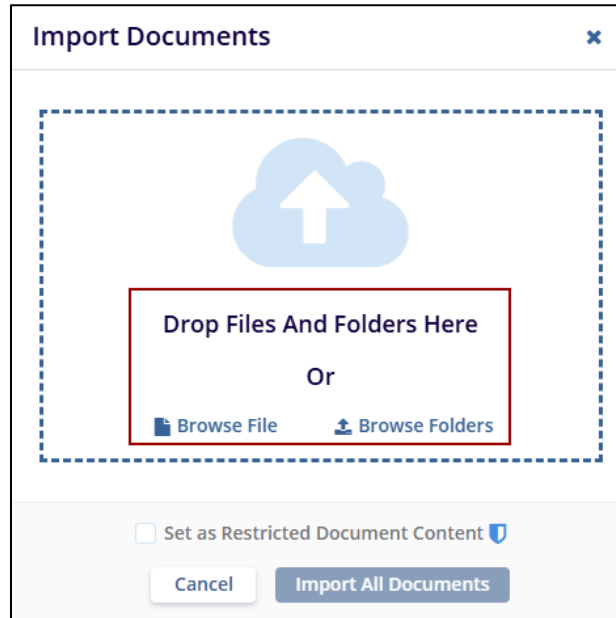
#### *Dashboard Upload*

This method is similar to the previous one: it does not provide additional metadata, and the documents are stored in the Upload system folder. It must be enabled for the specific study or room to be visible.

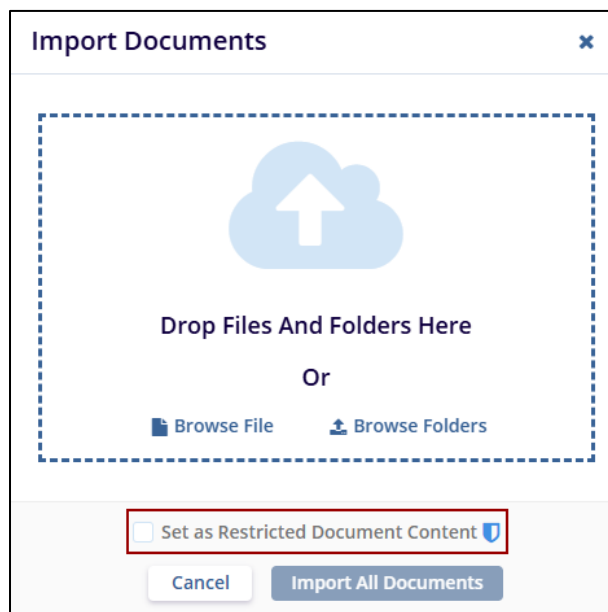
1. Click the room available on the Home Screen where the eTMF module is enabled.
2. Click the Upload dashlet in the Documents section of the eTMF Dashboard.  
Tip: The Upload dashlet may be hidden; use Edit Dashboard to search for and, if present, enable it.



3. Drag documents onto the upload area or click on the cloud icon to browse device contents.
4. The Import Documents screen is displayed with the Drop Files And Folders Here or Browse File/Browse Folders options.
5. Browse File/Folder should open the Windows Explorer, where the user can select the files/folders.
6. Drop Files And Folders Here, the user can drag and drop the files/folders directly.



7. The rooms enabled for Redaction; the user can lock the document to hide its content using the Set as Restricted Content button.



8. Review your list of documents, and click Import All Documents to finalize.

Import Documents



Drop Files And Folders Here

Or

 Browse File

 Browse Folders

☐ Set as Restricted Document Content 

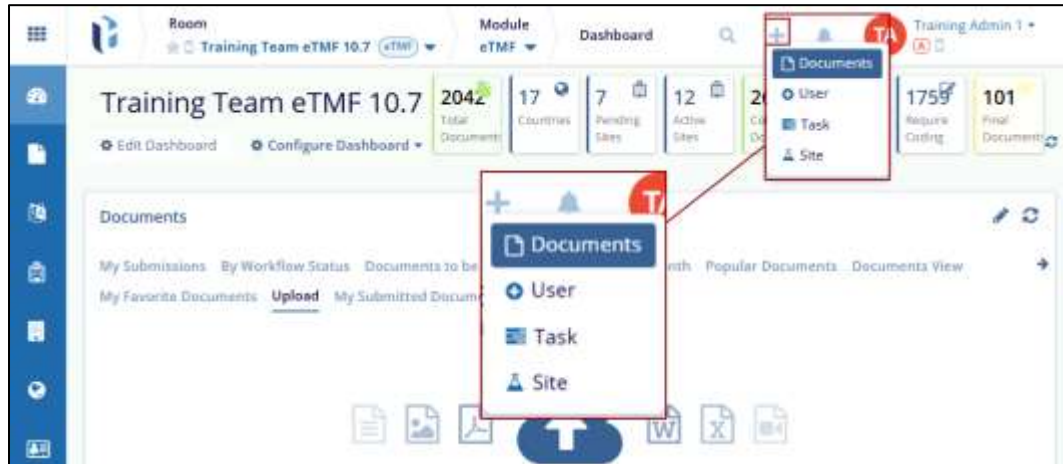
Cancel

Import All Documents

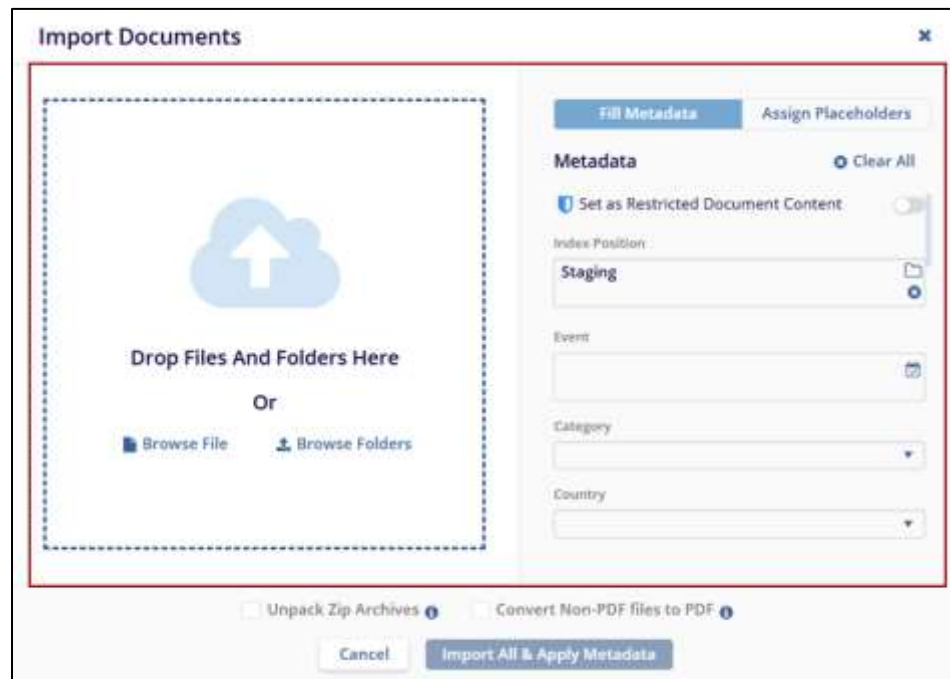
### Upload via the Add Button

Available at any time while in a room, the Add button offers a flexible way to upload documents. It allows you to define metadata if needed and choose the destination folder for the documents. The availability of these options depends on the configuration settings. By default, documents are usually placed in the Staging folder.

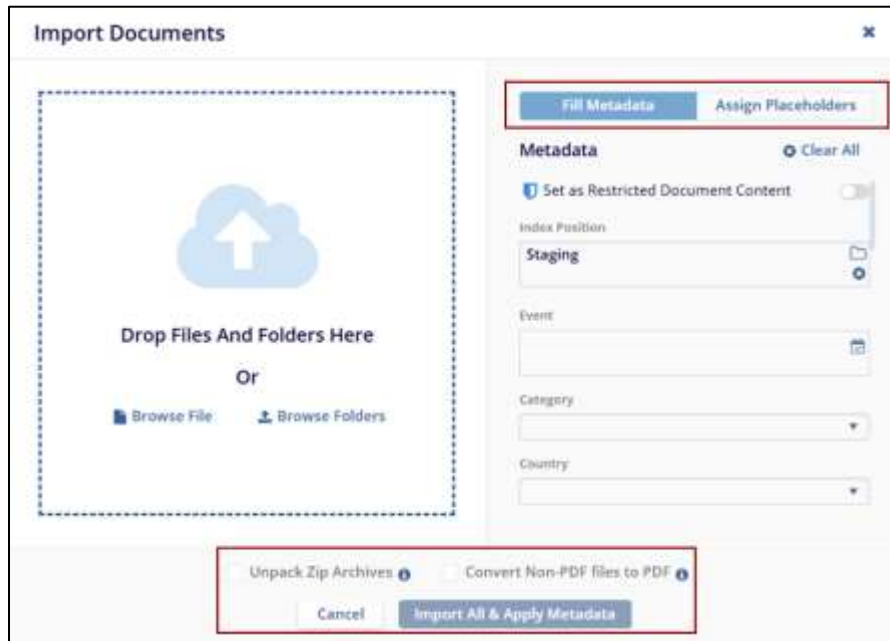
1. Locate the + icon near the username display on the eTMF Dashboard.



2. Select the option for Documents.
3. The Import Documents screen is displayed with the Drop Files And Folders Here or Browse File/Browse Folders options, including the Fill Metadata and Assign Placeholders options on the right side of the Import Documents screen.



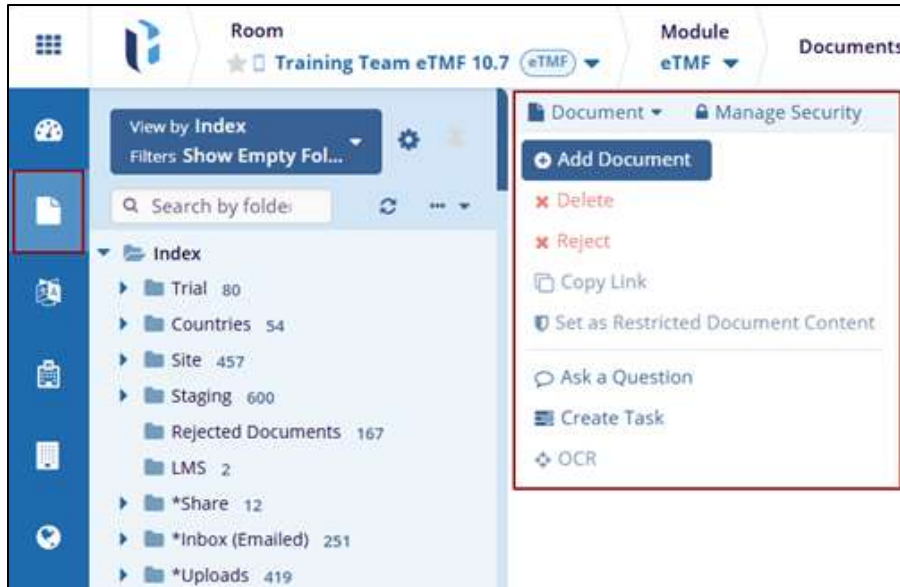
4. Browse File/Folder should open the Windows Explorer, where the user can select the files/folders.
5. Drop Files And Folders Here, the user can drag and drop the files/folders directly.
6. Select Fill Metadata or Assign Placeholders and complete the respective fields to match new documents with metadata and, for placeholders only, a specific location.
7. Review your list of documents, and click Import All & Apply Metadata to finalize.



### *Import to Documents View*

The ribbon in the Documents module provides two upload options: the Add Document function—covered here—which allows for uploading a single document with full metadata; and the Import Documents function, which works similarly to the Add button described previously, but may adjust the upload location based on the currently selected folder. Note that some views within the module do not offer these upload options.

1. Navigate to the Documents module and click the Document button on the top ribbon above the grid.
2. The drop-down options are displayed. Select Add Document option.

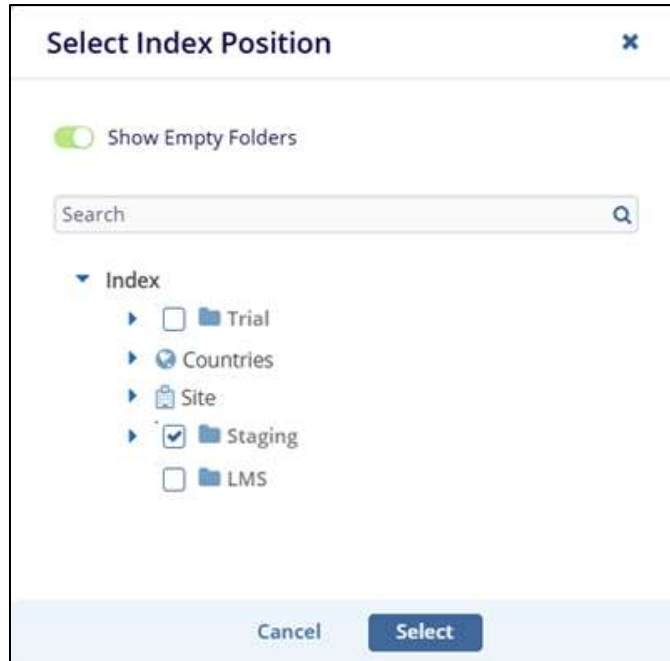


3. Start by selecting a document with Browse.
4. The New Document window is displayed. Fill in all the required fields, such as:
  - Index Position: The Select Index Position window will open, where the user needs to select the position of the document to be uploaded. Once selected, click the Select button.



The screenshot shows the 'New Document' window. The 'Index Position' field is highlighted with a red box, showing the value 'Staging'. The window includes a 'Metadata' section with 'Document Metadata' and options for 'Attachment' (File or URL) and 'Set as Restricted Document Content'. The 'Index Position' field is a dropdown menu with a folder icon and a plus sign.





- Event: Where the user needs to select the Event from the Event window. Once selected, click the Select button.

New Document

Metadata

Document Metadata

Attachment

File

URL

Browse

Set as Restricted Document Content

Index Position \*

Staging

Event \*

Event

Filter

|                                     | Event             | Event Type        | Description     | Due Date Per... | Category | Status    |
|-------------------------------------|-------------------|-------------------|-----------------|-----------------|----------|-----------|
| <input checked="" type="checkbox"/> | First Country ... | First Country ... |                 | 20              | Study    | Completed |
| <input type="checkbox"/>            | Milestone #1      | Milestone         | Protocol Ame... | 14              | Study    | Completed |
| <input type="checkbox"/>            | Yums              | Quarterly Do...   |                 | 30              | Site     | Completed |
| <input type="checkbox"/>            | Amendment ...     | Protocol Ame...   |                 |                 | Study    | Completed |
| <input type="checkbox"/>            | IMV #1            | IMV               |                 | 30              | Site     | Completed |
| <input type="checkbox"/>            | IMV #2            | IMV               |                 | 30              | Site     | Completed |
| <input type="checkbox"/>            | Site 1112 Clo...  | 9 - Close Out ... |                 | 2               | Site     | Completed |

Close

Select

- Category: Need to select the Category where the uploaded document takes place.

New Document

Metadata

Document Metadata

File
URL

Attachment

Browse

Set as Restricted Document Content

Index Position \*
Staging

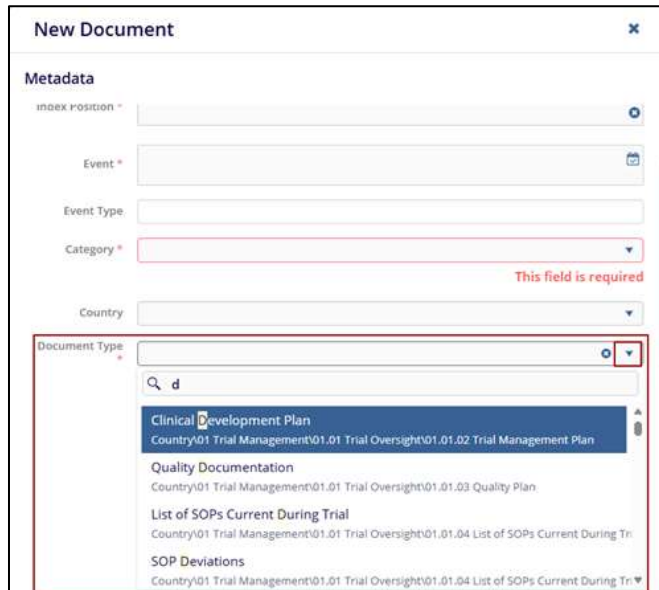
Event \*

Event Type

Category \*

Trial
Country
Site

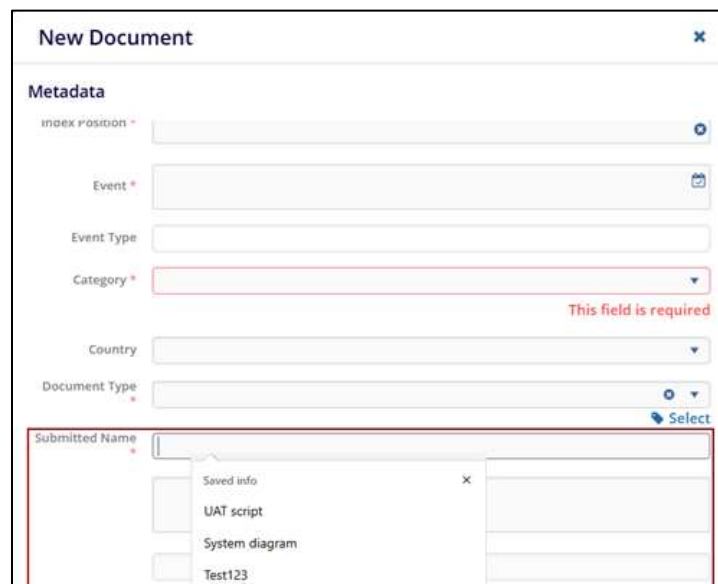
- Document Type: Where the document type should be specified.



The screenshot shows the 'New Document' form with the 'Document Type' dropdown menu open. The dropdown list includes the following options:

- Clinical Development Plan
- Country\01 Trial Management\01.01 Trial Oversight\01.01.02 Trial Management Plan
- Quality Documentation
- Country\01 Trial Management\01.01 Trial Oversight\01.01.03 Quality Plan
- List of SOPs Current During Trial
- Country\01 Trial Management\01.01 Trial Oversight\01.01.04 List of SOPs Current During Tr
- SOP Deviations
- Country\01 Trial Management\01.01 Trial Oversight\01.01.04 List of SOPs Current During Tr

- Submitted Name: Need to provide the name of the user who submitted the documents.



The screenshot shows the 'New Document' form with the 'Submitted Name' dropdown menu open. The dropdown list includes the following options:

- Saved info
- UAT script
- System diagram
- Test123

- Comments: Need to add any general document-related comments.
- Expiration Dates: Need to provide the expiration date of the document.

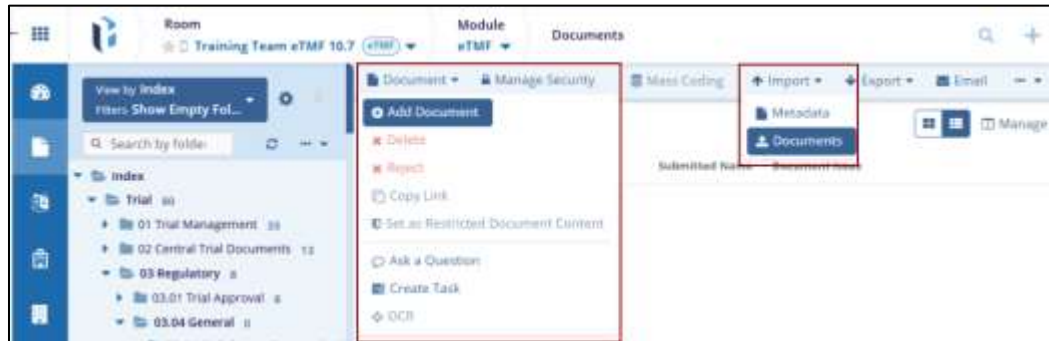
Note: It is usually convenient to complete the Document Type first.

5. Also, complete the discretionary metadata fields, review, and then click the Finish button.

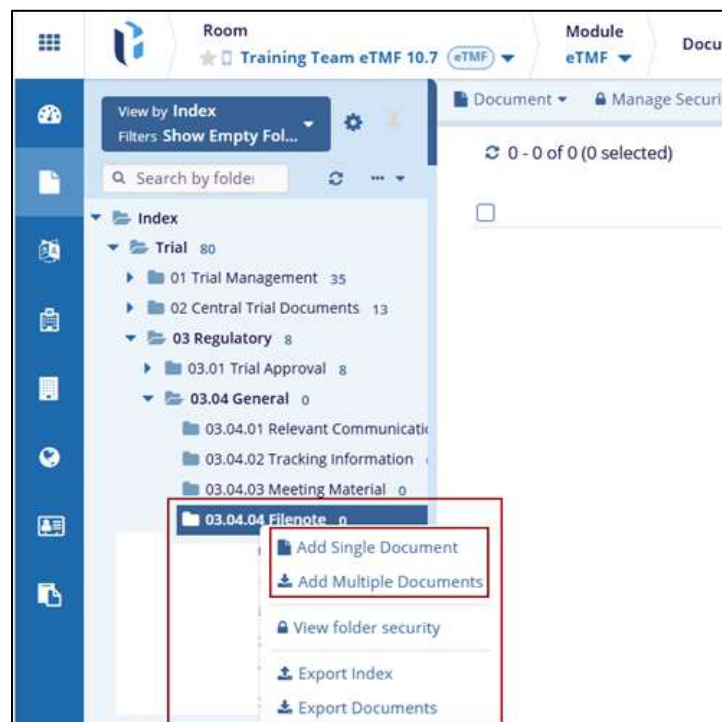
### Targeted Upload

Some upload methods are partially self-configuring, automatically drawing information from the room configuration instead of relying solely on user-provided document details.

1. Select a document folder in the Index.
2. Option 1: Use Add Document or Import Documents as previously described.



3. Option 2: Right-click on the folder name and select one of the Add options.



4. Repeat the steps provided in the Import to Documents View from steps 4 and 5.
5. Complete the metadata as necessary and click Finish to upload (Import All & Apply Metadata for multiple documents import).

## Documents Submission via Email

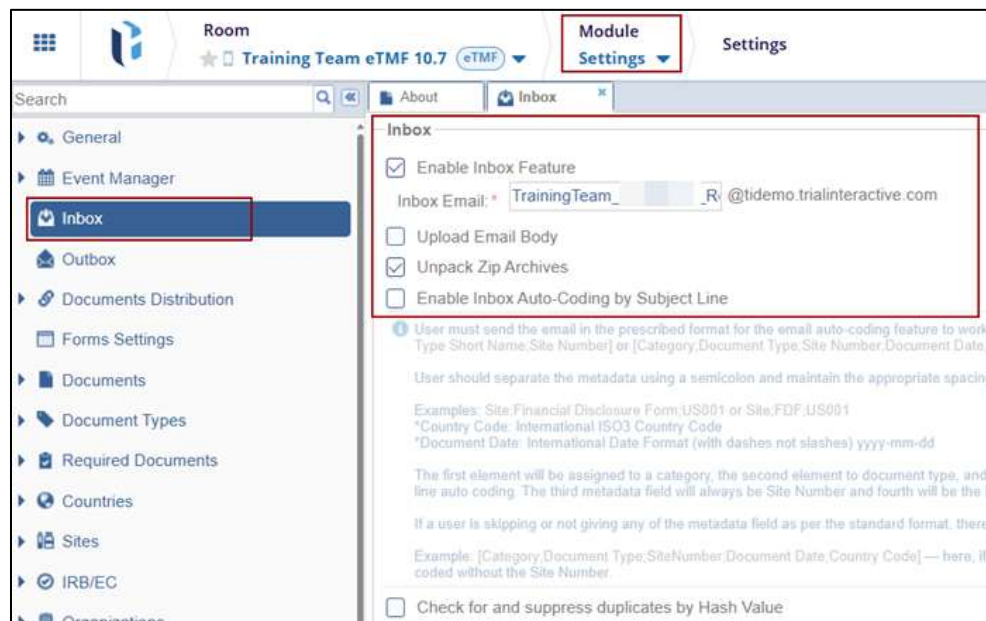
This information is intended to show the users how to submit documents via email to a Trial Interactive room. Room administrators can activate the Inbox by selecting the checkbox, allowing room participants to send trial documents directly to the room's inbox. The Target room should have at least one email inbox enabled.

### Rooms

- eTMF

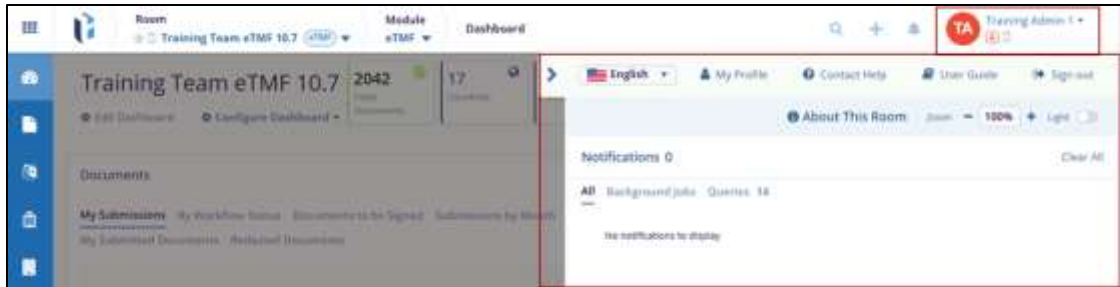
### Users

- Admin
- Manager

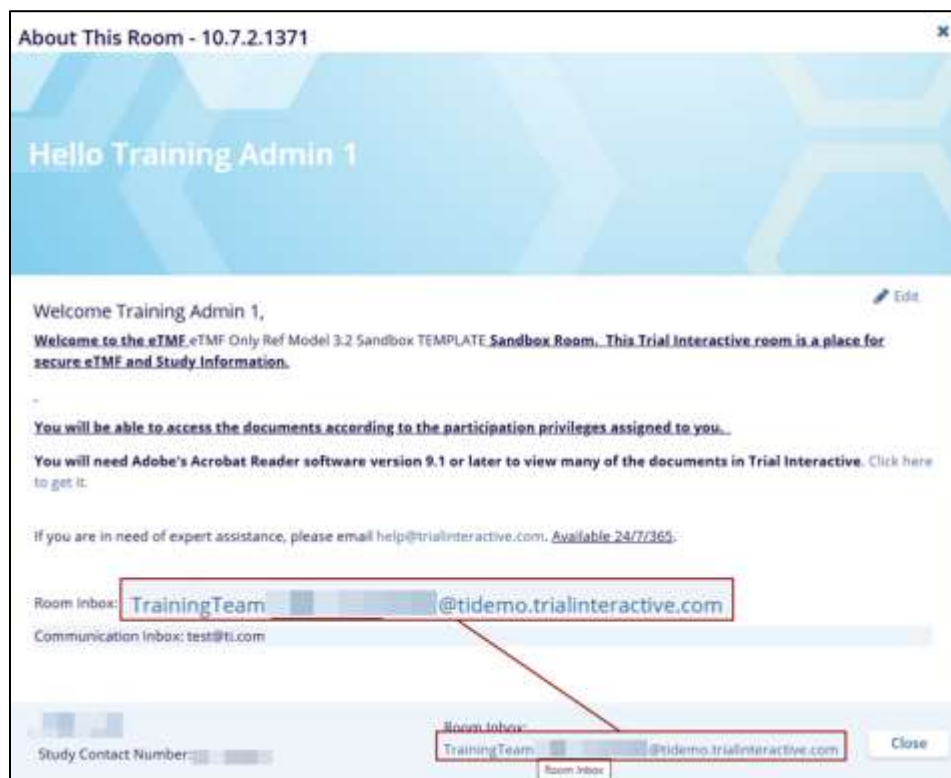


To send a document via email, follow the steps below:

1. Log in to the application where the eTMF module is enabled.
2. Click the User Name menu on the top right side of the screen and click on About This Room.
3. Locating the email address for the room.



4. Here on the About This Room screen the user can view the email address for the below:
- Room Inbox i.e., it keeps only the attached files to be sent for the review process for indexing.
  - Communication Inbox it preserves the Trial relevant communication as well as any attached documents. Emails sent to this inbox will be reviewed to verify their relevance before moving to the review process of indexing.

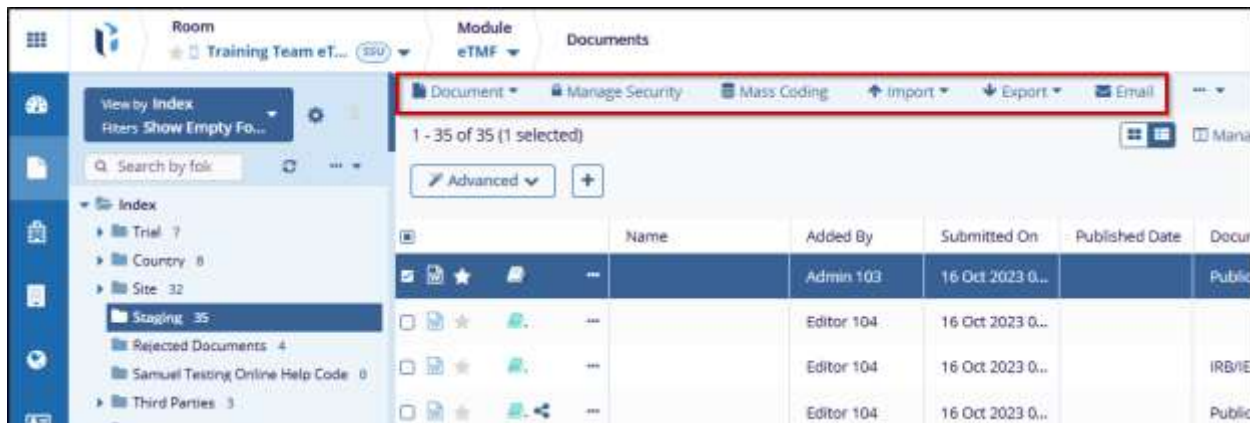


5. Users can employ their preferred email service to send content.
6. Use the room inbox address as the recipient of the email and ensure no alteration is present.
7. Attach the file/document to send. Most document and media type files are accepted

## Documents Module- Top Menu Ribbon

This menu is located at the top of the Documents module and allows access to various functionalities on documents:

- Document Activities
- Manage Security
- Mass Coding
- Import
- Export
- Email
- Move to Study Start-Up
- Print
- Compare
- Local Search
- Documents Cart

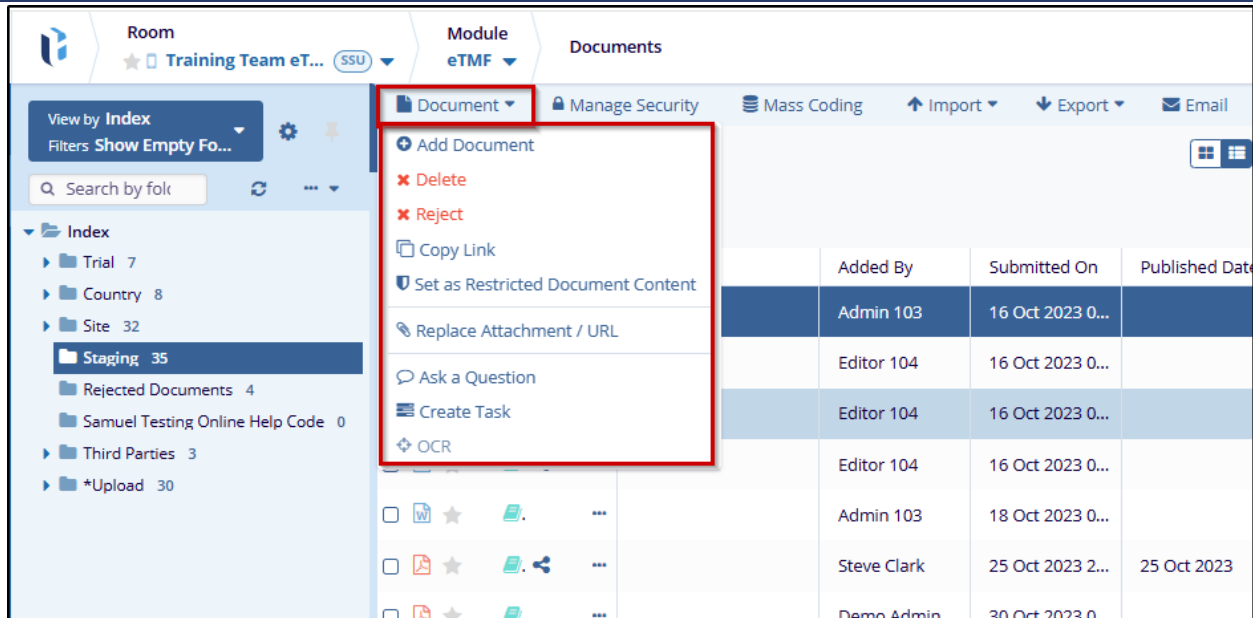


## Document

The options available in this dropdown menu are only available once a document has been selected in the grid and are a subset of the options available in the Document Activities menu mentioned in the section above.

Refer to the Document Activities Menu section for a more detailed description of these options.

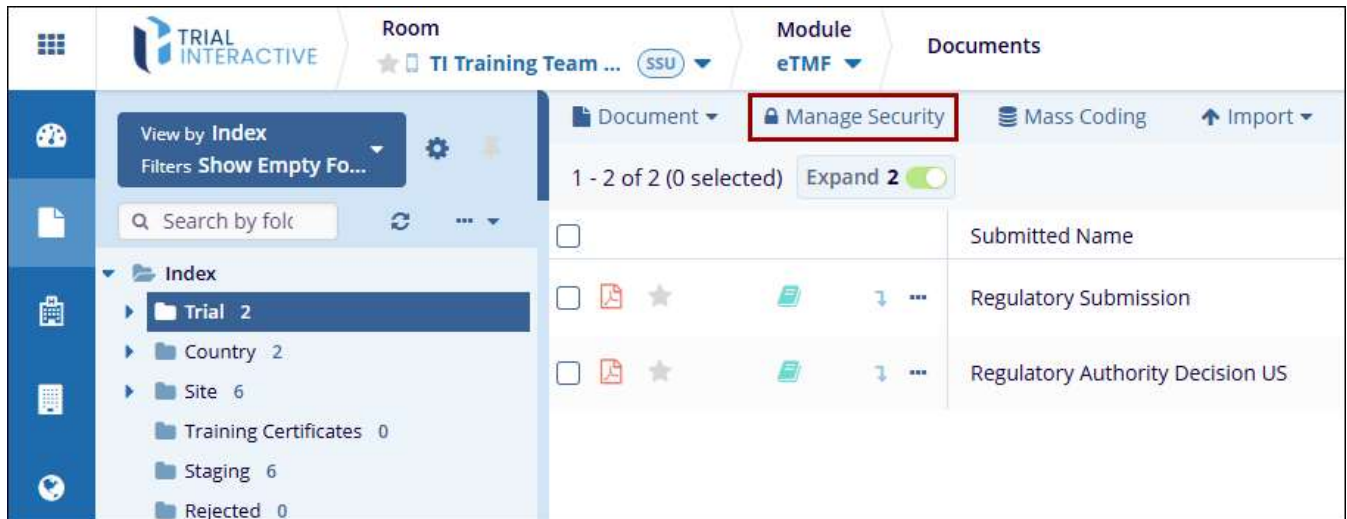




## Manage Security

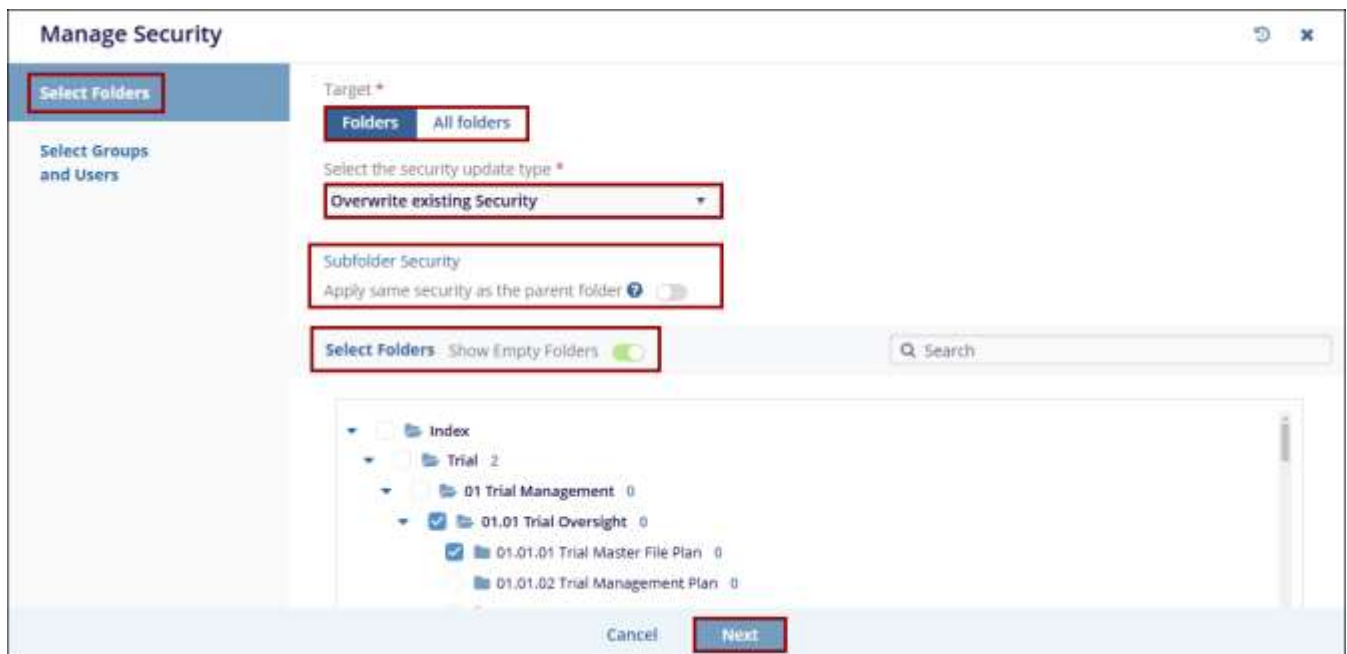
To manage folder security, follow the steps below.

1. Click Manage Security from the top ribbon bar. The Manage Security window opens.

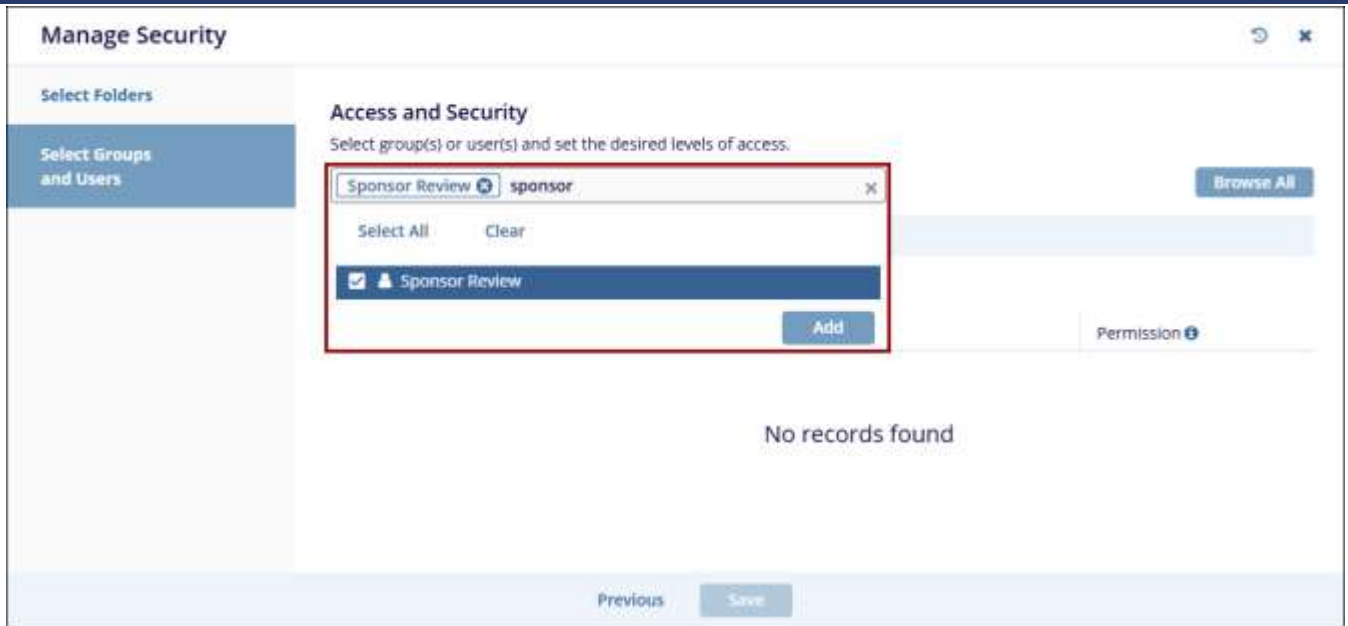


2. Within the Target\* section, click on the Folders tab and select the folders to apply security to. To search for a specific folder, enter the search term in the search box.
3. Click on the All Folders button to apply security to all the folders.
4. Select whether or not the changes should apply to all subfolders or only to the folders specifically chosen by accessing the Apply same security to the parent folder toggle switch.

5. Enable or disable the Show Empty Folders toggle switch to display and hide empty folders respectively.
6. Select a security type by accessing the Select the security update page\* dropdown options.
  - Update existing security: This option leaves all current security definitions in place and adds on any new definitions set in step two of the manage security process.
  - Overwrite existing security: This option erases all current security definitions and replaces them entirely with the definitions set in step two of the manage security process.
  - Remove from existing security: This option leaves intact any security definitions already assigned but removes access for any group(s) or user(s) specified in step two of the manage security process.
  - Restrict access to administrators only: This option erases all current security definitions in place and makes the target files/folders only viewable to administrators.
7. Click on the Next button.



8. On the Select Groups and Users screen, perform the following
  - Enter a keyword related to the users or groups, select the required groups and users from the dropdown options and click on the Add button.



**Manage Security**

Select Folders

Select Groups and Users

**Access and Security**  
Select group(s) or user(s) and set the desired levels of access.

Sponsor Review ☒ sponsor

Select All Clear

☒ ☒ ☒ Sponsor Review

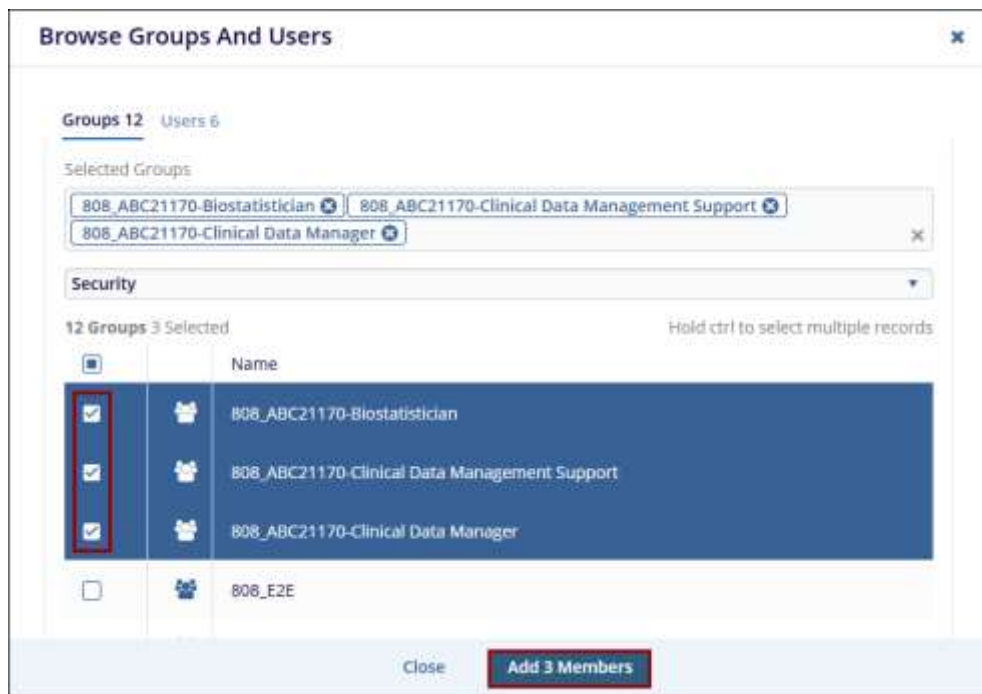
Add

Permission

No records found

Previous Save

- Additionally, click on the Browse All button and select the required users and groups by navigation to their respective tabs.



**Browse Groups And Users**

Groups 12 Users 6

Selected Groups

808\_ABC21170-Biostatistician 808\_ABC21170-Clinical Data Management Support  
808\_ABC21170-Clinical Data Manager

Security

12 Groups 3 Selected Hold ctrl to select multiple records

|                                     | Name                                          |
|-------------------------------------|-----------------------------------------------|
| <input checked="" type="checkbox"/> | 808_ABC21170-Biostatistician                  |
| <input checked="" type="checkbox"/> | 808_ABC21170-Clinical Data Management Support |
| <input checked="" type="checkbox"/> | 808_ABC21170-Clinical Data Manager            |
| <input type="checkbox"/>            | 808_E2E                                       |

Close Add 3 Members

- Once the required groups and users are added, click on the Permissions dropdown and provide the necessary permissions.
  1. Full Access: Users have unhindered access-level-appropriate access to the documents.
  2. Read-Only Access: Users can only view the documents.

3. No Access: These users will not even see this folder on their room index and cannot access any associated files.
4. No Watermark: This option will only appear for rooms in which the watermark option is enabled. It allows the selected user to view the documents in the chosen folders without the watermark.
5. Proxy Document Owner (For collaborate rooms): This allows the specified user to act as a document owner for any documents contained in the selected folders.



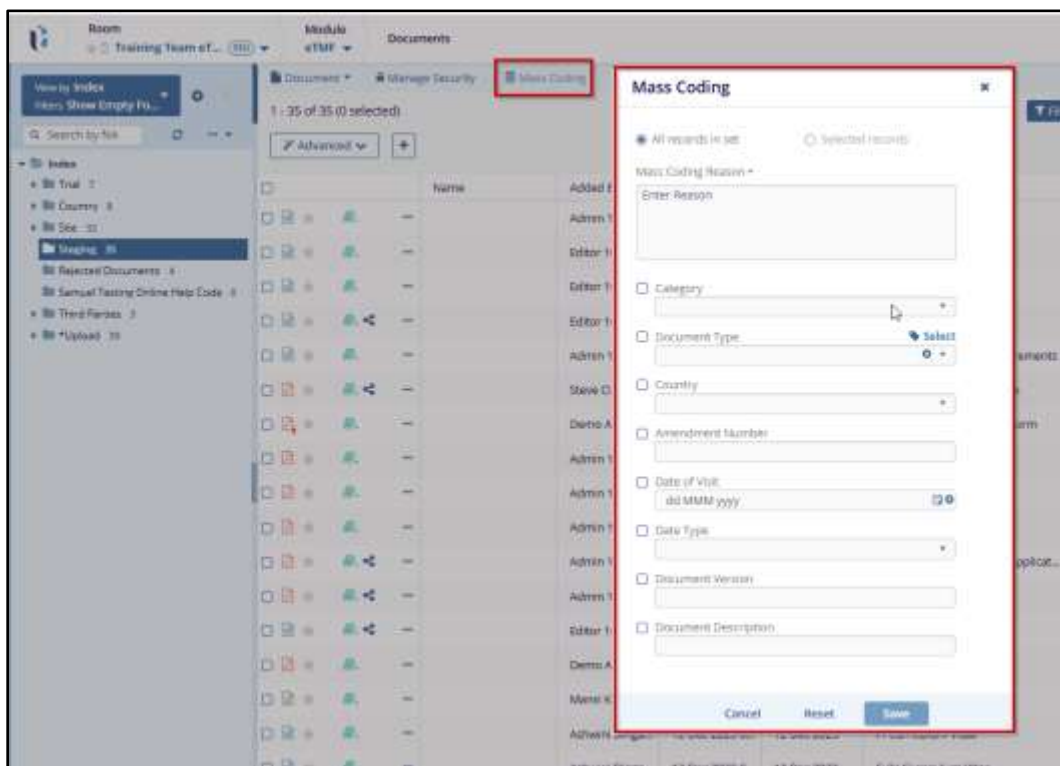
9. Once all the changes are made, click on the Save button.

## Mass Coding

The Mass Coding function, allows the user to apply metadata to multiple documents at the same time. A room can be configured to allow both Causality Tracking and Mass Coding.

To apply mass coding, follow the steps below.

1. Click on the Mass Coding button displayed in the top menu bar to open the popup window to mass code all documents in grid.
2. Otherwise, select an individual document and clicking on the Mass Coding button.
3. Mandatorily enter the reason in the Mass Coding Reason\* field
4. Additionally, select the fields to update by clicking on their respective checkboxes.
5. Click on the Save button displayed at the bottom of the popup window.



6. On the Confirm Mass Coding confirmation popup, click on the Yes button.

**Confirm Mass Coding**
✕

Are you sure you want to proceed with Mass Update?  
Following fields will be updated:

- Event
- Category

No
Yes

## Important

- If no document is selected from the grid, the Mass Coding window displays All Records in set selected by default.
- If an individual document is selected, the Selected Records radio button is selected by default.
- Alternatively, the user can also drag-drop the documents in document cart and select the Mass Coding option from the Actions dropdown menu.

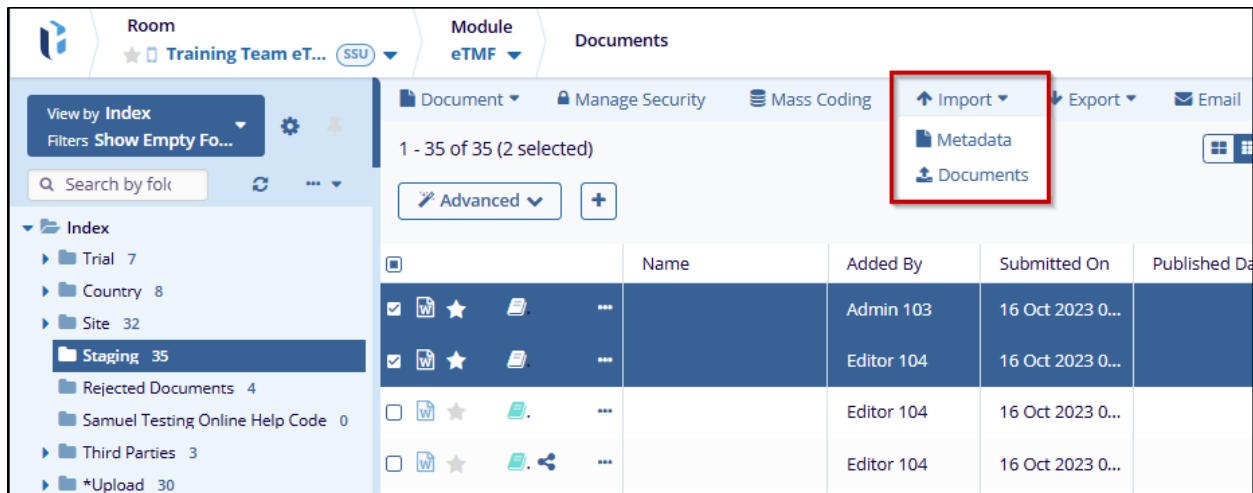
## Import

The Import function allows users to bring documents into the room, where permissible, the function also allows for the import of metadata.

### Documents

To import documents, follow the steps below.

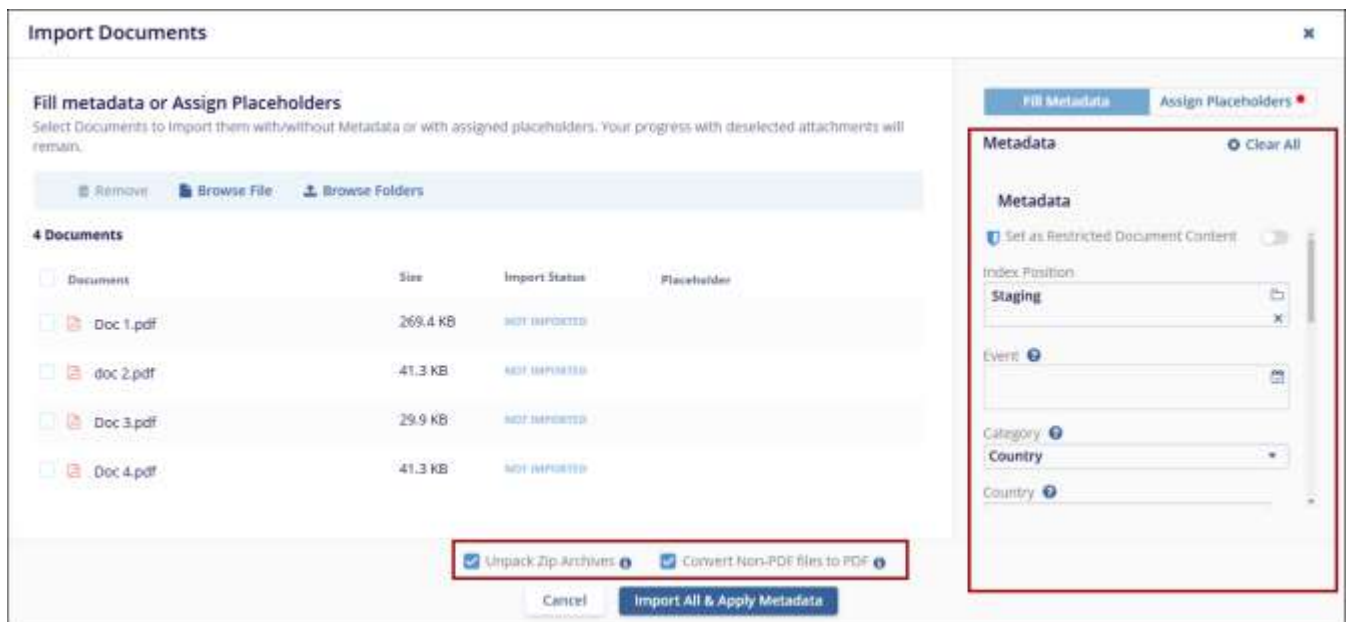
1. Click on the Import button from the top menu bar. This opens the Import Documents window.



2. On the Import Documents window, add single or multiple documents using the drag & drop functionality or manually upload the documents by selecting Browse File or Browse Folders.



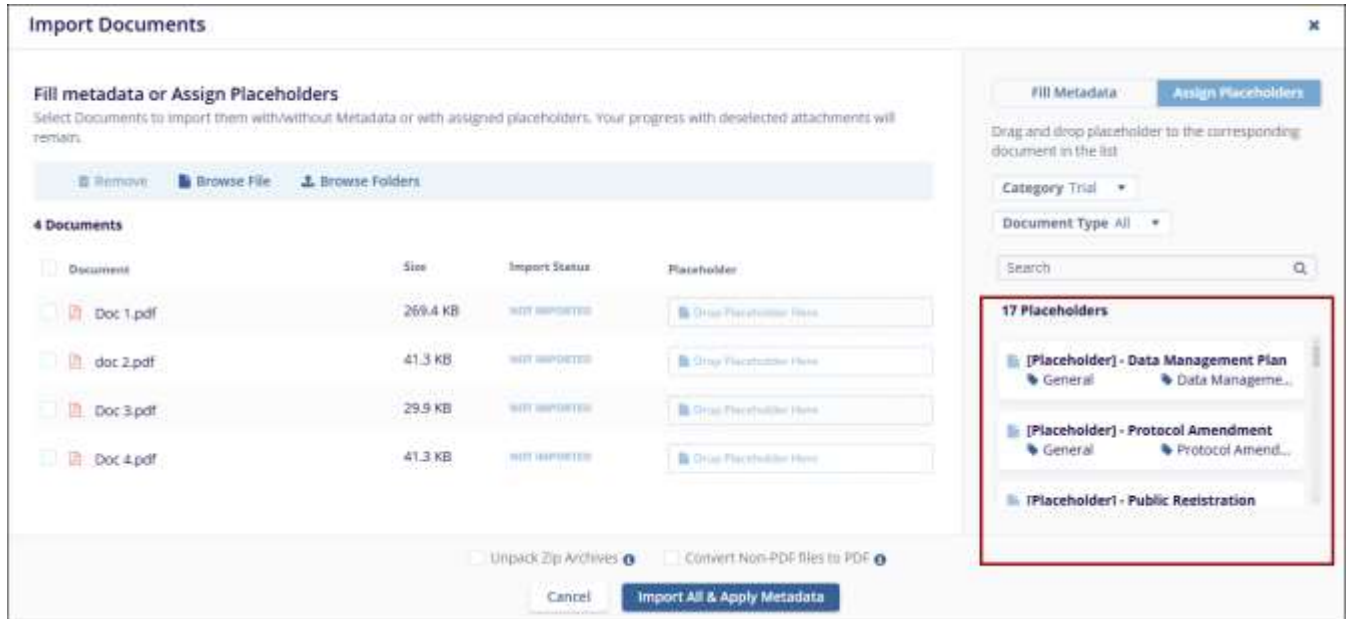
3. Once the documents are uploaded, add the necessary information in the Fill Metadata tab.
4. Select the following checkboxes
  - a. Unpack Zip Archives: Enable this option if a ZIP folder is uploaded and the documents within the ZIP folder need to be uploaded as separate documents.
  - b. Convert Non-PDF files to PDF: Enable this option to convert any file format into PDF files.



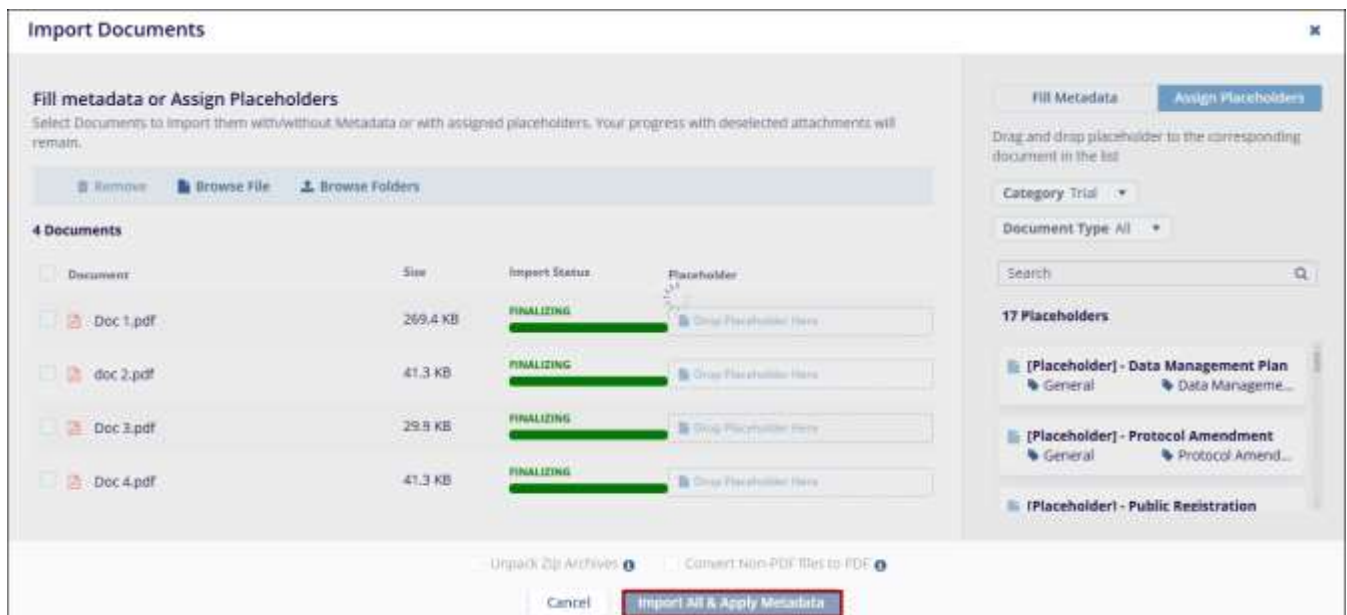


- If metadata fields are not added, navigate to the Assign Placeholders tab and drag & drop the placeholders within the designated area.

Note: If Category, Country and Document Type is selected within the Fill Metadata tab the Assign Placeholders tab will display the placeholders by default.



- Click on the Import All & Apply Metadata button once the metadata fields are updated or the placeholders are assigned.





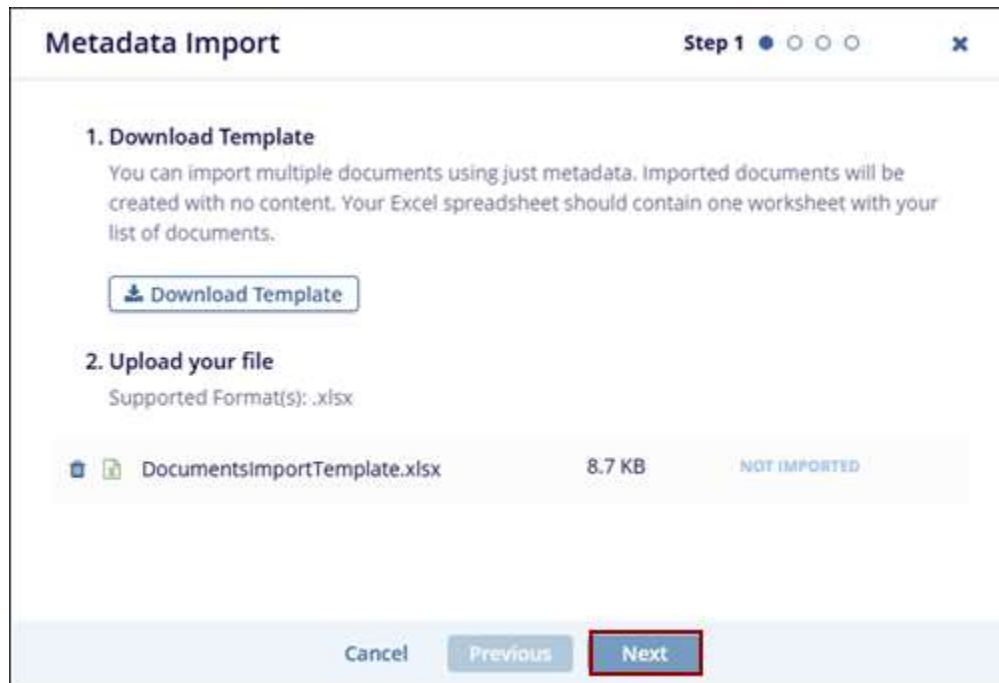
**Note:** If the metadata is applied to only a few of the documents, only those documents will be uploaded to the room.

## Metadata

The metadata Import option allows users to import metadata associated with documents, such as document type, category, country, or other key data. It enables the system to update or create metadata records in bulk, ensuring that documents are properly categorized and searchable.

To import the metadata, follow the steps below.

1. Click on the Import button, and select the Metadata option. The Metadata Import window opens.
2. In the Metadata Import window, click on Download Template to get a pre-formatted file that contains the required metadata fields.
3. Open the downloaded template and fill in the necessary details as per the systems guidelines.
4. Under the Upload Your File section, locate the Browse button. Click Browse to open the file explorer.
5. Select the appropriate file or folder containing the metadata information.
6. Once selected, the system will display the chosen file. Click Next to proceed.



**Metadata Import** Step 1 ● ○ ○ ○ ✕

**1. Download Template**  
You can import multiple documents using just metadata. Imported documents will be created with no content. Your Excel spreadsheet should contain one worksheet with your list of documents.

[Download Template](#)

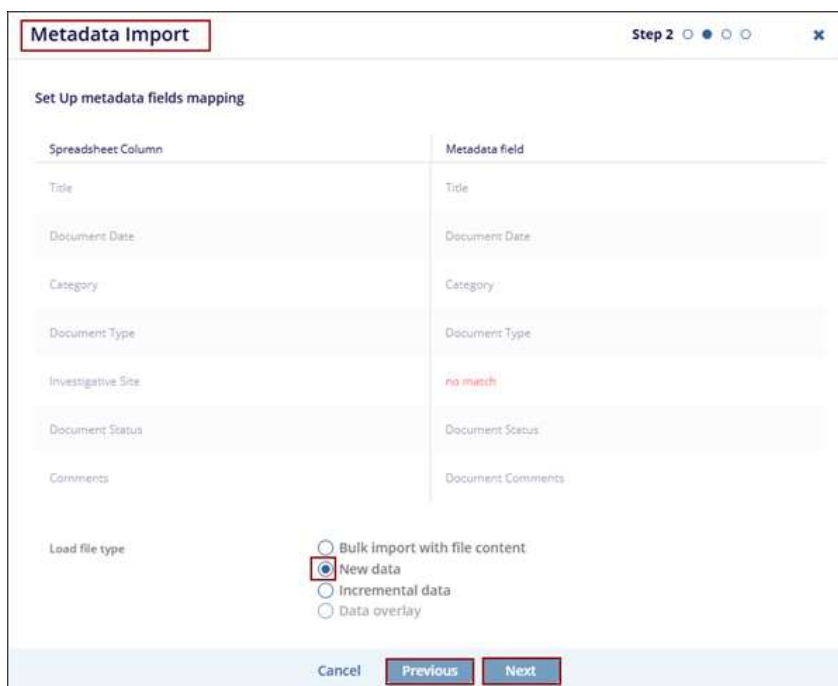
**2. Upload your file**  
Supported Format(s): .xlsx

|                                                                                                                  |        |              |
|------------------------------------------------------------------------------------------------------------------|--------|--------------|
|  DocumentsImportTemplate.xlsx | 8.7 KB | NOT IMPORTED |
|------------------------------------------------------------------------------------------------------------------|--------|--------------|

Cancel Previous **Next**

7. The system displays a Metadata Fields Mapping screen, ensuring that each column from the uploaded file is correctly mapped to the systems metadata fields.
8. Once the mapping is correctly set, click Next to proceed. If any errors are detected, click on the Previous button and go back to correct them.

9. Once confirmed, proceed by clicking Next to Import the data.



**Metadata Import** Step 2

Set Up metadata fields mapping

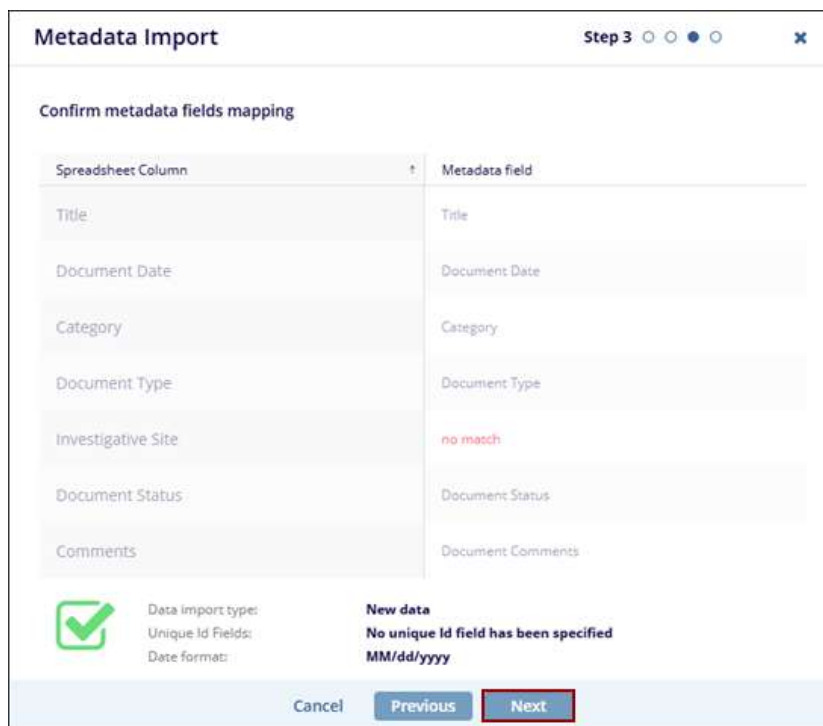
| Spreadsheet Column | Metadata field    |
|--------------------|-------------------|
| Title              | Title             |
| Document Date      | Document Date     |
| Category           | Category          |
| Document Type      | Document Type     |
| Investigative Site | no match          |
| Document Status    | Document Status   |
| Comments           | Document Comments |

Load file type:

- ☐ Bulk import with file content
- ☒ New data
- ☐ Incremental data
- ☐ Data overlay

Cancel Previous Next

10. Confirm whether the metadata field mapping is accurate and click on the Next button.



**Metadata Import** Step 3

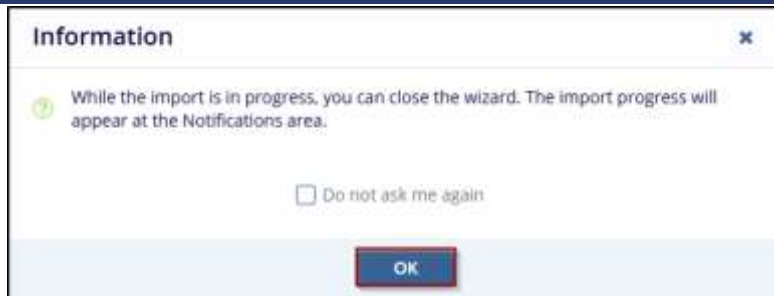
Confirm metadata fields mapping

| Spreadsheet Column | Metadata field    |
|--------------------|-------------------|
| Title              | Title             |
| Document Date      | Document Date     |
| Category           | Category          |
| Document Type      | Document Type     |
| Investigative Site | no match          |
| Document Status    | Document Status   |
| Comments           | Document Comments |


 Data import type: **New data**  
 Unique Id Fields: **No unique Id field has been specified**  
 Date format: **MM/dd/yyyy**

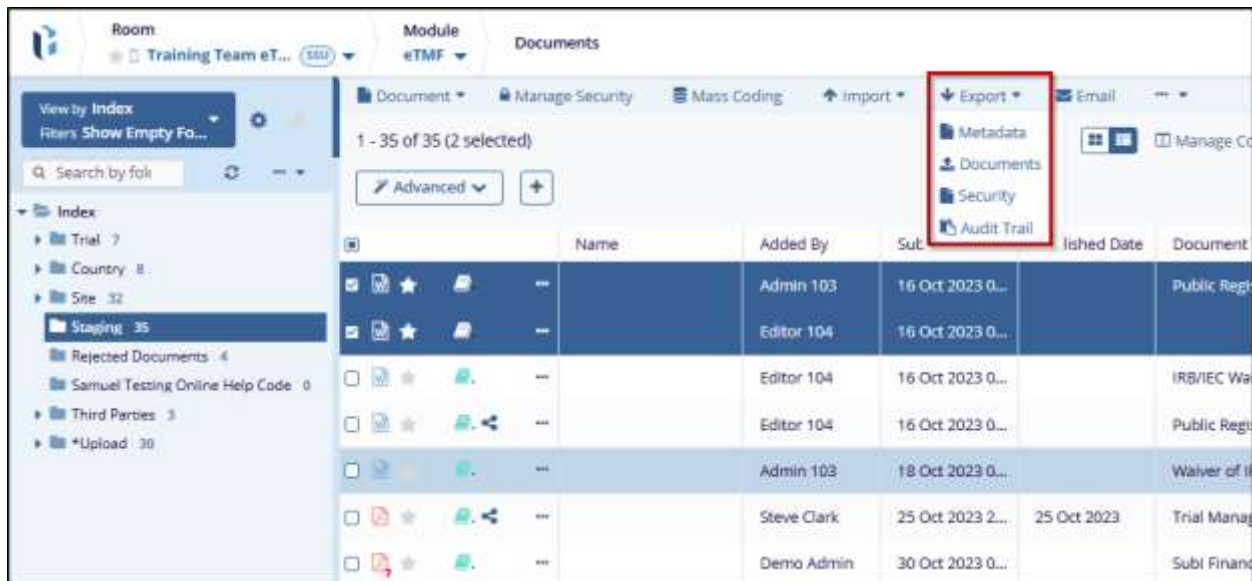
Cancel Previous Next

11. Click OK to view the results.



## Export

The Export function allows users to export either selected or all documents that are currently present in the grid. Like the Import function, this export can export documents, metadata, or both. Users with sufficient access will be able to export security and audit trial information.

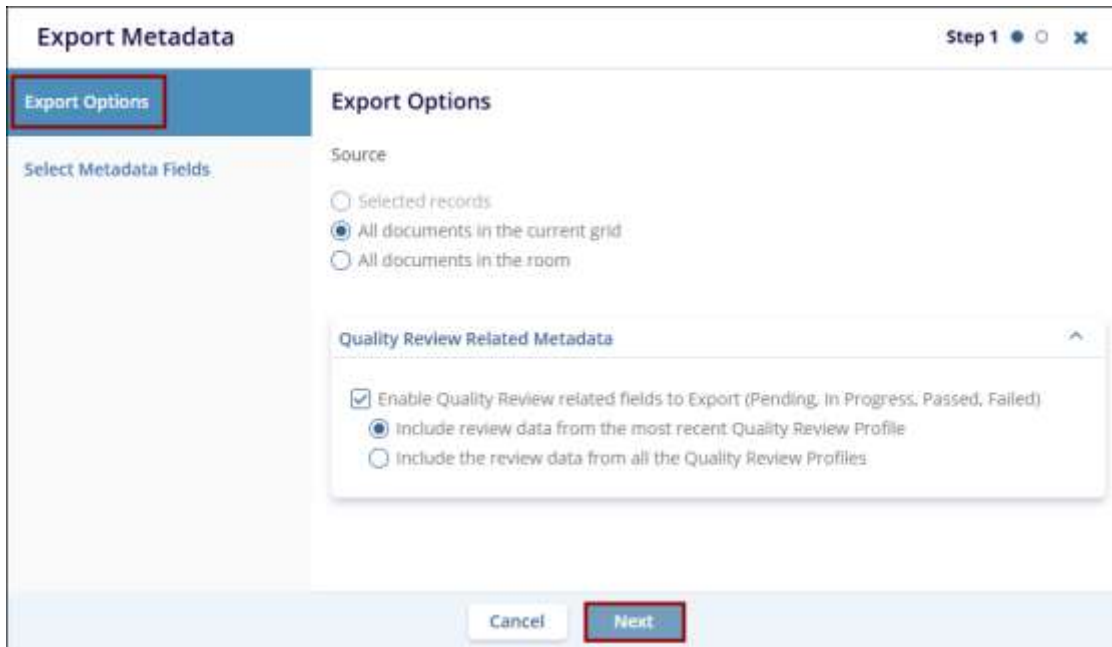


## Metadata

To export Metadata, follow the steps below.

1. Click on the Export button and select the Metadata option. The Export Metadata window opens.
2. In Step 1, Select any one option from the Source options.
  - Selected records
  - All documents in the current grid
  - All documents in the room
3. Choose whether or not the export should include Quality Review (audit) related Metadata. If yes, indicate whether all information should be provided or only the information from the most recent audit.

4. Click on the Next button.



**Export Metadata** Step 1

**Export Options**

Select Metadata Fields

Source

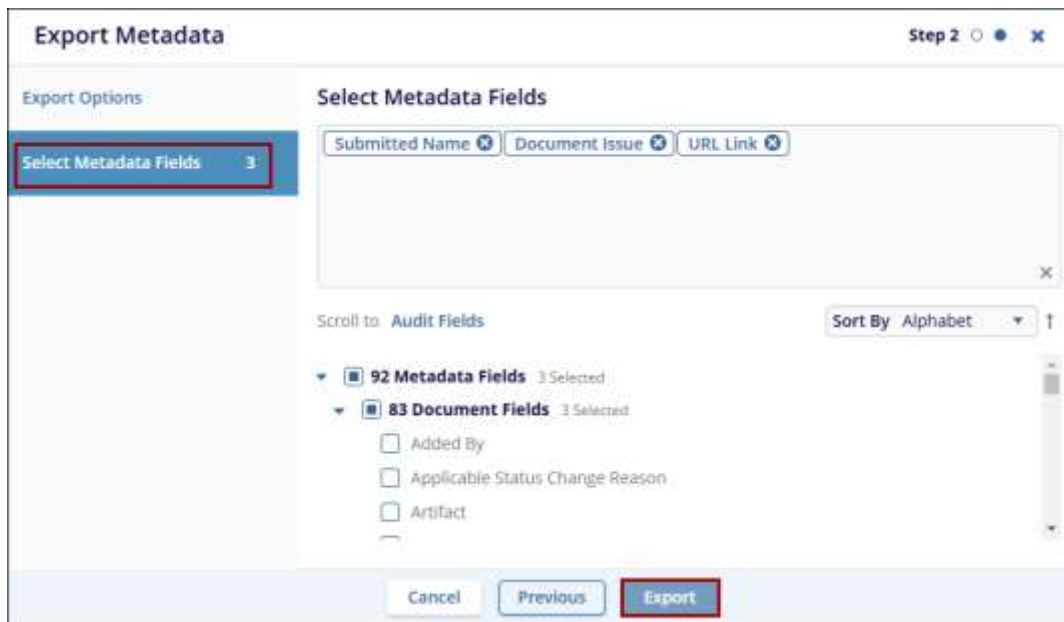
- ☐ Selected records
- ☒ All documents in the current grid
- ☐ All documents in the room

Quality Review Related Metadata

- ☒ Enable Quality Review related fields to Export (Pending, In Progress, Passed, Failed)
  - ☒ Include review data from the most recent Quality Review Profile
  - ☐ Include the review data from all the Quality Review Profiles

Cancel Next

5. In Step 2, select the required metadata fields and click on the Export button.



**Export Metadata** Step 2

Export Options

Select Metadata Fields 3

Submitted Name Document Issue URL Link

Scroll to: Audit Fields Sort By: Alphabet

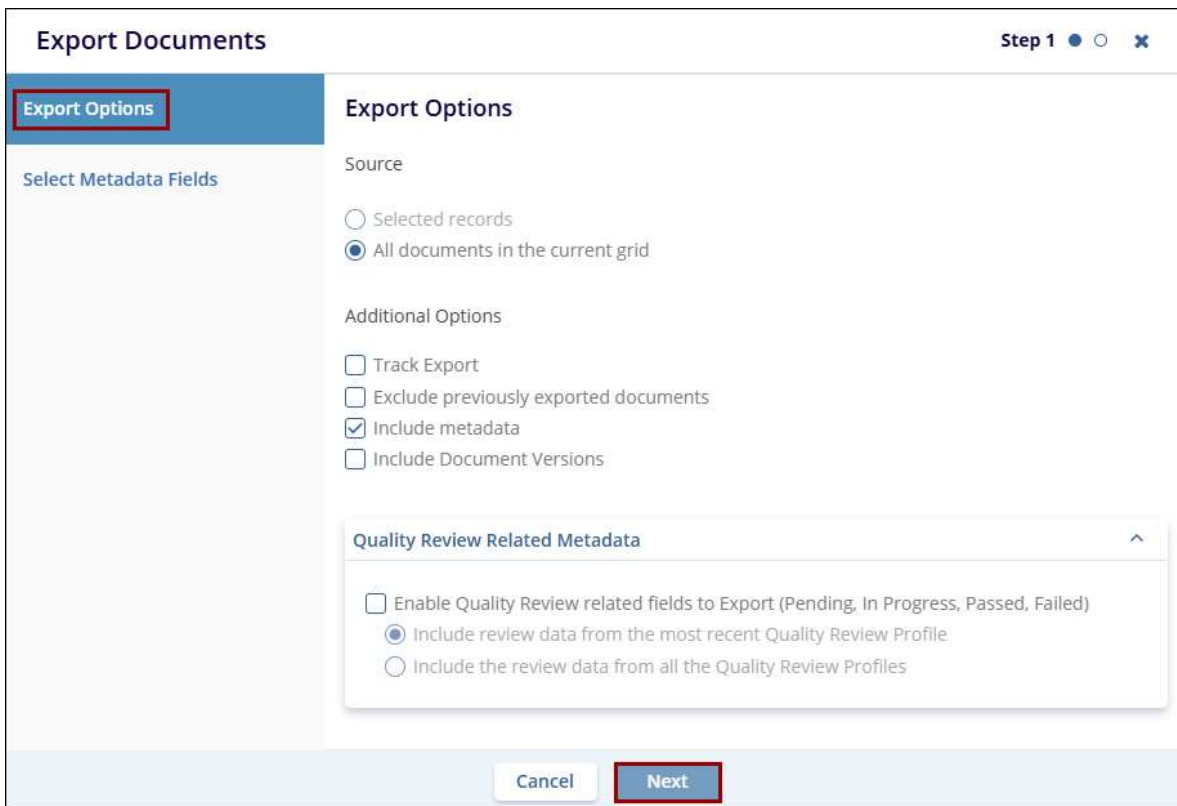
- 92 Metadata Fields 3 Selected
- 83 Document Fields 3 Selected
  - ☐ Added By
  - ☐ Applicable Status Change Reason
  - ☐ Artifact

Cancel Previous Export

## Documents

To export Documents, follow the steps below.

1. Click on the Export button and select the Documents option. The Export Documents window opens.
2. In Step 1, Select any one option from the Source options.
  - Selected records
  - All documents in the current grid
3. From the Additional Options section, select the required options. These options will vary depending upon user access rights.
  - Track Export
  - Exclude previously exported documents
  - Include Metadata
  - Include Document Versions
4. If the Include Metadata option is selected, choose whether or not the export should include Quality Review (audit) related Metadata.
  - If yes, indicate whether all information should be provided or only the information from the most recent audit.
5. Click on the Next button.



**Export Documents** Step 1

**Export Options**

Select Metadata Fields

Source

☐ Selected records

☒ All documents in the current grid

Additional Options

☐ Track Export

☐ Exclude previously exported documents

☒ Include metadata

☐ Include Document Versions

Quality Review Related Metadata

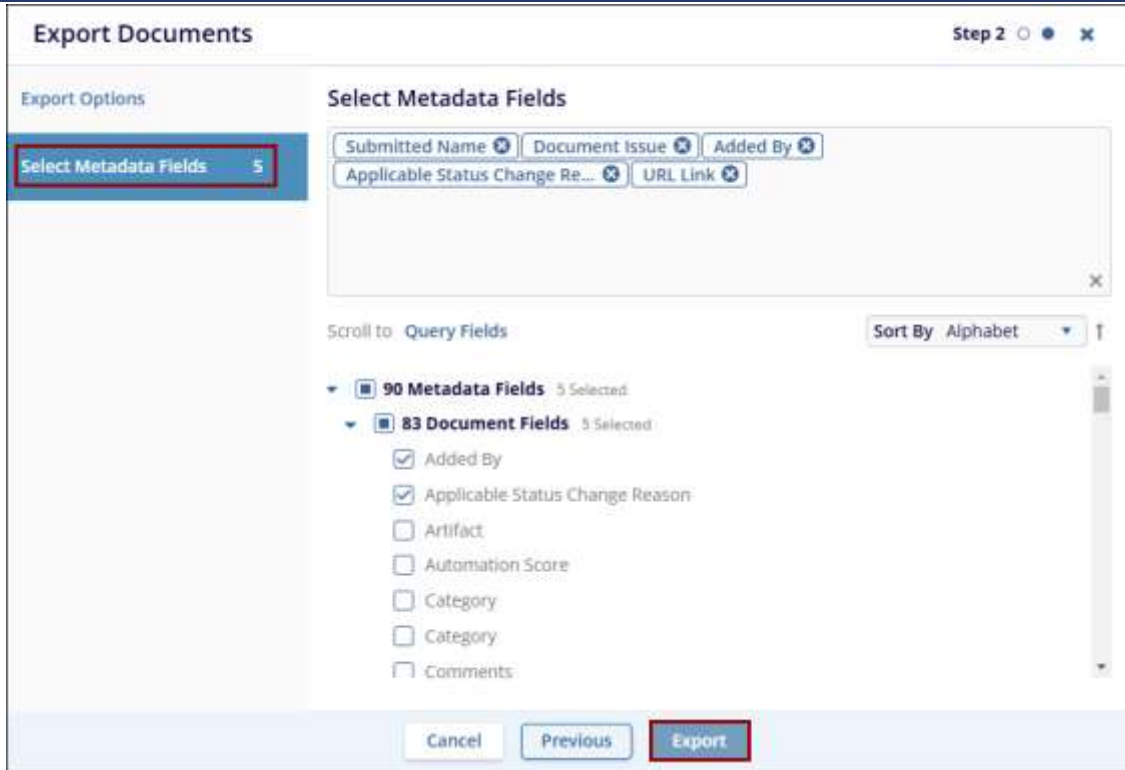
☐ Enable Quality Review related fields to Export (Pending, In Progress, Passed, Failed)

☒ Include review data from the most recent Quality Review Profile

☐ Include the review data from all the Quality Review Profiles

Cancel Next

6. In Step 2, select the required metadata fields and click on the Export button.



7. Click on the Get Job Results button to download the file.

## Security

To export Security Information, follow the steps below.

1. Click on the Export button and select the Security option. The Export Security window opens.
2. In Step 1, Select any one option from the Source options.
  - Selected records
  - All documents in the current grid
  - All documents in the room
  - All Folders
3. Click on the Next button.

Export Security

Step 1 ● ○ ✕

Export Options

Select Metadata Fields

Source

☐ Selected records
 ☒ All documents in the current grid
 ☐ All documents in the room
 ☐ All folders

Cancel

Next

- In Step 2, select the required metadata fields and click on the Export button.

Export Security

Step 2 ○ ● ✕

Export Options

Select Metadata Fields 14

Submitted Name ✕ Document Issue ✕ Full Access ✕ No Access ✕  
No Watermark ✕ Previous Full Access ✕ Previous No Access ✕  
Previous No Watermark ✕ Previous Redacted ✕ Previous View Only ✕  
Redacted ✕ Security Last Updated By ✕ Security Last Updated Date ✕  
View Only ✕

Scroll to Security Fields Query Fields

Sort By Alphabet ▾ ↑

101 Metadata Fields 14 Selected

82 Document Fields 2 Selected

☐ Added By
 ☐ Applicable Status Change Reason
 ☐ Artifact

Cancel

Previous

Export

- Click on the Get Job Results button to download the file.

## Audit Trials

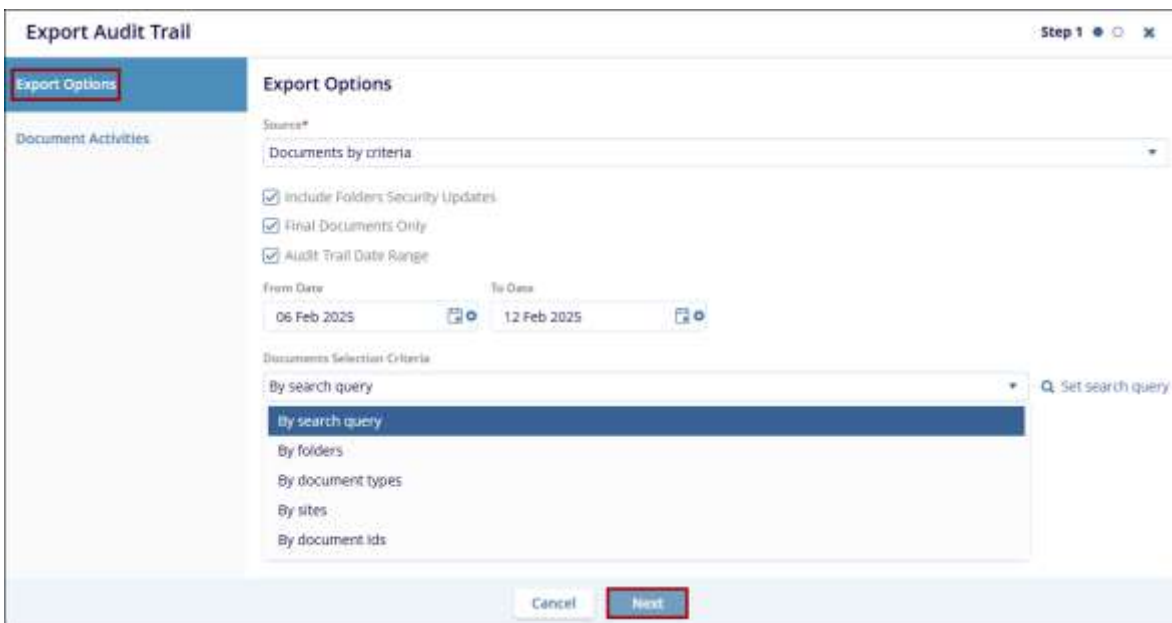
To export the audit trail, follow the steps below.

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CL: Public

Page 219 of 667

1. Click on the Export button and select the Security option. The Export Security window opens.
2. In Step 1, click on the Source\* dropdown and select the required option.
  - a. All documents in the current grid
  - b. Documents by criteria
  - c. Deleted documents
3. Select one or multiple options by clicking on the checkbox.
  - a. Include Folders Security Updates
  - b. Final Documents Only
  - c. Audit Trail Date Range
4. If Audit Trail Date Range is selected, specify the From Date and To Date.
5. If Documents by Criteria is selected, specify the Document Selection Criteria by accessing the dropdown options.
6. Click on the Next button.



7. In Step 2, review the document activities export options and click on the Export button.



Export Audit Trail

Step 2

Export Options

Document Activities

**Please review the document activities export options**

Export source: *documents by specific criteria*

Export criteria: *by documents search query: [not set]*

Export extras: *final documents only; activities by date range (from 06 Feb 2025 to 12 Feb 2025); include folders security updates*

Cancel

Previous

Export

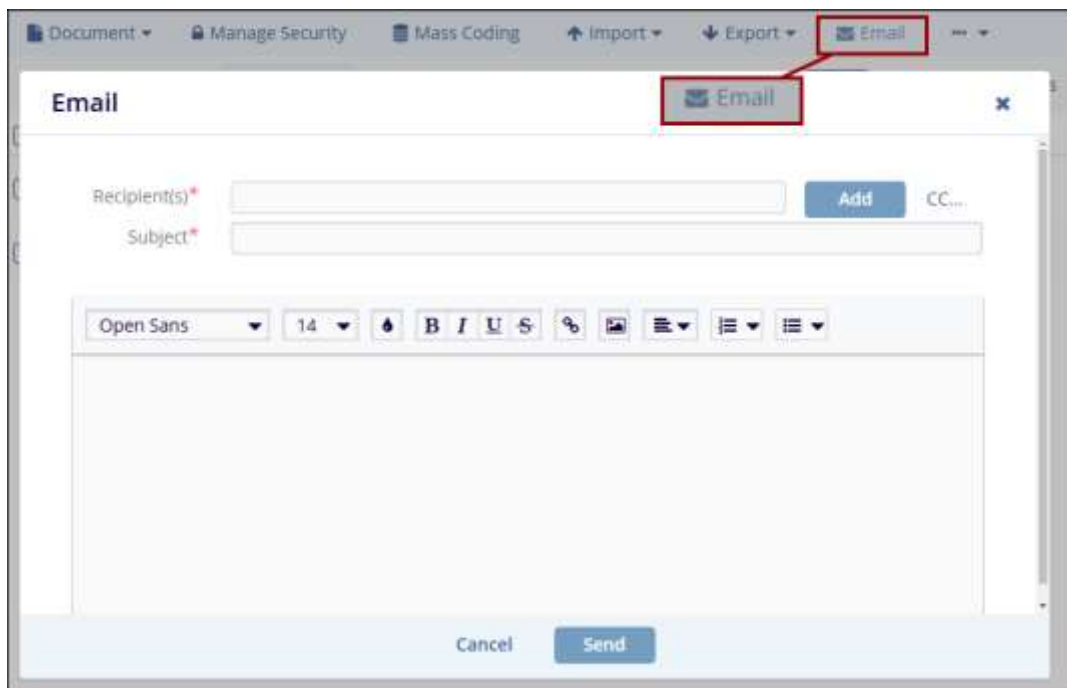
- Click on the Get Job Results button to download the file.

## Email

The email function allows users to send an email to another room user or contact which can be a document related email or other.

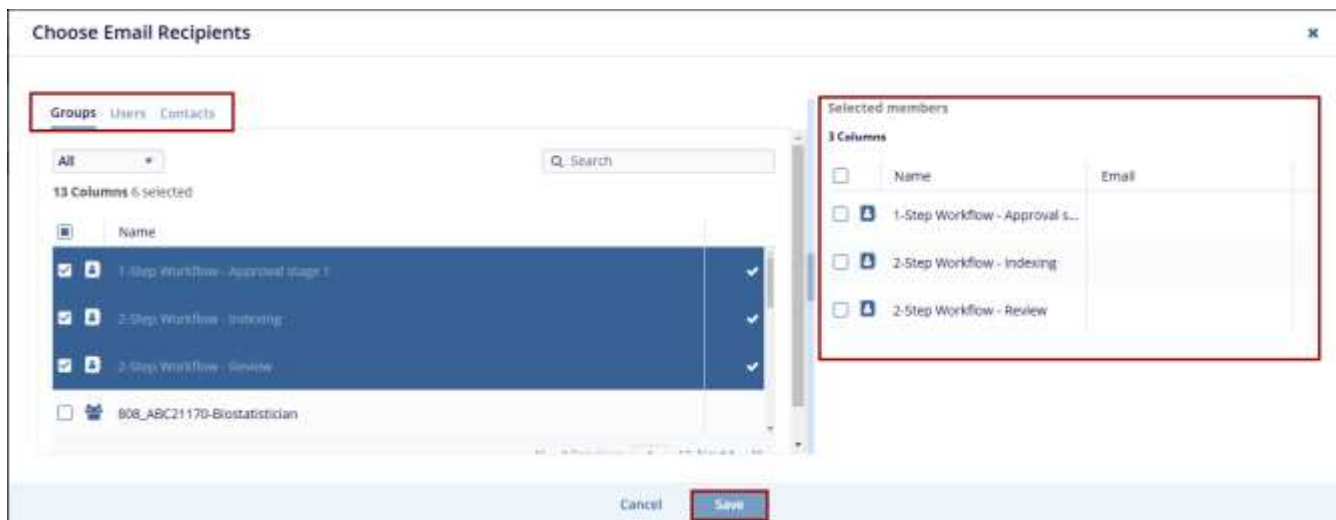
To send an email, follow the steps below.

- Select the documents by clicking on the checkboxes.
- Click on the Email button. This opens the Email window.



- Click on the Add button.

4. On the Choose Email Recipient screen, navigate to the Groups, Users and Contacts and tab and add them to the Selected members section.
5. Click on the Save button.



6. Additionally, click the CC button to specify the list of CC recipients.
7. Add the email subject and text.
8. Select the Files as Links radio button to share documents as links or select None if not required.
9. Click on the Send button.

Email

Recipient(s)\*

1-Step Workflow - Approval stage 1

2-Step Workflow - Indexing

2-Step Workflow - Review

Info

Add

CC...

Cc..

Specify the list of cc recipients here

Add

Subject\*

Email Documents

Open Sans

14

B

I

U

S

Email Documents

☒ Files as Links
☐ None

Cancel

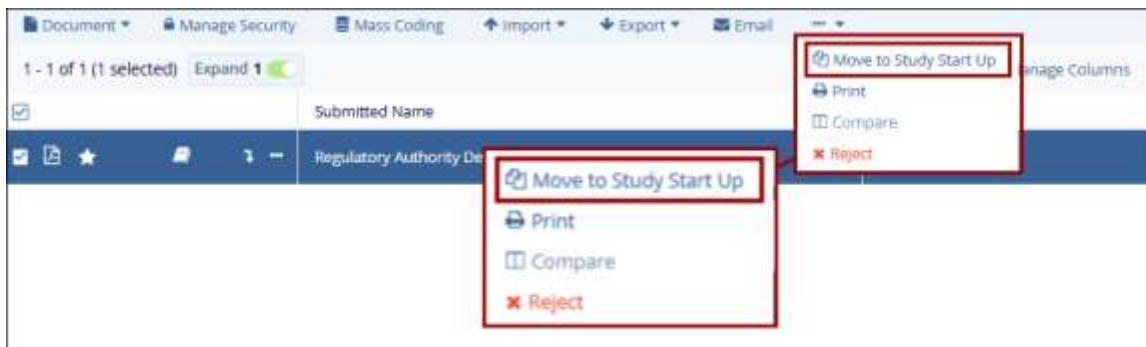
Send

## Move to Study Start-Up

This option is only available in rooms with Study Start-Up enabled.

To move documents to Study Start-Up, follow the steps below.

1. Check the documents checkbox to select the document.
2. Click on the three-dot menu and select the Move to Study Start-Up option.



3. Click on the Yes button on the confirmation popup.

**Confirmation Needed**
✕

Are you sure you want to move selected documents to Study Start Up?

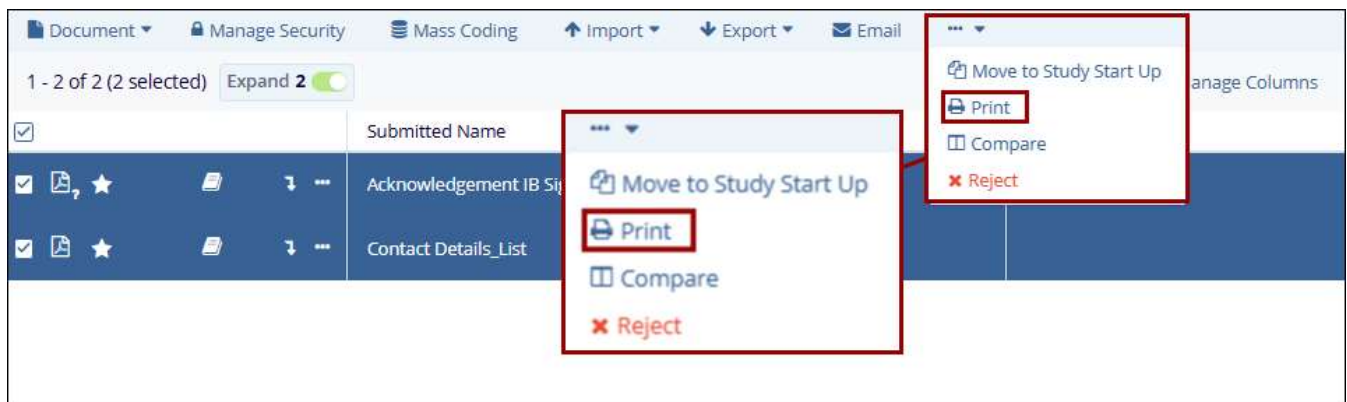
No
Yes

## Print

The Print function does not print the selected documents but merges them into a single PDF file which can then be downloaded or printed by the user.

To merge multiple documents into a single PDF file, follow the steps below.

1. Select multiple documents by clicking on their checkboxes.
2. Click on the three-dot menu and select the Print option



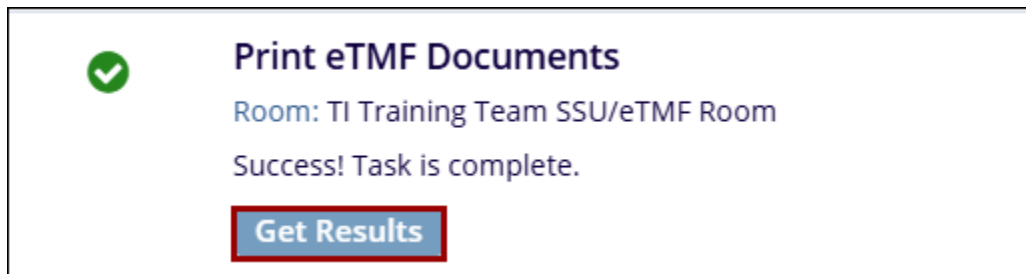
3. On the Print Documents popup select either Selected Records or All Records in Set radio button and click on the Print button.

**Print Documents**
✕

☒ Selected Records
 ☐ All Records in Set

Cancel
Print

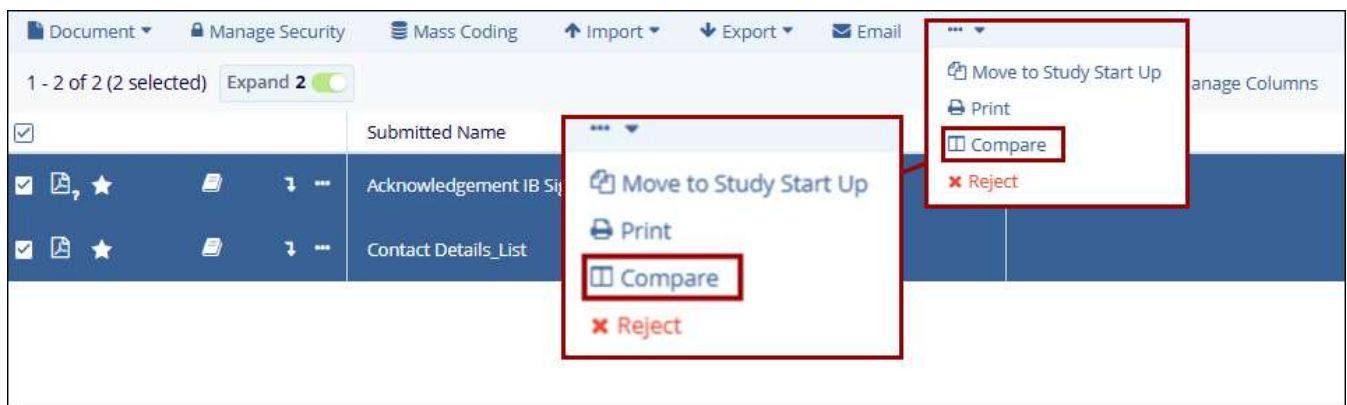
4. On the Print eTMF Documents success message popup, click on the Get Results button and a new tab will open displaying a single PDF file with pages merged from both the documents.



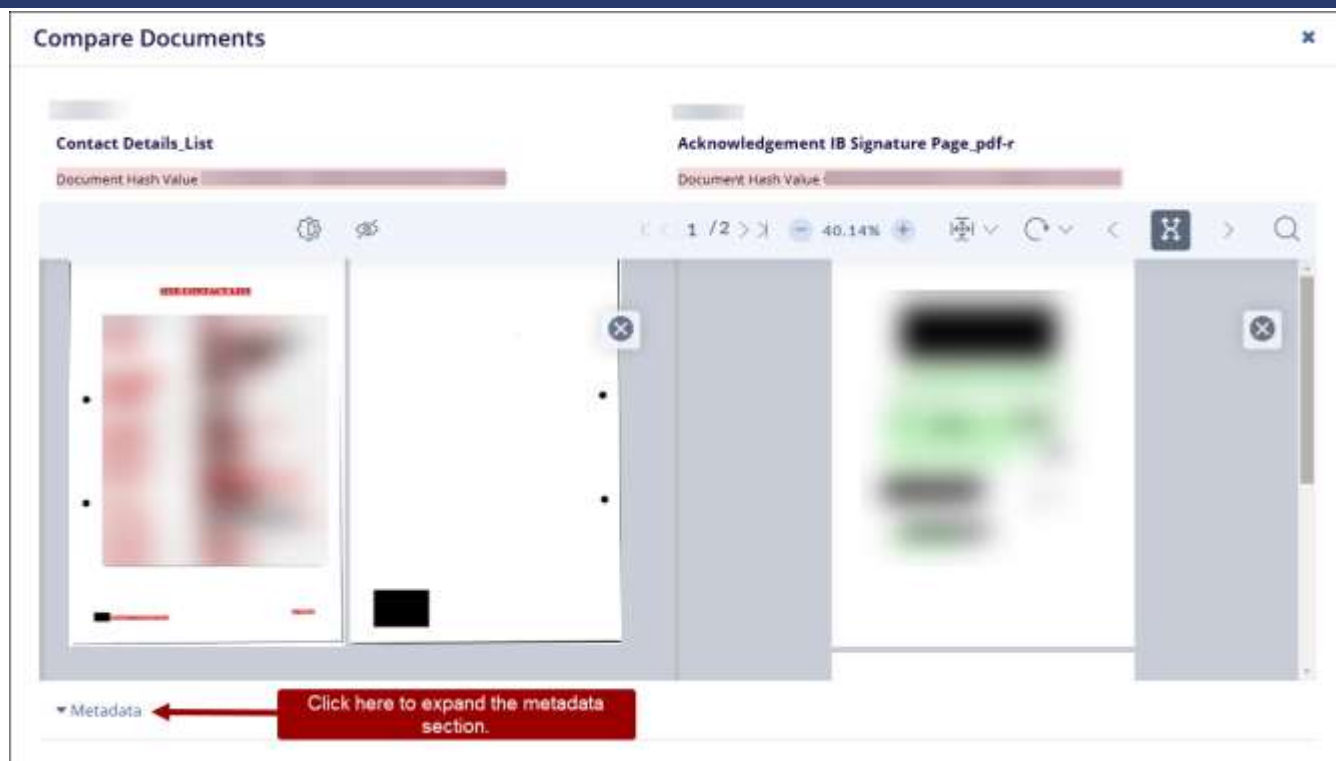
## Compare

To compare documents, follow the steps below.

1. Selecting two documents
2. Click on the three-dot menu and select the Compare option.



3. The selected documents will appear side-by-side in a pop-out window along with any associated metadata.
4. Expand the metadata section to view and edit the document metadata.



## Search

Above the documents grid, next to the documents cart, is a search bar. This is a local search and will search the currently selected index folder for relevant documents.



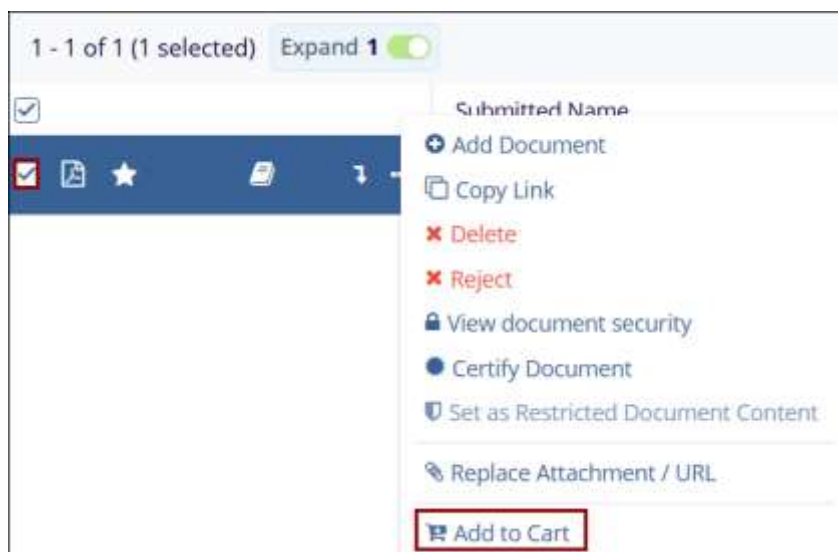
## Documents Cart

The functions available to a user in the document cart will depend on their access level. Users can add documents from various locations to the cart and perform actions such as Export, Mass Coding, Email, and others.

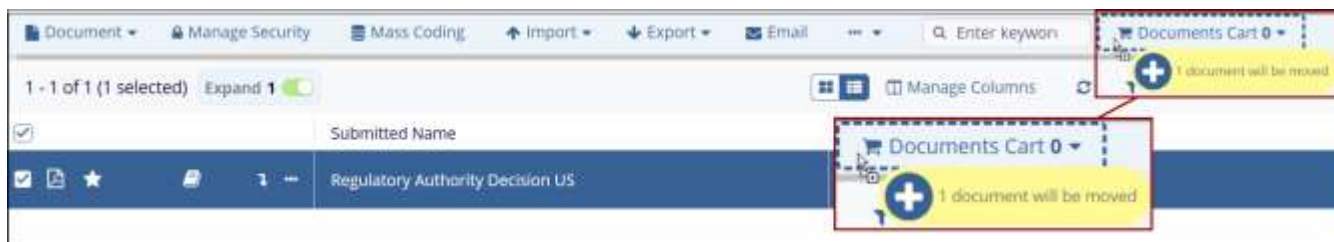
### Adding documents to the Documents Cart

To add documents to the cart, follow the steps below.

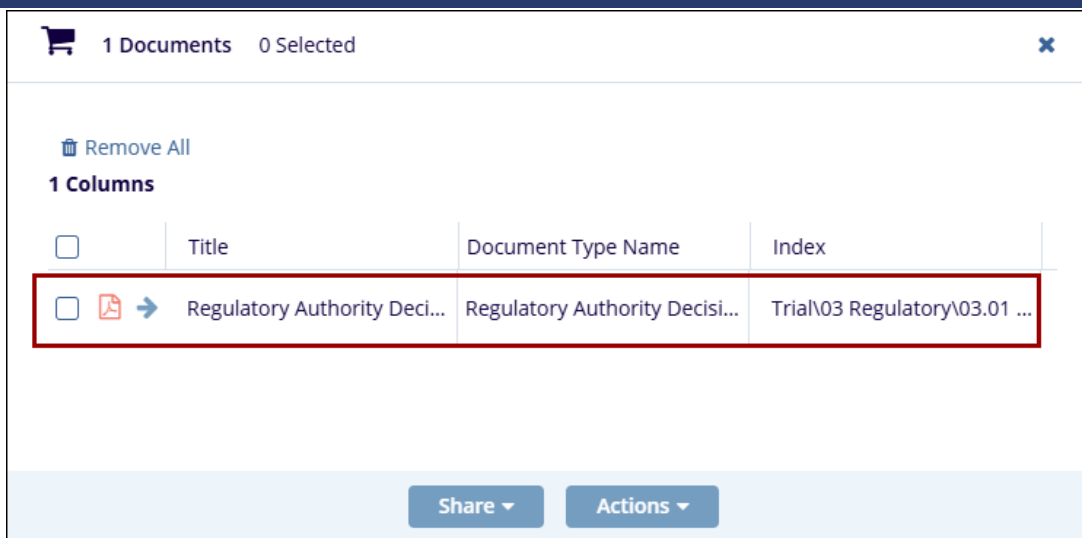
1. Locate the document which is to be added to the Document Cart and select the checkbox next to it.
2. Right-click and select the Add Selected to the Cart option.



3. Else, drag the document(s) to the documents cart.



4. Once a document is added, it will automatically update to reflect the number of documents available in the cart.

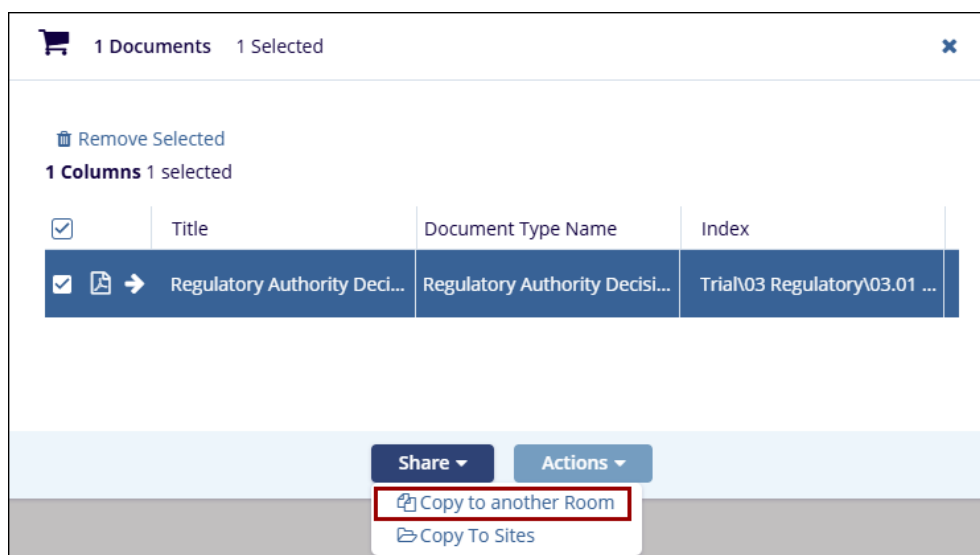


### Copy to another room

Trial Interactive allows Cross-Study Copy of Documents through this functionality. When users select the Copy to Other Rooms option from the Documents Cart, selected documents as well as their metadata will be copied to other rooms.

To copy documents to another room through the Documents Cart, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. Select the documents to copy to other rooms.
3. Click on the Share dropdown and select the Copy to other Room option.





4. On the Copy Documents screen, click on the Select button to add rooms.

Copy Documents

The following document will be copied to another room. Please select the room(s).

Rooms

Select

☐ Publish documents to index as final documents

[To see the detailed description on the copy documents behavior click here](#)

**1 Columns**

|                                                                                     | Title                          | Document Type Name             | Index                  |
|-------------------------------------------------------------------------------------|--------------------------------|--------------------------------|------------------------|
|  → | Regulatory Authority Decisi... | Regulatory Authority Decisi... | Trial\03 Regulatory\0: |

Cancel

Copy

5. On the Rooms screen, select the required rooms and click on the select button.

Rooms

Select Room

Choose Rooms where Selected Documents will be copied

☒ All Rooms

☐ Favorites

☐ Root
 

☐ Demo
 

☒

☐

☒

☐

☒

Cancel

Select

6. To publish documents to the index as final documents without going through the workflow, select the checkbox next to Publish documents to the index as final

documents.

7. Once the rooms are specified, click on the Copy button.

Copy Documents

The following document will be copied to another room. Please select the room(s).

Rooms

Internal TI10.5 eTMF-SSU Demo Room

TI Training Team Collaborate Room

Select

☒ Publish documents to index as final documents

[To see the detailed description on the copy documents behavior click here](#)

**1 Columns**

|                                                                                     | Title                          | Document Type Name             | Index                  |
|-------------------------------------------------------------------------------------|--------------------------------|--------------------------------|------------------------|
|  → | Regulatory Authority Decisi... | Regulatory Authority Decisi... | Trial\03 Regulatory\0: |

Cancel

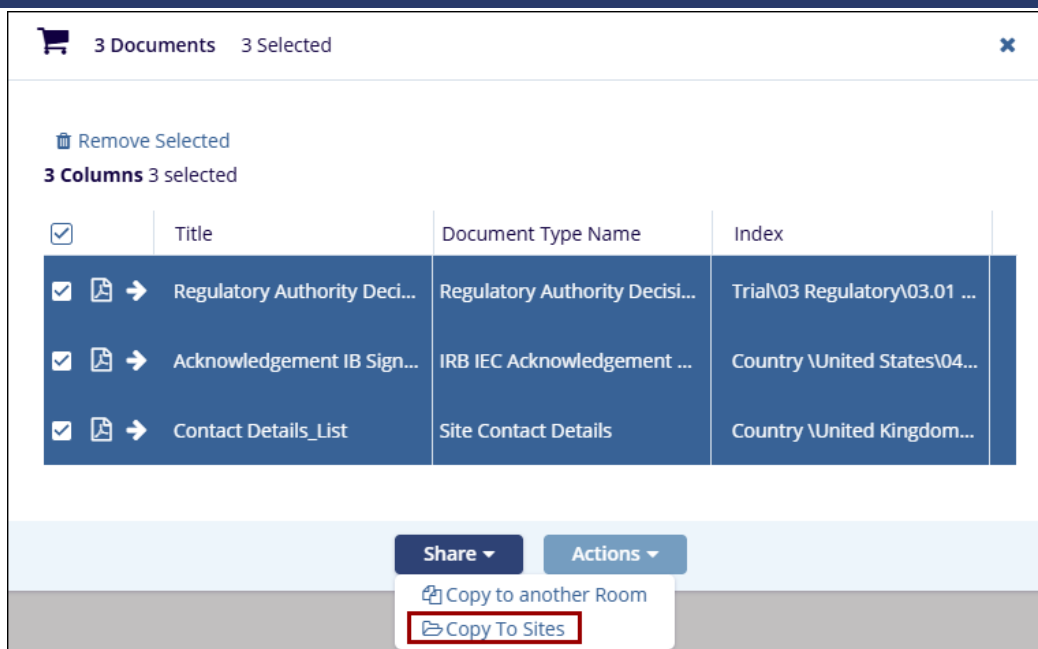
Copy

### Copy To Sites

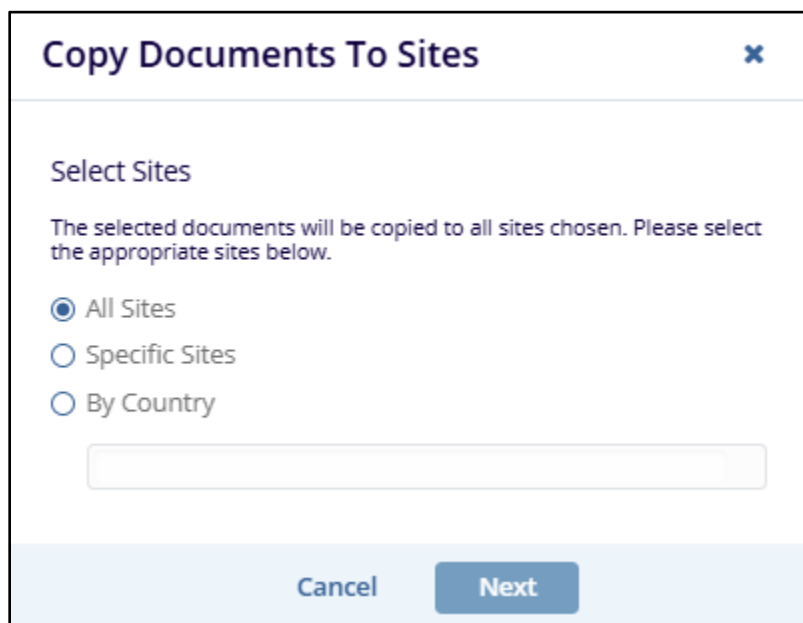
Administrators can access the documents cart to avoid copying documents such as training documents individually across different investigative sites.

To copy documents to sites, follow the steps below.

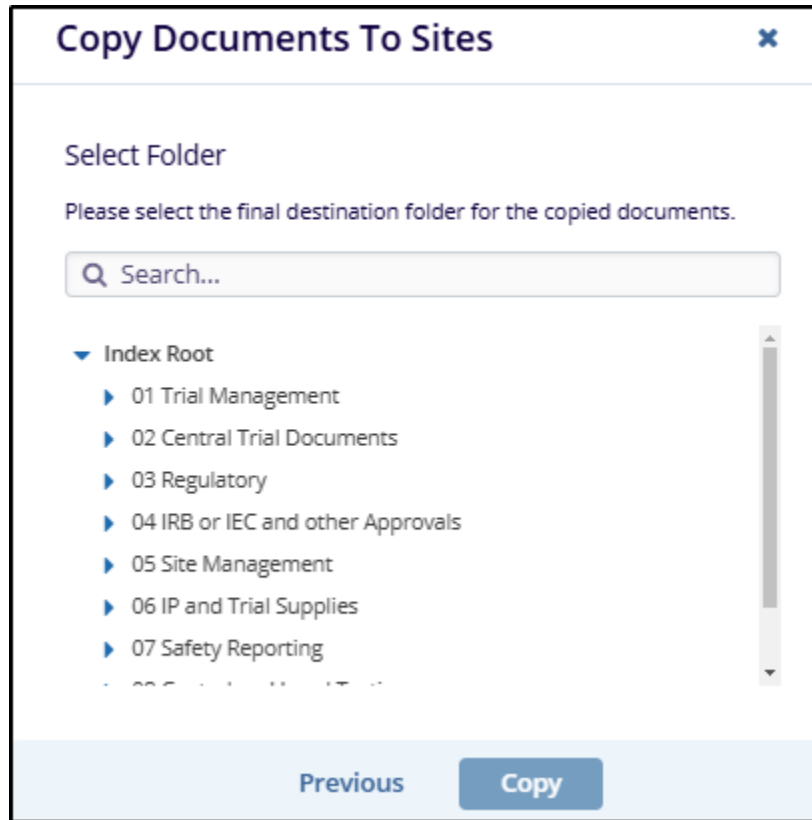
1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. Select the documents to copy other Investigative Sites.
3. Click on the Share dropdown and select Copy to Sites option.



4. On the Copy Documents to Sites window, select sites pertaining to specific criteria by clicking on the radio buttons.
  - a. Select the All Sites options, and click on the Next button to select the folder to which the documents will be copied.
  - b. Select the Specific Sites options, and click on the Next button to select the folder to which the documents will be copied.
  - c. Select the By Country option and select a country from the dropdown options.



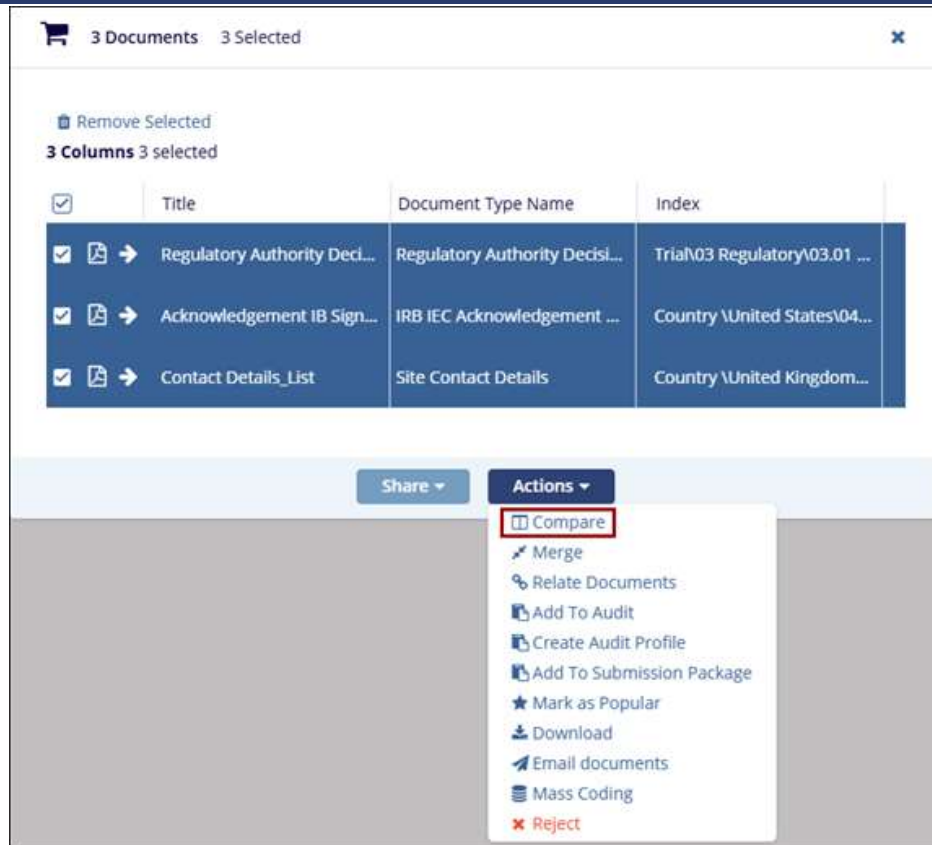
5. Click on the Next button once the criterion is selected
6. Select a folder and click on the Copy button. The documents are copied to the Investigative Site folder.



### Compare

To compare documents, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Compare option.

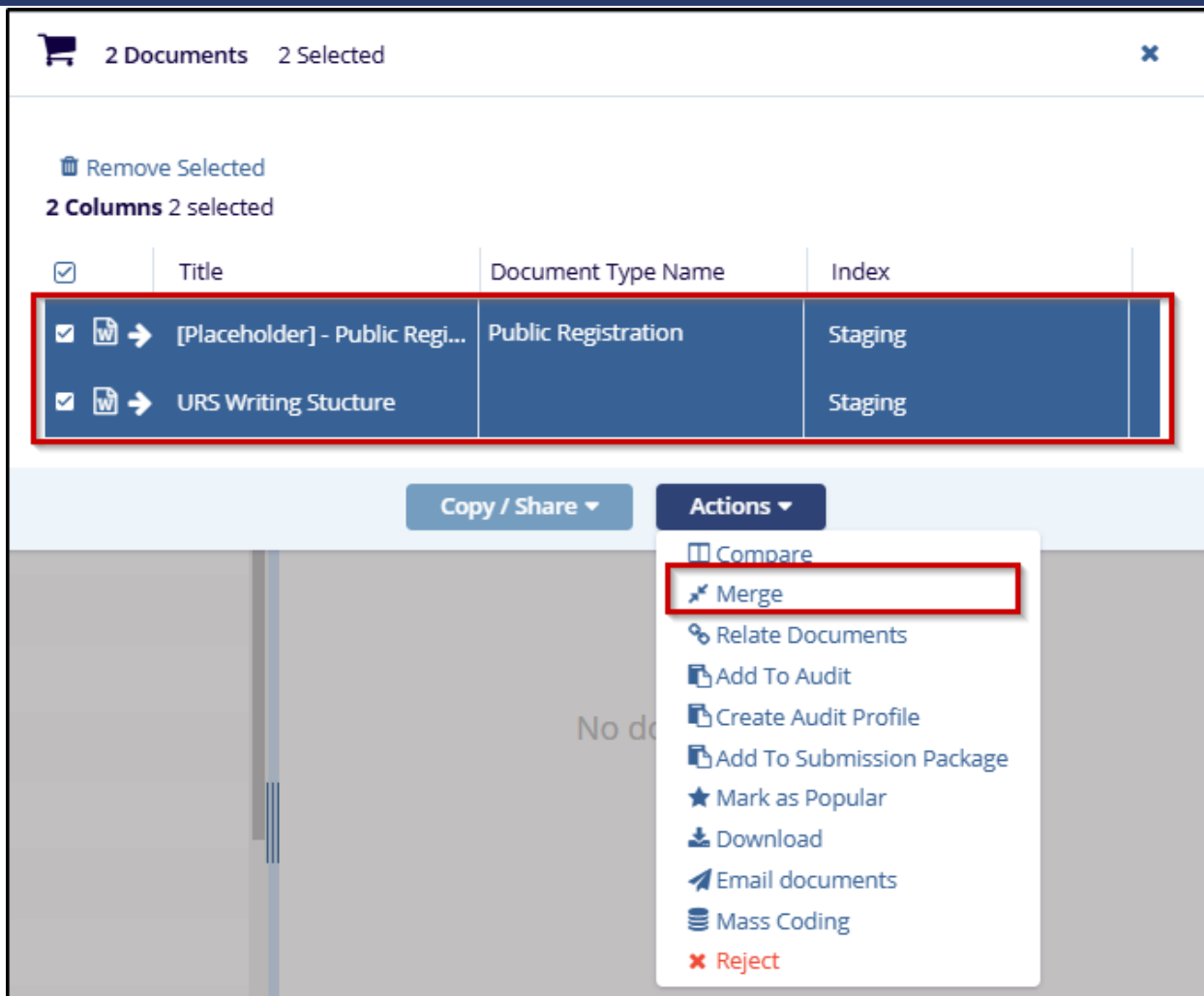


3. Refer to the Compare section for additional information.

#### *Merging documents*

Users with Administrator, Manager, and Editor access can merge two or more documents into one document.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Merge option.



2 Documents 2 Selected

Remove Selected

2 Columns 2 selected

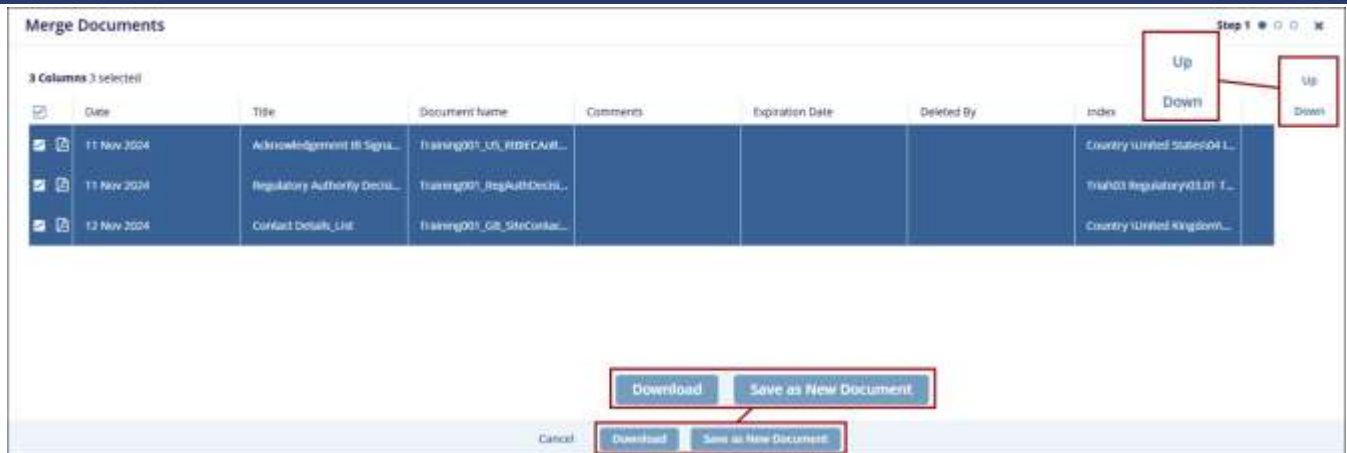
| <input checked="" type="checkbox"/> |                                                                                     | Title                          | Document Type Name  | Index   |
|-------------------------------------|-------------------------------------------------------------------------------------|--------------------------------|---------------------|---------|
| <input checked="" type="checkbox"/> |  → | [Placeholder] - Public Regi... | Public Registration | Staging |
| <input checked="" type="checkbox"/> |  → | URS Writing Stucture           |                     | Staging |

Copy / Share

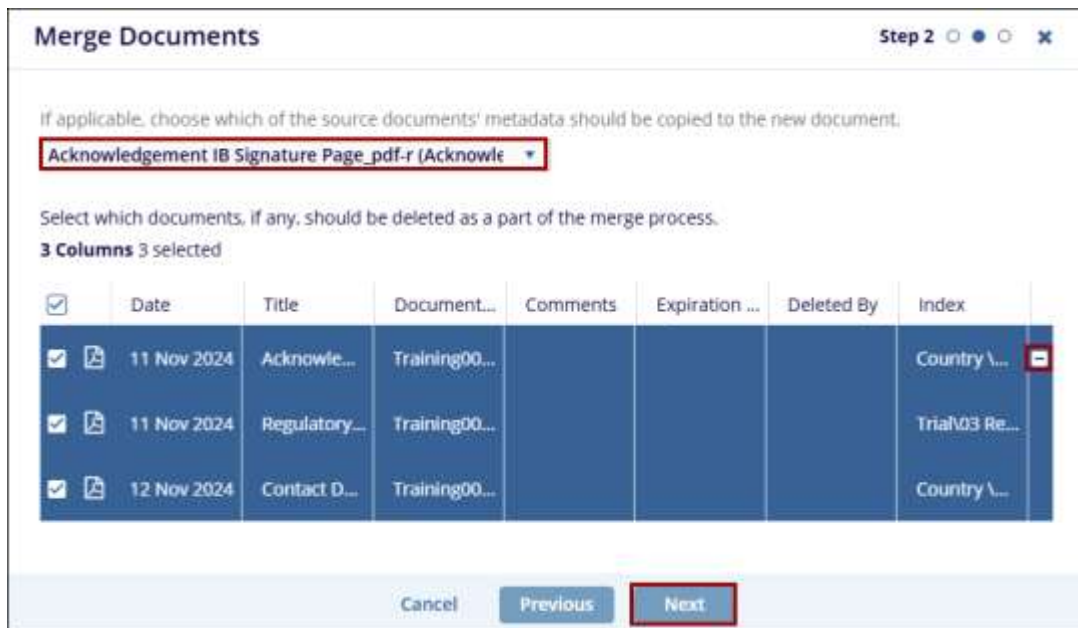
Actions

- Compare
- Merge
- Relate Documents
- Add To Audit
- Create Audit Profile
- Add To Submission Package
- Mark as Popular
- Download
- Email documents
- Mass Coding
- Reject

- On the Merge Documents screen, access the Up and Down buttons on the right side to rearrange the order of documents in the correct order of appearance in the final document.
- Click on either Download or Save as New Document.
  - Download: It will download the all documents merged as one PDF file.
  - Save as New Document: This will create the merged file as a new document in the study room.



- If Save as New Document is selected, access the dropdown and select a source document whose metadata should be copied to the new document.



- Click on the Next button.
- On the Merge Documents screen, confirm the metadata for the merged document and click on the Finish button.

Merge Documents
Step 3

Metadata

Document Metadata

Event

Category
Country

Country
United States

Document Type
IRB IEC Acknowledgement of Receipt of Sa

Submitted Name
Acknowledgement IB Signature Page\_pdf-r

Comments

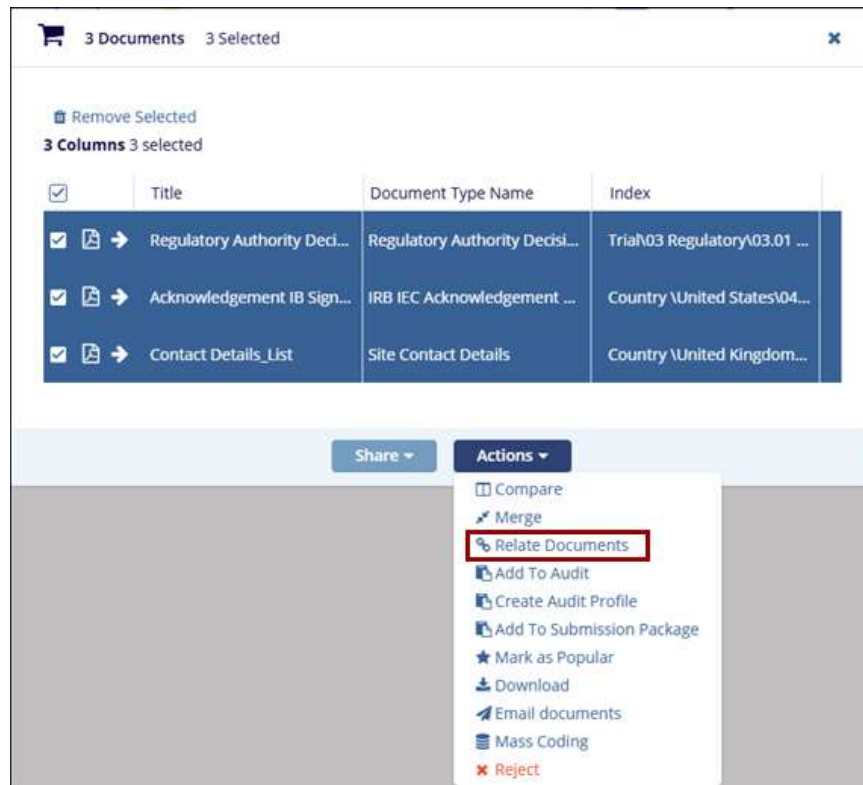
Documents merging progress - (100%)
Cancel
Finish



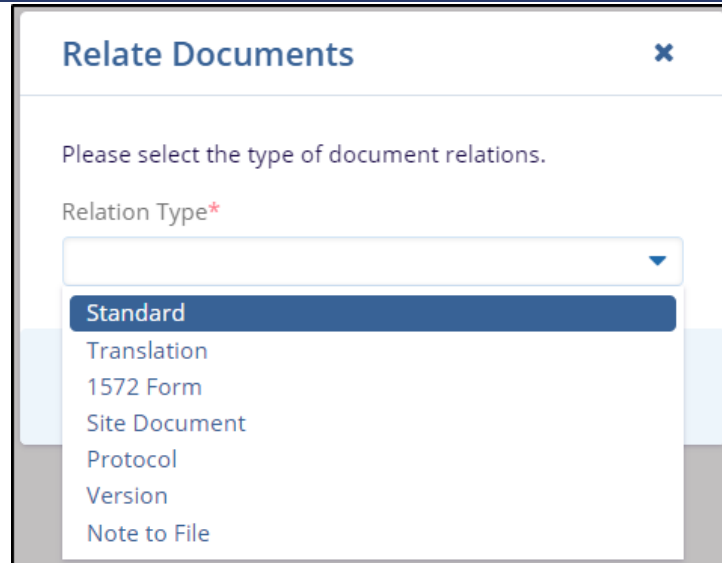
### Related documents

Users with Editor and Administrator access related the documents with this option.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Related Documents option.



3. On the Relate Documents window, select the appropriate option from the dropdown menu.



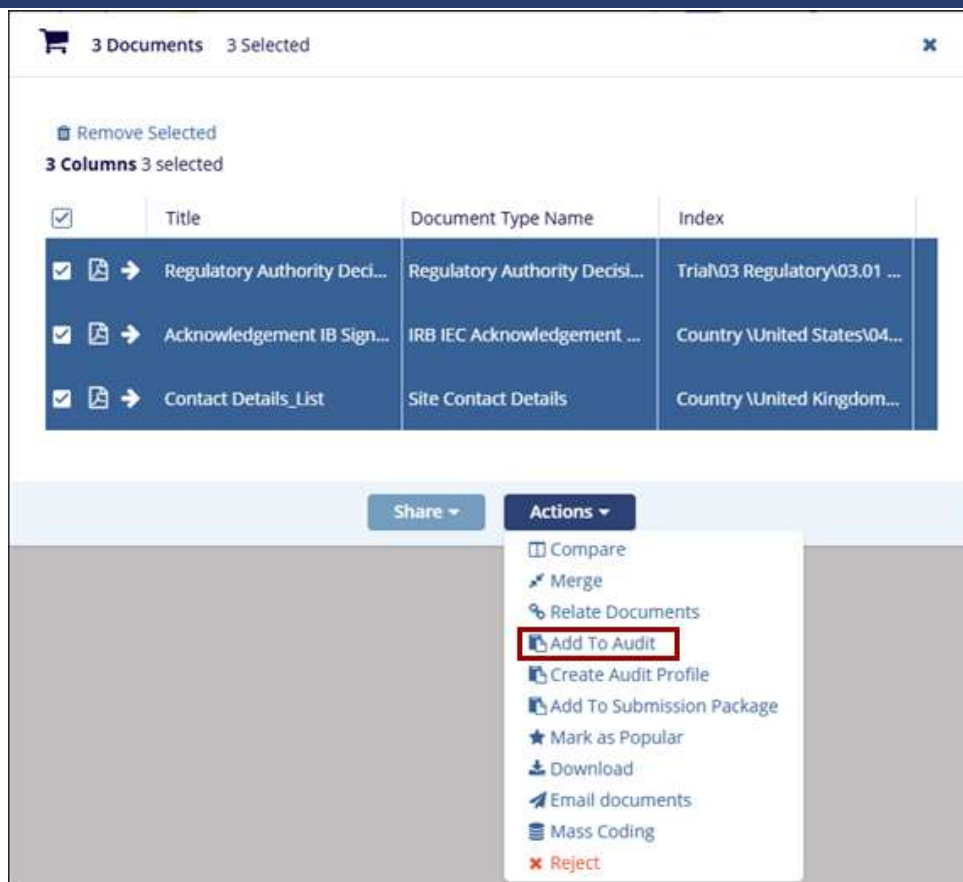
4. Click on the Save button to complete the related documents process. A notification Documents related is displayed in the top right corner of the screen.

#### *Adding documents to an Audit*

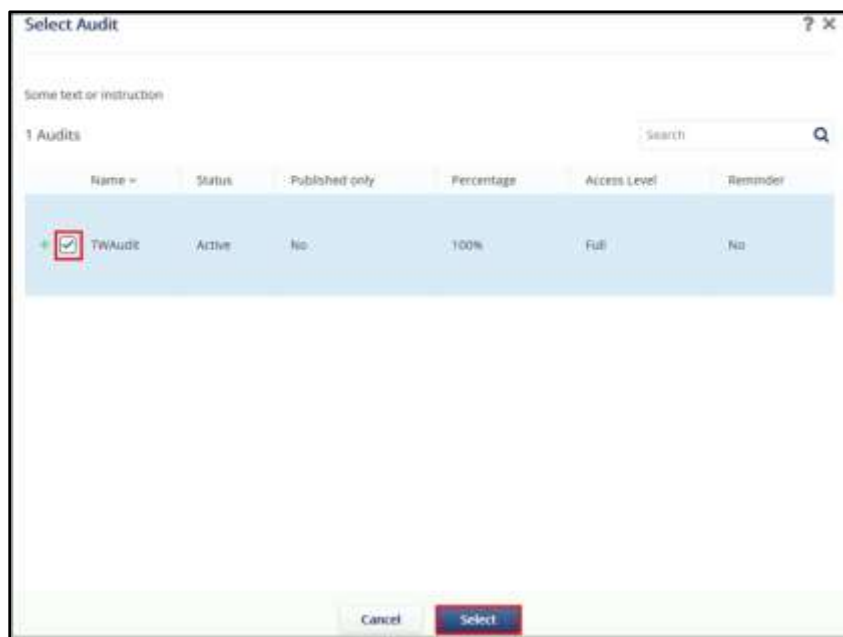
Administrator, Manager, and Editor users can add documents to the cart from the grid and include them in an existing audit by using the Add to Audit option.

To add documents to an audit, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Add To Audit option.



- On the Select Audit window, select the Audit to add documents to.
- Click on the Select button.



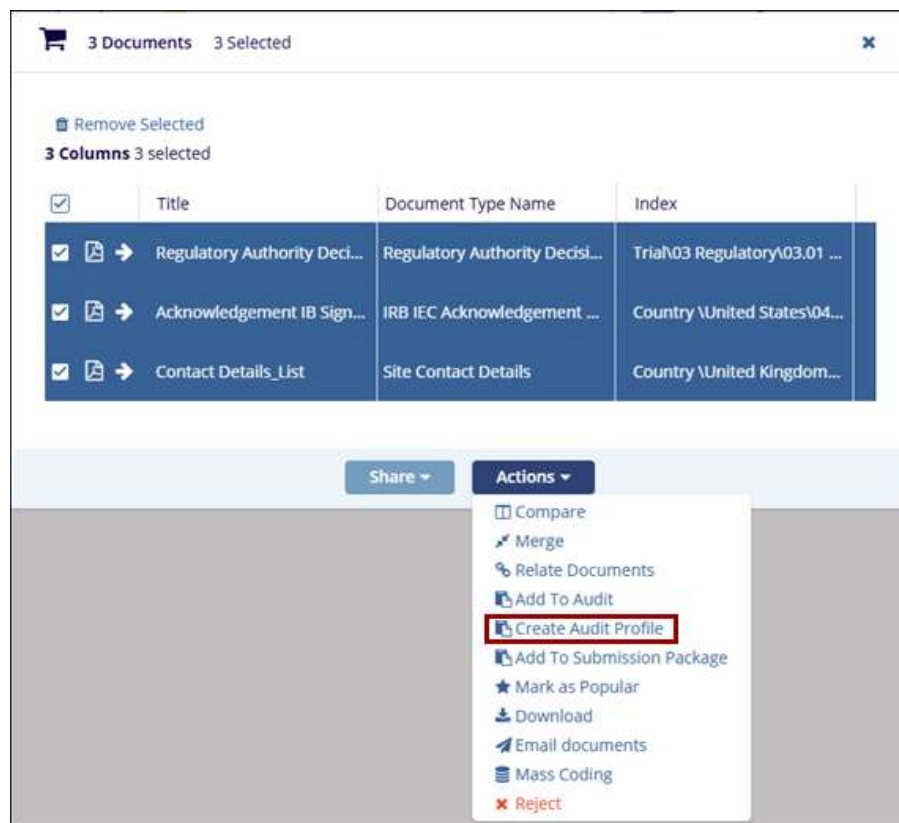
Note: The audits displayed are those that have been created in the Quality Review module specifically to have documents added to them in this manner. For additional information on creating the appropriate type of audit, refer the Quality Review module.

### [Create an Audit Profile](#)

Admins can add documents to the cart from the grid and create audit profiles using the Create Audit Profile option.

To create an audit profile, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Create Audit Profile option.



3. The Create Audit Profile popup opens.
4. On the Create Audit Profile form, create an audit by adding the necessary by following the instructions.

Note: Creating Audit Profiles is discussed under the Quality Review section in detail.

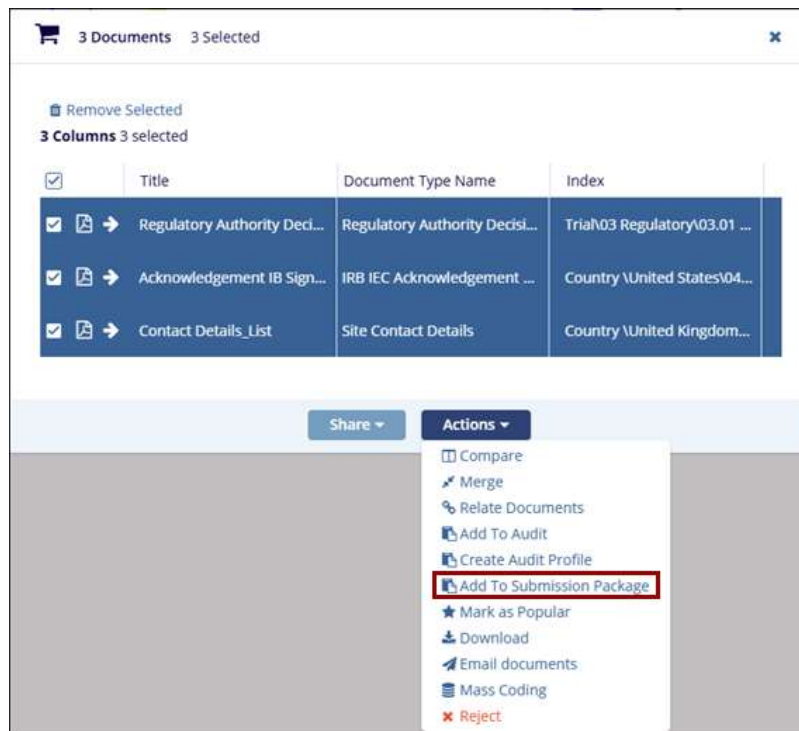
### *Adding Documents to a Submission Package*

Administrators, managers, and editors can add documents to the cart from the grid to include them in a start-up submission package by using this option.

Note: This option will only be available in rooms where Study Start-Up is enabled.

To add documents to the submission package, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Add to Submission Package option.



3. On the Select a Submission window, choose a submission package and click on the Select button.

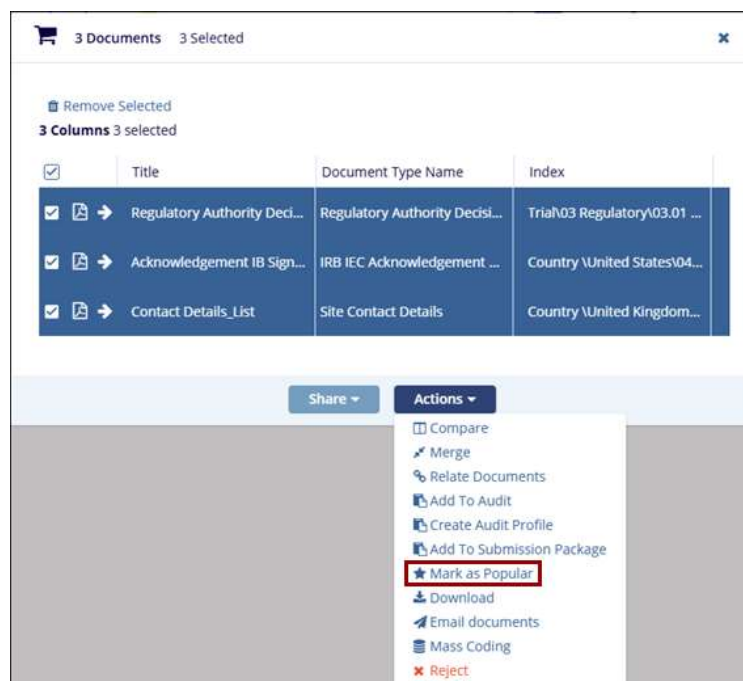


### Marking documents as Popular

Administrator, Manager, and Editor users can mark certain documents as popular using this option.

To mark documents as popular, follow the steps below.

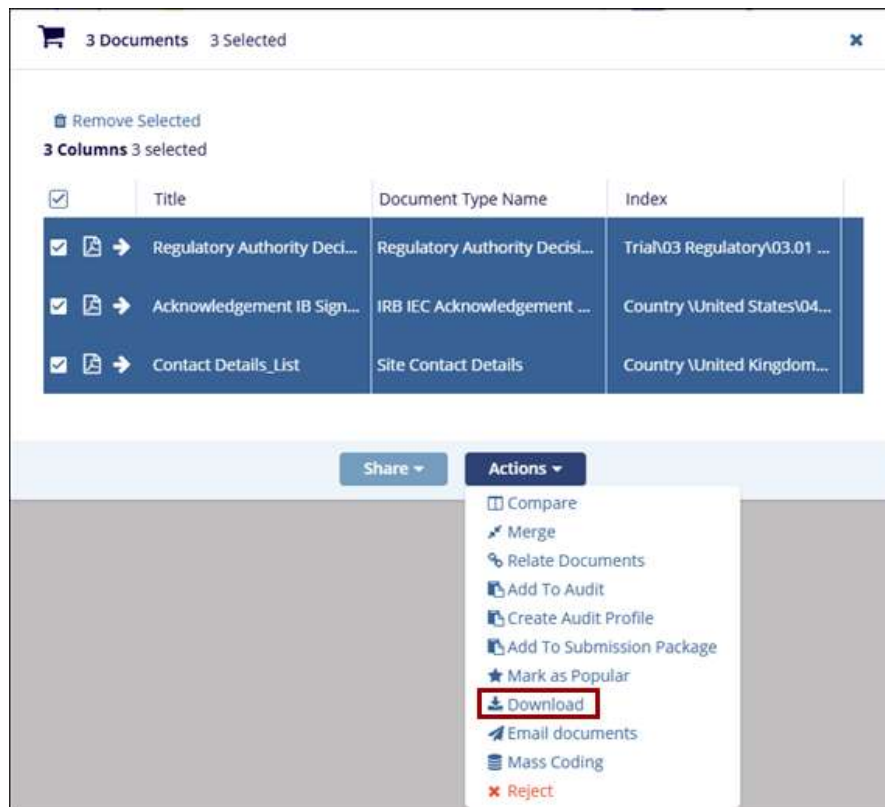
1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Mark as Popular option.



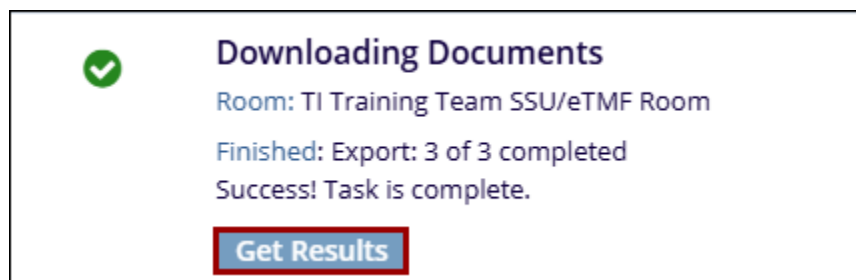
3. A success message appears stating the documents are successfully marked as popular.
4. The documents can be viewed on the Popular Documents dashlet.

#### Downloading documents

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Download option.



3. On the success message popup click on the Get Results button.

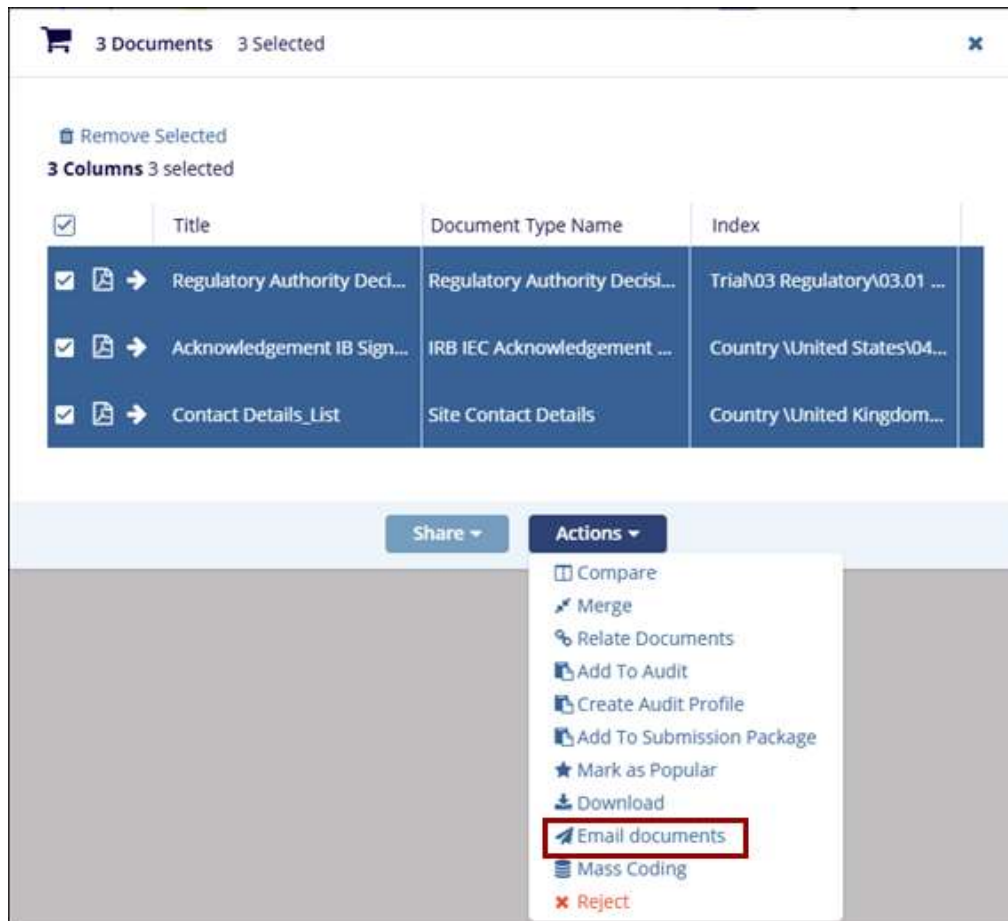


### Email

The email function allows users to send an email to another room user or contact. This could be a document-related email or not.

To send an email, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Email Documents option.



3. Refer to the Email section for the standard steps of sending an email to another user or a contact from another room.

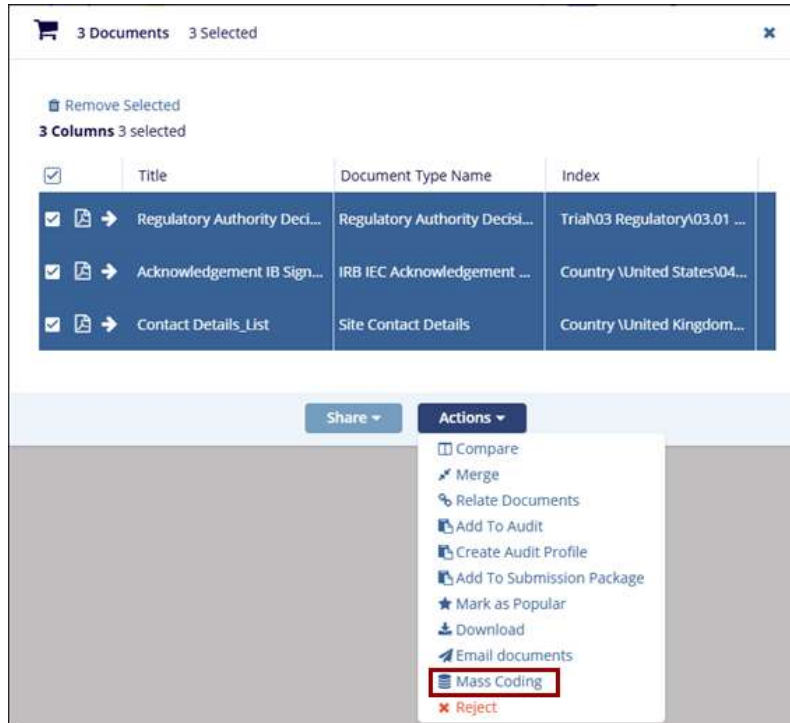
### Mass Coding

The Mass Coding function, allows the user to apply metadata to multiple documents at the same time. If the Causality Tracking feature is enabled in the room, then Mass Coding will be disabled.

To apply Mass Coding, follow the steps below.



1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Mass Coding option.

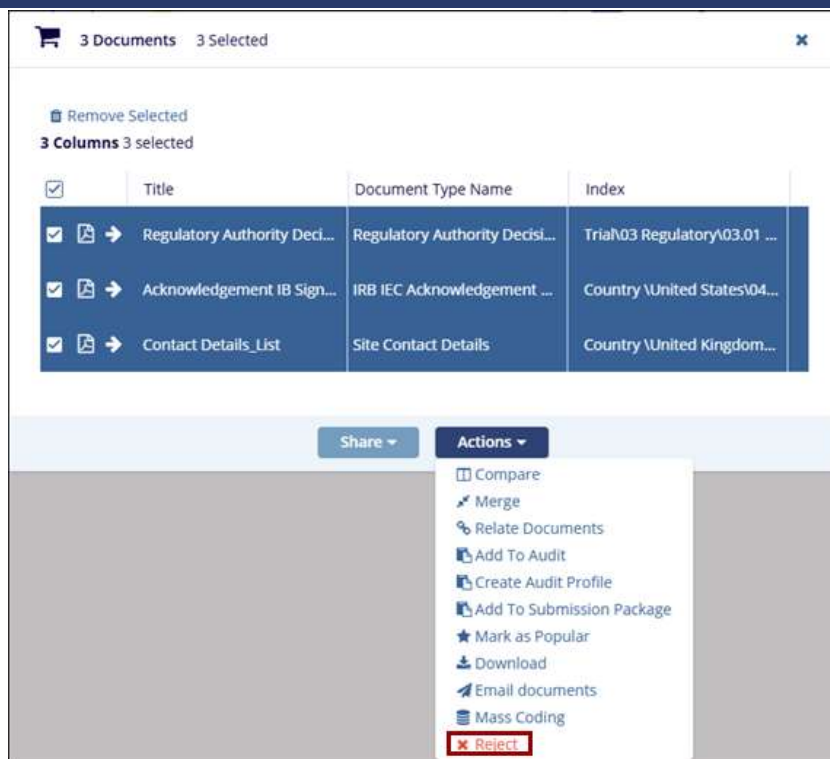


3. Refer to the standard steps of mass coding documents detailed in the Mass Coding section.

### Reject

To Reject a document through the documents cart, follow the steps below.

1. Add the required documents to the Documents Cart and click the arrow next to it to open the Documents Cart window.
2. On the Documents Cart window, click on the Actions dropdown and select the Reject option.



- On the Reject Document screen, add the rejection reason and click on the Reject button.

### Reject Document

1 document selected

Reason for Rejection\*

PI Change
Document Type Confirmation
Incorrect Protocol

Comments

Document Reject

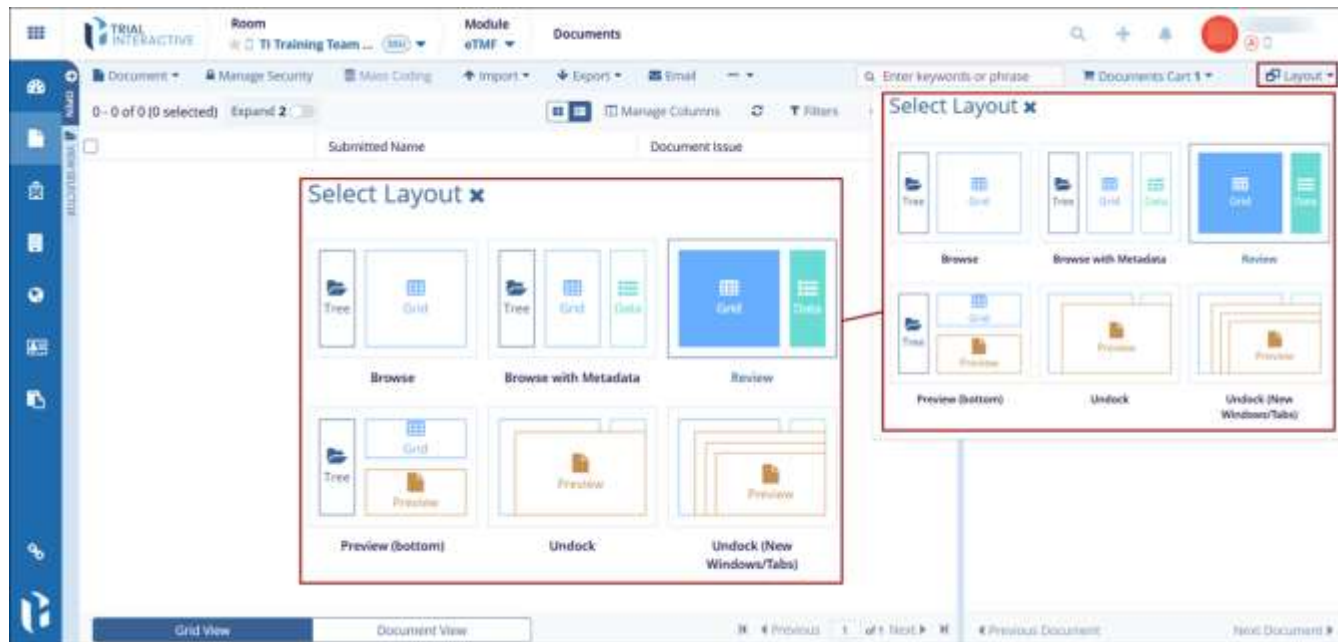
Cancel
Reject

## Layout

The layout menu, above the metadata pane, allows the user to choose from several page potential layouts.

- Browse

- Browse with Metadata
- Review
- Preview (bottom)
- Undock
- Undock (New Windows/Tabs)

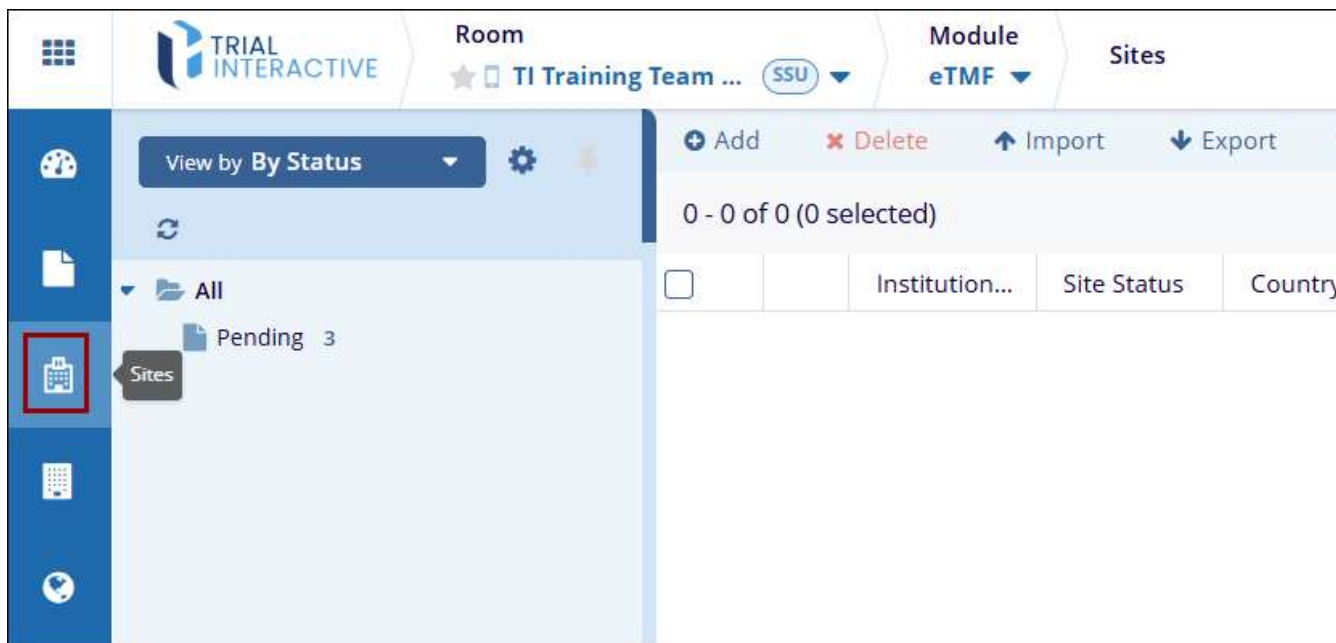


## Sites

This section provides detailed instructions on adding, deleting, importing, and exporting data, performing mass coding, managing security settings, and customizing columns. It also includes comprehensive guidance on General Information, Contacts, and Site Visits.

To access the Sites modal in eTMF, follow the steps below.

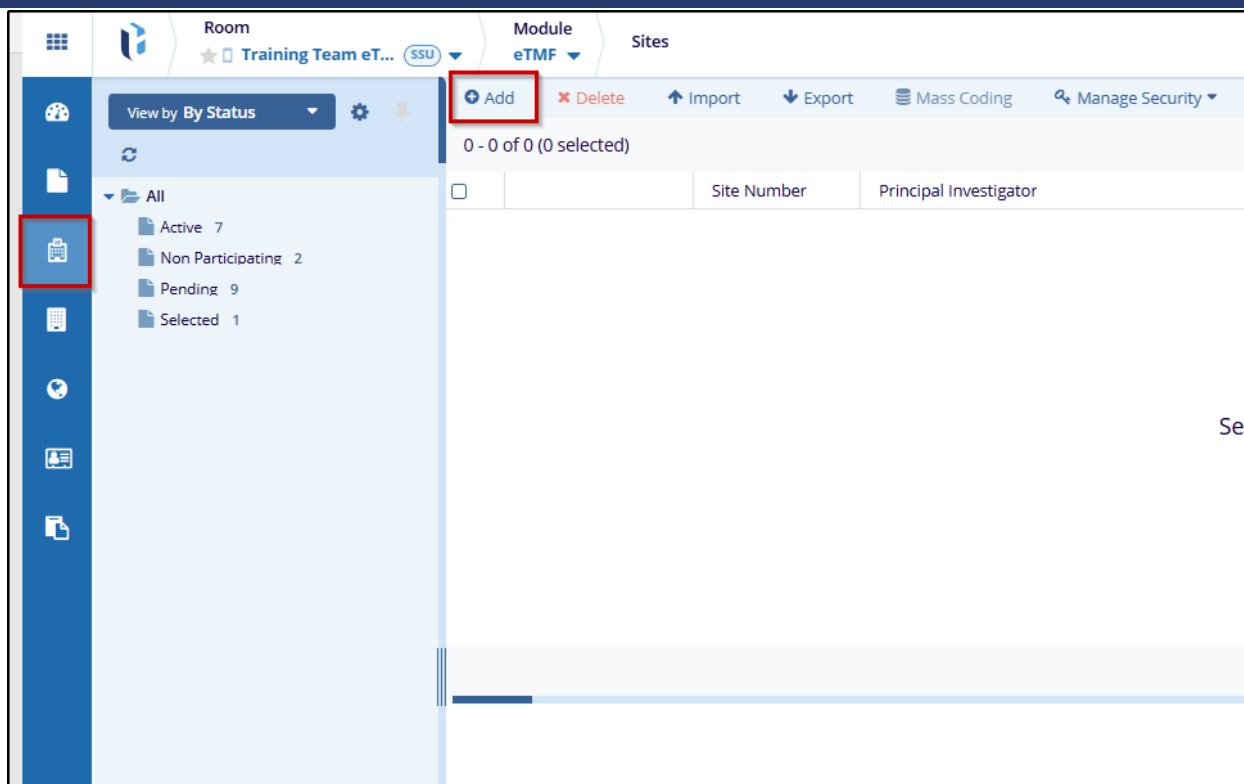
1. Select the eTMF module from the Module dropdown.
2. Click on the Sites modal from the left-hand navigation menu.



## Add Sites

To add new sites, follow the steps below.

1. Click on the Sites modal from the left-hand navigation pane within the eTMF module.
2. Click the +Add button to create a new site. This opens the New Site form.



3. In the General Info tab, expand the following sections and add the necessary information.

- Info: Add information to the following fields.
  1. Institution Name\*: Mandatorily add the institution name from available options.
  2. CRA: Select users from the dropdown options as CRAs
  3. Start-Up Specialist: Select users from the dropdown options as Start-Up Specialists.
  4. Site Number: Enter the site number.
  5. Site\*: Mandatorily enter the site name if Disable auto Site Name is disabled.
  6. Disable auto Site Name: Check the checkbox to manually add the site name or vice versa.
  7. Reason for not using the auto site name: Mandatorily provide a reason for not using the site if Disable auto Site Name is disabled.

New Site

General Info

Contacts

▲ Info

Institution Name \*

test site 001

...

CRA

Editor AP

×

...

Start-Up Specialist

Admin AP

×

...

Site Number

Site-001

Site \*

Site 1

☒ Disable auto Site name

Reason for not using auto Site name \*

Add Site Name

- Address: Add information to the following fields.
  1. Country: Select a country from the dropdown options.
  2. Website: Add a website
  3. Address: Add the address to the respective field
  4. City: Enter a city for the site
  5. State: Enter a state for the site
  6. Zip Code: Enter the ZIP Code for the site
  7. Phone: Enter phone number for the site
  8. Fax: Enter the fax number for the site
  9. Geo Code: Enter the geocode for the site.

General Info

Contacts

▲ Address

Country

United Kingdom

✕

Website

Address

City

State

Zip Code

Phone

Fax

Geo Code

- More: Add information to the following fields.

1. Expiration Date
2. Status
3. Site Email Domains
4. Preferred Communication Mode
5. Main IRB/EC Name
6. Reg Pack Sent Date
7. IRB/EC Submit Date
8. IRB/EC Approval Date
9. Site Activation Date
10. Reg Pack edelivery
11. eFeasibility Status
12. Effective Closure Date
13. Address Line 2
14. Address Line 3
15. Email
16. Other
17. Country Approval Date
18. Status Date
19. Organization Name

4. Once the necessary details are specified, click on the Add button.

New Site

General Info

Contacts

▲ More

Expiration Date

dd MMM yyyy

Status

Site Email Domains

Preferred Communication Mode

Main IRB/EC Name

Reg Pack Sent Date

dd MMM yyyy HH:mm:ss

IRB/EC Submit Date

dd MMM yyyy

IRB/EC Approval Date

dd MMM yyyy

Site Activation Date

dd MMM yyyy

☐ Reg Pack eDelivery

Cancel

Add

- On the Contacts tab, perform the following to configure the list of contacts within the site.

New Site

General Info

Contacts

+ Add

Edit

Delete

Deactivate

Convert to User

|                       | Last Name | First Name | Email | Contact Type |
|-----------------------|-----------|------------|-------|--------------|
| No records available. |           |            |       |              |

Cancel

Add



- Add Contacts: To add contacts, follow the steps below.
  1. On the Contacts tab, click on the +Add button.
  2. On the Add Contact form, add details to the mandatory metadata fields.
  3. Click on the Finish button.
  4. To add existing contact, switch to the Add Existing tab.

Add Contact

Create New

Add Existing

Email \*

dagabid625@jofuso.com

Prefix

First Name \*

Test User

Last Name \*

001

Suffix

Cancel

Finish

- Edit Contact: To edit a contact, follow the steps below.
  1. Select the contact within the contacts list.
  2. Click on the Edit button from the top menu bar.
  3. On the Edit Contacts screen, make the necessary changes.
  4. Once the details are modified, click on the Edit button at the bottom of the Edit Contacts screen.

Edit Contact

Email \*

dagabid625@jofuso.com

Prefix

First Name \*

Test User

Last Name \*

001

Suffix

Phone Number

Mobile Number

Contact Type \*

Clinical Research Associate

Cancel

Edit

- Delete Contact: To a contact, follow the steps below.
  1. Select the contact within the contacts list.
  2. Click on the Edit button from the top menu bar.

New Site

General Info

Contacts

+ Add

Edit

Delete

Deactivate

Convert to User

|                                     | Last Name | First Name | Email             | Contact Type  |
|-------------------------------------|-----------|------------|-------------------|---------------|
| <input checked="" type="checkbox"/> | 001       | Test User  | dagabid625@jof... | Clinical R... |

- De-activate Contact: To deactivate a contact, follow the steps below.
  1. Select the contact within the contacts list.
  2. Click on the De-activate button from the top menu bar.

### New Site

General Info
**Contacts**

+ Add
Edit
Delete
**Deactivate**
Convert to User

| <input checked="" type="checkbox"/> | Last Name | First Name | Email             | Contact Type  |
|-------------------------------------|-----------|------------|-------------------|---------------|
| <input checked="" type="checkbox"/> | 001       | Test User  | dagabid625@jof... | Clinical R... |

- **Activate Contact:** To activate the contact, follow the steps below.
  1. Select the contact within the contacts list.
  2. To activate, the contact, click on the Activate button from the top menu bar.

### New Site

General Info
**Contacts**

+ Add
Edit
Delete
**Activate**
Convert to User

| <input checked="" type="checkbox"/> | Last Name | First Name | Email             | Contact Type  |
|-------------------------------------|-----------|------------|-------------------|---------------|
| <input checked="" type="checkbox"/> | 001       | Test User  | dagabid625@jof... | Clinical R... |

- **Convert to User:** To convert a contact into a user, follow the steps below.
  1. Select the contact within the contacts list.
  2. Click on the Convert to User button from the top menu bar.
  3. On the Convert Select Site Contacts screen, provide a role and the actions to the user and click on the Convert Contact to Room User button.

### Convert Selected Site Contact(S) To User(S) ✕

Role \*  

Editor ▾

Actions  

Study Startup ✕
eSignature ✕
Page Manipulations ✕
✕

Cancel

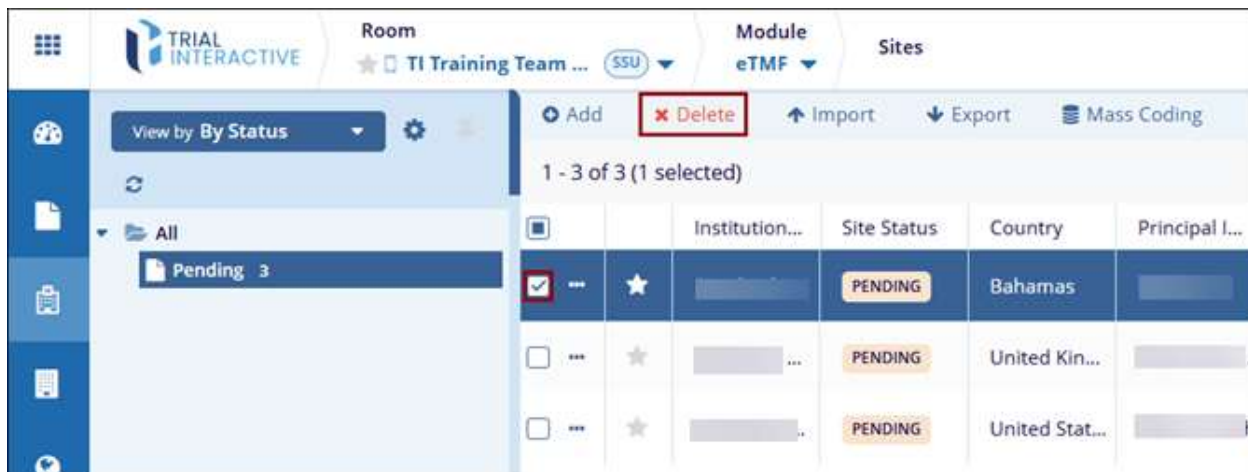
Convert Contact To Room User

- Once the General Info and Contact Details are added, click on the Add button.

## Delete Site

To delete a site, follow the steps below.

- On the Sites screen, check the box next to the site to delete,
- Click on the Delete button.



|                                     |     | Institution... | Site Status | Country        | Principal I... |
|-------------------------------------|-----|----------------|-------------|----------------|----------------|
| <input checked="" type="checkbox"/> | ... |                | PENDING     | Bahamas        |                |
| <input type="checkbox"/>            | ... |                | PENDING     | United Kin...  |                |
| <input type="checkbox"/>            | ... |                | PENDING     | United Stat... |                |

- On the Delete Site(s) dialog, enter the reason for deletion in the provided field. Optionally, select Delete reconciliation data or Remove Site from Audit Configuration if applicable.
- Click the Delete button to confirm the deletion.

Delete Site(S)
✕

Are you sure you want to Delete **1 Selected Site(s)**? This action is irreversible

Please enter the deletion reason\*

☐ Delete reconciliation data
☐ Remove Site from Audit Configuration

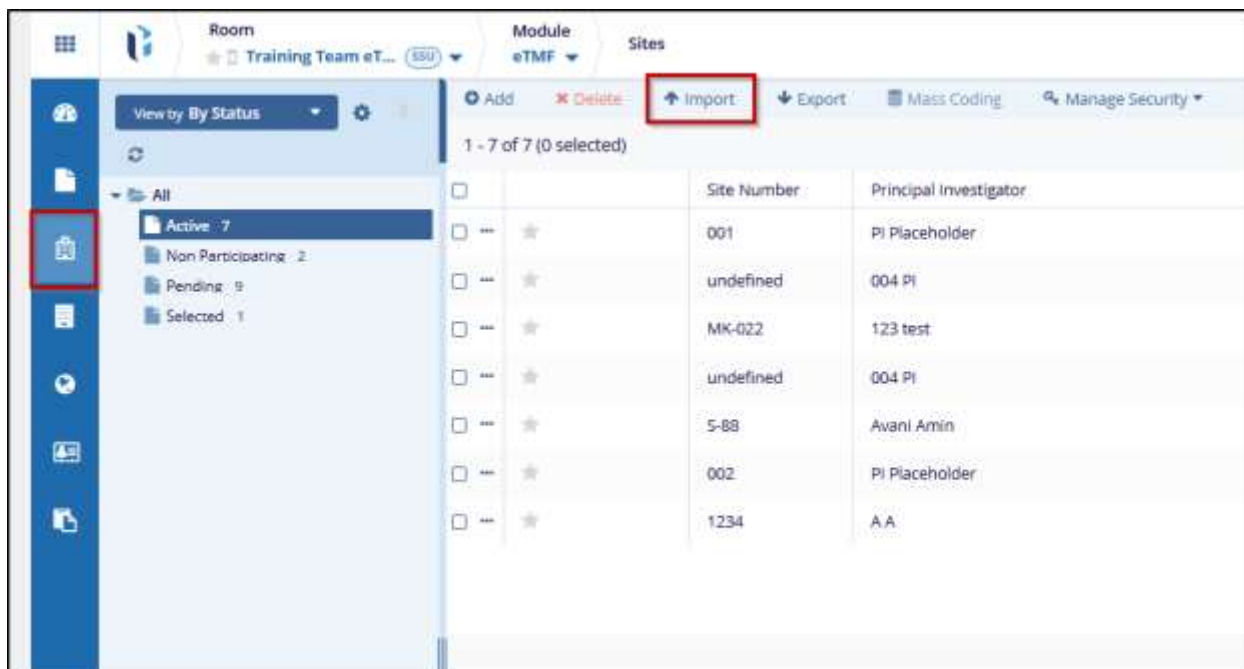
Cancel
Delete

Note: This action is irreversible, and a confirmation message will indicate the site has been deleted.

## Import Sites

step-by-step guide for importing sites in the eTMF module:

1. On the Sites screen, click the Import button from the top menu bar.



2. On the Sites Import dialog, click on the See the sample worksheet template to download a template and enter the necessary details.
3. Click Select to upload a metadata file in .xlsx format. Ensure that the spreadsheet contains two worksheets.
  - The first worksheet should list investigative site details.
  - The second worksheet should list contacts.

**Sites Import**

Step 1

Upload File

This wizard supports the import of many sites at once using a spreadsheet.  
The spreadsheet should contain two separate worksheets:  
  

Worksheet one should contain the list of institution names and addresses  
Worksheet two should contain the list of contacts including the Principal Investigator

Metadata File (format: .xlsx)\*:

Select

[See the sample worksheet template](#)

Cancel

Previous

Next

- After selecting the file, click Next to proceed with the import process.

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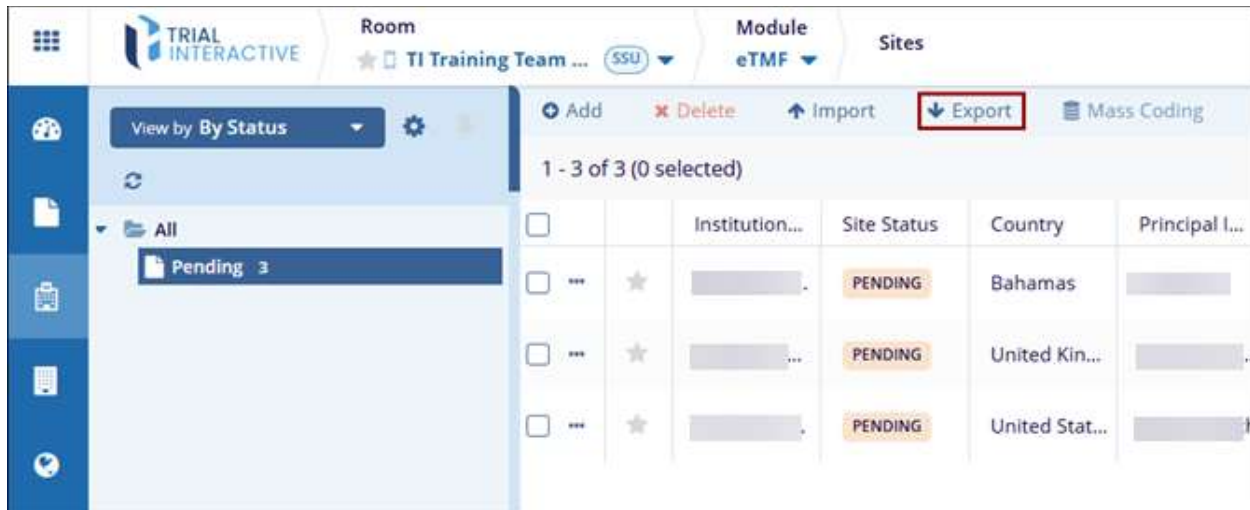
CL: Public

Page 259 of 667

## Export Sites

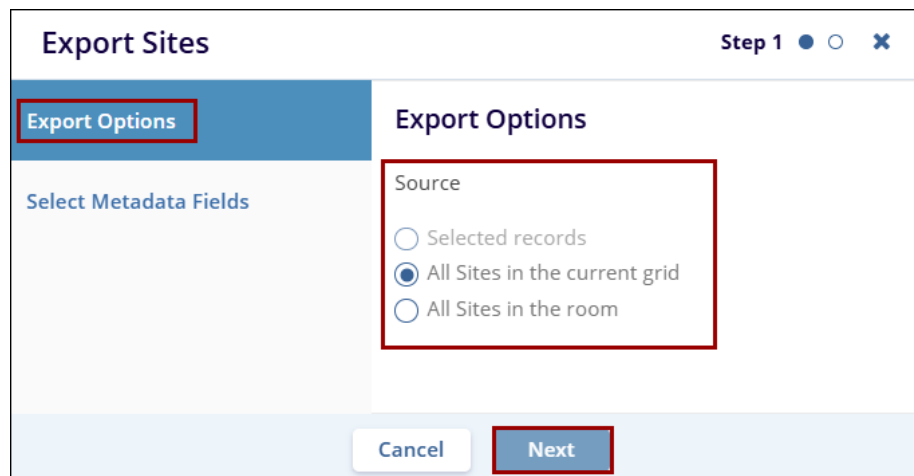
To Export sites, follow the steps below.

1. Click the Export button at the top of the screen to export all sites in the grid. To export specific sites, check the box next to the site name.



2. On the Export Sites dialog, under Export Options, select one of the following sources and click on the Next button.

- Selected records
- All Sites in the current grid
- All Sites in the room



3. In Step 2, choose the metadata fields to include in the export file and click on the Export button to finalize and start the export.



### Export Sites

Step 2

Export Options

Select Metadata Fields: 26

#### Select Metadata Fields

Site Status Country Principal Investigator Site Activation Date Progress %  
eFeasibility Status Main Contact Main Contact Phone Start-Up Specialist CRA  
Active Contact Address City Contact Type EmailAddress First Name  
Institution Name Last Name Mobile Number Phone Number Prefix  
SiteNumber State Suffix User Name ZipCode

Scroll to: Site Fields Contact Fields Additional Contact Fields

Sort By: Alphabet

62 Metadata Fields 26 Selected

27 Site Fields 9 Selected

- ☐ Address
- ☐ City
- ☐ Country Approval Date
- ☒ CRA
- ☒ eFeasibility Status
- ☐ Fax
- ☐ Geo Code
- ☐ Institution Name
- ☐ IRB/EC Approval Date

Cancel Previous **Export**

- On the Export Sites success message popup, click on the Get Results button.



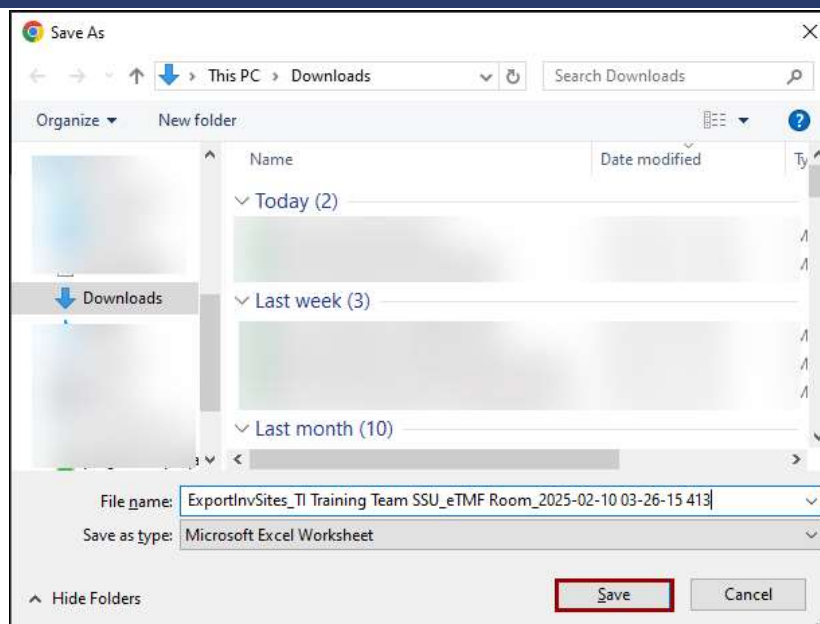
### Exporting Sites

Room: TI Training Team SSU/eTMF Room

Success! Task is complete.

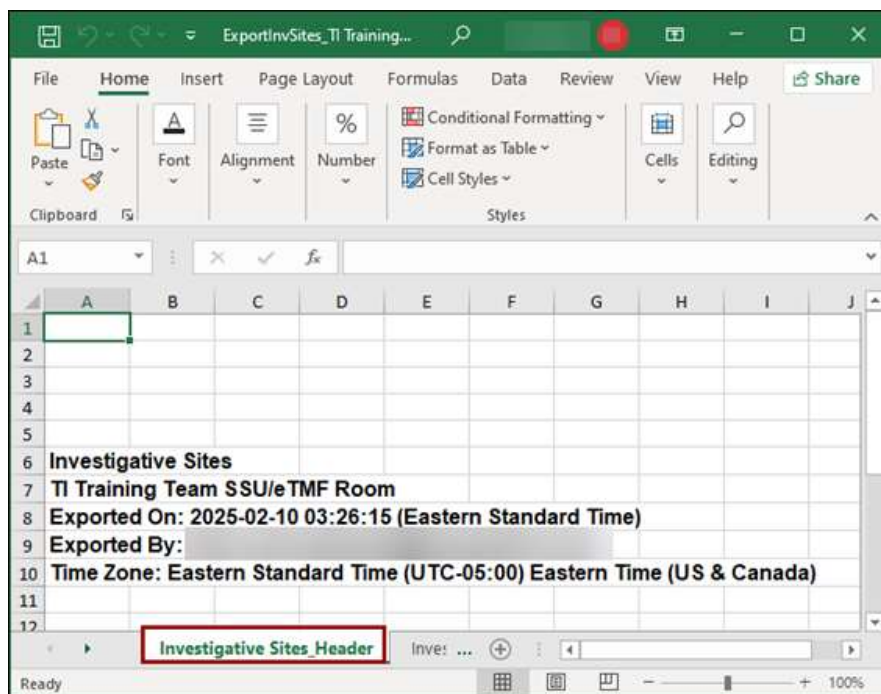
**Get Results**

- Download the export file into the system as Microsoft Excel Worksheet.



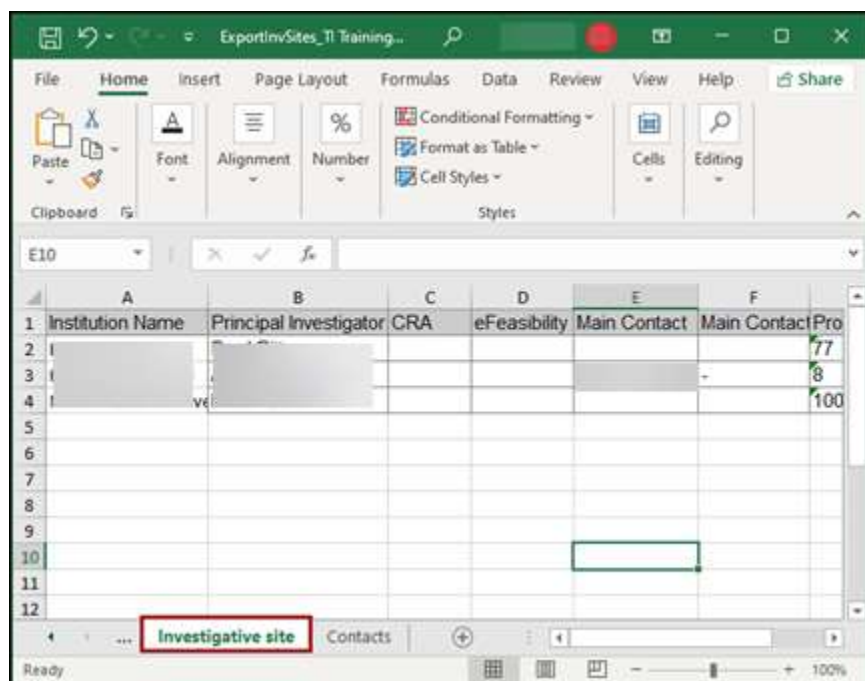
6. Within the downloaded file, click on the Investigative Sites\_Header tab to view details such as

1. Room Name
2. Exported On
3. Exported By
4. Time Zone



7. Click on the Investigative site tab to view the following details.

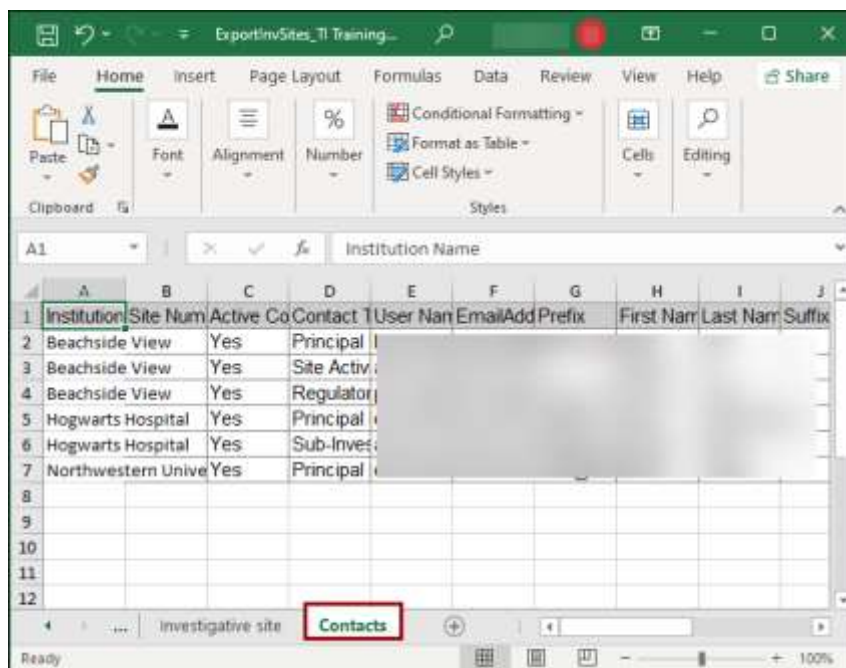
1. Institution Name
2. Principal Investigator
3. CRA
4. eFeasibility
5. Main Contact
6. Main Contact Phone
7. Progress
8. Site Activation Date
9. Status
10. Start-Up Specialist



8. Click on the Contacts tab to view the following details.

1. Institution Name
2. Site Number
3. Active Contact
4. Contact Type
5. User Name
6. Email Address
7. Prefix
8. First Name
9. Last Name
10. Suffix
11. Address
12. City
13. State

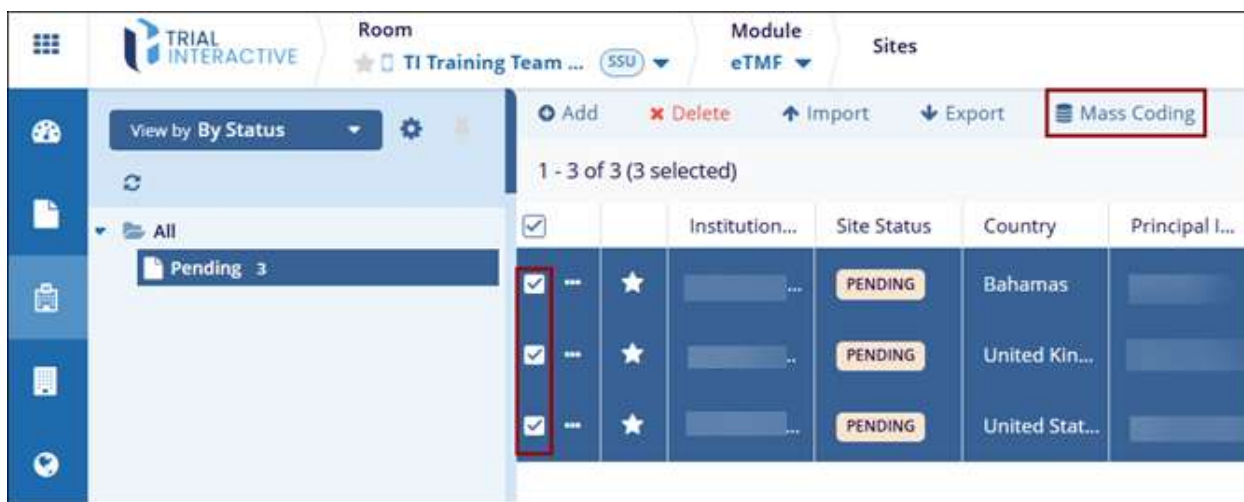
14. Country
15. Zip Code
16. Mobile number
17. Phone number



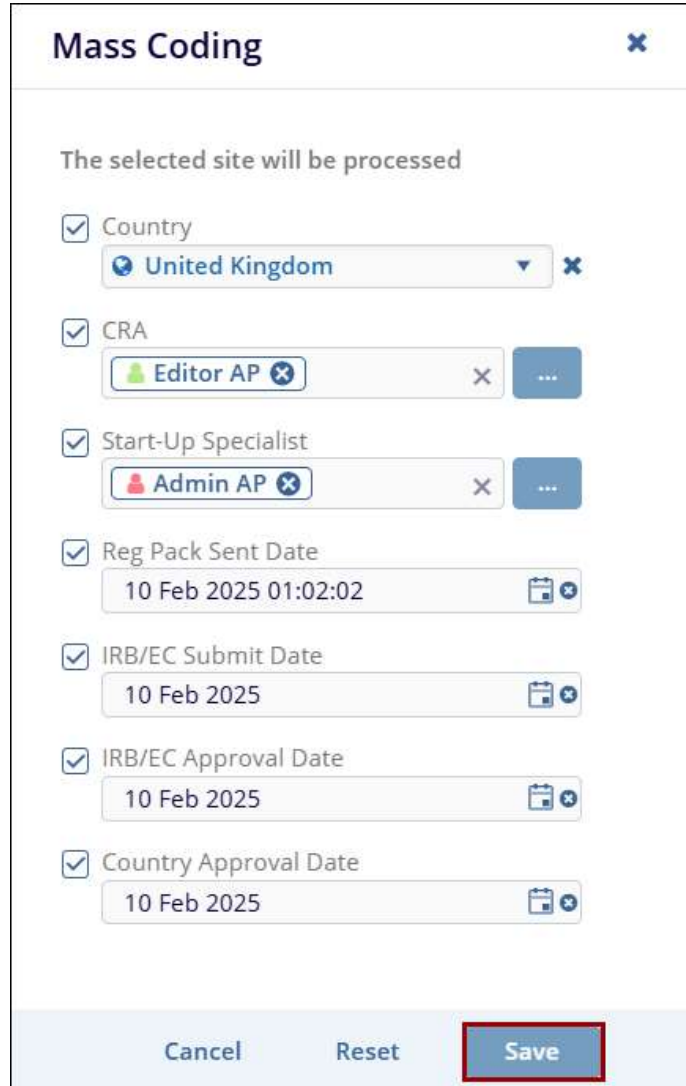
## Mass Coding Sites

To perform mass coding for sites, follow the steps below.

1. Select the site(s) to apply mass coding by checking the box next to the site name.
2. Click Mass Coding at the top of the screen.



3. In the Mass Coding dialog, select the relevant fields to code, such as Country, Expiration Date, CRA, Start-Up Specialist, or any other applicable fields, and fill in the details.
4. Once all information is entered, click on the Save button to apply the mass coding to the selected site(s).



**Mass Coding** ✕

The selected site will be processed

- ☒ Country  

🌐 United Kingdom
✕
- ☒ CRA  

👤 Editor AP
✕
...
- ☒ Start-Up Specialist  

👤 Admin AP
✕
...
- ☒ Reg Pack Sent Date  

10 Feb 2025 01:02:02
📅 ✕
- ☒ IRB/EC Submit Date  

10 Feb 2025
📅 ✕
- ☒ IRB/EC Approval Date  

10 Feb 2025
📅 ✕
- ☒ Country Approval Date  

10 Feb 2025
📅 ✕

Cancel
Reset
Save

5. On the confirmation popup, click on the Yes button.

### Confirm Mass Coding ✕

Are you sure you want to proceed with Mass Update?  
Following fields will be updated:

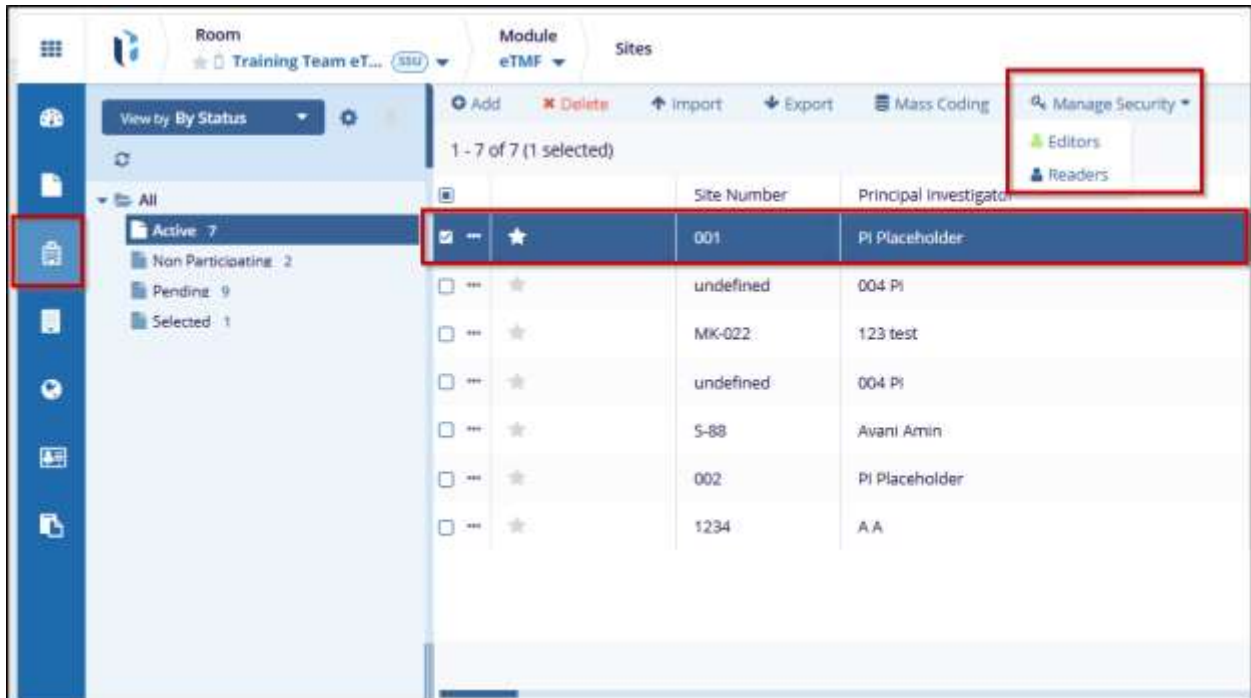
- CRA
- Start-Up Specialist
- Reg Pack Sent Date
- IRB/EC Submit Date
- IRB/EC Approval Date
- Country Approval Date
- Country

No
Yes

## Manage Security of Sites

To manage security settings for sites, follow the steps below.

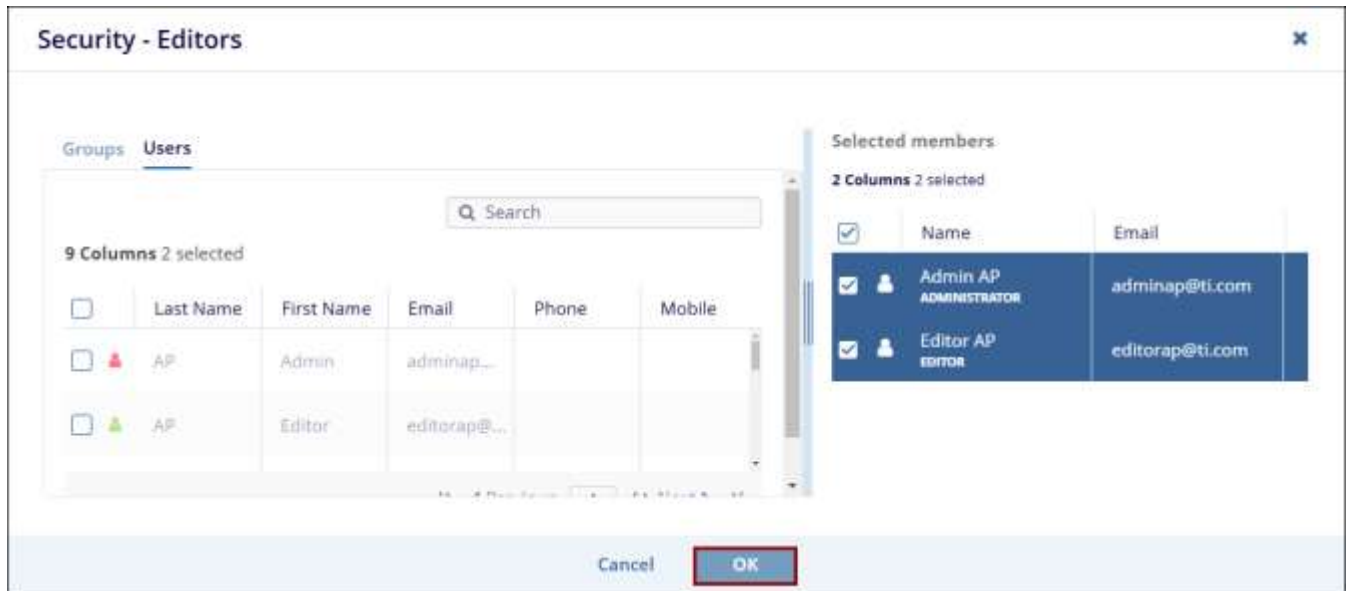
1. Check the box next to the site to manage security settings.
2. Click on the Manage Security button at the top of the screen, and choose either Editors or Readers to manage permissions.



|                                     | Site Number | Principal Investigator |
|-------------------------------------|-------------|------------------------|
| <input checked="" type="checkbox"/> | 001         | PI Placeholder         |
| <input type="checkbox"/>            | undefined   | 004 PI                 |
| <input type="checkbox"/>            | MK-022      | 123 test               |
| <input type="checkbox"/>            | undefined   | 004 PI                 |
| <input type="checkbox"/>            | S-88        | Avani Amin             |
| <input type="checkbox"/>            | 002         | PI Placeholder         |
| <input type="checkbox"/>            | 1234        | A A                    |

3. In the Security - Editors or Security - Readers dialog, switch to the Users or Groups tab.

4. Select the user(s) or group (s) by checking the box next to their name in the user list and add them to the Selected Members section.
5. Click on the OK button.



6. On the Security Update Options popup, select the options by clicking on their respective radio buttons.
  1. Source
    1. Selected Sites
    2. All Sites In The Current Grid
    3. All Sites In The Room
  2. Options
    1. Append New Security Members
    2. Replace Current Security Members
7. Once the necessary, click on the Append (for append new security members) or Replace (for replace current security members) button.

Security Update Options

Source

☐ Selected Sites
   
☒ All Sites In The Current Grid
   
☐ All Sites In The Room

Options

☒ Append New Security Members
   
☐ Replace Current Security Members

Cancel

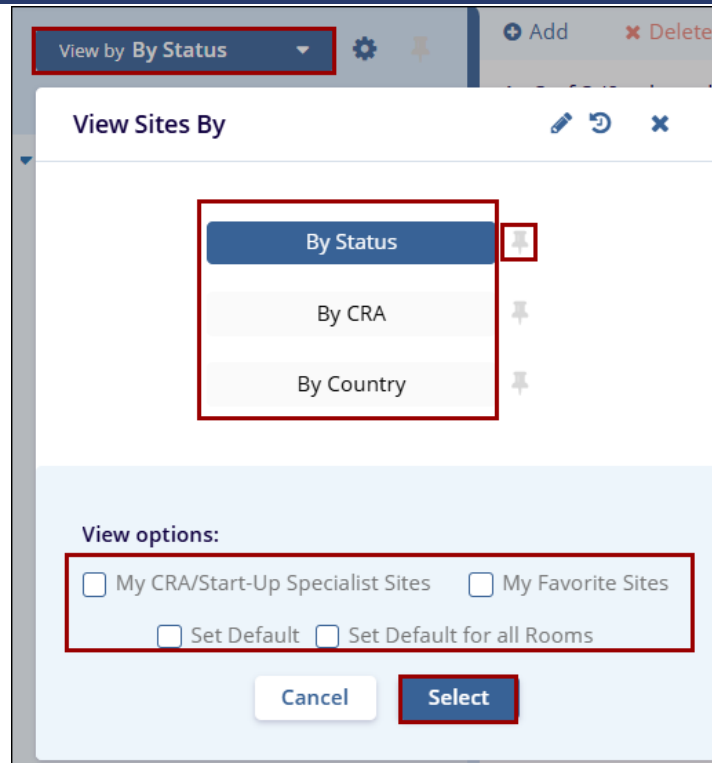
Append

## Site Views

To access and configure the site views, follow the steps below.

- On the Sites screen, click on the View by dropdown.
- On the View Contacts By window, select a view by clicking on the view name.
  - By Status: Displays the contacts grouped by the site.
  - By CRA: Displays the sites grouped by the associated CRA.
  - By Country: Displays contacts grouped by their country association.
- Click on the pin icon to pin a view and this view is selected once user access the Sites modal.
- Select the different view options by checking the box before their name.
- Click on the Select button once the desired view is selected.



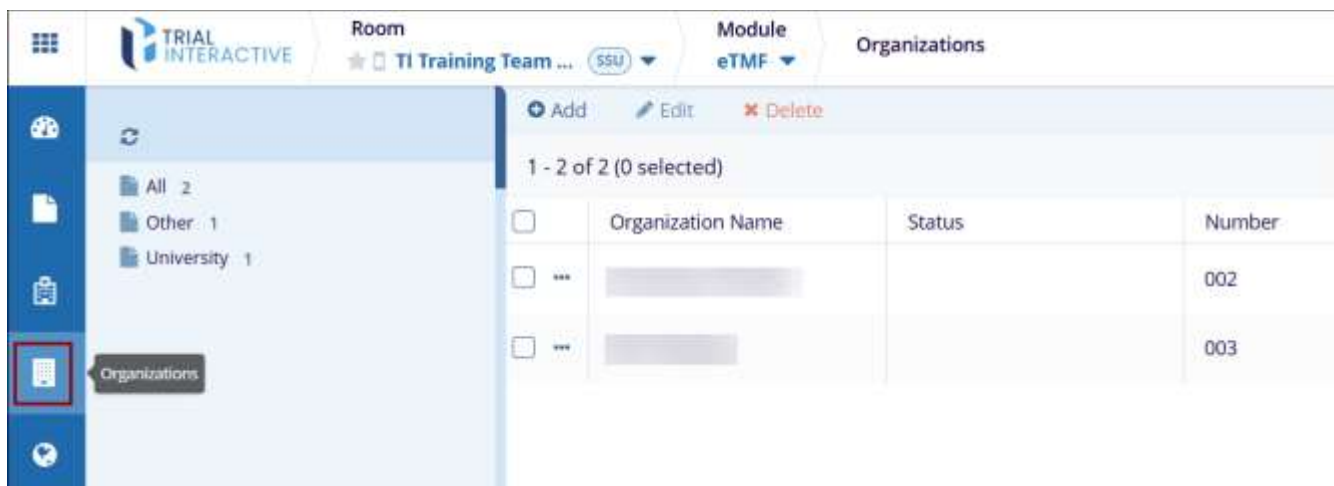


## Organizations

The Organizations feature simplifies the management of organizations within the eTMF or document management system. It provides comprehensive control over organizational data, allowing users to add, manage, and track organizations at the room level while linking relevant documents directly to each organization. The Organizations modal within eTMF ensures an organized and efficient workflow for managing organizations and their associated documentation from a centralized interface.

To access the Organization modal within eTMF, follow the steps below.

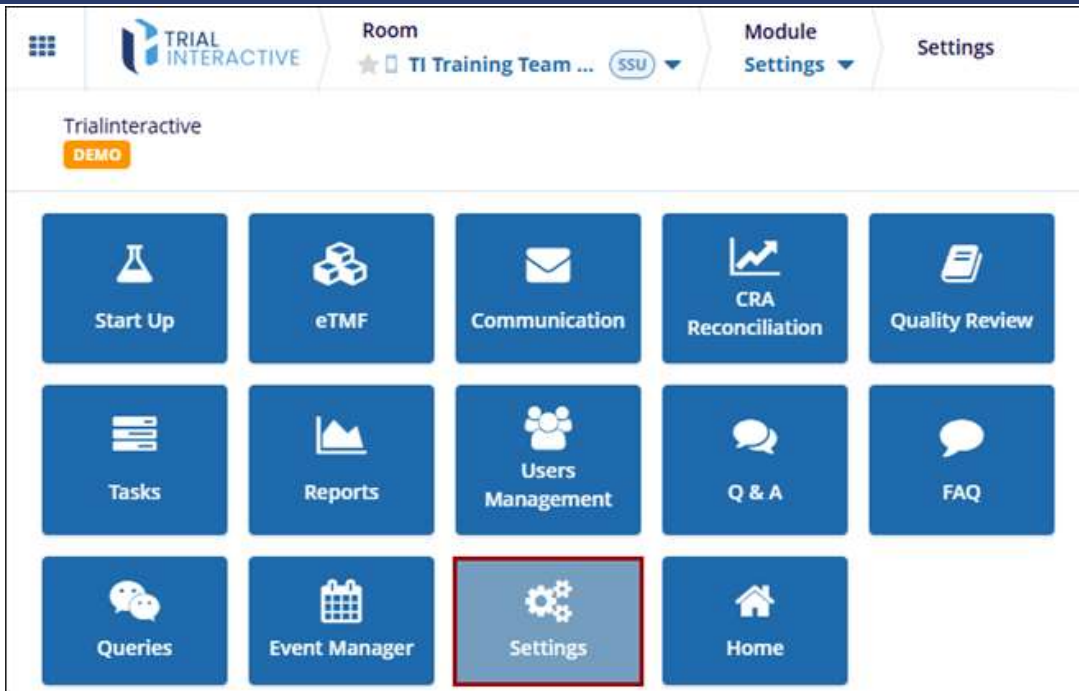
1. Click on the modules dropdown and select the eTMF module.
2. From the left-hand navigation menu, select the Organizations modal.
3. The Organizations screen displays the configured organizations and its associated data into the following columns.
  - a. Organization Name
  - b. Status
  - c. Number
  - d. Type
  - e. Countries



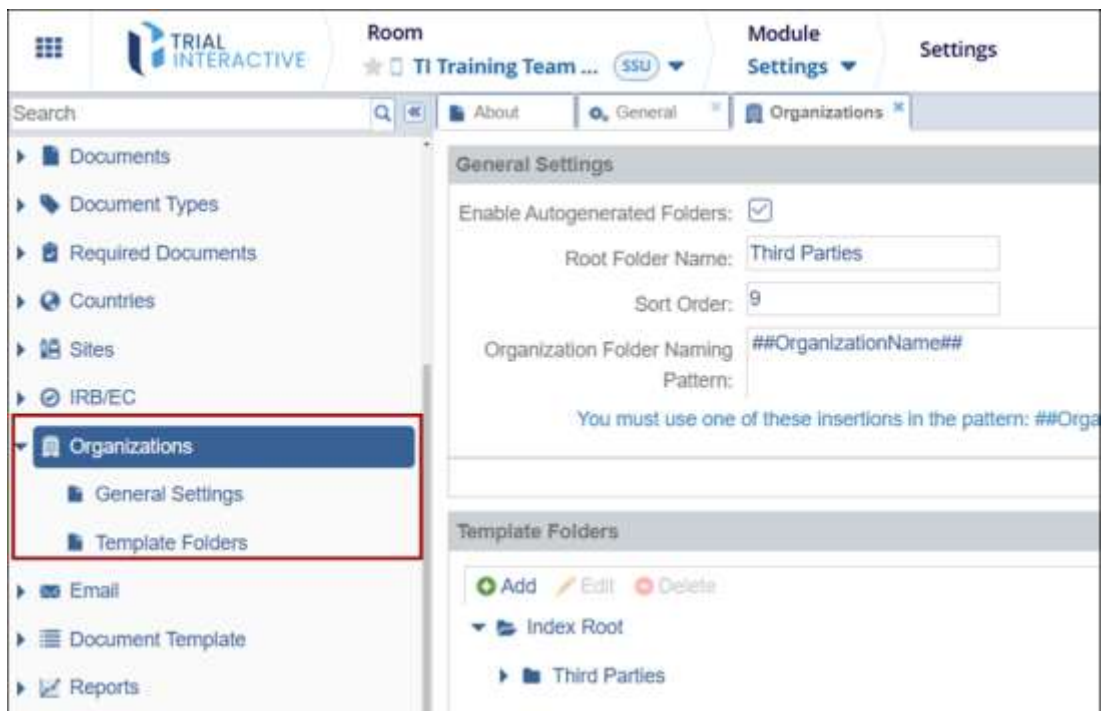
## Organization Settings

To view the organization modal and customize the settings, follow the steps below.

1. Click on the waffle icon and select the Settings module.

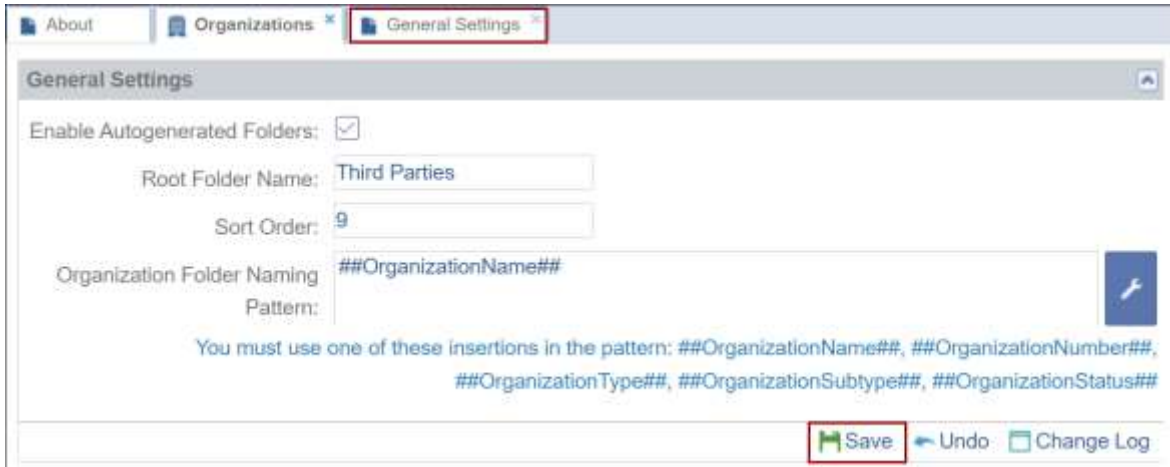


2. On the Settings screen, expand the Organizations setting dropdown from the left-hand navigation pane.



3. Select the General Settings option and configure the following
  - a. Enable Autogenerated Folders: Check the box to enable this setting and vice versa

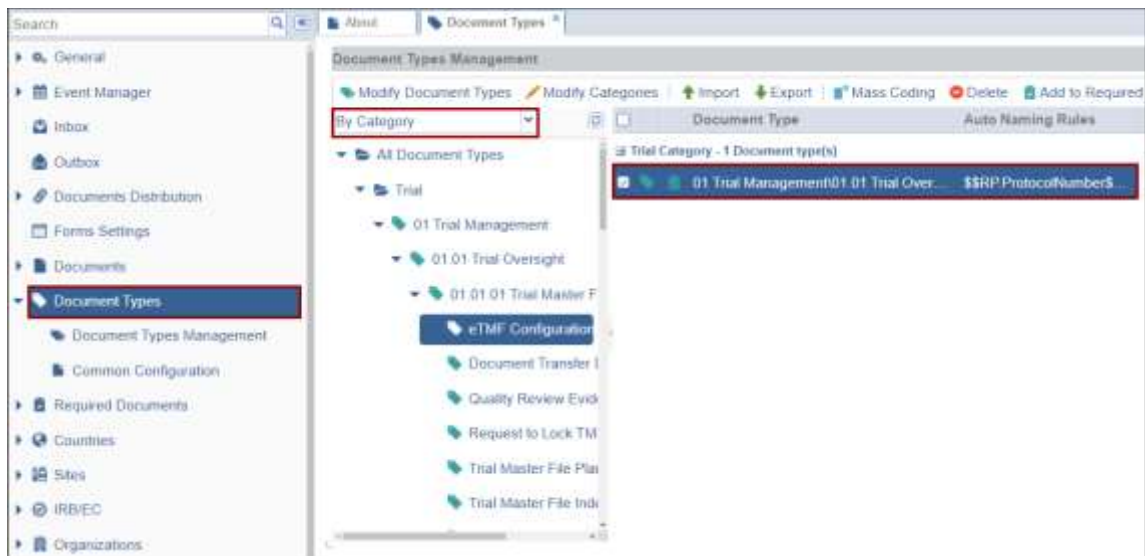
- b. Root Folder Name: Add a root folder name
  - c. Sort Order: Define the sort order
  - d. Organization Folder Naming pattern: Click on the wrench icon to add a new organization folder naming pattern. Organization Name is selected by default.
4. Once the settings are configured, click on the Save button.



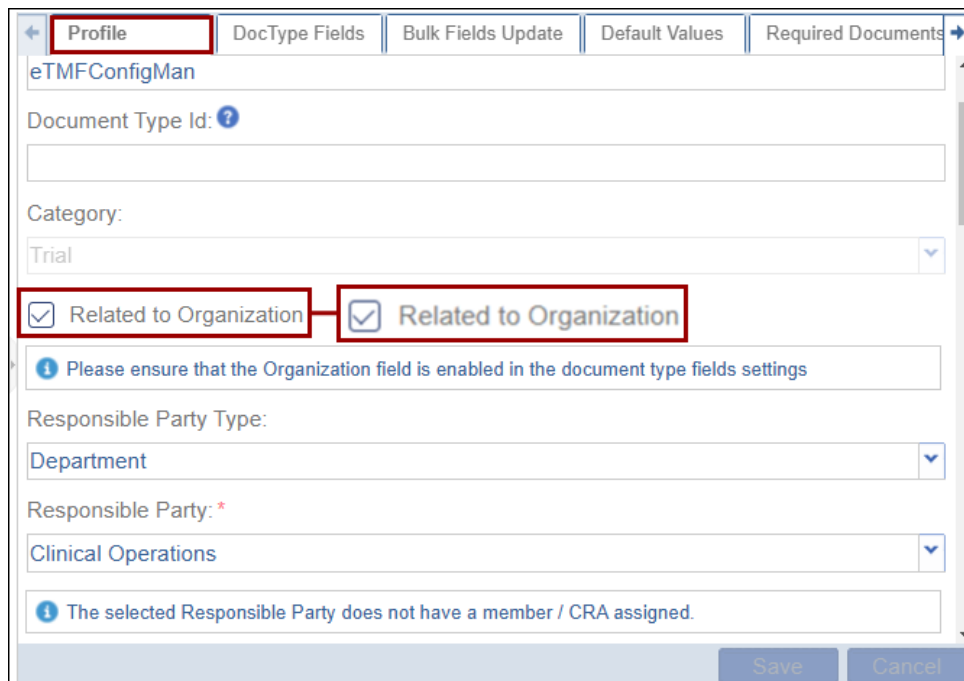
5. Select the Template Folders option and configure the following settings.
  - a. Add Folder: To add a root folder follow the steps below.
    - i. Click on the +Add button.
    - ii. Add the folder name.
  - b. Edit Folder: To edit the root folder, follow the steps below.
    - i. Select the root folder and click on the Edit button.
    - ii. Rename the folder name.
  - c. Delete Folder: To delete the root folder, follow the steps below.
    - i. Select the root folder and click on the Delete button.



6. From the left-hand navigation pane, select the Document Types setting.
7. Select a document type by applying the By Category sort criteria.



8. In the right-hand side metadata panel, click on the Profile tab and enable the Related to Organization setting.



9. Click on the Doc Type Fields tab, and make the organization field visible and/or required by clicking on the respective checkbox.
10. Click on the Save button.

Profile
DocType Fields
Bulk Fields Update
Default Values
Required Document

☐ Inherit from 01.01.0 ...
Tools
Field name...

| Title ▲                 | Visible                             | Required                 |
|-------------------------|-------------------------------------|--------------------------|
| Material Item Type      | <input type="checkbox"/>            | <input type="checkbox"/> |
| Name                    | <input type="checkbox"/>            | <input type="checkbox"/> |
| Not Applicable for eTMF | <input type="checkbox"/>            | <input type="checkbox"/> |
| Ongoing Review Id       | <input type="checkbox"/>            | <input type="checkbox"/> |
| Organization            | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Placeholder Id          | <input type="checkbox"/>            | <input type="checkbox"/> |
| Popular Document        | <input type="checkbox"/>            | <input type="checkbox"/> |
| Popular Document        | <input type="checkbox"/>            | <input type="checkbox"/> |

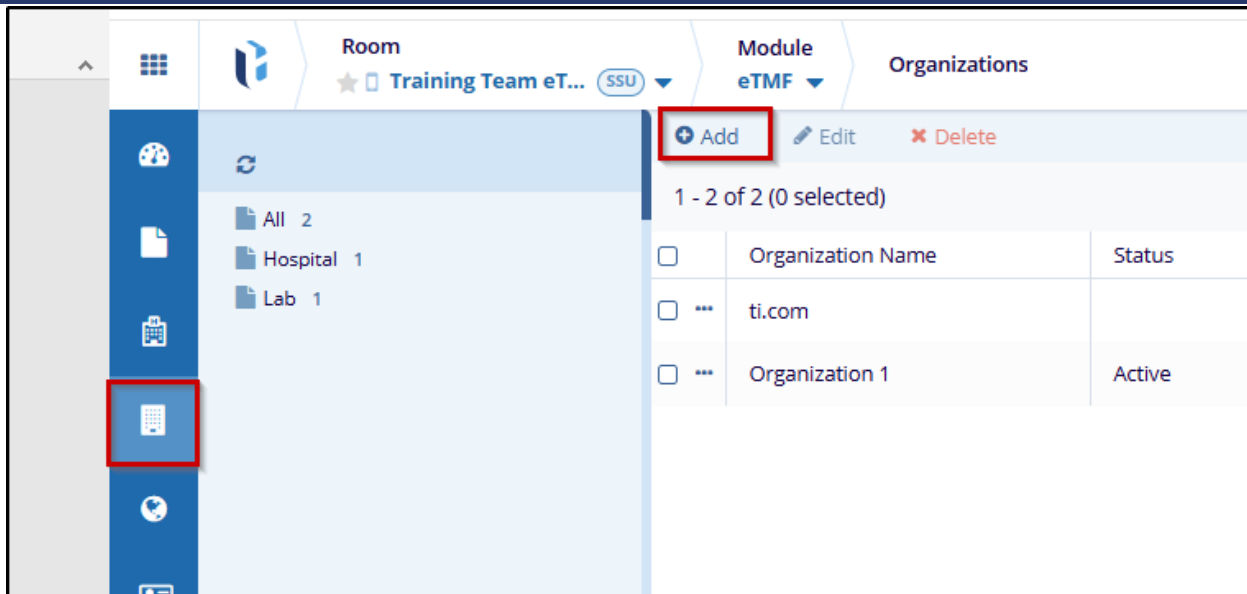
Options that appear greyed-out cannot be modified
Save
Cancel

Note: Super Administrators must create organizations, sub-organizations and services at the domain level since organizations are always set up at the client/domain level.

## Add an Organization

To add an organization, follow the steps below

1. In the eTMF module, go to the sidebar and click on the Organizations modal.
2. Click on the +Add button at the top of the grid.



3. Within the Add window, select an existing organization from the drop-down list labeled - Please select an existing organization to add to the dataroom.
4. Enter the relevant services in the Service Provided field from the available dropdown options.
5. Click the Add button.

Add

Please select an existing organization to add to the dataroom

TestUAT

Service Provided

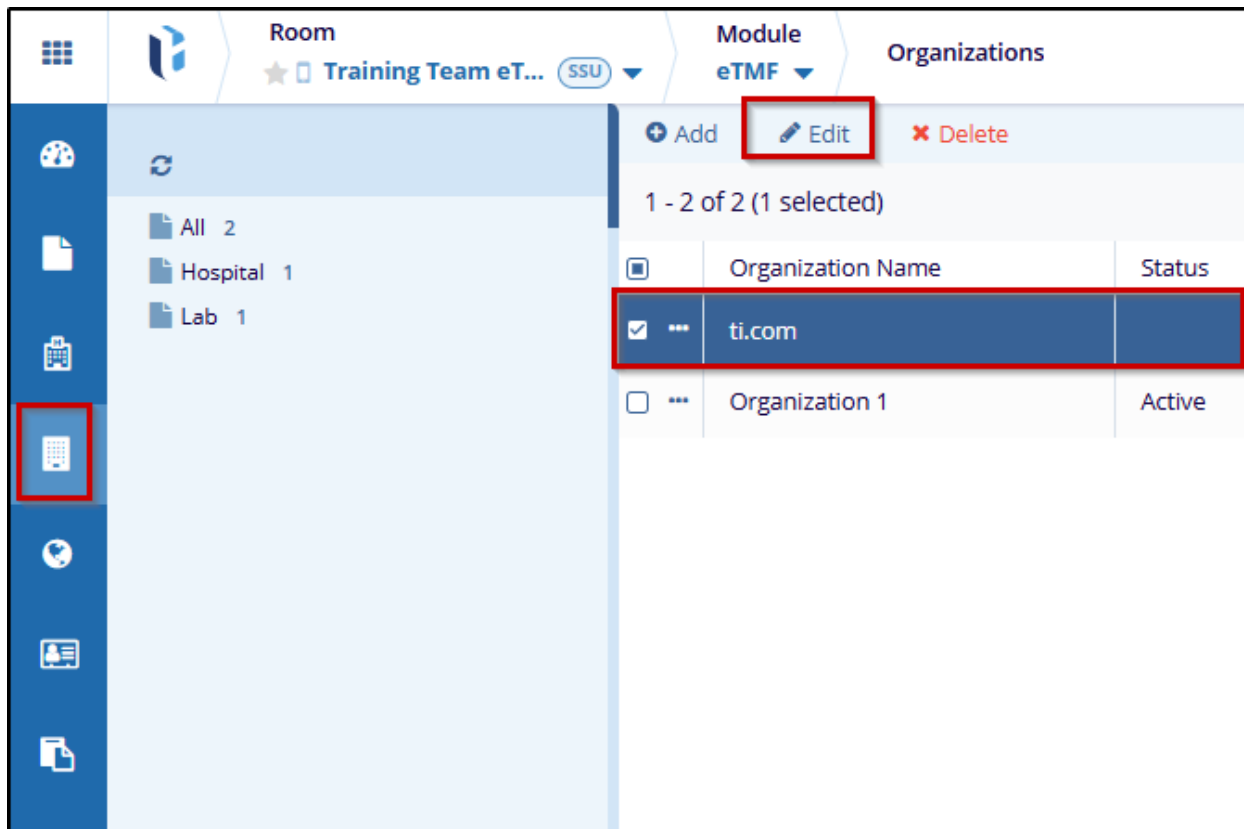
Cancel

Add

## Edit an Organization

To edit an organization, follow the steps below.

1. In the eTMF module, go to the sidebar and click on the Organizations modal.
2. From the organizations list, select the organization to edit by checking the box next to its name.
3. Click on the Edit button at the top of the grid.



4. On the Edit Organization window, make the necessary changes to the organization details, such as:
  1. Number
  2. Organization Name
  3. Type
  4. Subtype
  5. Status
  6. Countries
  7. Notes
5. In the Service Provided field, update the services by adding or removing options as required.



Edit Organization

Number

Organization Name

Type

Subtype

Status

Countries

Notes

Service Provided

Lab Services
Monitoring
Data Management

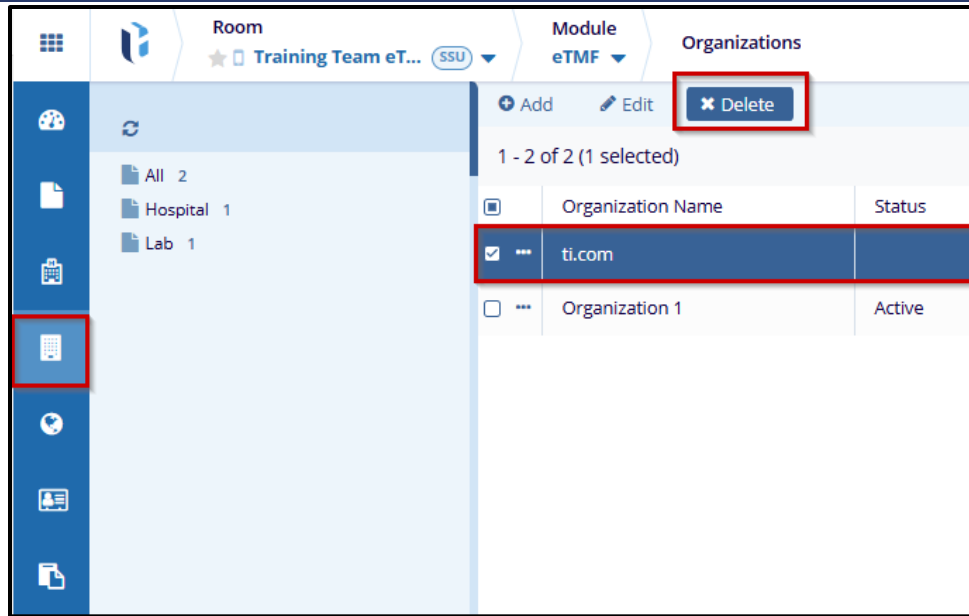
Cancel
Save

6. Once all changes are made, click the Save button.

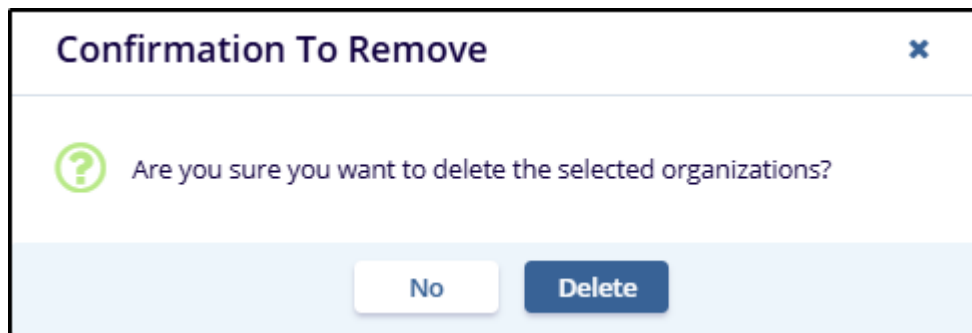
## Delete an Organization

To delete an organization, follow the steps below.

1. In the eTMF module, go to the sidebar and click on the Organizations modal.
2. From the organizations list, select the organization to delete by checking the box next to its name.
3. Click on the Delete button at the top of the grid.



4. A confirmation popup, click on the Delete button to confirm the deletion.



## Countries

To access the countries modal, follow the steps below.

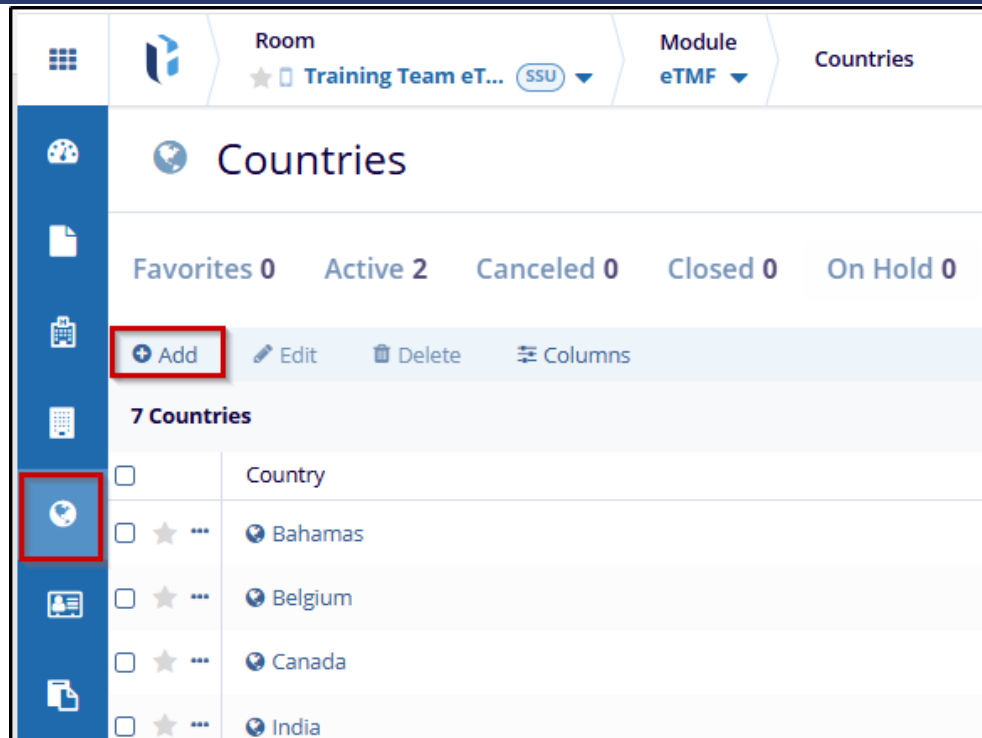
1. Click on the modules dropdown and select the eTMF module.
2. From the left-hand navigation menu, select the Countries modal.
3. The Countries screen displays the configured organizations and its associated data into the following columns.
  - a. Country
  - b. Status
  - c. Sites
  - d. Requirements
  - e. Language



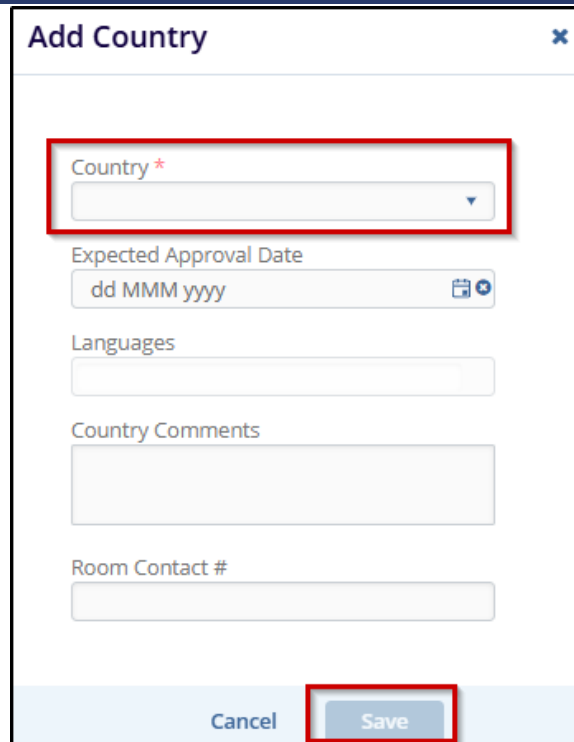
## Add Countries

To add a country, follow the steps below.

1. In the eTMF module, go to the sidebar and click on the Countries modal.
2. Click on the +Add button at the top of the grid.



3. In the Add Country form, select a country from the Country drop-down list.
4. Optionally, fill in additional details:
  - Expected Approval Date
  - Languages
  - Country Comments
  - Room Contact #



The image shows a modal dialog box titled "Add Country" with a close button (X) in the top right corner. The dialog contains several input fields: a "Country \*" dropdown menu (highlighted with a red rectangle), an "Expected Approval Date" field with a date format "dd MMM yyyy" and a calendar icon, a "Languages" text input field, a "Country Comments" text area, and a "Room Contact #" text input field. At the bottom of the dialog, there are two buttons: "Cancel" and "Save" (highlighted with a red rectangle).

2. Once all necessary information is entered, click on the Save button to add the country to the list.

## Edit Countries

To edit a country in the eTMF module, follow one of the methods below.

### Method 1

1. On the Countries screen, select the country to edit by checking the box next to its name.
2. Click on the Edit button. This opens the Edit Country panel on the right side of the screen.



## Countries

**Favorites 0**   **Active 1**   **Canceled 0**   **Closed 0**   **On Hold 0**

+ Add    **Edit**    Delete    Columns

**7 Countries**   1 selected

|                                                                                                                                                                                                         |                                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| <input type="checkbox"/>                                                                                                                                                                                | Country                                                                                   |
| <input checked="" type="checkbox"/>   |  Bahamas |
| <input type="checkbox"/>              |  France  |

- In the Edit Country panel, make the necessary changes under the Details tab.
  - Under General Information, update the Country name and Status if needed.
  - Add or modify Country Comments as required.
  - In Additional Information, set or update the Expected Approval Date.
- Click on the Sites tab to view the sites associated with the country.
- Click on the Status History button to view the status changes and users responsible for changing the status.
- Once the desired changes are made, click on the save button Save to apply the updates, or Save & Next button to edit the next country in the list.

★ **Bahamas**  
**PLANNED**

**Details** **Sites 3**

**General Information**

Country \*  
Bahamas

Status \*  
**PLANNED**

**Status History**

Country Comments

**Additional Information**

Expected Approval Date  
dd MMM yyyy

Cancel Save Save & Next

◀ Previous Next ▶

## Method 2

- On the Countries screen, click on the country name to edit.

Favorites 0

Active 1

Canceled 0

Closed 0

On Hold 0

+

Add

Edit

Delete

Columns

7 Countries

Country

★

...

Bahamas

★

...

France

- On the Country Details screen, Click on the Edit button.

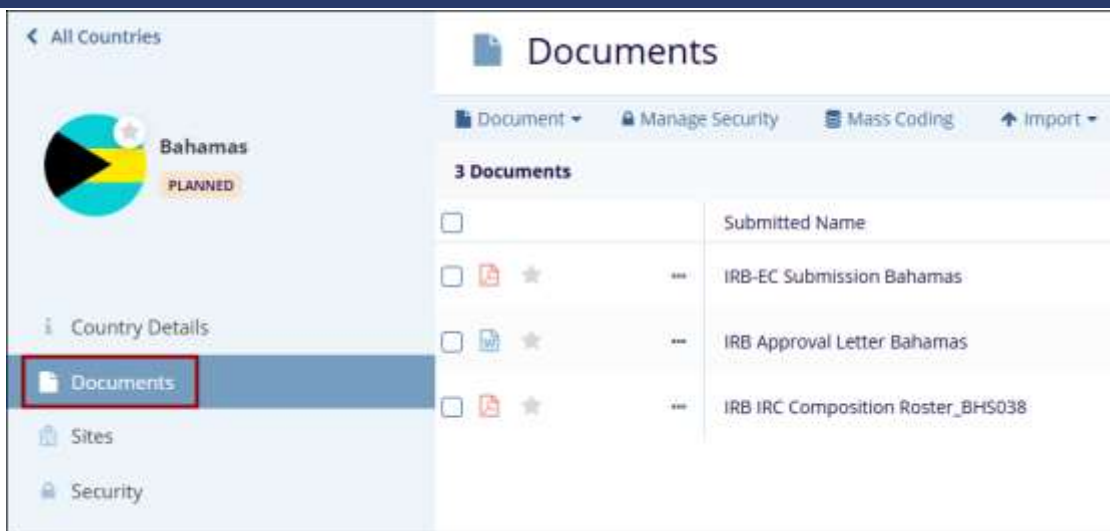


3. Make changes to the General and Additional Information sections and click on the Save button.



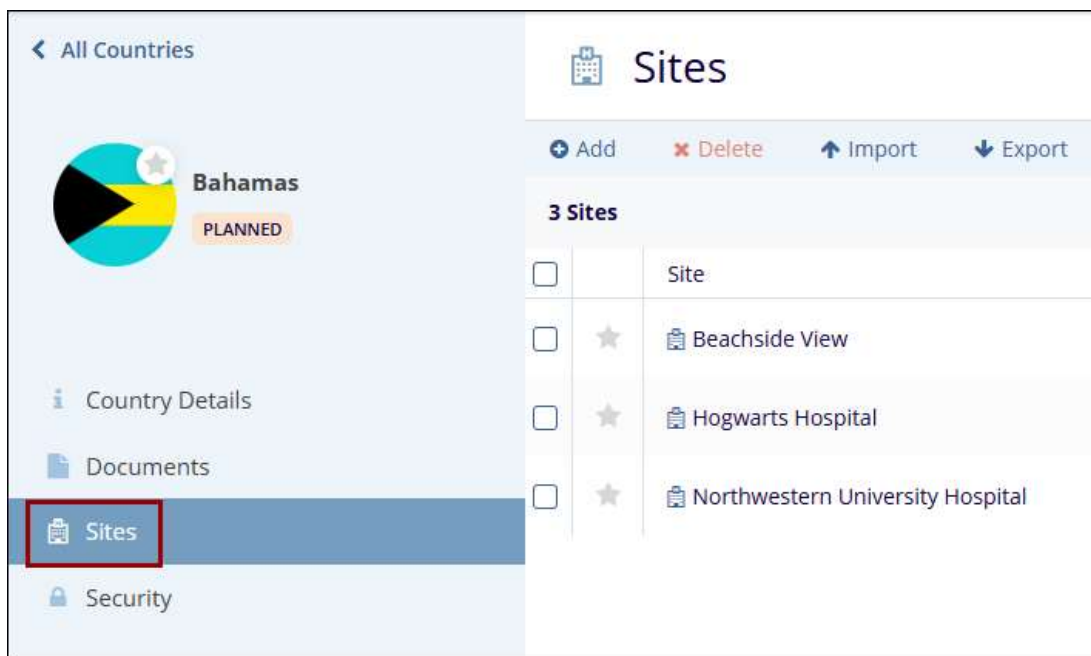
4. Click on the Documents tab from the left-hand navigation pane to add documents and access other functions.





Note: Refer to the Documents Module section to add documents and perform the other functions.

- Click on the Sites tab from the left-hand navigation pane to add and access other functions.



Note: Refer to the Sites section to add sites and perform the other functions.

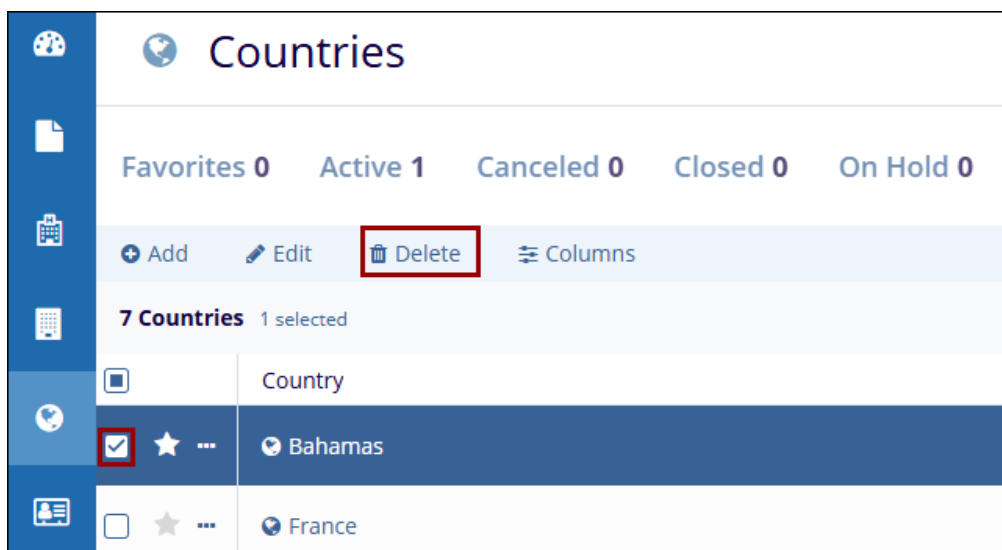
- Click on the Security tab from the left-hand navigation pane to grant users, the necessary access permissions.



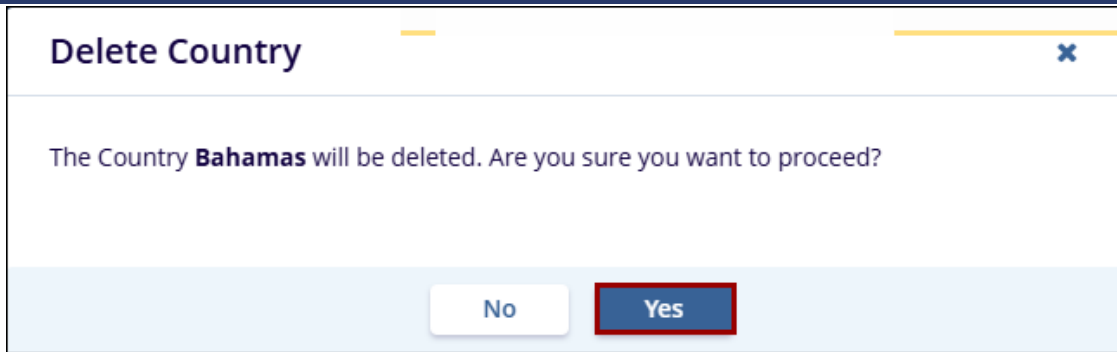
## Delete Countries

To delete a country in the eTMF module, follow the steps below:

1. On the Countries screen, select the country to delete by checking the box next to its name.
2. Click on the Delete button.



3. On the Delete Country confirmation popup, click on the Yes button.



## Manage Columns

To Manage columns within the countries screen, follow the steps below.

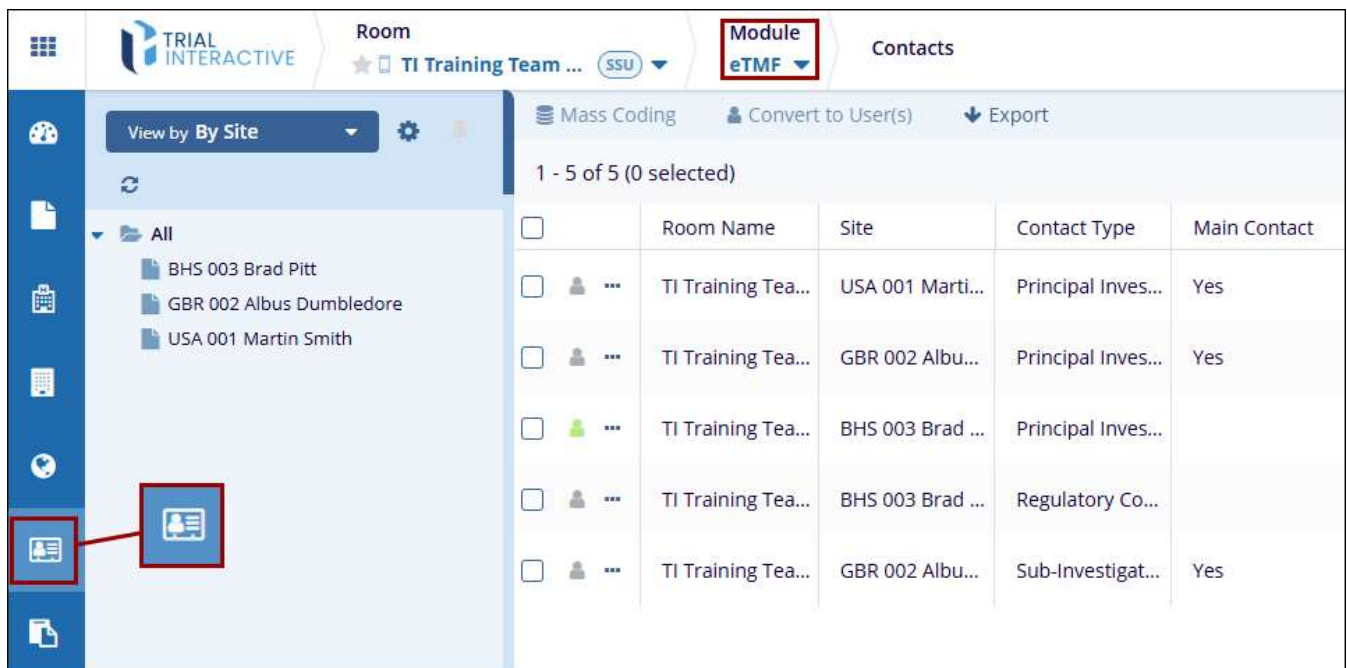
1. In the eTMF module, go to the relevant Countries in the sidebar.
2. Click on the Columns button in the toolbar at the top of the grid.

## Contacts

The contacts assigned to a site are shown in the Contacts modal within the eTMF module. Users with the necessary access permissions can edit contacts, apply mass coding, convert contacts into users, and export contact details and metadata.

To access the contacts modal within the eTMF module, follow the steps below.

1. Click on the modules dropdown and select the eTMF module.
2. From the left-hand navigation menu, select the Contacts modal.
3. The Contacts screen displays the contacts configured within the site and its associated data into the following columns.
  - a. Room Name
  - b. Site
  - c. Contact Type
  - d. Main Contact
  - e. Email Address
  - f. Full Name
  - g. Provide Document
  - h. Status



View by By Site

Mass Coding Convert to User(s) Export

1 - 5 of 5 (0 selected)

|                          | Room Name          | Site             | Contact Type       | Main Contact |
|--------------------------|--------------------|------------------|--------------------|--------------|
| <input type="checkbox"/> | TI Training Tea... | USA 001 Marti... | Principal Inves... | Yes          |
| <input type="checkbox"/> | TI Training Tea... | GBR 002 Albu...  | Principal Inves... | Yes          |
| <input type="checkbox"/> | TI Training Tea... | BHS 003 Brad ... | Principal Inves... |              |
| <input type="checkbox"/> | TI Training Tea... | BHS 003 Brad ... | Regulatory Co...   |              |
| <input type="checkbox"/> | TI Training Tea... | GBR 002 Albu...  | Sub-Investigat...  | Yes          |

## Edit Contacts

To edit contacts, follow the steps below.

1. Click on the checkbox next to the contact.

| Mass Coding                         |                                                                                       | Convert to User(s) | Export       |                |                |
|-------------------------------------|---------------------------------------------------------------------------------------|--------------------|--------------|----------------|----------------|
| 1 - 5 of 5 (1 selected)             |                                                                                       |                    |              | Refresh        | Manage Columns |
| <input type="checkbox"/>            |                                                                                       | Room Na...         | Site         | Contact T...   | Main Cont...   |
| <input checked="" type="checkbox"/> |  ... | TI Training...     | USA 001 ...  | Principal I... |                |
| <input type="checkbox"/>            |  ... | TI Training...     | GBR 002 A... | Principal I... | Yes            |
| <input type="checkbox"/>            |  ... | TI Training...     | BHS 003 B... | Principal I... |                |
| <input type="checkbox"/>            |  ... | TI Training...     | BHS 003 B... | Regulator...   |                |
| <input type="checkbox"/>            |  ... | TI Training...     | GBR 002 A... | Sub-Inves...   | Yes            |

2. Within the metadata panel on the right-hand side, make changes to the following metadata fields.
  - a. **Contact Type\***: Select a contact type from the dropdown list. Contact types are configured in Settings > Contact Types.  
Note: Refer to the Contact Types section in Room Settings for more details.
  - b. **Main Contact**: Check or uncheck the Main Contact checkbox to designate the contact as a main contact. If selected, the Main Contact column in the contacts screen will display Yes and vice versa.
  - c. **Email Address**: This field is non-editable.
  - d. **First Name**: Enter or update the contacts first name.
  - e. **Last Name**: Enter or update the contact's last name.
  - f. **Address**: Enter or update the contact's address.
  - g. **City**: Enter or update the contacts city.

Contact Type \*  
Principal Investigator ▼ ✕

☒ Main Contact

Email Address

First Name

Last Name

Address  
123 Main Street

City  
Chicago

- h. State: Enter or update the contact's state.
- i. Zip Code: Enter or update the contacts zip code.
- j. Country: Select a country from the dropdown list.
- k. Phone No: Enter or update the contacts phone number.
- l. Mobile No: Enter or update the contacts mobile number.

State  
IL

Zip Code

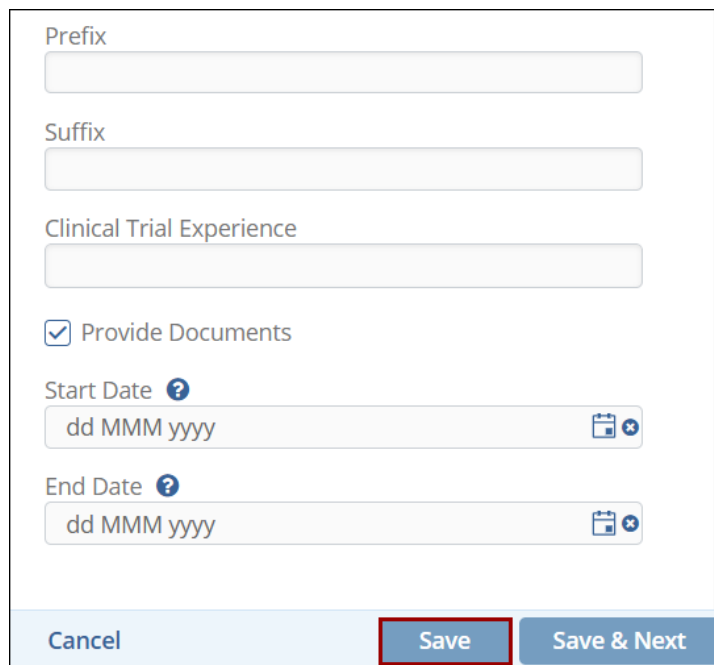
Country  
🌐 United States ▼ ✕

Phone No

Mobile No

- m. Prefix: Enter or update the contacts prefix.
- n. Suffix: Enter or update the contacts suffix.

- o. Clinical Trial Experience: Enter or update the contacts clinical trial experience.
  - p. Provide Documents: Check or uncheck the Provide Documents checkbox to enable or disable this setting. If selected, the Provide Document column in the contacts screen will display Yes and vice versa.
  - q. Start Date: Select or update the start date using the calendar icon. This indicates when the contact started working at the site.
  - r. End Date: Select or update the end date using the calendar icon. This indicates when the contact stopped working at the site.
3. Once all the changes are made, click on the Save button.



The screenshot shows a form for updating contact information. It includes text input fields for 'Prefix', 'Suffix', and 'Clinical Trial Experience'. There is a checked checkbox for 'Provide Documents'. Below this are two date pickers for 'Start Date' and 'End Date', both showing the format 'dd MMM yyyy' and featuring a calendar icon and a clear icon. At the bottom, there are three buttons: 'Cancel', 'Save' (highlighted with a red border), and 'Save & Next'.

## Mass Coding

The Mass coding functionality allows users to apply metadata updates in bulk to all or selected contacts.

To apply mass coding to all or selected contacts, follow the steps below.

1. Select a single or multiple contacts by clicking on their respective checkboxes.
2. Click on the Mass Coding button from the top menu bar.


Mass Coding


Convert to User(s)


Export

1 - 5 of 5 (1 selected)

|                                          |  | Room Name          | Site              | Contact Type        | Main Contact |
|---------------------------------------------------------------------------------------------------------------------------|--|--------------------|-------------------|---------------------|--------------|
| <input checked="" type="checkbox"/>  ... |  | TI Training Tea... | USA 001 Marti...  | Principal Invest... | Yes          |
| <input type="checkbox"/>  ...            |  | TI Training Tea... | GBR 002 Albus ... | Principal Invest... | Yes          |
| <input type="checkbox"/>  ...            |  | TI Training Tea... | BHS 003 Brad ...  | Principal Invest... | Yes          |
| <input type="checkbox"/>  ...            |  | TI Training Tea... | BHS 003 Brad ...  | Regulatory Con...   | Yes          |
| <input type="checkbox"/>  ...            |  | TI Training Tea... | GBR 002 Albus ... | Sub-Investigator    | Yes          |

3. On the Mass Coding window, select the following option by clicking on its radio button
  - a. All Records in set: The metadata updates will apply to all contact records
  - b. Selected records: The metadata updates will apply to selected contacts.
4. Check or Uncheck the Main Contact checkbox and enable or disable the toggle switch to designate the contact as the main contact.
5. Check or Uncheck the Provide Documents checkbox and enable or disable the toggle switch.
6. Click on the Save button.



Mass Coding

☐ All records in set
 ☒ Selected records

☒ Main Contact  
☒ Provide Documents

Cancel

Reset

Save

7. On the Confirm Mass Coding popup, click on the Yes button.

Confirm Mass Coding

Are you sure you want to proceed with Mass Update?

Following fields will be updated:

Main Contact

Provide Documents

No

Yes

8. On the success message popup, click on the Get Results button.



Mass Coding

Room: TI Training Team SSU/eTMF Room

Success! Task is complete.

Get Results

9. Once the task is complete, the Contacts screen displays the updated metadata fields.

## Convert to Users

Administrators can convert contact(s) to room user(s).

To convert a contact to a user, follow the steps below.

1. Select a single or multiple contacts by clicking on their respective checkboxes.
2. Click on the Convert to User(s) button from the top menu bar.

| <div>  Mass Coding           <div>  Convert to User(s)           </div> <div>  Export           </div> </div> |                                                                                    |                    |                   |                     |              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------------|-------------------|---------------------|--------------|
| 1 - 5 of 5 (2 selected)                                                                                                                                                                                                                                                                                                                                          |                                                                                    |                    |                   |                     |              |
| <input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                         |                                                                                    | Room Name          | Site              | Contact Type        | Main Contact |
| <input checked="" type="checkbox"/>                                                                                                                                                                                                                                                                                                                              |   | TI Training Tea... | USA 001 Marti...  | Principal Invest... | Yes          |
| <input checked="" type="checkbox"/>                                                                                                                                                                                                                                                                                                                              |   | TI Training Tea... | GBR 002 Albus ... | Principal Invest... | Yes          |
| <input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                         |   | TI Training Tea... | BHS 003 Brad ...  | Principal Invest... | Yes          |
| <input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                         |  | TI Training Tea... | BHS 003 Brad ...  | Regulatory Con...   | Yes          |

3. On the Convert Selected Site Contact(S) To User(S) window, click on the Role\* dropdown and select Editor or Reader.
4. Click on the Actions dropdown and select the actions that the user would be allowed to perform in addition to the basic rights associated with their user access role.  
Note: The Actions dropdown displays options based on the role selected.
5. Click on the Convert Contact to Room User button.

### Convert Selected Site Contact(S) To User(S)

Role \*  
Editor

Actions  
Study Startup  
Page Manipulations eSignature  
Communications

|  | Name | First Name | Email | Contact Type           |
|--|------|------------|-------|------------------------|
|  |      |            |       | Principal Investigator |
|  |      |            |       | Principal Investigator |

Previous 1 of 1 Next

Cancel Convert Contact To Room User

- Once the contact is successfully converted to a user, it is displayed in the users list within the User Management module.

## Export

To export contacts, follow the steps below.

- On the Contacts screen, select users or click the Export button in the top menu bar.

Mass Coding
Convert to User(s)
Export

1 - 5 of 5 (0 selected)

|                          | Room Name              | Site    | Contact Type           |
|--------------------------|------------------------|---------|------------------------|
| <input type="checkbox"/> | TI Training Team SS... | USA 001 | Principal Investigator |
| <input type="checkbox"/> | TI Training Team SS... | GBR 002 | Principal Investigator |
| <input type="checkbox"/> | TI Training Team SS... | BHS 003 | Principal Investigator |
| <input type="checkbox"/> | TI Training Team SS... | BHS 003 | Regulatory Contact     |

- On the Export Contacts screen, select any one of the export options and click on the Next button within the Step 1.
  - Selected records

- b. All contacts in the current grid
- c. All contacts in the room

Note: If no contacts are selected, the Selected records radio button will be grayed out.

Export Contacts

Step 1 ● ○ ✕

Export Options

Select Metadata Fields 8

Source

☐ Selected records
 ☒ All contacts in the current grid
 ☐ All contacts in the room

Cancel

Next

3. Within the Step 2, select the required metadata fields and click on the Export button.

## Export Contacts

Step 2

Export Options

Select Metadata Fields 8

### Select Metadata Fields

Room Name
Site
Contact Type
Main Contact
Email Address
Full Name
Provide Documents
Status

Sort By Alphabet

8 Metadata Fields
8 Selected

8 General Fields
8 Selected

☒ Contact Type
☒ Email Address
☒ Full Name
☒ Main Contact
☒ Provide Documents
☒ Room Name
☒ Site
☒ Status

Cancel
Previous
Export

- On the Export Contacts popup, click on the Get Results button.



### Exporting Contacts

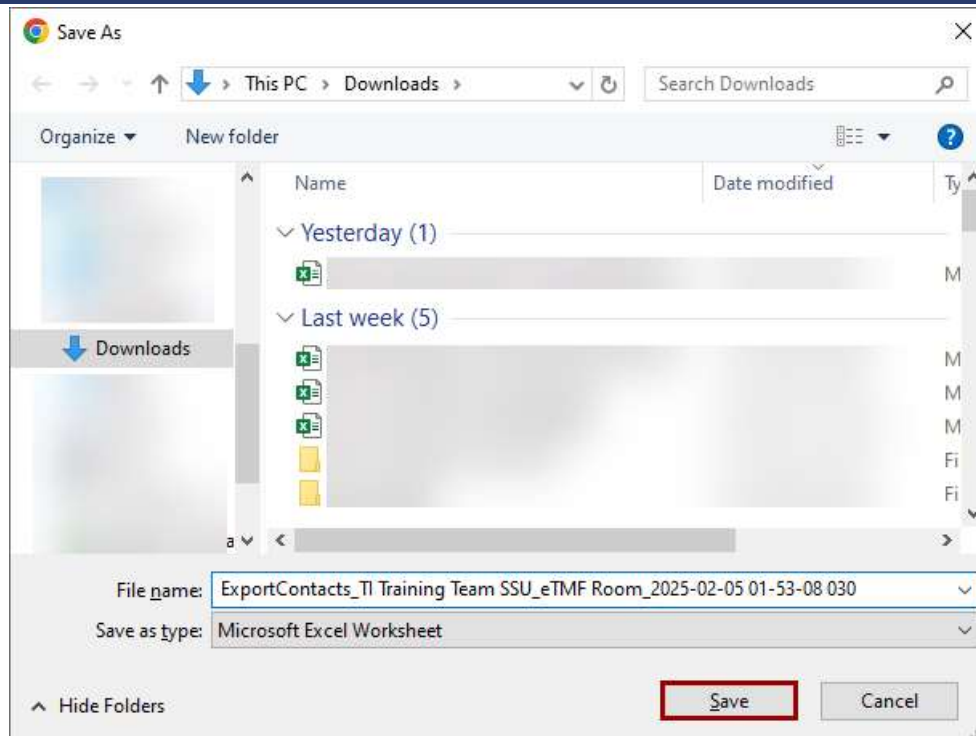
Room: TI Training Team SSU/eTMF Room

Finished: Export: 5 of 5 completed

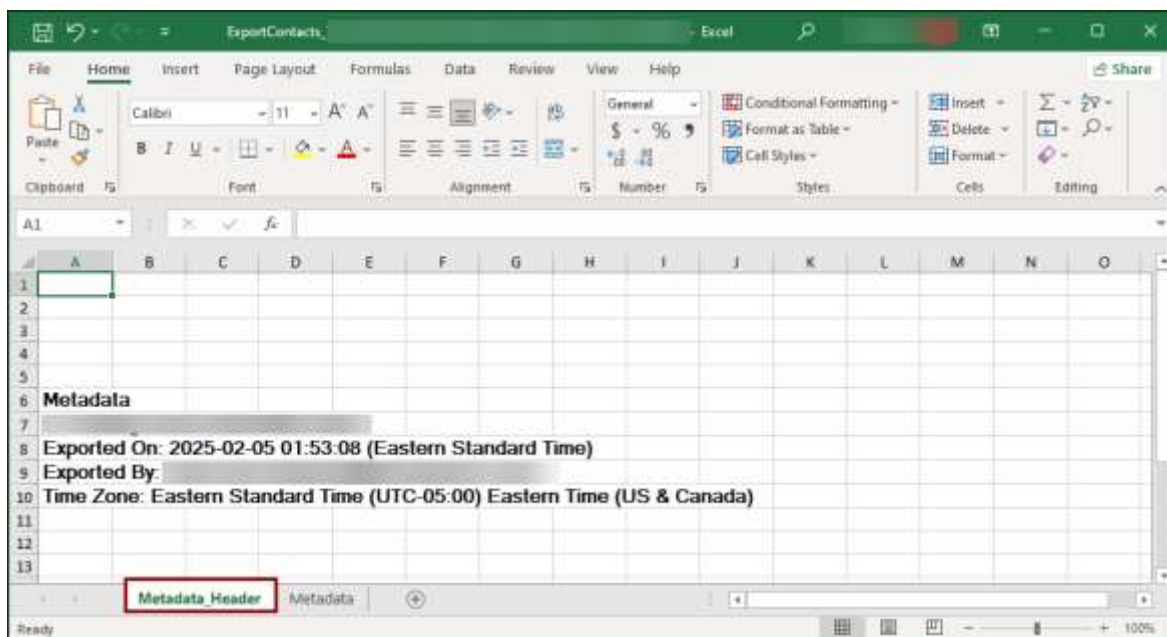
Success! Task is complete.

Get Results

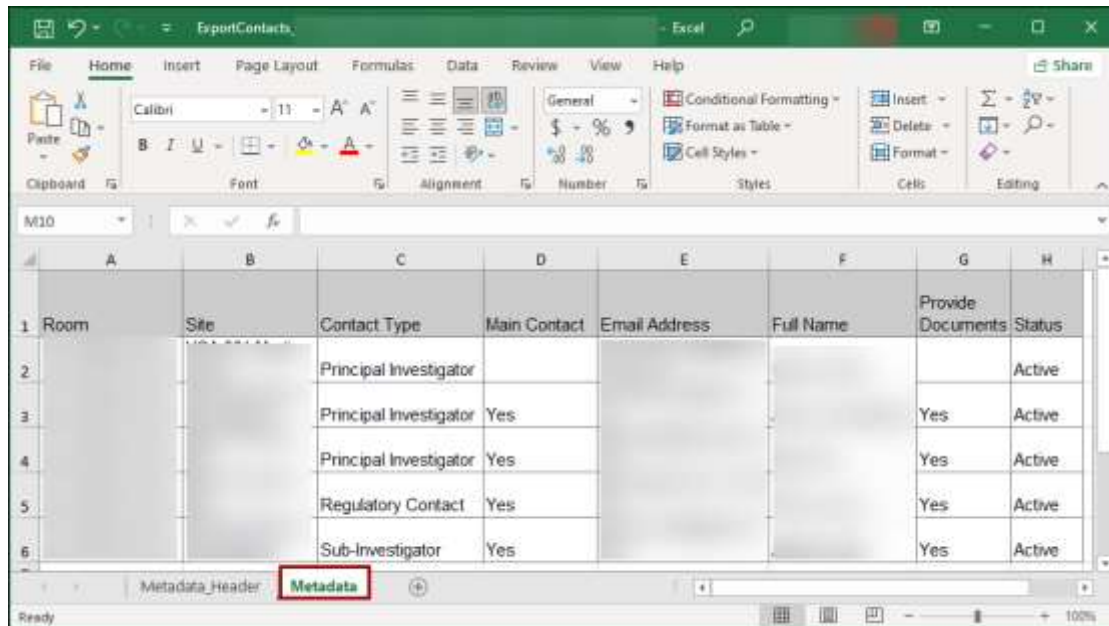
- Download the Microsoft Excel Worksheet on the local system.



6. On the downloaded file, click on the Metadata\_Header tab to view the header details i.e.,
  - a. Room name
  - b. Exported On
  - c. Exported By
  - d. Time zone



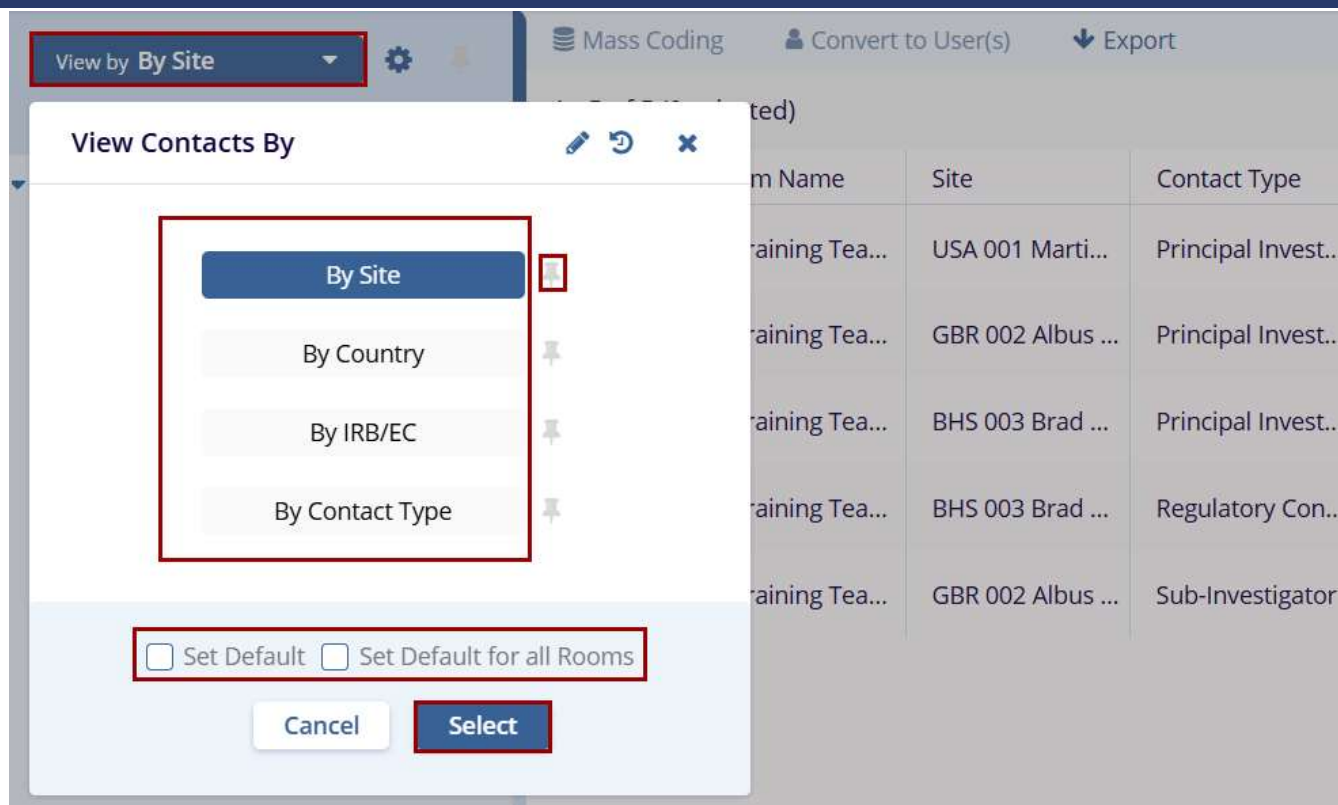
- Click on the Metadata tab, to view the contact details and the metadata.



## Contact Views

To access and configure the contact views, follow the steps below.

- On the Contacts screen, click on the View by dropdown.
- On the View Contacts By window, select a view by clicking on the view name.
  - By Site: Displays the contacts grouped by the site.
  - By Country: Displays contacts grouped by their country association.
  - By IRB/EC: Displays contacts grouped by the IRB/EC.
  - By Contact: Displays contacts grouped by the Contact Type.
- Click on the pin icon to pin a view and this view is selected once user access the Contacts modal.
- Check the Set Default checkbox to set the view as a default and Set Default for all Rooms to apply the view to all rooms.
- Click on the Select button once the desired view is selected.



## Customize Contacts views

Users can customize the contacts screen view by Managing columns and configuring views.

To manage columns and views on the Contacts screen, refer to the standard steps detailed in the Manage Columns section.



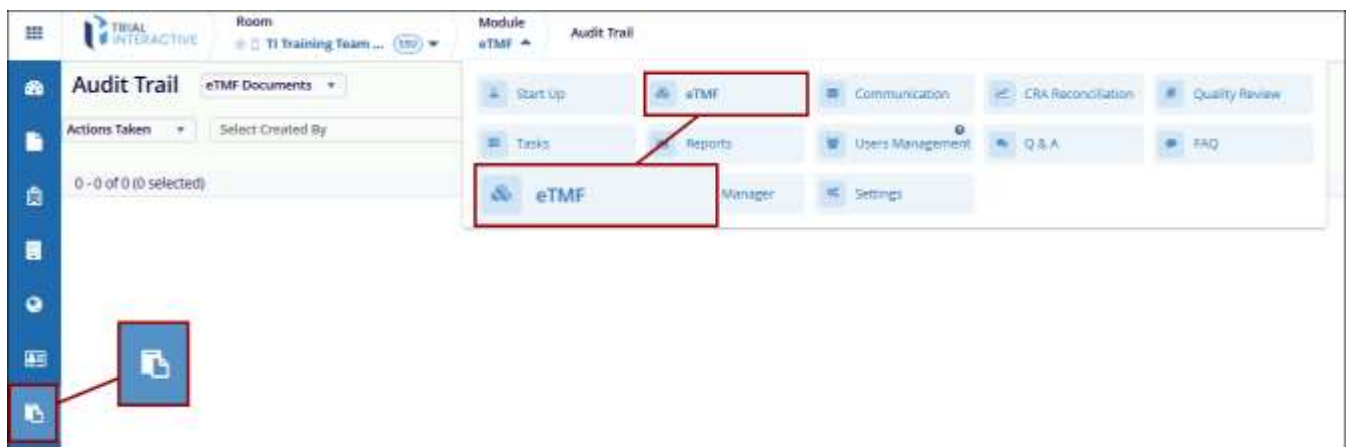
## Audit Trail

An Audit Trail is a security-relevant chronological set and source of records that provide evidence of the sequence of activities performed over a document. The changes made in a document by all users are displayed within the Audit Trail.

Note: By default, the audit trails grid pane is empty, and the documents are displayed only after entering and applying certain parameters and criteria.

To access the Audit Trail modal within the eTMF module, follow the steps below.

1. Click on the Module dropdown and select the eTMF option.
2. On the eTMF screen, navigate to the left-hand menu and select the Audit Trail modal.

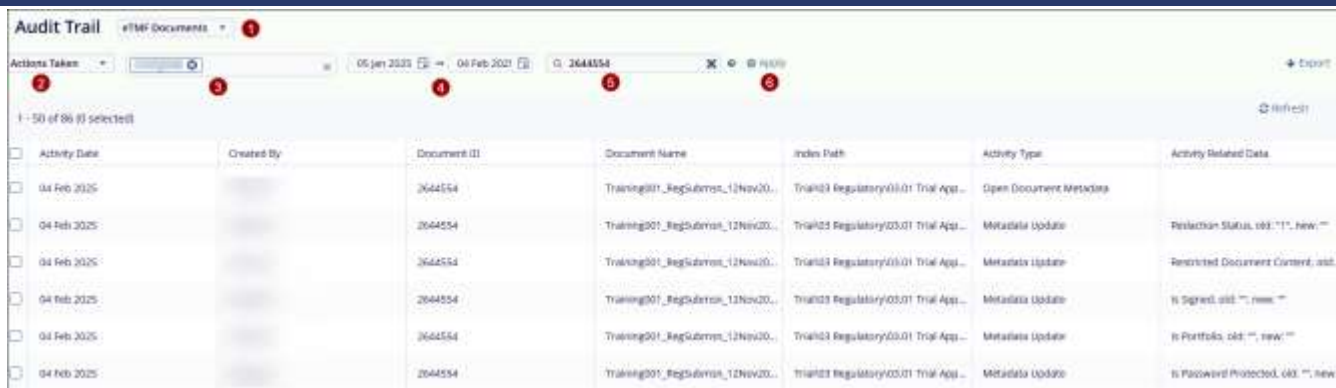


3. The Audit Trail screen displays options to apply certain filter criteria and export the audit trail details.

## Audit Trail Process

To retrieve the audit trail, follow the steps below.

1. On the Audit Trail screen, specify a parameter from the available dropdown options i.e., eTMF documents, Start-Up Documents, Start-Up and eTMF Documents, Folders, Placeholders, and Users.
2. Click on the Actions Taken dropdown and select or deselect actions by clicking on their respective checkboxes.
3. Specify one or multiple users in the Select Created By box.
4. Add the From and To dates by clicking on the calendar icon.
5. Add Document IDs separated by commas to retrieve data restricted to the specified document IDs.
6. Click on the Apply button.



| Activity Date | Created By | Document ID | Document Name                     | Index Path                            | Activity Type          | Activity Related Data                   |
|---------------|------------|-------------|-----------------------------------|---------------------------------------|------------------------|-----------------------------------------|
| 04 Feb 2025   |            | 2644554     | Training001_RegSubmiss_12Nov20... | Trials03 Regulatory03.01 Trial App... | Open Document Metadata |                                         |
| 04 Feb 2025   |            | 2644554     | Training001_RegSubmiss_12Nov20... | Trials03 Regulatory03.01 Trial App... | Metadata Update        | Protection Status, old: "1", new: ""    |
| 04 Feb 2025   |            | 2644554     | Training001_RegSubmiss_12Nov20... | Trials03 Regulatory03.01 Trial App... | Metadata Update        | Restricted Document Content, old: ""    |
| 04 Feb 2025   |            | 2644554     | Training001_RegSubmiss_12Nov20... | Trials03 Regulatory03.01 Trial App... | Metadata Update        | Is Signed, old: "", new: ""             |
| 04 Feb 2025   |            | 2644554     | Training001_RegSubmiss_12Nov20... | Trials03 Regulatory03.01 Trial App... | Metadata Update        | Is Portfolio, old: "", new: ""          |
| 04 Feb 2025   |            | 2644554     | Training001_RegSubmiss_12Nov20... | Trials03 Regulatory03.01 Trial App... | Metadata Update        | Is Password Protected, old: "", new: "" |

7. The Audit Trail screen displays data based on the applied filters and parameters.

Note: Refer to the sections below to understand filters, parameters and other actions within the Audit Trail modal.

## Audit Trail Parameters

Users can retrieve the audit trail based on selected parameters. The options in the "Actions Taken" dropdown are displayed according to the chosen parameter.

- eTMF Documents
- Start-Up Documents
- Start-Up and eTMF Documents
- Folders
- Placeholders
- Users



1. User Interface for eTMF Documents: When the audit trail for eTMF documents is retrieved, the data is presented in the following columns.

- Activity Date
- Created By
- Document ID
- Document Name
- Index Path

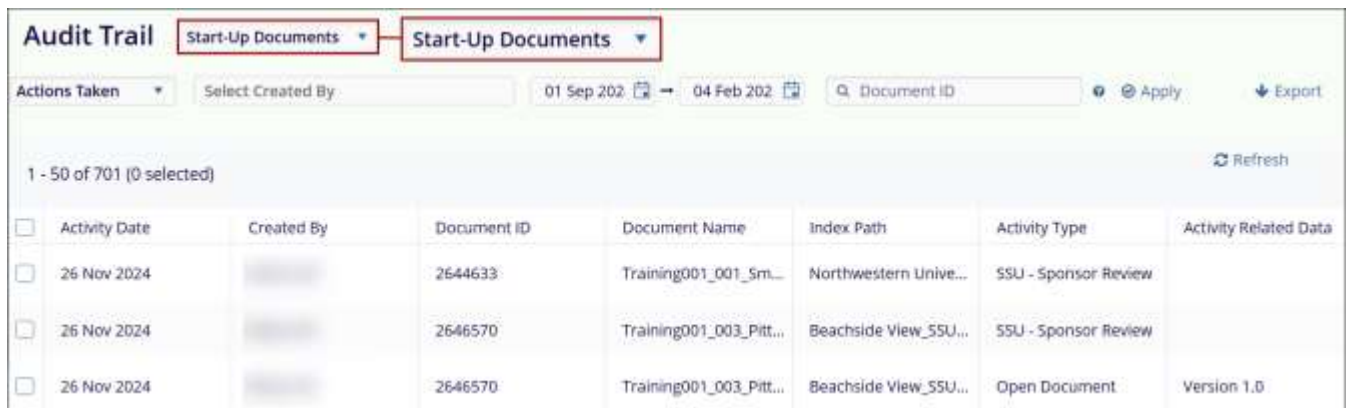
- f. Activity Type
- g. Activity Related Date



| Activity Date | Created By | Document ID | Document Name         | Index Path               | Activity Type   | Activity Related Data       |
|---------------|------------|-------------|-----------------------|--------------------------|-----------------|-----------------------------|
| 04 Feb 2025   |            | 2644554     | Training001_RegSub... | Trial\03 Regulatory\0... | Metadata Update | Is Signed, old: "", ne...   |
| 04 Feb 2025   |            | 2644554     | Training001_RegSub... | Trial\03 Regulatory\0... | Metadata Update | Is Portfolio, old: "", n... |
| 04 Feb 2025   |            | 2644554     | Training001_RegSub... | Trial\03 Regulatory\0... | Metadata Update | Is Password Protecte...     |

2. User Interface for Start-up Documents: When the audit trail for Start-up Documents is retrieved, the data is presented in the following columns.

- a. Activity Date
- b. Created By
- c. Document ID
- d. Document Name
- e. Index Path
- f. Activity Type
- g. Activity Related Date



| Activity Date | Created By | Document ID | Document Name           | Index Path            | Activity Type        | Activity Related Data |
|---------------|------------|-------------|-------------------------|-----------------------|----------------------|-----------------------|
| 26 Nov 2024   |            | 2644633     | Training001_001_Sm...   | Northwestern Unive... | SSU - Sponsor Review |                       |
| 26 Nov 2024   |            | 2646570     | Training001_003_Pitt... | Beachside View_SSU... | SSU - Sponsor Review |                       |
| 26 Nov 2024   |            | 2646570     | Training001_003_Pitt... | Beachside View_SSU... | Open Document        | Version 1.0           |

3. User Interface for Start-Up and eTMF documents: When the audit trail for Start-Up and eTMF Documents is retrieved, the data is presented in the following columns.

- a. Activity Date
- b. Created By
- c. Document ID
- d. Document Name
- e. Index Path

- f. Activity Type
- g. Activity Related Date

**Audit Trail** Start-Up and eTMF Documents Start-Up and eTMF Documents

Actions Taken Select Created By 01 Sep 2025 04 Feb 2025 Document ID Apply Export

1 - 50 of 1,973 (0 selected) Refresh

| <input type="checkbox"/> | Activity Date | Created By | Document ID | Document Name         | Index Path               | Activity Type        | Activity Related Data |
|--------------------------|---------------|------------|-------------|-----------------------|--------------------------|----------------------|-----------------------|
| <input type="checkbox"/> | 04 Feb 2025   |            | 2644554     | Training001_RegSub... | Trial\03 Regulatory\0... | Open Document Met... |                       |
| <input type="checkbox"/> | 04 Feb 2025   |            | 2644554     | Training001_RegSub... | Trial\03 Regulatory\0... | Open Document Met... |                       |
| <input type="checkbox"/> | 04 Feb 2025   |            | 2644554     | Training001_RegSub... | Trial\03 Regulatory\0... | Open Document Met... |                       |

4. Folders: When the audit trail for Folders is retrieved, the data is presented in the following columns.

- a. Activity Date
- b. Created By
- c. Folder ID
- d. Folder Name
- e. Index Path
- f. Activity Type
- g. Activity Related Date

**Audit Trail** Folders Folders

Actions Taken Select Created By 05 Jan 2025 04 Feb 2025 Select folders Select folders Apply Export

1 - 46 of 46 (0 selected) Refresh

| <input type="checkbox"/> | Activity Date | Created By | Folder id | Folder Name                    | Index Path                   | Activity Type       | Activity Related Data |
|--------------------------|---------------|------------|-----------|--------------------------------|------------------------------|---------------------|-----------------------|
| <input type="checkbox"/> | 31 Jan 2025   |            | 2643231   | 01.01.01 Trial Master File ... | Trial\01 Trial Management... | Open Folder Profile |                       |
| <input type="checkbox"/> | 31 Jan 2025   |            | 2643231   | 01.01.01 Trial Master File ... | Trial\01 Trial Management... | Open Folder Profile |                       |
| <input type="checkbox"/> | 31 Jan 2025   |            | 2643231   | 01.01.01 Trial Master File ... | Trial\01 Trial Management... | Open Folder Profile |                       |

5. Placeholders: When the audit trail for Placeholders is retrieved, the data is presented in the following columns.

- a. Activity Date
- b. Created By
- c. Placeholder ID
- d. Placeholder Name
- e. Index Path
- f. Activity Type
- g. Activity Related Date

| Audit Trail <span>Placeholders</span> <span>Placeholders</span>                                                                                                      |               |            |                |                                 |                 |                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|------------|----------------|---------------------------------|-----------------|-------------------------------------|
| <div> <div>Actions Taken</div> <div>Select Created By</div> <div>01 Sep 2024 → 04 Feb 2025</div> <div>Placeholder ID</div> <div>Apply</div> <div>Export</div> </div> |               |            |                |                                 |                 |                                     |
| <div>1 - 13 of 13 (0 selected)</div> <div>Refresh</div>                                                                                                              |               |            |                |                                 |                 |                                     |
| <input type="checkbox"/>                                                                                                                                             | Activity Date | Created By | Placeholder Id | Placeholder Name                | Activity Type   | Activity Related Data               |
| <input type="checkbox"/>                                                                                                                                             | 20 Nov 2024   | Reader AP  | 2658461        | Expected Protocol Amendment ... | Metadata update | Submitted Name, old: "", new: ""    |
| <input type="checkbox"/>                                                                                                                                             | 20 Nov 2024   | Reader AP  | 2658461        | Expected Protocol Amendment ... | Metadata update | Site Name, old: "", new: "26443..." |
| <input type="checkbox"/>                                                                                                                                             | 20 Nov 2024   | Reader AP  | 2658461        | Expected Protocol Amendment ... | Metadata update | Document Type, old: "", new: "2..." |

6. Users: When the audit trail for Users is retrieved, the data is presented in the following columns.

- Activity Date
- Created By
- User ID
- User Full Name
- User Email Address
- Activity Type
- Activity Related Data

Audit Trail

Users

Users

Actions Taken

Select Created By

05 Jan 2025

04 Feb 2025

All Users

Apply

Export

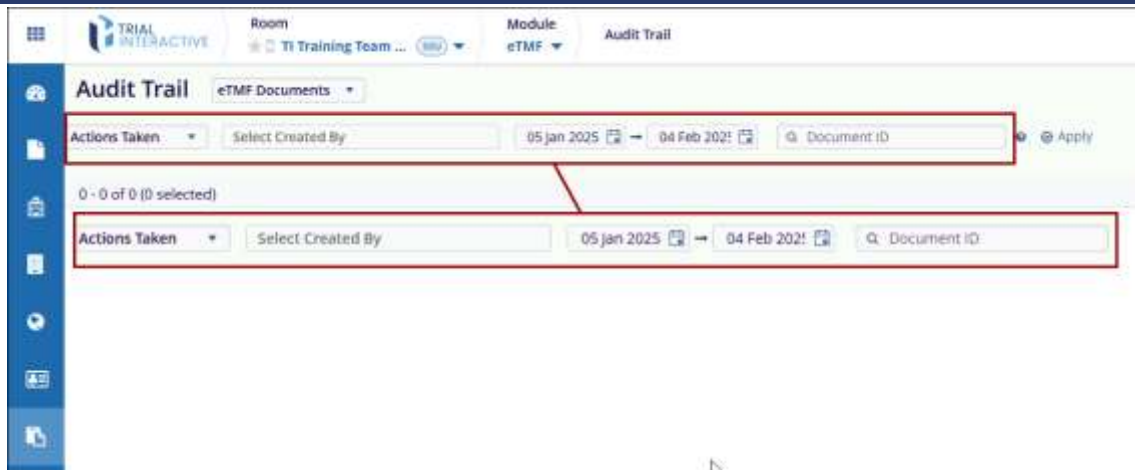
1 - 47 of 47 (0 selected)

Refresh

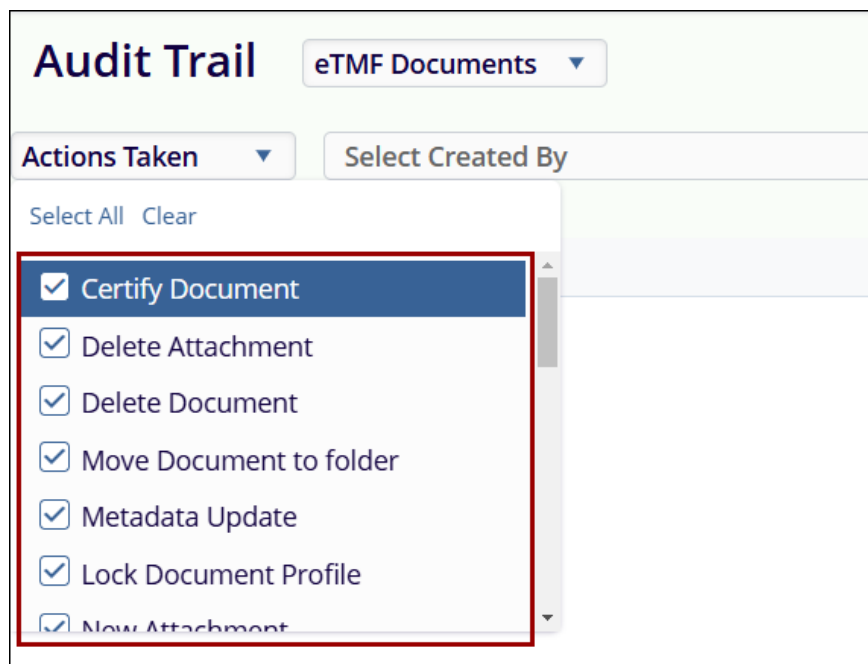
| <input type="checkbox"/> | Activity Date | Created By | User ID | User Full Name | User Email Address | Activity Type   | Activity Related Data         |
|--------------------------|---------------|------------|---------|----------------|--------------------|-----------------|-------------------------------|
| <input type="checkbox"/> | 04 Feb 2025   |            | 6352    |                |                    | Sign In To Room | Login to Room "TI Training... |
| <input type="checkbox"/> | 31 Jan 2025   |            | 6352    |                |                    | Sign In To Room | Login to Room "TI Training... |
| <input type="checkbox"/> | 31 Jan 2025   |            | 6352    |                |                    | Sign In To Room | Login to Room "TI Training... |

## Audit Trail Filters

Users can apply additional filters to the selected parameter. The following filters are available in the Audit Trail modal, allowing users to retrieve specific data.



1. **Actions Taken:** This dropdown displays a list of actions to be selected from the dropdown menu for filtering the audit trail as per the selected parameter. The Actions Taken dropdown populates and displays actions depending upon the parameter selected. Users can either select all actions or select specific actions by clicking on their respective checkboxes.



Refer to the table below to understand actions associated with each parameter.

| Parameter      | Actions Taken                                                                                                                                                                                                                                          |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| eTMF Documents | <ul style="list-style-type: none"> <li>• Certify Documents</li> <li>• Delete Attachment</li> <li>• Delete Document</li> <li>• Move Document to Folder</li> <li>• Metadata Update</li> <li>• Lock Document Profile</li> <li>• New Attachment</li> </ul> |

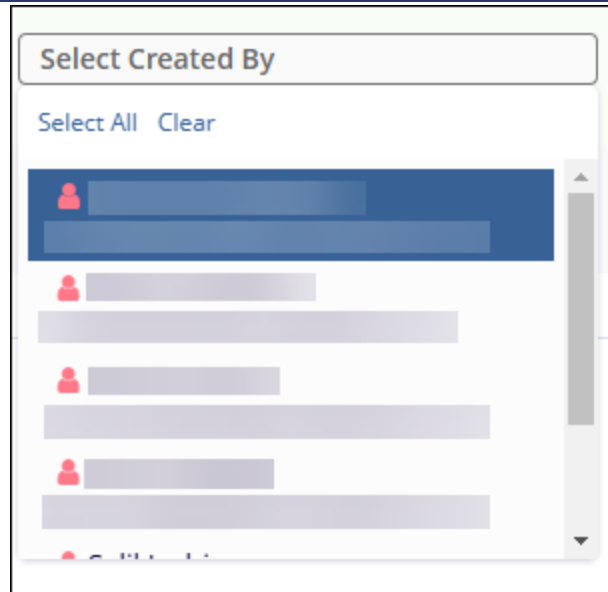
| Parameter                   | Actions Taken                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                             | <ul style="list-style-type: none"> <li>• New Document Profile</li> <li>• Open Document</li> <li>• Open Document Metadata</li> <li>• QC Workflow – Approve Document</li> <li>• QC Workflow – Claim Document</li> <li>• QC Workflow – Clarification</li> <li>• QC Workflow – Reassign</li> <li>• QC Workflow – Release Document</li> <li>• QC Workflow – Swim Lane</li> <li>• Query – Create Query</li> <li>• Query – Respond to Query</li> <li>• Query – Update Query</li> <li>• Replace Attachment</li> <li>• Security Update</li> <li>• Send eSignature Request</li> <li>• Send Mail</li> <li>• Unlock Document Profile</li> </ul>                                                     |
| Start-Up Documents          | <ul style="list-style-type: none"> <li>• Delete Document</li> <li>• Move Document to Folder</li> <li>• Metadata Update</li> <li>• New Attachment</li> <li>• New Document Profile</li> <li>• Not Applicable</li> <li>• Open Document</li> <li>• Open Document Metadata</li> <li>• SSU – New Essential Document</li> <li>• SSU – QC Review</li> <li>• SSU – Regulatory Review</li> <li>• SSU – Sponsor Review</li> </ul>                                                                                                                                                                                                                                                                  |
| Start-Up and eTMF Documents | <ul style="list-style-type: none"> <li>• Certify Documents</li> <li>• Delete Attachment</li> <li>• Delete Document</li> <li>• Move Document to Folder</li> <li>• Metadata Update</li> <li>• Lock Document Profile</li> <li>• New Attachment</li> <li>• New Document Profile</li> <li>• Not Applicable</li> <li>• Open Document</li> <li>• Open Document Metadata</li> <li>• QC Workflow – Approve Document</li> <li>• QC Workflow – Claim Document</li> <li>• QC Workflow – Clarification</li> <li>• QC Workflow – Reassign</li> <li>• QC Workflow – Release Document</li> <li>• QC Workflow – Swim Lane</li> <li>• Query – Create Query</li> <li>• Query – Respond to Query</li> </ul> |



| Parameter   | Actions Taken                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             | <ul style="list-style-type: none"> <li>• Query – Update Query</li> <li>• Replace Attachment</li> <li>• Security Update</li> <li>• Send eSignature Request</li> <li>• Send Mail</li> <li>• SSU – New Essential Document</li> <li>• SSU – QC Review</li> <li>• SSU – Regulatory Review</li> <li>• SSU – Sponsor Review</li> <li>• Unlock Document Profile</li> </ul>                                                                               |
| Folder      | <ul style="list-style-type: none"> <li>• Edit Folder</li> <li>• Metadata Update</li> <li>• Check Out</li> <li>• New Folder</li> <li>• Open Folder Profile</li> <li>• Security Update</li> <li>• Check In</li> </ul>                                                                                                                                                                                                                              |
| Placeholder | <ul style="list-style-type: none"> <li>• Delete Placeholder</li> <li>• Metadata Update</li> <li>• New Placeholder</li> <li>• Security Update</li> </ul>                                                                                                                                                                                                                                                                                          |
| Users       | <ul style="list-style-type: none"> <li>• Add to Contacts</li> <li>• Add User as Contact</li> <li>• Add User to Group</li> <li>• Assign Group Actions to User</li> <li>• Assign User Actions</li> <li>• Edit User</li> <li>• New User</li> <li>• Remove from Contacts</li> <li>• Remove Study Site Contact</li> <li>• Remove User from Group</li> <li>• Sign In to Room</li> <li>• User Access Level Update</li> <li>• User Invitation</li> </ul> |

2. **Select Created By:** In the Select Created By field, users can specify one or more usernames associated with document creation in eTMF. When a username is selected, the Audit Trail screen filters and displays records corresponding to the specified user.





3. **Date Filters:** Users must enter start and end dates in their respective fields to search for a document. By default, the start date is set to the previous month, and the end date is set to today. To select dates, click on the calendar icon. Once the dates are chosen, click the Apply button on the right side to view the search results. Users can also select dates from the previous year by scrolling up in the Months field.



4. **Document ID Filter:** The Document ID field allows users to retrieve audit trial for a specific document by entering its ID number, separated by commas. After entering the document ID, users must click the Apply button on the right side to view the search results.

**Audit Trail** eTMF Documents

Actions Taken Select Created By 05 Jan 2025 → 04 Feb 2025 2644554 X Apply

1 - 50 of 194 (0 selected)

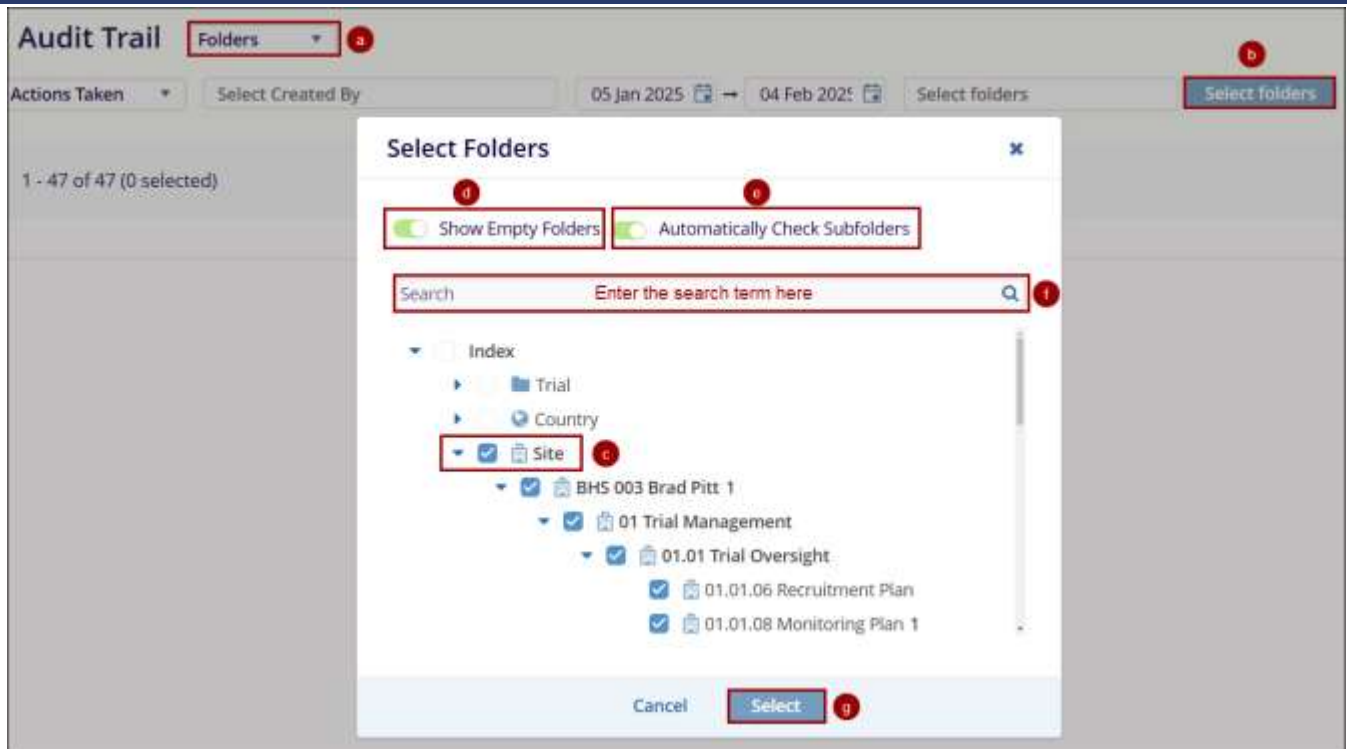
| <input type="checkbox"/> | Activity Date | Created By | Document ID | Document Name         | Index Path               | Activity Type        |
|--------------------------|---------------|------------|-------------|-----------------------|--------------------------|----------------------|
| <input type="checkbox"/> | 04 Feb 2025   |            | 2644554     | Training001_RegSub... | Trial\03 Regulatory\0... | Open Document Met... |
| <input type="checkbox"/> | 04 Feb 2025   |            | 2644554     | Training001_RegSub... | Trial\03 Regulatory\0... | Open Document Met... |
| <input type="checkbox"/> | 04 Feb 2025   |            | 2644554     | Training001_RegSub... | Trial\03 Regulatory\0... | Open Document Met... |

Note: The Document ID Filter is applicable only for eTMF Documents, Start-Up Documents and Start-Up and eTMF Documents.

5. **Select Folders:** The Select Folders field allows users to specify certain folders and retrieve the audit trail for those specified folders.

To specify folders, follow the steps below.

- a. Select Folders as the parameter.
- b. Click on the Select Folders button.
- c. On the Select Folders screen, expand the desired category and select the folder.
- d. Toggle on the Show Empty Folders switch to display empty folders.
- e. Enable the Automatically Check Subfolders toggle switch to automatically select folders associated with the parent category.
- f. To search for a specific folder, enter the search term in the Search box.
- g. Click on the Select button.



Note: The Select Folders Filter is applicable only for the Folders parameter.

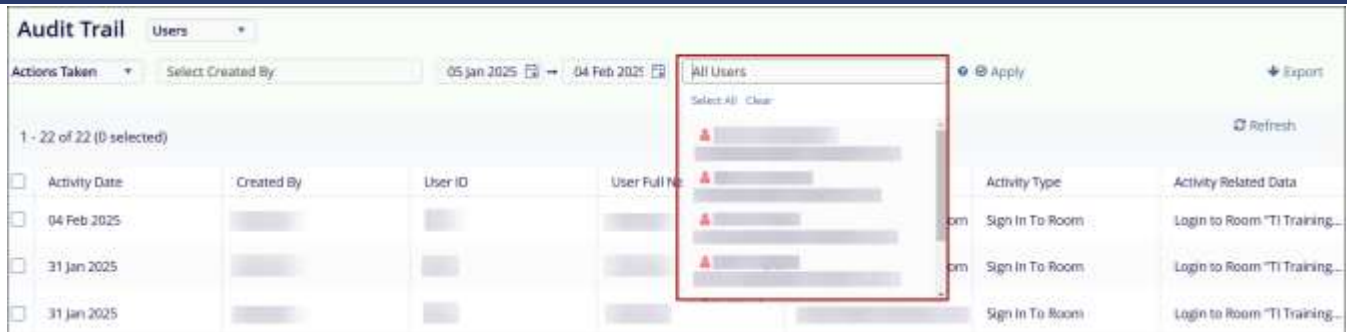
6. Placeholder ID: The Placeholder ID field allows users to retrieve audit trial for a specific placeholder by entering its ID number, separated by commas. After entering the placeholder ID, users must click the Apply button on the right side to view the search results.



| Activity Date | Created By | Placeholder Id | Placeholder Name                | Activity Type   | Activity Related Data                 |
|---------------|------------|----------------|---------------------------------|-----------------|---------------------------------------|
| 20 Nov 2024   | Reader AP  | 2658460        | Expected Protocol Amendment ... | Metadata update | Submitted Name, old: "", new: ""      |
| 20 Nov 2024   | Reader AP  | 2658460        | Expected Protocol Amendment ... | Metadata update | Document Type, old: "", new: ""       |
| 20 Nov 2024   | Reader AP  | 2658460        | Expected Protocol Amendment ... | Metadata update | Date Type, old: "", new: "Version..." |

Note: The Placeholder ID filter is applicable only for Placeholder's parameter.

7. All Users: The All Users filed allows users to retrieve audit trail for specific users by entering multiple user names. After specifying user names, users must click the Apply button on the right side to view the search results.



Note: The All Users filter is applicable only for Users parameter.

8. Refresh: The Refresh button is visible and accessible when the audit trail results are displayed. When a parameter or a filter is updated, users need to click the Refresh button to update the audit trail records as per the newly applied filters and parameters.



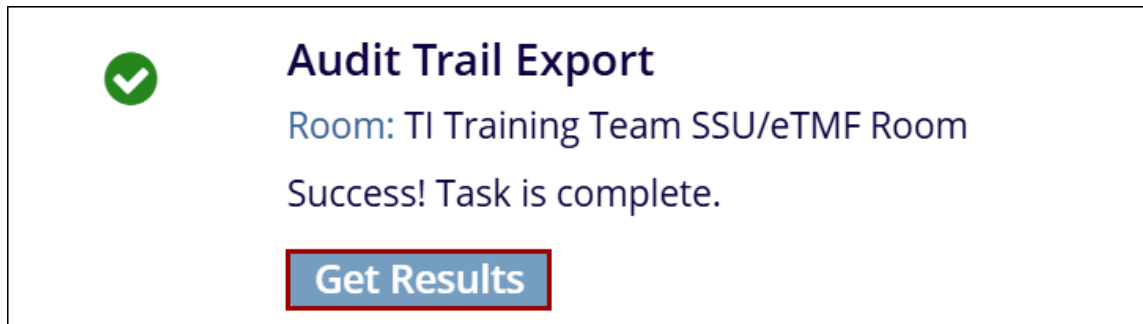
## Export Audit Trail

To export the Audit Trail data, follow the steps below.

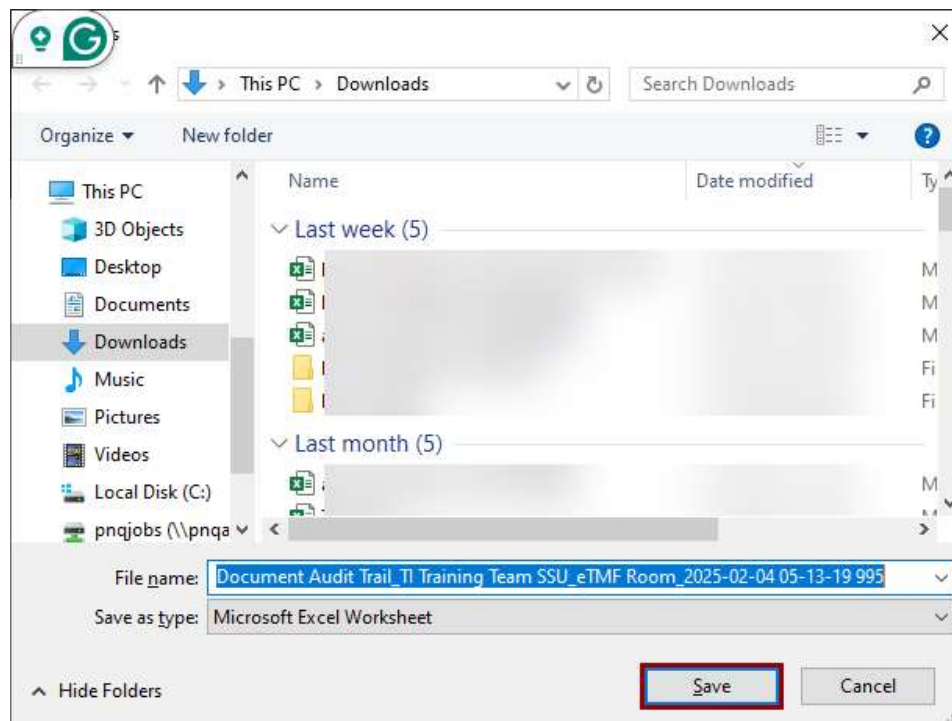
1. On the Audit Trail screen, click on the Export button.



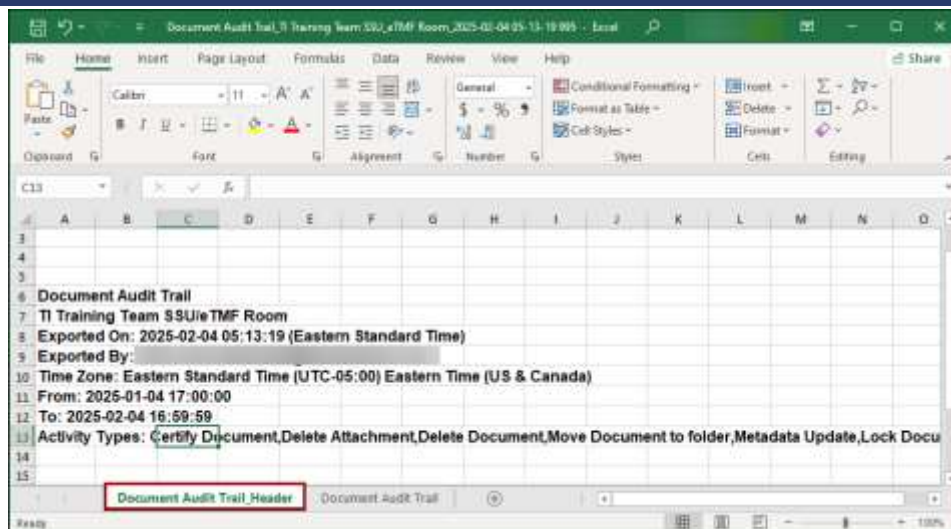
2. On the Audit Trail Export popup displaying the success message, click on the Get Results button.



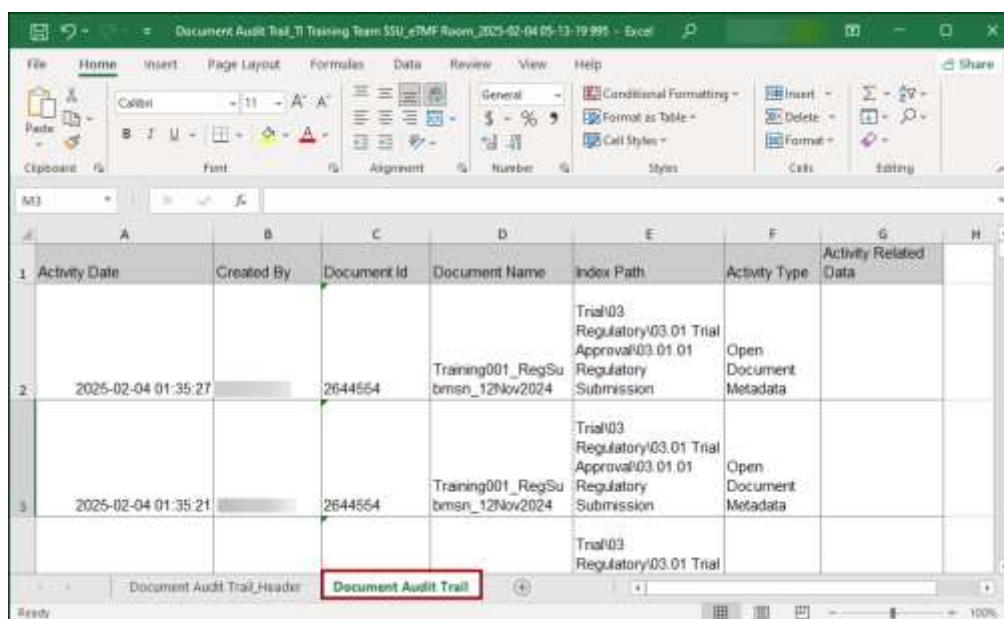
3. Download the Microsoft Excel Worksheet containing the export data into the local system.



4. On the downloaded file, click on the Document Audit Trail\_Header tab to view the header related details.



- Click the Download Audit Trail tab to access audit trail details.



The screenshot shows an Excel spreadsheet with the following data in the 'Document Audit Trail' table:

| Activity Date       | Created By | Document Id | Document Name                       | Index Path                                             | Activity Type                | Activity Related Data |
|---------------------|------------|-------------|-------------------------------------|--------------------------------------------------------|------------------------------|-----------------------|
|                     |            |             |                                     | Trial03<br>Regulatory/03.01 Trial<br>Approval/03.01.01 | Open<br>Document<br>Metadata |                       |
| 2025-02-04 01:35:27 |            | 2644554     | Training001_RegSu<br>bmsn_12Nov2024 | Regulatory<br>Submission                               |                              |                       |
| 2025-02-04 01:35:21 |            | 2644554     | Training001_RegSu<br>bmsn_12Nov2024 | Regulatory<br>Submission                               | Open<br>Document<br>Metadata |                       |
|                     |            |             |                                     | Trial03<br>Regulatory/03.01 Trial                      |                              |                       |

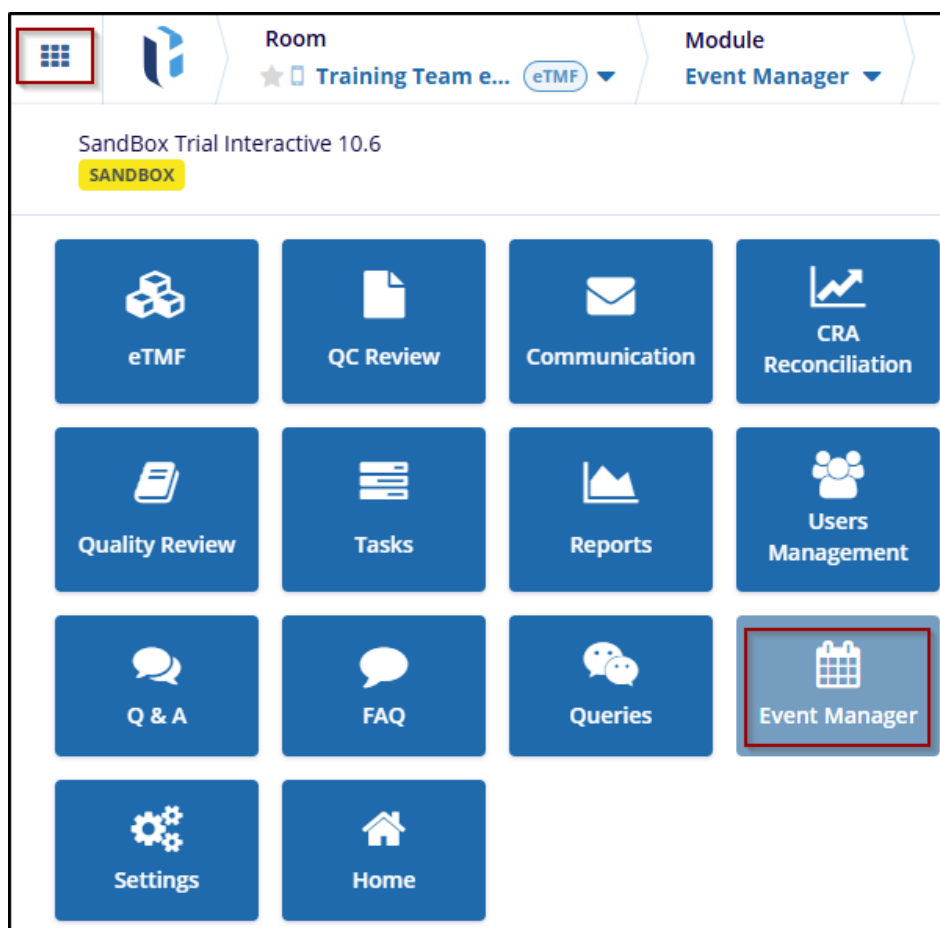
The 'Document Audit Trail' tab is selected and highlighted with a red box.

## CHAPTER 7. EVENTS MODULE

The Event Manager module was introduced to streamline the management of amendments, milestones, visits, and other events that occur during a clinical trial. It is essential to have a simple and efficient way to track clinical events as they happen to maintain an accurate picture of eTMF health. By doing so, the eTMF can automatically recognize the required documents associated with each event, plan their due dates, and assign responsible parties as amendments, visits, and other activities take place.

Events can be linked to eTMF Required Document and Placeholder definitions, offering an effective way to manage study milestones. This automatic application of planned documents enhances the quality of eTMF health measurement. Placeholders are defined and applied as part of amendments, milestones, visits, and other trial activities, with the flexibility to include or remove sites and countries as needed.

The Event Manager module can be accessed from the navigation grid at the top left corner.



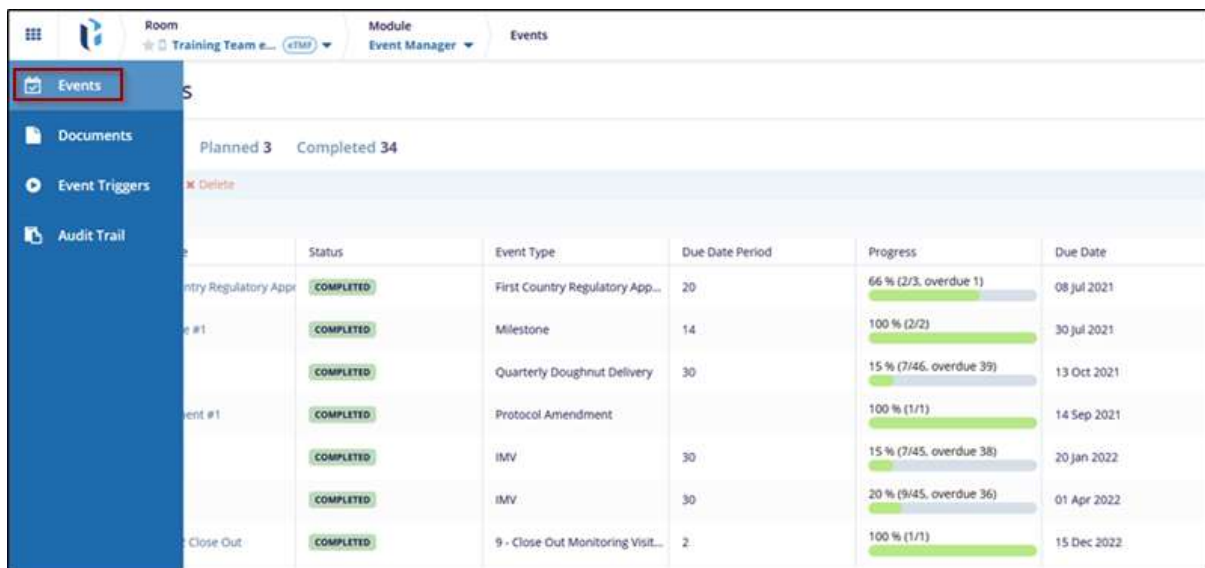


## Events

The Events section provides an organized view of all scheduled and completed events within the system. It includes filtering options for different event statuses such as All Events, Planned, and Completed.

Before creating a specific event in the system, ensure the event type has been created. If your room has pre-populated event types based on the system's default settings or milestones cloned from another room, the user can use those. However, there may be instances where creating a custom event type is necessary.

Users can access Events by selecting Events in the menu bar on the left-hand navigation pane.



| Status    | Event Type                        | Due Date Period | Progress                | Due Date    |
|-----------|-----------------------------------|-----------------|-------------------------|-------------|
| COMPLETED | First Country Regulatory App...   | 20              | 66 % (2/3, overdue 1)   | 08 Jul 2021 |
| COMPLETED | Milestone                         | 14              | 100 % (2/2)             | 30 Jul 2021 |
| COMPLETED | Quarterly Doughnut Delivery       | 30              | 15 % (7/46, overdue 39) | 13 Oct 2021 |
| COMPLETED | Protocol Amendment                |                 | 100 % (1/1)             | 14 Sep 2021 |
| COMPLETED | IMV                               | 30              | 15 % (7/45, overdue 38) | 20 Jan 2022 |
| COMPLETED | IMV                               | 30              | 20 % (9/45, overdue 36) | 01 Apr 2022 |
| COMPLETED | 9 - Close Out Monitoring Visit... | 2               | 100 % (1/1)             | 15 Dec 2022 |

Access the Events, any previously created events should be displayed in the window. Double-click on the Event to modify. The Event detail page will open. The event profile has three tabs:

- All Events: This tab includes the event name of the all status, any impacted sites or countries, event type, etc.
- Planned: This tab displays the planned events, with the event name, event type, planned date etc.
- Completed: This tab displays the completed events, with the event name, event type, completed date etc.

## Create Events

Before creating events, users must ensure that required documents are properly set up. It is recommended to make any necessary changes in the room's Configuration Manual and coordinate with the Trial Interactive Service Desk to ensure accuracy. Advanced users can refer to the section on updating required documents for instructions on adjusting these

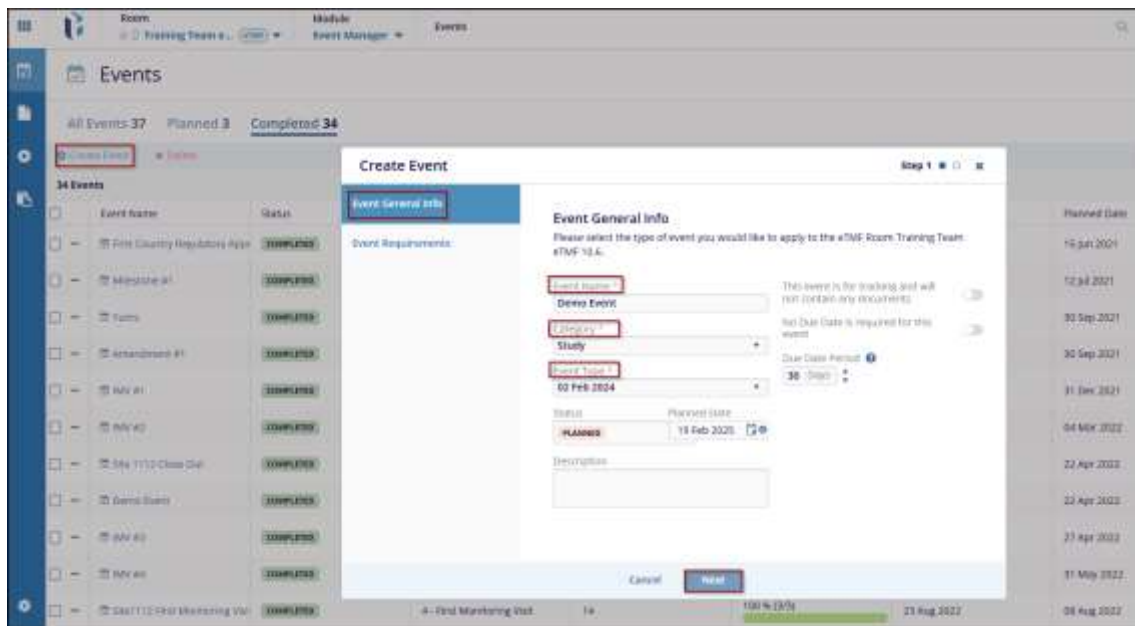


requirements.

Users will have the option to specify whether a document type is required 'Immediately' or upon 'Event Completion'. A placeholder will be automatically created for any document marked as required immediately. Documents associated with events may not be due right away; therefore, placeholders for these documents will only be generated once the associated event is created and marked as 'Completed'. When the event is marked as completed, the placeholders will become visible in the room and will affect eTMF completeness, but they will not appear before that.

To create event, follow these steps:

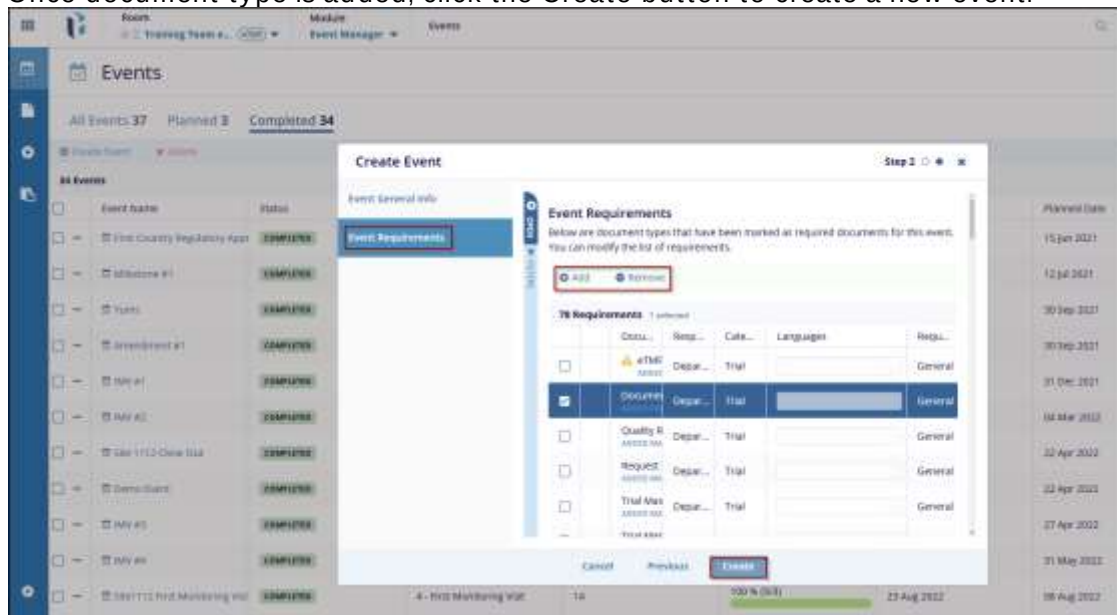
1. In Event Manager module, go to the Events section by clicking the calendar icon in the left pane
2. Click the Create Event button in the top menu bar above the list of events.
3. Using the Category field, indicate whether the event being planned is a Study, Country, or Site level event.
4. Choose the Event Type from the dropdown menu.
5. Give the event a name and fill out any other fields as desired.
  - The planned date field will be critical to tracking the timeliness of event document submissions.
  - The Due Date Period should be automatically populated based on the value entered during the creation of the event type.
  - The Status field can be used to indicate whether an event is being planned or has already been completed, most events will be created with the status of planned.



6. Press Next, the next screen allows the user to confirm whether all required document types for this event are displayed. The list will be populated based on the values chosen during the creation of the Event Type.

- If another document type is required, the user can press the Add button in the menu bar above the right panel. This will open the Add Document Type to Event window.
- Use the Search bar or manually drill down in the folder structure to locate the required document type and press Add.

7. Once document type is added, click the Create button to create a new event.

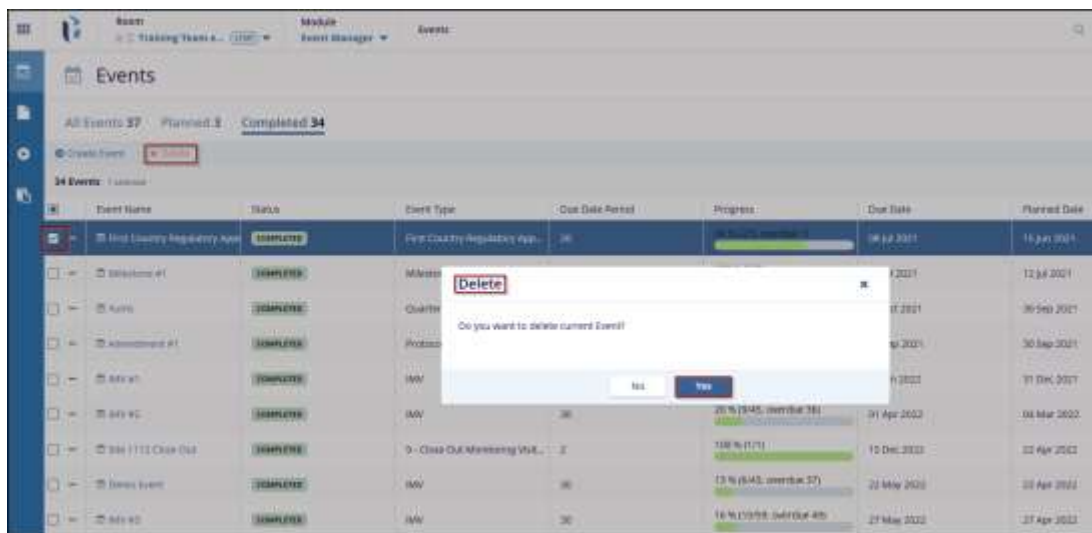


## Delete Events

The Delete button in the Events section allows users to remove selected events from the system

To Delete Events, follow these steps:

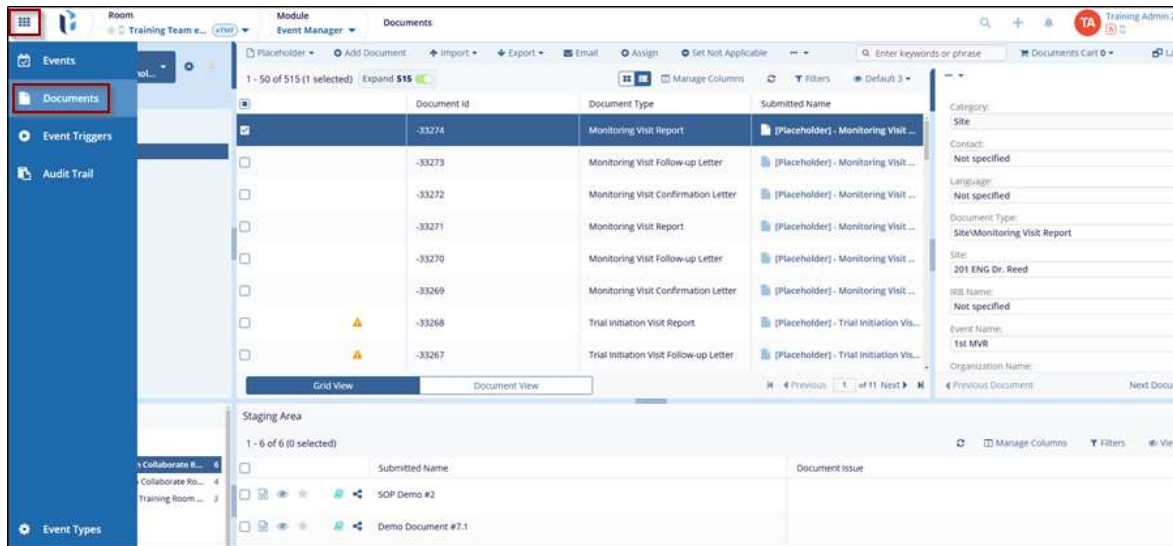
1. From the Events grid, select the event(s) you want to delete by checking the box next to the event name.
2. Click the Delete button in the top menu bar, next to Create Events
3. A confirmation pop-up will appear, click Yes to confirm the deletion or click No to cancel the deletion.
4. A success message will appear, indicating the event(s) were successfully deleted.



## Documents Events

The Documents Events section provides a structured interface for managing, tracking, and organizing documents associated with various events. It allows users to efficiently view and process document-related activities within an event-driven workflow.

Users can access documents events by selecting Documents in the menu bar on the left-side navigation pane.



## How to apply filter for View Documents

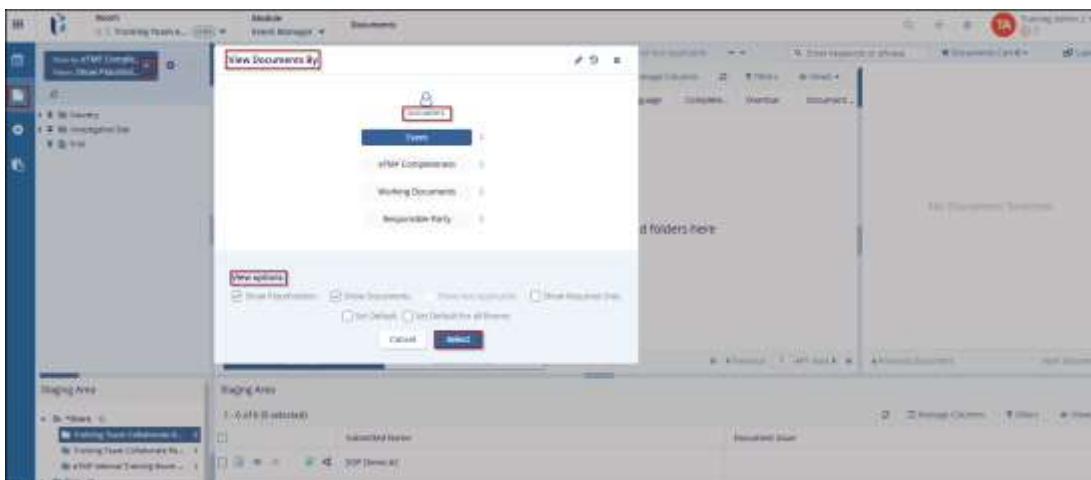
In the View Documents By, users can select a view for a documents event review based on requirements

Steps to apply View Documents By filter:

1. Navigate to the Documents section from the Event Manager module, at the top of the Index pane, click the View By dropdown menu.
2. This dropdown menu allows users to choose how they want to view the documents.
3. Select the available documents views under four categories: Event eTMF, Completeness, Working, Documents, Responsible Party.
4. Based on user requirements, select one of the options from View Documents by options.
5. If the user needs to review, the user has the option to make their selection the default view:

Set Default: this will set the selected view as the default for the current session.

Set Default for All Rooms: this will make the selection the default for all rooms, not just the current one.



6. After selecting the view documents by options, click Select to apply the changes, these changes will reflect at the top of the Index pane, or click the Cancel button to discard the changes.
7. After applying the selection from View Document by options, the user can see the folder, based on the selections.

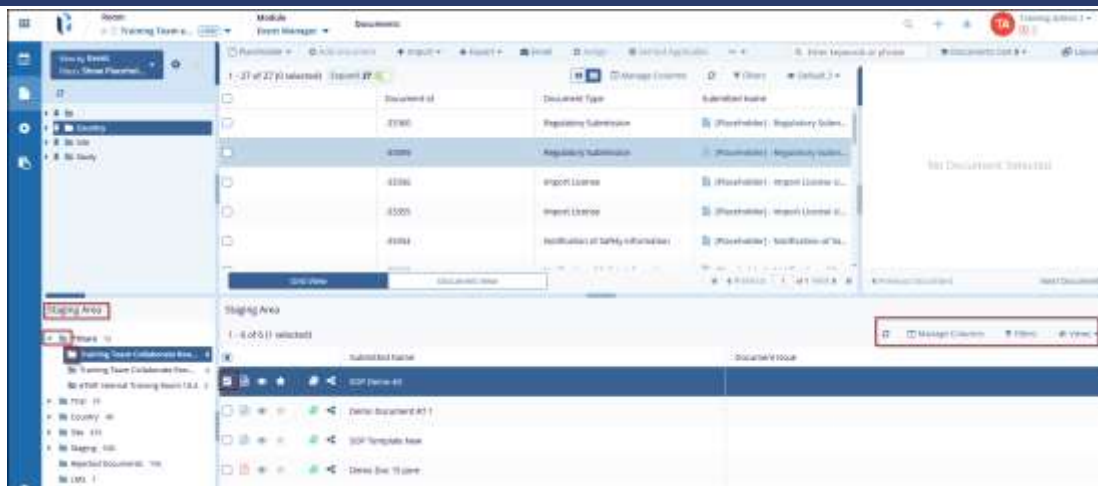
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## How to use Staging Area

In the Staging Area, user can find folder related to documents. Folder displays its eTMF Health measurement at the study, country, and site levels.

Steps to select Staging Area document:

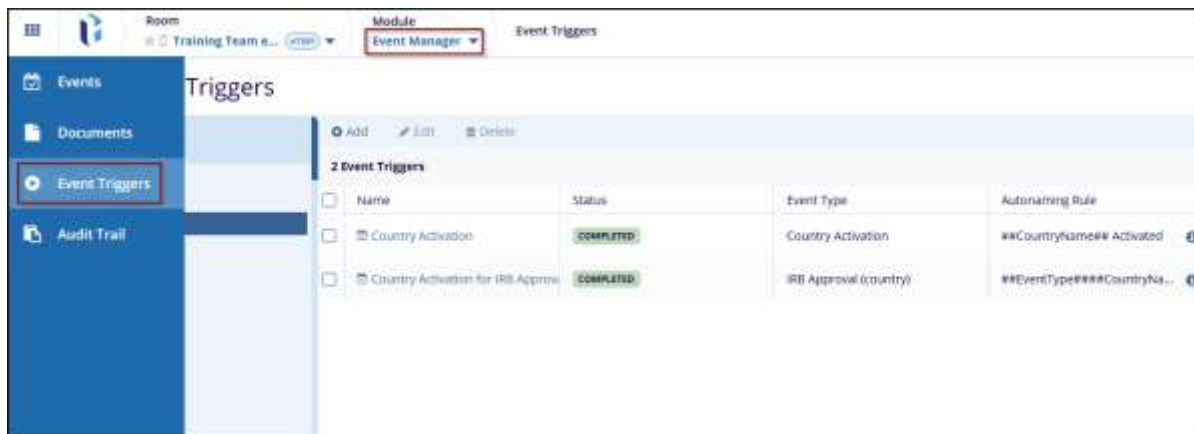
1. Navigate to the Documents section from the Event Manager module, at the top of the Index pane, click the Staging Area dropdown menu.
2. This dropdown menu allows users to select the documents, from the staging area folders.
3. Select the available documents views under folders: Share, Trial, Country, Site, etc.
4. Once folder is selected, documents are reflected on the right side of staging area, where user can access tools such as Refresh, Manage Column, Filter, Views, etc.



## Events Trigger

An Event Trigger display folder that carried statuses of each event at the study, country, and site levels.

Users can access the Events Trigger by selecting it from the menu bar on the left-side of navigation pane, this section will explain you how to add, edit and delete event trigger.



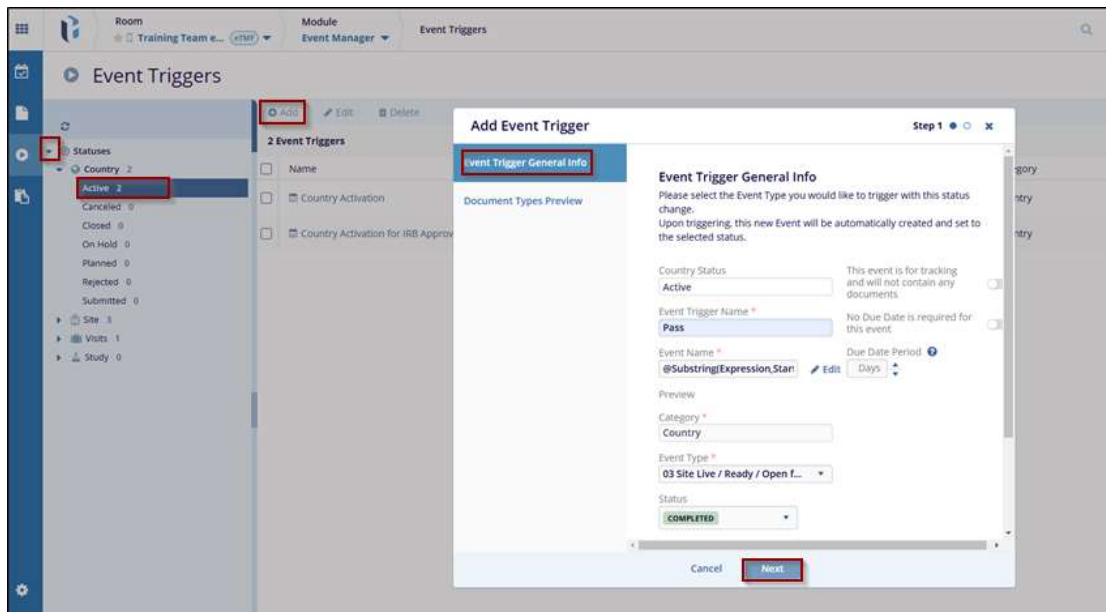
## Add Event Trigger

The Add button in the Event Trigger allows user to defining the event type and aligns it with the automatic creation of the event and set to the selected status.

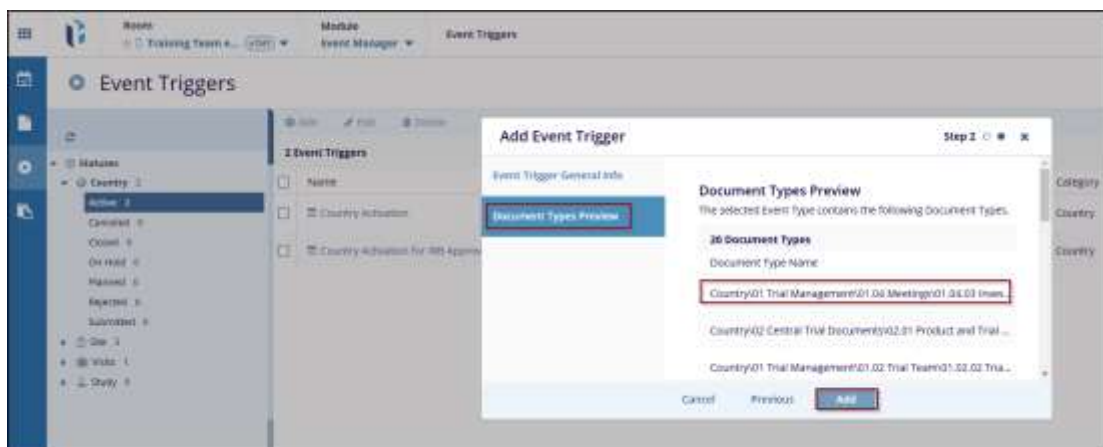
To Add Event Trigger, follow these steps:

1. Open the Event Manager module from the left-side menu and select Event Triggers to view existing triggers.
2. Click the statuses dropdown, select the statuses such as active or close in that user can add Event Trigger,

3. Click the Add button to create a new trigger in the selected statuses.
4. In the Event Trigger General Info screen, enter the Event Trigger Name, configure Event Name auto naming, if necessary, select the Category (e.g., Country), choose an Event Type, and optionally set a Due Date Period if required, choose an Event Type, set the Status to COMPLETED, select the Set Event Completed Date option (either 'Same as Status Date' from the Country profile or 'No Event Completed Date'), and add a Description if needed, then click Next.

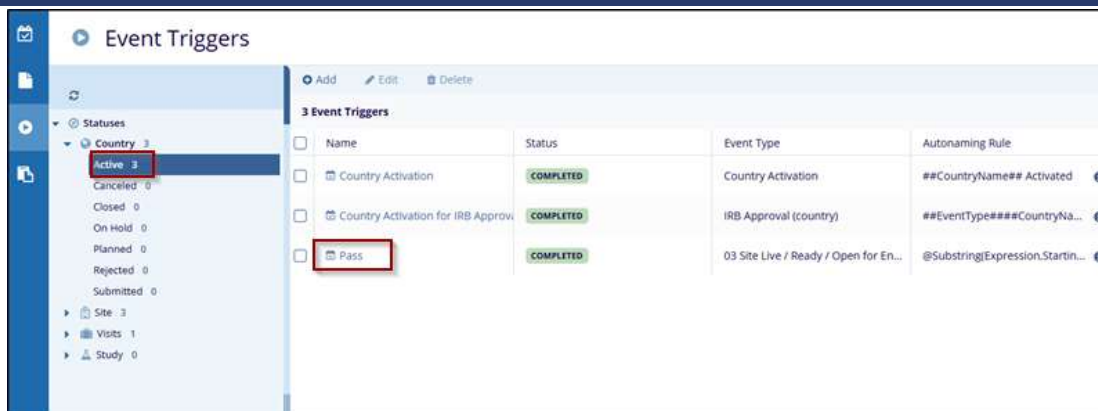


5. Click Next to proceed, review the details, and save the event trigger.



6. Added Trigger will be present in Grid.





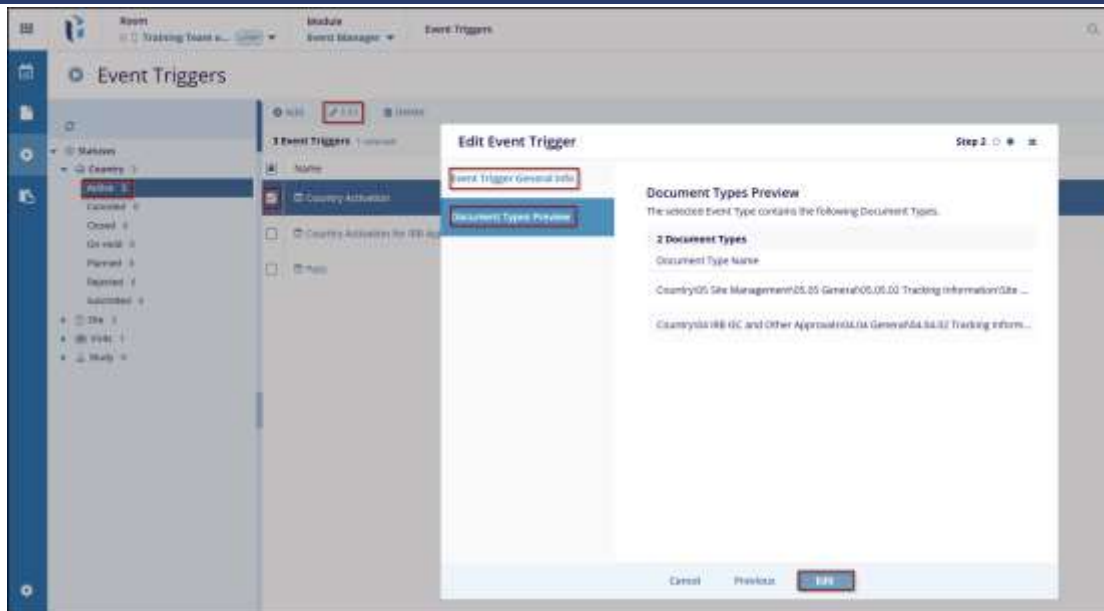
## Edit Event Trigger

The Edit button in the Event Trigger allows user to edit the event type and the selected status.

### Steps to Edit Event Trigger

1. Select Event Triggers from the Event Manager module to view the list of triggers.
2. check the box next to the trigger you want to edit, and click Edit.
3. In the Event Trigger General Info screen, make any necessary changes to fields such as Event Trigger Name, Event Name, Category, Event Type, and Due Date Period, then click Next.
4. On the Document Types Preview screen, review or edit the associated document types if needed, and click Edit to save your changes.
5. A confirmation message will appear, indicating the Event Trigger was successfully edited.



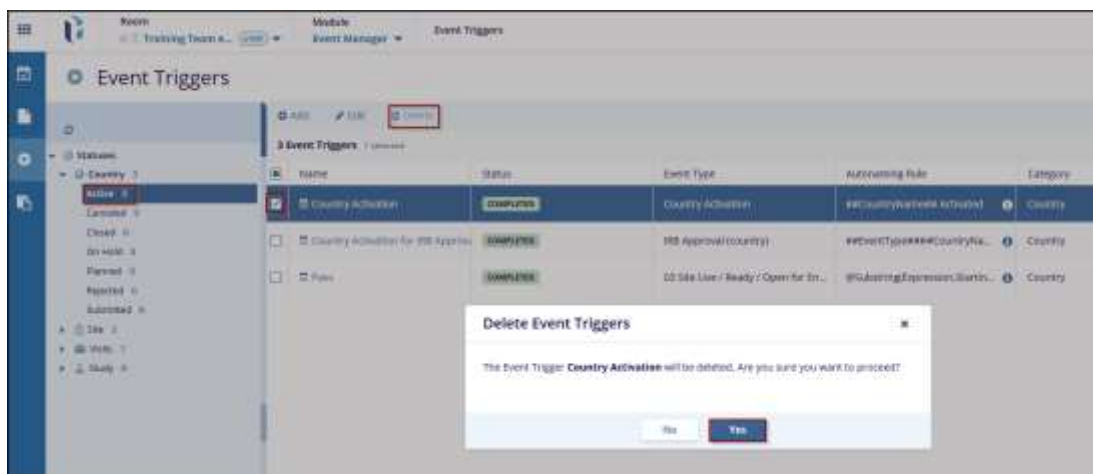


## Delete event Trigger

The Delete button allows user to delete the available Event Trigger in a grid view.

Steps to Delete Event Trigger

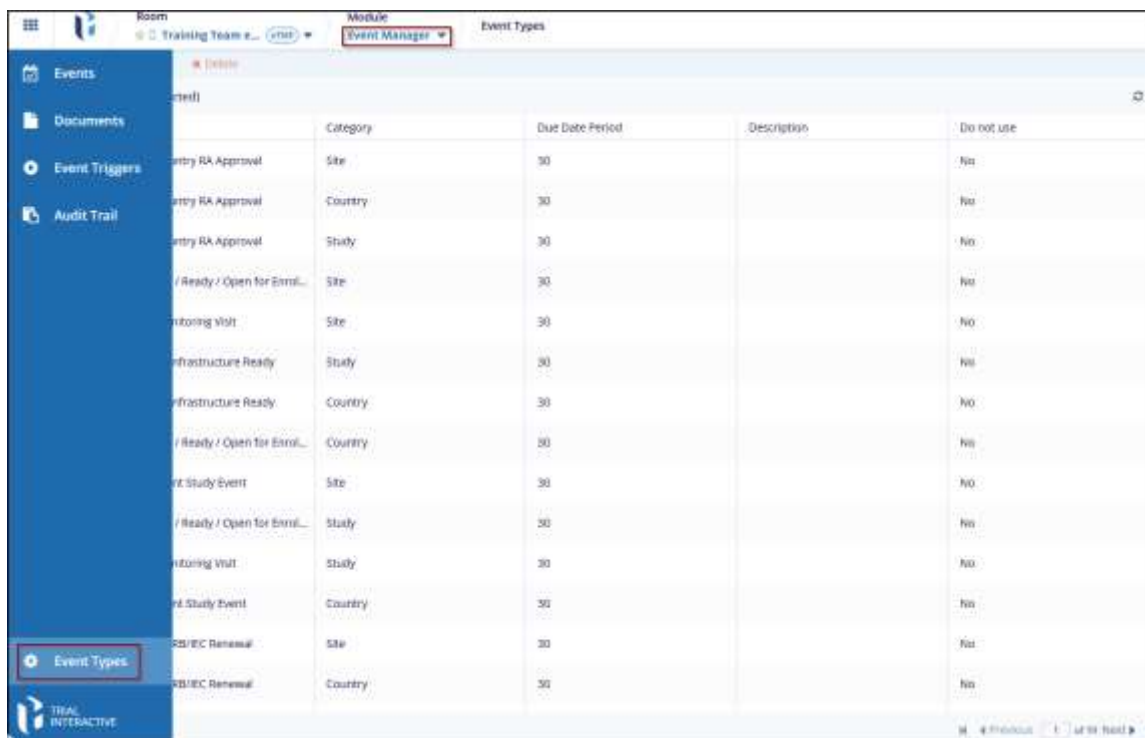
1. In the Event Triggers section, select the trigger you want to delete by checking the box next to its name, then click Delete, a confirmation prompt will appear asking if you want to proceed, click Yes to confirm.
2. A message will display, indicating that the Event Trigger was successfully deleted.



## Event Type

An Event Type refers to a category of events. Event types are used to categorize statuses that will trigger processes, workflows.

Users can access the Events Type by selecting gear icon at the bottom of left navigation pane.



|                             | Category | Due Date Period | Description | Do not use |
|-----------------------------|----------|-----------------|-------------|------------|
| Country RA Approval         | Site     | 30              |             | No         |
| Country RA Approval         | Country  | 30              |             | No         |
| Country RA Approval         | Study    | 30              |             | No         |
| / Ready / Open for Email... | Site     | 30              |             | No         |
| Monitoring Visit            | Site     | 30              |             | No         |
| Infrastructure Ready        | Study    | 30              |             | No         |
| Infrastructure Ready        | Country  | 30              |             | No         |
| / Ready / Open for Email... | Country  | 30              |             | No         |
| Study Event                 | Site     | 30              |             | No         |
| / Ready / Open for Email... | Study    | 30              |             | No         |
| Monitoring Visit            | Study    | 30              |             | No         |
| Study Event                 | Country  | 30              |             | No         |
| ES/EC Renewal               | Site     | 30              |             | No         |
| ES/EC Renewal               | Country  | 30              |             | No         |

## Create New Event Type

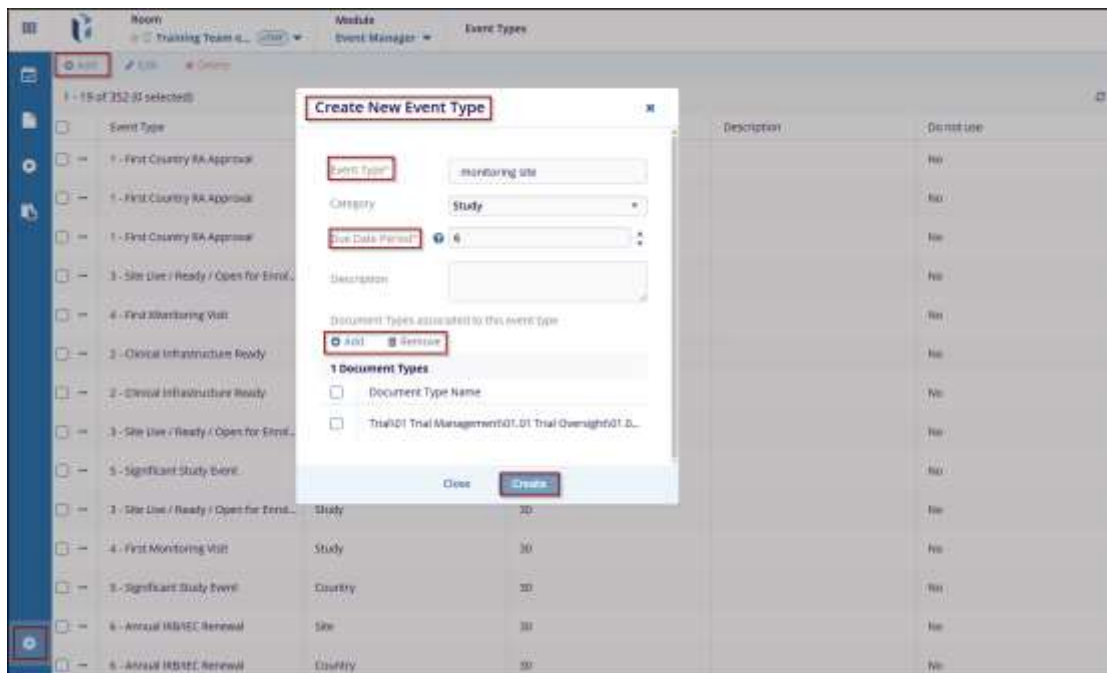
Once an appropriate Event Type has been defined, users can create specific events based on it. The eTMF team can update events at any time to ensure they reflect the latest content. Each created event will display its eTMF Health measurement at the study, country, and site levels.

The Add button is used to create new event type.

To Create an event type, follow these steps:

1. To access the Event Types in the Event Manager, click on the gearwheel icon located on the far left of the screen.
2. Click the Add button in the menu bar located above the list of existing events in the room.
3. The Create New Event Type window will open.
4. Fill out the required fields
  - The Event Type field allows you to name the new event.

- Category indicates whether this is related to a Study, Country, or Site level event.
  - The Due Date Period field allows you to indicate how long users have to submit the documents after the event. Also, we have a description textbox to enter the related information.
5. Use the Add button above the Document Type Name field to open the Select Document Type window.
  6. Use the search bar at the top of the window to find the document type, or navigate through the index structure to locate the correct entry.



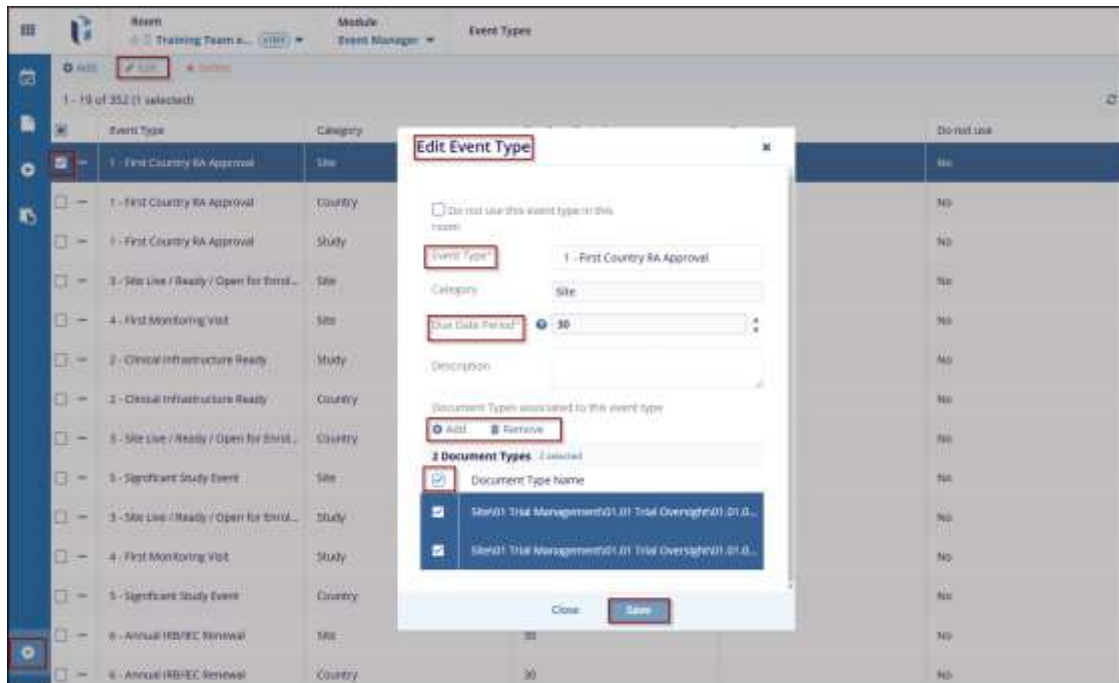
7. Select the desired document type(s) by checking the box next to them, then click on the Select to add the chosen document type(s) to the event.
8. To remove an added document type, check the box next to it and click the Remove button.
9. Once all document types have been added, press the Create button to create the event type.

## Edit Event Type

The Edit Event Type refers to the process of modifying or updating an existing event type in a system to reflect changes in the available event type.

To Edit the event type, follow these steps:

1. In Event Management, click the gear icon in the left pane to open the Event Types screen.
2. From the list of event types, select the checkbox next to the event type you want to edit (e.g., Country Submission).
3. From the right side of the screen event type details. Refer to the screenshot below.
4. Click the Edit button at the top of the screen.
5. In the Edit Event Type window, you can modify details like Due Date Period and associated Document Types:
6. To change the Due Date Period, update the value in the Due Date Period field.
7. To manage Document Types, click the Add or Remove buttons in the Document Types section. For adding document types, a modal will display where you can search and select the required document type. Selected types will appear in the list.



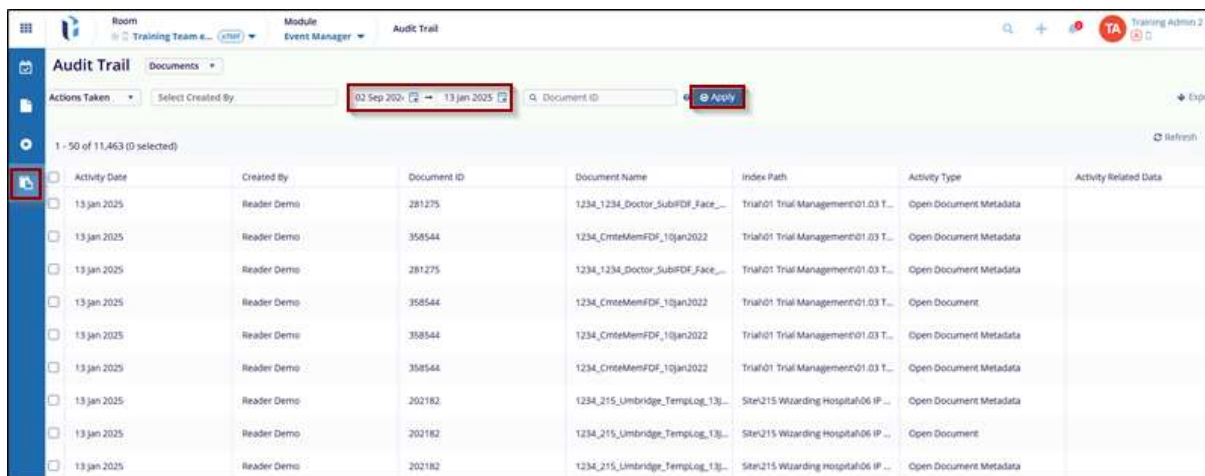
## Audit Trail

An Audit Trail is a security-relevant chronological set and source of records that provide evidence of the sequence of activities performed over a document. The changes made in a document by all users are displayed within the Audit Trail.

Users can access the Audit Trail by selecting it from the menu bar on the left-side of navigation pane.

Refer to the Audit Trail from the eTMF Module for a more detailed description of these options

Note: By default, the audit trail's grid pane is empty, and the documents are displayed only after entering and applying certain parameters and criteria.

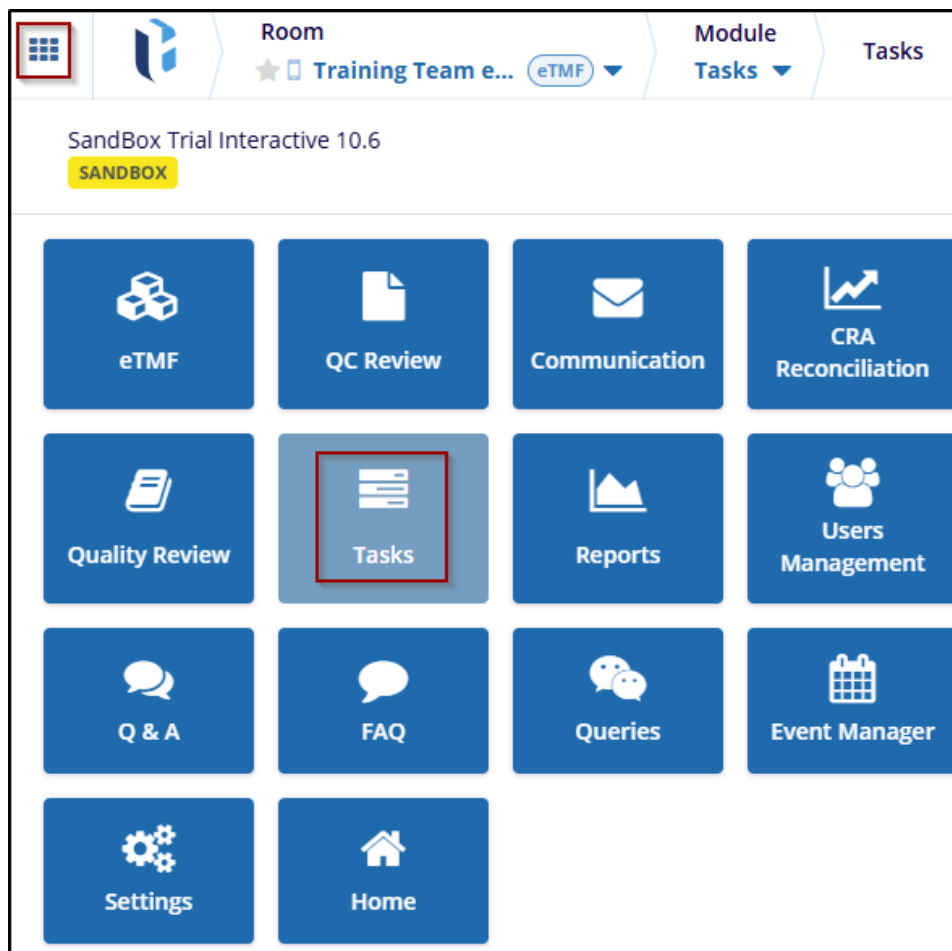


| Activity Date | Created By  | Document ID | Document Name                   | Index Path                         | Activity Type           | Activity Related Data |
|---------------|-------------|-------------|---------------------------------|------------------------------------|-------------------------|-----------------------|
| 13 Jan 2025   | Reader Demo | 281275      | 1234_1234_Doctor_SubPDF_Fact... | Trial01 Trial Management01.03 T... | Open Document Metadata  |                       |
| 13 Jan 2025   | Reader Demo | 358544      | 1234_CrntMemPDF_10Jan2022       | Trial01 Trial Management01.03 T... | Open Document Metadata  |                       |
| 13 Jan 2025   | Reader Demo | 281275      | 1234_1234_Doctor_SubPDF_Fact... | Trial01 Trial Management01.03 T... | Open Document Metadata  |                       |
| 13 Jan 2025   | Reader Demo | 358544      | 1234_CrntMemPDF_10Jan2022       | Trial01 Trial Management01.03 T... | Open Document           |                       |
| 13 Jan 2025   | Reader Demo | 358544      | 1234_CrntMemPDF_10Jan2022       | Trial01 Trial Management01.03 T... | Open Document Metadata  |                       |
| 13 Jan 2025   | Reader Demo | 358544      | 1234_CrntMemPDF_10Jan2022       | Trial01 Trial Management01.03 T... | Open Document Metadata  |                       |
| 13 Jan 2025   | Reader Demo | 202182      | 1234_215_Umbridge_TempLog_13... | Site215 Wzarding Hospital06 IP...  | Open Document Metadata  |                       |
| 13 Jan 2025   | Reader Demo | 202182      | 1234_215_Umbridge_TempLog_13... | Site215 Wzarding Hospital06 IP...  | Open Document           |                       |
| 13 Jan 2025   | Reader Demo | 202182      | 1234_215_Umbridge_TempLog_13... | Site215 Wzarding Hospital06 IP...  | Open Documents Metadata |                       |

## CHAPTER 8. TASKS

A Tasks module allows users to create tasks for specific rooms. Users can view tasks, add new ones, edit, delete, and export task records. The interface provides an option to filter tasks by different views.

Refer to the below screenshot:

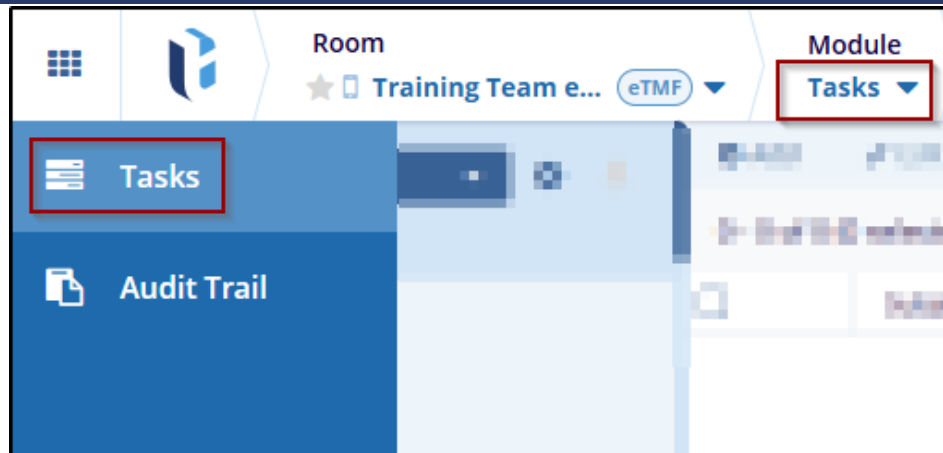


The Task module Includes:

- Tasks
- Audit Trails

### Tasks

In the Tasks section users can perform activities such as Create, Edit, Delete, and Export.

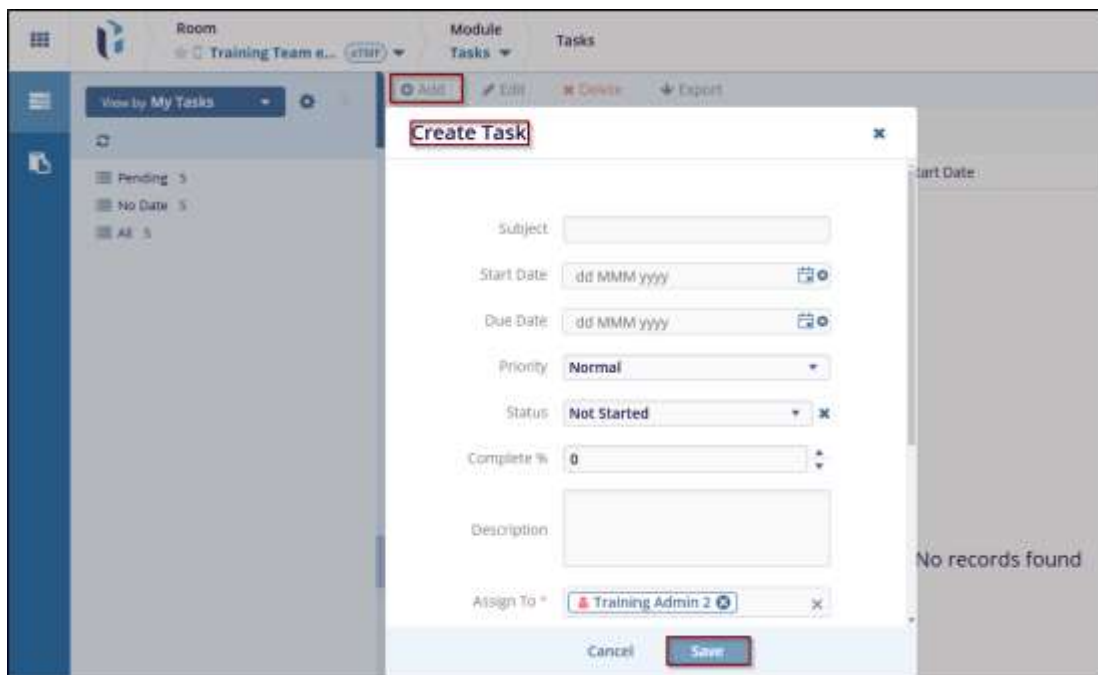


The Tasks can be filtered with the View Task By option allows users to filter tasks based on requirements such as My Tasks, Status, Owner, and Category. This task can be set as default for all and specific rooms, this improves to focus on relevant information.

The Task section can be customized with the Manage columns allows users to customize the columns that appear in a data table and the Layout provides users with different data viewing options. The choice of layout can help enhance user experience by making the data available to navigate.

## Steps to Create Tasks

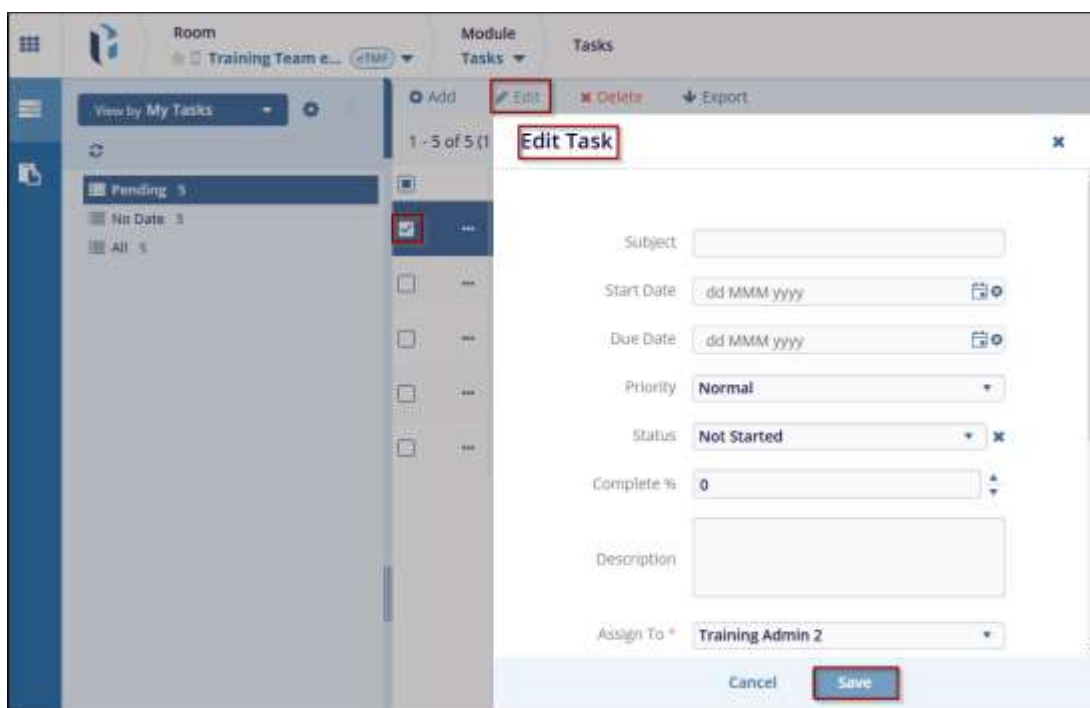
1. Click the Add button located in the top menu, this will open the Create Task window.
2. In the Create Task window, fill in the required data fields.



3. Click the Save button at the bottom of the window, to save the changes or click on Cancel to discard the changes.
4. Once saved, a confirmation message will popup 'Task was added successfully'

### Steps to Edit Tasks

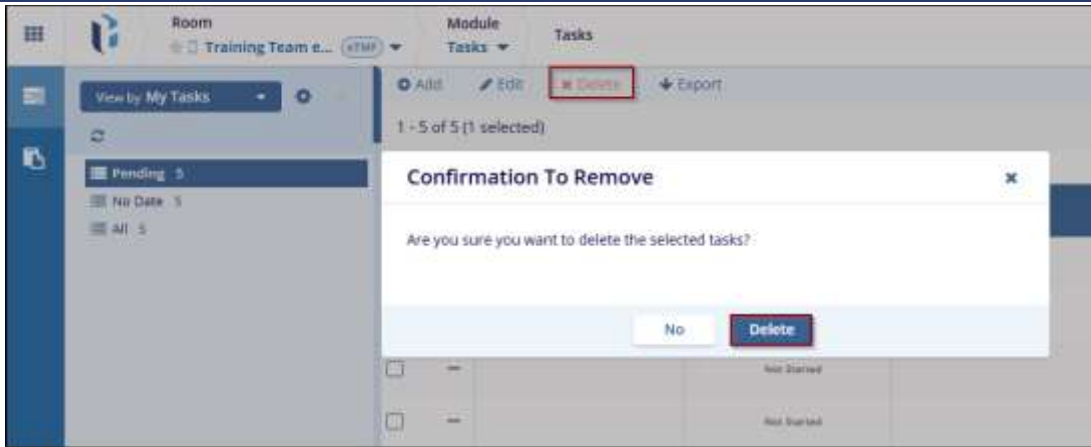
1. Select the single task from the grid and document view and click the Edit button at the top menu.
2. This will open the Edit Task window and fill in the required data fields.
3. To attach the attachment, click the add button to select the specific file.
4. Once changes are made, click the Save button to apply the changes successfully.



### Steps to Delete Tasks

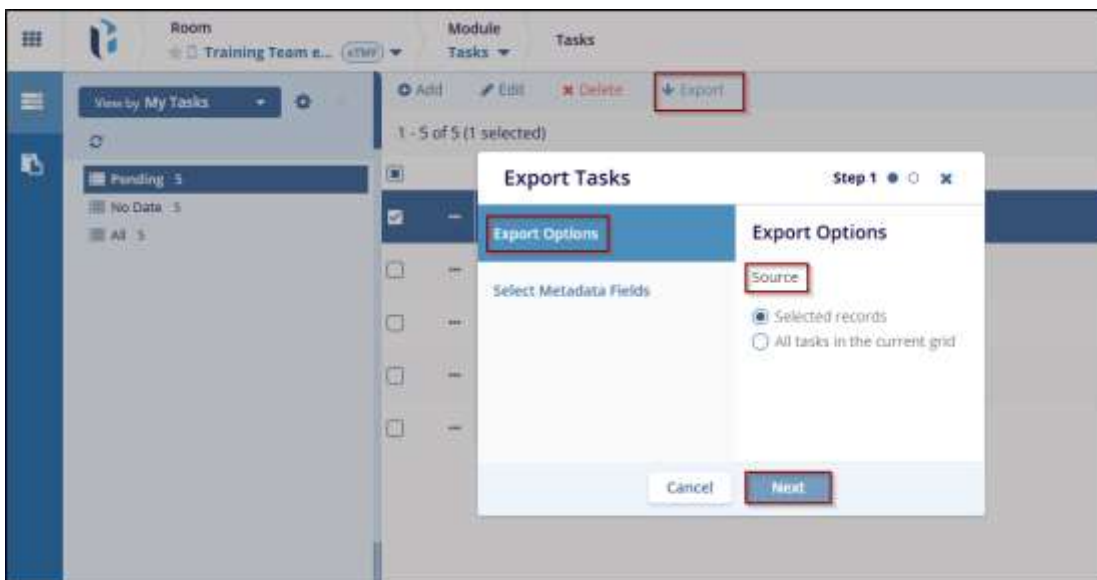
1. Select the specific task from the grid view and select the checkbox, next to task.
2. Click the Delete button at the top, this will pop up a confirmation message 'Are you sure you want to delete the selected tasks?'
3. Click on the Delete button to delete the task successfully.



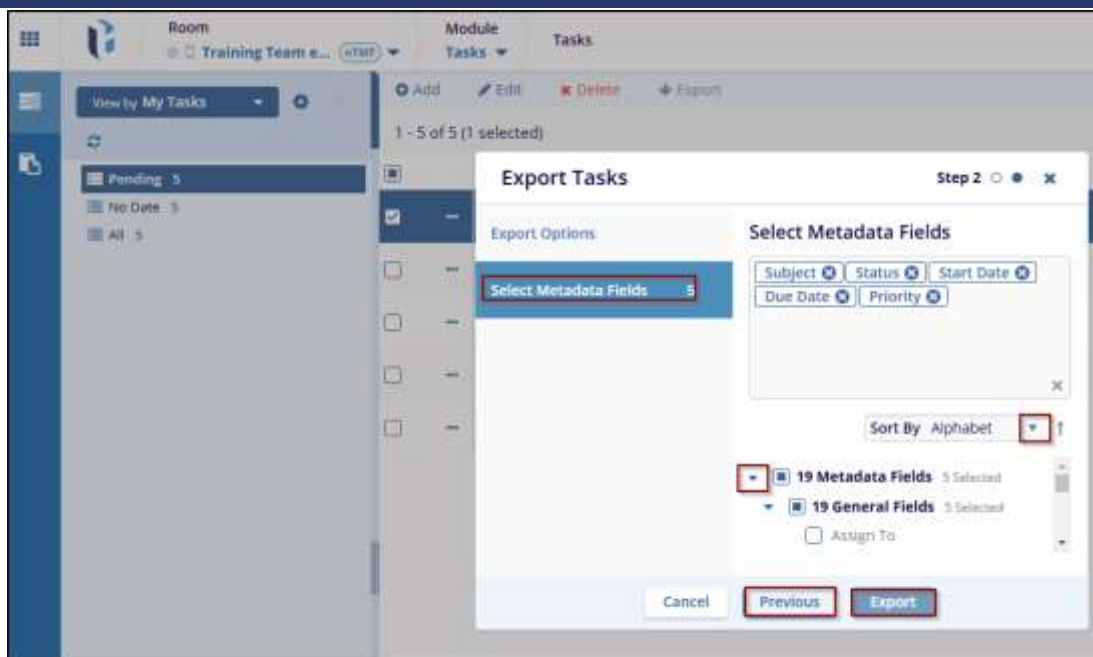


## Steps to Export Tasks

1. Click the Export button located in the top menu bar. This opens the Export Tasks window.
2. The Export Tasks window will display two options (by default export task is selected):
3. The Export Options are a set of queries that will be included in the export. The user can choose the task that should be exported and select any required source.
4. Click Next to proceed to the Select Metadata Fields section.



5. Once proceed to the Select Metadata Fields option and select the metadata fields that are required, the user can sort it by Alphabet or Logic to include in the export.
6. Metadata fields are characteristics of the queries, such as: (Subject, Status, Start date, Due date, etc.)
7. After selecting both options, click on the Previous button to go back and make changes, or click on the Export button to download the file.



8. Once click the Export button, a confirmation message will appear.

## Audit Trails

The Audit Trail in the Task module provides a comprehensive record of all actions performed on documents within a study room. This is designed to help users track activities for auditing and compliance purposes. Users can filter the audit trail by various criteria to efficiently retrieve specific records.

The audit trail can be filtered by:

- **Actions Taken:** Select specific types of actions, such as Created, Modified, or Deleted.
- **Created By:** Filter records based on the user who created.
- **Date Range:** Specify the start and end dates to view actions within a specific timeframe.
- **Documents, Folders, Placeholders, and Users:** Use these options to narrow down the search to specific entities.

| Audit Trail <span>Documents</span> |               |                    |                           |                                 |
|------------------------------------|---------------|--------------------|---------------------------|---------------------------------|
| Actions Taken                      |               | Select Created By  | 04 Aug 2024 → 02 Dec 2024 | Document ID: <span>App</span>   |
| 1 - 50 of 7,632 (0 selected)       |               |                    |                           |                                 |
| <input type="checkbox"/>           | Activity Date | Created By         | Document ID               | Document Name                   |
| <input type="checkbox"/>           | 03 Dec 2024   | SBTisa@origami.com | 351564                    | CTA                             |
| <input type="checkbox"/>           | 03 Dec 2024   | SBTisa@origami.com | 351564                    | CTA                             |
| <input type="checkbox"/>           | 03 Dec 2024   | SBTisa@origami.com | 351564                    | CTA                             |
| <input type="checkbox"/>           | 03 Dec 2024   | SBTisa@origami.com | 351564                    | CTA                             |
| <input type="checkbox"/>           | 03 Dec 2024   | SBTisa@origami.com | 351563                    | Confidentiality Agreement_pdf-r |

## CHAPTER 9. ESIGNATURE

Electronic signatures can be applied across all Trial Interactive (TI) room types. However, it is typically expected that this process is completed before submitting a document to the eTMF. Trial Interactive provides a built-in electronic signature feature called TI Sign, but your TI rooms can also be configured to work with other electronic signature software. For details on how to configure electronic signature settings.

### Send for eSignature

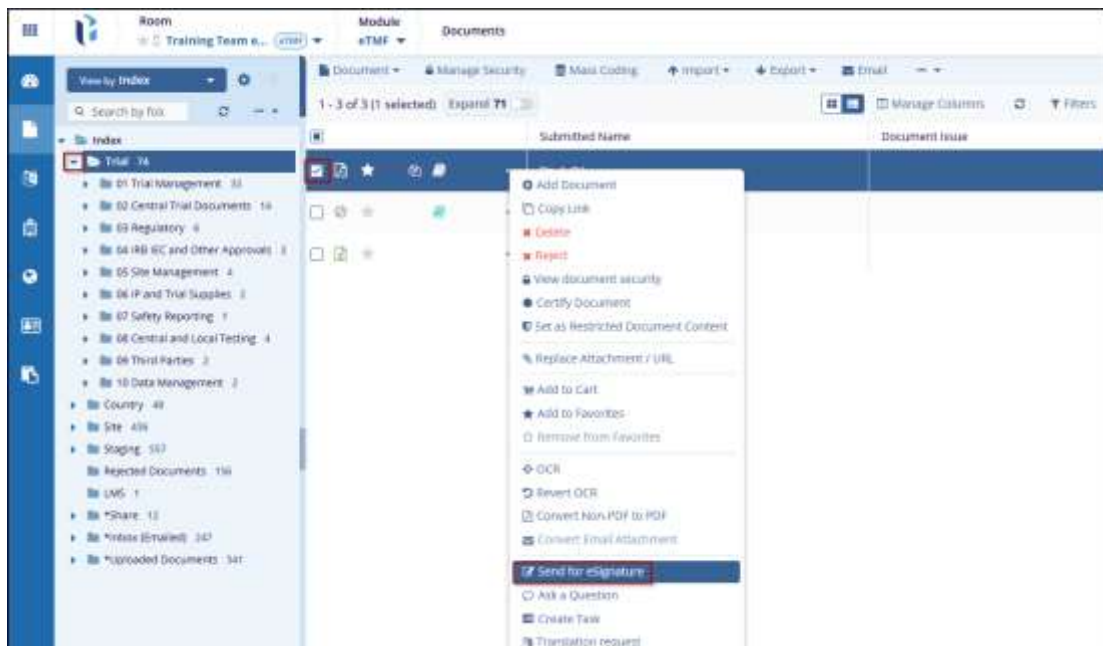
To send a document for signature or to sign a document, users must have the eSignature action assigned to their user profile. For additional instructions on assigning actions to user accounts, please refer to the User Management section.

#### Send document for eSignature from the Document module

The process to send a document for eSignature involves selecting the document and assigning the eSignature action to the user, allowing them to send it for signature.

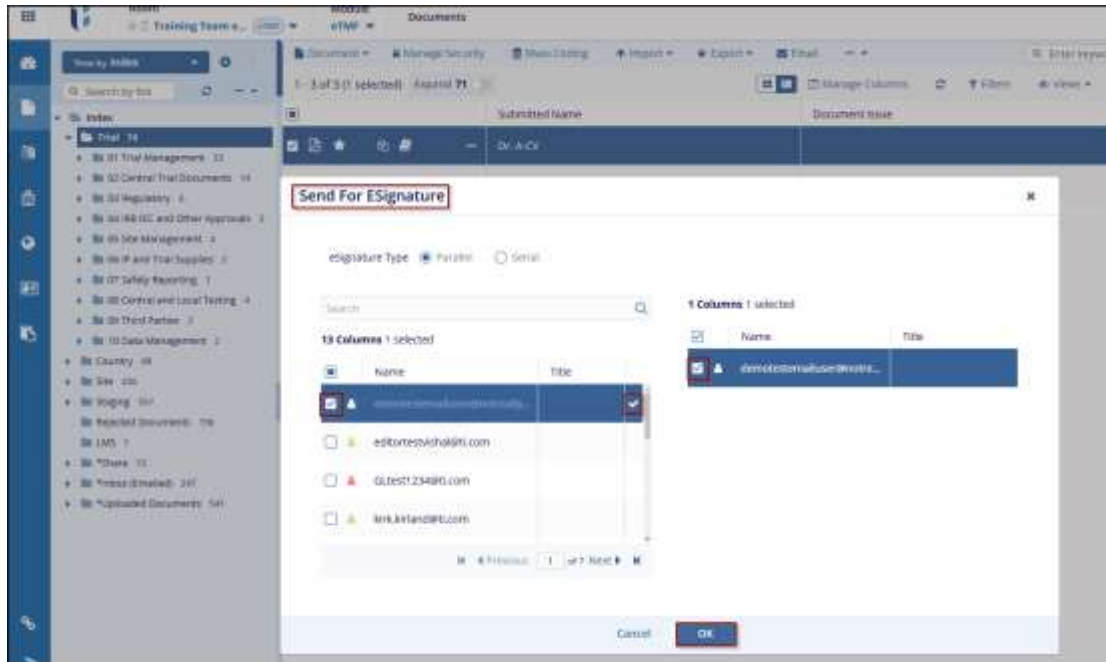
To send a document for signature, please follow these steps:

1. Locate the document in the Documents module or Documents Library.
2. Open the Document Activities menu by right-clicking on the document or by clicking on the three-dot icon on the document line in the grid.
3. Select the Send for eSignature option, this will open the Send for eSignature window.



4. Choose the user or users who will need to sign the document by moving them from the left side to the right side.

5. Using the radio buttons at the top-left, indicate whether the signatories (assuming that there is more than one signature required) should sign in parallel or if they need to be completed one at a time.
6. Press OK, from this point on, the steps will vary depending on which signature vendor your study room is using. For all but TI Sign, the system interface will open and the user can complete the process using the assigned vendor.



## Signing a Document

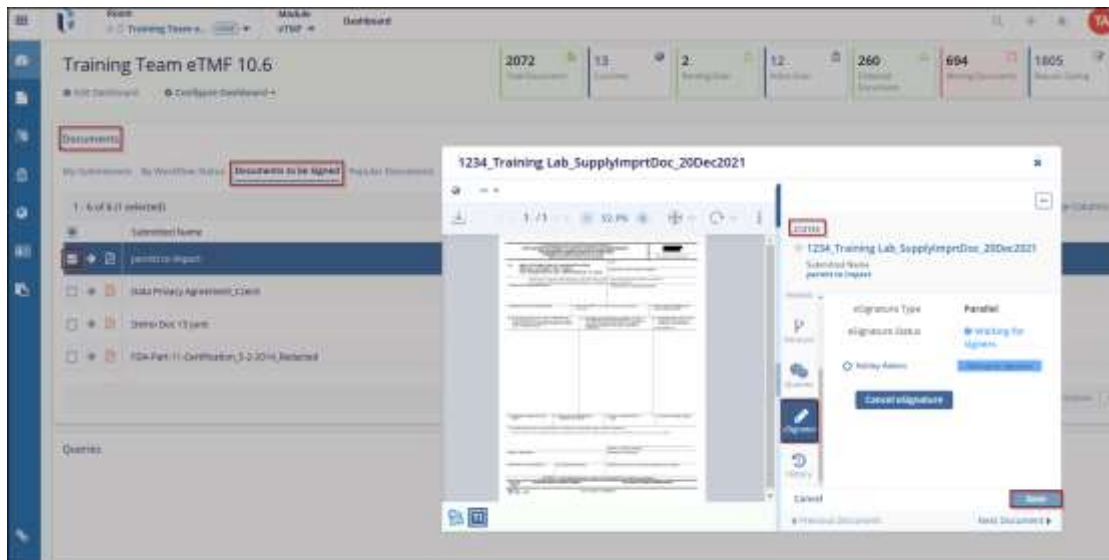
A user who has been assigned a document to review and sign can do so either via the related dashlet or directly from the Documents module.

### Signing a document from the Documents to be Signed tab

To signed a document from Documents to be Signed, follow these steps:

1. Navigate to the Dashboard section in the eTMF module, located at the top left of the Toolbar.
2. Once clicked on Dashboard, the user can see the Document section in the dashboard
3. Click on the Documents to be Signed, next to My Submissions.
4. This will open the document and the eSignature tab of the metadata panel in a popup window.
5. Indicate your reason (either for signing or for rejecting the document) using the dropdown menu. The reasons are populated from the Settings area and are usually set up during room configuration. Please check the Document section from eTMF Module for additional information.
6. Make any necessary comments and click the OK button for the appropriate action (Signing or Declining).

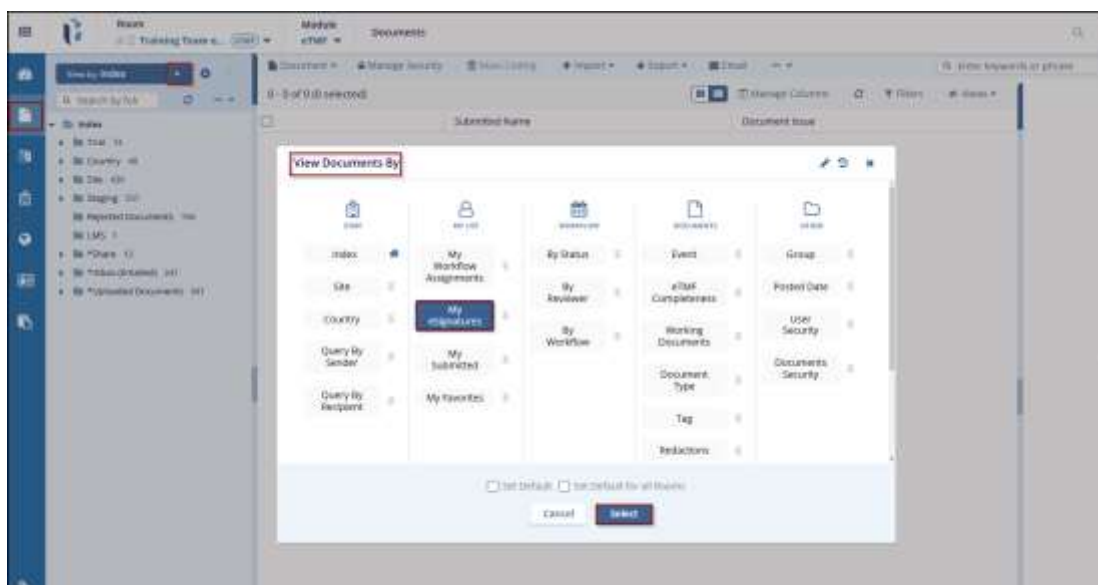
7. Use your Username and Password to verify your identity and complete the signature process and click on Save.



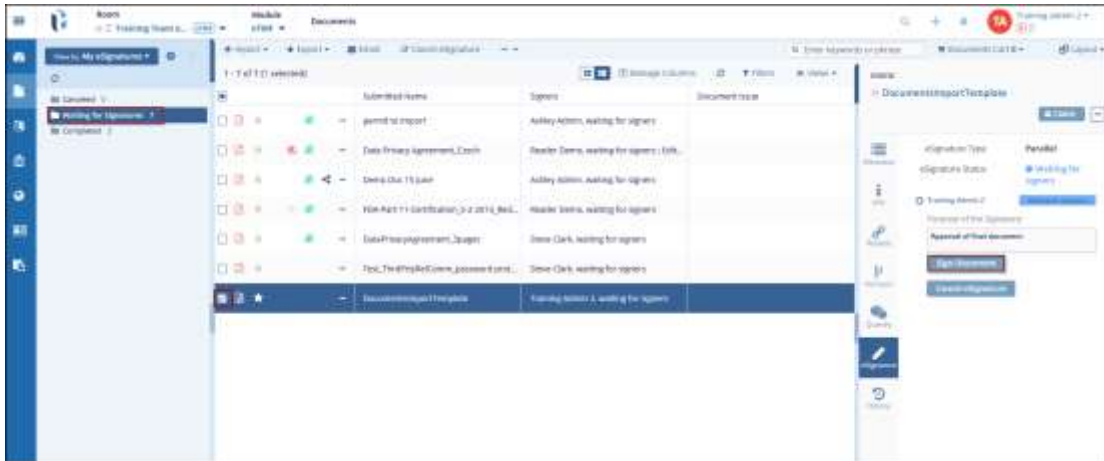
## Signing a document from the Documents module

To sign a document from Documents module, follow these steps:

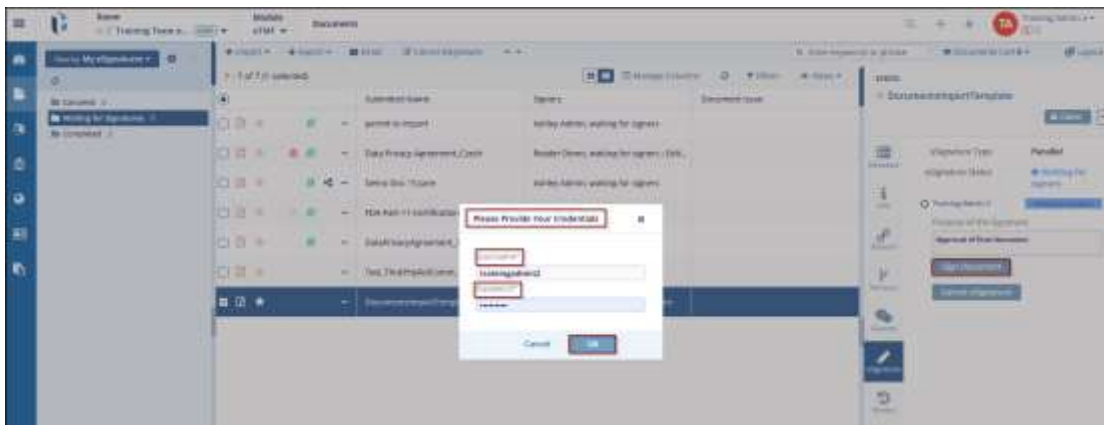
1. Navigate to the eTMF module, there select Document section, at the top of the Index Pane, the user will see the View Document By dropdown menu.
2. This dropdown menu allows users to choose how they want to view the documents.
3. Click on the dropdown to reveal the available columns.
4. Select the My eSignatures from My List columns and click on select button.



5. This selection will display the folder with document statuses that are sent for the user's eSignature and select the folder that needs to open for eSignature.
6. Selected folder will be displayed document in the grid views, check the checkbox, next to the Document icon to open the Metadata panel in the right pane.
7. From Metadata panel, click the eSignature option, enter the purpose of the signature and click on Sign Document button.



8. A new 'Please Provide Your Credentials' window will pop-up, where user needs to enter Username and Password to verify identity and complete the signature process by selecting OK button.





## CHAPTER 10. SEARCH IN TI

This section explains how to perform searches for documents in Trial Interactive.

The Trial Interactive platform provides a flexible search functionality with options to search across document content, and metadata. Users can perform full-text indexed searches within individual rooms or across multiple rooms by enabling the Cross-Room Search option. Filters can be applied to include or exclude documents from the search results, and users can switch between search modes such as Metadata and Document, the platform also features Search History and Saved Searches sections, allowing users to track recent searches or manage saved queries for future use.

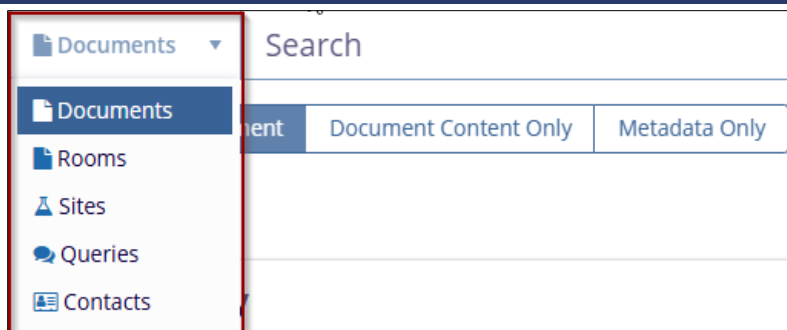
This new search interface has the following powerful capabilities:

- Users can perform searches across multiple rooms simultaneously, ensuring comprehensive results across different projects or workspaces.
- Multiple search modes are available, including:
  - a. Metadata and Document: Searches both the document content and its associated metadata.
  - b. Document Content Only: Limits the search to the content within the documents.
  - c. Metadata Only: Searches only within the metadata fields of the documents.
- Enables fast and accurate searches by indexing the entire content of documents and metadata fields.
- Users can apply filters to refine search results, such as including or excluding specific document types.
- Keeps a record of recent searches, allowing users to quickly revisit previous queries.
- Users can save frequently used search configurations and manage them for future reference.
- An advanced search option allows users to define complex search criteria by configuring detailed parameters.

### Search

The search functionality in Trial Interactive allows users to perform targeted searches across various record types, enhancing the efficiency of retrieving specific information. Users can select from five categories: Documents, Rooms, Sites, Queries, and Contacts. Depending on the selected category, the search results are refined accordingly. For documents, users can further filter by content, metadata, or both. Users can execute this search from the Home Page Search functionality.





## Documents Search

The Document Search allows users to find specific documents by entering keywords or criteria in the search bar. Results are displayed instantly, and users can apply filters Metadata and Document, Document Content Only, and Metadata Only, depending on the type of information they are seeking.

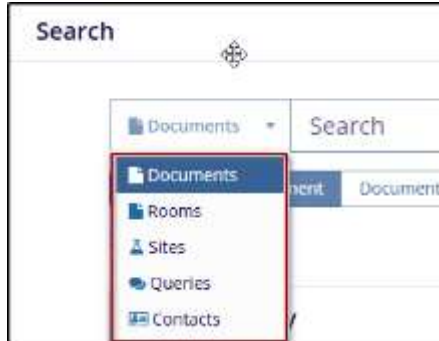
Users can perform two types of searches for documents:

- **Cross Room Search:** This is used during document searches to retrieve documents across multiple studies or rooms in a single query, eliminating the need to navigate each room individually. It ensures efficient, comprehensive searches by applying filters and criteria across all accessible rooms.
- **Document Search in Trial Interactive** allows users to efficiently locate specific documents by applying various filters and criteria. Users can search within document content, metadata, or both. To narrow down results, users can select the Limit search to the current room checkbox to search only within a specific room.

To perform the document search, follow the below Steps:

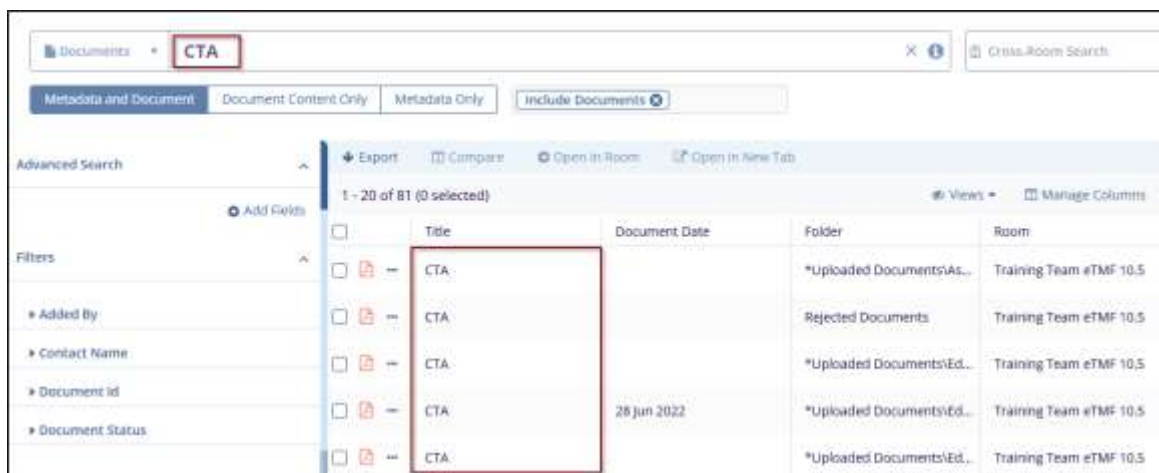
1. Navigate to the Home Page or the required Trial Interactive room.
2. Click the Search icon next to the username menu to open the Search popup.
3. From the dropdown menu in the Search popup, choose Document options:
  - Documents
  - Rooms
  - Sites
  - Queries

## Contacts



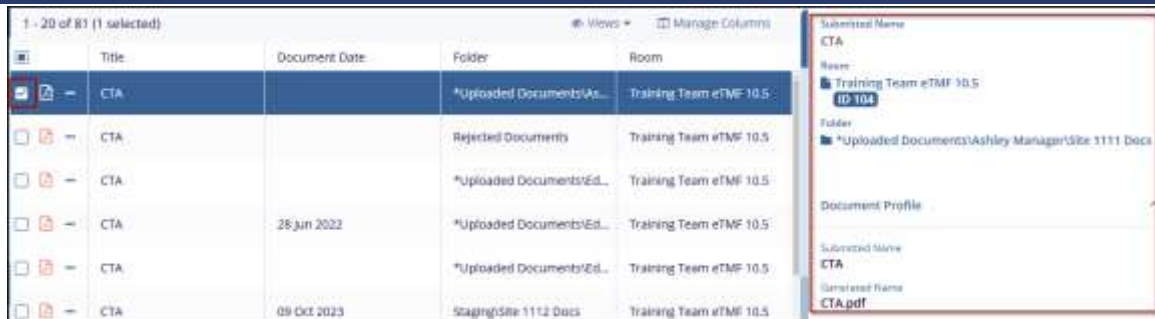
4. Enter the specific document name in the Search box. The system begins the search automatically as you type.
5. Results matching the entered criteria will appear in a grid view, below the Search box.

Refer to the below screenshot:



6. Hover over the Document icon to preview the documents.
7. Check the checkbox next to the document icon to open the Metadata panel in the right pane.

Refer to the below screenshot:



## Contacts search

The Contacts Search allows users to locate specific contacts by entering a name or keyword in the search bar. The results display relevant contact records, and selecting a record reveals detailed information in the Contacts Details panel.

To search for Contacts, follow the steps below:

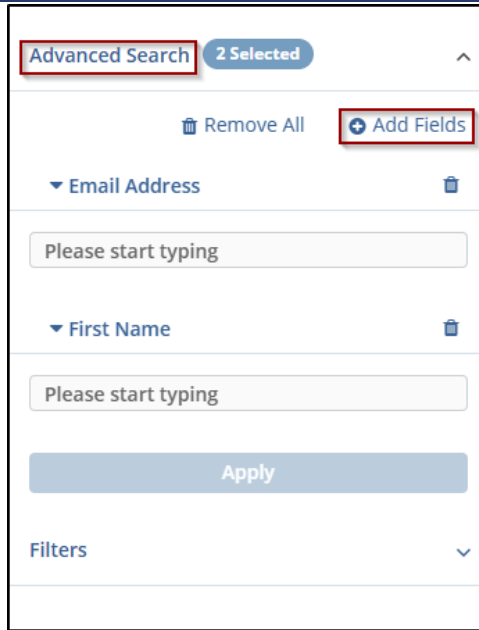
1. From the Home Page or within a specific room, click on the search drop-down and select Contacts from the list.
2. Enter the contact's name in the Search box. The system automatically displays matching contacts in the below section.
3. Select a contact from the results to view detailed information in the Contacts Details panel on the right which displays detailed information about the selected ID, including their email, name, status, and other relevant fields.

Refer to the below screenshot:



4. Use the Manage Columns option to add or remove fields displayed in the search results.
5. Click Export to download the search results for further use.
6. Click Advanced Search for the same contacts and add fields to apply more specific search criteria.

Refer to the below screenshot:



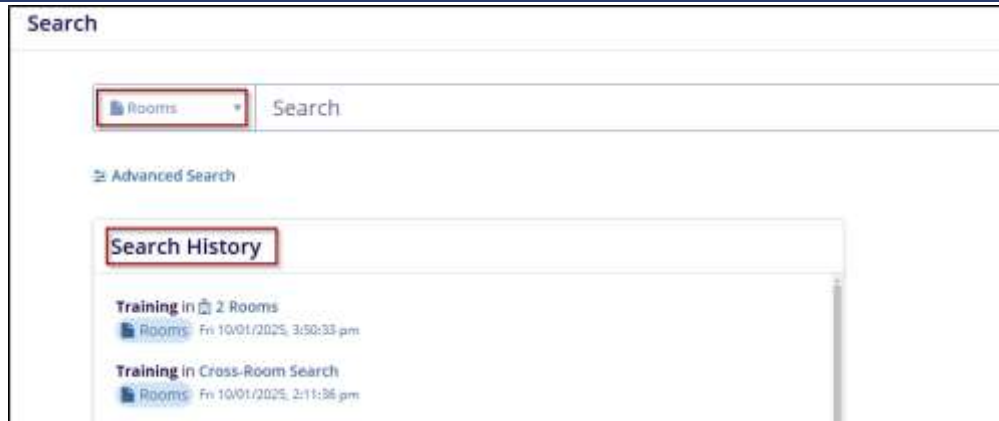
## Room Search

The Room Search enables users to quickly find specific rooms by entering a room name or keyword in the search bar on the home page only. The search results update automatically as text is entered, displaying matching rooms instantly.

To perform a room search, follow the below Steps:

1. Navigate to the top of the screen where the Search panel is displayed.
2. Click the Dropdown menu to choose the room search, and enter the desired keyword into the search field.
3. Click a result to open the corresponding room.
4. If the desired result isn't found, refine the search by modifying the keywords or adjusting the search scope.
5. Once finished, can close the search panel.

Refer to the below screenshot:



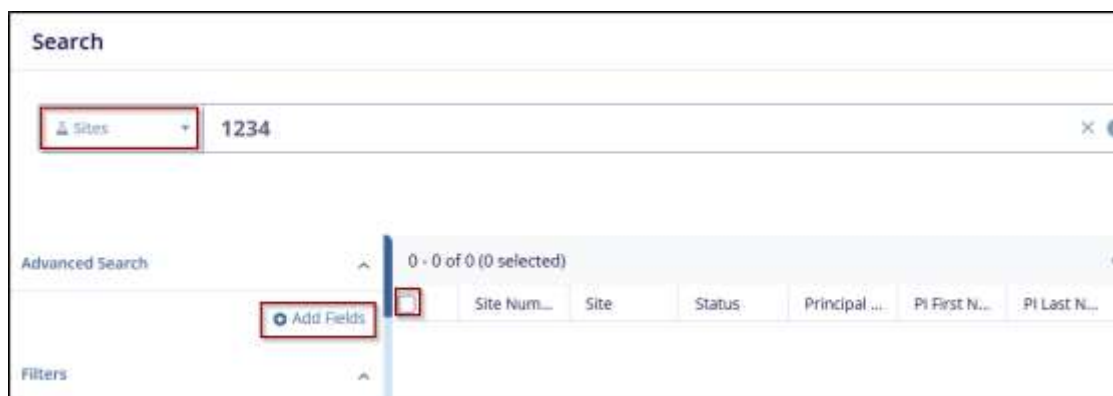
## Site Search

The Site Search enables users to locate specific documents or information within designated areas, known as rooms. This functionality ensures that document access is controlled and confined to specific sites, enhancing collaboration and efficient management within clinical trial sites. Site Search helps streamline the process of finding and managing site-related documents while keeping the search results relevant to the specific context of a room or site.

Steps to perform a site search:

1. In the Search panel, ensure that Sites is selected in the dropdown menu, as shown in the image.
2. Enter the relevant site name or site number (e.g., 1234) in the search bar.
3. If required, click the Add Fields button to include additional search parameters or filters (such as Site Number, Status, or Principal Investigator) to refine your search.
4. Once the search criteria are set, click the Search button to begin the search.
5. From the search results, select the specific site.

Refer to the below screenshot:



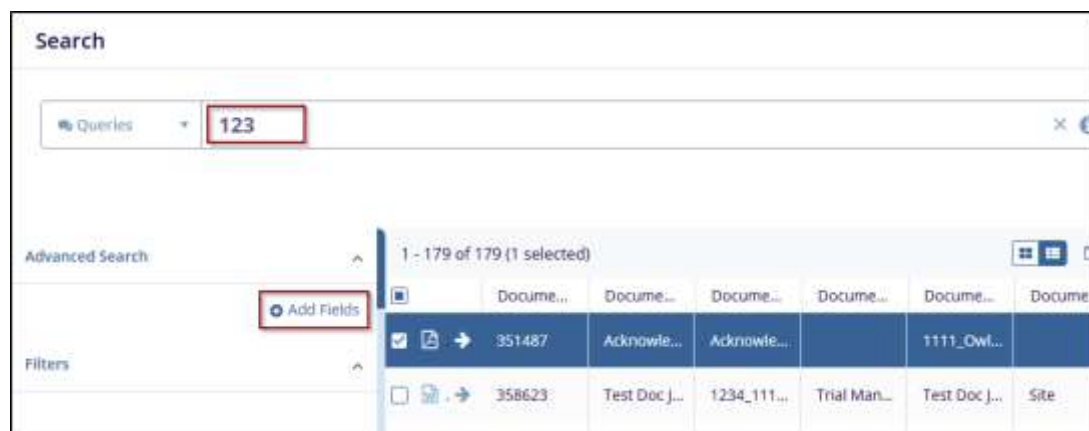
## Queries Search

The Queries Search enables users to locate specific queries related to clinical trial documents within designated areas, referred to as rooms. This feature simplifies the process of managing and resolving queries by filtering and displaying relevant query data, thus enhancing collaboration and ensuring compliance throughout the clinical trial process. Users can efficiently track and address queries associated with specific documents, maintaining context within the clinical trial or project room.

Steps to perform a query search:

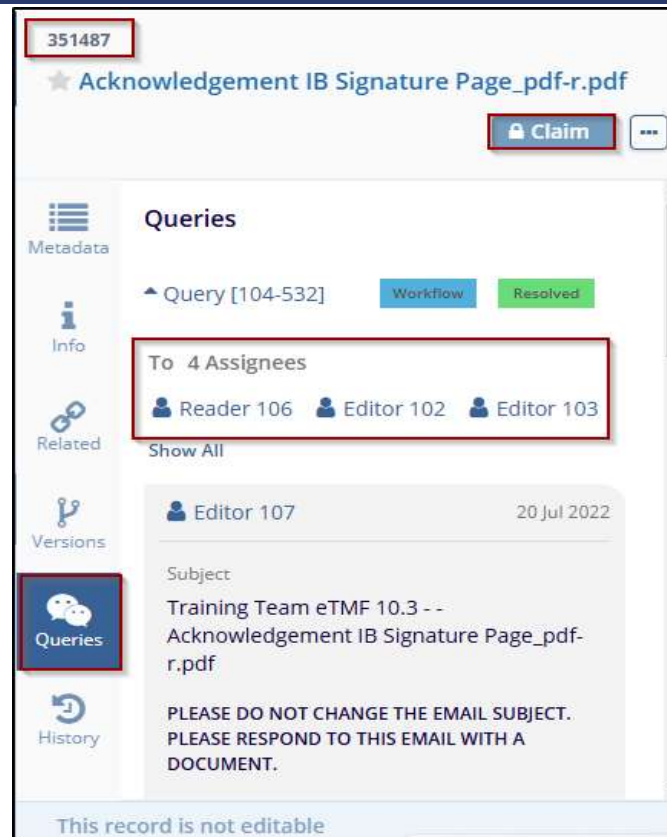
1. In the Search panel, choose Queries from the dropdown menu.
2. Enter the relevant query ID (e.g., 1234) or any other query-related term in the search bar.
3. If needed, click on Advanced Search and Add Fields to refine your search further, such as adding filters for document status or type.
4. Once the search parameters are set, click the Search button to perform the search.
5. From the search results, check the checkbox next to the document to select it.

Refer to the screenshot below:



6. After selecting the query, detailed information appears, including the query ID, status (e.g., Workflow or Resolved), and any associated query history.
7. If the user is responsible for addressing the query, click the Claim button to take ownership of the query.
8. The query details display the list of assignees (e.g., Reader 106, Editor 102, Editor 103). You can review or assign tasks to users related to this query.
9. Below the assignees, the Query History shows previous updates or comments related to the query, such as the message from Editor 107 on 20 Jul 2022. This provides context to the query resolution and allows you to respond effectively.

Refer to the screenshot below:



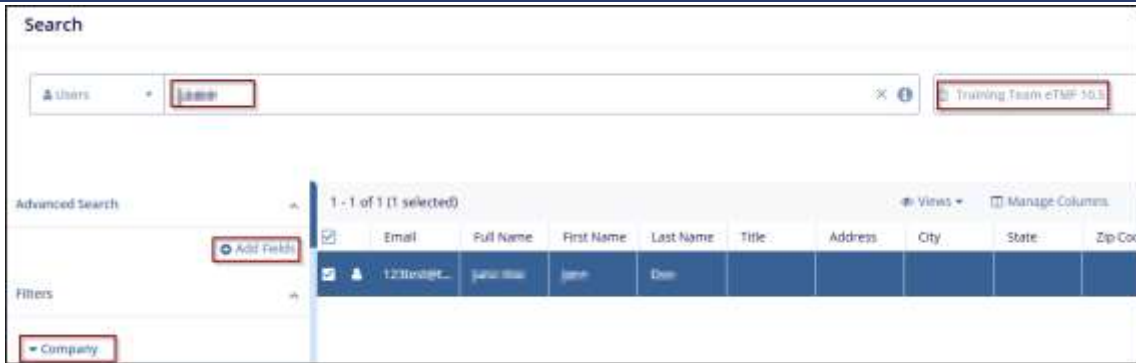
10. Depending on the user's permissions, the user can proceed with resolving the query or making any necessary updates to the document associated with the query, for more check queries module.

## Users Search

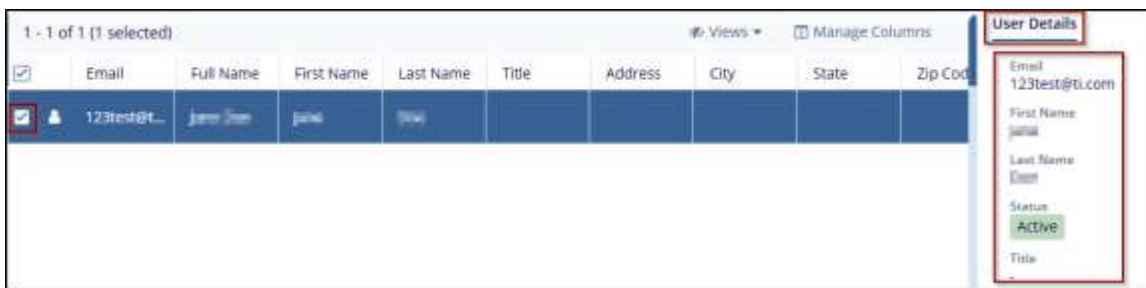
The User Search allows users to search for individuals within the context of a specific room, ensuring that the search results are filtered according to the current clinical trial phase or relevant project room. This feature helps to streamline collaboration by making it easier for users to find and connect with team members pertinent to their tasks within that specific room.

Steps to search for a user in a specific room:

1. Select the Room, In the Search panel, ensure the correct room or context is selected from the dropdown menu.
2. In the search bar, enter the user's name or relevant keyword (e.g., 123).
3. Optionally, use filters such as Company to narrow down the search results if needed.
4. Once the parameters are set, click the Search button, which will display the result. Refer to the screenshot below:



5. From the search results, check the checkbox next to the user's email to select it.
6. After selecting, it opens the user details in the right pane, which includes user data such as email, first name, last name, status, title, and mobile number.  
Refer to the screenshot below:



## Cross-Room Search

The Cross-Room Search feature in Trial Interactive enables users to perform searches across multiple rooms simultaneously. Users can easily toggle between two tabs: Favorites and All Rooms. The Favorites tab allows quick access to frequently used rooms, while the All-Rooms tab provides a complete list of available rooms for selection.

To perform cross-room search, follow the steps below:

1. Click on the Cross-Room Search option in the search interface.
2. Use the tabs at the top to switch between
  - Favorites: Displays frequently used rooms.
  - All Rooms: Shows a complete list of available rooms.
3. Enter the room name or keyword in the search bar to quickly find specific rooms.
4. Check the boxes next to the desired rooms to include them in the search.
5. Click the Apply button to start the search across the selected rooms.
6. Click Clear to remove all selected rooms.
7. Click Cancel to close the Cross-Room Search without applying any changes.

Refer to the screenshot below:





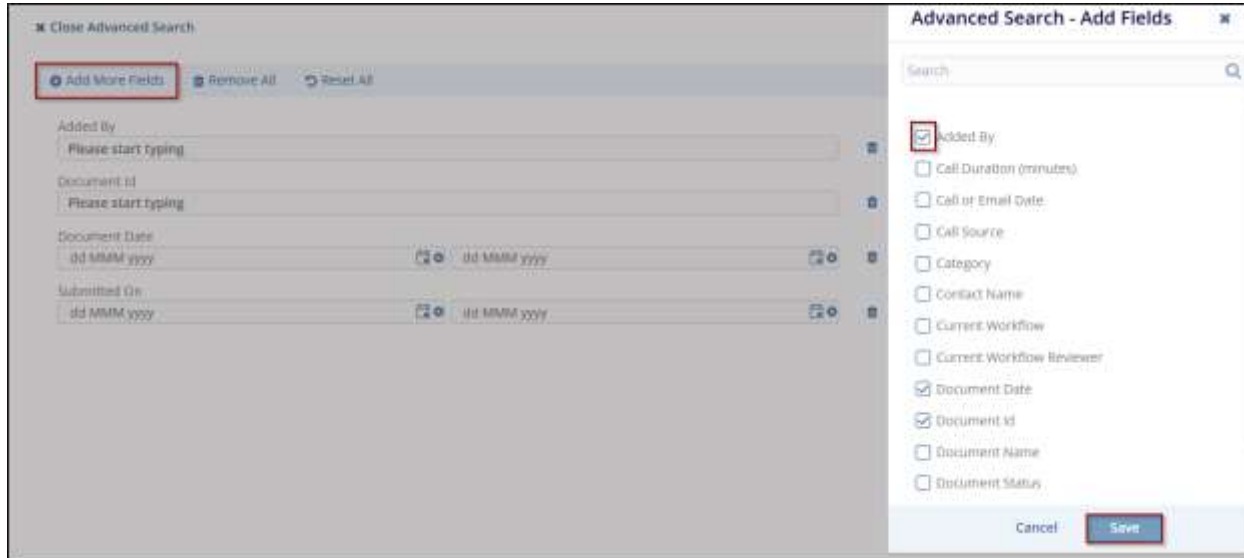
## Advanced search

An Advanced Search is a that allows users to refine their search queries by specifying various criteria, leading to more precise and relevant results.

This option is available in the Search bar Advanced Search - Add Fields section allows users to define their search parameters with greater specificity. These fields help to search by selecting certain attributes of the data they are looking for. The available fields for advanced searching include:

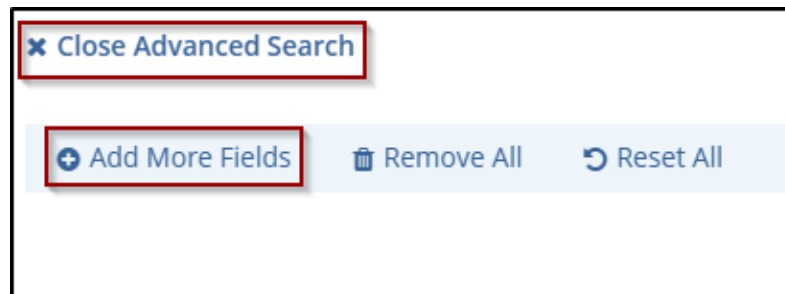
- Added By: Search based on the document added by the creator.
- Call Duration (minutes): Search based on the length of calls, measured in minutes.
- Call or Email Date: Filter results based on the date a call or email took place.
- Call Source: Specify the source or origin of the call.
- Category: Search for items within a particular category.
- Contact Name: Narrow results by a specific contact or person.
- Current Workflow: Search based on the current workflow or status of a process.
- Current Workflow Reviewer: Filter results by the person or entity reviewing the workflow.
- Document Date: Filter by the date a document was created or last updated.
- Document Id: Search for a specific document by its unique identifier.
- Document Name: Narrow down results based on the name of a document.
- Document Status: Filter by the current status of a document.
- Submitted On: Specify the date the document or item was submitted.
- Title: Search by the title of a document or item.

Refer to the screenshot below:



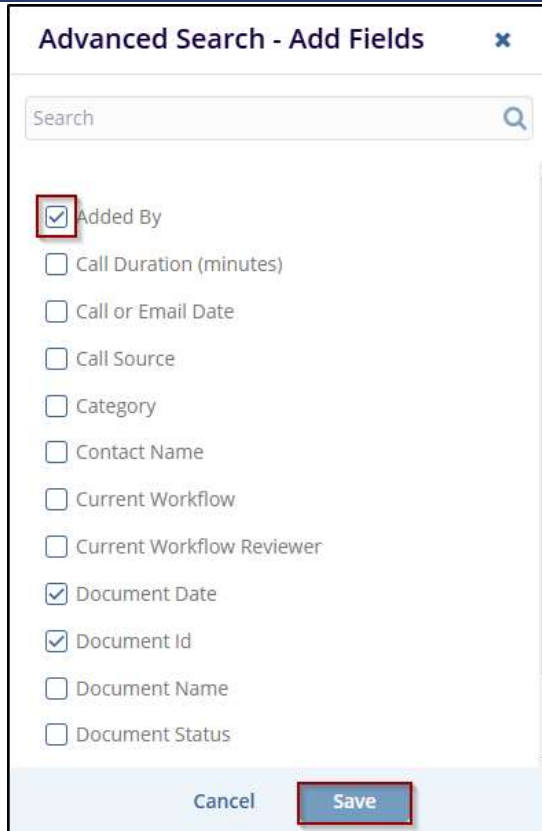
Steps to Perform an Advanced Search:

1. Navigate to the Advanced Search option, which is under the search bar.
2. Click the Add More Fields button to open the field selection dialog. Refer to the screenshot below.



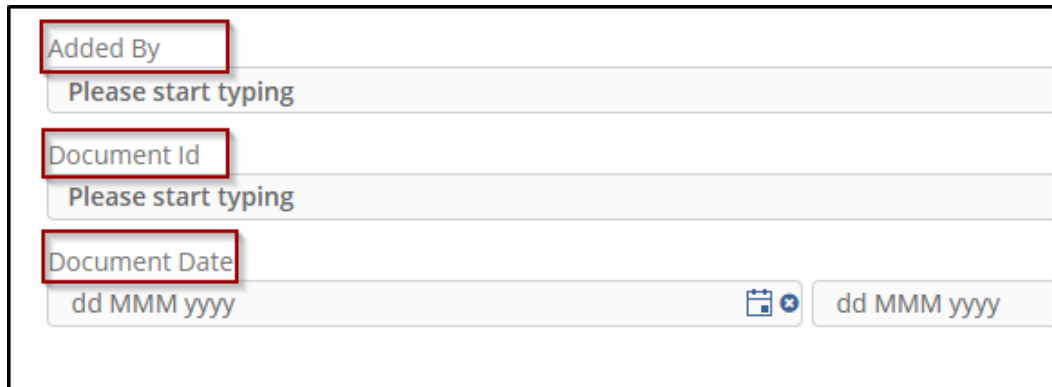
3. In the Advanced Search - Add Fields dialog, check the boxes next to the fields you want to include in your search.  
Example shown in below screenshot:
  - Added By
  - Document Date
  - Document Id

Refer to the below screenshot:



3. After selecting the desired fields, click the Save button. The selected fields will now be added to the Advanced Search interface.
4. Fill in the search criteria for the added fields:
  - Added By: Enter the name of the user who added the document.
  - Document Id: Enter the specific document ID to search for.
  - Document Date: Use the date picker to select a document date or date range.

Refer to the below screenshot:

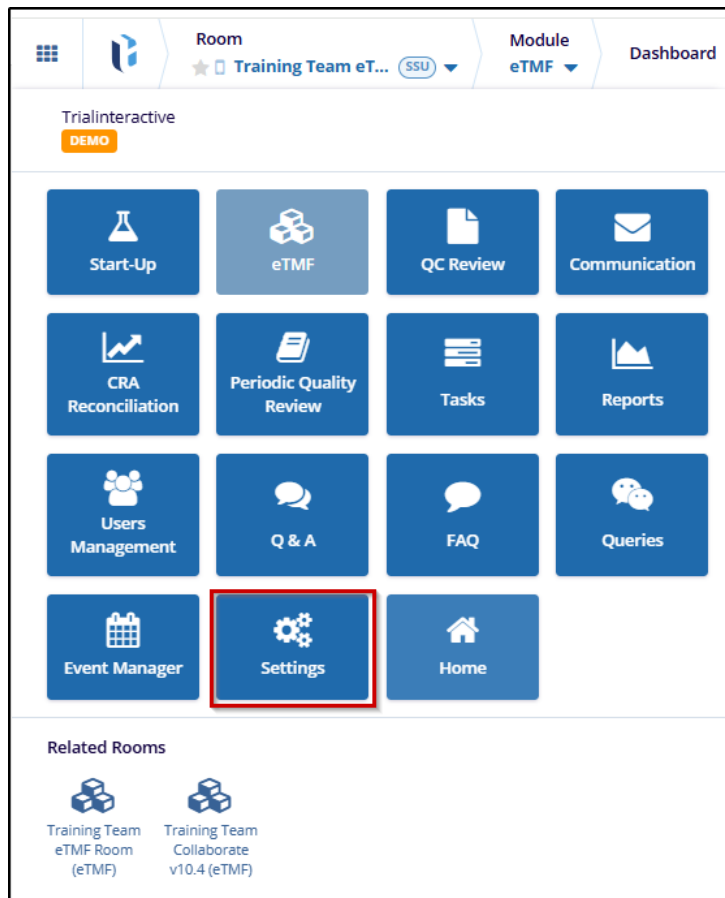


5. Click the Remove All button to clear all added fields and Reset All button to reset the entered search criteria to default values without removing the fields.

## CHAPTER 11. ROOM SETTINGS

Enter the specified room and access the Settings module from the Navigation Grid to open the Settings tile.

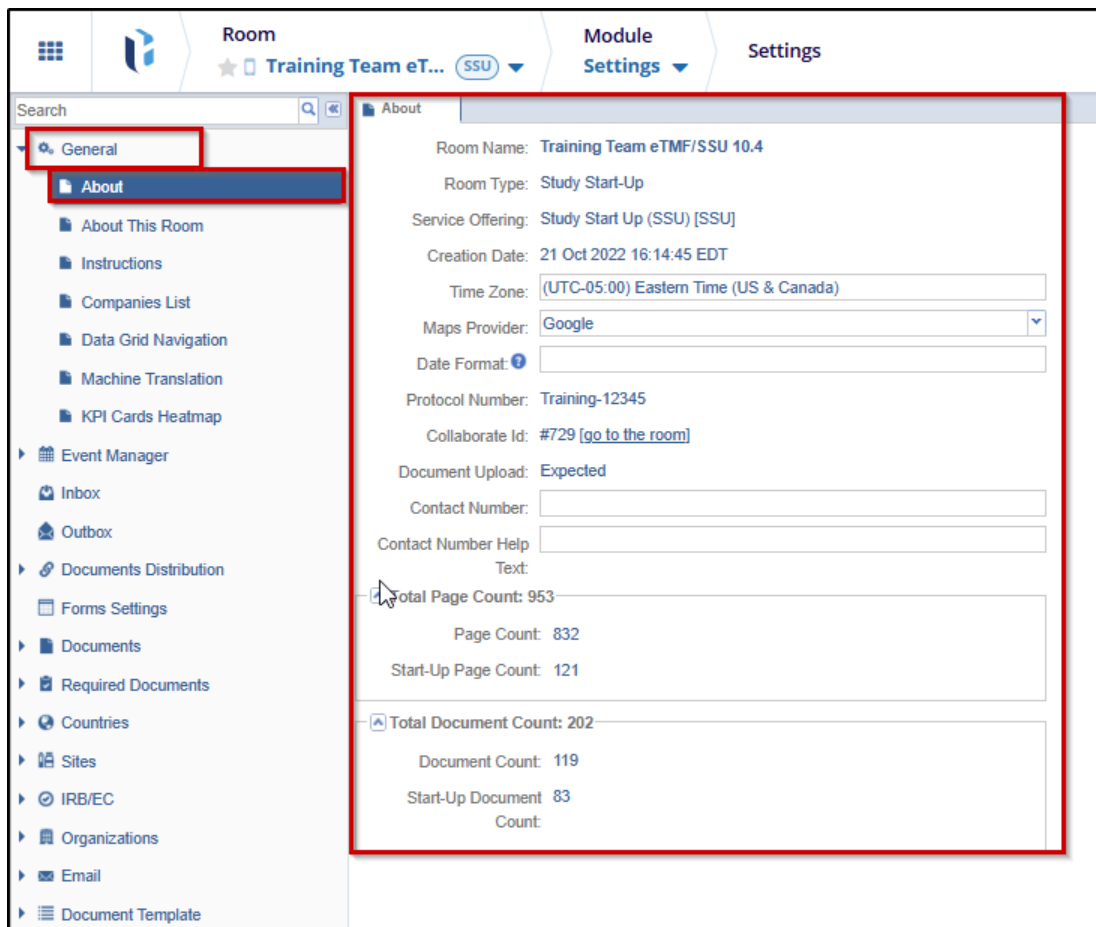
Refer to the screenshot below:



- Room administrators can access the available menus through the left pane on the Room Settings page.
- By default, when Administrator users click Settings, only the first item in the General Settings menu—the About page of the study room—is displayed.
- Most room settings menus in the left panel are organized into sub-menus, enabling targeted modifications for each category.
- To view and modify a specific sub-menu in Settings, click the arrow next to the main menu to expand it.
- Clicking a sub-menu opens it as a separate tab on the right side of the screen. If users click multiple sub-sections, a new tab is created for each item clicked.
- Right-clicking a tab provides an option to Close the Tab, Close Other Tabs, and Close All Tabs.
- A search box at the top of the left panel is available to help users quickly locate specific settings. (To understand more about Search functionality, refer to Search in the TI section)
- Administrator users can view and change most of the room settings in Trial Interactive.

- Room settings are usually determined during the initial room configuration and remain largely unchanged throughout the duration of the study.
- In most menus, a Save button is provided, which must be clicked to apply and retain any changes made to the room settings.

Refer to the screenshot below:



**Room**  
★ Training Team eT... (SSU) ▼

**Module**  
Settings ▼

**Settings**

Search

General

About

About This Room

Instructions

Companies List

Data Grid Navigation

Machine Translation

KPI Cards Heatmap

Event Manager

Inbox

Outbox

Documents Distribution

Forms Settings

Documents

Required Documents

Countries

Sites

IRB/EC

Organizations

Email

Document Template

**About**

Room Name: Training Team eTMF/SSU 10.4

Room Type: Study Start-Up

Service Offering: Study Start Up (SSU) [SSU]

Creation Date: 21 Oct 2022 16:14:45 EDT

Time Zone: (UTC-05:00) Eastern Time (US & Canada)

Maps Provider: Google

Date Format: ?

Protocol Number: Training-12345

Collaborate Id: #729 [\[go to the room\]](#)

Document Upload: Expected

Contact Number:

Contact Number Help:

Text:

Total Page Count: 953

Page Count: 832

Start-Up Page Count: 121

Total Document Count: 202

Document Count: 119

Start-Up Document Count: 83

## General

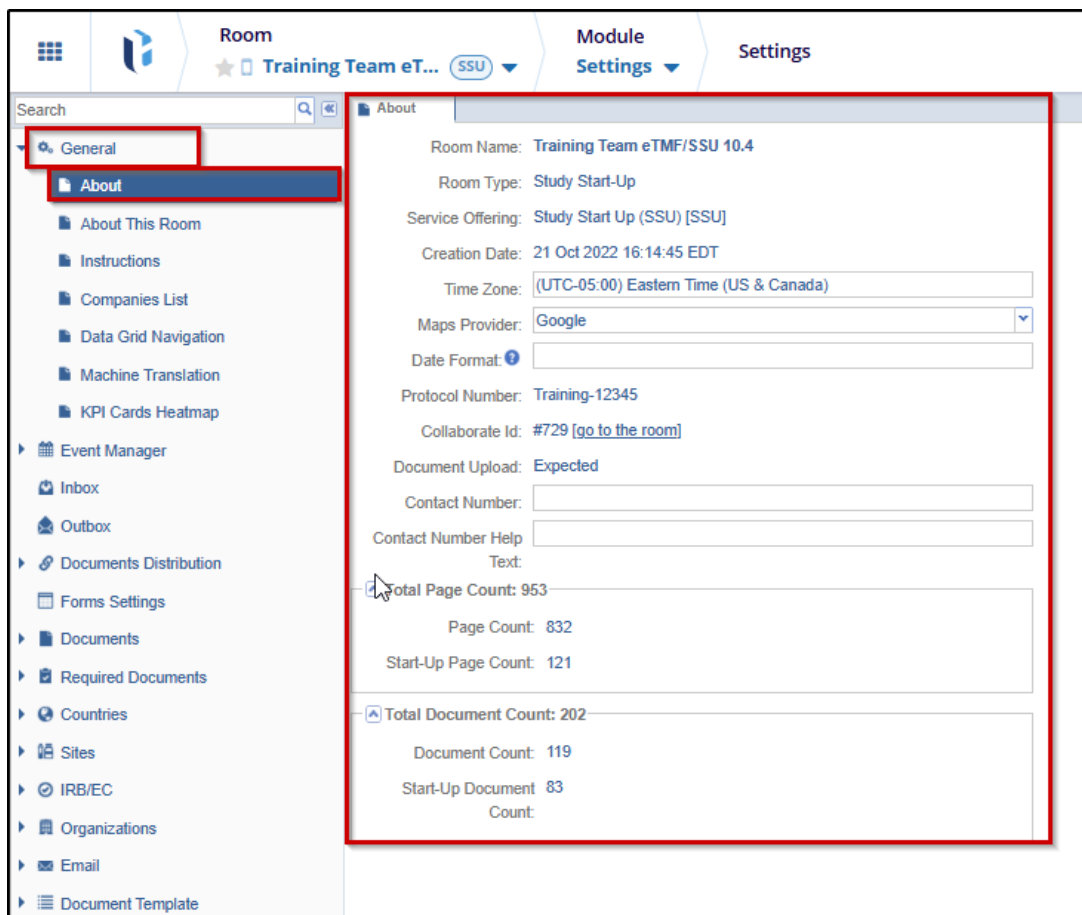
The General section describes an overview of the 'General Settings'.

### About

The About sub-section displays key details that are non-editable, as they are automatically populated with the relevant information by default such as:

- Room Name
- Room Type
- Service Offering
- Creation Date
- Time Zone
- Project Code
- Protocol Number
- Document Upload

Here, the user can add a Date in the Date Format field and contact Number for the Study contact person. Ensure you click Save to retain any changes made.



Room: Training Team eT... (SSU) | Module: Settings | Settings

Search

General

About

About This Room

Instructions

Companies List

Data Grid Navigation

Machine Translation

KPI Cards Heatmap

Event Manager

Inbox

Outbox

Documents Distribution

Forms Settings

Documents

Required Documents

Countries

Sites

IRB/EC

Organizations

Email

Document Template

About

Room Name: Training Team eTMF/SSU 10.4

Room Type: Study Start-Up

Service Offering: Study Start Up (SSU) [SSU]

Creation Date: 21 Oct 2022 16:14:45 EDT

Time Zone: (UTC-05:00) Eastern Time (US & Canada)

Maps Provider: Google

Date Format: ?

Protocol Number: Training-12345

Collaborate Id: #729 [go to the room]

Document Upload: Expected

Contact Number:

Contact Number Help:

Text:

Total Page Count: 953

Page Count: 832

Start-Up Page Count: 121

Total Document Count: 202

Document Count: 119

Start-Up Document Count: 83

The About This Room section displays the Welcome message containing information about the specific room. The user can include placeholders such as `##UserName##` and `##SourceRoomName##` to dynamically display the user's name and room name. Ensure you click Save to apply and retain any changes.

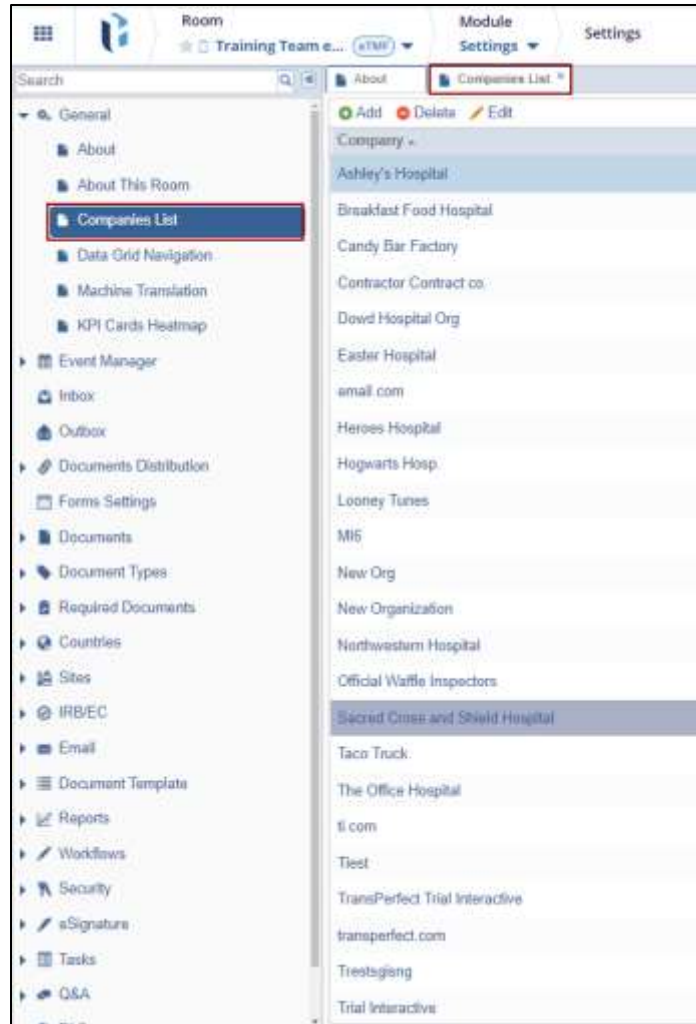
The screenshot shows the eTMT application interface. On the left is a vertical sidebar with a menu. The menu items include: Home, About, About This Room (highlighted with a red box), Comparison List, Data Grid Navigation, Machine Translation, KPI Cards Dashboard, Event Manager, Inbox, Outbox, Documents Distribution, Privacy Settings, Documents, Document Types, Registered Documents, Courses, Sites, iFRAGG, Thread, Document Template, Reports, Workflows, Security, eSignatures, Tools, and QA. The main content area on the right displays a 'Welcome' message for a user named 'User Name', followed by instructions about accessing documents and a link to view many documents. At the bottom, there is a footer with version information and a copyright notice.

The list of Companies gets populated and this menu allows the room administrator to Add, Edit, or Delete a company. Double-clicking on the company name allows you to rename the name. This normally becomes useful when a large number of room users have been invited via the Quick Invitation method because it allows users to specify their company. Normally, in instances like this, there are several variations created by the users via acronyms, abbreviations, and misspellings.

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CL: Public Page 356 of 667



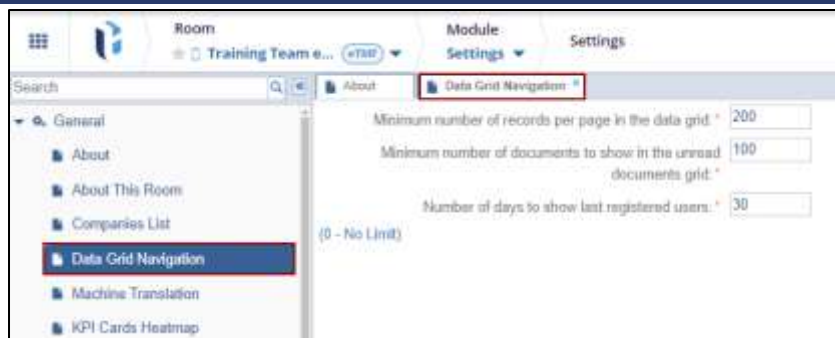


## Data Grid Navigation

The options in this menu vary based on room configuration but can be used as follows:

1. Minimum number of records per page in the data grid:
  - This option sets the maximum number of records displayed per page in the data grid.
2. Minimum number of documents to show in the unread documents grid:
  - This impacts the Documents dashlet on the dashboard and shows the maximum number of documents displayed in the unread documents view.
3. Number of days to show last registered users:
  - This option also impacts a dashlet. The Users dashlet has a toggle indicating whether it should display 'New' users or 'All' users. This field defines how many days a user appears on the 'New' list.

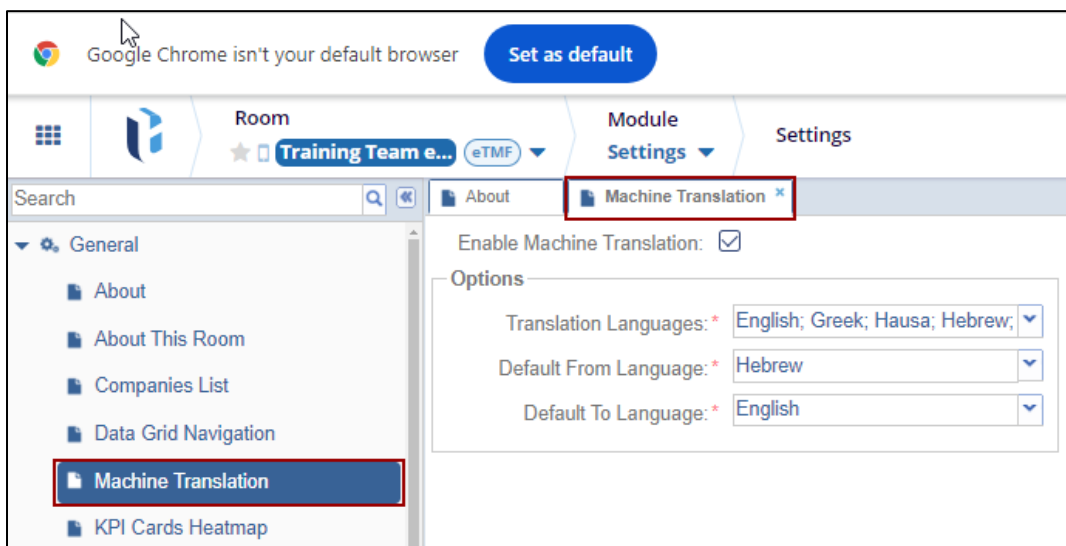
Ensure to click Save to apply and retain any changes.



## Machine Translation

The Menu Translation menu provides users with control over the 'Machine Translation' feature, offering three options to customize its behavior according to their specific needs.

- **Translation Languages:** This menu allows users to switch languages based on their preferences or specific requirements.
- **Default From Language:** This menu allows users to set the starting point for the translation process.  
Example: If most of your content is written in English, you would set "Default From Language" to English.
- **Default To Language:** This menu allows users to define the target language for translations.  
Example: If your audience primarily speaks Spanish, you would set "Default To Language" to Spanish.



Note: The Machine Translation function is compatible exclusively with .pdf documents that have undergone OCR (Optical Character Recognition) processing.

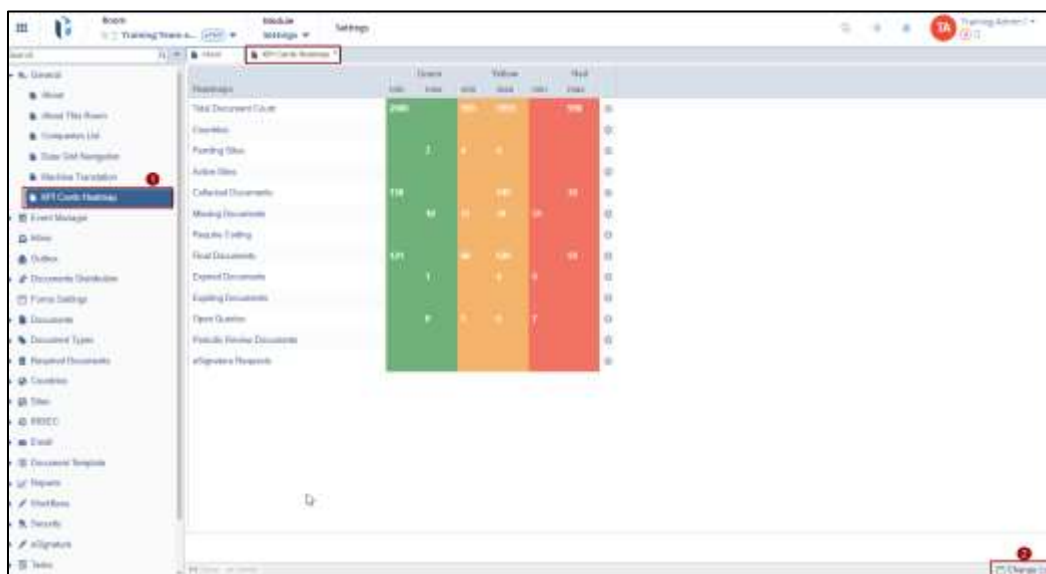
Ensure to click Save to apply and retain any changes.

## KPI Cards Heatmap

The KPI Cards Heatmap in the Trial Interactive settings provides a quick visual overview of key performance indicators (in numbers) across various categories such as:

- Total Document Count
- Countries
- Pending Sites
- Active Sites
- Collected Documents
- Require Coding
- Final Documents
- Expired Documents
- Open Queries
- Periodic Review Documents
- eSignature Requests

The heatmap uses color-coded thresholds (Green, Yellow, Red) to indicate performance levels or urgency.



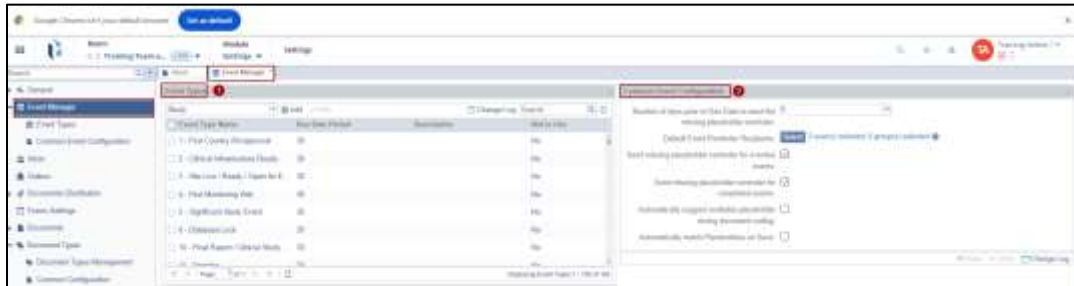
The Change Log option, located at the bottom right of the screen, displays a record of the KPI Cards Heatmap. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

## Event Manager

The 'Event Manager' section provides a detailed overview of the Event Manager settings, guiding users on how to configure and manage event-related options effectively i.e.,

- Event Types
- Common Event Configuration



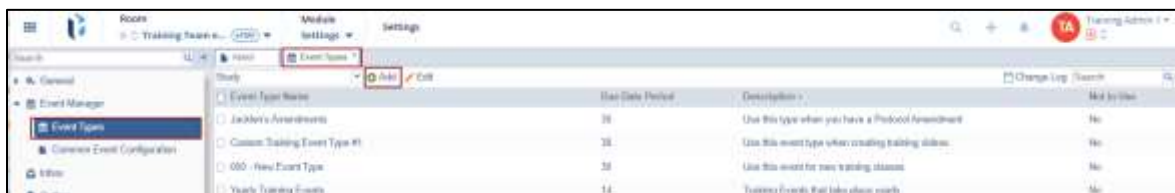
## Event Types

The 'Event Types' functions as an additional location for managing event types within at Study, Site, and Country levels. The room will display all the Event Types depending upon the criterion selected.

## Add an Event Type

To add an event type, follow these steps:

1. Click the Add button the Event Type Profile pop-up window is displayed.
2. Complete all mandatory fields and click OK.
3. The newly created event type will appear on the main page under the selected category.



Event Type Profile

Event Type Name: \*

Category: \*

Study

Due Date Period: \* ?

Description:

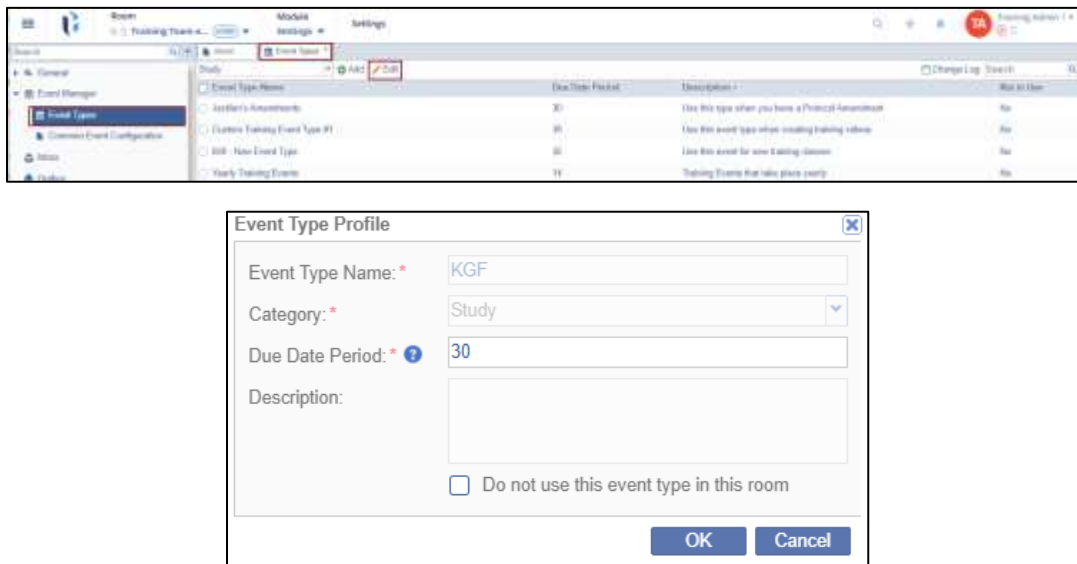
OK

Cancel

## Edit an Event Type

To edit an event type, follow these steps:

1. Click the Edit button, and the Event Type Profile pop-up window is displayed.  
Note: Here, the user can see the 'Due Date Period' field is editable.
2. Enter the number to set the due date for the selected event and click OK.
3. The updated due date period will appear on the main page under the Due Date Period column.



## Change Log in Event Types

The Change Log option provides a detailed record of event types added or modified by the user. It consists of two sections:

- The left section lists event types along with their creation and update statuses.
- The right section displays detailed information about the selected event type, including the date and timestamp of each update.

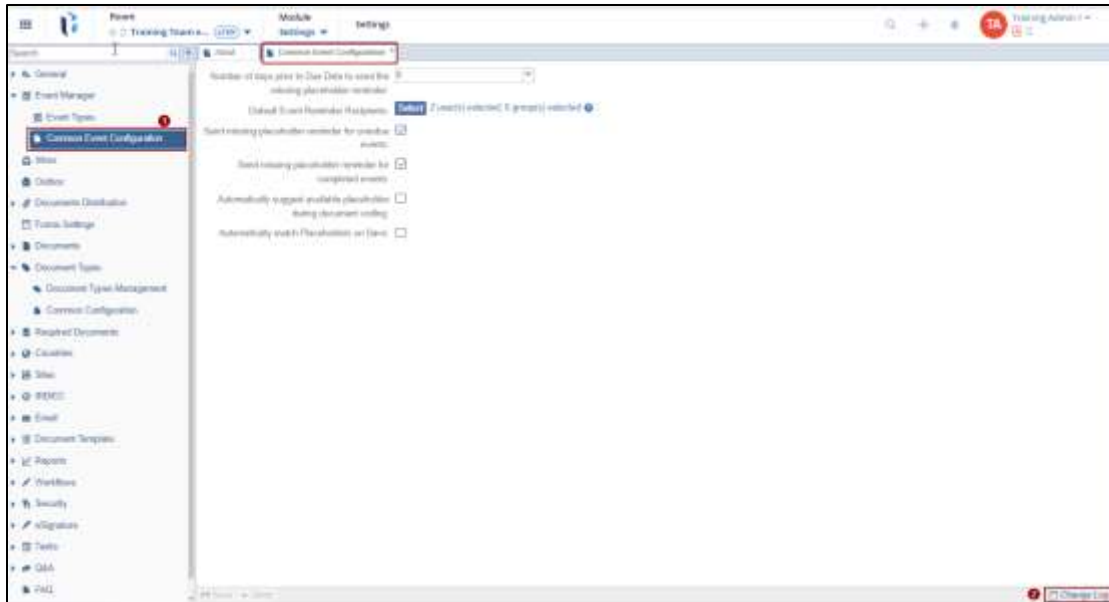
The log includes columns for Date, Author, Item Name, Action, and a Close button.

Ensure to click Save to apply and retain any changes.

## Common Event Configuration

The room administrator can configure the frequency of reminder notifications for placeholders generated by events, overdue events, and completed events. These notifications will be sent to members of the Responsible Department linked to the document types of the missing documents.

If Responsible Departments are not configured in your study room, you can use the "Default Event Reminder Recipients" option to designate users who will receive notifications for all missing event-related documents, regardless of department association.

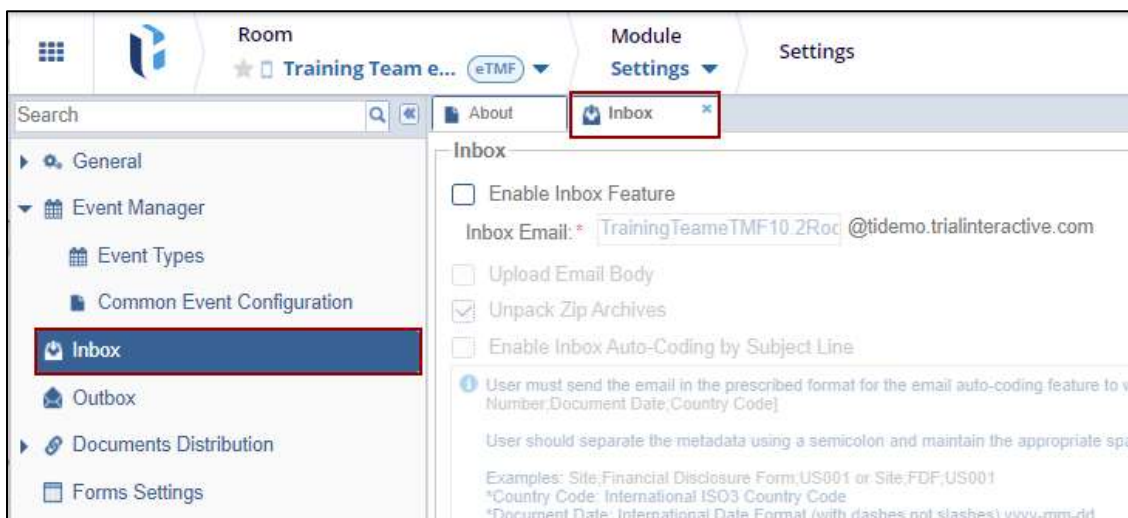


The Change Log option, located at the bottom right of the screen, displays a record of Common Event Configuration. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

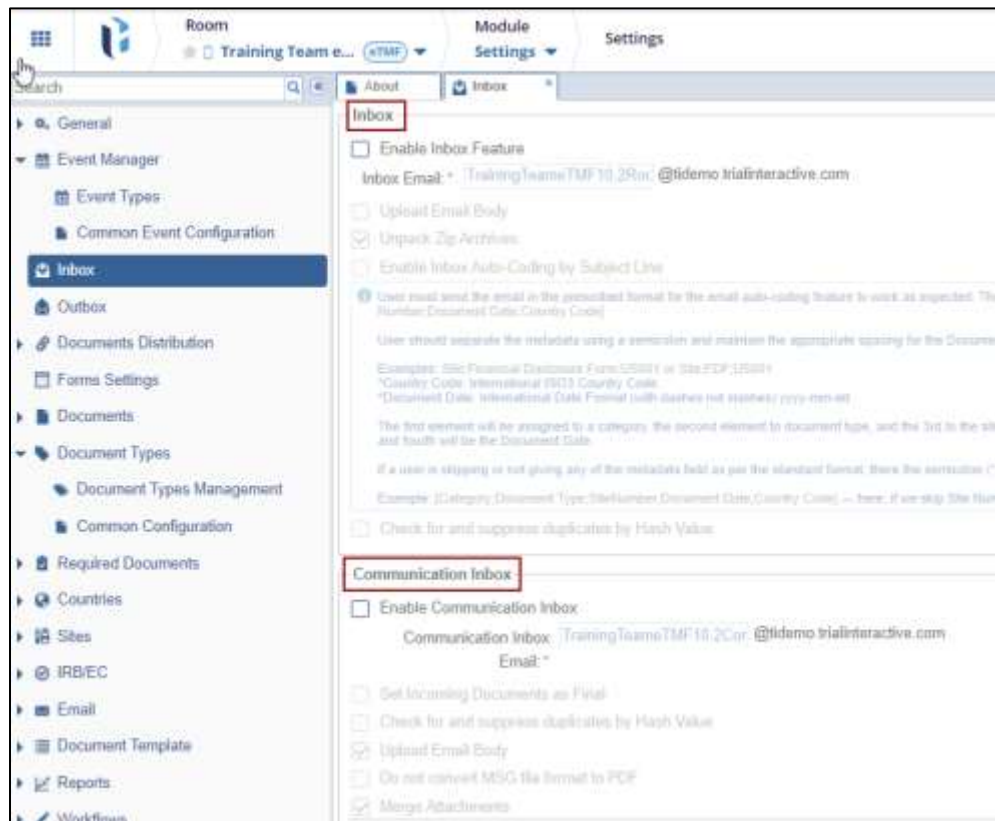
## Inbox

The Inbox in the Event Manager handles incoming emails related to clinical trial documents or communications. It automatically processes and categorizes emails by extracting metadata from the subject line, enabling efficient handling of tasks such as document uploads and communication management. This automated system ensures accurate metadata assignment, minimizing manual input and streamlining workflow efficiency.



## Sections of Inbox:

- Inbox
- Communication Inbox

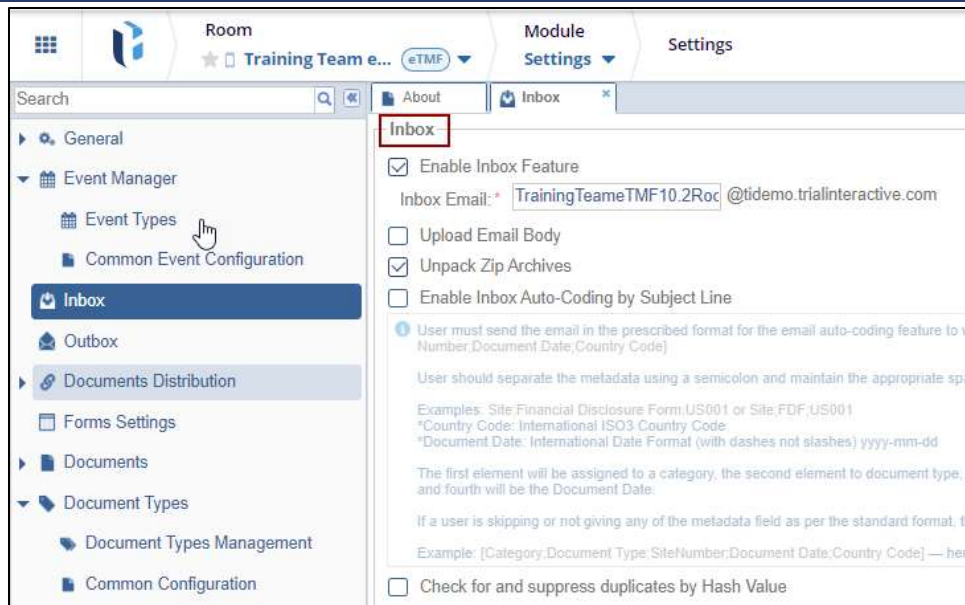


Ensure to click Save to apply and retain any changes.

## Inbox

- Room administrators can activate the Inbox by selecting the checkbox, allowing room participants to send trial documents directly to the room's inbox.
- Enabling the "Upload Email Body" option by checking the checkbox will automatically convert the body of incoming emails in the Inbox into PDF files for easier documentation and storage.
- Select the "Unpack Zip-Archives" option to automatically extract files from attached zip folders in incoming emails.
- The "Enable Inbox Auto Coding by Subject Line" option allows users to send emails to the room with subject lines formatted according to specific guidelines, ensuring that the received documents are automatically tagged with the appropriate metadata.
  - When the "Enable Inbox Auto-Coding by Subject Line" checkbox is selected, the corresponding tooltip becomes active, providing users with specific guidelines for formatting subject lines to ensure accurate automatic metadata assignment.
- Enable the "Check for and suppress duplicates by Hash Value" option to prevent duplicate publishing of email-converted documents by identifying and suppressing duplicates based on their hash value.

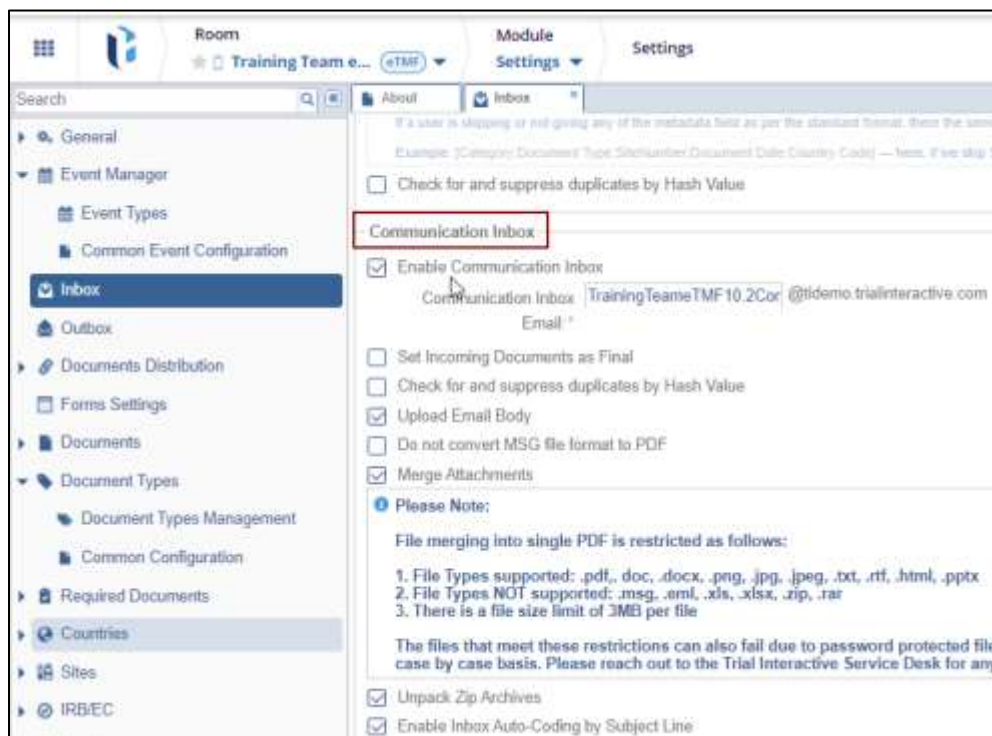




Ensure to click Save to apply and retain any changes.

## Communication Inbox Options

The Communication Inbox is a centralized section where study-related communications are organized and managed. This inbox allows users to review and classify communications for their relevance to the study. Communications are automatically converted into PDF format upon receipt and displayed in a tabular format for easy processing.

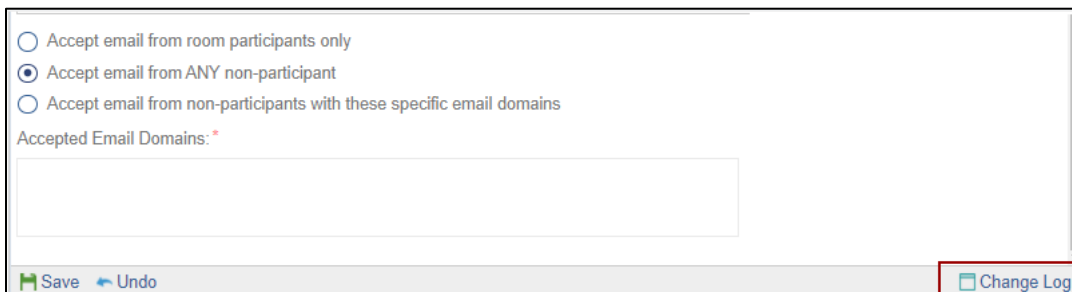




- Room administrators can enable the Communication Inbox by checking the checkbox, allowing room participants to receive the trial documents.
- Enabling the "Set Incoming Documents as Final" option ensures that documents received directly in the Communication Inbox are automatically marked as final upon receipt.
- Enable the "Check for and suppress duplicates by Hash Value" option to prevent duplicate publishing of email-converted documents by identifying and suppressing duplicates based on their hash value.
- Enabling the "Upload Email Body" option automatically converts the body of incoming emails in the Inbox into PDF files for easier documentation and storage.
- Selecting the "Do not convert MSG file format to PDF" option prevents the conversion of received emails in MSG format to PDF.
- Enabling the "Merge Attachments" option will combine all attachments received in the email into a single document for streamlined processing and storage.
- Select the "Unpack Zip-Archives" option to automatically extract files from attached zip folders in incoming emails.
- The "Enable Inbox Auto Coding by Subject Line" option allows users to send emails to the room with subject lines formatted according to specific guidelines, ensuring that the received documents are automatically tagged with the appropriate metadata.
  - When the "Enable Inbox Auto-Coding by Subject Line" checkbox is selected, the corresponding tooltip becomes active, providing users with specific guidelines for formatting subject lines to ensure accurate automatic metadata assignment.
- Users can choose to publish relevant communications from the Communication Inbox directly to the eTMF Index as final documents for seamless documentation and archiving.

In addition to the options mentioned above, you can enable the following features for the Inbox:

- Accept email from room participants only: When enabled, this option ensures that only emails from registered room participants are accepted. Emails from non-participants will be rejected.
- Accept email from ANY non-participant: When enabled, this option allows emails from any sender, regardless of their participation status in the room.
- Accept emails from non-participants with these specific email domains: When enabled, the room administrator can specify permitted email domains, allowing only emails from those domains to be accepted by the study room.



The Change Log option, located at the bottom right of the screen, displays a record of Inbox. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

## Outbox

This menu allows users to enable or disable the room's Outbox feature, which maintains a log of all emails sent from the room. For instance, query notifications are recorded in the Outbox. The Outbox is accessible through the room's Communications Module.



The Change Log option, located at the bottom right of the screen, displays a record of Outbox. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

## Documents Distribution

Users can be permitted to share documents from one room to another, creating a copy in the target room that remains functionally linked to the source document. This feature is commonly used when publishing documents from a TI Content Management room. Any updates or versioning of the shared document in the source room will automatically reflect in the target room once the new version becomes effective.

To use the Document Distribution function, users must have the appropriate permission assigned through the associated Action in their user profile.

Users must be granted the necessary permission through the associated Action in their user profile to enable the use of the Document Distribution function.



The Change Log option, located at the bottom right of the screen, displays a record of Common Configuration. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

| Change Log History            |                                                                                      |                                                                                      |              |                          |
|-------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------|--------------------------|
| Common Configuration          |                                                                                      |                                                                                      |              |                          |
| Item Name                     | New Value                                                                            | Old Value                                                                            | Updated By   | Updated On               |
| Enable Documents Distribution | Yes                                                                                  | No                                                                                   | Demo Admin   | 22 Feb 2023 02:53:49 EST |
| Enable Documents Distribution | No                                                                                   | Yes                                                                                  | Ashley Parik | 29 Nov 2022 07:27:20 EST |
| Share or Publish Document     | to Workflow (Document will be added to all active workflows in the destination room) | as Final                                                                             | Admin 102    | 24 Aug 2022 08:22:34 EDT |
| Share or Publish Document     | as Final                                                                             | to Workflow (Document will be added to all active workflows in the destination room) | Admin 102    | 24 Aug 2022 08:21:38 EDT |
| Enable Documents Distribution | Yes                                                                                  | No                                                                                   | Admin 102    | 17 Aug 2022 13:08:33 EDT |
| Enable Documents Distribution | No                                                                                   | Yes                                                                                  | Ashley Parik | 17 Aug 2022 10:25:27 EDT |
| Enable Documents Distribution | Yes                                                                                  | No                                                                                   | Admin 102    | 03 May 2022 10:40:59 EDT |
| Enable Documents Distribution | No                                                                                   | Yes                                                                                  | Admin 102    | 03 May 2022 10:40:00 EDT |
| Enable Documents Distribution | Yes                                                                                  | No                                                                                   | Admin 102    | 03 May 2022 10:39:52 EDT |
| Share or Publish Document     | to Workflow (Document will be added to all active workflows in the destination room) | as Final                                                                             | Admin 102    | 03 May 2022 10:38:53 EDT |
| Show All                      |                                                                                      |                                                                                      |              |                          |
| Close                         |                                                                                      |                                                                                      |              |                          |

## Common Configuration

This option allows users to enable or disable the Document Distribution function and specify whether shared documents will be directly published as final documents in the target room or require processing through the room's QC workflow before being finalized.

To activate the Document Distribution feature, the "Enable Document Distribution" checkbox must be selected, and the following radio buttons should be configured based on the requirement:

- Document Distribution Mode: Defines how documents are distributed across rooms.
- Share or Publish Document: Determines whether the document will be shared (linked with the source) or published (independent copy) as Final or to the Workflow.



## Linked Rooms

This option displays the linked rooms in the grid with the Edit Link and Unlink Rooms options.



## Edit Link

Follow the following steps:

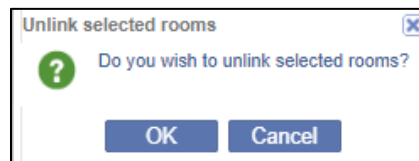
1. Select the room from the grid, the Edit Link option gets enabled.
2. Click the Edit Link button below the top menu bar. The Edit Link pop-up window is displayed.



## Unlink Rooms

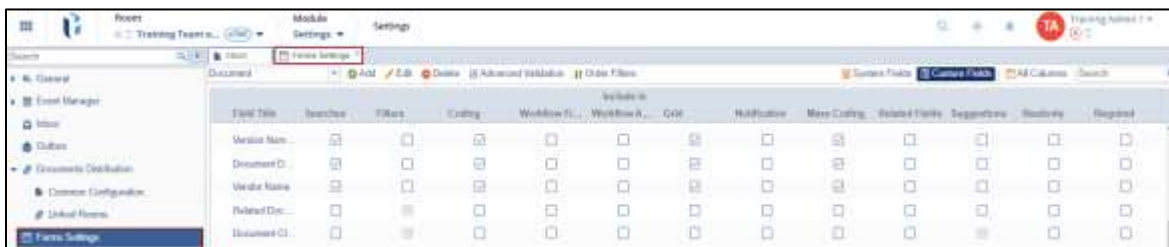
The Unlink option removes the selected linked room from the grid.

1. Select the room from the grid, the Unlink Rooms option gets enabled.
2. Click the Unlink Rooms button below the top menu bar. The Unlink selected rooms pop-up window is displayed.
3. Click OK.

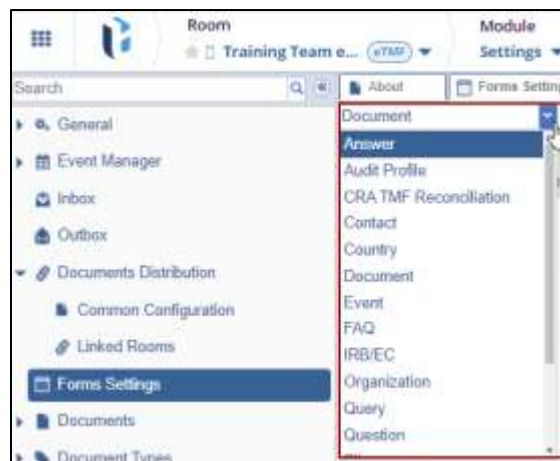


## Forms Settings

The Form Settings menu manages metadata and form settings across the study room. It allows customization of form fields used throughout the study, including document metadata fields, Question and Answer forms, and audit-related fields.

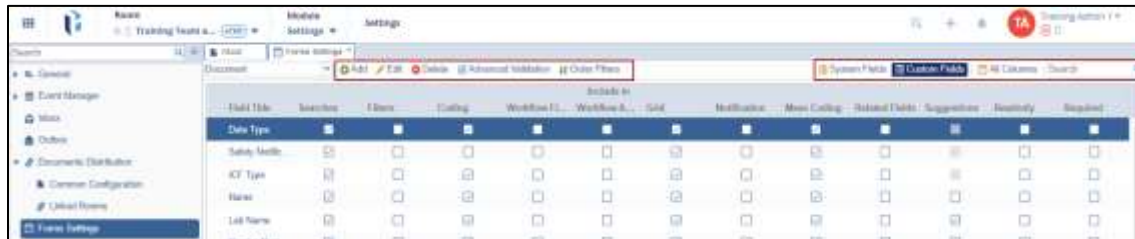


Users can choose the appropriate category based on their requirements, as illustrated in the screenshot below. This selection helps in organizing and categorizing documents or events efficiently within the study room.



Although individual fields and field options vary by form, the processes to Add, Delete, and Edit settings remain consistent across all forms.

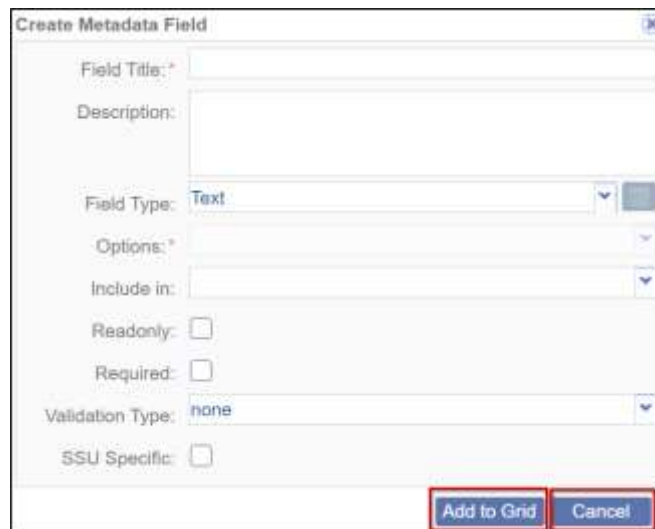
1. Navigate to the Settings module and select Forms Settings.
2. The Metadata Fields window opens in the grid. From this menu, you can perform the following functions:
  - Add
  - Edit
  - Delete
  - Advanced Validation
  - Order Fields
  - System Fields
  - Custom Fields
  - All Columns
  - Search



## Add

Follow the steps below:

1. Click Add from the menu bar.
2. The Create Metadata Field pop-up window opens. Fill in all the required fields with Add to Grid and Cancel options.
3. Click Add to Grid, and the created form gets displayed in the grid.



4. Select Field Type as Boolean in the Field Type field and choose the most appropriate option:
  - i. Checkbox – Displays the values as a list, allowing users to select one or more options.
  - ii. Radio – Displays the values as a list, requiring users to select only one option.

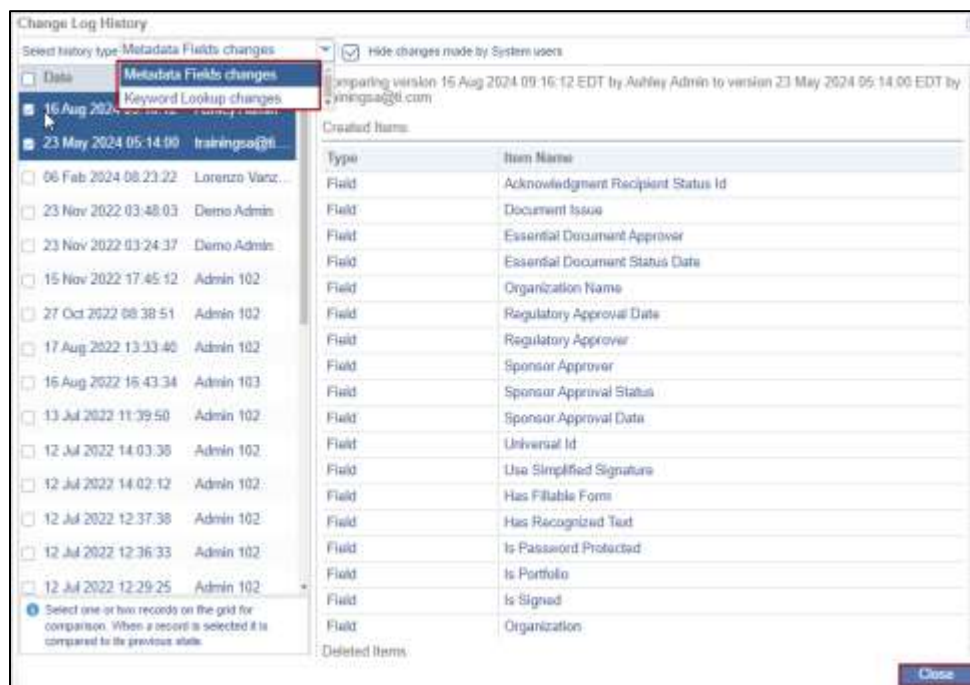


- iii. Combo – Provides a dropdown list from which users can select only one option.
5. Click the 'Include in' dropdown arrow and select the appropriate option from the list that will get populated in the grid.
6. The Search Option field is dependent on the selection made in the Include In field.
7. The options in this menu correspond to the options on the Forms Settings grid.
  - Click the Read-only checkbox if required.
  - Click the Required checkbox if necessary.
8. The Validation type field is dependent on the Field Type. For instance, if the Text Field Type is selected, you might restrict the entries made there to alphabetical characters or alphanumeric characters.
9. Click 'Add to Grid', and the view returns to the full Document Profile Form display.

The Change Log option, located in the bottom-right corner of the screen, provides a detailed record of Form Settings in 2 different ways i.e., 'Metadata Fields changes' and 'Keyword Lookup changes.' The interface is divided into two sections:

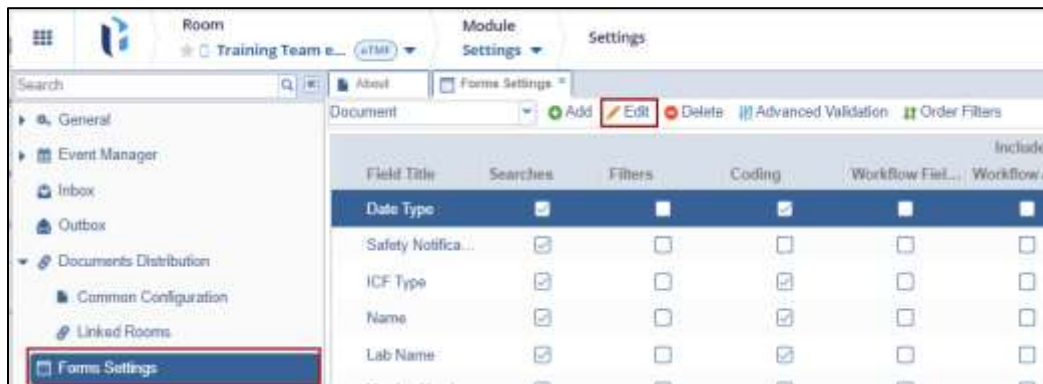
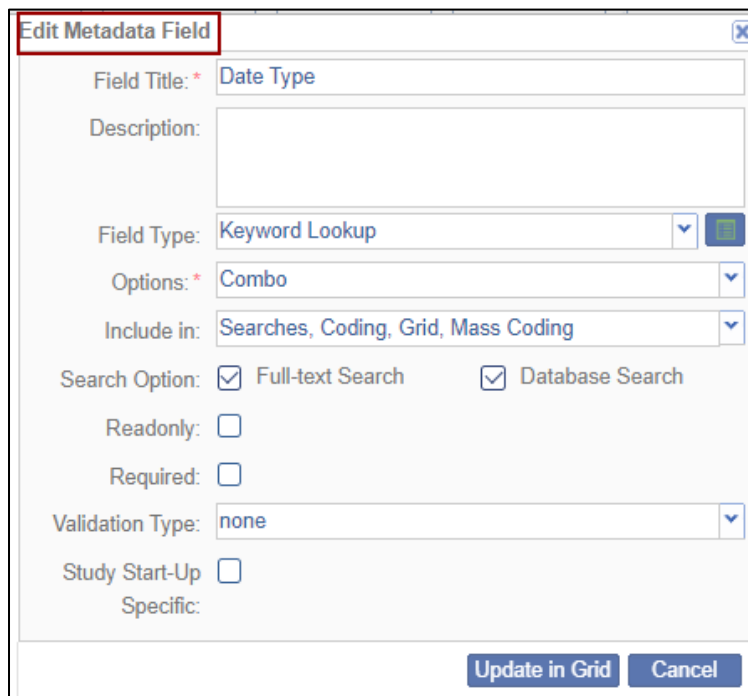
- Left Panel: Displays a history of changes categorized by Metadata Field updates and Keyword Lookup modifications, along with the corresponding date and author with Timestamp columns.
- Right Panel: Enables comparison between two selected dates, showing a breakdown of Created Items, Deleted Items, and Updated Items. A Close button is available for easy navigation.

Ensure you click Save to apply and retain any changes.



## Edit

1. Click Edit in the menu ribbon. The Edit Metadata Field pop-up window opens. Refer to the screenshot below:

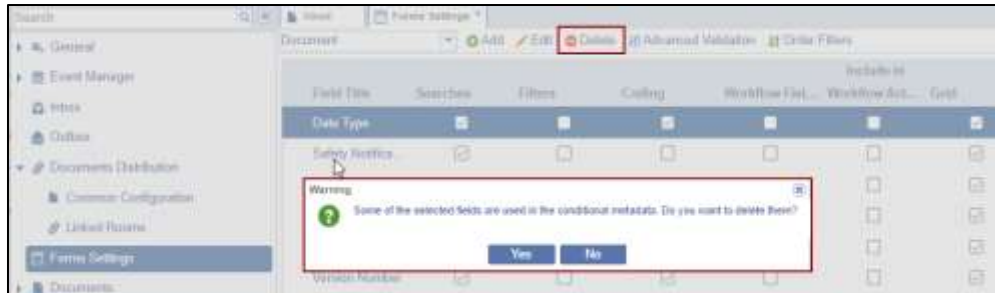
2. Make the required changes in the available fields.
3. Click 'Update in grid' at the bottom of the window. It is displayed in the grid.
4. Press 'Save' to keep any changes.

In this version, a new feature is added Search Option: Full-text Search Database Search.

## Delete

1. Select the field to be deleted. The row is highlighted in blue.
2. Click the Delete from the top menu bar.
3. The Warning pop-up window is displayed with Yes and No options.





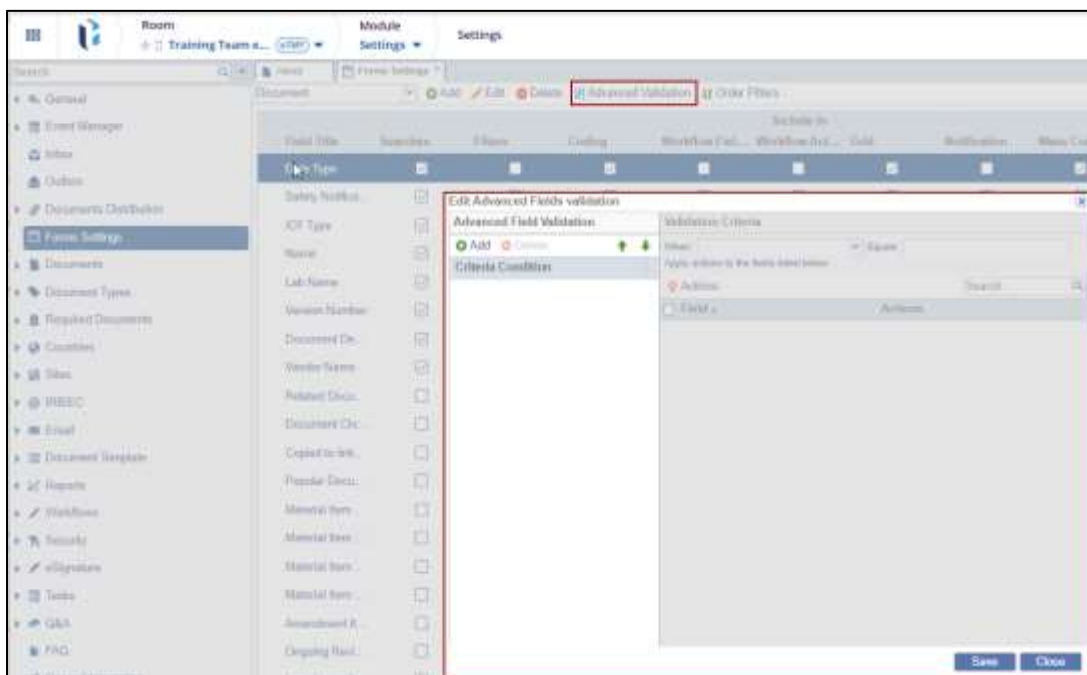
4. Press 'Yes' if the user wants to delete a field.
5. Press 'Save' to keep any changes or use the 'Undo' button if you want to undo the changes.

## Advanced Validation

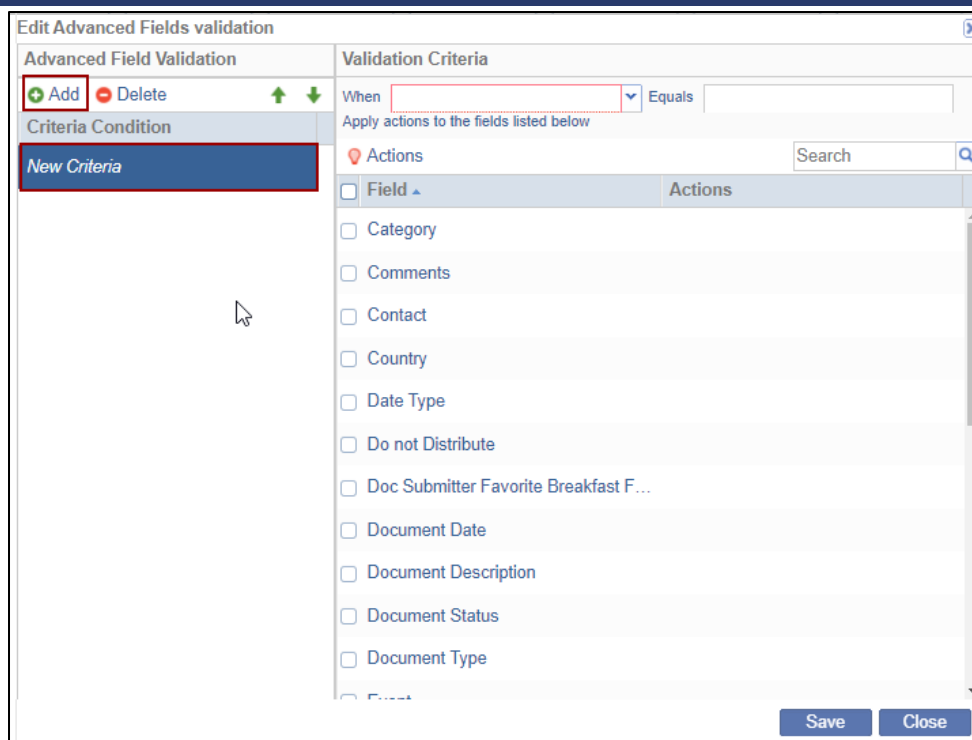
This advanced function links two or more metadata fields based on specified validation criteria and is not generally used by Administrators. We recommend partnering with the Trial Interactive Service Desk before making any changes to these settings.

1. Click Advanced Validation in the menu bar. The Edit Advanced Fields validation window opens.

Refer to the screenshot below:



2. Click Add in the Advanced Fields Validation panel on the left. The 'Validation Criteria' panel on the right activates.
3. The New Criteria field gets added below the Criteria Condition button. Double-click the 'New Criteria' field and the user can rename the same.



**Edit Advanced Fields validation**

**Advanced Field Validation**

+ Add - Delete ↑ ↓

Criteria Condition

New Criteria

**Validation Criteria**

When [ ] Equals [ ]

Apply actions to the fields listed below

Actions

Field Category

Category

Comments

Contact

Country

Date Type

Do not Distribute

Doc Submitter Favorite Breakfast F...

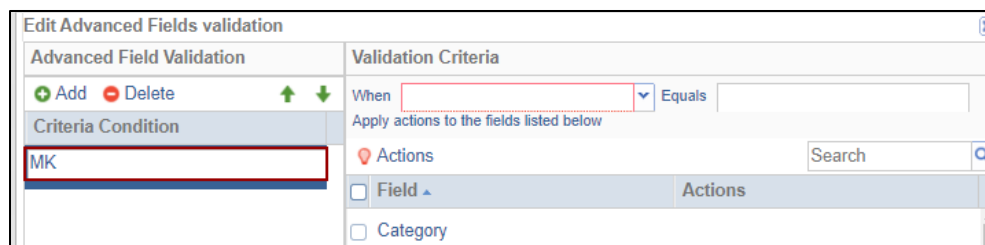
Document Date

Document Description

Document Status

Document Type

Save Close



**Edit Advanced Fields validation**

**Advanced Field Validation**

+ Add - Delete ↑ ↓

Criteria Condition

MK

**Validation Criteria**

When [ ] Equals [ ]

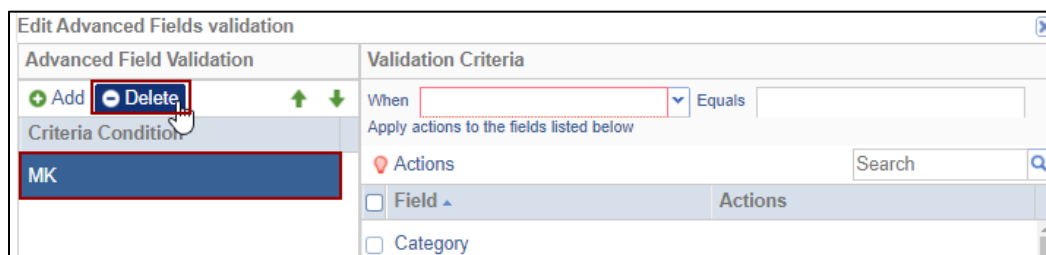
Apply actions to the fields listed below

Actions

Field Category

Category

- The user can delete the created New Criteria name by clicking on the Delete button in the Advanced Fields Validation panel on the left. The Criteria name disappears from the left panel.



**Edit Advanced Fields validation**

**Advanced Field Validation**

+ Add - Delete ↑ ↓

Criteria Condition

MK

**Validation Criteria**

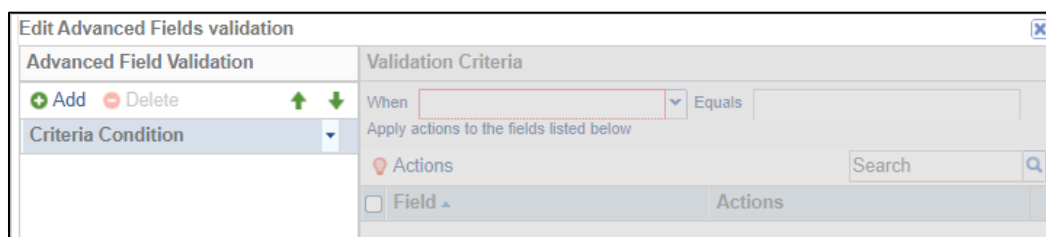
When [ ] Equals [ ]

Apply actions to the fields listed below

Actions

Field Category

Category



**Edit Advanced Fields validation**

**Advanced Field Validation**

+ Add - Delete ↑ ↓

Criteria Condition

**Validation Criteria**

When [ ] Equals [ ]

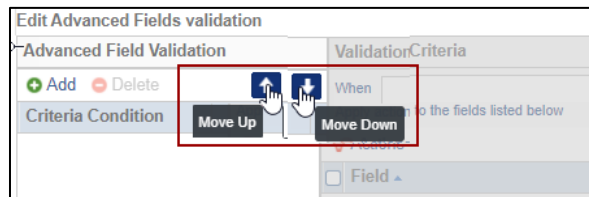
Apply actions to the fields listed below

Actions

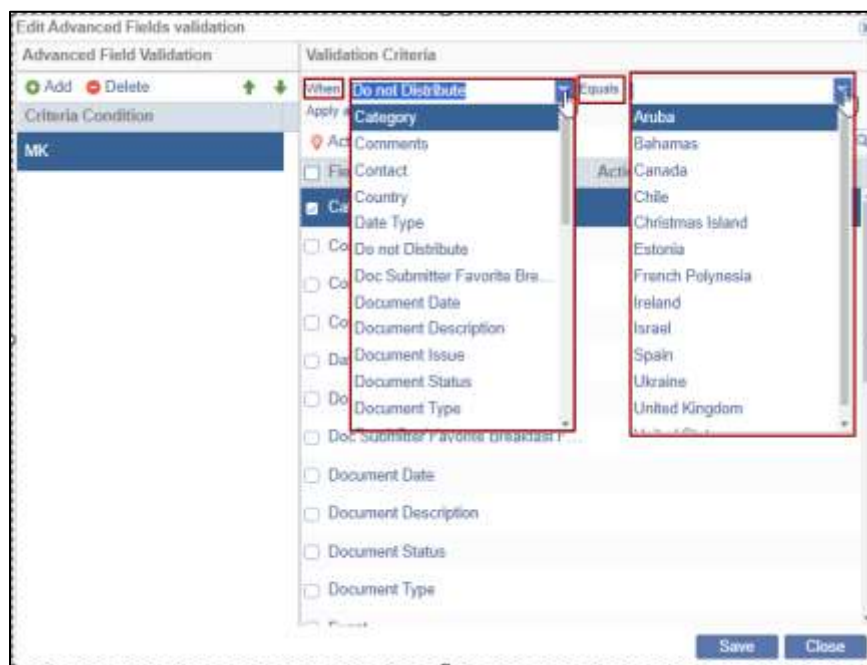
Field Category

Category

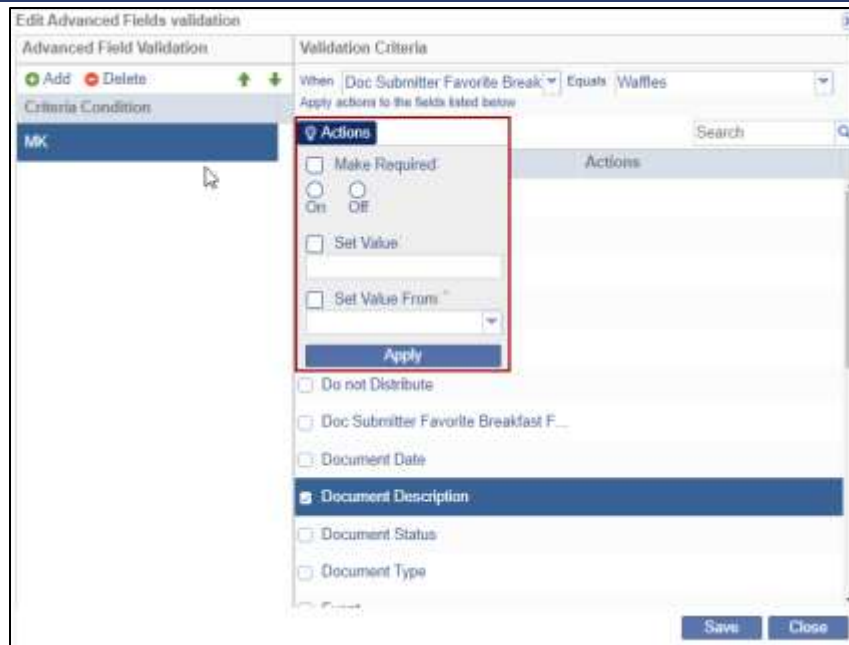
- The Arrows help the user to move up and down the added criteria if there are many.



- Click the drop-down arrow next to the When field in the right panel. Select the metadata field that will trigger an action in another metadata field.
- The Equals field is determined by the field selected in the When field.  
**Note:** For fields requiring data selection from a predefined set of options, use the dropdown menu.  
For example: date-related metadata fields, that are Equal to the field transform into a calendar selector, in some cases, the Equals field is presented as a text box for manual input.



- Click the Actions button. Select the appropriate radio button to define what action will be implemented in the field or fields that will be selected in the next step of the process.
- Click the checkbox or checkboxes for the field or fields that you want to be affected in this field validation.

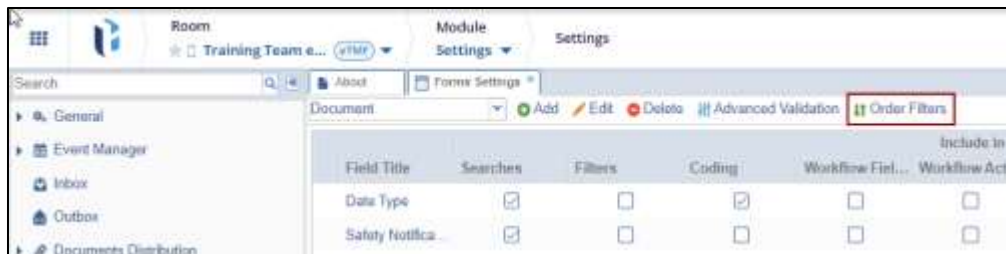


10. Click Save. The selected Action will apply to the selected Fields when the Validation Criteria you have set are met in a particular document's metadata.

## Order Filters

The user can manually reorder the facets (categories or elements) by dragging and placing them in a sequence of their choice, rather than relying on a predefined or automatic order. This allows for personalized organization based on preference or specific needs.

The Order Filters option allows users to sort items in ascending or descending order. Clicking Update in Grid applies the changes to the grid view.



Order Filters

Order A-Z
Order Z-A
Drag lines to order facets in an arbitrary way

| Field Name          | Field Title     |
|---------------------|-----------------|
| InvestigativeSiteId | Site            |
| DocumentTypeId      | Document Type   |
| \$\$DocumentId\$\$  | Document Id     |
| DocumentStatusId    | Document Status |
| IRBId               | IRB/EC          |
| \$DocumentOwnerId\$ | Document Owner  |
| \$\$AddedBy\$\$     | Added By        |
| PublishedBy         | Published By    |
| ContactId           | Contact         |
| \$UploadSource\$    | Upload Source   |

Update in Grid
Cancel

## System Fields

The System fields refer to metadata fields that are predefined and managed by the system itself, rather than being custom-defined by users. These fields typically capture essential or operational data required for the system's functionality.

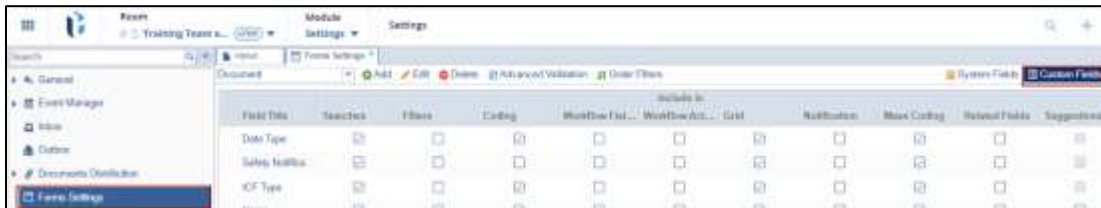
System fields are often non-editable by users and are automatically populated or maintained by the system based on specific actions or configurations. The 'Green' marked icon beside the field title name indicates that these field title names are System Fields.

| System Fields   |                                     |                          |                          |                          |                          |                          |                          |                          |                          |
|-----------------|-------------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Field Title     | Searchable                          | Filterable               | Catalog                  | Workflow Field           | Workflow Act.            | Grid                     | Notification             | Mass Coding              | Related Field            |
| Document No.    | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Revised Date    | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Published to e  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Global Post     | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Completed Date  | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Event           | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Event Type      | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| to CCWF Pass    | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Principal Issue | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Category        | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Site            | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Country         | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Contract        | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Document Type   | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

## Custom Fields

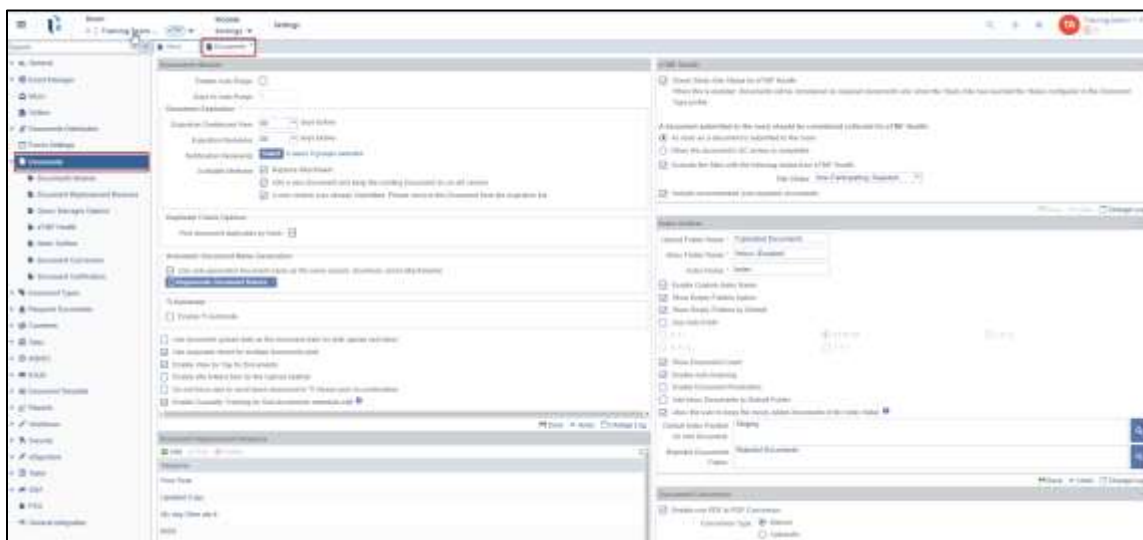
Custom fields are metadata fields created and defined by users or administrators to meet specific business or project requirements. Custom fields allow for flexibility and personalization.

Custom fields can often be configured with specific data types (e.g., text, date, dropdown) and validation rules to ensure consistency and relevance to the user's workflow.



## Documents

Here, you can manage all document-related settings for a room. The Document page provides the following options:



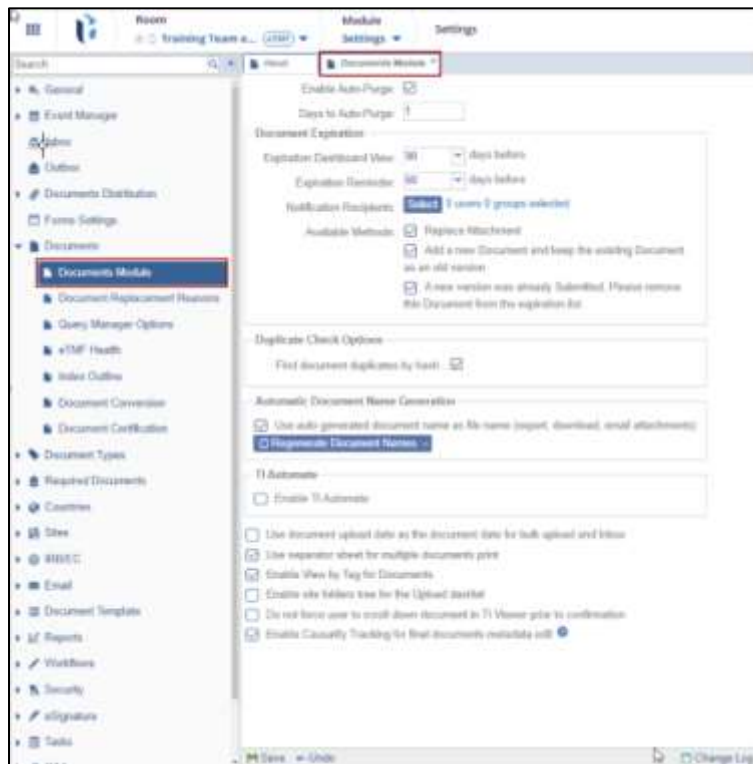
- Documents Module
- Document Replacement Reasons
- Query Manager Options
- eTMF Health
- Index Outline
- Document Conversion
- Document Certification

## Documents Module

### Auto Purge Settings

Trial Interactive offers the ability to permanently purge deleted documents as needed. This can be done manually from the Deleted Documents view in the Documents module or configured as an automated process. Follow the instructions below to set up Auto Purge.

1. Navigate to Navigation Grid -> Settings -> Documents -> Documents Module.
2. Click the checkbox next to Enable auto purge.
3. Once the Enable Auto-Purge checkbox is selected, the related options become active.

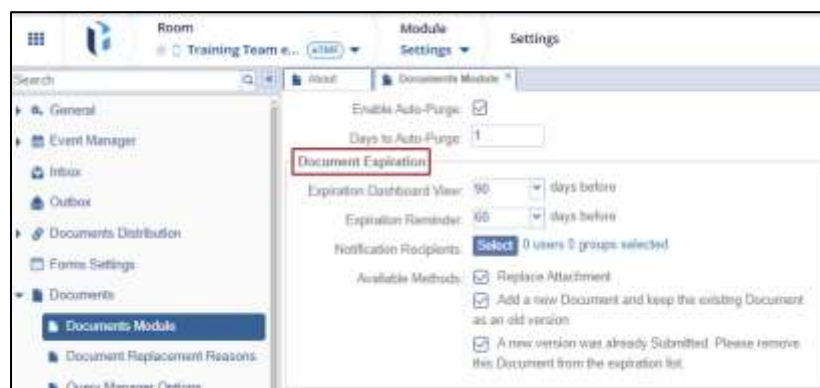


4. Adjust Days to auto-purge by entering the number of days in the box.
5. Click the Save button at the bottom of the page.

## Document Expiration Settings

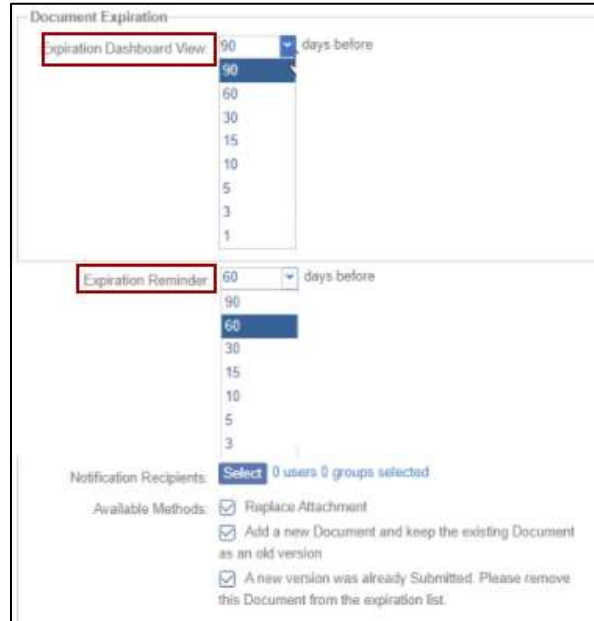
Document types with an applied expiration date may expire before the study concludes. To address this, Trial Interactive provides tools to detect and replace expired documents. The settings for managing these features are detailed here.

1. Navigate to Navigation Grid -> Settings -> Documents -> Documents Module.

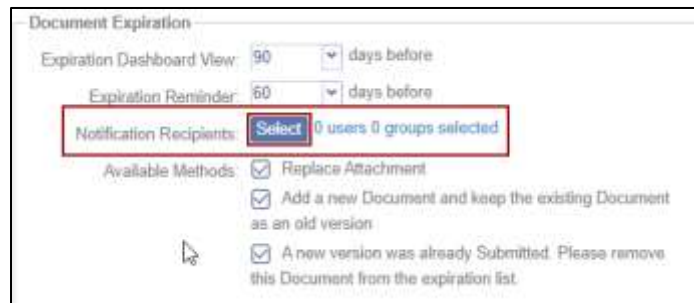




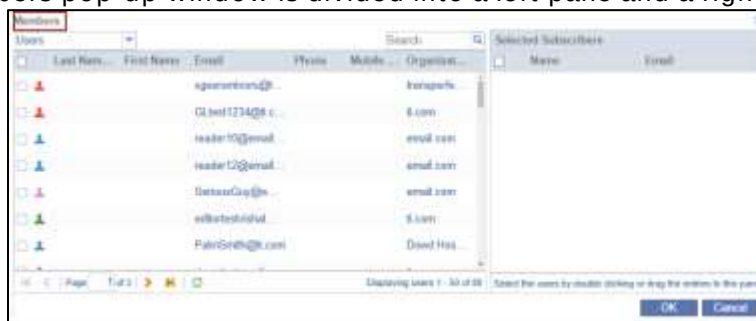
- The Expiration Dashboard View field determines the lead time users have to view and take action on an expiring document before its expiration date.
- The Expiration Reminder specifies when reminder emails are sent for documents approaching their expiration date.



- Click Select from the Notification Recipients the Members pop-up window is displayed.

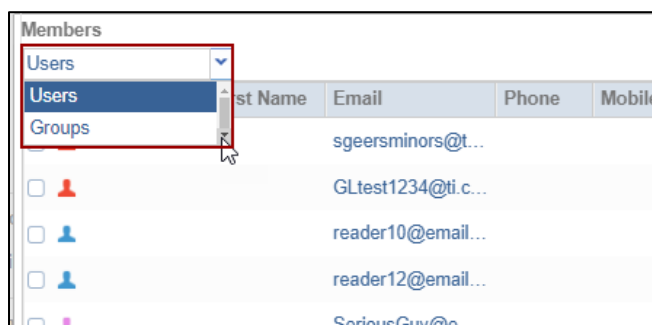


- The Members pop-up window is divided into a left pane and a right pane.





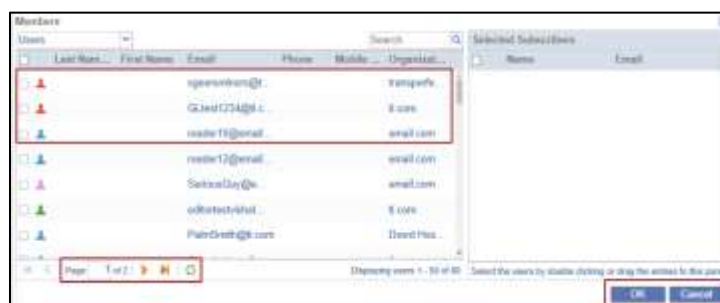
- Click the arrow next to the Users field to select Users/Groups.



- The selected Users/Groups will appear in the right pane. To select users, either double-click or drag the entries to the right pane.



- The notification emails received by the Users/Groups are listed in the left pane of the Member's pop-up window. The window also includes Pagination, a Refresh icon, and OK and Cancel buttons at the bottom.



- The Available Methods section enables room administrators to select the options accessible to users in the Expiring Documents dashlet.
  - The 'Replace Attachment' allows users to replace the file linked to the existing metadata. All document versions remain accessible in the Versions tab of the metadata panel.
  - The 'Add a New Document and Keep the Existing Document as an Old Version' enables users to retain the existing version for reference while adding a new document.
  - The 'A new version was already submitted. Please remove this document from the expiration list' option indicates that a newer version of the document has been submitted to the room as a separate document, and the expiring document should be removed from the expired/expiring documents list.

Document Expiration

Expiration Dashboard View: 90 days before

Expiration Reminder: 60 days before

Notification Recipients: [Select](#) 0 users 0 groups selected

Available Methods:

☒ Replace Attachment  
☒ Add a new Document and keep the existing Document as an old version  
☒ A new version was already Submitted. Please remove this Document from the expiration list.

### Duplicate Check Options

The methods used to detect duplicate documents are generally determined during room configuration. However, room administrators can modify one option if needed. For changes to duplicate detection requirements beyond this, consult the Service Desk, which has access to additional configuration options.

The Find Document Duplicates by Hash option allows room administrators to enable or disable this specific duplicate detection feature. A document hash is an alphanumeric code representing the unique characteristics of a document.

Duplicate Check Options

Find document duplicates by hash: ☐

### Automatic Document Name Generation

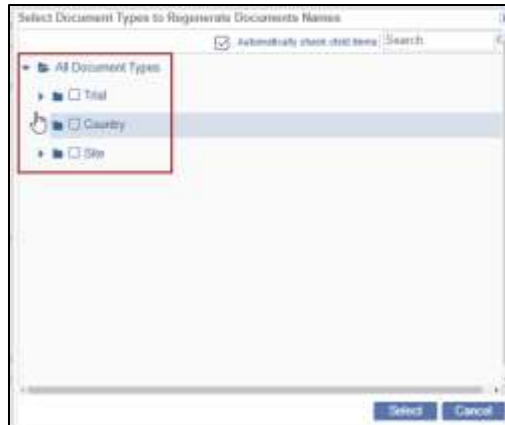
Room owners can configure an auto-naming pattern for a document type, allowing document names to be generated automatically based on the defined pattern. This setting is typically established during room configuration and is rarely modified during the study. If changes to the automatic name generation settings are required, it is recommended to collaborate with the Trial Interactive Service Desk.

Automatic Document Name Generation

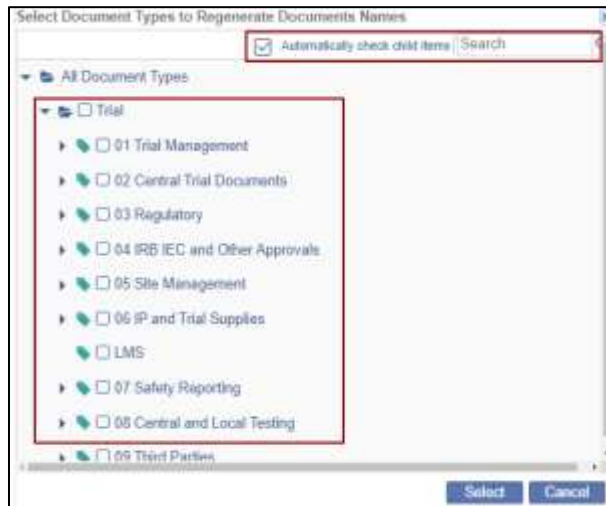
☒ Use auto generated document name as file name (export, download, email attachments)

[Regenerate Document Names](#)

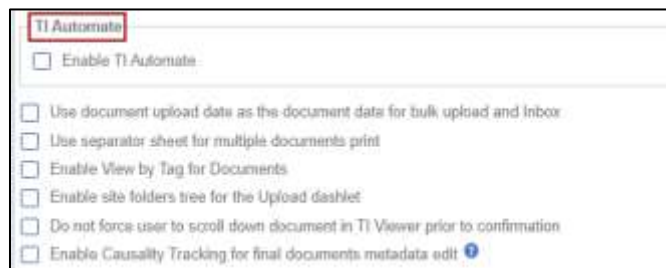
- Click the Regenerate Document Names, the 'Select Document Types to Regenerate Documents Names' pop-up window gets displayed with the below options:
  - Trial
  - Country
  - Site



2. The user can expand the arrow available beside the above options select the specific document type and click the Select option.  
Note: The user can search the child items when the 'Automatically check child items' checkbox is checked.



**TI Automate** – The new Artificial Intelligence service in TI Automate enables automatic document classification and metadata extraction upon upload to a room.

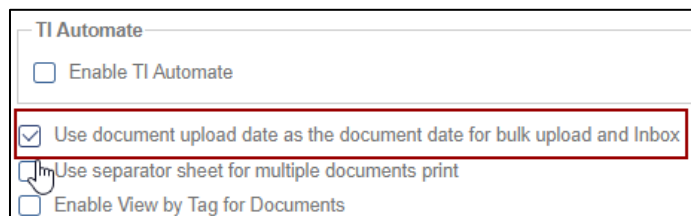


The following check box can be used as per the requirement:

Document Upload Date as Document Date

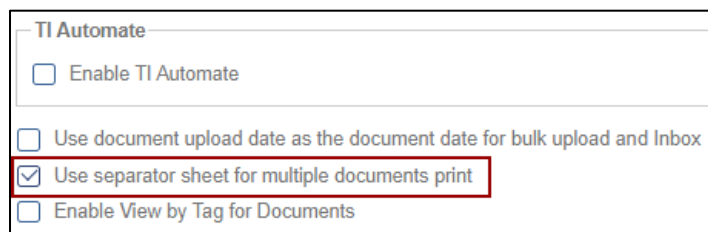
Note: Although not recommended, an Administrator can modify the naming and dating conventions applied to documents that are bulk uploaded or delivered to the room via the Inbox.

- Enable the 'Use Document Upload Date as the Document Date for Bulk Upload and Inbox' option by selecting the checkbox.
  - The upload date will now automatically be assigned as the document date in the document profile.



### Use Separator Sheet for Multiple Documents Print

This option affects the Print function in the Documents module. When users select multiple documents to print, the system first creates a single PDF file containing all the selected documents. This file can then be downloaded or printed locally. Enabling this option adds a separator sheet between each source document in the generated PDF.



### Enable View by Tag for Documents

Enabling this option allows room users to view documents in the Documents module based on the value in the Tag field. Like other metadata fields, the Tag field can be enabled or disabled and assigned to specific documents or all documents. However, enabling the View by Tag option here does not activate the metadata field itself. To enable the Tag field for use, either configure it during room setup or contact the Trial Interactive Service Desk.

The View by Tag metadata field allows users to apply tags (similar to hashtags used in social media) to documents, indicating that documents with the same tag are related. For example, documents submitted in a specific language could be tagged to group them, regardless of their document type. A key advantage of this feature is that multiple tags can be applied to a single document, enabling cross-referencing and the ability to associate a document with multiple categories or contexts.

TI Automate

☐ Enable TI Automate

☐ Use document upload date as the document date for bulk upload and Inbox

☐ Use separator sheet for multiple documents print

☒ Enable View by Tag for Documents

☐ Enable site folders tree for the Upload dashlet

☐ Do not force user to scroll down document in TI Viewer prior to confirmation

☐ Enable Causality Tracking for final documents metadata edit [?](#)

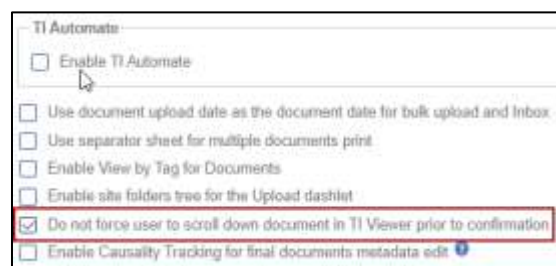
## Enable Site Folders Tree for the Upload Dashlet

This option allows users to view site-related folders within the Documents module and select the appropriate folder for uploading documents.



## Do not force the user to scroll down the document in TI Viewer prior to confirmation

When enabled, this option removes the requirement for users to scroll through the entire document in the TI Viewer before confirming their action.



## Enable Causality Tracking for Final Documents Metadata Edit

Enabling this option allows Administrators and Document Manager users to modify metadata for final documents within a study room. This setting has two effects:

- **Metadata Modification:** Grants permission to update metadata fields for finalized documents and should be requested to provide a reason for making the change.
- **Enhanced Flexibility:** Ensures greater control over document information while maintaining proper access restrictions. Mass Coding will be disabled in the study room.



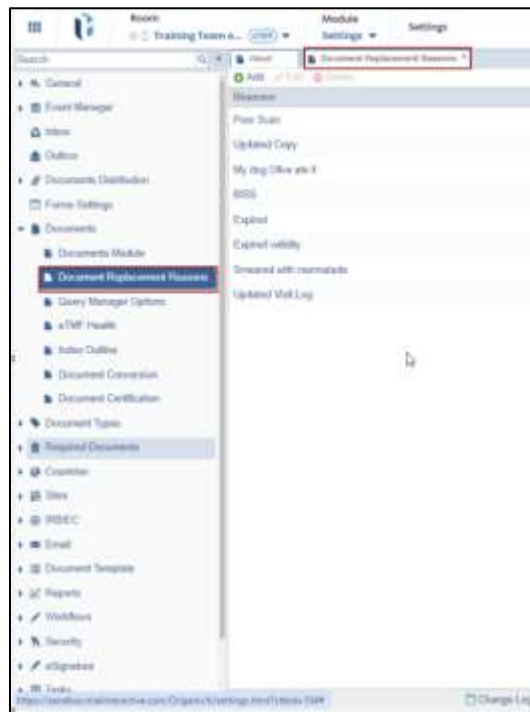
The Change Log option, located at the bottom-right of the screen, provides a record of activity in the Documents Module and includes two menus:

- Documents Module - It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp).
- Regenerate Documents Names - It displays the names of the regenerated documents along and a Close button.

Ensure to click Save to apply and retain any changes.

## Document Replacement Reasons

In this section, administrators can configure a list of reasons to be displayed in the dropdown menu when users replace an attachment for a document. These reasons help standardize and document the rationale for file replacements.

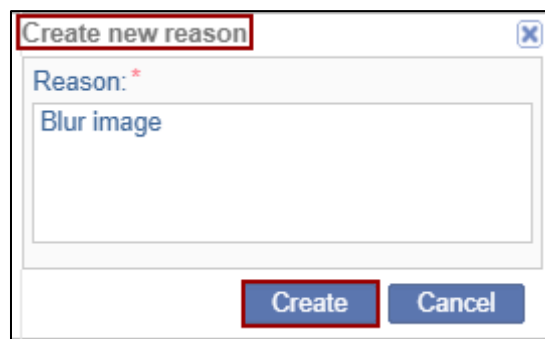


### Add

1. Navigate to Navigation Grid->Settings -> Documents -> Document Replacement Reasons.
2. Click 'Add' from the top ribbon bar.



3. The 'Create New Reason' popup window opens.
4. Enter the reason and click 'Create.'



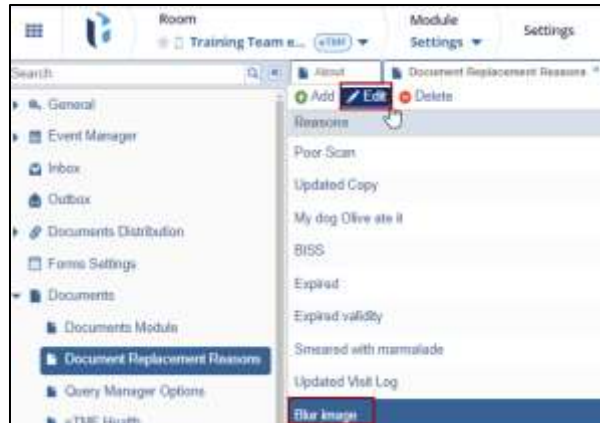
5. The reason created is added to the list of reasons shown in the list.



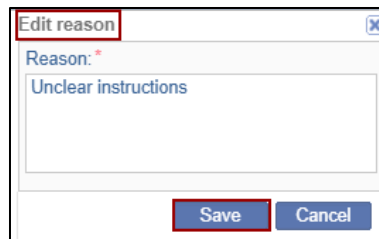
## Edit

1. Select the reason from the available list of reasons and click 'Edit' from the top ribbon bar.

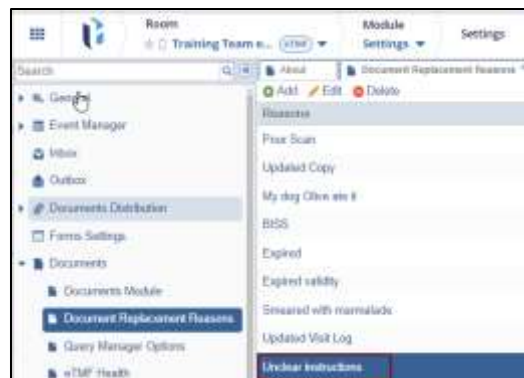




2. The 'Edit Reason' popup window opens.
3. Enter the reason and click 'Save.'

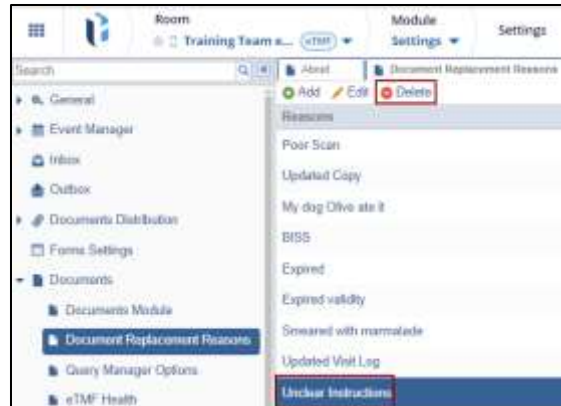


4. The reason edited is added to the list of reasons shown in the list.

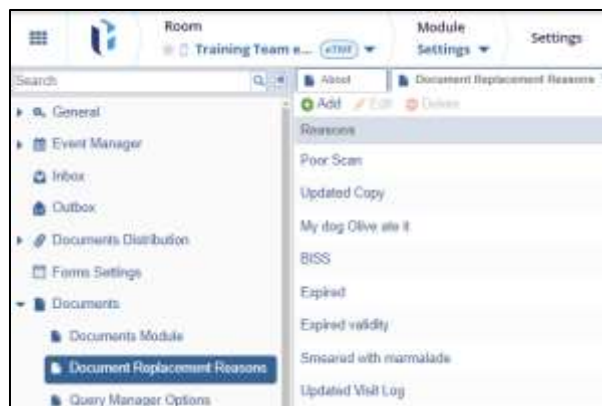


### Delete

1. Select the reason from the available list of reasons and click 'Delete' from the top ribbon bar.



2. The selected reason gets deleted from the list.



## Query Manager Options

Query Managers in Trial Interactive are users with permission to view all QC Workflow-related queries in the room and provide assistance as needed. The specific actions a Query Manager can perform are determined by the settings configured here. By selecting the appropriate checkboxes, room administrators can grant Query Managers the ability to resolve queries and/or respond to queries assigned to any user.



To assign a user as a Query Manager, add them to the Query Manager group in the User Management section.



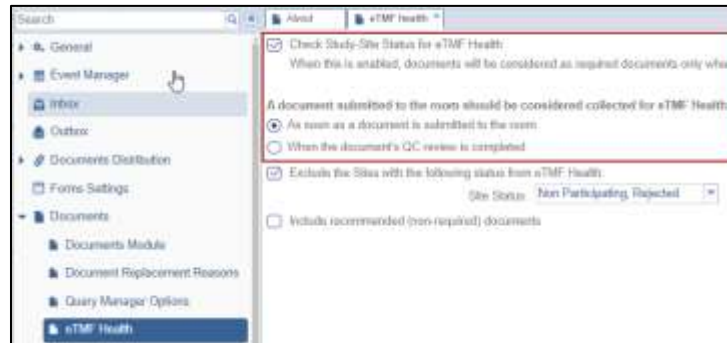
## eTMF Health Settings

- The 'Check Study-Site Status for eTMF Health' option can be enabled or disabled here. When enabled, documents will be considered as required documents only when the Study Site has reached the Status configured in the Document Type profile.

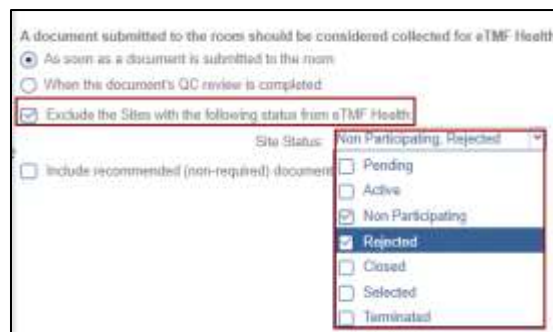


### A document submitted to the room should be considered collected for eTMF Health:

- Users can use the radio buttons on the screen to define when the system should consider a requirement as collected.
  - 'As soon as the document is submitted to the room' - This setting causes the room to mark a placeholder as successfully fulfilled immediately after a document with the corresponding metadata is uploaded.
  - 'When the document's QC review is completed' - This setting ensures that missing document placeholders can only be fulfilled by documents designated as 'Final' through the room's QC Workflow.

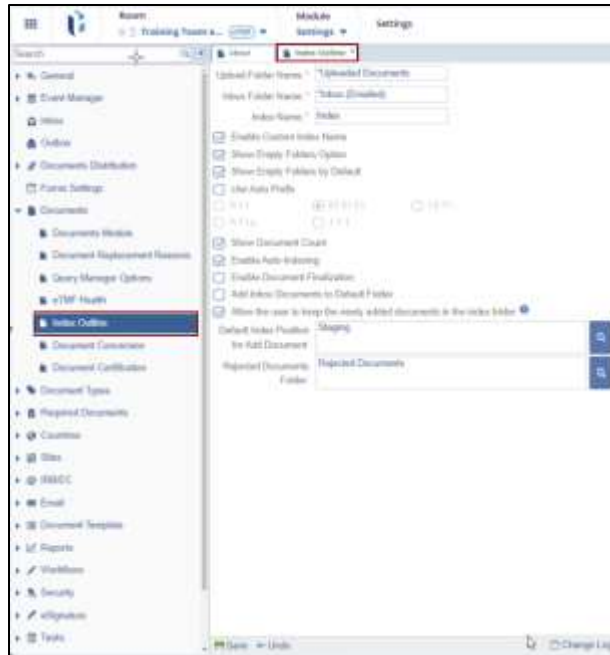


- The option 'Exclude the sites with the following status from the eTMF completeness tracking' ensures that document requirements for sites with the selected status are excluded from the room's eTMF health calculations.
- Administrators can configure whether recommended (non-required) documents are included in the calculation of the room's eTMF health.

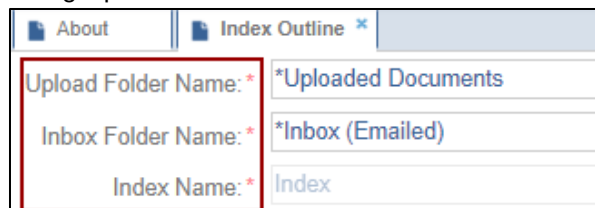


## Index Outline

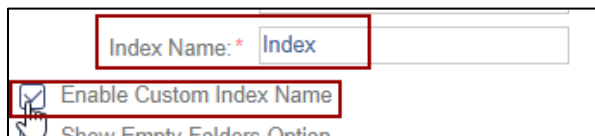
The administrator has the flexibility to configure various functions and visual aspects of the Trial Interactive room's index. To ensure accurate documentation, please notify your Trial Interactive representative of any changes made to the room settings, allowing the configuration manual to remain up-to-date.



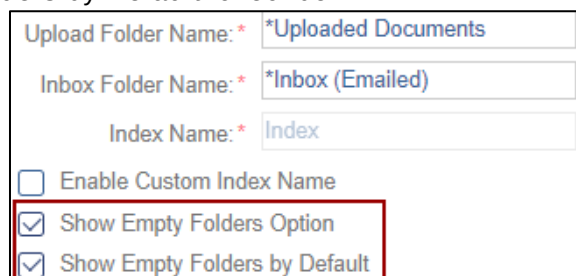
1. Navigate to Navigation Grid -> Settings -> Documents -> Index Outline.
2. The highlighted fields below are mandatory and must be completed.
3. All documents imported are populated in the Upload folder unless they have been assigned metadata during upload.



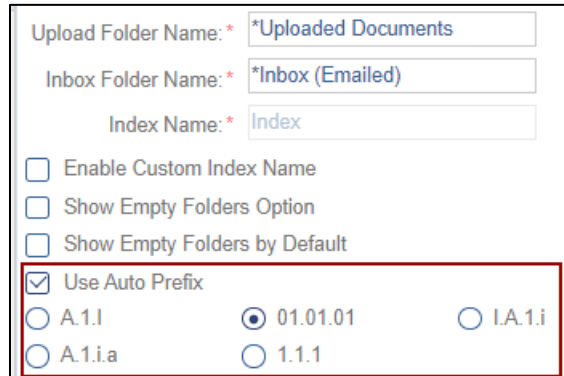
4. The 'Index Name' field gets activated only when the 'Enable Custom Index Name' field checkbox is checked.



5. The 'Show Empty Folders Option' allows users to decide whether to display empty folders based on their requirements or to display the empty folders by default, select the 'Show Empty Folders by Default' checkbox.



6. The folders in a room index are numbered, and the subfolders follow a standard numbering system.
  1. These folder numbers are referred to as Folder Prefixes, and their configuration can be managed through the Auto Prefix option.
  2. Enable or disable Auto Prefixing for folders in the room's index by selecting the 'Use Auto Prefix' checkbox.
  3. If the checkbox is not selected, folder titles in the index will appear exactly as entered during the creation of the room's index.
  4. Auto Prefixing automatically adds a chosen prefix of numbers or letters to distinguish folder levels in the index.



Upload Folder Name: \* \*Uploaded Documents

Inbox Folder Name: \* \*Inbox (Emailed)

Index Name: \* Index

☐ Enable Custom Index Name

☐ Show Empty Folders Option

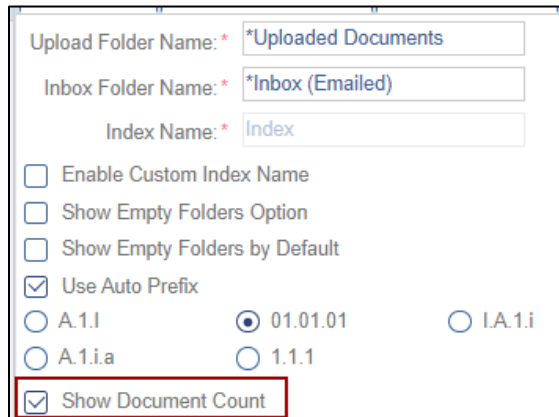
☐ Show Empty Folders by Default

☒ Use Auto Prefix

☐ A.1.I      ☒ 01.01.01      ☐ I.A.1.i

☐ A.1.i.a      ☐ 1.1.1

7. Numbers displayed next to folder names represent the count of documents available in each folder. To enable these numbers in the room's documents module, select the 'Show Document Count' option.



Upload Folder Name: \* \*Uploaded Documents

Inbox Folder Name: \* \*Inbox (Emailed)

Index Name: \* Index

☐ Enable Custom Index Name

☐ Show Empty Folders Option

☐ Show Empty Folders by Default

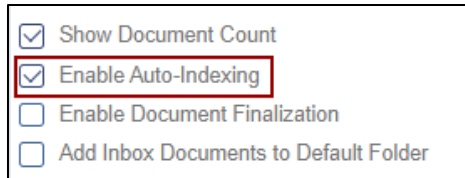
☒ Use Auto Prefix

☐ A.1.I      ☒ 01.01.01      ☐ I.A.1.i

☐ A.1.i.a      ☐ 1.1.1

☒ Show Document Count

8. Enable 'Auto Indexing' to automatically route documents to the appropriate index location based on the related document-type profile. However, the Auto-Indexing activates the below option:
  - Enable Document Finalization
  - Allow the user to keep the newly added documents in the index folder



☒ Show Document Count  
☒ **Enable Auto-Indexing**  
☐ Enable Document Finalization  
☐ Add Inbox Documents to Default Folder

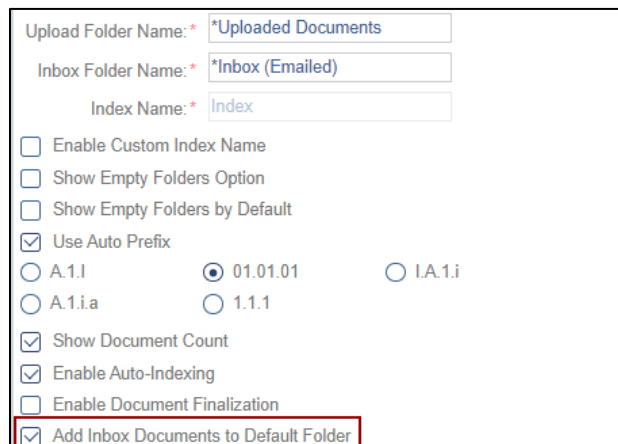
9. 'Allow the user to keep the newly added documents in the index folder': This level of flexibility allows for seamless organization and customization of documents to suit individual preferences and workflows. Users can easily manage their documents and maintain a clear and efficient folder structure without the need for constant administrative assistance. This feature enhances user autonomy and productivity while ensuring that access rights and document security are upheld.



☒ Show Document Count  
☒ Enable Auto-Indexing  
☐ Enable Document Finalization  
☐ Add Inbox Documents to Default Folder  
☒ **Allow the user to keep the newly added documents in the index folder**

When this setting is enabled the newly added document will be retained in the selected index folder. If the document completes its workflow, the document type auto-routing rule will determine the final index folder, and the document will be moved to that folder when the workflow is done.

10. Documents that are emailed into the room's inbox are usually stored in each user's Inbox folder, but this can be altered by choosing to enable the 'Add inbox documents to default folder' option which would then route all documents emailed to the room inbox directly to the default folder (Staging).



Upload Folder Name: \*   
 Inbox Folder Name: \*   
 Index Name: \*   
☐ Enable Custom Index Name  
☐ Show Empty Folders Option  
☐ Show Empty Folders by Default  
☒ Use Auto Prefix  
☐ A.1.I    ☒ 01.01.01    ☐ I.A.1.i  
☐ A.1.i.a    ☐ 1.1.1  
☒ Show Document Count  
☒ Enable Auto-Indexing  
☐ Enable Document Finalization  
☒ **Add Inbox Documents to Default Folder**

11. The default location for documents that have been uploaded with metadata assigned is indicated in the 'Default Index Position for Add document' field.



Default Index Position for Add Document:  

- To add a document to the index folder, click on the Search Icon the 'Select index position to place the document' pop-up window is displayed.

- Select the folder that you want to add the document in the index folder and click the OK button.

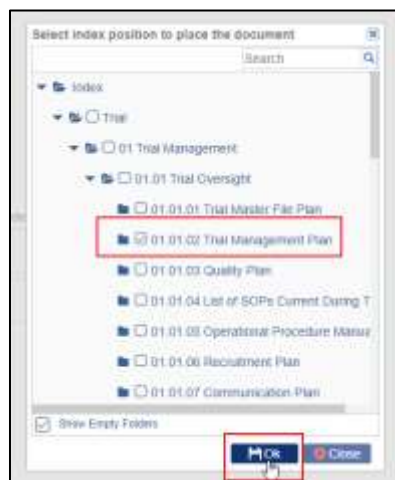


|                                             |     |                                                                                     |
|---------------------------------------------|-----|-------------------------------------------------------------------------------------|
| Default Index Position<br>for Add Document: | LMS |  |
|---------------------------------------------|-----|-------------------------------------------------------------------------------------|

- The 'Rejected Documents' Folder with the Search icon allows users to select the appropriate index position for uploading documents.

|                               |                    |                                                                                      |
|-------------------------------|--------------------|--------------------------------------------------------------------------------------|
| Rejected Documents<br>Folder: | Rejected Documents |  |
|-------------------------------|--------------------|--------------------------------------------------------------------------------------|

- To add a Rejected documents folder, click on the Search Icon the 'Select index position to place the document' pop-up window is displayed.
- Select the folder that you want to add to in rejected documents folder and click the OK button.

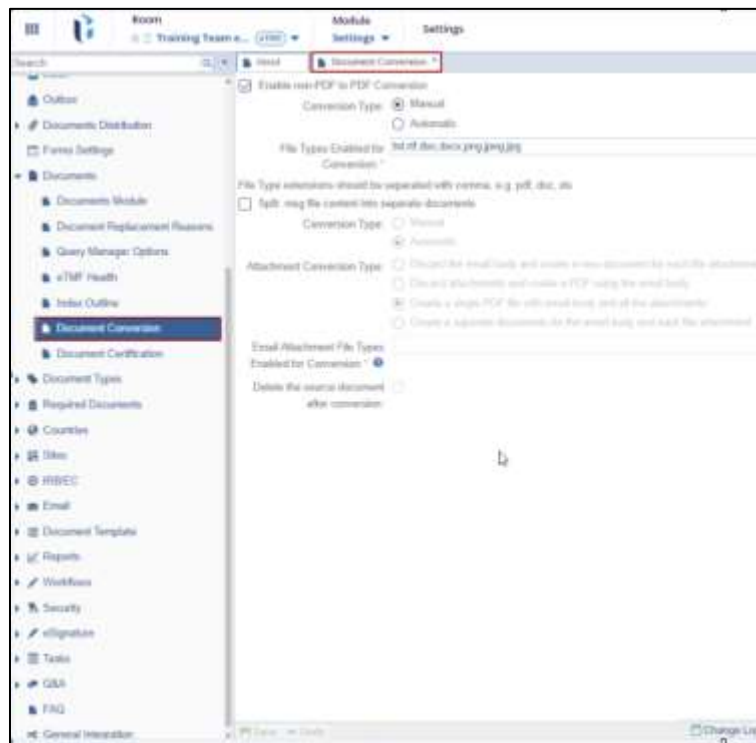


|                               |                                                                                |                                                                                       |
|-------------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Rejected Documents<br>Folder: | Trial\01 Trial Management\01.01 Trial Oversight\01.01.02 Trial Management Plan |  |
|-------------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|

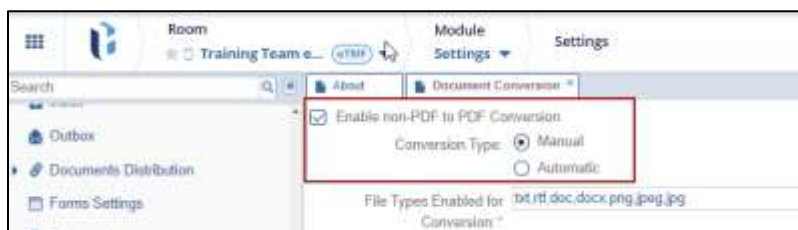


## Document Conversion

1. Navigate to Navigation Grid -> Settings -> Documents-> Document Conversion.



2. Check the checkbox to 'Enable Non-PDF to PDF conversion'. It includes 2 modes of conversation based on the conversion of the 'File Type get enabled':
  - Manual
  - Automatic
3. Select the appropriate radio button to make the conversion, Manual or Automatic.
4. Edit the list of file types that can be converted.

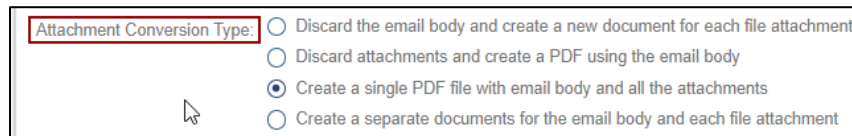


The File type extensions should be comma separated, e.g. pdf, doc, xls

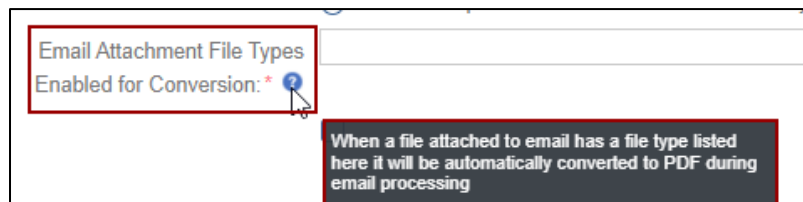
- When the checkbox for "Split .msg file content into separate documents" is selected, the "Queue Existing Documents" pop-up window appears. This occurs if the user has chosen PDF Manual conversion and opts to switch to Automatic conversion for splitting the content.



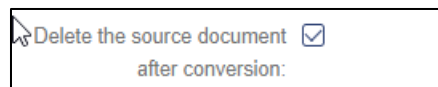
- The "Attachment Conversion Type" field specifies the action to be taken when an email message is dragged from Outlook into the Trial Interactive room.
  - The settings below clarify which attachment file types can be converted to .pdf as well as what to do with the source document after conversion.



- The "Email Attachment File Types Enabled for Conversion" option, when enabled, ensures that attachments of the specified file types are automatically converted to PDF during email processing.

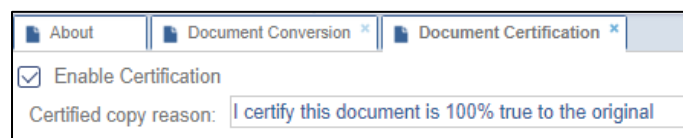


- When the "Delete the source document after conversion" option is enabled, the source file is automatically removed from the main location after the conversion process is complete.



## Document Certification

Trial Interactive allows users to submit certified copies of documents either through the myTI application or directly to the study room. Enabling the checkbox in this menu activates the function within the Documents module of the study room.



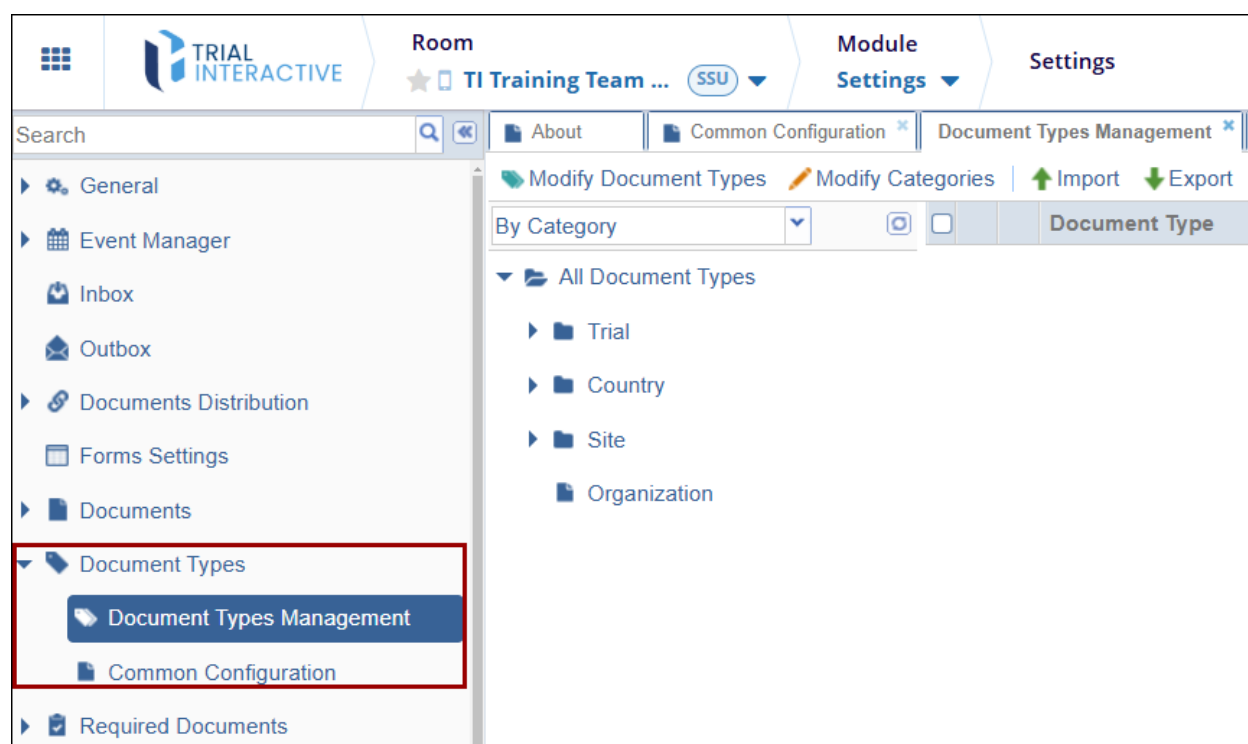
## Document Types

This section describes the settings associated with the Document Types

In the conduct of a clinical trial, scores if not hundreds of different kinds of documents need to be collected, categorized, and filed – some general documents, some documents that are specific to the countries in which studies are being conducted, and some documents that are specific to the investigative sites involved in the study.

To access the Document Type Settings, follow the steps below.

1. Navigate to the Settings module.
2. Expand the Document Types setting dropdown.
3. Select the Document Types Management or Common Configuration option.



## Document Types Management

Within the Document Types Management, users can perform the following

- Modify Document Types
- Building the Document Type Profile
- Specifying the Related Folder
- Include Phases/Milestones
- Adding Document Types to Required Documents
- Include in Document Tracker Report
- Auto Document Type Prediction Keyword(s)
- Modifying Document Types Fields
- Default Values

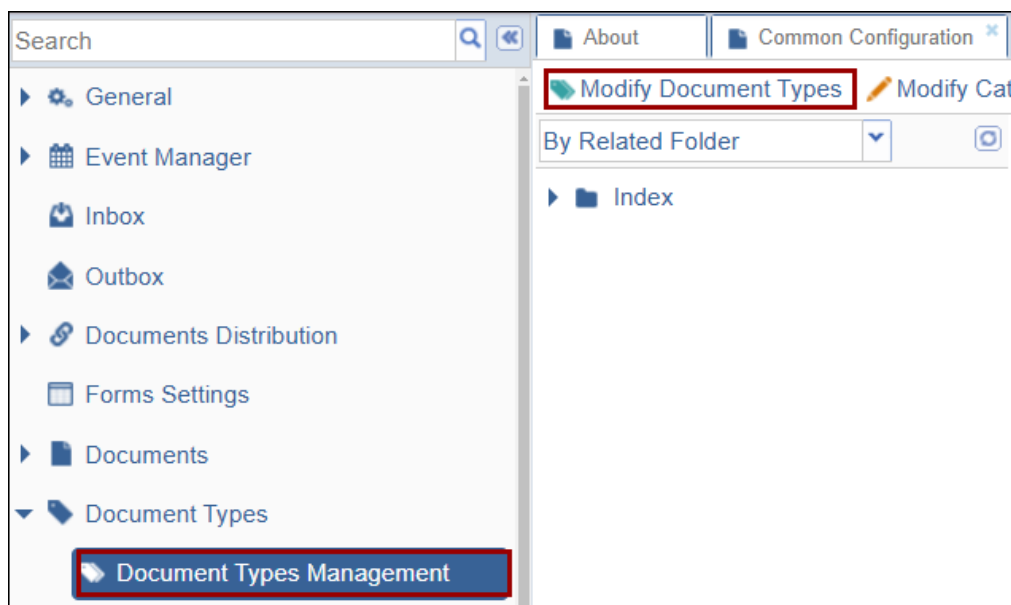
### Modify Document Types

The Modify Document Types setting allows users to add, edit, or delete document types to the respective category folders.

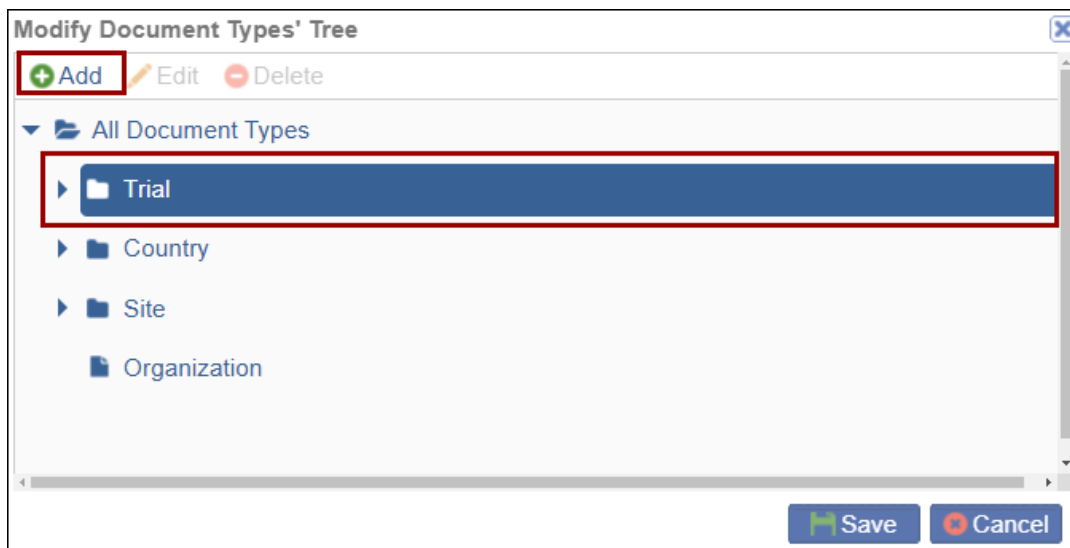
#### Add Document Type

To add a new document type, follow the steps below.

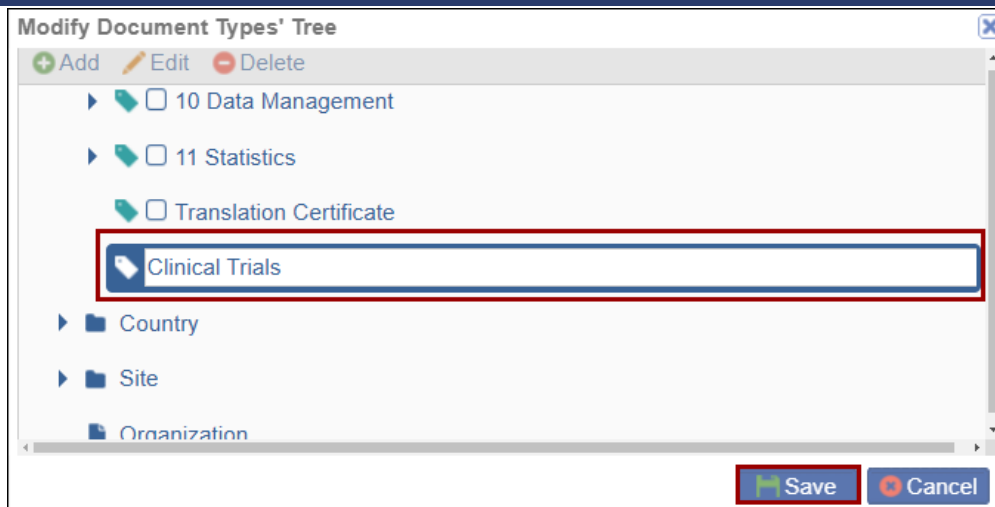
1. On the Document Types Management screen, click on the Modify Document Types tab from the top menu bar.



2. On the Modify Document Types' Tree window, select a folder and click on the Add button.



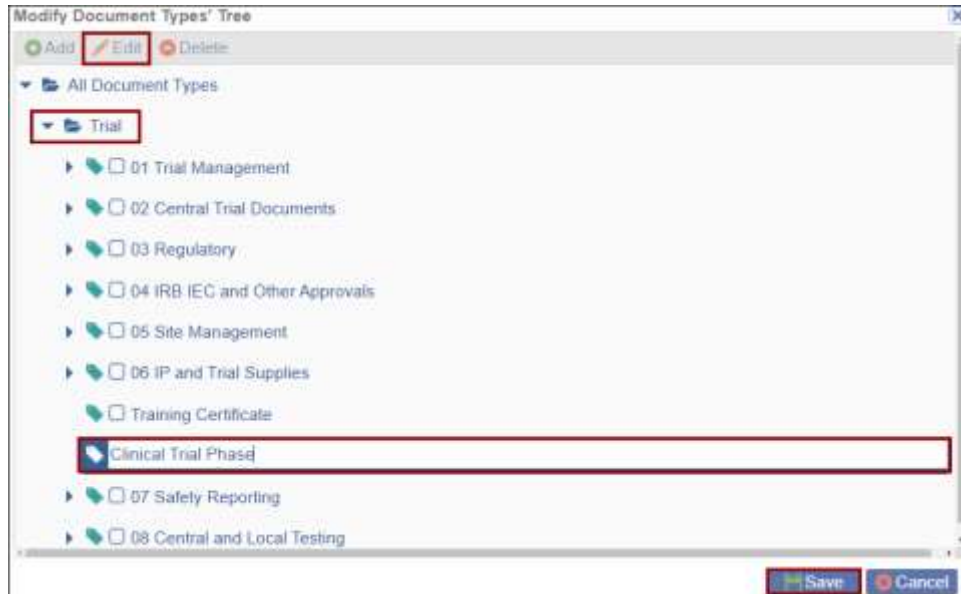
3. Enter a name for the newly added document type and click on the Save button.



### Edit Document Type

To edit the document type, follow the steps below.

1. On the **Modify Document Types' Tree** window expand the category folder where the new document type was added.
2. Select the Document Type by clicking on the checkbox and click on the Edit button.
3. Edit the document type name and click on the Save button.

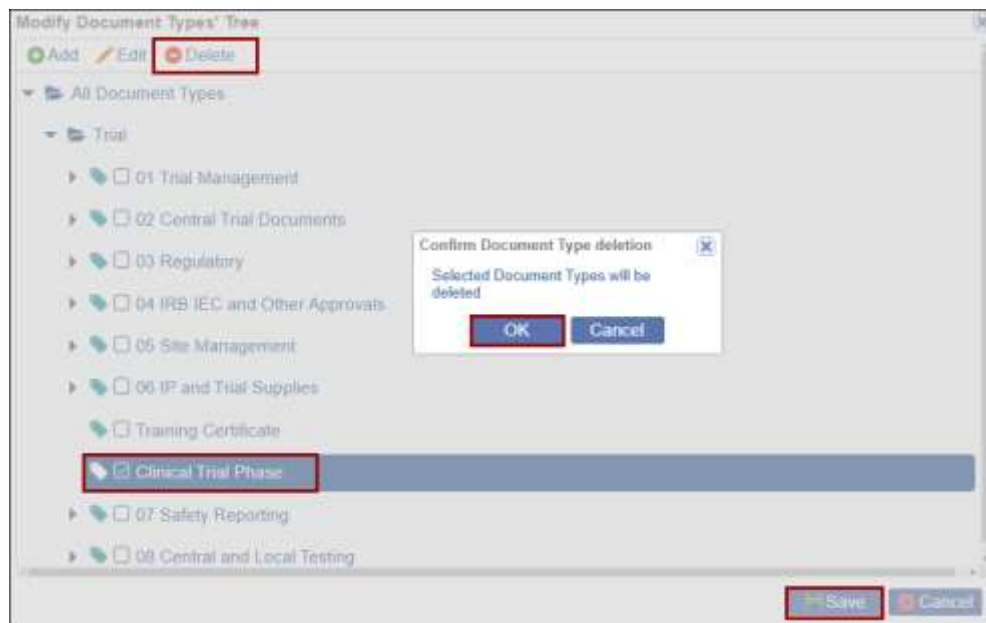


### Delete Document Type

To delete the document type, follow the steps below.

1. Select the document type by clicking on the checkbox.
2. Click on the Delete button

3. Confirm the document type deletion by clicking on the OK button on the confirmation popup.
4. Click on the Save button once the record is deleted.



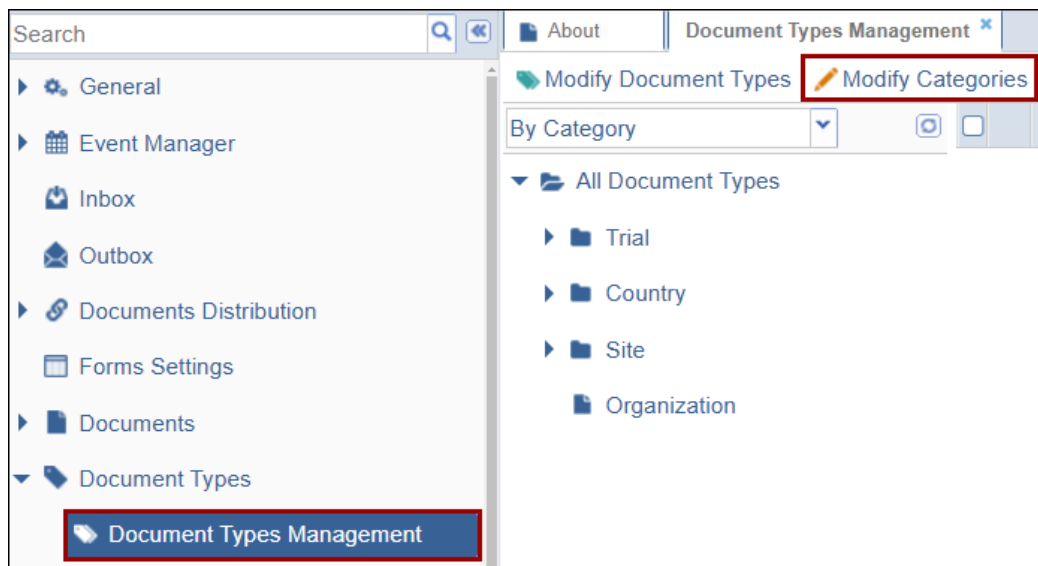
### Modify Categories

The Modify Categories tab allows users to configure the Categories the document types are associated with.

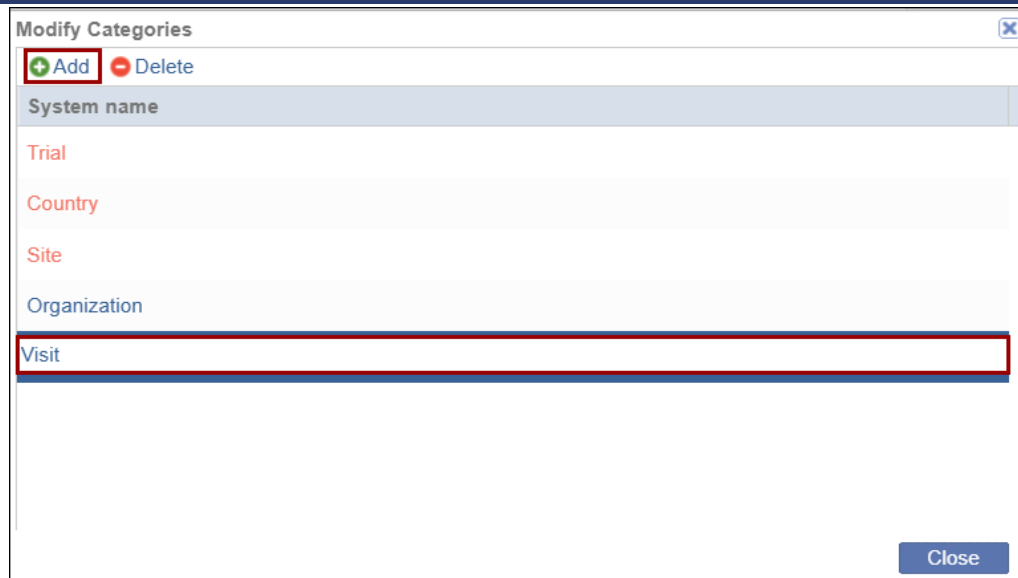
#### Add Category

To add a new category, follow the steps below.

1. Click on the Modify Categories tab from the top menu bar.



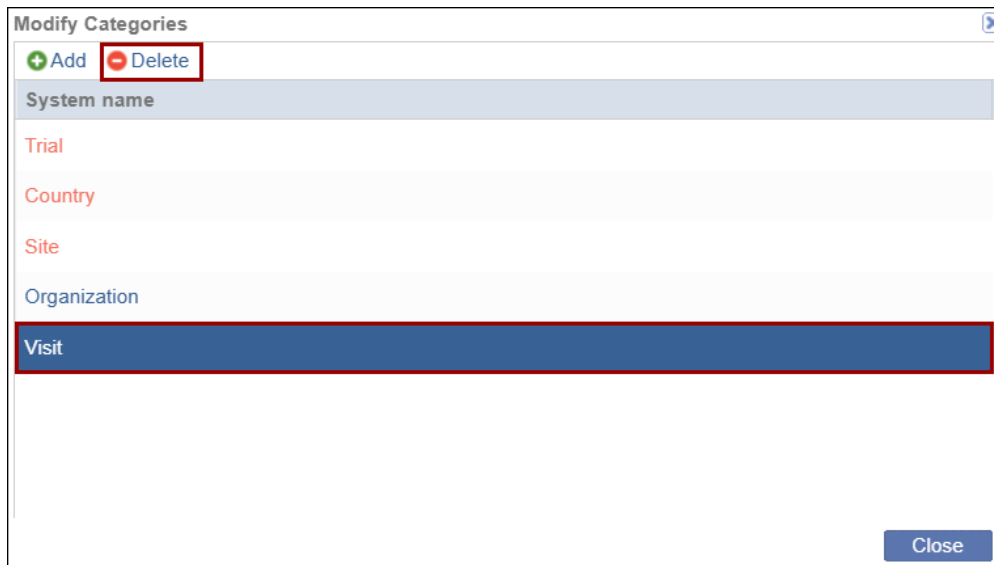
2. On the Modify Categories window, click on the +Add button and enter the new category name.



### Delete Category

To delete a category, follow the steps below.

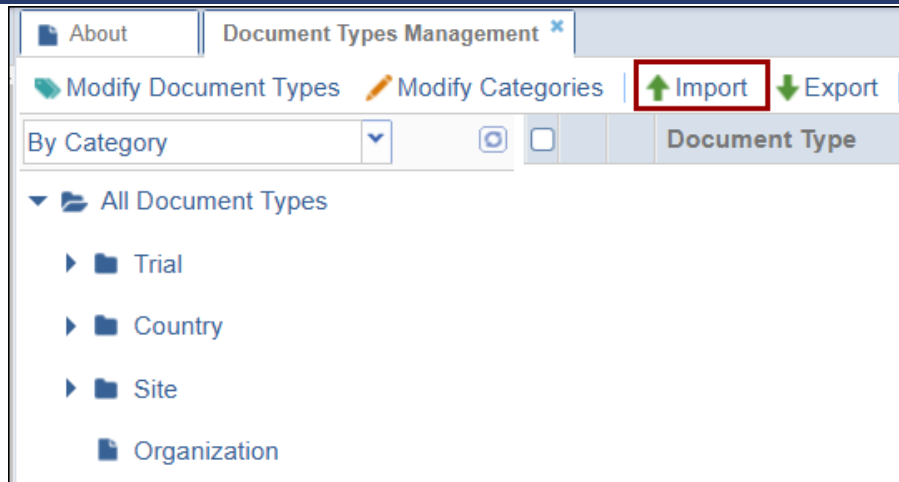
1. Select a category to delete
2. Click on the Delete button from the top menu bar.



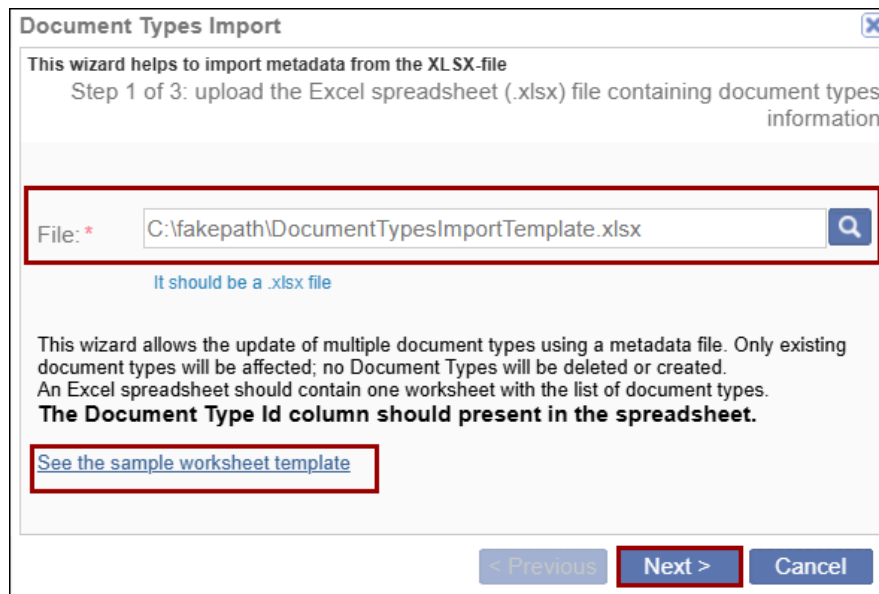
### *Import*

To import the document types, follow the steps below.

1. Click on the Import button from the top menu bar.



2. On the Document Types Import window, upload a file containing the metadata details in .XLSX file format.
3. Click on the 'See the sample worksheet template' to download a specimen template and add the metadata.
4. Once the file is uploaded, click on the Next button.



5. In Step 2, setup the metadata fields mapping.



**Document Types Import**

This wizard helps to import metadata from the XLSX-file

Step 2 of 4: setup metadata fields mapping

| Spreadsheet Column           | Metadata field          |
|------------------------------|-------------------------|
| Category                     | Category                |
| Index                        | CTMS Document Type Id   |
| Document Type                | Category                |
| Short Name                   | Do not Distribute       |
| Auto Name Rules              | Document Type System Id |
| Include In Monitoring Visits | Event Types             |
|                              | Related to Organization |
|                              | Responsible Party       |
|                              | Responsible Party Type  |
|                              | Universal ID            |

< Previous   **Next >**   Cancel

- In Step 3, verify & confirm the metadata fields mapping and click on the Next button.

**Document Types Import**

This wizard helps to import metadata from the XLSX-file

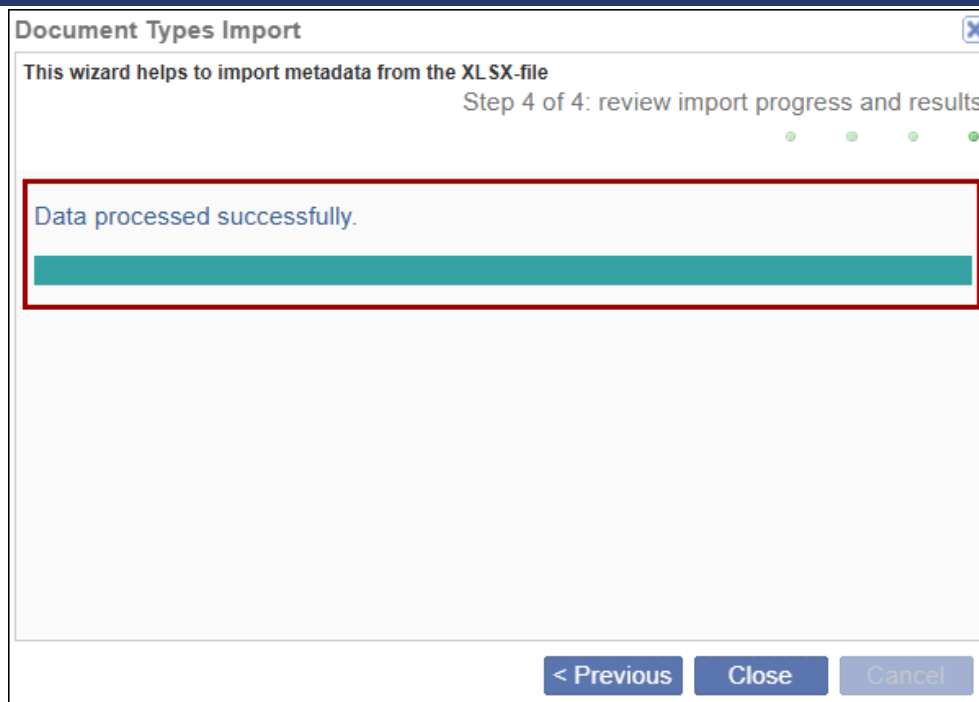
Step 3 of 4: confirm and proceed with the import

| Spreadsheet Column           | Metadata field               |
|------------------------------|------------------------------|
| Category                     | Category                     |
| Index                        | Index                        |
| Document Type                | Document Type                |
| Short Name                   | Short Name                   |
| Auto Name Rules              | Auto Name Rules              |
| Include In Monitoring Visits | Include In Monitoring Visits |

File type: data overlay

< Previous   **Next >**   Cancel

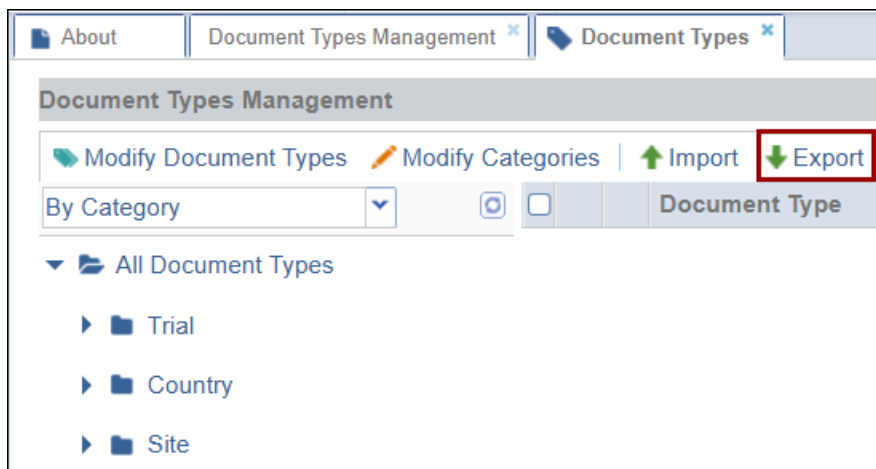
- In Step 4, review the import progress and results.



### Export

To export the document types, follow the steps below.

1. Click on the Export button from the top menu bar.



2. On the Export window, select any one options from the source category
  - a. All Document Types: This option will retrieve data for all document types.
  - b. Specific Categories: This options allows exporting document types associated with specific categories.
3. If Specific Categories option is selected, specific the Categories and Metadata fields into their respective fields.

- Click on the Export button once the necessary options are selected.

Export

Source:

☐ All document types
 ☒ Specific categories

Categories: \*

Metadata: \*

Category, Document Type, Document T

Export

Cancel

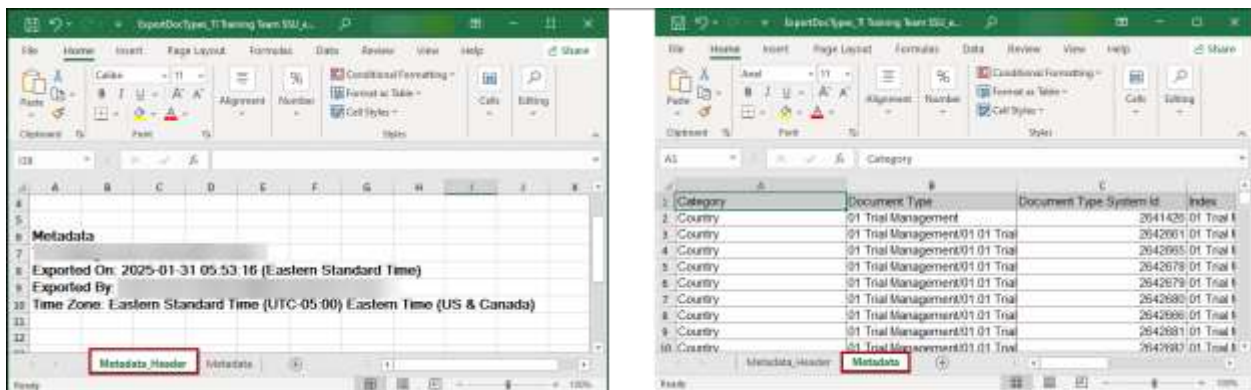
- Click on the Get Job Result button to download an Microsoft Excel Worksheet into the local system.



**Exporting metadata (document types)**  
 Finished: Export: 1762 of 1762 completed  
 (1762/1762)  
 31 Jan  
 16:23  

Get Job Result

- The downloaded file displays the Metadata Header and Metadata tabs with the respective details.



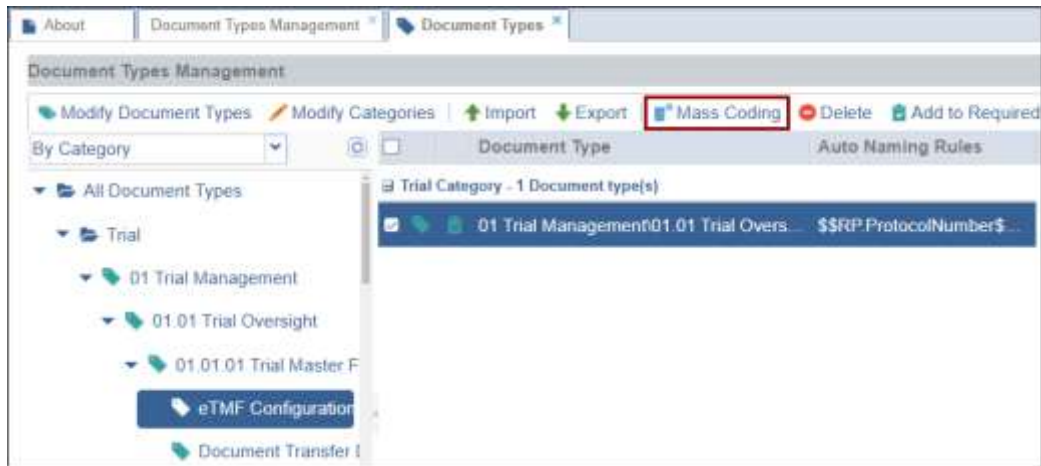
| Category | Document Type                | Document Type System Id | Index      |
|----------|------------------------------|-------------------------|------------|
| Country  | 01 Trial Management          | 2641425                 | 01 Trial I |
| Country  | 01 Trial Management/01 Trial | 2642001                 | 01 Trial I |
| Country  | 01 Trial Management/01 Trial | 2642093                 | 01 Trial I |
| Country  | 01 Trial Management/01 Trial | 2642679                 | 01 Trial I |
| Country  | 01 Trial Management/01 Trial | 2642679                 | 01 Trial I |
| Country  | 01 Trial Management/01 Trial | 2642690                 | 01 Trial I |
| Country  | 01 Trial Management/01 Trial | 2642690                 | 01 Trial I |
| Country  | 01 Trial Management/01 Trial | 2642691                 | 01 Trial I |
| Country  | 01 Trial Management/01 Trial | 2642691                 | 01 Trial I |
| Country  | 01 Trial Management/01 Trial | 2642691                 | 01 Trial I |

### Mass Coding

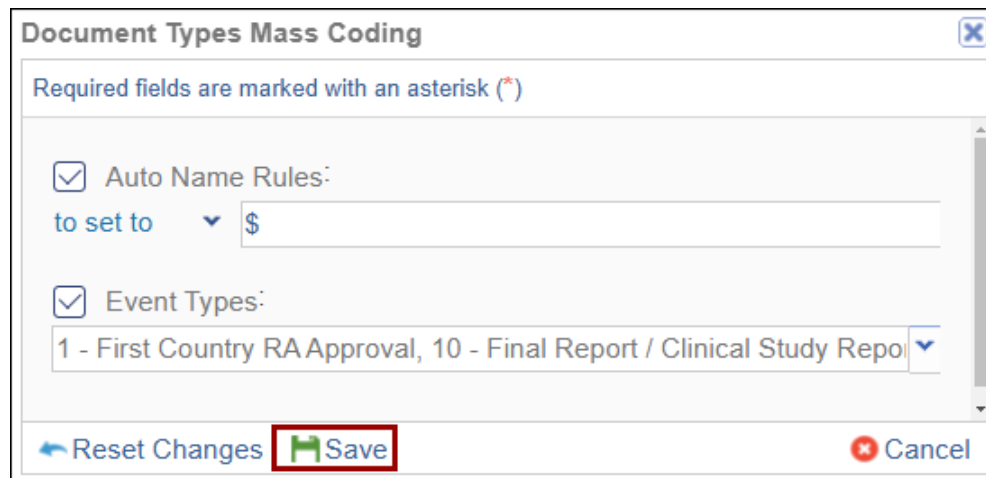
To mass code a document type, follow the steps below.

- Select a document type by expanding the category folders and associated sub-folders.

- Click on the Mass Coding button from the top menu bar.



- On the Document Types Mass Coding window, specify the Auto Name Rules and Event Types.
- Click on the Save button.



**Document Types Mass Coding**

Required fields are marked with an asterisk (\*)

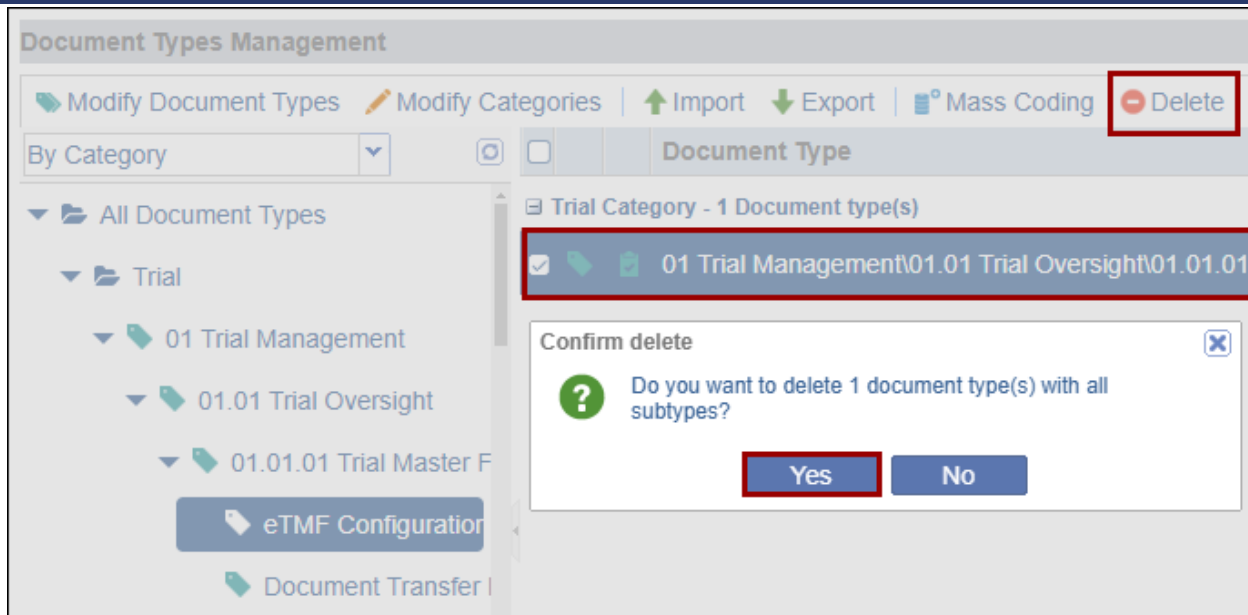
☒ Auto Name Rules:  
to set to

☒ Event Types:

### Delete

To delete a document type, follow the steps below.

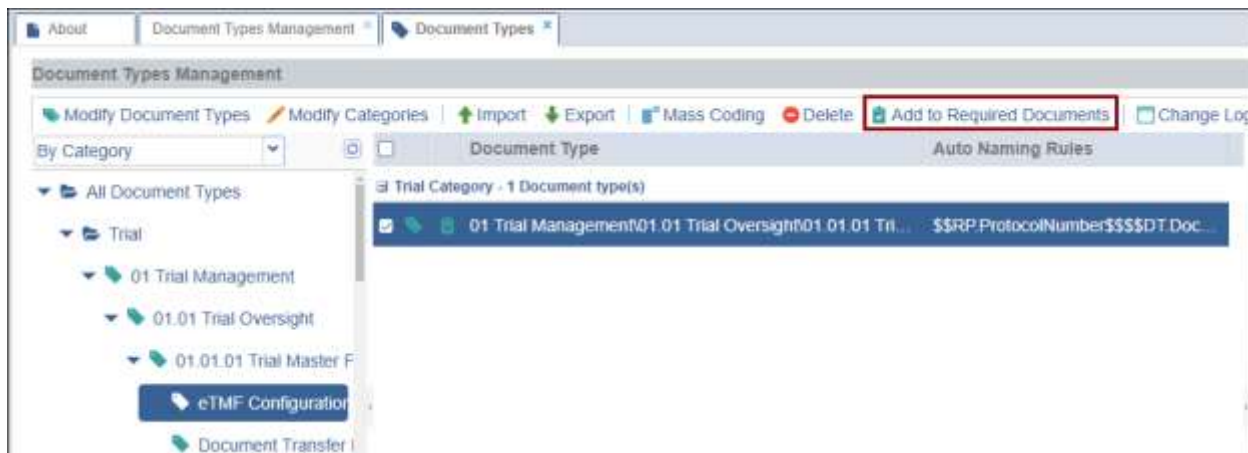
- Select a document type by expanding the category folders and associated sub-folders.
- Click on the Delete button from the top menu bar.
- Click on the Yes button on the confirmation popup.



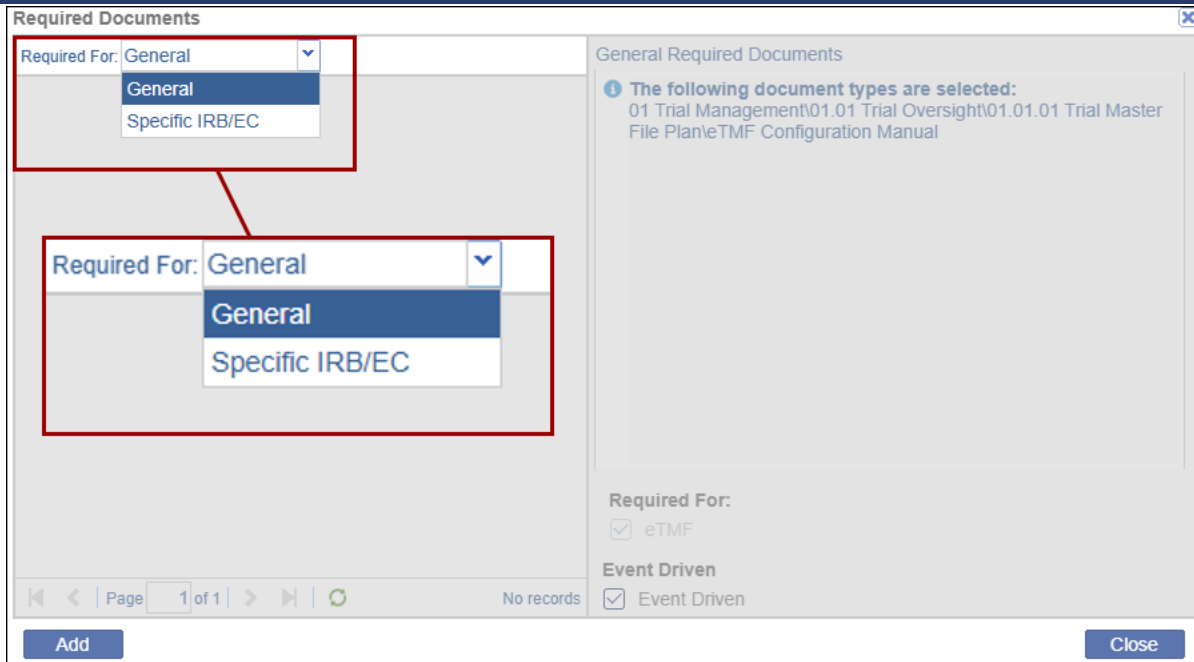
#### *Add to Required Documents*

To add documents as Required Documents, follow the steps below.

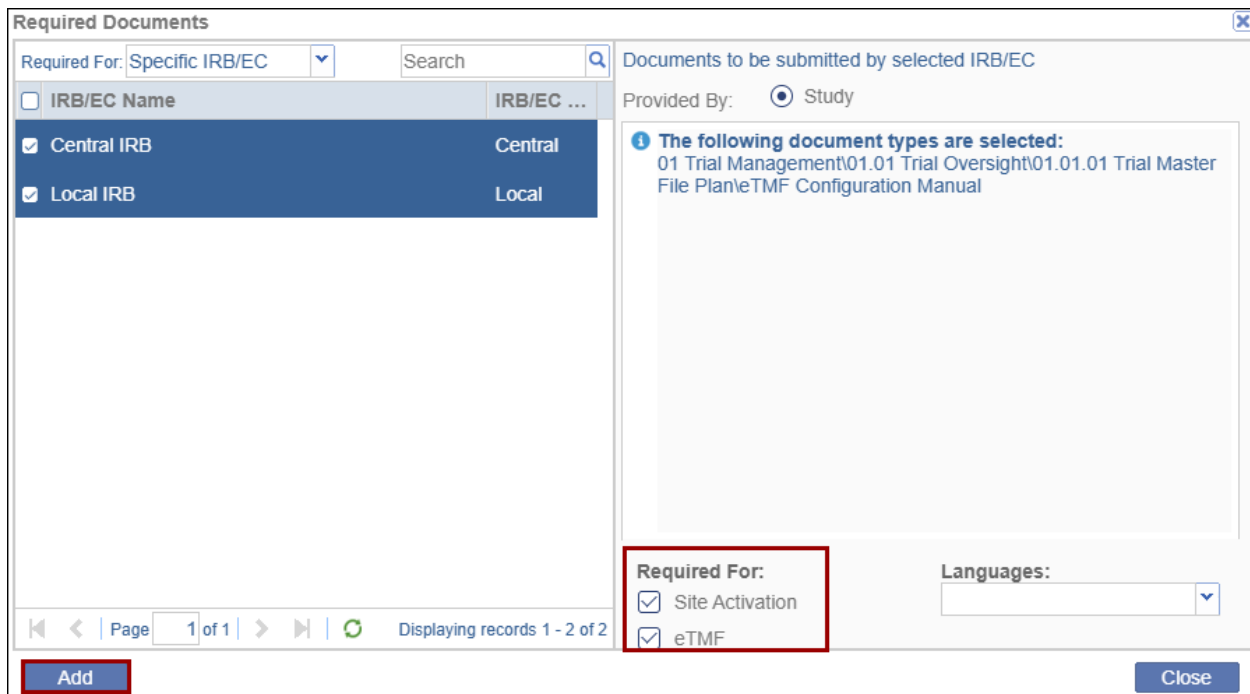
1. Select a document type by expanding the category folders and associated sub-folders.
2. Click on the Add to Required Documents button from the top menu bar.



3. On the Required Documents window, select General or Specific IRB/EC options from the Required For dropdown.



4. If a Specific IRB/EC option is selected, specify whether Central or Local IRB.
5. Mandatory to specify whether the document type is required for Site Activation or eTMF by clicking on the checkboxes.
6. Click on the Add button once the necessary details are configured.

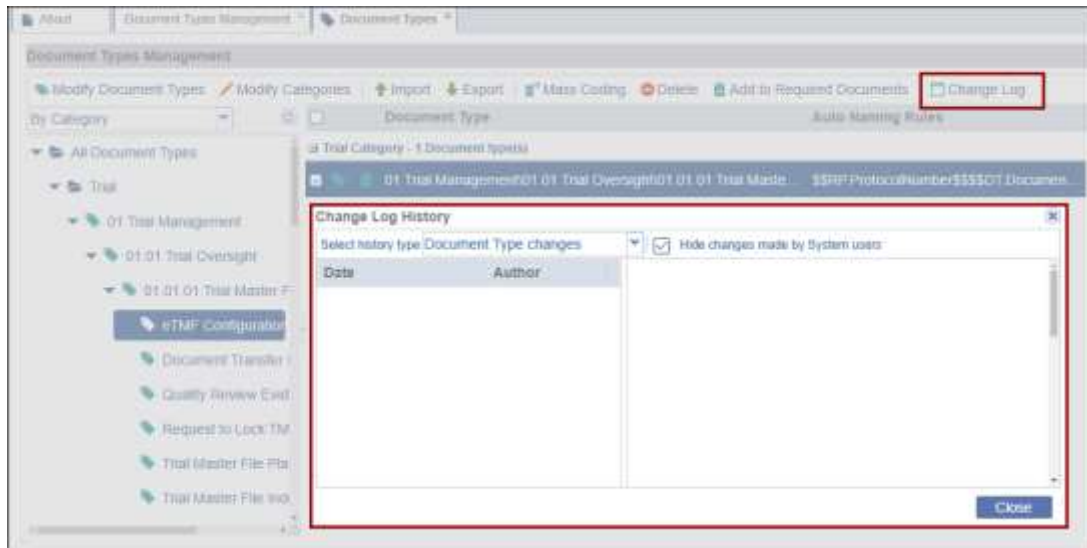


### Change Log

To view the change log history, follow the steps below.

1. Select a document type by expanding the category folders and associated sub-folders.

2. Click on the Change Log button from the top menu bar.
3. On the Change Log History window, view the changes made to the document type.



### Document Type Profile

To configure the document type profile, follow the steps below.

1. Select a document type by expanding the category folders and associated sub-folders.
2. Click on the Profile tab.
3. Within the profile tab, configure the following settings.
  - Document Type\*: The Document Type name is populated by default.
  - Short Name: Enter the Short Name for the document type. This can be the same as the Document Type name created in previous steps or an abbreviated version if the original name is long.
  - Document Type ID: This field is available only if IRB Integration is enabled in the room. Multiple values can be entered, separated by a semicolon, and must be unique within the document type category.
  - Category: The Category is preassigned based on the initial steps of creating the new document type.
  - Responsible Party\*: Provide the name of the organization who have a member/CRA assigned.
  - Auto name rules: Click the wrench icon next to the Auto Name Rules field. When metadata is filled out for documents of this type, the auto-naming rules configured here will be applied.
  - Related Folder:
  - Due Date: Due date will be calculated based on the submission date and the number of days.
  - Event Types: Displays the event types.
  - Include in Document Tracker Report
  - Zone
  - Section
  - Artifact

- Sub-Artifact
  - Index Number
  - Description
1. Select the new document type by clicking the checkbox next to the icon and the document type name. The panel on the far right becomes active.
  2. In the Profile tab, type in the Short Name for the document type. This can be the same as the Document Type name that you created in the previous steps, or it can be abbreviated if the original name is long.
  3. The IRB Document Type ID is one of the fields besides the Site ID and IRB Number that is required by the system for IRB Integration. This field will be available only if IRB Integration is enabled in the room. This field can accept multiple values separated by semi-colon and should be unique within the document type category.
  4. The Category has already been assigned by your first steps of creating the new document type.
  5. Click the wrench icon next to the Auto Name Rules field. When the metadata gets filled out for documents of this type, the auto-naming rules you set up here will be applied to these documents. All initial document types and auto-naming rules are determined by the configuration manual. An Auto Name Rules window opens. Refer to the screenshot below:

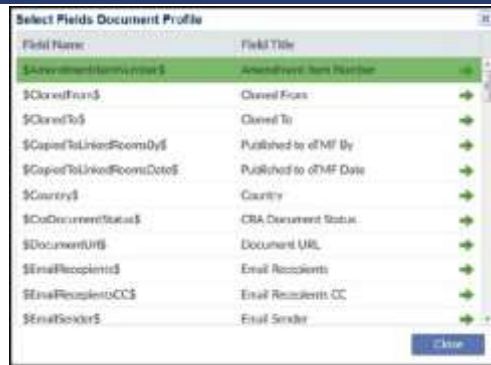


| Description                       | Insert Rule                        |
|-----------------------------------|------------------------------------|
| Principal Investigator First Name | ##PrincipalInvestigatorFirstName## |
| Principal Investigator Last Name  | ##PrincipalInvestigatorLastName##  |
| Sponsor Name                      | ##SponsorName##                    |
| Contact First Name                | ##ContactFirstName##               |
| Contact Last Name                 | ##ContactLastName##                |
| Program Name                      | ##ProgramName##                    |

The following set of instructions describes the insertion of a standard set of fields for the auto-naming of documents of a particular type. For this example, the proposed naming rules include the study Principal Investigator's first and last name and the Sponsor's Name.

1. Under the Hardcoded tab, double-click a description to be inserted as an auto-naming rule. The insertion appears in the Rule Editor.
2. If you want to include fields present under the Field Insertion tab, double-click the description, and click the green arrow in the Select Fields Document Profile. This gets appended in the Rule Editor. The order in which you select these naming elements is the order in which they will be displayed.

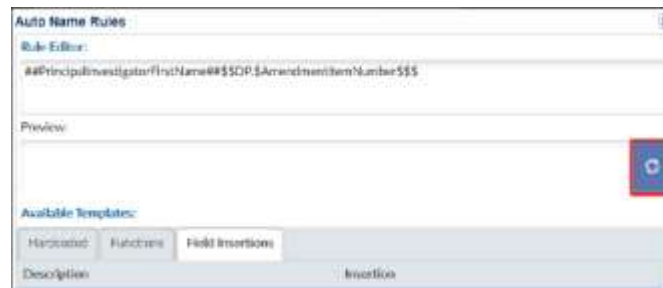




- Click Close when you have included all of the necessary fields.

Note: The fields stored under the Hardcoded tab are fields typically used in building auto-naming patterns. To include these, insert your cursor in the spot in the Rule Editor where you want this field to appear, then double-click the Description of the field and it will be inserted into the naming pattern.

- Back in the Auto Name Rules window, click the white arrows icon to the right of the Preview box. The box populates with a generic preview of the selected Auto Naming pattern. Refer to the screenshot below.



- Click OK at the bottom of the window to be returned to the main Document Types view.
- Click 'Save' at the bottom right of the Profile tab window.

## Specifying the Related Folder

- In the Profile tab in the panel on the right, click the magnifying glass icon next to the Related Folder box. A window opens, displaying the folders available for assigning the new document type.



- Select the proper folder or subfolder for the document type. In this example, we have chosen the Relevant Communications folder.



3. Click OK at the bottom of the window.
4. Back on the main Document Types view, click Save at the bottom of the panel on the right.

### Doc Type Fields

The Doc Type Fields section allows the user to determine which metadata fields are associated with any given document type. These values can be assigned to a specific document type or they can be inherited from a folder level.

- If the field is marked as 'Visible' then it will be displayed in the metadata field when the chosen document type is assigned to a file.
- If the field is marked as 'Required' (which can only be done for Visible fields) will be required for any document coded as the related document type.

Profile
DocType Fields
Bulk Fields Update
Default Values
Req

☐ Inherit from 01.01.0 ...
Tools
Field name...

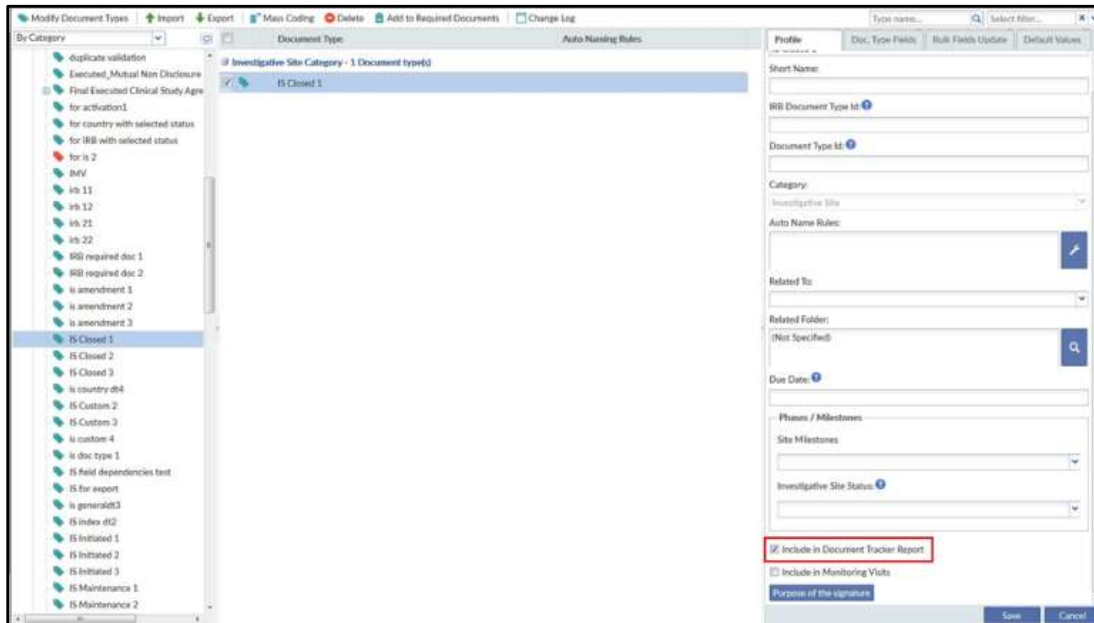
| Title                           | Visible                             | Required                            |
|---------------------------------|-------------------------------------|-------------------------------------|
| Amendment Item Number           | <input type="checkbox"/>            | <input type="checkbox"/>            |
| Applicable Status Change Reason | <input type="checkbox"/>            | <input type="checkbox"/>            |
| Category                        | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Cloned From                     | <input type="checkbox"/>            | <input type="checkbox"/>            |
| Comments                        | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Confidence Score                | <input type="checkbox"/>            | <input type="checkbox"/>            |
| Contact                         | <input type="checkbox"/>            | <input type="checkbox"/>            |
| Copied to linked rooms date     | <input type="checkbox"/>            | <input type="checkbox"/>            |

Options that appear greyed-out cannot be modified

Save
Cancel

## Include in Document Tracker Report

To specify that any Document Type will specifically be included in the Document Tracker Report, tick the Include in Document Tracker Report checkbox from the Document Types Profile window. After making any changes, be sure to click Save at the bottom of the window. Refer to the screenshot below:



## Reference Metadata

The standard set of TMF metadata is 'mappable' from Trial Interactive document types but it has not been available directly in the User Interface. Providing this information allows for better metadata exports and improves classification.

For eTMF rooms, this metadata is now included with each document type in a set of virtual fields. Fields now include:

- Zone
- Section
- Artifact
- Sub-Artifact
- Index Number
- Description
- Instructions

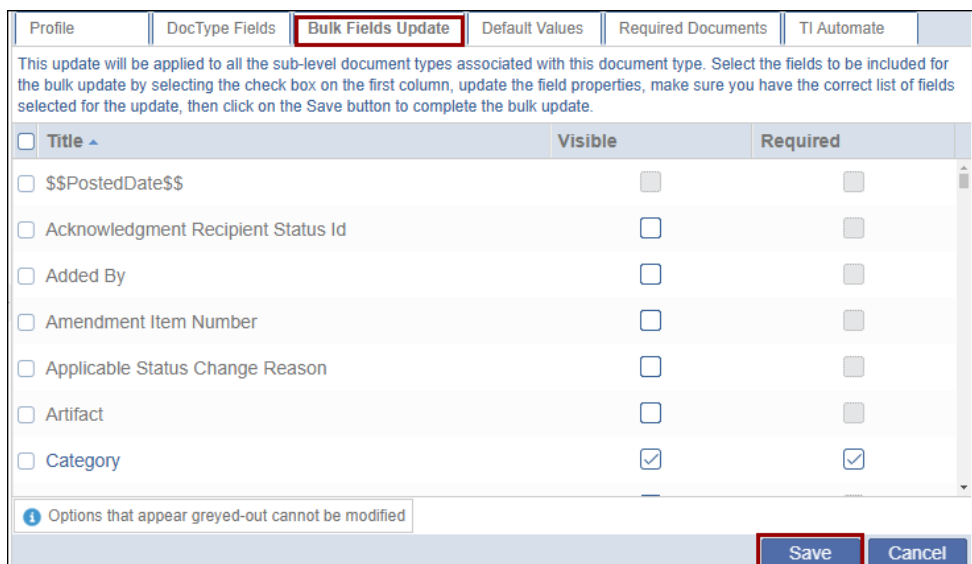
These fields will simplify the full implementation of sub-artifacts, particularly important for the TMF Reference Model v3.2.

Additionally, when selecting a document type, the Instructions field is now made available as flyover help.

Finally, these fields are all fully reportable and are made available in standard views, grid view metadata exports, standard reports, and archives.

### Bulk Fields Update

The Bulk Fields Update tab allows users to specify whether the field should be visible or required for all the sub-level document types associated with the parent document type. Refer to the instructions on bulk fields update detailed in the tab.



This update will be applied to all the sub-level document types associated with this document type. Select the fields to be included for the bulk update by selecting the check box on the first column, update the field properties, make sure you have the correct list of fields selected for the update, then click on the Save button to complete the bulk update.

| <input type="checkbox"/> Title ^                            | Visible                             | Required                            |
|-------------------------------------------------------------|-------------------------------------|-------------------------------------|
| <input type="checkbox"/> \$\$PostedDate\$\$                 | <input type="checkbox"/>            | <input type="checkbox"/>            |
| <input type="checkbox"/> Acknowledgment Recipient Status Id | <input type="checkbox"/>            | <input type="checkbox"/>            |
| <input type="checkbox"/> Added By                           | <input type="checkbox"/>            | <input type="checkbox"/>            |
| <input type="checkbox"/> Amendment Item Number              | <input type="checkbox"/>            | <input type="checkbox"/>            |
| <input type="checkbox"/> Applicable Status Change Reason    | <input type="checkbox"/>            | <input type="checkbox"/>            |
| <input type="checkbox"/> Artifact                           | <input type="checkbox"/>            | <input type="checkbox"/>            |
| <input type="checkbox"/> Category                           | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |

Options that appear greyed-out cannot be modified

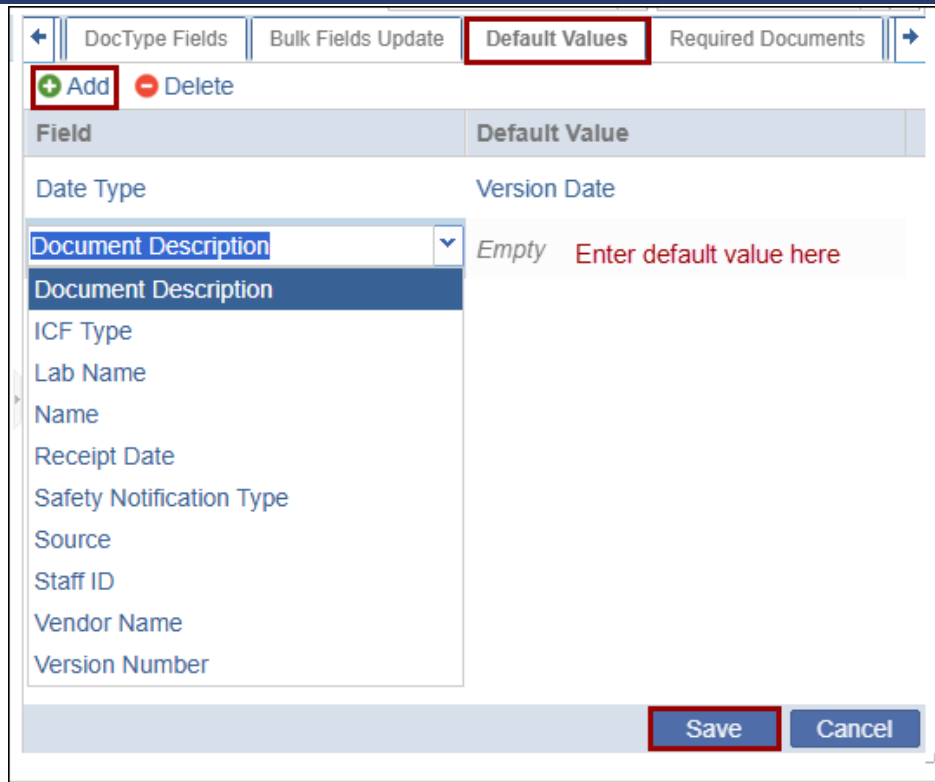
**Save** **Cancel**

### Default Values

By implementing the Default Values options when defining a document type's profile coding, users can set a specific metadata field value to auto-populate based on the document type.

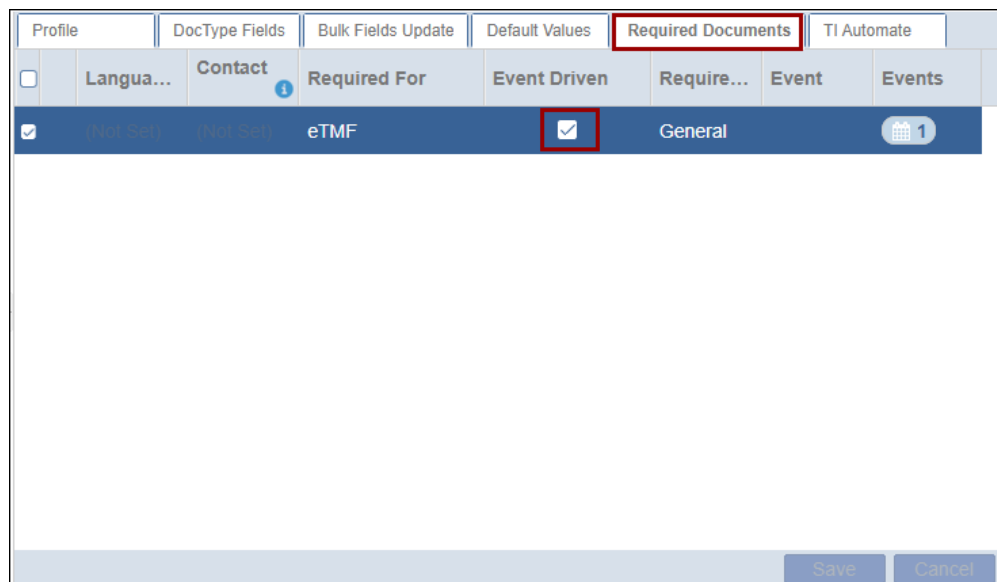
To use these new options, you must first create a custom metadata field in Form Settings. You must be sure to include the custom field in Coding before you save the final changes.

1. Click the Default Values tab.
2. Click the Add button. The Field textbox activates.
3. Click the dropdown arrow and select the necessary custom metadata field from the list.
4. Set the field's default value by typing the value in the textbox.
5. Click on the Save button.



### Required Documents

The Required Documents tab displays the document added to the Required Documents section. Users need to select the 'Event Driven' checkbox.

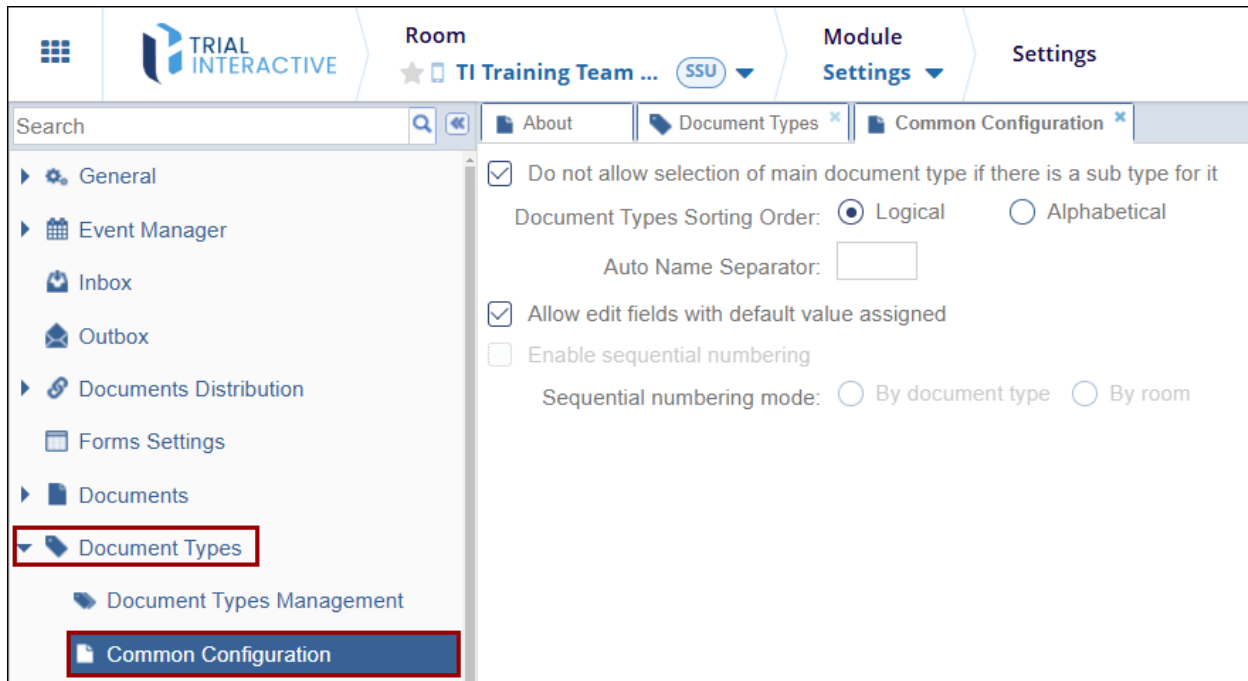


Note: When any document is assigned to that document type, the custom field will auto-populate with the default value you established.

### Common Configuration

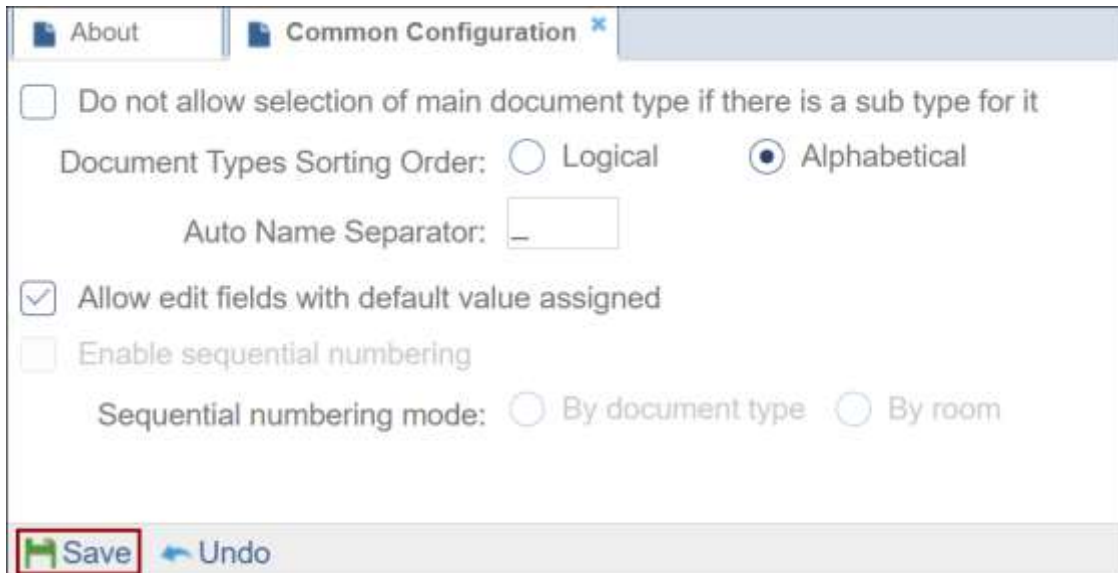
To access and configure the Common Configuration settings, follow the steps below.

1. Within the Settings module, click on the Document Types dropdown.
2. Select the Common Configurations option.



3. Within the Common Configurations tab, configure the following settings.
  - Do not allow selection of main document type if there is a sub type for it: Enable this setting by clicking on the checkbox. If this setting is enabled, the selection of the main document will be restricted if a sub-type is associated with it.
  - Document Types Sorting Order: Select any one of the options by clicking on their radio buttons.
    1. Logical: Selecting this option sort documents in the order in which they were uploaded.
    2. Alphabetical: Selecting this option sorts documents in alphabetical order.
  - Auto Name Separator: Enter a character in the box provided which will act as a name separator or add a blank space as a separator.
  - Allow edit fields with default value assigned: Enable this setting by clicking on the checkbox. If this setting is enabled, some document metadata fields will be filled automatically upon creating a document and selecting a document type from the configured list.

- Enable Sequential Numbering: Click on the checkbox to enable the setting that activates the Sequential number mode options.
  1. By document type
  2. By room
- 4. Once all the changes are made, click on the 'Save' button at the bottom of the screen.



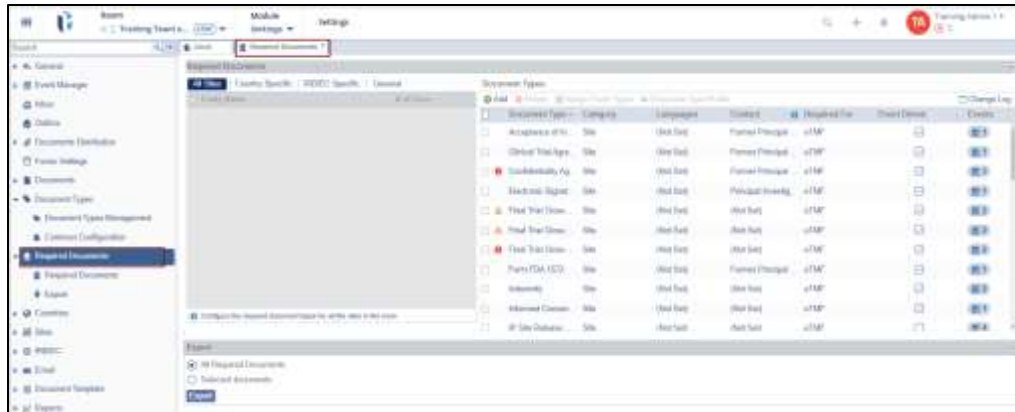
## Required Documents

The Required Documents Settings allow Administrators to define and manage the required documents for a study. Some document types may be mandatory for all investigative sites, while others may be required only for sites in specific countries. These settings are typically configured at the start of a study but can be adjusted if needed during the study. Once Document Types are set up for a room from Document Types Management, you can set up the Required Documents.

Note: It is recommended that administrators contact the Trial Interactive Project Management Team if any changes or additions are needed.

1. Navigate to Navigation Grid -> Settings Module
2. Select Required Documents from the menus on the left.

Refer to the screenshot below showing the options under Required Documents:



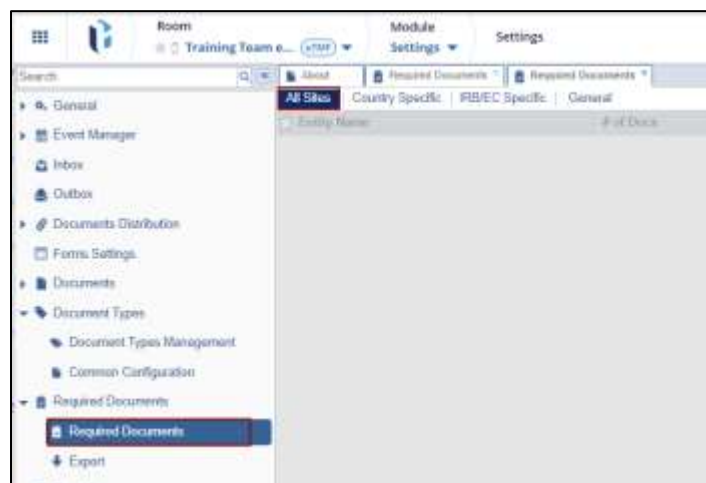
Required Documents can be defined for the following:

- All Sites
- Country Specific
- IRB/EC Specific

## Required Documents

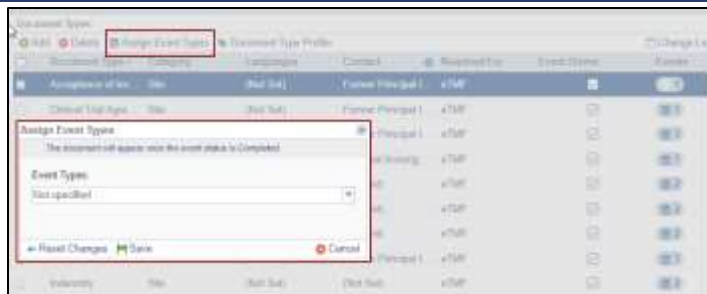
All Sites

1. From the left section of the panel, the user can select the category (Sites, Country, IRB/EC, and General) of the Required Documents. By default, the All-Sites category is chosen.

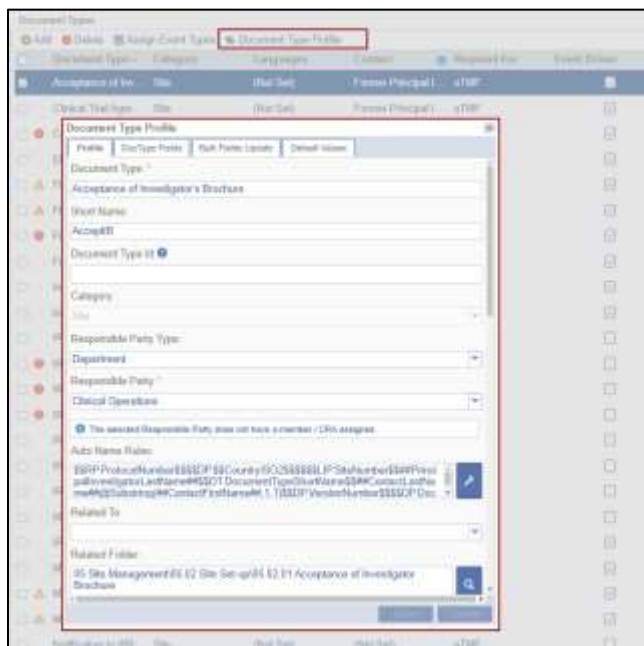


2. From the right section of the panel, named as Document Types, the user can:
  - a. Add or Delete a Required Document to the category selected from the left pane.
  - b. Assign Event types will help to enable Event Types.

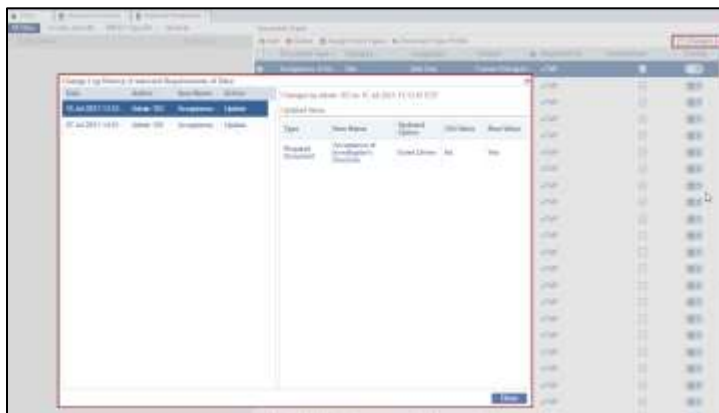




c. Document Type Profile display All fields shown in the screenshot below.



d. View the activity log of the selected category from the Change Log.

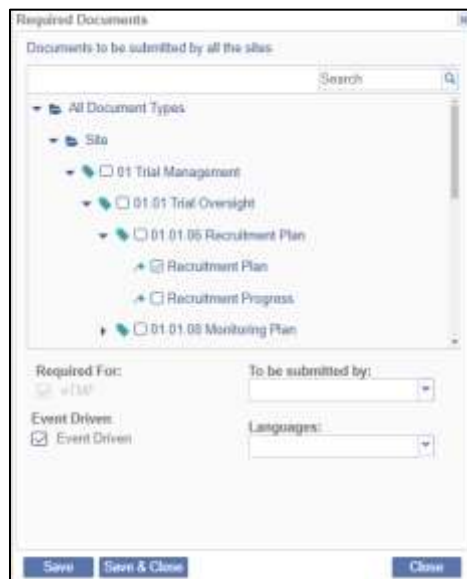


### Adding Documents to the List of Documents

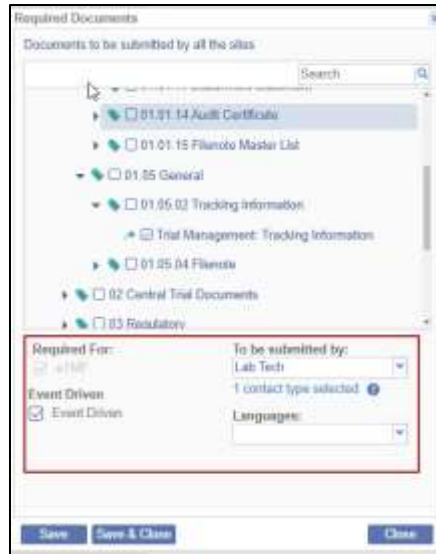
1. Click the relevant tab from the left panel of the Required Documents menu.
  - a. For Country and IRB/EC documents, pick the relevant country or IRB/EC.
2. Click Add from the top ribbon bar of the Document Types window on the right.



3. The Required Documents window is displayed to add Required Documents for All Sites under specific categories.
4. Click the folder from which you need to select the Required Documents and click the checkbox next to one or all of the documents to be required.



5. Select whether the document(s) will be required for Site Activation or eTMF by clicking the checkbox.
6. From the dropdown menus to the right, if necessary, select:
  - a. Required For: This is the Study Contact who is responsible for providing the selected required documents
  - b. Languages: Select the language from the list to be applicable to the Required Documents.



Note: Document types that need to be submitted by different contact types need to be set up separately.

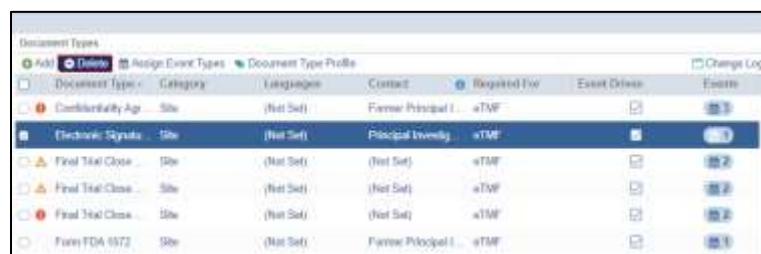
7. Click Save & Close if you have documents from only one category folder to add or click Save if you need to add more required documents.

Note: If documents are to be provided by different study contacts, click Save, then return to the documents list. Select the next set of documents, specify whether they are required for Site Activation or eTMF, choose the contact type from the dropdown, and click Save. Repeat this process until all required document types for all contacts have been added, then click Save & Close.

### Deleting Documents from the List of Required Documents

To delete a Required Document:

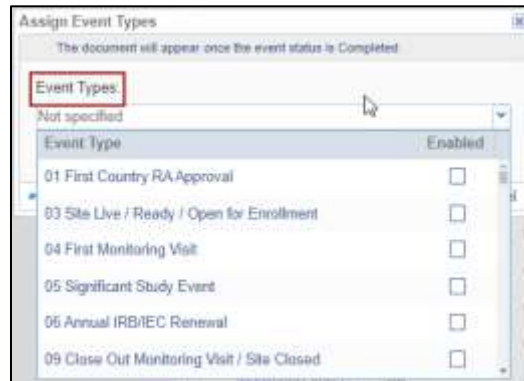
1. Click the All Sites tab from the left panel of the Required Documents Panel.
2. From the list of Required Document Types in the grid, tick the checkboxes to select the Required Document Types to be deleted.
3. Click Delete from the top ribbon bar of the Document Types window on the right.



4. The Required Document Types are removed from the list.

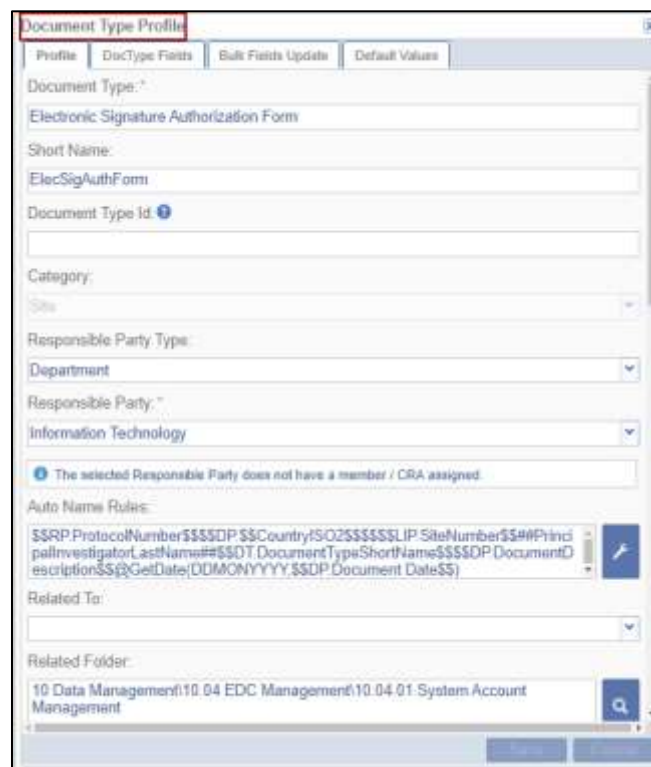
### Assign Event types

1. The Assign Event Types will help to enable Event Types.
2. Click Assign Event Types the Assign Event Types window is displayed.
3. The user needs to select the Event Types as per the requirement.
4. Either the user can Reset Changes or Save the changes.



### Document Type Profile

1. The Document Type Profile displays All fields available in the Required Documents.
2. Click Document Type Profile the Document Type Profile window is displayed.



Document Type Profile

Profile | DocType Fields | Bulk Fields Update | Default Values

Document Type: Electronic Signature Authorization Form

Short Name: ElecSigAuthForm

Document Type Id:

Category: Site

Responsible Party Type: Department

Responsible Party: Information Technology

The selected Responsible Party does not have a member / CRA assigned

Auto Name Rules:

\$\$\$RP.ProtocolNumber\$\$\$DP.\$CountryISO2\$\$\$SLIP.SiteNumber\$\$\$Princi  
palInvestigator.LastName\$\$\$DOT.DocumentType.ShortName\$\$\$DP.DocumentD  
escription\$\$\$GetDate(DDMMYYYY,\$\$DP.Document.Date\$\$)

Related To:

Related Folder: 10 Data Management\10.04 EDC Management\10.04.01 System Account Management

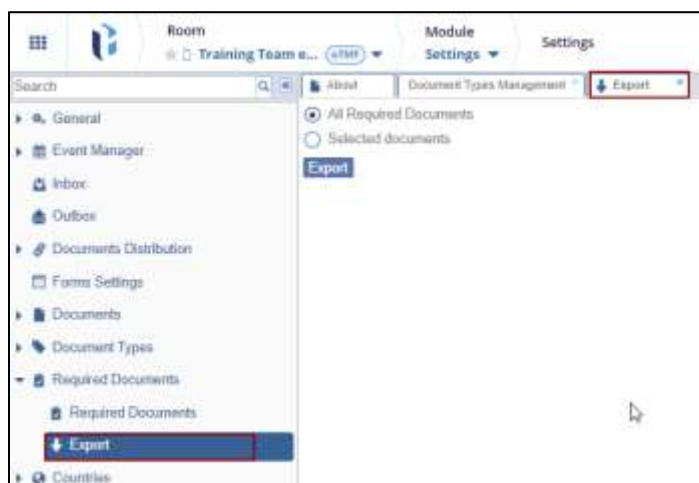
3. The Document Type Profile displays the following sections:
  - a. Profile
  - b. Doc Type Fields
  - c. Bulk Fields Update

#### d. Default Values

Note: To configure the Country Specific and IRB/EC Specific settings, refer to the standard steps of All Site settings detailed in the [Required Documents](#).

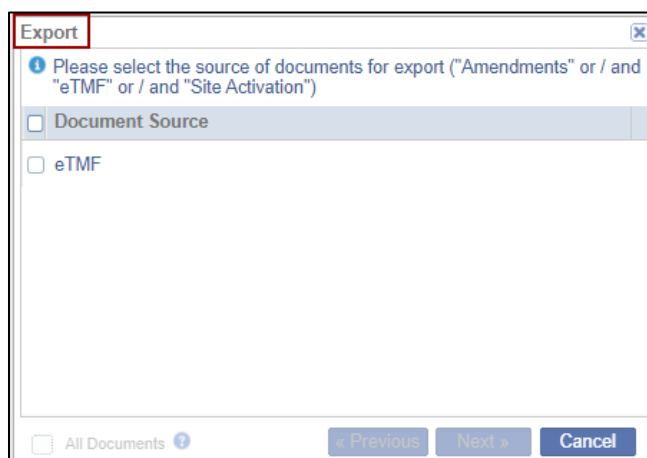
## Export

In this menu, Administrator users can export either All Required Documents or Selected documents. Refer to the screenshot below:

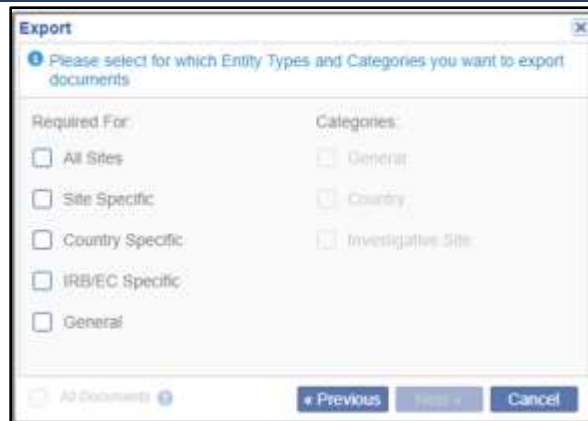


Required Documents can be exported in two ways:

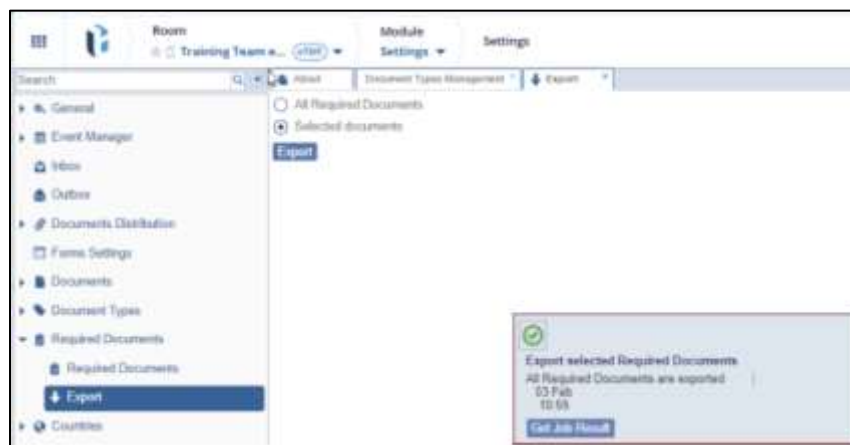
1. Select the 'All Required Documents' option to export documents from all document source categories.
2. Select the 'Selected documents' option to indicate which documents should be exported.
  - a. The Export window opens for you to choose from Amendments, Site Activation Requirements, or eTMF documents. Refer to the screenshot below:



- b. Select the required Document Source/s and click Next.
- c. A new Export window opens for you to select the required Entity Types and Categories. Refer to the screenshot below:



3. Click Next.
  - a. The final Export window will open for you to review the chosen criteria.
4. Click 'Previous' to make changes in the selections or click 'Next' to continue.
5. Press the 'Export' button to export the list of documents selected.
6. A notification will display indicating that the job was completed successfully.
7. Click Get Job Result on the right bottom of the screen.



8. An excel file is generated with a list of required documents and you can save the file for your records.

Refer to the screenshot below:

Required Documents

Training Team eTMF 10.6

Exported On: 2025-02-03 00:29:56 (Eastern Standard Time)

Exported By: Training Admin 1 (trainingadmin1@ti.com)

Time Zone: Eastern Standard Time (UTC-05:00) Eastern Time (US & Canada)

Required Documents Header

|  | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z | AA | AB | AC | AD | AE | AF | AG | AH | AI | AJ | AK | AL | AM | AN | AO | AP | AQ | AR | AS | AT | AU | AV | AW | AX | AY | AZ | BA | BB | BC | BD | BE | BF | BG | BH | BI | BJ | BK | BL | BM | BN | BO | BP | BQ | BR | BS | BT | BU | BV | BW | BX | BY | BZ | CA | CB | CC | CD | CE | CF | CG | CH | CI | CJ | CK | CL | CM | CN | CO | CP | CQ | CR | CS | CT | CU | CV | CW | CX | CY | CZ | DA | DB | DC | DD | DE | DF | DG | DH | DI | DJ | DK | DL | DM | DN | DO | DP | DQ | DR | DS | DT | DU | DV | DW | DX | DY | DZ | EA | EB | EC | ED | EE | EF | EG | EH | EI | EJ | EK | EL | EM | EN | EO | EP | EQ | ER | ES | ET | EU | EV | EW | EX | EY | EZ | FA | FB | FC | FD | FE | FF | FG | FH | FI | FJ | FK | FL | FM | FN | FO | FP | FQ | FR | FS | FT | FU | FV | FW | FX | FY | FZ | GA | GB | GC | GD | GE | GF | GG | GH | GI | GJ | GK | GL | GM | GN | GO | GP | GQ | GR | GS | GT | GU | GV | GW | GX | GY | GZ | HA | HB | HC | HD | HE | HF | HG | HH | HI | HJ | HK | HL | HM | HN | HO | HP | HQ | HR | HS | HT | HU | HV | HW | HX | HY | HZ | IA | IB | IC | ID | IE | IF | IG | IH | II | IJ | IK | IL | IM | IN | IO | IP | IQ | IR | IS | IT | IU | IV | IW | IX | IY | IZ | JA | JB | JC | JD | JE | JF | JG | JH | JI | IJ | JK | KL | KM | KN | KO | KP | KQ | KR | KS | KT | KU | KV | KW | KX | KY | KZ | LA | LB | LC | LD | LE | LF | LG | LH | LI | LJ | LK | LM | LN | LO | LP | LQ | LR | LS | LT | LU | LV | LW | LX | LY | LZ | MA | MB | MC | MD | ME | MF | MG | MH | MI | MJ | MK | ML | MM | MN | MO | MP | MQ | MR | MS | MT | MU | MV | MW | MX | MY | MZ | NA | NB | NC | ND | NE | NF | NG | NH | NI | NJ | NK | NL | NM | NN | NO | NP | NQ | NR | NS | NT | NU | NV | NW | NX | NY | NZ | OA | OB | OC | OD | OE | OF | OG | OH | OI | OJ | OK | OL | OM | ON | OO | OP | OQ | OR | OS | OT | OU | OV | OW | OX | OY | OZ | PA | PB | PC | PD | PE | PF | PG | PH | PI | PJ | PK | PL | PM | PN | PO | PP | PQ | PR | PS | PT | PU | PV | PW | PX | PY | PZ | QA | QB | QC | QD | QE | QF | QG | QH | QI | QJ | QK | QL | QM | QN | QO | QP | QR | QS | QT | QU | QV | QW | QX | QY | QZ | RA | RB | RC | RD | RE | RF | RG | RH | RI | RJ | RK | RL | RM | RN | RO | RP | RQ | RR | RS | RT | RU | RV | RW | RX | RY | RZ | SA | SB | SC | SD | SE | SF | SG | SH | SI | SJ | SK | SL | SM | SN | SO | SP | SQ | SR | SS | ST | SU | SV | SW | SX | SY | SZ | TA | TB | TC | TD | TE | TF | TG | TH | TI | TJ | TK | TL | TM | TN | TO | TP | TQ | TR | TS | TU | th | tv | <th>TW</th> <th>TX</th> <th>TY</th> <th>TZ</th> <th>UA</th> <th>UB</th> <th>UC</th> <th>UD</th> <th>UE</th> <th>UF</th> <th>UG</th> <th>UH</th> <th>UI</th> <th>UJ</th> <th>UK</th> <th>UL</th> <th>UM</th> <th>UN</th> <th>UO</th> <th>UP</th> <th>UQ</th> <th>UR</th> <th>US</th> <th>UT</th> <th>UU</th> <th>UV</th> <th>UW</th> <th>UX</th> <th>UY</th> <th>UZ</th> <th>VA</th> <th>VB</th> <th>VC</th> <th>VD</th> <th>VE</th> <th>VF</th> <th>VG</th> <th>VH</th> <th>VI</th> <th>VJ</th> <th>VK</th> <th>VL</th> <th>VM</th> <th>VN</th> <th>VO</th> <th>VP</th> <th>VQ</th> <th>VR</th> <th>VS</th> <th>VT</th> <th>VU</th> <th>VV</th> <th>VW</th> <th>VX</th> <th>VY</th> <th>VZ</th> <th>WA</th> <th>WB</th> <th>WC</th> <th>WD</th> <th>WE</th> <th>WF</th> <th>WG</th> <th>WH</th> <th>WI</th> <th>WJ</th> <th>WK</th> <th>WL</th> <th>WM</th> <th>WN</th> <th>WO</th> <th>WP</th> <th>WQ</th> <th>WR</th> <th>WS</th> <th>WT</th> <th>WU</th> <th>WV</th> <th>WW</th> <th>WX</th> <th>WY</th> <th>WZ</th> <th>XA</th> <th>XB</th> <th>XC</th> <th>XD</th> <th>XE</th> <th>XF</th> <th>XG</th> <th>XH</th> <th>XI</th> <th>XJ</th> <th>XK</th> <th>XL</th> <th>XM</th> <th>XN</th> <th>XO</th> <th>XP</th> <th>XQ</th> <th>XR</th> <th>XS</th> <th>XT</th> <th>XU</th> <th>XV</th> <th>XW</th> <th>XX</th> <th>XY</th> <th>XZ</th> <th>YA</th> <th>YB</th> <th>YC</th> <th>YD</th> <th>YE</th> <th>YF</th> <th>YG</th> <th>YH</th> <th>YI</th> <th>YJ</th> <th>YK</th> <th>YL</th> <th>YM</th> <th>YN</th> <th>YO</th> <th>YP</th> <th>YQ</th> <th>YR</th> <th>YS</th> <th>YT</th> <th>YU</th> <th>YV</th> <th>YW</th> <th>YX</th> <th>YY</th> <th>YZ</th> <th>ZA</th> <th>ZB</th> <th>ZC</th> <th>ZD</th> <th>ZE</th> <th>ZF</th> <th>ZG</th> <th>ZH</th> <th>ZI</th> <th>ZJ</th> <th>ZK</th> <th>ZL</th> <th>ZM</th> <th>ZN</th> <th>ZO</th> <th>ZP</th> <th>ZQ</th> <th>ZR</th> <th>ZS</th> <th>ZT</th> <th>ZU</th> <th>ZV</th> <th>ZW</th> <th>ZX</th> <th>ZY</th> <th>ZZ</th> | TW | TX | TY | TZ | UA | UB | UC | UD | UE | UF | UG | UH | UI | UJ | UK | UL | UM | UN | UO | UP | UQ | UR | US | UT | UU | UV | UW | UX | UY | UZ | VA | VB | VC | VD | VE | VF | VG | VH | VI | VJ | VK | VL | VM | VN | VO | VP | VQ | VR | VS | VT | VU | VV | VW | VX | VY | VZ | WA | WB | WC | WD | WE | WF | WG | WH | WI | WJ | WK | WL | WM | WN | WO | WP | WQ | WR | WS | WT | WU | WV | WW | WX | WY | WZ | XA | XB | XC | XD | XE | XF | XG | XH | XI | XJ | XK | XL | XM | XN | XO | XP | XQ | XR | XS | XT | XU | XV | XW | XX | XY | XZ | YA | YB | YC | YD | YE | YF | YG | YH | YI | YJ | YK | YL | YM | YN | YO | YP | YQ | YR | YS | YT | YU | YV | YW | YX | YY | YZ | ZA | ZB | ZC | ZD | ZE | ZF | ZG | ZH | ZI | ZJ | ZK | ZL | ZM | ZN | ZO | ZP | ZQ | ZR | ZS | ZT | ZU | ZV | ZW | ZX | ZY | ZZ |
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## Countries

When a study includes investigative sites located in different countries, those countries need to be added to the room. As a result of this, country-specific folders will be set up in the room's folder structure to accept and store country-specific documents and users will be able to choose the appropriate country when setting up new investigative sites in that country.

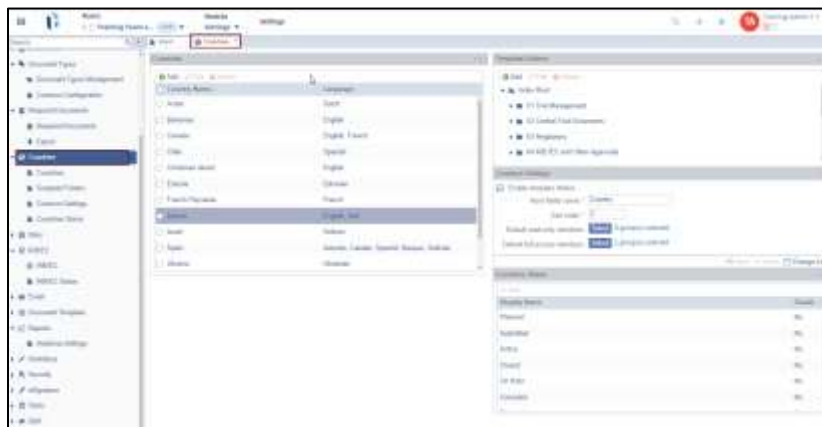
## Countries Settings

Trial Interactive allows administrators to make changes to Countries Settings.

Follow the steps below to make changes to the country settings:

1. Navigate to the Navigation Grid -> Settings Module
2. Go to the Countries settings from the left menu of the settings page.

Refer to the screenshot below:



Selecting countries will open the option in a tab in the next pane. As shown in the screenshot above, the list of countries where studies are being conducted is displayed. These countries can be added, edited, or deleted from the buttons in the ribbon above the country listing.

### Add Countries

Follow the steps below to add countries:

1. Click Add from the ribbon above the country listing.
  - o The Create Country window will open.
2. Click the dropdown arrow at the right end of the Country field. An alphabetized list of countries is populated to select from.
3. Select the name of the country to be added. The name of the selected country populates the Country field.





4. If there is a country-specific Study Contact #, include the associated number in the field.
5. Click 'Create.' The name of the newly added country appears in the alphabetized list.



6. Repeat these steps until you have added all of the countries associated with the study.

Additions and changes made here are saved automatically.

### Edit Countries

Once a country has been added to the list, you can add or change the study contact #, and adjust access to groups or users.

Follow the steps below to edit countries:

1. Select the required country from the grid to be edited. Click 'Edit' at the top of the Countries window.



2. The Edit Country window will open.

Edit Country

X

Country: \*

Room Contact #:

Read Only Members: Select 0 user(s) selected, 0 group(s) selected

Full Access Members: Select 0 user(s) selected, 2 group(s) selected

Save
Cancel

3. Click the Room Contact# field to add the room ID.
4. Click Select next to the 'Read Only Members' option.
5. The Read Only Members window is displayed in order to add Users/Groups by dragging the entries or by selecting them.
6. Click OK.

Read Only Members

X

Users

Groups

| Icon | First Name        | Email        | Phone | Mobile | Organization |
|------|-------------------|--------------|-------|--------|--------------|
|      | sgoersmiron@t...  | transperf... |       |        |              |
|      | GLtest1234@t...   | ti.com       |       |        |              |
|      | reader10@email... | email.com    |       |        |              |
|      | reader12@email... | email.com    |       |        |              |
|      | SeriousGuy@e...   | email.com    |       |        |              |
|      | willtest@chul...  | ti.com       |       |        |              |
|      | PalmSmith@ti.com  | Dowd Hous... |       |        |              |

Selected Members

| Icon | Name | Email |
|------|------|-------|
|------|------|-------|

OK
Cancel

7. Click Select next to the 'Full Access Members' option.
8. The Full Access Members window is displayed in order to add Users/Groups by dragging the entries or by selecting them.
9. Click OK.

Full Access Members

X

Users

Groups

| Icon | First Name        | Email        | Phone | Mobile | Organization |
|------|-------------------|--------------|-------|--------|--------------|
|      | sgoersmiron@t...  | transperf... |       |        |              |
|      | GLtest1234@t...   | ti.com       |       |        |              |
|      | reader10@email... | email.com    |       |        |              |
|      | reader12@email... | email.com    |       |        |              |
|      | SeriousGuy@e...   | email.com    |       |        |              |
|      | willtest@chul...  | ti.com       |       |        |              |
|      | PalmSmith@ti.com  | Dowd Hous... |       |        |              |

Selected Members

| Icon | Name | Email |
|------|------|-------|
|      | QC 1 |       |
|      | QC 2 |       |

OK
Cancel

10. Click Save on the 'Edit Countries' window.

Additions and changes made here are saved automatically.

### Delete Countries

Follow the steps below to delete the countries:

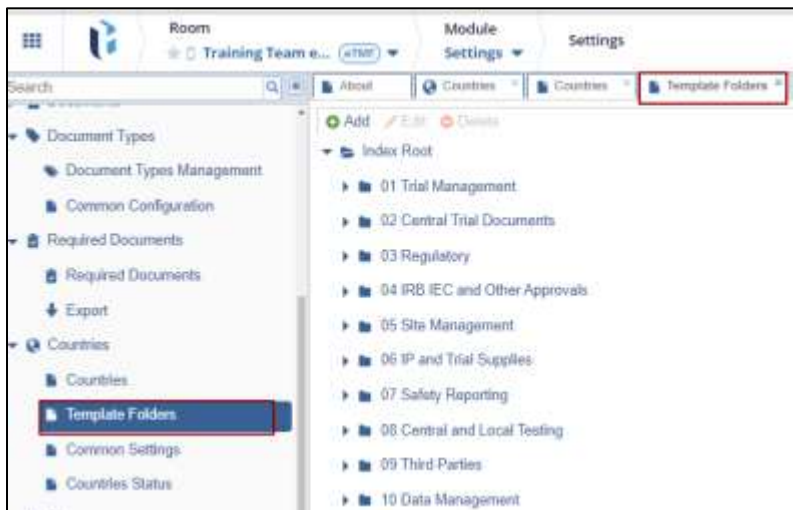
1. Select the country or countries that you need to delete from the list by clicking the checkbox next to the country's name(s).
2. Click Delete at the top of the Countries window. The country name(s) will be deleted automatically, without giving you a warning.



Note: Once documents are stored in the room's index folders, countries with associated documents cannot be deleted. However, the user can continue adding and editing entries in the Countries list as the study progresses.

## Template Folders

In this window, you can Add, Edit, or Delete template folders and subfolders in the root folder for managing country-specific documents.

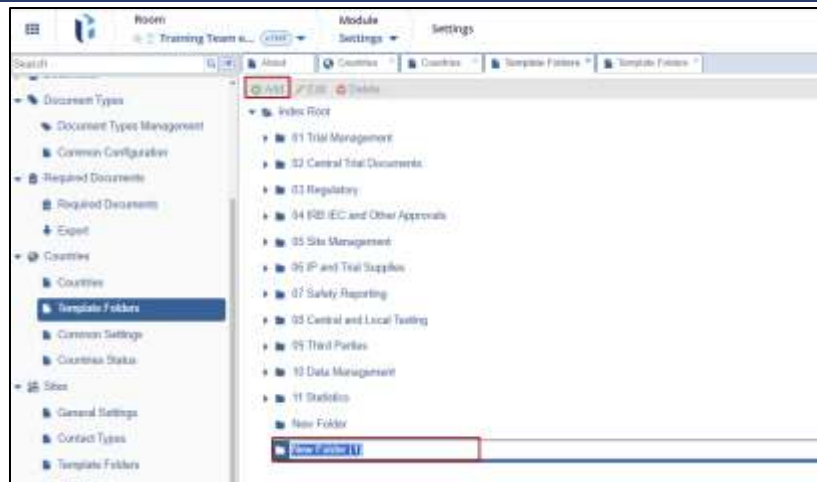


Note: The details required to complete this stage of room configuration are provided in the Configuration Manual. The folder structure is often consistent, but it is always study-specific.

## Adding Folders and Subfolders

Follow the steps below to add folders and subfolders:

1. Click Add to create the folder to the Index Root.
2. Click the 'Add' button near the top of the Template Folders window. A new folder naming field opens, temporarily named 'New Folder'.



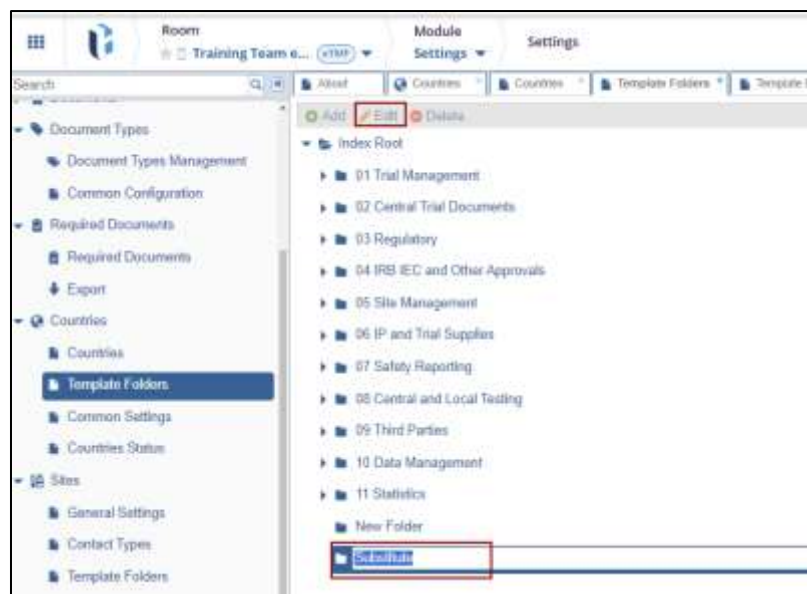
3. Type the name of the new folder name in the highlighted field.
4. Press Enter.
5. Repeat this process until you have entered all of the new folder names.

Additions and changes made here are saved automatically.

### Editing Names of Folders and Subfolders

Follow the steps below to edit the names of folders and subfolders:

1. Select the folder to be edited.
2. Click 'Edit' from the menu at the top of the window or right-click the folder name and select Edit from the available options.
3. Make the necessary changes to the folder name.
4. Press Enter.

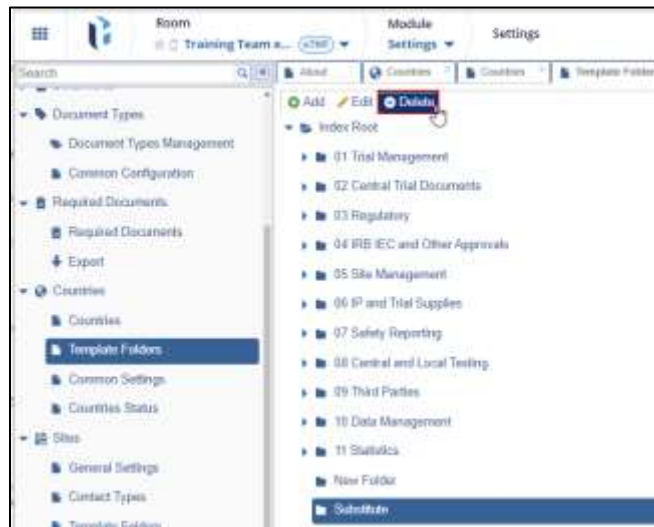


Additions and changes made here are saved automatically.

## Deleting Folders

Follow the steps below to delete folders and subfolders:

1. Select the folder to be deleted.
2. Click Delete from the menu at the top of the window or right-click the folder name and select 'Delete' from the available options. The folder will disappear from the index structure.



Note: Folders that contain subfolders or documents cannot be deleted.

## Common Settings

In the Common Settings window, the user can:

1. Enable or disable the Template Folders.
2. Edit the Root folder name.
3. Change the Sort Order, the place in the room's index structure where the Country Management folder appears.
4. The user can adjust the Read-Only and Full Access security settings.
5. Select the users or groups to set access. If the user can make any changes in this window, click Save.



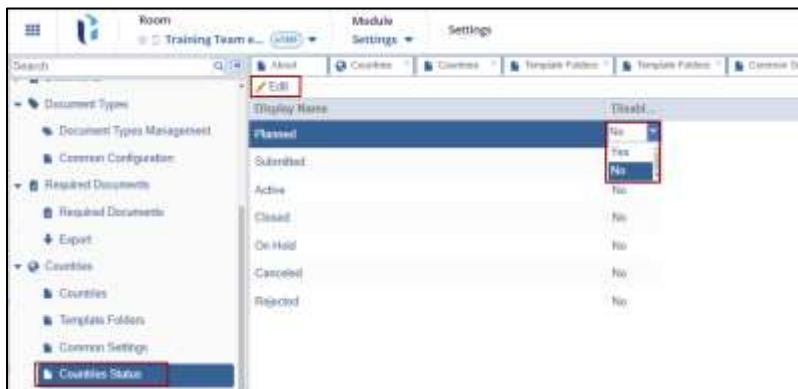
6. Click Select next to the 'Default read-only members' option.

7. The Default read-only members window is displayed in order to add Users/Groups by dragging the entries or by selecting them.
8. Click OK.
9. Click Select next to the 'Default full access members' option.
10. The Default full access members window is displayed in order to add Users/Groups by dragging the entries or by selecting them.
11. Click OK.

## Countries Status

In this panel, Administrator users can edit the Display Name of the Country Status.

- Locate the status and click the Edit button on the top or double-click on the specific display name to edit.
- Country statuses can be enabled or disabled as well.
- Click on the drop-down menu from the top-right corner and select Yes or No entry to change the value.

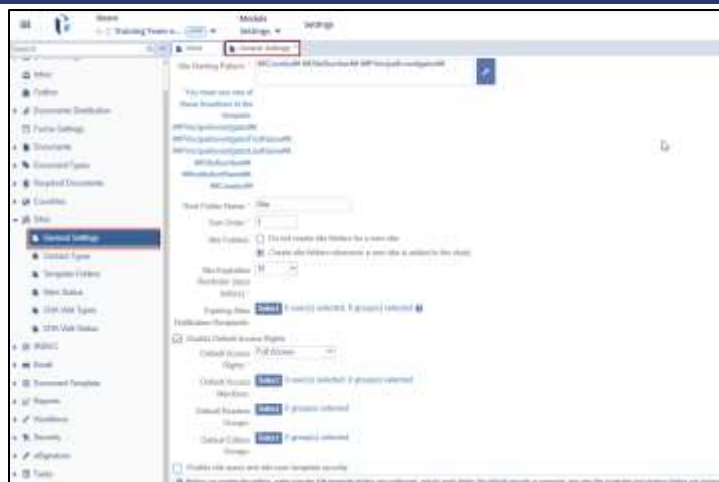


## Sites

Clicking the Investigative Sites menu allows the Administrator to manage settings for generic components of each investigative site in the study.

## General Settings

The General Settings for Sites describes the basic information regarding Site name and number, Address and Contact Details, etc. Explains about the Site statuses (e.g., Active, Pending, Closed) and transitions. Tracking essential regulatory documents, approvals, and certifications. Monitoring subject enrollment, site performance, and milestones. Defining user roles and access levels for site-related data and functionality.

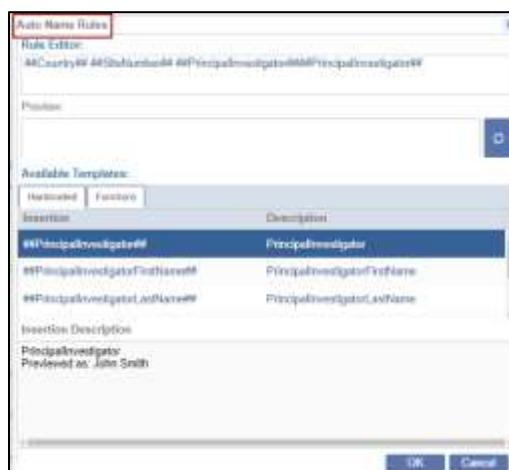


In order to set the general Site Settings, follow the instructions below:

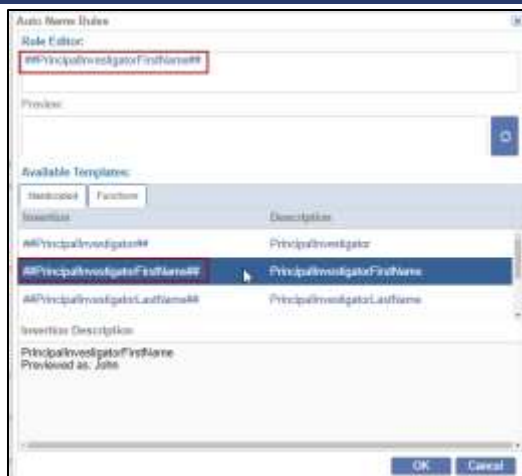
1. Click the Wrench icon to the right of the Site Naming Pattern box.



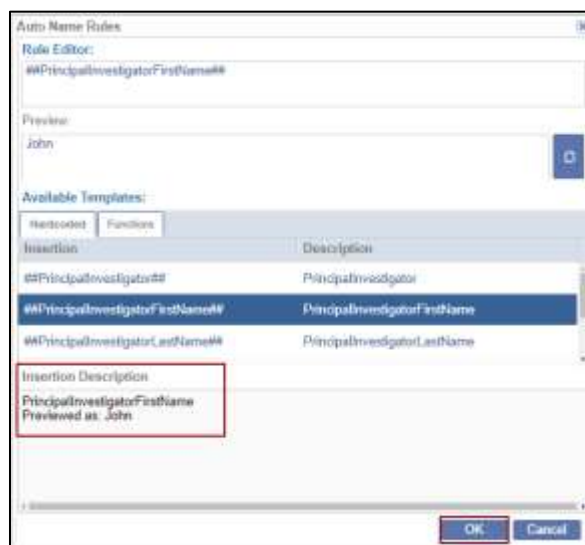
- a. An Auto Name Rules window opens.
- b. The 'Site Naming Pattern' is built and displayed in the Rule Editor box. The user can also type text into the Rule Editor.
- c. The information that populates in the 'Insertion' box is selected from the list of Available Templates (Hardcoded and Functions).



2. Click in the Rule Editor box.
3. Double-click the insertions in the Available Templates box in the order in which the user wants them to appear in the naming pattern.

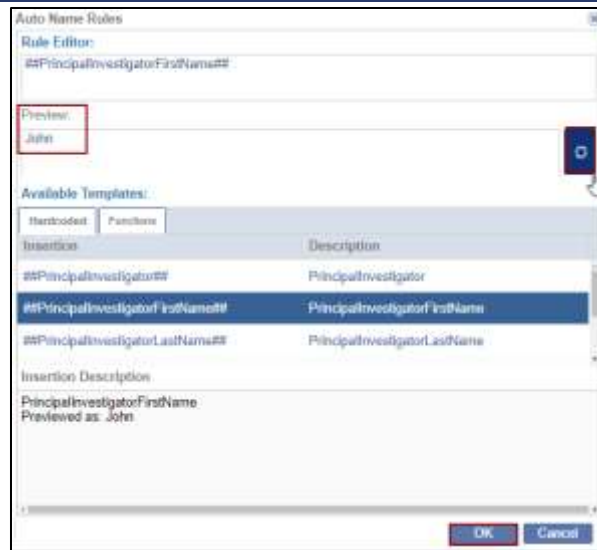


4. The Insertion Description displays the 'Insertion' and 'Previewed as' information.

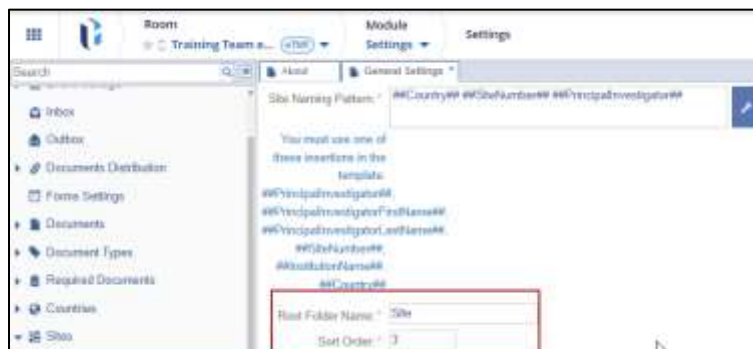


5. Once you have made the selections, click the blue box to the right of the Preview box to see how the folder names will appear in the room's index.
6. Once the naming pattern is set up correctly, click OK at the bottom of the window.

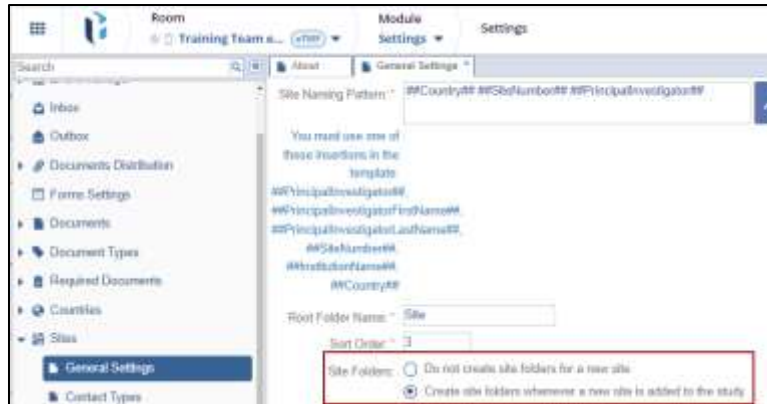




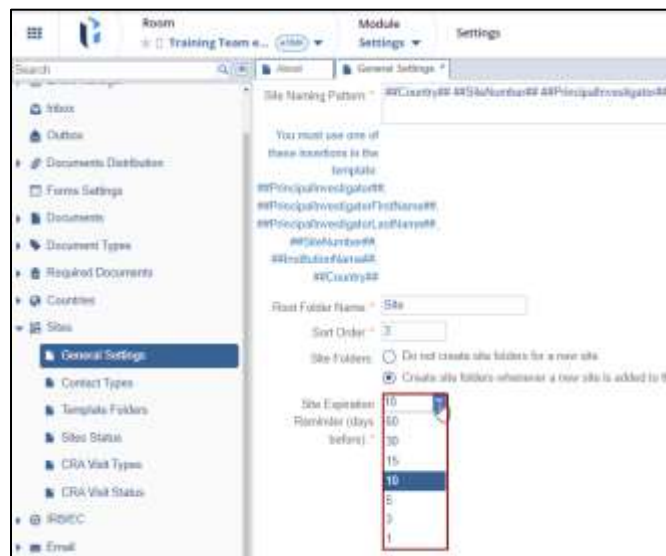
7. In the next available field, enter the Root Folder Name. This title will be assigned to the main folder in the room's index, which will contain subfolders for each investigative site involved in the study.
8. Click in the field and type the root folder name.
9. Selection of the Sort Order for the Site Management folder is made in the next field. This dictates where the folder appears in the room's folder index.
10. Click in the field and type the number order where it should appear in the index.



11. The next area contains two radio buttons for Site folder creation in the eTMF. Click the option that fits the user's needs.



12. The Site Expiration Reminder (days before) field offers a drop-down menu where users can select the number of days before the expiration date to receive the reminder.



Note: Hover the mouse over the question marks in blue circles for more information about specific options on the screen.

16. The Notification Recipients provides two options:

The Enable Default Access Rights have the following options that can be set as per the user's requirements.

- The Default Access Rights: provides Full Access or View Only.
- The Default Access Members: when clicked on Select, the Default Access Members pop-up window is displayed with the Users/Groups members.
- The Default Readers Groups: when clicked on Select, the Default Readers Groups pop-up window is displayed with the Groups members.
- The Default Editors Groups: when clicked on Select, the Default Editor Groups pop-up window is displayed with the Groups members.



17. The Enable site users and site user template security option is most typically enabled in eISF rooms where strict site security must be maintained. For additional information on these settings, please see the section on 'Investigative Site Template Folders'.

Note: Before you enable this setting, make sure the Site template folders are configured, and for each folder, the default security is assigned; and also the protected and staging folders are assigned.

18. Click Save after making any additions, selections, or changes in the General Settings panel.

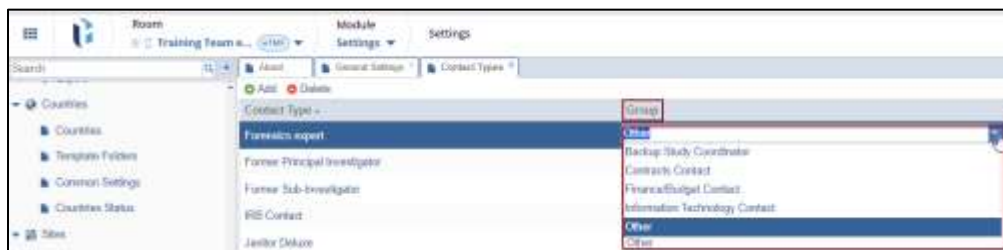
## Contact Types

In order to set up the Contact Types for the room, follow these steps:

1. Click Add. The Contact Type field becomes active.
2. Type the contact type name and hit Enter.



3. Double-click the field in the Group column to make it active.
4. Click the drop-down arrow and select the appropriate group.
5. Hit Enter.

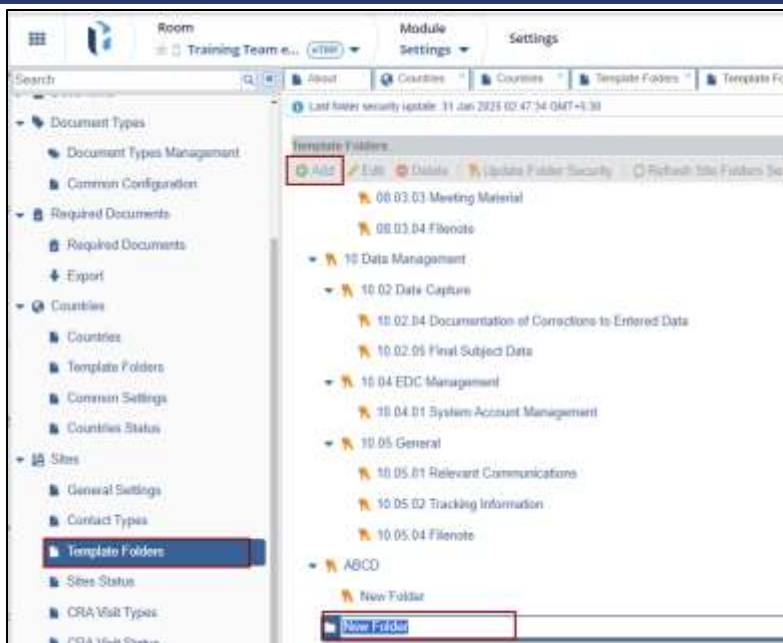


Additions and changes made here are saved automatically.

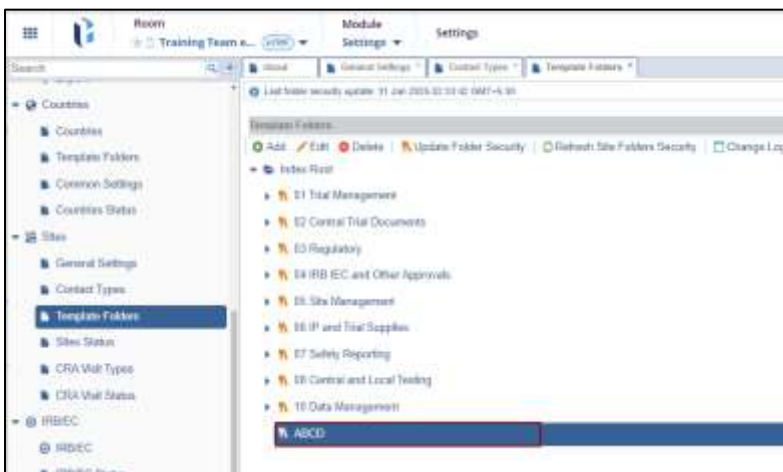
## Template Folders

The Template Folders panel is a crucial tool for generating the folder structure where all Investigative Sites' documents will be stored during the study. The structure created here follows the guidelines provided in the Configuration Manual.

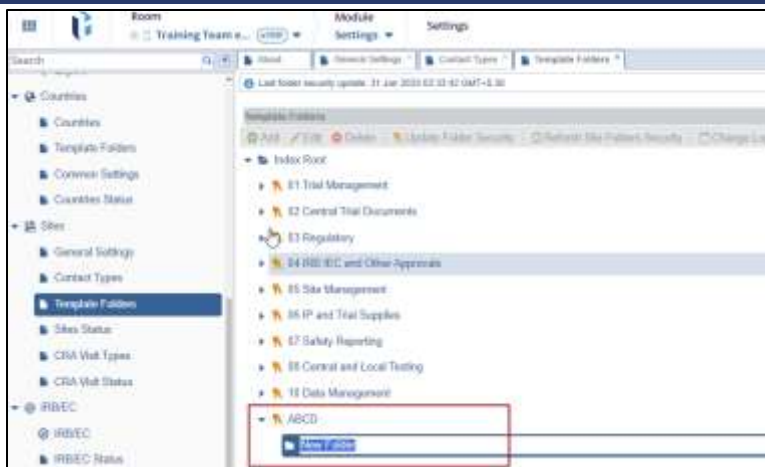
1. Click Add to create the first folder in the Template Folders.



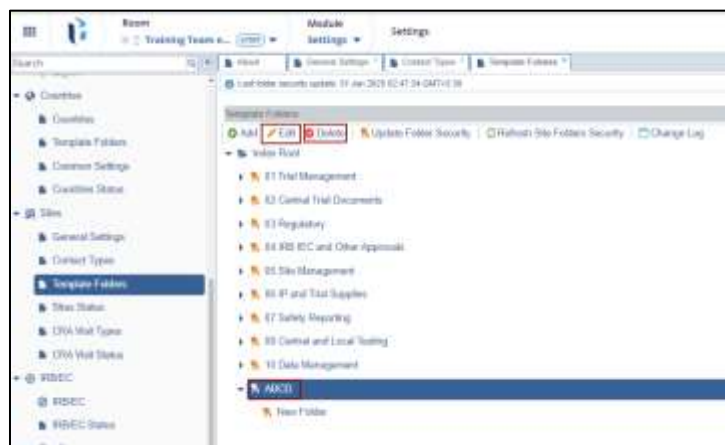
2. Type the name of the folder in the available field.
3. To add another folder at the same index level, click the Index Root folder and click Add.



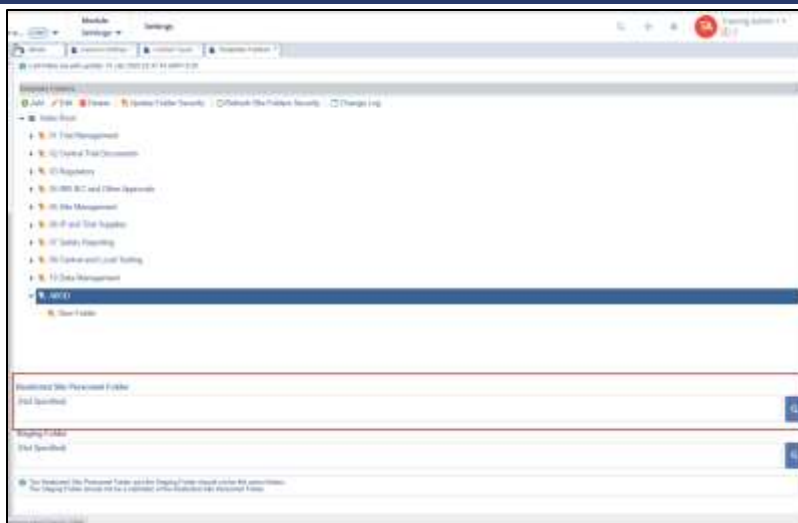
4. To add a subfolder inside a folder, you have already created, click the name of the new folder and click Add.



5. Continue adding folders and subfolders until the full Investigative Site Folder Index is complete and in compliance with the client's request.
6. Similarly, Edit or Delete the folders by selecting them as required.



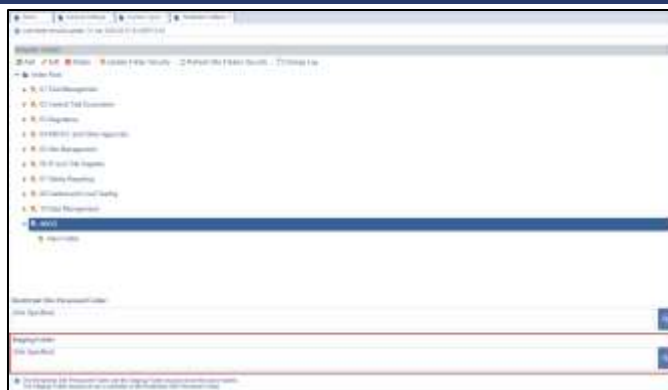
7. Click the Search icon beside the 'Restricted Site Personnel Folder'.



8. The Select Folder window is displayed with the list of folders. Select the appropriate folder.
9. Click OK.



10. Click the Search icon beside the 'Staging Folder'.



11. The Select Folder window is displayed with the list of folders. Select the appropriate folder.
12. Click OK.



- In eISF rooms, this is also where site folder security rules are created and maintained. These security rules are laid out in the configuration manual and should be adhered to throughout the study. If changes need to be made, please work with the Trial Interactive Service Desk.

Note: The Restricted Site Personnel Folder and the Staging Folder should not be the same folders.

The Staging Folder should not be a subfolder of the Restricted Site Personnel Folder.

## Site Status

In this panel, Administrator users can edit the Display Name of the Site Status.

- Locate the status and click the Edit button on the top or double-click on the specific display name to edit.
- Site statuses can be enabled or disabled as well. Click on the Drop-down menu from top- right corner and Select the Yes or No entry to change the value.





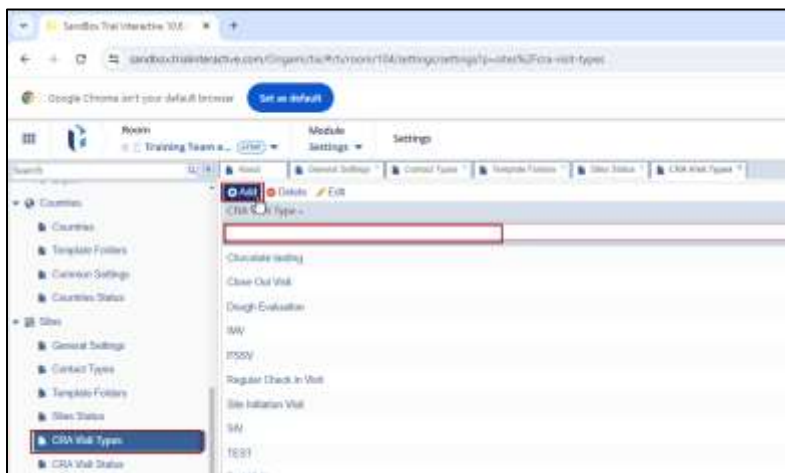
Additions and changes made here are saved automatically.

## CRA Visit Types

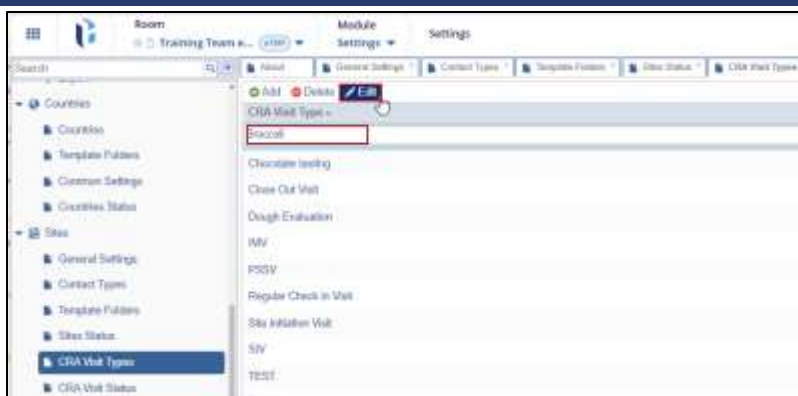
The visit types configured in this section are available to CRA users in the CRA Reconciliation module. When creating a CRA TMF Reconciliation Report, the CRA must select a visit type to ensure reports from multiple site visits can be easily distinguished.

Follow the steps to Add, Edit, and Delete the CRA Visit Type:

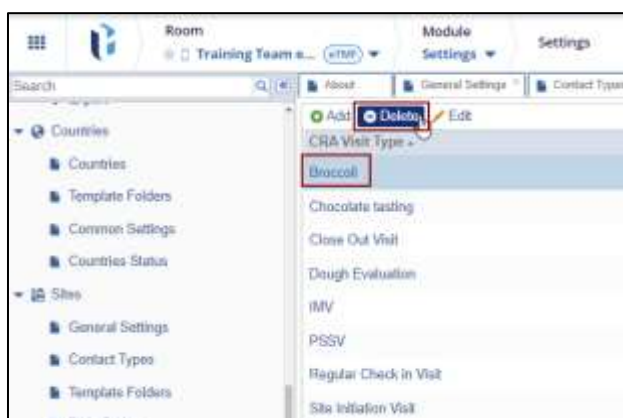
1. Click Add, the CRA Visit Type field gets enabled. Enter the name and hit Enter.
2. Type in the desired term and press Enter.
  - a. Changes made here are saved automatically.
  - b. These visit types automatically appear in the dropdown while creating the CRA TMF Reconciliation Report.



3. To edit a visit type, double-click the visit type, or select it and click the Edit button from the toolbar above.



- To delete a visit type, select the visit type and click Delete from the toolbar above.



Additions and changes made here are saved automatically.

## CRA Visit Status

In this panel, Administrator users can set the CRA Visit Status required during the Reconciliation Reports.

- To edit a visit type, double-click the visit status, or select it and click the Edit button from the toolbar above.

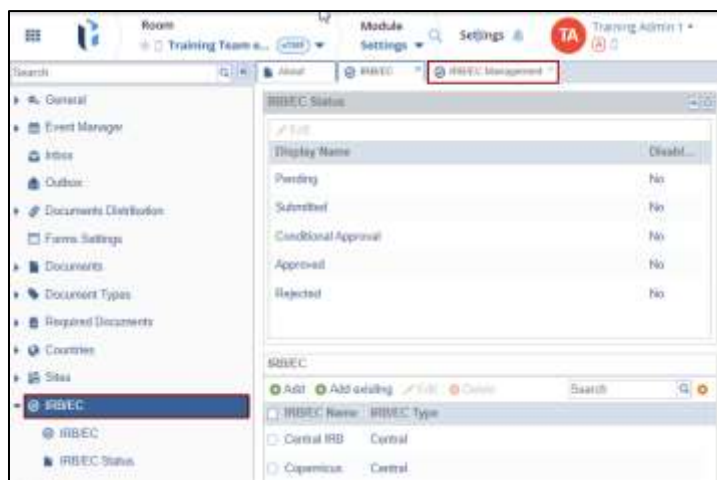


Additions and changes made here are saved automatically.

## IRB/EC

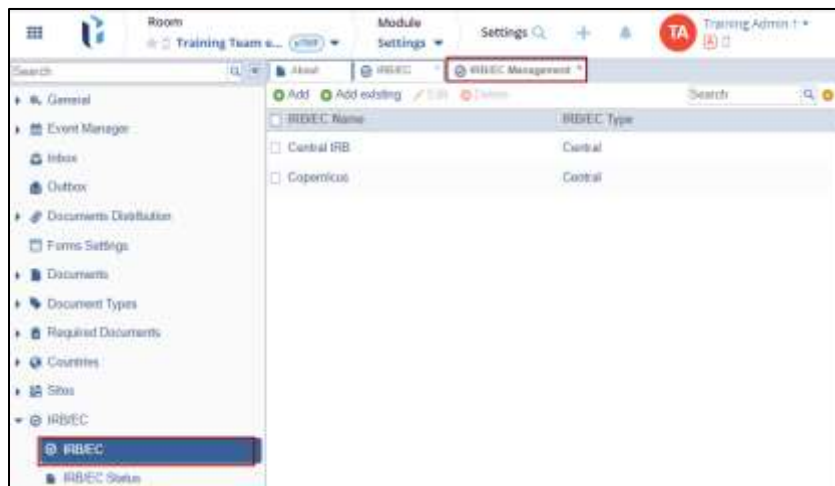
The IRB/EC organizations associated with the study will normally be identified and configured upon room creation.

The IRB/EC displays 2 categories IRB/EC Status and IRB/EC.



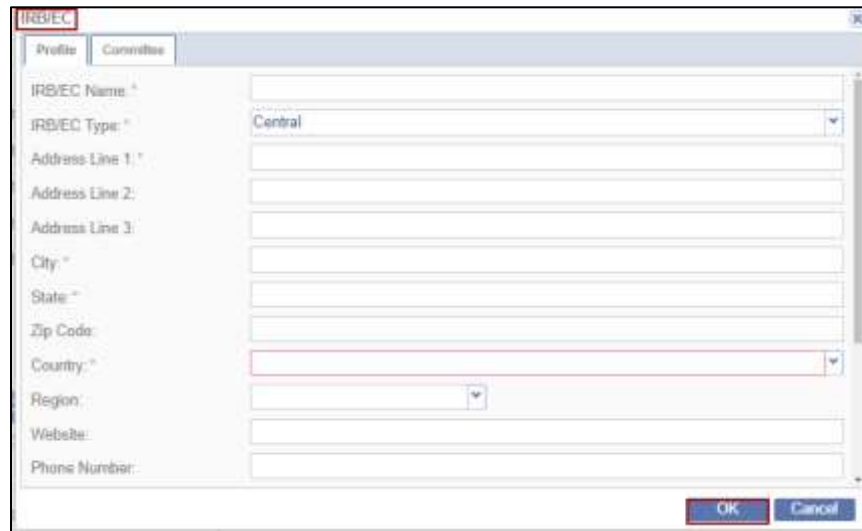
## IRB/EC

The additional IRB/EC organizations can be added, edited, or deleted as needed from this menu.



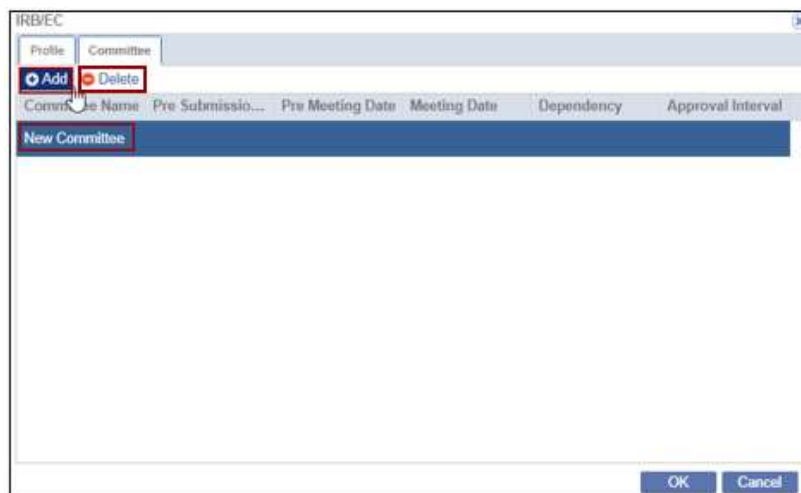
To add a new entry, follow the steps below:

1. Click the Add button. The IRB/EC window is displayed with the Profile tab by default.

The screenshot shows the 'IRB/EC' window with the 'Profile' tab selected. The form contains the following fields: 'IRB/EC Name', 'IRB/EC Type' (set to 'Central'), 'Address Line 1', 'Address Line 2', 'Address Line 3', 'City', 'State', 'Zip Code', 'Country' (set to 'United States'), 'Region', 'Website', and 'Phone Number'. The 'OK' button is highlighted with a red box.

2. Fill in all the required fields and click OK within the Profile tab.
3. Click the Committee tab within the IRB/EC window.
4. Click Add. The New Committee field gets added below. Double-click to rename the Committee.
5. Click OK.
6. Select the Committee and click Delete. The created committee is removed.



The screenshot shows the 'IRB/EC' window with the 'Committee' tab selected. At the top, there are 'Add' and 'Delete' buttons, both highlighted with red boxes. Below them is a table with columns: 'Committee Name', 'Pre Submission...', 'Pre Meeting Date', 'Meeting Date', 'Dependency', and 'Approval Interval'. The first row is labeled 'New Committee' and is highlighted with a blue background. The 'OK' button is highlighted with a red box at the bottom right.

### Adding Existing IRB/EC

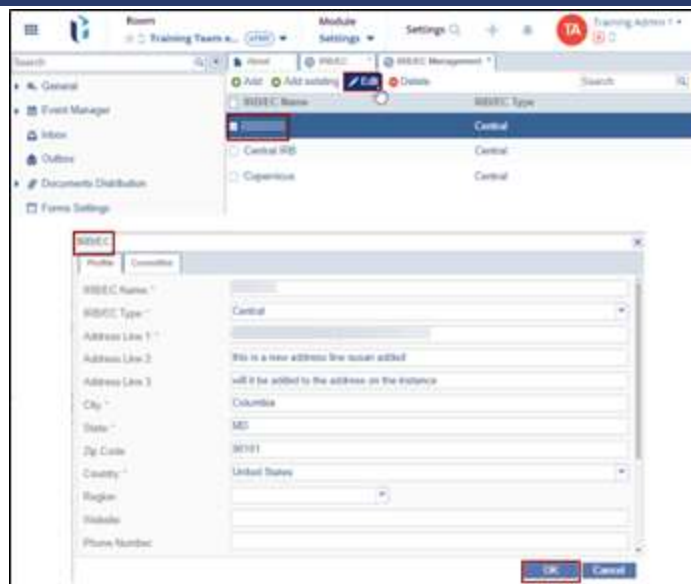
1. Click the Add Existing button. The list of organizations stored at a domain level is displayed.

2. Locate the appropriate organization and press the OK button to add them to the room list.



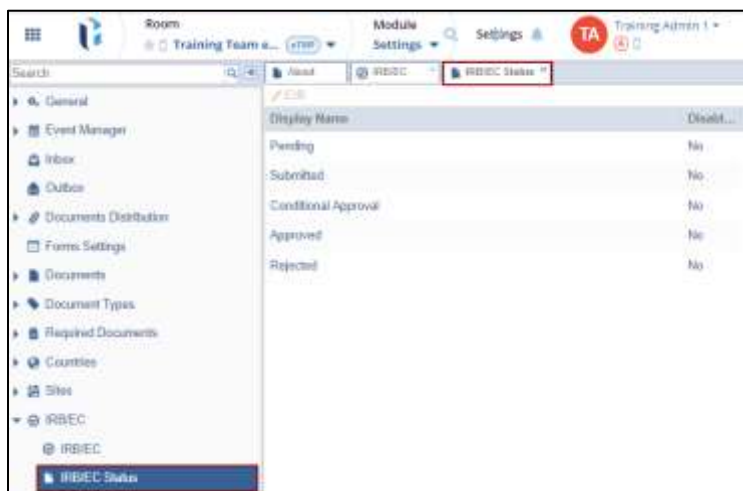
### Editing Existing IRB/EC

1. Locate the IRB/EC Name and click the Edit button.
2. The IRB/EC window opens with the existing information with the editable fields.
3. Make the changes and click OK.
4. Locate the IRB/EC Name and click the Delete button, the selected IRB/EC gets deleted.



## IRB/EC Status

The IRB/EC Status, the users can see the statuses of the IRB/EC documents. Refer to the screenshot below:



Follow the steps below:

1. Select the Display Name in the IRB/EC Status and click the Edit button.

|                      |           |               |
|----------------------|-----------|---------------|
| About                | IRB/EC    | IRB/EC Status |
| <b>Edit</b>          |           |               |
| Display Name         | Disabl... |               |
| Pending              | No        |               |
| Submitted            | No        |               |
| Conditional Approval | No        |               |
| Approved             | No        |               |
| Rejected             | No        |               |

- The user can see that the Disabled column gets editable and the user can see the drop-down options from where the user can assign the 'Yes' and 'No'

|                      |          |               |
|----------------------|----------|---------------|
| About                | IRB/EC   | IRB/EC Status |
| Edit                 |          |               |
| Display Name         | Disabled |               |
| Pending              | No       |               |
| Submitted            | Yes      |               |
| Conditional Approval | No       |               |

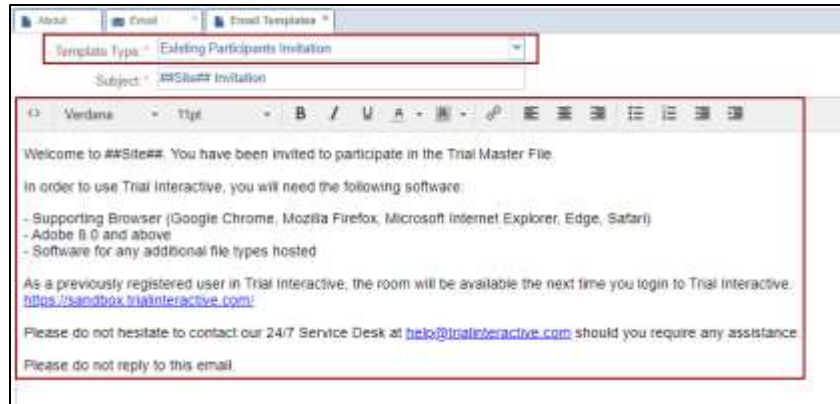
## Email

### Email Templates

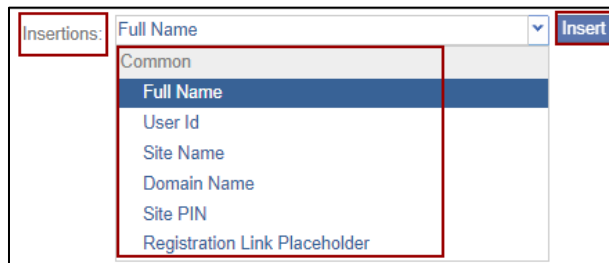
Generic email templates are preloaded for a room when the room has been cloned. Follow these instructions to make changes to any of the email templates.

- Select the Template Type from the dropdown menu by default the Subject Line gets populated in the 'Subject' field.
  - Once the user selects the 'Template Type' the message associated with the particular template will be displayed below it in the email format.





2. Edit the fields as per the user's requirement.
3. Insertions can be selected as per the requirement and click Insert.



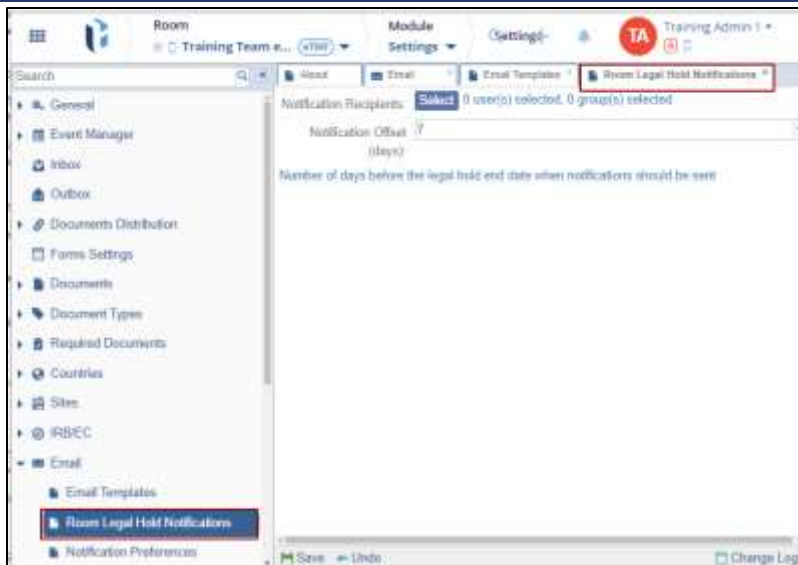
The Change Log option, located at the bottom right of the screen, displays a record of the Email Templates. It includes columns for Item Name, Setting, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

## Room Legal Hold Notification

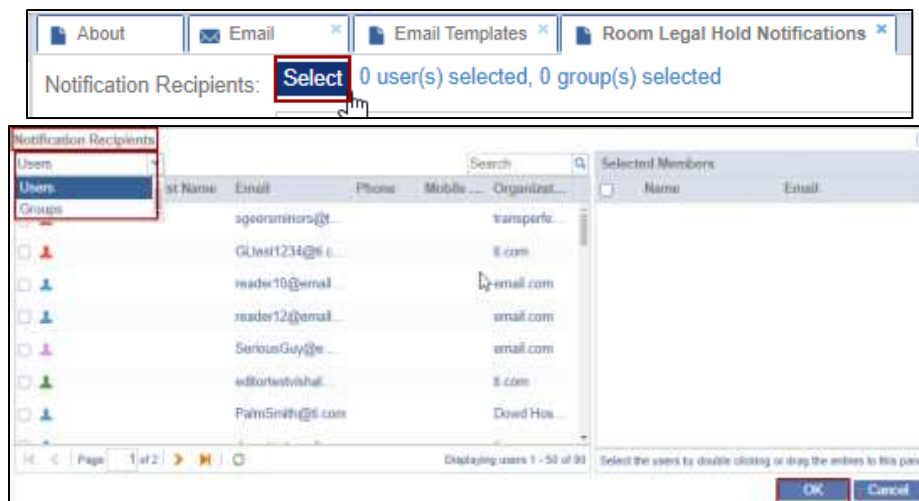
The Room Legal Hold Notification needs to be sent only when the number of days before the legal hold end date arrives.



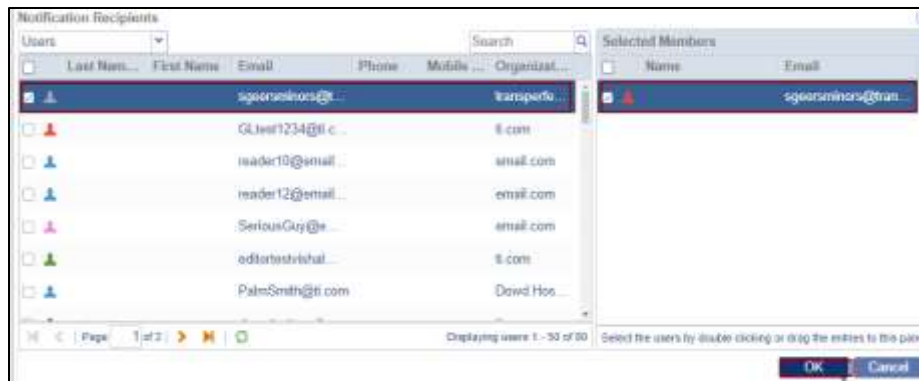


Follow the steps below:

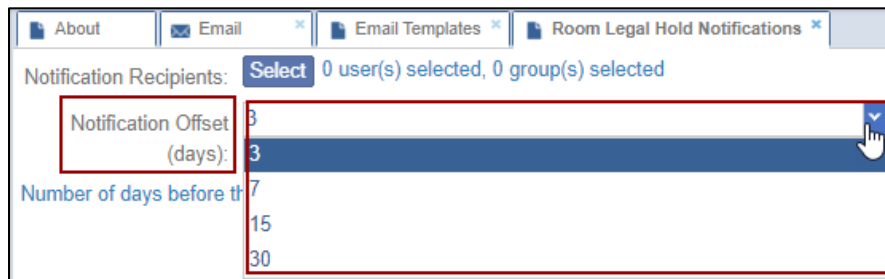
1. Click Select to set up the users who will be notified when a room is put on legal hold.
2. The Notification Recipients window opens with the list of Users/Groups.



3. Select the users by double-clicking or dragging the entries to the right pane.
4. Click OK. The selected user gets added to the right pane.



5. Select the number from the Notification offset (days) dropdown. It will decide the number of days before the legal hold end date when the notifications should be sent to those users.



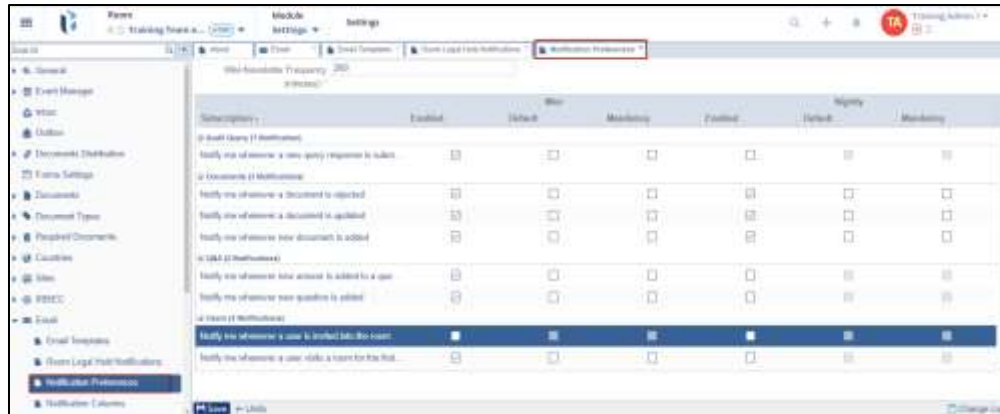
Note: Super Administrator users from the TI Service Desk can put a Legal Hold on Rooms when required.

The Change Log option, located at the bottom right of the screen, displays a record of the Room Legal Hold Notification. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

## Notifications Preferences

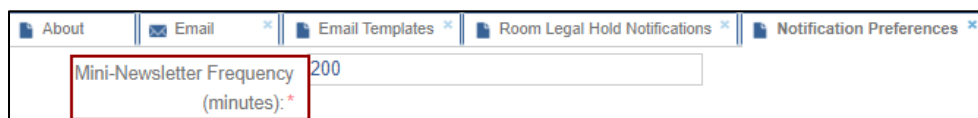
The Notifications Preferences section allows users to specify the email notifications they would like to enable for the study room.



Follow the steps below:

1. Enter the Mini newsletter Frequency (minutes) with which the Mini newsletters will be sent to the users.

Refer to the screenshot below:

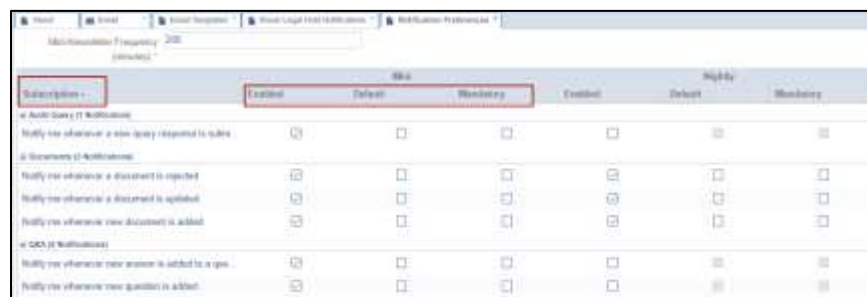


2. In the Subscription panel, enable the appropriate notifications that will be available to the room's users.

- Using the options grid on the right of the Subscriptions window, you can select which notifications the user would receive.

Below are the definitions of each notification type and their use:

- Enabled: This enables users to subscribe to related notifications.
- Default: This subscribes all users to the related notification by default but with the possibility to unsubscribe.
- Mandatory: All users get automatically subscribed without the possibility to unsubscribe.

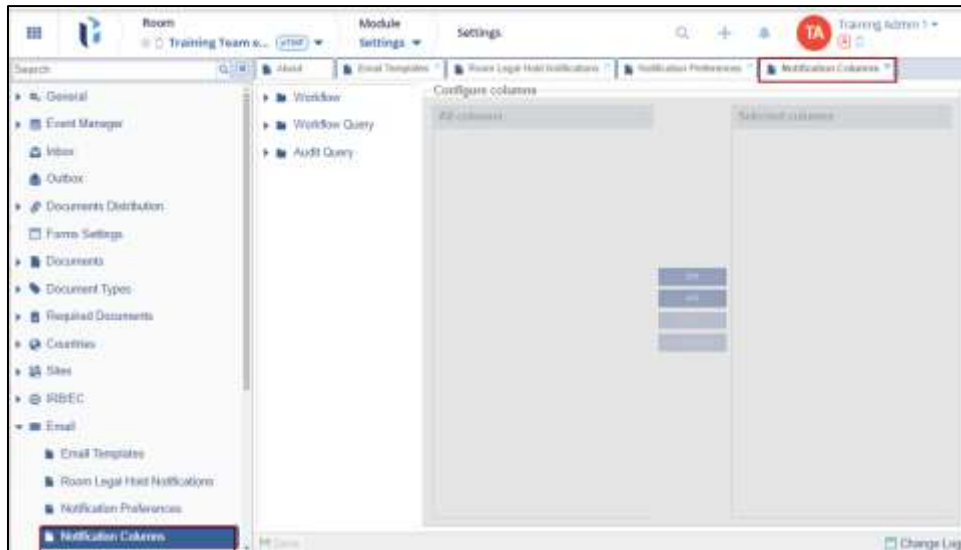


The Change Log option, located at the bottom right of the screen, displays a record of the Notifications Preferences. It includes columns for Scope, Item Name, New Value, Old Value, Updated By, Updated On (with the timestamp), and Close button.

Ensure to click Save to apply and retain any changes.

## Notification Columns

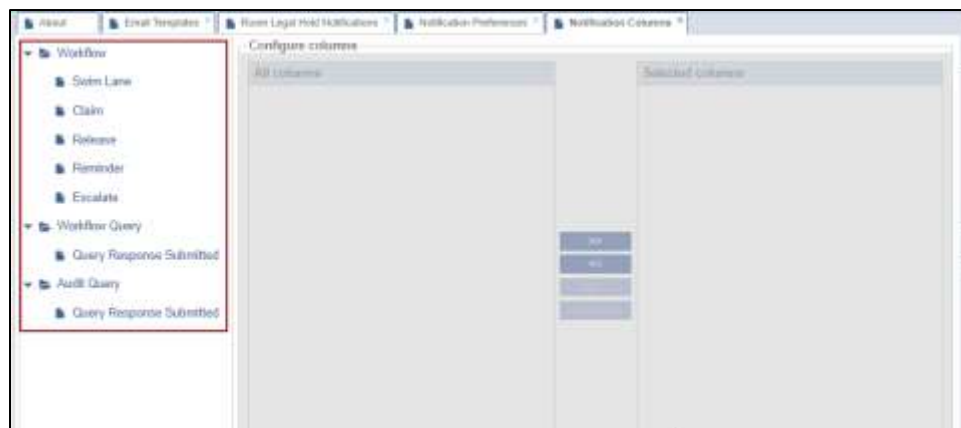
The Notification Columns are related to the list of fields that will be included in notification emails for notifications that the user wants to receive.



The Notification Columns are available for the following categories with sub-sections:

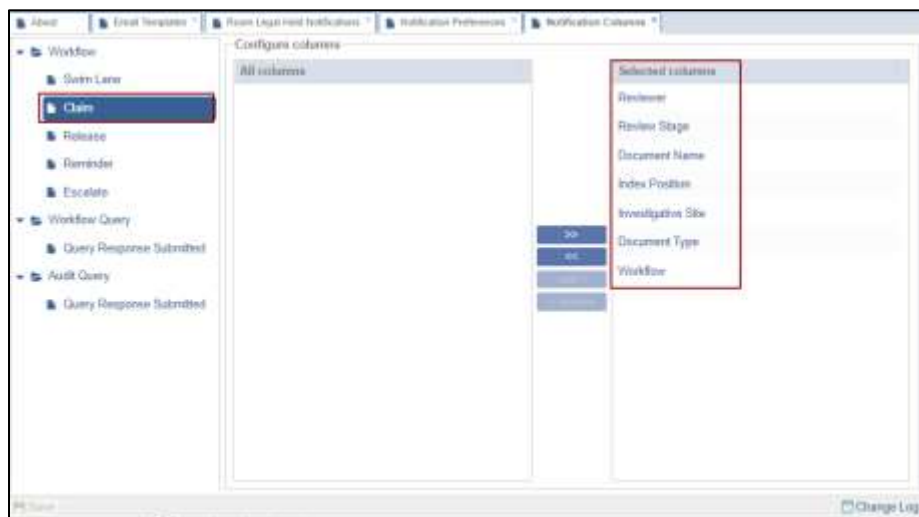
- Workflow
- Workflow Query
- Audit Query

Refer to the screenshot below:

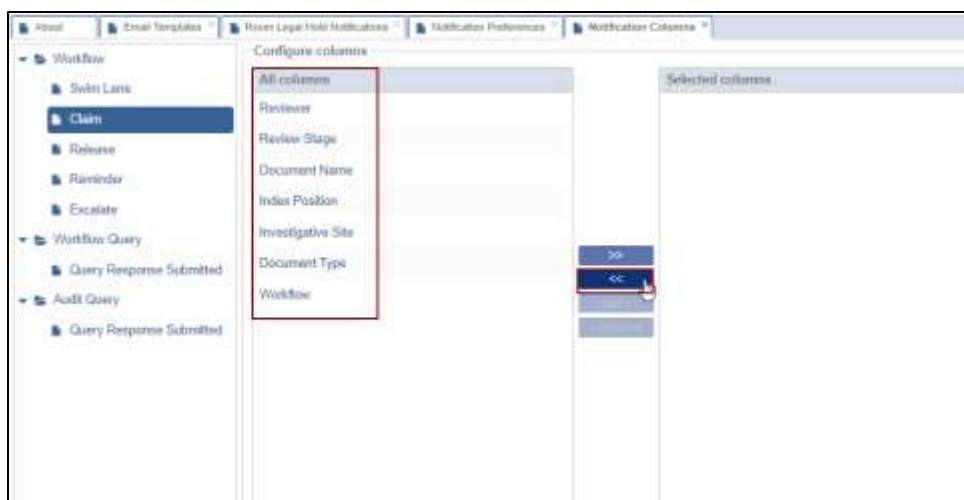


To filter the columns that would appear in the notification emails:

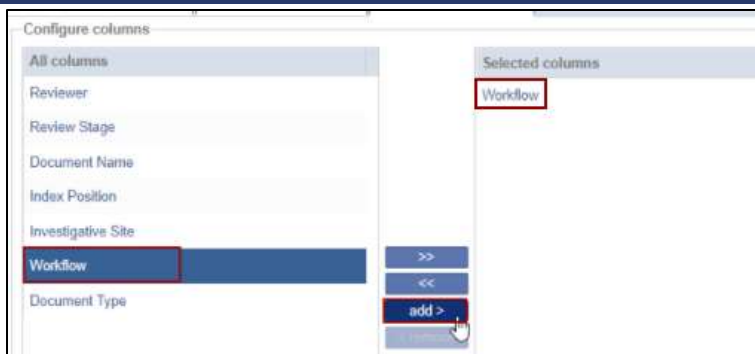
1. Expand the arrow available beside the Workflow and double-click to add the columns under the Selected Columns list.



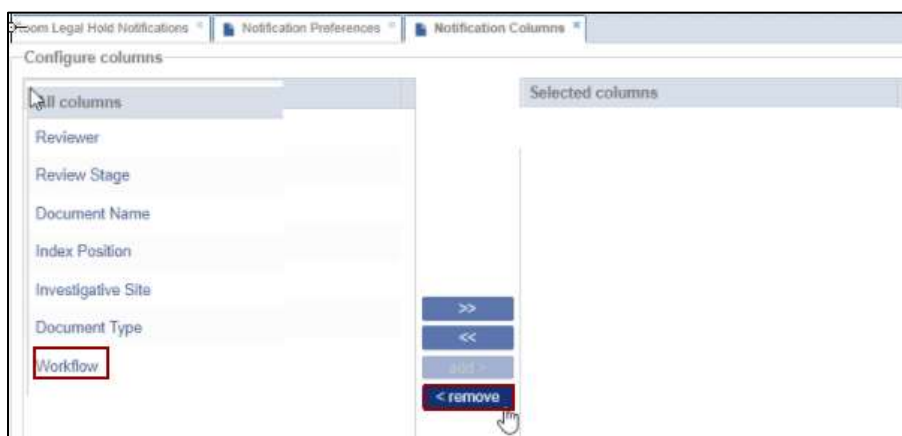
2. Click the Arrow so that the items available in the 'Selected columns' will be swapped in the 'All Columns' section.



3. Select the option from the 'All Columns' section and click add>. The selected option gets added to the 'Selected Columns' section.



4. Select the option from 'Selected Columns' and click <remove. The option will be removed.



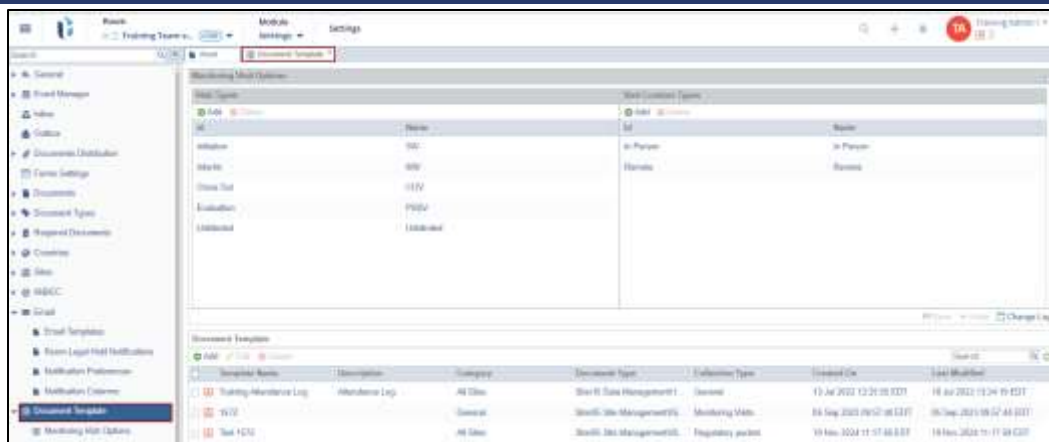
The Change Log option, located at the bottom right of the screen, displays a record of the Notifications Columns. It includes columns for Setting, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

## Document Template

In the Document Templates settings, Administrator users can add, edit, and delete document templates.

- Templates refer to source documents that can be used as a reference.
- Users can maintain a library of template documents, including multiple versions (e.g., one version in French and another in Korean).



## Monitoring Visit Options

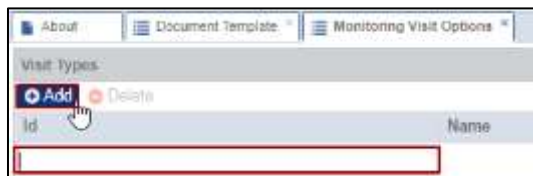
Monitoring Visit Options have 2 panes

- Visit Types
- Visit Conduct Types

### Visit Types

Follow the instructions below:

1. Click the '**Add**' button, the ID field gets editable.



2. Select the 'Visit Type ID' and click Delete the selected type disappears from the list.



### Visit Conduct Types

Follow the instructions below:

1. Click the '**Add**' button, the ID field gets editable.



2. Select the 'Visit Conduct Type ID' and click Delete the selected type disappears from the list.



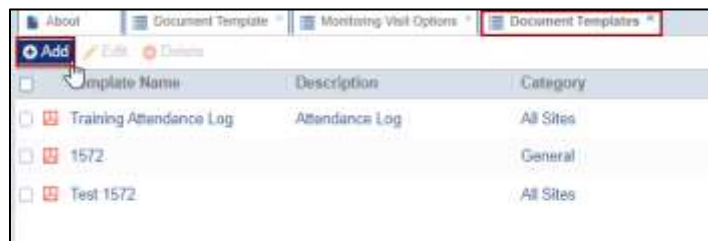
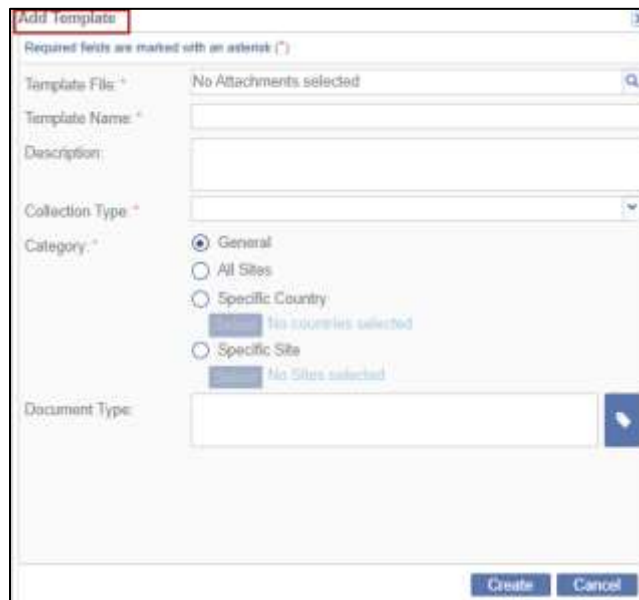


## Document Templates

In the Document Templates settings, Administrator users can add, edit, and delete document templates.

Follow the instructions below to add a new template document:

1. Click on the **'Add'** button above the grid area.
  - This will open the 'Add Template' window.

Required fields are marked with an asterisk (\*)

Template File: \* No Attachments selected

Template Name: \*

Description:

Collection Type: \*

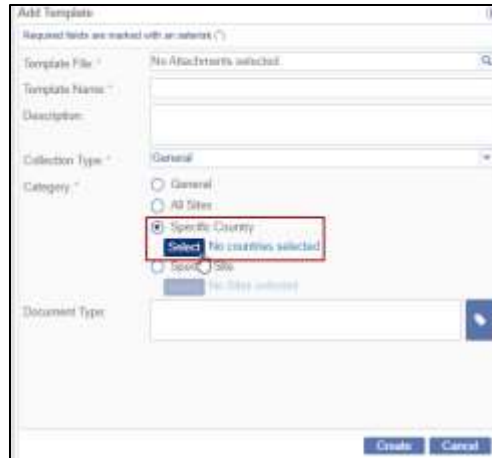
Category: \*

- ☒ General
- ☐ All Sites
- ☐ Specific Country
  - No countries selected
- ☐ Specific Site
  - No Sites selected

Document Type:

Create Cancel

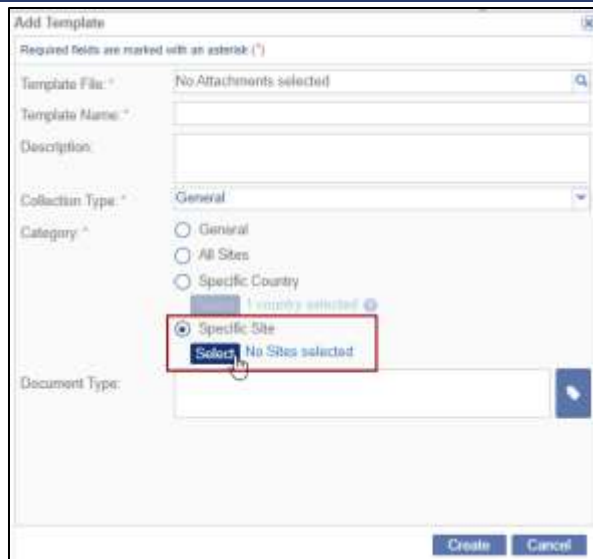
2. Upload the relevant file by clicking on the search icon.
3. Give the template document a name.
4. Give the template a description. (Optional)
5. Assign a Collection Type to the document using the dropdown menu.
  - General: This is more applicable to Collaborate or Docs-type rooms where new SOP documents are created, reviewed, and approved.
  - Regulatory Packets: This is applicable to rooms where SSU is enabled. Choose this option if this document should be sent out with the regulatory packet.
  - Monitoring visits: This option is appropriate for collaborative rooms integrated with our CTMS solution. These files can be used in generating documents related to monitoring visits as created and planned in the CTMS.
6. Select the 'Category' as per the user's requirement.
  - If the user selects the category as 'Specific Country' the Select button below it gets activated.



- Click the Select button, and the Available Countries pop-up window is displayed.
- Select the Country from the available list and click Select.
- The '1 country selected' message is displayed. However, hovering over the mouse on the tooltip displays the Country name side of the Select button.



7. If the user selects the category as 'Specific Site' the Select button below gets activated.



**Add Template**

Required fields are marked with an asterisk (\*)

Template File: \* No Attachments selected

Template Name: \*

Description:

Collection Type: \* General

Category: \*

- ☐ General
- ☐ All Sites
- ☐ Specific Country
- ☒ Specific Site

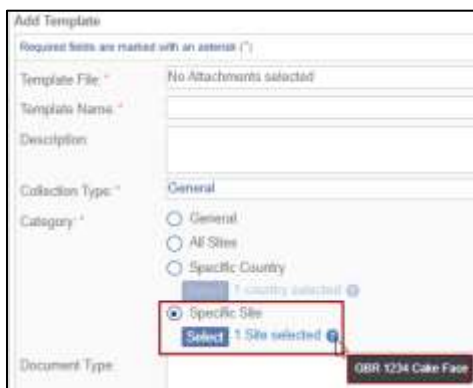
1 country selected

Select No Sites selected

Document Type:

Create Cancel

- Click the Select button and the Available Sites pop-up window is displayed.
- Select the Site from the available list and click Select.
- The '1 Site selected' message is displayed. However, hovering over the mouse on the tooltip displays the Site name side of the Select button.



**Add Template**

Required fields are marked with an asterisk (\*)

Template File: \* No Attachments selected

Template Name: \*

Description:

Collection Type: \* General

Category: \*

- ☐ General
- ☐ All Sites
- ☐ Specific Country
- ☒ Specific Site

1 country selected

Select 1 Site selected

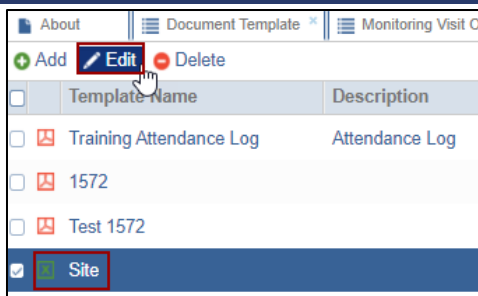
Document Type:

OBR 1234 Cake Face

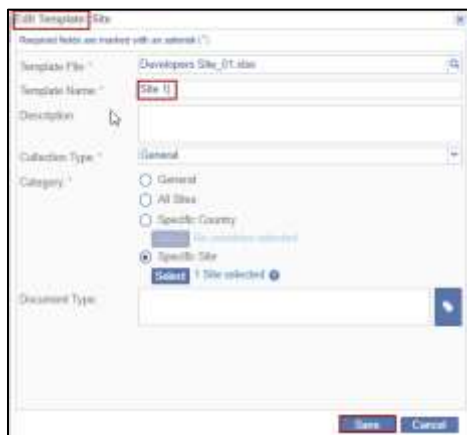
- Choose the appropriate 'Document Type' by clicking the Tag available beside. (Optional)
- When you have entered all the required information, press the Create button.

To Edit a new template document:

- Select the template and click Edit.

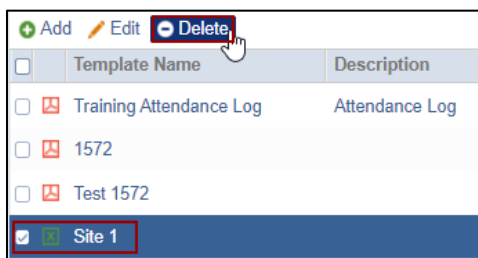


- The Edit Template pop-up window is displayed.
- Edit the changes and click the Save button.

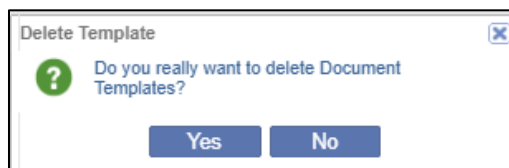


To Delete a new template document:

- Select the template and click Delete.



- The Delete Template pop-up window is displayed.



- Click Yes, the selected template gets deleted.

## Reports (Heatmap Settings)

Trial Interactive allows the display of cross-room metrics in the KPI Dashboard, which can be accessed from the Home screen.

- The KPI heatmap is color-coded, (Green, Yellow, and Red) highlighting metrics that fall outside the acceptable range.
- The values for these metrics can be adjusted here.
- Double-click any setting to edit its value.



The Target Period (in days) should be set for displaying the minimum and maximum numbers of the documents.



Click the X (cross) icon to remove the numbers displayed in the colors.



## Workflow Settings

In Workflow Settings, Admins configure key details such as workflow statuses, potential issues, timelines, and workflow group members. The workflow setup is outlined in the room's configuration manual and is established during room creation. To ensure accuracy and consistency, it is strongly recommended that any changes to the room's workflow settings be handled by the Trial Interactive Service Desk.

It is important to note that certain workflow functions are restricted to users at the Super Administrator level (Service Desk Personnel). Attempting to modify a room's workflow without the proper training and access could lead to data loss, document mishandling, or the unintended exclusion of documents from the QC workflow.

## Common Settings

Admin can adjust the following in the Common Settings area:

- Common Configuration
- Default Ranges Configuration
- Timeline Configuration
- Issue Email

- Rejection Email Configuration
- Query Reminder Configuration
- Auto-Claim Configuration

### Default Ranges Configuration

Default ranges configuration: Here the user can specify date ranges that would apply to your workflow.

- TI recognizes that different workflows may have varying review and submission periods. To accommodate this, it allows users to specify multiple values, separated by semicolons.
- These values will populate the corresponding dropdown menu during workflow creation, allowing you to select the most suitable option.

Refer to the screenshot below:



| Default ranges configuration        |          |
|-------------------------------------|----------|
| Review due date range (days): *     | 10;5;3   |
| Review reminder range (days): *     | 5;3;2;1  |
| Review release range (days): *      | 11;6;4   |
| Escalation frequency (times): *     | 3;2;-1   |
| Query reminder date range (days): * | 10;5;3;1 |
| <input type="button" value="Save"/> |          |

Each field above is editable, the user can enter the values separated by a semi-colon.

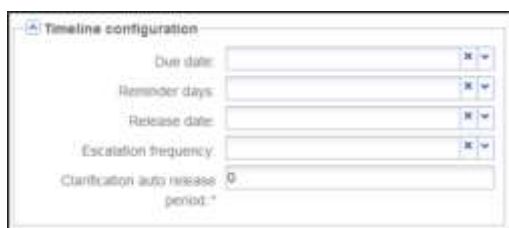
1. Review due date range (days).
  - a. Here the user specifies the days when the review would be due after claiming the documents for review.
  - b. The user may specify multiple values, all of which will be populated in the dropdown while creating the workflow to enable the user to select a value as appropriate.
2. Review reminder range
  - a. Here the user specifies the days before the due date when emails would be sent out to the reviewers reminding them of the pending review.
  - b. If multiple values are specified, all of them will be populated in the dropdown during workflow creation, and you may select multiple values as required.
  - c. In the screenshot above, the Reminder schedule is 5;3;2 which means:
    - i. the reviewer will receive reminders 5 days before the due date,
    - ii. then 3 days before the due date,
    - iii. and then 2 days before the due date if the reviews are pending.
3. Review release range days.
  - a. Here the user specifies the days after the claim when the documents would be automatically released from the reviewer's claim list.
  - b. The Auto-release date is always greater than the due date.
  - c. It will not allow the user to select a value less than the due date.
4. Escalation frequency
  - a. Escalations are reminders about not completed reviews.

- b. During workflow creation, an escalation group needs to be specified who will receive notifications about escalations.
  - c. Here, you specify the timeline for escalation notification frequency.
5. Query reminder date range
  - a. If the user does not respond to a query with a document, reminder emails are sent to the query recipients on the nth day as specified here.
  - b. So, if the setting is 10; 5; 3 reminders will be sent on the 10th day, 5th day, and the 3rd day.

### Timeline Configuration

If the user specifies values in the timeline, they will be automatically applied during workflow creation.

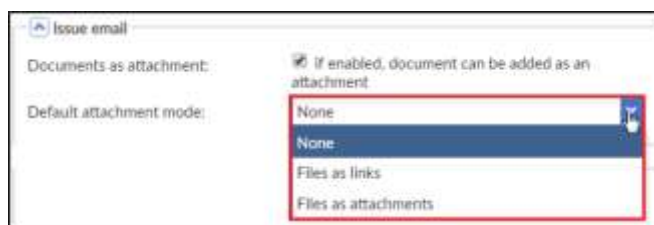
Refer to the screenshot below:



- If the user specifies values in the timeline, the values will be automatically set for the user at the time of workflow creation.
- If the user changes their mind during creation, the user can select values as needed, overriding those set in the timeline configuration.
- The configurations are optional here except for the Clarification auto-release, which means a document that is pending for clarification will be automatically released if it was not released back to the workflow by the reviewer within the defined time.
- Users can delete timeline values from a Workflow profile as well as for existing workflows by clicking the cross icon next to the fields in the Timeline Configuration panel or from the Timeline tab in a Workflow Profile Editor.

### Issue Email

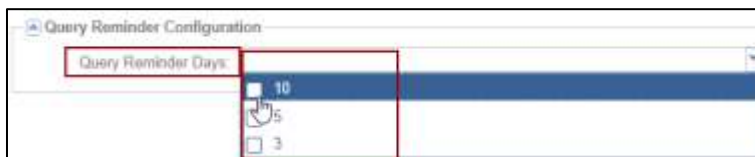
1. From this panel, Administrators can enable documents to be sent as attachments with query emails in a workflow session. Refer to the screenshot below:



2. Click the dropdown arrow to choose the attachment mode to be either Files as links or Files as attachments. Refer to the screenshot above.
3. Click Save from the bottom of the grid.

## Query Reminder Configuration

From here, room Administrators can configure a schedule by which reminder emails will be sent. Refer to the screenshot below:

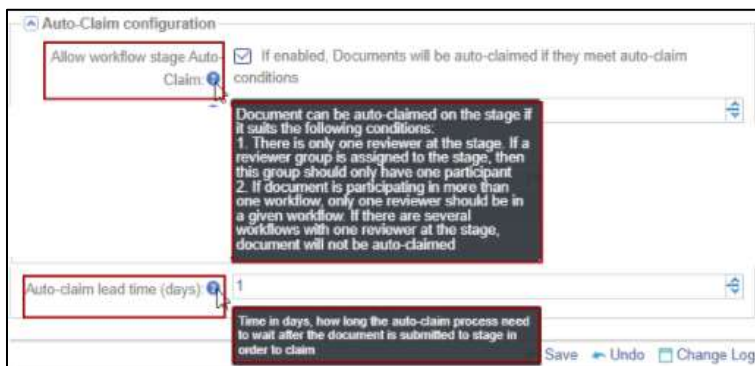


## Auto Claim Configuration

Note: If there is only one reviewer in a workflow the documents will be auto-claimed by the system and assigned to the lone reviewer for review.

To enable the auto-claiming of a document, the Administrator will need to enable the configuration from this panel.

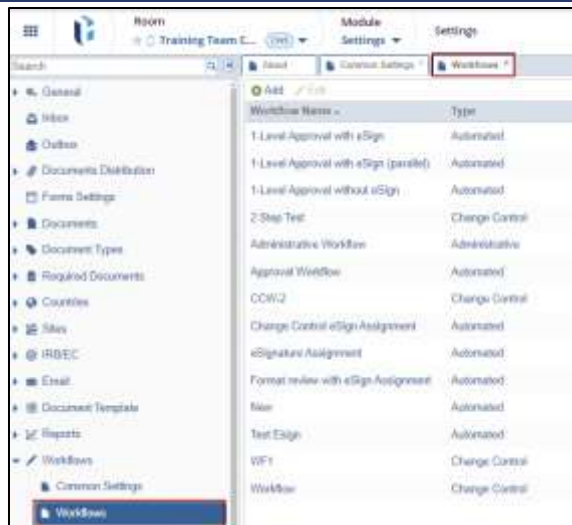
1. Tick the checkbox next to Allow workflow stage auto claim.
2. Enter the number of days after which if the reviewer has not claimed the documents, they will be auto-claimed by the system and assigned to the reviewer.



## Workflows

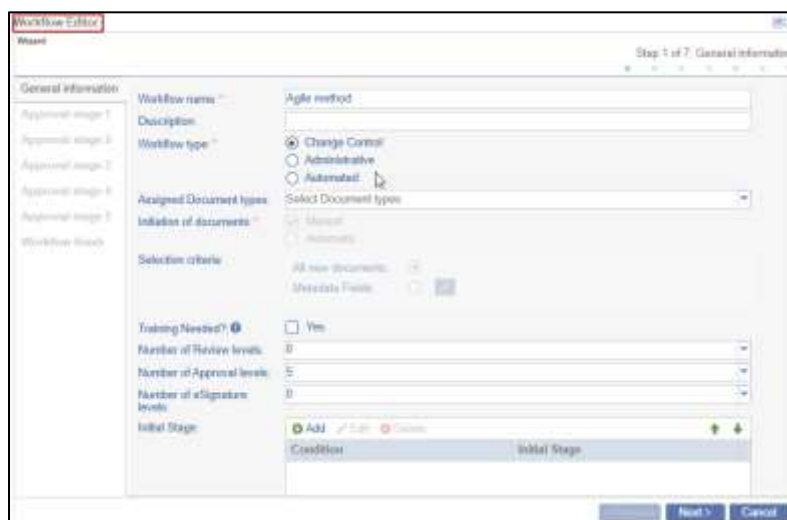
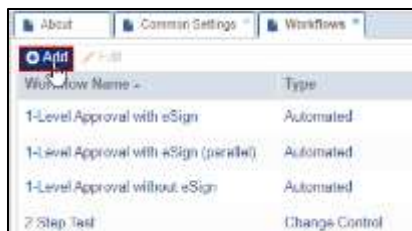
There are 2 types of Workflows 1-step Workflow and 2-step Workflow.



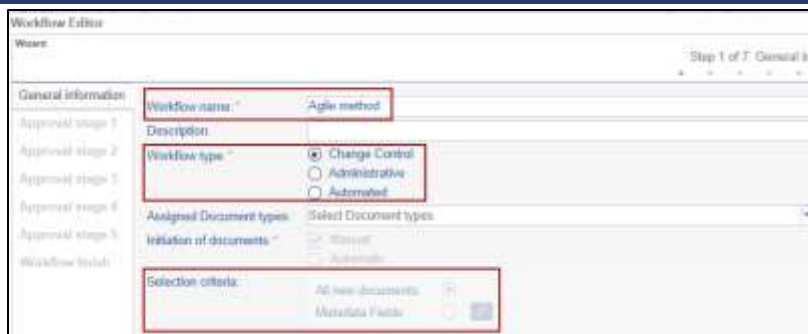


To create a Workflow, follow the procedure below:

- Click the Add button from the grid.
  - The Workflow Editor window will open. Refer to the screenshot below:



- Enter the 'Workflow name', 'Workflow type', and 'Initiation of documents'.
- The Selection Criteria should be 'All new documents' or only those 'Metadata fields' that need to be reviewed.



Workflow Editor

Step 1 of 7: General Information

General information

Workflow name: Agile method

Description:

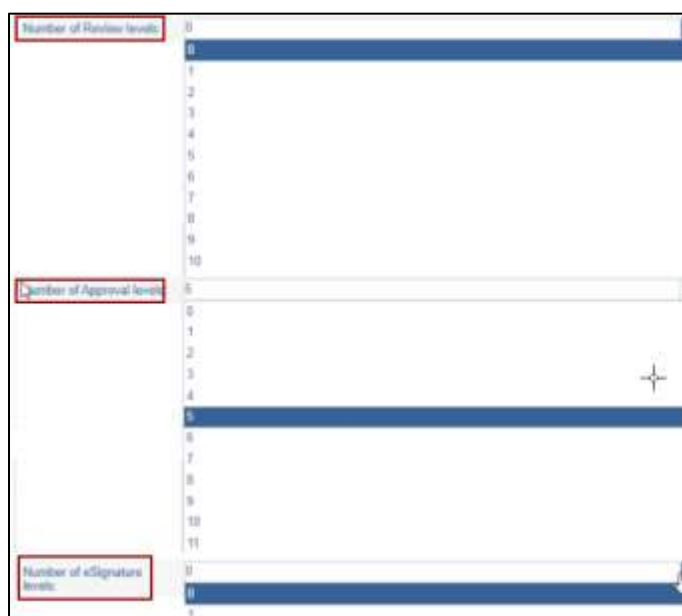
Workflow type: ☒ Change Control ☐ Administrative ☐ Automated

Assigned Document types: Select Document types

Initiation of documents: ☒ Manual ☐ Automated

Selection criteria: ☒ All new documents ☐ Metadata Fields

- The user can select the number of Review Levels, Approval Levels, and eSignature levels.



Number of Review levels: 0

Number of Approval levels: 5

Number of eSignature levels: 0

- Click Add on the Initial Stage option. The Initial Stage condition pop-up window is displayed. The user may apply a condition to select documents for review as per a particular condition.

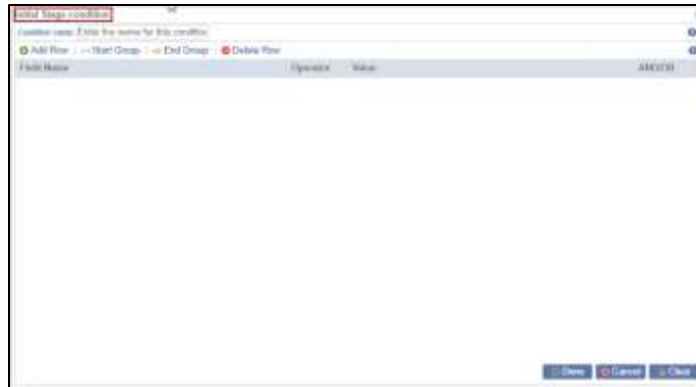


Initial Stage

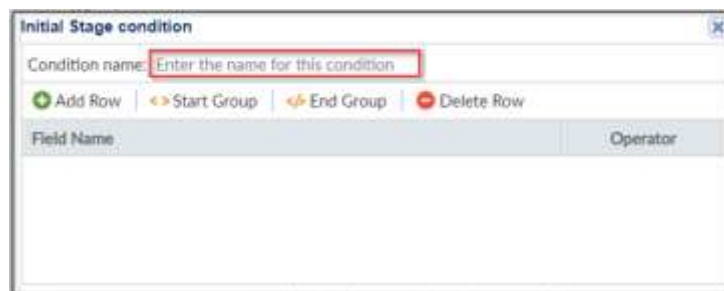
Add Edit Delete

Condition: Initial Stage

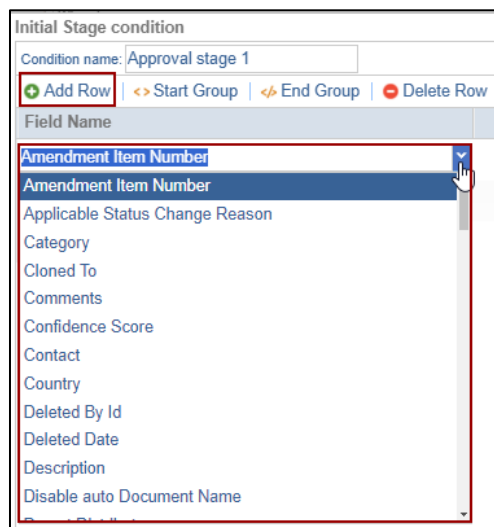
Previous Next > Cancel



6. Enter the Condition name in the blank field.



7. The user may add multiple conditions by clicking the Add button the field gets added below the Field Name.

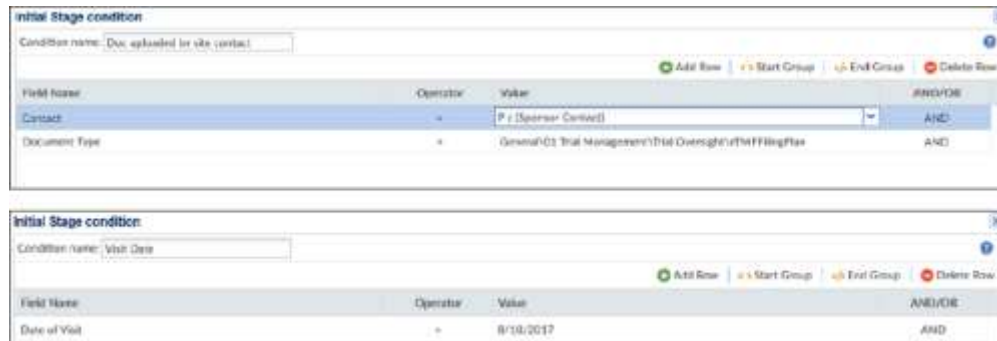


8. To decide their sequence filter documents with the green arrow keys. Use And / Or operators if you want all / either of the conditions to execute.



| Condition                    | Initial Stage    |
|------------------------------|------------------|
| Doc uploaded by site contact | Approval stage 1 |
| Visit Date                   | Approval stage 1 |

9. As per the screenshot above, documents uploaded by the site contact on a particular site visit date would be added to the workflow. The details of each condition are as below:



**Initial Stage condition**

Condition name: Doc uploaded by site contact

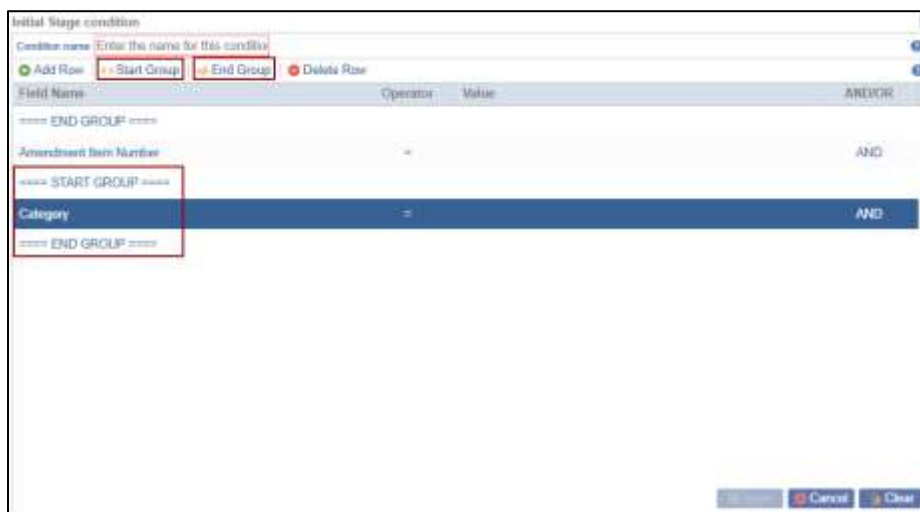
| Field Name    | Operator | Value                                                       | AND/OR |
|---------------|----------|-------------------------------------------------------------|--------|
| Contact       | =        | P r (Spencer Contact)                                       | AND    |
| Document Type | =        | General CD Trial Management/Trial Oversight/ITM Filing Plan | AND    |

**Initial Stage condition**

Condition name: Visit Date

| Field Name    | Operator | Value     | AND/OR |
|---------------|----------|-----------|--------|
| Date of Visit | =        | 8/10/2017 | AND    |

10. Click Start Group to start the group by adding the category by clicking the End Group the started group gets over.



**Initial Stage condition**

Condition name: Enter the name for this condition

Buttons: Add Row, Start Group, End Group, Delete Row

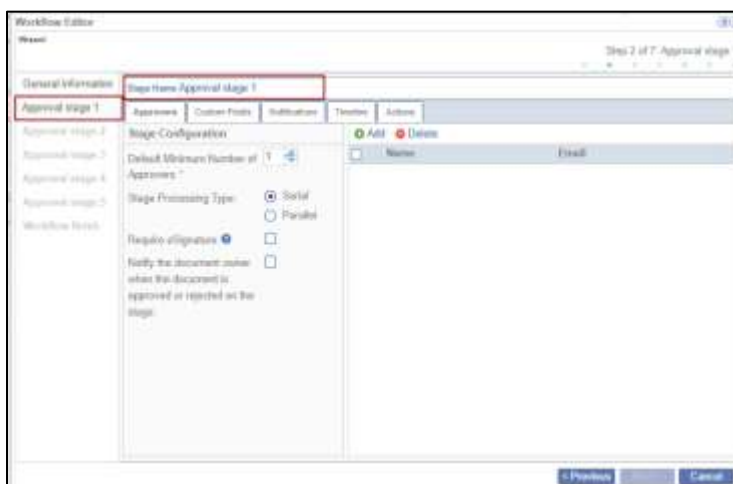
| Field Name            | Operator | Value | AND/OR |
|-----------------------|----------|-------|--------|
| Amendment Item Number | =        |       | AND    |
| Category              | =        | AND   | AND    |

Buttons: Cancel, OK

11. Select the row and click Delete Row to delete the added row.
12. Click Apply to apply the condition. Click the cross button at the top right corner of the Initial Stage condition window to close it.

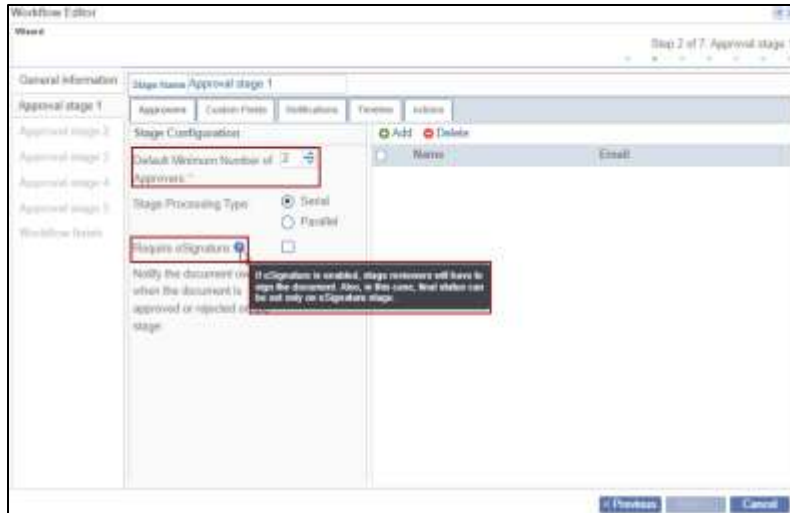


13. Click Next. This leads you to the configuration wizard of the first stage of the workflow. Refer to the screenshot below:

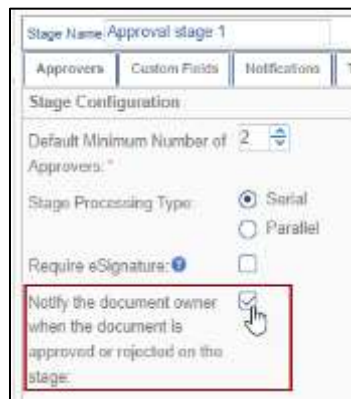


#### Approvers Tab:

1. Change the Stage Name, if desired. Click the Approvers tab. Refer to the screenshot above.
2. As per the user's requirement, the number of approves will be increased or decreased. The stage processing type will be in the Serial and Parallel.
3. If the 'Require eSignature' check box is checked then the document will go for signature purposes.

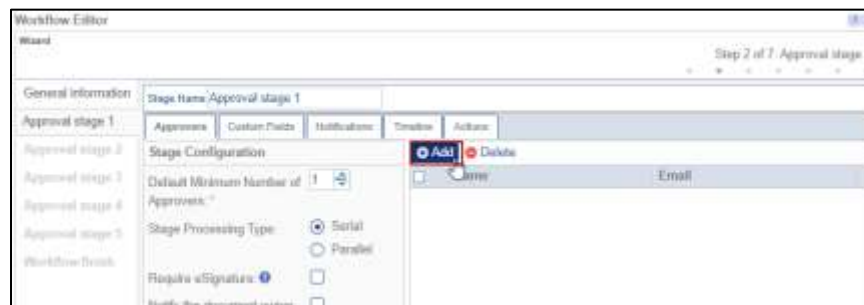


4. If the user wants to notify the owner about the document status 'Approved' or 'Rejected' then the 'Notify the document owner when the document is approved or rejected on the stage' checkbox should be checked.



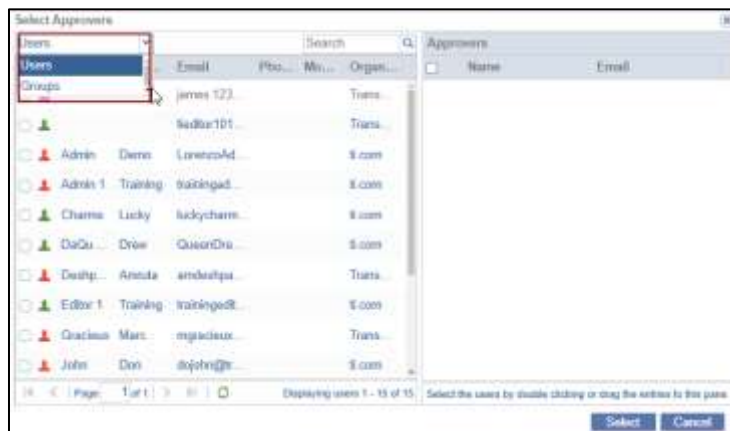
5. This allows the user to add users/groups as reviewers of the documents for a particular stage in the workflow.

Note: It is recommended to add a Group to save configuration time.

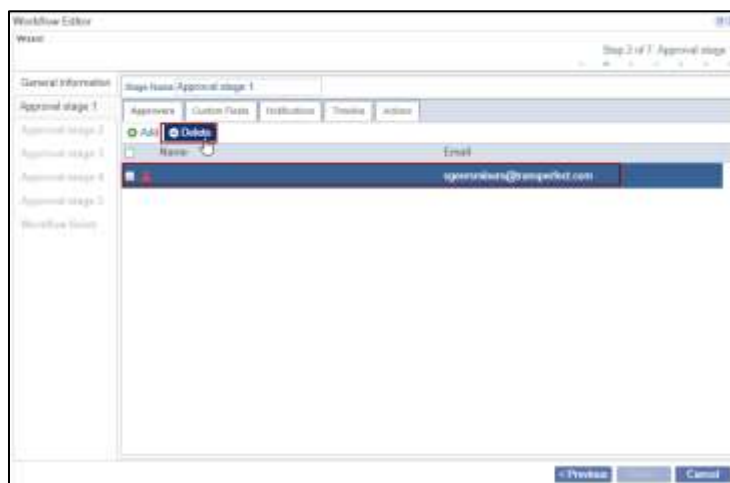


6. Select the user/group from the list. The selected user/group moves to the Approvers tab on the right side.

7. Click Select.

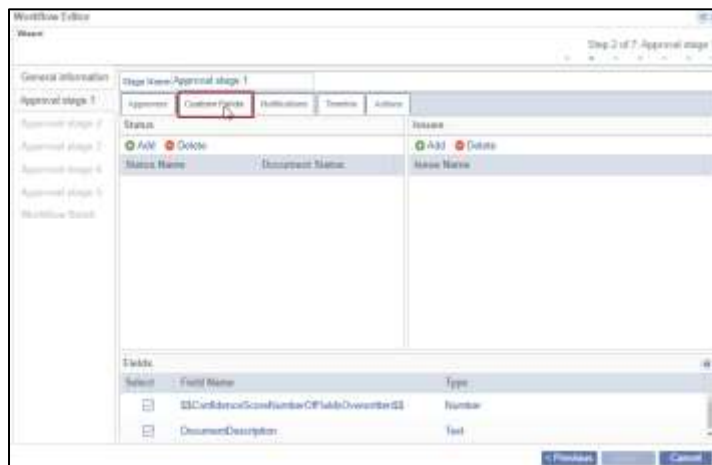


8. Click the Delete button to delete the selected users/groups.



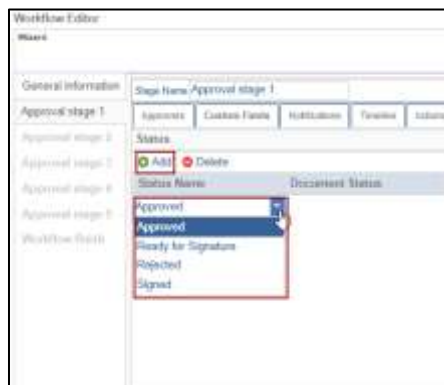
Custom Fields Tab:

1. Click the Custom Fields tab that displays the Status and Issues panels.

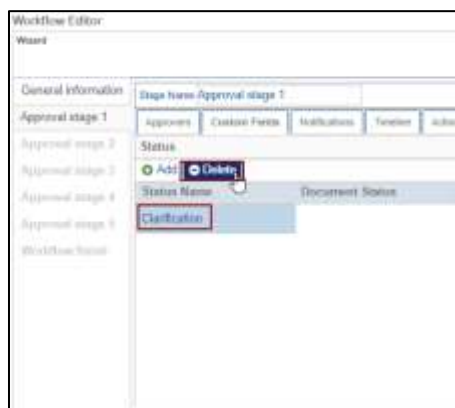


2. Click Add below the 'Status' section. The empty field gets added below the 'Status Name' with the following status:

- Approved
- Ready for Signature
- Rejected
- Signed

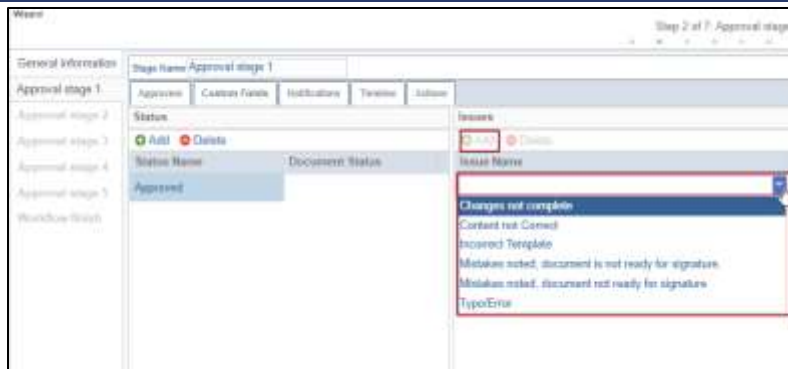


3. Click the Delete button to delete the selected Status Name.



4. Click Add below the 'Issues' section. The empty field gets added below the 'Issue Name' with the List of issues.
5. Click the issues to assign the reasons in case the reviewer rejects a document/asks for clarification.





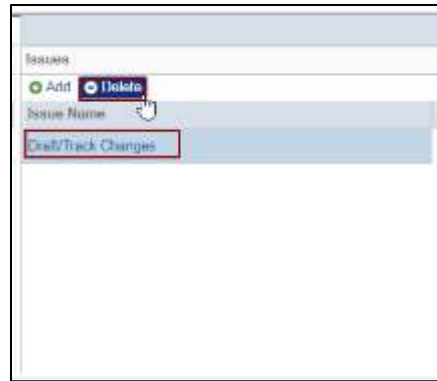
6. To make metadata fields, as required, available for a workflow configuration, proceed to Forms Settings and select the Workflow Fields, as required.
  - These fields will appear in the Fields panel at the bottom of the Custom Fields tab. Tick the fields as required for the review. Refer to the screenshot below:



- These checked fields will appear in the Review panel of a document in the eTMF/ Documents module once a document is claimed for review.
- As shown in the screenshots, the Submission Date, Approval Date, and Document Version fields checked in the workflow configuration appear in the Review Panel of the document metadata window.

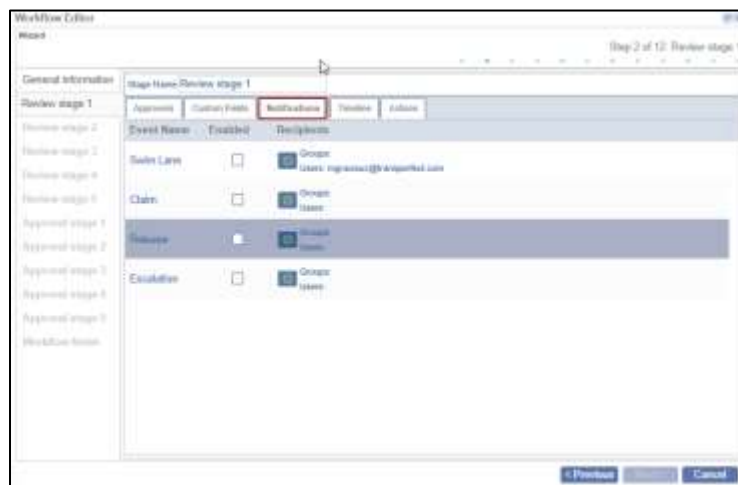


7. Click the Delete button to delete the selected Issues Name.

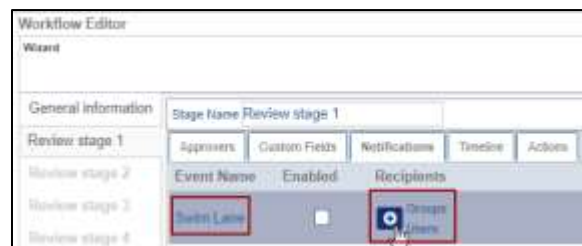


### Notifications Tab:

1. Click the Notifications tab.
  - Here, the user can allow for email notifications to be enabled for the event names listed.
  - For users who want to be notified only in case of Swim Lane, Claim, Release, or Escalation, Users/Groups can be added accordingly.

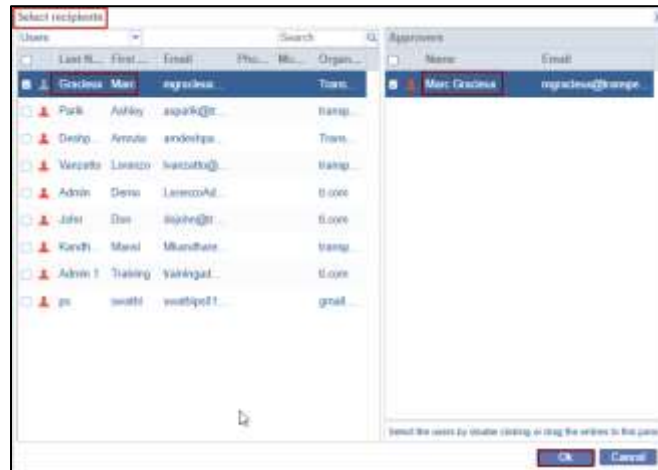


2. To add the Users/Groups to the specific Event Name
  - Click the + (plus) icon available beside the event name.

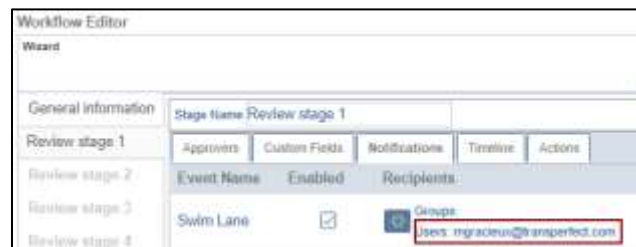


- The Select Recipients pop-up window is displayed with the list of Users/Groups.

- Select the users/groups by double-clicking or dragging the entries to the right pane and clicking OK.

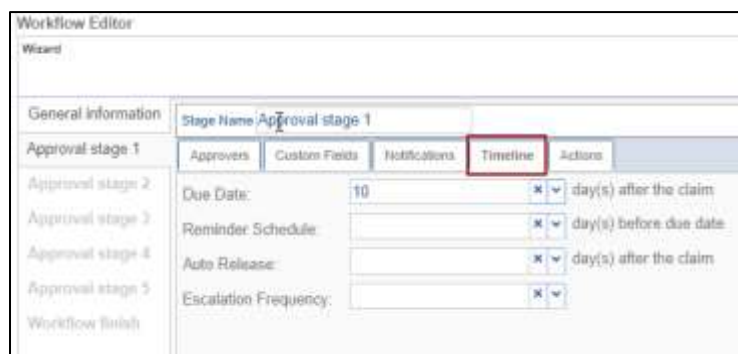


- The added users/groups are displayed on the 'Workflow Editor' pop-up window.



#### Timeline Tab:

1. In case you have fed in values in Timeline Configuration, the values would be populated by default in the Timeline tab. You may choose to override the previously set configurations if desired.

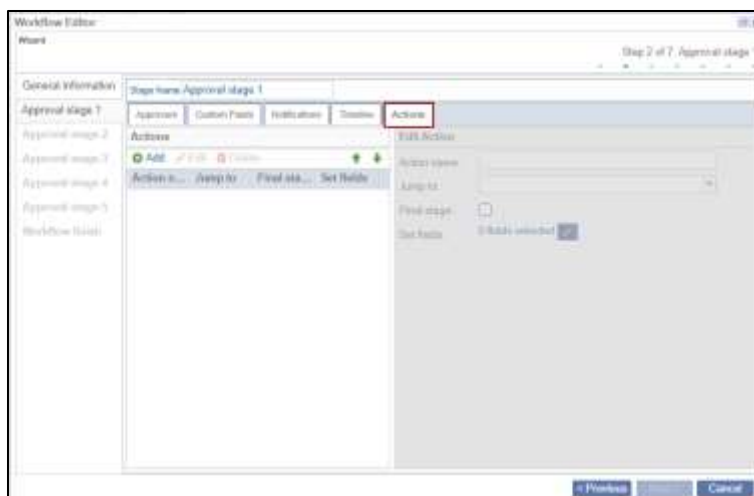


2. The Due Date displays the days once the document is claimed.
3. The Reminder Schedule displays the days before the due date comes.
4. The Auto Release displays the days after claiming the document.
5. The Escalation Frequency decides to escalate the document until the release.



### Actions Tab:

1. Actions is an optional tab allowing for complex workflow building.
  - It enables a workflow to have a jump. A specific document can jump to a certain stage.
  - For example, a Form FDA 1572 after QC1 review, can jump to a stage 3 review, where Regulatory Affairs performs a 2nd review on the document.
  - While efficient for complex workflows, it is not required for regular workflow creation.



2. Click Add in the 'Actions' panel, and the 'Action Creation' pop-up window is displayed.

Stage Name

Approvers | Custom Fields | Notifications | Timeline

Actions

**+ Add** Edit Delete

Action... Jump to Final sta... Set fields

Action Creation

Add Rows: Enter the name for this action

+ Add Row - Start Group - End Group - Delete Row

| Field Name | Operator | Value |
|------------|----------|-------|
|            |          |       |

Done Cancel Clear

- Click Add Row, the row is added below the 'Field Name' with the drop-down options and click Done.

Action Creation

Enter Name: Doubling

+ Add Row - Start Group - End Group - Delete Row

| Field Name                       | Operator | Value |
|----------------------------------|----------|-------|
| Unrecorded Item Number           | =        | ANDOR |
| Unrecorded Item Number           | =        | AND   |
| Application Status Change Reason | =        | AND   |
| Ashley's Favorite Food           |          |       |
| Category                         |          |       |
| Client's Name                    |          |       |
| Comments                         |          |       |
| Confidence Score                 |          |       |
| Contact                          |          |       |
| Copied to linked records date    |          |       |
| Country                          |          |       |
| Date Type                        |          |       |
| Deleted By Me                    |          |       |

Done Cancel Clear

- Click Start Group to start the group by adding the category by clicking the End Group the started group gets over.

**Action Creation**

Action Name:

| Field Name            | Operator | Value |
|-----------------------|----------|-------|
| Amendment Item Number | =        |       |
| Amendment Item Number | =        |       |
| ==== START GROUP ==== |          |       |
| Amendment Item Number | =        |       |
| ==== END GROUP ====   |          |       |

5. Select the row and click the Delete button.
6. Click the Save and Apply button.

**Action Creation**

Action Name:

| Field Name            | Operator | Value | AND/OR |
|-----------------------|----------|-------|--------|
| Amendment Item Number | =        |       | AND    |
| Amendment Item Number | =        |       | AND    |
| ==== START GROUP ==== |          |       |        |
| ==== END GROUP ====   |          |       |        |

7. Select the action and click the Edit button. The 'Action Creation' pop-up window is displayed.
8. Click Done once edited.

**Workflow Editor**

Wizard

Step 2 of 7: Approval stage 1

General Information

Stage Name: Approval stage 1

Approval stage 1

Approval stage 2

Approval stage 3

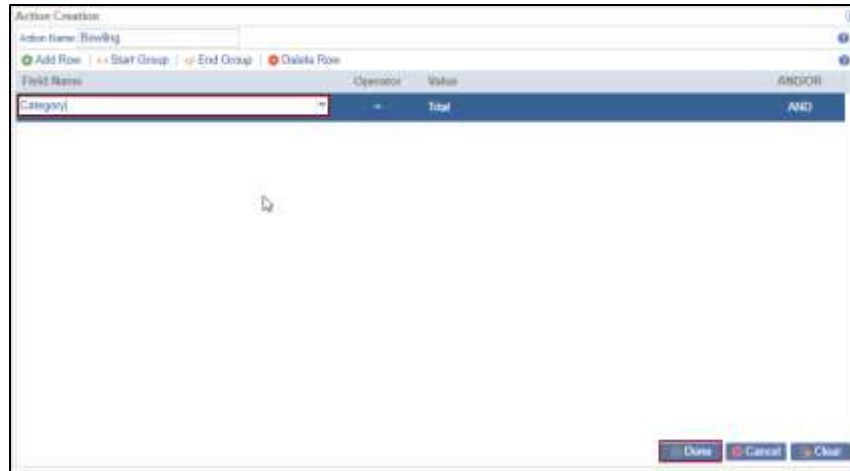
Approval stage 4

Approval stage 5

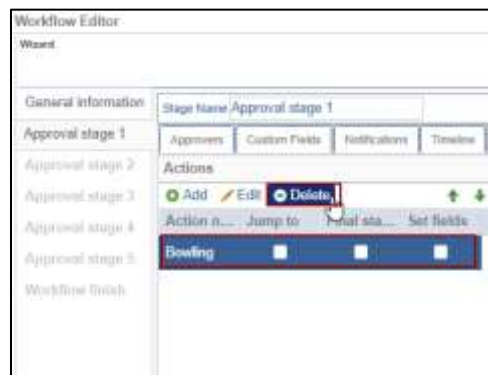
Workflow Items

Actions

Action Name:  Jump to:  Set fields



9. Select the action and click Delete the selected action gets deleted.



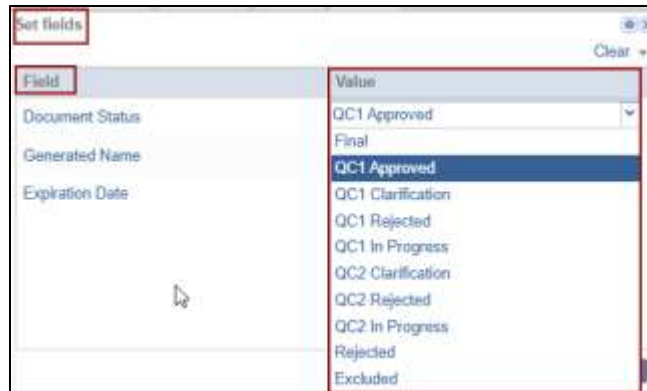
10. The Move Up and Move Down arrows help the user to move the actions as per the requirement.



11. On the right side of the 'Workflow Editor' pop-up window within the Edit Action panel, the user can see the following actions:

- Action name: the user adds the action name is displayed
- Jump to: the user can select the Approval Stages that are displayed in the drop-down list
- Final stage: if the checkbox is checked the user directly moves to the Final stage of the Workflow
- Set fields with edit icon:

- Click the edit icon and the Set fields pop-up window is displayed with the 2 columns 'Field' and 'Value.'
- The field column has 3 fields by default:
  - Document Status
  - Generated Name
  - Expiration Date
- Double-click on the field in the Value column. The drop-down options are displayed select the appropriate value and click Save.

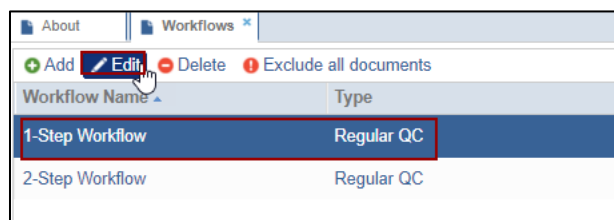


12. Click Next after reviewing all tabs.
  - Repeat these steps for each approval stage.
  - Settings, such as approvers, notifications, and timelines, may vary by stage.
13. When finished, click Next.
14. The Workflow Finish step is the final stage.
  - Any workflow errors will be displayed here and must be resolved.
  - If no errors are found, click Finish to complete the process.

## Editing an Existing Workflow

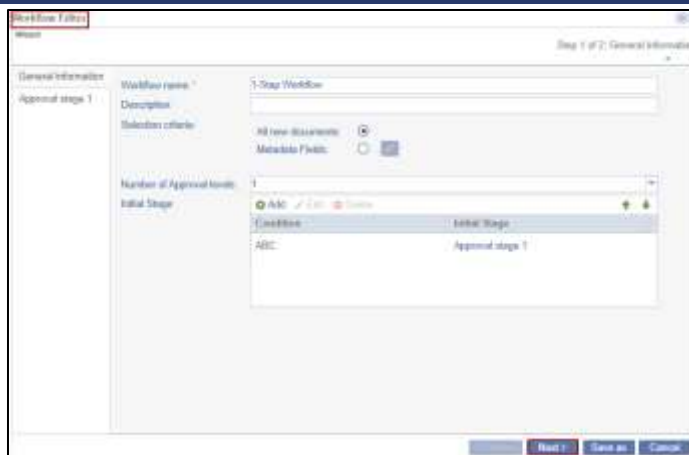
Steps to be followed:

1. Click the Edit button the 'Workflow Editor' pop-up window is displayed.

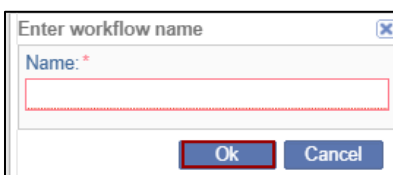
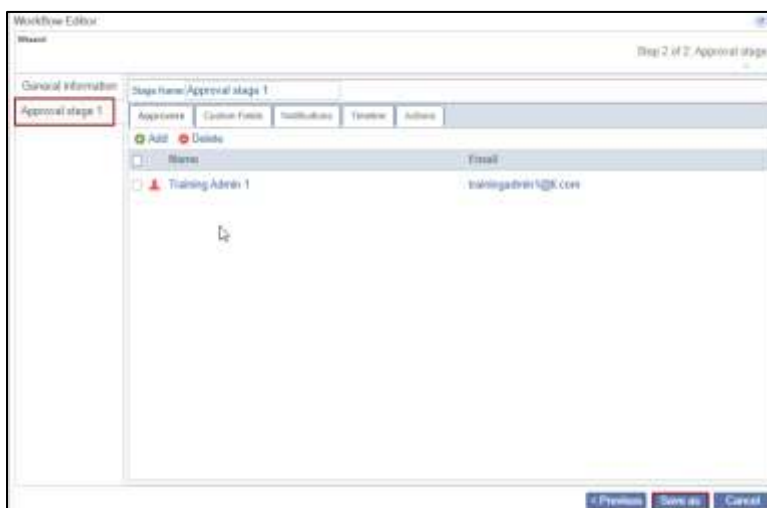


2. Edit the required fields and click Next will proceed to the 'Approval Stage 1' information page.





3. Edit the required fields and click Save As to save the workflow under a new name.
4. Click Save as.



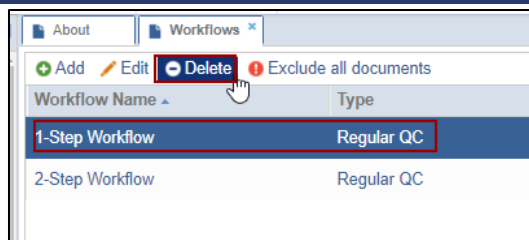
**CAUTION:** Editing of an existing workflow should be executed with caution because any saved changes require a new and revised workflow to be created.

As a result, only Super Administrators can edit an existing workflow.

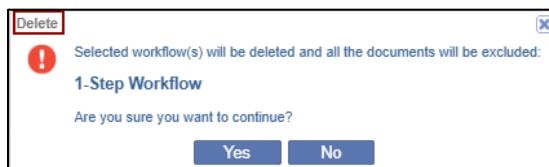
- To request workflow changes, contact the TI Service Desk.

## Deleting an Existing Workflow

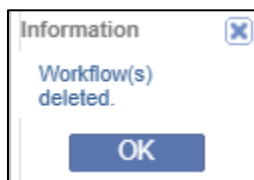
1. Select a workflow from the list you wish to delete and then click Delete from the top menu.



2. The Delete pop-up window is displayed.



3. If clicked Yes, the Information dialog is displayed.

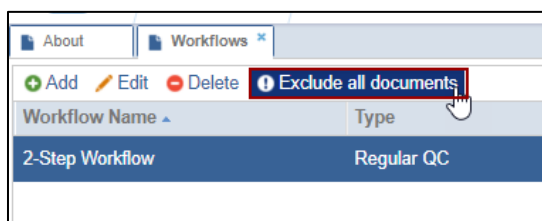


Deleting an existing workflow will result in the removal of any related status from documents previously processed as a part of the deleted workflow.

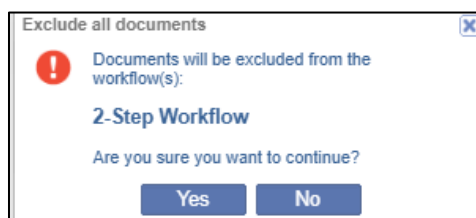
## Exclude all documents

The documents associated with the workflow will be excluded from it.

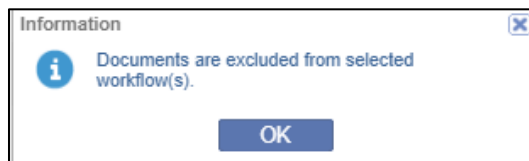
1. Click Exclude all documents button.



2. The Exclude all documents dialog is displayed.



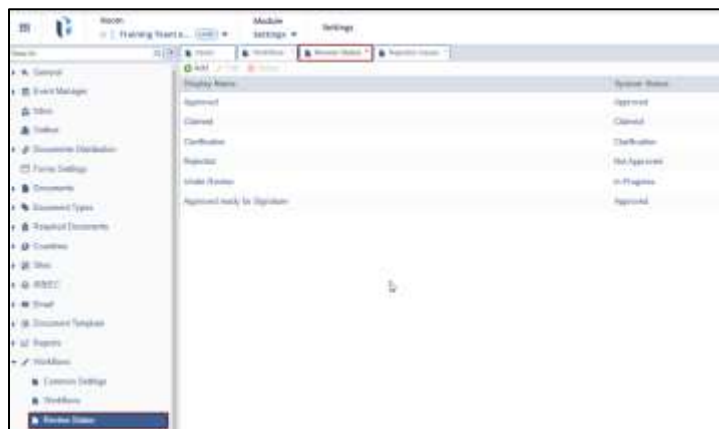
- If clicked Yes, the Information dialog is displayed.



## Review Status

Administrators can create review statuses to assign to documents at each stage of the workflow.

- The Display Name is the status name visible on the user interface, while the System Status refers to the predefined values assigned to the review status.
- Regardless of the Display Name, documents will be routed to the appropriate workflow folder in QC Review or My Reviews based on the System Status.



Follow the below steps:

- Click Add.
- Enter the Display Name.



- Double-click the System Status field, click the dropdown arrow, and select the System Status from the list.



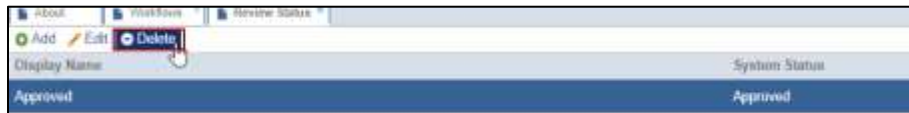
## Editing Review Status

1. Select the required Review Status/Display Name to be edited and click Edit.
2. The Review Status field becomes editable.
3. Make the required changes.
4. Double-click the System Status field, click the dropdown arrow, and select the System Status from the list.

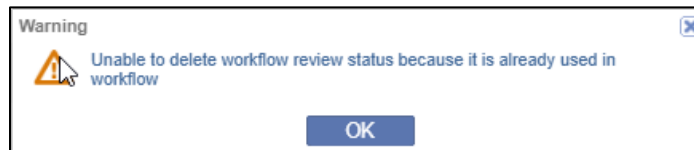


## Deleting Review Status

1. Select the required Review Status to be deleted.
2. Click Delete.



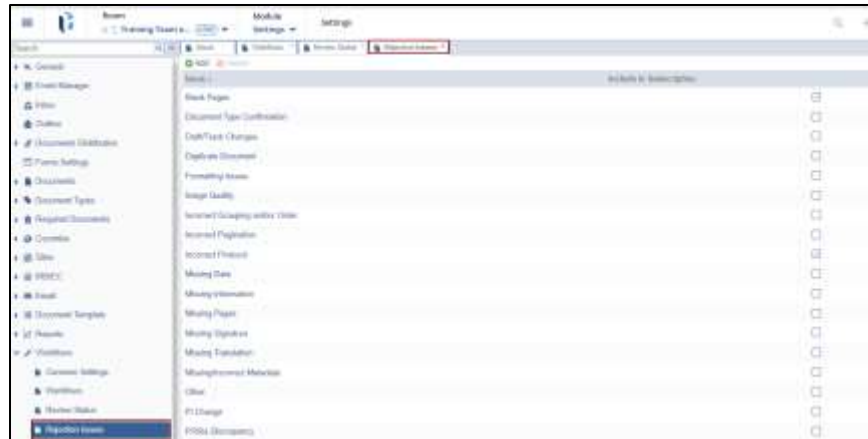
3. If the selected status is in use within a workflow, a pop-up dialog will appear. If the selected workflow is not in use, it will be deleted.



## Rejection Issues

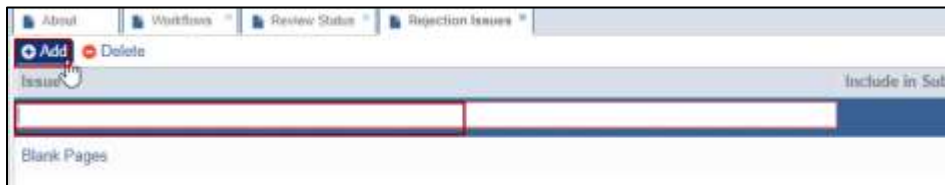
When adding a status to the workflow, if the user reports an issue, the issue will be added to the status in the Custom Field.

The reported issues will be added to the Rejection Issues section. Existing issues will also be marked and added under the Issue Name in the Custom Field.

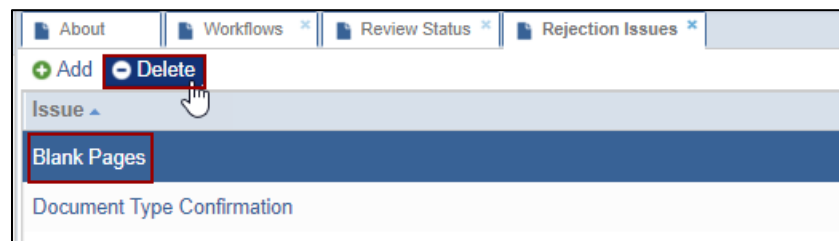


Follow the steps below:

- Click Add, the field gets activated and the user can add the Issue.

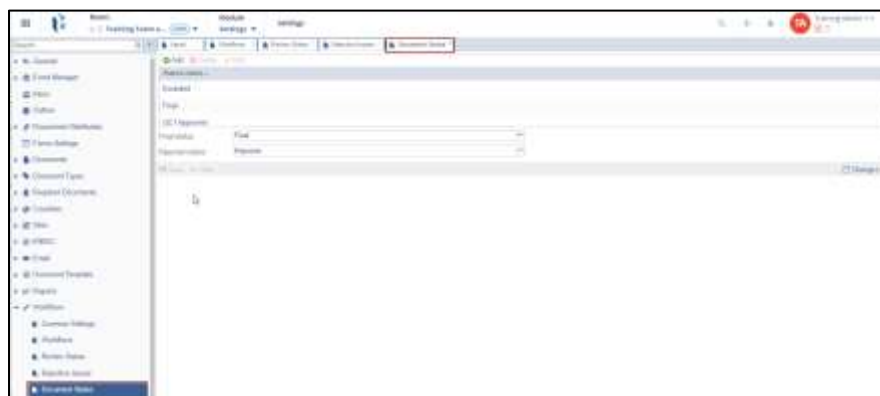


- Select the issue and click Delete. The selected issue will disappear from the list.



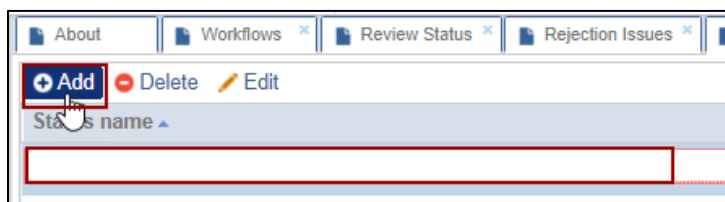
## Document Status

Document Status displays the status names that have been assigned to the documents.

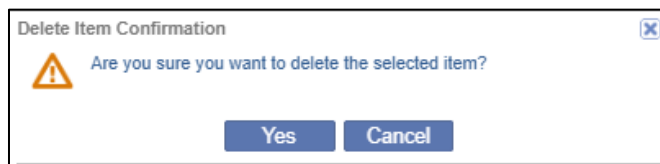
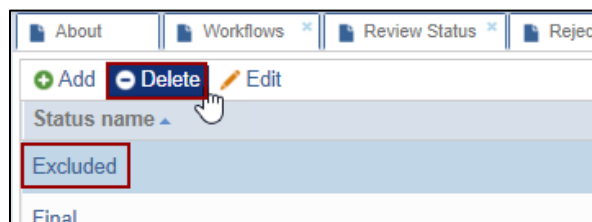


Follow the steps below:

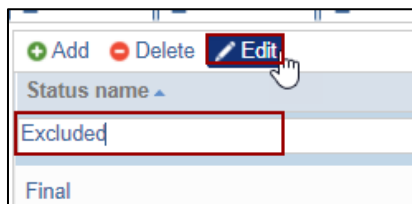
- Click Add to add the 'Status name'.



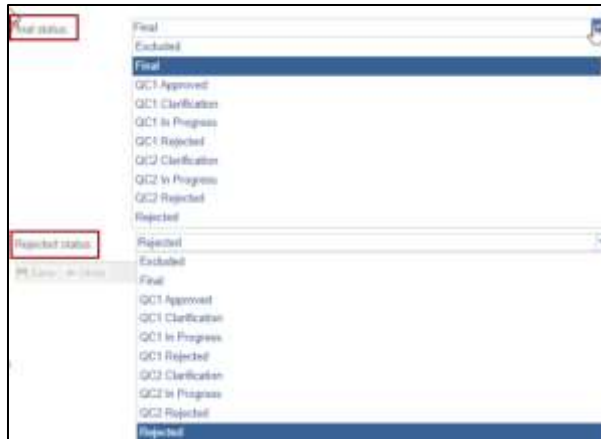
- Click Delete to delete the selected status name. The 'Delete Item Configuration' dialog box is displayed.



- Select the Status name and click Edit. The selected field gets editable.



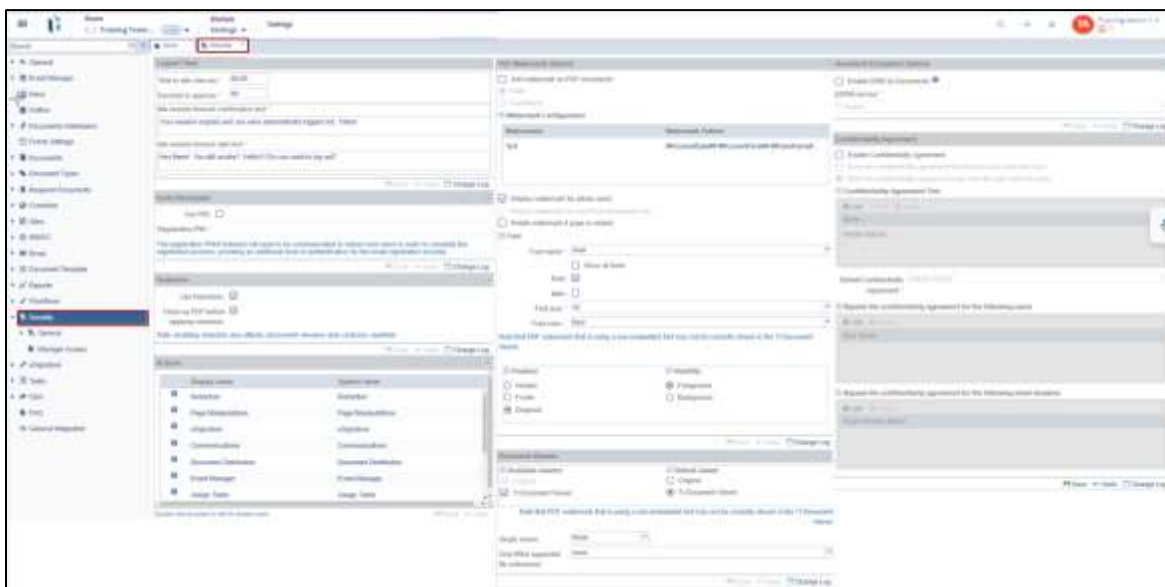
- The Final Status and the Rejected Status fields display the status that the user wants to associate.



Ensure to click the Save button to save the changes.

## Security

Most of the room's Security Settings are established at the start of the study and remain unchanged throughout its duration. Any changes made to these settings should be communicated to the Project Manager to ensure they are included in the Change Log.



## General Security Settings

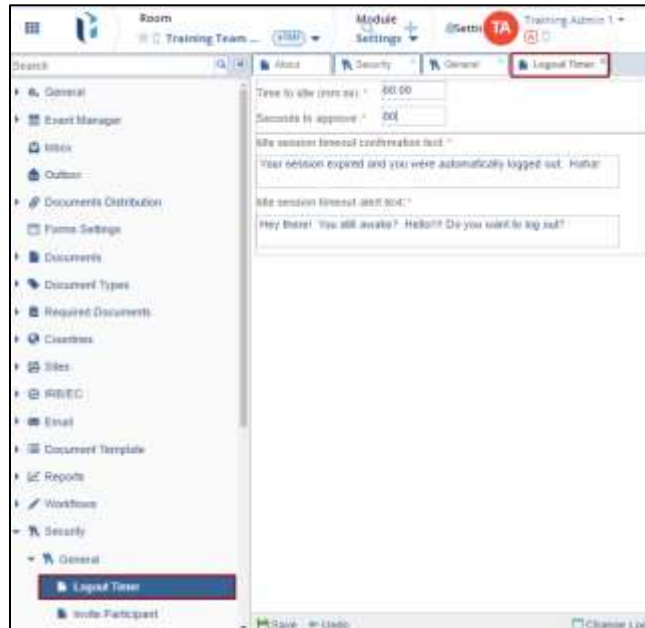
The General Security Settings can perform the following functions:

- Logout Timer
- Invite Participant
- Redaction
- Actions
- PDF Watermark Options
- Document Viewers
- Document Encryption Options
- Confidentiality Agreement

### Logout Timer

Room administrators can set a Logout Timer from the room settings. Refer to the screenshot below:

1. Adjust the time a user can remain logged in without being active in the study room.
2. You can also adjust the Seconds to approve field. This is the amount of time a user has to respond to the Idle session timeout confirmation message.
3. Enter the message that the user sees on the screen when the user is automatically logged out due to an idle session in the Idle session timeout alert text.
4. Click Save after any changes or Undo to revert back any changes made.



The Change Log option, located at the bottom right of the screen, displays a record of the Logout Timer. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

### Invite Participant

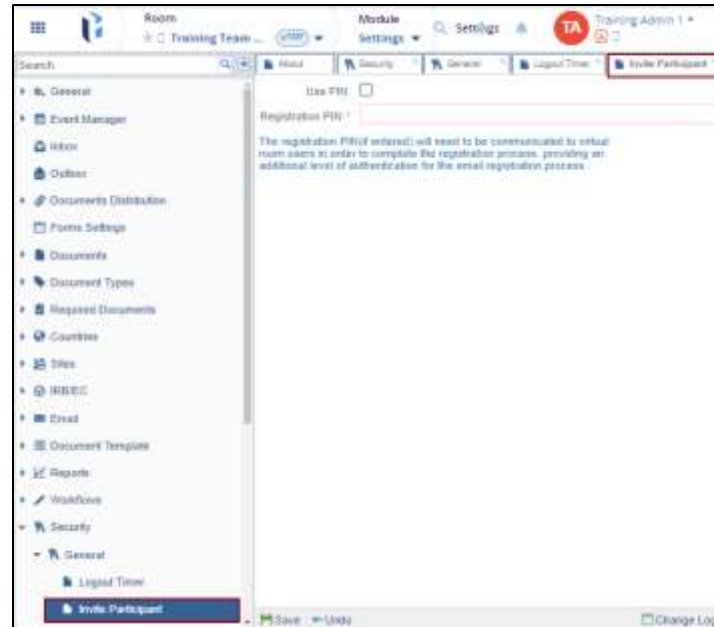
As an Administrator, the user can add a layer of security to the user registration process. Refer to the screenshot below:

To use this extra layer of security:

1. Click the Use PIN checkbox.
2. Enter a Registration PIN.

**Note:** The registration PIN (if entered) will need to be communicated to virtual room users in order to complete the registration process, providing an additional level of authentication for the email registration process.



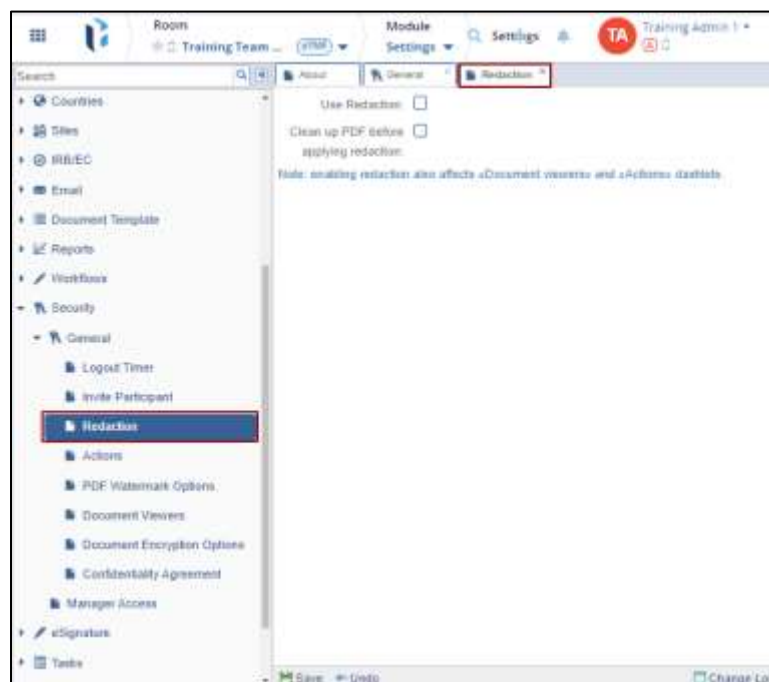


The Change Log option, located at the bottom right of the screen, displays a record of Invite Participant. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

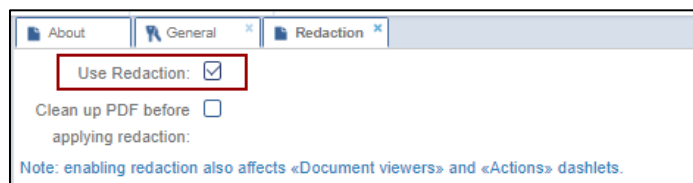
Ensure to click Save to apply and retain any changes.

### Redaction

Redaction or sanitization involves removing or protecting sensitive information from a document to ensure it can be safely distributed to a wider audience without compromising confidentiality or privacy.



Administrators can choose to enable or disable the Redaction option in the room by checking the box Use Redaction. Refer to the screenshot below:



The Clean up PDF Before Applying Redaction action prepares the document by removing any unnecessary or hidden content that may not be visible but could still contain sensitive information.

This ensures that only the relevant text and elements are present before applying redactions, preventing accidental exposure of sensitive data. It streamlines the redaction process and helps maintain document integrity.

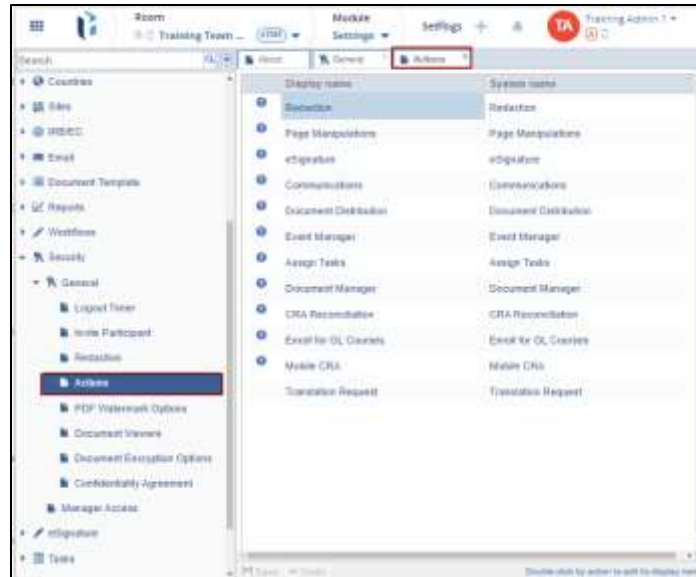


The Change Log option, located at the bottom right of the screen, displays a record of Redaction. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

### Actions

The Action pane displays the tasks enabled for users within a specific room. Each task name has a unique tooltip, which varies based on the 'Display Name' and 'System Name'. To check the description, hover the mouse on the tooltip icon beside the Display name. Refer to the screenshot below:

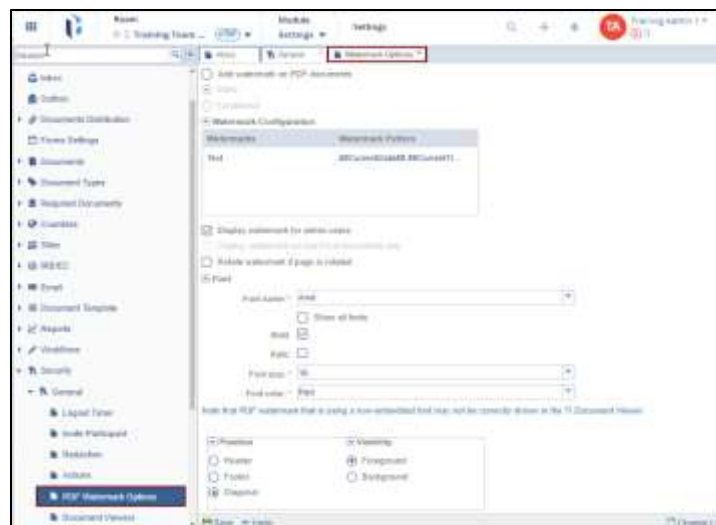


The 'Display name' is editable once the user double-click on the name.

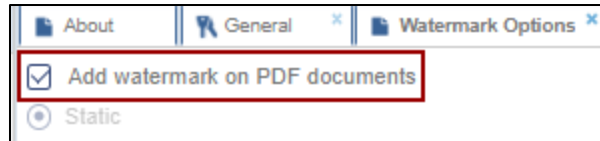
Ensure to click Save to apply and retain any changes.

### PDF Watermark Options

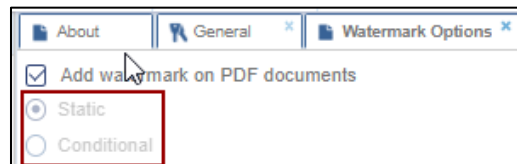
Watermarks can be added to documents downloaded or printed from a study room's file index.



- The 'Add watermark on PDF documents' checkbox is enabled the 'Display watermark on non-Final documents only' gets activated. Therefore, once the document becomes final, the watermark will no longer be available on the document; this is an automatic process.
  - Activation of this option also activates the option of allowing non-PDF documents to be printed or downloaded without watermarks.



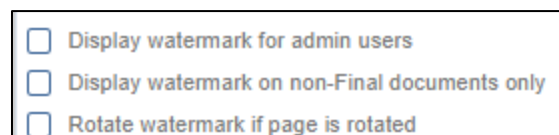
- **Static Watermark:** Apply a static watermark when you want the same watermark to appear on all pages of the document. This is typically used for documents that need to be marked with a permanent designation, such as "Confidential," or for documents that are shared with a specific group but should always carry the same label throughout the document.
- **Conditional Watermark:** Apply a conditional watermark when you need the watermark to change based on specific criteria or conditions, such as document status, user role, or security level. This is useful when different versions of the document or different users need to see different watermarks (e.g., "Draft" for internal users, "Final" for approved versions).



- Expand the arrow next to 'Watermark Configuration' to display the table below, where users can enter the desired text and select the watermark pattern to be applied to the document.
  - Double-click on the Watermark Pattern to enable editing.



- The checkbox below displays the watermark according to the criteria selected by the user.
  - **Display Watermark for Admin Users:** The watermark is displayed only when admin users grant permission for it to appear on the document.
  - **Display Watermark on Non-Final Documents Only:** The watermark is applied exclusively to non-final documents.
  - **Rotate Watermark if Page is Rotated:** The watermark will rotate along with the page when it is rotated.



- The user can decide the following as per the standard:

- Font name
- Bold
- Italic
- Font size
- Font color



- The Position and Visibility of the Watermark depend on the user's selection. Refer to the below screenshot.

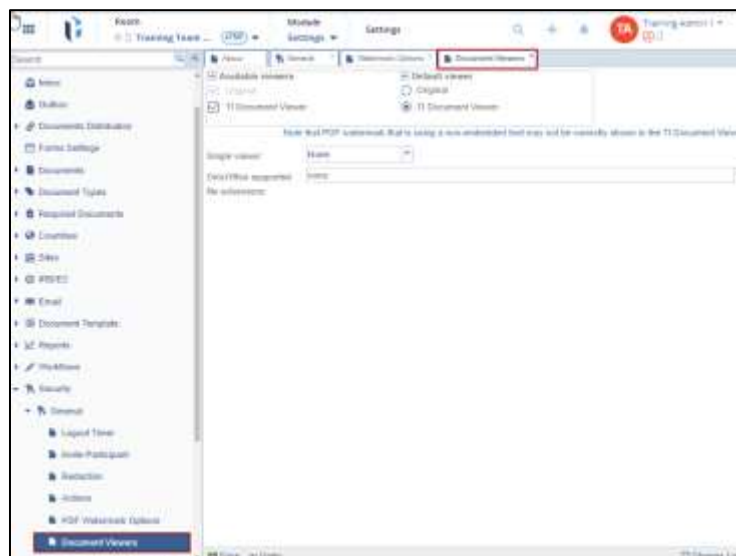


The Change Log option, located at the bottom right of the screen, displays a record of PDF Watermark Options. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

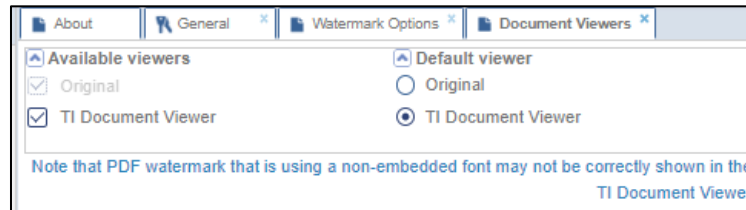
Ensure to click Save to apply and retain any changes.

### Document Viewers

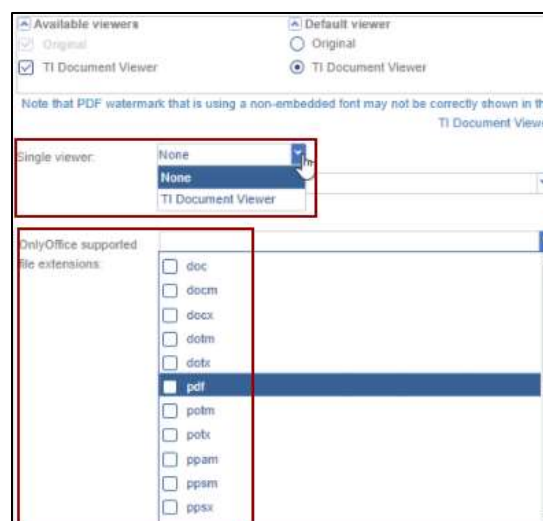
TI Viewer is an eTMF Document Viewer functionality that enhances the user's experience by performing actions on documents such as document rotation, zoom-in-out, and so on.



Administrators can choose which document viewers are available to room users and designate one of them as the room's default viewer. Refer to the screenshot below:



1. Select a Single viewer from the dropdown list if you want to restrict the availability for users.
2. A drop-down menu supports Only Office-supported file extensions.

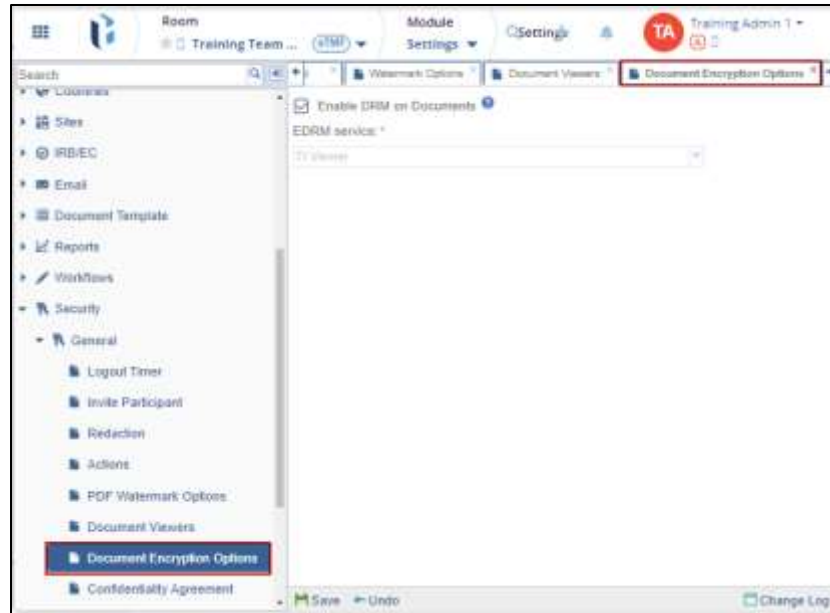


The Change Log option, located at the bottom right of the screen, displays a record of Document Viewers. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

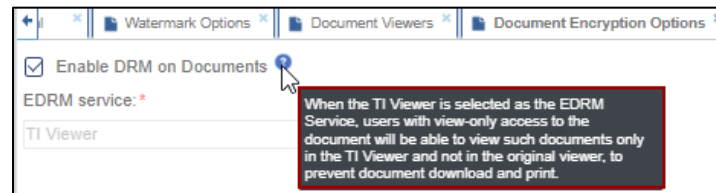
Ensure to click Save to apply and retain any changes.

### *Document Encryption Options*

The system provides Digital Rights Management (DRM) functionality. This feature provides additional security options to the users. Refer to the screenshot below:



Use the checkbox to Enable DRM on documents for enabling or disabling the documents.



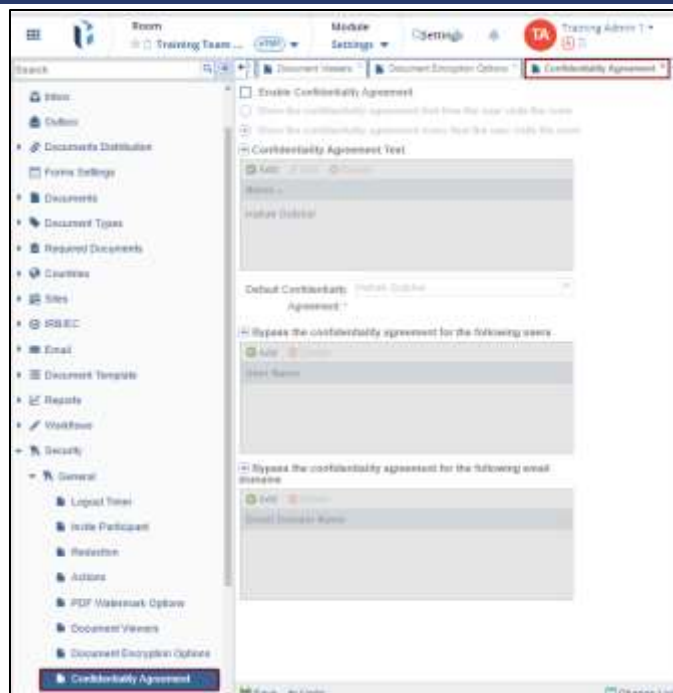
The Change Log option, located at the bottom right of the screen, displays a record of Document Encryption Options. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

### *Confidentiality Agreement*

An Administrator can enhance room security by adding a Confidentiality Agreement, providing an additional layer of protection for sensitive information.

- Once enabled, the user can choose to display the agreement only on a user's first visit to the room or have it appear each time users log in.
- The user can also designate specific users or groups of users, whose email addresses share a common domain name, to be exempt from clicking the agreement.



There are 3 types of Agreements that are:

- Confidentiality Agreement Text
- Bypass the confidentiality agreement for the following users
- Bypass the confidentiality agreement for the following email domains



## Confidentiality Agreement Text

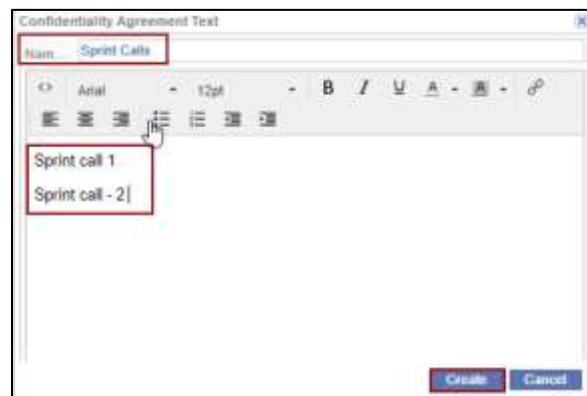
Follow these steps to enable the Confidentiality Agreement:



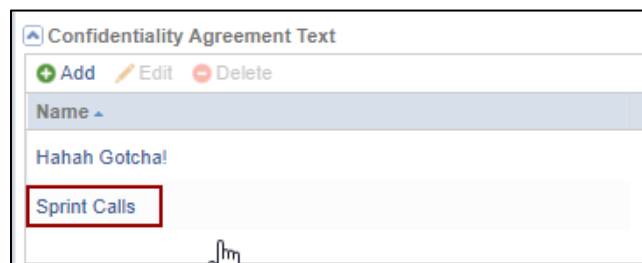
1. Tick the checkbox to enable/disable the Confidentiality Agreement on this room.  
Refer to the screenshot below:



- When enabled, select whether to have the agreement show only on the first time a user visits the room or every time a user visits the room.
2. Click Add to open the 'Confidentiality Agreement Text' pop-up window. Enter the 'Name of the Agreement' and provide clear and concise information on the main page. The agreement will only be created once this information is entered; otherwise, you will be prompted to provide it.



3. Click Create. The created agreement name appears on the page of the 'Confidentiality Agreement Text'.



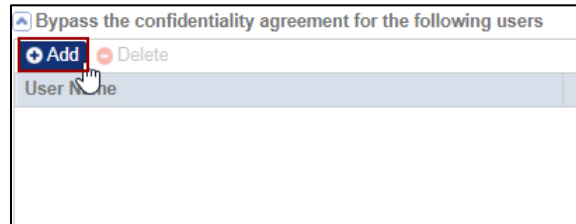
Users can view the added Confidentiality Agreement conveniently in the drop-down menu.



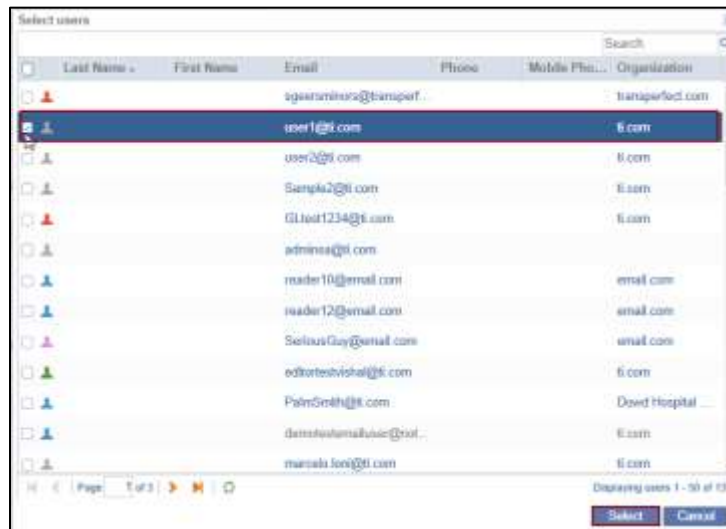
Bypass the confidentiality agreement for the following users

Follow these steps:

1. Click Add, and the 'Select users' pop-up window is displayed with the list of users.



2. Check the checkbox of the user from the list.
3. Click Select.



4. The selected user gets added to the 'Bypass the confidentiality agreement for the following users'.



### Bypass the confidentiality agreement for the following email domains

Follow these steps:

1. Click Add, and the below email field gets activated where the user can add the email ID of the required user.

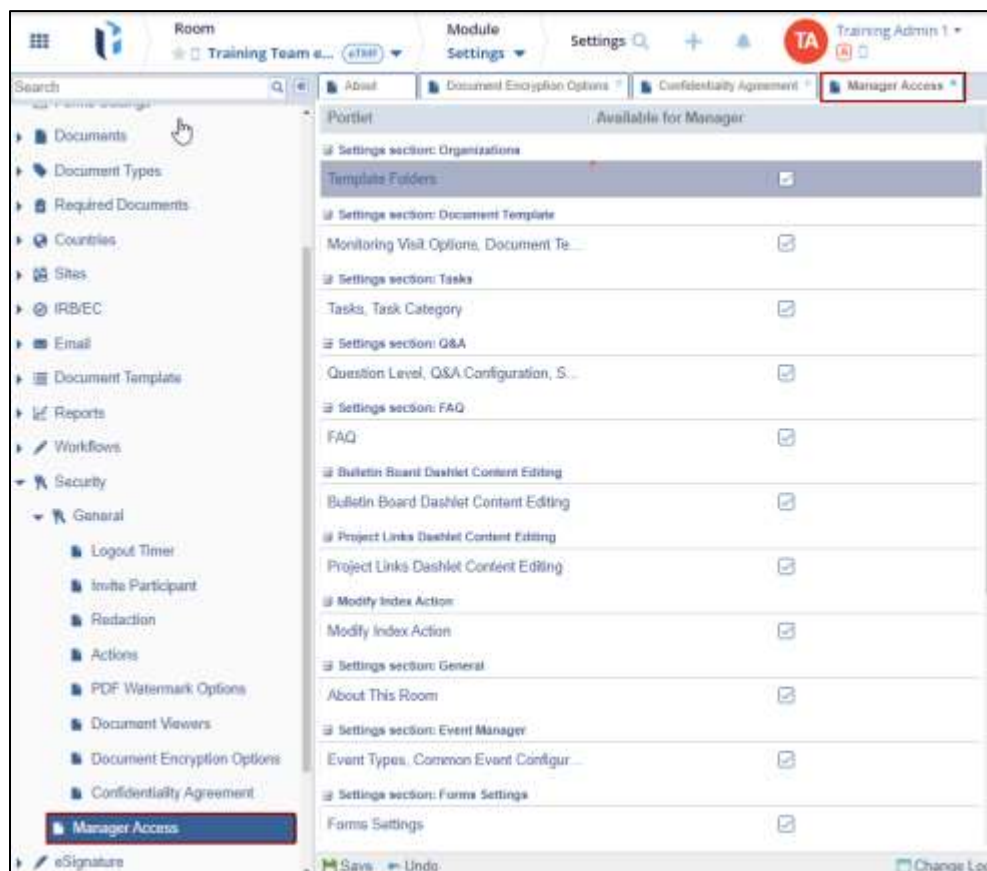


The Change Log option, located at the bottom right of the screen, displays a record of the Confidentiality Agreement. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

## Manager Access

The Manager role can be customized directly from this menu. Checkboxes allow you to enable or disable specific access rights and privileges associated with the role, tailoring it to your needs.

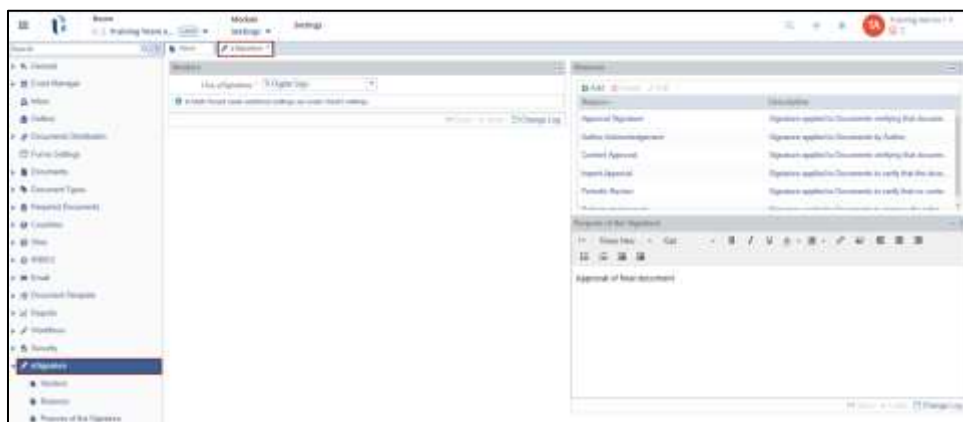


The Change Log option, located at the bottom right of the screen, displays a record of Manager Access. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

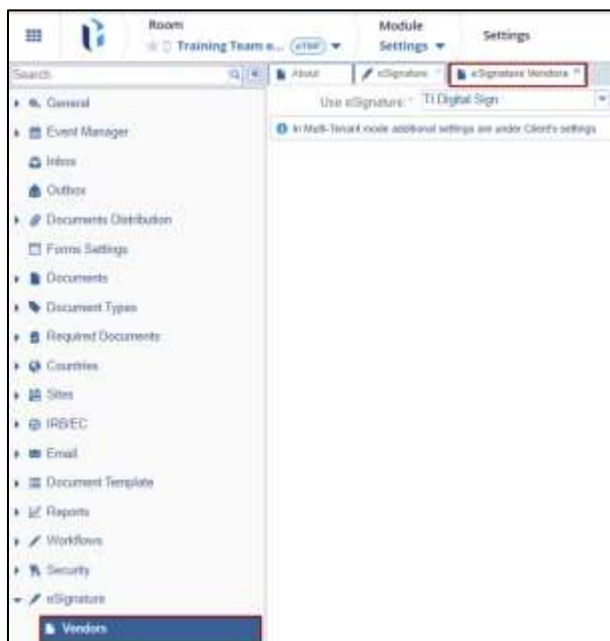
## e-Signature

This section describes the eSignature settings. Electronic signatures may be applied in all TI room types. However, we normally would expect this to be done prior to a document being submitted to the eTMF. Trial Interactive has a native electronic signature called TI Sign but your Trial Interactive rooms can also be configured to work with other electronic signature software.

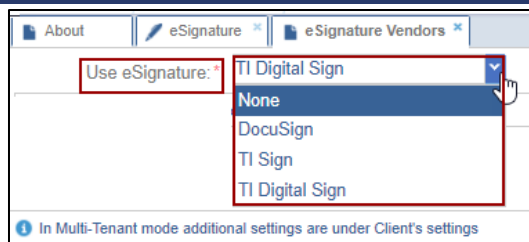


## Vendors

- The e-signature vendor available to the user is determined by the vendor selected by your organization.

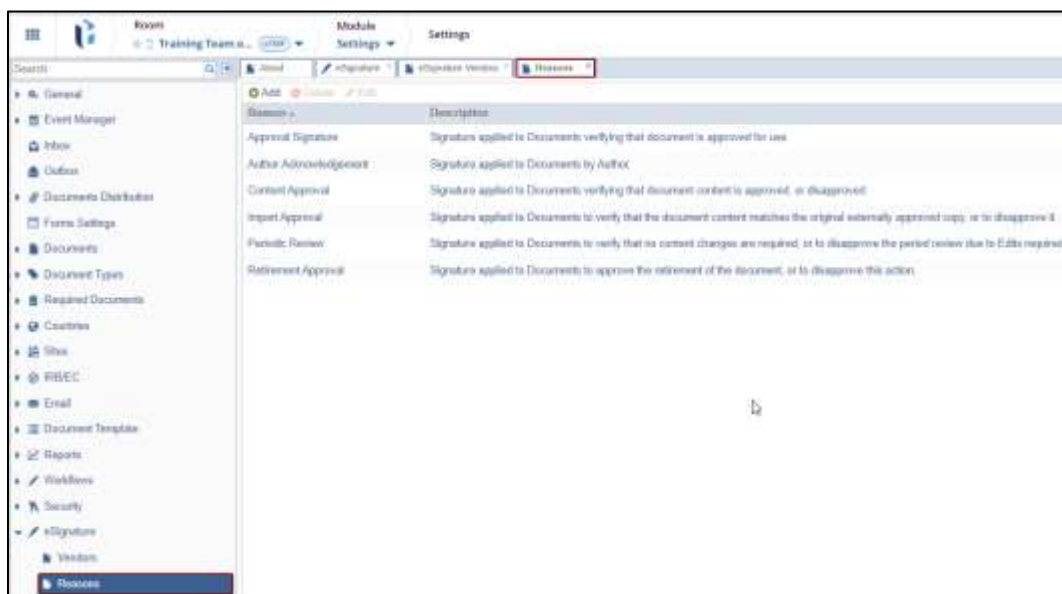


- Click the Use E-Signature dropdown to select the vendor. Refer to the screenshot below:



## Reasons

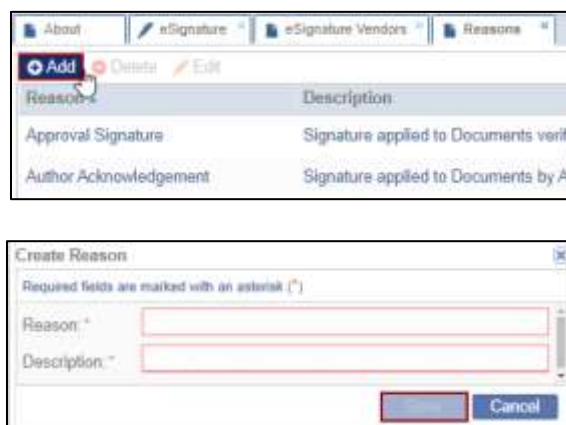
When e-signing a document, e-signers must specify the reasons for approving or declining it. Administrators can configure the available reasons for e-signature from this section.



## Adding a Reason

To add a Reason:

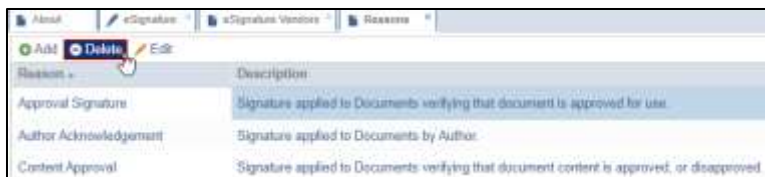
1. Click Add to create new reasons. The Create Reasons pop-up window is displayed.



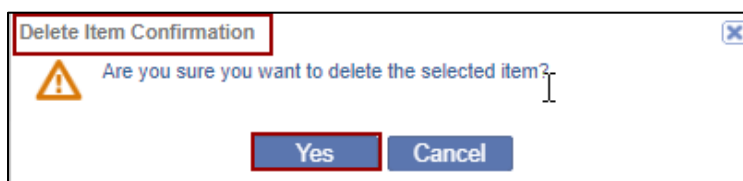
## Deleting a Reason

To delete a Reason:

1. Select the category and click Delete from the top ribbon.



2. A 'Delete Item Confirmation' pop-up window is displayed.
3. Click 'Yes' if the user wants to delete the question level.



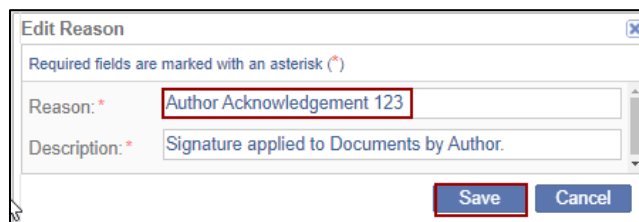
## Editing a Reason

To edit a Reason:

1. Select the category and click Edit from the top ribbon. You can also double-click the question level to edit.

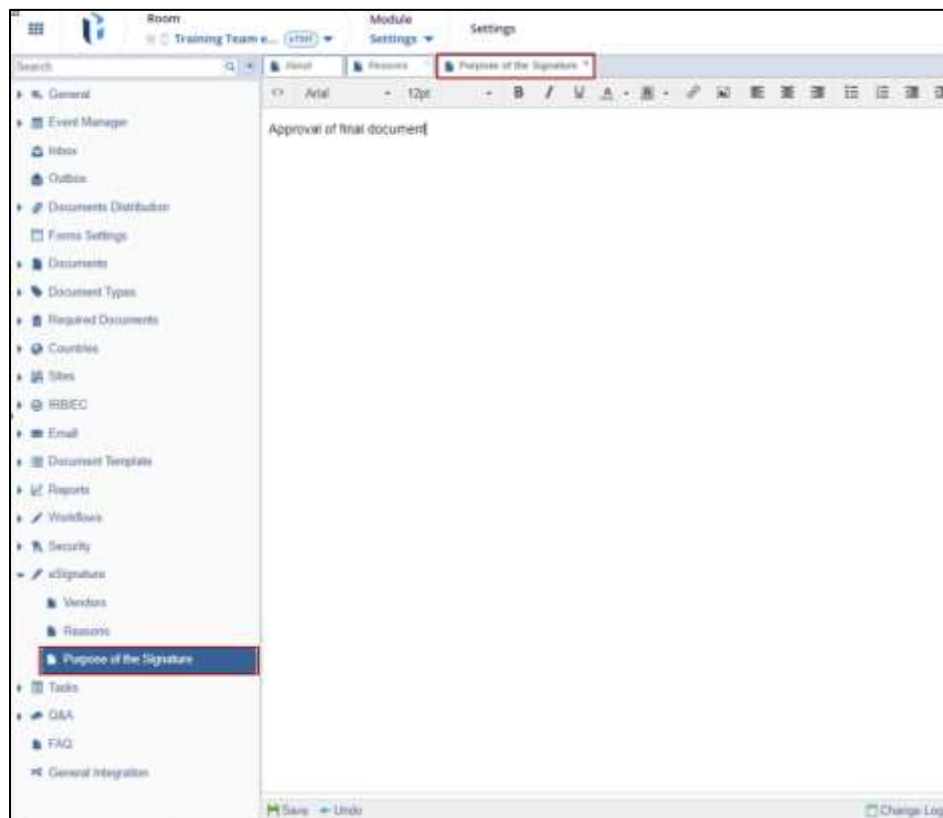


2. The 'Edit Reason' pop-up window is displayed. Edit the details as required and click Save.



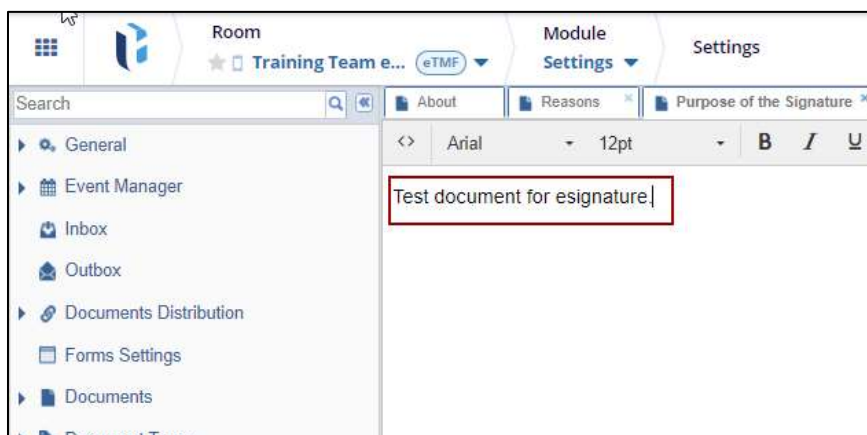
## Purpose of The Signature

The purpose of the e-signature is an additional text to display on the top of the send-to-e-signature form. Refer to the screenshot below:



### Steps to follow:

1. In the Right Panel, the user can write/edit the 'Purpose of the e-signature'.
2. Click Save.

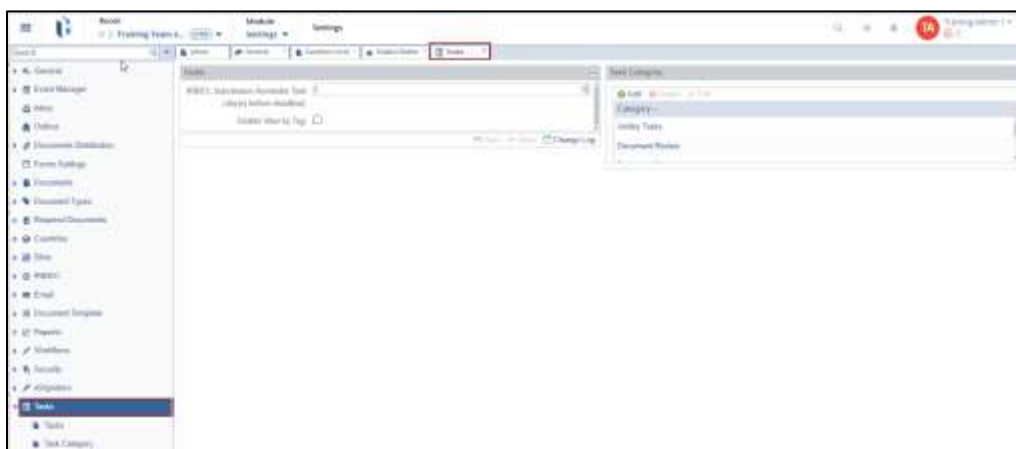


The Change Log option, located at the bottom right of the screen, displays a record of the Purpose of the Signature. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

Ensure to click Save to apply and retain any changes.

## Tasks

The administrator may need to set up certain configurations for tasks in a room.



The Tasks include 2 sections:

- Tasks
- Task Category

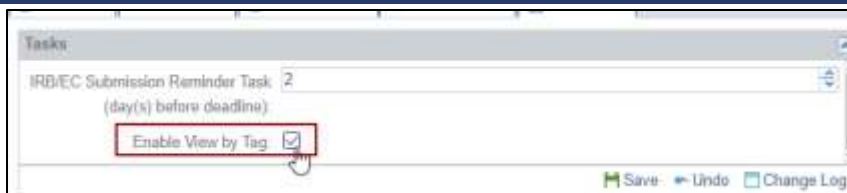
## Tasks

1. Navigate to Navigation Grid → Settings → Tasks → Tasks
2. Define the number of days from the IRB/EC submission reminder task option by clicking the up & down arrow.
3. This defines the number of days before the due date that the user will receive a reminder email regarding any task related to the IRB/EC.



Enabling "View by Tag" for tasks allows users to filter and organize tasks based on specific tags or labels. This feature provides a way to categorize tasks by relevant topics or themes, making it easier to locate and manage tasks related to particular subjects or priorities. By using tags, users can quickly see which tasks are associated with certain categories, improving task management and visibility within the system.





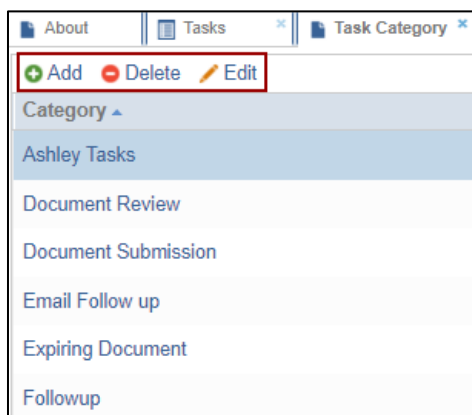
The Change Log option, located at the bottom right of the screen, displays a record of Tasks and Close button.

Ensure to click Save to apply and retain any changes.

## Task Category

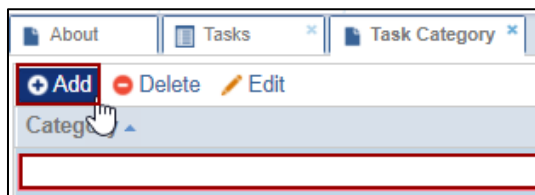
Task categories must be specified during task creation. These categories should be pre-created to ensure that users can select the appropriate one from the dropdown menu in the Task Creation window. This helps in organizing and classifying tasks effectively.

Task categories can be created, edited, or deleted through the buttons on the Task Category dashlet.



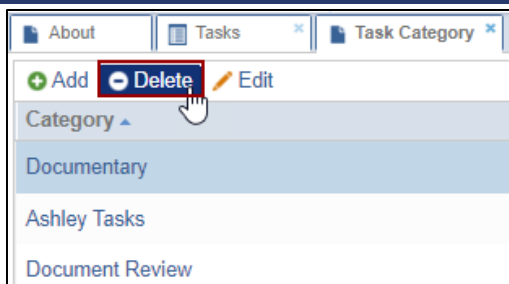
### Adding New Category

1. Click Add from the top ribbon.
2. A new row appears in the grid below.
3. Enter the name of the Category and click aside to save the change.

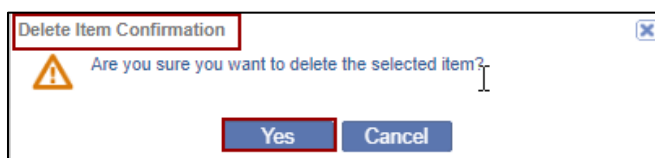


### Deleting New Category

1. Select the category and click Delete from the top ribbon.



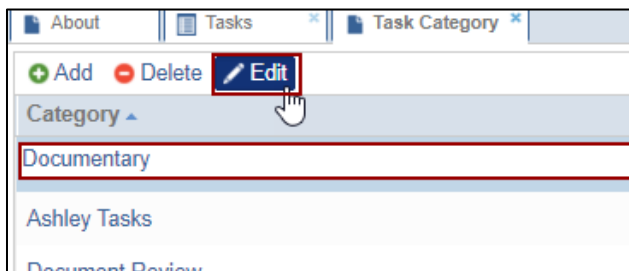
2. A 'Delete Item Configuration' pop-up window is displayed.
3. Click 'Yes' if a user wants to delete the question level.



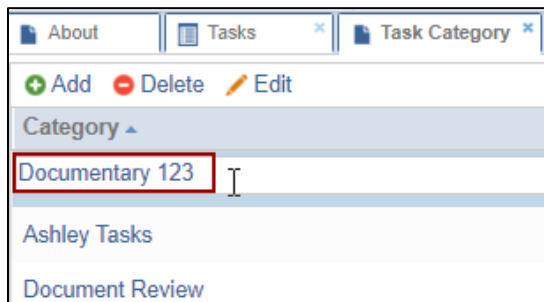
### Editing a Question Level

To edit a question level:

1. Select the category and click Edit from the top ribbon. You can also double-click the question level to edit.
  - o The field becomes editable.



2. Edit the details as required and click aside to save the changes.



## Q&A

### General

The Q&A functions must be activated in the room's Settings. The related icons will only appear if these functions were enabled when the room was created.

In the Q&A settings view, the user can add, edit, or delete Question Levels. The Q&A configuration panel allows you to enable or disable various options, including the ability to delete questions and answers, activate Subject Matter categories, and enable question issue levels.

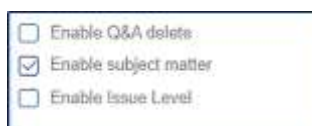


### Q&A Configuration

From here, you can enable and disable the following three options:

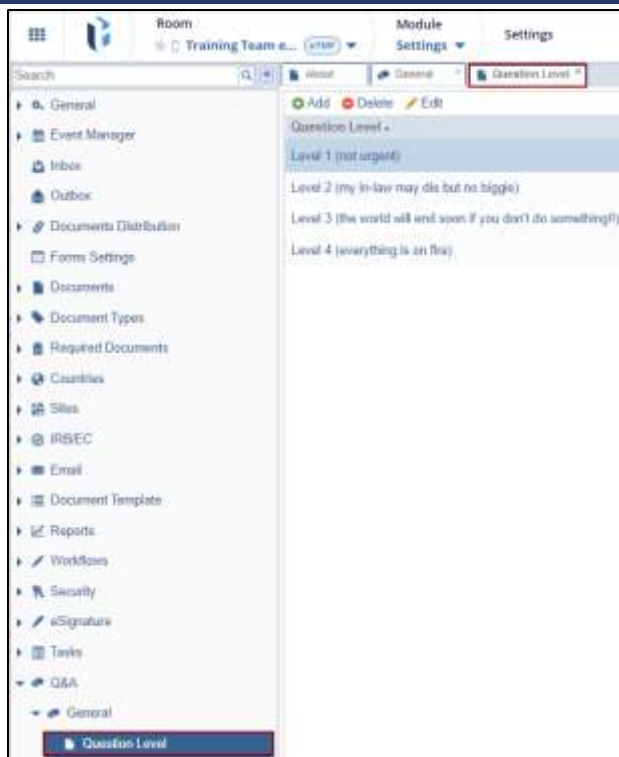
- Enable Q&A Deletion
- Enable Subject Matter
- Enable Issue Level

Refer to the screenshot below:



### Q&A Question Level

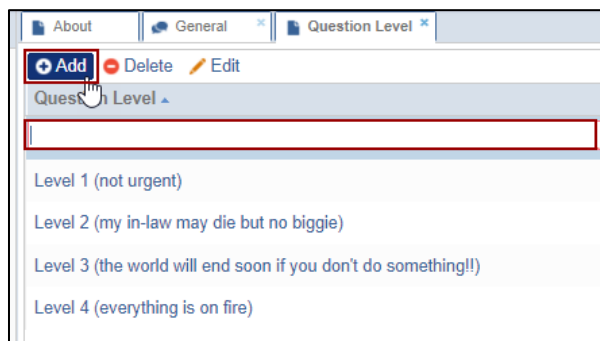
From here, you can create a list of issues associated with the documents. These issues are then assigned to Subject Matter Experts, who are responsible for providing answers to the questions. Refer to the screenshot below:



### Adding New Question Level

To add a new question level:

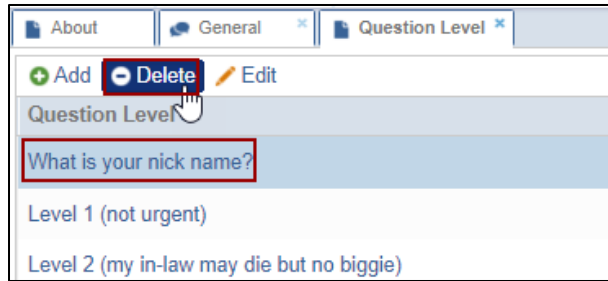
1. Click Add from the top ribbon.
2. A new row appears in the grid below.
3. Enter the question level and click aside to save the change.



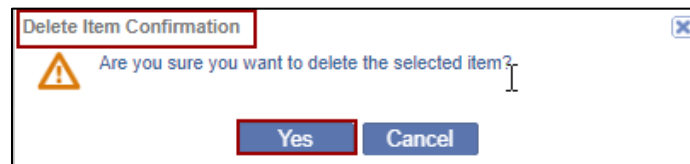
### Deleting a Question Level

To delete a question-level:

1. Select the question level and click Delete from the top ribbon.



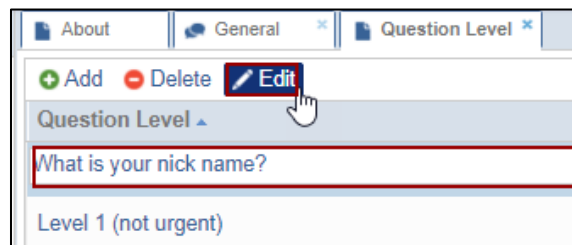
2. A 'Delete Item Configuration' pop-up window is displayed.
3. Click 'Yes' if the user wants to delete the question level.



### Editing a Question Level

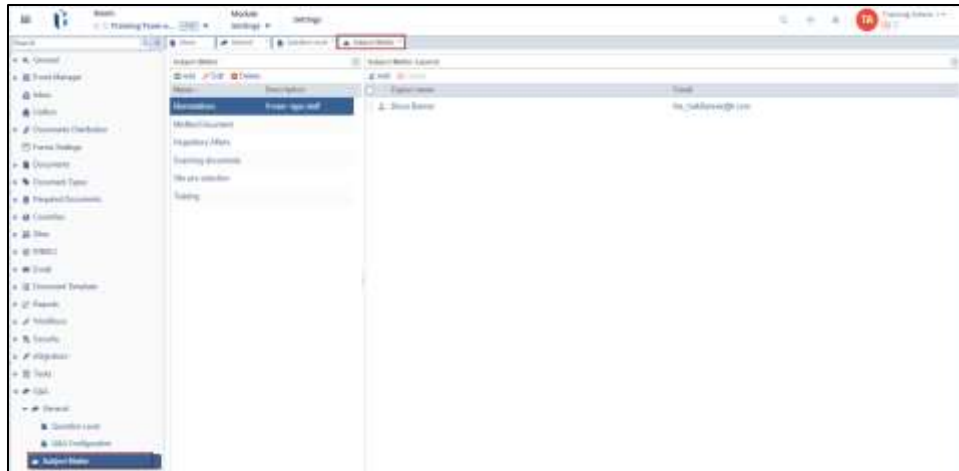
To edit a question level:

1. Select the level and click Edit from the top ribbon. You can also double-click the question level to edit.
  - The field becomes editable.
2. Edit the details as required and click aside to save the changes.



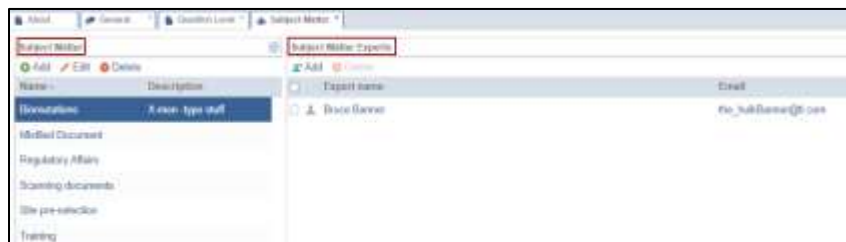
### Question Subject Matter

If Subject Matter is enabled in the Q&A Configuration, an additional set of options for Subject Matters is activated. You can access these options from the Q&A menu in the left panel of the Room Settings. Refer to the screenshot below:



This window consists of two panels:

- The Subject Matters panel from which subject matter categories can be added, edited, and deleted.
- Subject Matter Experts panel from which Subject Matter Experts can be assigned to or unassigned from the specific Subject Matter Categories. In this way, questions from particular categories can automatically be channeled to subject matter experts when the questions are submitted in the room.

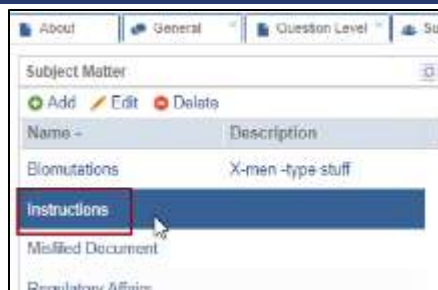


### Creating Subject Matters

1. Click Add, in the Subject Matters panel toolbar.
2. The 'Create Subject Matter' window opens. Refer to the screenshot below:



3. Type the name of the Subject matter category in the Name field. The Name field is required; the Description field is optional.
4. Click Create at the bottom of the window. The new Subject Matter category is added to the list.



## Editing Subject Matters

To edit Subject Matters:

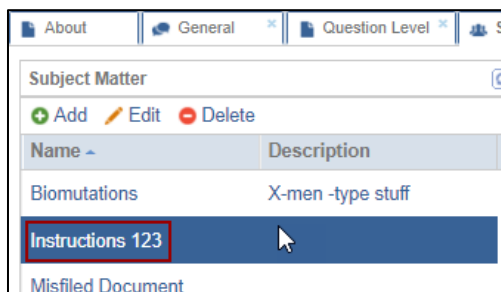
1. Click Edit, from the Subject Matters panel toolbar.



2. The 'Edit Subject Matter' window opens. Refer to the screenshot below:



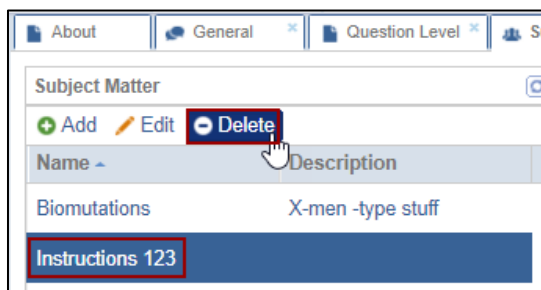
3. Edit the Subject Matter Category name and Description.
4. Click Save.
5. The changes are committed and visible in the list of categories.



## Deleting Subject Matters

To delete a Subject Matter category:

1. Click Delete, from the Subject Matters panel toolbar.
2. The 'Delete Subject Matter' pop-up window is displayed.
3. Click 'Yes', if the user wants to delete the Subject Matter Category.



## Assigning Subject Matter Experts to Subject Matters

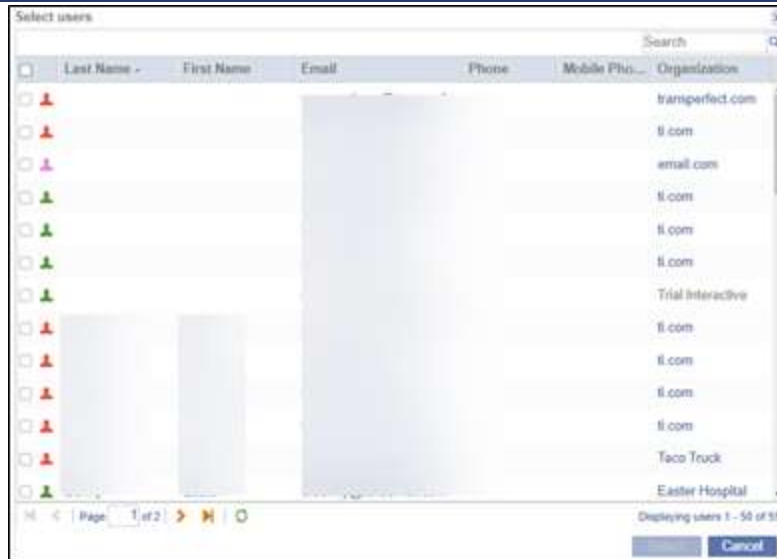
To assign a Subject Matter Expert to a subject matter, select a subject matter from the list on the left.

1. Click the Name of the Subject Matter and click the Add button from the Subject Matter Experts panel toolbar.
2. The existing Subject Matter Expert name is displayed in the grid by default.

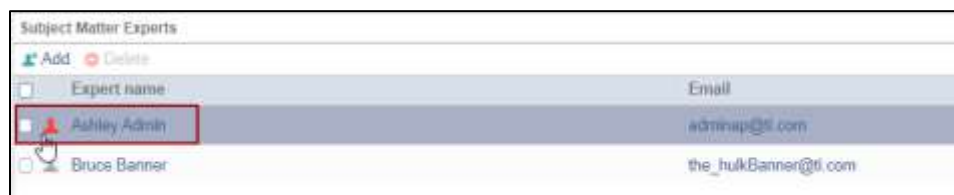
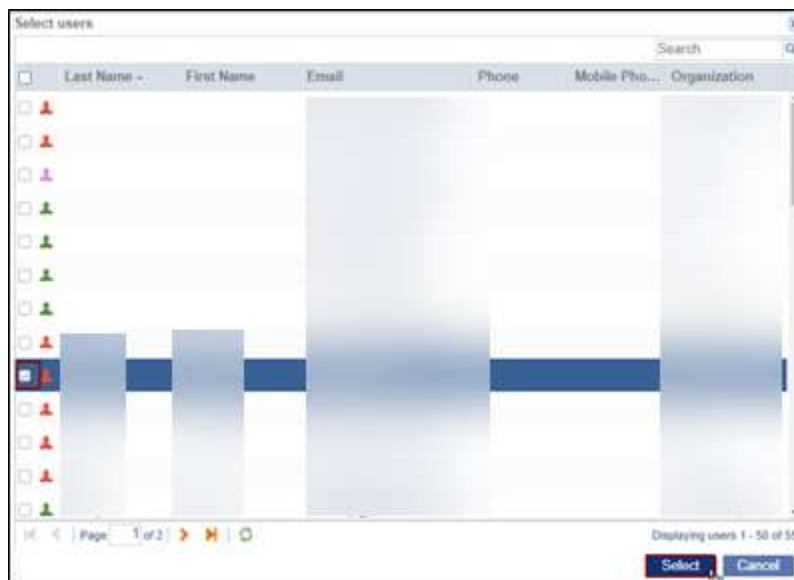


3. A Select Users window opens, displaying the full list of the room's registered users who are eligible to be assigned the role of Subject Matter Expert – users with Administrator or Editor access to the room.





4. Click the checkbox next to the name of the user you want to assign to the expert role.
5. Click Select at the bottom of the window. The changes are automatically saved and the users get added to the 'Subject Matter Expert panel. Refer to the screenshot below:

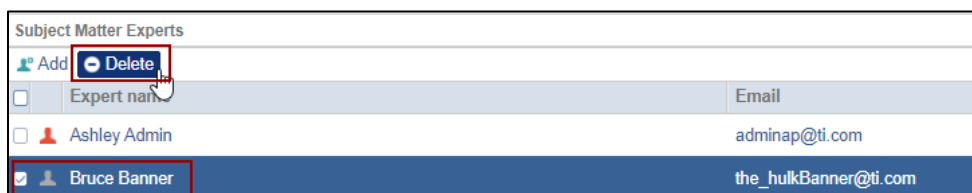


Now, when a user asks a question and assigns it to the Q&A category and Subject Matter during the creation of the question, the assigned expert will be notified that the question requires their attention. The expert can then view the question in the Q&A module.

## Removing Subject Matter Experts from Subject Matters

To remove a Subject Matter Expert from Subject Matters:

1. Click the Name of the Subject Matter.
2. The list of Subject Matter Experts appears in the Subject Matter Expert Panel.
3. Select the checkbox next to the name(s) of the Subject Matter Expert you want to delete and click Delete from the toolbar.
4. The names of the Subject Matter Experts are deleted from the list.



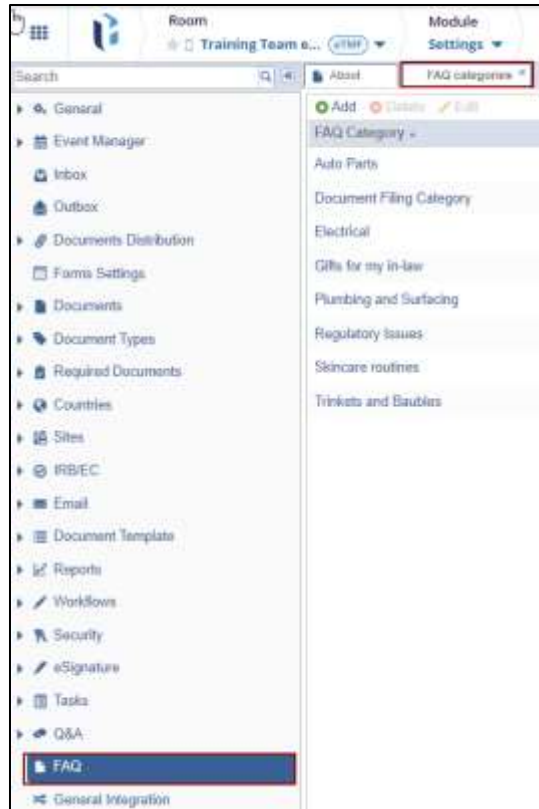
## FAQ Module

The Frequently Asked Questions (FAQ) Module in Trial Interactive offers a centralized and easily accessible location for your study team to store commonly asked questions related to your clinical trial. This module can be readily accessed by anyone with permissions to the eTMF, Site, or Study Collaborate rooms, as well as standard Content Management workspaces.

Throughout a Clinical Trial, a wide range of questions arise from the team, such as document naming conventions, instructions on classifying metadata and content, contact information for specific study details, and critical entries for each Investigative Site. Providing your CRAs, CTAs, and Clinical Document Specialists with access to the right answers can significantly improve the efficiency of your project. Simply click on the FAQ Module to find the information you need.

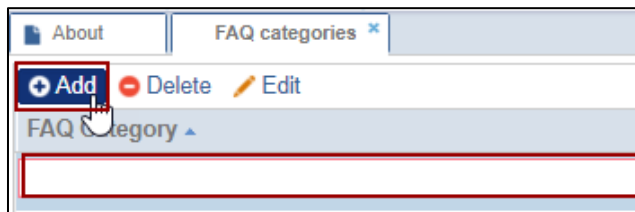
### How it Works

The FAQ icon in the Navigation Grid allows you to view the list of FAQs. You can reach this page by clicking the FAQ icon from the Navigation Grid. From this page, you may search for any FAQ, or simply view the listing and expand the answers you require. You can also view by date or category from the index, and also modify the columns, and create your own views as necessary. FAQs, both Questions and Answers, may contain rich text, images, and other information. Finally, FAQs may be emailed to other users in the room.



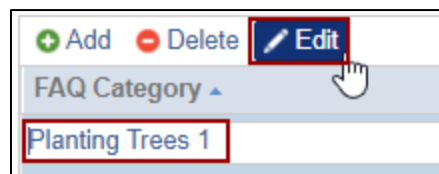
## Adding FAQ Categories

1. Navigate to Navigation Grid -> Settings -> FAQ
2. Click Add. The FAQ Category field gets added to the grid.
3. Click aside after making any changes to save it.



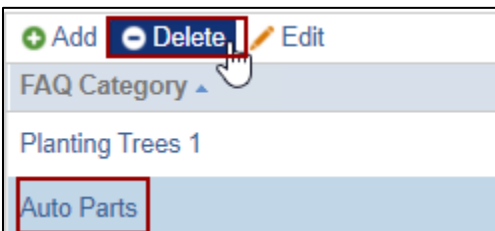
## Editing FAQ Categories

1. Double-click the FAQ category or select an existing FAQ category and click Edit.
2. Click aside after making any changes to save it.

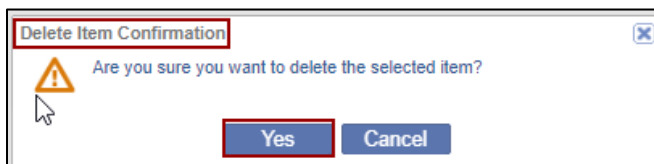


## Deleting FAQ Categories

1. Select a FAQ and click Delete. The 'Delete Item Confirmation' pop-up window is displayed.



2. Click 'Yes' if the user wants to delete the FAQ category.
3. Click aside after making any changes to save it.



## General Integration

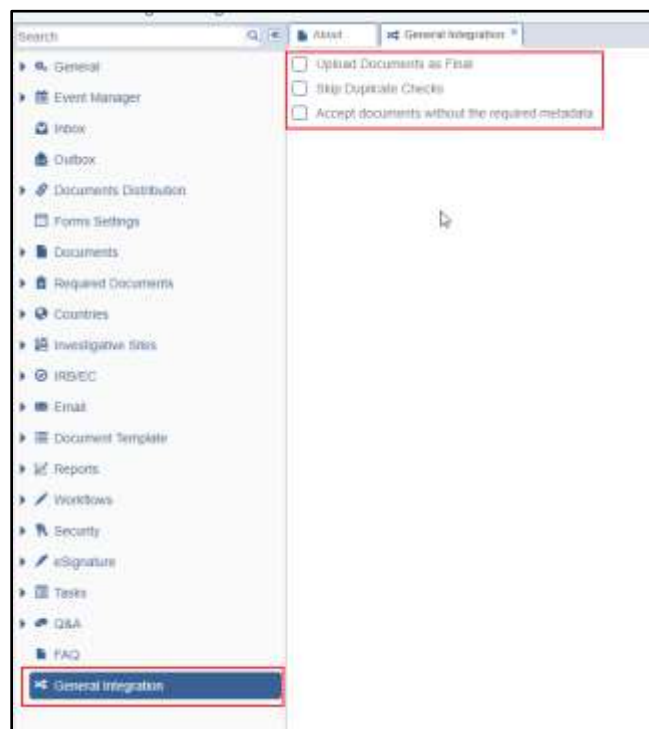
By default, all documents uploaded into the system are placed in a subfolder named after the user who uploaded the document. This subfolder is automatically created under the Upload folder, and the documents then proceed through the standard workflow process.

Through Integrations, clients can choose to bypass the workflow process for a document and upload it directly with a status of Final. To enable this, two criteria must be met:

- Assign a related folder for the document types of the documents to be uploaded
- Enable auto-indexing for the documents

Documents, upon being uploaded, would then move directly to the related folder assigned to their document types and acquire the status as final. Refer to the screenshot below:

1. Navigate to the Navigation Grid->Settings-> General Integration.
2. Tick the checkbox to Upload Documents as Final.
3. Tick the checkbox to skip validation of the duplicated document name by enabling the Skip Duplicate Checks.
4. Tick the checkbox to Accept documents without the required Metadata.

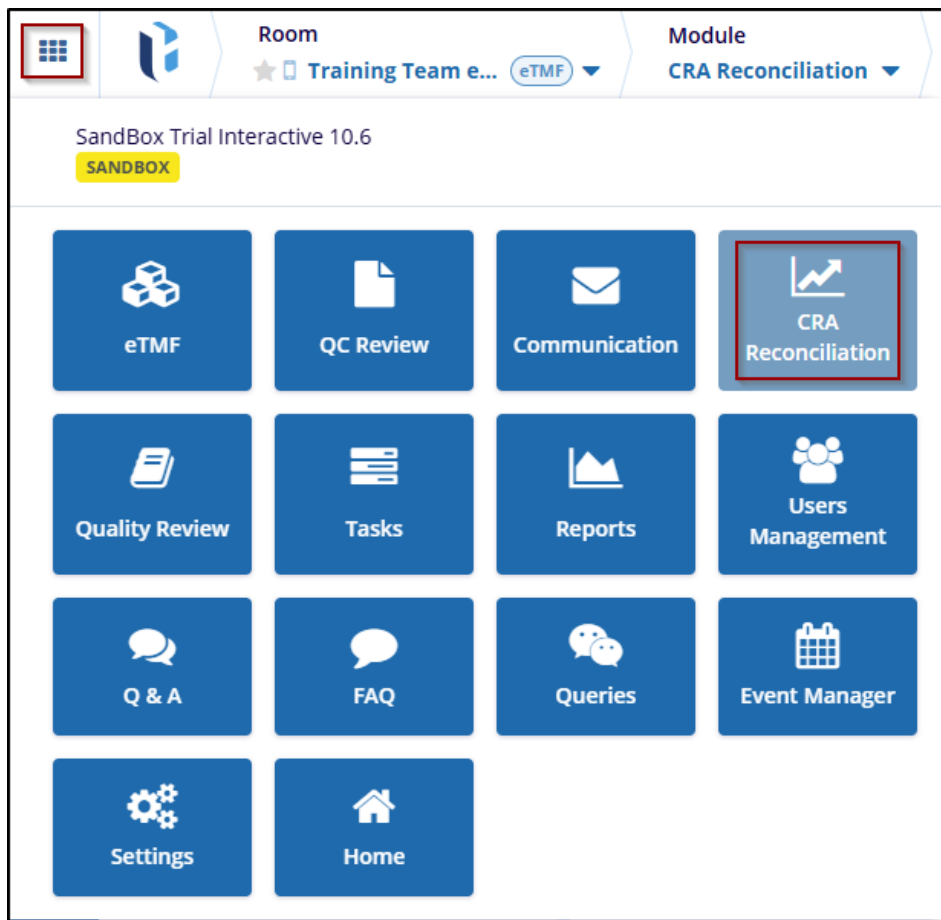


The Change Log option, located at the bottom right of the screen, displays a record of changes made to General Integration. It includes columns for Item Name, New Value, Old Value, Updated By, and Updated On (with the timestamp) and Close button.

## CHAPTER 12. CRA RECONCILIATION

The CRA Reconciliation module in Trial Interactive enables Clinical Research Associates (CRAs) to reconcile documents during site visits. This module helps CRAs verify document completeness, identify missing records, and generate reconciliation reports to support site monitoring decisions. Users need to have the CRA Reconciliation action on their user profile to see this module.

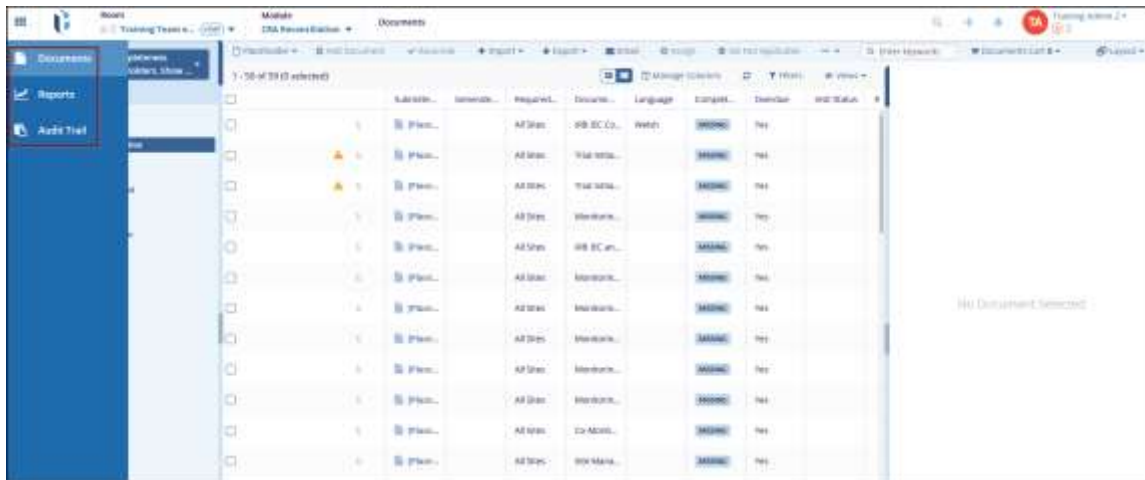
Users can access the CRA Reconciliation module from the navigation grid in the upper-left corner of the screen. While any user can be granted access, only those designated as a CRA for a site can perform reconciliation and reporting functions.



The CRA Reconciliation module has the following sections:

1. **Documents:** This allows the CRA to mark the documents as verified, missing in eTMF, missing in ISF, or add the placeholder for an expected document as a part of the reconciliation process.
2. **Reports:** This allows the CRA to create a CRA Report which will include all the documents reviewed by the CRA since the last report created by user.

3. **Audit Trail:** This is a security-relevant chronological set and source of records that provide evidence of the sequence of activities performed over a document. The changes made in a document by all users are displayed within the Audit Trail.



Note: The user can be granted access to the CRA Reconciliation module but the reconciliation and reporting functions will only be available to users who have been designated as a CRA for a site. This designation is not available to room administrators.

## Documents Reconciliation

The Document Reconciliation section provides a structured interface for managing, tracking, and organizing documents associated with various events. It allows users to efficiently apply filters to view the index location of document related activities within folders.

Users can access Document Reconciliation by selecting Documents in the left-side navigation pane. In the View Documents By section, users can choose a view based on their reconciliation requirements.

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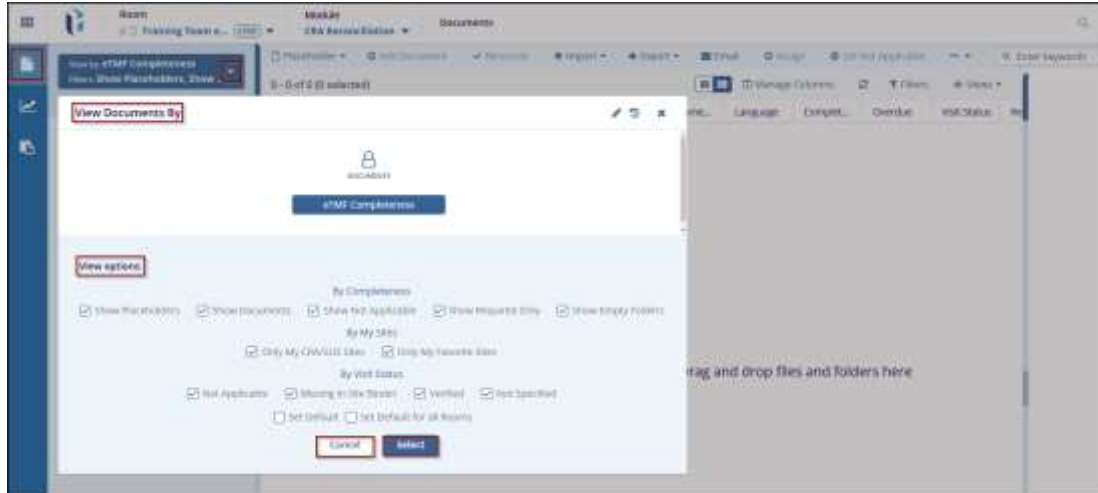
### View Documents By

In the View Documents By filter, users can select a view for a documents review based on requirements.

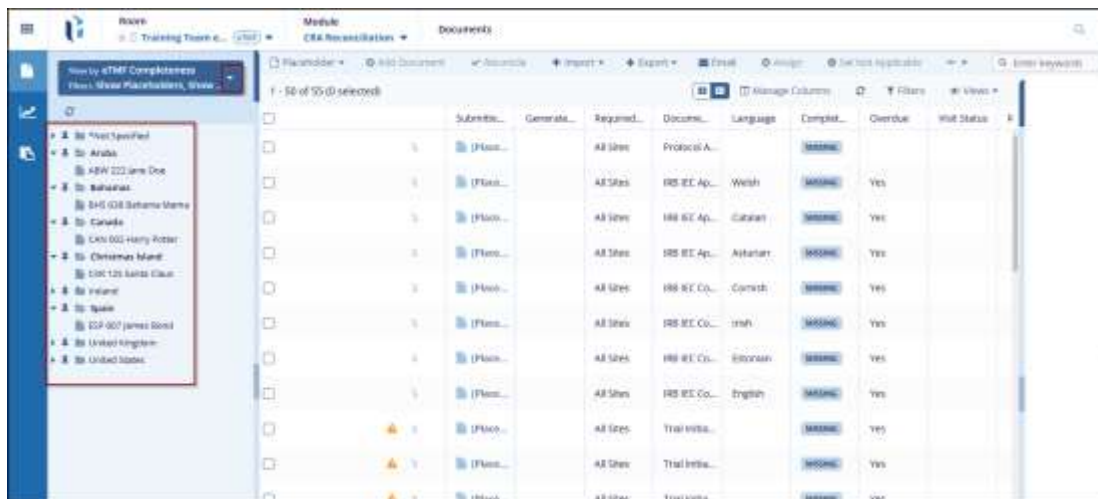
To apply View Documents By filter, follow these steps:

8. Navigate to the Documents section from the CRA Reconciliation module, at the top of the Index pane, click the View Document By dropdown menu.
9. This dropdown menu allows users to choose how they want to view the documents.
10. Select the available documents view: eTMF Completeness.
11. Based on user requirements, select one of the options from View options.
12. If the user needs to review, the user has the option to make their selection the default view:  
Set Default: this will set the selected view as the default for the current session.

Set Default for All Rooms: this will make the selection the default for all rooms, not just the current one.



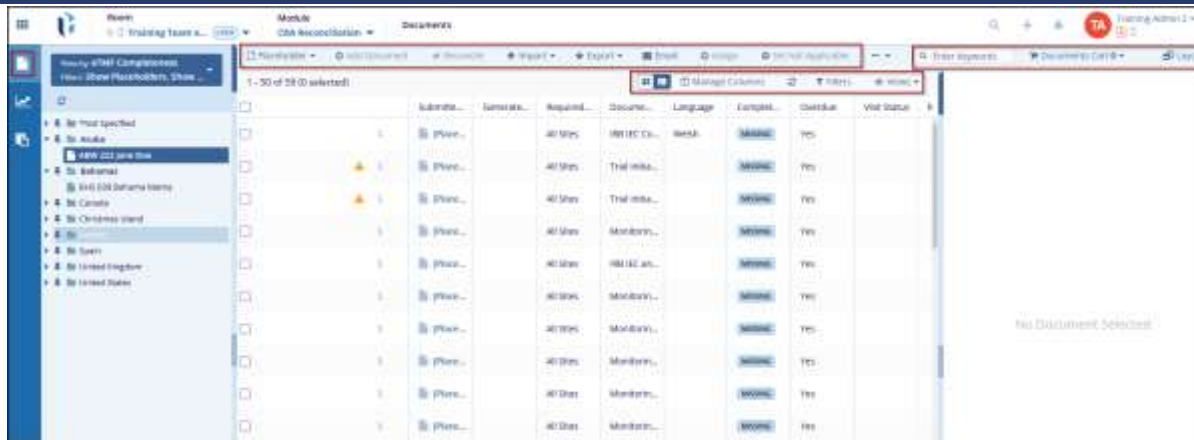
13. After selecting the view documents by options, click Select to apply the changes, these changes will reflect at the top of the Index pane, or click the Cancel button to discard the changes.
14. After applying the selection from View Document by options, the user can see the folder, based on the selections.



## CRA Reconciliation – Top Menu Ribbon

The top menu ribbon provides quick access to tools, that include Placeholder, Add Document, Reconcile, Set Not Applicable, Export, Assign, Document Cart, Layout, etc.

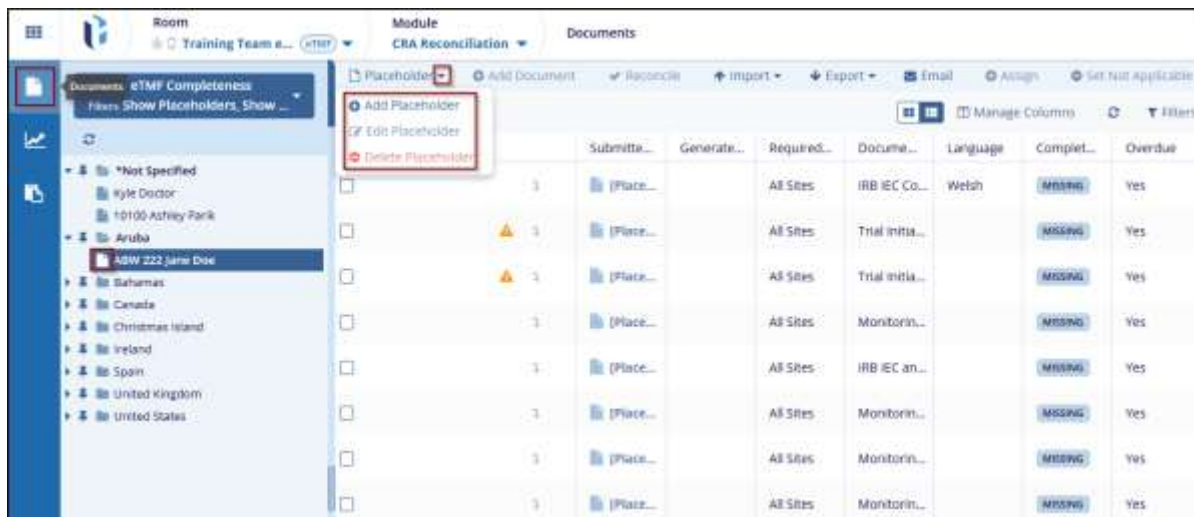




## Placeholder

A Placeholder is a reserved space within a document management system that indicates where a specific document needs to be added. It helps organize and track required documents by ensuring all necessary files are uploaded or linked appropriately.

This Include activities to Add, Edit and Delete Placeholder.

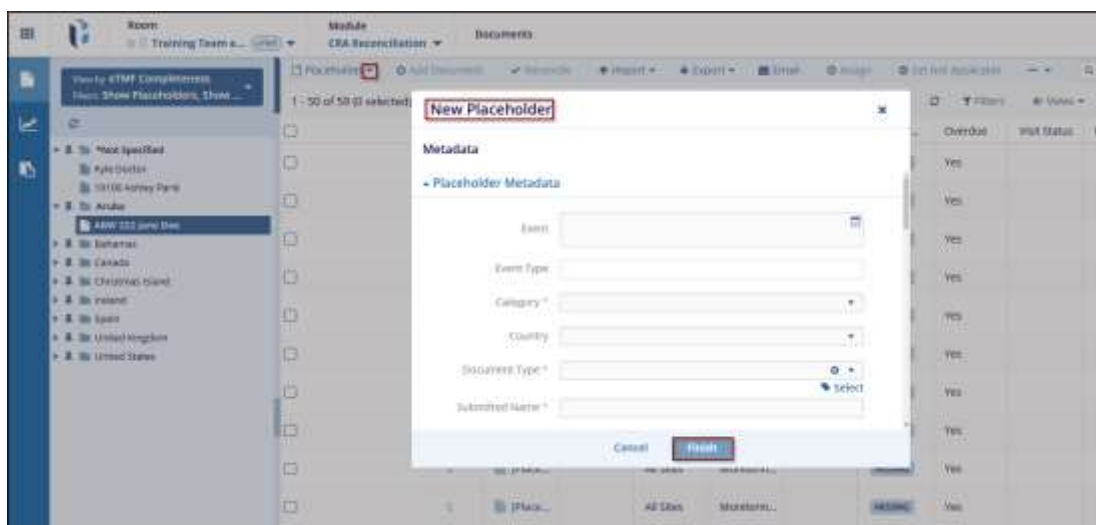


## Add Placeholder

Adding a placeholder creates a reserved space in the system for a document that needs to be uploaded. It helps users track required documents and ensure they are added at the appropriate time.

To Add Placeholder, follow these steps:

1. Click the Placeholder dropdown menu and select Add Placeholder.
2. A New Placeholder window will appear. Complete the required metadata fields for the placeholder.
3. Once metadata is filled, click the Finish button to apply the changes.

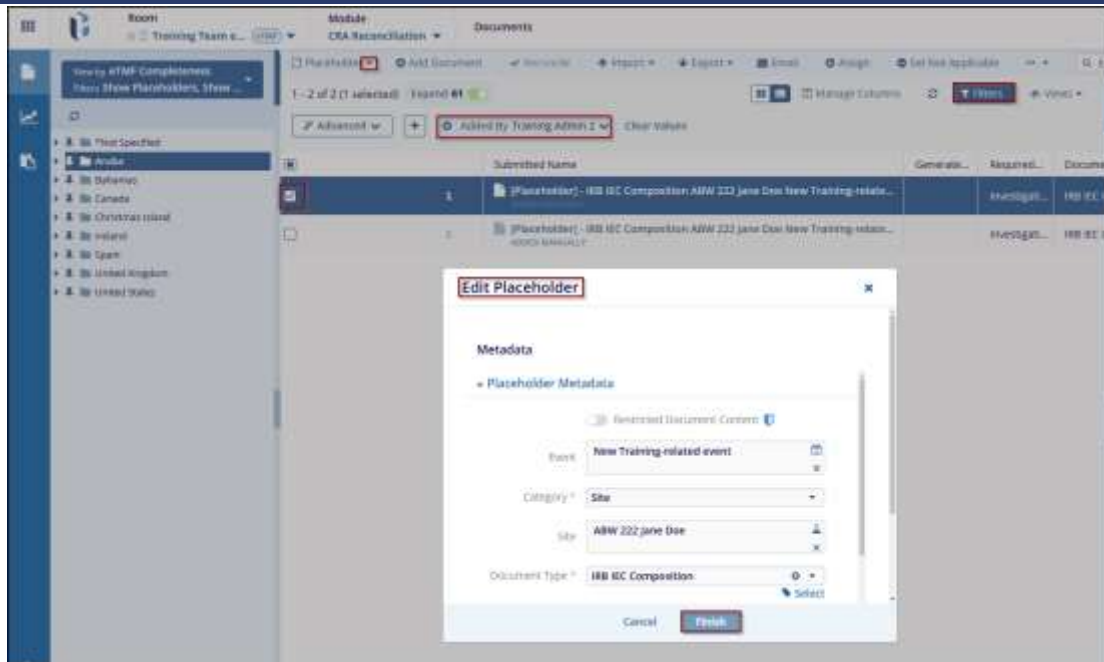


## Edit Placeholder

Editing a placeholder allows users to update its details, such as modifying the document name, category, or other attributes to reflect any changes in document requirements.

To Edit Placeholder, follow these steps:

1. Select the document from the grid, and the selected document's placeholder should be added by user.
2. Apply Filters: added by (User ID).
3. Click the Placeholder dropdown menu and select Edit Placeholder.
4. An Edit Placeholder window will appear, change the required metadata fields for the placeholder.
5. Once metadata is filled, click the Finish button to apply the changes.

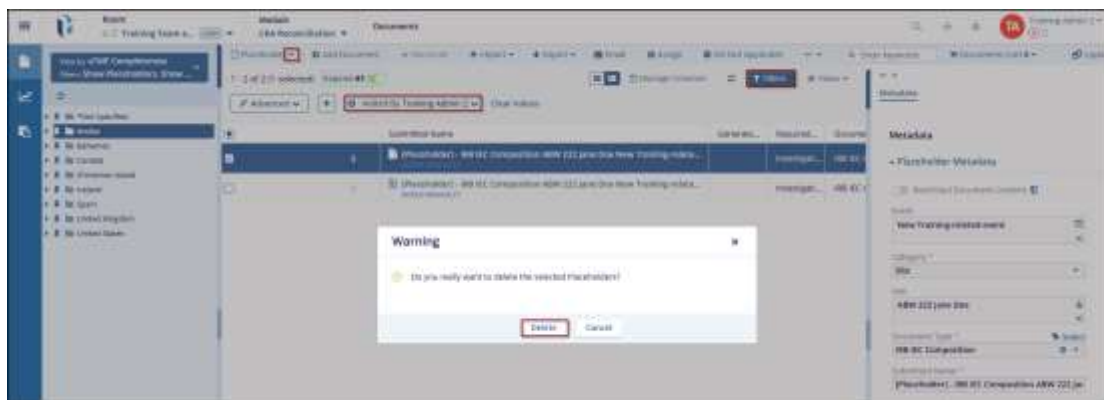


## Delete Placeholder

Deleting a placeholder removes the reserved space from the system, indicating that the document is no longer required or was added incorrectly. This action is irreversible and should be used with caution.

To Delete Placeholder, follow these steps:

1. Select the document from the grid, and the selected document's placeholder should be added by user.
2. Apply Filters: added by (User ID).
3. Click the Placeholder dropdown menu and select Delete Placeholder.
4. **A warning message window will open, with message 'Do you really want to delete the selected Placeholder'.**
5. Click the Delete button to remove selected placeholder from document.

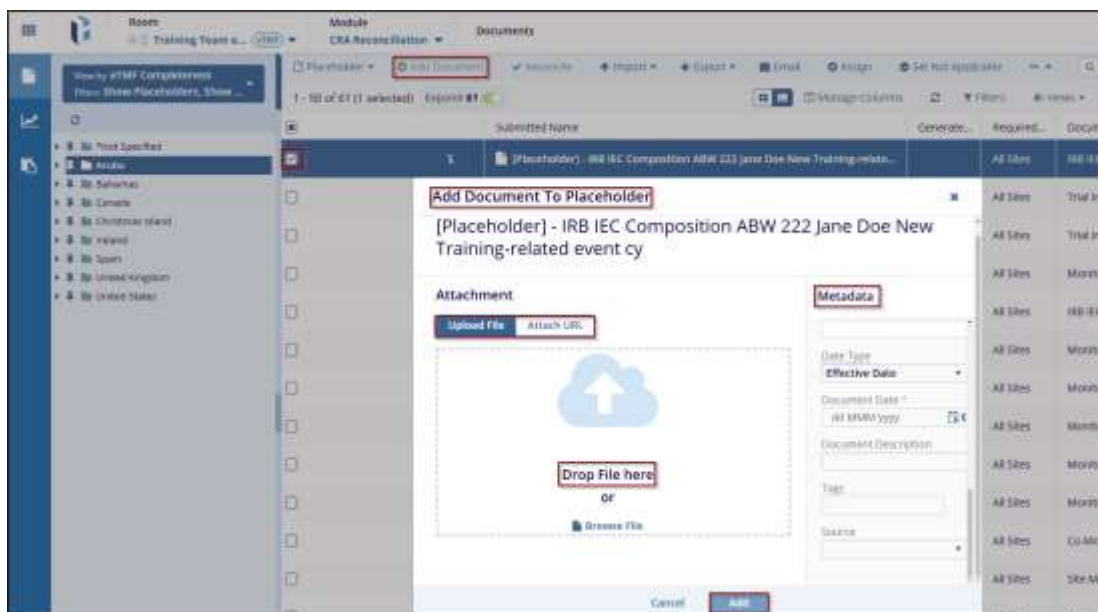


## Add Document to Placeholder

The Add Document refers to uploading a document or attaching a URL, such as an eTMF (Electronic Trial Master File) document. These documents may include queries, audits, or any other files that need to be added to placeholder.

To Add Document to Placeholder, follow these steps:

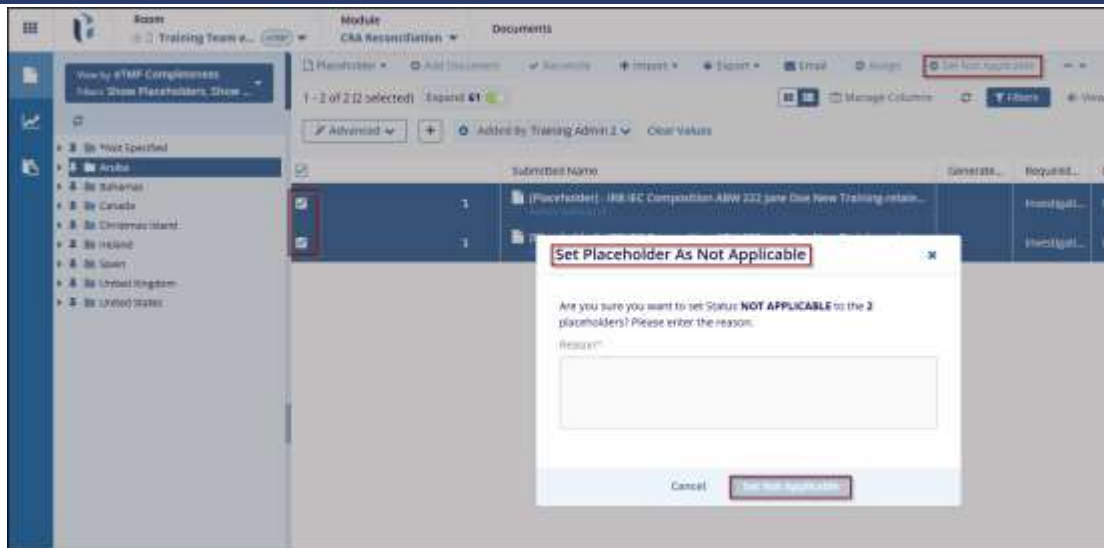
1. Click the Add Document button and a Add Document to Placeholder window will appear.
2. Upload file or Drag and Drop File in the pop-up window. Complete the required metadata fields to add document for the placeholder.
3. Once metadata is filled, click the Add button to apply the changes.



## Set Not Applicable

The Set Not Applicable refers to an option that allows users to mark a specific placeholder as not applicable to the selected document. This can help manage placeholders that are irrelevant for the selected document.

1. Click the Set Not Applicable button, and a Set Placeholder as Not Applicable window will appear.
2. Enter the specific reason to set the status not applicable for selected placeholder.
3. Click the Set Not Applicable button to apply the changes.



## Reconcile

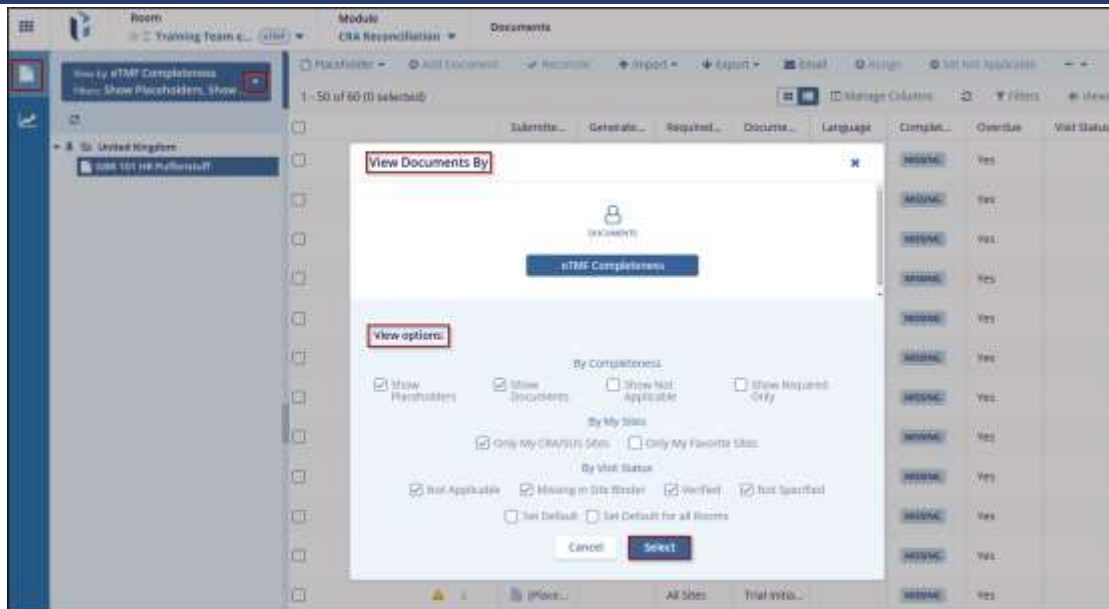
The Reconcile refers to the process of comparing and matching documents or data from different sources (e.g., eTMF and site binder) to ensure consistency and accuracy. It involves verifying that all necessary documents are in the correct locations. This is applicable to: Editor and Reader level.

Note: Users can accomplish this action only when their setup fulfills two conditions:

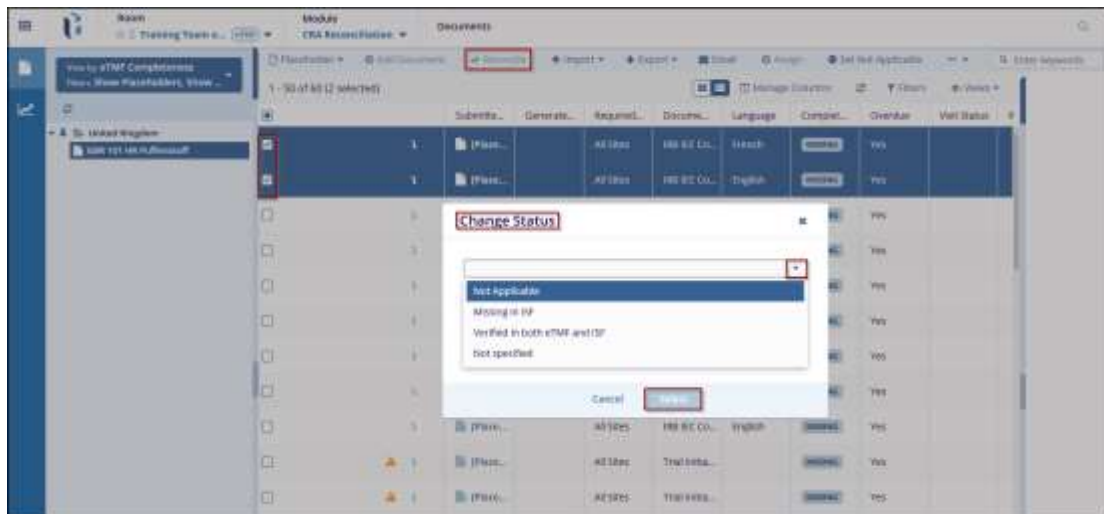
- The user is present in the CRA field within Site Details.
- The user has been endowed with the CRA Reconciliation action.

To Reconcile the document, follow these steps:

1. Navigate to the CRA Reconciliation Module via the Navigation Grid on the top left corner of the screen.
2. Click the View By dropdown setting, above the index panel.
3. Select the following option in the View Documents By window:
  - Show Placeholders
  - Show Documents
  - Only My CRA/SUS sites
  - By Visit Status
  - Not Applicable
  - Missing in Site Binder
  - Verified
  - Not Specified

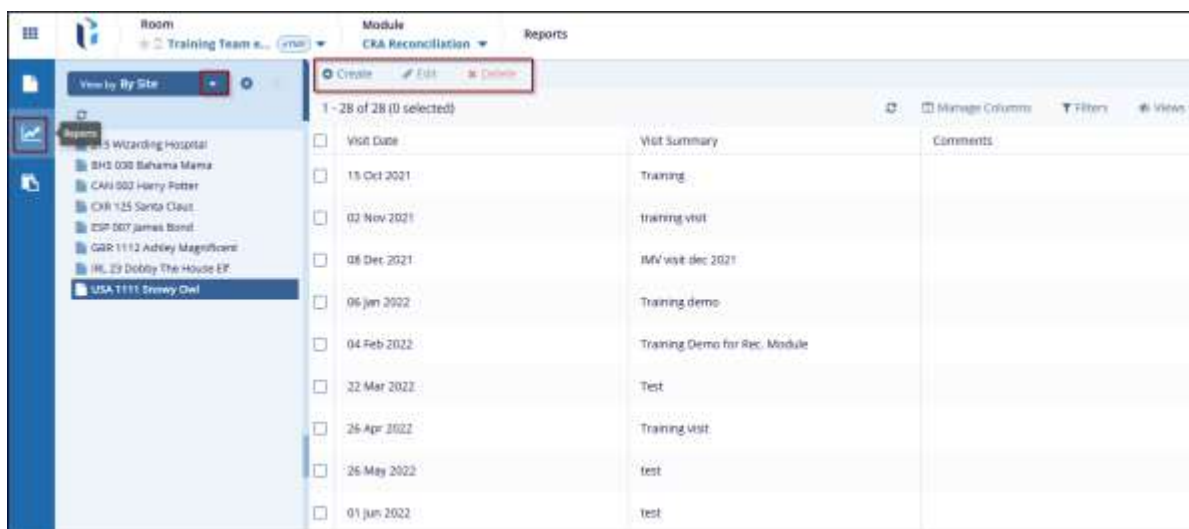


4. Drill down in the folders to locate the site to which the user has been assigned as a CRA.
5. Select a fulfilled placeholder from the list of documents.
6. Click the Reconcile button, available in top ribbon, this will open a new Change Status window.
7. Select the following option from the dropdown, such as: Not Applicable, Missing in ISF, Verified in both eTMF and ISF, Not specified
8. After selecting option, click the Select button to apply the changes.



## Reports Reconciliation

The Reports Reconciliation section provides details about CRA Reconciliation Reports, which help CRAs make informed decisions regarding site visits. CRAs must determine which documents need to be added to both the eTMF and site binder, which should be transferred from the eTMF to the site binder, and which need to be moved from the site binder to the eTMF. The Site Report provides this information, enabling CRAs to verify outstanding documents and ensure proper documentation during their next site visit.



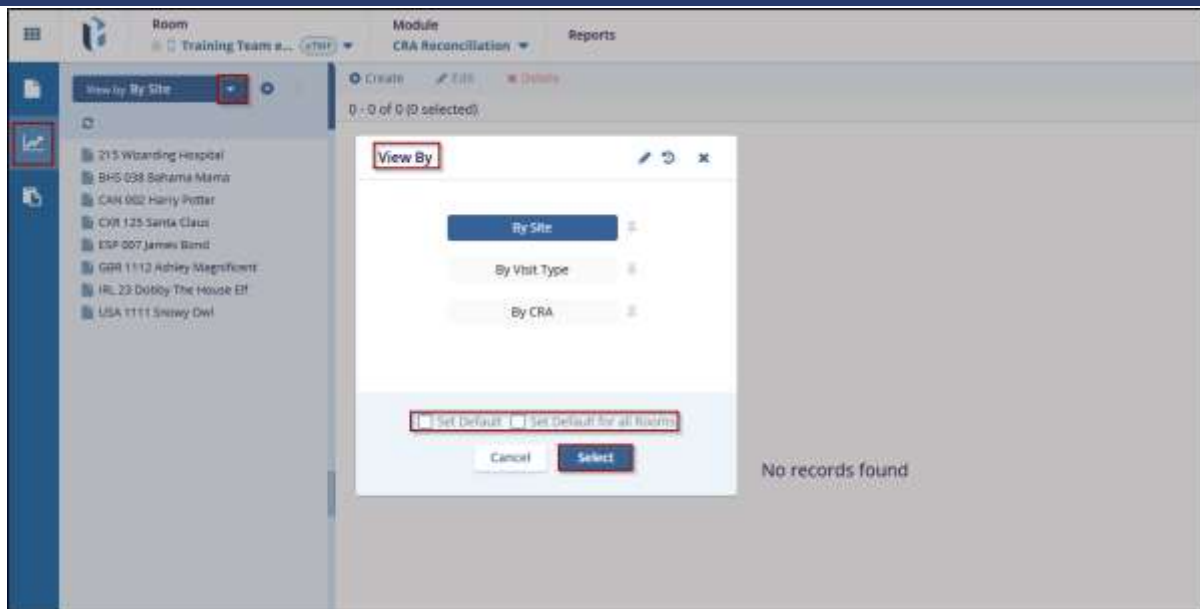
| Visit Date  | Visit Summary                 | Comments |
|-------------|-------------------------------|----------|
| 15 Oct 2021 | Training                      |          |
| 02 Nov 2021 | training visit                |          |
| 08 Dec 2021 | BMV visit dec 2021            |          |
| 06 Jan 2022 | Training demo                 |          |
| 04 Feb 2022 | Training Demo for Rec. Module |          |
| 22 Mar 2022 | Test                          |          |
| 26 Apr 2022 | Training visit                |          |
| 26 May 2022 | test                          |          |
| 01 Jun 2022 | test                          |          |

## Apply View By filter to Reports

The CRA TMF Reconciliation module serves as the repository for CRA TMF Reconciliation reports generated during site visits. Access this page from the Navigation Grid. Upon entering the reports area via the link on the left side of the screen, a list of reports will be displayed in the grid.

Users can choose to view the reports by Site, Visit Type, or CRA using the dropdown menu on the left. Clicking a report in the grid will populate the report information in the metadata panel on the right side of the screen. Additionally, users have the option to create, edit, or delete a CRA TMF Reconciliation Report using the Create, Edit, or Delete icons located in the top ribbon.

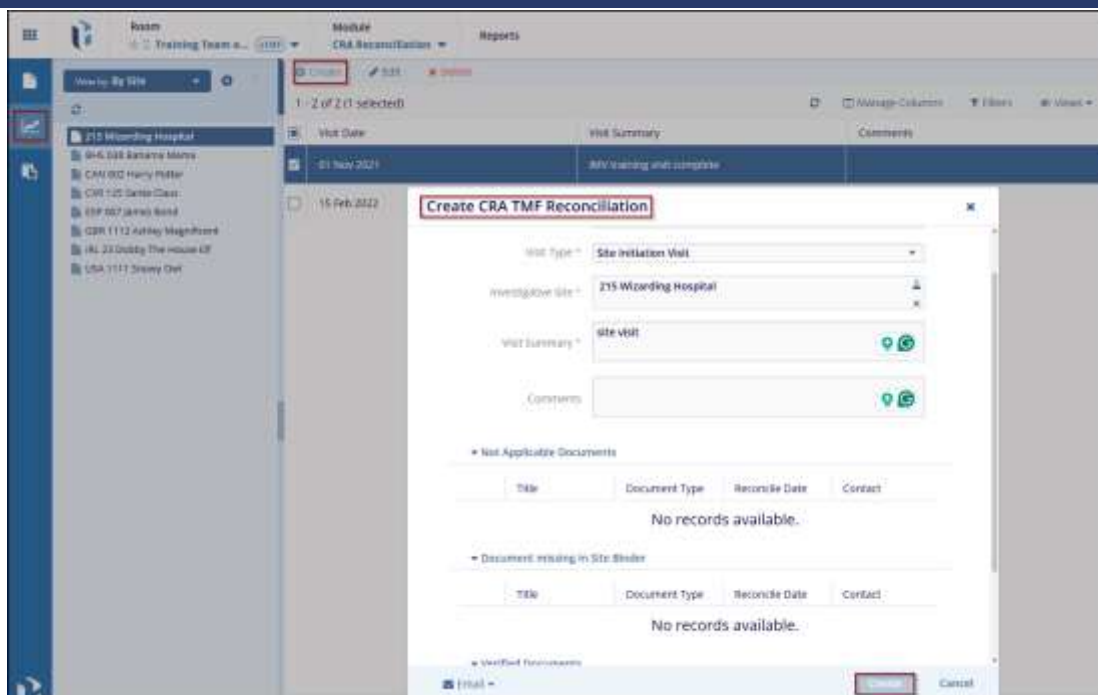




## Creating a CRA TMF Reconciliation Report

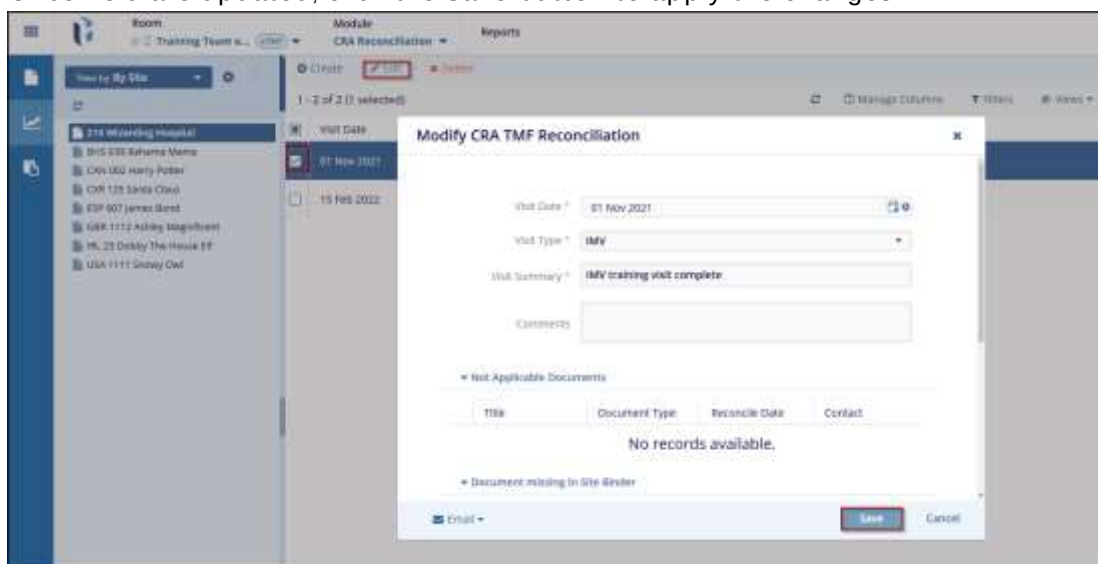
1. Select the appropriate filter from the View By dropdown. The relevant reports will then populate the grid.
2. Select the appropriate site and click Create button from the top ribbon.
3. A new Create CRA TMF Reconciliation window will open, Complete the required fields.
4. Fill in the appropriate details and click Create button to create a report.
5. User will receive a notification that the Site Report is created successfully. The report will then be displayed in the grid.





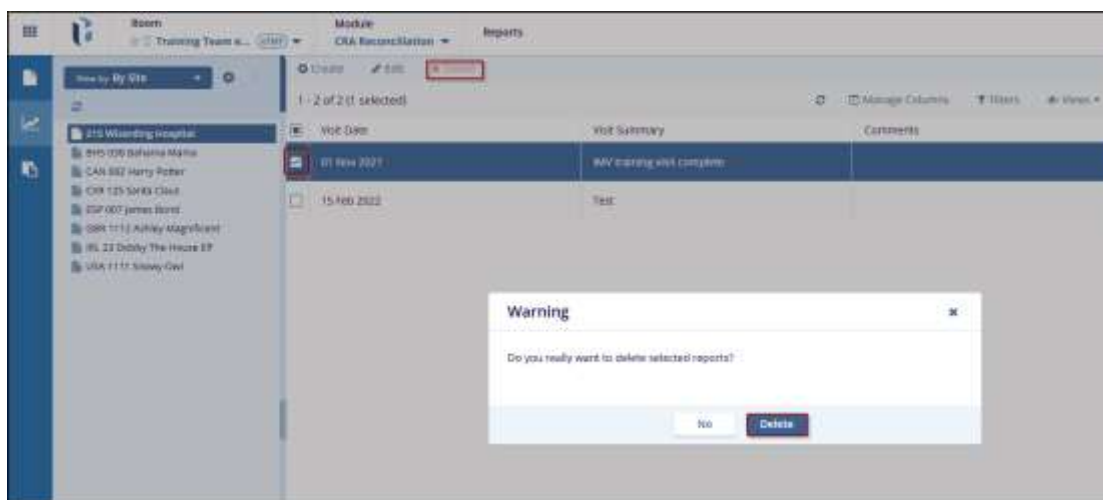
## Editing a CRA TMF Reconciliation Report

1. Select the required site from the Reports and click the Edit button on the top ribbon.
2. A new Modify CRA TMF Reconciliation window will open, Update or change the required fields.
3. Once field are updated, click the Save button to apply the changes.



## Deleting CRA TMF Reconciliation Report

1. Select the document from the grid, and click the Delete button on the top ribbon.
2. **A warning message window will open, with message 'Do you really want to delete the selected reports?'.**
3. Click the Delete button to remove selected placeholder from document.



## Audit Trail

An Audit Trail is a security-relevant chronological set and source of records that provide evidence of the sequence of activities performed over a document. The changes made in a document by all users are displayed within the Audit Trail.

Users can access the Audit Trail by selecting it from the menu bar on the left-side of navigation pane.

Refer to the Audit Trail from the eTMF Module for a more detailed description of these options.

**Note:** By default, the audit trails grid pane is empty, and the documents are displayed only after entering and applying certain parameters and criteria.

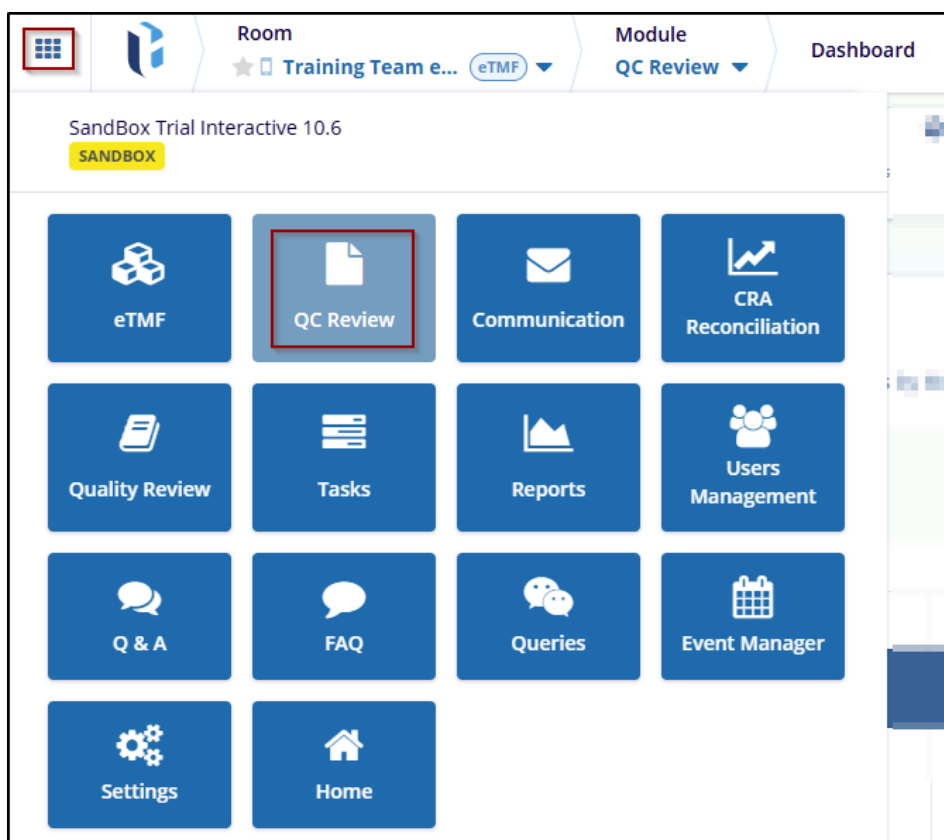
The screenshot shows the 'Audit Trail' section of the 'Training Team' module. The interface includes a header with navigation links and a search bar. Below the header, there's a filter section with 'Activity Type' set to 'Document' and a date range from '04 Aug 2024' to '02 Dec 2024'. The main table displays 10 rows of document updates. The columns are: Activity Date, Created By, Document ID, Document Name, Index Path, Activity Type, and Activity Related Data. The table lists updates for CTAs and Confidentiality Agreements, all created by 'l@thugugan.com' on 03 Dec 2024. The activity type is 'Metadata Update' for all entries. The activity related data includes 'Is Signed', 'Is Portfolio', 'Is Password Protected', and 'Has Recognized Text'.

| Activity Date | Created By     | Document ID | Document Name                 | Index Path                     | Activity Type   | Activity Related Data                   |
|---------------|----------------|-------------|-------------------------------|--------------------------------|-----------------|-----------------------------------------|
| 03 Dec 2024   | l@thugugan.com | 207566      | CTA                           | *uploaded Documents\Editor_107 | Metadata Update | Is Signed, old: "", new: ""             |
| 03 Dec 2024   | l@thugugan.com | 207566      | CTA                           | *uploaded Documents\Editor_107 | Metadata Update | Is Portfolio, old: "", new: ""          |
| 03 Dec 2024   | l@thugugan.com | 207566      | CTA                           | *uploaded Documents\Editor_107 | Metadata Update | Is Password Protected, old: "", new: "" |
| 03 Dec 2024   | l@thugugan.com | 207566      | CTA                           | *uploaded Documents\Editor_107 | Metadata Update | Has Recognized Text, old: "", new: ""   |
| 03 Dec 2024   | l@thugugan.com | 207566      | Confidentiality Agreement.pdf | *uploaded Documents\Editor_107 | Metadata Update | Is Signed, old: "", new: ""             |
| 03 Dec 2024   | l@thugugan.com | 207566      | Confidentiality Agreement.pdf | *uploaded Documents\Editor_107 | Metadata Update | Is Portfolio, old: "", new: ""          |
| 03 Dec 2024   | l@thugugan.com | 207566      | Confidentiality Agreement.pdf | *uploaded Documents\Editor_107 | Metadata Update | Is Password Protected, old: "", new: "" |
| 03 Dec 2024   | l@thugugan.com | 207566      | Confidentiality Agreement.pdf | *uploaded Documents\Editor_107 | Metadata Update | Has Recognized Text, old: "", new: ""   |
| 03 Dec 2024   | l@thugugan.com | 207566      | Confidentiality Agreement.pdf | *uploaded Documents\Editor_107 | Metadata Update | Is Signed, old: "", new: ""             |
| 03 Dec 2024   | l@thugugan.com | 207566      | Contact Details_L10           | *uploaded Documents\Editor_107 | Metadata Update | Is Signed, old: "", new: ""             |

## CHAPTER 13. QUALITY CONTROL

Quality control will primarily focus on workflows related to eTMF rooms. However, similar processes are also used across various TI Content Management room types. eTMF rooms typically follow a standardized one- or two-step QC review workflow, whereas Content Management rooms may involve multiple workflows based on site, sponsor, or other SOP requirements.

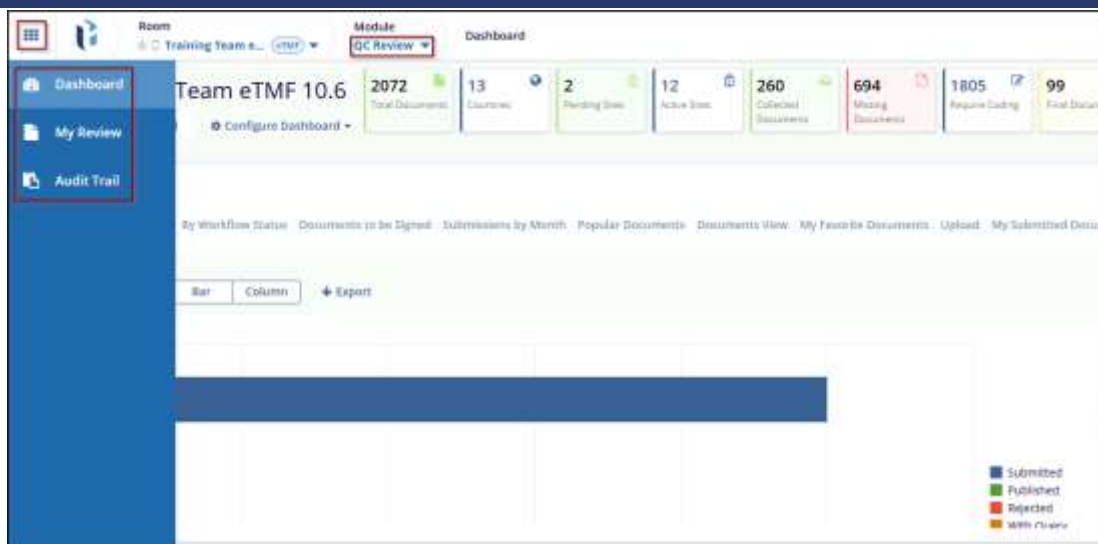
Due to potential challenges in designing and implementing workflows, its recommended to collaborate with the TI Support Desk regarding workflows. Workflows are created and managed in the Settings area of Trial Interactive. For more details, please refer to that section.



Navigate to the Quality Control Review module from the navigation grid.

Once the user accesses the Quality Control Review module, the user can see the tools bar available in the vertical menu at the left side of the screen, such as:

- **Dashboard:** The Dashboard is often the first screen users see and helps to navigate efficiently to various areas based on role.
- **My Review:** It allow users to claim, review, and finalize documents according to predefined workflows.
- **Audit Trail:** The section that tracks all actions taken during the review process.



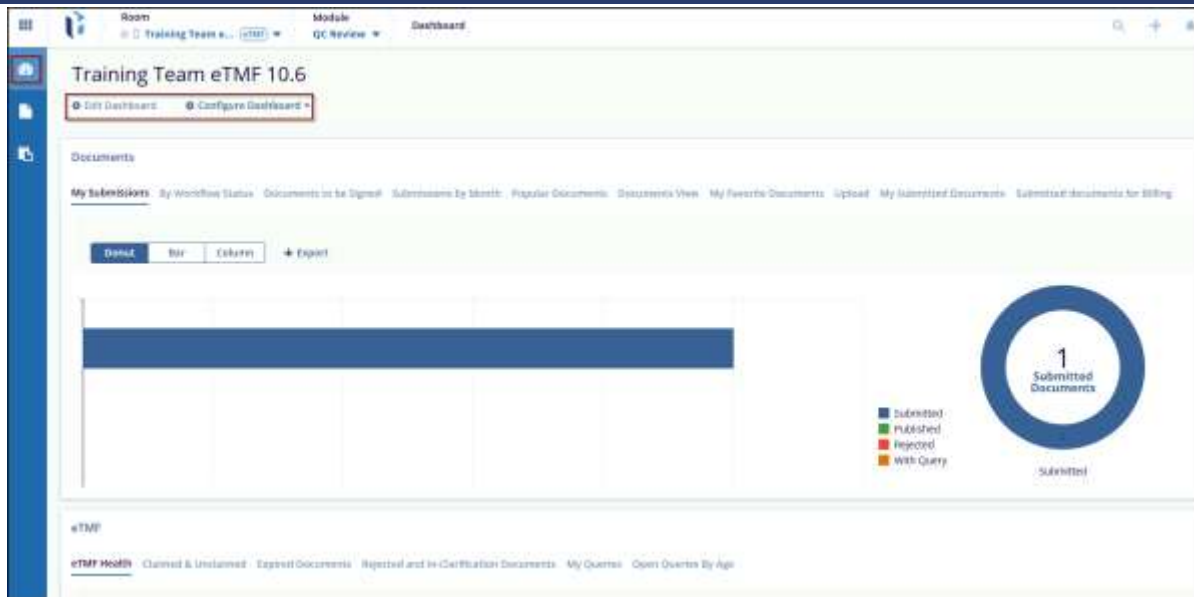
## Dashboard

The Dashboard allows users to customize their workspace by adding, removing, or rearranging tabs based on user preferences. Administrator-level users can configure default dashboards for users according to the user access levels. Unless restricted, users can modify their dashboards to suit the user's needs.

The dashboard includes the following edit options:

- **Edit Dashboard:** The Edit Dashboard allows users to customize the dashboard by adding or removing tabs, reorganizing layout options, and customizing the dashboard to show the information that is most important to the user. It ensures a personalized view for better accessibility of required data.
- **Configure Dashboard:** The Configure Dashboard helps the user to arrange the dashboard as required based on the role.

Refer to the Dashboard from the eTMF Module for a more detailed description of these options.



## My Review

My Review provides an overview of documents assigned to user within the 2-Step Workflow. It helps track the status of documents, manage reviews, and take action.

Editor, manager, and administrator level users can perform Quality Control Review, while reader level users cannot.

To participate in the quality control workflow, a user must be assigned to at least one QC-related group in the User Management area. For details on adding users to a group, refer to the relevant section of this guide.

In Content Management rooms, a user's group is typically based on their job function. The corresponding department or group is then selected for inclusion in the approval workflow. For more information on approving a document in a collaborative room, see the section on versioning a controlled document.

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## Claiming a Document

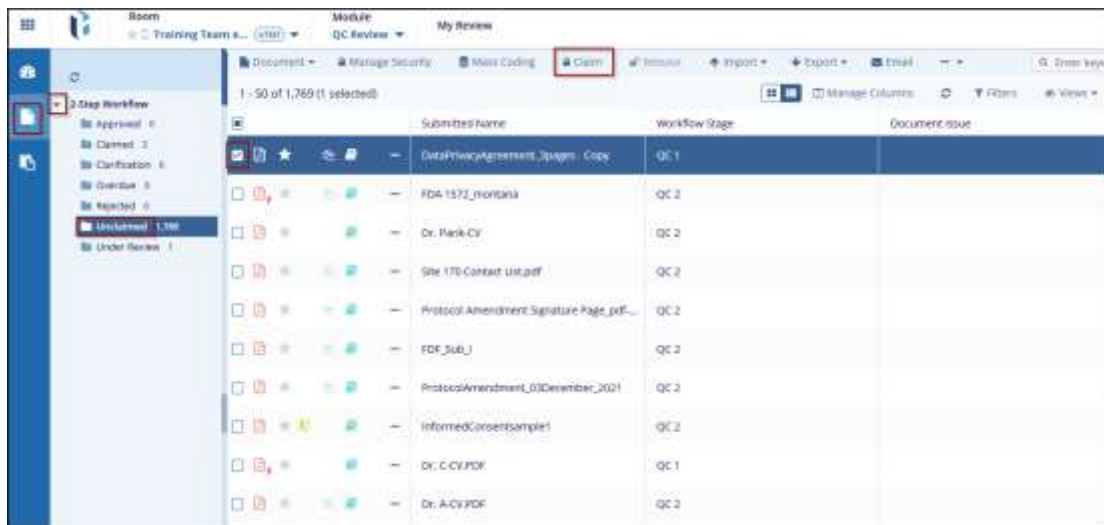
Once a user has been added to a QC workflow, the first step is to claim a document for review. The user must first claim the document because all newly added documents come into the workflow in a pool of documents normally referred to Review or Unclaimed.

To claim a document for review, please follow these steps:

1. Navigate to the My Review section available in the vertical menu at the left side of the screen.
2. Click the 2-Step Workflow dropdown menu above the index pane. This will display the folder with status.
3. Select the Unclaimed folder, the documents grid will populate with a list of documents that could potentially be claimed by the user. The list of documents may not be the

same for any two users depending upon what step of the workflow they are assigned to or not they have already reviewed the document.

4. Users who have reviewed a document in step 1 of a multi-step QC workflow will not be able to claim the document in any later step.
5. Check the checkbox of the documents to be claimed, the user could claim one document at a time but selecting multiple documents is far more efficient.
6. Click the Claim button available in the top menu.



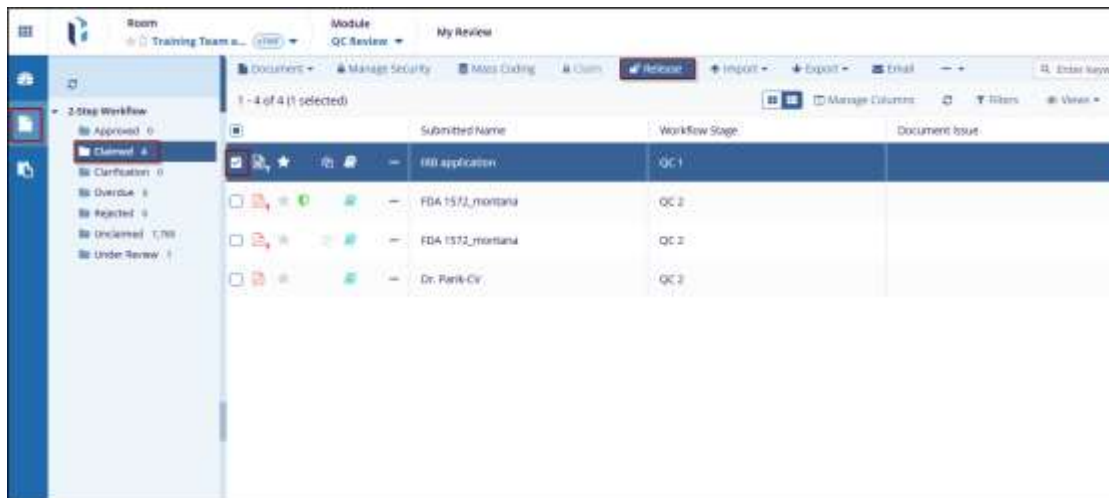
7. Once the documents have been claimed, they are moved to the Claimed folder and are no longer available in the current folder.

## Releasing a Claimed Document

A user will have claimed documents that need to be returned to the pool of available for Review documents so that someone else may claim them for review.

To release the claimed documents, follow these steps:

1. Navigate to the My Review section available in the vertical menu at the left side of the screen.
2. Click the 2-Step Workflow dropdown menu above the index pane. This will display the folder with status.
3. Click on the Claimed folder, all of the documents are currently claimed will populate the grid.
4. Check the checkbox to indicate which documents should be released.
5. Click the Release button above the grid.
6. Once released, the documents will be removed from Claimed folder and returned to the Unclaimed folder.
7. Alternately, this may be done by a room administrator using the three-dot menu at the top-right of the metadata pane.



## Reviewing a Document

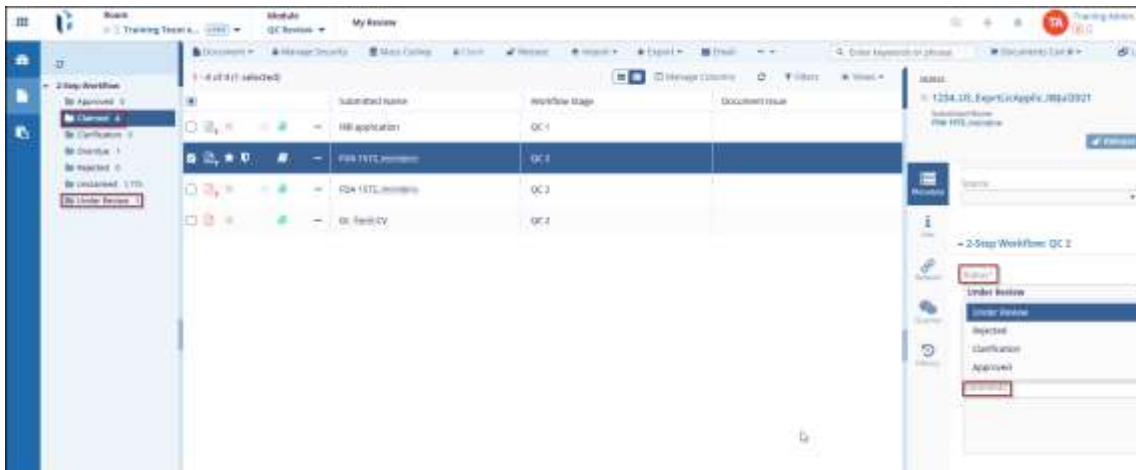
Once a document has been claimed, the reviewer must check it against quality control guidelines, apply necessary metadata, and determine whether to approve or reject it. QC reviewers can also launch a query for assistance with reviewing a document. For more details on launching a QC Workflow Query, see the Queries module.

To review a document and assign a status to it, follow the steps below:

1. Navigate to the My Review section available in the vertical menu at the left side of the screen.
2. Click the 2-Step Workflow dropdown menu above the index pane. This will display the folder with status.
3. Locate the document in Claimed folder. If the document has not been claimed, please see the section on Claiming a Document.
4. Check the checkbox and open the document and review it according to any established guidelines for the document type.
5. If the document is in good order and can be accepted, review the metadata associated with the document and make any corrections or fill in any required fields.
6. At the right side of the screen, in the metadata panel, there is a workflow status area. This section is named for the workflow QC1.
7. Assign the appropriate status to the document, such as:
  - a. **Approved:** This indicates that the document is correct and that it can either move on to the next step of the workflow or, if appropriate, be published as Final to the rooms index.
  - b. **Under review:** This status indicates that the document is currently being evaluated by the designated reviewer. The document cannot proceed to the next step until the review is completed and the necessary actions are taken.

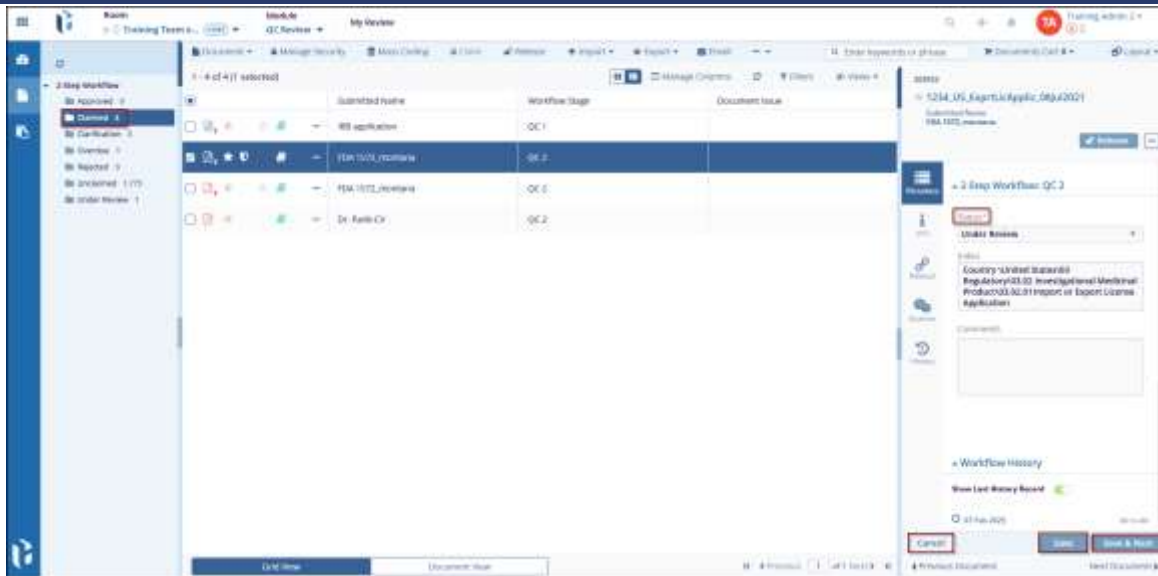


- c. **Rejected:** This indicates that the document has some feature that is incorrect and which will need to be rectified before the document is accepted into the rooms index as Final.
  - If this value is selected, the user does not need to fill in all of the metadata first.
  - Also, if this value is selected, the user will be required to indicate a reason why the document was rejected. The list of available issues is created along with the workflow and so may not contain exactly what is needed. It is strongly recommended to provide a comment in the box below to clarify the reason for rejection of the document.
  - Depending upon internal process requirements, the user may be asked to send the submitter a notification that their document has been rejected. For additional steps on how to do that, see the section below.
- d. **Clarification:** This indicates that the QC Workflow reviewer the user has a question about a document.
  - If this option is selected, the user will also need to indicate the reason for the inquiry (issue). The list of available issues is created along with the workflow and so may not contain exactly what is needed. It is strongly recommended that also provide a comment in the box below to clarify the reason for inquiry regarding the document.
  - The status indicates that the reviewer intends to launch a query. For more information regarding that process, please see the chapter on Queries.



Note: The available statuses are assigned when the workflow is created and may vary from those.

8. Once the appropriate status has been assigned, press Save or Save & Next.



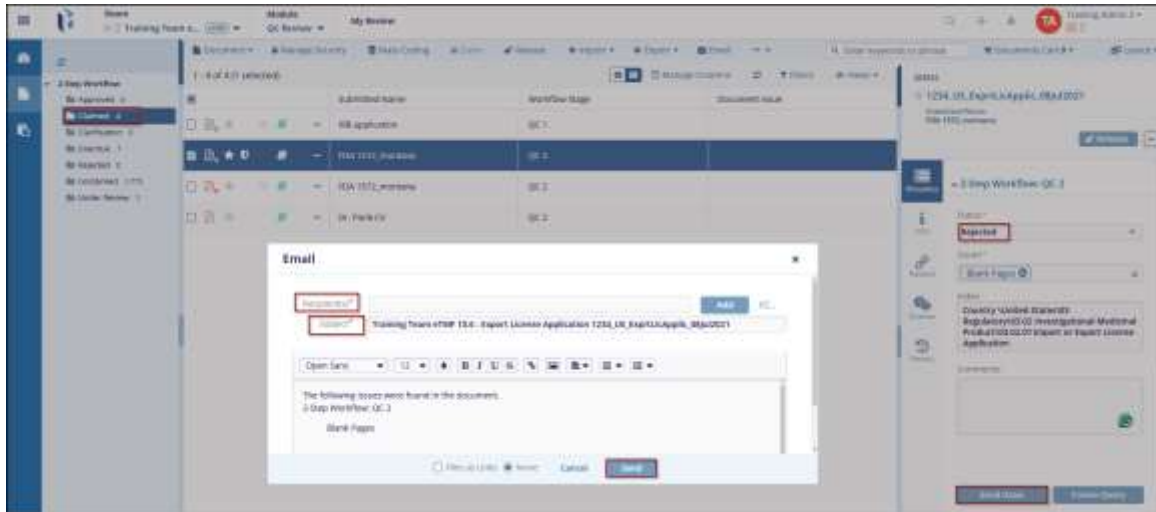
## Sending a Rejection Notification

The notification should include the reason for rejection, any necessary corrective actions, and instructions for resubmission if applicable. The format and method of notification (email, system alert, or both) should align with the organization's SOP requirements.

To send a rejection notification, follow these steps:

1. Navigate to the My Review section available in the vertical menu at the left side of the screen.
2. Click the 2-Step Workflow dropdown menu above the index pane. This will display the folder with status.
3. Locate the document in Claimed folder. If the document has not been claimed, please see the section on Claiming a Document.
4. Check the checkbox and open the document and review it according to any established guidelines for the document type.
5. If the document is in good order and can be accepted, review the metadata associated with the document and make any corrections or fill in any required fields.
6. At the right side of the screen, in the metadata panel, there is a workflow status area. This section is named for the workflow QC1.
7. Select the status: Rejected.
8. Below the workflow comments box are two buttons Send Issue and Create Query. Once the status has been assigned and the issues have been noted in the comments, press the Send Issue button, this will open an email window.
9. The submitter of the document is populated by default in the Recipients area. Add any additional recipients as appropriate.

10. The text that populates comes from both a standard email template and from any comments/issues indicated, make any necessary additions or changes to the displayed text.
11. Indicate, using the radio buttons at the lower left whether or not the document should be supplied to the recipient and, if so, in what manner.
12. Click the Save button to save these changes.

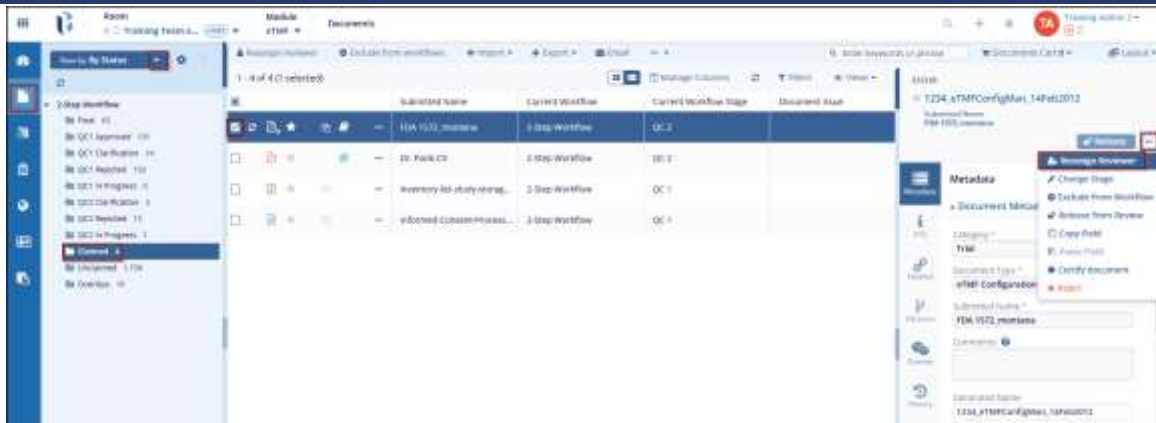


## Reassigning a Reviewer

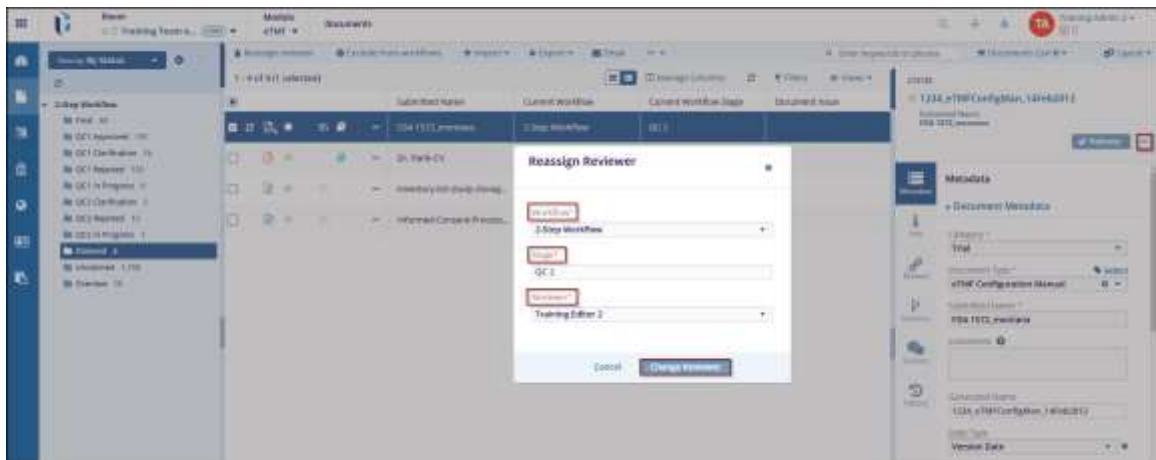
The process of changing the assigned reviewer of a document to another qualified individual. Occasionally, a room administrator may need to reassign a document reviewer.

To reassign a reviewer, follow the steps below:

1. Navigate to the Document section from the eTMF module, which is available in the vertical menu at the left side of the screen.
2. Select the By Status view from the dropdown menu above the index pane.
3. Select the from the 2-Step Workflow dropdown menu above the index pane.
4. Select the Claimed folder from the index pane.
5. Locate the document that needs to be reassigned. If necessary, expand the metadata pane.



6. Click the three-dot dropdown menu at the top-right of the metadata pane.
7. Click the Reassign Reviewer, the Reassign Reviewer window will open.
8. Choose the appropriate reviewer and click the Change Reviewer button.

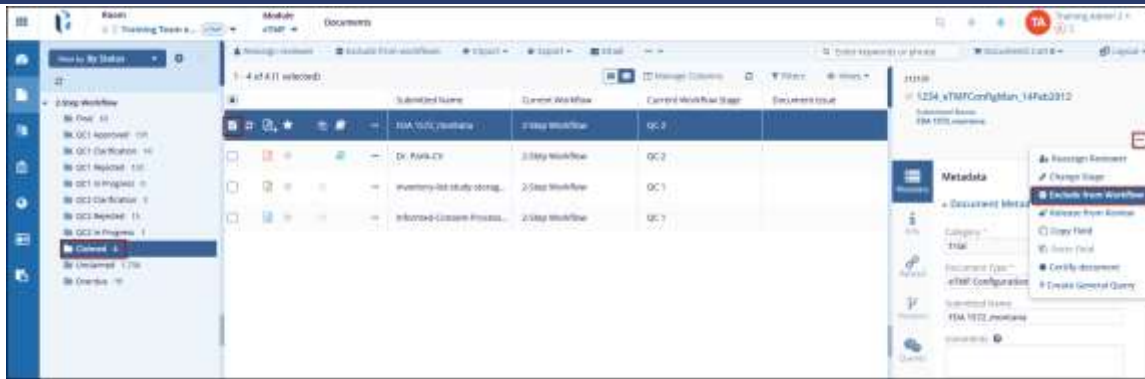


## Excluding a document from the Workflow

The process of manually removing a document from a predefined workflow, preventing it from progressing through review or approval.

To Exclude a document from the workflow, follow these steps:

1. Locate the document in Claimed folder. If the document has not been claimed, please see the section on Claiming a Document.
2. Check the checkbox and open the document and review it according to any established guidelines for the document type.
3. Using the three-dot menu at the top of the metadata pane, choose Exclude from Workflow. This will cause the Exclude document from Workflow window will open.



4. Enter the reason for the exclusion.
5. Click the Exclude button to make the changes.



## Audit Trail

An Audit Trail is a security-relevant chronological set and source of records that provide evidence of the sequence of activities performed over a document. The changes made in a document by all users are displayed within the Audit Trail.

Users can access the Audit Trail by selecting it from the menu bar on the left-side of navigation pane.

Refer to the Audit Trail from the eTMF Module for a more detailed description of these options.

Note: By default, the audit trail's grid pane is empty, and the documents are displayed only after entering and applying certain parameters and criteria.



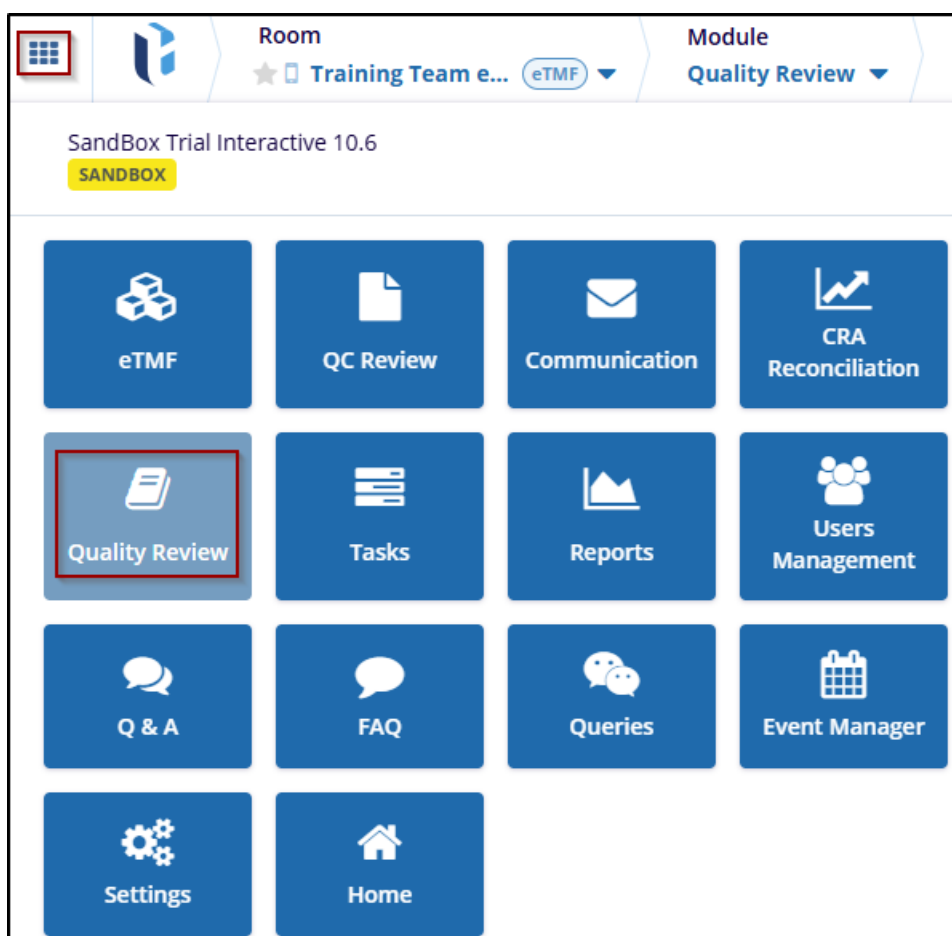
The screenshot displays the 'Audit Trail' section of the 'Training Admin 2' application. The interface includes a top navigation bar with the application name and a sidebar with a search icon. The main content area shows a table of audit trail records. The table has 7 columns: 'Activity Date', 'Created By', 'Document ID', 'Document Name', 'Action Path', 'Activity Type', and 'Activity Related Data'. There are 7 rows of data, all showing activities on '31 Jan 2023' created by 'Training Admin 2'. The document IDs are 800081, 202291, 202291, 202574, 202572, 202291, and 202291. The document names are 'TrainingAdminFormforIP', 'RCV.pdf', 'RCV.pdf', 'SCIS\_DualSubACV', 'SCIS\_DualSubACV', 'RCV.pdf', and 'PreTaskMonitoringReport.pdf'. The action paths are all 'Staging', and the activity types are all 'Open Document Metadata'. The activity related data is empty for all rows.

| Activity Date | Created By       | Document ID | Document Name               | Action Path | Activity Type          | Activity Related Data |
|---------------|------------------|-------------|-----------------------------|-------------|------------------------|-----------------------|
| 31 Jan 2023   | Training Admin 2 | 800081      | TrainingAdminFormforIP      | Staging     | Open Document Metadata |                       |
| 31 Jan 2023   | Training Admin 2 | 202291      | RCV.pdf                     | Staging     | Open Document Metadata |                       |
| 31 Jan 2023   | Training Admin 2 | 202291      | RCV.pdf                     | Staging     | Open Document Metadata |                       |
| 31 Jan 2023   | Training Admin 2 | 202574      | SCIS_DualSubACV             | Staging     | Open Document Metadata |                       |
| 31 Jan 2023   | Training Admin 2 | 202572      | SCIS_DualSubACV             | Staging     | Open Document Metadata |                       |
| 31 Jan 2023   | Training Admin 2 | 202291      | RCV.pdf                     | Staging     | Open Document Metadata |                       |
| 31 Jan 2023   | Training Admin 2 | 202291      | PreTaskMonitoringReport.pdf | Staging     | Open Document Metadata |                       |

## CHAPTER 14. QUALITY REVIEW

The Quality Review module of Trial Interactive is used in different ways based on individual study needs and internal SOP requirements. However, its most common use is for post-QC reviews to ensure the quality and accuracy of documents. These audits can be conducted internally or set up for external auditors or inspectors to review the study room. If an external auditor is conducting the review, the user may need to give them access as a Regulatory Agency Inspector to ensure that they receive proper training within a limited timeframe. For more details on User Management, view the relevant section in the user guide.

The Quality Review tile can be viewed by the room administrators. The Audit Responders make the corrections in the document within the Documents module and should not be able to view the quality review tile unless they hold either an Auditor or Audit Manager role for the tile to be visible.

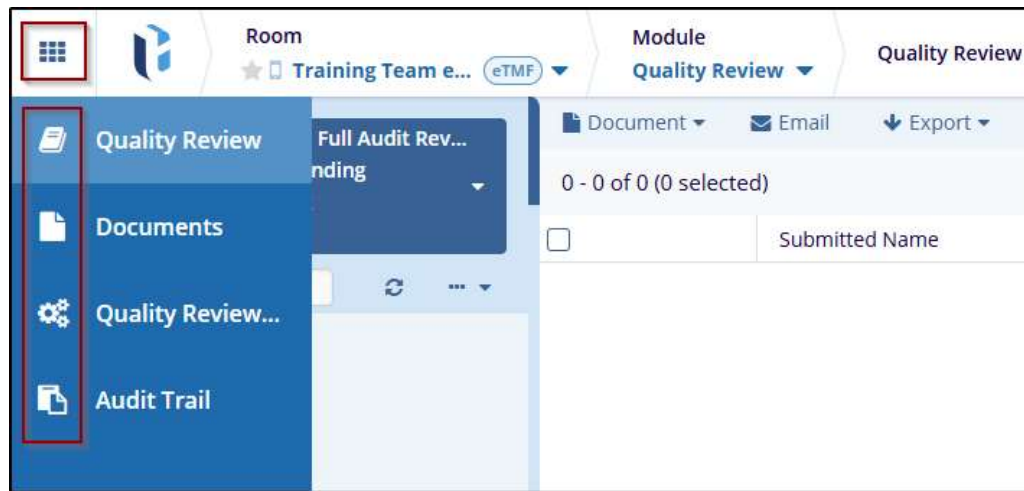


To perform the quality review, follow these steps:

1. Navigate to the Quality Review module from the navigation grid.
2. Ensure the user has the necessary permissions (Auditor or Audit Manager role) to access the Quality Review tile.



3. Once the user accesses the Quality Review module, the user can see the tools bar available in the vertical menu at the left side of the screen.
  - Quality Review: The section where you perform the actual document review.
  - Documents: The section used to manage and correct documents allows the user to search for documents within the index.
  - Quality Review Settings: The section for configuring settings related to the review process.
  - Audit Trail: The section that tracks all actions taken during the review process.



Note: If the user is assigned as an Auditor or Audit Manager in the trial room, the Quality Review is available in the Navigation Grid at the top left of the screen.

## Quality Review

The Quality Review section is used to review, and correct study-related documents. The Readers, Editors, and Managers can see audits they are part of as an Auditor or Audit Manager while Administrators can view all audits. The module allows users to track, comment on, and approve or reject documents to ensure accuracy, quality, and regulatory compliance.

### Choose View By

In the Choose View By section, users can select a view for a quality review based on requirements.

#### Documents:

- Index: Allows users to view or filter documents included in the index folder.
- Document Type: Provides the option to view documents by their type (e.g., Trial, Country, Sites, etc.).
- Country: Allows users to filter documents based on the country associated with them.

#### Queries:

- Query By Sender: This enables users to view queries based on who sent them.
- Query By Recipient: Allows filtering of queries based on the recipient.

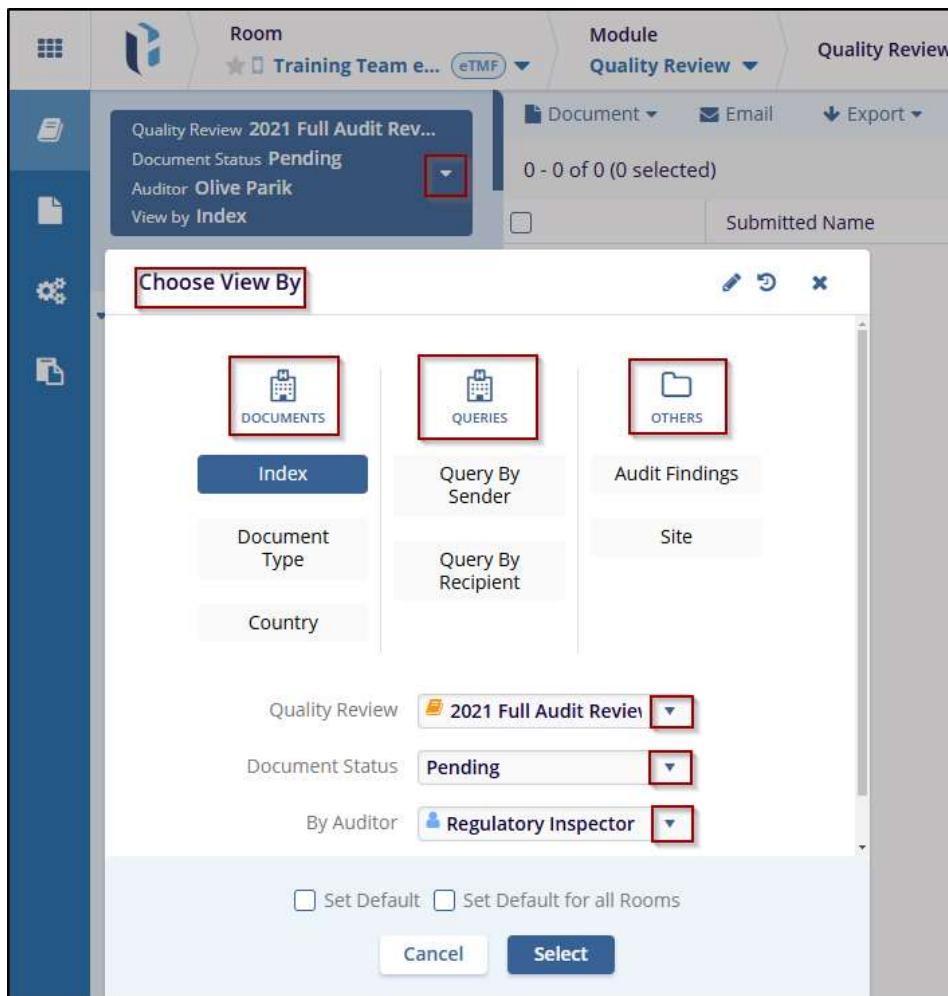


#### Others:

- **Audit Findings:** This option is likely for viewing documents or queries related to audit results or findings.
- **Site:** Filters content Based on the associated site (possibly for multiple site-based documents or records).

#### Additional filters:

- **Quality Review:** A dropdown for selecting the quality review file.
- **Document Status:** A dropdown for selecting the status of the document.
- **By Auditor:** A dropdown allows the selection of an auditor.
- **Set Default:** This will set the selected view as the default for the current session.
- **Set Default for All Rooms:** This will set the selected view as the default for all rooms, not just the current room.

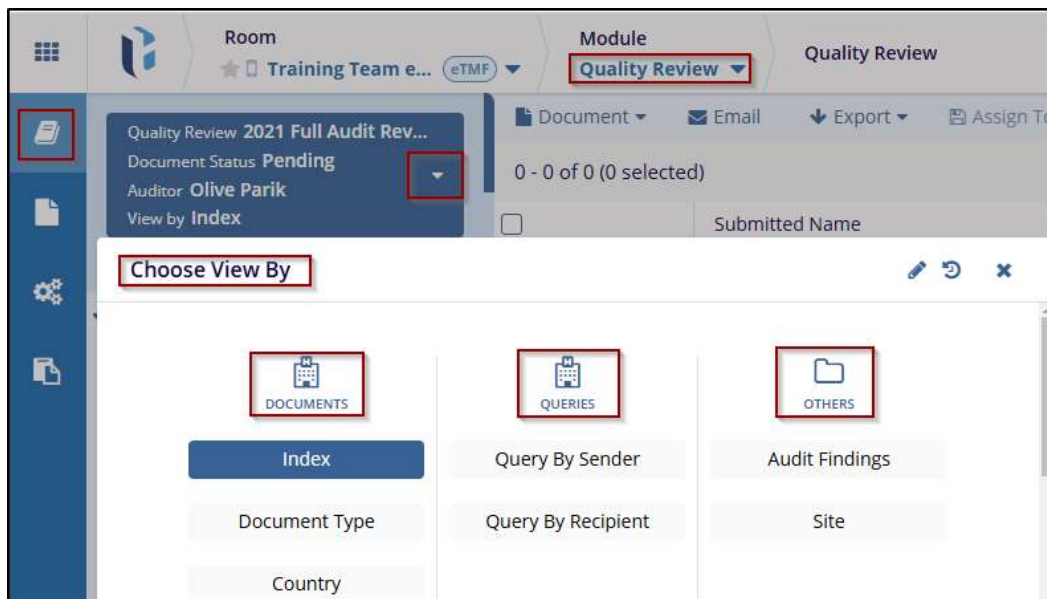


The screenshot shows the 'Choose View By' dialog box in the Trial Interactive eTMF interface. The dialog box is open, displaying various view options and filters. The 'DOCUMENTS' tab is selected, showing 'Index', 'Document Type', and 'Country' options. The 'QUERIES' tab shows 'Query By Sender' and 'Query By Recipient'. The 'OTHERS' tab shows 'Audit Findings' and 'Site'. Below the tabs, there are dropdown menus for 'Quality Review' (2021 Full Audit Review), 'Document Status' (Pending), and 'By Auditor' (Regulatory Inspector). At the bottom, there are checkboxes for 'Set Default' and 'Set Default for all Rooms', and 'Cancel' and 'Select' buttons.

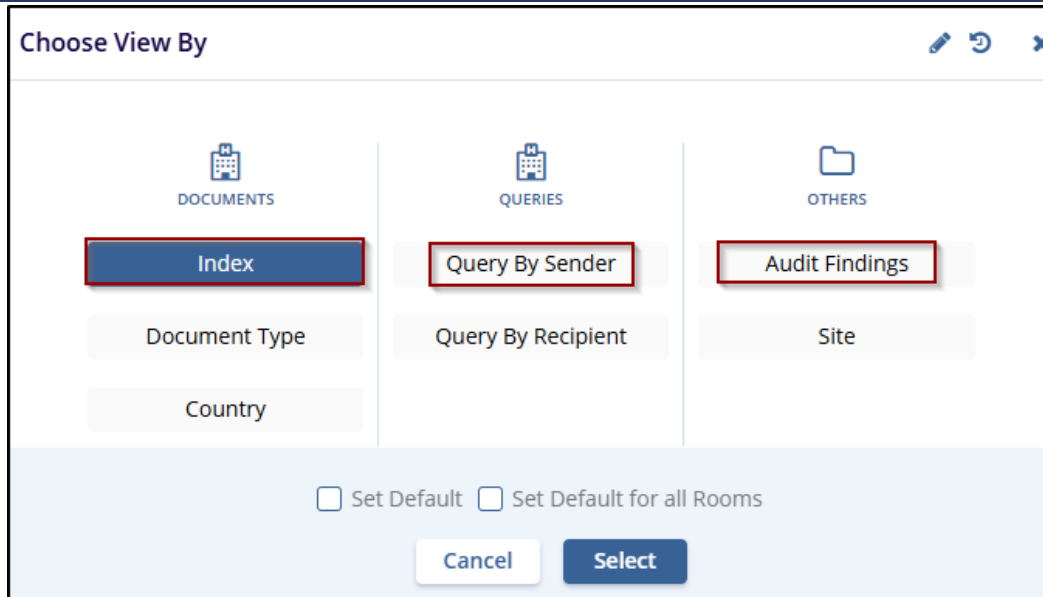
### Steps to select the Choose View By options:

1. Navigate to the Quality Review section, at the top of the Index Pane, the user will see the Choose View By dropdown menu.
2. This menu allows users to choose how they want to view the documents in the Quality Review section.
3. Click on the dropdown to reveal the available views under three main categories:
  - Documents: Includes options such as Index, Document Type, and Country.
  - Queries: Includes options like Query by Sender and Query by Recipient.
  - Others: Includes options like Audit Findings and Site.

Refer to the below screenshot:



4. Based on user requirements, select one of the options from Choose View by options.
5. For example, if the user wants to view documents by their index, select Index under documents.
6. If the user needs to review queries, select Query By Sender under the Queries column, for more select the others option.



**Choose View By**

**DOCUMENTS**

Index

Document Type

Country

**QUERIES**

Query By Sender

Query By Recipient

**OTHERS**

Audit Findings

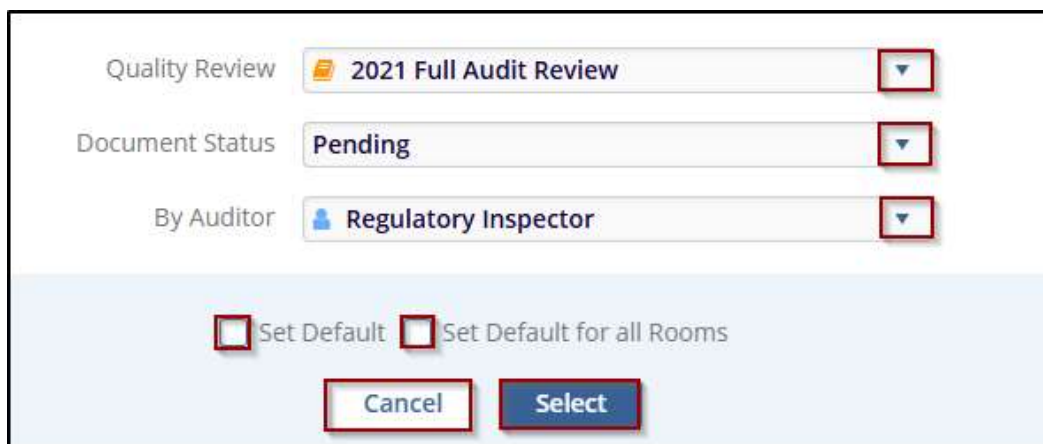
Site

☐ Set Default ☐ Set Default for all Rooms

Cancel Select

7. Below the view by dropdown, the user can see the fields for Quality Review, Document Status, and By Auditor.
8. Choose the specific file (e.g., 2021 Full Audit Review).
9. Set the Document Status (e.g., Pending) as per user requirement.
10. If the user wants to filter By Auditor, select the relevant auditor (e.g., Regulatory Inspector).
11. The user has the option to make their selection the default view:
  - Set Default: this will set the selected view as the default for the current session.
  - Set Default for All Rooms: this will make the selection the default for all rooms, not just the current one.
12. After selecting the view by options, click Select to apply the changes, these changes will reflect at the top of the Index pane, or click the Cancel button to discard the changes.

Refer to the below screenshot:



Quality Review 2021 Full Audit Review

Document Status Pending

By Auditor Regulatory Inspector

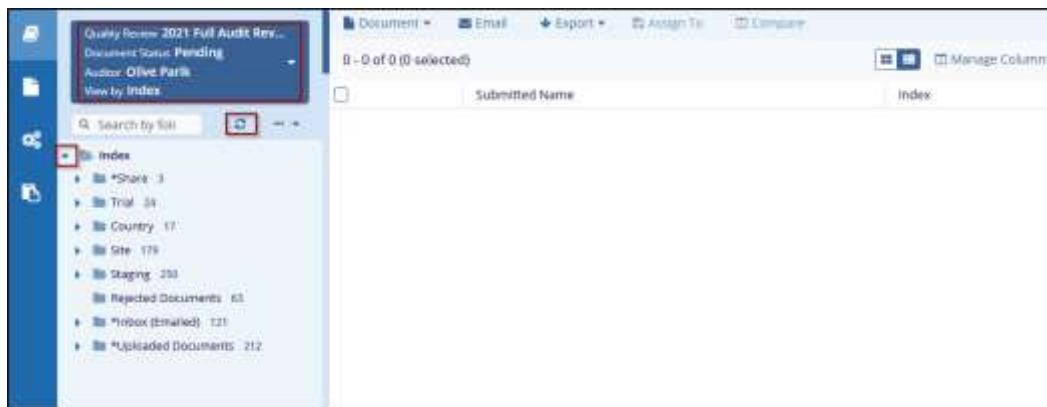
☐ Set Default ☐ Set Default for all Rooms

Cancel Select

Note: The View by option dropdown menu allows Reader, Editor, and Manager level users to see the audits are currently a part of either the Auditor or Audit Manager role. Administrators can see all audits here. Audit Managers will also have the option to view their audits (if they are also acting as an auditor for the audit) or they can check up on the progress of other auditors in the selected audit.

13. After applying the selection from View by options, the user can see the Index folder, based on the selections.

Refer to the below screenshot:

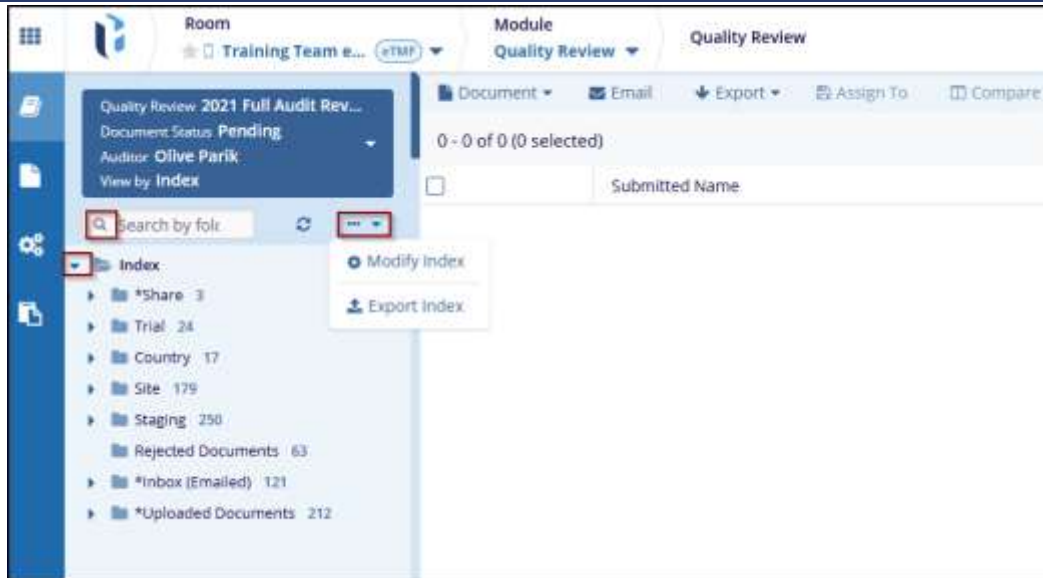


## Index

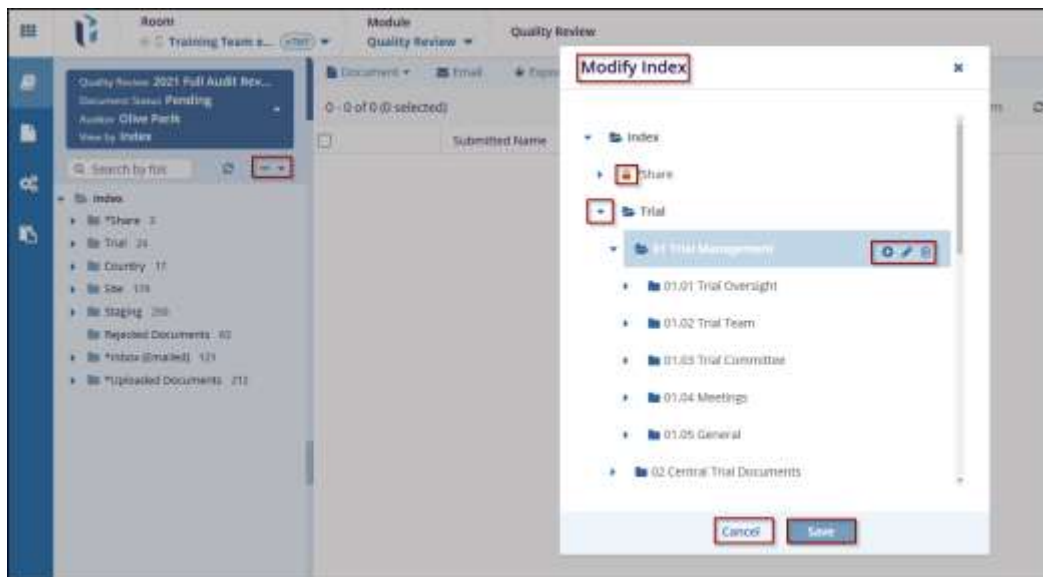
The index dropdown arrow allows the user to take actions to Modify Index and Export Index.

To modify the index, follow these steps:

1. Click the dropdown arrow next to search by folder on the left side of the screen, this will open a list of available folders, or click the search bar and the user can enter the required folder name or sub-folder name for a quick search.



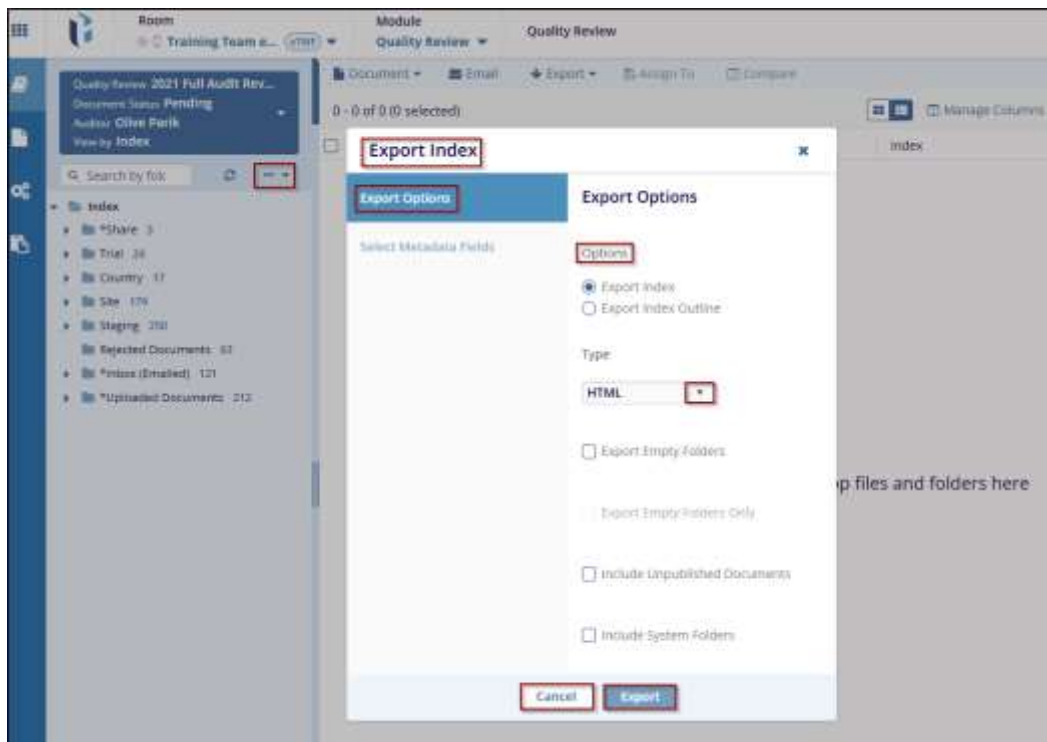
2. To refresh click the Refresh icon next to the search bar.
3. Click on the three-dot menu and select the Modify Index option from the dropdown options, a new window will open, where the user can see folders have lock icons that are restricted folders that cannot be edited, and some are not locked folders that can be edited by selecting the Pencil icon.
4. Click on the dropdown arrow and the + icon will open a list of available subfolders.
5. To delete the folder, click the delete icon next to the pencil icon.
6. To apply the changes, click on the Save button or click on the Cancel button to discard the changes.



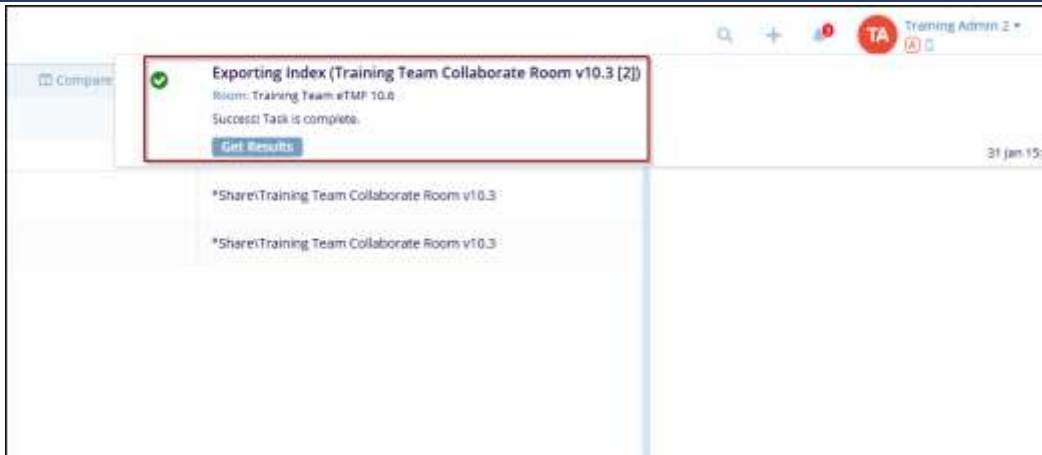
To export the index, follow these steps:

1. Select the Export Index from the Index dropdown to open a new window with available options Export Options and Select Metadata Fields.

2. By default, the Export option is selected, with the following options:
  - Export Index: select this option to export the entire index.
  - Export Index Outline: choose this if only need the structure of the index, without detailed folder data.
3. The default format in the dropdown is HTML and the users can also select other formats like Microsoft Word and Microsoft Excel while exporting.
4. The user can adjust additional options based on requirements:
  - Export Empty Folders: select this option if want the folders with no information in the export.
  - Export Empty Folders Only: this option will only export the empty folders.
  - Include Unpublished Documents: select this option if unpublished documents are to be included in the export.
  - Include System Folders: select this option if wish to include system folders in the export as well.



5. After selecting all required options, click on Export to get the result or click on Cancel to exit the dialog without making any changes.
6. Once clicked on Export, a message is displayed on the screen 'Success! Task is complete'.



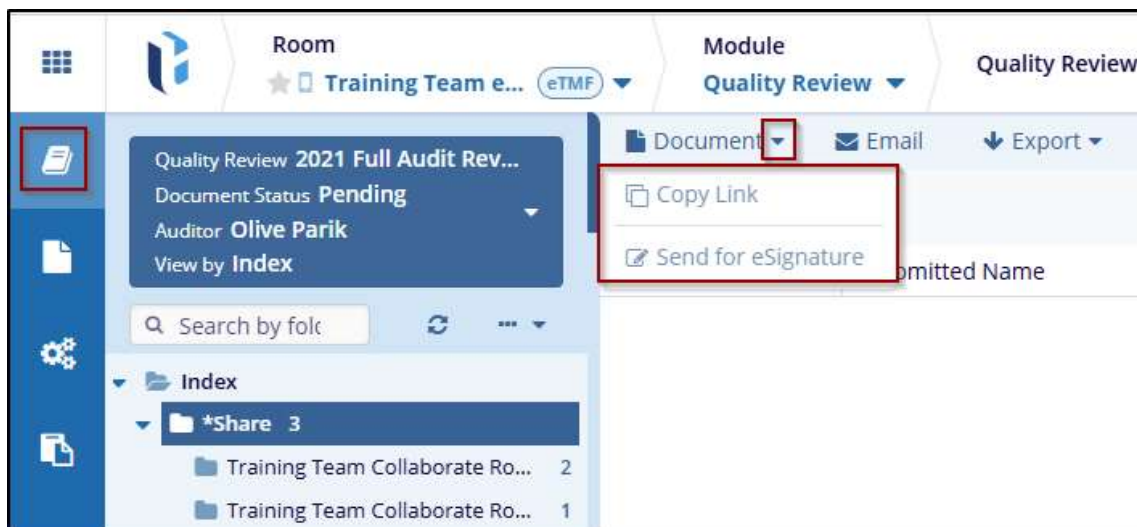
## Quality Review - Top Menu Ribbon

The top menu bar provides quick access to tools, that include Document, Email, Export, Assign To, Compare, Add to Cart, Document Cart, and Layout.

### *Document Activities*

Document refers to a file that is uploaded or created, such as an eTMF (electronic Trial Master File). These documents could be queries, audits, or any other file that needs to be shared or signed.

This includes a Copy link and Send for eSignature.

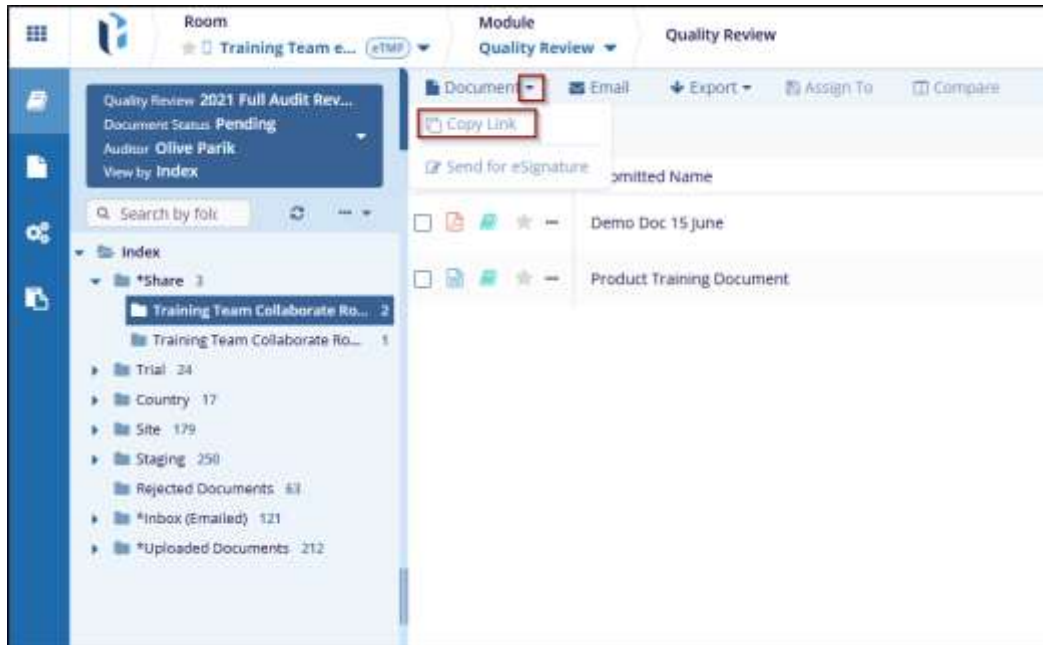


Note: The document button will be available to take action if the document is selected from the grid view below.

Steps to Copy Link:



- Click the Document dropdown, and select Copy Link. This will generate a URL link to the document, allowing the user to copy the link and share it with others.



- After selecting Copy Link, the message is displayed on the screen 'The link is copied to clipboard'.

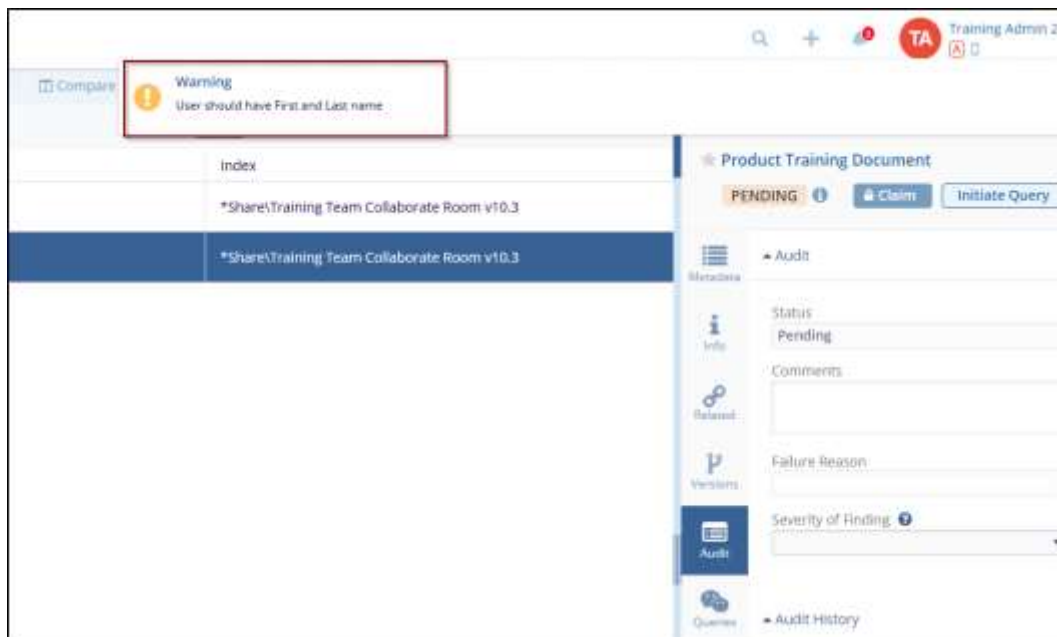
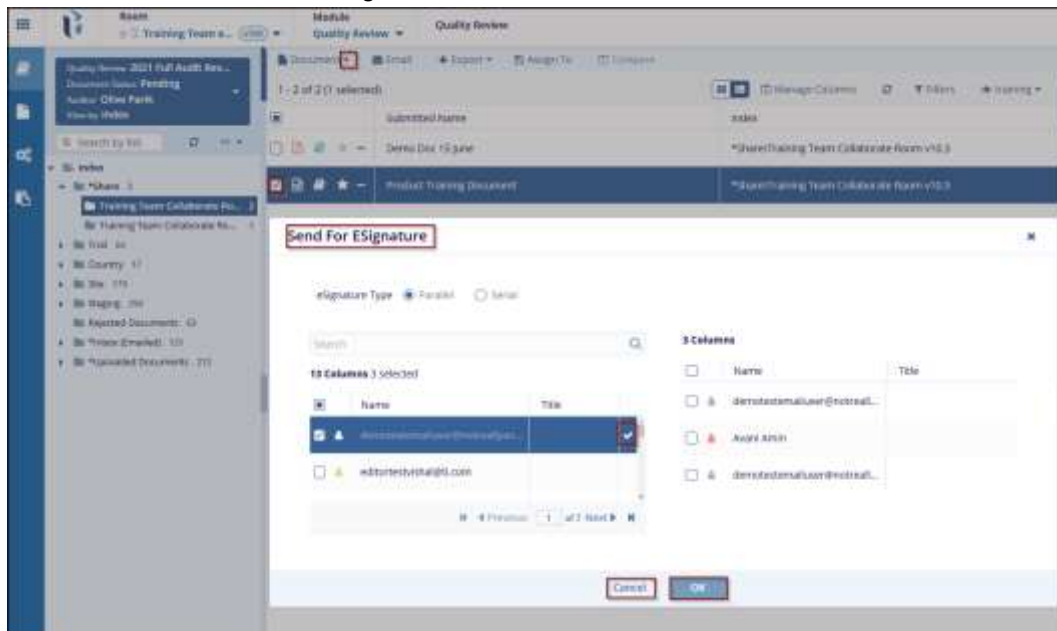


#### Steps to Send Document for eSignature:

- Click the Document dropdown, and select Send for eSignature, this will open a new window.
- From the window select the type of eSignature:
  - Parallel: the document at the same time can be signed in parallel.
  - Serial: the document one after another in a specified order.
- In the Search bar, enter the names or email addresses of the user who need to sign the document.
- The user can select multiple names from the list by selecting the checkbox.
- Hover over a name and the +sign will appear. Click on it to add the name in the right columns.



6. Use the Previous and Next buttons at the bottom to navigate through the list of available names.
7. After making selections, click OK to proceed with the request or click the Cancel button to discard the changes.



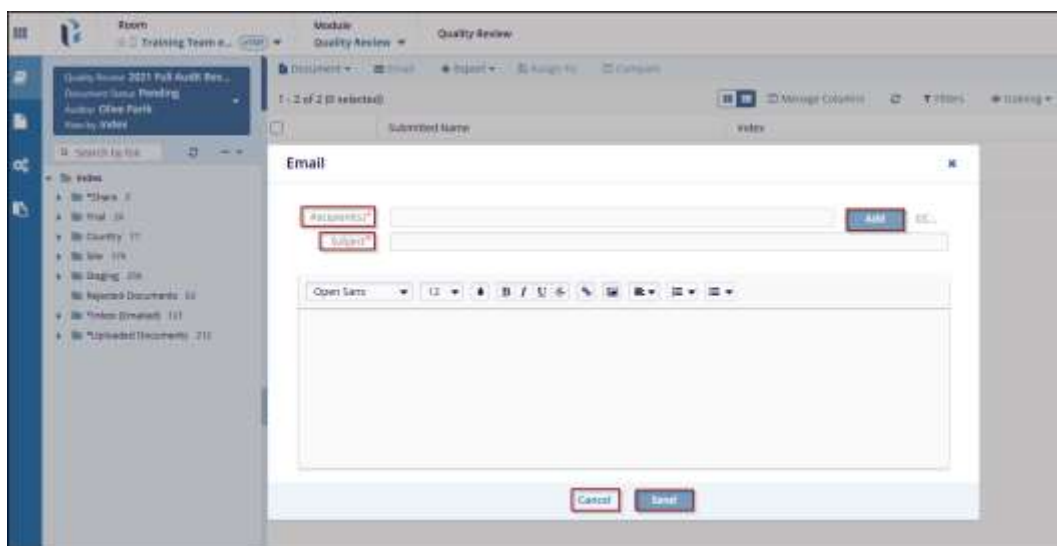
Note: To complete the request for eSignature, make sure the user has first and last name mentioned, while creating a user in the user management, else warning message is displayed.

## Email

The Email allows sending documents to one or more recipients directly from the system, with fields to specify recipients, subject, and message.

To send an email, follow these steps:

1. Select the documents by clicking on the checkboxes. Navigate to the top menu bar, and click the Email button. This opens the Email window.
2. In the Recipient(s) field, enter the email address, of the user to send the document.
3. Click the Add button if the user wants to add additional recipients or use the CC button to include people in the CC field.
4. In the subject field, enter a subject line for the email. This provides the recipient with an idea of what the email is about. This field is mandatory as indicated by the asterisk (\*).
5. Once filled in the recipient(s), subject, and message body, you can click Send to email the document.
6. Click the Cancel button to exit the email window without sending the message.



## Export

The Export option allows users to export different data types, such as Metadata, Documents, Security, Audit By View, or All Audits.



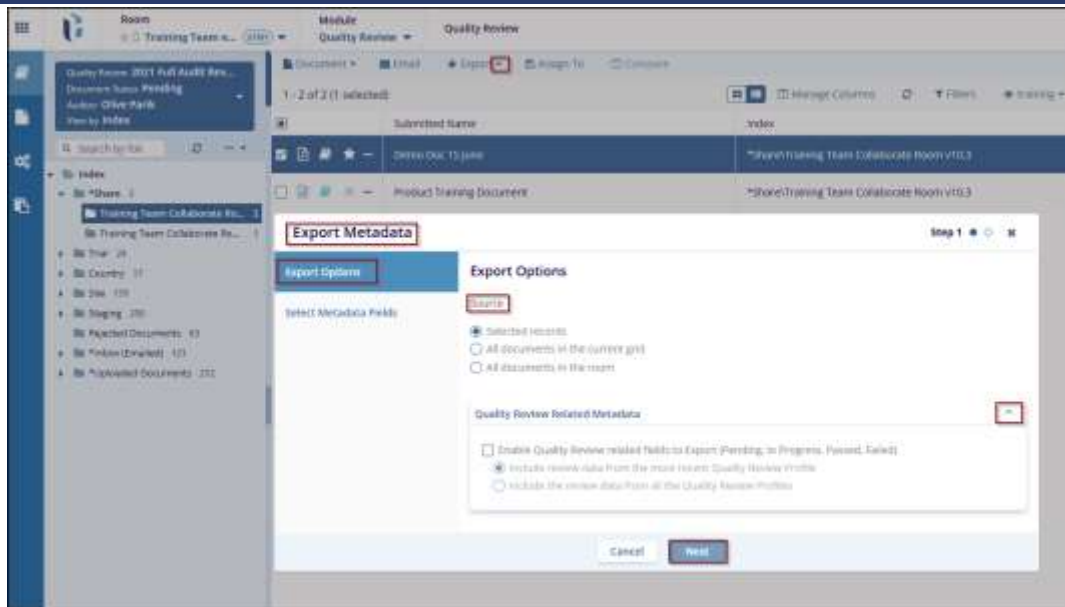
Note: The Export button will be available to take action if the document is selected from the below Grid view or Document view.

### Export Metadata

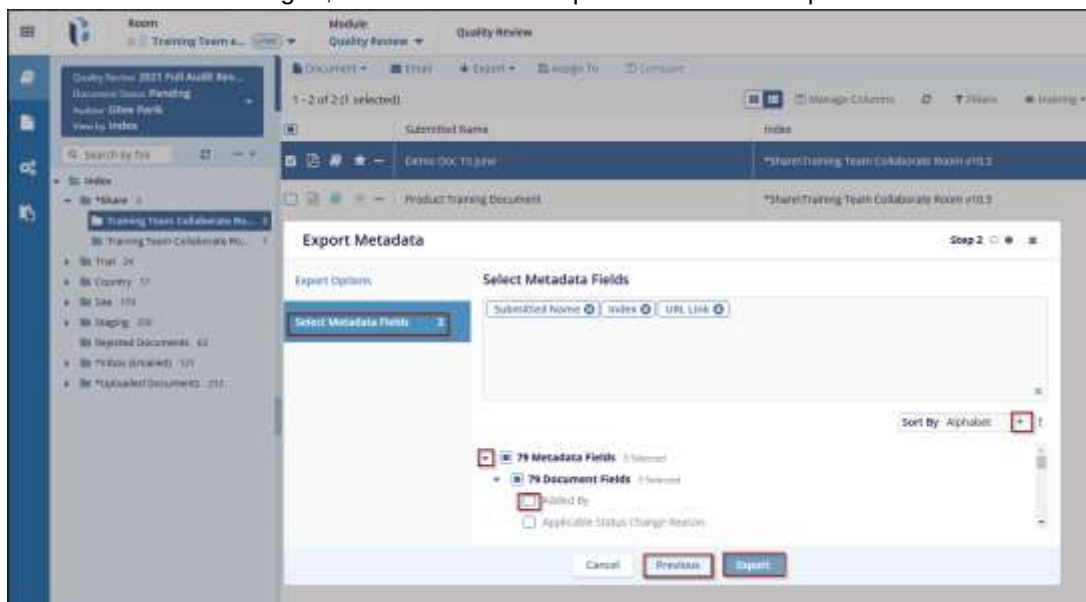
The Export Metadata involves extracting information from documents or records and exporting it in formats such as CSV, Excel, etc.

To Export Metadata, follow these steps:

1. Navigate to the top menu bar click on the dropdown and select Metadata. A new Export Metadata window will open, showing the options Export Options and Select Metadata Fields. By default, the Export Option is selected.
2. The Export Option allows the user to choose which queries to include in the export and select the required sources.
  - Selected records: exports only the queries the user has selected using the checkboxes in the grid view. This is useful when exporting a specific subset of queries.
  - All queries in the current grid: exports all the queries visible in the grid view when they are selected. This is ideal when the user wants to export all displayed queries, even if no specific queries are checked.
  - All queries in the room: export all queries in the current room, whether queries are visible in the grid. This option is used when the user wants to ensure that all queries within a room are exported.
  - Enable Quality Review Related Fields to Export: select this checkbox to include fields related to quality review (such as Pending, In Progress, Passed, Failed) in the export.
    - Include review data from the most recent quality review profile.
    - Include review data from all the quality review profiles.



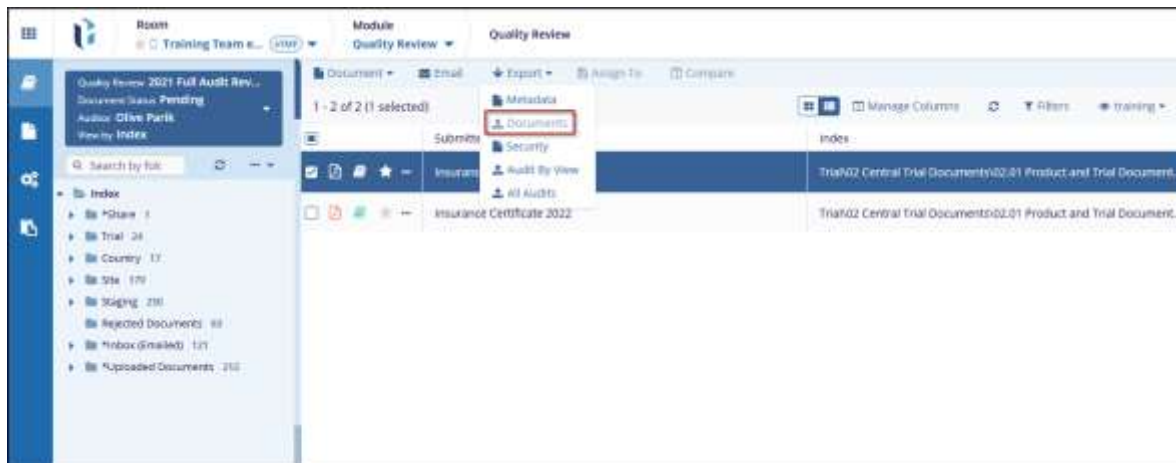
3. Click Next to proceed to the Select Metadata Fields section.
4. Once you proceed to the Select Metadata Fields option and select the required metadata fields, the user can sort them by Alphabet or Logic to include in the export.
5. Metadata fields are characteristics of the queries, such as: (Submitted name, Index, URL link, etc.)
6. After selecting both the Export Metadata options, click on the Previous button to go back and make changes, or click on the Export button to export the file.



7. Once clicked the Export button, a confirmation message will appear on the screen.

## Export Document

The Export Document allows users to export selected documents in formats like PDF, Excel, or CSV. It works similarly to metadata export see the steps above for more details.

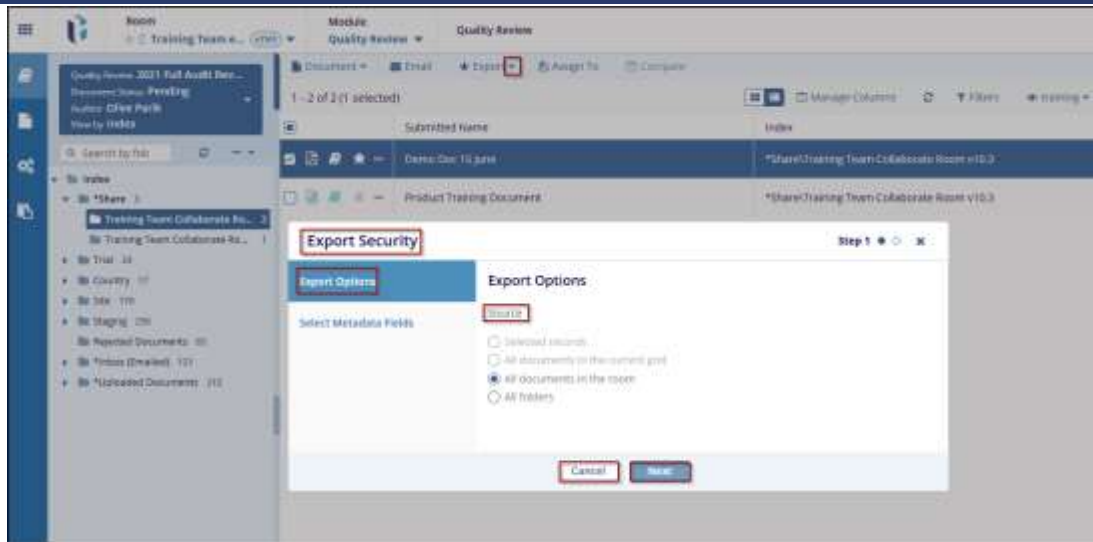


## Export Security

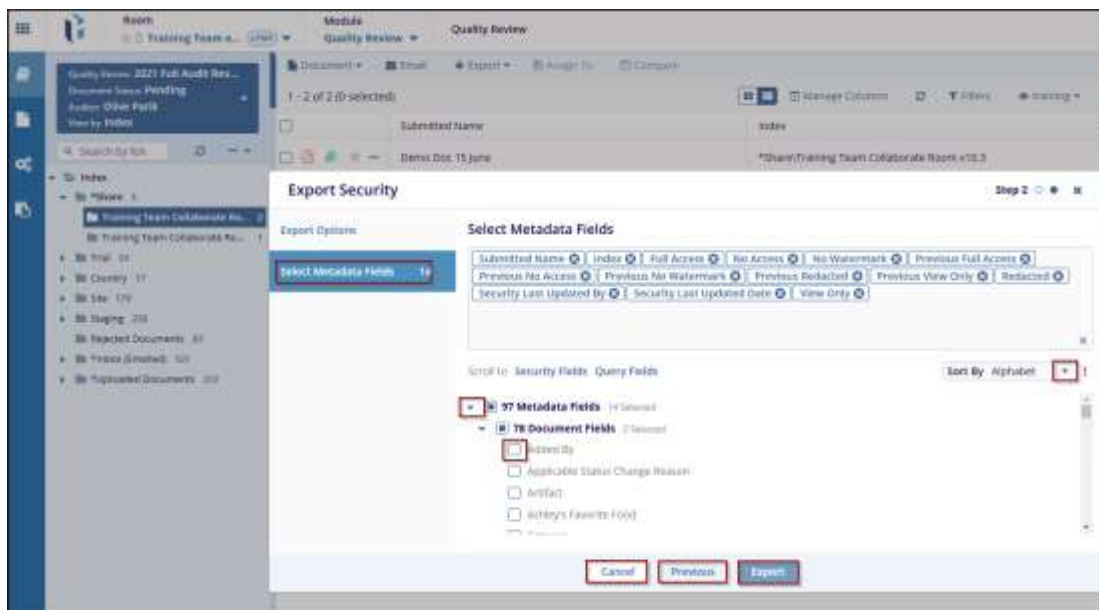
The Export Security steps are similar to Export Metadata, with additional options to manage access permissions. In this process, users can export not only the metadata but also the associated folders, with the ability to define specific security settings for each file. Users can assign access levels such as full access, no access, or restricted access based on security-related permissions.

To apply security while exporting, follow these steps:

1. Click the Export dropdown, and select Export Security. A new Export Security window will open, where the user can see the options, Export Options and Select Metadata Fields. By default, the Export option is selected.
2. In the Export Options under source, select the radio button as per requirement. For example, All Folders is selected.
3. Click the Next button to move to the next step, where the user can configure the metadata fields.



4. After clicking Next in the Export Options step to the Select Metadata Fields section.
5. Check the boxes next to the metadata fields that need to be included in the export.
6. Click Export to proceed to the final export step or click on the Previous Button to make changes to the previous option.
7. Click the cancel button to discard the changes.



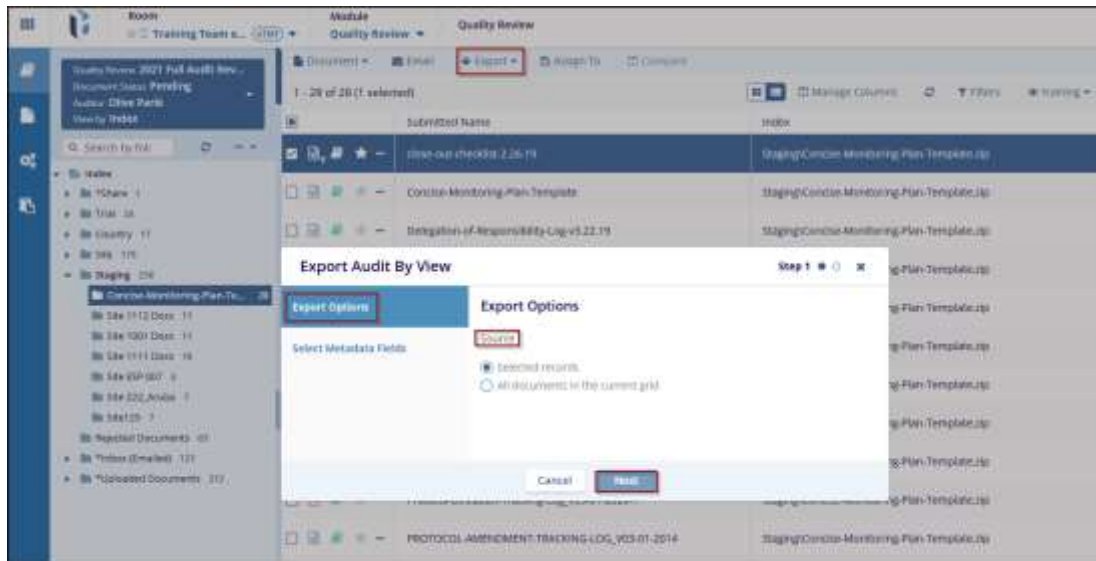
### Export Audit By View

The Export Audit by view is the process of extracting audit records based on a specific view or filter applied in the Select Metadata Fields. Users can select a view that displays the audit data, such as Added by, Category, Comments, Date type, etc.

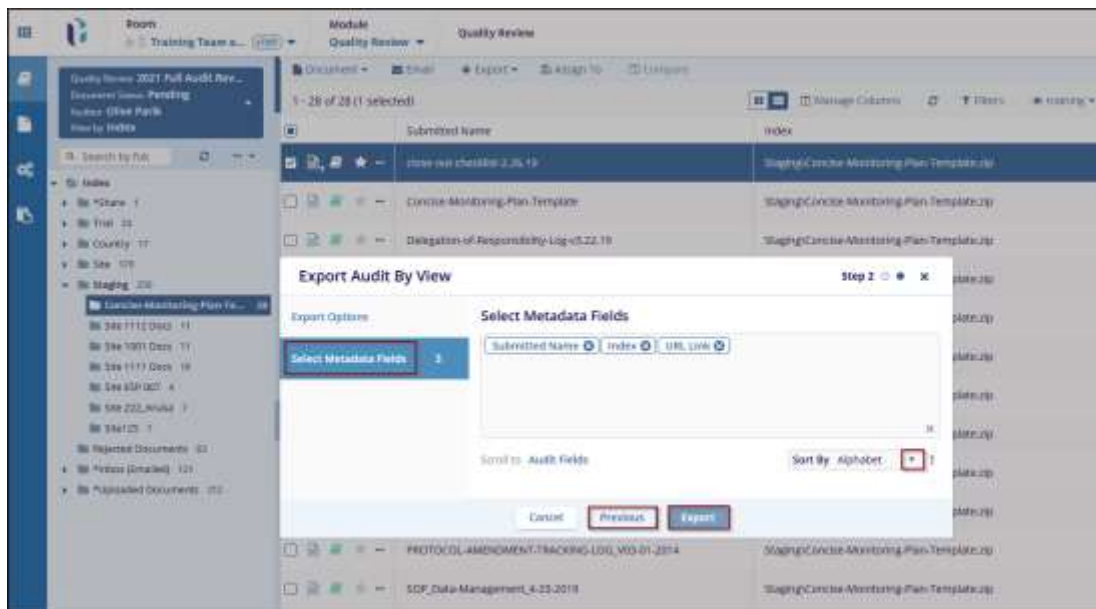
To Export Audit By View, follow these steps:



1. Click the Export dropdown, and select Export Audit by view. A new Export Audit by View window will open, where the user can see the options, Export Options and Select Metadata Fields. By default, the Export option is selected.
2. In the Export Options Under Source, select the radio button as per requirement, for example, All documents in the current grid.
3. Click the Next button to move to the next step, where the user can configure the metadata fields.



4. After clicking Next in the Export Options step, to the Select Metadata Fields section.
5. Check the boxes next to the metadata fields that need to be included in the export.
6. Click Export to proceed to the final export step or click on the Previous Button to make changes to the previous option.

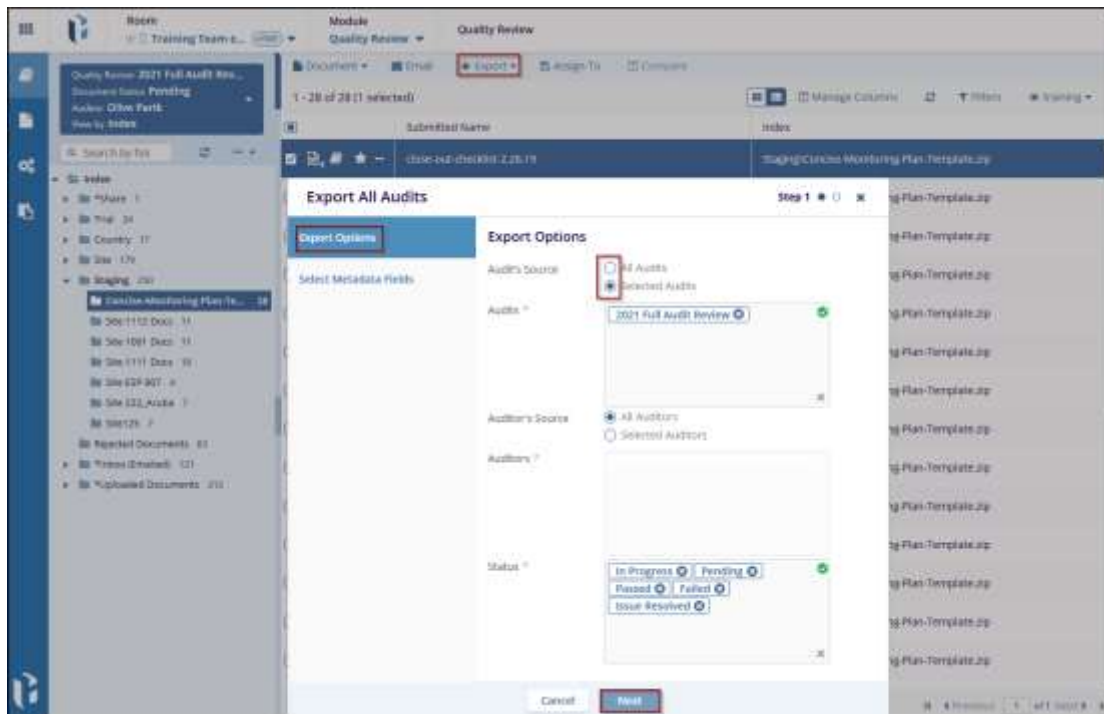


## Export All Audits

The Export All Audits refers to a comprehensive collection of audit records that includes all available audits. It typically encompasses the Audits Source, Audits, Auditors Source, Auditors, and Status.

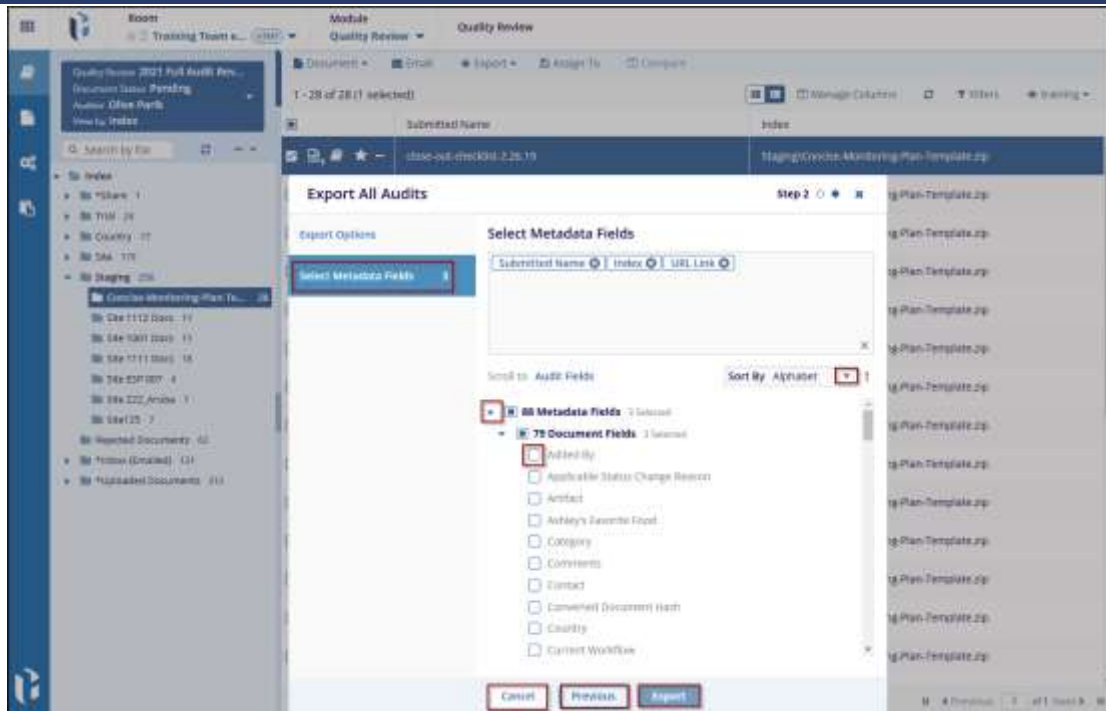
To Export All Audits, follow these steps:

1. Click the Export dropdown, and select Export All Audit. A new Export All Audit window will open, and the options are available such as Export Options and Select Metadata Fields. By default, the Export option is selected.
2. In the Export Options under Audit's source, select the radio button as per requirement. For example, All Audits or Selected Audits.
3. Click the Next button to move to the next step, where the user can configure the metadata fields.

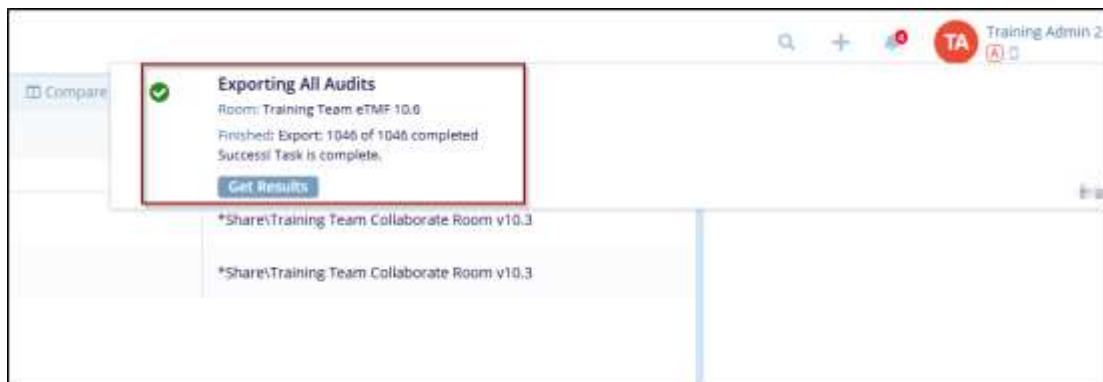


4. After selecting Next in the Export Options step to the Select Metadata Fields section.
5. Check the boxes next to the metadata fields that need to be included in the export.
6. Click the Export to proceed to the final export step or click on the Previous Button to make changes to the previous option. Click on Cancel to discard the changes and it will be returned to the previous screen.





- Once click the Export button, a confirmation message will display on the screen with the room name and finish.



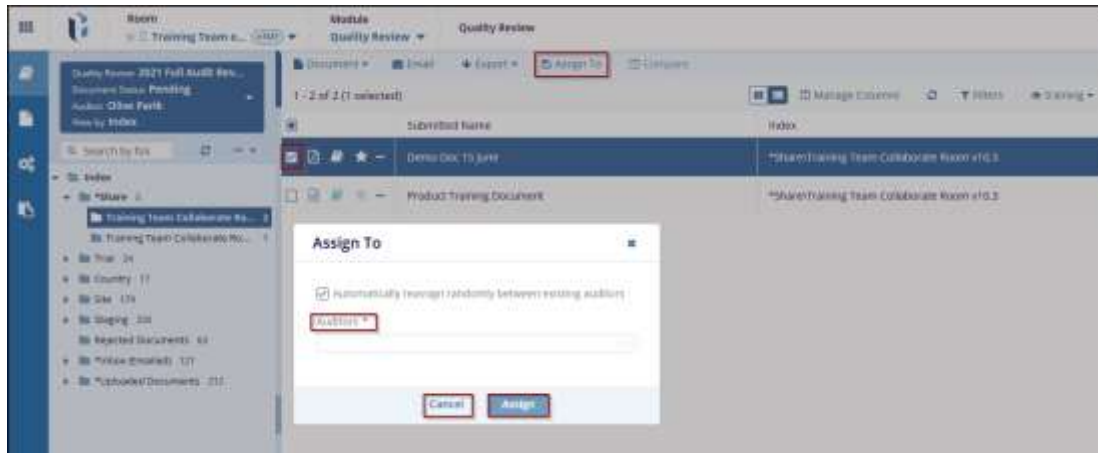
### Assign To

This allows users to assign the selected Documents to the specific Auditor or by selecting automatically reassign them randomly between existing auditors.

To Assign auditors, follow these steps:

- From the top menu bar, click on the Assign To button and a new Assign To window will open.
- Enter the auditor's name in the search option to find the specific Auditor or check the checkbox that will automatically reassign randomly between existing auditors.

- Click the Assign button to assign an Auditor to documents or click the Cancel button to discard the changes.



Note: The Assign To button will be available to take action if the document is selected from the below Grid view or Document view.

- Once clicked on the Assign button, the confirmation message will pop up Reassign document was successfully done.

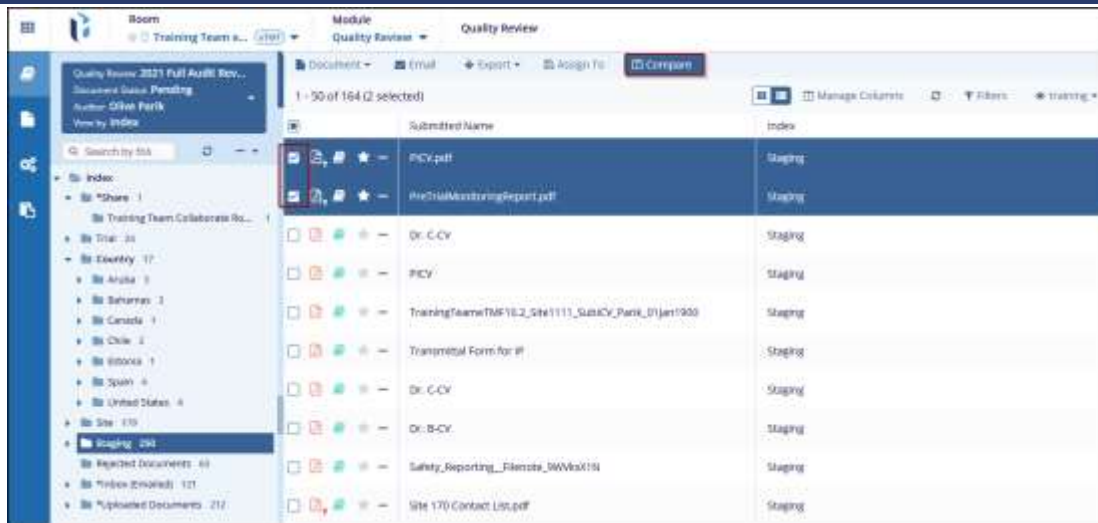


### Compare

The Compare refers to identifying differences and similarities in metadata. The users can compare documents by viewing them side-by-side, highlighting such as Restricted documents, Categories, File Names, and Document Dates.

To Compare documents, follow these steps:

- Select 2 or more documents from the grid view, and click on the Compare button to identify differences in metadata.

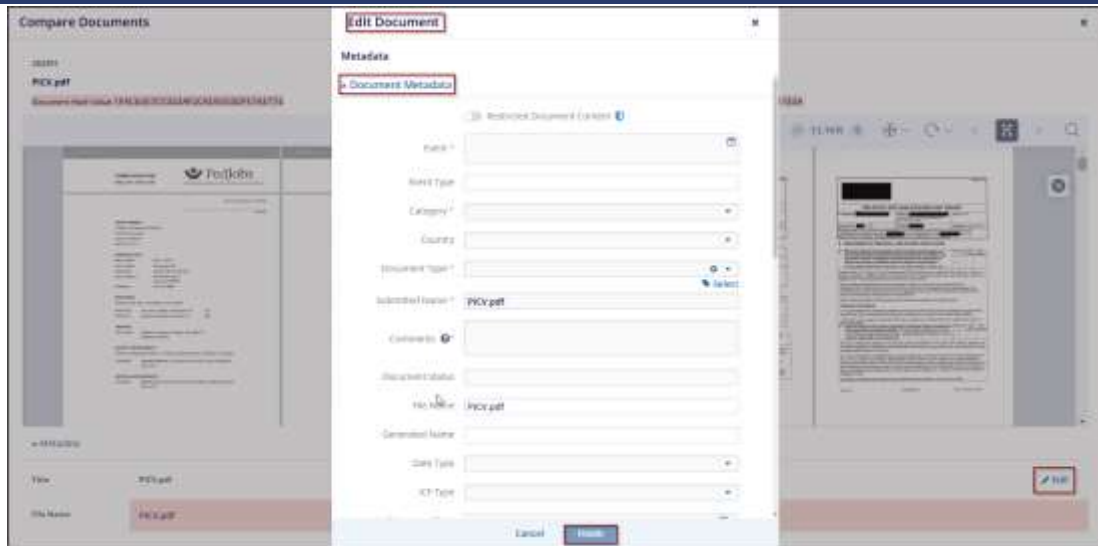


Note: The Compare button will be available to take action if two or more documents are selected from the below Grid view or Document view.

- Once clicked on the Compare button, a new window will open with comparing both documents.



- Click on the dropdown arrow next to Metadata to enlarge the metadata field.
- Select the Edit option to make changes to the document metadata. This will open a new Edit Document window.
- Once the required changes are made, click on Finish to save the updates.



[Add to Cart](#)

This button allows users to collect multiple documents with one click and add them to the document cart.

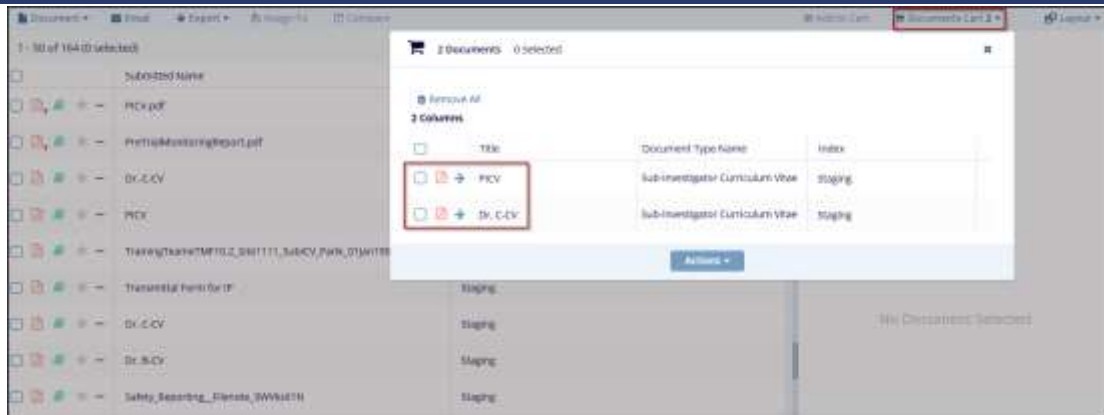
To add a document to the cart, follow these steps:

1. Select 2 or more documents from the grid view.
2. Click on the Add to Cart button to add the selected document to the Document Cart directly.

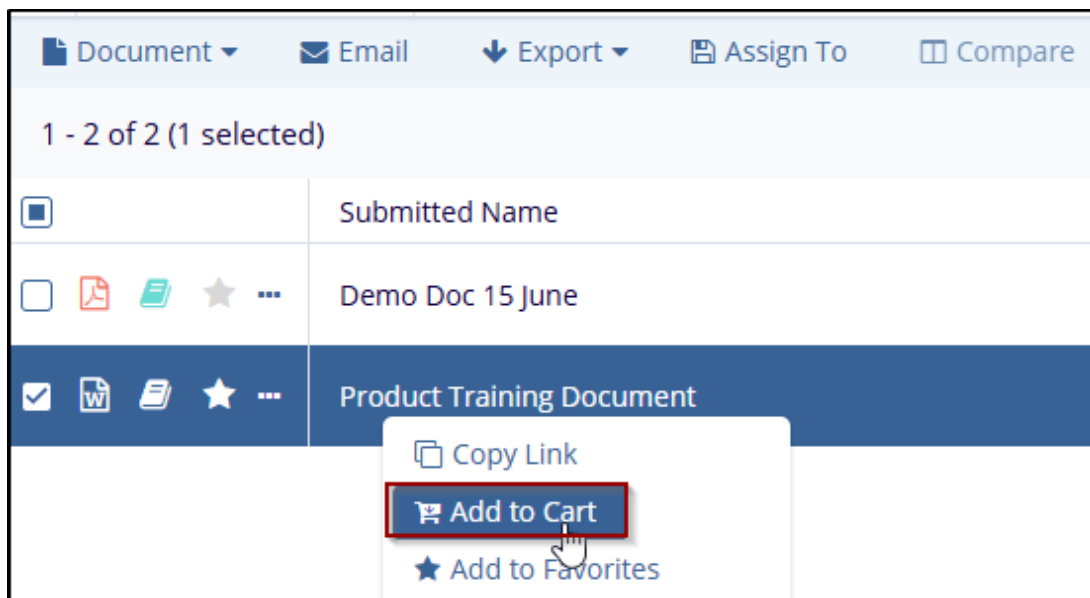


Note: The Add to Cart button will be available to take action if a document is selected from the below Grid view or Document view.

3. Once added, the selected document will be seen in the Document Cart.



4. Clicking the right button of the mouse on the query will provide the option to Add to Cart.

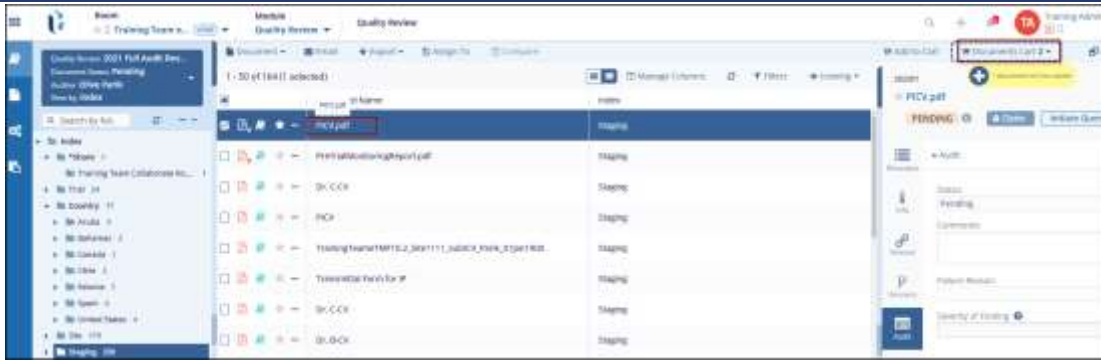


### Documents Cart

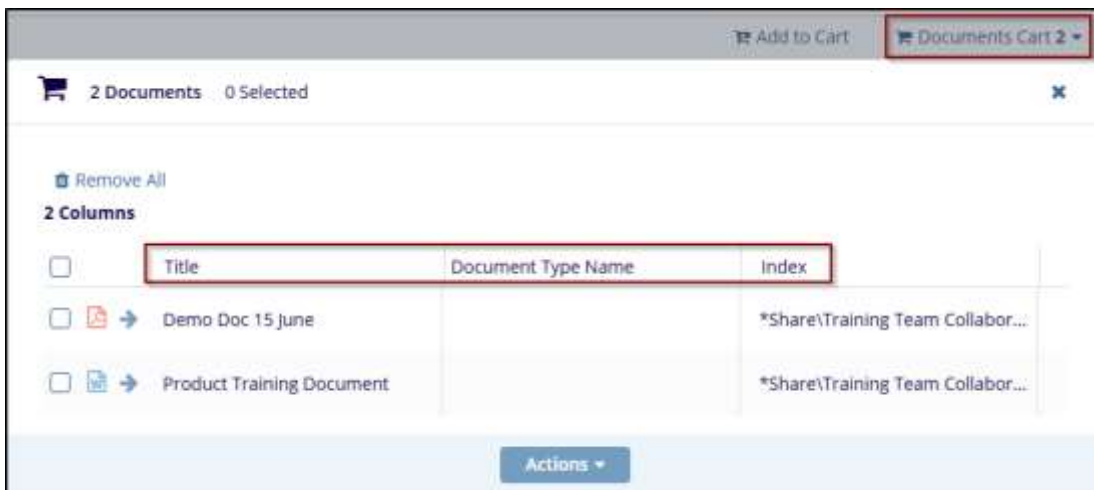
A Documents Cart allows users to collect queries for easier management. The Queries Cart helps streamline the process of handling multiple queries at once without repeatedly selecting them.

To add a document to the Document Cart, follow these steps:

1. In the grid view, Hover over the document that needs to be added to the cart.
2. Click and hold on to the query then drag it toward the Document Cart at the top and release the document into the cart.



- Once added click on Document Cart the added document will appear in the cart that is added to it and the documents are listed with a Title, Document Type Name, and Index.



- Check the checkbox next to the Query ID the query will be highlighted and the user can perform actions to Assign to. (To Assign Auditors, refer to the [Assign To](#) section above.)

## Layout

The Layout provides users with different data viewing options. The choice of layout can help enhance user experience by making the data easier to navigate or manage.

To apply a layout view, follow these steps:

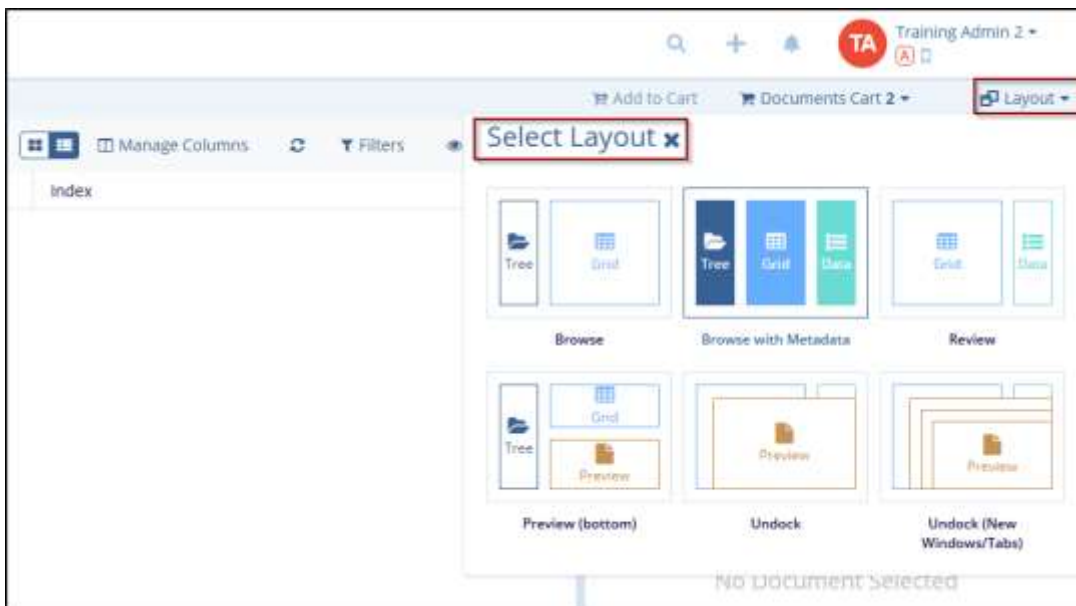
- At the top-right click on the Layout button. This will open a menu displaying available layout options.
- From the layout options displayed, select the one that best suits the user's needs:  
Browse: this is the default view for browsing data.  
Browse with Metadata: this option displays data along with associated metadata, which may be useful for understanding the context of the data.

Review: it is likely a review or approval view, useful for reviewing data before finalizing it.

Preview (Bottom): this view option displays a preview of the selected data or document at the bottom of the screen.

Undock: this option enables users to separate a section of the interface

Undock (New Windows/Tabs): this allows users to open a section or window in a new browser window or tab.

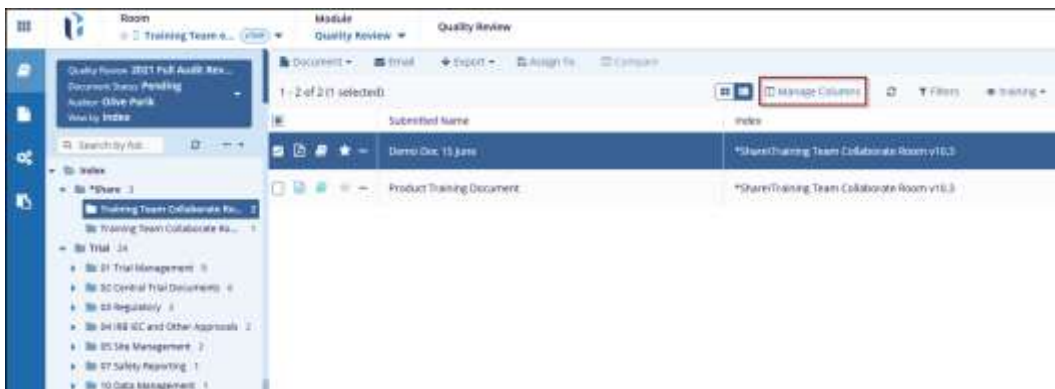


### Manage Columns

The Manage Columns allows users to customize the columns that appear in a data table. It provides the option to select, organize, and adjust the columns to display specific data as required.

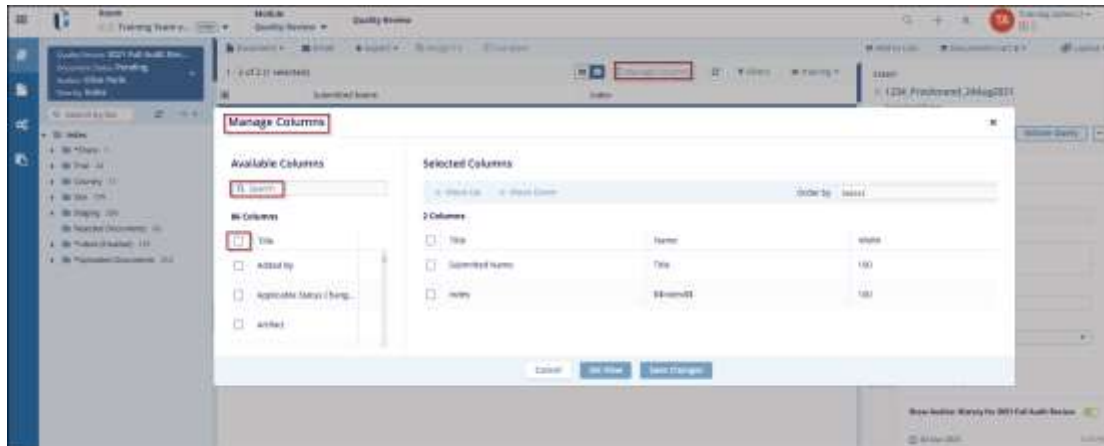
To customize the column display using Manage Columns, follow these steps:

1. Click on Manage Columns next to the refresh icon, Manage Columns window will pop up.

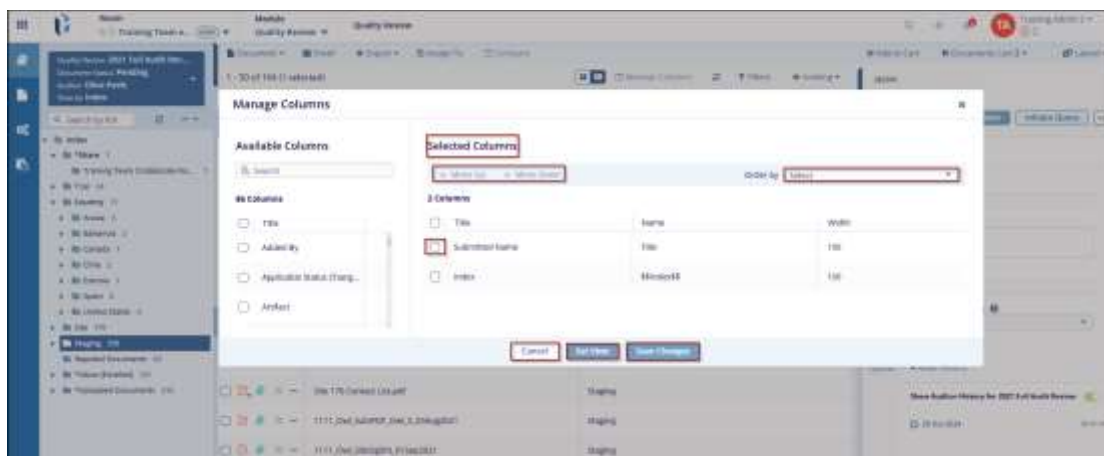




- On the left side of the manage column window, a list of Available Columns is used to add a title to the table.
- Users can use the search bar to find columns. Check the checkbox available for the title that the user wants to add to their view.

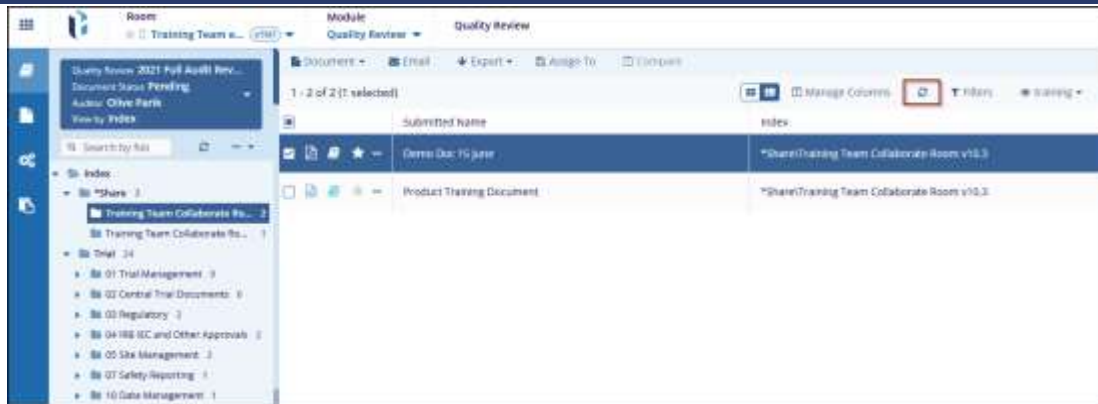


- In the Selected Columns section, the user can use the Move Up and Move Down buttons to reorder the columns in the selected list. For each selected column, the user can see its Title, Name, and Width.
- Use the Order by dropdown menu to select a column for sorting the data. Choose whether the user wants the sorting to be Ascending or Descending.
- After customizing the columns, click on Save Changes to apply the settings or the user can click Set View to apply and see the updated view. If the user wants to discard the changes, click on the Cancel button.



- Once the changes are applied, the user can click the Refresh icon to refresh the Columns.



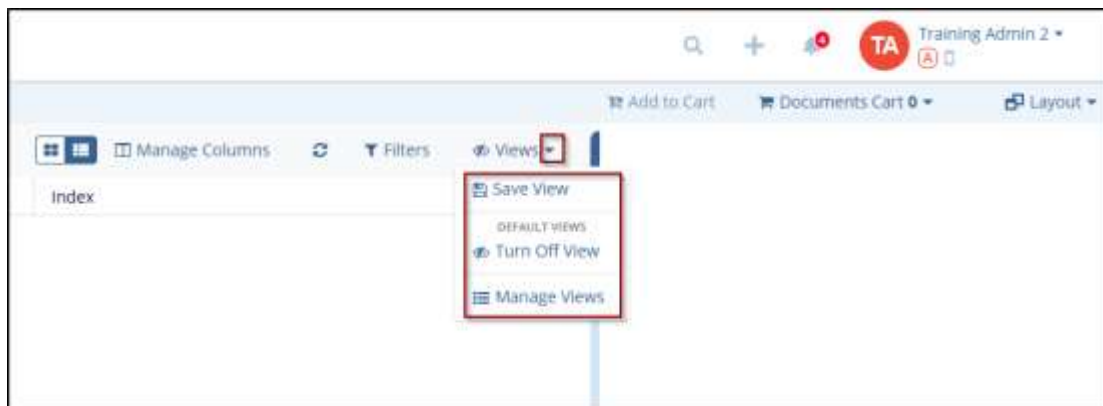


## Views

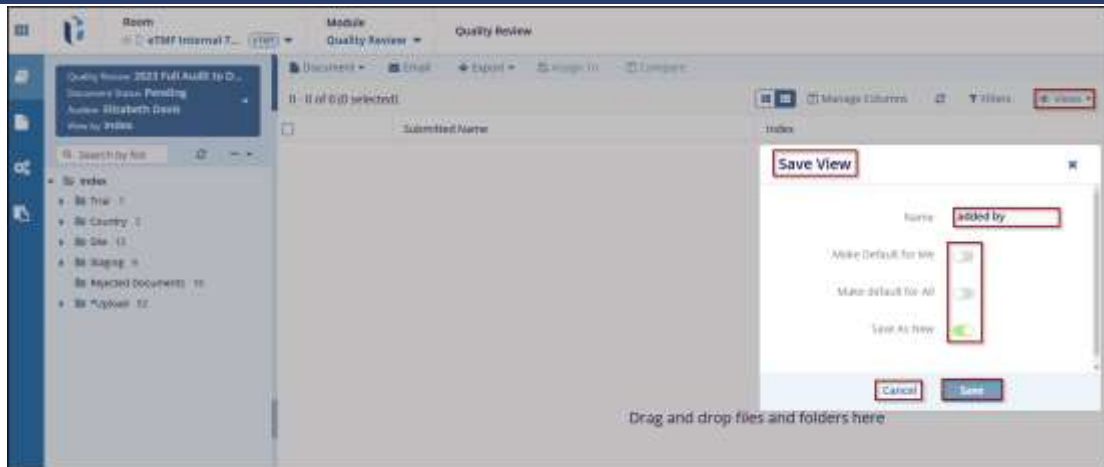
The Views dropdown provides options for Save View, Manage Views, or Turn Off View.

To apply a View, follow these steps:

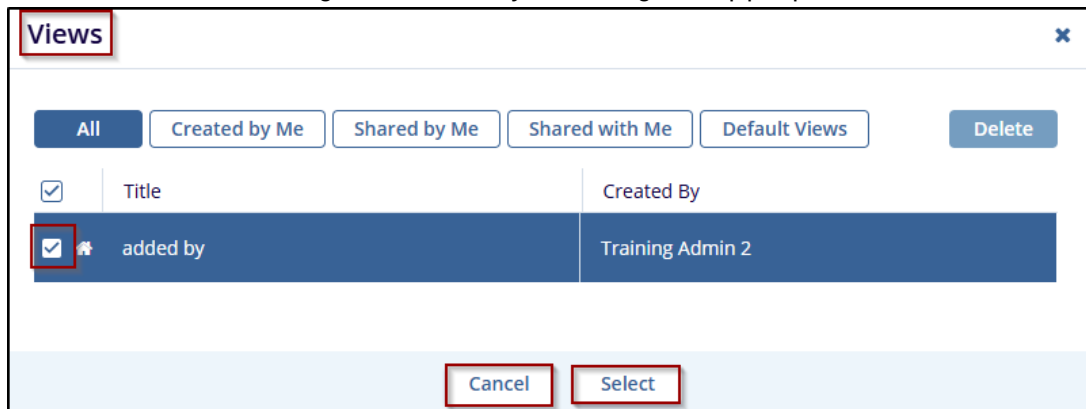
1. Click on the Views Dropdown menu, next to the Manage columns. The user can see options Save View, Turn off View, and Manage Views.



1. Click Save View from the dropdown menu, The Save View window will pop up.
2. In the Save View window, enter a Name for view.
3. Make Default for Me: toggle the switch to make this view the default for the user.
4. Make Default for All: toggle the switch to make this view the default for all users.
5. To save the current view as a new view, ensure the Save As New option is enabled.



6. Click the Save button to save the current view, If the user decides not to save the view, click the Cancel button to discard changes.
7. Click Turn Off View from the dropdown menu. If the user wants to revert to the default view or disable the current saved view.
8. Click on Manage Views from the dropdown menu, Manage Views window will pop up.
9. In the Manage Views window, the user can see all available view options under tabs such as All, Created by Me, Shared by Me, Shared with Me, and Default Views. The users can browse through the views by selecting the appropriate tab.



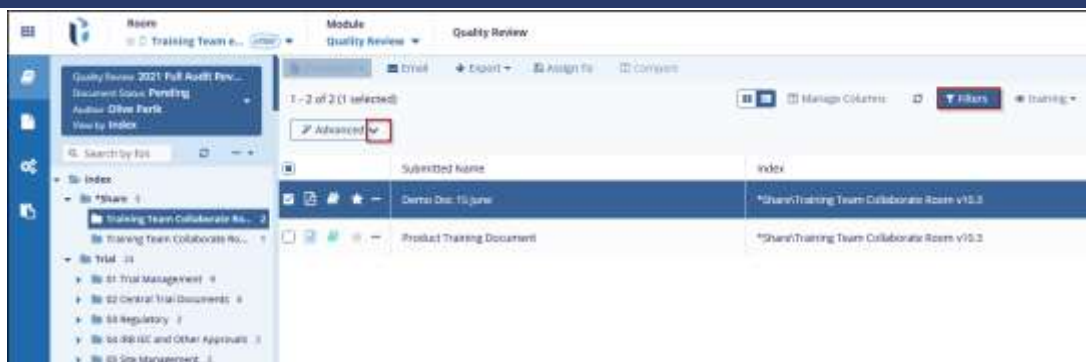
10. Check the checkbox next to the Title, to manage view.
11. After selecting a view, the user can delete it by selecting the Delete button.
12. Once finished managing views, click the Cancel button to discard any changes, or click Select to apply the changes to the selected view.

### Filters

The Filter provides advanced filtering capabilities to customize search results. Users can create new filters or manage existing ones to streamline data.

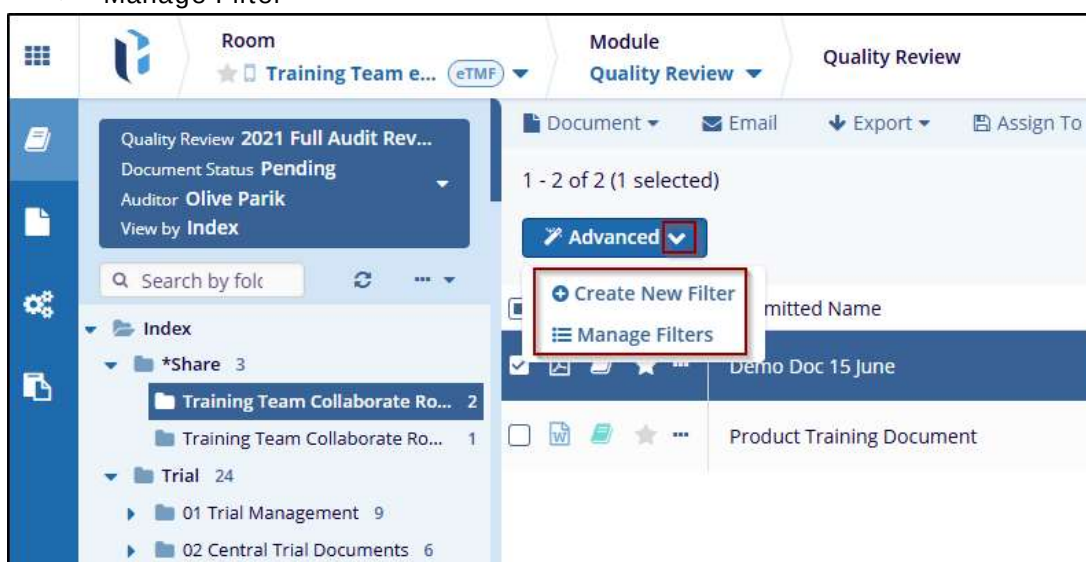
To apply filters, follow these steps:

1. Click on Filter, next to the Views option.



2. This filter will provide the Advance option, click on the dropdown option:

- Create New Filter
- Manage Filter



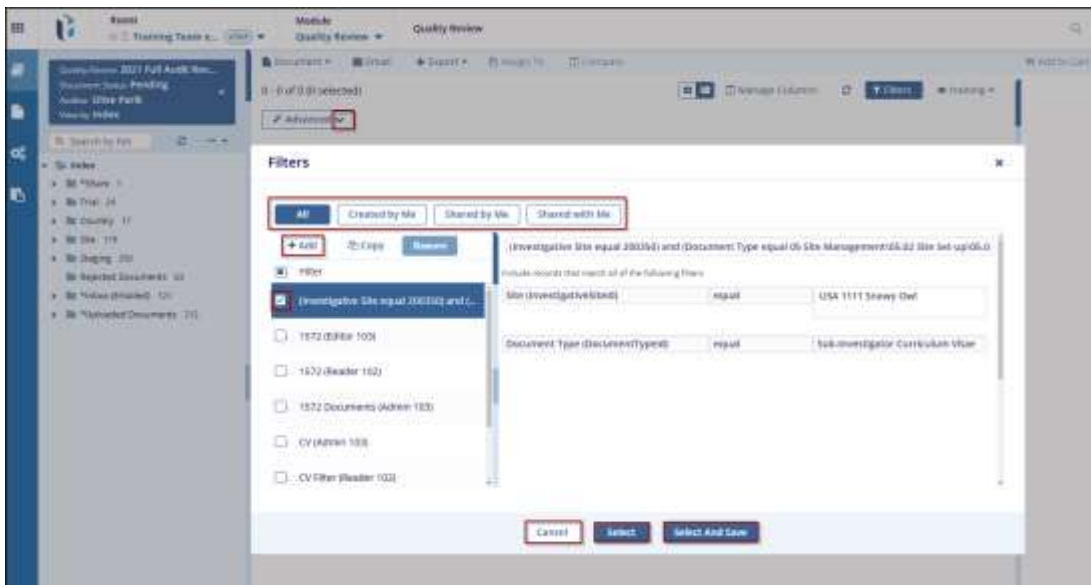
3. Click the Create New Filter will open a new window, the user can create a new filter by Add Filter button and by Add Group button.



4. Click the Create button to create a new filter to the current view, If the user decides not to save the changes, click the Cancel button to discard changes.
5. Once the Create Filter is applied go back to the Advanced button and click the Manage Filters to edit the current filter, by selecting Filter from the available list.



6. Once selected click the Select and Save to apply the changes or click the Cancel to discard the changes.



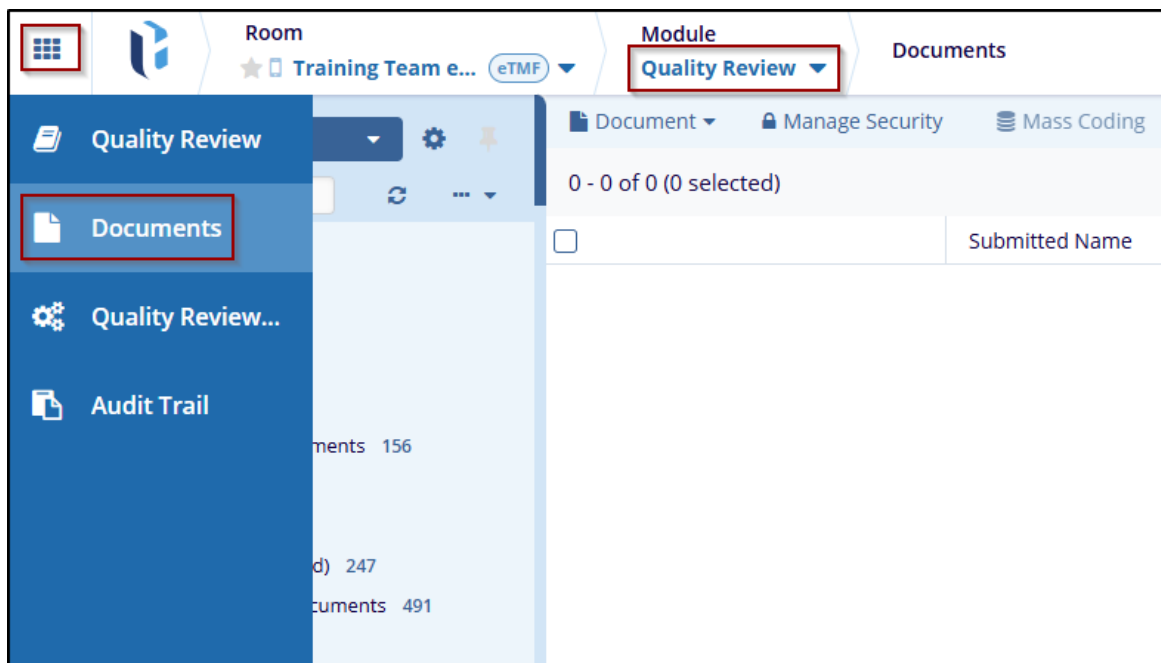
## Documents

The Documents section is the central repository for all clinical trial documents in their original digital format, including Digital Signatures where applicable. It also includes records or documents converted from other formats, such as paper documents, images converted to PDFs, videos, and recordings related to trials.

Here, users can configure and store essential documents about clinical trials, view and edit document attachments, manage security privileges, import and export documents and their metadata, and share them with other users.

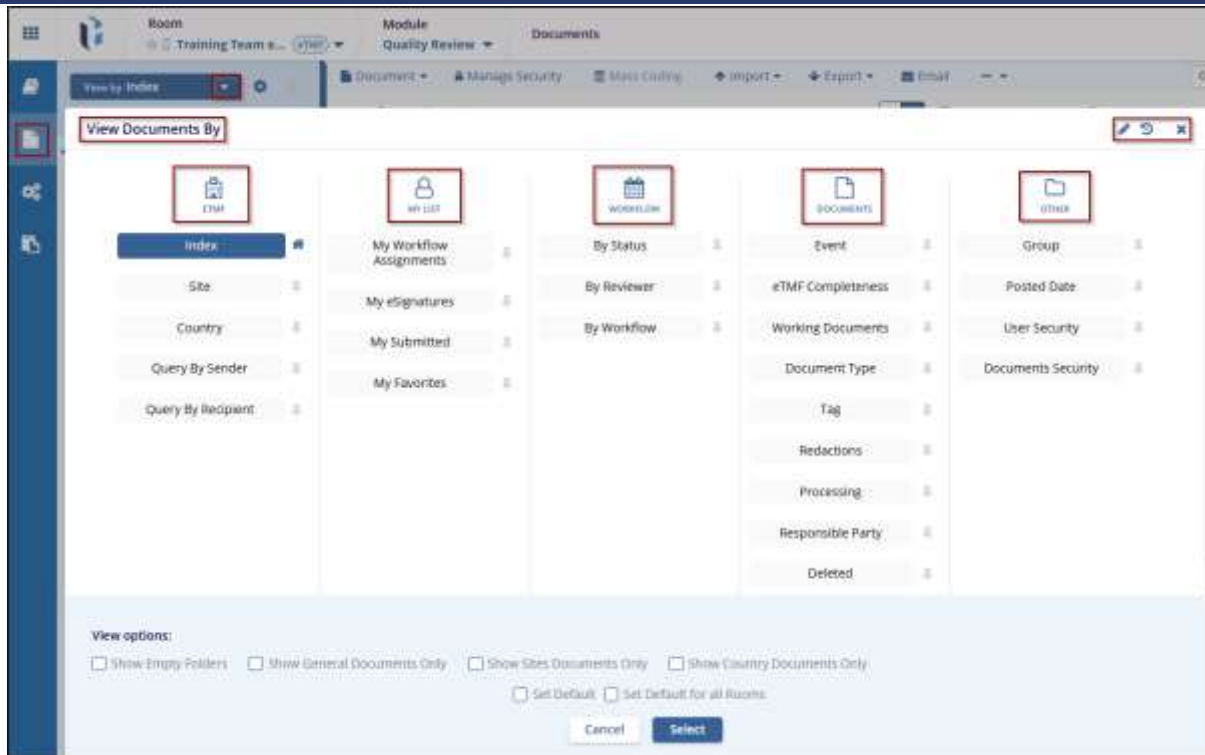
To ensure eTMF Completeness, users can track the progress of documents from collection to finalization. The application also allows users to post Questions and Answers and generate FAQs for further insights.

The documents are then subjected to Quality Control and Quality Review checks as per FDA regulations. Users can access the Documents View by clicking the Documents icon in the menu bar on the left-hand navigation pane.



## View Documents By

The View Document By allows users to filter documents based on requirements such as Index, Sender, Recipient, Status, Site, Document Type, etc. This improves document search for users to focus on relevant information. Navigate to View document by the dropdown menu at the top of the index pane. Use this menu to select the preferred view of the documents in the Grid view and Document view.



Choose a View Documents by including columns:

#### ETMF

- **Index:** Allows users to view or filter documents stored in the index folder, making it easier to locate specific files.
- **Site:** Filters documents based on the associated site, supporting the management of multiple site-based records.
- **Country:** Enables filtering of documents by the country associated with them, improving organization and compliance tracking.
- **Query By Sender:** Allows users to view documents categorized by the sender for better management tracking.
- **Query By Recipient:** Filters queries by the recipient to streamline follow-ups and tasks.

#### My List

- **My Workflow Assignments:** Displays documents assigned to the user for approval or requiring a status change.
- **My eSignatures:** Shows documents requiring the user's eSignature for approval or status updates.
- **My Submitted:** Lists documents submitted by the user in a grid view for easy reference.
- **My Favorites:** Displays documents marked as favorites by the user for quick access.

#### Workflow

- **By Status:** Filters documents or workflows by their current status for efficient tracking.

- By Reviewer: Organizes workflows by the reviewer for streamlined collaboration.
- By Workflow: Filters documents by their specific workflow for better oversight.

## Documents

- Event: Allows users to view or manage documents linked to specific events or milestones.
- eTMF Completeness: Tracks and displays documents to monitor their progress in achieving eTMF completeness.
- Document Type: Provides the ability to filter documents based on their type (e.g., Trial, Country, Site).
- Tag: Organizes and filters documents using tags for quick categorization.
- Redactions: Displays documents with applied redactions for compliance or confidentiality.
- Processing: Lists documents currently under processing for specific actions.
- Deleted: Displays deleted documents, allowing users to review or recover them if needed.

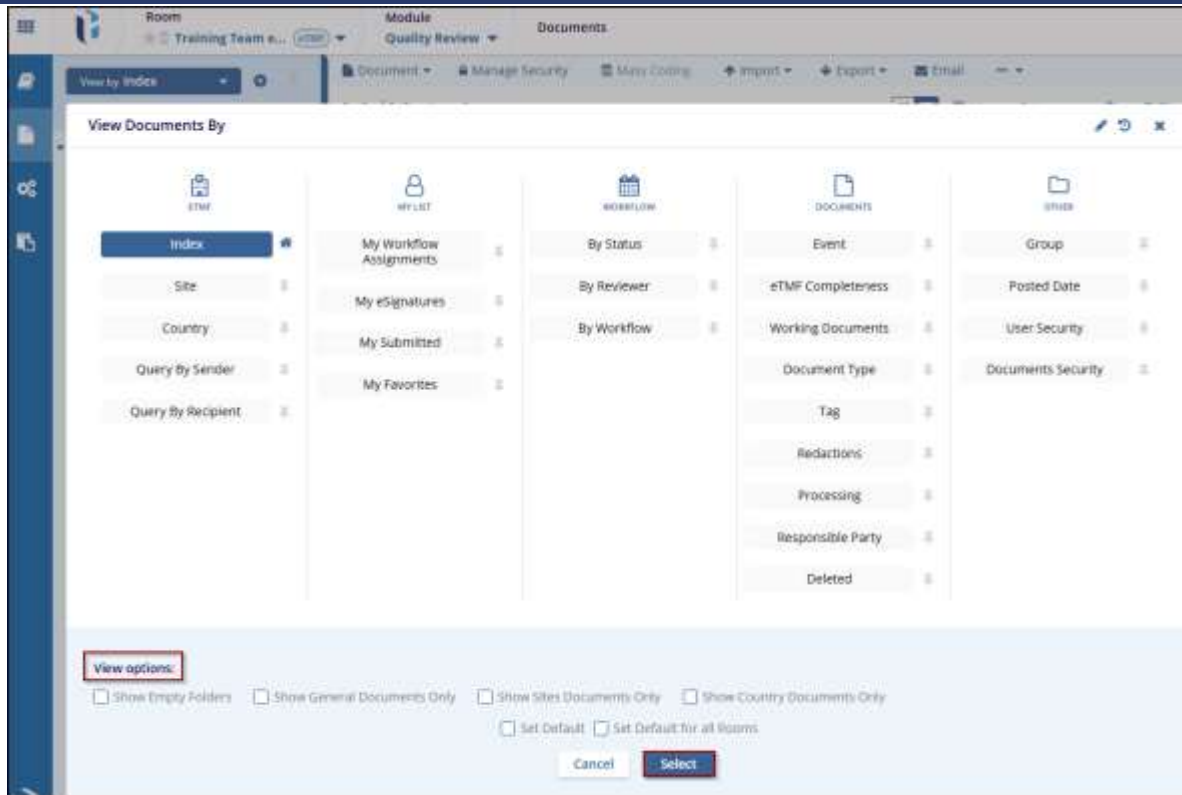
## Others

- Group: Organizes documents into groups for better classification.
- Posted Date: Filters documents by their posted date for time-based tracking.
- User Security: Manages user-based access privileges for documents to ensure secure handling.
- Documents Security: Allows users to manage security settings for documents, including adding, restricting, or modifying access permissions. This feature ensures that only authorized individuals can view or edit sensitive documents.

## [View Options](#)

The View Options section allows users to control the type of documents displayed in the list by selecting or deselecting options.





The View options:

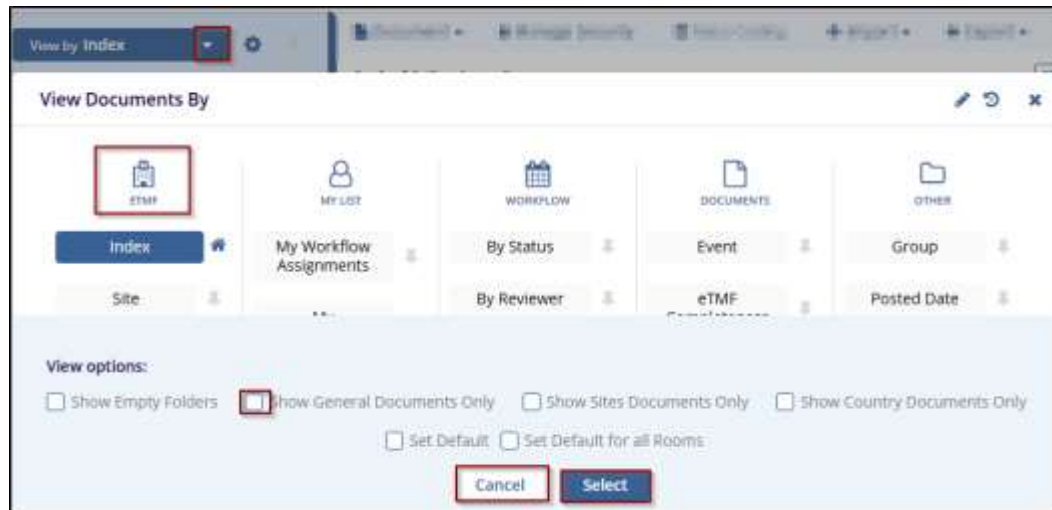
- Show Empty Folders: displays folders that currently do not contain any documents, providing an overview of the folder structure.
- Show General Documents only: Filters the view to display queries or documents that are not associated with specific documents, focusing on general or standalone records.
- Shows Site Documents only: Limits the view to display only documents related to specific sites, useful for site-focused tasks or reviews.
- Show Country Documents only: Restricts the view to documents associated with specific countries, aiding in country-specific document management and compliance.
- Set Default: Saves the users' selected view options as the default for the current session, simplifying navigation by retaining preferences.
- Set Default for all Rooms: Applies the selected view options as the default across all rooms for the user.

#### *Steps to select View Documents By options:*

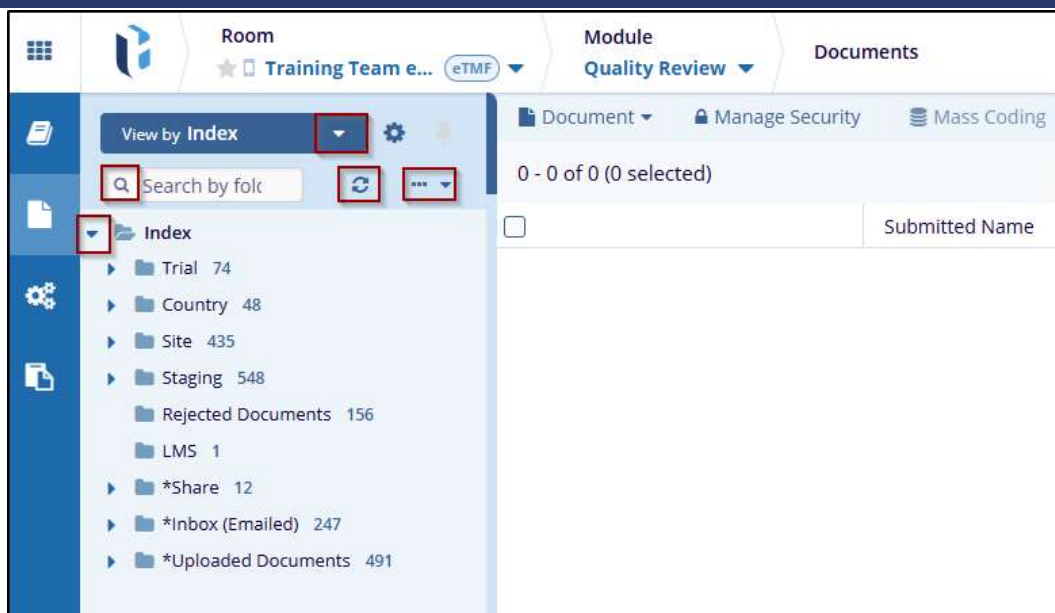
1. Navigate to the Document Section, from the Quality review module.
2. At the top of the Index Pane, the user will see the view by dropdown menu, this allows users to choose how they want to view the documents.
3. Click on the dropdown to reveal the available views under categories:
  - ETMF (e.g., Index, Site, Country)
  - My List (e.g., My Workflow Assignments, My eSignatures, My Submitted)
  - Workflow (e.g., By Status, By Reviewer)



- Documents (e.g., Event, eTMF Completeness, Document Type)
  - Other (e.g., Group, User Security).
4. Use the view options at the bottom of the window, such as:
    - Show Empty Folders
    - Show General Documents Only
    - Show Site or Country Documents Only
    - Select Set Default if you want to save your preference.
  5. Click the Select button to apply a chosen filter or Click Cancel if do not wish to make any changes.



6. The document list is now displayed based on the Index category.
7. The user can expand folders such as Trial, Country, Site, Staging, Rejected Documents, LMS, Share, Inbox (Emailed), and Uploaded Documents to view available documents.
8. Use the Search bar at the top to find specific documents.
9. Click the Refresh button to update results if needed.
10. Adjust settings using the Gear icon for Index.



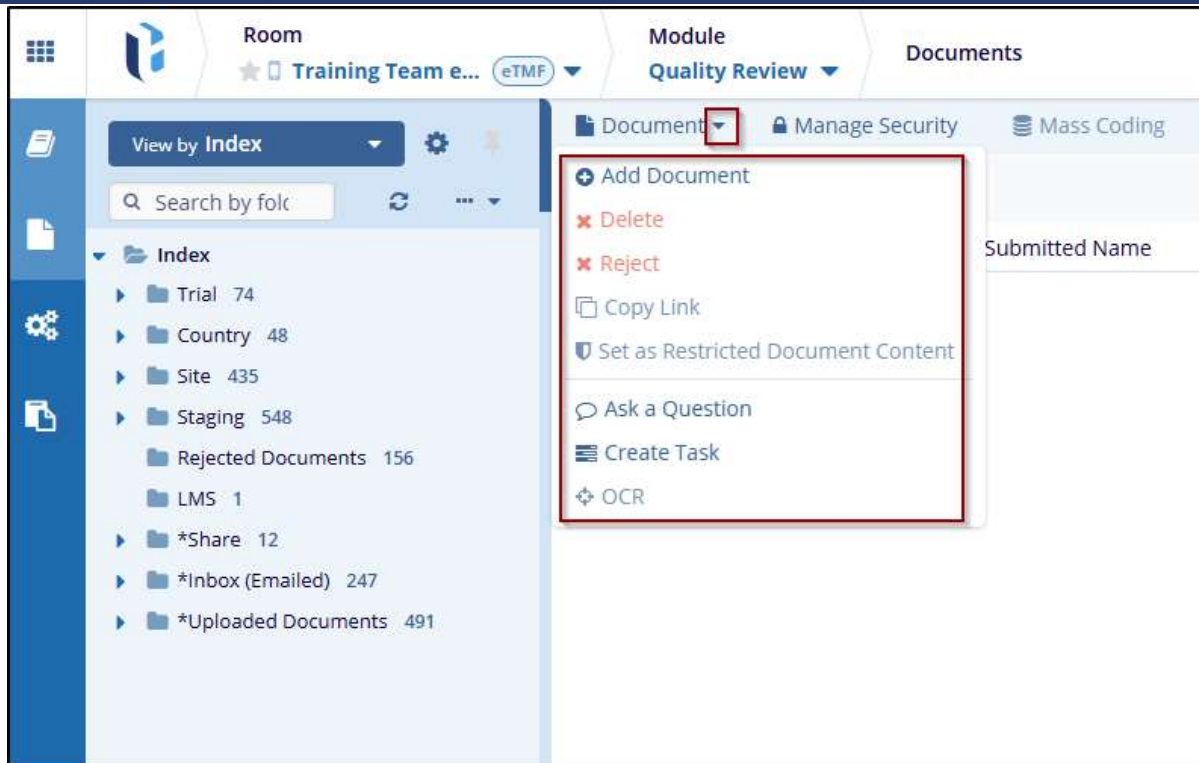
### Document - Top Menu Ribbon:

This menu is located at the top of the Document section, which includes Document, Manage Security, Mass Coding, Import, Etc.



### Document Activities Menu

The options available in this dropdown menu are only available once a document has been selected in the grid and are a subset of the options available in the Document Activities menu mentioned in the section.



Note: The view displayed above is that of a Room Administrator. The options available will vary based on the individual user's access rights. The section below covers several options, while others are discussed in topic-specific sections throughout the User Guide.

Refer to the Document Activities from the eTMF Module for a more detailed description of these options

### Manage Security

The Manage Security allows users to control access to documents and folders by configuring permissions. It ensures that only authorized individuals or groups can access or modify sensitive content.

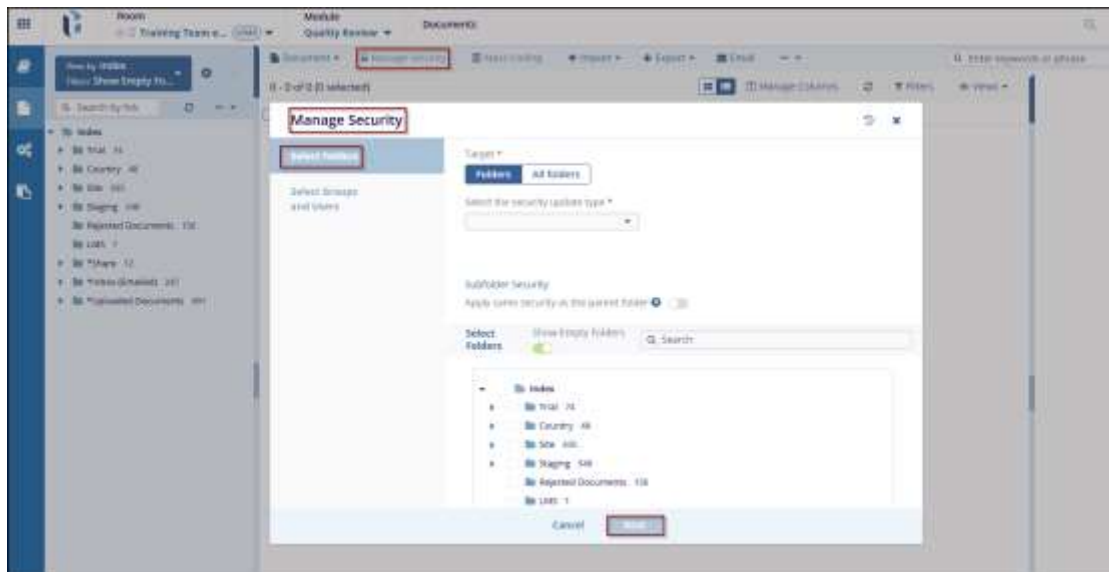
The two main options under Manage Security are:

- **Select Folder:** Users can choose a specific folder and set security permissions for it. This restricts or grants access to all documents contained within the selected folder based on user roles or groups.
- **Select Group and Users:** This option allows users to assign security permissions to specific groups or individual users, specifying the type of access (e.g., view, edit, delete) they have to the selected documents or folders.

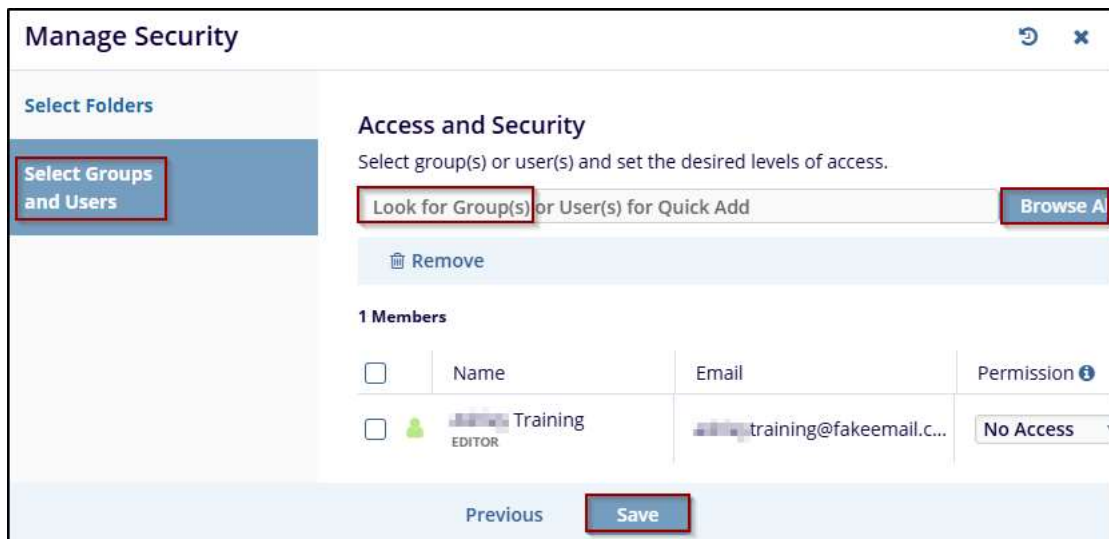
To access the Manage Security setting, follow these steps:

1. Navigate to the top menu bar, and click Manage Security, a new window will open.

2. The Manage Security window will display two options (by default select folders is selected).
3. Select the folder is the set of security that will apply to selected document folders.



4. Once done, click on Next to proceed to select Group and Users.
5. Enter the group or user name in the search bar and click on add to add below member or the user can browse, from the Browse All button.
6. Once added, click on Save to save the access for the user or group.

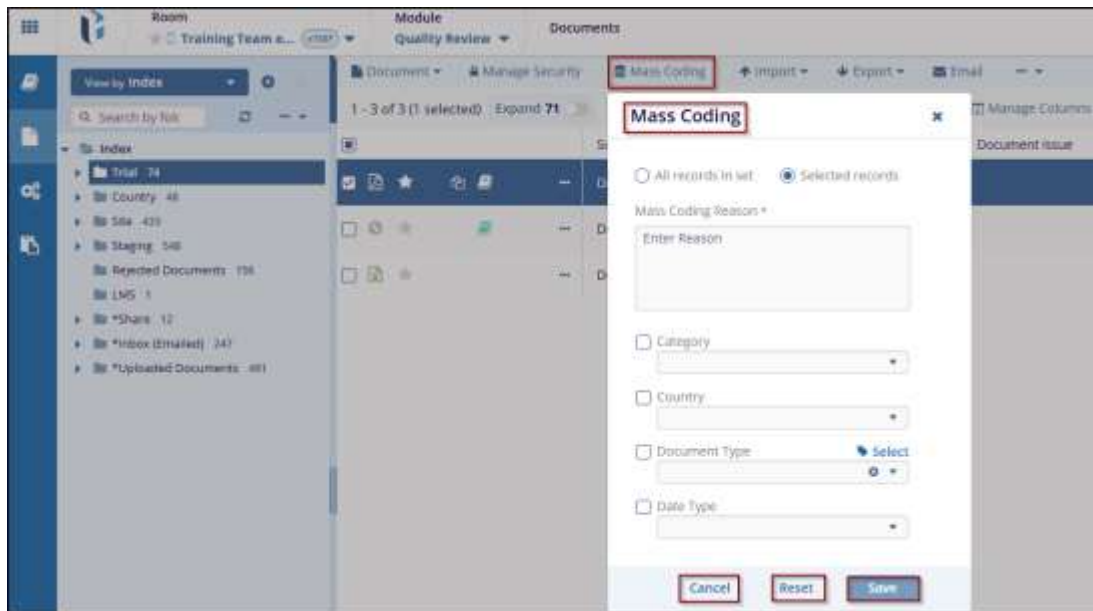


### Mass Coding

The Mass Coding allows the user to apply metadata to multiple documents at the same time. A room can be configured to allow both Causality Tracking and Mass Coding.

Steps to apply mass coding, follow these steps:

1. Click on the Mass Coding button displayed in the top menu bar to open the popup window to mass code all documents in the grid. A new window labeled Mass Coding will open.
2. Choose one of the two available options:
  - All records in the set – Applies mass coding to all records.
  - Select records – Allows manual selection of specific records.
3. Enter required details in Mass Coding Reason – Provide a reason for applying mass coding.
  - Category – Select the appropriate category.
  - Country – Choose the relevant country.
  - Document Type – Specify the document type.
4. Click Save to apply the changes or Click Reset to clear entered values, if do not wish to process Click Cancel to discard changes and exit the window.



### Importing Metadata and Document

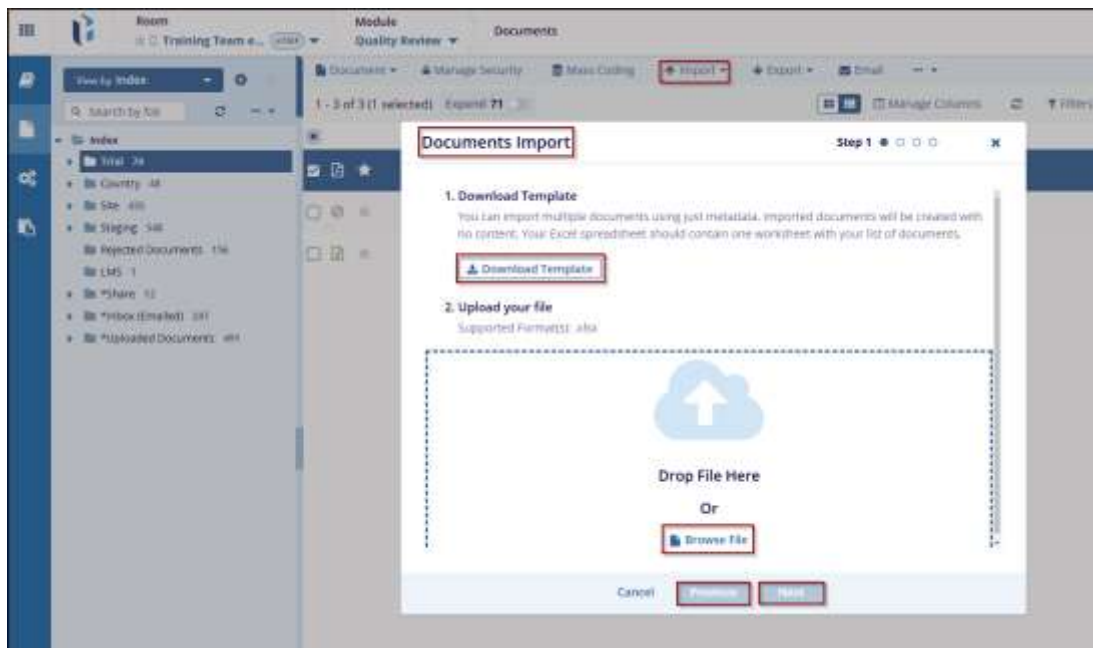
The Import allows users to bring documents and metadata into the system from external sources. There are two primary import options:

#### Metadata

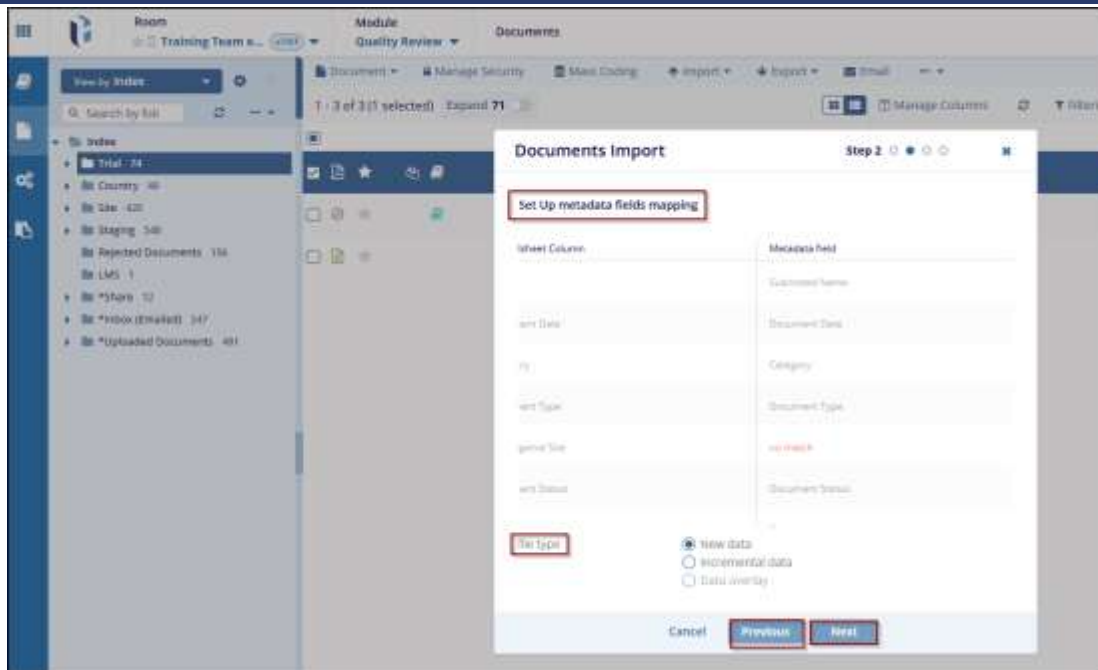
The metadata Import allows users to import metadata associated with documents, such as document type, category, country, or other key data. It enables the system to update or create metadata records in bulk, ensuring that documents are properly categorized and searchable.

To Import Metadata, follow these steps:

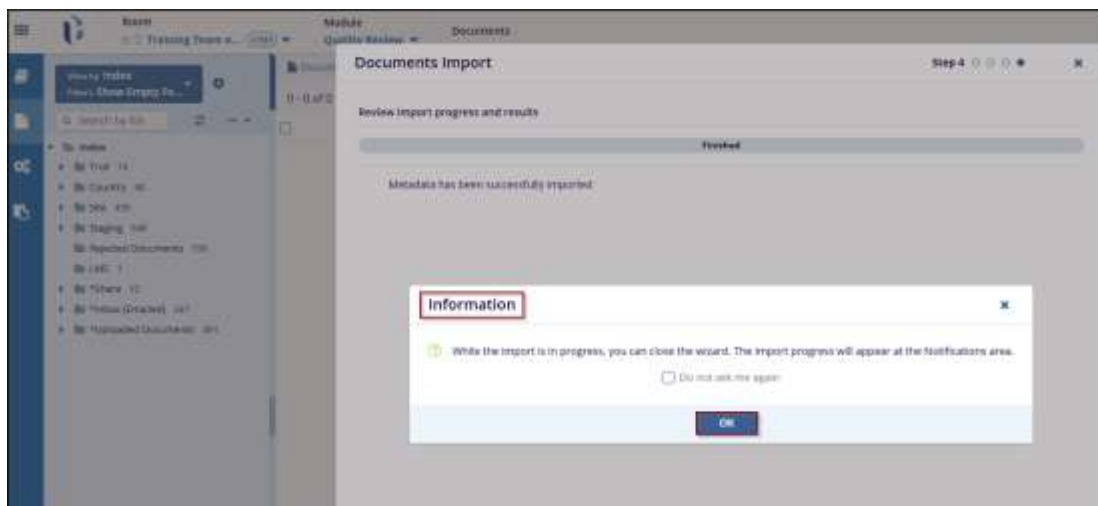
12. Click on the Metadata dropdown arrow, and select Metadata, a new window titled Document Imports will appear.
13. In the Document Imports window, click on Download Template to get a pre-formatted file that contains the required metadata fields.
14. Open the downloaded template and fill in the necessary details as per the system guidelines.
15. Under the Upload Your File section, locate the Browse button. Click Browse to open the file explorer.
16. Select the appropriate file or folder containing the metadata information.
17. Once selected, the system will display the chosen file. Click Next to proceed.



8. The system will present a metadata field mapping screen, ensuring that each column from the uploaded file is correctly mapped to the system's metadata fields.
9. Once the mapping is correctly set, click Next to proceed. If any errors are detected, click on the Previous button and go back to correct them.
10. Once confirmed, proceed by clicking Next to Import the data.



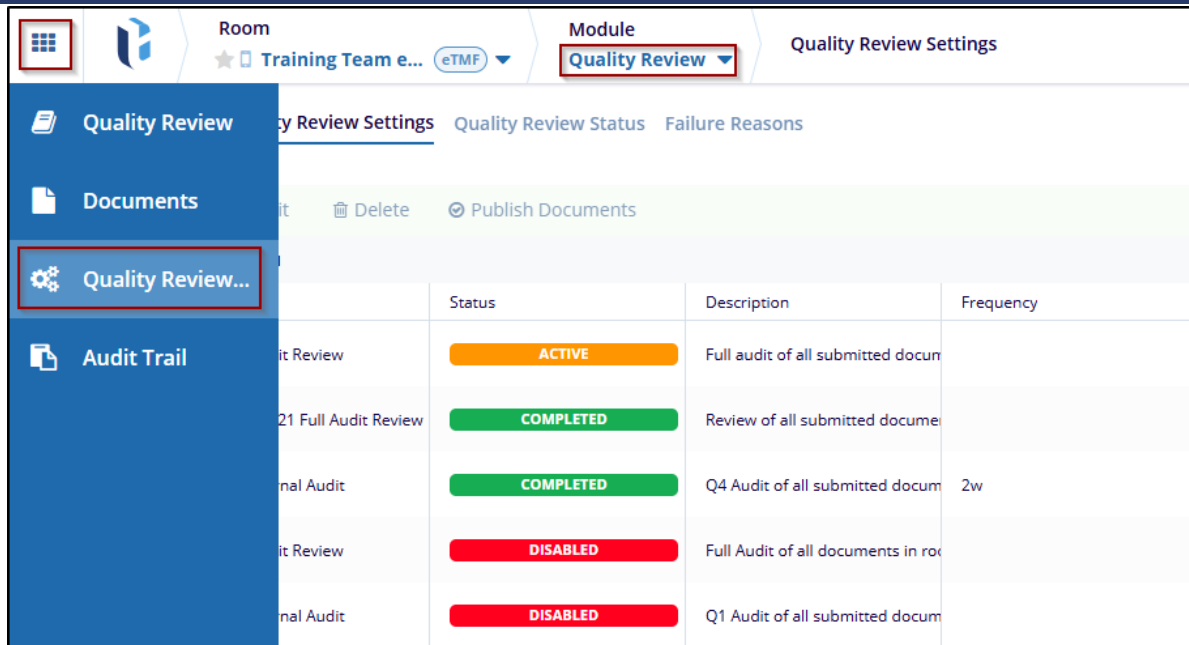
11. Click OK to View the results.



## Quality Review Setting

The Quality Review Setting section reviews and corrects study-related documents. It plays a vital role in ensuring that documents meet accuracy, quality, and regulatory standards. By applying the Quality Review settings, administrators and audit managers can set the parameters and criteria for reviewing documents, enhancing the reliability and integrity of the documentation.





The Quality Review Settings include the following sections:

- Documents Quality Reviews Settings.
- Quality Review Status.
- Failures Reasons.

## Documents Quality Reviews Setting

The Documents Quality Review Setting allows users to configure and manage the quality review process for study-related documents. It is designed to ensure that all documents adhere to the required standards of accuracy, completeness, and regulatory compliance. In this section, the user can add new documents for quality review, edit previously added documents, and Publish documents.

In Trial Interactive, before creating an Audit Profile, it is helpful to understand the various roles assigned to users as part of the audit creation process.

**Auditor:**

- Users assigned to this role are responsible for reviewing documents and assigning them a status of Passed or Failed.
- Any level of user can be assigned to this role.

**Audit Manager:**

- Users assigned to this role can see audit results, create an audit export, reassign documents to other auditors, release audit findings from review, and make changes to the audit profile.
- Only Editor-level and higher users can be assigned to this role.

**Audit Responder:**



- Users assigned to this role are responsible for taking action to rectify audit findings generated by the auditors during their review of the documents.
- Only Editor-level and higher users can be assigned to this role.



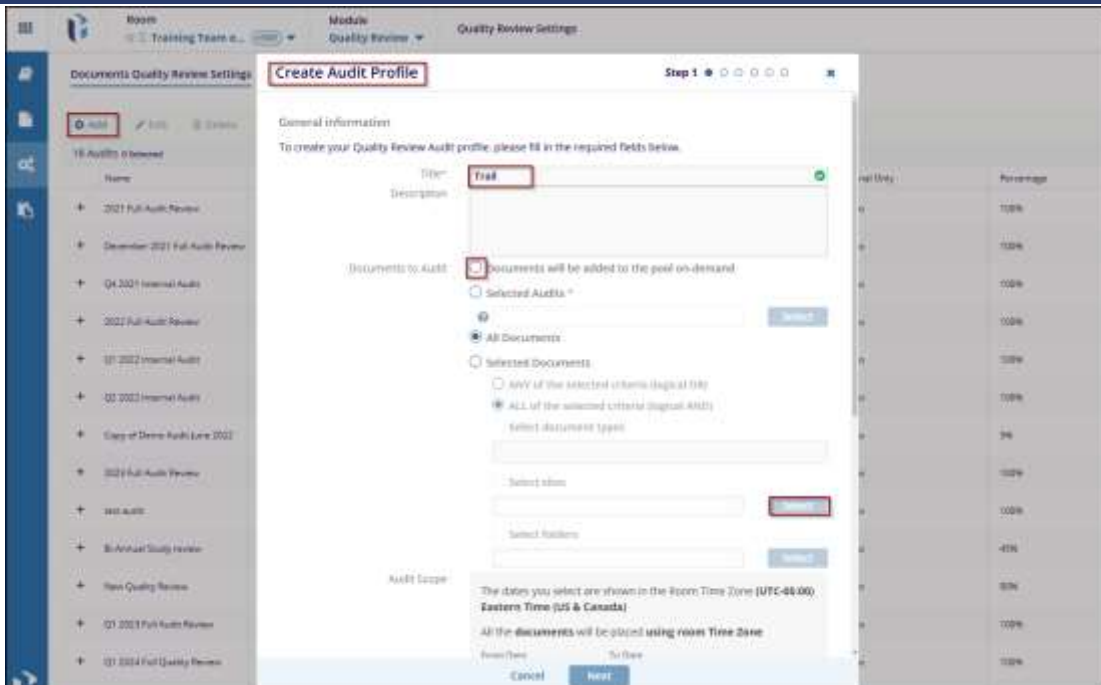
| Name                            | Status    | Description                           | Frequency | Scope                          | First Only | Percentage | Access Level | Revoke |
|---------------------------------|-----------|---------------------------------------|-----------|--------------------------------|------------|------------|--------------|--------|
| 2021 Full Audit Review          | On Hold   | Full audit of all submitted documents |           | All documents                  | No         | 100%       | Read Only    | No     |
| December 2021 Full Audit Review | Completed | Review of all submitted documents     |           | All documents                  | No         | 100%       | Full         | No     |
| Q4 2021 Interim Audit           | Completed | Q4 audit of all submitted documents   | Yes       | All documents                  | No         | 100%       | Full         | No     |
| 2022 Full Audit Review          | Completed | Full audit of all submitted documents |           | All documents                  | No         | 100%       | Full         | No     |
| Q1 2022 Interim Audit           | Completed | Q1 Audit of all submitted documents   |           | All documents                  | No         | 100%       | Full         | No     |
| Q2 2022 Interim Audit           | Completed | Q2 Audit of all submitted documents   |           | Documents will be added to the | No         | 100%       | Full         | No     |
| Copy of Demo Audit June 2022    | Completed |                                       |           | All documents                  | No         | 50         | Read Only    | No     |
| 2023 Full Audit Review          | Completed | 100% of all document submitted        |           | All documents                  | No         | 100%       | Read Only    | No     |
| 2024 audit                      | Completed |                                       |           | Selected documents             | No         | 100%       | Read Only    | No     |
| 2024 Annual Study Review        | Completed | 100% of study documents half Y1       | Yes       | All documents                  | No         | 40%        | Read Only    | Yes    |

### Create Audit Profile

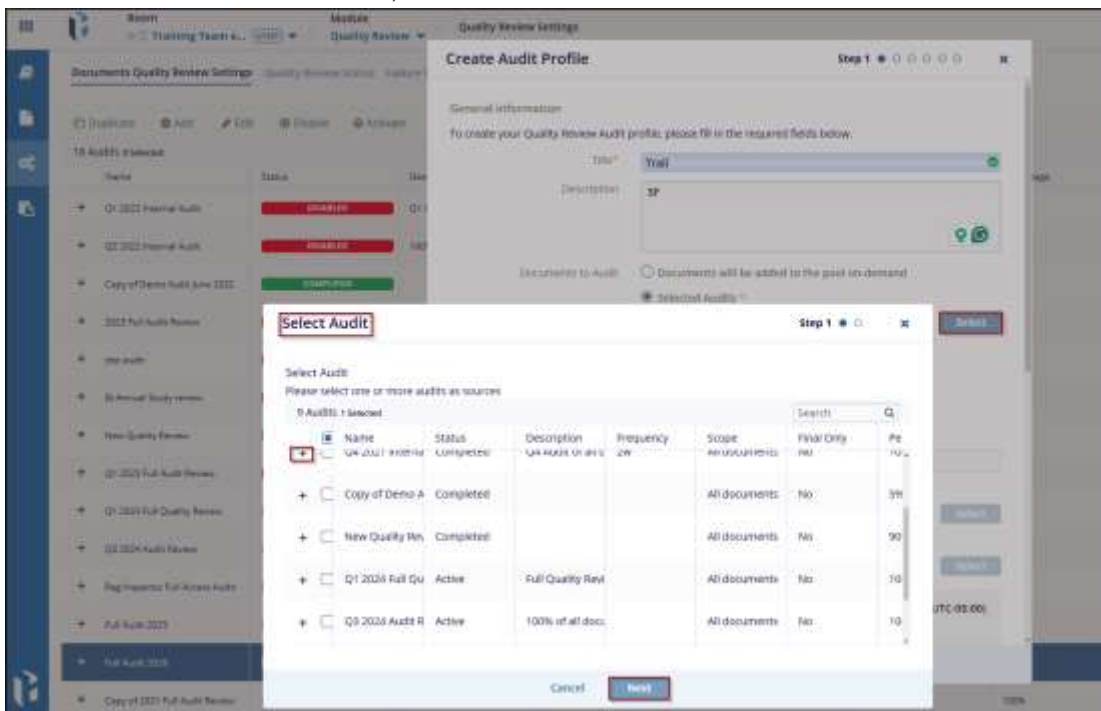
Selecting the Add button in the Document Quality Review setting enables users to create a new Audit Profile. Before starting this process, ensure that all applicable Quality Review Statutes are already created.

To Create an Audit Profile, follow these steps:

1. Navigate to the Quality Review Settings. By default, Documents Quality Review Settings is selected.
2. Click the Add button in the top menu bar above the audit's name. This opens the Create Audit Profile window.
3. Enter a Title for the audit profile. It is best to be as specific as possible.
4. Entering a Description in the field is optional but highly recommended, as it serves as a mission statement for the audit and helps in selecting the appropriate audit settings for the remaining fields.
5. The Documents to Audit area has several options to choose from:
  - a. Documents will be added to the pool on-demand: Create a blank audit with no documents. Editor, Manager, and Administrator users can manually add documents to the audit via the Documents Cart
  - b. Selected Audits: This option allows reviewing work done in a prior audit or set of audits. If selected, the user can specify which audit and auditor(s) to review.



6. Click the Select button to open the Select Audit window.
  - a. Select all documents that meet the criteria below (Please select one or more audits as sources)
  - b. Click the Next to select the auditors in the next step.
  - c. Selected Documents: Specifies criteria used by the system to gather documents for review, click the finish button.



| Name                         | Status    | Description      | Frequency | Scope         | Final Only | Pct |
|------------------------------|-----------|------------------|-----------|---------------|------------|-----|
| Q4 2021 Internal Audit       | Completed | Q4 Audit On-site | Q4        | RECURRING     | No         | 70  |
| Copy of Demo Audit June 2021 | Completed |                  |           | All documents | No         | 3%  |
| New Quality Rev              | Completed |                  |           | All documents | No         | 90  |
| Q1 2023 Full Quality Review  | Active    | Full Quality Rev |           | All documents | No         | 70  |
| Q3 2023 Audit R              | Active    | 100% of all doc  |           | All documents | No         | 70  |

7. The Audit Scope is applicable for audits reviewing documents from a specific timeframe.

8. Select whether to use Submitted Dates or Final dates to determine document inclusion in the audit scope:
  - a. Use Submitted Dates: The date the document was submitted.
  - b. Use Final Date: The date the document was made Final and published to the index.
9. Indicate whether the system should include documents already included in a previous audit.
10. Specify whether to include only documents with a final status.
11. If not checked, a document may go through the QC Workflow and Quality Review Audit simultaneously, which can lead to confusion and is not recommended.
12. Enable the option to Add modified documents back into the audit pool if metadata is updated when the Audit Responder addresses an audit finding. This ensures documents are re-added for further review if the following metadata fields are updated:
  - a. Index
  - b. Category
  - c. Document Type
13. Set the Percentage of new documents. This determines the random sampling percentage when the system gathers documents matching the criteria.
14. Use the Update Interval/Frequency field for ongoing audits that need updates at regular intervals. The system will gather new documents at the specified interval.
15. Indicate the auditor access level.
  - a. View only, no download: Restricts the auditor to view-only access.
  - b. Full Access: Allows the auditor to download or modify documents based on their user access level rights.
16. Specify whether auditors should have access to the Contains PHI function, which allows auditors to delete files containing PHI and assign them to the Audit Responder for redaction.
17. Choose whether the system should send audit notifications.
18. Click the Next button to proceed to the next step. The next step is to assign the Auditors for the audit.

Create Audit Profile
Step 1

Audit Scope

Select

The dates you select are shown in the Room Time Zone  
(UTC-05:00) Eastern Time (US & Canada)

All the **documents** will be placed **using room Time Zone**

From Date

To Date

dd MMM yyyy

dd MMM yyyy

Confirm

☒ Use Submitted Dates
☐ Use Final Dates

☐ Do not include already audited documents
☐ Final documents only
☐ Add modified documents back into the audit pool

Percentage of new documents \*

100

Update Interval / Frequency

week

Auditor access level

☒ View only, no download
☐ Full Access

Contains PHI

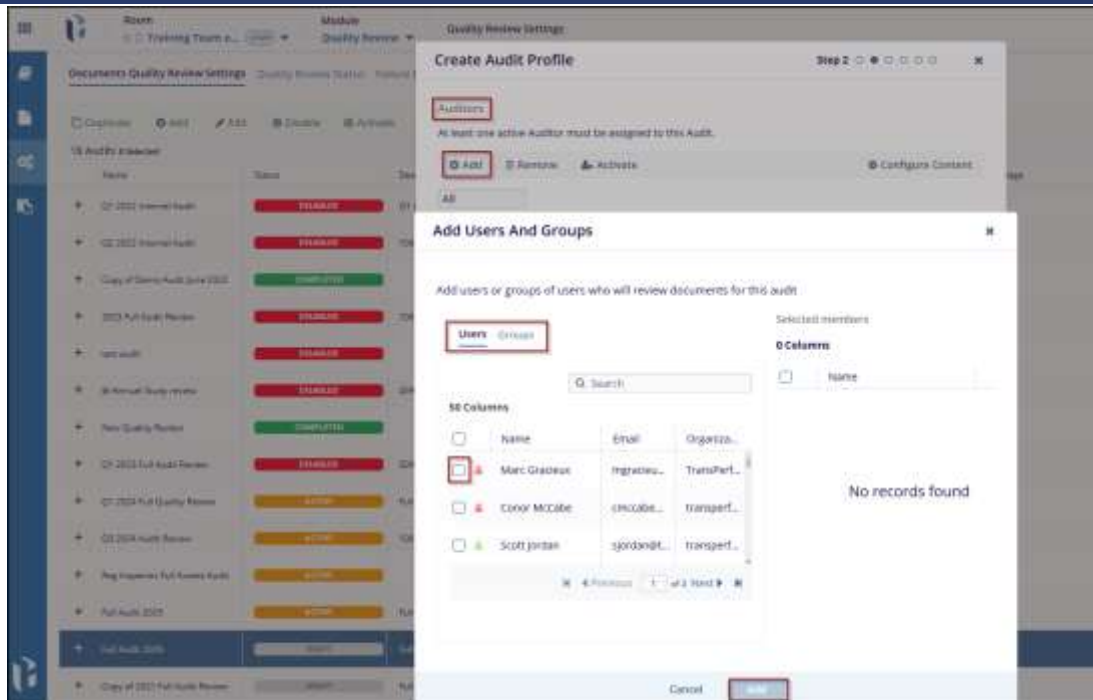
☐

☐ Send a notification when the documents are added into audit pool
☐ Send a notification for audit issues

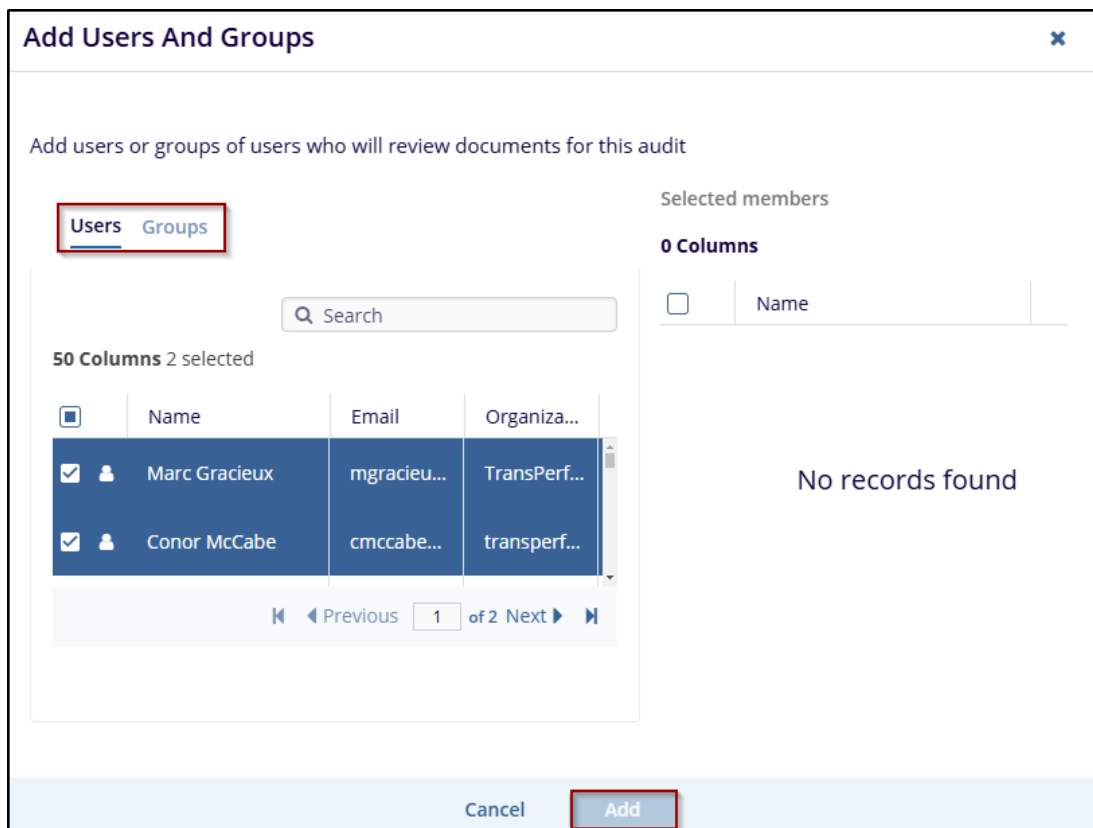
Cancel

Next

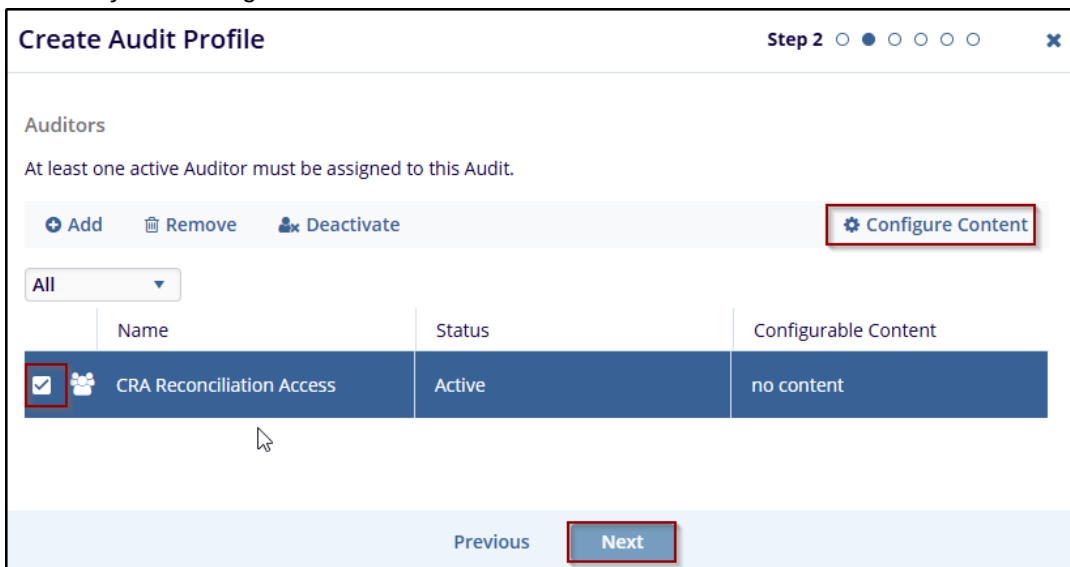
19. Click the Add button to open the Add Users and Groups window.



20. Move the applicable users and/or groups to the right panel by clicking, dragging, double-clicking, or pressing the + sign next to the user's name.
21. Click the Add button at the bottom of the popup window.



22. If multiple auditors are added, the Configure Content option can be used:
  - a. This option is most useful when you have chosen specific criteria such as document types or investigative sites and you would like a specific auditor to review a specific document type or all documents associated with a specific site.
  - b. Select the auditor and click the Configure Content button displayed in the top right corner.
  - c. Choose the criteria to assign documents to the selected auditor:
    - Document Types
    - Sites
    - Folders
  - d. Once selected, specify which document types, sites, or folders apply to the selected user.
23. Select the auditor who needs to be removed from the audit.
24. Click the Deactivate button.
  - a. This will open the Documents Reassignments window.
25. Choose what to do with the user's remaining documents.
  - a. Leaving the Automatically reassign all documents randomly between existing auditors box checked will do just that. The auditors' remaining documents will be reassigned randomly.
  - b. If the box is unchecked, you will be able to choose an auditor to reassign the documents to. Move the selected recipient from the left side of the window to the right side.
26. Press Add to proceed through the remainder of the Edit Audit wizard and press Finish to save your changes.



**Create Audit Profile** Step 2

**Auditors**

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

[Add](#)
[Remove](#)
[Deactivate](#)
[Configure Content](#)

All

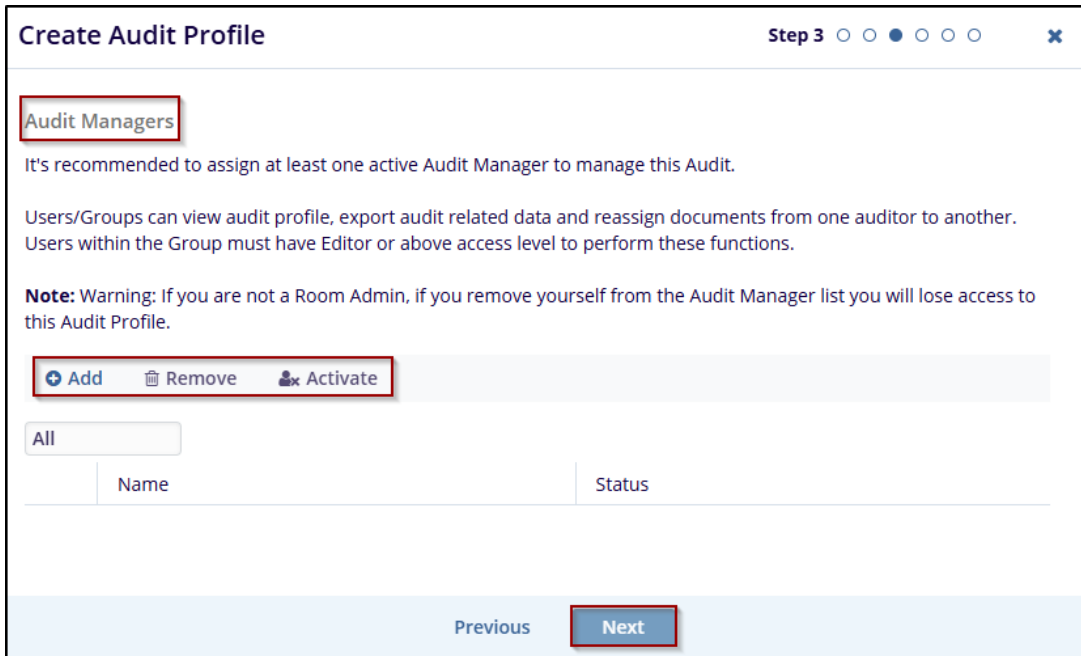
|                                     | Name                      | Status | Configurable Content |
|-------------------------------------|---------------------------|--------|----------------------|
| <input checked="" type="checkbox"/> | CRA Reconciliation Access | Active | no content           |

[Previous](#)
[Next](#)

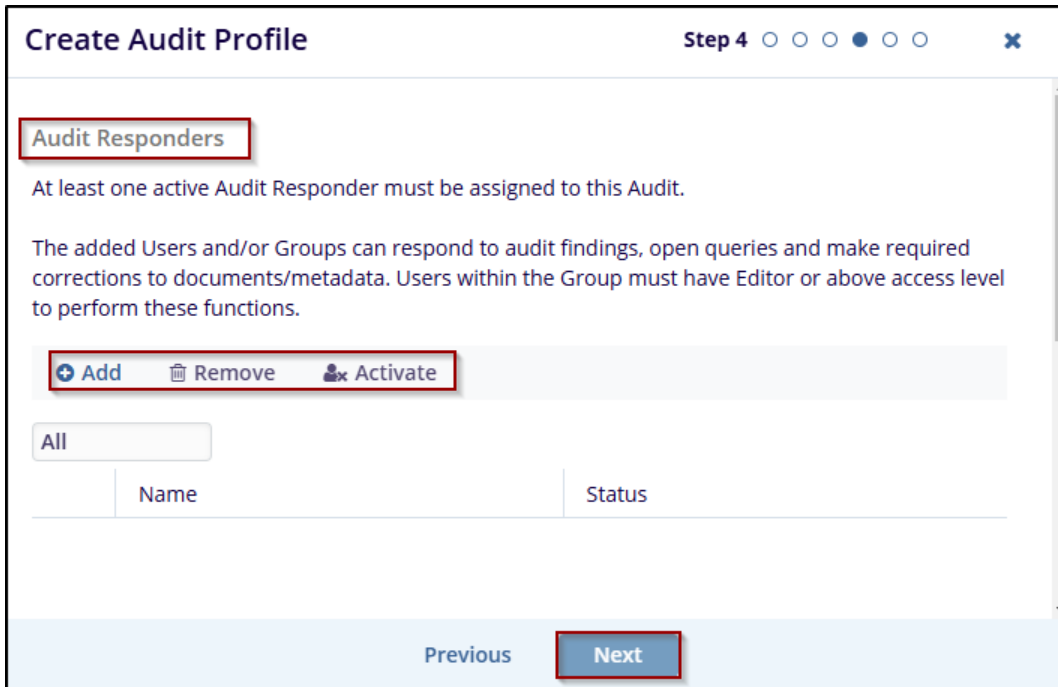
27. When you are done adding auditors and, if necessary, configuring content, click the Next button.
28. The next step is to assign the Audit Managers for the audit.
29. Click the Add button in the top-left corner of the popup window, this will open the Add Users and Groups window.
30. Move the applicable users and/or groups to the right panel by clicking and dragging,

double-clicking, or by pressing the + sign that appears at the right side of the user's line.

31. Click the Next button when done.



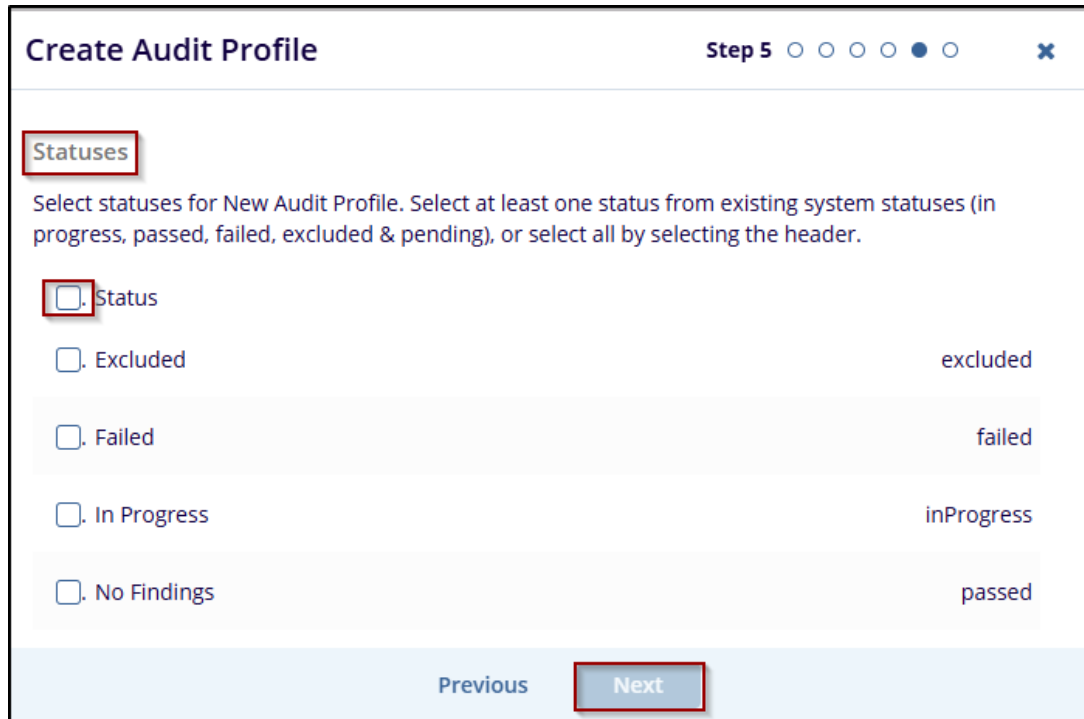
32. The selected Audit Managers will appear in the grid.
33. The next step is to assign the users who will be Audit Responders for the audit.



Note: The users cannot be the same for Audit Responders as those who are added as

Auditor Managers.

34. Click the Add button. This will open the Add Users and Groups window.
35. Move any applicable users and/or groups to the right panel by clicking and dragging, double-clicking, or pressing the + sign that appears at the right side of the user's line.
36. Click the Next button, once completed.
37. In the next window, choose the document statuses for the audit. These must have been created before the audit setup.
38. At least one status must be included for each of the basic five system statuses:
  - Passed
  - Failed
  - Pending
  - In Progress
  - Excluded
39. Click the Next button once done.



**Create Audit Profile** Step 5 ○ ○ ○ ○ ● ○ ✕

**Statuses**

Select statuses for New Audit Profile. Select at least one status from existing system statuses (in progress, passed, failed, excluded & pending), or select all by selecting the header.

|                                            |            |
|--------------------------------------------|------------|
| <input checked="" type="checkbox"/> Status |            |
| <input type="checkbox"/> Excluded          | excluded   |
| <input type="checkbox"/> Failed            | failed     |
| <input type="checkbox"/> In Progress       | inProgress |
| <input type="checkbox"/> No Findings       | passed     |

Previous **Next**

40. The final screen will display any detected errors (e.g., a user added as both an Audit Manager and an Audit Responder).
41. If errors are detected, use the section link to go back and correct the issue.
42. Once done, click the Finish button.



Create Audit Profile

Step 6 ○ ○ ○ ○ ● ✕

Statuses ↗

✔ No issues found

The following audit statuses were defined for the audit profile:

Excluded

Failed

In Progress

No Findings

Pending

Passed

You're fired!!!

Previous

Finish

43. A window will appear asking whether to activate the audit, click No to close the window, and the audit will be added to the list with an Inactive status, or click Yes to close the window, and the audit will be added to the list with an Active status.
44. The Document Quality Review Settings will display the newly created audit profile in the grid.

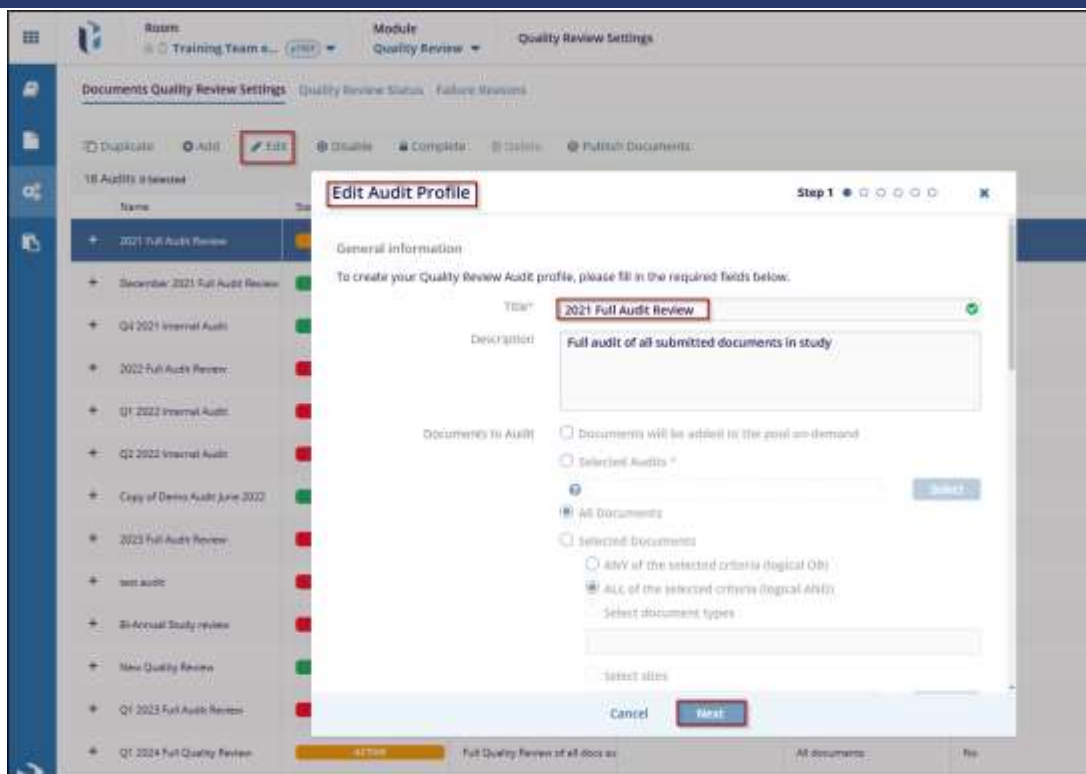
[Edit Audit Profile](#)

The Edit button allows for updates to be made without creating a new audit, ensuring that the ongoing process can be adapted or corrected based on changes in requirements.

Existing audits can be edited by any room administrator or users assigned as Audit Managers for a specific audit. For example, an Editor or Manager-level user designated as an Audit Manager for a quality review audit will have access to the Quality Review Settings menu. The key difference is that an Administrator can view all audits, while an Editor or Manager can only see audits where they are assigned as the Audit Manager.

To Edit an existing audit, follow these steps:

1. Select the audit from the list. Click the Edit button from the top menu bar, and the Edit Audit Profile window opens.
2. For more details on the steps, refer to Add Audit Profile and follow the instructions to make any necessary changes.

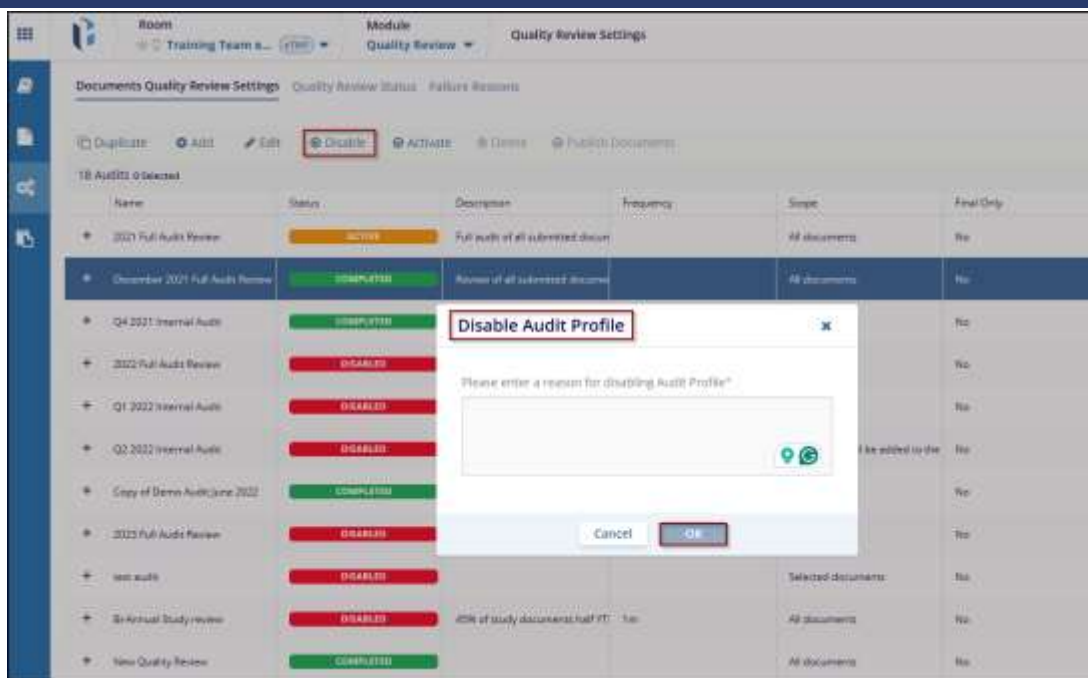


### Disable Audit Profile

An audit can be disabled by the user when it is no longer required.

To Disable the Audit Profile, follow these steps:

1. Click the Disable button displayed in the top menu bar.
2. Enter a reason in the popup window (mandatory).
3. Click the OK button displayed at the bottom of the popup window.

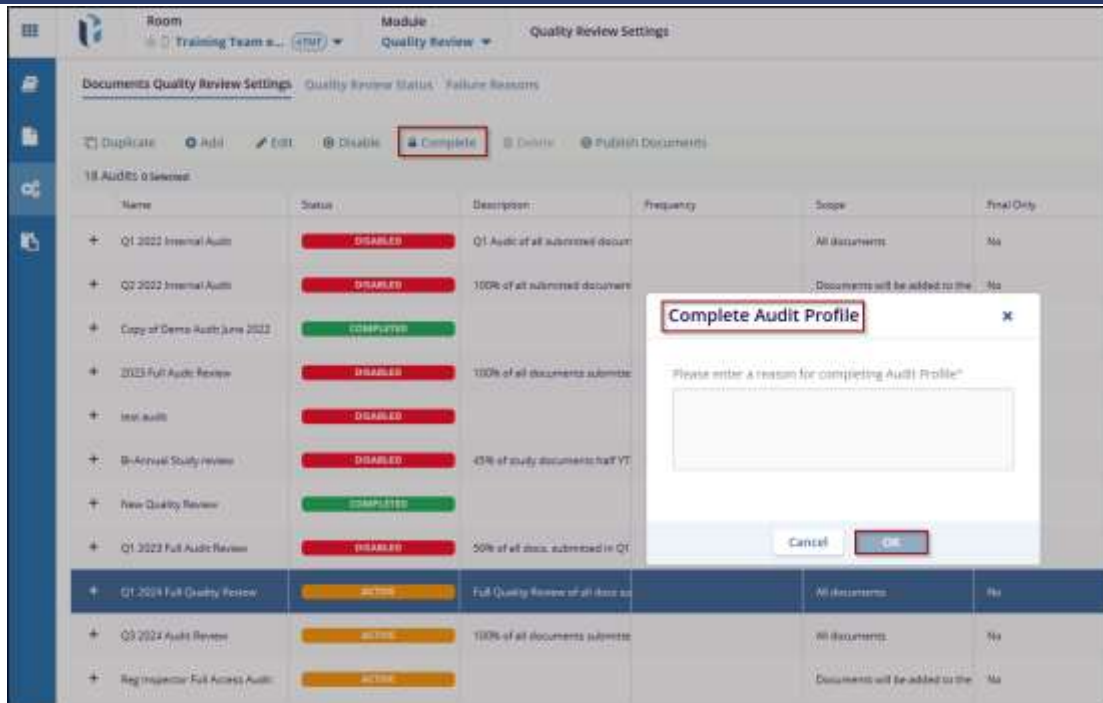


### Complete Audit Profile

The audit is complete only when the status column displays an Inactive status for a specific audit.

To complete the audit profile, follow these steps:

1. Select the audit that displays the Active status.
2. Click the Complete button displayed in the top menu bar.
3. Enter a reason in the popup window (mandatory).
4. Click the OK button displayed at the bottom of the popup window.



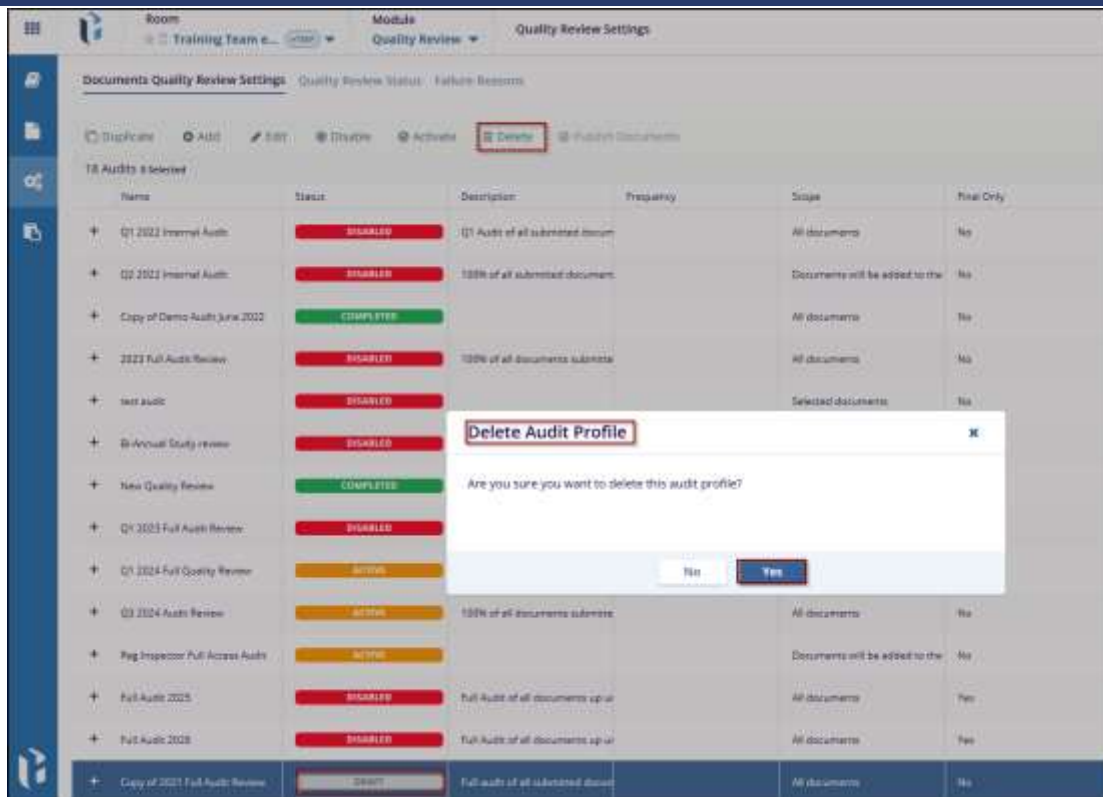
Note: Select an audit with Active status. The Complete button does not appear in the top menu bar for other statuses.

### Delete Audit Profile

An audit can only be deleted if no document has been reviewed. Once a document has been reviewed as part of the audit, the audit can only be stopped, not deleted.

To Delete an Audit Profile:

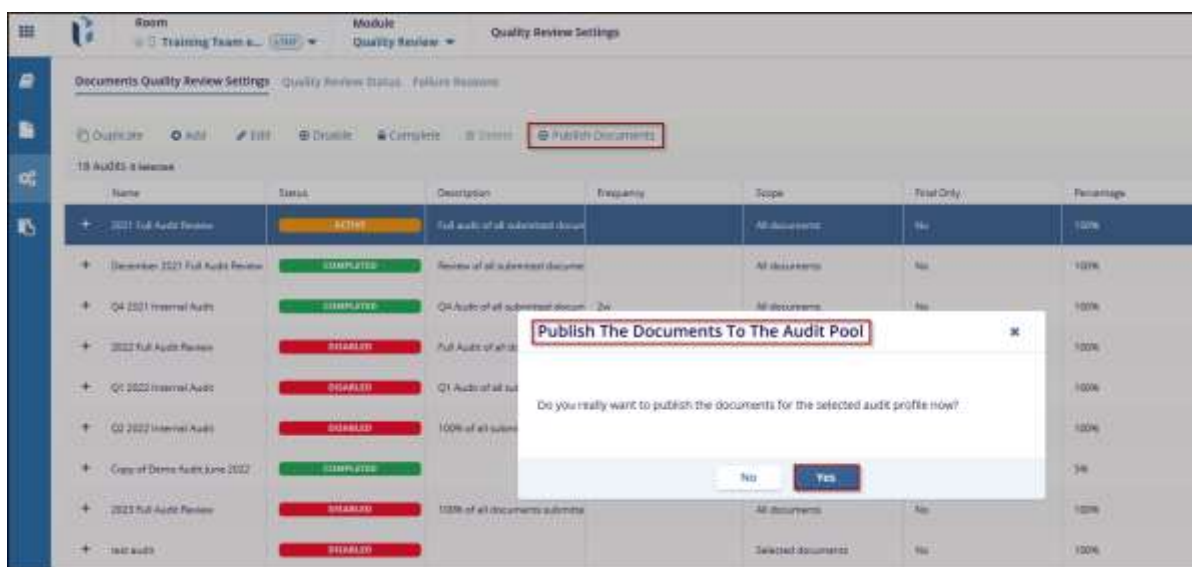
1. Select the audit from the list.
2. Click the Delete button displayed in the top menu bar. A new confirmation window will open.
3. Click on Yes, the audit will be removed from the list.



Note: The Delete button appears in the top menu bar, only if a Draft status audit is selected.

### Publish Documents

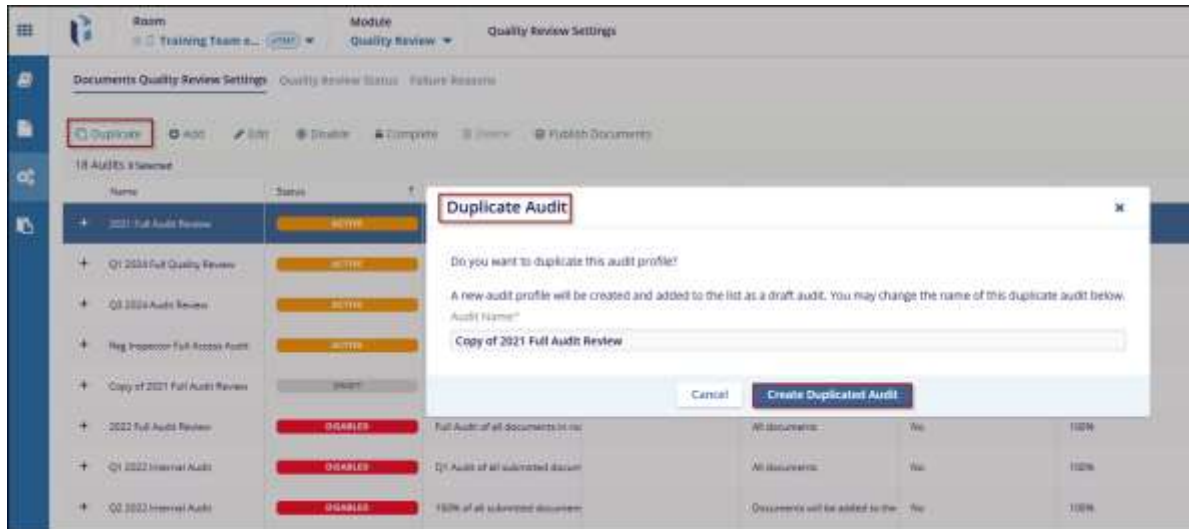
The user may need to deactivate and reactivate an audit profile in a study room. If the audit is reactivated and new documents need to be added, select the audit and click the Publish Documents button.



Note: Only those audit documents can be published that display an Active status.

## Duplicate Audit

Users of Trial Interactive often need to run the same quality review audit multiple times, making changes such as updating the participating auditors. Additionally, the audit scope may need to be modified after the audit has started, without impacting the current audit.

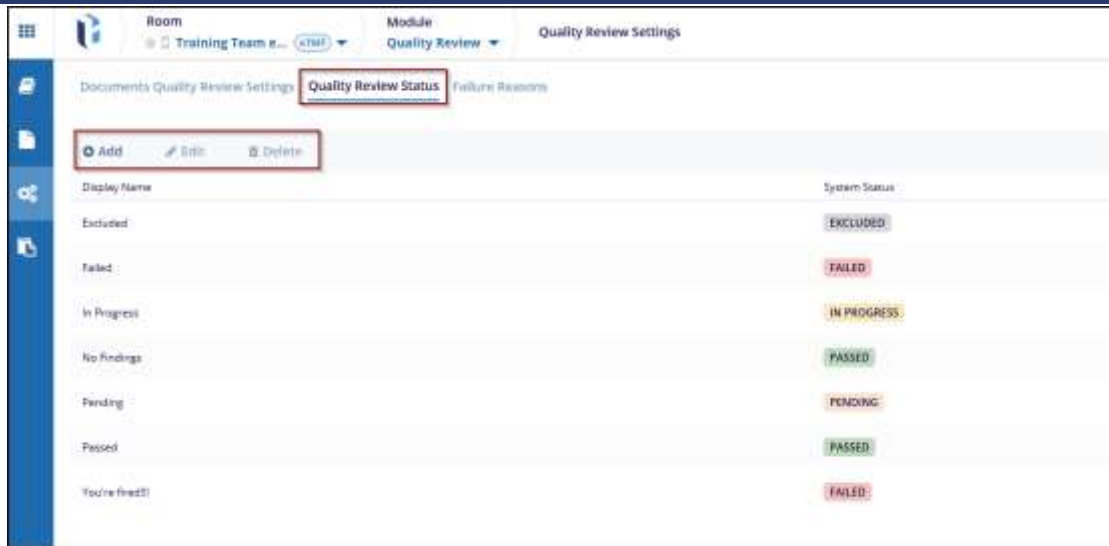


## Quality Review Status

Every status that can be assigned to a document during a quality review has to be added to the Quality Review Status before the related audit is built. The system allows users to create custom statuses but each one will represent one of the basic six system statuses:

The 6 basic system statuses:

- **Passed:** No findings are associated with the document, indicating it meets all required standards.
- **Failed:** The document has failed the review, generating an audit finding that needs to be reviewed and potentially corrected by the Audit Responders.
- **Pending:** The document is awaiting review by an auditor and has not yet been assessed.
- **In Progress:** A placeholder status used between Passed and Failed, representing ongoing evaluation or other review-related activities.
- **Excluded:** This status cannot be manually applied by users but may be automatically assigned by the system under specific conditions.
- **No Findings:** The document has no findings associated with it, indicating no issues were identified during the review process.

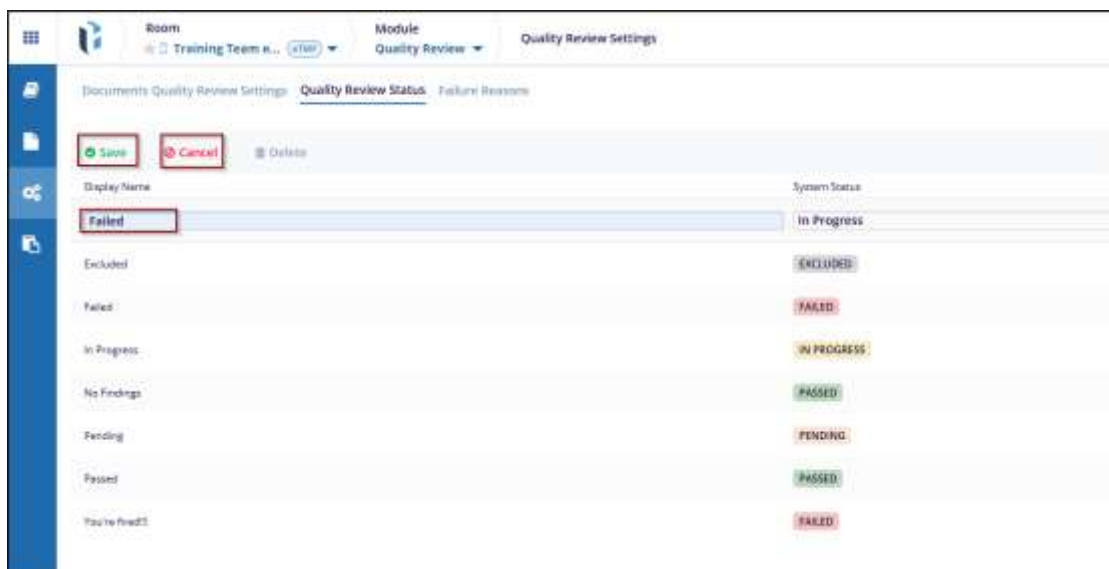


### Add Status

The Add button is used to add a new Status below.

To Add audit statuses, follow these steps:

1. Click the Add button on the Quality Review Status tab.
2. Once clicked on the Add button, the fields under the Display Name and System Status are available to edit.
3. Enter the statuses in the Display Name. Click on the dropdown arrow from the System Status field and select the established System Status term to associate with the newly added Display Name.
4. After adding, click the Save button to apply the changes and click on Cancel to discard the changes.

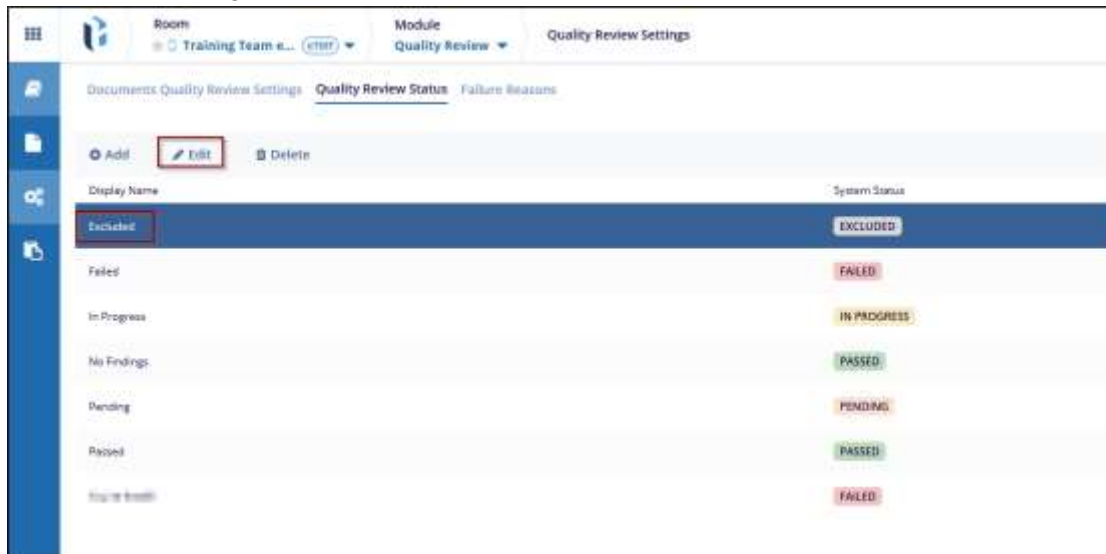


### Edit Status

The Edit button is used to edit the available audit status.

To Edit the available audit status, follow these steps:

1. Select the status from the list in the Display Name in the Quality Review Statuses tab.
2. The user can edit the audit in 2 ways, click the Edit button on the top ribbon bar or click the Edit button that appears when the user hovers the mouse over the status.
3. After Editing, click the Save button to apply the changes and click on Cancel to discard the changes.



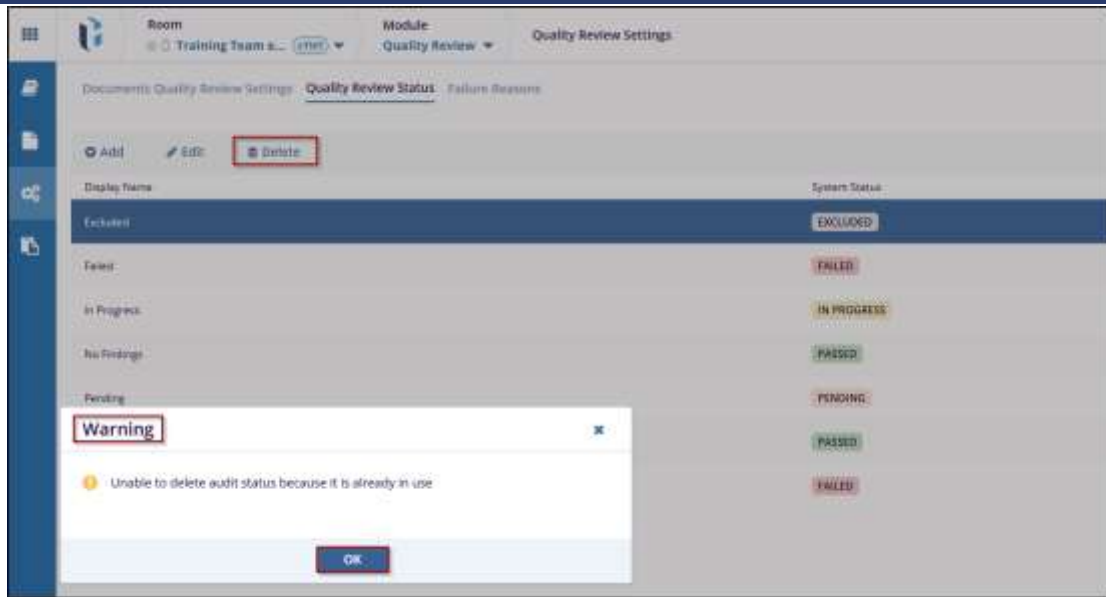
### Delete Status

The Delete button is used to delete the available statuses, in the quality review setting.

To delete an audit status, follow these steps:

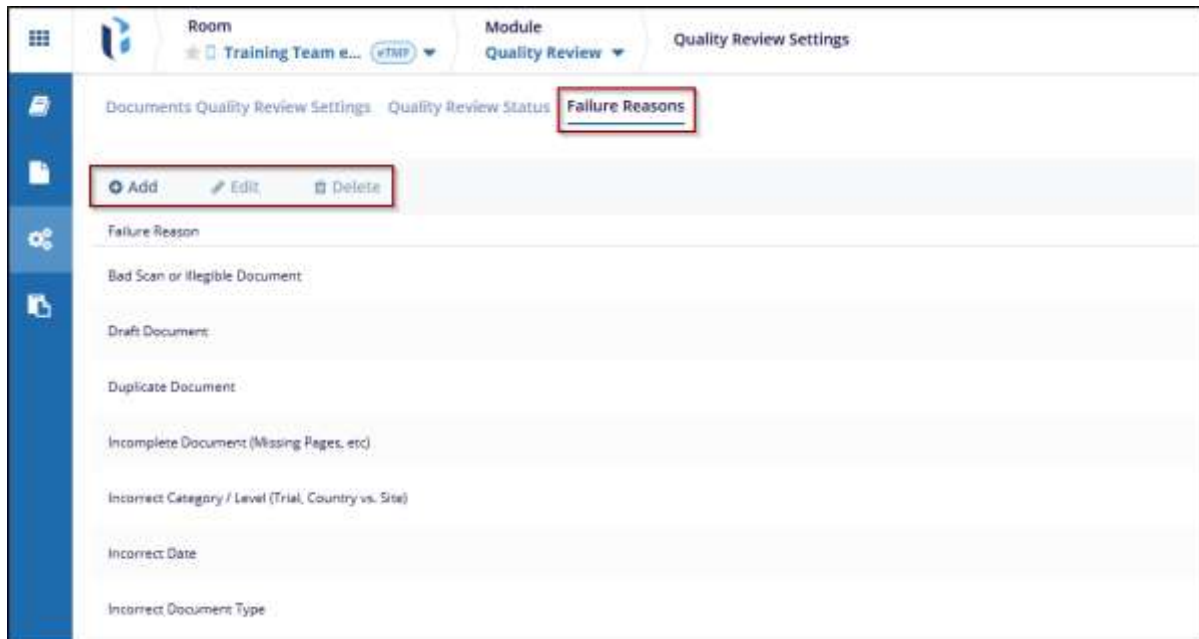
1. Select the status from the list in the Quality Review Status tab.
2. Click the Delete from the top ribbon bar or click the trash can icon that appears, after hovering the mouse over the status.





## Failure Reasons

The Failure reasons help categorize why a document failed while reviewing, allowing reviewers to track, report, and address recurring issues.



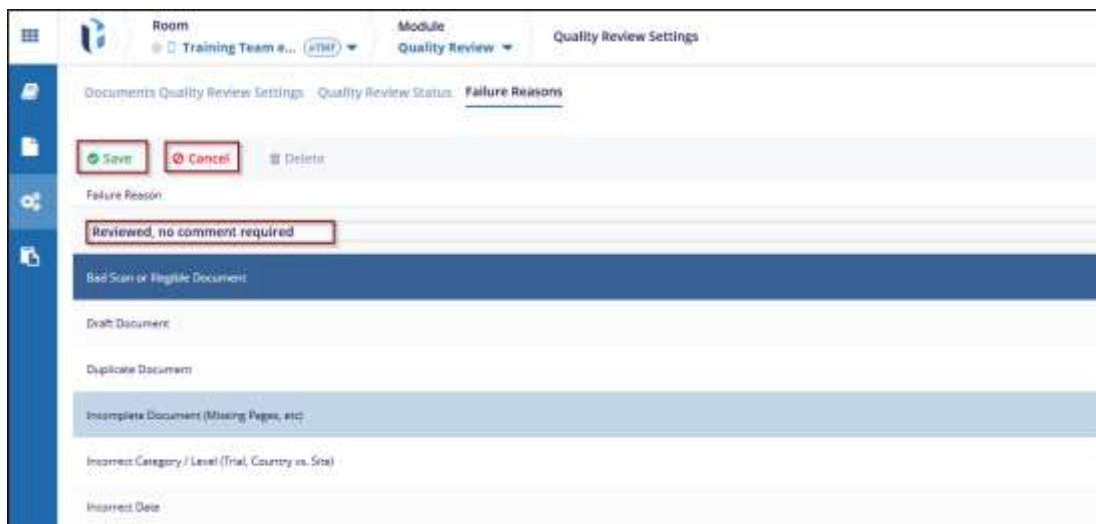
### Add Failure Reason

The Add button is used to add a new failure reason.

Steps to Add Failure Reasons:

1. Click the Add button on the Failure Reasons tab.

- Once clicked on the Add button, the fields under the Failure Reason are available to edit.
- Enter the Failure reasons below.
- After adding a reason, click the Save button to apply the changes and click on Cancel to discard the changes.



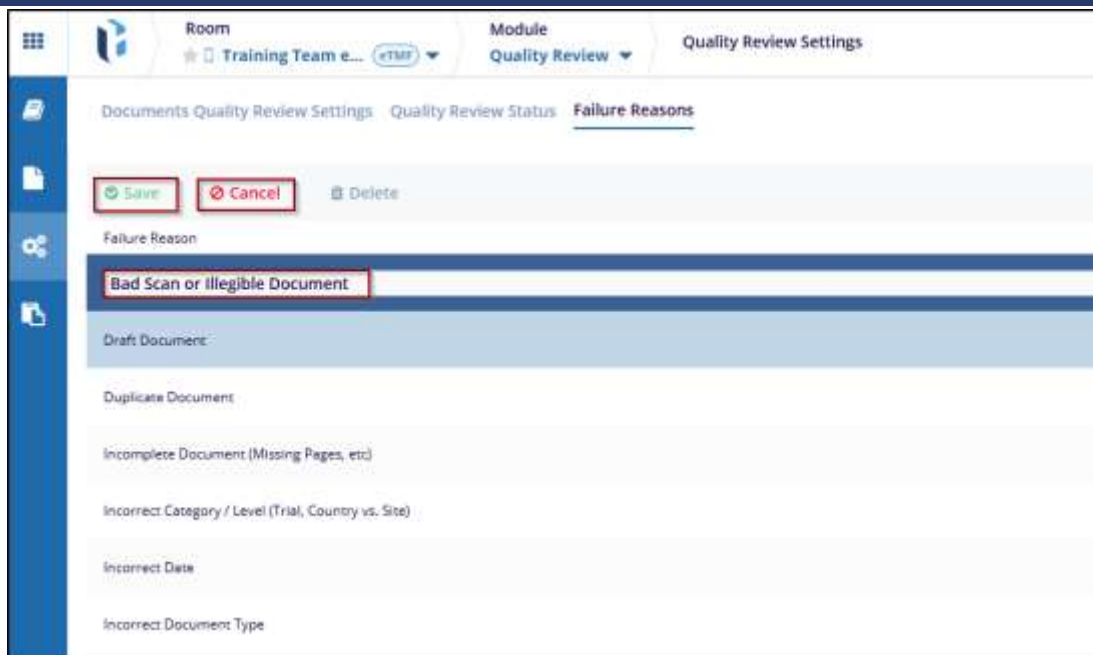
The screenshot displays the 'Failure Reasons' tab within the 'Quality Review' module. At the top, there are navigation links for 'Documents', 'Quality Review Settings', 'Quality Review Status', and 'Failure Reasons'. Below these links, there are three buttons: 'Save' (highlighted with a red box), 'Cancel' (highlighted with a red box), and 'Delete'. The main area shows a list of failure reasons, with 'Reviewed, no comment required' highlighted in blue. Other reasons listed include 'Bad Scan or Illegible Document', 'Draft Document', 'Duplicate Document', 'Incomplete Document (Missing Pages, etc)', 'Incorrect Category / Level (Trial, Country vs. Site)', and 'Incorrect Date'.

### *Edit Failure Reason*

The Edit button is used to edit the available failure reasons.

To Edit the available audit status:

- Select the reasons from the below display list, from the Failure Reasons tab.
- After editing, click the Save button to apply the changes and click on Cancel to discard the changes.

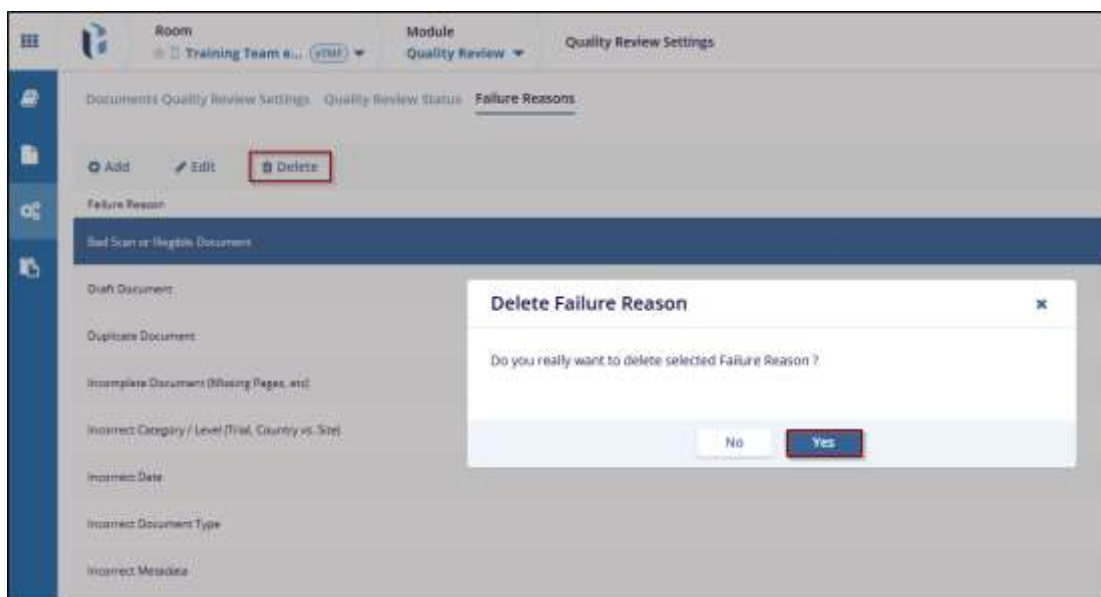


### Delete Failure Reason

The Delete button is used to remove the available statuses.

To delete an audit status:

1. Select the reasons from the below list in the Failure Reason tab.
2. Click the Delete from the top ribbon bar or click the trash can icon that appears, after hovering the mouse over the reason.



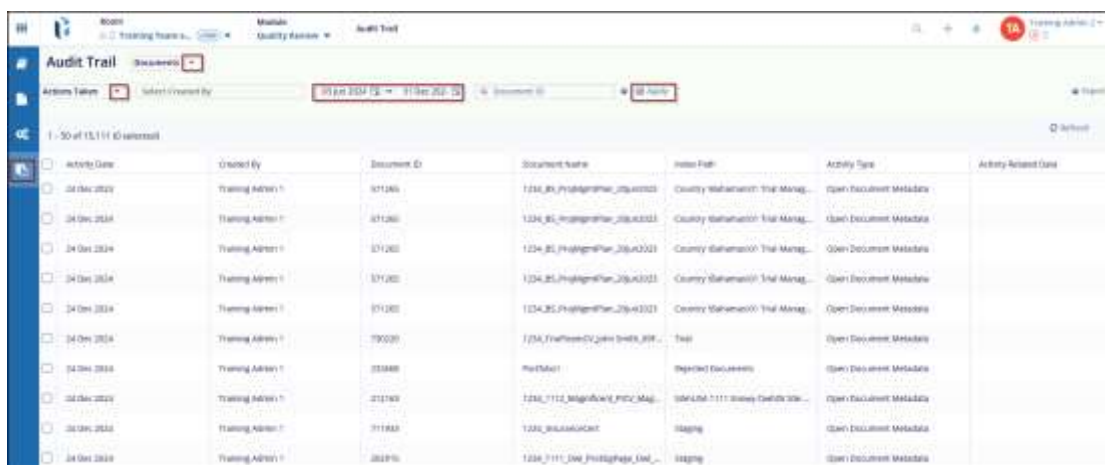
## Audit Trail

The Audit Trail in the Quality Review module provides a comprehensive record of all actions performed on documents within a study room. This is designed to help users track activities for auditing and compliance purposes. Users can filter the audit trail by various criteria to efficiently retrieve specific records.

For more detailed steps refer to Queries module.

The audit trail can be filtered by:

- **Actions Taken:** Select specific types of actions, such as Created, Modified, or Deleted.
- **Created By:** Filter records based on the user who created.
- **Date Range:** Specify the start and end dates to view actions within a specific timeframe.
- **Documents, Folders, Placeholders, and Users:** Use these options to narrow down the search to specific entities.



The screenshot shows the 'Audit Trail' interface. At the top, there are filters for 'Actions Taken' (set to 'All'), 'Created By' (set to 'Training Admin'), 'Date Range' (from 01 Jan 2024 to 31 Dec 2024), and 'Document ID' (set to 'All'). Below the filters, a table displays the audit trail records. The table has columns for 'Activity Date', 'Created By', 'Document ID', 'Document Name', 'Folder Path', 'Activity Type', and 'Activity Related Date'.

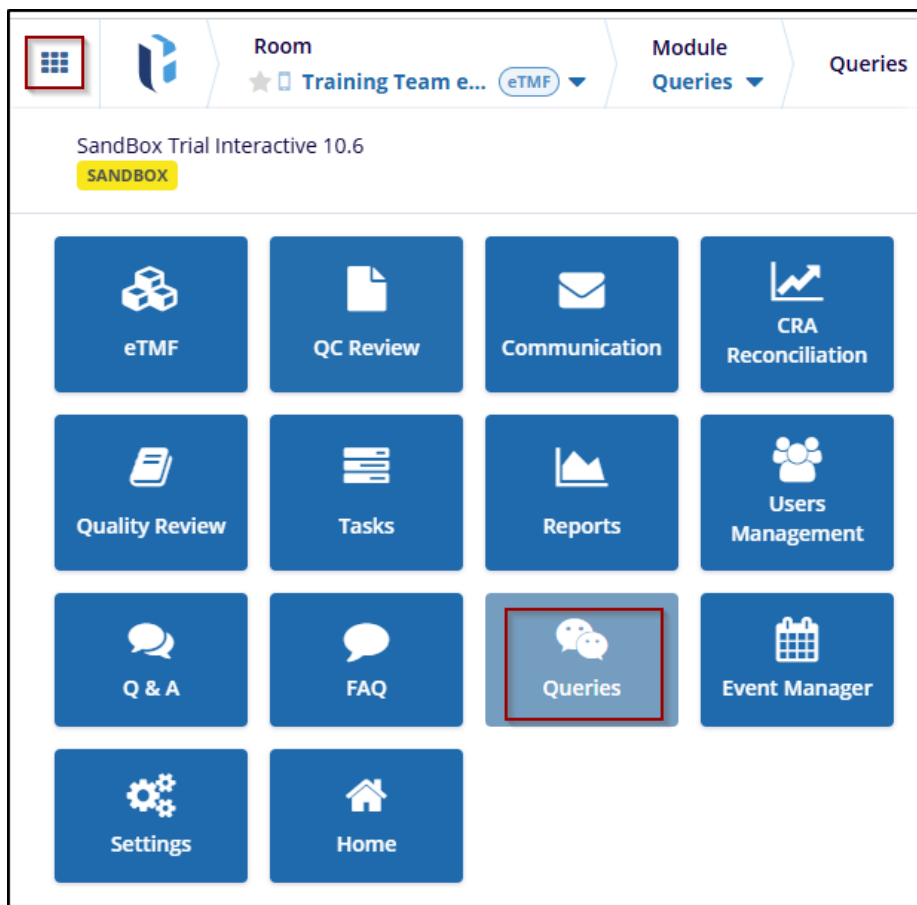
| Activity Date | Created By     | Document ID | Document Name                 | Folder Path                          | Activity Type          | Activity Related Date |
|---------------|----------------|-------------|-------------------------------|--------------------------------------|------------------------|-----------------------|
| 28 Dec 2023   | Training Admin | 121265      | 121265_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121266      | 121266_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121267      | 121267_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121268      | 121268_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121269      | 121269_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121270      | 121270_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121271      | 121271_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121272      | 121272_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121273      | 121273_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121274      | 121274_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121275      | 121275_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121276      | 121276_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121277      | 121277_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121278      | 121278_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121279      | 121279_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121280      | 121280_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121281      | 121281_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121282      | 121282_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121283      | 121283_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121284      | 121284_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121285      | 121285_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121286      | 121286_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121287      | 121287_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121288      | 121288_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121289      | 121289_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121290      | 121290_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121291      | 121291_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121292      | 121292_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121293      | 121293_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121294      | 121294_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121295      | 121295_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121296      | 121296_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121297      | 121297_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121298      | 121298_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121299      | 121299_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |
| 28 Dec 2023   | Training Admin | 121300      | 121300_Physiotherapy_20230223 | Country Maharashtra - Trial Manag... | Open Document Metadata |                       |

## CHAPTER 15. QUERIES MODULE

The Queries Module allows users to manage and view queries within a system, offering multiple ways to filter, categorize, and access information based on user needs. Queries can be associated with documents, workflow processes, or audit-related activities.

Users can access this module from the Navigation Grid in the upper-left corner of the screen, where the Queries Module is listed.

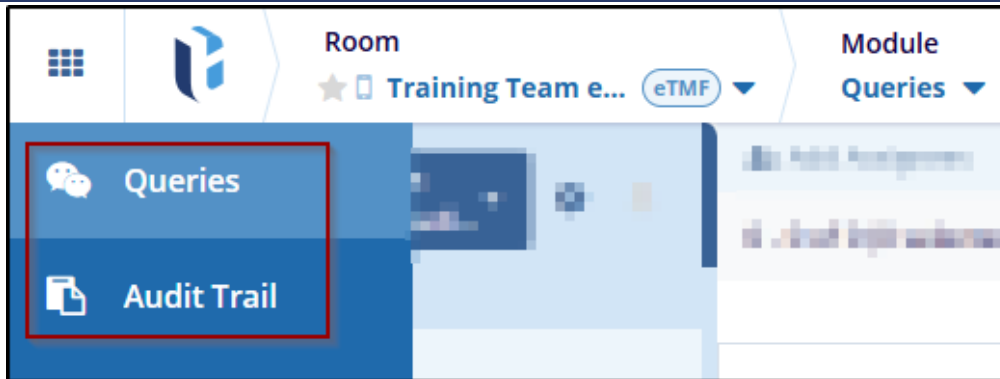
Refer to the screenshot below:



The Queries module includes:

- Queries
- Audit Trial

Refer to the screenshot below:



## Queries

Queries enable users to filter and organize the query according to requirements. The interface displays a customizable option, simplifying the process of tracking and managing queries effectively.

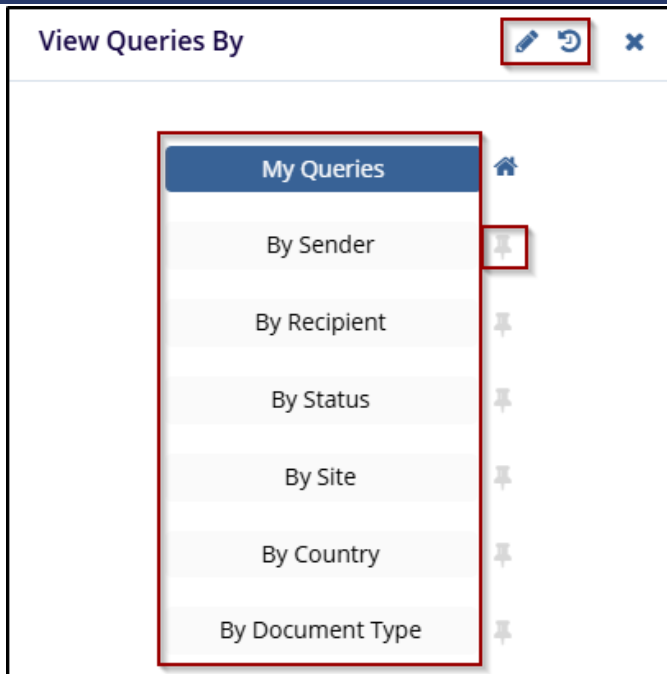
### View Queries by

The View Queries By allows users to filter queries based on requirements such as sender, recipient, status, site, or document type. This improves query management by allowing users to focus on relevant information.

The View Queries by options are:

- **My Queries:** This is a default view where users can view their queries across various filters.
- **By Sender:** View queries filtered by the sender of the query.
- **By Recipient:** View queries based on the recipient of the query.
- **By Status:** Sort queries by their status, such as Pending, In Progress, or Resolved.
- **By Site:** Filter queries based on the site associated with the query.
- **By Country:** Filter queries based on the country related to the query.
- **By Document Type:** Organize queries based on the type of document associated with the query.

Refer to the below screenshot:



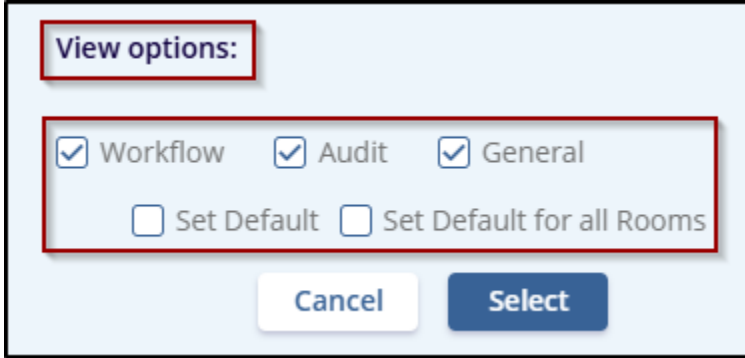
Note: In View Queries By options can be modified using the Pencil icon. Clicking the pencil icon allows users to edit the available filter options, Refresh the option using the Refresh icon, and enable them to pin or unpin specific criteria according to user preferences.

## Views option

The View Options section allows users to control the type of queries displayed in the list by selecting or deselecting options.

The View options are

- Workflow: Displays queries related to approvals or status-changed queries.
- Audit: Shows queries that involve audit trail actions.
- General: Includes queries that do not belong to specific queries.
- Set Default: Saves the selected view options as the default for the current session.
- Set Default for all Rooms: Applies the selected view options as the default across all rooms for the user.



**View options:**

☒ Workflow   ☒ Audit   ☒ General

☐ Set Default   ☐ Set Default for all Rooms

**Cancel**   **Select**

Steps to apply a filter for queries:

1. Click on the dropdown menu, View Queries By window will display.
2. Select My Queries from View Queries By.
3. Select the checkbox as per the user requirement from the View Options section on the View Queries By pop-up window.
4. Click Select to apply the changes or click Cancel to discard changes and retain previous settings.



**View Queries By**

**My Queries** 

By Sender 

By Recipient 

By Status 

By Site 

By Country 

By Document Type 

**View options:**

☒ Workflow   ☒ Audit   ☒ General

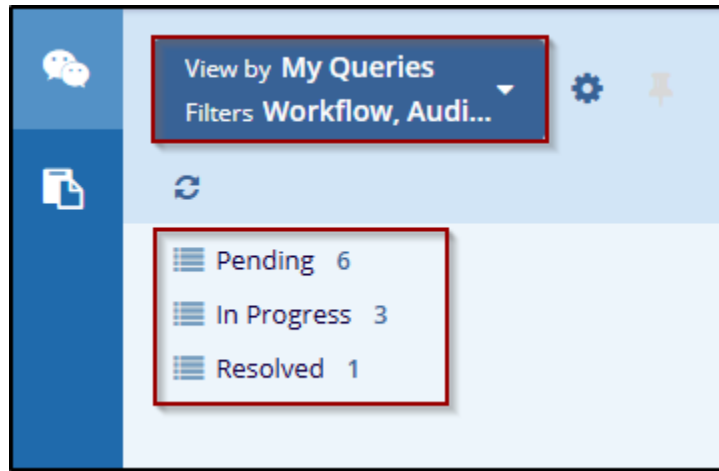
☐ Set Default   ☐ Set Default for all Rooms

**Cancel**   **Select**

5. The user will see the My Queries view along with the below status folders in the index panel:
  - Pending
  - In Progress
  - Resolved



6. After clicking on Select, three status options become visible, as per the selected view queries option it will show Pending, In Progress, and Resolved, each displaying the result in a grid view.

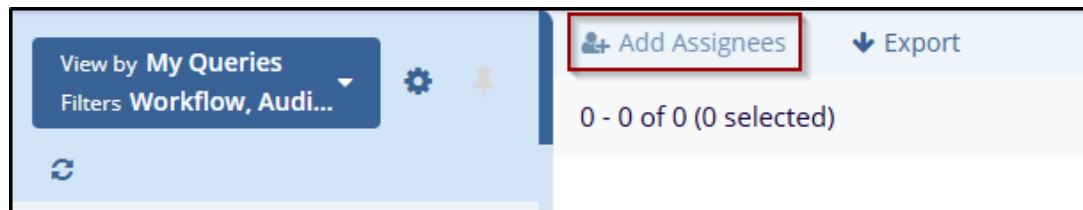


## Top Menu Bar

This defines the structure of the top menu bar, it includes Export, Add Assignees, Queries Cart, Enter Keywords or Phrase, Manage Columns, Layout, and Views.

### Add Assignees

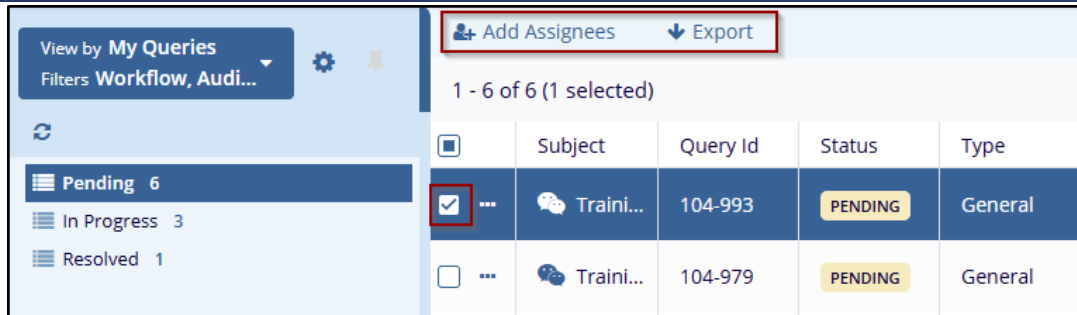
It allows users to assign individuals to the selected queries. Once checked, the user can select assignees from a list or search for a specific user.



Steps to Add Assignees for queries:

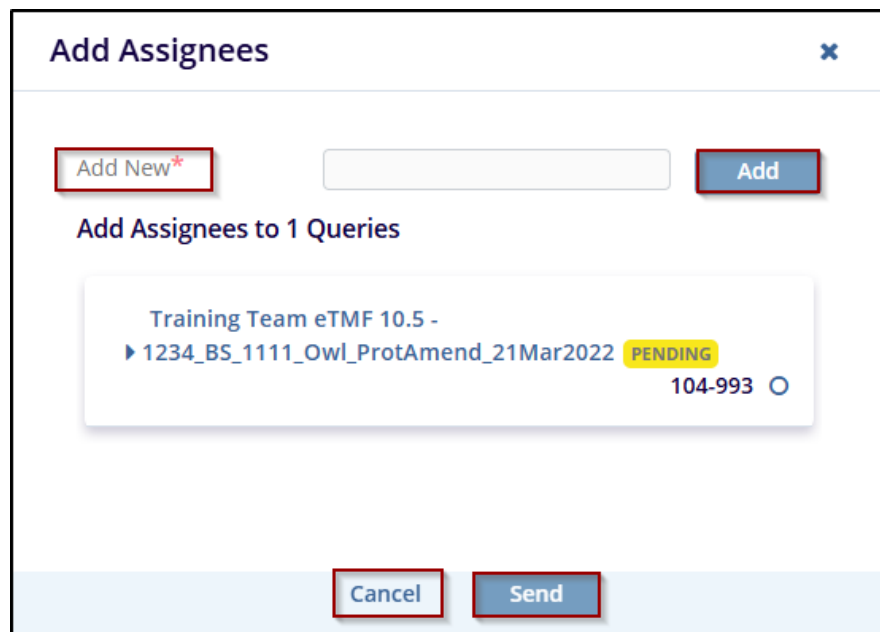
1. Navigate to the left panel, and select status as per user requirements (Pending, in Progress, Resolved). This will display queries in a grid view.
2. From the grid view click on the checkbox to select the queries, once the query is selected, the top menu bar will display options to take action on the selected query.

Refer to the below screenshot:



3. Click on the Add Assignees button in the top menu bar, this will open the Add Assignees window.
4. In the Add Assignees window, enter the assignees name in the Add New text box. Select the appropriate Assignee and click on Add to add it.
5. Below the user will see the query details for which queries the users are assigning. The query's subject, ID, and status will be displayed.
6. Once selected, click the Send button to assign the user to the query. This will confirm the assignment or click Cancel to discard changes.

Refer to the below screenshot:



7. Once click on the Send button, a confirmation message will appear in the same window.



### Add Assignees To Query

Room: Training Team eTMF 10.6

Finished: Sending email: 1 of 1 completed

Success! Task is complete.

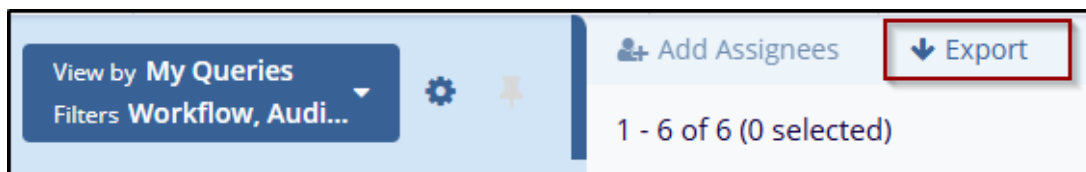
[Get Results](#)

## Export

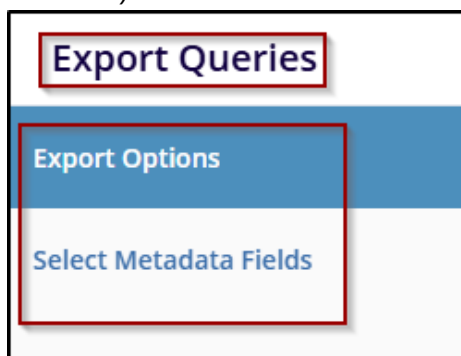
It enables users to export the selected queries, and documents in a format, such as CSV, PDF, Word, or Excel for analysis or reporting. The export will include all the details of the selected queries.

Steps to Export Selected Queries:

9. Click the Export button located in the top menu bar. This will open the Export Queries window.

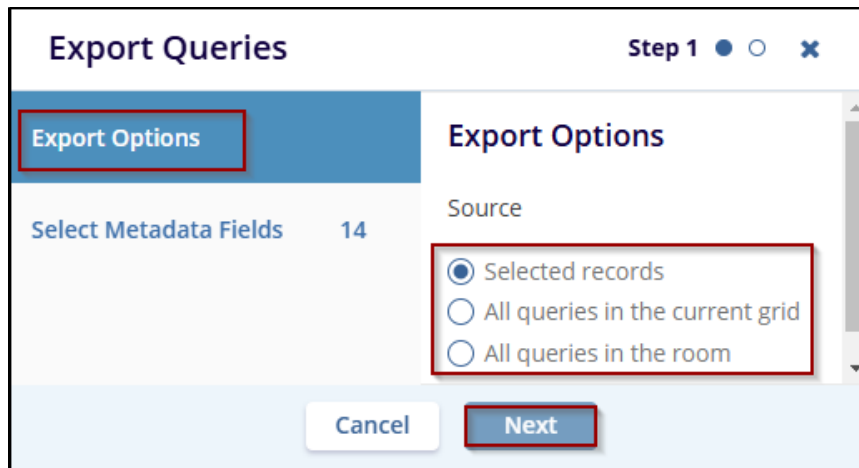


10. The Export queries window will display two options (by default export option is selected):



11. The Export Options are a set of queries that will be included in the export. It gives the flexibility to choose the queries that should be exported and select any source that is required from the below options.
  - Selected records: Exports only the queries the user has selected using the checkboxes in the grid view. This is useful when exporting a specific subset of queries.

- All queries in the current grid: Exports all the queries that are visible in the grid view at the time they are selected. This is ideal when the user wants to export all displayed queries, even if no specific queries are checked.
  - All queries in the room: Exports all queries in the current room, whether queries are visible in the grid or not. This option is used when the user wants to ensure that all queries within a room are exported.
12. Click Next to proceed to the Select Metadata Fields section.



**Export Queries** Step 1 ● ○ ✕

**Export Options**

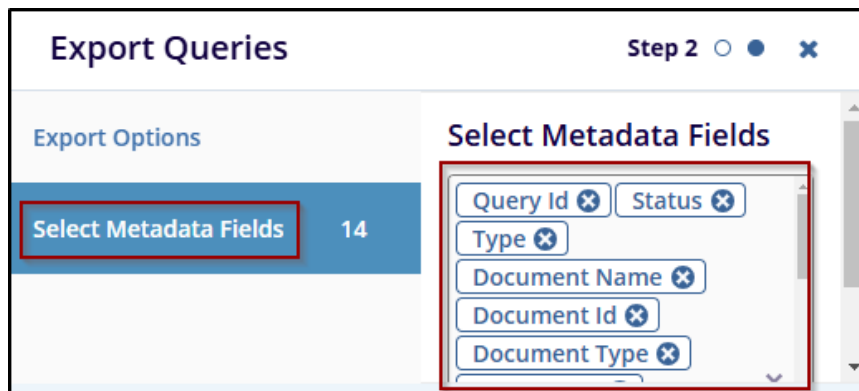
Select Metadata Fields 14

Source

- ☒ Selected records
- ☐ All queries in the current grid
- ☐ All queries in the room

Cancel Next

13. Once proceed to the Select Metadata Fields option and select the metadata fields that are required, the user can sort it by Alphabet or Logic to include in the export.
14. Metadata fields are characteristics of the queries, such as: (Query ID, Status, Type, Assignees, Created by, Query Date, etc.)



**Export Queries** Step 2 ○ ● ✕

**Select Metadata Fields**

14

- Query Id ✕
- Status ✕
- Type ✕
- Document Name ✕
- Document Id ✕
- Document Type ✕

15. After selecting both the Export Queries option, click on the Previous button to go back and make changes, or click on the Export button to download the file.

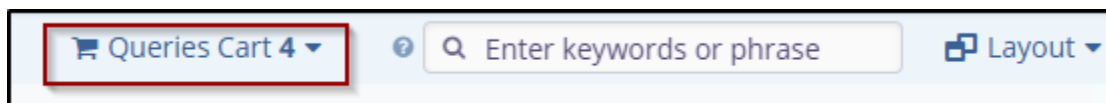


16. Once click on the Export button, a confirmation message will appear.



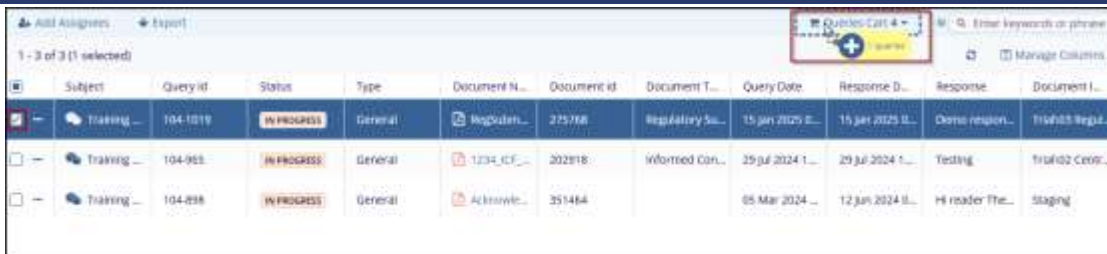
### Queries Cart

A Queries Cart allows users to collect queries for easier management. The Queries Cart helps streamline the process of handling multiple queries at once without repeatedly selecting them.



Steps to Add Queries to the Cart:

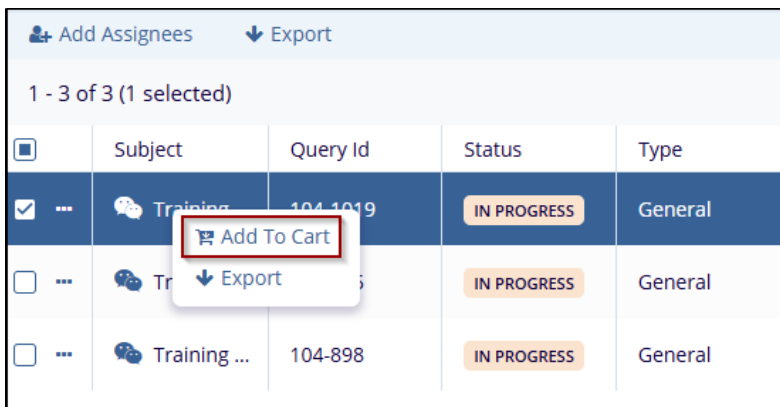
5. In the grid view, Hover over the queries that need to be added to the cart.
6. Click and hold on to the query, then drag it toward the Queries Cart at the top, and release the query into the cart.



|                                     | Subject      | Query Id | Status      | Type    | Document N... | Document id | Document T...    | Query Date       | Response D...    | Response        | Document I...    |
|-------------------------------------|--------------|----------|-------------|---------|---------------|-------------|------------------|------------------|------------------|-----------------|------------------|
| <input checked="" type="checkbox"/> | Training ... | 104-1019 | IN PROGRESS | General | RegSubm...    | 275786      | Regulatory Su... | 15 Jan 2025 B... | 15 Jan 2025 B... | Done respon...  | Training Regu... |
| <input type="checkbox"/>            | Training ... | 104-953  | IN PROGRESS | General | 1234_TCF...   | 202818      | Informed Can...  | 25 Jul 2024 1... | 29 Jul 2024 1... | Testing         | Training Cen...  |
| <input type="checkbox"/>            | Training ... | 104-898  | IN PROGRESS | General | Acknowle...   | 351484      |                  | 05 Mar 2024 ...  | 12 Jun 2024 B... | H reader The... | Staging          |

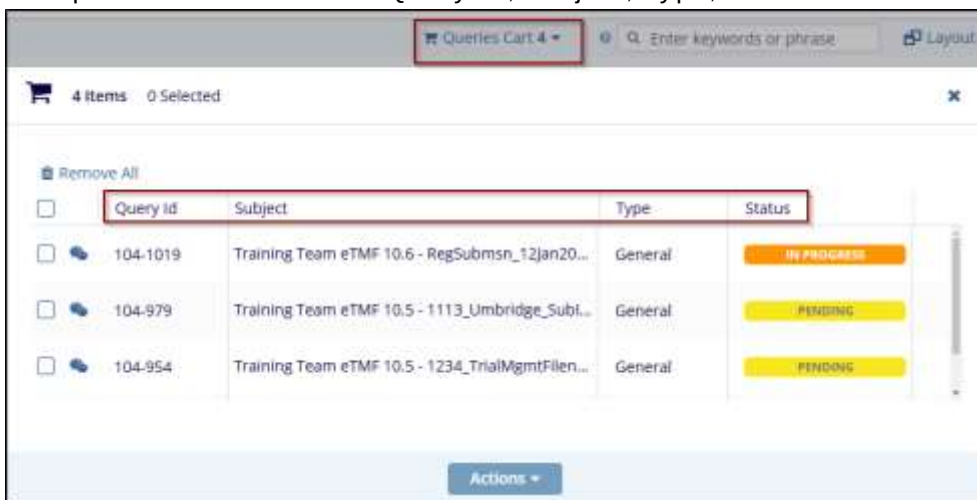
OR

- Clicking the right button of the mouse on the query will give the option to Add to Cart.



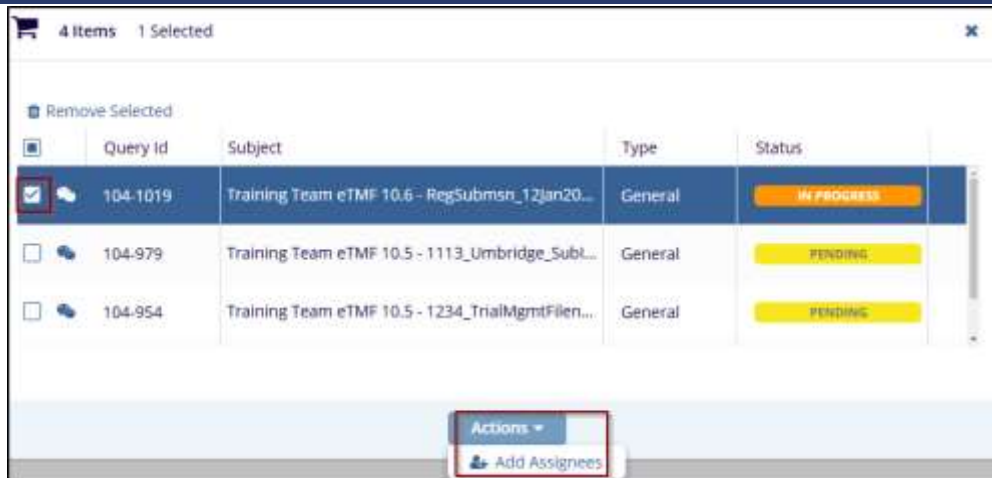
|                                     | Subject      | Query Id | Status      | Type    |
|-------------------------------------|--------------|----------|-------------|---------|
| <input checked="" type="checkbox"/> | Training ... | 104-1019 | IN PROGRESS | General |
| <input type="checkbox"/>            | Tr ...       |          | IN PROGRESS | General |
| <input type="checkbox"/>            | Training ... | 104-898  | IN PROGRESS | General |

- Once added, Click on Queries Cart the query will appear in the cart that is added to it and queries are listed with a Query ID, Subject, Type, and Status.



|                          | Query Id | Subject                                          | Type    | Status      |
|--------------------------|----------|--------------------------------------------------|---------|-------------|
| <input type="checkbox"/> | 104-1019 | Training Team eTMF 10.6 - RegSubmsn_12Jan20...   | General | IN PROGRESS |
| <input type="checkbox"/> | 104-979  | Training Team eTMF 10.5 - 1113_Umbridge_Subl...  | General | PENDING     |
| <input type="checkbox"/> | 104-954  | Training Team eTMF 10.5 - 1234_TrialMgmtFilen... | General | PENDING     |

- Click the checkbox next to the Query ID the query will be highlighted, and the user can perform actions to Add Assignees. (To Add Assignees, refer to the Add Assignees section above.)



### Enter Keywords or Phrase

Enter Keywords or Phrase allows users to filter or search for specific records based on keywords or phrases within a set of fields.

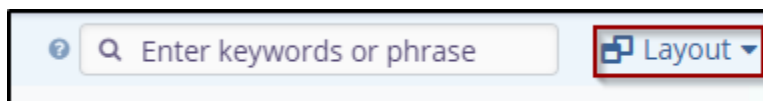
Steps to search Queries:

1. At the top right corner of the grid view, there is a Search bar.
2. Click into the Search bar and type the keyword or phrase. For example, training
3. Enter the keyword, and the grid view will automatically update to show only the queries that match the search keywords.
4. To clear the search and view, click on Refresh icon or click on the X icon available in the search bar.



### Layout

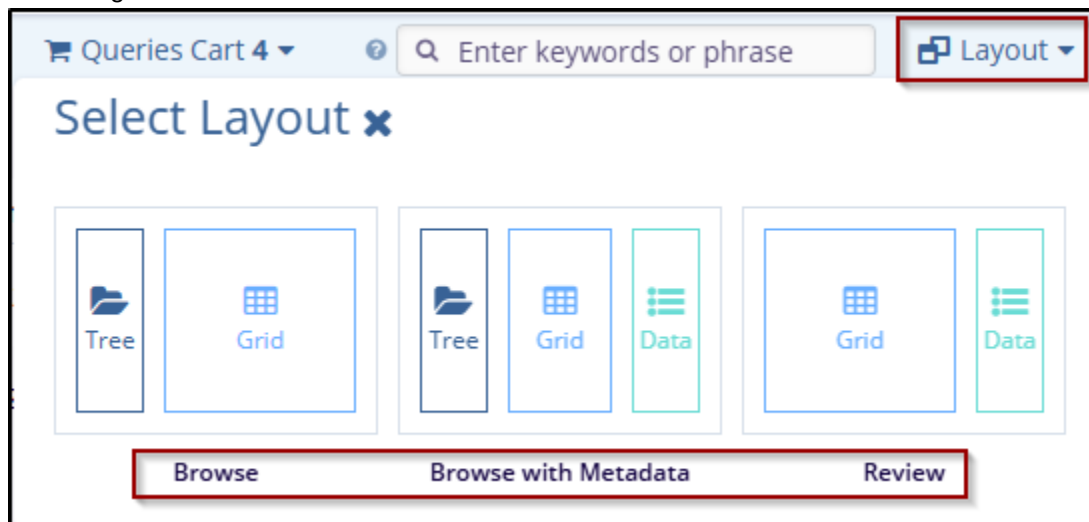
The layout provides users with different data viewing options. The choice of layout can help enhance user experience by making the data easier to navigate or manage.



Steps to Select a Layout:

3. At the top-right click on the Layout button. This will open a menu displaying available layout options.
4. From the layout options displayed, select the one that best suits the user's needs:
  - " Browse: This is the default view for browsing data.
  - " Browse with Metadata: This option displays data along with associated metadata, which may be useful for understanding the context of the data.

" Review: This is likely a review or approval view, useful for reviewing data before finalizing it.

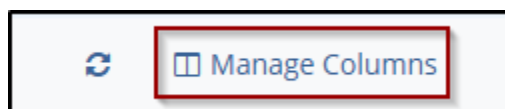


### Manage Columns

The Manage Columns allows users to customize the columns that appear in a data table. It provides the option to select, organize, and adjust the columns to display specific data as required.

Steps to setup manage columns:

8. Click on Manage Columns next to the refresh icon, Manage Columns window will pop up.



9. On the left side of the manage column window, a list of Available Columns is used to add a title to the table.
10. Users can use the search bar to find columns. Check the checkbox available for the title that the user wants to add to their view.



Manage Columns

Available Columns

Search

19 Columns 2 selected

☐

 Title

☒

 Created By

☒

 Document Category

☐

 Document File Name

11. In the Selected Columns section, the user can use the Move Up and Move Down buttons to reorder the columns in the selected list. For each selected column, the user can see its Title, Name, and Width.
12. Use the Order by dropdown menu to select a column for sorting the data. Choose whether the user wants the sorting to be Ascending or Descending.
13. After customizing the columns, click on Save Changes to apply the settings or the user can click Set View to apply and see the updated view. If the user wants to discard the changes, click on the Cancel button.

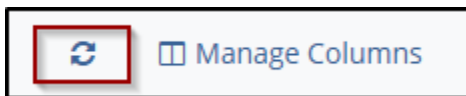
Selected Columns

Order by: Select ASC

12 Columns 1 selected

| <input checked="" type="checkbox"/> | Title          | Name                      | Width |
|-------------------------------------|----------------|---------------------------|-------|
| <input checked="" type="checkbox"/> | Subject        | \$\$QuerySubject\$\$      | 100   |
| <input type="checkbox"/>            | Query Id       | \$\$QueryId\$\$           | 100   |
| <input type="checkbox"/>            | Status         | \$\$QueryStatus\$\$       | 100   |
| <input type="checkbox"/>            | Type           | \$\$QueryType\$\$         | 100   |
| <input type="checkbox"/>            | Document Name  | \$\$DocumentName\$\$      | 100   |
| <input type="checkbox"/>            | Document Id    | \$\$DocumentId\$\$        | 100   |
| <input type="checkbox"/>            | Document Type  | \$\$DocumentType\$\$      | 100   |
| <input type="checkbox"/>            | Query Date     | \$\$QueryDate\$\$         | 100   |
| <input type="checkbox"/>            | Response Date  | \$\$QueryResponseDate\$\$ | 100   |
| <input type="checkbox"/>            | Response       | \$\$QueryResponse\$\$     | 100   |
| <input type="checkbox"/>            | Document Index | \$\$DocumentIndex\$\$     | 100   |

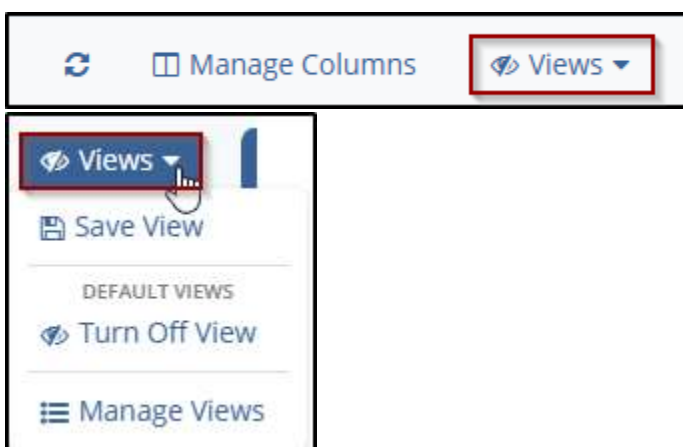
14. Once the changes are applied, the user can click the Refresh icon to refresh the Columns.



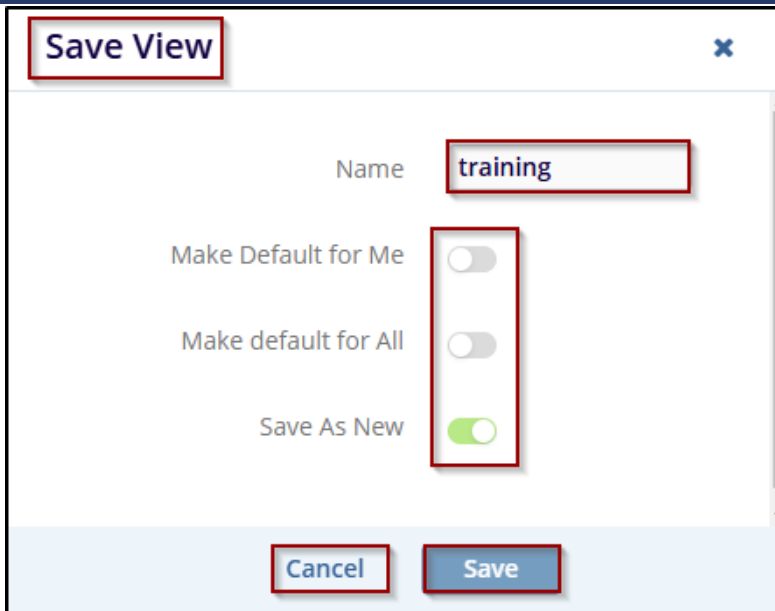
### Views

The Views dropdown provides options for saving, managing, or turning off customized views within the page.

13. Click on the Views Dropdown menu, next to the Manage columns. The user can see options Save View, Share View, Turn off View, Recent View, and Manage Views.



14. Click Save View from the dropdown menu, The Save Views window will pop up.
15. In the Save View window, enter a Name for view.
16. Make Default for Me: Toggle the switch to make this view the default for the user.
17. Make Default for All: Toggle the switch to make this view the default for all users.
18. To save the current view as a new view, ensure the Save As New option is enabled.



**Save View** [X]

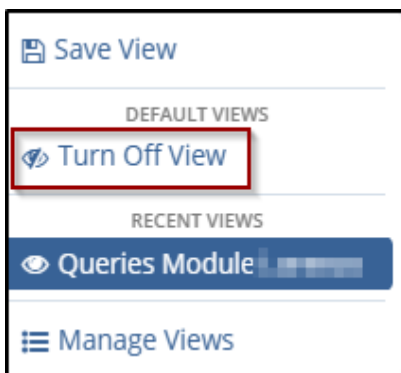
Name:

Make Default for Me: ☐

Make default for All: ☐

Save As New: ☒

19. Click the Save button to save the current view, If the user decides not to save the view, click the Cancel button to discard changes.
20. Click Turn Off View from the dropdown menu. If the user wants to revert to the default view or disable the current saved view.



 Save View

---

DEFAULT VIEWS

 Turn Off View

---

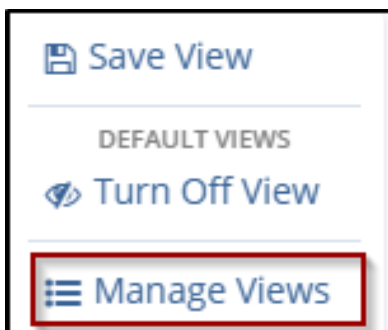
RECENT VIEWS

 Queries Module

---

 Manage Views

21. Click on Manage Views from the dropdown menu, Manage Views window will pop up.



 Save View

---

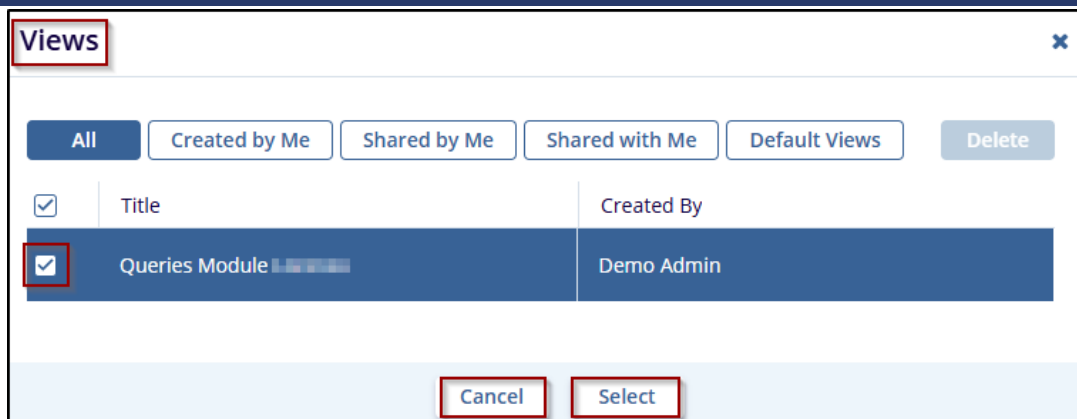
DEFAULT VIEWS

 Turn Off View

---

 Manage Views

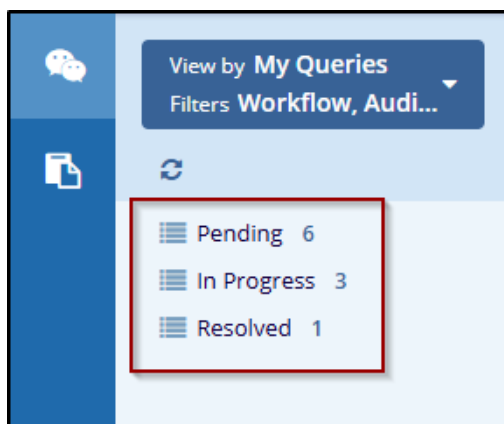
22. In the Manage Views window, the user can see all available view options under tabs such as All, Created by Me, Shared by Me, Shared with Me, and Default Views. The users can browse through the views by selecting the appropriate tab.



23. Check the checkbox next to the Title, to manage view.
24. After selecting a view, the user can delete it by clicking the Delete button.
25. Once finished managing views, click the Cancel button to discard any changes, or click Select to apply the changes to the selected view.

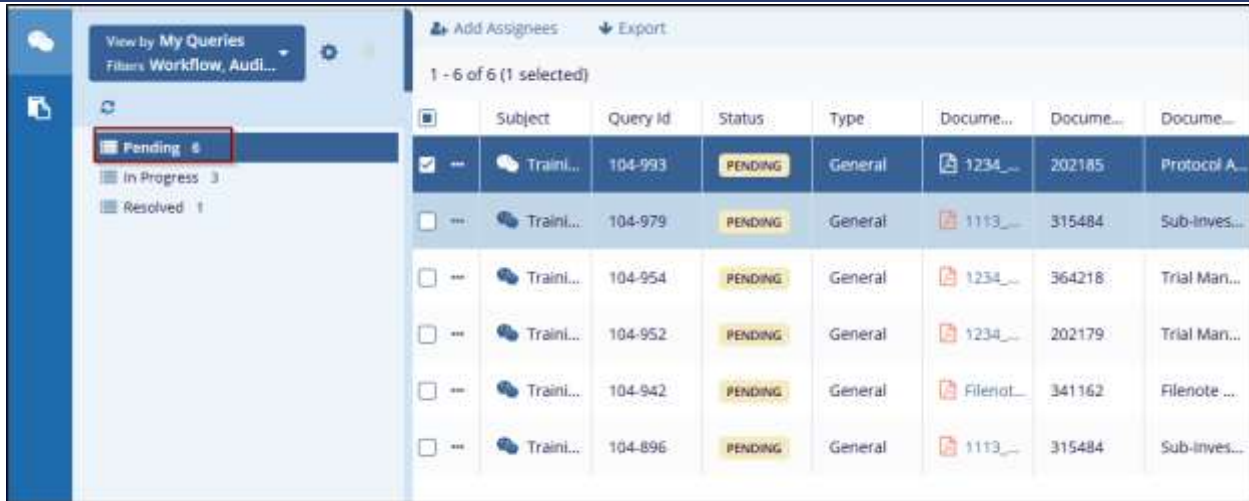
## Status

The status panel displays three categories of queries, each representing the current progress of a query



### Pending:

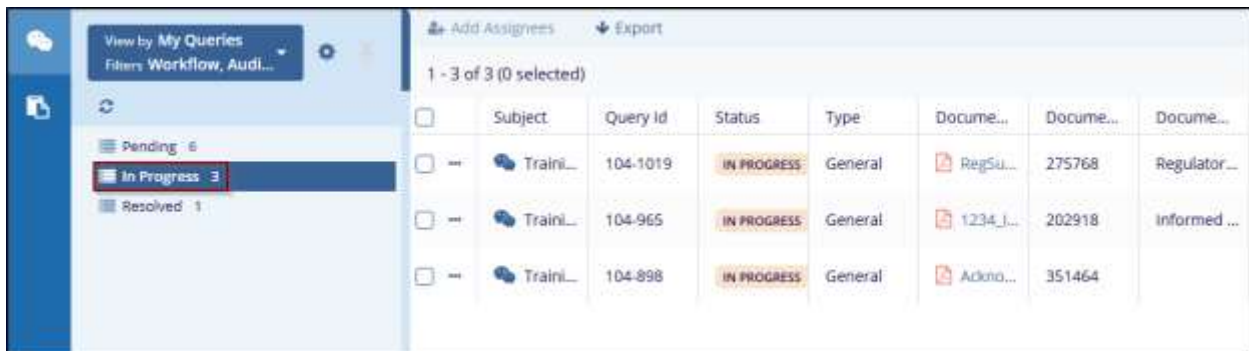
A Pending query refers to a request that has been raised but not yet addressed or responded. It requires user action to review, respond, or move forward in the workflow.



|                                     | Subject   | Query Id | Status  | Type    | Docume...  | Docume... | Docume...     |
|-------------------------------------|-----------|----------|---------|---------|------------|-----------|---------------|
| <input checked="" type="checkbox"/> | Traini... | 104-993  | PENDING | General | 1234_...   | 202185    | Protocol A... |
| <input type="checkbox"/>            | Traini... | 104-979  | PENDING | General | 1113_...   | 315484    | Sub-Inves...  |
| <input type="checkbox"/>            | Traini... | 104-954  | PENDING | General | 1234_...   | 364218    | Trial Man...  |
| <input type="checkbox"/>            | Traini... | 104-952  | PENDING | General | 1234_...   | 202179    | Trial Man...  |
| <input type="checkbox"/>            | Traini... | 104-942  | PENDING | General | Filenot... | 341162    | Filenote ...  |
| <input type="checkbox"/>            | Traini... | 104-896  | PENDING | General | 1113_...   | 315484    | Sub-Inves...  |

### In Progress:

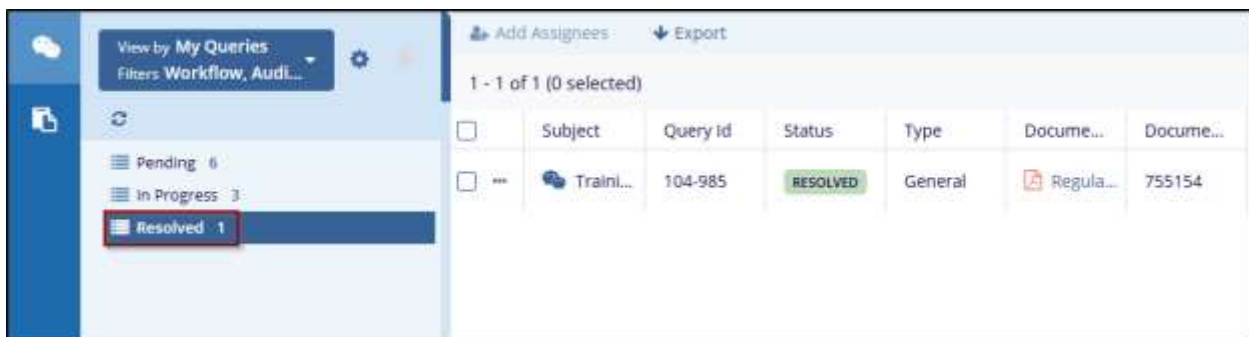
In Progress includes queries that are actively being worked on. Actions or responses are in progress, but the query has not been completely resolved.



|                          | Subject   | Query Id | Status      | Type    | Docume... | Docume... | Docume...    |
|--------------------------|-----------|----------|-------------|---------|-----------|-----------|--------------|
| <input type="checkbox"/> | Traini... | 104-1019 | IN PROGRESS | General | RegSu...  | 275768    | Regulator... |
| <input type="checkbox"/> | Traini... | 104-965  | IN PROGRESS | General | 1234_...  | 202918    | Informed ... |
| <input type="checkbox"/> | Traini... | 104-898  | IN PROGRESS | General | Ackno...  | 351464    |              |

### Resolved:

A Resolved folder contains queries that have been completed and marked as resolved. No further action is required.



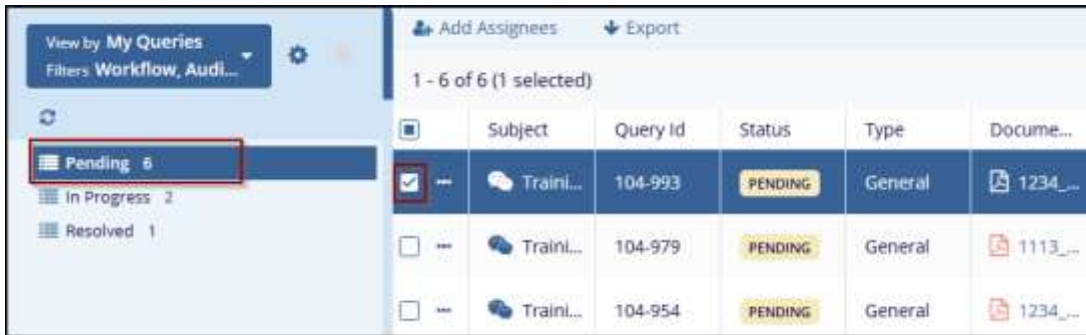
|                          | Subject   | Query Id | Status   | Type    | Docume... | Docume... |
|--------------------------|-----------|----------|----------|---------|-----------|-----------|
| <input type="checkbox"/> | Traini... | 104-985  | RESOLVED | General | Regula... | 755154    |

Refer to the below screenshot:

Steps to perform action on **Pending, Respond, and Resolve** Queries:

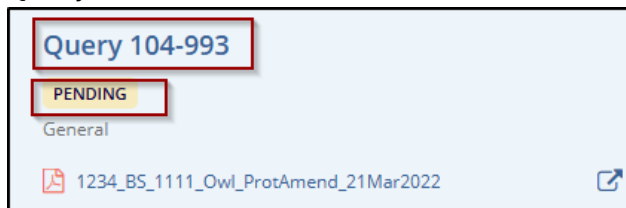
1. Click on Pending to filter and display only queries with the status Pending.
2. The grid view on the right will update to show all queries currently marked as Pending.

Refer to the below screenshot:

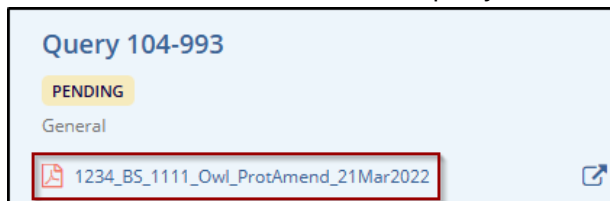


3. From the list of pending queries, click on the checkbox next to a query or click directly on the query row to select it.
4. The Metadata Panel on the right-hand side will open, displaying detailed information about the selected query.
5. In the Metadata Panel, review the following:

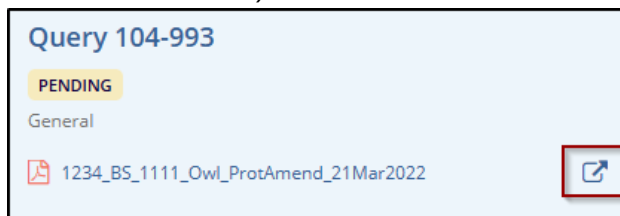
- Query ID and Status



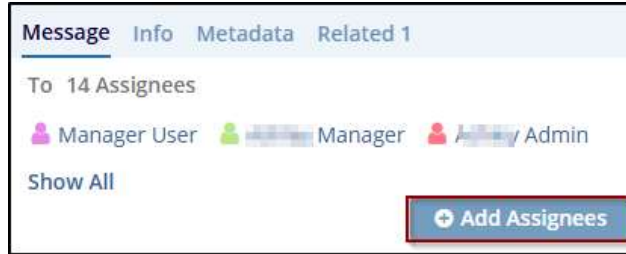
- Document associated with the query.



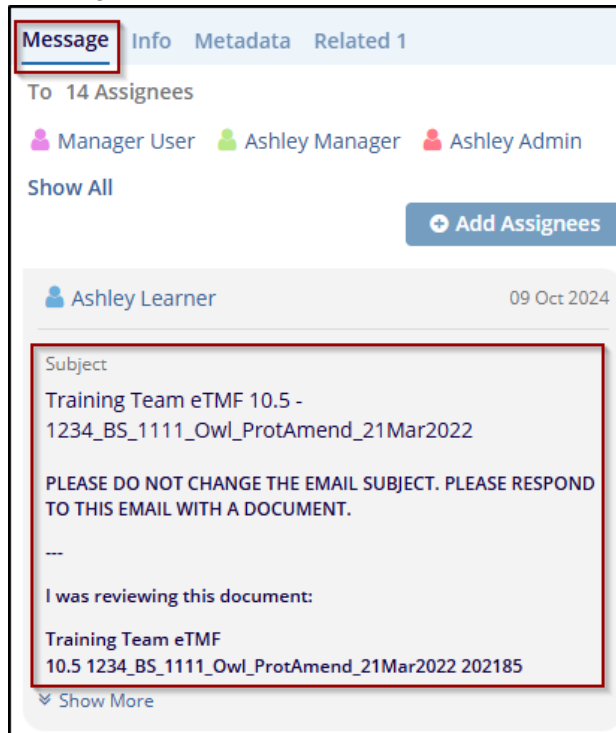
- Go to Document icon: This helps the user to open the document in the document section that is attached to the query. (For more check eTMF, Document section.)



- Add Assignees will add users that are responsible for resolving the query.



- Message section, which contains the query's subject and instructions.



- Info section provides general details about the query, such as the query ID, status, and creation date. It often includes the most relevant metadata related to the particular case or record.

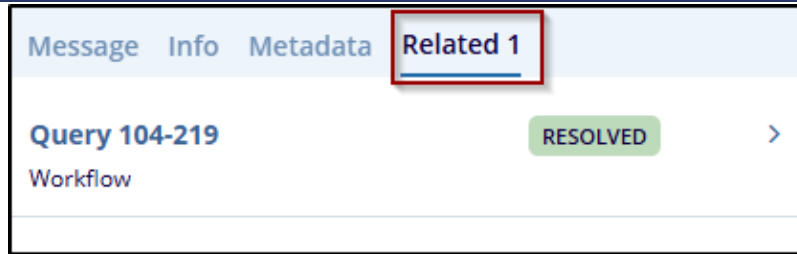
| Message      | <b>Info</b>    | Metadata           | Related 1 |
|--------------|----------------|--------------------|-----------|
| Query Id     |                | Type               |           |
| 104-993      |                | General            |           |
| Query Status |                |                    |           |
|              | <b>PENDING</b> |                    |           |
| Reminders    |                | Last Reminder Sent |           |
| 16 Oct 2024  |                | 06 Nov 2024        |           |
| 23 Oct 2024  |                |                    |           |
| 30 Oct 2024  |                |                    |           |
| 06 Nov 2024  |                |                    |           |
| Category     |                |                    |           |
| Site         |                |                    |           |
| Created      |                |                    |           |
| 09 Oct 2024  |                |                    |           |

- **Metadata** This section refers to information regarding the query, such as Document Metadata, Workflow History, and Audit History. This includes data that provide additional context to the query.

| Message             | Info | <b>Metadata</b> | Related 1 |
|---------------------|------|-----------------|-----------|
| <b>Metadata</b>     |      |                 |           |
| ▼ Document Metadata |      |                 |           |
| ▼ Workflow History  |      |                 |           |
| ▼ Audit History     |      |                 |           |

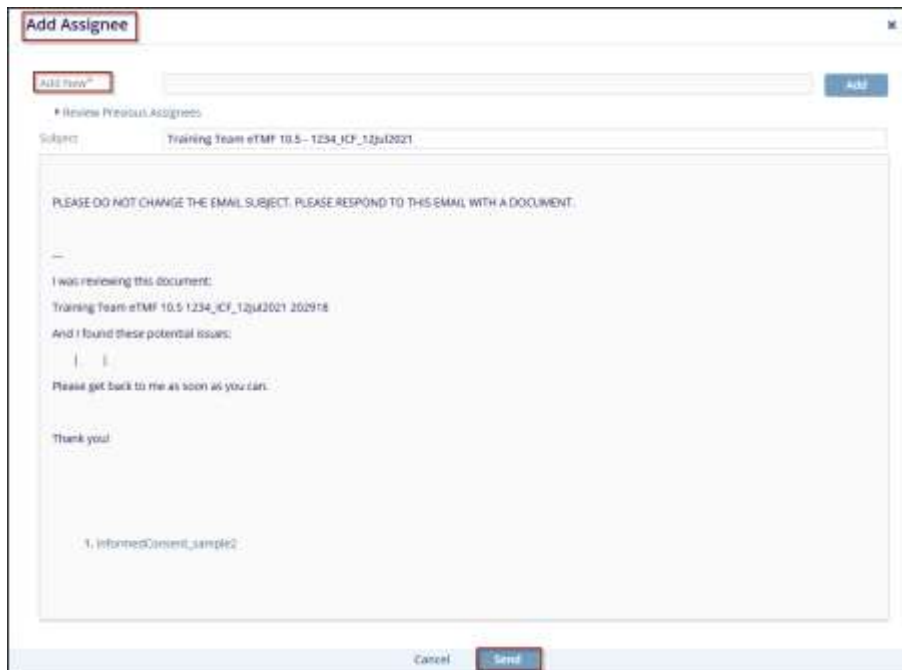
- **Related** is used to reference related queries that are connected to the main query. This could include relationships with other queries and tasks that are relevant for follow-up.





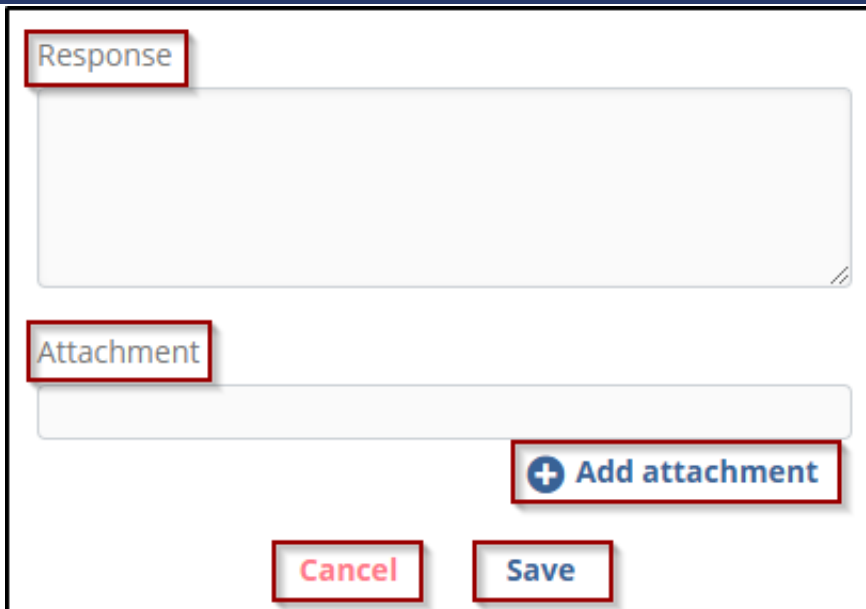
6. In the Assignees section, the user will see a list of users assigned to resolve the query.
7. Click the Add Assignee, a window that will pop up, enter the name or email of the person who needs to be added, and click on Send to send the response. (For more check the Add Assignees section available in the Top menu bar)

Refer to the below screenshot:

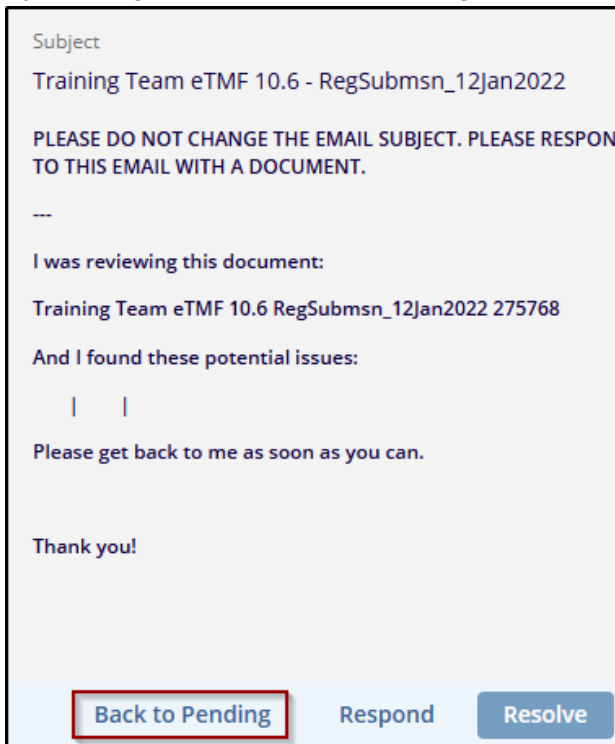


8. Based on the query message and requirements, perform the necessary action, such as:
  - Reviewing the associated document.
  - If required, respond.
9. Click on the Respond button at the bottom, and a Response window will pop up.
10. The user can type a message, attach a file, and click on the Save button to submit the response or click on the Cancel button to discard the response.

Refer to the below screenshot:



11. Once the initial review is complete, the status of the query changes to In Progress to indicate that work is actively being done on it.
12. After completing the required action, respond to the query in the Message section and attach the necessary supporting documents, the query will be In Progress folder. If a response is not provided, to the same message user can revert to back to Pending by clicking on the Back to Pending button.



Subject  
Training Team eTMF 10.6 - RegSubmsn\_12Jan2022

PLEASE DO NOT CHANGE THE EMAIL SUBJECT. PLEASE RESPOND TO THIS EMAIL WITH A DOCUMENT.

---

I was reviewing this document:  
Training Team eTMF 10.6 RegSubmsn\_12Jan2022 275768

And I found these potential issues:

| |

Please get back to me as soon as you can.

Thank you!

Back to Pending Respond Resolve

13. Click on the Resolve button to update the query status, Resolve Query window will pop up.
14. Select Resolution as Resolve and add comments to the same query.

### Resolve Query ✕

Resolution\*

Resolve

Comments \*

Cancel

Resolve

15. Click on the Resolve button to save the response and mark the query as Resolved, indicating that no further action is required.
16. Use the Previous Query or Next Query buttons to move between queries if there are multiple pending or in-progress queries.

#### Activity

Training Admin 2

RESOLUTION

10 Jan 2025

Training Admin 2

RESPONSE

10 Jan 2025

◀ Previous Query

Next Query ▶

View by: My Queries

Filters: Workflow, Audi...

Pending 6

In Progress 3

**Resolved 1**

Add Assignees

Export

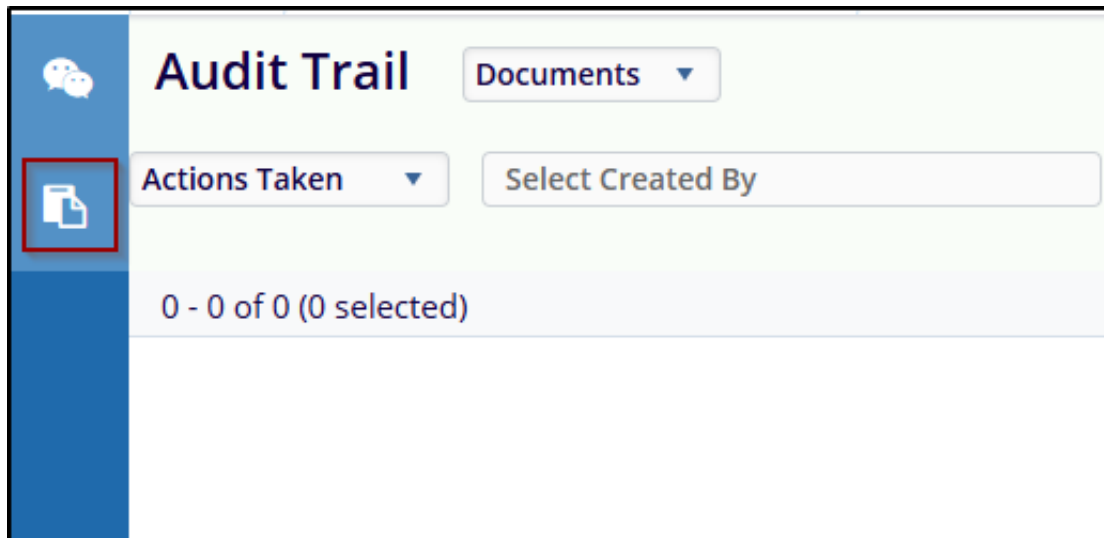
1 - 1 of 1 (1 selected)

|                                     | Subject  | Query Id | Status   | Type    | Docume... |
|-------------------------------------|----------|----------|----------|---------|-----------|
| <input checked="" type="checkbox"/> | Train... | 104-985  | RESOLVED | General | Regula... |

Note: Once the query has been fully addressed, the same query will be updated to Resolved status.

## Audit Trail

The Audit Trail in the Queries module provides a comprehensive record of all actions performed on communications and documents within a study room. This is designed to help users track activities for auditing and compliance purposes. Users can filter the audit trail by various criteria to retrieve specific records efficiently.



The audit trail can be filtered by:

- Actions Taken: Select specific types of actions, such as Created, Modified, or Deleted.
- Created By: Filter records based on the user who acted.
- Date Range: Specify the start and end dates to view actions within a particular timeframe.
- Document, Folder, Placeholder, and Users: Use these options to further narrow down the search to specific entities.

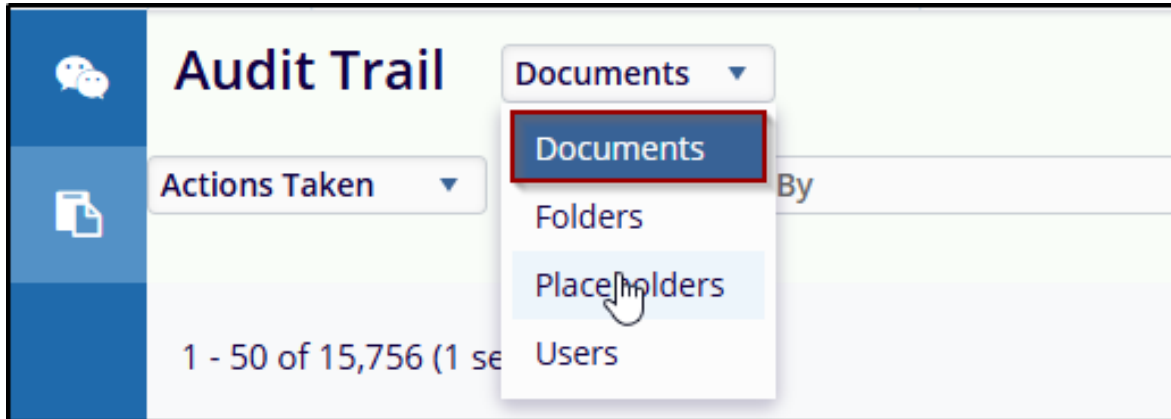
Steps to perform Audit Trail:

1. Navigate to the Audit Trail section under the Queries module.
2. Use the Record Type dropdown (default is Documents) to choose the type of record the user wants to filter.

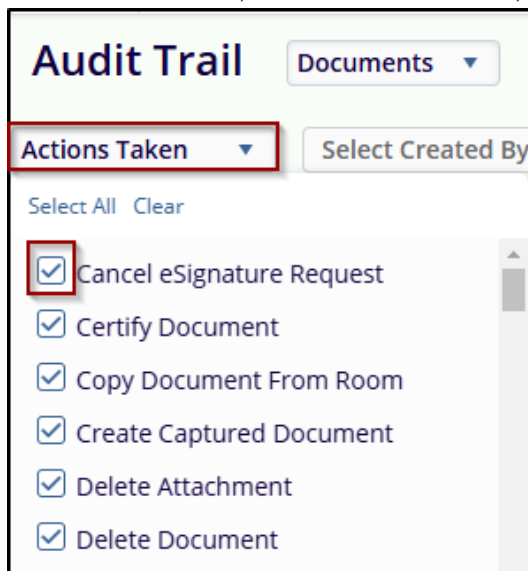
Example options may include:

- Documents
- Folders
- Placeholders
- Users

Refer to the below screenshot:



3. Select an option from the Actions Taken dropdown menu to filter the audit trail (e.g., Delete Document, Document e-mailed, copy document from room, etc.).



4. Specify a Start Date and End Date to limit the results to a specific period.
5. Enter a Document ID in the provided field to filter results for a specific document.
6. Once all criteria are set, click the Apply button to display the filtered results in the grid view.

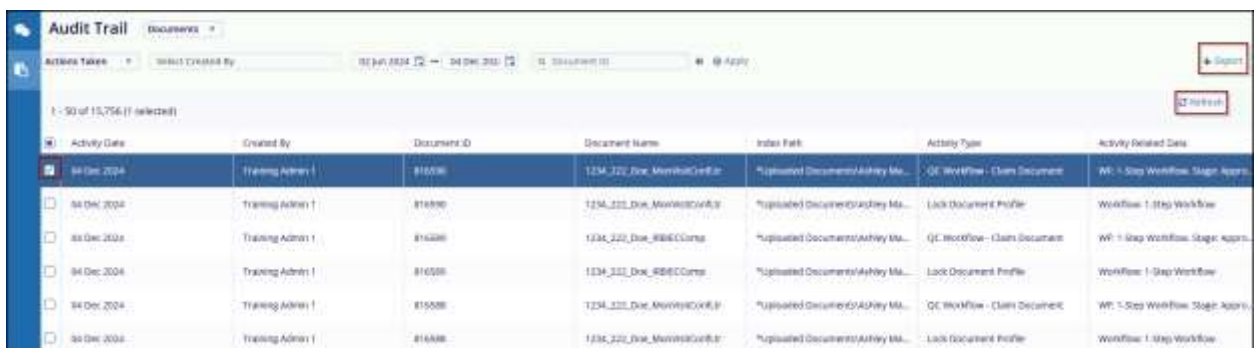
Refer to the below screenshot:



| Activity Date | Created By       | Document ID | Document Name                |
|---------------|------------------|-------------|------------------------------|
| 04 Dec 2024   | Training Admin 1 | 816590      | 1234_222_Doe_MonVslitConfLtr |
| 04 Dec 2024   | Training Admin 1 | 816590      | 1234_222_Doe_MonVslitConfLtr |
| 04 Dec 2024   | Training Admin 1 | 816589      | 1234_222_Doe_IRBIECComp      |

7. Check the checkbox before the date to select it.
8. After selecting, click the Export button to take an export of the document, and to refresh the page click on the Refresh Icon below the Export button.

Refer to the below screenshot:



| Activity Date | Created By       | Document ID | Document Name                | Index Path                        | Activity Type                | Activity Related Data                |
|---------------|------------------|-------------|------------------------------|-----------------------------------|------------------------------|--------------------------------------|
| 04 Dec 2024   | Training Admin 1 | 816590      | 1234_222_Doe_MonVslitConfLtr | Uploaded Documents\Activity Ma... | QC Workflow - Claim Document | WF: 1-Step Workflow, Stage: Appro... |
| 04 Dec 2024   | Training Admin 1 | 816590      | 1234_222_Doe_MonVslitConfLtr | Uploaded Documents\Activity Ma... | Lock Document Profile        | Workflow: 1-Step Workflow            |
| 04 Dec 2024   | Training Admin 1 | 816589      | 1234_222_Doe_IRBIECComp      | Uploaded Documents\Activity Ma... | QC Workflow - Claim Document | WF: 1-Step Workflow, Stage: Appro... |
| 04 Dec 2024   | Training Admin 1 | 816589      | 1234_222_Doe_IRBIECComp      | Uploaded Documents\Activity Ma... | Lock Document Profile        | Workflow: 1-Step Workflow            |
| 04 Dec 2024   | Training Admin 1 | 816590      | 1234_222_Doe_MonVslitConfLtr | Uploaded Documents\Activity Ma... | QC Workflow - Claim Document | WF: 1-Step Workflow, Stage: Appro... |
| 04 Dec 2024   | Training Admin 1 | 816589      | 1234_222_Doe_MonVslitConfLtr | Uploaded Documents\Activity Ma... | Lock Document Profile        | Workflow: 1-Step Workflow            |

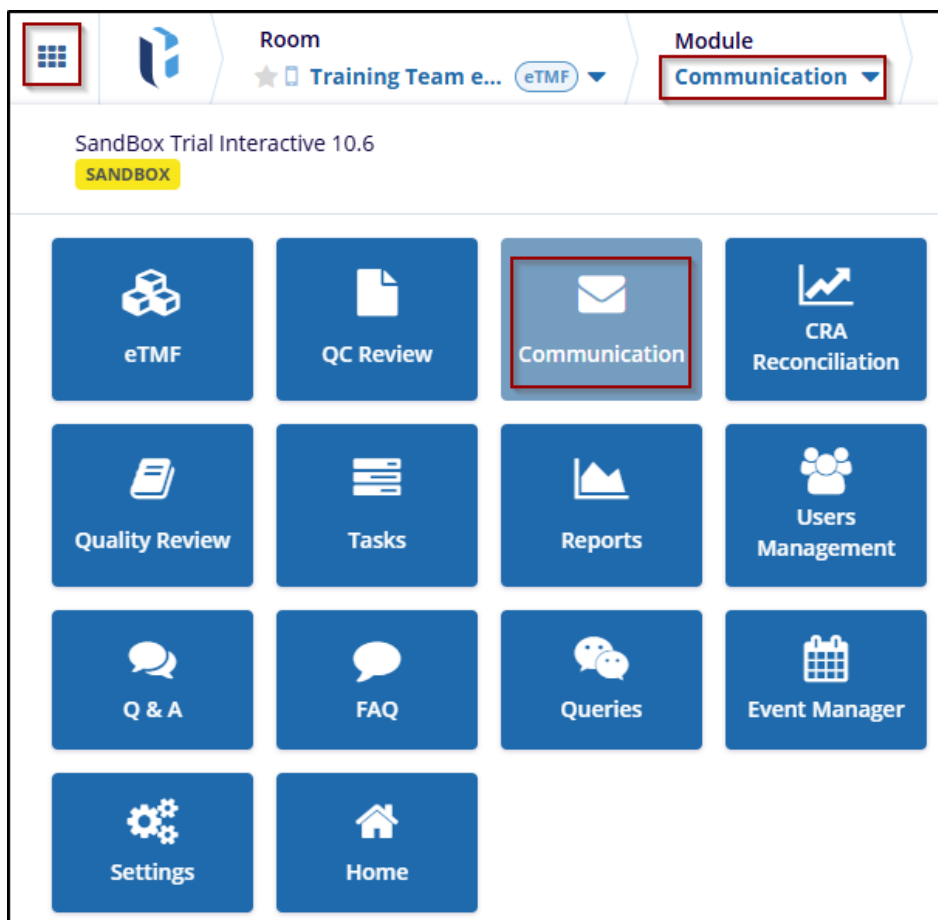
9. Once click the Export button confirmation message will pop up.



## CHAPTER 16. COMMUNICATIONS

The Communications module is used to capture and manage study-related communications. Emails sent to the Communications Inbox are automatically converted to PDF format. Study room users are required to review the received messages in the Communications Inbox to assess their relevance to the study before adding them to the room's QC workflow. The module can be accessed from the navigation grid in the upper-left corner of the screen.

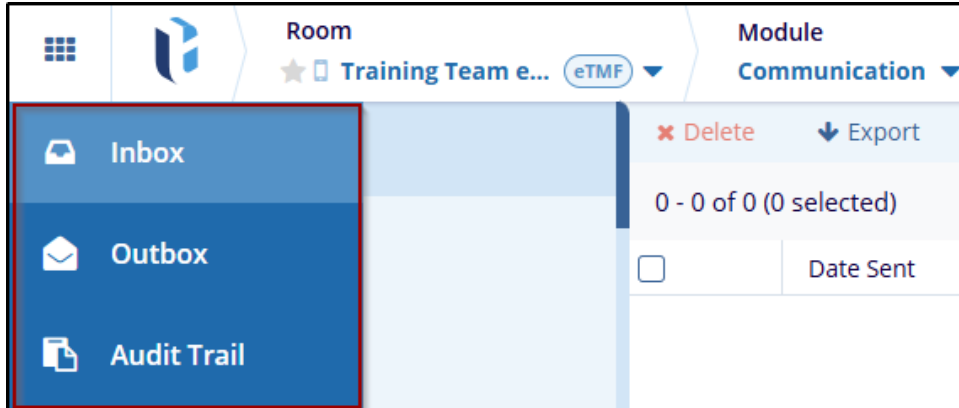
Refer to the below screenshot:



After opening the Communications module, use the left-hand menu to access the following views:

- Inbox
- Outbox
- Audit Trail

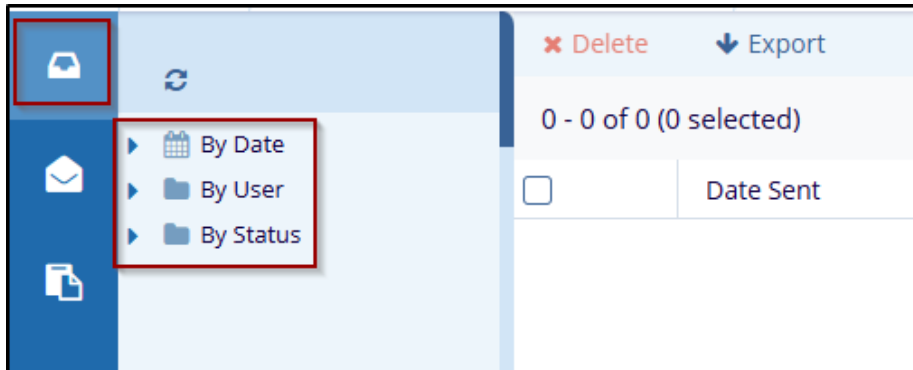
Refer to the below screenshot:



## Communication Inbox

The Communication Inbox is a centralized section within the Communications module where study-related communications are organized and managed. This inbox allows users to review and classify communications for their relevance to the study. Communications are automatically converted into PDF format upon receipt and displayed in a tabular format for easy processing.

Refer to the below screenshot:



The Communication Inbox categorizes messages using the following filters:

1. **By Date:**  
Allows users to view messages received during specific time periods such as Today, Last 7 Days, or This Month.
2. **By User:**  
Displays messages grouped by the sender, helping users quickly locate communications from specific individuals.
3. **By Status:**  
Organizes messages based on their current status:
  - **Pending:** Messages that have not yet been reviewed or classified.



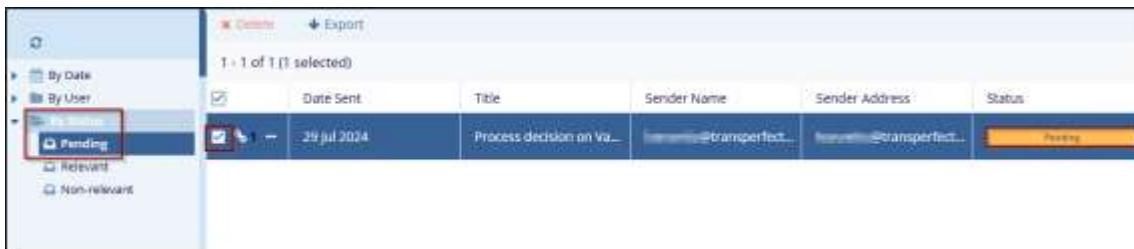
- Relevant: Communications deemed important to the study.
- Non-Relevant: Messages identified as not significant to the study.

Users can classify each communication as either 'Relevant' or 'Non-Relevant' based on its content and importance. Once classified, relevant communications can be added to the study's QC workflow

Steps to perform for this review:

1. Navigate to the Communications module, where messages are categorized as:
  - By Date
  - By User
  - By Status
2. Select a category to filter the communications, for example (By Status).
3. Click on a checkbook with a Pending status to load its details in the metadata pane.

Refer to the below screenshot:



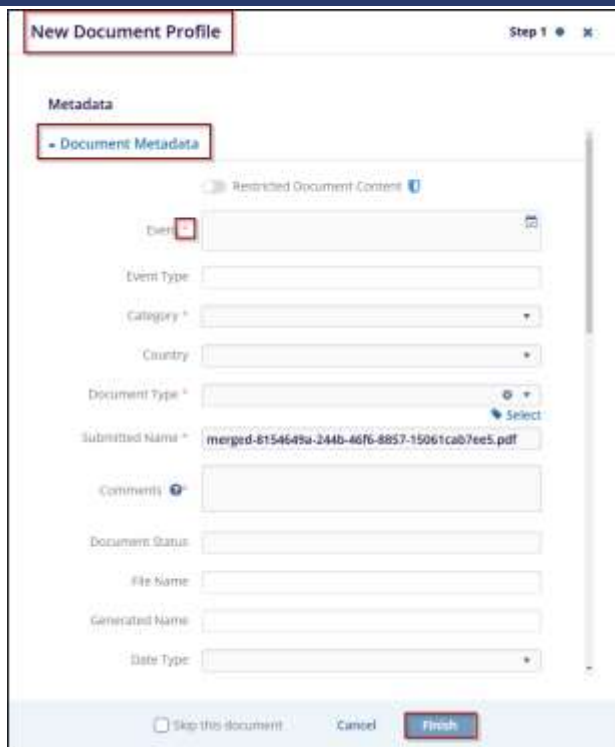
4. Open the attached PDF file from the metadata pane to review the content of the communication.
5. Based on the review, click either the Relevant or Non-Relevant button at the bottom of the metadata pane.
6. If the communication is marked as Relevant, the system will generate a new document for the study room.

Refer to the below screenshot:



7. Complete the required metadata fields in the New Document Profile window.
8. After entering the necessary metadata, click Finish to complete the document creation process.

Refer to the below screenshot:



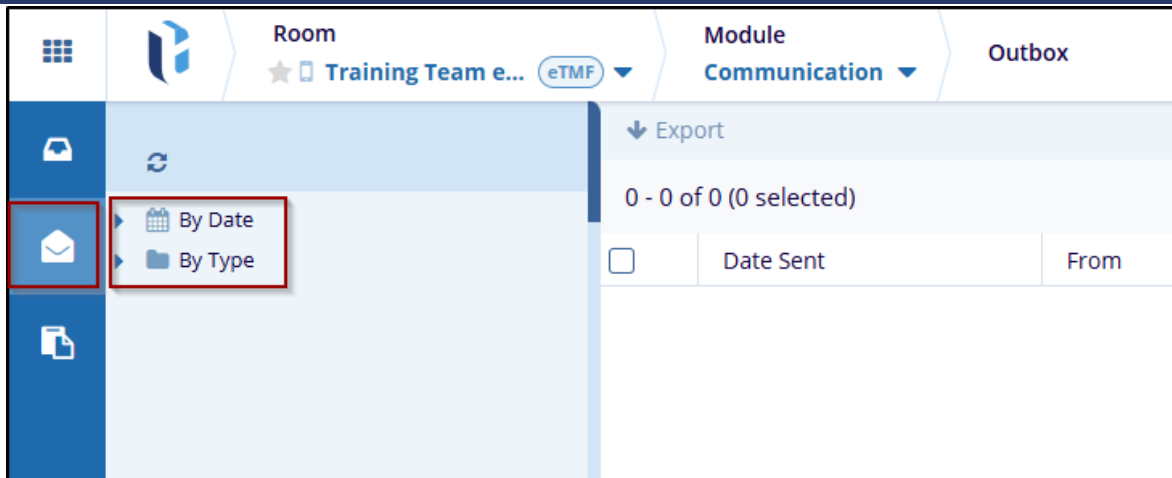
## Communication Outbox

The Communication Outbox is a centralized section within the Communications module where outgoing study-related documents and messages emailed from a Trial Interactive room are stored. It allows users to efficiently view, manage, and track all outgoing communications.

The Communication Outbox categorizes messages using the following filters:

- By Date: Displays emails based on the date they were sent.
- By Type: Groups emails by their communication type for easier tracking.

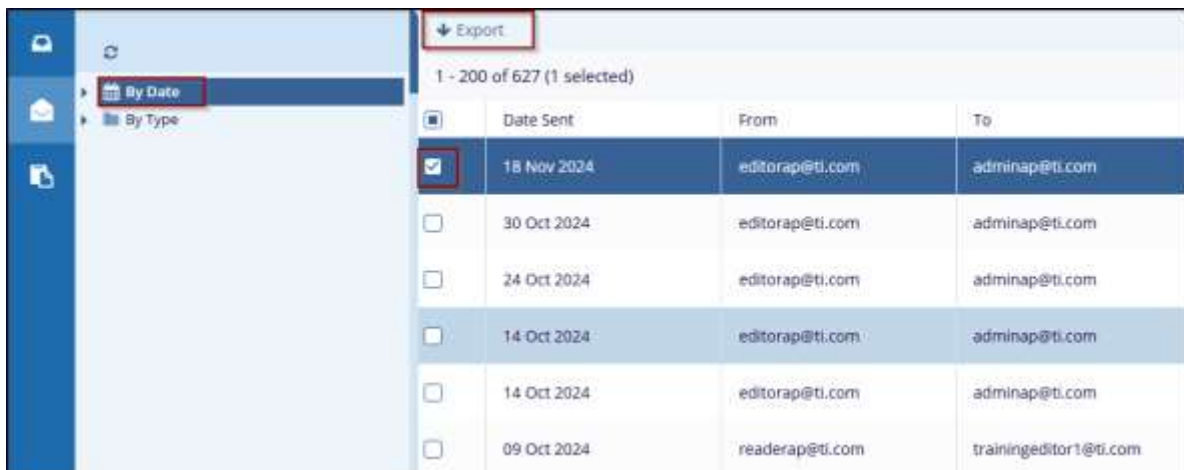
Refer to the below screenshot:



Steps to perform for this review:

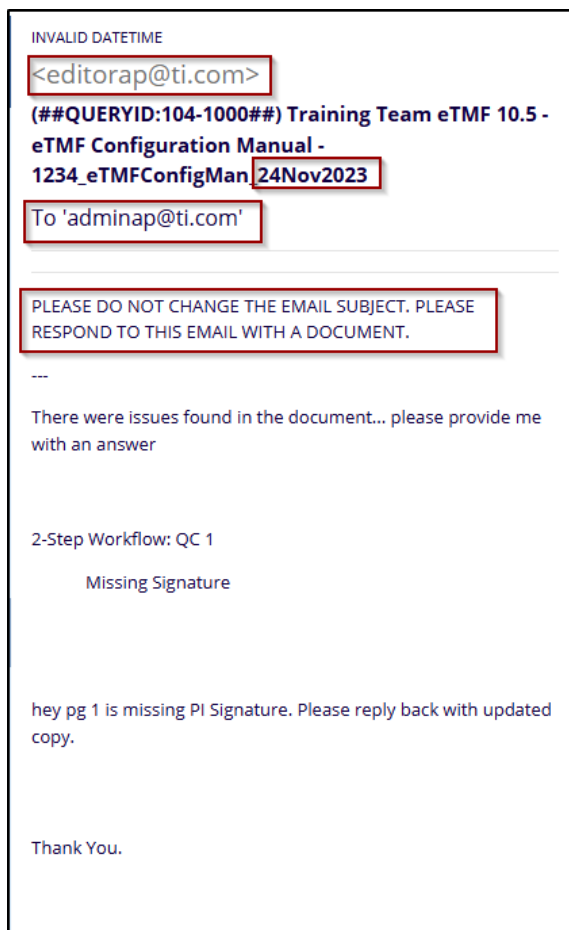
1. Navigate to the Outbox module under the Communications section.
2. To view the complete metadata of an email, either:
3. Click the message in the grid view, or Check the Checkbox next to the message to select it.
4. After selecting the desired emails, click the Export button at the top of the screen.
5. The system will generate an export file containing the selected communications. This file can be used for further processing or record-keeping purposes.

Refer to the below screenshot:



6. The selected email's metadata will be displayed in the metadata pane, including:
  - Body
  - Sender
  - Receiver
  - Subject
  - Sent Date
  - Attachments

Refer to the below screenshot:



## Audit Trail

The Audit Trail in the Communications module provides a comprehensive record of all actions performed on communications and documents within a study room. This feature is designed to help users track activities for auditing and compliance purposes. Users can filter the audit trail by various criteria to retrieve specific records efficiently.

The audit trail can be filtered by:

- **Actions Taken:** Select specific types of actions, such as Created, Modified, or Deleted.
- **Created By:** Filter records based on the user who performed the action.
- **Date Range:** Specify the start and end dates to view actions within a particular timeframe.
- **Document, Folder, Placeholder, and Users:** Use these options to further narrow down the search to specific entities.

Steps to perform for this review:

10. Navigate to the Audit Trail section under the Communications module.

11. Use the Record Type dropdown (default is eTMF Documents) to choose the type of record you want to filter.

Example options may include:

- Documents
- Folders
- Placeholders
- Users
- Start-Up Documents
- Start-Up and eTMF Document

Refer to the below screenshot:



12. Select an option from the Actions Taken dropdown to filter the audit trail by a specific action (e.g., Delete Document, Document e-mailed, copy document from room, etc.).
13. Specify a Start Date and End Date to limit the results to a specific period.
14. Enter a Document ID in the provided field to filter results for a specific document.
15. Once all criteria are set, click the Apply button to display the filtered results in the grid view.

Refer to the below screenshot:




| Activity Date | Created By     | Document ID | Document Name                         | Index Path                       | Activity Type          |
|---------------|----------------|-------------|---------------------------------------|----------------------------------|------------------------|
| 04 Dec 2024   | Ashley Manager | 816390      | 1234_123_Doe_MerWinConfLtr            | *Uploaded Documents\Ashley Ma... | Open Document Metadata |
| 04 Dec 2024   | Ashley Manager | 816390      | 1234_123_Doe_MerWinConfLtr            | *Uploaded Documents\Ashley Ma... | Open Document Metadata |
| 04 Dec 2024   | Ashley Manager | 816384      | Principal Investigator Medical Ltr... | *Uploaded Documents\Ashley Ma... | Open Document Metadata |

7. Check the checkbox before the date to select it.
8. After selecting, click the Export button to take an export of the document.

Actions Taken | Select Created By | 04 Aug 2024 | 03 Dec 2024 | R. Document ID | Apply

1 - 200 of 12,617 (1 selected)

Export

|                                     | Activity Date | Created By             | Document ID | Document Name                       | Index Path                         | Activity Type          | Activity Related Date         |
|-------------------------------------|---------------|------------------------|-------------|-------------------------------------|------------------------------------|------------------------|-------------------------------|
| <input checked="" type="checkbox"/> | 04 Dec 2024   | admin@transperfect.com | #10000      | T2H_202_Doc_MonitoringDoc           | *Uploaded Documents\Activity Ma... | Open Document Metadata |                               |
| <input type="checkbox"/>            | 04 Dec 2024   | admin@transperfect.com | #10000      | T2H_202_Doc_MonitoringDoc           | *Uploaded Documents\Activity Ma... | Open Document Metadata |                               |
| <input type="checkbox"/>            | 04 Dec 2024   | admin@transperfect.com | #10000      | Principal Investigator Medical L... | *Uploaded Documents\Activity Ma... | Open Document Metadata |                               |
| <input type="checkbox"/>            | 04 Dec 2024   | admin@transperfect.com | #10000      | Principal Investigator Medical L... | *Uploaded Documents\Activity Ma... | Open Document Metadata |                               |
| <input type="checkbox"/>            | 03 Dec 2024   | admin@transperfect.com | #10000      | transfer subject checklist          | *Uploaded Documents\Activity Ma... | Metadata update        | Popular Document: 03 Dec 2024 |
| <input type="checkbox"/>            | 04 Dec 2024   | admin@transperfect.com | #10000      | transfer subject checklist          | *Uploaded Documents\Activity Ma... | Open Document          | Version 1.0                   |

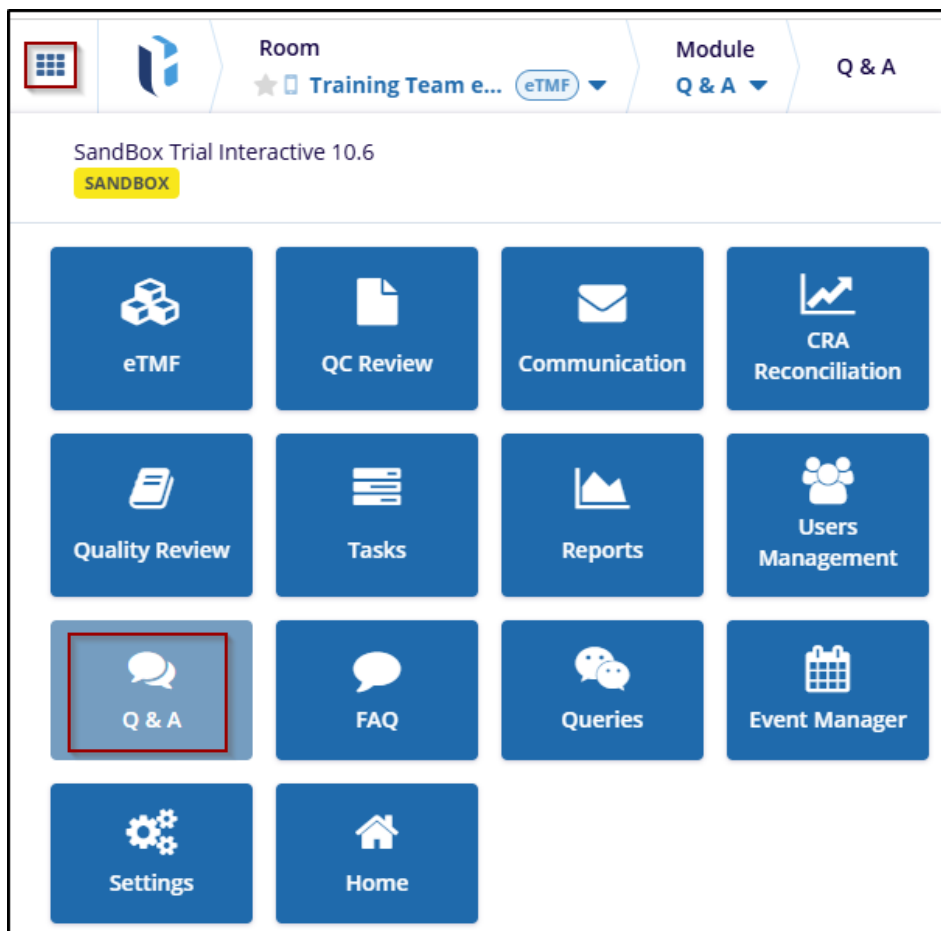
## CHAPTER 17. Q&A MODULE

Q&A refers to the process of asking questions and providing answers to address inquiries or resolve issues. The Q&A section consists of questions asked by users and the corresponding answers provided to address their inquiries. It helps resolve issues and efficiently manage user interactions.

Users can access the Q&A module from the navigation grid in the upper-left corner of the screen.

The Question & Answer module has the following sections:

- Q&A
- Audit Trail



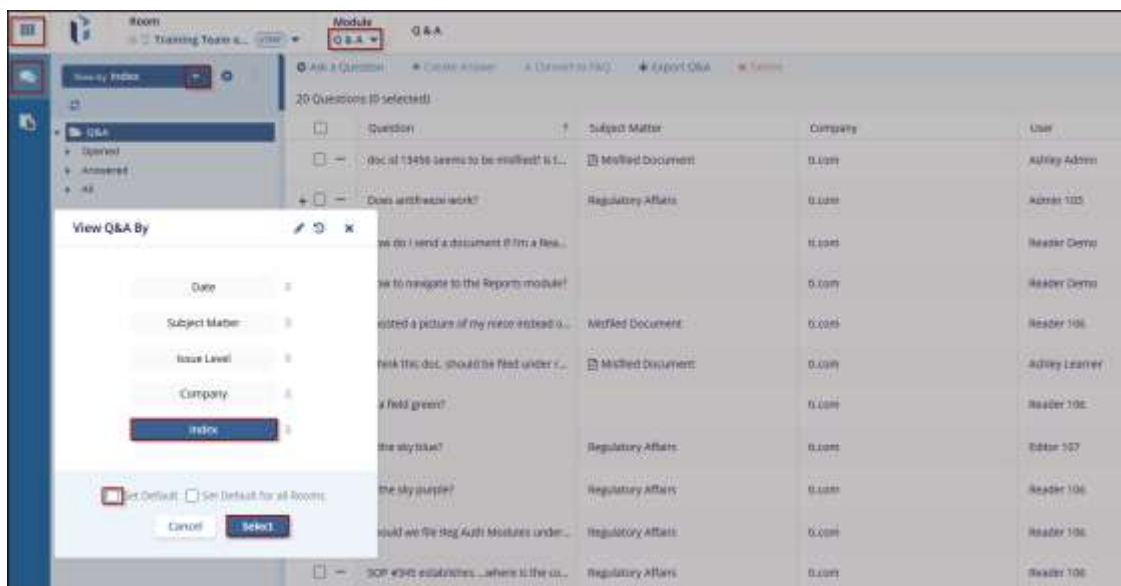
### View Q&A By

In the View Q&A By filter, users can select a view for question & answer review based on requirements.



To apply View Q&A By filter, follow these steps:

1. Navigate to the Q&A Module via the navigation grid on the top left corner of the screen.
2. Select the Q&A section and click the View Q&A By dropdown menu.
3. This dropdown menu allows users to choose how they want to apply filter and search questions.
4. Select the available options such as: Date, Subject Matter, Issue Level, Company, Index.
5. Based on user requirements, select one of the options.
6. If the user needs to review, the user has the option to make their selection the default view:  
Set Default: this will set the selected view as the default for the current session.  
Set Default for All Rooms: this will make the selection the default for all rooms, not just the current one.
7. After selecting the view Q&A by options, click the Select button to apply the changes, these changes will reflect at the top of the Index pane, or click the Cancel button to discard the changes.
8. After applying the selection from options, the user can see the folder, based on the selections.



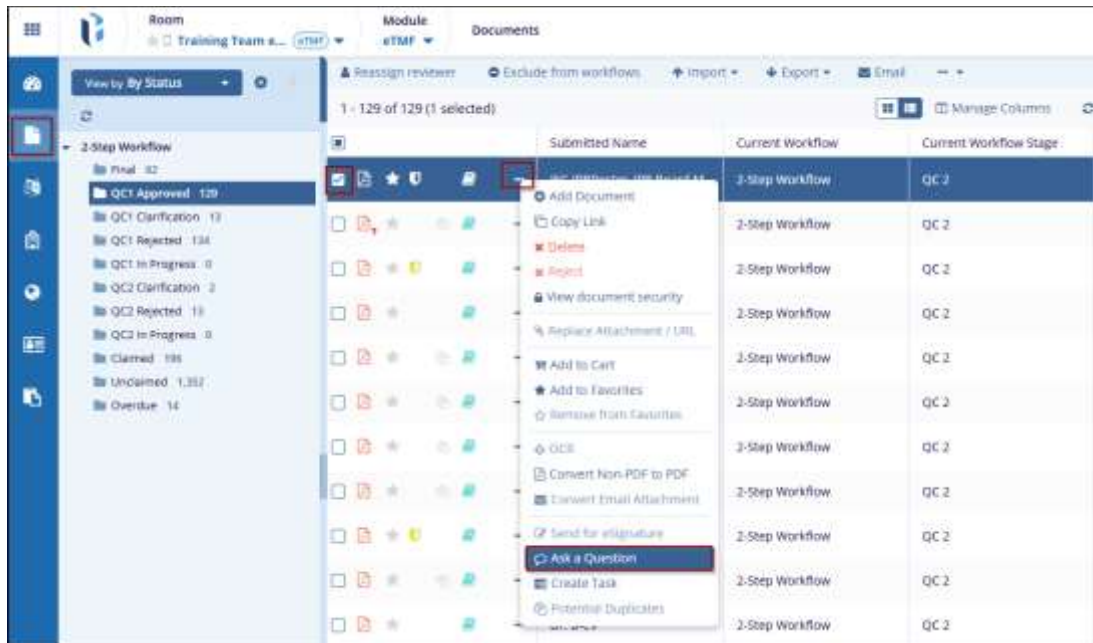
## Ask a Question

Ask a question can be done from three dots menu next to checkbox in Document module or directly from the Q&A module. Questions that are related to a specific document should be created.

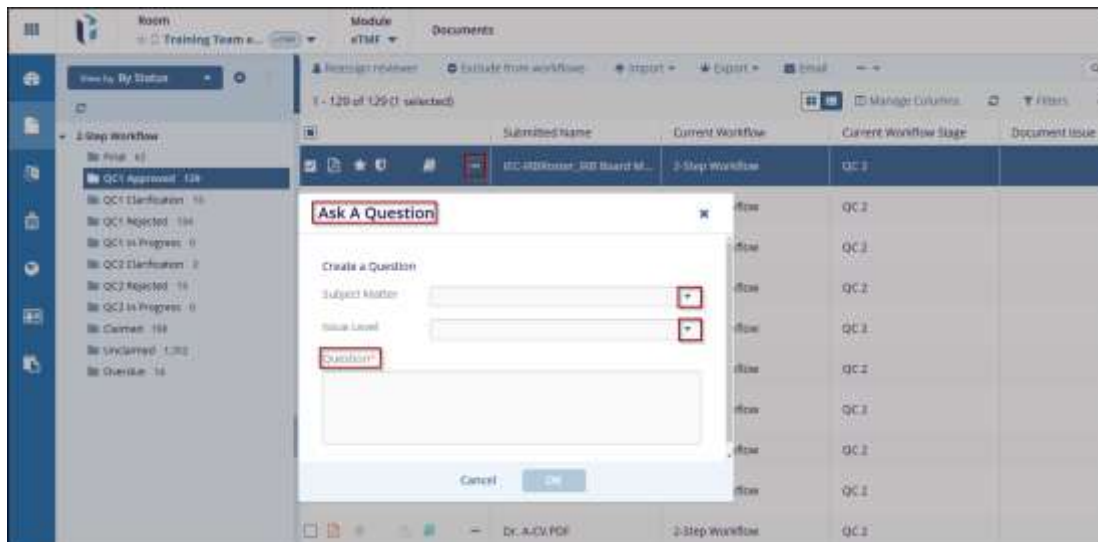
To create a Document Specific Question, follow these steps:

1. Navigate to the Document Module and select the Document section.

2. Open the Document Activities menu for that specific document by right-click on it or by click on the three-dot menu, next to book icon.

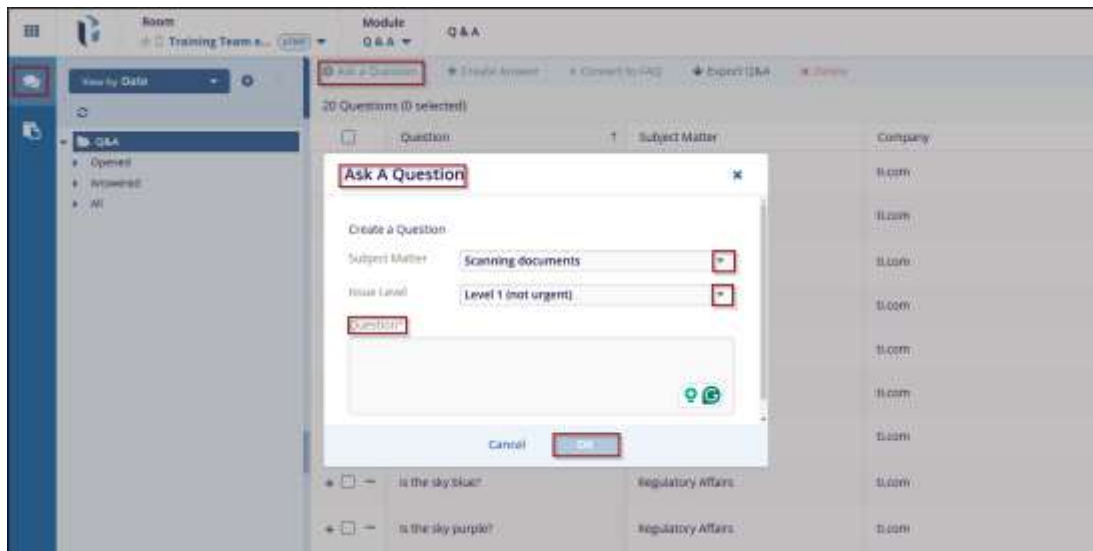


3. Click the Ask a Question, the Ask a Question window will open.
4. The fields that show will depend on the Q&A settings. For additional information, please see the section on Q&A Settings.
5. If necessary, indicate the applicable subject matter and issue level.
6. Type your question into the textbox.
7. Once done, click the OK button and the question will appear in the grid view.



To create a general Question, follow these steps:

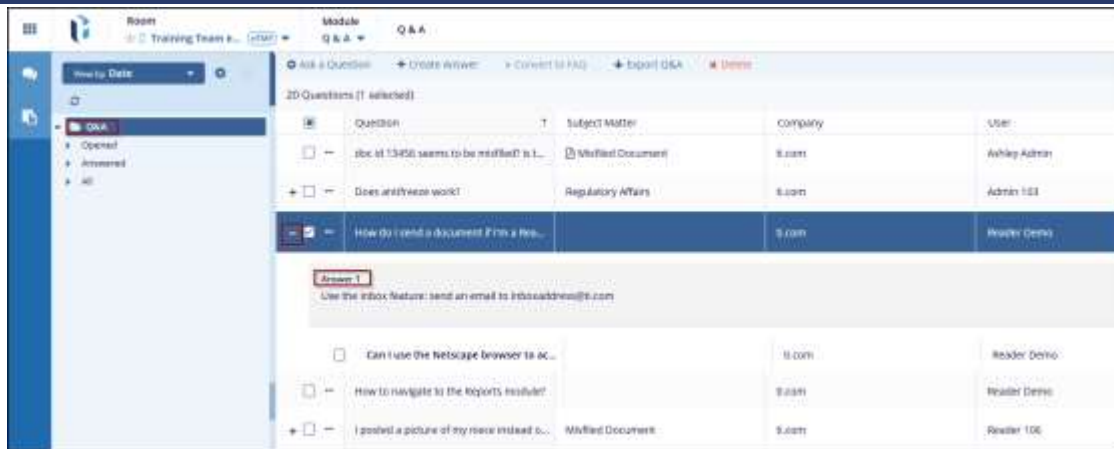
1. Navigate to the Q&A module, select Q&A section from the left vertical menu.
2. Click the Ask a Question button from the top menu bar above the index panel.
3. The Ask a Question window will open.
4. The fields that show will depend on the Q&A settings. For additional information, please see the section on Q&A Settings.
5. If necessary, indicate the applicable subject matter and issue level.
6. Type your question into the textbox.
7. Once done, click the OK button and the question will appear in the grid view.



## View Answer

To view the answer to a question, follow these steps:

1. Navigate to the Q&A module, select the Q&A section from the left vertical menu.
2. Click on the + icon next to the checkbox.
3. The answer will be displayed below the questions. In some cases, there may be multiples answer for a single question.

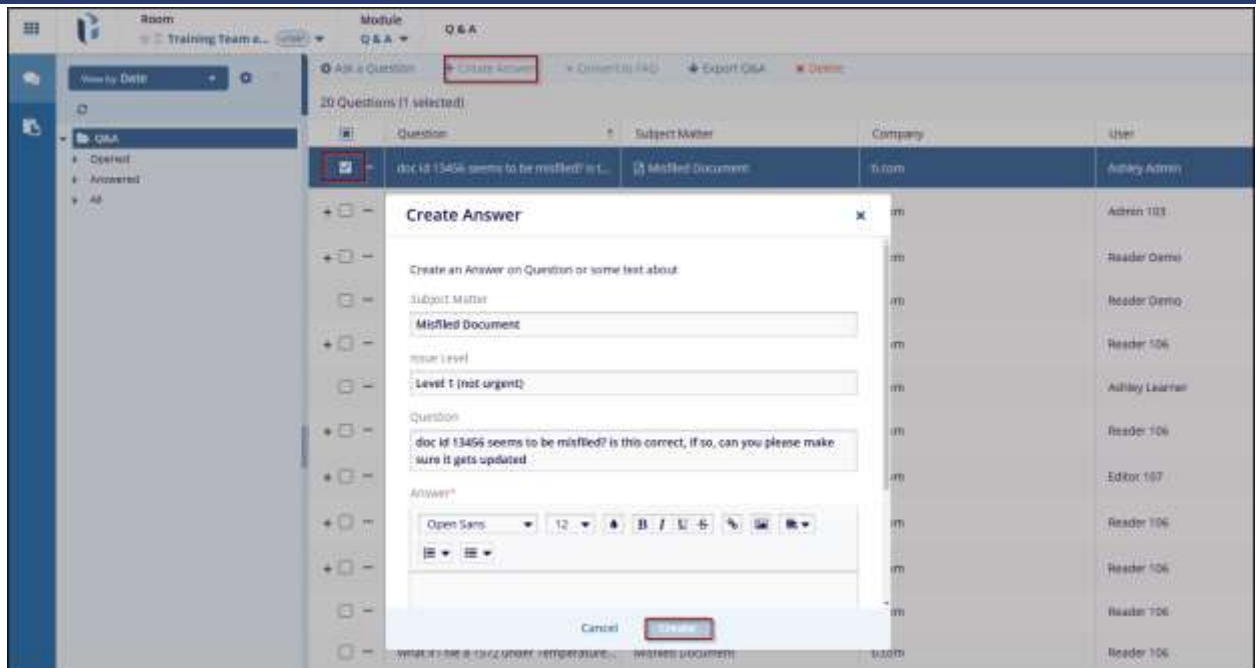


## Create Answer

Administrator users and those users indicated as Subject Matter Experts may create answers to questions in the Q&A module.

Follow these steps to answer a question in the Q&A module:

1. Navigate to the Q&A module, select the Q&A section from the left vertical menu.
2. Check the checkbox of the question for which the user wants to answer.
3. Click the Create Answer button from the top menu bar above the index panel.
4. This will open a new Create Answer window.
5. The fields that show will depend on the Q&A settings. For additional information, please see the section on Q&A Settings.
6. If necessary, indicate the applicable subject matter and issue level.
7. Type your Answer into the textbox below the Question.
8. Once done, click the Create Answer button to answer the selected question.



## Convert to FAQ

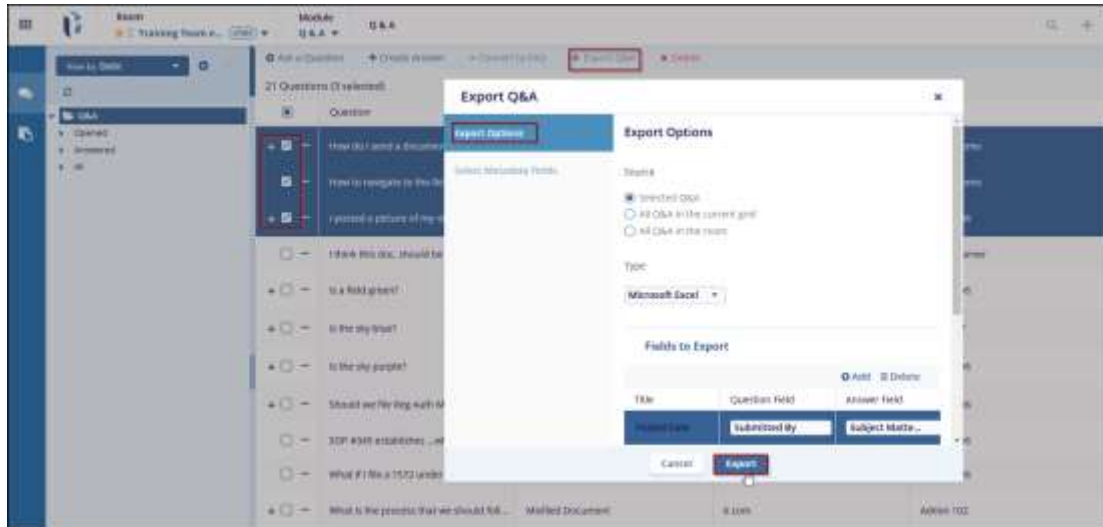
1. Navigate to the Q&A module, select Q&A section from the left vertical menu.
2. Click on the + icon, next to checkbox. The answer will be display below the questions.
3. Only one answered question will be available to converted as FAQ.
4. Click the Convert to FAQ button from the top menu bar above the index panel.
5. This will open the Convert to FAQ window.
6. Make any required edits to the Question and Answer.
7. Once done click on Create button to add this question to FAQ section.



## Exporting Q&A

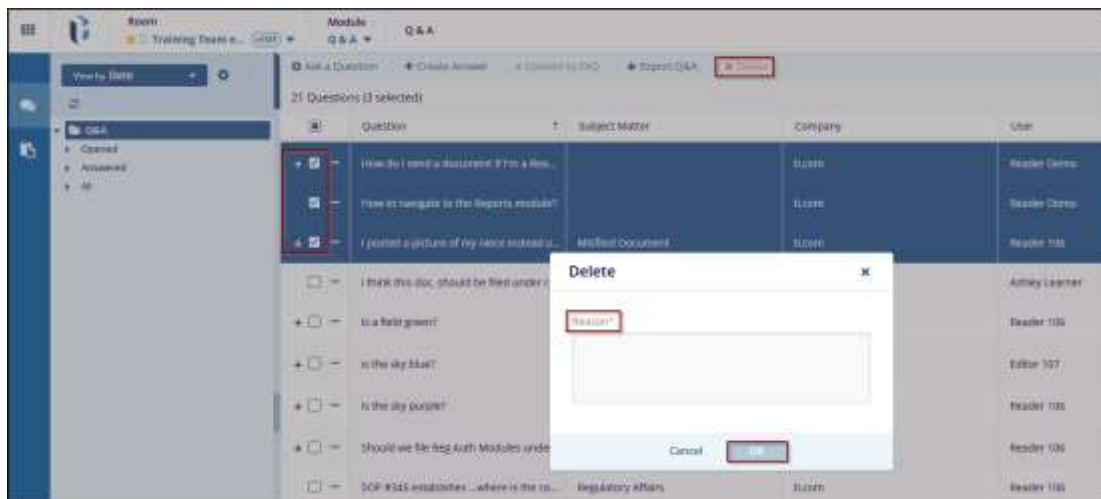
Administrator level users can export questions and answers. To do so, follow the steps below:

1. Navigate to the Q&A module, select Q&A section from the left vertical menu.
2. Select the question one or more, that need to export.
3. Click the Export Q&A button from the top menu bar above the index panel.
4. This will open a new Export Q&A window.
5. Select the require Export options and click on Export button to export Q&A.



## Deleting Q&A

1. Select the question for the grid.
2. Click the Delete button from the top menu bar above the index panel.
3. This will open a Delete window, enter the Reason for deleting the question and answer.
4. Once done, click the OK button and the question will removed from the grid view.



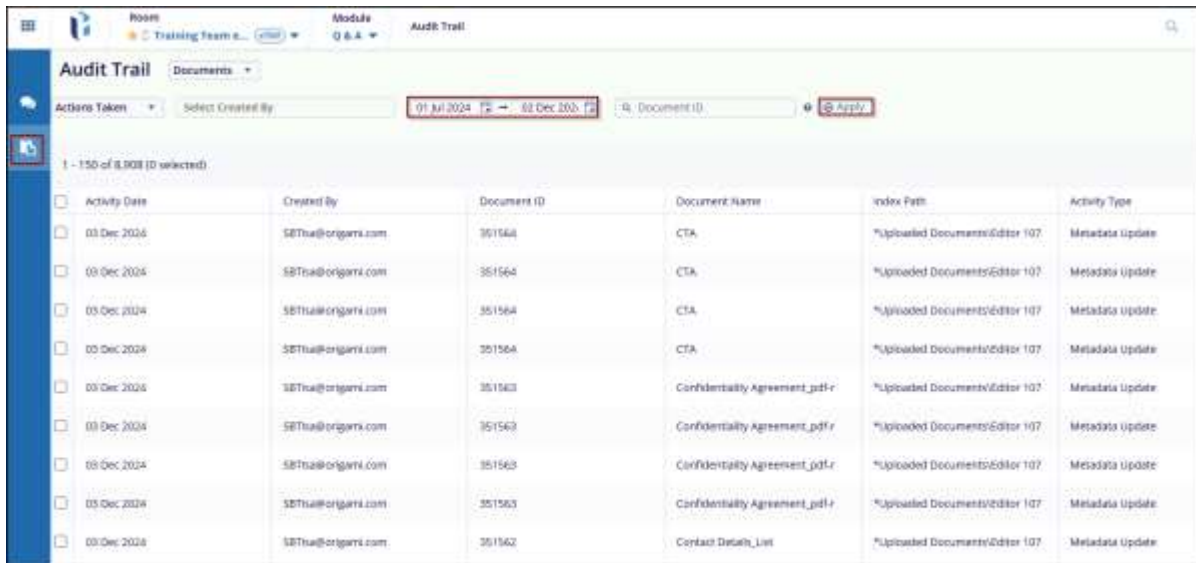
## Audit Trail

An Audit Trail is a security-relevant chronological set and source of records that provide evidence of the sequence of activities performed over a document. The changes made in a document by all users are displayed within the Audit Trail.

Users can access the Audit Trail by selecting it from the menu bar on the left-side of navigation pane.

Refer to the Audit Trail from the eTMF Module for a more detailed description of these options.

Note: By default, the audit trails grid pane is empty, and the documents are displayed only after entering and applying certain parameters and criteria.



| Activity Date | Created By         | Document ID | Document Name                   | Index Path                     | Activity Type   |
|---------------|--------------------|-------------|---------------------------------|--------------------------------|-----------------|
| 03 Dec 2024   | SBThua@origami.com | 351564      | CTA                             | %Uploaded Documents\Editor 107 | Metadata Update |
| 03 Dec 2024   | SBThua@origami.com | 351564      | CTA                             | %Uploaded Documents\Editor 107 | Metadata Update |
| 03 Dec 2024   | SBThua@origami.com | 351564      | CTA                             | %Uploaded Documents\Editor 107 | Metadata Update |
| 03 Dec 2024   | SBThua@origami.com | 351564      | CTA                             | %Uploaded Documents\Editor 107 | Metadata Update |
| 03 Dec 2024   | SBThua@origami.com | 351563      | Confidentiality Agreement.pdf-r | %Uploaded Documents\Editor 107 | Metadata Update |
| 03 Dec 2024   | SBThua@origami.com | 351563      | Confidentiality Agreement.pdf-r | %Uploaded Documents\Editor 107 | Metadata Update |
| 03 Dec 2024   | SBThua@origami.com | 351563      | Confidentiality Agreement.pdf-r | %Uploaded Documents\Editor 107 | Metadata Update |
| 03 Dec 2024   | SBThua@origami.com | 351563      | Confidentiality Agreement.pdf-r | %Uploaded Documents\Editor 107 | Metadata Update |
| 03 Dec 2024   | SBThua@origami.com | 351562      | Contact Details_List            | %Uploaded Documents\Editor 107 | Metadata Update |



## CHAPTER 18. FAQ MANAGEMENT

From within the FAQ module, users can perform the following actions

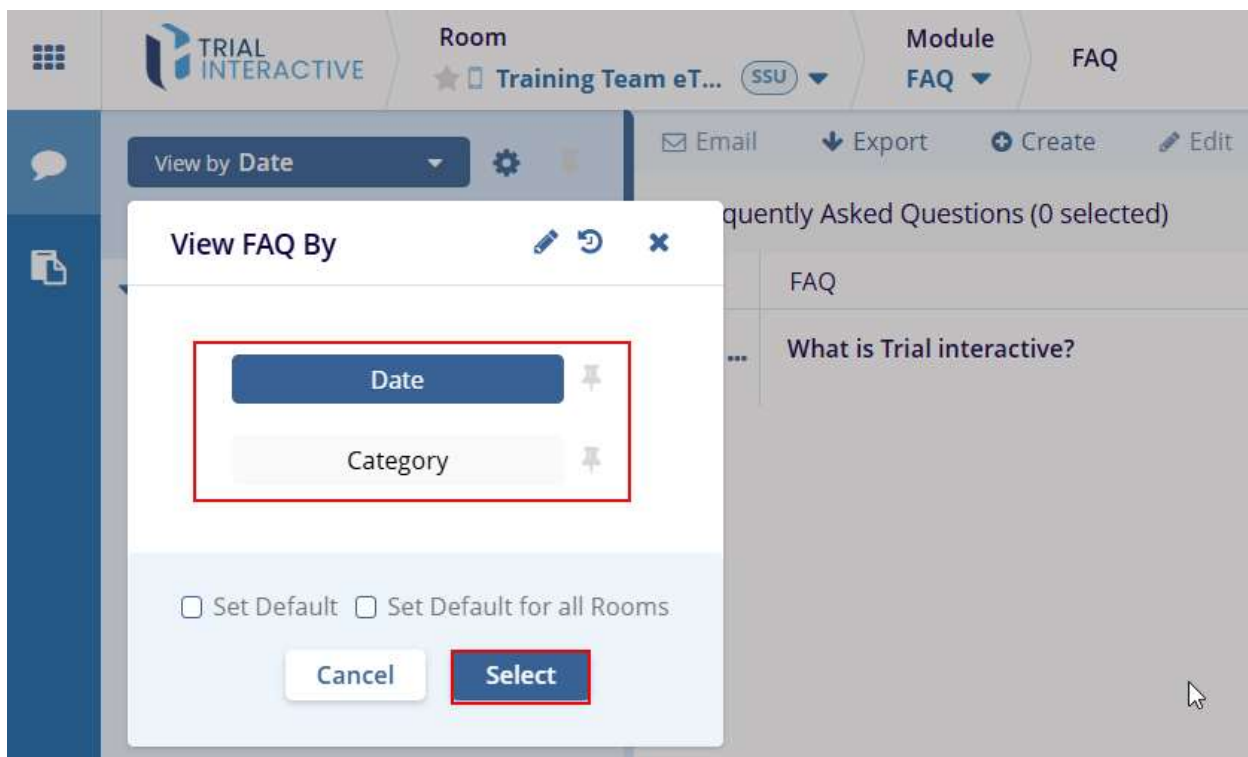
1. View the FAQ by
2. Create New FAQs
3. Edit FAQs
4. Delete FAQs
5. Export FAQs
6. Email FAQs

Each of these actions is described in the subsequent topics.

### View FAQ's

To access different FAQ views, follow the steps below.

1. Access the FAQ module from the Modules dropdown.
2. Click on the View by dropdown.
3. Select a view from the available dropdown list and click on the Select button.
  - a. Date: Displays the FAQs grouped by date.
  - b. Category: Displays the FAQs grouped by their category.

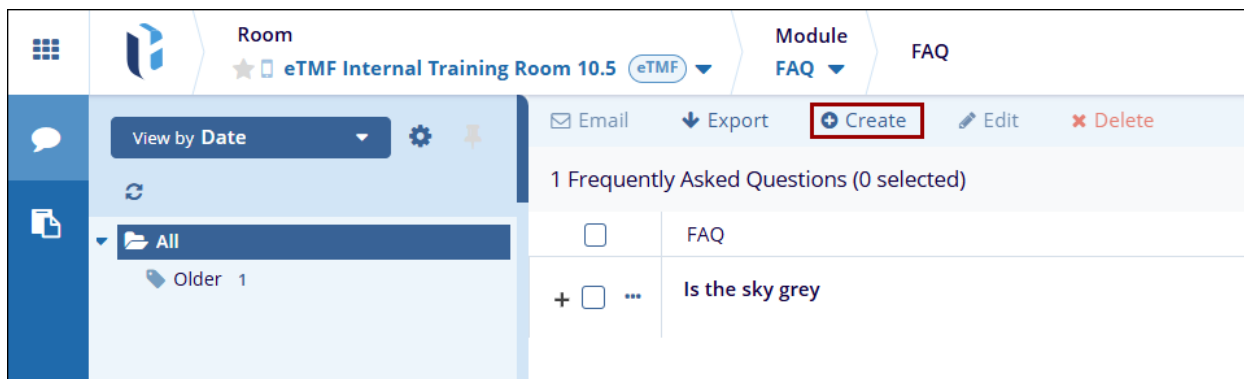




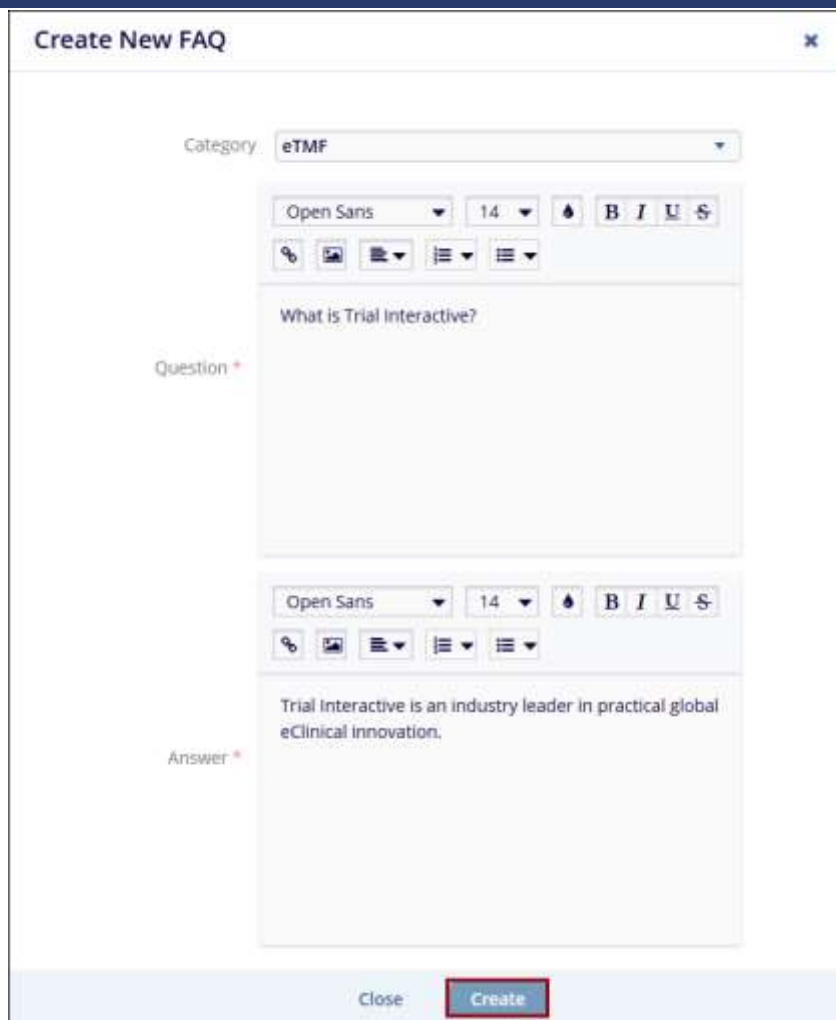
## Create FAQs

To create new FAQs, follow the steps below.

1. Within the FAQ module, click on the +Create button from the top menu bar.



2. On the Create New FAQ window, select the Category from the available dropdown options.
3. Enter the Question and Answer into the relevant fields.
4. Click on the Create button.



**Create New FAQ** [X]

Category: eTMF

Open Sans 14 [B] [I] [U] [S]

Question \*

What is Trial Interactive?

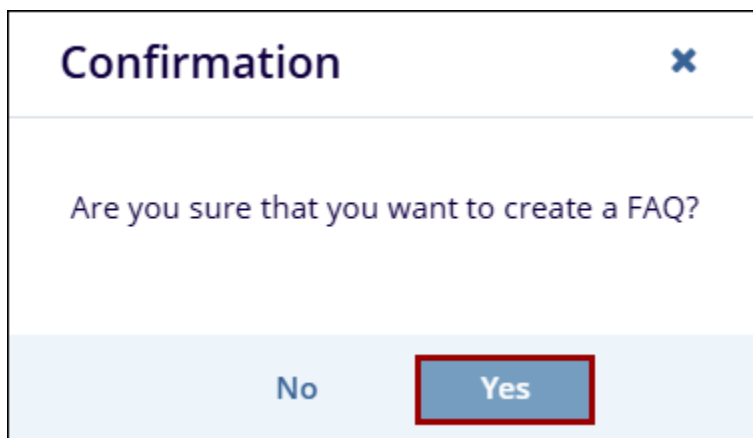
Open Sans 14 [B] [I] [U] [S]

Answer \*

Trial Interactive is an industry leader in practical global eClinical innovation.

Close Create

- On the Confirmation popup, click on the Yes button.



**Confirmation** [X]

Are you sure that you want to create a FAQ?

No Yes

- Once successfully created, the question appears on the FAQ main screen.

|                                           |                            |                      |               |
|-------------------------------------------|----------------------------|----------------------|---------------|
| Email   Export   Create   Edit   Delete   |                            |                      |               |
| 1 Frequently Asked Questions (0 selected) |                            |                      |               |
| <input type="checkbox"/>                  | FAQ                        | Created Date         | Category Name |
| + <input type="checkbox"/> ...            | What is Trial Interactive? | 25 Feb 2025 02:05... | eTMF          |

## Edit FAQs

To edit FAQ's, follow the steps below.

1. Select a FAQ to edit by clicking on the checkbox.
2. Click on the Edit button from the top menu bar.


Room  
★ TI Training Team ... (SSU)

Module  
FAQ

FAQ

View by Date

All  
Today 1  
This Week 1  
This Month 1

Email   Export   Create   Edit   Delete

1 Frequently Asked Questions (1 selected)

|                                           |                            |
|-------------------------------------------|----------------------------|
| <input checked="" type="checkbox"/>       | FAQ                        |
| + <input checked="" type="checkbox"/> ... | What is Trial Interactive? |

3. Make the required changes on the Edit FAQ window.
4. Click on the Edit button at the bottom of the window.

Edit FAQ

Category
eTMF

Open Sans
12
B I U

What is Trial Interactive?

Question \*

Open Sans
12
B I U

Trial Interactive is an industry leader in practical global eClinical innovation.

Answer \*

Close
Edit

- On the confirmation popup, click on the Yes button.

Confirmation

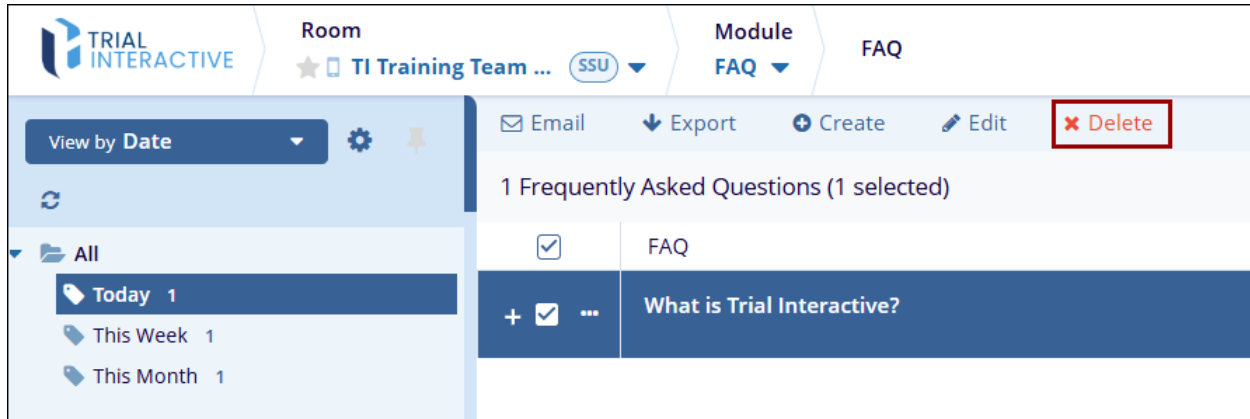
Are you sure that you want to edit the FAQ?

No
Yes

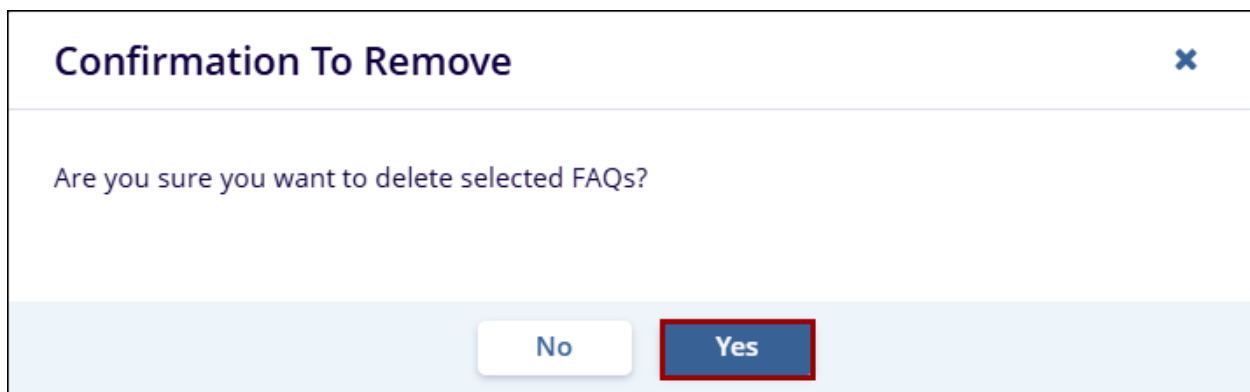
## Delete FAQs

To delete FAQs, follow the steps below.

1. Select a FAQ from the available list and click on the Delete button from the top menu bar.



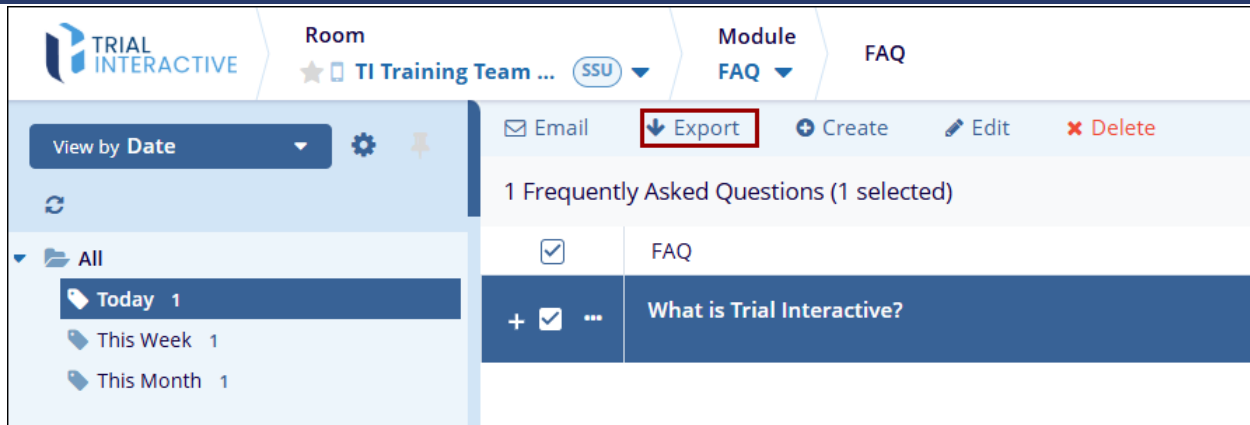
2. Click on the Yes button on the confirmation popup.



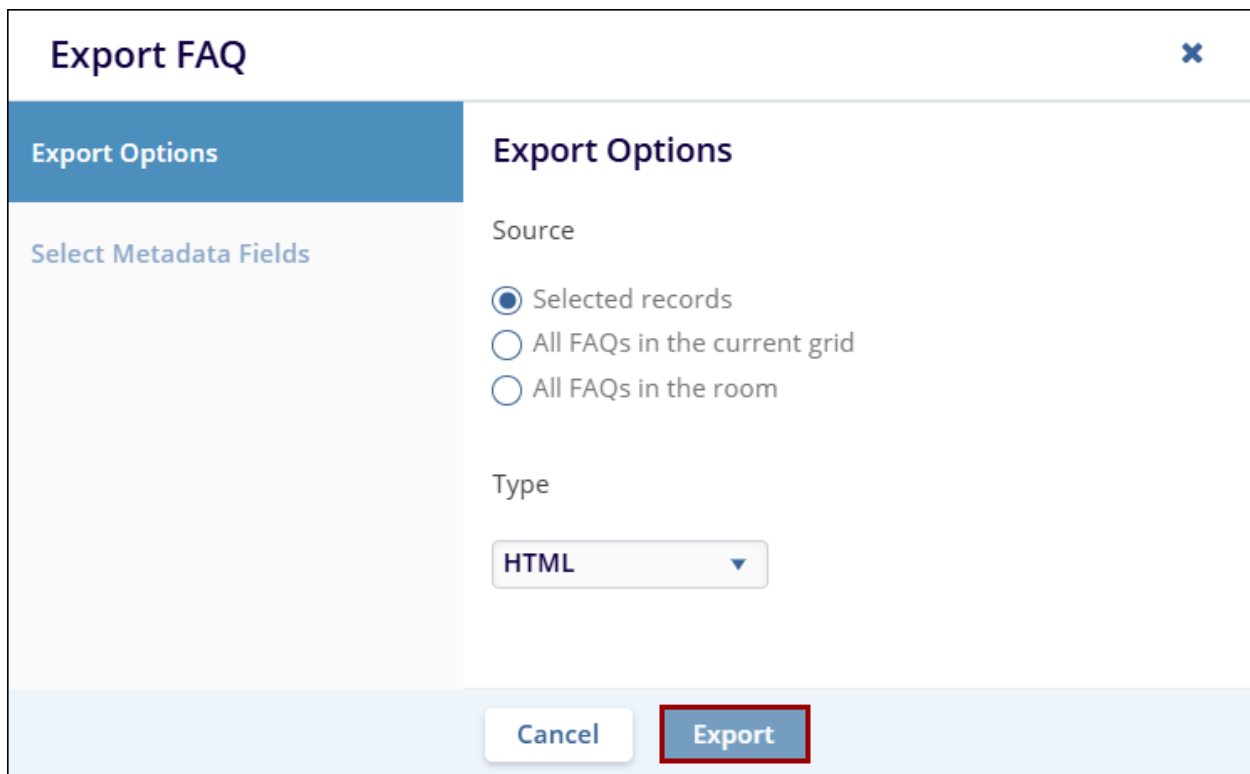
## Export FAQs

To export FAQs, follow the steps below.

1. Click on the Export button from the top menu bar.



2. On the Export FAQ page, select any one of the following from the Source section
  - a. Selected Records
  - b. All FAQs in the current grid
  - c. All FAQs in the room
3. Select any one option from the Type dropdown.
  - a. HTML
  - b. Microsoft Excel
  - c. Microsoft Word
4. Click on the Export button at the bottom of the window.



5. On the Exporting FAQ popup, click on the Get Results button.



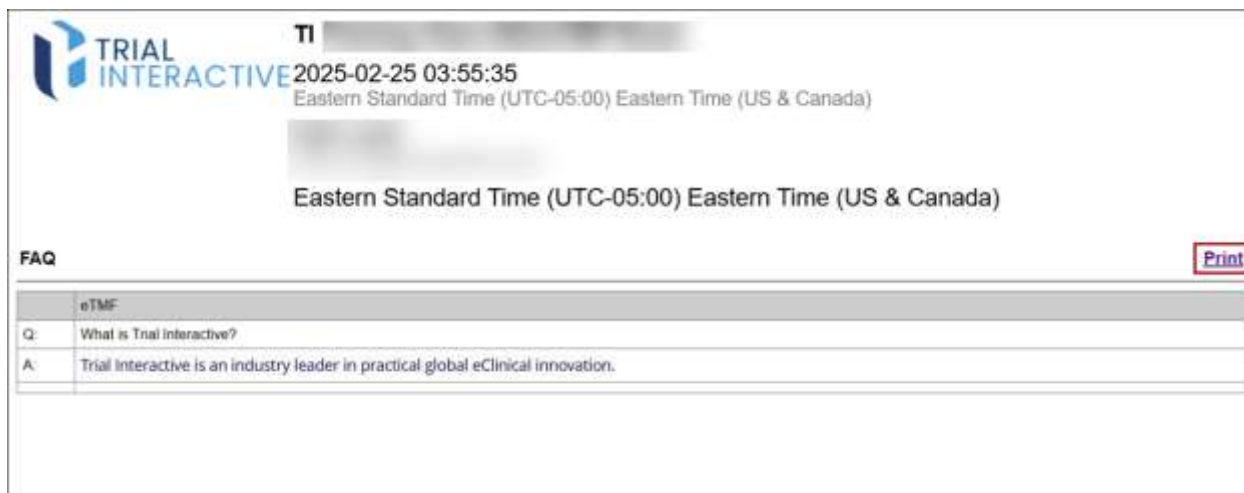
## Exporting FAQ

Room: TI Training Team SSU/eTMF Room

Success! Task is complete.

[Get Results](#)

- A new window opens with the list of FAQ and answers with an option to print.

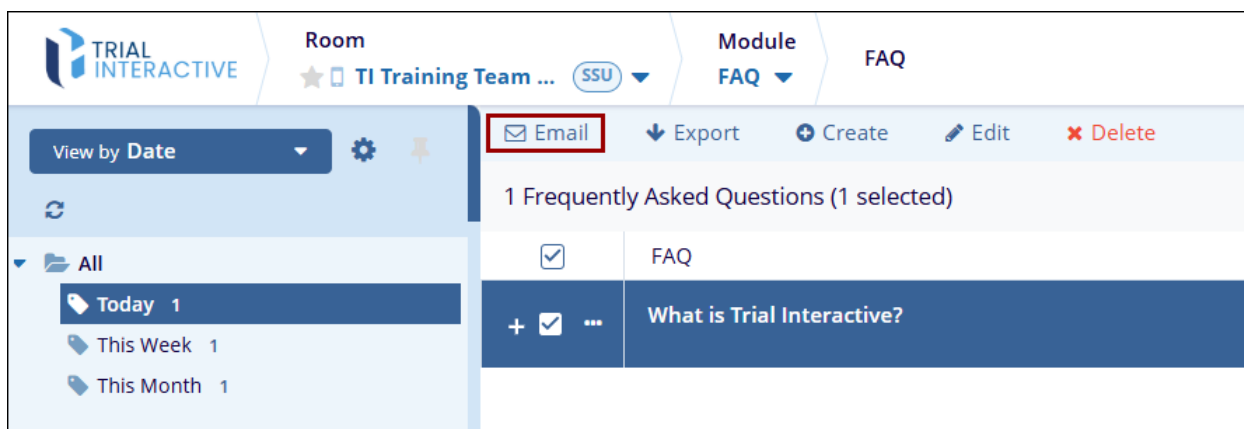


| FAQ |                                                                                   |
|-----|-----------------------------------------------------------------------------------|
| Q:  | What is Trial Interactive?                                                        |
| A:  | Trial Interactive is an industry leader in practical global eClinical innovation. |

## Email FAQs

To email FAQs, follow the steps below.

- Select the FAQs from the available list and click on the Email button from the top menu bar.



| FAQ                                 |                            |
|-------------------------------------|----------------------------|
| <input checked="" type="checkbox"/> | FAQ                        |
| <input checked="" type="checkbox"/> | What is Trial Interactive? |

- On the Send Email window, add the email recipients by clicking on the Add button.

3. Optionally add an attachment and notes in the designated area.
4. Once the necessary details are added, click on the Send Mail button.

Send Mail

Subject \*

T1 Training Team SS

Email \*

Admin AP

Add

Category

eTMF

Question

What is Trial Interactive?

Answer

Add Attachment

Select files...

Drop files here to upload

Open Sans

14

B

I

U

S

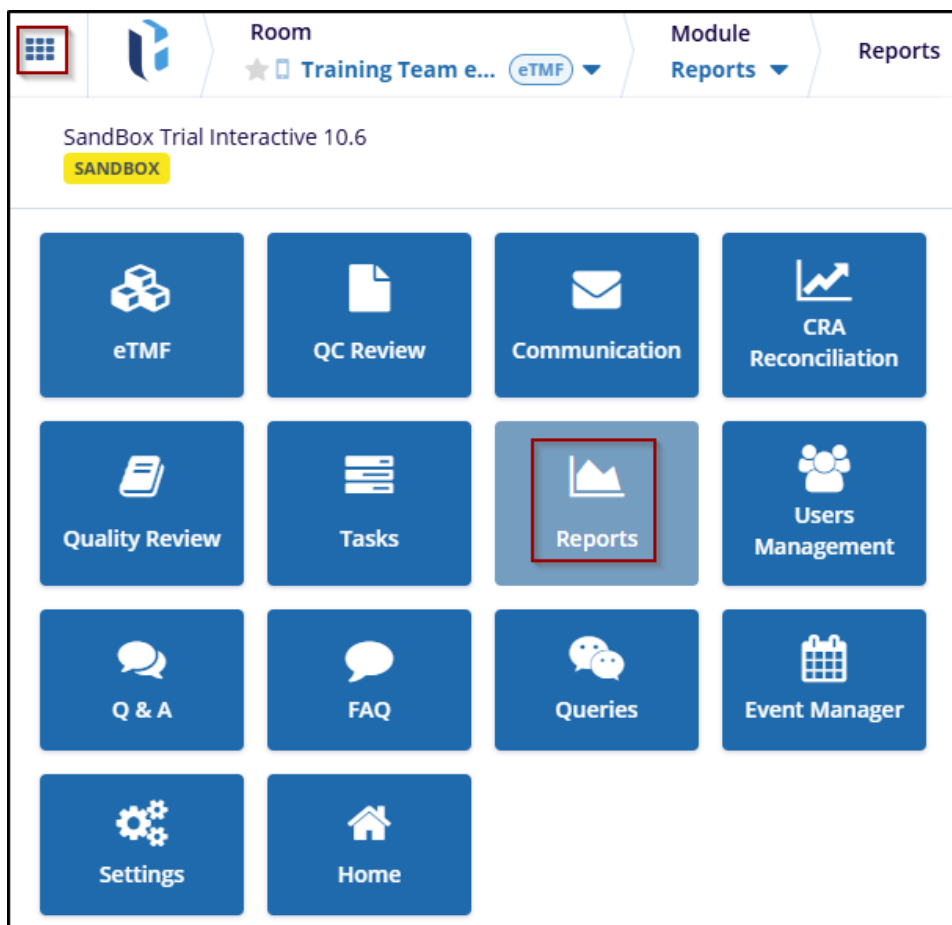
Send Mail



## CHAPTER 19. REPORTS

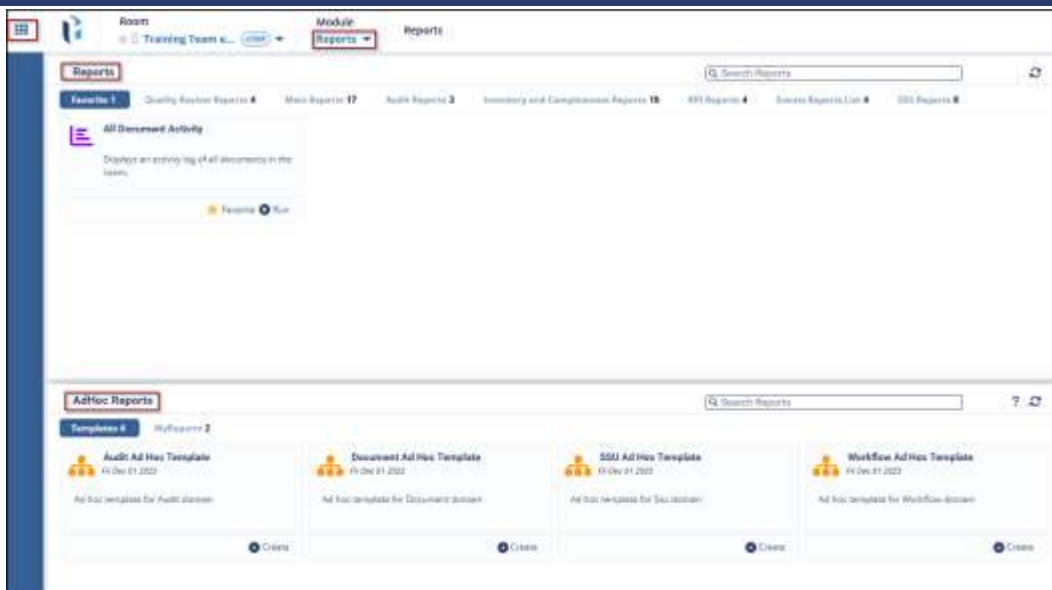
The Reports module provides activities and document actions, offering a summary of the reports. Users can access this module from the navigation grid in the upper-left corner of the screen, where the Report module is listed.

Refer to the screenshot below:



It includes the following tabs:

- Reports: These include Favorite, Main Reports, Audit Reports, KPI Reports, Inventory and Completeness Reports, SSU Reports, etc.
- Ad Hoc Reports: Customizable reports that allow users to generate reports based on requirements.

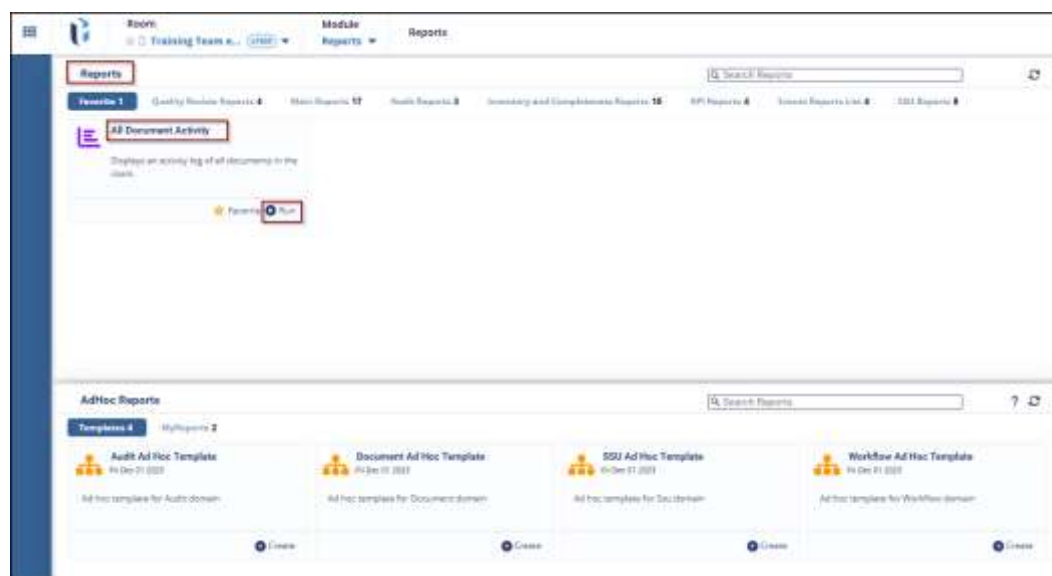


## Reports

The Reports tab displays a list of room activities and log activity.

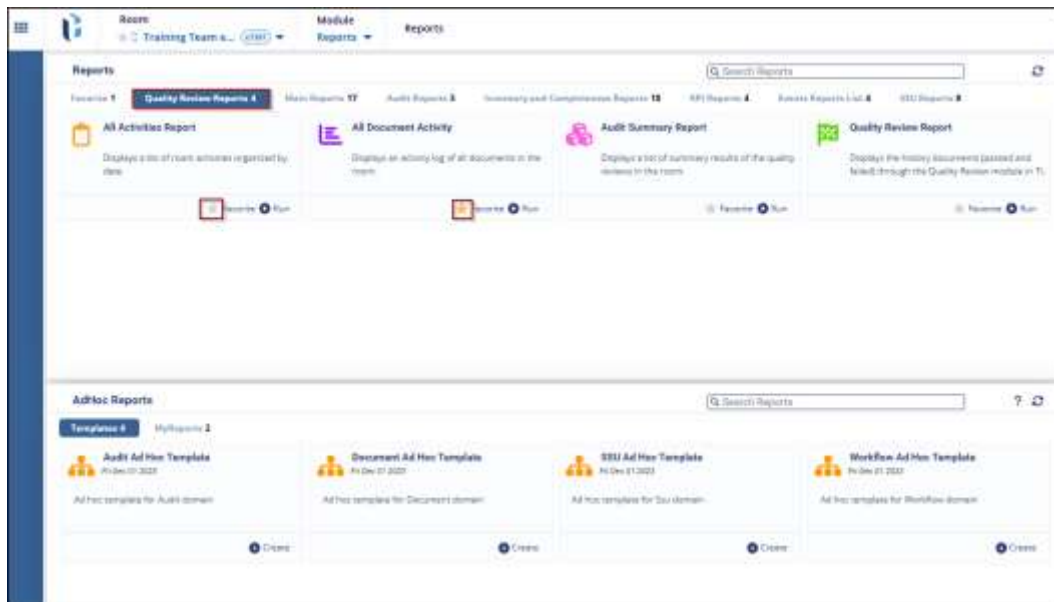
To run the reports, follow these steps:

1. Navigate to the Reports tab, and select any report from the below options (Favorite, Quality Review Reports, Main Reports, Audit Reports, etc.).
2. Click on the Run button to view the report.



To add a report as a favorite, follow these steps:

1. Select any reports from the Report tab, and the user can see the Star icon.
2. Click on the Star icon to mark that report as a favorite and the report will be added to the favorite option.

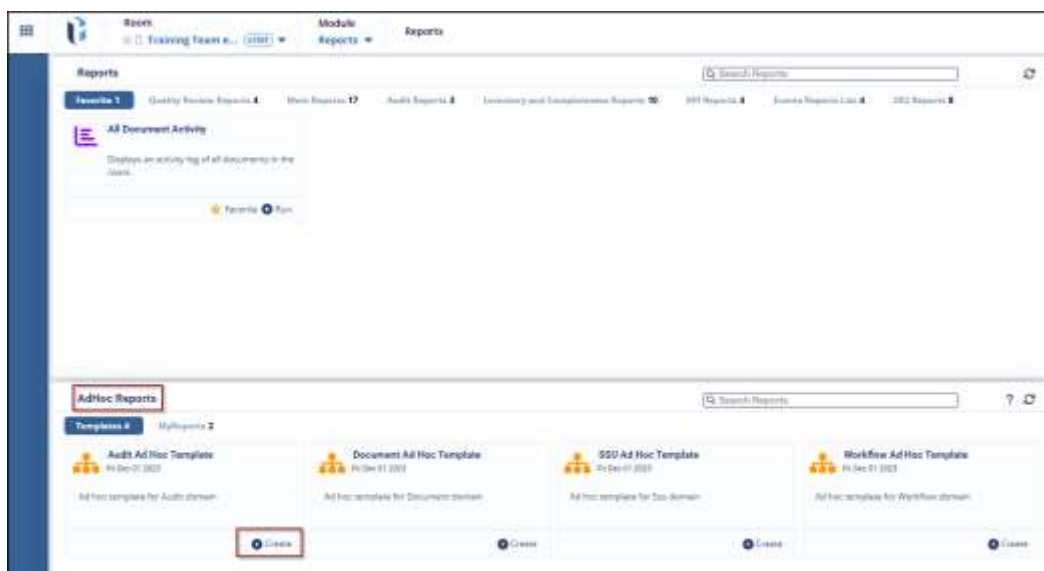


## AdHoc Reports

The AdHoc Reports allow users to generate or create reports based on requirements.

To create reports, follow these steps:

2. Navigate to the AdHoc Reports tab and select any templates.
3. Click the + Create, which will open the template reports, fill in the necessary details as per requirement, and save the report.



## CHAPTER 20. LITERATURE MONITORING SOLUTION

This section provides an overview of the Literature Monitoring Solution, explaining its functionality, key components, and system requirements.

This solution description provides a high-level description of the Literature Monitoring solution. This description is designed to inform TransPerfect personnel, and to facilitate discussions between customer-facing TransPerfect personnel and existing customers. It is intended to be used in conjunction with the Literature Monitoring Configuration Manual to provide a complete overview of the solution.

### Overview

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#### Background

Literature monitoring is the process of searching published literature for data about products. Sources of literature may be published newspapers, internet websites, medical journals, periodicals, radio broadcasts, or television broadcasts. The information generated from these sources can be commonly referred to as medical literature regardless of the source. Literature must be collected because it presents the "state of the science" or accumulated knowledge on a specific topic. The information collected can also be used to inform professionals and patients of the best available evidence when making healthcare decisions, influence policy, and identify future research priorities for a particular company. The key challenge inherent in the storage and management of literature is maintaining the integrity of the information while ensuring proper document accessibility and regulatory compliance. This involves several critical aspects:

1. **Collection of Data:** Information regarding products should be stored separately, preferably in a dedicated repository distinct from other company documents, to enhance the efficiency of information gathering and retrieval. This requires a robust system for categorizing and segregating documents.
2. **Access Control:** Strict access controls must be implemented to ensure that only authorized personnel can view potentially sensitive information and categorize collected literature. This includes setting permissions and audit trails to monitor who accesses what information and when.
3. **Regulatory Compliance:** Ensuring compliance with regulatory requirements when working with products such as Good Clinical Practice (GCP), GDPR, and other relevant guidelines is essential. This includes maintaining secure, traceable, and auditable records.
4. **Document Integrity:** Maintaining the integrity and confidentiality of product information while enabling necessary updates and collaboration can be challenging. This requires distinct control of user access and user permissions. This may also encompass certified translations of literature to or from multiple languages to ensure the integrity of the document content.

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#### What is a Literature Monitoring Solution?

Trial Interactive's Literature Monitoring solution provides a validated, dedicated repository to electronically store pieces of information for products from an unlimited amount of sources. It

also enables a literature review team to follow essential processes for metadata collection and document access.

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### What does the Solution do?

- Leverages configuration to support storage of over 250 file types.
- Provides quick and easy ability to categorize literature.
- Contains a streamlined filing structure developed from industry experts.
- Facilitate the ability of a user to identify sensitive document content prior to filing.

---

### System/Technical Requirements

- The Literature Monitoring solution is assumed to have an unlimited number of users with approved access to documents.
- This solution has a streamlined index targeting literature review file types.
- This solution has TransPort Translations enabled to easily request a certified translation of any documentation.
- This solution has the ability to perform Quality Review for oversight.

### High level technical capabilities:

- Users can view, modify metadata on documents within a workflow
- Users can Copy/move documents between rooms
- Users can perform translation requests for certified translations
- Users can run reports on Inventory, KPIs, User Access
- Ability to access Audit Trail
- Ability to add or remove user access

---

### Solutions available for interoperability:

- GlobalLearn
- TI Connector

## Target Audience

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### Target Organizations for This Solution

Clinical and Manufacturing Sponsors: the Business Lead at the sponsor will understand the requirements of continued product literature monitoring . Additionally, they will be able to advise on the approach necessary to handle the collection of literature to review.

---

### Users

The following distinct groups merit consideration when it comes to literature review (demographic, clinical characteristics of the population, etc.):

- Data Collectors and Data Managers
- Business Leads
- Statisticians

- Pharmacovigilance
- Members of data monitoring committees
- Medical/Technical Writers
- Auditors
- Translation Agents

## Business Use Cases

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### Biopharmaceutical Company: Product Safety Monitoring

Use Case: A company utilized a secure digital system to continuously monitor literature regarding its products, particularly following post-market surveillance.

Benefits:

- **Rapid Identification of Safety Signals:** The system enabled quick detection of emerging issues from scientific journals and clinical studies, facilitating timely risk assessments.
- **Regulatory Compliance:** Improved tracking and documentation of literature helps meet regulatory obligations for safety reporting, reducing the risk of non-compliance.
- **Informed Labeling Updates:** The ability to aggregate findings allowed for proactive updates to product labeling and risk communications, enhancing consumer safety and trust.

---

### Manufacturing Company: Enhancing Product Development

Use Case: A company implemented a secure digital system to monitor literature related to its products, including clinical outcomes and technological advancements.

Benefits:

- **Informed R&D Decisions:** Continuous access to the latest research on product efficacy and consumer feedback allowed for data-driven modifications during product development, enhancing product quality.
- **Competitive Advantage:** Monitoring competitor publications and innovations helped the company identify opportunities for differentiation in a crowded market.
- **Collaboration with experts:** The system facilitates the identification of experts involved in relevant studies, enabling targeted outreach for collaborations and endorsements.

---

### Consumer Health Company: Market Insights and Trends

Use Case: A consumer health company adopted a secure digital system to monitor literature about over-the-counter (OTC) products, including health trends and consumer preferences.

Benefits:

- **Market Trend Identification:** Real-time access to collated literature helped the company stay ahead of emerging health trends, allowing for timely adjustments to product lines.
- **Consumer Engagement:** Insights from monitored literature informed marketing strategies, leading to more effective consumer engagement and communication efforts.
- **Product Innovation:** Continuous literature monitoring fostered innovation by revealing gaps in the market, guiding the development of new OTC products that better address consumer needs.